RELEASE 13.1

# JReview®

# Exploring Clinical Data using JReview

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First Printing:November 2018

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# 1 Getting Started

# Introduction

## *What is JReview?*

JReview® (previously IReview) is the web-enabled version with functionality built based on the suggestions from many of the installed pharmaceutical and regulatory goverment customers. This comprehensive set of functionality is targeted specifically to clinical research use by clinicians, data managers, QA, medical writers, etc. It allows users to view, create, print, and interact with their JReview objects locally on an Intranet or securely over the Internet. JReview can be run in two different modes of operation (authoring and non-authoring) in addition to two modes of communication (clear-text and SSL).

- Plaintext Non-authoring

- Plaintext Authoring

- SSL Non-authoring

- SSL Authoring

## *Authoring versus Non-Authoring*

JReview is **Intuitive** to use; no programming knowledge required. It supports **direct and immediate access to data** stored in existing clinical database systems.

Non-authoring mode of JReview presents a run-time, read-only environment for browsing and re-executing JReview objects.  While the objects will interact as they would in authoring JReview, the user has no control over the specific object definitions. This mode is preferable when either trying to restrict how the data can be reviewed (e.g. using a library of validated objects) or when the end-user does not need to know the intricacies of creating objects.

The authoring mode of JReview allows the creation of objects (reports, graphs, crosstabs, patient profiles, etc). Objects are completely compatible across Integrated Clinical Systems' products for JReview and  retired Integrated Review (IReview).

## *Clinical Data Sources*

JReview now has a built in connector to Oracle LSH, without needing to use the traditional 'adapter' approach and setup. JReview has direct access to the Oracle LSH table instances using the native LSH Security Model. JReview respects LSH Data Blinding, Data Currency, and Snapshot Labels. It also offers the ability to include/exclude LSH hierarchy and data based on JReview specific tags.

**Clinical Data Management Systems:**

Oracle Clinical™

Oracle Clintrial™

**Drug Safety Systems:**

ARISg™

Oracle ARGUS

Oracle AERS

**RDC Systems by:**

Medidata Rave™

Phase Forward InForm™

ITM

**Clinical Data Warehouse Products:**

Oracle LSH

SAS Drug Development

Oracle CDC

eClinical Solutions CDR

JANUS

entimICE

### *Study Setup (Admin)*

Built-in knowledge of Oracle Clinical system tables, Oracle LSH, Oracle CDC, Clintrial, drug safety systems,etc. plus configurable knowledge of internal data warehouses. The result is that there's no study setup required as soon as a study is created in your clinical data source then it's immediately available in JReview.

# JReview Functionality and Features

### *New in Version 13.1*

**Data Quality Analysis** – **major new area -** A major new capability has been added to JReview version 13.1 – which provides an 'unsupervised' centralized statistical review of data in a trial – on an ongoing basis – directly against the data accessed by JReview. This area runs a battery of tests against the data – including duplicate patient detection, and a wide range of statistical tests, then generates a 'global score' for each geographic area (country, for example), and each site within the region.   The data to be included in the evaluation, as well as which tests should be included (default is all of the tests provided), plus weighting factors for generating the global score from the contributing tests – can all be selected/modified by the user setting up the defintions.

**Template Reports -** major addition to template report area adds the very commonly used 'AE Incidence Table' to the set.  Easy to use drag and drop interface – adding the AE coded term levels to the definition – typically SOC and PT, as well as a 'column' variable – either Study, some other categorical item, etc. and some 'general overview' statistics – to display number of patients with AEs as well as different subsets, for example, number of patients with Serious AEs, etc.

**Graph Browser -** adds two new graph types continuing the addition of several graph patterns/types supporting but not restricted to Oncology. They are the Line Chart Mean plus/minus Standard Error and the Spider Plot. Previously, the Line Chart only supported Standard Deviation.

- The Spider Plot is used to display data over time (calculating days since a reference date), and by default plotting the change from baseline values of the item on the y-axis.
- General – HRZ panels throughout - Previously, the HRZ panels (Vertical to Horizontal Panel definitions) were only available in New Mode Graphs and Reports. Now, the HRZ panels appear throughout JReview including their use in Patient Selection Criteria, Output Filter, and any of the browser definition areas.

**AE Risk Assessment -** Added the ability to export Risk Assessment information at multiple levels. After executing an AE Risk Assessment – the user can select 'File … Export' which displays a dialog where the user can select if they want to export all the details of the AE Risk Assessment, or just the top level.

## *New in Version 13.0*

**Dynamic Patient Select Criteria Panel -** Added a patient data filter panel similar to the graphics browser filter control panel. It works at the patient level, to specify patient subset characteristics by selecting/unselecting various patient criteria values, as a more visual, more intuitive method of selecting patients of interest. Patient selection filter panel contents are defined by an easy to use drag and drop interface, saving/sharing those with others, and having multiple filter panels to choose from.

Also, it is present in the Dashboard Views area. In Dashboard View mode the default Dynamic PSC is displayed automatically, but you can change to a different Dynamic PSC definition for a different set of selector questions.

**Patient Narrative enhancements -** Allow interleaving of medical writer text entries between ‘automated text’ sections – wherever the definer of the template had embedded ‘comment’ blocks. These comment blocks appear with a blue border, and are editable, in the displayed narrative during review. Any comments entered are saved to the database, then interleaved with the automated text. Only comment blocks with entered text take space in the resulting narrative (as an RTF or PDF): Supports defining multiple ‘target purpose’ narrative templates per study for different purpose narratives. Previously, it supported one narrative template per study. Definition of embedded object at the ‘standard text’ definition stage.

**Report Templates** - Easy to use ‘drag & drop’ report templates for a number of always used reports in clinical studies, for Subject demographics and baseline characteristics overview ( but can be used for any data items). Definition as drag & drop items, select from extensive list of information/functions, ‘group’ rows as appropriate.

**Report Notes -** Enhanced PREFILLNOTESCOPYDATA= ; functionality now when re-executing a report when this option is enabled in config.options, any rows that had a reviewstatus or comment updated in a previous report execution, compares the previous value for each data column for the row with the current values, and highlights any cells that are different between current and previous report execution.

**Risk Based Monitoring -** New capability to export ‘RBM current state’ display to Excel spreadsheet with color highlighting of site/KRI results to represent low, medium, high risk indicators (green, yellow, red), with information on KRI definitions/thresholds, etc.

**General -** Any PDF displays for Formatted Patient Profiles, Formatted Reports, SAS/R output displays are updated with new PDF viewer. It now supports a wide variety of paging methods, PDF bookmark selection (if available in PDF), as well as PDF forms used in Patient Narratives. The enhanced PDF viewer capabilities in Formatted Patient Profiles supports multiple page viewing, smooth scrolling, book page turn, etc. Plus, a built-in search function.

**Workbook Patient Profile -** Suppress paging and Filters/Sorting on multiple worksheets outputs when exported to EXCEL. Also, support ‘no wrap’ option.

**Graph Browser -** New Graph Types added:

- **Waterfall Plot -** especially useful in Oncology trials.
- **Swimmer Lane Plot** - especially useful in Oncology trials.
- **Spider Plot** - especially useful in Oncology trials.
- **SunBurst plot Interactive SunBurst plot** – useful displaying sets of data by category – nested – to see relative proportions of patients between groups – interactive drill into/explode selected level/segment – to zoom to more details.

**Output Filters** - Added right-click popup menu to Output Filter table area offering "Clear all", "Copy all" & "Paste all" choices as applicable. The menu choices are only shown and/or enabled when they are applicable in the context. The new features/popmenu is enabled/available for all Output Filter dialogs ***except*** the output filter dialogs for Workbook and Formatted Patient Profiles and Patient Visit Data Report (due to complexities in those filters).

## *General*

The below list highlights some of the major capabilities supported in JReview all with built-in functionality.

**Dynamic Multi Study Pooling -** JReview provides a built in capability of dynamically pooling multiple studies - just by multi-selecting each study of interest using the usual Windows convention of Shift or CTRL + mouse click. Then, any of the reports, graphs, etc. will run against the pooled set of study data. No data moving or copying of data is needed as it happens automatically and on the fly.

**Awareness of Baseline & Endpoint -** JReview knows about patient's baseline, endpoint, or any time-related event and allows users to select patients based on these functions to report or graph these events, for example, patients with 10% elevation of LDH from baseline.

**Patient Selection Criteria -** Users can select any items from any table/dataset in the study, to use as part of the criteria for including or excluding entire patients into any displayed reports, graphs, patient profiles, etc.

**Patient Identification-** This is built-in automatic behavior which requires no setup and is a general capability throughout JReview by clicking one or a number of patient graph points, or report lines to provide patient detail information.

**Vertical to Horizontal Panels -** Typically (especially in CDISC SDTM), data domains such as labs or vital signs are stored in a vertical structure which is not ideal for visual analytics purposes. Once a panel/domain has been defined as a vertical structure, JReview displays the lab category and lab tests, for example, as if they were normal columns in the domain so users can easily select panel items to define new reporting objects, regardless of the underlying data structure.

**Alerts -** Users can define patient data conditions that they'd like to be notified about whenever the condition becomes true, i.e., if a Serious AE (Adverse Event) is entered, etc., the system sends an email to the user or list of users to be notified.

**Notes -** Patient, Visit or Data Item level notes can be posted throughout JReview. Keep notes for yourself, or share with others, regarding your findings or observations during data review.

**Batch Scheduling -** Most JReview defined reporting objects for reports, graphs, crosstabs, etc. can be scheduled for later execution in batch as very handy if some reports are retrieving a large amount of data from the database.

**Output Spec reuse -** Report, Graph, Patient profile specifications can be saved at Study, Project, Study Group or Global, and shared widely. If changes are needed, one instance of definitions are updated and automatically available to all studies in ‘scope’ (project, studygroup, global).

**New ‘Document’ feature in Manage/Migrate -** to generate formatted documentation for any JReview reporting object (graphs, crosstabs, reports, patient profiles, RBM definitions). The documentation is stored in an Excel spreadsheet and downloaded to the user’s PC.

**DVG/Code Lookup -** Built-in awareness of DVGs, code lists, SAS formats are automatically referenced in any report, graph, etc. as Cached and applied in server process.

**Email attachments (reports, etc.)** ***(requires print server)*** Expanded scheduling support for ability to specify list of email recipients for scheduled reports, etc. This feature needs to be configured with outbound email server information, and is a privilege that can be disabled for all, or enabled for specific users or usergroups.

**Integrated Duo Security Authentication into JReview Client** – separate build for JReview client supporting two factor authentication where appropriate.

## *Patient Profiles*

**Patient Review Tracking ‘workflow’ -** As users are reviewing patient data, they can check the ‘I Reviewed’ checkbox so the system keeps track of which patients have been reviewed and by what department/function. The user may apply Color codes and comments to patients. JReview can display review status for all patients, as well as display highlighted rows in the patient profile when new data is received since it was last reviewed.

**Graphical Patient Profiles -** Time-oriented (days on drug) graph display of user selected parameters taken directly from database items. Users can choose which categories and items they’d like to include – on the fly - without going back to a programmer or other support personnel. Select a value and Drilldown to selected data of interest.

**Tabular Patient Profile-Spreadsheet -** Tabular display of patient data for all or selected data by Table/View or by Visit. The Default includes all views/items with automatic row ‘band/wrap’. Export the profile to Excel, HTML, etc. Also, when used with Patient Review tracking the ‘New Data’ highlights rows (purple).

Tabular Patient Profile-Formatted - CRT Listing -Tabular display of patient data for all or selected data by Table/View or by Visit. The Default includes all views/items. The user simply selects which tables are to be included, the desired order, and which items are to be included for each selected table. Automatic row 'band/wrap' is supported with export to PDF. This is an alternative to what most companies do by lots of SAS programming. Formatted Patient Profiles can be scheduled to run in batch as well with scheduling server.

**Tabular Patient Profiles – Data Highlighting -** Same functionality that's built into Detail Reports and Formatted Detail Reports. Now the Patient Profiles (Workbook and Formatted) can have specific cells or rows highlighted in specified colors based on values out of range, or comparison between cells of the same row.

**Scheduling Support** – if Patient Profile Scheduling Server is licensed (optional license). Previously, Formatted Patient Profiles could be scheduled as a batch job to generate the PDFs for each of the patients (either selected patients or all patients in a subset). The generated PDFs were accessible directly through the JReview 'Review Output' tab, but could also be directed to be saved to a study specific directory which could be externally accessible to users. JReview version 12.0 extends this to now include the same functionality for **Workbook Patient Profiles** – generating Excel spreadsheets for each patient, also accessible externally if desired.

## *Reports*

**Drag-and-Drop User Interface -** This interactive preview mode lets you see the report as you add columns - previewing the results on a subset of data in real time. The drag-and-drop user interface added to Reports, CrossTabs and Graphs provides immediate preview of output results for further refinement before saving and sharing the object definitions.

**Detail Data & Summary listings with 'New Data' highlighting -** Standard Detail Data and Summary Report listings now optionally display 'New Data' highlighting associated with our Patient Review Tracking feature. In these spreadsheet style reports, the user now sees which rows are new or updated since each patient was last reviewed. ** 'New Data' highlighting is unique to JReview, where detail data listing capability is not.

**Formatted Reports (PDF) -** Detail and Summary nicely formatted PDF reports are designed to look like submission quality data listings with no programming required.

**Special 'Date Merge' report -** Patient Visit Data Report is a special multi-pass date merge report developed with the NCI. No SQL joins for date merge in the JReview client. It is very useful for AE-ConMed display or any other data which is aligned more naturally by observed date (start date, onset date, etc) rather than typical visit joins.

**Mapping text terms -** provides user definition through a remapping definition window. It allows users to select a text item (for example AE Preferred Term), then defining a 'mapped' term and selecting which of the available existing terms (AE Preferred Term, for example) should belong to that remapped term.

**Report Reviewer Notations** - Any detailed data listing report defined in JReview can also have a 'report review' template table of review items added to it to support report row reviewer comments, etc.

## *CrossTabs*

**Nested & 'Side by Side' -** Cross tabulations support both nested and 'side by side' display with patient counts in cells, optionally with % of specified denominator (all patients, patients in by Groups, etc). Clicking in a cell identifies the patients and broadcasts a list of patients to any other displayed output. ** CrossTab capability is not unique to JReview, but N (%), denominator selection and patient cell clicking is unique.

**CrossTab browser – Incidence counts/ percent of some denominator, etc. -** now support Incidence tabulations by unchecking 'Count Subjects', then adding the row variable. Also, as the Cell Variable then check 'Count' and he Crosstabs switch to 'incidence mode' including percentage of some denominator which can be either row totals or column totals. Descending Sort is also supported.

## *Graphs*

**Special Graph types for Clinical Data -** Baseline/Endpoint plots, Shift Plots, Hy's Law Plots, and many more scientific, clinically relevant graph types for clinical data visualization are supported with patient identification built in. There is no need to setup any drill down rules for patient drill down as patient identification is native to JReview.

**Graph Type Exposure by Dose -** On the fly days since some reference date calculation, displaying number of patients by By Variable (if defined) – on drug/receiving dose – by day – to provide a quick comparison of different patient groups dose exposure experience, off drug, etc.

**Graph Type Disposition Percent -** On the fly days since some reference date calculation, displaying percent of patients either Active, Completed or Withdrawn over the course of the study.

**Graph Type Tree Map -** A very flexible, easy to define implementation of Tree Maps. It allows definition of multiple 'levels' – category variables at each level, with size of included nodes based typically on counts of the lowest level object, with coloration based on any other information. For example, a TreeMap of AE SOC, AE PT with size based on count (incidence) of AEs, with coloration based on mean age of patients within that 'leaf'.

**Graph Type Cumulative Count by Time -** A line graph that displays a cumulative count of events or occurrences across time or a cumulative count across time of patients with whom an instance of an event or occurrence is associated.

**Volcano Plot** – provides relative risk ratio information ( on the x axis – as a log scale), and p value on the Y axis – for each of the plotted items (AE terms, etc.). If the user clicks on any of the plotted points, or lasso's any of the points, they'll see the terms and associated risk ratio information and p-values in the options windows to the left of the graph. In addition, any of those points highlighted, or clicking on any of the term entries in the displayed list on the left – sends a message throughout JReview to highlight those patients who have the selected terms.

**Histogram –** display the distribution of any numeric variable in the study, with By Variable and Page Variable supported. Displays 'buckets' and number of patients in each 'bucket' - by default, 10 buckets, but configurable, along with the normal distribution curve. Also, an option to display the mean and standard deviation details in a table below the graph.

**Composite Visualization of Liver Tests** - for assessing patients for Drug Induced Liver Injury. Based on very recent discussions with the US FDA, we've added a new graph type. JReview already includes the 'classical Hy's Law plot', and we've added a new graph type which includes initial categorization of each patient at baseline regarding their position in a Hy's Law chart, then plots each patient's peak values on a composite graph for each of the 4 possible liver injury states – Normal, Cholestasis, Hy's Law or Temple's Corollary, with color coding based on the legend as to their baseline condition.

## *AE Risk Assessment*

**AE Risk Assessment - Dot Plots -** This AE Risk Assessment area was developed with the FDA and provides interactive 'dot plots' with Patient Subgroup distribution analysis, as well the usual JReview patient identification features with other output displays.

**AE Risk Assessment – Tree Map -** This AE Risk Assessment area was developed with the FDA and also provides ’forest plots’/’tree-map’ display of AEs organized by SOC, then PT within the tree-map. Each segment in the tree-map is interactive and clicking on any of the sections of interest highlights the patients represented in the section in any other patient level output.

**Benefit Risk Analysis -** New graph type added at the request of the FDA based on design by FDA statistician (Jonathan Norton). A high level overview of benefit and risk of the trial is presented as a whole, displaying each patient as a row with color coded segments based on time period categorization for benefit, risk, both, neither or withdrawal.

## *Risk Based Monitoring (RBM)*

**Definition of Key Risk Indicators -** Centralized monitoring teams can define risk categories and key risk indicators from all clinical and operational source data available, set thresholds, and specify suggested actions with scheduled periodic analyses.

**RBM Data Browser -** Use the JReview RBM Data Browser to view Indicator Results Visualization area and subset by categories, site attrributes and interactively sort any column for site ranking.  View site distribution over time (box whiskers), with a selected site noted as line chart.

**RBM Tree Map -** The RBM tree map allows for the inspection of the weightings of selected key risk indicators by site, country, or region.

**RBM Reporting iPad App -** Aggregated RBM reports can be scheduled in regular intervals to push monitoring activity plans out to site monitors for follow-up actions. A newly developed native iPad app will be released soon that will provide easy access to key RBM Metrics and recommended actions for CRAs and monitors in the field.

## *SAS & R Integration*

**Ad hoc SAS analysis -** Perform Ad hoc SAS analyses from within JReview environment which writes the SAS program and executes it for the user using SAS.

**SAS data access -** IRServer access SAS datasets via SAS Share directly for very high performance, and awareness of SAS Format Libraries by JReview.

**Execute your own SAS programs -** Supports the ability to launch customer written SAS programs from within **JReview environment.**

**Register R Scripts -** Ability to register any R scripts stored on the server side – to be executed from any JReview user's session thereafter.

**R Script Composites -** JReview supports item name remapping, as well as forming R dataframe 'composites' – from different SAS datasets – where join logic has already been determined and implemented by JReview.

**Enable Composites in SAS program registration** - when accessing a database data source (Oracle, SQLServer, PostgreSQL). This feature has been supported for R scripts previously.

**SAS Program scheduling –** repetitive scheduling is supported.

**ErrorList – support for importing SAS dataset based 'error reports' –** bringing them into a single 'neutral' table for each study, but adding a 'virtual' reference to each original dataset with SAS labels, etc. So all 'error lists' can be reviewed separately (editable status/comment columns), but common table can be summarized with number Open, Closed, etc.

## *Patient Narratives*

**Narrative Checkout Browser -** The narrative checkout browser contains a list of patients who require a narrative based on the predefined patient selection criteria in accordance with FDA requirements. This browser allows narrative authors to checkout patients in order to complete narratives, or can be used by reviewers to choose patients to view already completed narratives. This list can be filtered and sorted.

**Narrative Status -** After selecting patients to check out, each author maintains their own list of narratives to complete. Once a patient is checked out by one author, it is protected from being checked out by anyone else. After completion the author can submit a predefined status change like "Needs Review' or "Needs more data" or "Final", and return the patient back to the pool of patients in the checkout browser.

**Writer's Panel -** The narrative is auto-filled with header information and standard text. Based on information gleaned from predefined reports, notes, or patient profiles, the user can check the reason and write additional information in the clinical summary. Also, JReview defined graphs or reports to support the narrative can be embedded by the writer. Any notes that might be useful to the data collection process can be added from here as well.

**Patient Narrative -** The narrative can be saved to the database, or saved as a pdf or rtf , and viewed by the writer. Future enhancements to patient narratives include working with the FDA to provide an export in a specific XML feed to help support data standards for use in FDA review.

**Narrative Definition -** During the template definition process, the patients who need to have narratives written and the standard information in the narrative are predefined once per study or group of studies. The status types and reasons for narratives, standard header and text with conditional logic, and any embedded or associated objects are defined according to company preferences.

**Map PSC -** Capability to map each Patient Selection Criteria referenced to retrieve a selected group of patients to a 'reason for narrative' default setting. This is especially useful when generating patient narratives in batch.

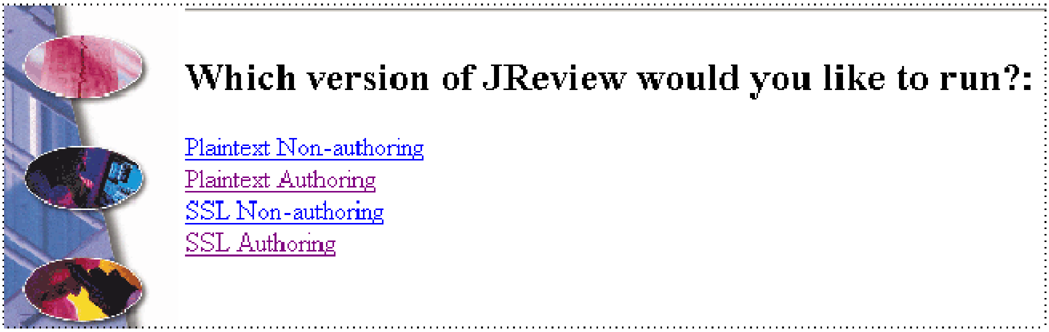
**Schedule Patient Narratives** - by generating the RTF files for each patient in batch and saving the resulting RTF files for access from within JReview, as well as, in an externally accessible directory.

# Starting the application

## *Logging on*

Go to your JReview Web site's home page. The login dialog can vary between sites based on the installion. The following is being shown as a typical installation.

1. Select your JReview link (SSL for normal Internet use, Clear-text for LAN/in-office use). Authoring versions are available if you have permission to create and save objects in JReview™.



Which version of JReview would you like to run?:

Plaintext Non-authoring
Plaintext Authoring
SSL Non-authoring
SSL Authoring

2. Enter your web server logon information.

Connect to www.jreview.com

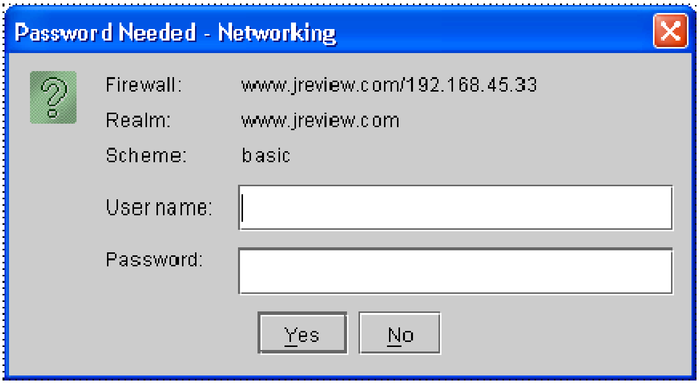
www.jreview.com

User name:

Password:

☐ Remember my password

3. If your web server is protected, enter your web server logon information.



Password Needed - Networking

Firewall: www.jreview.com/192.168.45.33

Realm: www.jreview.com

Scheme: basic

User name:

Password:

4. Click **Yes** to the Security Warning.

Warning - Security

Do you want to trust the signed applet distributed by "Integrated Clinical Systems Inc."?

Publisher authenticity verified by: "Thawte Consulting cc"

The security certificate was issued by a company that is trusted.

The security certificate has not expired and is still valid.

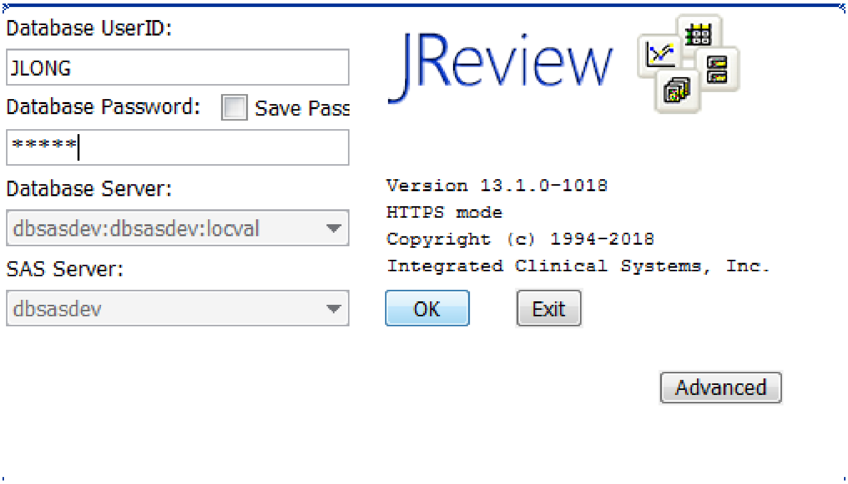
Caution: "Integrated Clinical Systems Inc." asserts that this content is safe. You should only accept this content if you trust "Integrated Clinical Systems Inc." to make that assertion.

5. Enter your Database UserID, password and server names (and instance ID where applicable), to connect to the appropriate Database and SAS servers, using the tab key to move from field to field.

   The **Authoring Mode** checkbox overrides any link request. There is a checkbox to Save Password.

   ***Login attempts are prevented when NodeID, Username or Password are blank/empty.***

6. Click **OK**.



Database UserID: JLONG

Database Password: ☐ Save Pass

*****

Database Server: dbsasdev:dbsasdev:locval

SAS Server: dbsasdev

Version 13.1.0-1018
HTTPS mode
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## *Database and SAS server*

The Database and SAS server hostnames or IP addresses in the JReview LOGON screen default to ‘localhost’. Using localhost in these two fields tells the JRserver the clinical database is running on the Web server (an unlikely setup). Your administrator should provide the Database and SAS IP addresses or hostnames for access to your clinical data.

The Database and SAS server entries have the hostname or IP address of the machine(s) running the Oracle instance for your clinical data project (Oracle Server IP) and the IP address of the machine to run SAS jobs (SAS Server IP) if applicable.

## *Choosing an ORACLE database*

By default, JReview™ connects to a default ORACLE instance on the specified server. You can specify the instance ID of another ORACLE instance from the client application.

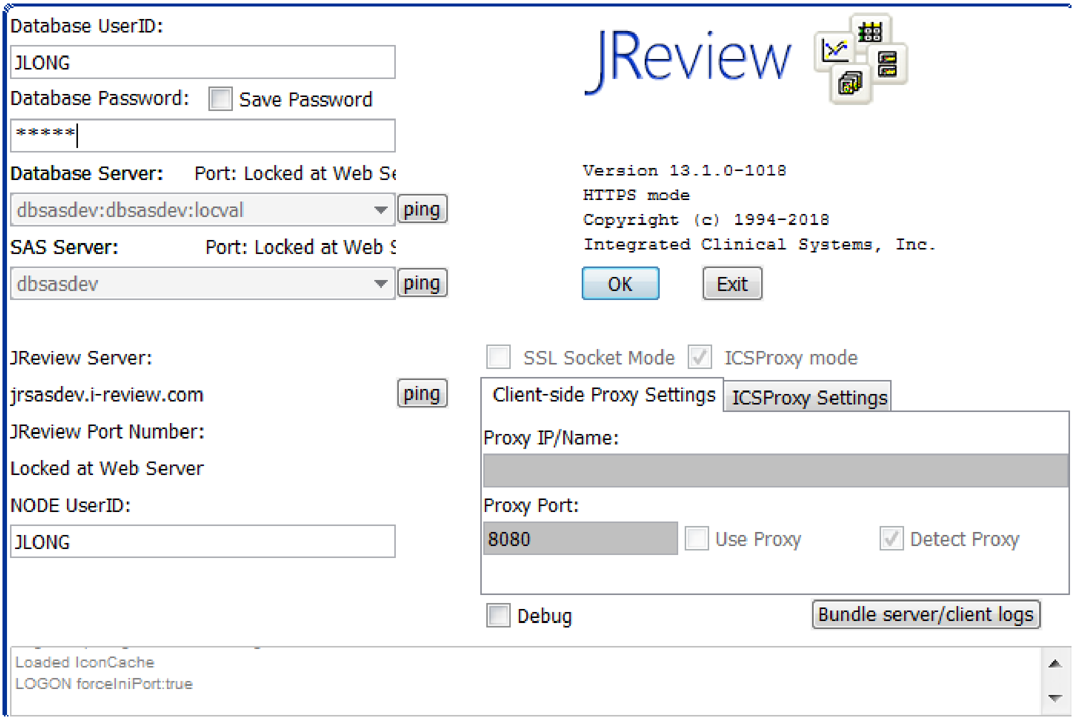
If you want to access an ORACLE database other than the default database that you normally connect to, add the specified database identifier (ORACLE SID) to the end of the ORACLE Server name separated by a colon (:) in the text entry box within the opening Logon dialog box. If the Oracle instance is not the default instance, specify the instance with a colon prefix: **172.16.0.172:oracle8**

## JReview Server

The JReview server is the IP address or Domain name of the machine running the JRService process. A default of blank indicates that the Web server is running the JRService/JRServer process. If JRService/JRServer is NOT running on the Web server where you loaded JReview, enter the IP address or Domain name of the machine running the JRService process as the IP address. **Most installs require the JReview Server to be blank.**

## NODE UserID

When you log into Review, you will need your UserID and Password, as well as the server name and database instance. However, it is necessary that each JReview client has a unique NODE UserID. Select the **Advanced button** to designate a unique NODE UserID.



Database UserID:
JLONG
Database Password: ☐ Save Password
*****
Database Server: Port: Locked at Web Se
dbsasdev:dbsasdev:locval
SAS Server: Port: Locked at Web S
dbsasdev

JReview Server:
jrsasdev.i-review.com
JReview Port Number:
Locked at Web Server
NODE UserID:
JLONG

```
Version 13.1.0-1018
HTTPS mode
Copyright (c) 1994-2018
Integrated Clinical Systems, Inc.
```

☐ SSL Socket Mode ☑ ICSProxy mode

Proxy IP/Name:
Proxy Port:
8080 ☐ Use Proxy ☑ Detect Proxy

☐ Debug

```
Loaded IconCache
LOGON forceIniPort:true
```

This screen displays when connected to server and attempting to login.

Target SAS server is ''
Connected to server, attempting to login

*Wrong password?*

If you have entered an incorrect or invalid Database user ID or Database password, the application notifies you after you click **OK**. Review requests that you enter a valid user ID and password.

You are allotted three incorrect entries before the application denies access.

- We recommend that you dedicate an internet browser session to JReview. Open up another session if you want to browse other web pages. Moving to and from the JReview web page will cause JReview to logout and present the logon screen.
- We suggest that you use JReview’s File -> Exit to leave JReview (although exiting the browser or leaving the JReview web page should achieve the same result). After exiting JReview, the browser will show a blank screen and is ready for the other web browsing.
- If you wish to logout and login again to JReview, use JReview’s File -> Exit. After pressing “**OK**” to shut down JReview, press your browser “**Refresh**” or “**Reload**” key. This should redisplay JReview’s logon screen without exiting the browser.
- There is a UsageLogging enhancement where now ‘Full’ usagelogging level records each FULL SQL statement executed for each step in a multi-SQL reporting object, in a separate new table named REVIEWADMIN.USAGELOGGINGSQL.

## *Change password*

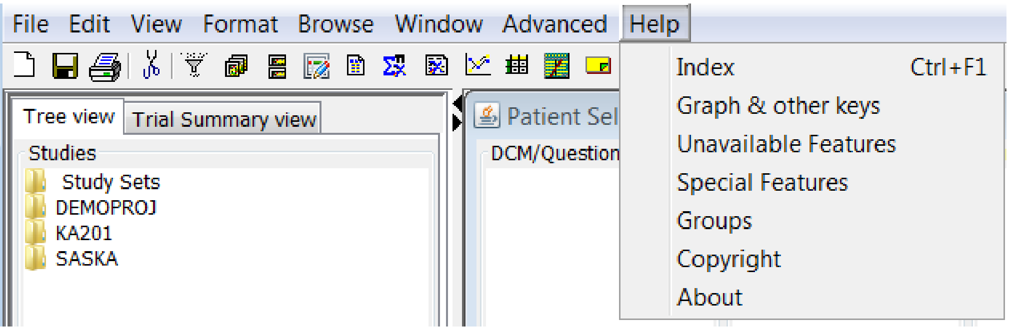
If a user changes their password in the CDMS and they have scheduled jobs in JReview, and they do NOT login to JReview to force the password change through to the jobschedule table; then the reporting server process continually tries to run that job and login with the incorrect password. Eventually this could lock out the user from the database due to too many failed login attempts.

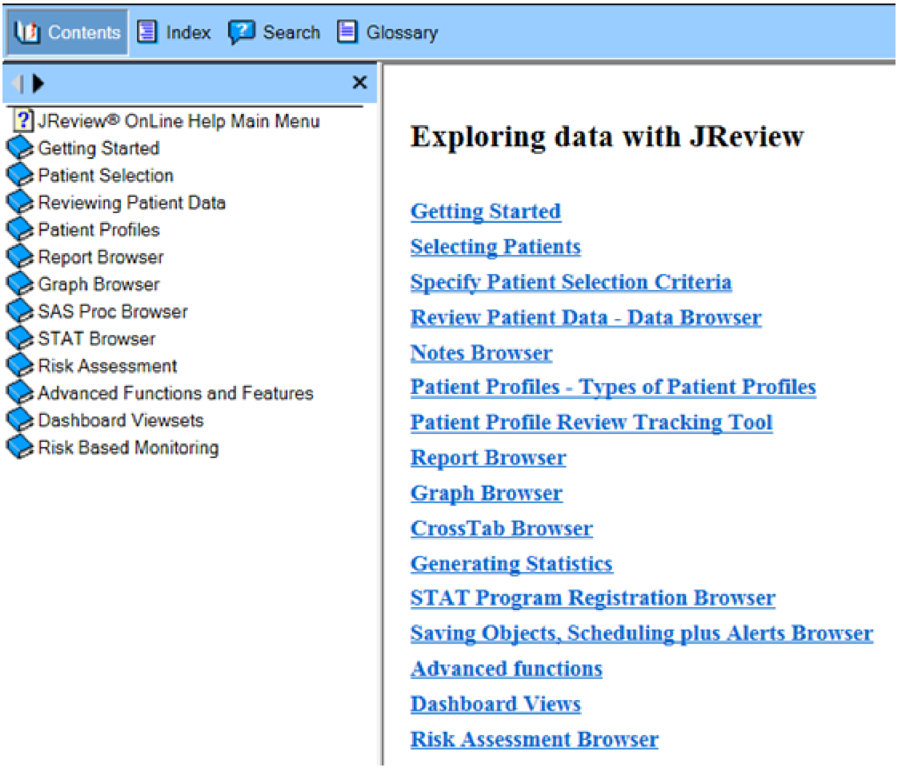
The user needs to login to JReview after changing their password to have the password change propegated through to the scheduleing table. However, this current behavior could be changed in the future to eliminate the need to do that or at least not have this process try so many times that the user/password gets locked.

# Quick tour

## *On-line Help*

Our system of **On-line Help** can be accessed by clicking **Help** from the Menu Bar and select **Index**.

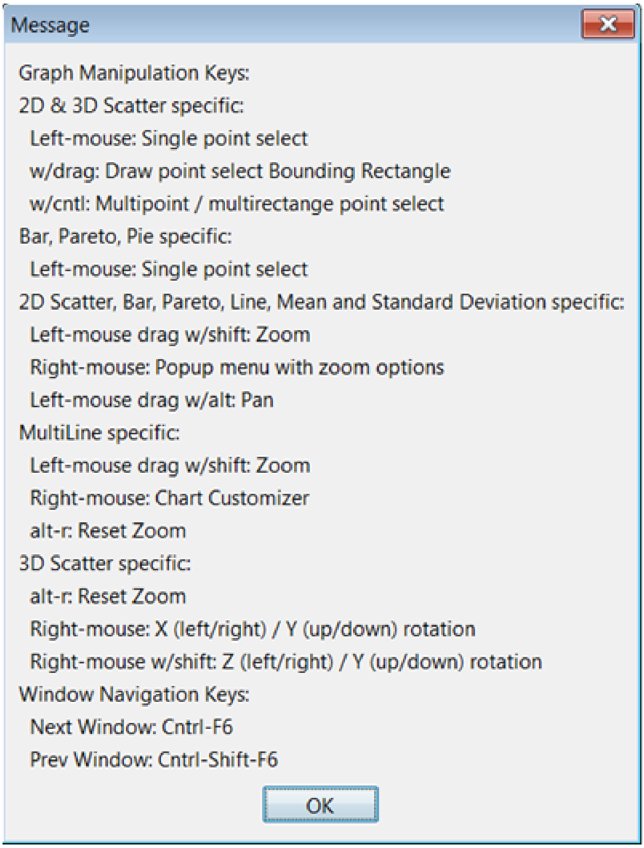




*General instructions*

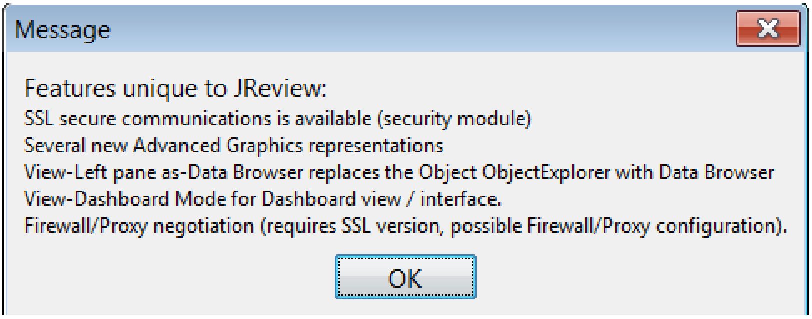
You can view information about application version, groups, products features and user tips by clicking on **Help** in the menu bar. Select choices from the drop down menu.

- Select to view information for **Graph & other keys**.



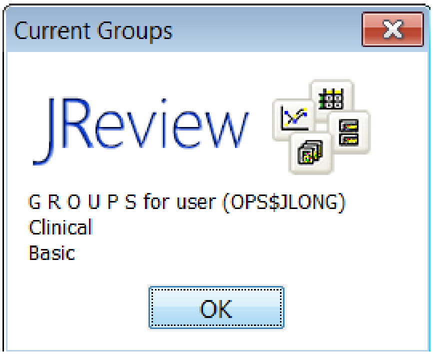
Graph Manipulation Keys:
2D & 3D Scatter specific:
  Left-mouse: Single point select
  w/drag: Draw point select Bounding Rectangle
  w/cntl: Multipoint / multirectange point select
Bar, Pareto, Pie specific:
  Left-mouse: Single point select
2D Scatter, Bar, Pareto, Line, Mean and Standard Deviation specific:
  Left-mouse drag w/shift: Zoom
  Right-mouse: Popup menu with zoom options
  Left-mouse drag w/alt: Pan
MultiLine specific:
  Left-mouse drag w/shift: Zoom
  Right-mouse: Chart Customizer
  alt-r: Reset Zoom
3D Scatter specific:
  alt-r: Reset Zoom
  Right-mouse: X (left/right) / Y (up/down) rotation
  Right-mouse w/shift: Z (left/right) / Y (up/down) rotation
Window Navigation Keys:
  Next Window: Cntrl-F6
  Prev Window: Cntrl-Shift-F6

- Select to view information about **Special Features**.



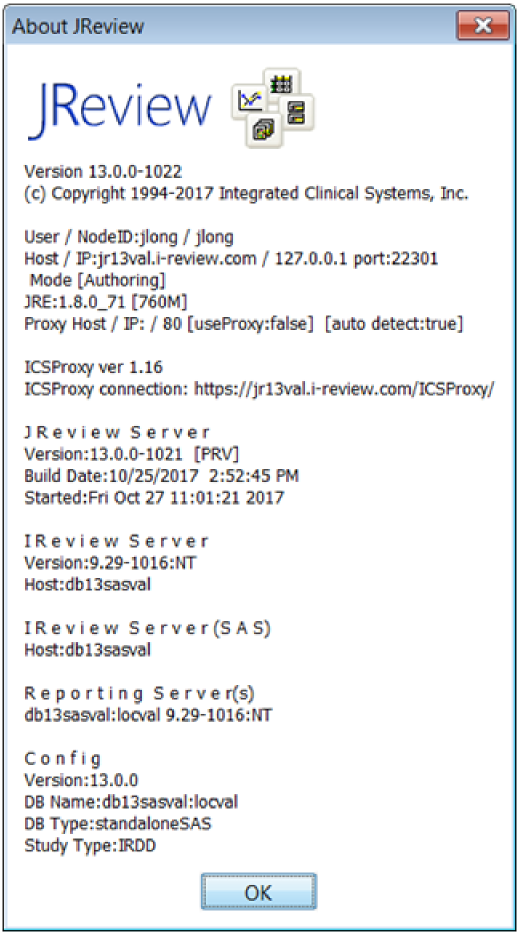
Features unique to JReview:
SSL secure communications is available (security module)
Several new Advanced Graphics representations
View-Left pane as-Data Browser replaces the Object ObjectExplorer with Data Browser
View-Dashboard Mode for Dashboard view / interface.
Firewall/Proxy negotiation (requires SSL version, possible Firewall/Proxy configuration).

- Select **Groups** to view information for UserGroup usage.



GROUPS for user (OPS$JLONG)
Clinical
Basic

- Select **About** for JReview's client version information to help understand the environment for Customer Support Tickets.



Version 13.0.0-1022
(c) Copyright 1994-2017 Integrated Clinical Systems, Inc.

User / NodeID:jlong / jlong
Host / IP:jr13val.i-review.com / 127.0.0.1 port:22301
Mode [Authoring]
JRE:1.8.0_71 [760M]
Proxy Host / IP: / 80 [useProxy:false] [auto detect:true]

ICSProxy ver 1.16
ICSProxy connection: https://jr13val.i-review.com/ICSProxy/

JReview Server
Version:13.0.0-1021 [PRV]
Build Date:10/25/2017 2:52:45 PM
Started:Fri Oct 27 11:01:21 2017

IReview Server
Version:9.29-1016:NT
Host:db13sasval

IReview Server(SAS)
Host:db13sasval

Reporting Server(s)
db13sasval:locval 9.29-1016:NT

Config
Version:13.0.0
DB Name:db13sasval:locval
DB Type:standaloneSAS
Study Type:IRDD

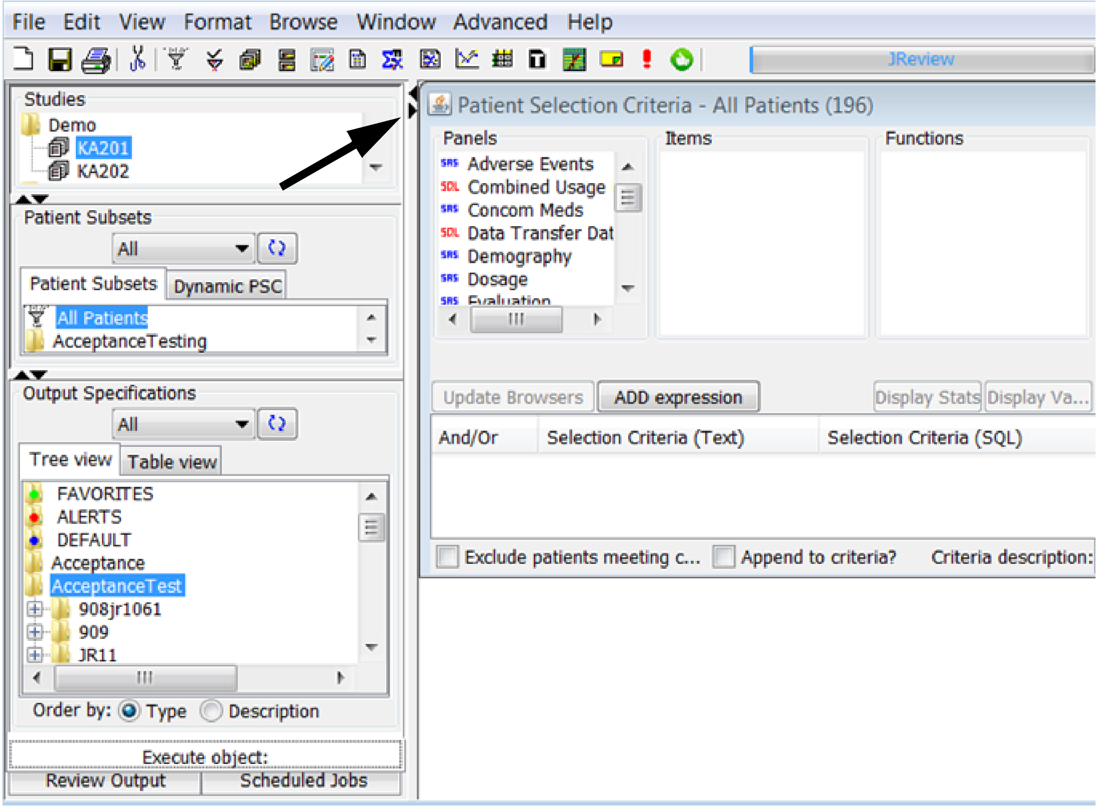
## *Main window*

After you successfully log into the ORACLE database (on the computer storing your clinical data), the main window of JReview opens.

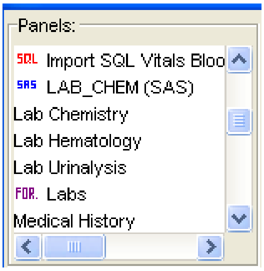
The Object Explorer Window is docked at the left side. The main split pane divider between the Explorer pane and desktop pane now can be re-sized with one touch expandable arrows. This allows you to quickly pan the divider left and right to decrease or increase the window area as needed.

In the Object Explorer Window select a project, for example ‘Drug KALIL’ and protocol ‘KA201’. JReview retrieves all previously stored Output Specification objects created and organized in folders.

***Note: SSL JReview has a little yellow lock in the JReview menu bar which isn’t displayed in clear text JReview.***



To assist you, a colored prefix may be displayed in front of a panel or file name to identify the data source as SQL, SAS, PIVOT, XLS , FOR (Foreign) or tranformed Vertical-to-Horizontal panel as HRZ.



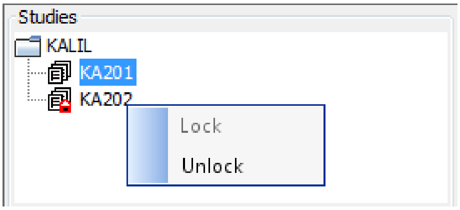
The following chapters discuss the individual browsers used for building, modifying and saving Output Specification objects into folders viewed through JReview. Once the objects are saved, they can be quickly located and launched from within these folders in JReview. The results are displayed in the Output Specifications window and Patient Subsets window.

***Note: The individual who creates and saves an object definition has sole security to delete or modify it. SuperUsers have extended privileges.***

In addition, a browser icon displays along side the object description to quickly identify the various output results, such as Reports, Graphs, CrossTabs, Registered SAS Programs, etc. A filter icon lets you know that a patient selection criteria was saved with the output specification object. A red colored filter icon saved with the output specification object means the patient selection criteria is required for the output object. Patient selection criteria may also be saved as separate objects in the Patient Subsets window.

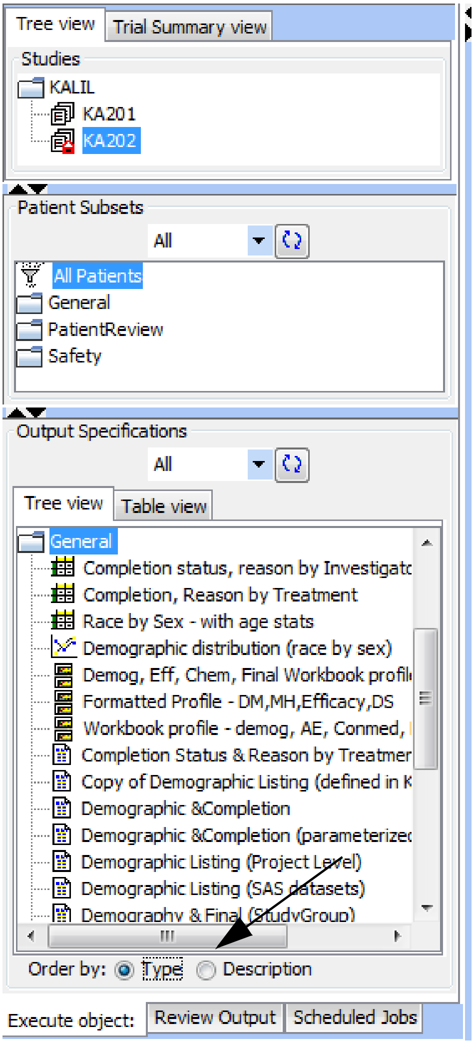
## *Study Lock Status*

A red lock icon may be displayed to alert users that certain studies have a "**Lock**" status.  Simply right mouse click to display a floating menu and select study lock status.



## *Order Output*

Once you selected a study(s) any saved objects are displayed in their designated folders under the Patient Subsets and Output Specifications windows. You can change sort for the Order Output Specifications to display by the icon type or object descriptions. Simply click on your preference to change the order display.



Order by: ● Type ○ Description

## *Launch a saved object*

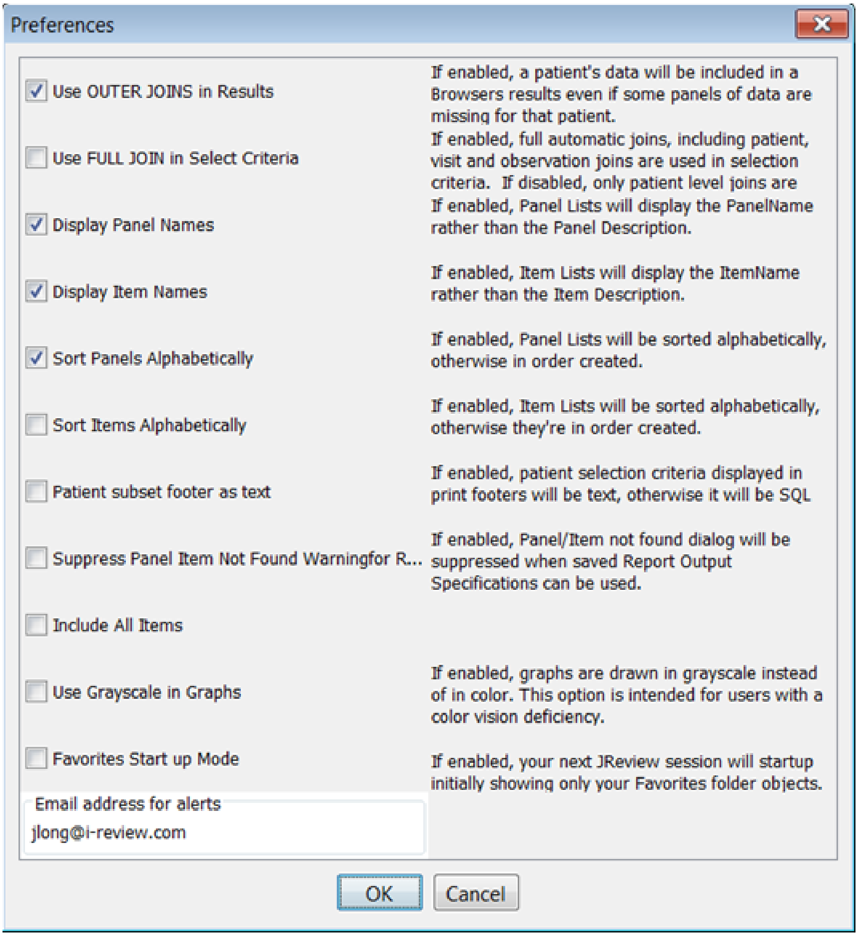
Once the application has started, you select your patient population. You can double click on a saved object in the Patient Subsets window or build your own Patient Selection Criteria. This topic is covered in detail in the next chapter.

When you initally open JReview or double click on a saved object to generate and display the results output window, a Communication's Progress window will briefly display. This feature is similar to the hour glass symbol typically seen when an application is in processing mode.  The process bar is located in the far right corner of the tool bar.

Not all communication requests are processed in a separate thread. This means that JReview may appear to freeze momentarily upon certain requests. The progress bar will appear for all delayed requests.

## *Preferences*

JReview Preference options are available from the **Edit Menu** under **Preferences**. When you change a preference, the change is reflected for the duration of the session from that point forward.



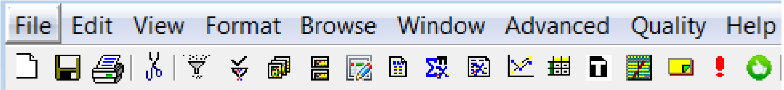
Preferences

| | |
|---|---|
| ☑ Use OUTER JOINS in Results | If enabled, a patient's data will be included in a Browsers results even if some panels of data are missing for that patient. |
| ☐ Use FULL JOIN in Select Criteria | If enabled, full automatic joins, including patient, visit and observation joins are used in selection criteria. If disabled, only patient level joins are |
| ☑ Display Panel Names | If enabled, Panel Lists will display the PanelName rather than the Panel Description. |
| ☑ Display Item Names | If enabled, Item Lists will display the ItemName rather than the Item Description. |
| ☑ Sort Panels Alphabetically | If enabled, Panel Lists will be sorted alphabetically, otherwise in order created. |
| ☐ Sort Items Alphabetically | If enabled, Item Lists will be sorted alphabetically, otherwise they're in order created. |
| ☐ Patient subset footer as text | If enabled, patient selection criteria displayed in print footers will be text, otherwise it will be SQL |
| ☐ Suppress Panel Item Not Found Warningfor R... | If enabled, Panel/Item not found dialog will be suppressed when saved Report Output Specifications can be used. |
| ☐ Include All Items | |
| ☐ Use Grayscale in Graphs | If enabled, graphs are drawn in grayscale instead of in color. This option is intended for users with a color vision deficiency. |
| ☐ Favorites Start up Mode | If enabled, your next JReview session will startup initially showing only your Favorites folder objects. |

Email address for alerts
jlong@i-review.com

## *ToolBar and Browser Menu Bar*

You can access some functions through the Browser Menu Bar and Browser Builkd windows with the button icons in the toolbar.



***Caution:* *Do not use the web menu bar to print. This will generate a system error.***

The individual browser **ToolBar buttons** are for creating and saving object specifications. These are the same browser icons displayed along side the stored object descriptions to identify the object type.

New: Clears the current specifications in the active area.

Print: Prints the specifications, spreadsheet, report or graph, or whatever is active.

Selection Criteria: Makes the Selection Criteria Window active. Returns to Main Menu in Review.

Dynamic PSC: Patient data filter panel that works at the patient level, to specify patient subset characteristics by selecting/unselecting various patient criteria values.

Data Browser: Starts the Data Browser.

Patient Profile Browser: Starts the Patient Profile Browser.

Patient Narratives: allows medical writers to access created patient narrative templates to enter and check out.

Report Browser: Starts the Report Browser.

Graph Browser: Starts the Graph Browser.

CrossTabs Browser: Starts the CrossTabs Browser.

Report Templates Browser: ‘drag & drop’ report templates for a number of always used reports in clinical studies.

Risk Assessment Browser: produces a risk difference or risk ratio output typically used to analyze adverse event data.

SAS Proc Browser: Starts the Statistics Browser.

STAT Program Browser: Registered SAS Programs Library for immediate execution against selected patient populations.

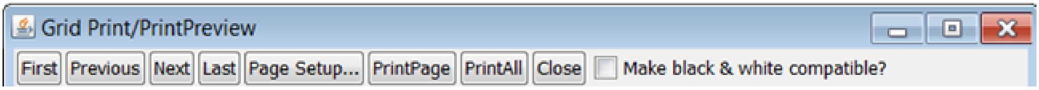
Notes Browser: Opens the Notes Browser.

Alerts Browser: Starts the Alerts Browser.

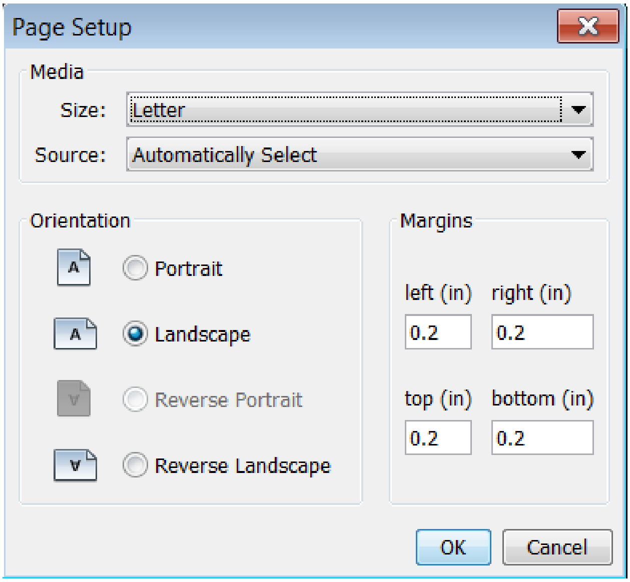
Risk Based Monitoring Data Browser.

To select an object to print, you must select its frame (make the titlebar blue). See the following suggestions and limitations.

***Caution:*** *Do not use the Internet Browser's Print button to print, use JReview's Print button or from the* ***File*** *menu, select* ***Print****.*



1. Since landscaping printing can present problems, we recommend that you do not change printer orientation settings prior to printing (use the defaults).



Size: Letter
Source: Automatically Select

○ Portrait
● Landscape
○ Reverse Portrait
○ Reverse Landscape

| left (in) | right (in) |
|---|---|
| 0.2 | 0.2 |

| top (in) | bottom (in) |
|---|---|
| 0.2 | 0.2 |

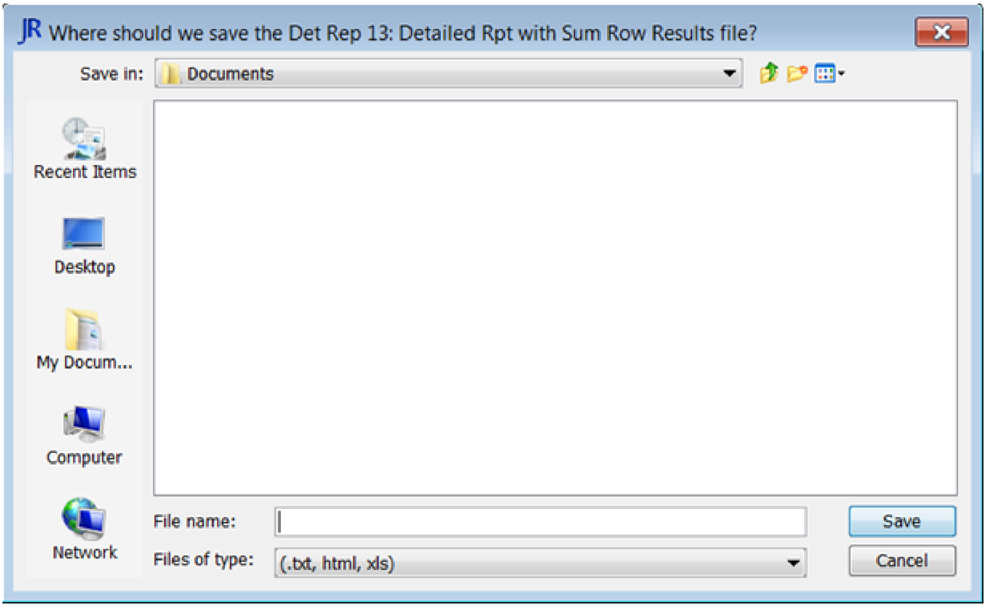
2. If your printer supports reducing the resolution of the printout, we recommend that you reduce the print resolution to 300 dpi. This will significantly speed the printing process.

- In Microsoft Internet Explorer, you may resize (or use View -> Fullscreen) the JReview session screen at anytime. In Netscape, you must resize the browser window prior to starting JReview.
- Most grid objects support copy and paste.

  Use the mouse (click and drag) to highlight a range of grid cells, press CNTRL-C (or the copy toolbar icon) and copy the contents to other applications such as Excel. CNTRL-A will select entire grids in most cases.

  Or

  Use the mouse (click and drag) to highlight a range of grid cells, Select the **Edit** menu and click **Copy**.
- Exporting objects to native file formats is available. To select an object to export, you must select its frame (make the titlebar blue). Select the **File** menu and click **Export**. Select the file type and enter the file name with the appropriate file extension.


Where should we save the Det Rep 13: Detailed Rpt with Sum Row Results file?

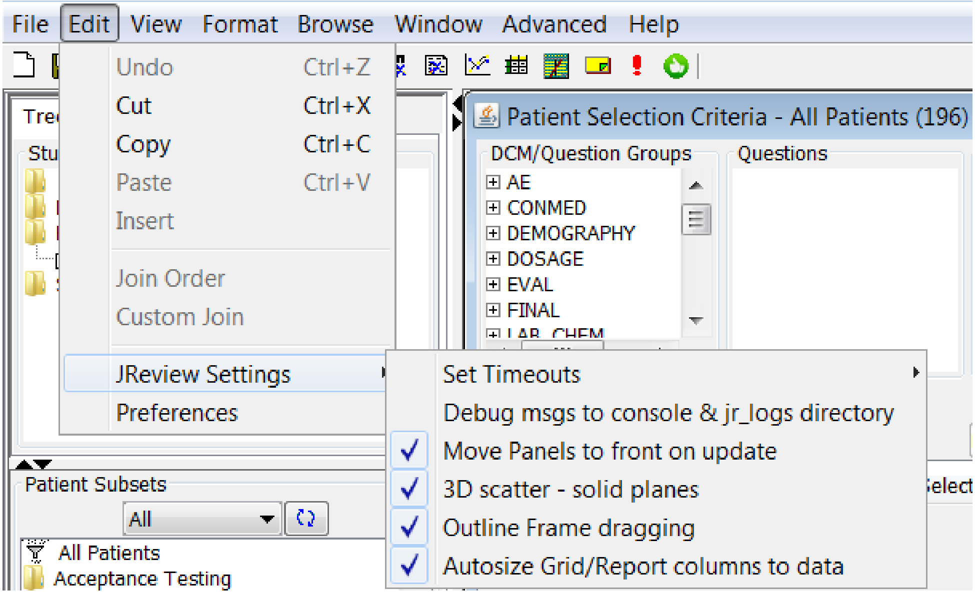
Save in: Documents

File name:

Files of type: (.txt, html, xls)

## *JReview Settings*

JReview execution and viewing options are available from the **Edit Menu** under **JReview Settings**. When you change a setting, the change is reflected for the duration of the session from that point forward.



- **Set Timeouts** – Controls the length of time JReview will wait for a request response from the server. Each timeout profile has two associated times; Database (DB) which refers to standard requests, and BATCH which refers to long-turnaround requests such as SAS jobs and any Formatted output. Default setting is “Medium”, but installations often set this to “Long” via JReview properties file.
- **Debug Options** – Production releases only have the “Debug msgs to your jr_logs directory” option. This is a debugging assistance setting and should only be used if instructed to do so by your JReview administrator or Integrated Clinical Systems, Inc.
- **Move Panels to front on update** – If enabled (default), causes JReview to bring any open panels (from the Data Browser) to the front/top layer of the JReview desktop when a new subject is selected. Subjects can be selected from a variety of JReview objects including the Data Browser, Detail Reports and Graphs.
- **3D scatter – solid planes** – If enabled (default), causes 3D scatter plot to have solid surface planes. If disabled, points in 3D scatter plots will show through the planes so that points that may be hidden can be selected.

- **Outline Frame dragging** – If enabled (default), JReview will only show the outline of internal window frames as they are dragged or resized. If disabled, JReview will show (repaint) the contents of windows as they are dragged or resized (could be sluggish on some machines).
- **Autosize Grid cols to data** - If enabled (default), JReview will size column widths to data shown in spreadsheet-style reports (considers top 240 rows of data by default). If disabled, JReview will use a fixed size for the columns of a spreadsheet-style report. Older or slower client machines may present reports more quickly if this option is disabled.
- **Show Selection Criteria (Text)** – If disabled (default), JReview will show Select Criteria as SQL code in its “Who?” / PSC object queries. If enabled, JReview will show Selection Criteria Text returned from the server in its “Who?” / PSC object query dialogs.
- **JReview Console** - If selected displays the JReview Console window.
- **Test JPUT** - If selected use to test export function.

# 2 Selecting Patients

# Specify Patient Selection Criteria

## *Review sub-populations*

JReview is segmented into “Browsers” which allows you to build reports, patient profiles, crosstabs and graph clinical data. These objects are built and potentially saved with the ability to share with other. The separation of “Who” versus “What” is critical to JReview and the “Who” is defined by the patient selection criteria. You are able to filter the available patient population from the selected protocols into sub-populations using the patient selection criteria. The patient selection criteria allows you to focus on these segregated sub-populations in the production of reports, statistics, patient profiles and graphs. This function supports the concept of the patient paradigm in that all information for the selected patients is available for display including multiple visit data.

If you do not specify a patient selection criteria, by default you have access to the whole patient population.

## *Focused analysis*

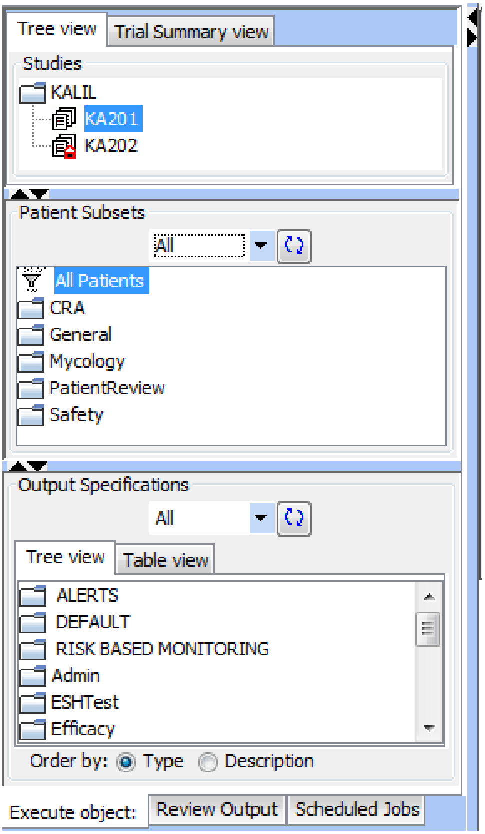
The patient selection criteria ***(aka PSC)*** focuses JReview’s analysis on the patient sub-population for all available data and doesn’t restrict the results to the individual data observations or visits of the patients to be analyzed. Another function, the Filter Output discussed in the next chapters is designed to focus on particular observations and visits. The Filter Output is another level of filtering used to restrict or select specific patient data for multiple visits, observations and Adverse Events. Access to the Filter Output function is located within each browser when you define your output specification. The patient selection criteria and filter output can be used in conjunction with each other or as individual functions to meet your needs.

The patient selection criteria you create can be saved by description and managed in folders for future use. The saved patient selection criteria are organized in your folders and displayed in the Patient Subsets Window for quick and easy access. If you do not specify a patient selection criteria, you have access to the whole patient population.

# Steps for Patient Selection Criteria

## *Select a project*

After logging into JReview, the Object Explorer window displays the Studies organized by tabs for Tree view and Trial Summary view. In the Studies Tree view tab, select a study from the list of project folders by single clicking to open a study folder. As soon as you have selected one of the Projects, for example 'Drug KALIL', JReview opens that project folder to display the protocols stored in your clinical data base.



### *Single-protocol mode*

You can click and select a protocol that you want to explore. If you click on one protocol, you are in single-protocol mode. The lists of panels and items that are displayed corresponds to all panels and items in that protocol.

### *Multi-protocol mode*

If you select multiple protocols, you are in multi-protocol mode. The lists of panels and items that you see correspond to common panels and items between the protocols selected. In Browsers, the item StudyID, is used for protocol comparison.

You can select multiple protocols in one of the following ways. For contiguous protocols (protocols listed next to each other): Click the first protocol, then hold the shift key and mouse click and drag the cursor over the protocols you would like to review.  For non-contiguous protocols (protocols not listed next to each other): select the protocols you want while holding the **Ctrl** key, then click each protocol you want to select.

Optionally, there is a site preference, ReviewAdmin database **USERPREFS** configuration setting to warn when a user selects multiple studies to be pooled. VARNAME=MULTISTUDYWARNTEXT with varvalue of preferred text to users with userindex = -1 for default for all users.  Similarly, VARNAME=SHOWMULTISTUDYWARNING value=1(Yes), 0(No) with userindex = -1 sets default for the site.  If not present or varvalue=0, users won't see the warning.  If default is 1(Yes), when a user sees the warning message, and they say they don't need to see it again, a 0(No) is stored for their userid, so they won't see it again.

### *Multiple study level hierarchy*

Studies can be selected from different projects. For example, multiple hierarchy folders for different therapeutic areas containing folders for multiple projects which contain multiple studies. Select multiple studies using a single click. The common panels and items are used between the studies from the different therapeutic areas. ***Object specifications may be saved at Study or Global level.***

Therapeutic area folders ----> Clinical Project folders ----> Studies

## Access to SAS datasets

SAS datasets are listed with the panels generated from Oracle tables. Items from SAS datasets can be used like other items for patient selection criteria.

***Note: The current restriction is you cannot mix items from SAS datasets and Oracle table generated panels within the same patient selection criteria expression.***

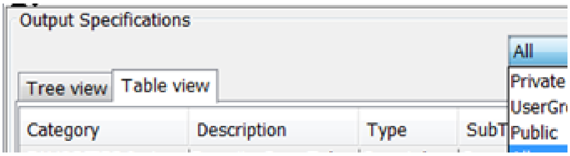
## Trial Summary View

JReview client version 11.0.1 introduces an additional new way that Projects and Studies can be shown and selected in JReview - the Trial Summary Table view. This is in addition to the standard Project / Study "tree view" that is always available.

The Trial Summary view tab displays a table with ‘Trial Summary’ information sortable and dynamically filtered, to let users select multiple studies based on study characteristics.

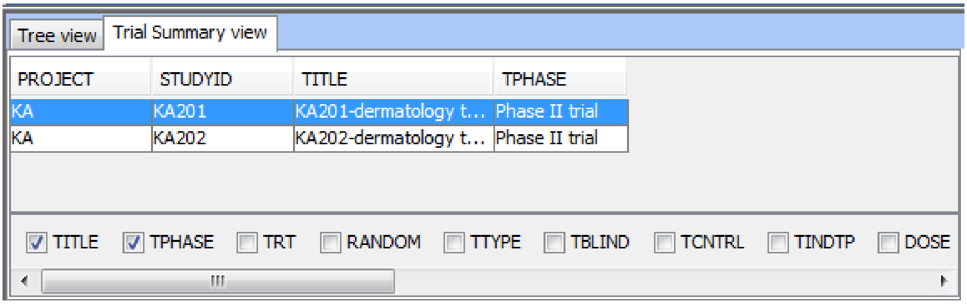
The Trial Summary information is configured in ReviewAdmin by defining Config.TrialSummarySelect. In addition, to the standard "tree view" of projects and studies, the JReview client shows a "Trial Summary view" tab containing the contents of a configured trial summary table. It has these features and behaviors:

- Use of a mouse left-click on a single row to select that Project / Study.
- Holding down SHIFT or CTRL key prior to and while selecting Project / Studies, upon release of the SHIFT or CTRL key a multi-study selection occurs.
- Supports sorting (to 3 levels) through left mouse click on column headers, and AND column filtering through right mouse click on column headers.
- Regular expressions directives may be used in addition to normal as-you-type case-insensitive, substring-match filtering.



- Column checkboxes choose which columns show (DB/back-end configured names and ordering, first two columns are always shown), columns can be resized but not drag-reordered.
- There is no linkage/highlighting between/across the "tree view" selection and this "table view". Nor is there any right-click popup menu available for Trial Summary view rows.

When the ‘**Trial Summary View**’ tab is selected (a table view of the trial summary information), the first few columns of the table are displayed.

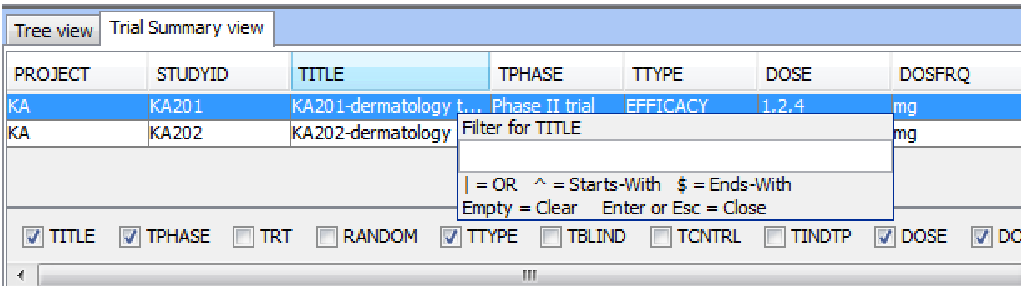


| PROJECT | STUDYID | TITLE | TPHASE |
|---|---|---|---|
| KA | KA201 | KA201-dermatology t... | Phase II trial |
| KA | KA202 | KA202-dermatology t... | Phase II trial |

☑ TITLE ☑ TPHASE ☐ TRT ☐ RANDOM ☐ TTYPE ☐ TBLIND ☐ TCNTRL ☐ TINDTP ☐ DOSE

It supports ‘browsing’ and ‘filtering’ of the trail summary information. Other columns may be displayed if you just check the checkbox by the name of the column you’d like to see. The user may want to browse studies by characteristics, where they’d probably need to look at some information but not all of the trial summary columns. So, there is the option to display additional columns by checking the other column checkboxes.

The columns are sortable similar to detailed reports, but also dynamic/interactive filtering is available if you right mouse click on the title of the column. The dynamic filtering happens as you’re typing – so as soon as you start typing a substring, only those rows that match are visible. You can also use ‘|’ for ‘OR’ and you can include DOUBLE BLIND | OPEN which would include both DOUBLE BLIND trials or OPEN LABEL trials – if you had filteres on the TBLIND column. Those columns are the standard SDTM TS variable values for the typical trial summary information.



| PROJECT | STUDYID | TITLE | TPHASE | TTYPE | DOSE | DOSFRQ |
|---|---|---|---|---|---|---|
| KA | KA201 | KA201-dermatology t... | Phase II trial | EFFICACY | 1,2,4 | mg |
| KA | KA202 | KA202-dermatology |  |  |  | mg |

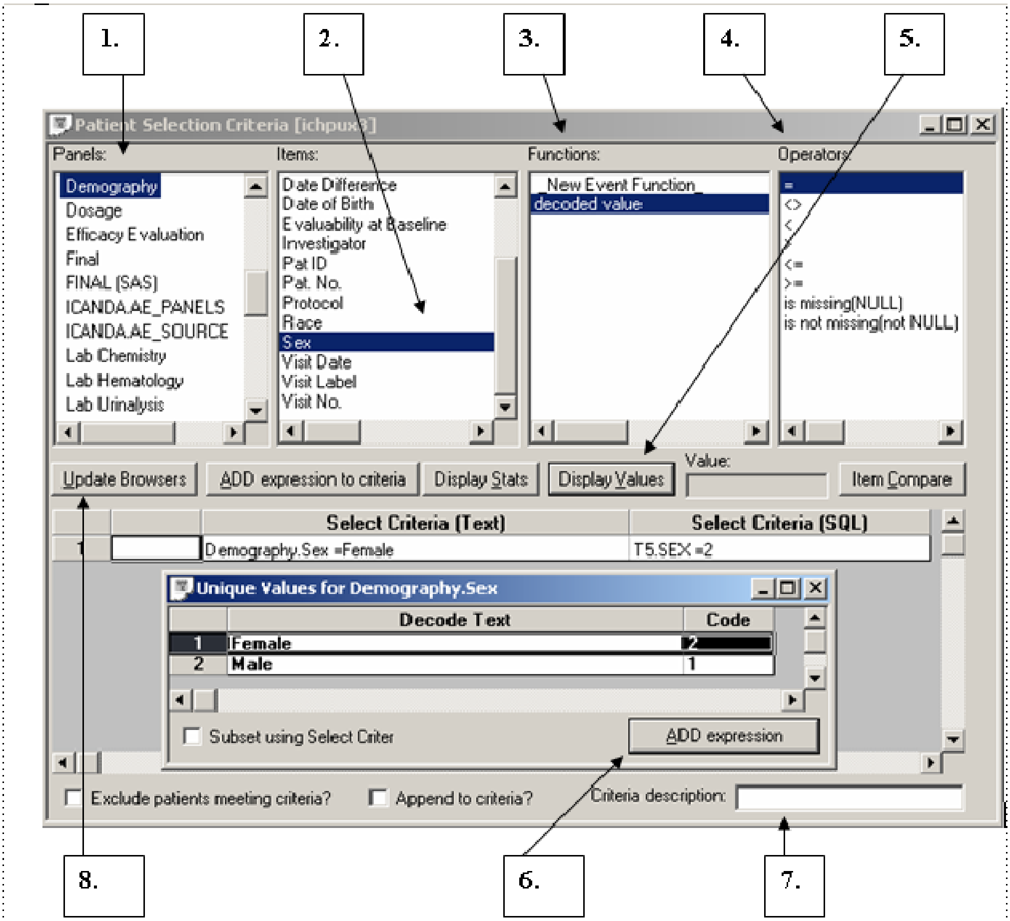
Filter for TITLE

| = OR ^ = Starts-With $ = Ends-With
Empty = Clear Enter or Esc = Close

☑ TITLE ☑ TPHASE ☐ TRT ☐ RANDOM ☑ TTYPE ☐ TBLIND ☐ TCNTRL ☐ TINDTP ☑ DOSE ☑ DC

## *Steps for selection criteria*

After you open a clinical project folder and select a study, you can subset your available patient population using the Patient Selection Criteria.



| | | Select Criteria (Text) | Select Criteria (SQL) |
|---|---|---|---|
| 1 | | Demography.Sex =Female | T5.SEX =2 |

| | Decode Text | Code |
|---|---|---|
| 1 | Female | 2 |
| 2 | Male | 1 |

1. Select a Panel.
2. Select a Item.
3. Select a function.
4. Select an operator.
5. Enter a value or select a value from Display Values.

   Display Statistics (optional), Compare Items (optional).
6. Add expression to criteria.
7. Add criteria description (optional).
8. Update Browsers.

# Building criteria expressions

## Criteria expressions

Patient selection criteria are made up of logical expressions, such as '**AGE > 50**', connected by Boolean operators, such as AND, ANDSELECT, or OR. You create these expressions by clicking on various listboxes.  Your goal is to build a patient selection criteria to describe the patient population that you want to explore.

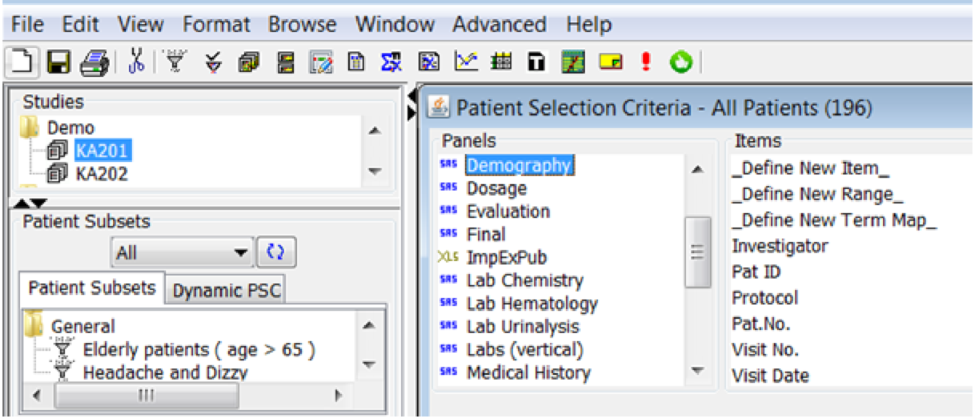
There is a ReviewAdmin Config Options string for ‘WARNMULTIABLEOR’. When present, the patient selection criteria issues a warning, with explainations of join logic behavior; if the user has included more than one table, and at least one ‘OR’ logical operator.

## Selecting a panel

Panels are logical groups of items for collecting and storing your clinical data, in an on-line representation of your case report form. The Panel you select determines which items are displayed in the item list, such as ‘Demography’, ‘Final Report’, and ‘Vital Signs’. Each panel contains a group of data items, such as age, sex, race, and date of birth. For the protocol of interest, a panel of data in the database contains all data collected for all observations and all patients (as appropriate for the type of panel) in the protocol.

The first step in defining a logical expression is to select the panel that contains the item to be used in your expression, such as Demography. Panels and items are selected individually to define the selection criteria expressions.

1. Select the panel that contains the item to be used in your expression.

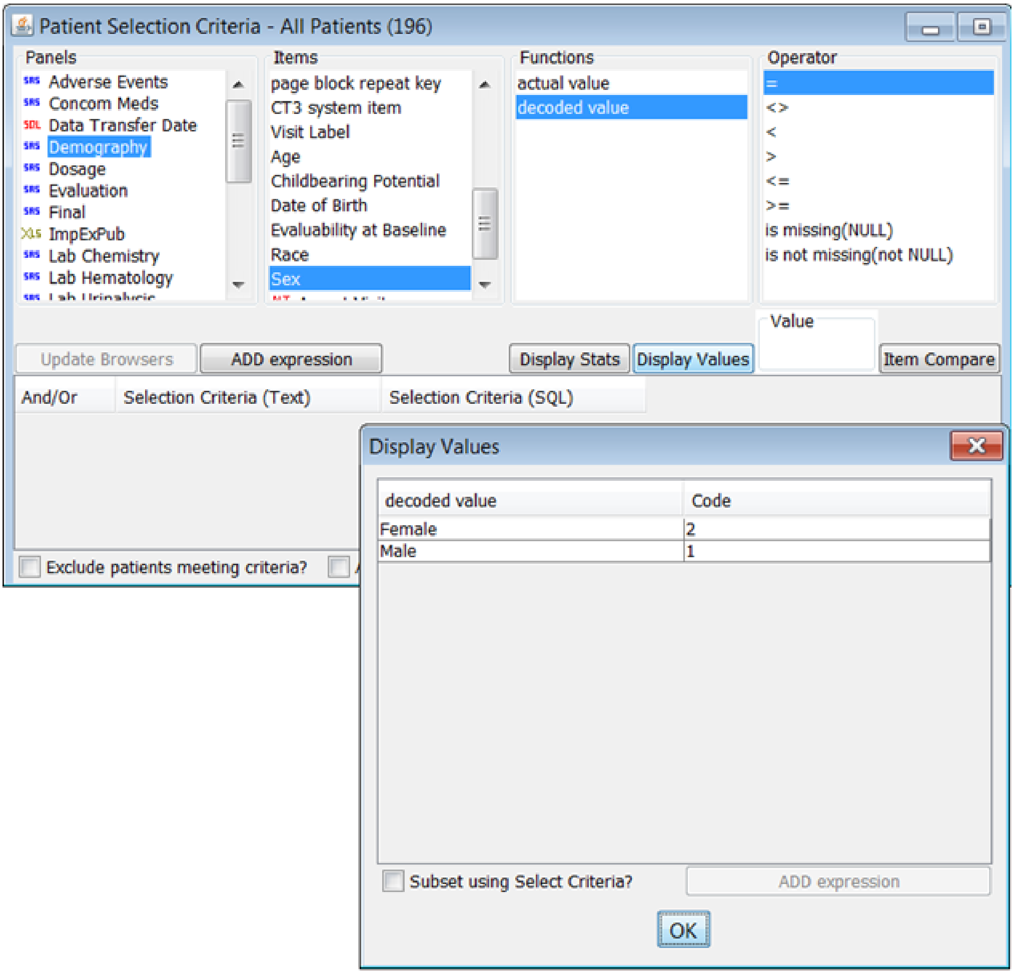


### *Selecting an item*

After you have selected the Demography panel**,** JReview retrieves and presents a list of all the items stored in the Demography Panel.

2. Select an item.
3. Select an operator. The list of Functions and Operators displayed will vary dependent upon the item's data type.
4. Click **Display Values**. Select the value and click **Add Expression to criteria**.

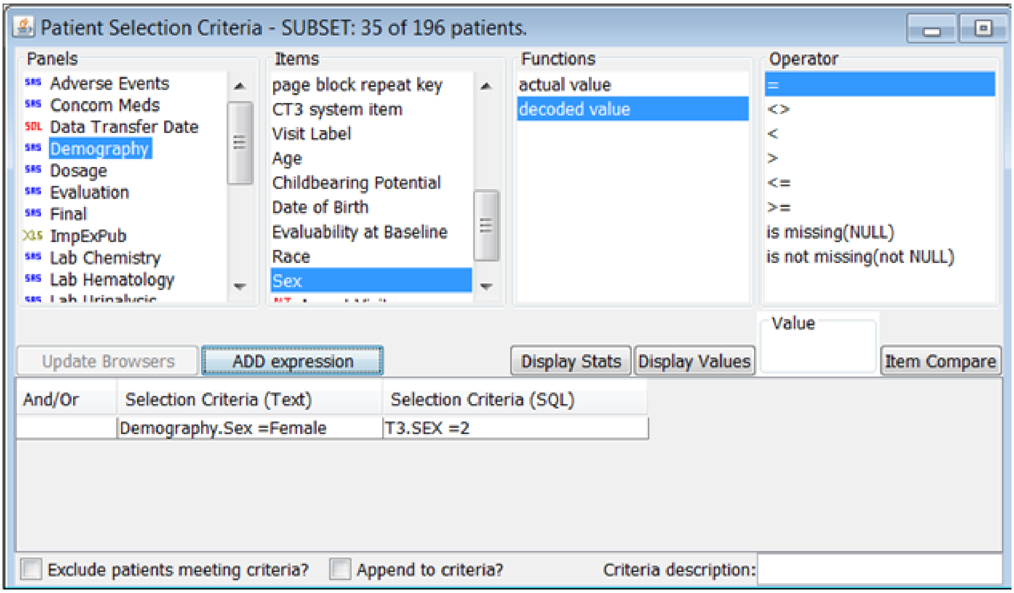
***Shortcut*** **-** If you double-click on the single value of interest in the Unique Values spreadsheet, the expression is automatically added to the next available row in the Patient Selection Criteria window.



| decoded value | Code |
|---|---|
| Female | 2 |
| Male | 1 |

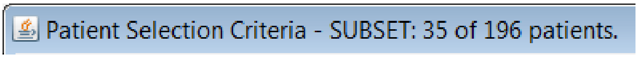
Close the Unique Values Window when you are through adding the expression to your selection criteria.

5. When you are through adding expressions to your selection criteria, click **Update Browsers**.



| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
|  | Demography.Sex =Female | T3.SEX =2 |

The SUBSET patient count displayed in the title bar is disabled by default, unless the System Administrator sets the ReviewAdmin configuration option for RETRIEVEPATIENTCOUNTS. This setting permits the Patient Selection Criteria header display to update, showing the number of patients in the current active selection criteria.

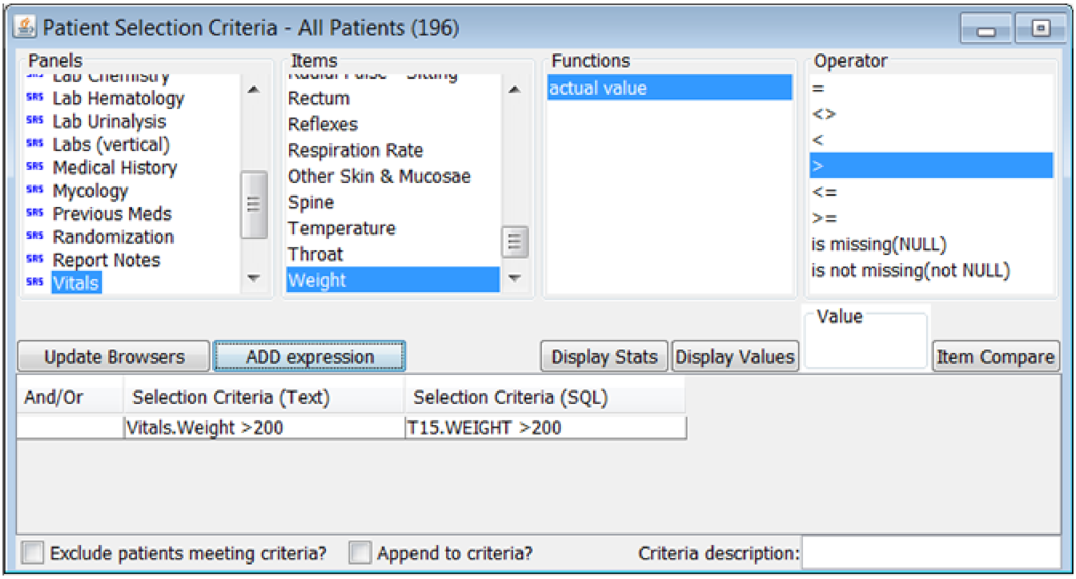

Patient Selection Criteria - SUBSET: 35 of 196 patients.

## *Supplying a value*

If you know the value that you want to specify in the expression, you can enter you can enter the value in the **Value box** and click **ADD Expression**.

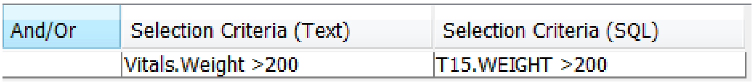
1. Click on the panel that contains the data.
2. Click on an item**.**
3. Click on one of the default function values or user-defined functions.
4. Select a logical operator appropriate to the expression you are building, such as '=' or '>'.
5. Enter the value in the **Value box** and click **Add Expression**.
6. Click **Update Browsers**.

The expression is added to the next row of the spreadsheet containing the active **Patient Selection Criteria**. Repeat these steps if you want to continue to add more criteria expressions or click **Update Browsers** when done.



| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Vitals.Weight >200 | T15.WEIGHT >200 |

Your expression has been added in two different ways. The expression appears in the Select Criteria (Text) field exactly as specified in the list boxes. Also, the expression appears in the Select Criteria (SQL) column in a way that is understandable to the system.



| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Vitals.Weight >200 | T15.WEIGHT >200 |

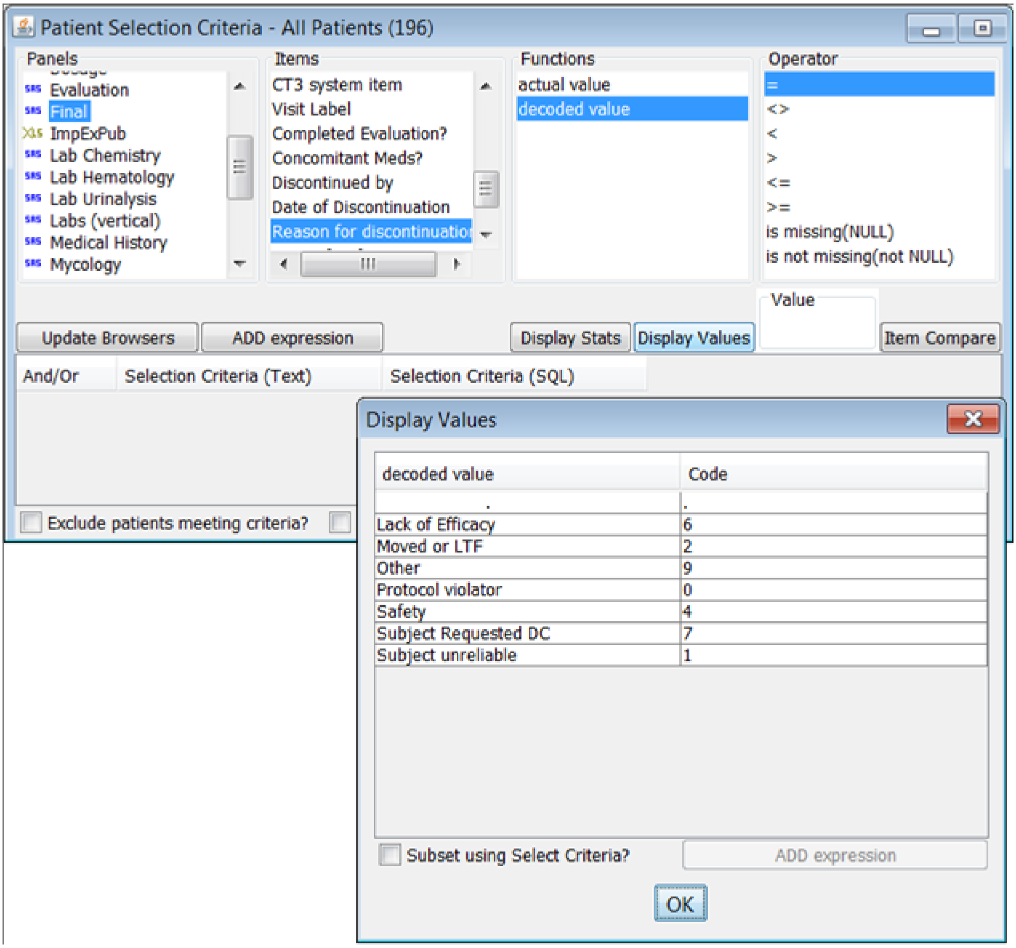
## *Displaying item values*

Another way to add select criteria expressions besides directly entering a value is to open the **Display Values** window. Once you have added expressions by entering a value, you can capture perspectives of your data that are uniquely informative. Suppose you are interested in exploring patients who were discontinued from the protocol due to safety issues. For example, select the Final panel and item Reason for Discontinuation. This item type references a data dictionary file associated to the discontinuation reasons by a code.

To list all the values of this item in the protocol(s):

1. Select a panel, such as Final Report.
2. Select an item, such as Reason for Discontinuation.
3. Click **Display Values**. The Dispaly Values window does not automatically open for decode items.

   JReview displays the Unique Values window for the selected item. All the values are displayed with the internal codes if an item is coded.
4. Highlight the selected row and click **ADD expression** or double click on the row.

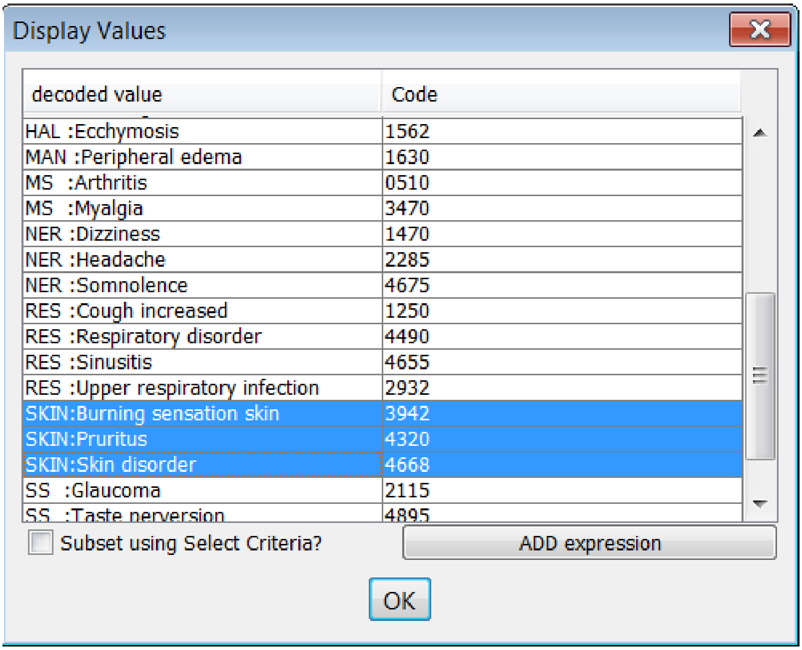


| decoded value | Code |
|---|---|
| . | . |
| Lack of Efficacy | 6 |
| Moved or LTF | 2 |
| Other | 9 |
| Protocol violator | 0 |
| Safety | 4 |
| Subject Requested DC | 7 |
| Subject unreliable | 1 |

## *Selecting multiple values*

If you need to select multiple items of interest within the same Unique Values window, the selected operator must be '='. Then click **Display Values** to open the Unique Values window.

To select multiple contiguous values, click on a value and drag over the other values. To select multiple non-contiguous values, click on a value and hold down the **Ctrl** key when clicking the other values.

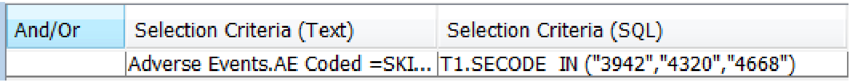


| decoded value | Code |
|---|---|
| HAL :Ecchymosis | 1562 |
| MAN :Peripheral edema | 1630 |
| MS :Arthritis | 0510 |
| MS :Myalgia | 3470 |
| NER :Dizziness | 1470 |
| NER :Headache | 2285 |
| NER :Somnolence | 4675 |
| RES :Cough increased | 1250 |
| RES :Respiratory disorder | 4490 |
| RES :Sinusitis | 4655 |
| RES :Upper respiratory infection | 2932 |
| SKIN:Burning sensation skin | 3942 |
| SKIN:Pruritus | 4320 |
| SKIN:Skin disorder | 4668 |
| SS :Glaucoma | 2115 |
| SS :Taste perversion | 4895 |

☐ Subset using Select Criteria?

When you click **ADD expression to criteria**, JReview adds your expression, including the value you selected from the Unique Values spreadsheet, to the next available row in the Patient Selection Criteria window.

If you want to select multiple values from the Unique Values spreadsheet, the selected operator must be '='. When the expression is pasted into the Patient Selection Criteria window, it is automatically turned into a **SQL 'IN List'** expression, which means that patients will be selected if the value of the item specified is any of those in the list.



| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
|  | Adverse Events.AE Coded =SKI... | T1.SECODE IN ("3942","4320","4668") |

## *Selecting an operator*

JReview can refer to item values exactly as they exist in the database by using the function 'actual value', or it can present derived forms of the values, such as Baseline or Endpoint. The list of functions and operators displayed will vary dependent upon the item's data type.

If you select a function other than 'actual value', JReview automatically introduces additional calculation or extraction logic options for the expression you are building.

If a selected item's data type is TEXT, the following function is available: actual value. For NUMERIC data, the available functions also include 'chg. from baseline' and '% chg. from baseline'.

***Note: JReview automatically selects an appropriate default function based on the data type of the item you have selected.***

The list of **Operators** changes according to the item's data type.

1. Click on the panel that contains the data.
2. Click on the item.
3. Click on one of the default function values or user-defined functions (see below).
4. Select a logical operator appropriate to the expression you are building, such as '=' or '>'.

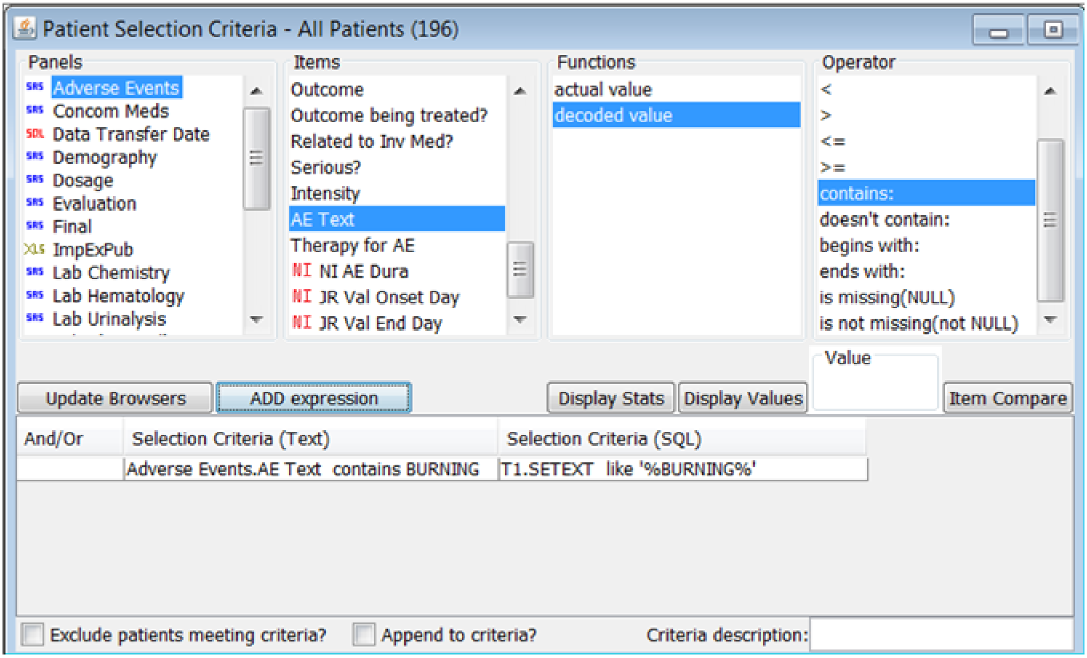
***Note: If the item is a Text data type, you see the following text strings:***

a. contains:
b. doesn't contain:
c. begins with:
d. ends with:
e. is missing (NULL)
f. is not missing (not NULL)

These text string operators allow you to search for partial strings anywhere within the field. If the item is a numeric data type (such as age), or a date field (such as date of birth), the string operators do not appear in the Operator ListBox.

### *Building a string expression*

If you are building a string expression, (for example, patients whose ‘Adverse Drug Event’ field contains the string 'RASH' anywhere in the text of the item), click the 'contains' operator and enter the string ‘RASH’ in the **‘**Value**’** field. The string search is case sensitive and you can determine how the data is stored by clicking **Display Values**.



| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Adverse Events.AE Text contains BURNING | T1.SETEXT like '%BURNING%' |

## Joining criteria expressions

### *Boolean operators*

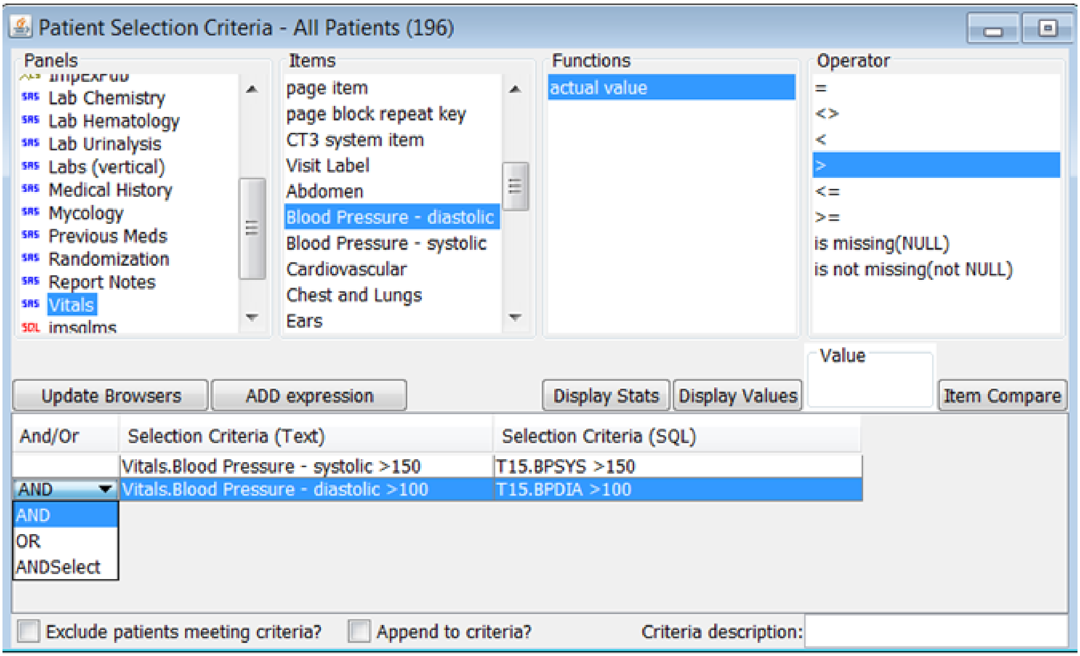
When you add additional expressions, an AND operator is added between next row of criteria in the Select Criteria logical Operator column. This means that the previous expression and the current expression will be used with an AND between them. The patients selected pass the previous criteria expression AND the current criteria expression so both expressions must be true. In the previous example, for Age > 50 AND Sex = Female, only those patients who meet both criteria expressions as true are selected into the patient sub-population or patient subset for analysis. This is a simple example where the Demography data is a single panel type collected only once for each patient.

## *Additional criteria expressions*

If you to want additional criteria applied to the patient selection criteria, repeat the previous steps:

1. Select a panel.
2. Select an item.
3. Select an operator.
4. Supply a value.
5. Add expression to criteria.

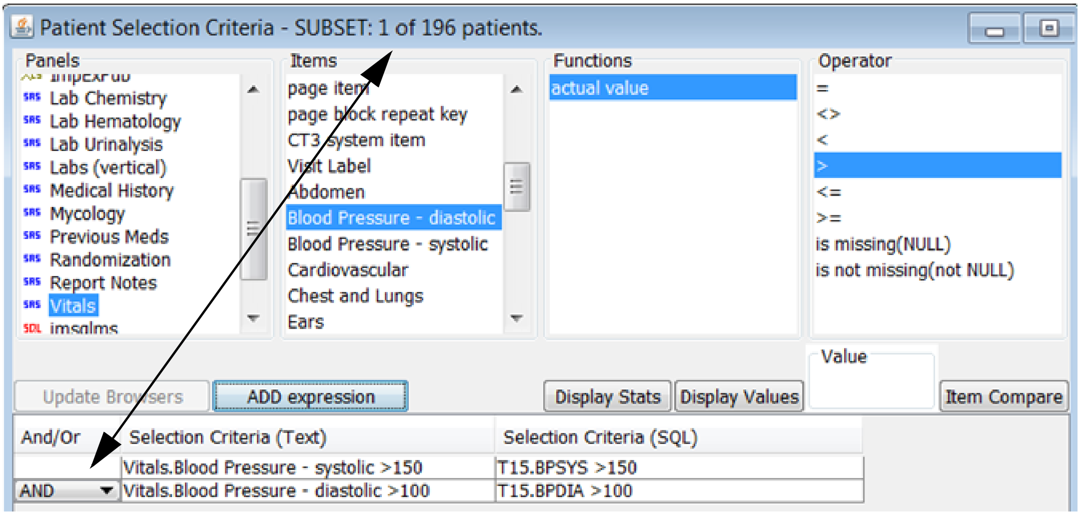
When you add additional expressions, an AND operator is added to the second row of criteria. If this is not appropriate, you can change the AND to an OR or ANDSelect.



| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Vitals.Blood Pressure - systolic >150 | T15.BPSYS >150 |
| AND | Vitals.Blood Pressure - diastolic >100 | T15.BPDIA >100 |

The expression is added to the next row of the spreadsheet containing the active **Patient Selection Criteria (PSC)**.

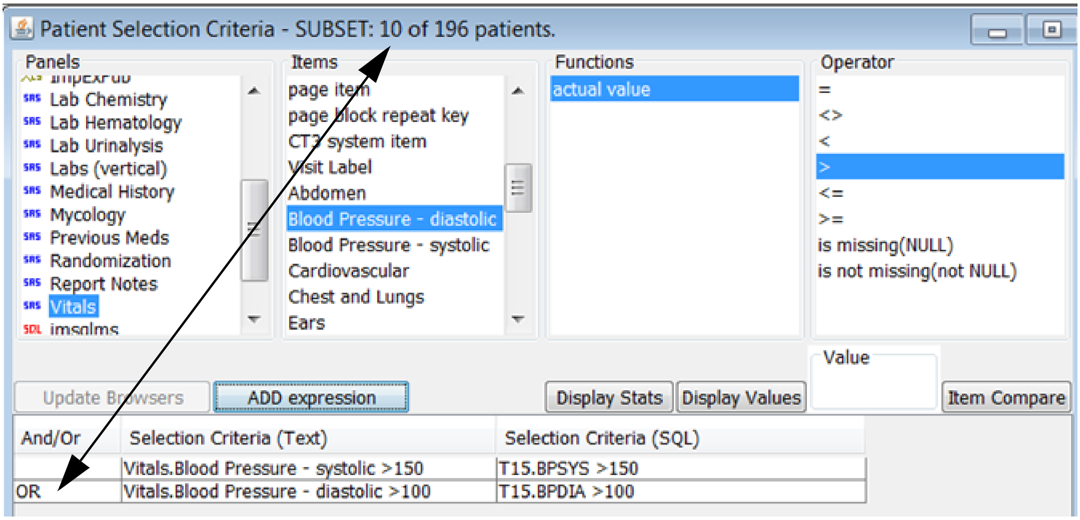
6. When you are through adding expressions to your selection criteria, click **Update Browsers**. The title bar updates to show the number of patients in the current active selection criteria.



Patient Selection Criteria - SUBSET: 1 of 196 patients.

| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Vitals.Blood Pressure - systolic >150 | T15.BPSYS >150 |
| AND | Vitals.Blood Pressure - diastolic >100 | T15.BPDIA >100 |

Here is the result when the expression use ‘OR’ for the Boolean operator.

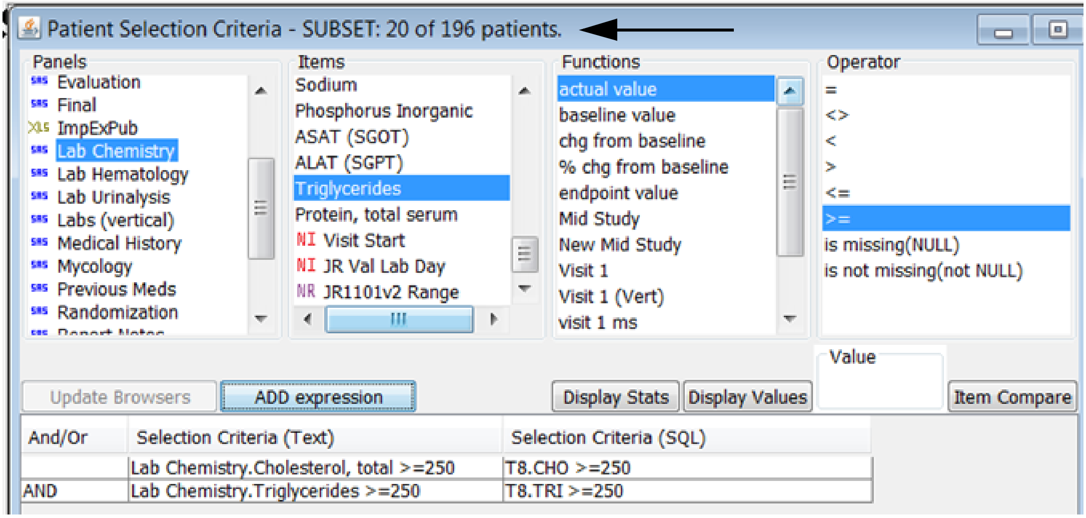


Patient Selection Criteria - SUBSET: 10 of 196 patients.

| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Vitals.Blood Pressure - systolic >150 | T15.BPSYS >150 |
| OR | Vitals.Blood Pressure - diastolic >100 | T15.BPDIA >100 |

## *AND operator*

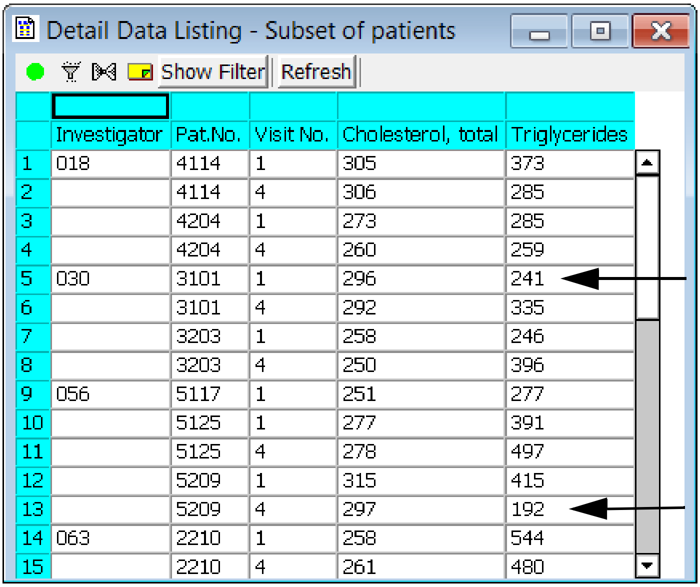
The PSC becomes more detailed when you choose a multiple record panel or multiple visit panel type for example, Adverse Events, Lab Chemistry or Vital Signs. In this example, both of the selected data items came from the same multiple visit panel Lab Chemistry.



| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Lab Chemistry.Cholesterol, total >=250 | T8.CHO >=250 |
| AND | Lab Chemistry.Triglycerides >=250 | T8.TRI >=250 |

The patients selected have a minimum of one visit where both the Cholesterol AND Triglycerides are >= 250 within the same visit. the patient selection criteria results are 20 patients in the patient subset from the total patient population of 196.

Hint: ***View a detail data listing of the data items in the selection criteria is helpful when defining and validating patient selection criteria with multiple expressions and different operators.***

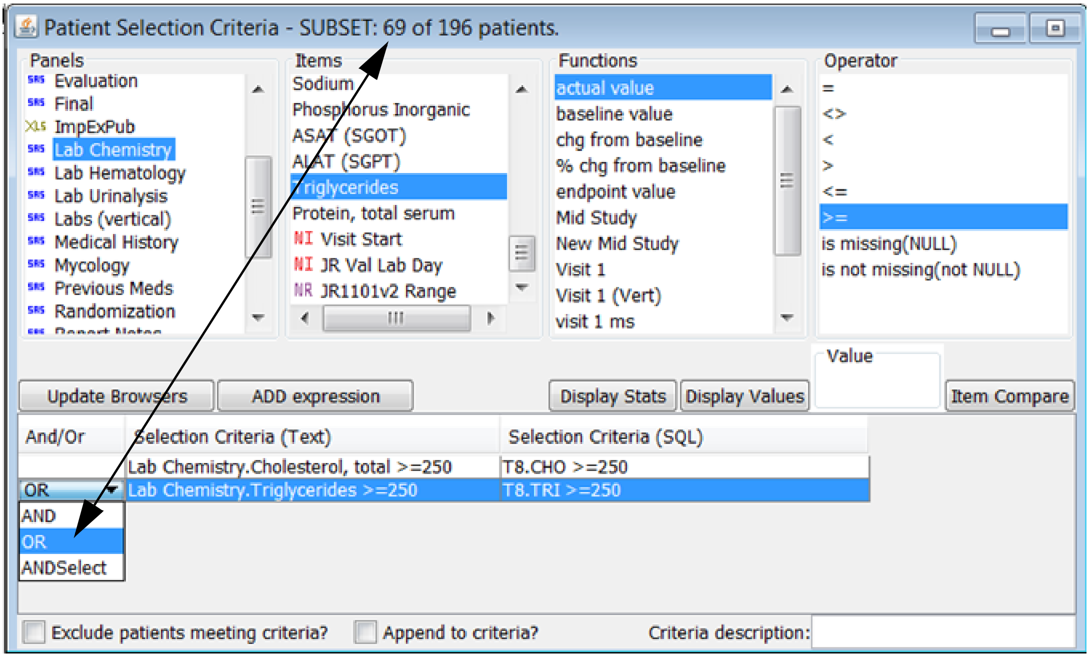


| | Investigator | Pat.No. | Visit No. | Cholesterol, total | Triglycerides |
|---|---|---|---|---|---|
| 1 | 018 | 4114 | 1 | 305 | 373 |
| 2 | | 4114 | 4 | 306 | 285 |
| 3 | | 4204 | 1 | 273 | 285 |
| 4 | | 4204 | 4 | 260 | 259 |
| 5 | 030 | 3101 | 1 | 296 | 241 |
| 6 | | 3101 | 4 | 292 | 335 |
| 7 | | 3203 | 1 | 258 | 246 |
| 8 | | 3203 | 4 | 250 | 396 |
| 9 | 056 | 5117 | 1 | 251 | 277 |
| 10 | | 5125 | 1 | 277 | 391 |
| 11 | | 5125 | 4 | 278 | 497 |
| 12 | | 5209 | 1 | 315 | 415 |
| 13 | | 5209 | 4 | 297 | 192 |
| 14 | 063 | 2210 | 1 | 258 | 544 |
| 15 | | 2210 | 4 | 261 | 480 |

Notice in the detail data listing contains some patient visits which do not meet the selection criteria as show by the arrows. Remember the patient selection criteria is based upon the patient paradigm and all the patient's data is displayed. If you do not want the visits (rows) to display in your output, then you would define a Filter Output to be discussed in detail in the browser chapters.

## *OR operator*

If this is not appropriate, you can change the AND to an OR or ANDSelect. Click on the AND in the Select Criteria logical Operator column to display the dropdown list for other operator options.

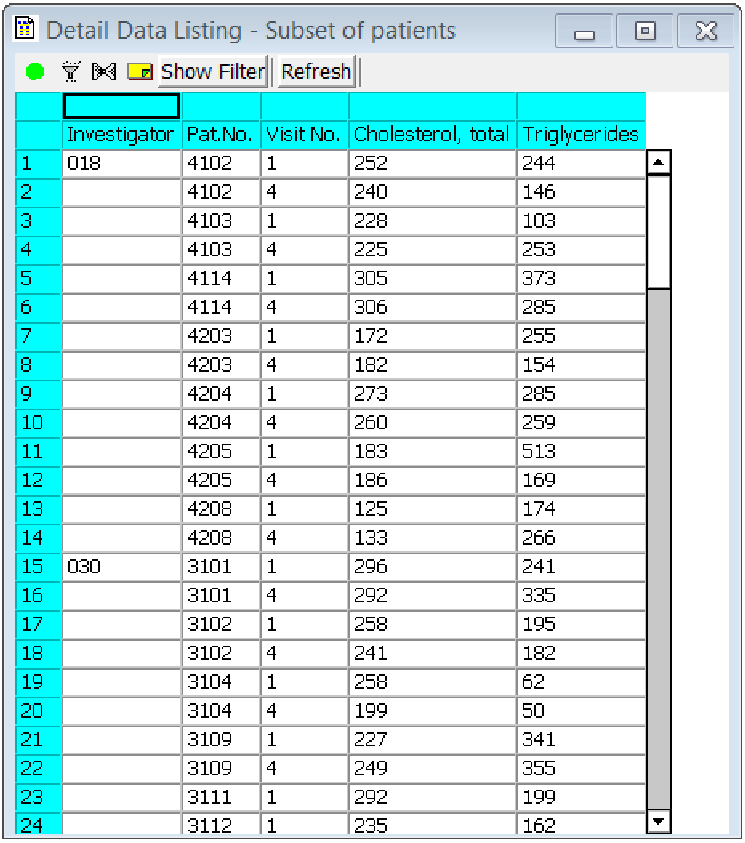


Patient Selection Criteria - SUBSET: 69 of 196 patients.

| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Lab Chemistry.Cholesterol, total >=250 | T8.CHO >=250 |
| OR | Lab Chemistry.Triglycerides >=250 | T8.TRI >=250 |

If you use the previous example and change the operator to OR, the patients selected must have the first or second expression as true within the same visit (row). For a patient to be selected they must have a minimum of one visit where either Cholesterol or Triglycerides or both data item values are >= 250 within the same visit (row). All the patient’s visits are displayed for the selected patient subset including the visits where both data items values are <= 250. The patient selection criteria results are 69 patients contained in the patient subset from the total patient population of 196.

Observe in each row at least one of the criteria expressions is true.

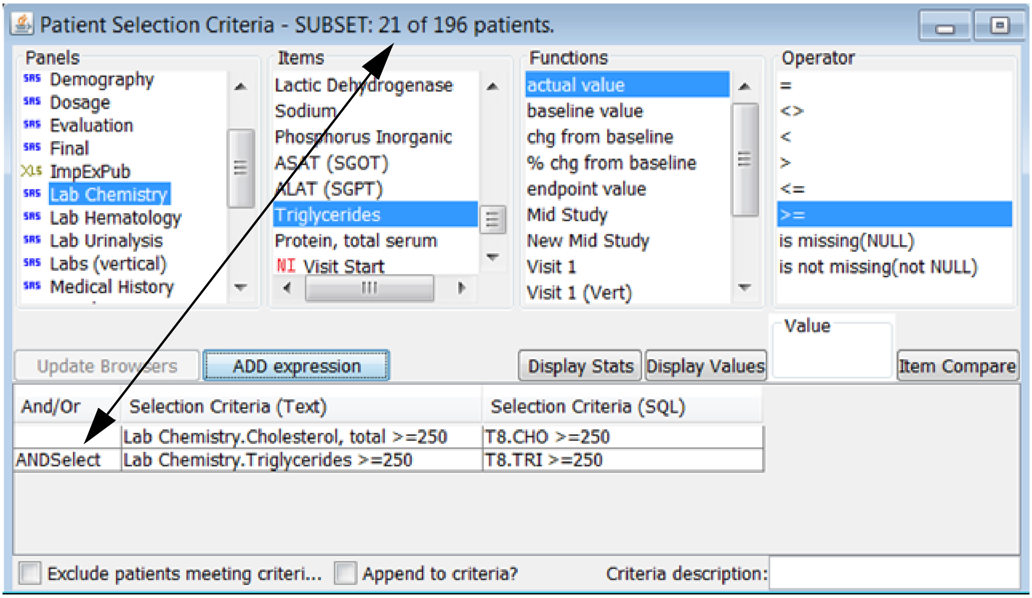


| | Investigator | Pat.No. | Visit No. | Cholesterol, total | Triglycerides |
|---|---|---|---|---|---|
| 1 | 018 | 4102 | 1 | 252 | 244 |
| 2 | | 4102 | 4 | 240 | 146 |
| 3 | | 4103 | 1 | 228 | 103 |
| 4 | | 4103 | 4 | 225 | 253 |
| 5 | | 4114 | 1 | 305 | 373 |
| 6 | | 4114 | 4 | 306 | 285 |
| 7 | | 4203 | 1 | 172 | 255 |
| 8 | | 4203 | 4 | 182 | 154 |
| 9 | | 4204 | 1 | 273 | 285 |
| 10 | | 4204 | 4 | 260 | 259 |
| 11 | | 4205 | 1 | 183 | 513 |
| 12 | | 4205 | 4 | 186 | 169 |
| 13 | | 4208 | 1 | 125 | 174 |
| 14 | | 4208 | 4 | 133 | 266 |
| 15 | 030 | 3101 | 1 | 296 | 241 |
| 16 | | 3101 | 4 | 292 | 335 |
| 17 | | 3102 | 1 | 258 | 195 |
| 18 | | 3102 | 4 | 241 | 182 |
| 19 | | 3104 | 1 | 258 | 62 |
| 20 | | 3104 | 4 | 199 | 50 |
| 21 | | 3109 | 1 | 227 | 341 |
| 22 | | 3109 | 4 | 249 | 355 |
| 23 | | 3111 | 1 | 292 | 199 |
| 24 | | 3112 | 1 | 235 | 162 |

## ANDSelect operator

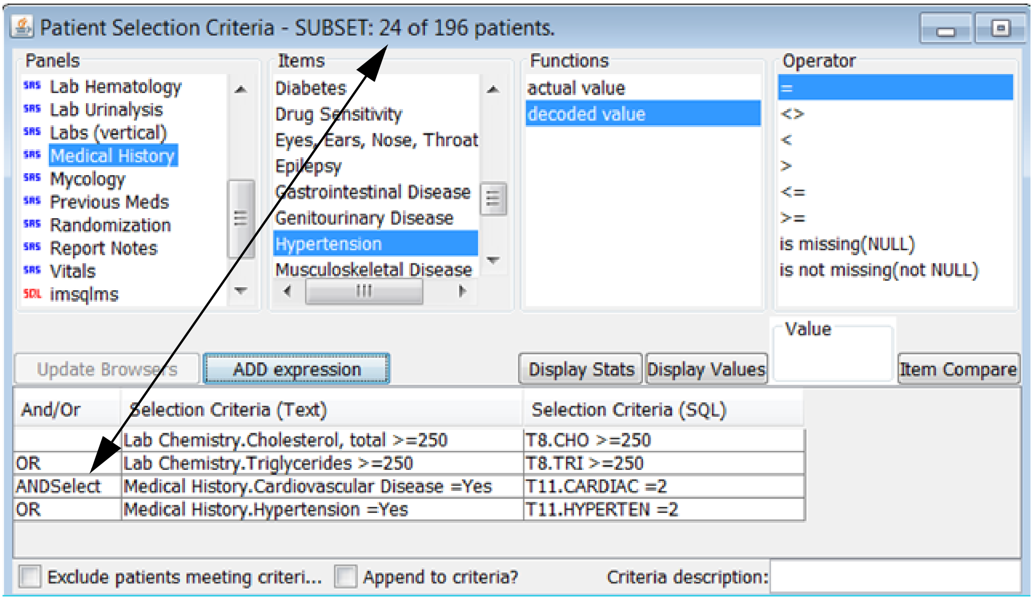
When you change the boolean operator to ANDSELECT, the patient selection criteria is partitioned into two segments executed in succession. ANDSELECT is the equivalent of adding parentheses into the Patient Selection Criteria and forces the execution into a multi-step process.

In this example, the data item values are no longer restricted to the same visit (row) for the multiple visit laboratory Chemistry panel due to the ANDSELECT operator. The patient selection criteria results are 21 patients in the patient subset from the total patient population of 196.



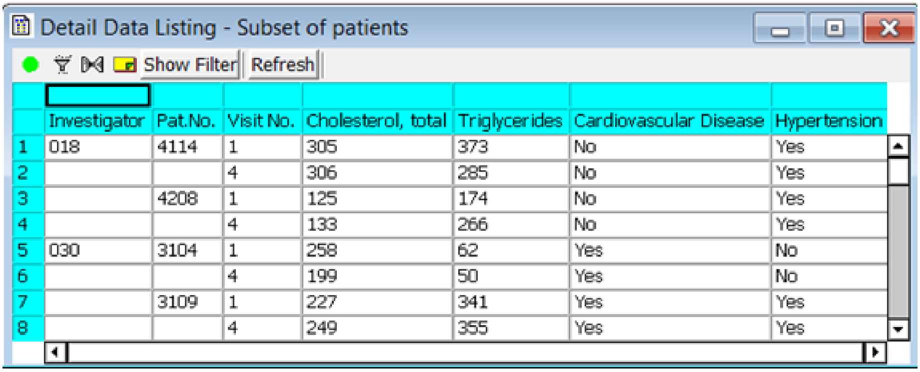
| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Lab Chemistry.Cholesterol, total >=250 | T8.CHO >=250 |
| ANDSelect | Lab Chemistry.Triglycerides >=250 | T8.TRI >=250 |

You can apply various combinations of operators to the selection criteria to subset the available patient population. For example, previously we selected patients with elevated Cholesterol OR Triglycerides >= 250 within the same visit. You can add selection criteria from Medical History data items for Cardiovascular Disease OR Hypertension as ‘yes’ to see if there is any relation to the laboratory results.



| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Lab Chemistry.Cholesterol, total >=250 | T8.CHO >=250 |
| OR | Lab Chemistry.Triglycerides >=250 | T8.TRI >=250 |
| ANDSelect | Medical History.Cardiovascular Disease =Yes | T11.CARDIAC =2 |
| OR | Medical History.Hypertension =Yes | T11.HYPERTEN =2 |

The ANDSELECT operator partitions the patient selection criteria to be executed into two subqueries. First JReview processes the multiple selection criteria by retrieving a list of patients who meet the first selection criteria subquery for elevated Cholesterol OR Triglycerides. Then from this first subset of patients a second subset of patients is generated who meet the second selection criteria subquery. The second selection criteria subquery results in the final patient subset. In this way the patients meet all the multiple selection criteria.



| | Investigator | Pat.No. | Visit No. | Cholesterol, total | Triglycerides | Cardiovascular Disease | Hypertension |
|---|---|---|---|---|---|---|---|
| 1 | 018 | 4114 | 1 | 305 | 373 | No | Yes |
| 2 | | | 4 | 306 | 285 | No | Yes |
| 3 | | 4208 | 1 | 125 | 174 | No | Yes |
| 4 | | | 4 | 133 | 266 | No | Yes |
| 5 | 030 | 3104 | 1 | 258 | 62 | Yes | No |
| 6 | | | 4 | 199 | 50 | Yes | No |
| 7 | | 3109 | 1 | 227 | 341 | Yes | Yes |
| 8 | | | 4 | 249 | 355 | Yes | Yes |

## Build a complex patient selection criteria

Sometimes it is necessary to select patients who meet a particular criteria at a particular visit, (for example, at baseline), and who also meet criteria at another visit (for example, at endpoint). Normally, introducing Visit or any other item twice in the same expression with different selection values yields a “no patients selected” outcome, as they are mutually exclusive. JReview introduces a concept of selection segments to access such patient selection criteria. Each selection segment is tested in succession, not all at once. This provides you with a unique versatility at visualizing and analyzing particular data sets.

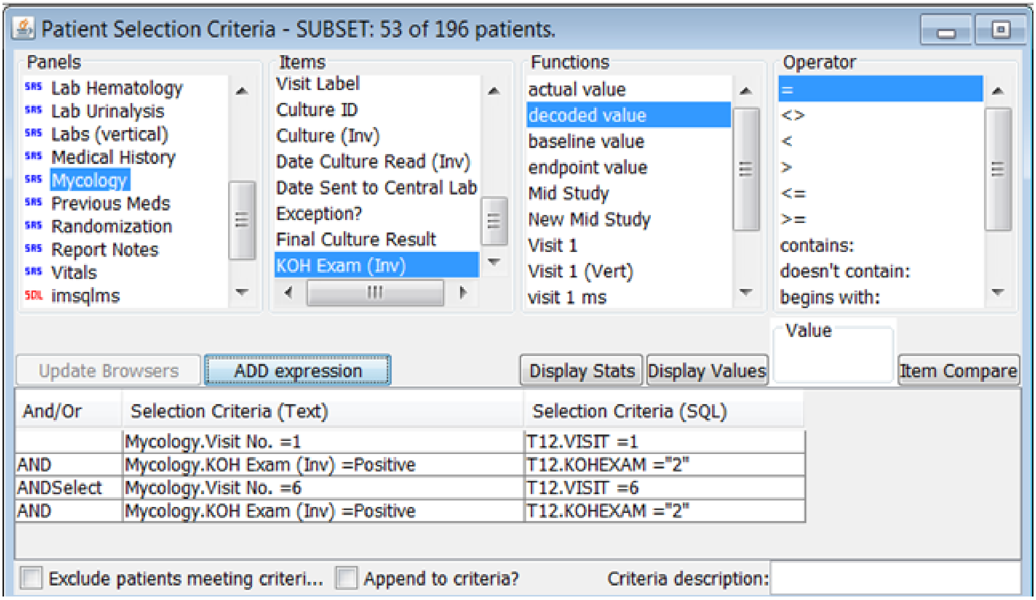
To define the start of a new selection segment, click on the ANDSelect logical operator. An example Patient Selection Criteria using this technique is:

KOHEXAM = 2 (Positive) **1st Subquery**

AND VISIT NO = 1

ANDSelect {Creates nested subqueries}

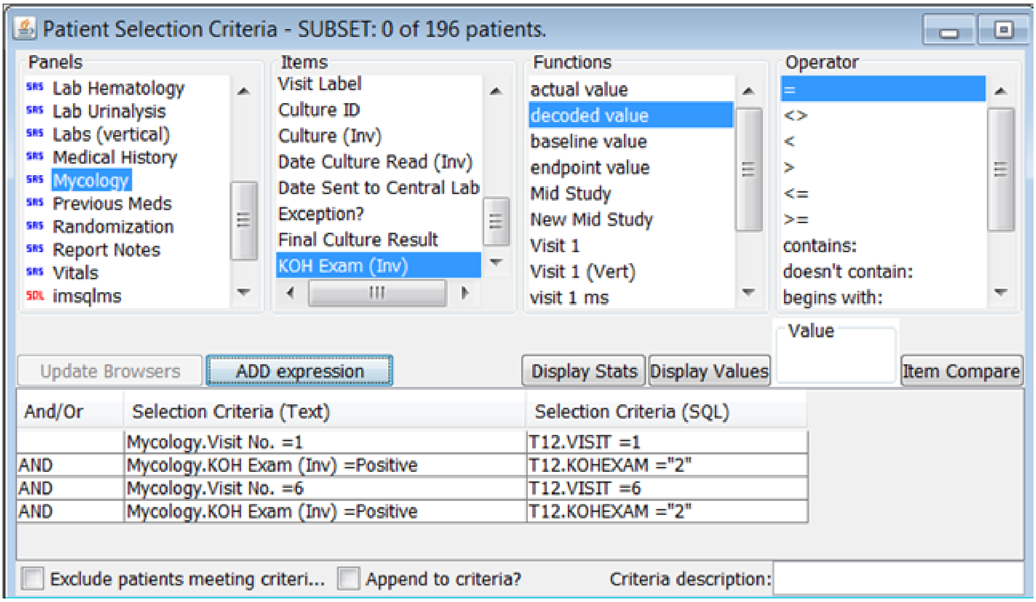
KOHEXAM = 2 (Positive) **2nd Subquery**
AND VISIT NO = 6



| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Mycology.Visit No. =1 | T12.VISIT =1 |
| AND | Mycology.KOH Exam (Inv) =Positive | T12.KOHEXAM ="2" |
| ANDSelect | Mycology.Visit No. =6 | T12.VISIT =6 |
| AND | Mycology.KOH Exam (Inv) =Positive | T12.KOHEXAM ="2" |

☐ Exclude patients meeting criteri... ☐ Append to criteria? Criteria description:

The ANDSELECT statement partitions this patient selection criteria into two segments. Partitioning this patient selection criterion creates Review’s selection segments, which are executed in succession and prevent each segment from excluding the other. The system processes such multiple selection segment criteria by retrieving a list of patients who meet the first selection segment criteria, then retrieving a list of patients who meet the second selection segment criteria, who are also in the first list of patients. The result would be 0 patients if the tests were run without Review's selection segments or run simultaneously. You could not normally test for the mutually exclusive selection values VISITNO = 1 **AND** VISITNO = 6.



| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Mycology.Visit No. =1 | T12.VISIT =1 |
| AND | Mycology.KOH Exam (Inv) =Positive | T12.KOHEXAM ="2" |
| AND | Mycology.Visit No. =6 | T12.VISIT =6 |
| AND | Mycology.KOH Exam (Inv) =Positive | T12.KOHEXAM ="2" |

***Note: In order for Review to run a complex SQL statement containing OR or ANDSelect, sometimes it is necessary to add parentheses to the "Select Criteria (SQL)" column dependent. The default processing of the various expressions might be different than the intended behavior. So – it's important to review the intent, and insert (or) in the SQL column (3rd column).***

## *Changing the selection criteria*

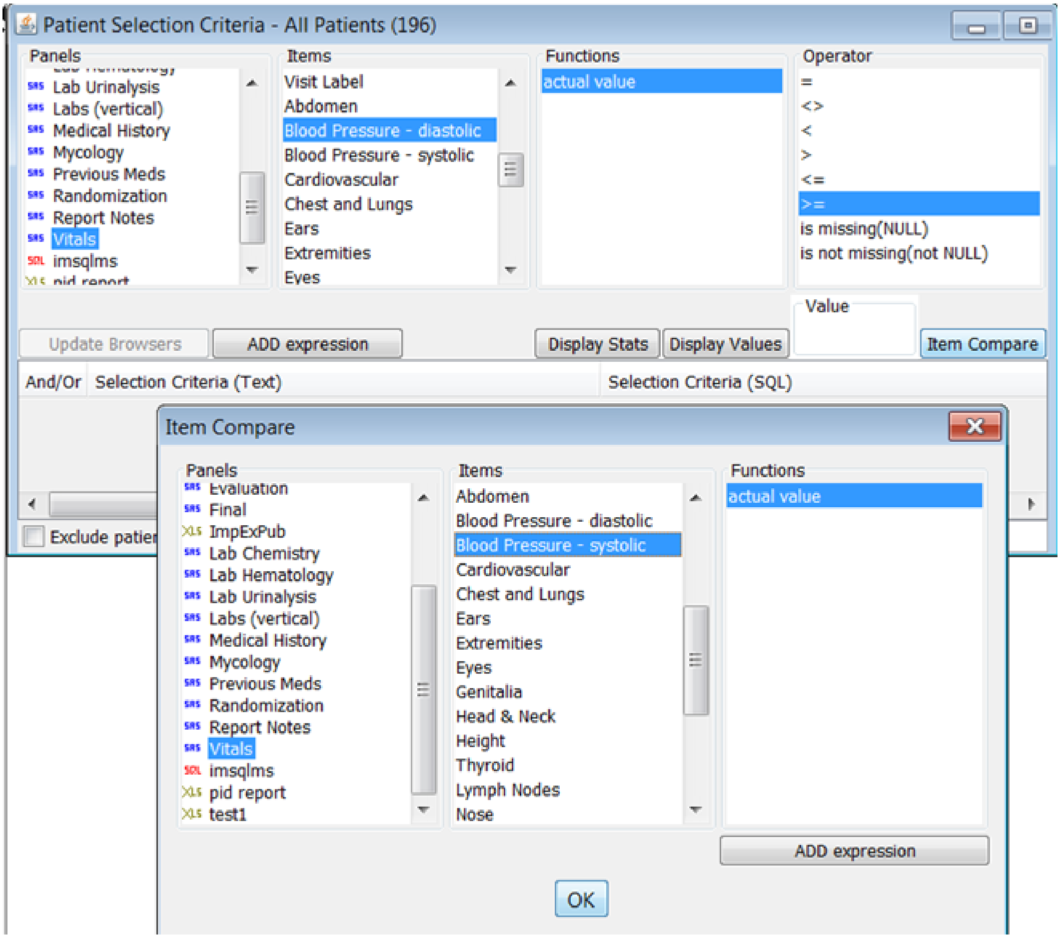
If you want to change the patient selection criteria, click anywhere in the row that you want to change:

1. To modify the patient selection criteria, you can click on the row and edit it.
2. To remove a row, click ✂ or from the **Edit** menu, select **Cut**. This will delete the highlighted row from the expression.
3. To remove all rows, click 🗋.
4. Click **Update Browsers** to apply the updated patient selection criteria.

# Item comparison selector

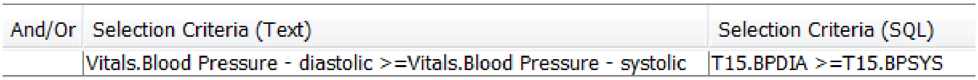
## *Compare items*

An alternative mechanism to the basic patient selection criteria is the item comparison selector. This mechanism provides the functionality to base selection criteria on the value of another item, not just a fixed value. Select a panel, an item, and an operator. Items can be compared within the same panel or between panels.



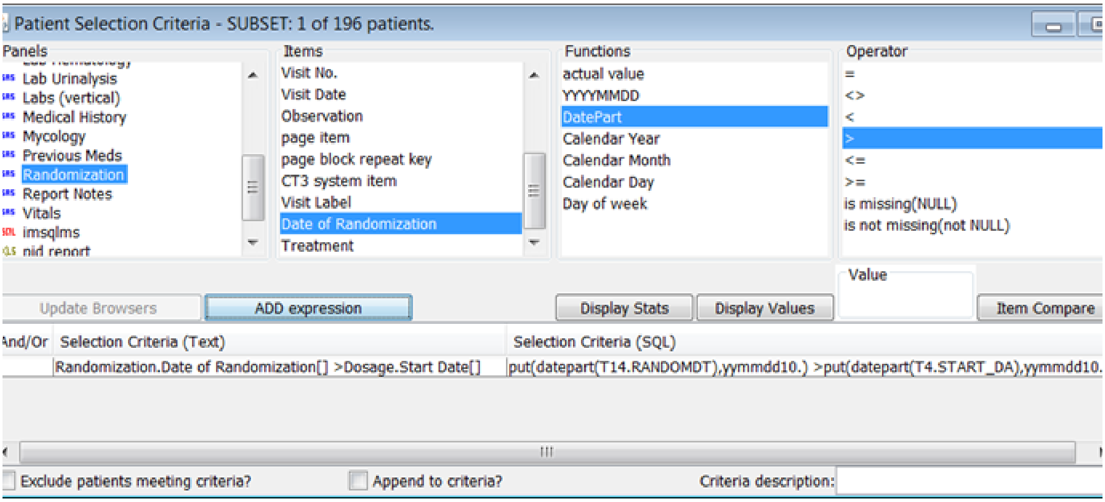
1. Click **Item Compare**. The Item Comparison selector window opens:
2. Select the panel, item, and function value to compare to.
3. Click **ADD expression to criteria**.
4. Close the Item Comparison window.
5. Click **Update Browsers**.

The SQL text that is created when compare Vitals panel item Diastolic BP >= than Systolic BP actual values.



| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Vitals.Blood Pressure - diastolic >=Vitals.Blood Pressure - systolic | T15.BPDIA >=T15.BPSYS |

This example compares dates between panels for treatment randomization date after the dose start date.

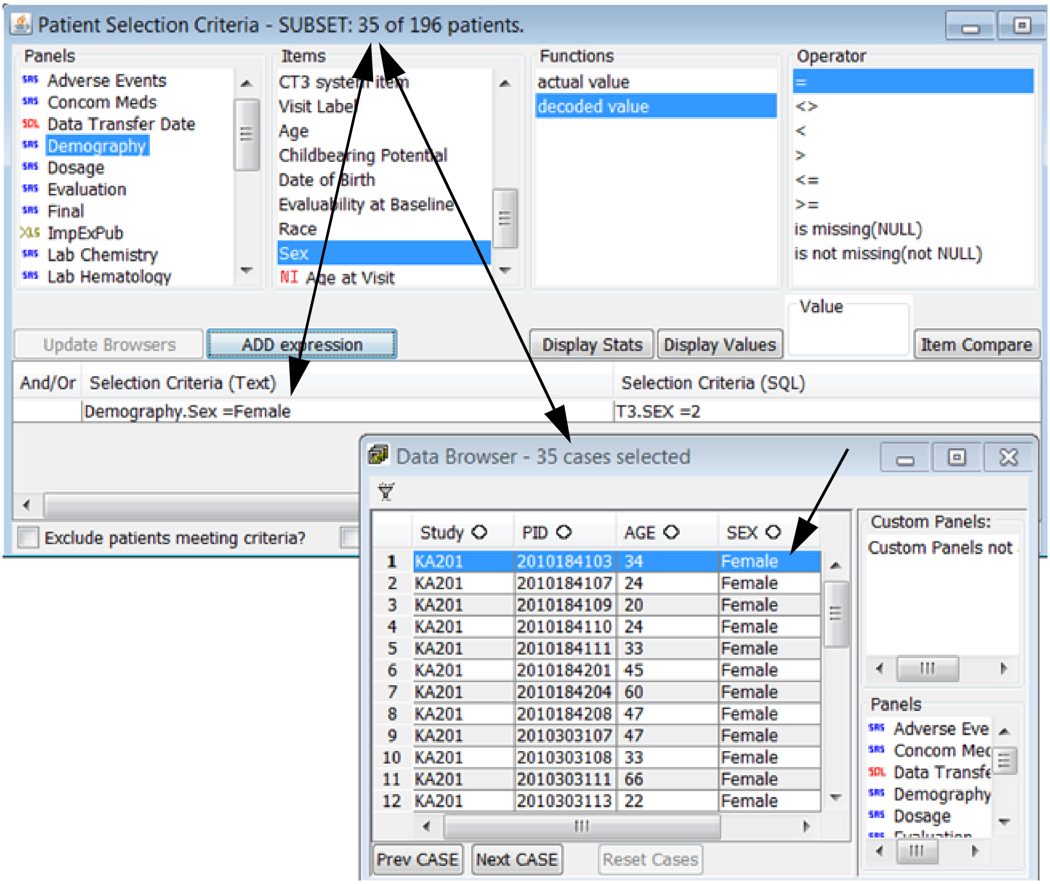


| nd/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Randomization.Date of Randomization[] >Dosage.Start Date[] | put(datepart(T14.RANDOMDT),yymmdd10.) >put(datepart(T4.START_DA),yymmdd10. |

# Exclude patient criteria

## Display excluded patients

You have the ability to view those patients who are not in your current selection criteria by setting **Exclude patients meets criteria?**. Click the button in the lower right corner of the Patient Selection Criteria Window to set this option on. For example, build a patient selection criteria for female patients and open the Data Browser Window to display all patients who meet this selection criteria.



Patient Selection Criteria - SUBSET: 35 of 196 patients.

| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Demography.Sex =Female | T3.SEX =2 |

☐ Exclude patients meeting criteria?

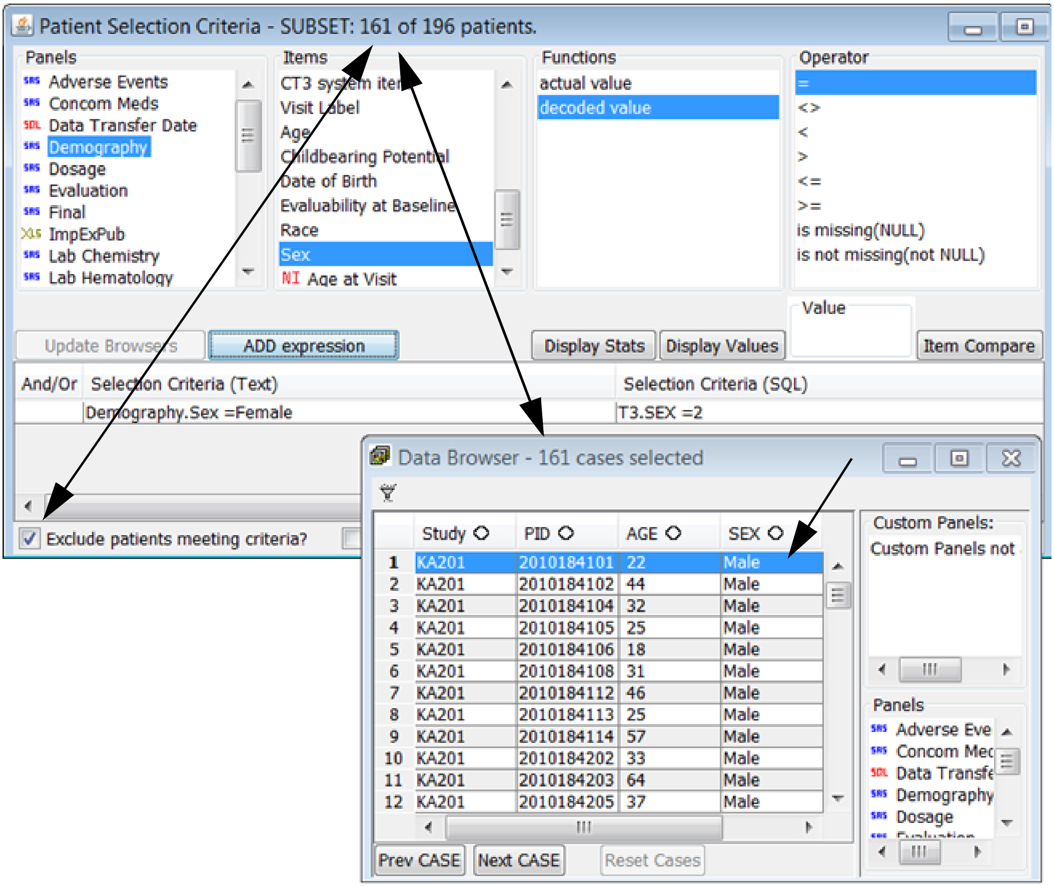
Data Browser - 35 cases selected

| | Study | PID | AGE | SEX |
|---|---|---|---|---|
| 1 | KA201 | 2010184103 | 34 | Female |
| 2 | KA201 | 2010184107 | 24 | Female |
| 3 | KA201 | 2010184109 | 20 | Female |
| 4 | KA201 | 2010184110 | 24 | Female |
| 5 | KA201 | 2010184111 | 33 | Female |
| 6 | KA201 | 2010184201 | 45 | Female |
| 7 | KA201 | 2010184204 | 60 | Female |
| 8 | KA201 | 2010184208 | 47 | Female |
| 9 | KA201 | 2010303107 | 47 | Female |
| 10 | KA201 | 2010303108 | 33 | Female |
| 11 | KA201 | 2010303111 | 66 | Female |
| 12 | KA201 | 2010303113 | 22 | Female |

To view patients excluded from your current selection criteria:

1. Click the box for ☐ Exclude patients meeting criteria? .
2. Click **Update Browsers**.

The example shown displays all male patients or all the patients who were not included in the patient selection criteria. You can apply this patient exclude option to any patient select criteria to display all the patients who are not in the current selection criteria. This feature saves you the steps of building a separate selection criteria if you want to see the patients excluded.



| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Demography.Sex =Female | T3.SEX =2 |

| | Study | PID | AGE | SEX |
|---|---|---|---|---|
| 1 | KA201 | 2010184101 | 22 | Male |
| 2 | KA201 | 2010184102 | 44 | Male |
| 3 | KA201 | 2010184104 | 32 | Male |
| 4 | KA201 | 2010184105 | 25 | Male |
| 5 | KA201 | 2010184106 | 18 | Male |
| 6 | KA201 | 2010184108 | 31 | Male |
| 7 | KA201 | 2010184112 | 46 | Male |
| 8 | KA201 | 2010184113 | 25 | Male |
| 9 | KA201 | 2010184114 | 57 | Male |
| 10 | KA201 | 2010184202 | 33 | Male |
| 11 | KA201 | 2010184203 | 64 | Male |
| 12 | KA201 | 2010184205 | 37 | Male |

# Functions

## *Types of function values*

Review can refer to Item values directly and as they exist in the database, or allow for user-defined function values. For example, the function ‘actual value' presents the raw data, or ‘Baseline’ presents a user-defined time-related milestone value.

The list of functions changes according to the data type (Fixed, Text, Date, or Time) of the item selected.

1. Click on the panel that contains the data.
2. Click on the item of interest:
3. Click on one of the default functions or user-defined functions.

## *Decoded value*

When you select an item associated with a data dictionary file, the decoded value is the default versus the actual coded value. For example, the default decode for ‘Male’ versus the code as ‘M’.

## *Actual value function*

When you select a function other than actual value, which is the actual raw data of the last value entered. Review automatically introduces additional calculation or extraction logic options for the expression you are building.

## *Derived function values*

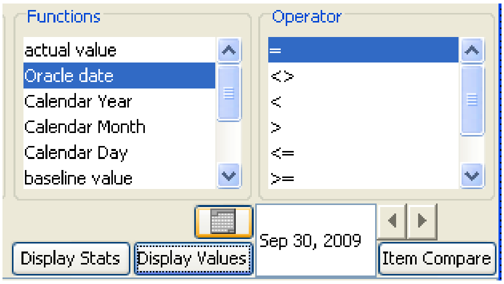
Review provides default derived values, however derived forms of the functions, such as Baseline or Endpoint, can also be selected. The _New Event Function_ allows you to define a variety of time-related milestone functions.

## *Date function*

If you select 'Calendar Year' as a function for a Date type item for a selected panel, Review adds programming logic to reference the year portion of the Date type item. For example, you can enter '1994' in the Value box to retrieve all patients whose Date type item is in the year '1994'.

Default date formats are set to 4 digit year (Year 2000 compliance) throughout the product. Also, local country specific conventions for dates and numbers.

For Oracle Clinical data source if the date type (char type) is not stored in standard YYYYMMDD format, a config.options parameter is available. OCDATEMASK = can be set to tell the system the expected date format for use in the Oracle date function to convert to a real Oracle date.



Character (Text) type data is referenced with the following list of functions:

- actual value
- decoded value (if coded type)
- baseline value
- endpoint value

Numeric type data adds the following functions:

- chg. from baseline: Defined in the configuration tables and/or user-defined using _New Event Function_.
- % chg. from baseline: Defined in the configuration tables and/or user-defined using _New Event Function_.
- chg. from previous: Default derived value (measure determined from the last two measures).

*Note: Review selects an appropriate function by default with respect for the data type of the item selected. The default function is assigned as the most likely function to be used for that type of item.*

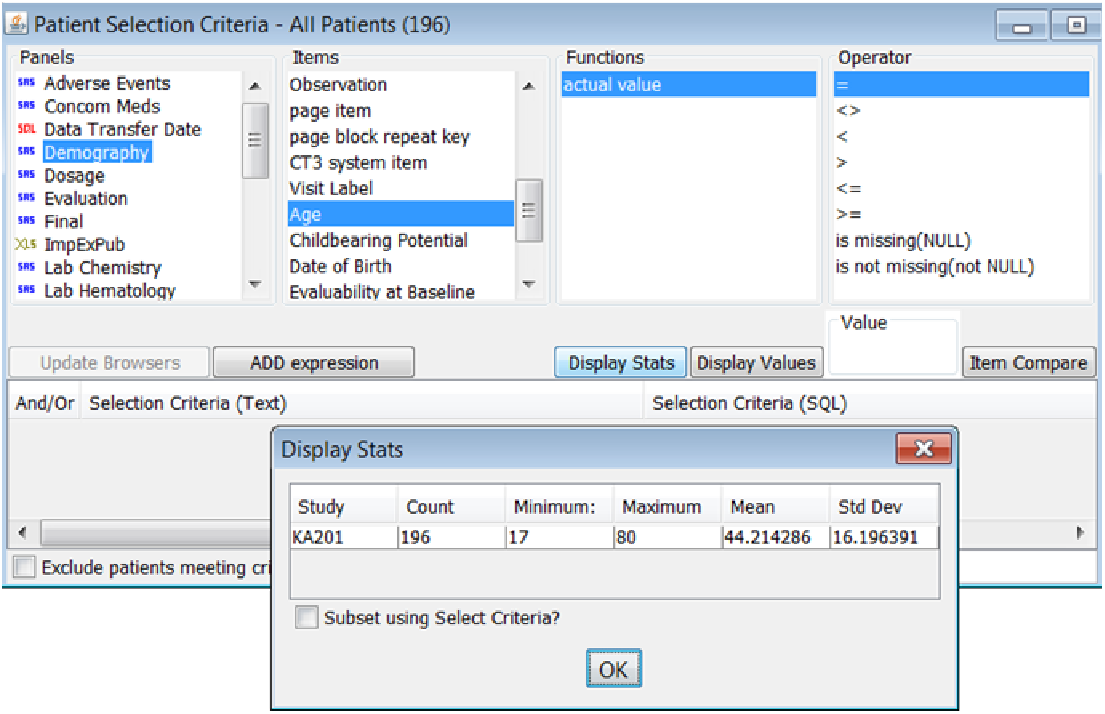
# Item Statistics

## *Display item statistics*

Alternatively, you can display the range and other basic statistics of the item by selecting an item and clicking **Display Stats**.

***Hint: This function has meaning when applied to numeric data items and may not be significant for other values.***

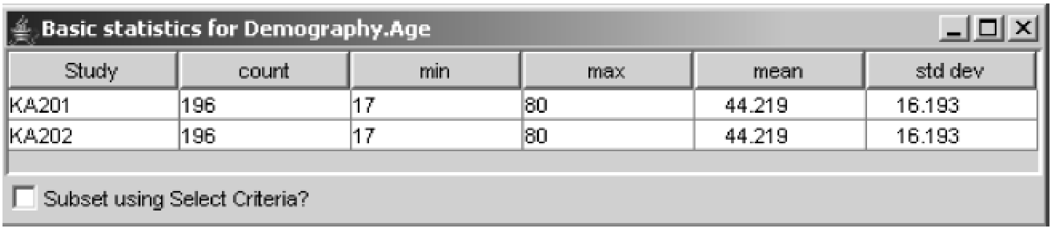
The example for the patient age shows the total count of values, minimum value and maximum value. If the value is numeric, then the mean and standard deviation are included. This example represents the total population of patients within the protocols selected and the selected function.



| Study | Count | Minimum: | Maximum | Mean | Std Dev |
|---|---|---|---|---|---|
| KA201 | 196 | 17 | 80 | 44.214286 | 16.196391 |

☐ Subset using Select Criteria?

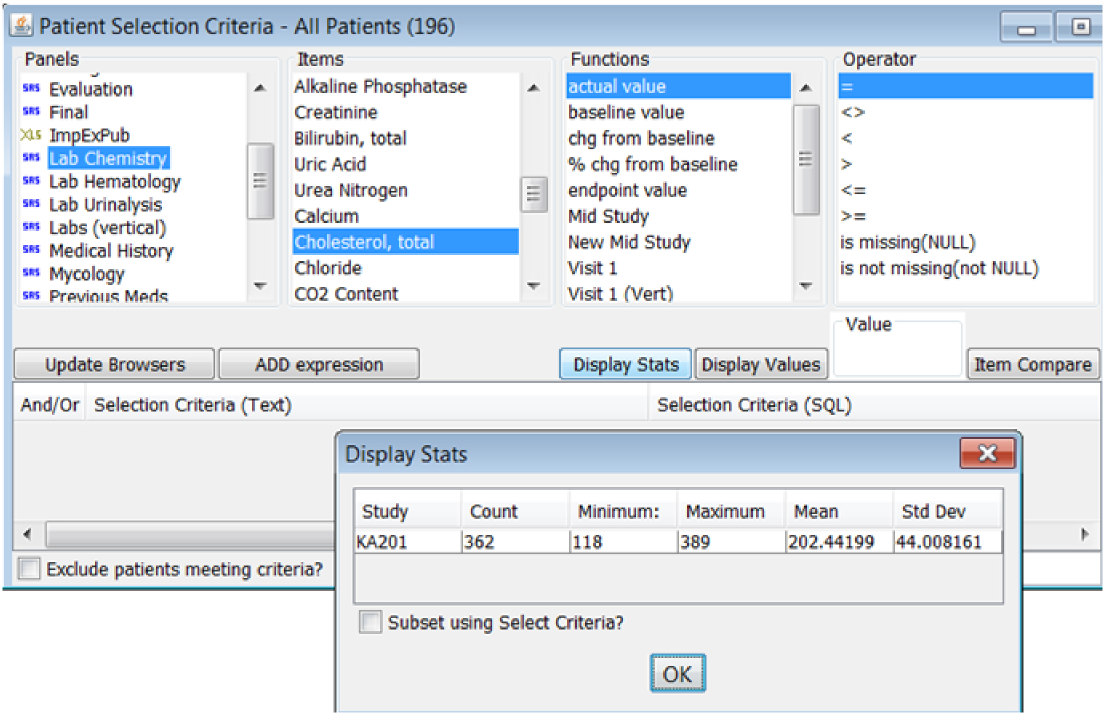
If multiple protocols are selected the basic statistics display on separate rows for each study.


Basic statistics for Demography.Age

| Study | count | min | max | mean | std dev |
|---|---|---|---|---|---|
| KA201 | 196 | 17 | 80 | 44.219 | 16.193 |
| KA202 | 196 | 17 | 80 | 44.219 | 16.193 |

☐ Subset using Select Criteria?

This example for lab item cholesterol counts the individual lab values across multiple visits to display the basic statistics for the lab item.



Display Stats

| Study | Count | Minimum: | Maximum | Mean | Std Dev |
|---|---|---|---|---|---|
| KA201 | 362 | 118 | 389 | 202.44199 | 44.008161 |

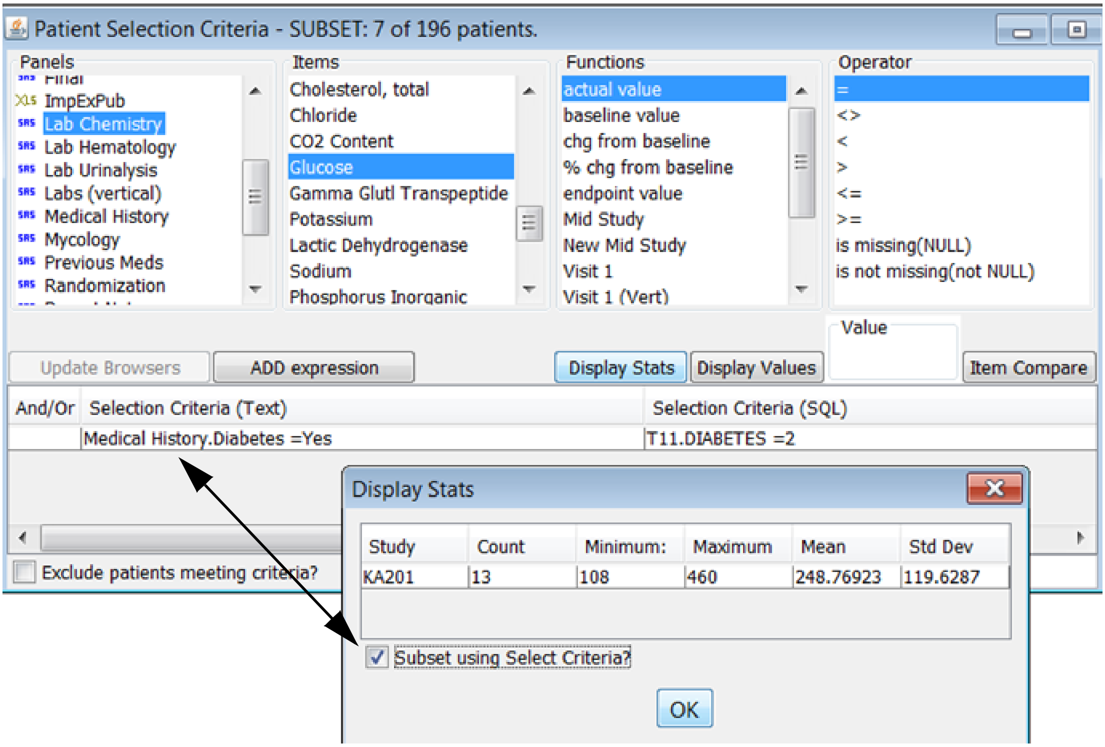
☐ Subset using Select Criteria?

OK

## *Displaying subsets of protocol population*

You can limit the displayed statistics for the patients meeting the patient selection criteria by checking ‘Subset using Select Criteria?’. If the checkbox is not checked, the statistics are for the total patient population.

When **‘Subset using Select Criteria?’** is checked, the statistics in the corresponding window reflect the sub-population of patients that falls within your patient selection criteria. The patient selection criteria will only be applied to the population when **Subset using Selection Criteria** is clicked. Any changes that you make in the Patient Selection Criteria that need to be reflected in the subset statistics must be preceded by clicking **Update Browsers**.



Patient Selection Criteria - SUBSET: 7 of 196 patients.

| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Medical History.Diabetes =Yes | T11.DIABETES =2 |

☐ Exclude patients meeting criteria?

Display Stats

| Study | Count | Minimum: | Maximum | Mean | Std Dev |
|---|---|---|---|---|---|
| KA201 | 13 | 108 | 460 | 248.76923 | 119.6287 |

☑ Subset using Select Criteria?

# Dynamic Patient Selection Criteria

## *Dynamic PSC*

The Dynamic Patient Select Criteria Panel is a patient data filter panel. It works at the patient level, to specify patient subset characteristics by selecting/unselecting various patient criteria values, as a more visual, more intuitive method of selecting patients of interest. Patient selection filter panel contents are defined by an easy to use drag and drop interface, saving/sharing those with others, and having multiple filter panels to choose from. Also, it is present in the Dashboard Views area.

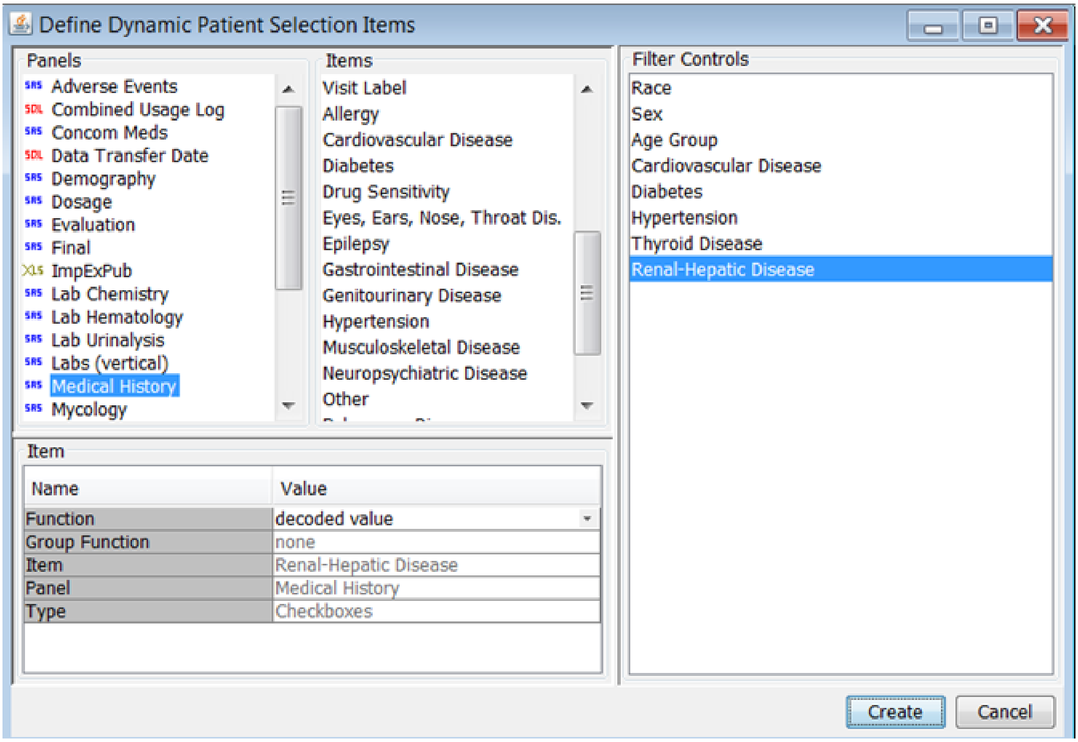
The Dynamic PSC feature provides UI controls (i.e., combo boxes with sliders, check boxes, and lists) to interactively set the current PSC. The controls are similar to those found in JReview's filter controls available for detail graphs. In effect, the feature simplifies the changing of the current PSC. The controls are presented in a panel initially positioned at the right-side of the JReview frame. The user changes the current PSC by changing the settings of the individual controls, and then clicking the **Update Browsers button**. The **Reset button** resets the values for the controls to the original values: the values for range controls are determined by the range of values in the dataset and the toggle values are set to true.

The Dynamic PSC overlays the existing PSC module. When Update Browsers is clicked, PSC criteria are added to the regular PSC window. The criteria generated by the Dynamic PSC feature are presented in italics in order to make them distinctive. Changing the Dynamic PSC controls settings and clicking Update Browsers results in any pre-existing Dynamic PSC criteria in the Window being deleted, and the new settings being added.

## *Define Dynamic PSC*

Click on the **Dynamic PSC icon** presented on the JReview tool bar to open the Dynamic PSC definition window. It is the icon next to the PSC funnel icon with the “check mark” over the funnel.

The definition screen is similar in operation to other NUI browsers: it has a drag-and-drop style and includes a property table for the selected items. When the **Create button** is clicked, the Dynamic PSC viewer frame is opened (if it is not opened already) with the viewer’s controls updated to correspond to the definition contained in the definitional screen. The Define Dynamic Patient Selection Items window opens. Simply select a panel then drag and drop each item of interest to the **Filter Controls** area.

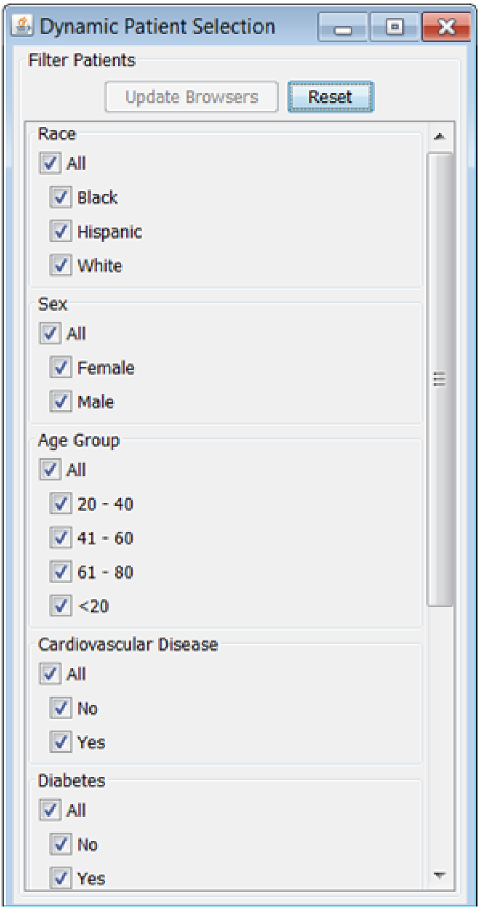


| Name | Value |
|---|---|
| Function | decoded value |
| Group Function | none |
| Item | Renal-Hepatic Disease |
| Panel | Medical History |
| Type | Checkboxes |

Click **Create** to generate the Dynamic Patient Selection window with a list of checkboxes or ranges to filter patients.

In the normal JReview user interface, the Dynamic PSC selector window appears at a floating window on the right side of the application area, but is moveable, resizeable, but always on top.

Each selected item that was added to the **Filter Controls** are listed as checkboxes. The default is “All Patients” the same as Patient Selection Criteria window. Select patients to display with checkboxes checked ON for selected versus unchecked as not selected. Click **Update Browsers** to update patients.



Race
- ☑ All
  - ☑ Black
  - ☑ Hispanic
  - ☑ White

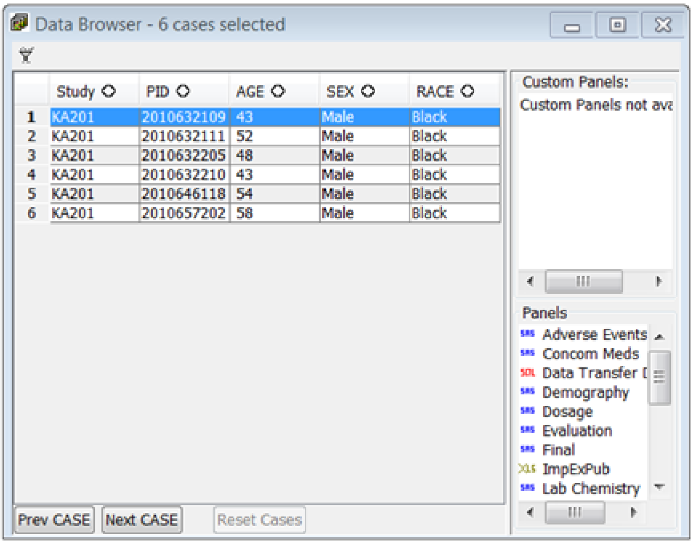
Sex
- ☑ All
  - ☑ Female
  - ☑ Male

Age Group
- ☑ All
  - ☑ 20 - 40
  - ☑ 41 - 60
  - ☑ 61 - 80
  - ☑ <20

Cardiovascular Disease
- ☑ All
  - ☑ No
  - ☑ Yes

Diabetes
- ☑ All
  - ☑ No
  - ☑ Yes

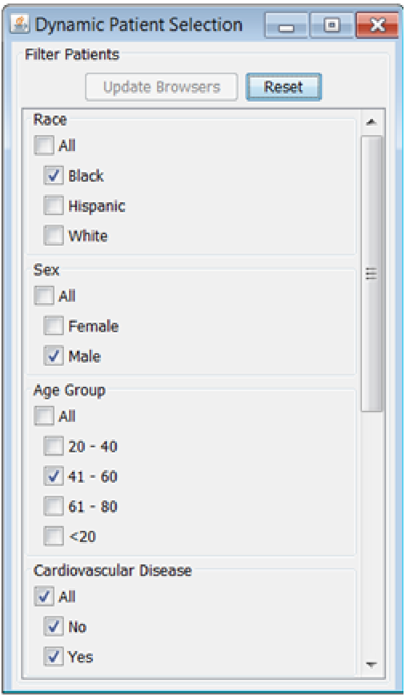
When you click **Update Browsers** any open output for reports, graphs, crosstabs and the Data Browser update to display the selected patients.



|  | Study | PID | AGE | SEX | RACE |
|---|---|---|---|---|---|
| 1 | KA201 | 2010632109 | 43 | Male | Black |
| 2 | KA201 | 2010632111 | 52 | Male | Black |
| 3 | KA201 | 2010632205 | 48 | Male | Black |
| 4 | KA201 | 2010632210 | 43 | Male | Black |
| 5 | KA201 | 2010646118 | 54 | Male | Black |
| 6 | KA201 | 2010657202 | 58 | Male | Black |

Custom Panels:
Custom Panels not ava

Panels
- Adverse Events
- Concom Meds
- Data Transfer
- Demography
- Dosage
- Evaluation
- Final
- ImpExPub
- Lab Chemistry



Race
- ☐ All
- ☑ Black
- ☐ Hispanic
- ☐ White

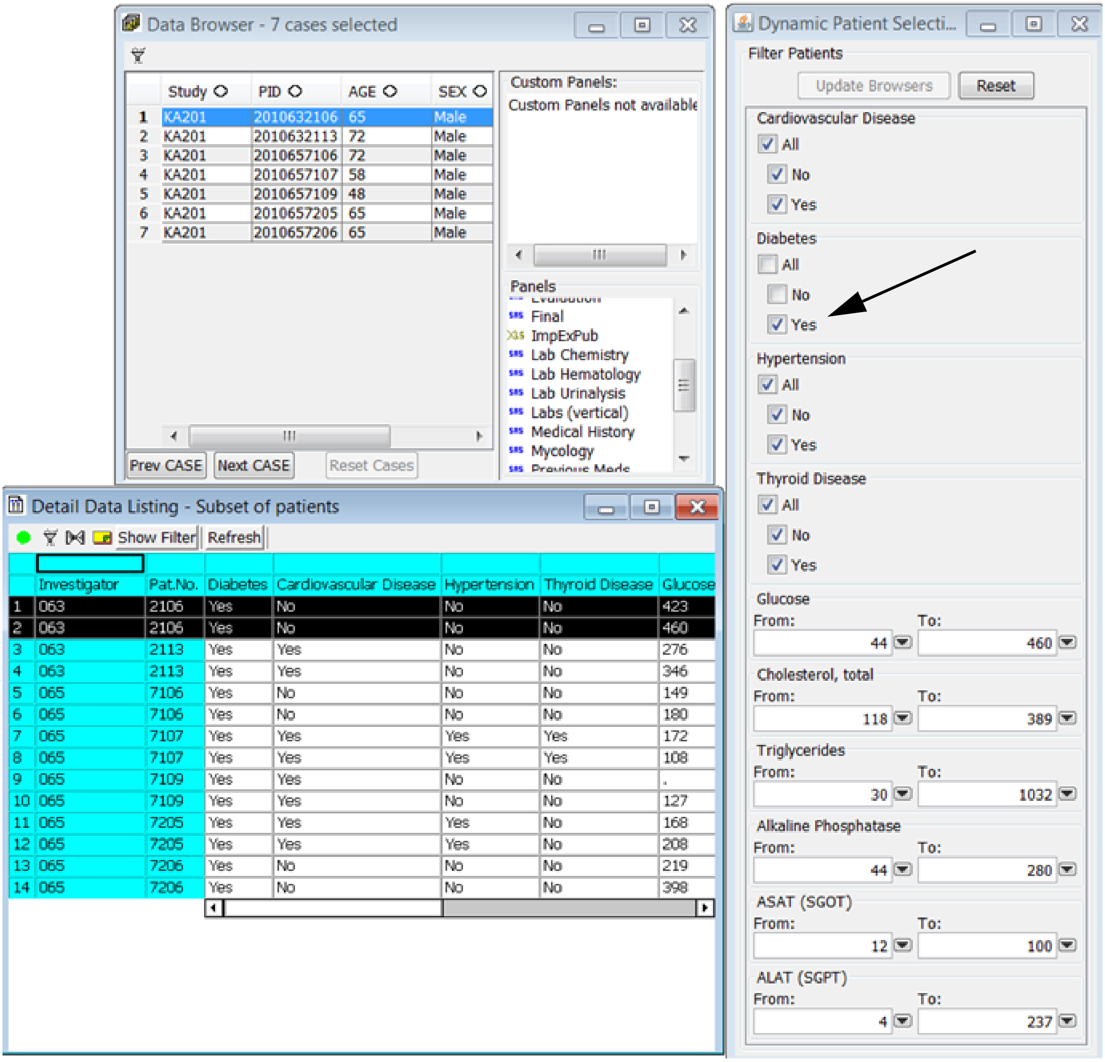
Sex
- ☐ All
- ☐ Female
- ☑ Male

Age Group
- ☐ All
- ☐ 20 - 40
- ☑ 41 - 60
- ☐ 61 - 80
- ☐ <20

Cardiovascular Disease
- ☑ All
- ☑ No
- ☑ Yes

Click **Reset** to clear any selections and click **Update Browsers** to return to All Patients selected.

This example includes laboratory data. The lab ranges shown represent all available results from minimum to maximum. Diabetes was checked for ‘Yes’ to view those patients. Then click **Update Browsers**.



| | Study | PID | AGE | SEX |
|---|---|---|---|---|
| 1 | KA201 | 2010632106 | 65 | Male |
| 2 | KA201 | 2010632113 | 72 | Male |
| 3 | KA201 | 2010657106 | 72 | Male |
| 4 | KA201 | 2010657107 | 58 | Male |
| 5 | KA201 | 2010657109 | 48 | Male |
| 6 | KA201 | 2010657205 | 65 | Male |
| 7 | KA201 | 2010657206 | 65 | Male |

| | Investigator | Pat.No. | Diabetes | Cardiovascular Disease | Hypertension | Thyroid Disease | Glucose |
|---|---|---|---|---|---|---|---|
| 1 | 063 | 2106 | Yes | No | No | No | 423 |
| 2 | 063 | 2106 | Yes | No | No | No | 460 |
| 3 | 063 | 2113 | Yes | Yes | No | No | 276 |
| 4 | 063 | 2113 | Yes | Yes | No | No | 346 |
| 5 | 065 | 7106 | Yes | No | No | No | 149 |
| 6 | 065 | 7106 | Yes | No | No | No | 180 |
| 7 | 065 | 7107 | Yes | Yes | Yes | Yes | 172 |
| 8 | 065 | 7107 | Yes | Yes | Yes | Yes | 108 |
| 9 | 065 | 7109 | Yes | Yes | No | No | . |
| 10 | 065 | 7109 | Yes | Yes | No | No | 127 |
| 11 | 065 | 7205 | Yes | Yes | Yes | No | 168 |
| 12 | 065 | 7205 | Yes | Yes | Yes | No | 208 |
| 13 | 065 | 7206 | Yes | No | No | No | 219 |
| 14 | 065 | 7206 | Yes | No | No | No | 398 |

Cardiovascular Disease
☑ All
☑ No
☑ Yes

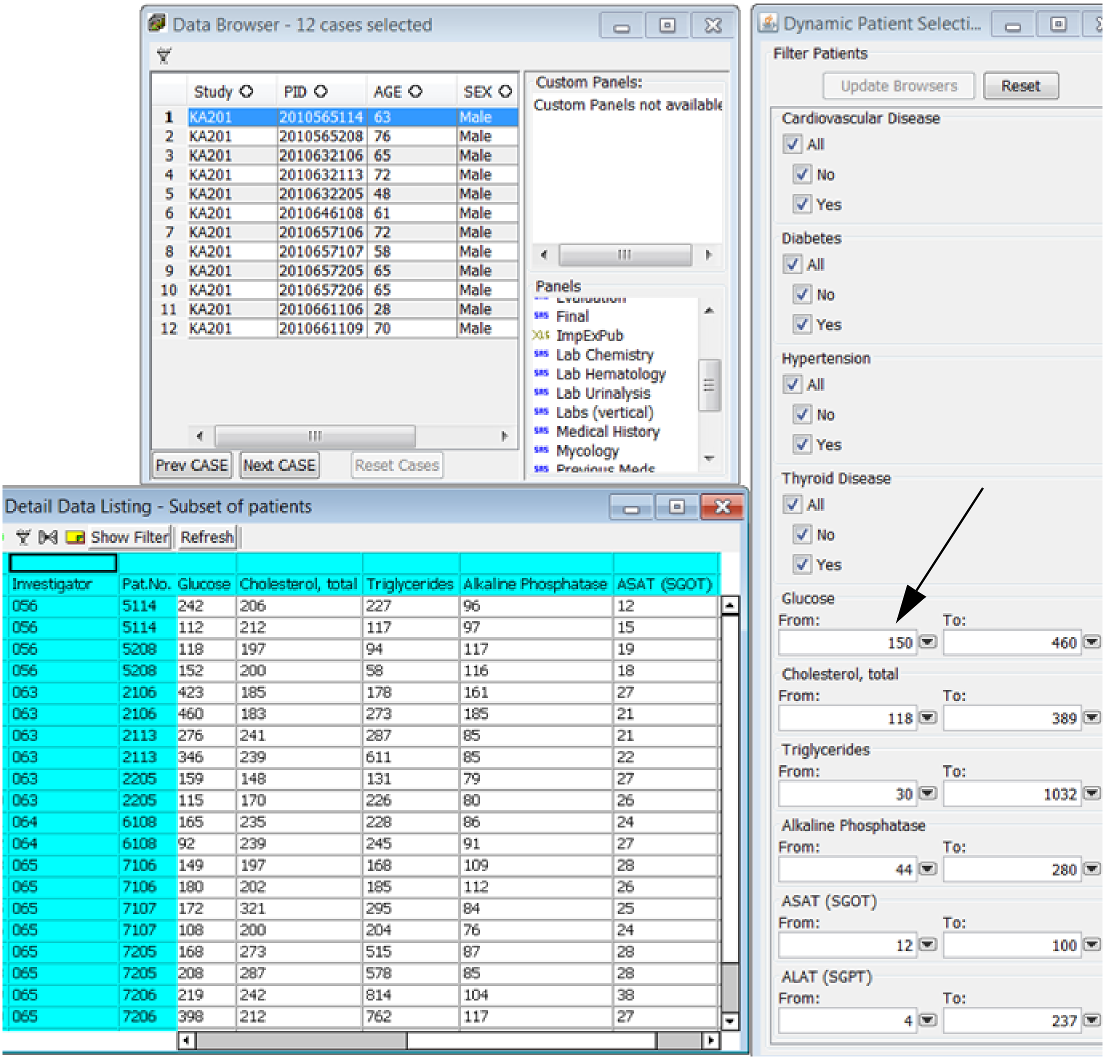
Diabetes
☐ All
☐ No
☑ Yes

Hypertension
☑ All
☑ No
☑ Yes

Thyroid Disease
☑ All
☑ No
☑ Yes

| | From: | To: |
|---|---|---|
| Glucose | 44 | 460 |
| Cholesterol, total | 118 | 389 |
| Triglycerides | 30 | 1032 |
| Alkaline Phosphatase | 44 | 280 |
| ASAT (SGOT) | 12 | 100 |
| ALAT (SGPT) | 4 | 237 |

This example checked Diabetes back to ‘All’ and the previous Glucose range was changed. Enter the numeric values or click the arrow to display a sliding scale bar. Remember to click Update Browsers.



| | Study | PID | AGE | SEX |
|---|---|---|---|---|
| 1 | KA201 | 2010565114 | 63 | Male |
| 2 | KA201 | 2010565208 | 76 | Male |
| 3 | KA201 | 2010632106 | 65 | Male |
| 4 | KA201 | 2010632113 | 72 | Male |
| 5 | KA201 | 2010632205 | 48 | Male |
| 6 | KA201 | 2010646108 | 61 | Male |
| 7 | KA201 | 2010657106 | 72 | Male |
| 8 | KA201 | 2010657107 | 58 | Male |
| 9 | KA201 | 2010657205 | 65 | Male |
| 10 | KA201 | 2010657206 | 65 | Male |
| 11 | KA201 | 2010661106 | 28 | Male |
| 12 | KA201 | 2010661109 | 70 | Male |

Custom Panels:
Custom Panels not available

| Investigator | Pat.No. | Glucose | Cholesterol, total | Triglycerides | Alkaline Phosphatase | ASAT (SGOT) |
|---|---|---|---|---|---|---|
| 056 | 5114 | 242 | 206 | 227 | 96 | 12 |
| 056 | 5114 | 112 | 212 | 117 | 97 | 15 |
| 056 | 5208 | 118 | 197 | 94 | 117 | 19 |
| 056 | 5208 | 152 | 200 | 58 | 116 | 18 |
| 063 | 2106 | 423 | 185 | 178 | 161 | 27 |
| 063 | 2106 | 460 | 183 | 273 | 185 | 21 |
| 063 | 2113 | 276 | 241 | 287 | 85 | 21 |
| 063 | 2113 | 346 | 239 | 611 | 85 | 22 |
| 063 | 2205 | 159 | 148 | 131 | 79 | 27 |
| 063 | 2205 | 115 | 170 | 226 | 80 | 26 |
| 064 | 6108 | 165 | 235 | 228 | 86 | 24 |
| 064 | 6108 | 92 | 239 | 245 | 91 | 27 |
| 065 | 7106 | 149 | 197 | 168 | 109 | 28 |
| 065 | 7106 | 180 | 202 | 185 | 112 | 26 |
| 065 | 7107 | 172 | 321 | 295 | 84 | 25 |
| 065 | 7107 | 108 | 200 | 204 | 76 | 24 |
| 065 | 7205 | 168 | 273 | 515 | 87 | 28 |
| 065 | 7205 | 208 | 287 | 578 | 85 | 28 |
| 065 | 7206 | 219 | 242 | 814 | 104 | 38 |
| 065 | 7206 | 398 | 212 | 762 | 117 | 27 |

Cardiovascular Disease
☑ All
☑ No
☑ Yes

Diabetes
☑ All
☑ No
☑ Yes

Hypertension
☑ All
☑ No
☑ Yes

Thyroid Disease
☑ All
☑ No
☑ Yes

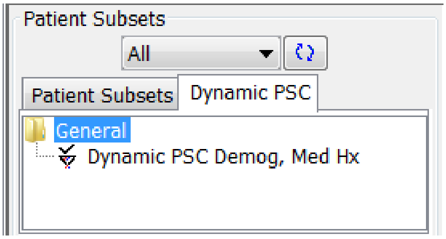
| | From: | To: |
|---|---|---|
| Glucose | 150 | 460 |
| Cholesterol, total | 118 | 389 |
| Triglycerides | 30 | 1032 |
| Alkaline Phosphatase | 44 | 280 |
| ASAT (SGOT) | 12 | 100 |
| ALAT (SGPT) | 4 | 237 |

## Dynamic PSC Tab

The definition in the Dynamic PSC definition screen can be saved in a way similar to saving the definition in the "regular" PSC window.

Saved Dynamic PSC definitions are presented in the Dynamic PSC tab in JReview's Object Explorer. A right-mouse popup menu provides options for deleting the object and for making the object the "default" Dynamic PSC. When the saved definition is set to be the "default", the Dynamic PSC control panel will be opened automatically in Dashboard mode with the definition.

Select the Define Dynamic Patient Selection Items window as the active window to save the Dyanmic PSC defintion. See the next section for ***Object Storage: Saving your work***. Saved Dynamic PSC objects are listed in the Dynamic PSC tab within the Patient Subsets window.



# Object storage: Saving your work

## Saving the selection criteria

To save the patient selection criteria you have created for later use:

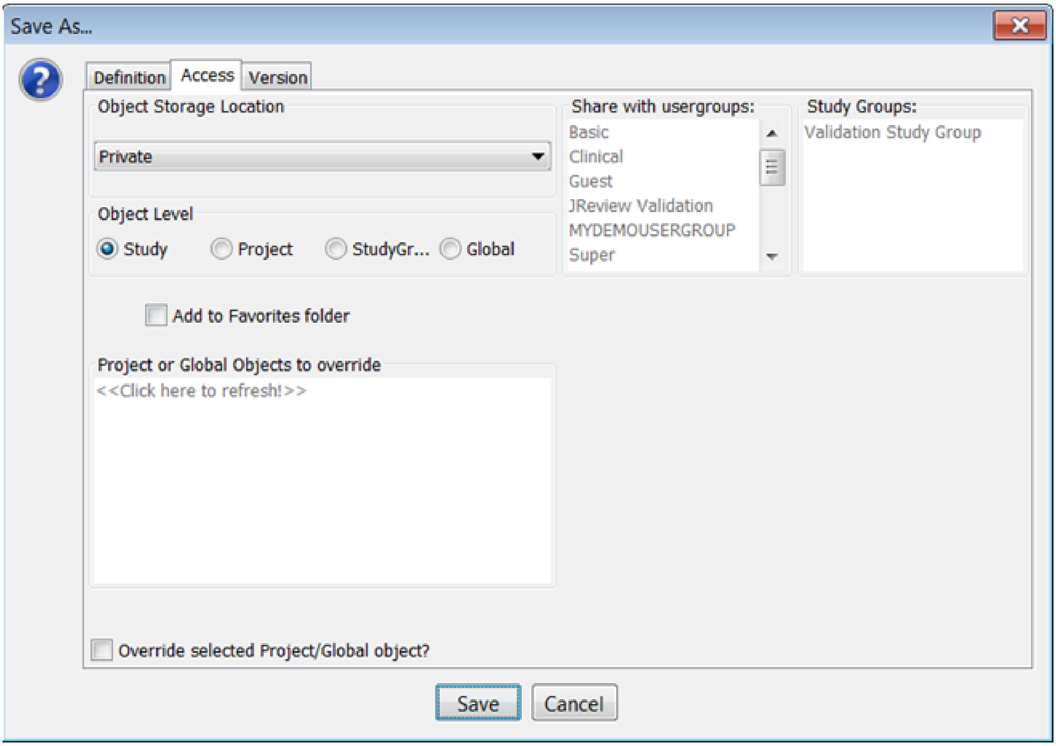
1. Make certain that the **Patient Selection Criteria window** or **Define Dynamic Patient Selection Items window** is the active window by clicking on its title bar.

   Click 💾, or from the **File** menu select **Save.**

   JReview displays the **Save window** organized by tabs associated with saving an object.

## Access tab

2. The **Save window** opens on the **Access tab**, select an **Object Storage Location**.



Save As...

Object Storage Location: Private

Object Level: ● Study ○ Project ○ StudyGr... ○ Global

Share with usergroups: Basic, Clinical, Guest, JReview Validation, MYDEMOUSERGROUP, Super

Study Groups: Validation Study Group

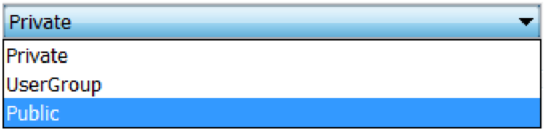
☐ Add to Favorites folder

Project or Global Objects to override: <<Click here to refresh!>>

☐ Override selected Project/Global object?

## *Object storage location*

Saving on database object storage sites, requires the author to have “Publishing Authorization” defined in the configuration tables. **(See *ReviewAdmin Users Manual*)**

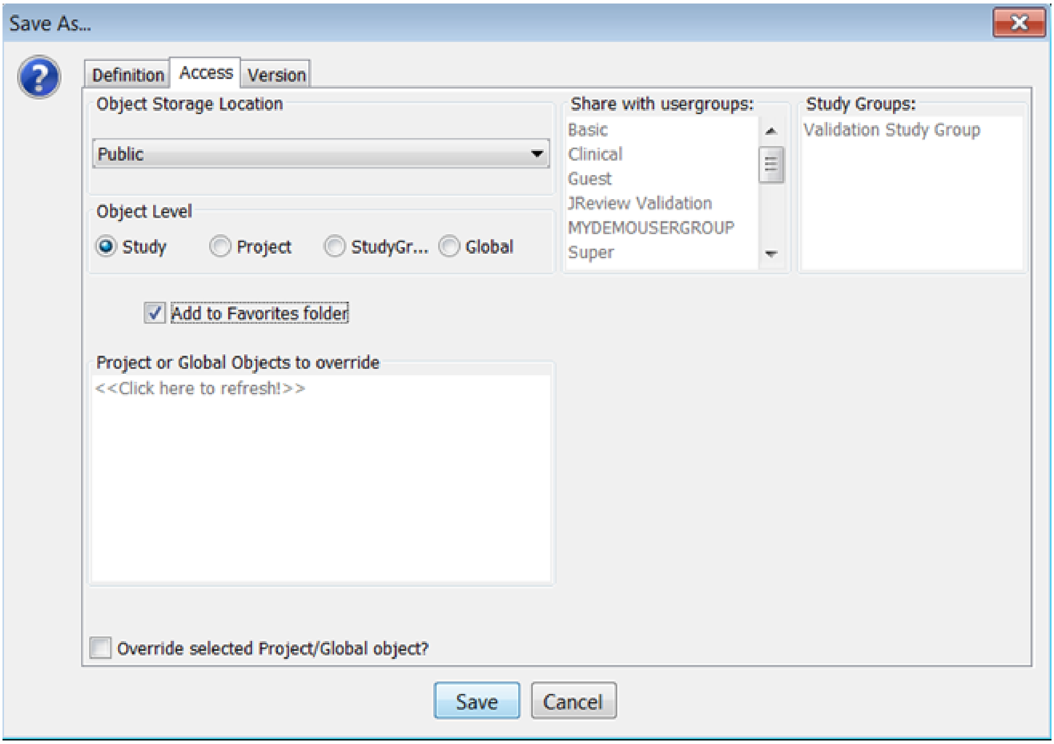


There are three user access levels to store the object specification: Private (db), User Group (db) and Public (db). User access levels designated as ‘db’ for database makes the object available for scheduling. Objects may be saved at the study, user group or global level

- **Private** is a database object storage for sole access by the user. IRAdmin review privilege for Protected_Category at UserID level.
- **User Group** is a database object storage for defined User Groups in the configuration tables. Object storage in User Group level allows you to specify sharing with multiple User Groups. When you are a member in a User Group and click User Group, the ‘Share with usergroups’ list box is made available for selection. Click on a usergroup to share the object, use the CTRL or SHIFT key to make multiple selections.

  IRAdmin review privilege for User Group Save where users in a usergroup can update and delete other user group member objects. The privilege is set at either the UserID or User Group level. Also, IRAdmin review privilege for Protected_Category at User Group level.
- **Public** also has shared network drive for storage where all users have access to public objects, but authorization is required to save an object as public.

Optionally ‘**Add to Favorites folder**’.



Object Storage Location: Public

Object Level: ● Study ○ Project ○ StudyGr... ○ Global

☑ Add to Favorites folder

☐ Override selected Project/Global object?

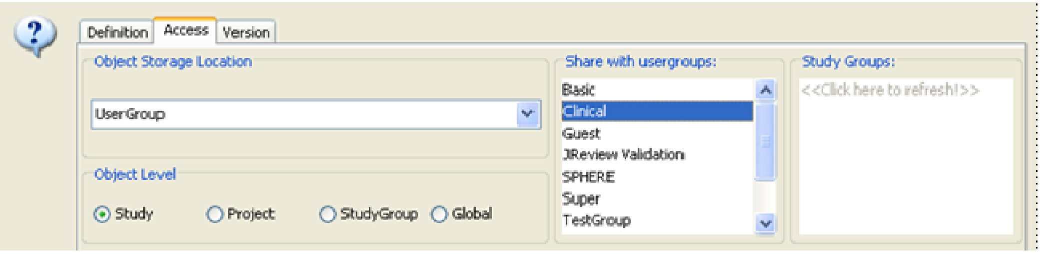
## *Study Override*

You can override a previously saved object at the Project or Global level with a Study level object. When you select Study level, the ‘Override selected Project/Global object?’ check box is made available for selection.

Save at the Study Object Level, when you can choose to override a previously saved Project or Global level object. Select the previously saved project or global level object from the ‘Projects or Global Objects to override’ list. The chosen Project or Global level object will be replaced by the new Study level object when you click SAVE. The original Project/Global object is still available for selection in other studies, but is overridden for the selected study.

## *Share with user groups*

When UserGroup is selected the ‘Share with usergroups:’ box is enabled allowing you to select other usergroups to share access with the object specification. Use the CTRL or SHIFT key to make multiple selections.



Object Storage Location: UserGroup

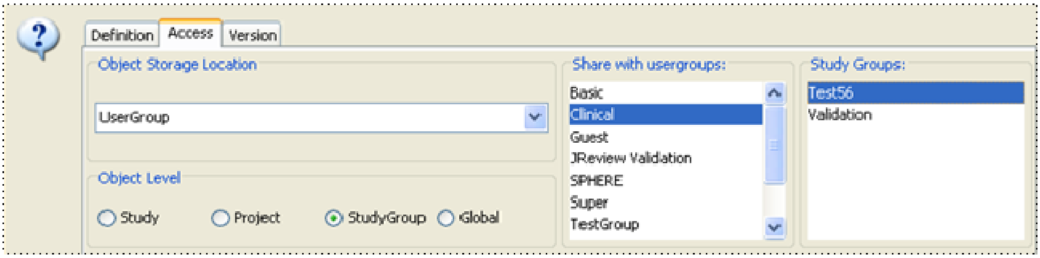
Object Level: ● Study ○ Project ○ StudyGroup ○ Global

Share with usergroups: Clinical

## *Publish for study groups*

The study group save privilege allows the user to save objects to Study Groups and selected in the ‘Publish for Study Groups’ list. The Study Groups are non-visual groupings of studies set in Review Admin, and are not project specific. They can, and are intended to cross projects. Users can create a study group from within Review Admin, assign studies when this option is turned ON, objects can be saved to the study group. These groups are not visible in JReview (like project and study are), but rather help group studies of common architecture.

For example, if three ongoing projects were built on one database standard and each may have two studies. The “Standards Committee” decides on new standards which will affect all future studies. So, the next studies that each of the projects start up will use a new standard. This is a good place to create two study groups. The first study group will have the initial six studies (two from each of the three projects) and another study group will contain all future new studies. The user within JReview does not see the study groups until he/she goes to save an object. This option allows the user to be able to save objects as a global report, but only to a subset of studies that could be across protocols.



Object Storage Location: UserGroup

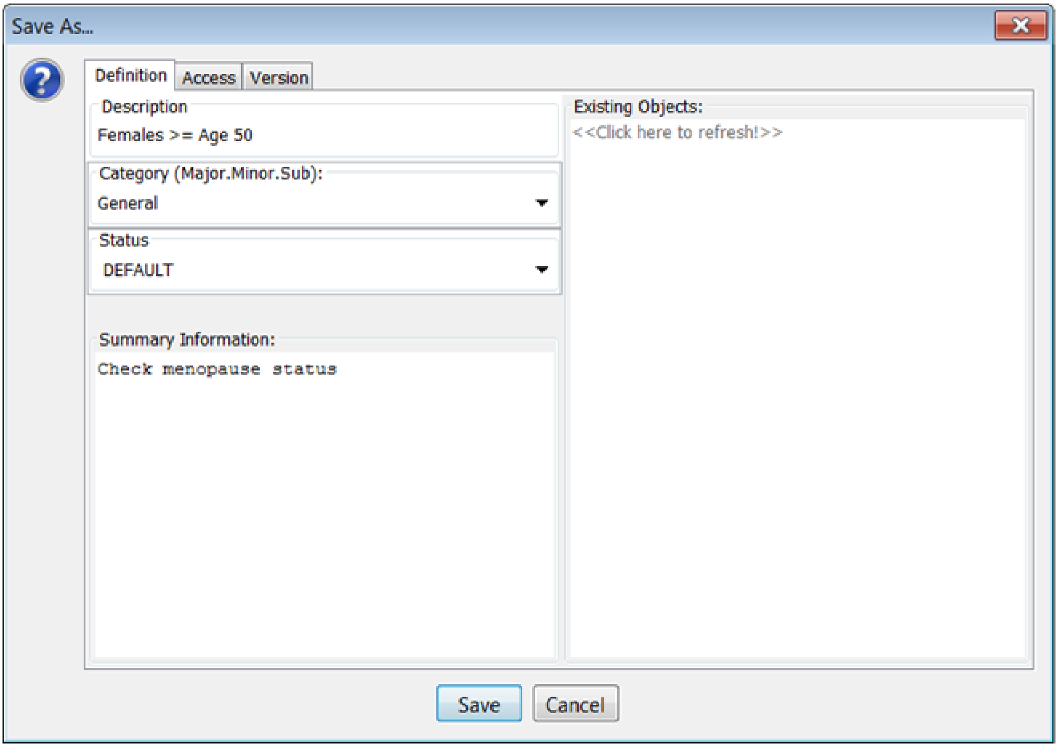
Object Level: ○ Study ○ Project ● StudyGroup ○ Global

Share with usergroups: Clinical

Study Groups: Test56

## *Definition Tab*

3. In the **Definition tab**, enter an appropriate **Description**. This description is displayed in the **Object Explorer window**.



Description
Females >= Age 50

Category (Major.Minor.Sub):
General

Status
DEFAULT

Summary Information:
Check menopause status

Existing Objects:
<<Click here to refresh!>>

4. Enter the folder(s) information in the **Category** box.

   Each folder (major, minor and subfolder) is separated by a period where folder titles can consist of more than one word separated by a space. For example, the major folder for ‘Safety’ has two minor folders ‘Safety.AEs’ and ‘Safety.Labs’.

   Folder names are **case-sensitive** and after the folder(s) are initially created, they are selected from the dropdown list box.

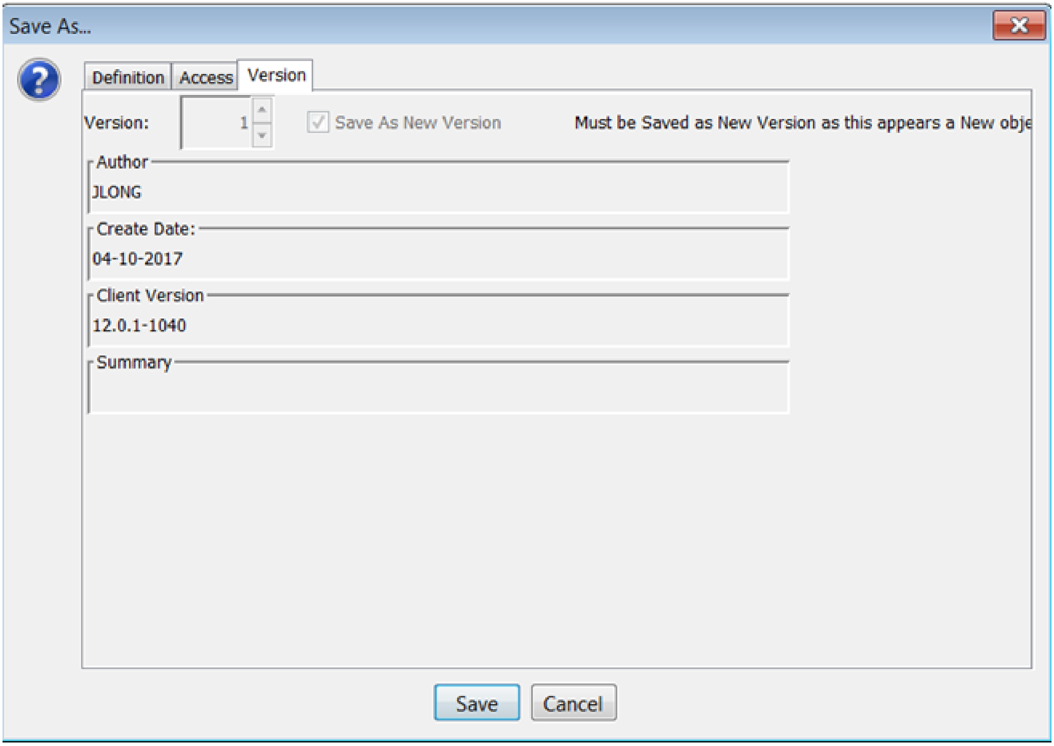
5. Enter a **Status** for the object. The Status may be used when managing objects to create Object Groups for launching groups of objects with the same status.

6. You can include **Summary Information** for future reference to be viewed by yourself or others later (optional).

   An ID Number is assigned and used internally by Review to track the object.

## *Version tab*

JReview has the following “Allow Updates” privilege settings apply to Save and Update an object. A new object must be saved as New Version as there are no prior saved versions. Click on **Save,** to save the object specification or defined patient selection criteria to the Object Explorer window.



Version: 1

☑ Save As New Version

Must be Saved as New Version as this appears a New obje

Author: JLONG

Create Date: 04-10-2017

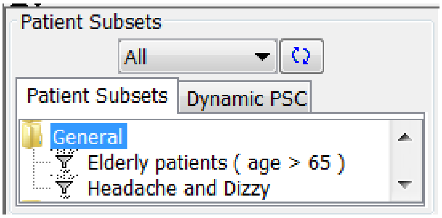
Client Version: 12.0.1-1040

Summary:

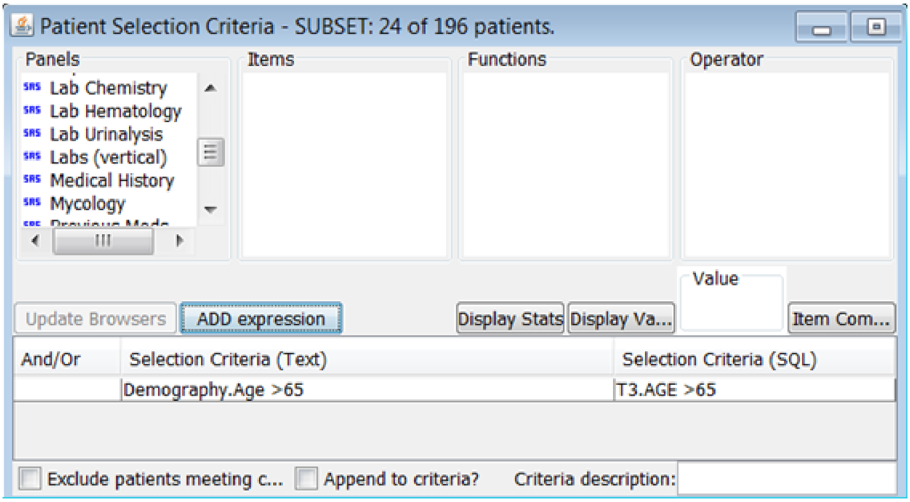
## *Retrieve a saved selection criteria*

If you want to retrieve a saved patient selection criteria:

1. Double click to open a folder. The filter icon displays along side the description to indicate the stored object is a patient selection criteria.

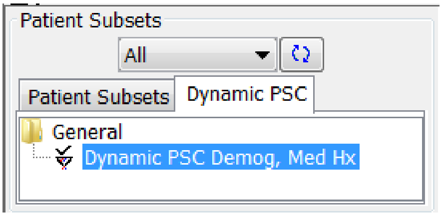


2. Double click to paste the selected patient selection criteria into the Patient Selection Criteria Window.
3. Click **Update Browsers**.



| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Demography.Age >65 | T3.AGE >65 |

You would launch a saved Dynamic PSC using the same steps. The Dynamic Patient Selection is generated with a list of checkboxes to filter patients.



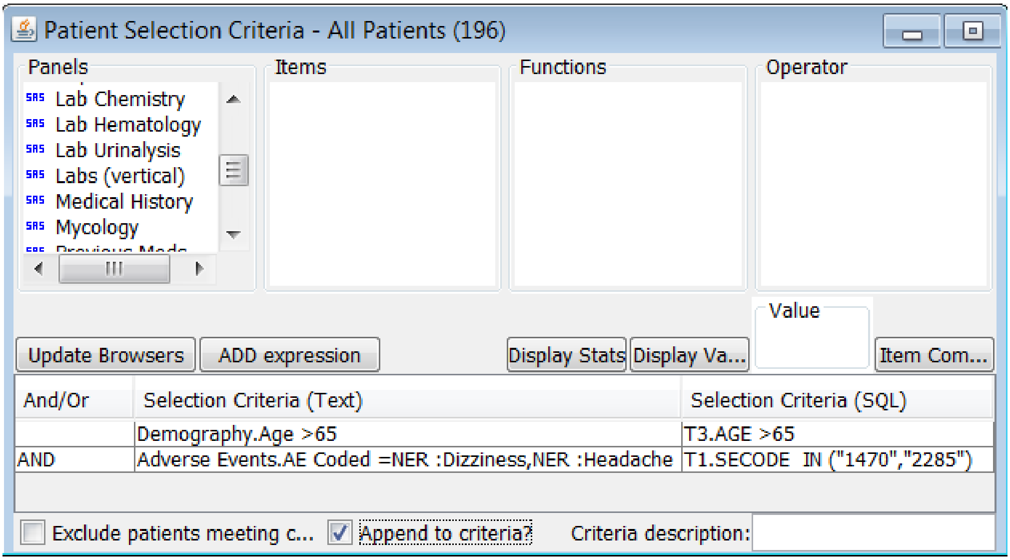
## *Append to criteria*

At this point, you can either click **Update Browsers** to enable your selection criteria, or continue to add more previously saved criteria objects to the end of the currently loaded selection criteria with the ‘Append to criteria?’ check box. You can modify the patient selection criteria and resave to a new description and folder.

***Note: To save time, you can launch and paste previously saved patient selection criteria from the Object Explorer Window to edit and resave as new stored objects. However, you must load the previously stored object first into the Patient Selection Criteria Window then append to or modify it.***

You can append a saved patient selection criteria to the current saved patient selection criteria object:

1. Select and double click to add the first selection criteria object.
2. Click ☑ Append to criteria? .
3. Select and double click another selection criteria object to append.

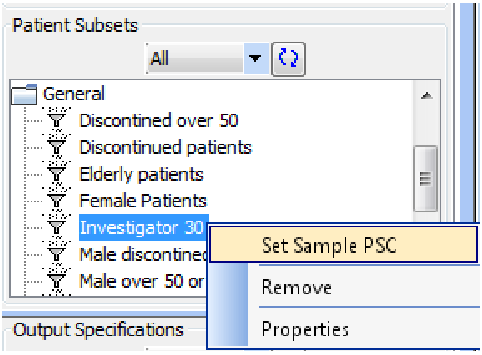


| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Demography.Age >65 | T3.AGE >65 |
| AND | Adverse Events.AE Coded =NER :Dizziness,NER :Headache | T1.SECODE IN ("1470","2285") |

## Set Sample PSC

The **Drag and Drop** functionality is used to define output specification for graph, report, and crosstab with a preview of results. Users with ReviewAdmin priv63 may assign a "**Sample PSC**" to preview results while building the object specification. The Sample PSC is saved at the study level as public. The Set Sample PSC icon is outlined with a **green box**. The default sample PSC saves time instead of creating the output on a larger patient population.

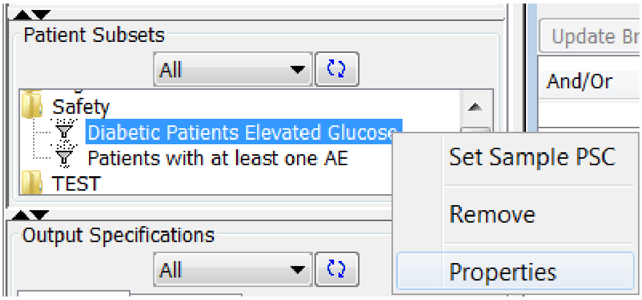
You would select a previously saved PSC, then right mouse click to display a floating menu. Select **Set Sample PSC** to preview results within the output browsers.



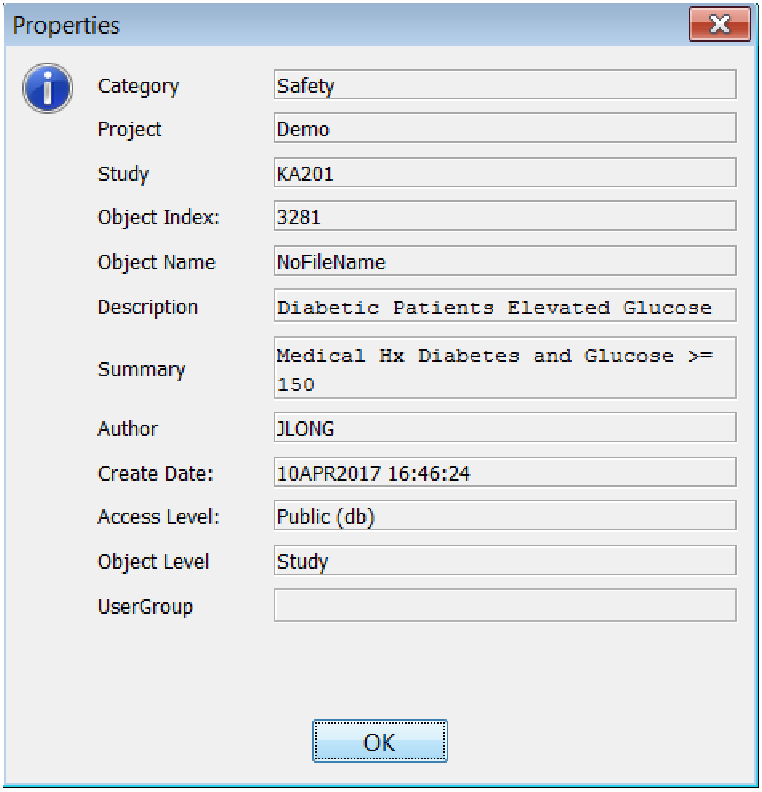
## *Object properties*

You can view information about an object when you select “Properties”.

1. Select the stored object with a single click.
2. Right-mouse click to display a floating menu.



3. Click **Properties** to display details and click **OK** to close window.

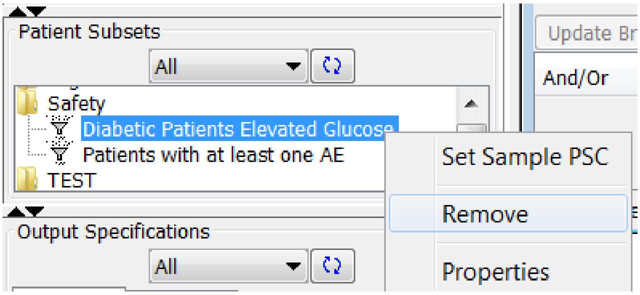


| | |
|---|---|
| Category | Safety |
| Project | Demo |
| Study | KA201 |
| Object Index: | 3281 |
| Object Name | NoFileName |
| Description | Diabetic Patients Elevated Glucose |
| Summary | Medical Hx Diabetes and Glucose >= 150 |
| Author | JLONG |
| Create Date: | 10APR2017 16:46:24 |
| Access Level: | Public (db) |
| Object Level | Study |
| UserGroup | |

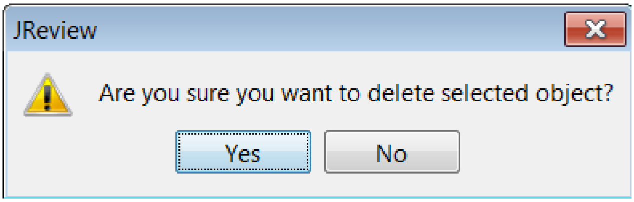
## *Quick remove*

You can quickly delete a saved patient selection criteria in the Object Explorer window under Patient Subsets.

1. Select the stored object with a single click.
2. Right-mouse click to display a floating menu.



3. Then click **Remove**. You are prompted “Are you sure you want to delete the object?” and click **Yes**.



Are you sure you want to delete selected object?

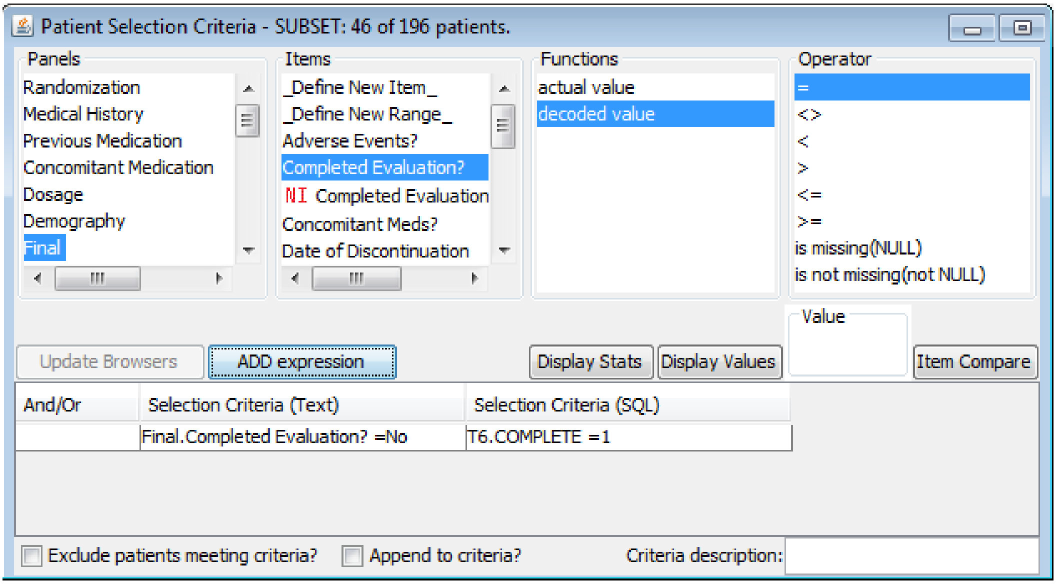
The Remove function is a quick way to delete stored objects provided the user is the creator or a SuperUser. It works for ‘UserGroup’ or ‘Public’ objects equally.

# 3 Review Patient Data

# Data Browser

## *Subset patients*

The Data Browser presents a list of patients who meet the current patient selection criteria. It provides the user with the ability to look at data for an individual patient. After building the patient selection criteria, you can quickly view a detailed list of the selected patients by using the Data Browser. If you do not define a patient selection criteria then by default all available patients in the database will display.



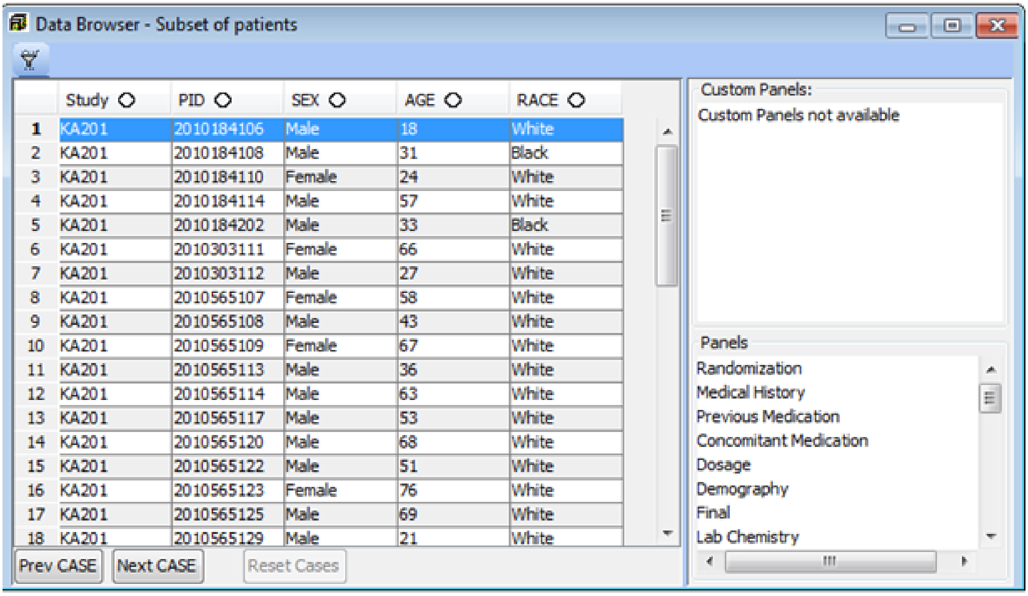
Patient Selection Criteria - SUBSET: 46 of 196 patients.

| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
|  | Final.Completed Evaluation? =No | T6.COMPLETE =1 |

## *Opening the Data Browser*

Click in the toolbar or from the **Browse** menu, select **Data**.

JReview opens a new window that displays a list of patients who meet the current patient selection criteria.



|  | Study ○ | PID ○ | SEX ○ | AGE ○ | RACE ○ |
|---|---|---|---|---|---|
| 1 | KA201 | 2010184106 | Male | 18 | White |
| 2 | KA201 | 2010184108 | Male | 31 | Black |
| 3 | KA201 | 2010184110 | Female | 24 | White |
| 4 | KA201 | 2010184114 | Male | 57 | White |
| 5 | KA201 | 2010184202 | Male | 33 | Black |
| 6 | KA201 | 2010303111 | Female | 66 | White |
| 7 | KA201 | 2010303112 | Male | 27 | White |
| 8 | KA201 | 2010565107 | Female | 58 | White |
| 9 | KA201 | 2010565108 | Male | 43 | White |
| 10 | KA201 | 2010565109 | Female | 67 | White |
| 11 | KA201 | 2010565113 | Male | 36 | White |
| 12 | KA201 | 2010565114 | Male | 63 | White |
| 13 | KA201 | 2010565117 | Male | 53 | White |
| 14 | KA201 | 2010565120 | Male | 68 | White |
| 15 | KA201 | 2010565122 | Male | 51 | White |
| 16 | KA201 | 2010565123 | Female | 76 | White |
| 17 | KA201 | 2010565125 | Male | 69 | White |
| 18 | KA201 | 2010565129 | Male | 21 | White |

Custom Panels not available

JReview displays the number of cases selected before the list of patients. When Oracle Clinical data is the primary source the key clinical information for each patient, such as case ID, sex, age, treatment group, other, are also displayed and are custom-configurable through ReviewAdmin.

The Data Browser default panel orientation is vertical. ReviewAdmin source.options configuration parameter also allows for horizontal orientation as DEFPANELORIENT=H; (or = V; which is the current default).

When studies are pure SAS datasets there is a study level override in ReviewAdmin to support study level configuration override for the Data Browser patient list from SAS dataset.

## *Expand spreadsheet columns*

When JReview displays multiple observations in the panel view spreadsheet, each column is automatically sized to a fixed width size. You can expand or contract the columns in the spreadsheet just as you would in any window's spreadsheet program.

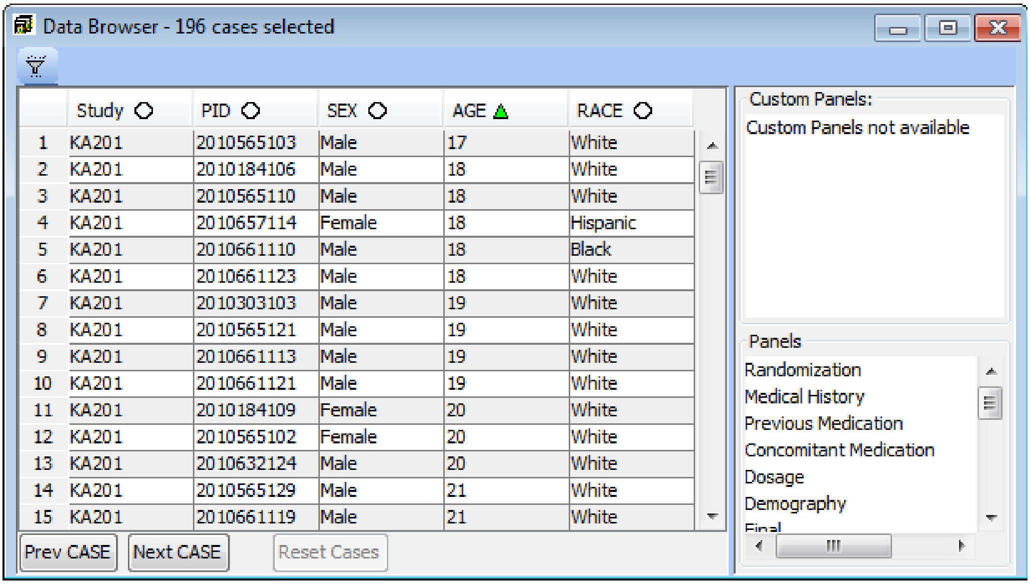
Click and drag the cursor on the line between the column heading tabs to the width desired.

## *Sort columns*

You may select and sort any column in the main Data Browser window where the column header contains the corresponding symbol next to the description. The **Sort Columns** is only enabled and allowed when there is no patient selection criteria or select patients applied. The corresponding sort symbol is designed not to display when a selection criteria is applied.

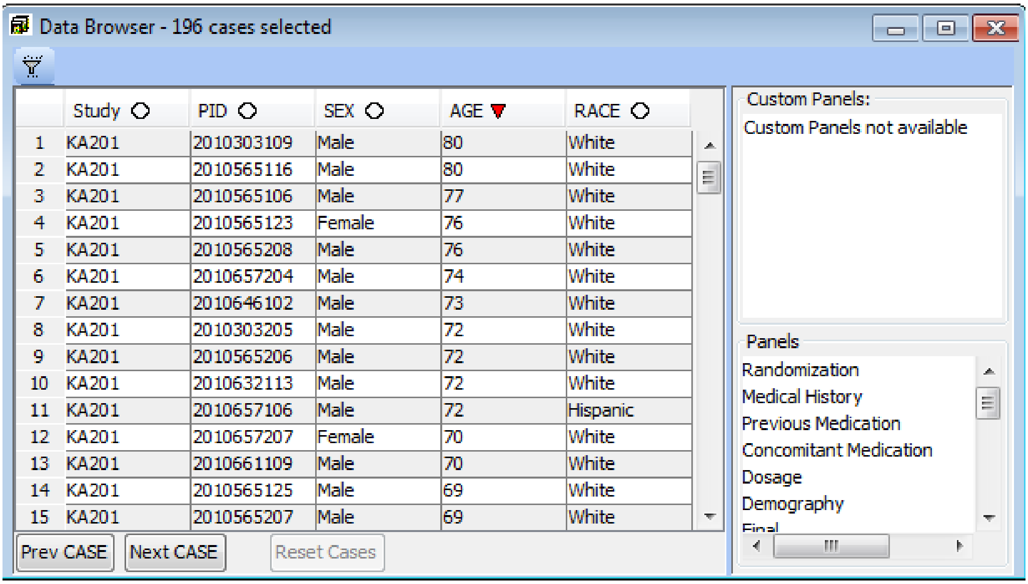
Simply click on the column symbol to change from descending, ascending or return to original display sort.

Click on the column symbol and the green up triangle changes the selected column sort to ascending order.



| | Study ○ | PID ○ | SEX ○ | AGE ▲ | RACE ○ |
|---|---|---|---|---|---|
| 1 | KA201 | 2010565103 | Male | 17 | White |
| 2 | KA201 | 2010184106 | Male | 18 | White |
| 3 | KA201 | 2010565110 | Male | 18 | White |
| 4 | KA201 | 2010657114 | Female | 18 | Hispanic |
| 5 | KA201 | 2010661110 | Male | 18 | Black |
| 6 | KA201 | 2010661123 | Male | 18 | White |
| 7 | KA201 | 2010303103 | Male | 19 | White |
| 8 | KA201 | 2010565121 | Male | 19 | White |
| 9 | KA201 | 2010661113 | Male | 19 | White |
| 10 | KA201 | 2010661121 | Male | 19 | White |
| 11 | KA201 | 2010184109 | Female | 20 | White |
| 12 | KA201 | 2010565102 | Female | 20 | White |
| 13 | KA201 | 2010632124 | Male | 20 | White |
| 14 | KA201 | 2010565129 | Male | 21 | White |
| 15 | KA201 | 2010661119 | Male | 21 | White |

Click on the column symbol and the red down triangle changes the selected column sort to descending order.



|  | Study ○ | PID ○ | SEX ○ | AGE ▼ | RACE ○ |
|---|---|---|---|---|---|
| 1 | KA201 | 2010303109 | Male | 80 | White |
| 2 | KA201 | 2010565116 | Male | 80 | White |
| 3 | KA201 | 2010565106 | Male | 77 | White |
| 4 | KA201 | 2010565123 | Female | 76 | White |
| 5 | KA201 | 2010565208 | Male | 76 | White |
| 6 | KA201 | 2010657204 | Male | 74 | White |
| 7 | KA201 | 2010646102 | Male | 73 | White |
| 8 | KA201 | 2010303205 | Male | 72 | White |
| 9 | KA201 | 2010565206 | Male | 72 | White |
| 10 | KA201 | 2010632113 | Male | 72 | White |
| 11 | KA201 | 2010657106 | Male | 72 | Hispanic |
| 12 | KA201 | 2010657207 | Female | 70 | White |
| 13 | KA201 | 2010661109 | Male | 70 | White |
| 14 | KA201 | 2010565125 | Male | 69 | White |
| 15 | KA201 | 2010565207 | Male | 69 | White |

Custom Panels:
Custom Panels not available

Panels
Randomization
Medical History
Previous Medication
Concomitant Medication
Dosage
Demography
Final

## *Browse patient data*

To view individual patient data as follows:

1. Select an individual patient to view their patient data.
2. Select the panels that you are interested in reviewing.
3. Position and size the panel view windows.
4. Click anywhere in the row of the patient of interest. You can use **Prev CASE** or **Next CASE** to view data for the next or previous patient.

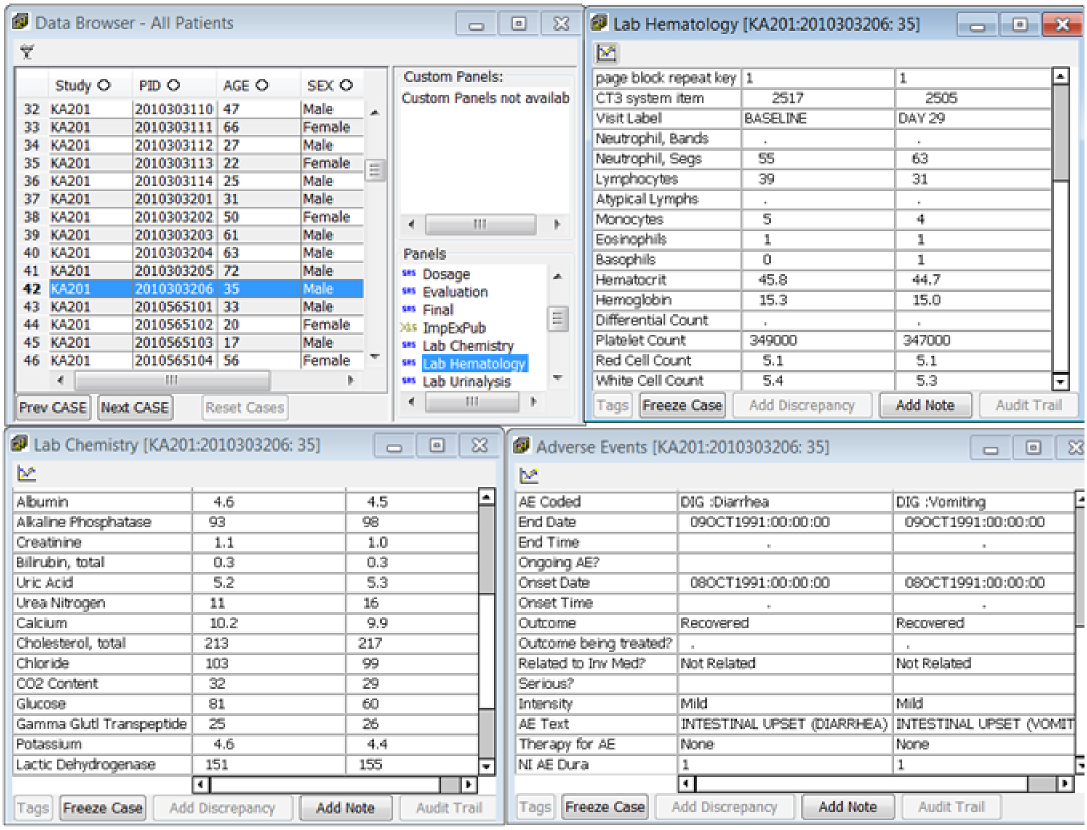
   Each time another patient is selected, each open panel view window is updated to reflect the data for the currently selected patient.
5. If the ‘Freeze Case/ Case Frozen’ function is toggled to **Case Frozen**, the panel view window displayed remains displayed(frozen) with the patient data they were frozen with.

   A Case Frozen Panel View is a static Panel View, even as you select other patients that will update in only **Freeze Case** Panel Views. When tags are on, the tags column updates with the Panel Detail Data View, reflecting the tags for the currently selected patient.

You can select several panels from the list of available panels in the protocol. Each panel selected displays a new window with a spreadsheet containing descriptions and data for the selected patient.

If the panel displayed contains multiple observations, all observations for this patient are displayed in the spreadsheet.

The default vertical panels for Lab Chemistry and Lab Hematology displays for the data ordered by the Visit Date.



| | Study ○ | PID ○ | AGE ○ | SEX ○ |
|---|---|---|---|---|
| 32 | KA201 | 2010303110 | 47 | Male |
| 33 | KA201 | 2010303111 | 66 | Female |
| 34 | KA201 | 2010303112 | 27 | Male |
| 35 | KA201 | 2010303113 | 22 | Female |
| 36 | KA201 | 2010303114 | 25 | Male |
| 37 | KA201 | 2010303201 | 31 | Male |
| 38 | KA201 | 2010303202 | 50 | Female |
| 39 | KA201 | 2010303203 | 61 | Male |
| 40 | KA201 | 2010303204 | 63 | Male |
| 41 | KA201 | 2010303205 | 72 | Male |
| 42 | KA201 | 2010303206 | 35 | Male |
| 43 | KA201 | 2010565101 | 33 | Male |
| 44 | KA201 | 2010565102 | 20 | Female |
| 45 | KA201 | 2010565103 | 17 | Male |
| 46 | KA201 | 2010565104 | 56 | Female |

| | | |
|---|---|---|
| page block repeat key | 1 | 1 |
| CT3 system item | 2517 | 2505 |
| Visit Label | BASELINE | DAY 29 |
| Neutrophil, Bands | . | . |
| Neutrophil, Segs | 55 | 63 |
| Lymphocytes | 39 | 31 |
| Atypical Lymphs | . | . |
| Monocytes | 5 | 4 |
| Eosinophils | 1 | 1 |
| Basophils | 0 | 1 |
| Hematocrit | 45.8 | 44.7 |
| Hemoglobin | 15.3 | 15.0 |
| Differential Count | . | . |
| Platelet Count | 349000 | 347000 |
| Red Cell Count | 5.1 | 5.1 |
| White Cell Count | 5.4 | 5.3 |

| | | |
|---|---|---|
| Albumin | 4.6 | 4.5 |
| Alkaline Phosphatase | 93 | 98 |
| Creatinine | 1.1 | 1.0 |
| Bilirubin, total | 0.3 | 0.3 |
| Uric Acid | 5.2 | 5.3 |
| Urea Nitrogen | 11 | 16 |
| Calcium | 10.2 | 9.9 |
| Cholesterol, total | 213 | 217 |
| Chloride | 103 | 99 |
| CO2 Content | 32 | 29 |
| Glucose | 81 | 60 |
| Gamma Glutl Transpeptide | 25 | 26 |
| Potassium | 4.6 | 4.4 |
| Lactic Dehydrogenase | 151 | 155 |

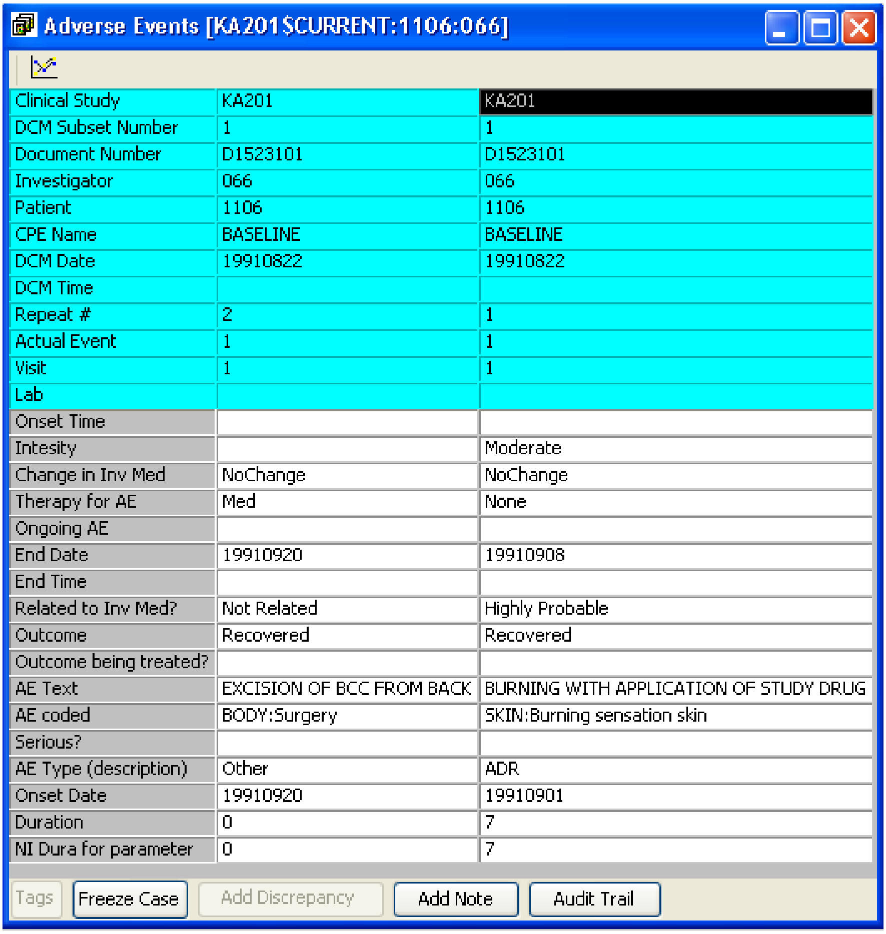
| | | |
|---|---|---|
| AE Coded | DIG :Diarrhea | DIG :Vomiting |
| End Date | 09OCT1991:00:00:00 | 09OCT1991:00:00:00 |
| End Time | . | . |
| Ongoing AE? | | |
| Onset Date | 08OCT1991:00:00:00 | 08OCT1991:00:00:00 |
| Onset Time | . | . |
| Outcome | Recovered | Recovered |
| Outcome being treated? | . | . |
| Related to Inv Med? | Not Related | Not Related |
| Serious? | | |
| Intensity | Mild | Mild |
| AE Text | INTESTINAL UPSET (DIARRHEA) | INTESTINAL UPSET (VOMIT |
| Therapy for AE | None | None |
| NI AE Dura | 1 | 1 |

***Note: The Data Browser display cannot be saved as an Output Specification.***

## View Audit

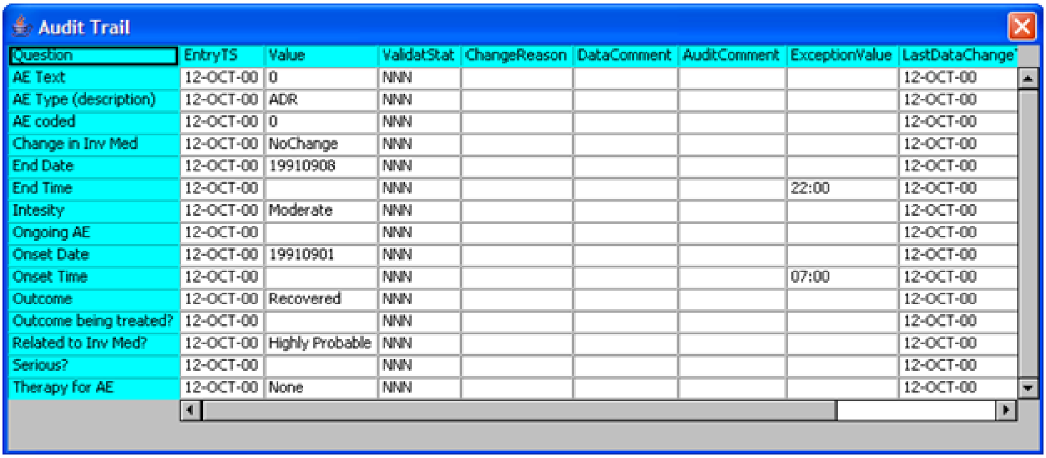
You may view select Data Audit information as follows:

1. Select a patient.
2. Select a panel.
3. Select a visit.
4. Click on the Audit Trail button.



Adverse Events [KA201$CURRENT:1106:066]

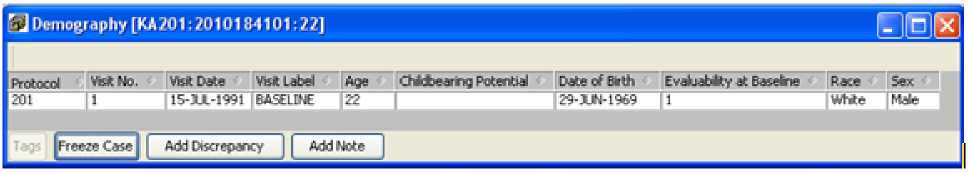
| | | |
|---|---|---|
| Clinical Study | KA201 | KA201 |
| DCM Subset Number | 1 | 1 |
| Document Number | D1523101 | D1523101 |
| Investigator | 066 | 066 |
| Patient | 1106 | 1106 |
| CPE Name | BASELINE | BASELINE |
| DCM Date | 19910822 | 19910822 |
| DCM Time | | |
| Repeat # | 2 | 1 |
| Actual Event | 1 | 1 |
| Visit | 1 | 1 |
| Lab | | |
| Onset Time | | |
| Intesity | | Moderate |
| Change in Inv Med | NoChange | NoChange |
| Therapy for AE | Med | None |
| Ongoing AE | | |
| End Date | 19910920 | 19910908 |
| End Time | | |
| Related to Inv Med? | Not Related | Highly Probable |
| Outcome | Recovered | Recovered |
| Outcome being treated? | | |
| AE Text | EXCISION OF BCC FROM BACK | BURNING WITH APPLICATION OF STUDY DRUG |
| AE coded | BODY:Surgery | SKIN:Burning sensation skin |
| Serious? | | |
| AE Type (description) | Other | ADR |
| Onset Date | 19910920 | 19910901 |
| Duration | 0 | 7 |
| NI Dura for parameter | 0 | 7 |



| Question | EntryTS | Value | ValidatStat | ChangeReason | DataComment | AuditComment | ExceptionValue | LastDataChange |
|---|---|---|---|---|---|---|---|---|
| AE Text | 12-OCT-00 | 0 | NNN | | | | | 12-OCT-00 |
| AE Type (description) | 12-OCT-00 | ADR | NNN | | | | | 12-OCT-00 |
| AE coded | 12-OCT-00 | 0 | NNN | | | | | 12-OCT-00 |
| Change in Inv Med | 12-OCT-00 | NoChange | NNN | | | | | 12-OCT-00 |
| End Date | 12-OCT-00 | 19910908 | NNN | | | | | 12-OCT-00 |
| End Time | 12-OCT-00 | | NNN | | | | 22:00 | 12-OCT-00 |
| Intesity | 12-OCT-00 | Moderate | NNN | | | | | 12-OCT-00 |
| Ongoing AE | 12-OCT-00 | | NNN | | | | | 12-OCT-00 |
| Onset Date | 12-OCT-00 | 19910901 | NNN | | | | | 12-OCT-00 |
| Onset Time | 12-OCT-00 | | NNN | | | | 07:00 | 12-OCT-00 |
| Outcome | 12-OCT-00 | Recovered | NNN | | | | | 12-OCT-00 |
| Outcome being treated? | 12-OCT-00 | | NNN | | | | | 12-OCT-00 |
| Related to Inv Med? | 12-OCT-00 | Highly Probable | NNN | | | | | 12-OCT-00 |
| Serious? | 12-OCT-00 | | NNN | | | | | 12-OCT-00 |
| Therapy for AE | 12-OCT-00 | None | NNN | | | | | 12-OCT-00 |

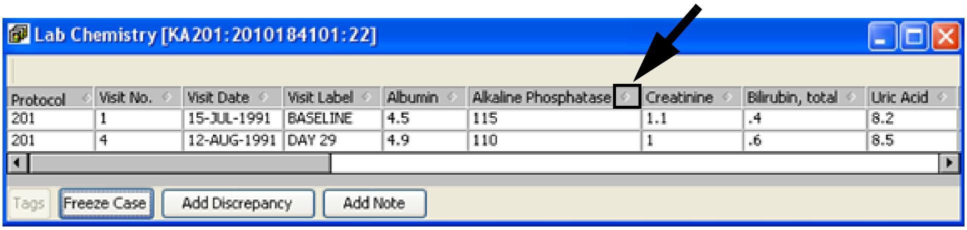
## *Horizontal data display*

Optional horizontal panel display of the data is supported within ReviewAdmin by a configuration option.



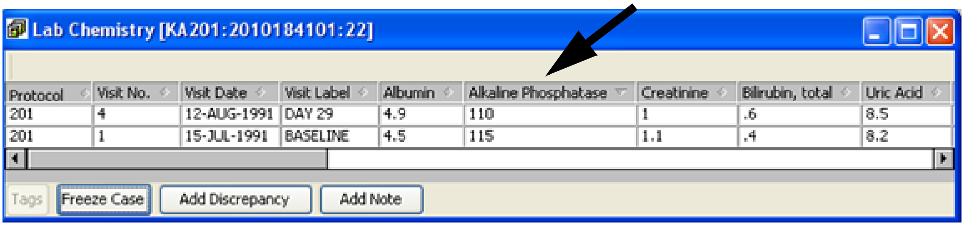
| Protocol | Visit No. | Visit Date | Visit Label | Age | Childbearing Potential | Date of Birth | Evaluability at Baseline | Race | Sex |
|---|---|---|---|---|---|---|---|---|---|
| 201 | 1 | 15-JUL-1991 | BASELINE | 22 | | 29-JUN-1969 | 1 | White | Male |

Data sorting by selecting a column is supported for horizontally displayed panels only.



| Protocol | Visit No. | Visit Date | Visit Label | Albumin | Alkaline Phosphatase | Creatinine | Bilirubin, total | Uric Acid |
|---|---|---|---|---|---|---|---|---|
| 201 | 1 | 15-JUL-1991 | BASELINE | 4.5 | 115 | 1.1 | .4 | 8.2 |
| 201 | 4 | 12-AUG-1991 | DAY 29 | 4.9 | 110 | 1 | .6 | 8.5 |

Simply click on the column symbol to change the column sort order.

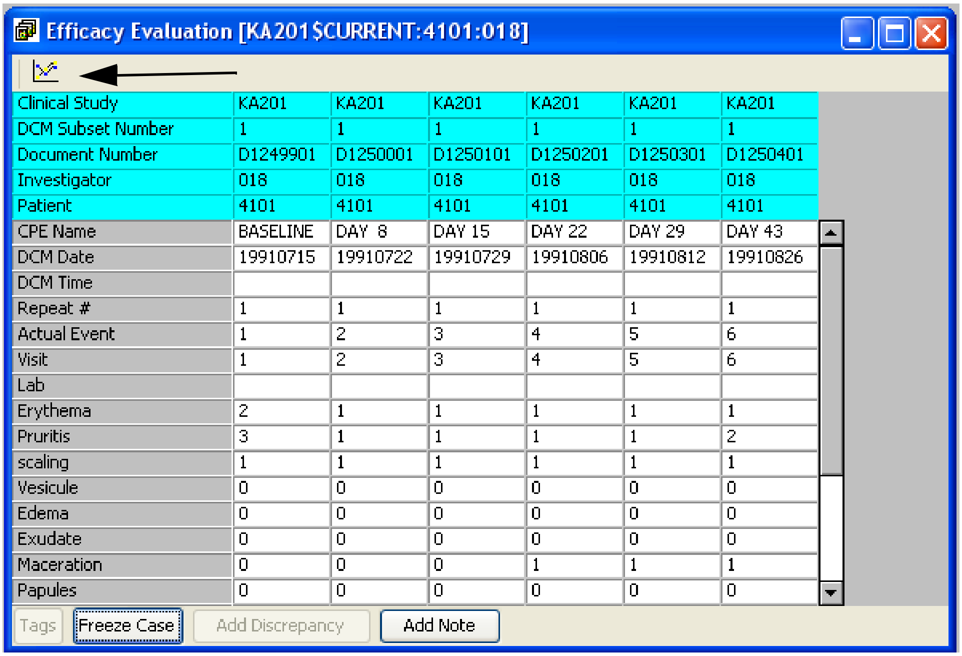


| Protocol | Visit No. | Visit Date | Visit Label | Albumin | Alkaline Phosphatase | Creatinine | Bilirubin, total | Uric Acid |
|---|---|---|---|---|---|---|---|---|
| 201 | 4 | 12-AUG-1991 | DAY 29 | 4.9 | 110 | 1 | .6 | 8.5 |
| 201 | 1 | 15-JUL-1991 | BASELINE | 4.5 | 115 | 1.1 | .4 | 8.2 |

## *Graph format display*

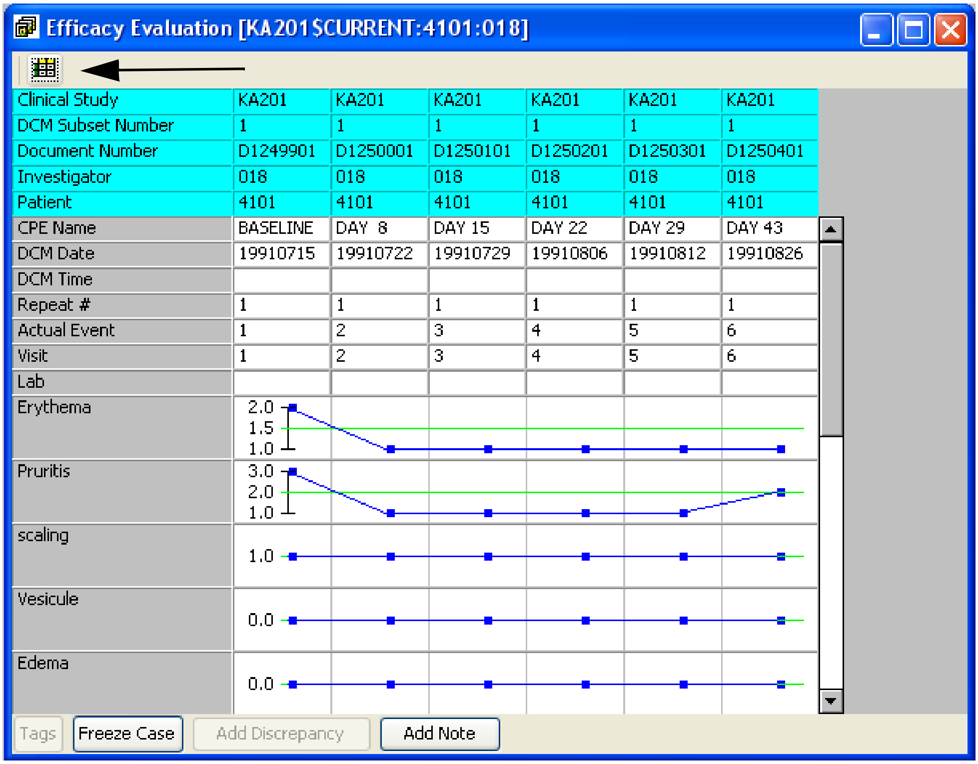
You can view a graph representation of the data from panels collected as multiple visits or observations with numeric data. Initially when you open a panel the default display is the table format.

If you click the graph icon, the data is converted to a graph format.



| | | | | | | |
|---|---|---|---|---|---|---|
| Clinical Study | KA201 | KA201 | KA201 | KA201 | KA201 | KA201 |
| DCM Subset Number | 1 | 1 | 1 | 1 | 1 | 1 |
| Document Number | D1249901 | D1250001 | D1250101 | D1250201 | D1250301 | D1250401 |
| Investigator | 018 | 018 | 018 | 018 | 018 | 018 |
| Patient | 4101 | 4101 | 4101 | 4101 | 4101 | 4101 |
| CPE Name | BASELINE | DAY 8 | DAY 15 | DAY 22 | DAY 29 | DAY 43 |
| DCM Date | 19910715 | 19910722 | 19910729 | 19910806 | 19910812 | 19910826 |
| DCM Time | | | | | | |
| Repeat # | 1 | 1 | 1 | 1 | 1 | 1 |
| Actual Event | 1 | 2 | 3 | 4 | 5 | 6 |
| Visit | 1 | 2 | 3 | 4 | 5 | 6 |
| Lab | | | | | | |
| Erythema | 2 | 1 | 1 | 1 | 1 | 1 |
| Pruritis | 3 | 1 | 1 | 1 | 1 | 2 |
| scaling | 1 | 1 | 1 | 1 | 1 | 1 |
| Vesicule | 0 | 0 | 0 | 0 | 0 | 0 |
| Edema | 0 | 0 | 0 | 0 | 0 | 0 |
| Exudate | 0 | 0 | 0 | 0 | 0 | 0 |
| Maceration | 0 | 0 | 0 | 1 | 1 | 1 |
| Papules | 0 | 0 | 0 | 0 | 0 | 0 |

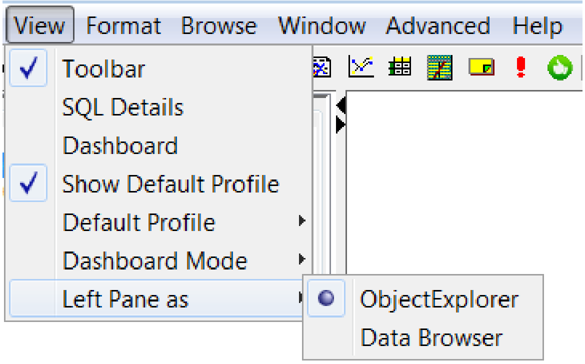
The graph displays as a Trend Plot with the patient's minimum and maximum values listed in the first column. Click the table icon to switch the display back to the spreadsheet format.



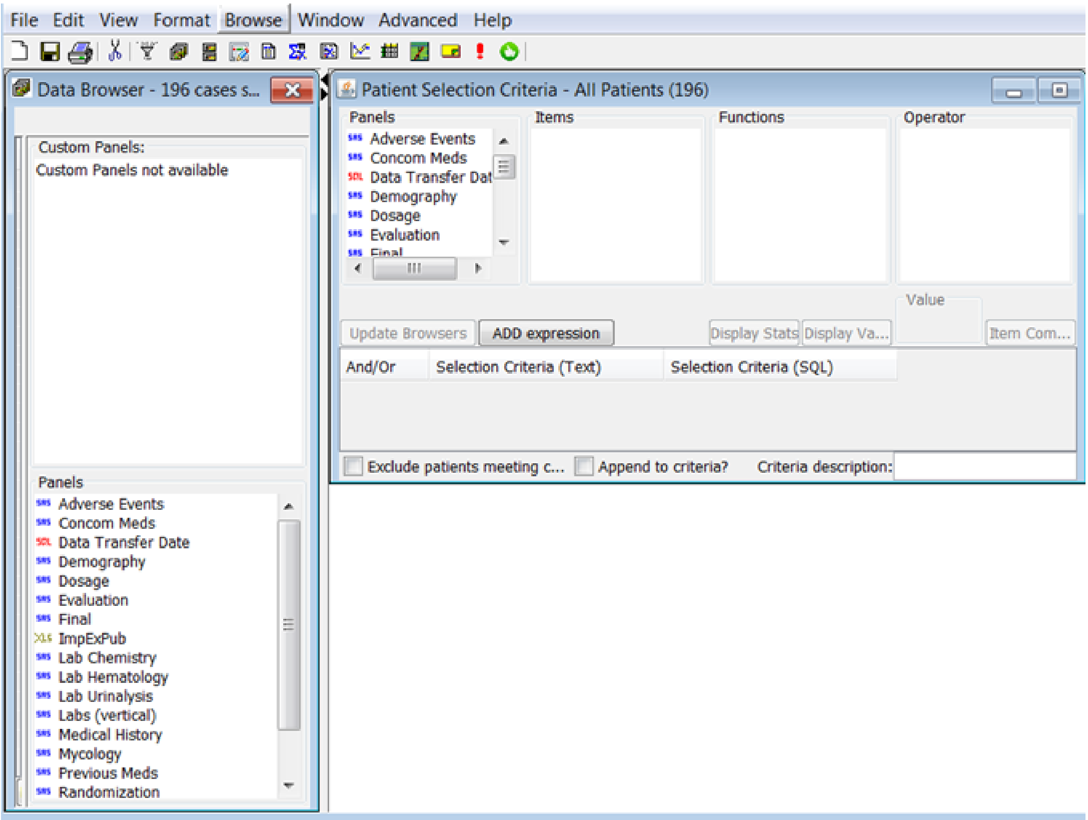
| | | | | | | |
|---|---|---|---|---|---|---|
| Clinical Study | KA201 | KA201 | KA201 | KA201 | KA201 | KA201 |
| DCM Subset Number | 1 | 1 | 1 | 1 | 1 | 1 |
| Document Number | D1249901 | D1250001 | D1250101 | D1250201 | D1250301 | D1250401 |
| Investigator | 018 | 018 | 018 | 018 | 018 | 018 |
| Patient | 4101 | 4101 | 4101 | 4101 | 4101 | 4101 |
| CPE Name | BASELINE | DAY 8 | DAY 15 | DAY 22 | DAY 29 | DAY 43 |
| DCM Date | 19910715 | 19910722 | 19910729 | 19910806 | 19910812 | 19910826 |
| DCM Time | | | | | | |
| Repeat # | 1 | 1 | 1 | 1 | 1 | 1 |
| Actual Event | 1 | 2 | 3 | 4 | 5 | 6 |
| Visit | 1 | 2 | 3 | 4 | 5 | 6 |
| Lab | | | | | | |
| Erythema | 2.0<br>1.5<br>1.0 | | | | | |
| Pruritis | 3.0<br>2.0<br>1.0 | | | | | |
| scaling | 1.0 | | | | | |
| Vesicule | 0.0 | | | | | |
| Edema | 0.0 | | | | | |

## *View Data Browser*

You may optionally replace the Object Explorer left window pane to view the Data Browser when viewing open reports, graphs, crosstabs, etc. Simply click on the View in the Menu bar, select **Left Pane as Data Browser**.



The left window pane is replaced with the Data Browser.



# Notes Browser

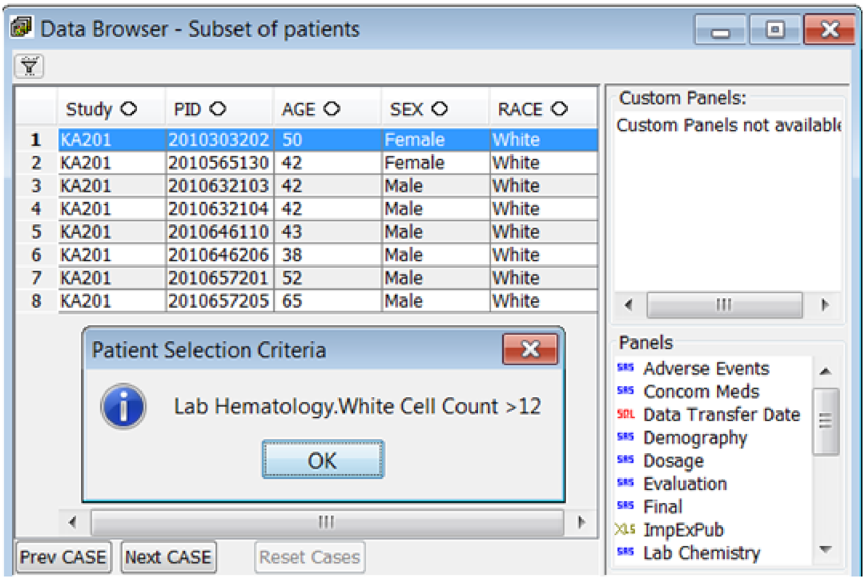
## *Store patient notes*

You can store and retrieve patient level notes observed during data review within the Notes Browser. For example, you may need to save a patient note to validate data information for future reference. A separate response may be added later by the note author or another user. The notes can be stored at Object Storage Levels as Private, UserGroup and Public. The author of the note has sole security to edit or remove the note(s), unless the individual has SuperUser privileges. The same restrictions apply to the user entering a response as the author to edit or remove the response. **(See *Chapter 12: Advanced Topics: SuperUser Privileges)***

## *Add note from Data Browser*

You add a patient note from the Data Browser by selecting a patient and a specific panel then adding the note. The note may be added at the patient, panel, visit or item level.

1. Click , or from the **Browse** menu, select **Data**.
2. Select a patient to highlight in the Data Browser.
3. Select the panel that you are interested in reviewing.



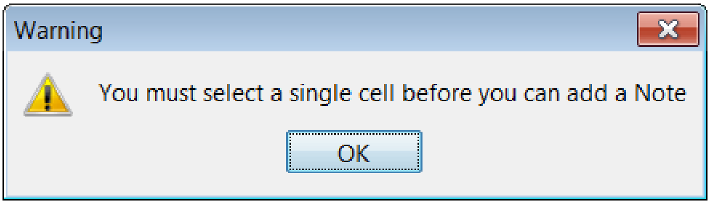
| | Study | PID | AGE | SEX | RACE |
|---|---|---|---|---|---|
| 1 | KA201 | 2010303202 | 50 | Female | White |
| 2 | KA201 | 2010565130 | 42 | Female | White |
| 3 | KA201 | 2010632103 | 42 | Male | White |
| 4 | KA201 | 2010632104 | 42 | Male | White |
| 5 | KA201 | 2010646110 | 43 | Male | White |
| 6 | KA201 | 2010646206 | 38 | Male | White |
| 7 | KA201 | 2010657201 | 52 | Male | White |
| 8 | KA201 | 2010657205 | 65 | Male | White |

Patient Selection Criteria

Lab Hematology.White Cell Count >12

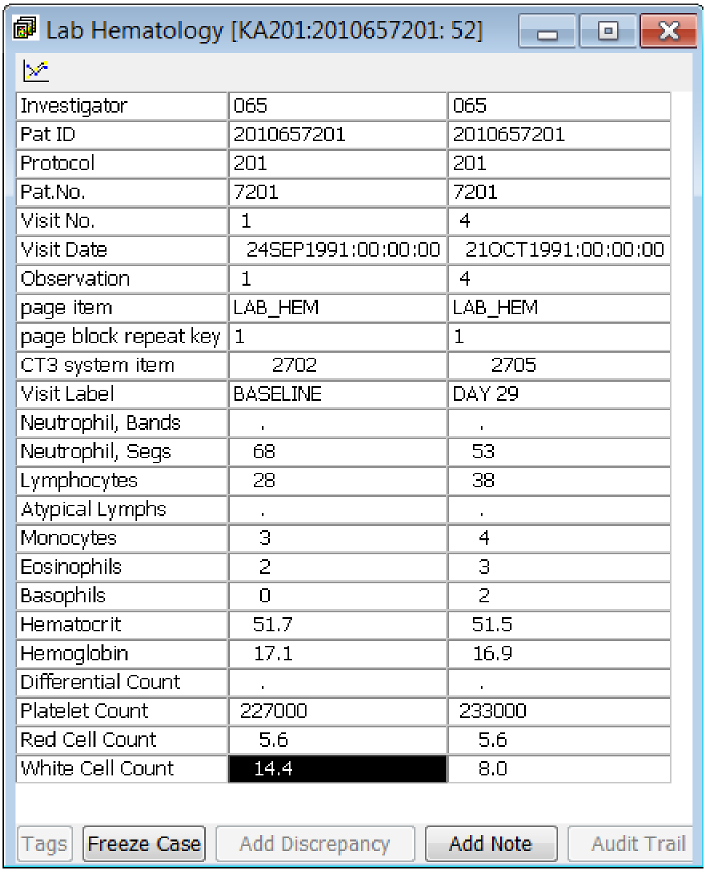
OK

4. Click on an item cell within a visit data column. You may not click on a header cell item.



You must select a single cell before you can add a Note

5. Click **Add Note**. The Add Note window opens.

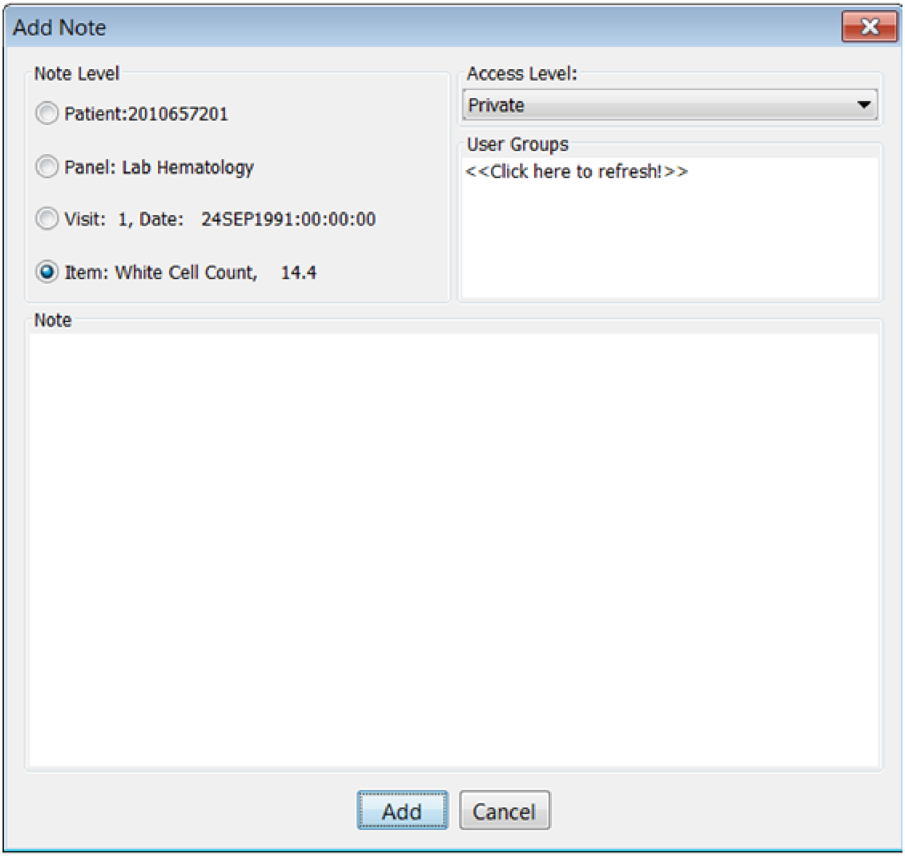


| | | |
|---|---|---|
| Investigator | 065 | 065 |
| Pat ID | 2010657201 | 2010657201 |
| Protocol | 201 | 201 |
| Pat.No. | 7201 | 7201 |
| Visit No. | 1 | 4 |
| Visit Date | 24SEP1991:00:00:00 | 21OCT1991:00:00:00 |
| Observation | 1 | 4 |
| page item | LAB_HEM | LAB_HEM |
| page block repeat key | 1 | 1 |
| CT3 system item | 2702 | 2705 |
| Visit Label | BASELINE | DAY 29 |
| Neutrophil, Bands | . | . |
| Neutrophil, Segs | 68 | 53 |
| Lymphocytes | 28 | 38 |
| Atypical Lymphs | . | . |
| Monocytes | 3 | 4 |
| Eosinophils | 2 | 3 |
| Basophils | 0 | 2 |
| Hematocrit | 51.7 | 51.5 |
| Hemoglobin | 17.1 | 16.9 |
| Differential Count | . | . |
| Platelet Count | 227000 | 233000 |
| Red Cell Count | 5.6 | 5.6 |
| White Cell Count | 14.4 | 8.0 |

The **Note Level** details display for the selected data column which are later displayed in the Notes Browser spreadsheet after the note is saved. Your note level selection determines if minimal note level details or all note level details are displayed after the note is saved.

When you selected and highlighted the data item for WBC the Note Level is entered as **Item**, then all note level details for patient, panel, visit and item are displayed in the Notes Browser spreadsheet.

For example, if your note content is general to the patient or panel type you would select patient or panel level. The columns for visit and item would display as blank in the Notes Browser spreadsheet. Item level displays the most detail in the Notes Browser spreadsheet.



○ Patient:2010657201

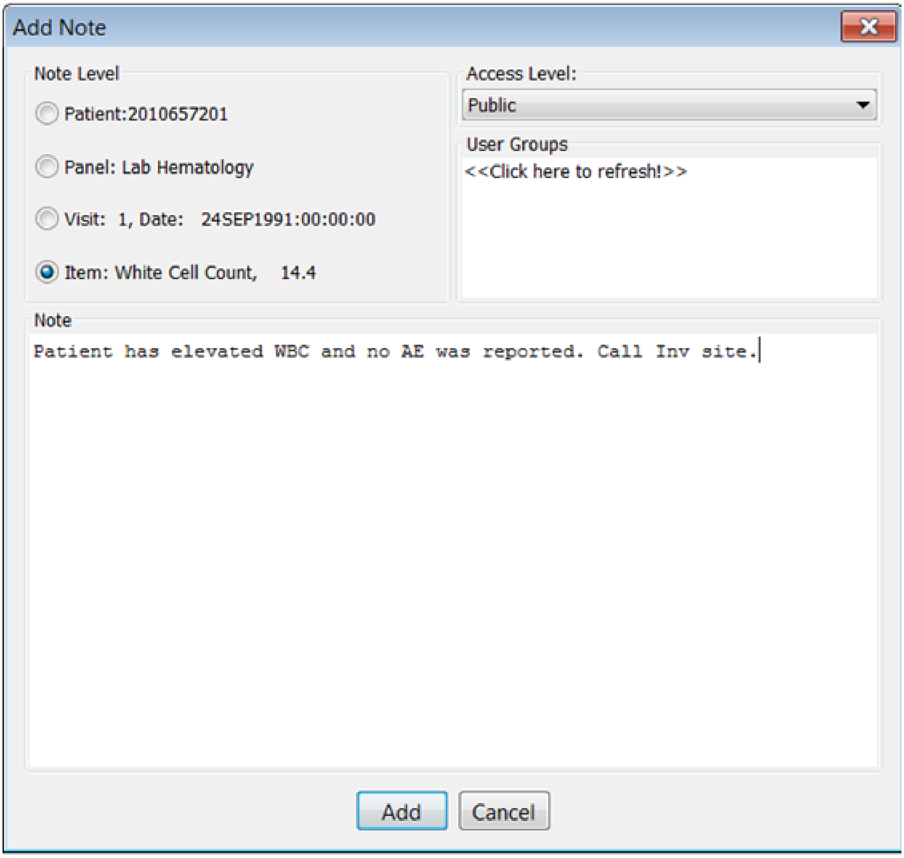
○ Panel: Lab Hematology

○ Visit: 1, Date: 24SEP1991:00:00:00

● Item: White Cell Count, 14.4

Access Level: Private

6. Enter the **Note** text. Click the cursor in the Note box to enter up to 2000 characters.



○ Patient:2010657201

○ Panel: Lab Hematology

○ Visit: 1, Date: 24SEP1991:00:00:00

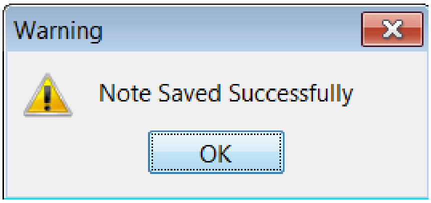
● Item: White Cell Count, 14.4

Access Level: Public

User Groups: <<Click here to refresh!>>

Note: Patient has elevated WBC and no AE was reported. Call Inv site.

7. Select the **Note Level** to apply the note at either Patient, Panel, Visit or Item level.
8. Select **Note Access Level** for viewing access as Private, UserGroup or Public. Click **Add** to save the note.



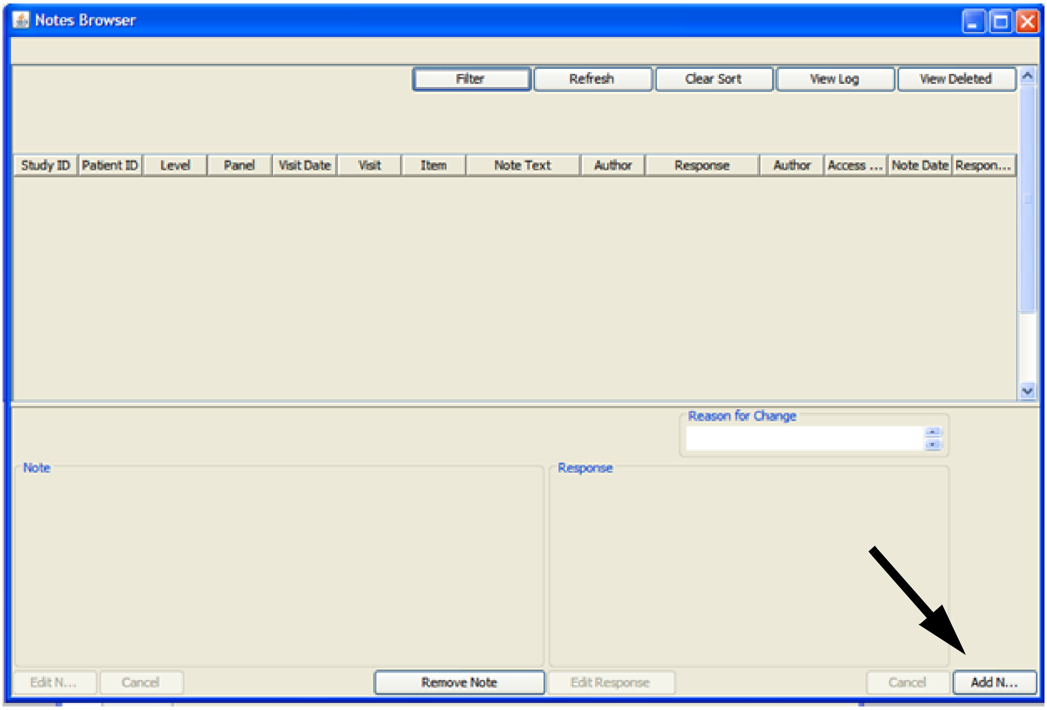
Note Saved Successfully

## *Add note from output window*

The ‘**Add Notes**’ icon is available in certain output displays in the results tool bar. You may apply patient notes from the following Browser output windows:

- **Report Browser -** Detail Data Listing and Patient Visit Data Report types display the Add Note icon in the result tool bar. Click on a patient row to highlight the patient, then click on the Add Note icon.
- **Patient Profile Browser -** displays the Add Note icon in the patient profile output display. Simply click on the Add Note icon in the tool bar.
- **Graph Browser -** Scatter Plots display the Add Note icon in the tool bar. Click on a data point in the graph to highlight the patient, then click on the Add Note icon.

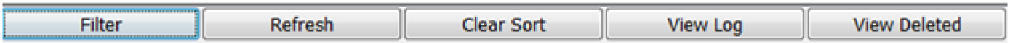
The **Notes Browser** window opens where you would click the **Add Note** button. The **Add Note window** opens to add the patient note details.



## *Locate patient note*

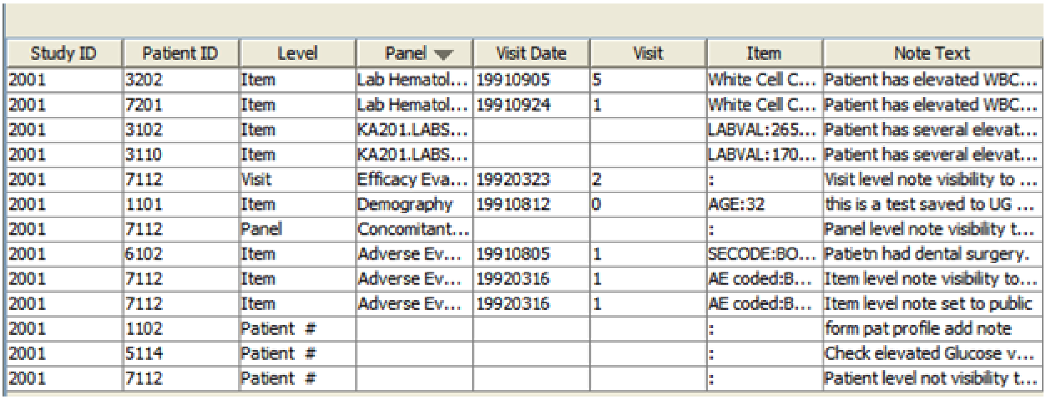
To view patient note details, use the scroll bar and select a patient to display the Note text. If the patient has multiple notes, you may need to select the specific note.

Use the **Filter** and **Sort** buttons to assist in locating patient notes.



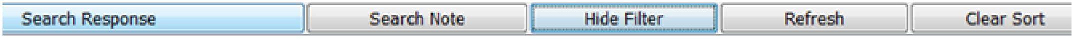
1. Click on a column header, to initiate multi-level (up to 3 levels) of column sorting for ascending or descending order.  Simply click on the column arrow to reverse the sort order.

   Sort on dates, numeric data, PatientID, panel description, Visit, Item, Note Text, Author, and more.
2. Use the **Refresh** and **Clear Sort** buttons to return to the initial notes list.



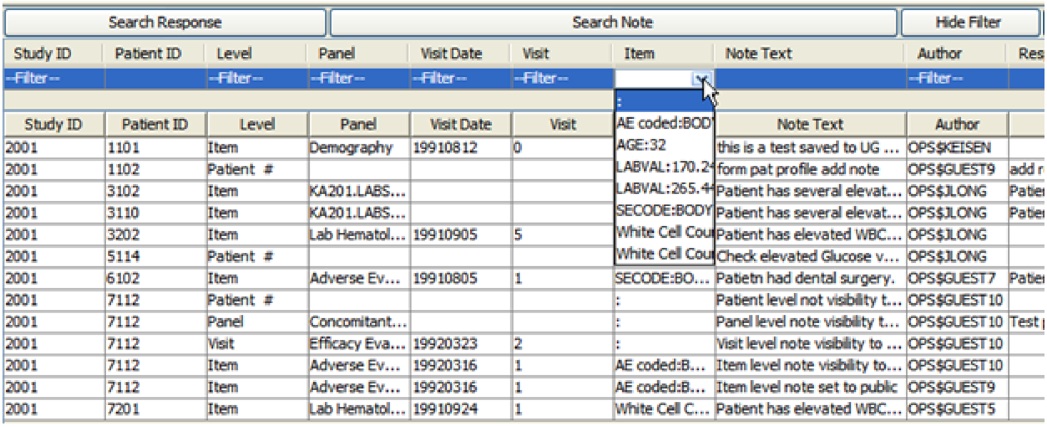
| Study ID | Patient ID | Level | Panel | Visit Date | Visit | Item | Note Text |
|---|---|---|---|---|---|---|---|
| 2001 | 3202 | Item | Lab Hematol… | 19910905 | 5 | White Cell C… | Patient has elevated WBC… |
| 2001 | 7201 | Item | Lab Hematol… | 19910924 | 1 | White Cell C… | Patient has elevated WBC… |
| 2001 | 3102 | Item | KA201.LABS… | | | LABVAL:265… | Patient has several elevat… |
| 2001 | 3110 | Item | KA201.LABS… | | | LABVAL:170… | Patient has several elevat… |
| 2001 | 7112 | Visit | Efficacy Eva… | 19920323 | 2 | : | Visit level note visibility to … |
| 2001 | 1101 | Item | Demography | 19910812 | 0 | AGE:32 | this is a test saved to UG … |
| 2001 | 7112 | Panel | Concomitant… | | | : | Panel level note visibility t… |
| 2001 | 6102 | Item | Adverse Ev… | 19910805 | 1 | SECODE:BO… | Patietn had dental surgery. |
| 2001 | 7112 | Item | Adverse Ev… | 19920316 | 1 | AE coded:B… | Item level note visibility to… |
| 2001 | 7112 | Item | Adverse Ev… | 19920316 | 1 | AE coded:B… | Item level note set to public |
| 2001 | 1102 | Patient # | | | | : | form pat profile add note |
| 2001 | 5114 | Patient # | | | | : | Check elevated Glucose v… |
| 2001 | 7112 | Patient # | | | | : | Patient level not visibility t… |

3. When you click on the **Filter** button, the individual data columns display Filter headers. The Notes Browser tool bar changes to display these additional button features.



Use the **Hide Filter** and **Refresh** buttons to return to the initial notes list.

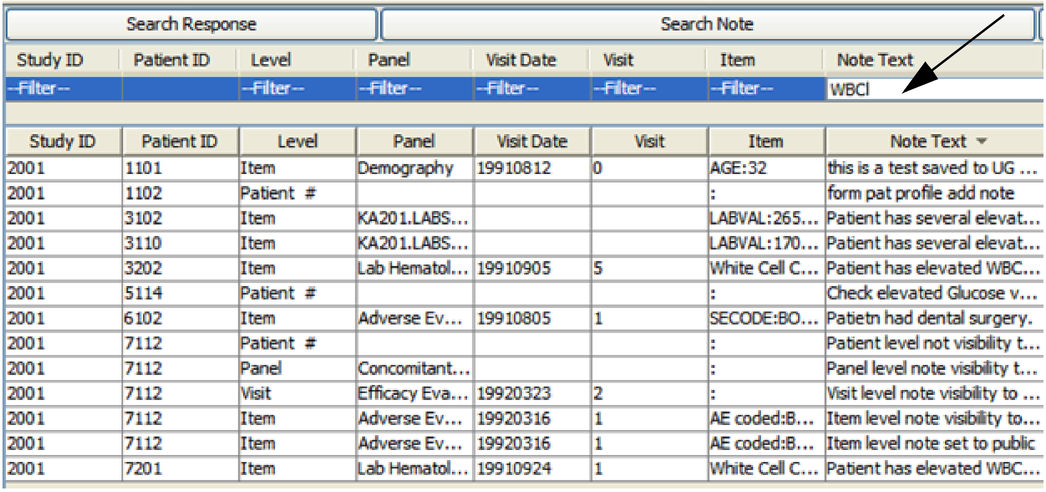
4. Select and click on a particular column filter. A drop down list displays for the selected data column item where you select the preferred filter option.



| Study ID | Patient ID | Level | Panel | Visit Date | Visit | Item | Note Text | Author | Res |
|---|---|---|---|---|---|---|---|---|---|
| --Filter-- | | --Filter-- | --Filter-- | --Filter-- | --Filter-- | | | --Filter-- | |

| Study ID | Patient ID | Level | Panel | Visit Date | Visit | Item | Note Text | Author | |
|---|---|---|---|---|---|---|---|---|---|
| 2001 | 1101 | Item | Demography | 19910812 | 0 | | this is a test saved to UG ... | OPS$KEISEN | |
| 2001 | 1102 | Patient # | | | | | form pat profile add note | OPS$GUEST9 | add r |
| 2001 | 3102 | Item | KA201.LABS... | | | | Patient has several elevat... | OPS$JLONG | Patie |
| 2001 | 3110 | Item | KA201.LABS... | | | | Patient has several elevat... | OPS$JLONG | Patie |
| 2001 | 3202 | Item | Lab Hematol... | 19910905 | 5 | | Patient has elevated WBC... | OPS$JLONG | |
| 2001 | 5114 | Patient # | | | | | Check elevated Glucose v... | OPS$JLONG | |
| 2001 | 6102 | Item | Adverse Ev... | 19910805 | 1 | SECODE:BO... | Patietn had dental surgery. | OPS$GUEST7 | Patie |
| 2001 | 7112 | Patient # | | | | : | Patient level not visibility t... | OPS$GUEST10 | |
| 2001 | 7112 | Panel | Concomitant... | | | : | Panel level note visibility t... | OPS$GUEST10 | Test |
| 2001 | 7112 | Visit | Efficacy Eva... | 19920323 | 2 | : | Visit level note visibility to ... | OPS$GUEST10 | |
| 2001 | 7112 | Item | Adverse Ev... | 19920316 | 1 | AE coded:B... | Item level note visibility to... | OPS$GUEST10 | |
| 2001 | 7112 | Item | Adverse Ev... | 19920316 | 1 | AE coded:B... | Item level note set to public | OPS$GUEST9 | |
| 2001 | 7201 | Item | Lab Hematol... | 19910924 | 1 | White Cell C... | Patient has elevated WBC... | OPS$GUEST5 | |

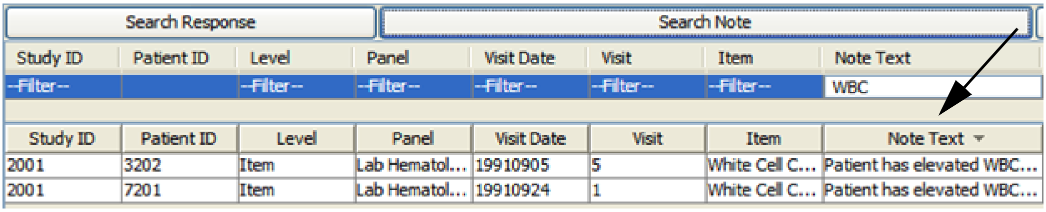
5. You may search on either a “**Search Response**” or “**Search Note**”. Double click in the Note, or Response Text box and enter your text search.



| Study ID | Patient ID | Level | Panel | Visit Date | Visit | Item | Note Text |
|---|---|---|---|---|---|---|---|
| --Filter-- | | --Filter-- | --Filter-- | --Filter-- | --Filter-- | --Filter-- | WBC |

| Study ID | Patient ID | Level | Panel | Visit Date | Visit | Item | Note Text |
|---|---|---|---|---|---|---|---|
| 2001 | 1101 | Item | Demography | 19910812 | 0 | AGE:32 | this is a test saved to UG ... |
| 2001 | 1102 | Patient # | | | | : | form pat profile add note |
| 2001 | 3102 | Item | KA201.LABS... | | | LABVAL:265... | Patient has several elevat... |
| 2001 | 3110 | Item | KA201.LABS... | | | LABVAL:170... | Patient has several elevat... |
| 2001 | 3202 | Item | Lab Hematol... | 19910905 | 5 | White Cell C... | Patient has elevated WBC... |
| 2001 | 5114 | Patient # | | | | : | Check elevated Glucose v... |
| 2001 | 6102 | Item | Adverse Ev... | 19910805 | 1 | SECODE:BO... | Patietn had dental surgery. |
| 2001 | 7112 | Patient # | | | | : | Patient level not visibility t... |
| 2001 | 7112 | Panel | Concomitant... | | | : | Panel level note visibility t... |
| 2001 | 7112 | Visit | Efficacy Eva... | 19920323 | 2 | : | Visit level note visibility to ... |
| 2001 | 7112 | Item | Adverse Ev... | 19920316 | 1 | AE coded:B... | Item level note visibility to... |
| 2001 | 7112 | Item | Adverse Ev... | 19920316 | 1 | AE coded:B... | Item level note set to public |
| 2001 | 7201 | Item | Lab Hematol... | 19910924 | 1 | White Cell C... | Patient has elevated WBC... |

6. Then click the corresponding **Search Note** or **Search Response** button.



| Study ID | Patient ID | Level | Panel | Visit Date | Visit | Item | Note Text |
|---|---|---|---|---|---|---|---|
| --Filter-- | | --Filter-- | --Filter-- | --Filter-- | --Filter-- | --Filter-- | WBC |

| Study ID | Patient ID | Level | Panel | Visit Date | Visit | Item | Note Text |
|---|---|---|---|---|---|---|---|
| 2001 | 3202 | Item | Lab Hematol... | 19910905 | 5 | White Cell C... | Patient has elevated WBC... |
| 2001 | 7201 | Item | Lab Hematol... | 19910924 | 1 | White Cell C... | Patient has elevated WBC... |

## *Edit note in Notes Browser*

An existing note may be edited by the author directly to the Notes Browser at the patient level.

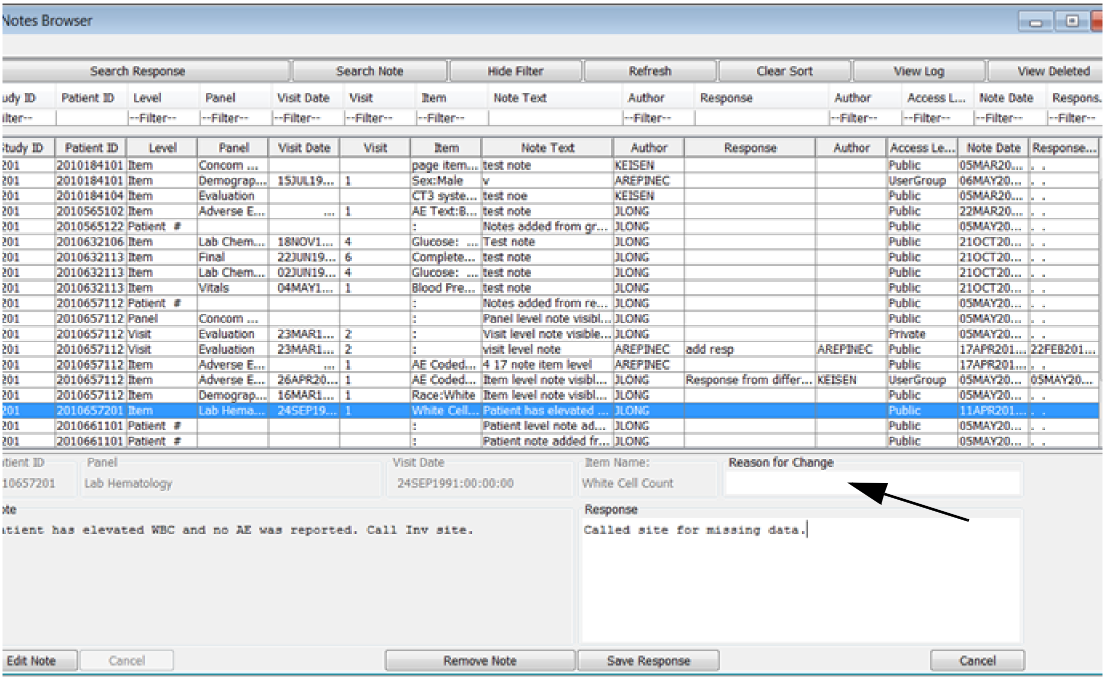
1. Click , or from the **Browse** menu, select **Notes**.

   The Notes Browser window opens. All patients with saved notes are listed. You may enter a patient selection criteria to list specific patients.

2. Select and highlight the patient in the patient list.
3. Optionally select **Edit Note** or **Remove Note**. You cannot edit or remove a note if you are not the author.

   The patient note information is displayed for the selected patient. The **Edit Note** and **Remove Note** buttons are available.

4. Click the cursor in the Note box to enter up to 2000 characters of text. The Note box is now unshaded and active. If you edit the patient note, the Edit Note button status changes to **Save Note**.
5. You must enter a **Reason for Change** everytime an edit or deletion is performed on a patient's note.



| tudy ID | Patient ID | Level | Panel | Visit Date | Visit | Item | Note Text | Author | Response | Author | Access Le... | Note Date | Response... |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 201 | 2010184101 | Item | Concom ... | | | page item... | test note | KEISEN | | | Public | 05MAR20... | . . |
| 201 | 2010184101 | Item | Demograp... | 15JUL19... | 1 | Sex:Male | v | AREPINEC | | | UserGroup | 06MAY20... | . . |
| 201 | 2010184104 | Item | Evaluation | | | CT3 syste... | test noe | KEISEN | | | Public | 05MAR20... | . . |
| 201 | 2010565102 | Item | Adverse E... | ... | 1 | AE Text:B... | test note | JLONG | | | Public | 22MAR20... | . . |
| 201 | 2010565122 | Patient # | | | | : | Notes added from gr... | JLONG | | | Public | 05MAY20... | . . |
| 201 | 2010632106 | Item | Lab Chem... | 18NOV1... | 4 | Glucose: ... | Test note | JLONG | | | Public | 21OCT20... | . . |
| 201 | 2010632113 | Item | Final | 22JUN19... | 6 | Complete... | test note | JLONG | | | Public | 21OCT20... | . . |
| 201 | 2010632113 | Item | Lab Chem... | 02JUN19... | 4 | Glucose: ... | test note | JLONG | | | Public | 21OCT20... | . . |
| 201 | 2010632113 | Item | Vitals | 04MAY1... | 1 | Blood Pre... | test note | JLONG | | | Public | 21OCT20... | . . |
| 201 | 2010657112 | Patient # | | | | : | Notes added from re... | JLONG | | | Public | 05MAY20... | . . |
| 201 | 2010657112 | Panel | Concom ... | | | : | Panel level note visibl... | JLONG | | | Public | 05MAY20... | . . |
| 201 | 2010657112 | Visit | Evaluation | 23MAR1... | 2 | : | Visit level note visible... | JLONG | | | Private | 05MAY20... | . . |
| 201 | 2010657112 | Visit | Evaluation | 23MAR1... | 2 | : | visit level note | AREPINEC | add resp | AREPINEC | Public | 17APR201... | 22FEB201... |
| 201 | 2010657112 | Item | Adverse E... | ... | 1 | AE Coded... | 4 17 note item level | AREPINEC | | | Public | 17APR201... | . . |
| 201 | 2010657112 | Item | Adverse E... | 26APR20... | 1 | AE Coded... | Item level note visibl... | JLONG | Response from differ... | KEISEN | UserGroup | 05MAY20... | 05MAY20... |
| 201 | 2010657112 | Item | Demograp... | 16MAR1... | 1 | Race:White | Item level note visibl... | JLONG | | | Public | 05MAY20... | . . |
| 201 | 2010657201 | Item | Lab Hema... | 24SEP19... | 1 | White Cell... | Patient has elevated ... | JLONG | | | Public | 11APR201... | . . |
| 201 | 2010661101 | Patient # | | | | : | Patient level note ad... | JLONG | | | Public | 05MAY20... | . . |
| 201 | 2010661101 | Patient # | | | | : | Patient note added fr... | JLONG | | | Public | 05MAY20... | . . |

tient ID: 10657201

Panel: Lab Hematology

Visit Date: 24SEP1991:00:00:00

Item Name: White Cell Count

Reason for Change:

te: tient has elevated WBC and no AE was reported. Call Inv site.

Response: Called site for missing data.

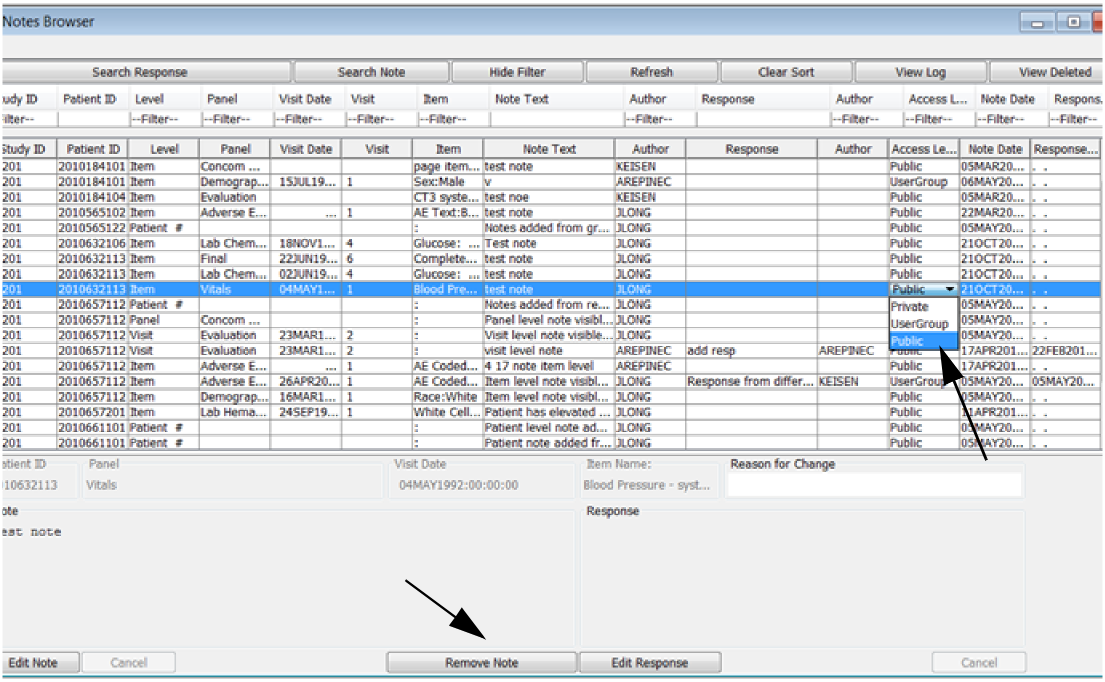
6. Click **Save Note**. The note is saved at the “Patient” level in the Notes Browser. If you click **Cancel** before clicking the Save Note button then the note is not added.

   The Note box becomes shaded or inactive after clicking Save Note and the button status changes to **Edit Note**. You may select another patient or continue with the same patient.

   Only the author of the note may edit or remove the note.

You do not have permission to edit this note.

7. In the row for the selected patient, the author may change the note Access Level.  Click on the patient row for **Access Level**, to display the drop down list for Private, UserGroup or Public.



| Study ID | Patient ID | Level | Panel | Visit Date | Visit | Item | Note Text | Author | Response | Author | Access Le... | Note Date | Response... |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 201 | 2010184101 | Item | Concom ... | | | page item... | test note | KEISEN | | | Public | 05MAR20... | . . |
| 201 | 2010184101 | Item | Demograp... | 15JUL19... | 1 | Sex:Male | v | AREPINEC | | | UserGroup | 06MAY20... | . . |
| 201 | 2010184104 | Item | Evaluation | | | CT3 syste... | test noe | KEISEN | | | Public | 05MAR20... | . . |
| 201 | 2010565102 | Item | Adverse E... | ... | 1 | AE Text:B... | test note | JLONG | | | Public | 22MAR20... | . . |
| 201 | 2010565122 | Patient # | | | | : | Notes added from gr... | JLONG | | | Public | 05MAY20... | . . |
| 201 | 2010632106 | Item | Lab Chem... | 18NOV1... | 4 | Glucose: ... | Test note | JLONG | | | Public | 21OCT20... | . . |
| 201 | 2010632113 | Item | Final | 22JUN19... | 6 | Complete... | test note | JLONG | | | Public | 21OCT20... | . . |
| 201 | 2010632113 | Item | Lab Chem... | 02JUN19... | 4 | Glucose: ... | test note | JLONG | | | Public | 21OCT20... | . . |
| 201 | 2010632113 | Item | Vitals | 04MAY1... | 1 | Blood Pre... | test note | JLONG | | | Public | 21OCT20... | . . |
| 201 | 2010657112 | Patient # | | | | : | Notes added from re... | JLONG | | | | 05MAY20... | . . |
| 201 | 2010657112 | Panel | Concom ... | | | : | Panel level note visibl... | JLONG | | | | 05MAY20... | . . |
| 201 | 2010657112 | Visit | Evaluation | 23MAR1... | 2 | : | Visit level note visible... | JLONG | | | | 05MAY20... | . . |
| 201 | 2010657112 | Visit | Evaluation | 23MAR1... | 2 | : | visit level note | AREPINEC | add resp | AREPINEC | | 17APR201... | 22FEB201... |
| 201 | 2010657112 | Item | Adverse E... | ... | 1 | AE Coded... | 4 17 note item level | AREPINEC | | | Public | 17APR201... | . . |
| 201 | 2010657112 | Item | Adverse E... | 26APR20... | 1 | AE Coded... | Item level note visibl... | JLONG | Response from differ... | KEISEN | UserGroup | 05MAY20... | 05MAY20... |
| 201 | 2010657112 | Item | Demograp... | 16MAR1... | 1 | Race:White | Item level note visibl... | JLONG | | | Public | 05MAY20... | . . |
| 201 | 2010657201 | Item | Lab Hema... | 24SEP19... | 1 | White Cell... | Patient has elevated ... | JLONG | | | Public | 11APR201... | . . |
| 201 | 2010661101 | Patient # | | | | : | Patient level note ad... | JLONG | | | Public | 05MAY20... | . . |
| 201 | 2010661101 | Patient # | | | | : | Patient note added fr... | JLONG | | | Public | 05MAY20... | . . |

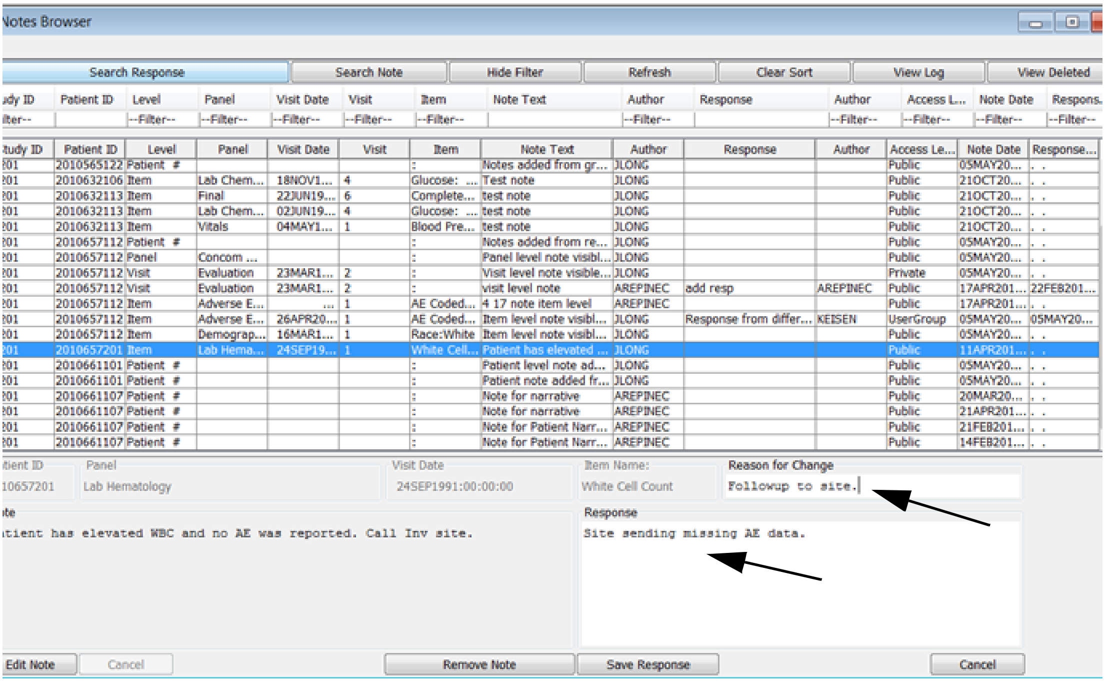
atient ID: 10632113
Panel: Vitals
Visit Date: 04MAY1992:00:00:00
Item Name: Blood Pressure - syst...
Reason for Change
ote
est note
Response

8. The Note Author may select a patient note and click **Remove Note**. Close the Notes Browser window.

## *Add response in Notes Browser*

A response may be entered by the author of the note or another user with access. Only the author of the response may edit or remove the response after the response has been saved.

1. Click **Edit Response**. The Response box is now unshaded and active.
2. Click the cursor in the Response box to enter up to 2000 characters.



| tudy ID | Patient ID | Level | Panel | Visit Date | Visit | Item | Note Text | Author | Response | Author | Access Le... | Note Date | Response... |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 201 | 2010565122 | Patient # | | | | : | Notes added from gr... | JLONG | | | Public | 05MAY20... | . . |
| 201 | 2010632106 | Item | Lab Chem... | 18NOV1... | 4 | Glucose: ... | Test note | JLONG | | | Public | 21OCT20... | . . |
| 201 | 2010632113 | Item | Final | 22JUN19... | 6 | Complete... | test note | JLONG | | | Public | 21OCT20... | . . |
| 201 | 2010632113 | Item | Lab Chem... | 02JUN19... | 4 | Glucose: ... | test note | JLONG | | | Public | 21OCT20... | . . |
| 201 | 2010632113 | Item | Vitals | 04MAY1... | 1 | Blood Pre... | test note | JLONG | | | Public | 21OCT20... | . . |
| 201 | 2010657112 | Patient # | | | | : | Notes added from re... | JLONG | | | Public | 05MAY20... | . . |
| 201 | 2010657112 | Panel | Concom ... | | | : | Panel level note visibl... | JLONG | | | Public | 05MAY20... | . . |
| 201 | 2010657112 | Visit | Evaluation | 23MAR1... | 2 | : | Visit level note visible... | JLONG | | | Private | 05MAY20... | . . |
| 201 | 2010657112 | Visit | Evaluation | 23MAR1... | 2 | : | visit level note | AREPINEC | add resp | AREPINEC | Public | 17APR201... | 22FEB201... |
| 201 | 2010657112 | Item | Adverse E... | ... | 1 | AE Coded... | 4 17 note item level | AREPINEC | | | Public | 17APR201... | . . |
| 201 | 2010657112 | Item | Adverse E... | 26APR20... | 1 | AE Coded... | Item level note visibl... | JLONG | Response from differ... | KEISEN | UserGroup | 05MAY20... | 05MAY20... |
| 201 | 2010657112 | Item | Demograp... | 16MAR1... | 1 | Race:White | Item level note visibl... | JLONG | | | Public | 05MAY20... | . . |
| 201 | 2010657201 | Item | Lab Hema... | 24SEP19... | 1 | White Cell... | Patient has elevated ... | JLONG | | | Public | 11APR201... | . . |
| 201 | 2010661101 | Patient # | | | | : | Patient level note ad... | JLONG | | | Public | 05MAY20... | . . |
| 201 | 2010661101 | Patient # | | | | : | Patient note added fr... | JLONG | | | Public | 05MAY20... | . . |
| 201 | 2010661107 | Patient # | | | | : | Note for narrative | AREPINEC | | | Public | 20MAR20... | . . |
| 201 | 2010661107 | Patient # | | | | : | Note for narrative | AREPINEC | | | Public | 21APR201... | . . |
| 201 | 2010661107 | Patient # | | | | : | Note for Patient Narr... | AREPINEC | | | Public | 21FEB201... | . . |
| 201 | 2010661107 | Patient # | | | | : | Note for Patient Narr... | AREPINEC | | | Public | 14FEB201... | . . |

tient ID: 10657201

Panel: Lab Hematology

Visit Date: 24SEP1991:00:00:00

Item Name: White Cell Count

Reason for Change: Followup to site.

te: tient has elevated WBC and no AE was reported. Call Inv site.

Response: Site sending missing AE data.

3. You must enter a **Reason for Change** everytime an edit or deletion is performed on a patient’s note.
4. Click **Save Response**. The response is saved at the same note level and access level as the original note. If you click **Cancel** before clicking the Save Response button then the response is not added.

   The Response box becomes shaded or inactive after clicking Save Response and the button status changes to **Edit Response**.
5. If you need to delete or remove the response and you are the author; click **Edit Response**, edit or delete the text, enter a reason; then click **Save Response**.
6. Close the Notes Browser window.

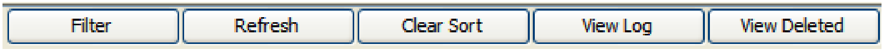
## *Add Note from output*

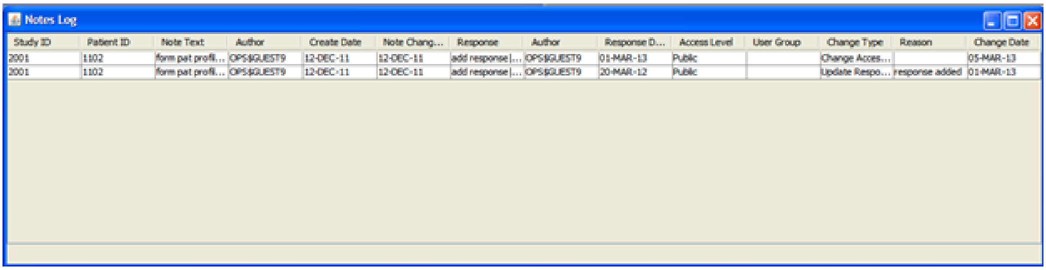
Individual patient notes may be added from detail data listing, scatter plot and patient profiles. Select the patient row in the report or graph data point then click on the yellow Notes icon in the output toolbar. The Notes Browser window displays. Click the **Add Note** button in the lower right corner to enter note for selected patient.

## *View Log*

Whenever updating or deleting patient notes a transaction is stored in a companion 'Audit' table for Patient Notes. You may view the **Full auditing** of patient notes in a transaction log available from the Notes Browser.

The information included everytime an edit or deletion is performed on a note is the type of change, reason and date of change. Select a single patient row in the Notes Browser and click **View Log**.

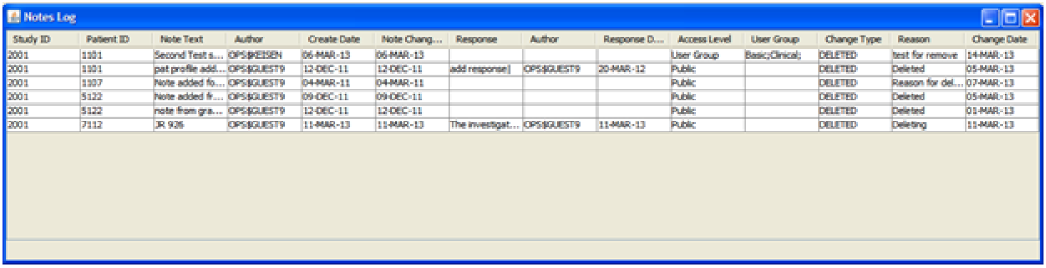




| Study ID | Patient ID | Note Text | Author | Create Date | Note Chang... | Response | Author | Response D... | Access Level | User Group | Change Type | Reason | Change Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2001 | 1102 | form pat profil... | OPS$GUEST9 | 12-DEC-11 | 12-DEC-11 | add response\|... | OPS$GUEST9 | 01-MAR-13 | Public |  | Change Acces... |  | 05-MAR-13 |
| 2001 | 1102 | form pat profil... | OPS$GUEST9 | 12-DEC-11 | 12-DEC-11 | add response\|... | OPS$GUEST9 | 20-MAR-12 | Public |  | Update Respo... | response added | 01-MAR-13 |

## *View Delete*

The View Delete log will always show all deleted records. Once a record is deleted it will not be displayed in the Notes browser, so the only way to see previously deleted records, click **View Deleted**.

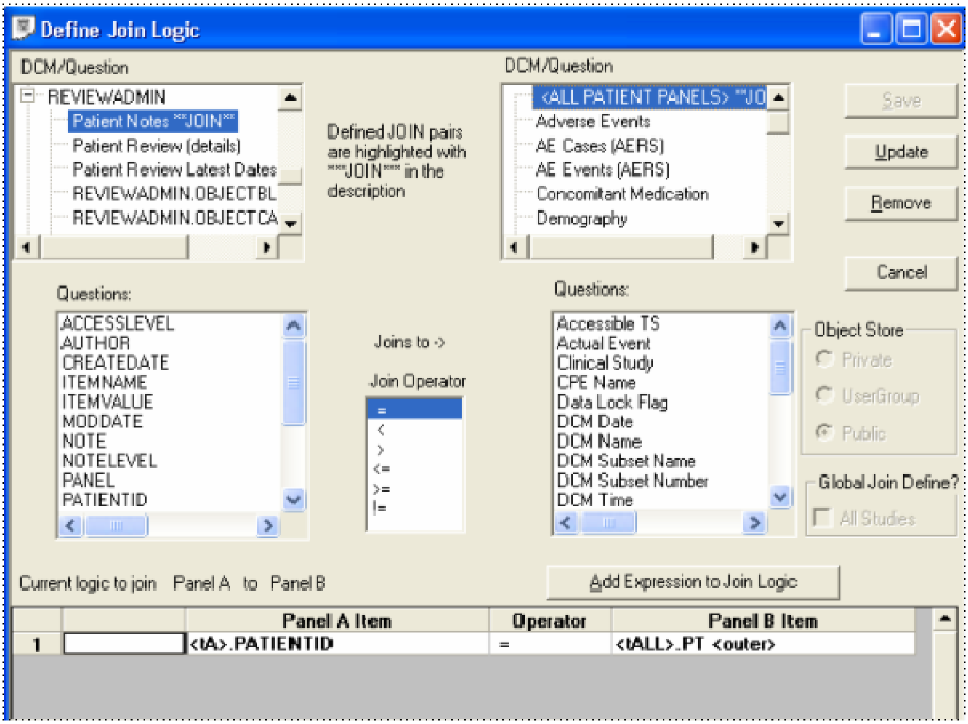


| Study ID | Patient ID | Note Text | Author | Create Date | Note Chang... | Response | Author | Response D... | Access Level | User Group | Change Type | Reason | Change Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2001 | 1101 | Second Test s... | OPS$KEISEN | 06-MAR-13 | 06-MAR-13 |  |  |  | User Group | Basic;Clinical; | DELETED | test for remove | 14-MAR-13 |
| 2001 | 1101 | pat profile add... | OPS$GUEST9 | 12-DEC-11 | 12-DEC-11 | add response\| | OPS$GUEST9 | 20-MAR-12 | Public |  | DELETED | Deleted | 05-MAR-13 |
| 2001 | 1107 | Note added fo... | OPS$GUEST9 | 04-MAR-11 | 04-MAR-11 |  |  |  | Public |  | DELETED | Reason for del... | 07-MAR-13 |
| 2001 | 5122 | Note added fr... | OPS$GUEST9 | 09-DEC-11 | 09-DEC-11 |  |  |  | Public |  | DELETED | Deleted | 05-MAR-13 |
| 2001 | 5122 | note from gra... | OPS$GUEST9 | 12-DEC-11 | 12-DEC-11 |  |  |  | Public |  | DELETED | Deleted | 01-MAR-13 |
| 2001 | 7112 | JR 926 | OPS$GUEST9 | 11-MAR-13 | 11-MAR-13 | The investigat... | OPS$GUEST9 | 11-MAR-13 | Public |  | DELETED | Deleting | 11-MAR-13 |

The Notes Browser spreadsheet can be exported, or copied to clipboard with the same features as a report.

Additional supplemental reports may be defined using patient selection criteria and filtering against ReviewAdmin tables to support the Notes Browser. In some circumstances it may be necessary to register Foreign panels (Patient Notes) from ReviewAdmin tables and then define Join Logic. **(See *Chapter 12: Advanced Topics - Define Join Logic)***

After the Foreign panels are made available in JReview and the Join Logic is saved, then users may define and apply patient selection criteria, user defined reports and output filters to the data fields in the Notes Browser.



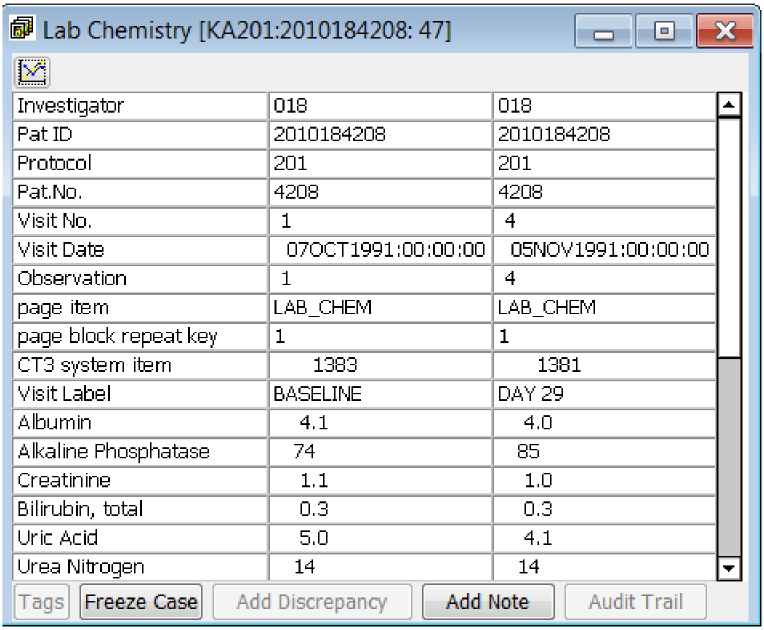
| | | Panel A Item | Operator | Panel B Item |
|---|---|---|---|---|
| 1 | | <tA>.PATIENTID | = | <tALL>.PT <outer> |

# Multiple-patient mode

## *Freezing a case*

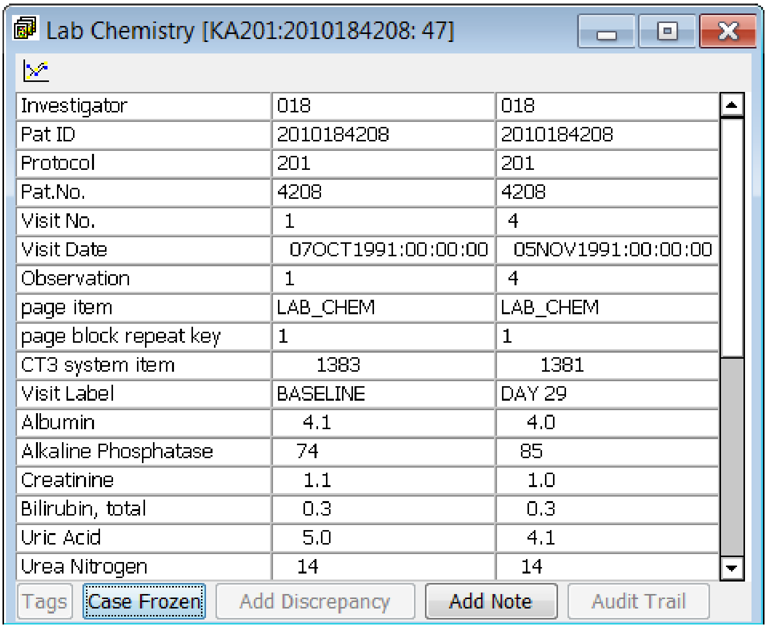
As you browse through patient data in the Data Browser, you notice that each patient selection updates the open panel views. JReview has an optional multiple-patient mode for the Data Browser. The multiple-patient mode allows the review of different patient's data at the same time.

Each panel view has a **Freeze Case** button in the lower right corner.



| | | |
|---|---|---|
| Investigator | 018 | 018 |
| Pat ID | 2010184208 | 2010184208 |
| Protocol | 201 | 201 |
| Pat.No. | 4208 | 4208 |
| Visit No. | 1 | 4 |
| Visit Date | 07OCT1991:00:00:00 | 05NOV1991:00:00:00 |
| Observation | 1 | 4 |
| page item | LAB_CHEM | LAB_CHEM |
| page block repeat key | 1 | 1 |
| CT3 system item | 1383 | 1381 |
| Visit Label | BASELINE | DAY 29 |
| Albumin | 4.1 | 4.0 |
| Alkaline Phosphatase | 74 | 85 |
| Creatinine | 1.1 | 1.0 |
| Bilirubin, total | 0.3 | 0.3 |
| Uric Acid | 5.0 | 4.1 |
| Urea Nitrogen | 14 | 14 |

When you click this button, the button text changes to **Case Frozen**.



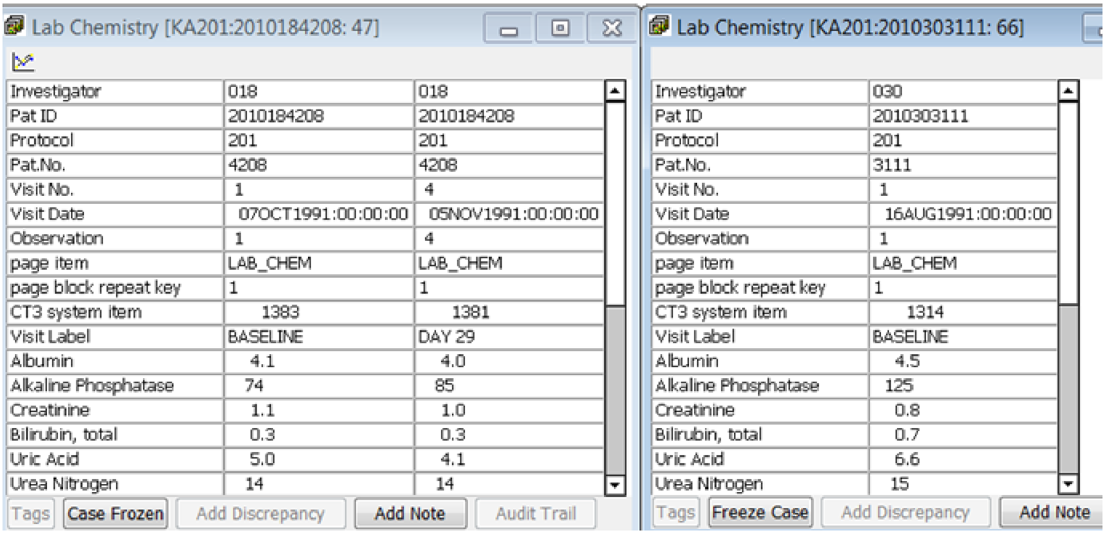
| | | |
|---|---|---|
| Investigator | 018 | 018 |
| Pat ID | 2010184208 | 2010184208 |
| Protocol | 201 | 201 |
| Pat.No. | 4208 | 4208 |
| Visit No. | 1 | 4 |
| Visit Date | 07OCT1991:00:00:00 | 05NOV1991:00:00:00 |
| Observation | 1 | 4 |
| page item | LAB_CHEM | LAB_CHEM |
| page block repeat key | 1 | 1 |
| CT3 system item | 1383 | 1381 |
| Visit Label | BASELINE | DAY 29 |
| Albumin | 4.1 | 4.0 |
| Alkaline Phosphatase | 74 | 85 |
| Creatinine | 1.1 | 1.0 |
| Bilirubin, total | 0.3 | 0.3 |
| Uric Acid | 5.0 | 4.1 |
| Urea Nitrogen | 14 | 14 |

When the **Case Frozen** button is present, data in the panel view is frozen, and will not update when you select another patient.

To freeze multiple panel views:

1. Select a patient.
2. Select a panel.
3. Click **Freeze Case**.

This freezes the panel view on the screen, dedicating it to the patient that was selected at the time of freezing the case. The freezing function allows you to display many patients with the same panel view open at the same time, providing you with a useful comparative clinical protocols tool.



Lab Chemistry [KA201:2010184208: 47]

| | | |
|---|---|---|
| Investigator | 018 | 018 |
| Pat ID | 2010184208 | 2010184208 |
| Protocol | 201 | 201 |
| Pat.No. | 4208 | 4208 |
| Visit No. | 1 | 4 |
| Visit Date | 07OCT1991:00:00:00 | 05NOV1991:00:00:00 |
| Observation | 1 | 4 |
| page item | LAB_CHEM | LAB_CHEM |
| page block repeat key | 1 | 1 |
| CT3 system item | 1383 | 1381 |
| Visit Label | BASELINE | DAY 29 |
| Albumin | 4.1 | 4.0 |
| Alkaline Phosphatase | 74 | 85 |
| Creatinine | 1.1 | 1.0 |
| Bilirubin, total | 0.3 | 0.3 |
| Uric Acid | 5.0 | 4.1 |
| Urea Nitrogen | 14 | 14 |

Lab Chemistry [KA201:2010303111: 66]

| | |
|---|---|
| Investigator | 030 |
| Pat ID | 2010303111 |
| Protocol | 201 |
| Pat.No. | 3111 |
| Visit No. | 1 |
| Visit Date | 16AUG1991:00:00:00 |
| Observation | 1 |
| page item | LAB_CHEM |
| page block repeat key | 1 |
| CT3 system item | 1314 |
| Visit Label | BASELINE |
| Albumin | 4.5 |
| Alkaline Phosphatase | 125 |
| Creatinine | 0.8 |
| Bilirubin, total | 0.7 |
| Uric Acid | 6.6 |
| Urea Nitrogen | 15 |

***Note: A Case Frozen will not update with the selection of a new patient. A new window is generated when you click on the panel to be displayed, and/or updates the previously selected and open panel views not frozen.***

To unfreeze a panel view, click **Case Frozen**.

A panel view that is not frozen will be updated when a different patient is selected. If you have frozen a number of panel views, and would like to unfreeze it and close them, you can close each one with or without unfreezing them by clicking on the System menu button in the upper left corner of each window, or you can close the Data Browser window itself and all open panel views will be closed. If you want to update all the frozen panel views click **Case Frozen** and select a new patient.

The panel view updates to the selected patient and you can proceed to freeze that view for a new comparative exercise.

***Note: If you have opened more than one panel view of the same panel, any left in the unfrozen state become active updating panel views. You may want to individually close all but one unfrozen panel view per panel to reduce screen clutter and needless repetitious presentations of the same data.***

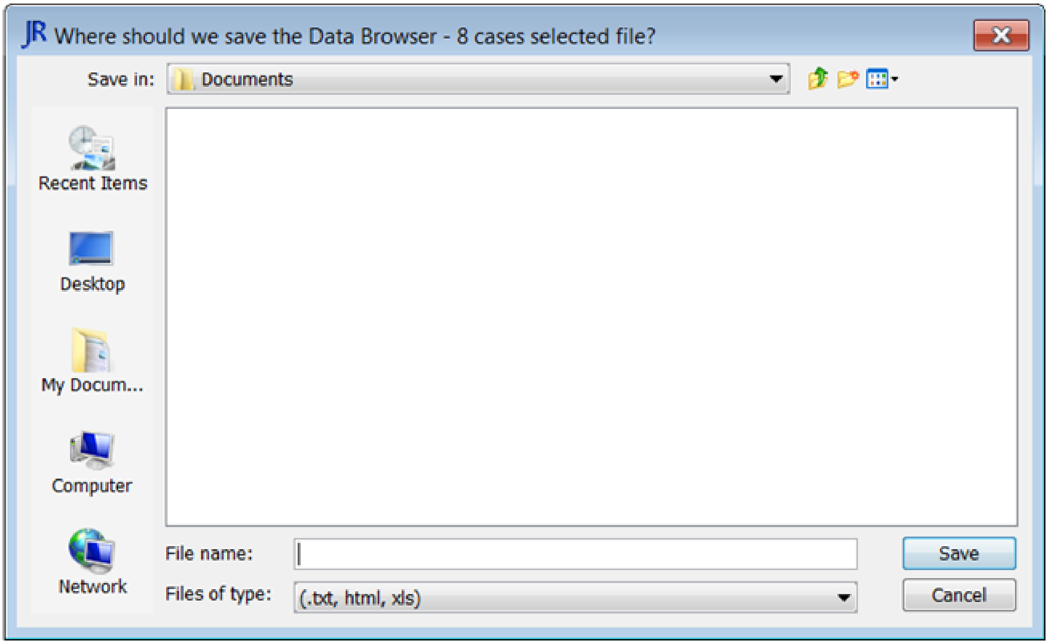
# Export and Print listings and panel views

## *Export a data browser spreadsheet*

To export the Data Browser window or data from a patient’s data panel view in Excel, HTML format or tab delimited files:

1. Select the desired window as the active window.
2. From the **File** menu, select **Export**.

   JReview displays the **Save In** window.



3. Open the storage location (folder).
4. Enter a File name.
5. Enter the File type.
6. Click **Save.**

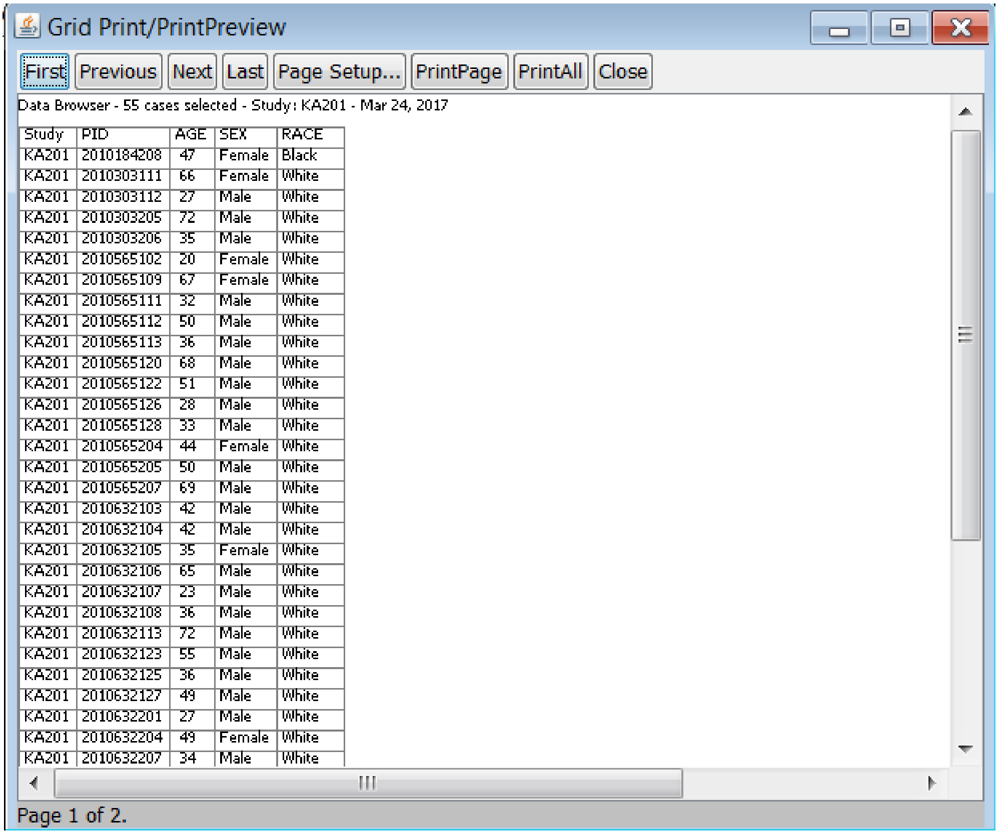
Your patient list or panel view is exported to the currently selected disk directory. **(See *Chapter 12: Advanced Topics: Export Browser Display Spreadsheets; Copy and Paste Browser Results; Copying to Clipboard)***

## *Print Preview*

To print patients meeting the current patient selection criteria in the Data Browser window or data from a patient's data panel:

1. Click on the title bar of the Data Browser window or Panel window to make it the active window.
2. Click 🖨, or from the JReview **File** menu, select **Print**.

***Caution:*** JReview displays a screen shot of the selected active screen. You can use the buttons to scroll through the pages of the output. ***Do not select the Internet Browser's FILE menu Print option.***



Data Browser - 55 cases selected - Study: KA201 - Mar 24, 2017

| Study | PID | AGE | SEX | RACE |
|---|---|---|---|---|
| KA201 | 2010184208 | 47 | Female | Black |
| KA201 | 2010303111 | 66 | Female | White |
| KA201 | 2010303112 | 27 | Male | White |
| KA201 | 2010303205 | 72 | Male | White |
| KA201 | 2010303206 | 35 | Male | White |
| KA201 | 2010565102 | 20 | Female | White |
| KA201 | 2010565109 | 67 | Female | White |
| KA201 | 2010565111 | 32 | Male | White |
| KA201 | 2010565112 | 50 | Male | White |
| KA201 | 2010565113 | 36 | Male | White |
| KA201 | 2010565120 | 68 | Male | White |
| KA201 | 2010565122 | 51 | Male | White |
| KA201 | 2010565126 | 28 | Male | White |
| KA201 | 2010565128 | 33 | Male | White |
| KA201 | 2010565204 | 44 | Female | White |
| KA201 | 2010565205 | 50 | Male | White |
| KA201 | 2010565207 | 69 | Male | White |
| KA201 | 2010632103 | 42 | Male | White |
| KA201 | 2010632104 | 42 | Male | White |
| KA201 | 2010632105 | 35 | Female | White |
| KA201 | 2010632106 | 65 | Male | White |
| KA201 | 2010632107 | 23 | Male | White |
| KA201 | 2010632108 | 36 | Male | White |
| KA201 | 2010632113 | 72 | Male | White |
| KA201 | 2010632123 | 55 | Male | White |
| KA201 | 2010632125 | 36 | Male | White |
| KA201 | 2010632127 | 49 | Male | White |
| KA201 | 2010632201 | 27 | Male | White |
| KA201 | 2010632204 | 49 | Female | White |
| KA201 | 2010632207 | 34 | Male | White |

Page 1 of 2.

3. Click either **PrintPage**, **PrintAll** or **Close**. The PrintPage option will print only the first page of your output. The PrintAll option will print the entire output.

***Note: Use the Convert to pure black & white? option is only applicable to graphs where multiple colors are displayed. If your printer is non-color click this feature for better black and white print resolution of graphs.***

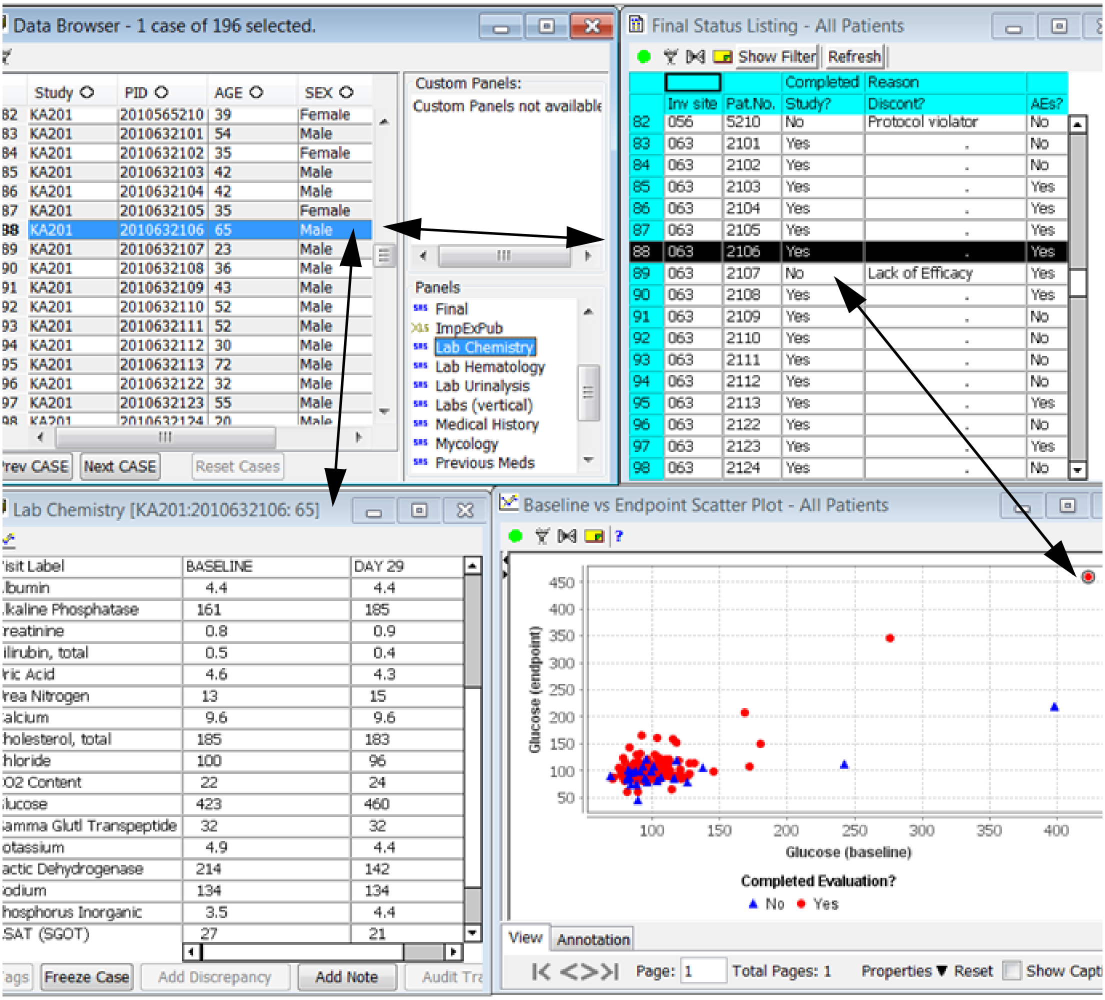
# Exploring data

## *Changing the patient selection criteria*

Each time you modify the patient selection criteria, the Data Browser instantaneously provides a listing of the patient population that meet the patient selection criteria. Using the Data Browser, you can rapidly review all selected patient data, and compare it to data for other patients or to CRF image sources, and note and review tagged patient data. You can also review all data editing with audit trail access, for any data item.

All patient-level browser displays interact with the patient selection criteria similarly, and update to display the patient inclusion defined in the patient selection criteria.

You can select and subset multiple patients from all patient level displays of data and CrossTab result tables, to generate corresponding patient listings in the Data Browser and Detail Data Listing Reports. This facilitates patient identification and detailed patient data review via the reviewing tools of the Data Browser.



| | Study | PID | AGE | SEX |
|---|---|---|---|---|
| 82 | KA201 | 2010565210 | 39 | Female |
| 83 | KA201 | 2010632101 | 54 | Male |
| 84 | KA201 | 2010632102 | 35 | Female |
| 85 | KA201 | 2010632103 | 42 | Male |
| 86 | KA201 | 2010632104 | 42 | Male |
| 87 | KA201 | 2010632105 | 35 | Female |
| 88 | KA201 | 2010632106 | 65 | Male |
| 89 | KA201 | 2010632107 | 23 | Male |
| 90 | KA201 | 2010632108 | 36 | Male |
| 91 | KA201 | 2010632109 | 43 | Male |
| 92 | KA201 | 2010632110 | 52 | Male |
| 93 | KA201 | 2010632111 | 52 | Male |
| 94 | KA201 | 2010632112 | 30 | Male |
| 95 | KA201 | 2010632113 | 72 | Male |
| 96 | KA201 | 2010632122 | 32 | Male |
| 97 | KA201 | 2010632123 | 55 | Male |
| 98 | KA201 | 2010632124 | 20 | Male |

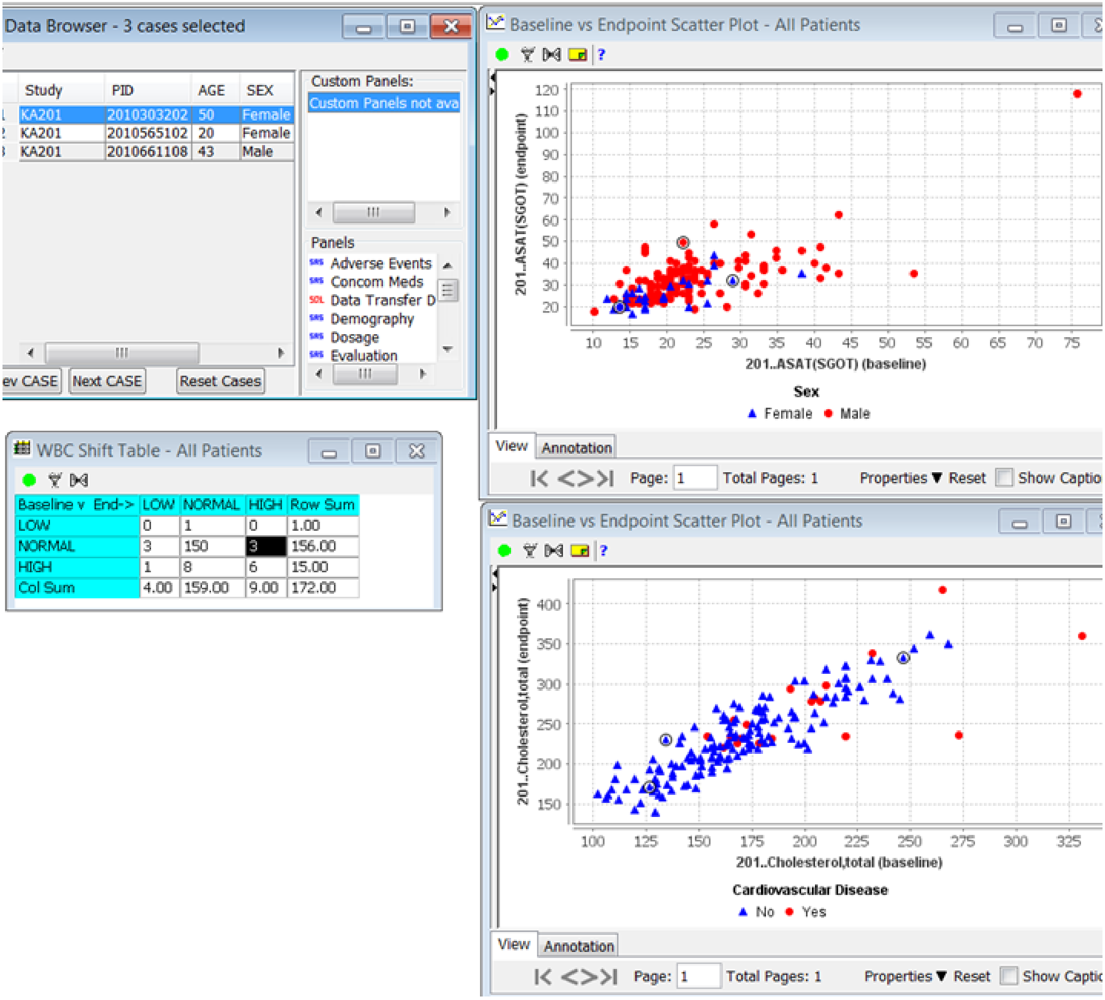
| | | | Completed | Reason | |
|---|---|---|---|---|---|
| | Inv site | Pat.No. | Study? | Discont? | AEs? |
| 82 | 056 | 5210 | No | Protocol violator | No |
| 83 | 063 | 2101 | Yes | . | No |
| 84 | 063 | 2102 | Yes | . | No |
| 85 | 063 | 2103 | Yes | . | Yes |
| 86 | 063 | 2104 | Yes | . | Yes |
| 87 | 063 | 2105 | Yes | . | Yes |
| 88 | 063 | 2106 | Yes | . | Yes |
| 89 | 063 | 2107 | No | Lack of Efficacy | Yes |
| 90 | 063 | 2108 | Yes | . | Yes |
| 91 | 063 | 2109 | Yes | . | No |
| 92 | 063 | 2110 | Yes | . | No |
| 93 | 063 | 2111 | Yes | . | No |
| 94 | 063 | 2112 | Yes | . | No |
| 95 | 063 | 2113 | Yes | . | Yes |
| 96 | 063 | 2122 | Yes | . | No |
| 97 | 063 | 2123 | Yes | . | Yes |
| 98 | 063 | 2124 | Yes | . | No |

| isit Label | BASELINE | DAY 29 |
|---|---|---|
| lbumin | 4.4 | 4.4 |
| kaline Phosphatase | 161 | 185 |
| reatinine | 0.8 | 0.9 |
| ilirubin, total | 0.5 | 0.4 |
| ric Acid | 4.6 | 4.3 |
| rea Nitrogen | 13 | 15 |
| alcium | 9.6 | 9.6 |
| holesterol, total | 185 | 183 |
| hloride | 100 | 96 |
| O2 Content | 22 | 24 |
| lucose | 423 | 460 |
| amma Glutl Transpeptide | 32 | 32 |
| otassium | 4.9 | 4.4 |
| actic Dehydrogenase | 214 | 142 |
| odium | 134 | 134 |
| hosphorus Inorganic | 3.5 | 4.4 |
| SAT (SGOT) | 27 | 21 |

## *CrossTab Browser results*

Clicking on a patient categorical count in the results CrossTab tables updates the open patient listing in the Data Browser, and refreshes Detail Data Listing reports (if open) to display those patients underlying the selected patient count. This feature facilitates patient identification from the CrossTab categorical patient counts, to the underlying patient data via the Data Browser.

***Note: The CrossTab Browser does not allow multiple protocol selection. (See CrossTab Browser: Patient selection criteria)***



| Study | PID | AGE | SEX |
|---|---|---|---|
| KA201 | 2010303202 | 50 | Female |
| KA201 | 2010565102 | 20 | Female |
| KA201 | 2010661108 | 43 | Male |

| Baseline v End-> | LOW | NORMAL | HIGH | Row Sum |
|---|---|---|---|---|
| LOW | 0 | 1 | 0 | 1.00 |
| NORMAL | 3 | 150 | 3 | 156.00 |
| HIGH | 1 | 8 | 6 | 15.00 |
| Col Sum | 4.00 | 159.00 | 9.00 | 172.00 |

### *Discrepancy reports*

You can manually browse patient data, identify discrepancies and document your review of the study data. You can instantly create automatic discrepancy reports based on the data value, multiple values, or columnar data clusters that you highlight.

### *Detail Data Listing reports*

You can click and on a patient row of interest and release. Instantly, the open Data Browser, Scatter Plot Graphs, update to reflect the selected patient. The selected patient will be highlighted in patient listings and highlighted in Scatter Plot Graphs.

### *Scatter plot graphs*

You can click and drag to outline a region on a graph. All patients within the outlined region comprise the new patient subset. The open Data Browser patient listing, open Detail Data Listing reports, and other open Scatter Plot graphs update to identify and characterize the new subset of patients.

## Closing panel views and the Data Browser

### *Closing a panel view*

If you are finished reviewing data for a particular panel, double-click on the window's close box, as you would with any other window.

### *Closing the Data Browser window*

If you are finished reviewing the panel view completely, double-click on the close box of the Data Browser window. JReview closes all panel views currently opened.

# 4 Patient Profiles

# Types of Patient Profiles

## *Patient profile types*

JReview users with access to Patient Profiles can select different patient profile types to execute. In JReview, Authoring mode is required to define and save patient profile objects at the global, project and study levels. The following three types of patient profiles can be defined and saved for execution in JReview.

JReview users with access to Patient Profiles can define and save the WorkBook Profiles, Graphic Profiles and Formatted Profiles.

- **Workbook Profile** generate as a patient profile spreadsheet organized by panels/questions groups or visits and the visit representation as row or column in the spreadsheet display. The results can display and print in single or multiple worksheet modes.
- **Graphic Profile** where first templates are defined and then accessed to create graphic profiles where data is viewed in time oriented graphic displays as duration bars, trend plots and line charts.
- **Formatted Profile** are the workbook profile type with applied formats for fonts, headings, footers, page breaks and panel orientation.

In addition, users may track patient review status with the Patient Review Tracking Tool within all the Patient Profile types.

## *Access to SAS datasets*

SAS datasets are listed with the panels generated from Oracle tables. Items from SAS datasets can be used like other items for building patient profiles.

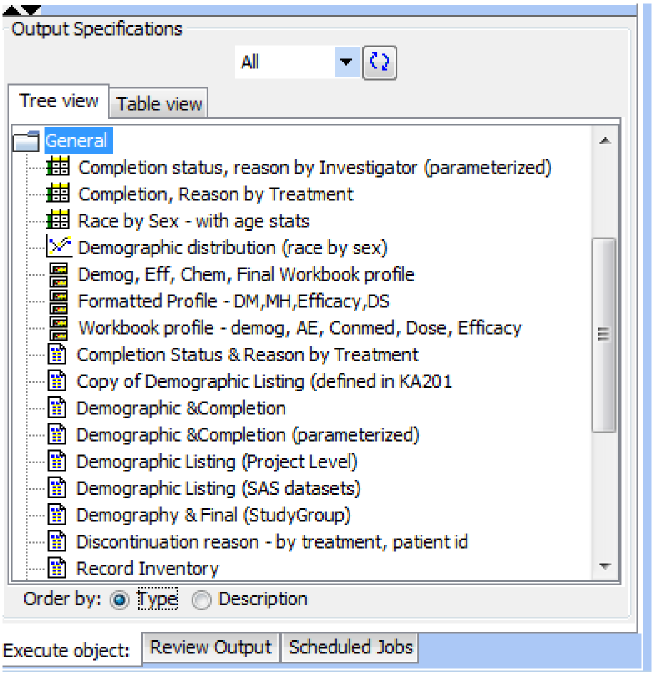
***Note: The current restriction is you cannot mix items from SAS datasets and Oracle table generated panels within the same patient profile.***

# Execute patient profile

## *Quick execute*

JReview displays a list of categorical folders for stored patient subsets and output specifications at the selected storage location. Simply select one of the storage locations to display it's specific folders and contents.

Icons are displayed along with the stored object to identify the source as report, graph, registered SAS program, etc. When a patient selection criteria is saved with the stored object; the filter icon displays with the specific browser icon. JReview aids users to quickly locate and launch these stored objects.



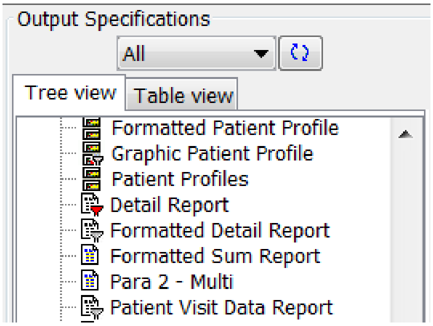
All

General
- Completion status, reason by Investigator (parameterized)
- Completion, Reason by Treatment
- Race by Sex - with age stats
- Demographic distribution (race by sex)
- Demog, Eff, Chem, Final Workbook profile
- Formatted Profile - DM,MH,Efficacy,DS
- Workbook profile - demog, AE, Conmed, Dose, Efficacy
- Completion Status & Reason by Treatment
- Copy of Demographic Listing (defined in KA201
- Demographic &Completion
- Demographic &Completion (parameterized)
- Demographic Listing (Project Level)
- Demographic Listing (SAS datasets)
- Demography & Final (StudyGroup)
- Discontinuation reason - by treatment, patient id
- Record Inventory

Order by: ● Type ○ Description

Stored object specifications saved with an included patient selection criteria in the definition will display a filter icon next to the object description.

- If the patient selection criteria was saved as “required”, the filter will display in the color red to indicate the selection criteria cannot be changed.
- If a filter icon is present but is not colored red, then you can alter and update the patient selection criteria for the opened output specification.



## Selection criteria

In JReview, you can select a previously saved Patient Subset, a saved Dynamic PSC or define your own patient selection criteria for use in the Patient Profile Browser. After launching the patient selection criteria, you can launch a previously saved patient profile object created or define a patient profile in JReview from the Patient Profile Browser.

## Retrieve a stored output specification

To retrieve a saved output specification:

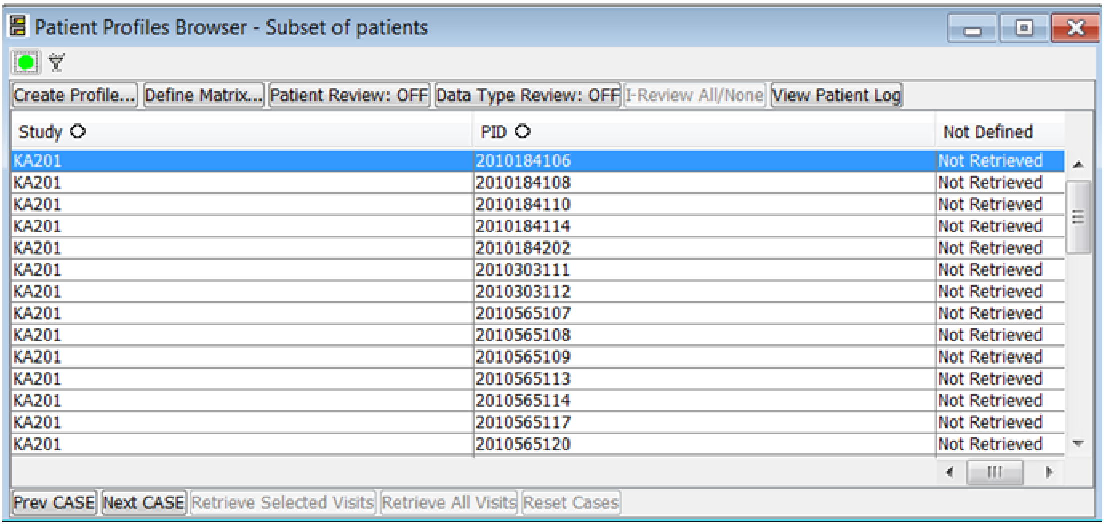
1. Double click to open a folder in Output Specifications.
2. Double click on the object to launch in a single step. The stored output specification will be launched.

# Patient profile features

## *View saved patient profile*

After selecting a previously saved patient profile from the Output Specifications window, JReview opens the Patient Profiles Browser window which displays a list of patients who meet the patient selection criteria, or all patients if no selection criteria was entered.

Select a patient from the list and click **Create Profile**. Only one patient profile can be open at a time and gives a specific stored/required patient selection criteria warning. A warning dialog will be present when trying to open a new Patient Profile if a Snapshot/Frozen or “Req’d PSC” for a Patient Profile is open. The user must close such Patient Profile before a new one can be opened.



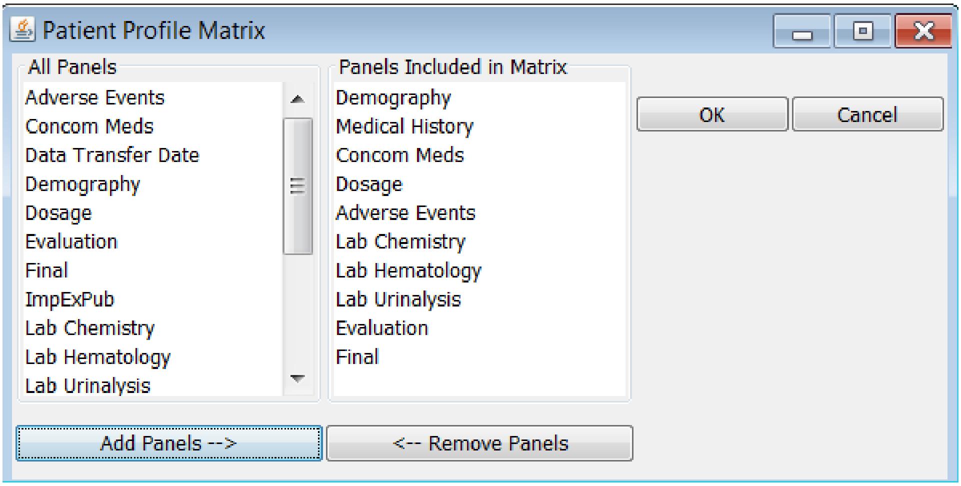
| Study | PID | Not Defined |
|---|---|---|
| KA201 | 2010184106 | Not Retrieved |
| KA201 | 2010184108 | Not Retrieved |
| KA201 | 2010184110 | Not Retrieved |
| KA201 | 2010184114 | Not Retrieved |
| KA201 | 2010184202 | Not Retrieved |
| KA201 | 2010303111 | Not Retrieved |
| KA201 | 2010303112 | Not Retrieved |
| KA201 | 2010565107 | Not Retrieved |
| KA201 | 2010565108 | Not Retrieved |
| KA201 | 2010565109 | Not Retrieved |
| KA201 | 2010565113 | Not Retrieved |
| KA201 | 2010565114 | Not Retrieved |
| KA201 | 2010565117 | Not Retrieved |
| KA201 | 2010565120 | Not Retrieved |

## *Define patient profile matrix*

Visit numbers for patient related panels found in the database, can be retrieved for display after you Define Matrix. This feature supports a way to track individual patient study status by visit. The visits are not required to display when you select a patient to view their patient profile. ***All patient related panels and included items are listed, not foreign panels or pivot panels.***

When the Patient Profiles Browser window initially opens, the patient visit information is not yet retrieved until you define the patient profile matrix. **Define Matrix** is ***optional,*** and not required to select a patient for **Create Profile**. The patients listed display a message stating ‘Not Retrieved’. This allows for faster retrieval of detailed patient visit information and lets you select the patients and visits you want to view.

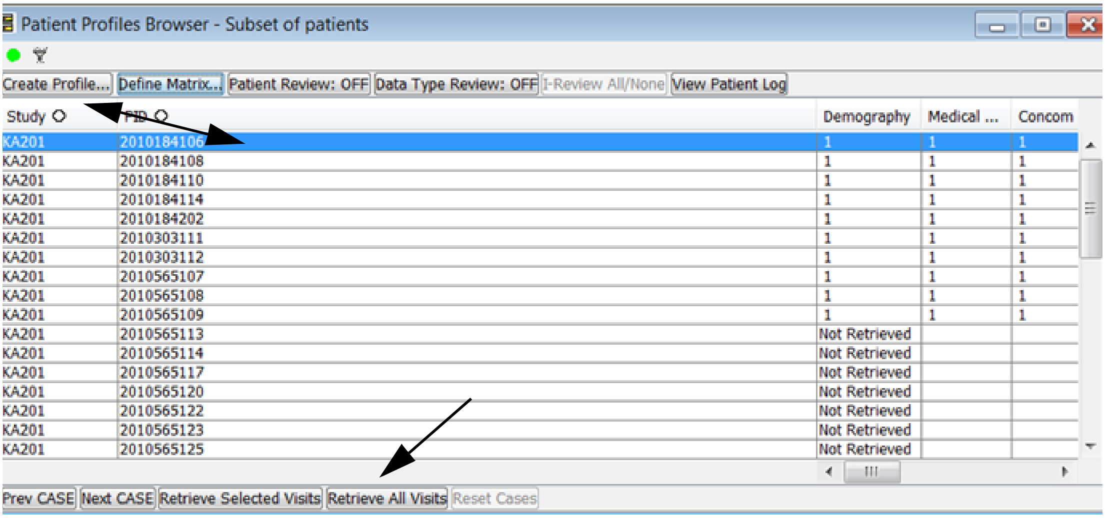
1. Click **Define Matrix**.
2. Use the **Add Panels** and **Remove Panels** buttons to select panels.
3. Click **OK**.



The first 10 patients display all their visit information. All visit numbers are listed for the active patients as a way to track individual patient study status by visit. The remaining patients listed display the message stating ‘Not Retrieved’.

4. To retrieve additional patients, highlight multiple patients and click **Retrieve Selected Visits.**

5. Click **Retrieve All Visits** for all remaining patients.

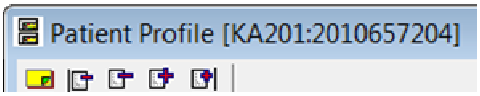


| Study | PID | Demography | Medical ... | Concom |
|---|---|---|---|---|
| KA201 | 2010184106 | 1 | 1 | 1 |
| KA201 | 2010184108 | 1 | 1 | 1 |
| KA201 | 2010184110 | 1 | 1 | 1 |
| KA201 | 2010184114 | 1 | 1 | 1 |
| KA201 | 2010184202 | 1 | 1 | 1 |
| KA201 | 2010303111 | 1 | 1 | 1 |
| KA201 | 2010303112 | 1 | 1 | 1 |
| KA201 | 2010565107 | 1 | 1 | 1 |
| KA201 | 2010565108 | 1 | 1 | 1 |
| KA201 | 2010565109 | 1 | 1 | 1 |
| KA201 | 2010565113 | Not Retrieved | | |
| KA201 | 2010565114 | Not Retrieved | | |
| KA201 | 2010565117 | Not Retrieved | | |
| KA201 | 2010565120 | Not Retrieved | | |
| KA201 | 2010565122 | Not Retrieved | | |
| KA201 | 2010565123 | Not Retrieved | | |
| KA201 | 2010565125 | Not Retrieved | | |

6. Select a patient and click **Create Profile**. The previously saved Workbook profile specification opens for the selected patient.

## *Add patient note*

Optionally, you may add patient notes from any patient profile output display. The '**Add Notes**' icon is available in the patient profile tool bar (see the first yellow icon).



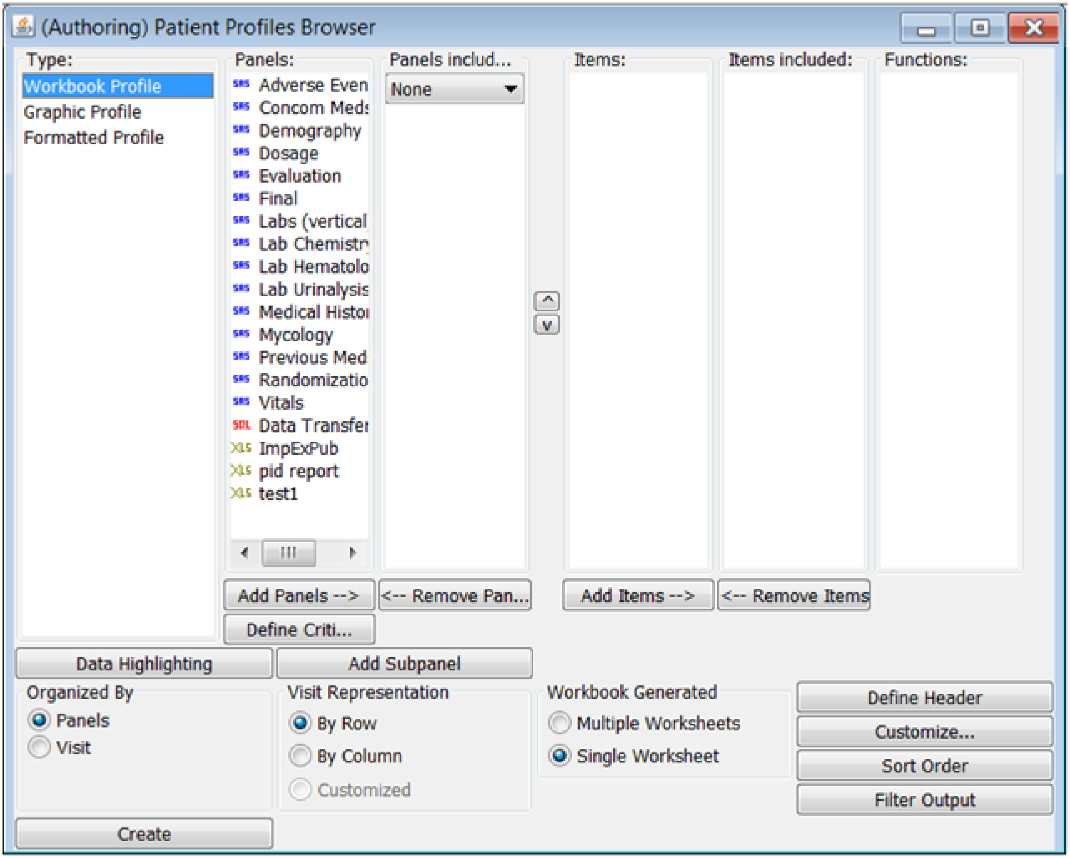
Simply click on the Add Note icon in the tool bar to add a patient note for the selected patient. The Notes Browser window opens where you would click on **Add Note**. ***(See Chapter 3: Review Patient Data: section on Notes Browser)***

# Define Patient Profile

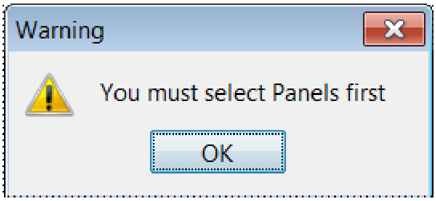
## *Select workbook profile*

In JReview, Authoring mode is required to define and save patient profile objects. The Patient Profiles Browser facilitates the creation of customized patient profiles of the selected patients into various Workbook Profile types as single worksheet mode or multiple worksheet mode. In addition, the spreadsheet display can be sorted by visit or panel and the visit representation as row or column.

1. Click , or from the **Browse** menu, select **Patient Profiles**.
2. The Patient Profiles Browser window opens, the default profile type is **Workbook Profile**. A configuration setting controls whether No panels (None), All panels, or Critical Study defined panels are included in the profile by default.



If you click **Create** before defining the patient profile, a message displays indicating the patient profile contents are empty.



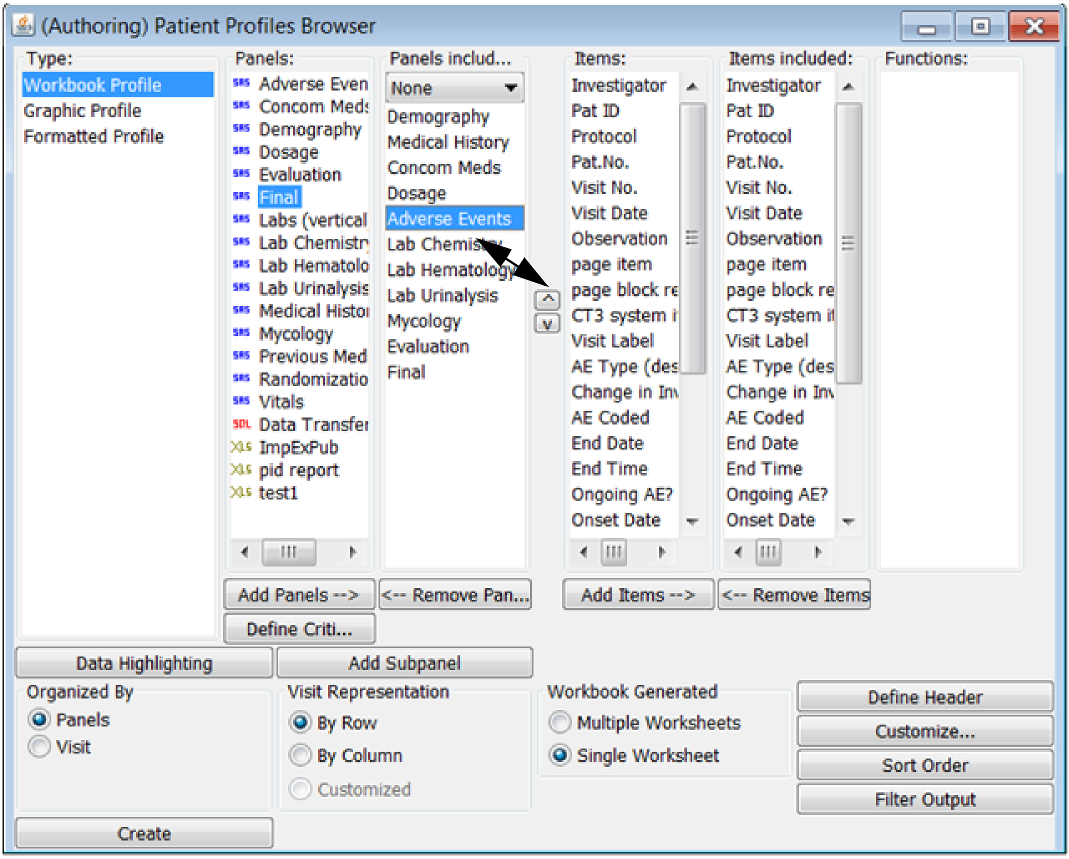
You must select Panels first

You must first include panels and items for display in the patient profile:

***Note: Patient Profiles do not support Vertical to Horizontal panels (HRZ) in workbook and formatted patient profiles. HRZ panels are supported in Report and Graph Browsers.***

3. Select panels from the **Panels** list to move to the **Panels Included** list. Click the **Add Panels** and **Remove Panels** buttons, to select and move panels defining the patient profile.

4. Use the **Up** and **Down arrows** located next to the **Panels Included** list box, to change the sort order of the panels displayed.



(Authoring) Patient Profiles Browser

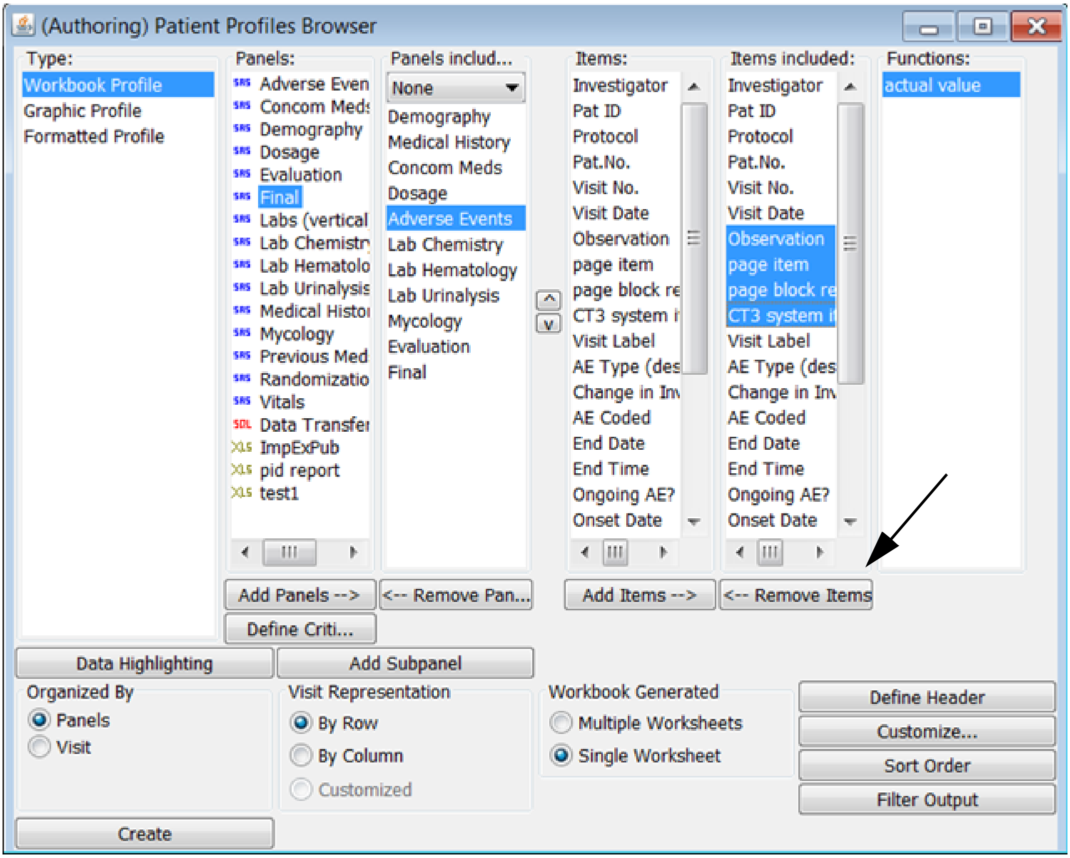
Type: Workbook Profile

Organized By: ● Panels ○ Visit

Visit Representation: ● By Row ○ By Column ○ Customized

Workbook Generated: ○ Multiple Worksheets ● Single Worksheet

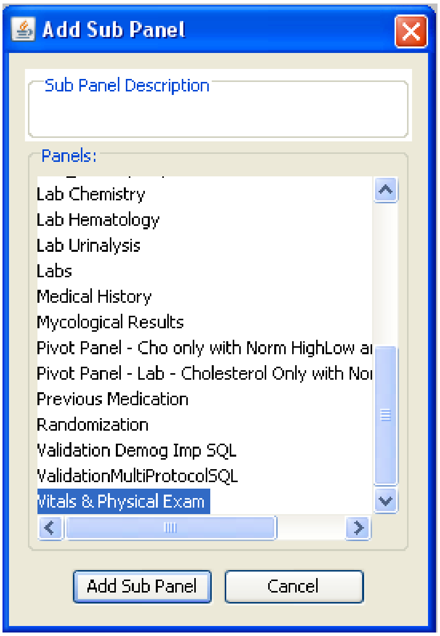
5. Use the **Add Items** and **Remove Items** buttons, to select specific items for display. Select multiple items with the CTRL or SHIFT key.
6. **Reorder** the individual items within a selected panel by using drag and drop.



## Add Subpanel

The **Add Subpanel** function is similar to cloning a panel. If you have a complex panel with different types of data you may wish to divide the panel into more meaningful categories or sub panels. For example, Physical Exam and Vital Signs panel can be split into sub panels for easier viewing.

1. Click the **Add Subpanel button**. The Add Sub Panel window opens.

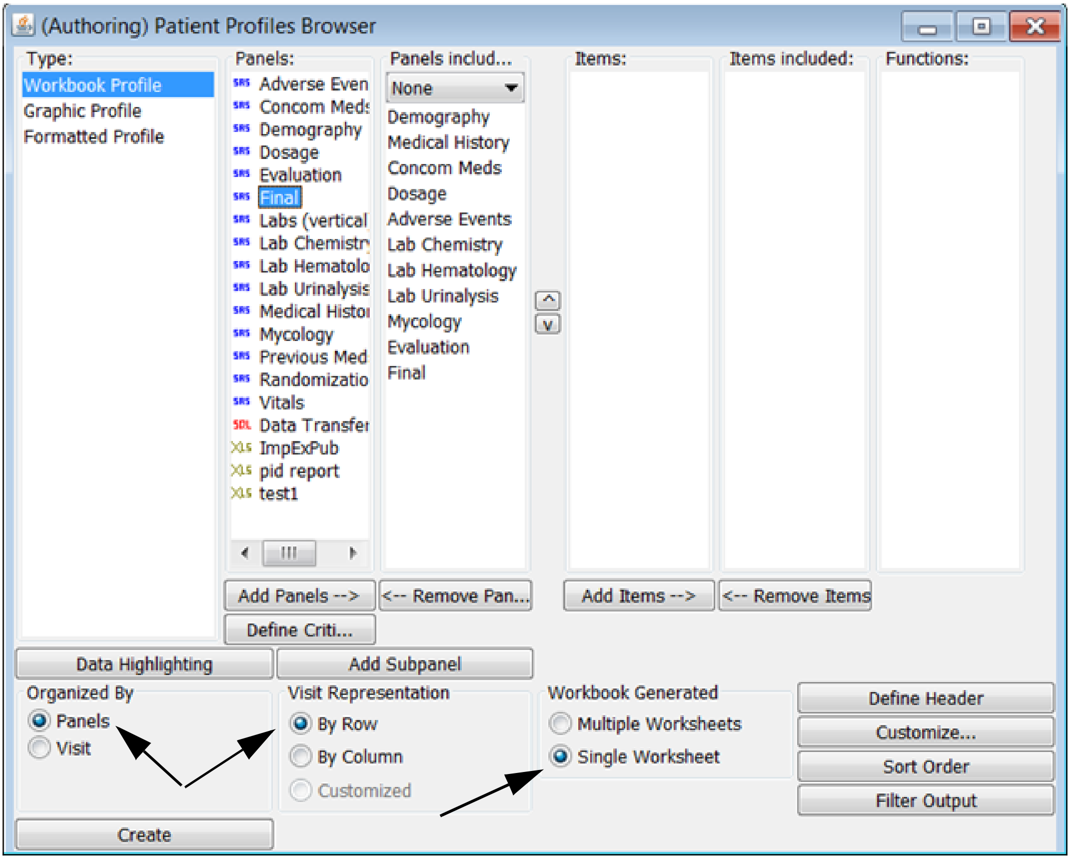


2. Select the panel. When defining a sub panel you can only select a single panel. Multiple visit panels display as vertical or horizontal.
3. Enter a **Sub Panel Description**.
4. Click **Add Sub Panel**. The new sub panel is added to the Panels Included list for selection to add and remove items for display.

# Type of workbook

## *Organize data*

Initially the Patient Profiles Browser opens for **Workbook Profile type** with default settings for the data organized by panels, and visit related data is represented by row for single worksheet display.

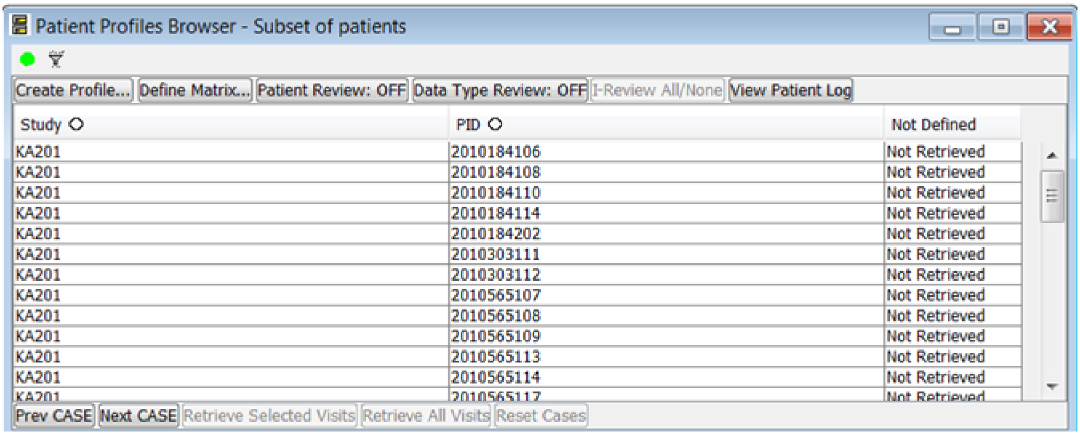


Organized By
● Panels
○ Visit

Visit Representation
● By Row
○ By Column
○ Customized

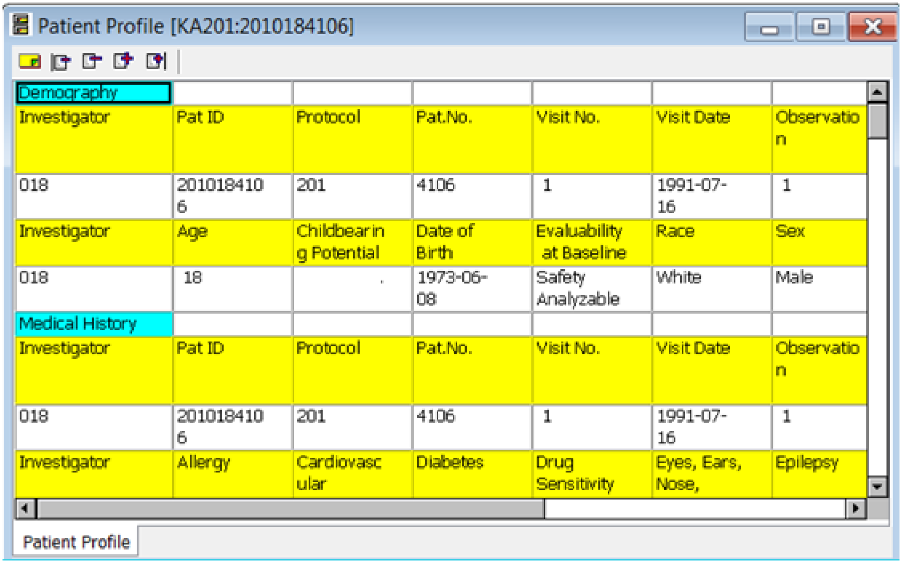
Workbook Generated
○ Multiple Worksheets
● Single Worksheet

After you define the workbook profile by adding selected panels and items; click **Create** to use the default settings. The Patient Profile Browser window displays the patient list for the selected patients.



| Study ○ | PID ○ | Not Defined |
|---|---|---|
| KA201 | 2010184106 | Not Retrieved |
| KA201 | 2010184108 | Not Retrieved |
| KA201 | 2010184110 | Not Retrieved |
| KA201 | 2010184114 | Not Retrieved |
| KA201 | 2010184202 | Not Retrieved |
| KA201 | 2010303111 | Not Retrieved |
| KA201 | 2010303112 | Not Retrieved |
| KA201 | 2010565107 | Not Retrieved |
| KA201 | 2010565108 | Not Retrieved |
| KA201 | 2010565109 | Not Retrieved |
| KA201 | 2010565113 | Not Retrieved |
| KA201 | 2010565114 | Not Retrieved |
| KA201 | 2010565117 | Not Retrieved |

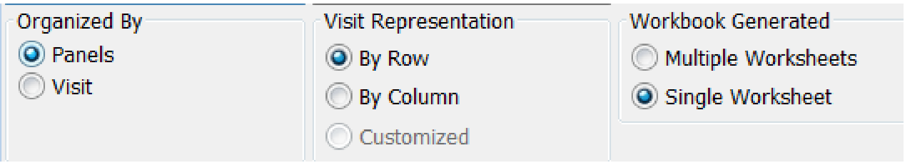
Select a patient, and click **Create Profile** to view your defined patient profille.



| | | | | | | |
|---|---|---|---|---|---|---|
| Demography | | | | | | |
| Investigator | Pat ID | Protocol | Pat.No. | Visit No. | Visit Date | Observation |
| 018 | 2010184106 | 201 | 4106 | 1 | 1991-07-16 | 1 |
| Investigator | Age | Childbearing Potential | Date of Birth | Evaluability at Baseline | Race | Sex |
| 018 | 18 | . | 1973-06-08 | Safety Analyzable | White | Male |
| Medical History | | | | | | |
| Investigator | Pat ID | Protocol | Pat.No. | Visit No. | Visit Date | Observation |
| 018 | 2010184106 | 201 | 4106 | 1 | 1991-07-16 | 1 |
| Investigator | Allergy | Cardiovascular | Diabetes | Drug Sensitivity | Eyes, Ears, Nose, | Epilepsy |

## *Single worksheet mode*

The single worksheet mode can be organized by Panels or Visit. This topic is covered in the workbook profile display options.



Organized By
● Panels
○ Visit

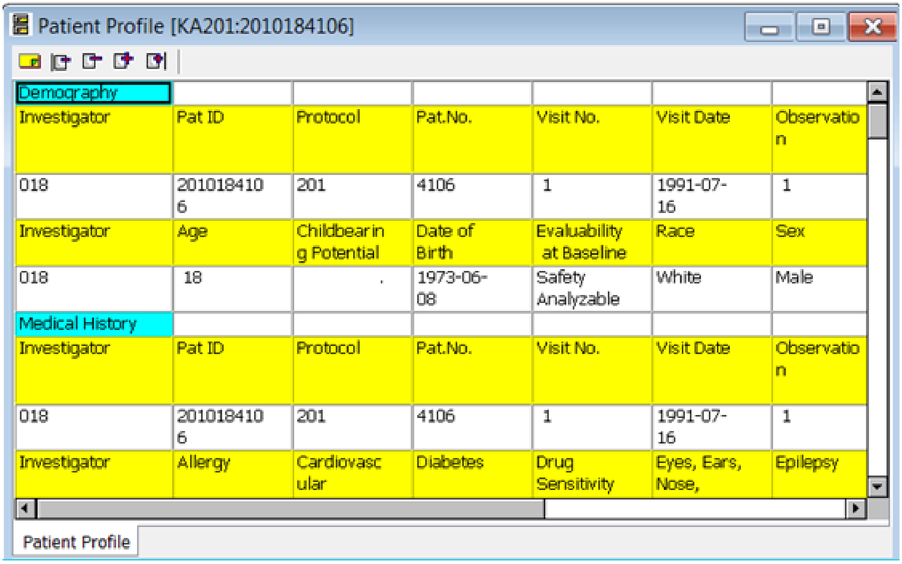
Visit Representation
● By Row
○ By Column
○ Customized

Workbook Generated
○ Multiple Worksheets
● Single Worksheet

- ***By panel*** lists a single worksheet for all data for all panels included where there is data for the active patient. It will display in the order that has been defined and visits are sorted numerically.
- ***By visit*** lists a single worksheet for all data for all visits for the active patient. The visits are sorted numerically.

  Visit representation only pertains to data collected as multiple visits where there exists one observation per patient per visit. You select the display option by row where each row represents a visit or by column where each column represents a visit. This applies only when the worksheet is organized ***by panel***.

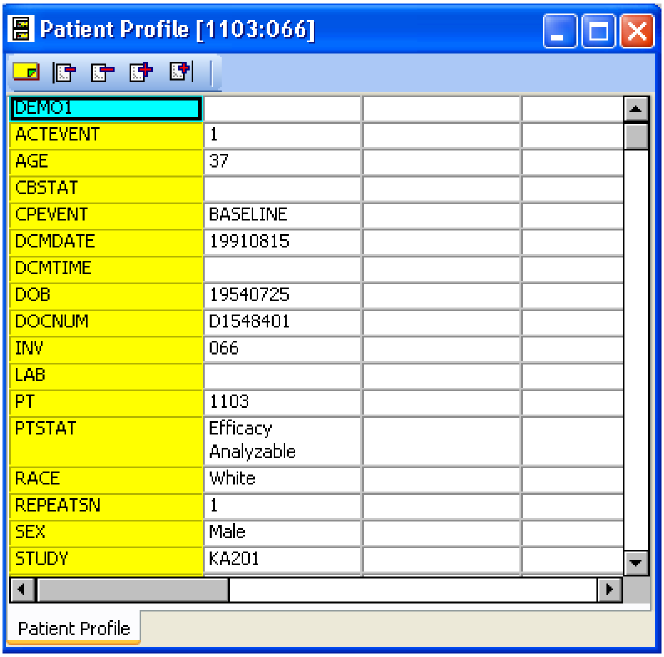
The example below shows the Patient Profiles Browser in single worksheet mode for the options ***by panel*** and visit representation as row.



Patient Profile [KA201:2010184106]

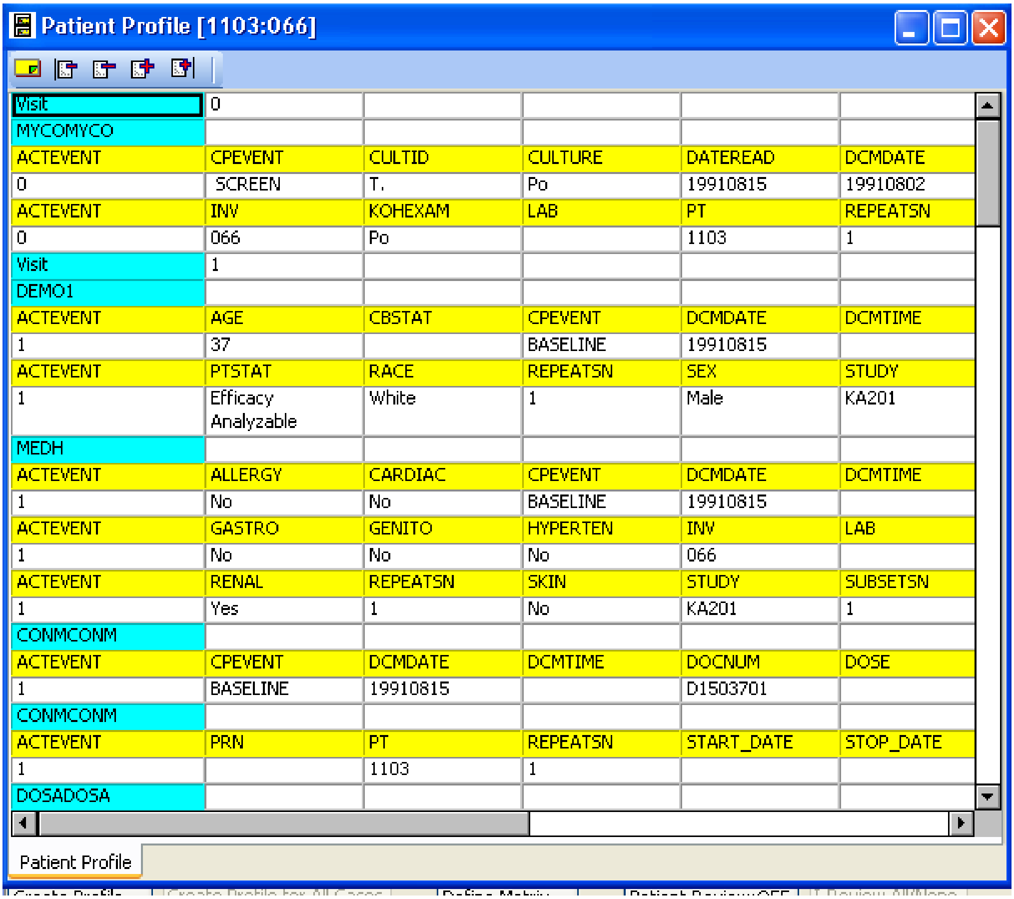
| | | | | | | |
|---|---|---|---|---|---|---|
| Demography | | | | | | |
| Investigator | Pat ID | Protocol | Pat.No. | Visit No. | Visit Date | Observation |
| 018 | 2010184106 | 201 | 4106 | 1 | 1991-07-16 | 1 |
| Investigator | Age | Childbearing Potential | Date of Birth | Evaluability at Baseline | Race | Sex |
| 018 | 18 | . | 1973-06-08 | Safety Analyzable | White | Male |
| Medical History | | | | | | |
| Investigator | Pat ID | Protocol | Pat.No. | Visit No. | Visit Date | Observation |
| 018 | 2010184106 | 201 | 4106 | 1 | 1991-07-16 | 1 |
| Investigator | Allergy | Cardiovascular | Diabetes | Drug Sensitivity | Eyes, Ears, Nose, | Epilepsy |

The next example shows the Patient Profiles Browser in single worksheet mode for the options ***by panel*** and visit representation as column.



| | | | |
|---|---|---|---|
| DEMO1 | | | |
| ACTEVENT | 1 | | |
| AGE | 37 | | |
| CBSTAT | | | |
| CPEVENT | BASELINE | | |
| DCMDATE | 19910815 | | |
| DCMTIME | | | |
| DOB | 19540725 | | |
| DOCNUM | D1548401 | | |
| INV | 066 | | |
| LAB | | | |
| PT | 1103 | | |
| PTSTAT | Efficacy Analyzable | | |
| RACE | White | | |
| REPEATSN | 1 | | |
| SEX | Male | | |
| STUDY | KA201 | | |

This example shows the Patient Profiles Browser in single worksheet mode ***by visit***.



| | | | | | |
|---|---|---|---|---|---|
| Visit | 0 | | | | |
| MYCOMYCO | | | | | |
| ACTEVENT | CPEVENT | CULTID | CULTURE | DATEREAD | DCMDATE |
| 0 | SCREEN | T. | Po | 19910815 | 19910802 |
| ACTEVENT | INV | KOHEXAM | LAB | PT | REPEATSN |
| 0 | 066 | Po | | 1103 | 1 |
| Visit | 1 | | | | |
| DEMO1 | | | | | |
| ACTEVENT | AGE | CBSTAT | CPEVENT | DCMDATE | DCMTIME |
| 1 | 37 | | BASELINE | 19910815 | |
| ACTEVENT | PTSTAT | RACE | REPEATSN | SEX | STUDY |
| 1 | Efficacy Analyzable | White | 1 | Male | KA201 |
| MEDH | | | | | |
| ACTEVENT | ALLERGY | CARDIAC | CPEVENT | DCMDATE | DCMTIME |
| 1 | No | No | BASELINE | 19910815 | |
| ACTEVENT | GASTRO | GENITO | HYPERTEN | INV | LAB |
| 1 | No | No | No | 066 | |
| ACTEVENT | RENAL | REPEATSN | SKIN | STUDY | SUBSETSN |
| 1 | Yes | 1 | No | KA201 | 1 |
| CONMCONM | | | | | |
| ACTEVENT | CPEVENT | DCMDATE | DCMTIME | DOCNUM | DOSE |
| 1 | BASELINE | 19910815 | | D1503701 | |
| CONMCONM | | | | | |
| ACTEVENT | PRN | PT | REPEATSN | START_DATE | STOP_DATE |
| 1 | | 1103 | 1 | | |
| DOSADOSA | | | | | |

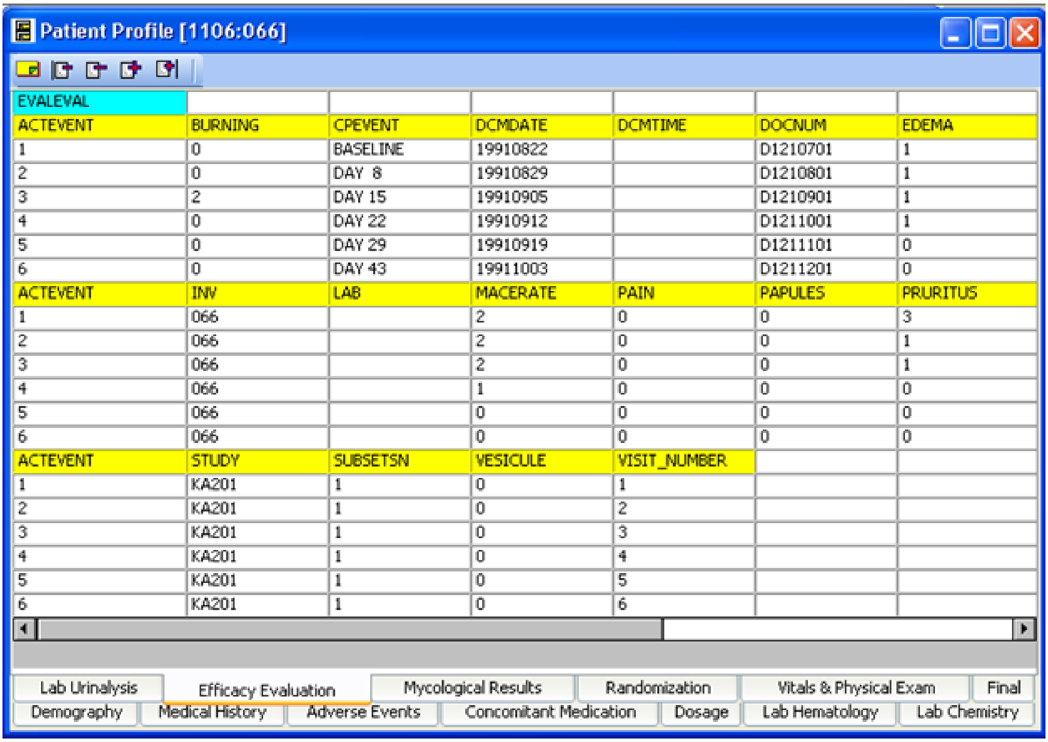
## Multiple worksheet mode

The multiple worksheet mode can be organized by panel or visit.

- By panel creates separate worksheets for each panel that has been included and there is data for the active patient. It will display in the order that has been defined.
- By visit creates separate worksheets for each visit that has been included and there is data for the active patient. It will display in the order that has been defined.

This example shows the Patient Profiles Browser in multiple worksheet mode for the options ***by panel*** and visit representation as row.

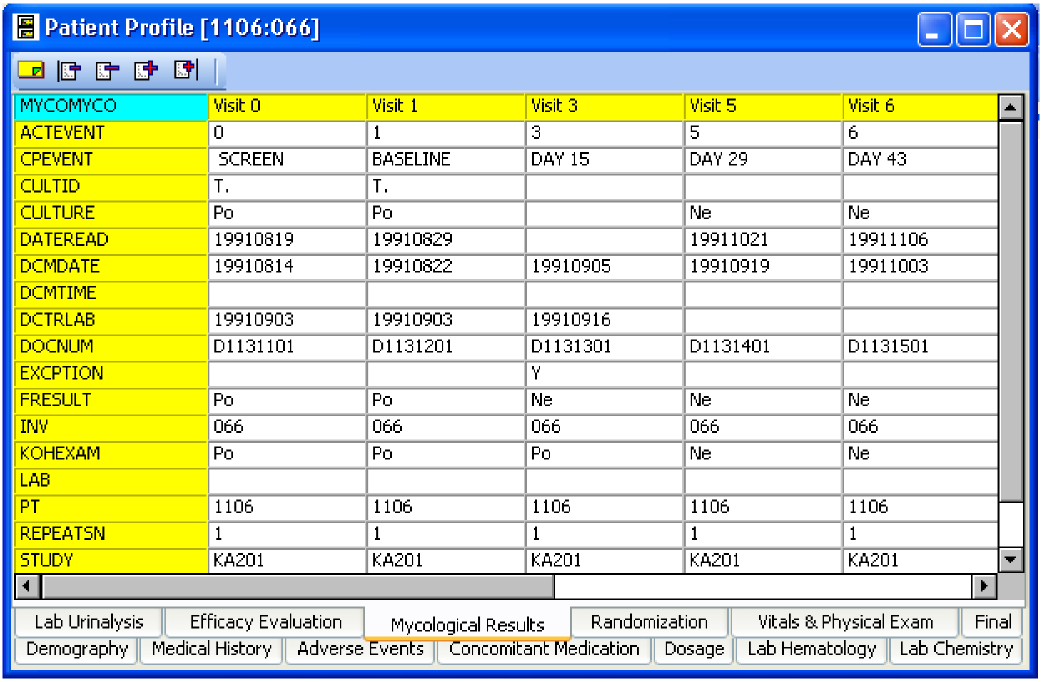
This option displays the tabs organized by panel label



| | | | | | | |
|---|---|---|---|---|---|---|
| EVALEVAL | | | | | | |
| ACTEVENT | BURNING | CPEVENT | DCMDATE | DCMTIME | DOCNUM | EDEMA |
| 1 | 0 | BASELINE | 19910822 | | D1210701 | 1 |
| 2 | 0 | DAY 8 | 19910829 | | D1210801 | 1 |
| 3 | 2 | DAY 15 | 19910905 | | D1210901 | 1 |
| 4 | 0 | DAY 22 | 19910912 | | D1211001 | 1 |
| 5 | 0 | DAY 29 | 19910919 | | D1211101 | 0 |
| 6 | 0 | DAY 43 | 19911003 | | D1211201 | 0 |
| ACTEVENT | INV | LAB | MACERATE | PAIN | PAPULES | PRURITUS |
| 1 | 066 | | 2 | 0 | 0 | 3 |
| 2 | 066 | | 2 | 0 | 0 | 1 |
| 3 | 066 | | 2 | 0 | 0 | 1 |
| 4 | 066 | | 1 | 0 | 0 | 0 |
| 5 | 066 | | 0 | 0 | 0 | 0 |
| 6 | 066 | | 0 | 0 | 0 | 0 |
| ACTEVENT | STUDY | SUBSETSN | VESICULE | VISIT_NUMBER | | |
| 1 | KA201 | 1 | 0 | 1 | | |
| 2 | KA201 | 1 | 0 | 2 | | |
| 3 | KA201 | 1 | 0 | 3 | | |
| 4 | KA201 | 1 | 0 | 4 | | |
| 5 | KA201 | 1 | 0 | 5 | | |
| 6 | KA201 | 1 | 0 | 6 | | |

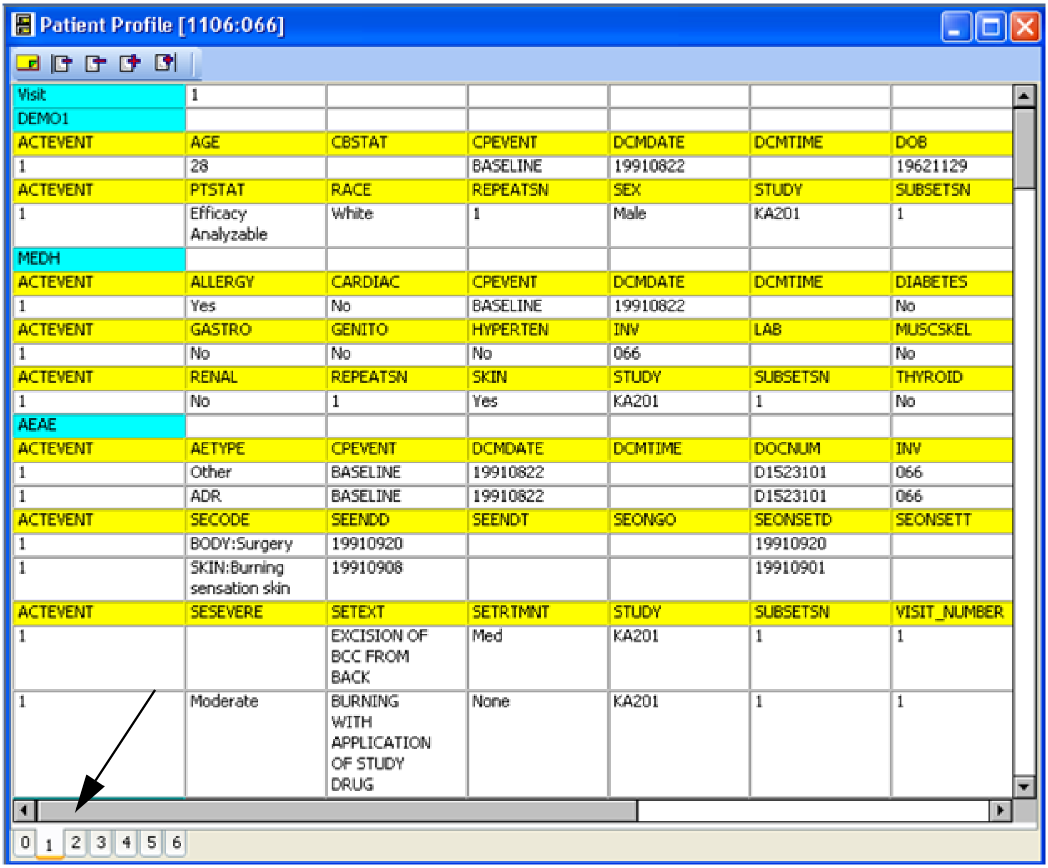
The next example shows the Patient Profiles Browser in multiple worksheet mode for the options ***by panel*** and visit representation as column.

The tabs are also organized by panel description.



| MYCOMYCO | Visit 0 | Visit 1 | Visit 3 | Visit 5 | Visit 6 |
|---|---|---|---|---|---|
| ACTEVENT | 0 | 1 | 3 | 5 | 6 |
| CPEVENT | SCREEN | BASELINE | DAY 15 | DAY 29 | DAY 43 |
| CULTID | T. | T. | | | |
| CULTURE | Po | Po | | Ne | Ne |
| DATEREAD | 19910819 | 19910829 | | 19911021 | 19911106 |
| DCMDATE | 19910814 | 19910822 | 19910905 | 19910919 | 19911003 |
| DCMTIME | | | | | |
| DCTRLAB | 19910903 | 19910903 | 19910916 | | |
| DOCNUM | D1131101 | D1131201 | D1131301 | D1131401 | D1131501 |
| EXCPTION | | | Y | | |
| FRESULT | Po | Po | Ne | Ne | Ne |
| INV | 066 | 066 | 066 | 066 | 066 |
| KOHEXAM | Po | Po | Po | Ne | Ne |
| LAB | | | | | |
| PT | 1106 | 1106 | 1106 | 1106 | 1106 |
| REPEATSN | 1 | 1 | 1 | 1 | 1 |
| STUDY | KA201 | KA201 | KA201 | KA201 | KA201 |

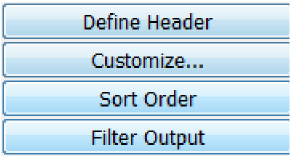
This example shows the Patient Profiles Browser in multiple worksheet mode for the options ***by visit***. The tabs are sequenced by visit number.



| | | | | | | |
|---|---|---|---|---|---|---|
| Visit | 1 | | | | | |
| DEMO1 | | | | | | |
| ACTEVENT | AGE | CBSTAT | CPEVENT | DCMDATE | DCMTIME | DOB |
| 1 | 28 | | BASELINE | 19910822 | | 19621129 |
| ACTEVENT | PTSTAT | RACE | REPEATSN | SEX | STUDY | SUBSETSN |
| 1 | Efficacy Analyzable | White | 1 | Male | KA201 | 1 |
| MEDH | | | | | | |
| ACTEVENT | ALLERGY | CARDIAC | CPEVENT | DCMDATE | DCMTIME | DIABETES |
| 1 | Yes | No | BASELINE | 19910822 | | No |
| ACTEVENT | GASTRO | GENITO | HYPERTEN | INV | LAB | MUSCSKEL |
| 1 | No | No | No | 066 | | No |
| ACTEVENT | RENAL | REPEATSN | SKIN | STUDY | SUBSETSN | THYROID |
| 1 | No | 1 | Yes | KA201 | 1 | No |
| AEAE | | | | | | |
| ACTEVENT | AETYPE | CPEVENT | DCMDATE | DCMTIME | DOCNUM | INV |
| 1 | Other | BASELINE | 19910822 | | D1523101 | 066 |
| 1 | ADR | BASELINE | 19910822 | | D1523101 | 066 |
| ACTEVENT | SECODE | SEENDD | SEENDT | SEONGO | SEONSETD | SEONSETT |
| 1 | BODY:Surgery | 19910920 | | | 19910920 | |
| 1 | SKIN:Burning sensation skin | 19910908 | | | 19910901 | |
| ACTEVENT | SESEVERE | SETEXT | SETRTMNT | STUDY | SUBSETSN | VISIT_NUMBER |
| 1 | | EXCISION OF BCC FROM BACK | Med | KA201 | 1 | 1 |
| 1 | Moderate | BURNING WITH APPLICATION OF STUDY DRUG | None | KA201 | 1 | 1 |

## *Modify profile*

The profile content and appearance can additionally be modified with the following functions:



When defining the profile content you may define a header from all the patient related panels types (not foreign or pivot) that are one observation per patient. The defined header information will appear only once at the top in the single worksheet mode. In the multiple worksheet mode, it will display at the top of each worksheet whether organized by panel or visit.

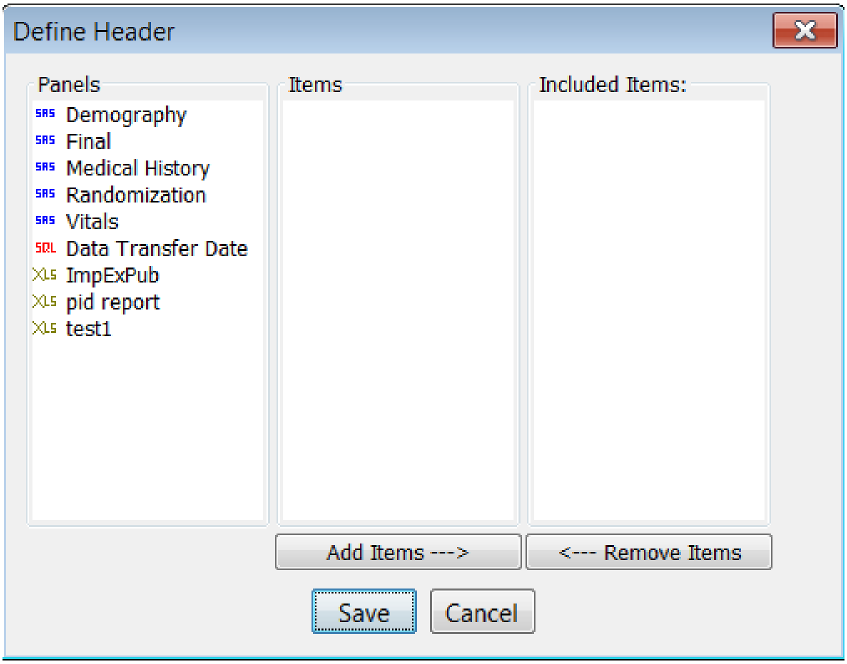
**Sort Order** is available for **Organized by Panel**. It is disabled for Organized by Visit.

## *Define Header*

Click **Define Header** to open the Header Definition window which lists all the patient related panels types (not foreign or pivot) that are one observation per patient. You can select up to nine items from the listed panels by using the add item button and multiple items can be selected.

1. Click **Define Header** from the Patient Profiles Browser window.
2. Select a panel.
3. Select the items from the various panels to add as header information. Use the **Add Items** and **Remove Items** buttons to include or remove items from the header definition. As a short cut, you can double click on the individual items to add them or highlight multiple items to add or remove.

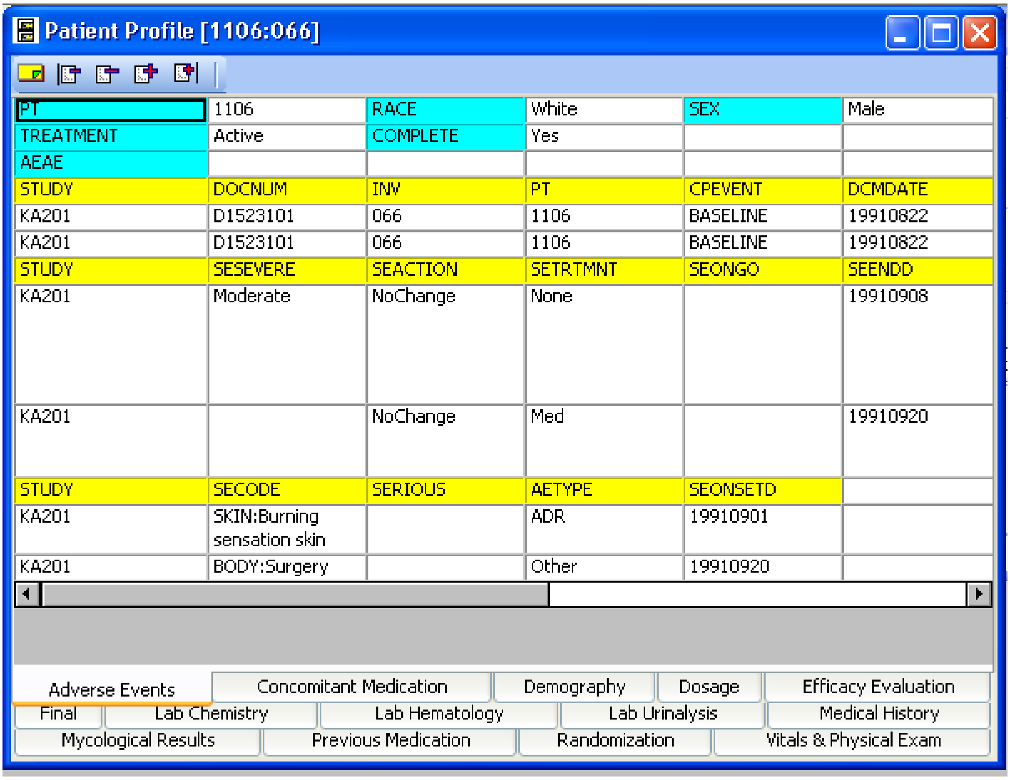
4. Use the drag and drop to change the order that the items are displayed.



5. Click **Save Header** and close window. The Patient Profiles Browser window will show the status of the button changed to '**Header is Defined**'.

6. Select a patient from the patient list and click **Create Profile**.

   Once a patient profile is created and displayed, you can change the active patient selected and the patient profile will be updated. However, if you choose to modify any of the display options while the patient profile display window is open the profile will not be updated.

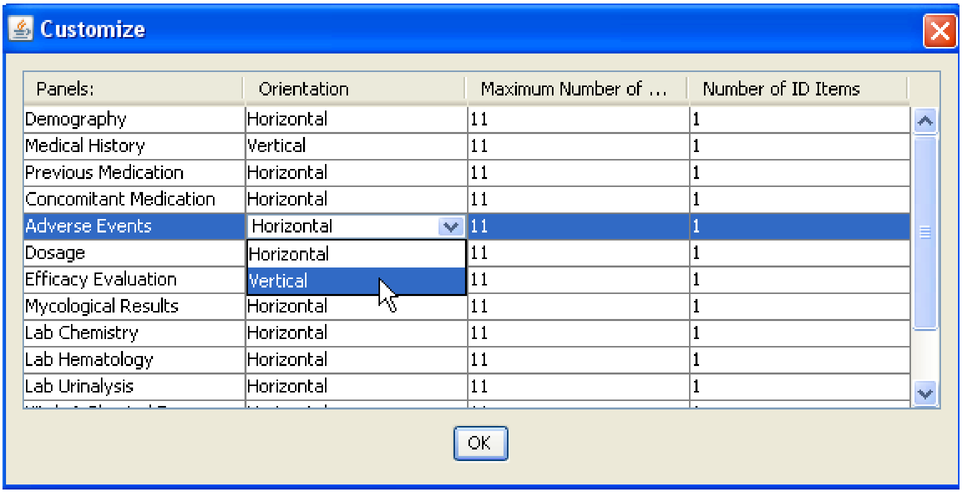


| | | | | | |
|---|---|---|---|---|---|
| PT | 1106 | RACE | White | SEX | Male |
| TREATMENT | Active | COMPLETE | Yes | | |
| AEAE | | | | | |
| STUDY | DOCNUM | INV | PT | CPEVENT | DCMDATE |
| KA201 | D1523101 | 066 | 1106 | BASELINE | 19910822 |
| KA201 | D1523101 | 066 | 1106 | BASELINE | 19910822 |
| STUDY | SESEVERE | SEACTION | SETRTMNT | SEONGO | SEENDD |
| KA201 | Moderate | NoChange | None | | 19910908 |
| KA201 | | NoChange | Med | | 19910920 |
| STUDY | SECODE | SERIOUS | AETYPE | SEONSETD | |
| KA201 | SKIN:Burning sensation skin | | ADR | 19910901 | |
| KA201 | BODY:Surgery | | Other | 19910920 | |

## *Customize output*

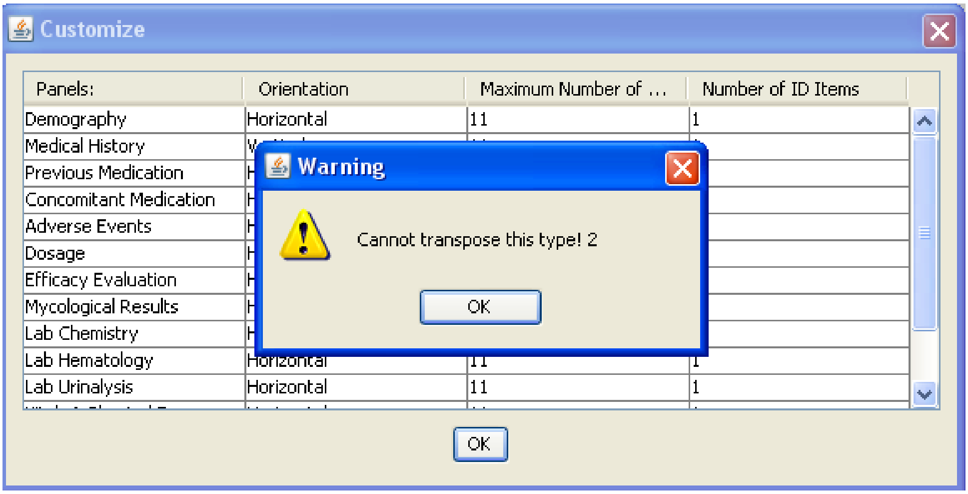
You can make changes on a individual panel basis to panel options regarding display orientation, maximum number of columns and number of ID items.

1. Click **Customize** to view the default settings.
2. Click on the panel cell for **Orientation** to access the drop down list to select horizontal or vertical.



| Panels: | Orientation | Maximum Number of ... | Number of ID Items |
|---|---|---|---|
| Demography | Horizontal | 11 | 1 |
| Medical History | Vertical | 11 | 1 |
| Previous Medication | Horizontal | 11 | 1 |
| Concomitant Medication | Horizontal | 11 | 1 |
| Adverse Events | Horizontal | 11 | 1 |
| Dosage | Horizontal | 11 | 1 |
| Efficacy Evaluation | Vertical | 11 | 1 |
| Mycological Results | Horizontal | 11 | 1 |
| Lab Chemistry | Horizontal | 11 | 1 |
| Lab Hematology | Horizontal | 11 | 1 |
| Lab Urinalysis | Horizontal | 11 | 1 |

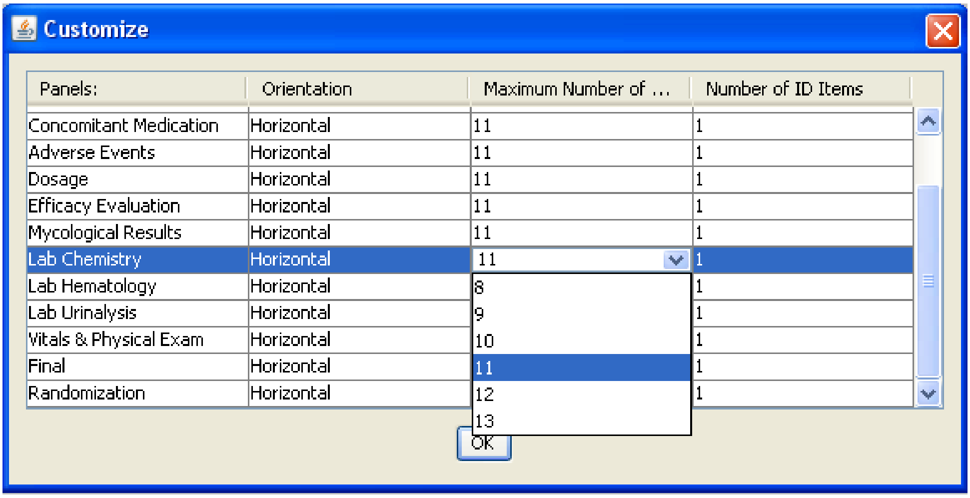
If the panel orientation cannot be changed than the following message displays.



| Panels: | Orientation | Maximum Number of ... | Number of ID Items |
|---|---|---|---|
| Demography | Horizontal | 11 | 1 |
| Medical History | V | | |
| Previous Medication | H | | |
| Concomitant Medication | H | | |
| Adverse Events | H | | |
| Dosage | H | | |
| Efficacy Evaluation | H | | |
| Mycological Results | H | | |
| Lab Chemistry | H | | |
| Lab Hematology | Horizontal | 11 | 1 |
| Lab Urinalysis | Horizontal | 11 | 1 |

Cannot transpose this type! 2

3. Click on the panel cell for **Maximum Number of Columns** to access the drop down list. The maximum number of columns displayed per row can also be changed within the range for 8 through 13.



| Panels: | Orientation | Maximum Number of ... | Number of ID Items |
|---|---|---|---|
| Concomitant Medication | Horizontal | 11 | 1 |
| Adverse Events | Horizontal | 11 | 1 |
| Dosage | Horizontal | 11 | 1 |
| Efficacy Evaluation | Horizontal | 11 | 1 |
| Mycological Results | Horizontal | 11 | 1 |
| Lab Chemistry | Horizontal | 11 | 1 |
| Lab Hematology | Horizontal | | 1 |
| Lab Urinalysis | Horizontal | | 1 |
| Vitals & Physical Exam | Horizontal | | 1 |
| Final | Horizontal | | 1 |
| Randomization | Horizontal | | 1 |

4. Click on the panel cell for **Number of ID Items**. The option to display ID items as represented by the PatientNo and VisitNo are also selected from a drop down list for choices are 0, 1 and 2.

   If a panel row wraps beyond the maximum number of columns defined, you can repeat the display of ‘1’ or ‘2’ ID items onto the next row. If you select ‘0’ ID items then only the initial row contains ID items.

5. Click **OK** to save changes.

## *No Wrap option*

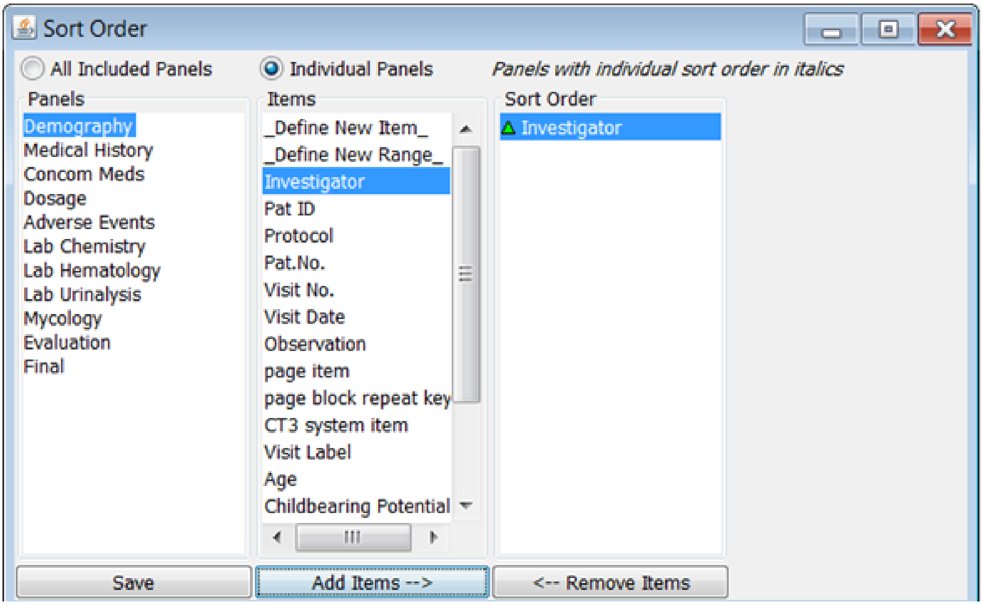
This feature is intended for Workbook Patient Profile to Suppress Paging and Filters/Sorting on Multiple worksheets outputs.

This **No Wrap option** for WPP's is specific to support printing and **must** be done from Excel and **not** within JReview.

If the checkbox is selected, the Headers and Column Headers will not repeat and the columns will not wrap. This is ***not implemented*** for filtering or sorting. This option is best observed in create a multi-sheet WPP by Panel. Then **export** it to Excel for the filtering and sorting functionality.

## *Sort Order*

Click **Sort Order** to open the Profile Sort window. It is advised to define all areas of the profile prior to defining the sort. When you apply any sort options they are applied within the individual patient profile. Sort Order can be applied to **All Included Panels** or **Individual Panels**.



- The **All Included Panels** option allows you to define a sort order on those items present in all the included panels. This option will apply the sort order across all panels in the Patient Profile.

  ***Note: When a profile is organized by visit the user does not have the option to sort panels by any other items. The Sort Order button is shaded and disabled.***

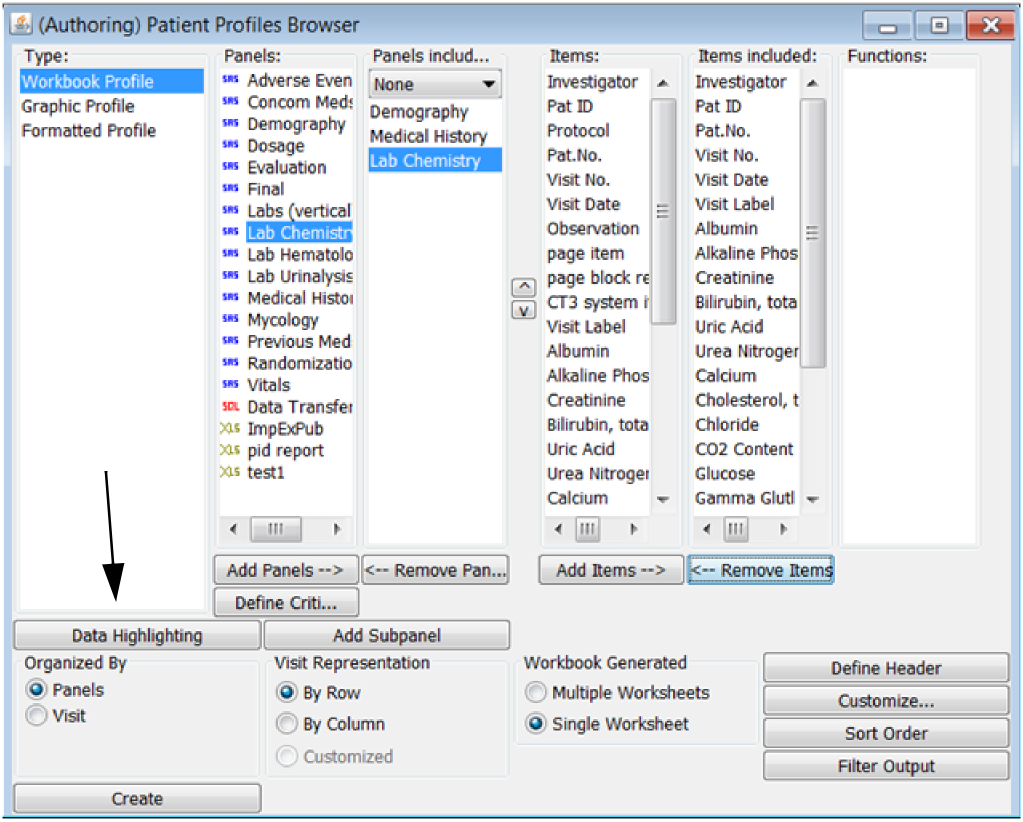
- The **Individual Panels** option allows you to define a sort order based on specific panels and items. This option will apply the sort order across to specific panels.
- For each individual panel selected and a sort option entered, an asterisk displays next to the panel name flagging the panel has an active sort option.
- An item can be removed or added to the sort order with the **Add Item** and **Remove Item** buttons.
- When you select multiple items the sort order can be changed by using drag and drop.
- Double-click on an item to change ascending versus descending sort.

## *Conditional Data Highlighting*

The Patient Profiles (Workbook and Formatted) can have specific cells or rows highlighted in specified colors based on values out of range, or comparison between cells of the same row.  This is similar to the functionality that's built into Detail Reports and Formatted Detail Reports **except patient profiles do not support Vertical to Horizontal panel types (HRZ).**

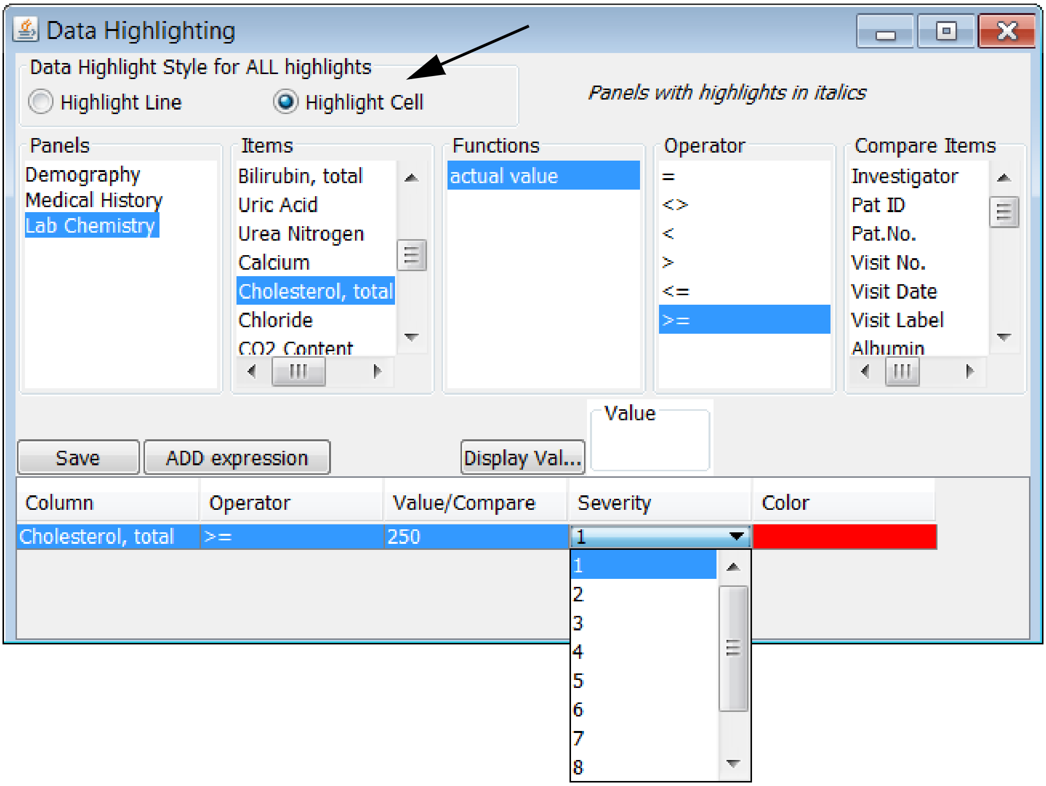
***(See Chapter 6: Report Browser - Conditional Data Highlighting)***

After adding items to the patient profile specification, click the **Data Highlighting** button.



The **Data Highlighting window** opens which looks and operates similar to the output filter window.

Enter the data lighting filter expression and assign the Severity numeric value with the drop down list for values 1 through 10.  Assign a corresponding color with a drop down list.



Data Highlight Style for ALL highlights

○ Highlight Line ● Highlight Cell

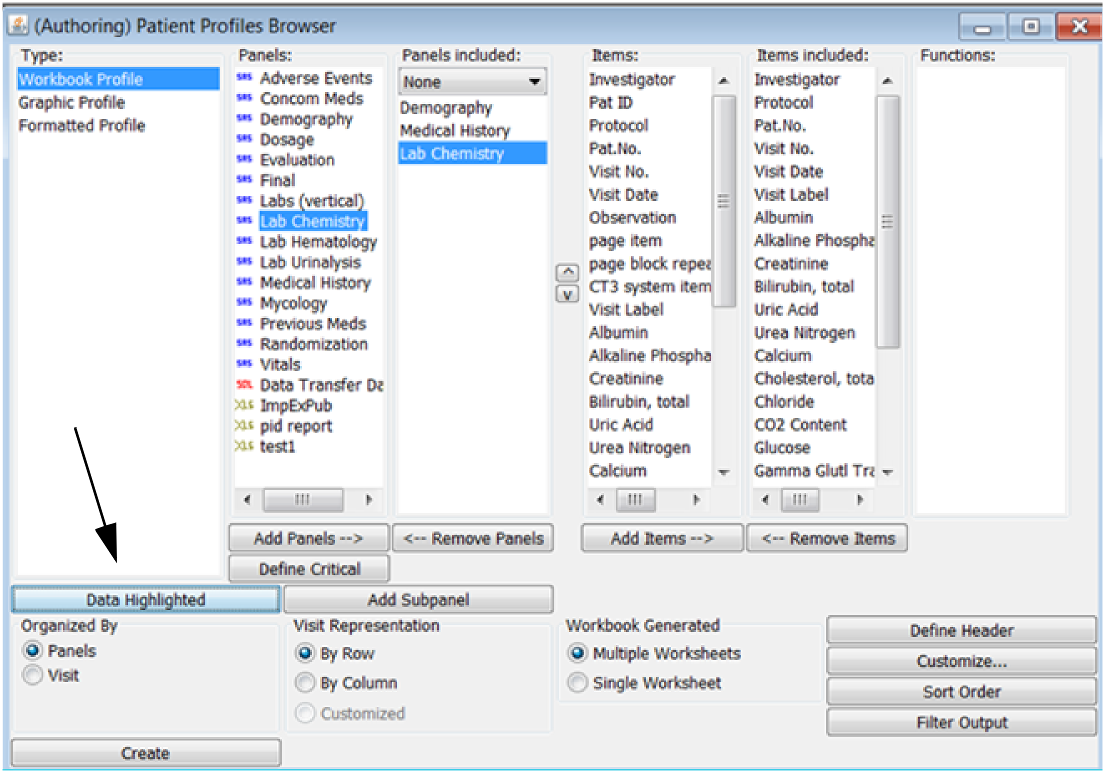
*Panels with highlights in italics*

| Column | Operator | Value/Compare | Severity | Color |
|---|---|---|---|---|
| Cholesterol, total | >= | 250 | 1 | 🟥 |

Select to **Highlight Line** or **Highlight Cell** in the patient profile**,** then click **Save**.

*Note:* ***Date items are not supported in Data Highlighting definitions.***

When the Data Highlighting definition is saved the button status changes to Data Highlighted.

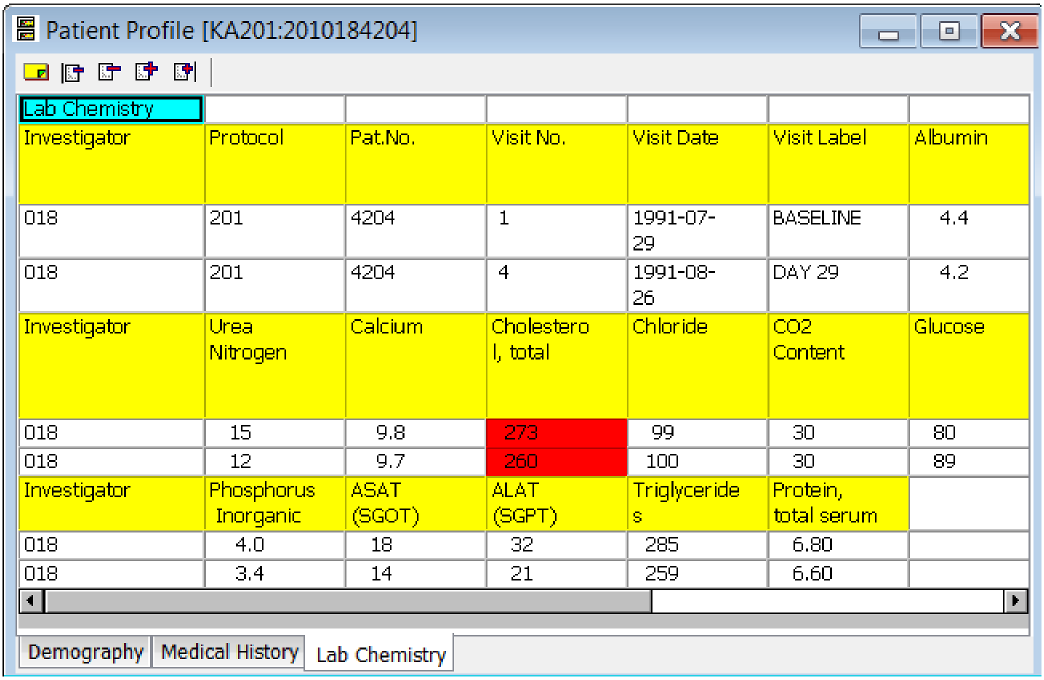


Organized By
● Panels
○ Visit

Visit Representation
● By Row
○ By Column
○ Customized

Workbook Generated
● Multiple Worksheets
○ Single Worksheet

Select a patient and click **Create Profile.** The patient profile displays with the option set to Highlight Cell.



| | | | | | | |
|---|---|---|---|---|---|---|
| Lab Chemistry | | | | | | |
| Investigator | Protocol | Pat.No. | Visit No. | Visit Date | Visit Label | Albumin |
| 018 | 201 | 4204 | 1 | 1991-07-29 | BASELINE | 4.4 |
| 018 | 201 | 4204 | 4 | 1991-08-26 | DAY 29 | 4.2 |
| Investigator | Urea Nitrogen | Calcium | Cholesterol, total | Chloride | CO2 Content | Glucose |
| 018 | 15 | 9.8 | 273 | 99 | 30 | 80 |
| 018 | 12 | 9.7 | 260 | 100 | 30 | 89 |
| Investigator | Phosphorus Inorganic | ASAT (SGOT) | ALAT (SGPT) | Triglycerides | Protein, total serum | |
| 018 | 4.0 | 18 | 32 | 285 | 6.80 | |
| 018 | 3.4 | 14 | 21 | 259 | 6.60 | |

# Filter Output

## *Patient Profile Filter Output*

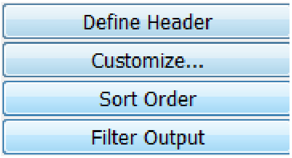
After you define the specifications of your patient profile, you can use the Filter Output as a data exploration tool by filtering data inclusion, then comparing filtered and unfiltered results.

Filter Output works in the Patient Profiles (both workbook and graphic) where only included panels (or panels behind included graphic categories) are viewable and selectable for filtering in the Filter Output window. So if you did not include any panels/categories in your graphic profile, even if they are defined in your template, you would see nothing in the Filter Output window.

The reason behind this is that in a patient profile, each panel is displayed individually and is not joined with any other panel. Therefore, filtering criteria from any other panel would not apply to a panel used in profiles.

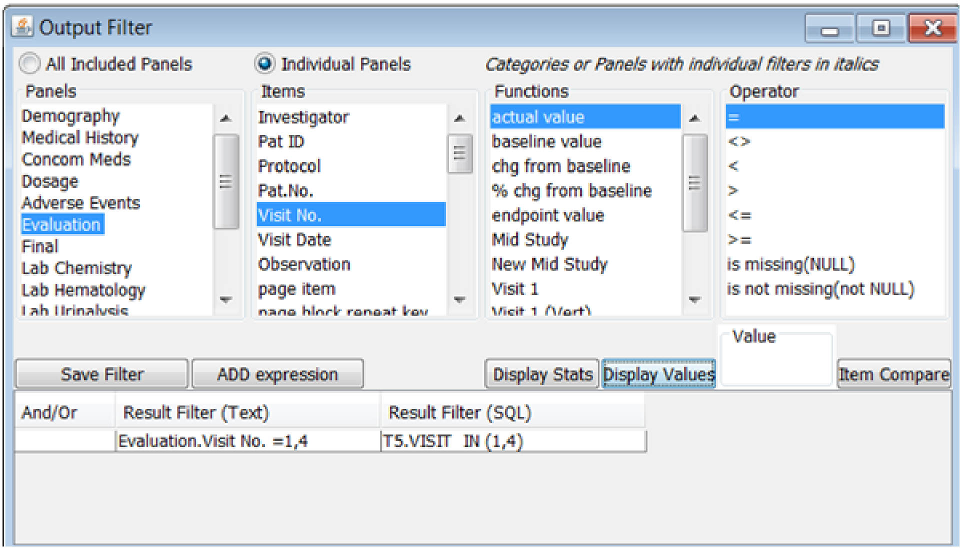
The only exception to this is in Graphic profiles when a category is defined by more than one panel (i.e. dosage and treatment). In this case, both these panels will appear in the Filter Output window and filtering criteria from one panel would affect the other panel.

1. Click the **Filter Output button** in the Patient Profiles Browser window. The Output Filter window opens.



2. The **All Included Panels** option allows you to define an output filter based on those items present in all the included panels. This option will apply the output filter across all panels in the Patient Profile.

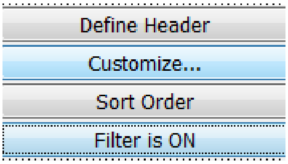
3. The **Individual Panels** option allows you to define an output filter based on specific panels and items.



○ All Included Panels ● Individual Panels

| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | Evaluation.Visit No. =1,4 | T5.VISIT IN (1,4) |

4. Click **Save Filter.** The **Filter Output** button in the Patient Profiles Browser window toggles to **Filter is ON**. The output filter is applied to the patient profile when you click **Create Profile**.



The panel names displays in italic, flagging the panel has an active output filter entered in the Filter Output window.

5. To **Remove** the output filter, open the Output Filter window to clear and resave for All Included Panels option. When Individual Panels option then the panel name will display in italics, so you know which individual panels have an output filter applied.

# Patient Profile Review Tracking Tool

## *Patient Tracking functions*

The Patient Profile Review Tracking Tool is designed to meet the users requirement to track which patients were reviewed by userid, date/time stamp and the review status assigned by the user. Other users may view this detailed information for tracking and reporting purposes.

The entire function is enabled within the PATPROREVIEW option in the ReviewAdmin configuration and controls user access of the function. There are three privilege settings defined within the options:

1. **View Patient Tracking** – Allows access to view the patient review status in the patient profile browser as well as access to view the detailed Patient Log. It does not allow access to update the patient review status.
2. **Update Patient Tracking** – Allows access to update the patient review tracking and view the detailed Patient Log.
3. **Define Critical Panels and Items -** Allows the user to define panels and items with a critical status.

***Note: It is highly recommended to subset the patient population when using the Patient Profile Review Tracking functions. The status updating for individual patients and checking for new data may affect response time.***

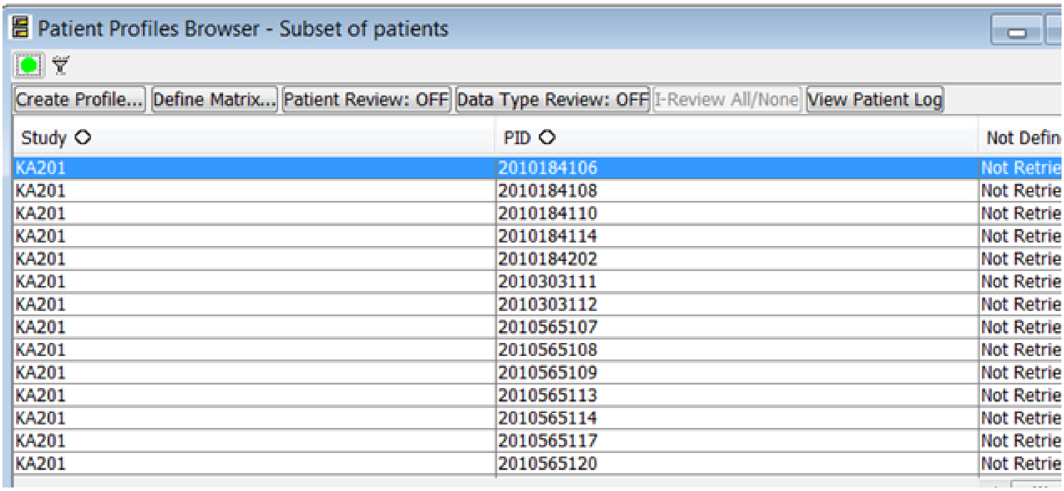
ReviewAdmin allows the site to configure the Patient Profile Review Tracking window for column content and sort order. The Review default settings are turned ON for “Review Level” and “Review Info” when the function is enabled.

The required column in the Patient Profile Review Tracking window is the “IReviewed” column. Additional columns are available when the Patient Review is turned ON. The configurations for this option are defined in ReviewAdmin where the administrator has the ability to set Yes or No, for the additional columns when Patient Review is turned ON.

These other columns can be included or not – Review Level, Review Info, Color Coding, and Comment. The system has sort numbers defined for each column display option, so the column can be sorted.

If the user has access to either View Patient Tracking or Update Patient Tracking then the Patient Review and View Patient Log buttons are displayed on the patient profile browser window. The Patient Review button defaults to OFF.

Additionally, ReviewAdmin has the option to automatically default Patient Review to ON for users with access. It skips the step to click the Patient Review button each time the function is opened.



| Study | PID | Not Defin |
|---|---|---|
| KA201 | 2010184106 | Not Retrie |
| KA201 | 2010184108 | Not Retrie |
| KA201 | 2010184110 | Not Retrie |
| KA201 | 2010184114 | Not Retrie |
| KA201 | 2010184202 | Not Retrie |
| KA201 | 2010303111 | Not Retrie |
| KA201 | 2010303112 | Not Retrie |
| KA201 | 2010565107 | Not Retrie |
| KA201 | 2010565108 | Not Retrie |
| KA201 | 2010565109 | Not Retrie |
| KA201 | 2010565113 | Not Retrie |
| KA201 | 2010565114 | Not Retrie |
| KA201 | 2010565117 | Not Retrie |
| KA201 | 2010565120 | Not Retrie |

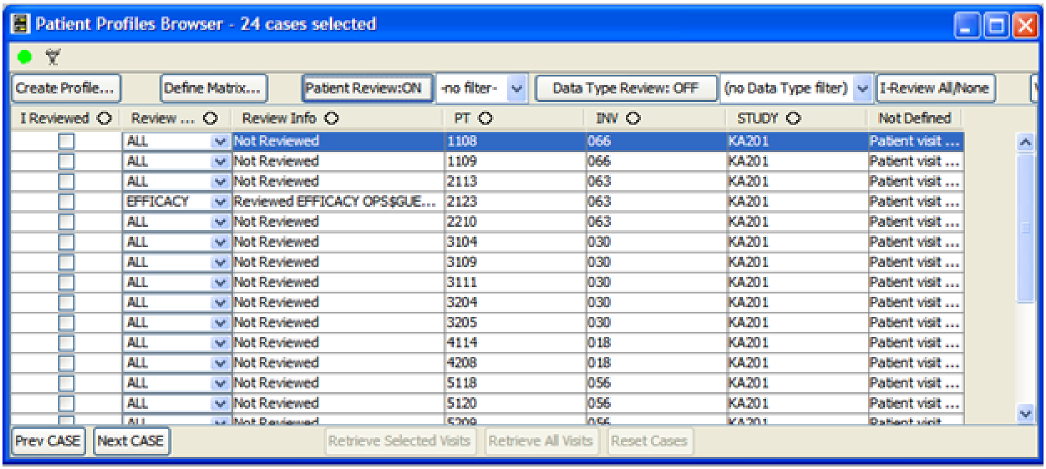
If the user does not have access to update the patient tracking status but is allowed to view the current patient review status; the Review Information column displays when the user clicks the Patient Review button ON.

## *Patient Review Levels*

The **Review Information** column shows the current review status with review level, userid and date time stamp of last activity. The Review Levels are:

- **Not Reviewed** - The initial review status for patient data that has never been reviewed by a user.
- **Reviewed** - The user had checked the "I Reviewed" checkbox to update the patient review status and selected a Review Level for "All" or "Critical". The userid with the data time stamp is displayed.
- **Reviewed (New Data)** - The patient data was previously reviewed however new data has been added or changed since the last review occurred.

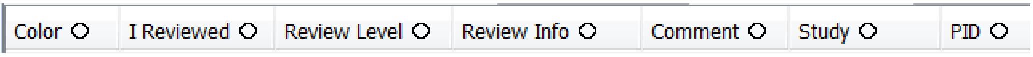
When a user with access to update patient tracking status clicks the Patient Review button ON, the "I Reviewed" and "Review Level" columns display populated with the current patient review status.



| I Reviewed | Review ... | Review Info | PT | INV | STUDY | Not Defined |
|---|---|---|---|---|---|---|
| ☐ | ALL | Not Reviewed | 1108 | 066 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 1109 | 066 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 2113 | 063 | KA201 | Patient visit ... |
| ☐ | EFFICACY | Reviewed EFFICACY OPS$GUE... | 2123 | 063 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 2210 | 063 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 3104 | 030 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 3109 | 030 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 3111 | 030 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 3204 | 030 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 3205 | 030 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 4114 | 018 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 4208 | 018 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 5118 | 056 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 5120 | 056 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 5209 | 056 | KA201 | Patient visit |

## *Sort columns*

You may select and sort any column in the Patient Review Tracking window where the header contains the corresponding **column symbol** <> next to the description.



1. Click on the **column symbol** <> to change from descending, ascending or return to original display sort.
2. Click on the **column symbol** <> and the green up triangle changes the selected column sort to ascending order.
3. Click on the **column symbol** <> and the red down triangle changes the selected column sort to descending order.

## *Define Critical*

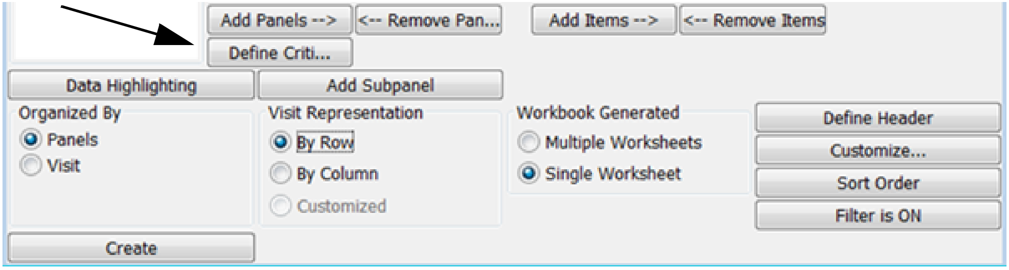
The user privilege to define specific panels or data items as critical enables access for high priority review and to automatically add critical panels/items to a patient profile. When critical panels and items are defined a table is created in ReviewAdmin marked as “Critical”.

The user privilege to define critical panels and items is set in ReviewAdmin allowing the user access to the **_Define Critical_** function in patient profiles. When critical panels and items are defined then all users have access to select them to create patient profiles. The Panels Included drop down list box contains None, All and all defined critical panels/items, for example:

- Critical: Study Level,
- Critical: StudyGroup Level,
- Critical: Project Level,
- Critical: Global Level.

***Warning: You may generate an error if you include user defined Foreign Panels, Pivot Panels or Import SQL in your patient profile. The highlighting feature relies on specific data fields in Oracle Clinical and Clintrial for date time stamp to determine if new data has occurred. If these fields are missing in the included panel then an error is generated.***

If the PATPROEMPTY option in ReviewAdmin is set, then the drop down list box displays as “None” and no panels are listed. When the patproempty option is not set, then the drop down list displays as “All” and all panels are included.

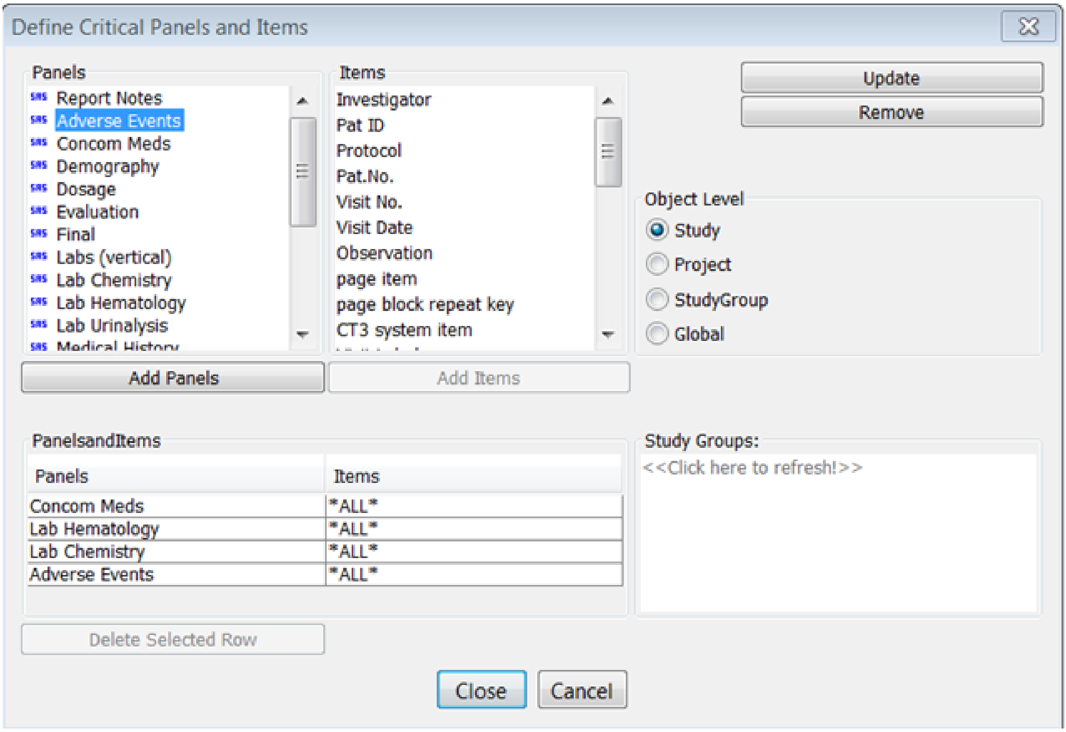


Organized By
● Panels
○ Visit

Visit Representation
● By Row
○ By Column
○ Customized

Workbook Generated
○ Multiple Worksheets
● Single Worksheet

1. Click on **Define Critical** button. The Define Critical window opens.
2. Select a panel and click **Add DCM/Question Groups** or select individual items and click **Add Questions**. The panels are added in alphabetic order and in the same order on the Panels Included drop down list box. Users may change the order in the Include list.



Object Level
● Study
○ Project
○ StudyGroup
○ Global

PanelsandItems

| Panels | Items |
|---|---|
| Concom Meds | *ALL* |
| Lab Hematology | *ALL* |
| Lab Chemistry | *ALL* |
| Adverse Events | *ALL* |

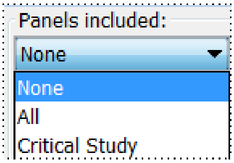
Study Groups:
<<Click here to refresh!>>

3. If you need to remove an added row, select the row and click **Delete Selected Row.**

   Select the **Object Level** to save panels or question groups. The critical panels and items can be saved at the Study, StudyGroup, Project or Global object levels.

   If you select StudyGroup as the object level you must also select a study group from the list box.

4. Click **Save**. The defined Critical Panels or Questions Groups are added to the Included drop down list box by the saved level.



5. Select the Critical Panel level for high priority review and to automatically add the panels/items to the patient profile.

   If you had selected “All” from the Panels Included list then all available panels and items are included in the patient profile.

6. Click **Create**. The Patient Profile Browser window displays the patient list for the selected patients.

7. Select a patient from the patient list, and click **Create Profile**. Only the Critical panels and items are displayed in the patient profile output.

8. Close the patient profile spreadsheet window. Next you can update the patient review tracking status.

## Update Patient Tracking Status

After you have completed your review of the patient data, you may update your review status for the selected patient. This patient review tracking feature is accessible across all the Patient Profile types.

The creation of a patient profile is not required or linked, to the Patient Profile Review Tracking function for entry of a patient review status. If the users within a department prefer to use a different output, such as a detail data listing for patient review; you may still select a patient from the patient list to update the patient review status, as an alternative tracking process.

The ***required column*** in the Patient Profile Review Tracking window is the "**IReviewed**" column, when the Patient Review is turned ON.

***Note: Always select the Review Level first before clicking the "I Reviewed" check box. This will avoid generating erroneous review level records, if you then go back and alter the review level.***

Additional columns are available and optional; Review Level, Review Info, Color Coding, and Comment. The system has sort numbers defined for each column display option, so the column can be ordered.

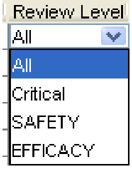
Patient Review Tracking retrieves all current state patient review tracking information from the PatientReview_LatestDates Table.

## Select review level

9. In the row for the selected patient; click the **Review Level** drop down list box to select the review level as "All" or "Critical".

   The option to select "Critical" will only display if Critical Panels are defined.

   Additional Review Level descriptions may be added through ReviewAdmin in PATPROREVIEWLEVELS for "Safety" or "Efficacy". Users would determine what panels and data they require for these review level descriptions.



10..Optionally add a comment when Patient Review is turned ON. Click in the comment to enter text and save the comment.

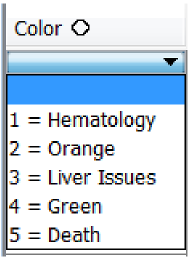
The configurations for the comments option is defined in ReviewAdmin. The comment field can be viewed in the ***patientpostit table***.

## *Color coding*

The Color options configurations are defined in ReviewAdmin. There are 5 default colors available – Red, Orange, Yellow, Green and Black where sort numbers defined for each color to sort on this column. The color field can be viewed in the ***patientpostit table***.

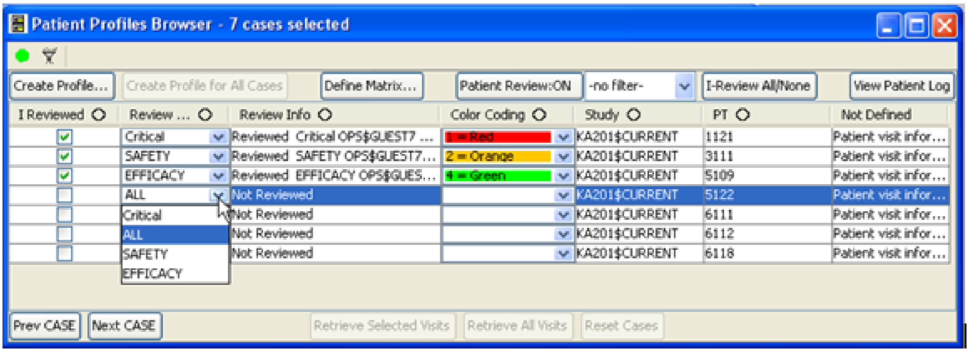
These color options can be defined by the site for review purposes. For example, Red may be associated with Hematology or Panic, Yellow for Renal or Warning and any other site preferred review labels.

11.In the row for the selected patient; click the **Color** drop down list box to select the color label.



12.Click the “**I Reviewed”** check box to log your userid, date time stamp and review level for the patient.

The patient review information is now tracked in the **Patient Log** as a detailed audit trail.



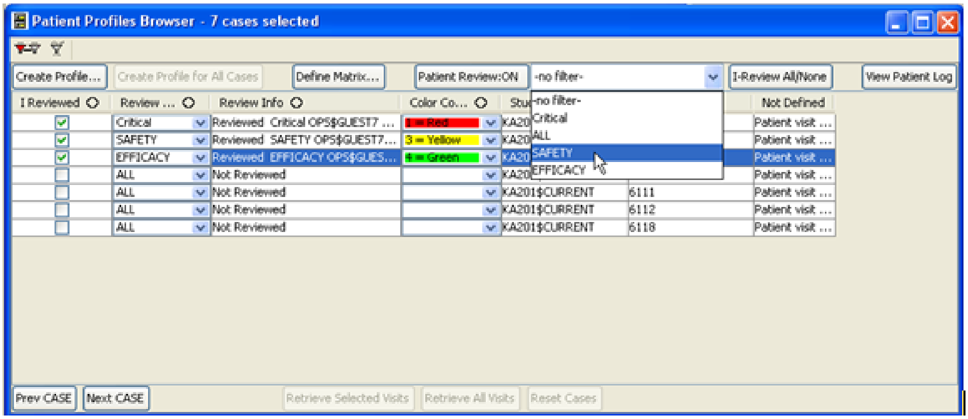
| I Reviewed ○ | Review ... ○ | Review Info ○ | Color Coding ○ | Study ○ | PT ○ | Not Defined |
|---|---|---|---|---|---|---|
| ☑ | Critical | Reviewed Critical OPS$GUEST7 ... | 1 = Red | KA201$CURRENT | 1121 | Patient visit infor... |
| ☑ | SAFETY | Reviewed SAFETY OPS$GUEST7... | 2 = Orange | KA201$CURRENT | 3111 | Patient visit infor... |
| ☑ | EFFICACY | Reviewed EFFICACY OPS$GUES... | 4 = Green | KA201$CURRENT | 5109 | Patient visit infor... |
| ☐ | ALL | Not Reviewed | | KA201$CURRENT | 5122 | Patient visit infor... |
| ☐ | | Not Reviewed | | KA201$CURRENT | 6111 | Patient visit infor... |
| ☐ | | Not Reviewed | | KA201$CURRENT | 6112 | Patient visit infor... |
| ☐ | | Not Reviewed | | KA201$CURRENT | 6118 | Patient visit infor... |

The “I Reviewed” checkbox and the Review Level only displays the current status if there is no new data and the user was the owner of the last patient “review” and it’s within the system defined time frame allowing the user to “uncheck” their review.

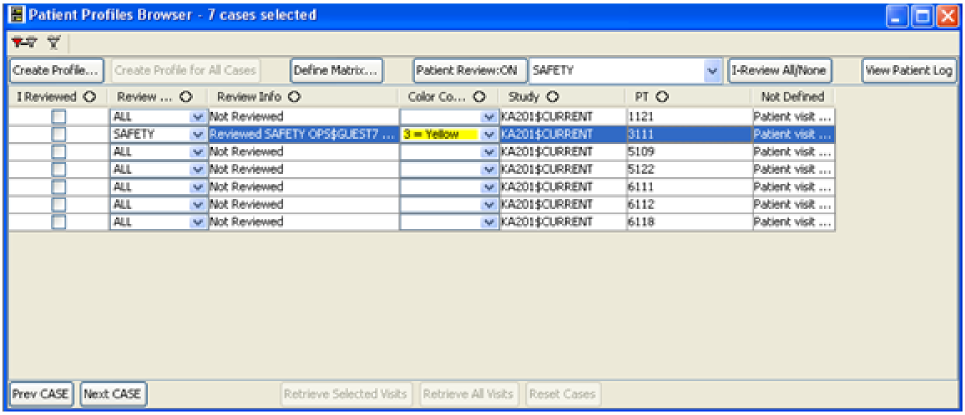
If the user unchecks the “I Reviewed” box for a particular patient review then a DELETE DATE record is generated with the data time stamp in the Patient Log. The default is 24 hours and the amount of time can be defined as an ReviewAdmin config option in REVIEWSTATUSLIMIT=1 where the value can be 1 to 24 hours. Otherwise, the “I Reviewed” and “Review Level” returns to their default status, unchecked and ALL.

## Filter review

In the filter drop down list box, if one of the entries other than **–no filter-** is selected, then the Review Info patient list updates to only include patient review entries either matching the selected entry (All, Safety, Efficacy or Critical in that case) or ‘Not Reviewed’. The ‘No Filter’ condition goes back to the default condition, which displays the ‘latest review state’, regardless of the review type/level.



| I Reviewed | Review ... | Review Info | Color Co... | Stu |  | Not Defined |
|---|---|---|---|---|---|---|
| ☑ | Critical | Reviewed Critical OPS$GUEST7 ... | 1 = Red | KA20 |  | Patient visit ... |
| ☑ | SAFETY | Reviewed SAFETY OPS$GUEST7... | 3 = Yellow | KA20 |  | Patient visit ... |
| ☑ | EFFICACY | Reviewed EFFICACY OPS$GUES... | 4 = Green | KA20 |  | Patient visit ... |
| ☐ | ALL | Not Reviewed |  | KA20 |  | Patient visit ... |
| ☐ | ALL | Not Reviewed |  | KA201$CURRENT | 6111 | Patient visit ... |
| ☐ | ALL | Not Reviewed |  | KA201$CURRENT | 6112 | Patient visit ... |
| ☐ | ALL | Not Reviewed |  | KA201$CURRENT | 6118 | Patient visit ... |

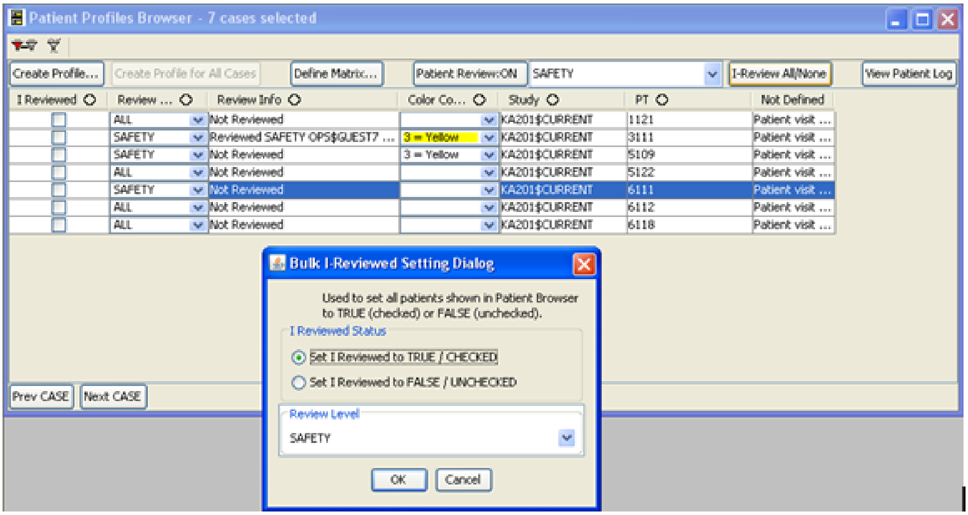


| I Reviewed | Review ... | Review Info | Color Co... | Study | PT | Not Defined |
|---|---|---|---|---|---|---|
| ☐ | ALL | Not Reviewed | | KA201$CURRENT | 1121 | Patient visit ... |
| ☐ | SAFETY | Reviewed SAFETY OPS$GUEST7 ... | 3 = Yellow | KA201$CURRENT | 3111 | Patient visit ... |
| ☐ | ALL | Not Reviewed | | KA201$CURRENT | 5109 | Patient visit ... |
| ☐ | ALL | Not Reviewed | | KA201$CURRENT | 5122 | Patient visit ... |
| ☐ | ALL | Not Reviewed | | KA201$CURRENT | 6111 | Patient visit ... |
| ☐ | ALL | Not Reviewed | | KA201$CURRENT | 6112 | Patient visit ... |
| ☐ | ALL | Not Reviewed | | KA201$CURRENT | 6118 | Patient visit ... |

## Bulk review setting

Bulk updates the review status of listed patients displayed in the Patient Browser. Click the I-Review All/None button and the Bulk I-Reviewed Setting dialog displays.

Select option to set as "I Reviewed CHECKED ON" for true; or select option for "I Reviewed UNCHECKED" for false.



| I Reviewed | Review ... | Review Info | Color Co... | Study | PT | Not Defined |
|---|---|---|---|---|---|---|
| ☐ | ALL | Not Reviewed | | KA201$CURRENT | 1121 | Patient visit ... |
| ☐ | SAFETY | Reviewed SAFETY OPS$GUEST7 ... | 3 = Yellow | KA201$CURRENT | 3111 | Patient visit ... |
| ☐ | SAFETY | Not Reviewed | 3 = Yellow | KA201$CURRENT | 5109 | Patient visit ... |
| ☐ | ALL | Not Reviewed | | KA201$CURRENT | 5122 | Patient visit ... |
| ☐ | SAFETY | Not Reviewed | | KA201$CURRENT | 6111 | Patient visit ... |
| ☐ | ALL | Not Reviewed | | KA201$CURRENT | 6112 | Patient visit ... |
| ☐ | ALL | Not Reviewed | | KA201$CURRENT | 6118 | Patient visit ... |

Used to set all patients shown in Patient Browser to TRUE (checked) or FALSE (unchecked).

I Reviewed Status

● Set I Reviewed to TRUE / CHECKED

○ Set I Reviewed to FALSE / UNCHECKED

Review Level: SAFETY

## *Track selection criteria*

You may optionally capture and display the patient selection criteria text/description (SUBSET), when checking 'I Reviewed' patient during Patient Review Tracking. This option and other column options are enabled or disabled through the ReviewAdmin utility.

The display subset option will save the current patient selection, applied during the patient review status update. Different reviewers may use different patient subsets, for review purposes.  By collecting the various subsets, users can later sort the patient list by the saved subset descriptions.

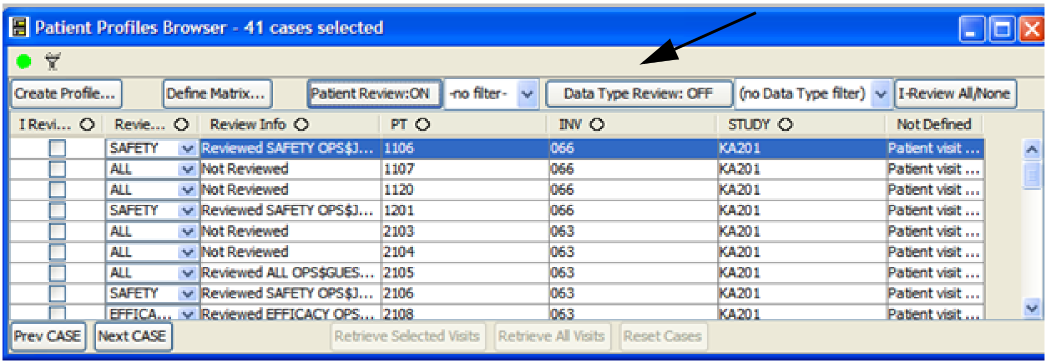
## *Data Type Review*

If your database/environment is set up for 'last change date' processing, and some or all patients have been previously marked as reviewed (in the patient profile - patient review tracking area) - then that 'last date review' information is compared to the 'last change date'  for each patient's data rows.

The user can declare which DataTypes (Panel/Table) they're reviewing to track individual DataType (Panel/Table), if they do not review the entire patient. When the user checks the 'I-Review'd checkbox, JReview keeps track of which DataTypes were reviewed for the checked patient on that date/time.

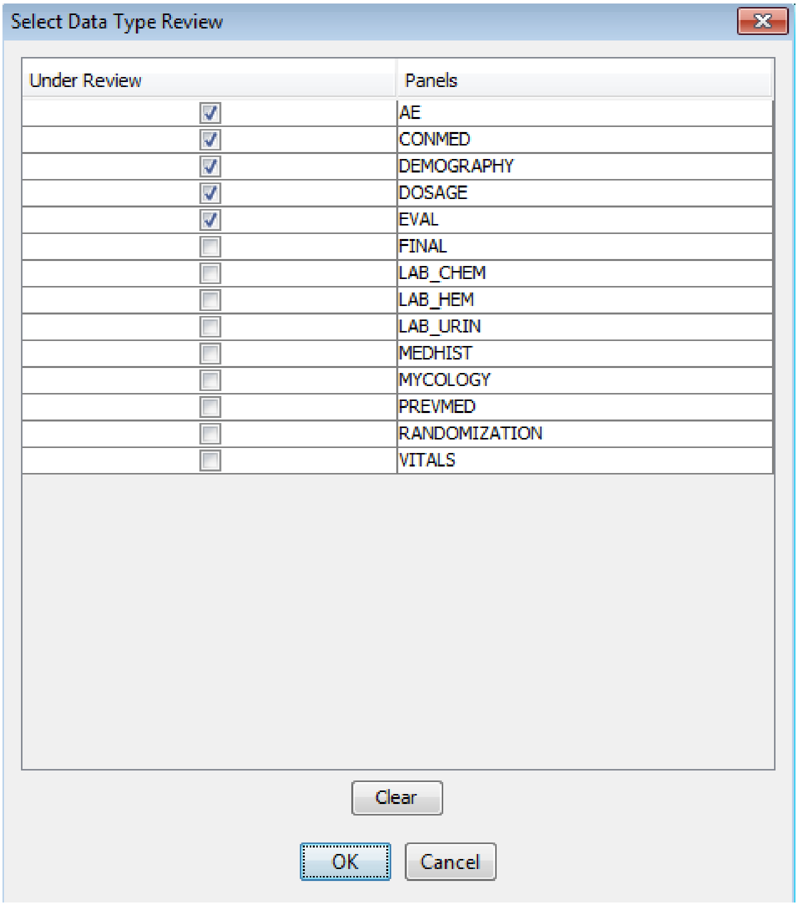
Click on the '**PatientReview:OFF**' button to toggle **PatientReview:ON.**

If the user clicks the **DataType Review:OFF** button, a dialog displays letting the user select which types of data they're going to declare they've reviewed for each patient.



| I Revi... | Revie... | Review Info | PT | INV | STUDY | Not Defined |
|---|---|---|---|---|---|---|
| ☐ | SAFETY | Reviewed SAFETY OPS$J... | 1106 | 066 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 1107 | 066 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 1120 | 066 | KA201 | Patient visit ... |
| ☐ | SAFETY | Reviewed SAFETY OPS$J... | 1201 | 066 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 2103 | 063 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 2104 | 063 | KA201 | Patient visit ... |
| ☐ | ALL | Reviewed ALL OPS$GUES... | 2105 | 063 | KA201 | Patient visit ... |
| ☐ | SAFETY | Reviewed SAFETY OPS$J... | 2106 | 063 | KA201 | Patient visit ... |
| ☐ | EFFICA... | Reviewed EFFICACY OPS... | 2108 | 063 | KA201 | Patient visit ... |

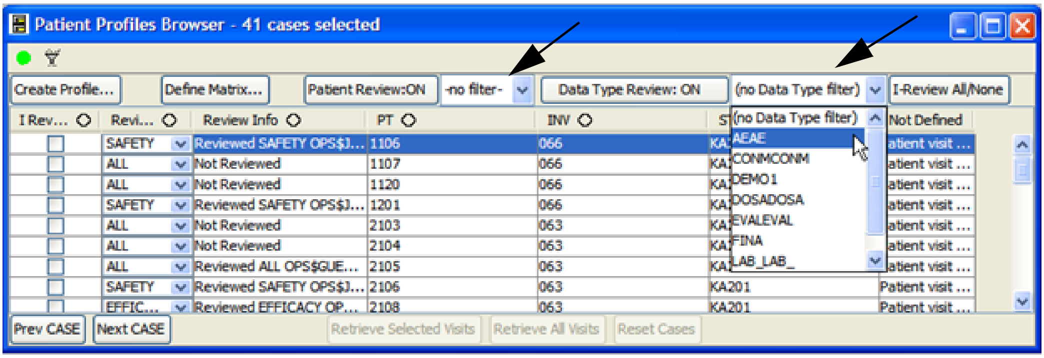
The **Select Data Type Review** window opens. Select the panels to include in review when the user checks the **I-Review'd** checkbox. Then when new or updated data comes in for any of those types of data - the last change date is compared to the last review date for that data type rather than the patient level last review date - and the data is highlighted in green. ***(See Section - Data Type Highlighting)***



| Under Review | Panels |
|---|---|
| ☑ | AE |
| ☑ | CONMED |
| ☑ | DEMOGRAPHY |
| ☑ | DOSAGE |
| ☑ | EVAL |
| ☐ | FINAL |
| ☐ | LAB_CHEM |
| ☐ | LAB_HEM |
| ☐ | LAB_URIN |
| ☐ | MEDHIST |
| ☐ | MYCOLOGY |
| ☐ | PREVMED |
| ☐ | RANDOMIZATION |
| ☐ | VITALS |

The Data Type Review will initialize a list of the panels checked based on which panels/datasets are included in the selected patient profile. These details are viewed in the Patient Review Log.

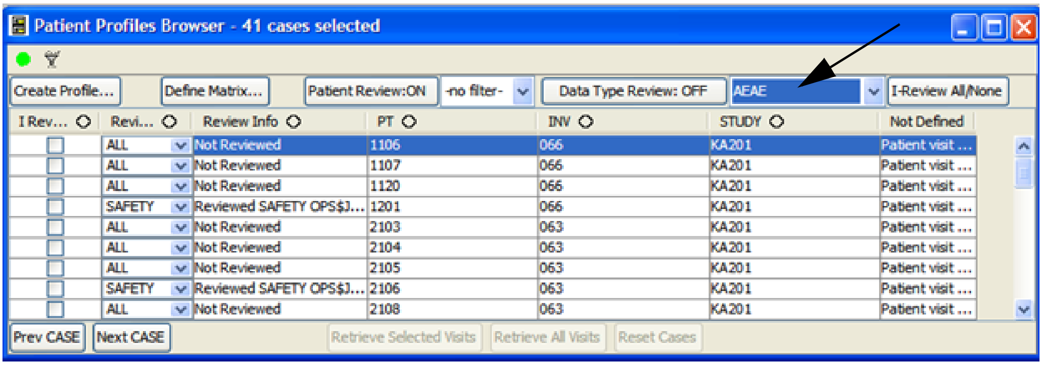
Now the user can use either or both of the filtering combo listboxes, in the Review Level combo box (type of review that was declared) and/or the Data Type Filter combo listbox for DataTypes that have been reviewed. After selecting either or both of the filtering values, the list of patient’s review status reflects those filter choices.



| I Rev... | Revi... | Review Info | PT | INV | ST | Not Defined |
|---|---|---|---|---|---|---|
| ☐ | SAFETY | Reviewed SAFETY OPS$J... | 1106 | 066 | KA | atient visit ... |
| ☐ | ALL | Not Reviewed | 1107 | 066 | KA | atient visit ... |
| ☐ | ALL | Not Reviewed | 1120 | 066 | KA | atient visit ... |
| ☐ | SAFETY | Reviewed SAFETY OPS$J... | 1201 | 066 | KA | atient visit ... |
| ☐ | ALL | Not Reviewed | 2103 | 063 | KA | atient visit ... |
| ☐ | ALL | Not Reviewed | 2104 | 063 | KA | atient visit ... |
| ☐ | ALL | Reviewed ALL OPS$GUE... | 2105 | 063 | KA | atient visit ... |
| ☐ | SAFETY | Reviewed SAFETY OPS$J... | 2106 | 063 | KA201 | Patient visit ... |
| ☐ | EFFIC... | Reviewed EFFICACY OP... | 2108 | 063 | KA201 | Patient visit ... |

For example, if a user had previously selected ‘AE’ as the DataType under review, and checked a number of patients as being reviewed, then selects ‘AE’ as the DataType Filter value, they’ll see the current state of review for only the AE data type. Also, any patients whose AE data has not been declared as reviewed will be listed as ‘Not Reviewed’.

See the Patient Log to view details of the Data Type Review.

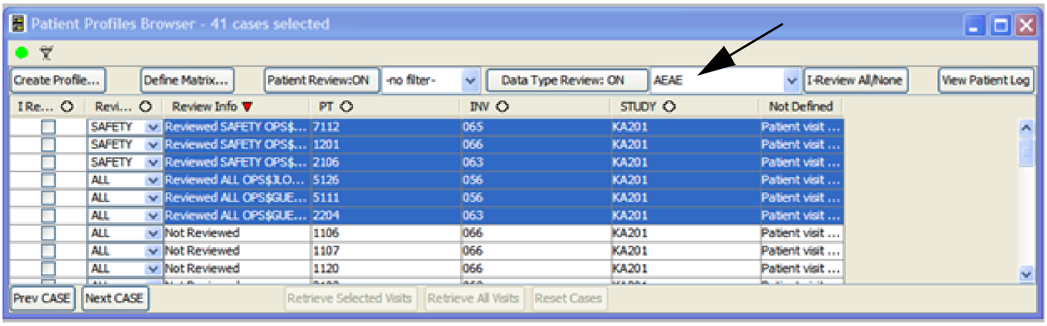


| I Rev... | Revi... | Review Info | PT | INV | STUDY | Not Defined |
|---|---|---|---|---|---|---|
| ☐ | ALL | Not Reviewed | 1106 | 066 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 1107 | 066 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 1120 | 066 | KA201 | Patient visit ... |
| ☐ | SAFETY | Reviewed SAFETY OPS$J... | 1201 | 066 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 2103 | 063 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 2104 | 063 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 2105 | 063 | KA201 | Patient visit ... |
| ☐ | SAFETY | Reviewed SAFETY OPS$J... | 2106 | 063 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 2108 | 063 | KA201 | Patient visit ... |

## *View Patient Log*

You may view the detailed audit trail of a patient(s) review status by clicking the View Patient Log button.

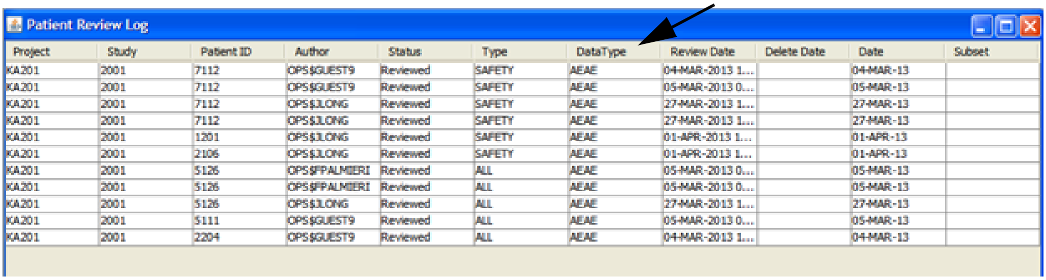
Select a patient from the ***patient column,*** then click **View Patient Log** button. Multiple patients may be selected with the CTRL or SHIFT key and if no patient is selected the default displays the first patient in the list.



| I Re... | Revi... | Review Info | PT | INV | STUDY | Not Defined |
|---|---|---|---|---|---|---|
| ☐ | SAFETY | Reviewed SAFETY OPS$... | 7112 | 065 | KA201 | Patient visit ... |
| ☐ | SAFETY | Reviewed SAFETY OPS$... | 1201 | 066 | KA201 | Patient visit ... |
| ☐ | SAFETY | Reviewed SAFETY OPS$... | 2106 | 063 | KA201 | Patient visit ... |
| ☐ | ALL | Reviewed ALL OPS$JLO... | 5126 | 056 | KA201 | Patient visit ... |
| ☐ | ALL | Reviewed ALL OPS$GUE... | 5111 | 056 | KA201 | Patient visit ... |
| ☐ | ALL | Reviewed ALL OPS$GUE... | 2204 | 063 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 1106 | 066 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 1107 | 066 | KA201 | Patient visit ... |
| ☐ | ALL | Not Reviewed | 1120 | 066 | KA201 | Patient visit ... |

*Note:* ***When highlighting to select multiple patients from the patient list avoid clicking in the first 2 columns which may inadvertently check and alter a current patient status. Always select patients from the patient column.***

The Patient Review Log window opens with a detailed audit trail for the selected patients. Any records removed are show by the Delete Date.



| Project | Study | Patient ID | Author | Status | Type | DataType | Review Date | Delete Date | Date | Subset |
|---|---|---|---|---|---|---|---|---|---|---|
| KA201 | 2001 | 7112 | OPS$GUEST9 | Reviewed | SAFETY | AEAE | 04-MAR-2013 1... |  | 04-MAR-13 |  |
| KA201 | 2001 | 7112 | OPS$GUEST9 | Reviewed | SAFETY | AEAE | 05-MAR-2013 0... |  | 05-MAR-13 |  |
| KA201 | 2001 | 7112 | OPS$JLONG | Reviewed | SAFETY | AEAE | 27-MAR-2013 1... |  | 27-MAR-13 |  |
| KA201 | 2001 | 7112 | OPS$JLONG | Reviewed | SAFETY | AEAE | 27-MAR-2013 1... |  | 27-MAR-13 |  |
| KA201 | 2001 | 1201 | OPS$JLONG | Reviewed | SAFETY | AEAE | 01-APR-2013 1... |  | 01-APR-13 |  |
| KA201 | 2001 | 2106 | OPS$JLONG | Reviewed | SAFETY | AEAE | 01-APR-2013 1... |  | 01-APR-13 |  |
| KA201 | 2001 | 5126 | OPS$FPALMIERI | Reviewed | ALL | AEAE | 05-MAR-2013 0... |  | 05-MAR-13 |  |
| KA201 | 2001 | 5126 | OPS$FPALMIERI | Reviewed | ALL | AEAE | 05-MAR-2013 0... |  | 05-MAR-13 |  |
| KA201 | 2001 | 5126 | OPS$JLONG | Reviewed | ALL | AEAE | 27-MAR-2013 1... |  | 27-MAR-13 |  |
| KA201 | 2001 | 5111 | OPS$GUEST9 | Reviewed | ALL | AEAE | 05-MAR-2013 0... |  | 05-MAR-13 |  |
| KA201 | 2001 | 2204 | OPS$GUEST9 | Reviewed | ALL | AEAE | 04-MAR-2013 1... |  | 04-MAR-13 |  |

You can print the Patient Review Log window by clicking the **Printer icon**.

To export the Patient Review Log, open the File menu and click **Export** to export your Patient Review Log in Excel files, HTML format or Tabbed Txt files.

Close the Patient Review Log window.

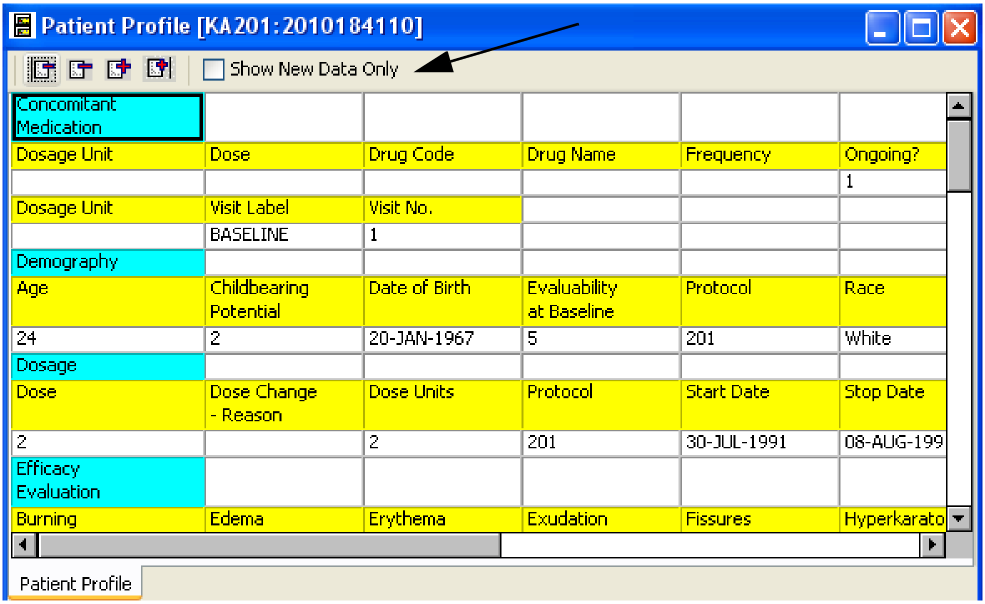
## *Highlight New Data*

There are two ways to highlight new patient data, either at the patient level or data type level (panel type). The ‘Patient Level’ patient review tracking for ‘New Data’ highlighting will highlight in purple.

New data can be highlighted for patients in ReviewAdmin with configuration settings. Patients who have been reviewed show a status as “Reviewed” in the Review Information column. When a patient has new data added or changed since the last review date time stamp the patient review status is updated to “Reviewed (New Data)”. These patients display highlighted in purple. This is to distinguish these patients who were previously reviewed from those patients never reviewed with a status of “Not Reviewed”. The highlighting of new data is available in Workbook Profile and Formatted Profile.

The Patient Review button needs to be clicked ON in order for patient profiles to run with the highlighting feature on “Reviewed (New Data)”. Highlighting of data at the observation level only occurs if the patient had already been reviewed with a previous status of “Reviewed”.

In Reviewed Mode (Patient Tracking Mode), when viewing Workbook Patient Profiles, select a patient and click Create Profile. When the Patient Profile displays click the checkbox to “**Show New Data Only**”.



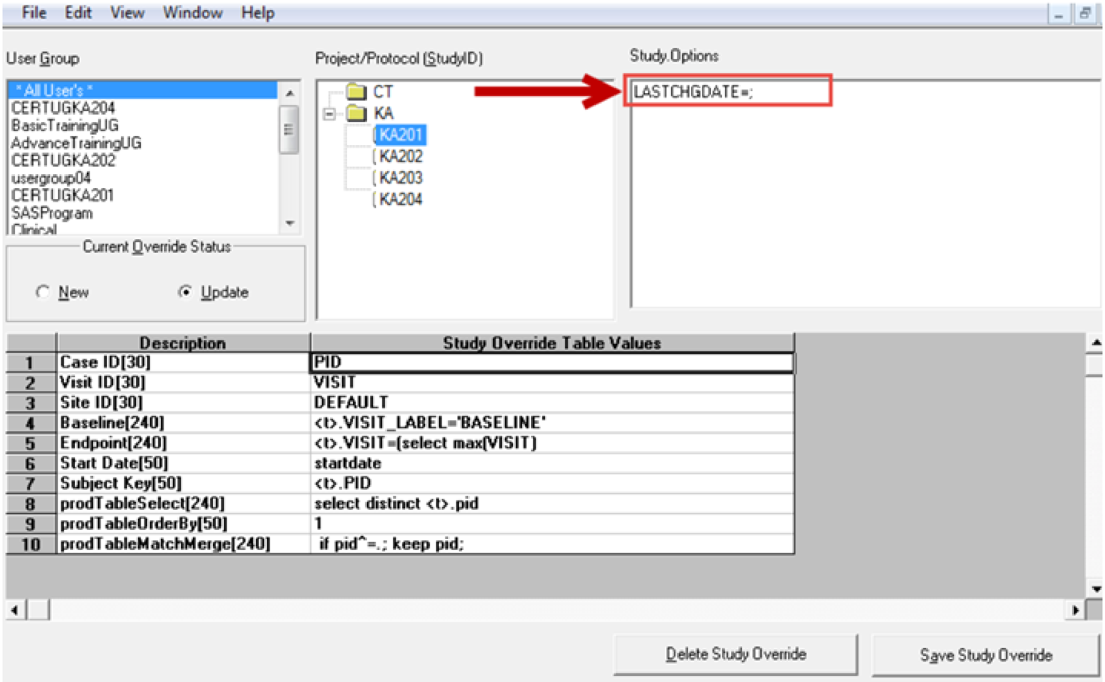
| | | | | | |
|---|---|---|---|---|---|
| Concomitant Medication | | | | | |
| Dosage Unit | Dose | Drug Code | Drug Name | Frequency | Ongoing? |
| | | | | | 1 |
| Dosage Unit | Visit Label | Visit No. | | | |
| | BASELINE | 1 | | | |
| Demography | | | | | |
| Age | Childbearing Potential | Date of Birth | Evaluability at Baseline | Protocol | Race |
| 24 | 2 | 20-JAN-1967 | 5 | 201 | White |
| Dosage | | | | | |
| Dose | Dose Change - Reason | Dose Units | Protocol | Start Date | Stop Date |
| 2 | | 2 | 201 | 30-JUL-1991 | 08-AUG-199 |
| Efficacy Evaluation | | | | | |
| Burning | Edema | Erythema | Exudation | Fissures | Hyperkarato |

All the panel heading rows are displayed to show they've been checked for new data AND new data rows are displayed highlighted in **purple**. New Data Columns behave similarly.

Select a patient with a status "Reviewed (New Data)" and create a patient profile. Only the new data is highlighted in the patient profile at the observation level to expedite quick location and review.

Patient Review for Last Change Date processing has been added within ReviewAdmin. This feature is used to support studies that have item names that are differnt in each table, but all have the same suffix, i.e., LASTCHGDATE=%_LAST_UPD_DTM; where it matches /uses each specific item that ends in _LAST_UPD_DTM.

Screenshot from ReviewAdmin.



Study Options: LASTCHGDATE=;

Current Override Status: ○ New ● Update

|  | Description | Study Override Table Values |
|---|---|---|
| 1 | Case ID[30] | PID |
| 2 | Visit ID[30] | VISIT |
| 3 | Site ID[30] | DEFAULT |
| 4 | Baseline[240] | <t>.VISIT_LABEL='BASELINE' |
| 5 | Endpoint[240] | <t>.VISIT=(select max(VISIT) |
| 6 | Start Date[50] | startdate |
| 7 | Subject Key[50] | <t>.PID |
| 8 | prodTableSelect[240] | select distinct <t>.pid |
| 9 | prodTableOrderBy[50] | 1 |
| 10 | prodTableMatchMerge[240] | if pid^=.; keep pid; |

## *Data Type Highlighting*

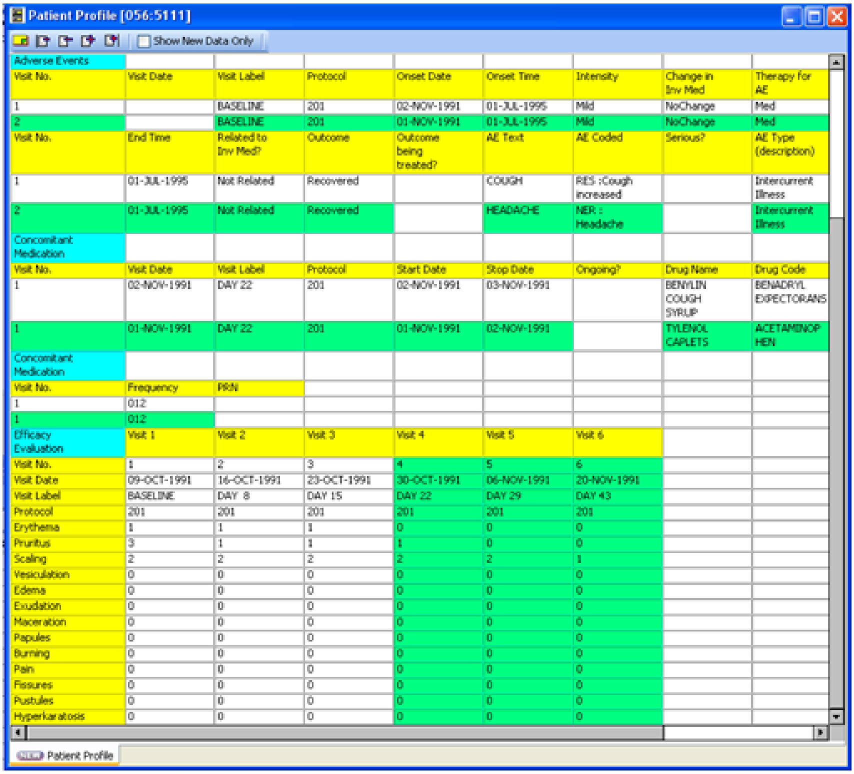
The green highlighting only appears if the user is in ‘Data Type’ review mode. The ‘Data Type’ review mode compares LastReviewDate, at the DataType (Panel Type) level compared to the last update for that specific type of data. It highlights ‘new data’ in this mode as **green**.

The ‘Reviewed (New Data ) … ‘ designation for any patient when this filter condition is enabled – tells us that the patient has new or updated AE data since the last AE data was reviewed.

**‘Data Highlighting’** is supported if your database/environment is set up for ‘last change date’ processing, and some or all patients have been previously been marked as being reviewed (in the patient profile – patient review tracking area), then that ‘last review date’ information is compared to the ‘last change date’ for each patient’s data rows.

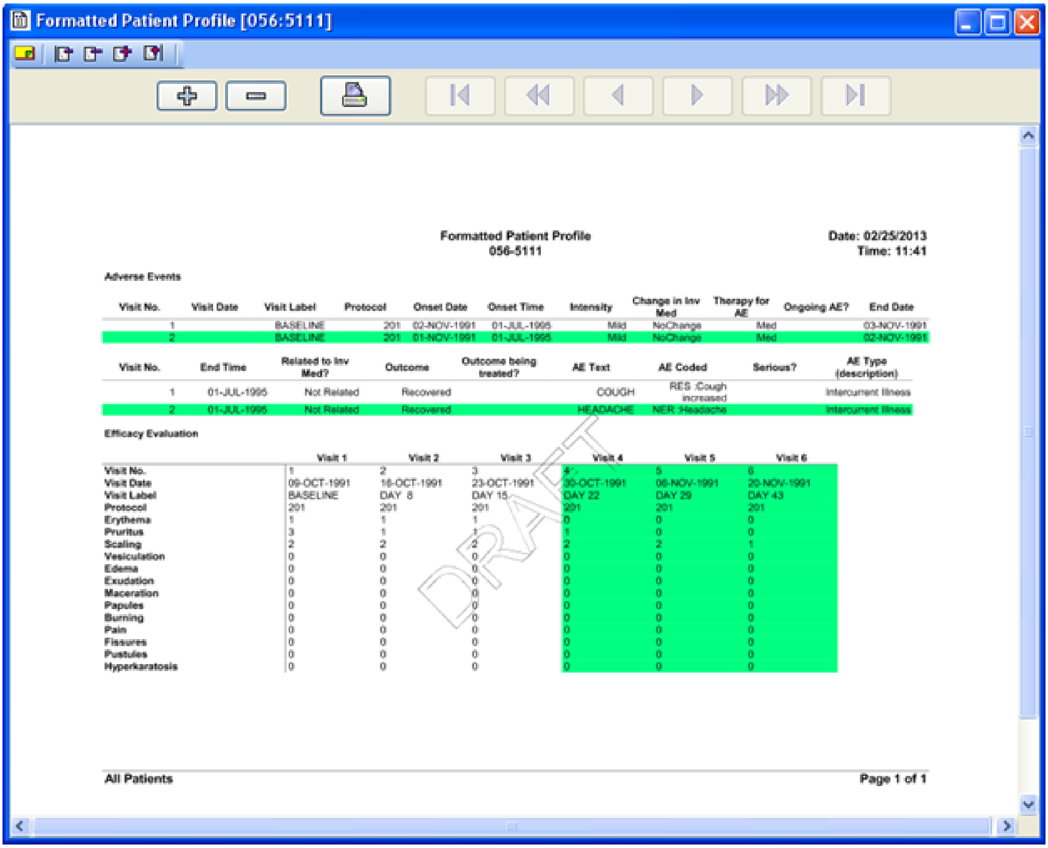
In that mode, each time the user checks the **I-Review’d** checkbox for a patient, a record is added to the PatientReview internal tables, for each of the types of data the user has declared as being under review, with the current date/time. Then when new or updated data comes in for any of those types of data, the last change date is compared to the last review date for that data type rather than the patient level last review date, and the data is highlighted in green.

A Workbook Patient Profile with ‘green’ DataType level highlighting example.



| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Adverse Events | | | | | | | | |
| Visit No. | Visit Date | Visit Label | Protocol | Onset Date | Onset Time | Intensity | Change in Inv Med | Therapy for AE |
| 1 | | BASELINE | 201 | 02-NOV-1991 | 01-JUL-1995 | Mild | NoChange | Med |
| 2 | | BASELINE | 201 | 01-NOV-1991 | 01-JUL-1995 | Mild | NoChange | Med |
| Visit No. | End Time | Related to Inv Med? | Outcome | Outcome being treated? | AE Text | AE Coded | Serious? | AE Type (description) |
| 1 | 01-JUL-1995 | Not Related | Recovered | | COUGH | RES :Cough increased | | Intercurrent Illness |
| 2 | 01-JUL-1995 | Not Related | Recovered | | HEADACHE | NER : Headache | | Intercurrent Illness |
| Concomitant Medication | | | | | | | | |
| Visit No. | Visit Date | Visit Label | Protocol | Start Date | Stop Date | Ongoing? | Drug Name | Drug Code |
| 1 | 02-NOV-1991 | DAY 22 | 201 | 02-NOV-1991 | 03-NOV-1991 | | BENYLIN COUGH SYRUP | BENADRYL EXPECTORANS |
| 1 | 01-NOV-1991 | DAY 22 | 201 | 01-NOV-1991 | 02-NOV-1991 | | TYLENOL CAPLETS | ACETAMINOPHEN |
| Concomitant Medication | | | | | | | | |
| Visit No. | Frequency | PRN | | | | | | |
| 1 | 012 | | | | | | | |
| 1 | 012 | | | | | | | |
| Efficacy Evaluation | Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 | | |
| Visit No. | 1 | 2 | 3 | 4 | 5 | 6 | | |
| Visit Date | 09-OCT-1991 | 16-OCT-1991 | 23-OCT-1991 | 30-OCT-1991 | 06-NOV-1991 | 20-NOV-1991 | | |
| Visit Label | BASELINE | DAY 8 | DAY 15 | DAY 22 | DAY 29 | DAY 43 | | |
| Protocol | 201 | 201 | 201 | 201 | 201 | 201 | | |
| Erythema | 1 | 1 | 1 | 0 | 0 | 0 | | |
| Pruritus | 3 | 1 | 1 | 1 | 0 | 0 | | |
| Scaling | 2 | 2 | 2 | 2 | 2 | 1 | | |
| Vesiculation | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Edema | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Exudation | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Maceration | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Papules | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Burning | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Pain | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Fissures | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Pustules | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Hyperkaratosis | 0 | 0 | 0 | 0 | 0 | 0 | | |

An example of a Formatted Patient Profile with New Data highlighted at the DataType level.



**Formatted Patient Profile**
**056-5111**

**Date: 02/25/2013**
**Time: 11:41**

**Adverse Events**

| Visit No. | Visit Date | Visit Label | Protocol | Onset Date | Onset Time | Intensity | Change in Inv Med | Therapy for AE | Ongoing AE? | End Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | BASELINE | 201 | 02-NOV-1991 | 01-JUL-1995 | Mild | NoChange | Med | | 03-NOV-1991 |
| 2 | | BASELINE | 201 | 01-NOV-1991 | 01-JUL-1995 | Mild | NoChange | Med | | 02-NOV-1991 |

| Visit No. | End Time | Related to Inv Med? | Outcome | Outcome being treated? | AE Text | AE Coded | Serious? | AE Type (description) |
|---|---|---|---|---|---|---|---|---|
| 1 | 01-JUL-1995 | Not Related | Recovered | | COUGH | RES :Cough increased | | Intercurrent Illness |
| 2 | 01-JUL-1995 | Not Related | Recovered | | HEADACHE | NER :Headache | | Intercurrent Illness |

**Efficacy Evaluation**

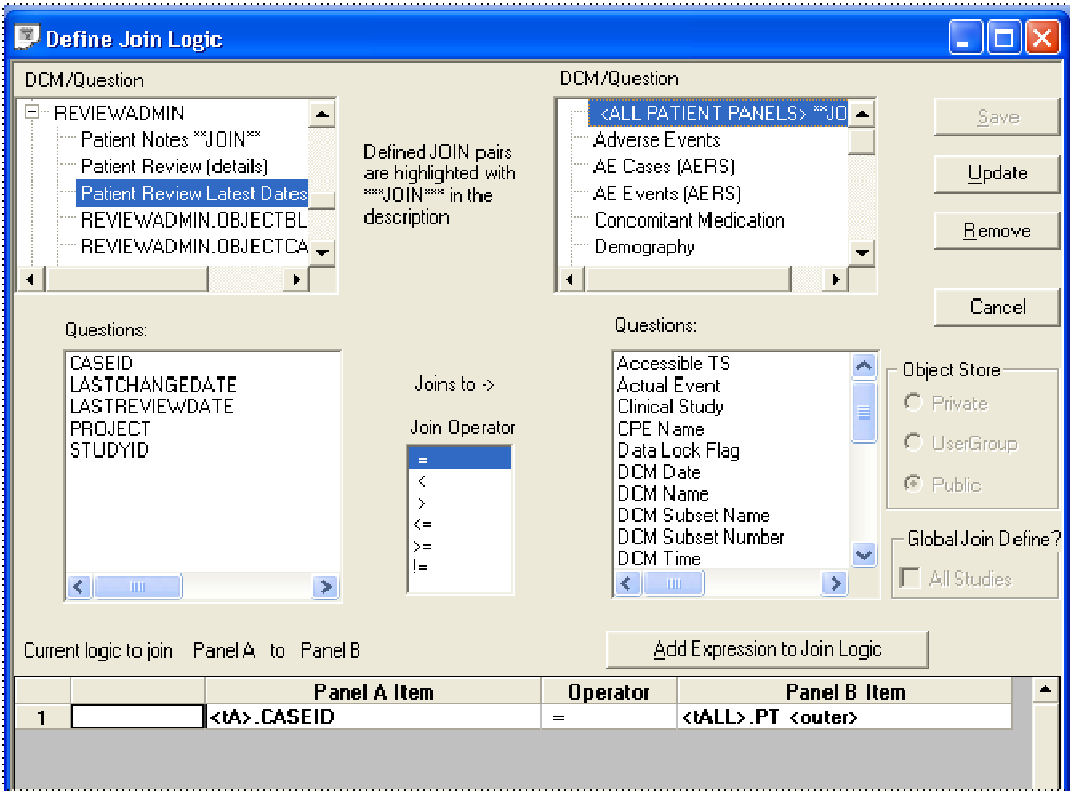
| | Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 |
|---|---|---|---|---|---|---|
| **Visit No.** | 1 | 2 | 3 | 4 | 5 | 6 |
| **Visit Date** | 09-OCT-1991 | 16-OCT-1991 | 23-OCT-1991 | 30-OCT-1991 | 06-NOV-1991 | 20-NOV-1991 |
| **Visit Label** | BASELINE | DAY 8 | DAY 15 | DAY 22 | DAY 29 | DAY 43 |
| **Protocol** | 201 | 201 | 201 | 201 | 201 | 201 |
| **Erythema** | 1 | 1 | 1 | 0 | 0 | 0 |
| **Pruritus** | 3 | 1 | 1 | 1 | 0 | 0 |
| **Scaling** | 2 | 2 | 2 | 2 | 2 | 1 |
| **Vesiculation** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Edema** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Exudation** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Maceration** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Papules** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Burning** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Pain** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Fissures** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Pustules** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Hyperkaratosis** | 0 | 0 | 0 | 0 | 0 | 0 |

**All Patients** **Page 1 of 1**

## User defined tracking reports

Supplemental reports may be defined using patient selection criteria and filtering against ReviewAdmin tables to support Patient Review Tracking. In some circumstances it may be necessary to register Foreign panels (Patient Review tables) from ReviewAdmin tables and then define Join Logic. **(See *Chapter 12: Advanced Topics - Define Join Logic*)**

After the Foreign panels are made available in JReview and the Join Logic is saved, then users may define and apply patient selection criteria, user defined reports and output filters to the data fields in the Patient Review tables.

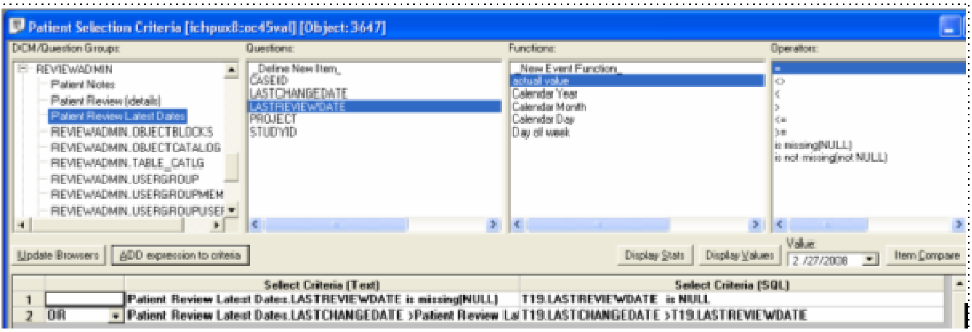


Defined JOIN pairs are highlighted with ***JOIN*** in the description

Current logic to join Panel A to Panel B

| | | Panel A Item | Operator | Panel B Item |
|---|---|---|---|---|
| 1 | | <tA>.CASEID | = | <tALL>.PT <outer> |

This is an example of a patient selection criteria selecting all patients not yet reviewed or with a last date change after the last reviewed date.



Value: 2 /27/2008

| | | Select Criteria (Text) | Select Criteria (SQL) |
|---|---|---|---|
| 1 | | Patient Review Latest Dates.LASTREVIEWDATE is missing(NULL) | T19.LASTREVIEWDATE is NULL |
| 2 | OR | Patient Review Latest Dates.LASTCHANGEDATE >Patient Review La | T19.LASTCHANGEDATE >T19.LASTREVIEWDATE |

## *Study lock*

The privilege to lock or unlock a study is a high level manager function enabled in ReviewAdmin which allows the user to display a lock status on an individual study. If a study is not locked, then Review will check for data updates and new data for that study the first time the user turns ON the Patient Profile Review Tracking tool that day. This function is for user viewing purposes and does NOT physically block or prevent data updates from appearing in JReview.

In ReviewAdmin the REVIEWSTATUSLIMIT option is set to the hour reference (numeric value) setting the number of hours after the “I Reviewed” list box is checked, that it can be unchecked. Valid values are 1 to 24 hours where 24 is the default if the option is not set. The check for data updates are posted once daily at most. This means in study unlock mode when a user clicks the Patient Review ON button, Review checks for any new data transactions from the last date time stamp when a patient was reviewed against the date time stamp of the data management posted updates.

When a selected study is set to Lock mode the following conditions occur in the Patient Profile Review Tracking tool.

- The daily process to check if new data is available is turned OFF.
- The patient list in the Patient Profile Browser window will NOT display the status for “Reviewed (New Data)”.
- The highlighting of new data is turned OFF when a patient profile is created and viewed.

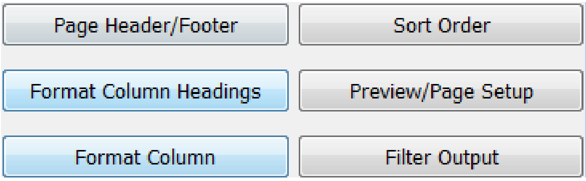
Select a study and right mouse click to display the floating menu.

A red lock icon displays for the selected study to identify Lock status.

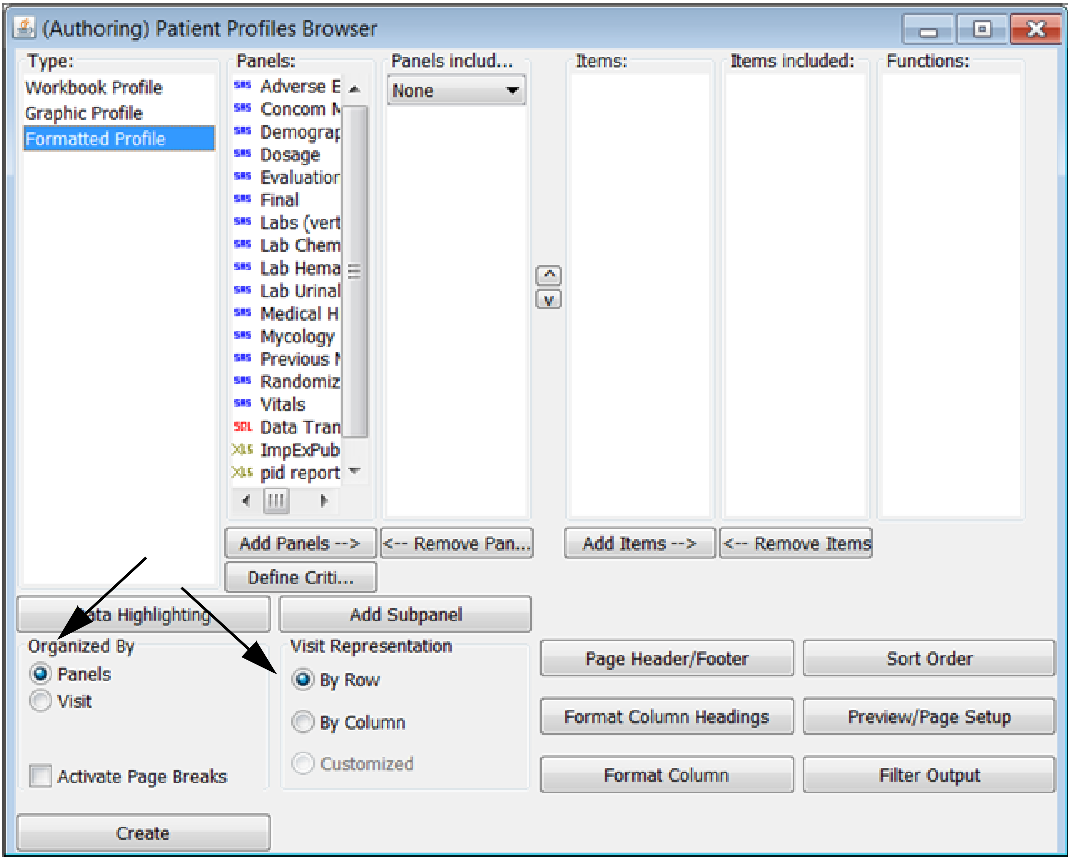
# Formatted Patient Profile

## *Select formatted profile*

When you select the **Formatted Profile** type the format options menu displays for you to apply setting changes.

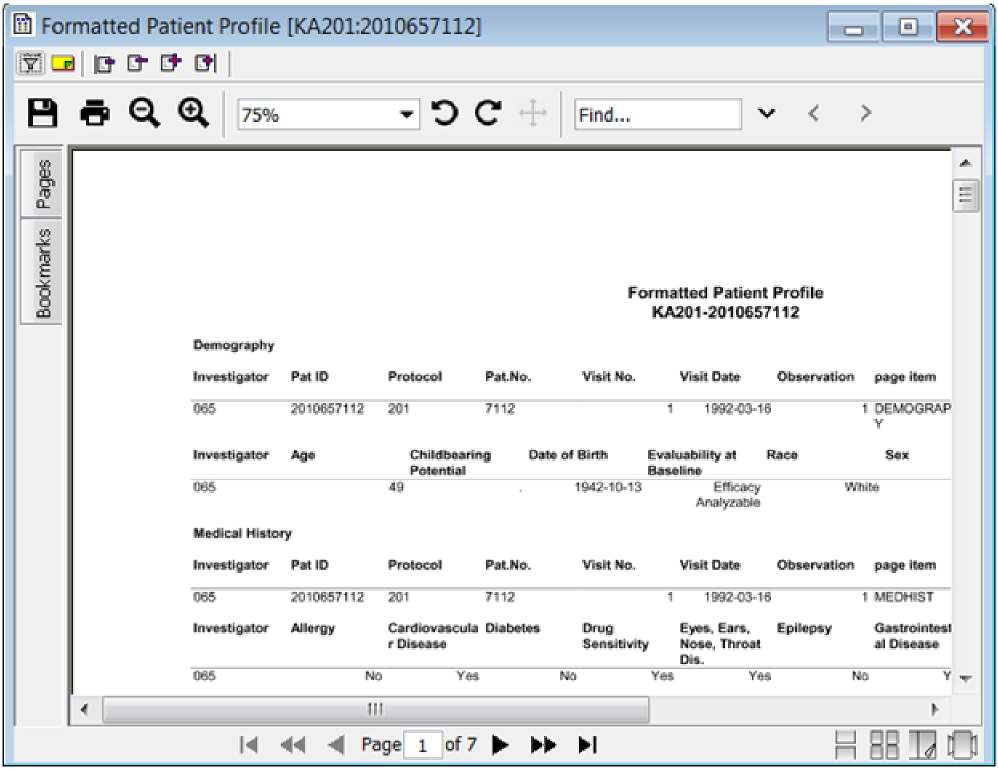


A configuration setting controls whether No panels (None), All panels, or Critical Study defined panels are included in the profile by default. Initially if you click create profile the default settings are organized by ***panel*** and visit representation as ***by row***.



## *Activate Page Break*

This is a partial view of a formatted profile with default settings.



Formatted Patient Profile
KA201-2010657112

**Demography**

| Investigator | Pat ID | Protocol | Pat.No. | Visit No. | Visit Date | Observation | page item |
|---|---|---|---|---|---|---|---|
| 065 | 2010657112 | 201 | 7112 | 1 | 1992-03-16 | 1 | DEMOGRAPY |

| Investigator | Age | Childbearing Potential | Date of Birth | Evaluability at Baseline | Race | Sex |
|---|---|---|---|---|---|---|
| 065 | 49 | . | 1942-10-13 | Efficacy Analyzable | White | |

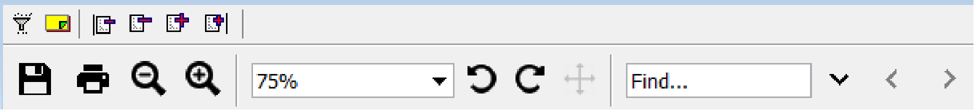
**Medical History**

| Investigator | Pat ID | Protocol | Pat.No. | Visit No. | Visit Date | Observation | page item |
|---|---|---|---|---|---|---|---|
| 065 | 2010657112 | 201 | 7112 | 1 | 1992-03-16 | 1 | MEDHIST |

| Investigator | Allergy | Cardiovascular Disease | Diabetes | Drug Sensitivity | Eyes, Ears, Nose, Throat Dis. | Epilepsy | Gastrointestinal Disease |
|---|---|---|---|---|---|---|---|
| 065 | No | Yes | No | Yes | Yes | No | Y |

The activate page break default is set to OFF.  However, you can turn ON page breaks for **Organized By Panel** or **Visit**.


☐ Activate Page Breaks

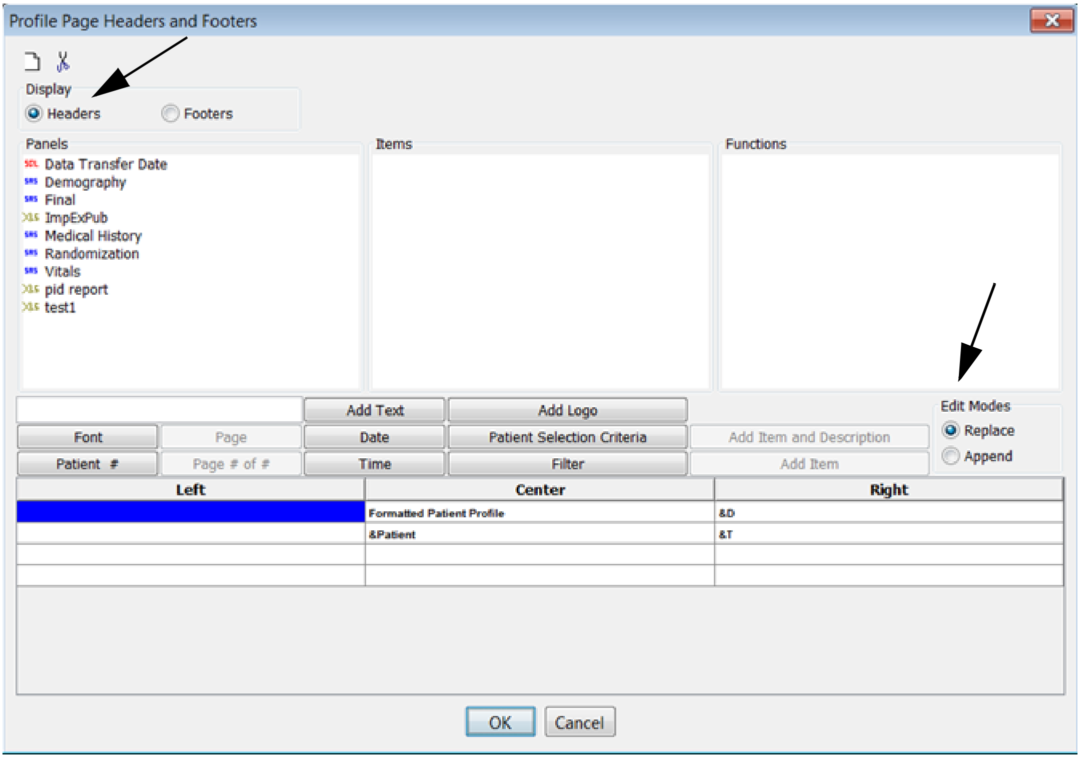


- Use the yellow icon is the **Add Notes** for  patient.
- Use the plus and minus icons go to the next or previous patient.
- Use the arrows in the footer bar to move between pages within a single patient profile with a sliding scroll bar on the right.
- A Save file icon supports saving the FPP externally.
- The printer icon is next .  Magnify buttons to zoom in/out of view.
- Find supports text search.

## *Apply Page Header and Footer*

To enter descriptive information to the Header and Footer area:

1. Click on the **Page Header/Footer** button to open Profile Page Headers and Footers window.



| Left | Center | Right |
|---|---|---|
|  | Formatted Patient Profile | &D |
|  | &Patient | &T |
|  |  |  |
|  |  |  |

The default settings for Headers are:

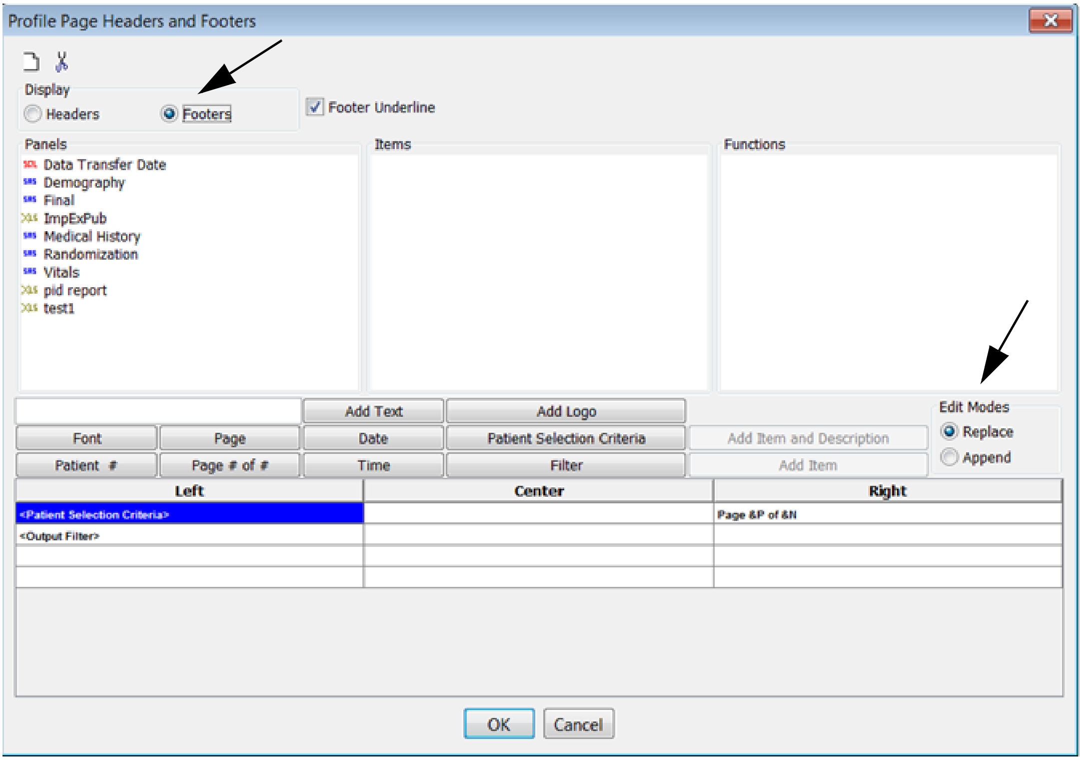
a. Default title is the profile type displayed in the center cell as Formatted Profile with PatientID below.

b. Date and Time on the right.

c. Font is BOLD **10.**

2. Click a particular column/row cell within the template for your item or text entry location. Each cell can contain up to two items.
3. Use the **Edit Modes** to Replace or Append changes.
4. Use the various item button selections to add Header information and the **Add Text** button to enter free text descriptions.
5. Click on a cell and use the **Scissors icon** to delete the selected cell contents or click the **New icon** to clear all cell contents.
6. Click the Font button to change font, style and size.

7. Optionally, **Add Logo** to either the Header or Footer definition. The display contents of ‘logo.gif’ file is located in the JR Server directory.
8. Click Display Footers.



Profile Page Headers and Footers

Display: ○ Headers ● Footers

☑ Footer Underline

Panels:
- Data Transfer Date
- Demography
- Final
- ImpExPub
- Medical History
- Randomization
- Vitals
- pid report
- test1

Edit Modes: ● Replace ○ Append

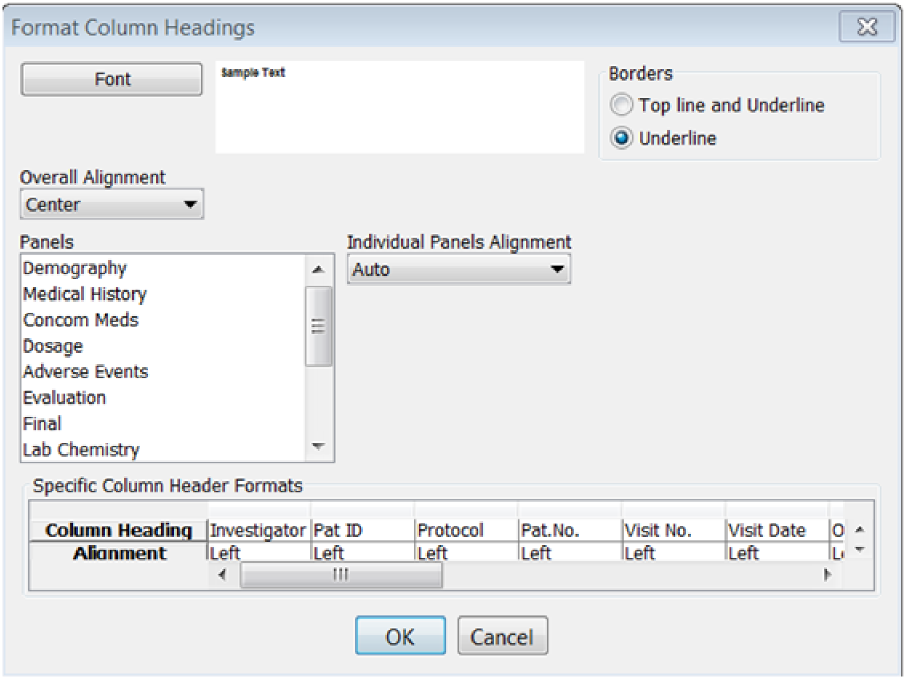
| Left | Center | Right |
|---|---|---|
| <Patient Selection Criteria> | | Page &P of &N |
| <Output Filter> | | |
| | | |
| | | |

9. Follow the same steps to enter and make changes to the footer. The default settings for footers are:
   a. Patient Selection Criteria and Output Filter on the Left.
   b. Page number on the right.
   c. Underline above the footer.
   d. Font is BOLD **10**.
10. Turn the Footer Underline ON or OFF.
11. Click **OK** to apply format changes.

## *Format Column Headings*

To apply Overall Column Header Formats:

1. Click on the **Format Column Headings** button. The Format Column Headings window opens. The default settings for all column headings are:
    a. Font is **BOLD 8.**
    b. Overall Alignment - Center.
    c. Individual Panel Alignment - Center.
    d. Borders set to Underline is ON.
2. Click the Font button to change font, style and size.
3. Change the borders.
4. Apply a Specific Column Header Format by clicking the drop down list for alignment. Change from default center to auto, left, or right.
5. Change Overall Alignment or Individual Panel Alignment.
6. Optionally, modify column headings to be more descriptive.
7. Click **OK** to apply format changes.



Borders
○ Top line and Underline
● Underline

Overall Alignment: Center

Individual Panels Alignment: Auto

Panels
Demography
Medical History
Concom Meds
Dosage
Adverse Events
Evaluation
Final
Lab Chemistry

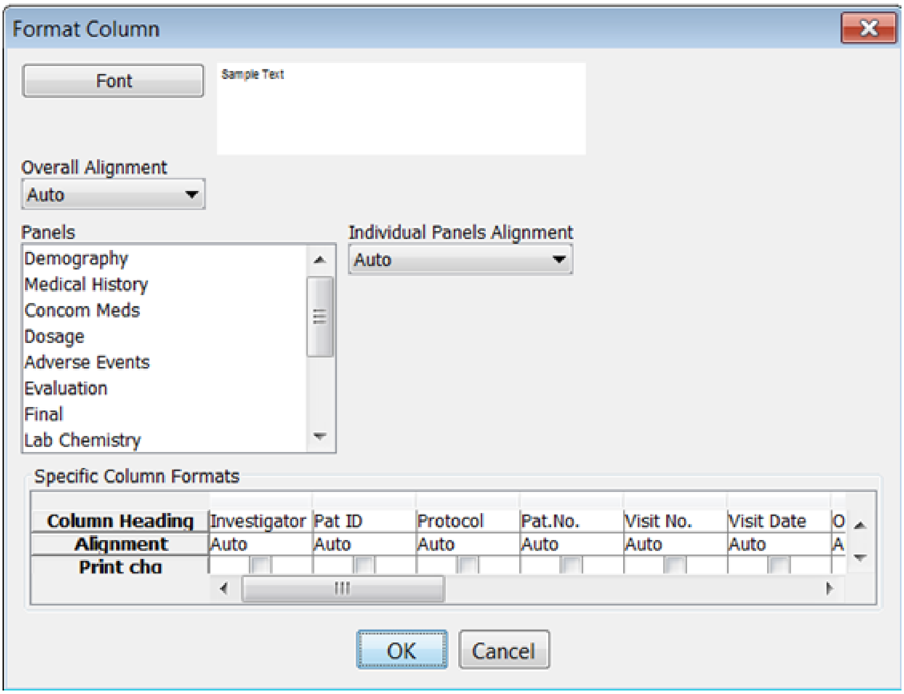
Specific Column Header Formats

| **Column Heading** | Investigator | Pat ID | Protocol | Pat.No. | Visit No. | Visit Date | O |
|---|---|---|---|---|---|---|---|
| **Alignment** | Left | Left | Left | Left | Left | Left | L |

## *Format Columns*

To apply overall formats to font, style and size:

1. Click on the **Format Column** button to open the **Format Column** window. The default settings for all columns are:
    a. Font is Regular 8**.**
    b. Overall Alignment - Auto.
    c. Individual Panel Alignment - Auto.
2. Change Overall Alignment or Individual Panel Alignment from auto to left, center or right.
3. Click the Individual Panel Alignment drop down list to align the item display for auto, left, center, or right.
4. Click Row Results to apply Print Change for a particular column.
5. Click **OK** to apply format changes.



Overall Alignment: Auto

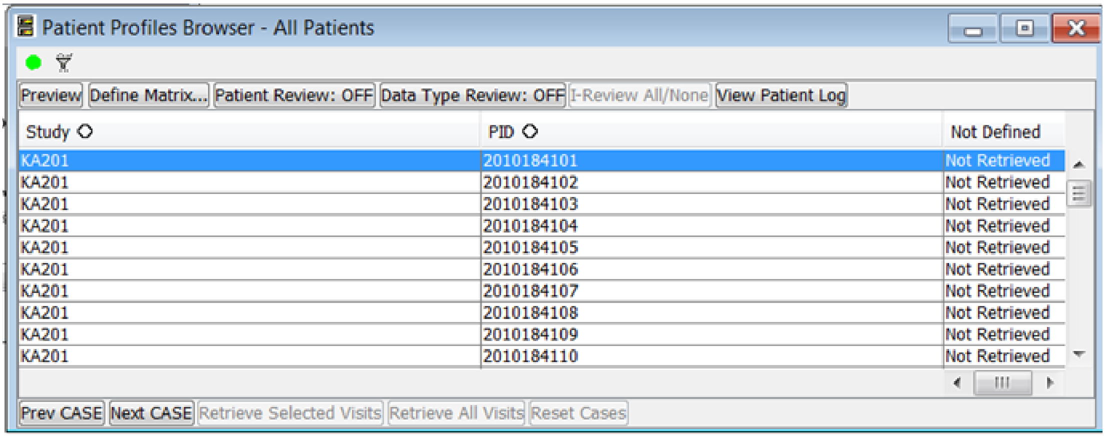
Individual Panels Alignment: Auto

| **Column Heading** | Investigator | Pat ID | Protocol | Pat.No. | Visit No. | Visit Date | O |
|---|---|---|---|---|---|---|---|
| **Alignment** | Auto | Auto | Auto | Auto | Auto | Auto | A |
| **Print chg** | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |

## *Preview/Page Setup*

Click **Preview/Page Setup** to view the Preview window of the formatted profile.

Select a patient from the list and click **Preview**.



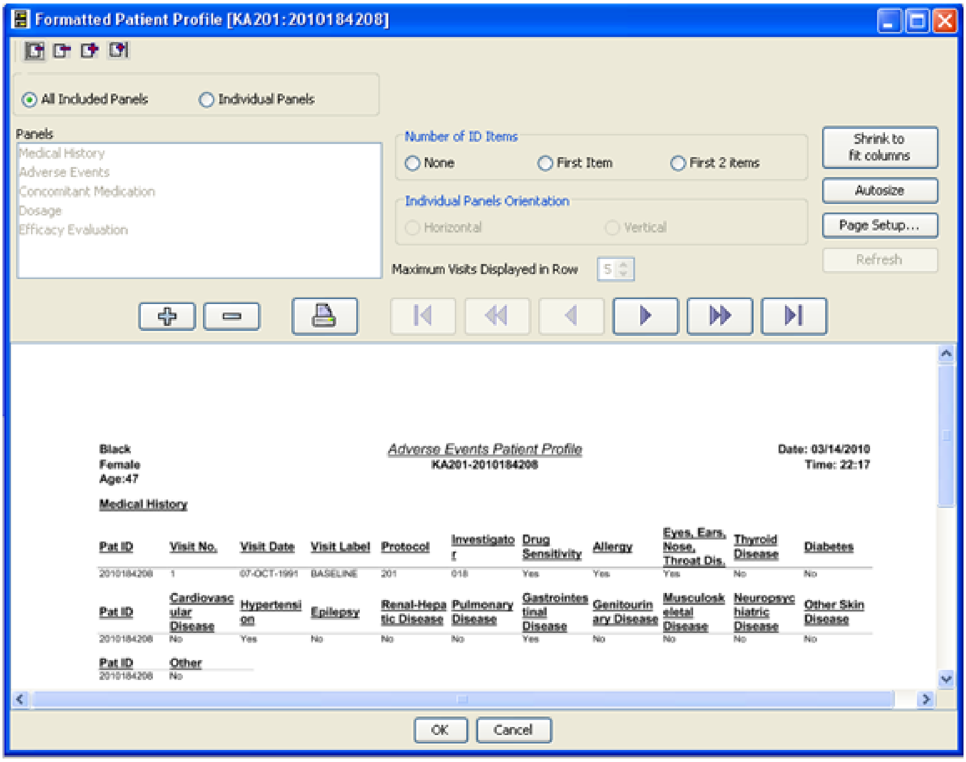
| Study | PID | Not Defined |
|---|---|---|
| KA201 | 2010184101 | Not Retrieved |
| KA201 | 2010184102 | Not Retrieved |
| KA201 | 2010184103 | Not Retrieved |
| KA201 | 2010184104 | Not Retrieved |
| KA201 | 2010184105 | Not Retrieved |
| KA201 | 2010184106 | Not Retrieved |
| KA201 | 2010184107 | Not Retrieved |
| KA201 | 2010184108 | Not Retrieved |
| KA201 | 2010184109 | Not Retrieved |
| KA201 | 2010184110 | Not Retrieved |

You may access the Patient Review Tracking tool by clicking the Patient Review button to ON.

It is recommended to apply any settings in the following sequence since sizing of the individual columns on the grid in design mode will change the column widths. It is advised to set **Page Setup** before the setting of the column widths since changing the page orientation, left margin size or right margin size will set the column widths back to their default settings.

1. Start with **Page Setup**.
2. Apply **Number of ID Items**.
3. Apply **Individual Panel Orientation** for horizontal versus vertical.
4. Column width can be set in one of three ways: **Shrink to fit columns**, **Autosize** or adjust **individual columns**.

5. Click **Refresh** to view changes.



Formatted Patient Profile [KA201:2010184208]

● All Included Panels ○ Individual Panels

Panels
Medical History
Adverse Events
Concomitant Medication
Dosage
Efficacy Evaluation

Number of ID Items: ○ None ○ First Item ○ First 2 items

Individual Panels Orientation: ○ Horizontal ○ Vertical

Maximum Visits Displayed in Row: 5

Black
Female
Age:47

*Adverse Events Patient Profile*
KA201-2010184208

Date: 03/14/2010
Time: 22:17

Medical History

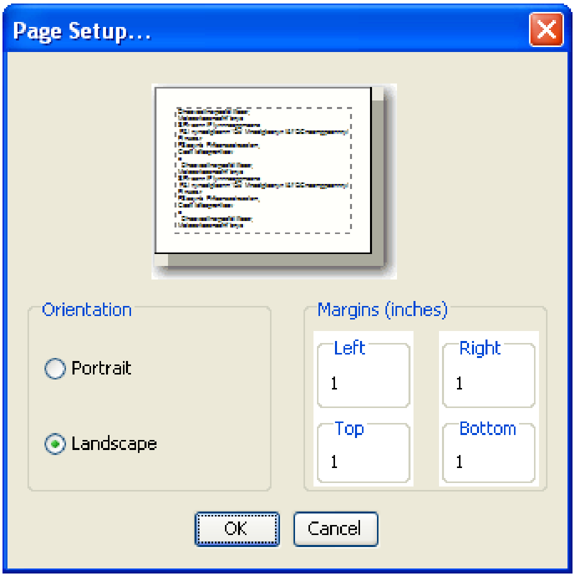
| Pat ID | Visit No. | Visit Date | Visit Label | Protocol | Investigator | Drug Sensitivity | Allergy | Eyes, Ears, Nose, Throat Dis. | Thyroid Disease | Diabetes |
|---|---|---|---|---|---|---|---|---|---|---|
| 2010184208 | 1 | 07-OCT-1991 | BASELINE | 201 | 018 | Yes | Yes | Yes | No | No |

| Pat ID | Cardiovascular Disease | Hypertension | Epilepsy | Renal-Hepatic Disease | Pulmonary Disease | Gastrointestinal Disease | Genitourinary Disease | Musculoskeletal Disease | Neuropsychiatric Disease | Other Skin Disease |
|---|---|---|---|---|---|---|---|---|---|---|
| 2010184208 | No | Yes | No | No | No | Yes | No | No | No | No |

| Pat ID | Other |
|---|---|
| 2010184208 | No |

## Page Setup

The default display is landscape and the settings are maximum column width of one inch. The width is set to fit all columns on a page depending upon the number of columns in the profile. The default number of columns is ‘11’ of all equal widths.



Orientation
○ Portrait
● Landscape

Margins (inches)
Left: 1
Right: 1
Top: 1
Bottom: 1

## Number of ID items

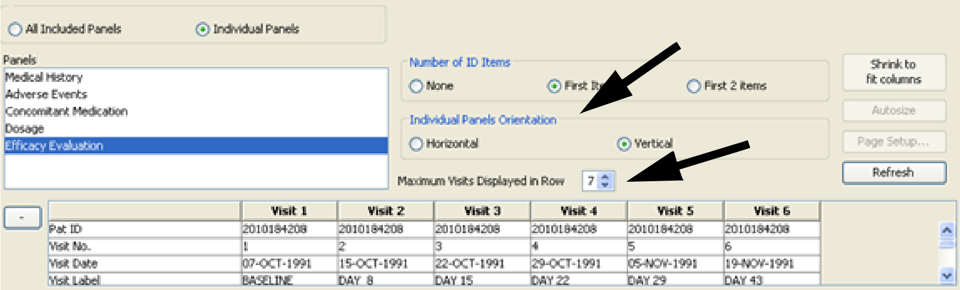
The option to display Number of ID items as represented by the PatientID and VisitNo has selections for ‘None’, ‘First Item’ or ‘First 2 Items’. If a panel row wraps beyond the maximum number of columns defined, you can repeat the display of ‘First Item’ or ‘First 2 Items’ onto the next row. If you select ‘None’ then only the initial row contains ID items. The selection can be made from All Included Panels or Individual Panels.

The default setting is for ‘First Item’ where the first row of all panels always displays the PatientID and VisitNo with any wrapped row displaying the PatientID.

## Panel Orientation

Changing the individual panel orientation is restricted to visit oriented data collection where one record is collected once for each visit. For example, vital signs or laboratory results may be collected once for each patient at a visit. Data collected only once or multiple times for each patient and not related to a particular visit is restricted to horizontal display, i.e., Concomitant Medication, Medical History, etc.

1. To change an individual panel orientation, select **Individual Panels**.
2. Select the panel. The default setting is horizontal.
3. Select the Individual Panel Orientation for horizontal or vertical orientation.
4. Select vertical orientation and change the **Maximum Visits Displayed in Row** selecting from the drop down list. The choices are 5 to 9.



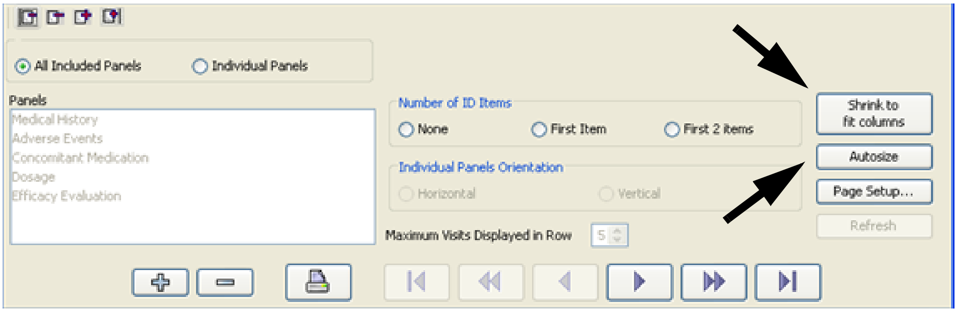
| | Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 |
|---|---|---|---|---|---|---|
| Pat ID | 2010184208 | 2010184208 | 2010184208 | 2010184208 | 2010184208 | 2010184208 |
| Visit No. | 1 | 2 | 3 | 4 | 5 | 6 |
| Visit Date | 07-OCT-1991 | 15-OCT-1991 | 22-OCT-1991 | 29-OCT-1991 | 05-NOV-1991 | 19-NOV-1991 |
| Visit Label | BASELINE | DAY 8 | DAY 15 | DAY 22 | DAY 29 | DAY 43 |

5. Click **Refresh** to view panel orientation change.

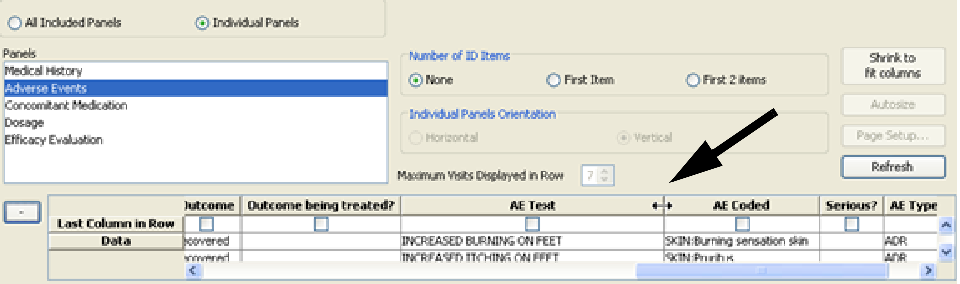
***Note: The grid in design mode only displays when you select Individual Panels.***

## *Column width*

- Click the **Shrink to Fit Columns** and **Refresh** to view all columns to fit on the page. All columns are of equal width with horizontal default set to 11 columns.
- Click the **Autosize Columns** and **Refresh** to expand each column to it's maximum width. The individual data column width is adjusted for heading and data.

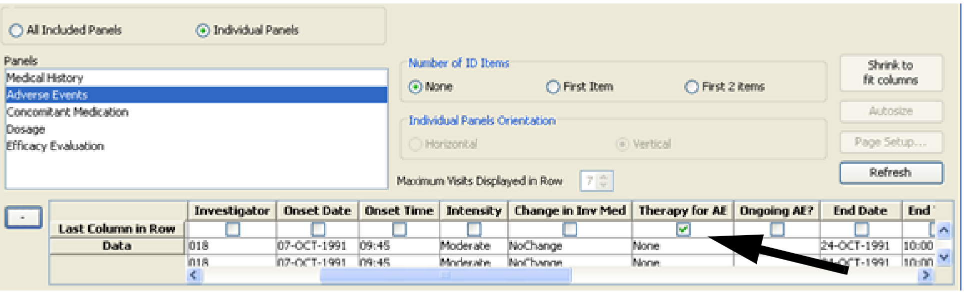


- Click **Individual Panels** to display the design grid. Select a panel and resize individual columns within the selected panel. Click and drag the cursor on the line between the column heading tabs to the desired width. Click **Refresh**.



| | utcome | Outcome being treated? | AE Text | AE Coded | Serious? | AE Type |
|---|---|---|---|---|---|---|
| **Last Column in Row** | ☐ | ☐ | ☐ | ☐ | ☐ | |
| **Data** | covered | | INCREASED BURNING ON FEET | SKIN:Burning sensation skin | | ADR |
| | covered | | INCREASED ITCHING ON FEET | SKIN:Pruritus | | ADR |

- When you select **Individual Panels** and select a panel, you can apply a row break at a particular item by clicking the check box for **Last Column in Row.** Click **Refresh** to view your changes.



| | Investigator | Onset Date | Onset Time | Intensity | Change in Inv Med | Therapy for AE | Ongoing AE? | End Date | End |
|---|---|---|---|---|---|---|---|---|---|
| **Last Column in Row** | ☐ | ☐ | ☐ | ☐ | ☐ | ☑ | ☐ | ☐ | ☐ |
| **Data** | 018 | 07-OCT-1991 | 09:45 | Moderate | NoChange | None | | 24-OCT-1991 | 10:00 |
| | 018 | 07-OCT-1991 | 09:45 | Moderate | NoChange | None | | 24-OCT-1991 | 10:00 |

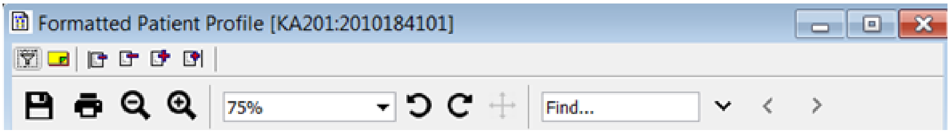
# Print and Export Patient Profiles

## Print Workbook Profile

To print a workbook profileof the selected patient, click on the **Printer icon** in the toolbar. The **Grid Print/Print Preview** window displays with the optioins to **Print Page** displayed or **Print All** pages.

## Print Formatted Profile

To print a formatted profile of the selected patient, you must use the **Printer button** in the PDF viewer to print. The Print dialog window is displayed.



## Display watermark on formatted profile

The watermark is a ‘configurable’ option entered by a ReviewAdmin user (admin user) by modifying the Reviewadmin.StatusCode table entries, specifically the Watermark item. The StatusCode table contains an entry for each Status type that’s been defined in JReview, which are the same status codes/values that appear in the Save dialog. The default code is ‘DEFAULT’, but sites can enter different codes. An optional Watermark text can be set for each specific status code, so if someone saves a FPP object definition with a different Status code, the watermark that corresponds to that status code will show up in the output.

Customers may request to display a watermark this allows the ability to add a ‘watermark’ for ‘Confidential’ or ‘Internal Use Only’ or ‘Draft’, etc.

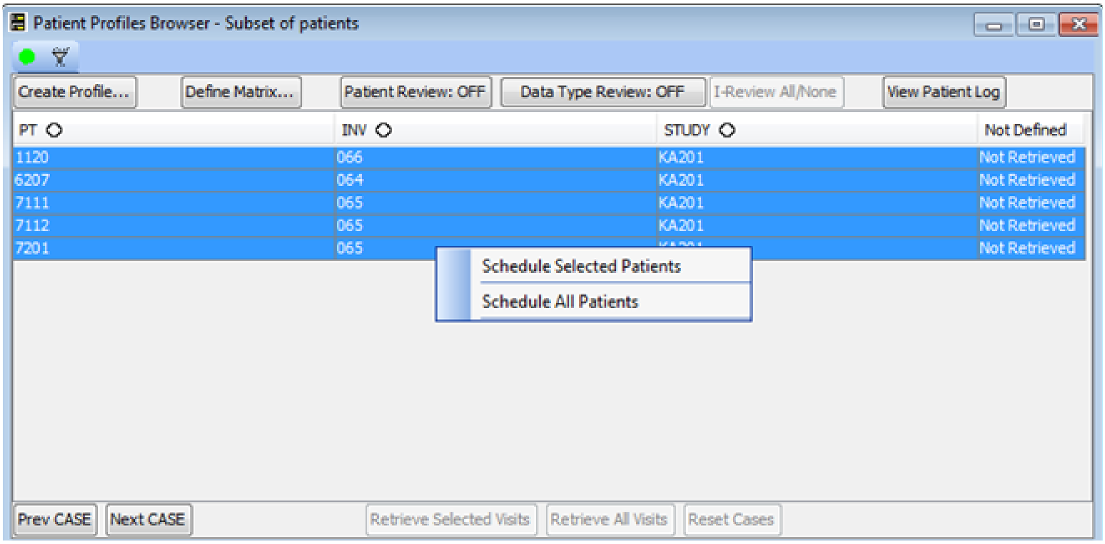
## *Patient Profile Browser Scheduler*

This is an optional module requiring additional license to work with JReview. The Patient Profile Scheduling Server (optional license) provides end users the ability to schedule many patient profiles to be generated in a batch, so they do not need to wait for processing of each patient profile individually. It provides end user scheduling of ***Formatted Patient Profiles*** for batch execution (later one-time or repetitive scheduling).

The user can request batch scheduling of either all patients in a study, or those selected based on the current Patient Selection Criteria, or just selected patients. After the scheduled job completes, the generated PDFs were accessible directly through the JReview '**Review Output**' tab, but could also be directed to be saved to a study specific directory which could be externally accessible to users.

***Note: Scheduling Formatted Patient Profiles requires optional printer server module.***

Display the Patient Profiles Browser window with list of patients. Select to highlight the patient rows you wish to schedule. Right mouse-click to display the floating menu to **Schedule Selected Patents**, or **Schedule All Patients**.



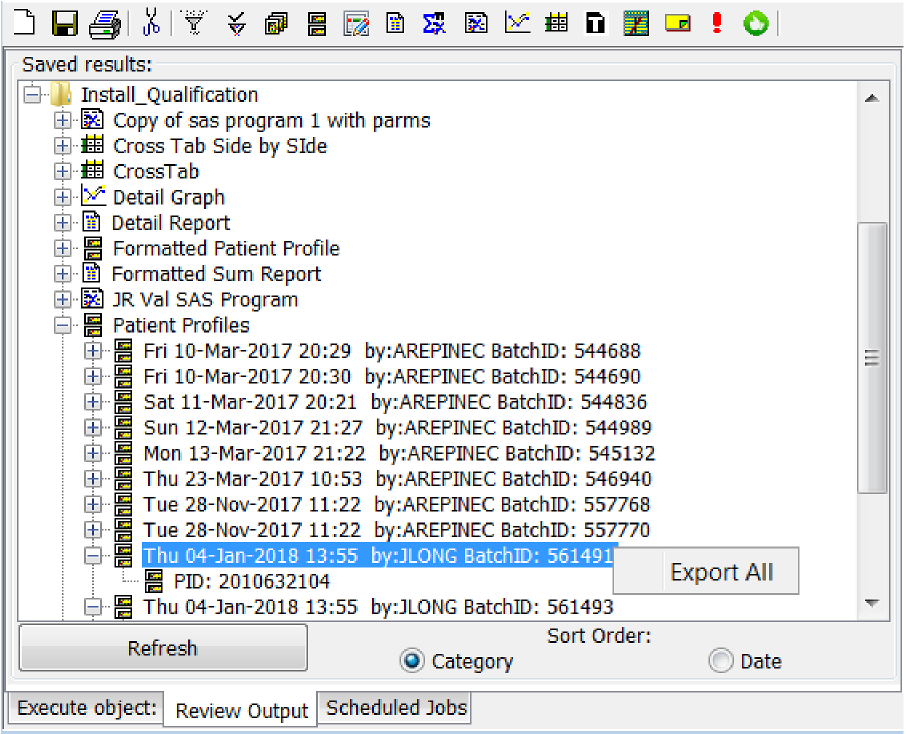
| PT ○ | INV ○ | STUDY ○ | Not Defined |
|---|---|---|---|
| 1120 | 066 | KA201 | Not Retrieved |
| 6207 | 064 | KA201 | Not Retrieved |
| 7111 | 065 | KA201 | Not Retrieved |
| 7112 | 065 | KA201 | Not Retrieved |
| 7201 | 065 | [illegible] | Not Retrieved |

## *Schedule workbook profiles*

The same scheduling functionality for **Workbook Patient Profiles** is available generating Excel spreadsheets for each patient , also accessible **externally** if desired.

After the scheduled workbook profile object has run, select the batch job within the **Review Output** tab and right click to select **Export All**.  The window opens to Choose Directory to Save the File.

***(See Chapter 11 - Saving Manage Objects, Scheduling plus Alerts Browser: section Schedule Patient Profiles and Narratives)***



Saved results:

- Install_Qualification
  - Copy of sas program 1 with parms
  - Cross Tab Side by SIde
  - CrossTab
  - Detail Graph
  - Detail Report
  - Formatted Patient Profile
  - Formatted Sum Report
  - JR Val SAS Program
  - Patient Profiles
    - Fri 10-Mar-2017 20:29  by:AREPINEC BatchID: 544688
    - Fri 10-Mar-2017 20:30  by:AREPINEC BatchID: 544690
    - Sat 11-Mar-2017 20:21  by:AREPINEC BatchID: 544836
    - Sun 12-Mar-2017 21:27  by:AREPINEC BatchID: 544989
    - Mon 13-Mar-2017 21:22  by:AREPINEC BatchID: 545132
    - Thu 23-Mar-2017 10:53  by:AREPINEC BatchID: 546940
    - Tue 28-Nov-2017 11:22  by:AREPINEC BatchID: 557768
    - Tue 28-Nov-2017 11:22  by:AREPINEC BatchID: 557770
    - Thu 04-Jan-2018 13:55  by:JLONG BatchID: 561491
      - PID: 2010632104
    - Thu 04-Jan-2018 13:55  by:JLONG BatchID: 561493

Sort Order: ● Category ○ Date

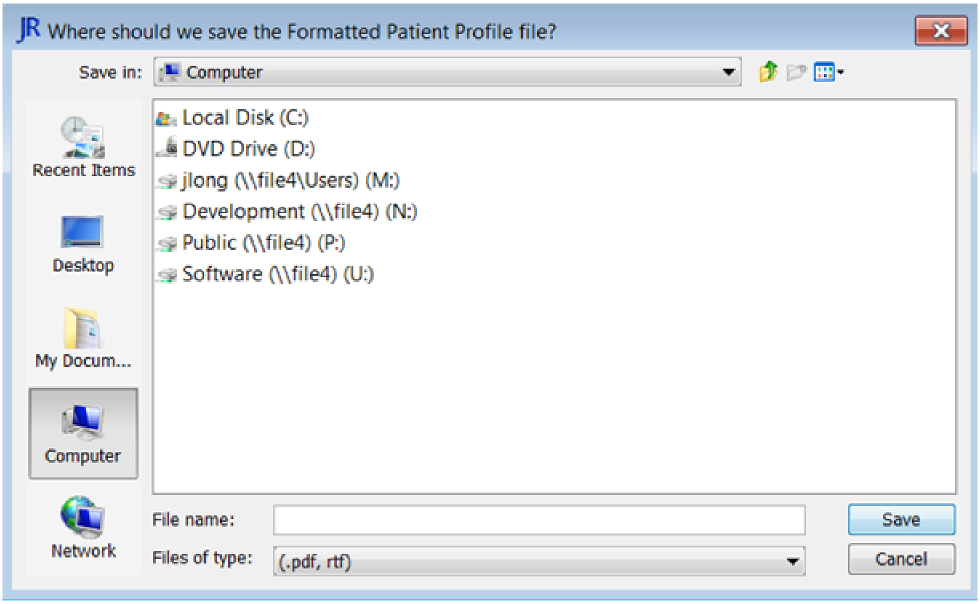
## *Export patient profile*

You can use the Export function to export your results. The file options are dependent upon the result type, and display the appropriate export file options available.

**Formatted Patient Profiles** can be exported as .pdf or .rtf files. **Workbook Profiles** may be in .txt, html or .xls files.

To export your patient profile:

1. Select the object to export, it must be the active window.
2. Select the **File** menu and click **Export**. JReview displays the **Save File** window.


Where should we save the Formatted Patient Profile file?

Save in: Computer

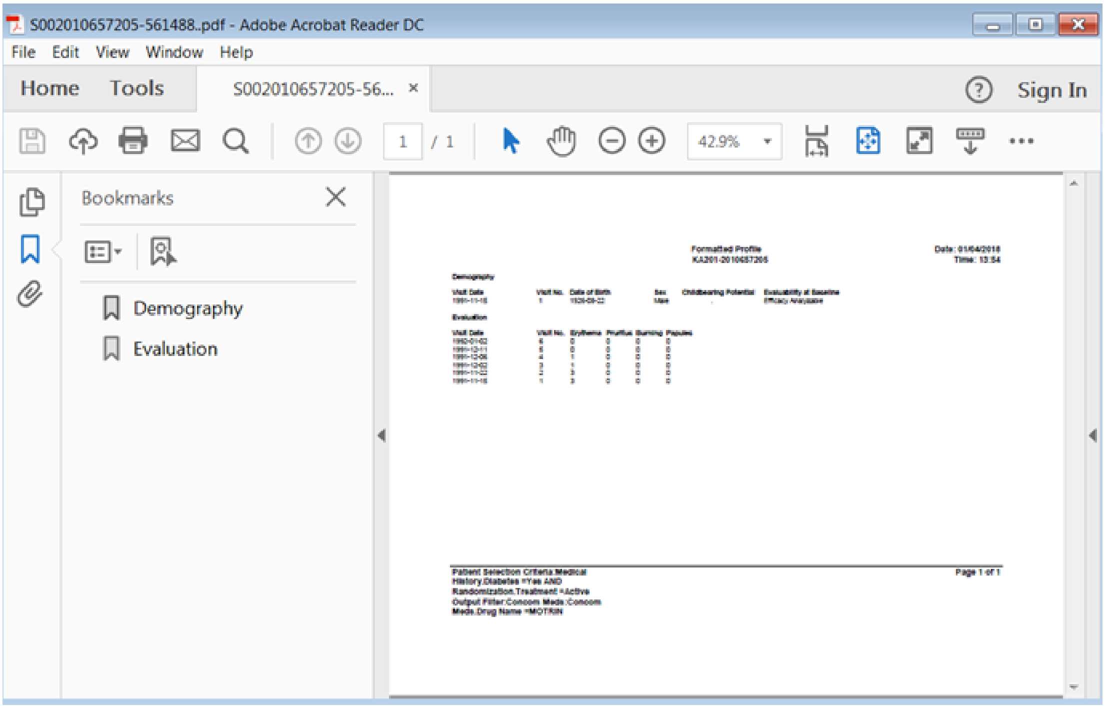
Local Disk (C:)
DVD Drive (D:)
jlong (\\file4\Users) (M:)
Development (\\file4) (N:)
Public (\\file4) (P:)
Software (\\file4) (U:)

File name:

Files of type: (.pdf, rtf)

3. Select the **storage location**.
4. Enter the **File Name,** and select the **storage type**.
5. Click **Save**. Your patient profile is exported to the currently selected directory.

After the formatted patient profile is exported, it displays with bookmarks of the Panel/Question Group or Visit dependent on how the formatted patient profiled was organized. ***(Requires an Active X Control to generate the bookmarks after the file is exported.)***.



## *Export multiple formatted profiles*

Users may export all formatted patient profiles in a given batch to be copied to the users indicated directory location.

In the Review Output List, right click on the formatted patient profile output folder for the job to view menu, and select **Export All** .

# Object Storage

For detailed instructions on how to save, retrieve and remove object specifications (reports, graphs, crosstabs, etc.) ***See Chapter 11 - Saving Manage Objects, Scheduling plus Alerts Browser.***

Close Patient Profiles Browser

## *Closing the Patient Profiles windows*

If you are finished with all Patient Profiles, and do not want to define any other Patient Profiles: double-click on the close box of the Patient Profiles Browser window.

Review closes all Patient Profiles windows currently opened.

# 5 Graphic Patient Profiles

# Graphic Patient Profile

## *Access Graphic Patient Profile*

Users with access to the Patient Profiles have the option to access Graphic Patient Profiles where the data is viewed in intuitive, graphic format. You can create, execute and save graphic patient profile objects at the global, project, studygroup and study levels and in either private, usergroup or public object locations.

The graphic patient profile specifications are created within the limits set by the currently defined graphic patient profile templates.

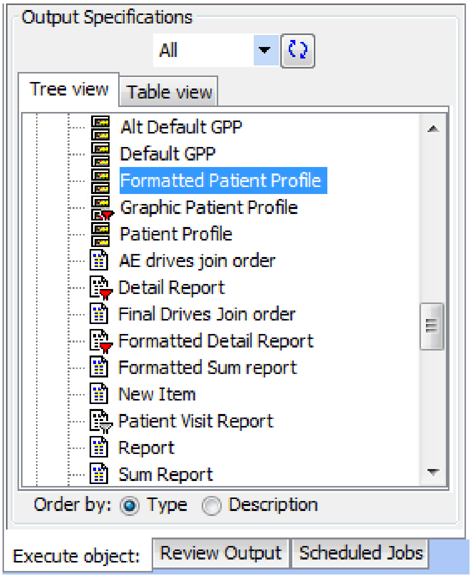
- Graphic Patient Profiles display a single patient's data graphically over time.
- It is **required** to map the "panels" from the Clinical Data Management System to the "categories" in Review accomplished through Graphic Patient Profile Templates.
- The activity of creating and editing Graphic Patient Profile Templates is typically done ***infrequently***.

***Note: The Review Administrator application must be updated to allow the granting of these privileges to specific users or groups.***

The patient data is displayed from multiple data domains and plotted against a common time axis. The display style for each domain depends upon the kind of data, for example, duration events such as Adverse Events are plotted as horizontal bars showing the duration of the event, from onset date to end date.

Graphic patient profiles are very complex, due to the different types of data can best be represented by different types of graphs. The individual graphs are aligned along a similar time axis, however, each graph may consist of a different plot type based upon the type of data "event" that is depicted. Each graph may be based on data from multiple tables in the underlying database.

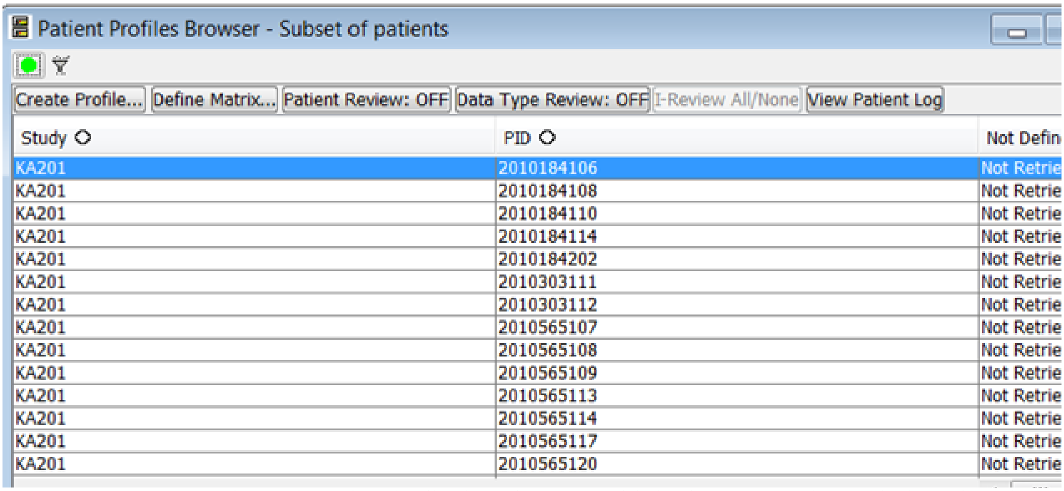
Previously saved graphic patient profiles can be selected and executed from the Object Explorer window.



JReview opens the Patient Profile Browser which displays a list of patients who meet the patient selection criteria, or all available patients if no selection criteria was defined. The first patient listed is the default selection, or select a patient and click **Create Profile**.

There is a ReviewAdmin option to automatically create/open the first patient GPP in the list. The System Administrator would set this default feature as ON/OFF per the user site preference.

Another ReviewAdmin option will display a “Subset” column in place of the Study column, to indicate if the patient belongs to a saved patient subset.

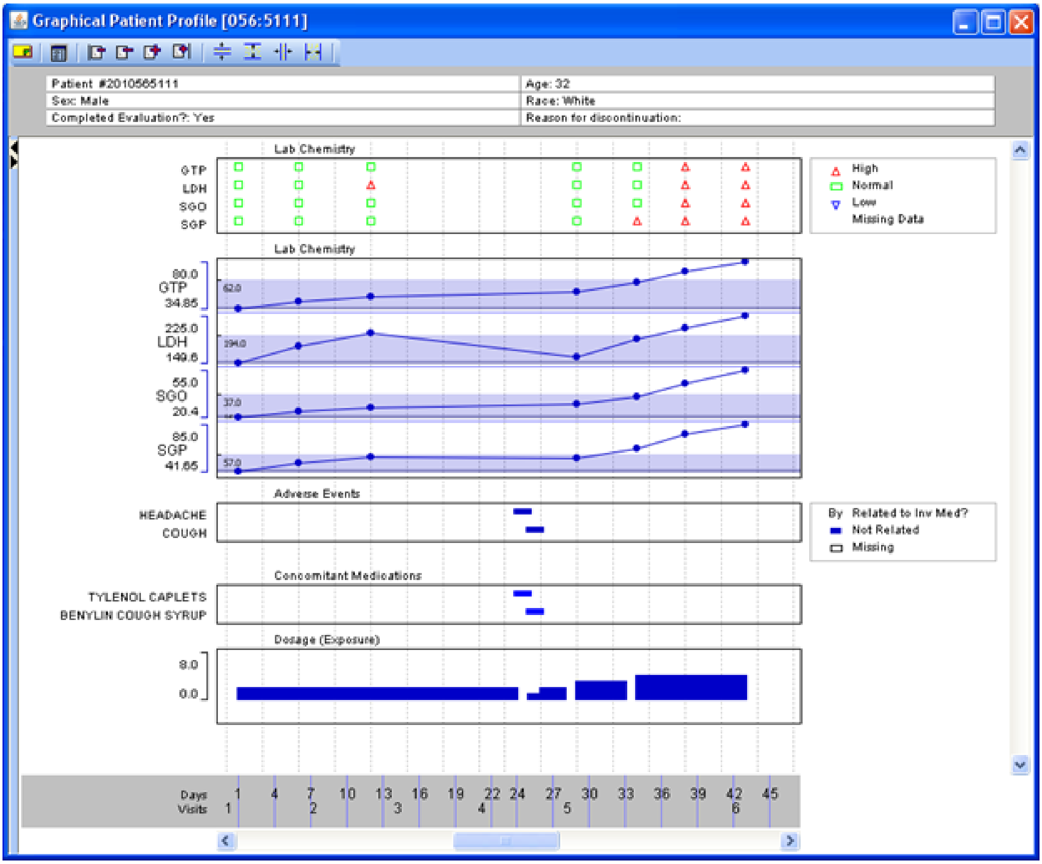


| Study ○ | PID ○ | Not Defin |
|---|---|---|
| KA201 | 2010184106 | Not Retrie |
| KA201 | 2010184108 | Not Retrie |
| KA201 | 2010184110 | Not Retrie |
| KA201 | 2010184114 | Not Retrie |
| KA201 | 2010184202 | Not Retrie |
| KA201 | 2010303111 | Not Retrie |
| KA201 | 2010303112 | Not Retrie |
| KA201 | 2010565107 | Not Retrie |
| KA201 | 2010565108 | Not Retrie |
| KA201 | 2010565109 | Not Retrie |
| KA201 | 2010565113 | Not Retrie |
| KA201 | 2010565114 | Not Retrie |
| KA201 | 2010565117 | Not Retrie |
| KA201 | 2010565120 | Not Retrie |

The patient data is displayed from multiple data categories and plotted against a common time axis. The display style for each domain depends upon the kind of data, for example, duration events such as Adverse Events are plotted as horizontal bars showing the duration of the event, from onset date to end date. There is fixed/frozen viewing behavior applied to the graphic patient profiles, so the user always sees the following information:

- If the Header area was defined for the graphic patient profile, it always displays for example: treatment, completion status, etc.
- Left side axis text to always view Adverse Event, Conmed, or other text.
- Right side axis text for the Legend Box details/text to see the appropriate legend for a particular part of the GPP.
- Day/Visit Axis is always in view to avoid additional scrolling.

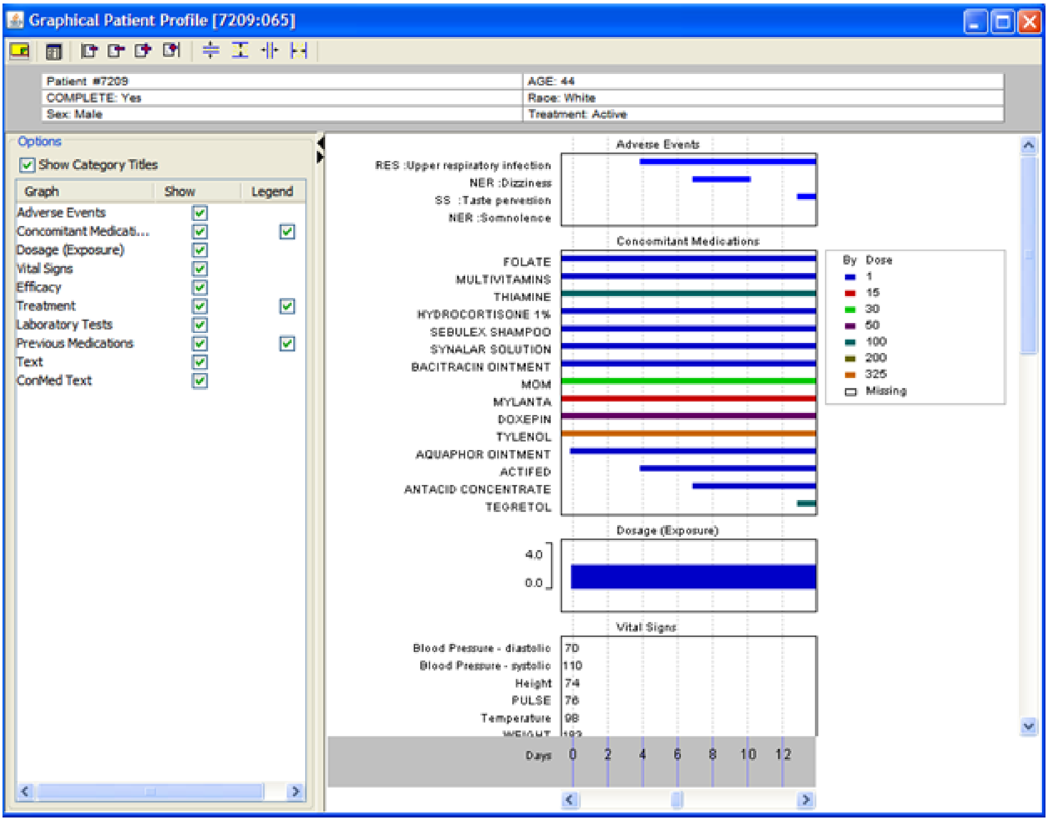
The body of the graph 'scrolls' within these 4 frozen areas, always keeping its anchor to the corresponding information.



Graphical Patient Profile [056:5111]

| | |
|---|---|
| Patient #2010565111 | Age: 32 |
| Sex: Male | Race: White |
| Completed Evaluation?: Yes | Reason for discontinuation: |

A window toggle allows the user to interactively include or suppress categories and legends in the graphic profile at runtime. Use the checkboxes to select which categories or legend to display or suppress.



| | |
|---|---|
| Patient #7209 | AGE: 44 |
| COMPLETE: Yes | Race: White |
| Sex: Male | Treatment: Active |

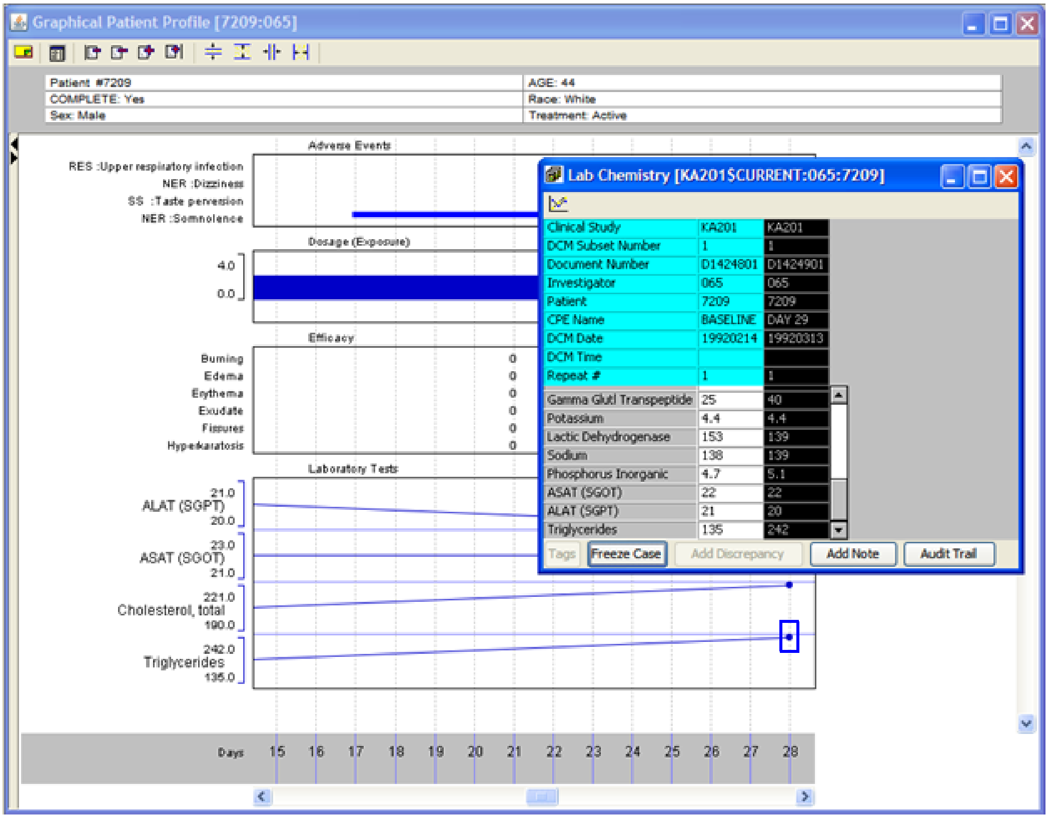
Options

☑ Show Category Titles

| Graph | Show | Legend |
|---|---|---|
| Adverse Events | ☑ | |
| Concomitant Medicati... | ☑ | ☑ |
| Dosage (Exposure) | ☑ | |
| Vital Signs | ☑ | |
| Efficacy | ☑ | |
| Treatment | ☑ | ☑ |
| Laboratory Tests | ☑ | |
| Previous Medications | ☑ | ☑ |
| Text | ☑ | |
| ConMed Text | ☑ | |

Once the graphic patient profile displays, the following functions are available to assist you in further examining each graphic data display.

- Use the scroll bar to move through the multiple graphic plots within the patient.
- Select a data point on a graph display and left mouse click to select and invoke drill down with the Data Browser.



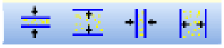
Patient #7209
COMPLETE: Yes
Sex: Male
AGE: 44
Race: White
Treatment: Active

| | | |
|---|---|---|
| Clinical Study | KA201 | KA201 |
| DCM Subset Number | 1 | 1 |
| Document Number | D1424801 | D1424901 |
| Investigator | 065 | 065 |
| Patient | 7209 | 7209 |
| CPE Name | BASELINE | DAY 29 |
| DCM Date | 19920214 | 19920313 |
| DCM Time | | |
| Repeat # | 1 | 1 |
| Gamma Glutl Transpeptide | 25 | 40 |
| Potassium | 4.4 | 4.4 |
| Lactic Dehydrogenase | 153 | 139 |
| Sodium | 138 | 139 |
| Phosphorus Inorganic | 4.7 | 5.1 |
| ASAT (SGOT) | 22 | 22 |
| ALAT (SGPT) | 21 | 20 |
| Triglycerides | 135 | 242 |

- The first button in the toolbar is to apply **Patient Notes**. ***(See Chapter 3 Data Browser: section for Patient Notes)***
- The second button in the toolbar is for **Show Settings**. ***(See section for Graph Setting)***

- To move between patients, use the icons in the toolbar with the appearance of little pages with - and + signs. The first page button always takes you to the first patient. The second page button moves you one patient back. The third page button moves you one patient forward. The last page button always takes you to the last patient.

- Use the last scale icons to adjust the scale to decrease or increase the plot for compressing or expanding the rows.



Super Users are able to save templates at the object storage level for global, project, study group and study levels as only one per level. The templates are saved at the object storage location for public only.

Once a graphic patient profile is saved the template information is saved with the profile. Therefore, a saved profile uses the original template information that existed at the time it was created to avoid conflicts with updated or newly created templates.

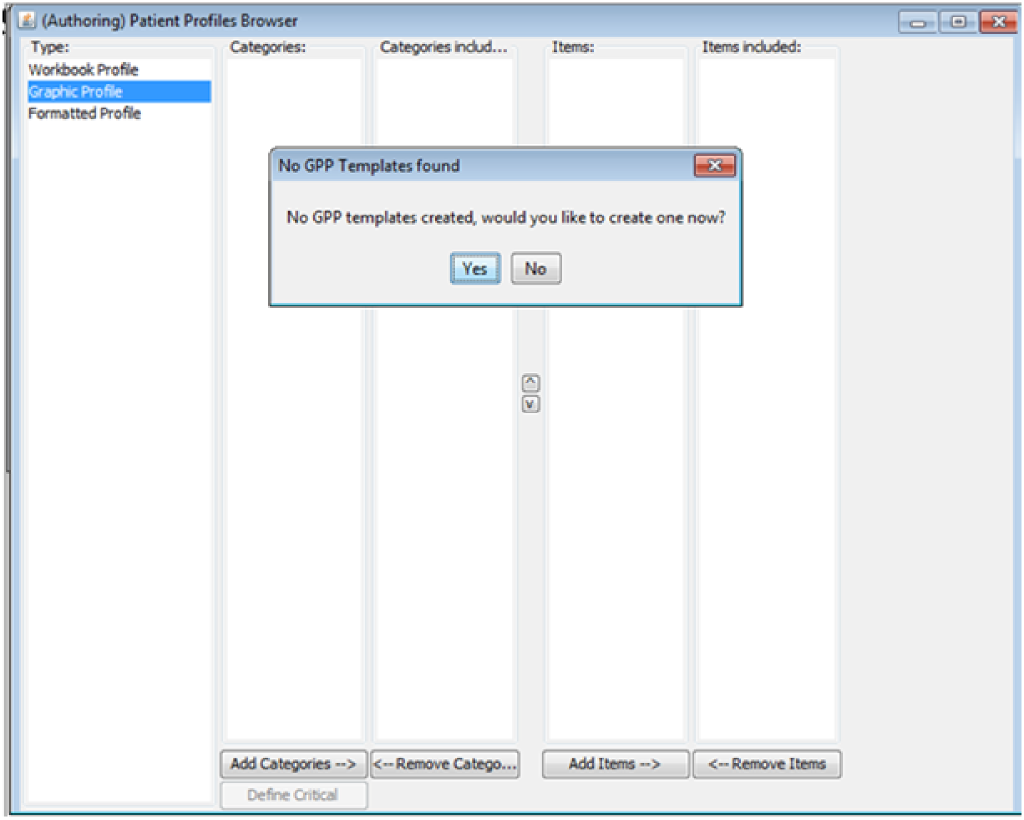
# Define Graphic Profile Template

## *Open Patient Profiles Browser*

Prior to defining a graphic patient profile for time, select categories and plot types a graphic patient profile template is **required** to access those included categories and define the study start**.**

Click ▤ on the toolbar or from the **Browse** menu, select **Patient Profiles**.

JReview opens the Patient Profiles Browser window to the default profile type for **Workbook Profile**. Click on the **Graphic Profile** type.



No GPP Templates found

No GPP templates created, would you like to create one now?

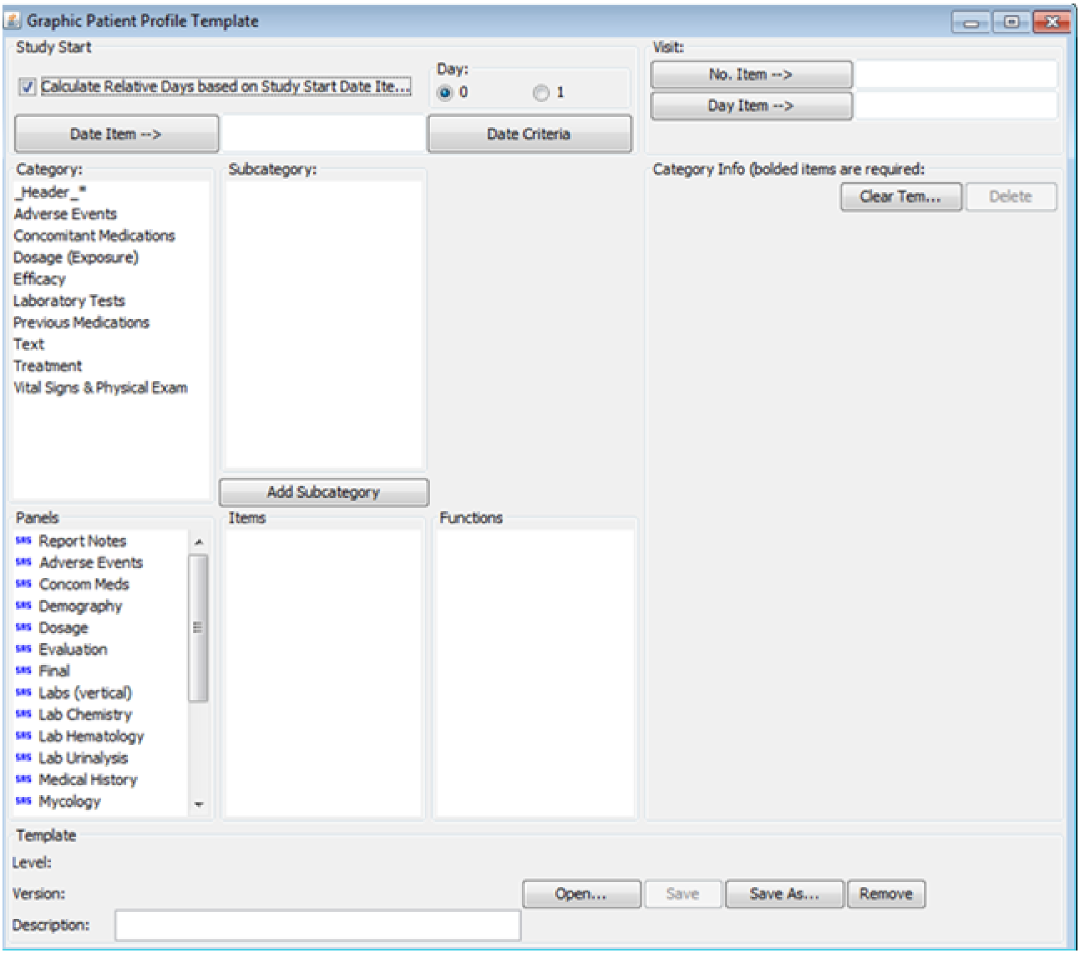
## *Open Graphic Profile Template*

A Graphic Patient Profile template must be defined first before users can create graphic patient profile specifications.

SuperUsers with the privilege to “Create Graphic Patient Profile Templates” access the Graphic Patient Profile template feature from the Patient Profiles Browser window within the Graphic Profile option.

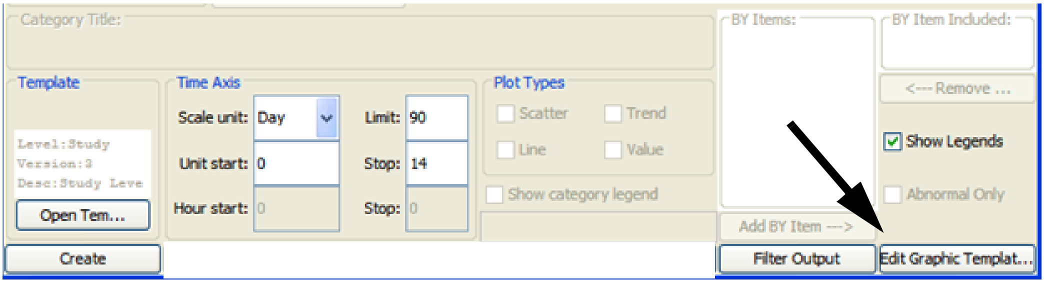
If none exists, a message displays and the user is exited from the graphic patient profile option. If you have authoring privileges to define a graphic template; a message box displays asking if you wish to create a template now.

Click **Yes** and the Graphic Patient Profile Template window opens.


☑ Calculate Relative Days based on Study Start Date Ite...

Day: ● 0 ○ 1

If there are previous graphic templates already saved, click on the **Edit Graphic Template** button to open the Graphic Patient Profile Template window.

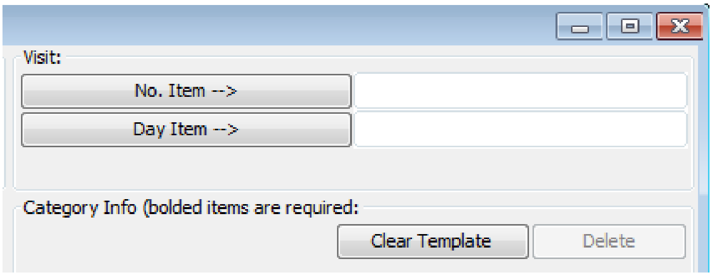


Level:Study
Version:3
Desc:Study Leve

Scale unit: Day
Limit: 90
Unit start: 0
Stop: 14
Hour start: 0
Stop: 0

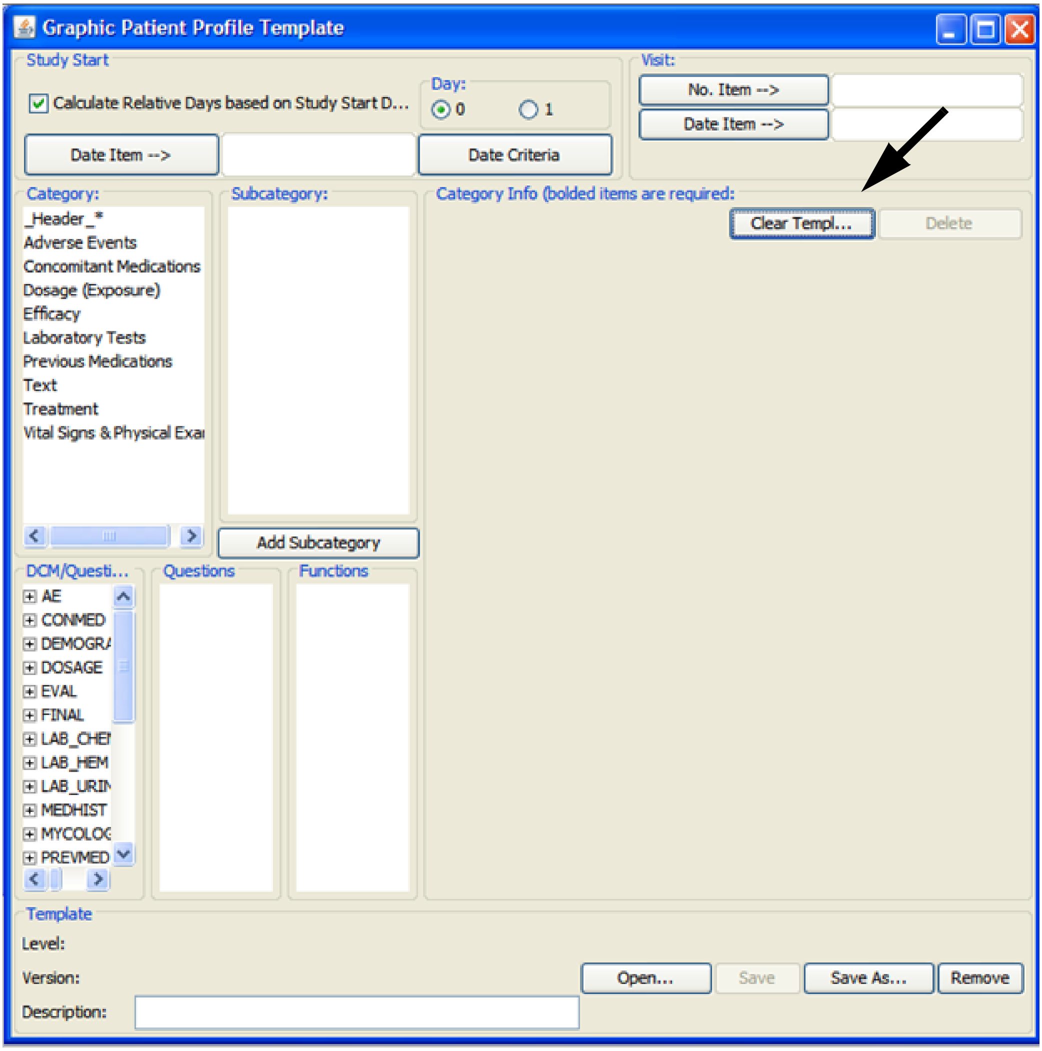
☐ Scatter
☐ Trend
☐ Line
☐ Value
☐ Show category legend
☑ Show Legends
☐ Abnormal Only

The current graphic template will be displayed.  In the upper right corner of the window, click the **Clear Template** button to define a ***new*** graphic patient profile template.



The Graphic Patient Profile Template is where the “Categories” used by the end user within the Graphic Patient Profiles are matched to the “panels” and “items” from the database. For some categories, such as labs, select as many possible items. Then during creation of the Graphic Patient Profile, the user has more selection options similar to a menu.

The Graphic Patient Profile Template dialogs are dependent upon the category. The type of information collected will vary to generate text, duration bar or numeric plots.



## *Define study start date*

Entry of the Study Start Date is **required** unless the database utilizes an item for day calculations.

The Study Start check box is defaulted ON for “Calculate Relative days based on Study Start Item (and possibly Date Criteria)?”. When checked, you must define an item that contains a unique single value for each patient’s study start date as Day 1 or Day 0.

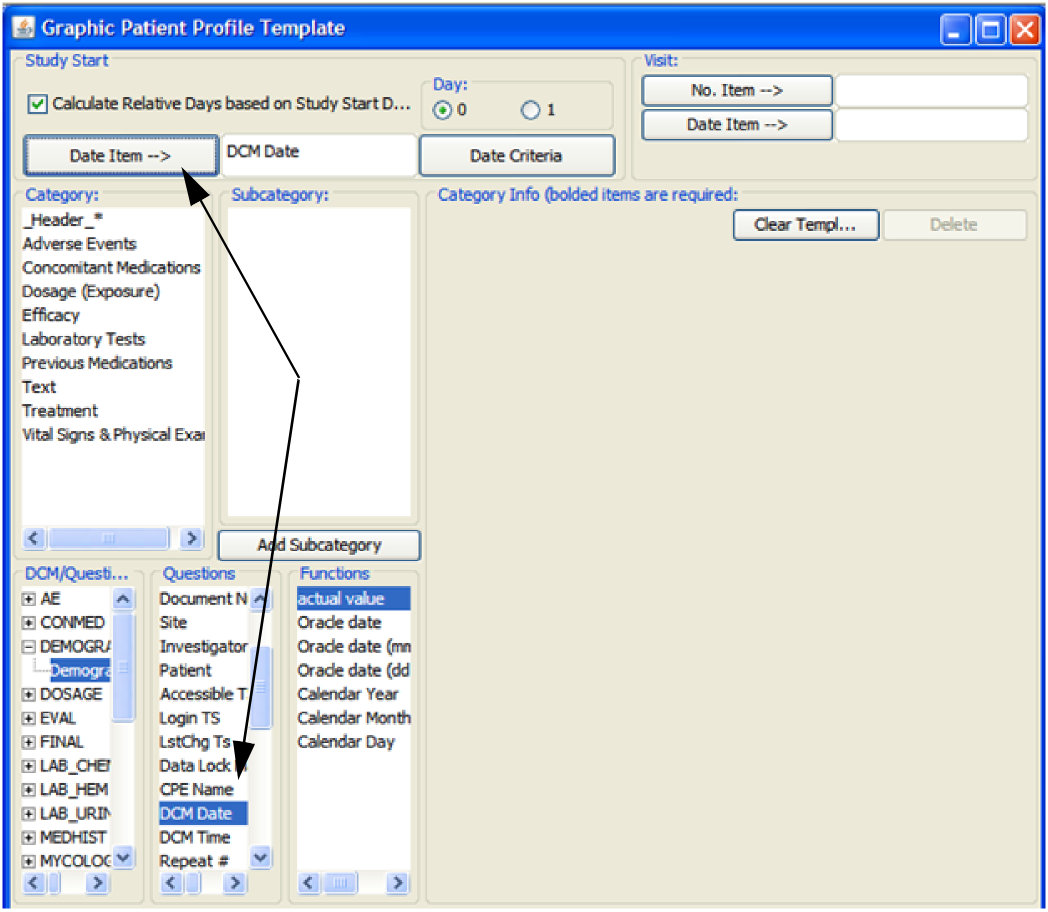
For example, a date item located on a single record per patient such as the Demography data panel. If a multiple record data panel is chosen, then the selected date item **requires** the Date Criteria be applied to filter down to a unique patient study start date such as visit label is baseline, visit number is 1, etc.

The Study Start Date is **required** to create a Graphic Patient Profile. Therefore, if you forget to enter a study start date you would be **unable** to save the template.

If your database contains a calculated Day item, then you can uncheck the Study Start box and all other items in the Study Start box are disabled. The buttons previously labeled as “Date” then display as “Day” when you enter details for the various categories.

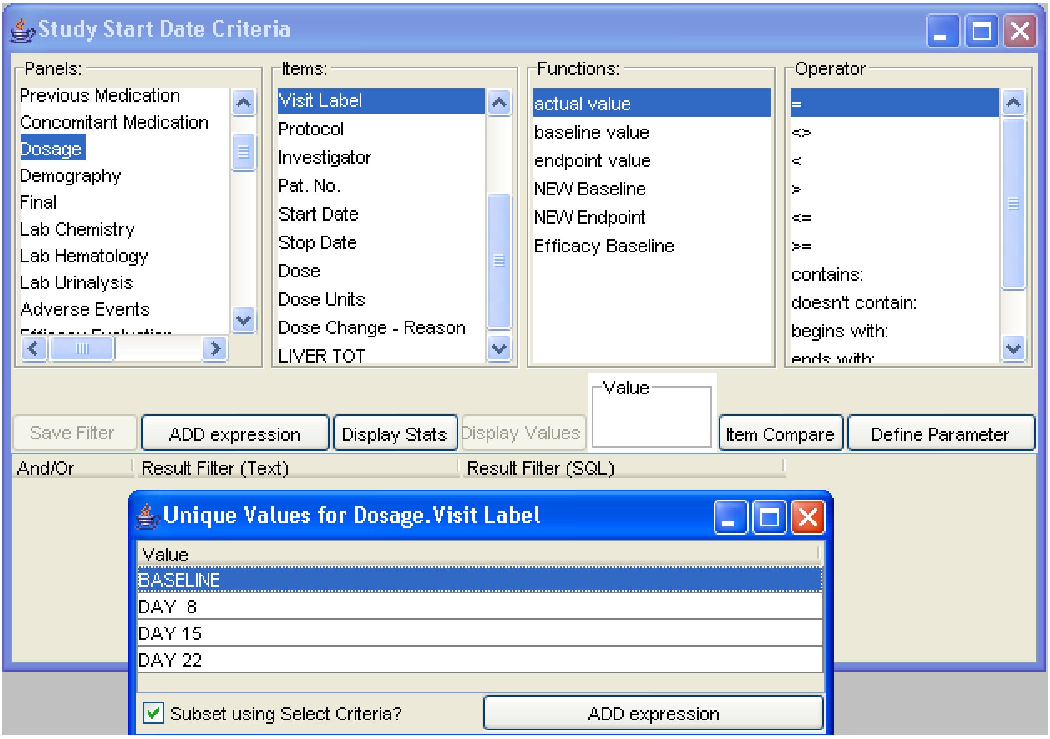
Enter the precalculated Day item created in your database (not JReview). You are required to select at least one item per defined category that contains numeric values denoting ***relative days from study start*** (i.e., for a single event category such as “Laboratory Test” you would enter an item containing values of the relative day the lab test was performed). The relative day item would be another item located in the same panel. For duration events such as “Adverse Events” you would enter the item containing the values of the relative day each Adverse Event started and a second item containing the relative day each Adverse Event ended.

1. To enter the Study Start Date Item, select a panel and date item. Click **Date Item**.
2. Enter the date item as **Day 0** or **Day 1**.



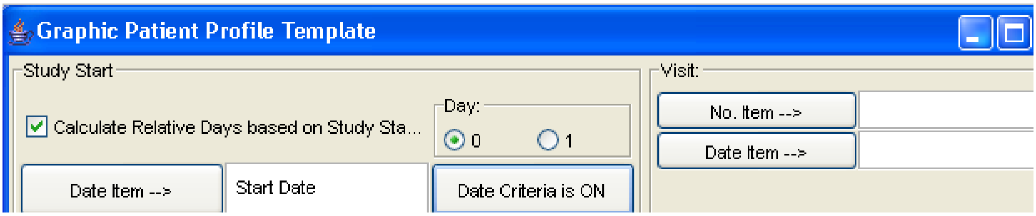
If you had entered a study start date from a multiple record panel then you need to further specify the date by clicking **Date Criteria**. For example, if you had selected the Start Date item from the Dosage Panel, the Date Criteria is **required** for this multiple record panel.

The Study Start Date Criteria window opens for you to specify details such as a visit label or visit number for your selected date.



3. Click **Save Filter** and close the window.

   The **Date Criteria** button status changes to ‘Date Criteria ON’.

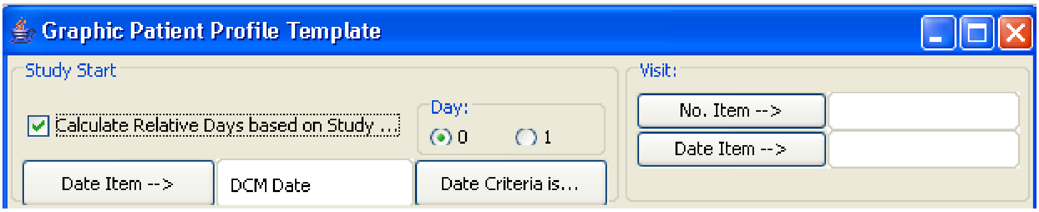


## *Define Visit*

You can optionally calculate relative “Days on Drug” to plot the graphic display with multiple Visit information. Study Start Date and Visit information are independent functions from each other and can utilize dates from different panel sources.

Information entered in the Visit function for “No. Item” and “Date Item” are **required** to come from the same panel source as the entries for Visit Number and Visit Date. The resulting calculation for relative “Days on Drug” is displayed and plotted against the visit number along the X Axis on the graphic profile.

For example, if Demography Visit Date is entered as the Study Start Date and you need the graphic display plotted against the relative days calculated from the multiple visit Efficacy panel. By entering Efficacy Visit No item and Visit Date for the Visit information calculates the relative days between the two date items and is plotted on the graphic profile.



☑ Calculate Relative Days based on Study ...

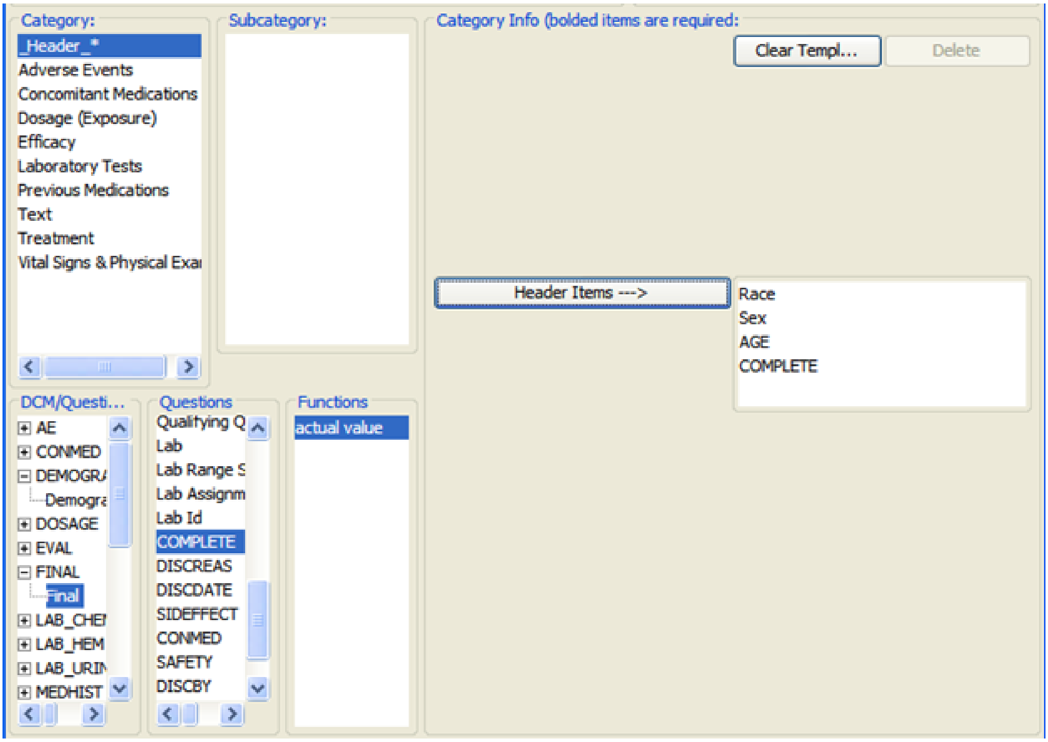
Day: ● 0 ○ 1

Date Item --> DCM Date

## *Define header items*

Adding a header is optional. The PatientID defaults if left blank.

4. Click **Header** from the Category list.
5. Go to the Panels list and Items list to select and add header items to display in the graphic patient profile.
6. Click **Header Items** button to add items. Highlight and click scissors in the tool bar to remove items.



## *Category types*

Different types of data can be best represented by different types of graphs. Data with start and stop dates (i.e., duration events) are graphed as horizontal bar charts over time. Data collected on a given date(s) as time point events (i.e., labs, vitals) are graphed as scatter plot graphs. Data with no date associated are displayed as text.

Different information about data panels/tables and items/fields are needed in order to create each type of graph (bar, line or scatter). This database information may come from multiple database panels/tables and are organized into a data category. The data category "bucket" contains the type of data (or event) to be graphed; the type of graphs to be plotted for this type of data (or event); and additional necessary information on panels/tables and items/fields to get the correct data from the database to generate the desired graphs (i.e., lab normals).

- A data category contains specifications about the data for a specific type of data "event".
- Allows for these specifications to be based on multiple database tables restricting that only one-to-one or one-to-many table relationships be allowed.
- Associates the type of data event to be graphed with the appropriate types of plots.

The following table lists the data categories.

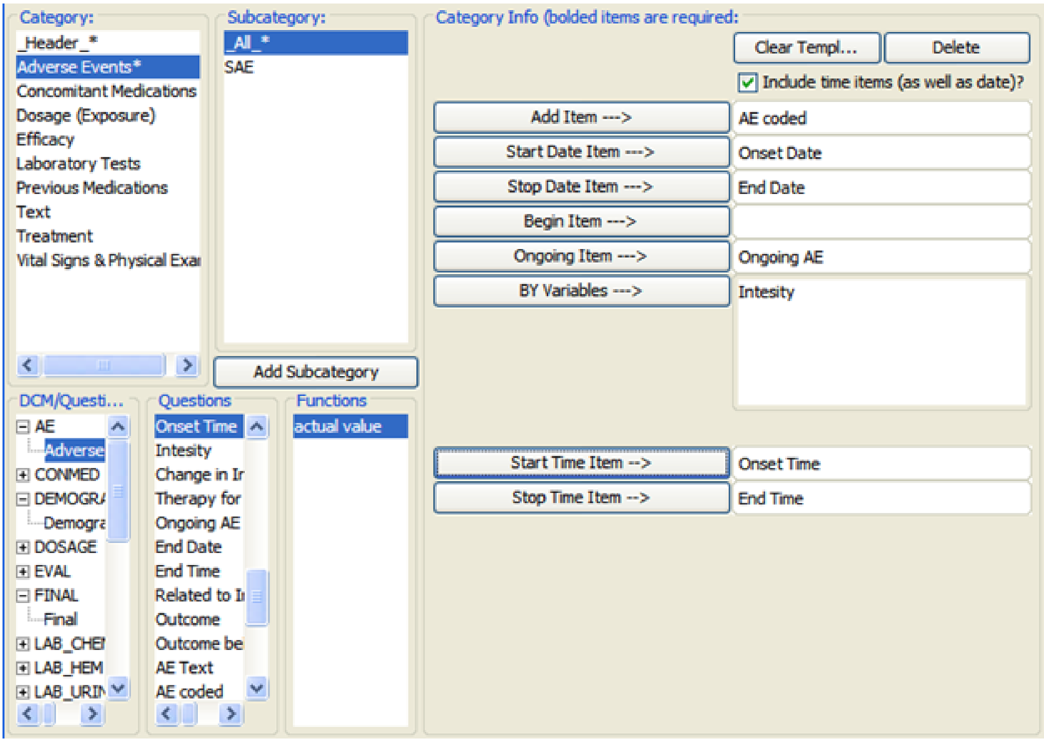
| **Category Type** | **Definition** | **Plot Type(s)** |
|---|---|---|
| Duration | Data collection event that has a start and stop time point. | Horizontal Bar |
| Time Plot | Data collection event that occurred at a specific point in time. | Data Value Line Plot |
| Lab | Lab test data collection event that can be compared to normal range values if they are defined in the data. | Scatter Plot Line Plot Trend Plot Data Value |
| Dosage | Dosage data collection event that has a standardized dose value and start and stop time points. | Vertical Bar |
| Non-Time Aligned or Text | Data not associated with a specific point in time (i.e., gender, sex) | Free form text |

## *Define Category Information*

The SuperUser specifies the category information from a pre-defined categories list and can further select or **Add Subcategory** to create user defined subcategories for Adverse Events, Laboratory Tests, Text, etc.

1. Select a **Category** to display the corresponding template for entering category information.
2. Optionally, if the category collects time data, click the **Include time items** box to activate the time items to display with the date items.
3. Select the **Panel(s)** and **Items** to define the category information. Select the item function as actual value or decoded value.
4. Repeat the steps to add or select a subcategory. Click the **Clear** button to remove current items and reselect items. Or, click **Delete** to remove a user defined subcategory.
5. Click the **Add Subcategory** button to add a new subcategory.

   When a category is added an asterisk displays next to the category in the category list noting it has been defined.



☑ Include time items (as well as date)?

Add Item ---> AE coded

Start Date Item ---> Onset Date

Stop Date Item ---> End Date

Begin Item --->

Ongoing Item ---> Ongoing AE

BY Variables ---> Intesity

Start Time Item --> Onset Time

Stop Time Item --> End Time

## *Missing data*

Missing data is displayed for line plots and scatter plots as blank. Duration plots will display as an empty box for a missing BY variable value.

Only Adverse Event and Concmed data for duration plots are handled with the 'B' and 'E' display. This condition only applies to these two categories. If an Adverse Event or Conmed have a missing Start date, and only have an End Date, then display a 'E' for End at the stop day. If an Adverse Event or Conmed have a missing Stop date, and only have a start date, then display a 'B' for begin at the start day.

Ongoing would have a start date/day, and no stop date, but the ongoing flag would be set. In this situation, the duration bar continues as drawn/displayed all the way to the right, with a right arrow at the very end.

These display details are driven by the "Ongoing" template entry if present or blank, and how it is defined in the graphic profile for "Limit" setting.

## *Ongoing Item*

**Table 1: Ongoing status is not collected during the study, and the 'Ongoing Item' set to blank in the Template.**

| Start Date | Stop Date | Date Status | Graph Display |
|---|---|---|---|
| Present | Present | Both Start and Stop Dates were entered. | Duration Bar |
| Present | Blank | Missing Stop Date. | Letter 'B' in Start Date |
| Blank | Present | Missing Start Date. | Letter 'E' in Stop Date |
| Blank | Blank | Both dates missing. | Blank |

**Table 2: Ongoing status is collected during study, and the ‘Ongoing Item’ is entered in the Template.**

| Start Date | Stop Date | Date Status | Ongoing Status | Graph Display |
|---|---|---|---|---|
| Present | Present | Both Start and Stop Dates were entered. | Blank | Duration Bar |
| Present | Present | Both Start and Stop Dates were entered. | Present | Ongoing Bar |
| Present | Blank | Missing Stop Date. | Present | Ongoing Bar |
| Blank | Present | Missing Start Date. | Blank | Letter ‘E’ in Stop Date |
| Blank | Blank | Both dates missing. | Blank | Blank |

## *Time Axis scale*

If you include time data items in any category definition by clicking the ‘Include time items’ checkbox, then Start and Stop Time Items will display for entry. In addition, the Time Axis scale in the graphic patient profile will include hours and minutes. The default displays the date items and ‘Include time items’ as unchecked for displaying time items.


☑ Include time items (as well as date)?

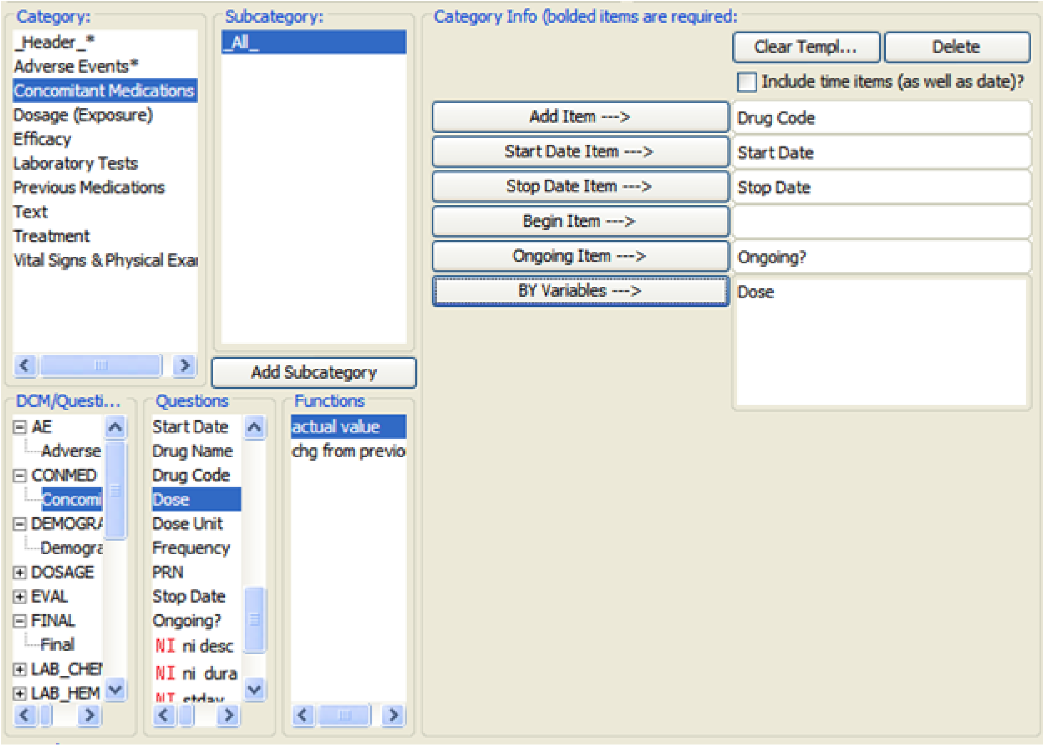
The following conditions are true with time items present:

- Existing templates and objects without the option for time are still processed from a prior release.
- Time is stored as days.hours in saved graphic patient profile objects so prior versions of the Review client will retrieve correctly in days.
- New templates will include the time option but you cannot go back and edit an existing template from a prior release.
- Time items of type character, numeric or time will process.
- Hours and Minutes are included in the Time Axis scale if the time item was included in the opened template and graphic patient profile object.
- Hours and Minutes are not included in the Time Axis scale if no time items were included in the opened template and graphic patient profile object.
- If a new graphic patient profile object is opened with hours as the scale with an older Review client, then the scale will present in days and the data will display accurately.
- Negative days and hours are handled.

## *Duration Category Type*

Duration type categories include Adverse Events, Concomitant Medications, Previous Medications and Treatment require the following item information to be entered:

- **Add Item** is the field to be graphed.
- **Ongoing Item** and **BY Variables** are optional. The **BY Variables** display details as a legend option.



☐ Include time items (as well as date)?

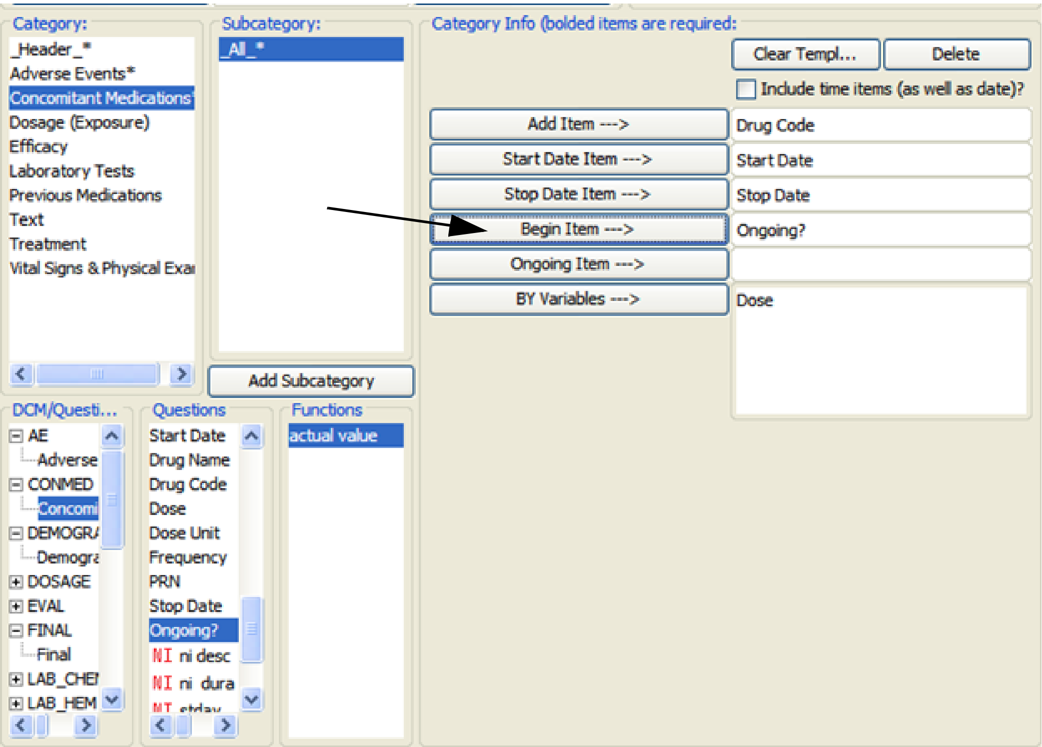
Add Item ---> Drug Code
Start Date Item ---> Start Date
Stop Date Item ---> Stop Date
Begin Item --->
Ongoing Item ---> Ongoing?
BY Variables ---> Dose

## *Begin Item*

In the GPP template, you may specify a variable for end continued as “Ongoing”, but also for begin continued. For example, in some clinical trials the medication was started a long time before trial start. Therefore, it is sufficient to specify "begin continued" instead of a real start date. The ‘**Begin Item**’ allows you to specify the begin continued variable directly in the GPP template.

The **Begin Continued Item** is located above the Ongoing Item in individual category definitions. This item only applies to categories with a Start Date item such as Adverse Events, Conmeds (duration types), or Dosage. The selected field works the same as the Ongoing field. If value is empty or has a first character beginning with “N”, it will be assumed to not signify a begin date before the study start. Otherwise, it will be treated as such and will be displayed as an arrow from the left side of the display through to the end date of the display line.

Internally if Begin Continue item is not empty for a category, then the value would be checked to see if the start date should be set to Jan 1, 1990.



☐ Include time items (as well as date)?

Add Item ---> Drug Code

Start Date Item ---> Start Date

Stop Date Item ---> Stop Date

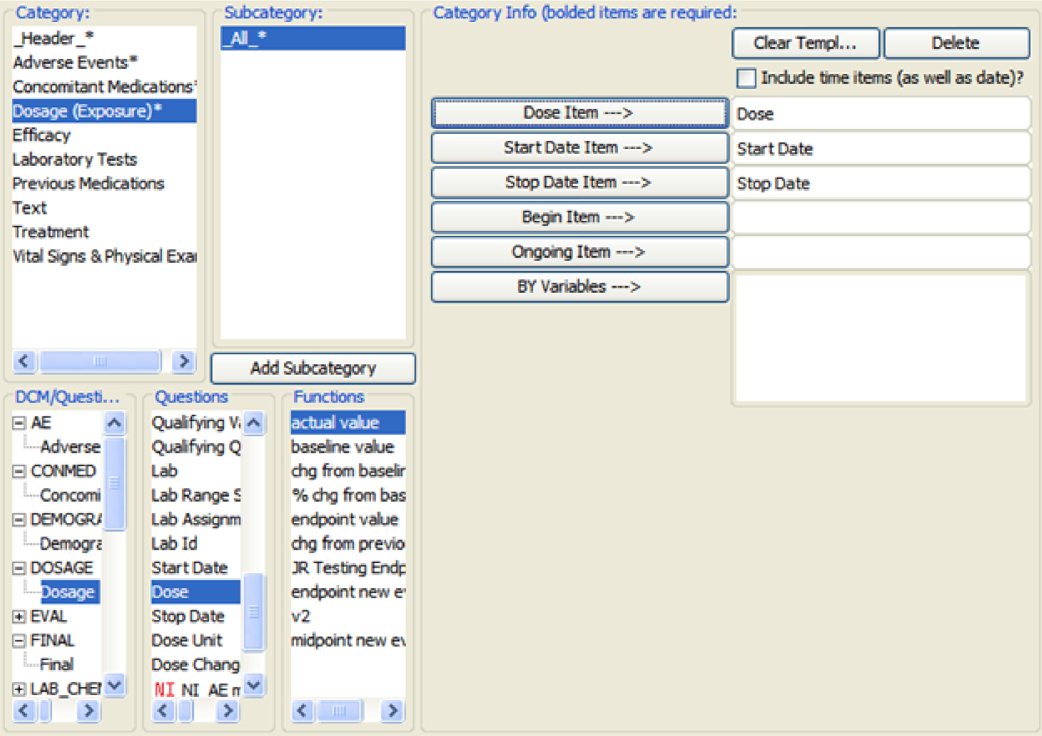
Begin Item ---> Ongoing?

Ongoing Item --->

BY Variables ---> Dose

## Dosage Category Type

The dosage category is a special case of duration **requiring a numeric** field representing dosage values for the item to graph. The dosage category supports multiple dosing regimens when you add subcategories.



☐ Include time items (as well as date)?

Dose Item ---> Dose

Start Date Item ---> Start Date

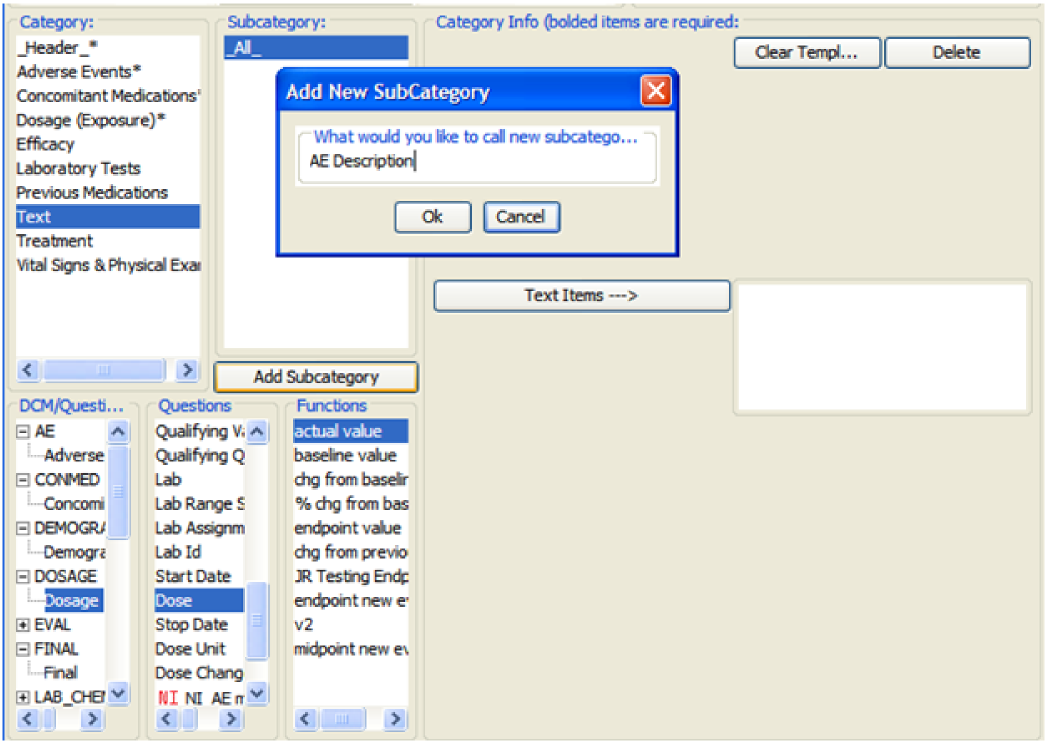
Stop Date Item ---> Stop Date

## *Text Category Type*

The text category is a text type which initially contains no subcategories. The SuperUser defines subcategories and assigns specific database items/fields from the panels/tables to either categorize itself or a subcategory. The items are displayed as non-time aligned data.

To add a Text Category:

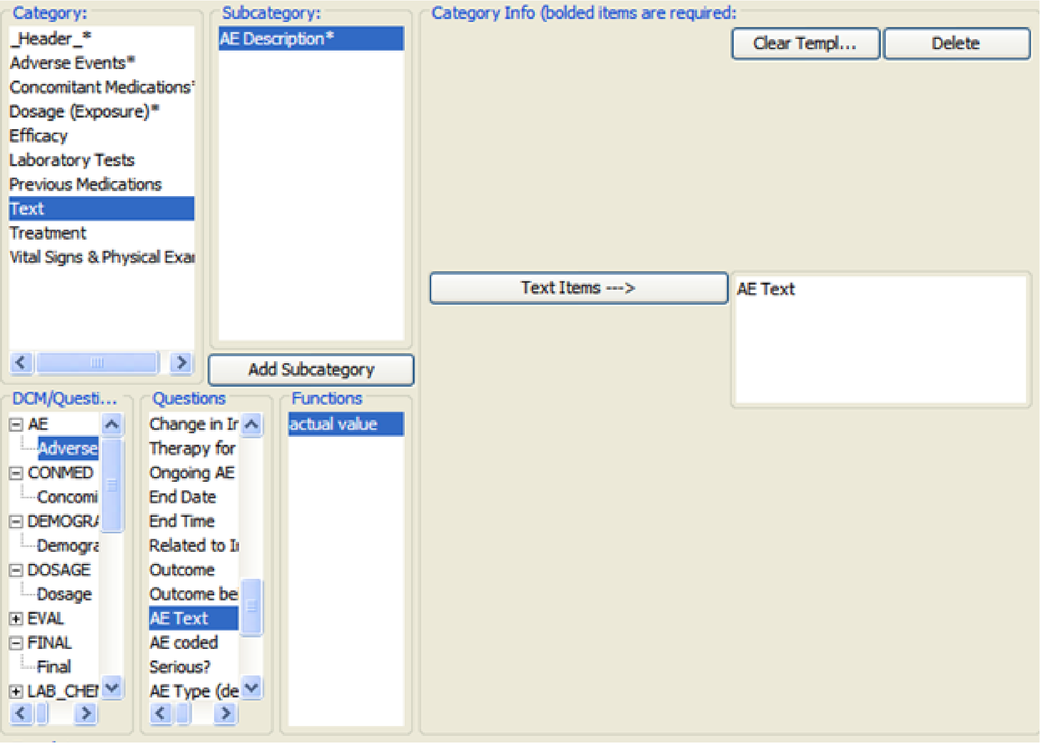
1. Select **Text** in the **Category** list and click **Add Subcategory button**.
2. The **Add New Subcategory window** opens for you to enter the subcategory.
3. Click **OK**.



What would you like to call new subcatego...

AE Description

4. Select the Panel(s) and item(s).
5. Click the **Text Items** button to add.



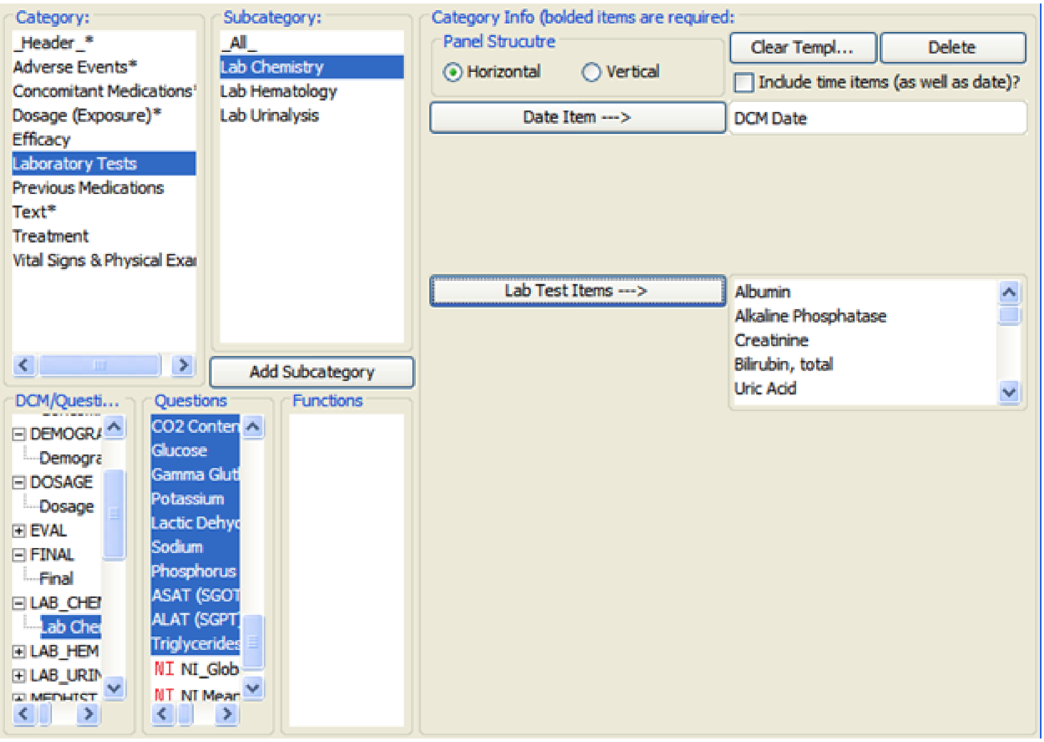
6. The Text subcategory is added. Click the **Delete** button to remove.

## *Laboratory Category Type*

The laboratory category is special due to the fact that lab data can be structured in either a *horizontal* (a separate field for each lab test) or *vertical* (one field for the lab test name and a second field for the lab result value for all labs) format. In addition, vertical lab data has each lab test associated with a lab normal range and units which may or may not be in another table.

Horizontal panel structure requires:

- Date Item - the field containing the date of the event.
- Item(s) - the fields which the user may select for graphing.



Category: Laboratory Tests

Subcategory: Lab Chemistry

Category Info (bolded items are required:

Panel Strucutre: ● Horizontal ○ Vertical

☐ Include time items (as well as date)?

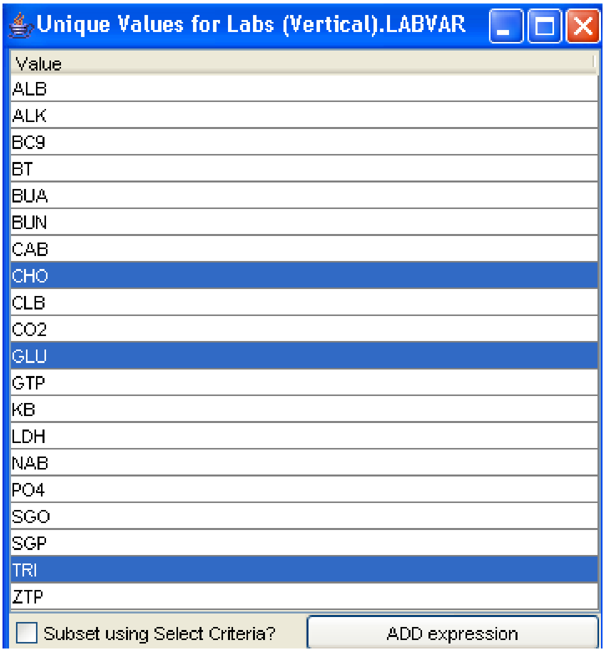
Date Item ---> DCM Date

Lab Test Items --->
Albumin
Alkaline Phosphatase
Creatinine
Bilirubin, total
Uric Acid

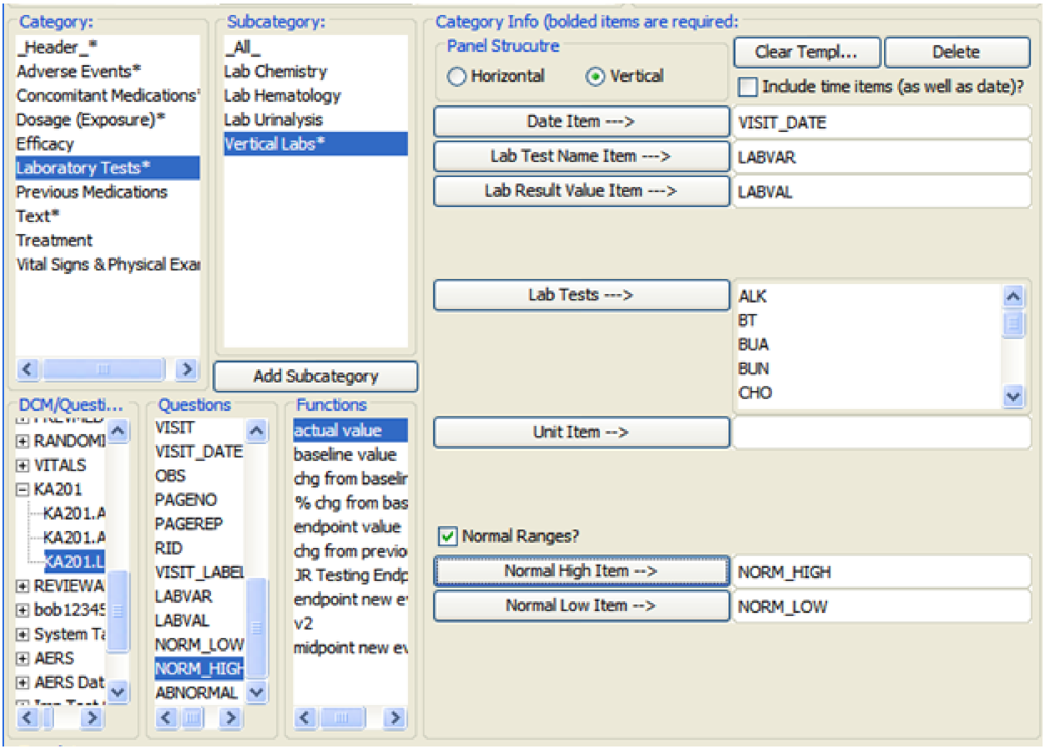
Vertical panel structure requires:

- Date Item - the field containing the date of the event.
- Lab Test Name Item - the field containing the lab test name.
- Lab Result Name Item - the field containing the lab test result or value.
- Lab Test(s) - the list of lab tests which the user may select for graphing. The overall list of lab test names is derived from the lab test name data item.

  To select multiple contiguous values, click on a value and drag over the other values. To select multiple non-contiguous values, click on a value and hold down the **Ctrl** key when clicking the other values.



| Value |
|---|
| ALB |
| ALK |
| BC9 |
| BT |
| BUA |
| BUN |
| CAB |
| CHO |
| CLB |
| CO2 |
| GLU |
| GTP |
| KB |
| LDH |
| NAB |
| PO4 |
| SGO |
| SGP |
| TRI |
| ZTP |



Panel Strucutre: ○ Horizontal ● Vertical

☐ Include time items (as well as date)?

Date Item ---> VISIT_DATE

Lab Test Name Item ---> LABVAR

Lab Result Value Item ---> LABVAL

Lab Tests ---> ALK, BT, BUA, BUN, CHO

Unit Item -->

☑ Normal Ranges?

Normal High Item --> NORM_HIGH

Normal Low Item --> NORM_LOW

- **Unit Item** - are the units associated with the lab tests.
- **Normal Ranges** - are the normal ranges for the lab tests. Click this box to enter the Normal High Item and Normal Low Item.

  *Note:This assumes that a join criteria has been previously defined between the lab and normal range panels.*
- **Normal High Item** - the field containing the lab normal high value.
- **Normal Low Item** - the field containing the lab normal low value.

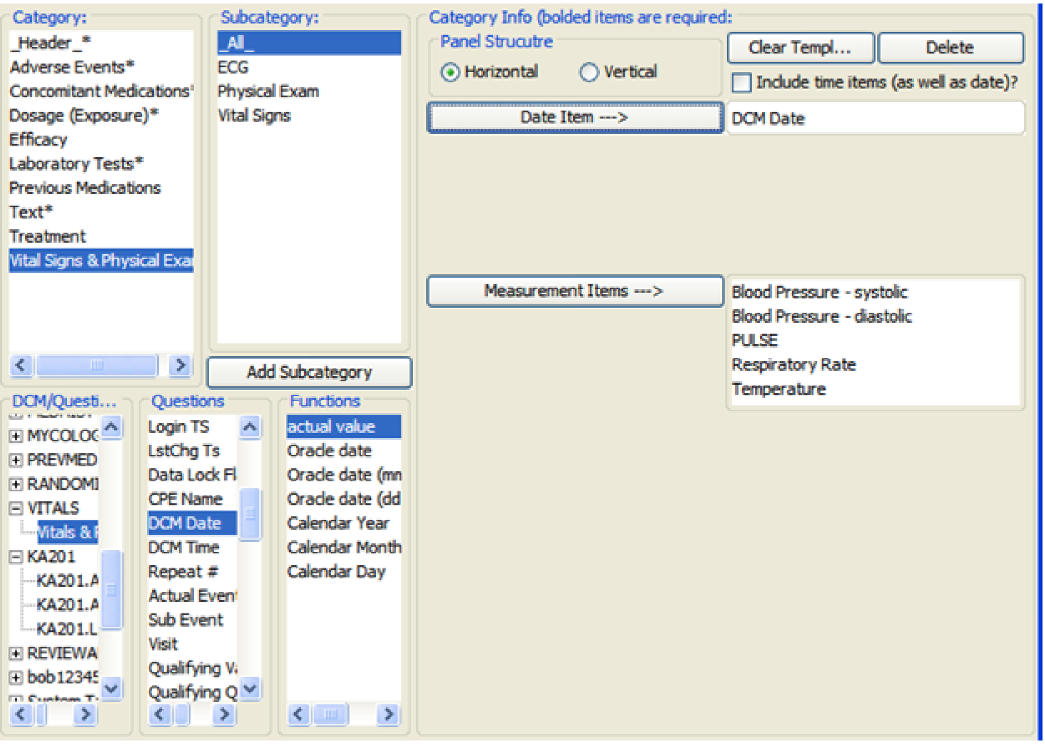
## *Time Point Type category*

Time point type categories also includes Vitals and Efficacy panels and may be either horizontal or vertical.

Panel Structure: ● Horizontal ○ Vertical

Horizontal panel structure requires:

- Date Item - the field containing the date of the event.
- Item(s) - the fields which the user may select for graphing.



Category: Vital Signs & Physical Exa

Subcategory: _All_

Panel Strucutre: ● Horizontal ○ Vertical

☐ Include time items (as well as date)?

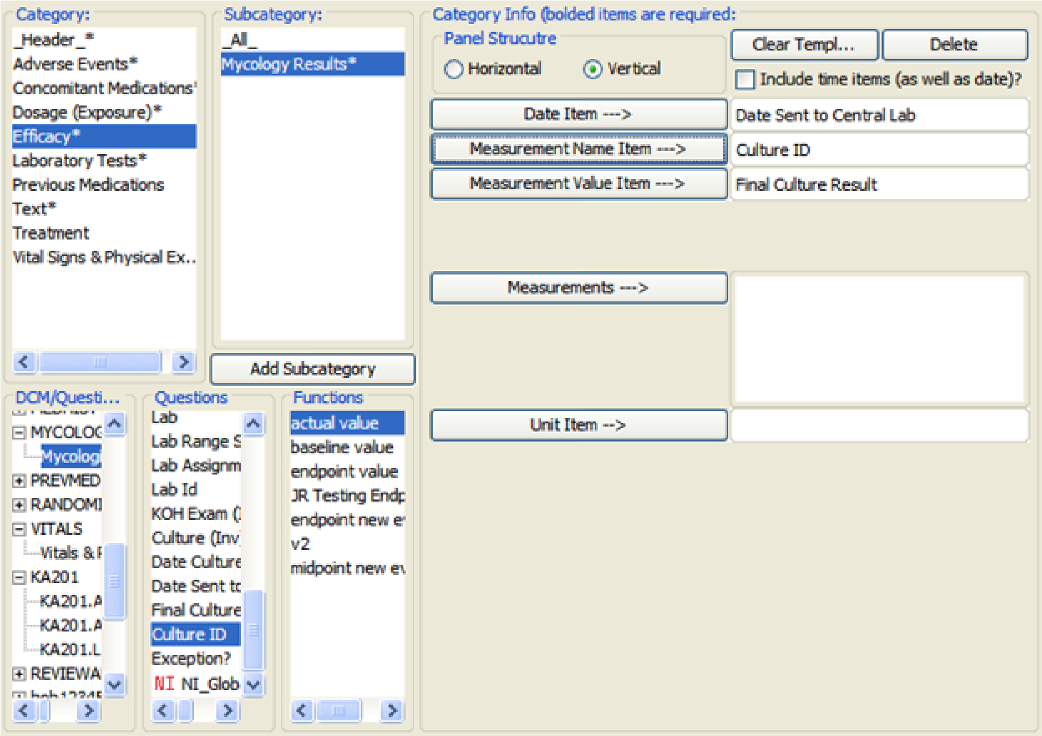
Date Item ---> DCM Date

Measurement Items --->
Blood Pressure - systolic
Blood Pressure - diastolic
PULSE
Respiratory Rate
Temperature

Vertical panel structure requires:

- Date Item - the field containing the date of the event.
- Measurement Name Item - the field containing the measurement name.
- Measurement Value Item - the field containing the measurement value.
- Measurements - the list of measurements which the user may select for graphing. The overall list of measurement names is derived from the measurement name field.

In the example, the ‘Mycological Results’ category was added as a subcategory and panel structure selected for vertical format.



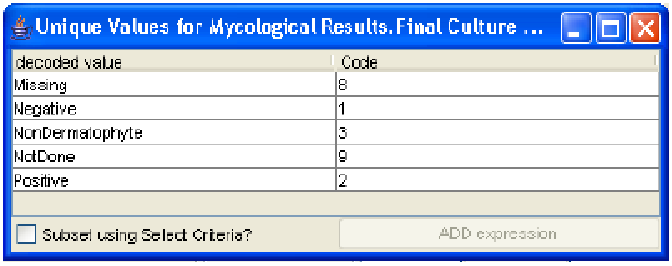
Panel Strucutre: ○ Horizontal ● Vertical

☐ Include time items (as well as date)?

Date Item ---> Date Sent to Central Lab

Measurement Name Item ---> Culture ID

Measurement Value Item ---> Final Culture Result

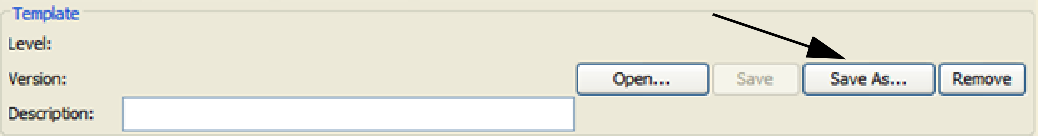


| decoded value | Code |
|---|---|
| Missing | 8 |
| Negative | 1 |
| NonDermatophyte | 3 |
| NotDone | 9 |
| Positive | 2 |

☐ Subset using Select Criteria?

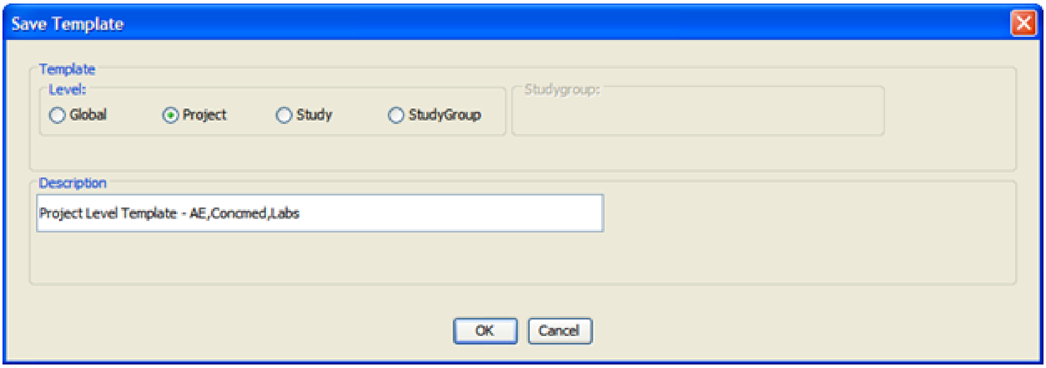
## *Save new template*

When you have added all categories and subcategories to the template, click **Save As**.



The **Save Template** window opens to save the new ‘Template Definition’. The Graph Patient Profile Template definition allows the builder to save multiple named templates at each object storage level, as well as retrieving previous versions of each.

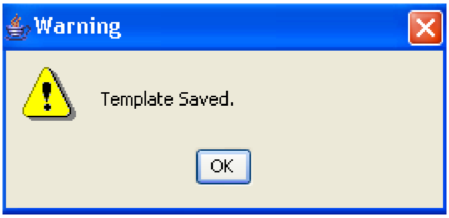
Super Users are able to save templates at the object storage level for global, project and study levels. If the study selected belongs to a Study Group previously defined in ReviewAdmin, then the Study Group option is also available. The templates are saved at the object storage location for public only. Select the **Template Level** to save and enter the template **Description**. Click OK.



Level: ○ Global ● Project ○ Study ○ StudyGroup

Description: Project Level Template - AE,Concmed,Labs

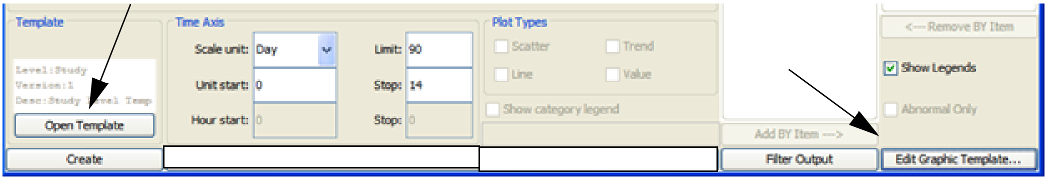
The message window displays the template has been saved. The default is the lowest level (Study, Project, Global) to highest most recent template version.



Template Saved.

## *Edit graphic template*

The **Edit Graphic Template** button is available if the user has permission to save or **edit** an existing template. Also, use the **Edit Graphic Template** button to add a new template not previously defined.  Click on the **Open Template** button, to edit a previously saved graphic template.



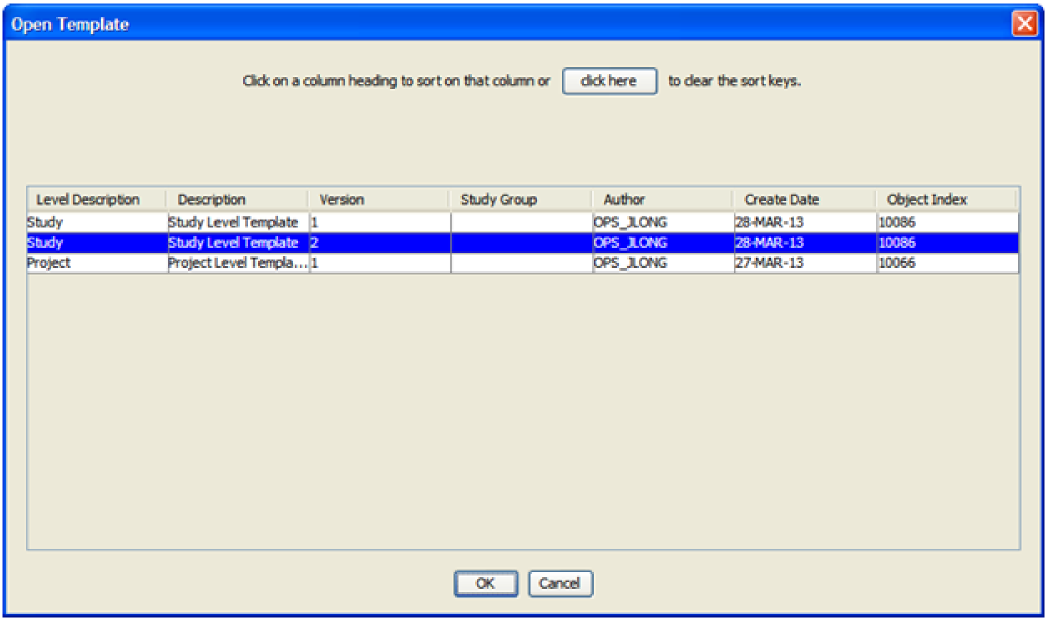
Level:Study
Version:1
Desc:Study Level Temp

Scale unit: Day
Limit: 90
Unit start: 0
Stop: 14
Hour start: 0
Stop: 0

☐ Scatter
☐ Trend
☐ Line
☐ Value
☐ Show category legend
☑ Show Legends
☐ Abnormal Only

The **Open Template** window displays a list of previously saved graphic templates. Multiple graphic templates may be saved at each object level, as well as multiple versions of a particular graphic template. The same graphic template saved multiple times with changes will be saved with the same **Object Index** number. A new/different template description will be saved with a new object - new Object Index number to distinguish each saved graphic template. The **Versions** are listed to show the most recent updates for each graphic **Template Description**.

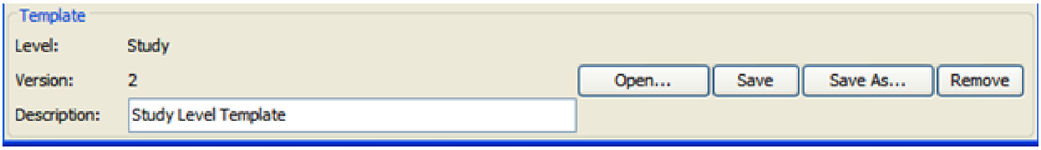
Select the graphic template from the list and click OK. The **Graphic Patient Profile Template** window opens for the selected graphic template to edit.



Click on a column heading to sort on that column or click here to clear the sort keys.

| Level Description | Description | Version | Study Group | Author | Create Date | Object Index |
|---|---|---|---|---|---|---|
| Study | Study Level Template | 1 |  | OPS_JLONG | 28-MAR-13 | 10086 |
| Study | Study Level Template | 2 |  | OPS_JLONG | 28-MAR-13 | 10086 |
| Project | Project Level Templa... | 1 |  | OPS_JLONG | 27-MAR-13 | 10066 |

When defining or updating a Graphic Patient Profile definition, the user can choose to either continue to use the internally stored, referenced graphic template, or to update the definition to reference a different template definition. Rather than just saving a template at one of the available Object Storage Levels, the builder can use the similar actions used for Save/SaveAs dialog options at the bottom of the GPP Template window.



Level: Study

Version: 2

Description: Study Level Template

Another way to select a graphic template to edit is to click on the **Edit Graphic Template** button. Initially the **Graphic Patient Prfoile Template** window opens to what ever graphic template is currently active. Click **Open** at the bottom of the window and use the previous steps.

## *Update graphic template*

After you have applied changes to the selected graphic template:

- Click **Save** to save your updates to the current selected graphic template **Description** and **Object Index number**. This save will generate a ***new version*** for the selected graphic template.
- Click **Save As** to save as a ***new*** graphic template with a different graphic template **Description** and **Object Index number**.

You may also use the **Save As** to copy a graphic template. Select and modify a previously saved graphic template, then you could save at a new object storage level, with new description and Object Index number.

## *Remove graphic template*

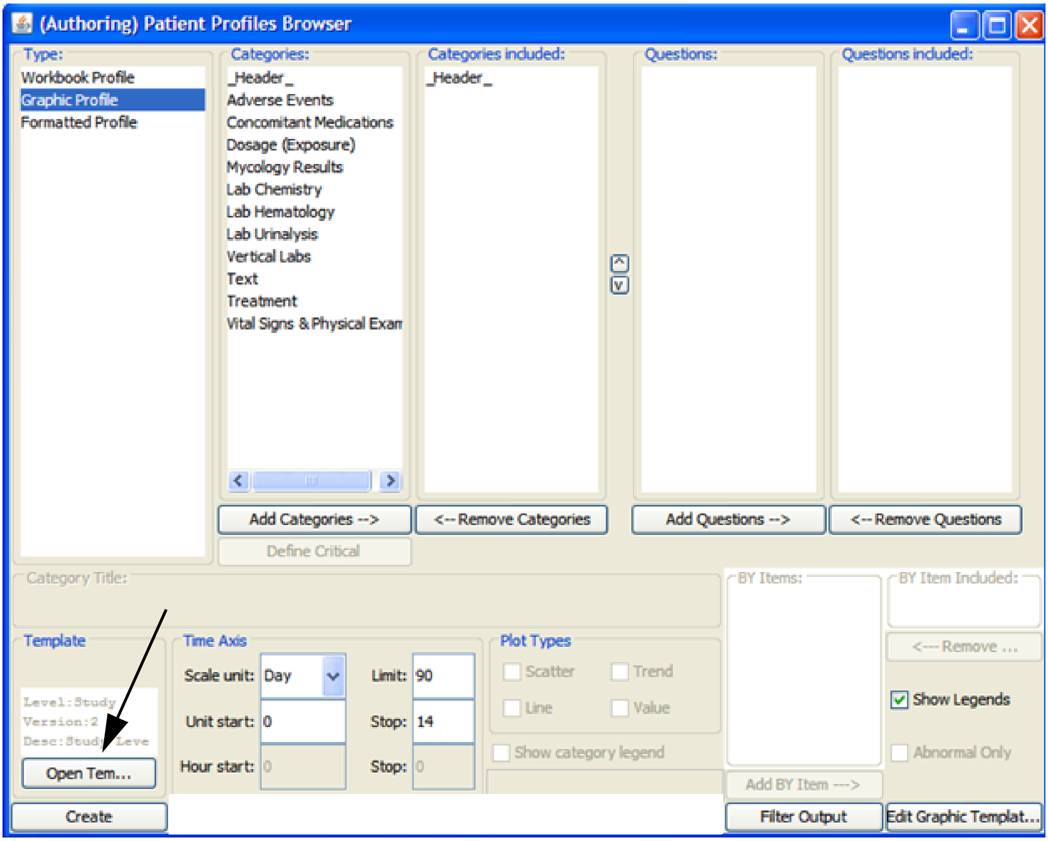
Select the graphic template and click **Remove**. All versions for the selected graphic template Description associated with the Object Index number are removed.

# Define Graphic Profile

## *Select graphic profile*

After graphic patient profile templates have been defined and saved then users with access in authoring mode can create, execute and save graphic patient profile objects at the global, project, study group and study levels and in either local, usergroup or public object locations.

1. Click , or from the **Browse** menu, select **Patient Profiles**.
2. The Patient Profile Browser window opens, select **Graphic Profile** as the type.



Type: Graphic Profile

Level:Study
Version:2
Desc:Study Leve

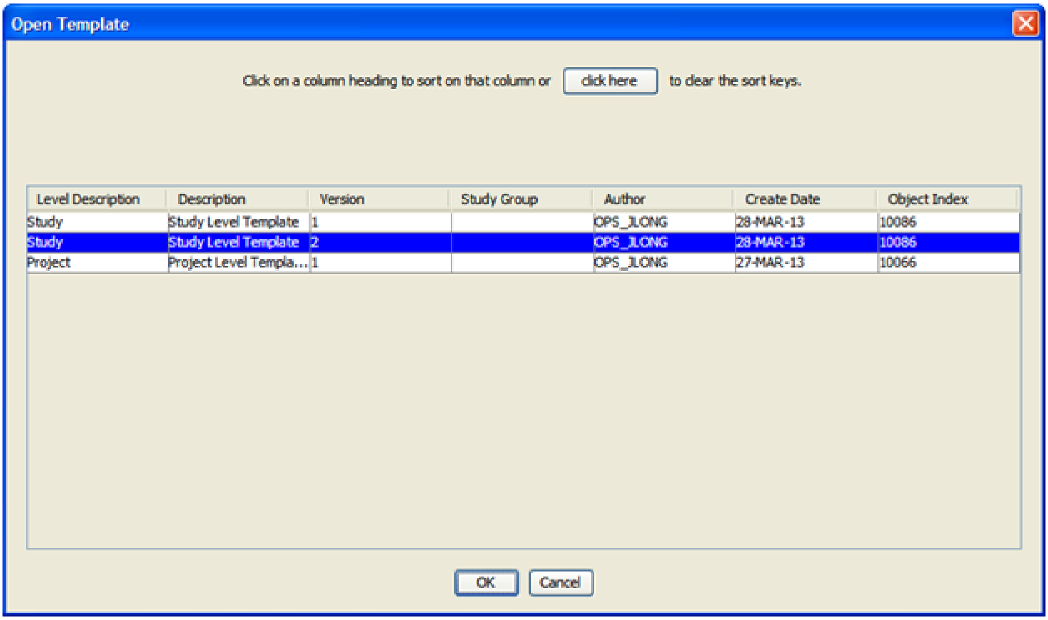
Scale unit: Day
Limit: 90
Unit start: 0
Stop: 14
Hour start: 0
Stop: 0

☑ Show Legends
☐ Abnormal Only

## Select defined template

Next, you must select a graphic template before defining a graphic patient profile. Graphic templates are saved at various object storage levels and may include multiple versions.

3. Click on the **Open Template** button. The **Open Template** window displays a list of saved graphic templates.
4. Select the **Template Level Description** and preferred version, then click OK. The selected template level is loaded to define the graphic profile.



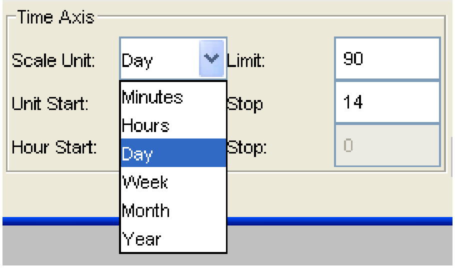
Click on a column heading to sort on that column or click here to clear the sort keys.

| Level Description | Description | Version | Study Group | Author | Create Date | Object Index |
|---|---|---|---|---|---|---|
| Study | Study Level Template | 1 |  | OPS_JLONG | 28-MAR-13 | 10086 |
| Study | Study Level Template | 2 |  | OPS_JLONG | 28-MAR-13 | 10086 |
| Project | Project Level Templa... | 1 |  | OPS_JLONG | 27-MAR-13 | 10066 |

## *Change Time Axis*

You can define the Time Axis before or after you select your categories and items. When you enter the Time Axis once for any category, it will default across all the selected categories as the common time axis. If time items are included in any of the defined categories then the Time Axis will include the options to select **Hours** or **Minutes**.

5. You can change the **Time Axis** defaults for the graph plots by selecting from the dropdown **Scale** list and entering the **Start** and **Stop** range.



Time Axis

Scale Unit: Day

Limit: 90

Unit Start:

Stop 14

Hour Start:

Stop: 0

Simply enter the Start and Stop value for the selected time scale. The Start and Stop values are strictly for the purpose to define the desired ‘view port’ of number of days (or weeks, etc.) to display when the GPP initially opens.

For example, the Start and Stop settings represent the ‘View Port’ days. If a patient has data from Day -14 to Day 180, and the Start Stop are set to 0 and 45; the initial display should start at Day 0 and end at Day 45 to represent the full extent of the visible area in the GPP. However, since the patient had 180 days worth of data, then the graph image would be horizontally scrollable all the way out to Day 180.

## Change Limit value

The **Limit** value denotes how much of a duration event to show before and after the first and last time point event. The limit feature “limits” how far out the time axis will go past “time point events” such as a lab test, or vitals or efficacy measurements. For example, if you have a long running Concomitant Medication with a stop date past your defined stop range, you can limit how much you want to see.

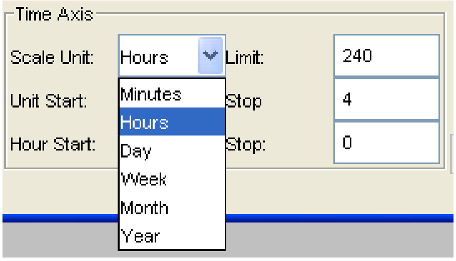
The default is 240 for hours, 90 for days, 12 for weeks and 1 for years. You may change it to any positive number to show more of the duration events that occurred before and after the first and last time point event. Choosing a limit of zero will show the shortest time axis possible (only from the first to last time event). Entering a negative number, (-1 for example) will show the entire time axis from the beginning to the end of the first and last duration.

So, the Limit value is not related with the Start and Stop. The limit value is added to the very last discrete date and subtracted from the very first discrete date, creating a window around those discrete dates which allow for continuous items to displayed as ongoing within.

The limit tells the system how far to continue to draw to the left or to the right for continuing AEs or Conmeds, meaning to either side of ‘hard data’ day results (suchs as Labs visits, Vitals, Soage, efficacy, etc).

## Display Time items

If a template category was defined to display time items you may set the scale to **Hours** or **Minutes**. The Start and Stop Hours scale displays with a dropdown list to select within a 23 hour range before changing to the next day.



Time Axis

Scale Unit: Hours

Limit: 240

Unit Start:

Stop 4

Hour Start:

Stop: 0

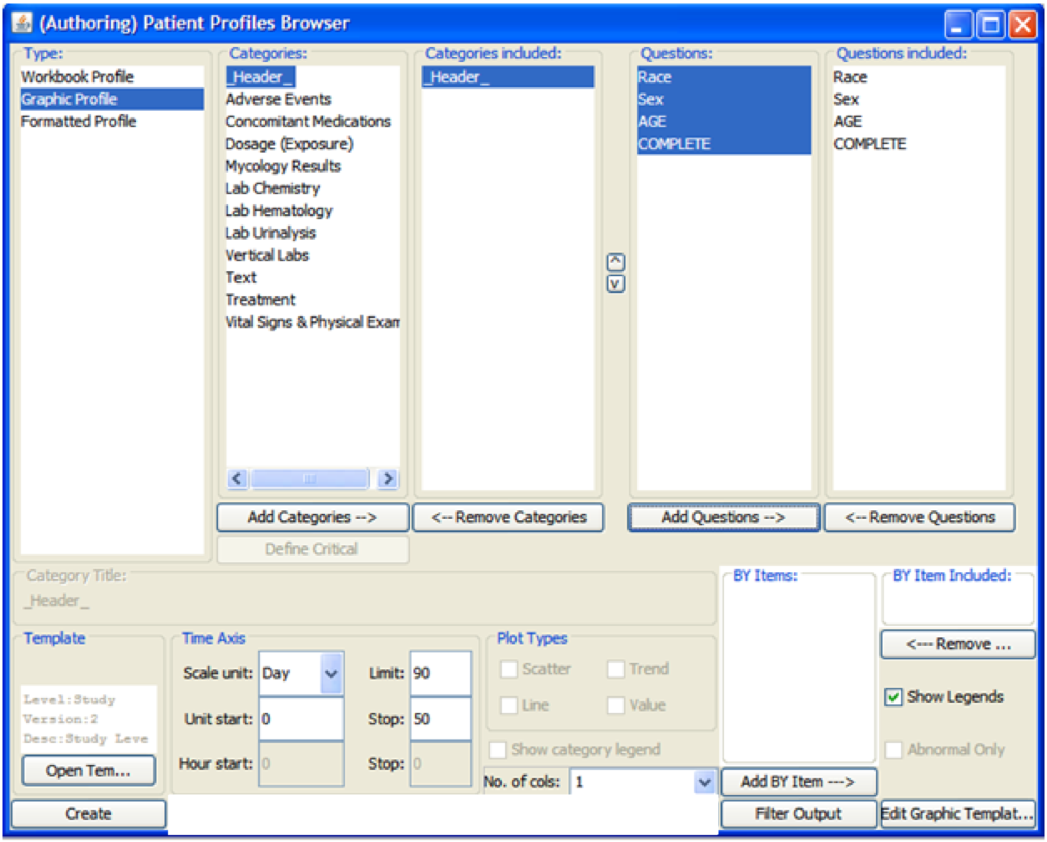
*Note: When selecting the Hours Scale it is best to apply to a minimal day range duration of not more than 4 days for meaningful results. If you select the Minutes Scale keep the range within 6 hours in order to view the 15 minute intervals with clarity.*

## *Select categories for display*

Graphic patient profiles are very complex due to the different types of data can best be represented by different types of graphs. The individual graphs are aligned along a similar time axis, however, each graph may consist of a different plot type based upon the type of data “event” that is depicted. Each graph may be based on data from multiple tables in the underlying database.

After you select a preferred template you are able to select those available categories to be included in the graphic patient profile. Optional **Header** information if available may have been defined for the selected template.

6. Select the Header category and click the **Add Categories** button.
7. Select individual items or use the CTRL or SHIFT key to multi-select item. Click **Add Questions** button to move items to the included column.



Scale unit: Day

Limit: 90

Unit start: 0

Stop: 50

Hour start: 0

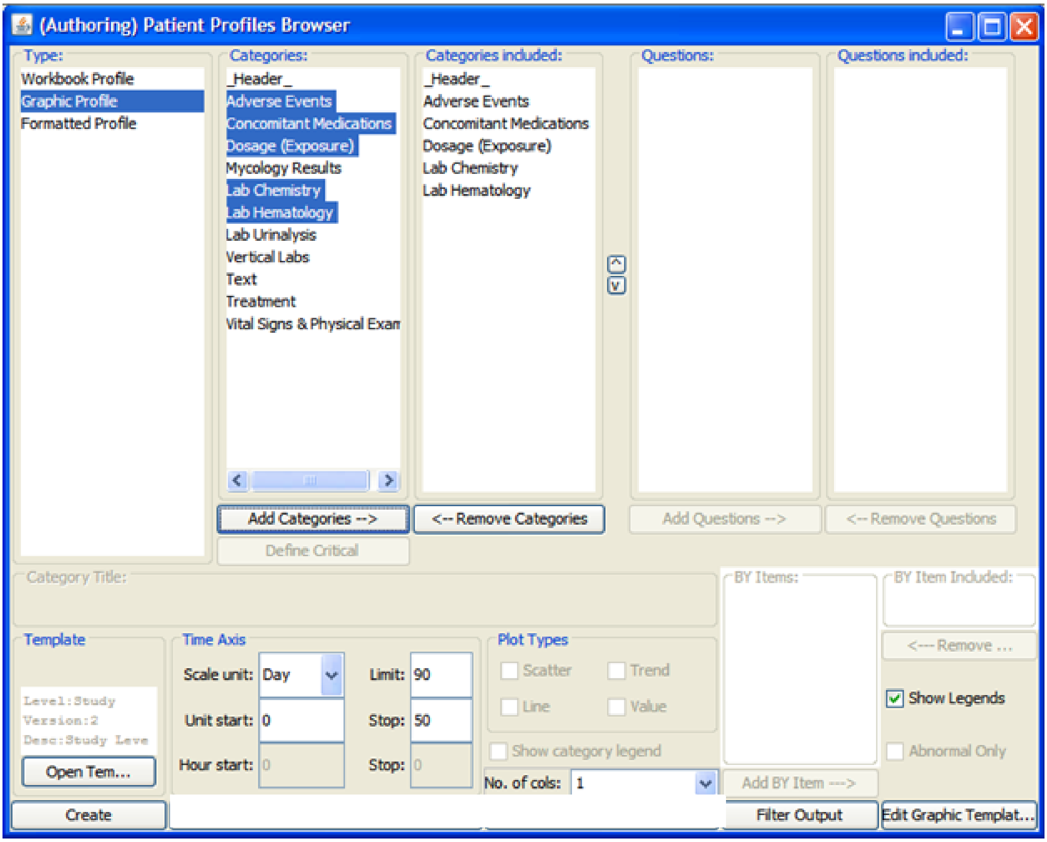
Stop: 0

No. of cols: 1

8. Highlight the categories to be included in the graphic profile and click **Add Categories**. Highlight and move single or multiple categories with the **SHIFT** or **CTRL** key for multiple selections.

   Use the **Remove Categories** button to remove a selected category.

9. Reorder the **Categories Included** with the **up** and **down** arrows.



Level:Study
Version:2
Desc:Study Leve

Scale unit: Day

Limit: 90

Unit start: 0

Stop: 50

Hour start: 0

Stop: 0

No. of cols: 1

☑ Show Legends

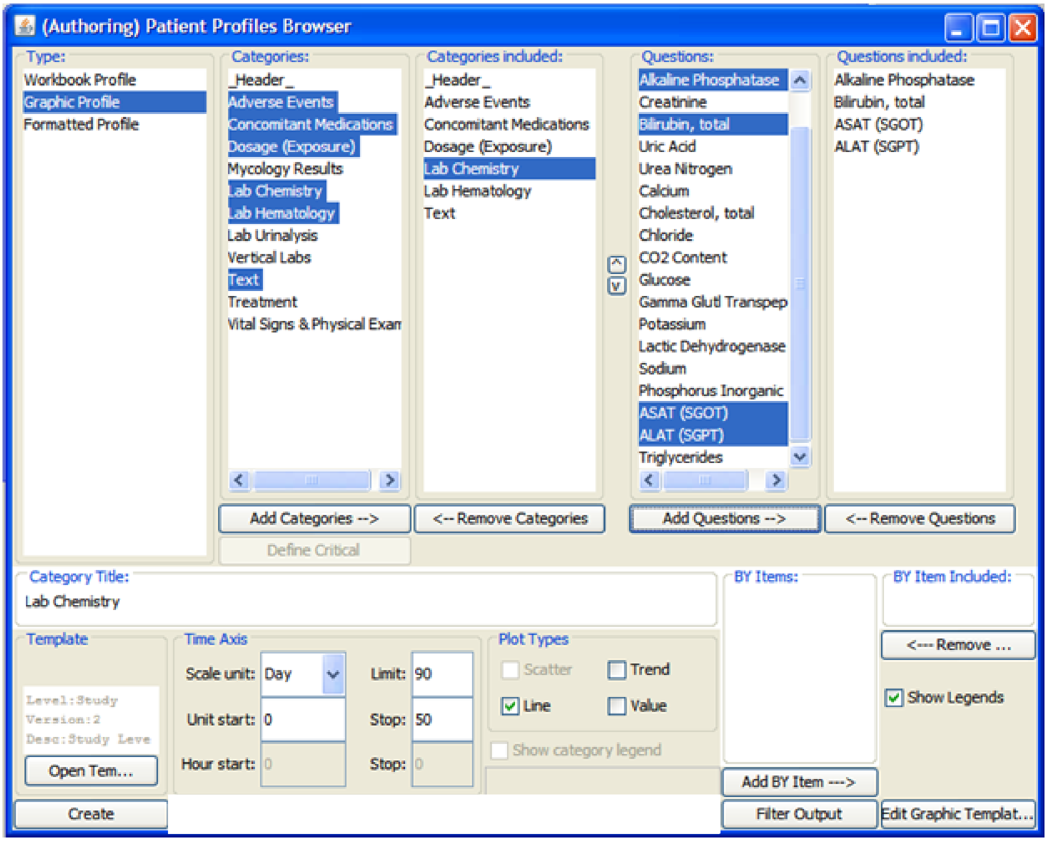
☐ Abnormal Only

## *Select items for display*

10. Select each **included category** and view the list of **Items** and **By Items** (where applicable) for the graph plots.

11. Highlight the item(s) and click **Add Items** button to select from available items to be included in the graphic profile. Use the **Remove Items** button to remove selected items.

12. Use drag and drop to reorder how the added items are displayed in the **Included Items** list box.



Category Title: Lab Chemistry

Scale unit: Day
Limit: 90
Unit start: 0
Stop: 50
Hour start: 0
Stop: 0

☐ Scatter ☐ Trend
☑ Line ☐ Value
☐ Show category legend
☑ Show Legends

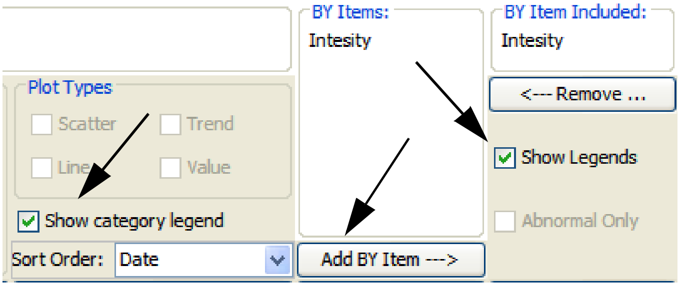
You must go through the entire list of **Categories Included** and select each category (and the items) you want included in the graphic profile. Otherwise, a ***message displays alerting*** you of an included category without items or BY items included.

13. Select the **BY Item** (if applicable) for the selected category and click the **Add BY Item** button.

The BY Item becomes available for display in the Legend when you click “yes”. If a BY Item is not added for the category then the information is not available for display in the Legend.

The selected item is moved to the BY Item Included list box. Only one BY Item may be selected per category.

The **Show category legend** only applies when a BY item is included, where as **Show Legends** applies to all included categories.



BY Items: Intesity

BY Item Included: Intesity

☑ Show Legends

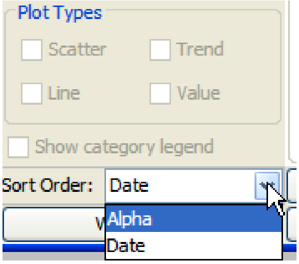
☑ Show category legend

Sort Order: Date

14. You can change the **Category Title** of any included category (except for the header which will always display the PatientID).

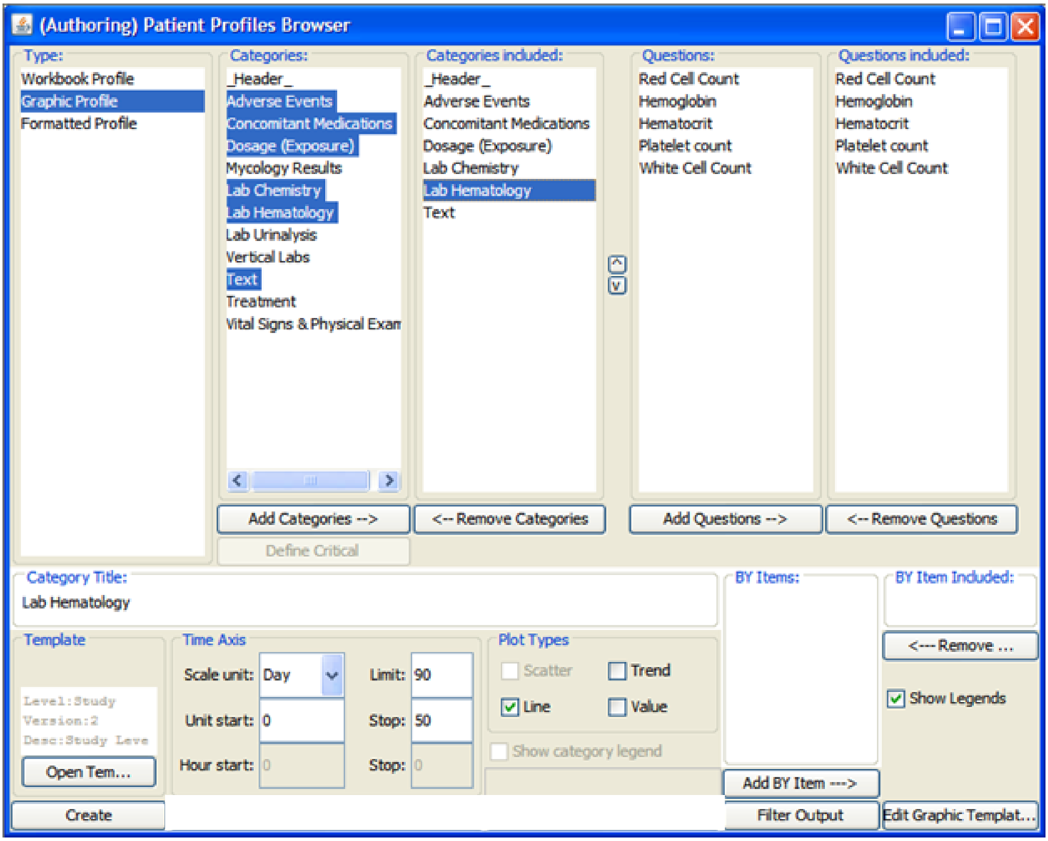
Category Title: Adverse Events

15. The **Sort Order** is dependent upon the selected category is only available if the data item selected is alpha. For example, adverse events or concomitant medications. These data items are associated with dates, so there is the option to sort by alpha or default date in the graphic profile.



Sort Order: Date

16. Add or change the default **Plot Types**. The available plot types are dependent on the category type defined.

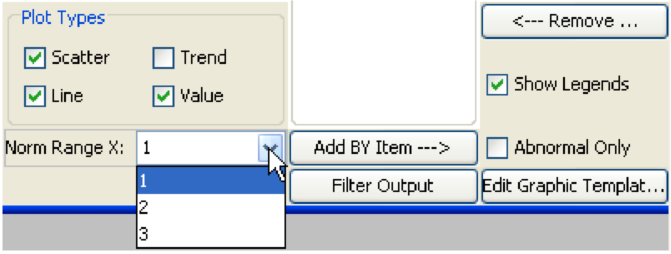


Category Title: Lab Hematology

Scale unit: Day
Limit: 90
Unit start: 0
Stop: 50
Hour start: 0
Stop: 0

## *Normal range multiplier*

The Multiplier feature for ‘Normal Range’ and display ‘Abnormal Only’ values applies to Vertical Labs only where Lab Normals may be entered.



☑ Scatter
☐ Trend
☑ Line
☑ Value
☑ Show Legends
Norm Range X: 1
☐ Abnormal Only

The Show Legends option applies for all categories to display ‘BY variables’ in the Legend box when checked Yes; or to the right of each ‘duration bar’ on the right side of the graphics region when checked No.

The ‘Abnormal Only’ labs option in Lab graphic displays scans all included Lab tests in the graphic profile and only includes each lab test if at least one lab test value is abnormal for that patient. Otherwise, the lab test is dropped from the graphic display.

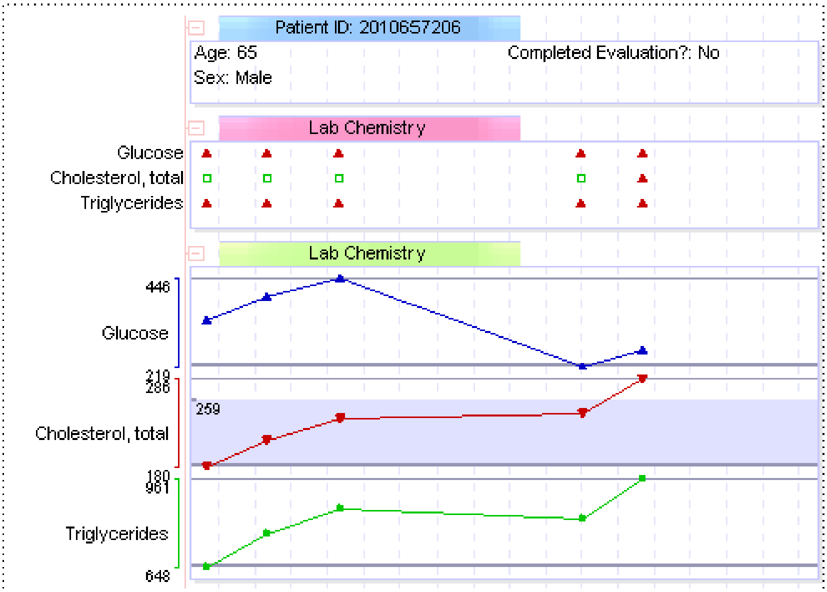
A normal range ‘multiplier’ option for labs allows you to specify if you only want to ‘flag’ or mark as low or high, those labs that are outside N times the normal range values. It is implemented as normal high times N versus normal low divided by N.

17. You can only select 1, 2 or 3 for the normal range multipliers with the default set to 1.

For comparison, first view out of range labs for Normal Range multiplier set to 1 and then change the normal range multiplier to 2. Select Plot Type of “Scatter” for labs and notice some points that were out of range previously changed to in-range from the up/down triangle to box plot point. If you selected Plot Type of “Line” you will notice the normal range “band” within the line graph has expanded for the normal range.

The Lab values display as color coded based on the normal range where red for high, blue for low and green for normal.

Normal Range set to 1. The scatter plot shows data indicating the values outside the normal range. Also, the Line Plot type for glucose and triglycerides shows values above the colored band for normal range.



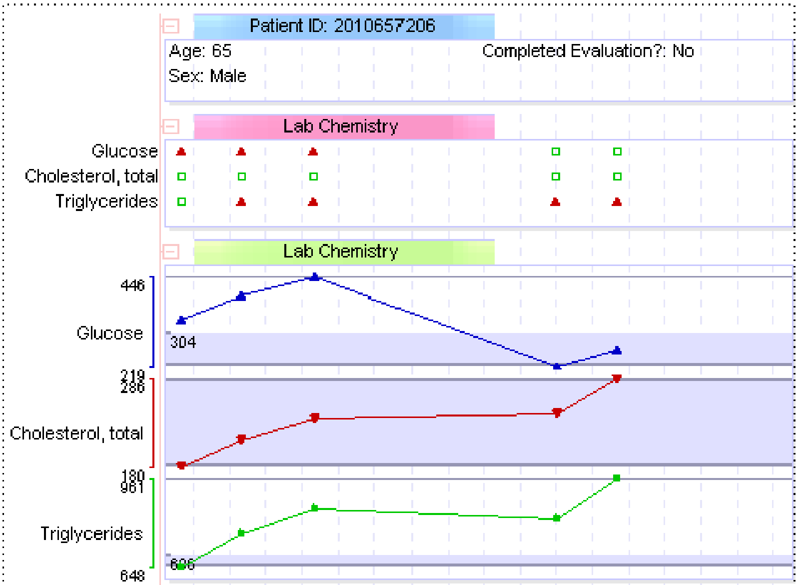
Patient ID: 2010657206

Age: 65

Sex: Male

Completed Evaluation?: No

Normal Range set to 2. The scatter plot shows boxes indicating the values inside the normal range multiplier of 2. Also, the Line Plot type for glucose now shows values within the colored band for normal range.



Patient ID: 2010657206

Age: 65

Sex: Male

Completed Evaluation?: No

Guidelines if normal range values are missing:

- Scatter Plots -

  Display an N instead of missing.

- Line Plots - No gray background if missing normal ranges.

  Separate into different bars if normal range changes between points.

  Place missing normal ranges on separate bar if changes between points.

  If a normal range changes it will create a second plot where the new range starts and for missing, it won't plot the high/low lines.

## *Create Graphic Patient Profile*

After you have defined all included categories and items included:

1. Click **Create**.

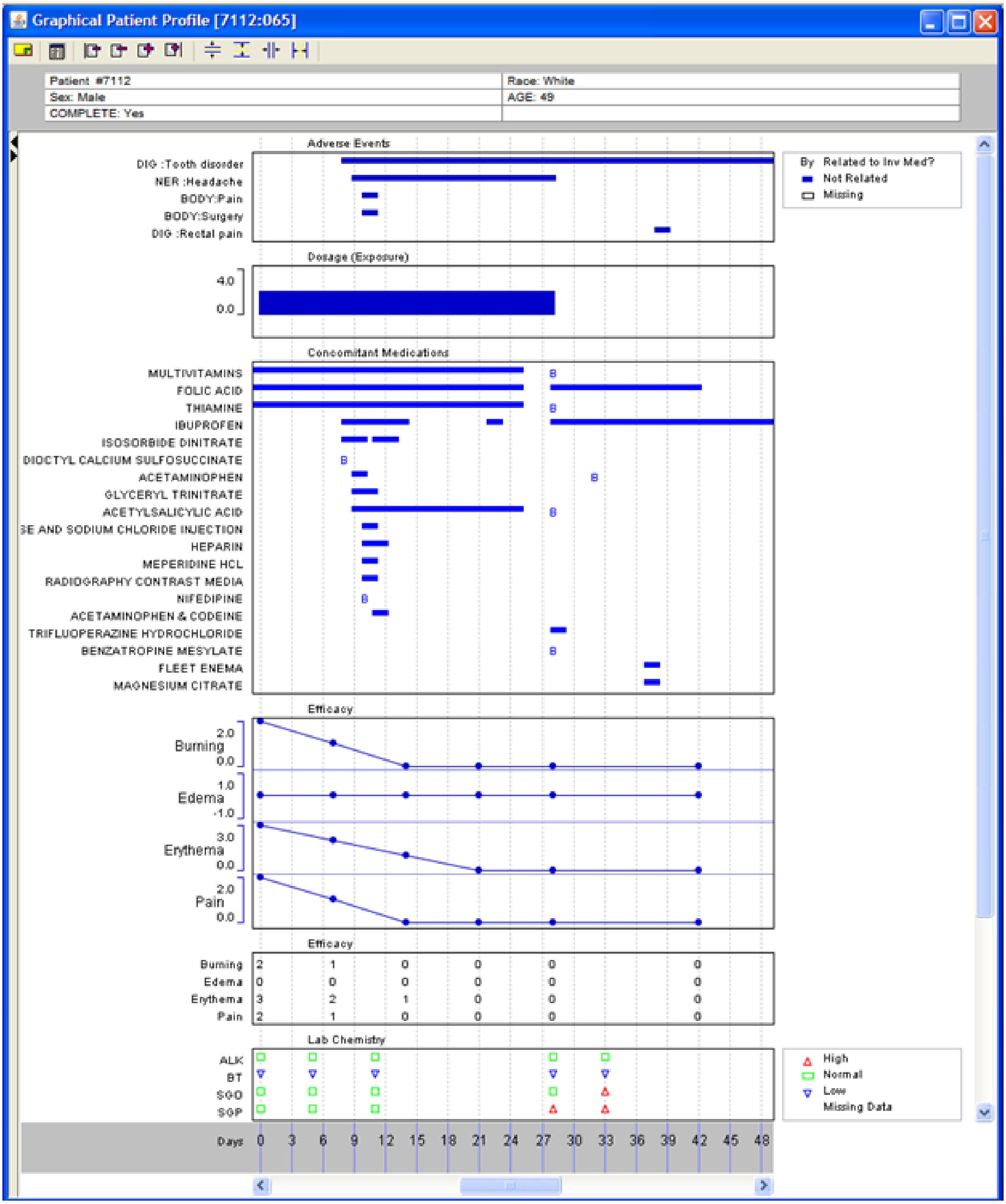
   The Patient Profile Browser window opens to display the list of patients who meet the patient selection criteria or view a list for all patients if no selection criteria was defined. The study and PID (patient id) are listed for identification in the patient list.

2. Select a patient and click **Create Profile**.

   The Graphic Patient Profile window opens and displays all labels on the left and legends on the right side of the graph plots.

   Use the scroll bar in the right margin to display additional graph information.

3. To save to the object specification for your Graphic Patient Profile, *See Chapter 11: Saving Objects, plus Alerts Browser.*



Patient #7112
Sex: Male
COMPLETE: Yes
Race: White
AGE: 49

Efficacy

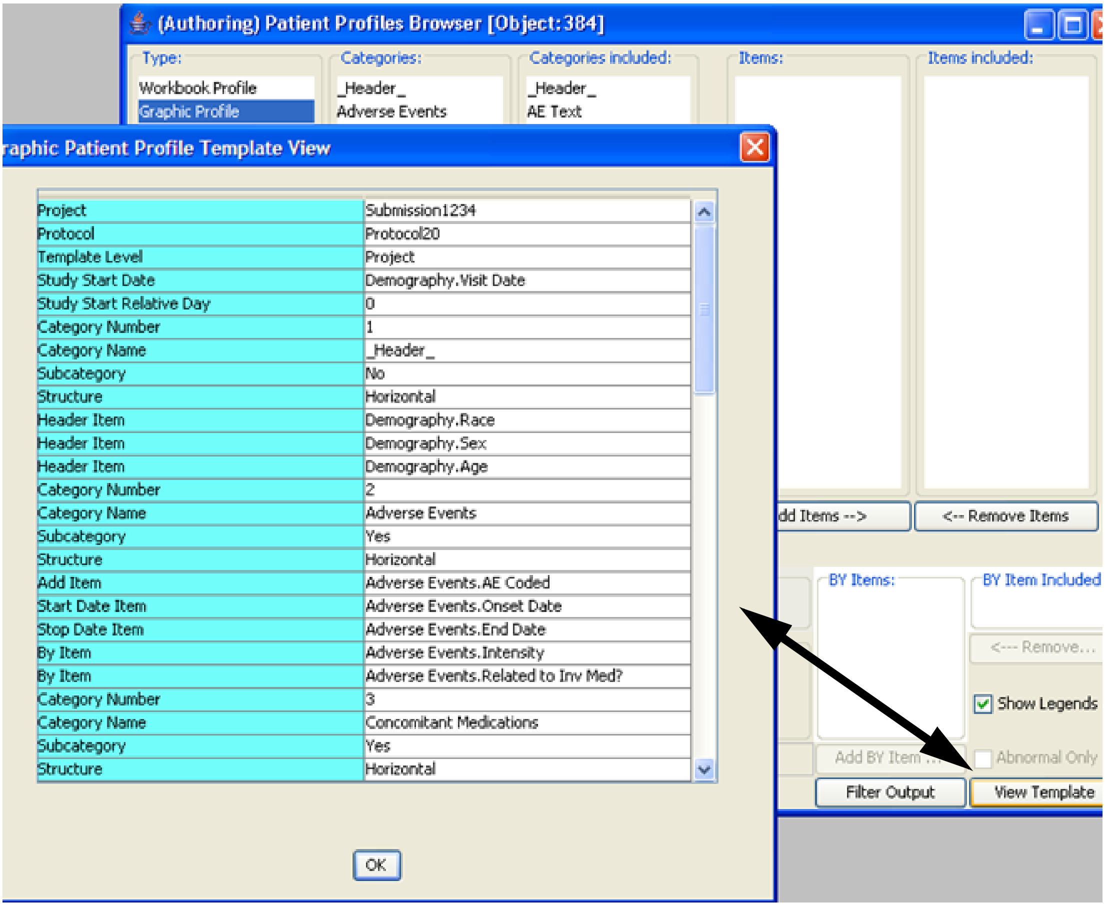
| | | | | | | |
|---|---|---|---|---|---|---|
| Burning | 2 | 1 | 0 | 0 | 0 | 0 |
| Edema | 0 | 0 | 0 | 0 | 0 | 0 |
| Erythema | 3 | 2 | 1 | 0 | 0 | 0 |
| Pain | 2 | 1 | 0 | 0 | 0 | 0 |

## *View Graphic Template*

Once a graphic patient profile is saved, the specific template information is saved along with the patient profile.

Therefore, a saved patient profile uses the original template information that existed at the time it was created. This avoids conflicts with updated, or newly created templates.

Users may view the Graphic Template saved with a Graphic Patient Profile, by opening the 'Object Properties'. The '**Edit Graphic Template**' button displays as '**View Template**' button.



| | |
|---|---|
| Project | Submission1234 |
| Protocol | Protocol20 |
| Template Level | Project |
| Study Start Date | Demography.Visit Date |
| Study Start Relative Day | 0 |
| Category Number | 1 |
| Category Name | _Header_ |
| Subcategory | No |
| Structure | Horizontal |
| Header Item | Demography.Race |
| Header Item | Demography.Sex |
| Header Item | Demography.Age |
| Category Number | 2 |
| Category Name | Adverse Events |
| Subcategory | Yes |
| Structure | Horizontal |
| Add Item | Adverse Events.AE Coded |
| Start Date Item | Adverse Events.Onset Date |
| Stop Date Item | Adverse Events.End Date |
| By Item | Adverse Events.Intensity |
| By Item | Adverse Events.Related to Inv Med? |
| Category Number | 3 |
| Category Name | Concomitant Medications |
| Subcategory | Yes |
| Structure | Horizontal |

## *Select Alternate Template*

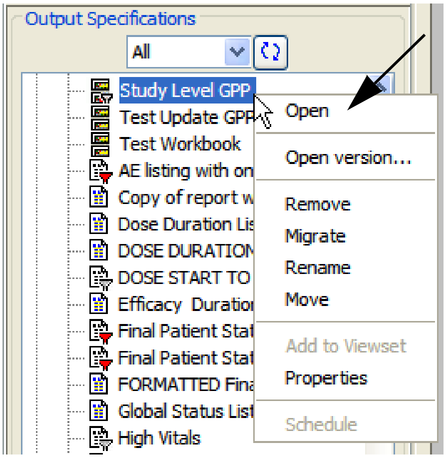
Once a graphic patient profile is saved the template information is saved along with the profile. Therefore, a saved profile uses the original template information that existed at the time it was created to avoid conflicts with updated or newly created templates.

Graph Patient Profiles have the capability to reference an updated GPP template category definitions into a previously saved GPP object definition.

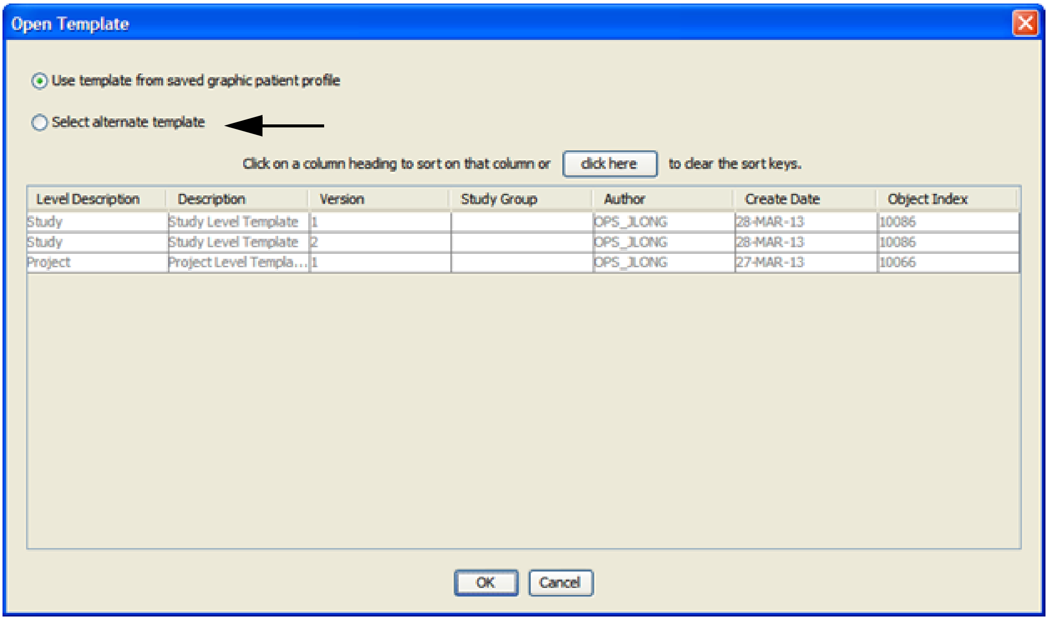
Previously, saved GPP objects could only reference a snapshot of the GPP template that was available at the time of the object save. Now the user can choose to either continue to reference the ‘snapshot’ version of the template category definitions, or to reference and include category definitions from an updated template.

The GPPs will only store “included” categories and GPP specific global information such as start date definition and the level of the template that was used to store it.

When a GPP object is opened, it will default to the current template at the level stored it was stored at. Only included categories from the GPP object itself will be validated against the current study thus speeding up the opening of the object. The list of included categories will come from the saved GPP object as well as category level filters and global GPP template information. The list of categories to choose from will come from the current template. When an opened GPP object is executed it will include user information from the current template to calculate study start date, visit information, etc.



If the GPP author chooses they may modify the saved GPP object to include added or changed categories in the current updated GPP template.



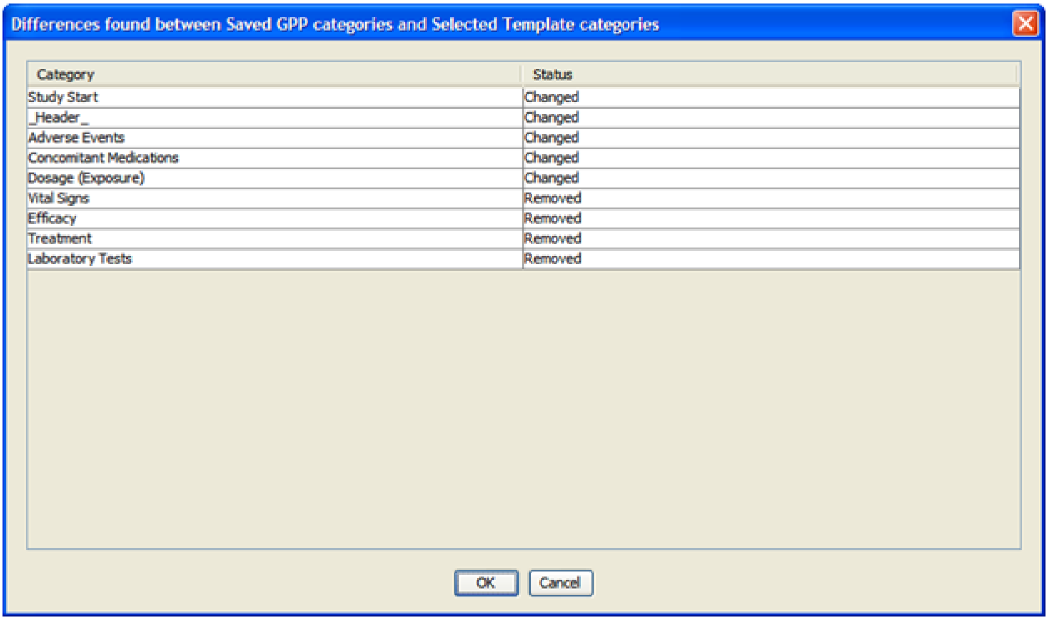
● Use template from saved graphic patient profile

○ Select alternate template

Click on a column heading to sort on that column or click here to clear the sort keys.

| Level Description | Description | Version | Study Group | Author | Create Date | Object Index |
|---|---|---|---|---|---|---|
| Study | Study Level Template | 1 | | OPS_JLONG | 28-MAR-13 | 10086 |
| Study | Study Level Template | 2 | | OPS_JLONG | 28-MAR-13 | 10086 |
| Project | Project Level Templa... | 1 | | OPS_JLONG | 27-MAR-13 | 10066 |

**Select alternate template** shows the differences between the Saved GPP categories and the Selected Template categories.



| Category | Status |
|---|---|
| Study Start | Changed |
| _Header_ | Changed |
| Adverse Events | Changed |
| Concomitant Medications | Changed |
| Dosage (Exposure) | Changed |
| Vital Signs | Removed |
| Efficacy | Removed |
| Treatment | Removed |
| Laboratory Tests | Removed |

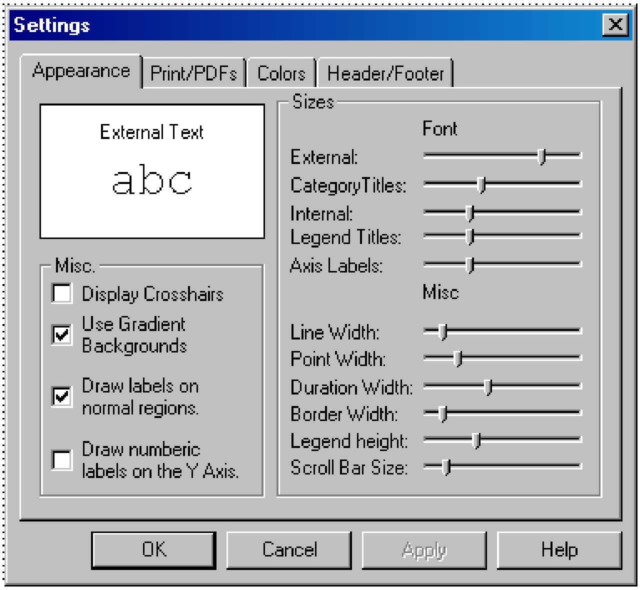
# Graph settings

## *Select settings*

On the Toolbar, click the first button to display **Show Settings** options.

## *Appearance options*

The settings window opens to the first tab for Appearance options. Each of the sliders, when moved with the mouse, will change the contents of the white box to help you visualize the setting. For example, when you click and move the 'External' slider under 'Fonts'.



Misc.

☐ Display Crosshairs

☑ Use Gradient Backgrounds

☑ Draw labels on normal regions.

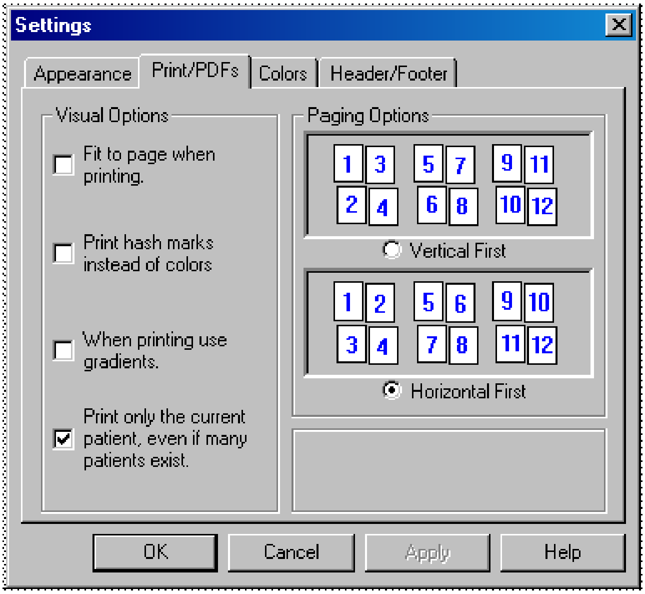
☐ Draw numberic labels on the Y Axis.

The size of the text “abc” will be the actual size of the text on the graph. The same occurs for the 'Misc.' size settings, except the white box will contain a line of the appropriate width.

The 'Display Crosshairs' checkbox toggles a cross hair following the mouse. This is good for visualizing alignments. 'Use gradients', when checked, will display gradient backgrounds to almost all rectangles drawn on the display. 'Draw labels on normal region' toggles the little markers that display the value of the normal range border. 'Draw numeric labels on y axis' label each row.

## Printing and PDF output settings

There are many options that allow you to customize how the Graphical Patient Profile prints. The printing options are found on the 'Print/PDFs' tab in the settings window.



☐ Fit to page when printing.

☐ Print hash marks instead of colors

☐ When printing use gradients.

☑ Print only the current patient, even if many patients exist.

○ Vertical First

● Horizontal First

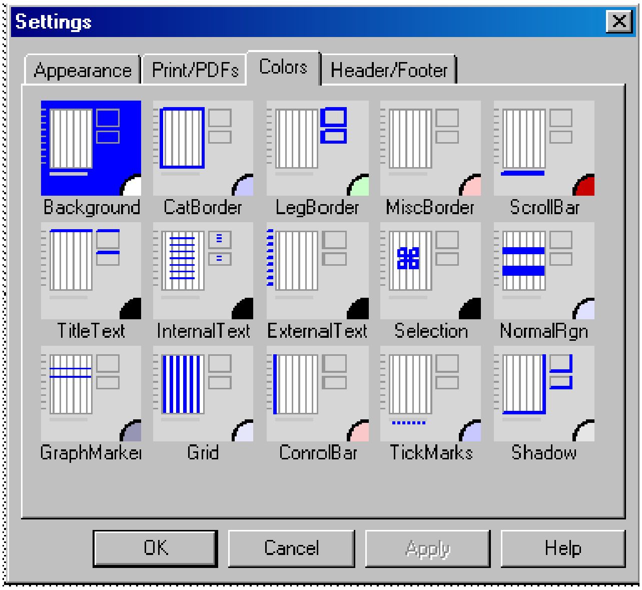
The most important of these options is the first, 'Fit to page when printing'. This option has precedence over all other printing options. If it is selected, then a page will be printed on one page regardless of the view range or the height per row. The default for "fitting" is true. Ideally, it is easiest to visualize the data when it is contained on one page. When this is not possible, the other paging options come in to play. The paging options are used to change the order in which the pages print. Basically it allows you to choose between moving horizontal or vertical first. The picture on the dialog is pretty self explanatory, across many patients.

You can chose to print the current patient only, or all pages. A print job of multiple patients, each of which is multiple pages, can get extremely large very quickly. These options like this have been added to help the you have control.

Finally, if color printers are unavailable, there is the print hash marks option. This makes it easy for the user to distinguish between the different by-variables and categories without the use of color.

## Color settings

There are 15 icons on top, each of which controls a certain aspect of the screen. Each button contains a little image, which highlights the part it refers to. So for example, the background button (top left) has a highlighted blue background, while the rest of the graph remains unchanged.

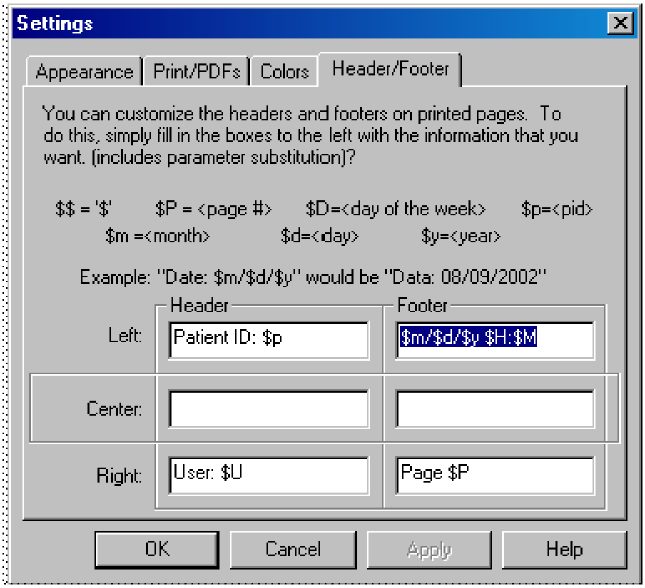


The color of the background is not blue however. The actual color of the background is white, which is shown by the little circle in the bottom right corner. This method of conveying the color clearly distinguishes each part of the graph while at the same time gives you a sense of color. So to change a color, simply click on the button.

The Category Colors at the bottom of the tab is used to modify the order of the category colors. These colors work from left to right (so light blue is the color of the first category). To change the color, simply use the left mouse button over the appropriate button.

## *Headers and footers*

You can control the information that is printed on the top and bottom of the graphic display. There are seven entries which allow you to insert 'special strings'. For example, if you type “p$P” into one of the edit boxes, it will appear as p1 on a printout (where 1 is the number of the page. This allows you to control both static and dynamic strings.



You can customize the headers and footers on printed pages. To do this, simply fill in the boxes to the left with the information that you want. (includes parameter substitution)?

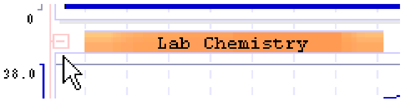
$$ = '$'  $P = <page #>  $D=<day of the week>  $p=<pid>
$m =<month>  $d=<day>  $y=<year>

Example: "Date: $m/$d/$y" would be "Data: 08/09/2002"

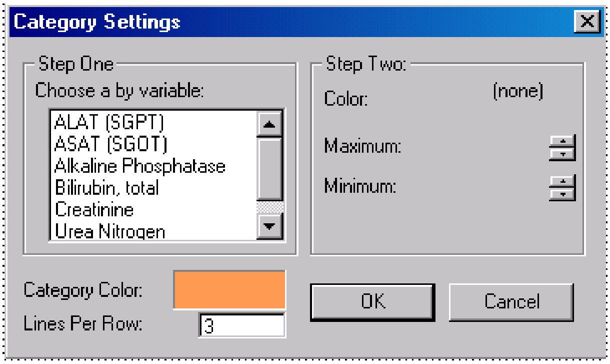
| | Header | Footer |
|---|---|---|
| Left: | Patient ID: $p | $m/$d/$y $H:$M |
| Center: | | |
| Right: | User: $U | Page $P |

## *Category settings*

Each category has its own category settings dialog box. In the Graphic Patient Profile window use the right mouse button on the control bar next to the category title.



Each graph's dialog has unique characteristics. Every category contains a category color box, on the bottom left of the dialog box.



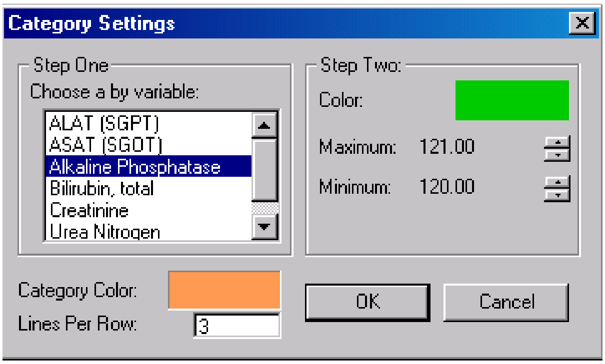
Color: (none)

Maximum:

Minimum:

Lines Per Row: 3

Line, trend, and block graphs also contain the 'lines per row option' which is used to modify how many graph lines each display will use. The list box under 'Step One' contains a list of the BY variables for the current panel. When the user clicks on one, the variables on the right side will be populated.



Maximum: 121.00

Minimum: 120.00

Lines Per Row: 3

You can change the color of the particular BY variable by clicking on the color with the left mouse button. You also have the ability to modify the maximum and minimum. There are no limits on the minimum and maximum except that the min must be less than the max. The range on 'lines per row' is 1 to 10.

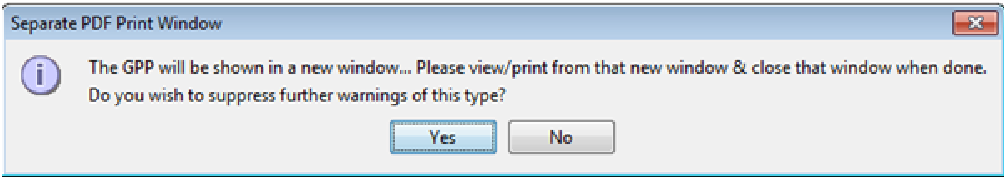
# Printing and Exporting Patient Profiles

## *Print graphic profile*

Make the selected patient graphic profile the active window.

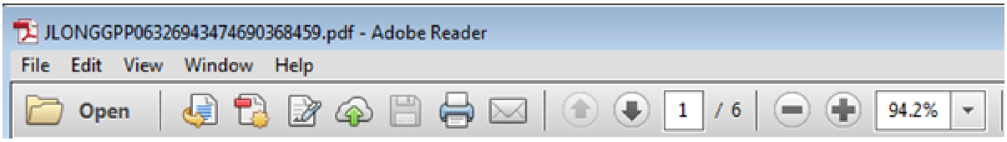
1. Click 🖨, or from the **File** menu, select **Print**.

   The following message is displayed.



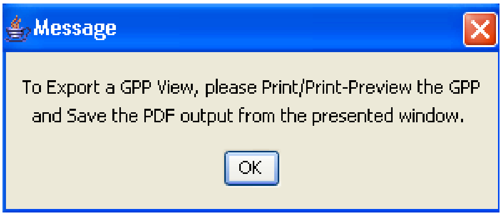
The GPP will be shown in a new window... Please view/print from that new window & close that window when done.
Do you wish to suppress further warnings of this type?

2. The PDF file is created for the graphic profile results. See the PDF toolbar to print or export the GPP results.

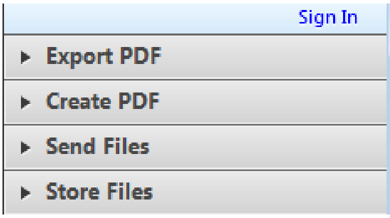


## *Export graphic profile*

Use the same steps to print the graphic profile results to generate a PDF, then from the PDF window select to EXPORT graphic profile results.



To Export a GPP View, please Print/Print-Preview the GPP and Save the PDF output from the presented window.



### *Edit menu Copy*

1. Click on the result window to make it the active window.
2. Select **Edit** in the menu bar.
3. Select the **Copy** function, to copy the currently displayed graphic profile output to clipboard for pasting into Word, etc.

# Object Storage

For detailed instructions on how to save, retrieve and remove object specifications (reports, graphs, crosstabs, etc.) *See Chapter 11: Saving Objects, plus Alerts Browser.*

***Note: Patient Profiles cannot be scheduled.***

# Close Patient Profiles Browser

### *Closing the Patient Profiles windows*

If you are finished with all Patient Profiles, and do not want to define any other Patient Profiles: double-click on the close box of the Patient Profiles Browser window.

Review closes all Patient Profiles windows currently opened.

# 6

# Report Browser

# Execute report

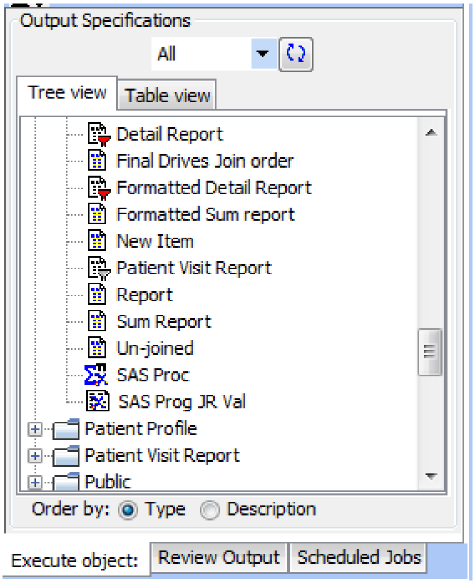
## *Selection set*

In JReview, you can select a previously saved Patient Subset, a saved Dynamic PSC or define your own selection criteria for use in the Report Browser. After launching the saved patient subset or building your own patient selection criteria, you can explore stored customized reports of items for each of the patients who meet the selection criteria.

## *Quick execute*

JReview displays a list of categorical folders for stored patient subsets and output specifications at the selected storage location.

1. Select one of the storage locations to display it's specific folders and contents.
2. Double click on the object description to launch in a single step. The stored output specification will be launched.



Icons are displayed along with the stored object to identify the source as report, graph, registered SAS program, etc. When a patient selection criteria is saved with the stored object; the filter icon displays with the specific browser icon. JReview aids users to quickly locate and launch these stored objects.

Stored object specifications saved with an included patient selection criteria in the definition will display a filter icon next to the object icon and description. If the patient selection criteria was saved as “required”, the filter will appear in the color “red” to indicate the selection criteria cannot be changed. If a filter icon is present but is not colored red, then you can alter and update the selection criteria for the opened output specification.

# Report types and features

## *Type of report*

The Report Browser facilitates customized groupings of item values for patients currently included in the patient selection criteria. JReview provides point and click report creation, without panel join limitations.

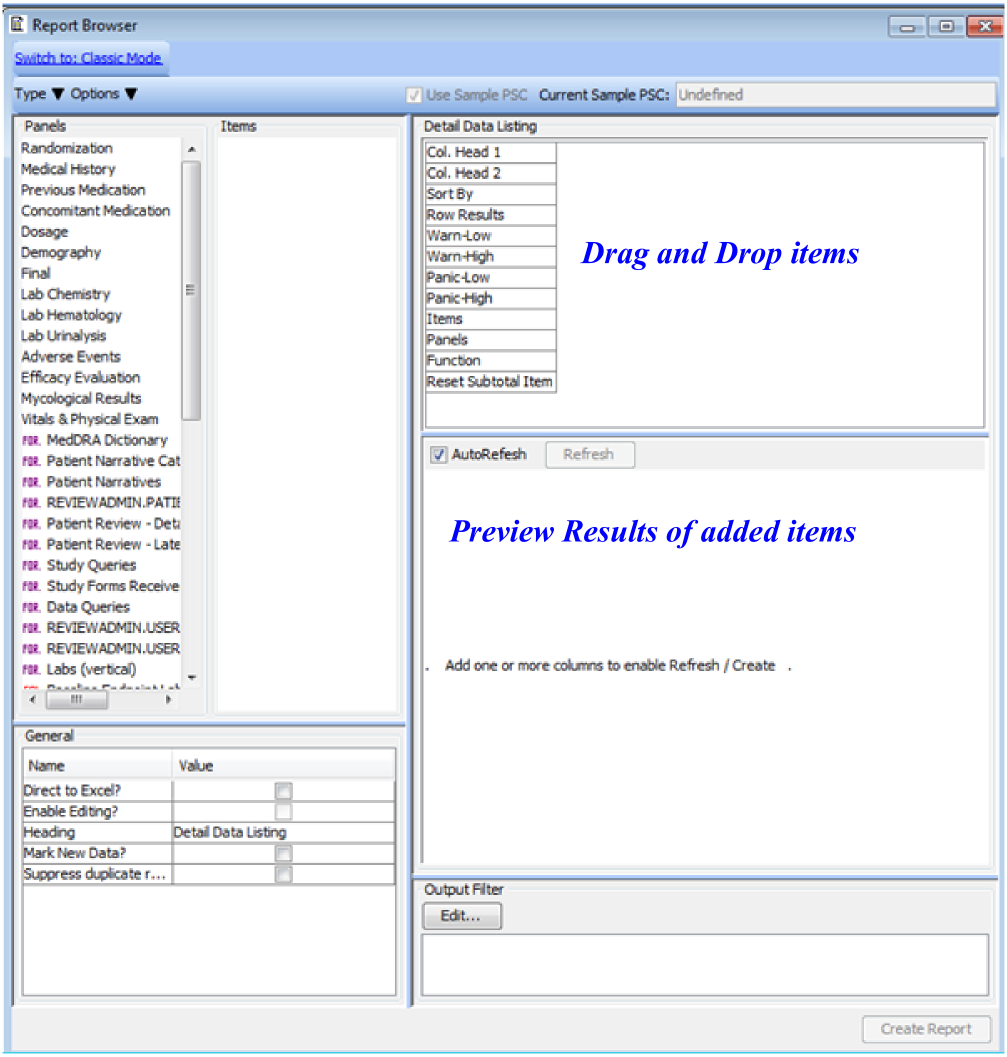
There are five report types available in JReview for defining report specifications which are available to launch in JReview.

- Detail Data Listing generate one report line for each patient observation.
- Summary Listing generate one report line containing summary information such as summary category, counts, mean, and so on.
- Formatted Detail Data Listing and Formatted Summary Listing provide the same basic functions as Detail Data Listing and Summary Listing with extensive formatting features.
- Patient Visit Data Report contains patient results organized by patientid and visit where multiple visit panels are easily joined and displayed per row.

# Defining Report Specifications - New Mode

## *New Mode versus Classic mode*

New in JReview Version 11 is **Drag and Drop** functionality to define spreadsheet reports with a preview of results. Open the Report Browser from the Browse menu, or click on the icon in the toolbar. The Report Browser will open in “**New Mode**” for drag and drop functions. The default report type is Detail Data Listing.



☑ Use Sample PSC **Current Sample PSC:** Undefined

*Drag and Drop items*

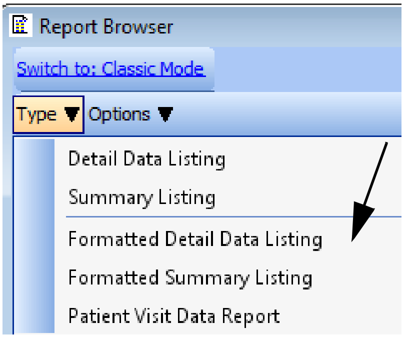
☑ AutoRefesh

*Preview Results of added items*

Add one or more columns to enable Refresh / Create

| Name | Value |
|---|---|
| Direct to Excel? | ☐ |
| Enable Editing? | ☐ |
| Heading | Detail Data Listing |
| Mark New Data? | ☐ |
| Suppress duplicate r... | ☐ |

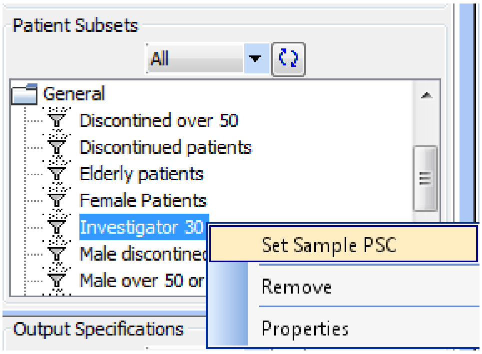
All the Classic Mode features to build detail data listings and summary listings are available in New Mode.  Click on **Type** to display the drop down list for other report types. When you select a report type listed below the line the Report Browser will change to Classic Mode.  Optionally, the user may click the **Switch to: Classic Mode** button for traditional building of output definitions.



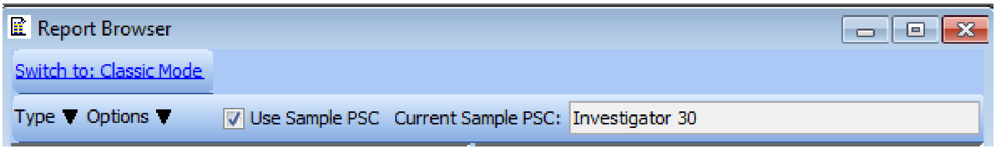
## *Set Sample PSC*

Users may assign a "**Sample PSC**" to preview results while building the report definition, instead of creating the report to view. The Sample PSC is applied to the report preview and NEVER used to create the report results.

Users with ReviewAdmin priv63 may assign a "**Sample PSC**" to preview results while building the object specification.  The Sample PSC is saved at the study level as public.  Select a previously saved PSC, then right mouse click to display a floating menu. Select **Set Sample PSC** to preview results within the output browsers.



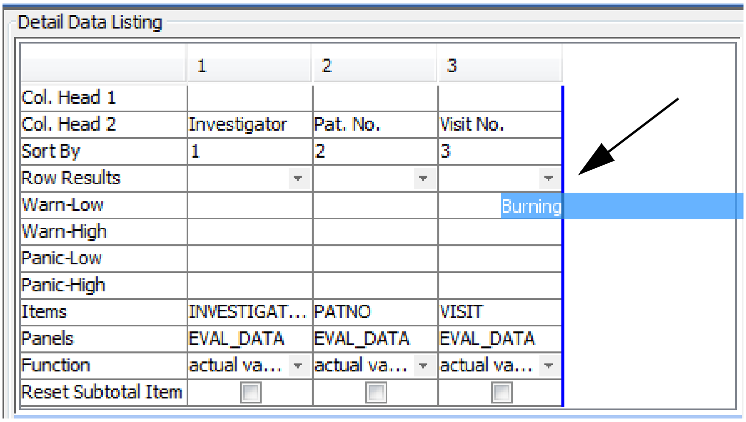
The **Sample PSC** description displays in the Report Browser toolbar. When unchecked all patients or the current selection criteria is applied.



☑ Use Sample PSC Current Sample PSC: Investigator 30

## Drag & Drop items

Select a panel and item(s) then drag and drop to the top right spreadsheet area. An individual item may be also added with a double-click. Use the CONTROL or SHIFT key to select multiple items then drag and drop. When dragging the initial item(s) to the spreadsheet, an arrow will display with a small box containing a plus sign. This symbol will indicate the items will be dropped here. Additional data items will be added to the outer right edge of the last item added. Then a ‘Blue’ line acts as a cursor locator to add more items to the right side of it. If you wish to insert an item, drag to the column and add the item to the right side of the Blue line.



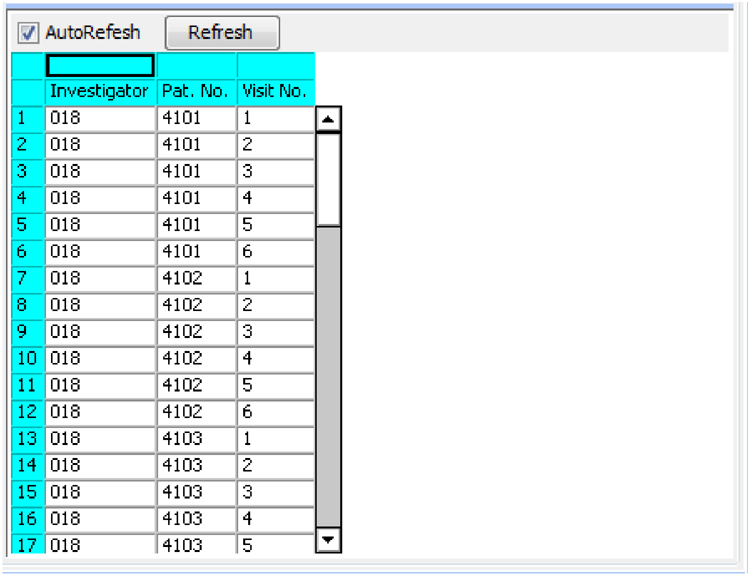
| | 1 | 2 | 3 |
|---|---|---|---|
| Col. Head 1 | | | |
| Col. Head 2 | Investigator | Pat. No. | Visit No. |
| Sort By | 1 | 2 | 3 |
| Row Results | ▾ | ▾ | ▾ |
| Warn-Low | | | Burning |
| Warn-High | | | |
| Panic-Low | | | |
| Panic-High | | | |
| Items | INVESTIGAT... | PATNO | VISIT |
| Panels | EVAL_DATA | EVAL_DATA | EVAL_DATA |
| Function | actual va... ▾ | actual va... ▾ | actual va... ▾ |
| Reset Subtotal Item | ☐ | ☐ | ☐ |

Select an item to **delete** in the body of the column and not the column numeric header. Use any of the following:

- Scissors in the toolbar
- Delete key
- CTRL X

**Move** a column by dragging to the new location.

The interactive drag and drop definition interface allows for interactive preview mode. Located below the definition spreadsheet, a preview of the report with a data sample will display as you add definitions.



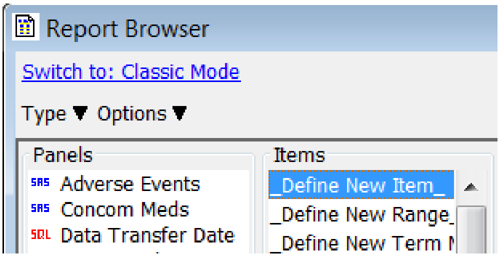
☑ AutoRefesh

| | Investigator | Pat. No. | Visit No. |
|---|---|---|---|
| 1 | 018 | 4101 | 1 |
| 2 | 018 | 4101 | 2 |
| 3 | 018 | 4101 | 3 |
| 4 | 018 | 4101 | 4 |
| 5 | 018 | 4101 | 5 |
| 6 | 018 | 4101 | 6 |
| 7 | 018 | 4102 | 1 |
| 8 | 018 | 4102 | 2 |
| 9 | 018 | 4102 | 3 |
| 10 | 018 | 4102 | 4 |
| 11 | 018 | 4102 | 5 |
| 12 | 018 | 4102 | 6 |
| 13 | 018 | 4103 | 1 |
| 14 | 018 | 4103 | 2 |
| 15 | 018 | 4103 | 3 |
| 16 | 018 | 4103 | 4 |
| 17 | 018 | 4103 | 5 |

## *Define New Item*

The function to **Define New Item** as a new 'URL' type, or define an existing item in the database as a 'URL' type – via the ReviewAdmin 'Item Override' capability. Then when the 'URL' data column is added to the report, when the user clicks on the 'URL' symbol in the cell – JReview opens another JReview managed/embedded web browser to display the contents of that URL. This is useful for displaying the contents of an EDC page, or displaying image scans, etc.

***(See Chapter 12 - Advanced Topics: Define New Item)***

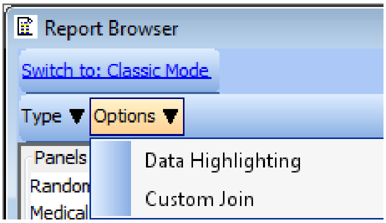


## *Options menu*

The functions for **Data Highlighting** and **Custom Join** are listed within the **Options** menu.

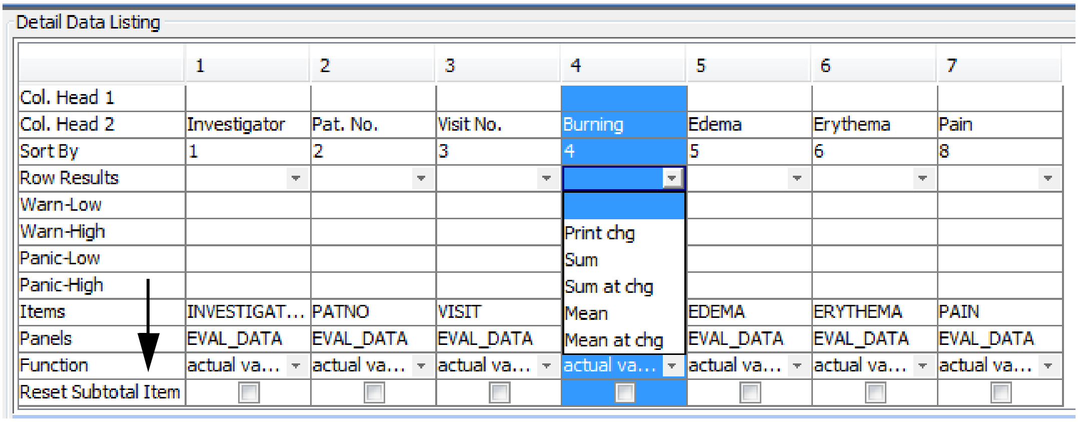
***(See Chapter 6 - Report Browser: Conditional Data Highlighting)***

***(See Chapter 12 - Advanced Topics: Custom Join)***



## New Mode Functions

All functions available in Classic Mode are available in New mode. Some prior features are listed in the spreadsheet build area for **Function** and **Reset Subtotal Item**. Click on **Row Results** or **Function** to display a drop down list for selection. ***(See Chapter 6 - Report Browser: Defining Report Specifications - Classic Mode)***

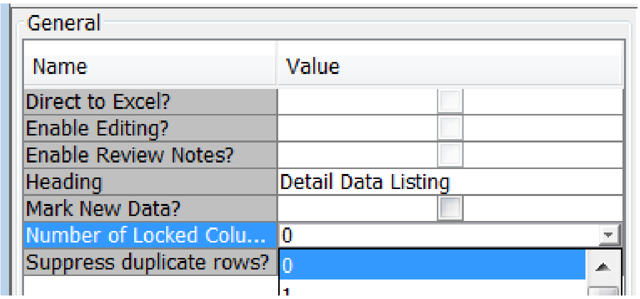


Detail Data Listing

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | | |
| Col. Head 2 | Investigator | Pat. No. | Visit No. | Burning | Edema | Erythema | Pain |
| Sort By | 1 | 2 | 3 | 4 | 5 | 6 | 8 |
| Row Results | | | | | | | |
| Warn-Low | | | | | | | |
| Warn-High | | | | | | | |
| Panic-Low | | | | | | | |
| Panic-High | | | | | | | |
| Items | INVESTIGAT… | PATNO | VISIT | | EDEMA | ERYTHEMA | PAIN |
| Panels | EVAL_DATA | EVAL_DATA | EVAL_DATA | | EVAL_DATA | EVAL_DATA | EVAL_DATA |
| Function | actual va… | actual va… | actual va… | actual va… | actual va… | actual va… | actual va… |
| Reset Subtotal Item | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

## New Mode General table

The **General table** area contains a list of value checkboxes for the various button features available within Classic Mode. Change the default Detail Data Listing Heading by double clicking in the value box to replace the report Heading.



General

| Name | Value |
|---|---|
| Direct to Excel? | ☐ |
| Enable Editing? | ☐ |
| Enable Review Notes? | ☐ |
| Heading | Detail Data Listing |
| Mark New Data? | ☐ |
| Number of Locked Colu… | 0 |
| Suppress duplicate rows? | |

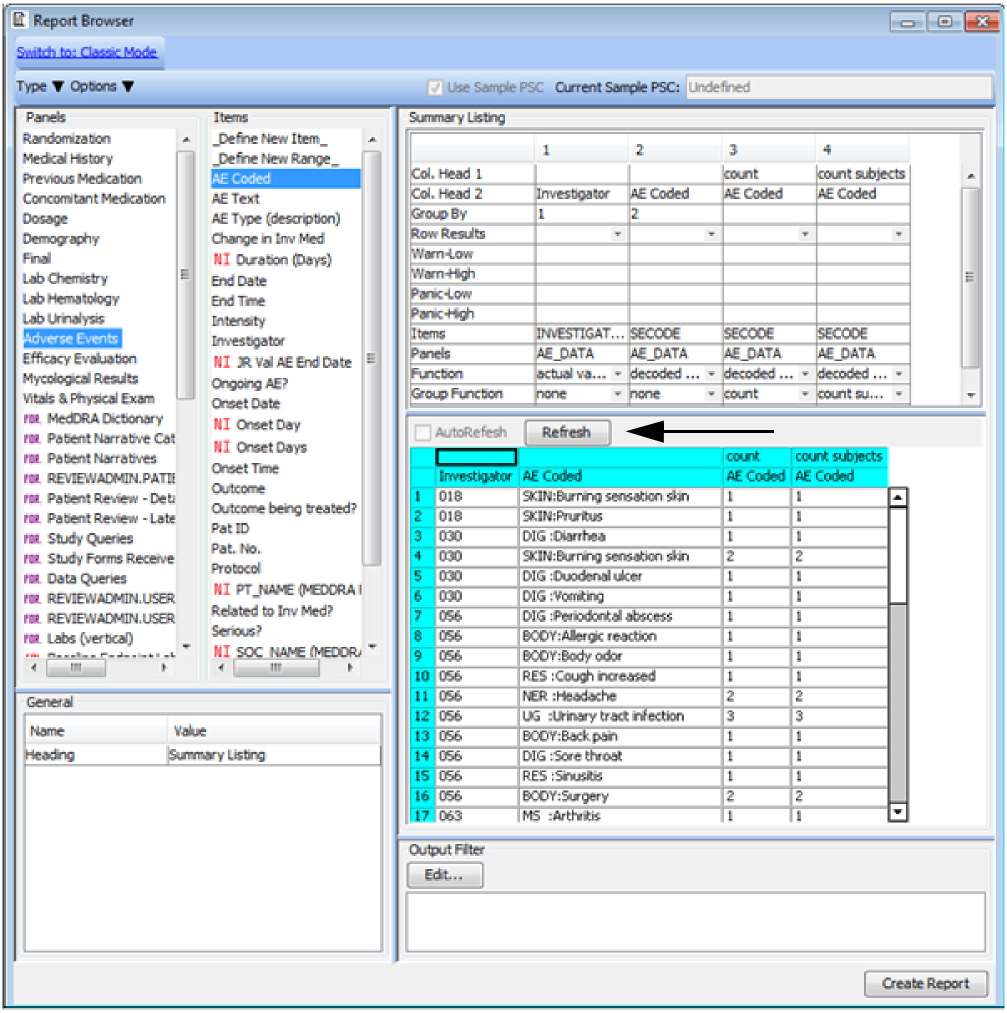
**Direct to Excel** applies only for detail data listing. To enable/disable this feature set privilege (p67) in ReviewAdmin.

**Enable Editing** data values applies to ***Foreign panel data only*** with permission granted in ReviewAdmin.

## *New Mode Summary Listing*

The Summary Listing within New Mode has the similar features and layout as the detail data listing, with the addition of Group Function.

A preview of the results may be viewed while adding items to the spreadsheet by clicking **Refresh**.



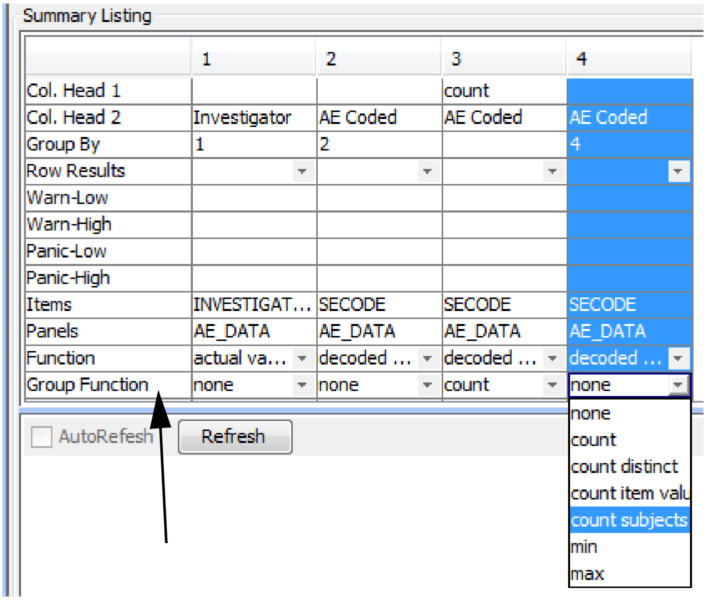
General

| Name | Value |
|---|---|
| Heading | Summary Listing |

| | 1 | 2 | 3 | 4 |
|---|---|---|---|---|
| Col. Head 1 | | | count | count subjects |
| Col. Head 2 | Investigator | AE Coded | AE Coded | AE Coded |
| Group By | 1 | 2 | | |
| Row Results | | | | |
| Warn-Low | | | | |
| Warn-High | | | | |
| Panic-Low | | | | |
| Panic-High | | | | |
| Items | INVESTIGAT... | SECODE | SECODE | SECODE |
| Panels | AE_DATA | AE_DATA | AE_DATA | AE_DATA |
| Function | actual va... | decoded ... | decoded ... | decoded ... |
| Group Function | none | none | count | count su... |

| | | | count | count subjects |
|---|---|---|---|---|
| | Investigator | AE Coded | AE Coded | AE Coded |
| 1 | 018 | SKIN:Burning sensation skin | 1 | 1 |
| 2 | 018 | SKIN:Pruritus | 1 | 1 |
| 3 | 030 | DIG :Diarrhea | 1 | 1 |
| 4 | 030 | SKIN:Burning sensation skin | 2 | 2 |
| 5 | 030 | DIG :Duodenal ulcer | 1 | 1 |
| 6 | 030 | DIG :Vomiting | 1 | 1 |
| 7 | 056 | DIG :Periodontal abscess | 1 | 1 |
| 8 | 056 | BODY:Allergic reaction | 1 | 1 |
| 9 | 056 | BODY:Body odor | 1 | 1 |
| 10 | 056 | RES :Cough increased | 1 | 1 |
| 11 | 056 | NER :Headache | 2 | 2 |
| 12 | 056 | UG :Urinary tract infection | 3 | 3 |
| 13 | 056 | BODY:Back pain | 1 | 1 |
| 14 | 056 | DIG :Sore throat | 1 | 1 |
| 15 | 056 | RES :Sinusitis | 1 | 1 |
| 16 | 056 | BODY:Surgery | 2 | 2 |
| 17 | 063 | MS :Arthritis | 1 | 1 |

The **Group Function** is listed within the spreadsheet options. Click on a particular item for Group Function to select from the drop down list.

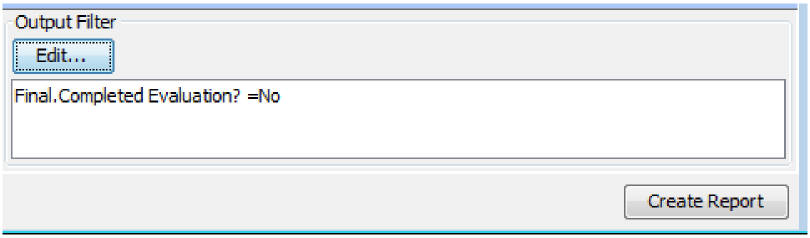


Summary Listing

| | 1 | 2 | 3 | 4 |
|---|---|---|---|---|
| Col. Head 1 | | | count | |
| Col. Head 2 | Investigator | AE Coded | AE Coded | AE Coded |
| Group By | 1 | 2 | | 4 |
| Row Results | | | | |
| Warn-Low | | | | |
| Warn-High | | | | |
| Panic-Low | | | | |
| Panic-High | | | | |
| Items | INVESTIGAT… | SECODE | SECODE | SECODE |
| Panels | AE_DATA | AE_DATA | AE_DATA | AE_DATA |
| Function | actual va… | decoded … | decoded … | decoded … |
| Group Function | none | none | count | none |

Optionally, define and save an **Output Filter.** When an output filter is saved the output filter description is displayed in the view box. A blank view box means there is no saved output filter.

When the report specification is complete, click **Create Report** to view the entire results for the specified selection criteria, if one was used. The **Set Sample PSC** will be ignored when the report is created.



Output Filter

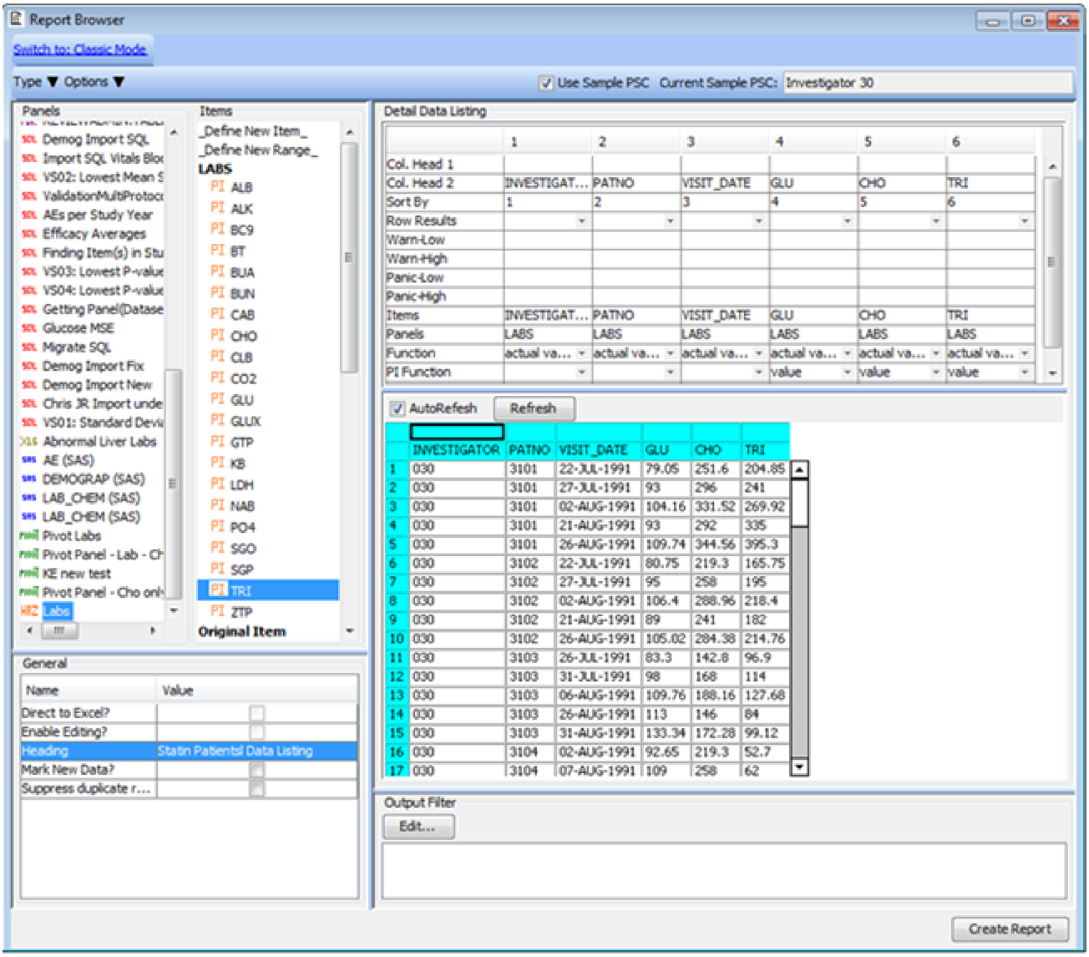
Final.Completed Evaluation? =No

## *Vertical tables*

Vertical tables can be transformed to horizontal format “**HRZ**” that include the reference ranges. The saved horizontal panel displays with the “**HRZ**” prefix to identify as a transformed vertical to horizontal panel. The individual laboratory tests are listed with the “Original Item” listed below. HRZ panels are available for New Mode and ***will not*** display in the panels list in Classic Mode.

***(See Chapter 12 - Advanced Topics: Vertical to Horizontal Panel)***

Simply drag and drop items to display within the data listing.



☑ Use Sample PSC Current Sample PSC: Investigator 30

General

| Name | Value |
|---|---|
| Direct to Excel? | ☐ |
| Enable Editing? | ☐ |
| Heading | Statin Patients' Data Listing |
| Mark New Data? | ☐ |
| Suppress duplicate r... | ☐ |

Detail Data Listing

| | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | |
| Col. Head 2 | INVESTIGAT... | PATNO | VISIT_DATE | GLU | CHO | TRI |
| Sort By | 1 | 2 | 3 | 4 | 5 | 6 |
| Row Results | | | | | | |
| Warn-Low | | | | | | |
| Warn-High | | | | | | |
| Panic-Low | | | | | | |
| Panic-High | | | | | | |
| Items | INVESTIGAT... | PATNO | VISIT_DATE | GLU | CHO | TRI |
| Panels | LABS | LABS | LABS | LABS | LABS | LABS |
| Function | actual va... | actual va... | actual va... | actual va... | actual va... | actual va... |
| PI Function | | | | value | value | value |

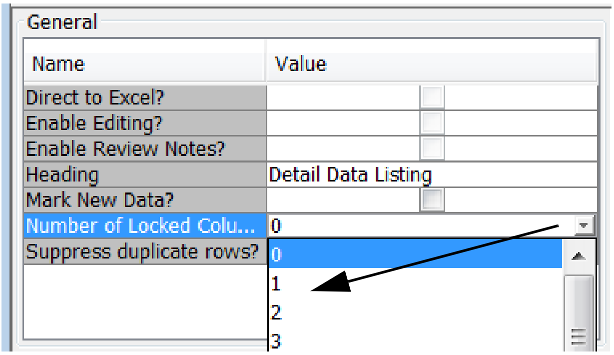
☑ AutoRefesh Refresh

| | INVESTIGATOR | PATNO | VISIT_DATE | GLU | CHO | TRI |
|---|---|---|---|---|---|---|
| 1 | 030 | 3101 | 22-JUL-1991 | 79.05 | 251.6 | 204.85 |
| 2 | 030 | 3101 | 27-JUL-1991 | 93 | 296 | 241 |
| 3 | 030 | 3101 | 02-AUG-1991 | 104.16 | 331.52 | 269.92 |
| 4 | 030 | 3101 | 21-AUG-1991 | 93 | 292 | 335 |
| 5 | 030 | 3101 | 26-AUG-1991 | 109.74 | 344.56 | 395.3 |
| 6 | 030 | 3102 | 22-JUL-1991 | 80.75 | 219.3 | 165.75 |
| 7 | 030 | 3102 | 27-JUL-1991 | 95 | 258 | 195 |
| 8 | 030 | 3102 | 02-AUG-1991 | 106.4 | 288.96 | 218.4 |
| 9 | 030 | 3102 | 21-AUG-1991 | 89 | 241 | 182 |
| 10 | 030 | 3102 | 26-AUG-1991 | 105.02 | 284.38 | 214.76 |
| 11 | 030 | 3103 | 26-JUL-1991 | 83.3 | 142.8 | 96.9 |
| 12 | 030 | 3103 | 31-JUL-1991 | 98 | 168 | 114 |
| 13 | 030 | 3103 | 06-AUG-1991 | 109.76 | 188.16 | 127.68 |
| 14 | 030 | 3103 | 26-AUG-1991 | 113 | 146 | 84 |
| 15 | 030 | 3103 | 31-AUG-1991 | 133.34 | 172.28 | 99.12 |
| 16 | 030 | 3104 | 02-AUG-1991 | 92.65 | 219.3 | 52.7 |
| 17 | 030 | 3104 | 07-AUG-1991 | 109 | 258 | 62 |

## Column display features

Detailed Reports have the added option to apply locked columns, specified column width, or auto size, etc. There is the capability to specify the number of locked/frozen columns in a definition, so that in the generated report those number of columns on the ***left will be locked or frozen***, when the remainder of the report is horizontally scrolled.

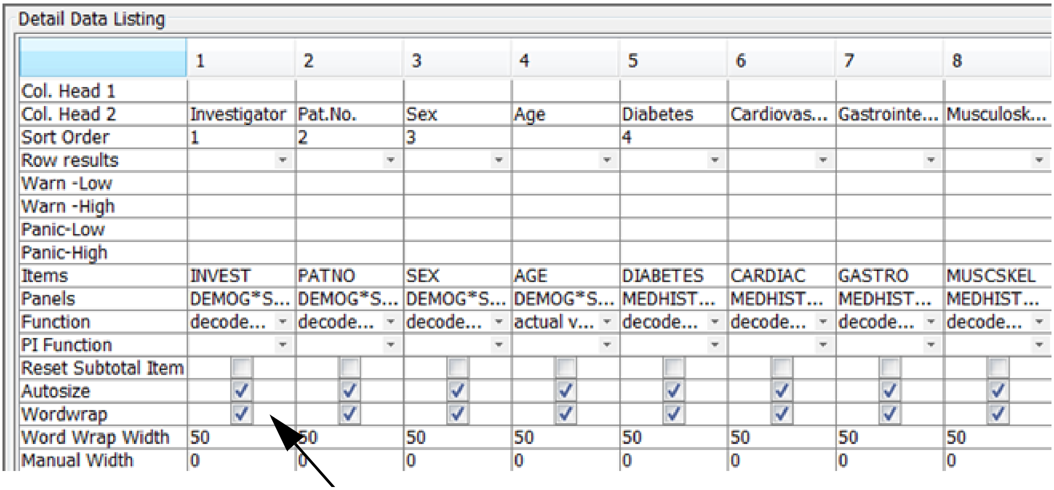
The option for **Number of Locked Columns** is located in the **General table**. This feature is for New Mode and Classic Mode Detailed Data Listings only.



General

| Name | Value |
|---|---|
| Direct to Excel? | ☐ |
| Enable Editing? | ☐ |
| Enable Review Notes? | ☐ |
| Heading | Detail Data Listing |
| Mark New Data? | ☐ |
| Number of Locked Colu... | 0<br>0<br>1<br>2<br>3 |
| Suppress duplicate rows? | |

Also, column width can be specified by sizing the definition column or leaving the autosize checkbox checked (default), and whether to word wrap column contents, etc. These features are available in both New Mode and Classic Mode Detail Data and Summary listings.



Detail Data Listing

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | | | |
| Col. Head 2 | Investigator | Pat.No. | Sex | Age | Diabetes | Cardiovas... | Gastrointe... | Musculosk... |
| Sort Order | 1 | 2 | 3 | | 4 | | | |
| Row results | | | | | | | | |
| Warn -Low | | | | | | | | |
| Warn -High | | | | | | | | |
| Panic-Low | | | | | | | | |
| Panic-High | | | | | | | | |
| Items | INVEST | PATNO | SEX | AGE | DIABETES | CARDIAC | GASTRO | MUSCSKEL |
| Panels | DEMOG*S... | DEMOG*S... | DEMOG*S... | DEMOG*S... | MEDHIST... | MEDHIST... | MEDHIST... | MEDHIST... |
| Function | decode... | decode... | decode... | actual v... | decode... | decode... | decode... | decode... |
| PI Function | | | | | | | | |
| Reset Subtotal Item | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Autosize | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Wordwrap | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Word Wrap Width | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| Manual Width | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

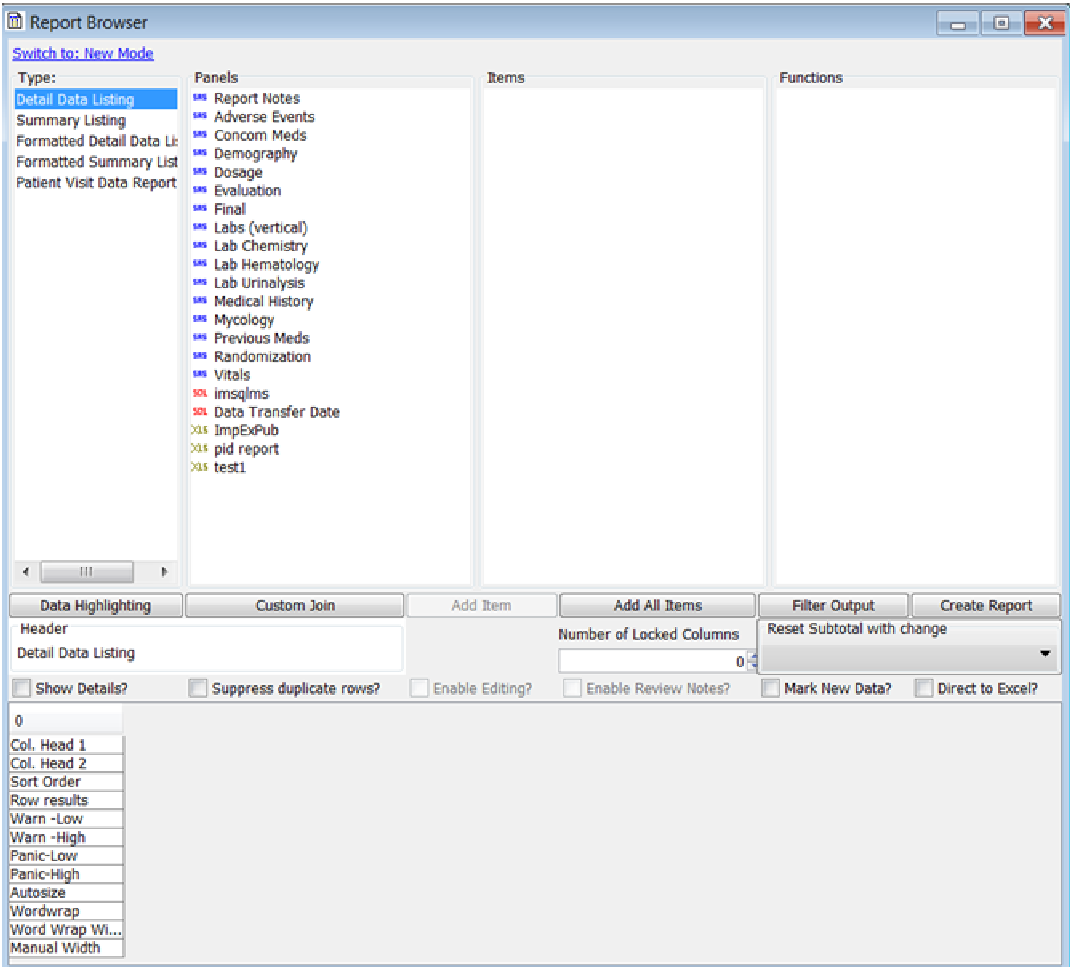
Change the Manual Width in New mode window, from the created output window. Slide the column size and return to the browser build window to view/save changed column width. In Classic Mode, change the manual width value in the cell. Create report to view column changes.

# Defining Report Specifications - Classic Mode

## *Selecting a panel, item, and function*

To open the Report Browser, from the **Browse** menu, select **Reports** or click on the toolbar. Click **Switch to: Classic Mode**. Define the report using the same method used to build the patient selection criteria:

1. Select a panel.
2. Select each item of interest.
3. For each item, select an appropriate function or use the default function type for the type of item selected.



## *Adding items*

Select individual items and click **ADD Item** to add the selected item to the report content spreadsheet. Or double click on the individual items to add each item to the report content spreadsheet.

A short cut for adding non-contiguous items within the same panel:

1. Select the items you want while holding the **Ctrl** key.
2. Click **ADD Item** to add the item to the report content spreadsheet in the order they appear in the panel.

OR

3. Click **Add All Items** to add all items in the selected panel to the current report. You can select and combine items from all panels.
4. To remove the item; select the added item column and click the scissors icon in the tool bar.

## *User-defined functions*

In JReview you can view user-defined functions defined for the browsers. Users can select predefined functions from a function value list. Users can utilize these functions to create new user-defined functions such as new item, new events and new ranges that are fully supported in the various browsers. **(See *Chapter 12 - Advanced Topics: Derived Items and New Range Variables*)**

The predefined functions ‘Baseline’, ‘Endpoint’, ‘Chg from Baseline’ which calculates the change from the last measure and all other default functions are pre-configured in the Review Administrative Configuration Tables. **(See *Review Configuration Guide*)**

## *Access to SAS datasets*

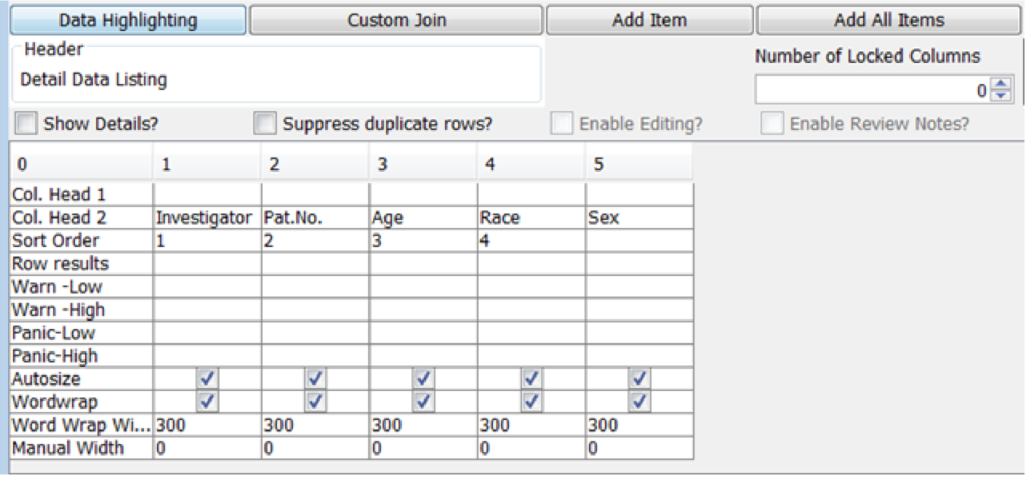
SAS datasets are listed with the panels generated from Oracle tables. Items from SAS datasets can be used like other items for building reports.

***Note: The current restriction is you cannot mix items from SAS datasets and Oracle table generated panels within the same report.***

## *Edit item sort order*

To make changes to the individual item **Sort Order**:

1. Double-click on the default sort order values 1, 2, 3 and change the values. The Sort Order 1 will be the item in which the primary sort will take place, sub-sorted by Sort Order 2, and so on.

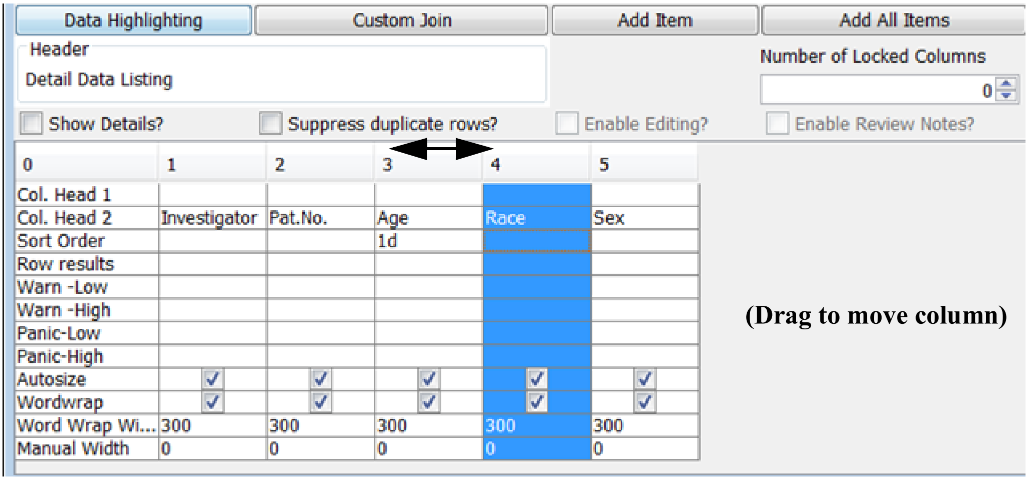


Number of Locked Columns: 0

☐ Show Details? ☐ Suppress duplicate rows? ☐ Enable Editing? ☐ Enable Review Notes?

| 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| Col. Head 1 | | | | | |
| Col. Head 2 | Investigator | Pat.No. | Age | Race | Sex |
| Sort Order | 1 | 2 | 3 | 4 | |
| Row results | | | | | |
| Warn -Low | | | | | |
| Warn -High | | | | | |
| Panic-Low | | | | | |
| Panic-High | | | | | |
| Autosize | ☑ | ☑ | ☑ | ☑ | ☑ |
| Wordwrap | ☑ | ☑ | ☑ | ☑ | ☑ |
| Word Wrap Wi... | 300 | 300 | 300 | 300 | 300 |
| Manual Width | 0 | 0 | 0 | 0 | 0 |

2. Delete, replace, edit or add Sort Order values for the particular item.
3. Optional descending sort is specified by a trailing 'D' after the Sort Order number.



Number of Locked Columns: 0

☐ Show Details? ☐ Suppress duplicate rows? ☐ Enable Editing? ☐ Enable Review Notes?

| 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| Col. Head 1 | | | | | |
| Col. Head 2 | Investigator | Pat.No. | Age | Race | Sex |
| Sort Order | | | 1d | | |
| Row results | | | | | |
| Warn -Low | | | | | |
| Warn -High | | | | | |
| Panic-Low | | | | | |
| Panic-High | | | | | |
| Autosize | ☑ | ☑ | ☑ | ☑ | ☑ |
| Wordwrap | ☑ | ☑ | ☑ | ☑ | ☑ |
| Word Wrap Wi... | 300 | 300 | 300 | 300 | 300 |
| Manual Width | 0 | 0 | 0 | 0 | 0 |

**(Drag to move column)**

## *Change column order*

Click on the column you want to move and drag the column to the desired location.

## *Column autosizing*

JReview automatically autosizes the report column widths as shown by check **AutoSize Columns ON**.

## *Edit column display*

See the previous section on ***Column Display Features*** for topics:

- **Number of Locked Columns**
- **Autosize**
- **Wordwrap**
- **Word Wrap width**
- **Manual width**

## *Changing the report specifications*

To change the report specification that you have defined:

1. Click anywhere in the report layout (heading, sort order, column headings, row results, delete or add panel item function values, or define (or re-define) join logic.

   For example, in a column that you want to delete (and perhaps replace later).

   a. Click ✂ or from the **Edit** menu, select **Cut**. This deletes the column from the report specification.

   b. To place the column in a new order location, click on a column and from the **Edit** menu, select **Insert**. The cut column is inserted to the left of the highlighted column. Or, highlight the column(‘s), and use the directional arrows to reposition the columns highlighted.

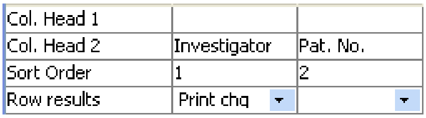
2. To clear the entire report specification, click 🗋.

## Edit column heading

You can edit the column headings for Col. Head 1 and Col. Head 2, by clicking within the text cell, edit the text and press **Enter.**

## Print Change

Print Change means print the value, only if it has changed from the previous line of output.



| | | |
|---|---|---|
| Col. Head 1 | | |
| Col. Head 2 | Investigator | Pat. No. |
| Sort Order | 1 | 2 |
| Row results | Print chg | |

## Defining a report title

Edit the report heading to easily identify the report window and printouts. You can enter a title for your report that will be displayed as the caption in the report window, as well as, in any printouts. By default, the Report Browser assigns the report type as the heading of the report. Enter the title text in the 'Heading' field.

Heading
Lab Chemistry Listing

The report heading displays either 'All Patients' or 'Subset' if a patient selection criteria was entered. If you modify the report heading the patient population status of either 'All Patients' or 'Subset' still displays.

## Show Details

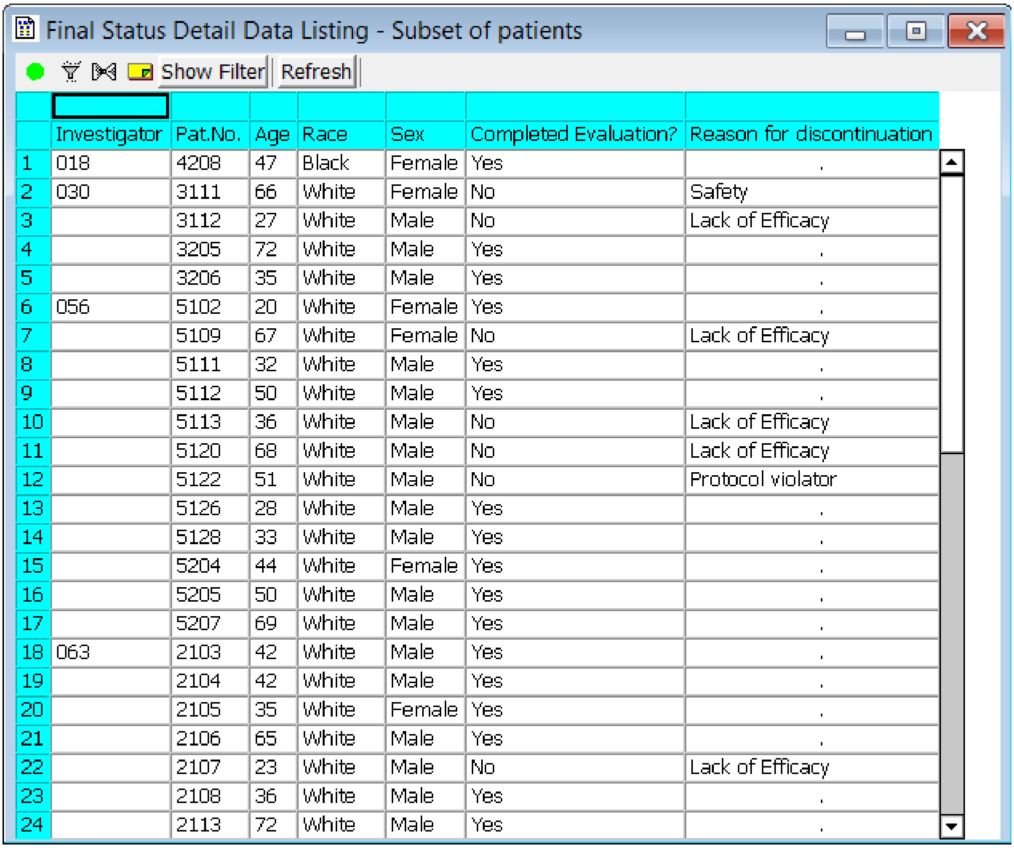
The 'Show Details?' feature can be used after you have added items to your report specification. Show Details is helpful after you define and save a report definition and look back to view it's source contents.

The Show Details doesn't change the report content or definition but instead displays some additional rows of information at the bottom of the report template. The extra rows display the source of the items selected in the report columns. Most of the report types show Items and Panels. In addition, the Patient Visit Data Report when accessing vertical data shows two additional rows for Pivot Item and Pivot Value.

***Note: The Items and Panels names are displayed from the Data Dictionary and not the Items and Panels Description.***

## *Create report*

When all report specifications have been entered click **Create Report.** The report is displayed in a Report Browser window containing a spreadsheet of your report. The ‘**Print Change**’ feature is turned on for Investigator to only print if the Investigator value changes.



| | Investigator | Pat.No. | Age | Race | Sex | Completed Evaluation? | Reason for discontinuation |
|---|---|---|---|---|---|---|---|
| 1 | 018 | 4208 | 47 | Black | Female | Yes | . |
| 2 | 030 | 3111 | 66 | White | Female | No | Safety |
| 3 | | 3112 | 27 | White | Male | No | Lack of Efficacy |
| 4 | | 3205 | 72 | White | Male | Yes | . |
| 5 | | 3206 | 35 | White | Male | Yes | . |
| 6 | 056 | 5102 | 20 | White | Female | Yes | . |
| 7 | | 5109 | 67 | White | Female | No | Lack of Efficacy |
| 8 | | 5111 | 32 | White | Male | Yes | . |
| 9 | | 5112 | 50 | White | Male | Yes | . |
| 10 | | 5113 | 36 | White | Male | No | Lack of Efficacy |
| 11 | | 5120 | 68 | White | Male | No | Lack of Efficacy |
| 12 | | 5122 | 51 | White | Male | No | Protocol violator |
| 13 | | 5126 | 28 | White | Male | Yes | . |
| 14 | | 5128 | 33 | White | Male | Yes | . |
| 15 | | 5204 | 44 | White | Female | Yes | . |
| 16 | | 5205 | 50 | White | Male | Yes | . |
| 17 | | 5207 | 69 | White | Male | Yes | . |
| 18 | 063 | 2103 | 42 | White | Male | Yes | . |
| 19 | | 2104 | 42 | White | Male | Yes | . |
| 20 | | 2105 | 35 | White | Female | Yes | . |
| 21 | | 2106 | 65 | White | Male | Yes | . |
| 22 | | 2107 | 23 | White | Male | No | Lack of Efficacy |
| 23 | | 2108 | 36 | White | Male | Yes | . |
| 24 | | 2113 | 72 | White | Male | Yes | . |

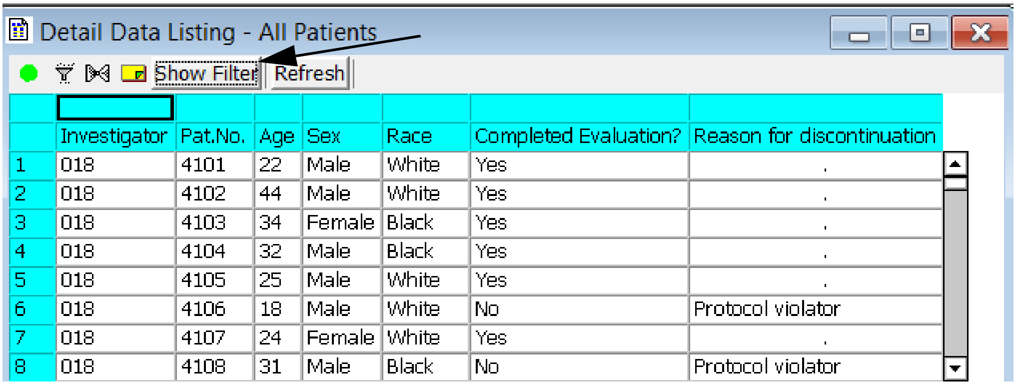
# View Output

## *Show Filter*

The Show Filter function allows the user to apply interactive column filters while viewing the output window. This feature only applies to the Detail Data Listing report type. When a detail data listing is created two additional icons display in the report toolbar for ‘**Show Filter**’ and ‘**Refresh**’.

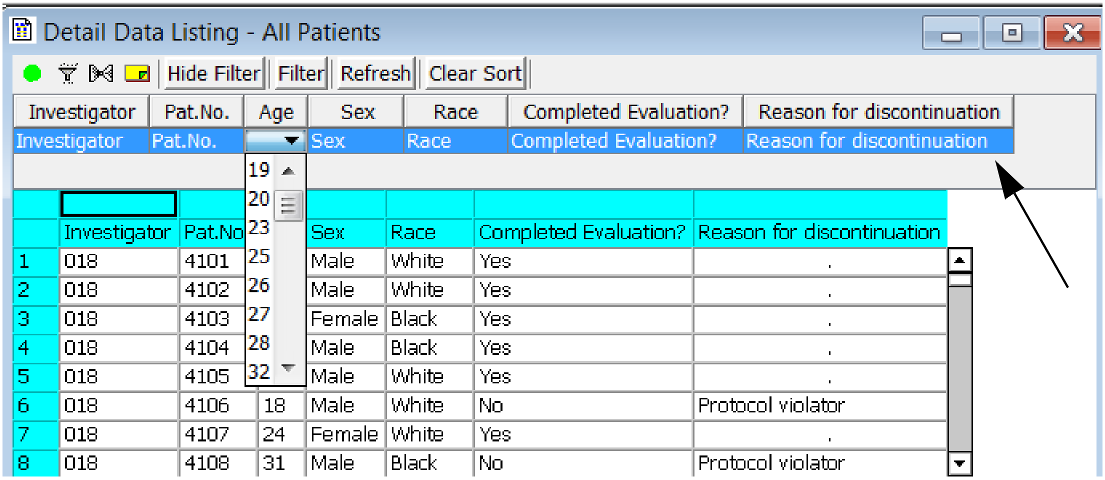
*Note:* ***Avoid applying Print Change, Sum, and Mean to the data listing definition which interfere with some applied column filters.***

1. Click on the **Show Filter** icon to enable the individual column filters.



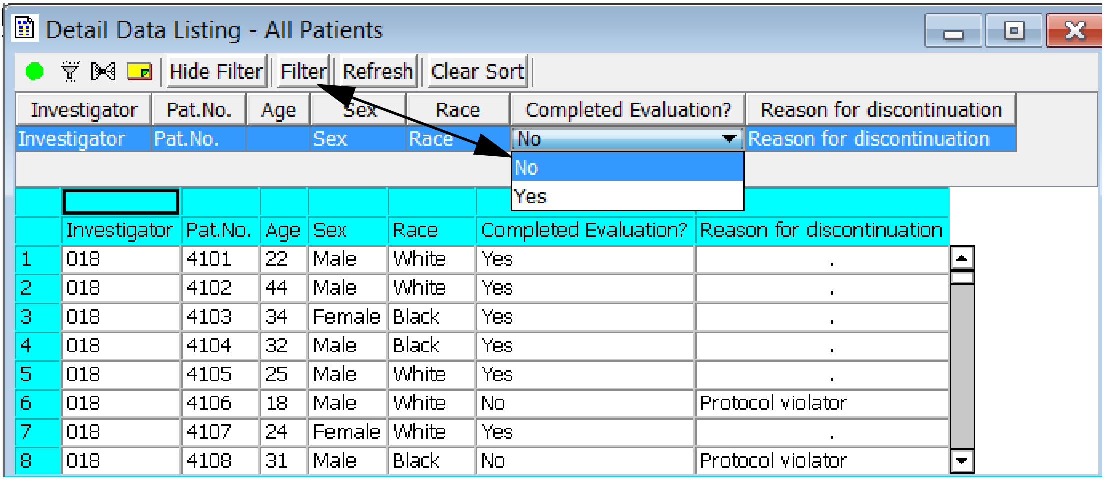
|  | Investigator | Pat.No. | Age | Sex | Race | Completed Evaluation? | Reason for discontinuation |
|---|---|---|---|---|---|---|---|
| 1 | 018 | 4101 | 22 | Male | White | Yes | . |
| 2 | 018 | 4102 | 44 | Male | White | Yes | . |
| 3 | 018 | 4103 | 34 | Female | Black | Yes | . |
| 4 | 018 | 4104 | 32 | Male | Black | Yes | . |
| 5 | 018 | 4105 | 25 | Male | White | Yes | . |
| 6 | 018 | 4106 | 18 | Male | White | No | Protocol violator |
| 7 | 018 | 4107 | 24 | Female | White | Yes | . |
| 8 | 018 | 4108 | 31 | Male | Black | No | Protocol violator |

The report tool bar displays the column filters as a ***filter bar*** between the report header and tool bar.



|  | Investigator | Pat.No | Age | Sex | Race | Completed Evaluation? | Reason for discontinuation |
|---|---|---|---|---|---|---|---|
| 1 | 018 | 4101 |  | Male | White | Yes | . |
| 2 | 018 | 4102 |  | Male | White | Yes | . |
| 3 | 018 | 4103 |  | Female | Black | Yes | . |
| 4 | 018 | 4104 |  | Male | Black | Yes | . |
| 5 | 018 | 4105 |  | Male | White | Yes | . |
| 6 | 018 | 4106 | 18 | Male | White | No | Protocol violator |
| 7 | 018 | 4107 | 24 | Female | White | Yes | . |
| 8 | 018 | 4108 | 31 | Male | Black | No | Protocol violator |

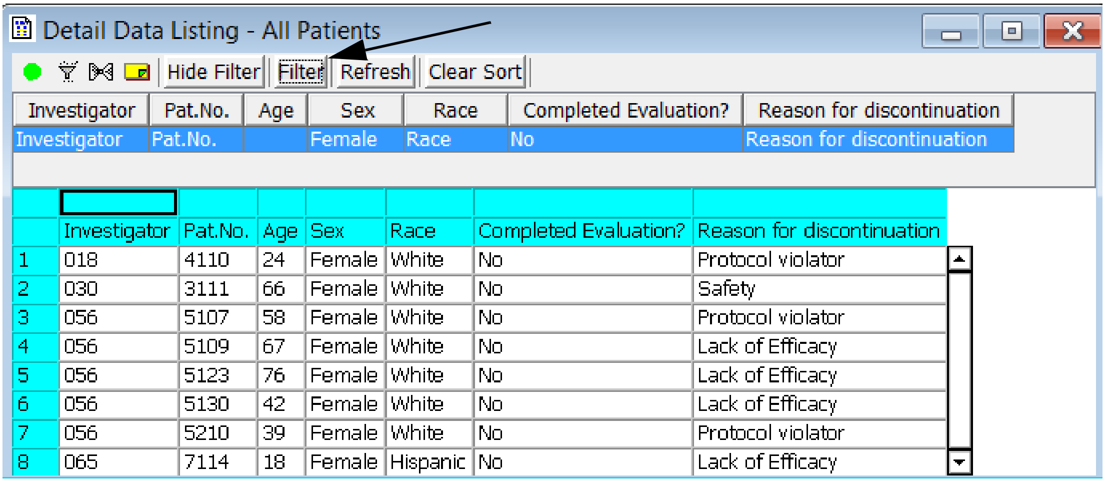
2. Click on a column filter to display the combo box for a value selection. Select a value to filter on.



| Investigator | Pat.No. | Age | Sex | Race | Completed Evaluation? | Reason for discontinuation |
|---|---|---|---|---|---|---|
| Investigator | Pat.No. |  | Sex | Race | No | Reason for discontinuation |

| | Investigator | Pat.No. | Age | Sex | Race | Completed Evaluation? | Reason for discontinuation |
|---|---|---|---|---|---|---|---|
| 1 | 018 | 4101 | 22 | Male | White | Yes | . |
| 2 | 018 | 4102 | 44 | Male | White | Yes | . |
| 3 | 018 | 4103 | 34 | Female | Black | Yes | . |
| 4 | 018 | 4104 | 32 | Male | Black | Yes | . |
| 5 | 018 | 4105 | 25 | Male | White | Yes | . |
| 6 | 018 | 4106 | 18 | Male | White | No | Protocol violator |
| 7 | 018 | 4107 | 24 | Female | White | Yes | . |
| 8 | 018 | 4108 | 31 | Male | Black | No | Protocol violator |

After selecting the filter value you must click on the **Filter button**. The column filter is applied for the selected value. You may select across different column filters to select values to filter on.



| Investigator | Pat.No. | Age | Sex | Race | Completed Evaluation? | Reason for discontinuation |
|---|---|---|---|---|---|---|
| Investigator | Pat.No. |  | Female | Race | No | Reason for discontinuation |

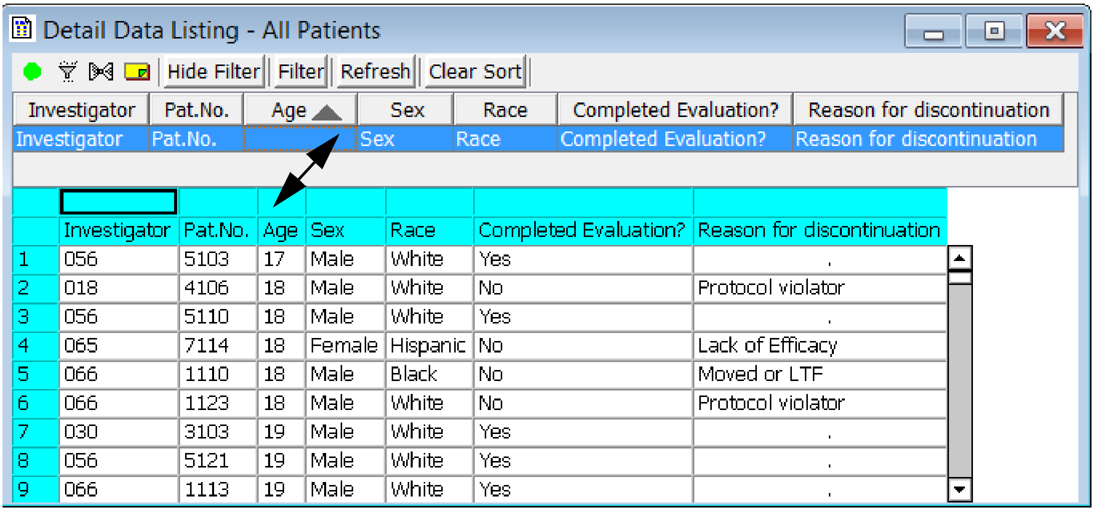
| | Investigator | Pat.No. | Age | Sex | Race | Completed Evaluation? | Reason for discontinuation |
|---|---|---|---|---|---|---|---|
| 1 | 018 | 4110 | 24 | Female | White | No | Protocol violator |
| 2 | 030 | 3111 | 66 | Female | White | No | Safety |
| 3 | 056 | 5107 | 58 | Female | White | No | Protocol violator |
| 4 | 056 | 5109 | 67 | Female | White | No | Lack of Efficacy |
| 5 | 056 | 5123 | 76 | Female | White | No | Lack of Efficacy |
| 6 | 056 | 5130 | 42 | Female | White | No | Lack of Efficacy |
| 7 | 056 | 5210 | 39 | Female | White | No | Protocol violator |
| 8 | 065 | 7114 | 18 | Female | Hispanic | No | Lack of Efficacy |

3. Click on **Refresh** to clear applied column filters and restore to the initial report display. This step is necessary to reselect a different filter value for the same data column. The results output window returns back to the original results.

## *Sort output*

4. Optionally, you may sort on a select column for alpha or numeric sort order. Click on the column header to select preferred ascending or descending sort order. Click the **Clear Sort** to clear applied column sort.

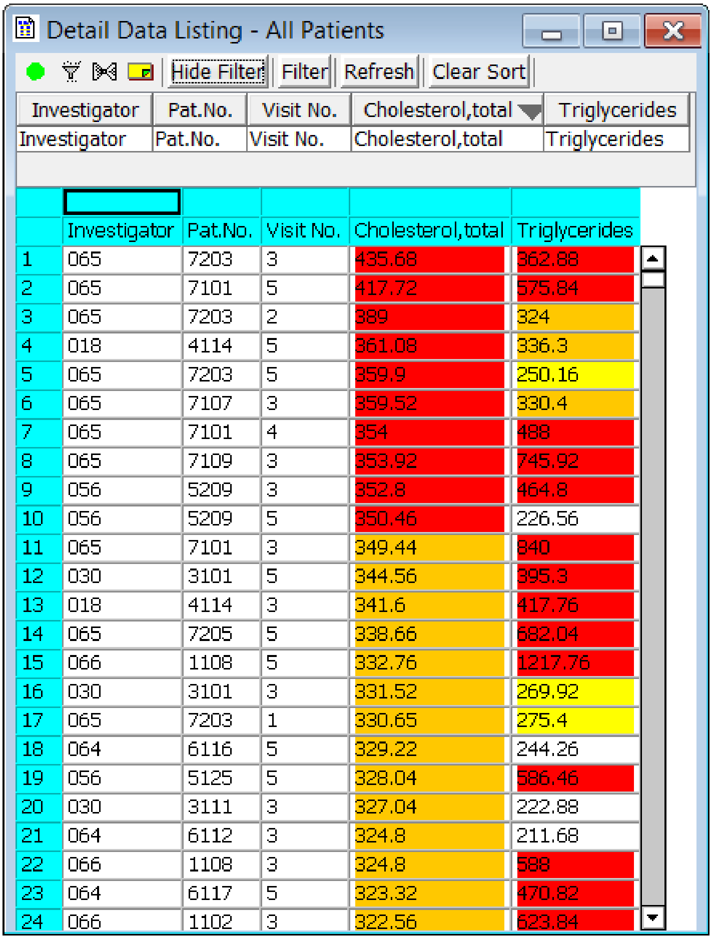
   When applying a three level sort you ***must*** use the C**lear Sort** button then re-enter the new three level sort. Clicking on the individual sort columns will not clear a three level sort.



|  | Investigator | Pat.No. | Age | Sex | Race | Completed Evaluation? | Reason for discontinuation |
|---|---|---|---|---|---|---|---|
| 1 | 056 | 5103 | 17 | Male | White | Yes | . |
| 2 | 018 | 4106 | 18 | Male | White | No | Protocol violator |
| 3 | 056 | 5110 | 18 | Male | White | Yes | . |
| 4 | 065 | 7114 | 18 | Female | Hispanic | No | Lack of Efficacy |
| 5 | 066 | 1110 | 18 | Male | Black | No | Moved or LTF |
| 6 | 066 | 1123 | 18 | Male | White | No | Protocol violator |
| 7 | 030 | 3103 | 19 | Male | White | Yes | . |
| 8 | 056 | 5121 | 19 | Male | White | Yes | . |
| 9 | 066 | 1113 | 19 | Male | White | Yes | . |

5. Click the **Hide Filter** button to hide the column filter bar and return to the initial tool bar status.

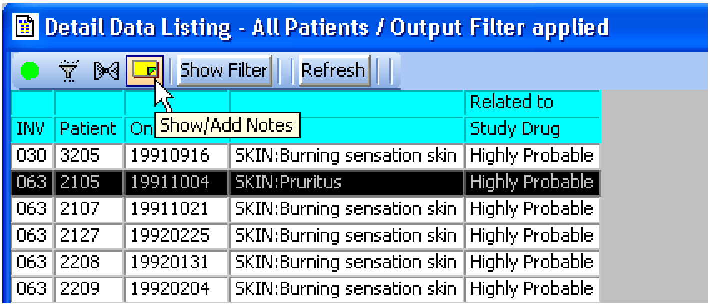
Sorting on columns with conditional data highlighting is supported. In this example, the sort is applied to the Cholesterol column to view values with applied highlights in descending order.



| | Investigator | Pat.No. | Visit No. | Cholesterol,total | Triglycerides |
|---|---|---|---|---|---|
| 1 | 065 | 7203 | 3 | 435.68 | 362.88 |
| 2 | 065 | 7101 | 5 | 417.72 | 575.84 |
| 3 | 065 | 7203 | 2 | 389 | 324 |
| 4 | 018 | 4114 | 5 | 361.08 | 336.3 |
| 5 | 065 | 7203 | 5 | 359.9 | 250.16 |
| 6 | 065 | 7107 | 3 | 359.52 | 330.4 |
| 7 | 065 | 7101 | 4 | 354 | 488 |
| 8 | 065 | 7109 | 3 | 353.92 | 745.92 |
| 9 | 056 | 5209 | 3 | 352.8 | 464.8 |
| 10 | 056 | 5209 | 5 | 350.46 | 226.56 |
| 11 | 065 | 7101 | 3 | 349.44 | 840 |
| 12 | 030 | 3101 | 5 | 344.56 | 395.3 |
| 13 | 018 | 4114 | 3 | 341.6 | 417.76 |
| 14 | 065 | 7205 | 5 | 338.66 | 682.04 |
| 15 | 066 | 1108 | 5 | 332.76 | 1217.76 |
| 16 | 030 | 3101 | 3 | 331.52 | 269.92 |
| 17 | 065 | 7203 | 1 | 330.65 | 275.4 |
| 18 | 064 | 6116 | 5 | 329.22 | 244.26 |
| 19 | 056 | 5125 | 5 | 328.04 | 586.46 |
| 20 | 030 | 3111 | 3 | 327.04 | 222.88 |
| 21 | 064 | 6112 | 3 | 324.8 | 211.68 |
| 22 | 066 | 1108 | 3 | 324.8 | 588 |
| 23 | 064 | 6117 | 5 | 323.32 | 470.82 |
| 24 | 066 | 1102 | 3 | 322.56 | 623.84 |

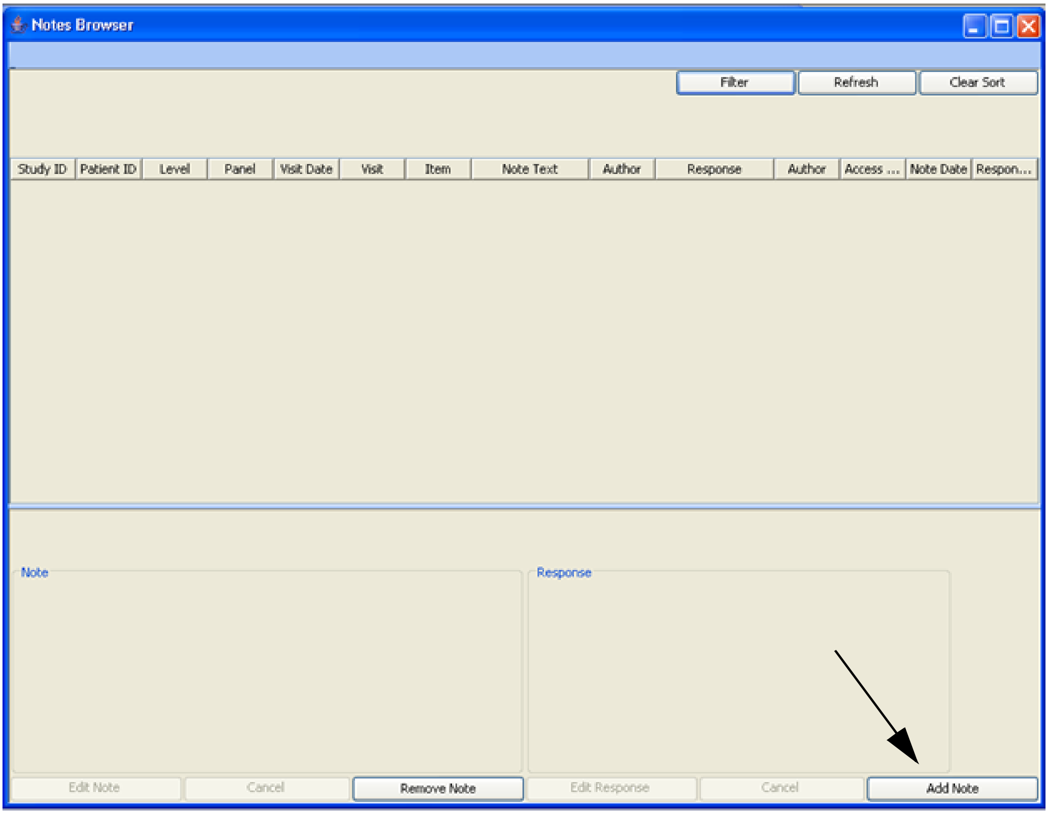
## *Add patient note*

Detail Data Listings and Patient Visit Data Reports support ‘**Add Notes**’ when you select an individual patient. Click on a patient row to highlight the patient, then click on the **Add Note** icon in the report tool bar.



| INV | Patient | On |  | Related to Study Drug |
|---|---|---|---|---|
| 030 | 3205 | 19910916 | SKIN:Burning sensation skin | Highly Probable |
| 063 | 2105 | 19911004 | SKIN:Pruritus | Highly Probable |
| 063 | 2107 | 19911021 | SKIN:Burning sensation skin | Highly Probable |
| 063 | 2127 | 19920225 | SKIN:Burning sensation skin | Highly Probable |
| 063 | 2208 | 19920131 | SKIN:Burning sensation skin | Highly Probable |
| 063 | 2209 | 19920204 | SKIN:Burning sensation skin | Highly Probable |

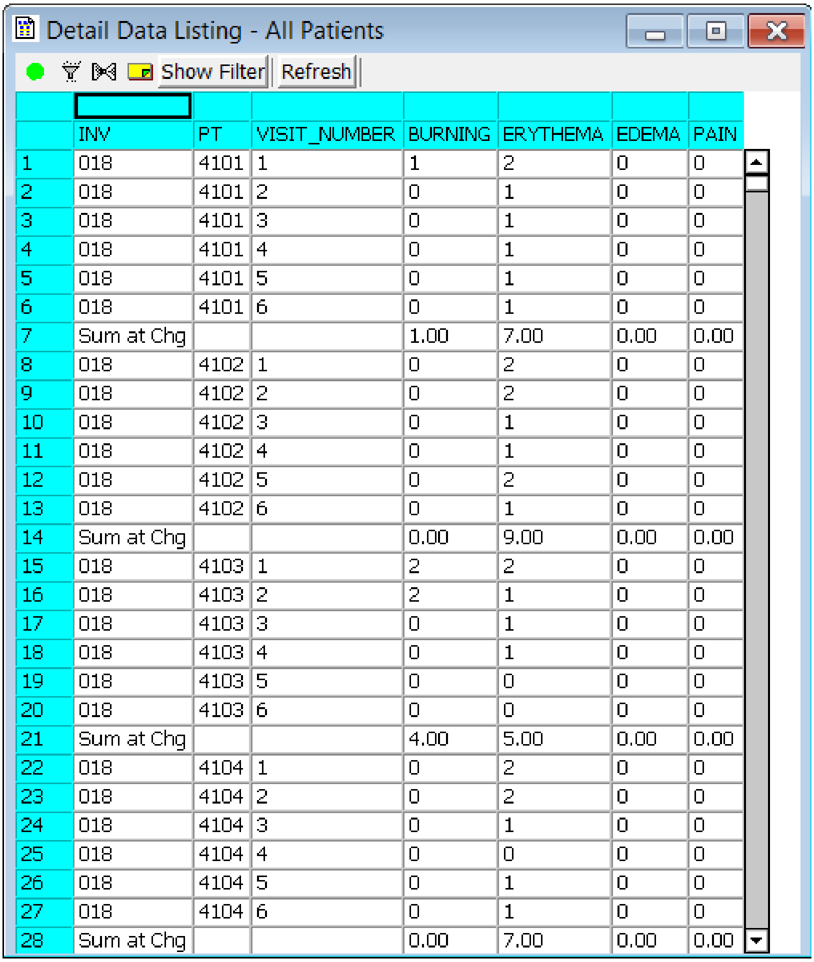
The **Notes Browser** window opens to view existing notes for the selected patient. Click on **Add Note** to add a new note. ***(See Chapter 3: Review Patient Data, see section on Notes Browser)***



# Detail Data Listing features

## *Defining row results*

A numeric data type provides clinically pertinent options, such as mean or sum. Numeric row results generate report summations (for example, Selecting Sum or Mean), or break point summations that the report will generate in summation or at break points for example, change in PID, Sum at Change and Mean at Change. The Row Results drop down list below is for non-formatted report types.

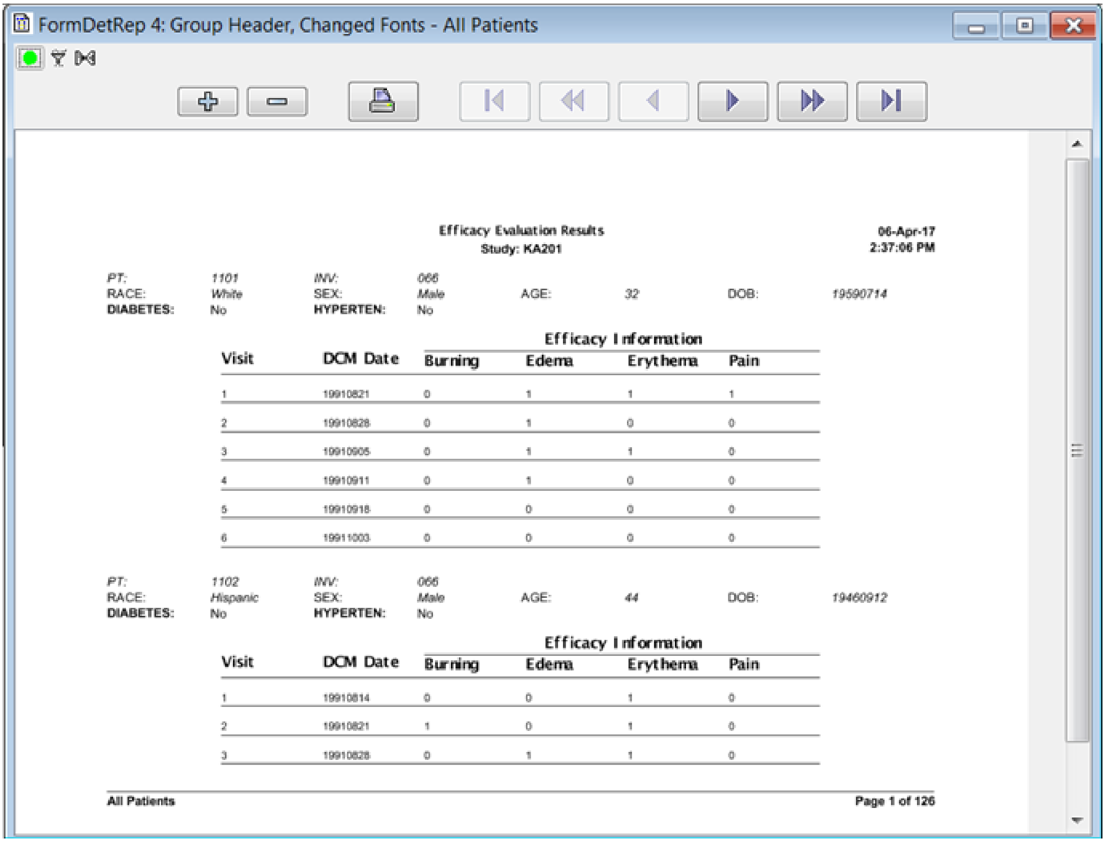


| | INV | PT | VISIT_NUMBER | BURNING | ERYTHEMA | EDEMA | PAIN |
|---|---|---|---|---|---|---|---|
| 1 | 018 | 4101 | 1 | 1 | 2 | 0 | 0 |
| 2 | 018 | 4101 | 2 | 0 | 1 | 0 | 0 |
| 3 | 018 | 4101 | 3 | 0 | 1 | 0 | 0 |
| 4 | 018 | 4101 | 4 | 0 | 1 | 0 | 0 |
| 5 | 018 | 4101 | 5 | 0 | 1 | 0 | 0 |
| 6 | 018 | 4101 | 6 | 0 | 1 | 0 | 0 |
| 7 | Sum at Chg | | | 1.00 | 7.00 | 0.00 | 0.00 |
| 8 | 018 | 4102 | 1 | 0 | 2 | 0 | 0 |
| 9 | 018 | 4102 | 2 | 0 | 2 | 0 | 0 |
| 10 | 018 | 4102 | 3 | 0 | 1 | 0 | 0 |
| 11 | 018 | 4102 | 4 | 0 | 1 | 0 | 0 |
| 12 | 018 | 4102 | 5 | 0 | 2 | 0 | 0 |
| 13 | 018 | 4102 | 6 | 0 | 1 | 0 | 0 |
| 14 | Sum at Chg | | | 0.00 | 9.00 | 0.00 | 0.00 |
| 15 | 018 | 4103 | 1 | 2 | 2 | 0 | 0 |
| 16 | 018 | 4103 | 2 | 2 | 1 | 0 | 0 |
| 17 | 018 | 4103 | 3 | 0 | 1 | 0 | 0 |
| 18 | 018 | 4103 | 4 | 0 | 1 | 0 | 0 |
| 19 | 018 | 4103 | 5 | 0 | 0 | 0 | 0 |
| 20 | 018 | 4103 | 6 | 0 | 0 | 0 | 0 |
| 21 | Sum at Chg | | | 4.00 | 5.00 | 0.00 | 0.00 |
| 22 | 018 | 4104 | 1 | 0 | 2 | 0 | 0 |
| 23 | 018 | 4104 | 2 | 0 | 2 | 0 | 0 |
| 24 | 018 | 4104 | 3 | 0 | 1 | 0 | 0 |
| 25 | 018 | 4104 | 4 | 0 | 0 | 0 | 0 |
| 26 | 018 | 4104 | 5 | 0 | 1 | 0 | 0 |
| 27 | 018 | 4104 | 6 | 0 | 1 | 0 | 0 |
| 28 | Sum at Chg | | | 0.00 | 7.00 | 0.00 | 0.00 |

***Note:** Mathematical row results options are different between non-formatted and formatted report types.*

The formatted reports have more mathematical options. In addition, formatted reports support Sum at Change, Mean at Change, Mean at Change and Mean, and Sum at Change and Sum.

The Formatted Report options also apply formats to modify the headers, footer, page breaks, column headings and more.



Efficacy Evaluation Results
Study: KA201

06-Apr-17
2:37:06 PM

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| *PT:* | *1101* | *INV:* | *066* | | | | |
| RACE: | *White* | SEX: | *Male* | AGE: | *32* | DOB: | *19590714* |
| **DIABETES:** | No | **HYPERTEN:** | No | | | | |

| Visit | DCM Date | Efficacy Information | | | |
|---|---|---|---|---|---|
| | | Burning | Edema | Erythema | Pain |
| 1 | 19910821 | 0 | 1 | 1 | 1 |
| 2 | 19910828 | 0 | 1 | 0 | 0 |
| 3 | 19910905 | 0 | 1 | 1 | 0 |
| 4 | 19910911 | 0 | 1 | 0 | 0 |
| 5 | 19910918 | 0 | 0 | 0 | 0 |
| 6 | 19911003 | 0 | 0 | 0 | 0 |

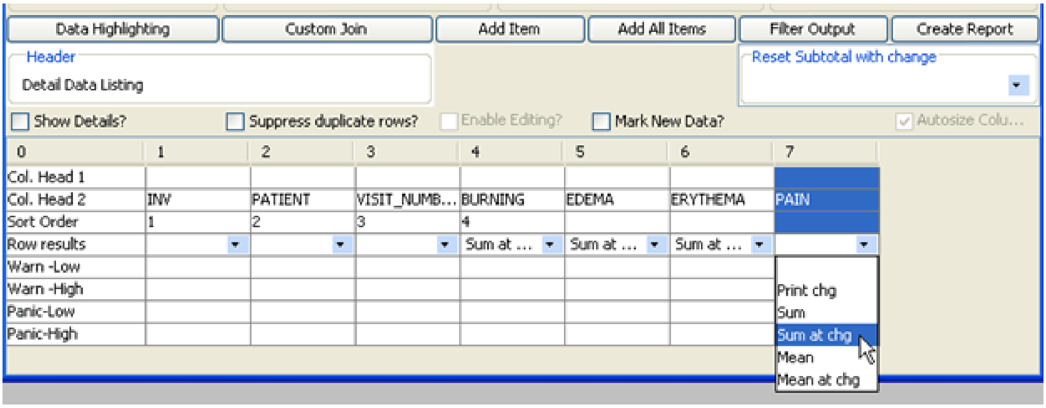
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| *PT:* | *1102* | *INV:* | *066* | | | | |
| RACE: | *Hispanic* | SEX: | *Male* | AGE: | *44* | DOB: | *19460912* |
| **DIABETES:** | No | **HYPERTEN:** | No | | | | |

| Visit | DCM Date | Efficacy Information | | | |
|---|---|---|---|---|---|
| | | Burning | Edema | Erythema | Pain |
| 1 | 19910814 | 0 | 0 | 1 | 0 |
| 2 | 19910821 | 1 | 0 | 1 | 0 |
| 3 | 19910828 | 0 | 1 | 1 | 0 |

**All Patients** **Page 1 of 126**

## *Reset subtotal in row results*

The mathematical row results options are available in the Detail Data Listing and Summary Listing.



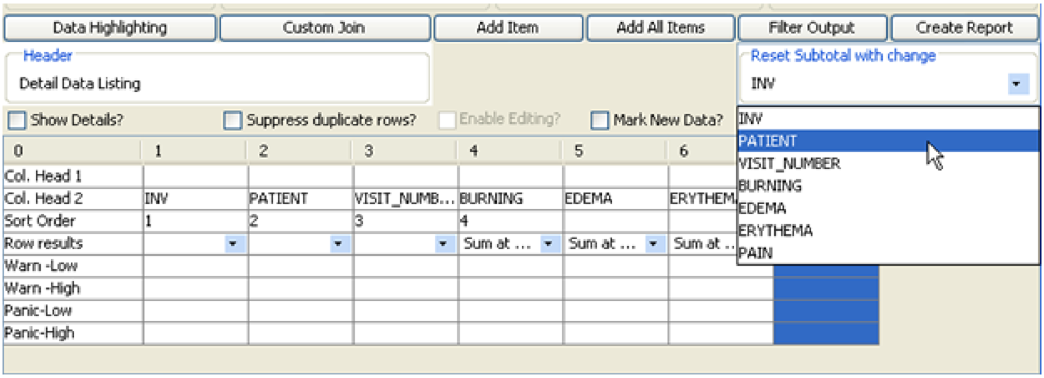
Header: Detail Data Listing

Reset Subtotal with change:

☐ Show Details? ☐ Suppress duplicate rows? ☐ Enable Editing? ☐ Mark New Data? ☑ Autosize Colu...

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | | |
| Col. Head 2 | INV | PATIENT | VISIT_NUMB... | BURNING | EDEMA | ERYTHEMA | PAIN |
| Sort Order | 1 | 2 | 3 | 4 | | | |
| Row results | | | | Sum at ... | Sum at ... | Sum at ... | |
| Warn -Low | | | | | | | |
| Warn -High | | | | | | | |
| Panic-Low | | | | | | | |
| Panic-High | | | | | | | |

You must select the item to 'break on' when utilizing the mathematical row results. This required selection is enforced when you have selected a mathematical row result 'Sum at change' or 'Mean at change' or 'Mean at Change and Mean'. The possible break items are listed in the 'Reset Subtotal with Change' drop-down list.



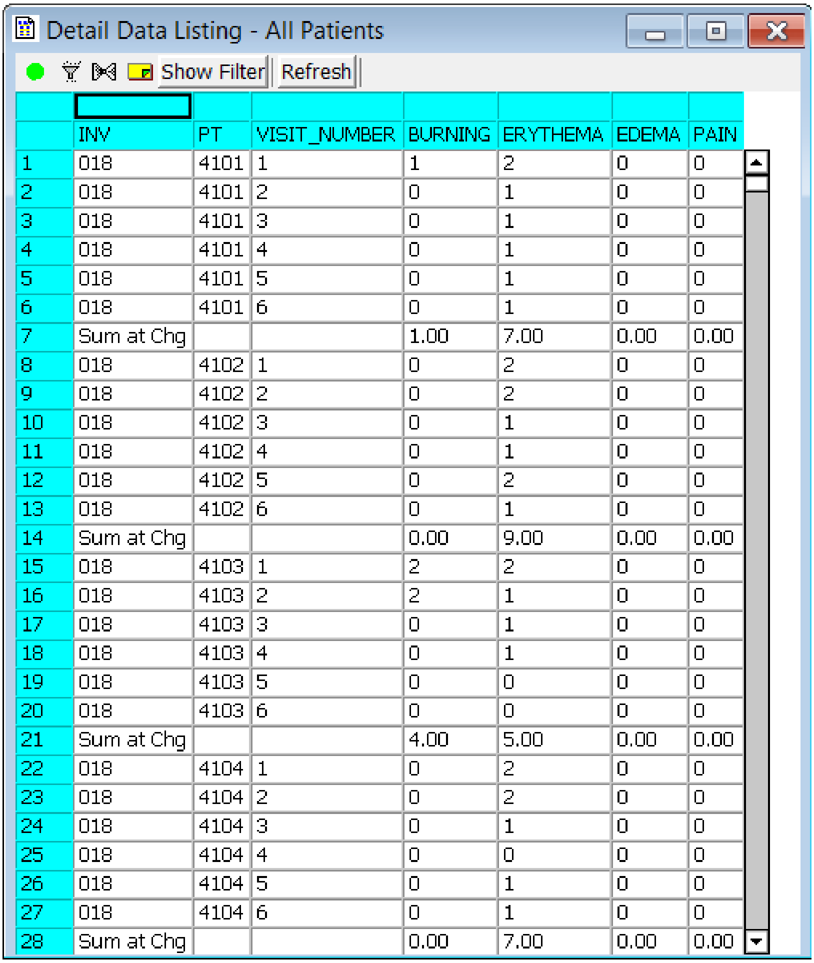
Header: Detail Data Listing

Reset Subtotal with change: INV

☐ Show Details? ☐ Suppress duplicate rows? ☐ Enable Editing? ☐ Mark New Data?

| 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | |
| Col. Head 2 | INV | PATIENT | VISIT_NUMB... | BURNING | EDEMA | ERYTHEM |
| Sort Order | 1 | 2 | 3 | 4 | | |
| Row results | | | | Sum at ... | Sum at ... | Sum at .. |
| Warn -Low | | | | | | |
| Warn -High | | | | | | |
| Panic-Low | | | | | | |
| Panic-High | | | | | | |

The mathematical break point is applied to the Pat No. with 'Sum at change' row result selected for Efficacy Evaluation items.

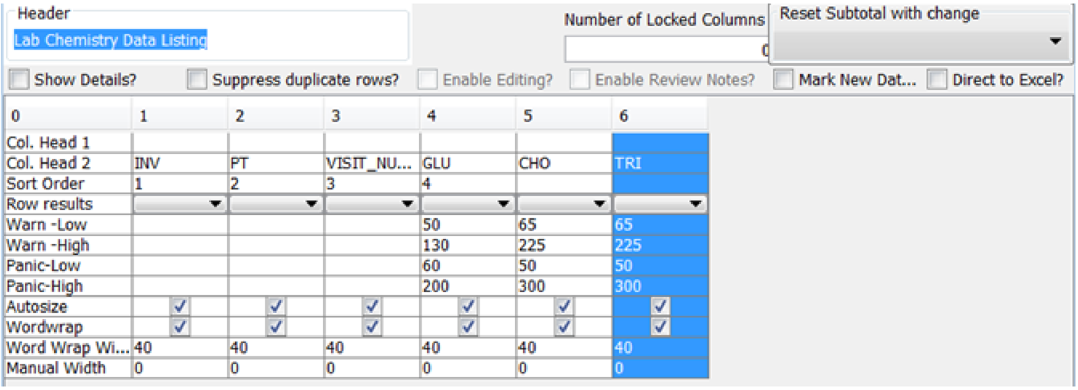


| | INV | PT | VISIT_NUMBER | BURNING | ERYTHEMA | EDEMA | PAIN |
|---|---|---|---|---|---|---|---|
| 1 | 018 | 4101 | 1 | 1 | 2 | 0 | 0 |
| 2 | 018 | 4101 | 2 | 0 | 1 | 0 | 0 |
| 3 | 018 | 4101 | 3 | 0 | 1 | 0 | 0 |
| 4 | 018 | 4101 | 4 | 0 | 1 | 0 | 0 |
| 5 | 018 | 4101 | 5 | 0 | 1 | 0 | 0 |
| 6 | 018 | 4101 | 6 | 0 | 1 | 0 | 0 |
| 7 | Sum at Chg | | | 1.00 | 7.00 | 0.00 | 0.00 |
| 8 | 018 | 4102 | 1 | 0 | 2 | 0 | 0 |
| 9 | 018 | 4102 | 2 | 0 | 2 | 0 | 0 |
| 10 | 018 | 4102 | 3 | 0 | 1 | 0 | 0 |
| 11 | 018 | 4102 | 4 | 0 | 1 | 0 | 0 |
| 12 | 018 | 4102 | 5 | 0 | 2 | 0 | 0 |
| 13 | 018 | 4102 | 6 | 0 | 1 | 0 | 0 |
| 14 | Sum at Chg | | | 0.00 | 9.00 | 0.00 | 0.00 |
| 15 | 018 | 4103 | 1 | 2 | 2 | 0 | 0 |
| 16 | 018 | 4103 | 2 | 2 | 1 | 0 | 0 |
| 17 | 018 | 4103 | 3 | 0 | 1 | 0 | 0 |
| 18 | 018 | 4103 | 4 | 0 | 1 | 0 | 0 |
| 19 | 018 | 4103 | 5 | 0 | 0 | 0 | 0 |
| 20 | 018 | 4103 | 6 | 0 | 0 | 0 | 0 |
| 21 | Sum at Chg | | | 4.00 | 5.00 | 0.00 | 0.00 |
| 22 | 018 | 4104 | 1 | 0 | 2 | 0 | 0 |
| 23 | 018 | 4104 | 2 | 0 | 2 | 0 | 0 |
| 24 | 018 | 4104 | 3 | 0 | 1 | 0 | 0 |
| 25 | 018 | 4104 | 4 | 0 | 0 | 0 | 0 |
| 26 | 018 | 4104 | 5 | 0 | 1 | 0 | 0 |
| 27 | 018 | 4104 | 6 | 0 | 1 | 0 | 0 |
| 28 | Sum at Chg | | | 0.00 | 7.00 | 0.00 | 0.00 |

## Highlighting data check ranges

When you define a detail data listing which includes numeric parameters such as laboratory data, vital signs or scores, you can enter warning and panic ranges that will be used to color highlight the data in the report display. If the report specifications are saved, these data check ranges are also stored within the report.

Simply enter your data check ranges within the spreadsheet cells labeled “Warn-Low”, “Warn-High”, “Panic-Low” and “Panic-High”.



Header: Lab Chemistry Data Listing

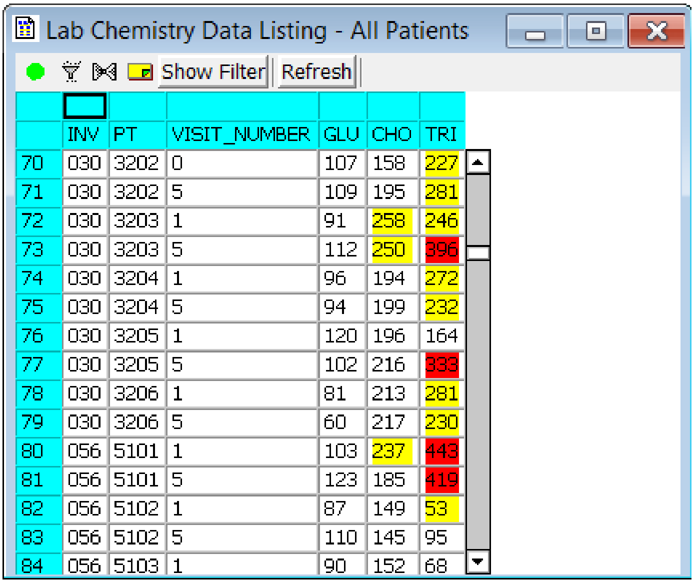
Number of Locked Columns: 0

Reset Subtotal with change

☐ Show Details? ☐ Suppress duplicate rows? ☐ Enable Editing? ☐ Enable Review Notes? ☐ Mark New Dat... ☐ Direct to Excel?

| 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | |
| Col. Head 2 | INV | PT | VISIT_NU... | GLU | CHO | TRI |
| Sort Order | 1 | 2 | 3 | 4 | | |
| Row results | | | | | | |
| Warn -Low | | | | 50 | 65 | 65 |
| Warn -High | | | | 130 | 225 | 225 |
| Panic-Low | | | | 60 | 50 | 50 |
| Panic-High | | | | 200 | 300 | 300 |
| Autosize | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Wordwrap | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Word Wrap Wi... | 40 | 40 | 40 | 40 | 40 | 40 |
| Manual Width | 0 | 0 | 0 | 0 | 0 | 0 |

Variable values outside the ranges you define display as yellow and red.



Lab Chemistry Data Listing - All Patients

| | INV | PT | VISIT_NUMBER | GLU | CHO | TRI |
|---|---|---|---|---|---|---|
| 70 | 030 | 3202 | 0 | 107 | 158 | 227 |
| 71 | 030 | 3202 | 5 | 109 | 195 | 281 |
| 72 | 030 | 3203 | 1 | 91 | 258 | 246 |
| 73 | 030 | 3203 | 5 | 112 | 250 | 396 |
| 74 | 030 | 3204 | 1 | 96 | 194 | 272 |
| 75 | 030 | 3204 | 5 | 94 | 199 | 232 |
| 76 | 030 | 3205 | 1 | 120 | 196 | 164 |
| 77 | 030 | 3205 | 5 | 102 | 216 | 333 |
| 78 | 030 | 3206 | 1 | 81 | 213 | 281 |
| 79 | 030 | 3206 | 5 | 60 | 217 | 230 |
| 80 | 056 | 5101 | 1 | 103 | 237 | 443 |
| 81 | 056 | 5101 | 5 | 123 | 185 | 419 |
| 82 | 056 | 5102 | 1 | 87 | 149 | 53 |
| 83 | 056 | 5102 | 5 | 110 | 145 | 95 |
| 84 | 056 | 5103 | 1 | 90 | 152 | 68 |

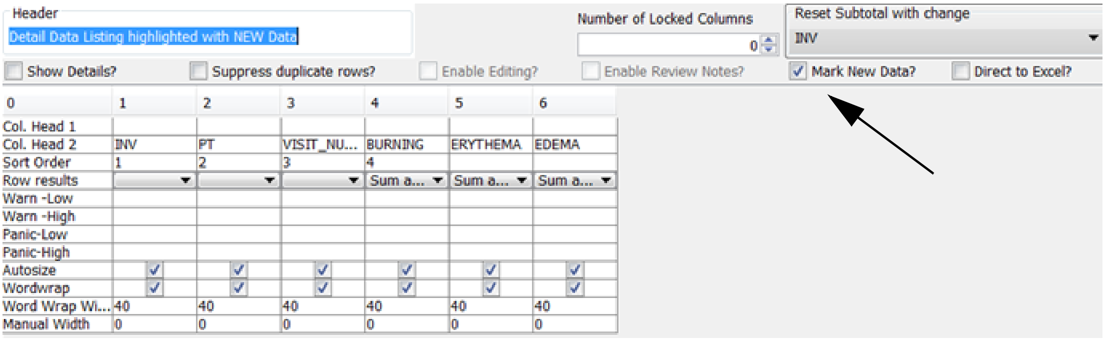
## *Mark New Data*

The **Mark New Data** option in the Report Browser allows the user to highlight data that is date/time stamped (based on the **Last Change Date**), after that patient has been reviewed in the Patient Profile Review Tracking component in Patient Profiles. The ability to "Mark New Data?" is a function of Patient Profile Review Tracking tool. ***(See Chapter 4 - Patient Profiles: Highlight New Data)***

In order to use this similar feature in detail data listing you must use the Patient Profile Review Tracking tool by creating a saved patient profile object (workbook profile, formatted profile or graphic profile) to generate the Patient Profile Browser Patient List dialog. The Patient Profile Review Tracking tool can be accessed and individual patient review status for "I Reviewed" with date stamp are saved and updated here. This information is used within JReview and teh reviewed dates are used to determine when "Mark New Data?" has occurred. Only after a patient status has been reviewed and saved in the Patient Profile Review Tracking tool will highlighted new data be observed for those patients who have been tracked.

When you define a detail data listing, you may optionally highlight "Updated data" meaning new or updated data. Last Change Date must be set in ReviewAdmin for this feature to be available. It can be set at the individual study level or across the project level.

After you define your report specification, click the check box for "**Mark New Data?**".

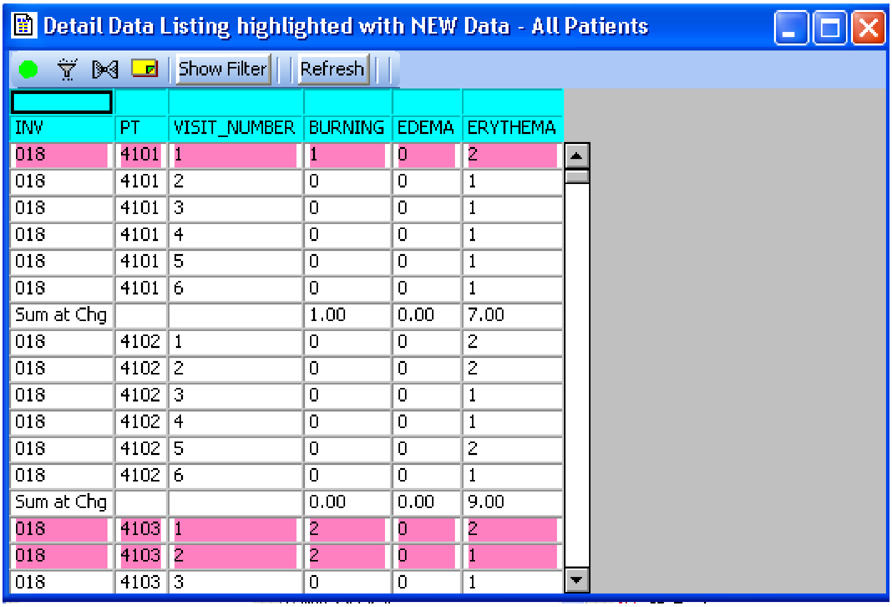


Header: Detail Data Listing highlighted with NEW Data
Number of Locked Columns: 0
Reset Subtotal with change: INV

☐ Show Details? ☐ Suppress duplicate rows? ☐ Enable Editing? ☐ Enable Review Notes? ☑ Mark New Data? ☐ Direct to Excel?

| 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | |
| Col. Head 2 | INV | PT | VISIT_NU... | BURNING | ERYTHEMA | EDEMA |
| Sort Order | 1 | 2 | 3 | 4 | | |
| Row results | | | | Sum a... | Sum a... | Sum a... |
| Warn -Low | | | | | | |
| Warn -High | | | | | | |
| Panic-Low | | | | | | |
| Panic-High | | | | | | |
| Autosize | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Wordwrap | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Word Wrap Wi... | 40 | 40 | 40 | 40 | 40 | 40 |
| Manual Width | 0 | 0 | 0 | 0 | 0 | 0 |

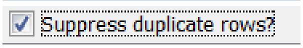
Any new or updated data for the included patients are highlighted in the report.



| INV | PT | VISIT_NUMBER | BURNING | EDEMA | ERYTHEMA |
|---|---|---|---|---|---|
| 018 | 4101 | 1 | 1 | 0 | 2 |
| 018 | 4101 | 2 | 0 | 0 | 1 |
| 018 | 4101 | 3 | 0 | 0 | 1 |
| 018 | 4101 | 4 | 0 | 0 | 1 |
| 018 | 4101 | 5 | 0 | 0 | 1 |
| 018 | 4101 | 6 | 0 | 0 | 1 |
| Sum at Chg | | | 1.00 | 0.00 | 7.00 |
| 018 | 4102 | 1 | 0 | 0 | 2 |
| 018 | 4102 | 2 | 0 | 0 | 2 |
| 018 | 4102 | 3 | 0 | 0 | 1 |
| 018 | 4102 | 4 | 0 | 0 | 1 |
| 018 | 4102 | 5 | 0 | 0 | 2 |
| 018 | 4102 | 6 | 0 | 0 | 1 |
| Sum at Chg | | | 0.00 | 0.00 | 9.00 |
| 018 | 4103 | 1 | 2 | 0 | 2 |
| 018 | 4103 | 2 | 2 | 0 | 1 |
| 018 | 4103 | 3 | 0 | 0 | 1 |

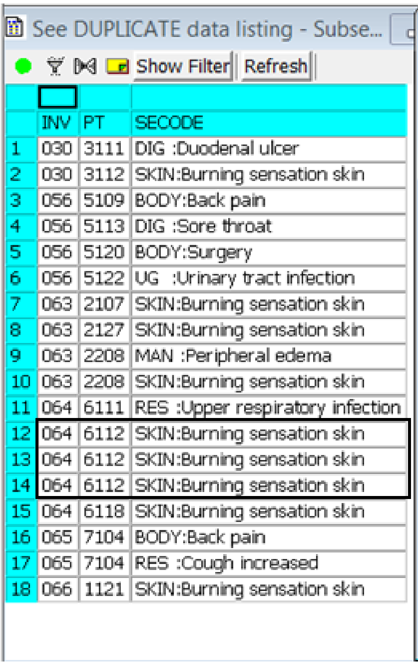
## *Suppress duplicate rows*

If you want to display only unique rows (unique based on all items being displayed), click on the checkbox for ‘Suppress duplicate rows?’. When you turn this feature on, it includes “DISTINCT” in the select statement generated which has the effect of only displaying unique rows.



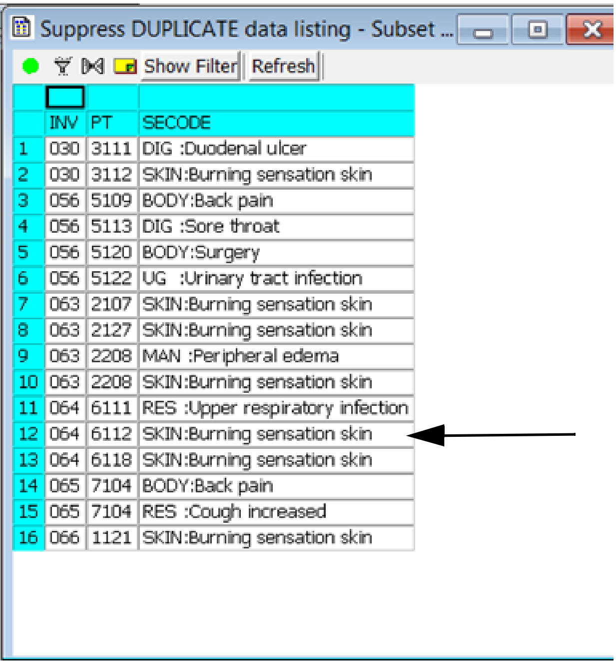
☑ Suppress duplicate rows?

The examples show the difference between this report when the suppress duplicate rows is turned off versus on. For example, see PatNo 6112.



See DUPLICATE data listing - Subse...

| | INV | PT | SECODE |
|---|---|---|---|
| 1 | 030 | 3111 | DIG :Duodenal ulcer |
| 2 | 030 | 3112 | SKIN:Burning sensation skin |
| 3 | 056 | 5109 | BODY:Back pain |
| 4 | 056 | 5113 | DIG :Sore throat |
| 5 | 056 | 5120 | BODY:Surgery |
| 6 | 056 | 5122 | UG :Urinary tract infection |
| 7 | 063 | 2107 | SKIN:Burning sensation skin |
| 8 | 063 | 2127 | SKIN:Burning sensation skin |
| 9 | 063 | 2208 | MAN :Peripheral edema |
| 10 | 063 | 2208 | SKIN:Burning sensation skin |
| 11 | 064 | 6111 | RES :Upper respiratory infection |
| 12 | 064 | 6112 | SKIN:Burning sensation skin |
| 13 | 064 | 6112 | SKIN:Burning sensation skin |
| 14 | 064 | 6112 | SKIN:Burning sensation skin |
| 15 | 064 | 6118 | SKIN:Burning sensation skin |
| 16 | 065 | 7104 | BODY:Back pain |
| 17 | 065 | 7104 | RES :Cough increased |
| 18 | 066 | 1121 | SKIN:Burning sensation skin |



Suppress DUPLICATE data listing - Subset ...

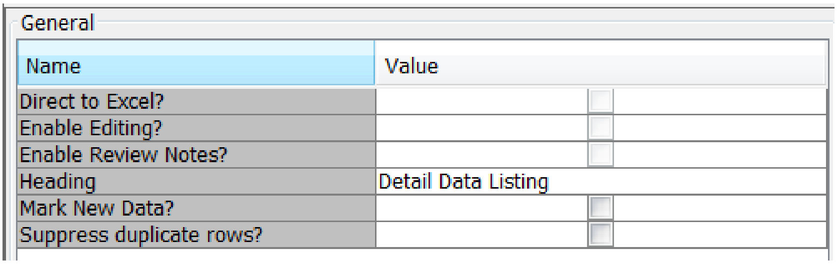
| | INV | PT | SECODE |
|---|---|---|---|
| 1 | 030 | 3111 | DIG :Duodenal ulcer |
| 2 | 030 | 3112 | SKIN:Burning sensation skin |
| 3 | 056 | 5109 | BODY:Back pain |
| 4 | 056 | 5113 | DIG :Sore throat |
| 5 | 056 | 5120 | BODY:Surgery |
| 6 | 056 | 5122 | UG :Urinary tract infection |
| 7 | 063 | 2107 | SKIN:Burning sensation skin |
| 8 | 063 | 2127 | SKIN:Burning sensation skin |
| 9 | 063 | 2208 | MAN :Peripheral edema |
| 10 | 063 | 2208 | SKIN:Burning sensation skin |
| 11 | 064 | 6111 | RES :Upper respiratory infection |
| 12 | 064 | 6112 | SKIN:Burning sensation skin |
| 13 | 064 | 6118 | SKIN:Burning sensation skin |
| 14 | 065 | 7104 | BODY:Back pain |
| 15 | 065 | 7104 | RES :Cough increased |
| 16 | 066 | 1121 | SKIN:Burning sensation skin |

# Enable Editing in Detail Data Listings

## *Enable Editing*

In Classic Mode, the check the 'Enable Editing?' checkbox is only enabled if you've added at least one editable field (controlled in IRAdmin foreign panel registration), then click create. The editable columns are highlighted in green which means that they are editable. The editable fields are ***not allowed*** for any actual clinical data. Editable fields are only allowed for ancillary data which would be registered as a Foreign Panel. This would typically be used to change the status of customer generated error logs.

In New Mode the 'Enable Editing?' checkbox is located in the General table.



General

| Name | Value |
|---|---|
| Direct to Excel? | ☐ |
| Enable Editing? | ☐ |
| Enable Review Notes? | ☐ |
| Heading | Detail Data Listing |
| Mark New Data? | ☐ |
| Suppress duplicate rows? | ☐ |

# Report Reviewer Notations

## *What is report review?*

Any detailed report defined in JReview can also have a '**report review**' template table of review items added to support report row reviewer comments, etc. The 'report review' template (defined as a Foreign Panel using IRAdmin) table doesn't initially have any rows corresponding to this report. As the user makes comments the 'report review' rows are inserted with other related information in addition to the reviewers comments, and stored in the 'report review' table. This editable values include the possibility of 'codelist lookup based' drop down listboxes, configurable transition state rules, free text entry, etc. (all driven by the Foreign Panel definition) but is very open ended, as the 'report review' template can be added to any report.

The types of reports that would typically be used would be either exception reports or full reports with exceptions highlighted. The exception reports are those where only rows containing one or more of the 'problems' that had been defined in the report filtering conditions are included in the report. The 'full report with exceptions highlighted', would include all data rows but highlight the issues, so that they're able to be reviewed in context with the rest of the 'non-problematic' rows.

## *Enable Review Notes*

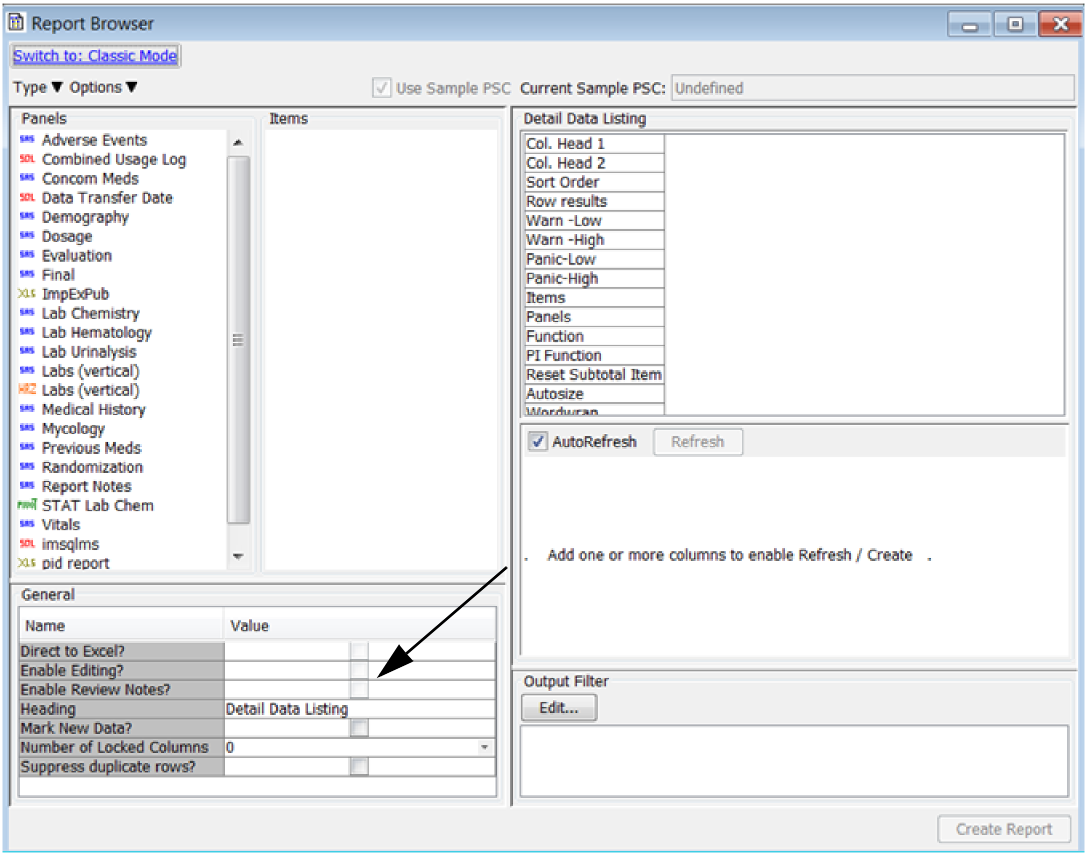
The **ReportNotes table** is added to JReview configurations by default during the upgrade to version 12.

A checkbox is located within the Report Browser build window to '**Enable Review Notes?'** when in NUI mode. There is an editable display type information for the **ReportNotes table** so fields are marked as editable. When you add any of those columns (comment 1, 2, 3 or status fields - all are editable) then the 'Enable Editing' checkbox is enabled. When checked, the Enable Report Notes becomes enabled (after you check the Enable Editing checkbox).

If a report author adds columns from the ReportNotes table (or similar configured foreign panel) with editable comment and status fields, the 'Enable Editing' checkbox is enabled. Checking that then enables 'Enable Reviewer Notes?' checkbox. If both are enabled, after saving the report definition, users can then add notes, status, etc., to those fields in those reports - typically deiscrepancy listings.

The ReportNotes Table is a regular table visible throughout the product in case users want to do listing of it itself. But the 'report notes' feature , i.e., the editing of those fields only become enabled through the Report Browser with those checkboxes.

The checkbox(s) are located within the General table in the Report Browser New mode build window.



Current Sample PSC: Undefined

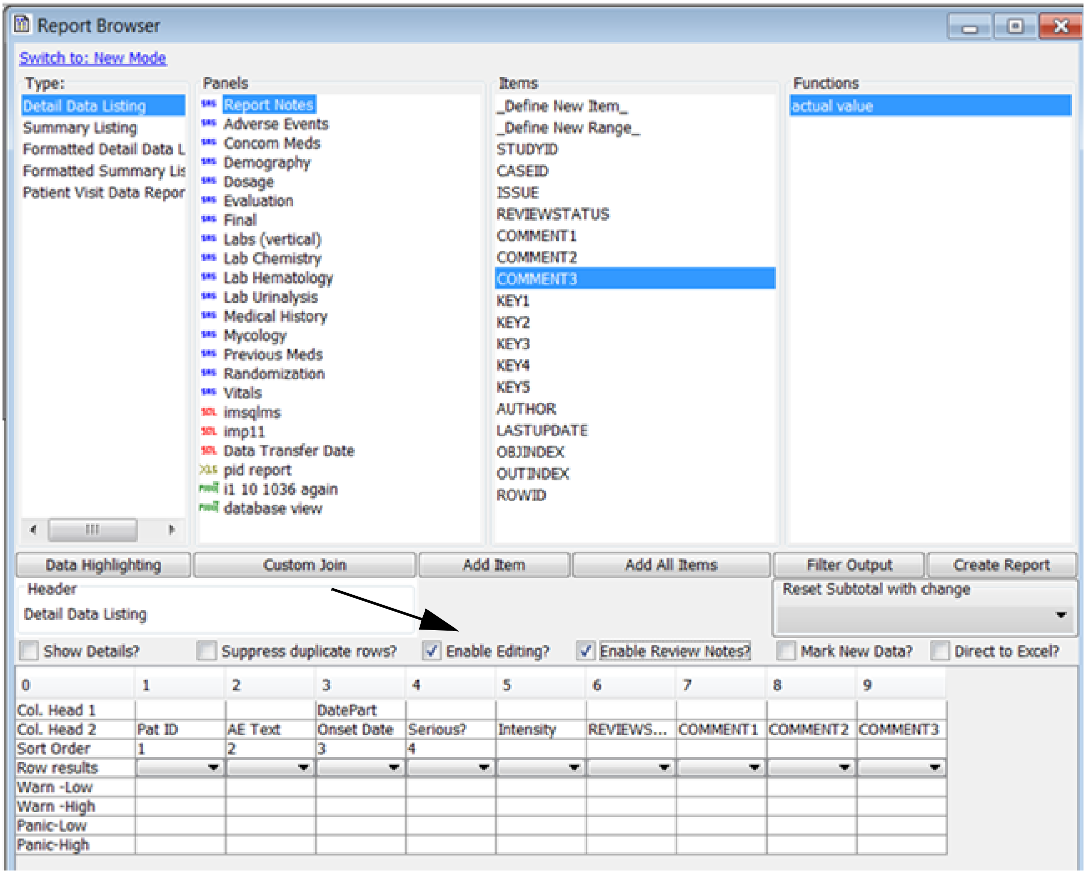
☑ AutoRefresh

Add one or more columns to enable Refresh / Create

General

| Name | Value |
|---|---|
| Direct to Excel? | ☐ |
| Enable Editing? | ☐ |
| Enable Review Notes? | ☐ |
| Heading | Detail Data Listing |
| Mark New Data? | ☐ |
| Number of Locked Columns | 0 |
| Suppress duplicate rows? | ☐ |

A checkbox(s) is located within the Report Browser Classic mode build window.



Type:
Detail Data Listing
Summary Listing
Formatted Detail Data L
Formatted Summary Lis
Patient Visit Data Repor

Panels
Report Notes
Adverse Events
Concom Meds
Demography
Dosage
Evaluation
Final
Labs (vertical)
Lab Chemistry
Lab Hematology
Lab Urinalysis
Medical History
Mycology
Previous Meds
Randomization
Vitals
imsqlms
imp11
Data Transfer Date
pid report
i1 10 1036 again
database view

Items
_Define New Item_
_Define New Range_
STUDYID
CASEID
ISSUE
REVIEWSTATUS
COMMENT1
COMMENT2
COMMENT3
KEY1
KEY2
KEY3
KEY4
KEY5
AUTHOR
LASTUPDATE
OBJINDEX
OUTINDEX
ROWID

Functions
actual value

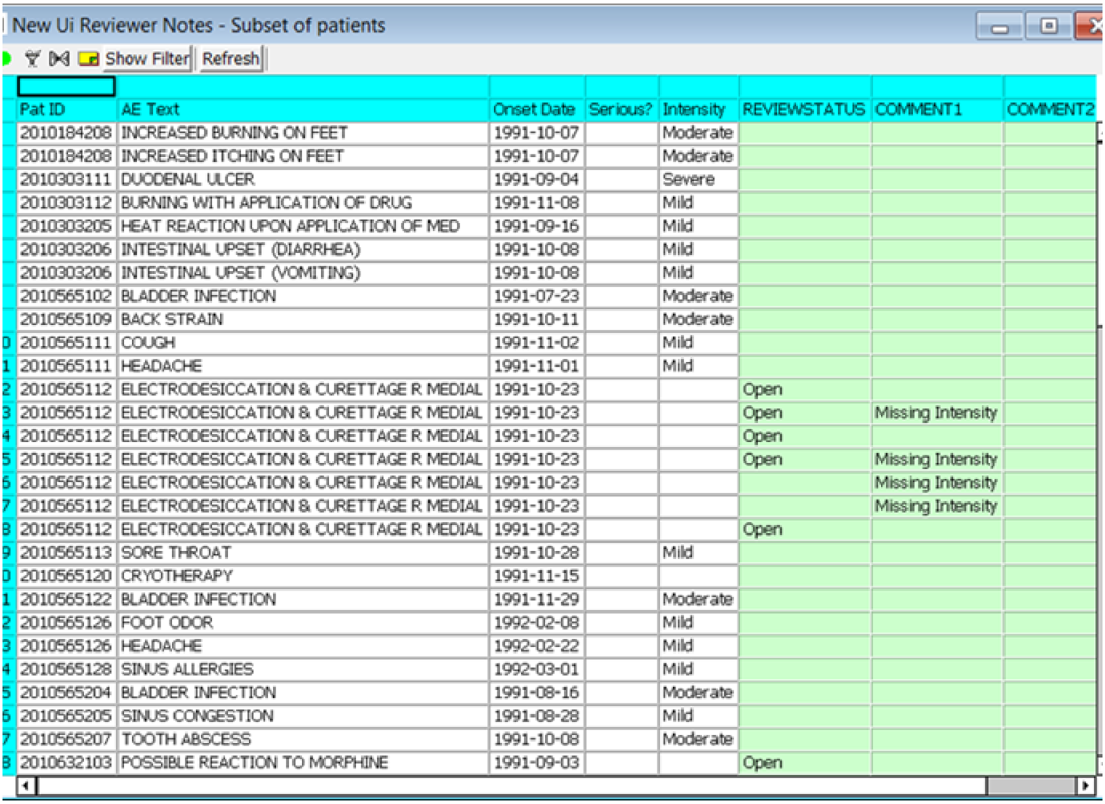
Header
Detail Data Listing

Reset Subtotal with change

☐ Show Details? ☐ Suppress duplicate rows? ☑ Enable Editing? ☑ Enable Review Notes? ☐ Mark New Data? ☐ Direct to Excel?

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|
| Col. Head 1 | | | DatePart | | | | | | |
| Col. Head 2 | Pat ID | AE Text | Onset Date | Serious? | Intensity | REVIEWS... | COMMENT1 | COMMENT2 | COMMENT3 |
| Sort Order | 1 | 2 | 3 | 4 | | | | | |
| Row results | | | | | | | | | |
| Warn -Low | | | | | | | | | |
| Warn -High | | | | | | | | | |
| Panic-Low | | | | | | | | | |
| Panic-High | | | | | | | | | |

Any added columns for comment 1, 2, 3 or status fields are all editable.



| Pat ID | AE Text | Onset Date | Serious? | Intensity | REVIEWSTATUS | COMMENT1 | COMMENT2 |
|---|---|---|---|---|---|---|---|
| 2010184208 | INCREASED BURNING ON FEET | 1991-10-07 | | Moderate | | | |
| 2010184208 | INCREASED ITCHING ON FEET | 1991-10-07 | | Moderate | | | |
| 2010303111 | DUODENAL ULCER | 1991-09-04 | | Severe | | | |
| 2010303112 | BURNING WITH APPLICATION OF DRUG | 1991-11-08 | | Mild | | | |
| 2010303205 | HEAT REACTION UPON APPLICATION OF MED | 1991-09-16 | | Mild | | | |
| 2010303206 | INTESTINAL UPSET (DIARRHEA) | 1991-10-08 | | Mild | | | |
| 2010303206 | INTESTINAL UPSET (VOMITING) | 1991-10-08 | | Mild | | | |
| 2010565102 | BLADDER INFECTION | 1991-07-23 | | Moderate | | | |
| 2010565109 | BACK STRAIN | 1991-10-11 | | Moderate | | | |
| 2010565111 | COUGH | 1991-11-02 | | Mild | | | |
| 2010565111 | HEADACHE | 1991-11-01 | | Mild | | | |
| 2010565112 | ELECTRODESICCATION & CURETTAGE R MEDIAL | 1991-10-23 | | | Open | | |
| 2010565112 | ELECTRODESICCATION & CURETTAGE R MEDIAL | 1991-10-23 | | | Open | Missing Intensity | |
| 2010565112 | ELECTRODESICCATION & CURETTAGE R MEDIAL | 1991-10-23 | | | Open | | |
| 2010565112 | ELECTRODESICCATION & CURETTAGE R MEDIAL | 1991-10-23 | | | Open | Missing Intensity | |
| 2010565112 | ELECTRODESICCATION & CURETTAGE R MEDIAL | 1991-10-23 | | | | Missing Intensity | |
| 2010565112 | ELECTRODESICCATION & CURETTAGE R MEDIAL | 1991-10-23 | | | | Missing Intensity | |
| 2010565112 | ELECTRODESICCATION & CURETTAGE R MEDIAL | 1991-10-23 | | | Open | | |
| 2010565113 | SORE THROAT | 1991-10-28 | | Mild | | | |
| 2010565120 | CRYOTHERAPY | 1991-11-15 | | | | | |
| 2010565122 | BLADDER INFECTION | 1991-11-29 | | Moderate | | | |
| 2010565126 | FOOT ODOR | 1992-02-08 | | Mild | | | |
| 2010565126 | HEADACHE | 1992-02-22 | | Mild | | | |
| 2010565128 | SINUS ALLERGIES | 1992-03-01 | | Mild | | | |
| 2010565204 | BLADDER INFECTION | 1991-08-16 | | Moderate | | | |
| 2010565205 | SINUS CONGESTION | 1991-08-28 | | Mild | | | |
| 2010565207 | TOOTH ABSCESS | 1991-10-08 | | Moderate | | | |
| 2010632103 | POSSIBLE REACTION TO MORPHINE | 1991-09-03 | | | Open | | |

## Report Reviewer Notes Config options

There is a configuration for ‘PREFILLNOTES’ config.options - if present, report reviewer notes are prefilled with ‘Open’ state, rather than the default, post note record as you go. That way, number of Open, Closed, etc. issues can be tallied.

Another variation is ‘PREFILLNOTESCOPYDATA’ – if present, this option works as the ‘PREFILLNOTES’ case above, but when the user makes a change to any of the editable note fields, a full copy of the data from that line is also copied to the report notes table – for later comparison. Then the next time that same report is executed, with new or updated data, any rows that had note or status changes have the previous notes and status copied to the current state, but then the data in that line is compared – with the previous data state – and if any items were changed – the status and comments are reset to initial state (Open, etc.). But as a reference, the user can also see the previous status and comments that had been made in the previous context.

1. **Original mode** – no configuration entries needed, just define report, add report notes columns, and check the ‘Enable Editing’ checkbox and ‘ Enable Review Notes’ checkbox.

   This mode adds an entry to the reportnotes table as you make entries in the green report notes columns for a report. So report entries that you haven’t made any comments or status changes to won’t have corresponding entries in the report notes table, and will appear as empty in the report.

2. **PREFILLNOTES** – this is enabled by a configuration update in the environments (database or IRADM sas datasets) – in the CONFIG.OPTIONS string – adding the entry: PREFILLNOTES=Open; (tells the system to use the PREFILLNOTES option, and initialize the ReviewStatus column to ‘Open’ – one of the default status entries) this can be changed for each customer site based on the codelist entries associated with the ReviewStatus column.

   When you define a report the same method as for #1 – defining the custom join and checking the checkboxes, after you save the report, then run the report from the output explorer (not just by clicking Create – report notes don’t work from there – only when run from the saved object) – then you’ll see that each row in the report – has a corresponding ReviewStatus field initialized to ‘Open’ in this case. That means that each row in the report will have an entry inserted in the reportnotes table with initial ReviewStatus of ‘Open’ (or whatever was the initial value specified in the configuration setting). This mode is useful if a customer wants to be able to count not only how many subjects or entries have different ReviewStatus values, but will also count the initial ‘Open’ entries. That can be done by doing a summary report on the reportnotes table directly – but also including the ObjectIndex column which is how it links back to a specific report.

3. **PREFILLNOTESCOPYDATA** – this is enabled by a configuration update in the environments (database or IRADM sas datasets) – in the

CONFIG.OPTIONS string – adding the entry: PREFILLNOTESCOPYDATA=Open;  (tells the system to use the PREFILLNOTESCOPYDATA option, and initialize the ReviewStatus column to ‘Open’ – one of the default status entries (this can be changed for each customer site – based on the codelist entries associated with the ReviewStatus column.

Now when re-executing a report when this option is enabled in config.options, any rows that had a reviewstatus or comment updated in a previous report execution, compares the previous value for each data column for the row with the current values, and highlights any cells that are different between current and previous report execution.

This option works the same way that #2 does for report definition, and report use.  The only difference is that when you change any entries in the report notes columns – reviewstatus or comments – it stores those values, but it also stores the current value of each of the other columns in the report, i.e., other AE columns in the report – if that’s the data that’s being displayed.  The reason is that when the report is run again, the system compares each column from the previous run report’s values against the new report values – and if they’re different – it resets the ReviewStatus to the initial state – for example ‘Open’, and clears the comments.

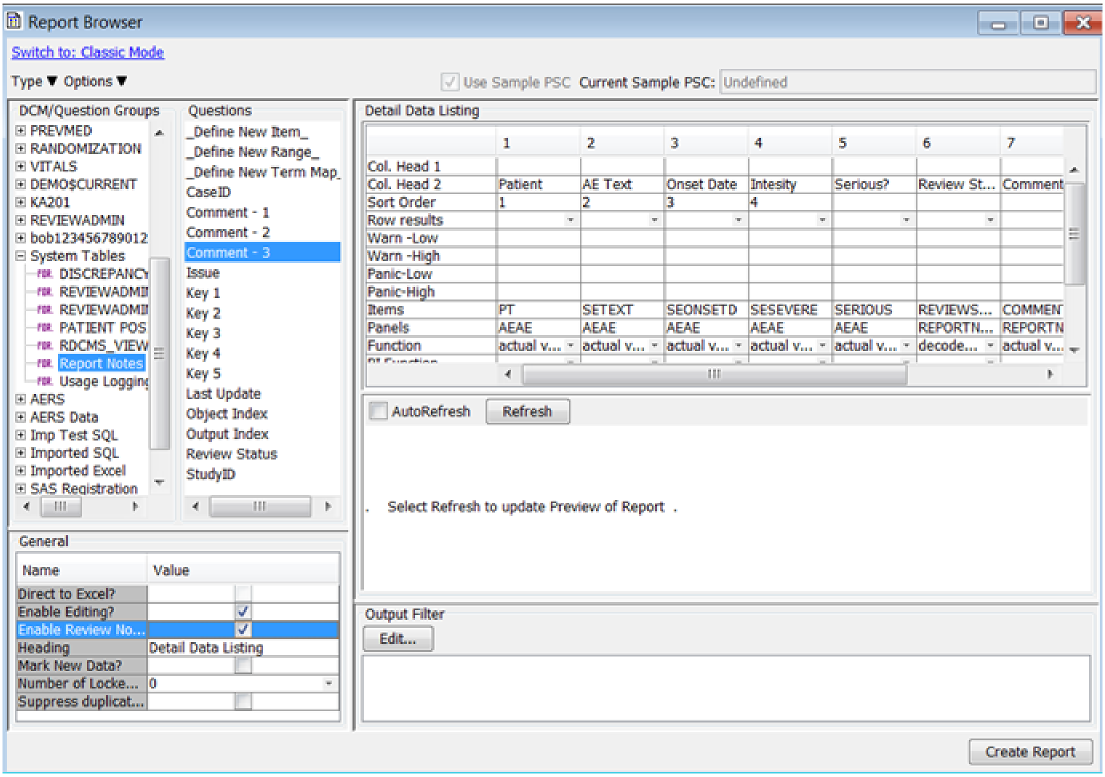
## *Define Reviewer Report*

The steps to define a detail data listing for reviewer notes are:

1. Define the base exception report.  If a report author adds columns from the ReportNotes table (or similar configured foreign panel) with editable comment and status fields, the ‘Enable Editing’ checkbox is enabled.
2. Click ‘**Enable Editing**’ checkbox.
3. Click ‘**Enable Reviewer Notes?**’ checkbox.  If both are enabled, after saving the report definition, users can then add notes, status, etc., to those fields in those reports - typically discrepancy listings.
4. Add the Output Filter exception filtering.
5. Add columns from the Report Notes Table.
6. Define the **Custom Join Logic *(required)***.
7. Save the report ***(required).***

***The report notes capability only updates if it's run from a saved object***. A warning message displays if you click Create Output from the definition browser. The green fields display but if you click into any of them a message that updating isn't active displays unless run from a saved object.

Here is an example of a report defined in New mode. The Report Notes items were added to the end of the report definition. AutoRefresh was turned OFF. The check boxes for "Enable Editing?" and "Enable Reviewer Notes?" were checked ON , prior to saving the report object.



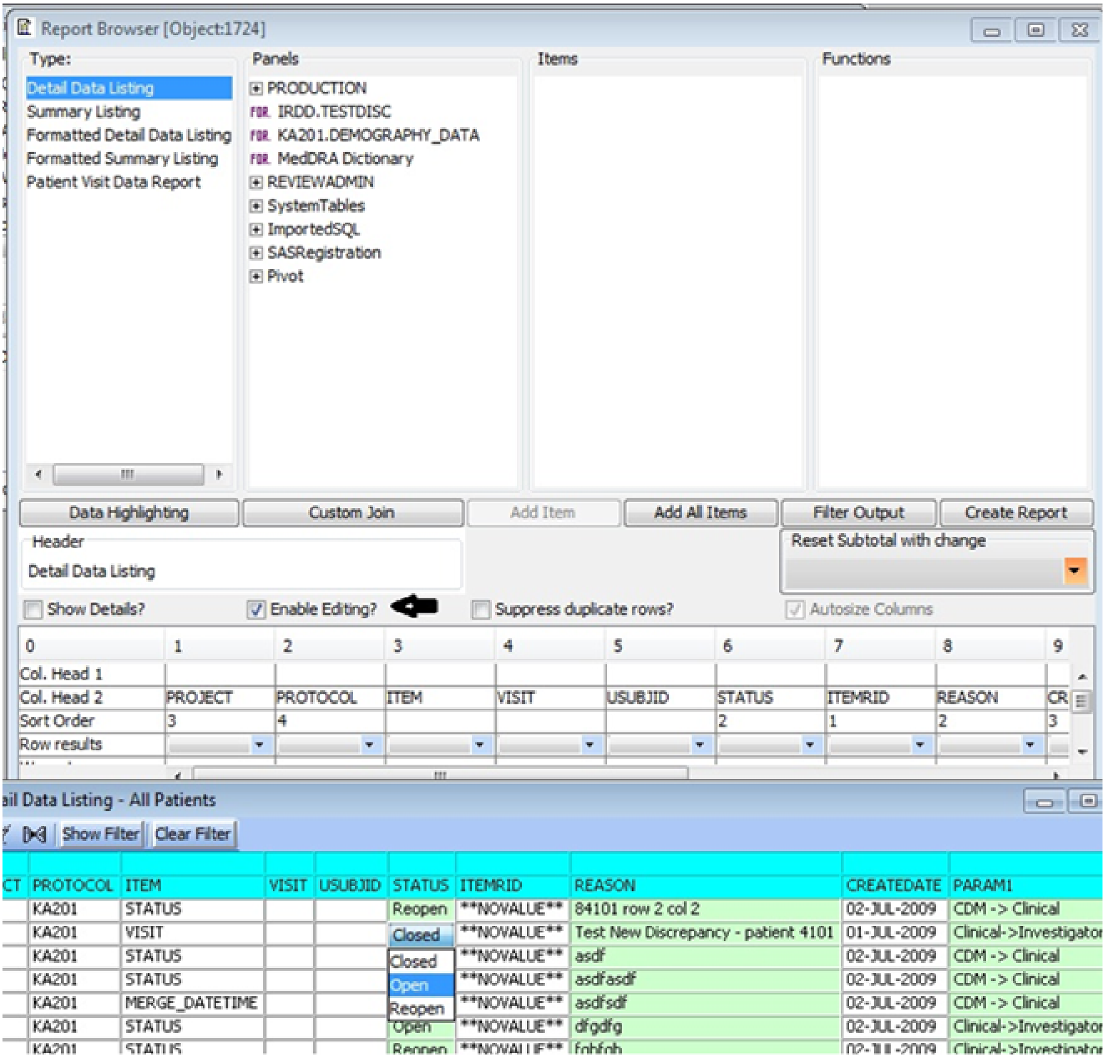
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | | |
| Col. Head 2 | Patient | AE Text | Onset Date | Intesity | Serious? | Review St... | Comment |
| Sort Order | 1 | 2 | 3 | 4 | | | |
| Row results | | | | | | | |
| Warn -Low | | | | | | | |
| Warn -High | | | | | | | |
| Panic-Low | | | | | | | |
| Panic-High | | | | | | | |
| Items | PT | SETEXT | SEONSETD | SESEVERE | SERIOUS | REVIEWS... | COMMENT |
| Panels | AEAE | AEAE | AEAE | AEAE | AEAE | REPORTN... | REPORTN |
| Function | actual v... | actual v... | actual v... | actual v... | actual v... | decode... | actual v... |

. Select Refresh to update Preview of Report .

General

| Name | Value |
|---|---|
| Direct to Excel? | ☐ |
| Enable Editing? | ☑ |
| Enable Review No... | ☑ |
| Heading | Detail Data Listing |
| Mark New Data? | ☐ |
| Number of Locke... | 0 |
| Suppress duplicat... | ☐ |

Here is a report definition defined in Classic mode.



Header
Detail Data Listing

☐ Show Details? ☑ Enable Editing? ☐ Suppress duplicate rows? ☑ Autosize Columns

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | | | | |
| Col. Head 2 | PROJECT | PROTOCOL | ITEM | VISIT | USUBJID | STATUS | ITEMRID | REASON | CR |
| Sort Order | 3 | 4 | | | | 2 | 1 | 2 | 3 |
| Row results | | | | | | | | | |

| CT | PROTOCOL | ITEM | VISIT | USUBJID | STATUS | ITEMRID | REASON | CREATEDATE | PARAM1 |
|---|---|---|---|---|---|---|---|---|---|
| | KA201 | STATUS | | | Reopen | **NOVALUE** | 84101 row 2 col 2 | 02-JUL-2009 | CDM -> Clinical |
| | KA201 | VISIT | | | Closed | **NOVALUE** | Test New Discrepancy - patient 4101 | 01-JUL-2009 | Clinical->Investigator |
| | KA201 | STATUS | | | Closed | **NOVALUE** | asdf | 02-JUL-2009 | CDM -> Clinical |
| | KA201 | STATUS | | | Open | **NOVALUE** | asdfasdf | 02-JUL-2009 | CDM -> Clinical |
| | KA201 | MERGE_DATETIME | | | Reopen | **NOVALUE** | asdfsdf | 02-JUL-2009 | CDM -> Clinical |
| | KA201 | STATUS | | | Open | **NOVALUE** | dfgdfg | 02-JUL-2009 | Clinical->Investigator |
| | KA201 | STATUS | | | Reopen | **NOVALUE** | fghfgh | 02-JUL-2009 | Clinical->Investigator |

## *Define report join logic*

Report joins are ***required*** to define a Report Reviewer Notations listing. For other discrepancy reports, as any data tables it would be acceptable, however, the issue is if there are sufficient items in the base table that could be a unique key to join the report notes row to its original data row.

Other examples for any visit based data, i.e., labs (regular horizontal versions), efficacy, etc., would be PID=CASEID and VISIT=KEY1

In the KA201 database example, the Adverse Events are joined by PID, AETEXT and OnsetDate, however, today with remote electronic data capture most AE data have an AE sequence number within a patient and would used as a valid key value.

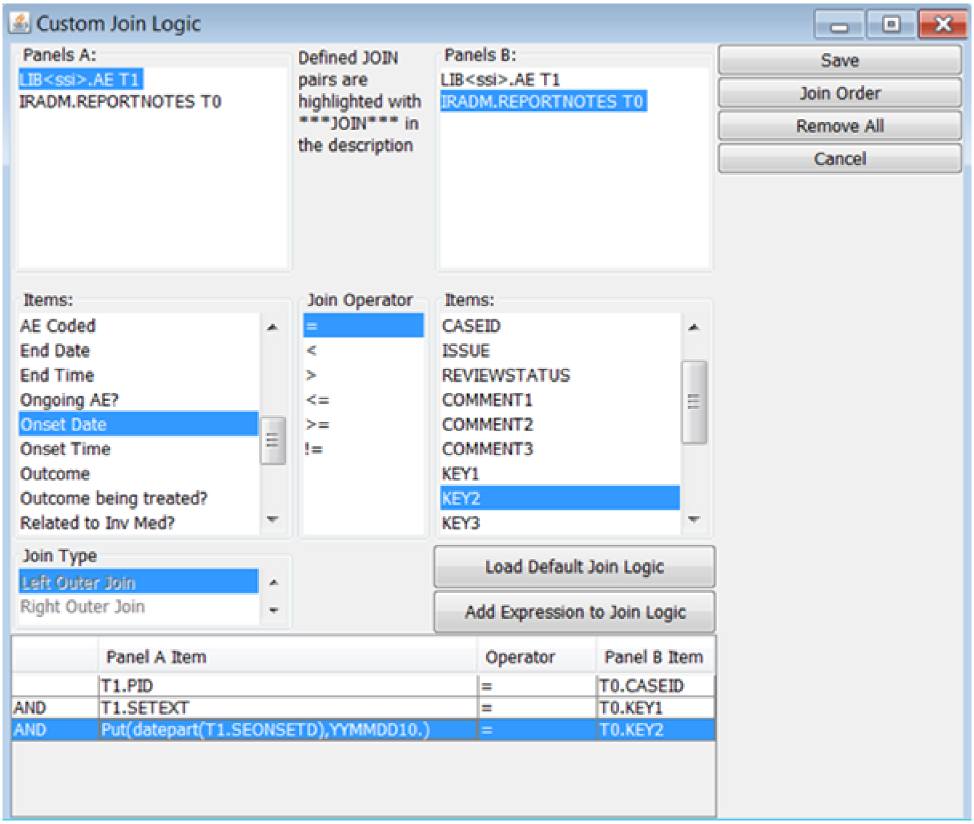
Two report examples are under the Data Review folder – one for AE's – probably or highly probably and the other – Efficacy – baseline values 0's for key items.

The SAS environment is tricky in that SAS isn't at all forgiving when comparing items in a join that are different item types. In the Efficacy example, it's joining on PID and VISIT where all keyX values are being stored as characters in the report notes table, but VISIT is numeric in the dataset, so it's necessary to convert the KEY2 character value to a numeric – to be able to compare with the VISIT variable – hence: VISIT = input(KEY2,3.)

Similarly with the AE listing which joins by PID, AEText and OnsetDate – the tricky item there is the date. Dates are stored as number of days or seconds since 1960 – so it's stored as a number in SAS, but we're storing the externally readable date in the report – based on a put( ) statement generated. So in that case, it's necessary to add the same put( ) statement around the ONSETDATE field on the left – in the custom join:

Put(datepart(ONSETDATE),yymmdd10.) = KEY3

Oracle is much easier as it doesn't require that type of conversions – it does it itself.



Panels A: LIB<ssi>.AE T1
IRADM.REPORTNOTES T0

Defined JOIN pairs are highlighted with ***JOIN*** in the description

Panels B: LIB<ssi>.AE T1
IRADM.REPORTNOTES T0

Items: AE Coded
End Date
End Time
Ongoing AE?
Onset Date
Onset Time
Outcome
Outcome being treated?
Related to Inv Med?

Join Operator: =
<
>
<=
>=
!=

Items: CASEID
ISSUE
REVIEWSTATUS
COMMENT1
COMMENT2
COMMENT3
KEY1
KEY2
KEY3

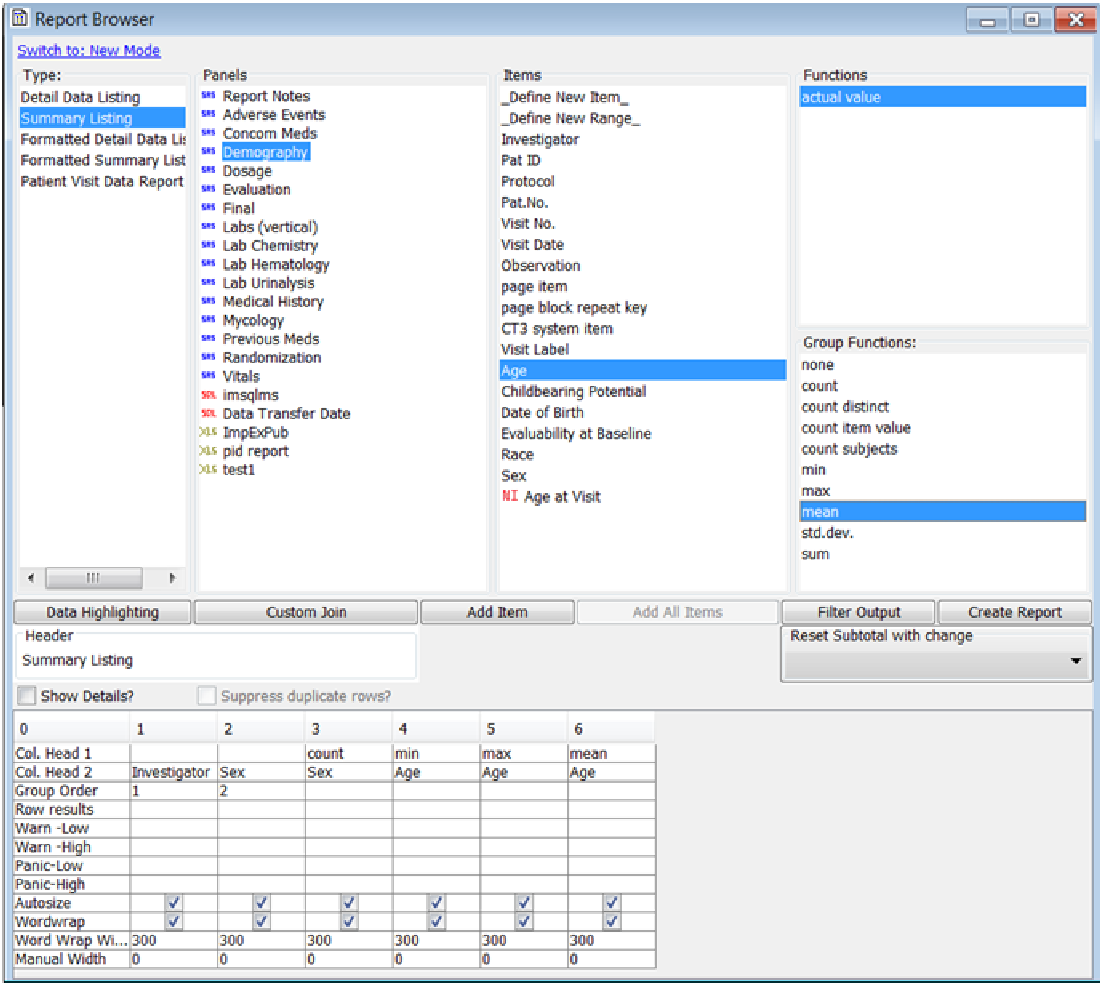
Join Type: Left Outer Join
Right Outer Join

| | Panel A Item | Operator | Panel B Item |
|---|---|---|---|
| | T1.PID | = | T0.CASEID |
| AND | T1.SETEXT | = | T0.KEY1 |
| AND | Put(datepart(T1.SEONSETD),YYMMDD10.) | = | T0.KEY2 |

# Summary Listing features

## *Group functions*

The Summary Listing have different Group functions available dependent upon the item selected:



Header

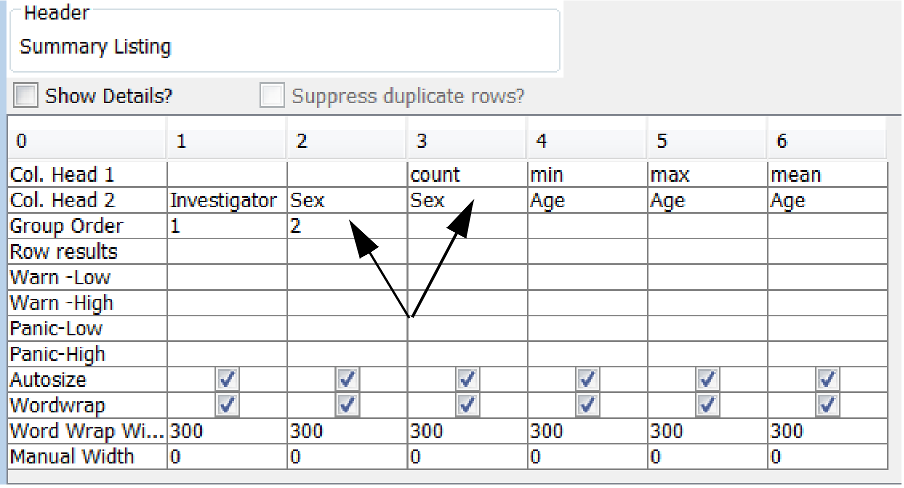
Summary Listing

☐ Show Details?

☐ Suppress duplicate rows?

| 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| Col. Head 1 | | | count | min | max | mean |
| Col. Head 2 | Investigator | Sex | Sex | Age | Age | Age |
| Group Order | 1 | 2 | | | | |
| Row results | | | | | | |
| Warn -Low | | | | | | |
| Warn -High | | | | | | |
| Panic-Low | | | | | | |
| Panic-High | | | | | | |
| Autosize | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Wordwrap | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Word Wrap Wi... | 300 | 300 | 300 | 300 | 300 | 300 |
| Manual Width | 0 | 0 | 0 | 0 | 0 | 0 |

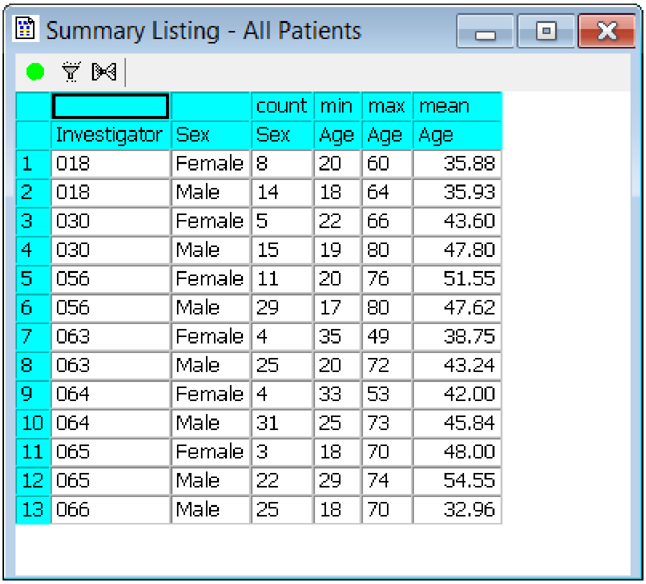
When building a Summary Listing it is typical to first select an item with a group function of ‘none’ and then follow it by the item with a group function applied. This method displays the item first as a row label followed by the items with group functions applied.



Header
Summary Listing

☐ Show Details? ☐ Suppress duplicate rows?

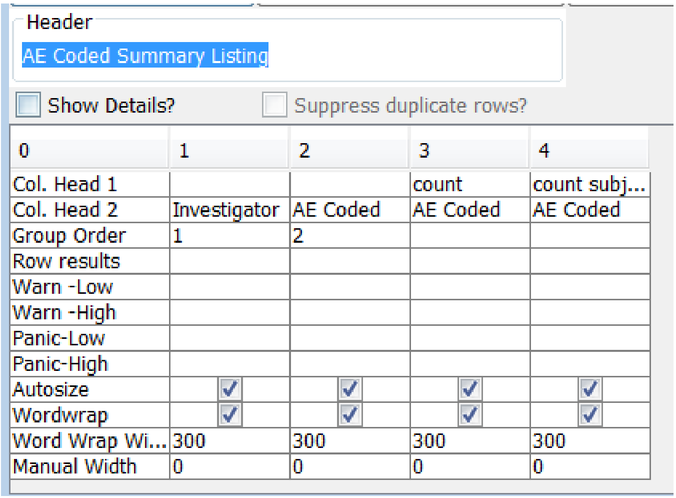
| 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| Col. Head 1 | | | count | min | max | mean |
| Col. Head 2 | Investigator | Sex | Sex | Age | Age | Age |
| Group Order | 1 | 2 | | | | |
| Row results | | | | | | |
| Warn -Low | | | | | | |
| Warn -High | | | | | | |
| Panic-Low | | | | | | |
| Panic-High | | | | | | |
| Autosize | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Wordwrap | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Word Wrap Wi... | 300 | 300 | 300 | 300 | 300 | 300 |
| Manual Width | 0 | 0 | 0 | 0 | 0 | 0 |



Summary Listing - All Patients

| | | | count | min | max | mean |
|---|---|---|---|---|---|---|
| | Investigator | Sex | Sex | Age | Age | Age |
| 1 | 018 | Female | 8 | 20 | 60 | 35.88 |
| 2 | 018 | Male | 14 | 18 | 64 | 35.93 |
| 3 | 030 | Female | 5 | 22 | 66 | 43.60 |
| 4 | 030 | Male | 15 | 19 | 80 | 47.80 |
| 5 | 056 | Female | 11 | 20 | 76 | 51.55 |
| 6 | 056 | Male | 29 | 17 | 80 | 47.62 |
| 7 | 063 | Female | 4 | 35 | 49 | 38.75 |
| 8 | 063 | Male | 25 | 20 | 72 | 43.24 |
| 9 | 064 | Female | 4 | 33 | 53 | 42.00 |
| 10 | 064 | Male | 31 | 25 | 73 | 45.84 |
| 11 | 065 | Female | 3 | 18 | 70 | 48.00 |
| 12 | 065 | Male | 22 | 29 | 74 | 54.55 |
| 13 | 066 | Male | 25 | 18 | 70 | 32.96 |

The item ‘AE Coded’ is entered first with a group function of ‘none’ followed by the group functions ‘count’ and ‘count subjects’.

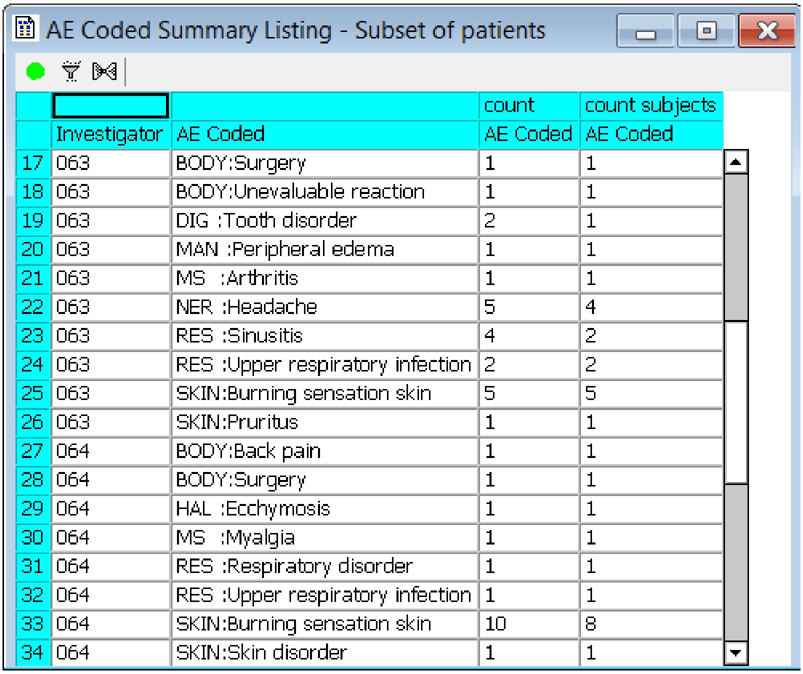


Header

AE Coded Summary Listing

☐ Show Details? ☐ Suppress duplicate rows?

| 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|
| Col. Head 1 | | | count | count subj... |
| Col. Head 2 | Investigator | AE Coded | AE Coded | AE Coded |
| Group Order | 1 | 2 | | |
| Row results | | | | |
| Warn -Low | | | | |
| Warn -High | | | | |
| Panic-Low | | | | |
| Panic-High | | | | |
| Autosize | ☑ | ☑ | ☑ | ☑ |
| Wordwrap | ☑ | ☑ | ☑ | ☑ |
| Word Wrap Wi... | 300 | 300 | 300 | 300 |
| Manual Width | 0 | 0 | 0 | 0 |

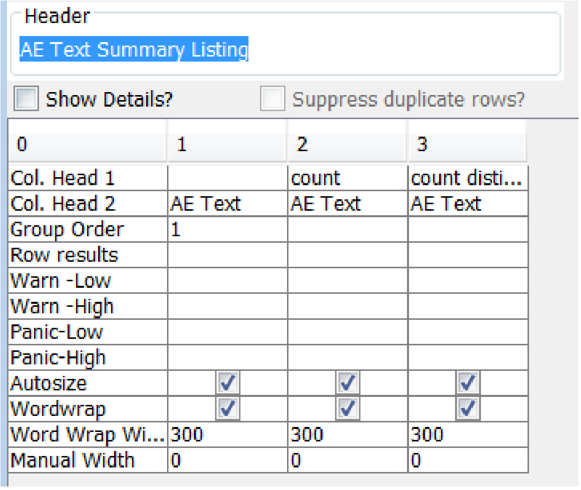


AE Coded Summary Listing - Subset of patients

| | | | count | count subjects |
|---|---|---|---|---|
| | Investigator | AE Coded | AE Coded | AE Coded |
| 17 | 063 | BODY:Surgery | 1 | 1 |
| 18 | 063 | BODY:Unevaluable reaction | 1 | 1 |
| 19 | 063 | DIG :Tooth disorder | 2 | 1 |
| 20 | 063 | MAN :Peripheral edema | 1 | 1 |
| 21 | 063 | MS :Arthritis | 1 | 1 |
| 22 | 063 | NER :Headache | 5 | 4 |
| 23 | 063 | RES :Sinusitis | 4 | 2 |
| 24 | 063 | RES :Upper respiratory infection | 2 | 2 |
| 25 | 063 | SKIN:Burning sensation skin | 5 | 5 |
| 26 | 063 | SKIN:Pruritus | 1 | 1 |
| 27 | 064 | BODY:Back pain | 1 | 1 |
| 28 | 064 | BODY:Surgery | 1 | 1 |
| 29 | 064 | HAL :Ecchymosis | 1 | 1 |
| 30 | 064 | MS :Myalgia | 1 | 1 |
| 31 | 064 | RES :Respiratory disorder | 1 | 1 |
| 32 | 064 | RES :Upper respiratory infection | 1 | 1 |
| 33 | 064 | SKIN:Burning sensation skin | 10 | 8 |
| 34 | 064 | SKIN:Skin disorder | 1 | 1 |

### *Count distinct*

The group function for ‘count distinct’ is the same as the count subjects, except the value being counted are the unique values of the item specified. For example, if you selected Adverse Event text and specified ‘count distinct’, you would only display the number of unique adverse event text values. The select item phrase generated: count (distinct <item).

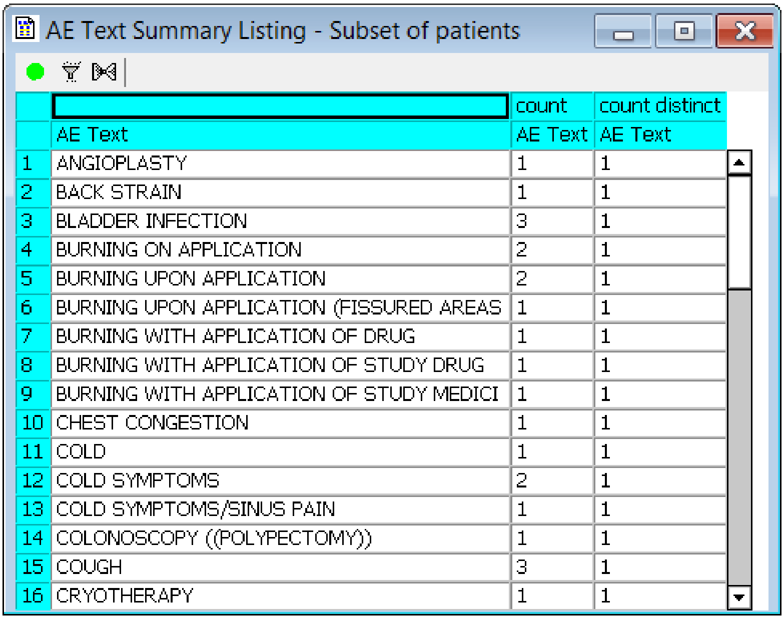


Header

AE Text Summary Listing

☐ Show Details? ☐ Suppress duplicate rows?

| 0 | 1 | 2 | 3 |
|---|---|---|---|
| Col. Head 1 | | count | count disti... |
| Col. Head 2 | AE Text | AE Text | AE Text |
| Group Order | 1 | | |
| Row results | | | |
| Warn -Low | | | |
| Warn -High | | | |
| Panic-Low | | | |
| Panic-High | | | |
| Autosize | ☑ | ☑ | ☑ |
| Wordwrap | ☑ | ☑ | ☑ |
| Word Wrap Wi... | 300 | 300 | 300 |
| Manual Width | 0 | 0 | 0 |



AE Text Summary Listing - Subset of patients

| | | count | count distinct |
|---|---|---|---|
| | AE Text | AE Text | AE Text |
| 1 | ANGIOPLASTY | 1 | 1 |
| 2 | BACK STRAIN | 1 | 1 |
| 3 | BLADDER INFECTION | 3 | 1 |
| 4 | BURNING ON APPLICATION | 2 | 1 |
| 5 | BURNING UPON APPLICATION | 2 | 1 |
| 6 | BURNING UPON APPLICATION (FISSURED AREAS | 1 | 1 |
| 7 | BURNING WITH APPLICATION OF DRUG | 1 | 1 |
| 8 | BURNING WITH APPLICATION OF STUDY DRUG | 1 | 1 |
| 9 | BURNING WITH APPLICATION OF STUDY MEDICI | 1 | 1 |
| 10 | CHEST CONGESTION | 1 | 1 |
| 11 | COLD | 1 | 1 |
| 12 | COLD SYMPTOMS | 2 | 1 |
| 13 | COLD SYMPTOMS/SINUS PAIN | 1 | 1 |
| 14 | COLONOSCOPY ((POLYPECTOMY)) | 1 | 1 |
| 15 | COUGH | 3 | 1 |
| 16 | CRYOTHERAPY | 1 | 1 |

## *Count item value*

The group function for ‘count item value’ counts the number of entries of a particular item, which has a particular value. This feature is especially useful for reports counting patients having different categories. It enables you to select items from ‘Unique Values’ as a column to count the item.

1. Select a panel.
2. Select each item with group function for ‘count item value’. Click ADD Item and the ‘Unique Values’ window opens.
3. Select the individual value for a column where you want to count item value and click Select value.
4. Repeat the same steps to continue to add columns to your report with ADD Item and the Display Values window. These values will be counted as different categories.

## *New item with aggregate functions*

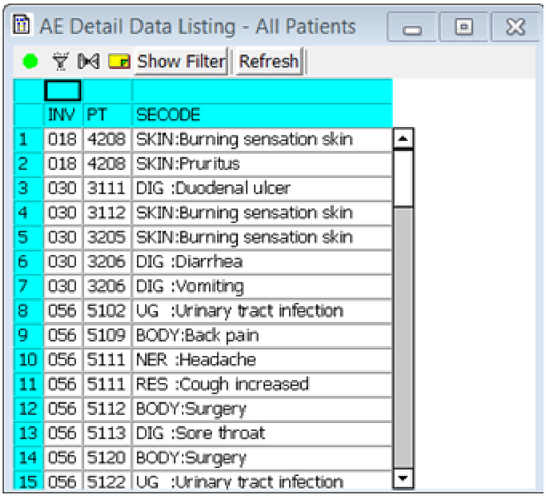
There is the ability to create a new item in the Summary Listing window for aggregate functions.

***( See Chapter 12: Advanced Topics - Define New Item )***

# Object toolbar

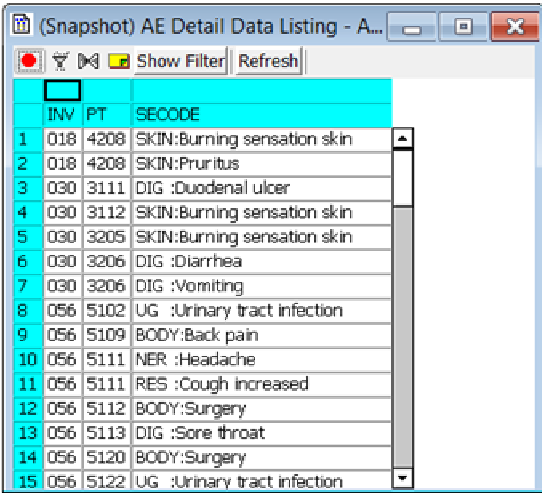
## *Snapshot output*

When the object window opens a toolbar displays in the upper left corner for you to reference the active patient selection criteria, output filters or to snapshot the output window (freeze the results image).



|  | INV | PT | SECODE |
|---|---|---|---|
| 1 | 018 | 4208 | SKIN:Burning sensation skin |
| 2 | 018 | 4208 | SKIN:Pruritus |
| 3 | 030 | 3111 | DIG :Duodenal ulcer |
| 4 | 030 | 3112 | SKIN:Burning sensation skin |
| 5 | 030 | 3205 | SKIN:Burning sensation skin |
| 6 | 030 | 3206 | DIG :Diarrhea |
| 7 | 030 | 3206 | DIG :Vomiting |
| 8 | 056 | 5102 | UG :Urinary tract infection |
| 9 | 056 | 5109 | BODY:Back pain |
| 10 | 056 | 5111 | NER :Headache |
| 11 | 056 | 5111 | RES :Cough increased |
| 12 | 056 | 5112 | BODY:Surgery |
| 13 | 056 | 5113 | DIG :Sore throat |
| 14 | 056 | 5120 | BODY:Surgery |
| 15 | 056 | 5122 | UG :Urinary tract infection |

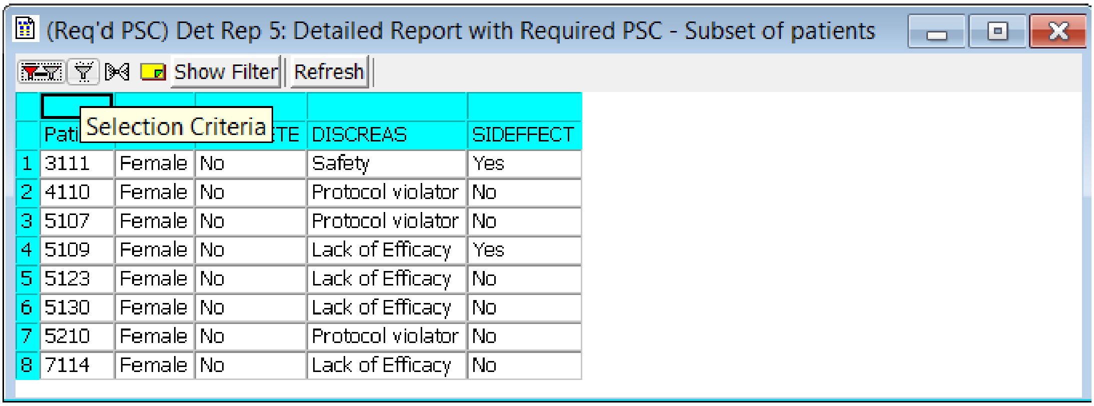
If you click on Snapshot the green button changes to red to indicate the window is frozen and the heading changes to Snapshot' mode. This results window is now blocked to any updates from the patient selection criteria.



|  | INV | PT | SECODE |
|---|---|---|---|
| 1 | 018 | 4208 | SKIN:Burning sensation skin |
| 2 | 018 | 4208 | SKIN:Pruritus |
| 3 | 030 | 3111 | DIG :Duodenal ulcer |
| 4 | 030 | 3112 | SKIN:Burning sensation skin |
| 5 | 030 | 3205 | SKIN:Burning sensation skin |
| 6 | 030 | 3206 | DIG :Diarrhea |
| 7 | 030 | 3206 | DIG :Vomiting |
| 8 | 056 | 5102 | UG :Urinary tract infection |
| 9 | 056 | 5109 | BODY:Back pain |
| 10 | 056 | 5111 | NER :Headache |
| 11 | 056 | 5111 | RES :Cough increased |
| 12 | 056 | 5112 | BODY:Surgery |
| 13 | 056 | 5113 | DIG :Sore throat |
| 14 | 056 | 5120 | BODY:Surgery |
| 15 | 056 | 5122 | UG :Urinary tract infection |

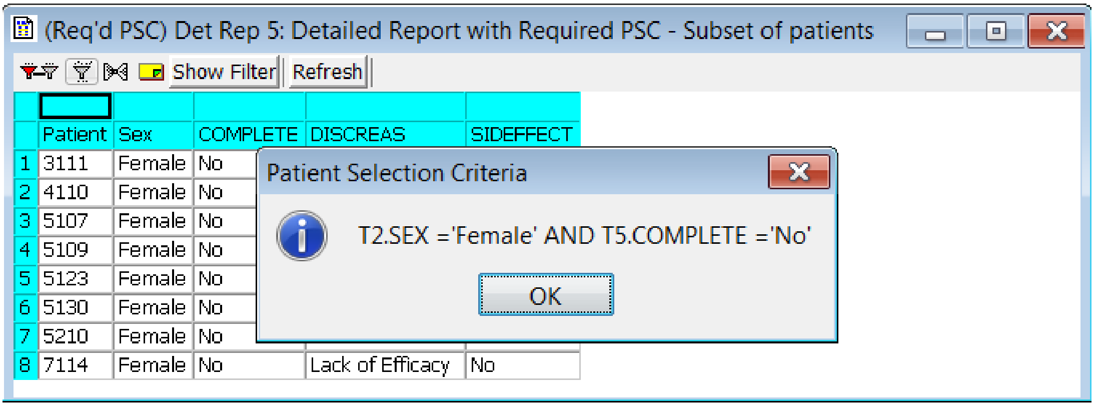
## Who icon

When you click the Selection Criteria icon a message window opens to identify any patient selection criteria active on the output window.



| | Pati | | TE | DISCREAS | SIDEFFECT |
|---|---|---|---|---|---|
| 1 | 3111 | Female | No | Safety | Yes |
| 2 | 4110 | Female | No | Protocol violator | No |
| 3 | 5107 | Female | No | Protocol violator | No |
| 4 | 5109 | Female | No | Lack of Efficacy | Yes |
| 5 | 5123 | Female | No | Lack of Efficacy | No |
| 6 | 5130 | Female | No | Lack of Efficacy | No |
| 7 | 5210 | Female | No | Protocol violator | No |
| 8 | 7114 | Female | No | Lack of Efficacy | No |

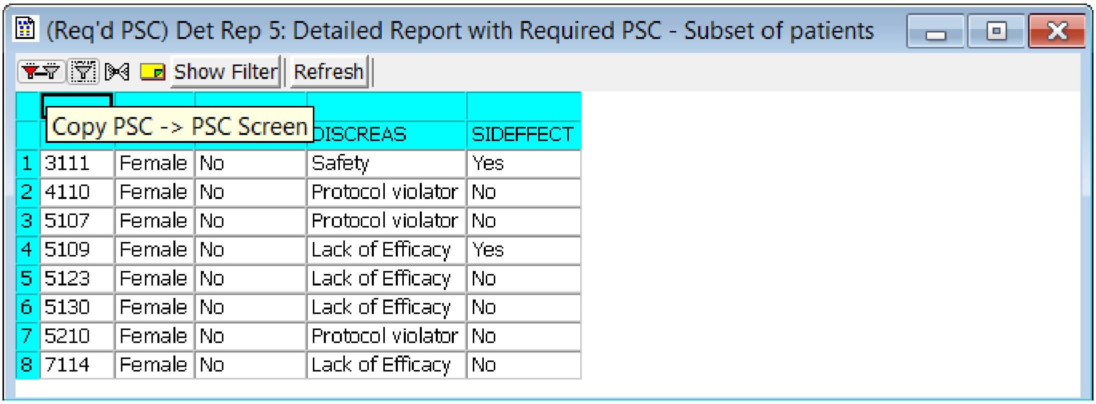
Click OK to close the window.



T2.SEX ='Female' AND T5.COMPLETE ='No'

| | Patient | Sex | COMPLETE | DISCREAS | SIDEFFECT |
|---|---|---|---|---|---|
| 1 | 3111 | Female | No | | |
| 2 | 4110 | Female | No | | |
| 3 | 5107 | Female | No | | |
| 4 | 5109 | Female | No | | |
| 5 | 5123 | Female | No | | |
| 6 | 5130 | Female | No | | |
| 7 | 5210 | Female | No | | |
| 8 | 7114 | Female | No | Lack of Efficacy | No |

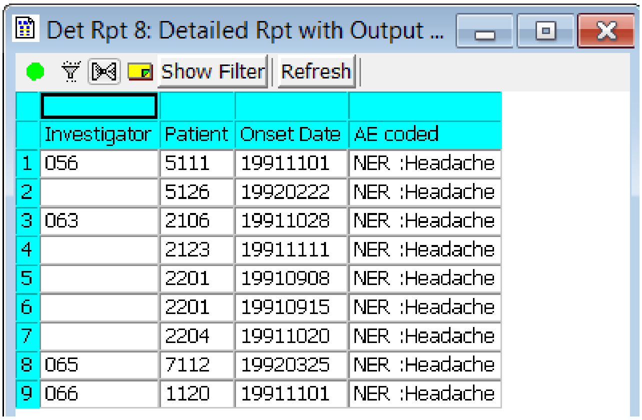
Output objects saved with a required PSC display with a red filter.



| | | | | DISCREAS | SIDEFFECT |
|---|---|---|---|---|---|
| 1 | 3111 | Female | No | Safety | Yes |
| 2 | 4110 | Female | No | Protocol violator | No |
| 3 | 5107 | Female | No | Protocol violator | No |
| 4 | 5109 | Female | No | Lack of Efficacy | Yes |
| 5 | 5123 | Female | No | Lack of Efficacy | No |
| 6 | 5130 | Female | No | Lack of Efficacy | No |
| 7 | 5210 | Female | No | Protocol violator | No |
| 8 | 7114 | Female | No | Lack of Efficacy | No |

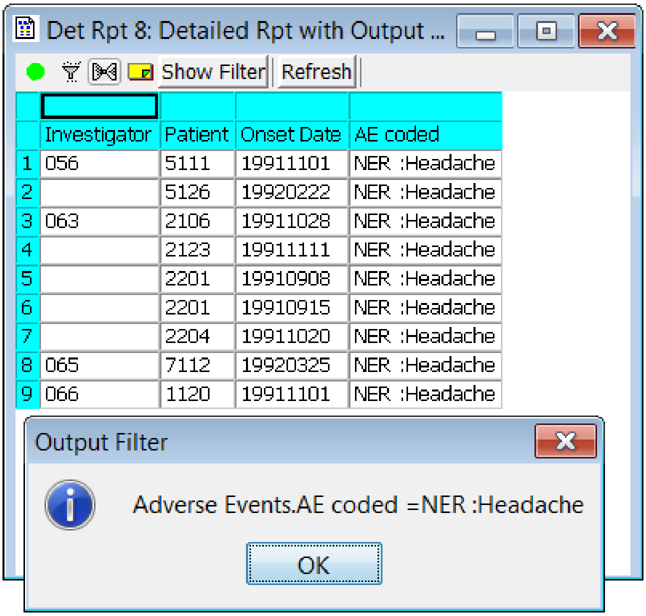
## *Output filter icon*

When you click the Output Filter icon a message window opens to identify any active Output Filters on the output window.



| | Investigator | Patient | Onset Date | AE coded |
|---|---|---|---|---|
| 1 | 056 | 5111 | 19911101 | NER :Headache |
| 2 | | 5126 | 19920222 | NER :Headache |
| 3 | 063 | 2106 | 19911028 | NER :Headache |
| 4 | | 2123 | 19911111 | NER :Headache |
| 5 | | 2201 | 19910908 | NER :Headache |
| 6 | | 2201 | 19910915 | NER :Headache |
| 7 | | 2204 | 19911020 | NER :Headache |
| 8 | 065 | 7112 | 19920325 | NER :Headache |
| 9 | 066 | 1120 | 19911101 | NER :Headache |

Click **OK** to close the window.



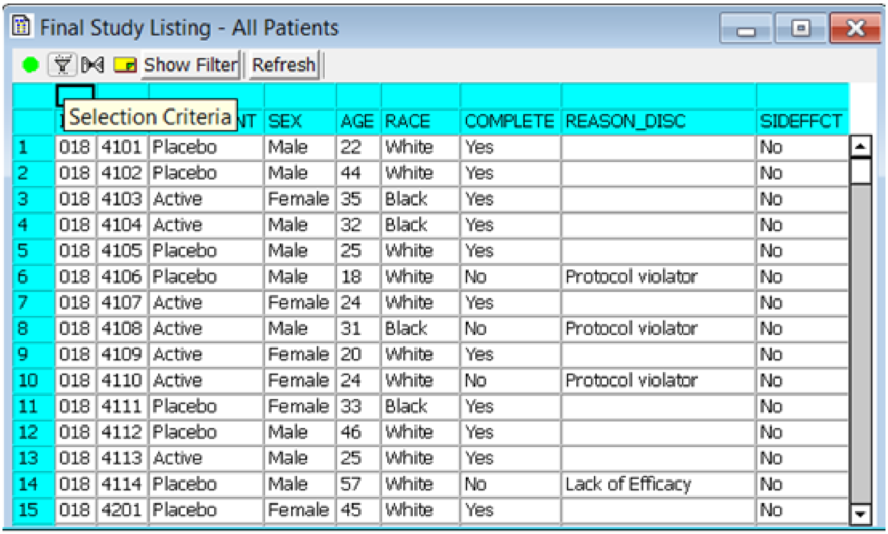
| | Investigator | Patient | Onset Date | AE coded |
|---|---|---|---|---|
| 1 | 056 | 5111 | 19911101 | NER :Headache |
| 2 | | 5126 | 19920222 | NER :Headache |
| 3 | 063 | 2106 | 19911028 | NER :Headache |
| 4 | | 2123 | 19911111 | NER :Headache |
| 5 | | 2201 | 19910908 | NER :Headache |
| 6 | | 2201 | 19910915 | NER :Headache |
| 7 | | 2204 | 19911020 | NER :Headache |
| 8 | 065 | 7112 | 19920325 | NER :Headache |
| 9 | 066 | 1120 | 19911101 | NER :Headache |

Adverse Events.AE coded =NER :Headache

## *Multiple population mode*

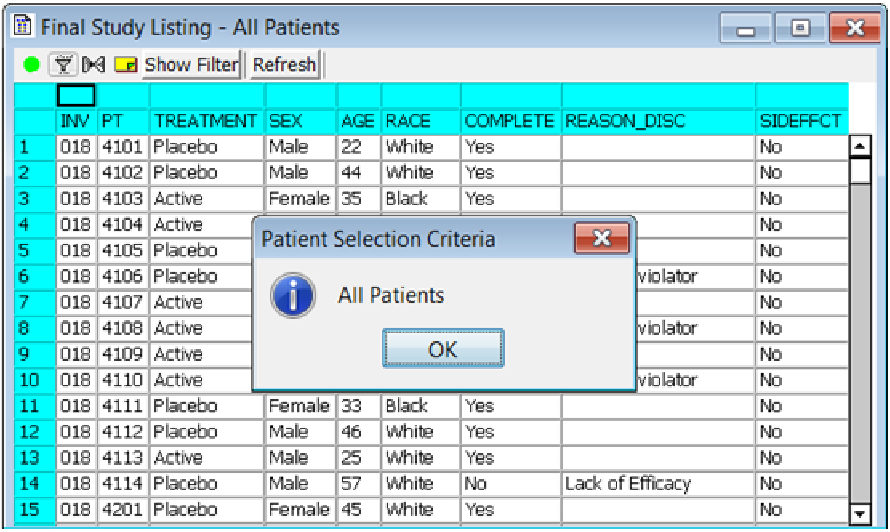
JReview has an optional multiple-population mode available within the individual browsers output window. When the results are executed and displayed from the browser output window, three icons are displayed for “Snapshot”, “Selection Criteria?” and “Output Filter”. The Snapshot output allows you to freeze the current output window and then change the patient selection criteria and view the different output within the browser at the same time.

*Note:* ***If the stored object definition has a required patient selection criteria defined, you will not be allowed to change it.***



| | I | | NT | SEX | AGE | RACE | COMPLETE | REASON_DISC | SIDEFFCT |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 018 | 4101 | Placebo | Male | 22 | White | Yes | | No |
| 2 | 018 | 4102 | Placebo | Male | 44 | White | Yes | | No |
| 3 | 018 | 4103 | Active | Female | 35 | Black | Yes | | No |
| 4 | 018 | 4104 | Active | Male | 32 | Black | Yes | | No |
| 5 | 018 | 4105 | Placebo | Male | 25 | White | Yes | | No |
| 6 | 018 | 4106 | Placebo | Male | 18 | White | No | Protocol violator | No |
| 7 | 018 | 4107 | Active | Female | 24 | White | Yes | | No |
| 8 | 018 | 4108 | Active | Male | 31 | Black | No | Protocol violator | No |
| 9 | 018 | 4109 | Active | Female | 20 | White | Yes | | No |
| 10 | 018 | 4110 | Active | Female | 24 | White | No | Protocol violator | No |
| 11 | 018 | 4111 | Placebo | Female | 33 | Black | Yes | | No |
| 12 | 018 | 4112 | Placebo | Male | 46 | White | Yes | | No |
| 13 | 018 | 4113 | Active | Male | 25 | White | Yes | | No |
| 14 | 018 | 4114 | Placebo | Male | 57 | White | No | Lack of Efficacy | No |
| 15 | 018 | 4201 | Placebo | Female | 45 | White | Yes | | No |

The output example shows a stored report object with no patient selection criteria. A snapshot was taken of the current output.



Final Study Listing - All Patients

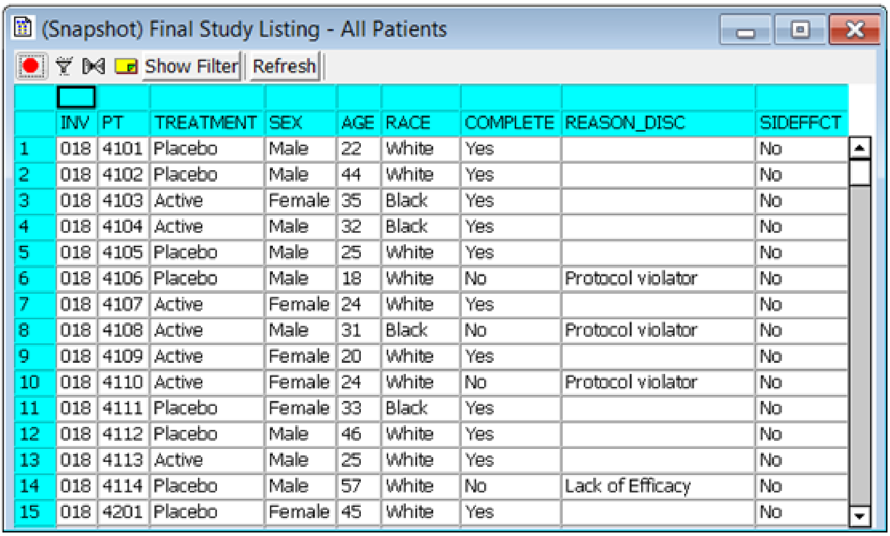
| | INV | PT | TREATMENT | SEX | AGE | RACE | COMPLETE | REASON_DISC | SIDEFFCT |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 018 | 4101 | Placebo | Male | 22 | White | Yes | | No |
| 2 | 018 | 4102 | Placebo | Male | 44 | White | Yes | | No |
| 3 | 018 | 4103 | Active | Female | 35 | Black | Yes | | No |
| 4 | 018 | 4104 | Active | | | | | | No |
| 5 | 018 | 4105 | Placebo | | | | | | No |
| 6 | 018 | 4106 | Placebo | | | | | violator | No |
| 7 | 018 | 4107 | Active | | | | | | No |
| 8 | 018 | 4108 | Active | | | | | violator | No |
| 9 | 018 | 4109 | Active | | | | | | No |
| 10 | 018 | 4110 | Active | | | | | violator | No |
| 11 | 018 | 4111 | Placebo | Female | 33 | Black | Yes | | No |
| 12 | 018 | 4112 | Placebo | Male | 46 | White | Yes | | No |
| 13 | 018 | 4113 | Active | Male | 25 | White | Yes | | No |
| 14 | 018 | 4114 | Placebo | Male | 57 | White | No | Lack of Efficacy | No |
| 15 | 018 | 4201 | Placebo | Female | 45 | White | Yes | | No |

Patient Selection Criteria

All Patients

OK

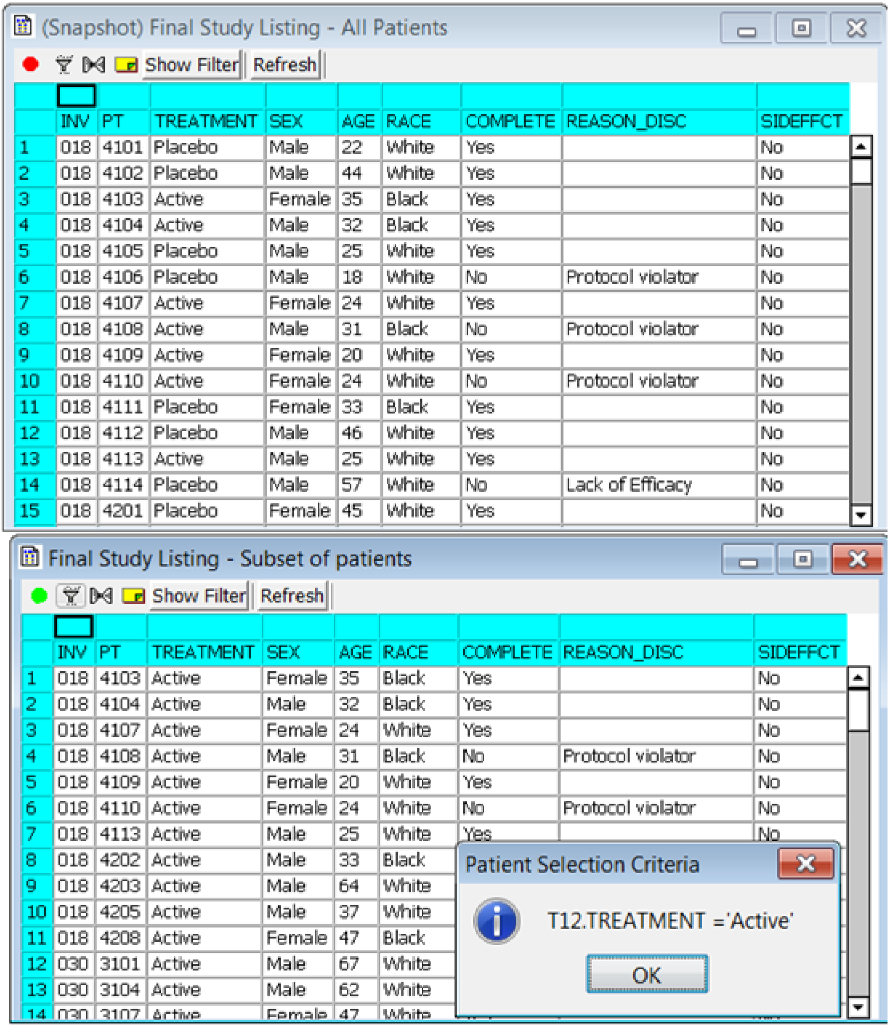
Clicking on Snapshot locks the output window.



(Snapshot) Final Study Listing - All Patients

| | INV | PT | TREATMENT | SEX | AGE | RACE | COMPLETE | REASON_DISC | SIDEFFCT |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 018 | 4101 | Placebo | Male | 22 | White | Yes | | No |
| 2 | 018 | 4102 | Placebo | Male | 44 | White | Yes | | No |
| 3 | 018 | 4103 | Active | Female | 35 | Black | Yes | | No |
| 4 | 018 | 4104 | Active | Male | 32 | Black | Yes | | No |
| 5 | 018 | 4105 | Placebo | Male | 25 | White | Yes | | No |
| 6 | 018 | 4106 | Placebo | Male | 18 | White | No | Protocol violator | No |
| 7 | 018 | 4107 | Active | Female | 24 | White | Yes | | No |
| 8 | 018 | 4108 | Active | Male | 31 | Black | No | Protocol violator | No |
| 9 | 018 | 4109 | Active | Female | 20 | White | Yes | | No |
| 10 | 018 | 4110 | Active | Female | 24 | White | No | Protocol violator | No |
| 11 | 018 | 4111 | Placebo | Female | 33 | Black | Yes | | No |
| 12 | 018 | 4112 | Placebo | Male | 46 | White | Yes | | No |
| 13 | 018 | 4113 | Active | Male | 25 | White | Yes | | No |
| 14 | 018 | 4114 | Placebo | Male | 57 | White | No | Lack of Efficacy | No |
| 15 | 018 | 4201 | Placebo | Female | 45 | White | Yes | | No |

A different patient selection criteria can be applied and with the same report object re-executed to display the two output results together for comparison. The selection criteria message box shows the revised selection criteria definition.



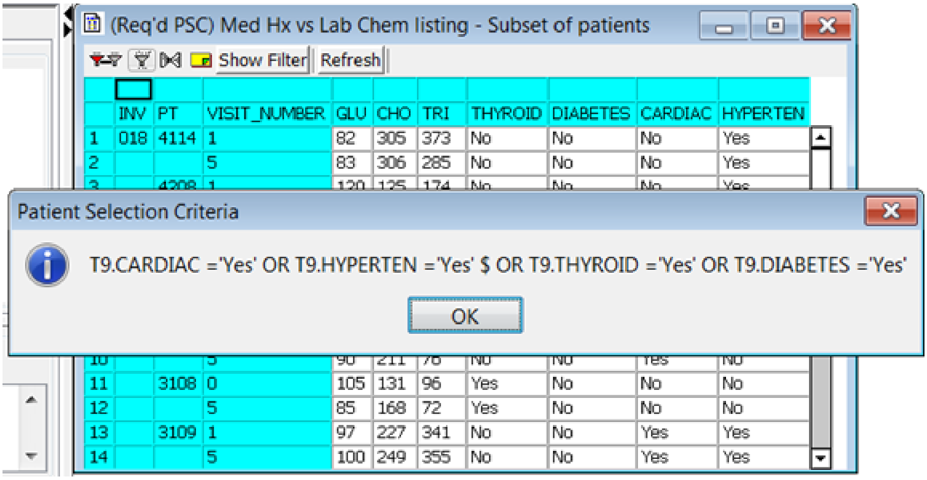
| | INV | PT | TREATMENT | SEX | AGE | RACE | COMPLETE | REASON_DISC | SIDEFFCT |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 018 | 4101 | Placebo | Male | 22 | White | Yes | | No |
| 2 | 018 | 4102 | Placebo | Male | 44 | White | Yes | | No |
| 3 | 018 | 4103 | Active | Female | 35 | Black | Yes | | No |
| 4 | 018 | 4104 | Active | Male | 32 | Black | Yes | | No |
| 5 | 018 | 4105 | Placebo | Male | 25 | White | Yes | | No |
| 6 | 018 | 4106 | Placebo | Male | 18 | White | No | Protocol violator | No |
| 7 | 018 | 4107 | Active | Female | 24 | White | Yes | | No |
| 8 | 018 | 4108 | Active | Male | 31 | Black | No | Protocol violator | No |
| 9 | 018 | 4109 | Active | Female | 20 | White | Yes | | No |
| 10 | 018 | 4110 | Active | Female | 24 | White | No | Protocol violator | No |
| 11 | 018 | 4111 | Placebo | Female | 33 | Black | Yes | | No |
| 12 | 018 | 4112 | Placebo | Male | 46 | White | Yes | | No |
| 13 | 018 | 4113 | Active | Male | 25 | White | Yes | | No |
| 14 | 018 | 4114 | Placebo | Male | 57 | White | No | Lack of Efficacy | No |
| 15 | 018 | 4201 | Placebo | Female | 45 | White | Yes | | No |

| | INV | PT | TREATMENT | SEX | AGE | RACE | COMPLETE | REASON_DISC | SIDEFFCT |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 018 | 4103 | Active | Female | 35 | Black | Yes | | No |
| 2 | 018 | 4104 | Active | Male | 32 | Black | Yes | | No |
| 3 | 018 | 4107 | Active | Female | 24 | White | Yes | | No |
| 4 | 018 | 4108 | Active | Male | 31 | Black | No | Protocol violator | No |
| 5 | 018 | 4109 | Active | Female | 20 | White | Yes | | No |
| 6 | 018 | 4110 | Active | Female | 24 | White | No | Protocol violator | No |
| 7 | 018 | 4113 | Active | Male | 25 | White | Yes | | No |
| 8 | 018 | 4202 | Active | Male | 33 | Black | | | |
| 9 | 018 | 4203 | Active | Male | 64 | White | | | |
| 10 | 018 | 4205 | Active | Male | 37 | White | | | |
| 11 | 018 | 4208 | Active | Female | 47 | Black | | | |
| 12 | 030 | 3101 | Active | Male | 67 | White | | | |
| 13 | 030 | 3104 | Active | Male | 62 | White | | | |
| 14 | 030 | 3107 | Active | Female | 47 | White | | | |

T12.TREATMENT ='Active'

## *Multiple output for required selection criteria*

When a stored object definition has a required selection criteria, you are not allowed to modify the selection criteria. The output window displays a notation in the heading “Req’d PSC” with a double filter icon. You can open multiple objects with “Req’d PSC” and toggle between the required selection criteria to update your Data Browser display or other open objects where a selection criteria definition is not required.

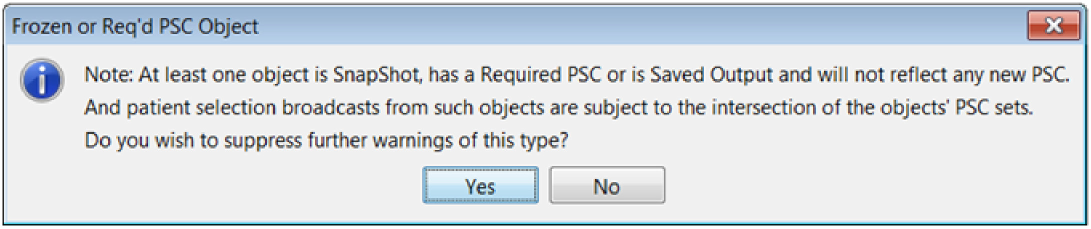


| | INV | PT | VISIT_NUMBER | GLU | CHO | TRI | THYROID | DIABETES | CARDIAC | HYPERTEN |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 018 | 4114 | 1 | 82 | 305 | 373 | No | No | No | Yes |
| 2 | | | 5 | 83 | 306 | 285 | No | No | No | Yes |
| 3 | | 4208 | 1 | 120 | 125 | 174 | No | No | No | Yes |
| 10 | | | 5 | 90 | 211 | 76 | No | No | Yes | No |
| 11 | | 3108 | 0 | 105 | 131 | 96 | Yes | No | No | No |
| 12 | | | 5 | 85 | 168 | 72 | Yes | No | No | No |
| 13 | | 3109 | 1 | 97 | 227 | 341 | No | No | Yes | Yes |
| 14 | | | 5 | 100 | 249 | 355 | No | No | Yes | Yes |

Patient Selection Criteria

T9.CARDIAC ='Yes' OR T9.HYPERTEN ='Yes' $ OR T9.THYROID ='Yes' OR T9.DIABETES ='Yes'

JReview gives a warning when opening a “Stored/Req’d PSC” subset object and allows the user to suppress the warning after the first time. A warning dialog will be presented when trying to update the patient selection criteria if a Snapshot/Frozen or “Req’d PSC” object is open. The warning informs the user that any open Snapshot/Frozen or “Req’d PSC” objects will not respect the new patient selection criteria (and the patient selection criteria update will proceed for other objects). The user has the option of suppressing future appearances of the warning.

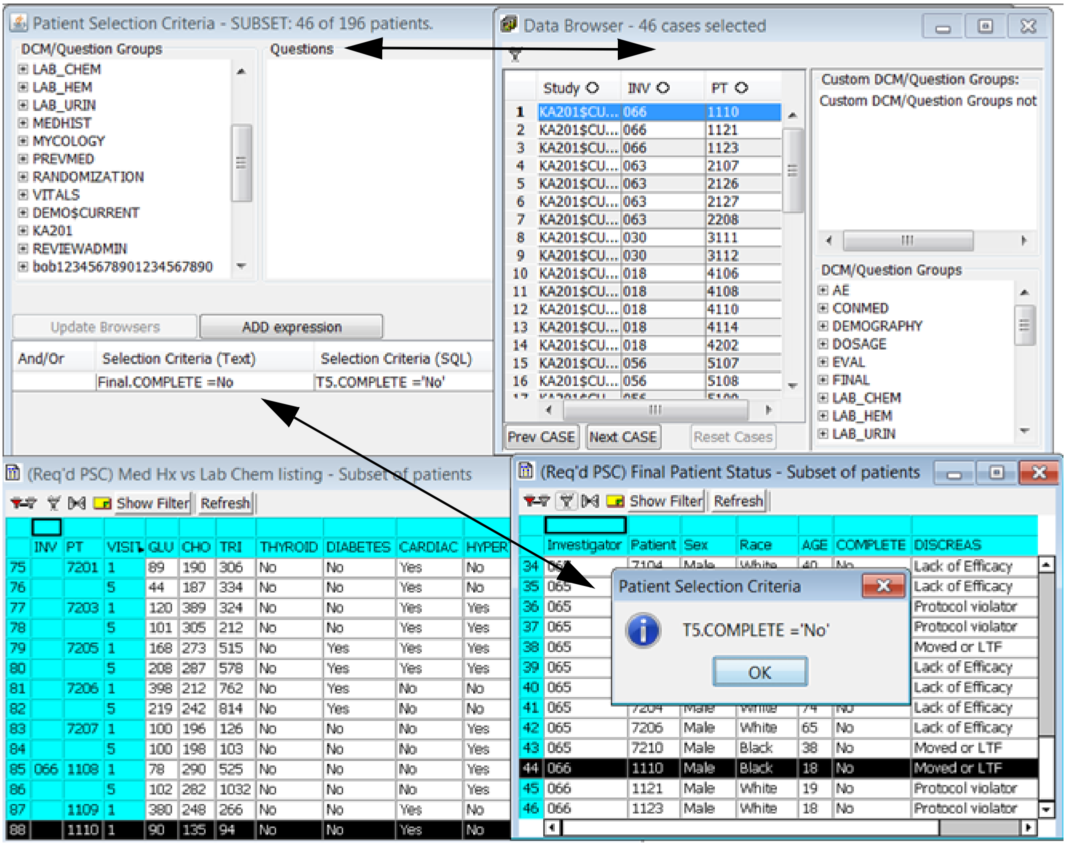


Frozen or Req'd PSC Object

Note: At least one object is SnapShot, has a Required PSC or is Saved Output and will not reflect any new PSC.
And patient selection broadcasts from such objects are subject to the intersection of the objects' PSC sets.
Do you wish to suppress further warnings of this type?

The last launched object with a required selection criteria is loaded into the Patient Selection Criteria window and the patients are listed in the Data Browser window. The Data Browser always reflects the current patient selection criteria.

The first object launched with a required PSC is locked and the results display does not update.



| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | Final.COMPLETE =No | T5.COMPLETE ='No' |

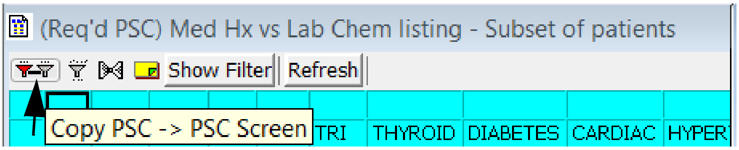
| | Study | INV | PT |
|---|---|---|---|
| 1 | KA201$CU... | 066 | 1110 |
| 2 | KA201$CU... | 066 | 1121 |
| 3 | KA201$CU... | 066 | 1123 |
| 4 | KA201$CU... | 063 | 2107 |
| 5 | KA201$CU... | 063 | 2126 |
| 6 | KA201$CU... | 063 | 2127 |
| 7 | KA201$CU... | 063 | 2208 |
| 8 | KA201$CU... | 030 | 3111 |
| 9 | KA201$CU... | 030 | 3112 |
| 10 | KA201$CU... | 018 | 4106 |
| 11 | KA201$CU... | 018 | 4108 |
| 12 | KA201$CU... | 018 | 4110 |
| 13 | KA201$CU... | 018 | 4114 |
| 14 | KA201$CU... | 018 | 4202 |
| 15 | KA201$CU... | 056 | 5107 |
| 16 | KA201$CU... | 056 | 5108 |

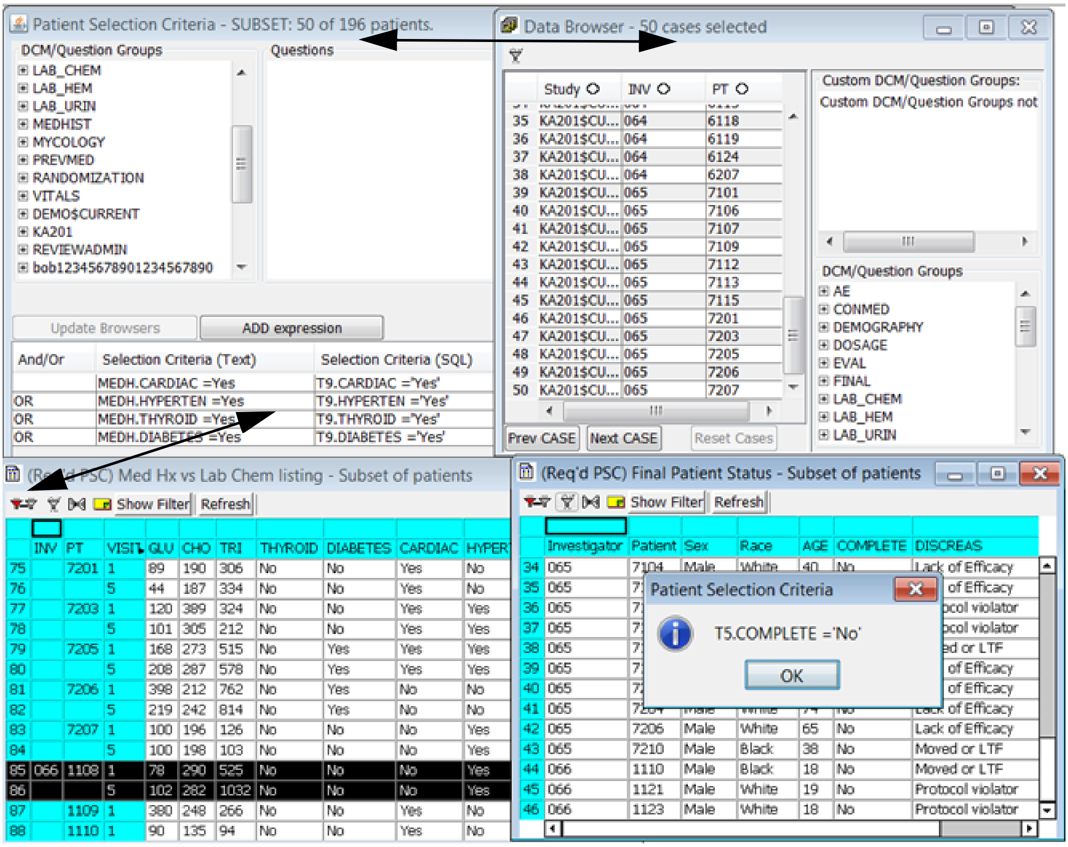
| | INV | PT | VISIT | GLU | CHO | TRI | THYROID | DIABETES | CARDIAC | HYPER |
|---|---|---|---|---|---|---|---|---|---|---|
| 75 | | 7201 | 1 | 89 | 190 | 306 | No | No | Yes | No |
| 76 | | | 5 | 44 | 187 | 334 | No | No | Yes | No |
| 77 | | 7203 | 1 | 120 | 389 | 324 | No | No | Yes | Yes |
| 78 | | | 5 | 101 | 305 | 212 | No | No | Yes | Yes |
| 79 | | 7205 | 1 | 168 | 273 | 515 | No | Yes | Yes | Yes |
| 80 | | | 5 | 208 | 287 | 578 | No | Yes | Yes | Yes |
| 81 | | 7206 | 1 | 398 | 212 | 762 | No | Yes | No | No |
| 82 | | | 5 | 219 | 242 | 814 | No | Yes | No | No |
| 83 | | 7207 | 1 | 100 | 196 | 126 | No | No | No | Yes |
| 84 | | | 5 | 100 | 198 | 103 | No | No | No | Yes |
| 85 | 066 | 1108 | 1 | 78 | 290 | 525 | No | No | No | Yes |
| 86 | | | 5 | 102 | 282 | 1032 | No | No | No | Yes |
| 87 | | 1109 | 1 | 380 | 248 | 266 | No | No | Yes | No |
| 88 | | 1110 | 1 | 90 | 135 | 94 | No | No | Yes | No |

| | Investigator | Patient | Sex | Race | AGE | COMPLETE | DISCREAS |
|---|---|---|---|---|---|---|---|
| 34 | 06 | 7104 | Male | White | 40 | No | Lack of Efficacy |
| 35 | 065 | | | | | | Lack of Efficacy |
| 36 | 065 | | | | | | Protocol violator |
| 37 | 065 | | | | | | Protocol violator |
| 38 | 065 | | | | | | Moved or LTF |
| 39 | 065 | | | | | | Lack of Efficacy |
| 40 | 065 | | | | | | Lack of Efficacy |
| 41 | 065 | 7204 | Male | White | 74 | No | Lack of Efficacy |
| 42 | 065 | 7206 | Male | White | 65 | No | Lack of Efficacy |
| 43 | 065 | 7210 | Male | Black | 38 | No | Moved or LTF |
| 44 | 066 | 1110 | Male | Black | 18 | No | Moved or LTF |
| 45 | 066 | 1121 | Male | White | 19 | No | Protocol violator |
| 46 | 066 | 1123 | Male | White | 18 | No | Protocol violator |

T5.COMPLETE ='No'

To load the previous object’s selection criteria, click on the double filter icon “Copy PSC -> PSC Screen”. The selection criteria is copied into the Patient Selection Criteria window. You must click **Update Browsers** to update the Data Browser display.





| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | MEDH.CARDIAC =Yes | T9.CARDIAC ='Yes' |
| OR | MEDH.HYPERTEN =Yes | T9.HYPERTEN ='Yes' |
| OR | MEDH.THYROID =Yes | T9.THYROID ='Yes' |
| OR | MEDH.DIABETES =Yes | T9.DIABETES ='Yes' |

| | Study | INV | PT |
|---|---|---|---|
| 35 | KA201$CU... | 064 | 6118 |
| 36 | KA201$CU... | 064 | 6119 |
| 37 | KA201$CU... | 064 | 6124 |
| 38 | KA201$CU... | 064 | 6207 |
| 39 | KA201$CU... | 065 | 7101 |
| 40 | KA201$CU... | 065 | 7106 |
| 41 | KA201$CU... | 065 | 7107 |
| 42 | KA201$CU... | 065 | 7109 |
| 43 | KA201$CU... | 065 | 7112 |
| 44 | KA201$CU... | 065 | 7113 |
| 45 | KA201$CU... | 065 | 7115 |
| 46 | KA201$CU... | 065 | 7201 |
| 47 | KA201$CU... | 065 | 7203 |
| 48 | KA201$CU... | 065 | 7205 |
| 49 | KA201$CU... | 065 | 7206 |
| 50 | KA201$CU... | 065 | 7207 |

| | INV | PT | VISIT | GLU | CHO | TRI | THYROID | DIABETES | CARDIAC | HYPER |
|---|---|---|---|---|---|---|---|---|---|---|
| 75 | | 7201 | 1 | 89 | 190 | 306 | No | No | Yes | No |
| 76 | | | 5 | 44 | 187 | 334 | No | No | Yes | No |
| 77 | | 7203 | 1 | 120 | 389 | 324 | No | No | Yes | Yes |
| 78 | | | 5 | 101 | 305 | 212 | No | No | Yes | Yes |
| 79 | | 7205 | 1 | 168 | 273 | 515 | No | Yes | Yes | Yes |
| 80 | | | 5 | 208 | 287 | 578 | No | Yes | Yes | Yes |
| 81 | | 7206 | 1 | 398 | 212 | 762 | No | Yes | No | No |
| 82 | | | 5 | 219 | 242 | 814 | No | Yes | No | No |
| 83 | | 7207 | 1 | 100 | 196 | 126 | No | No | No | Yes |
| 84 | | | 5 | 100 | 198 | 103 | No | No | No | Yes |
| 85 | 066 | 1108 | 1 | 78 | 290 | 525 | No | No | No | Yes |
| 86 | | | 5 | 102 | 282 | 1032 | No | No | No | Yes |
| 87 | | 1109 | 1 | 380 | 248 | 266 | No | No | Yes | No |
| 88 | | 1110 | 1 | 90 | 135 | 94 | No | No | Yes | No |

| | Investigator | Patient | Sex | Race | AGE | COMPLETE | DISCREAS |
|---|---|---|---|---|---|---|---|
| 34 | 065 | 7104 | Male | White | 40 | No | Lack of Efficacy |
| 35 | 065 | 7 | | | | | of Efficacy |
| 36 | 065 | 7 | | | | | ocol violator |
| 37 | 065 | 7 | | | | | ocol violator |
| 38 | 065 | 7 | | | | | ed or LTF |
| 39 | 065 | 7 | | | | | of Efficacy |
| 40 | 065 | 7 | | | | | of Efficacy |
| 41 | 065 | 72 | Male | White | 7 | No | Lack of Efficacy |
| 42 | 065 | 7206 | Male | White | 65 | No | Lack of Efficacy |
| 43 | 065 | 7210 | Male | Black | 38 | No | Moved or LTF |
| 44 | 066 | 1110 | Male | Black | 18 | No | Moved or LTF |
| 45 | 066 | 1121 | Male | White | 19 | No | Protocol violator |
| 46 | 066 | 1123 | Male | White | 18 | No | Protocol violator |

T5.COMPLETE ='No'

If you open another stored object which doesn’t include a selection criteria, the output will display with the previously launched required selection criteria.

***Note: Stored objects with required selection criteria will take precedence over object definitions without required selection criteria when you toggle back.***

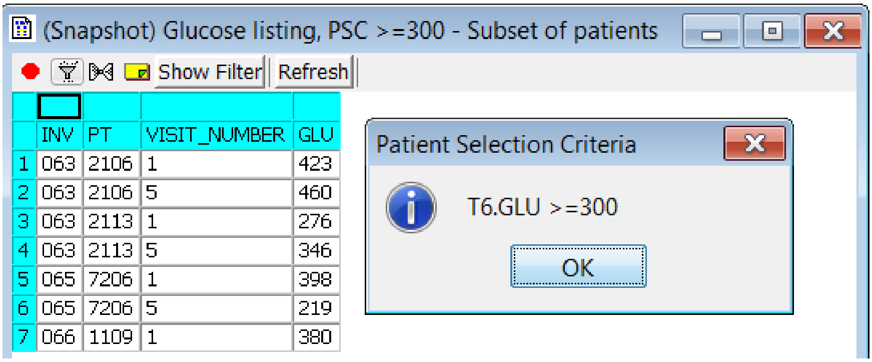
# Output filter

## *Subset data*

The reviewing strategy of an Output Filter is to provide a tool that instantly highlights and subsets a group of patients with a particular observation (such as Adverse Event: Gastrointestinal) and/or visit measures (such as Visit Label with a particular data Item value.) The output filter is designed to focus in on particular observations and visits; it is not designed to be used for the patient selection criteria.

For example, if you want to see all the patients who had Adverse Events with an intensity of ‘Serious’, you need to decide whether to define the data subset at the patient level or observation/visit level. If you define the data selection with a patient selection criteria and apply it to a detail data listing, all the patients who have a serious adverse event are selected and in addition their other adverse events are displayed. This subsetting option provides for a complete clinical profile of the patient when you apply a patient selection criteria to the patient population. However, to view only ‘Serious’ adverse events and not display other adverse events you would define an Output Filter. So when selecting from multiple observation/visit data you need to determine which subset function to apply for viewing at patient level or visit level.

The examples show a glucose data listing with a patient selection criteria applied for values >= 300”. The glucose selection was defined instead as an output filter.



(Snapshot) Glucose listing, PSC >=300 - Subset of patients

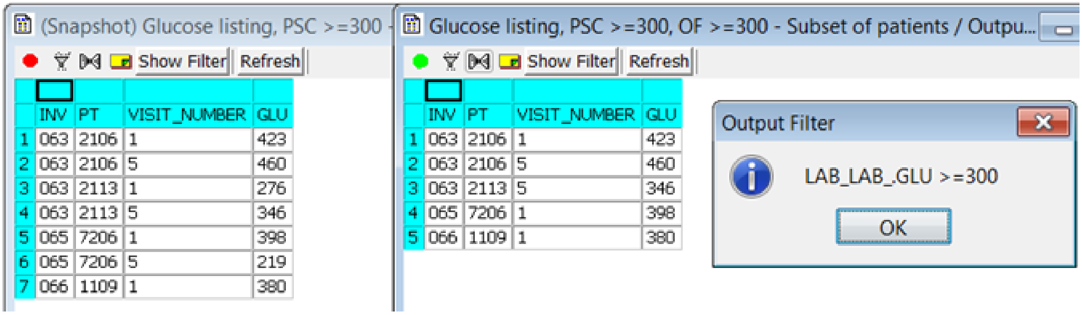
|   | INV | PT | VISIT_NUMBER | GLU |
|---|---|---|---|---|
| 1 | 063 | 2106 | 1 | 423 |
| 2 | 063 | 2106 | 5 | 460 |
| 3 | 063 | 2113 | 1 | 276 |
| 4 | 063 | 2113 | 5 | 346 |
| 5 | 065 | 7206 | 1 | 398 |
| 6 | 065 | 7206 | 5 | 219 |
| 7 | 066 | 1109 | 1 | 380 |

Patient Selection Criteria

T6.GLU >=300

Next the output filter was applied and the previous patient selection criteria was removed. The exact same patients are selected. However, the difference is the patient selection criteria displays all the visits for selected patients, while the output filter selects only those visits with the elevated values as defined.

You may apply both patient selection criteria and output filters to an object specification and both would be saved in the object specification.



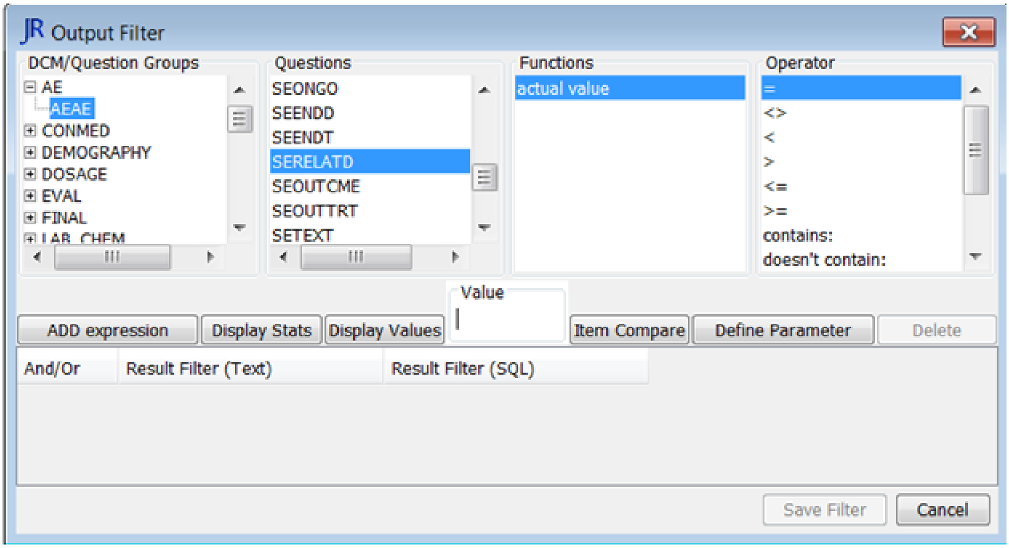
| | INV | PT | VISIT_NUMBER | GLU |
|---|---|---|---|---|
| 1 | 063 | 2106 | 1 | 423 |
| 2 | 063 | 2106 | 5 | 460 |
| 3 | 063 | 2113 | 1 | 276 |
| 4 | 063 | 2113 | 5 | 346 |
| 5 | 065 | 7206 | 1 | 398 |
| 6 | 065 | 7206 | 5 | 219 |
| 7 | 066 | 1109 | 1 | 380 |

| | INV | PT | VISIT_NUMBER | GLU |
|---|---|---|---|---|
| 1 | 063 | 2106 | 1 | 423 |
| 2 | 063 | 2106 | 5 | 460 |
| 3 | 063 | 2113 | 5 | 346 |
| 4 | 065 | 7206 | 1 | 398 |
| 5 | 066 | 1109 | 1 | 380 |

LAB_LAB_GLU >=300

## *Creating report output filter*

Click **Filter Output** before you click **Create Report.** The Report Output Filter window opens.



- The output filter looks and operates similar to the patient selection criteria window.
- You select the panel item and value or range value to create a row filtering criteria.
- The selection of the values or range values are supported by **Display Stats** and **Display Values**.
- Horizontal to Vertical panels (HRZ) are supported in Output Filters in Reports. So a pivoted item (PI) can be referenced in the output filter, for example, cholesterol > 250.

As in the patient selection criteria, **Display Stats** instantly provides the basic descriptive statistics for the highlighted item, function, and value, and **Display Values** provides a listing of all values possible for the selected item, function, and value. Both **Display Stats** and **Display Values** present their respective listings for the whole protocol(‘s) population, unless you check Subset by Patient Selection Criteria. With Subset by Patient Selection Criteria checked, the respective information in these windows is limited to the patient subset created by the current patient selection criteria. **(See *Chapter 2: Selecting Patients: Display Values* and *Display Stats*)**

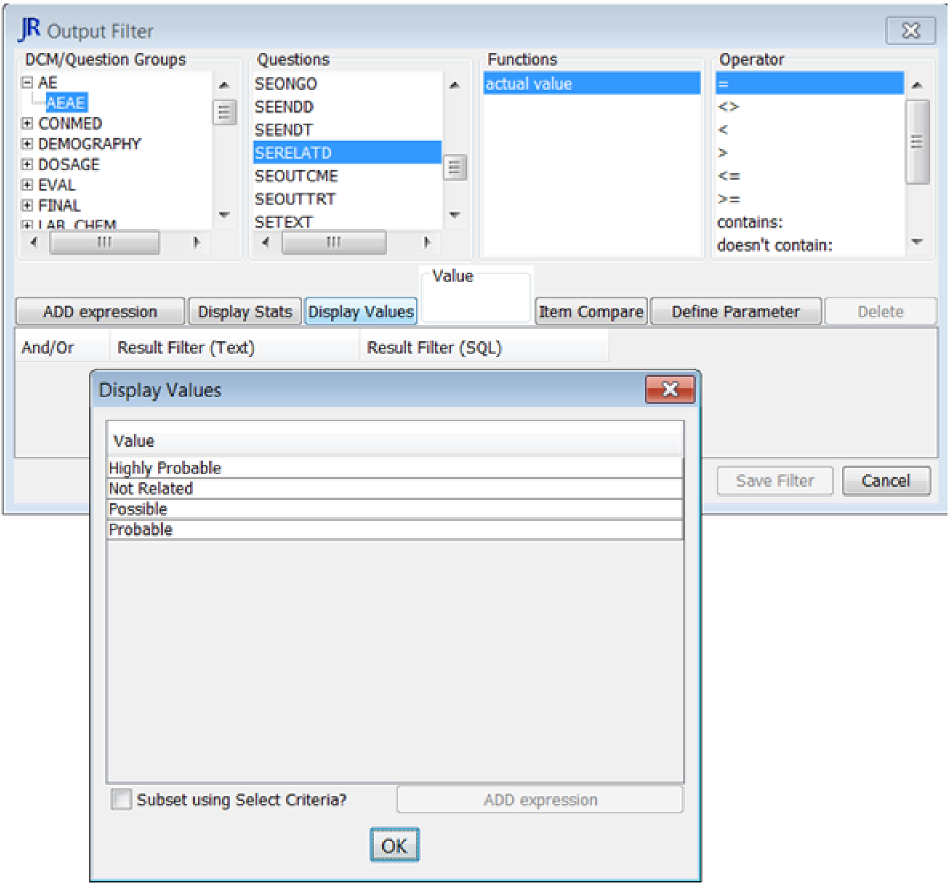
## *Comparing items*

Click **Item Compare** if you want to create a criteria expression that is based on the relationship of two item values. **(See *Chapter 2: Selecting Patients: Compare Items*)**

## *Adding expressions*

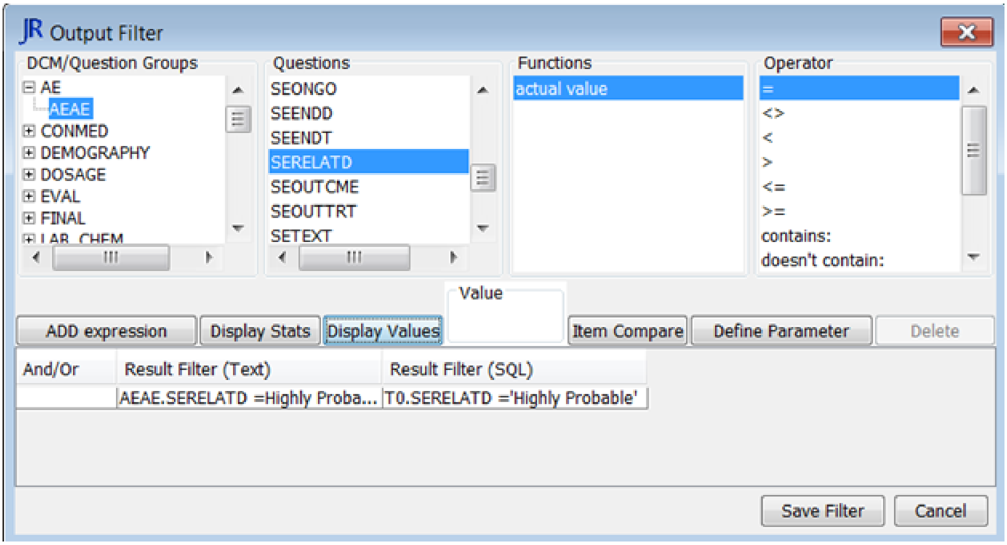
Click **ADD Expression** once a row filtering criteria has been created. The expression is immediately entered in the Result Filter (Text) and Result Filter (SQL) columns.

Add as many row filter criteria as needed to limit the rows of observations and visits included in the report analysis. Each result filter expression is automatically joined by the AND operator. However, just as in the patient selection criteria, the operator OR is also available for non-dependent filter expressions. AND Select is not an option in the output filter.



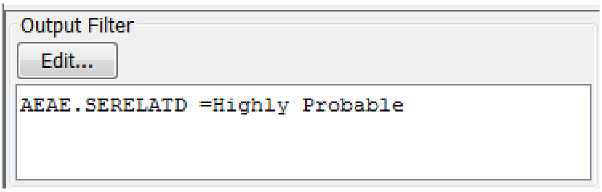
| Value |
|---|
| Highly Probable |
| Not Related |
| Possible |
| Probable |

When the output filter is entered, click **Save Filter** to apply to the next generated report.



| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | AEAE.SERELATD =Highly Proba... | T0.SERELATD ='Highly Probable' |

In New Mode the saved output filter displays in the Report Browser as:

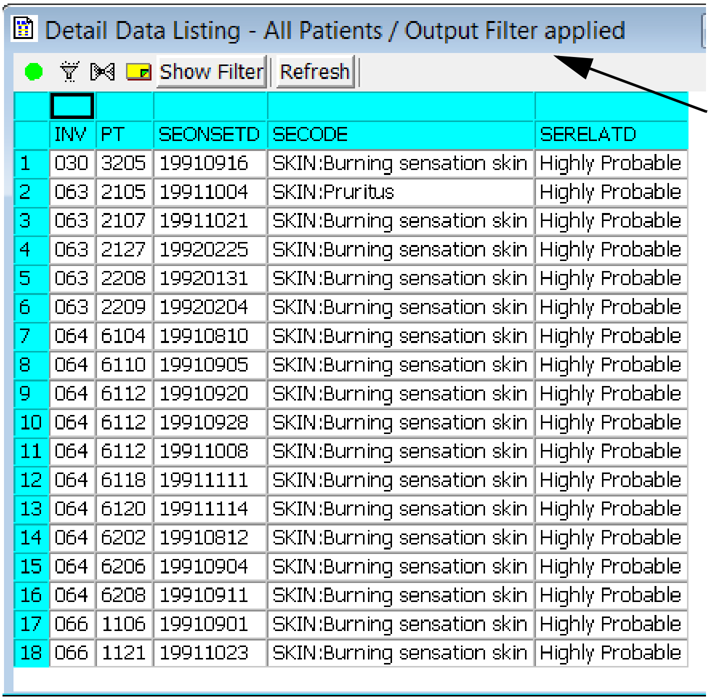


```
AEAE.SERELATD =Highly Probable
```

In Classic Mode the Report Browser updates the **Filter Output** button status to **Filter is ON.**

## *View output filter*

Now you can click **Create Report**. The report displays only those observations defined by the filter output criteria(s). The report heading indicates the output filter status as applied.



Detail Data Listing - All Patients / Output Filter applied

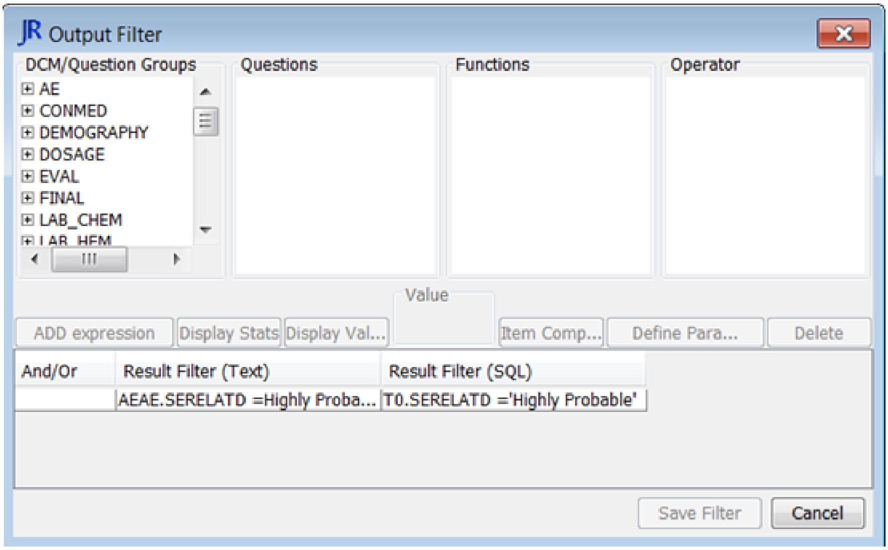
| | INV | PT | SEONSETD | SECODE | SERELATD |
|---|---|---|---|---|---|
| 1 | 030 | 3205 | 19910916 | SKIN:Burning sensation skin | Highly Probable |
| 2 | 063 | 2105 | 19911004 | SKIN:Pruritus | Highly Probable |
| 3 | 063 | 2107 | 19911021 | SKIN:Burning sensation skin | Highly Probable |
| 4 | 063 | 2127 | 19920225 | SKIN:Burning sensation skin | Highly Probable |
| 5 | 063 | 2208 | 19920131 | SKIN:Burning sensation skin | Highly Probable |
| 6 | 063 | 2209 | 19920204 | SKIN:Burning sensation skin | Highly Probable |
| 7 | 064 | 6104 | 19910810 | SKIN:Burning sensation skin | Highly Probable |
| 8 | 064 | 6110 | 19910905 | SKIN:Burning sensation skin | Highly Probable |
| 9 | 064 | 6112 | 19910920 | SKIN:Burning sensation skin | Highly Probable |
| 10 | 064 | 6112 | 19910928 | SKIN:Burning sensation skin | Highly Probable |
| 11 | 064 | 6112 | 19911008 | SKIN:Burning sensation skin | Highly Probable |
| 12 | 064 | 6118 | 19911111 | SKIN:Burning sensation skin | Highly Probable |
| 13 | 064 | 6120 | 19911114 | SKIN:Burning sensation skin | Highly Probable |
| 14 | 064 | 6202 | 19910812 | SKIN:Burning sensation skin | Highly Probable |
| 15 | 064 | 6206 | 19910904 | SKIN:Burning sensation skin | Highly Probable |
| 16 | 064 | 6208 | 19910911 | SKIN:Burning sensation skin | Highly Probable |
| 17 | 066 | 1106 | 19910901 | SKIN:Burning sensation skin | Highly Probable |
| 18 | 066 | 1121 | 19911023 | SKIN:Burning sensation skin | Highly Probable |

You can save the report specification for later use and results validation. All saved reports with an output filter ON are saved with the filter specification, and the filter will be active when relaunched.

## *Remove Output Filter*

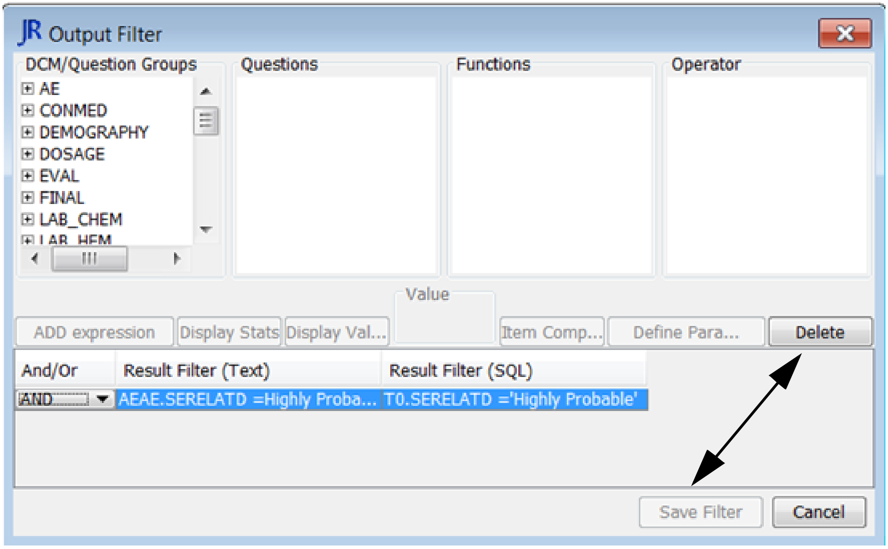
To remove the Output Filter the steps are slightly different between New Mode versus Classic Mode.

1. In **Classic Mode**, click **Filter is ON** button and the Output Filter window opens.
2. Use the same steps as clearing a patient selection criteria and click **New icon**.
3. Click **Save Filter** to save the cleared filter status before closing the Output Filter window. The Report Browser window updates the button to **Filter Output** indicating NO Output Filter is defined.



| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
|  | AEAE.SERELATD =Highly Proba... | T0.SERELATD ='Highly Probable' |

1. To remove the Output Filter from **New Mode**, click **Output Filter Edit button.**
2. The Output Filter window opens and you must select / highlight the filter row(s) to remove. Click **Delete**.
3. Click **Save Filter** to save the cleared filter status before closing the Output Filter window.

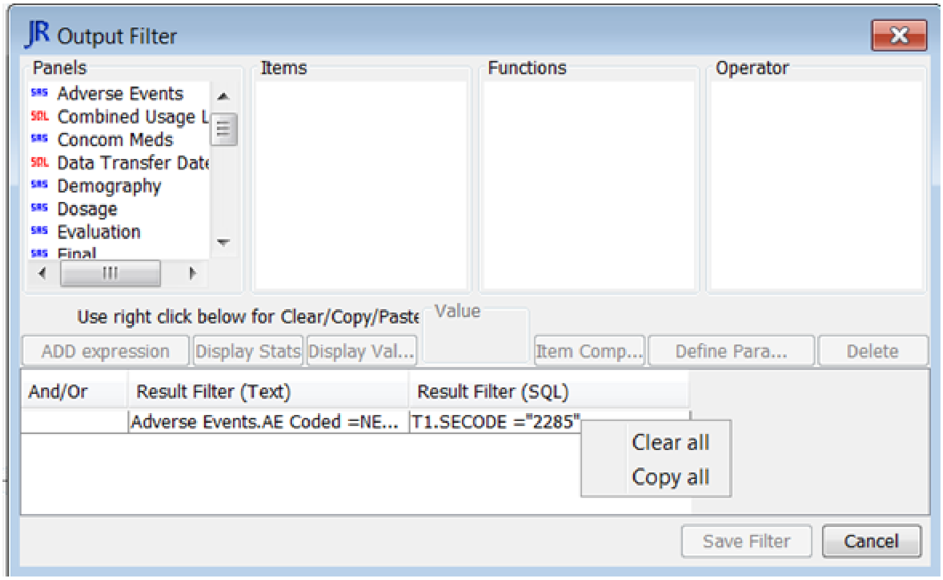


| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| AND | AEAE.SERELATD =Highly Proba... | T0.SERELATD ='Highly Probable' |

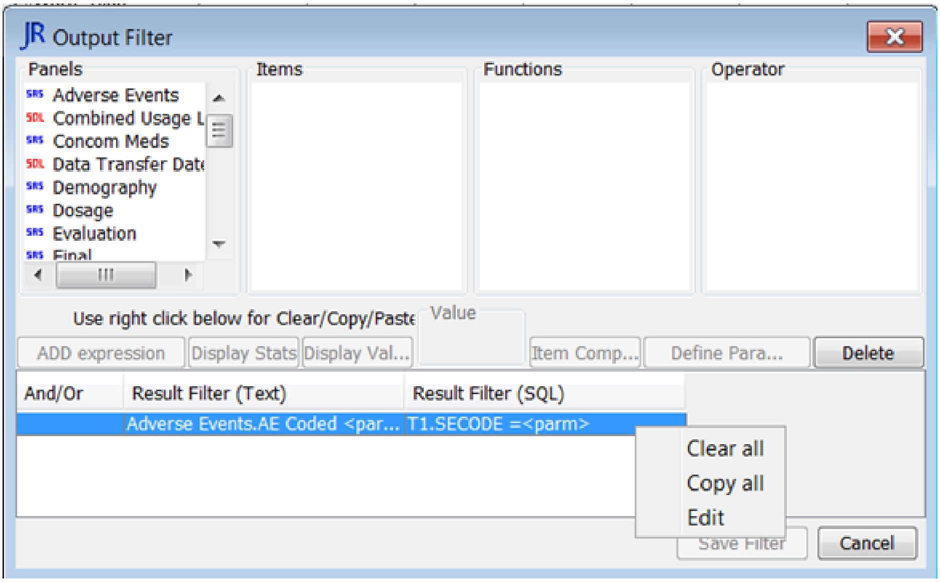
## *Copy/Paste Output Filter*

Add right-click popmenu to Output Filter table area offering "Clear all", "Copy all" & "Paste all" choices as applicable. The menu choices are only shown and/or enabled when they are applicable in the context. Clear all & Copy all only offered/enabled when there is non-empty output filter, Paste all only when there's a copied output filter in the buffer, in target output filter dialog types**.**

These features/popmenu is enabled/available for all Output Filter dialogs except the output filter dialogs for Workbook and Formatted Patient Profiles and Patient Visit Data Report (due to complexities in those filters).



| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | Adverse Events.AE Coded =NE... | T1.SECODE ="2285" |



| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | Adverse Events.AE Coded <par... | T1.SECODE =<parm> |

*Note:* The previously implemented "Edit" popmenu choice remains and is only enabled/available if a single Defined Parameter output filter row is selected (blue).

# Define Runtime filters

## *Runtime parameter*

Defining runtime parameters is another way to select Output Filters to subset your patients and data observations. The object specification (reports, graphs, crosstabs) are first saved with the defined parameters. When the object specifications is executed the Output Filter View Choices window with the defined parameters displays for selection to the user.

The same basic steps used to define an output filter are used to select the panel, item and operator before you click **Define Parameter**.

Initially when you define the parameters you can specify the parameter type as free text, between two values, choose from a specified list, or choose from all possible values (Display Values). The user can define a user defined SQL statement to return a list of values. This is typically used when the “Display Values” option against the original table performs slowly.

The defaulted parameter text can be edited to an end-user prompt or question.

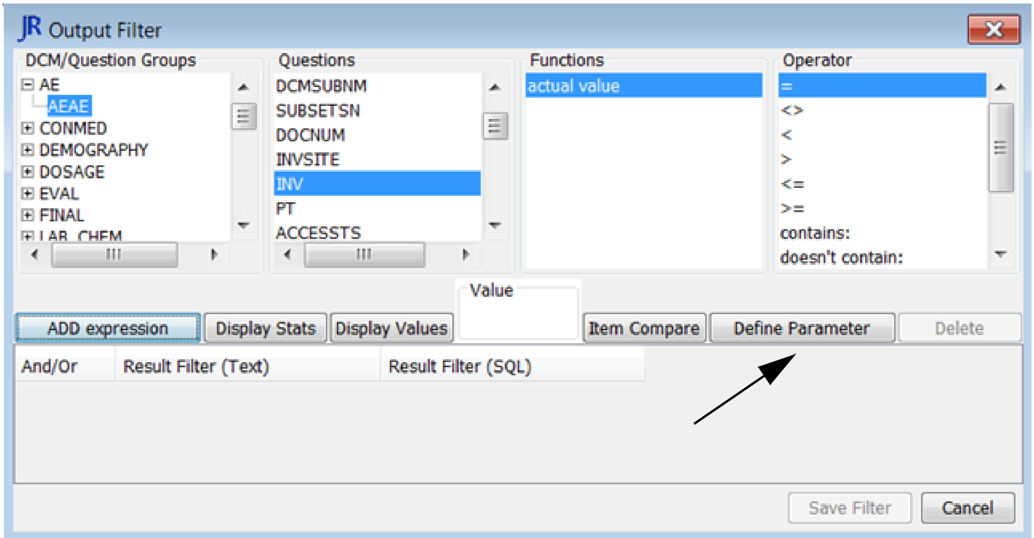
Also, you can specify with a checkbox if filtering is required for the parameter. Otherwise, when the object is executed the user can click the ‘Disable Filtering’ checkbox prior to creating the output to not include filtering on a particular parameter.

This feature provides flexibility for the user to select various combinations of parameters to generate output to select and to limit the rows of data returned.

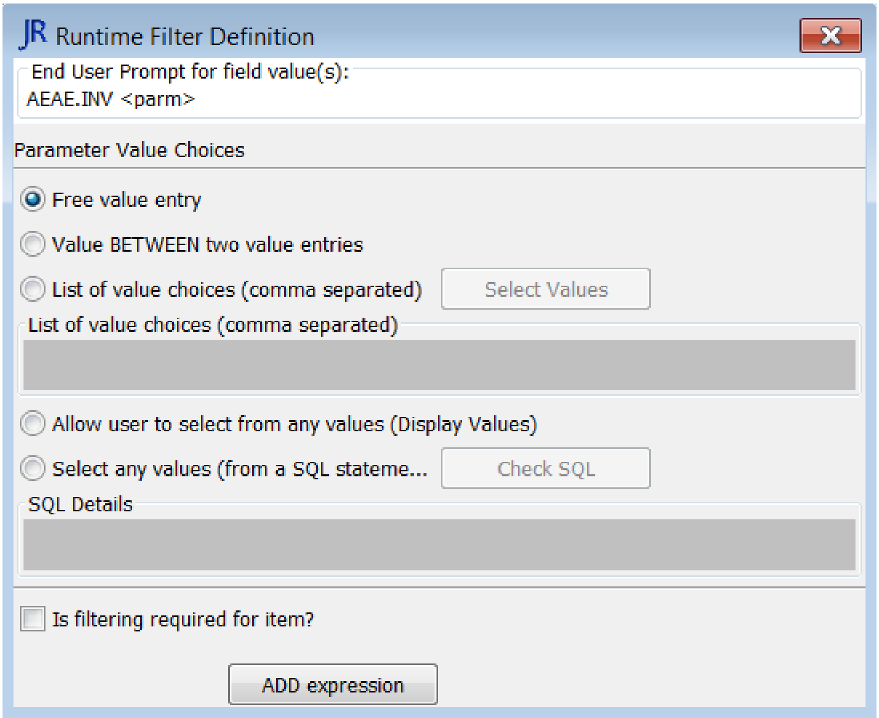
## *Create parameter*

The Define Parameter function is accessed within the Filter Output window in the various browsers (reports, graphs, crosstabs). You may combine standard output filter definitions along with defining parameters when you click **Save Filter**. The operating features of **Define Parameter** are similar to selecting a panel and item for an output filter. You have access to all panels and underlying data items when creating a parameter.

1. From the browser window, click the **Filter Output** button (Classic mode) or the **Output Filter Edit** button (New mode) to open the Output Filter window.
2. Select a panel.
3. Select an item.
4. Select the operator.
5. Click **Define Parameter**.



The ‘**Runtime Filter Definition**’ window opens.



End User Prompt for field value(s):
AEAE.INV <parm>

Parameter Value Choices

● Free value entry
○ Value BETWEEN two value entries
○ List of value choices (comma separated)

List of value choices (comma separated)

○ Allow user to select from any values (Display Values)
○ Select any values (from a SQL stateme...

SQL Details

☐ Is filtering required for item?

6. Select one of the **Parameter Value Choices.**

When selecting which parameter value choice to apply to your data you must consider the data type. For example, whether the data is date, numeric, free text or references a data dictionary file.

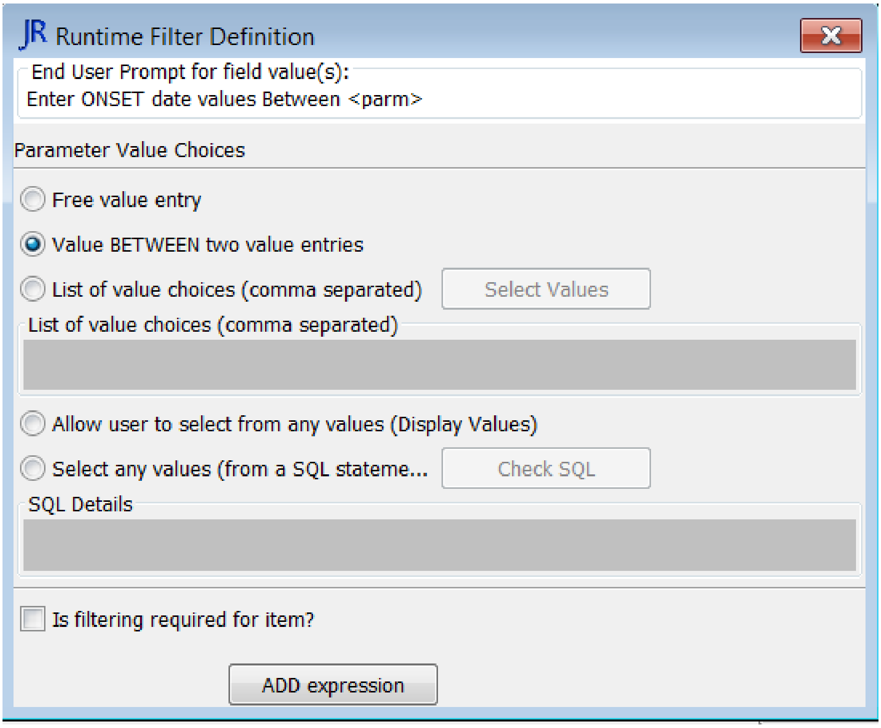
The free value entry can be used for free text data such as Adverse Event Text or Concomitant Medication Text.

The option to select a value between two value entries can be applied for date ranges or numeric data, i.e., age, labs, vitals, etc.

Coded data referencing a data dictionary file is best defined by allowing the user to select from any values (Display Values) as the entry required is the coded value.

Large tables can be accessed for selecting values from an SQL statement.

7. Optionally, replace the default text in the End User Prompt for field value(s) by typing over the description. Also, remove the **<parm>** label as not needed in the End User Prompt description field.
8. Check if filtering is required for item? (optional)
9. Click **ADD expression**. Repeat the steps to add another parameter.



Runtime Filter Definition

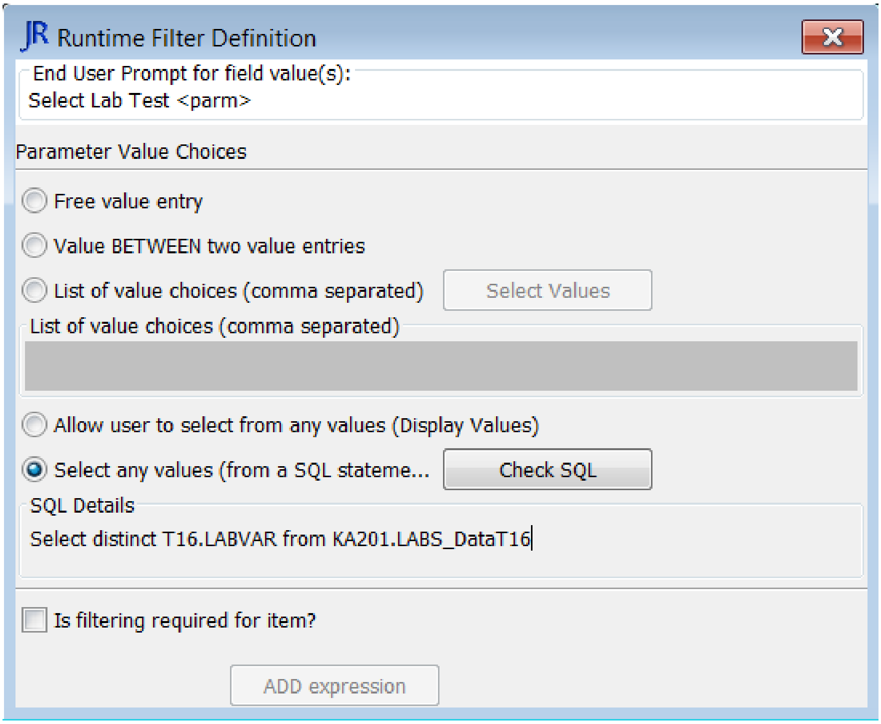
End User Prompt for field value(s):
Enter ONSET date values Between <parm>

Parameter Value Choices

○ Free value entry
● Value BETWEEN two value entries
○ List of value choices (comma separated)
List of value choices (comma separated)
○ Allow user to select from any values (Display Values)
○ Select any values (from a SQL stateme...
SQL Details
☐ Is filtering required for item?

If you select the parameter option for '**Select any values (from a SQL statement)',** enter the SQL statement.

Click the **Check SQL** button which goes to the database and checks the SQL syntax then returns an Oracle error if present. Click **OK** to close the message window.



End User Prompt for field value(s):
Select Lab Test <parm>

Parameter Value Choices

○ Free value entry
○ Value BETWEEN two value entries
○ List of value choices (comma separated)

List of value choices (comma separated)

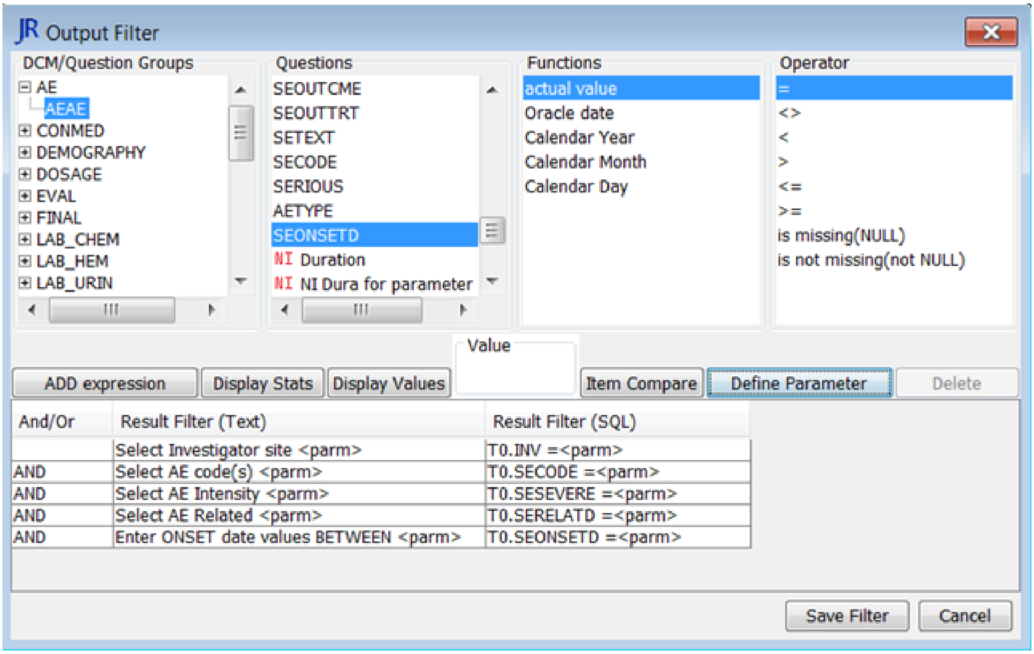
○ Allow user to select from any values (Display Values)
● Select any values (from a SQL stateme...

SQL Details

Select distinct T16.LABVAR from KA201.LABS_DataT16

☐ Is filtering required for item?

10. Change the Boolean Operators in the Output Filter window if needed, then click **Save Filter**.



| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | Select Investigator site <parm> | T0.INV =<parm> |
| AND | Select AE code(s) <parm> | T0.SECODE =<parm> |
| AND | Select AE Intensity <parm> | T0.SESEVERE =<parm> |
| AND | Select AE Related <parm> | T0.SERELATD =<parm> |
| AND | Enter ONSET date values BETWEEN <parm> | T0.SEONSETD =<parm> |

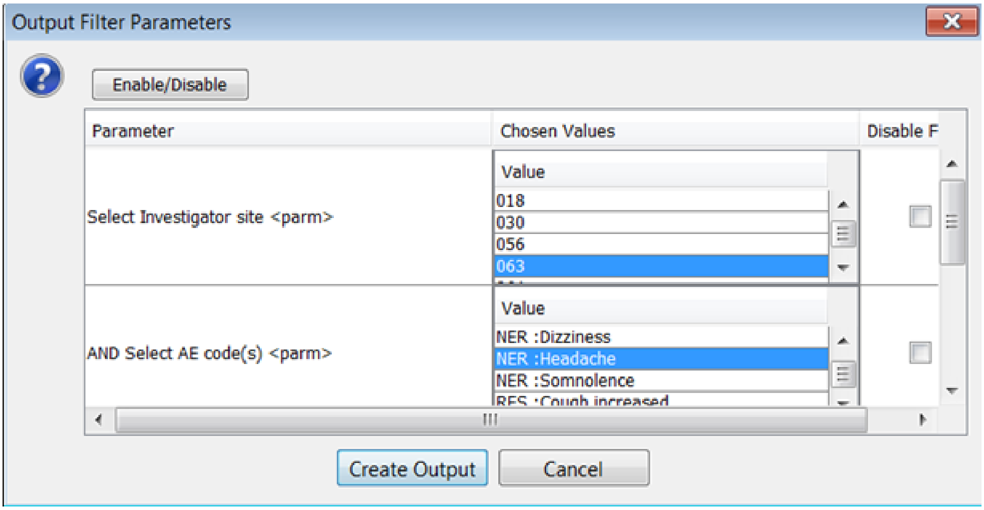
## *Enter runtime parameter*

When the user executes a report, graph or crosstab object with runtime parameter prompts define, first they see the **Output Filter Parameters** window prompting for all parameters.

Use the scroll bar to the right to view multiple parameters within the window.

The user may select multiple parameters with the CTRL or SHIFT key in the Display Values option.

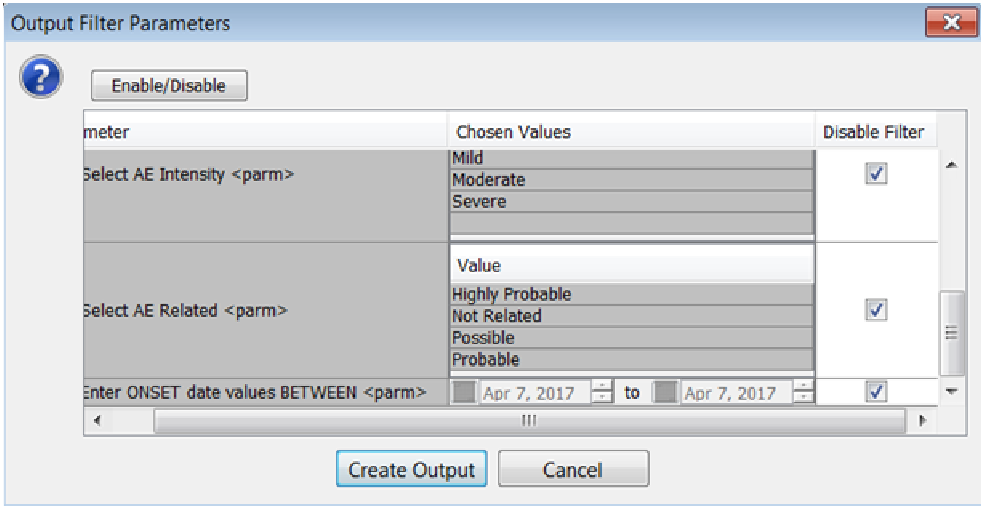
***Note: If the Parameter description appears truncated you can stretch the column width by dragging the header border.***



| Parameter | Chosen Values | Disable F |
|---|---|---|
| Select Investigator site <parm> | Value<br>018<br>030<br>056<br>063 | ☐ |
| AND Select AE code(s) <parm> | Value<br>NER :Dizziness<br>NER :Headache<br>NER :Somnolence<br>RES :Cough increased | ☐ |

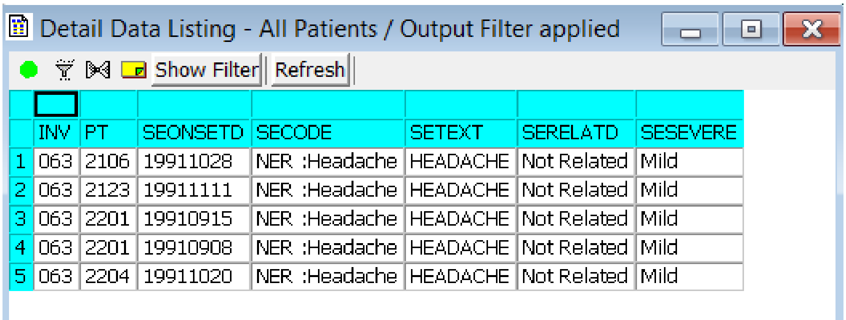
The ‘Disable Filter’ checkbox allows the user the flexibility to ‘turn off’ filtering for a particular item. If the ‘Disable Filter’ checkbox is grayed out then you cannot disable the runtime filter parameter as it was defined as required by the author in the output specification.

Click the ‘Enable/Disable’ button to enable or disable all the filters.



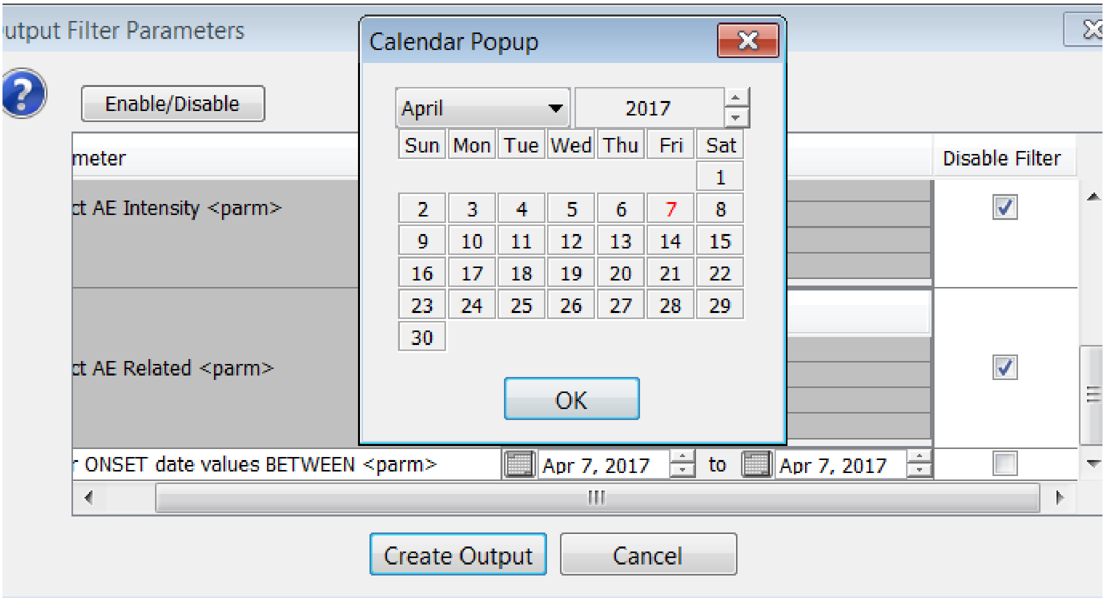
| meter | Chosen Values | Disable Filter |
|---|---|---|
| Select AE Intensity <parm> | Mild<br>Moderate<br>Severe | ☑ |
| Select AE Related <parm> | Value<br>Highly Probable<br>Not Related<br>Possible<br>Probable | ☑ |
| Enter ONSET date values BETWEEN <parm> | Apr 7, 2017 to Apr 7, 2017 | ☑ |

After making parameter selections, click **Create Output** to generate the results.



| | INV | PT | SEONSETD | SECODE | SETEXT | SERELATD | SESEVERE |
|---|---|---|---|---|---|---|---|
| 1 | 063 | 2106 | 19911028 | NER :Headache | HEADACHE | Not Related | Mild |
| 2 | 063 | 2123 | 19911111 | NER :Headache | HEADACHE | Not Related | Mild |
| 3 | 063 | 2201 | 19910915 | NER :Headache | HEADACHE | Not Related | Mild |
| 4 | 063 | 2201 | 19910908 | NER :Headache | HEADACHE | Not Related | Mild |
| 5 | 063 | 2204 | 19911020 | NER :Headache | HEADACHE | Not Related | Mild |

If the parameter defines a date the scroll bar next to the date field may be used to select the month, day, and year or display a calendar for selection. Use the month and year scrolls selecting the day, click OK closes the calendar window. The selected date is displayed date field.



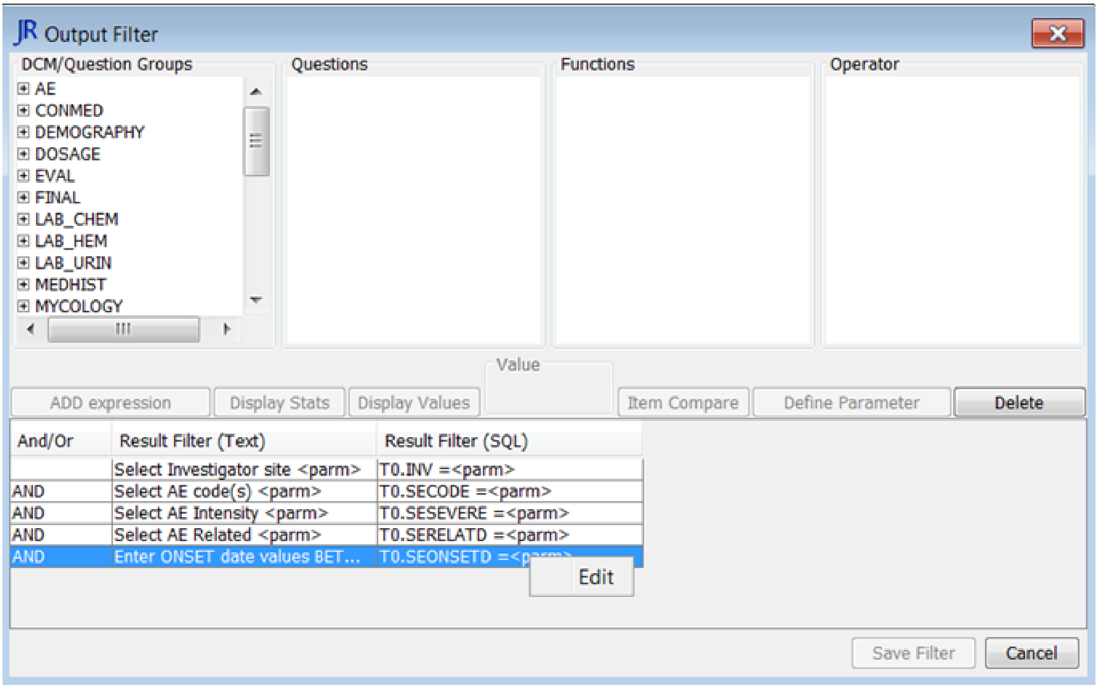
ct AE Intensity <parm> ☑

ct AE Related <parm> ☑

r ONSET date values BETWEEN <parm> Apr 7, 2017 to Apr 7, 2017 ☐

## *Edit runtime filter*

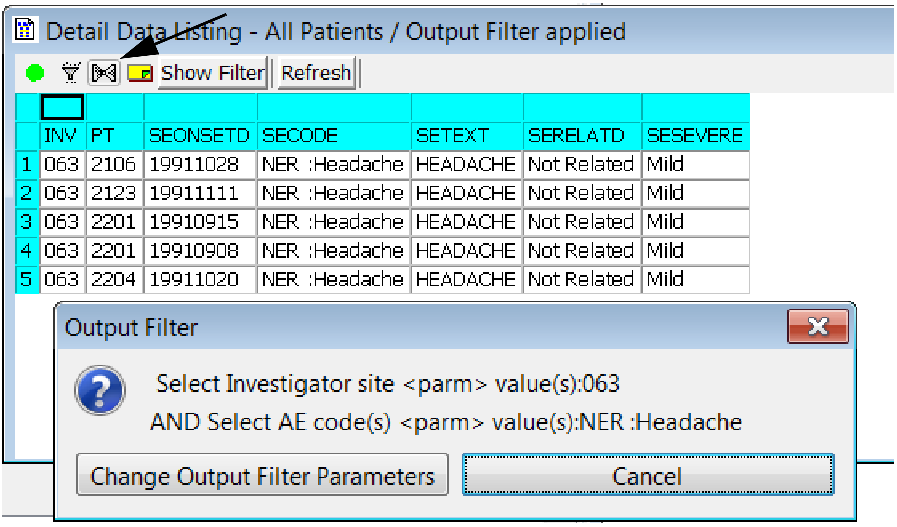
You may edit paramaterized filter definitions for reports, graphs, and crosstabs. After opening the saved output specification, click on the **FILTER ON** button (Classic mode) or **Output Filter Edit** button (New mode) to display the Output Filter window. Right mouse click on the parameter line to be edited. A floating **EDIT** button displays to access the Parameter Definition window to apply edits.



| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | Select Investigator site <parm> | T0.INV =<parm> |
| AND | Select AE code(s) <parm> | T0.SECODE =<parm> |
| AND | Select AE Intensity <parm> | T0.SESEVERE =<parm> |
| AND | Select AE Related <parm> | T0.SERELATD =<parm> |
| AND | Enter ONSET date values BET... | T0.SEONSETD =<parm> |

## Reset filter parameters

After you have created your output to view the results, you have the option to change the parameter filters from a particular result view. Click the Output Filter icon in the output window to open the Output Filter window.



| | INV | PT | SEONSETD | SECODE | SETEXT | SERELATD | SESEVERE |
|---|---|---|---|---|---|---|---|
| 1 | 063 | 2106 | 19911028 | NER :Headache | HEADACHE | Not Related | Mild |
| 2 | 063 | 2123 | 19911111 | NER :Headache | HEADACHE | Not Related | Mild |
| 3 | 063 | 2201 | 19910915 | NER :Headache | HEADACHE | Not Related | Mild |
| 4 | 063 | 2201 | 19910908 | NER :Headache | HEADACHE | Not Related | Mild |
| 5 | 063 | 2204 | 19911020 | NER :Headache | HEADACHE | Not Related | Mild |

Select Investigator site <parm> value(s):063
AND Select AE code(s) <parm> value(s):NER :Headache

The Output Filter window opens to display the selected parameter details with the option to **Change Output Filter Parameters.**

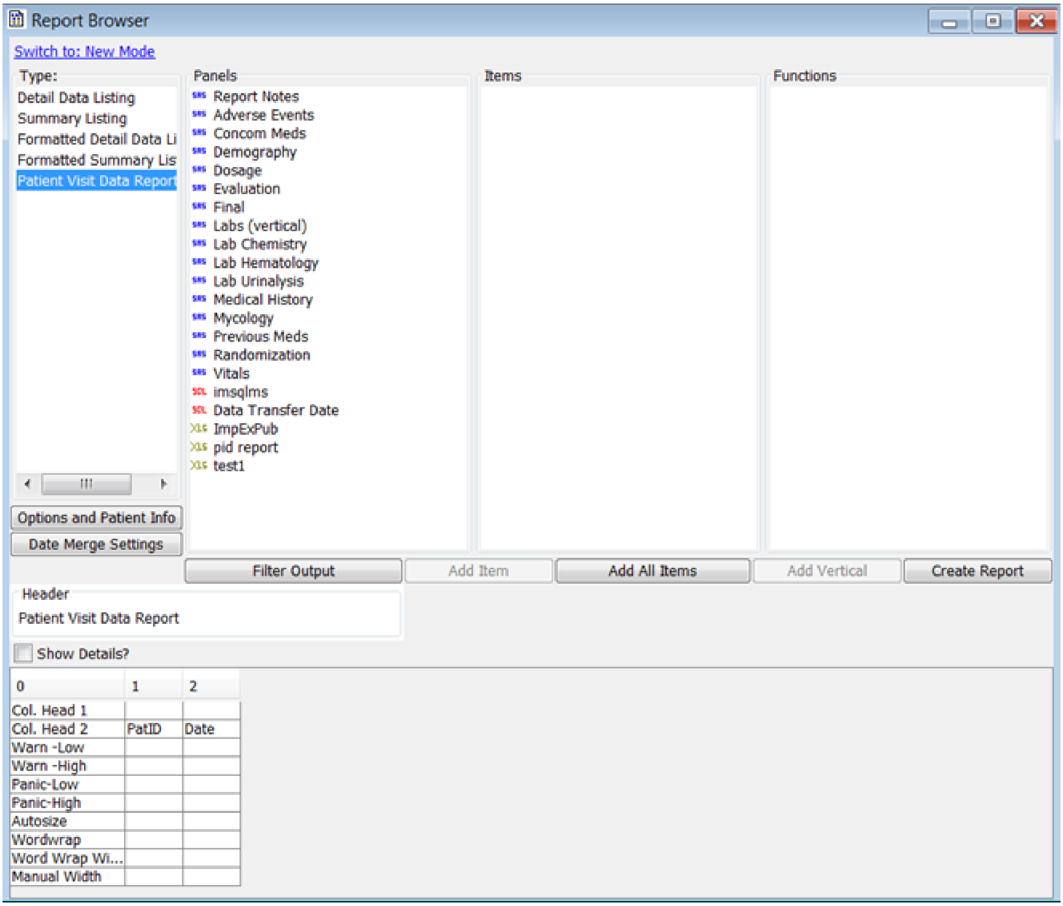
1. Click **Change Output Filter Parameters** to return to the Output Filters Parameters window.
2. Enter different parameter values.
3. Click **Create Output** and the current output window is refreshed with the new output filter parameters.
4. If you simply want to view the Output Filter details, click **OK** and close the window.

# Patient Visit Data Report

## *Select panel visit data report*

The patient visit data report supports joining multiple visit data into a single report without the usual problems encountered with multiple joins. You can select data from different panels containing multiple visit data and the records are linked by the Visit Date.

If a record contains several date fields you have the option to select which date for reference in your report specification. Initially when you select this report type the PatientID and Date are fixed items in the report and are required.



Header
Patient Visit Data Report

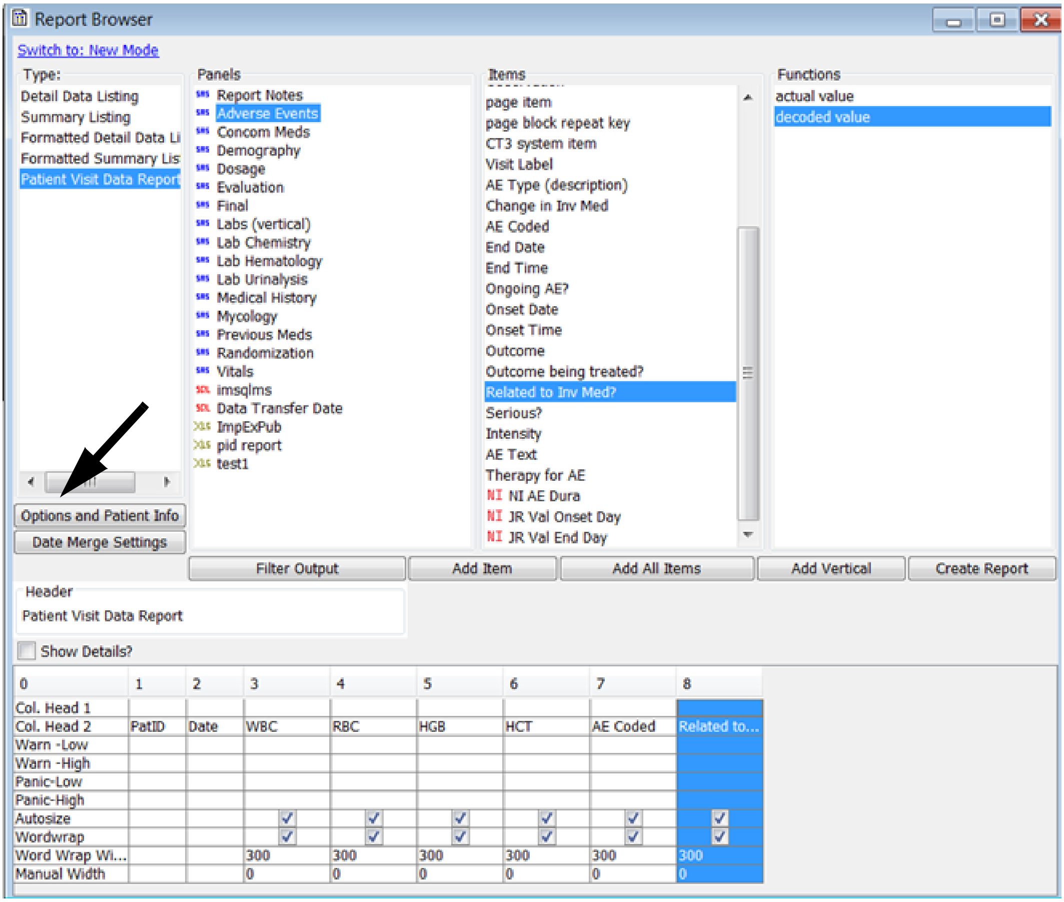
☐ Show Details?

| 0 | 1 | 2 |
|---|---|---|
| Col. Head 1 | | |
| Col. Head 2 | PatID | Date |
| Warn -Low | | |
| Warn -High | | |
| Panic-Low | | |
| Panic-High | | |
| Autosize | | |
| Wordwrap | | |
| Word Wrap Wi... | | |
| Manual Width | | |

## *Define patient visit data report*

You define the contents of a patient visit data report using the same method that you used to build the detail data listing:

1. Select a panel.
2. Select each item of interest.
3. For each item, select an appropriate function or use the default function type for the type of item selected.



Header
Patient Visit Data Report

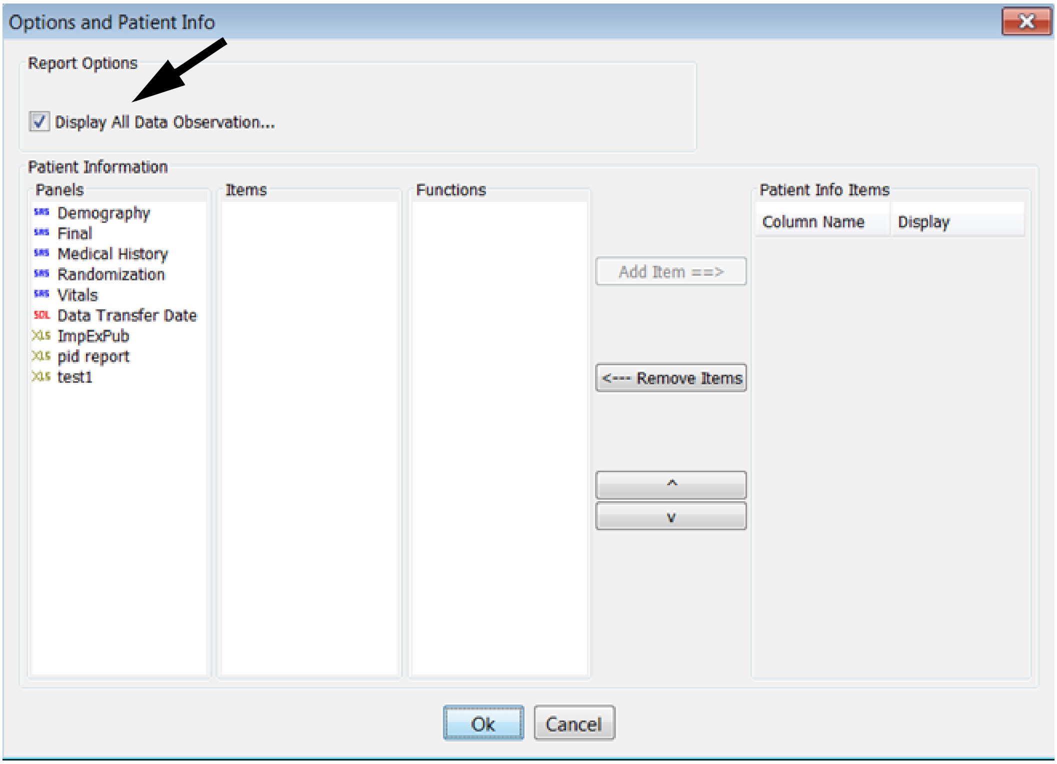
☐ Show Details?

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | | | |
| Col. Head 2 | PatID | Date | WBC | RBC | HGB | HCT | AE Coded | Related to... |
| Warn -Low | | | | | | | | |
| Warn -High | | | | | | | | |
| Panic-Low | | | | | | | | |
| Panic-High | | | | | | | | |
| Autosize | | | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Wordwrap | | | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Word Wrap Wi... | | | 300 | 300 | 300 | 300 | 300 | 300 |
| Manual Width | | | 0 | 0 | 0 | 0 | 0 | 0 |

## *Report options*

After adding all your items to the report template you can apply additional report options, patient information, formats and date merge settings.

4. Click **Options and Patient Info**. The Report Options and Patient Information window opens.



☑ Display All Data Observation...

5. **Report Options** supports multiple observations with the default set to ON for '**Display All Data Observations for each day?**'. For example, if there are multiple Adverse Events with the same Onset Date, they'll be listed on separate report rows as floating for that patient. The first Adverse Event row listed displays the Onset Date details, the next Adverse Event displays on the next row with the date field blank implying that it's from the same Onset Date.

   If you uncheck '**Display All Data Observations for each day?**' it only displays one value on the specified date, typically the last one for that date based upon the time/observation item setting.

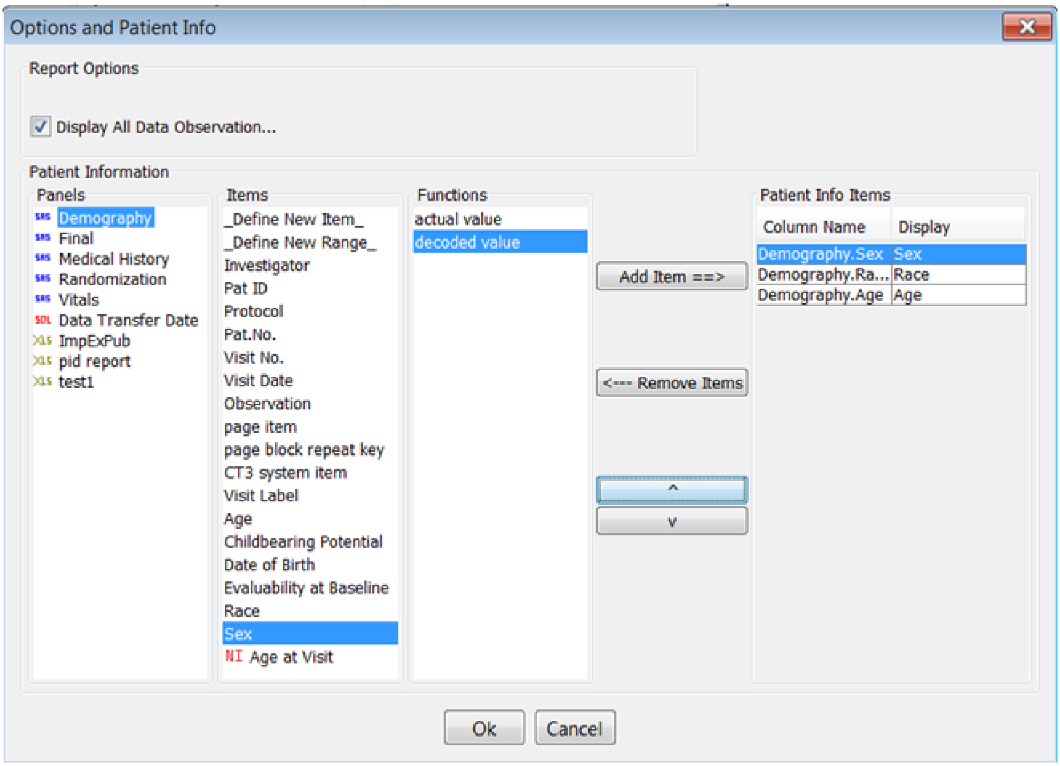
☑ Display All Data Observations for each day?

6. Optionally, click **Column Head Font** and **Data Font** to change fonts for Column Headers and Report Data.

## *Add Patient Info Items*

You can add patient information items to display as a column under the PatientID. For example, demographic or medical history information.

7. Select the panel and item.
8. Click **Add Item** and **Remove Item** to add or remove items from the Patient Info Items list.



☑ Display All Data Observation...

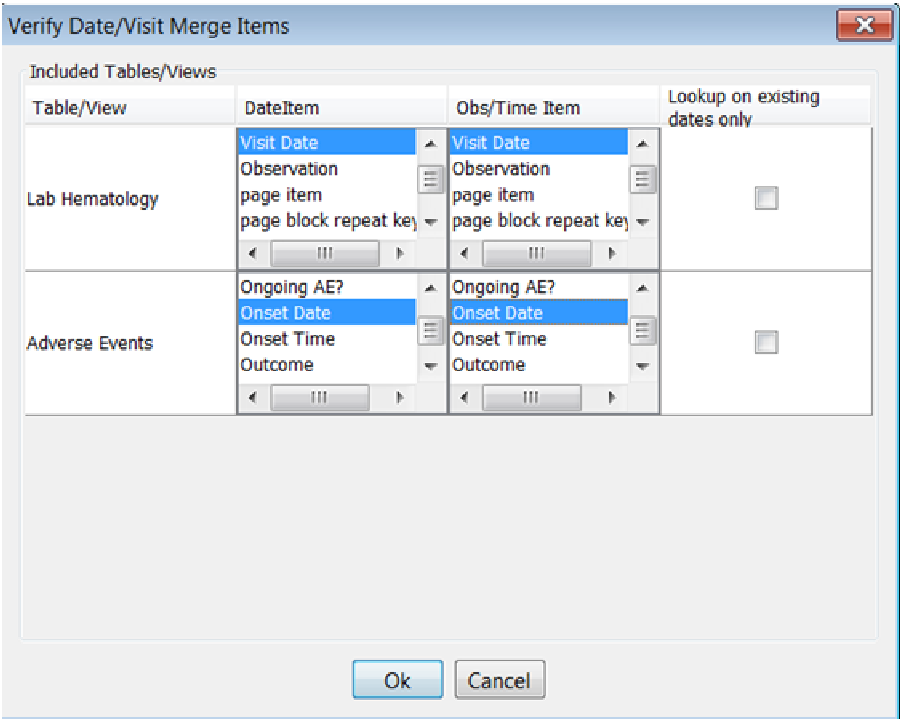
| Column Name | Display |
|---|---|
| Demography.Sex | Sex |
| Demography.Ra... | Race |
| Demography.Age | Age |

9. Use the Up/Down to reorder the added Patient Info Items list.
10. Click **OK.**

## *Define Date Merge Settings*

When you add items to your report specification the user must tell JReview what date fields to merge by for each panel being used in the report. If a panel contains multiple date fields you have the option to specify a more appropriate date. For example, if Onset Date is preferred in the Adverse Events panel instead of the default Visit Date. A message displays requiring you to select a specific date item if you included panels containing multiple dates.

11.Click **Date Merge Settings**. The Verify Date/Visit Merge Items window opens.



Verify Date/Visit Merge Items

Included Tables/Views

| Table/View | DateItem | Obs/Time Item | Lookup on existing dates only |
|---|---|---|---|
| Lab Hematology | Visit Date<br>Observation<br>page item<br>page block repeat key | Visit Date<br>Observation<br>page item<br>page block repeat key | ☐ |
| Adverse Events | Ongoing AE?<br>Onset Date<br>Onset Time<br>Outcome | Ongoing AE?<br>Onset Date<br>Onset Time<br>Outcome | ☐ |

12.Select the preferred Date Item and Obs/Time Item for each table/View.

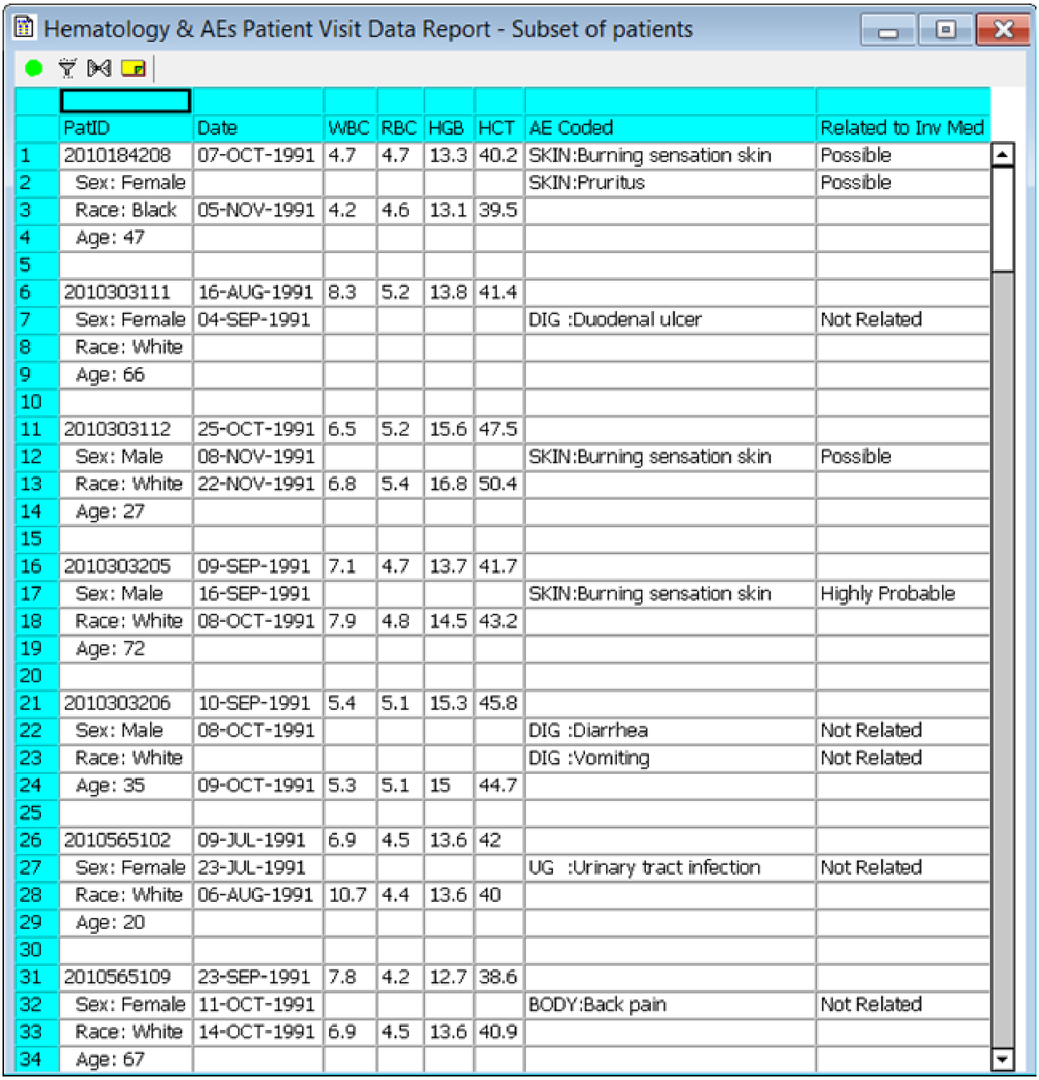
13.Click **OK**.

14. Enter a report Heading.

15.Click **Create Report**.

Observe the Adverse Events where the Onset Date is different from the Visit Date and displays on a new row. This distinguishes the Adverse Event data from the scheduled visit data for the Hematology results.

If a time/observation item were applicable it only orders items within it’s own panel or table, so joined panels are independent of each other regarding sort.

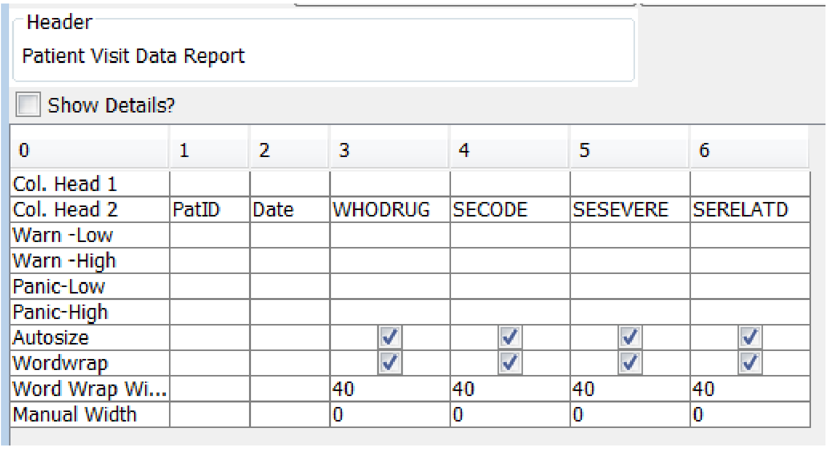


Hematology & AEs Patient Visit Data Report - Subset of patients

| | PatID | Date | WBC | RBC | HGB | HCT | AE Coded | Related to Inv Med |
|---|---|---|---|---|---|---|---|---|
| 1 | 2010184208 | 07-OCT-1991 | 4.7 | 4.7 | 13.3 | 40.2 | SKIN:Burning sensation skin | Possible |
| 2 | Sex: Female | | | | | | SKIN:Pruritus | Possible |
| 3 | Race: Black | 05-NOV-1991 | 4.2 | 4.6 | 13.1 | 39.5 | | |
| 4 | Age: 47 | | | | | | | |
| 5 | | | | | | | | |
| 6 | 2010303111 | 16-AUG-1991 | 8.3 | 5.2 | 13.8 | 41.4 | | |
| 7 | Sex: Female | 04-SEP-1991 | | | | | DIG :Duodenal ulcer | Not Related |
| 8 | Race: White | | | | | | | |
| 9 | Age: 66 | | | | | | | |
| 10 | | | | | | | | |
| 11 | 2010303112 | 25-OCT-1991 | 6.5 | 5.2 | 15.6 | 47.5 | | |
| 12 | Sex: Male | 08-NOV-1991 | | | | | SKIN:Burning sensation skin | Possible |
| 13 | Race: White | 22-NOV-1991 | 6.8 | 5.4 | 16.8 | 50.4 | | |
| 14 | Age: 27 | | | | | | | |
| 15 | | | | | | | | |
| 16 | 2010303205 | 09-SEP-1991 | 7.1 | 4.7 | 13.7 | 41.7 | | |
| 17 | Sex: Male | 16-SEP-1991 | | | | | SKIN:Burning sensation skin | Highly Probable |
| 18 | Race: White | 08-OCT-1991 | 7.9 | 4.8 | 14.5 | 43.2 | | |
| 19 | Age: 72 | | | | | | | |
| 20 | | | | | | | | |
| 21 | 2010303206 | 10-SEP-1991 | 5.4 | 5.1 | 15.3 | 45.8 | | |
| 22 | Sex: Male | 08-OCT-1991 | | | | | DIG :Diarrhea | Not Related |
| 23 | Race: White | | | | | | DIG :Vomiting | Not Related |
| 24 | Age: 35 | 09-OCT-1991 | 5.3 | 5.1 | 15 | 44.7 | | |
| 25 | | | | | | | | |
| 26 | 2010565102 | 09-JUL-1991 | 6.9 | 4.5 | 13.6 | 42 | | |
| 27 | Sex: Female | 23-JUL-1991 | | | | | UG :Urinary tract infection | Not Related |
| 28 | Race: White | 06-AUG-1991 | 10.7 | 4.4 | 13.6 | 40 | | |
| 29 | Age: 20 | | | | | | | |
| 30 | | | | | | | | |
| 31 | 2010565109 | 23-SEP-1991 | 7.8 | 4.2 | 12.7 | 38.6 | | |
| 32 | Sex: Female | 11-OCT-1991 | | | | | BODY:Back pain | Not Related |
| 33 | Race: White | 14-OCT-1991 | 6.9 | 4.5 | 13.6 | 40.9 | | |
| 34 | Age: 67 | | | | | | | |

## *Lookup on existing date*

A ‘Lookup’ question within the DateMerge dialog allows you to control which data contributes dates or to only lookup on existing dates. In the following patient visit data report example, data was specified for Conmeds and Adverse Events.



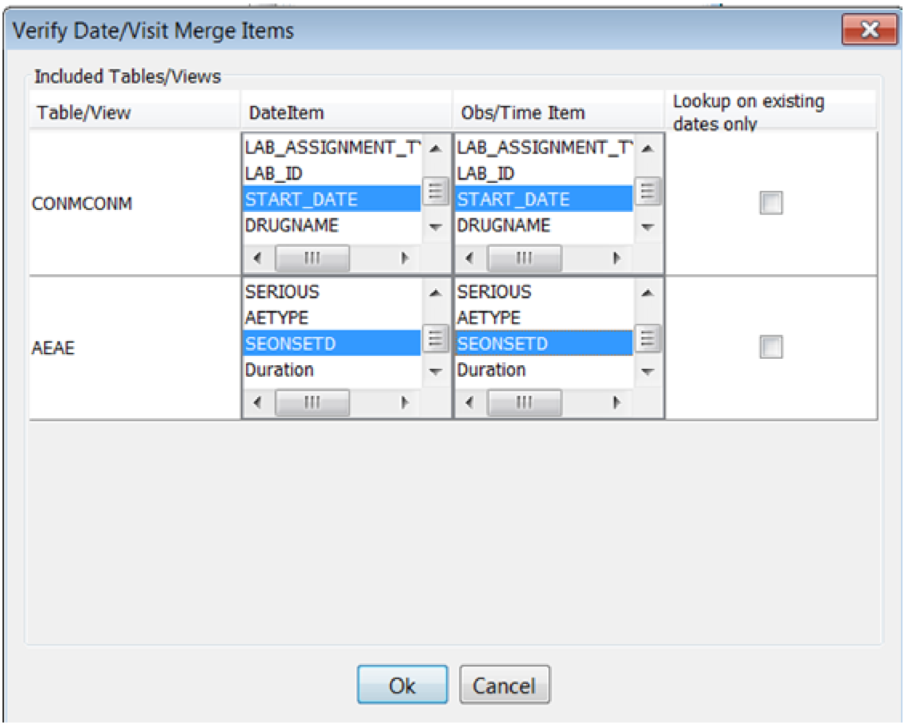
Header

Patient Visit Data Report

☐ Show Details?

| 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | |
| Col. Head 2 | PatID | Date | WHODRUG | SECODE | SESEVERE | SERELATD |
| Warn -Low | | | | | | |
| Warn -High | | | | | | |
| Panic-Low | | | | | | |
| Panic-High | | | | | | |
| Autosize | | | ☑ | ☑ | ☑ | ☑ |
| Wordwrap | | | ☑ | ☑ | ☑ | ☑ |
| Word Wrap Wi... | | | 40 | 40 | 40 | 40 |
| Manual Width | | | 0 | 0 | 0 | 0 |

The first listing shows the DateMerge lookup questions with the default settings for ‘NO’.



Verify Date/Visit Merge Items

Included Tables/Views

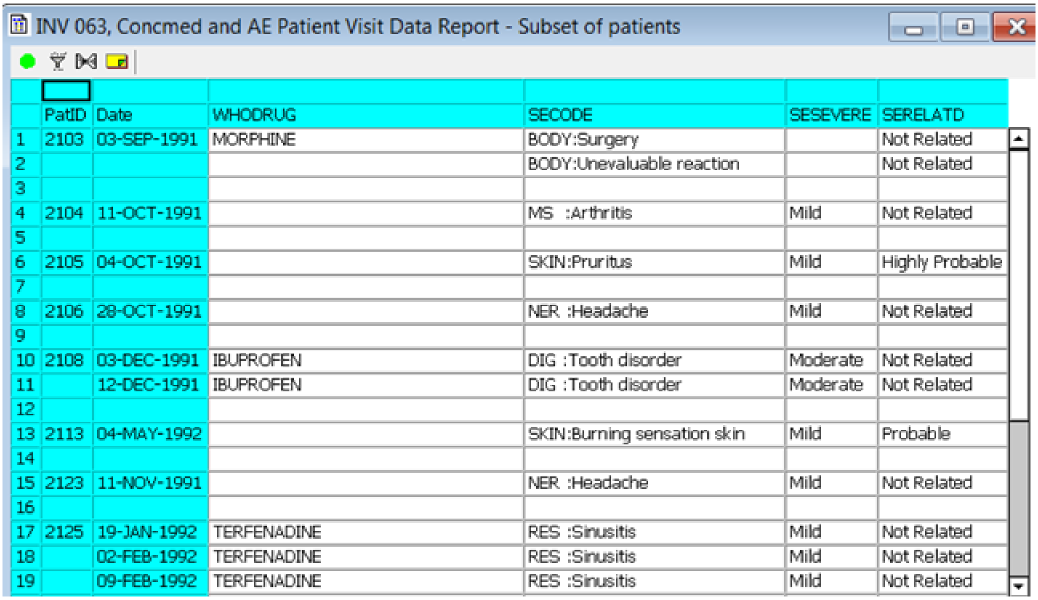
| Table/View | DateItem | Obs/Time Item | Lookup on existing dates only |
|---|---|---|---|
| CONMCONM | LAB_ASSIGNMENT_T<br>LAB_ID<br>START_DATE<br>DRUGNAME | LAB_ASSIGNMENT_T<br>LAB_ID<br>START_DATE<br>DRUGNAME | ☐ |
| AEAE | SERIOUS<br>AETYPE<br>SEONSETD<br>Duration | SERIOUS<br>AETYPE<br>SEONSETD<br>Duration | ☐ |

A patient selection criteria was applied to select only the patients for Investigator 063. The listing shows all records are displayed if present for Conmeds and Adverse Events.

INV 063, Concmed and AE Patient Visit Data Report - Subset of patients

| | PatID | Date | WHODRUG | SECODE | SESEVERE | SERELATD |
|---|---|---|---|---|---|---|
| 1 | 2103 | 01-AUG-1991 | NAPROXEN | | | |
| 2 | | 03-SEP-1991 | MORPHINE | BODY:Surgery | | Not Related |
| 3 | | | | BODY:Unevaluable reaction | | Not Related |
| 4 | | 05-SEP-1991 | PROPOXYPHENE-N/APAP | | | |
| 5 | | | | | | |
| 6 | 2104 | 11-OCT-1991 | ACETYLSALICYLIC ACID | MS :Arthritis | Mild | Not Related |
| 7 | | | | | | |
| 8 | 2105 | 03-OCT-1991 | MULTIVITAMINS | | | |
| 9 | | 04-OCT-1991 | | SKIN:Pruritus | Mild | Highly Probable |
| 10 | | | | | | |
| 11 | 2106 | 01-JAN-1981 | GLYBURIDE | | | |
| 12 | | 01-JAN-1988 | SELEGILINE | | | |
| 13 | | | SINEMET | | | |
| 14 | | 28-OCT-1991 | ACETYLSALICYLIC ACID | NER :Headache | Mild | Not Related |
| 15 | | | | | | |
| 16 | 2108 | 03-DEC-1991 | IBUPROFEN | DIG :Tooth disorder | Moderate | Not Related |
| 17 | | 12-DEC-1991 | IBUPROFEN | DIG :Tooth disorder | Moderate | Not Related |
| 18 | | | | | | |
| 19 | 2113 | 01-JAN-1989 | GLYBURIDE | | | |
| 20 | | | DILTIAZEM HYDROCHLORIDE | | | |
| 21 | | | GLYBURIDE | | | |
| 22 | | 04-MAY-1992 | | SKIN:Burning sensation skin | Mild | Probable |
| 23 | | | | | | |
| 24 | 2123 | 01-JAN-1986 | ATENOLOL | | | |
| 25 | | 11-NOV-1991 | MIDRIN | NER :Headache | Mild | Not Related |
| 26 | | | | | | |
| 27 | 2125 | 19-JAN-1992 | TERFENADINE | RES :Sinusitis | Mild | Not Related |
| 28 | | 02-FEB-1992 | TERFENADINE | RES :Sinusitis | Mild | Not Related |
| 29 | | 09-FEB-1992 | TERFENADINE | RES :Sinusitis | Mild | Not Related |
| 30 | | | | | | |
| 31 | 2127 | 25-FEB-1992 | | SKIN:Burning sensation skin | Mild | Highly Probable |
| 32 | | 02-MAR-1992 | BISACODYL | | | |
| 33 | | | FLEET PHOSPHO-SODA | | | |
| 34 | | | | | | |
| 35 | 2201 | 08-SEP-1991 | IBUPROFEN | NER :Headache | Mild | Not Related |
| 36 | | 15-SEP-1991 | IBUPROFEN | NER :Headache | Mild | Not Related |

The next report output shows the Conmed lookup on existing date question is checked ON. Now the listing displays only those Conmed records with the same date as the Adverse Event records. Conmed records with a different date than the Adverse Event records are dropped from the report.

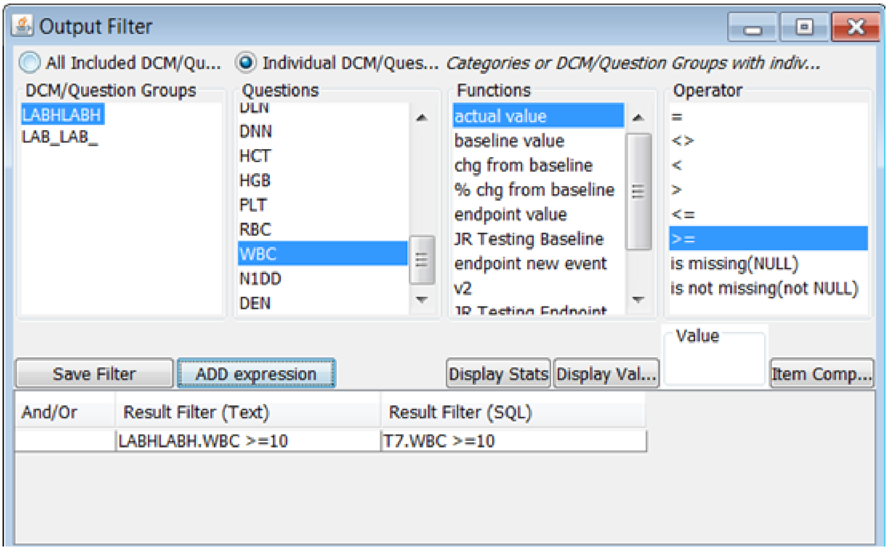

INV 063, Concmed and AE Patient Visit Data Report - Subset of patients

| | PatID | Date | WHODRUG | SECODE | SESEVERE | SERELATD |
|---|---|---|---|---|---|---|
| 1 | 2103 | 03-SEP-1991 | MORPHINE | BODY:Surgery | | Not Related |
| 2 | | | | BODY:Unevaluable reaction | | Not Related |
| 3 | | | | | | |
| 4 | 2104 | 11-OCT-1991 | | MS :Arthritis | Mild | Not Related |
| 5 | | | | | | |
| 6 | 2105 | 04-OCT-1991 | | SKIN:Pruritus | Mild | Highly Probable |
| 7 | | | | | | |
| 8 | 2106 | 28-OCT-1991 | | NER :Headache | Mild | Not Related |
| 9 | | | | | | |
| 10 | 2108 | 03-DEC-1991 | IBUPROFEN | DIG :Tooth disorder | Moderate | Not Related |
| 11 | | 12-DEC-1991 | IBUPROFEN | DIG :Tooth disorder | Moderate | Not Related |
| 12 | | | | | | |
| 13 | 2113 | 04-MAY-1992 | | SKIN:Burning sensation skin | Mild | Probable |
| 14 | | | | | | |
| 15 | 2123 | 11-NOV-1991 | | NER :Headache | Mild | Not Related |
| 16 | | | | | | |
| 17 | 2125 | 19-JAN-1992 | TERFENADINE | RES :Sinusitis | Mild | Not Related |
| 18 | | 02-FEB-1992 | TERFENADINE | RES :Sinusitis | Mild | Not Related |
| 19 | | 09-FEB-1992 | TERFENADINE | RES :Sinusitis | Mild | Not Related |

## *Apply output filter*

After you define the specifications of your patient visit data report, you can use the Filter Output to filter data for inclusion comparing filtered and unfiltered results.

1. Click the **Filter Output button** in the Report Browser window. The Output Filter window opens.
2. The **All Included Panels** option allows you to define an output filter based on those items present in all the included panels. This option will apply the output filter across all panels included in the patient visit data report.
3. The **Individual Panels** option allows you to define an output filter based on specific panels and items. This option will apply the output filter across to specific panels.
4. The output filter looks and operates similar to the patient selection criteria window. Select the panel item and value or range value to create a row filtering criteria. The selection of the values or range values are supported by **Display Stats** and **Display Values**.



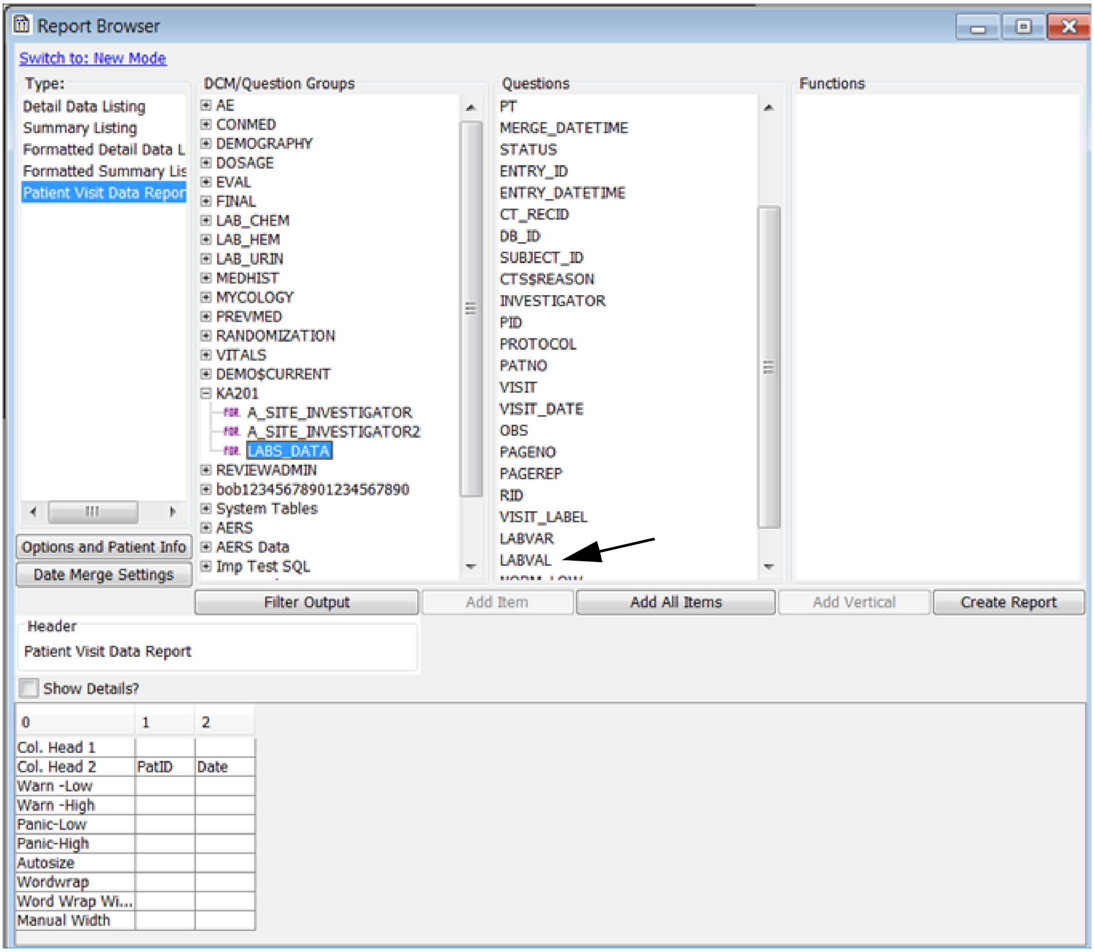
| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | LABHLABH.WBC >=10 | T7.WBC >=10 |

5. Click **Save Filter.** The **Filter Output** button in the Report Browser window toggles to **Filter is ON**. The output filter is applied to the report output when you click **Create Report.**

## *Add vertical lab*

For a vertical lab panel it is necessary to select the ‘Lab Value’ and pivot the individual selected lab data items. Select a vertical lab panel and access a ‘Lab Value’ item (data items representing the lab result) then click the ‘Add Vertical’ button which functions to pivot the item. A list displays for all the lab variable names where you select the lab items to add to your report template. The lab item displays a column for the selected lab test to the report while the data is being pulled dynamically from the vertical lab table. Repeat each step to add more lab data items to the report display.

1. Select a vertical lab panel.
2. Select the ‘Lab Value’ and click **ADD Vertical**.



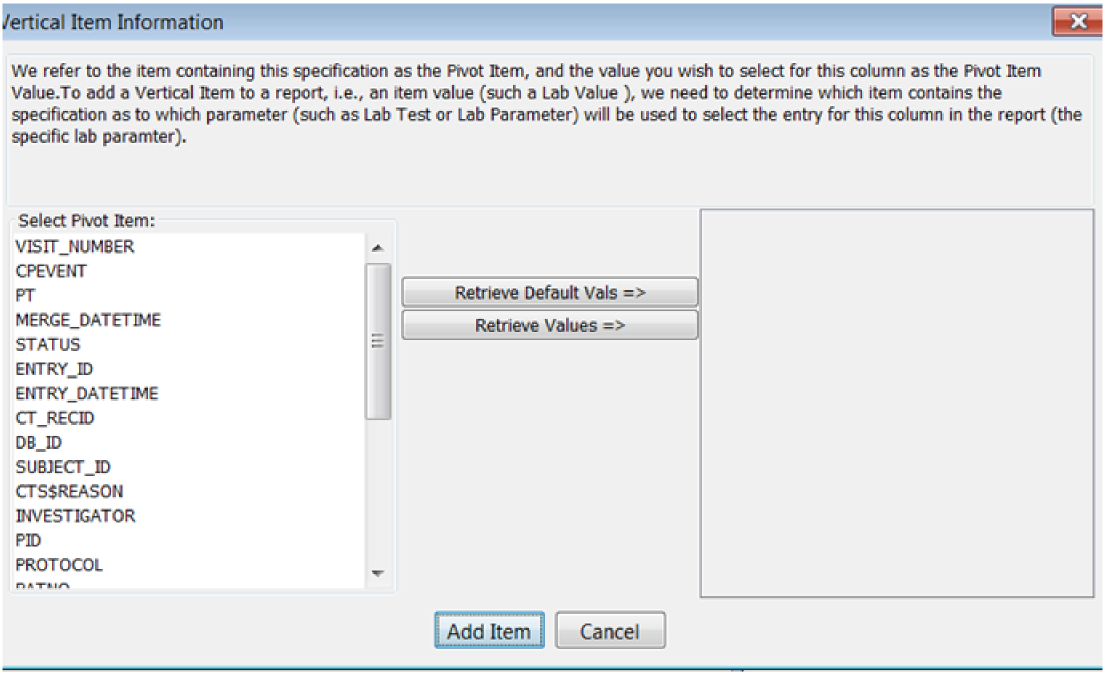
Header
Patient Visit Data Report

☐ Show Details?

| 0 | 1 | 2 |
|---|---|---|
| Col. Head 1 | | |
| Col. Head 2 | PatID | Date |
| Warn -Low | | |
| Warn -High | | |
| Panic-Low | | |
| Panic-High | | |
| Autosize | | |
| Wordwrap | | |
| Word Wrap Wi... | | |
| Manual Width | | |

The **Vertical Item Information** window opens. The instructions explain how to select the data item which represents the individual lab tests.

3. Select the Pivot Item Value,i.e., the item which contains the test name or description.
4. Click **Retrieve Values**.



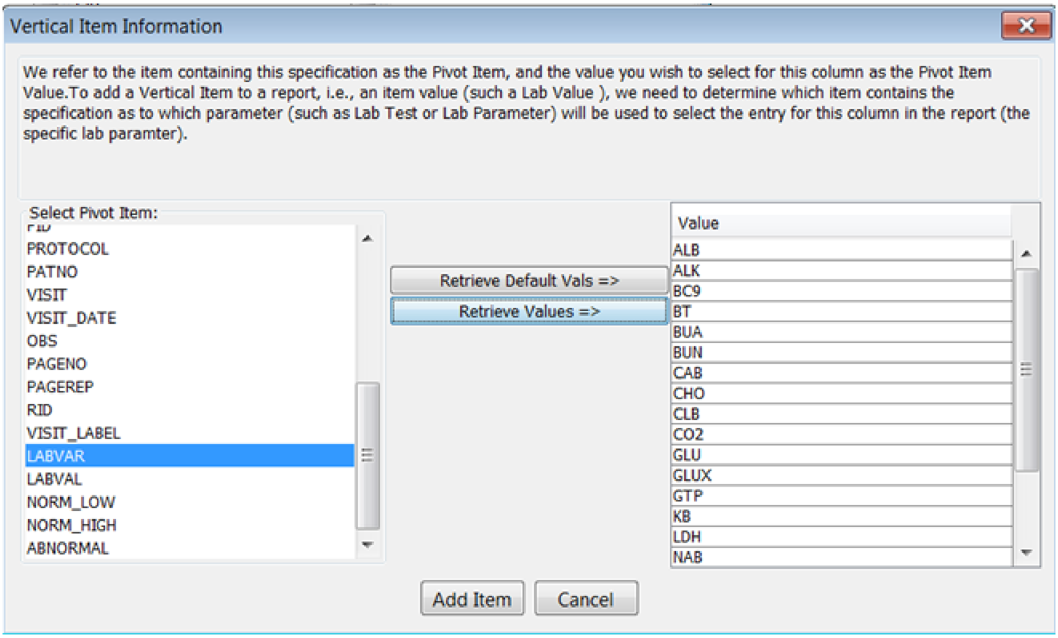
We refer to the item containing this specification as the Pivot Item, and the value you wish to select for this column as the Pivot Item Value.To add a Vertical Item to a report, i.e., an item value (such a Lab Value ), we need to determine which item contains the specification as to which parameter (such as Lab Test or Lab Parameter) will be used to select the entry for this column in the report (the specific lab paramter).

The "**Retrieve Default Vals**" button is only enabled for Oracle Clinical database and calls a JRServer command to gather the list contents on right of dialog.

The difference between the two buttons is the **Retrieve Values** button returns a list of unique values (similar to the Display Values), by accessing the actual data table and returning the unique occurrences in the data. This may be a slow process for large tables such as Labs.

The **Retrieve Default Vals** button instead accesses a list of values from a table available in Oracle Clinical which essentially has a list of possible values. This will impact for faster performance. JReview supports this feature automatically as the user is accessing their Oracle Clinical database, and they're accessing a field that has the table information behind it to support this access. Not all columns have that information in Oracle Clinical.

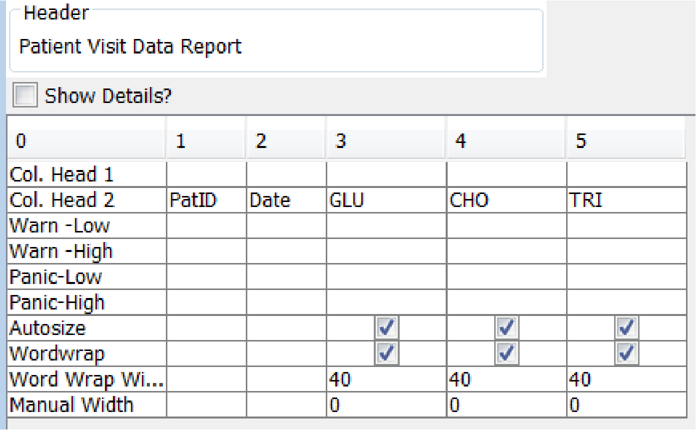
5. Select the **Pivot Item Value** and click **ADD Item**.



Vertical Item Information

We refer to the item containing this specification as the Pivot Item, and the value you wish to select for this column as the Pivot Item Value.To add a Vertical Item to a report, i.e., an item value (such a Lab Value ), we need to determine which item contains the specification as to which parameter (such as Lab Test or Lab Parameter) will be used to select the entry for this column in the report (the specific lab paramter).

6. Repeat the steps to add additional lab tests to the report.



Header

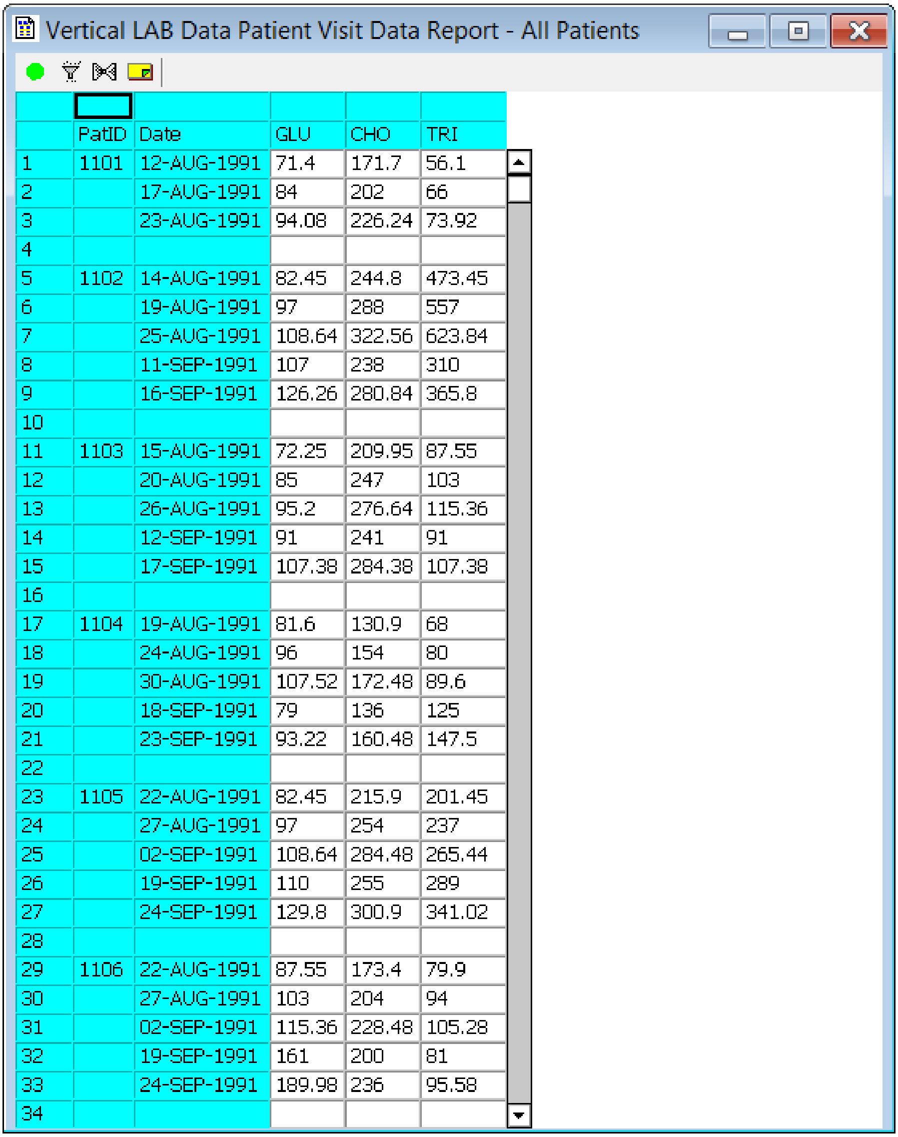
Patient Visit Data Report

☐ Show Details?

| 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| Col. Head 1 | | | | | |
| Col. Head 2 | PatID | Date | GLU | CHO | TRI |
| Warn -Low | | | | | |
| Warn -High | | | | | |
| Panic-Low | | | | | |
| Panic-High | | | | | |
| Autosize | | | ☑ | ☑ | ☑ |
| Wordwrap | | | ☑ | ☑ | ☑ |
| Word Wrap Wi... | | | 40 | 40 | 40 |
| Manual Width | | | 0 | 0 | 0 |

7. Add report options for patient information (optional).
8. Enter Date Merge Settings (required).
9. Enter a report Heading.

10.Click **Create Report**.



Vertical LAB Data Patient Visit Data Report - All Patients

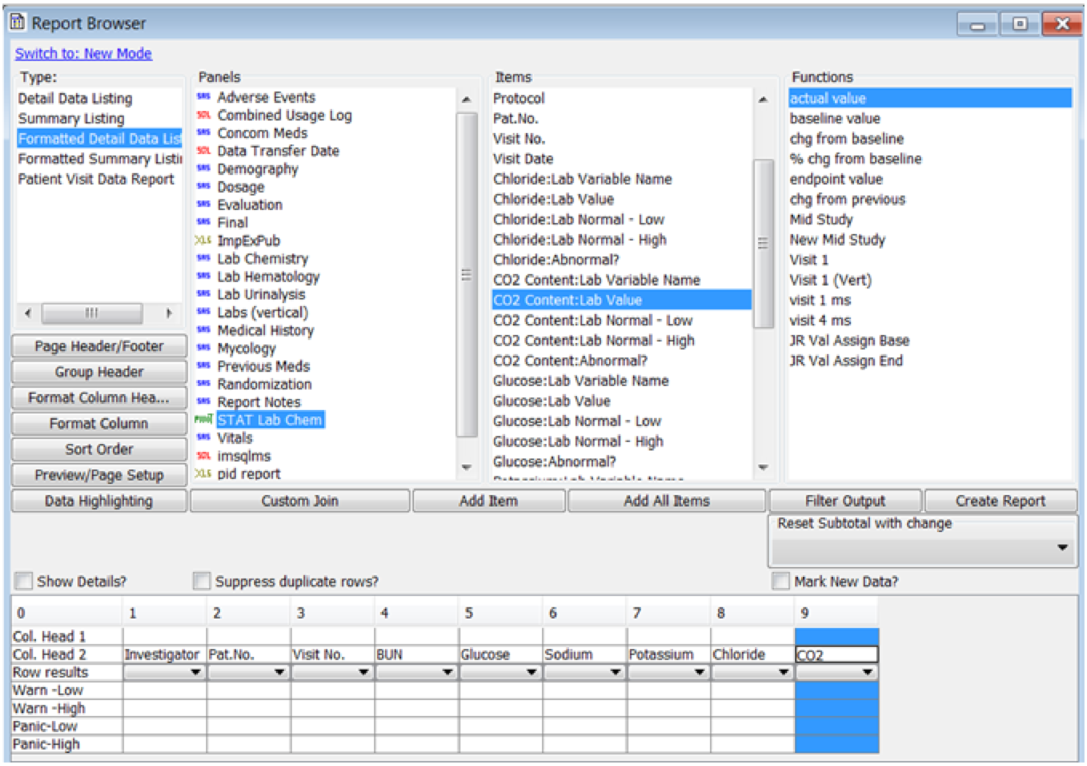
| | PatID | Date | GLU | CHO | TRI |
|---|---|---|---|---|---|
| 1 | 1101 | 12-AUG-1991 | 71.4 | 171.7 | 56.1 |
| 2 | | 17-AUG-1991 | 84 | 202 | 66 |
| 3 | | 23-AUG-1991 | 94.08 | 226.24 | 73.92 |
| 4 | | | | | |
| 5 | 1102 | 14-AUG-1991 | 82.45 | 244.8 | 473.45 |
| 6 | | 19-AUG-1991 | 97 | 288 | 557 |
| 7 | | 25-AUG-1991 | 108.64 | 322.56 | 623.84 |
| 8 | | 11-SEP-1991 | 107 | 238 | 310 |
| 9 | | 16-SEP-1991 | 126.26 | 280.84 | 365.8 |
| 10 | | | | | |
| 11 | 1103 | 15-AUG-1991 | 72.25 | 209.95 | 87.55 |
| 12 | | 20-AUG-1991 | 85 | 247 | 103 |
| 13 | | 26-AUG-1991 | 95.2 | 276.64 | 115.36 |
| 14 | | 12-SEP-1991 | 91 | 241 | 91 |
| 15 | | 17-SEP-1991 | 107.38 | 284.38 | 107.38 |
| 16 | | | | | |
| 17 | 1104 | 19-AUG-1991 | 81.6 | 130.9 | 68 |
| 18 | | 24-AUG-1991 | 96 | 154 | 80 |
| 19 | | 30-AUG-1991 | 107.52 | 172.48 | 89.6 |
| 20 | | 18-SEP-1991 | 79 | 136 | 125 |
| 21 | | 23-SEP-1991 | 93.22 | 160.48 | 147.5 |
| 22 | | | | | |
| 23 | 1105 | 22-AUG-1991 | 82.45 | 215.9 | 201.45 |
| 24 | | 27-AUG-1991 | 97 | 254 | 237 |
| 25 | | 02-SEP-1991 | 108.64 | 284.48 | 265.44 |
| 26 | | 19-SEP-1991 | 110 | 255 | 289 |
| 27 | | 24-SEP-1991 | 129.8 | 300.9 | 341.02 |
| 28 | | | | | |
| 29 | 1106 | 22-AUG-1991 | 87.55 | 173.4 | 79.9 |
| 30 | | 27-AUG-1991 | 103 | 204 | 94 |
| 31 | | 02-SEP-1991 | 115.36 | 228.48 | 105.28 |
| 32 | | 19-SEP-1991 | 161 | 200 | 81 |
| 33 | | 24-SEP-1991 | 189.98 | 236 | 95.58 |
| 34 | | | | | |

# Formatted reports

## Select formatted listing type

When you select the report type for Formatted Detail Data Listing or Formatted Summary Listing the associated function buttons are displayed. JReview provides default formats to assist in the report setup. Overall report default settings are:

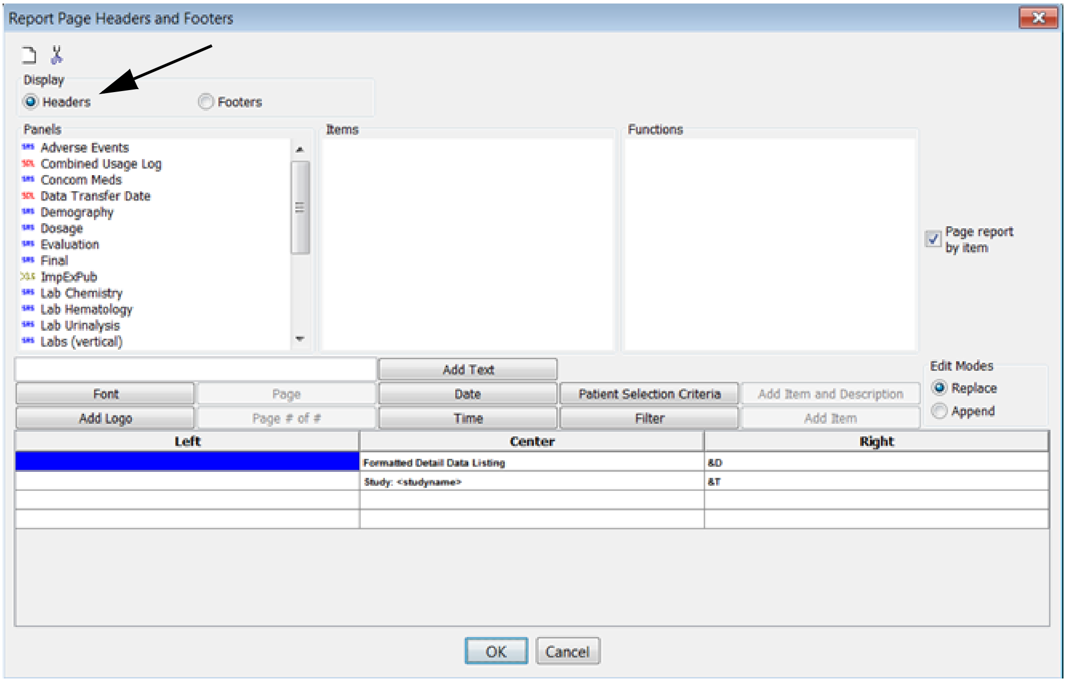
- Font is Arial.
- Page Setup for landscape with one inch margins.



## *Apply Page Header and Footer*

To enter descriptive information to the Header and Footer area:

1. Click on the Page Header/Footer button to open Report Page Headers and Footers window. The default settings for headers are:
    a. Default title is the report type displayed in the center cell as Formatted Detail Data Listing or Formatted Summary Listing.
    b. Date and Time on the right.
    c. Font is BOLD **10.**
    d. Page Report By Item.



● Headers ○ Footers

☑ Page report by item

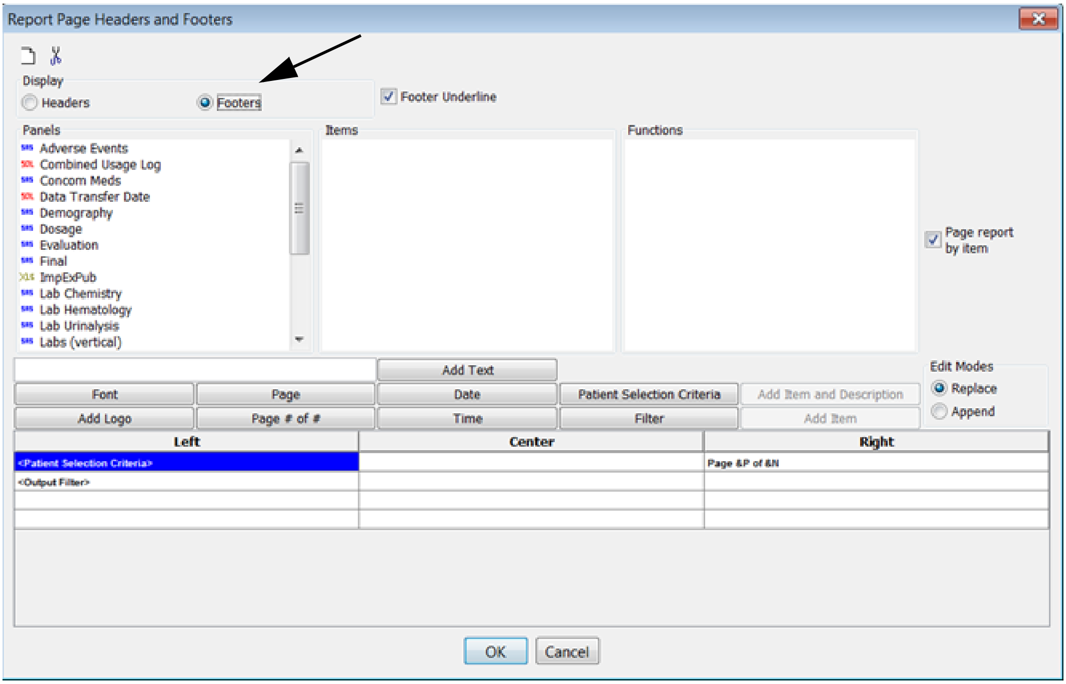
Edit Modes: ● Replace ○ Append

| Left | Center | Right |
|---|---|---|
| | Formatted Detail Data Listing | &D |
| | Study: <studyname> | &T |
| | | |
| | | |

2. Click a particular column/row cell within the template for your item or text entry location. Each cell can contain up to two items.
3. Use the Edit Modes to Replace or Append changes.
4. Use the various item button selections to add Header information and the Add Text button to enter free text descriptions. You may click on a cell and use the scissors icon to delete the contents.
5. Select an item to generate a page break in your report for a specified item with **Page Report By Item**.

    ***Note: It is not required to have an item be defined as a page by item, and more than one item can be defined.***

6. Click the Font button to change font, style and size.
7. Optionally, **Add Logo** to either Header or Footer definition. The display contents of ‘logo.gif’ file is located in the JR Server directory.
8. Click Display Footers. Follow the same steps to enter and make changes to the footer. The default settings for footers are:
    a. Patient Selection Criteria and Output Filter on the Left.
    b. Page number on the right.
    c. Underline above the footer.
    d. Font is BOLD **10**.
9. Turn the Footer Underline ON or OFF.
10. Click **OK** to save Header and Footer.



Display: ○ Headers ● Footers

☑ Footer Underline

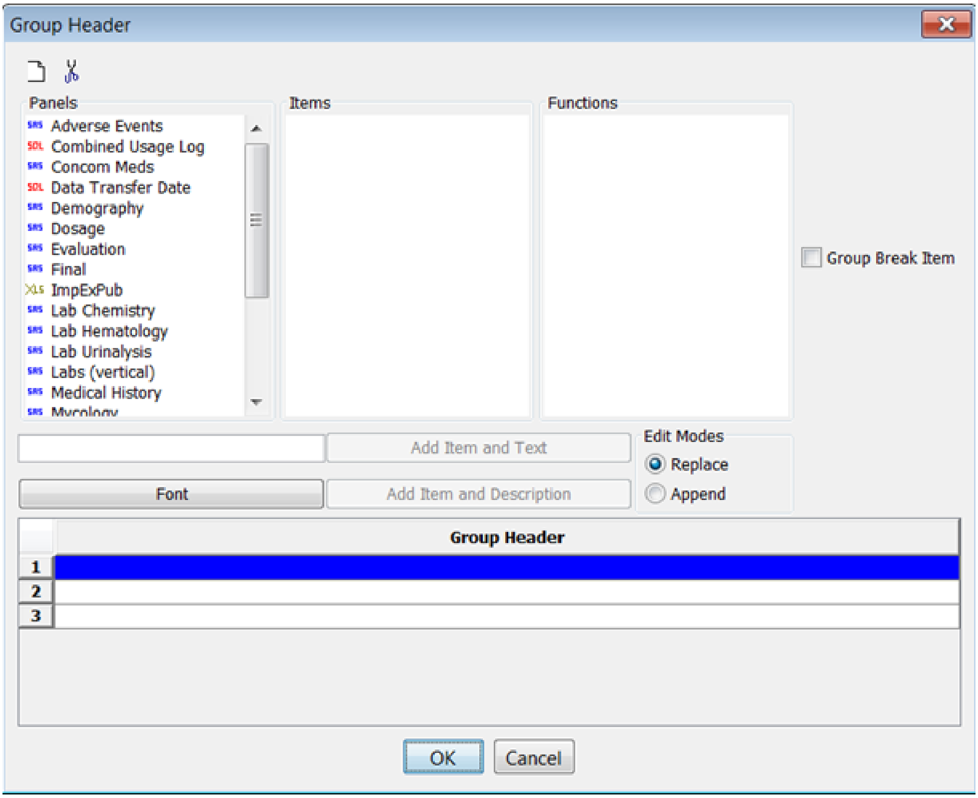
☑ Page report by item

Edit Modes: ● Replace ○ Append

| Left | Center | Right |
|---|---|---|
| <Patient Selection Criteria> | | Page &P of &N |
| <Output Filter> | | |
| | | |
| | | |

## Enter a Group Header

1. Click on the Group Header button to open the Group Header window.



2. Enter panel and item selection to the Group Header with the Edit Mode buttons to Replace or Append changes.

   Only one item can defined as the Group Break item.

   There is a maximum of 4 group headers consisting of 3 rows each.

3. Click the Font button to change font, style and size.

   The default setting for font is BOLD 10.

4. Use the Add Item and Text button to enter items.

   If you do not enter a free text description, the item will be added alone without text or description.

   Text cannot be added alone without an item.

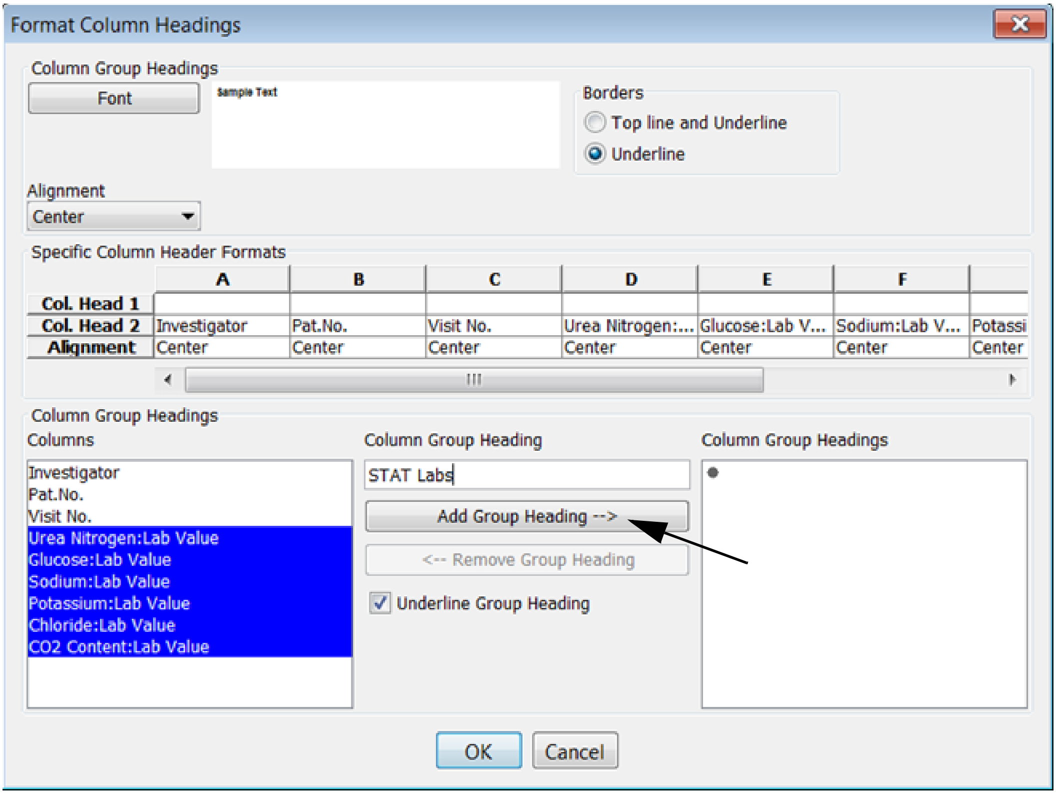
5. Click on a row and use the scissors icon to delete the contents.

6. Click **OK**, to save Group Header.

## *Format Column Headings*

To open the Report Column Headings Formatting window click on the Format Column Headings button. The default settings for all column headings are:

- Font is BOLD **8.**
- Alignment - Center.
- Borders set to Underline and Underline Group Heading is ON.



Borders: ○ Top line and Underline ● Underline

Alignment: Center

| | A | B | C | D | E | F | |
|---|---|---|---|---|---|---|---|
| **Col. Head 1** | | | | | | | |
| **Col. Head 2** | Investigator | Pat.No. | Visit No. | Urea Nitrogen:... | Glucose:Lab V... | Sodium:Lab V... | Potassi |
| **Alignment** | Center | Center | Center | Center | Center | Center | Center |

Columns

Investigator
Pat.No.
Visit No.
Urea Nitrogen:Lab Value
Glucose:Lab Value
Sodium:Lab Value
Potassium:Lab Value
Chloride:Lab Value
CO2 Content:Lab Value

Column Group Heading: STAT Labs

☑ Underline Group Heading

Column Group Headings

●

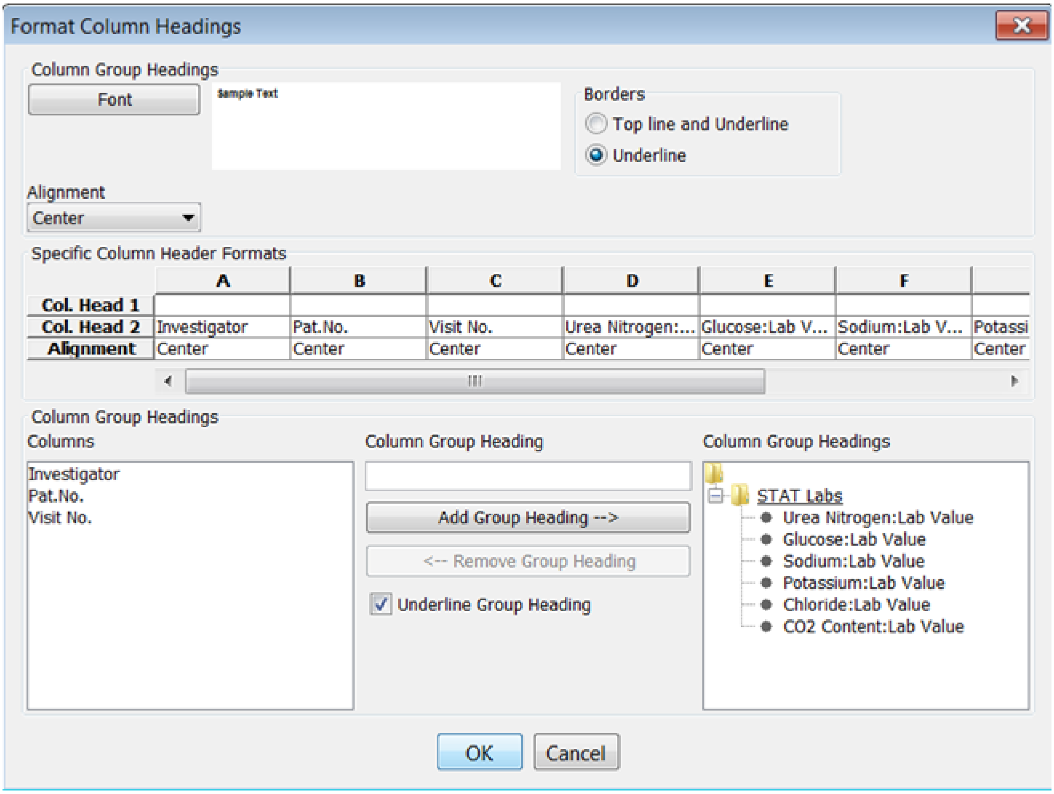
***To apply Overall Column Header Formats:***

1. Click the Font button to change font, style and size.
2. Change the borders.
3. Apply a Specific Column Header Format by clicking the drop down list for alignment. Change from default center to auto, left, or right.

   Edit the column headings for Col. Head 1 and Col. Head 2 from the Report Browser window. See edit column heading.

***To apply Column Group Headings:***

4. Highlight the items you want included in the group.
5. Enter a Column Group Heading.
6. Click Add Group Heading.



Borders
○ Top line and Underline
● Underline

Alignment: Center

| | A | B | C | D | E | F | |
|---|---|---|---|---|---|---|---|
| **Col. Head 1** | | | | | | | |
| **Col. Head 2** | Investigator | Pat.No. | Visit No. | Urea Nitrogen:... | Glucose:Lab V... | Sodium:Lab V... | Potassi |
| **Alignment** | Center | Center | Center | Center | Center | Center | Center |

Columns
- Investigator
- Pat.No.
- Visit No.

Column Group Heading

☑ Underline Group Heading

Column Group Headings
- STAT Labs
  - Urea Nitrogen:Lab Value
  - Glucose:Lab Value
  - Sodium:Lab Value
  - Potassium:Lab Value
  - Chloride:Lab Value
  - CO2 Content:Lab Value

7. Use **Remove Group Heading** to make changes. If a Column Group Heading is removed the items are added back to the list columns in the original order.
8. Click box to **Underline the Group Heading**.
9. Click **OK**, to save Format Column Headings.

## *Format Columns*

1. To open the Report Column Formatting window, click on the **Format Column** button.

   The default setting alignment is automatic based on the data type.

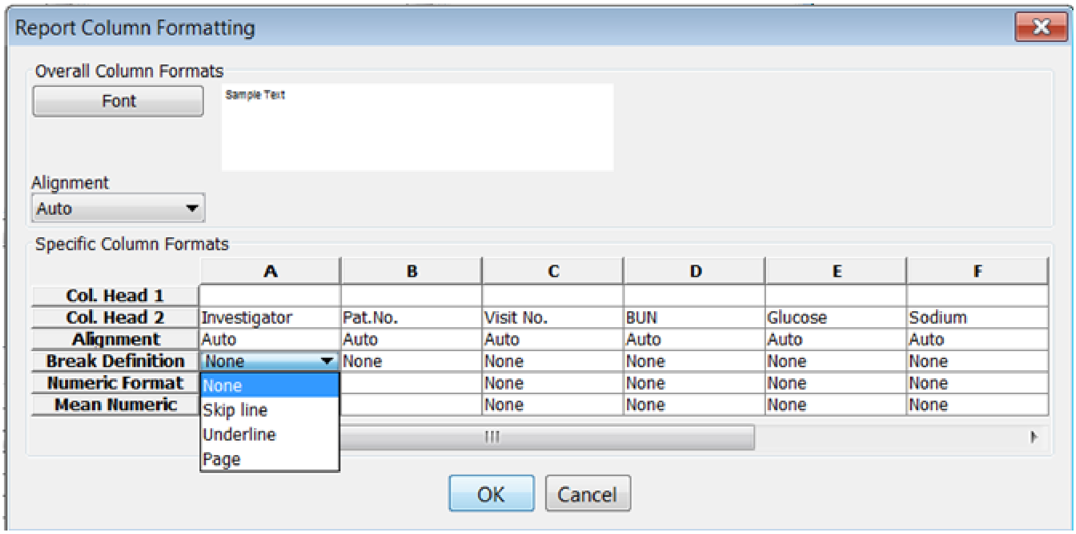
   Break definition is set to none and font is regular **8.**

2. Click **Overall Column Formats** to apply overall formats to font, style and size. The overall Alignment is Auto.

   Or, you can apply individual Specific Column Formats.

3. Click the **Alignment** drop down list to align the item display for auto, left, center, or right.

4. Click the **Break Definition** drop down list for None, Skip line, Underline, Page.



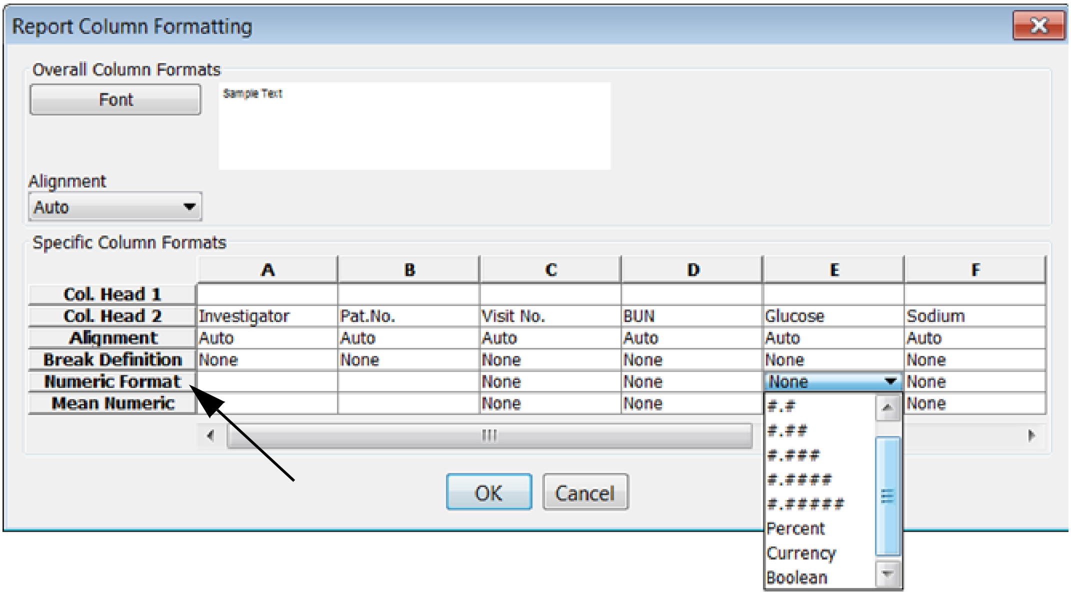
Alignment: Auto

| | A | B | C | D | E | F |
|---|---|---|---|---|---|---|
| **Col. Head 1** | | | | | | |
| **Col. Head 2** | Investigator | Pat.No. | Visit No. | BUN | Glucose | Sodium |
| **Alignment** | Auto | Auto | Auto | Auto | Auto | Auto |
| **Break Definition** | None | None | None | None | None | None |
| **Numeric Format** | | | None | None | None | None |
| **Mean Numeric** | | | None | None | None | None |

5. Click the **Numeric Format** drop down list for any numeric item included as a column in the report.

   The best way to use the Percent Numeric format option is to apply it to a calculated field that is a percentage which has not been multiplied by 100. For example, if the calculated field is 0.67 percent and you apply the% format to display as 67%.

   The Boolean numeric format would be used on a calculated field where ‘0=False’ and all other numeric values will display as ‘True’.

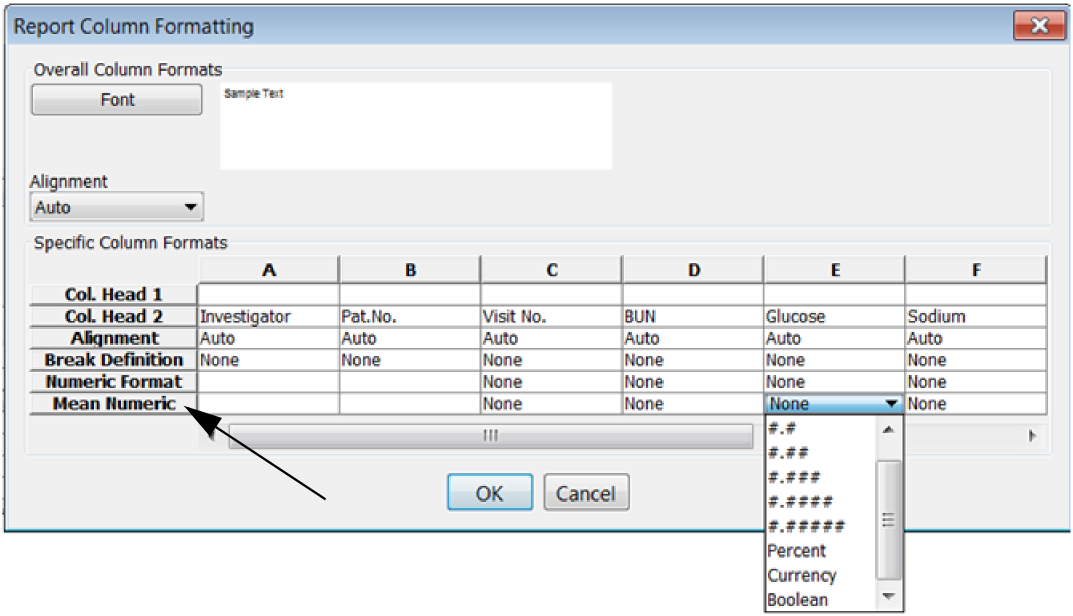


Alignment: Auto

| | A | B | C | D | E | F |
|---|---|---|---|---|---|---|
| **Col. Head 1** | | | | | | |
| **Col. Head 2** | Investigator | Pat.No. | Visit No. | BUN | Glucose | Sodium |
| **Alignment** | Auto | Auto | Auto | Auto | Auto | Auto |
| **Break Definition** | None | None | None | None | None | None |
| **Numeric Format** | | | None | None | None | None |
| **Mean Numeric** | | | None | None | | None |

The numeric formatting is also available for Change from Baseline and %Change from Baseline items.

6. Click the **Mean Numeric Format** drop down list for any row result defined as Mean, Mean at Change or Mean at Change and Mean.



Alignment
Auto

| | A | B | C | D | E | F |
|---|---|---|---|---|---|---|
| **Col. Head 1** | | | | | | |
| **Col. Head 2** | Investigator | Pat.No. | Visit No. | BUN | Glucose | Sodium |
| **Alignment** | Auto | Auto | Auto | Auto | Auto | Auto |
| **Break Definition** | None | None | None | None | None | None |
| **Numeric Format** | | | None | None | None | None |
| **Mean Numeric** | | | None | None | None | None |

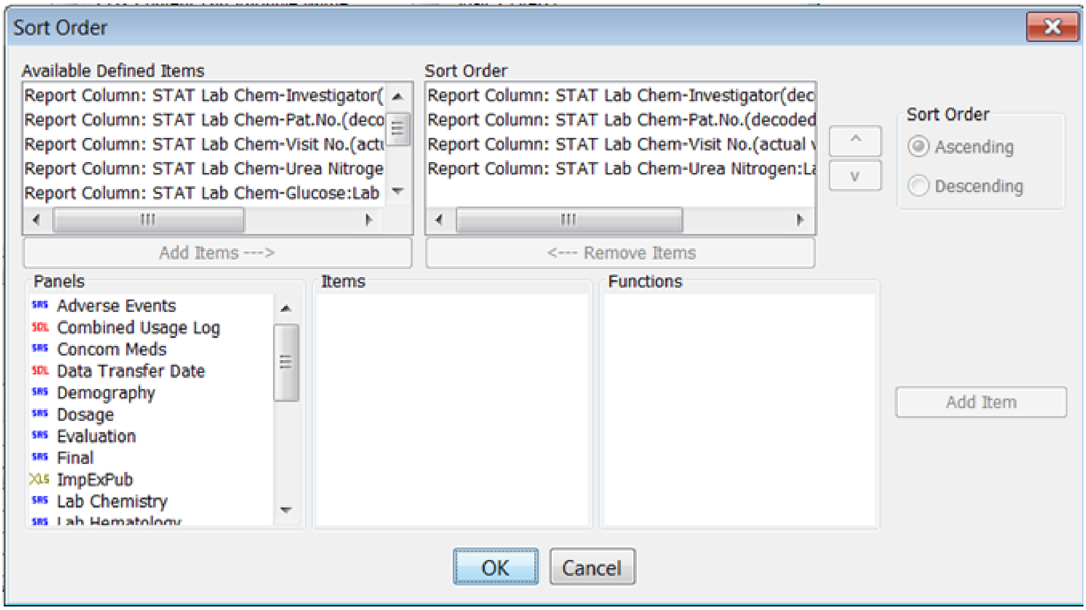
7. Click **OK**, to save Report Column Formatting.

## *Sort Order*

The default order of data items:

1. Headers
2. Footers
3. Group Headers
4. First 4 columns added to the report.
5. Items are defaulted in ascending order.

***Note: It is advised to define all areas of the report prior to defining the sort.***



Available Defined Items:
Report Column: STAT Lab Chem-Investigator(
Report Column: STAT Lab Chem-Pat.No.(deco
Report Column: STAT Lab Chem-Visit No.(actu
Report Column: STAT Lab Chem-Urea Nitroge
Report Column: STAT Lab Chem-Glucose:Lab

Sort Order:
Report Column: STAT Lab Chem-Investigator(dec
Report Column: STAT Lab Chem-Pat.No.(decoded
Report Column: STAT Lab Chem-Visit No.(actual v
Report Column: STAT Lab Chem-Urea Nitrogen:La

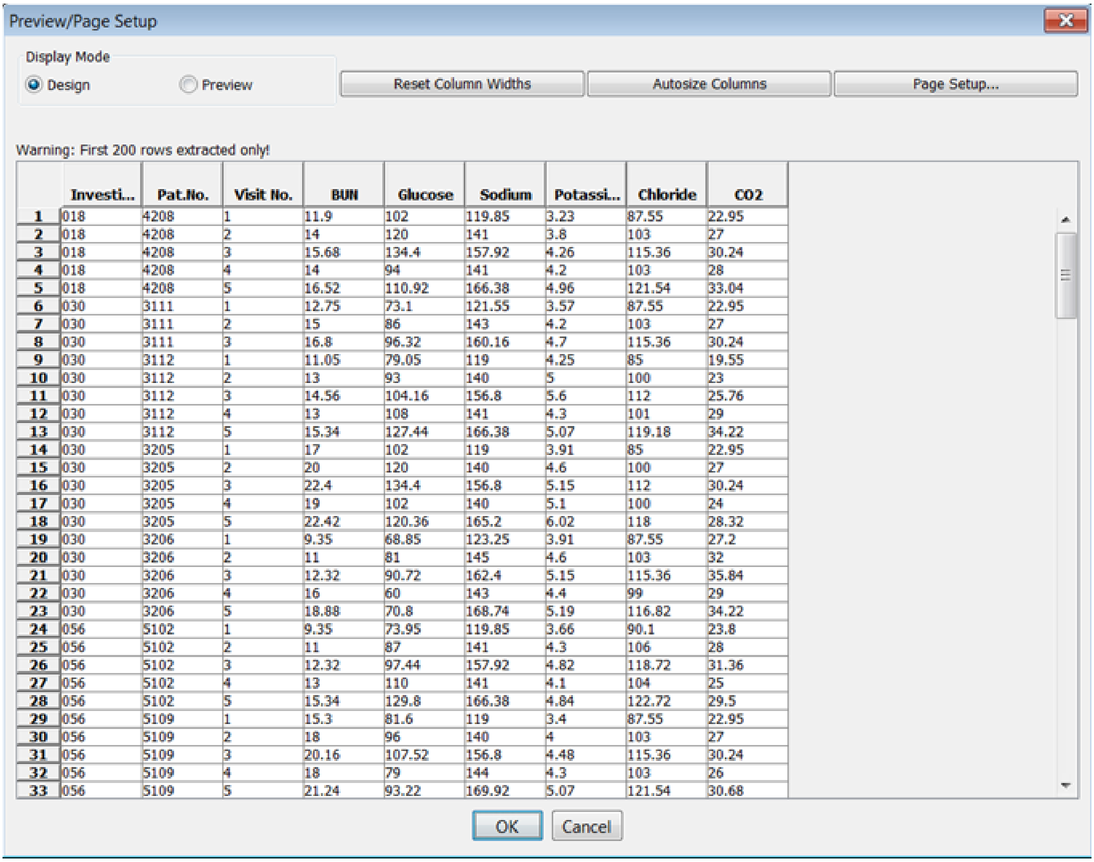
Panels:
SRS Adverse Events
SDL Combined Usage Log
SRS Concom Meds
SDL Data Transfer Date
SRS Demography
SRS Dosage
SRS Evaluation
SRS Final
XLS ImpExPub
SRS Lab Chemistry
SRS Lab Hematology

- All items added to the report in the header, footer, group header or as columns will display as Available Defined Items.
- The sort order can be changed by clicking on the item and using the arrow buttons.
- Any item in the sort order can be identified as ascending or descending by clicking the item and the Sort Options.
- An item can be removed or added to the sort order with the Add Item and Remove Item buttons.
- An Item not displayed in the report can be added for sorting purposes only by selecting the item from the Panels column.

## *Preview/Page Setup*

1. Click **Preview/Page Setup** to view the **Design** window or to **Preview** the report. Both the Design and Preview functions allow you to view the first 200 records only from the database to determine column widths and page setup for orientation and margins. This function is specific to formatted reports only.

   The Preview/Page Setup opens in Display Mode for ‘Design’.



Warning: First 200 rows extracted only!

| | Investi... | Pat.No. | Visit No. | BUN | Glucose | Sodium | Potassi... | Chloride | CO2 |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 018 | 4208 | 1 | 11.9 | 102 | 119.85 | 3.23 | 87.55 | 22.95 |
| 2 | 018 | 4208 | 2 | 14 | 120 | 141 | 3.8 | 103 | 27 |
| 3 | 018 | 4208 | 3 | 15.68 | 134.4 | 157.92 | 4.26 | 115.36 | 30.24 |
| 4 | 018 | 4208 | 4 | 14 | 94 | 141 | 4.2 | 103 | 28 |
| 5 | 018 | 4208 | 5 | 16.52 | 110.92 | 166.38 | 4.96 | 121.54 | 33.04 |
| 6 | 030 | 3111 | 1 | 12.75 | 73.1 | 121.55 | 3.57 | 87.55 | 22.95 |
| 7 | 030 | 3111 | 2 | 15 | 86 | 143 | 4.2 | 103 | 27 |
| 8 | 030 | 3111 | 3 | 16.8 | 96.32 | 160.16 | 4.7 | 115.36 | 30.24 |
| 9 | 030 | 3112 | 1 | 11.05 | 79.05 | 119 | 4.25 | 85 | 19.55 |
| 10 | 030 | 3112 | 2 | 13 | 93 | 140 | 5 | 100 | 23 |
| 11 | 030 | 3112 | 3 | 14.56 | 104.16 | 156.8 | 5.6 | 112 | 25.76 |
| 12 | 030 | 3112 | 4 | 13 | 108 | 141 | 4.3 | 101 | 29 |
| 13 | 030 | 3112 | 5 | 15.34 | 127.44 | 166.38 | 5.07 | 119.18 | 34.22 |
| 14 | 030 | 3205 | 1 | 17 | 102 | 119 | 3.91 | 85 | 22.95 |
| 15 | 030 | 3205 | 2 | 20 | 120 | 140 | 4.6 | 100 | 27 |
| 16 | 030 | 3205 | 3 | 22.4 | 134.4 | 156.8 | 5.15 | 112 | 30.24 |
| 17 | 030 | 3205 | 4 | 19 | 102 | 140 | 5.1 | 100 | 24 |
| 18 | 030 | 3205 | 5 | 22.42 | 120.36 | 165.2 | 6.02 | 118 | 28.32 |
| 19 | 030 | 3206 | 1 | 9.35 | 68.85 | 123.25 | 3.91 | 87.55 | 27.2 |
| 20 | 030 | 3206 | 2 | 11 | 81 | 145 | 4.6 | 103 | 32 |
| 21 | 030 | 3206 | 3 | 12.32 | 90.72 | 162.4 | 5.15 | 115.36 | 35.84 |
| 22 | 030 | 3206 | 4 | 16 | 60 | 143 | 4.4 | 99 | 29 |
| 23 | 030 | 3206 | 5 | 18.88 | 70.8 | 168.74 | 5.19 | 116.82 | 34.22 |
| 24 | 056 | 5102 | 1 | 9.35 | 73.95 | 119.85 | 3.66 | 90.1 | 23.8 |
| 25 | 056 | 5102 | 2 | 11 | 87 | 141 | 4.3 | 106 | 28 |
| 26 | 056 | 5102 | 3 | 12.32 | 97.44 | 157.92 | 4.82 | 118.72 | 31.36 |
| 27 | 056 | 5102 | 4 | 13 | 110 | 141 | 4.1 | 104 | 25 |
| 28 | 056 | 5102 | 5 | 15.34 | 129.8 | 166.38 | 4.84 | 122.72 | 29.5 |
| 29 | 056 | 5109 | 1 | 15.3 | 81.6 | 119 | 3.4 | 87.55 | 22.95 |
| 30 | 056 | 5109 | 2 | 18 | 96 | 140 | 4 | 103 | 27 |
| 31 | 056 | 5109 | 3 | 20.16 | 107.52 | 156.8 | 4.48 | 115.36 | 30.24 |
| 32 | 056 | 5109 | 4 | 18 | 79 | 144 | 4.3 | 103 | 26 |
| 33 | 056 | 5109 | 5 | 21.24 | 93.22 | 169.92 | 5.07 | 121.54 | 30.68 |

***Note: See Print Preview function from the File menu for non-formatted reports.***

The default display is landscape and the settings are maximum column width of one inch. The width is set to fit all columns on a page depending upon the number of columns in the report.

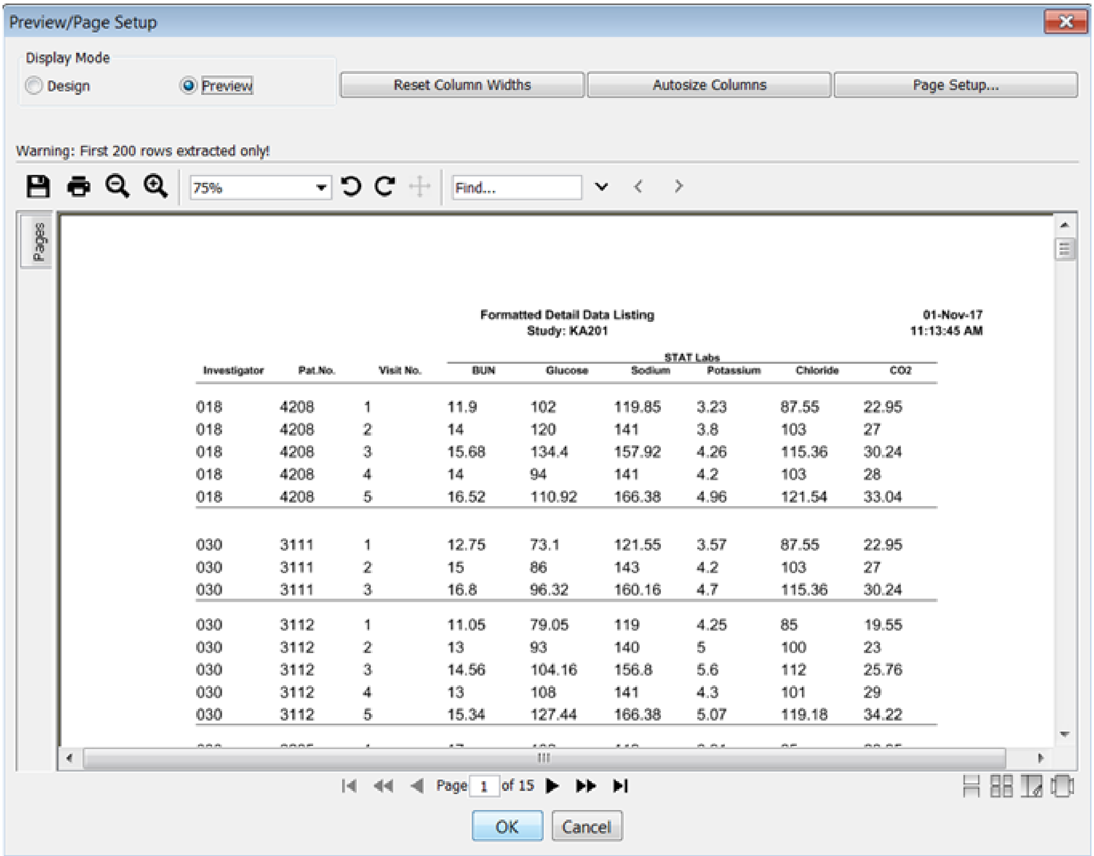
2. The following options are available in Design mode:

- Click the Reset Columns Widths to view all columns to fit on the page.
- Click the Autosize Columns to expand each column to it’s maximum width.
- Click Page Setup window to enter paper size, changing the page orientation for portrait versus landscape and setting the margins in inches for top, bottom, right and left.

Sizing of the individual columns on the grid in design mode will change the column widths. It is advised to set page setup before the setting of the column widths since changing the page orientation, left margin size or right margin size will set the column widths back to their default settings. Use Preview for sizing the columns as well.

***Note: You must use the Create Report to print the entire records contained in your report. The Preview function is used to determine report layout dimensions and specifications only.***

3. Select Display Mode for ‘Preview’.



Display Mode
○ Design ● Preview

Warning: First 200 rows extracted only!

**Formatted Detail Data Listing**
**Study: KA201**

**01-Nov-17**
**11:13:45 AM**

| Investigator | Pat.No. | Visit No. | STAT Labs<br>BUN | Glucose | Sodium | Potassium | Chloride | CO2 |
|---|---|---|---|---|---|---|---|---|
| 018 | 4208 | 1 | 11.9 | 102 | 119.85 | 3.23 | 87.55 | 22.95 |
| 018 | 4208 | 2 | 14 | 120 | 141 | 3.8 | 103 | 27 |
| 018 | 4208 | 3 | 15.68 | 134.4 | 157.92 | 4.26 | 115.36 | 30.24 |
| 018 | 4208 | 4 | 14 | 94 | 141 | 4.2 | 103 | 28 |
| 018 | 4208 | 5 | 16.52 | 110.92 | 166.38 | 4.96 | 121.54 | 33.04 |
| 030 | 3111 | 1 | 12.75 | 73.1 | 121.55 | 3.57 | 87.55 | 22.95 |
| 030 | 3111 | 2 | 15 | 86 | 143 | 4.2 | 103 | 27 |
| 030 | 3111 | 3 | 16.8 | 96.32 | 160.16 | 4.7 | 115.36 | 30.24 |
| 030 | 3112 | 1 | 11.05 | 79.05 | 119 | 4.25 | 85 | 19.55 |
| 030 | 3112 | 2 | 13 | 93 | 140 | 5 | 100 | 23 |
| 030 | 3112 | 3 | 14.56 | 104.16 | 156.8 | 5.6 | 112 | 25.76 |
| 030 | 3112 | 4 | 13 | 108 | 141 | 4.3 | 101 | 29 |
| 030 | 3112 | 5 | 15.34 | 127.44 | 166.38 | 5.07 | 119.18 | 34.22 |

The page you are currently viewing and the total number of pages for the first 200 records in the report are displayed with arrows to move through the listing. Use the magnify button to enlarge the report preview display. You may use the Printer icon to print a sample of the first 200 records of the report from the Preview window.

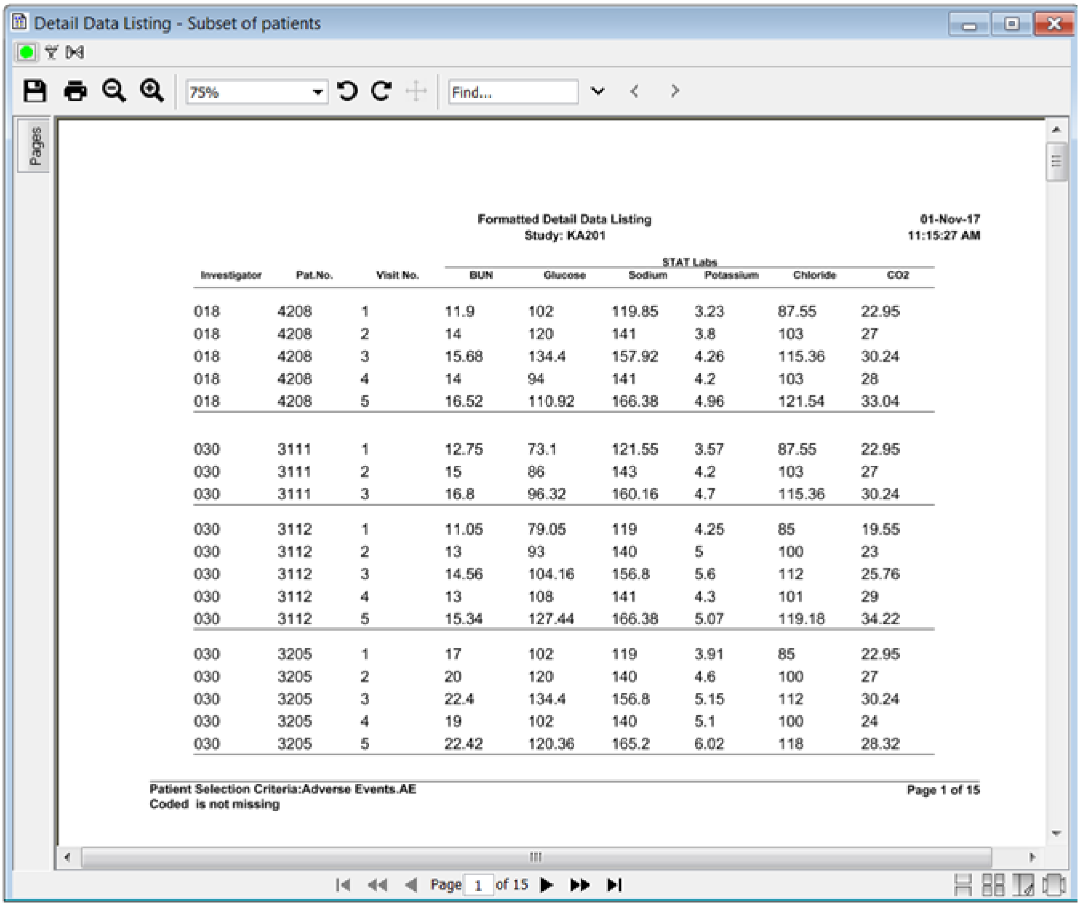
A ‘**Watermark**’ text capability is available based on ReviewAdmin StatusCode for Watermark/Text field contents for object’s status.

Formatted Reports and Formatted Patient Profiles are supported for configurable watermark color, to allow customer specified color and darkness for watermark by adding CONFIG.OPTIONS string parameter: WATERMARKRGB=15,15,15; where the RGB values (15,15,15 in this case) are the RGB color levels.

## Create formatted report

You must create the report to view and print the entire records contained in the report.

1. Click **OK** in the Preview window and return to the Report Browser window.
2. Click **Create Report**. The PDF viewer provides several viewing options such as; continuous stream of pages, or two at a time like a magazine, four up, etc. – but also has built in ‘bookmark’ access (useful in formatted reports or formatted patient profiles – which both generate bookmarks), plus a built in **Search function**.
3. Use the tool bar buttons to scroll through the pages or change the image scale with the plus and minus signs.
4. Use the printer icon to print the output results.



Formatted Detail Data Listing
Study: KA201

01-Nov-17
11:15:27 AM

| | | | STAT Labs | | | | | |
|---|---|---|---|---|---|---|---|---|
| Investigator | Pat.No. | Visit No. | BUN | Glucose | Sodium | Potassium | Chloride | CO2 |
| 018 | 4208 | 1 | 11.9 | 102 | 119.85 | 3.23 | 87.55 | 22.95 |
| 018 | 4208 | 2 | 14 | 120 | 141 | 3.8 | 103 | 27 |
| 018 | 4208 | 3 | 15.68 | 134.4 | 157.92 | 4.26 | 115.36 | 30.24 |
| 018 | 4208 | 4 | 14 | 94 | 141 | 4.2 | 103 | 28 |
| 018 | 4208 | 5 | 16.52 | 110.92 | 166.38 | 4.96 | 121.54 | 33.04 |
| 030 | 3111 | 1 | 12.75 | 73.1 | 121.55 | 3.57 | 87.55 | 22.95 |
| 030 | 3111 | 2 | 15 | 86 | 143 | 4.2 | 103 | 27 |
| 030 | 3111 | 3 | 16.8 | 96.32 | 160.16 | 4.7 | 115.36 | 30.24 |
| 030 | 3112 | 1 | 11.05 | 79.05 | 119 | 4.25 | 85 | 19.55 |
| 030 | 3112 | 2 | 13 | 93 | 140 | 5 | 100 | 23 |
| 030 | 3112 | 3 | 14.56 | 104.16 | 156.8 | 5.6 | 112 | 25.76 |
| 030 | 3112 | 4 | 13 | 108 | 141 | 4.3 | 101 | 29 |
| 030 | 3112 | 5 | 15.34 | 127.44 | 166.38 | 5.07 | 119.18 | 34.22 |
| 030 | 3205 | 1 | 17 | 102 | 119 | 3.91 | 85 | 22.95 |
| 030 | 3205 | 2 | 20 | 120 | 140 | 4.6 | 100 | 27 |
| 030 | 3205 | 3 | 22.4 | 134.4 | 156.8 | 5.15 | 112 | 30.24 |
| 030 | 3205 | 4 | 19 | 102 | 140 | 5.1 | 100 | 24 |
| 030 | 3205 | 5 | 22.42 | 120.36 | 165.2 | 6.02 | 118 | 28.32 |

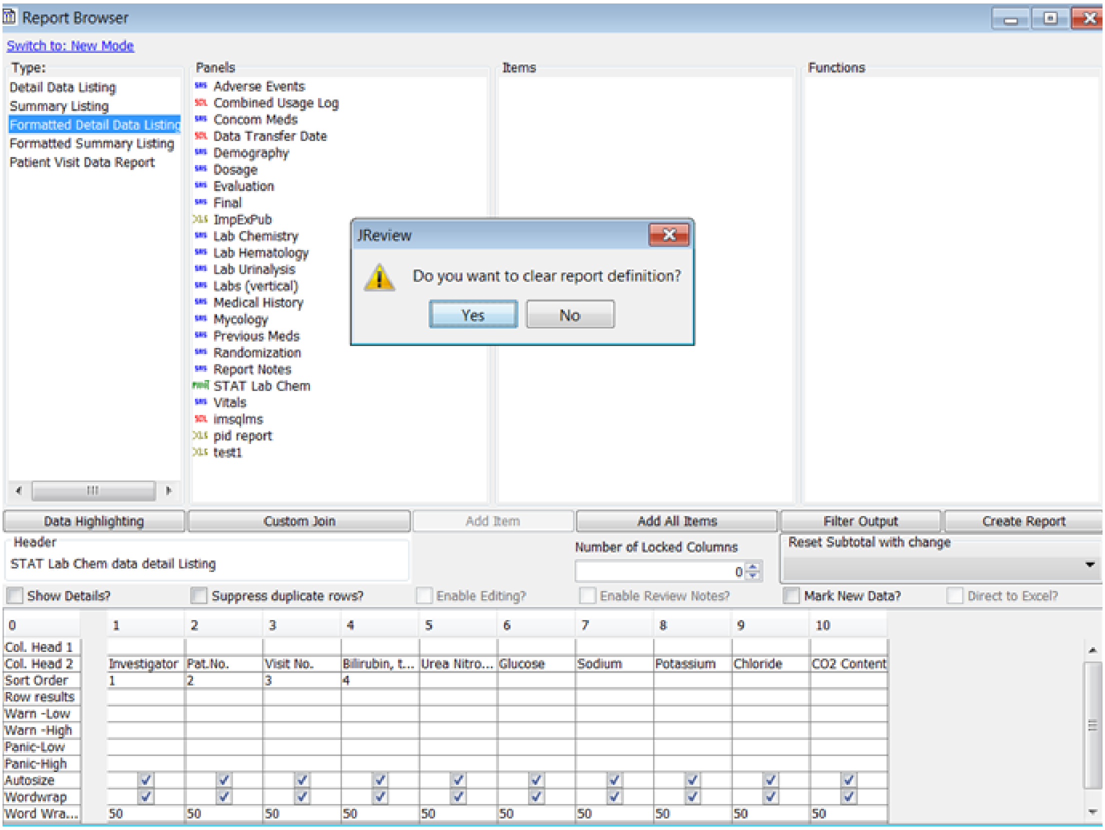
Patient Selection Criteria:Adverse Events.AE
Coded is not missing

Page 1 of 15

## Convert to Formatted

The user is only able to convert a detailed data listing to a formatted listing in Classic mode. Converting to formatted reports are **not** supported in the New mode.

If the user designs a detail data listing or summary listing (spreadsheet reports), then clicks on the respective 'Formatted' versions of each, JReview prompts the user if they want to clear the definition. Responding No – copies the definition into the formatted version of the report, so the user doesn't need to redefine the report definition.



Do you want to clear report definition?

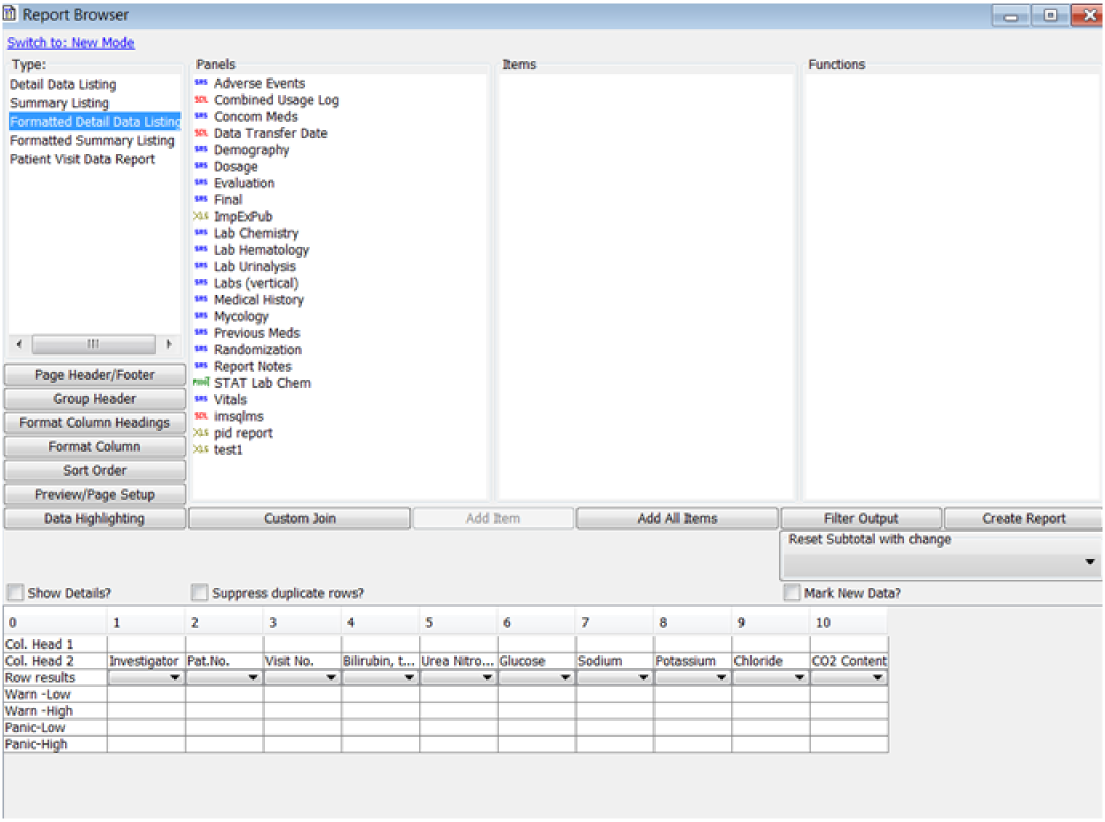
Header: STAT Lab Chem data detail Listing

Number of Locked Columns: 0

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | | | | | |
| Col. Head 2 | Investigator | Pat.No. | Visit No. | Bilirubin, t... | Urea Nitro... | Glucose | Sodium | Potassium | Chloride | CO2 Content |
| Sort Order | 1 | 2 | 3 | 4 | | | | | | |
| Row results | | | | | | | | | | |
| Warn -Low | | | | | | | | | | |
| Warn -High | | | | | | | | | | |
| Panic-Low | | | | | | | | | | |
| Panic-High | | | | | | | | | | |
| Autosize | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Wordwrap | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Word Wra... | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |

Also, you may open a previously saved detail data listing object. Right mouse click and select to **Open in Classic Mode**, then select the report type for Formatted Detail Data Listing. Save the new formatted report object to it's own object index number. The original Classic mode unformatted listing is still available under it's object index number which you may choose to keep or delete.

Click **No**, the report definition is copied into the formatted detail data listing to allow the user to apply report formats without redefining the spreadsheet content.



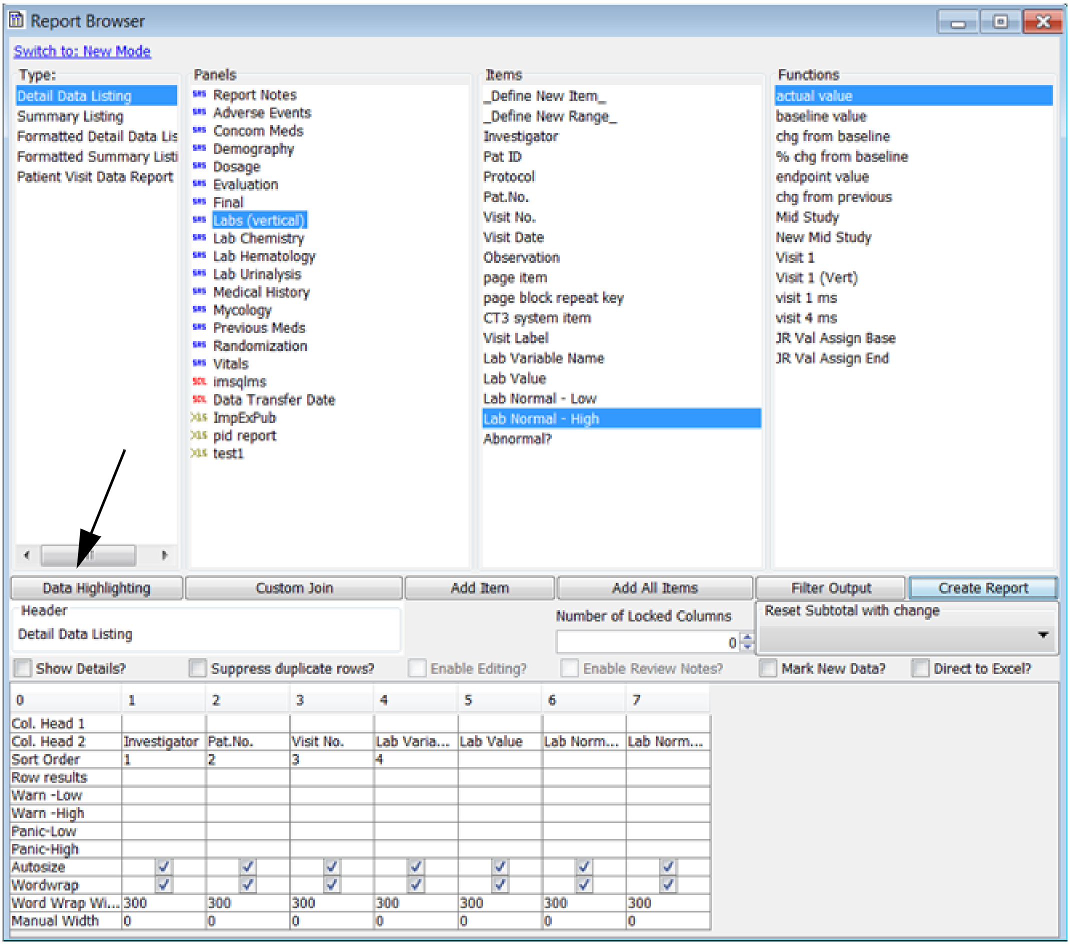
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | | | | | |
| Col. Head 2 | Investigator | Pat.No. | Visit No. | Bilirubin, t... | Urea Nitro... | Glucose | Sodium | Potassium | Chloride | CO2 Content |
| Row results | | | | | | | | | | |
| Warn -Low | | | | | | | | | | |
| Warn -High | | | | | | | | | | |
| Panic-Low | | | | | | | | | | |
| Panic-High | | | | | | | | | | |

# Conditional Data Highlighting

## *Define data highlighting*

The Data Highlighting feature allows you to create conditional highlighting in reports similar to entering the warning and panic row values. The data highlights can be applied to both regular reports (Detail Data Listing and Summary Listing) and formatted reports.

First define the report specification, then select the **Data Highlighting** button in the Report Browser Classic Mode build window.



Header
Detail Data Listing

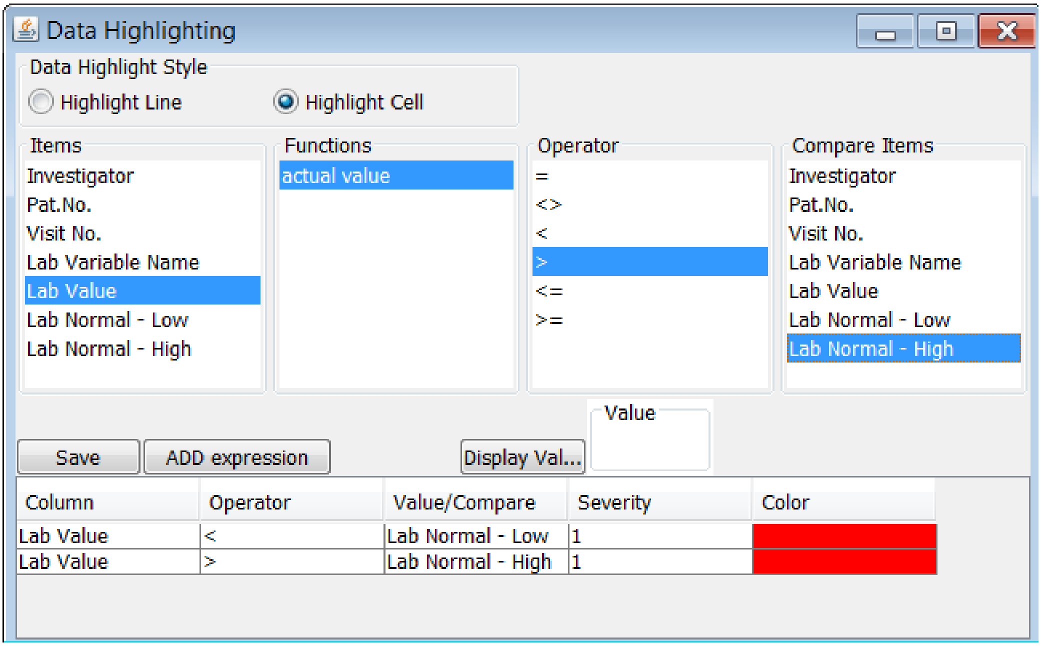
Number of Locked Columns
0

Reset Subtotal with change

☐ Show Details? ☐ Suppress duplicate rows? ☐ Enable Editing? ☐ Enable Review Notes? ☐ Mark New Data? ☐ Direct to Excel?

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | | |
| Col. Head 2 | Investigator | Pat.No. | Visit No. | Lab Varia... | Lab Value | Lab Norm... | Lab Norm... |
| Sort Order | 1 | 2 | 3 | 4 | | | |
| Row results | | | | | | | |
| Warn -Low | | | | | | | |
| Warn -High | | | | | | | |
| Panic-Low | | | | | | | |
| Panic-High | | | | | | | |
| Autosize | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Wordwrap | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Word Wrap Wi... | 300 | 300 | 300 | 300 | 300 | 300 | 300 |
| Manual Width | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

In addition, it allows the data highlight definition to select two items for comparison to each other. This is useful when designing reports to reference normal ranges included in tables such as laboratory data.

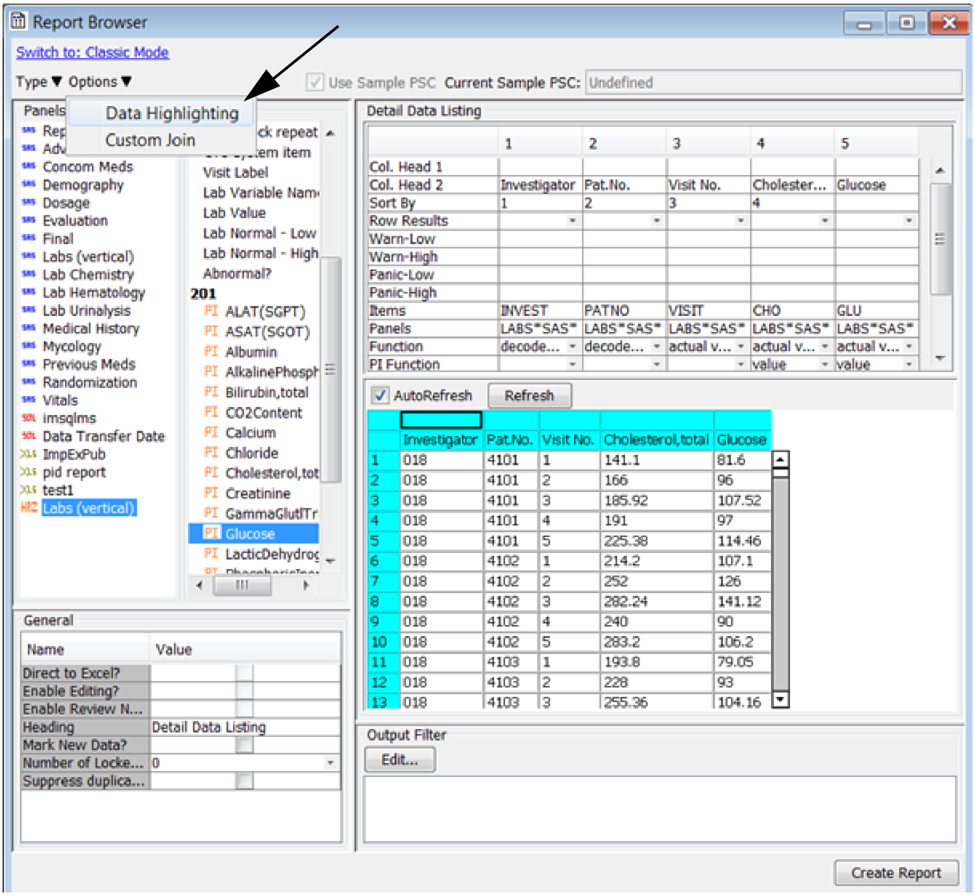


○ Highlight Line ● Highlight Cell

| Column | Operator | Value/Compare | Severity | Color |
|---|---|---|---|---|
| Lab Value | < | Lab Normal - Low | 1 | 🟥 |
| Lab Value | > | Lab Normal - High | 1 | 🟥 |

***Note: Data Highlighting is not applicable in the Patient Data Visit Report.***

In the Report Browser New Mode, first define the report specification then select the **Options menu** in the toolbar for **Data Highlighting**.

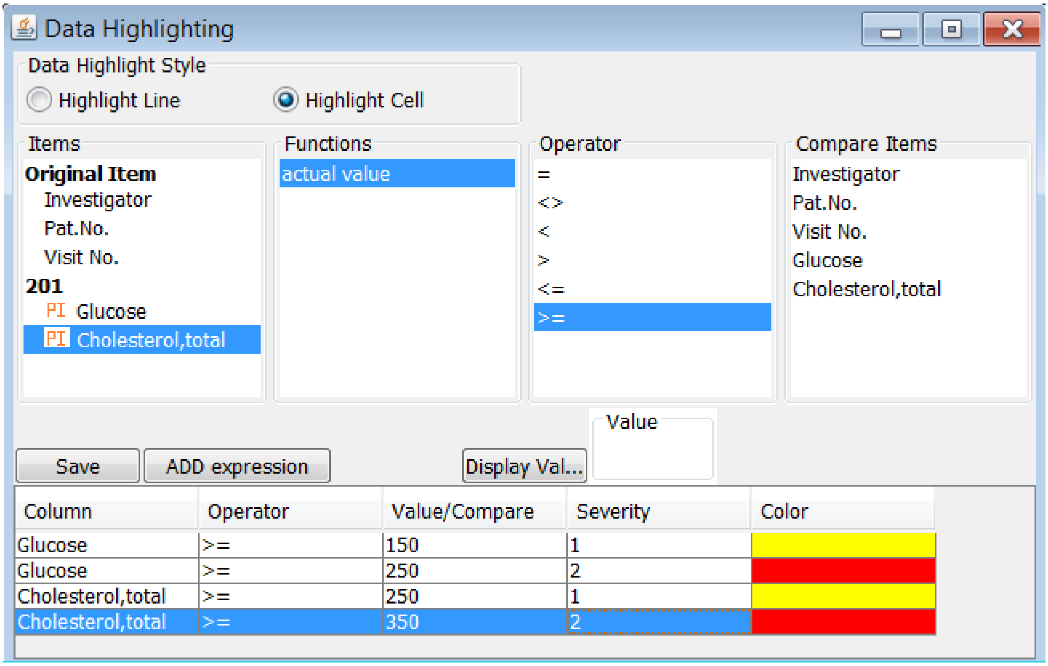


| | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| Col. Head 1 | | | | | |
| Col. Head 2 | Investigator | Pat.No. | Visit No. | Cholester... | Glucose |
| Sort By | 1 | 2 | 3 | 4 | |
| Row Results | | | | | |
| Warn-Low | | | | | |
| Warn-High | | | | | |
| Panic-Low | | | | | |
| Panic-High | | | | | |
| Items | INVEST | PATNO | VISIT | CHO | GLU |
| Panels | LABS*SAS* | LABS*SAS* | LABS*SAS* | LABS*SAS* | LABS*SAS* |
| Function | decode... | decode... | actual v... | actual v... | actual v... |
| PI Function | | | | value | value |

| | Investigator | Pat.No. | Visit No. | Cholesterol,total | Glucose |
|---|---|---|---|---|---|
| 1 | 018 | 4101 | 1 | 141.1 | 81.6 |
| 2 | 018 | 4101 | 2 | 166 | 96 |
| 3 | 018 | 4101 | 3 | 185.92 | 107.52 |
| 4 | 018 | 4101 | 4 | 191 | 97 |
| 5 | 018 | 4101 | 5 | 225.38 | 114.46 |
| 6 | 018 | 4102 | 1 | 214.2 | 107.1 |
| 7 | 018 | 4102 | 2 | 252 | 126 |
| 8 | 018 | 4102 | 3 | 282.24 | 141.12 |
| 9 | 018 | 4102 | 4 | 240 | 90 |
| 10 | 018 | 4102 | 5 | 283.2 | 106.2 |
| 11 | 018 | 4103 | 1 | 193.8 | 79.05 |
| 12 | 018 | 4103 | 2 | 228 | 93 |
| 13 | 018 | 4103 | 3 | 255.36 | 104.16 |

| Name | Value |
|---|---|
| Direct to Excel? | ☐ |
| Enable Editing? | ☐ |
| Enable Review N... | ☐ |
| Heading | Detail Data Listing |
| Mark New Data? | ☐ |
| Number of Locke... | 0 |
| Suppress duplica... | ☐ |

1. After adding items to the report specification, select **Data Highlighting** to open the Data Highlighting window which looks and operates similar to the output filter window.



○ Highlight Line ● Highlight Cell

| Column | Operator | Value/Compare | Severity | Color |
|---|---|---|---|---|
| Glucose | >= | 150 | 1 | 🟨 |
| Glucose | >= | 250 | 2 | 🟥 |
| Cholesterol,total | >= | 250 | 1 | 🟨 |
| Cholesterol,total | >= | 350 | 2 | 🟥 |

2. Select an item from the ‘Columns’ list and an operator.

   If the item type is numeric, the operator display options are: =, <>, >, <, >=, <= for code and decode values.

3. Select another item in the ‘Compare Columns’ list and click the **ADD expression** button, or enter a value in the ‘Value’ box and click the **ADD expression** button. If you use the **Display Values** list only single selections are allowed.

4. Click on the **Severity** cell to display a drop down list of numeric values 1 to 10 with lower values to represent less severe.

   The Severity value is required and a message displays if left blank.

5. Click on a **Color** cell for a particular row variable to display a color table for selection.

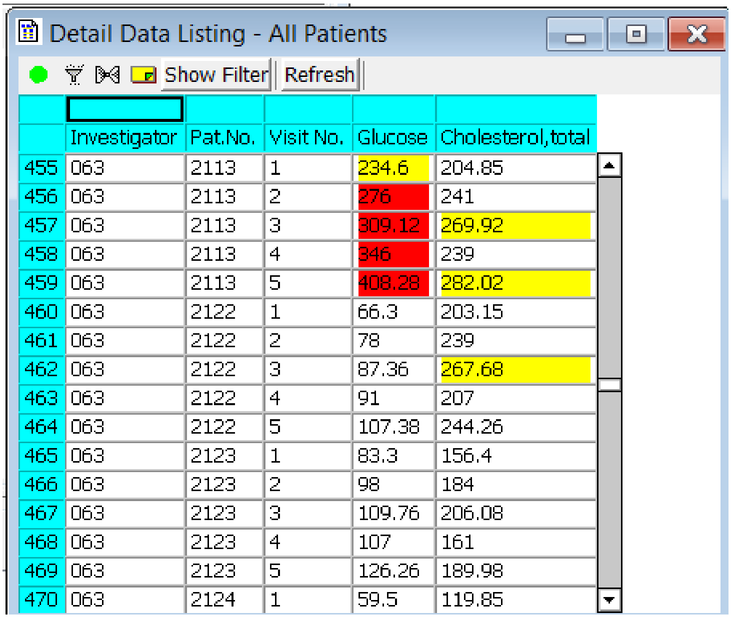
6. Select to ‘Highlight Line’ or ‘Highlight Cell’. The default is ‘Highlight Line’.

   If Highlight Line is selected, the entire row is highlighted in the report if the data meets the highlighting criteria. The last highlighted item in the row determines the line (row) color displayed. Or select Highlight Cell to highlight only the particular item in the row.

7. Click the **Save** button and close the Data Highlighting window.

8. Click the **Create Report** button in the Report Browser.

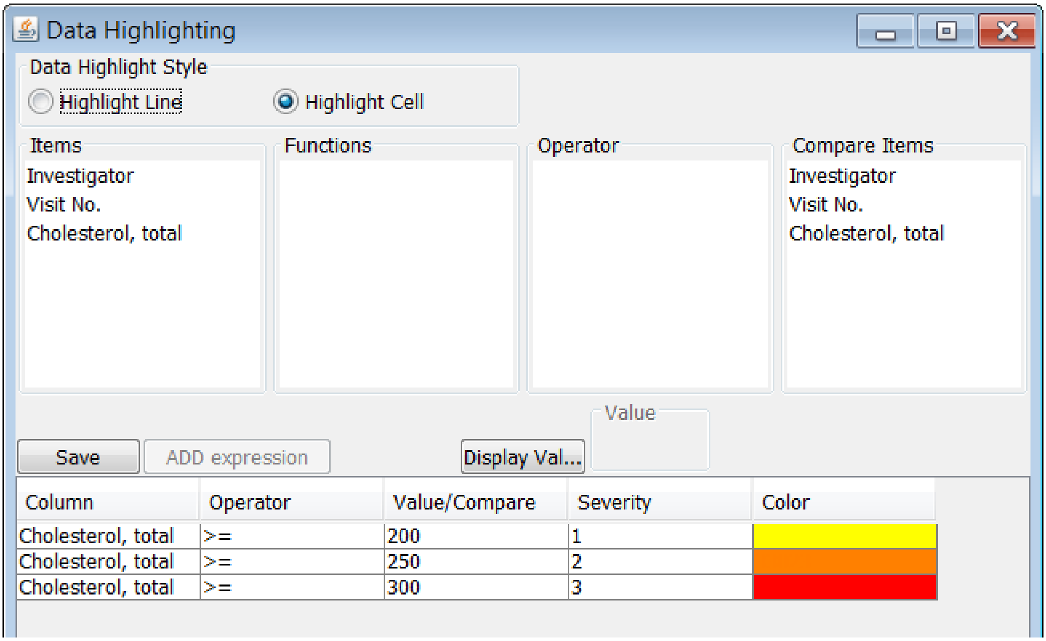
The report displays with the option selected to Highlight Line or Cell.



| | Investigator | Pat.No. | Visit No. | Glucose | Cholesterol,total |
|---|---|---|---|---|---|
| 455 | 063 | 2113 | 1 | 234.6 | 204.85 |
| 456 | 063 | 2113 | 2 | 276 | 241 |
| 457 | 063 | 2113 | 3 | 309.12 | 269.92 |
| 458 | 063 | 2113 | 4 | 346 | 239 |
| 459 | 063 | 2113 | 5 | 408.28 | 282.02 |
| 460 | 063 | 2122 | 1 | 66.3 | 203.15 |
| 461 | 063 | 2122 | 2 | 78 | 239 |
| 462 | 063 | 2122 | 3 | 87.36 | 267.68 |
| 463 | 063 | 2122 | 4 | 91 | 207 |
| 464 | 063 | 2122 | 5 | 107.38 | 244.26 |
| 465 | 063 | 2123 | 1 | 83.3 | 156.4 |
| 466 | 063 | 2123 | 2 | 98 | 184 |
| 467 | 063 | 2123 | 3 | 109.76 | 206.08 |
| 468 | 063 | 2123 | 4 | 107 | 161 |
| 469 | 063 | 2123 | 5 | 126.26 | 189.98 |
| 470 | 063 | 2124 | 1 | 59.5 | 119.85 |

*Note:* ***Date items are not supported in Data Highlighting definitions.***

Here is another example to demonstrate the severity order of values and their assigned colors.



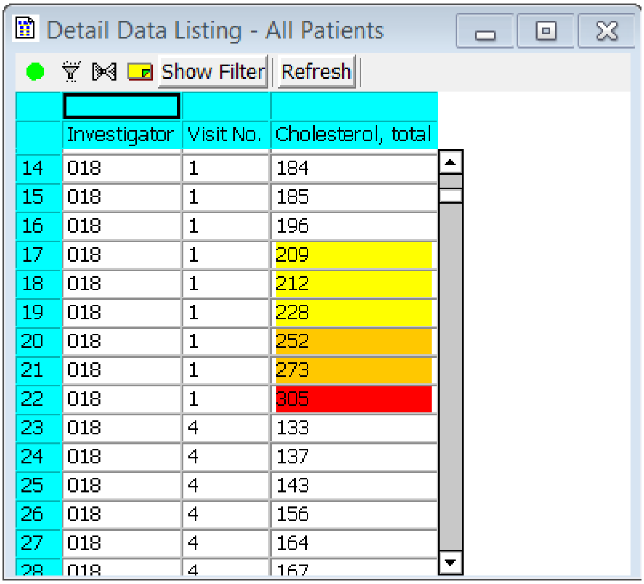
○ Highlight Line ● Highlight Cell

Items: Investigator, Visit No., Cholesterol, total

Compare Items: Investigator, Visit No., Cholesterol, total

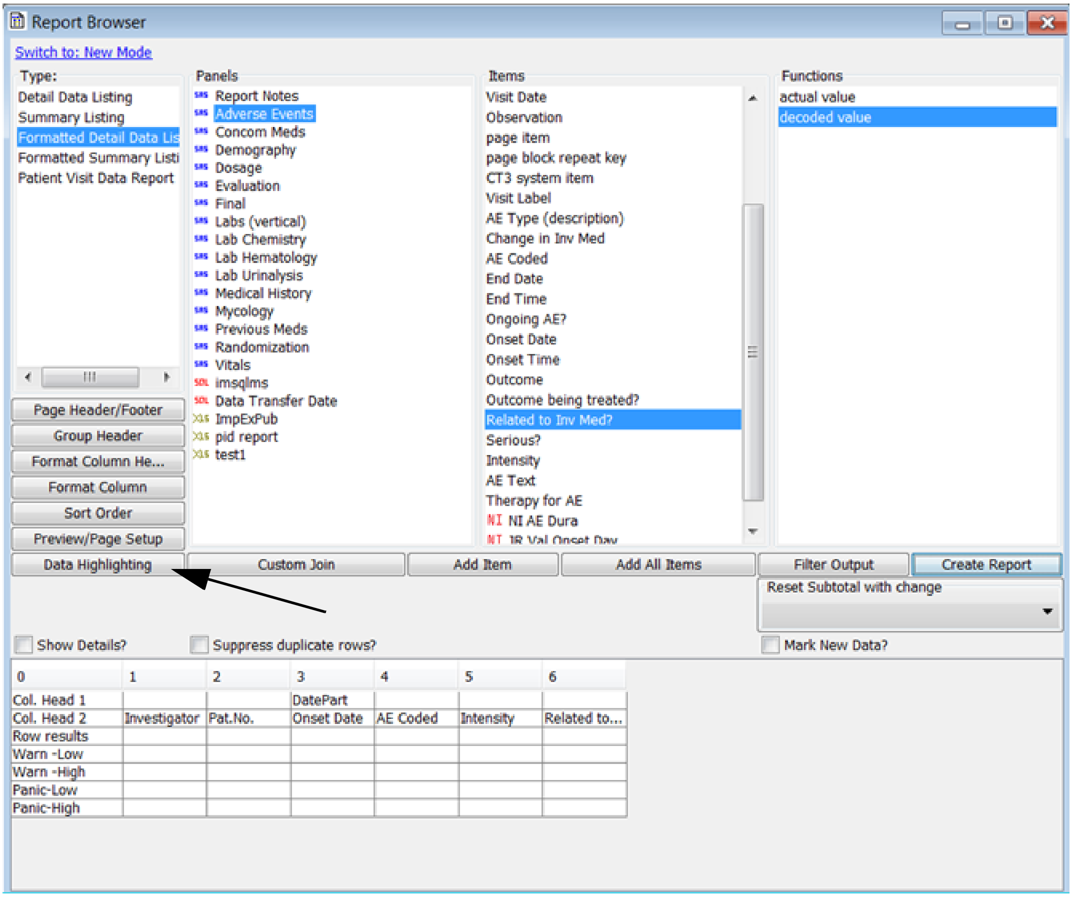
| Column | Operator | Value/Compare | Severity | Color |
|---|---|---|---|---|
| Cholesterol, total | >= | 200 | 1 | 🟨 |
| Cholesterol, total | >= | 250 | 2 | 🟧 |
| Cholesterol, total | >= | 300 | 3 | 🟥 |

Severity 2 and 3 are defined with higher elevated lab values than Severity 1 as abnormal but not considered critical or panic values.



| | Investigator | Visit No. | Cholesterol, total |
|---|---|---|---|
| 14 | 018 | 1 | 184 |
| 15 | 018 | 1 | 185 |
| 16 | 018 | 1 | 196 |
| 17 | 018 | 1 | 209 🟨 |
| 18 | 018 | 1 | 212 🟨 |
| 19 | 018 | 1 | 228 🟨 |
| 20 | 018 | 1 | 252 🟧 |
| 21 | 018 | 1 | 273 🟧 |
| 22 | 018 | 1 | 305 🟥 |
| 23 | 018 | 4 | 133 |
| 24 | 018 | 4 | 137 |
| 25 | 018 | 4 | 143 |
| 26 | 018 | 4 | 156 |
| 27 | 018 | 4 | 164 |
| 28 | 018 | 4 | 167 |

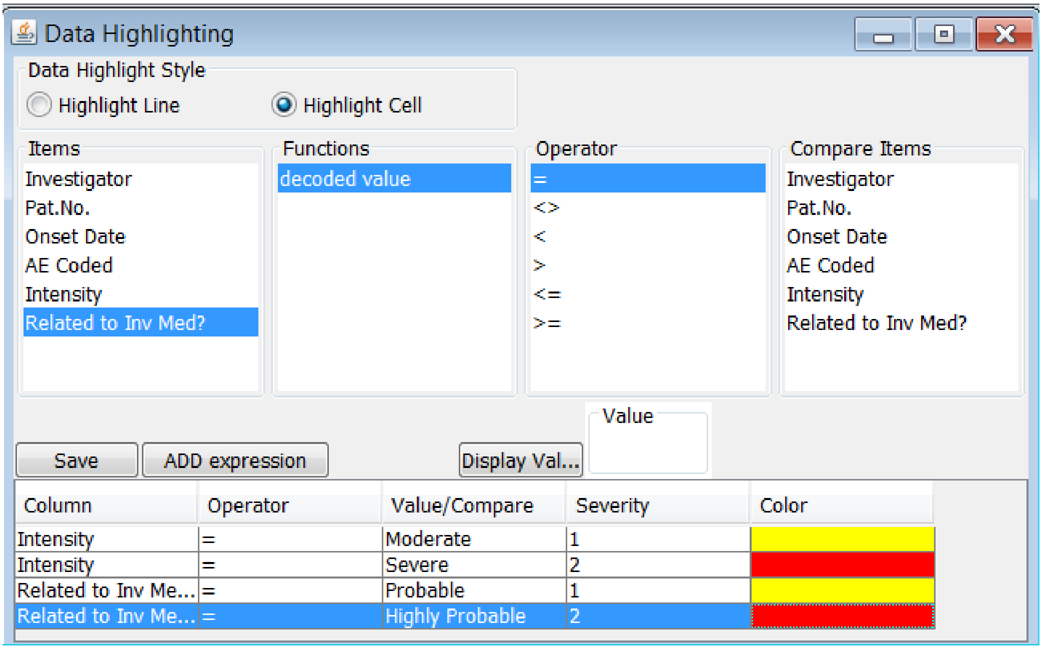
The following example is a formatted detail data listing of Adverse Events highlighting character data from a decode file.



☐ Show Details? ☐ Suppress duplicate rows? ☐ Mark New Data?

| 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| Col. Head 1 | | | DatePart | | | |
| Col. Head 2 | Investigator | Pat.No. | Onset Date | AE Coded | Intensity | Related to... |
| Row results | | | | | | |
| Warn -Low | | | | | | |
| Warn -High | | | | | | |
| Panic-Low | | | | | | |
| Panic-High | | | | | | |

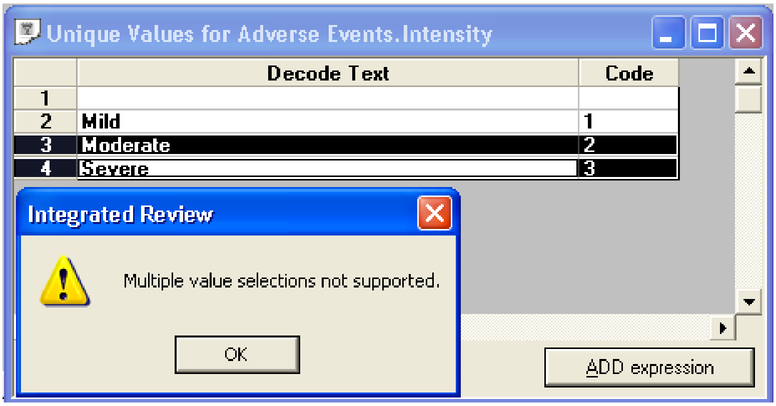
Data highlighting was applied to character decode values for ‘Intensity’ and ‘Related to Inv Med?’. Severity levels and color were entered and data highlighting set to ‘Highlight Cell’.



○ Highlight Line ● Highlight Cell

| Column | Operator | Value/Compare | Severity | Color |
|---|---|---|---|---|
| Intensity | = | Moderate | 1 | 🟨 |
| Intensity | = | Severe | 2 | 🟥 |
| Related to Inv Me... | = | Probable | 1 | 🟨 |
| Related to Inv Me... | = | Highly Probable | 2 | 🟥 |

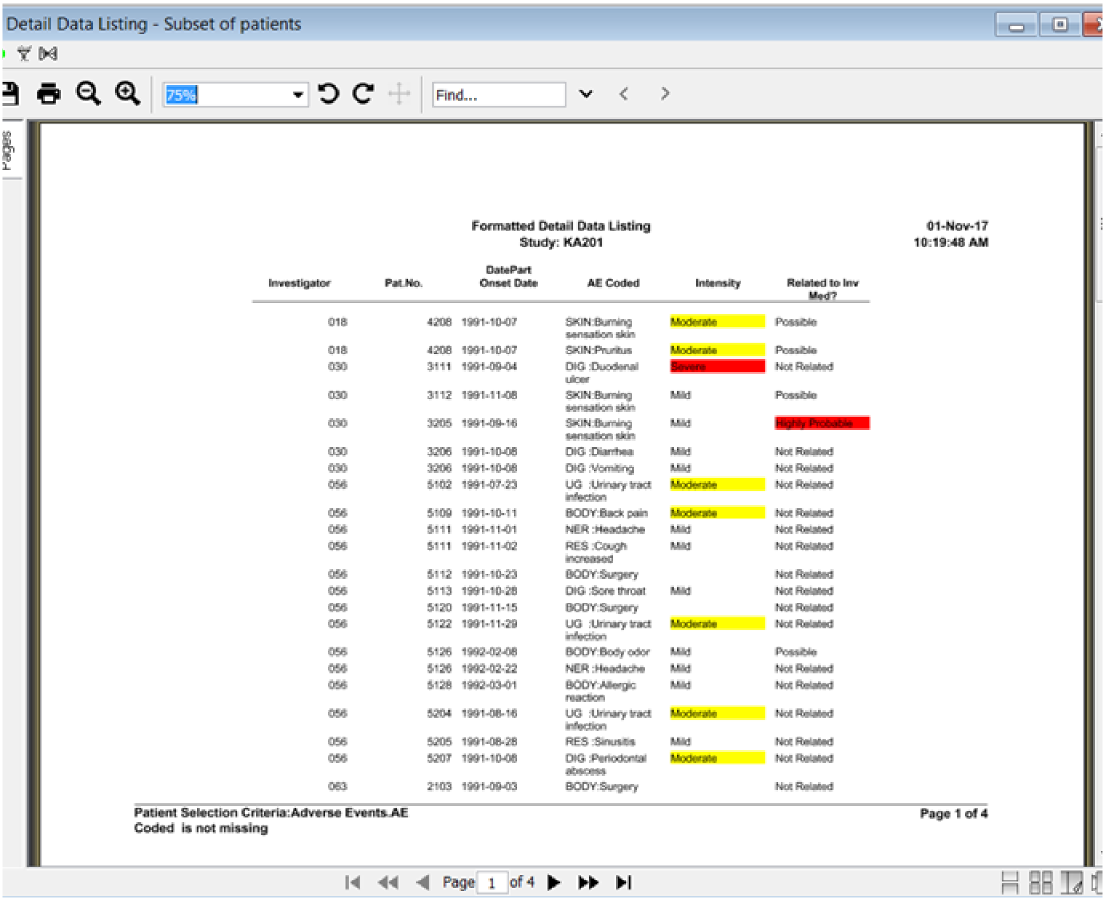
Selecting multiple items from the Unique Values list is not allowed. Each item must be an individual selection to assign a Severity and Color.



| | Decode Text | Code |
|---|---|---|
| 1 | | |
| 2 | Mild | 1 |
| 3 | Moderate | 2 |
| 4 | Severe | 3 |

Multiple value selections not supported.

Individual data items are highlighted for ‘Intensity’ and ‘Related to Inv Med?’ based on the saved data highlighting criteria.



Formatted Detail Data Listing
Study: KA201

01-Nov-17
10:19:48 AM

| Investigator | Pat.No. | DatePart Onset Date | AE Coded | Intensity | Related to Inv Med? |
|---|---|---|---|---|---|
| 018 | 4208 | 1991-10-07 | SKIN:Burning sensation skin | Moderate | Possible |
| 018 | 4208 | 1991-10-07 | SKIN:Pruritus | Moderate | Possible |
| 030 | 3111 | 1991-09-04 | DIG :Duodenal ulcer | Severe | Not Related |
| 030 | 3112 | 1991-11-08 | SKIN:Burning sensation skin | Mild | Possible |
| 030 | 3205 | 1991-09-16 | SKIN:Burning sensation skin | Mild | Highly Probable |
| 030 | 3206 | 1991-10-08 | DIG :Diarrhea | Mild | Not Related |
| 030 | 3206 | 1991-10-08 | DIG :Vomiting | Mild | Not Related |
| 056 | 5102 | 1991-07-23 | UG :Urinary tract infection | Moderate | Not Related |
| 056 | 5109 | 1991-10-11 | BODY:Back pain | Moderate | Not Related |
| 056 | 5111 | 1991-11-01 | NER :Headache | Mild | Not Related |
| 056 | 5111 | 1991-11-02 | RES :Cough increased | Mild | Not Related |
| 056 | 5112 | 1991-10-23 | BODY:Surgery |  | Not Related |
| 056 | 5113 | 1991-10-28 | DIG :Sore throat | Mild | Not Related |
| 056 | 5120 | 1991-11-15 | BODY:Surgery |  | Not Related |
| 056 | 5122 | 1991-11-29 | UG :Urinary tract infection | Moderate | Not Related |
| 056 | 5126 | 1992-02-08 | BODY:Body odor | Mild | Possible |
| 056 | 5126 | 1992-02-22 | NER :Headache | Mild | Not Related |
| 056 | 5128 | 1992-03-01 | BODY:Allergic reaction | Mild | Not Related |
| 056 | 5204 | 1991-08-16 | UG :Urinary tract infection | Moderate | Not Related |
| 056 | 5205 | 1991-08-28 | RES :Sinusitis | Mild | Not Related |
| 056 | 5207 | 1991-10-08 | DIG :Periodontal abscess | Moderate | Not Related |
| 063 | 2103 | 1991-09-03 | BODY:Surgery |  | Not Related |

Patient Selection Criteria:Adverse Events.AE Coded is not missing

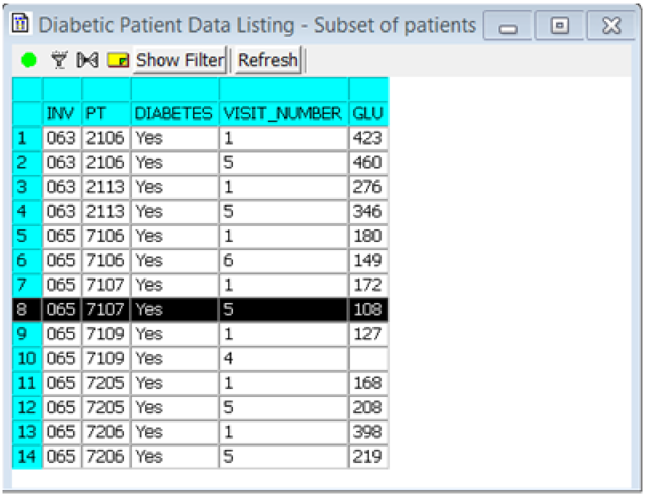
Page 1 of 4

# Highlighting patients

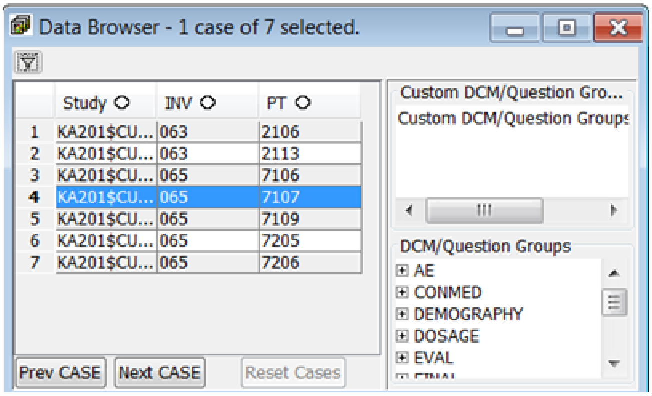
## *Single patient mode*

If you have created multiple patient-level displays of your data from all of the applicable browsers, you can click on any row in one of the report windows to highlight a patient of interest in a Detail Data Listing Report.

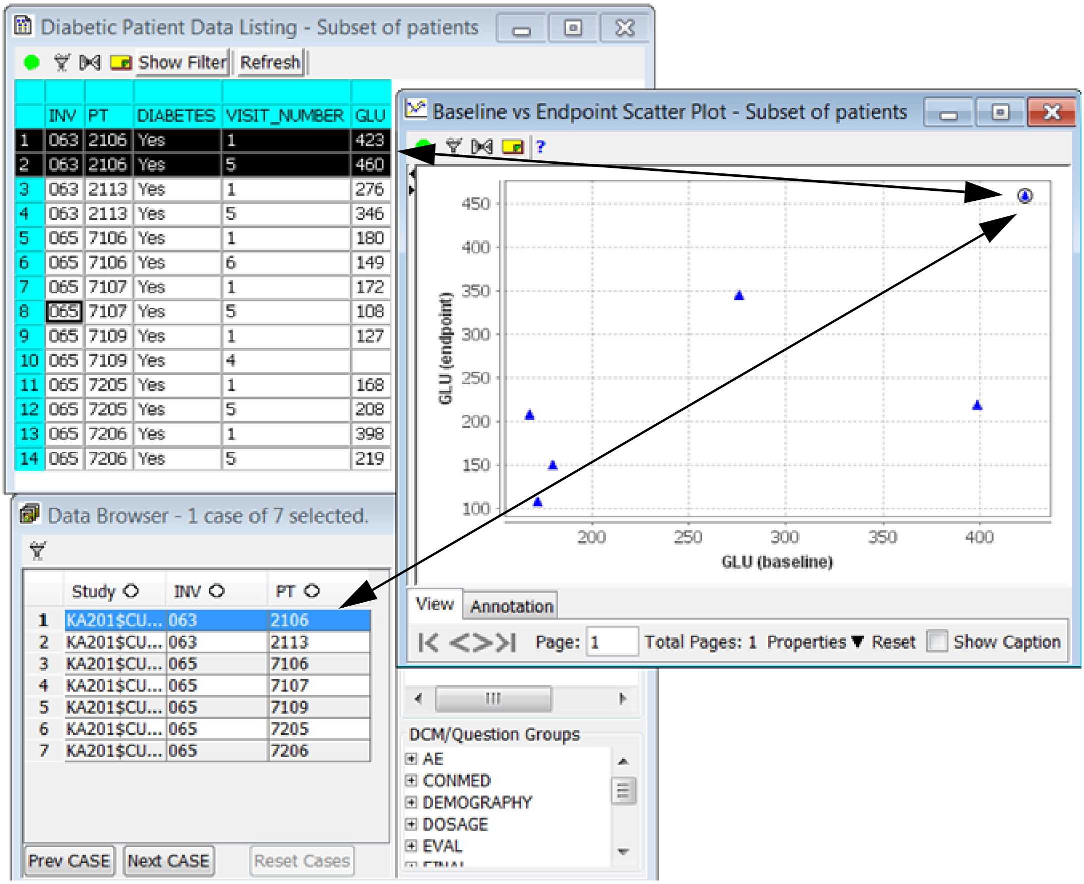
Click on one patient row instantly highlights the corresponding patient and data in any other active patient-level reports, patient listings, and Scatter Plot graphs. In an active scatter graph, the selected patient's data point is highlighted.



|  | INV | PT | DIABETES | VISIT_NUMBER | GLU |
|---|---|---|---|---|---|
| 1 | 063 | 2106 | Yes | 1 | 423 |
| 2 | 063 | 2106 | Yes | 5 | 460 |
| 3 | 063 | 2113 | Yes | 1 | 276 |
| 4 | 063 | 2113 | Yes | 5 | 346 |
| 5 | 065 | 7106 | Yes | 1 | 180 |
| 6 | 065 | 7106 | Yes | 6 | 149 |
| 7 | 065 | 7107 | Yes | 1 | 172 |
| 8 | 065 | 7107 | Yes | 5 | 108 |
| 9 | 065 | 7109 | Yes | 1 | 127 |
| 10 | 065 | 7109 | Yes | 4 |  |
| 11 | 065 | 7205 | Yes | 1 | 168 |
| 12 | 065 | 7205 | Yes | 5 | 208 |
| 13 | 065 | 7206 | Yes | 1 | 398 |
| 14 | 065 | 7206 | Yes | 5 | 219 |



|  | Study | INV | PT |
|---|---|---|---|
| 1 | KA201$CU... | 063 | 2106 |
| 2 | KA201$CU... | 063 | 2113 |
| 3 | KA201$CU... | 065 | 7106 |
| 4 | KA201$CU... | 065 | 7107 |
| 5 | KA201$CU... | 065 | 7109 |
| 6 | KA201$CU... | 065 | 7205 |
| 7 | KA201$CU... | 065 | 7206 |



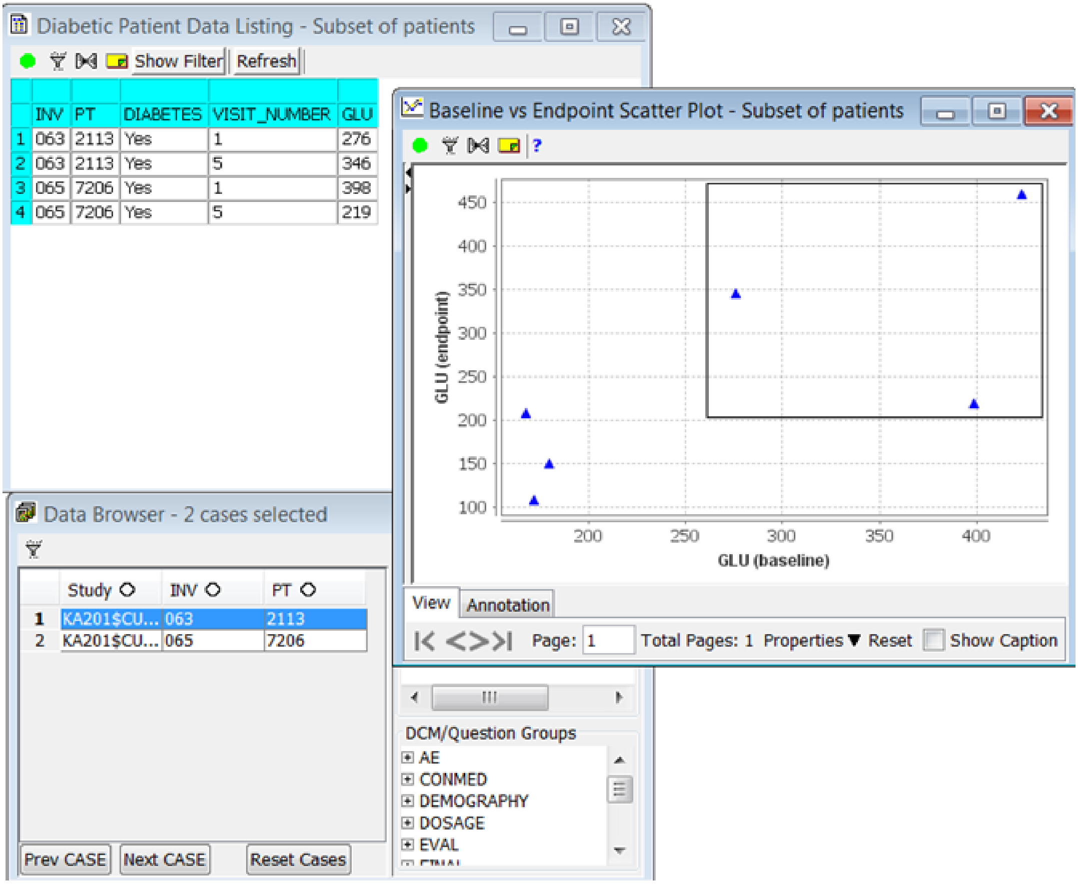
| | INV | PT | DIABETES | VISIT_NUMBER | GLU |
|---|---|---|---|---|---|
| 1 | 063 | 2106 | Yes | 1 | 423 |
| 2 | 063 | 2106 | Yes | 5 | 460 |
| 3 | 063 | 2113 | Yes | 1 | 276 |
| 4 | 063 | 2113 | Yes | 5 | 346 |
| 5 | 065 | 7106 | Yes | 1 | 180 |
| 6 | 065 | 7106 | Yes | 6 | 149 |
| 7 | 065 | 7107 | Yes | 1 | 172 |
| 8 | 065 | 7107 | Yes | 5 | 108 |
| 9 | 065 | 7109 | Yes | 1 | 127 |
| 10 | 065 | 7109 | Yes | 4 | |
| 11 | 065 | 7205 | Yes | 1 | 168 |
| 12 | 065 | 7205 | Yes | 5 | 208 |
| 13 | 065 | 7206 | Yes | 1 | 398 |
| 14 | 065 | 7206 | Yes | 5 | 219 |

| | Study ○ | INV ○ | PT ○ |
|---|---|---|---|
| 1 | KA201$CU... | 063 | 2106 |
| 2 | KA201$CU... | 063 | 2113 |
| 3 | KA201$CU... | 065 | 7106 |
| 4 | KA201$CU... | 065 | 7107 |
| 5 | KA201$CU... | 065 | 7109 |
| 6 | KA201$CU... | 065 | 7205 |
| 7 | KA201$CU... | 065 | 7206 |

***Multi-Line Chart not yet supported by JReview.*** In an active Multi-Line Chart Item Value vs. Category by Case graph, a highlighted line within the graph will update all patient-level displays of data to highlight the patient underlying the case data.

## *Multiple-patient mode*

When multiple patients are highlighted and selected from any patient-level display of data, the Detail Data Listing Reports are updated to display only the patients that are highlighted and selected. **(See *Chapter 6: Graph Browser - Multiple Patient Mode.*)**



|   | INV | PT | DIABETES | VISIT_NUMBER | GLU |
|---|---|---|---|---|---|
| 1 | 063 | 2113 | Yes | 1 | 276 |
| 2 | 063 | 2113 | Yes | 5 | 346 |
| 3 | 065 | 7206 | Yes | 1 | 398 |
| 4 | 065 | 7206 | Yes | 5 | 219 |

|   | Study ○ | INV ○ | PT ○ |
|---|---|---|---|
| 1 | KA201$CU... | 063 | 2113 |
| 2 | KA201$CU... | 065 | 7206 |

The CrossTab Browser results are categorical patient counts.  A selected and highlighted count within a CrossTab or Shift Results Table activates all patient level displays to be in the multiple patient mode.

When a patient count is highlighted in the CrossTab results window, all Detail Data Listing Reports are instantly updated to display only the patients underlying the patient count highlighted from the CrossTab Browser results table.

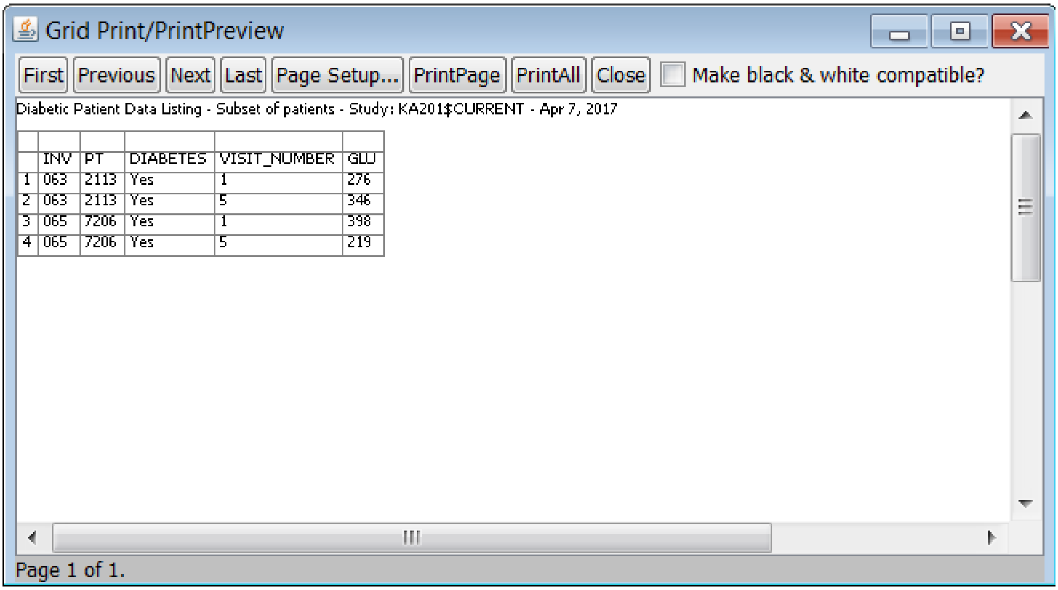
# Printing and Exporting Results

## *Printing the result*

The Print function is applicable to all browsers with output results. To get a printed copy of your output:

1. Click on the generated output window to make it the active window.
2. Click 🖨 , or from the JReview **File** menu, select **Print**.

JReview displays a screen shot of the selected active screen. You can use the buttons to scroll through the pages of the output.



Diabetic Patient Data Listing - Subset of patients - Study: KA201$CURRENT - Apr 7, 2017

|  | INV | PT | DIABETES | VISIT_NUMBER | GLU |
|---|---|---|---|---|---|
| 1 | 063 | 2113 | Yes | 1 | 276 |
| 2 | 063 | 2113 | Yes | 5 | 346 |
| 3 | 065 | 7206 | Yes | 1 | 398 |
| 4 | 065 | 7206 | Yes | 5 | 219 |

3. Click either **PrintPage**, **PrintAll** or **Close**. The PrintPage option will print only the first page of your output. The PrintAll option will print the entire output. The report prints on the currently selected printer.

***Note:*** ***Use the Convert to pure black & white? option is only applicable to graphs where multiple colors are displayed. If your printer is non-color click this feature for better black and white print resolution of graphs.***

***Caution:*** ***Do not select the Internet Browser's FILE menu Print option. This will cause a system error.***

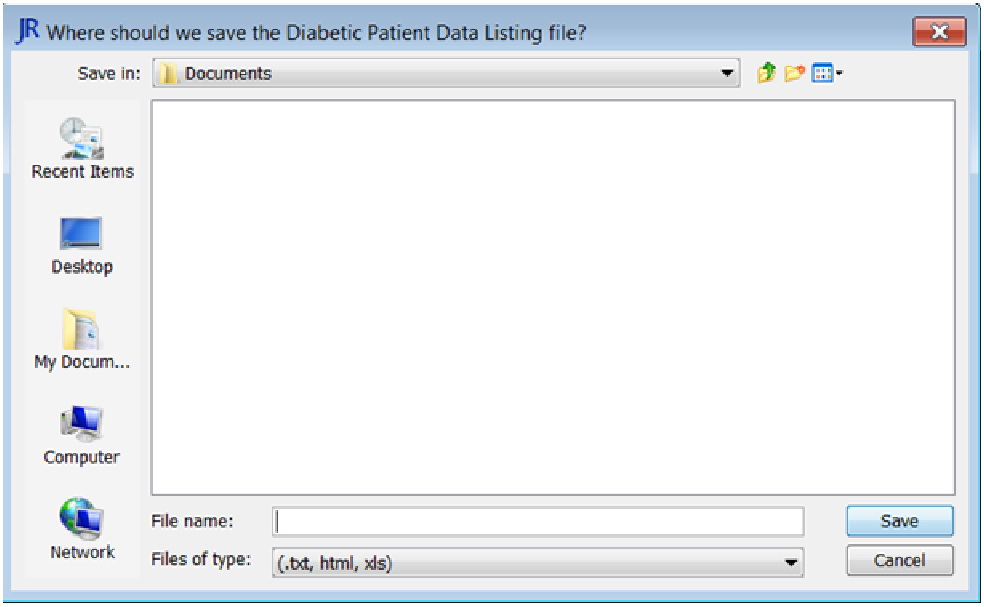
## *Exporting the result*

You can use the Export function to export your results. When you select this option an export window opens to select a file type and directory. The file options are dependent upon the result type and display the appropriate export file options available. For example, tabular data has export options for HTML, EXCEL, TXT, PDFs for formatted objects and GIF for graph images.

***Note: Only Formatted Report types can be exported to PDF files. Non-formatted reports can only be exported to HTML, Excel and TXT.***

1. To select an object to export, it must be the active window. Select the **File** menu and click **Export**.

   JReview displays the **Save** window.



2. Enter the storage location.
3. Enter the File name.
4. Select the file type.
5. Click **Save**. The result is exported to the selected directory.

To copy and paste results ***See Chapter 1: Getting Started for General Instructions.***

## *Direct to Excel*

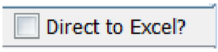
Users may choose to use the '**Direct to Excel**' feature for several reasons:

1. The Report Browser Export feature was limited to 64,000 rows based on the Excel2003 standard which had that limitation.
2. Numeric columns were saved as character type columns in the exported spreadsheet.
3. Performance reasons – very slow for very large reports.

The '**Direct to Excel**' feature addresses this by:

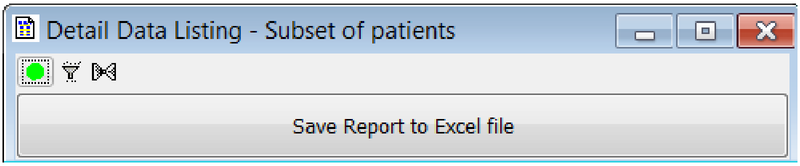
1. The Excel spreadsheet created by the JRServer is an Excel2007 format with the *maximum* worksheet size is 1048576 *rows* by 16384 columns.
2. Numeric columns are stored as numeric so the user can do arithmetic on the numeric cells without needing to fix the columns.
3. Performance should be much quicker since it's not transferring the data to the JReview client, then doing the export from there – but rather just transferring the completed Excel spreadsheet.

This feature may be used when defining a Detailed Data Listing. The '**Direct to Excel**' is located in the middle definition window of the Report Browser as a checkbox option.



***<u>NOTE:</u> Current release only available in Classic Mode.***

If the user checks this checkbox, then the JRServer creates the Excel spreadsheet on the JReview server and doesn't display the report output in the window, but rather displays a large button in the 'output window'.



When the user clicks on this large button the JReview client displays the the JReview client displays the normal file save dialog to choose where to store the file.

# Object Storage

For detailed instructions on how to save, retrieve, schedule output and remove object specifications (reports, graphs, crosstabs, etc.).
(***See Chapter 11: Saving and Manage Objects, Scheduling plus Alerts Browser)***

# Exploring data

## *Changing the patient selection criteria*

After you have executed a stored object, you can use the object(s) that are currently displayed as data exploration views by doing the following:

1. Change the patient selection criteria, redefining it by adding additional expressions, or removing existing expressions.
2. Click **Update Browsers** in the Patient Selection Criteria window to update all active browsers according to the new criteria.

   All browser objects that are displayed will be updated according to your new criteria. Each object generated with a filter on will update with the same filter criteria with which it was created.

***Note: Restrictions apply if the stored object definition has a required patient selection criteria applied.***

## *Patient Identification*

Multiple patients can be selected from all patient-level displays of data results. Selecting more than one patient activates JReview's multiple-patient mode, which updates patient-level displays of data to highlight only the selected patient data. This facilitates patient identification and subsetting, for exploration of the selected patient data with the reviewing facilities of the Data Browser and all of JReview's browser tools.

# 7 Graph Browser

# Patient selection criteria

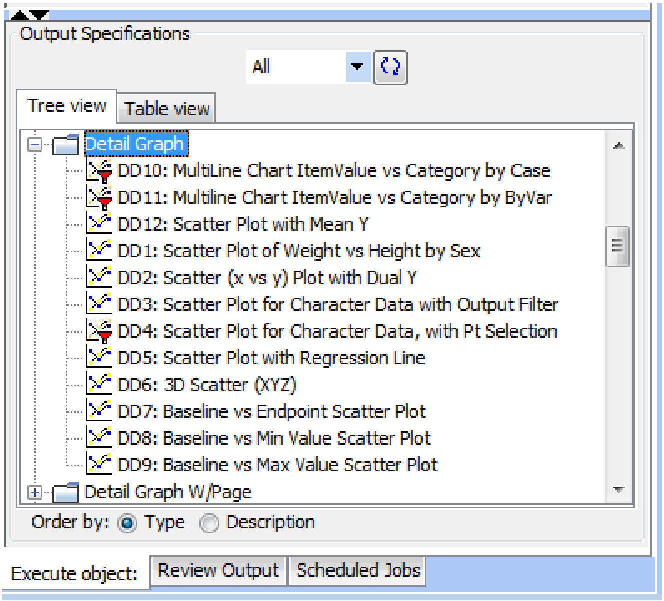
## *Selection set*

In JReview, you can explore selected data items of the selected patients graphically by using the Graph Browser. After launching the saved patient subset, Dynamic PSC or building your own patient selection criteria, you can explore a variety of stored graphs. Previously stored graph objects may be created in the Graph Browser from JReview.

# Execute a graph

## *Quick execute*

JReview displays a list of categorical folders for stored patient subsets and output specifications at the selected storage location. Simply select one of the user access storage locations to display it's specific folders and contents. Icons identify the source as report, graph, crosstab, etc. and a filter icon displays when a patient selection criteria is saved with the stored object. ***(See Chapter 5: Report Browser for Execute a Report. The same instructions apply for the Graph Browser.)***



Detail Graph
- DD10: MultiLine Chart ItemValue vs Category by Case
- DD11: Multiline Chart ItemValue vs Category by ByVar
- DD12: Scatter Plot with Mean Y
- DD1: Scatter Plot of Weight vs Height by Sex
- DD2: Scatter (x vs y) Plot with Dual Y
- DD3: Scatter Plot for Character Data with Output Filter
- DD4: Scatter Plot for Character Data, with Pt Selection
- DD5: Scatter Plot with Regression Line
- DD6: 3D Scatter (XYZ)
- DD7: Baseline vs Endpoint Scatter Plot
- DD8: Baseline vs Min Value Scatter Plot
- DD9: Baseline vs Max Value Scatter Plot

Detail Graph W/Page

Order by: ● Type ○ Description

# Graph types and features

## *Graph features*

Graphs are pictorial representations of the relationships between two (or more) variables, and are an important part of descriptive statistics. They can be used any time one wants to visually summarize the relationships between variables, especially if the data set is large or unmanageable. Graphs are routinely used with reports to underscore a particular statement about a data set and to enhance readability.

## *Detail data graph*

Detail Data Graphs display individual patient data points for each patient observation. Create the following Detail Data Graphs in JReview:

- Scatter (itemX vs itemY) Plot
- Scatter (itemX vs itemY) Plot with Regression Line
- Scatter (itemX vs itemY) Upper Limit Normal Range Plot
- 3D Scatter (XYZ)
- Baseline vs Endpoint Scatter Plot
- Baseline vs Min Value Scatter Plot
- Baseline vs Max Value Scatter Plot
- Multiline Chart Item Value vs Category by Case
- Multiline Chart Item Value vs Category by ByVar
- Benefit Risk
- Napoleons March
- Timeline Trellis by Patient
- Spaghetti Plot

## *Summary data graph*

Summary Data Graphs display summary information such as summary category, counts, means, etc.  Create the following Summary Graphs in JReview:

- 2D BarChart Frequency Distribution
- 3D BarChart Frequency Distribution
- 2D BarChart Item Summary vs Category

  - 3D BarChart Item Summary vs Category
  - Pareto Chart Frequency Distribution
  - Pie Chart Item Summary vs Category
  - Line Chart Item Summary vs Category
  - Mean + Std Dev vs Category
  - Box Whiskers Plot
  - Kaplan Meier
  - Bubble Chart
  - Timeline Trellis by Patient Group

The **3-D** bar charts do NOT support the showing/hiding series for BY variable values. Therefore, the series filters panels are not shown for 3D bar charts. Also, Pie charts will not show a filter panel either.

## *Bar styles*

The following Bar Styles are available for 2D BarCharts only:

- Clustered bar (Vertical)
- Clustered bar (Horizontal)
- Stacked bar (Vertical)
- Stacked bar (Horizontal)

## *Group functions*

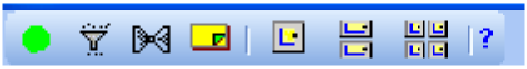
All general purpose graph types (2D Scatter and BarChart) allow all normal data function selections displayed in the Functions listbox. In addition, the following summary graphs support Group Functions (count, count subjects, min, max, mean, std dev, sum) dependent upon the item selected:

- 2D BarChart Item Summary vs Category
- 3D BarChart Item Summary vs Category
- Pie Chart Item Summary vs Category
- Line Chart Item Summary vs Category
- Spaghetti Plot

# Graph display results

## 2D Graph Toolbar

When you click Create Graph the graph toolbar is displayed at the top of the results output window. The first and second buttons are the ‘Snapshot’ and ‘Who?’ buttons and are available for all output browsers. Only Scatter Plot graphs display the “Add Notes” icon in the scatter plot icon toolbar.



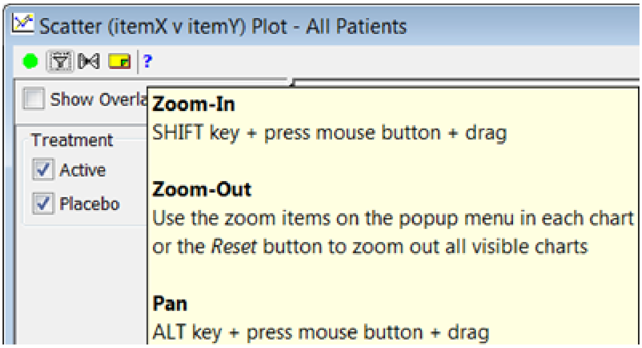
If you generate a graph without the multi-page option enabled the toolbar displays the buttons for ‘Snapshot’, ‘Who?’ and ‘Output Filter’.

Initially the graph opens and displays in single mode. If a Page By item variable was defined, you can move within single mode between the individual pages with the up/down arrow keys.

The toolbar displayed in your graph results window is dependent upon the graph you specified. Select 2D graphs have optional multi-page graph display buttons enabled, when the Page By item variable is defined in the graph specification.

The next button applies to the multi-page graphing capability for select 2D graphs where multiple graphs can display on the same window. The Page By item variable is optional when you define the graph specification. Simply click a multi-page graph button to view several graphs displayed on the same window.

The “Question Mark” functions as a tooltip to display a graph manipulation key.



**Zoom-In**
SHIFT key + press mouse button + drag

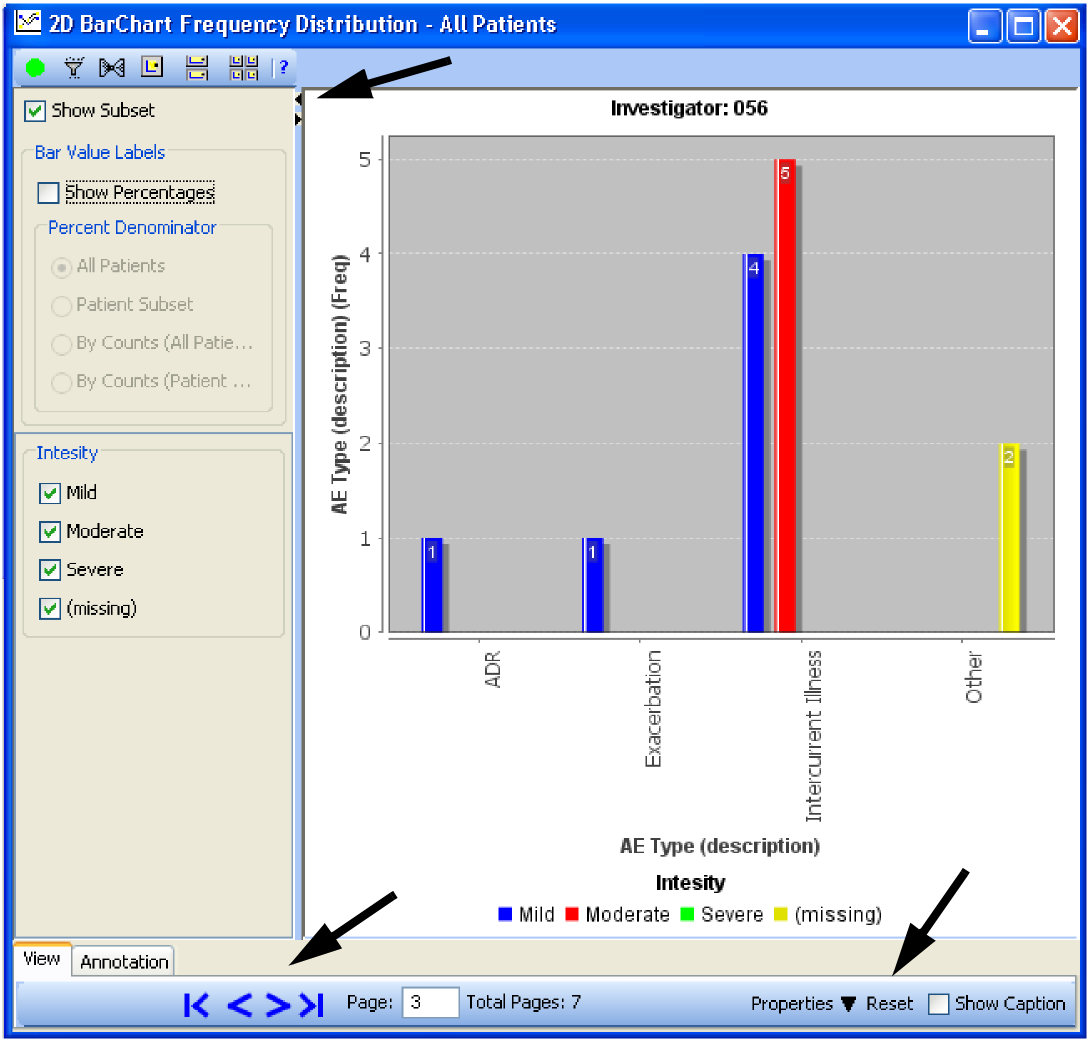
**Zoom-Out**
Use the zoom items on the popup menu in each chart or the *Reset* button to zoom out all visible charts

**Pan**
ALT key + press mouse button + drag

If you use the graph manipulations keys to zoom or pan the display, you can reset the graph to the original display image by clicking “Reset”, located in the graph footer.

In this example, the **Page By** item variable for “Investigator”, is displayed at the top of each graph. The page number is displayed at the bottom.

Use the top left black arrows to minimize, or display the legend **Series**.



2D BarChart Frequency Distribution - All Patients

☑ Show Subset

Bar Value Labels

☐ Show Percentages

Percent Denominator

● All Patients
○ Patient Subset
○ By Counts (All Patie…
○ By Counts (Patient …

Intesity

☑ Mild
☑ Moderate
☑ Severe
☑ (missing)

Page: 3 Total Pages: 7

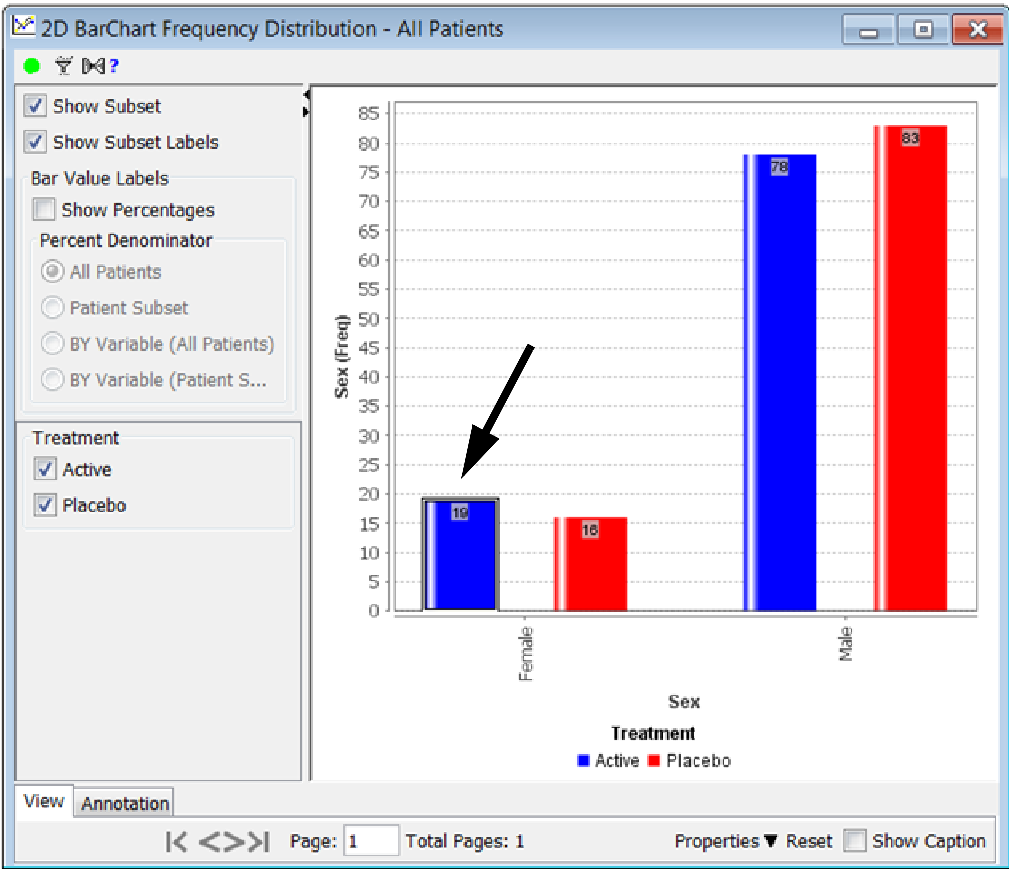
☐ Show Caption

## *Show Subset*

Bar Graphs are “summary” data charts and by definition do not display the individual PIDs of the retrieved drill-down data. However, a bar in a Bar Graph is selectable with the consequent activation of the “drill-down” mechanism. The PIDs used from the selected bar are propagated to the Data Browser and Scatter plot graphs.

The **Bar Selection Subset** feature allows Bar Graphs to be responsive to the selection of a bar in another bar-graph view. When a bar is selected in a Bar Graph, any other open Bar Graphs (in separate views) are subset.

Here, the user clicked on ‘Females Active Treatment’ in the Bar Graph.



2D BarChart Frequency Distribution - All Patients

☑ Show Subset

☑ Show Subset Labels

Bar Value Labels

☐ Show Percentages

Percent Denominator

● All Patients

○ Patient Subset

○ BY Variable (All Patients)

○ BY Variable (Patient S...

Treatment

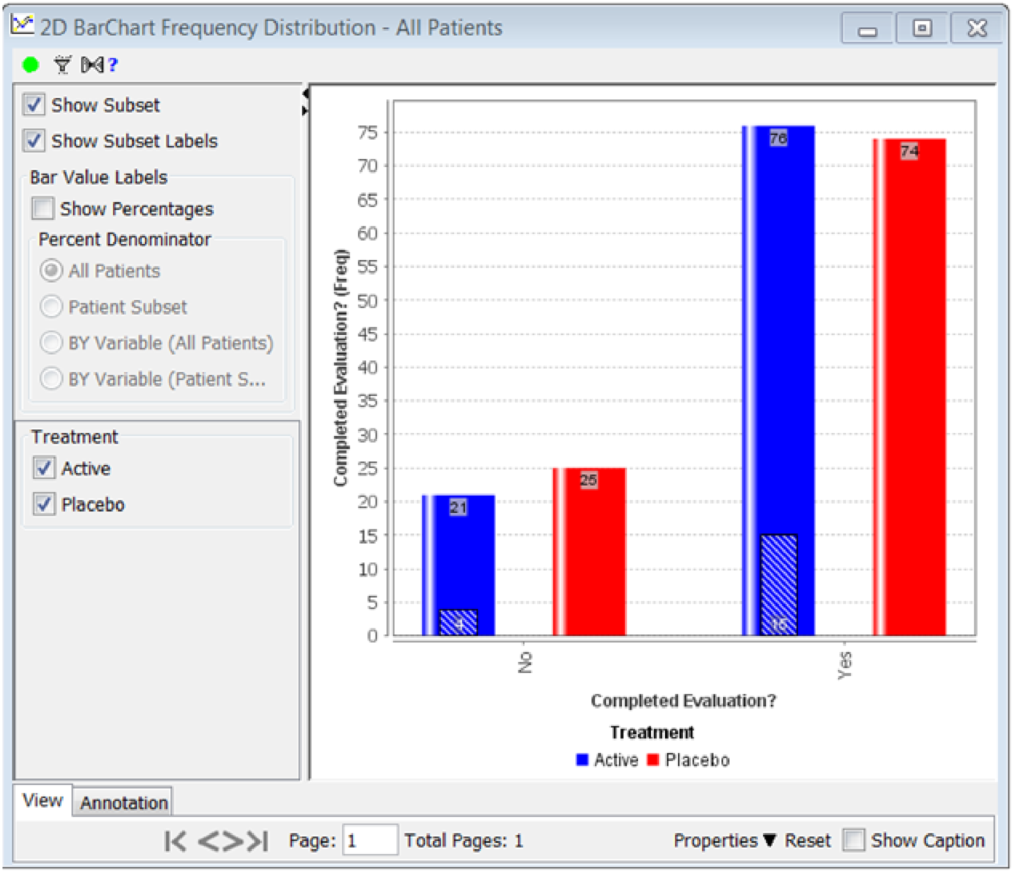
☑ Active

☑ Placebo

Page: 1 Total Pages: 1

☐ Show Caption

As a result, the following bar graph displays the subset data. The diagonally striped bar drawn inside each bar represents the subset value. In this case, the frequency value displayed in the overlay for each age group counts only Females on Active Treatment. The subset data is then presented as an overlay on the bars. In effect, the selected bar defines an “output filter“for the receiving bar graphs.



2D BarChart Frequency Distribution - All Patients

☑ Show Subset

☑ Show Subset Labels

Bar Value Labels

☐ Show Percentages

Percent Denominator

● All Patients

○ Patient Subset

○ BY Variable (All Patients)

○ BY Variable (Patient S...

Treatment

☑ Active

☑ Placebo

Page: 1 Total Pages: 1

☐ Show Caption

Also, both the specification that defines the originating bar graph, including any of its output filters, and any parameters describing the selected bar are passed to each of the recipient bar graphs. Each of these recipient bar graphs may then "append" this passed data, to its own graph specification to retrieve the subset data.

The Bar Selection Subset feature is applicable to both Frequency bar graphs and Item-Summary versus Category bar graphs. However, there is a restriction for the Y-axis of an Item-Summary versus Category bar graph: The Group Function must be a *count;* a "mean", for example, is not allowed. No subset data will be retrieved for an "Item-Summary versus Category" graph that is defined with a Group Function that is not a count.

The users may show or hide the subset data using checkbox.

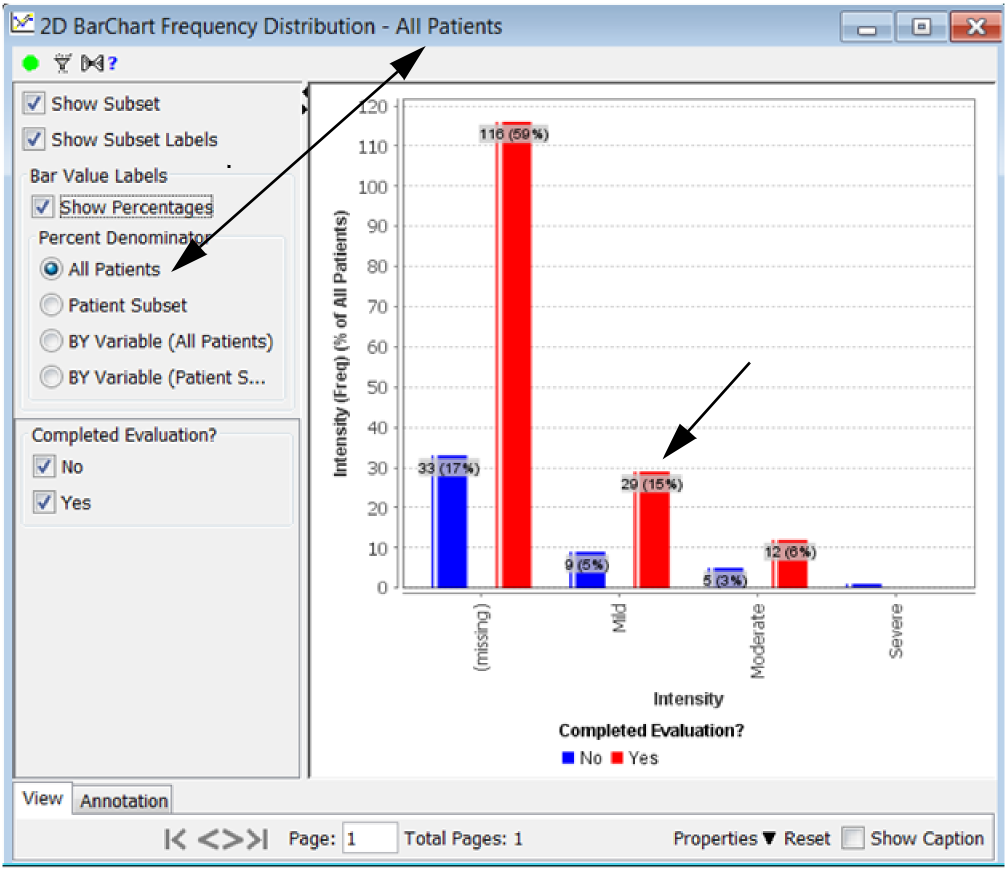
## *Show Percentages*

You may optionally show percentages for Frequency Bar Charts, Baseline with Reference Range graphs, and Hy's Law graphs. When you click the **Show Percentages checkbox** you enable the display for counts and percent annotations for bars.

If a patient selection criteria was applied, choose the preferred **Percent Denominator** option for All Patients versus Patient Subset.

In our example, the **Show Percentages** has Percent Denominator set to **All Patients**. See patients with Mild AE Intensity who Completed Study (tallest red bar) when set to **All Patients,** calculates as:

(29 patients /total 196 patients) * 100% = 15%


2D BarChart Frequency Distribution - All Patients

☑ Show Subset

☑ Show Subset Labels

Bar Value Labels

☑ Show Percentages

Percent Denominator

● All Patients

○ Patient Subset

○ BY Variable (All Patients)

○ BY Variable (Patient S...

Completed Evaluation?

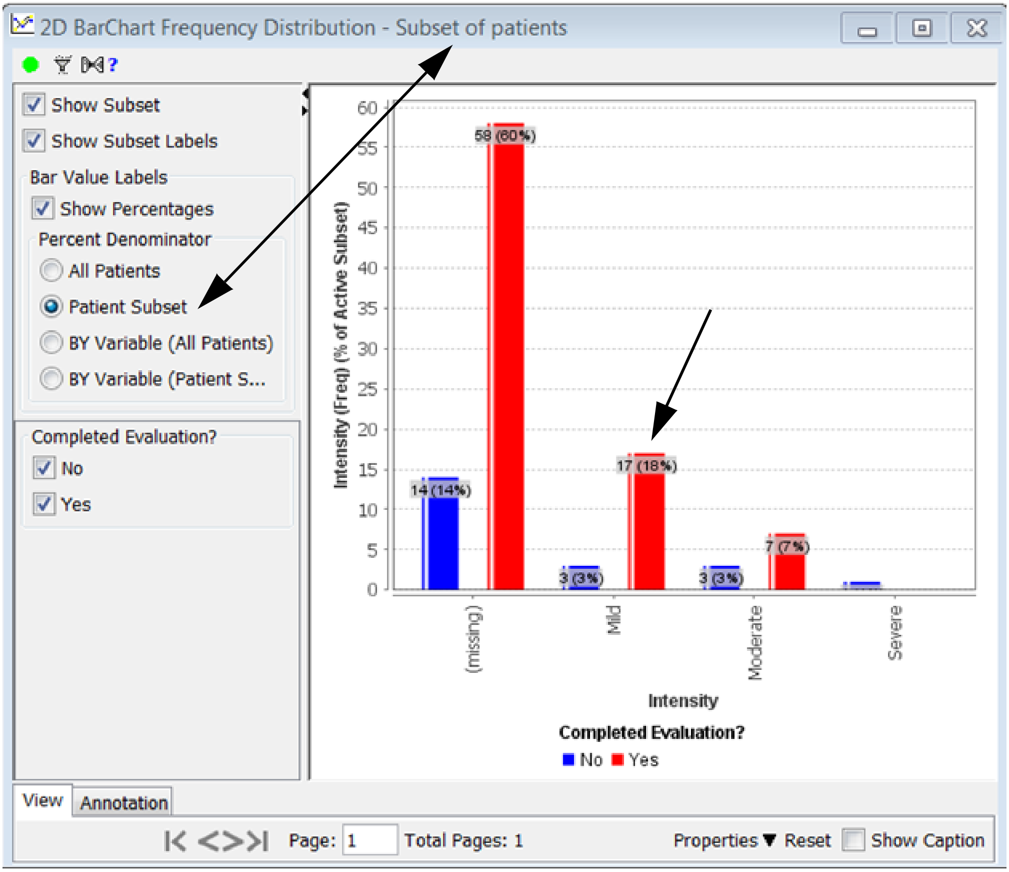
☑ No

☑ Yes

Here is the same graph with a patient selection criteria applied for ‘Active Treatment’ to subset 97 patients on Active treatment out of 196 total patients. Now the Percent Denominator is selected for **Patient Subset**.

See **Show Percentages** for patients with Mild AE Intensity who Completed Study with Percent Denominator set to **Patient Subset** calculates as:

(17 patients/97 subset) *100% = 18%

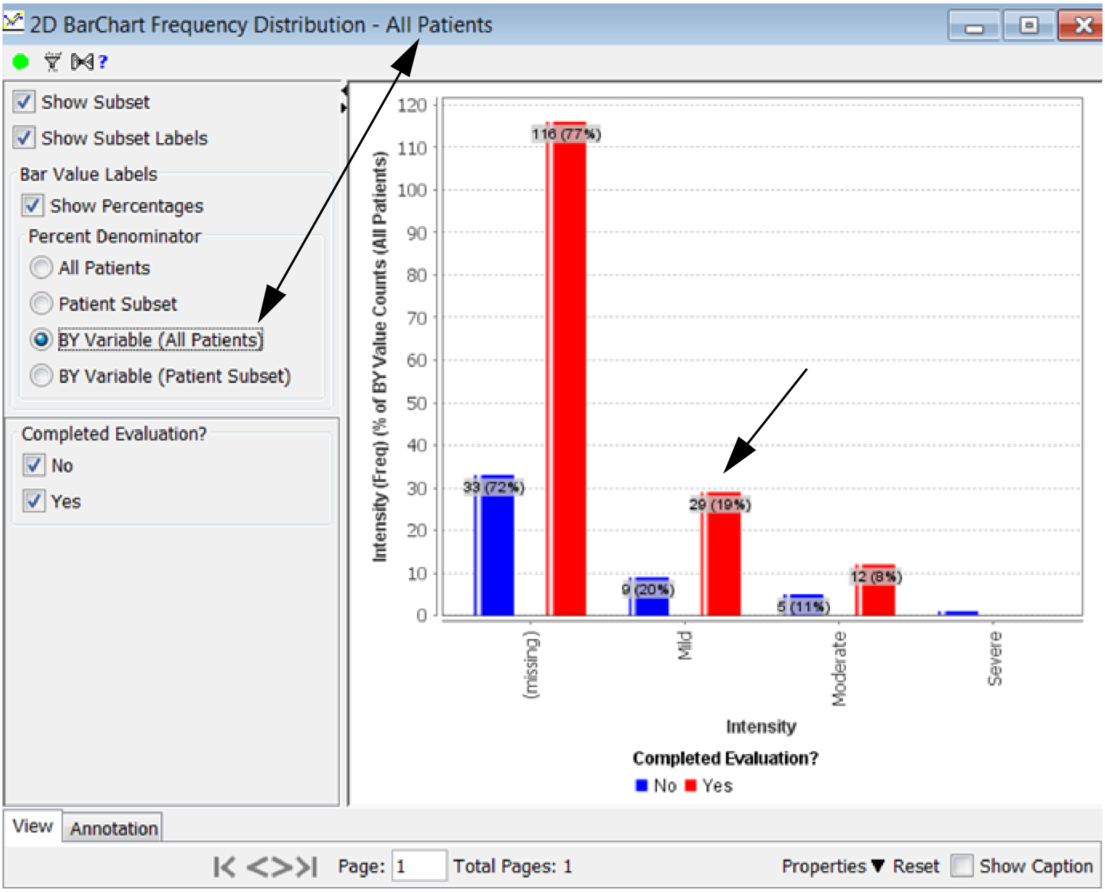


☑ Show Subset
☑ Show Subset Labels
Bar Value Labels
☑ Show Percentages
Percent Denominator
○ All Patients
● Patient Subset
○ BY Variable (All Patients)
○ BY Variable (Patient S...
Completed Evaluation?
☑ No
☑ Yes

In this graph example, the Percent Denominator is selected for **BY Variable (All Patients).** Completed Study is the BY Variable for 150 patients who completed study and 46 patients who discontinued.

See patients with Mild AE Intensity who Completed Study (tallest red bar) calculate as:

(29 patients / 150 patients who Completed Study) * 100% = 19%



2D BarChart Frequency Distribution - All Patients

☑ Show Subset

☑ Show Subset Labels

Bar Value Labels

☑ Show Percentages

Percent Denominator

○ All Patients

○ Patient Subset

● BY Variable (All Patients)

○ BY Variable (Patient Subset)

Completed Evaluation?

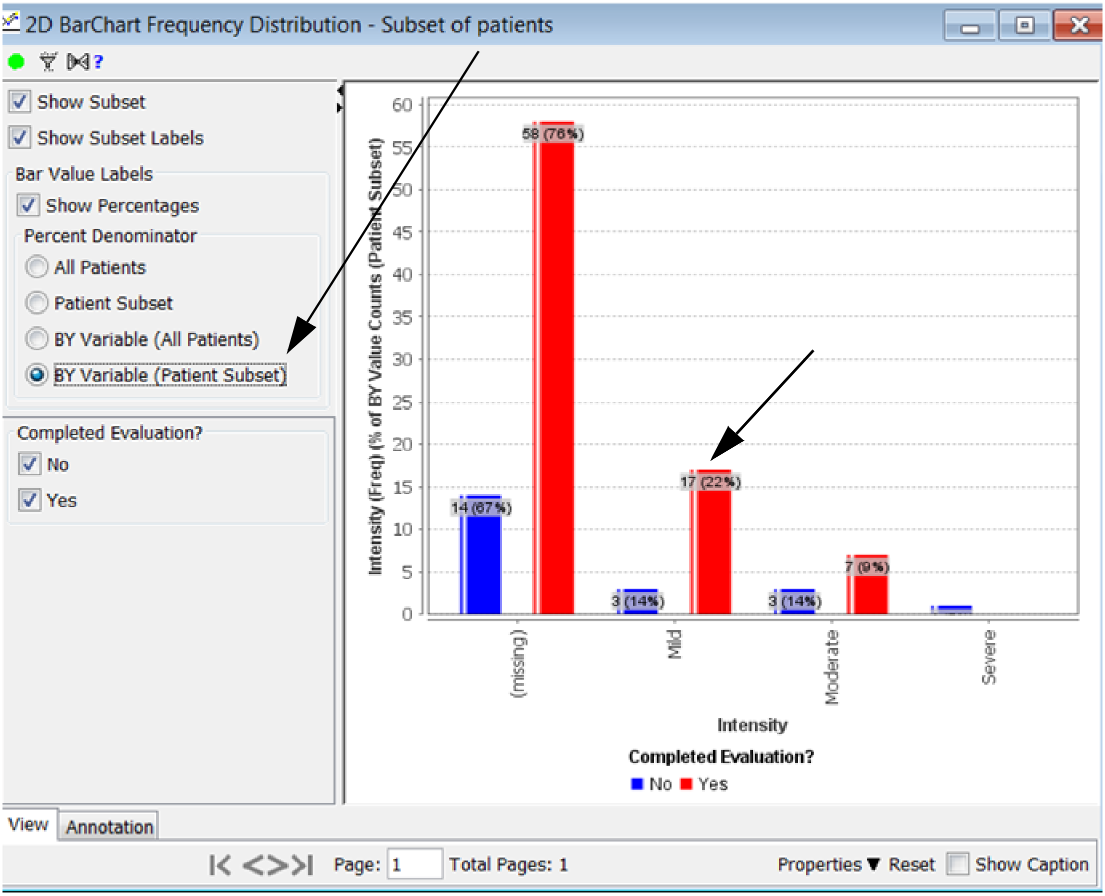
☑ No

☑ Yes

Next we applied the patient selection criteria for ‘Active Treatment’ and get 97 patients on Active treatment out of 196 total patients. In this patient subset there are 76 patients who Completed Study.

The Percent Denominator is selected for **BY Variable (Patient Subset).** Now see the patients with Mild AE Intensity who Completed study (tallest red bar) with calculated BY Variable as:

(17 patients / 76 patients on Active Treatment who Completed Study) * 100% = 22%



2D BarChart Frequency Distribution - Subset of patients

☑ Show Subset

☑ Show Subset Labels

Bar Value Labels

☑ Show Percentages

Percent Denominator

○ All Patients

○ Patient Subset

○ BY Variable (All Patients)

● BY Variable (Patient Subset)

Completed Evaluation?

☑ No

☑ Yes

Page: 1 Total Pages: 1

☐ Show Caption

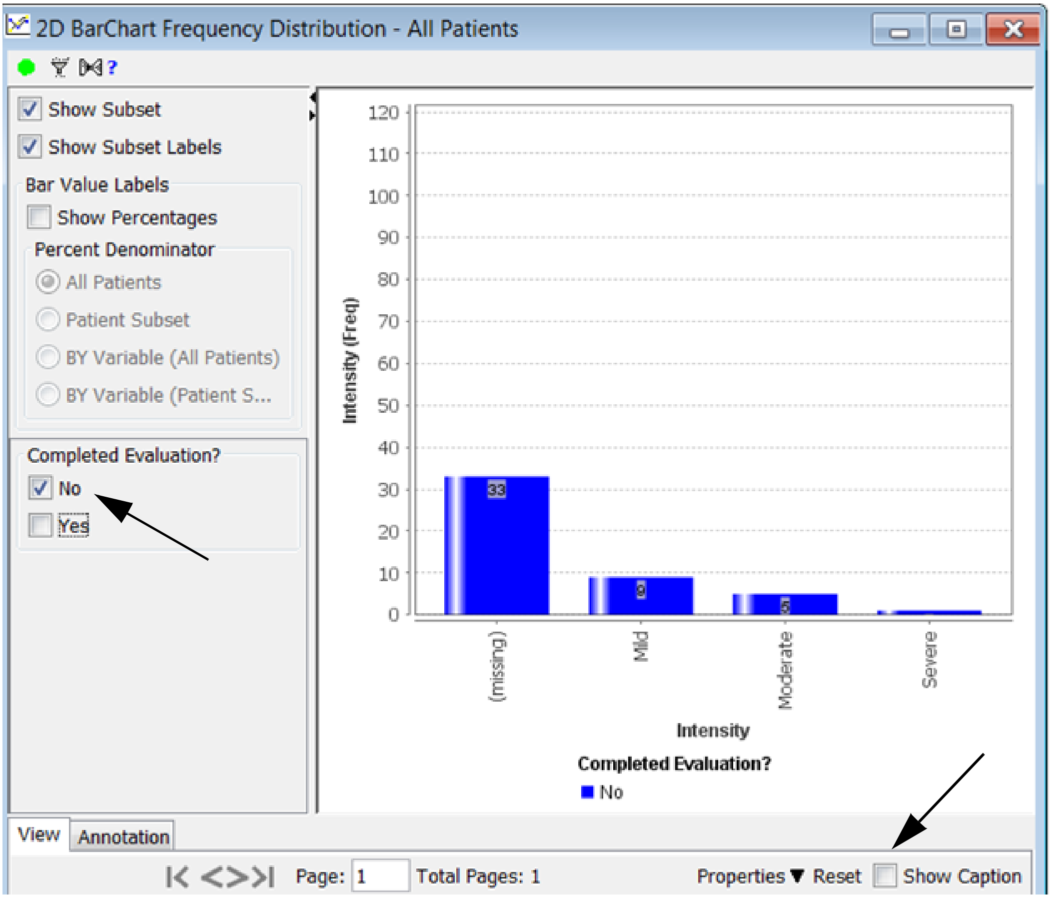
When the configuration is set in ReviewAdmin for a property in the JNLP file: "graphUserSelectableDenominator", then the Graph Bar Chart FREQ Distribution % options set the default BY Variable (Patient Subset). The radio buttons controlling the denominator choice for percent labels are applied in Freq Bar Graphs, Baseline-* with Reference Range graphs, and Hy's Law graphs.

The denominator type choice is available to end-users on a per customer basis. In other words, depending on a configuration setting, the user may or may not be able to select the denominator type. In automatic mode, JReview selects the denominator type. If a PSC is active then the denominator type will be one of the two PSC choices; similarly, if there is a BY variable defined, then the denominator type will be one of the two BY variable choices. Thus, if there is both a BY variable and an active PSC, the choice is "BY Variable (Patient Subset)". The user cannot change this choice under this configuration, and the radio buttons representing the other alternatives are disabled. If the configuration setting is not "automatic" mode, then the user can freely choose among the denominator types and none of the radio buttons is disabled.

***(See Review Admin Manual for illustrations of configuration modes)***

### *Display BY variable*

You may select which BY variable to display in the graph. In it ally the graph opens with all color coded BY variables displayed as checked ON. Click on a check box to turn off a BY variable from displaying in the graph. In this example, we turned off the patients who completed the study from displaying in the barchart (un-checked “Yes”).



2D BarChart Frequency Distribution - All Patients

☑ Show Subset
☑ Show Subset Labels

Bar Value Labels
☐ Show Percentages

Percent Denominator
● All Patients
○ Patient Subset
○ BY Variable (All Patients)
○ BY Variable (Patient S...

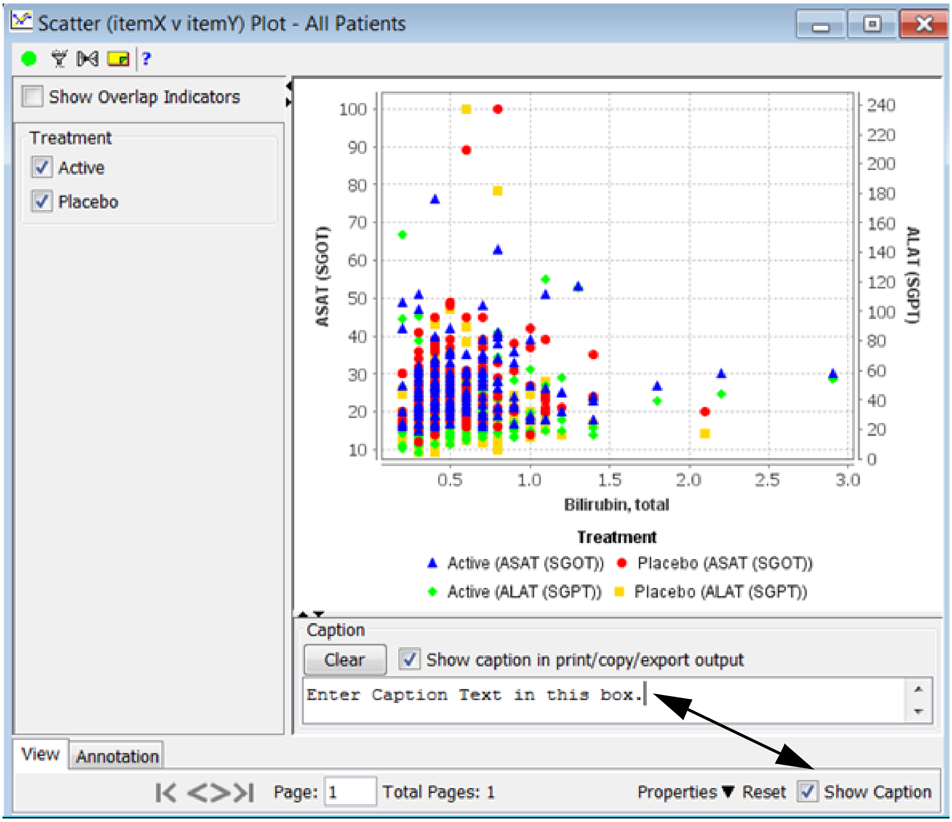
Completed Evaluation?
☑ No
☐ Yes

Page: 1 Total Pages: 1

☐ Show Caption

## *Show Caption*

The Show Caption checkbox option displays on all generated graph display windows. Click on the checkbox to enter annotation text describing the graph. It is especially useful when applying the Filter Control checkbox to describe current filter conditions for the graph result.



☑ Show caption in print/copy/export output

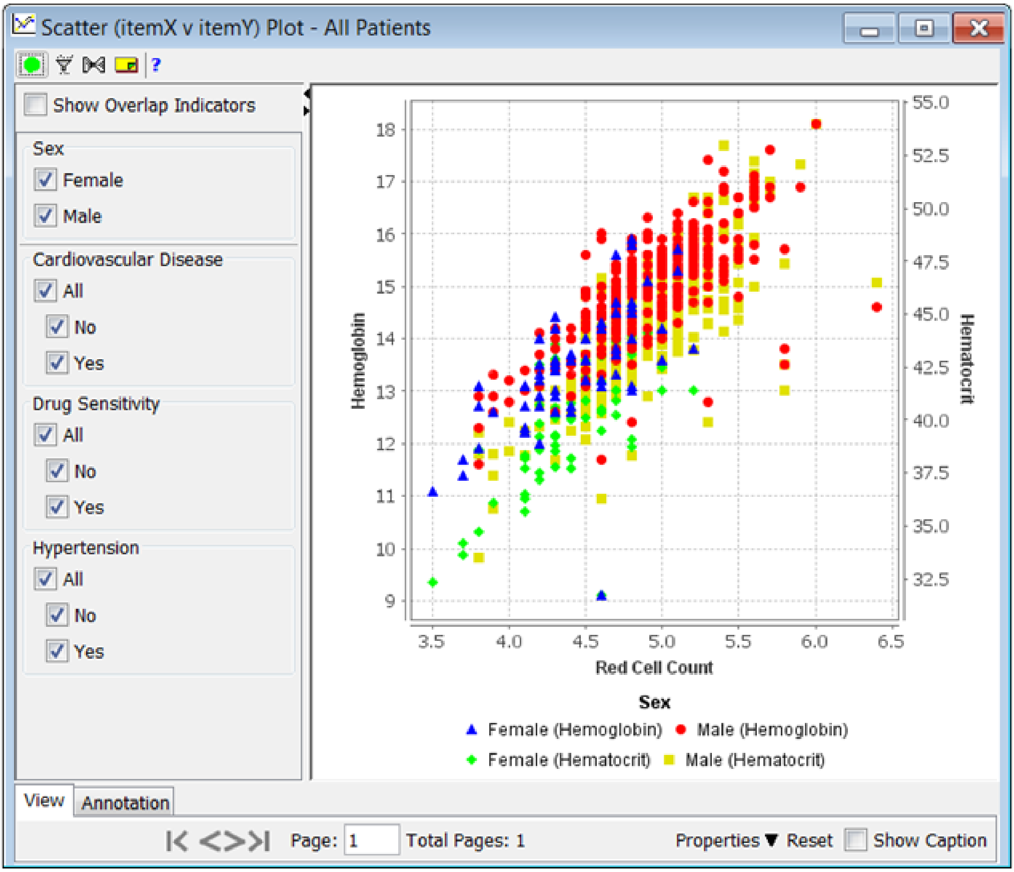
Enter Caption Text in this box.

Page: 1

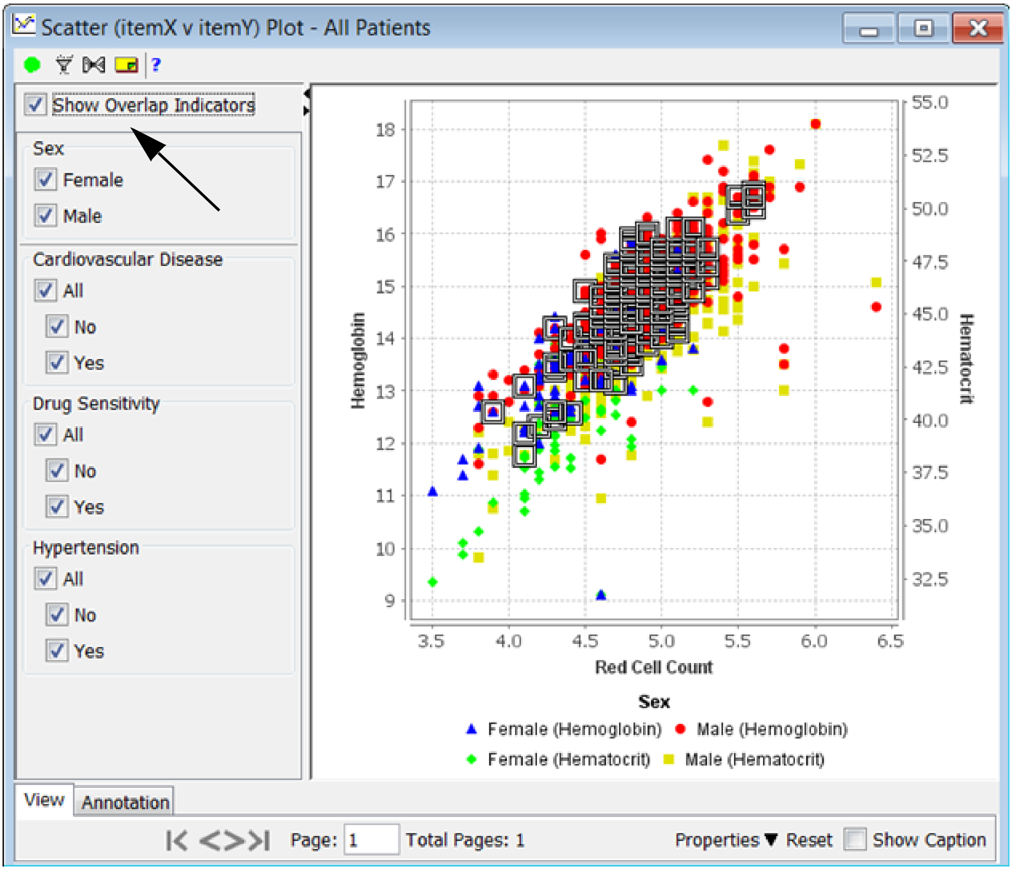
☑ Show Caption

## Show Overlap Indicators

This feature is available in Scatter Plots to allow the user to toggle from the display as on/off. The ‘overlapping symbols’ will display if multiple scatter points are plotted at the same location. Default off to not display overlap indicators.



**Show Overlap Indicators** toggled ON.



☑ Show Overlap Indicators

Sex
☑ Female
☑ Male

Cardiovascular Disease
☑ All
☑ No
☑ Yes

Drug Sensitivity
☑ All
☑ No
☑ Yes

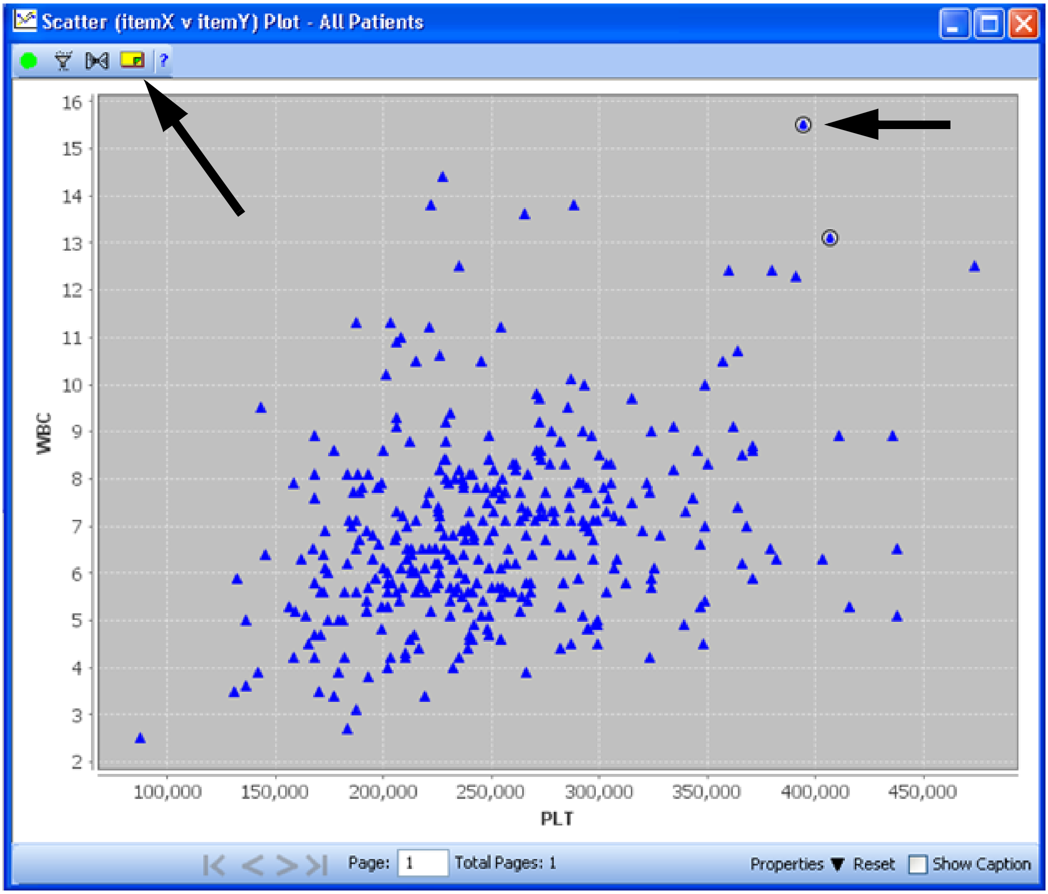
Hypertension
☑ All
☑ No
☑ Yes

Page: 1 Total Pages: 1

☐ Show Caption

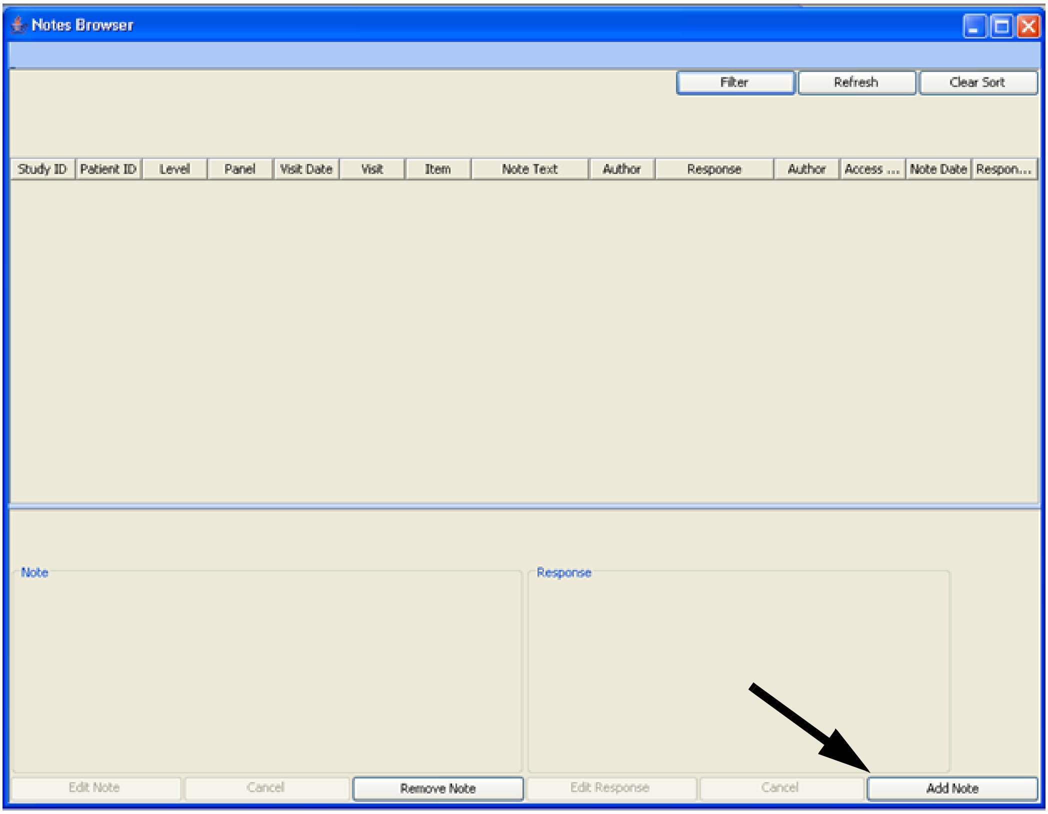
## *Add patient note*

When you generate a Scatter Plot the ‘**Add Notes**’ icon is available in the plot toolbar. It supports adding a patient note when you click on a data point in the graph and then click on the Add Notes icon.



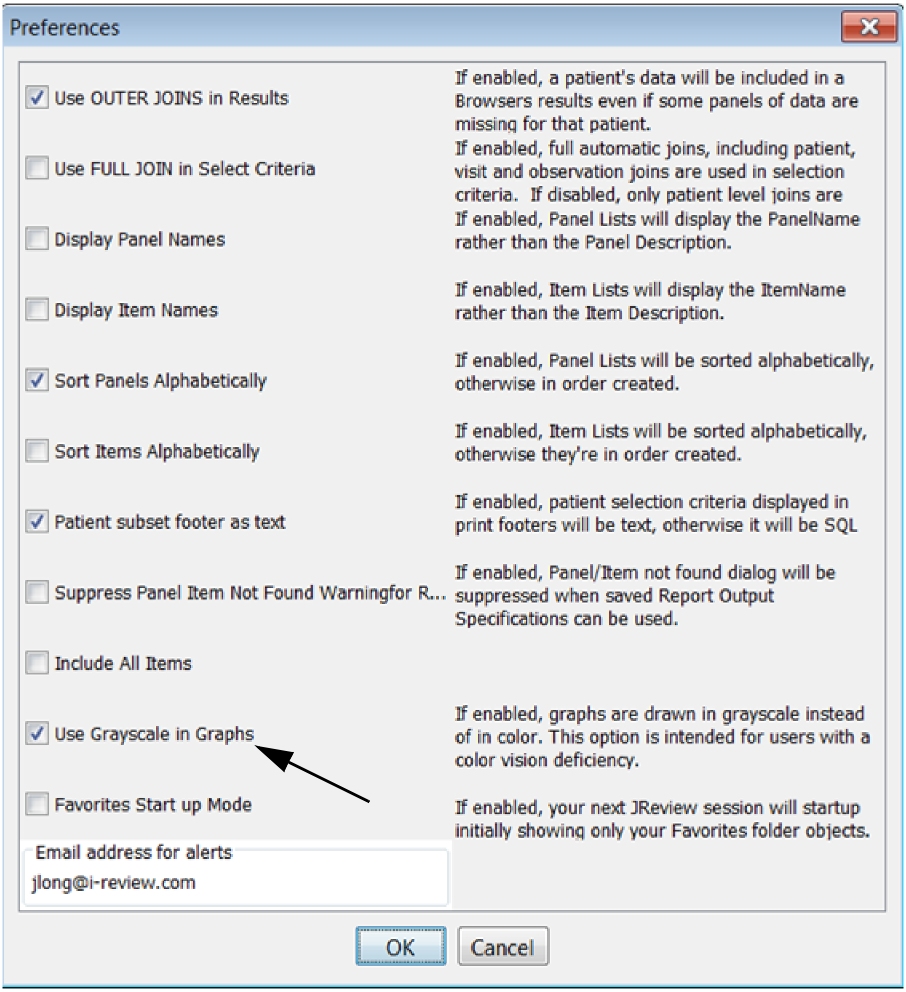
The **Notes Browser** window opens to view existing notes for the selected patient or you may click on **Add Note** to add a new note.

***See Chapter 3: Review Patient Data, see section on Notes Browser.***



## *Graph Grayscale*

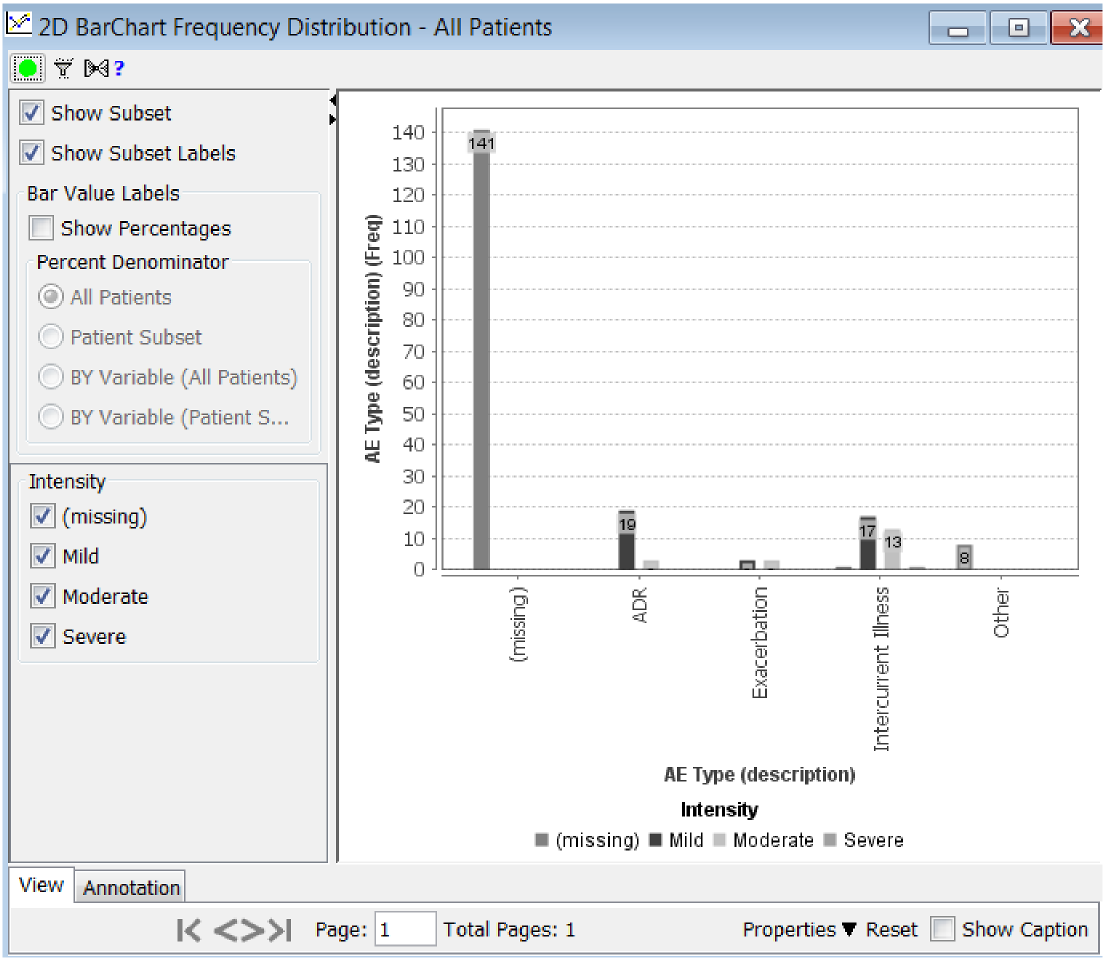
Users with difficulty viewing color may optionally change their graphic displays to grayscale. In the Edit menu, select Preferences to check on option for ‘Use Grayscale in Graphs’.



| | |
|---|---|
| ☑ Use OUTER JOINS in Results | If enabled, a patient's data will be included in a Browsers results even if some panels of data are missing for that patient. |
| ☐ Use FULL JOIN in Select Criteria | If enabled, full automatic joins, including patient, visit and observation joins are used in selection criteria. If disabled, only patient level joins are |
| ☐ Display Panel Names | If enabled, Panel Lists will display the PanelName rather than the Panel Description. |
| ☐ Display Item Names | If enabled, Item Lists will display the ItemName rather than the Item Description. |
| ☑ Sort Panels Alphabetically | If enabled, Panel Lists will be sorted alphabetically, otherwise in order created. |
| ☐ Sort Items Alphabetically | If enabled, Item Lists will be sorted alphabetically, otherwise they're in order created. |
| ☑ Patient subset footer as text | If enabled, patient selection criteria displayed in print footers will be text, otherwise it will be SQL |
| ☐ Suppress Panel Item Not Found Warningfor R... | If enabled, Panel/Item not found dialog will be suppressed when saved Report Output Specifications can be used. |
| ☐ Include All Items | |
| ☑ Use Grayscale in Graphs | If enabled, graphs are drawn in grayscale instead of in color. This option is intended for users with a color vision deficiency. |
| ☐ Favorites Start up Mode | If enabled, your next JReview session will startup initially showing only your Favorites folder objects. |

Email address for alerts
jlong@i-review.com

When the Preference option is check on then the graph output will display as grayscale instead of color.



2D BarChart Frequency Distribution - All Patients

☑ Show Subset

☑ Show Subset Labels

Bar Value Labels

☐ Show Percentages

Percent Denominator

● All Patients

○ Patient Subset

○ BY Variable (All Patients)

○ BY Variable (Patient S...

Intensity

☑ (missing)

☑ Mild

☑ Moderate

☑ Severe

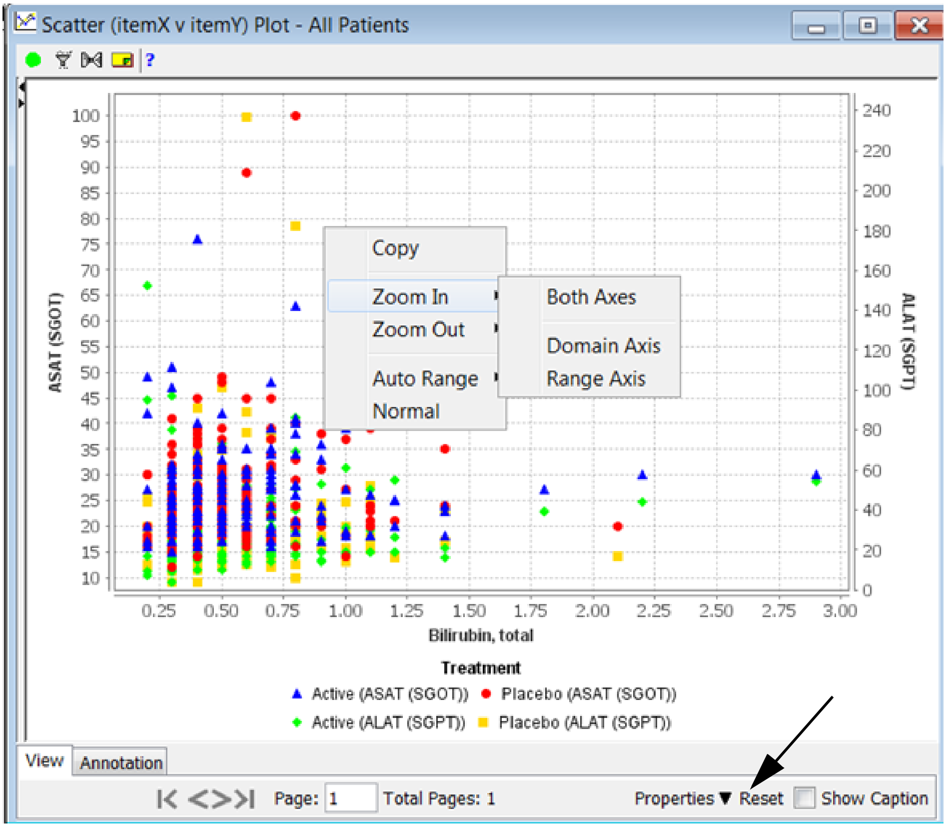
Page: 1 Total Pages: 1

☐ Show Caption

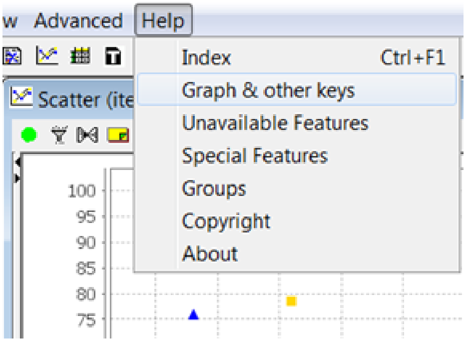
# Graph display keys

## *Graph manipulation keys*

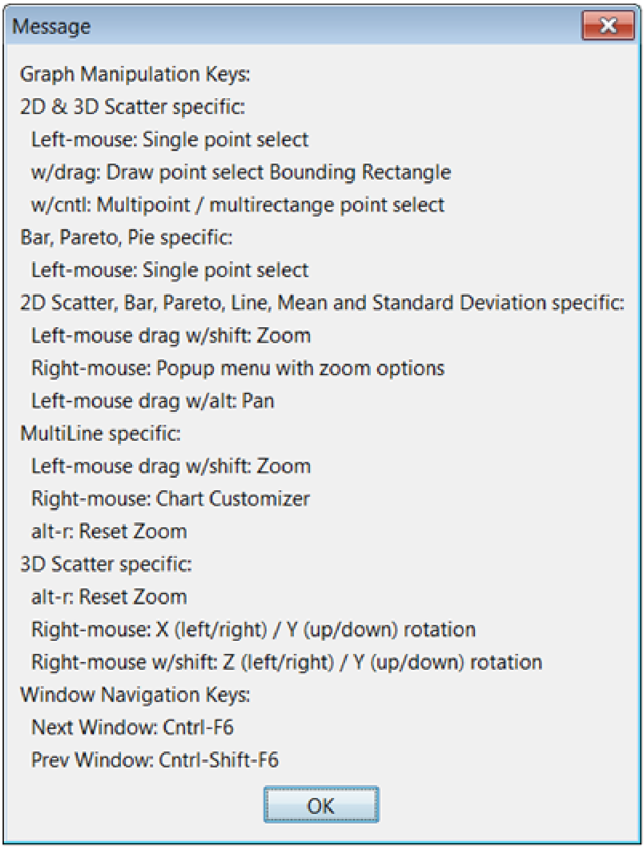
Once you create your graph, you can right-mouse click anywhere on the graph to open the **JClass Chart Properties** window.  Click the **Reset** button ar the bottom to return to the original graph display.



Click on the **HELP** menu in the tool bar and select **Graph & other keys**.



The message window displays outlining directions for the various graph manipulation keys.



Graph Manipulation Keys:
2D & 3D Scatter specific:
  Left-mouse: Single point select
  w/drag: Draw point select Bounding Rectangle
  w/cntl: Multipoint / multirectange point select
Bar, Pareto, Pie specific:
  Left-mouse: Single point select
2D Scatter, Bar, Pareto, Line, Mean and Standard Deviation specific:
  Left-mouse drag w/shift: Zoom
  Right-mouse: Popup menu with zoom options
  Left-mouse drag w/alt: Pan
MultiLine specific:
  Left-mouse drag w/shift: Zoom
  Right-mouse: Chart Customizer
  alt-r: Reset Zoom
3D Scatter specific:
  alt-r: Reset Zoom
  Right-mouse: X (left/right) / Y (up/down) rotation
  Right-mouse w/shift: Z (left/right) / Y (up/down) rotation
Window Navigation Keys:
  Next Window: Cntrl-F6
  Prev Window: Cntrl-Shift-F6

# Defining a graph specification - New Mode

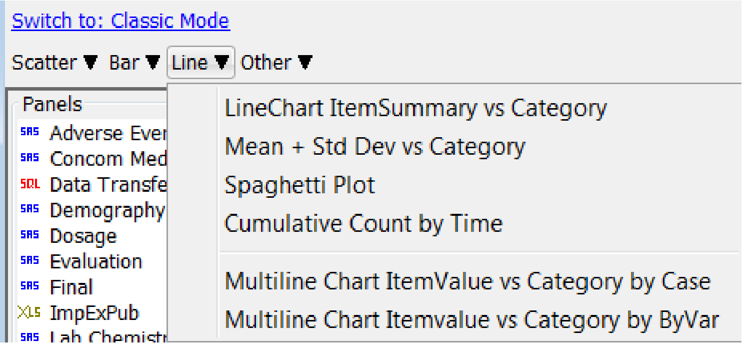
## *New Mode versus Classic Mode*

The New Mode Graph Browser uses **drag and drop** functionality to define graphs with a preview of results. It is assumed that the user is familiar with the previous methods for defining graphs in the Graph Browser.

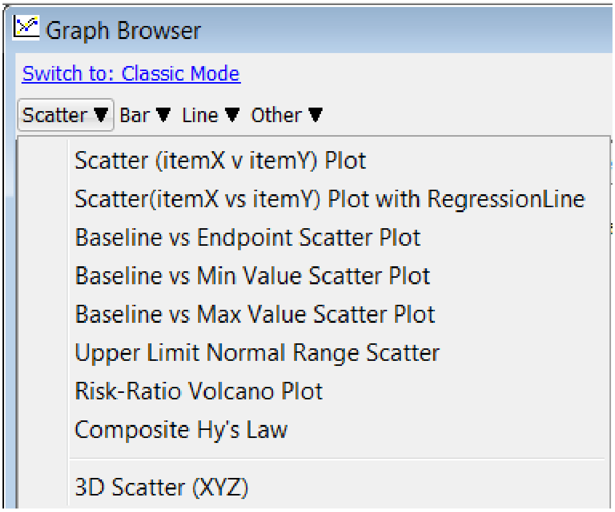
***(See section on Defining a graph specification - Classic Mode).***

The new graph browser uses drag-and-drop to specify panel items, provide previews of the contructed graph as it is specified, and employ “property tables” for setting the attributes of the panel items and the graph. The “New User Interface” (“NUI”) has restructured the layout and appearance of controls in the graph browser.

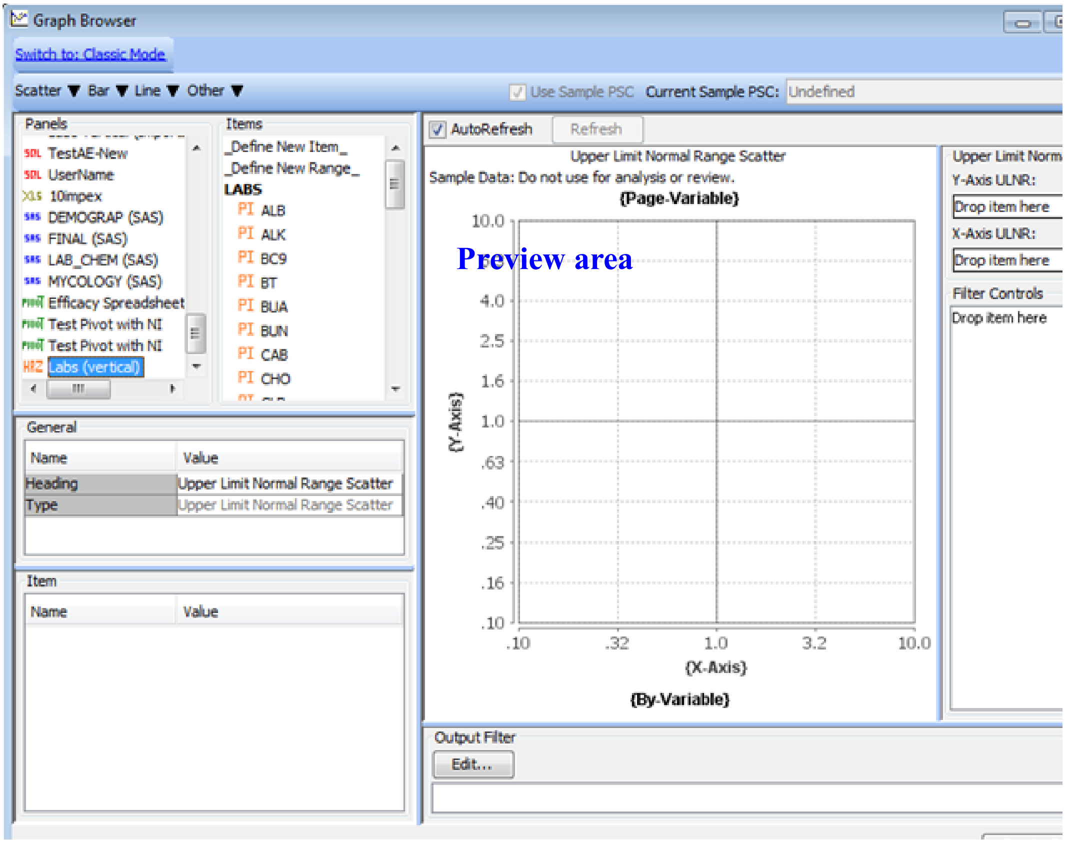
Open the Graph Browser from the Browse menu, or click on the 📈 icon in the toolbar.  The user selects the graph type from the menus in the toolbar. All graph types are listed; a horizontal line in the menus separate the graph types supported in New Mode and those supported only in Classic Mode; the graph-types that are supported in New Mode are listed first. If a graph is not supported, the Classic Mode browser is opened.



Click on a graph style for **Scatter, Bar, Line or Other** to display the drop down list to select the graph. Optionally, the user may **Switch to: Classic Mode** for traditional building of graph definitions.



Here is the unpopulated screen for defining **Upper Limit Normal Range Scatter Plot.** The different graphs will have different specifications and the screen details will vary.

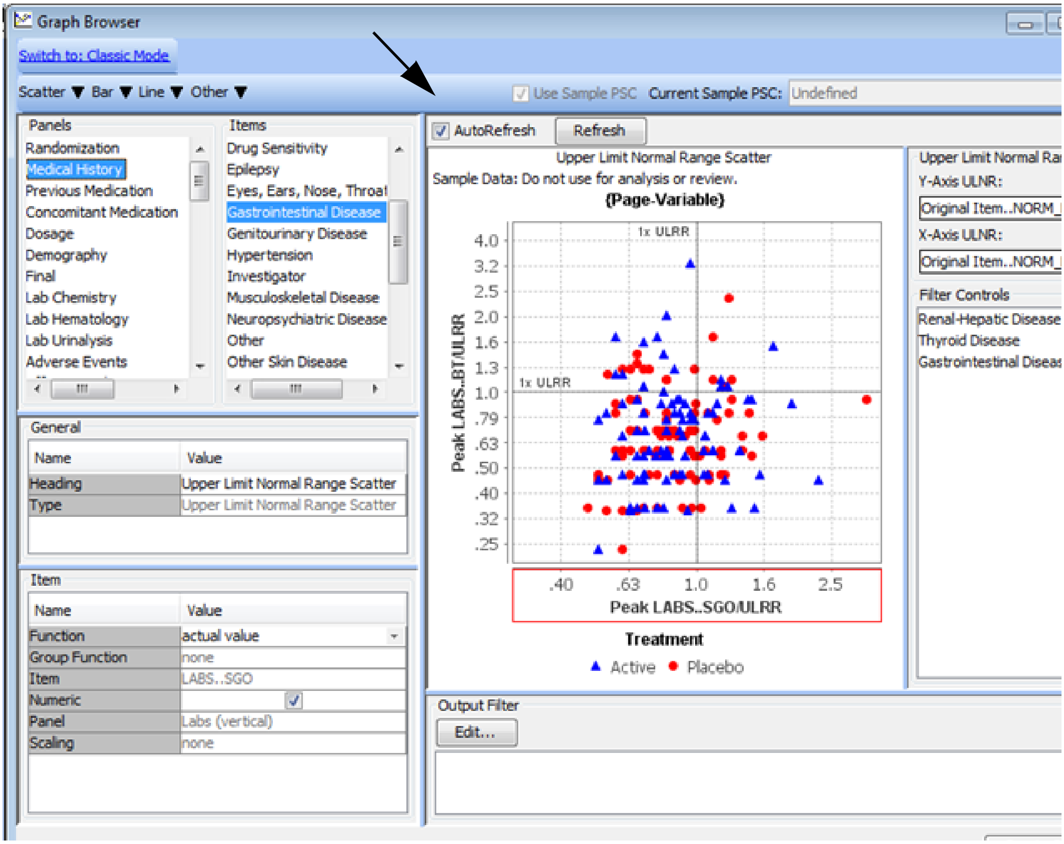


General

| Name | Value |
|---|---|
| Heading | Upper Limit Normal Range Scatter |
| Type | Upper Limit Normal Range Scatter |

The central area is the graph **Preview.** When a sufficient number of graph variables are defined to construct a graph, the Preview populates the graph with **sample** data. As properties and items are modified, the sample data may be refreshed and the graph redrawn.

The data presented is a ***sample only***, and is not to be used for clinical analysis. A ***warning message*** in the Preview states this usage limitation: ***Do not use for analysis or review.***



Sample Data: Do not use for analysis or review.

General

| Name | Value |
|---|---|
| Heading | Upper Limit Normal Range Scatter |
| Type | Upper Limit Normal Range Scatter |

Item

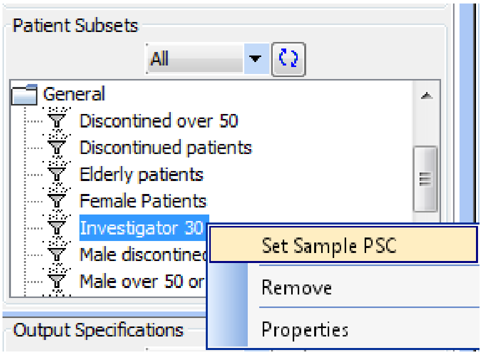
| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | LABS..SGO |
| Numeric | ☑ |
| Panel | Labs (vertical) |
| Scaling | none |

## *Set Sample PSC*

Users with ReviewAdmin priv63 may assign a "**Sample PSC**" that is saved at the study level as public. The Set Sample PSC icon is outlined with a **green box**.

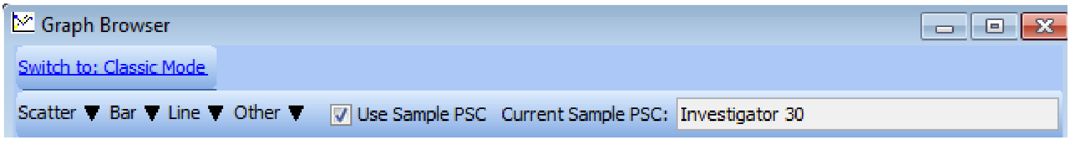
A"**Sample PSC**" is used to preview results while building the graph definition to limit the amount of sample data, so that the Preview can be refreshed quickly. It is important that the user select a patient subset to serve as a filter on the Preview's sample data.

1. Right click on a Patient Subset in JReview's Patient Subsets tree; and select "**Set Sample PSC**".



2. The name of the Sample PSC Item is displayed at the right side of the New Mode Graph Browser's toolbar.
3. The checkbox "**Use Sample PSC**" is next to the **Current Sample PSC** description to enable/disable the PSC Sample filter for the graph Preview.

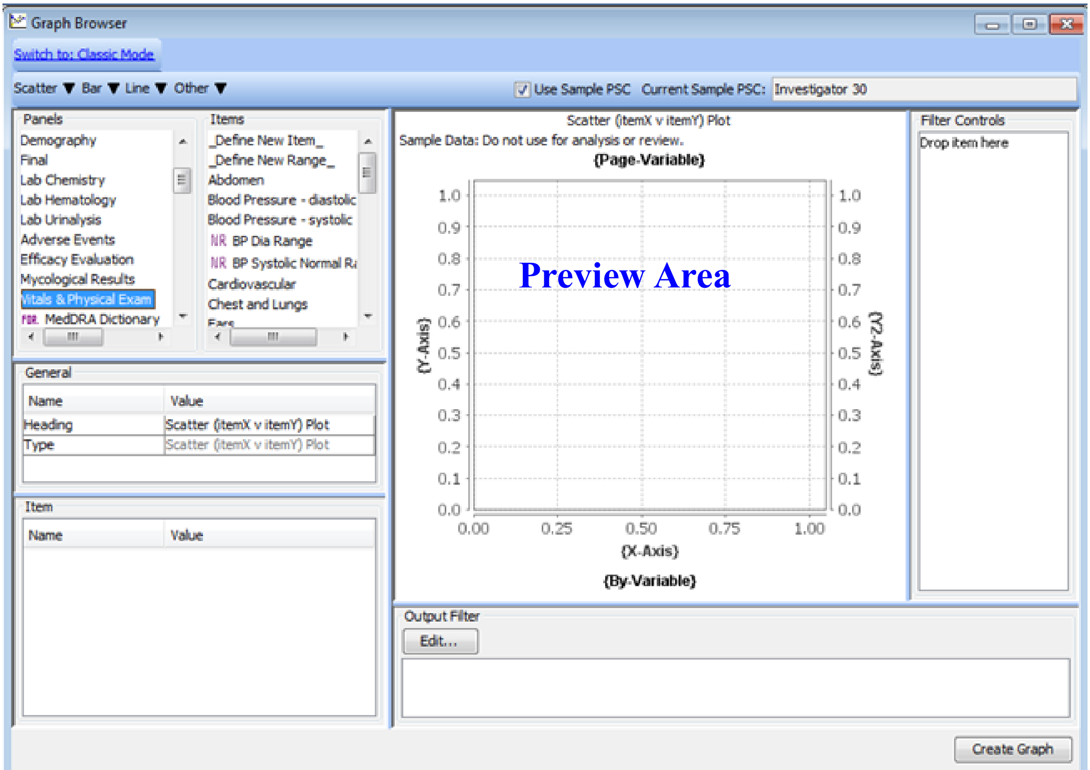
The graph displays a message for **"Sample Data: Do not use for analysis or review".** When unchecked all patients or the current selection criteria is applied.



☑ Use Sample PSC Current Sample PSC: Investigator 30

## *Drag & Drop Items*

There are several major components of the New Mode Graph Browser. The **DraggablePIFPanel** enables an item to be dragged to a target. The central area is the Graph Preview. The users define a graph by dropping items on target locations.



☑ Use Sample PSC Current Sample PSC: Investigator 30

Sample Data: Do not use for analysis or review.

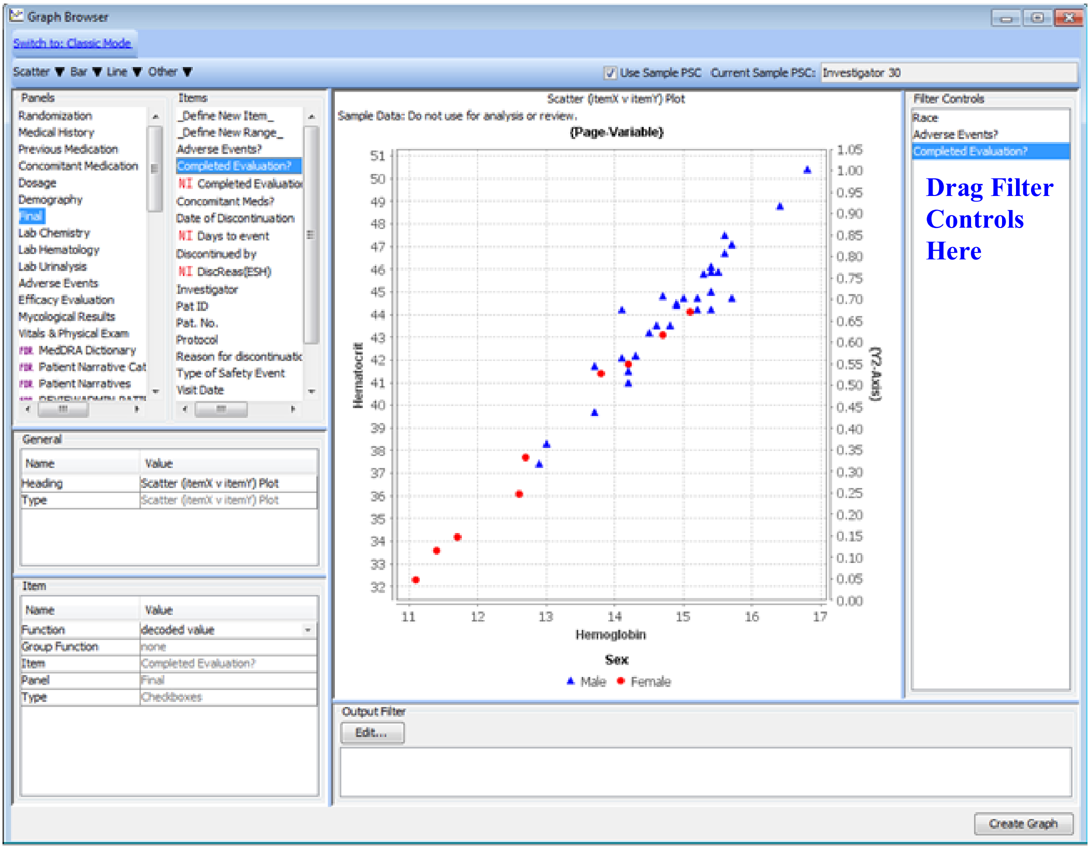
Drop item here

| Name | Value |
|---|---|
| Heading | Scatter (itemX v itemY) Plot |
| Type | Scatter (itemX v itemY) Plot |

The labels surrounded by brackets are drop targets; for example, {X-axis}, {Y-axis}, {Page-Variable}, and {By-Variable} are drop targets. The user drags an item from the PIFPanel to a drop target to define a variable. If the user drops an item on a drop target that is already defined, the newly dropped item replaces the current item. When the item is dropped, the drop target "area", e.g., the area under the X-axis, is selected, and its properties are presented in the Item property table. All drop targets are selectable, and multiple drop targets can be selected using the Control key.

Clicking on an already selected drop target, unselects the target. When multiple targets are selected, no properties are shown in the Item property table. When an item is dragged into the Preview area, all drop targets are highlighted with an outline.

Start by selecting the preferred graph style - the graph default is basic Scatter (itemX vs itemY) Plot. Specify the contents of the graph by selecting a panel and each item to drag and drop to the X-axis and Y-axis with optional By Variable. As each axis item is added, the graph preview will update the axis labels and display data for the **Use Sample PSC**. The **Item list** will display information for the selected item for function, panel, type, etc.



General

| Name | Value |
|---|---|
| Heading | Scatter (itemX v itemY) Plot |
| Type | Scatter (itemX v itemY) Plot |

Item

| Name | Value |
|---|---|
| Function | decoded value |
| Group Function | none |
| Item | Completed Evaluation? |
| Panel | Final |
| Type | Checkboxes |

Select an axis item or By Variable to **delete** where it was initially dragged. Use any of the following:

- Scissors in the toolbar
- Delete key
- CTRL X

In the **General** list, change the graph **Heading** by double clicking in the **Value** text box.

***Note:*** In some graphs, there are Preview entities besides drop targets that are selectable. For example, the Y-axis of the Frequency Bar graph and the Baseline vs. Endpoint graph is selectable. This allows the user to edit properties even if the Y-axis variable is automatically populated when an item is dropped on the X-axis. However, axes are not selectable in all graphs: the Y-axis in Baseline vs. Min and Baseline vs. Max is not selectable, and neither axis is selectable in the Kaplan-Meier graph.

## *Property Tables*

The Property Tables present and support the editing of properties. Properties that cannot be edited are “gray” in the **Value Column**. In New Mode there are two property tables:

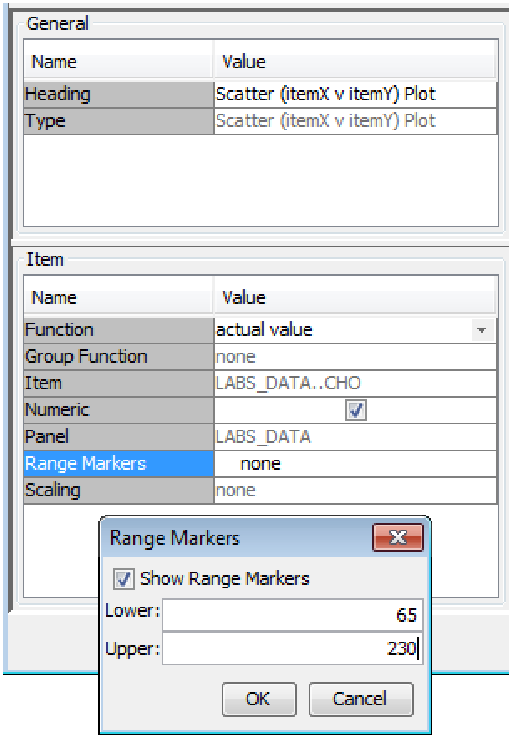
- The **General** property table presents properties that are global to the graph; for example, “Heading” is a General property.
- The **Item** property table is used to set the item function and the item group function when applicable. Default functions and group functions are provided. The **Item** property table presents and supports the editing of item properties that are a part of the graph defintion. To view or edit properties associated with an item, the user selects the item. For example, if the user clicks on the X-axis in the **Preview area** and the X-axis is defined, the properties of the X-axis variable (e.g., Function, Scaling) are displayed in the item property table.

Some properties can be edited only if some another condition is fulfilled. An axis “scaling” property is editable only if a Page item is specified.

Those options found in Classic Mode for Scaling, Numeric, Reference Ranges, and Bar Graph Style, have been moved to these Property tables.

Reference Ranges are available for two graph types: Scatter (item-X vs item-Y) Plot and Scatter (item-X vs item-Y) Plot with regression Line. Reference Ranges are entered into **Range Markers** on the build window and may be changed by the viewer in the created graph output window.

When applying Range Markers as reference ranges in scatter plots, select each axis to highlight and specify the lower and upper range.



General

| Name | Value |
|---|---|
| Heading | Scatter (itemX v itemY) Plot |
| Type | Scatter (itemX v itemY) Plot |

Item

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | LABS_DATA..CHO |
| Numeric | ☑ |
| Panel | LABS_DATA |
| Range Markers | none |
| Scaling | none |

Range Markers

☑ Show Range Markers

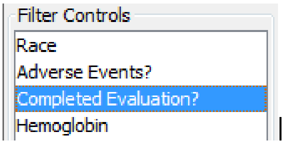
Lower: 65

Upper: 230

The generated graph will display the reference range lines as vertical and horizontal lines. The graph is segmented into nine labeled “range” plot sectors providing the patients count and events count. ***(see section: Detail Data Graph Styles - Include Reference Range)***

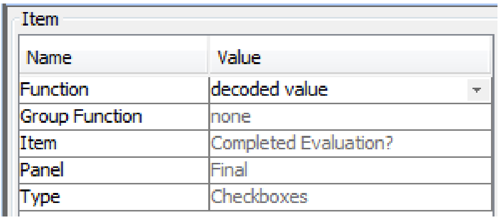
## *Graph Filter Controls*

A **Filter Control** is defined by dropping an item onto the list positioned to the right of the Preview. Using drag-and-drop, the items can be repositioned within the list. The selected filter items are automatically displayed in the Filter Controls. The Item list adds each item with a description.



Filter Controls

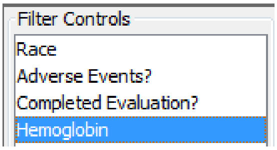
- Race
- Adverse Events?
- Completed Evaluation?
- Hemoglobin



Item

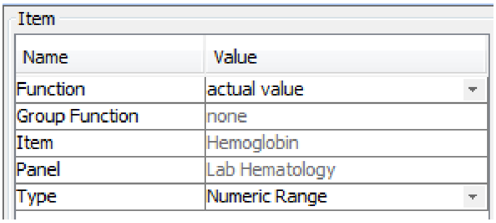
| Name | Value |
|---|---|
| Function | decoded value |
| Group Function | none |
| Item | Completed Evaluation? |
| Panel | Final |
| Type | Checkboxes |

JReview recognizes the item as character or numeric data, whether to display the selected item in the Filter Control as checkbox or numeric range.



Filter Controls

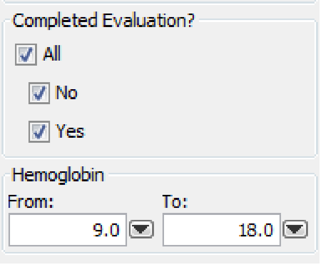
- Race
- Adverse Events?
- Completed Evaluation?
- Hemoglobin



Item

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | Hemoglobin |
| Panel | Lab Hematology |
| Type | Numeric Range |

This is how the Filter Controls will display in the created output results.



Completed Evaluation?

☑ All

☑ No

☑ Yes

Hemoglobin

From: 9.0

To: 18.0

## *Graph Output Filter*

The control for the **Output Filter** differs from that found in the Classic Mode. Click on the Output Filter control button positioned below the Preview to define and edit the filter. The filter expressions are displayed in a text area in this control (a popup is no longer needed to view the current filter). When the Edit button is clicked the Output Filter Dialog is displayed for editing and creating a filter. A “Delete” button is provided at the right side of the dialog’s button row.

When the graph specification is complete, click **Create Graph** to display the graph defined in a Graph Viewer. The entire results will display for the graph specification and specified selection criteria, if one was used. The **Set Sample PSC** will be ignored when the graph is created.

## *Study Start Date*

The Study Start Date is necessary when defining certain graph types for Kaplan Meier, Napolean’s march, Trellis Plots, etc. Instead of adding this information into each graph definition the user enters the Study Start Date once.

**WARNING:** ***Some graph types will not be listed in the graph menus if the Study Parameters are NOT set. Likewise, if an object that uses these study parameters is saved and the parameters are then deleted - the object will still show up in the Object Explorer but instead displays a message.***

Go to the **Advanced Menu** and select ‘**Study Parameters’** to enter into the definition dialog. By doing it once for the study, then it automatically will be available for any of the graphs that need a study start date. So, if the user defines and saves the study start date for a particular study, for example, Date of Randomization, then go to the Graph Browser, then select Kaplan Meier under the ‘Other’ graph types. The ‘**Start Date Item**’ will be filled in automatically by the defined study start date item.

***(See Chapter 12 - Advanced Topics: Study Start Parameters)***

## *Define Baseline Endpoint*

The B*aseline/Endpoint* definitional capabilities have been added to the ***Study Start Date* dialog**. These capabilities allow the user to specify the baseline/endpoint items and values in a dialog accessible in the JReview client through the ***Advanced* menu**. The feature is implemented by extending the drag-and-drop Start Date Dialog to include controls for baseline and endpoint specification. To reflect the enhancement, the menu item in the Advanced menu and the dialog are renamed to “Study Parameters”; in other words, the label “Study Start Date” is replaced by “Study Parameters”.

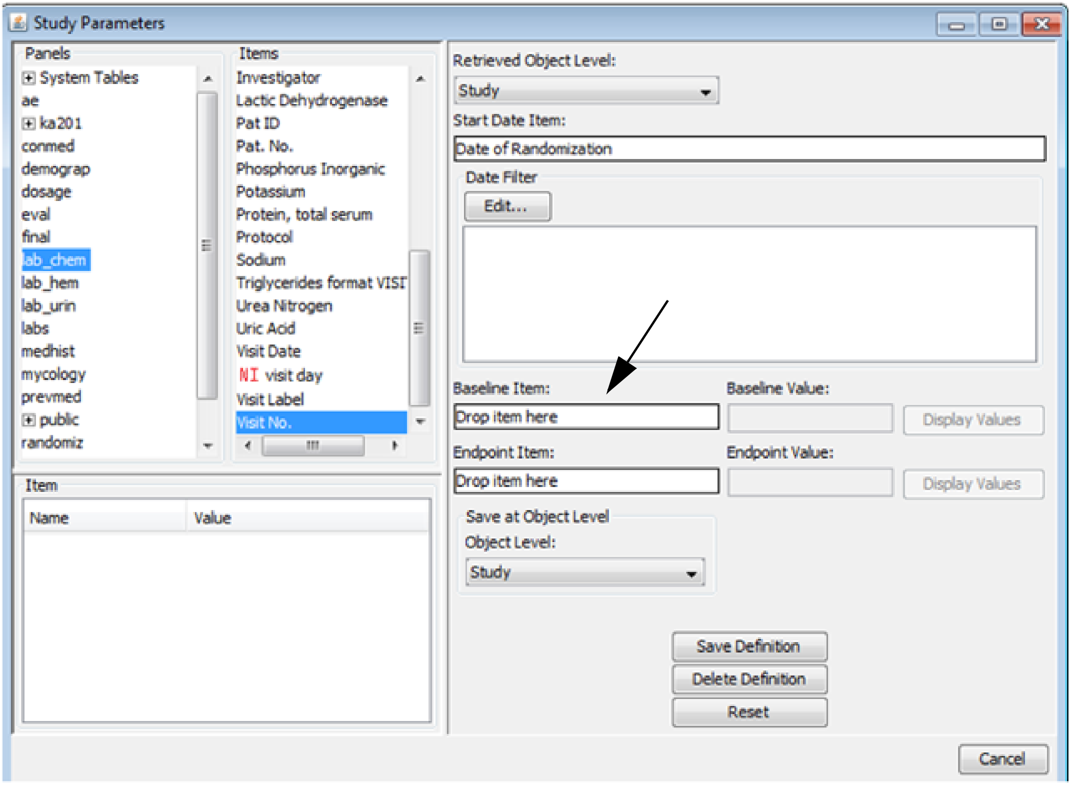
The method of specifying the baseline or the endpoint differs from that found in JReview’s Administrative tool where the user types the item name and value. In the Study Parameters dialog, the users selects an *example* item by dragging it onto a drop area control from the “PIF Panel”. The item name is derived from the chosen item. When an item is dropped onto the control, an associated button for launching a dialog containing the list of values for that item becomes enabled. Clicking on this button launches the modal “values” dialog. The user then selects a “value” from the list.

For example, to create a “baseline” definition, the user might drag “Visit No.” from the “Lab Chem” panel onto the Baseline Item drop area. The user then clicks the button associated with this drop area, and then selects visit “1” from the dialog’s values list. The user then clicks “OK”.

***Note:*** the user should choose an example item (e.g., “Visit No.”) from a panel that contains the intended values for that item; some panels may not contain all the “Visit No.” values.

At least one item in the dialog must be defined in order to save the definition. However, not all the items need to be defined in order to save the definition. More generally, the Save operation works as it did previously.

The figures below illustrate defining a “baseline” in the dialog.  Figure 1 - From the Advanced menu, select Study Start Date to view the previoulsy defined Study Start Date for Study level.  Added to htis function are the Baseline and Endpoint Items.


Study Parameters

Retrieved Object Level: Study

Start Date Item: Date of Randomization

Baseline Item: Drop item here

Baseline Value:

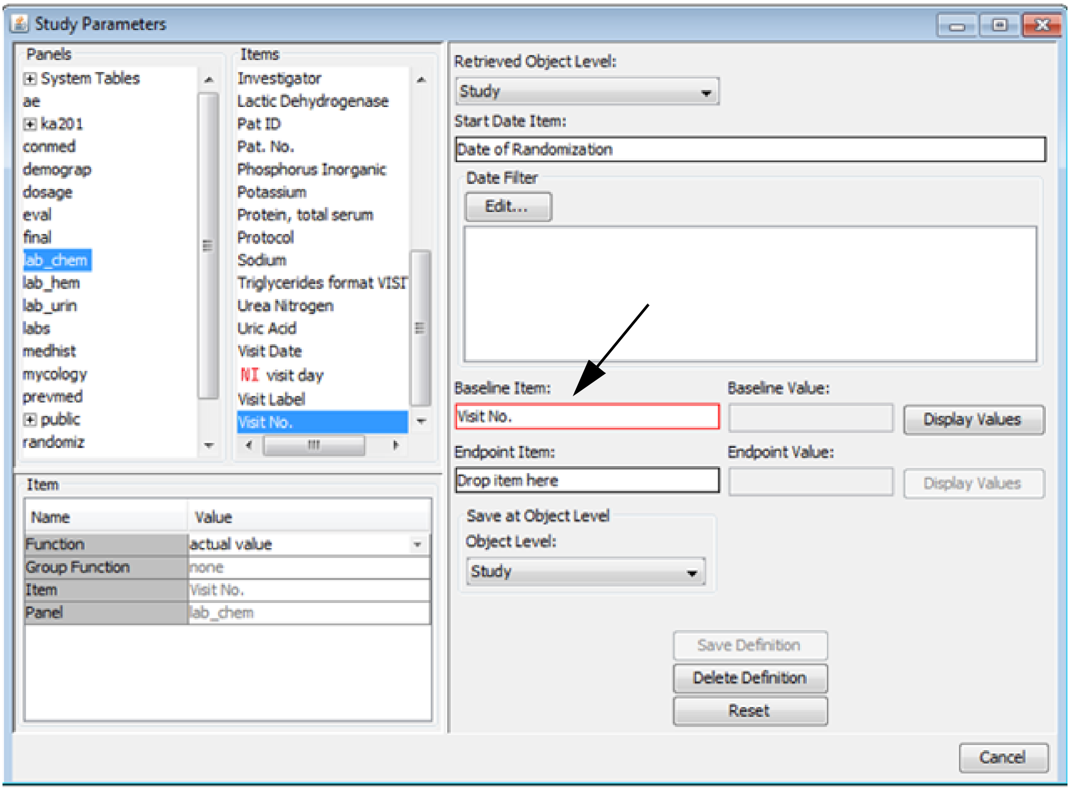
Endpoint Item: Drop item here

Endpoint Value:

Save at Object Level

Object Level: Study

Figure 2 - VisitNo was selected for the Baseline Item.  Click Display Values.



Retrieved Object Level: Study

Start Date Item: Date of Randomization

Baseline Item: Visit No.

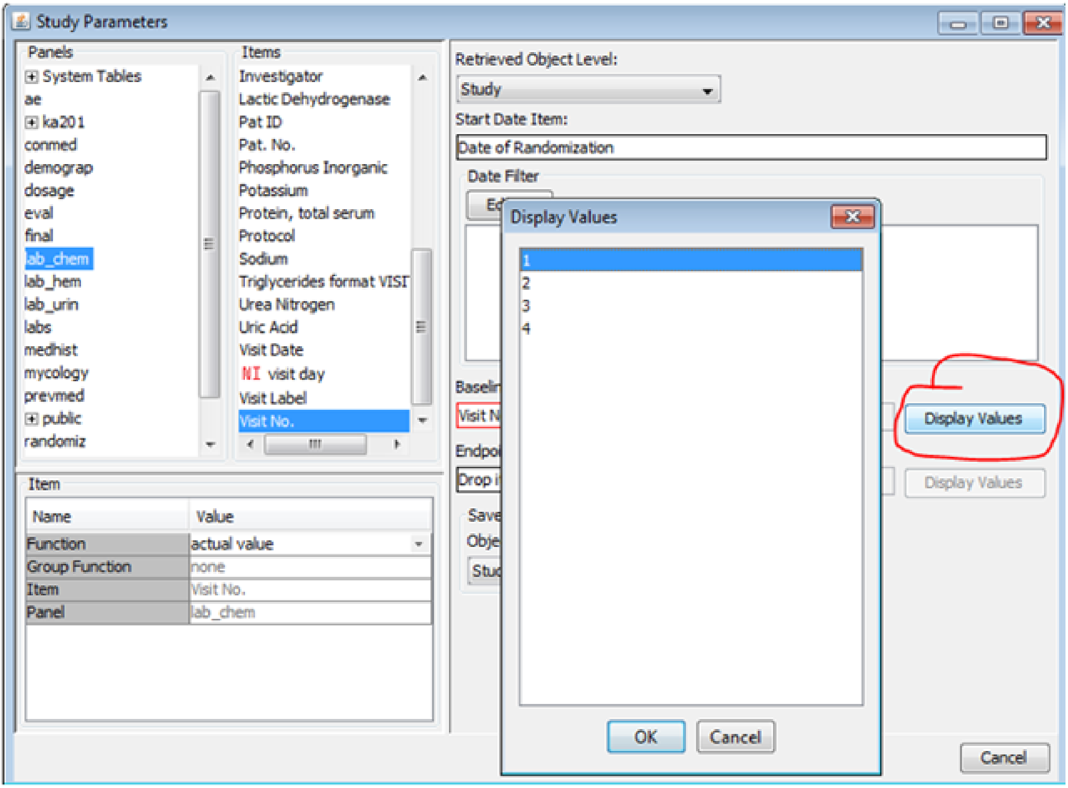
Endpoint Item: Drop item here

Object Level: Study

Item

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | Visit No. |
| Panel | lab_chem |

Figure 3 - The Display Values opens for selection.  Visit 1 is selected.



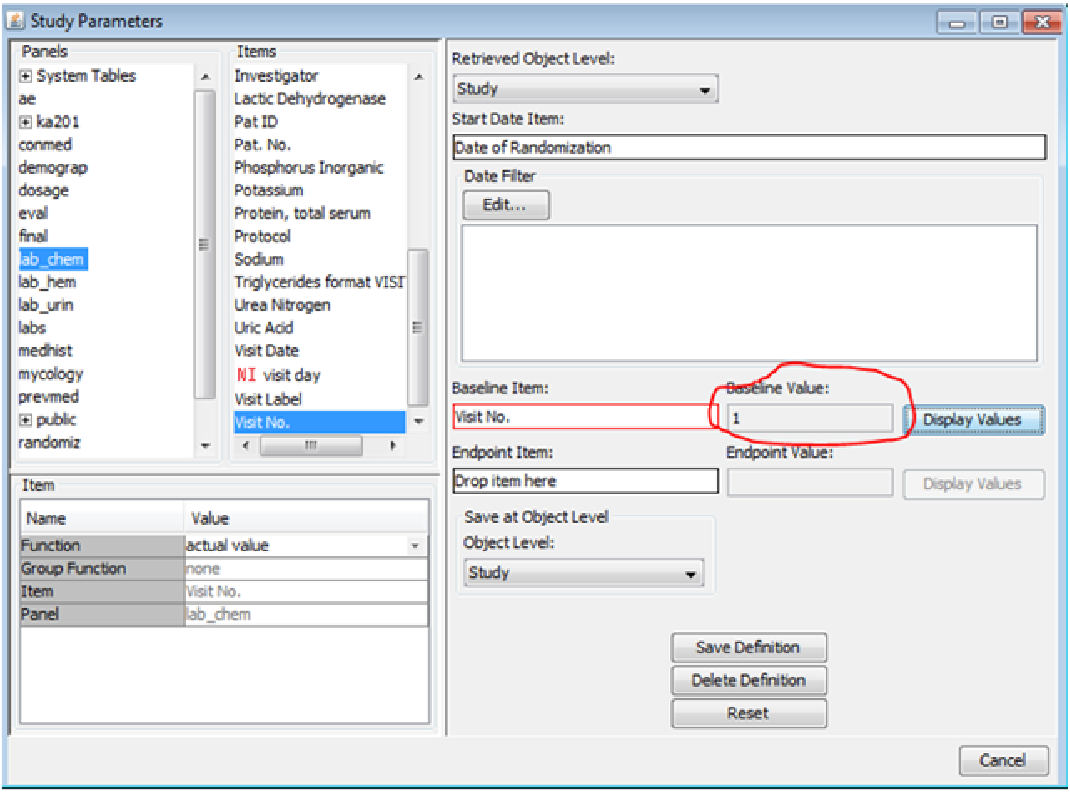
Retrieved Object Level: Study

Start Date Item: Date of Randomization

Visit N

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | Visit No. |
| Panel | lab_chem |

Figure 4 - The Baseline value is added.  Repeat steps to add Endpoint item and save.



| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | Visit No. |
| Panel | lab_chem |

Retrieved Object Level: Study

Start Date Item: Date of Randomization

Baseline Item: Visit No.

Baseline Value: 1

Endpoint Item: Drop item here

Endpoint Value:

Object Level: Study

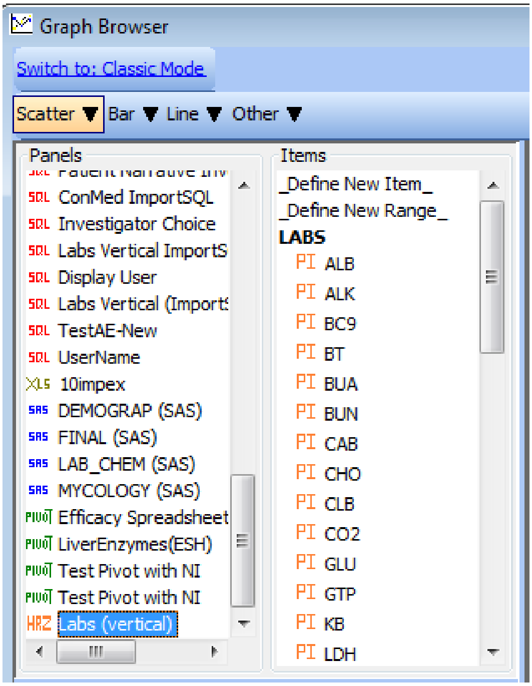
## *Vertical tables*

Vertical tables can be transformed to horizontal format “**HRZ**” that include the reference ranges. HRZ panels are available for New Mode and will not display in the panels list in Classic Mode.

***(See Chapter 12 - Advanced Topics: Vertical to Horizontal Panel)***

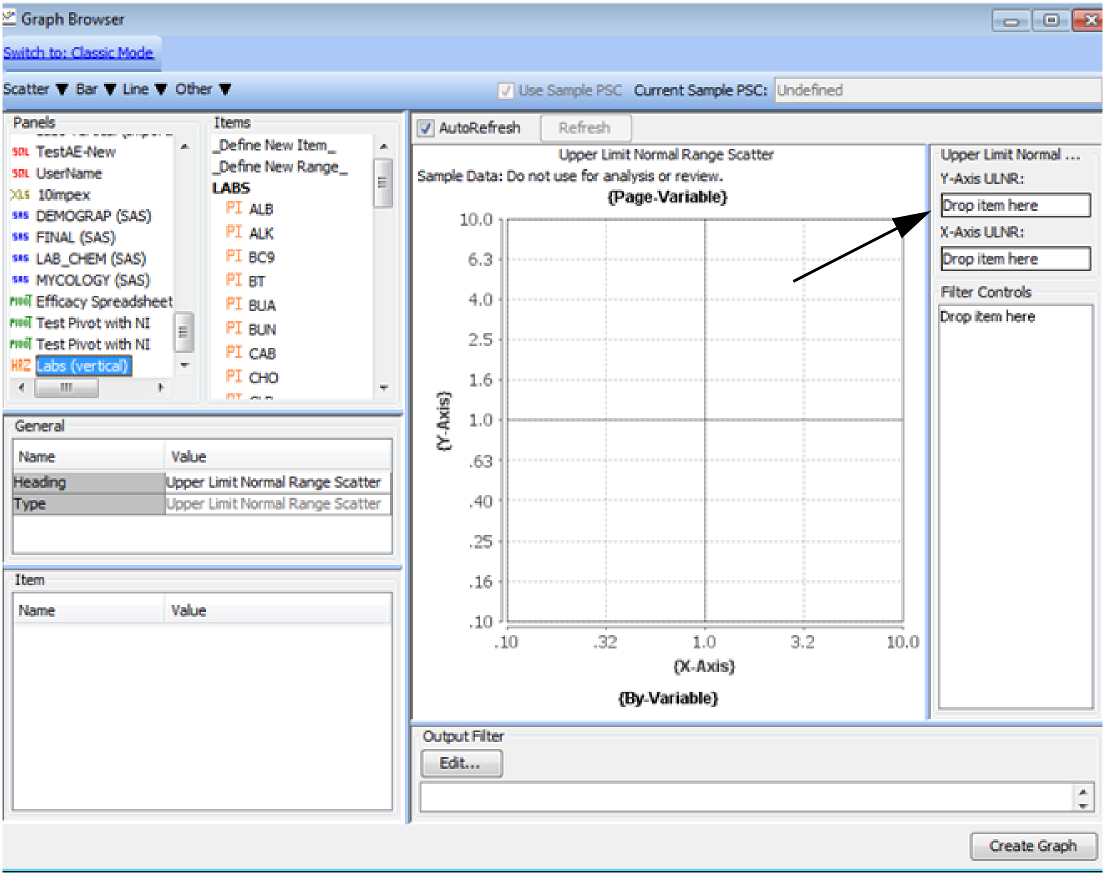
In addition, Horizontal to Vertical panels (HRZ) are supported in Patient Selection Criteria, Output Filters, and any of the browser definition areas. So a pivoted item (PI) can be referenced in the output filter, for example, cholesterol > 250.

Users in the New Mode Graph Browser will no longer need to select separate reference ranges for vertical laboratory data, when defining certain scatter plots. The saved horizontal panel displays with the “**HRZ**” prefix to identify as a transformed vertical to horizontal panel. The individual laboratory tests are listed with included reference range.



Not all variables for the graph are necessarily defined within the Preview area. As shown in the ULNR example, the **Upper Limit Normal Ranges** for both axes are defined using “drop-target” components outside the Preview. These drop target components are labeled rectangular areas; when empty these components display the message “**Drop item here**”.

These components are selectable when they are populated; when a component populated with an item is selected, the item’s properties are displayed in the Item property table.



☑ Use Sample PSC Current Sample PSC: Undefined

Sample Data: Do not use for analysis or review.

General

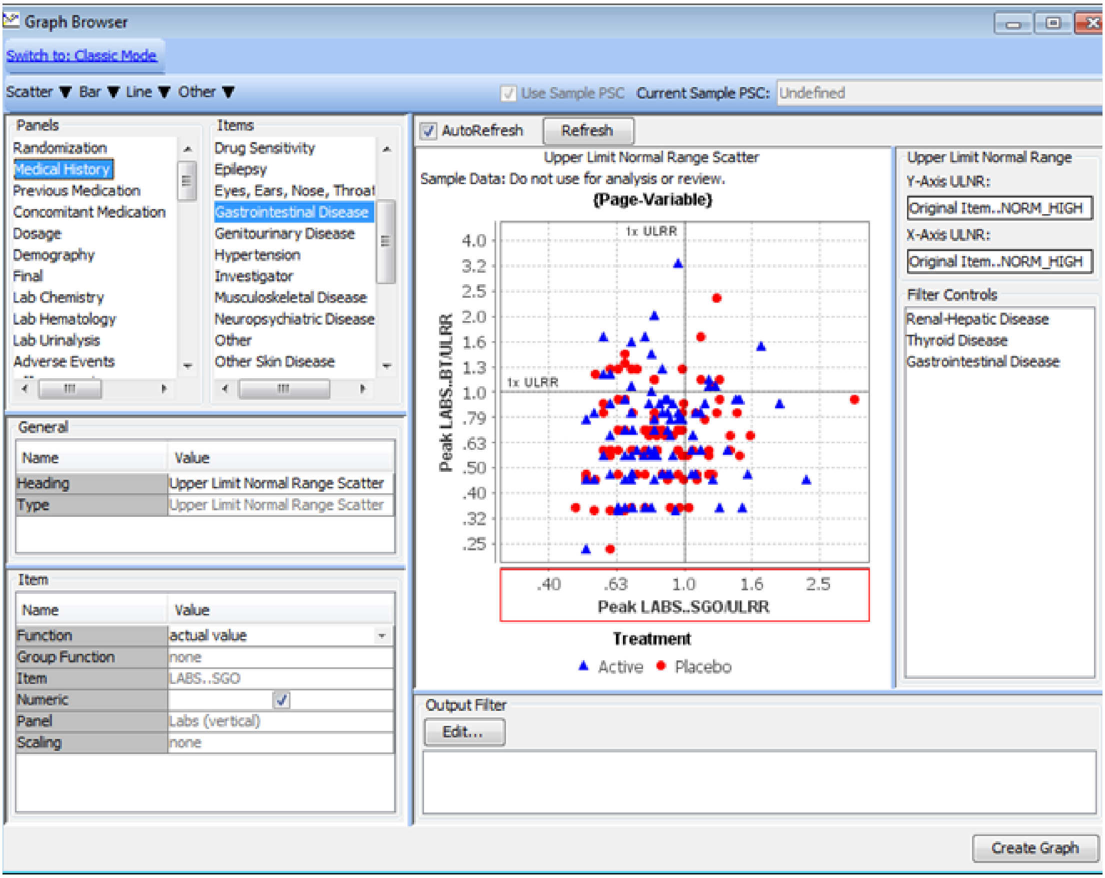
| Name | Value |
|---|---|
| Heading | Upper Limit Normal Range Scatter |
| Type | Upper Limit Normal Range Scatter |

Item

| Name | Value |
|---|---|

The selections inside and outside of the Preview are reciprocal; selecting a component outside the Preview deselects all selections in the Preview, and selecting within the Preview deselects selections outside the Preview.

When a HRZ definition is used to populate an axis in the ULNR Scatter graph, and that HRZ definition specifies an Upper Limit Normal Range Item, the ULNR for that axis will be automatically populated when the axis is defined with an item. The user can subsequently ***override*** this item, by dragging and dropping a different item onto the ULNR component.



Y-Axis ULNR: Original Item..NORM_HIGH

X-Axis ULNR: Original Item..NORM_HIGH

General

| Name | Value |
|---|---|
| Heading | Upper Limit Normal Range Scatter |
| Type | Upper Limit Normal Range Scatter |

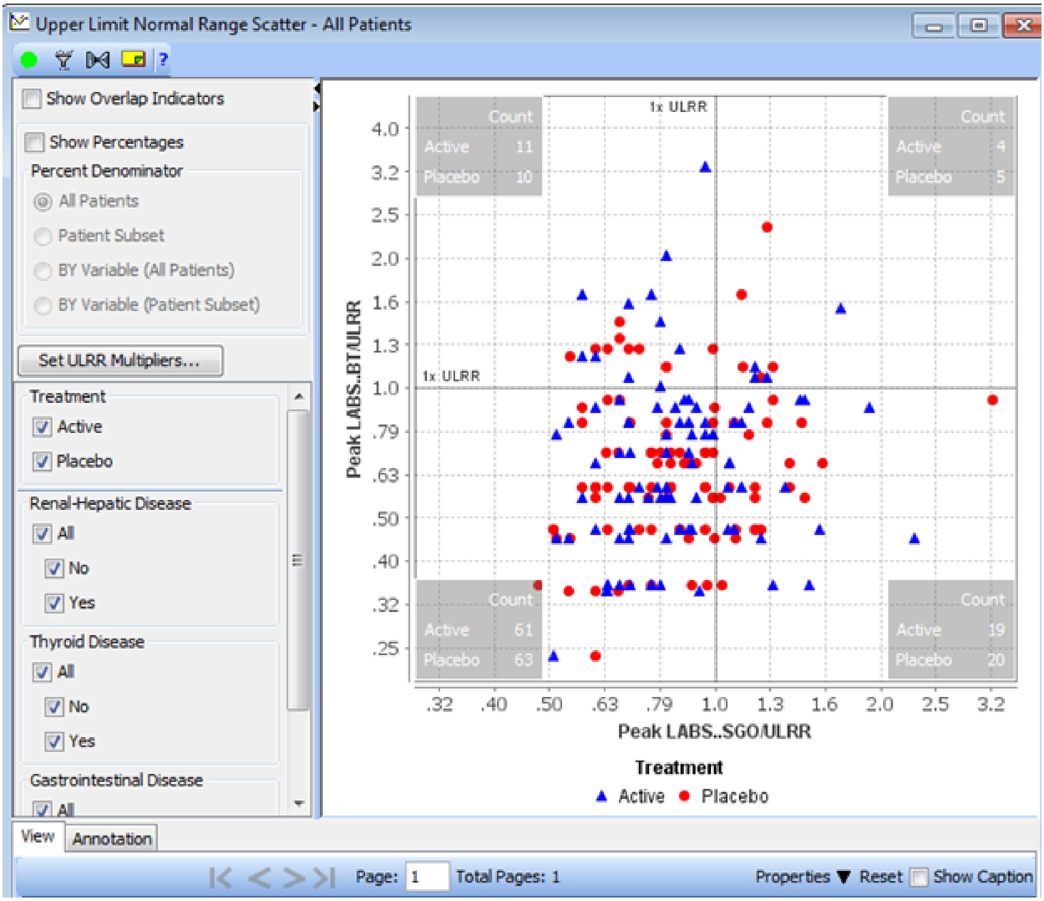
Item

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | LABS..SGO |
| Numeric | ☑ |
| Panel | Labs (vertical) |
| Scaling | none |

Click the **Create Graph** button to display the defined ULNR Scatter Plot in a Graph Viewer

Use the Filter Control checkboxes to adjust the data display.

.



☐ Show Overlap Indicators

☐ Show Percentages

Percent Denominator

● All Patients

○ Patient Subset

○ BY Variable (All Patients)

○ BY Variable (Patient Subset)

Treatment

☑ Active

☑ Placebo

Renal-Hepatic Disease

☑ All

☑ No

☑ Yes

Thyroid Disease

☑ All

☑ No

☑ Yes

Gastrointestinal Disease

☑ All

Page: 1 Total Pages: 1

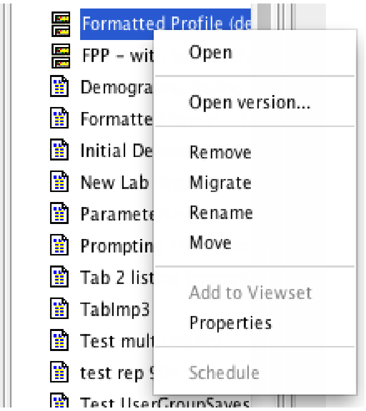
☐ Show Caption

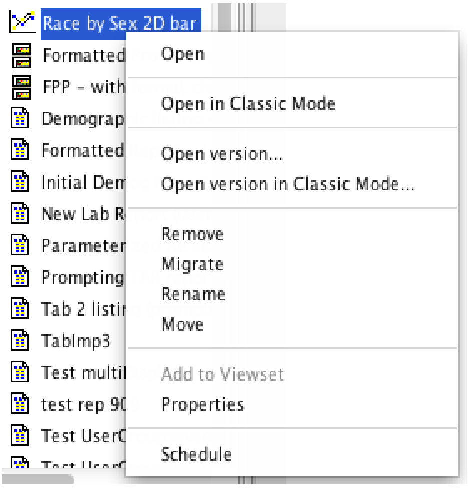
## *Open saved graph object*

The following conditions apply when opening a saved graph object:

- If a saved graph object was created in Classic Mode and uses the “Vertical Node” for defining the graph, i.e.,, directly uses a vertical panel, then the graph definition is always opened in Classic Mode, and New Mode is not available for the graph.
- If a saved graph object defined in New Mode uses the HRZ (Vertical-to-Horizontal Transform) feature, then the graph defintion will always open in New Mode, and Classic Mode is unavailable.
- The JReview version or the Graph Browser mode used when saving the graph object does NOT determine the selection of the initial mode, ***except*** for those graph definitions only available in Classic Mode.
- If the Graph Browser is open and a saved object is then opened, the definition will be opened in whatever is the current Graph Browser mode, ***except*** for those graph definitions only available in Classic Mode.

When the user selects an output object in the Object Explorer and right-click the Classic Mode options only show for Reports, Graphs, and Crosstabs.

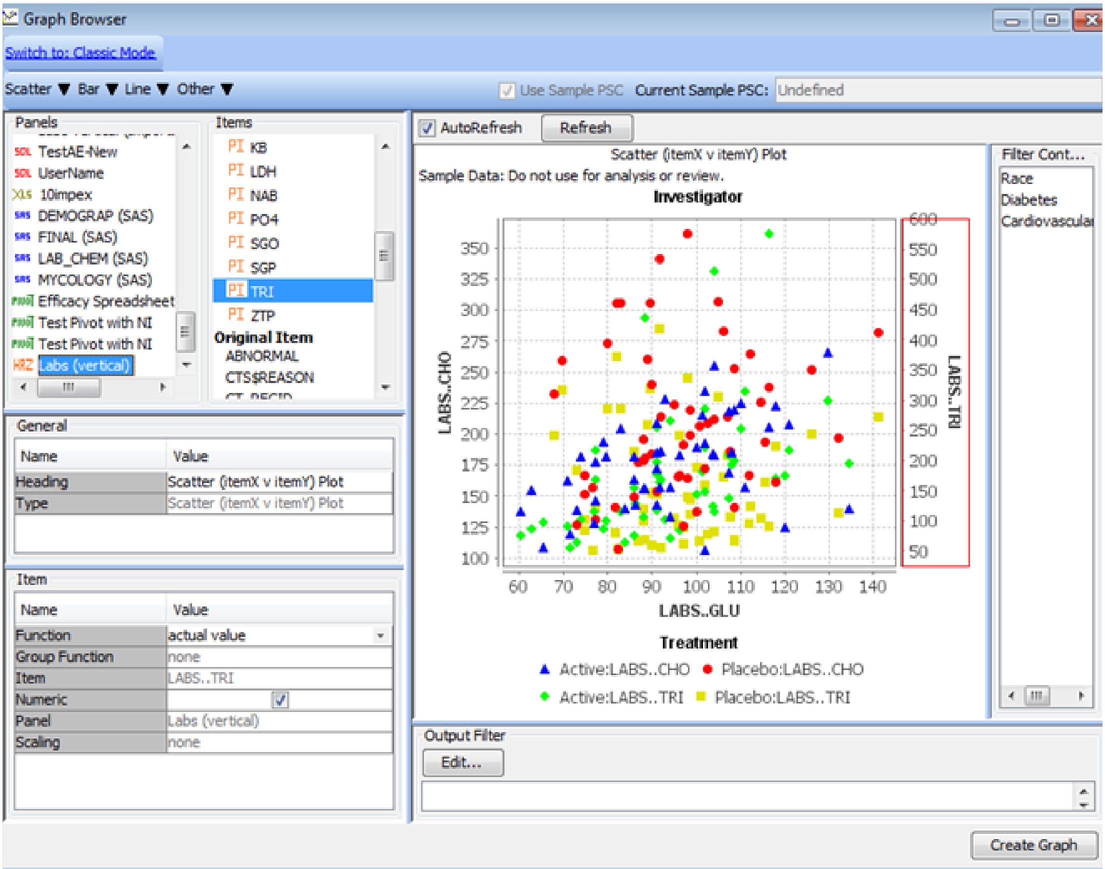




# Graph Viewer Styles - New Mode

## *Scatter Graphs*

Here is an example for  Scatter Plot. A scatter plot with a regression line is similar. The Y-axis item is selected and the Y-axis item’s properties are displayed.



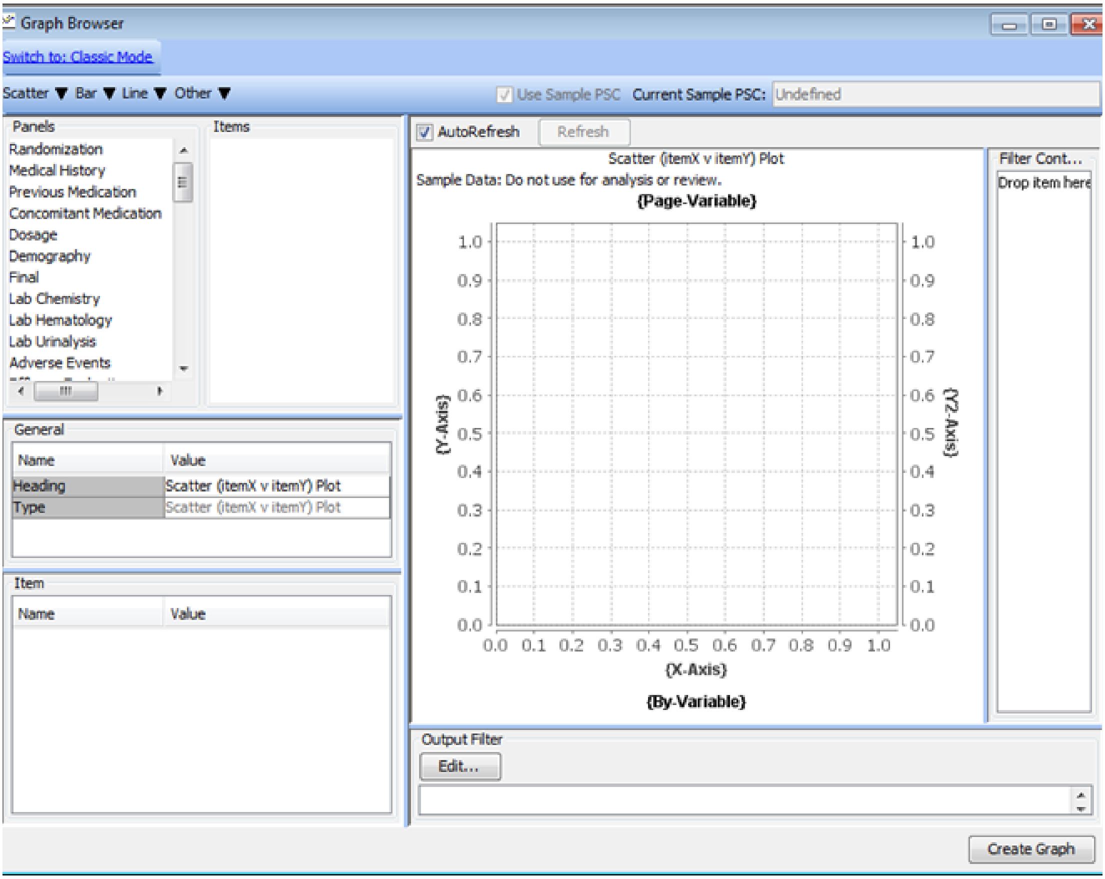
General

| Name | Value |
|---|---|
| Heading | Scatter (itemX v itemY) Plot |
| Type | Scatter (itemX v itemY) Plot |

Item

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | LABS..TRI |
| Numeric | ☑ |
| Panel | Labs (vertical) |
| Scaling | none |

This is the New Mode Graph Browser for the unpopulated Baseline vs. Endpoint Scatter Plot screen. In the Baseline vs. Endpoint, the Baseline vs. Min, or Baseline vs, Max plots, the item is dropped on the X-axis. The Y-axis is then automatically populated with the item. The Y-axis is selectable for the Baseline vs. Endpoint, which allows the user to select an alternative function in the property table. However, for Min or Max versions the Y-axis is not selectable.

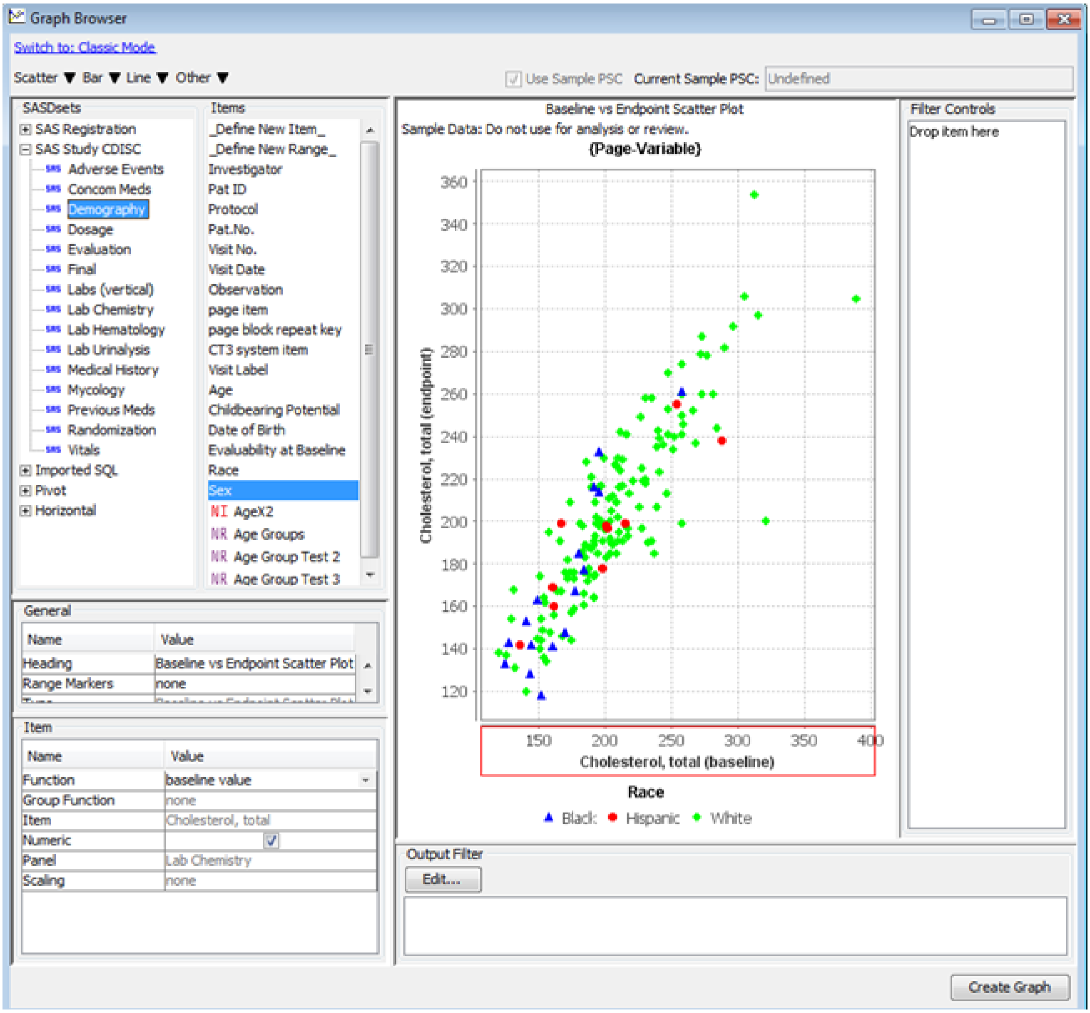


☑ Use Sample PSC Current Sample PSC: Undefined

☑ AutoRefresh

| Name | Value |
|---|---|
| Heading | Scatter (itemX v itemY) Plot |
| Type | Scatter (itemX v itemY) Plot |

Here is the Preview of Baseline vs. Endpoint Scatter Plot.



General

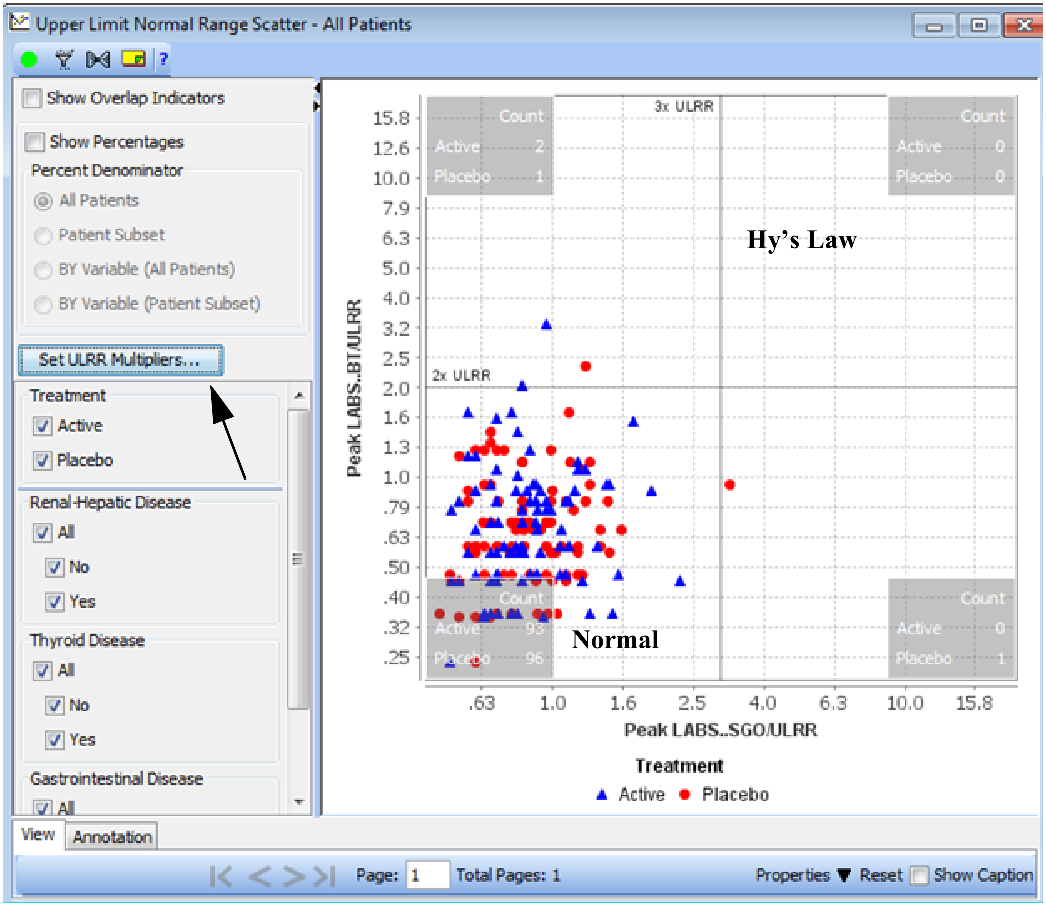
| Name | Value |
|---|---|
| Heading | Baseline vs Endpoint Scatter Plot |
| Range Markers | none |

Item

| Name | Value |
|---|---|
| Function | baseline value |
| Group Function | none |
| Item | Cholesterol, total |
| Numeric | ☑ |
| Panel | Lab Chemistry |
| Scaling | none |

## *Hy's Law plot*

The Hy's Law type plot is supported by the **Scatter Plot for Upper Limit Normal Range Plot**. It is typically used when evaluating Lab Chemistry data for Liver Enzymes for drug-induced liver injury (DILI) from experimental drugs. Select this graph type from the **Scatter** drop down menu.



Upper Limit Normal Range Scatter - All Patients

☐ Show Overlap Indicators

☐ Show Percentages

Percent Denominator

● All Patients

○ Patient Subset

○ BY Variable (All Patients)

○ BY Variable (Patient Subset)

Treatment
- ☑ Active
- ☑ Placebo

Renal-Hepatic Disease
- ☑ All
  - ☑ No
  - ☑ Yes

Thyroid Disease
- ☑ All
  - ☑ No
  - ☑ Yes

Gastrointestinal Disease
- ☑ All

Page: 1 Total Pages: 1

☐ Show Caption

Click **Set ULRR Multipliers** to change the ranges, and re-create the graph. The Output is presented with updated ranges.

***(See Chapter 7 - Graph Browser: Interactive Range Markers)***

## *Composite Hy's Law plot*

The following graph type is a Composite Visualization of Liver Tests for assessing patients for Drug Induced Liver Injury. JReview already includes the 'classical Hy's Law plot'. This added graph type which includes initial categorization of each patient at baseline regarding their position in a Hy's Law chart, then plots each patient's peak values on a composite graph for each of the 4 possible liver injury states – Normal, Cholestasis, Hy's Law or Temple's Corollary, with color coding based on the legend as to their baseline condition.

While it shares some aspects with JReview's Upper-Limit Normal Range graph, the Composite Hy's Law Graph is focused specifically on liver function and based on Hy's Law functionality. The FDA originated the concept for this graph. For background and a description, see

**http://www.phusewiki.org/docs/CSS%202016%20Posters/PP18_Final.pdf**

In the standard Hy's Law formulation, the X and Y axes are tied to laboratory tests used to assess liver function – typically, Bilirubin is associated with the Y-axis and ALT or AST with the X-axis. The x and y values for a data point shown in a Hy's Law graph are ratios of the respective lab test value to the upper-limit normal range value of that lab test for a patient. The Hy's Law plot is divided into quadrants: the divider value for each axis is a specified multiple of the upper-limit of the normal range. For example, if the multiple was 2x on the Y-axis and 3x on the X-axis, a data point with an x ratio value of 4 and a y ratio value of 3 would fall into the upper right quadrant of a Hy's Law plot.

While the Composite Hy's Law graph is based on Hy's Law computations, it is graphically distinct. In general terms, the Composite Hy's Law graph is defined in the following way:

1. As in the Upper Limit Normal Range graph, items defining lab tests for the X-axis (i.e., ALT or AST item) and the Y-axis (i.e., Bilirubin item) are chosen. Associated Upper-Limit of Normal Range items for the X and Y items are also chosen. "Multiplier" values are then selected for the Upper-Limit of the Normal Range items. The Multipliers determine the size of the ratios, i.e. multiples of the upper-limit normal range, that are X and Y "cut" points for dividing patient data into quadrants.
2. The Hy's Law definition of #1 is first used to categorize BASELINE lab test values into quadrants. The four colored icons shown in the legend of Figure 1 each represent the quadrant in which a BASELINE measurement fell.
3. The Hy's Law definition of #1 is again applied, but this time the quadrant categorization is applied to the PEAK POST-BASELINE values. This categorization determines in which of the four ***subplots*** a PEAK POST-BASELINE value is presented. ***Each subplot represents a Hy's Law quadrant.***
4. In the Composite Hy's Law graph, unlike the Hy's Law graph, the X and Y axes do NOT represent ratios of a lab test value to an upper-limit normal range value. Instead, the ratios are the PEAK POST-BASELINE value relative to the BASELINE value for that patient (i.e., PEAK POST-BASELINE/BASELINE) . Note that the axes are ***logarithmically scaled.***

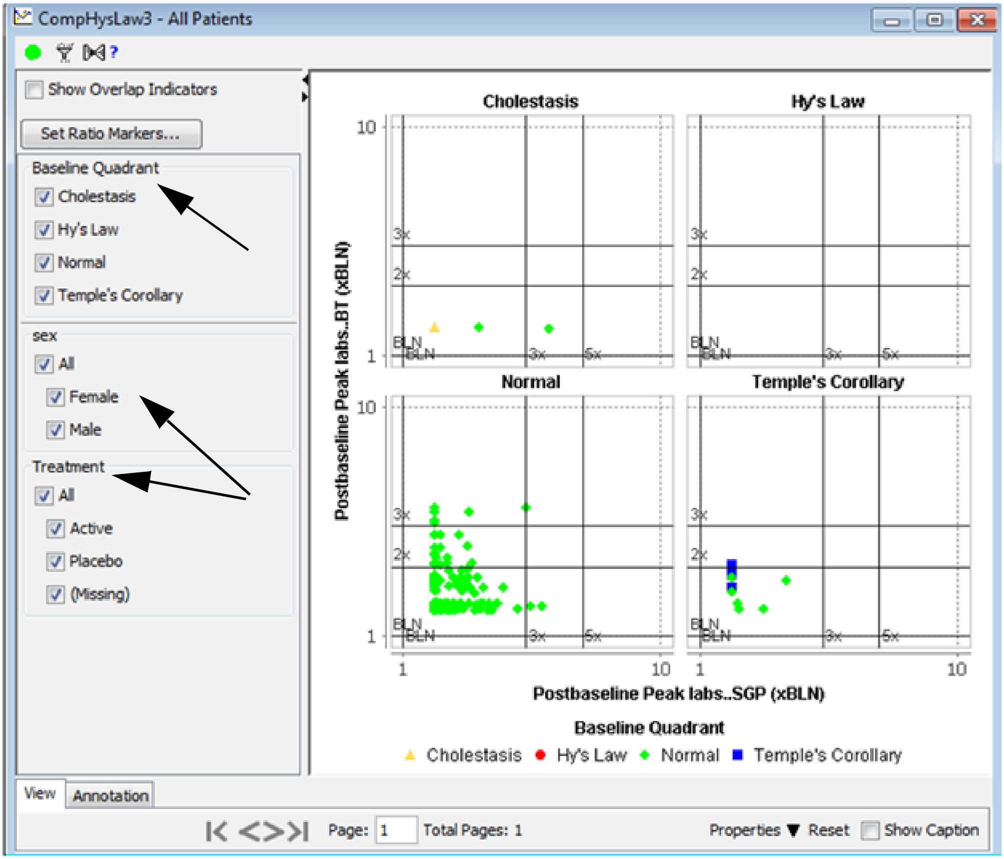
The Composite Hy's Law plot is dependent upon additional study parameters for baseline and endpoint information defined in the Advanced Menu. Some studies also use post-baseline data which may included. These study parameters *are required* for the Composite Hy's Law plot. An error message will display if these study parameters are not defined.

***Note: The Composite Hy's Law Graph requires that a Baseline and the Post-Baseline be defined (see Study Parameters).***

***(See Chapter 12 - Advanced Functions: Study Parameters)***

The Composite Hy’s Law graph does NOT support Paging or By-Variables. To view patient subsets, the user may optionally specify filter controls. The example shown contains two filter controls: Sex and Treatment Arm.

A further control is a set of checkboxes (Baseline Quadrant) that set visibility of the scatter plot data points according to their baseline quadrant categorization.



☐ Show Overlap Indicators

Baseline Quadrant
☑ Cholestasis
☑ Hy's Law
☑ Normal
☑ Temple's Corollary

sex
☑ All
☑ Female
☑ Male

Treatment
☑ All
☑ Active
☑ Placebo
☑ (Missing)

Page: 1 Total Pages: 1 ☐ Show Caption

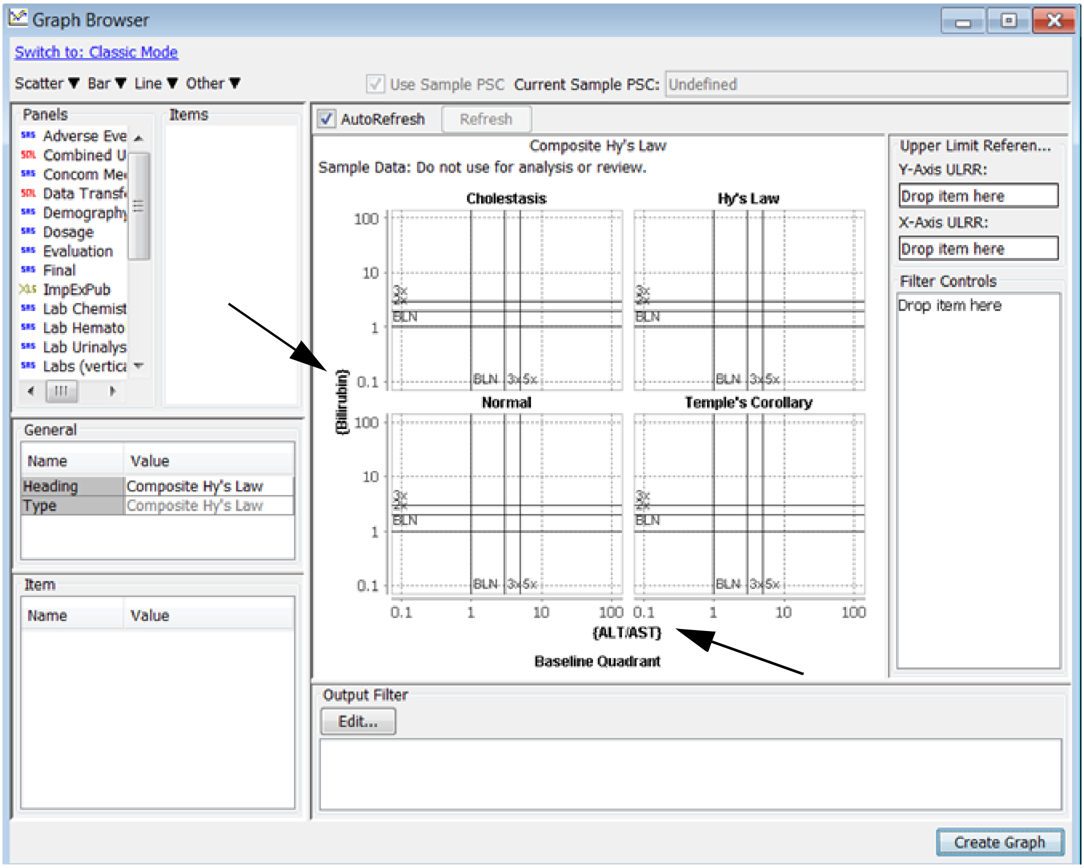
## *Define Composite Hy’s Law plot*

Select this graph type from the **Scatter** drop down menu. It supports using the HRZ Labs horizontal table defined for vertical lab tables.

The Graph Browser definition screen for Composite Hy’s Law is similar to the Upper-Limit Normal Range definition screen. However, the preview graph is different.

The default ULNR multipliers are set for the Composite Hy's Law graph to 2x for the Y-axis and 3x for the X-axis.

Drag and drop the appropriate lab items to their designated axis. Optionally drag/drop Filter Control items.



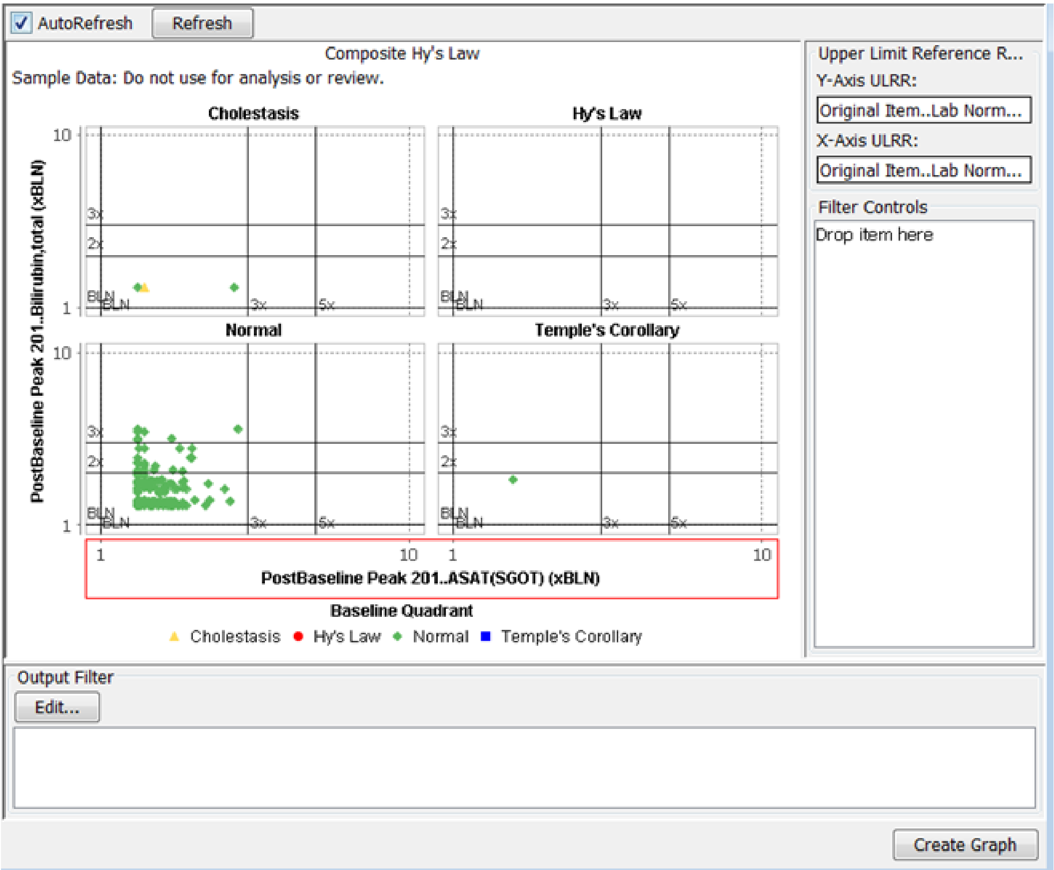
☐ Use Sample PSC Current Sample PSC: Undefined

☑ AutoRefresh

Sample Data: Do not use for analysis or review.

| Name | Value |
|---|---|
| Heading | Composite Hy's Law |
| Type | Composite Hy's Law |

The preview window opens with the Y axis precalibrated for entry of Total Bilirubin values. The X axis is set for ALT or AST lab values. Click **Create Graph**.



Composite Hy's Law

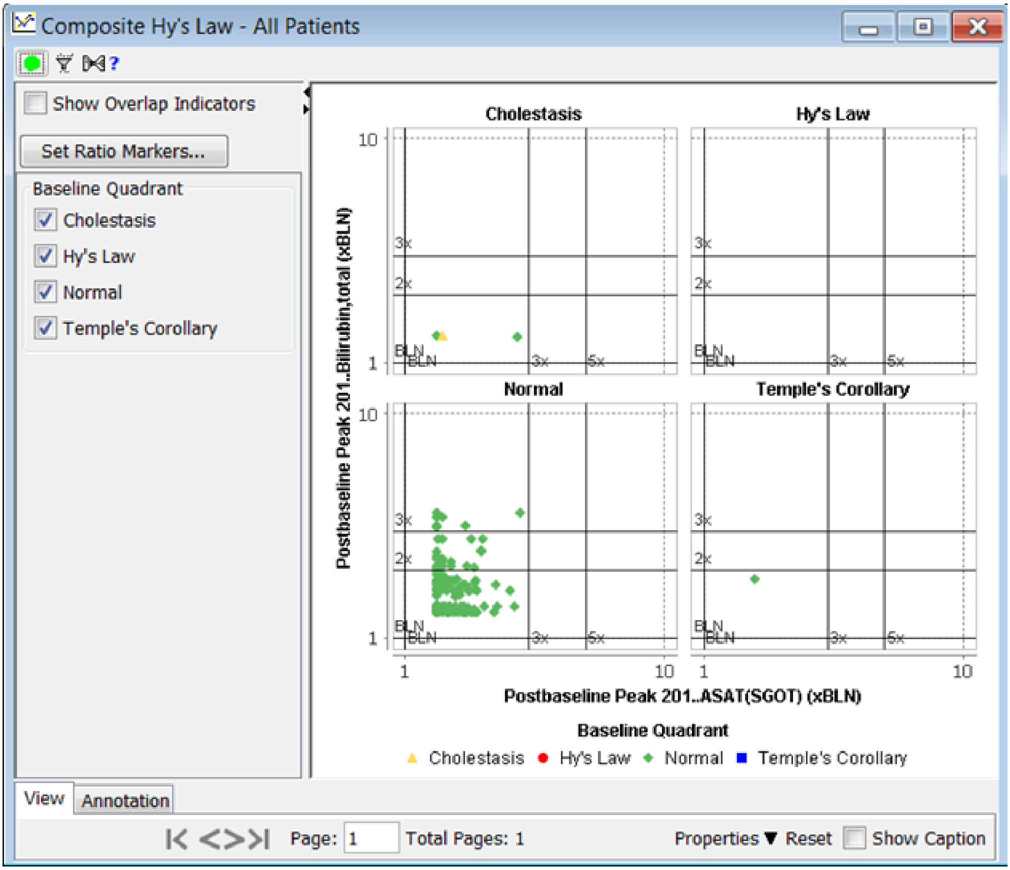
Sample Data: Do not use for analysis or review.

Upper Limit Reference R...

Y-Axis ULRR: Original Item..Lab Norm...

X-Axis ULRR: Original Item..Lab Norm...

The composite graph is created for each possible liver injury states for **Evaluation of drug-induced serious hepatotoxicity (eDISH).**



☐ Show Overlap Indicators

Baseline Quadrant

☑ Cholestasis

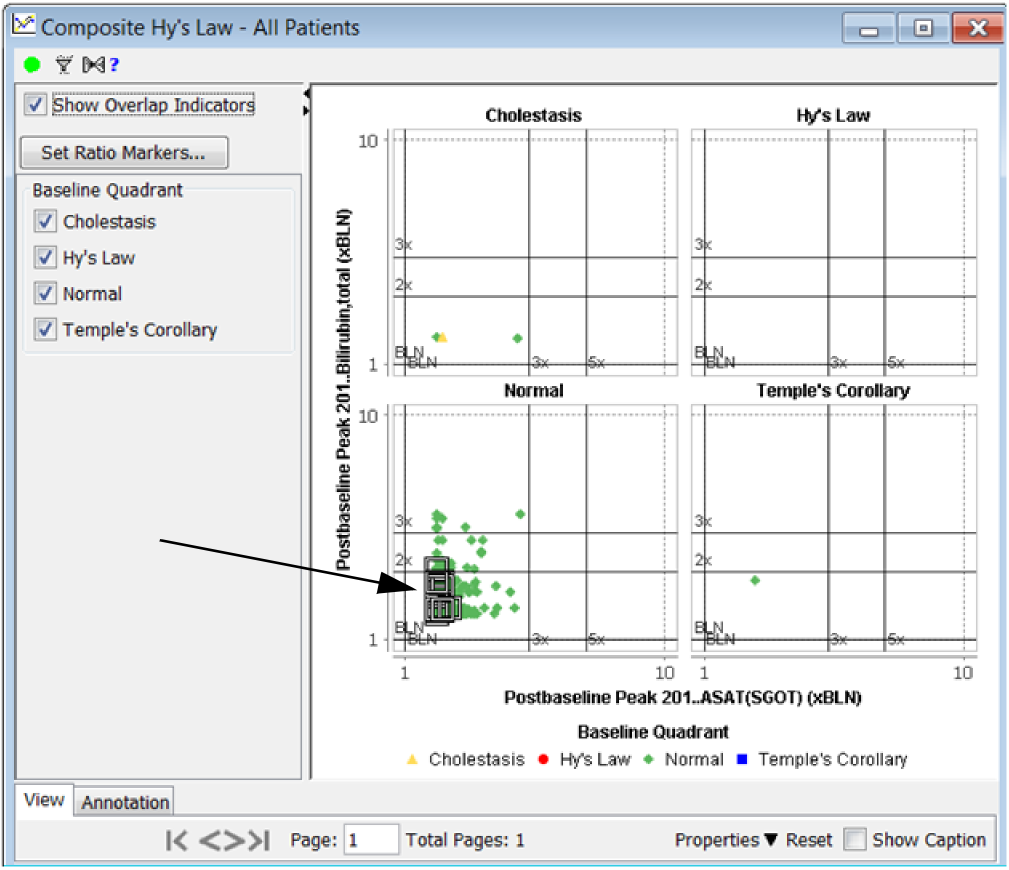
☑ Hy's Law

☑ Normal

☑ Temple's Corollary

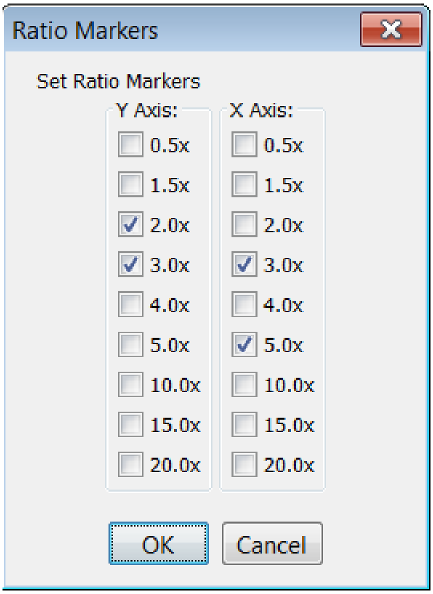
☐ Show Caption

Click **Show Overlap indicators**.



Click **Set Ratio Markers** to make changes to default display settings.

The “Set Ratio Markers” option is provided in the graph viewer. Clicking on the button results in the presentation of a dialog with two groups of checkboxes; one group is associated with Y-axis and the other group is associated with X-axis. The checkboxes allow the user to set the number and location of vertical and horizontal makers. In the graph example, the X-axis has makers at 3x and 5x; however, the set of makers that are presented can be changed using the “Set Ratio Markers” option.

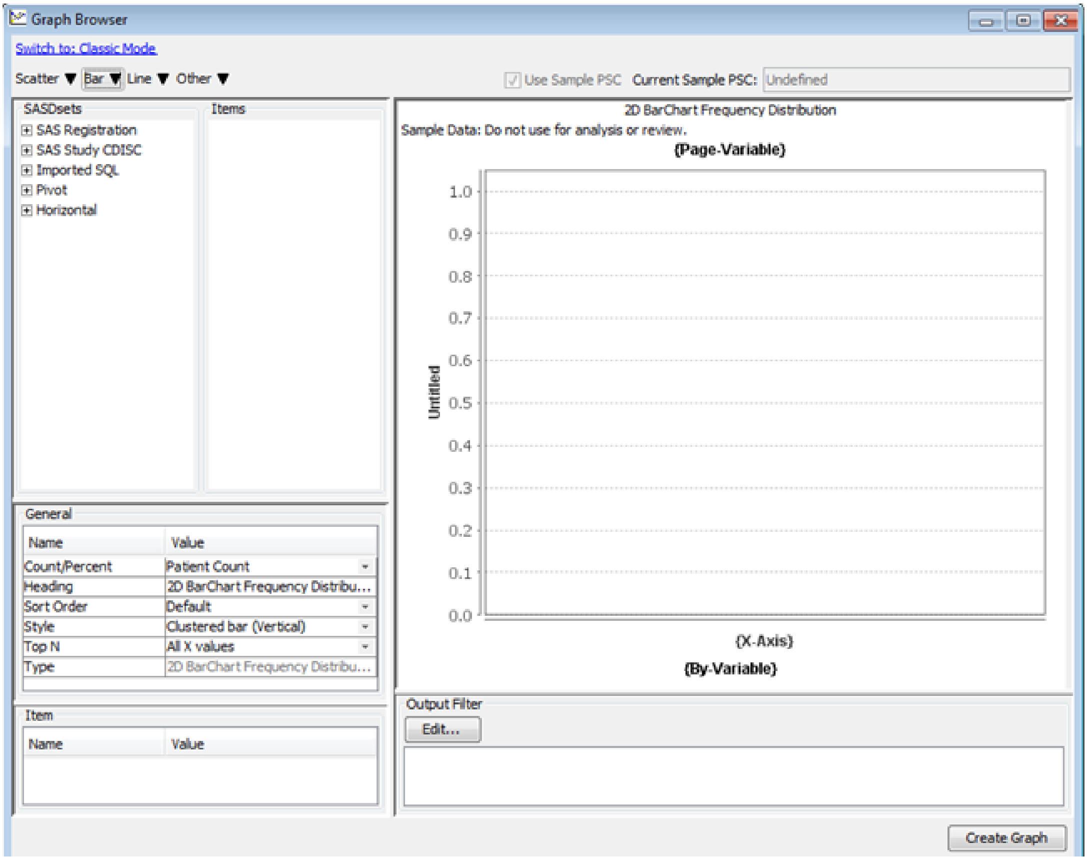


Set Ratio Markers

| Y Axis: | X Axis: |
|---|---|
| ☐ 0.5x | ☐ 0.5x |
| ☐ 1.5x | ☐ 1.5x |
| ☑ 2.0x | ☐ 2.0x |
| ☑ 3.0x | ☑ 3.0x |
| ☐ 4.0x | ☐ 4.0x |
| ☐ 5.0x | ☑ 5.0x |
| ☐ 10.0x | ☐ 10.0x |
| ☐ 15.0x | ☐ 15.0x |
| ☐ 20.0x | ☐ 20.0x |

## *Frequency Bar Graphs*

In the Frequency Bar Graphs, the user drops the item that defines the axes on the ***X-axis***. An item cannot be dropped on the Y-axis: it is automatically populated when an item is dropped on the X-axis. Both axes are selectable; this allows the user to set the "Scaling" option for the Y-axis when there is Paging. The General property table lists the editable and non-editable properties of the Bar Graph.



Current Sample PSC: Undefined

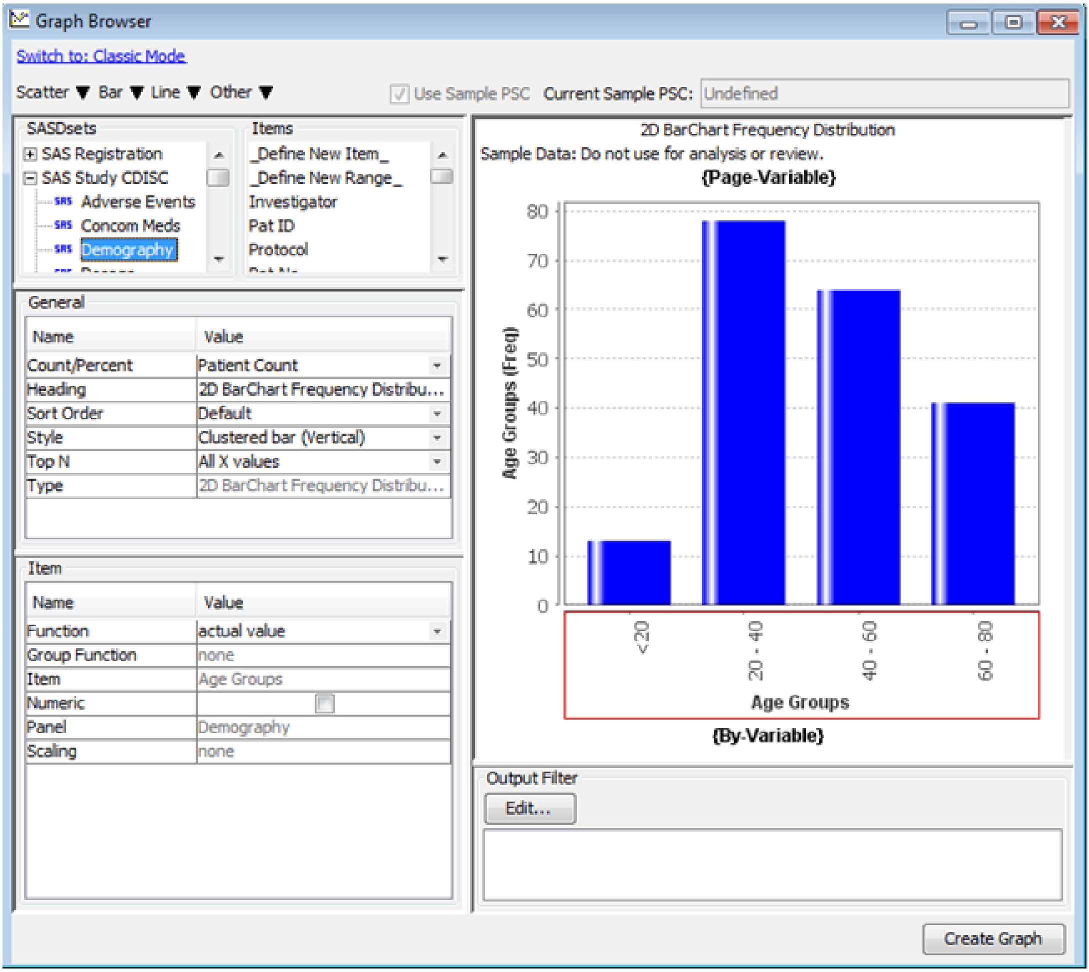
2D BarChart Frequency Distribution

Sample Data: Do not use for analysis or review.

General

| Name | Value |
|---|---|
| Count/Percent | Patient Count |
| Heading | 2D BarChart Frequency Distribu... |
| Sort Order | Default |
| Style | Clustered bar (Vertical) |
| Top N | All X values |
| Type | 2D BarChart Frequency Distribu... |

Here are the preview graph results for 2D Bar Chart Frequency Distribution Plot.



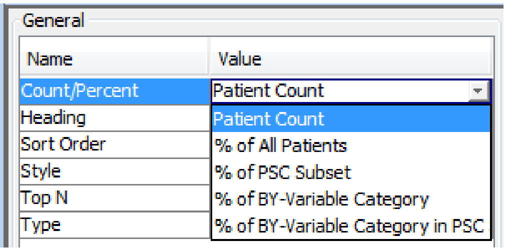
General

| Name | Value |
|---|---|
| Count/Percent | Patient Count |
| Heading | 2D BarChart Frequency Distribu... |
| Sort Order | Default |
| Style | Clustered bar (Vertical) |
| Top N | All X values |
| Type | 2D BarChart Frequency Distribu... |

Item

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | Age Groups |
| Numeric | ☐ |
| Panel | Demography |
| Scaling | none |

The Percent/Count is functionally the same as the “Classic” Relative Percent. The checkbox and percent options are a single drop down list.  Patient Count is the non-percent option in the New Mode.



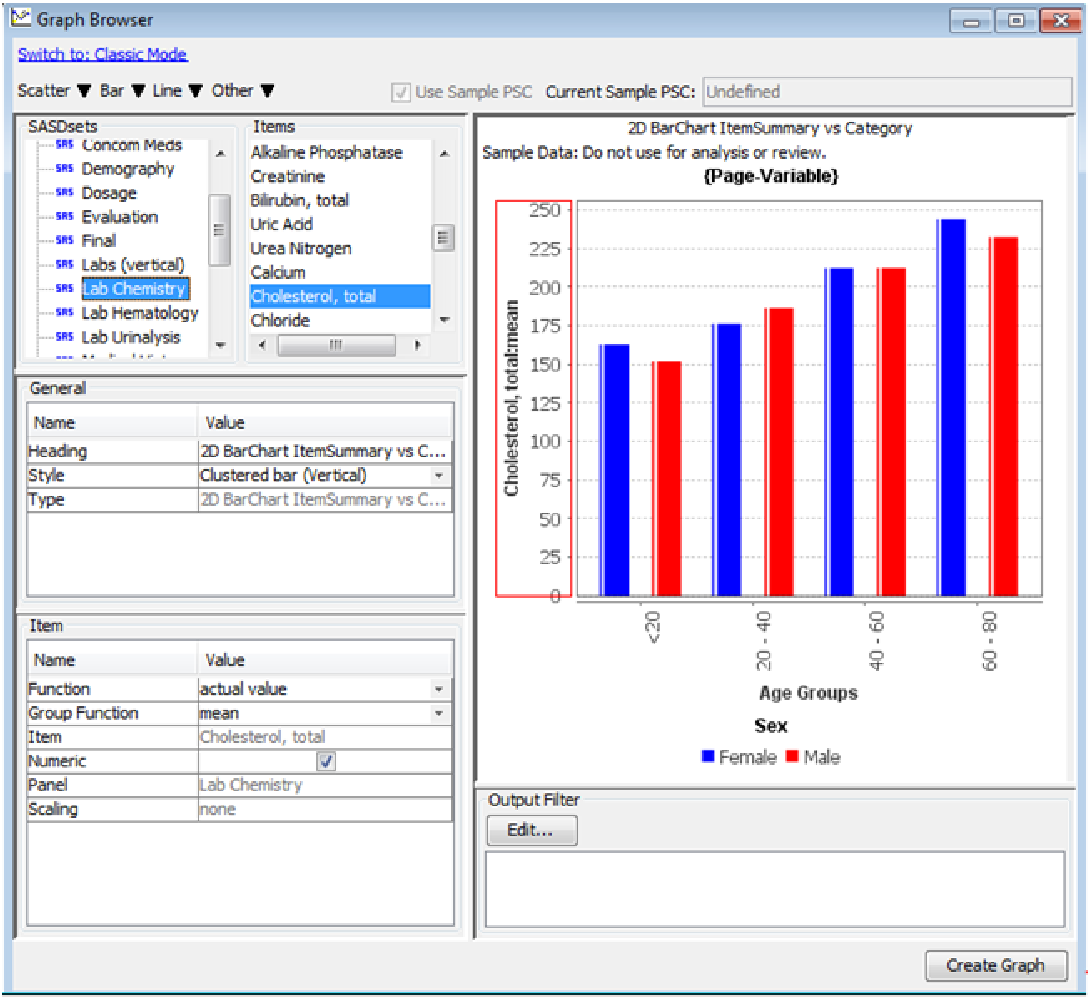
General

| Name | Value |
|---|---|
| Count/Percent | Patient Count |
| Heading | Patient Count |
| Sort Order | % of All Patients |
| Style | % of PSC Subset |
| Top N | % of BY-Variable Category |
| Type | % of BY-Variable Category in PSC |

## *Bar Chart Item Summary vs Category*

In the Bar Chart Item Summary vs. Category screens, both axes are selectable and are drop targets. The default “Group Function” for the Y-axis is “**mean**”, but an alternative may be chosen in the **Item** property table. **Sort Order** and **Top N** options are available.

See the **General** property table where “Style” may be changed by clicking on the drop down list. Here is the preview graph results for Bar Chart Item Summary vs. Category graph.



General

| Name | Value |
|---|---|
| Heading | 2D BarChart ItemSummary vs C... |
| Style | Clustered bar (Vertical) |
| Type | 2D BarChart ItemSummary vs C... |

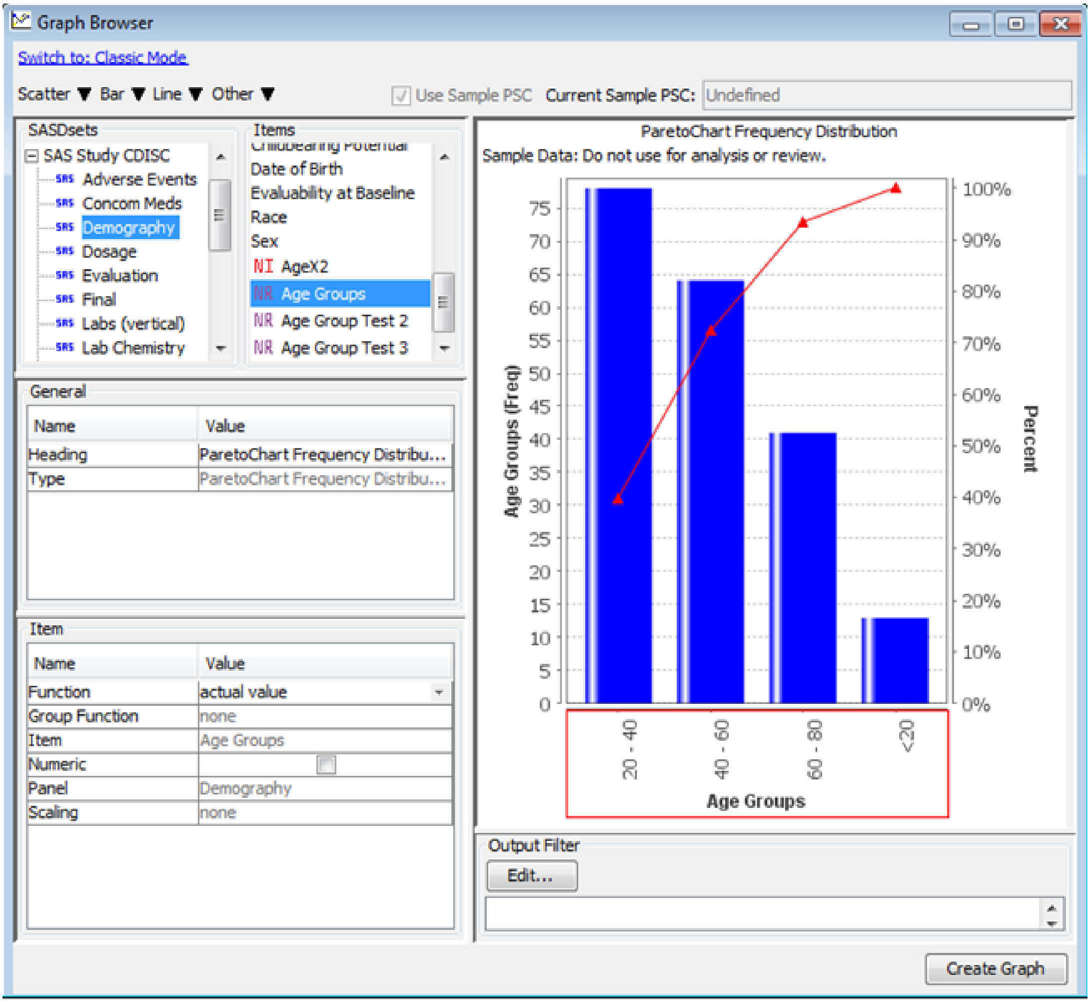
Item

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | mean |
| Item | Cholesterol, total |
| Numeric | ☑ |
| Panel | Lab Chemistry |
| Scaling | none |

## *Pareto Graph*

In the Pareto Graph the X-axis is a drop target, and the Y-axis is not a drop target but is automatically populated when an item is dropped on the X-axis.

The X-axis was defined for Age Groups and is displayed in the Preview. The General property table shows values as shaded which are **not** editable.



Current Sample PSC: Undefined

General

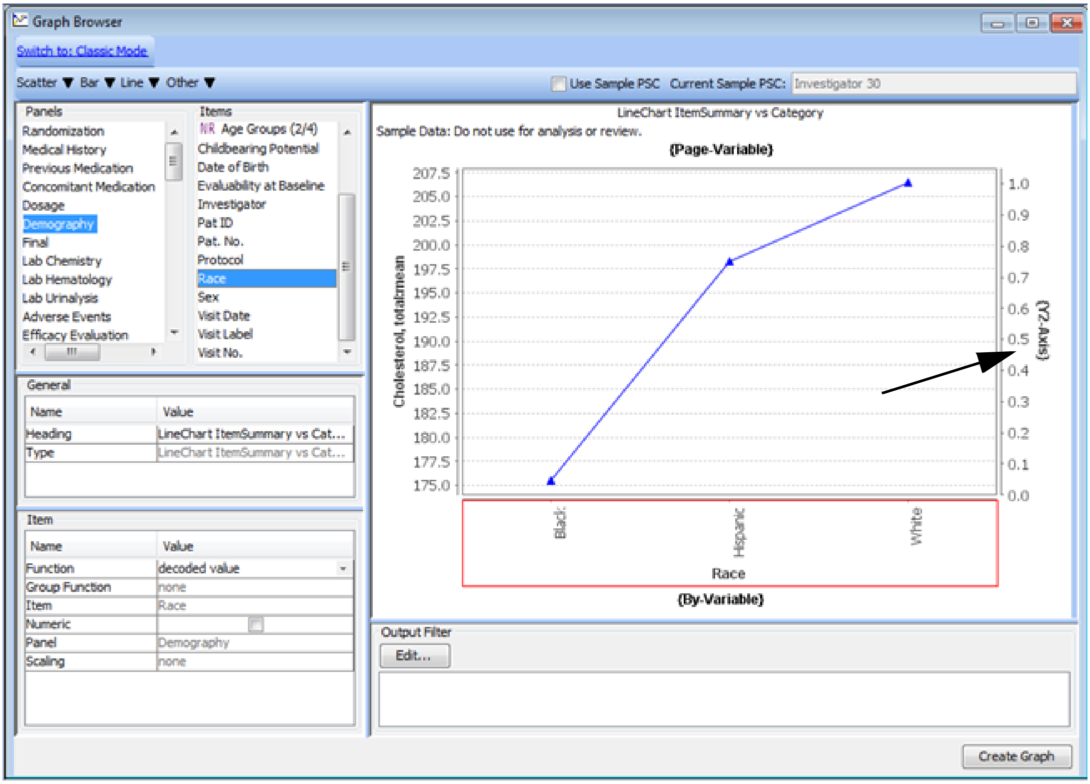
| Name | Value |
|---|---|
| Heading | ParetoChart Frequency Distribu... |
| Type | ParetoChart Frequency Distribu... |

Item

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | Age Groups |
| Numeric | ☐ |
| Panel | Demography |
| Scaling | none |

## *Line Charts*

LineChart Item Summary vs. Category and Mean Std Dev vs. Category are shown in following screens. Both axes are selectable in these charts. In LineChart ItemSummary vs. Category, the Y2-axis on the right side is also selectable.



☐ Use Sample PSC Current Sample PSC: Investigator 30

Sample Data: Do not use for analysis or review.

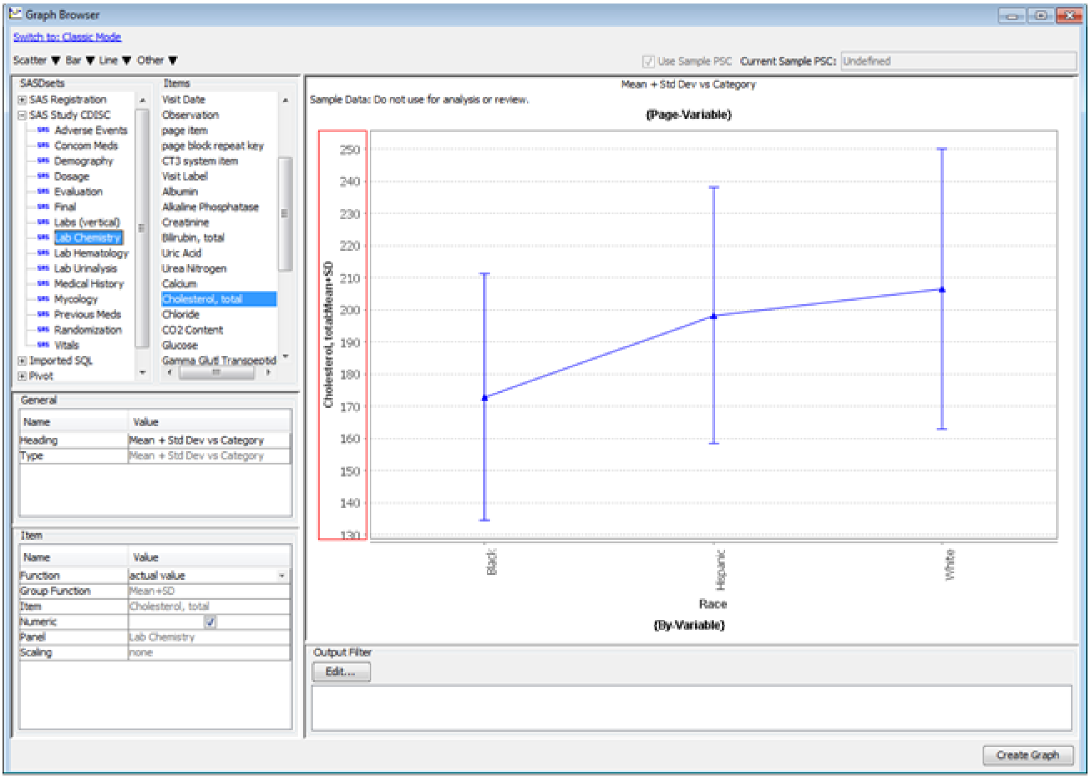
General

| Name | Value |
|---|---|
| Heading | LineChart ItemSummary vs Cat... |
| Type | LineChart ItemSummary vs Cat... |

Item

| Name | Value |
|---|---|
| Function | decoded value |
| Group Function | none |
| Item | Race |
| Numeric | ☐ |
| Panel | Demography |
| Scaling | none |

The Group Function of the Y-axis of the Mean Std Dev vs. Category chart is labeled “Mean+SD”.



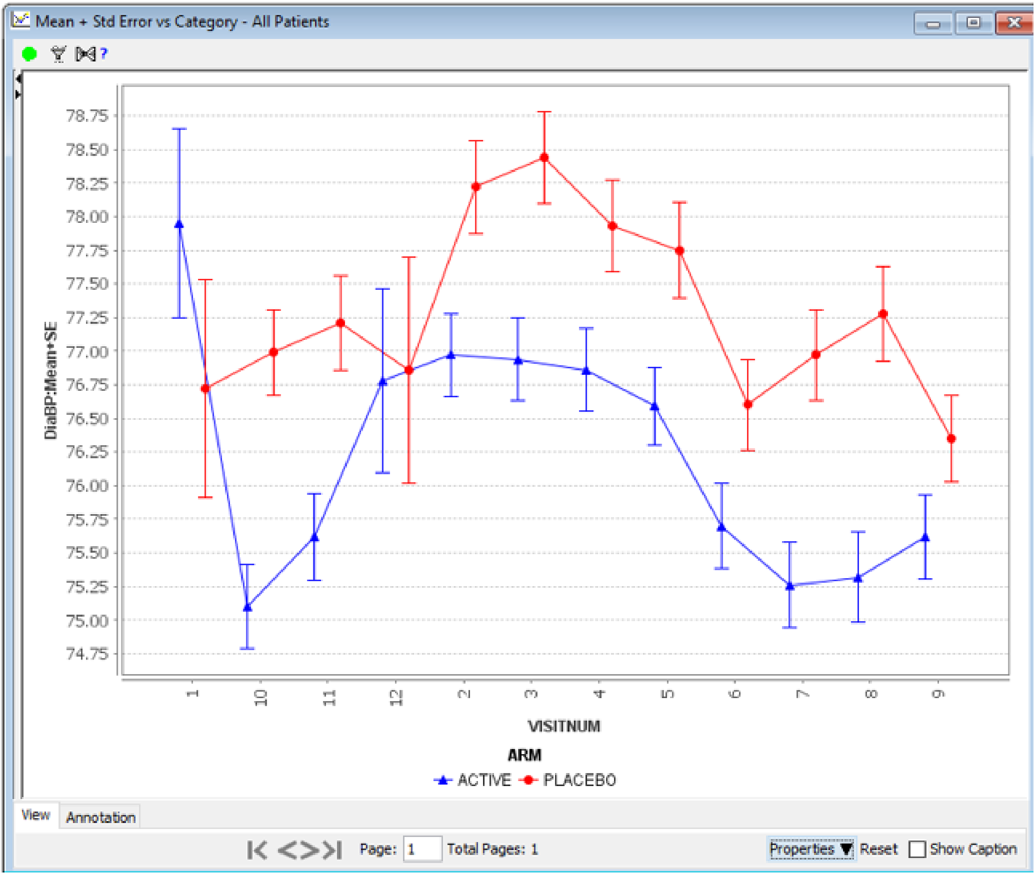
General

| Name | Value |
|---|---|
| Heading | Mean + Std Dev vs Category |
| Type | Mean + Std Dev vs Category |

Item

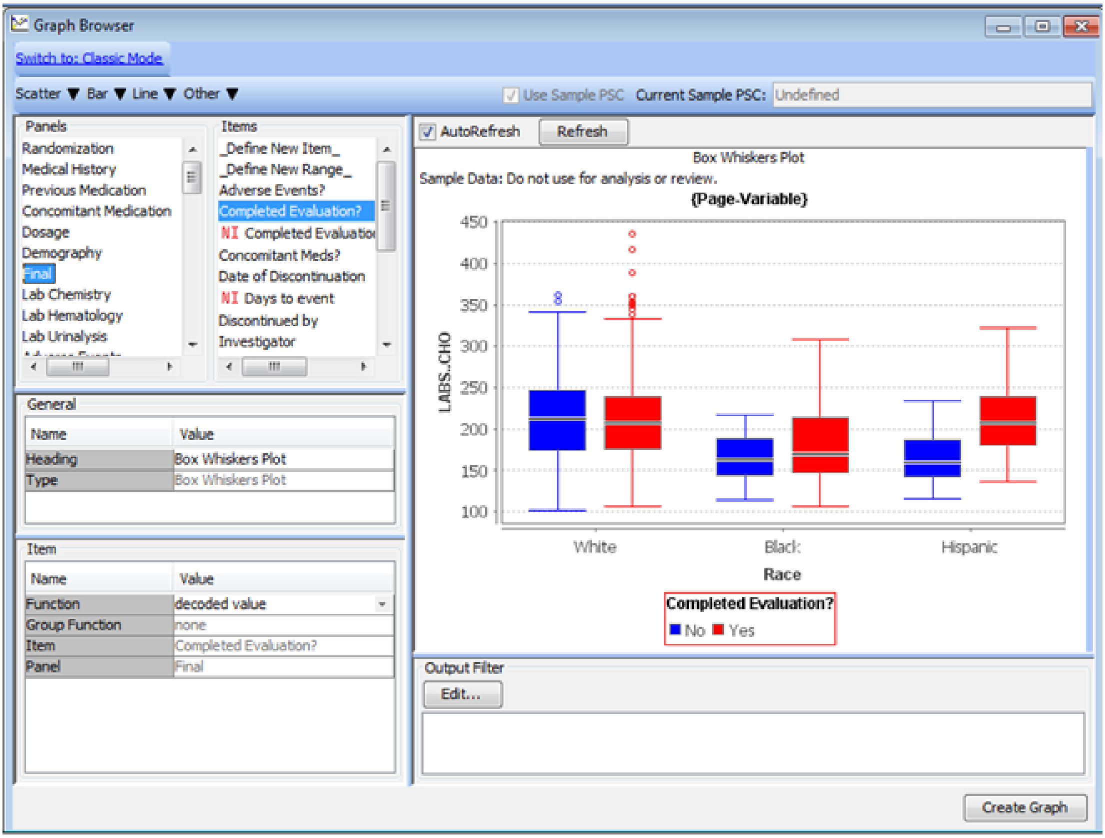
| Name | Value |
|---|---|
| Function | actual value |
| Group Function | Mean+SD |
| Item | Cholesterol, total |
| Numeric | ☑ |
| Panel | Lab Chemistry |
| Scaling | none |

The Line Chart for Mean plus /minus Standard Error (SE) was added to support oncology studies. The error bars included in this line chart are the Standard Error bars.



## *Box Whiskers Plot*

The Box Whiskers Plot preview is shown. The **Show Data Table** may be displayed after the graph is created.



Current Sample PSC: Undefined

Sample Data: Do not use for analysis or review.

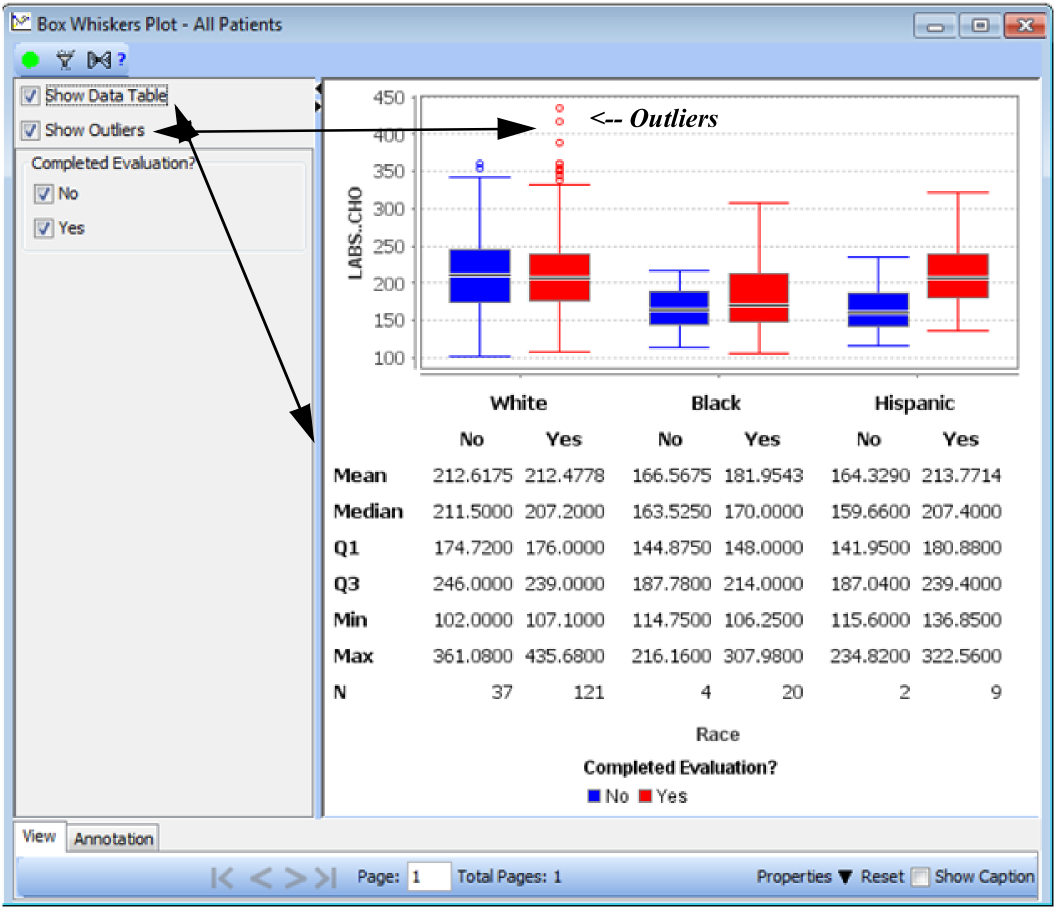
General

| Name | Value |
|---|---|
| Heading | Box Whiskers Plot |
| Type | Box Whiskers Plot |

Item

| Name | Value |
|---|---|
| Function | decoded value |
| Group Function | none |
| Item | Completed Evaluation? |
| Panel | Final |

Click **Show Data Tables** to view details for table of counts and stats: mean, median, 1st quartile, 3rd quartile, min, max, count.



☑ Show Data Table

☑ Show Outliers

Completed Evaluation?

☑ No

☑ Yes

|  | White |  | Black |  | Hispanic |  |
|---|---|---|---|---|---|---|
|  | No | Yes | No | Yes | No | Yes |
| **Mean** | 212.6175 | 212.4778 | 166.5675 | 181.9543 | 164.3290 | 213.7714 |
| **Median** | 211.5000 | 207.2000 | 163.5250 | 170.0000 | 159.6600 | 207.4000 |
| **Q1** | 174.7200 | 176.0000 | 144.8750 | 148.0000 | 141.9500 | 180.8800 |
| **Q3** | 246.0000 | 239.0000 | 187.7800 | 214.0000 | 187.0400 | 239.4000 |
| **Min** | 102.0000 | 107.1000 | 114.7500 | 106.2500 | 115.6000 | 136.8500 |
| **Max** | 361.0800 | 435.6800 | 216.1600 | 307.9800 | 234.8200 | 322.5600 |
| **N** | 37 | 121 | 4 | 20 | 2 | 9 |

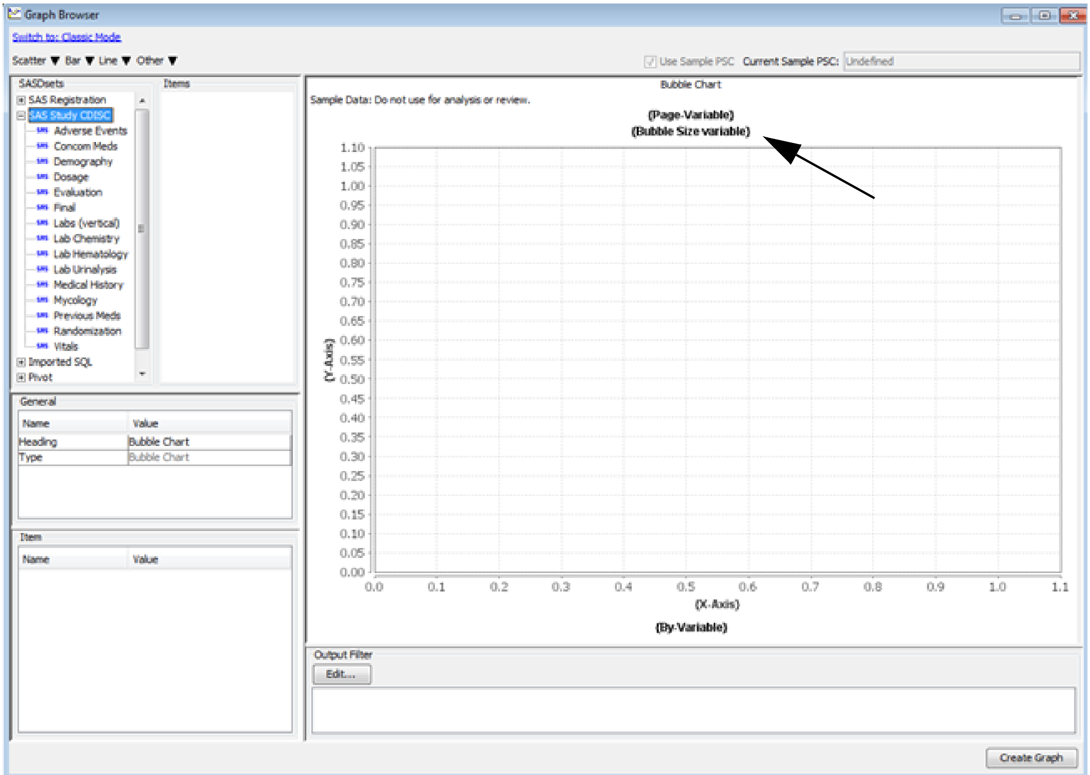
Race

**Completed Evaluation?**

🟦 No 🟥 Yes

## *Bubble Graph*

This is the Bubble Graph build screen. Box axes are selectable. The drop target for the “**Bubble Size variable**” is located above the plot, for example, as drop item PatNo.

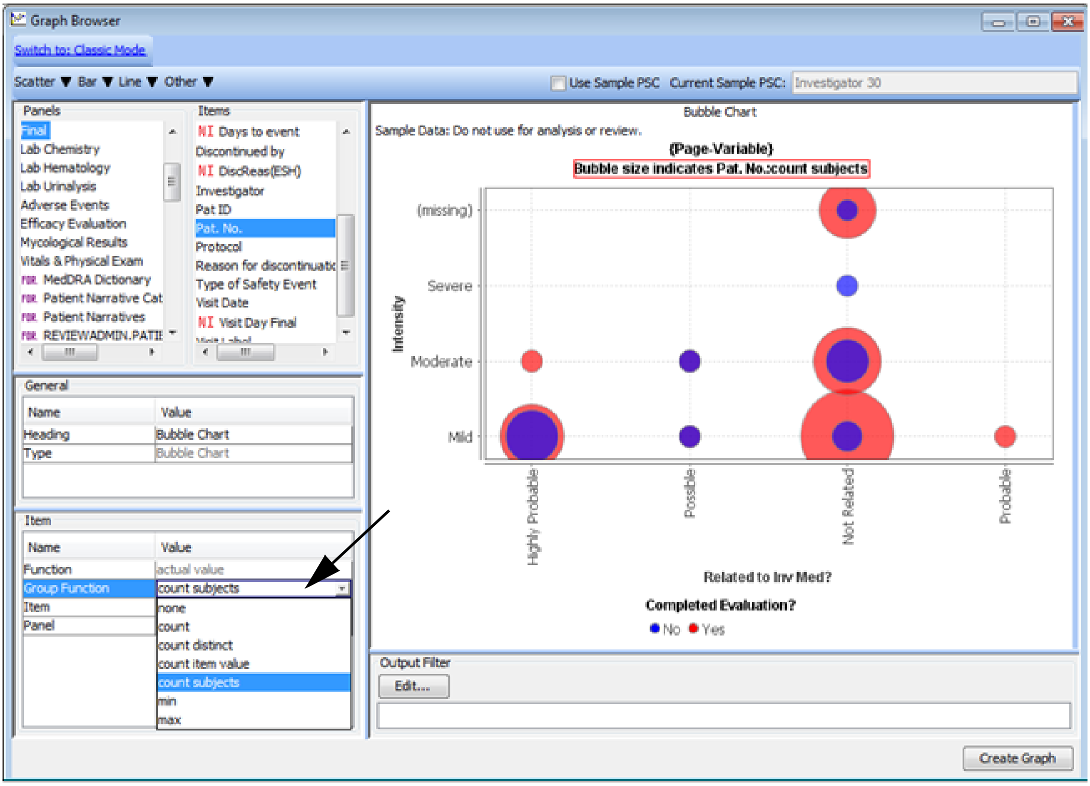


Current Sample PSC: Undefined

Sample Data: Do not use for analysis or review.

| Name | Value |
|---|---|
| Heading | Bubble Chart |
| Type | Bubble Chart |

Now the **Group Function** is available for the Bubble Size variable in the **Item** property table.



General

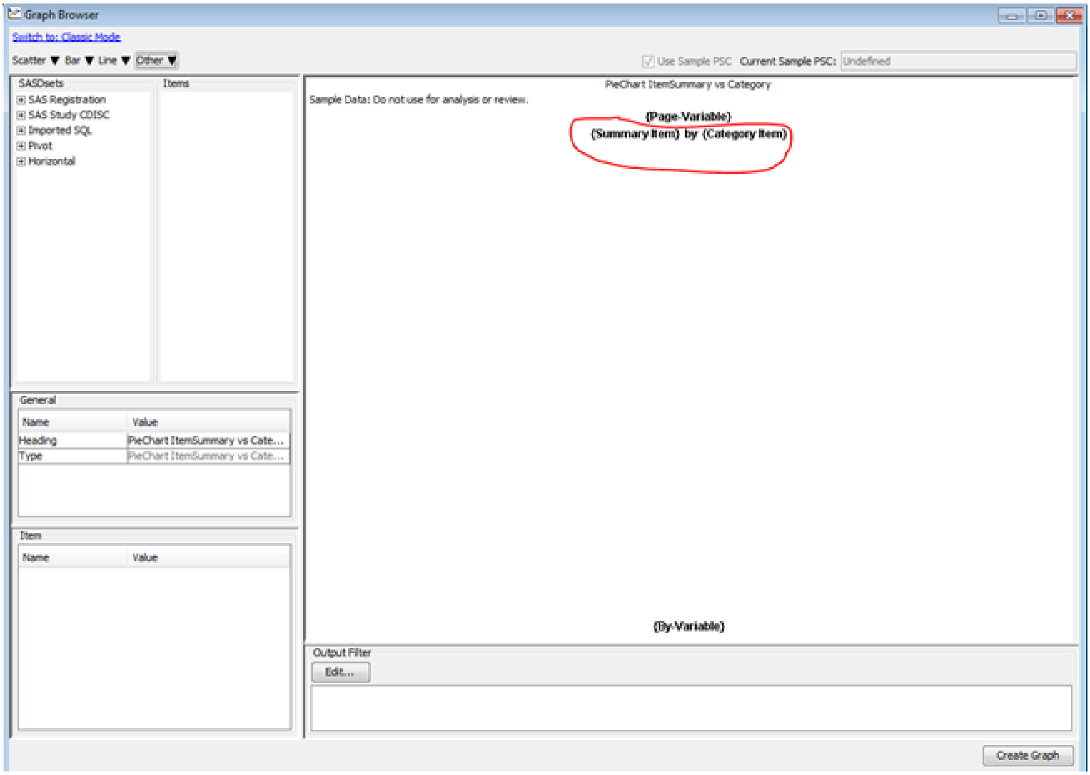
| Name | Value |
|---|---|
| Heading | Bubble Chart |
| Type | Bubble Chart |

Item

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | count subjects |
| Item | |
| Panel | |

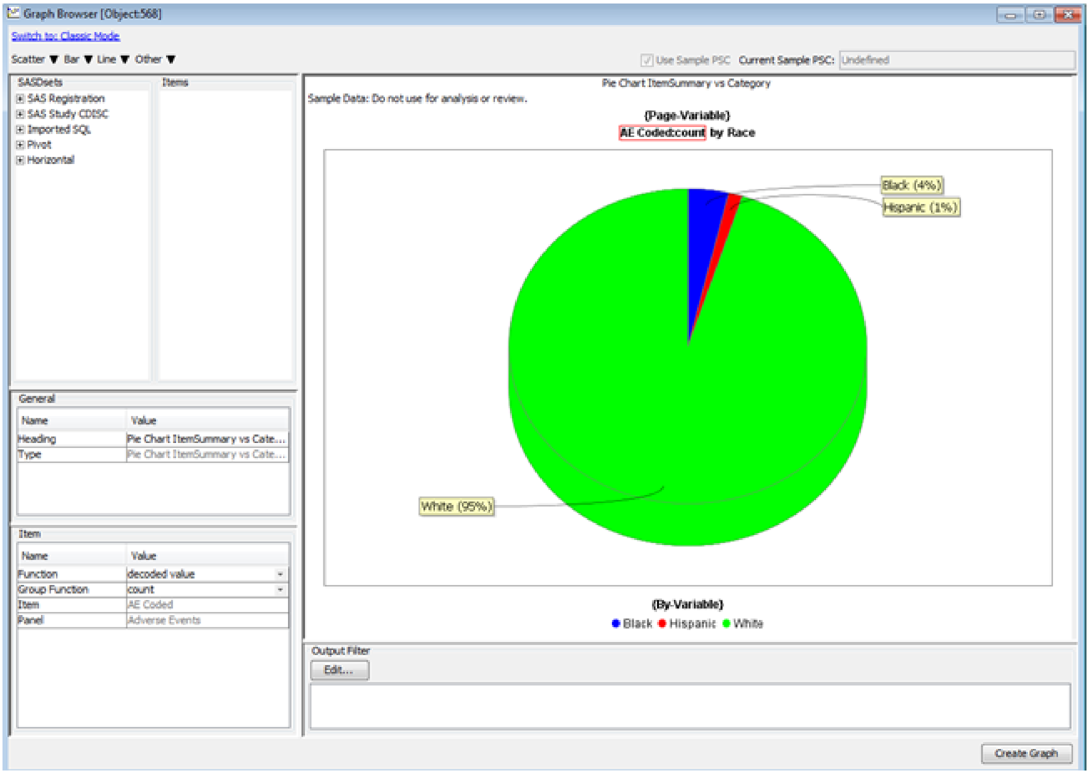
## Pie Chart

The PieChart Item Summary vs. Category plot are shown. Obviously, a pie chart has no axes. However, in Classic Mode, the two main variables that specify the chart are called “Y-axis” and “X-axis”. However, in New Mode, these variables are called Summary Item and Category Item to parallel the name of the graph in JReview. The drop targets for these variable is placed above the graph area: “{Summary Item} by {Category Item}”.



Sample Data: Do not use for analysis or review.

| Name | Value |
|---|---|
| Heading | PieChart ItemSummary vs Cate... |
| Type | PieChart ItemSummary vs Cate... |



Current Sample PSC: Undefined

Sample Data: Do not use for analysis or review.

General

| Name | Value |
|---|---|
| Heading | Pie Chart ItemSummary vs Cate... |
| Type | Pie Chart ItemSummary vs Cate... |

Item

| Name | Value |
|---|---|
| Function | decoded value |
| Group Function | count |
| Item | AE Coded |
| Panel | Adverse Events |

In JReview Release Version 12, the Kaplan Meier - New Mode Graph Browser has been reworked with new features. There is the added capability to define a filter for the Event definition and a filter for the Censor as a new feature. A "filter control" component is added to the Event definition screen and to Censor definition screen. The feature is ***available in "New Mode" only***.

***Note: Due to these changes graphs produced with the new mode version may appear different from the Classic Mode. These differences are:***

- Negative values are prevented from occurring.
- A patient will only appear once in the graph. This will be the first event or censor. If a patient has an event and censor on the same day, the event will take precedence.
- The patient pool has changed where the total number of patients is now drawn from the case table. The graph will include all patients present in the study and to restrict this the PSC must be used.
- The start date filter will not restrict which patients appear in the graph. It will only restrict the events or censors that appear.
- The drill down has been slightly modified as well. The patients shown are those that have not had a previous event or censor.

These new Event and Censor filters act only on their specific section. So the event filter only effects the events that appear and they do not restrict the total population counts. They are specifically to restrict the events or censors that are shown in the graph. The start date filter is still present and this applies to both event and censor data, but again will not effect the population counts. The population can only be changed through the patient selection criteria.

The filters can be used with or without the start date filter . The panels used for the filters can be the same as the event/censor item and different. Different combinations of multiline and single line filters can be defined. Saved Kaplan Meier objects can be opened in both New and Classic modes, however, if the object had filters the object would only open in New mode. Drill down on the graph counts can be compared to the Data Browser.

The Kaplan-Meier graph axes for this graph type are NOT drop targets or selectable. As the Kaplan-Meier requires relatively complex sets of variables and filters, form-based components are used to define the graph's characteristics for time, events, and censor data. Each of these components is presented one-at-time in a "paging" manner. While each of these components resembles a step in the construction of the definition, no strict ordering is enforced. The components are displayed in a UI control placed above the plot area. Each of these "steps" defines a logical dimension in the graph's definition.

Selectable drop targets do exist in the plot area for Paging and By-Variables.

The **General table** contains the checkbox of the plot for **Descending Probability** versus Ascending Probability of Y axis, where Probability of Survival versus Probability of Death.

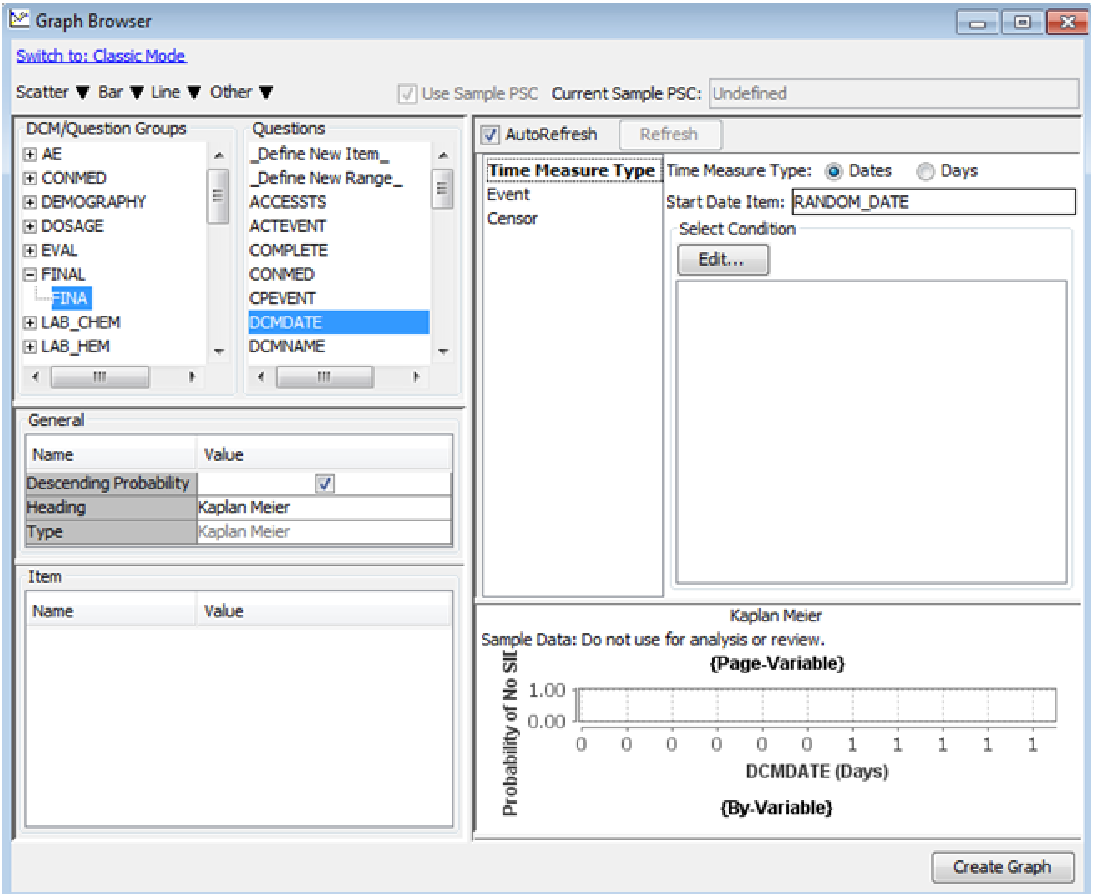
The "steps" in defining the graph are listed in a list component. One step in the list is always selected. The user selects a step by clicking on the step in the list. Each step component can have a variety of UI controls, including radio buttons, selectable drop-target components, and filter controls. The user may drag an item from the PIFPanel and drop it on a drop-target component, and then edit the properties in the Item property table. Despite the somewhat different organization of the components, the functionality parallels that of the Classic Mode.

The **"Time Measure Type"** screen is used to define the time-related parameters.

1. Radio buttons select whether the time-related items in the database that will be used for the graph are Dates or are Days. If Days is selected, then the date-related components described in #2 and #3 below will not be visible.
2. If Dates is selected, then a Start Date must be defined so that the number of days to an event can be calculated; the Start Date Item drop-target component is used for this purpose.

   ***The Start Date Item may be auto-populated, if a default Study-wide Start Date item has been defined. Study Start Date is a new feature in Version 11, see previous section: Defining a graph specification - New Mode.***

   Using drag-and-drop, the user can override an auto-populated default value. The auto-population only occurs when the Graph Browser for Kaplan-Meier is first opened.
3. A Filter Control allows the user to optionally refine the definition of the Start Date. This control is enabled when the Start Date is populated.



☑ Use Sample PSC Current Sample PSC: Undefined

☑ AutoRefresh

Time Measure Type: ● Dates ○ Days

Start Date Item: RANDOM_DATE

General

| Name | Value |
|---|---|
| Descending Probability | ☑ |
| Heading | Kaplan Meier |
| Type | Kaplan Meier |

Item

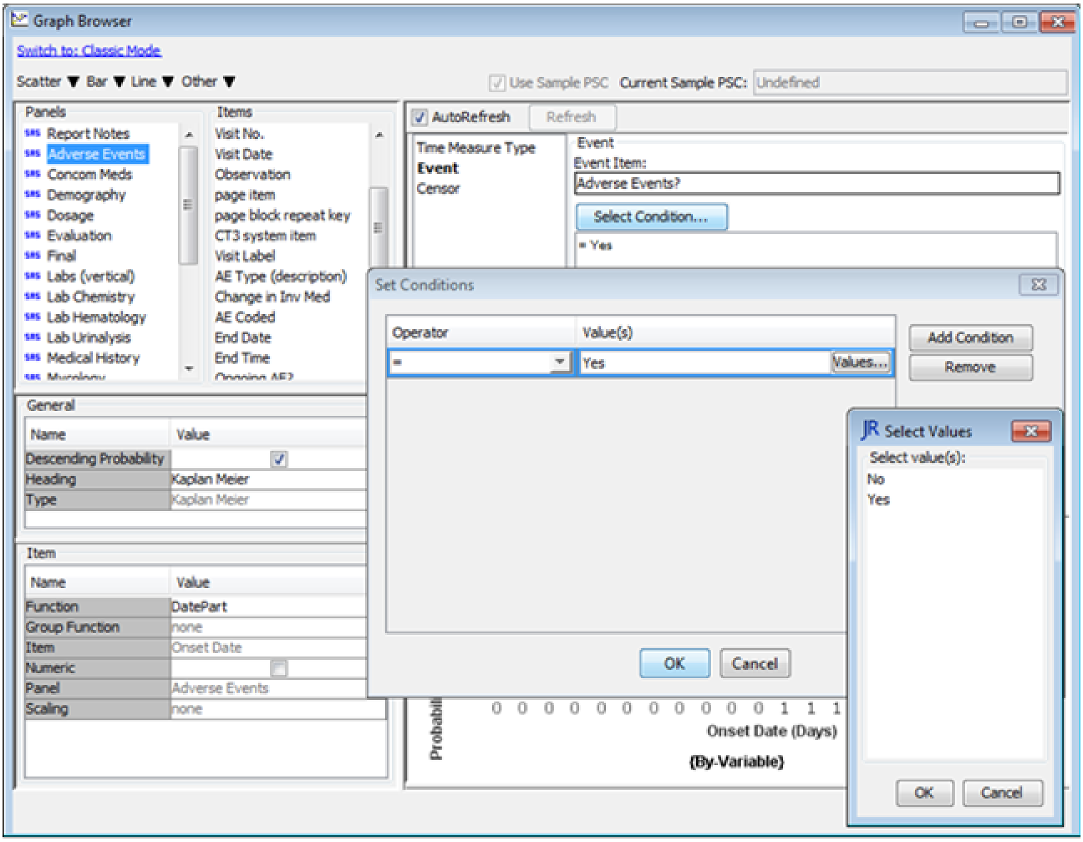
| Name | Value |
|---|---|

Kaplan Meier

Sample Data: Do not use for analysis or review.

The **“Event”** screen is used to specify the events. For example, it may be used to define the Adverse Events to include in the graph. The following are the contained components:

1. An **Event Item** drop-target component to specify the item that defines the event.
2. Optionally select the Event Condition by setting the conditions for a specified operator and Select Values.



☑ AutoRefresh

Event Item: Adverse Events?

= Yes

| Operator | Value(s) |
|---|---|
| = | Yes |

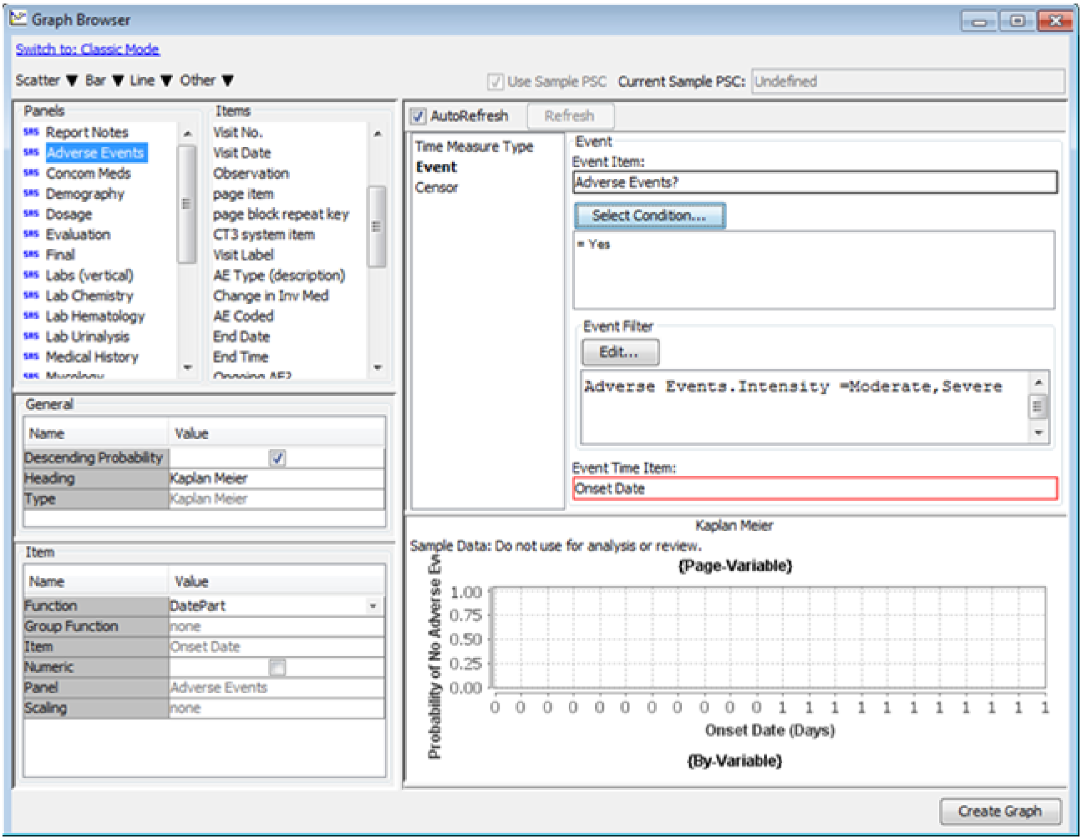
General

| Name | Value |
|---|---|
| Descending Probability | ☑ |
| Heading | Kaplan Meier |
| Type | Kaplan Meier |

Item

| Name | Value |
|---|---|
| Function | DatePart |
| Group Function | none |
| Item | Onset Date |
| Numeric | ☐ |
| Panel | Adverse Events |
| Scaling | none |

3. Optionally enter an Event Filter to refine the event specification. This control is enabled when the Event Item is populated.
4. An Event Time Item drop-target component to specify the item that defines the time (date or days) of the event.



☑ Use Sample PSC Current Sample PSC: Undefined

☑ AutoRefresh

Event

Event Item: Adverse Events?

= Yes

Event Filter

Adverse Events.Intensity =Moderate,Severe

Event Time Item: Onset Date

General

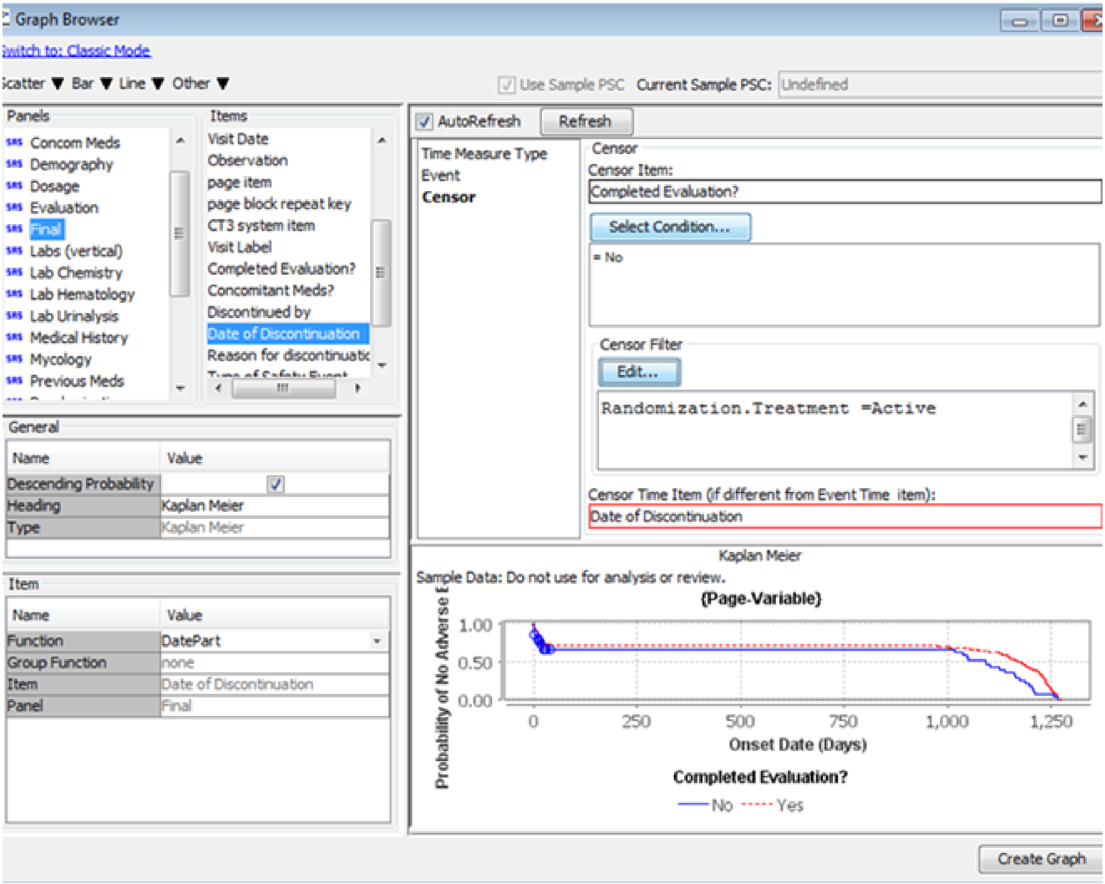
| Name | Value |
|---|---|
| Descending Probability | ☑ |
| Heading | Kaplan Meier |
| Type | Kaplan Meier |

Item

| Name | Value |
|---|---|
| Function | DatePart |
| Group Function | none |
| Item | Onset Date |
| Numeric | ☐ |
| Panel | Adverse Events |
| Scaling | none |

The "**Censor**" screen is used to define the Censor data. For example, it may be used to define an item that indicates when a patient dropped-out of the study. The following are the contained components.

1. A **Censor Item** drop-target component to specify the Censor data.
2. Optionally select the Censor Condition by setting the conditions for a specified operator and Select Values.
3. A Consor Filter control for optionally refining the Censor data specification. This control is enabled when Censor Item is populated.
4. A Censor Time Item drop-target component to specify the item that defines the time (date or days) of the Censor data occurrence. This field does not need to be specified if the Event Time Item and Censor Time Item are identical.
5. Page Variable is an option.  View Preview and Create Graph.



Censor

Censor Item: Completed Evaluation?

= No

Censor Filter

Randomization.Treatment =Active

Censor Time Item (if different from Event Time item): Date of Discontinuation

General

| Name | Value |
|---|---|
| Descending Probability | ☑ |
| Heading | Kaplan Meier |
| Type | Kaplan Meier |

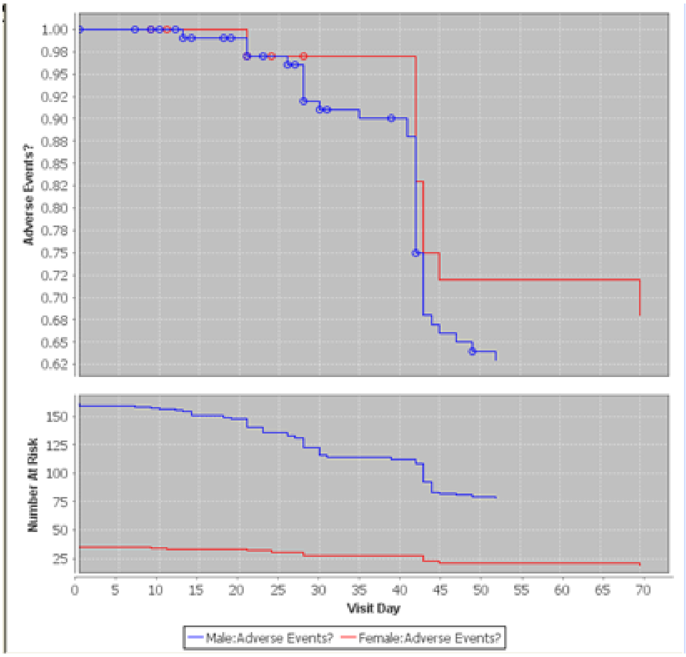
Item

| Name | Value |
|---|---|
| Function | DatePart |
| Group Function | none |
| Item | Date of Discontinuation |
| Panel | Final |

The plots are summary in nature and require drill down. This is basically a line plot over time on the X axis. The Y axis shows probability of survival (or non-survival) for the selected patient group. The Kaplan Meier plots supports multi-study mode.

The survival curves are shown as a step function.

Below is an example of a Kaplan Meier and Survival Plot:

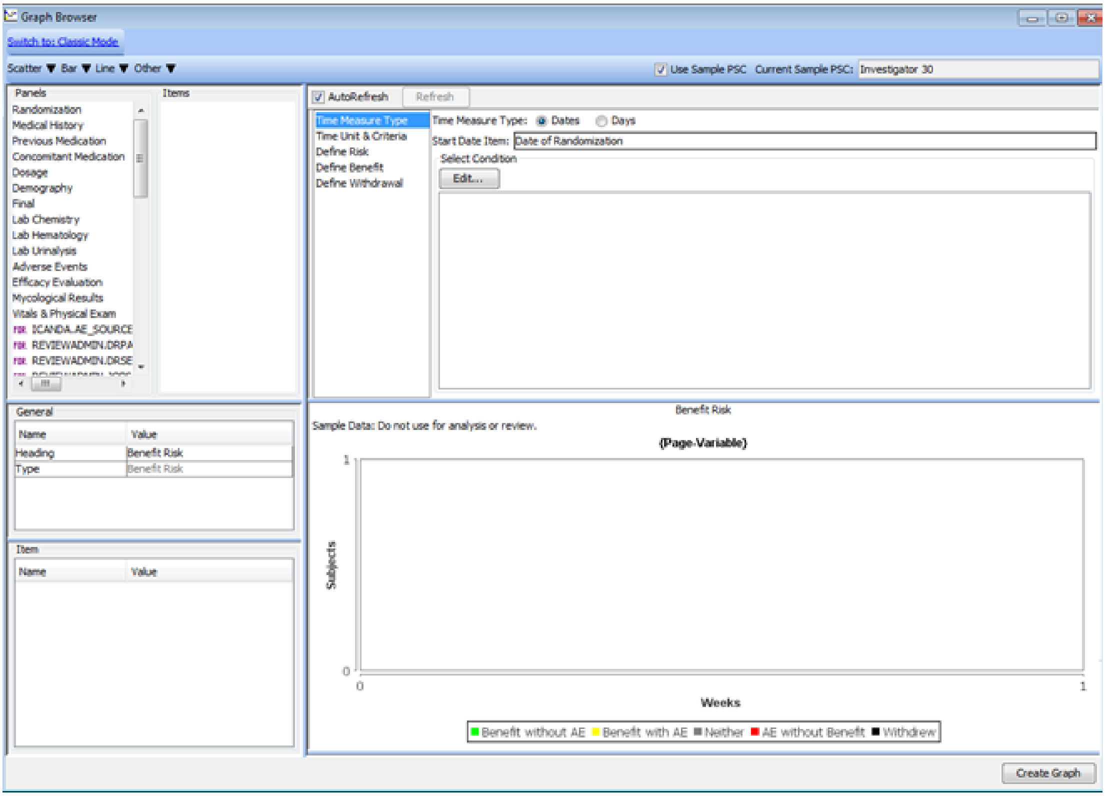


## *Benefit Risk graph*

New Mode support for Benefit Risk graphs is similar in style to the New User Interface( NUI ) Kaplan-Meier UI, and uses a combination of drag-and-drop and popup filter dialogs.

The handling of the “single panel for all items” constraint differs somewhat from the Classic Mode. The user can select items and create filters in any order in the **Risk, Benefit,** and **Withdrawal** sub-forms. If the sub-form detects the use of multiple panels, the “All items must be from the same panel” instruction is displayed in a red color. Before updating the preview or creating a graph, a validity check is made. The validity check makes sure the single panel constraint is met and all required data is entered.

Select Benefit Risk plot from the “Other” graph type drop down list. The specifications for define Risk, Benefit, and Withdrawal are each separately defined as output filters. The five color coding scheme descriptions display in the graph footer. ***(See Graph Browser: Classic Mode section on Benefit Risk Analysis for detailed steps.)***



☑ Use Sample PSC  Current Sample PSC: Investigator 30

☑ AutoRefresh

Time Measure Type: ● Dates ○ Days

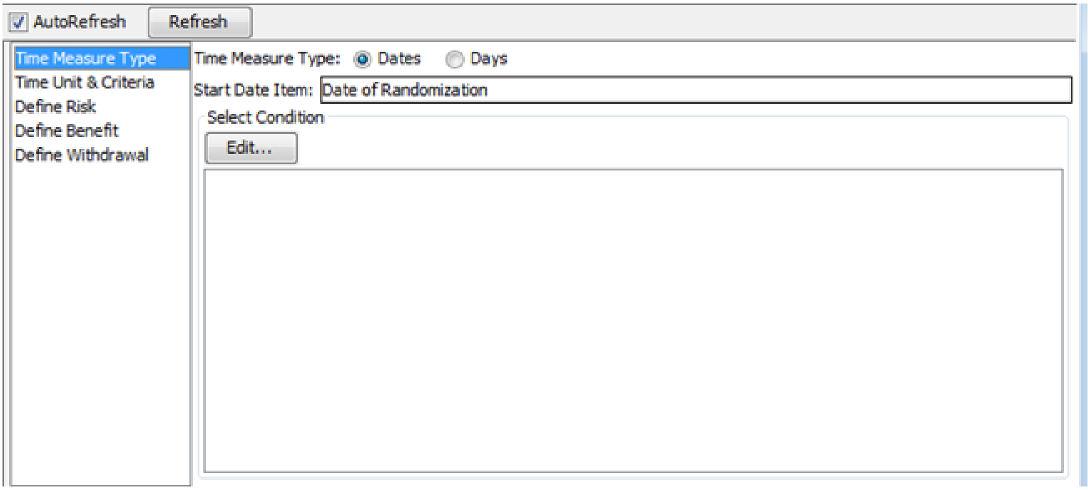
Start Date Item: Date of Randomization

| Name | Value |
|---|---|
| Heading | Benefit Risk |
| Type | Benefit Risk |

Sample Data: Do not use for analysis or review.

Select the **Time Measure Type**, by choosing the time variable based on Dates or Days (in the clinical trial).

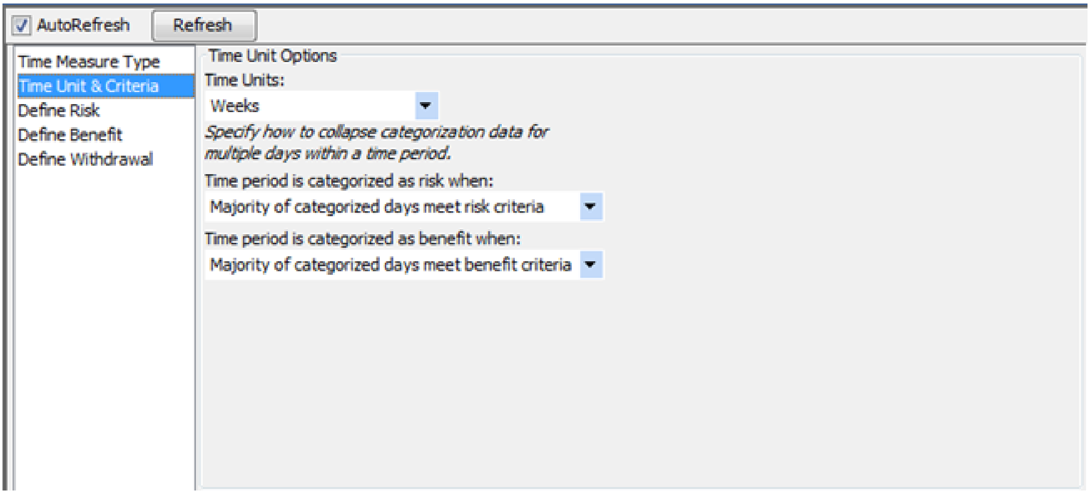
Next, you must enter a Study Start Date when the Time Measure Type is set for Dates.



Time Measure Type: ● Dates ○ Days

Start Date Item: Date of Randomization

Select Time Units under **Time Unit & Criteria** for how to display study data over longer time periods.  Select for how the Time period is categorized as risk when.



Time Units: Weeks

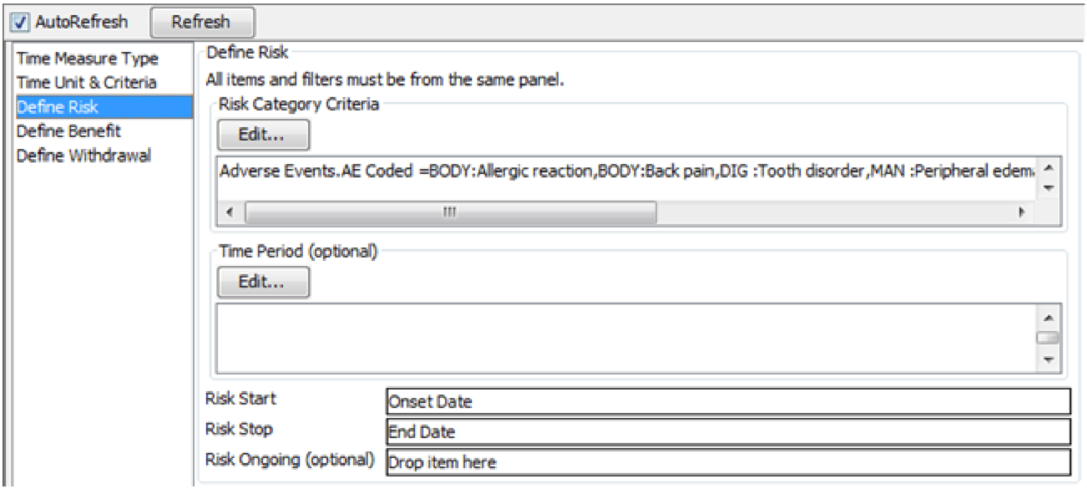
*Specify how to collapse categorization data for multiple days within a time period.*

Time period is categorized as risk when: Majority of categorized days meet risk criteria

Time period is categorized as benefit when: Majority of categorized days meet benefit criteria

Select **Define Risk** then click **Edit** to enter the Risk Category Criteria.

Next, select Risk dates (days) for **Risk Start** and where a **Risk Stop** is required, and optionally a **Risk Ongoing** variable may be chosen.



All items and filters must be from the same panel.

Adverse Events.AE Coded =BODY:Allergic reaction,BODY:Back pain,DIG :Tooth disorder,MAN :Peripheral edem

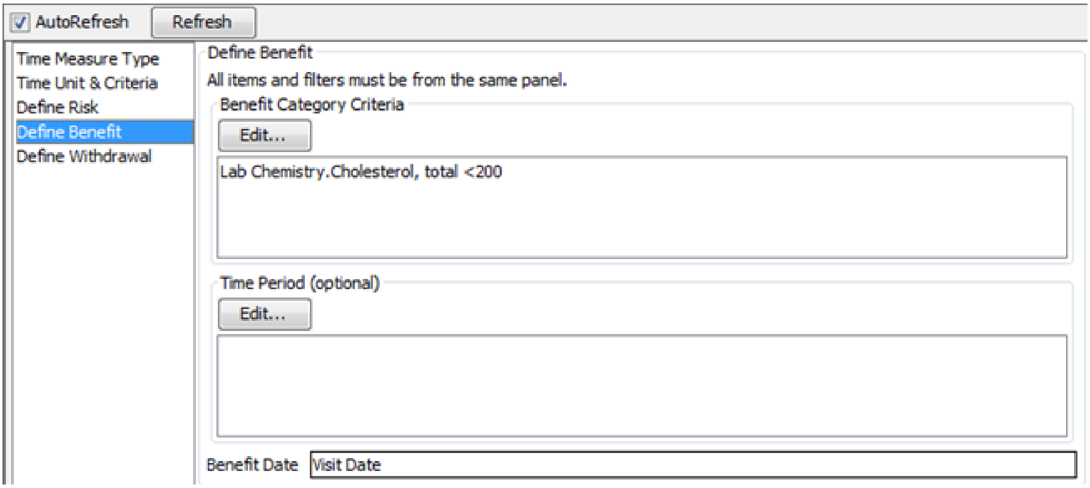
Risk Start: Onset Date

Risk Stop: End Date

Risk Ongoing (optional): Drop item here

Select **Define Benefit** then click **Edit** to enter the Benefit Category Criteria. The Define Benefit allows the filter expressions to reference multiple panels.

Enter a **Benefit Date**. The date (day) item is selected from one of the panels in the Benefits filter expressions.



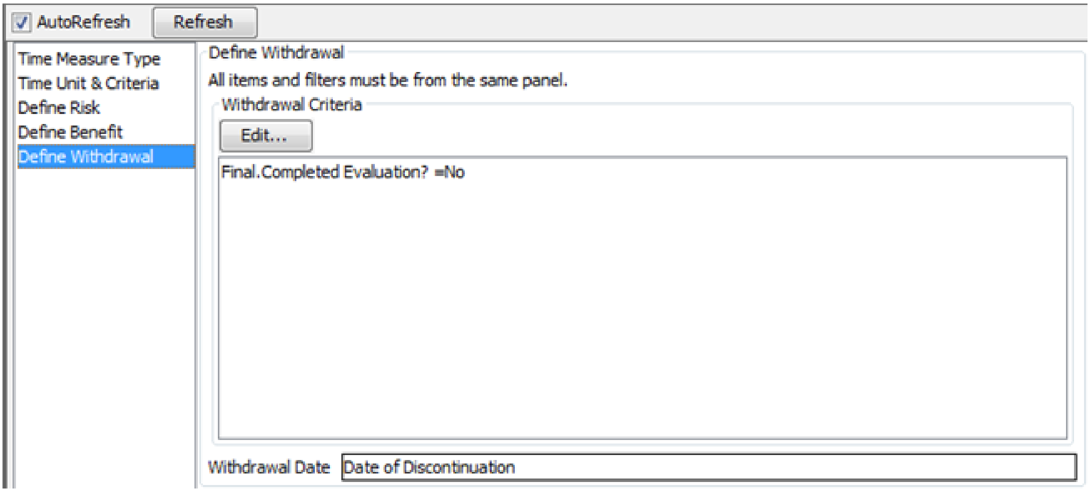
All items and filters must be from the same panel.

Lab Chemistry.Cholesterol, total <200

Benefit Date: Visit Date

Select **Define Withdrawal** then click Edit to enter the Withdrawal Criteria.

Enter a **Withdrawal Date** which will be selected from the same panel that defined the Withdrawal filter condition.

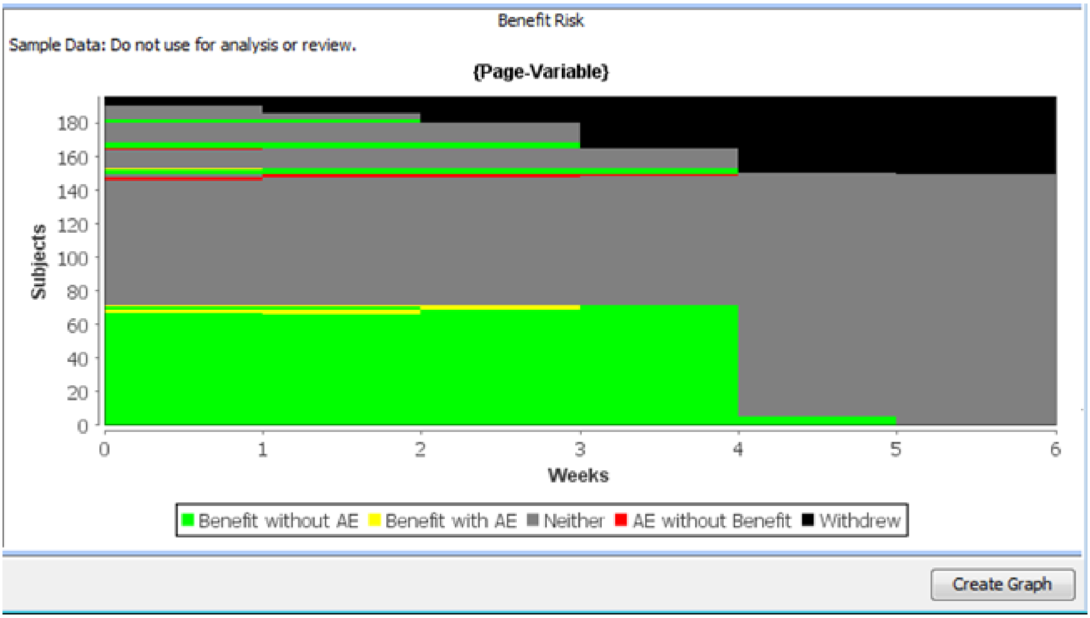


All items and filters must be from the same panel.

Final.Completed Evaluation? =No

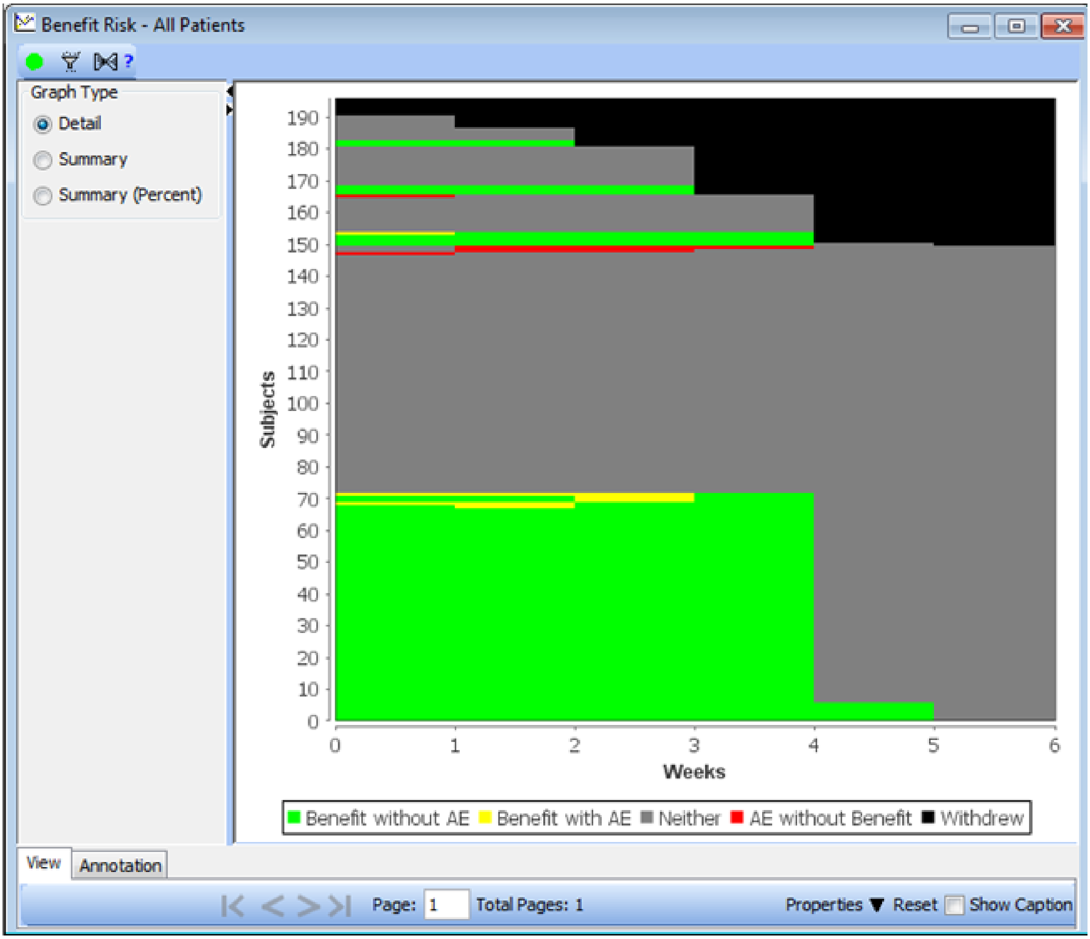
Withdrawal Date: Date of Discontinuation

See Preview **Sample Data: Do not use for analysis or review.** Click Create Graph.

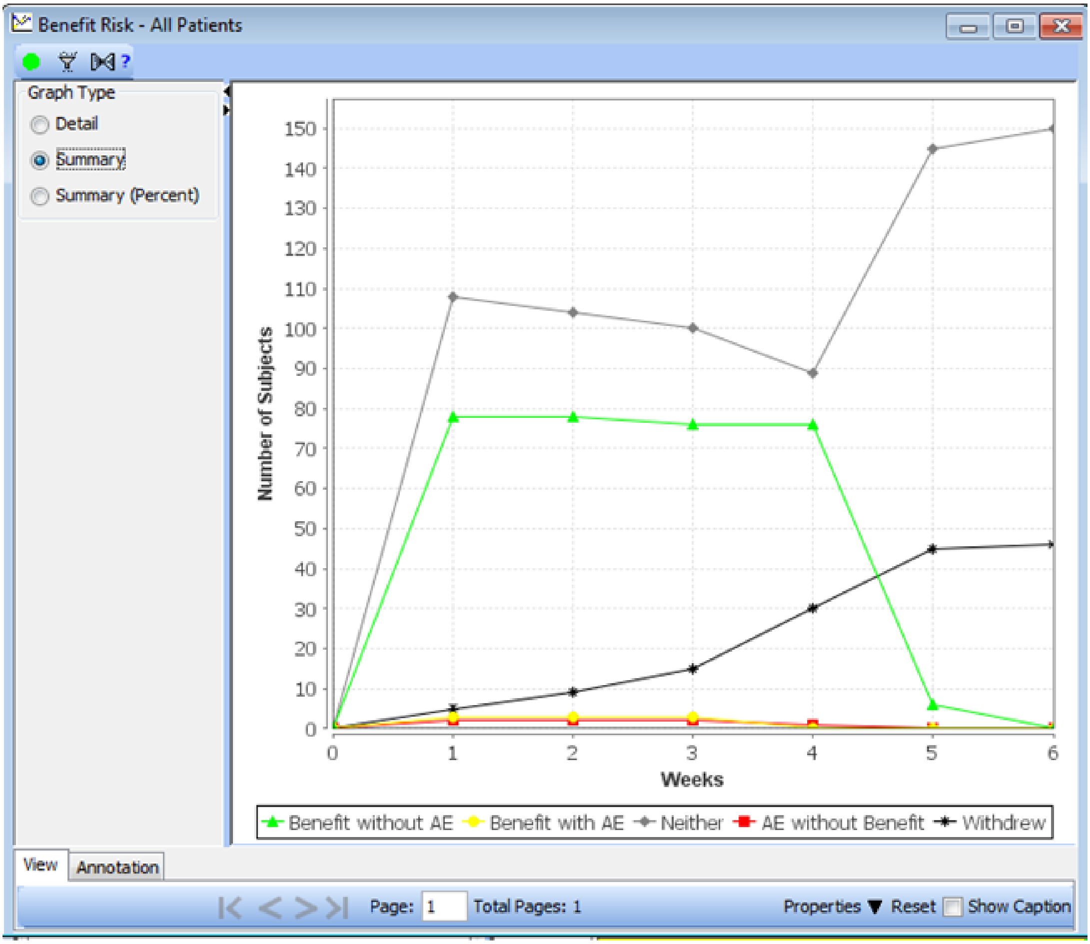


Sample Data: Do not use for analysis or review.

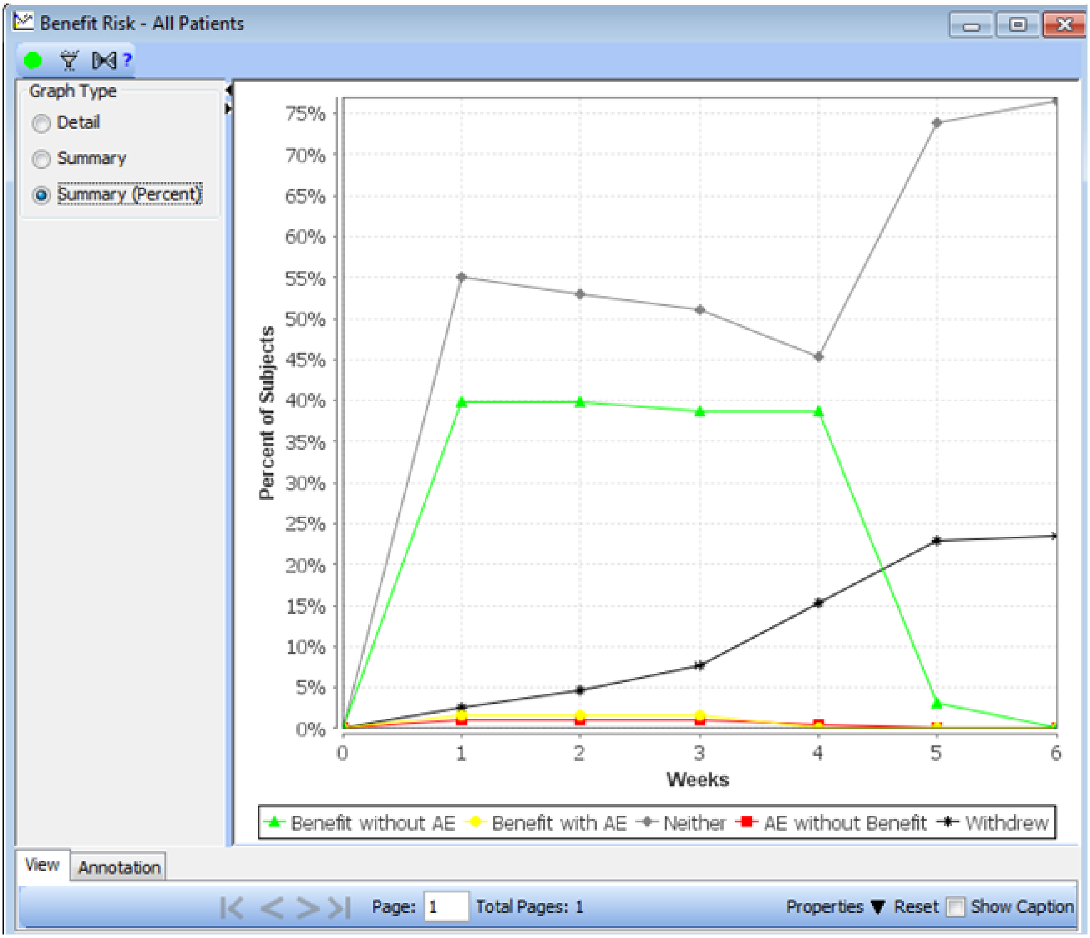
Initially the Benefit Risk result window opens in **Detail** mode.



Click on the Graph Type for **Summary option** to view Summary Benefit Risk display.



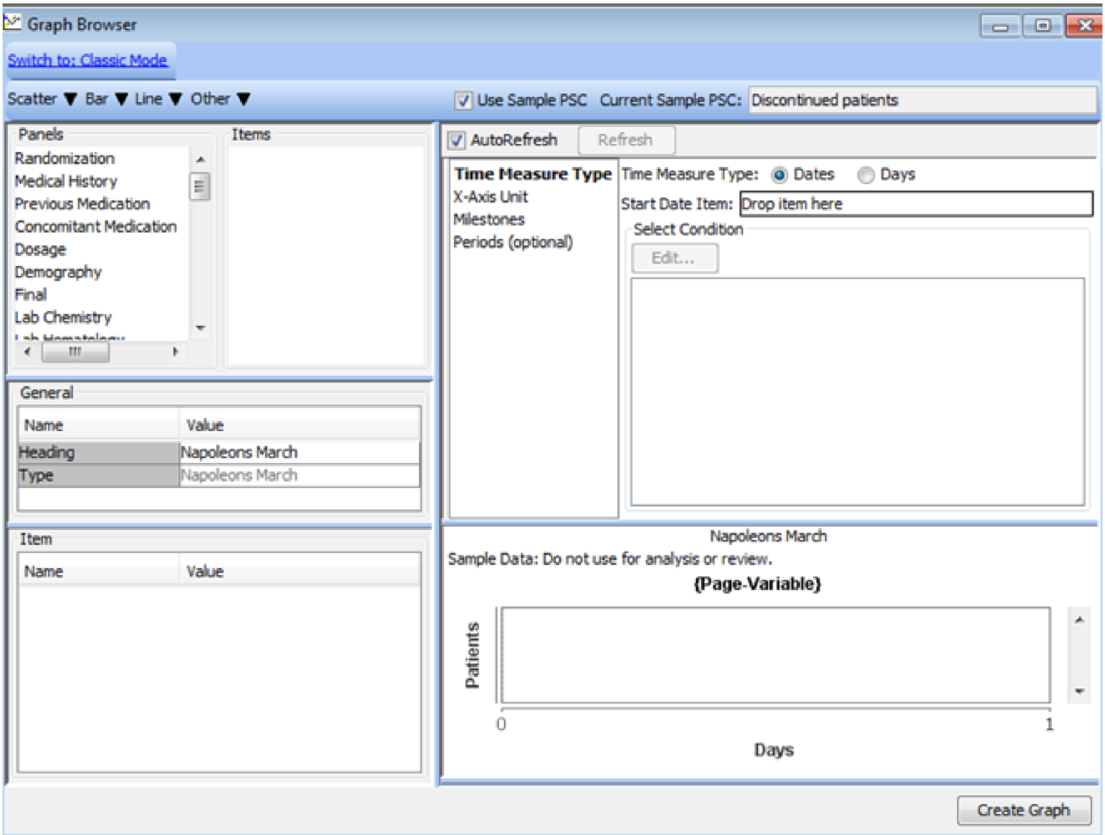
Click a third checkbox to the Benefit-Risk chart's control panel for "**Summary (Percent)**".



## *Napoleons March Plot*

The Napoleon's March Chart is now available in Graph Browser New Mode. (***See Graph Browser Classic Mode section for more information on Napoleons March Plot).***

This is the New Mode browser for Napoleons March Plot to graphically display individual patients against a time axis with user defined Milestones. The menu item for choosing this plot is in the **Other** menu.



☑ Use Sample PSC   Current Sample PSC: Discontinued patients

☑ AutoRefresh

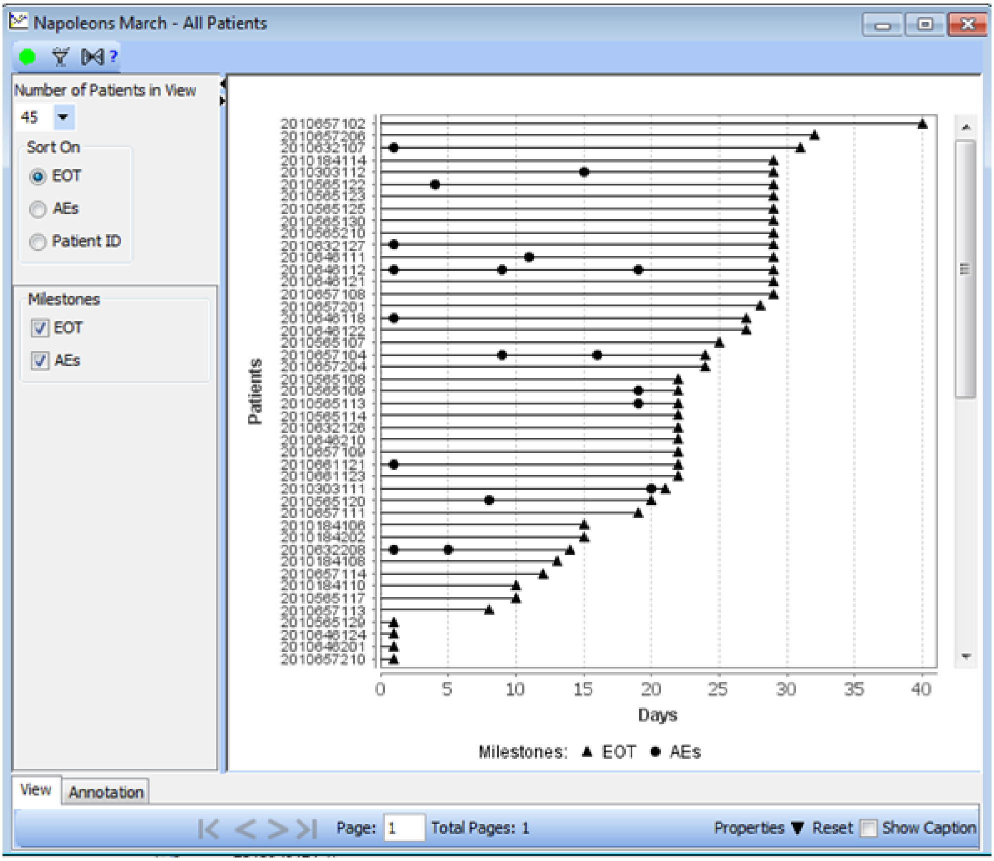
Time Measure Type: ● Dates ○ Days

Start Date Item: Drop item here

| Name | Value |
|---|---|
| Heading | Napoleons March |
| Type | Napoleons March |

There are no BY-variables used with Napoleon's March charts. The paging variable can be used with the Napoleon's March chart. Unlike other graphs, when more one page is presented simultaneously, multiple pages are positioned in a single row, that is, with a horizontal layout.

The Napoleon's March Chart presents a set of patient identifiers on the vertical axis and time (e.g., days, weeks, months) on the horizontal axis. Graphically, for each patient, a horizontal line is drawn from the lower limit of the horizontal axis (e.g., study start time) to the "termination" milestone. If a termination milestone is specified, JReview will automatically use the first occurrence of that milestone event. This example shows two user defined milestones for all adverse event occurrences and End of Treatment for termination milestone.



Napoleons March - All Patients

Number of Patients in View: 45

Sort On: ● EOT ○ AEs ○ Patient ID

Milestones: ☑ EOT ☑ AEs

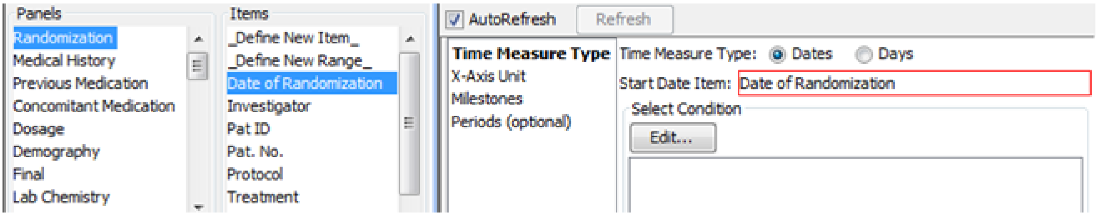
Page: 1 Total Pages: 1

☐ Show Caption

When there is more than one milestone specified, a control panel supports check boxes to toggle a milestone display.

The total number of patients in the graph may require more vertical space than can be accommodated in one "view." By default, 45 patients are shown in the graph at any one time. The user can change the number of viewable patients and scroll through the sample of patients. Also, resize the graph window and increase the chart's height, the user can increase the number of simultaneously viewed patients. So, the degree of "cramping" in the display can be controlled by the user.

Start by selecting the **Time Measure Type** for Dates or Days and entering the **Start Date Item**.

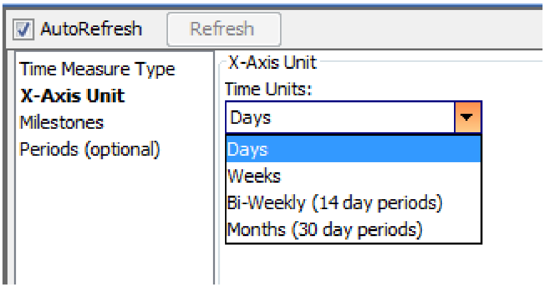


☑ AutoRefresh

Time Measure Type: ● Dates ○ Days

Start Date Item: Date of Randomization

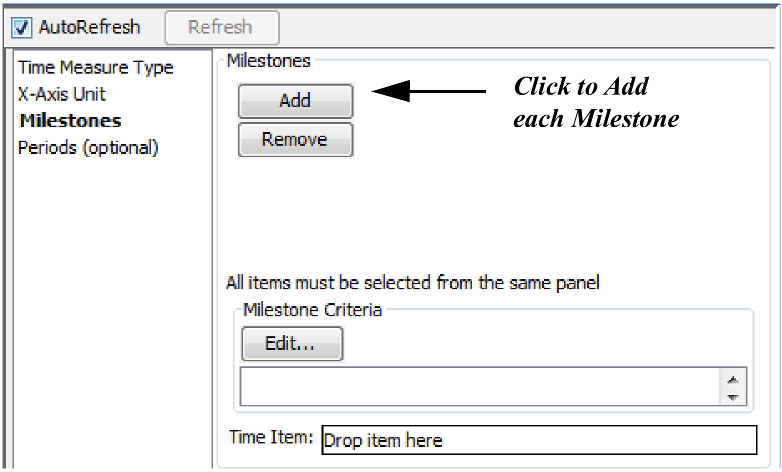
The time axis typically represents “Days in the Study.”



☑ AutoRefresh

Time Units: Days

“**Milestones**” are plotted for each patient - the user may define up to three different milestones. Example milestones are the onset of Adverse Events and End-Of-Treatment.

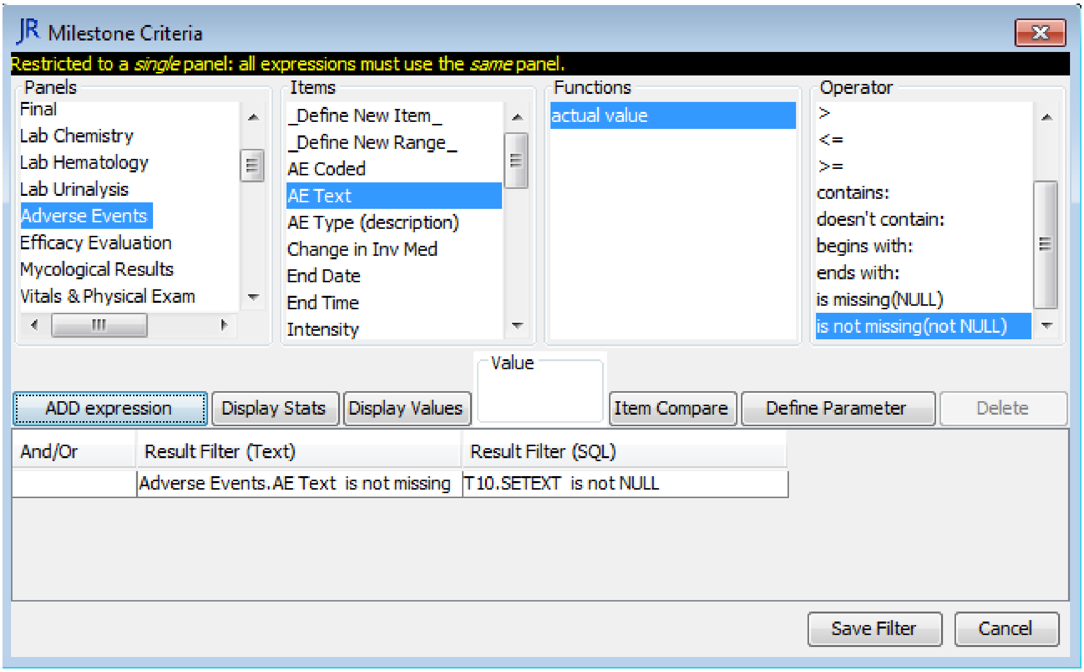


***Click to Add each Milestone***

All items must be selected from the same panel

Time Item: Drop item here

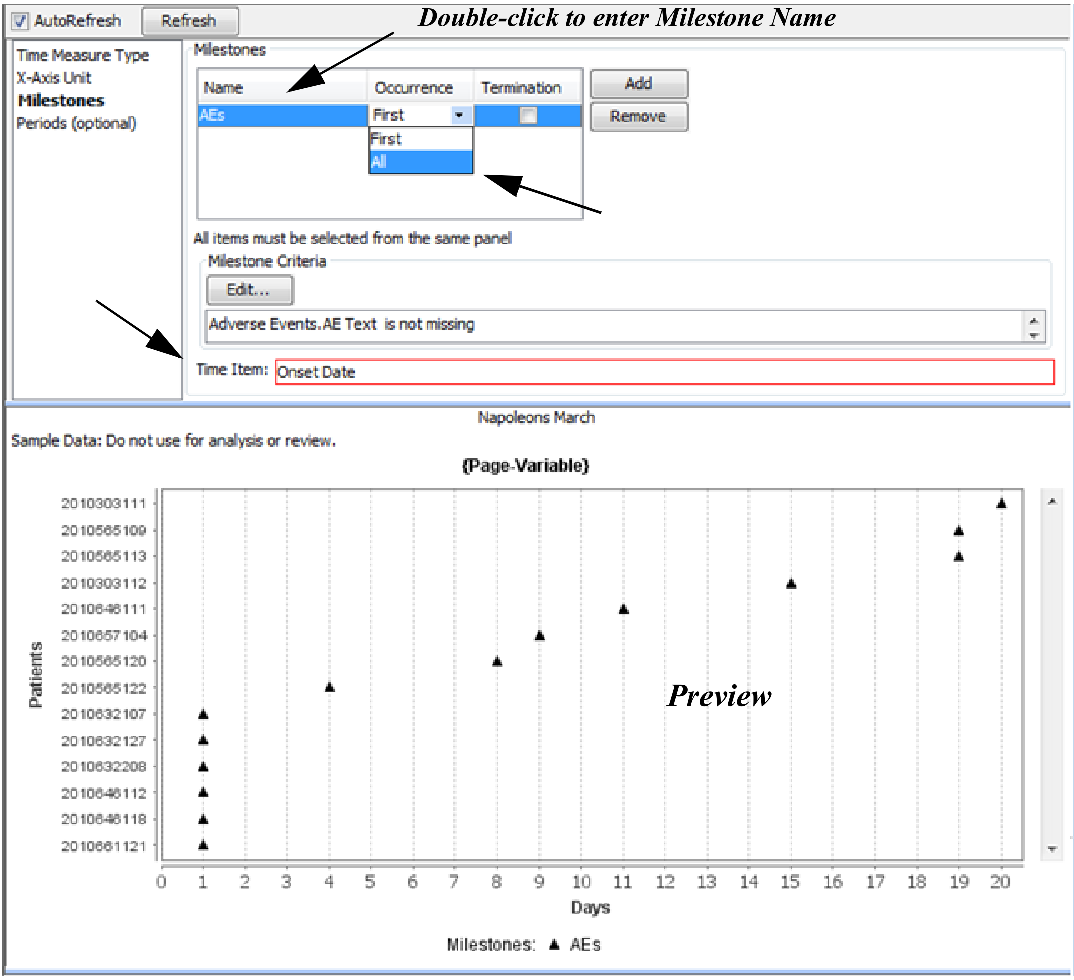
Each milestone is specified using a control similar to JReview's filter mechanism; a variable defining the time (e.g., day, date) at which a milestone occurred must also be specified.



Restricted to a *single* panel: all expressions must use the *same* panel.

| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | Adverse Events.AE Text is not missing | T10.SETEXT is not NULL |

Double-click within the Name to enter a milestone description. Add the **Time Item** from the same panel as the defined milestone. ***Both a "filter" and a time variable must be defined.***



***Double-click to enter Milestone Name***

| Name | Occurrence | Termination |
|---|---|---|
| AEs | First | ☐ |

All items must be selected from the same panel

Adverse Events.AE Text is not missing

Time Item: Onset Date

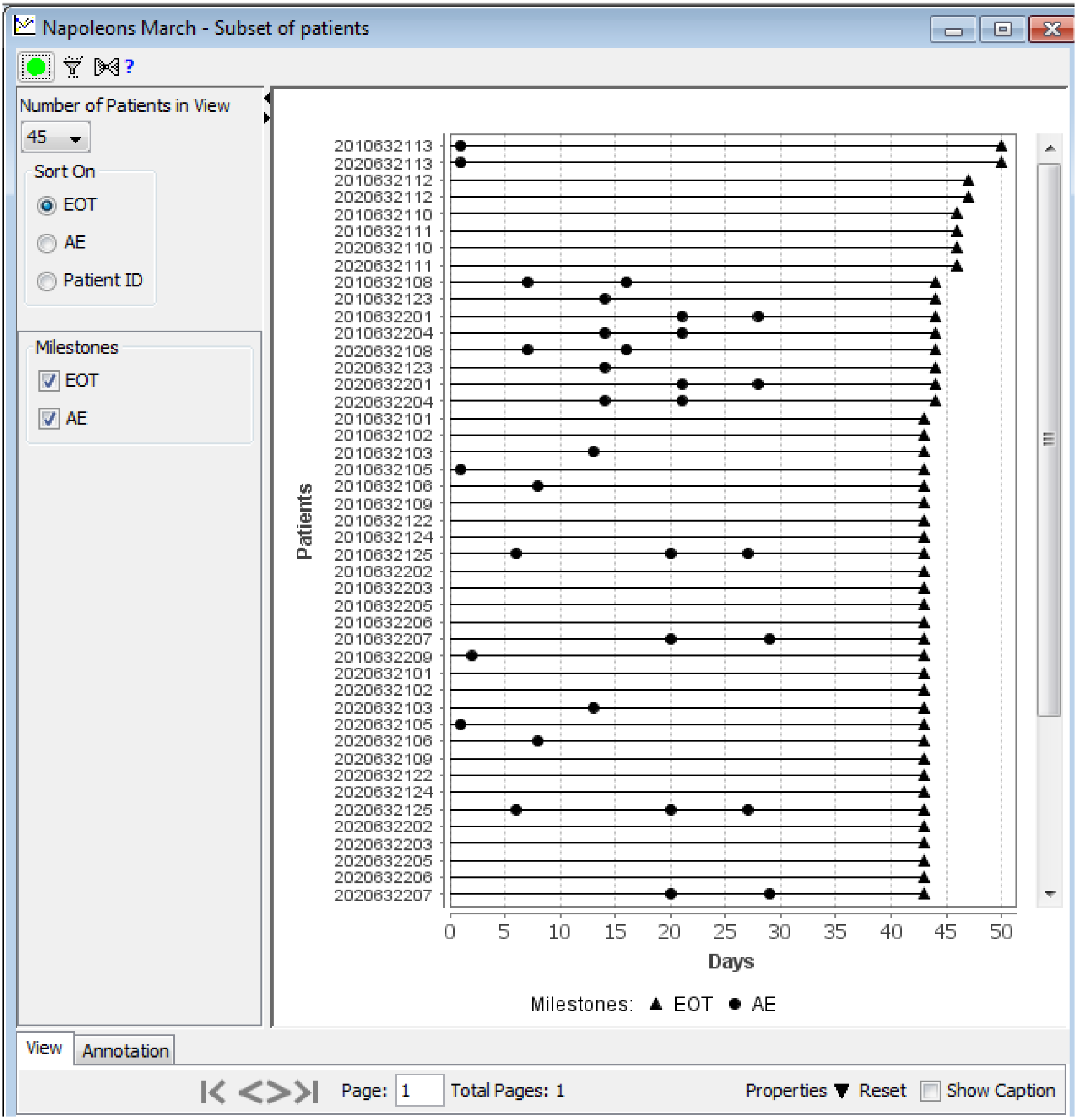
Napoleons March

Sample Data: Do not use for analysis or review.

{Page-Variable}

***Preview***

The user can specify whether just the ***First*** occurrence of the milestone should be shown or whether or ***All*** occurrences should be shown. Optionally, a special "termination" milestone can be specified; this milestone type indicates some terminating event such as End-Of-Treatment or Death. Graphically, for each patient, a horizontal line is drawn from the lower limit of the horizontal axis (e.g., study start time) to the "termination" milestone. If a termination milestone is specified,  JReview will automatically use the first occurrence of that milestone event.



Napoleons March - Subset of patients

Number of Patients in View: 45

Sort On
● EOT
○ AE
○ Patient ID

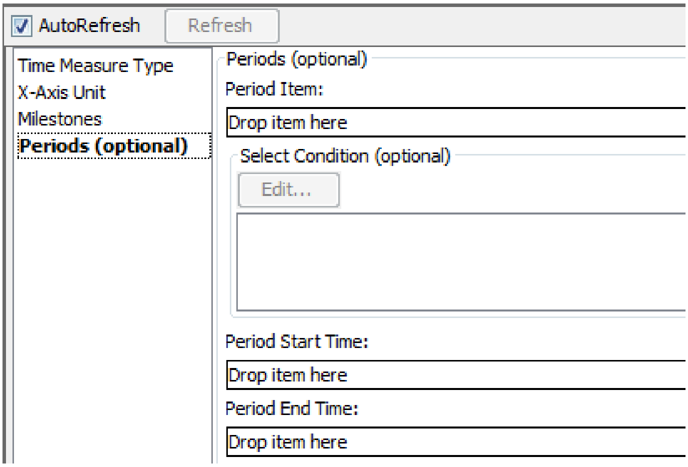
Milestones
☑ EOT
☑ AE

Page: 1 Total Pages: 1

Properties ▼ Reset ☐ Show Caption

If no termination Milestone data exists for a patient, it is not drawn and the horizontal line is not drawn for that patient. So, if the milestone was “completed treatment” and the patient never completed, that milestone would not appear for that patient. If there’s no data associated with a patient, that patient does not appear in the graph.

Optional **Period** controls are used to specify the “periods” as the time that a patient is in a study divided into time *periods*. Each time period is associated with a different condition for each patient. For example, a patient might be assigned to different treatment conditions (e.g., drug dose levels) during different time periods in the course of a study. Perhaps, an individual drug dosage is temporally reduced for some time interval. Another scenario might be that a study has different phases or a sequence of phases through which patients move; the amount of time spend in each phase may vary across patients.



The “periods” feature is optional. To define “periods”, items are chosen for the “Periods” variable and for the start time and end time. The “time” items must be consistent with the choice in the “Dates vs. Days” control, and all of these three items should be chosen from the same panel. So, to specify this feature, the user defines the filter and two time variables (e.g., days, date): start time and end time.

To represent these "periods", the Napoleon's March chart draws color coded horizontal line segments for each patient to indicate the assigned condition of a patient during a period of time.

Periods (optional)

Period Item: Dose

Select Condition (optional)

Dosage.Dose is not missing

Period Start Time: Start Date

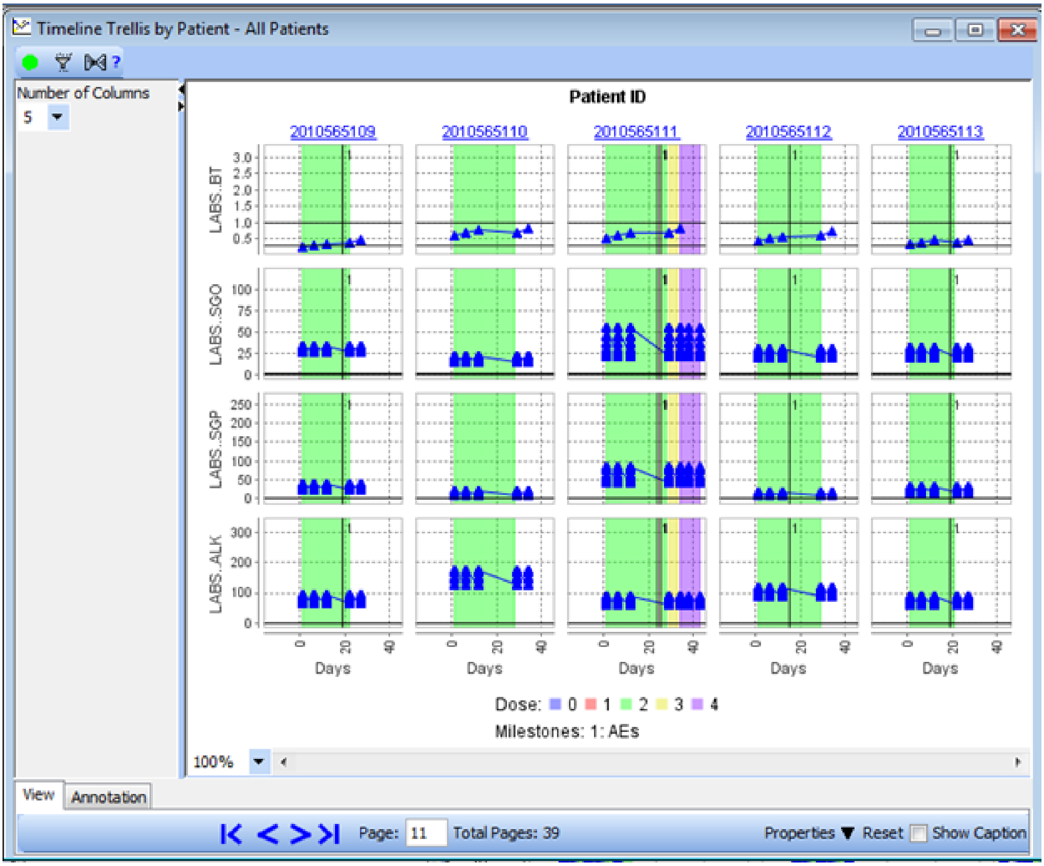
Period End Time: Stop Date

## Time Trellis Plot by Individual Patients

JReview’s ***Timeline Trellis by Individual Patients*** graph is composed of a matrix of individual subplots with the following general characteristics:

- Each column represents a patient.
- The X-axis, shown at the bottom of each column, represents a time variable such as “Days in Study”.
- Each row has a Y-axis shown on the left side. These Y-Axes typically represent different laboratory tests or other patient measures such as “blood pressure”.
- Each subplot is a ***line chart*** that plots Y-axis values over time.

The user can reset the number of columns to be displayed in each plot, i.e., the number of columns that appear on each page. Changing the number of displayed columns alters the total number of pages. If the user has drawn annotations on the graphs, these will be deleted when the number of columns is changed; a Warning dialog is presented before proceeding with this operation.



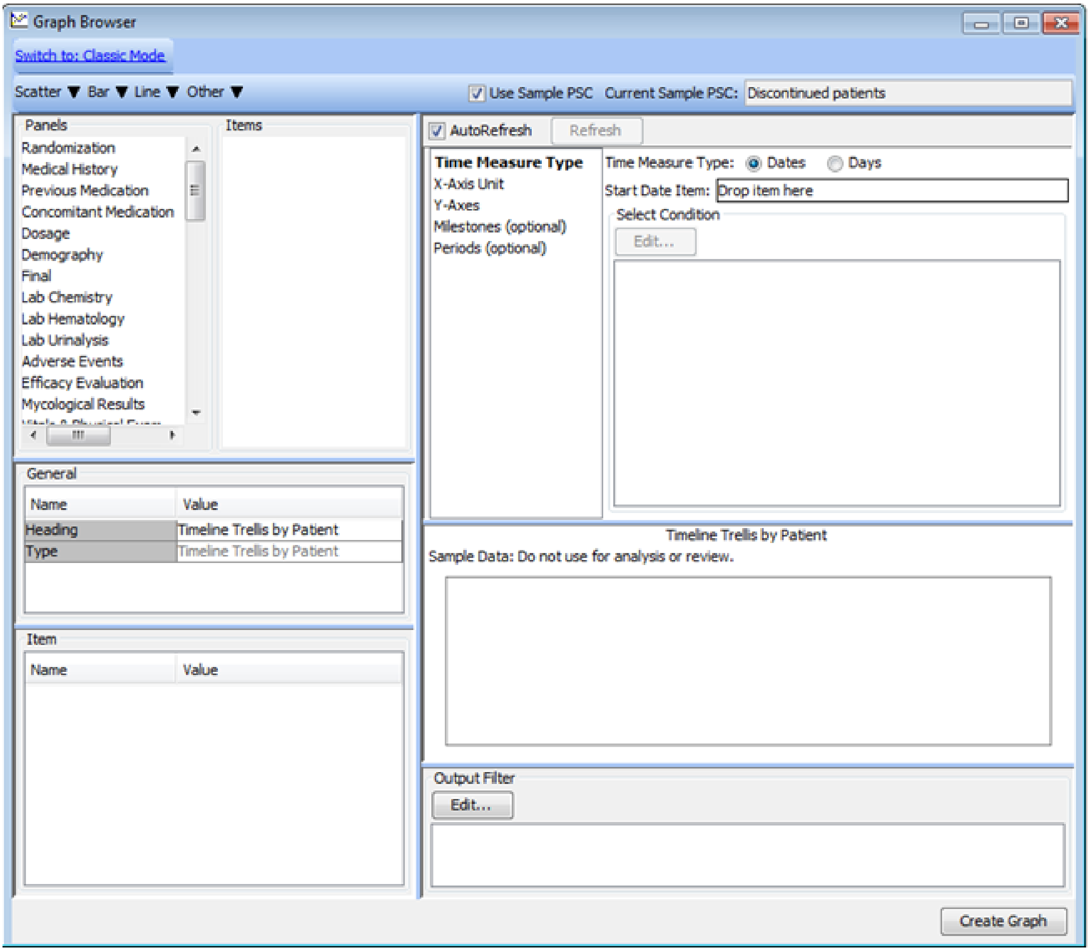
Timeline Trellis by Patient - All Patients

Number of Columns: 5

Page: 11 Total Pages: 39

As there are usually more columns than can be shown at once, the charts are drawn on a sequence of pages, with each page having multiple columns. The column titles are the patient identifiers, so clicking on a title results in a "drill-down".

Here is the New Mode Graph Browser for Timeline Trellis by patient. The menu item for choosing this plot is in the **Other** menu.



☑ Use Sample PSC Current Sample PSC: Discontinued patients

☑ AutoRefresh

Time Measure Type: ● Dates ○ Days

Start Date Item: Drop item here

General

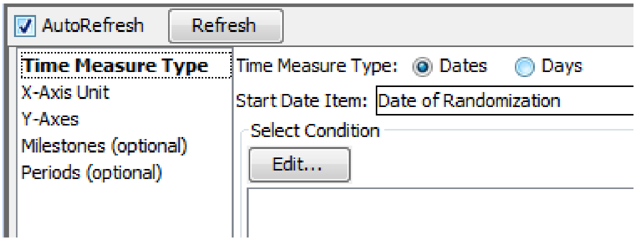
| Name | Value |
|---|---|
| Heading | Timeline Trellis by Patient |
| Type | Timeline Trellis by Patient |

Timeline Trellis by Patient

Sample Data: Do not use for analysis or review.

The X-axis is time-based with controls generally the same or very similar to those in Napoleon's March and some other existing JRevew graphs.

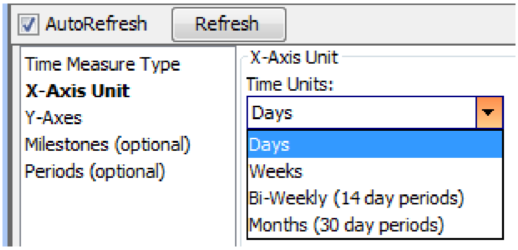
The user may specify whether “dates” or “days” are to be used in determining time values. If “dates” is selected as the time mode, then a start date must be specified, and all variables in the overall specification must have the accompanying “time” specification made in terms of dates. Some datasets have time values that are pre-calculated as days. If “days” is selected, then the start date is not defined and all time variables must be “days”.



Time Measure Type: ● Dates ○ Days

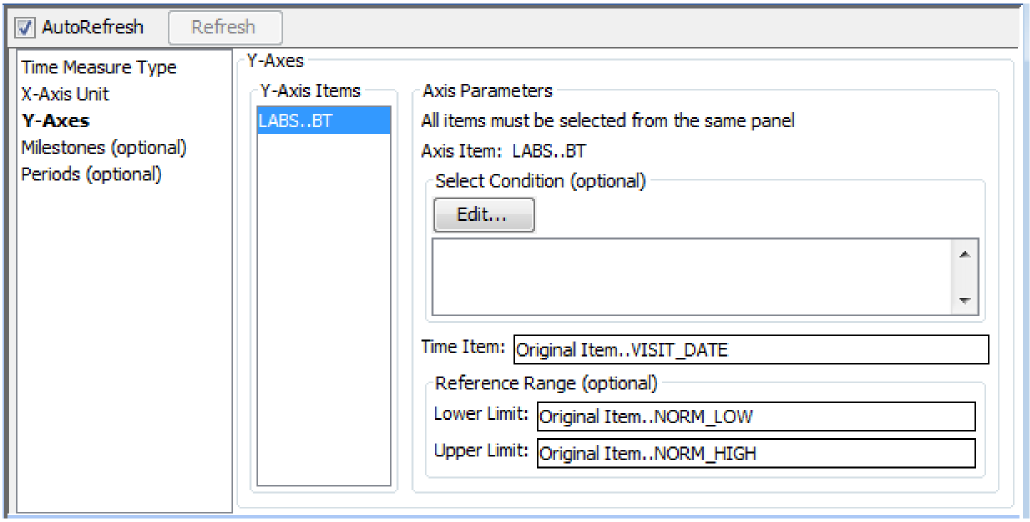
Start Date Item: Date of Randomization

The user may specify the X-axis’s time units to display the X-axis values calculated as Days, Weeks, Bi-Weekly, or Months.



Time Units: Days

Next, the New Mode Graph Browser supports the complex control to specify the Y-Axes where at least one Y-axis must be specified.  Not more than eight Y-Axes can be specified. The individual Y-axis variables can be added from transformed vertical tables (HRZ).



☑ AutoRefresh   Refresh

Time Measure Type
X-Axis Unit
**Y-Axes**
Milestones (optional)
Periods (optional)

Y-Axes

Y-Axis Items: LABS..BT

Axis Parameters

All items must be selected from the same panel

Axis Item:  LABS..BT

Select Condition (optional)

Edit...

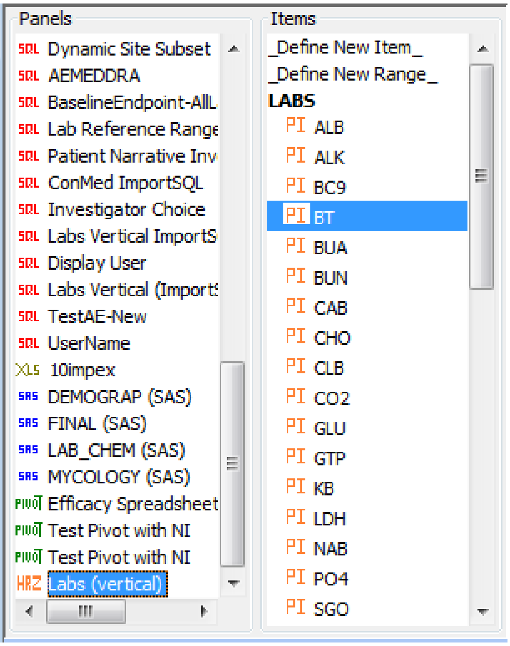
Time Item: Original Item..VISIT_DATE

Reference Range (optional)

Lower Limit: Original Item..NORM_LOW

Upper Limit: Original Item..NORM_HIGH

Vertical tables can be transformed to horizontal format “**HRZ**” that include the reference ranges. ***(See Chapter 12 - Advanced Topics: Vertical to Horizontal Panel)***



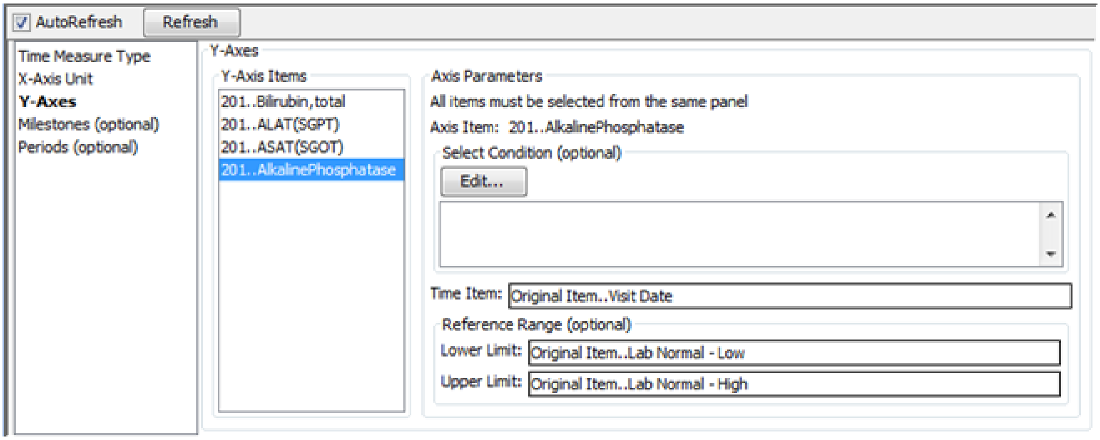
Panels

SQL Dynamic Site Subset
SQL AEMEDDRA
SQL BaselineEndpoint-AllL
SQL Lab Reference Range
SQL Patient Narrative Inv
SQL ConMed ImportSQL
SQL Investigator Choice
SQL Labs Vertical ImportS
SQL Display User
SQL Labs Vertical (Import
SQL TestAE-New
SQL UserName
XLS 10impex
SAS DEMOGRAP (SAS)
SAS FINAL (SAS)
SAS LAB_CHEM (SAS)
SAS MYCOLOGY (SAS)
PIVOT Efficacy Spreadsheet
PIVOT Test Pivot with NI
PIVOT Test Pivot with NI
HRZ Labs (vertical)

Items

_Define New Item_
_Define New Range_
**LABS**
PI ALB
PI ALK
PI BC9
PI BT
PI BUA
PI BUN
PI CAB
PI CHO
PI CLB
PI CO2
PI GLU
PI GTP
PI KB
PI LDH
PI NAB
PI PO4
PI SGO

Users in the New Mode Graph Browser will no longer need to select separate reference ranges for vertical laboratory data. The saved horizontal panel displays with the “**HRZ**” prefix to identify as a transformed vertical to horizontal panel. The individual laboratory tests are listed with included reference range. When the user drag and drops the selected lab item to the Y-axis Item - the Time Item, Lower and Upper Limits are automatically included.

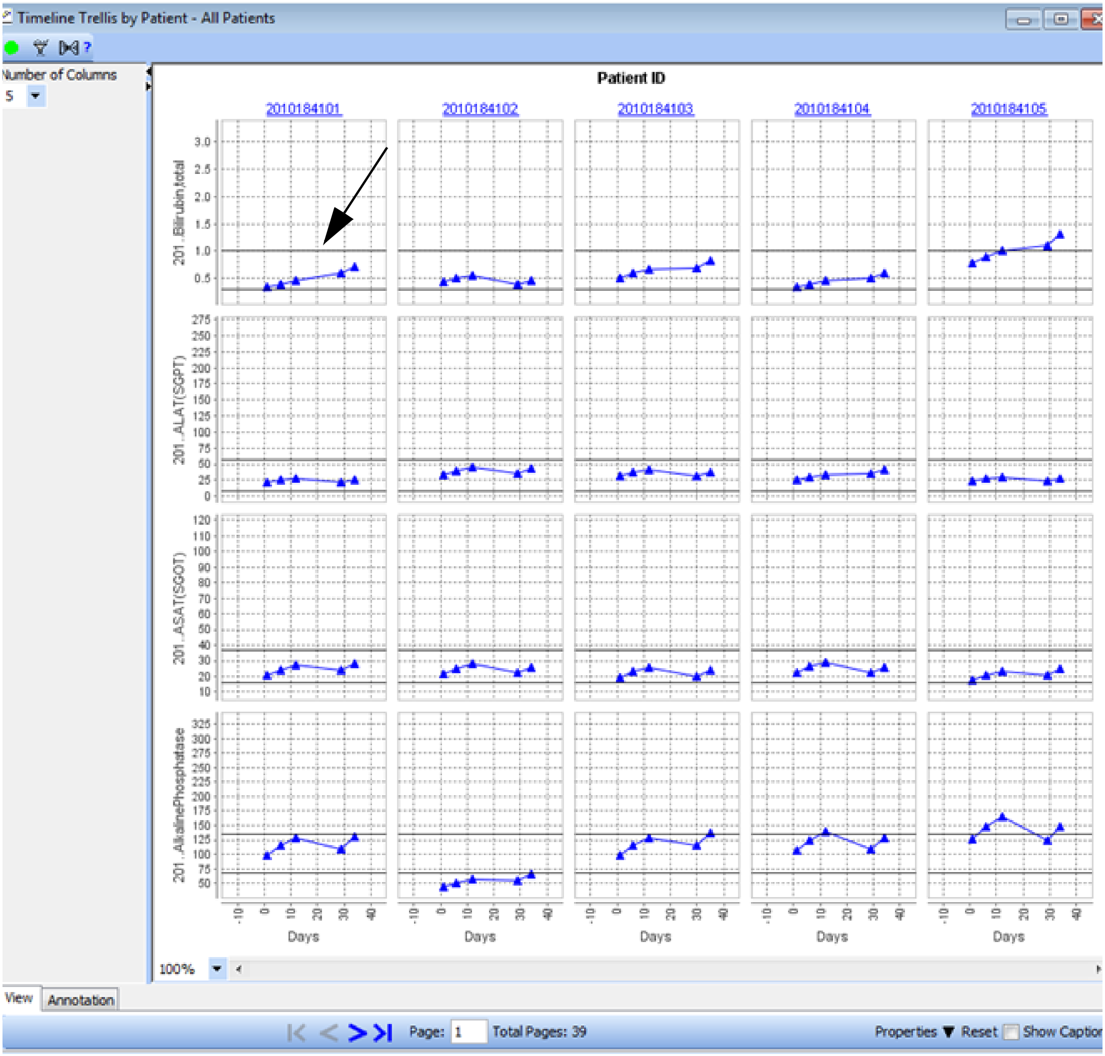


201..Bilirubin,total
201..ALAT(SGPT)
201..ASAT(SGOT)
201..AlkalinePhosphatase

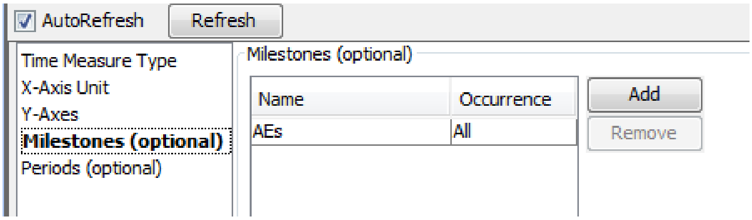
All items must be selected from the same panel
Axis Item: 201..AlkalinePhosphatase
Time Item: Original Item..Visit Date
Lower Limit: Original Item..Lab Normal - Low
Upper Limit: Original Item..Lab Normal - High

Change the order of an added Y-Axis Item by selecting the item and drag/drop to preferred location.

Observe the lines in the created graph output identify the included reference ranges.

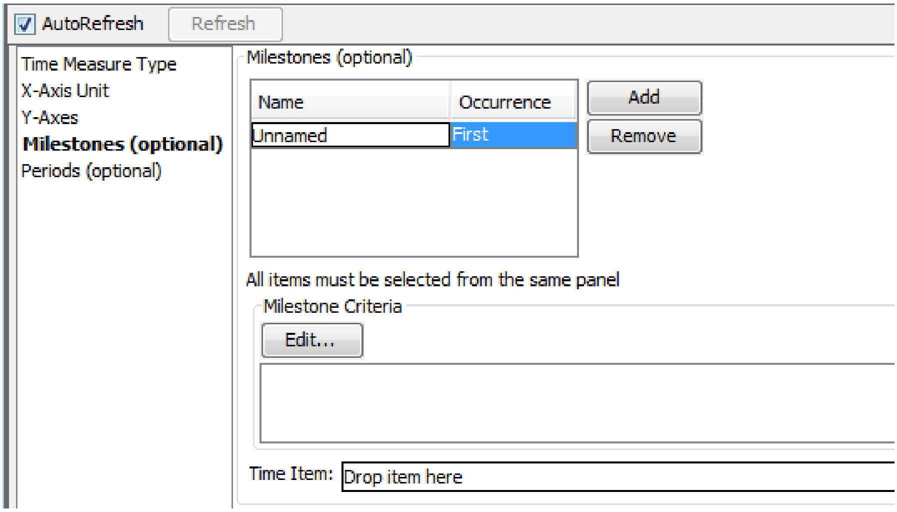


The user may optionally specify "**Milestones**," which are events such as the onset of an Adverse Event or a laboratory test measure that exceeds some extreme value. Each milestone event occurrence appears as a vertical line positioned at some position on the timeline. Each vertical line has a numeric label to identify the type of milestone, as there can be multiple milestone types. The numeric label is tied to an ordinal value in the graph's Milestone Legend.



| Name | Occurrence |
|---|---|
| AEs | All |

To create a milestone, click on the **Add** button. Clicking these buttons adds a new row to the table just beneath the buttons. The first column of the table is the name of the milestone. The entries in the first column are editable; while a "temporary" name is automatically, the user should type a meaningful into the table cell. The **Occurrence** may be further specified for First or All.

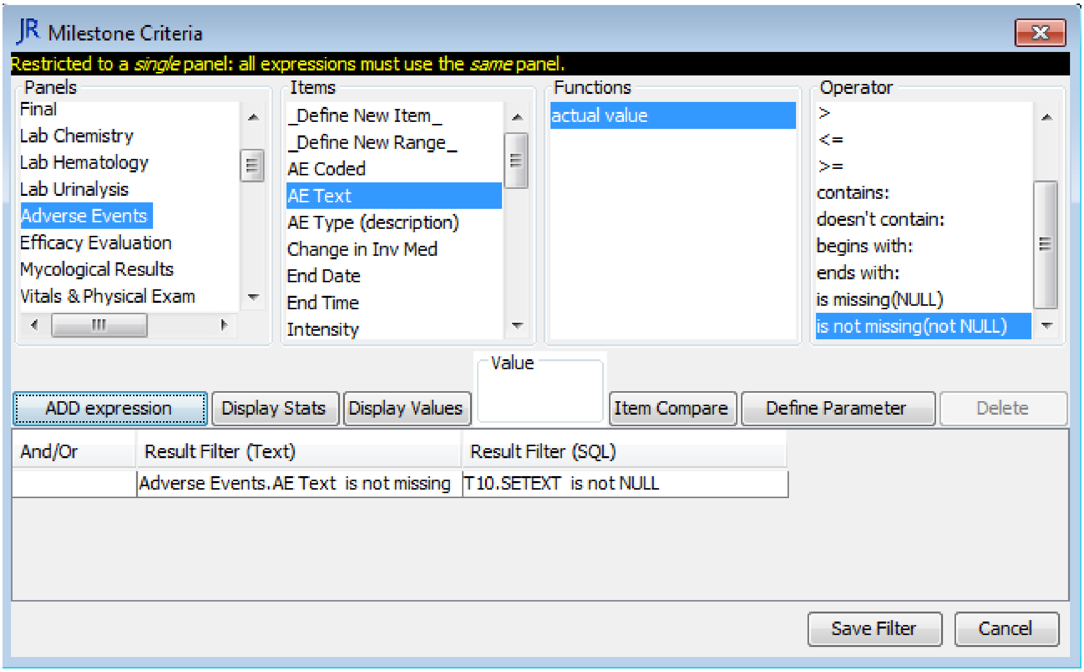


| Name | Occurrence |
|---|---|
| Unnamed | First |

All items must be selected from the same panel

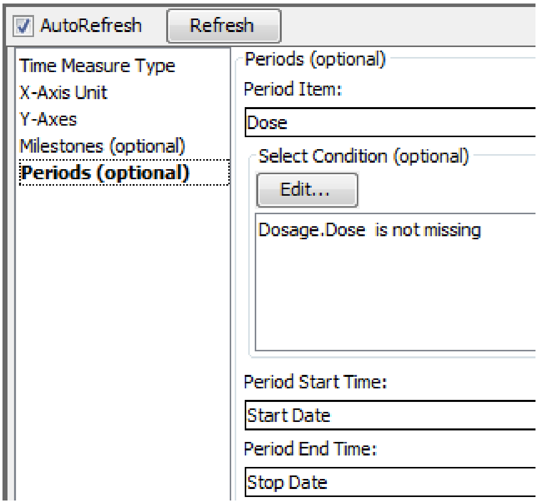
Time Item: Drop item here

Next, the user must define the milestone with **Select Condition** to enter a filter defining the Milestone. This step and entering the **Milestone Time** is ***required*** to define the milestone.



| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | Adverse Events.AE Text is not missing | T10.SETEXT is not NULL |

Optional Periods may be defined by selecting the items choosen for the "Periods" variable and for the start time and end time. The "time" items must be consistent with the choice in the "Dates vs. Days" control, and all of these three items should be chosen from the same panel. So, to specify this feature, the user defines the filter and two time variables (e.g., days, date): start time and end time.



Periods (optional)

Period Item: Dose

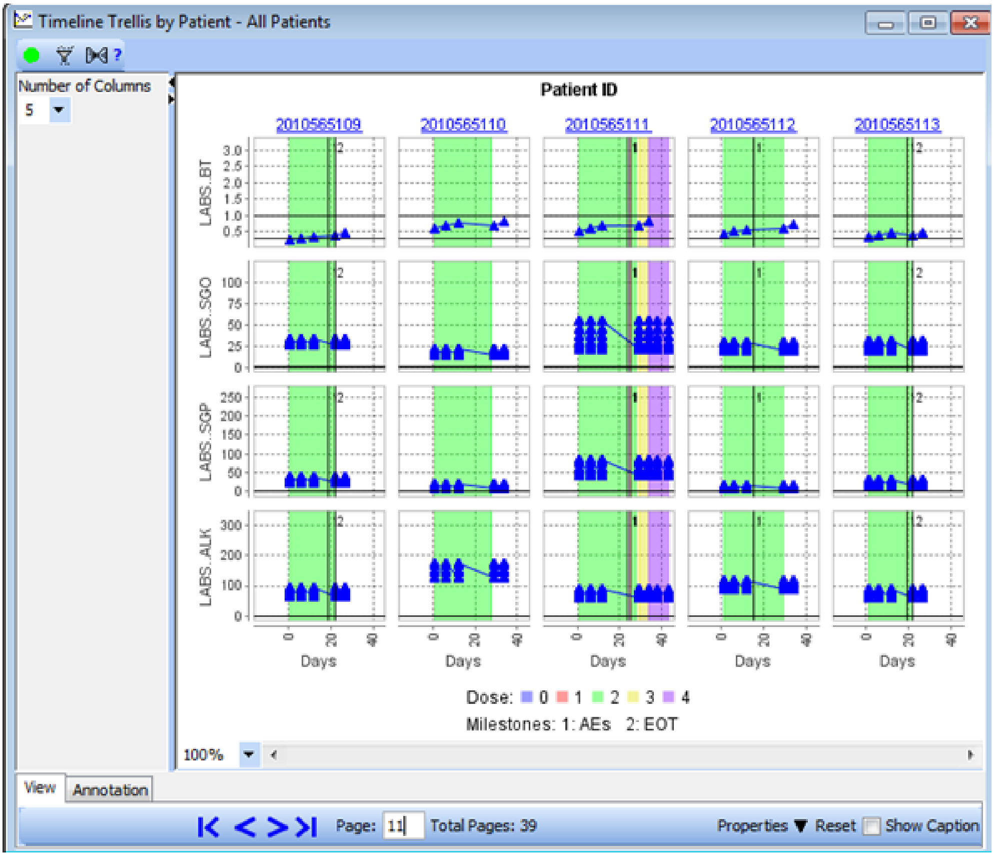
Select Condition (optional)

Dosage.Dose is not missing

Period Start Time: Start Date

Period End Time: Stop Date

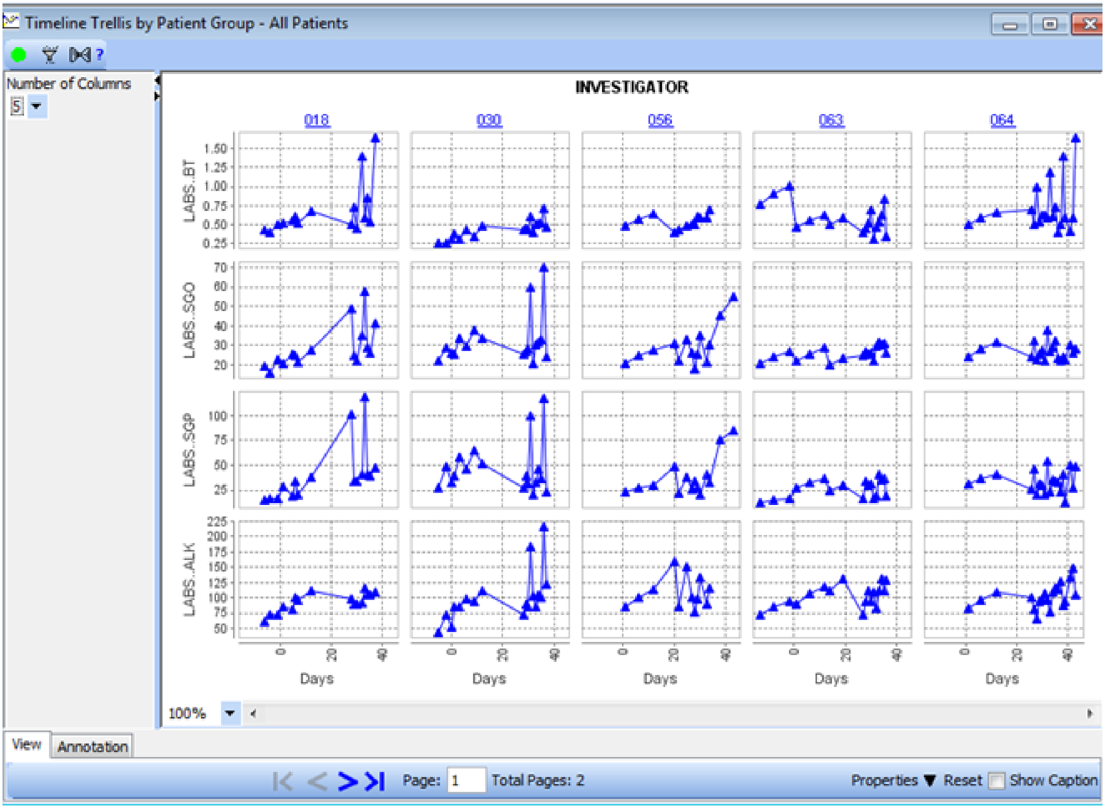
Click **Create Graph**. See the vertical line has a numeric label to identify the type of milestone, as there can be multiple milestone types. The numeric label is tied to an ordinal value in the graph's Milestone Legend. In this example, 1 represents AEs.



## Timeline Trellis Plot by Patient Group

JReview’s ***Timeline Trellis by Patient Group*** graph is composed of a matrix of Group By subplots with the following general characteristics:

- Each column represents a **Patient Grouping**.
- The X-axis, shown at the bottom of each column, represents a time variable such as “Days in Study”.
- Each row has a Y-axis shown on the left side. These Y-Axes typically represent different laboratory tests or other patient measures such as “blood pressure”.
- Each subplot is a ***line chart*** that plots Y-axis values over time.



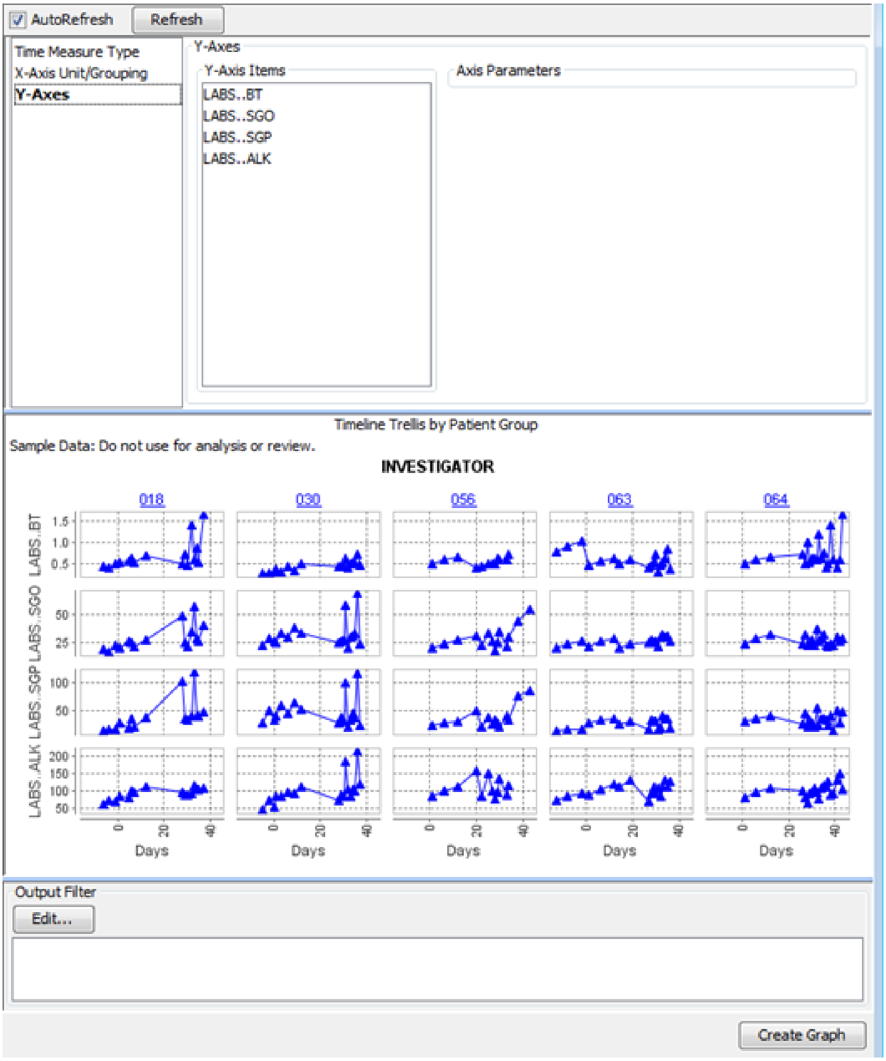
Number of Columns 5

Page: 1 Total Pages: 2

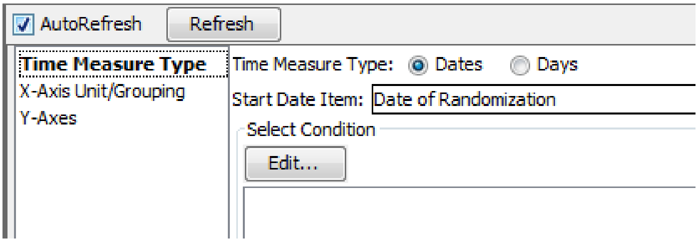
The column titles are the **Patient Grouping** identifiers, so clicking on a title results in a “drill-down” to subset those patients.

As there are usually more columns than can be shown at once, the charts are drawn on a sequence of pages, with each page having multiple columns.

Here is the New Mode Graph Browser for Timeline Trellis by Patient Group. The menu item for choosing this plot is in the **Other** menu.



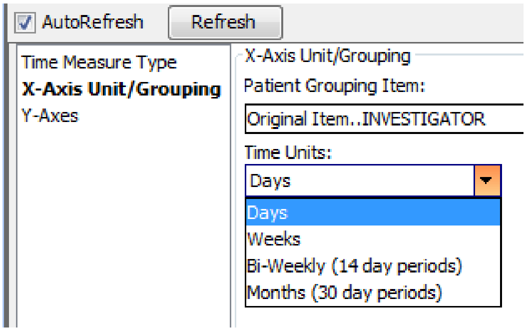
The build steps are very similar to the Timeline Trellis by Patient plot. The user may specify whether “dates” or “days” are to be used in determining time values.



Time Measure Type: ● Dates ○ Days

Start Date Item: Date of Randomization

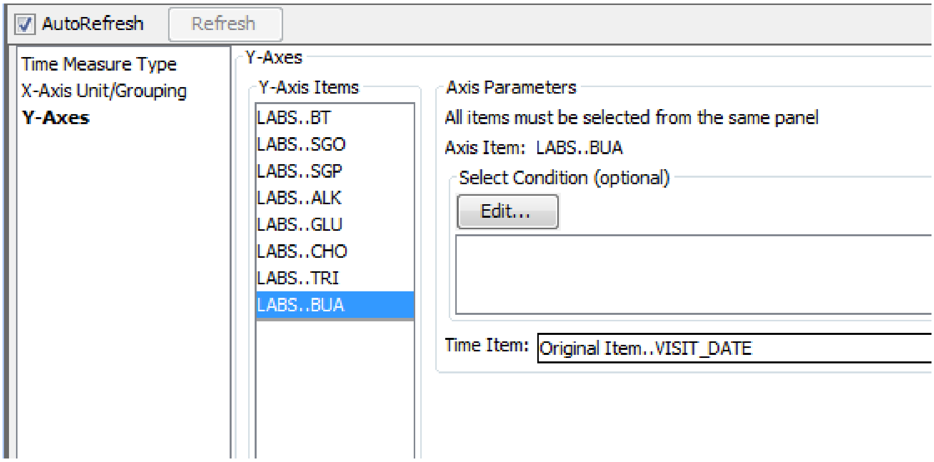
Add X-Axis Unit/Grouping for the Patient Grouping Item and the Time Units. This example uses Investigator site for patient grouping.



Patient Grouping Item: Original Item..INVESTIGATOR

Time Units: Days

Lastly, a maximum of 8 Y-Axis Items may be added. You may change the added order of Y-Axis Items by selecting an item, then drag/drop to preferred position.



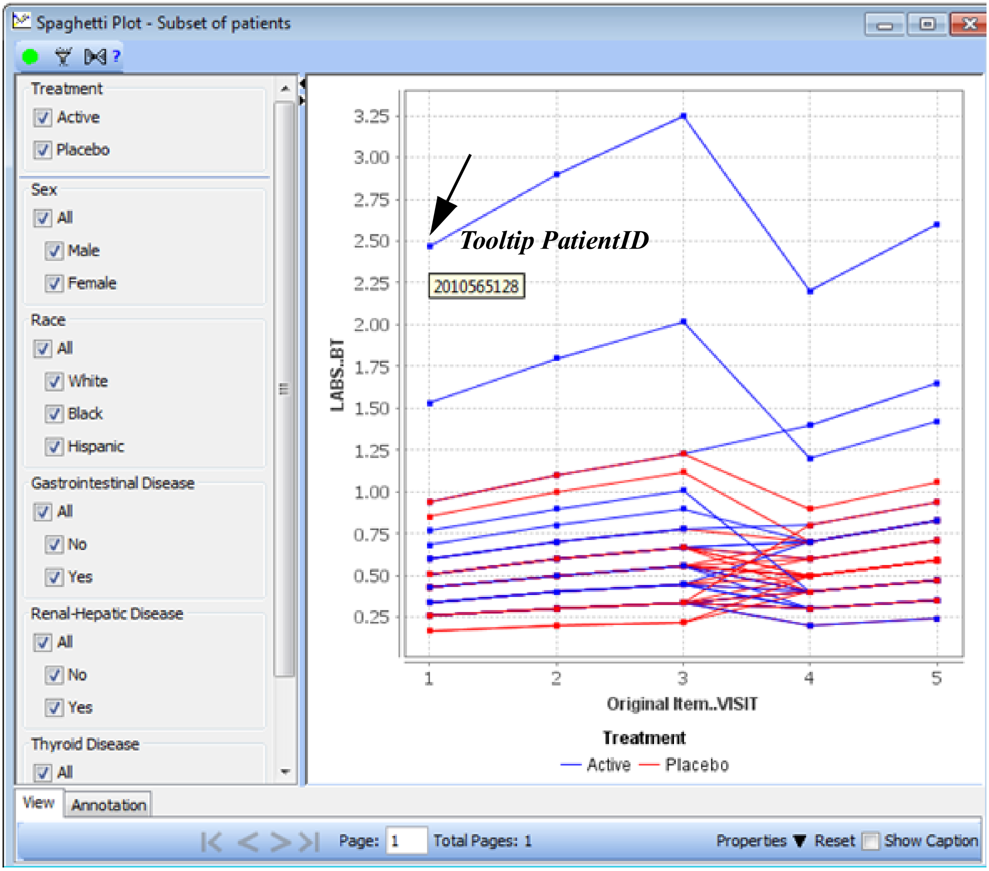
All items must be selected from the same panel

Axis Item: LABS..BUA

Time Item: Original Item..VISIT_DATE

## *Spaghetti Plot*

The Spaghetti plot is a detail line graph in which each line represents data for a patient. For example, the X-axis might represent Visit Number and the Y-Axis might represent a laboratory test result; as shown in the example below. ***The Spaghetti plot is NOT available in the "Classic mode" Graph Browser***.



Treatment
☑ Active
☑ Placebo

Sex
☑ All
☑ Male
☑ Female

Race
☑ All
☑ White
☑ Black
☑ Hispanic

Gastrointestinal Disease
☑ All
☑ No
☑ Yes

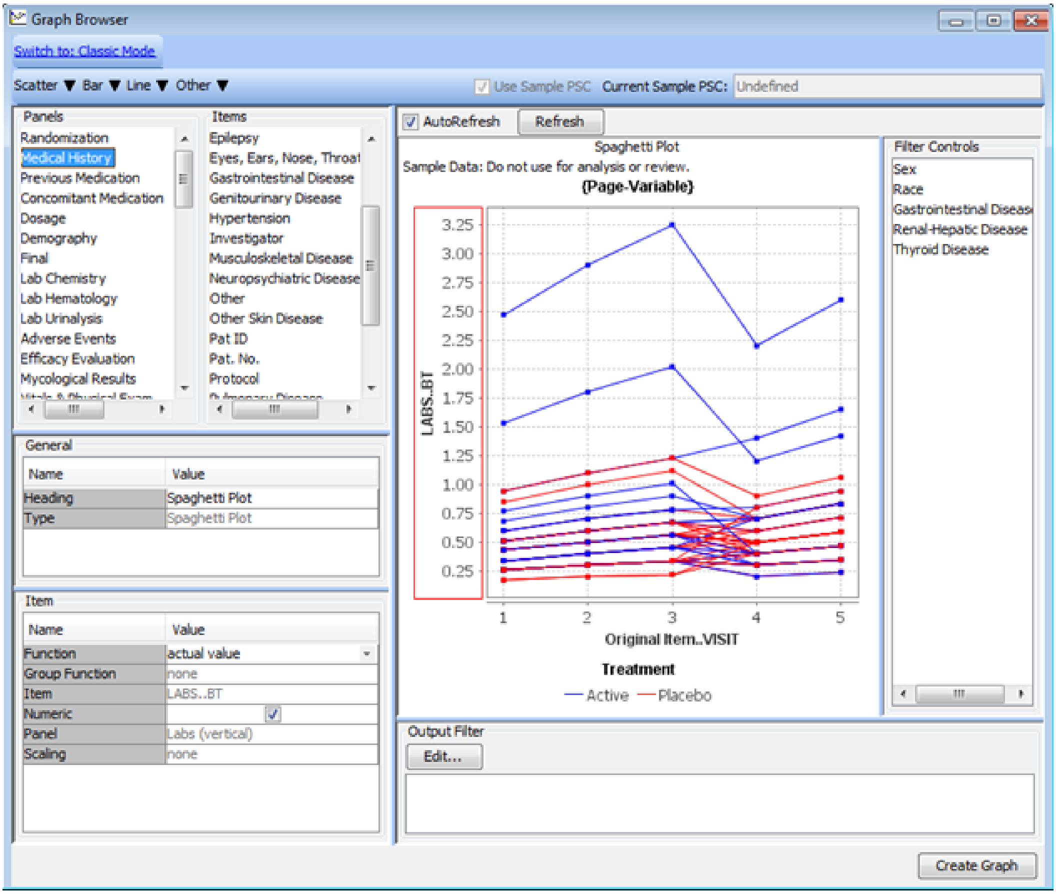
Renal-Hepatic Disease
☑ All
☑ No
☑ Yes

Thyroid Disease
☑ All

Page: 1 Total Pages: 1 ☐ Show Caption

A "By" variable (e.g., Treatment Arm) may be specified for the graph, and the color of each line will then depend on which By-variable value (e.g., Active, Placebo) the patient represented by the line is associated. A further representational feature that may differ with conventional Spaghetti plots is that a small marker is placed at the data points on the line; the line is drawn by connecting these data points. A patient is not included in the graph if there are less than two data points for that patient.

Here is the New Mode Graph Browser screen for the Spaghetti Plot. The menu item for choosing this plot is in the Line menu. Spaghetti Plots support Paging. However, the plots are limited to only one Y-Axis, and “Ranges” are not a feature of this plot type.



General

| Name | Value |
|---|---|
| Heading | Spaghetti Plot |
| Type | Spaghetti Plot |

Item

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | LABS..BT |
| Numeric | ☑ |
| Panel | Labs (vertical) |
| Scaling | none |

The Spaghetti Plot is somewhat similar in its functionality to JReview’s Scatter Plot. Hovering the mouse cursor over a line displays a tooltip containing a patient identifier. Each line is selectable, and when a line is selected, the patient id is broadcast to other viewers interested in patient selection such as the Data Browser. When the user selects patients in other viewers, these patients will be selected in the Spaghetti plot. “Grab Handles”, i.e., rectangles, are drawn at the data points of a selected line, which is a conventional way to show line selection in interactive graphics.

Filter Controls may be optionally specified for a Spaghetti Plot. This allows the user to hide various patient subsets in the plot. In other words, these controls show or hide lines in the graphs.

## *Spider Plot*

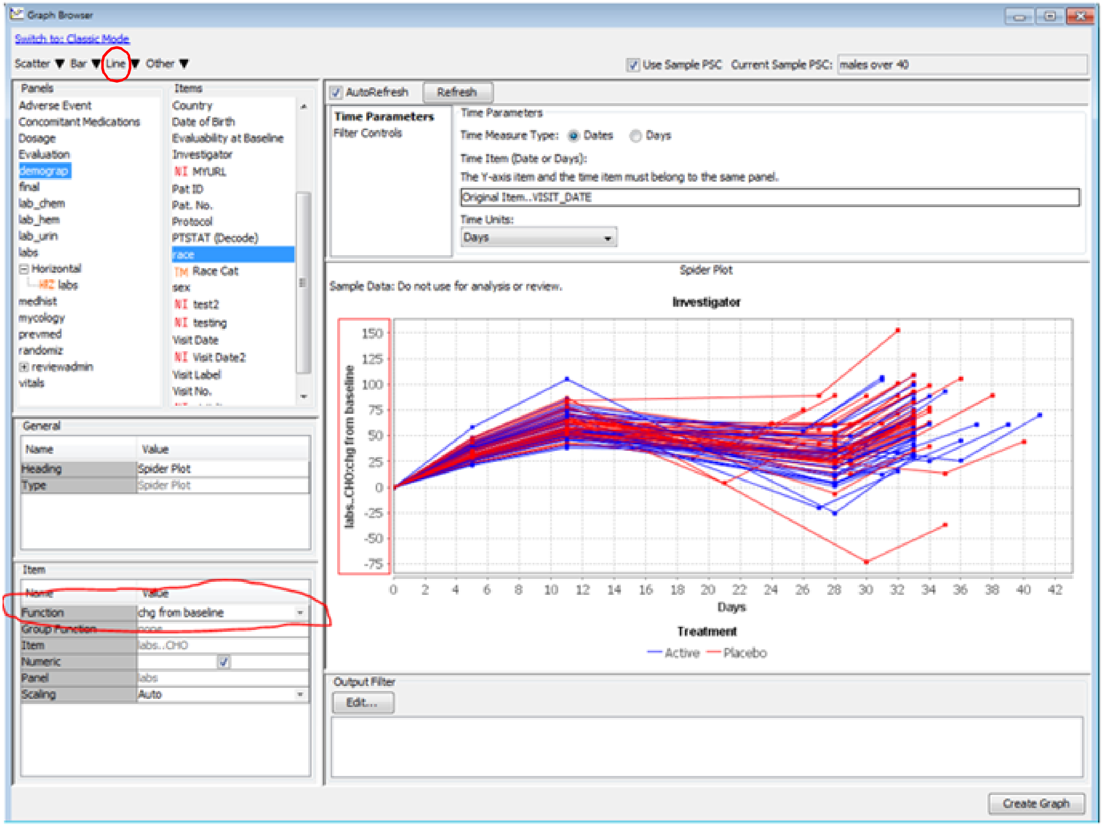
The Spider Plot is a detail line graph where each line represents data for an individual patient. While it is similar to JReview's Spaghetti Plot, the X and Y axes of the Spider Plot are defined in more specific ways. The X-axis is "time" relative to a baseline visit; for example, the X-axis might be the number of days or weeks before or after the baseline visit. The Y-axis is a *numeric* variable with either a "change-from-baseline" or "percent-change-from-baseline" function. With the plot defined in this way, the Y-axis value, i.e., the change value, on the baseline visit "day" is zero.

The Spider Plot is used in the oncology clinical trial domain where the Y-axis variable is "change in tumor size." However, JReview's Spider Plot's use is not restricted to that variable or to oncology. Note that "Spider Plot" is sometimes used as an alternative name for Radar Plot, but the Radar Plot is a different plot than the Spider Plot described here.

The JReview Spider Plot, like the Spaghetti plot, supports drill-down, By-Variables, Paging, Filter Controls, and Output Filters.

## *Define Spider Plot*

The Spider Plot definition screen is opened from the **Line graph menu** in the Graph Browser; it is available ***only*** in the **New Mode** (drag-and-drop) browser. The Y-axis variable, and the optional By-variable and Paging variable, are defined by dragging-and-dropping items on the Preview area in the conventional way. The Y-axis variable must support the "chng-from-baseline" and "% chg from baseline" functions. The user may choose one of these two function options in the Graph Browser's item property table positioned on the left side of the screen.



☑ Use Sample PSC  Current Sample PSC: males over 40

☑ AutoRefresh

Time Parameters

Time Measure Type: ● Dates ○ Days

Time Item (Date or Days):

The Y-axis item and the time item must belong to the same panel.

Original Item..VISIT_DATE

Time Units: Days

Sample Data: Do not use for analysis or review.

General

| Name | Value |
|---|---|
| Heading | Spider Plot |
| Type | Spider Plot |

Item

| Name | Value |
|---|---|
| Function | chg from baseline |
| Group Function | none |
| Item | labs..CHO |
| Numeric | ☑ |
| Panel | labs |
| Scaling | Auto |

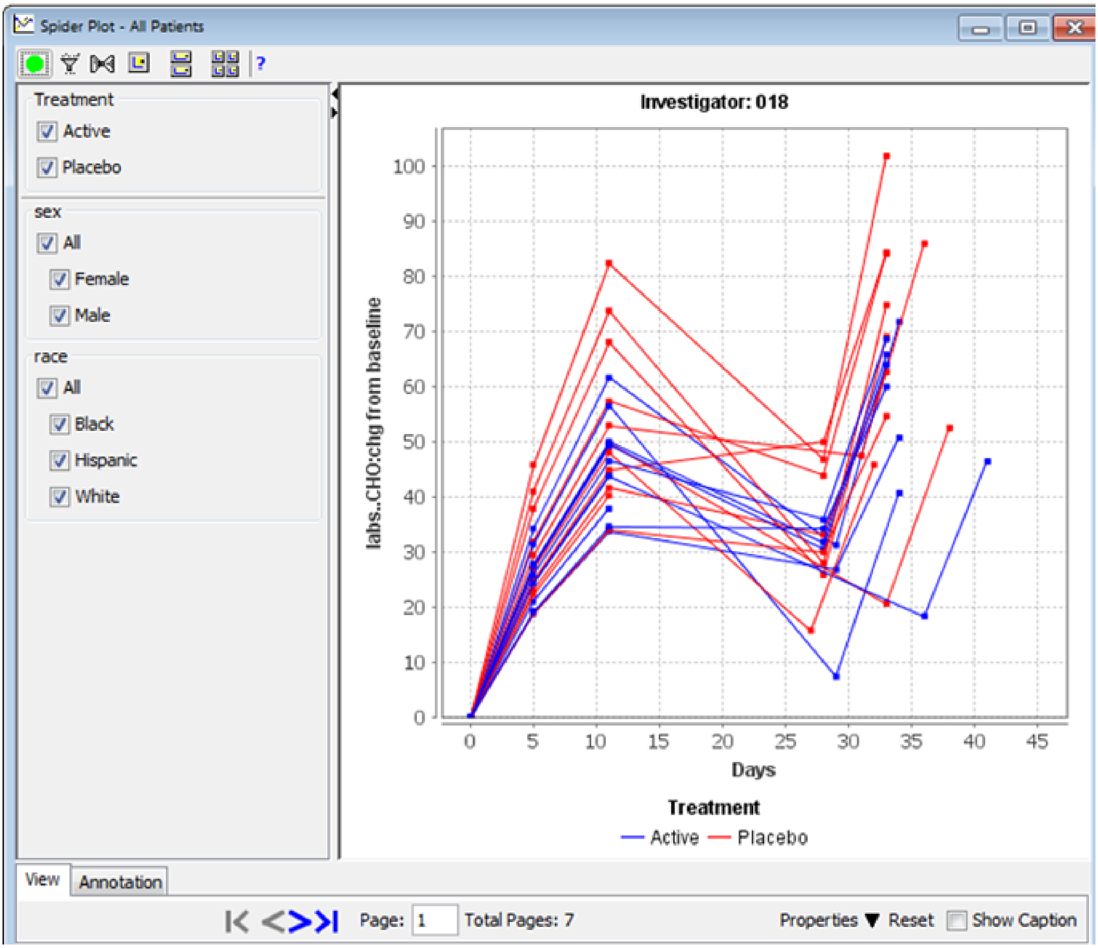
The form at the top of the browser is divided into two “pages”: the first page defines the “time parameters” and the second page defines the “filter controls”. All the time parameters are required, but the “filter controls” are an optional feature.

The “Time Item” is a variable (e.g., “Visit_Date” or “Visit_Day”) that provides the basis for the X-axis values. ***The time item must belong to the same panel as the Y-axis item.*** The time item can either be a “date” item or a “days” item. The type of the time item, i.e., “dates” or “days”, is specified using the “Time Measure Type” radio buttons.

As with other JReview time-based graphs, the time units (“Days”, “Weeks”, Bi-Weeks”, “Months”) for the X-axis are set using the “combo-box” drop down menu.

## *Spider Graph Viewer*

The Spider Plot Graph Viewer is shown in the figure below.



Treatment
☑ Active
☑ Placebo

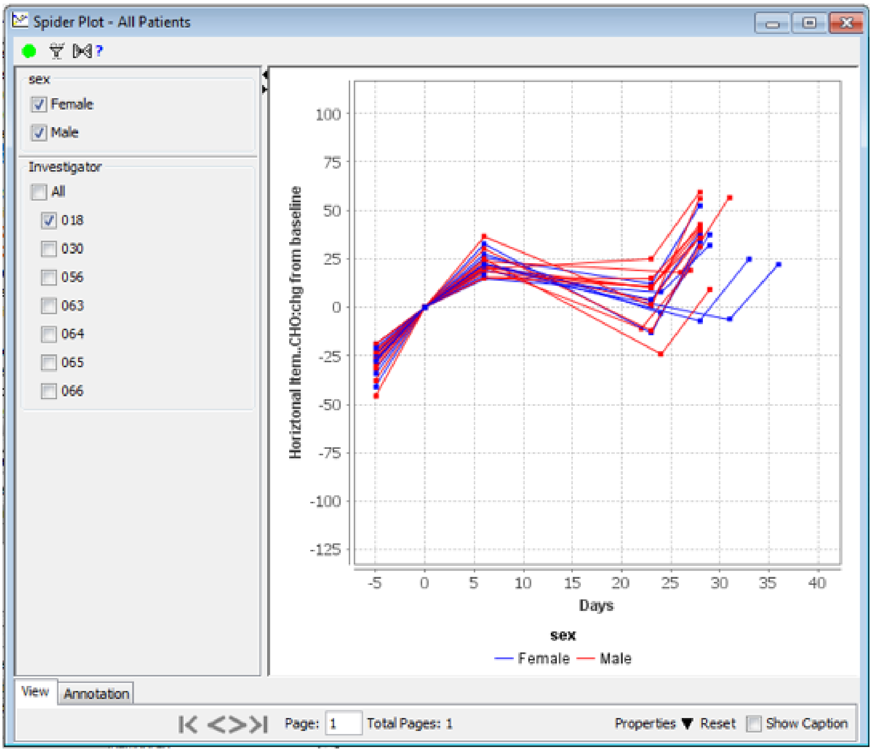
sex
☑ All
☑ Female
☑ Male

race
☑ All
☑ Black
☑ Hispanic
☑ White

Page: 1 Total Pages: 7

☐ Show Caption

Here's another generated Spider Plot, with filter controls, to include/exclude specific groups, studies, etc.



Spider Plot - All Patients

sex
☑ Female
☑ Male

Investigator
☐ All
☑ 018
☐ 030
☐ 056
☐ 063
☐ 064
☐ 065
☐ 066

Page: 1 Total Pages: 1

☐ Show Caption

## *Exposure by Dose graph*

The **Exposure by Dose** graph is a Summary graph that shows the number of patients in each By-variable subgroup over time, i.e., number of days. One targeted use case for this graph is the examination of the number of patients “exposed” to a drug dosage level (e.g., high dose, low dose, and placebo) over time. Typically, the number of patients being exposed in each group decreases over time, although the amount of the decrease may vary across subgroups over time.

The graph presentation may be conceptualized as a Stacked Bar graph with a bar for each day. The Y-axis is the Number of Patients and the X-axis is the number of days. The different subgroups are presented in different colors as is done generally for By-variable values in JReview graphs.

As in most other timeline graphs, the graph definition can use either Days or Dates items; the Dates vs. Days mode is chosen using radio buttons.  If the “Dates” mode is chosen, a Start Date item (e.g., Date of Randomization) must be specified, and all other “items” must be date items. If the “Days” mode is specified, all “time” items must be “days” items.

The Exposure Dosage graph definition requires a “Period Start Time” and a “Period End Time.” (In Dates mode, the “Period Start Time” is made in addition to a “Start Date” specification.) The Period Start Time and Period End Time are conventional items in a Dosage panel.

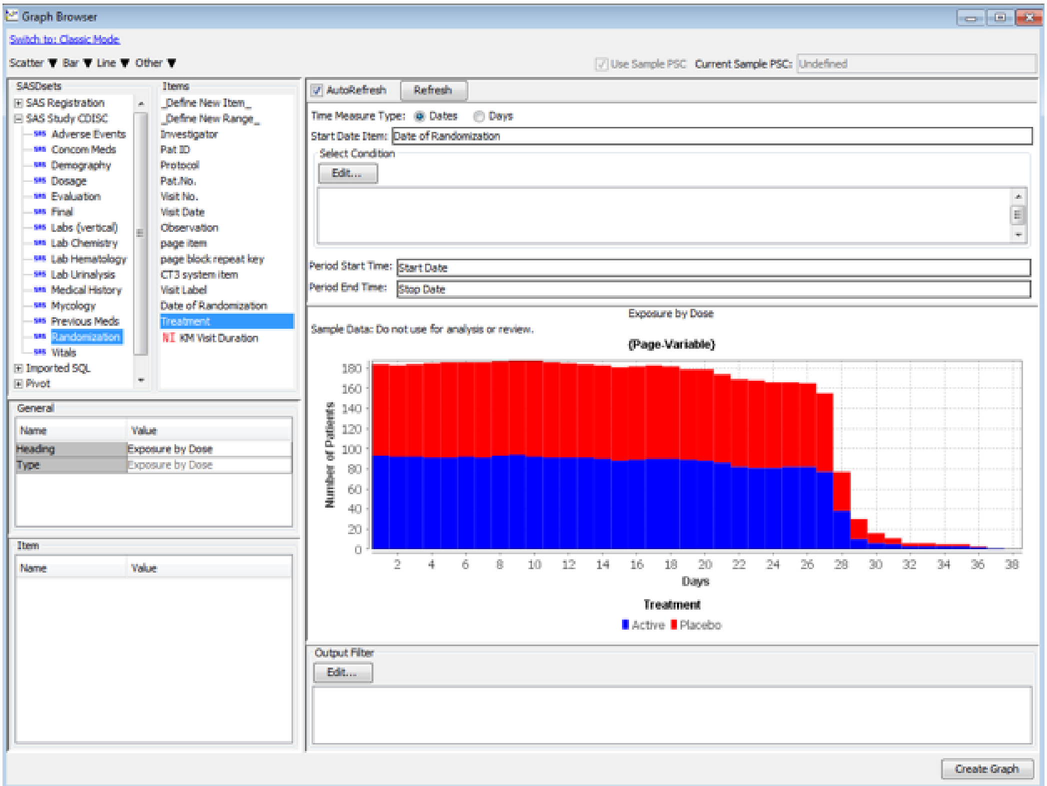
In the Dates mode, the Period Start Time item and the Start Date item may be identical. This would be the case where the “first” day for the graph data is to be, for example, the first dosage date and not the Date of Randomization.

## *Define Dose graph*

Steps to define Exposure by Dose Graph.

1. Click on the Graph Browser icon or select Graphs in Browse menu.
2. Click on Other graph styles and select Exposure by Dose.
3. Set the Time Measure Type and enter the Start Date Item.
4. Optionally Select Condition.
5. Select the Dosage panel start item and drag to Period Start Time. Select the stop item and drag to Period End Time.
6. Select By Variable to drag/drop.
7. Page Variable is an option.
8. Create Graph.

Preview of Exposure by Dose Graph Browser.



☑ Use Sample PSC Current Sample PSC: Undefined

☑ AutoRefresh

Time Measure Type: ● Dates ○ Days

Start Date Item: Date of Randomization

Period Start Time: Start Date

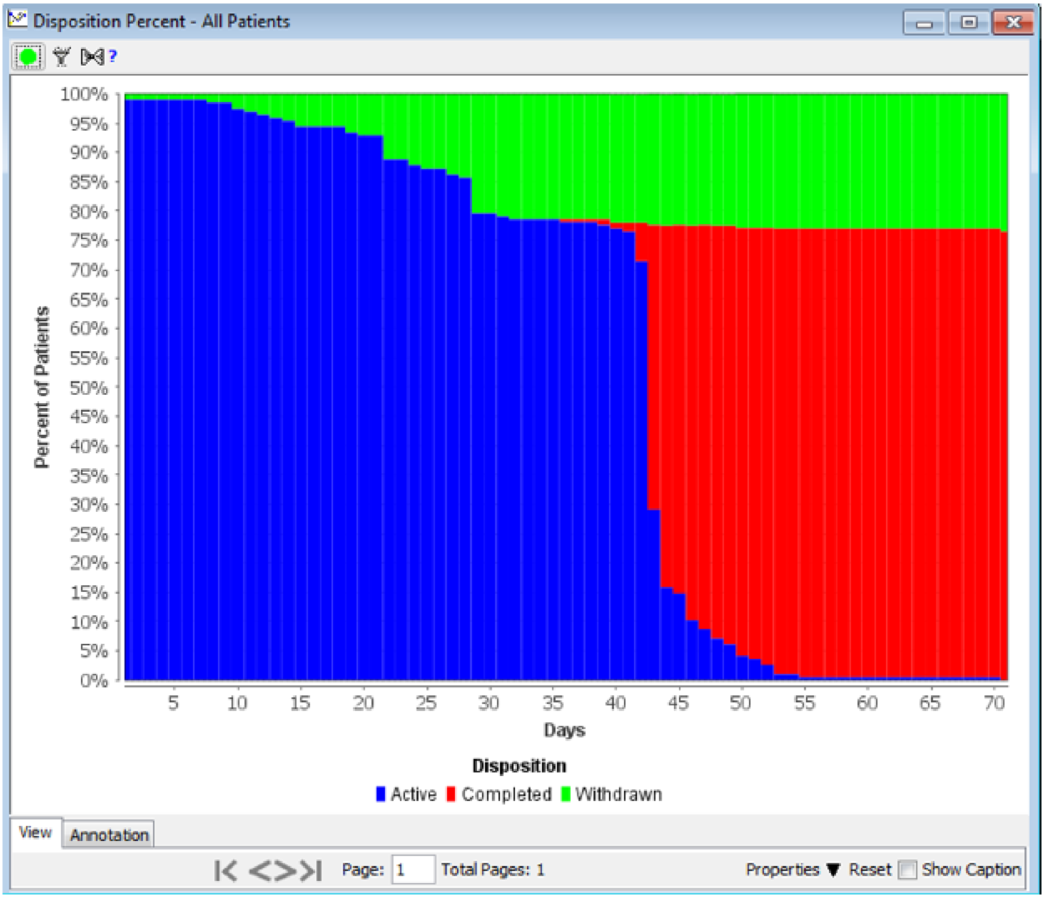
Period End Time: Stop Date

| Name | Value |
|---|---|
| Heading | Exposure by Dose |
| Type | Exposure by Dose |

Sample Data: Do not use for analysis or review.

## *Disposition Percent Graph*

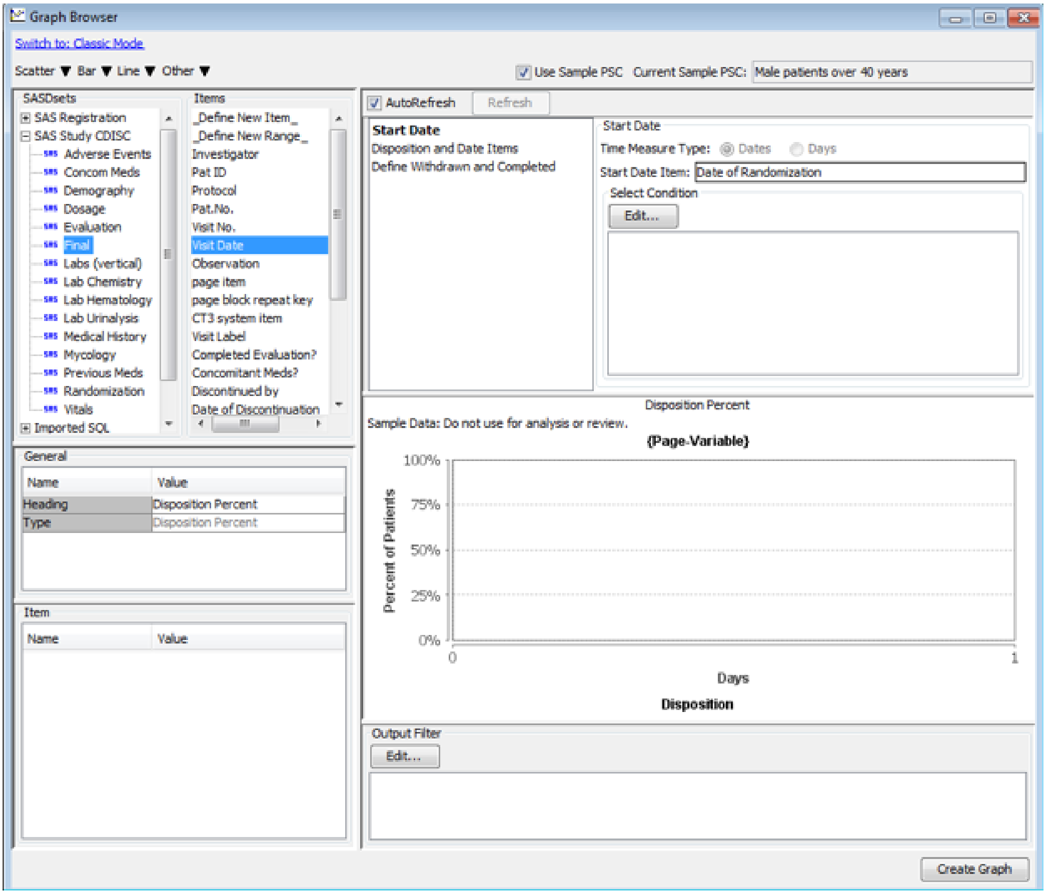
The **Disposition Percent Graph** is a Summary graph that shows the percent of patients in each of one of the following “disposition” status conditions: active, withdrawn, and completed. An active patient is in a treated status, for example, receiving medication or in the placebo condition. During the course of the study a patient might be withdrawn; this event might due to reasons such as an adverse event or the patient voluntarily withdrew. When the patient has finished the “treatment”, the patient’s status is changed to “completed.”



The Disposition Percent graph can only be defined in the “New Mode” Graph Browser. It has the “wizard-like” screens seen in other New Mode Graph Browsers. This graph type does not permit the specification of a BY-variable.

Disposition Percent graph is a type of timeline graph in that it shows the percent of patients in each of the three conditions on each day of the study. In terms of presentation, the graph may be described as a Stacked Bar graph where there is a bar for each day of the study. Typically, all the patients are initially in the Active condition, and the percent of patients in the Withdrawn or Completed conditions grows as the study progresses over time. Consequently, it is typical that the percent of patients in the Active condition decreases over time.

The first "page" presents the functions for choosing the Start Date and optionally defining a filter for the Start Date. Only the "dates" mode can be specified for this graph, and the "Dates vs. Days" radio buttons are disabled. The graph definition requires the specification of a Start Date. Unlike other JReview timeline graphs, there is no "Dates vs. Days" option: all time calculations are based on dates. The initial (total) pool of Active patients is determined by the Start Date variable.



☑ Use Sample PSC  Current Sample PSC: Male patients over 40 years

Time Measure Type: ● Dates ○ Days

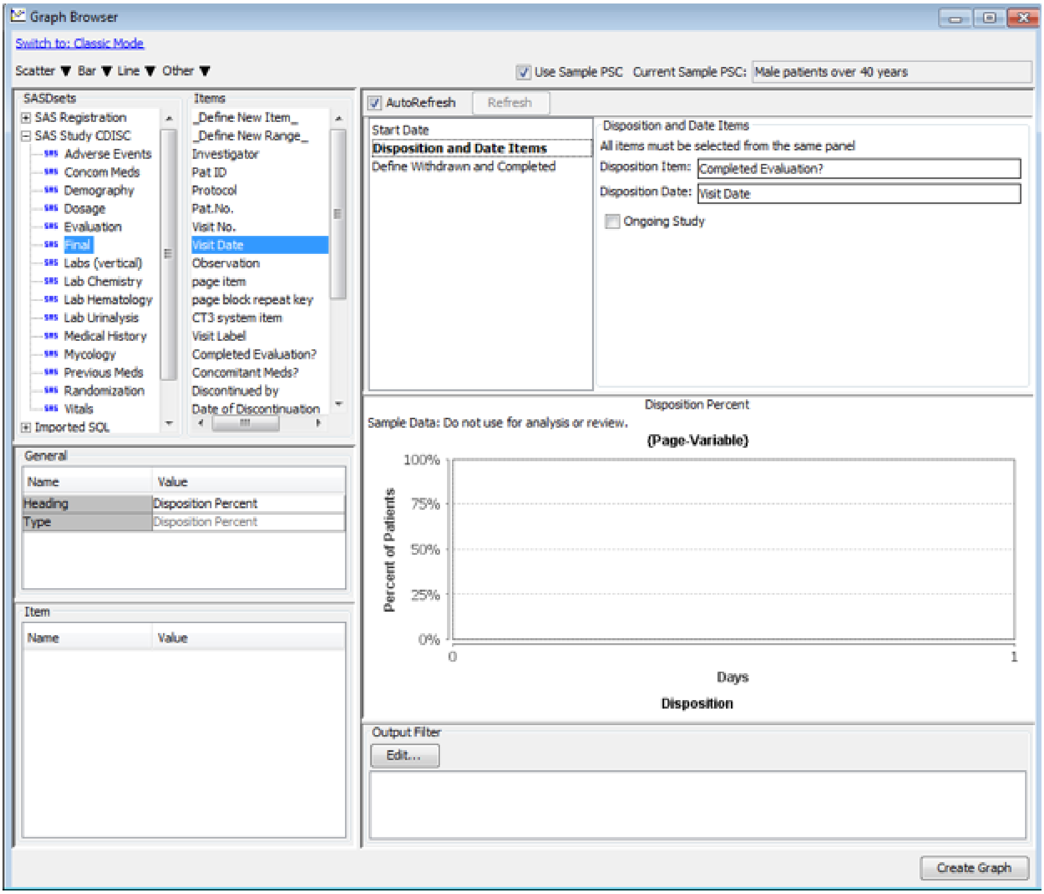
Start Date Item: Date of Randomization

Sample Data: Do not use for analysis or review.

General

| Name | Value |
|---|---|
| Heading | Disposition Percent |
| Type | Disposition Percent |

The second "page" provides controls for the specification of the Disposition item and its associated date item. The Disposition item selection determines the values that are available on the third "page." An "Ongoing Study" checkbox is used to designate whether the study is still ongoing. If a study is still ongoing, then some patients may not have completed treatment and still have an active status. In the situation where "Ongoing Study" is selected and some patients have neither withdrawn nor completed, then the current date (i.e., "today's date") is used for calculating the last day that appears in the graph. If "Ongoing Study" is not selected or all patients have reached a completed or withdrawn state, then the last day on which there is a Completed or Withdrawn event becomes the last day in the graph.



☑ Use Sample PSC  Current Sample PSC: Male patients over 40 years

☑ AutoRefresh

All items must be selected from the same panel

Disposition Item: Completed Evaluation?

Disposition Date: Visit Date

☐ Ongoing Study

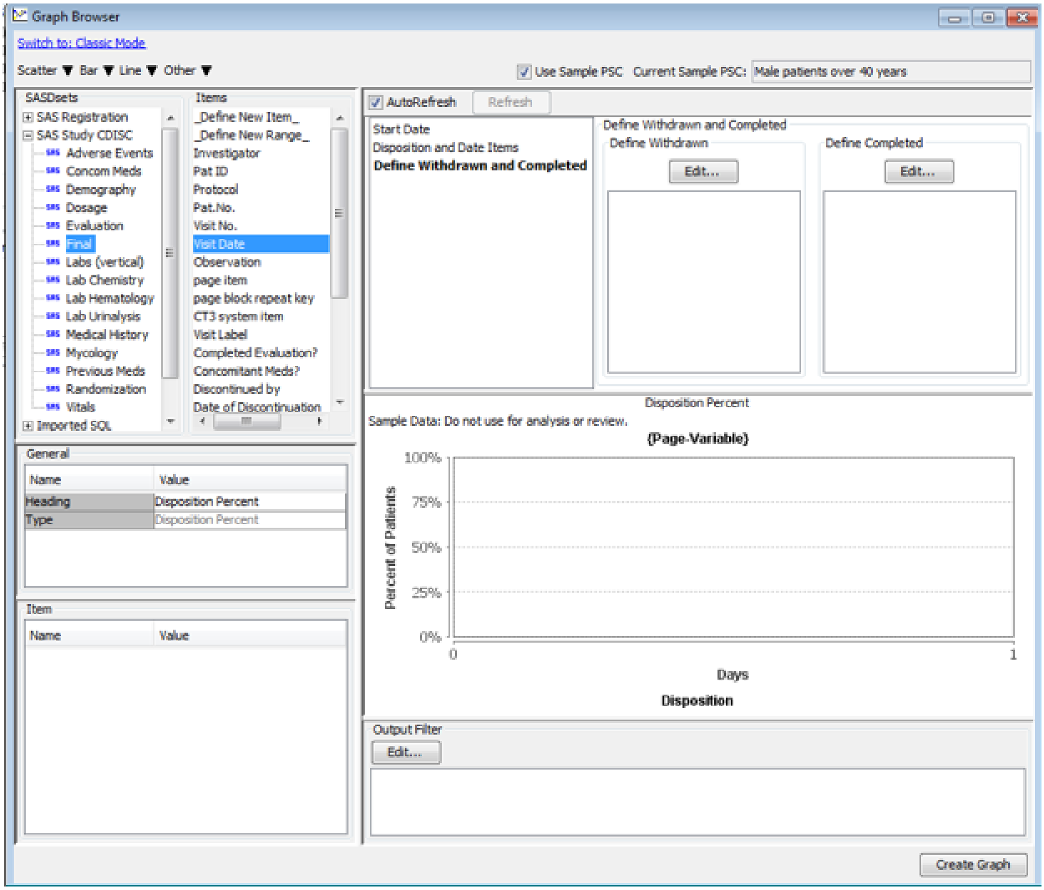
Sample Data: Do not use for analysis or review.

General

| Name | Value |
|---|---|
| Heading | Disposition Percent |
| Type | Disposition Percent |

In CDISC-style study databases, there is a ***Disposition*** panel containing event data that records the status of a patient. For this graph, the item in the panel containing the values that define the Withdrawn and Completed conditions must be specified. In addition, a date item *from the same panel* must be specified.

The third “page” presents the controls for choosing the Withdrawn and Completed values. The chosen values are displayed in lists in the Withdrawn and Completed panels. Clicking the Edit button opens a dialog that allows the user to add or subtract values from the list of chosen values.



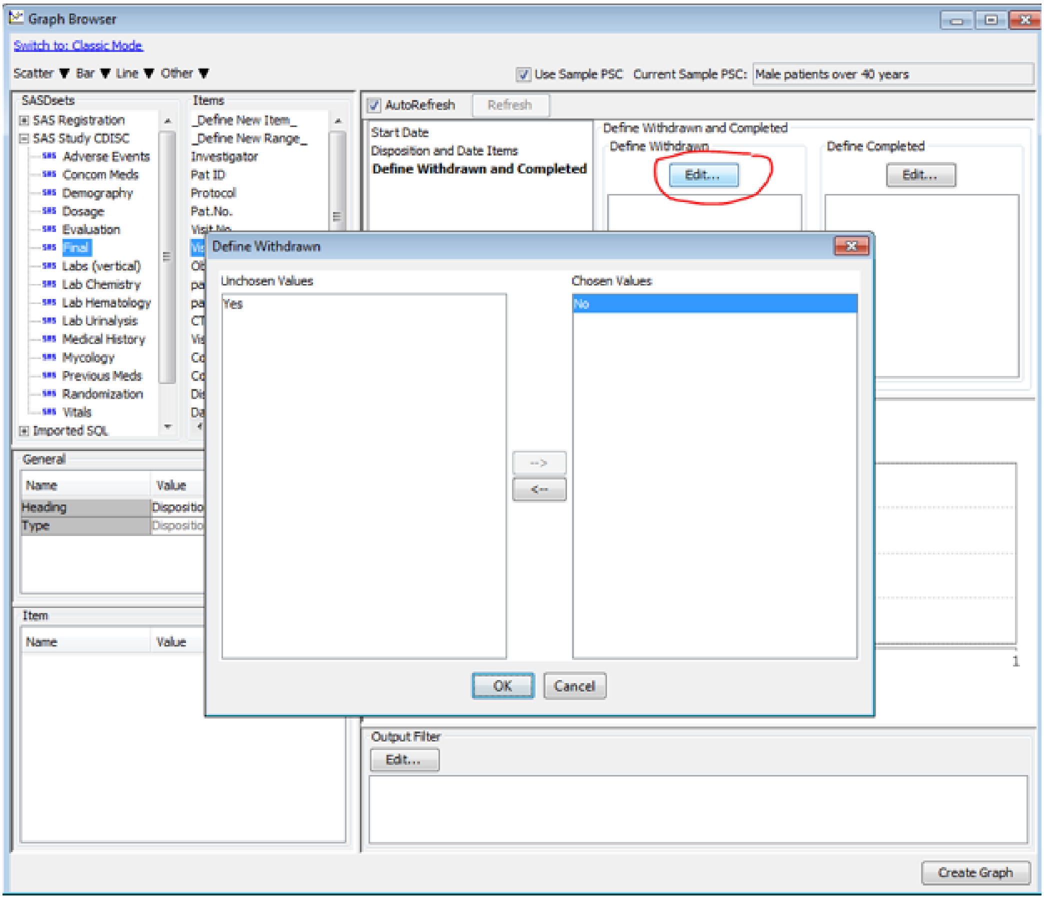
☑ Use Sample PSC  Current Sample PSC: Male patients over 40 years

☑ AutoRefresh

General

| Name | Value |
|---|---|
| Heading | Disposition Percent |
| Type | Disposition Percent |

The last specification parameters are the Disposition item's values that define the Withdrawn and Completed. (The Disposition item must be selected before these values can be chosen.) In other words, the user chooses which values represent events that define Withdrawn and Completed, respectively. For example, a "completed" value might be used to define the Completed condition. Multiple values may be chosen to define a condition; For example, in the case of Withdrawn, there may be various events that result in a "Withdrawn" status. The Withdrawn and Completed parameters are optional.



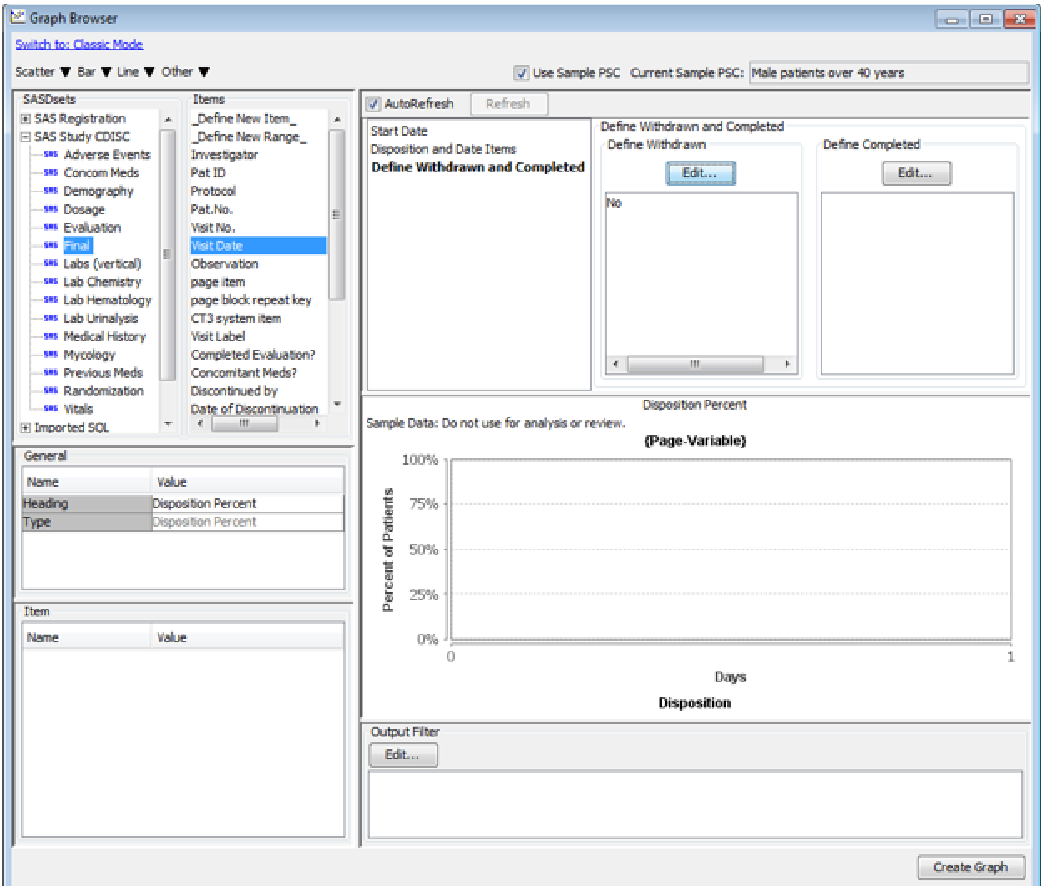
☑ Use Sample PSC  Current Sample PSC: Male patients over 40 years

| Name | Value |
|---|---|
| Heading | Dispositio |
| Type | Dispositio |

Unchosen Values: Yes

Chosen Values: No

Note that the set of values from which the choices can be made is limited to values found for the Disposition item. The specific values in the database reflect only those associated with actual events in the panel item, and are not necessarily a dictionary of all possible values. The universe of values may be larger than the subset of values found for the current patient data in the study.



☑ Use Sample PSC Current Sample PSC: Male patients over 40 years

☑ AutoRefresh

Define Withdrawn: No

Sample Data: Do not use for analysis or review.

General

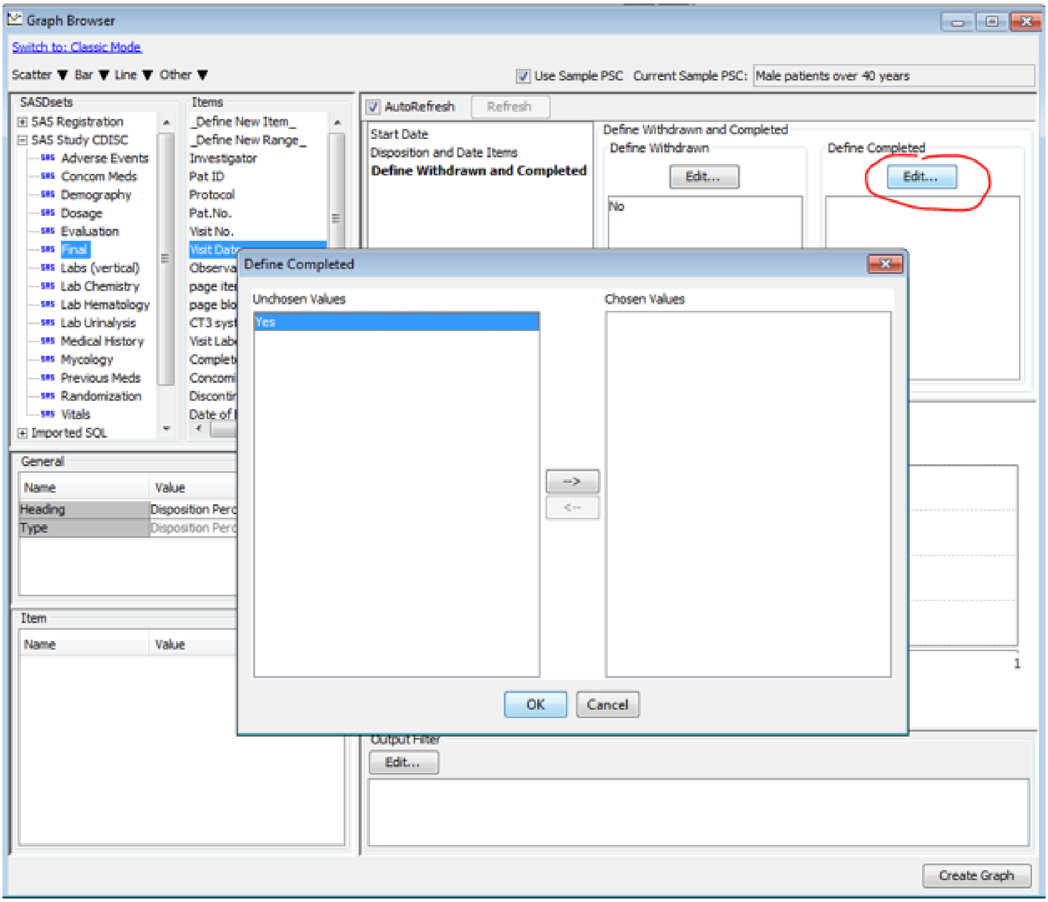
| Name | Value |
|---|---|
| Heading | Disposition Percent |
| Type | Disposition Percent |

Item

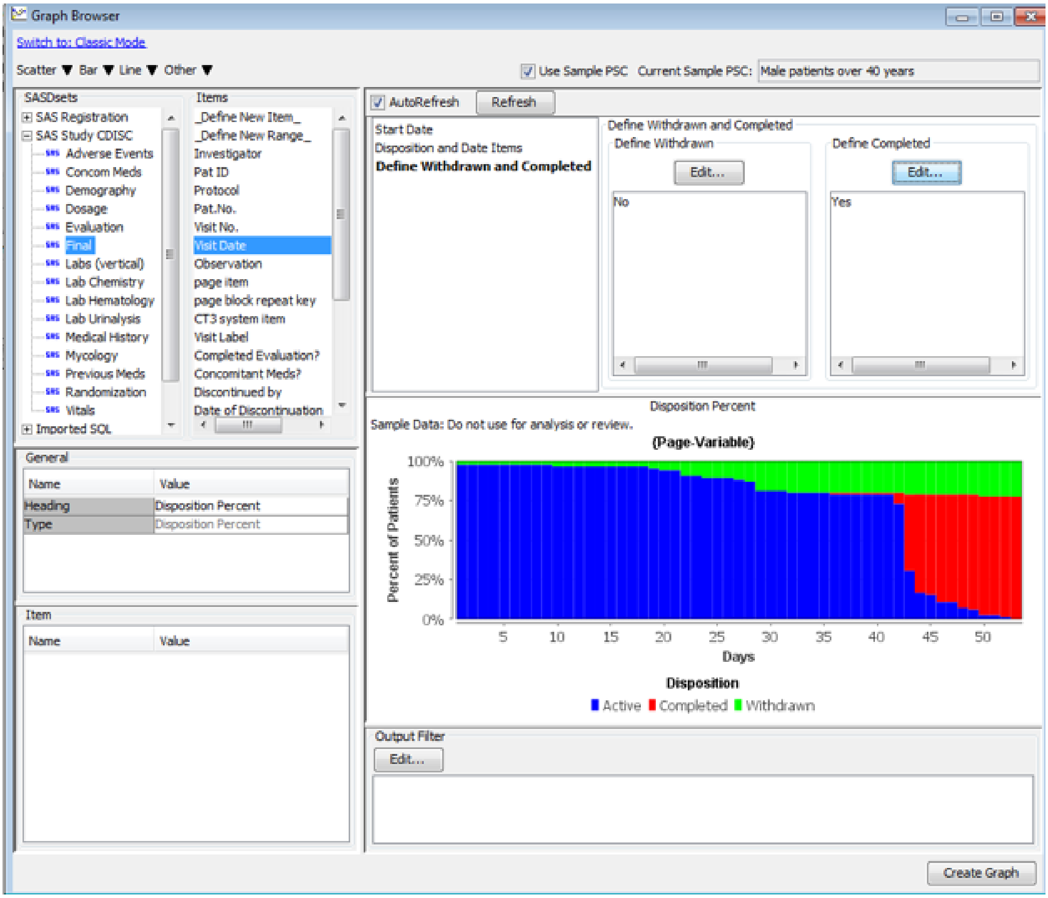
| Name | Value |
|---|---|

If there is no Disposition event for a patient included in the initial Active pool, that patient is considered to be still “active” at the end of the study.

A Page Variable may be specified, but there is “no axis scaling.” There is no specifiable By-variable for this graph.



Preview Disposition Percent graph.



☑ Use Sample PSC Current Sample PSC: Male patients over 40 years

☑ AutoRefresh

**Define Withdrawn and Completed**

Define Withdrawn: No

Define Completed: Yes

Sample Data: Do not use for analysis or review.

| Name | Value |
|---|---|
| Heading | Disposition Percent |
| Type | Disposition Percent |

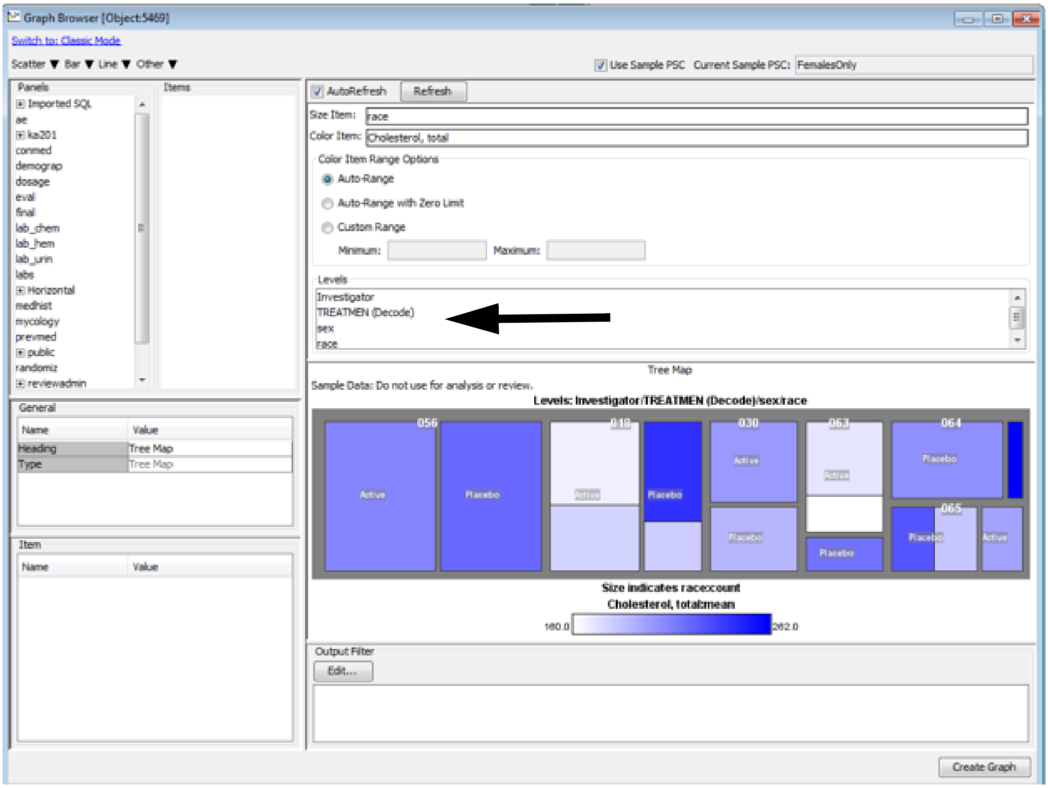
## *TreeMap Graph*

A TreeMap Graph is added to the library of JReview graphs. Special purpose TreeMap graphs are already implemented in JReview's Risk-Assessment and Risk-Based Monitoring (RBM) modules. A TreeMap graph is now available for more general use within JReview.

TreeMaps present data that is hierarchically organized. That is, the data presentation is tree-structured with the data presented in nested rectangles. Each node of a tree is a rectangle, and a "parent" node (i.e. higher-order node) can contain "child" nodes (i.e., lower-order nodes). So, lower-order nodes are nested within higher-order nodes. The "leaf" nodes are the lowest level nodes. These "leaf" nodes can be associated with either one or two data items: an item that defines the size of the rectangle (i.e., the size of the rectangle is proportional to the data value for a given leaf node) and/or an item that defines color of the rectangle.

The following is a simple example appropriate to JReview. Investigator, Treatment, Sex and Race are defined as the "levels" of the hierarchy. Each level is defined by an "item". Thus, for example, 018/Placebo/Female/White might be one of the leaf nodes in the tree and be represented by a White rectangle nested within a Female rectangle that is in turn is nested within the Placebo rectangle, and finally nested within the 018 rectangle. The size of the leaf node is defined by a separate item. To make the rectangle size proportional to the number of patients that are contained in the "race" leaf node subgroup (for example, the number of whites who are female, in the Placebo group, and assigned to Investigator 018)), the Demographic.Race item with "patient count" as the group function could be used. Color might be tied to Cholesterol with "mean" as the group function; the higher the cholesterol value for the subgroup, the more saturated will be the color. Figures 1 and 2 illustrate the example.

(Figure 1)



☑ Use Sample PSC  Current Sample PSC: FemalesOnly

☑ AutoRefresh

Size Item: race

Color Item: Cholesterol, total

● Auto-Range

○ Auto-Range with Zero Limit

○ Custom Range

Levels:
Investigator
TREATMEN (Decode)
sex
race

Sample Data: Do not use for analysis or review.

General

| Name | Value |
|---|---|
| Heading | Tree Map |
| Type | Tree Map |

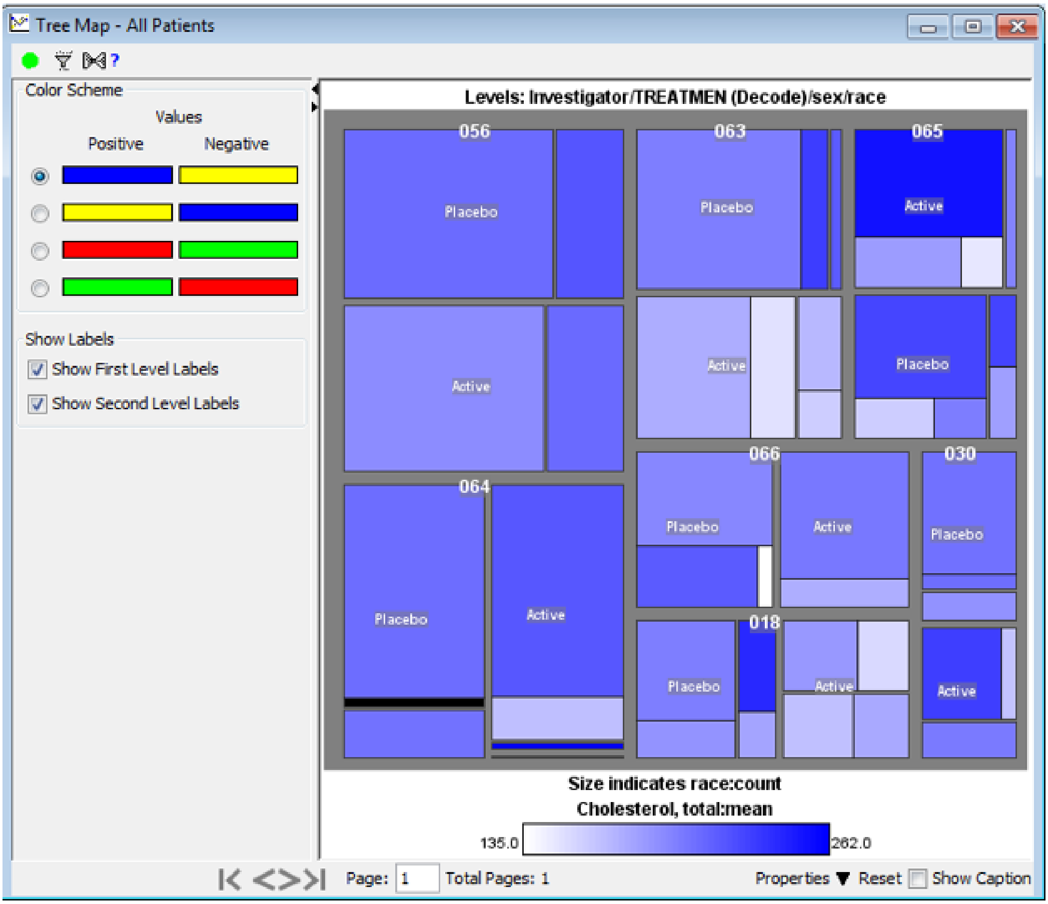
Item

| Name | Value |
|---|---|

Patient drill-down is supported for the leaf nodes. Clicking on a leaf nodes invokes the drill-down for that node: patient IDs for the selected node are retrieved from the server and propagated to other data viewers. The set of retrieved patients is determined by the “levels” items and not by the size or color items.

Paging and By-Variables are not supported in this graph.

(Figure 2)



Color Scheme: ● Positive 🟦 / Negative 🟨

☑ Show First Level Labels

☑ Show Second Level Labels

Levels: Investigator/TREATMEN (Decode)/sex/race

Size indicates race:count

Cholesterol, total:mean

Page: 1 Total Pages: 1

Color presentation is handled in two different ways depending on the type of item that is used to define this dimension. The choice of color mode depends on whether the data is a numeric, or it is "category" data ***defined by a New Range Item.***

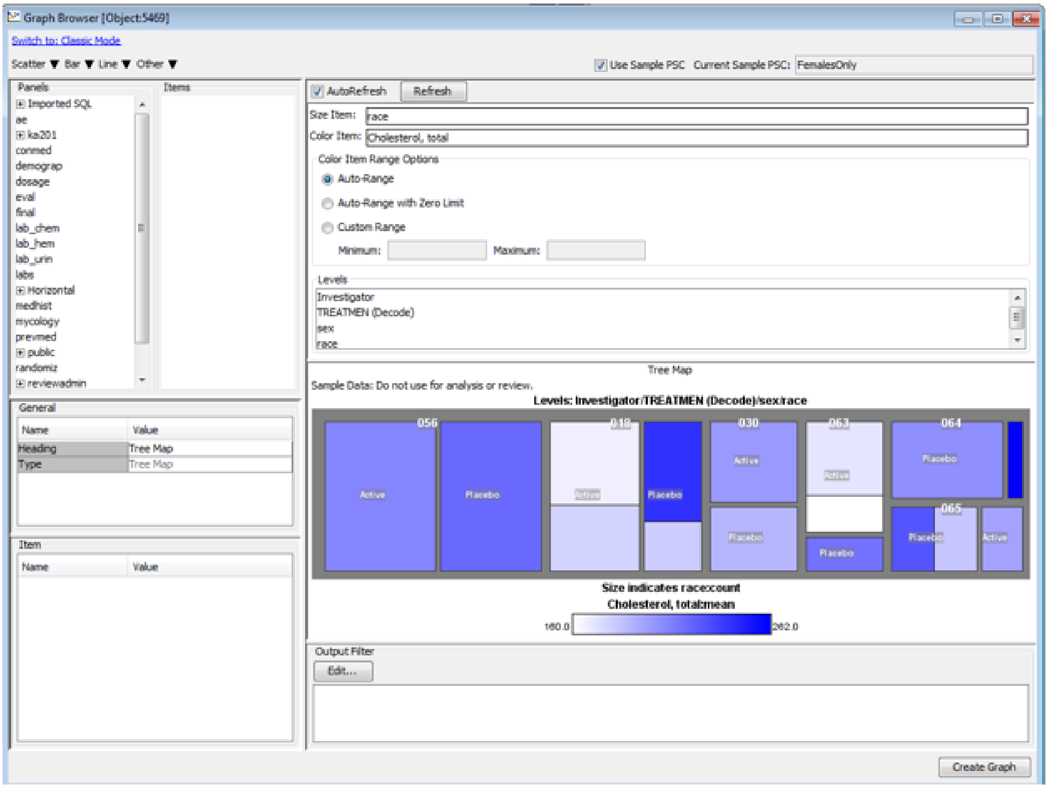
If the color data is numeric such as mean cholesterol, a color gradient is used to display the colors. The greater the (absolute) numeric value, the more saturated is the color. If both negative and positive values appear in the data, different colors are used to represent negative and positive values. The default colors are blue for positive values and yellow for negative values. The user may select alternative color combinations from a set of provided options in the Graph Viewer: blue-yellow, yellow-blue, red-green, and green-red. The user may select a color combination based on individual preference, color deficiency in vision, or on semantics related to the data. The color for a particular value is based on a calculation of the percent of the total value range. The user is presented with three options for defining the total range. The first option is Auto-Range where the actual data values define the lower and upper limits. The second option is Auto-Range with Zero Limit; this options defines "zero" as the lower limit for a data set with only positive values and zero as the maximum for a data set with only negative values. The third option is Custom Range in which the user directly enters the minimum and maximum values. Custom Range is useful for keeping the color for a particular value constant as the actual data range varies with changes in the dataset or with filtering.

If the user defines the color variable with a New Range Item, JReview assumes a "category" color mode. Each category is assigned a different color in a way that is similar to the color assignment to By-variable values in Bar and other graph types. The range definition options are not relevant to this mode, and are disabled when a New Range Item is chosen. The user may customize the color assignments using the Graph Viewer's Properties (Preferences) editor. Note that grouping functions are used to determine the subrange assignment of a leaf node.

As mentioned above, the size of a leaf node's rectangle is proportional to the size item's data value for that node in the hierarchy. If no size item is specified, all leaf-node rectangles are assigned the same size. The Group Functions for size items are limited to count, count distinct, count subjects and sum. Note that "duplicates" are not removed in the higher-order nodes. For example, if leaf nodes are AE types and the size is the patient count for the AE type, the same patient can be counted in multiple leaf nodes. The higher-order nodes do not prune these duplicates.

## TreeMap Graph Browser

The TreeMap Graph Browser defines a TreeMap graph. This browser is available only in the New Mode. To open the TreeMap Graph Browser, select "Tree Map" in the "Other" menu. The Graph Browser realizes the above functionality description. (Figure 1)



☑ Use Sample PSC Current Sample PSC: FemalesOnly

☑ AutoRefresh

Size Item: race

Color Item: Cholesterol, total

● Auto-Range

Levels:
Investigator
TREATMEN (Decode)
sex
race

| Name | Value |
|---|---|
| Heading | Tree Map |
| Type | Tree Map |

Sample Data: Do not use for analysis or review.

**Levels: Investigator/TREATMEN (Decode)/sex/race**

**Size indicates race:count**

**Cholesterol, total:mean**

The levels are defined by adding items (via drag-and-drop) to the ***Levels*** list. A maximum of four levels is allowed. The order of the levels in the lists defines the order in the hierarchy. The items in the list may be reordered using drag-and-drop within the list.

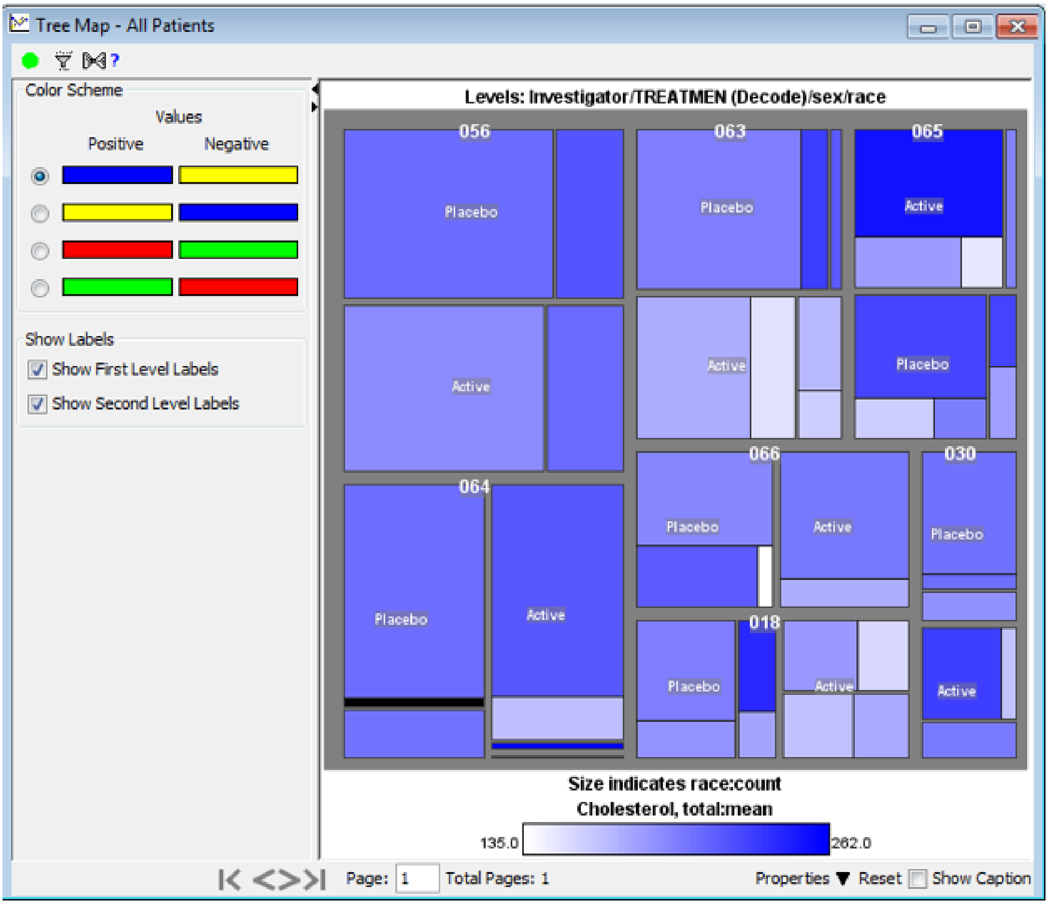
The ***Size Item*** field is an item drop area for the item that defines the size of the leaf-node rectangles. The *Color Item* field is an item drop area for the item that defines the color of rectangle. If the Graph Browser determines that the color item is a New Range Item, then it will automatically consider the color to be "category" mode.

If the color item is specified and it is not a New Range Item, the controls in the ***Color Item Range Options*** panel are enabled. These controls define data values that set the limits for the range of colors. The presented color for a data value is calculated by determining the fraction of the distance between the lower and upper limit data values, i.e., the color is determined by scaling. The radio buttons provide the controls for selecting among the range options: ***Auto-Range***, ***Auto-Range with Zero Limit*, and *Custom Range***. If Custom Range is selected, the two text fields (i.e., Minimum value and Maximum value) in the panels are enabled. The user enters the numeric values that bound the range for color scaling by typing the values into the text fields. When Custom Range is selected, numeric values must be entered in both text fields and the minimum value must be less than the maximum value.

The conventional JReview Output Filter is accessible for this browser.

## *TreeMap Graph Viewer*

The TreeMap Graph Viewer shows a graph defined with the “gradient” color scheme for a numeric range of data values. (Figure 2)



Tree Map - All Patients

Color Scheme

Values

Positive Negative

● 🟦 🟨
○ 🟨 🟦
○ 🟥 🟩
○ 🟩 🟥

Show Labels

☑ Show First Level Labels

☑ Show Second Level Labels

This graph output shows a graph defined with a New Range Item that produces a “category” color scheme. (Figure 3)

Tree Map - All Patients

Show Labels

☑ Show First Level Labels

☑ Show Second Level Labels

Levels: Investigator/TREATMEN (Decode)/sex/race

Size indicates race:count

Page: 1 Total Pages: 1

The user can “zoom-in” and “zoom-out” on a node in the tree. A popup menu will appear when right clicking on a node. The popup menu items allow the user to traverse up and down the hierarchy. Double-clicking on a node results in a zoom-in action.

When the mouse is moved over a leaf node, it darkens in color; additionally, a tooltip appears that identifies the node and the data associated with the node. Also, the highest level visible node that contains the mouse pointer is outlined with a white rectangle.

If no color item is defined, then all rectangles will be white. If there is a “missing” color data value for a rectangle, the rectangle will be drawn with a black background. If no size item is defined for the graph, all leaf rectangles will be equal in size.

By default, labels are presented for the highest two node levels for those nodes that are currently in the view. Labels that cannot fit are not drawn. Too many labels can clutter the view. Two checkbox are provided in the left-side control panel to toggle labels on or off by level.

In graphs using the gradient color scheme, like that shown in Figure 2, the user may click on one of four radio buttons in the control panel to change the two base colors used in the graph; one color is used for positive data values and the other is used for negative data values. The legend for the gradient is shown near the bottom of the graph; it displays the range of colors and data values for the lower and upper limits of the range defined for color scaling. The item that defines the color item is named in a label positioned above the legend.

As shown in Figure 3, a graph with a category color scheme assigns a different color (e.g., red, blue, green, etc.) to each category. This is unlike the gradient scheme where the same base color (e.g., blue) is changed in saturation. A legend that lists the categories and the associated colors is positioned to the right of the graph. The same set of colors used for distinguishing By-variable values in the other graphs (such as the Bar Graph) are used here for the category colors. The assignment of colors and the legend use the New Range Item definition itself to define the categories; the categories and the colors remain constant even if the data is filtered or changed.

(Figure 3)

Tree Map - All Patients

Show Labels

☑ Show First Level Labels

☑ Show Second Level Labels

Levels: Investigator/TREATMEN (Decode)/sex/race

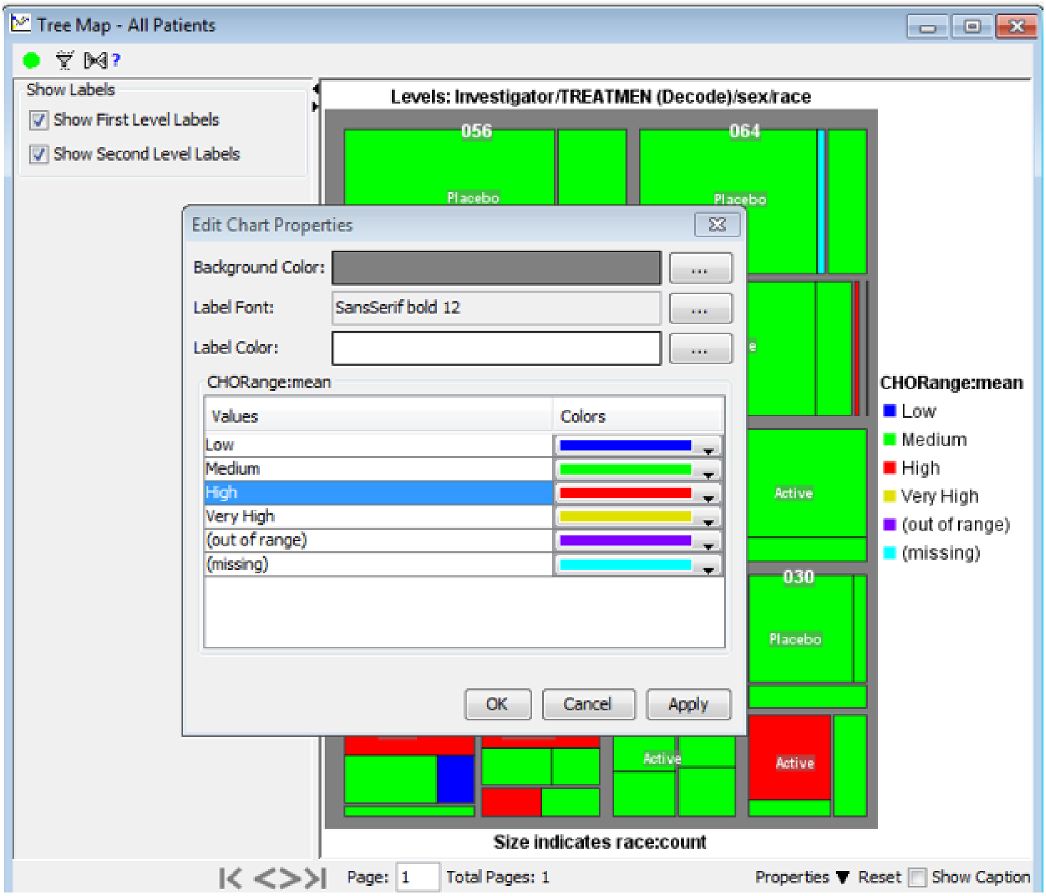
Size indicates race:count

Page: 1 Total Pages: 1

☐ Show Caption

For the category color scheme, the Property Editor for the TreeMap allows the user to reassign colors (see Figure 4). The second column presents Combo Box controls to reset the color for a category by selecting a color from the set of colors provided. The editor prevents assigning the same color to multiple categories by “swapping” the existing color with whatever category currently owns the selected color.

(Figure 4)



Tree Map - All Patients

Show Labels

☑ Show First Level Labels

☑ Show Second Level Labels

Edit Chart Properties

Background Color:

Label Font: SansSerif bold 12

Label Color:

CHORange:mean

| Values | Colors |
|---|---|
| Low | 🟦 |
| Medium | 🟩 |
| High | 🟥 |
| Very High | 🟨 |
| (out of range) | 🟪 |
| (missing) | 🟦 |

## *Cumulative Count by Time graph*

The **Cumulative Count by Time** is a line graph that displays a cumulative count of events or occurrences across time or a cumulative count across time of patients with whom an instance of an event or occurrence is associated. The X-axis of the graph is time, and the Y-axis is a count or a patient count. The graph supports two Y-axes, with the second Y-axis being optional. A By-variable and a Paging variable, as well as an Output Filter, may be specified. The graph may be defined only in the New Mode Graph Browser. The browser for this graph is launched from an item in the "Line" graph menu.

The X-axis represents time, and the tick marked time units may be defined in terms of Days, Weeks (7-day intervals, Bi-Weekly (14-day) intervals, or Month (30-day) intervals. Time may be defined either in terms of dates relative to a defined start date or in terms of "days" where there is a day item in the database panel or one has been added as a New Item. Using "Dates" or "Days" are different "modes", meaning that the graph definition must be in one mode or the other consistently throughout the graph definition. If "Days" mode is chosen, no Start Date is explicitly defined.

The Y-axis variable defines the events or occurrences, such as Adverse Events, to be counted. A filter may be optionally added to refine the Y-axis definition. For example, perhaps only an Adverse Event of a certain type is wanted. A "time" item (i.e., "Date" or "Day") that defines when the event occurred is required for the Y-axis specification.

The Group Function for the Y-axis variable is restricted to two values: 1) count; 2) count patients. The Group Function is selected in the Graph Browser's property table for the selected Y-axis variable. "Count" counts the number events, such as Adverse Events. The number of events that occur on a particular day are summed, and then added to the sum of events occurring on earlier days in the study. Thus, as time increases, the count of events (e.g., Adverse Events) increases.

When "Count Subjects" is the group function, the Y-axis indicates the number of patients who have a recorded event. As time increases, for example, more patients may exhibit an Adverse Event. Each patient is counted only once. The patient is counted and added to the cumulative sum when the first event occurs for that patient. If later events associated with that patient occur, the patient **is not** counted again and not added to the cumulative patient count.

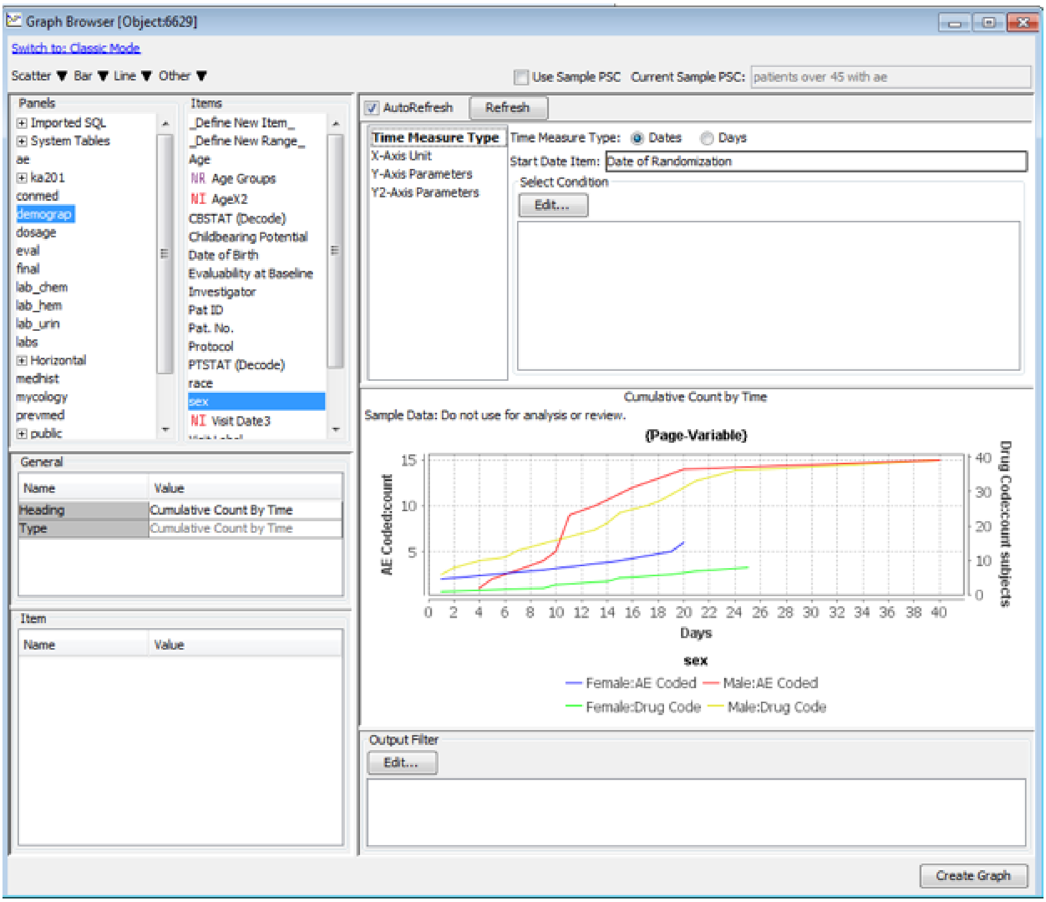
A second Y axis may be optionally defined. For example, the graph may display the use of "Conmeds" over time along with the Adverse Event data.

The Graph Browser for defining the graph is illustrated in the following figures. The variables for the Y-axes, By-variable, and Paging variable are set by dragging an item onto the Preview graph and dropping it on the appropriate drop zone. Other parameters are chosen using the wizard-like control above the preview area.

***Note: If there is only one data point for a data series, no line can be drawn for that series. Later updates of this graph will present a marker where there is only a single point.***

***Note: Drill-down is NOT supported in this graph.***

**Time Measure Type** is selected for Dates for Start Date Item entered as Date of Randomization. The Start Date Item is required for Dates.



Graph Browser [Object:6629]

☐ Use Sample PSC Current Sample PSC: patients over 45 with ae

☑ AutoRefresh

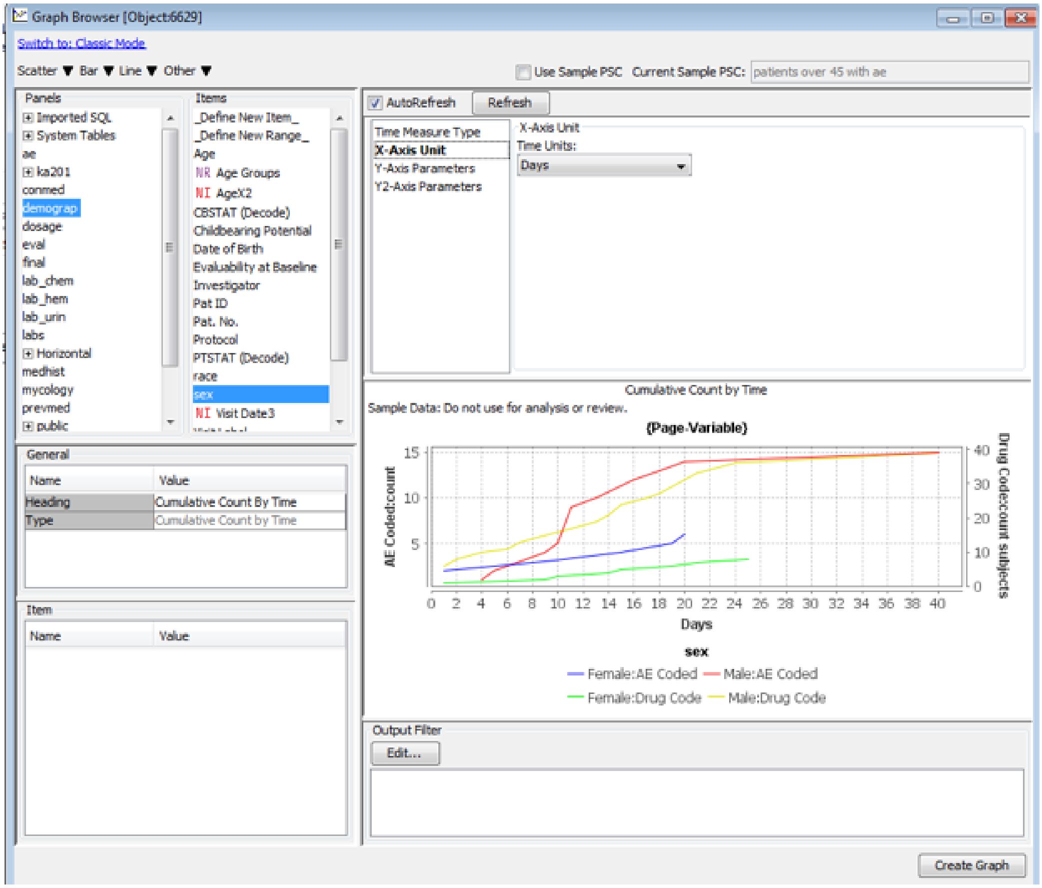
Time Measure Type: ● Dates ○ Days

Start Date Item: Date of Randomization

| Name | Value |
|---|---|
| Heading | Cumulative Count By Time |
| Type | Cumulative Count by Time |

Sample Data: Do not use for analysis or review.

**X-Axis Unit** is selected for Days.



Current Sample PSC: patients over 45 with ae

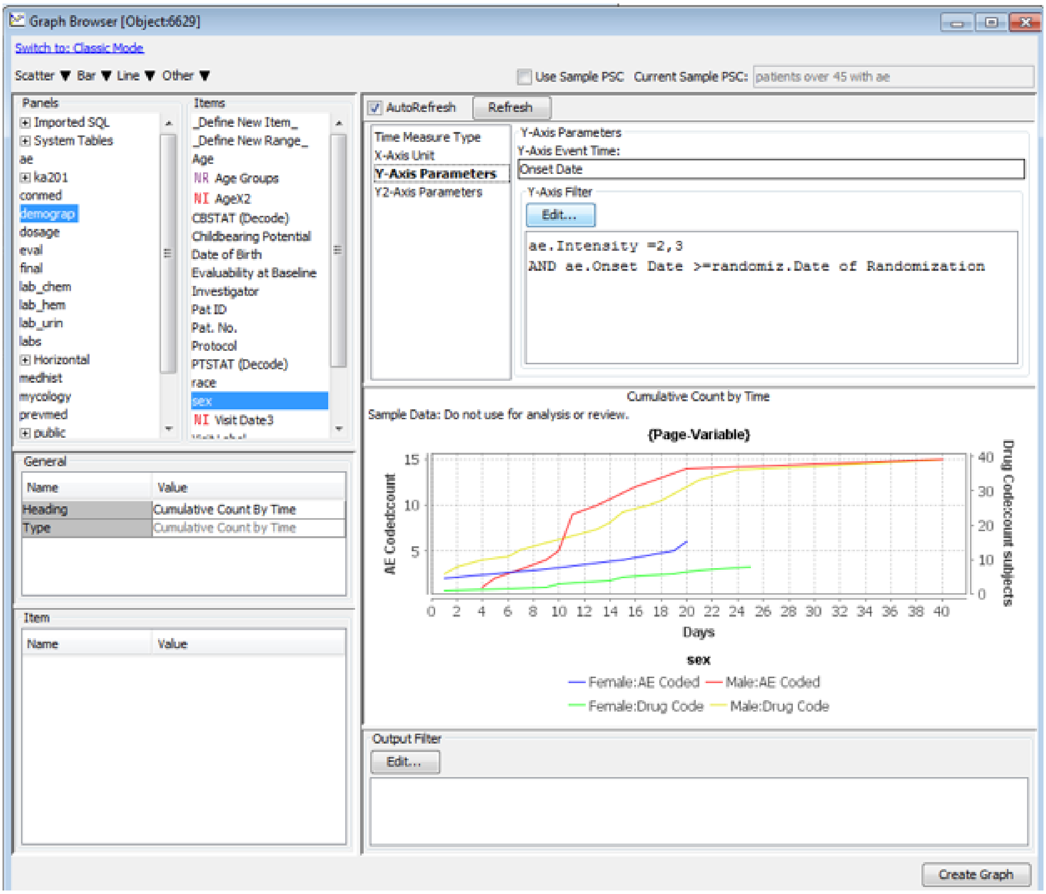
| Name | Value |
|---|---|
| Heading | Cumulative Count By Time |
| Type | Cumulative Count by Time |

X-Axis Unit

Time Units: Days

Sample Data: Do not use for analysis or review.

**Y-Axis Parameters** entered for Adverse Events data where Y-Axis Event Time is Onset Date.  Y-Axis Filter was defined for AE.Intensity is moderate or severe, and AE.Onset Date greater than/equal to the Date of Randomization.



☐ Use Sample PSC   Current Sample PSC: patients over 45 with ae

☑ AutoRefresh

Y-Axis Parameters

Y-Axis Event Time: Onset Date

Y-Axis Filter

```
ae.Intensity =2,3
AND ae.Onset Date >=randomiz.Date of Randomization
```

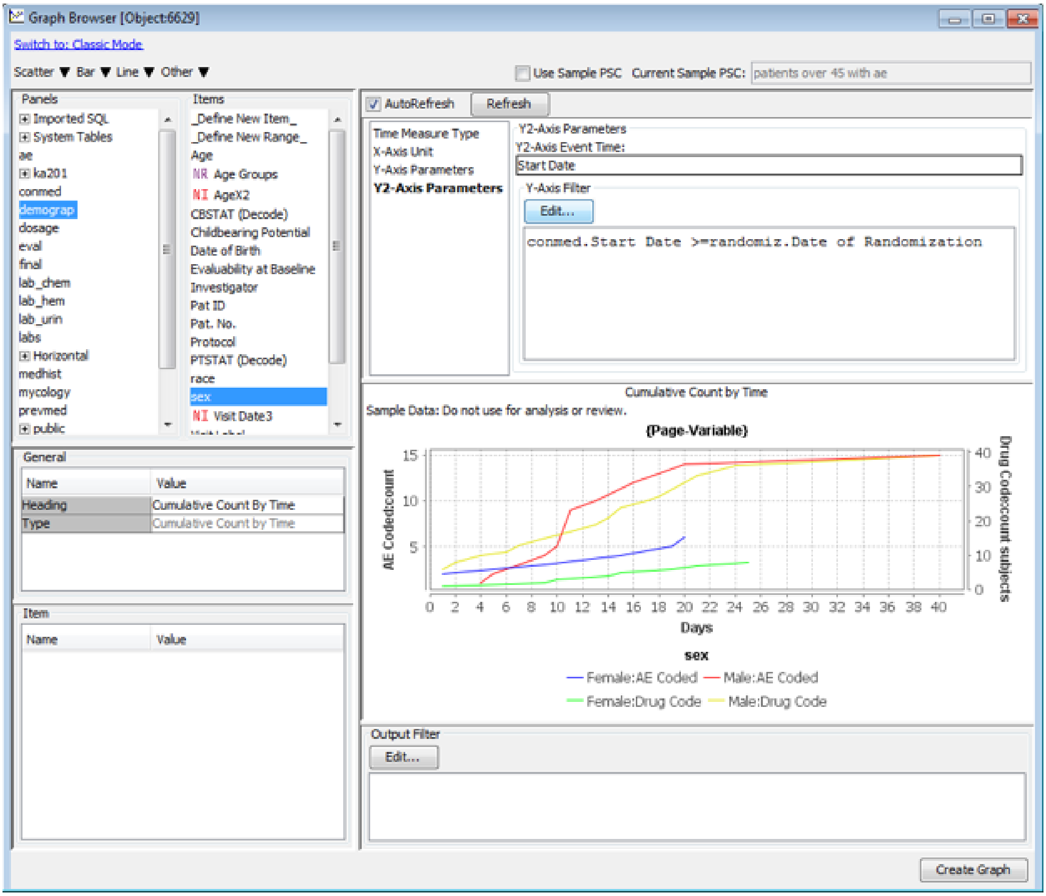
General

| Name | Value |
|---|---|
| Heading | Cumulative Count By Time |
| Type | Cumulative Count by Time |

Item

| Name | Value |
|---|---|

**Y2-Axis Parameters** entered for Concomitant Medication data where Y2-Axis Event Time is Start Date. Y2-Axis Filter was defined for Conmed.Start Date greater than/equal to the Date of Randomization. Sex was included as the By Variable.  There is an optional Page Variable.



Graph Browser [Object:6629]

Switch to: Classic Mode

☐ Use Sample PSC  Current Sample PSC: patients over 45 with ae

☑ AutoRefresh

Y2-Axis Parameters

Y2-Axis Event Time: Start Date

Y-Axis Filter

```
conmed.Start Date >=randomiz.Date of Randomization
```

General

| Name | Value |
|---|---|
| Heading | Cumulative Count By Time |
| Type | Cumulative Count by Time |

Item

| Name | Value |
|---|---|

Cumulative Count by Time

Sample Data: Do not use for analysis or review.

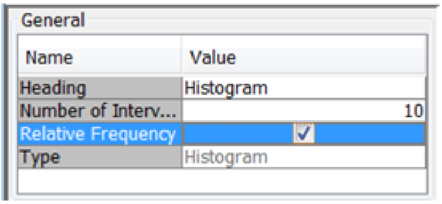
## *Histogram*

The Histogram is a type of frequency bar graph. The range of values for a **numerical** x-axis is divided into intervals that are sometimes called “bins,” and the number of values in each bin are counted. The graph is used to represent the distribution of values for a numerical variable.

In JReview, a Normal Distribution curve that overlays the Histogram is constructed. By default, the normal distribution curve is shown. However, the Graph Viewer contains a “Show Normal Distribution” checkbox that toggles the visibility of the normal distribution curve.

The Histogram specification screen is accessed from the “Histogram” item in the “New Mode” Graph Browser’s “Bar” menu. (***This graph type is not available in Classic Mode.***)

There is an option to choose either “Frequency” or “Relative Frequency.” With relative frequency, the frequencies are divided by the number of values in the series. The control for this option is the “Relative Frequency” checkbox in the Graph Browser’s “General” property table. The tick marks and label for the y-axis reflect the frequency type.



General

| Name | Value |
|---|---|
| Heading | Histogram |
| Number of Interv... | 10 |
| Relative Frequency | ☑ |
| Type | Histogram |

The “Number of Intervals” control in the “General” property table sets the number of bins. The default number of bins is 10.

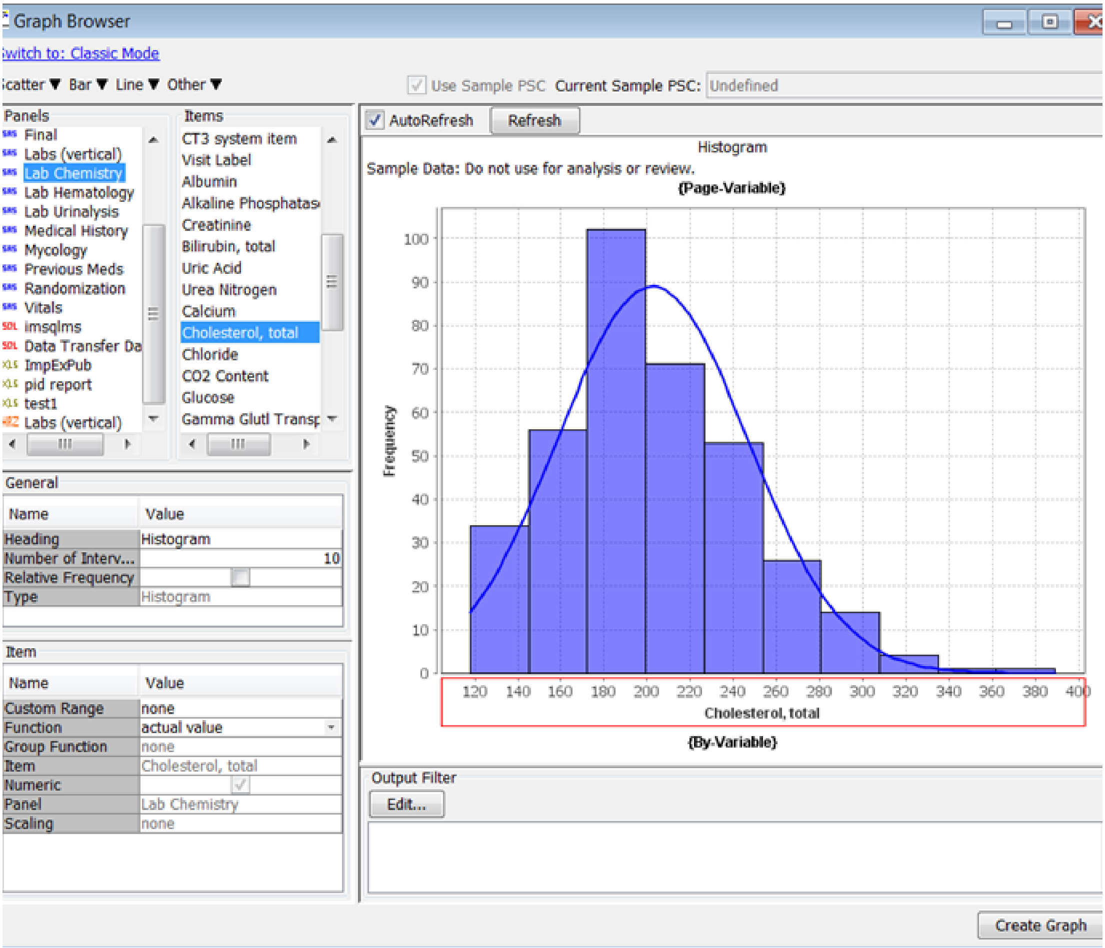
Specifying a numerical item as the x-axis variable is the minimal user action to define a Histogram. The range for the x-axis values is either determined by the set of actual data values, or, optionally, can be specified by the user. The lower and upper bounds for the set of bins are defined by default to be, respectively, the lowest and highest values in the data set. ***Note*** **-** that if an actual value is either lower or higher than a user-defined range, the actual values are used to define the range. The “Custom Range” control in the Item property table sets the range option.

By choosing an appropriate combination of range limits and number of bins, each bin’s bounds may be positioned at “desirable” locations. For example, if the x-axis is “weight,” the range might be specified as “100-400” and the number of bins specified as “30”. With this example combination, the bin bounds will be at located integer values that are divisible by ten: 100, 110, 120, 130, etc.

Both the Paging and By-Variable features are supported. In the case where a By-variable is defined, the same range and bin locations apply across the data sets for the By-variable values. In other words, there is only one set of bins in the graph. Moreover, the bins and range are constant across pages. One advantage of this scheme, is that the bins align across the multiple By-variable distributions. It is possible that the distributions of the different By-variables data sets overlap. To accommodate this overlap situation, the bars of the Histogram are drawn with a translucent color. ***The Histogram should not be confused with a "stacked bar graph":*** the bars for the histogram may overlap. While a By-variable may be defined for the Histogram, it may not always result in a usable presentation. When used, the number of By-variable values should be very small; also, a better presentation results when the amount of overlap among the distributions is small.

The Graph Viewer can optionally present a data table containing the mean, median, and standard deviation for each distribution. By default, the table is not shown. The "Show Mean and Standard Deviation" checkbox in the Graph Viewer toggles the visibility of the data table. The number fractional digits, i.e., the number of digits after the decimal point, may be customized in the Graph Viewer's popup Property Editor dialog in the same way that is done for the Box-Whiskers graphs.

Figure 1. Histogram Graph Browser is selected from the **Bar menu.**



☑ Use Sample PSC Current Sample PSC: Undefined

☑ AutoRefresh

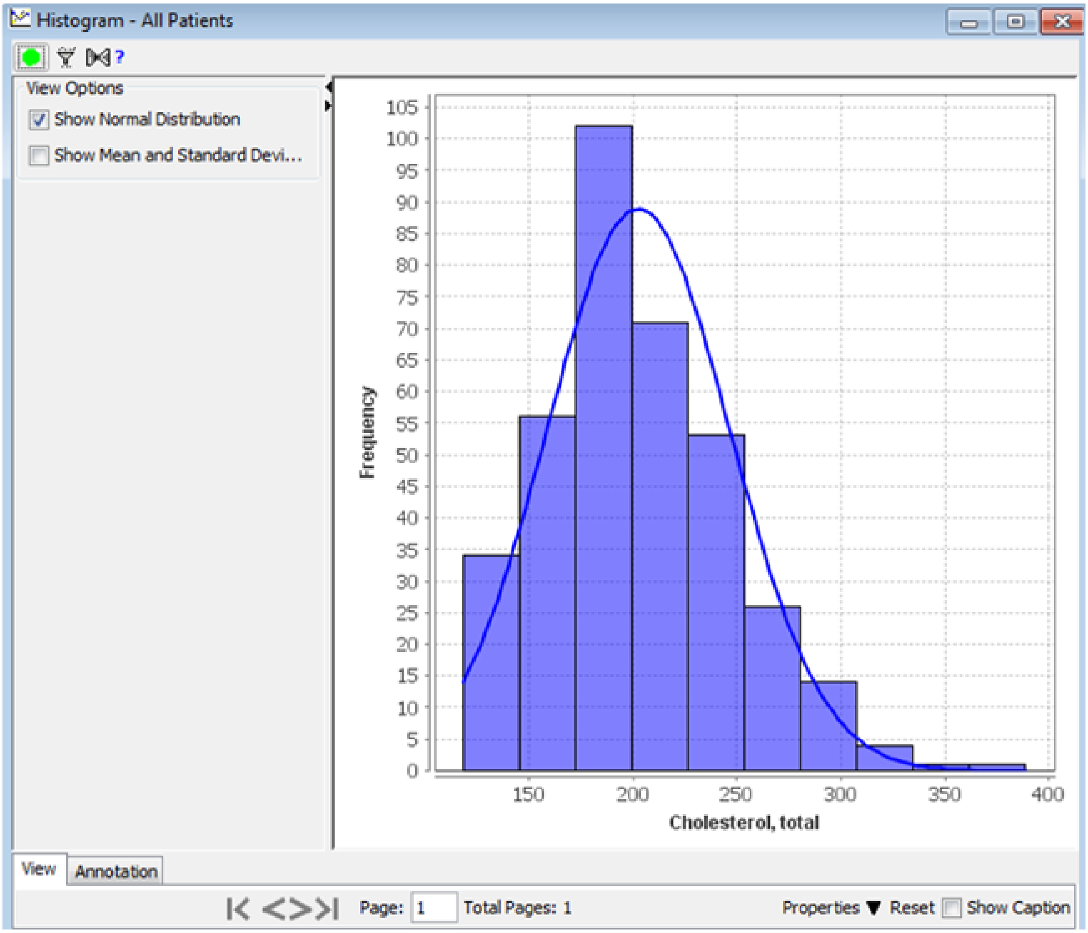
General

| Name | Value |
|---|---|
| Heading | Histogram |
| Number of Interv... | 10 |
| Relative Frequency | ☐ |
| Type | Histogram |

Item

| Name | Value |
|---|---|
| Custom Range | none |
| Function | actual value |
| Group Function | none |
| Item | Cholesterol, total |
| Numeric | ☑ |
| Panel | Lab Chemistry |
| Scaling | none |

Figure 2. Histogram Graph Viewer



Histogram - All Patients

View Options

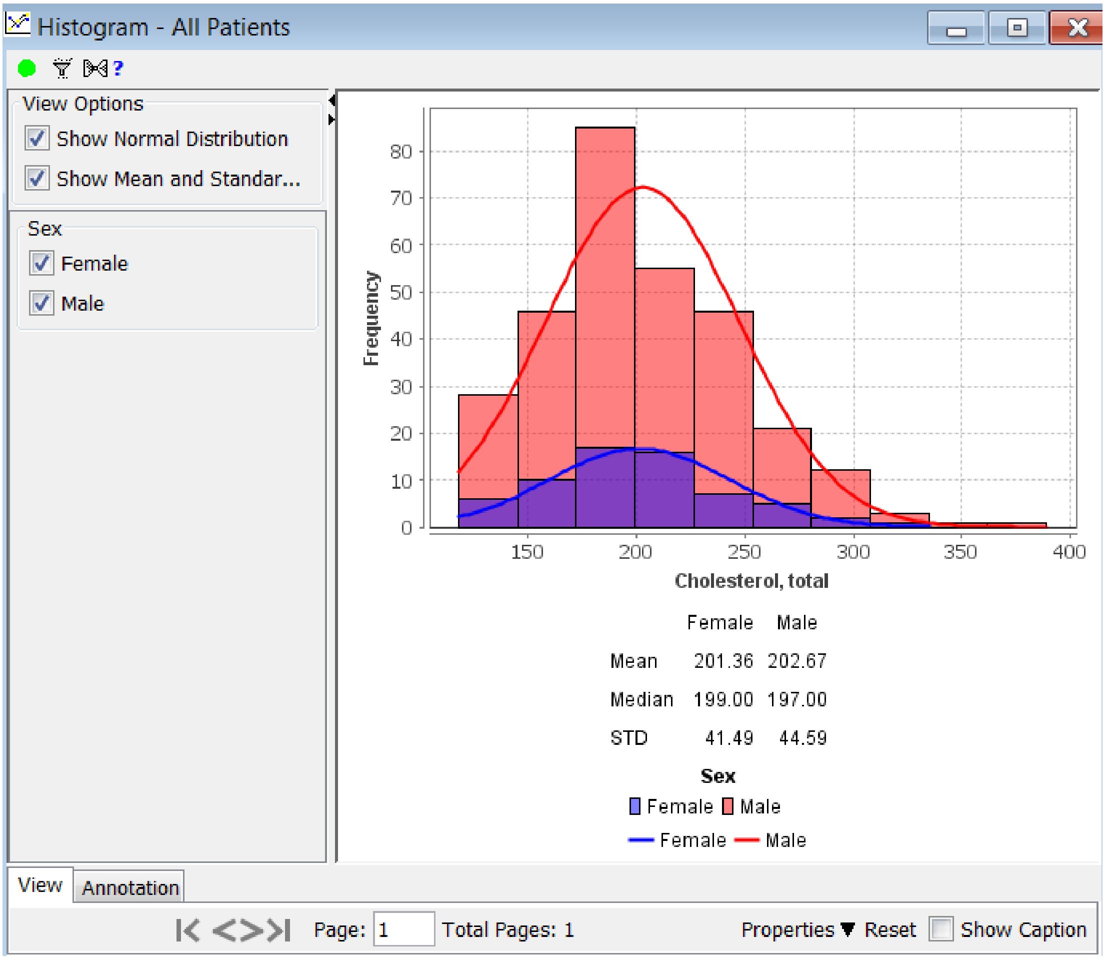
☑ Show Normal Distribution

☐ Show Mean and Standard Devi...

Page: 1 Total Pages: 1

☐ Show Caption

Figure 3. Histogram with BY-Variable and visible Data Table



View Options

☑ Show Normal Distribution

☑ Show Mean and Standar...

Sex

☑ Female

☑ Male

|  | Female | Male |
|---|---|---|
| Mean | 201.36 | 202.67 |
| Median | 199.00 | 197.00 |
| STD | 41.49 | 44.59 |

Page: 1 Total Pages: 1

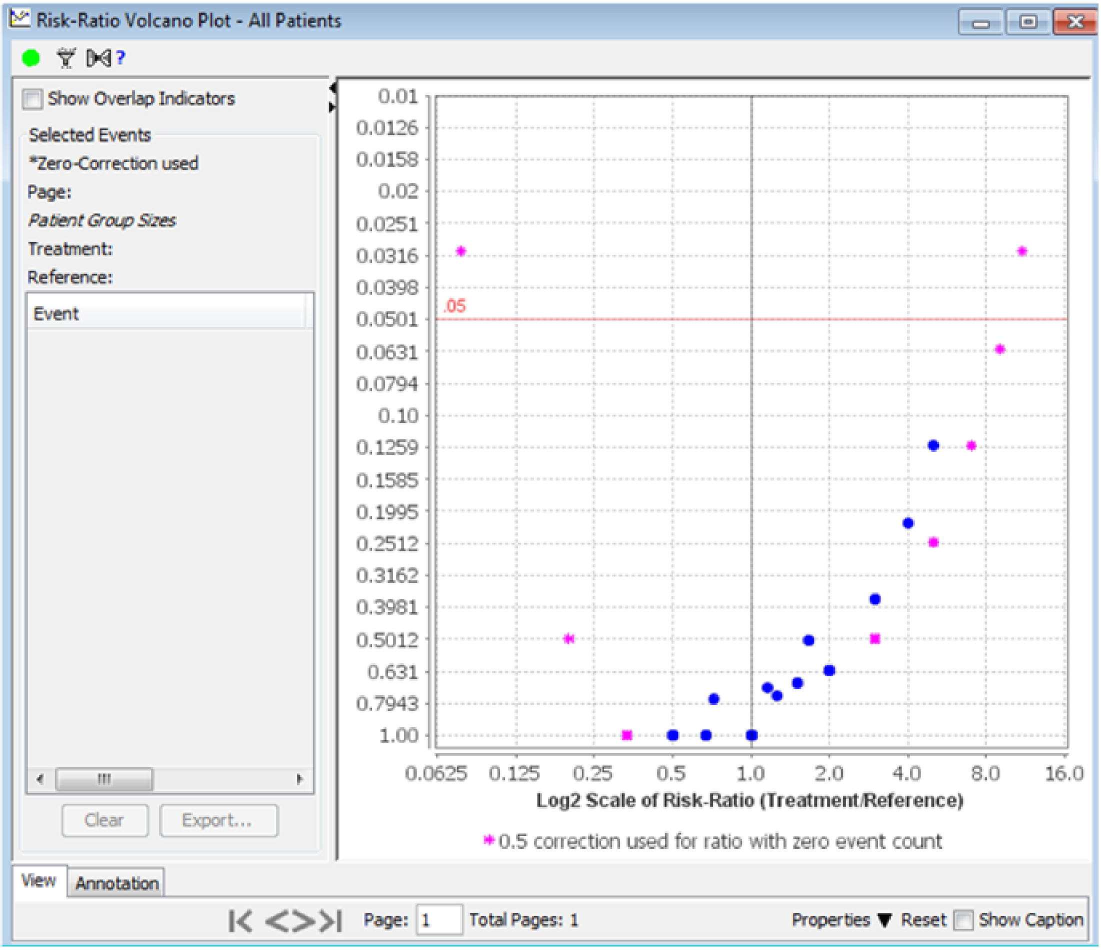
☐ Show Caption

Remember that this is **not a stacked bar graph**. The bars are translucent so you can see one bar that is covered by another, but clicking on a bar always uses the topmost bar – the bar that is drawn in **front of** any bars underneath it. If one bar completely overlaps another, the bar that is overlapped may not be clickable for drill down. However, by hiding some of the BY-variables (e.g., hide females) the overlapped (i.e., covered) bars can be exposed. The checkboxes in the control panel can be used for this purpose.

***Note:*** ***The Risk-Ratio Volcano Plot requires that the R statistical package including the svMisc package be installed in the JRServer environment and that JRServer be configured so that it is informed of R's location in the directory system. Additionally, the user privileges must be set to allow the statistical use of R. The installation of R for JRServer and privilege settings are described in next topic for Installation steps. R performs the statistical computations necessary for this plot. If R is not installed, or the JRServer cannot locate R, or the user privilege is not set to allow the statistical use of R, the menu item for invoking this graph type in the Graph Browser will not be shown and saved Risk-Ratio Volcano plots will not appear in the Object Explorer's tree.***

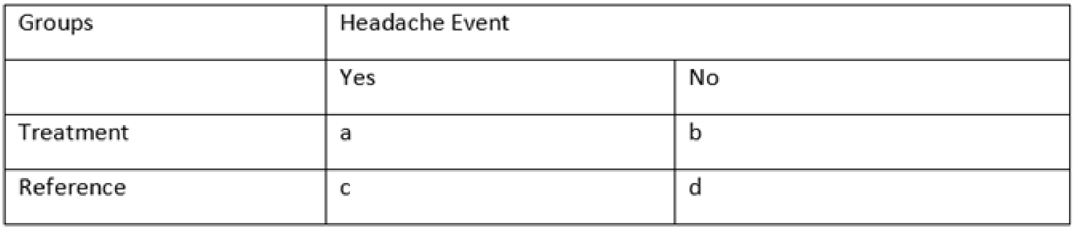
JReview's **Risk-Ratio Volcano Plot** (see Figure 1.) is a type of scatter plot in which each displayed data point represents an event type. The event is typically an "adverse event" such as "headache". It is unlike other JReview scatter plots in that each data point does not represent an observation for an individual patient. This graph is used to compare the relative incidence of events for two treatment conditions (e.g., "Active" vs. "Placebo"). More specifically, the x-value is a "relative risk ratio", and the y-value is the "p-value" resulting from a statistical test based on the number of patients exhibiting the event type in each of the two treatment groups. The "relative risk ratio" is calculated in the same way as it is in the Risk Assessment module. Moreover, the Risk Ratio Volcano Plot may be regarded as a complement to the functionality of the Risk Assessment module.

Figure 1.


Risk-Ratio Volcano Plot - All Patients
☐ Show Overlap Indicators
Selected Events
*Zero-Correction used
Page:
*Patient Group Sizes*
Treatment:
Reference:
Event
Clear
Export...
0.01
0.0126
0.0158
0.02
0.0251
0.0316
0.0398
.05
0.0501
0.0631
0.0794
0.10
0.1259
0.1585
0.1995
0.2512
0.3162
0.3981
0.5012
0.631
0.7943
1.00
0.0625
0.125
0.25
0.5
1.0
2.0
4.0
8.0
16.0
Log2 Scale of Risk-Ratio (Treatment/Reference)
* 0.5 correction used for ratio with zero event count
View
Annotation
Page: 1
Total Pages: 1
Properties ▼
Reset
☐ Show Caption

For the plot, the "relative risk ratio" is the ratio of the probability of an event in one patient group (i.e., a "treatment" group) to the probability of that event in another group (i.e., a "reference" group). In Table 1 below, the Risk Ratio is calculated as (a/(a+b))/(c/(c+d)). A ratio of "1" means that the probabilities for the two groups are identical. A vertical line is draw in the graph to mark where "1" is positioned, which is a "center" value. If the ratio is greater than "1", the data point is displayed on the right half of the graph, and indicates that the relative incidence is higher in the "treatment" group than in the reference group; the higher the probability in the treatment group relative to the probability in the reference group, the further to the right a data point is positioned. A data point positioned in the left half of the graph indicates that the "reference" group's probability is higher that the "treatment" groups probability.

Patient counts for the number of patients in each group having or not having an adverse event type ("headache"). The cells a, b, c, and d, are patient counts. Table 1.



| Groups | Headache Event | |
|---|---|---|
| | Yes | No |
| Treatment | a | b |
| Reference | c | d |

The x-axis is scaled logarithmically with a base of 2. Because a logarithmic value cannot be generated for a zero (ratio) value, and to handle potential divide-by-zero situations, whenever there are no events found for a particular event type (e.g., either "a" or "c" in Table 1. is zero), a "zero-correction" value of 0.5 is added to each term in the ratio. This is a conventional technique to deal with the zero condition in calculating risk ratios. When a zero-correction is applied in calculating a risk ratio, the data point is drawn with a "star" shape and with a distinctive color. ***(Note - that the zero correction does not affect the statistical computations and the resulting p-values).***

The y-axis represents "p-values". The values run from largest (1.0) at the bottom of the axis to the smallest at the top of the axis. The minimum p-value that will be displayed in the plot is **.0001**. Any values less than this minimum are reset to ".0001". Thus, p-values less than or equal to .0001 are shown as "<=.0001". The y-axis is logarithmically scaled with a base of 10. There is a red horizontal line at the .05 p-value, which is the typical value for "statistical significance."

A p-value is calculated for each event type presented in the graph. The p-values are generated as a result of performing a statistical test. Two basic test options are supported: *Fisher Exact Test* and *Chi-Square*. An additional option is *Chi-Square with Yates* correction. The statistical computations are performed on the data shown in the 2x2 Contingency table (see Table 1).

The logarithm of $x$ to *base* $b$, denoted $\log_b(x)$, is the unique real number $y$ such that

$b^y = x$.

For example, as $64 = 2^6$, then:

$\log_2(64) = 6$

The logarithm to base 10 (that is $b = 10$) is called the common logarith and has many applications in science and engineering.

As multiple comparisons, i.e., multiple statistical tests, are being performed, *False Discovery Rate (FDR)* may be a concern in some studies. Three options to adjust the p-values in the light of FDR are offered: *None*, i.e., no adjustment procedure, *Benjamini-Hochberg* procedure, and *Benjamini-Yekutieli* procedure.

Paging is supported in this graph type. *By-Variable* is not supported.

## *Interactivity and selected setting in Volcano Plot*

Hovering over a data point in the graph causes a tooltip to appear. The tooltip lists the event identifiers for the items located at the mouse location.

Data points may be selected in the same manner as in the other JReview scatter graphs – using either mouse clicks or the rubber-banding box. A scrollable table in the left-side panel of the Graph Viewer presents data associated with each of the selected events in the plot. This table is somewhat analogous to the Data Browser. As the user selects different subsets of events in the plot, the data in the table changes. Each selected event item is presented as a row in the table. The columns in the table are the event identifier, the risk-ratio value, the p-value, number of patients in the treatment group with the observed event, and number of patients in the reference group with the observed event. The rows are sorted on the p-value in ascending order, and sorted secondarily on the risk-ratio values. The risk-ratio values where a zero correction has been applied are preceded with an asterisk.

Deselecting all the events in the graph (e.g., by clicking in an empty space) does not remove the current selected set in the table. However, changing the “page” that is in view clears the table. The user may select a row in the table by clicking on the row. ***Only one row at a time in the table may be selected.*** When the user selects a row in the table, the corresponding data item in the plot itself is selected, and all other items in the plot are deselected. Clicking on a row does not change the selected set presented in the table. Selecting an event in the table can help disambiguate overlapping items in the plot and to locate a particular data item.

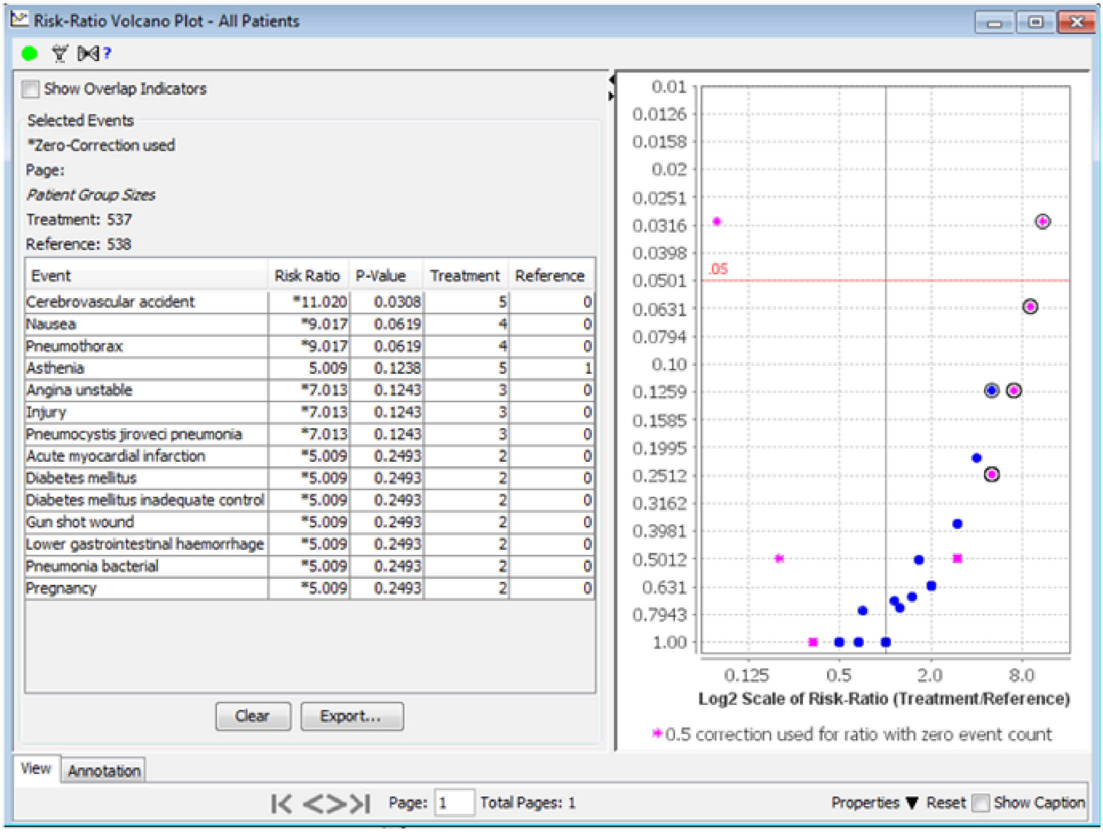
When event items in the plot are selected, either directly in the graph or in the table, there is a resulting “drill-down” operation: the client requests that the server send the list of patients underlying the event, i.e., the patients for whom the event has been observed; this patient list includes those in both the “treatment” and “reference” groups. The patient identifier list is propagated to viewers interested in drill-down updates.

Header information above the table contains data relevant to the selected set in the table: the page name for the page where the selections were made, the number of patients in the “treatment” group and the number of patients in the “reference” group. The patient counts are specific to the page. For example, if the paging variable is “Sex”, the numbers in the “treatment” and “reference” groups may differ for males and females.

As with other JReview scatter plots, a checkbox that turns on the highlighting of overlapping items is provided.

Two buttons are provided below the table. “Clear” clears the contents of the table and deselects all items. ‘Export…” exports the contents of the table to Excel.

Figure 2.



Selected Events

*Zero-Correction used

Page:

*Patient Group Sizes*

Treatment: 537

Reference: 538

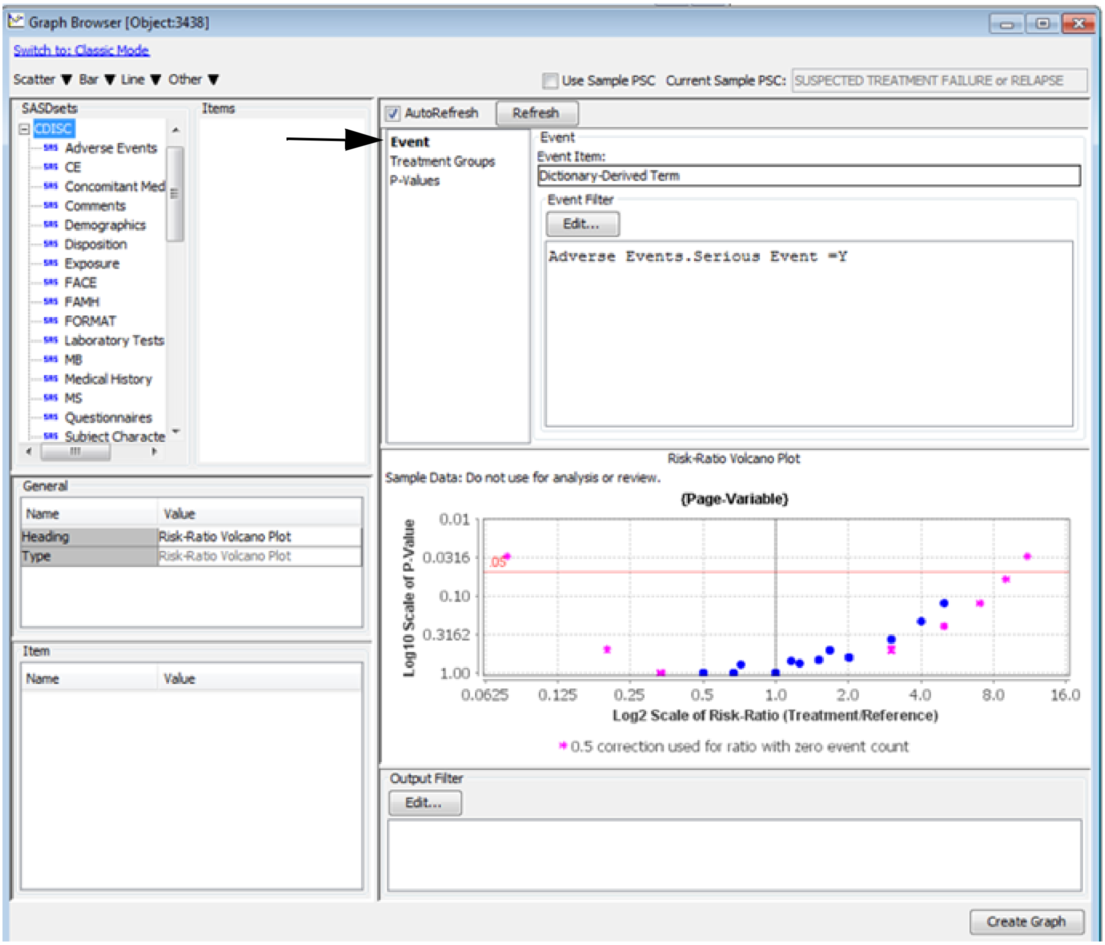
| Event | Risk Ratio | P-Value | Treatment | Reference |
|---|---|---|---|---|
| Cerebrovascular accident | *11.020 | 0.0308 | 5 | 0 |
| Nausea | *9.017 | 0.0619 | 4 | 0 |
| Pneumothorax | *9.017 | 0.0619 | 4 | 0 |
| Asthenia | 5.009 | 0.1238 | 5 | 1 |
| Angina unstable | *7.013 | 0.1243 | 3 | 0 |
| Injury | *7.013 | 0.1243 | 3 | 0 |
| Pneumocystis jiroveci pneumonia | *7.013 | 0.1243 | 3 | 0 |
| Acute myocardial infarction | *5.009 | 0.2493 | 2 | 0 |
| Diabetes mellitus | *5.009 | 0.2493 | 2 | 0 |
| Diabetes mellitus inadequate control | *5.009 | 0.2493 | 2 | 0 |
| Gun shot wound | *5.009 | 0.2493 | 2 | 0 |
| Lower gastrointestinal haemorrhage | *5.009 | 0.2493 | 2 | 0 |
| Pneumonia bacterial | *5.009 | 0.2493 | 2 | 0 |
| Pregnancy | *5.009 | 0.2493 | 2 | 0 |

Page: 1

## *Specifying Risk-Ratio Volcano Plot*

The menu item in the Graph Browser for specifying the Risk-Ratio Volcano Plot is located in the **Scatter menu**. The Graph Browser for this plot is available only in the New Mode. Three screens are used to compose the specification: **Event**; **Treatment Groups**; **P-Values** as illustrated in Figure 3 – 5.

Figure 3. The **Event** screen requires an item that defines the event. Optionally, a filter to refine the definition of the event may be specified.



☐ Use Sample PSC  Current Sample PSC: SUSPECTED TREATMENT FAILURE or RELAPSE

Event

Event Item: Dictionary-Derived Term

Event Filter

Adverse Events.Serious Event =Y

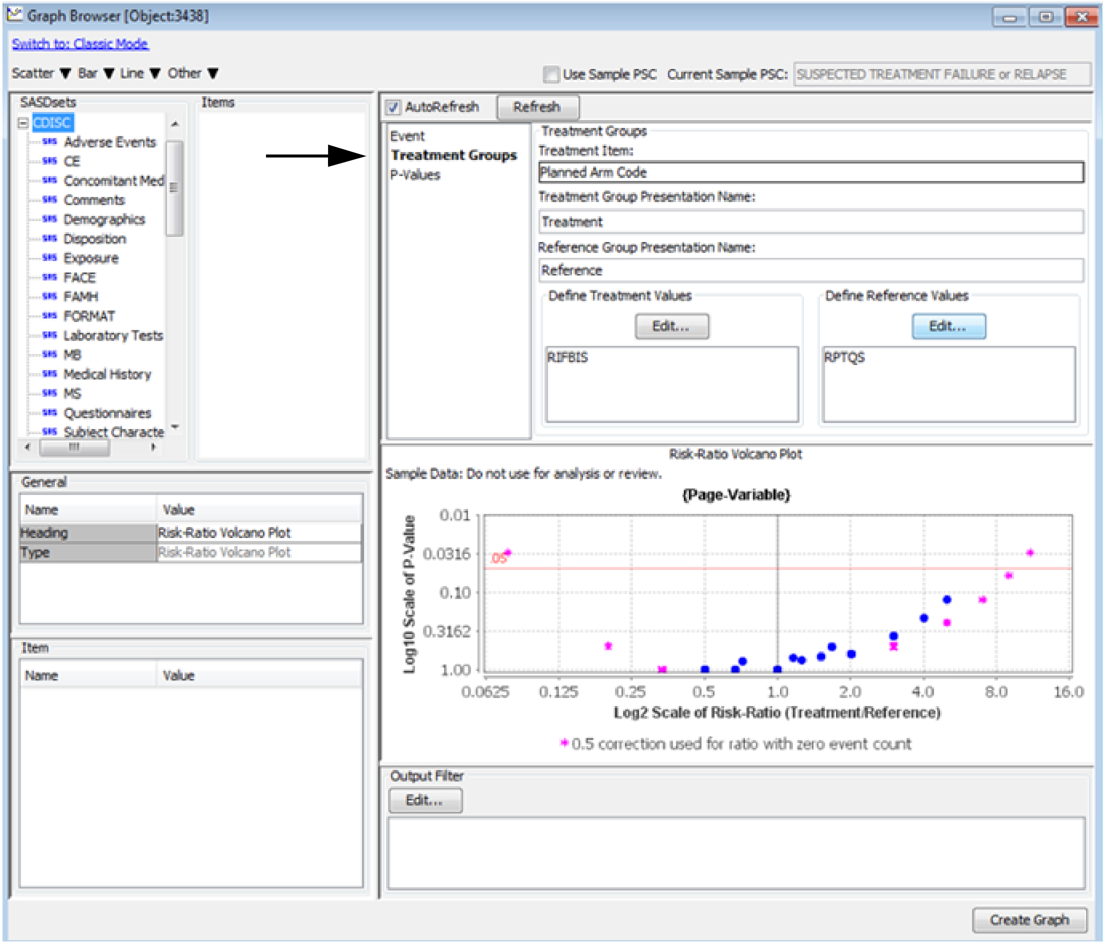
General

| Name | Value |
|---|---|
| Heading | Risk-Ratio Volcano Plot |
| Type | Risk-Ratio Volcano Plot |

Item

| Name | Value |
|---|---|

Figure 4. Treatment Groups



Current Sample PSC: SUSPECTED TREATMENT FAILURE or RELAPSE

| Name | Value |
|---|---|
| Heading | Risk-Ratio Volcano Plot |
| Type | Risk-Ratio Volcano Plot |

Treatment Item: Planned Arm Code

Treatment Group Presentation Name: Treatment

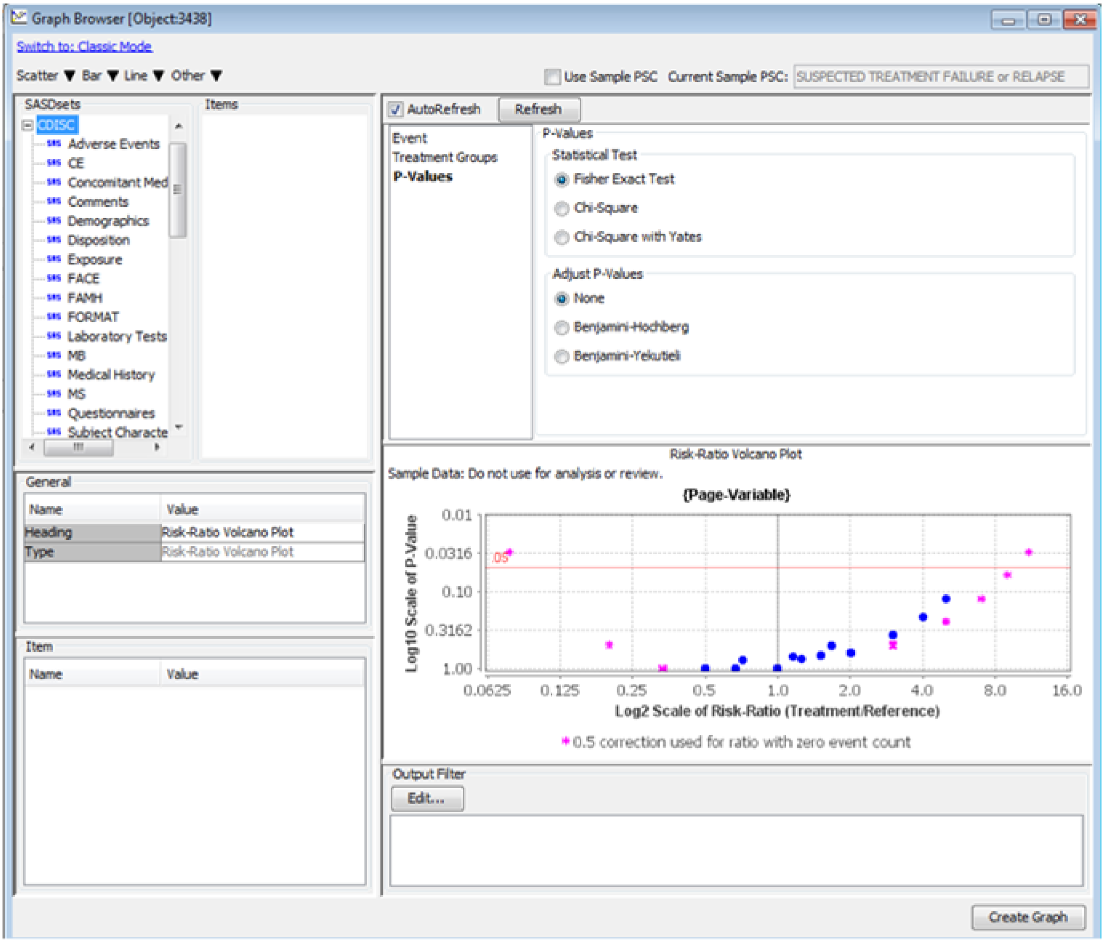
Reference Group Presentation Name: Reference

Define Treatment Values: RIFBIS

Define Reference Values: RPTQS

Sample Data: Do not use for analysis or review.

Figure 5. The P-Values offers a number of statistical options.



General

| Name | Value |
|---|---|
| Heading | Risk-Ratio Volcano Plot |
| Type | Risk-Ratio Volcano Plot |

Item

| Name | Value |
|---|---|

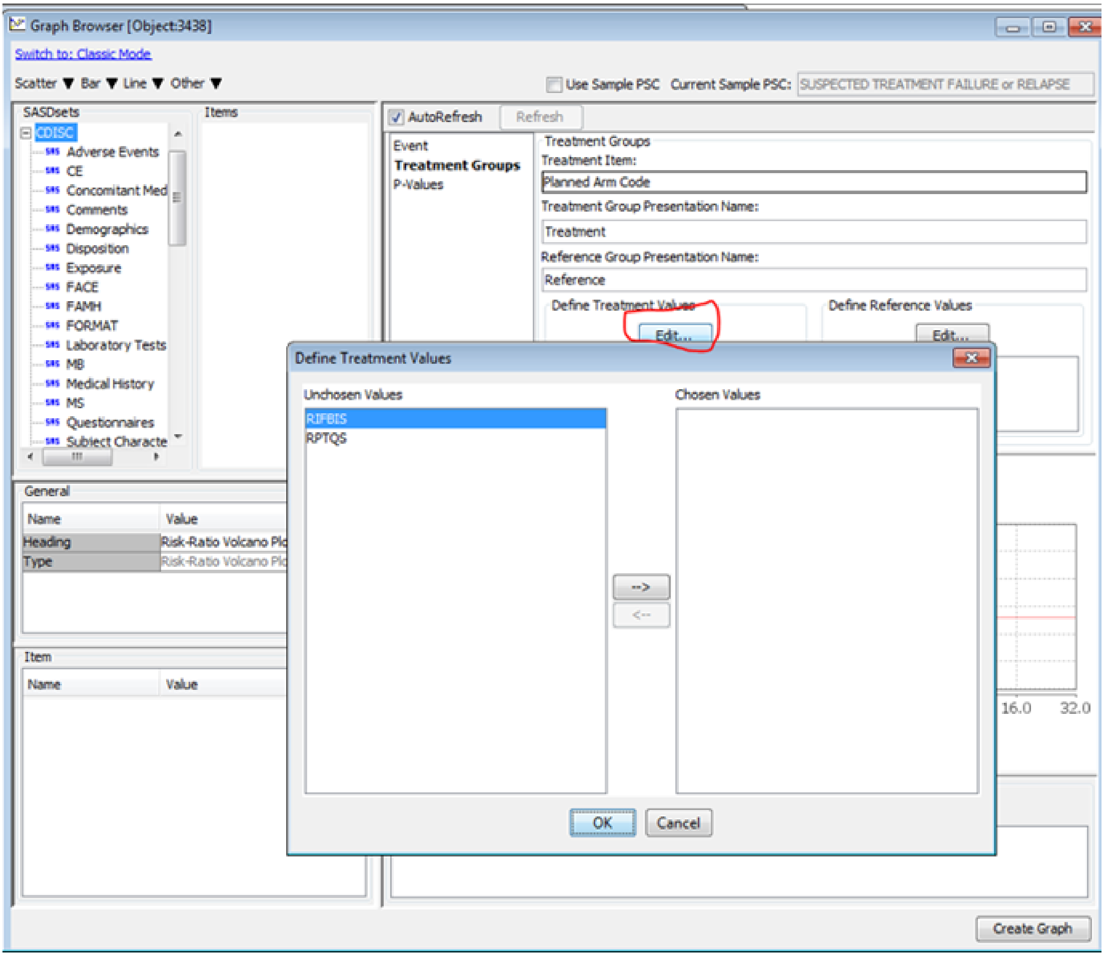
P-Values

Statistical Test
- ● Fisher Exact Test
- ○ Chi-Square
- ○ Chi-Square with Yates

Adjust P-Values
- ● None
- ○ Benjamini-Hochberg
- ○ Benjamini-Yekutieli

The Treatment Groups screen requires an item that defines the Treatment groups. For example, this might be an item that defines the Treatment arms of the study. This screen also requires the user to select “values” of the item that define “Treatment” and “Reference” groups (see Figure 6 and Figure 7). Multiple values may be chosen to define a single group. For a treatment arms example, “high dose” and “medium dose” might both be used to define the treatment arm. The screen also supports (optionally) specifying custom presentation names for the “Treatment” and “Reference” groups. Because multiple values can be used to a define group, it is advantageous for the user to generate a descriptive name for the group rather relying an auto-generated name.

Figure 6.



Graph Browser [Object:3438]

☐ Use Sample PSC Current Sample PSC: SUSPECTED TREATMENT FAILURE or RELAPSE

☑ AutoRefresh

Treatment Groups

Treatment Item: Planned Arm Code

Treatment Group Presentation Name: Treatment

Reference Group Presentation Name: Reference

General

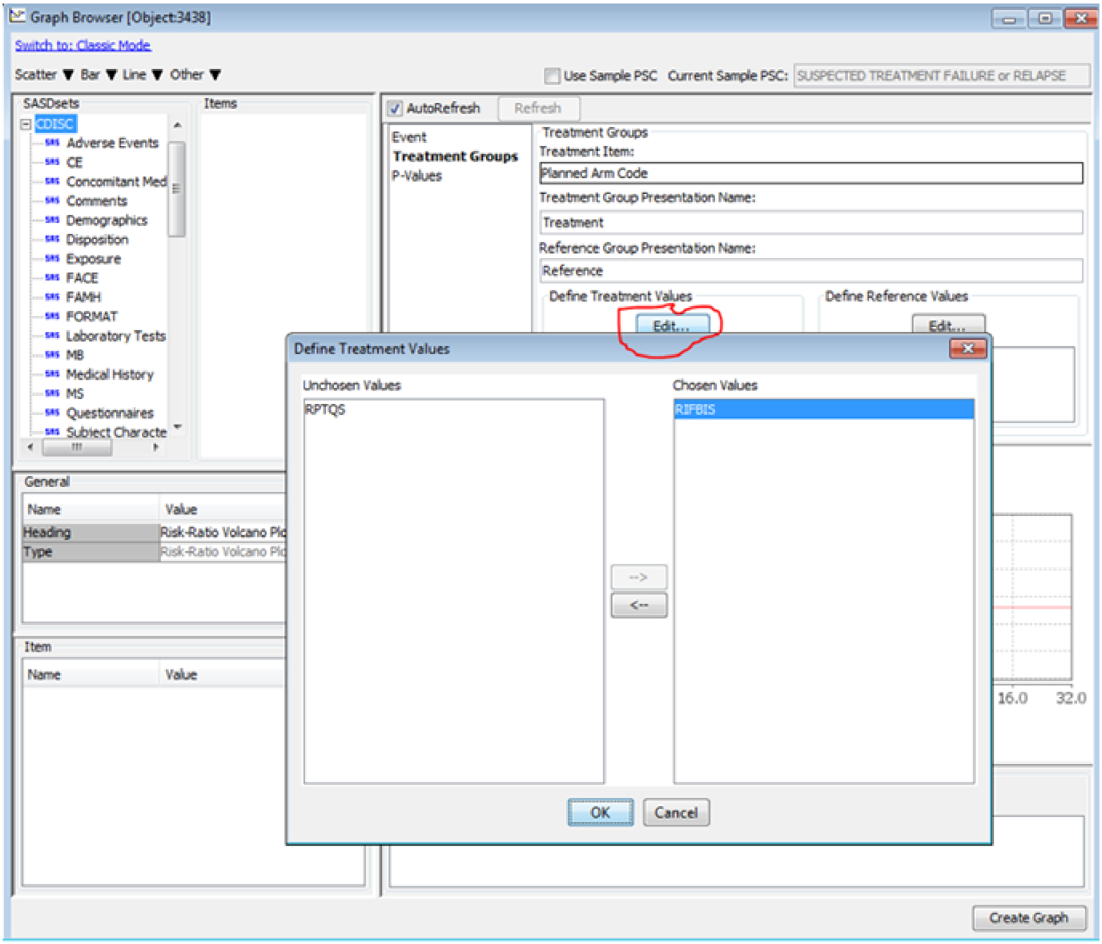
| Name | Value |
|---|---|
| Heading | Risk-Ratio Volcano Plo |
| Type | Risk-Ratio Volcano Plo |

Define Treatment Values

Unchosen Values: RIFBIS, RPTQS

Chosen Values:

Figure 7.



Current Sample PSC: SUSPECTED TREATMENT FAILURE or RELAPSE

Treatment Item: Planned Arm Code

Treatment Group Presentation Name: Treatment

Reference Group Presentation Name: Reference

| Name | Value |
|---|---|
| Heading | Risk-Ratio Volcano Plo |
| Type | Risk-Ratio Volcano Plo |

Unchosen Values: RPTQS

Chosen Values: RIFBIS

## *Installing R for Use with JReview*

***The Risk-Ratio Volcano Plot requires that the R statistical package including the svMisc package be installed in the JRServer environment and that JRServer be configured so that it is informed of R's location in the directory system.***

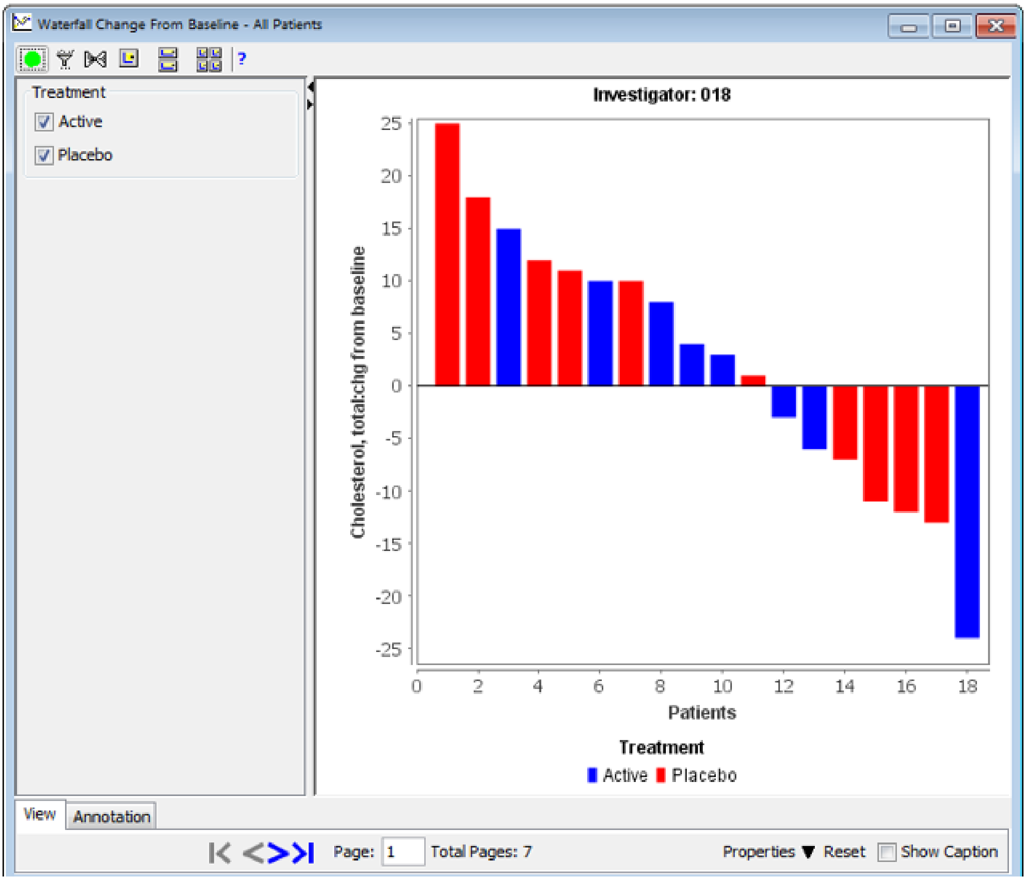
1. Download the most recent version (at least 2.13.0 newer is recommended) of R from **https://www.r-project.org/**
2. Install R. This must be on a drive that the JRserver can access. The further away R is from the server the greater the impact on performance. Optimally both would be on the same drive.
3. There is one R library that needs to be installed. Type the following command in R and execute - install.packages("svMisc"). Now select the location nearest to you for the download.
4. The JReview R scripts must be located in the same directory as the JRserver executable in a file named JR Scripts.
5. In the JRServer configuration file (JRserver.ini) the R directory needs to be added. The format is R=the location of the R executable. EX. R=C:\R\R-3.2.0\bin\R.exe
6. The statistics privilege (presently named SAS Proc Level) must be set to the correct level in IRadmin. There are 3 levels Full, Basic and None. Full will allow the user access to any object that requires R, including statistics based objects. Basic will allow the use of objects that require R, but will not allow the use of objects that have statistics. None will not allow the use of any objects that require R. In addition to the restricted use no saved objects that require a level of access that the user does not have will not be shown.

If R is not installed, the location of R is wrong or is not defined, then all objects and saved objects that require R will not appear.

## Waterfall Change from Baseline Plot

The **Waterfall Change from Baseline plot** is both a bar graph and a detail graph (see Figure 1). A primary use-case for this graph is representing the change in tumor size for a set of individual patients in an oncology study. Each bar in the graph represents the “change from baseline” or “percent change from baseline” value for an individual patient. In other words, the y-axis is a numeric variable item that is specified by the user, and the user may choose either “chng from baseline” or “% chng from baseline” as the item’s function. The values are sorted in descending order. In a typical example, the largest positive value is on the left side of the x-axis, and the value with the largest negative value is on the right side of the x-axis. The x-axis tick labels each displays the count of patients to the left of the tick mark, that is, it is a cumulative count. There are no labels on the bars.

Figure1



Waterfall Change From Baseline - All Patients

Treatment

☑ Active

☑ Placebo

Page: 1 Total Pages: 7

☐ Show Caption

If the value for a patient is zero, no bar is drawn for that patient, but the bar space for that patient is still allotted; thus, the area where the values cross from positive to negative may be shown as a gap in the sequence of bars. Note that “zero” values may be eliminated from the graph by using an Output Filter (e.g., “ItemABC[chng from baseline] <> 0”).

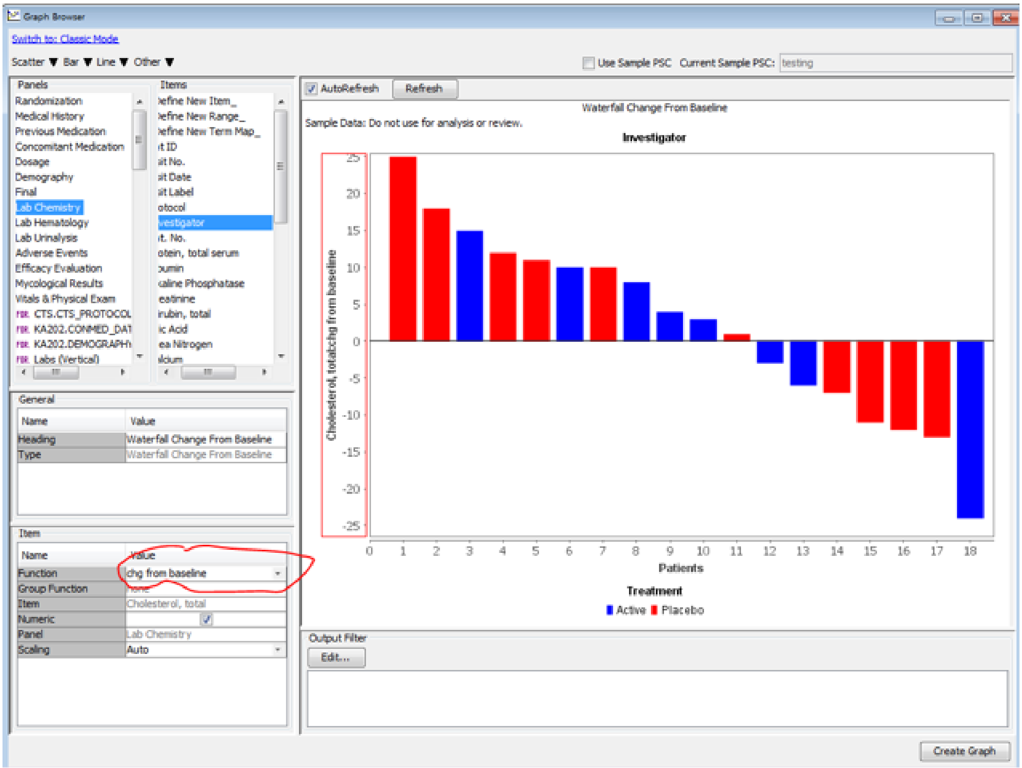
The Waterfall graph supports drill-down, by-variables, and paging. A tooltip displaying the Patient Identifier and the Y-axis value for a bar is shown when the mouse hovers over a bar.

The Waterfall’s specification screen is accessed from the New Mode Graph Browser’s “Bar” graphs menu. This graph type is not supported in Classic Mode.

The Graph Browser for the Waterfall graph is shown in Figure 2. The user defines the Y-axis by dragging an item from item panel and dropping it on the graph’s Y-axis drop zone. Only two item functions are supported: “chng from baseline” and “% chng from baseline.” The Y-axis must be a numeric variable. Range items are disallowed for the Y-axis, and the item must support the “chng from baseline” and “% chng from baseline” functions. There is no “Group” function for this variable.

The user does not specify an X-axis item.

Figure 2



Sample Data: Do not use for analysis or review.

General

| Name | Value |
|---|---|
| Heading | Waterfall Change From Baseline |
| Type | Waterfall Change From Baseline |

Item

| Name | Value |
|---|---|
| Function | chg from baseline |
| Group Function | None |
| Item | Cholesterol, total |
| Numeric | ☑ |
| Panel | Lab Chemistry |
| Scaling | Auto |

## *Sunburst Graph*

The **Sunburst Graph** is a visualization of tree-structured data. It is also sometimes referred to as a “multilevel pie plot”. Each level of the hierarchy is a ring in the graph. The innermost ring is the highest level in the hierarchy, and the outermost level is the lowest level in the hierarchy. In terms of use cases, it is often considered as an alternative to the Tree-Map graph. The Sunburst Graph provides a clearer representation of the intermediate levels in the hierarchy, although it is less compact than the Tree-Map.

The Sunburst Graph is divided into “sectors”, which is a somewhat similar to a conventional pie chart. “Nodes” in the tree data are represented by sectors in the Sunburst graph. A sector is further subdivided into “sub-sectors”, each representing a node lower in the hierarchy. The size of the sector, i.e., the size of the angle in the circular graph, is proportional to the value (e.g., Adverse Event counts) of the associated node. Colors are assigned to the sectors of the innermost ring, and these colors are “inherited” by the sub-sectors.

In JReview, the values for lowest level sectors typically corresponds to summary data found for variable such as the Adverse Event counts. The value for each higher-order sector (i.e., sectors in the intermediate and innermost rings) is calculated by ***summing*** the values of its immediate sub-sectors.

Figure 1 illustrates an example Sunburst Graph. The hierarchy levels from top-to-bottom are “Country”, “Age Groups”, and “Sex”. The values are Adverse Event counts. Each country’s sector is displayed in a different color.

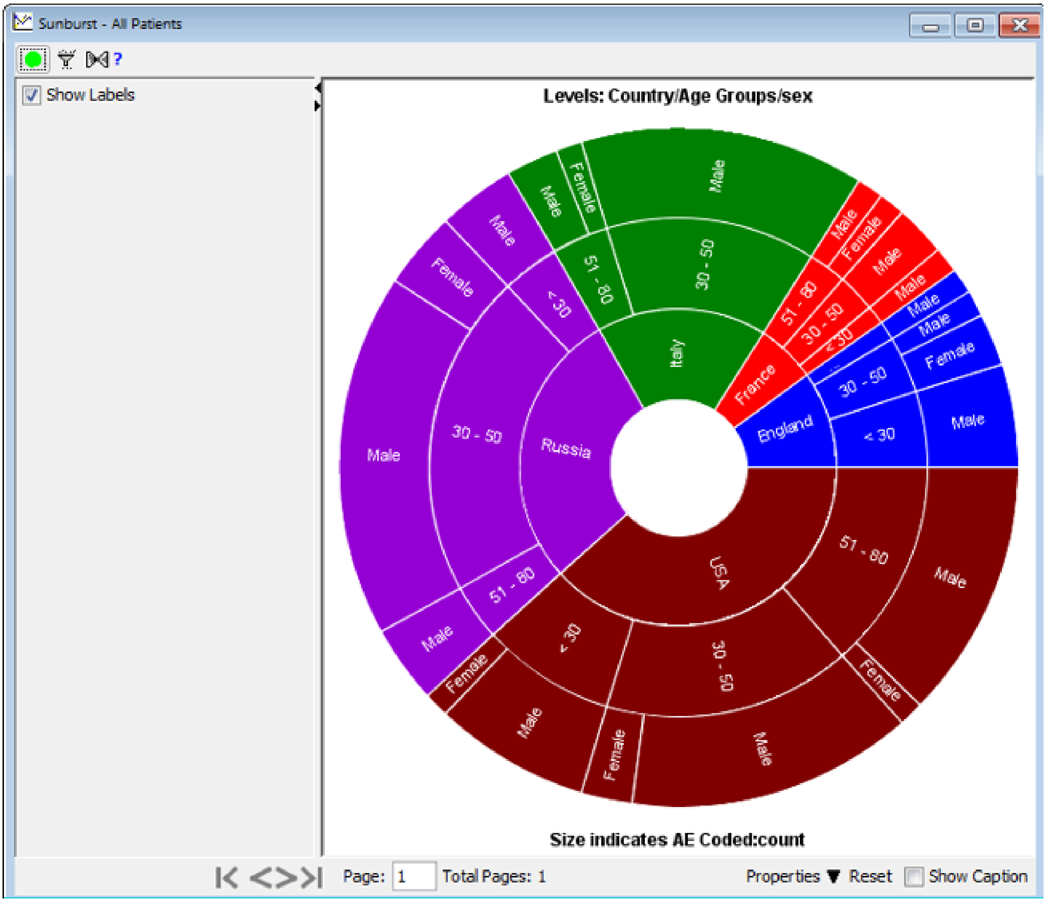
A label is drawn for each sector. If the label does not fit within its sector, the label may shortened and an ellipsis (“…”) added. If the shortened label does not fit, then no label is drawn for the sector. A checkbox option is provided to toggle the visibility of all the labels.

In addition to labels, a tooltip will appear if the user “hovers” the mouse over a sector. The tooltip displays the name of the sector and its value.

A sector will be highlighted as the mouse moves over it.

Clicking on a sector initiates JReview’s standard *“drill-down”*. The drill-down operates in a way that is similar to other Summary graphs.

Figure 1



☑ Show Labels

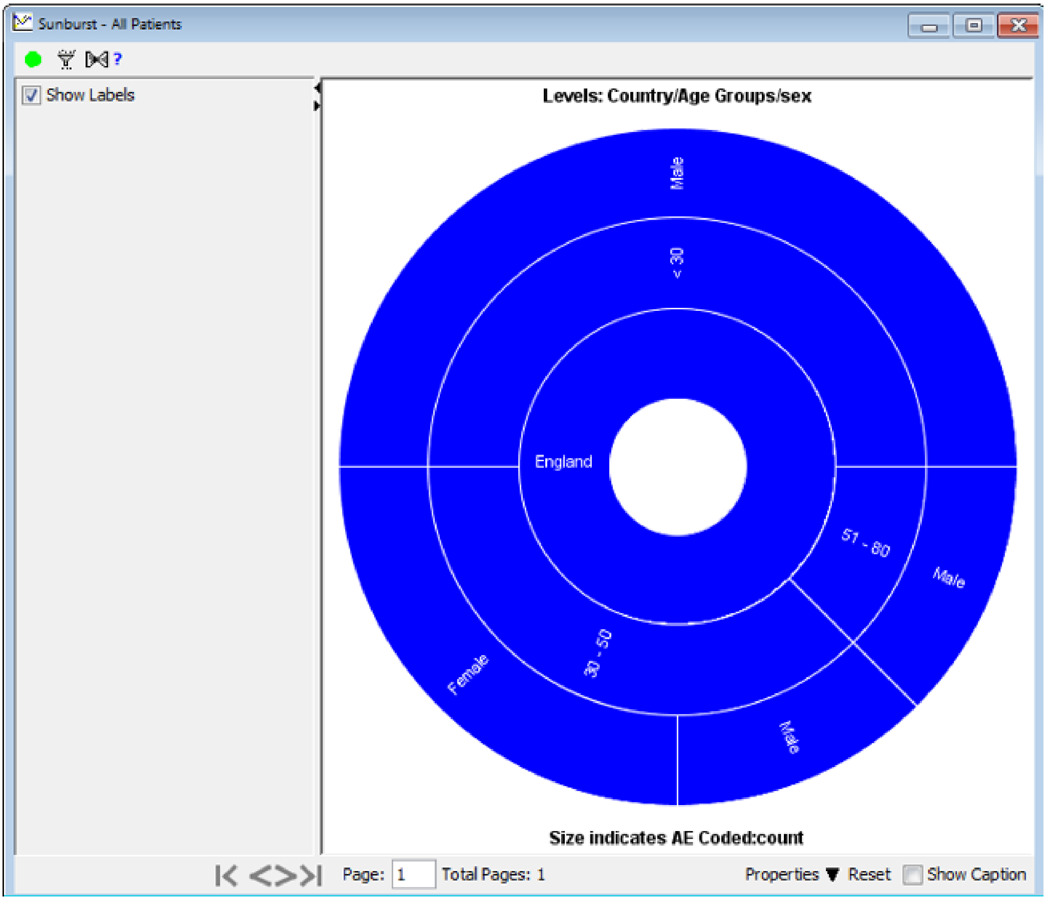
Page: 1 Total Pages: 1

☐ Show Caption

Figure 2 illustrates the graph after “zooming.” The user can zoom into a sector; the zoomed sector becomes the innermost ring of the graph. To zoom, the user may double click on a sector or use the popup context menu while locating the mouse over a sector. The popup menu offers the following zoom options: “zoom-in”, “zoom-out”, and “view all”. The “zoom-out” option zooms out to one level above the zoomed in sector – that is, to the parent node in tree. “View-All “displays the top level view, i.e., the entire graph is displayed. Double clicking on the center disk area results in a zoom-out operation.

The property customization editor can be used to customize the graph’s subtitle text, subtitle font, and label font. The sector colors may also be customized.

Paging, By-variables, and Annotations are ***NOT supported*** for this graph type.
Figure 2



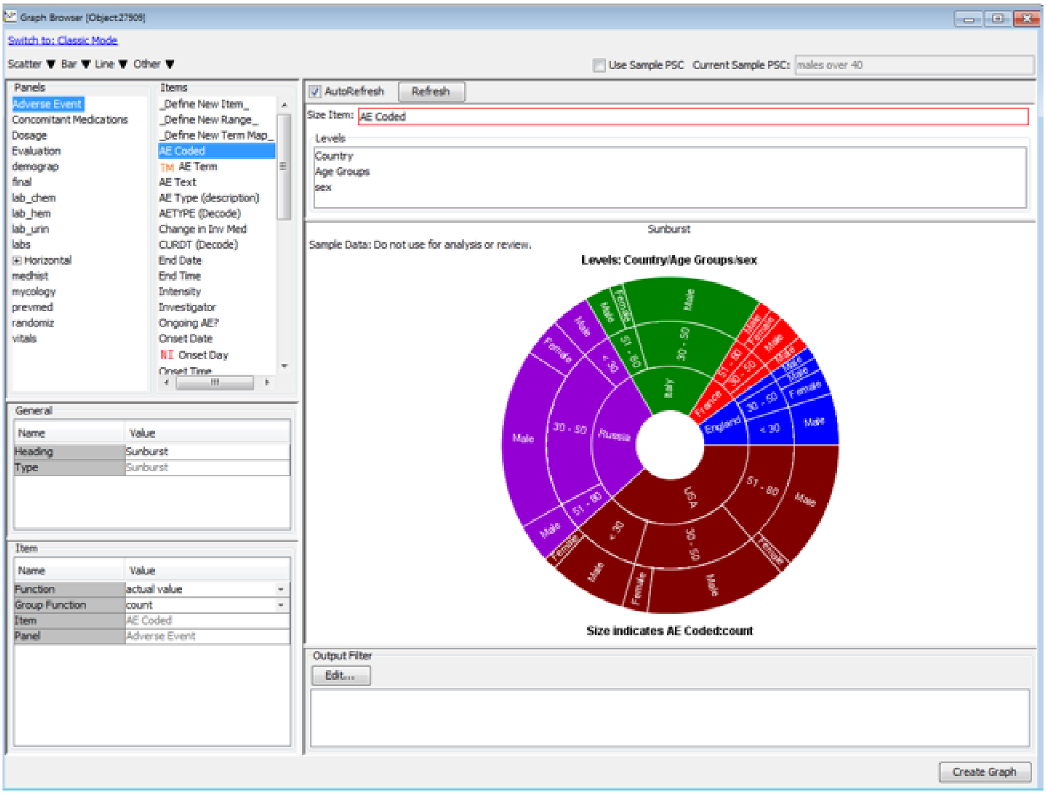
## *Define Sunburst Graph*

A Sunburst Graph is defined in a New Mode Graph Browser. (A Classic Mode Browser for this graph is not supported). The Sunburst Graph Browser is illustrated in Figure 3 below.

The Sunburst graph browser controls are a subset of those found for the TreeMap graph. Using drag-and-drop, the user chooses the variables that define the hierarchy "levels"; each level is defined by a different variable. These variables are typically "category" variables such as Country, Site, Age Group, and Sex. In addition, the variable that defines what values are being summarized (e.g., Adverse Event Counts) must be specified in the Size Item field, which is populated through drag-and drop.

When ***patient counts*** are used for the Size Item, there is no guarantee that the same patient is not counted multiple times as the data sums are calculated at the upper levels in the hierarchy. For example, if the same patient contributes to counts shown in multiple sectors in the outer ring, and these sectors represent nodes that are descendants of the same node represented in the innermost ring, the patient count values for the sector in the innermost ring may not be a count of ***unique*** patients. When the interest is in counts of unique patients, the chosen levels variables should divide the patients into mutually exclusive categories.

Figure 3



Graph Browser [Object:27909]

Use Sample PSC Current Sample PSC: males over 40

Size Item: AE Coded

Levels
Country
Age Groups
sex

Sunburst

Sample Data: Do not use for analysis or review.

**Levels: Country/Age Groups/sex**

**Size indicates AE Coded:count**

General

| Name | Value |
|---|---|
| Heading | Sunburst |
| Type | Sunburst |

Item

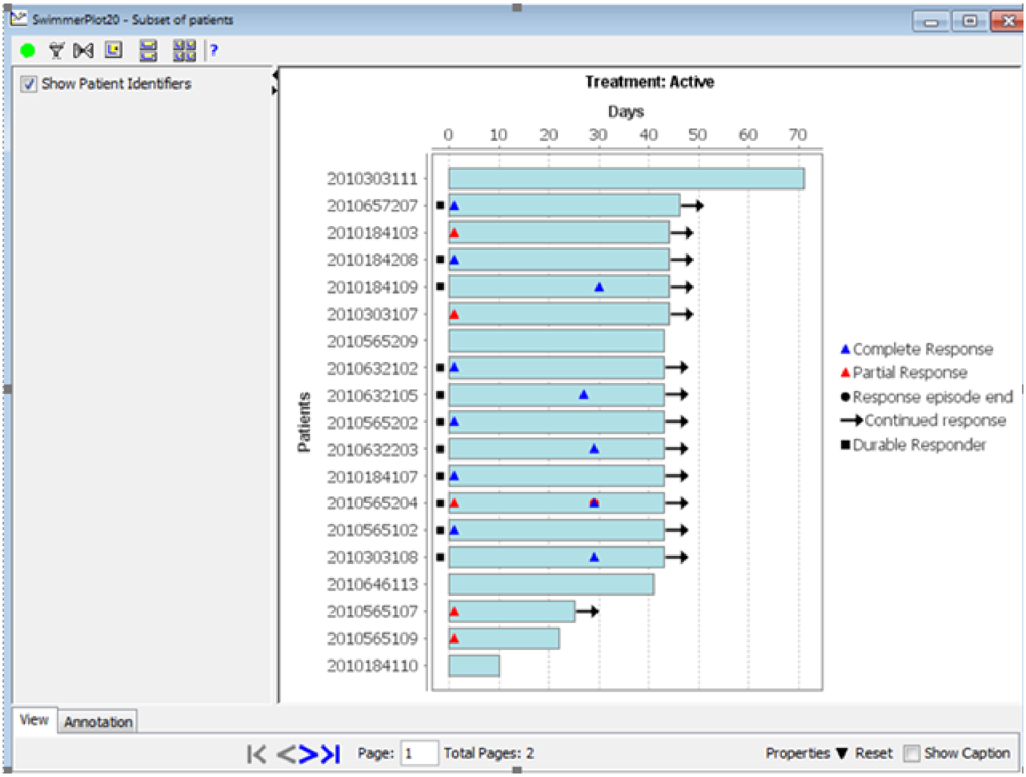
| Name | Value |
|---|---|
| Function | actual value |
| Group Function | count |
| Item | AE Coded |
| Panel | Adverse Event |

## Swimmer Plot

The Swimmer Plot is a type of bar graph used in oncology studies where a relatively small number of patients appear in the graph.  The JReview version approximates the graphical conventions found for this plot.   (see, **https://www.pharmasug.org/proceedings/2014/DG/PharmaSUG-2014-DG07.pdf)**

Each row in the plot represents a single patient. The length of the bar indicates treatment duration.  Superimposed on the bar are start and end response-episode markers.  “Complete Response” and “Partial Response” are examples of such episodes.  A triangle is used as an episode start symbol and a solid circle is the end-of-episode symbol. Each episode type is assigned a different color. The bar color is a BY-variable value in JReview terminology; typically, this value is a patient category such as baseline cancer stage.

“**Show Patient Identifiers**” option is available in the Swimmer Plot.



☑ Show Patient Identifiers

Page: 1 Total Pages: 2

There are two other symbols that appear in this plot. A small rectangle is placed at the left side of a row to indicate that the patient is a ***Durable Responder***. The user specifies the criteria for a patient being a durable responder in terms of the length of a selected episode type. For example, a “durable responder” might be defined as a patient who has a “complete response” episode that is at least 6 months in duration.

A right arrow at the end of the treatment duration bar indicates that a response episode continues beyond either the study period or, optionally, the treatment duration period for that patient: ***Continued Response***. For a Continued Response, there is no end point for the episode.

Note that the rows are not labeled with patient identifiers. This appears to be a “convention” for this plot type in the literature. ***However, tool-tips are available in JReview.***

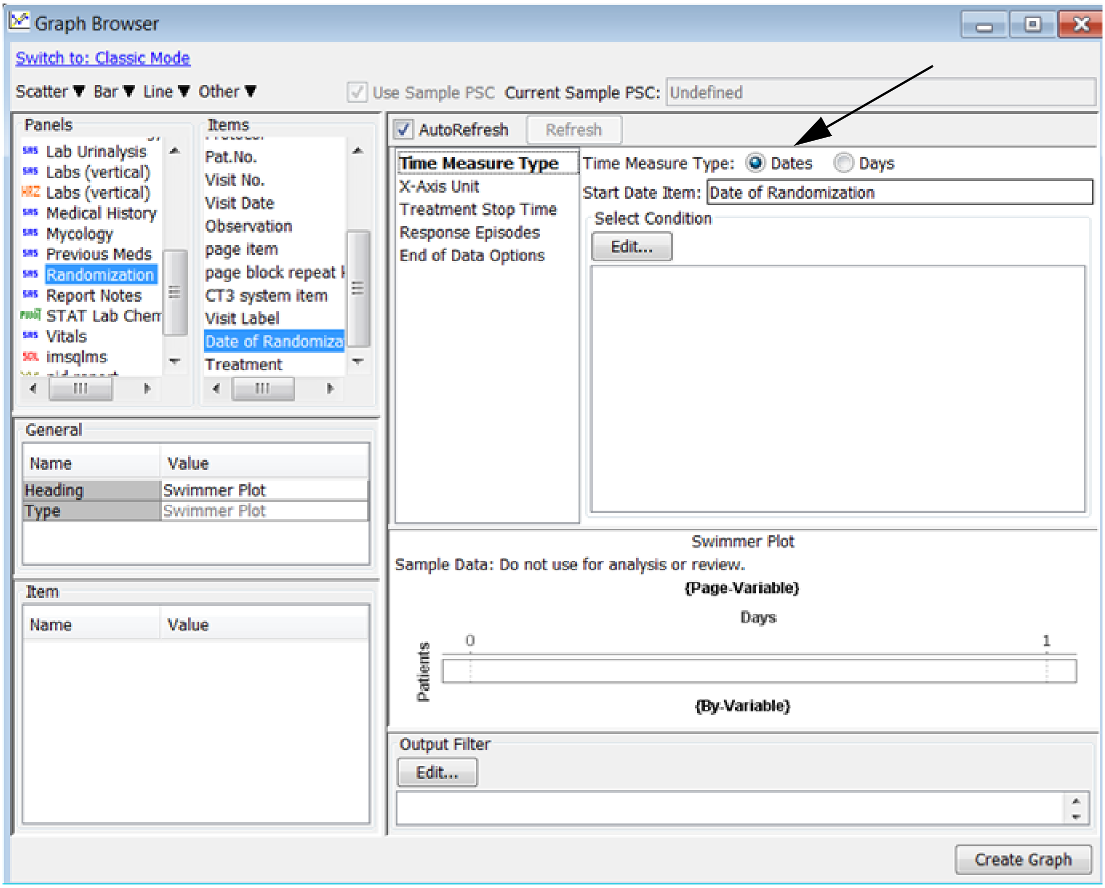
Paging and drill-down are supported.

## *Define Swimmer Plot*

The Swimmer Plot Graph Browser is accessed from a menu item in the New Mode Graph Browser’s Bar Graph menu. Like the Napoleon’s March and several other JReview graphs, the Swimmer Plot’s horizontal axis is time, and thus shares some definitional aspects with these other graphs such as Start Time, the time axis units, and the Date vs. Day modes. The Swimmer Plot Graph Browser is only available in New Mode.

The By-variable and the Paging items can be specified using the drag-and-drop operation directly on the Preview plot. There are five part drag-and-drop forms to specify the remainder of the parameters.

1. Use the **Time Measure Type form** to enter **Start Date Item** to specify the treatment start date and the Date or Days mode.



☑ AutoRefresh

Time Measure Type: ● Dates ○ Days

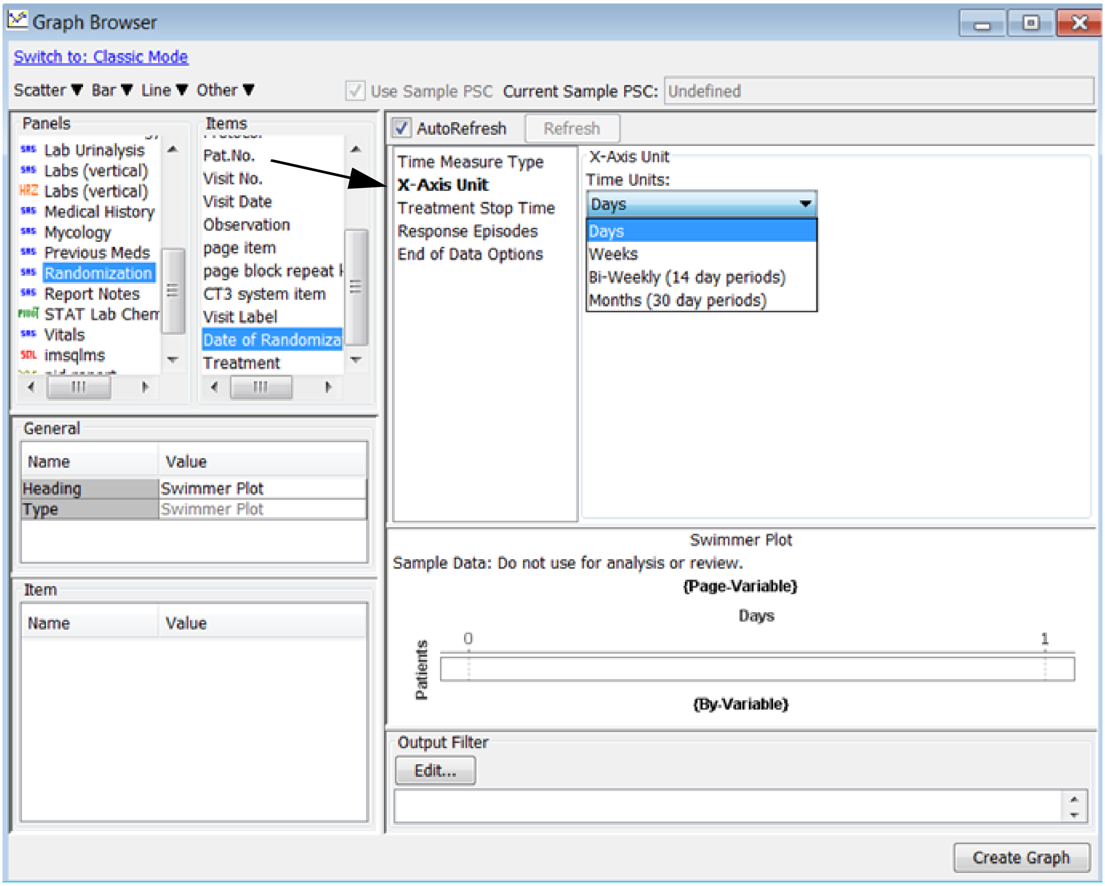
Start Date Item: Date of Randomization

| Name | Value |
|---|---|
| Heading | Swimmer Plot |
| Type | Swimmer Plot |

Swimmer Plot

Sample Data: Do not use for analysis or review.

2. Use the **X-Axis Unit form,** to select from the **Time Units** combo-box a choice for the horizontal axis time units: Days, Weeks, Bi-Weekly, or Months.



☑ Use Sample PSC Current Sample PSC: Undefined

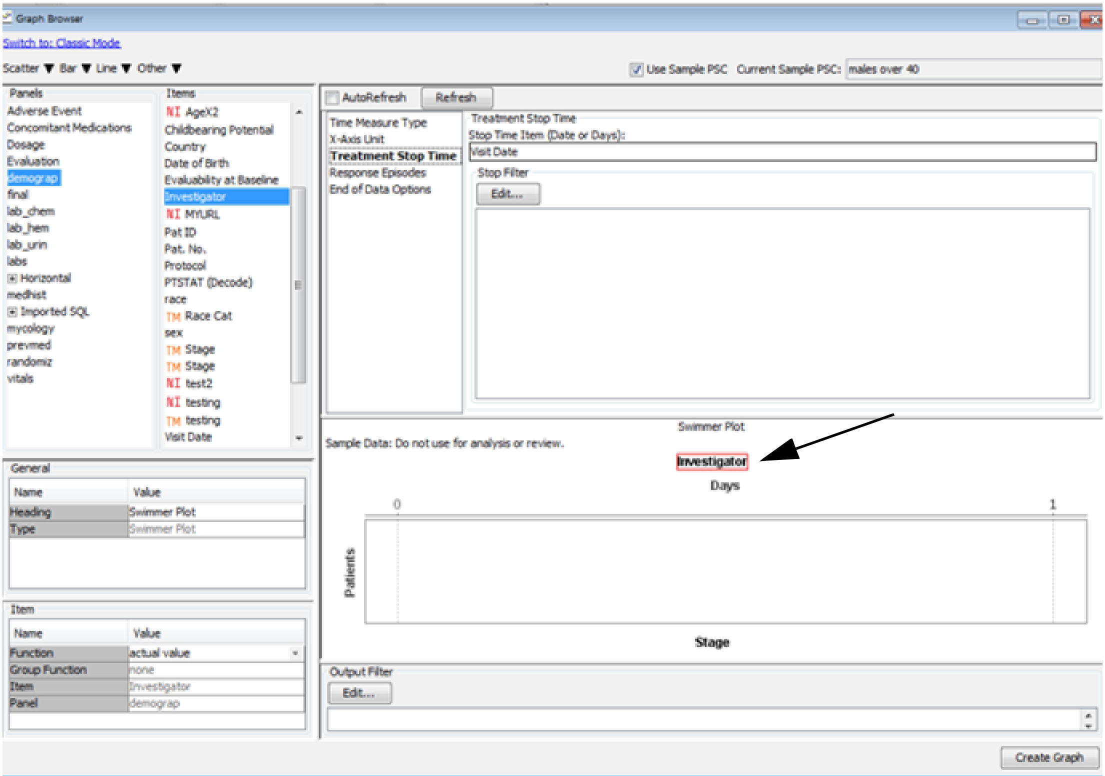
Time Units: Days

| Name | Value |
|---|---|
| Heading | Swimmer Plot |
| Type | Swimmer Plot |

Sample Data: Do not use for analysis or review.

3. Use the **Treatment Stop Time form** to specify when the treatments ends. For example, Stop date for Dosage or Visit Date from Final panel would be another option.

   Optionally, enter a **Page By item**.



☑ Use Sample PSC  Current Sample PSC: males over 40

☐ AutoRefresh

Treatment Stop Time

Stop Time Item (Date or Days): Visit Date

General

| Name | Value |
|---|---|
| Heading | Swimmer Plot |
| Type | Swimmer Plot |

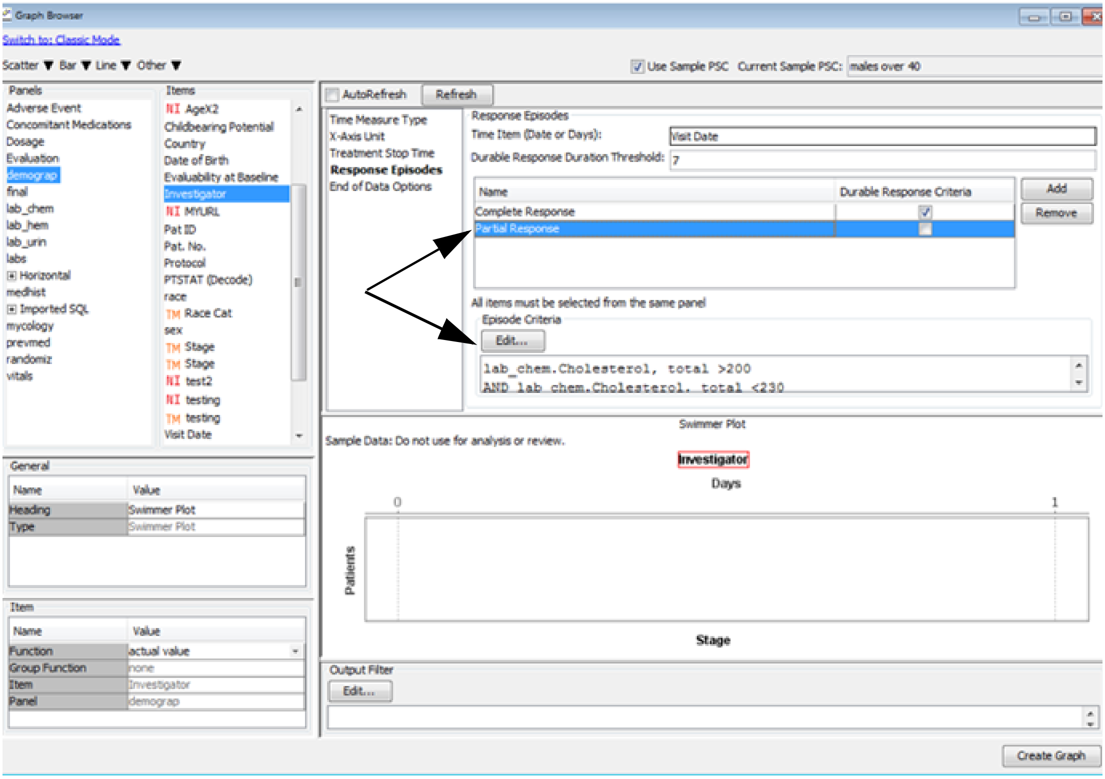
Item

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | Investigator |
| Panel | demograp |

4. Use the **Response Episodes form** to define the episode types, which episode, if any, are to be used in the Durable Responder definition, and the time item (date or days) for the episodes. At least one episode must be defined. The Add button adds an episode to the Episodes table. The episodes can be reordered using drag-and-drop. The Remove button deletes selected episodes. The user provides a name for the episode by typing into a cell in the first column. A default name is initially provided. Duplicate names are not permitted. The checkbox in the second column allows the user to choose which episode(s) is (are) used for determining a durable response. A single numeric text field external to the episodes table is used to specify the minimum duration, i.e., threshold, of a durable response.

When a single row is selected in the table, a ***required*** "filter" component is displayed. This filter is used to define the criteria of an episode type. For example, the filter might specify the size of a tumor or a flag value for example, Complete Response ("CR"). A filter criteria ***is required*** for each added response episode.

If more than one episode is selected as part of the durable response calculation, JReview determines that there is a durable response if any of the selected episodes meet or exceed the defined minimum duration of a durable response.



☑ Use Sample PSC Current Sample PSC: males over 40

Response Episodes

Time Item (Date or Days): Visit Date

Durable Response Duration Threshold: 7

| Name | Durable Response Criteria |
|---|---|
| Complete Response | ☑ |
| Partial Response | ☐ |

All items must be selected from the same panel

Episode Criteria

```
lab_chem.Cholesterol, total >200
AND lab_chem.Cholesterol, total <230
```

Sample Data: Do not use for analysis or review.

General

| Name | Value |
|---|---|
| Heading | Swimmer Plot |
| Type | Swimmer Plot |

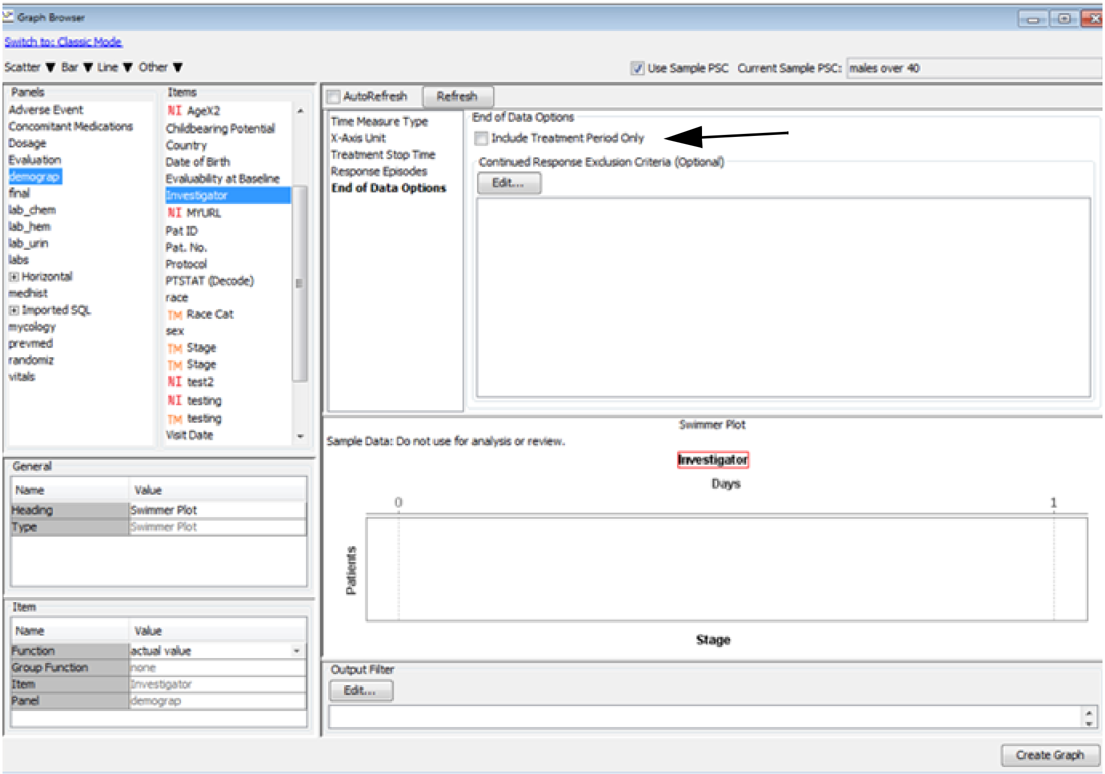
Item

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | Investigator |
| Panel | demograp |

5. **End-of-Data Options form** is used to define the data endpoint for a patient. By default, when determining a Durable Responder or Continued Response, data beyond the defined end-of-treatment, e.g., follow-up data, is also included in the analysis. A checkbox in this form allows the user to constrain the analysis to the treatment period only.

For continued response and durable responders; the check box is related to what date is used. If the box is checked then only data that exists between the start and stop date will be used. In other words if there is data for a patient which has a date greater than the stop date it is not used to calculate the durable responder and the continuous response. When the box is un-check is the default), then all data that is greater than the start date is used for these calculations. This does not mean however, that these data points will be displayed on the graph. Only data that exists between the start and stop dates will be displayed.

A filter component in this form permits the users to further refine the definition of “end-of-data” for the Continued Response. The user may set exclusion criteria that when met will result in a Continued Response arrow not being displayed for that patient. For example, the criteria may include one for “Withdrew from Study” or “Changed Treatment Regimen” which when occurring, preclude a Continued Response status.



☑ Use Sample PSC  Current Sample PSC: males over 40

☐ AutoRefresh

☐ Include Treatment Period Only

Sample Data: Do not use for analysis or review.

General

| Name | Value |
|---|---|
| Heading | Swimmer Plot |
| Type | Swimmer Plot |

Item

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | Investigator |
| Panel | demograp |

The **Continued Response Exclusion Criteria** is an ***optional*** field. To calculate the continued response, JReview determines whether or not the patient is in an episode of remission at the end of treatment. Although this may be true, there could be certain situations in which the patient would still not be considered continued response. So this field is used to define events or filter criteria which would prevent a patient from being considered continued response. For instance, withdrawn from study (final reasons for discontinuation and choose the reasons you wish to use). So being this is an optional field, if nothing is specified the server will decide if it is continued response based solely on the last available data point.

Here is a description from a customer about the continued response, for how they would use this plot type.

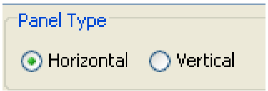
***"Disease response is evaluated on a regular basis. Once a response has started, disease response will be performed every 6-12 weeks (depending on protocol) until the patient stops responding (experiences progressive disease / relapsed disease), starts subsequent anticancer treatment, withdraws consent, or discontinues study participation for other reasons. The "continuing response" arrow should be used in cases when no criteria for end of response have been met. Triggers (event or censor) would be same as for a PFS curve."***

# Defining a graph specification - Classic Mode

## *Creating a graph specification*

Specify the contents of a graph by applying the same method that you used to build the patient selection criteria.

1. Select a Graph Type.
2. Select a Graph Style.
3. Optionally, select Panel Type as Horizontal or Vertical data tables, applicable to all 2D Scatter Plot type.



Panel Type

● Horizontal ○ Vertical

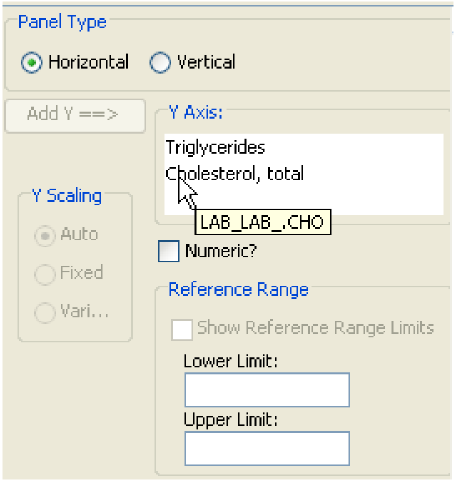
4. Optionally, click on the Numeric checkbox below each axis choice; to allow control whether an item is to be understood as numeric, or character when plotting. This will affect sorting on the output display.
5. Select a panel and item with the appropriate function for the item.
6. Depending on the graph type and style selected, click the appropriate graph axis button to add the item to the graph specification.

   For example, click to add the selected item to the Y-axis on the right side of the Graph Browser window.
7. Enter a Add BY variable to group the data (optional).
8. Enter a Page BY variable (optional).
9. Enter a Graph Heading or default the selected graph style.

   The graph heading displays either ‘All Patients’ or ‘Subset’ if a patient selection criteria was entered. If you modify the graph heading the patient population status of either ‘All Patients’ or ‘Subset’ still displays.
10. Click Create Graph.

## *Show Details*

The **Show Details** feature can be used after you have added items to your graph specification. Simply the hold mouse over the item in the graph definition to view it’s source contents.



● Horizontal ○ Vertical

Triglycerides
Cholesterol, total

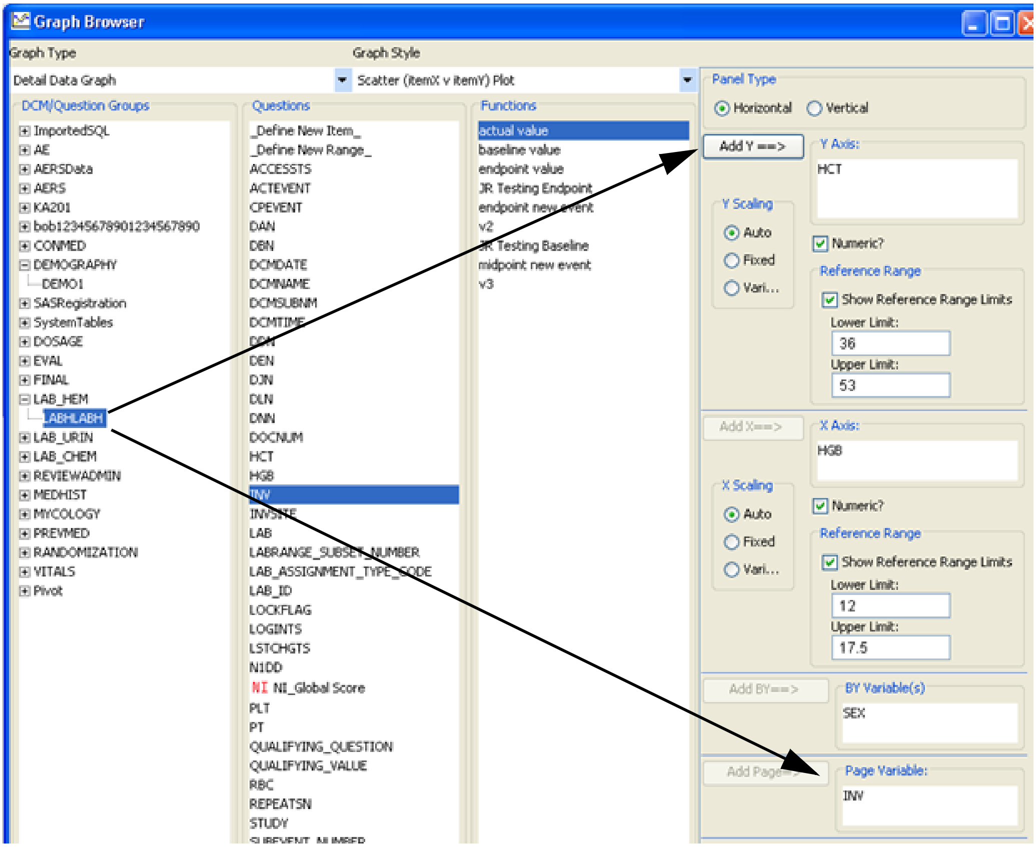
LAB_LAB_.CHO

☐ Numeric?

☐ Show Reference Range Limits

## *Change graph specifications*

1. To change the graph specifications you defined:
   a. Click on the Y-axis or X-axis to be deleted.
   b. Click ✂ or from the **Edit** menu select **Cut**.
   c. If you want to clear the graph specifications entirely, click 🗋.



Graph Type: Detail Data Graph

Graph Style: Scatter (itemX v itemY) Plot

Panel Type: ● Horizontal ○ Vertical

Y Axis: HCT

Y Scaling: ● Auto

☑ Numeric?

Reference Range: ☑ Show Reference Range Limits

Lower Limit: 36

Upper Limit: 53

X Axis: HGB

X Scaling: ● Auto

☑ Numeric?

Reference Range: ☑ Show Reference Range Limits

Lower Limit: 12

Upper Limit: 17.5

BY Variable(s): SEX

Page Variable: INV

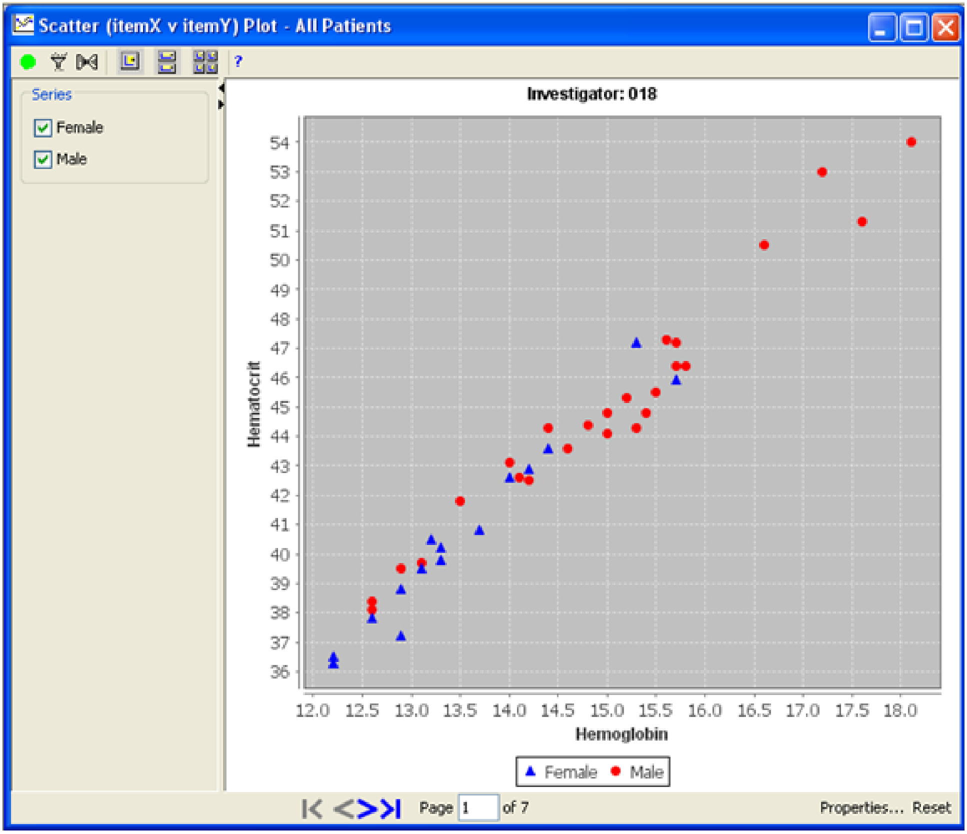
## *Page BY variable*

When you apply a Page variable item such as investigator which may be common to most of your panels, select the investigator data item from the same panel as your axis items. In this example, the lab items and investigator were selected from the Lab Hematology panel.

This will avoid creating complex outer joins or possible discrepancies where the Page variable item may be missing in a particular panel.

***Note: Select 2D graphs in Detail Data Graphs for Scatter Plots and Summary Graphs for 2D Barcharts support the Add Page variable.***

The Page By item variable selected in this example for Investigator is displayed in the header and the page number in the footer.



## *X and Y scaling*

The X-axis and Y-axis scaling on the graph browser screen only appears when line charts or 2D bars are the selected graph styles.

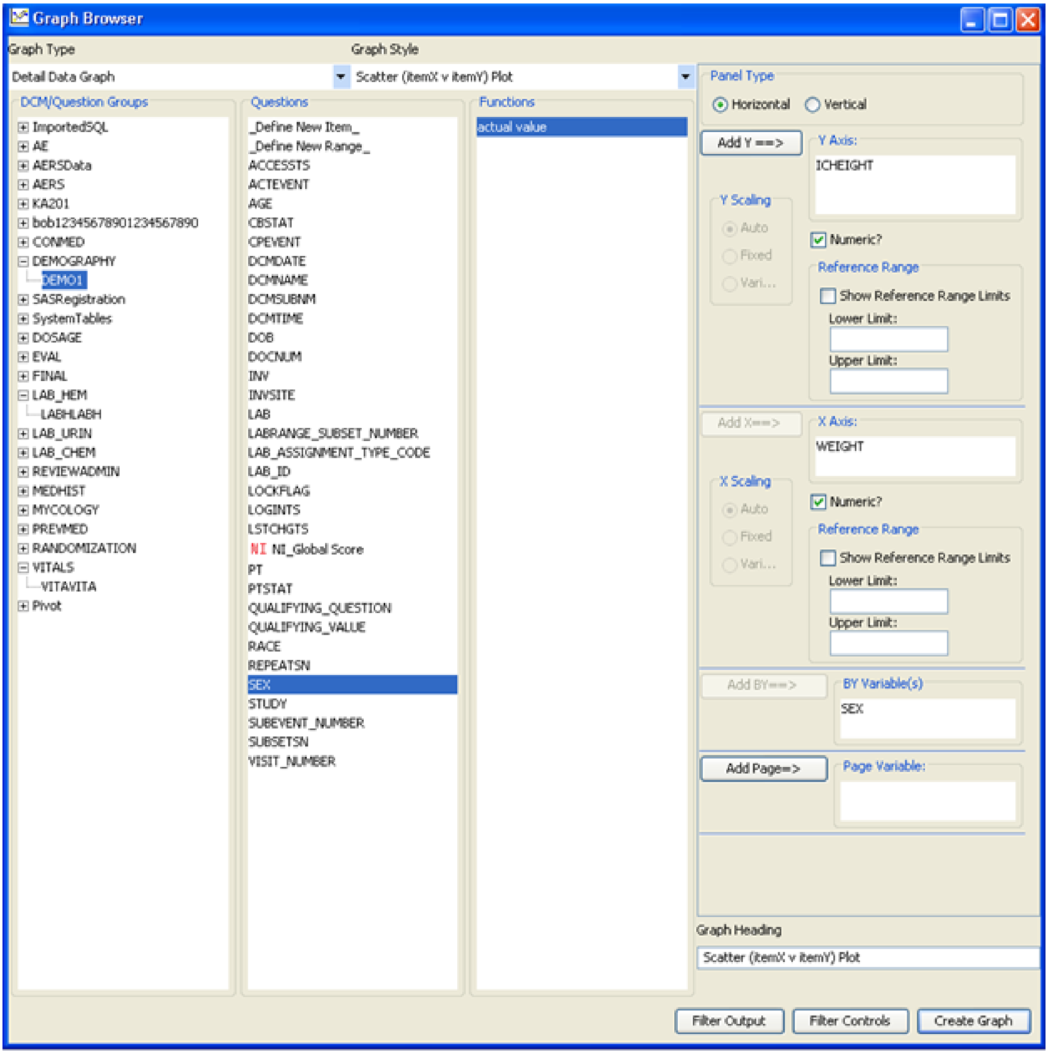
They are inactive and initially set to Auto until a page variable is selected. Then you may pick either Auto (0), Fixed (1), or Variable (2). When you save any graph, an X and Y scaling value will be saved. These values will be 0 unless you changed them on the screen. For old saved graphs, if no X and Y values exist, it will read as 0.

***Note: You must use Add Page for the scaling features to be activated.***

# Detail Data Graph Styles

## Scatter (Item X vs. Item Y) Plot

In a Scatter (Item X vs. Item Y) Plot graph, each data point corresponds to each patient's observation for item X and item Y. Use the BY variable to subset graphic displays. Optionally, change the default graph style for the graph header.



Graph Type: Detail Data Graph

Graph Style: Scatter (itemX v itemY) Plot

Panel Type: ● Horizontal ○ Vertical

Y Axis: ICHEIGHT

☑ Numeric?

☐ Show Reference Range Limits

X Axis: WEIGHT

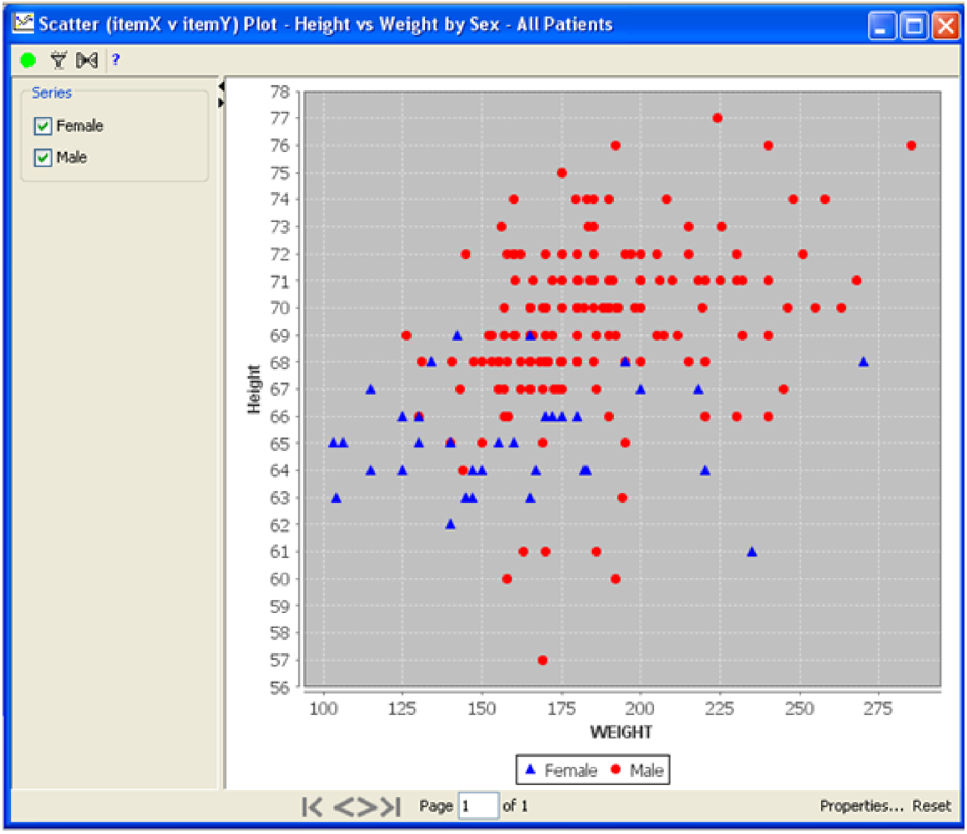
☑ Numeric?

☐ Show Reference Range Limits

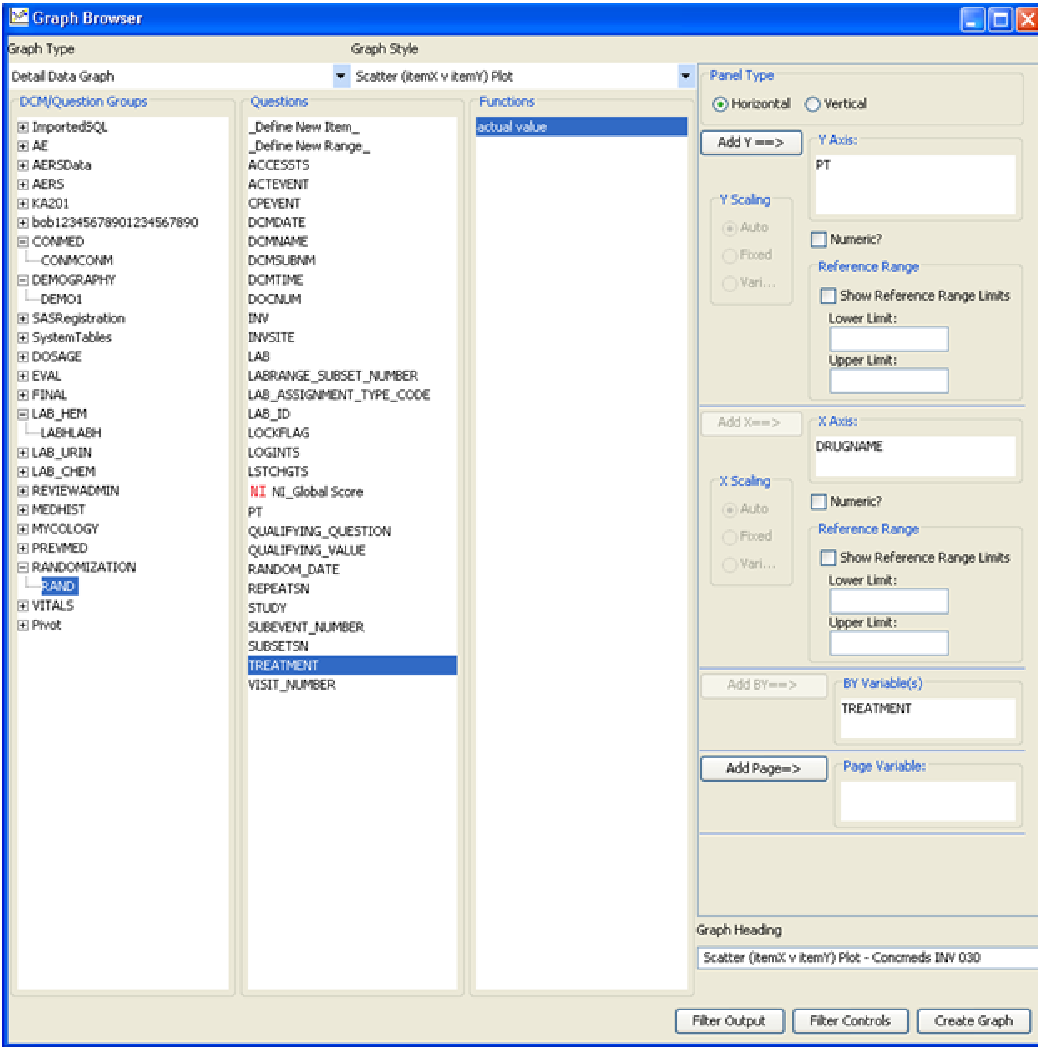
BY Variable(s): SEX

Graph Heading: Scatter (itemX v itemY) Plot

This scatter plot example displays numeric data. There is no restriction on the data type used.



Character data is also supported. This example of the same graph type Scatter (Item X vs. Item Y) Plot with character data shows concomitant medications for individual patients.



Graph Type: Detail Data Graph

Graph Style: Scatter (itemX v itemY) Plot

Functions: actual value

Panel Type: ● Horizontal ○ Vertical

Y Axis: PT

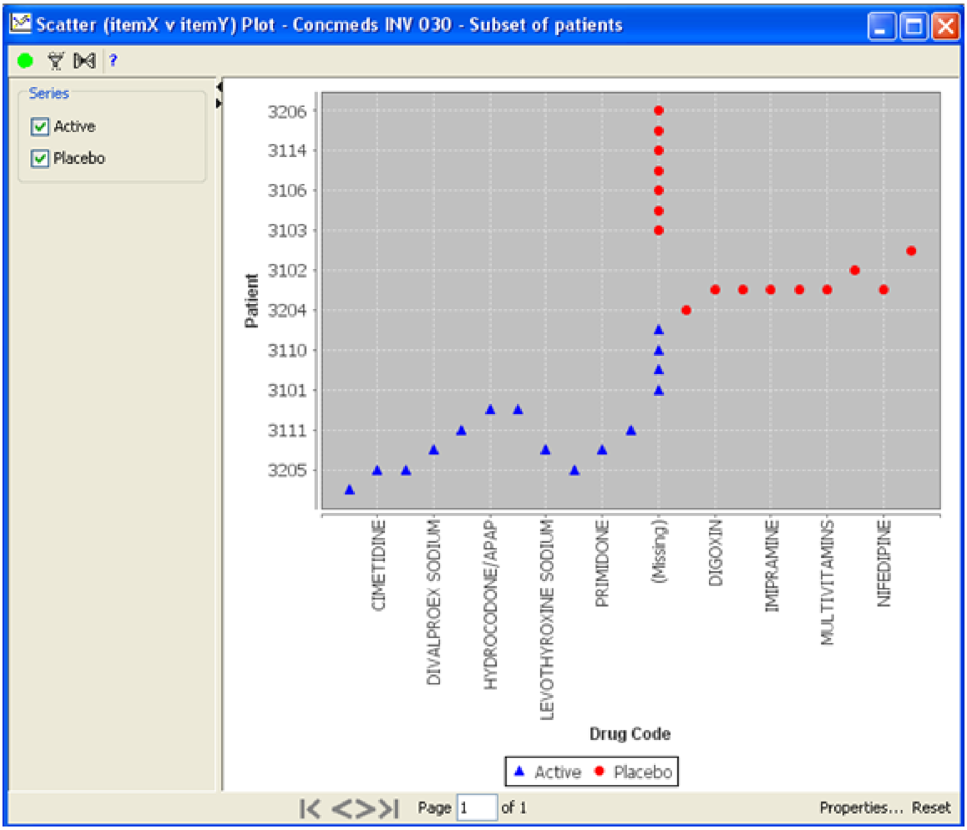
X Axis: DRUGNAME

BY Variable(s): TREATMENT

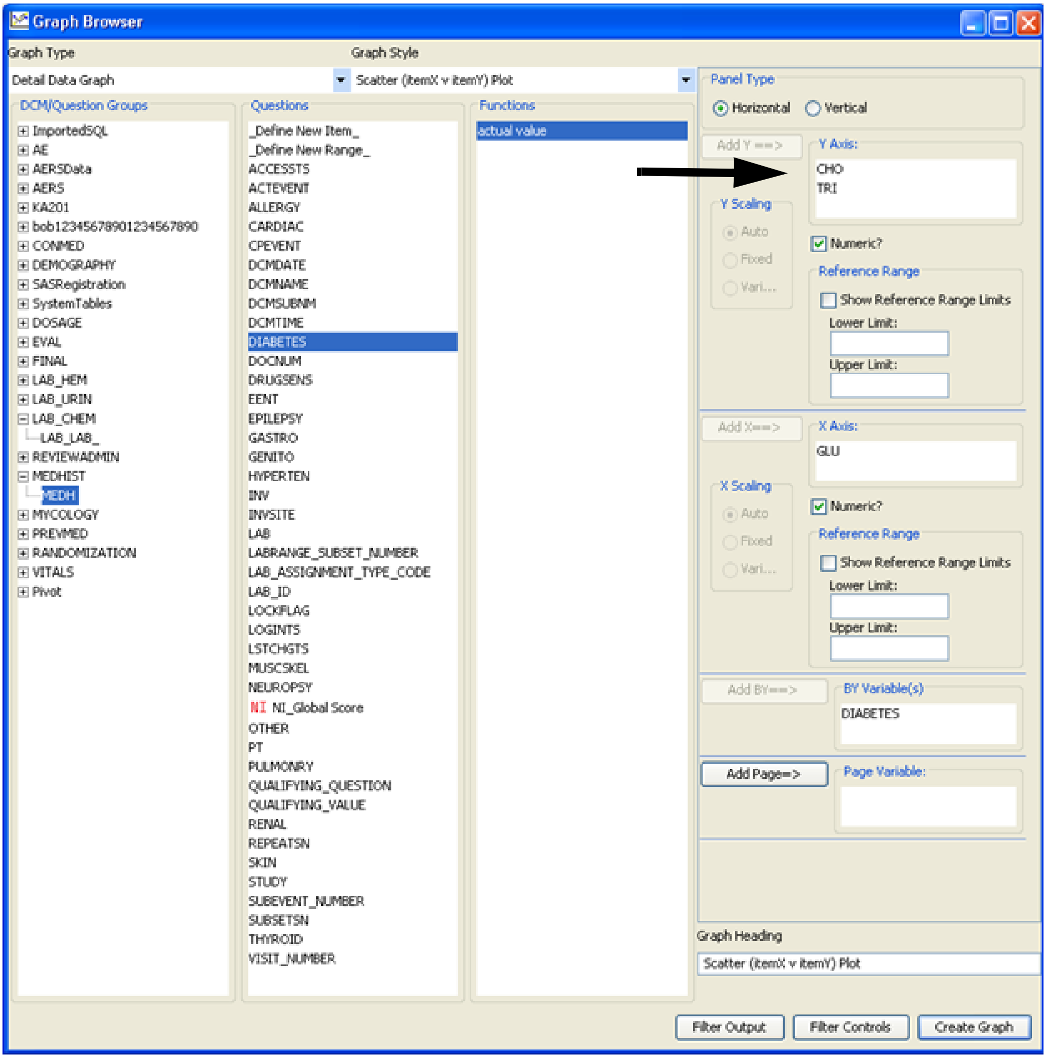
Graph Heading: Scatter (itemX v itemY) Plot - Concmeds INV 030

For this example, the data was subset for manageable size in viewing (approximately 20 values maximum on either the X-axis or Y-axis). A patient selection criteria was applied for investigator site 030.

*Note:* ***You may need to limit the number of patients displayed.***



The Scatter (Item X vs. Item Y) Plot can also be plotted as two variables on the Y-axis (dual Y-axis mode).



Graph Type: Detail Data Graph

Graph Style: Scatter (itemX v itemY) Plot

Panel Type: ● Horizontal ○ Vertical

Y Axis: CHO, TRI

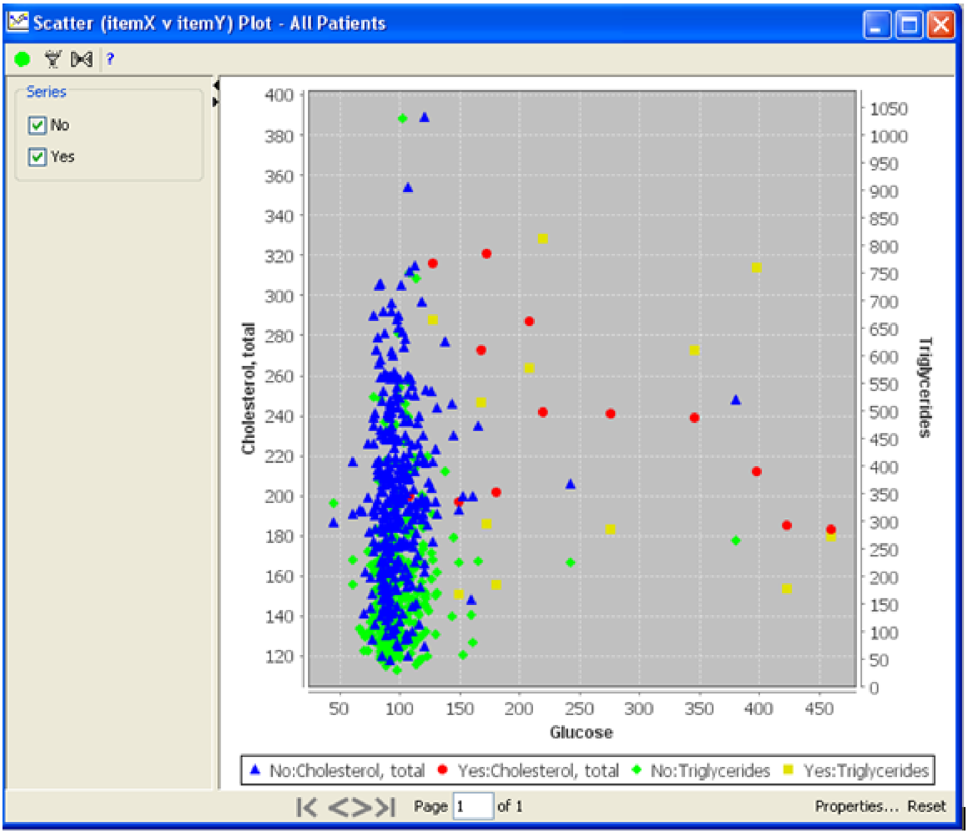
☑ Numeric?

X Axis: GLU

☑ Numeric?

BY Variable(s): DIABETES

Graph Heading: Scatter (itemX v itemY) Plot



Scatter (itemX v itemY) Plot - All Patients

Series

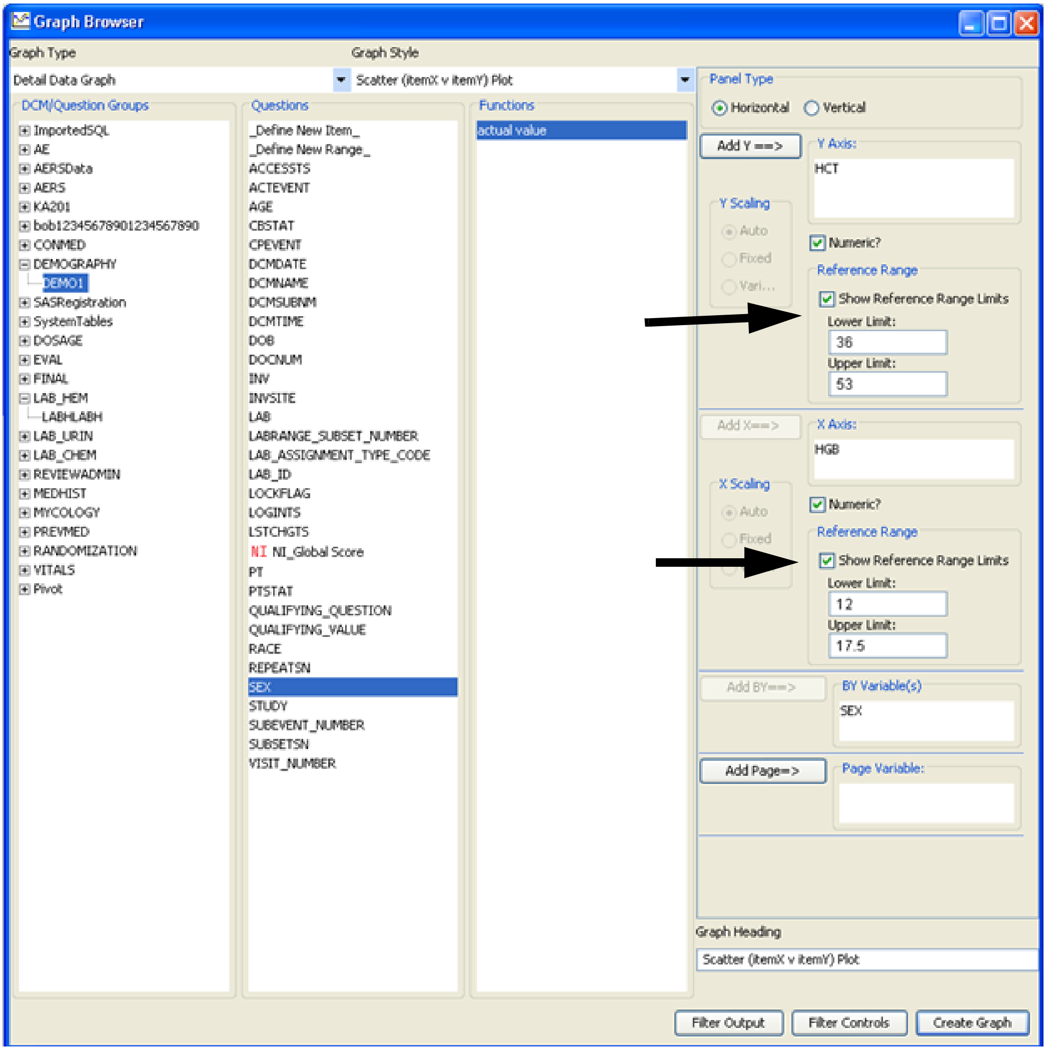
☑ No

☑ Yes

## *Include Reference Range*

You may also apply a **Reference Range** to the Y-axis and X-axis for numeric data.

Click on the check box for **Show Reference Range Limits.** Enter the Lower and Upper Limits for Y-axis and X-axis.



Graph Type: Detail Data Graph

Graph Style: Scatter (itemX v itemY) Plot

Panel Type: ● Horizontal ○ Vertical

Y Axis: HCT

☑ Numeric?

Reference Range

☑ Show Reference Range Limits

Lower Limit: 36

Upper Limit: 53

X Axis: HGB

☑ Numeric?

Reference Range

☑ Show Reference Range Limits

Lower Limit: 12

Upper Limit: 17.5

BY Variable(s): SEX

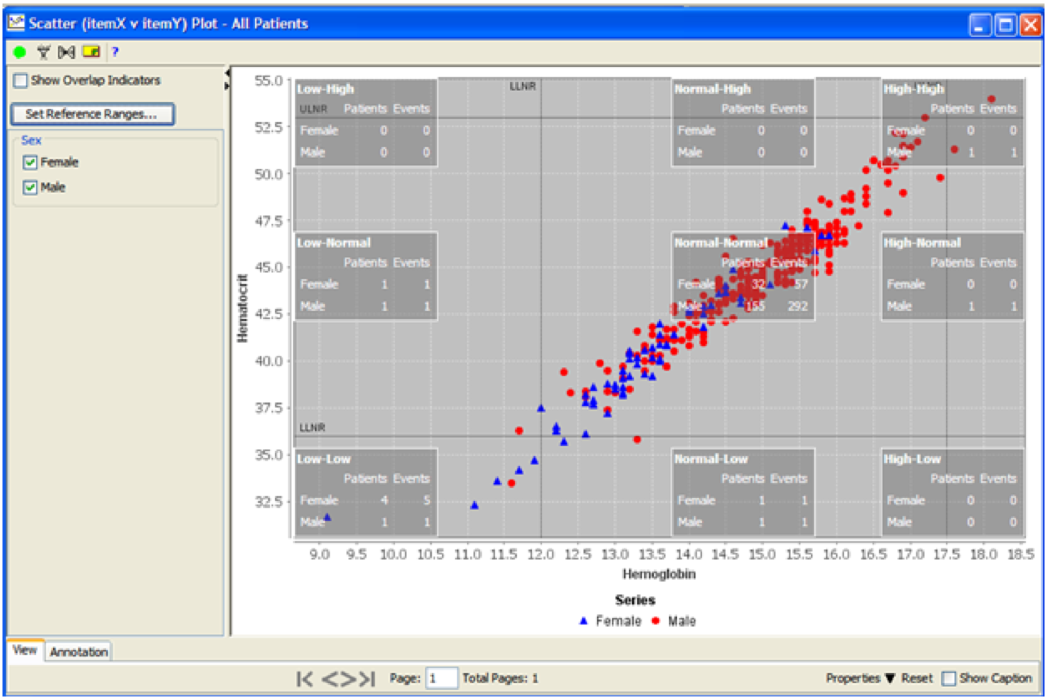
Page Variable:

Graph Heading: Scatter (itemX v itemY) Plot

The generated graph will display the reference range lines as vertical and horizontal lines.

The lower limit and upper limit reference range values can be specified separately for Y-axis and X-axis. The graph is segmented into nine labeled “range” plot sectors providing the patient count. The number of data points in each range plot sector are counted for each BY variable value. There can be multiple data points for a single patient, so the graph calculates how many distinct patients are contained in a plot sector as well as how many “Events”. Each range label displays the number of Patients and Events that fall into a range sector area. For example, the range sector “Low-Low” shows 4 Female patients with 5 Events, and 1 Male patient with 1 Event. The label text boxes can be dragged to other locations for ease of viewing.

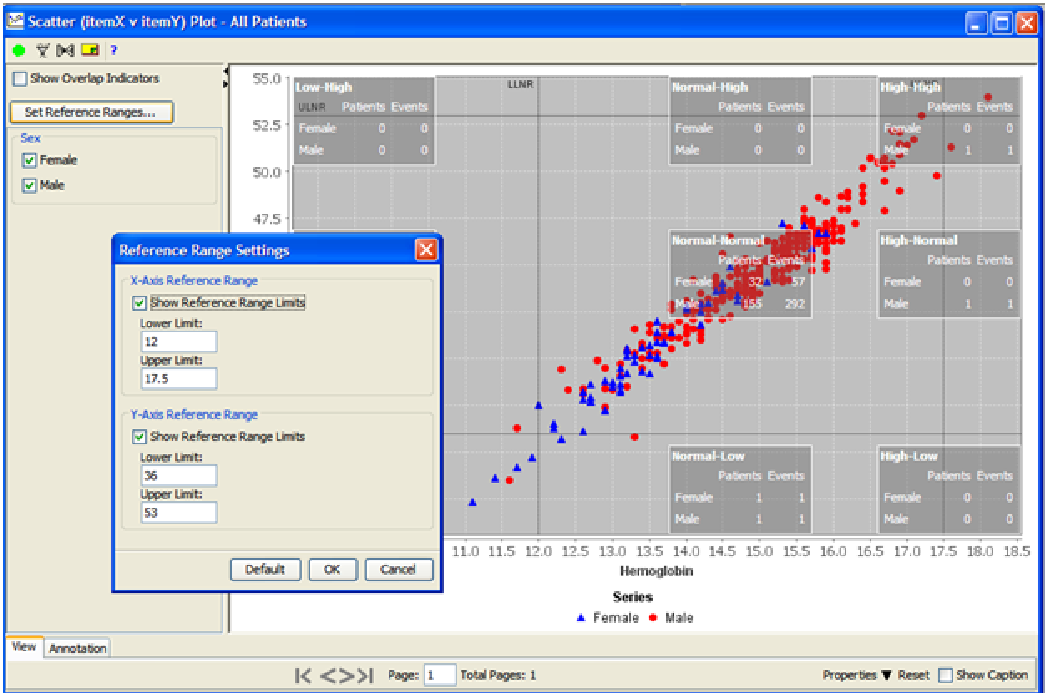
***Note: You cannot apply Reference Range for dual Y-axis plots.***



## *Interactive Range Markers*

When a Detail Data graph scatter plot is assigned reference ranges the created output allows you to change the ranges. Click **Set Reference Range** button to change the ranges, and re-create the graph. The Output is presented with updated ranges. This feature is available for Scatter (item X vs. Y) Upper Limit Normal Range Plot (Hy's Law).

Click Set ULRR Multipliers button to change the multipliers and re-create the graph. The Output presents with updated range multipliers.



☐ Show Overlap Indicators

Sex
☑ Female
☑ Male

☐ Show Caption

Reference Range Settings

X-Axis Reference Range
☑ Show Reference Range Limits
Lower Limit: 12
Upper Limit: 17.5

Y-Axis Reference Range
☑ Show Reference Range Limits
Lower Limit: 36
Upper Limit: 53

| Low-High | Patients | Events |
|---|---|---|
| Female | 0 | 0 |
| Male | 0 | 0 |

| Normal-High | Patients | Events |
|---|---|---|
| Female | 0 | 0 |
| Male | 0 | 0 |

| High-High | Patients | Events |
|---|---|---|
| Female | 0 | 0 |
| Male | 1 | 1 |

| Normal-Normal | Patients | Events |
|---|---|---|
| Female | 32 | 57 |
| Male | 155 | 292 |

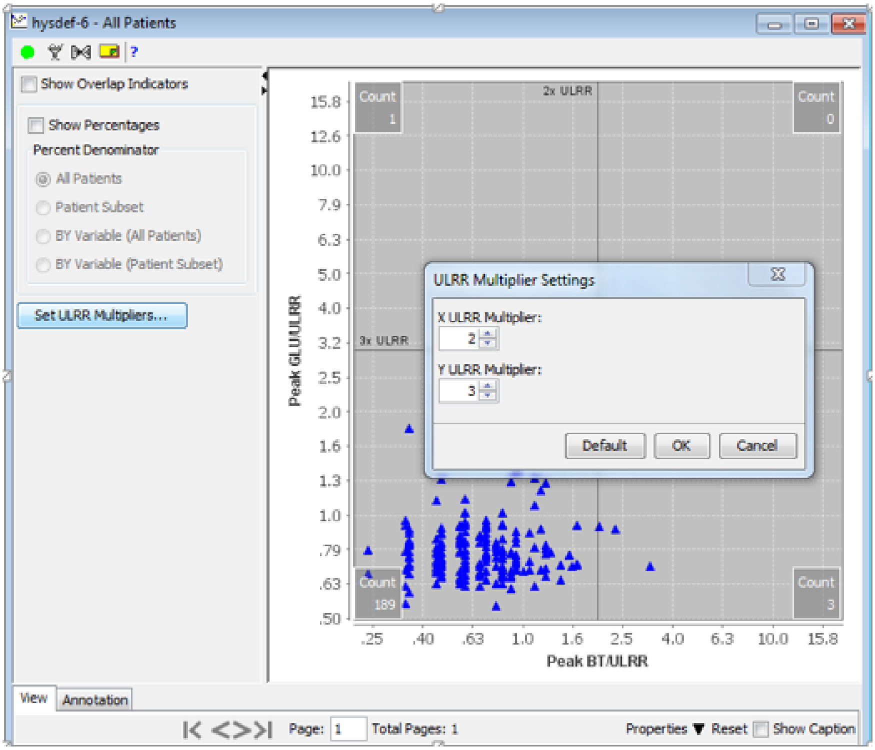
| High-Normal | Patients | Events |
|---|---|---|
| Female | 0 | 0 |
| Male | 1 | 1 |

| Normal-Low | Patients | Events |
|---|---|---|
| Female | 1 | 1 |
| Male | 1 | 1 |

| High-Low | Patients | Events |
|---|---|---|
| Female | 0 | 0 |
| Male | 0 | 0 |

The Hy's Law Scatter Graphs and Scatter Graphs that have Lower-Limit/Upper-Limit of Normal Range defined in the Graph Browser have an enhancement in the Graph Viewer that allows the user to reset the parameters for the range markers. In both cases, ULNR *multiplier* values and the LL/UL settings, the user can change the settings in modal dialog that is opened from a new button placed in the Graph Viewer's control panel.

The Hy's Law Multipliers are set using Spinner controls for the X and Y axes. The spinner's values can range from 1 to 10. The Spinner arrows increment/decrement the current value by one. As an exception, the value 1.5 is only decimal value in the default sequence.



ULRR Multiplier Settings

X ULRR Multiplier: 2

Y ULRR Multiplier: 3

☐ Show Overlap Indicators

☐ Show Percentages

Percent Denominator

● All Patients

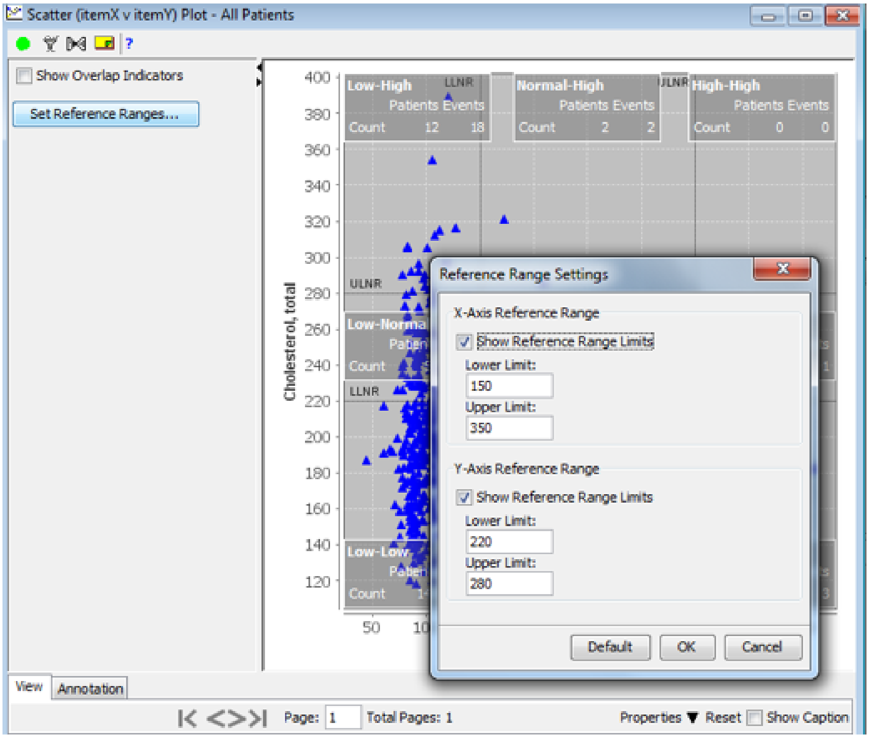
○ Patient Subset

○ BY Variable (All Patients)

○ BY Variable (Patient Subset)

Page: 1 Total Pages: 1

For Scatter graphs with LL/UL the dialog presents two text fields to set the Lower and Upper Limits of the Normal Range. The user can enable or disable these text fields by clicking on a checkbox associated with these two fields. If the checkbox is unselected, the limit markers will not be drawn on the graph. Baseline-* graphs have only one panel containing these controls. Other Scatter plots have two panels of these controls: one panel is for the X-Axis and the other is for the Y-Axis. If the user clicks the entered values are validated. For example, lower limit cannot be equals to or higher than the upper limit and there must be values entered for both limits; blanks are not valid. If the text fields are disabled via the checkbox, then there is no need to validate these values.



Reference Range Settings

X-Axis Reference Range

☑ Show Reference Range Limits

Lower Limit: 150

Upper Limit: 350

Y-Axis Reference Range

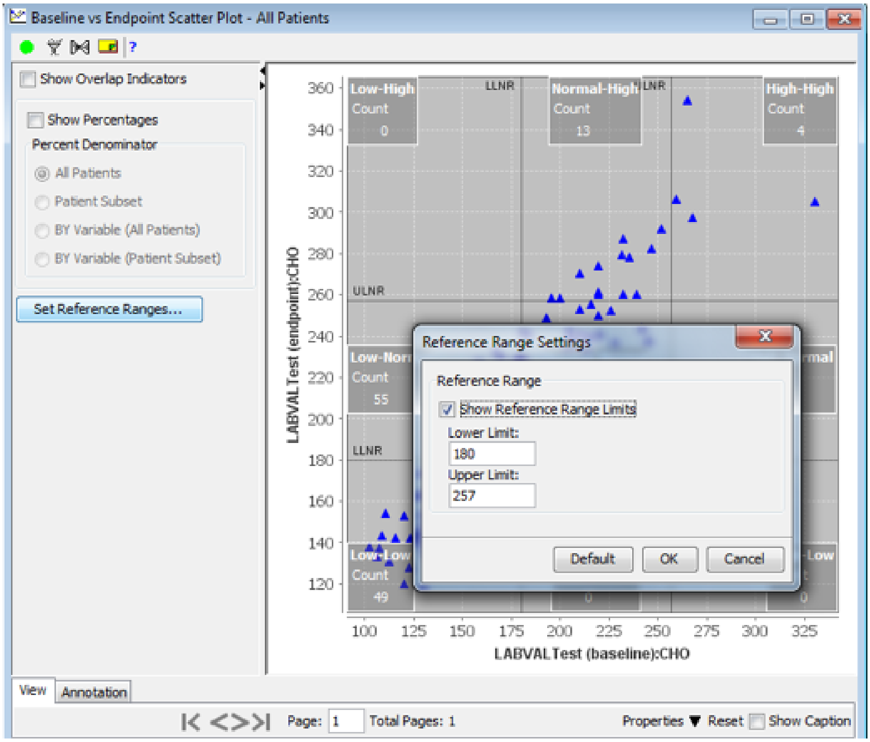
☑ Show Reference Range Limits

Lower Limit: 220

Upper Limit: 280

The Default button resets the values to the original values that were specified when the graph was defined in the Graph Browser.

When the LL/UL values or the Hy’s Law multiplier values are changed, the floating text boxes containing patient counts that are displayed in the graph itself are updated. The patient counts are updated to reflect the possibly changed categorization of the patient plot values – a plot point may fall into a different sector than it was located previously.



Reference Range Settings

Reference Range

☑ Show Reference Range Limits

Lower Limit: 180

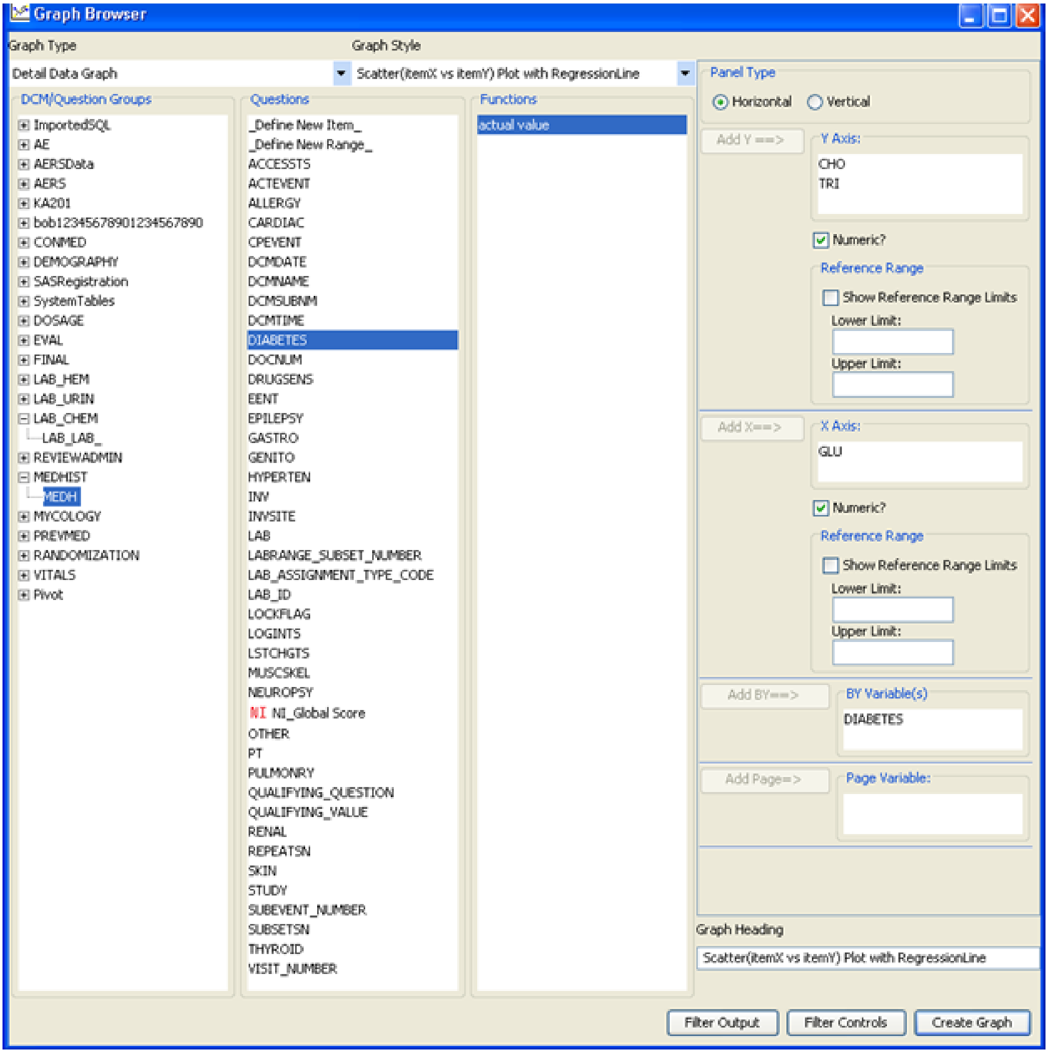
Upper Limit: 257

## Scatter Plot with Regression Line

In a Scatter (Item X vs. Item Y) Plot with Regression Line (least mean square algorithm), each data point corresponds to each patient's observation for item X and item Y. There is no restriction on the data type used.

***Testing of Regression formula of Y on X: (y = a + b * x)***

The Scatter Plot with Regression Line can also be plotted as two variables on the Y axis (dual Y axis mode).



Graph Type: Detail Data Graph

Graph Style: Scatter(itemX vs itemY) Plot with RegressionLine

Functions: actual value

Panel Type: ● Horizontal ○ Vertical

Y Axis: CHO, TRI

☑ Numeric?

Reference Range: ☐ Show Reference Range Limits

X Axis: GLU

☑ Numeric?

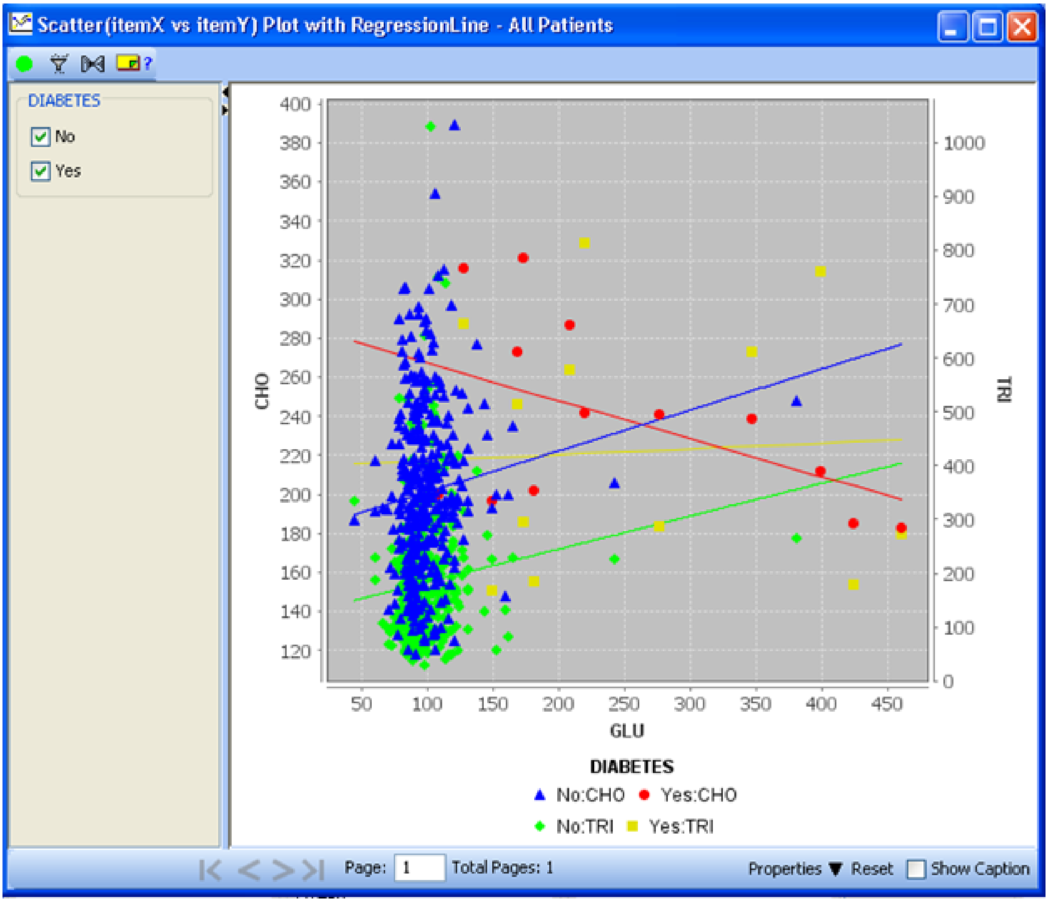
Reference Range: ☐ Show Reference Range Limits

BY Variable(s): DIABETES

Page Variable:

Graph Heading: Scatter(itemX vs itemY) Plot with RegressionLine

Optionally, you may apply Reference Range for the Y-axis and X-axis but ***not*** for dual Y-axis mode plots.



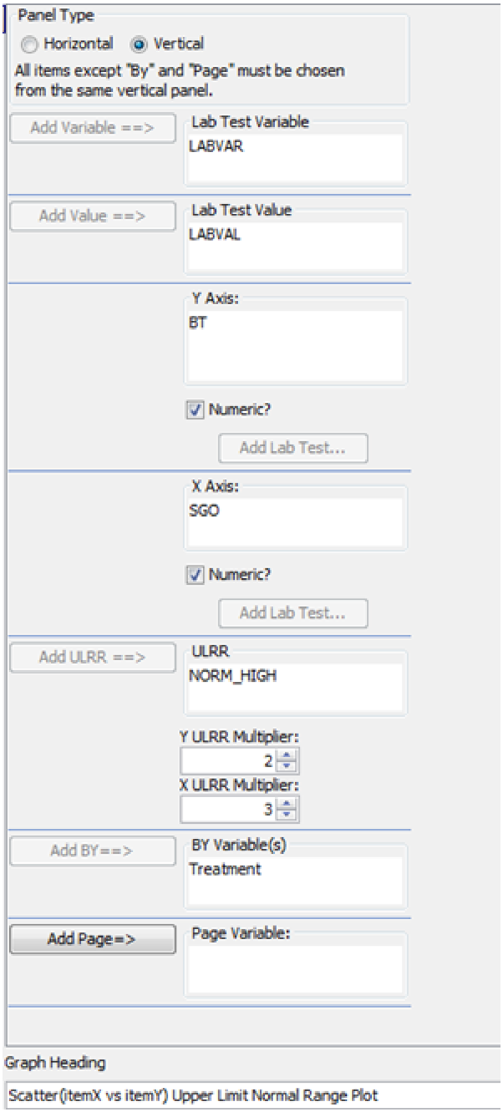
DIABETES
☑ No
☑ Yes

## *Scatter Upper Limit Normal Range Plot*

The Hy’s Law type plot is supported by the Scatter Plot for Upper Limit Normal Range Plot. It is typically used when evaluating Lab Chemistry data for Liver Enzymes for drug-induced liver injury (DILI) from experimental drugs.

In the example, Vertical Panel Type is selected where all items except “BY” and “PAGE” must be chosen from the same vertical panel.

First, the items for Lab Test Variable and Lab Test Value are added. Then the individual lab tests are added as the X axis and Y axis variables. The Upper Limit Reference Range item is entered for “ULRR”. Optionally, you may apply an X-axis and Y-axis ULRR multiplier.



Panel Type
○ Horizontal ● Vertical
All items except "By" and "Page" must be chosen from the same vertical panel.

Lab Test Variable
LABVAR

Lab Test Value
LABVAL

Y Axis:
BT
☑ Numeric?

X Axis:
SGO
☑ Numeric?

ULRR
NORM_HIGH

Y ULRR Multiplier: 2
X ULRR Multiplier: 3

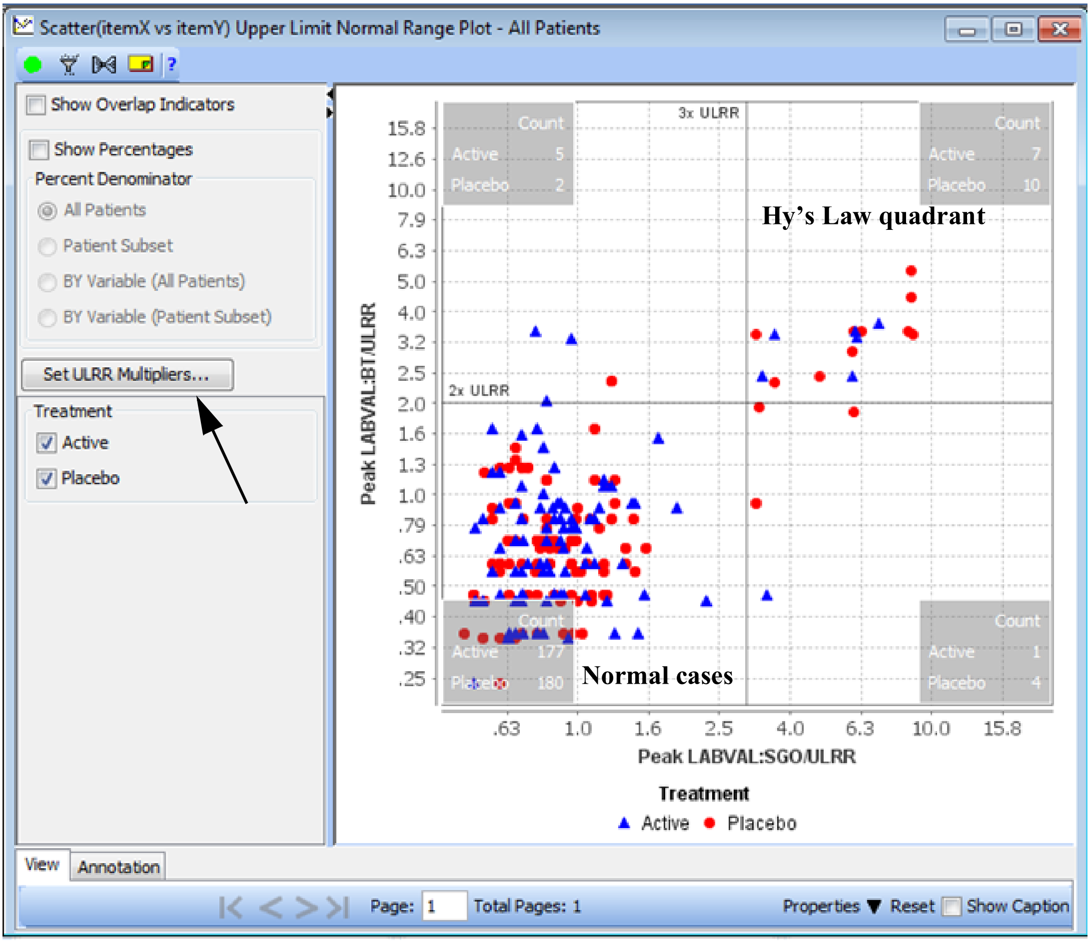
BY Variable(s)
Treatment

Page Variable:

Graph Heading
Scatter(itemX vs itemY) Upper Limit Normal Range Plot

In the graph, for each subject, the peak BT (Total Bilirubin) divided by the upper limit of the reference range (Y ULRR), is plotted against the peak SGO divided by the upper limit reference range (X ULRR), on log scale 10. Reference lines for Y ULRR and X ULRR multipliers are drawn to divide the plane into four quadrants. Normal cases are in the lower left quadrant. The upper right quadrant is referred as Hy's Law quadrant. Any subject that falls into this quadrant is subject to further special investigation for toxicity concerns.

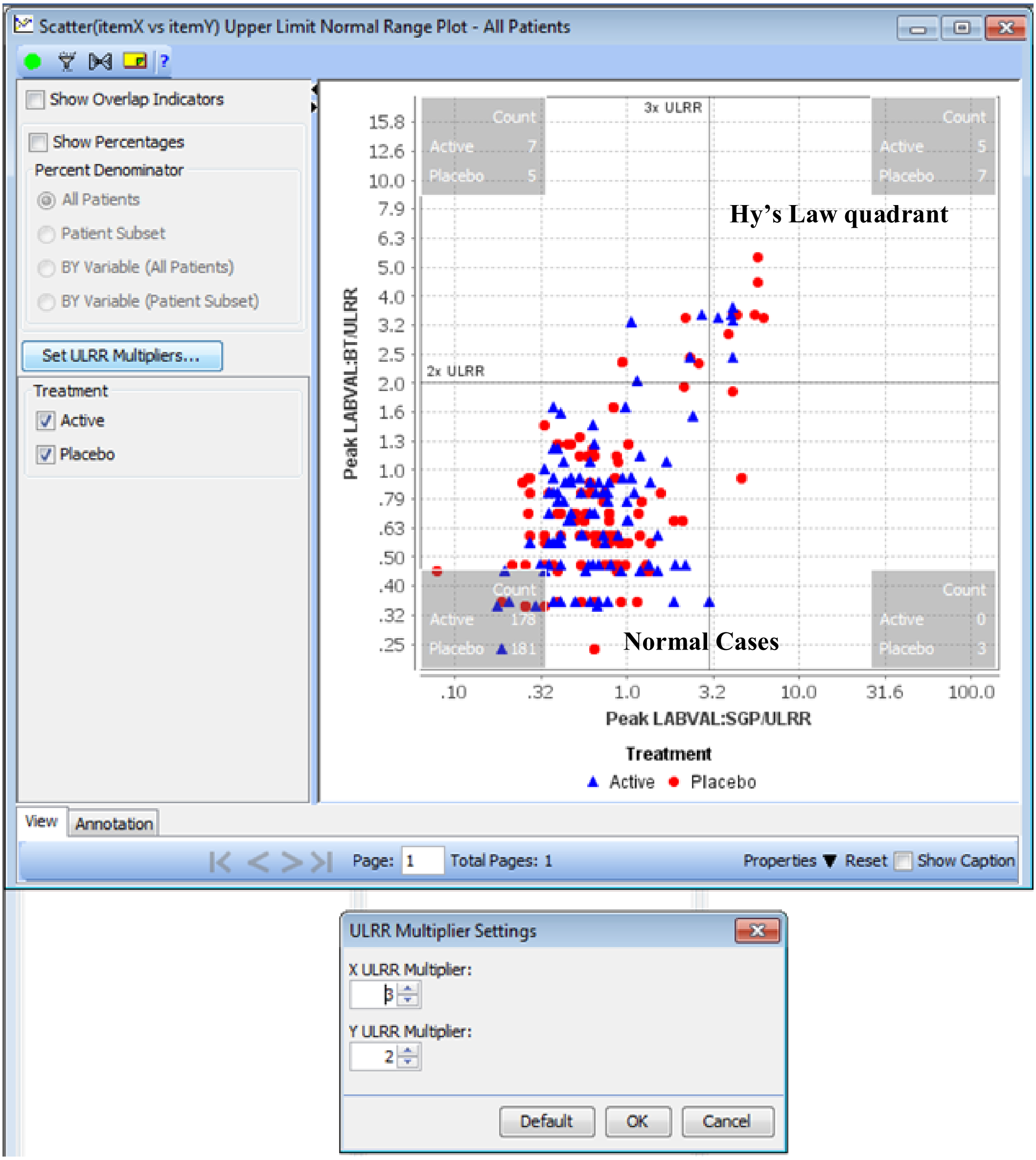
The corner cell counts represent patient counts for that quadrant.



**Hy's Law quadrant**

**Normal cases**

Click **Set ULRR Multipliers** to button, to interactively change the multipliers and re-create the graph. The Output presents with updated range multipliers.



Scatter(itemX vs itemY) Upper Limit Normal Range Plot - All Patients

☐ Show Overlap Indicators

☐ Show Percentages

Percent Denominator
● All Patients
○ Patient Subset
○ BY Variable (All Patients)
○ BY Variable (Patient Subset)

Treatment
☑ Active
☑ Placebo

ULRR Multiplier Settings

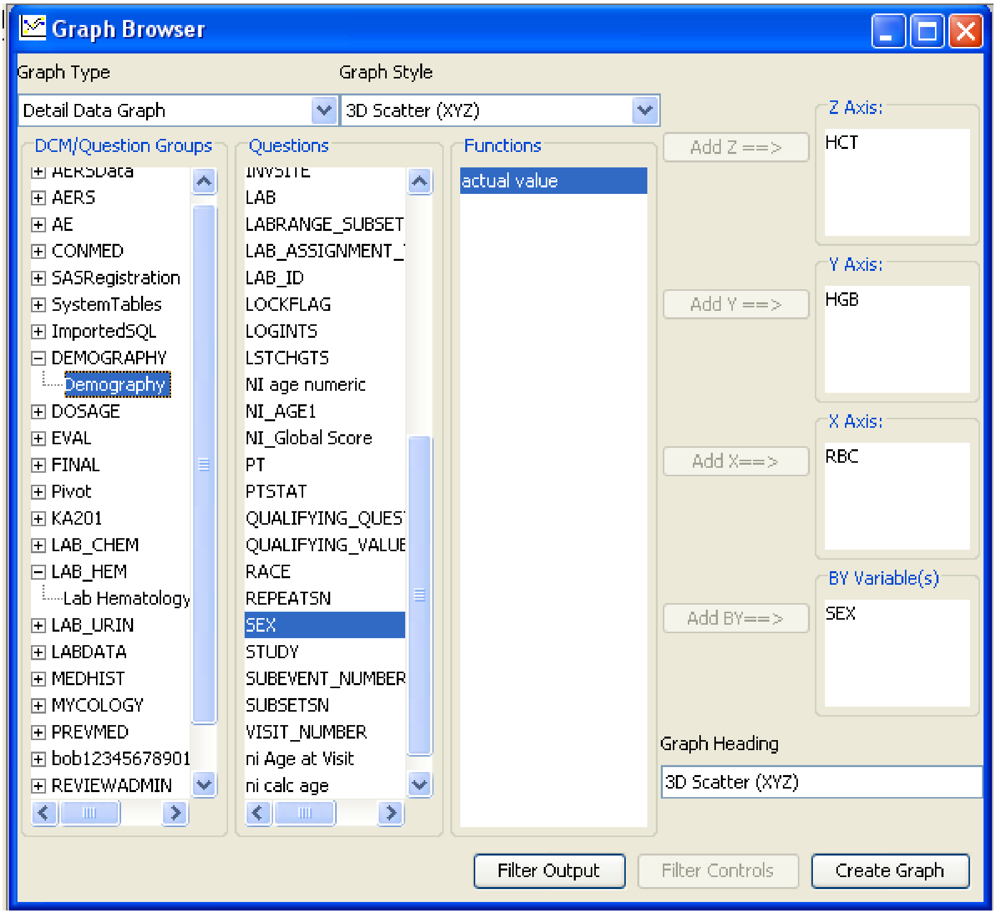
X ULRR Multiplier: 3

Y ULRR Multiplier: 2

## *3-D Scatter Plot*

The 3D Scatter (Item X vs. Item Y vs. Item Z) Plot displays three-dimensional data. Each patient's data points for X and Y coordinates are plotted against the Z elevation value.

Use the **BY variable** to subset graphic displays.



Graph Type: Detail Data Graph

Graph Style: 3D Scatter (XYZ)

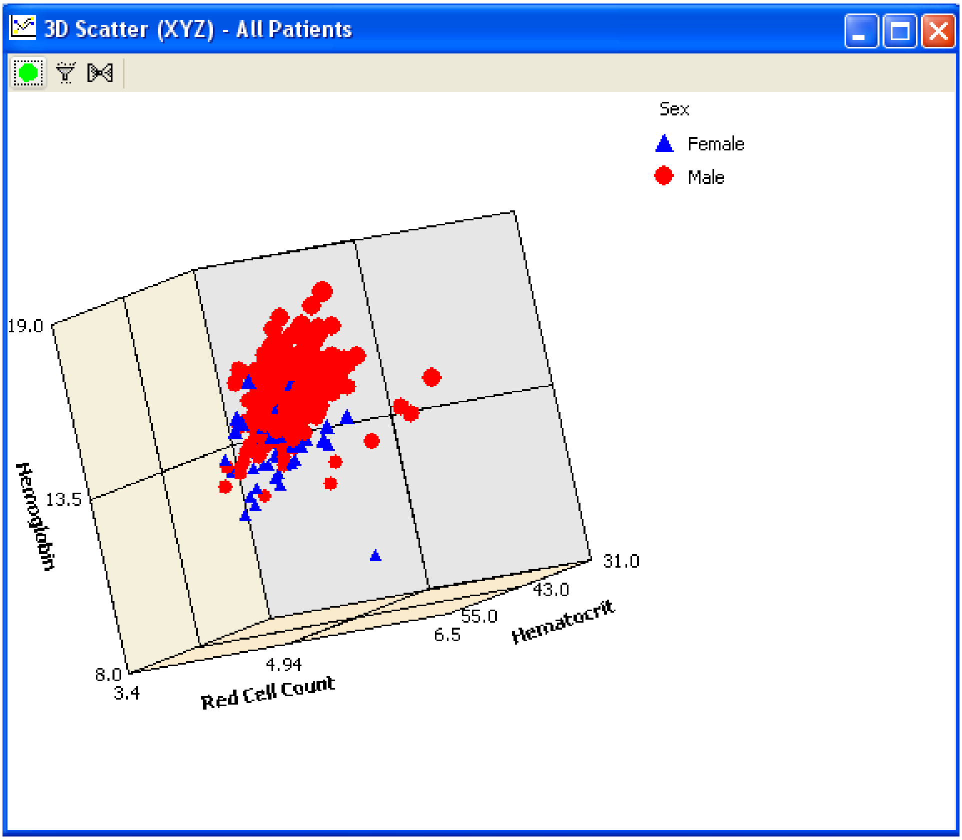
Z Axis: HCT

Y Axis: HGB

X Axis: RBC

BY Variable(s): SEX

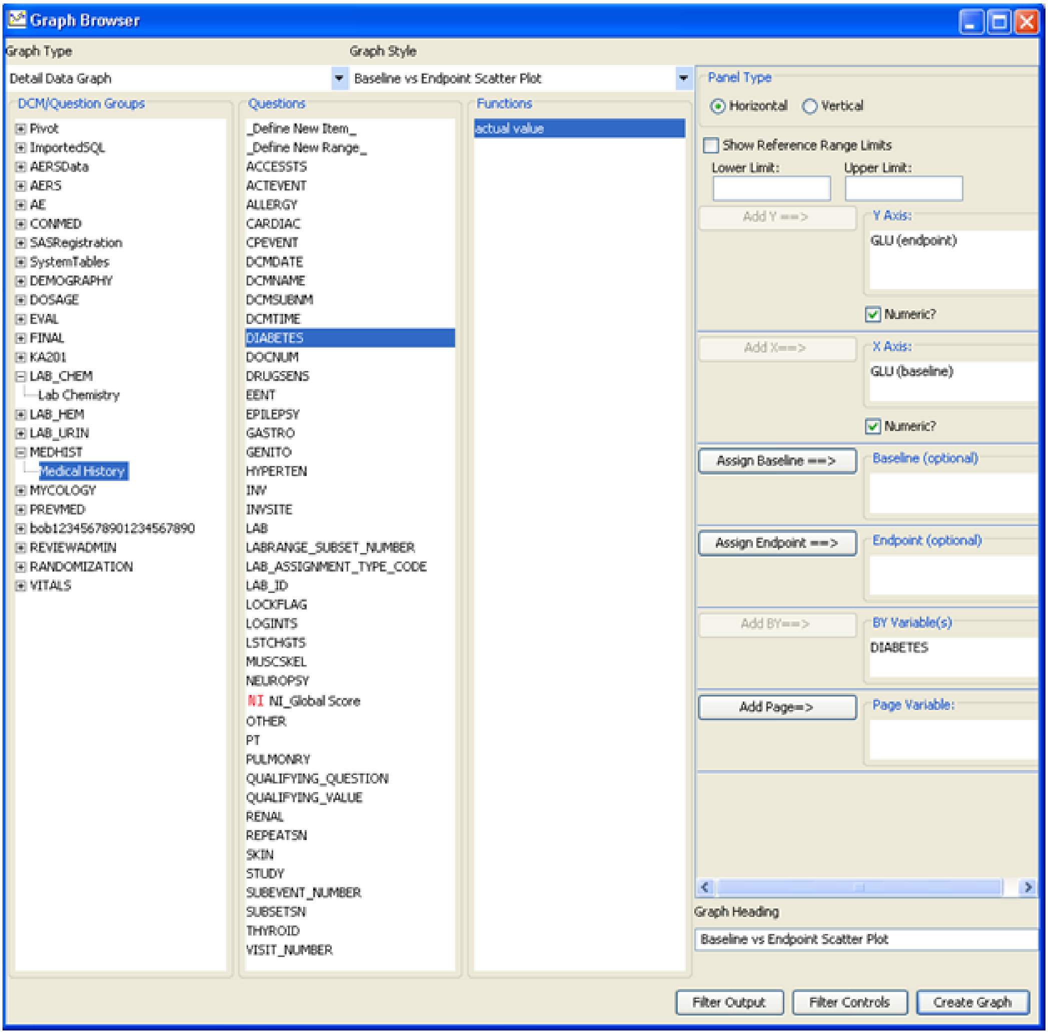
Graph Heading: 3D Scatter (XYZ)


3D Scatter (XYZ) - All Patients
Sex
▲ Female
● Male
19.0
13.5
8.0
Hemoglobin
3.4
4.94
6.5
Red Cell Count
31.0
43.0
55.0
Hematocrit

## *Baseline vs. Endpoint Scatter Plot*

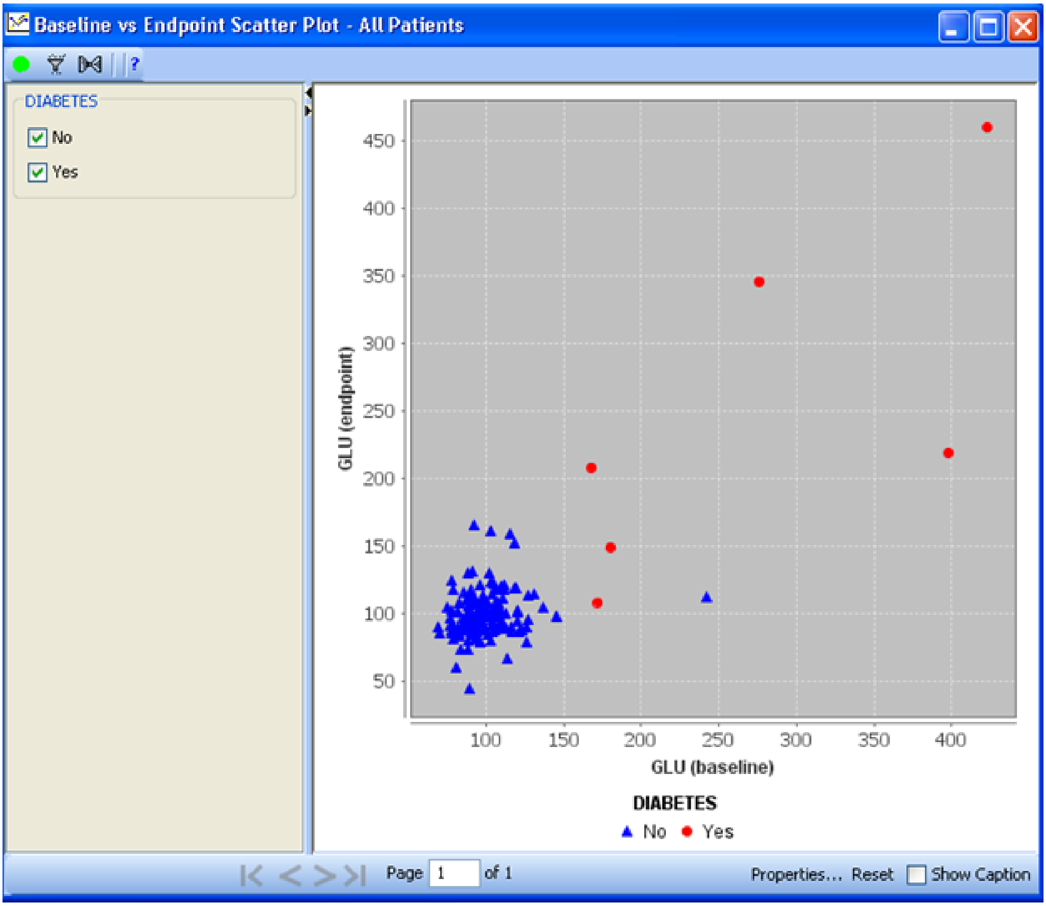
In a Baseline vs. Endpoint scatter plot each data point represents a patient's baseline (X-axis) and endpoint (Y-axis) for the item. The system default for this particular scatter plot requires the 'Baseline value' and 'Endpoint value' study definitions to be entered in ReviewAdmin.

The Baseline versus Endpoint scatter plot definition below is defined with minimal data for "GLU", added to the Y axis as the endpoint and GLU baseline was default to the X axis. Optionally you could use the **BY variable** to subset the graphic displays. Medical History for "Diabetes" was added as the BY Variable.



Graph Type: Detail Data Graph
Graph Style: Baseline vs Endpoint Scatter Plot
Panel Type: ● Horizontal ○ Vertical
☐ Show Reference Range Limits
Y Axis: GLU (endpoint) ☑ Numeric?
X Axis: GLU (baseline) ☑ Numeric?
BY Variable(s): DIABETES
Graph Heading: Baseline vs Endpoint Scatter Plot

The Glucose scatter plot is created using the default baseline and endpoint entered in ReviewAdmin specific for this particular study. A BY Variable was applied for Diabetes from the Medical History.



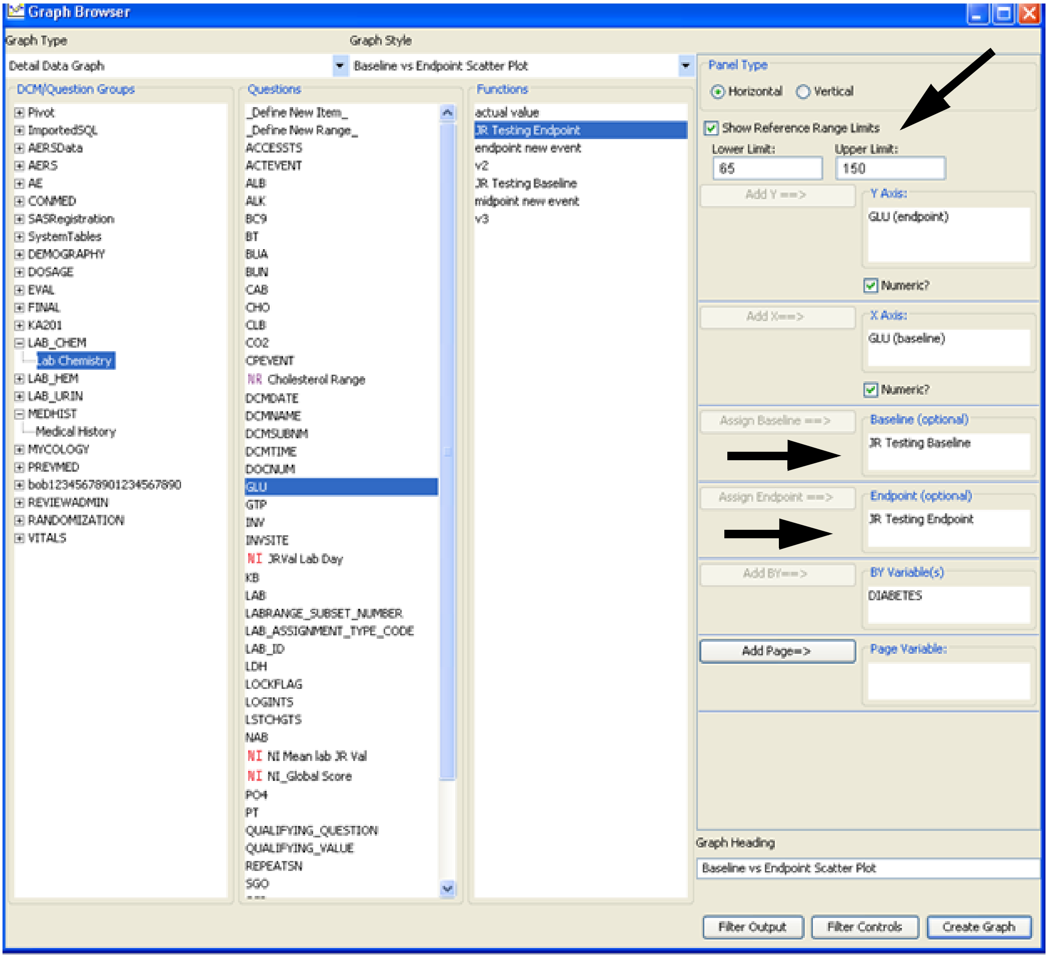
*Note:* ***When using New Mode to drag and drop items within the graph; drag the Baseline item to the X-axis and the Y-axis will default to Endpoint. The Y-axis is NOT selectable and the user cannot set the item function for this axis.***

Optionally, you can ***assign*** Baseline and Endpoint values from the Functions list box. These values would be previously defined within JReview as **New Event** values and used in place of the study specific values entered, or not entered through ReviewAdmin. This feature is very similar to the Shift Table in the Cross Tab Browser. *(See Chapter 8: CrossTab Browser - see section for Create Shift Table)*

JReview also provides graphing formats for Baseline vs. Min. Value Scatter Plot, as well as Baseline vs. Max Value Scatter Plot of selected items.

Previously, JReview automatically determined the Baseline and Endpoint values from ReviewAdmin entries. Users can now (optionally) specify the *functions* (e.g., “Visit 4”) associated with a variable that select the Baseline and Endpoint. With Baseline/Min.-Value and Baseline/Max-Value versions of this chart type, the user can (optionally) specify a function for the Baseline, but not the Endpoint.

Also, you can enter **Show Reference Range Limits.**



Graph Type: Detail Data Graph

Graph Style: Baseline vs Endpoint Scatter Plot

Panel Type: ● Horizontal ○ Vertical

☑ Show Reference Range Limits

Lower Limit: 65

Upper Limit: 150

Y Axis: GLU (endpoint)

☑ Numeric?

X Axis: GLU (baseline)

☑ Numeric?

Baseline (optional): JR Testing Baseline

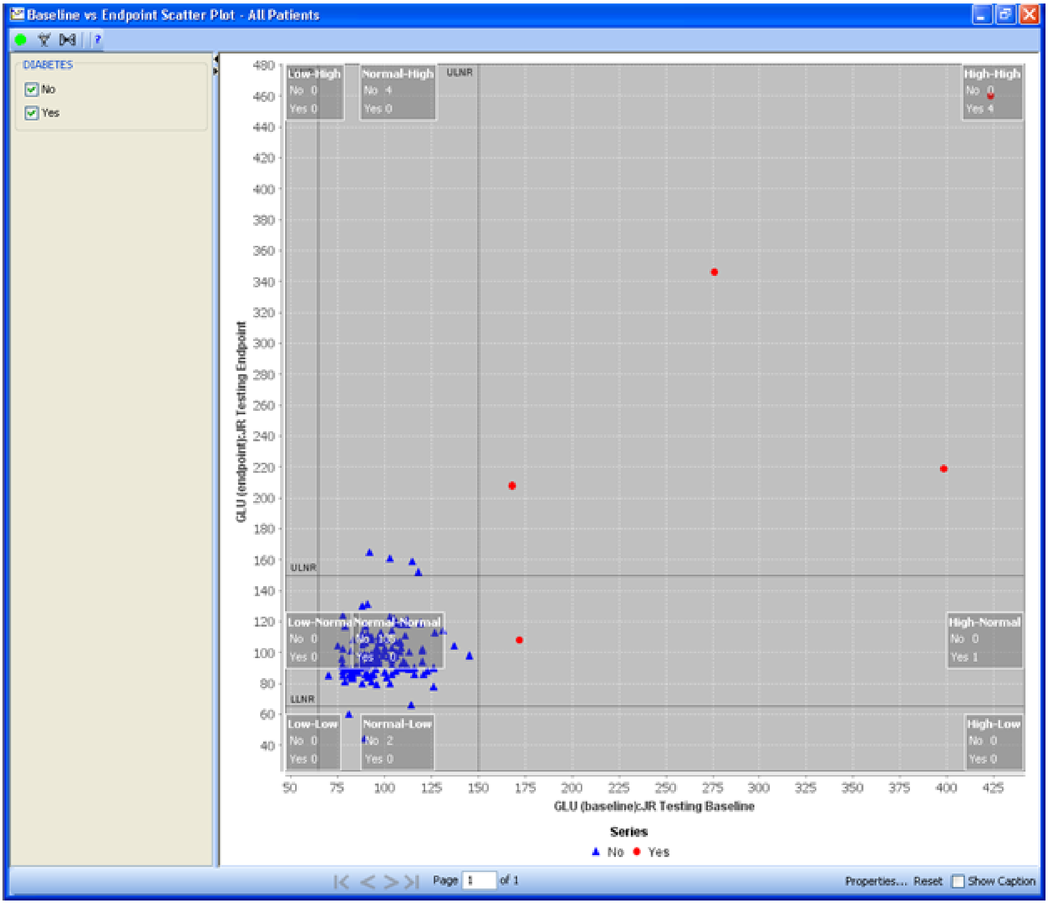
Endpoint (optional): JR Testing Endpoint

BY Variable(s): DIABETES

Page Variable:

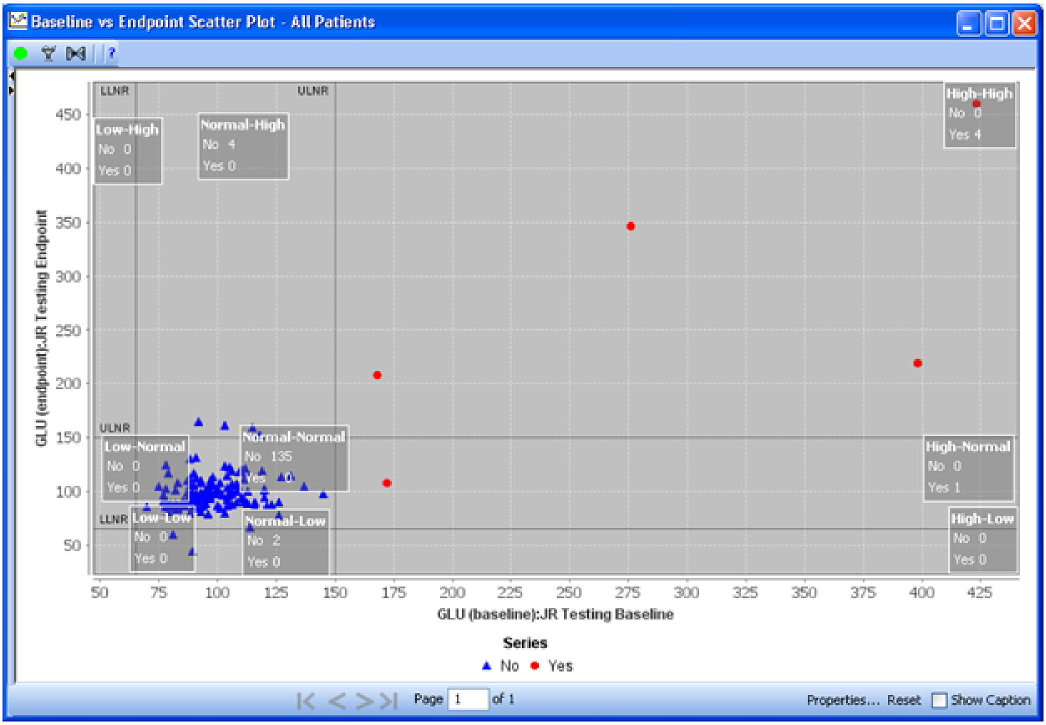
Graph Heading: Baseline vs Endpoint Scatter Plot

The enhanced features applied to the Baseline versus Endpoint Scatter plots allow them to serve as (rough) analogues to the **Shift Table** found in Crosstab. The Shift plot is created with the specified Baseline and Endpoint, plus defined referenced range low and high values.



The generated graph will display vertical and horizontal lines indicating the normal low and high values. The graph is segmented into nine labeled “ranges.” Each label displays the number of observations that fall into a category. For example, “Normal-High” means that the patient was in the “normal” range at the baseline measurement, but fell into the “high” range at the endpoint. The labels can be dragged to other locations for ease of viewing.

A popup menu accessed through a RIGHT-MOUSE click contains options to hide/show the labels. Click **Reset** for the labels to the return to the default positions.



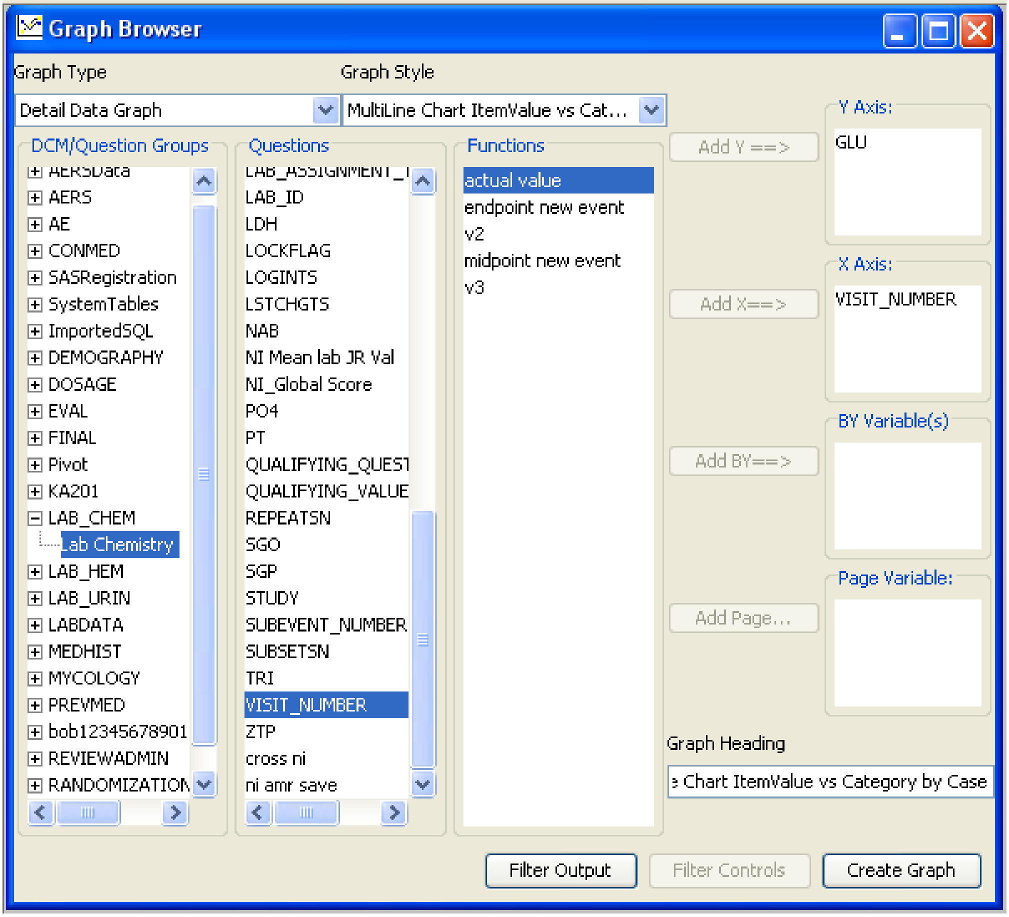
## MultiLine Chart Item Value vs. Category by Case

In a MultiLine Chart Item Value vs. Category by Case graph, each patient is represented by a line.

PID is defaulted for the patient identification. The Page variable is not allowed.

Click on a line and the underlying patient will be highlighted in all patient-level displays of data.

***Hint: You may need to limit the number of patients displayed.***



Graph Type: Detail Data Graph

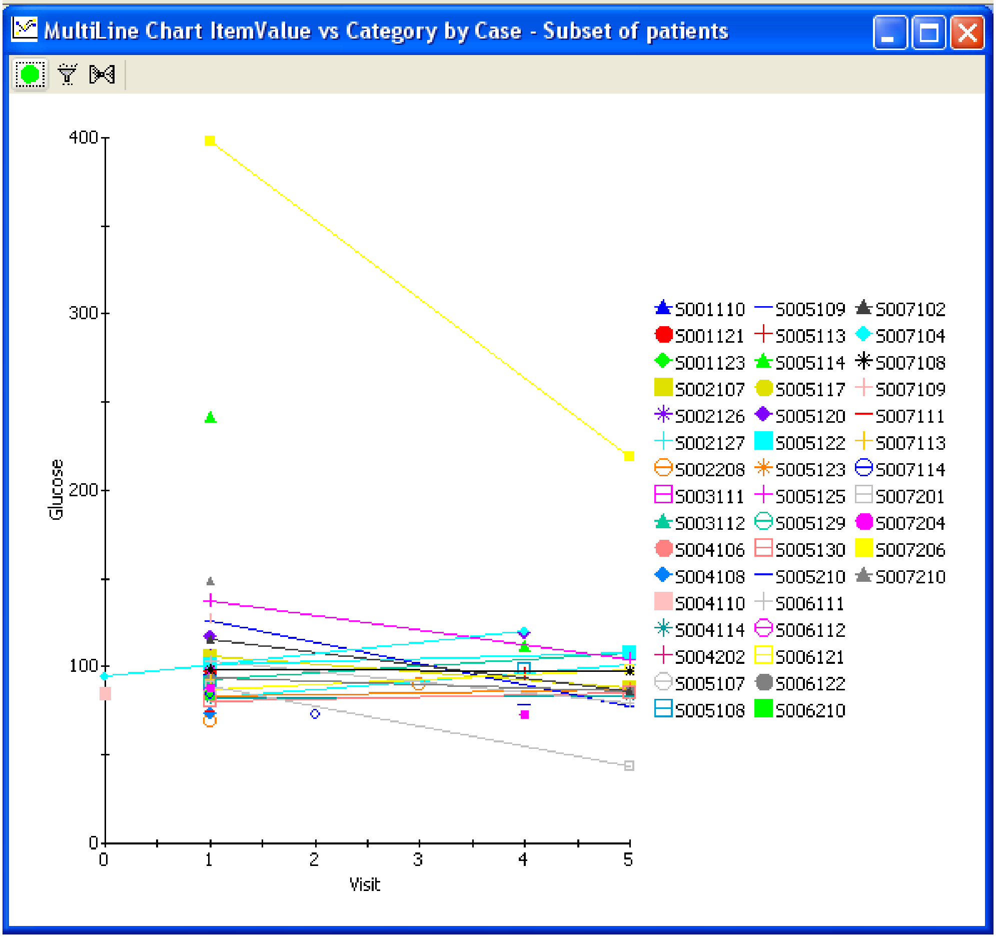
Graph Style: MultiLine Chart ItemValue vs Cat…

Y Axis: GLU

X Axis: VISIT_NUMBER

Graph Heading: e Chart ItemValue vs Category by Case

In this example, a Patient selection criteria was applied for discontinued patients.

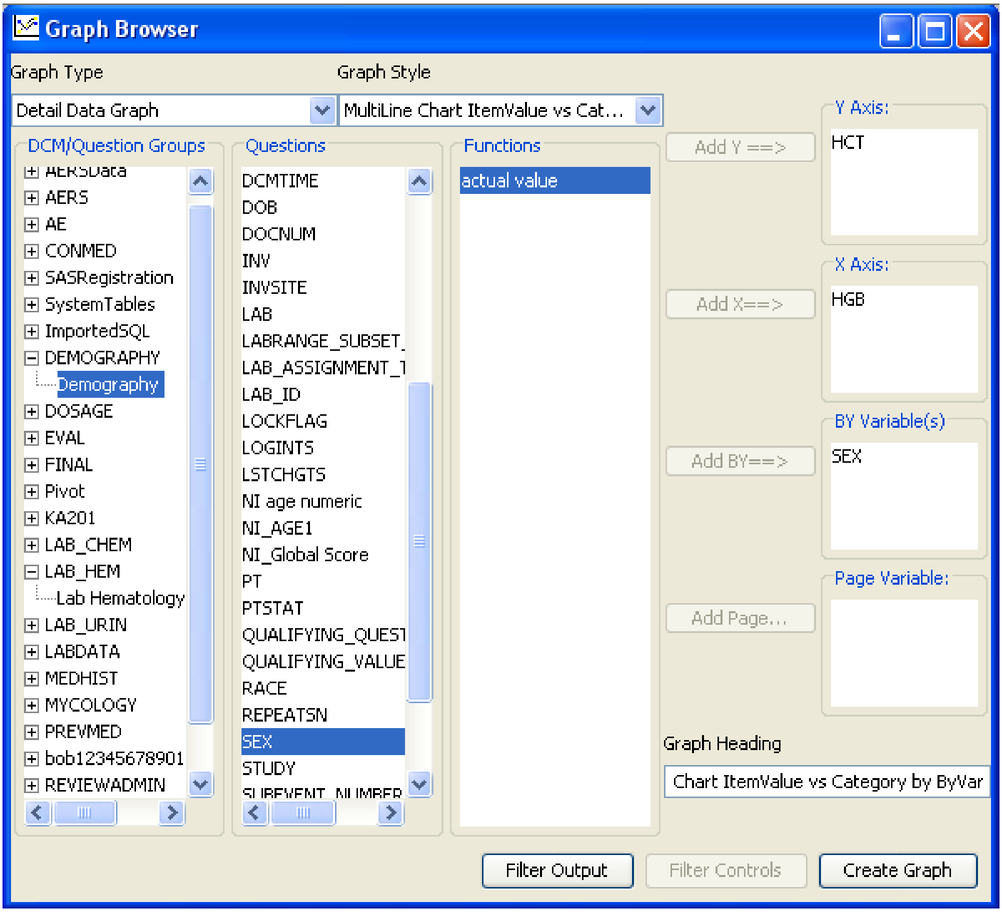


## *MultiLine Chart Item Value vs. Category by ByVar*

The MultiLine Chart Item Value vs. Category by ByVar graph, provides the same functionality as the MultiLine Chart item Value vs. Category by Case graph. However, you select the patient identification item.

Each patient is represented by a line. Click on a line and the underlying patient will be highlighted in all patient-level displays of data.

***Hint: You may need to limit the number of patients displayed.***


Graph Browser

Graph Type: Detail Data Graph

Graph Style: MultiLine Chart ItemValue vs Cat…

DCM/Question Groups: Demography

Questions: SEX

Functions: actual value

Y Axis: HCT

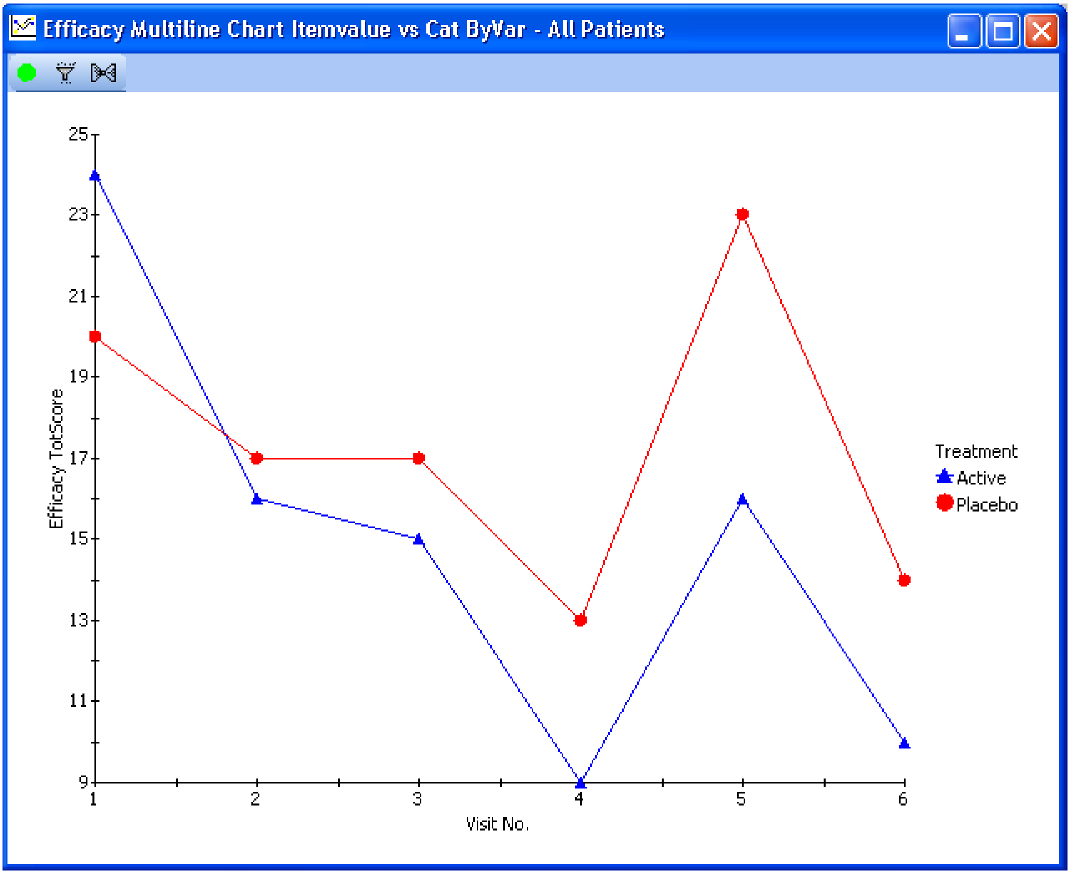
X Axis: HGB

BY Variable(s): SEX

Page Variable:

Graph Heading: Chart ItemValue vs Category by ByVar

In this example, a Patient selection criteria was applied for discontinued patients.



## Benefit Risk Graph

The **Benefit Risk Graph** is a visualization analysis designed by:

**Jonathan D. Norton, Ph.D. - A Longitudinal Model and Graphic for Benefit-Risk Analysis, with Case Study. Drug Information Journal, Vol. 45, pp. 741–747, 2011 • 0092-8615/2011**

The Benefit Risk graph simultaneously presents risk (e.g., adverse events (AE)) and benefit over time. The underlying model represents a patient's benefit-risk at a given time as one of five discrete clinical states, one being premature study withdrawal.

The user can see how a treatment affects groups of patients and further examine how individuals are affected. It is possible to tell whether the beneficial and harmful outcomes are correlated. The graph uses colors to represent each patient's changing state during the clinical trial.

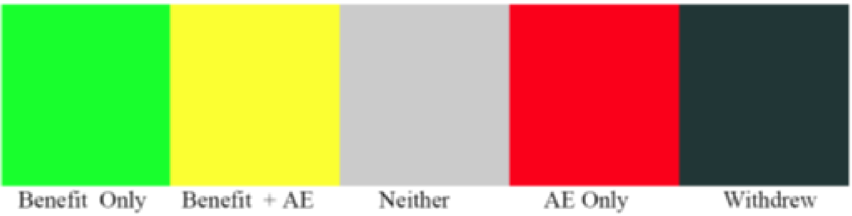
## Analyze Benefit Risk results

The Benefit Risk graph uses a color coding scheme to represent five discrete outcome categories:

1. Green: Benefit without AE
2. Yellow: Benefit with AE
3. Gray: Neither benefit nor AE
4. Red: AE without Benefit
5. Black: Withdrew

***Note: Benefit Risk Graph modified 'gray scale' behavior to add 'light purple/dark purple' in addition to gray scale for better differentiation.***

Benefit Risk analysis shows the comparison of the risk of a situation to its related benefits. It is used to assess patient data from a benefit versus risk point of view. The Benefit Risk graph is designed to meet these needs based on the Chuang-Stein model; where each patient’s outcome is in one of the following categories:

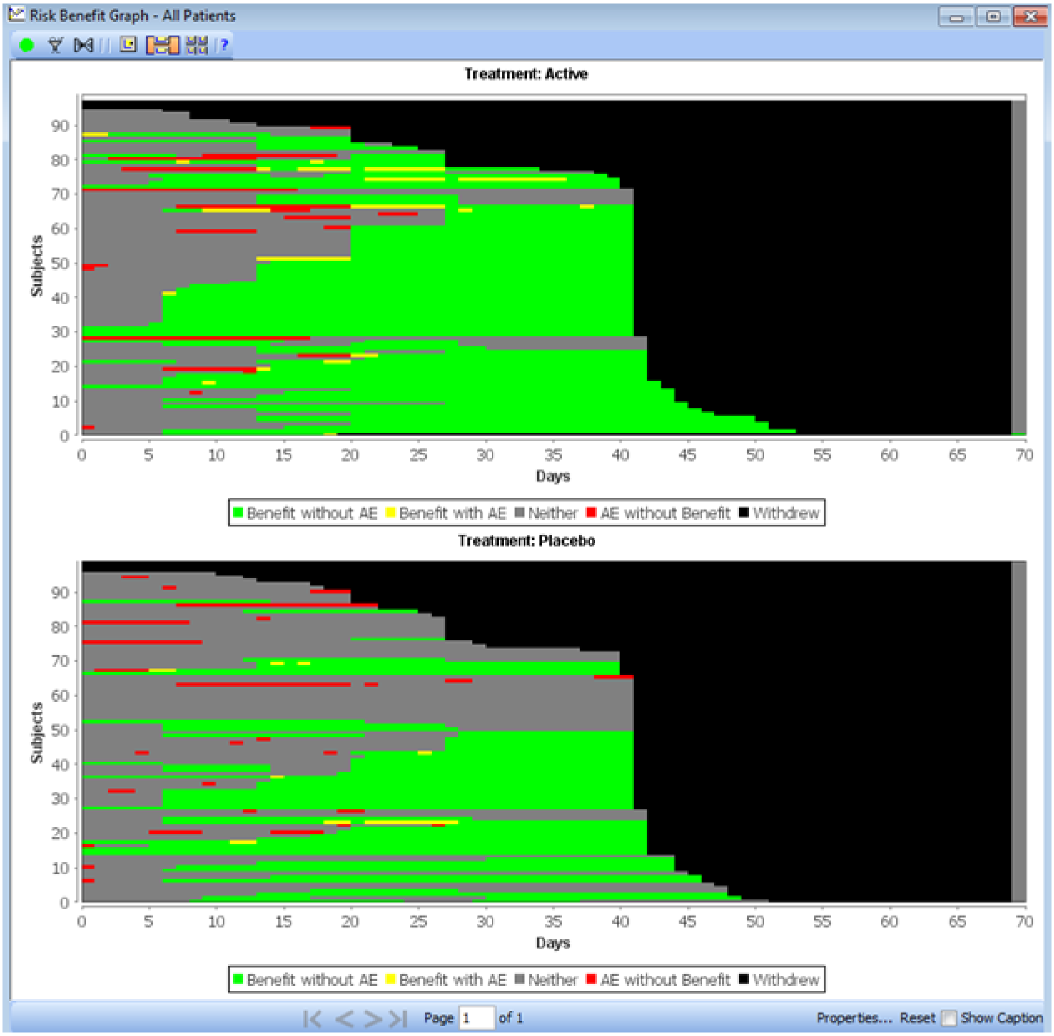


The graph would have one row per patient along the Y axis and time along the X axis. Specific colors are used to distinguish the different categories. The purpose of the graph plots of individual patients to display the overall outcome pattern formed by the color clusters.

The Time intervals (e.g., days on drug – or some reference date) are plotted along the X-axis.

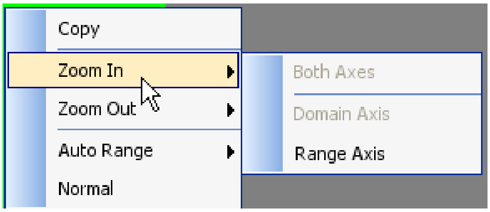
Each patient is represented by an individual “row” in the graph.

The Y-axis tick labels represent the patient counts.

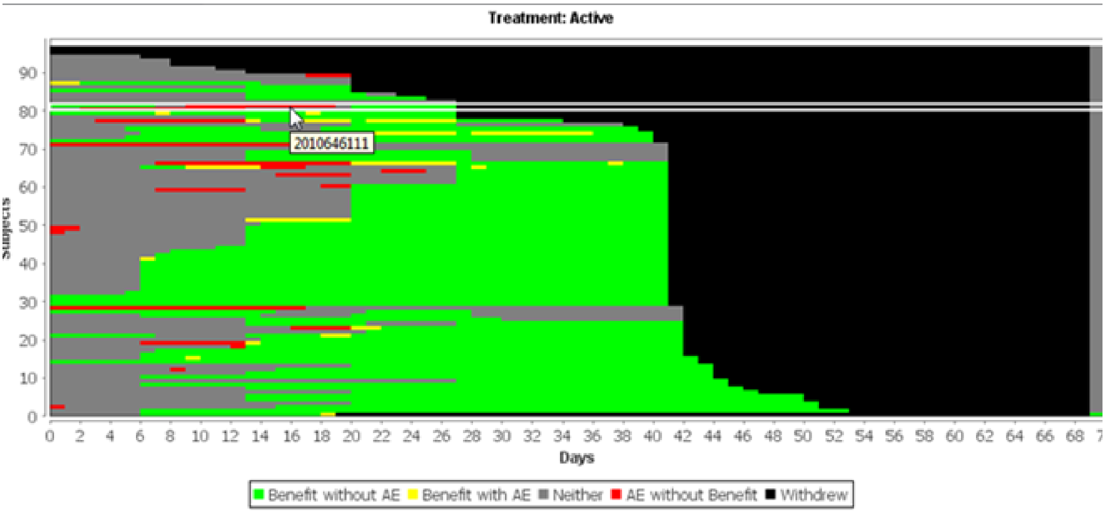


When the mouse is moved over a row, the individual subject row is highlighted by a drawing white box around it and a tool tip presenting the patient identifier appears. The user can select a row by clicking on it with the mouse. Multiple patients may be selected using drag select and/or pressing the control-key when selecting patients. The selected patients are marked at the right margin of the charts, and has the same drill-down side-effect as other details graphs. View the selected patients by opening the Data Browser to access patient details.

Users may zoom-in to enlarge the height of the rows. Right mouse click to display floating menu to zoom.

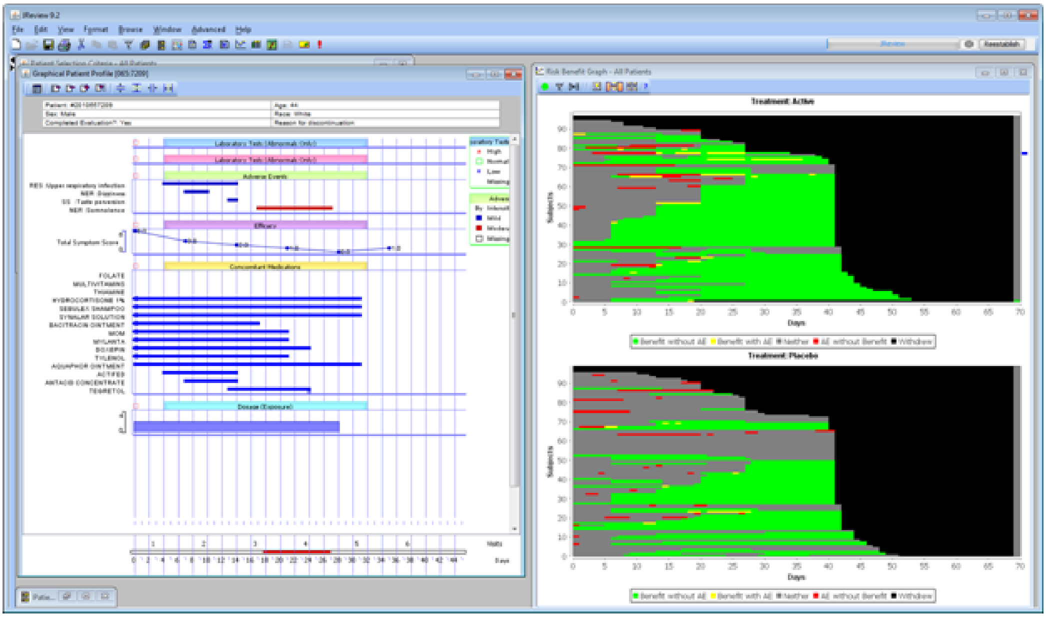


A category value for each color cell is calculated: each cell is a value for an individual patient at a specific time interval. If a ‘page by’ variable has been defined, for example, for treatment, the Benefit Risk graph will be displayed for each value of the page by variable.



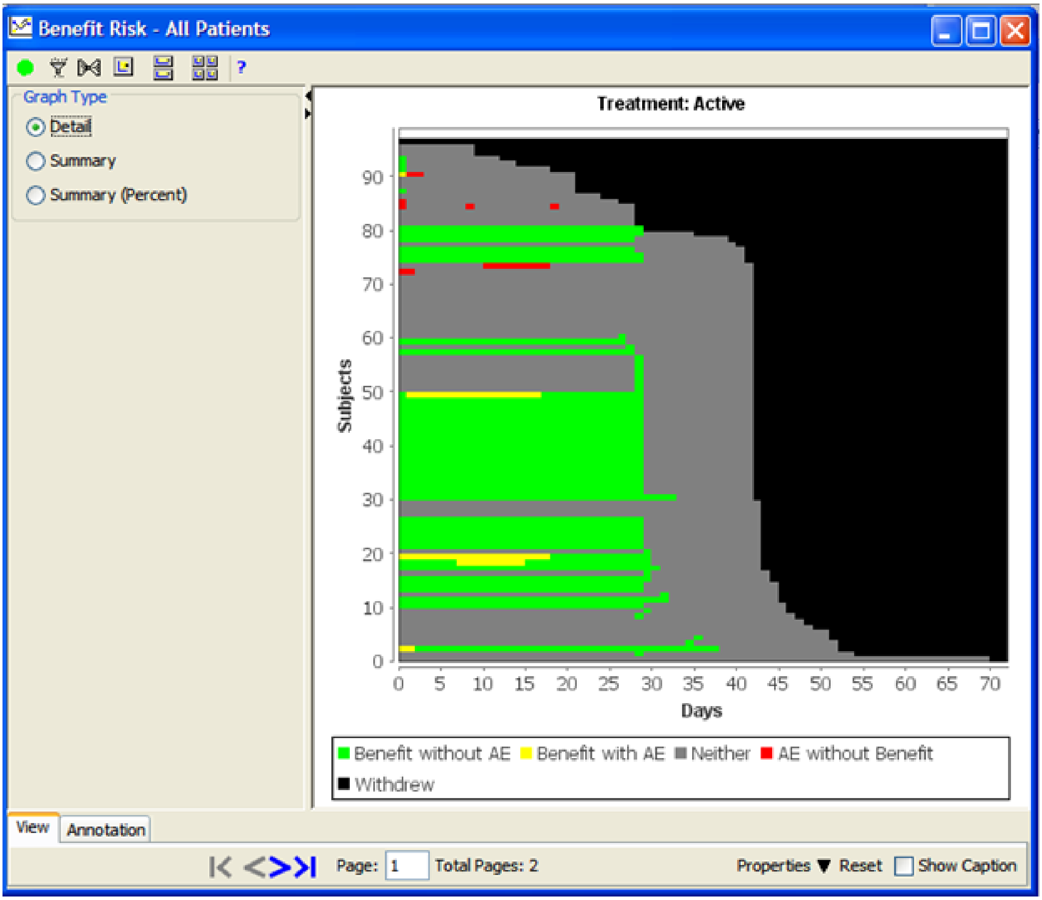
While individual patients are plotted in the graph, displaying the overall outcome pattern formed by the color clusters is a purpose of the graph. To serve this purpose, the patients are sorted based on their category scores at each time interval. By default, patients are sorted on category scores with scores at later time periods given precedence – “green” at later time periods will cluster at the bottom right of the graph.

An interesting example of use of the Benefit Risk Graph is with ‘drill down’, to the selected patient’s Graph Patient Profile.

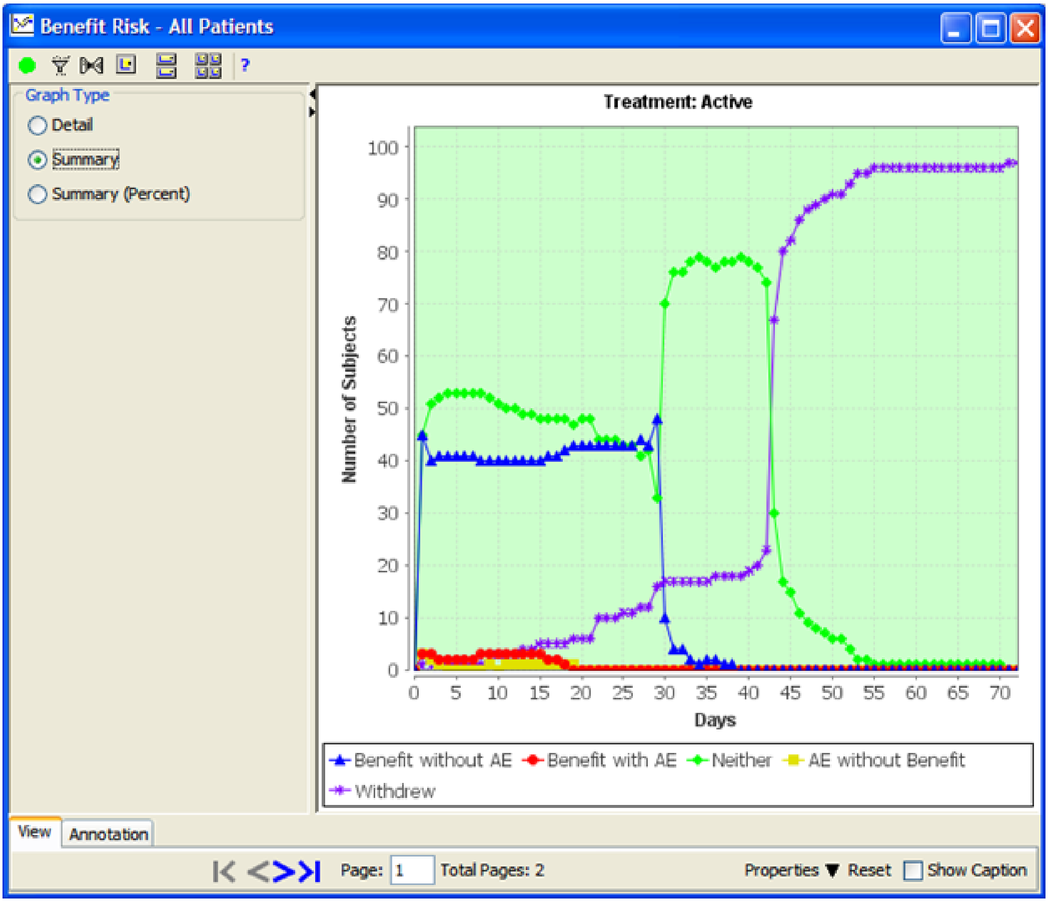


## Summary Benefit Risk

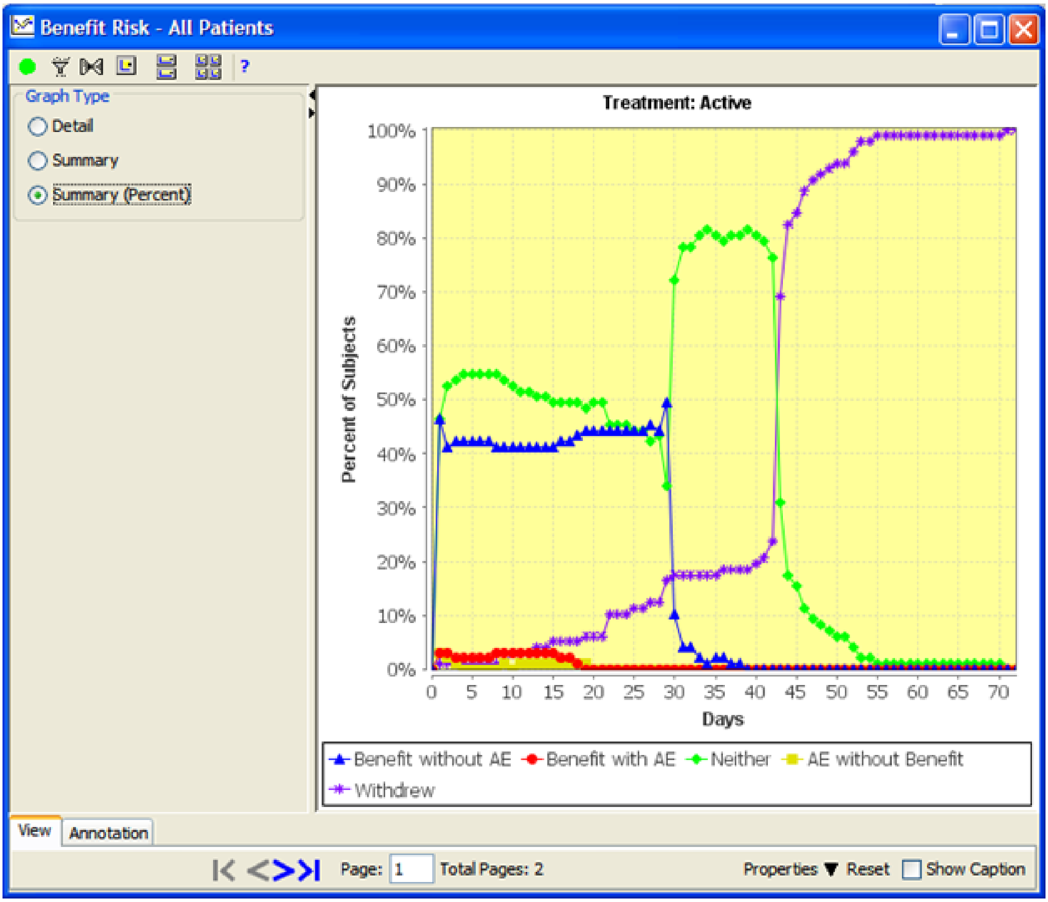
Initially the Benefit Risk result window opens in Detail mode.



Click on the Graph Type for Summary option to view Summary Benefit Risk display.



Click a third checkbox to the Benefit-Risk chart's control panel for "Summary (Percent)". This additional Summary chart for Benefit Risk displays for the Y-axis values calculated as percents of the number of patients in the "page" (i.e., the category that the page represents such Active Treatment arm).

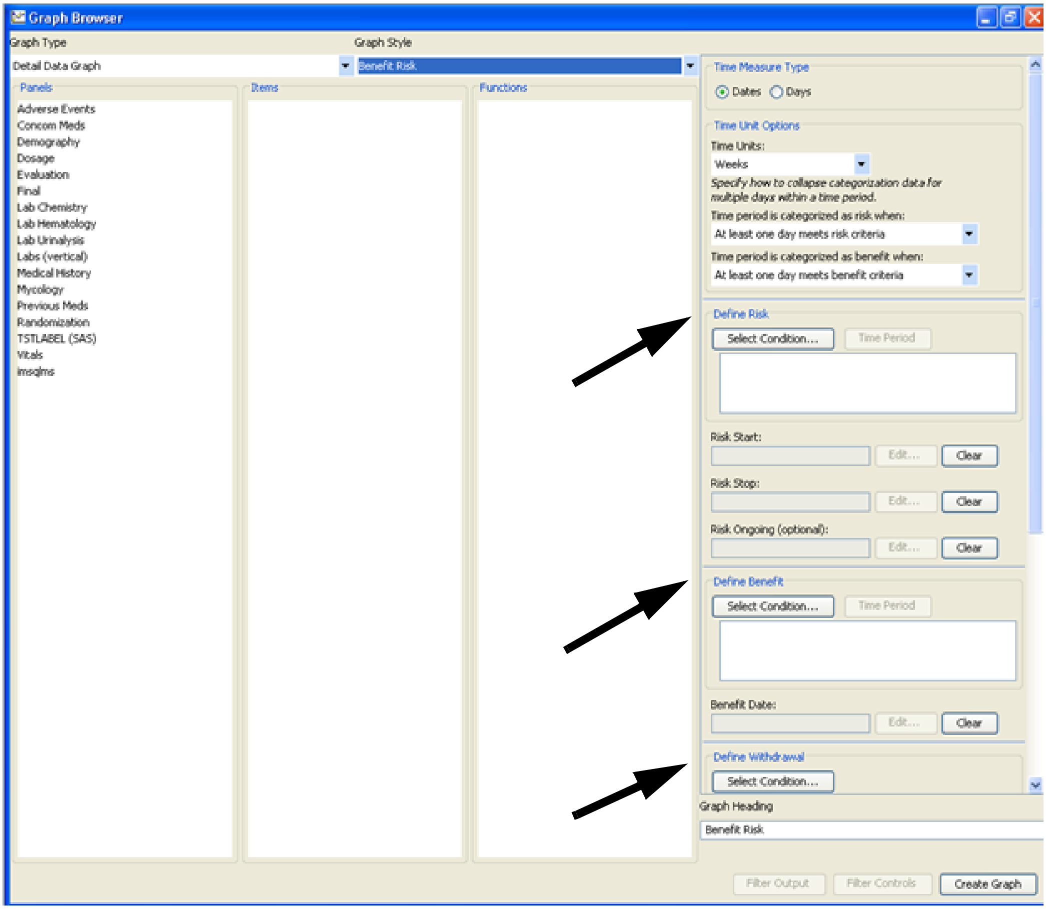


## *Define Benefit Risk analysis*

The Benefit Risk Graph is a detail graph type specified in the Graph Browser, however, the specification differs from other graphs.

The specifications for define Risk, Benefit, and Withdrawal are ***each*** separately defined as output filters. Users define each of the filters by opening an output filter dialog associated with Risk, Benefit, or Withdrawal. The filter dialog is launched by clicking on the “**Select Condition…**” button. The saved filter expressions are shown in separate view-only text fields.

1. To start, select Detail Data Graph for Graph Style as Benefit Risk.



Graph Type: Detail Data Graph

Graph Style: Benefit Risk

Time Measure Type: ● Dates ○ Days

Time Units: Weeks

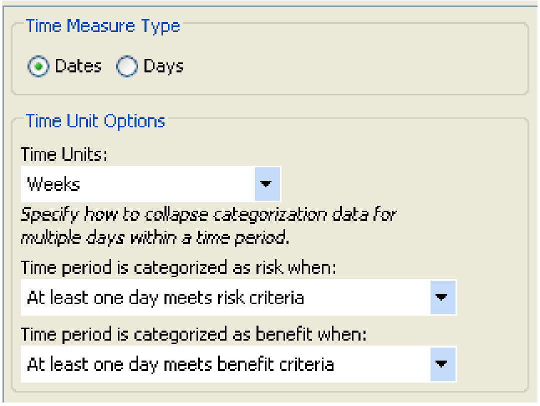
*Specify how to collapse categorization data for multiple days within a time period.*

Time period is categorized as risk when: At least one day meets risk criteria

Time period is categorized as benefit when: At least one day meets benefit criteria

Graph Heading: Benefit Risk

2. Select the **Time Measure Type,** by choosing the time variable based on ***Dates*** or ***Days*** (in the clinical trial). Choose the ***Days*** option, if days have already been calculated and stored in the data. Otherwise, select ***Dates*** so JReview can do the day calculations for you.



Time Measure Type

● Dates ○ Days

Time Unit Options

Time Units: Weeks

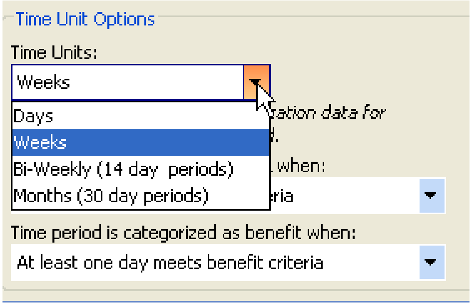
*Specify how to collapse categorization data for multiple days within a time period.*

Time period is categorized as risk when: At least one day meets risk criteria

Time period is categorized as benefit when: At least one day meets benefit criteria

The Risk, Benefit, and Withdrawal condition filters require a date (or days) variable to be associated with them. The Time Measurement variables are needed so that JReview can compute the time intervals for risk, benefit or withdrawal occurrences.

3. Select **Time Units** under **Time Unit Options** for how to display study data over longer time periods. It supports easier viewing of benefit and risk trends within the reported adverse events.

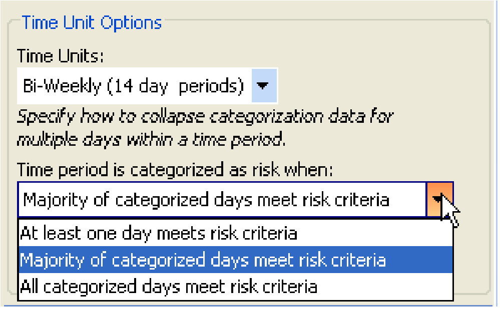


Time Unit Options

Time Units: Weeks

Time period is categorized as benefit when: At least one day meets benefit criteria

4. Select for how the **Time period is categorized as risk when**:



Time Unit Options

Time Units:

Bi-Weekly (14 day periods)

*Specify how to collapse categorization data for multiple days within a time period.*

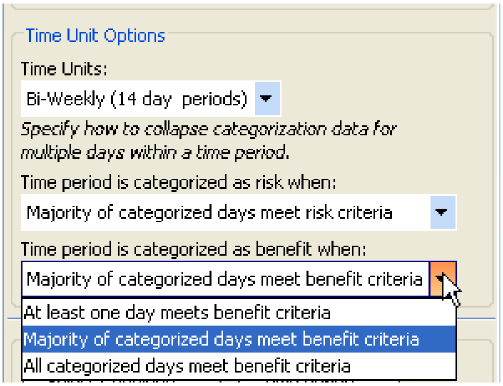
Time period is categorized as risk when:

Majority of categorized days meet risk criteria

There are three options for how to categorize risk when:

- **At least one day meets risk criteria.** This is the least restrictive option, where one day with risk criteria within a time period shows risk.
- **Majority of the categorized days meet the risk criteria.** This is the middle level for restriction.
- **All categorized days meet the risk criteria** is the most restrictive option.

5. Next, select how the **Time period is categorized as benefit when**:



Time Unit Options

Time Units:

Bi-Weekly (14 day periods)

*Specify how to collapse categorization data for multiple days within a time period.*

Time period is categorized as risk when:

Majority of categorized days meet risk criteria

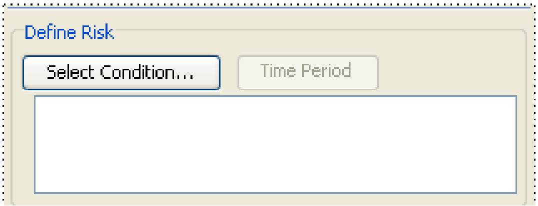
Time period is categorized as benefit when:

Majority of categorized days meet benefit criteria

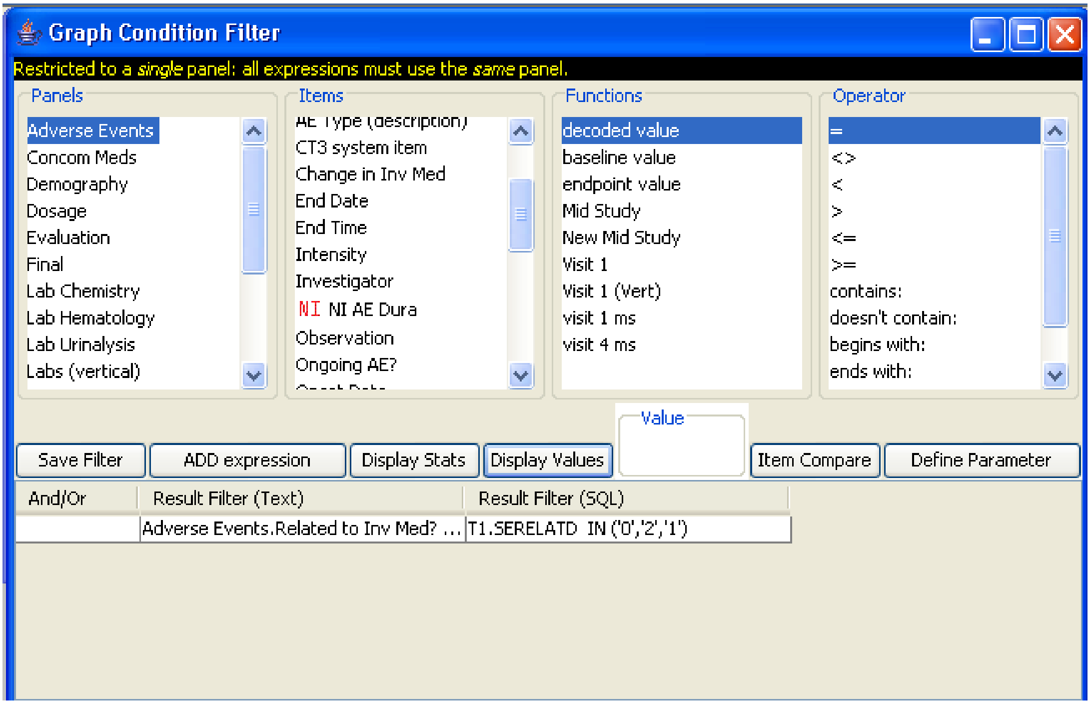
There are three options for how to categorize benefit when:

- **At least one day meets benefit criteria**. This is the least restrictive option, where one day with benefit criteria within a time period shows benefit.
- **Majority of the categorized days meet the benefit criteria.** This is the middle level for restriction.
- **All categorized days meet the benefit criteria** is the most restrictive option.

6. Click **Select Condition** button for **Define Risk**.



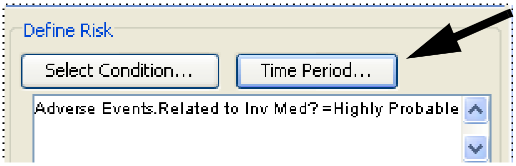
The Graph Condition Filter window opens. It is restricted to a single panel where all expressions must use the same panel. The choice of filter expressions is validated when the user clicks the save button in the filter dialog. Otherwise, an error message will display if the filter expressions to do not comply with the restrictions.



Restricted to a *single* panel: all expressions must use the *same* panel.

| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | Adverse Events.Related to Inv Med? ... | T1.SERELATD IN ('0','2','1') |

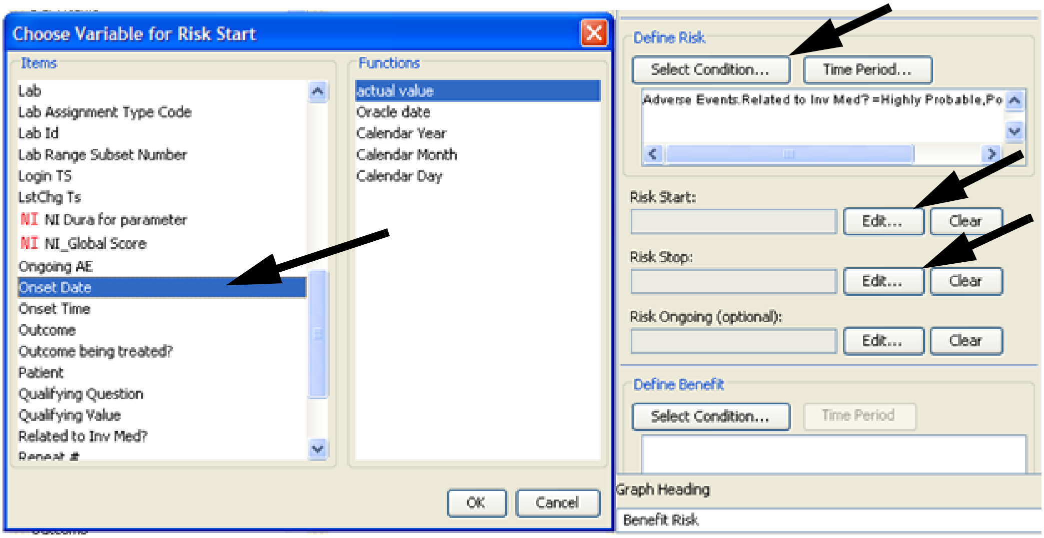
Optionally, you may enter a **Time Period** as a filter feature to restrict the defined risk criteria to specific visits, visit labels, etc.



Adverse Events.Related to Inv Med? =Highly Probable

7. Select Risk dates (days) for **Risk Start** and where a **Risk Stop** is required, and optionally a **Risk Ongoing** variable may be chosen. If the patient discontinued, then the study date (day) of discontinued will over ride all other dates.
   - Each of these time-based variables can only be chosen ***after*** the corresponding filter expressions are saved.
   - The panels selected in the corresponding filter expressions determine the available items for the time-based variables.
   - The controls are enabled or disabled appropriately to enforce these conditions.

   To enter a Risk Start, Stop, and Ongoing time-based variable, click on the corresponding **Edit** button. The **Choose Variable** dialog displays for the associated panel from the Select Condition. Use the **Clear** button to remove an entry.



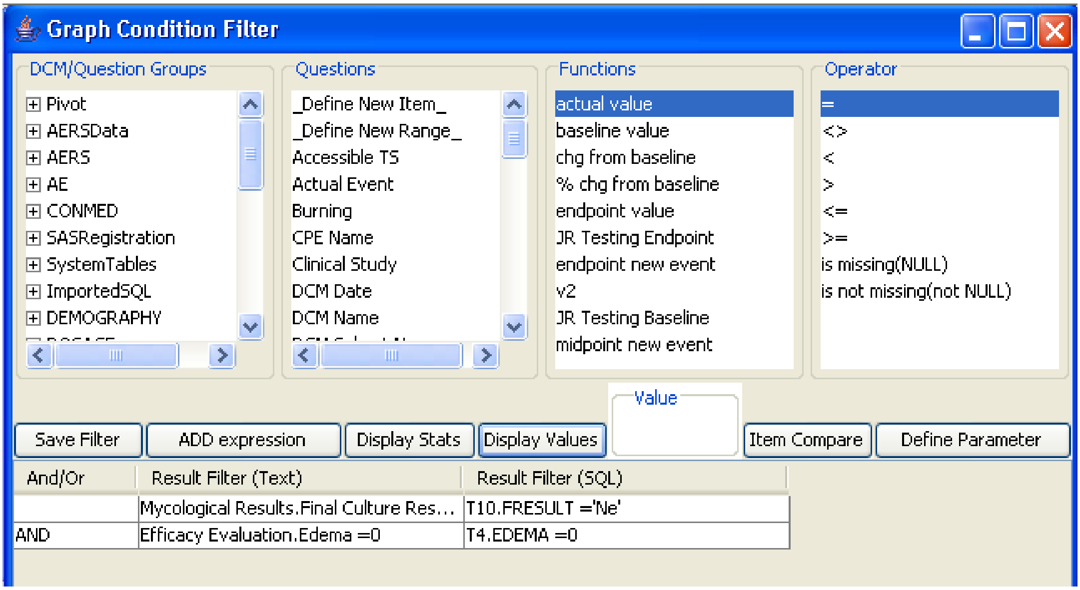
Adverse Events.Related to Inv Med? =Highly Probable,Po

Benefit Risk

8. Click on **Select Condition** for **Define Benefit**.

   The Graph Condition Filter window opens ***without*** the panel restrictions applicable to Define Risk.

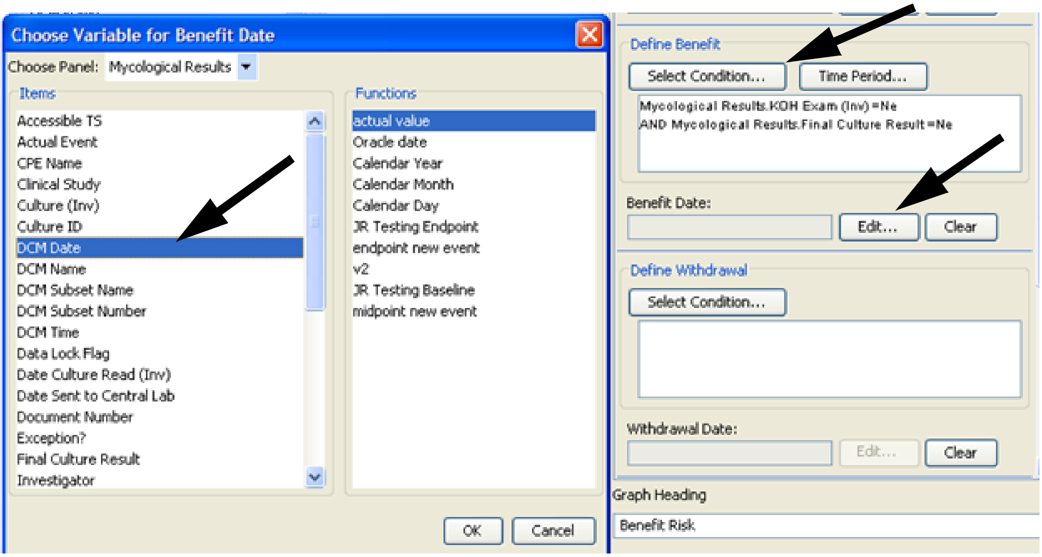
   The Define Benefit allows the filter expressions to reference multiple panels.



| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | Mycological Results.Final Culture Res... | T10.FRESULT ='Ne' |
| AND | Efficacy Evaluation.Edema =0 | T4.EDEMA =0 |

9. Enter a **Benefit Date**. The date (day) item is selected from one of the panels in the Benefits filter expressions.

   The Output Filter dialog for choosing the associated date/day item contains a Combo Box listing those panels contained in the Benefit filter expressions. The user can only select one date/day item by choosing a panel, select item and function.



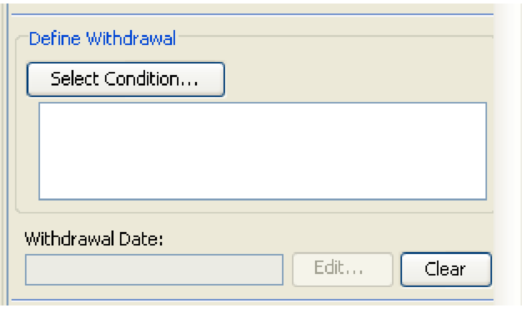
Choose Variable for Benefit Date

Choose Panel: Mycological Results

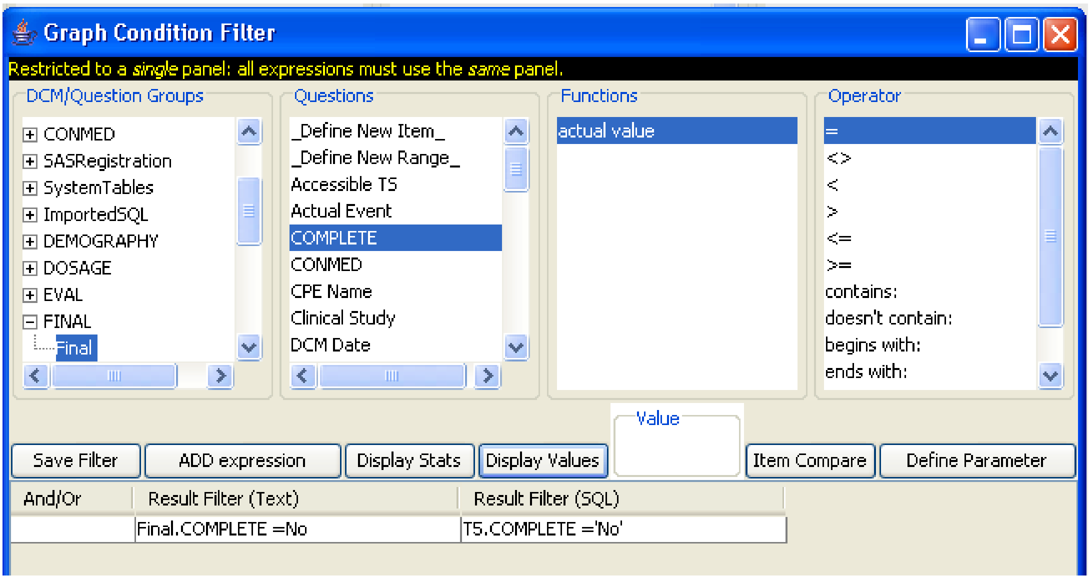
Mycological Results.KOH Exam (Inv)=Ne
AND Mycological Results.Final Culture Result=Ne

Graph Heading: Benefit Risk

10. Click on **Select Condition** button to **Define Withdrawal**.

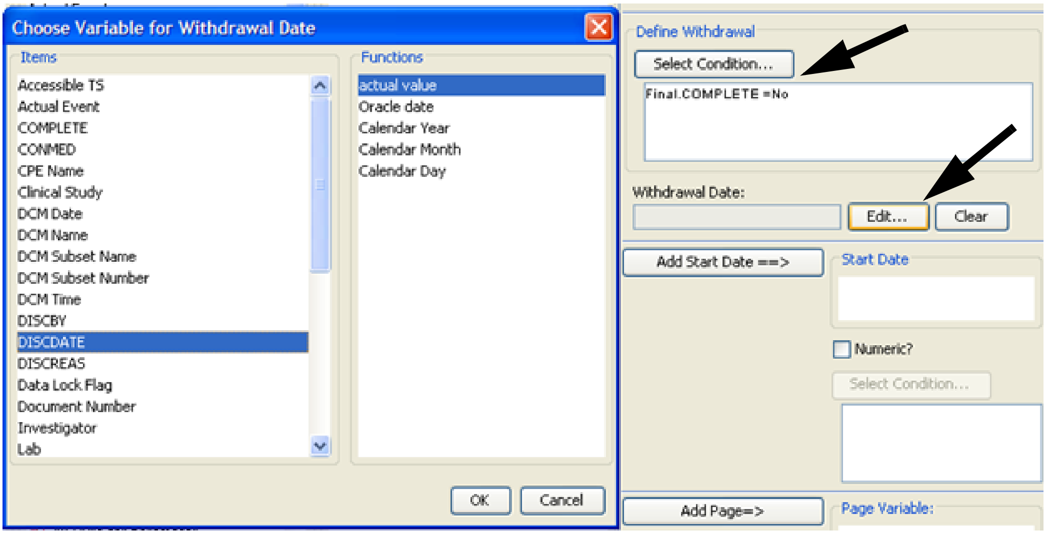


The Graph Condition Filter window opens. It is restricted to a single panel where all expressions must use the same panel.



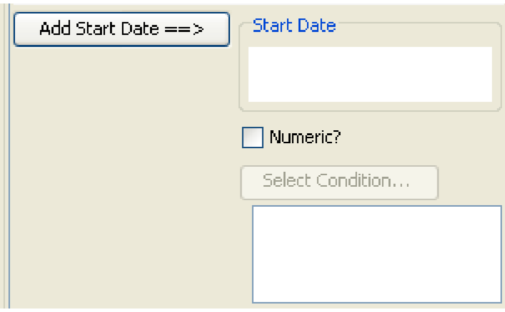
| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | Final.COMPLETE =No | T5.COMPLETE ='No' |

11. Enter a **Withdrawal Date** which will be selected from the same panel that defined the Withdrawal filter condition.



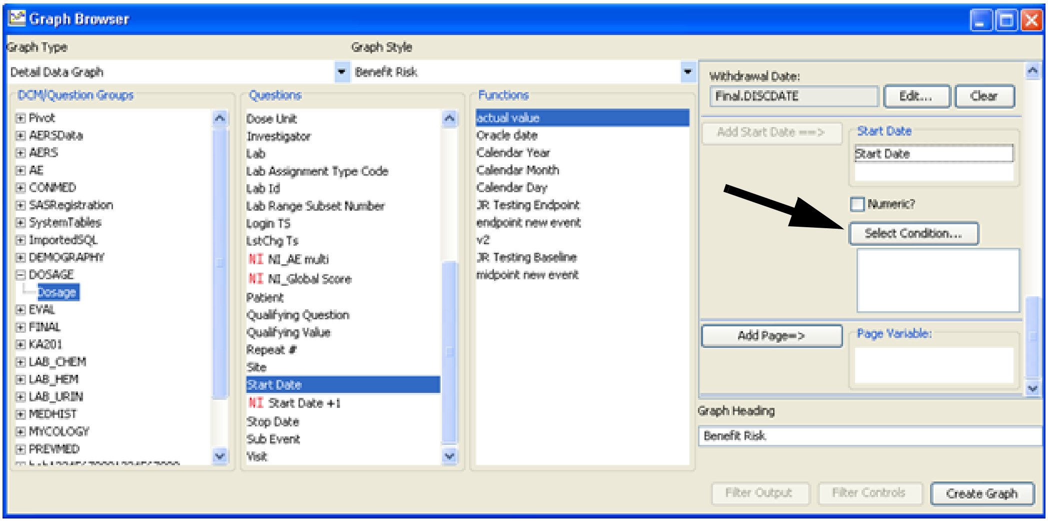
Final.COMPLETE =No

12. Next, you must enter a **Study Start Date** when the **Time Measure Type** is set for ***Dates.*** If you entered the **Time Measure Type** for ***Days*****,** then the **Add Start Date** button is shaded and disabled.



In this step, *s*elect a panel from the Panels list and the date item from the Items list. The study day calculation are determined as Risk Start and Risk End dates minus Randomization date, Visit date minus Randomization date, etc.

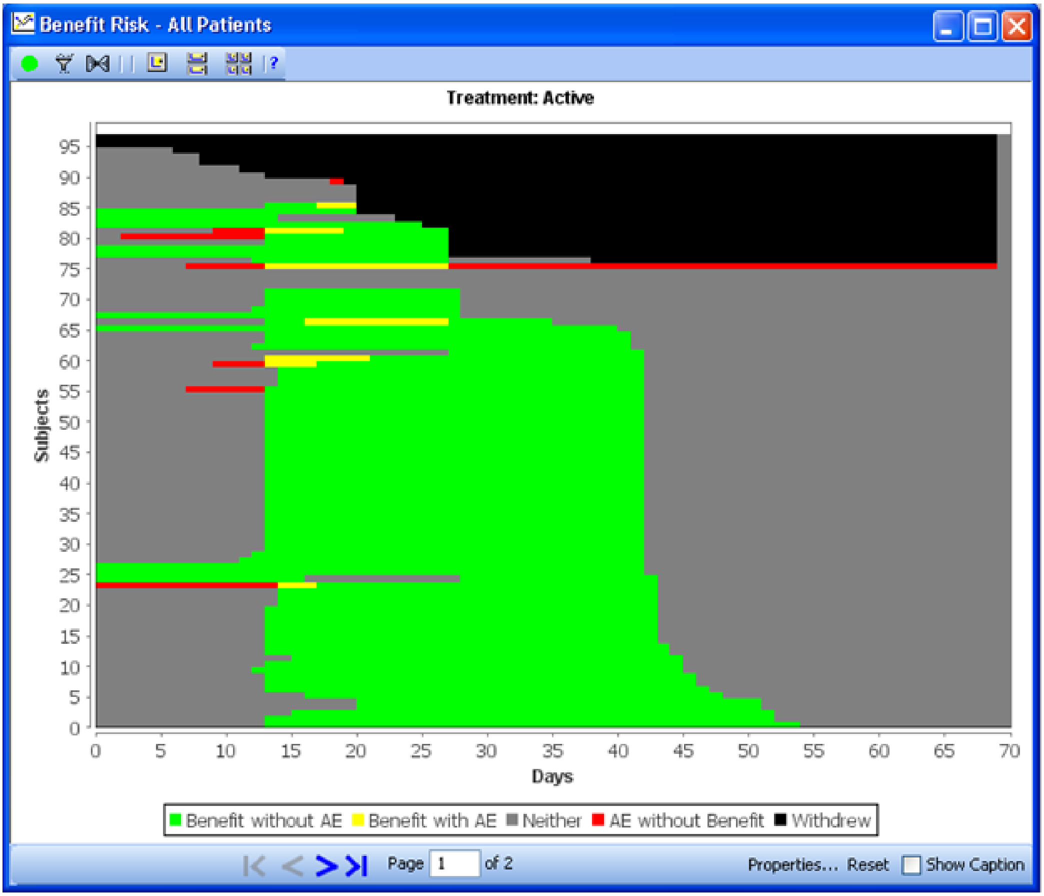
If you choose a ‘Start Date’ from a table/dataset with multiple visits per patient i.e., Dosage; you must also click on the ‘**Select Condition**’ button to define the filter condition to select which record should be chosen for each patient.


Graph Type: Detail Data Graph
Graph Style: Benefit Risk
Withdrawal Date: Final.DISCDATE
Start Date: Start Date
Graph Heading: Benefit Risk

13. Optionally, add **Page Variable** for the further categorization of data (i.e. per investigator, site, treatment, etc.).

***Note: The overall output filter for a graph is NOT allowed for Benefit Risk graph, and the output filter button is disabled.***

14.Click **Create Graph**.

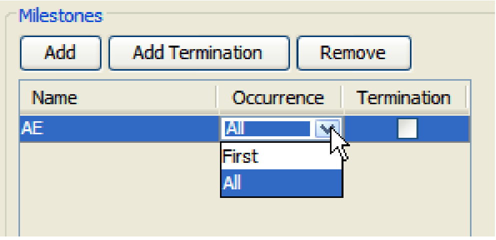


## *Napoleons March graph*

The Napoleon's March Chart is analogous in its presentation of events over time to Minard's classic nineteenth-century graph of data associated with the Napoleonic army's advance and retreat from Russia. The design of JReview's version of Napoleon's March is based on FDA documents and other sources. However, there is variability in the features contained in the different published examples of this chart. JReview 's version incorporates selected features from across these examples. In addition, JReview's version provides scrolling so that the chart is not limited to small patient sizes.

The Napoleon's March Chart presents a set of patient identifiers on the vertical axis and time (e.g., days, weeks, months) on the horizontal axis. The time axis typically represents something like "Days in the Study." "Milestones" are plotted for each patient. End-users define the milestones. Example milestones are the onset of Adverse Events and End-Of-Treatment. JReview allows the user to specify up to three different milestones. Each milestone is specified using a control similar JReview's filter mechanism; a variable defining the time (e.g., day, date) at which a milestone occurred must also be specified.

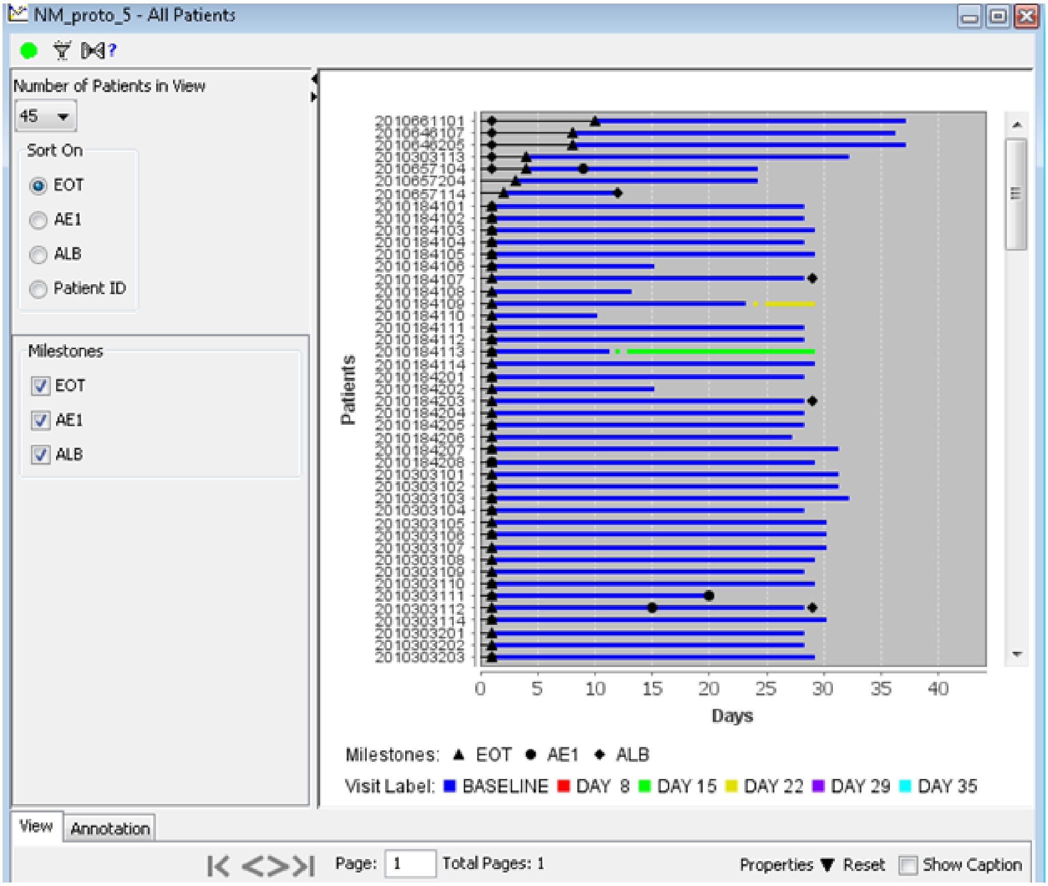
The user can specify whether just the *first* occurrence of the milestone should be shown or whether or *all* occurrences should be shown. Optionally, a special "termination" milestone can be specified; this milestone type indicates some terminating event such as End-Of-Treatment or Death. Graphically, for each patient, a horizontal line is drawn from the lower limit of the horizontal axis (e.g., study start time) to the "termination" milestone. If a termination milestone is specified,  JReview will automatically use the first occurrence of that milestone event.



| Name | Occurrence | Termination |
|---|---|---|
| AE | All | ☐ |

The time that a patient is in a study may be divided into time *periods*. Each time period is associated with a different condition for each patient. For example, a patient might be assigned to different treatment conditions (e.g., drug dose levels) during different time periods in the course of a study. Perhaps, an individual drug dosage is temporally reduced for some time interval. Another scenario might be that a study has different phases or a sequence of phases through which patients move; the amount of time spend in each phase may vary across patients.

To represent these “periods”, the Napoleon’s March chart draws color coded horizontal line segments for each patient to indicate the assigned condition of a patient during a period of time. This feature is optional. To specify this feature, the user defines filter and two time variables (e.g., days, date): start time and end time.Napolen’s March chart with Periods and single page shown.


NM_proto_5 - All Patients

Number of Patients in View: 45

Sort On
- ● EOT
- ○ AE1
- ○ ALB
- ○ Patient ID

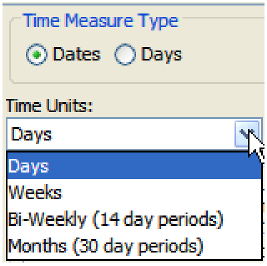
Milestones
- ☑ EOT
- ☑ AE1
- ☑ ALB

Page: 1 Total Pages: 1

☐ Show Caption

The user may define whether “time” is calculated by “date” variables or more directly from a “days” variables (i.e., “days in study “variables). If time is not directly provided in “days” variables, then a start date to be used for all date-based time calculations must be specified. Time variables must be consistent across: either they are always “dates” or always “days.”

Users can specify the time units to be used on the time (horizontal) axis. The time units are: days, weeks, bi-weekly, and months.

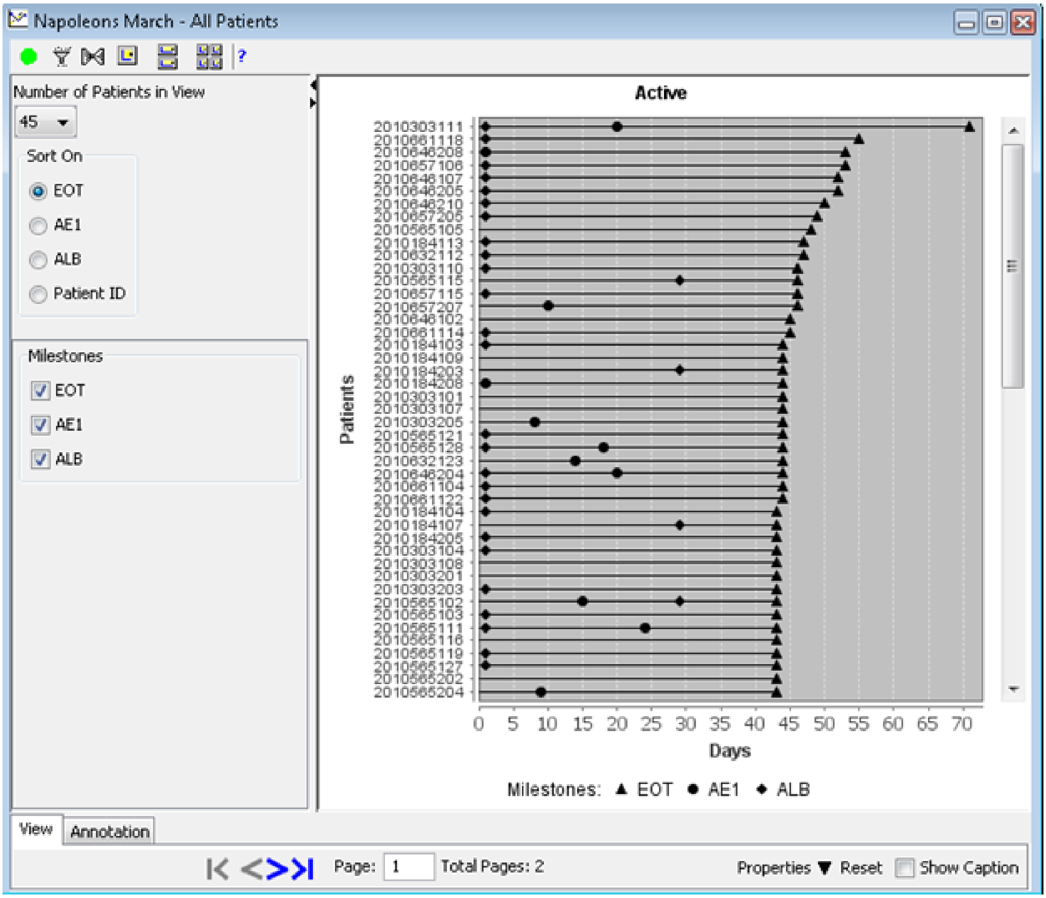


The paging variable can be used with the Napoleon’s March chart. Unlike other graphs, when more one page is presented simultaneously, multiple pages are positioned in a single row, that is, with a horizontal layout. There are no BY-variables used with Napoleon’s March charts.

The total number of patients in the graph may require more vertical space for readable presentation that can accommodated in one “view.” Therefore a vertical scrollbar is provided so that users can scroll through the sample of patients in the chart. By default, 45 patients are shown in the graph at any one time. The user can change the number of simultaneously viewable patients by choosing an option from the Combo Box contained in the control for the chart(s). For example, if the user resizes the graph window and increases the chart’s height, there may be room for more patients; in such a case the user can increase the number of simultaneously viewed patients. Thus, degree of “cramping” in the display can be controlled by the user.

A set of radio buttons are provided in the control panel to manipulate sorting. The user can choose the milestone on which to sort. Sorting on milestones has a descending order. In the case of a milestone with multiple occurrences, the maximum time value (e.g., days in study) is used for each patient. The sort can be also based on the Patient Identifier; in this case, the sort is alphabetical in an ascending order.Napoleon's March chart with No periods specified.

When there is more than one milestone specified, a set of check boxes are shown in the control panel. Each of these checkboxes toggles the visibility of a milestone.



Napoleons March - All Patients

Number of Patients in View: 45

Sort On
● EOT
○ AE1
○ ALB
○ Patient ID

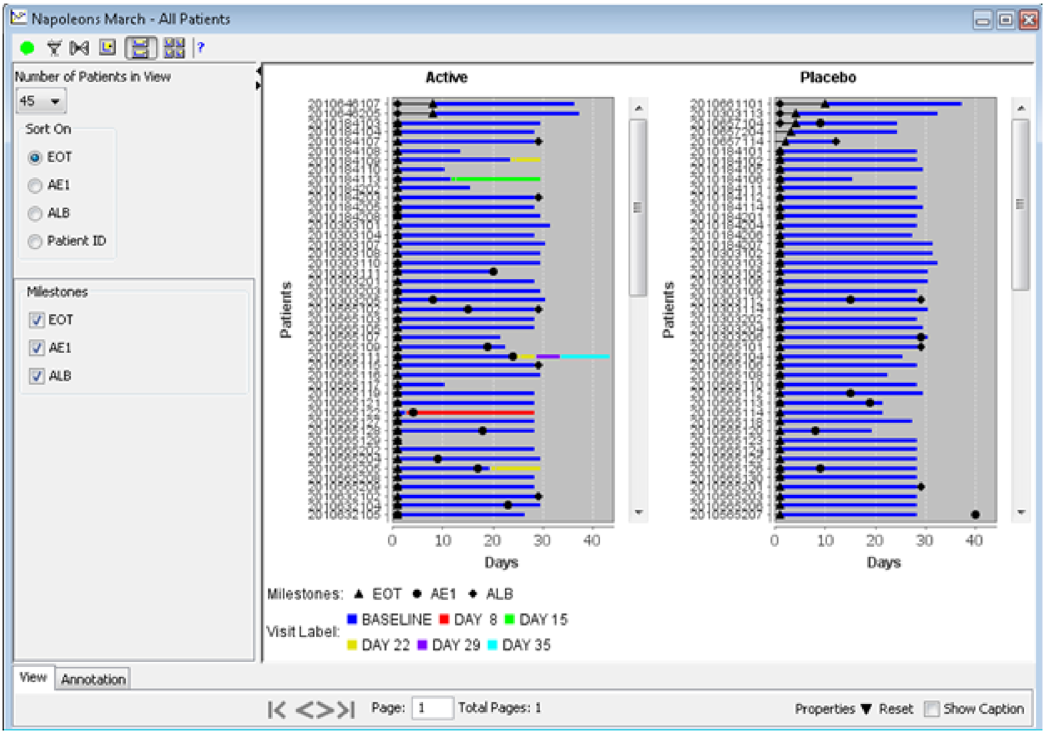
Milestones
☑ EOT
☑ AE1
☑ ALB

Page: 1 Total Pages: 2

☐ Show Caption

The Napoleon’s March chart is a Detail graph. It supports *drill-down*. The patient identifier labels on the vertical axis are clickable and selectable. Also, the Napoleon’s March chart will highlight the labels of any patients received via the PID selection mechanism. For example, selecting a patient in the Data Browser may result in highlighting the label for that patient in Napoleon’s March chart.

Napoleon’s March chart with Periods defined and multiples pages shown.



Napoleons March - All Patients

Number of Patients in View: 45

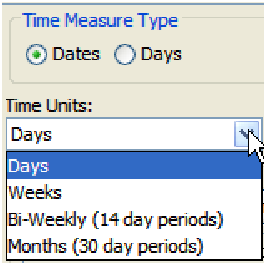
Sort On
● EOT
○ AE1
○ ALB
○ Patient ID

Milestones
☑ EOT
☑ AE1
☑ ALB

Page: 1 Total Pages: 1

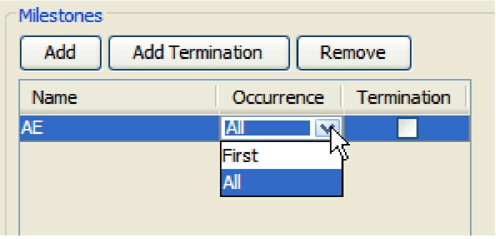
☐ Show Caption

Radio buttons in the Time Measure type control whether time is based on date or day variables. If “Dates” is selected, then the user must choose a start date variable in the Start Date panel. The Start Date control is enabled only when “Dates” is selected. The combo box in the Time Units panel allows the user to specify whether the units on the time axis should be days, weeks, bi-weekly (14 day periods), or monthly (30 day periods).



The Milestones panel specifies the milestone definitions and the time variable associated with each one. At least one milestone must be specified; the maximum number of milestones is five. Optionally, one of the milestones may be a “termination” milestone.

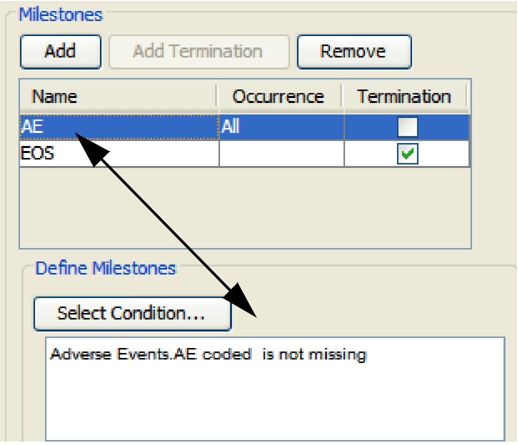
To create a milestone, click on either the Add or Add Termination button. The Add button is enabled if there are less than 3 milestones already specified and the Add Termination is enabled if there are less than 3 milestones already added and no “termination” milestone has been already added.



Clicking these buttons adds a new row to the table just beneath the buttons. The first column of the table is the name of the milestone. The entries in the first column are editable; while a “temporary” name is automatically, the user should type a meaningful into the table cell. (Note: the milestone is defined by a filter, which is a set of SQL-like clauses, and not a variable that has a name). Milestone names entered into this table should be duplicated within this table, that is, the name should be unique with the graph specification.) The second column also contains editable entries except where the milestone is a “termination.” The entries in the second column allow the user to specify either the First occurrence of a milestone event or All event occurrence of the milestone being defined in the row. Clicking on a cell in the second column displays a combo box for making this choice. A termination milestone automatically has a “first” occurrence value, and this value cannot be changed by the user. The third column indicates whether the milestone is a termination milestone. The checkboxes in the third column are not editable.

Selecting a row in the milestones table flips the **Define Milestone** panel to a set of controls for defining the milestone represented in that row. If no row is selected, then no controls are shown – the panel is blank. The controls for defining a milestone are similar to those found for the Benefit-Risk chart.

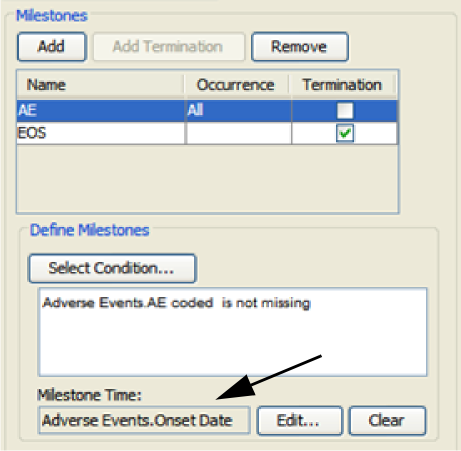
The user clicks on the “**Select Condition…**” button to open an “output filter” dialog. **All filter expressions (i.e., items) for a milestone must be chosen from the same “panel.”** An error message will be presented if multiple panes are chosen when attempting to “save’ the filter.



| Name | Occurrence | Termination |
|---|---|---|
| AE | All | ☐ |
| EOS | | ☑ |

Adverse Events.AE coded is not missing

An additional control is used to choose a time variable for the milestone. The items presented the time variable dialog belong to the panel chosen for the filter. The time variable control is enabled after a filter is created. **Both a “filter” and a time variable must be defined.** JReview checks that the required data is entered and the milestone names are unique when the user attempts to save the graph definition or create a graph directly. An error message is presented if these conditions are violated.

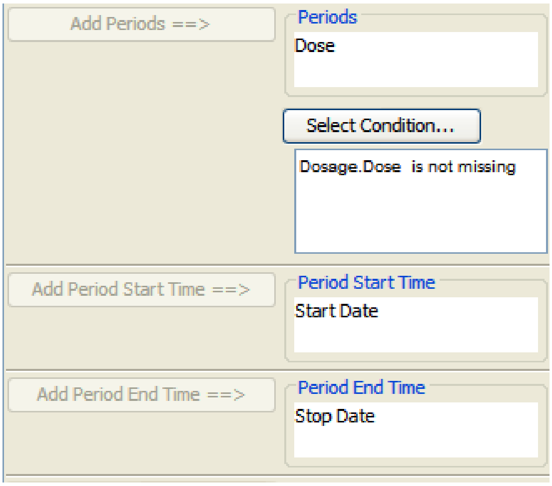


| Name | Occurrence | Termination |
|---|---|---|
| AE | All | ☐ |
| EOS | | ☑ |

Adverse Events.AE coded is not missing

Milestone Time: Adverse Events.Onset Date

The Periods controls are used to specify the “periods” described above. The “periods” feature is optional. To define “periods”, items are chosen for the “Periods” variable and for the start time and end time. The “time” items must be consistent with the choice in the “Dates vs. Days” control, and all of these three items should be chosen from the same panel.



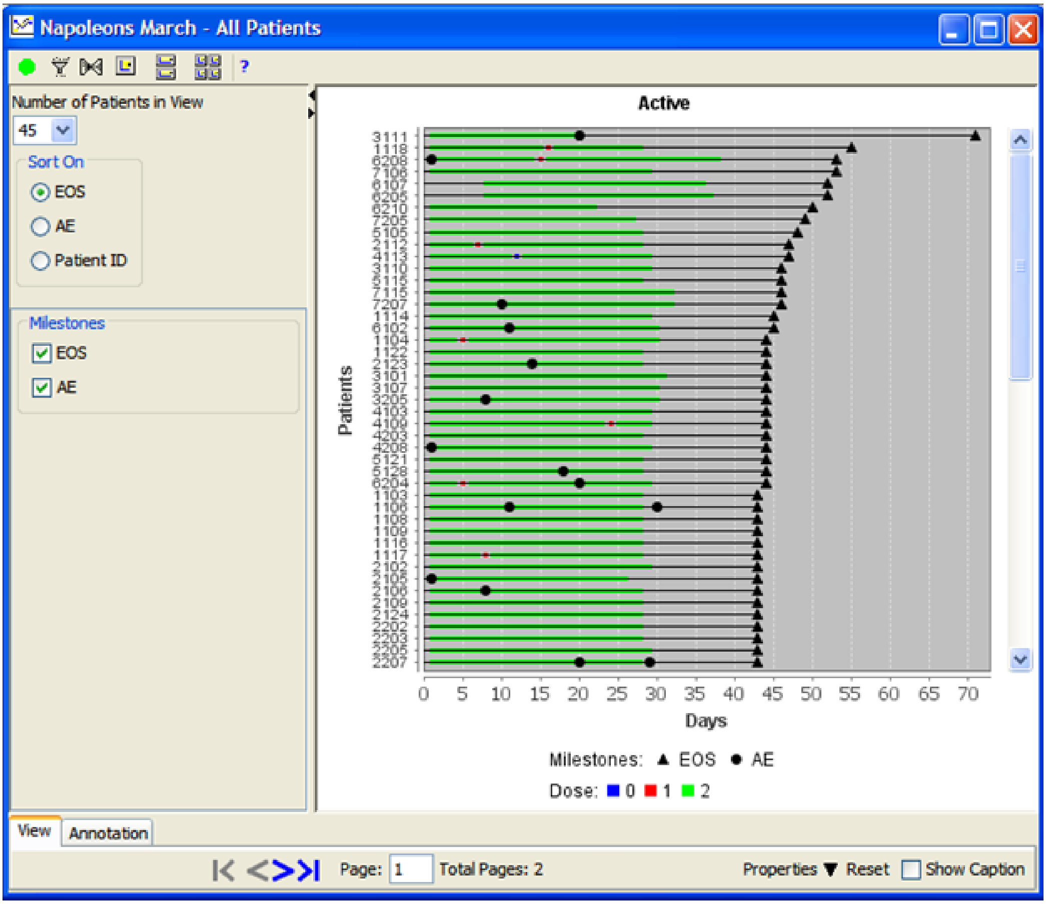
Periods: Dose

Dosage.Dose is not missing

Period Start Time: Start Date

Period End Time: Stop Date

Optionally apply a **Page BY** variable.



Number of Patients in View: 45

Sort On: ● EOS

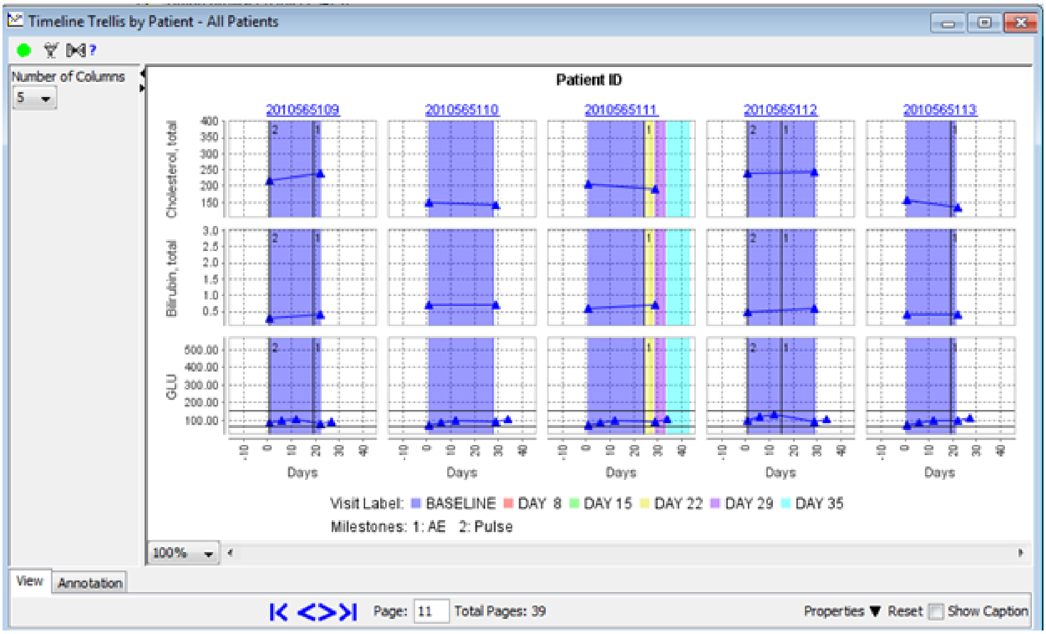
Milestones: ☑ EOS ☑ AE

Page: 1 Total Pages: 2

## Timeline Trellis by Patient graph

JReview's ***Timeline Trellis by Individual Patients*** graph is composed of a matrix of individual subplots with the following general characteristics:

- Each column represents a patient.
- The X-axis, shown at the bottom of each column, represents a time variable such as "Days in Study".
- Each row has a Y-axis shown on the left side. These Y-Axes typically represent different laboratory tests or other patient measures such as "blood pressure".
- Each subplot is a ***line chart*** that plots Y-axis values over time.
- As there are usually more columns than can be shown at once, the charts are drawn on a sequence of pages, with each page having multiple columns.



Number of Columns: 5

100%

Page: 11 Total Pages: 39

The column titles are the patient identifiers, so clicking on a title results in a "drill-down".

The user can reset the number of columns to be displayed in each plot, i.e., the number of columns that appear on each page. Changing the number of displayed columns alters the total number of pages. If the user has drawn annotations on the graphs, these will be deleted when the number of columns is changed; a Warning dialog is presented before proceeding with this operation.

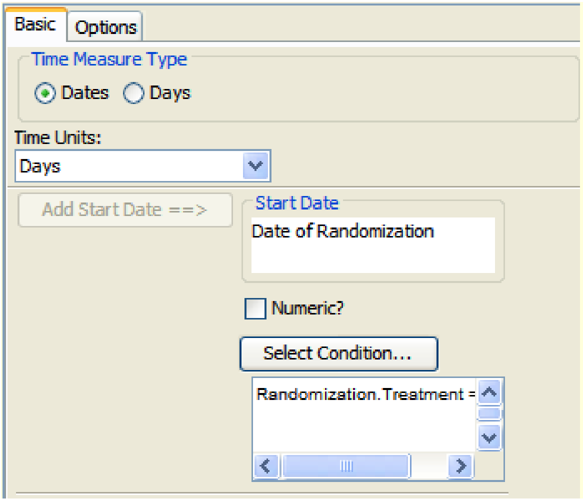
## *Define Timeline Trellis Basic tab*

The Graph Browser controls for the ***Timeline Trellis by Individual Patient*** graph are presented in a tab panel. The first tab, “Basic”, contains the controls for the defining line chart itself (and the Normal Range limits in the case of Vertical Panels).

The X-axis is time-based with controls generally the same or very similar to those in Napoleon’s March and some other existing JRevew graphs.

The user may specify whether “dates” or “days” are to be used in determining time values. If “dates” is selected as the time mode, then a start date must be specified, and all variables in the overall specification must have the accompanying “time” specification made in terms of dates. Some datasets have time values that are pre-calculated as days. If “days” is selected, then the start date is not defined and all time variables must be “days”.

The user may specify the X-axis’s time units to display the X-axis values calculated as Days, Weeks, Bi-Weekly, or Months.



Time Measure Type

● Dates ○ Days

Time Units: Days

Start Date: Date of Randomization

☐ Numeric?

Randomization.Treatment =

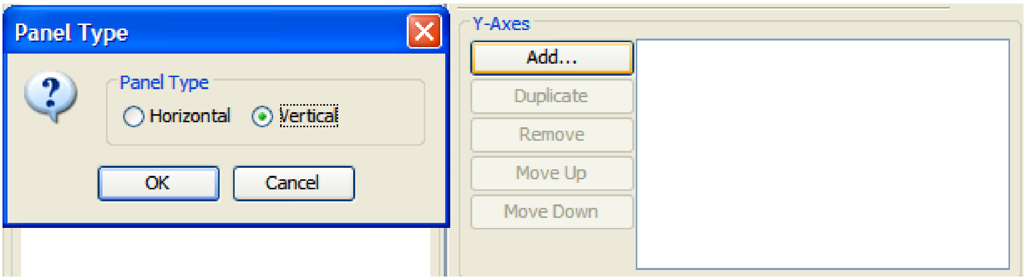
Optionally, the user may “**Select Condition**” which is applied as a defined filter.

## *Select Vertical panel type*

Next, there is a complex control provided to specify the Y-Axes where at least one Y-axis must be specified.  Not more than eight Y-Axes can be specified. The individual Y-axis variables may be defined from either a Vertical panel or a Horizontal panel.

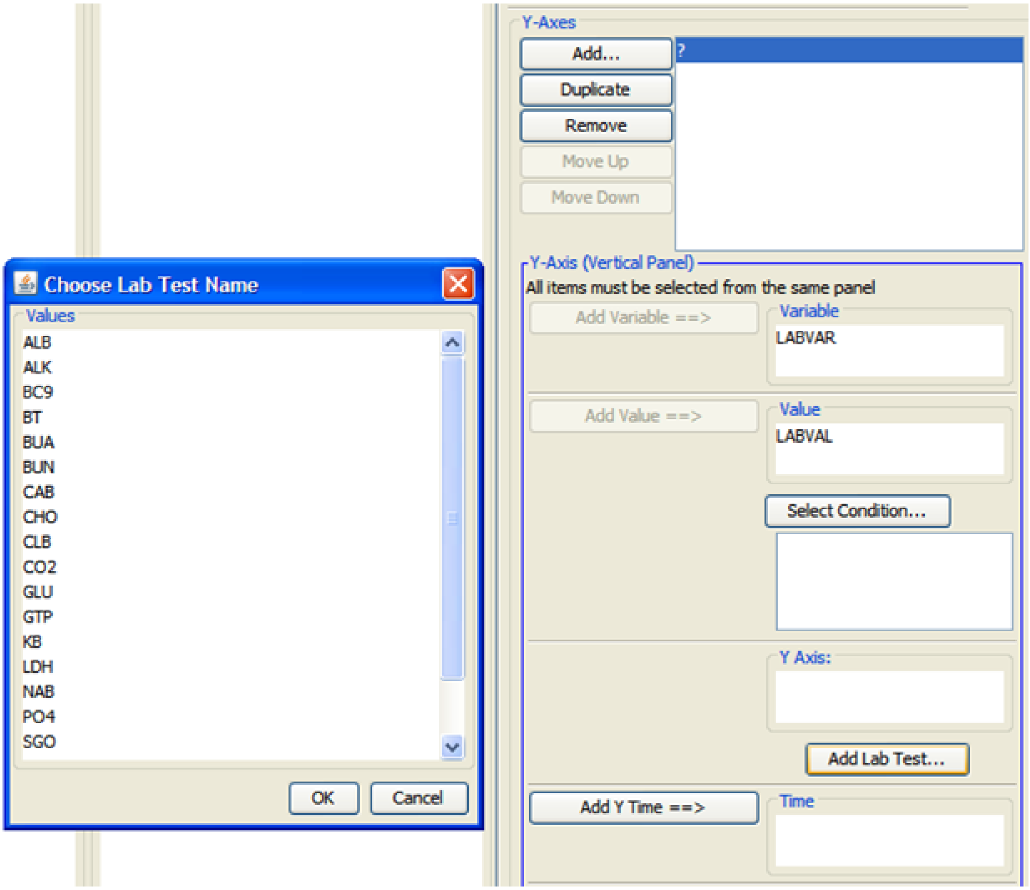
The complex control for specifying Y-Axes has two parts. The upper part contains a list of the Y-Axes and a button panel. The button panel contains the following buttons:

1. Add a new Y-axis definition. Clicking on the **Add** button displays a **Panel Type** dialog asking the user whether the definition uses a Vertical or Horizontal panel. When the panel type is selected, either a Vertical or Horizontal version of the form is displayed in the bottom portion of the complex control.
2. Select **Vertical** panel type.



The Y-axis Vertical Panel form displays. Before the appropriate specification for naming is made, a question mark (“**?**”) is used as the list item’s text.

3. Next, select to add the data items containing the lab variable and lab values. Use the **Add Variable** and **Add Value** buttons. For Vertical Panels, the Lab Variable value provides the lab test name.
4. Optionally, the user may “**Select Condition**” which is applied as a defined filter.
5. Click **Add Lab Test** to display a list of available Lab Test Names. Only one lab test may be selected.



?

All items must be selected from the same panel

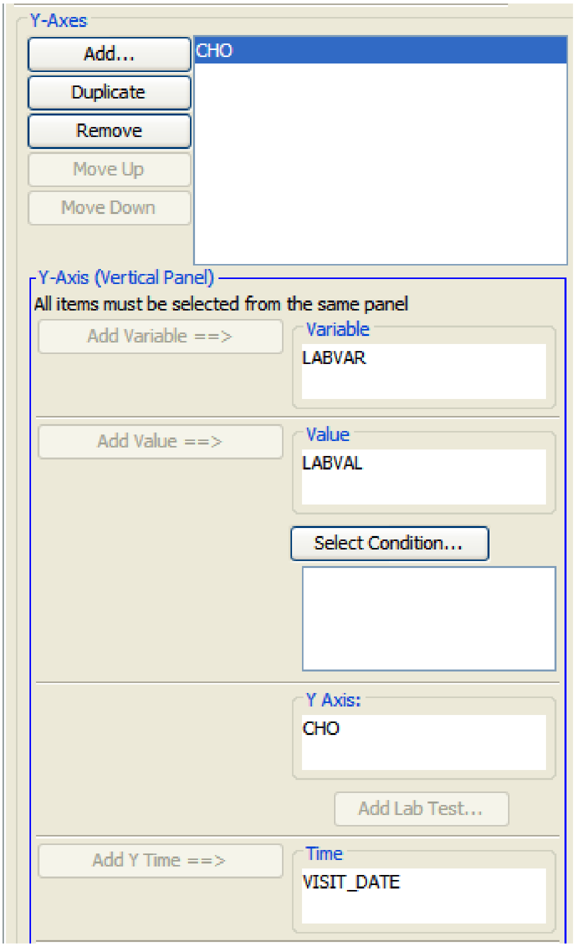
Variable: LABVAR

Value: LABVAL

ALB
ALK
BC9
BT
BUA
BUN
CAB
CHO
CLB
CO2
GLU
GTP
KB
LDH
NAB
PO4
SGO

6. Enter the visit or collection date the exam was performed.

   Each Y-axis item requires an associated **Time** item. This is the visit or collection date the exam was performed. The time item must be added for each Y-axis item by hi-lighting the item in the Y-axes list; then select the time item and click **Add Y Time**.



CHO

All items must be selected from the same panel

Variable: LABVAR

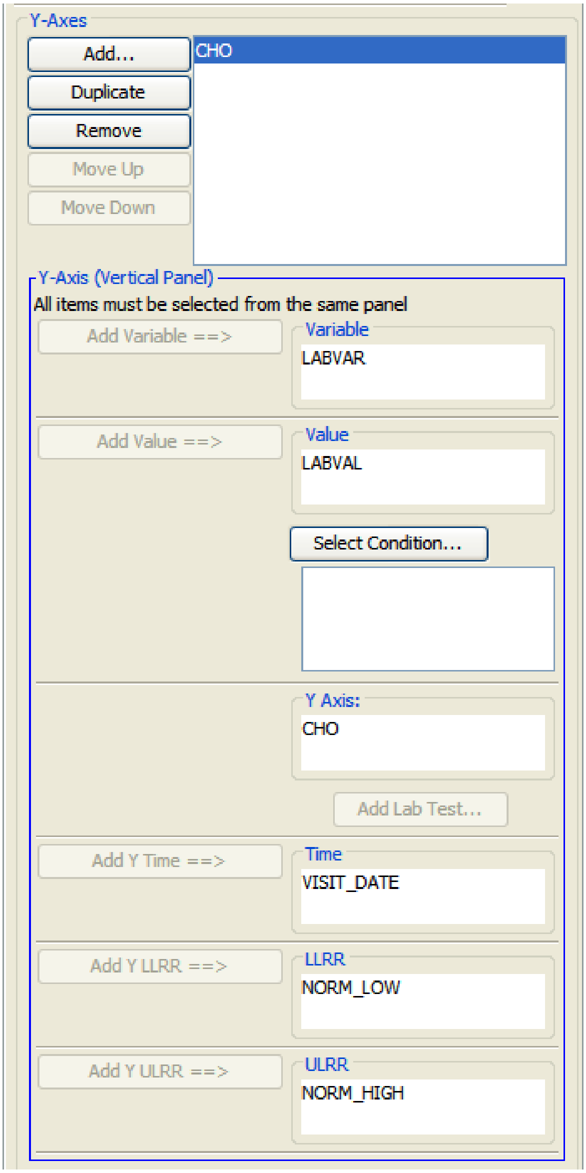
Value: LABVAL

Y Axis: CHO

Time: VISIT_DATE

The Vertical Panel allows the use of reference ranges to be applied individually to each patient as each patient has his/her own reference range values. Different patients can have different threshold values; for example, for a particular lab test, the threshold may vary with a patient’s age or sex.

7. When a Vertical Panel is used, the user may optionally specify the limit variables for the ***Upper Limit Normal Range*** and the ***Lower Limit Normal Range***. These range limits are shown as horizontal lines in each subplot.



Y-Axes: CHO

All items must be selected from the same panel

Variable: LABVAR

Value: LABVAL

Y Axis: CHO

Time: VISIT_DATE

LLRR: NORM_LOW

ULRR: NORM_HIGH

8. Repeat the steps starting with **Add** for additional lab test or exam items. Each added item requires the collection or visit **Time** be entered. Optionally, include lower and upper limit variables will vary between added exams or lab items.

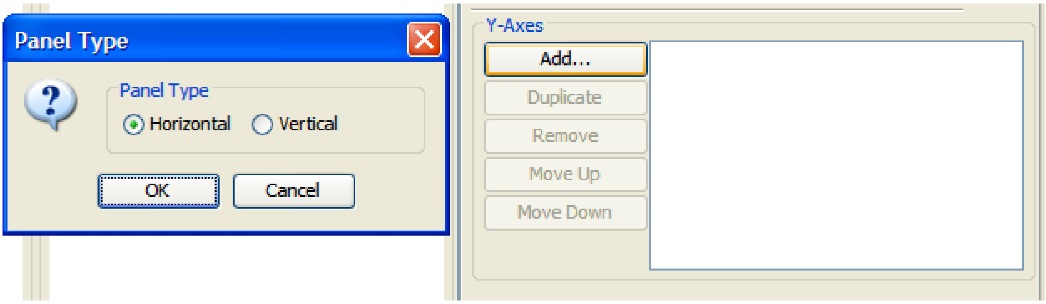
The remaining button panel functions are used to:

- ***Duplicate*** - the selected item. It is a convenience for adding a new Y-axis definition.
- ***Remove* -** the selected Y-axis definitions in the list. Note that the global cut mechanism ("scissors") cannot be applied to this list. If the form for a removed definition is currently displayed, it will be removed.
- ***Move Up and Down*** - move the selected list items up or down in the list; this feature allows the user to reorder the Y-axes.

## *Select Horizontal panel type*

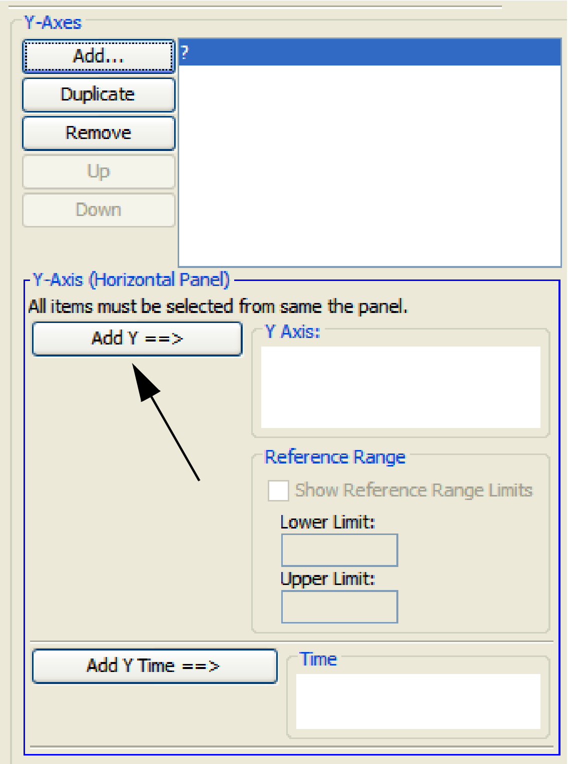
For Horizontal panels the variable name serves as the name of the Y-axis. After entering the **Time Measure Type** as Dates or Days:

1. Click **Add** for Y-Axes and select **Horizonal** panel type.



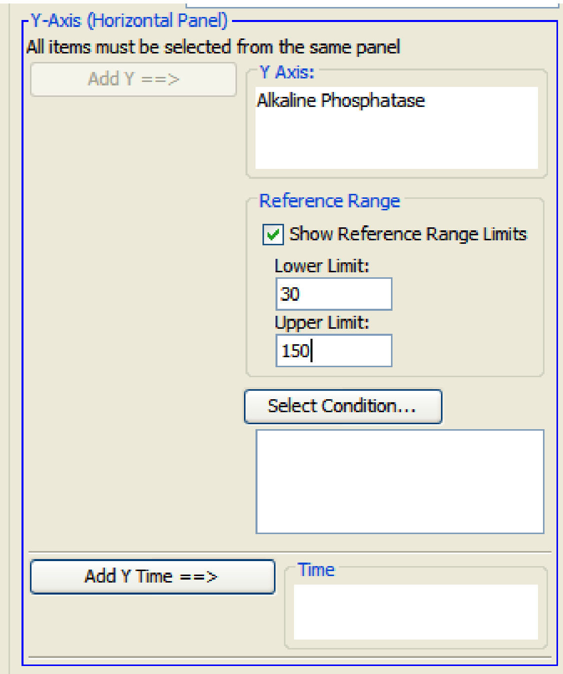
Before the appropriate specification for naming is made, a question mark (“**?**”) is used as the list item’s text.

2. Select the horizontal panel and data item for the lab test name or exam. Click **Add Y**.



All items must be selected from same the panel.

3. The item is added to the Y-axis lower part where a Reference Range can be entered. Click **Show Reference Range Limits** and enter range values that apply to all patients.
4. Each Y-axis item ***requires*** an associated **Time** item. This is the visit or collection date the exam was performed. The time item must be added for each Y-axis item by hi-lighting the item in the Y-axes list; then select the time item and click **Add Y Time**.



Alkaline Phosphatase

☑ Show Reference Range Limits

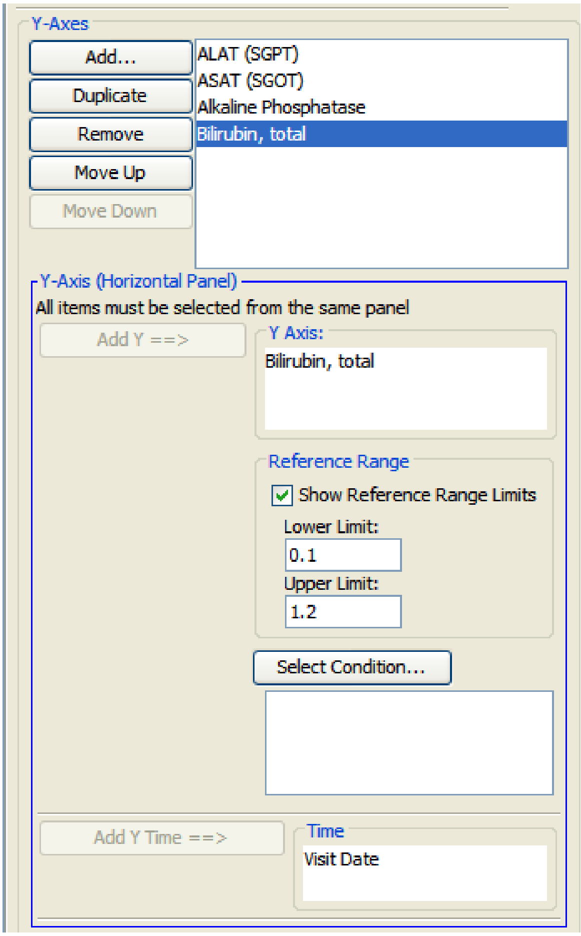
Lower Limit: 30

Upper Limit: 150

Repeat these steps to add each item to the Y-Axes list.

The remaining button panel functions are used to:

- ***Duplicate*** - the selected item. It is a convenience for adding a new Y-axis definition.
- ***Remove -*** the selected Y-axis definitions in the list. Note that the global cut mechanism (“scissors”) cannot be applied to this list. If the form for a removed definition is currently displayed, it will be removed.
- ***Move Up and Down*** - move the selected list items up or down in the list; this feature allows the user to reorder the Y-axes.



ALAT (SGPT)
ASAT (SGOT)
Alkaline Phosphatase
Bilirubin, total

All items must be selected from the same panel

Y Axis: Bilirubin, total

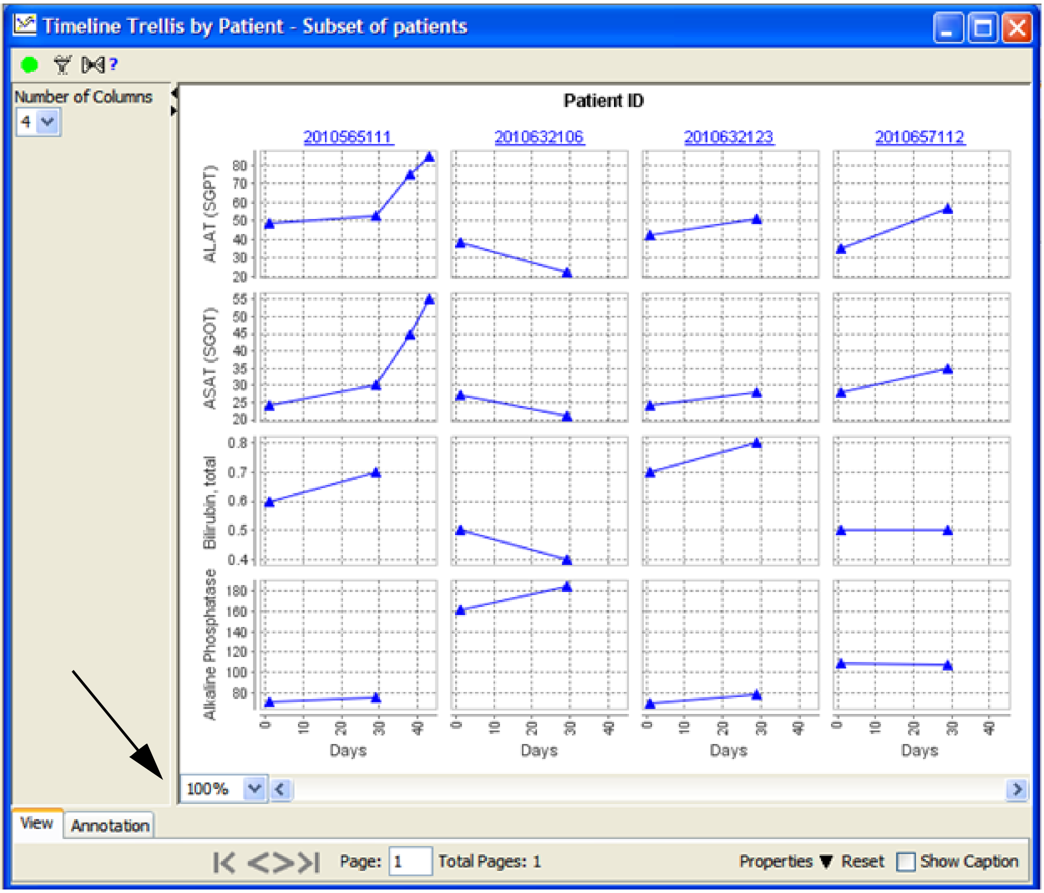
☑ Show Reference Range Limits

Lower Limit: 0.1

Upper Limit: 1.2

Time: Visit Date

After the user has entered the “Basic” required information for the Timeline Trellis by Patient, they may click **Create Graph**.



Number of Columns: 4

100%

Page: 1 Total Pages: 1

☐ Show Caption

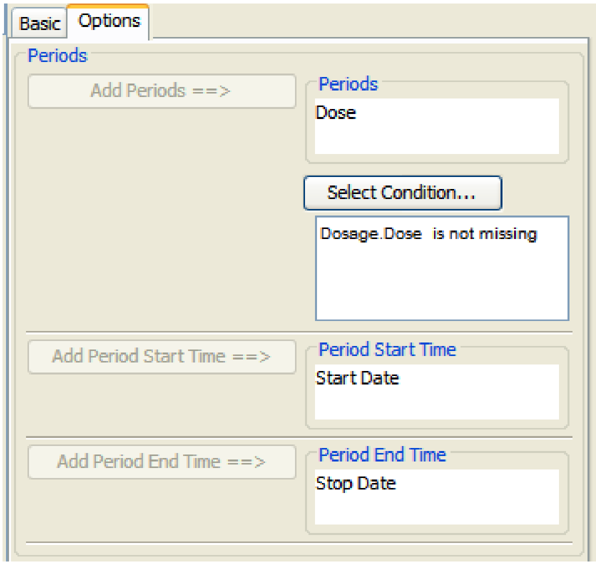
A special X-axis zoom control, i.e., a combo box, is placed at the lower-left corner of the graph. When the user “zooms-in”, the thumb of the horizontal scrollbar is displayed, allowing the user to scroll along the X-axis.

## Timeline Trellis Options tab

The second tab, “**Options**”, contains the controls for specifying optional features: **Periods** and **Milestones**. These controls are very similar to the controls for the Napoleon’s March graph. The main difference is that there is no “termination” milestone for the trellis graph.

Two major optional features are provided in these graphs:

1. The user may specify a “**Periods**” variable, which are represented in the graph by a color-coded background that extends across a time interval from the start day to the end day of the period instance. One typical “period” variable is “treatment”: in some studies, a patient may be assigned to different treatment conditions (e.g. various drugs or dosages levels) during the course of the study.



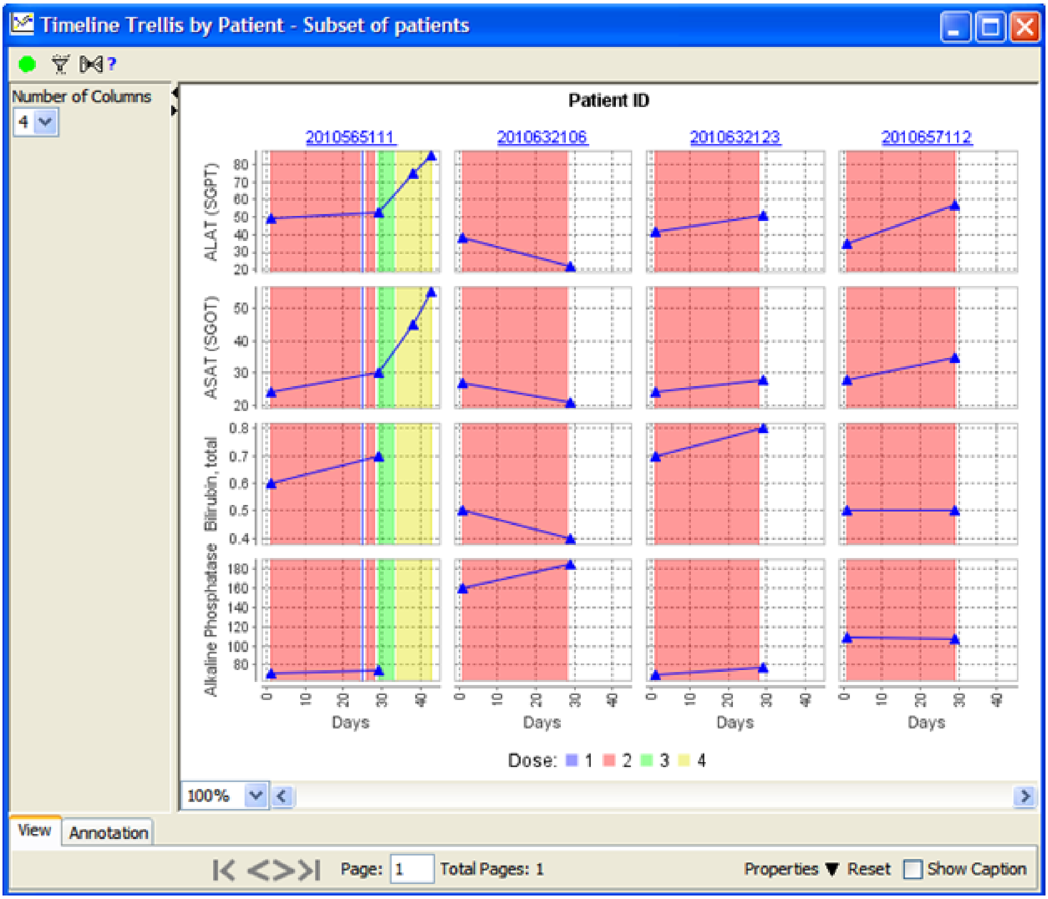
Periods: Dose

Dosage.Dose is not missing

Period Start Time: Start Date

Period End Time: Stop Date

Dose periods viewed with color coding.



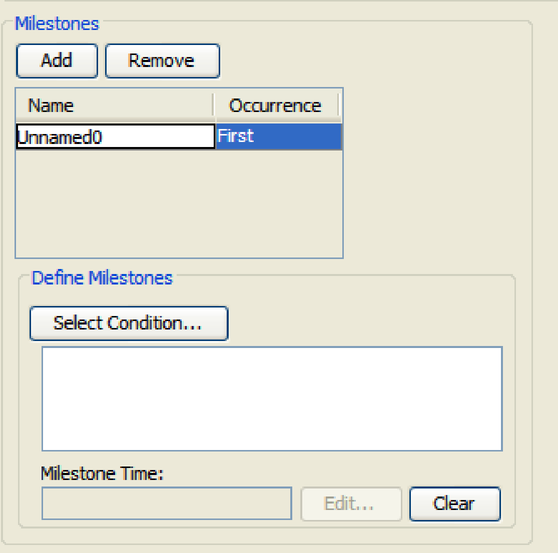
Number of Columns: 4

100%

Page: 1 Total Pages: 1

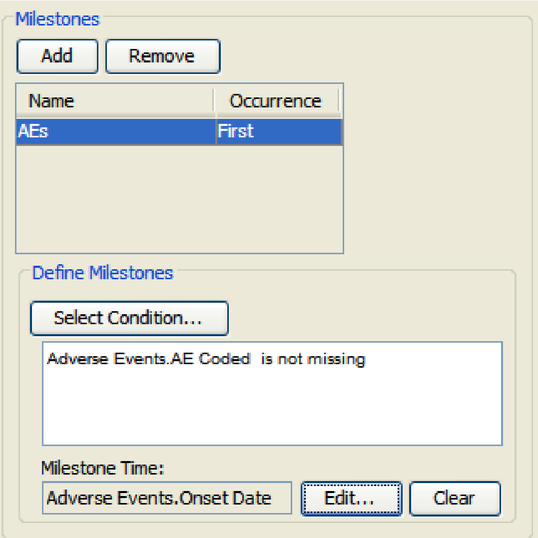
2. The user may specify “**Milestones**,” which are events such as the onset of an Adverse Event or a laboratory test measure that exceeds some extreme value. Each milestone event occurrence appears as a vertical line positioned at some position on the timeline. Each vertical line has a numeric label to identify the type of milestone, as there can be multiple milestone types. The numeric label is tied to an ordinal value in the graph’s Milestone Legend.

   To create a milestone, click on the **Add** button. Clicking these buttons adds a new row to the table just beneath the buttons. The first column of the table is the name of the milestone. The entries in the first column are editable; while a “temporary” name is automatically, the user should type a meaningful into the table cell. The **Occurrence** may be further specified for First or All.



| Name | Occurrence |
|---|---|
| Unnamed0 | First |

Next, the user must define the milestone with **Select Condition** to enter a filter defining the Milestone. This step and entering the **Milestone Time** is ***required*** to define the milestone.

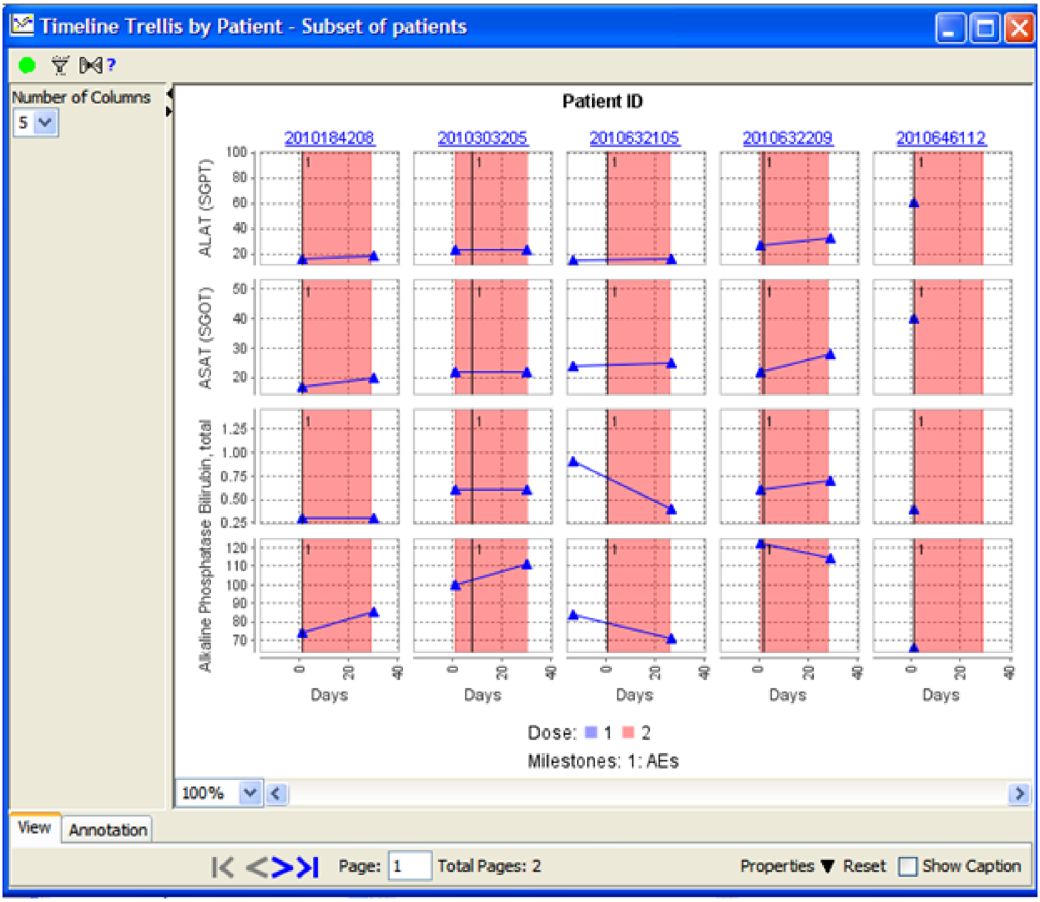


| Name | Occurrence |
|---|---|
| AEs | First |

Adverse Events.AE Coded is not missing

Milestone Time: Adverse Events.Onset Date

Click Create Graph. See the vertical line has a numeric label to identify the type of milestone, as there can be multiple milestone types. The numeric label is tied to an ordinal value in the graph’s Milestone Legend. In this example, 1 represents AEs.



Number of Columns: 5

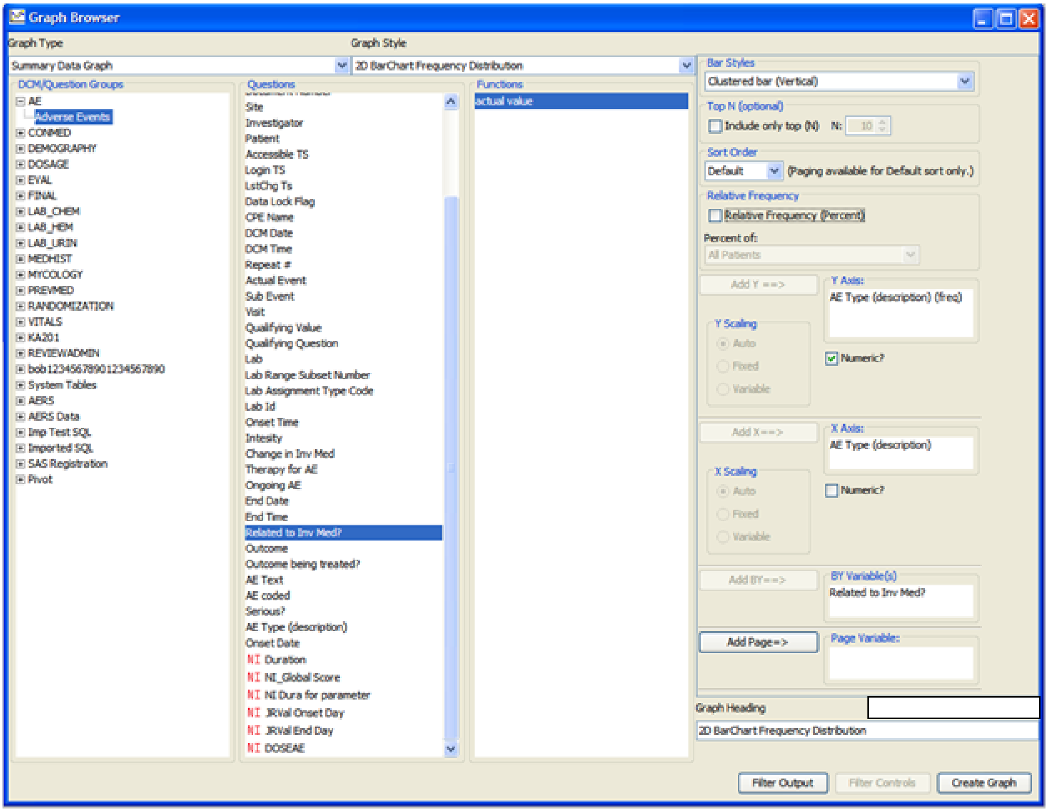
Page: 1 Total Pages: 2

# Summary Graph Styles

## 2-D Bar Chart Frequency Distribution

In the 2D BarChart Frequency Distribution graph, each bar represents the category value of the item with the Y-axis representing the frequency.

Bar style options are clustered bar versus stacked bar in vertical or horizontal orientation.



Graph Browser

Graph Type: Summary Data Graph

Graph Style: 2D BarChart Frequency Distribution

DCM/Question Groups: AE – Adverse Events

Questions: Related to Inv Med?

Functions: actual value

Bar Styles: Clustered bar (Vertical)

Top N (optional): ☐ Include only top (N) N: 10

Sort Order: Default (Paging available for Default sort only.)

Relative Frequency: ☐ Relative Frequency (Percent)

Percent of: All Patients

Y Axis: AE Type (description) (freq)

Y Scaling: ● Auto ○ Fixed ○ Variable

☑ Numeric?

X Axis: AE Type (description)

X Scaling: ● Auto ○ Fixed ○ Variable

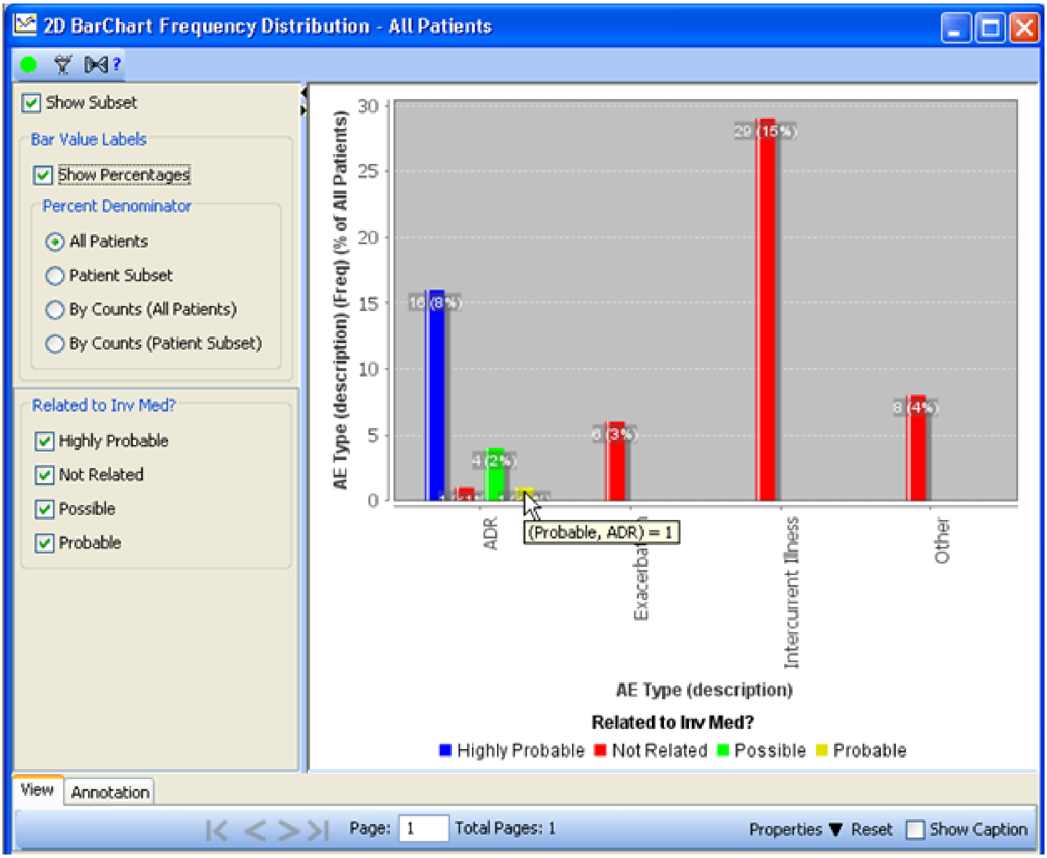
☐ Numeric?

BY Variable(s): Related to Inv Med?

Page Variable:

Graph Heading: 2D BarChart Frequency Distribution

The 2D BarChart Frequency Distribution supports the Show Subset feature. Optionally, show percentages.



☑ Show Subset

Bar Value Labels

☑ Show Percentages

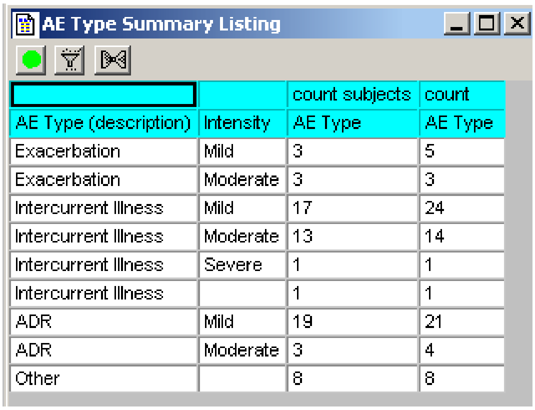
Percent Denominator

● All Patients
○ Patient Subset
○ By Counts (All Patients)
○ By Counts (Patient Subset)

Related to Inv Med?

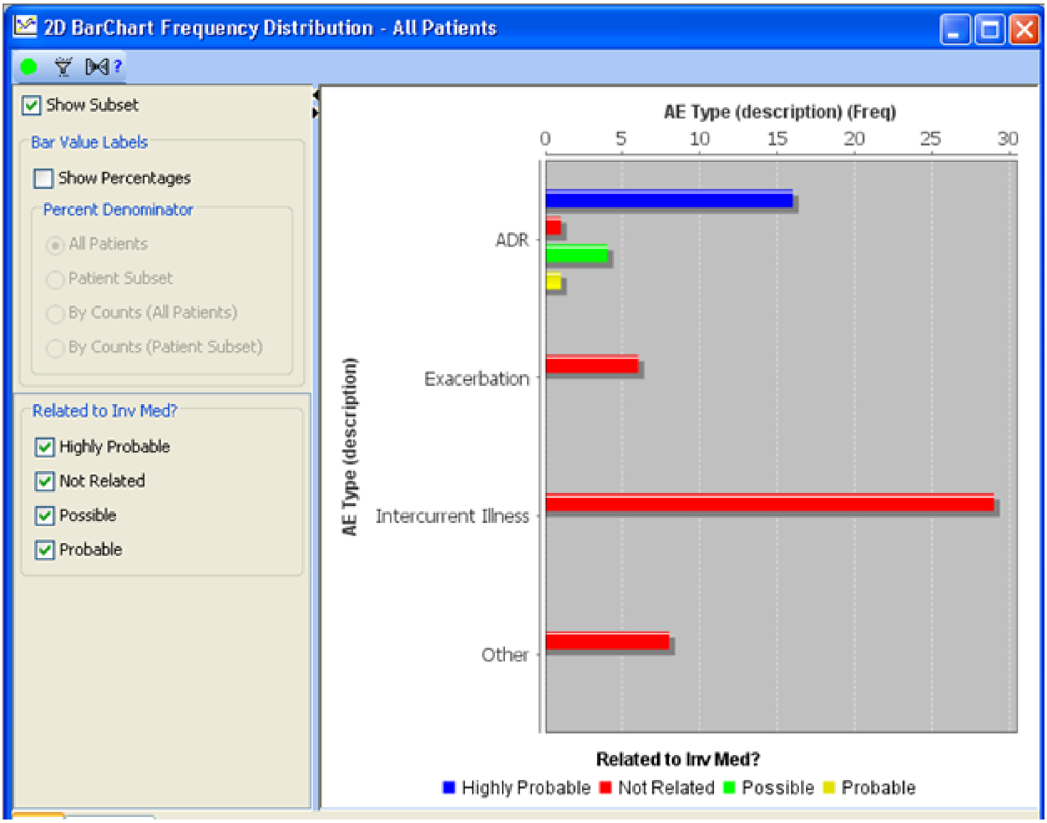
☑ Highly Probable
☑ Not Related
☑ Possible
☑ Probable

The frequency bar counts represent patients as compared to a Summary Listing showing patient counts versus item counts.



| | | count subjects | count |
|---|---|---|---|
| AE Type (description) | Intensity | AE Type | AE Type |
| Exacerbation | Mild | 3 | 5 |
| Exacerbation | Moderate | 3 | 3 |
| Intercurrent Illness | Mild | 17 | 24 |
| Intercurrent Illness | Moderate | 13 | 14 |
| Intercurrent Illness | Severe | 1 | 1 |
| Intercurrent Illness | | 1 | 1 |
| ADR | Mild | 19 | 21 |
| ADR | Moderate | 3 | 4 |
| Other | | 8 | 8 |

This example shows the same graph type and style, but with a different Bar style option.



☑ Show Subset

Bar Value Labels

☐ Show Percentages

Percent Denominator

● All Patients

○ Patient Subset

○ By Counts (All Patients)

○ By Counts (Patient Subset)

Related to Inv Med?

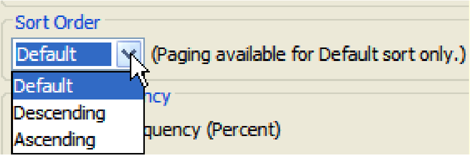
☑ Highly Probable

☑ Not Related

☑ Possible

☑ Probable

There is a **Sort Order** option for Descending or Ascending with Default display by alpha order of label descriptions. Use the **BY variable** to subset graphic displays.

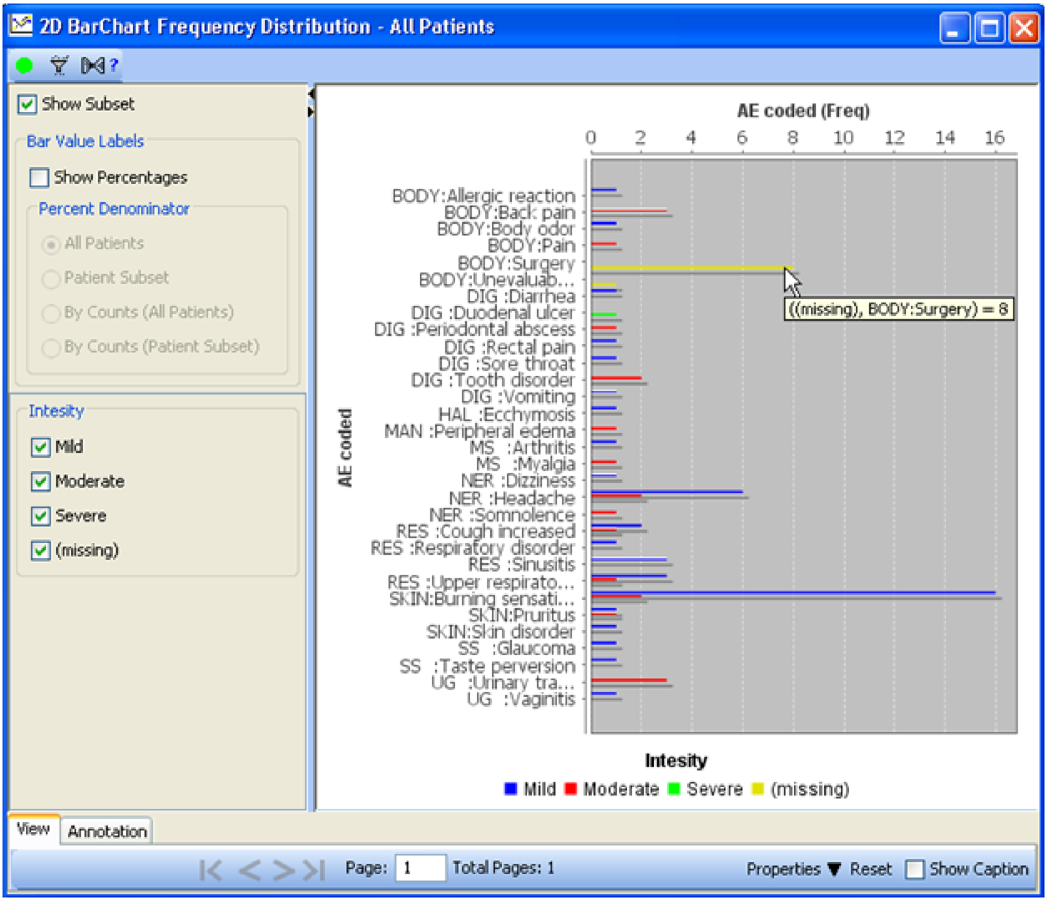


Sort Order

Default (Paging available for Default sort only.)

This example of a 2D Barchart Frequency Distribution plots Adverse Event data. The counts represent patient counts and not the individual adverse events.  Some patients may have reported the same Adverse Event multiple times.

*Hint:*   ***Place mouse over bar to view description and count.***



2D BarChart Frequency Distribution - All Patients

☑ Show Subset

Bar Value Labels

☐ Show Percentages

Percent Denominator

● All Patients
○ Patient Subset
○ By Counts (All Patients)
○ By Counts (Patient Subset)

Intesity

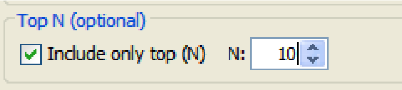
☑ Mild
☑ Moderate
☑ Severe
☑ (missing)

((missing), BODY:Surgery) = 8

Page: 1 Total Pages: 1

## *Include Top N*

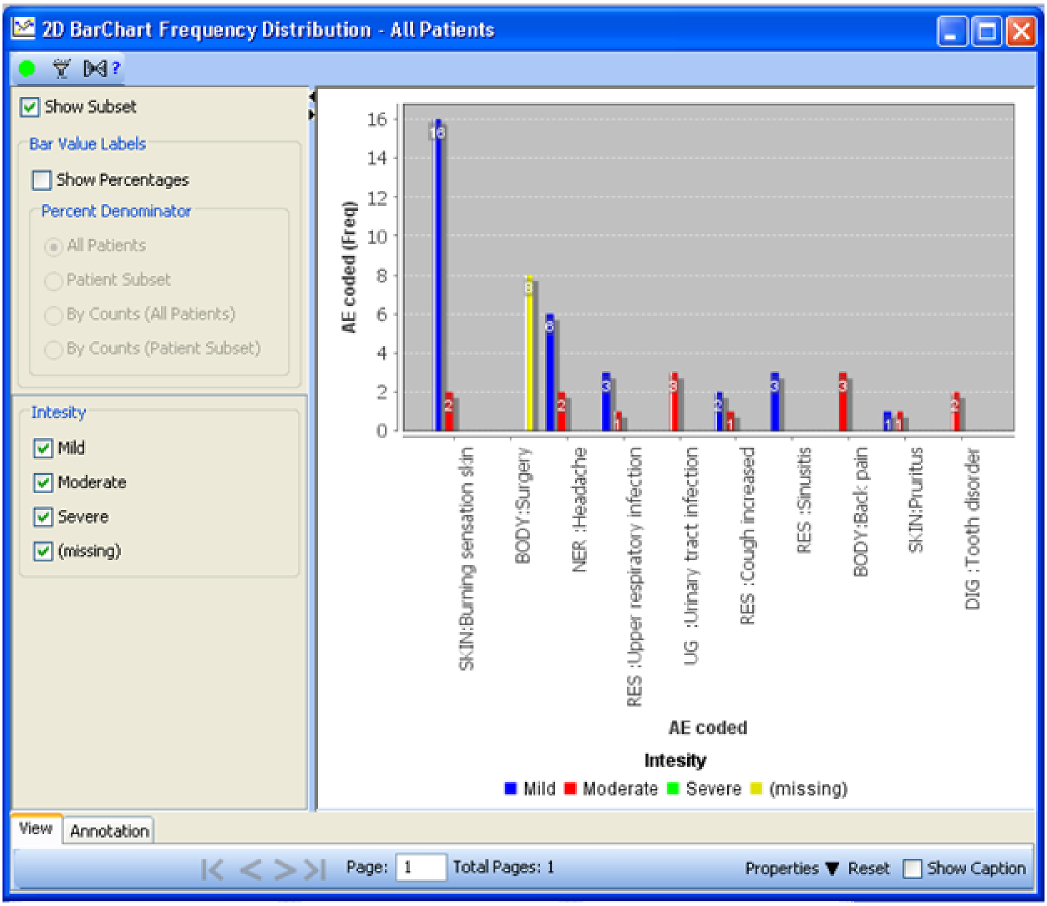
Optionally, display the 'Top N' option when you click the checkbox On, and enter a preferred N value.



Top N (optional)

☑ Include only top (N) N: 10

Include only the Top N, where N = 10.



2D BarChart Frequency Distribution - All Patients

☑ Show Subset

Bar Value Labels

☐ Show Percentages

Percent Denominator

● All Patients

○ Patient Subset

○ By Counts (All Patients)

○ By Counts (Patient Subset)

Intesity

☑ Mild

☑ Moderate

☑ Severe

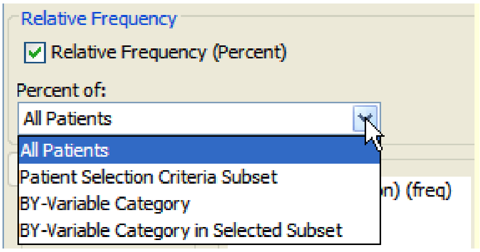
☑ (missing)

Page: 1 Total Pages: 1

☐ Show Caption

## *Relative Frequency Percent*

This is the **Relative Frequency** (Percent) option available in 2-D Frequency Bar Graphs.



☑ Relative Frequency (Percent)

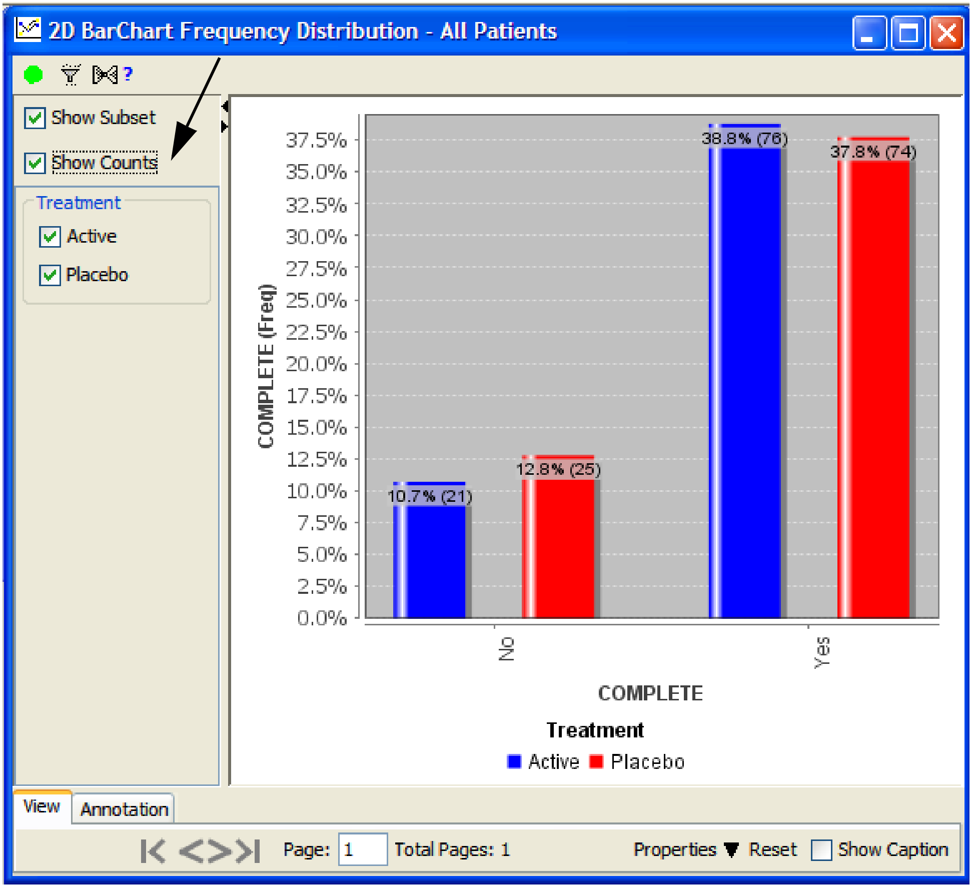
Percent of: All Patients

When the “graphUserSelectableDenominator” setting in ReviewAdmin is set to FALSE, the combo box for choosing the denominator type is not shown, and the denominator type is automatically chosen by JReview. The chosen denominator type depends on whether a BY-Variable is specified and whether a PSC is active.

The **Relative Frequency (Percent)** checkbox allows the user to choose the Relative Frequencies (Percent) option. When this option is chosen, the combo box containing the denominator types becomes enabled. If the user chooses one of the BY-Variable denominator types but has not specified a BY-Variable, an error message is presented when the user attempts to create or save the graph specification, and the operation is not completed.

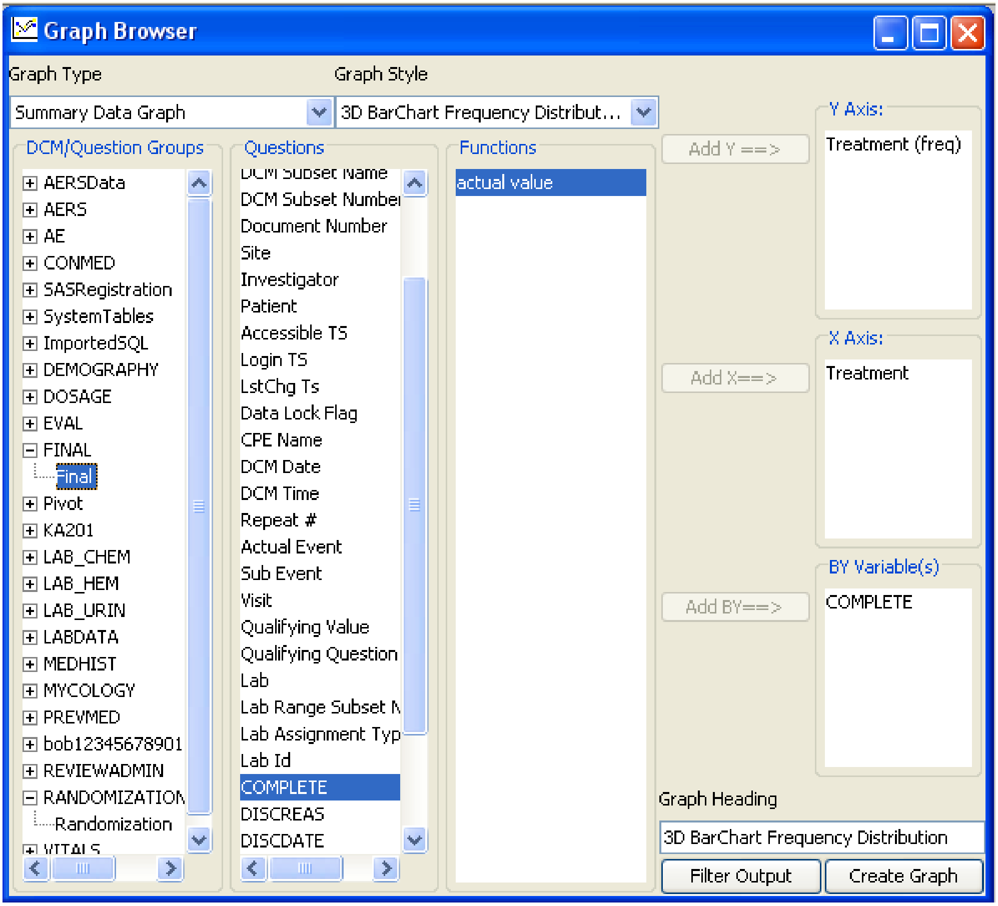
This option allows users to have the Y-axis computed as *Relative* Frequency (Percent) values rather than as patient counts. The denominator options for the percent values are: All Patients; Patient Selection Criteria Subset; BY-Variable Category; BY-Variable Category in Selected Subset.

The percent values for the bars are computed and there is a label option in the Graph View to **Show Counts** for the patient count for each bar. It allows the user to specify to calculate the Y-axis as Percent values.



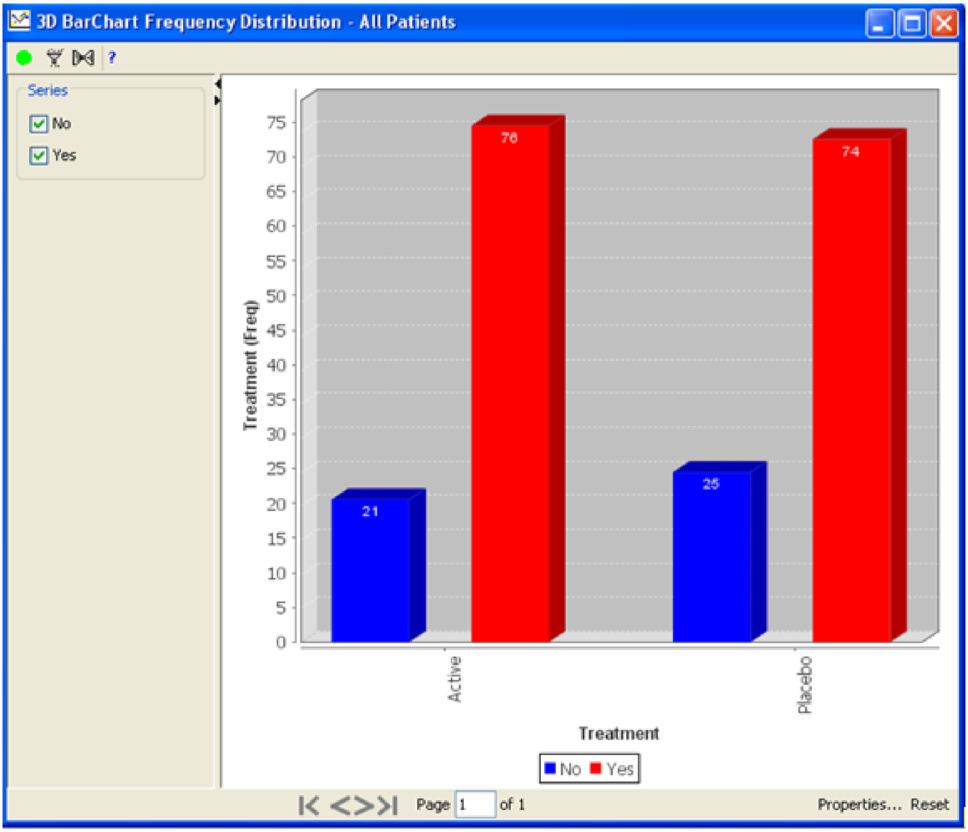
## *3D BarChart Frequency Distribution*

In a 3D BarChart Frequency Distribution graph, each bar represents the category value of the item with the Y-axis representing the frequency.



Graph Type: Summary Data Graph
Graph Style: 3D BarChart Frequency Distribut...
Y Axis: Treatment (freq)
X Axis: Treatment
BY Variable(s): COMPLETE
Graph Heading: 3D BarChart Frequency Distribution

Use the BY variable to subset graphic displays.



***Note:* *This not a true 3D bar chart; it is a 3D style that makes the bars look solid rather than flat. JReview currently does not have a true 3D bar chart.***

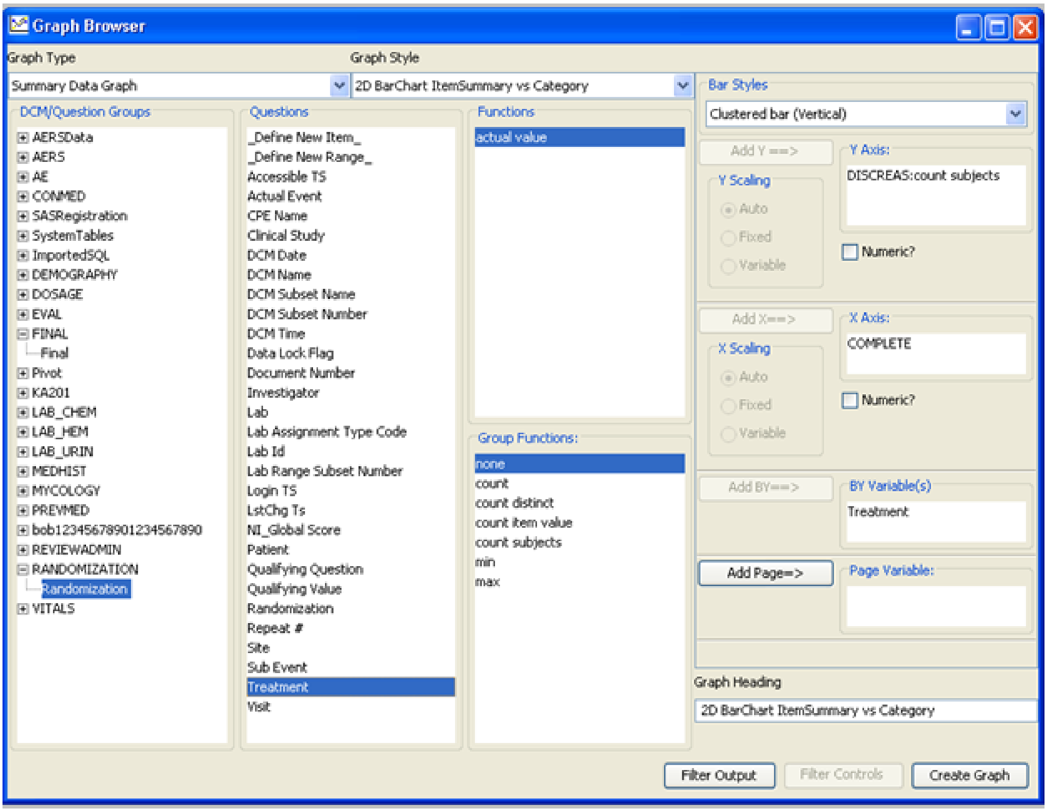
## *2-D Bar Chart Item Summary vs. Category*

In a 2D BarChart item Summary vs. Category, each bar represents a category value X-axis versus a summary statistic (mean, count, sum) Y-axis.

The Graph Browser window provides a separate group functions for the Y-axis; dependent upon the graph style selected.

Use the **BY variable** to subset graphic displays.

In this example, the Y-axis was added with Group Function for count subjects as “Reason Discontinued: Count Subjects”.



Graph Type: Summary Data Graph

Graph Style: 2D BarChart ItemSummary vs Category

Bar Styles: Clustered bar (Vertical)

Y Axis: DISCREAS:count subjects

☐ Numeric?

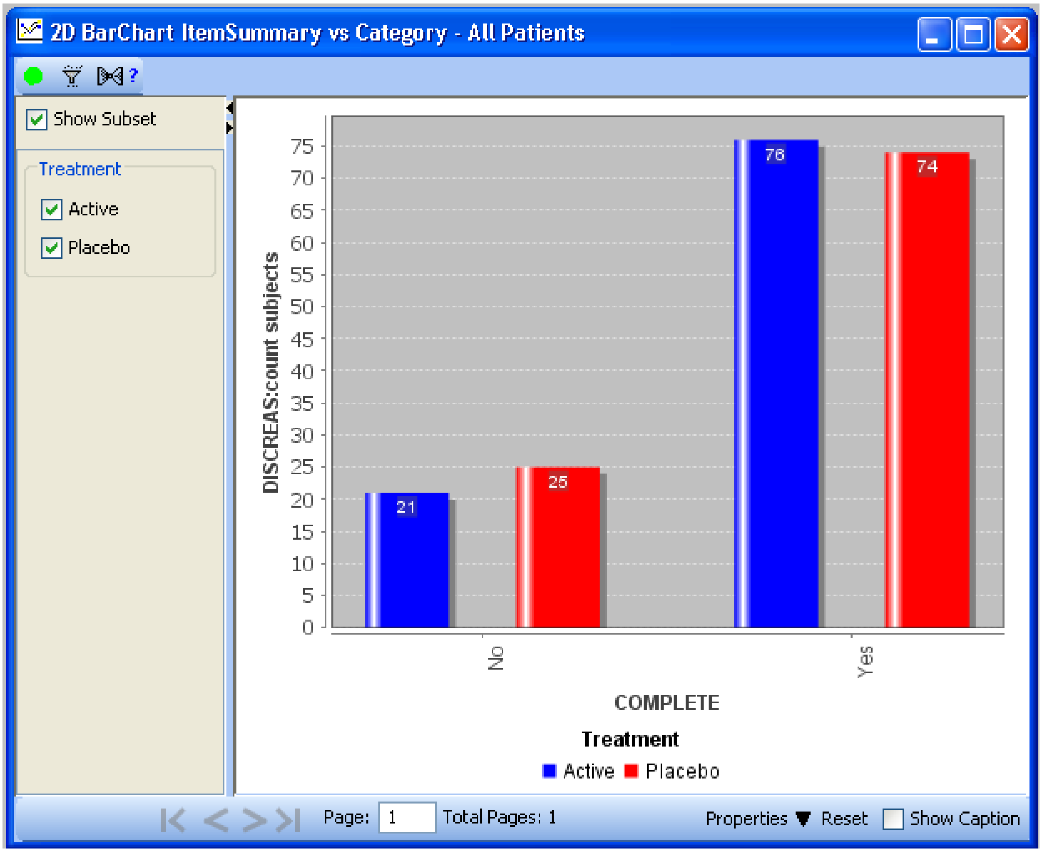
X Axis: COMPLETE

☐ Numeric?

BY Variable(s): Treatment

Graph Heading: 2D BarChart ItemSummary vs Category

The 2D BarChart Item Summary versus Category supports the Show Subset feature.

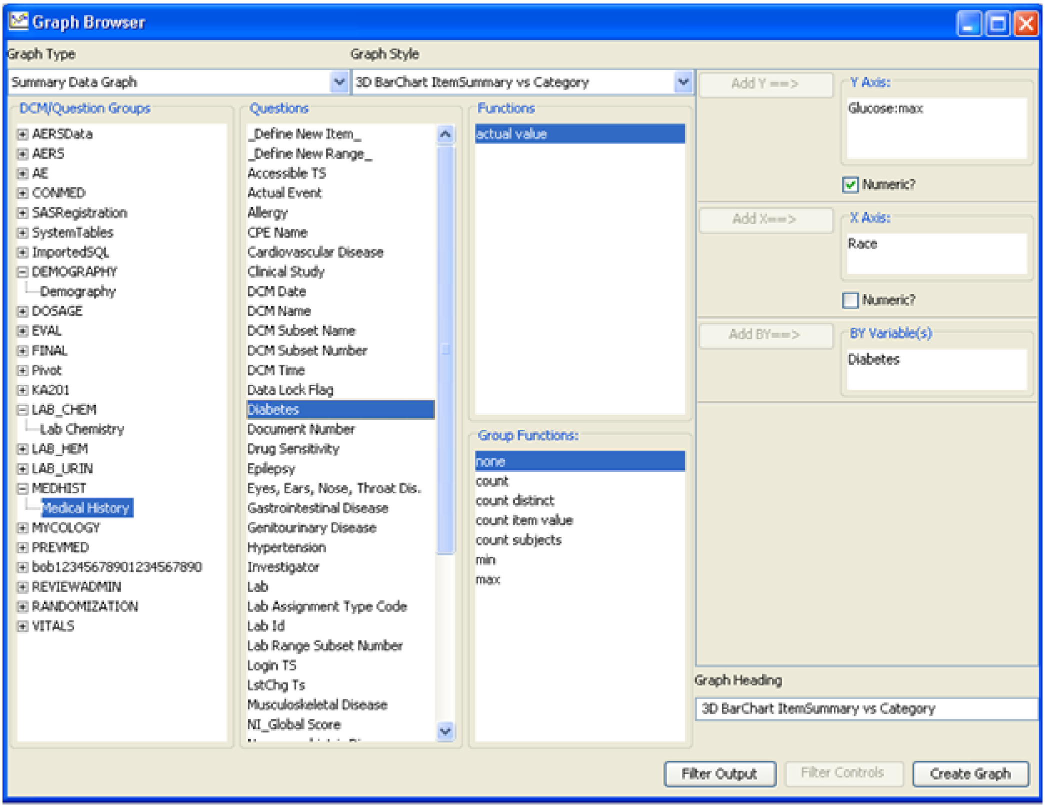


## *3D BarChart Item Summary vs.Category*

In a 3D BarChart Item Summary vs. Category, each bar represents a category value X-axis versus a summary statistic (mean, count, sum) Y-axis.

The Graph Browser window provides a separate list of group functions for the Y-axis. Use the **BY variable** to subset graphic displays.

In this example, the Y-axis was added with Group Function for 'max' as "Glucose: Max".



Graph Type: Summary Data Graph

Graph Style: 3D BarChart ItemSummary vs Category

Y Axis: Glucose:max

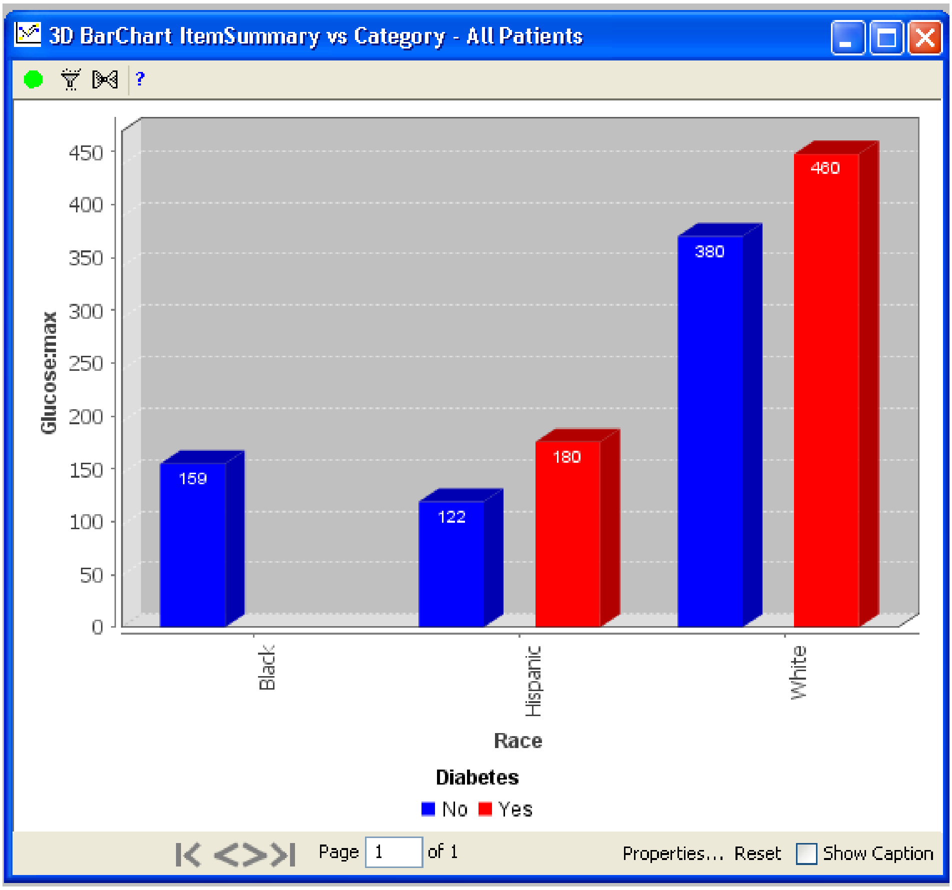
☑ Numeric?

X Axis: Race

☐ Numeric?

BY Variable(s): Diabetes

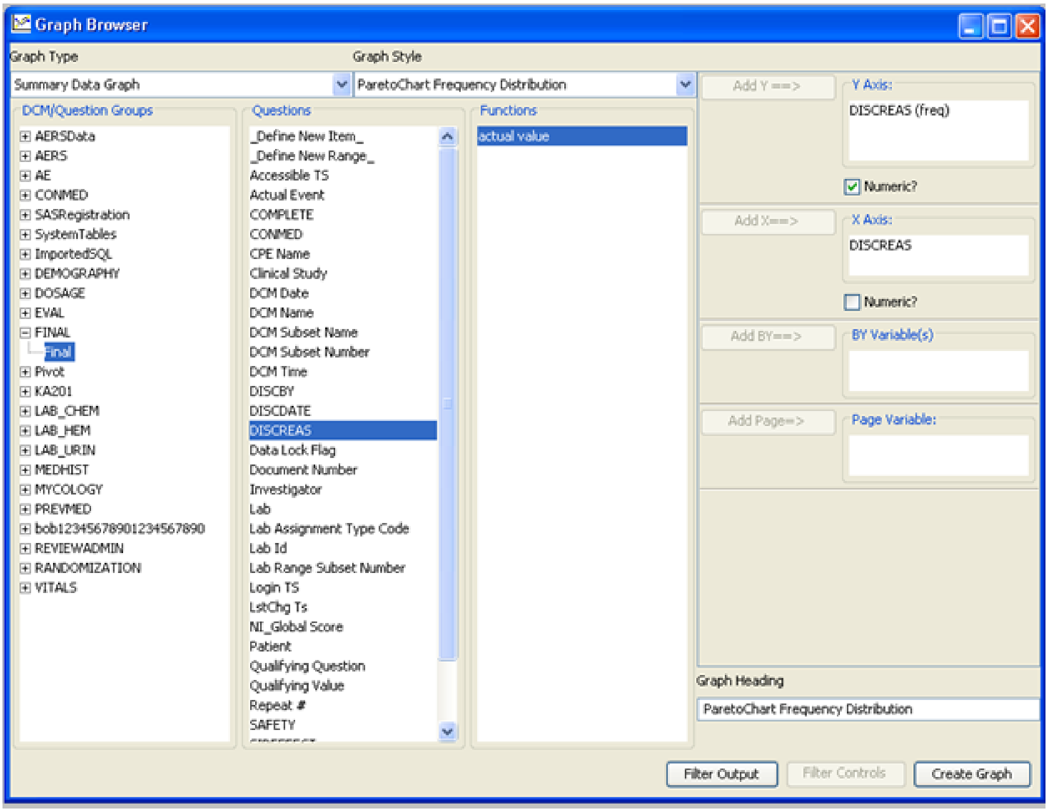
Graph Heading: 3D BarChart ItemSummary vs Category



***Note:** This not a true 3D bar chart; it is a 3D style that makes the bars look solid rather than flat. JReview currently does not have a true 3D bar chart.*

## *Pareto Chart Frequency Distribution*

In a Pareto chart frequency Distribution, each bar represents a category value that corresponds to the plotted Y-axis.



Graph Type: Summary Data Graph

Graph Style: ParetoChart Frequency Distribution

Y Axis: DISCREAS (freq)

☑ Numeric?

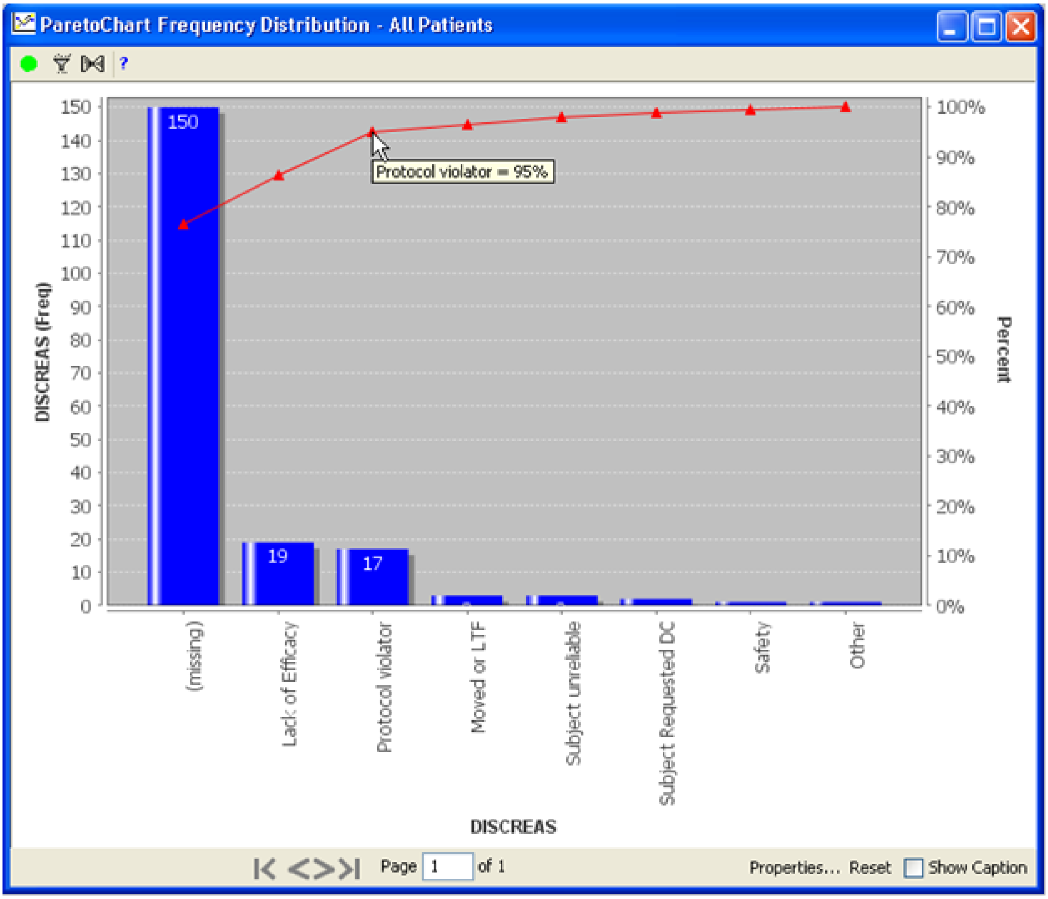
X Axis: DISCREAS

☐ Numeric?

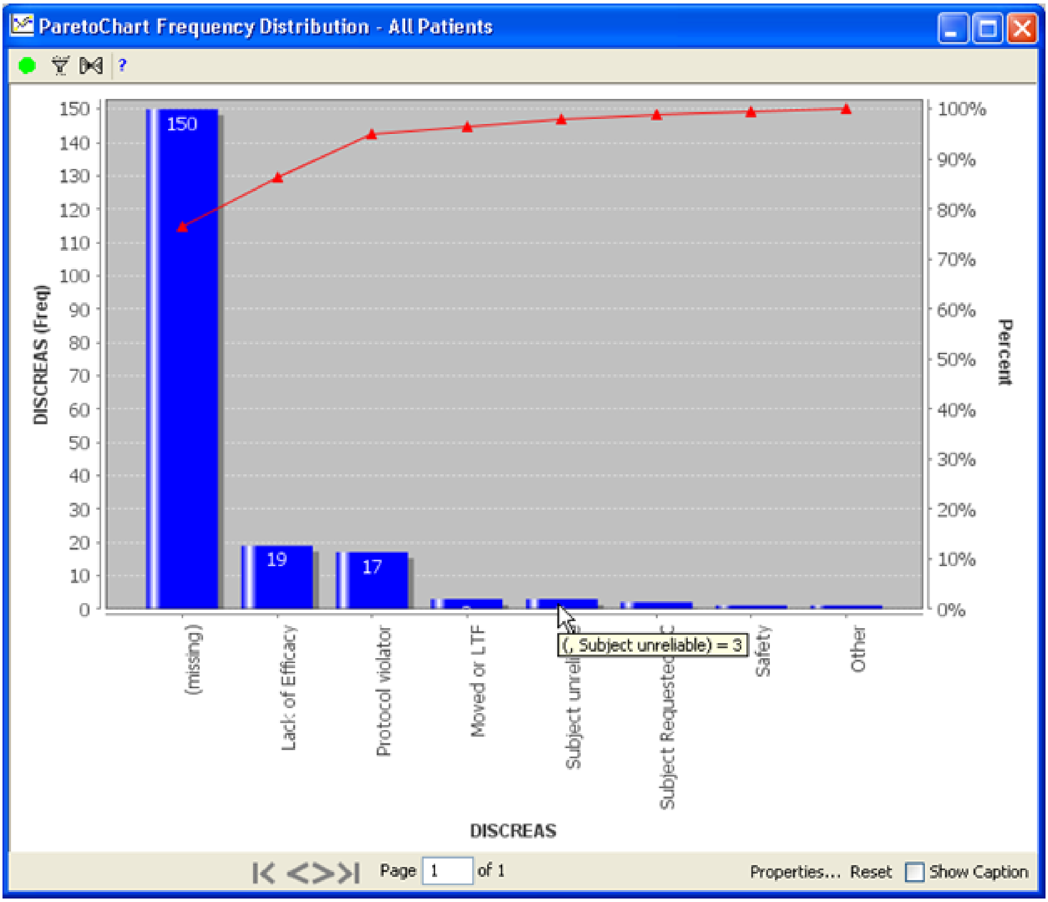
Graph Heading: ParetoChart Frequency Distribution

The line above the bars shows the cumulative percentage.

Pareto charts display the Y-axis bars in descending order of frequency.



*Hint:* ***Place the mouse over a bar to view description and count.***

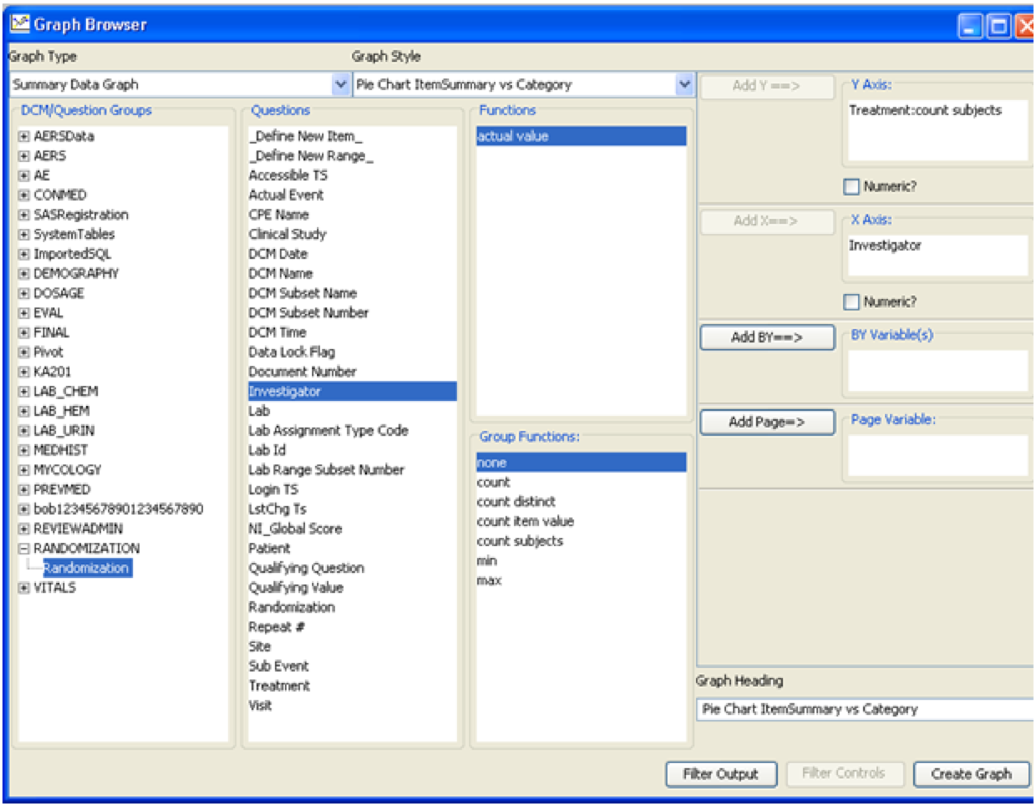


## *Pie Chart Item Summary vs. Category*

The Pie Chart Item Summary vs. Category, draws each slice to represent a category value X-axis versus a Y-axis summary statistic (mean, count, sum).

The Graph Browser window provides a separate list of group functions for the Y-axis. Use the **BY variable** to display multiple pie charts of grouped data.

For this example, the Y-axis Group Function was selected for count subjects as “Treatment: count subjects”.



Graph Type: Summary Data Graph

Graph Style: Pie Chart ItemSummary vs Category

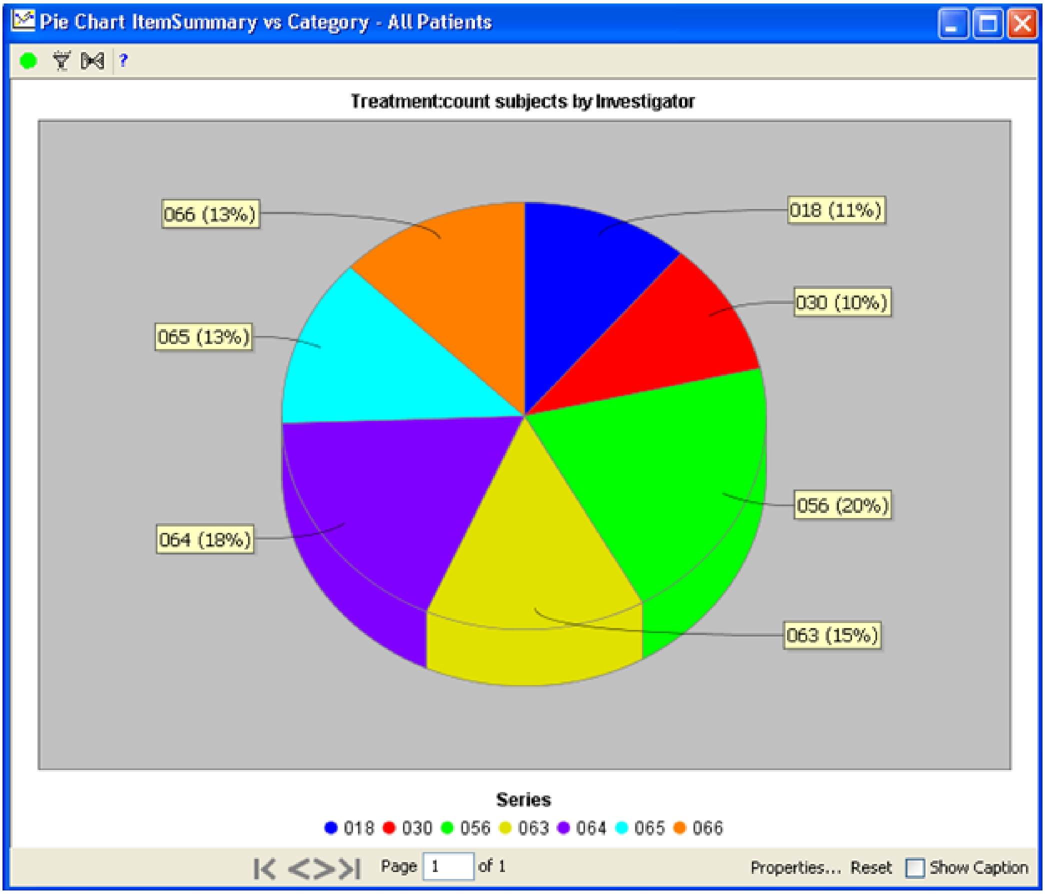
Y Axis: Treatment:count subjects

☐ Numeric?

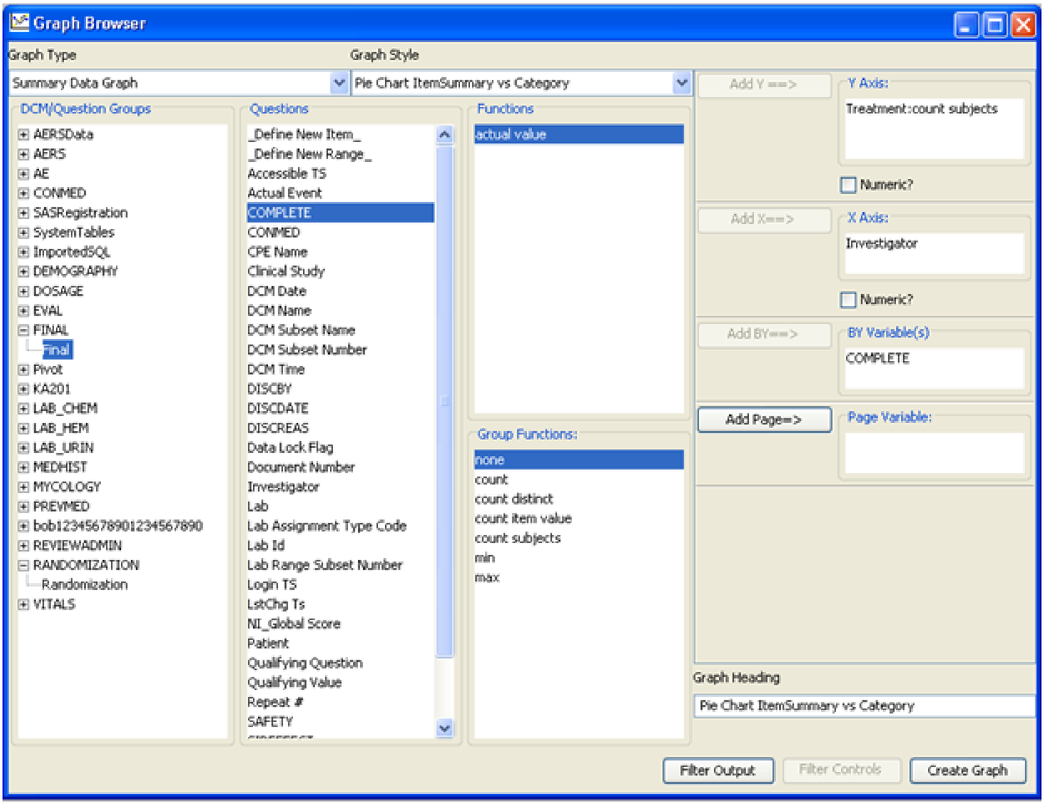
X Axis: Investigator

☐ Numeric?

Graph Heading: Pie Chart ItemSummary vs Category


Pie Chart ItemSummary vs Category - All Patients
?
Treatment:count subjects by Investigator
066 (13%)
018 (11%)
030 (10%)
065 (13%)
056 (20%)
064 (18%)
063 (15%)
Series
● 018 ● 030 ● 056 ● 063 ● 064 ● 065 ● 066
Page 1 of 1
Properties... Reset
☐ Show Caption

Here is the same Pie chart with **BY variable** added for completed study.



Graph Type: Summary Data Graph

Graph Style: Pie Chart ItemSummary vs Category

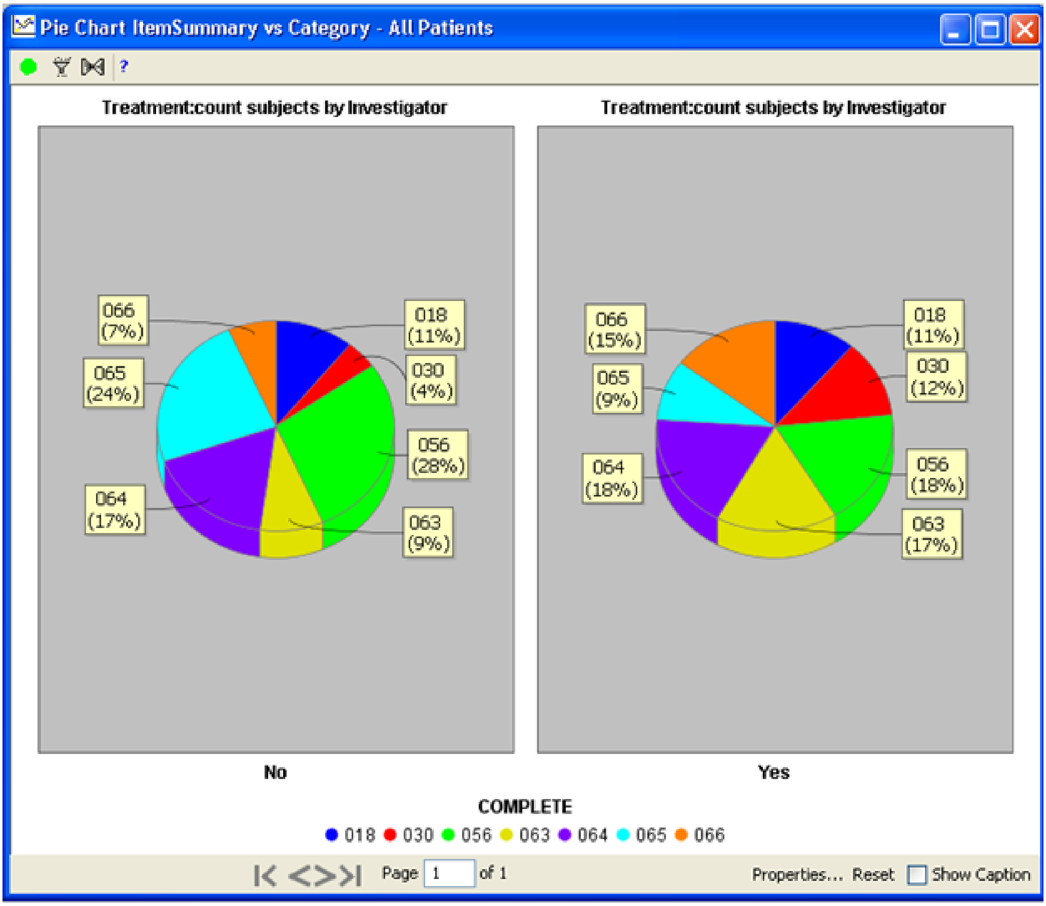
Y Axis: Treatment:count subjects

X Axis: Investigator

BY Variable(s): COMPLETE

Graph Heading: Pie Chart ItemSummary vs Category

The **BY variable** displays multiple pie charts of grouped data.

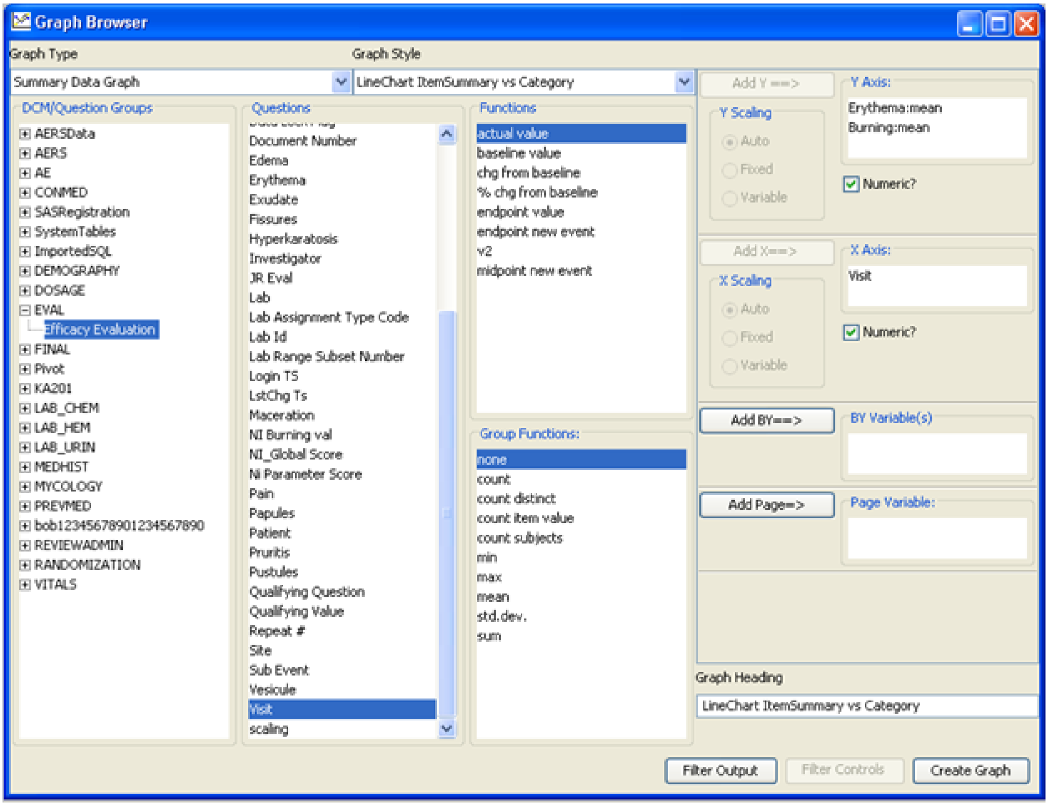


## Line Chart-item vs. Category

In a Line Chart-item Summary vs. Category, trends over time or other categorical items can be presented. With the use of a categorical BY variable, two or more populations can be represented, and comparatively viewed.

The Graph Browser window provides a separate list of group functions for the Y-axis.

For this example, both Erythema and Burning were added to the Y-axis as Group Function for “Mean”.



Graph Type: Summary Data Graph

Graph Style: LineChart ItemSummary vs Category

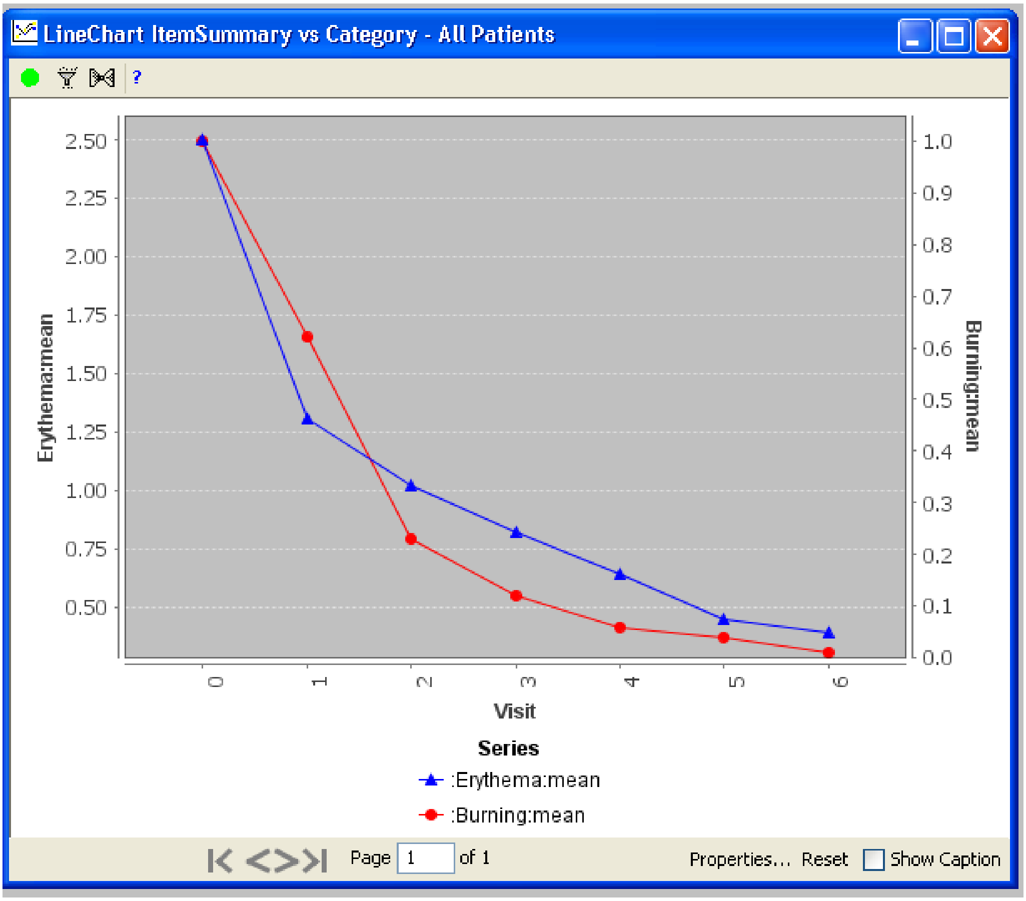
Y Axis:
Erythema:mean
Burning:mean

☑ Numeric?

X Axis: Visit

☑ Numeric?

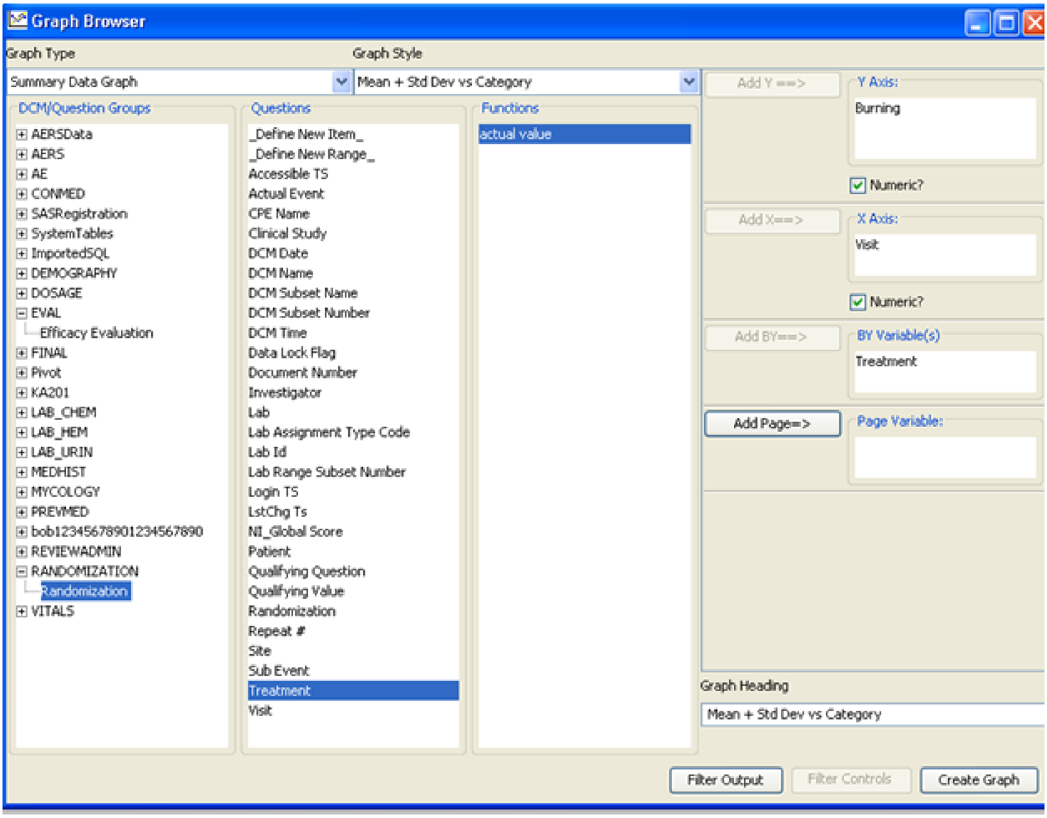
Graph Heading: LineChart ItemSummary vs Category


LineChart ItemSummary vs Category - All Patients
?
Erythema:mean
2.50
2.25
2.00
1.75
1.50
1.25
1.00
0.75
0.50
Burning:mean
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
0
1
2
3
4
5
6
Visit
Series
:Erythema:mean
:Burning:mean
Page
1
of 1
Properties...
Reset
☐ Show Caption

## *Item Mean and Standard Deviation vs. Category*

In a Item Mean and Standard Deviation vs. Category graph, the standard deviation is represented by range bars at each categorical data point. Available functions supported are baseline, change from baseline, etc.

In this example, the Y-axis was added as “Burning Mean + SD”.



Graph Type: Summary Data Graph

Graph Style: Mean + Std Dev vs Category

Functions: actual value

Y Axis: Burning

☑ Numeric?

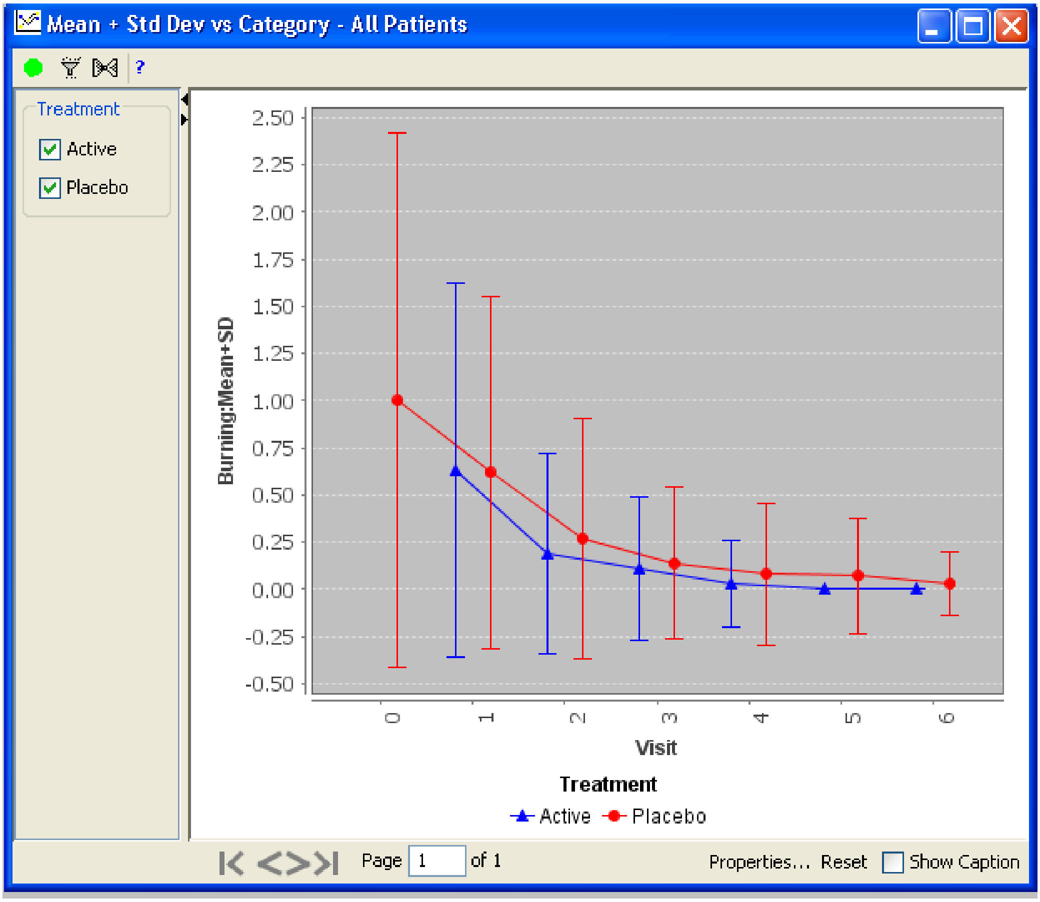
X Axis: Visit

☑ Numeric?

BY Variable(s): Treatment

Page Variable:

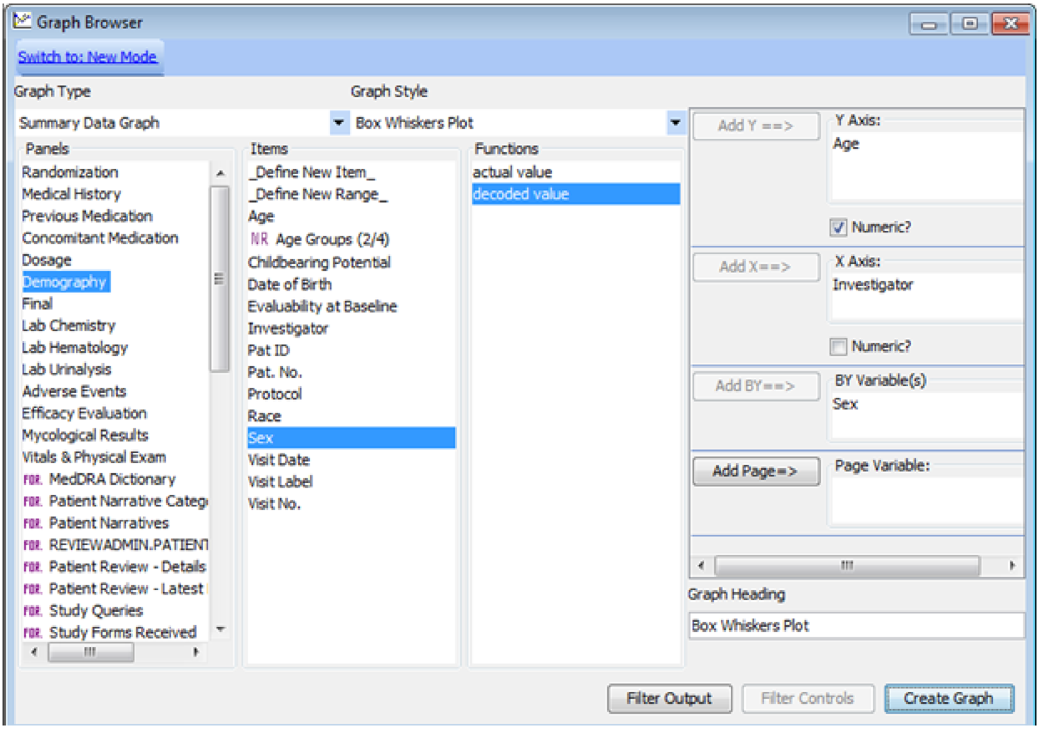
Graph Heading: Mean + Std Dev vs Category


Mean + Std Dev vs Category - All Patients
?
Treatment
☑ Active
☑ Placebo
2.50
2.25
2.00
1.75
1.50
1.25
1.00
0.75
0.50
0.25
0.00
-0.25
-0.50
Burning:Mean+SD
0
1
2
3
4
5
6
Visit
Treatment
Active
Placebo
Page
1
of 1
Properties…
Reset
☐ Show Caption

## *Box Whiskers Plot*

The Box Whiskers plot is used to display a set of data so that you can easily see where most of the values are distributed. It is based on the medians. Therefore, discrete data is used where the quartiles (25% percentile, median (50% percentile) and 75% percentile) should return values from the list of existing data, i.e., no interpolated values (like those with decimal points).

***Note: The Box Whiskers plots only works if going against an Oracle 9 database.***



Graph Type: Summary Data Graph

Graph Style: Box Whiskers Plot

Y Axis: Age

☑ Numeric?

X Axis: Investigator

☐ Numeric?

BY Variable(s): Sex

Page Variable:

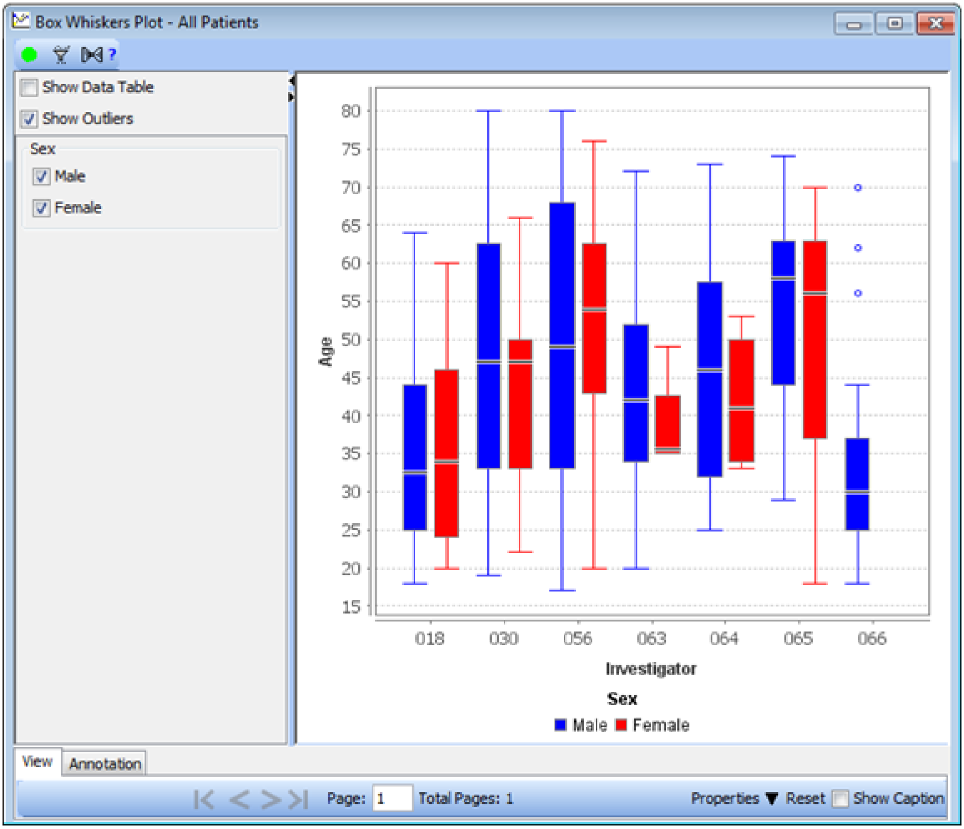
Graph Heading: Box Whiskers Plot

The Box Whiskers plot is used to display a set of data, so that you can easily see where most of the data values are distributed. It divides the range of Y values into sub-ranges. It is based on medians where the horizontal line in the box is the median.

Next, the lower median is identified as the middle of the lower values and the upper median as the middle of the upper values. The lower and upper median values are endpoints for the box boundaries.

The bottom of the box represents the first quartile (Q1), and the top box represents the third quartile (Q3).

The whiskers extend out to the data's lowest and highest values. The data values are ordered in the graph from low to high and the median (middle value) of all the values identified.

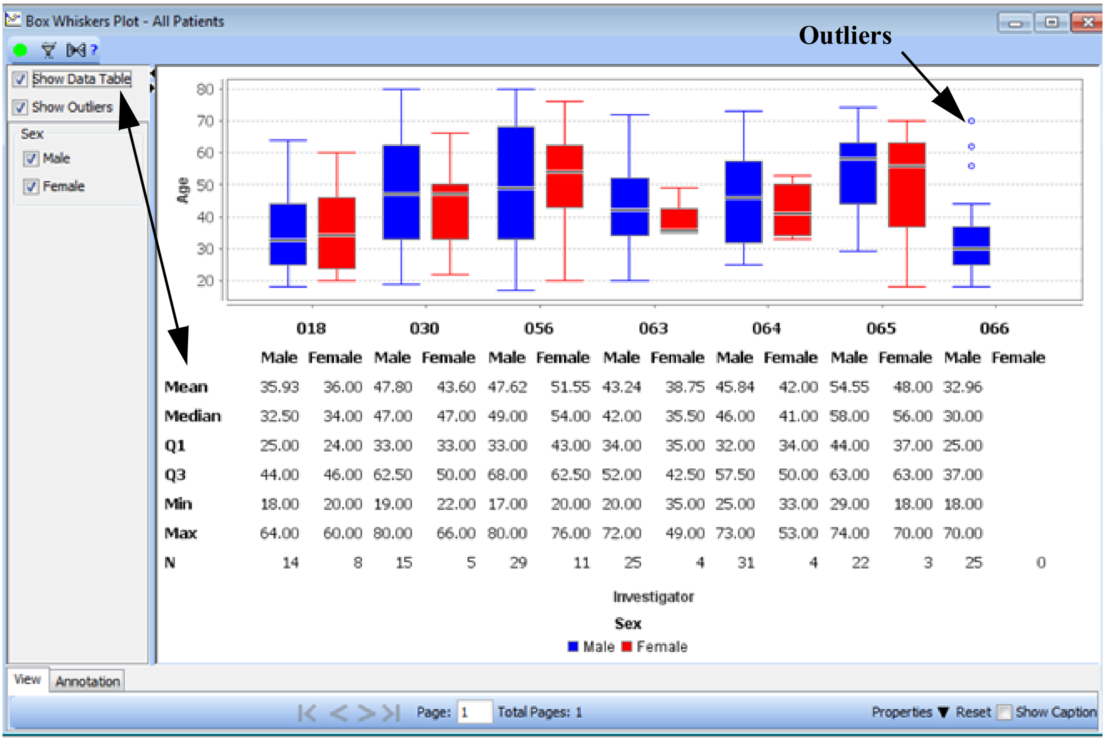


☐ Show Data Table
☑ Show Outliers

Sex
☑ Male
☑ Female

## Show Data Tables

Click **Show Data Tables** to view details for table of counts and stats: mean, median, 1st quartile, 3rd quartile, min, max, count.



**Outliers**

| | 018 | | 030 | | 056 | | 063 | | 064 | | 065 | | 066 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Male | Female | Male | Female | Male | Female | Male | Female | Male | Female | Male | Female | Male | Female |
| Mean | 35.93 | 36.00 | 47.80 | 43.60 | 47.62 | 51.55 | 43.24 | 38.75 | 45.84 | 42.00 | 54.55 | 48.00 | 32.96 | |
| Median | 32.50 | 34.00 | 47.00 | 47.00 | 49.00 | 54.00 | 42.00 | 35.50 | 46.00 | 41.00 | 58.00 | 56.00 | 30.00 | |
| Q1 | 25.00 | 24.00 | 33.00 | 33.00 | 33.00 | 43.00 | 34.00 | 35.00 | 32.00 | 34.00 | 44.00 | 37.00 | 25.00 | |
| Q3 | 44.00 | 46.00 | 62.50 | 50.00 | 68.00 | 62.50 | 52.00 | 42.50 | 57.50 | 50.00 | 63.00 | 63.00 | 37.00 | |
| Min | 18.00 | 20.00 | 19.00 | 22.00 | 17.00 | 20.00 | 20.00 | 35.00 | 25.00 | 33.00 | 29.00 | 18.00 | 18.00 | |
| Max | 64.00 | 60.00 | 80.00 | 66.00 | 80.00 | 76.00 | 72.00 | 49.00 | 73.00 | 53.00 | 74.00 | 70.00 | 70.00 | |
| N | 14 | 8 | 15 | 5 | 29 | 11 | 25 | 4 | 31 | 4 | 22 | 3 | 25 | 0 |

Investigator

Sex

🟦 Male 🟥 Female

The stems (lines) extending vertically from the top and bottom of the box define the range of "regular" values. These bounds are calculated by multiplying the inter-quartile range (i.e., Q3 - Q1) by a coefficient, which is, by convention, 1.5. In other words, the top line extends up to Q3 + 1.5 * (Q3 - Q1), and the bottom line extends down to Q1 - 1.5 * (Q3 - Q1).

## Show Outliers

These calculations define the limits of regular values; the drawn lines themselves bound the actual regular values. Any value above or below the range of "regular" values is considered an "outlier." The outliers are drawn as circles.

Optionally hide or show (default) outlier data point display.

## *Kaplan Meier analysis*

The Kaplan-Meier Analysis is a “time-to-event” analysis, also used as a survival function. It shows the time-dependence of events as fractions of subjects with event-free survival over time. It takes into account the subjects who withdraw and/or are lost to follow-up.

Kaplan-Meier plots are used for survival analysis to show “survival probabilities” and “non-survival probabilities” over time. The purpose is to estimate a population survival curve where in most studies there are patients lost to follow-up, drop out, etc., who cannot be followed until death. A Kaplan-Meier analysis allows estimation over time, even when patients drop out and are studied for different lengths of time.

Kaplan-Meier Analysis is used when ***time*** matters in:

- Progression-free survival in Oncology trials.
- Time to progression in Chronic diseases.
- Event-free survival in Cardiovascular studies (time to stroke, MI, hospitalization, death).
- Time to healing resolution.
- Safety analyses where “Time to event” = “Event-free Survival”.

## *Kaplan-Meier requirements*

The Kaplan -Meier analysis are calculated off three pieces of information required for all patients. It determines how patients are censored or not in the analysis.

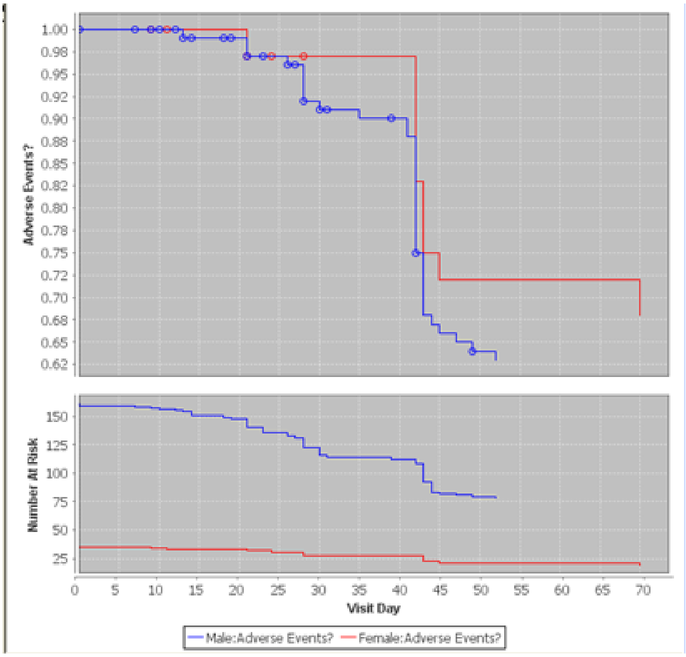
1. ***Did the subject experience an event?*** If an event occurred, the subject is not censored. If no event, the subject is censored.
2. ***When did the event occur, and if no event, when was their last follow-up?*** Time is a number (days, weeks, months, years).
3. ***What is the treatment group?***

In clinical trials, the time until patients in a study present a specific event or endpoint is tracked. The patients are followed beginning at a certain starting-point, and the time is recorded and needed for the event if it occurs. The end of the study is usually reached before all the patients have presented this event, and the outcome of the remaining patients is unknown. Outcome is also unknown for patients who withdrawal from the study and their time of follow-up is recorded as “censored data”.

The plots are summary in nature and require drill down. This is basically a line plot over time on the X axis. The Y axis shows probability of survival (or non-survival) for the selected patient group. The Kaplan Meier plots supports multi-study mode.

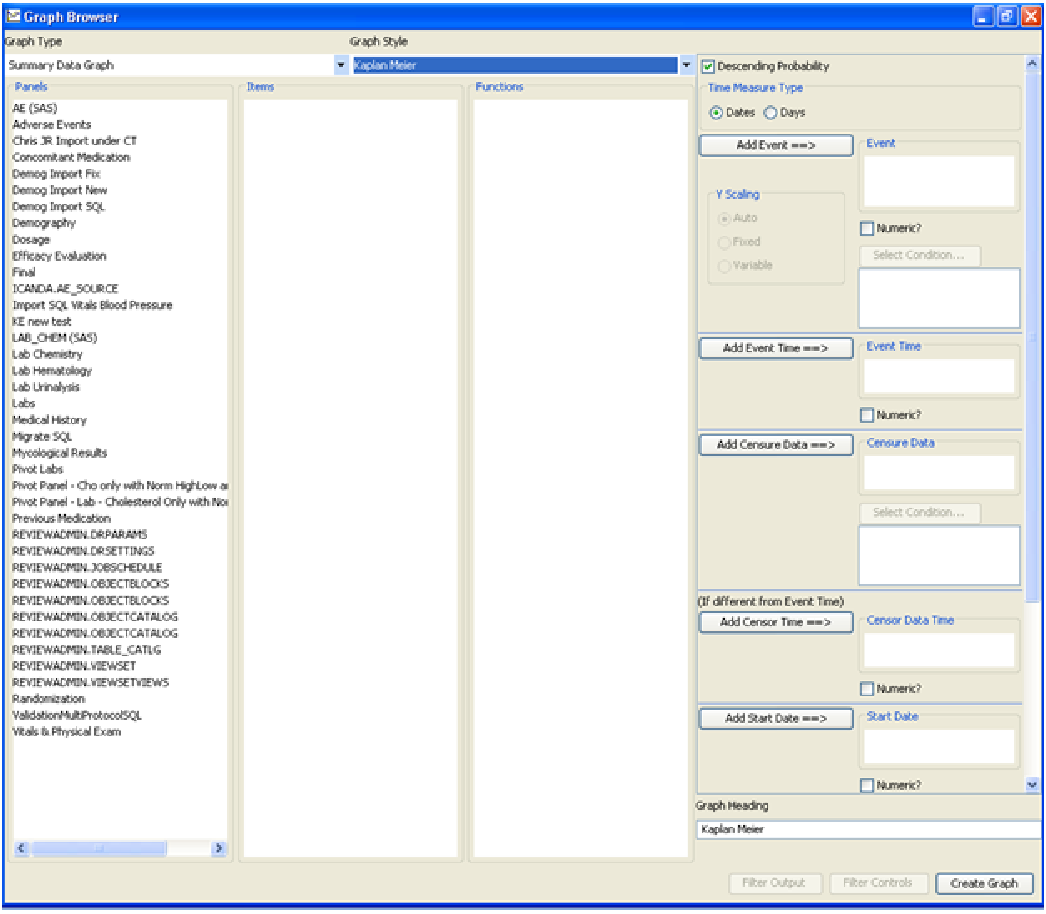
The survival curves are shown as a step function.

Below is an example of a Kaplan Meier and Survival Plot:



## *Define Kaplan Meier plot*

To start, select the Graph Type for Summary Data Graph for Kaplan-Meier. The graphic definition window displays:



Graph Type: Summary Data Graph

Graph Style: Kaplan Meier

☑ Descending Probability

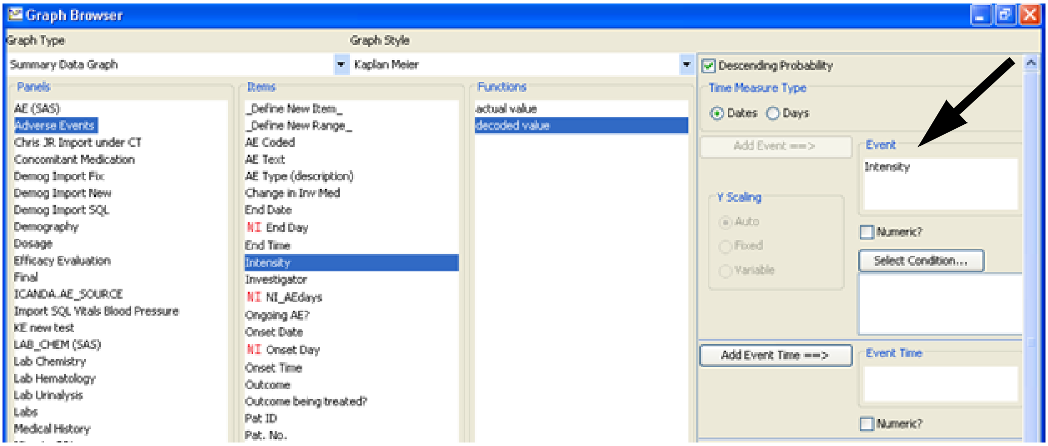
Time Measure Type: ● Dates ○ Days

Graph Heading: Kaplan Meier

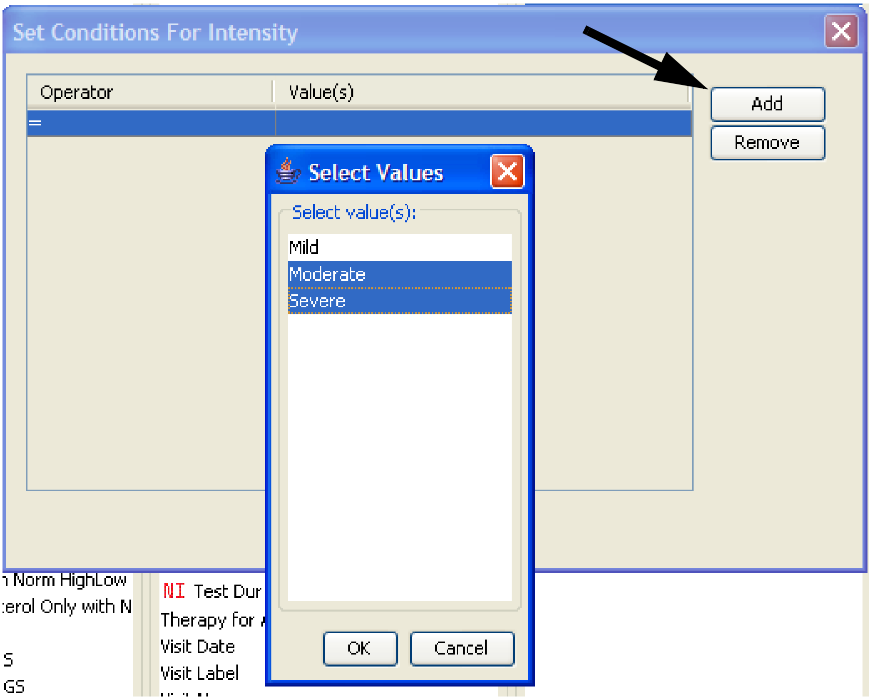
1. Select the direction of the plot for **Descending Probability** versus Ascending Probability of Y axis, where Probability of Survival versus Probability of Death.
2. Select a **Time Measure Type** to specify whether the variables associated with the "time" of event and censor occurrences are ***dates*** or ***time durations*** (e.g., "how many ***days*** to the event occurrence").

   The Event and Censure condition filters require a date (or days) variable to be associated with them. Choose ***Days*** if days have already been calculated and stored in the data, otherwise, select ***Dates*** so JReview can do the day calculations for you.

3. Select the Y axis scaling variable for **Add Event,** by selecting a panel in the Panels list, and select item from the Items List. The **Select Condition** filter control button is enabled.



4. Click on the Event **"Select Condition..."** button. The Set Conditions dialog opens which contains a table with two columns. You ***must*** click on the **Add button** to activate this window to load the default operator and values.

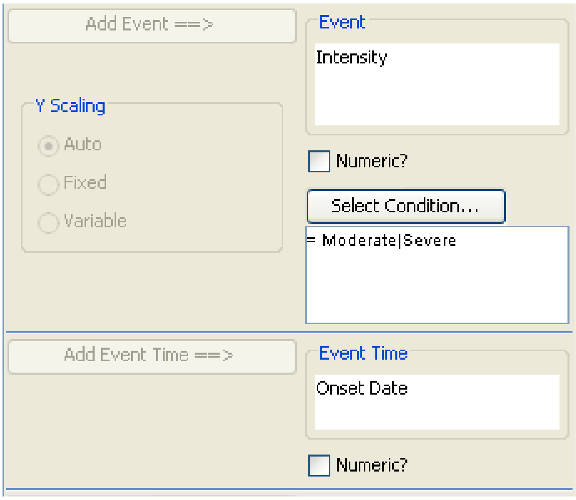


The left column allows the user to select an **Operator** such as “=”, “>”, “<=”, etc. Optionally, change the default operator by double-click in the **Operator** column for a drop down list. Each row can have only one operator selected.

The second column contains values that can either be directly typed into the table cell field, or selected from a popup dialog. Double-click in the **Values** column to display the **Select Values** list box. Select value(s) and click **OK** to save.

5. For Event and Censor Data, users must select a variable that specifies where to find the time of these occurrences. If the Event and Censor Data time variables are the same, then only the Event Time variable needs to be specified by the user.

   Select an Event Time from the Panels and Item lists, then click **Add Event Time** button. This field represents a Date/Time for the event. Typically the Event and Event Time are selected from the same panel.



Event: Intensity

● Auto
○ Fixed
○ Variable

☐ Numeric?

= Moderate|Severe

Event Time: Onset Date

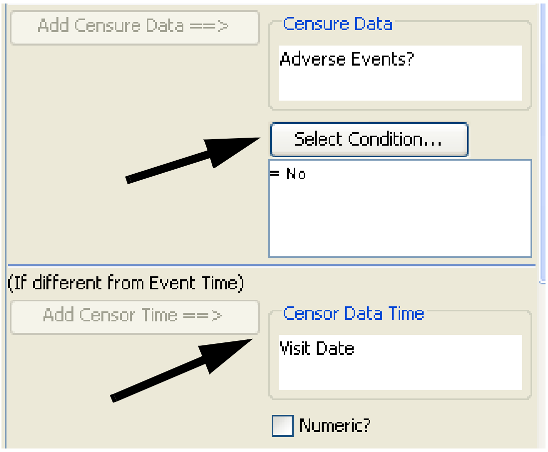
☐ Numeric?

6. Next, select the Censure Data for **Add Censure Data** by selecting a panel in the Panels list, and select item from the Items List. The **Select Condition** button is now enabled to filter on the selected Censure Data item.

   Click on the Censure Data **Select Condition** button. You must click on the **Add button,** to activate this window to load the default operator.

   Optionally, double-click in the **Operator** column for a drop down list to change the default operator. Double click in the **Values** column to display the **Select Values** list box. Click **OK** to save.

   Add Censor Time if different from the Event Time. Select a **Censor Data Time** from the Panels and Item lists, then click on **Add Censor Time** button.



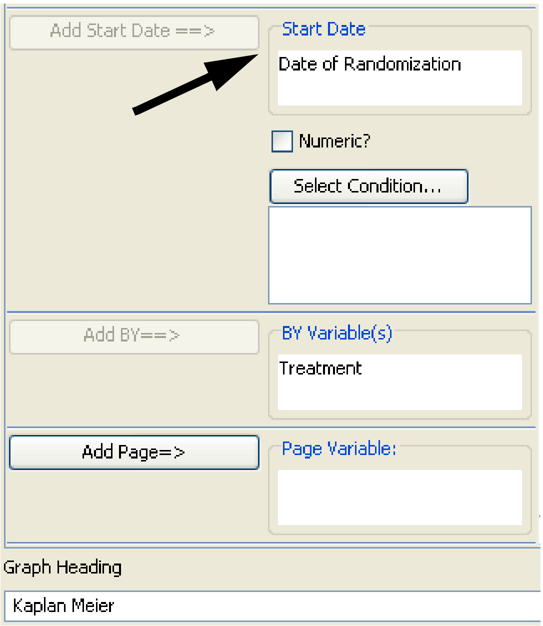
Censure Data: Adverse Events?

= No

Censor Data Time: Visit Date

☐ Numeric?

7. The **Start Date** variable is required only when the Event/Censor Data are ***Date*** types. It is disabled if the Time Measurement Type is Days. Select a panel from the Panels list and the date item from the Items list.



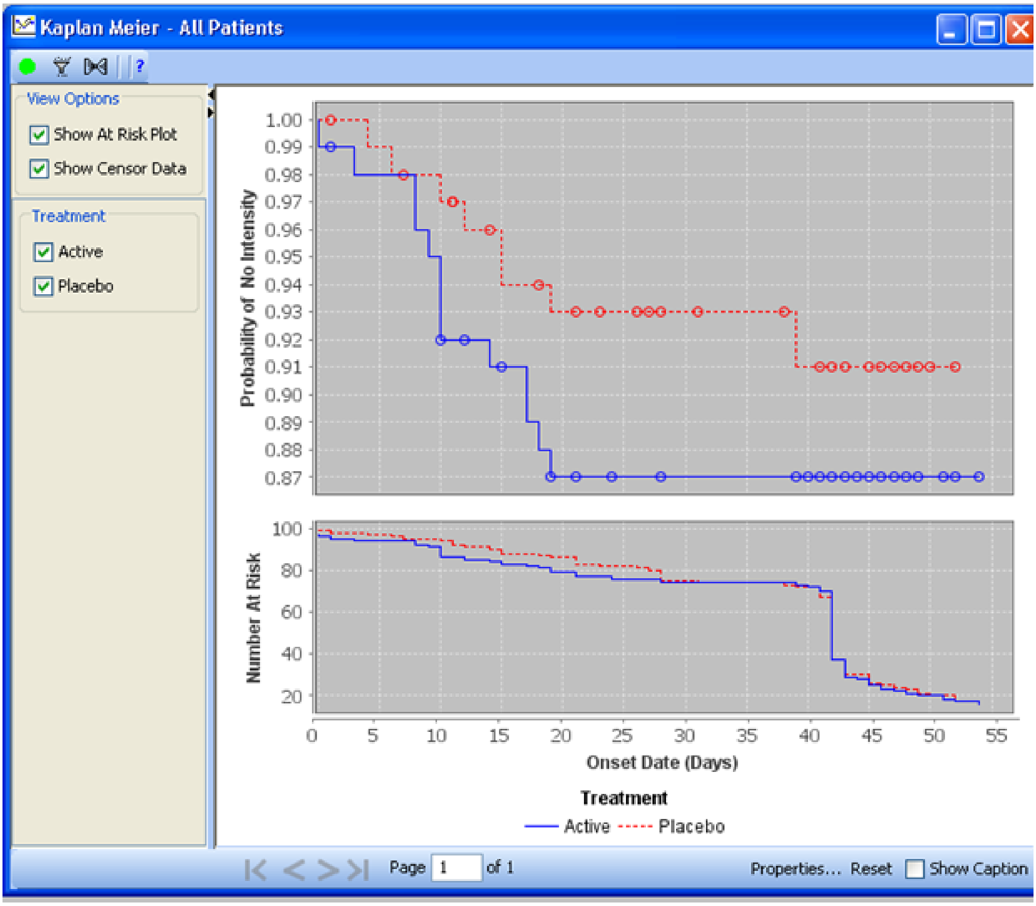
In this step, ***s***elect a panel from the Panels list and the date item from the Items list. The study day calculation are determined as Risk Start and Risk End dates minus Randomization date, Visit date minus Randomization date, etc.

If you choose a 'Start Date' from a table/dataset with multiple visits per patient i.e., Dosage; you must also click on the '**Select Condition**' button to define the filter condition to select which record should be chosen for each patient.

8. Optionally, enter a **BY Variable** (i.e., treatment).
9. Optionally, add **Page Variable** for the further categorization of data (i.e. per investigator, site, treatment, etc.).
10. Click Create Graph.

The Kaplan-Meier plot is contained in the top graph. The bottom graph, is not part of the Kaplan-Meier graph itself, but is a supporting plot that displays the number of patients at risk across time, i.e., the bottom graph shows the sample size for the time periods. This supporting graph shares the X axis with the Kaplan-Meier plot.

Optionally click on the View Options to only Show at Risk Plot, or Show Censor Data.



Kaplan Meier - All Patients

View Options

☑ Show At Risk Plot

☑ Show Censor Data

Treatment

☑ Active

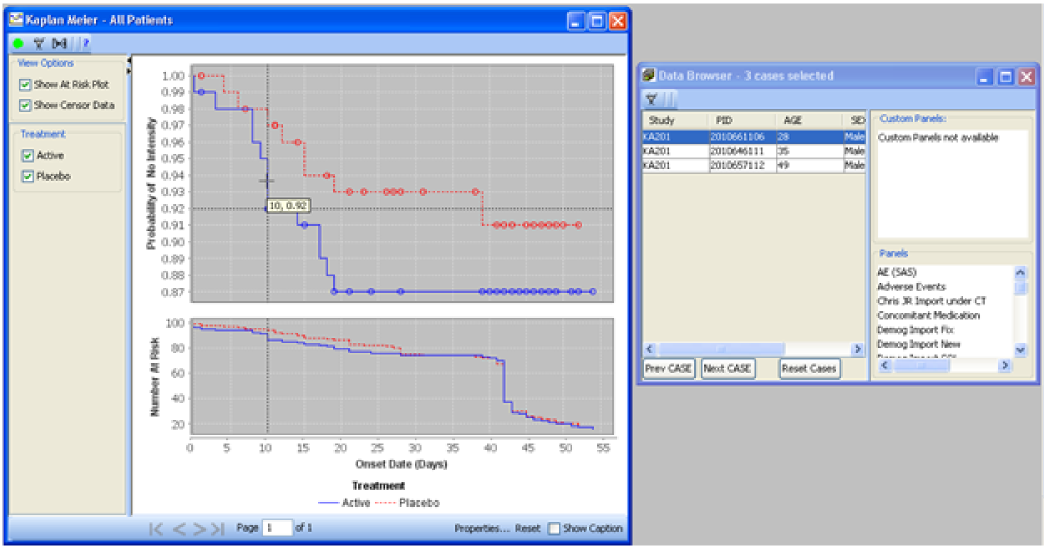
☑ Placebo

Page 1 of 1

☐ Show Caption

You may select patient(s) to view represented on the vertical Y axis, by clicking on the vertical line with the open Data Browser to access patient details.

Click on a circle to view a select censored patient. When the mouse is moved over a vertical line, or censor point, the tool tip displays to present Onset Days and Probability.



| Study | PID | AGE | SE |
|---|---|---|---|
| KA201 | 2010661106 | 28 | Male |
| KA201 | 2010646111 | 35 | Male |
| KA201 | 2010657112 | 49 | Male |

Custom Panels not available

AE (SAS)
Adverse Events
Chris JR Import under CT
Concomitant Medication
Demog Import Fix
Demog Import New

## Kaplan-Meier calculations

The Kaplan-Meier graph plots a probability, frequently a "probability of survival," on the Y axis, and time (e.g., "Days in study") on the X axis. The probability is calculated as a (cumulative) conditional probability. A specified ***event*** such as the death of a patient changes the value of the probability calculation for a specific time period (e.g., "day 2"). For example, if there are 100 patients in the study on day 2 and one patient dies on that day, the survival probability drops to .99 (99/100). If another patient dies on day 3, the survival probability is .98 ((99/100)*(98/99)). These calculations are reflected in the plot as a line that descends in a step wise manner as time progresses from left to right on the X-axis.

Observe that the graph is not limited to survival; for example, time to first serious adverse event might also be plotted. While the descending line plot is typical, the graph may also be plotted in an *ascending* direction (e.g. "probability of death").

For some patients, data may be unavailable for the full-length of the study. For example, a patient may withdraw from the study, so patients for whom data is no longer available are called ***censored***. The point at which a patient is considered censored is marked on the plot with a circle.

***Note: Sometimes the patient count in Kaplan-Meier graph shown censor tool tip, may be inconsistent with the number of patients shown in the Data Browser. This is due, under certain circumstances, to the inclusion of patients who have earlier exhibited an event.***

The occurrence of censor data affects the probability calculation by changing the number of patients in the sample at a given time. In our example, if a patient withdraws from the study on day 1 and a different patient dies on day 2, the survival probability on day 2 is .9899 (98/99).

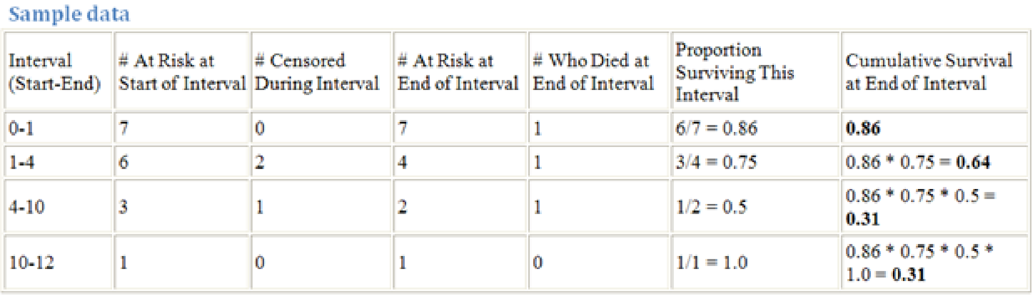
The plot starts at 100% (0% in the non-survival case) and drops down (rises up in the non-survival case) at intervals, when a patient event such as death occurs. However, there are also points on the Y axis called “censor data” where patient drop outs not due to an event like death are counted. Also, there is a secondary plot along with the survival plot showing Number of patients at Risk, or the number of patients still in the study. These two plots are both shown against the same X axis.

The Kaplan-Meier curve works for each interval, where survival probability is calculated as the number of patients surviving by the number of patients at risk. Patient who have died, dropped out, or have not reached the time yet are not counted as “at risk”. The lost patients are “censored” and **not** counted in the denominator.

The probability of surviving to any point is estimated from cumulative probability of surviving each of the preceding time intervals (calculated as the product of the preceding probabilities). The probability calculated at any given interval isn’t very accurate due to the small number of events, however; the overall probability of surviving to each point is more accurate.

The vertical axis represents the estimated probability of survival for a hypothetical cohort, not the actual percentage surviving. The precision of the estimates depends on the number of observations, so estimates on the left side are more precise than at the right side (due to small number of deaths and dropouts).

These are the base calculations that are necessary to plot a Kaplan Meier graph:



Sample data

| Interval (Start-End) | # At Risk at Start of Interval | # Censored During Interval | # At Risk at End of Interval | # Who Died at End of Interval | Proportion Surviving This Interval | Cumulative Survival at End of Interval |
|---|---|---|---|---|---|---|
| 0-1 | 7 | 0 | 7 | 1 | 6/7 = 0.86 | **0.86** |
| 1-4 | 6 | 2 | 4 | 1 | 3/4 = 0.75 | 0.86 * 0.75 = **0.64** |
| 4-10 | 3 | 1 | 2 | 1 | 1/2 = 0.5 | 0.86 * 0.75 * 0.5 = **0.31** |
| 10-12 | 1 | 0 | 1 | 0 | 1/1 = 1.0 | 0.86 * 0.75 * 0.5 * 1.0 = **0.31** |

Proportion Surviving This Interval = (# At Risk at Start of Interval –

# Censored During Interval –

# Who Died at End of Interval) /

(# At Risk at Start of Interval –

# Censored During Interval)

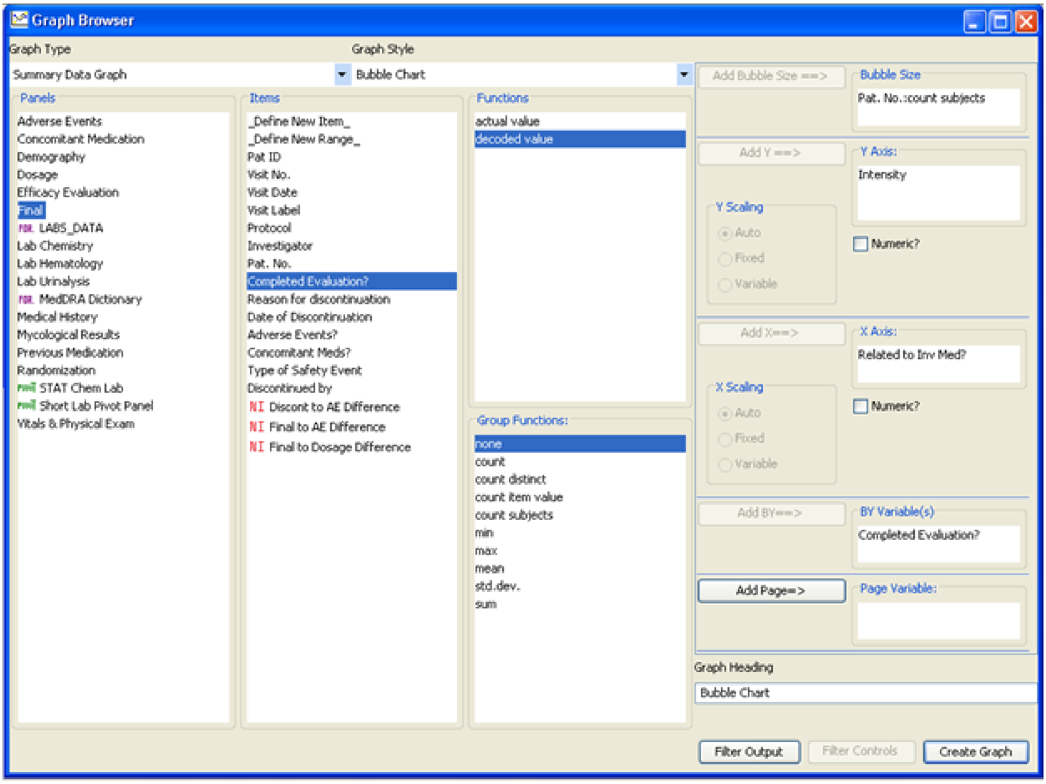
Cumulative Survival at End of Interval = Proportion Surviving all proceeding intervals multiplied together.

# At Risk at End of Interval = # At Risk at Start of Interval – # Censored During Interval.

## Bubble Chart

A Bubble Chart is a type of Summary graph that displays three dimensions of data. In some ways, the Bubble Chart is similar to a Scatter plot, but instead of individual data points (e.g., a value for an individual patient), "bubbles" (i.e., circles are presented).

In JReview, the variable represented by the bubble has a user-specified Group function such as "mean" or "count" associated with it. The specified variables for X-axis and Y-axis may be numeric or character (i.e., category) type data.



Graph Type: Summary Data Graph

Graph Style: Bubble Chart

Bubble Size: Pat. No.:count subjects

Y Axis: Intensity

X Axis: Related to Inv Med?

BY Variable(s): Completed Evaluation?

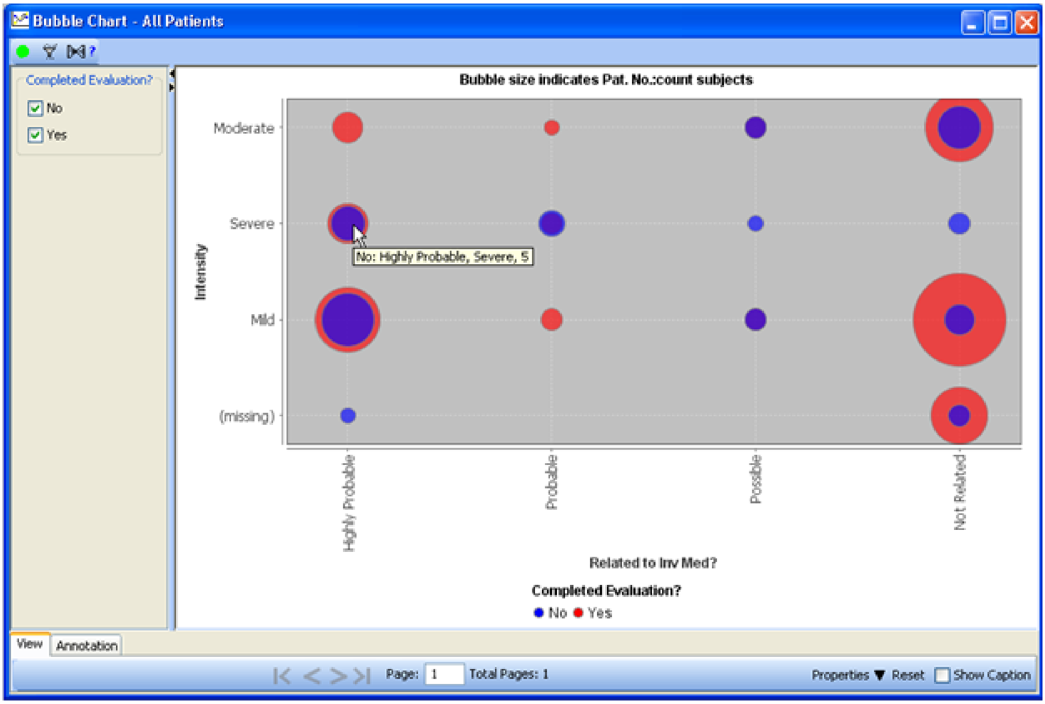
Page Variable:

Graph Heading: Bubble Chart

The size of the bubble (i.e., the Bubble's radius) is proportional to the magnitude of the data value. When the values are negative, the bubble is draw as an outline circle with an "X" within it. A zero value is drawn as a small filled square. The color of the Bubble is translucent to provide a cue when bubbles overlap.

This example used the Adverse Events panel as Bubble Size: PatientNo : count subjects, Y-axis=Intensity, X-axis=Related to Inv Med, with a BY variable Final panel for  Completed Evaluation status.

A tooltip will appear when the user hovers over a bubble. Drill-down is supported in the Bubble Chart where the user may click on a bubble to initiate a drill-down with the Data Browser or Patient Profiles Browser.



Completed Evaluation?
☑ No
☑ Yes

No: Highly Probable, Severe, 5

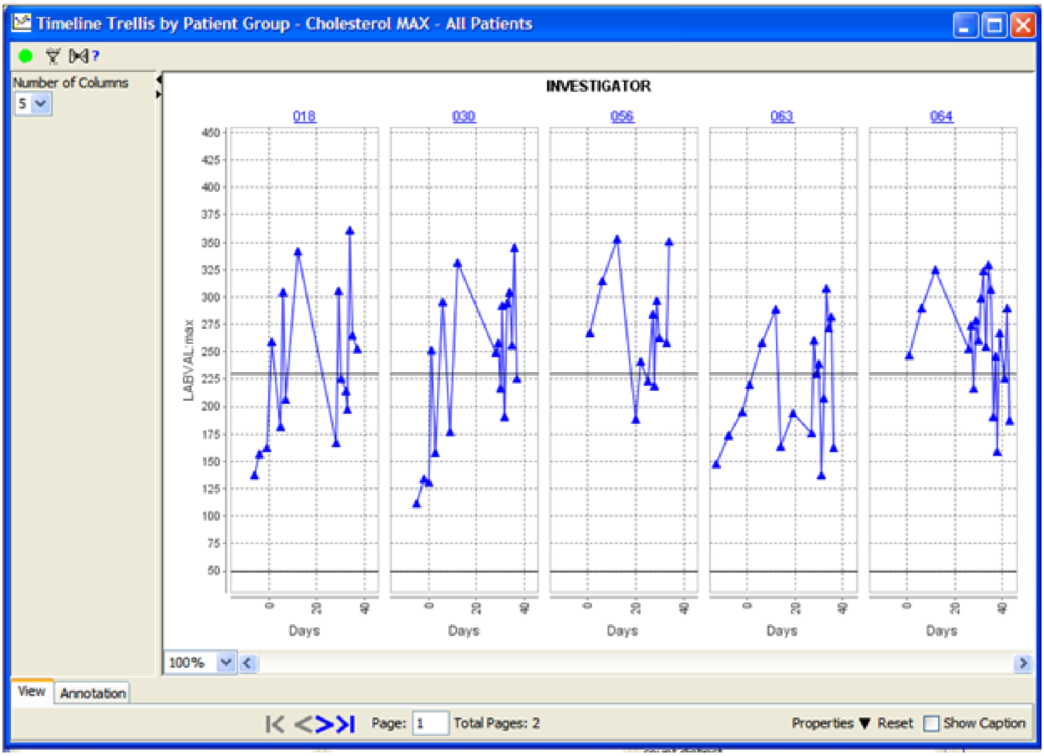
Page: 1 Total Pages: 1

☐ Show Caption

## Timeline Trellis by Patient Group

JReview’s ***Timeline Trellis by Patient Group*** graph is composed of a matrix of Group By subplots with the following general characteristics:

- Each column represents a **Patient Grouping**.
- The X-axis, shown at the bottom of each column, represents a time variable such as “Days in Study”.
- Each row has a Y-axis shown on the left side. These Y-Axes typically represent different laboratory tests or other patient measures such as “blood pressure”.
- Each subplot is a ***line chart*** that plots Y-axis values over time.



Timeline Trellis by Patient Group - Cholesterol MAX - All Patients

Number of Columns: 5

Page: 1 Total Pages: 2

The column titles are the **Patient Grouping** identifiers, so clicking on a title results in a “drill-down” to subset those patients.

As there are usually more columns than can be shown at once, the charts are drawn on a sequence of pages, with each page having multiple columns.

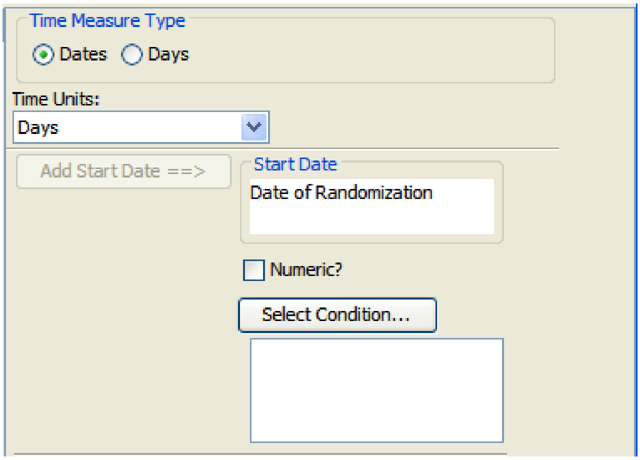
The user can reset the number of columns to be displayed in each plot, i.e., the number of columns that appear on each page. Changing the number of displayed columns alters the total number of pages. If the user has drawn annotations on the graphs, these will be deleted when the number of columns is changed; a Warning dialog is presented before proceeding with this operation.

## *Define by Patient Grouping*

The X-axis is time-based with controls generally the same or very similar to those in Napoleon's March and some other existing JRevew graphs.

The user may specify whether "dates" or "days" are to be used in determining time values. If "dates" is selected as the time mode, then a start date must be specified, and all variables in the overall specification must have the accompanying "time" specification made in terms of dates. Some datasets have time values that are pre-calculated as days. If "days" is selected, then the start date is not defined and all time variables must be "days".

The user may specify the X-axis's time units to display the X-axis values calculated as Days, Weeks, Bi-Weekly, or Months. Optionally the user may "**Select Condition**" which is applied as a defined filter.



Time Measure Type

● Dates ○ Days

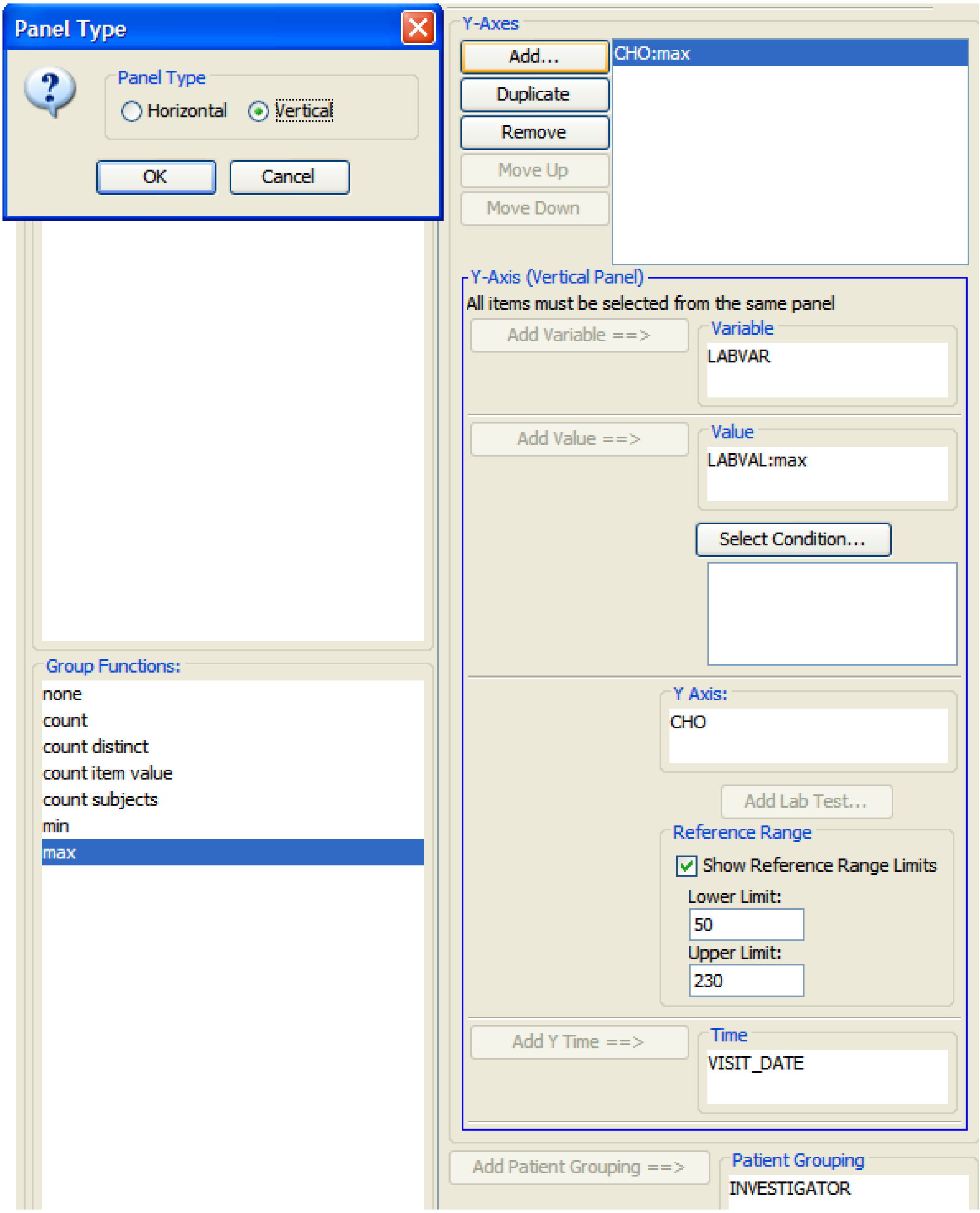
Time Units: Days

Start Date: Date of Randomization

☐ Numeric?

Next, there is a complex control provided to specify the Y-Axes where at least one Y-axis must be specified. Not more than eight Y-Axes can be specified. The individual Y-axis variables may be defined from either a Vertical or Horizontal panel type.

**See STEPS for Detail Data Graph - Timeline Trellis by Patient.**



Panel Type

Panel Type: ○ Horizontal ● Vertical

Y-Axes: CHO:max

Y-Axis (Vertical Panel)

All items must be selected from the same panel

Variable: LABVAR

Value: LABVAL:max

Y Axis: CHO

Reference Range

☑ Show Reference Range Limits

Lower Limit: 50

Upper Limit: 230

Time: VISIT_DATE

Patient Grouping: INVESTIGATOR

Group Functions: max

Optionally, enter **Reference Range Limits** for either horizontal or vertical panel type data. The Summary graph version "summarizes" data across patients in a group (e.g., an investigator), so there are **no** individual patient reference ranges.

Repeat the steps starting with **Add** for additional lab test or exam items. Each added item requires the collection or visit **Time** be entered. Optionally, include lower and upper limit variables will vary between added exams or lab items.

The remaining button panel functions are used to:

- ***Duplicate*** - the selected item. It is a convenience for adding a new Y-axis definition.
- ***Remove -*** the selected Y-axis definitions in the list. Note that the global cut mechanism ("scissors") cannot be applied to this list. If the form for a removed definition is currently displayed, it will be removed.
- ***Move Up and Down*** - move the selected list items up or down in the list; this feature allows the user to reorder the Y-axes.

# Output Filter

The output filter is designed to focus in on particular observations and visits; it is not designed to be used for the patient selection criteria.

***(See Chapter 6: Report Browser for Output Filter and Run Time Parameters. The same instructions apply for the Graph Browser.)***

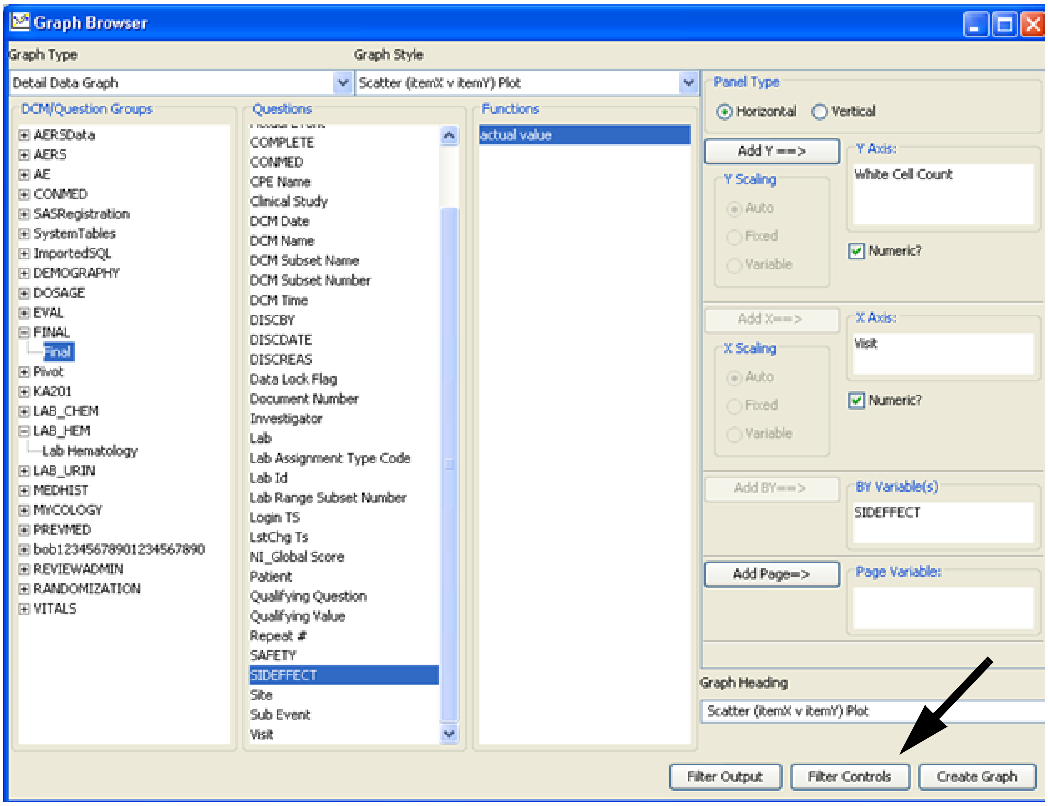
## *Filter Controls*

The **Filter Controls** feature allows users to define a ‘patient subgroup’ by selecting a set of variables to serve as “filters” in Scatter plots. This allows for interactive modification of generated scatter plots.

The filters are of two main types: check boxes for category type data, and sliders for numeric range type data. When the number of categories is large for a variable, the check boxes are presented as a scrolling list.

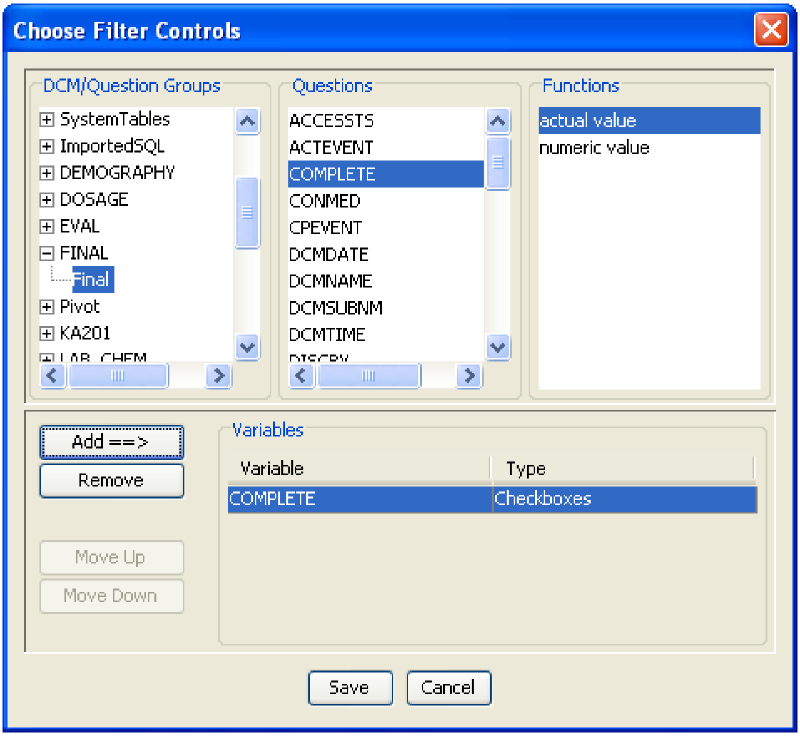
For example, for a Scatter plot with Y-axis for “WBC”, and “VISIT” on the X-axis, and Side Effects as the BY variable was defined. After defining the scatter plot, you may add filter controls to the graph.

1. Click on the **Filters Control** button.


Graph Type: Detail Data Graph
Graph Style: Scatter (itemX v itemY) Plot
Panel Type: ● Horizontal ○ Vertical
Y Axis: White Cell Count
☑ Numeric?
X Axis: Visit
☑ Numeric?
BY Variable(s): SIDEFFECT
Graph Heading: Scatter (itemX v itemY) Plot

The **Choose Filter Controls** dialog displays to turn on/off the various included control filters. The user might select “completed study”, and “WBC” as control filters.

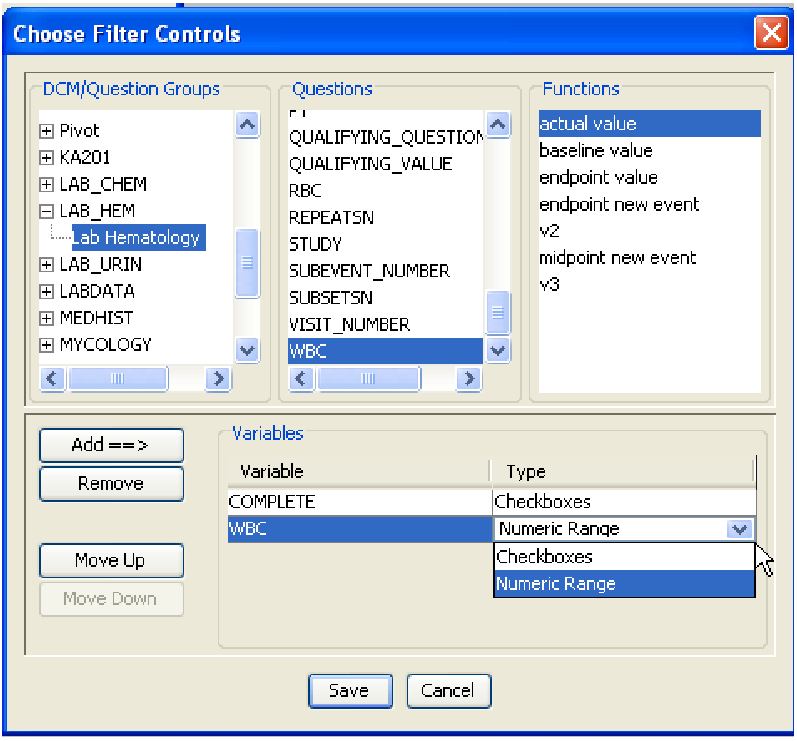
2. Select the DCM/Question Group (panel) and Question (item). Optionally select the function.
3. Click on **Add**. The filter control variable is added. Check boxes is the default type. If the variable is numeric, you have the option to select Numeric Range. A selected date item will display as checkboxes.



| Variable | Type |
|---|---|
| COMPLETE | Checkboxes |

The variable for “Completed Study” is added as check boxes.

The numeric variable for “WBC” is added and Numeric Range is selected.



| Variable | Type |
|---|---|
| COMPLETE | Checkboxes |
| WBC | Numeric Range |

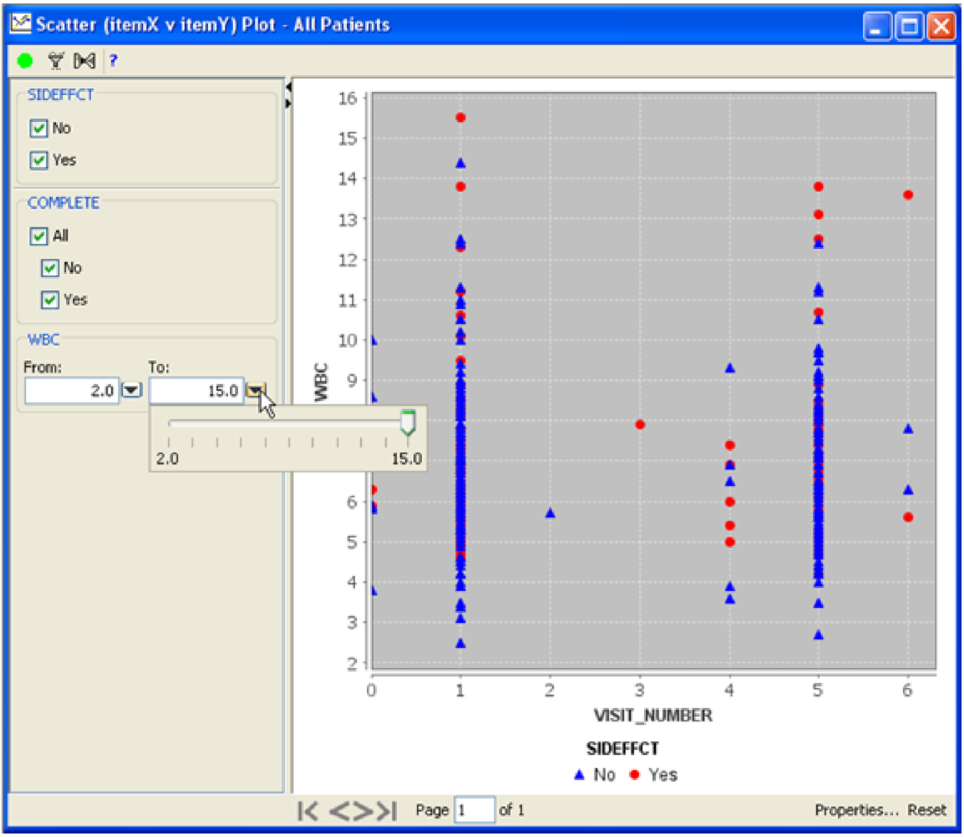
4. Click **Save**. The Filter Controls are saved. The button status changes to Filter Controls ON.
5. Click **Create Graph**.

The saved Filter Controls are listed with the BY variable if added. Initially the graph displays with all values.

6. Click on the check boxes to select which filter values to display and subset different patient sub-populations.
7. Change the values by directly typing an entry and click enter; or click the drop down arrow to access the range slide bar.

   Numeric Ranges initially display the minimal and maximum values.

   You must click **Enter**, to update the graph display.



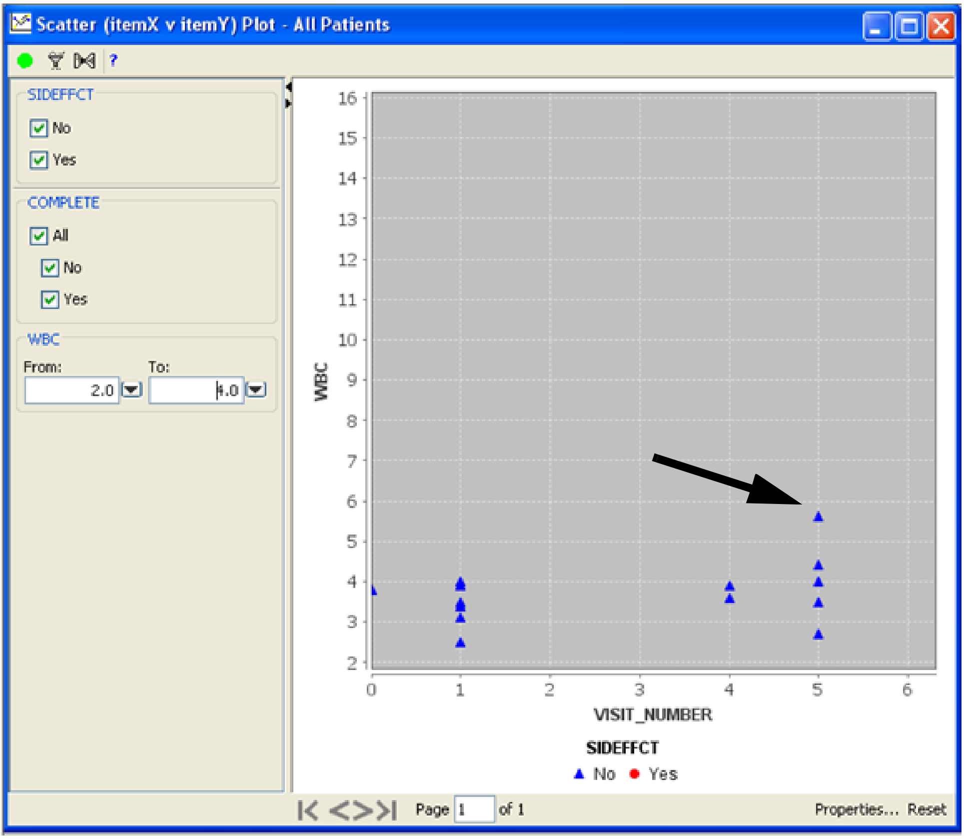
SIDEFFCT
☑ No
☑ Yes

COMPLETE
☑ All
  ☑ No
  ☑ Yes

WBC
From: 2.0 To: 15.0

The WBC range was changed to a maximum value of “4.0”. Observe some values may still display if higher than maximum value entered. This same patient had multiple visits with WBC values of “5.6” and “3.4”.

With category filters, a patient is shown if they fall into any of the checked categories. Essentially, the categories for a variable have an “OR” relationship. In this case, the patient is shown because their WBC value at another visit is “3.4”, and out of range.



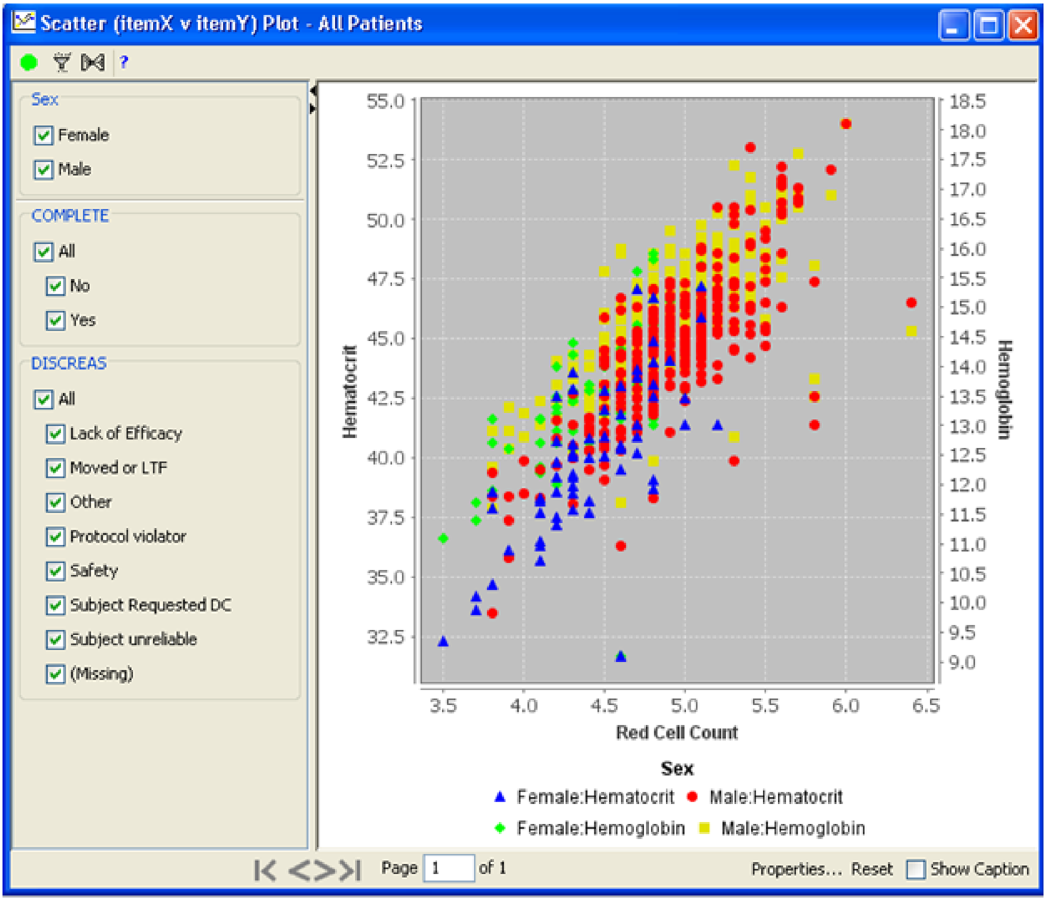
SIDEFFCT
☑ No
☑ Yes

COMPLETE
☑ All
☑ No
☑ Yes

WBC
From: 2.0 To: 4.0

Page 1 of 1

Here is another example of a dual axis scatter plot for laboratory data, with numerous Filter Controls were added. Initially all patients and their data values are displayed upon creating the graph.



Sex
☑ Female
☑ Male

COMPLETE
☑ All
  ☑ No
  ☑ Yes

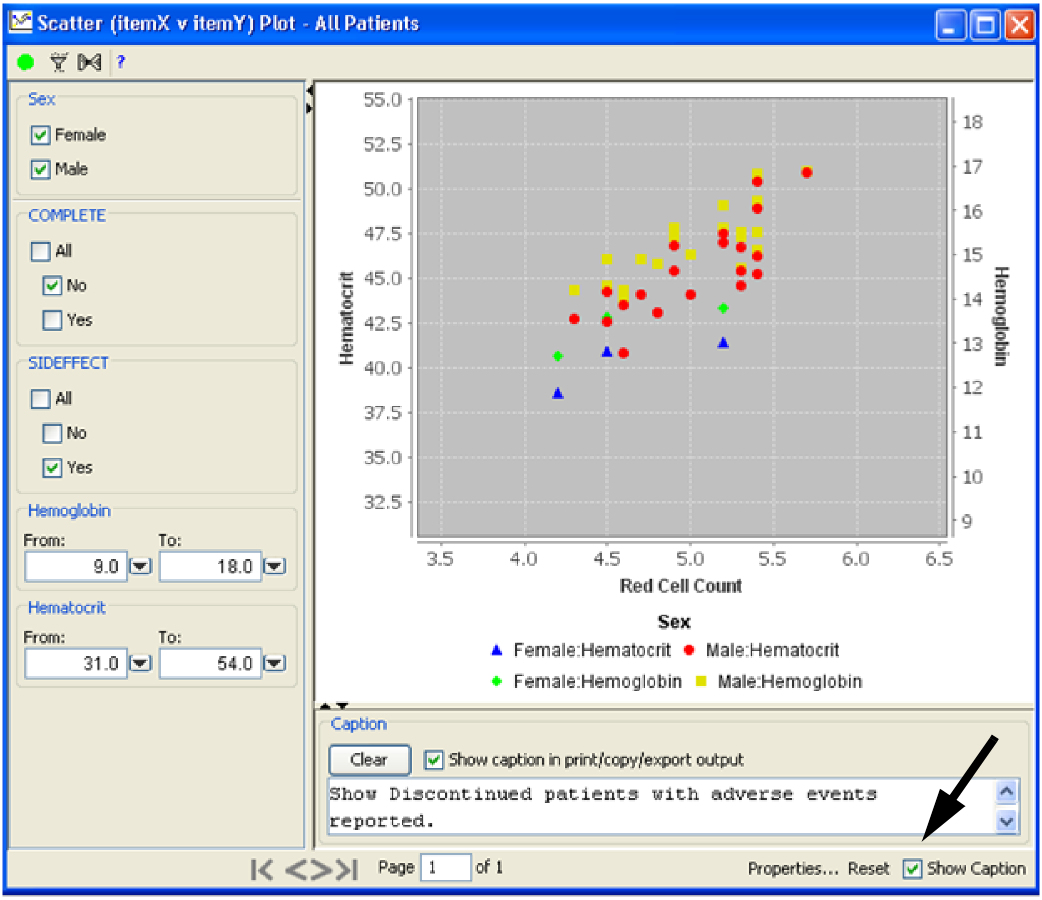
DISCREAS
☑ All
  ☑ Lack of Efficacy
  ☑ Moved or LTF
  ☑ Other
  ☑ Protocol violator
  ☑ Safety
  ☑ Subject Requested DC
  ☑ Subject unreliable
  ☑ (Missing)

Page 1 of 1

☐ Show Caption

Next, the Filter Controls were selected to show both males and females, only those patients who discontinued the study and reported side effects. The graph display updates to the new patient sub-population as shown.

The 'Show Caption' was checked On, and text describing the current filter conditions entered.



Sex
☑ Female
☑ Male

COMPLETE
☐ All
☑ No
☐ Yes

SIDEFFECT
☐ All
☐ No
☑ Yes

Hemoglobin
From: 9.0 To: 18.0

Hematocrit
From: 31.0 To: 54.0

☑ Show caption in print/copy/export output

```
Show Discontinued patients with adverse events
reported.
```

Page 1 of 1

☑ Show Caption

To edit or remove Filter Controls:

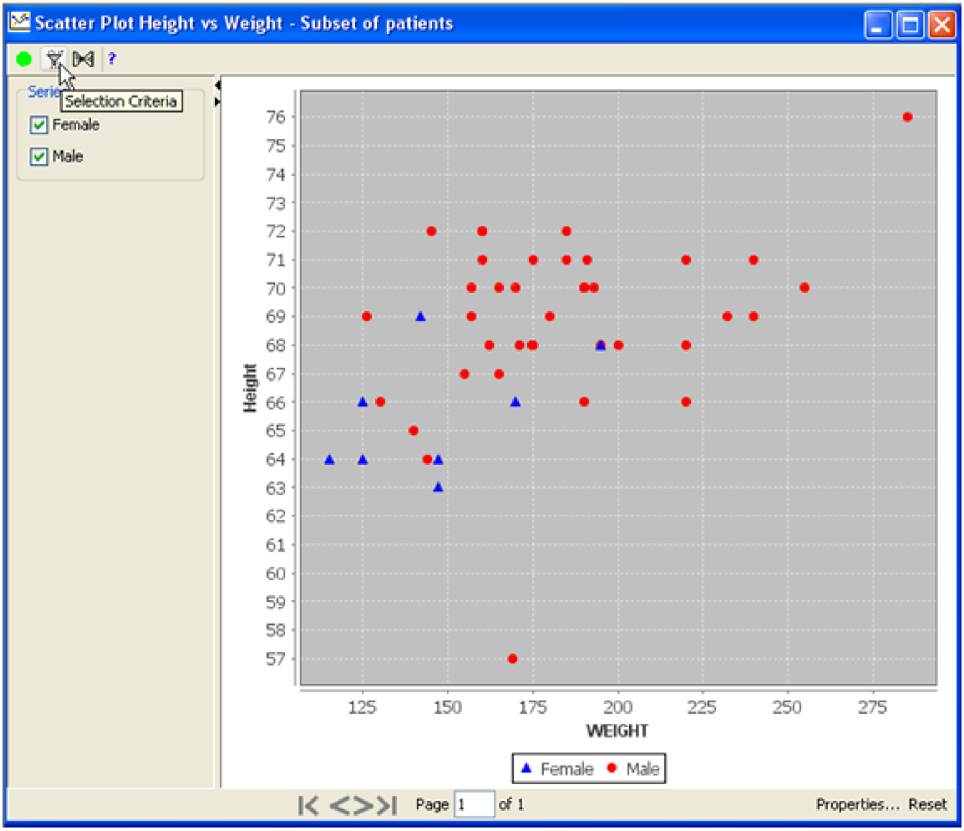
1. Click on the **Filters Control** button.
2. Select the Filter Control variable, then click on the **Remove** button.
3. You must remove each individual filter control variable, to turn off the entire function.
4. Click **Save**.

# Snapshot output

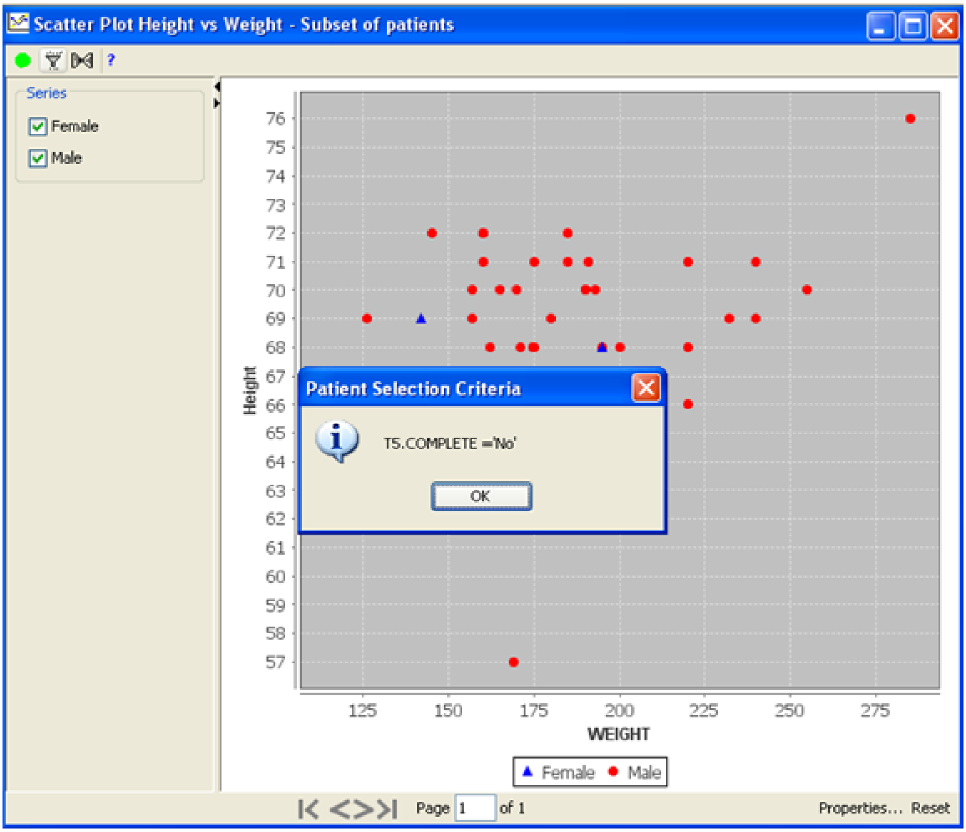
## *Multiple population mode*

JReview has an optional multiple-population mode available within the individual browsers output window. When the results are executed and displayed from the browser output window, two icons are displayed for “Snapshot” and “Selection Criteria?”.

The Selection Criteria button opens a message box to display the current patient selection criteria. The Snapshot output allows you to freeze the current output window; then change the patient selection criteria, and view the different output within the browser at the same time.



The output example shows a stored graph object with previous patient selection criteria defined.



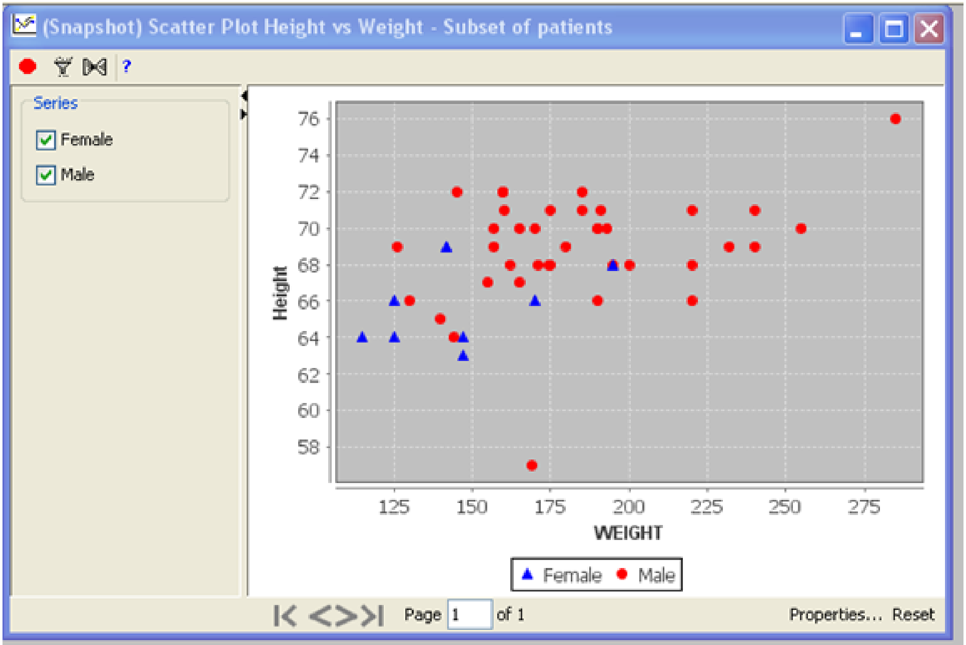
Patient Selection Criteria

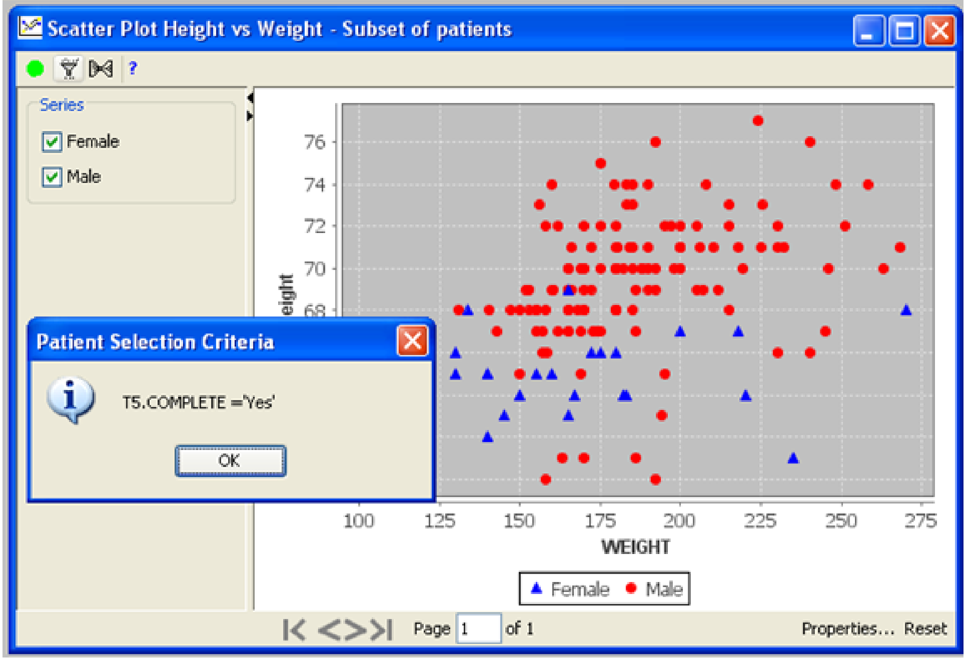
T5.COMPLETE ='No'

***Note: If the stored object definition already has a required patient selection criteria defined, you will not be allowed to change it.***

Simply click on the Snapshot button to take a snapshot of the current output.

A patient selection criteria was applied and then the same graph object re-executed to display the two output windows together for comparison. The selection criteria message box shows the new graph output window has a selection criteria for "Completed Study".


(Snapshot) Scatter Plot Height vs Weight - Subset of patients


Scatter Plot Height vs Weight - Subset of patients

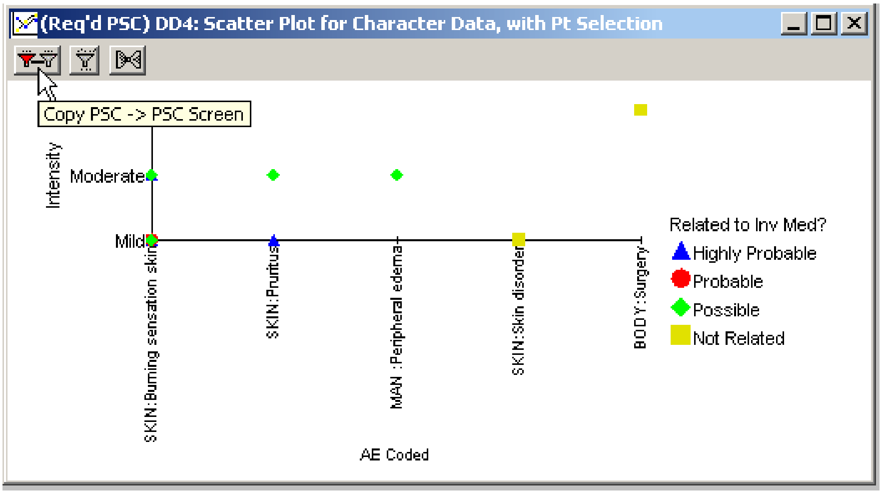
Patient Selection Criteria

T5.COMPLETE ='Yes'

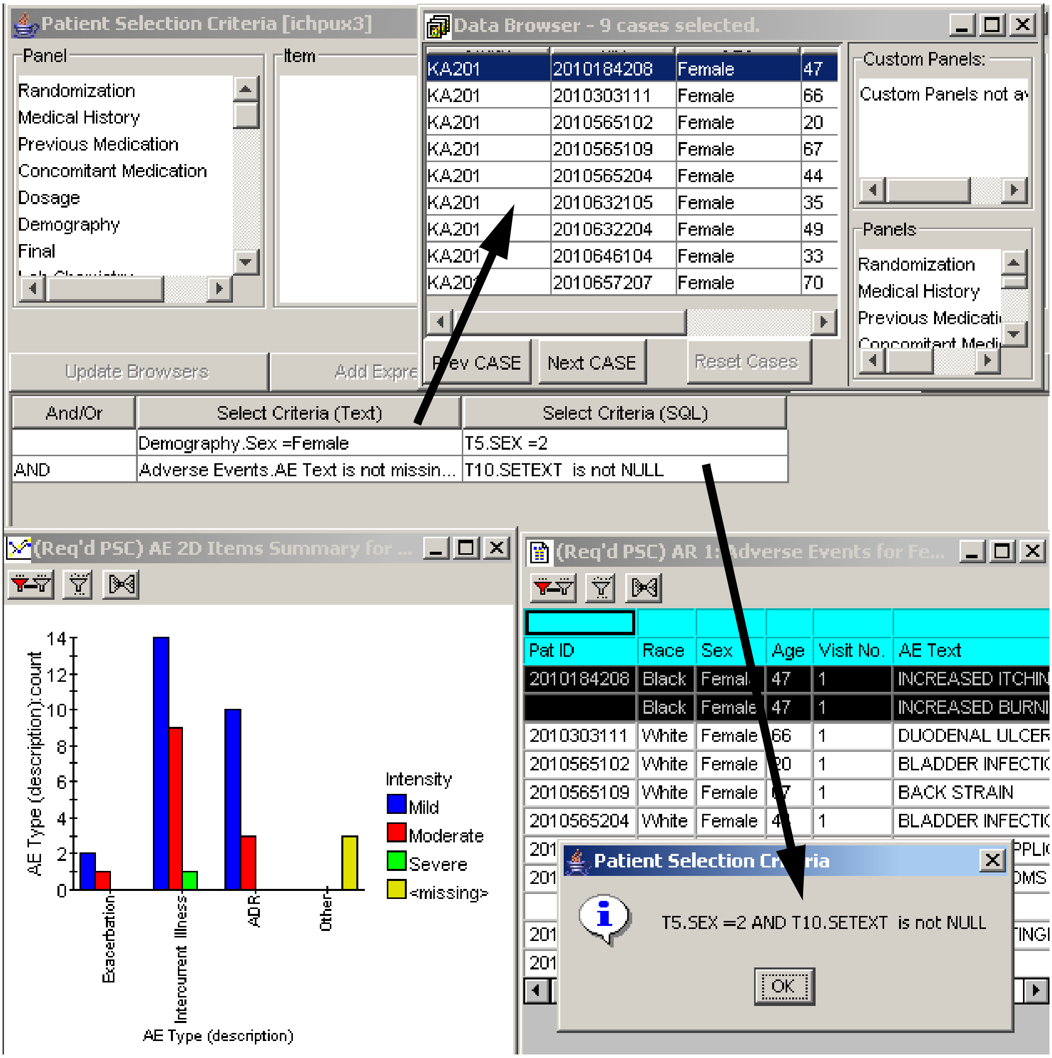
## Multiple output for required selection criteria

When a stored object definition has a required selection criteria, you are not allowed to modify the selection criteria. The output window displays a notation in the heading “Req’d PSC” with a double filter icon.

You can open multiple objects with “Req’d PSC” and toggle between the required selection criteria to update your Data Browser display or other objects where a selection criteria definition isn’t required.



The last launched object with a required selection criteria is loaded into the Patient Selection Criteria window.



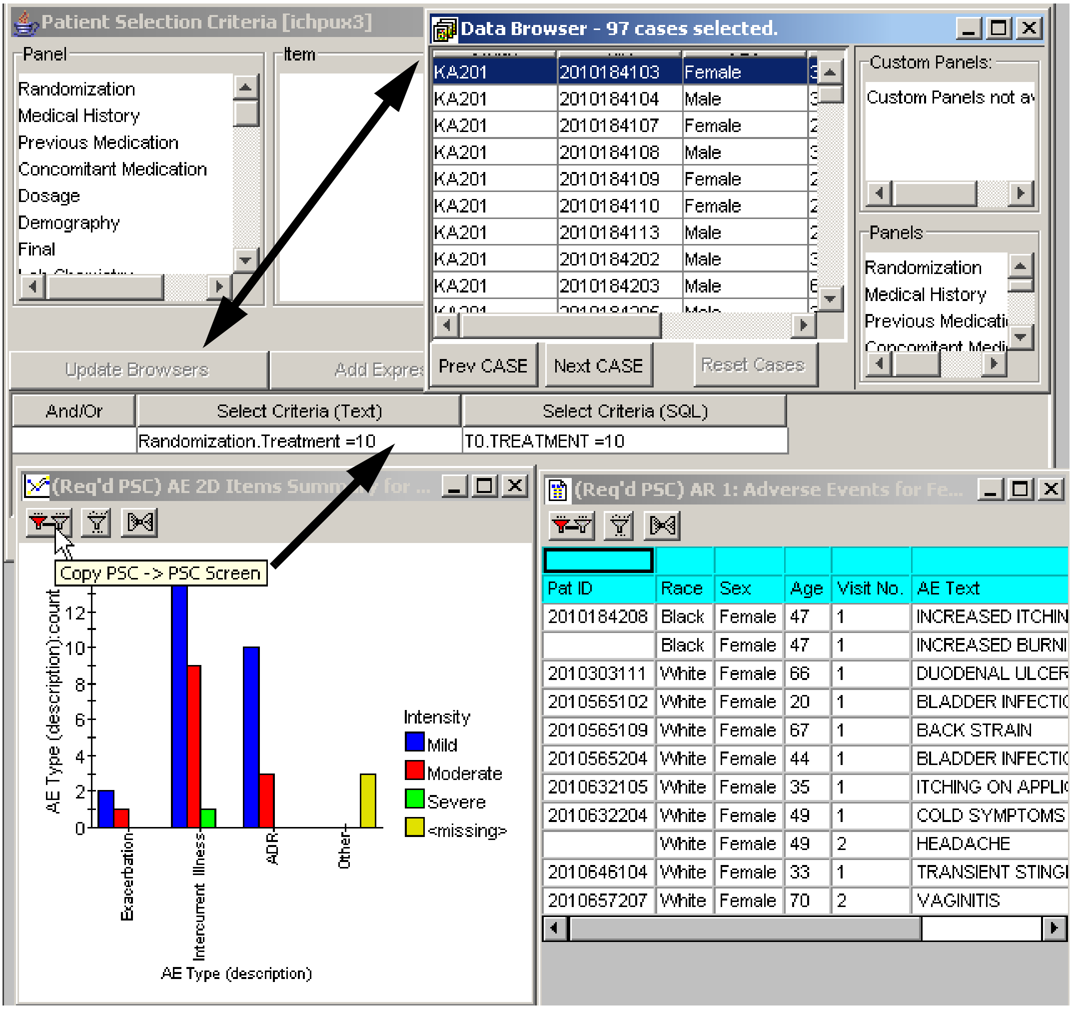
| | | | |
|---|---|---|---|
| KA201 | 2010184208 | Female | 47 |
| KA201 | 2010303111 | Female | 66 |
| KA201 | 2010565102 | Female | 20 |
| KA201 | 2010565109 | Female | 67 |
| KA201 | 2010565204 | Female | 44 |
| KA201 | 2010632105 | Female | 35 |
| KA201 | 2010632204 | Female | 49 |
| KA201 | 2010646104 | Female | 33 |
| KA201 | 2010657207 | Female | 70 |

| And/Or | Select Criteria (Text) | Select Criteria (SQL) |
|---|---|---|
| | Demography.Sex =Female | T5.SEX =2 |
| AND | Adverse Events.AE Text is not missin... | T10.SETEXT is not NULL |

| Pat ID | Race | Sex | Age | Visit No. | AE Text |
|---|---|---|---|---|---|
| 2010184208 | Black | Femal | 47 | 1 | INCREASED ITCHIN |
| | Black | Female | 47 | 1 | INCREASED BURNI |
| 2010303111 | White | Female | 66 | 1 | DUODENAL ULCER |
| 2010565102 | White | Female | 20 | 1 | BLADDER INFECTIO |
| 2010565109 | White | Female | 67 | 1 | BACK STRAIN |
| 2010565204 | White | Female | 44 | 1 | BLADDER INFECTIO |
| 201 | | | | | PPLIC |
| 201 | | | | | OMS |
| | | | | | |
| 201 | | | | | TINGI |
| 201 | | | | | |

T5.SEX =2 AND T10.SETEXT is not NULL

To load the previous object's selection criteria, click on it's double filter icon "Copy PSC -> PSC Screen". The selection criteria is copied into the Patient Selection Criteria window. Click **Update Browsers** to update the Data Browser display.



| | | | |
|---|---|---|---|
| KA201 | 2010184103 | Female | 3 |
| KA201 | 2010184104 | Male | 3 |
| KA201 | 2010184107 | Female | 2 |
| KA201 | 2010184108 | Male | 3 |
| KA201 | 2010184109 | Female | 2 |
| KA201 | 2010184110 | Female | 2 |
| KA201 | 2010184113 | Male | 2 |
| KA201 | 2010184202 | Male | 3 |
| KA201 | 2010184203 | Male | 6 |

| And/Or | Select Criteria (Text) | Select Criteria (SQL) |
|---|---|---|
| | Randomization.Treatment =10 | T0.TREATMENT =10 |

| Pat ID | Race | Sex | Age | Visit No. | AE Text |
|---|---|---|---|---|---|
| 2010184208 | Black | Female | 47 | 1 | INCREASED ITCHIN |
| | Black | Female | 47 | 1 | INCREASED BURNI |
| 2010303111 | White | Female | 66 | 1 | DUODENAL ULCER |
| 2010565102 | White | Female | 20 | 1 | BLADDER INFECTIC |
| 2010565109 | White | Female | 67 | 1 | BACK STRAIN |
| 2010565204 | White | Female | 44 | 1 | BLADDER INFECTIC |
| 2010632105 | White | Female | 35 | 1 | ITCHING ON APPLI( |
| 2010632204 | White | Female | 49 | 1 | COLD SYMPTOMS |
| | White | Female | 49 | 2 | HEADACHE |
| 2010646104 | White | Female | 33 | 1 | TRANSIENT STINGI |
| 2010657207 | White | Female | 70 | 2 | VAGINITIS |

If you open another stored object which doesn't include a selection criteria, the output will display with the previously launched required selection criteria.

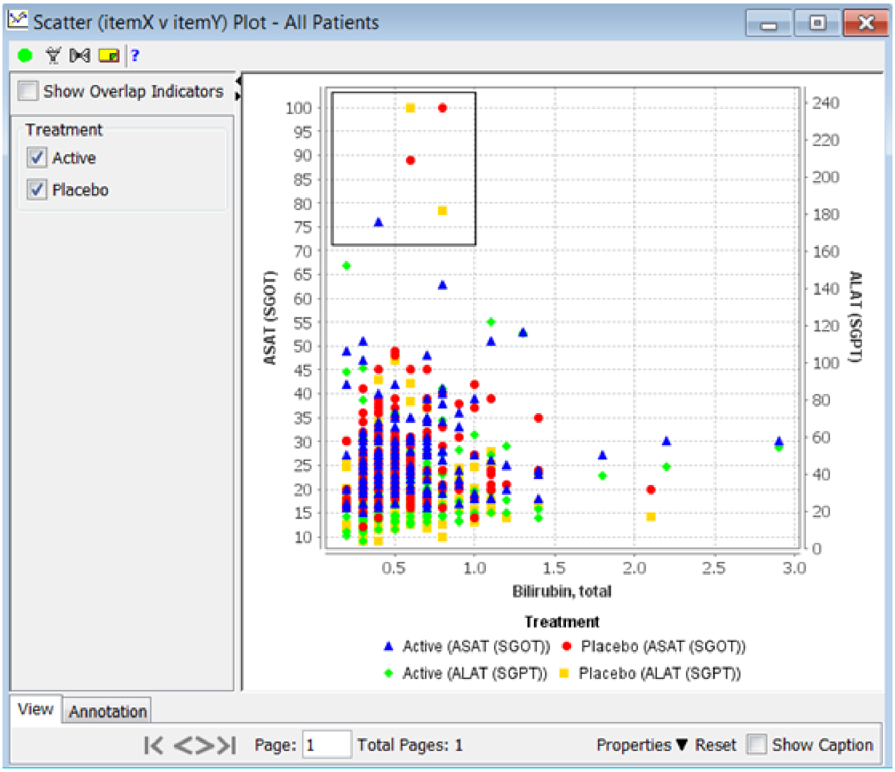
***Note: Stored objects with required selection criteria will take precedence over object definitions without required selection criteria when you toggle back.***

# Highlighting patients

## *Data point select*

You can identify patients by selecting data points on a scatter plot with the Data Browser window open.

1. Single point select, click on the left mouse for a single point.
2. Multiple point select, click on the left mouse and drag to select a bounding rectangle.
3. Hold down the **CTRL** key, and left mouse click on random points.



Scatter (itemX v itemY) Plot - All Patients

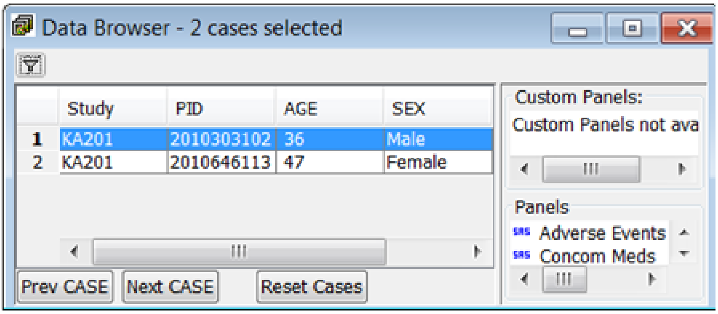
☐ Show Overlap Indicators

Treatment
☑ Active
☑ Placebo

Page: 1 Total Pages: 1

☐ Show Caption

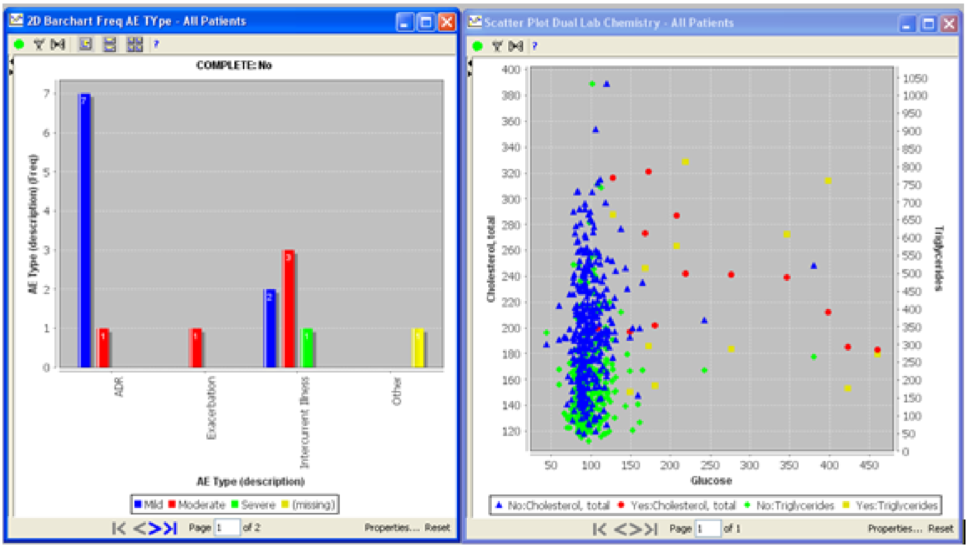
The Data Browser updates to display the selected cases.



|  | Study | PID | AGE | SEX |
|---|---|---|---|---|
| 1 | KA201 | 2010303102 | 36 | Male |
| 2 | KA201 | 2010646113 | 47 | Female |

## *Multiple graphs*

You can have multiple graphs active at the same time by executing multiple graph objects.



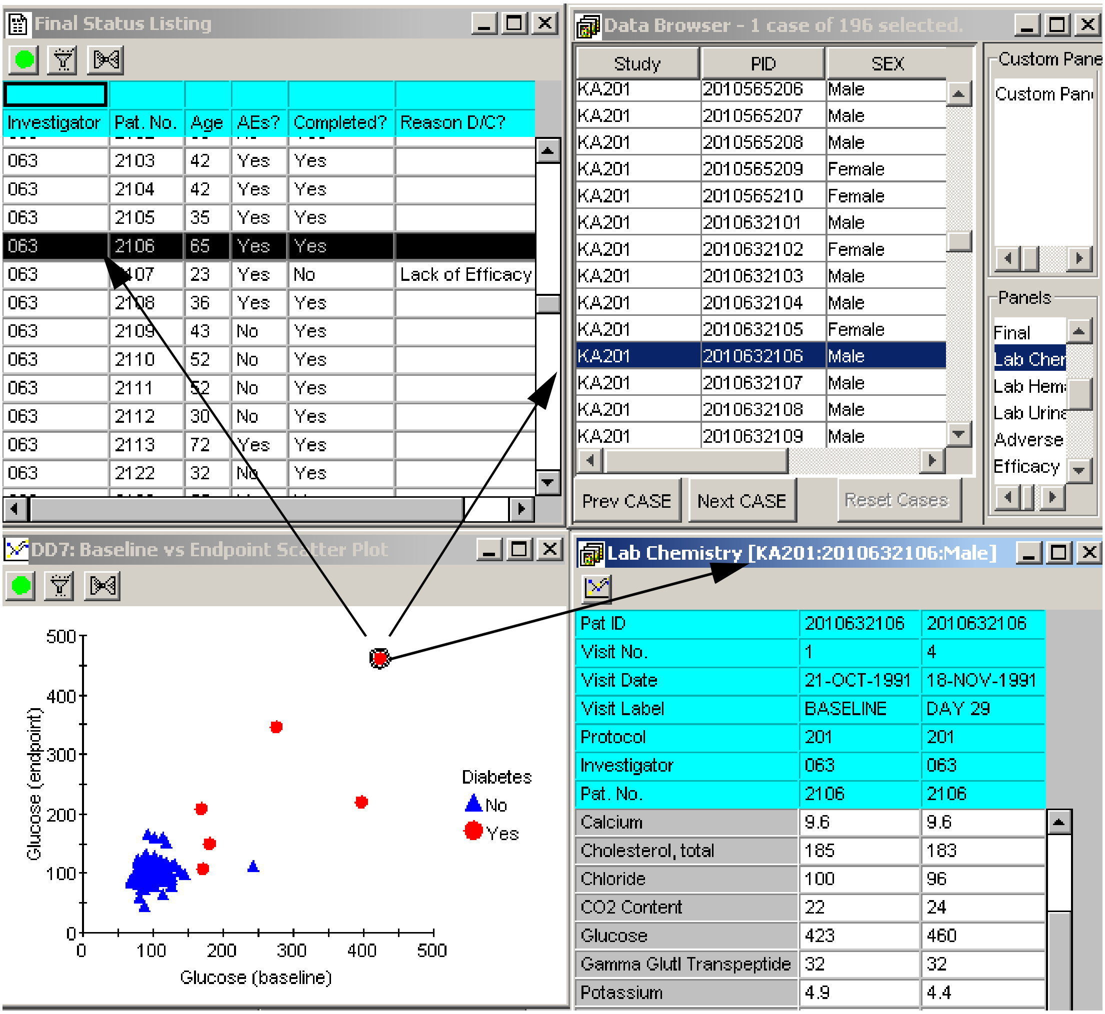
### *Single patient mode*

Scatter Plot graphs are patient-level graphs, and each data point represents an individual patient's data value for the respective variables.

A click on any data point facilitates identification of the underlying patient and access to all respective patient data in the single patient mode.

1. Activate the Data Browser to display a list of patients in the current patient selection, or activate the Report Browser to create and display any Detail Data Report (a list of patient data with customized data item groupings).
2. Click on any data point in the Scatter Plot graph. Review highlights the clinical data point clicked on within the graph.

   The selected patient is highlighted throughout any open Detail Data Listing Reports, open Scatter Plot graphs, and/or the Data Browser patient list and open data Panels.
3. If you click on a patient's row in a Detail Data Listing Report or Data Browser patient list, the selected patient's data point is highlighted in any scatter plot.

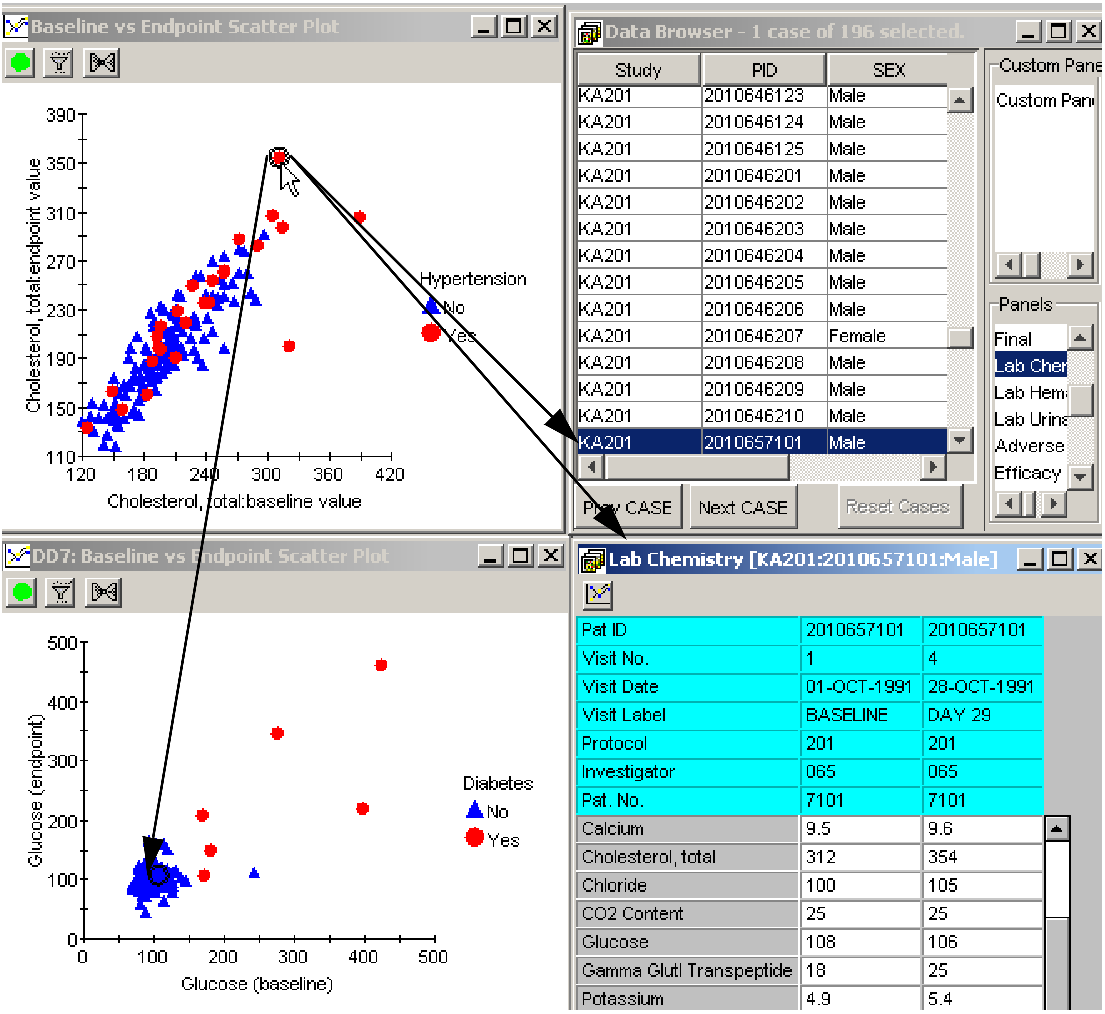


| Investigator | Pat. No. | Age | AEs? | Completed? | Reason D/C? |
|---|---|---|---|---|---|
| 063 | 2103 | 42 | Yes | Yes | |
| 063 | 2104 | 42 | Yes | Yes | |
| 063 | 2105 | 35 | Yes | Yes | |
| 063 | 2106 | 65 | Yes | Yes | |
| 063 | 2107 | 23 | Yes | No | Lack of Efficacy |
| 063 | 2108 | 36 | Yes | Yes | |
| 063 | 2109 | 43 | No | Yes | |
| 063 | 2110 | 52 | No | Yes | |
| 063 | 2111 | 52 | No | Yes | |
| 063 | 2112 | 30 | No | Yes | |
| 063 | 2113 | 72 | Yes | Yes | |
| 063 | 2122 | 32 | No | Yes | |

| Study | PID | SEX |
|---|---|---|
| KA201 | 2010565206 | Male |
| KA201 | 2010565207 | Male |
| KA201 | 2010565208 | Male |
| KA201 | 2010565209 | Female |
| KA201 | 2010565210 | Female |
| KA201 | 2010632101 | Male |
| KA201 | 2010632102 | Female |
| KA201 | 2010632103 | Male |
| KA201 | 2010632104 | Male |
| KA201 | 2010632105 | Female |
| KA201 | 2010632106 | Male |
| KA201 | 2010632107 | Male |
| KA201 | 2010632108 | Male |
| KA201 | 2010632109 | Male |

| Pat ID | 2010632106 | 2010632106 |
|---|---|---|
| Visit No. | 1 | 4 |
| Visit Date | 21-OCT-1991 | 18-NOV-1991 |
| Visit Label | BASELINE | DAY 29 |
| Protocol | 201 | 201 |
| Investigator | 063 | 063 |
| Pat. No. | 2106 | 2106 |
| Calcium | 9.6 | 9.6 |
| Cholesterol, total | 185 | 183 |
| Chloride | 100 | 96 |
| CO2 Content | 22 | 24 |
| Glucose | 423 | 460 |
| Gamma Glutl Transpeptide | 32 | 32 |
| Potassium | 4.9 | 4.4 |

4. If there are multiple scatter plots or Baseline vs. Endpoint plots active, each plot highlights the selected patient's data point. Click on a patient's data point in one graph, to see where that patient's data point is displayed in other graphs.



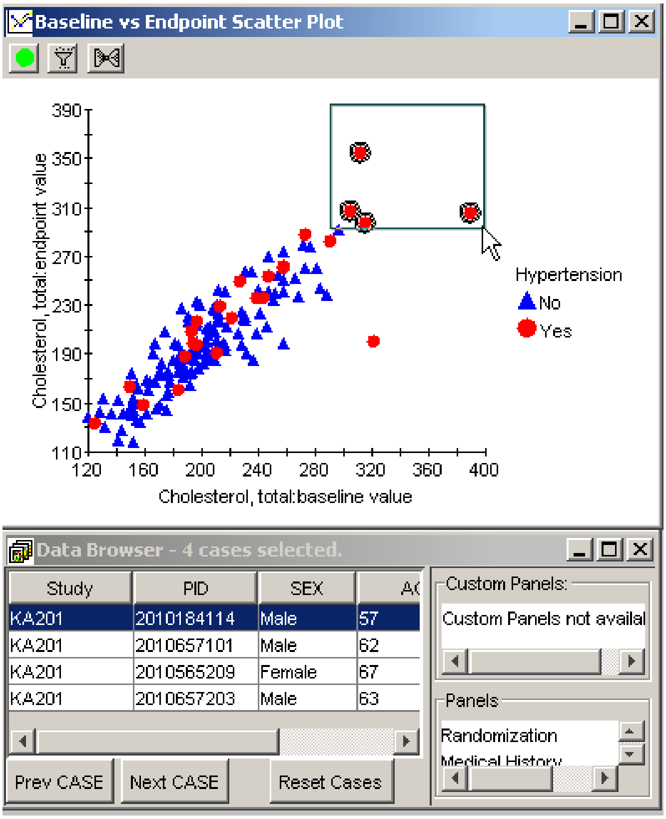
| Study | PID | SEX |
|---|---|---|
| KA201 | 2010646123 | Male |
| KA201 | 2010646124 | Male |
| KA201 | 2010646125 | Male |
| KA201 | 2010646201 | Male |
| KA201 | 2010646202 | Male |
| KA201 | 2010646203 | Male |
| KA201 | 2010646204 | Male |
| KA201 | 2010646205 | Male |
| KA201 | 2010646206 | Male |
| KA201 | 2010646207 | Female |
| KA201 | 2010646208 | Male |
| KA201 | 2010646209 | Male |
| KA201 | 2010646210 | Male |
| KA201 | 2010657101 | Male |

| | | |
|---|---|---|
| Pat ID | 2010657101 | 2010657101 |
| Visit No. | 1 | 4 |
| Visit Date | 01-OCT-1991 | 28-OCT-1991 |
| Visit Label | BASELINE | DAY 29 |
| Protocol | 201 | 201 |
| Investigator | 065 | 065 |
| Pat. No. | 7101 | 7101 |
| Calcium | 9.5 | 9.6 |
| Cholesterol, total | 312 | 354 |
| Chloride | 100 | 105 |
| CO2 Content | 25 | 25 |
| Glucose | 108 | 106 |
| Gamma Glutl Transpeptide | 18 | 25 |
| Potassium | 4.9 | 5.4 |

# Multiple patient mode

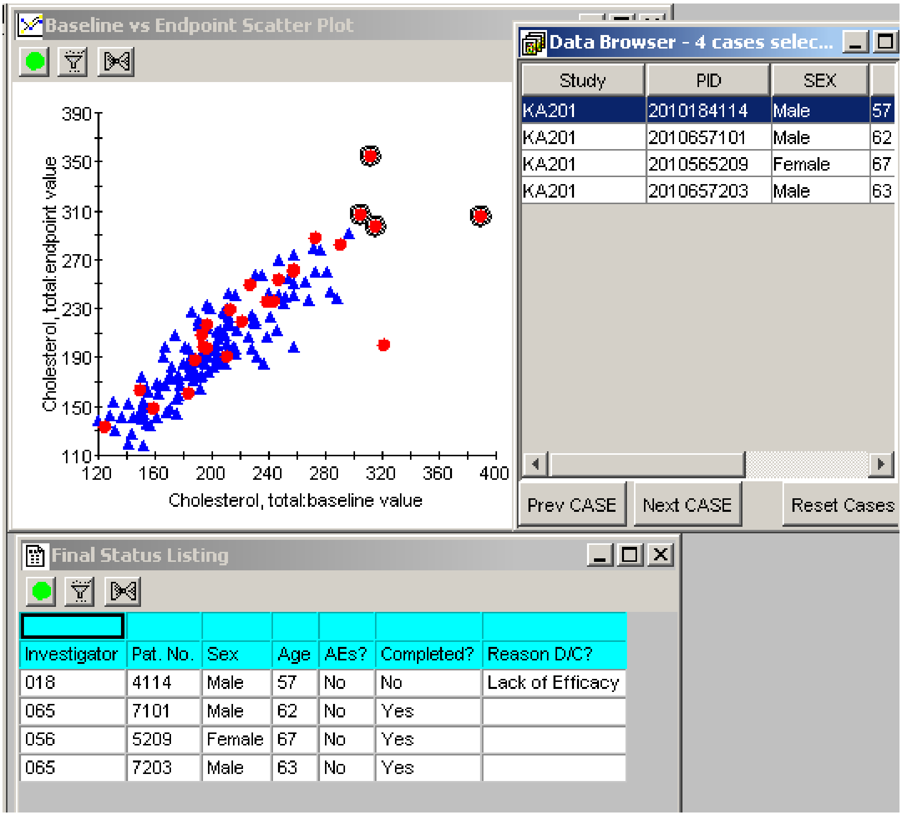
## *Scatter plot graph*

The Graph Browser Scatter Plot graphs provide a click and drag function to outline a region of a graph, thus selecting the patients within that region. Graphic regional patient selection sets Review in the multiple patient mode.



| Study | PID | SEX | A( |
|---|---|---|---|
| KA201 | 2010184114 | Male | 57 |
| KA201 | 2010657101 | Male | 62 |
| KA201 | 2010565209 | Female | 67 |
| KA201 | 2010657203 | Male | 63 |

Detail Data Listing Reports, the Data Browser patient listing, and other Scatter Plot graphs are updated to display only the patients that are highlighted in a active Scatter Plot graph in multiple-patient mode.

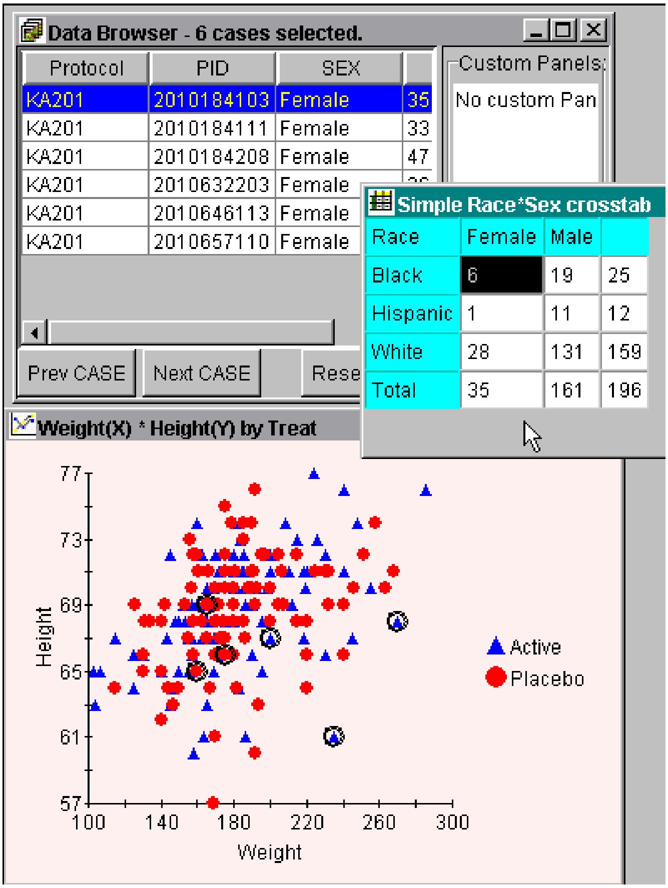


| Study | PID | SEX | |
|---|---|---|---|
| KA201 | 2010184114 | Male | 57 |
| KA201 | 2010657101 | Male | 62 |
| KA201 | 2010565209 | Female | 67 |
| KA201 | 2010657203 | Male | 63 |

| Investigator | Pat. No. | Sex | Age | AEs? | Completed? | Reason D/C? |
|---|---|---|---|---|---|---|
| 018 | 4114 | Male | 57 | No | No | Lack of Efficacy |
| 065 | 7101 | Male | 62 | No | Yes | |
| 056 | 5209 | Female | 67 | No | Yes | |
| 065 | 7203 | Male | 63 | No | Yes | |

The CrossTab Browser results tables are categorical patient counts; a highlighted count within a CrossTab or Shift Table activates all patient level displays to be in the multiple patient mode.

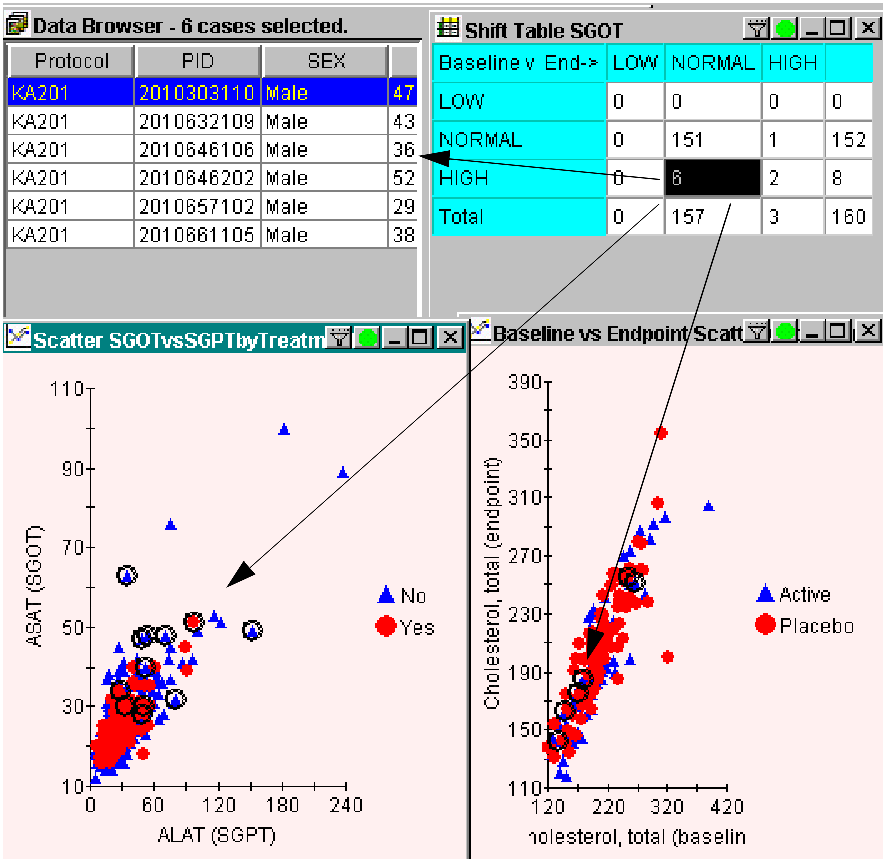
When a patient count is highlighted in the CrossTab results window, instantly all Detail Data Listings, Reports, Scatter Plot graphs, and the Data Browsers patient listing are updated with only the patients underlying the patient count highlighted from the CrossTab Browser results table.



| Protocol | PID | SEX | |
|---|---|---|---|
| KA201 | 2010184103 | Female | 35 |
| KA201 | 2010184111 | Female | 33 |
| KA201 | 2010184208 | Female | 47 |
| KA201 | 2010632203 | Female | |
| KA201 | 2010646113 | Female | |
| KA201 | 2010657110 | Female | |

Simple Race*Sex crosstab

| Race | Female | Male | |
|---|---|---|---|
| Black | 6 | 19 | 25 |
| Hispanic | 1 | 11 | 12 |
| White | 28 | 131 | 159 |
| Total | 35 | 161 | 196 |



Data Browser - 6 cases selected.

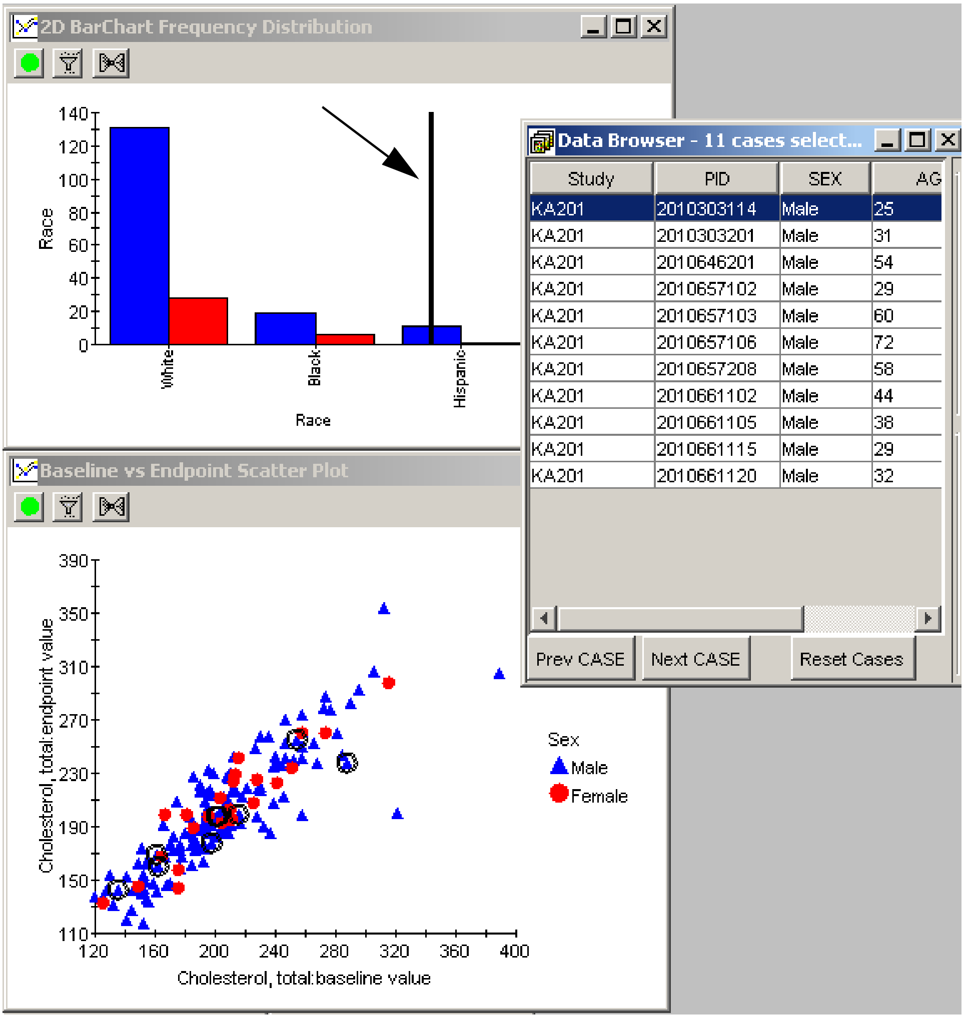
| Protocol | PID | SEX | |
|---|---|---|---|
| KA201 | 2010303110 | Male | 47 |
| KA201 | 2010632109 | Male | 43 |
| KA201 | 2010646106 | Male | 36 |
| KA201 | 2010646202 | Male | 52 |
| KA201 | 2010657102 | Male | 29 |
| KA201 | 2010661105 | Male | 38 |

Shift Table SGOT

| Baseline v End-> | LOW | NORMAL | HIGH | |
|---|---|---|---|---|
| LOW | 0 | 0 | 0 | 0 |
| NORMAL | 0 | 151 | 1 | 152 |
| HIGH | 0 | 6 | 2 | 8 |
| Total | 0 | 157 | 3 | 160 |

## *BarChart graph*

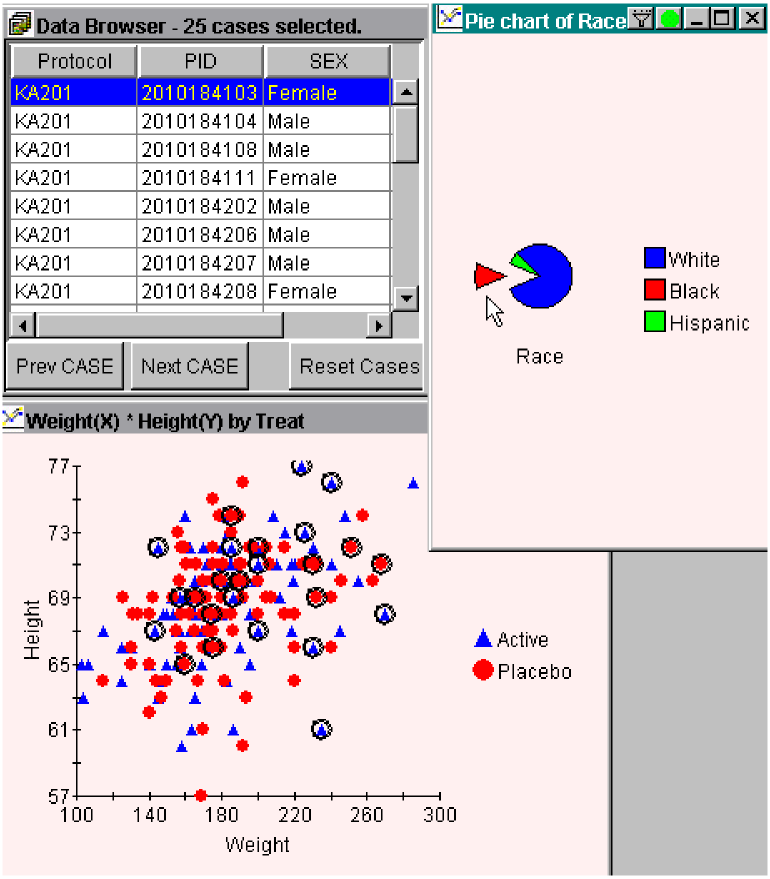
All bars depict a subset patient populations in the BarChart graphs. Click on a bar within a BarChart graph and all underlying patients will be subset in all open patient-level displays of data.



| Study | PID | SEX | AG |
|---|---|---|---|
| KA201 | 2010303114 | Male | 25 |
| KA201 | 2010303201 | Male | 31 |
| KA201 | 2010646201 | Male | 54 |
| KA201 | 2010657102 | Male | 29 |
| KA201 | 2010657103 | Male | 60 |
| KA201 | 2010657106 | Male | 72 |
| KA201 | 2010657208 | Male | 58 |
| KA201 | 2010661102 | Male | 44 |
| KA201 | 2010661105 | Male | 38 |
| KA201 | 2010661115 | Male | 29 |
| KA201 | 2010661120 | Male | 32 |

## *Pie Chart*

All slices depict a subset patient populations in the Pie Chart. Click on a slice within a Pie Chart and all underlying patients will be subset in all open patient-level displays of data.



**Data Browser - 25 cases selected.**

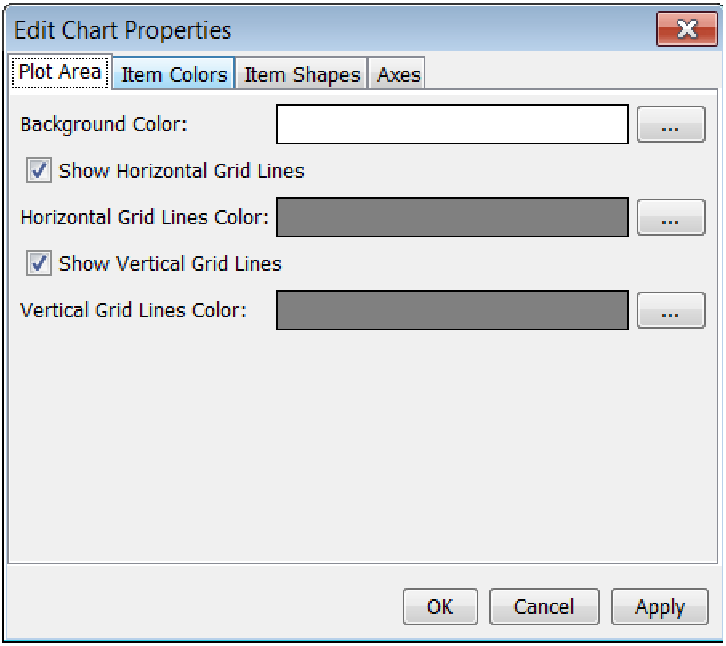
| Protocol | PID | SEX |
|---|---|---|
| KA201 | 2010184103 | Female |
| KA201 | 2010184104 | Male |
| KA201 | 2010184108 | Male |
| KA201 | 2010184111 | Female |
| KA201 | 2010184202 | Male |
| KA201 | 2010184206 | Male |
| KA201 | 2010184207 | Male |
| KA201 | 2010184208 | Female |

# Graph Editing

## *Graph settings*

Click on “Properties” located in the graph footer, to display the Chart Properties window.

Once you create your graph, you can right-mouse click anywhere on the graph to open the **JClass Chart Properties** window. You can apply a variety of graph format changes with the setting options available.



Background Color:

☑ Show Horizontal Grid Lines

Horizontal Grid Lines Color:

☑ Show Vertical Grid Lines

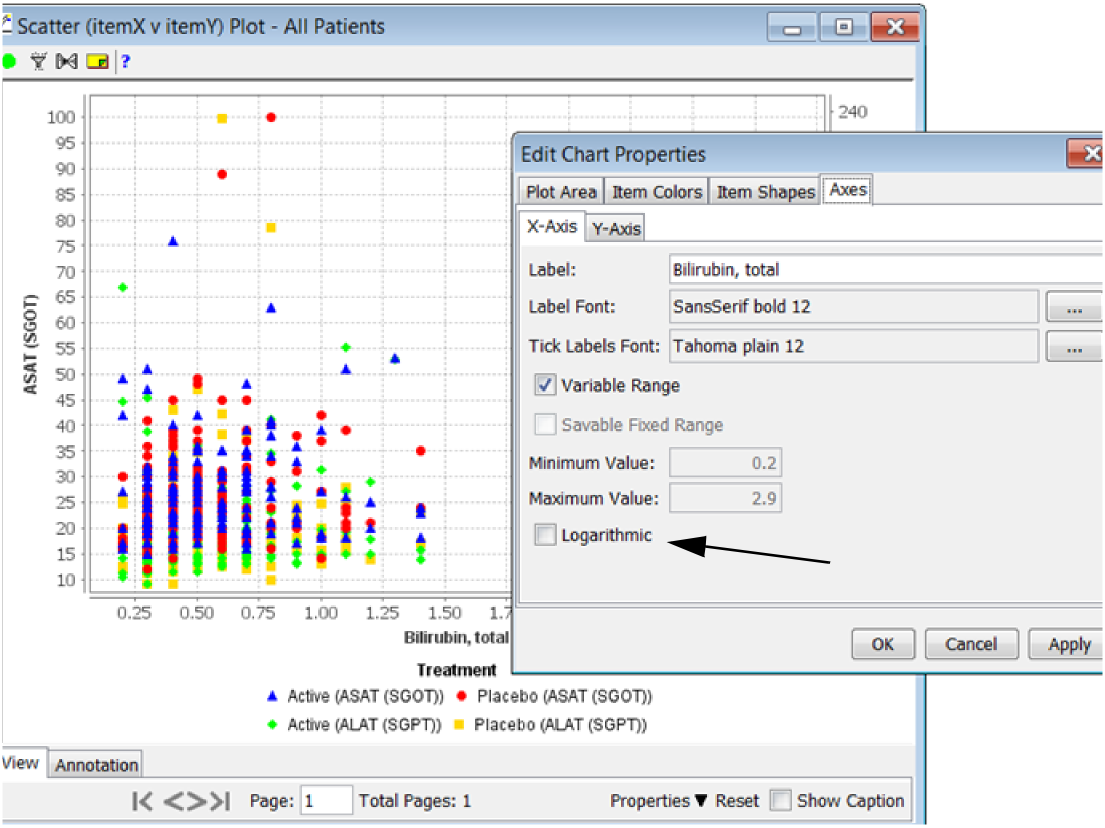
Vertical Grid Lines Color:

## *Chart Properties*

There is log axis feature that can be set in **Edit Chart Properties Dialog** and allows persistence. This feature is applicable to ***Detail/2D-Scatter*** (but not ***Scatter-Upper Limit Normal Range*** subtype, which is already logarithmic) and ***Summary/Line Chart Item Summary vs. Category*** charts. For ***Summary/Line Chart Item Summary vs. Category*****,** the log property is only applicable to the y-axes.

Log values cannot be computed for original values that are less than or equal to zero. Any original values in the range less than or equal to zero are omitted from the plot when using a log axis. If such out-of-range values are found, a warning message is displayed at the top of the graph. To use a logarithmic axis, the original values must be numeric. The tick labels on a log axis are the original values, not the logarithmic values. That is, the tick label and data positions are positioned according to the logarithmic values, but the tick label text is the corresponding “original value.

After creating the graph output, click on **Properties** in the footer to apply logarithmic values.



Label: Bilirubin, total

Label Font: SansSerif bold 12

Tick Labels Font: Tahoma plain 12

☑ Variable Range

☐ Savable Fixed Range

Minimum Value: 0.2

Maximum Value: 2.9

☐ Logarithmic

# Graph Annotation

## What is graph annotation?

The Graph Annotation feature is applicable to all JReview graphs except Pie Charts and the two legacy graphs: 3D Scatter Plot and the Detail Multiline Chart Item Value graphs.

Graph Annotations is an overlay of user created graphical entities**.** There are 3 types of graphical entities:

- Text boxes
- Lines
- Lines with an arrowhead

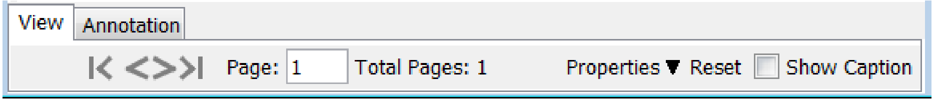
The user creates and edits these entities using conventional interaction techniques such as drag-and-drop and setting attributes of selected graphics using menus. The User-Interface controls including checkboxes, menus, and toggle buttons are contained in a toolbar dedicated to annotation functionality.

Annotations can be saved to the user's *local* file system. The saved annotations are saved in an XML format and is not meant to be readable or directly editable by end-users. The purpose of the XML file is to allow the user to save the annotation graphics, so that they can be used at a later time such as another JReview session or when the same graph is re-executed.

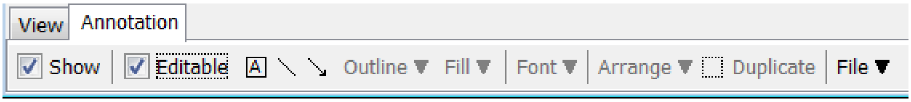
## Edit annotation

For graphs supporting annotations, the controls at the bottom of the graph are grouped into two tabs. Each tab contains a toolbar.

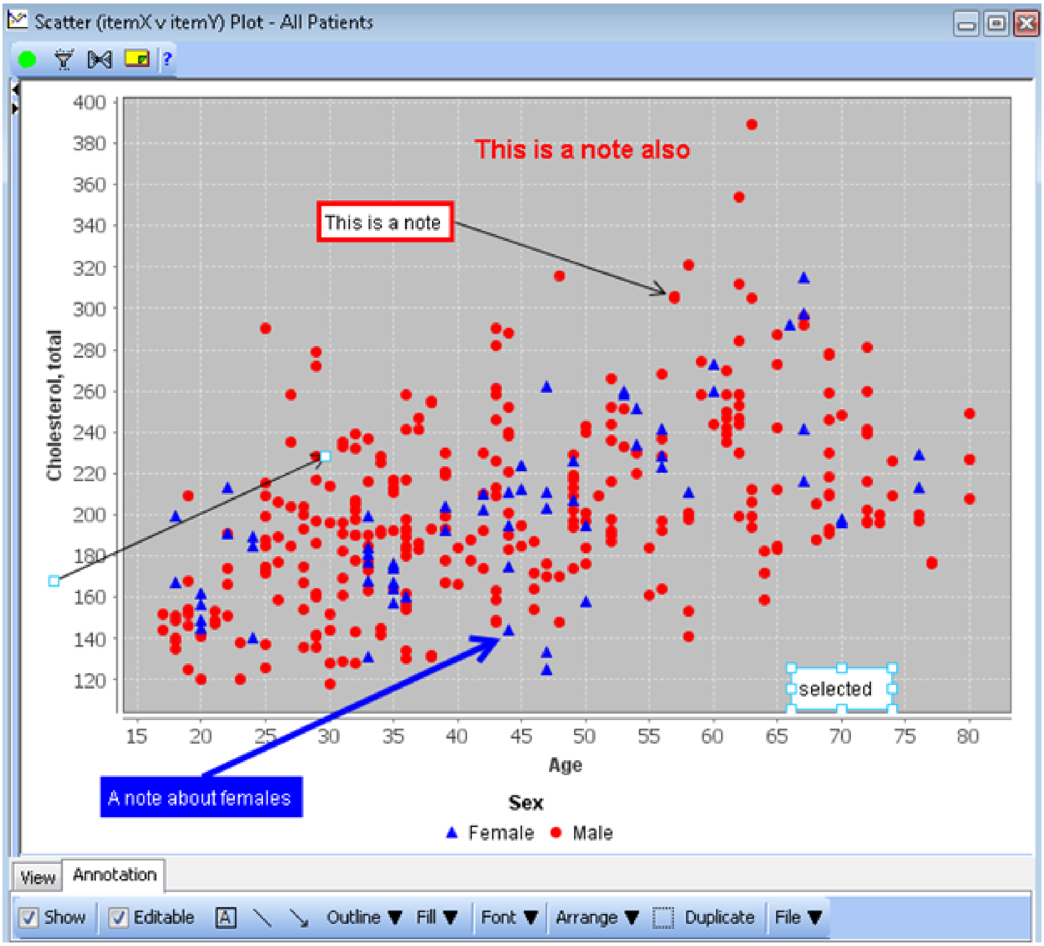
The"**View**" tab is the default tab. It contains the toolbar for page navigation, changing the zoom level, and accessing graph preferences dialogs and controls.



The “**Annotations**” tab contains a toolbar with a “**Show**” checkbox for showing/hiding any existing annotation graphics.



When the “**Show**” check box is selected, a second checkbox, i.e., “**Editable**”, becomes enabled. If the “Show” check box is deselected, the “**Editable**” checkbox is set to an unselected state and is disabled.



When the “**Editable**” check box is selected, the following occurs:

- Annotations become selectable
- Editing and other annotation-specific controls become visible
- Graph is set to single-page viewing mode; multipage controls are disabled
- Graph is set to its “normal” view where the graph cannot be zoomed or panned

When the user selects the “**View**” tab, the Editable check box is deselected and the Edit Mode is exited. Clicking the “**View**” tab does not affect the “**Show**” state.

## *Annotation Creation mode*

The annotation creation mode is set by selecting one of the toggle buttons that set a creation mode; toggle buttons for creating a text box, a line, and a line with arrowhead are provided. Only one of these buttons can be selected at a time.

When in a creation mode, the user can initiate an annotation using a gesture with the mouse: dragging the mouse displays a rubber-banding outline of the object; the object is created when the mouse is released.

## *Text Box Annotation*

The text box is a rectangular object that displays text. Multiline text is supported. The user creates and edits text by typing directly into a selected Text Box instance. A Text Box without any text will be automatically deleted when it loses focus (e.g., the text cursor is moved elsewhere).

The Text Box can be repositioned by dragging. The user should locate the mouse over the margin area when dragging.

The user can set the following attributes on a Text Box. Font attributes are applied to all of the text characters in a Text Box instance. (Applying attributes to a range of text is not supported).

- The user can set the color and line width of a Text Box's border (i.e., outline). There is also the option not to display a border for a Text Box.
- The user can set the background color of a Text Box, or can make the background transparent.
- The font attributes for a text box can be set: size, style (bold, italic, plain), font family, color.

The user can set the width of a Text Box when it is created using the drag gesture. A selected Text Box can also be resized by dragging a displayed drag-handle. The Text Box automatically adjusts to support text, font height, and line-wrapping.

## *Line Annotation*

The Line Annotation is defined by the positions of its endpoints. It is created by a drag gesture. The entire line can be repositioned by dragging. A selected Line Annotation displays drag-handles at its endpoints. Dragging one of these drag-handles will reposition the line's endpoint.

The user can set the following attributes of a Line Annotation:

- Line Width
- Color

## *Line with Arrow Head Annotation*

A line can be displayed with an arrowhead. In all other ways, it is identical to a simple Line Annotation.

## *Annotation Selection*

All annotations are selectable. Selection is generally done with a mouse-press action. If the control-key is pressed when performing a select action, the selection state of an annotation under the mouse location is toggled. Pressing the control key while selecting allows the user to add or remove an annotation from the selected set. Following the usual conventions, pressing the mouse over an area not occupied by an annotation, deselects all annotations.

If the user selects an unselected annotation and the control-key is not pressed, all other selected annotations are deselected. If the mouse is located over a selected annotation, the control-key is not pressed, and the user does not drag this annotation, other selected annotations are deselected when the mouse is released.

When a Text Box is selected, it is bounded by a rectangular outline with six drag-handles. These drag-handles allow the user to resize (the width) of a Text Box. (Note that dragging a corner drag-handle can, in effect, relocate the Text Box.)

A selected line annotation has drag-handles located at its endpoints.

When a drag-handle is dragged, a rubber-banding outline figure is drawn.

## *Connect lines to text box*

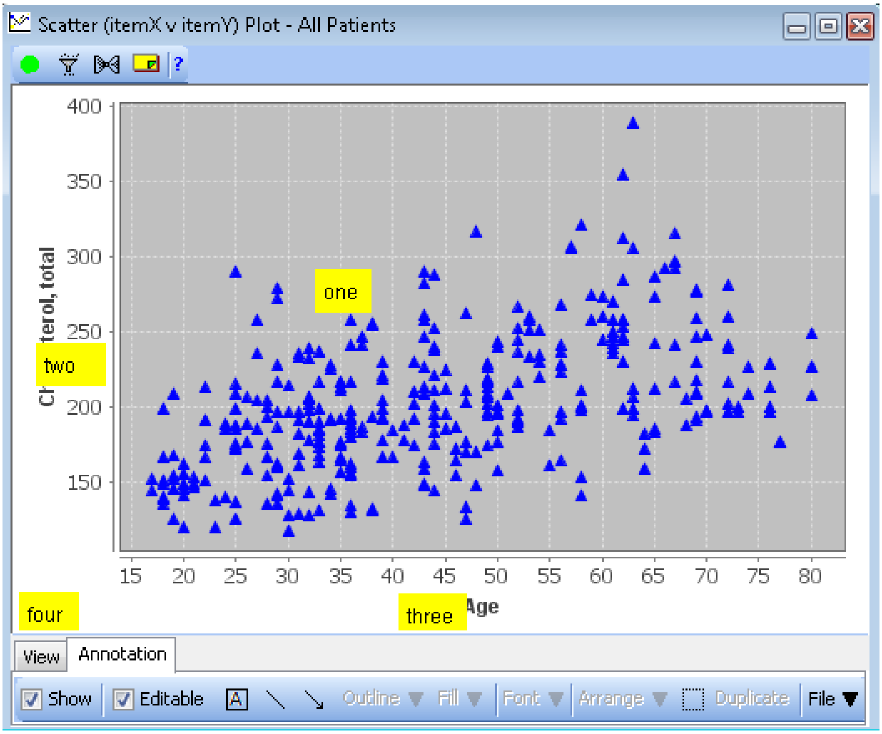
Line Annotations can be connected to a Text Box at one of four attachment locations at the edge of the Text Box: mid-top, mid-bottom, mid-left, mid-right. A Line Annotation can be attached to a Text Box by dragging an endpoint to an attachment location and then dropping it at that location. When an endpoint is dragged over a Text Box, the attachment points for that Text Box are displayed. The Line Annotation can be detached by simply dragging the endpoint off the attachment location.

If a Text Box with attached Line Annotations is dragged, the attached endpoints of these Line Annotations are moved with the Text Box. As the Text Box is dragged to a new location, the Line Annotation outlines will “rubber-band.”

This feature is especially useful when a Text Box has an associated arrow that points to a particular graph location. The Text Box can be easily relocated without needing to readjust the arrow annotation.

## Annotation Coordinates

The Text Box location is determined by the coordinate of the upper-left corner. The two endpoints of a Line Annotation determine its coordinates. (Figure 1)

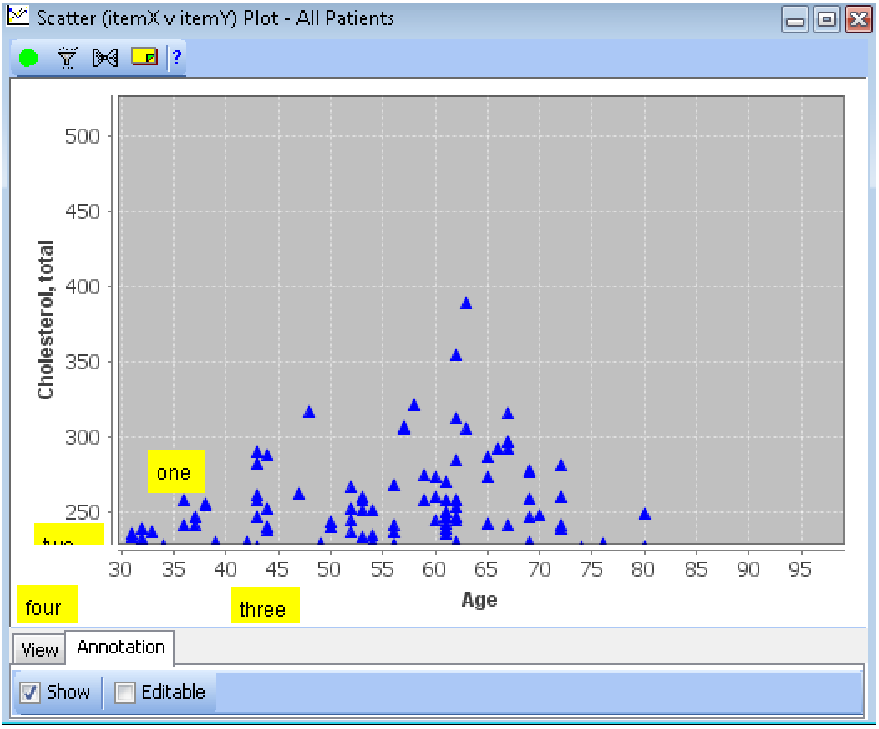


In general terms, if an annotation's location is positioned between the lower and upper ends of an axis, the location is calculated relative to the axis values. When the axis represents numeric values and a non-nominal scale, the value is based on the actual data space. For example, in the Scatter plot of Figure 1 where the X-axis variable is Age and the Y-axis is Cholesterol Level, the coordinate for an annotation location might be "x is 33 (age) and y is 285 (cholesterol-level)." A consequence of tying the annotations position to an axis value is that an annotation will maintain its position relative to the axis values when the plot is zoomed or panned, or the frame is resized.

It is possible for a user to position an annotation outside the physical bounds of an axis or both axes. In other words, the user may drag an annotation outside the plot area proper. For example, the user might locate annotation to the left of the lower end of the X-axis or beneath the lower end of the Y-axis (see Figure 1). In these cases, the X or Y value of a coordinate is a value that is calculated as a proportion of the distance between the edge of the plot area and the edge of the graph panel.

Figure 2 below illustrates a pan action that moves the plot down and to the left. (Note that only the plot area itself is panned, and that the entire graph area is not panned; legends and axis labels cannot be panned). The "two" Text Box moves down and is clipped by the bottom of the plot area; however, this Text Box maintains its horizontal location because its X-value is not tied to an axis value.

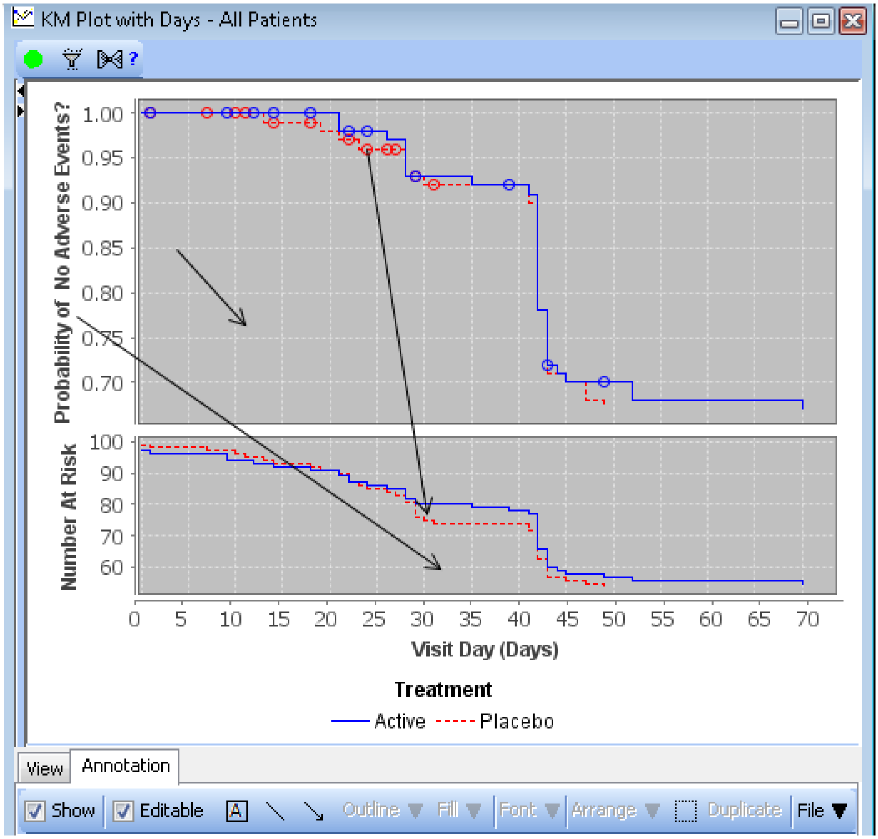
(Figure 2)



☑ Show ☐ Editable

Summary Graphs typically have “nominal” data (i.e., categories) on one axis. The positioning with an axis having this type of data is done by calculating the position relative to the distance between the outer edges of the categories (that is, the bounds of the categories in terms of axis locations).

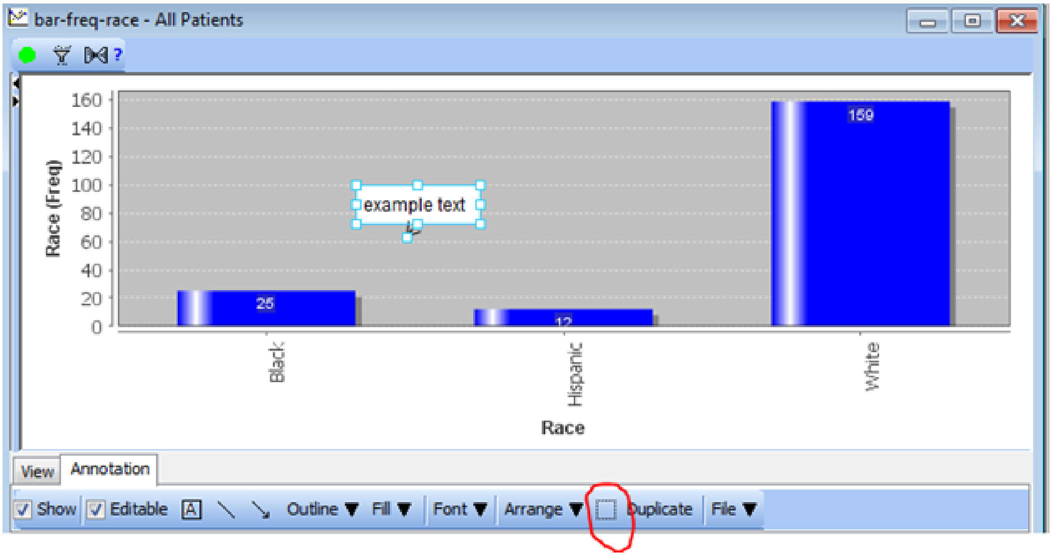
It is possible that a Line Annotation may have one endpoint in the space of one graph and the other endpoint in the space of a second graph. This is the case where multiple plots share a common axis. JReview’s Kaplan-Meier graph has two plots sharing a common X-axis. (Figure 3)



## *Annotation toolbar*

The tool bar contains the controls specific to the annotation functionality and the controls for setting the various modes (see previous section on modes).

The Select All control for selecting Annotation graphics (not Scatter plot data points)) is circled in the figure below. There is a tooltip associated with it (“Select all annotations”).



## *Choose annotation colors*

There are two ways to specify colors for backgrounds, outlines, or fonts. The menu items labeled “Color…” instantiate the Java Swing Color Chooser dialog that supports multiple ways to select a color and provides a very flexible way to specify a color.

A second type of color-related menu items, labeled “Standard Colors…”, instantiates a secondary menu containing color “swatches” that match the colors used in the graphs (e.g., the color of the bars in a bar graph). A user might select from this menu, for example, if the intent was to match the background color of a Text Box with the color shown in the legend for a BY-Variable value (say, Females with a Sex By-Variable). The actual colors used in the menu reflect whether gray scale has been specified for the graphs. (The swatches color menu does not support keyboard traversal in this release.)

## *Enabling Controls*

The Annotation toolbar has 2 checkboxes: “Show” and “Editable”. When “Show” is selected, the annotations are displayed; if “Show” is unselected, the annotations are hidden. If “Show” is selected, the annotations are shown no matter which of the two toolbar tabs (i.e., “View” or “Annotations”) is currently selected. In other words, the annotations can be displayed when the “View” tab is selected.

The Editable mode is different: it can only be active when the Annotations toolbar is visible, i.e., the Annotations tab is the current toolbar tab. So, if the user is in the Edit mode, but clicks on the “View” tab, the annotations remain visible, but the Edit Mode is terminated, and the annotations cannot be selected or edited.

The controls on the toolbar that are dependent on the prior selection of annotations are enabled only if annotations are selected. The Font Menu is enabled only if a Text Box is selected.

## *Annotation Menus*

Menus are used instead of individual controls like Combo Boxes in order to save screen space.

- **Outline Menu** - sets attributes for Text Box borders and Line Annotation lines. Attributes include Color, Standard Color, and Line Weight (width). The None menu item is applicable to Text Boxes only; it has no effect on Line Annotations. Setting the outline to None indicates that no border should be drawn.
- **Fill Menu** - contains items for setting the background of Text Boxes. It is not applicable to Line Annotations. Both the Color and Standard Color items are provided. The None item sets the background to *transparent*.
- **Font Menu** - contains items for font attributes for selected Text Boxes.
    - **Style Checkboxes** for Bold and Italic font styles are available. If both checkboxes are unselected, the font style is plain. Users can select one or both of the checkboxes.
    - **Font Family** (Type) - Selecting this item opens a *scrollable* submenu with a list of font family names.
    - **Font Size** - Selecting this item opens a submenu containing a list of font sizes.
    - **Color** - Selecting this item opens the standard Java Swing Color Chooser dialog (see discussion above).
    - **Standard Colors** - Selecting this item opens the Color Swatch submenu (see discussion above).

- **File Menu** - contains items for saving an annotation and opening (and loading) a saved annotation. It also contains a New item that is described below. Saving of annotations is different from saving an object such as a graph specification.

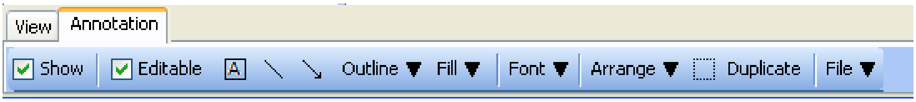
## *Annotation button functions*

- **Duplicate** - Clicking this button causes the selected annotations to be duplicated. (A more general copy/paste utility is not supported.)
- **Select All** - Clicking this button selects all annotations.
- **Cut** - delete items on JReview's Edit Menu and JReview's tool bar are used to delete annotations.
- **PSC Change** - If the data is change due to a PSC update, the annotations are deleted.

## *Apply annotations*

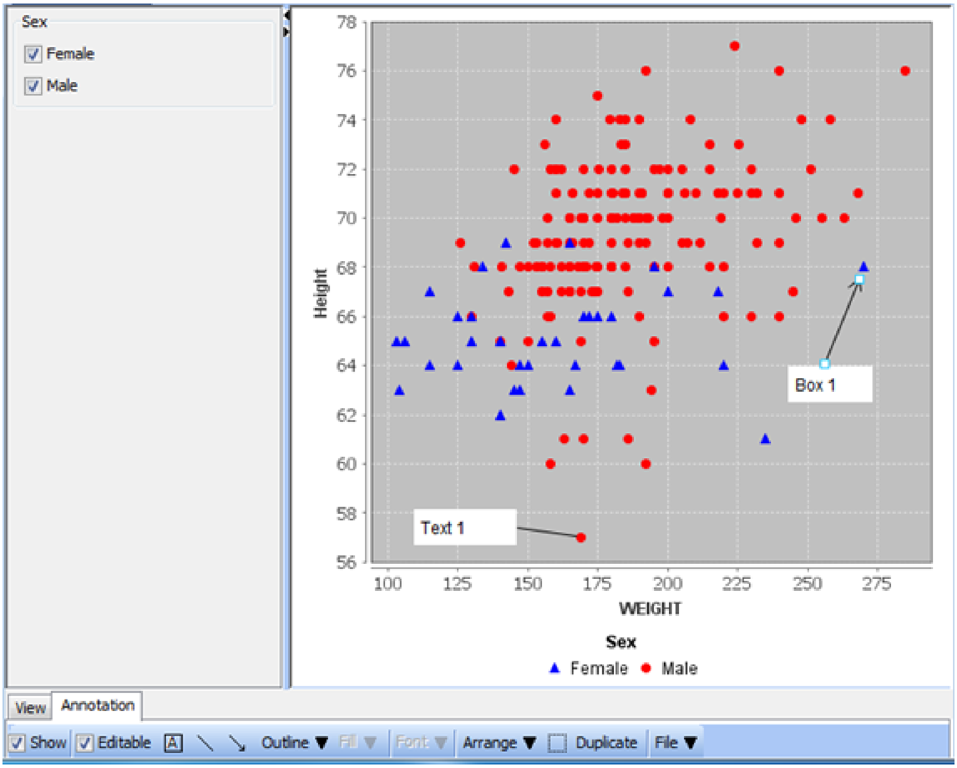
The following steps are used to apply graph annotations after creating graph output:

1. Click the **Annotations tab** at the bottom of the graph window. The Show Box becomes active and the Editable box becomes available.
2. Click the **Show** box. The Editable box becomes active.
3. Click the **Editable** box. The annotation options becomes available.



4. Click the **text box** and add a text box on the graph output.
5. Click the **line option** and draw a line on the graph. Use the usual JReview "cut" toolbar item to delete the annotations.
6. Click the text box and add another text box with text on the graph output.

7. Click the **line-arrow option** and draw a line-arrow on the graph.



8. With that box active, click the **Duplicate button**. An additional box is added to the graph.

9. Select text box, select the **Outline option**, click the Color option. Click OK. The outline color is changed.

10. Click the **Arrange option** and select Move Backward. The box is moved backwards one spot and the Box 3 becomes active.

11. Select text box, click the Arrange option and select Move to Back. The box is moved to the back.

12. Select text box, select **Fill option**, click Color option. Click OK. The fill color is changed. Select Fill option, and click None and the fill color is removed.

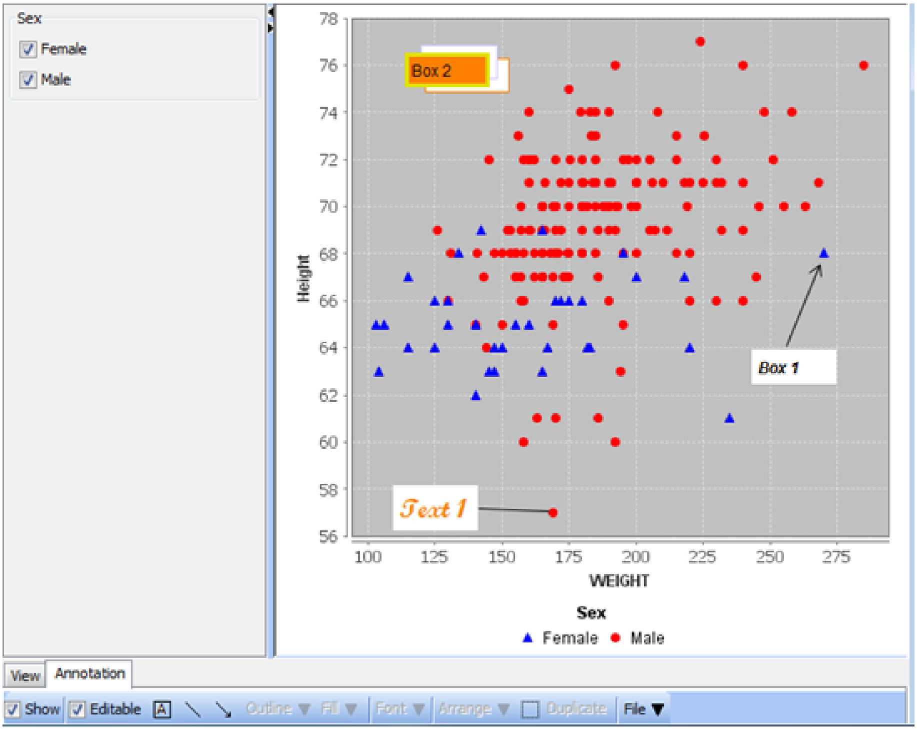
13. Select text box, select **Font** and select option. The font type is changed. Select Font, select **Font Size** and select option. The font size is changed.

14. Click on the Printer icon and Print Page. Close Print Preview window.

## *Save annotation*

The Save (and Save As) in the file menu on the Annotation toolbar allow the user to save an XML description of the annotations. This is a textual specification and not an image.

1. Create a graph (e.g., scatter plot).
2. Create some annotations (e.g. a text box).
3. Save the annotations to a file on your local computer using the “Save” item on the Annotation toolbar’s File menu. The Save window opens.
4. Name the Graph Annotation file, and click Save.
5. Create previous Graph output. Use the Open item on the Annotation file menu to load the previously saved annotations back onto the graph. Select the File option, and select Open.



The user can save and reload an annotation for a graph. If the graph definition changes since the annotation was saved, then a reload might fail or give unexpected results – some error handling for this occurrence is built into the annotation software.

When saving, the annotations are serialized into an XML format; the XML is written to a user selected file on the local file system. If a graph has multiple pages, the annotations for all pages (where annotations exist) are saved. The graph type and number of pages are stored with annotations. When an annotation file is opened, the annotation software checks whether the current graph matches the stored graph type parameter and the stored page count parameter. The software does NOT guarantee that the data and the data-specification of the current graph is the same as that associated with the graph when the annotations were stored.

One reason for placing the save/open in a File Menu on the annotation tool bar is that the meaning of save is very different from that of the File Menu on JReview's menu bar.

JReview uses features asking the user whether an existing file can be overwritten. The application manages the Save/Open operations, remembers the last accessed file for the graph, and uses it as the default choice for Save As and Open operations. When no annotation file has been saved or opened for the graph instance, selecting "Save" is functionally the same as selecting "Save As…", that is, the user must specify where to save the annotations. If there is a "current" annotations file, selecting "Save" will silently save the annotations.

- **New** - operates in an analogous way to the New item on JReview's main File Menu. This item deletes existing annotations on all pages. If annotations exist, the user is asked whether these annotations should be saved before being deleted. Users may also cancel the operation.
- **Open** - This item opens a saved annotation file. This operation may fail due to graph incompatibility. The software is constructed to trap thrown errors in this regard.
- **Save As** - This item presents the file chooser dialog and allows the user to select (or create) a file in which to save the annotations.
- **Save** - This item saves the annotations. If the annotations for the current graph instance have already been saved or they were constructed from an opened file, this operation proceeds silently; otherwise, the file chooser dialog is presented.

## *Share annotations*

There are various ways of communicating the annotations to other users, for presentation or reporting purposes, and are not limited to personal use by a single user. Annotations can be:

- Included on printed copies of the graph
- Exported as images of the graph
- Direct copy-paste of the graph from the JReview Graph Viewer into a Word document, or Power Point slides

Multiple JReview users, perhaps at different stages of the work flow,  can share the Graph Annotation through file copying. For example, one user could provide another user with the annotation file in the case where both users are looking at the same graph. A graph defined in a saved object where the underlying data is unchanged. However, JReview itself offers no formal mechanism for sharing the Graph Annotation files. The files can be located in any local directory (having the necessary read/write permissions) that the JReview client can access.

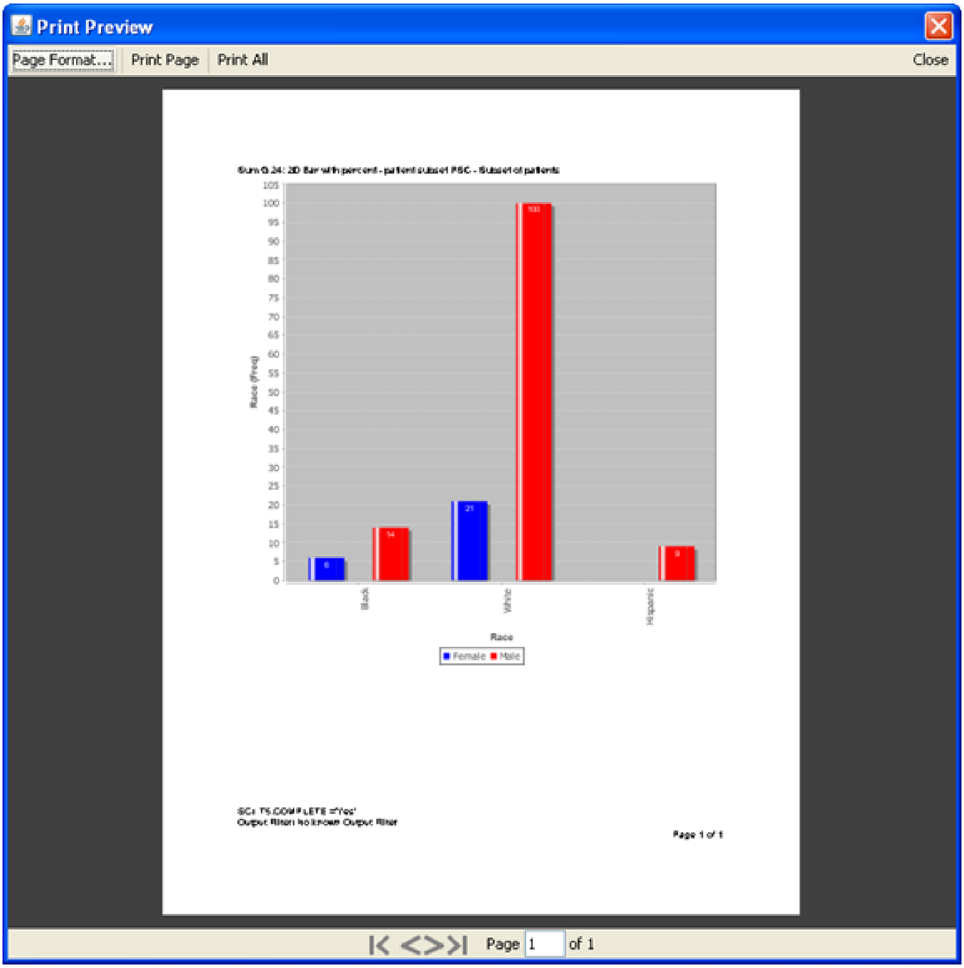
***Note:  End-users should avoid loading annotations from a file into graph that has different data or a different data specification than the graph that was used to create the annotation file.***

# Printing and Exporting Graphs

## *Printing the graph*

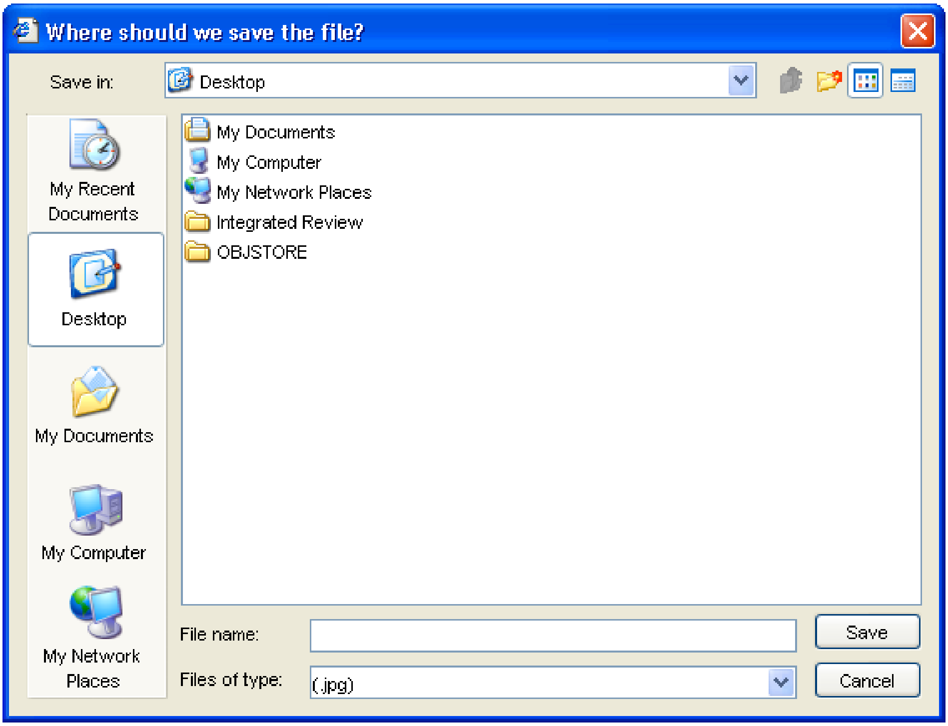
To get a printed copy of your graph you must access a **Print Preview window** and menu bar.

1. Click on the result window to make it the active window.
2. Click , or from the **Browser File** menu, select **Print**.
3. Click either **PrintPage**, **PrintAll** or **Close**. The PrintPage option will print only the first page of your output. The PrintAll option will print the entire output. The result prints on the currently selected printer.



### *Exporting the graph*

1. From the menu bar in the **Print Plot window**, click **Export to JPG**. The save dialog window opens.
2. Select a folder location and enter a **File Name**.
3. Click **Save** to export the graph results.



## *Export EPS graph*

Graphs and RBM Graphs (Risk Based Monitoring) may be "exported" to a file in EPS (Encapsulated Postscript) format. The content of this file is a Postscript program that describes a graph. EPS formatted files are sometimes required when the graph is to be included in a paper submitted for publication.

For the user, the procedure to export a graph to EPS is similar to the current one for exporting to a JPEG file:

1. The user clicks on "Export" in the File menu, or in the case of the RBM graphs, clicks on the Export button.
2. The modal dialog for saving an image file is presented (see Figure 1 below).
3. The user navigates to the directory where the file is to be written.
4. The user names the file. EPS files require "eps" as the file extension (e.g., "mygraph.eps"). The user may either type the EPS extension ".eps" as part of the file name or select the "eps" file type from the dialog's combo box.
5. The JReview client will then generate the EPS file.

While the EPS file may be inserted into a Microsoft Word document, the quality appears significantly better when viewed in Adobe or Adobe competitor products.

A number of limitations should be noted:

1. The EPS representation does NOT support Java's "Gradient Paint" (see Figure 2). The bars in a bar chart may use a Gradient Paint. When exporting a Bar chart to EPS, the user should choose the "Flat Look" option in the chart customization dialog.
2. The EPS representation does NOT support the "alpha channel" for colors. In other words, translucency is not supported. Thus, for example, bar labels in Bar charts, and the drag-enabled data boxes available for Scatter plots with reference ranges will be opaque when viewed as EPS. The Timeline Trellis by Patient with "Periods" specified should not be exported to EPS.

### *Edit menu Copy*

1. Click on the result window to make it the active window.
2. Select Edit in the menu bar.
3. Select the Copy function, to copy the currently displayed output window to clipboard for pasting into Word, etc.

## Object Storage

Any changes applied to the graph properties are saved, if you click on **Save** with the graph output window open. The **Save** window opens and you can save the changed properties with the graph.

For detailed instructions on how to save, retrieve, schedule output and remove object specifications (reports, graphs, crosstabs, etc.), ***See Chapter 11: Saving and Manage Objects, Scheduling plus Alerts Browser.***

## Exploring data

### *Changing the patient selection criteria*

After you have executed a stored object, you can use the object(s) that are currently displayed as data exploration views by doing the following:

1. Change the patient selection criteria, redefining it by adding additional expressions, or removing existing expressions.
2. Click **Update Browsers** in the Patient Selection Criteria window to update all active browsers according to the new criteria.

   All browser objects that are displayed will be updated according to your new criteria. Each object generated with a filter on will update with the same filter criteria with which it was created.

***Note: Restrictions apply if the stored object definition has a required patient selection criteria applied.***

### *Patient Identification*

Multiple patients can be selected from all patient-level displays of data results. Selecting more than one patient activates Review's multiple-patient mode, which updates patient-level displays of data to highlight only the selected patient data. This facilitates patient identification and subsetting, for exploration of the selected patient data with the reviewing facilities of the Data Browser and all of Review's browser tools.

## Closing graphs and the Graph Browser

### *Closing a graph window*

If you are finished reviewing a graph, and do not need to use the Graph to review any other patient populations: double-click the window's close box.

### *Closing the Graph Browser*

If you are finished with all graphs, and do not need to define any other graphs, double-click the close box of the Graph Browser window.

# 8 CrossTab Browser

# Patient selection criteria

## *Selection set*

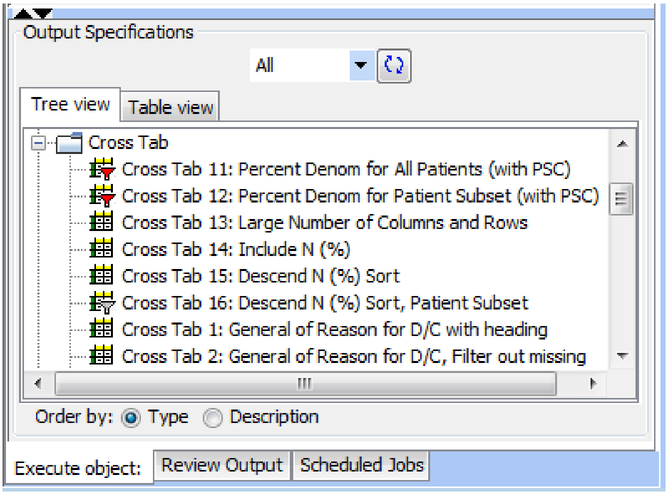
In JReview, you can select a previously saved Patient Subset, Dynamic PSC or define your own selection criteria for use in the CrossTab Browser. After launching the saved patient subset or building your own patient selection criteria, you can explore CrossTab objects created in the CrossTab Browser.

# Execute CrossTab

## *Quick execute*

JReview displays a list of categorical folders for stored patient subsets and output specifications at the selected storage location. Simply select one of the storage locations to display it's specific folders and contents.

Icons are displayed along with the stored object to identify the source as report, crosstab, registered SAS program, etc. When a patient selection criteria is saved with the stored object; the filter icon displays with the specific browser icon. JReview aids users to quickly locate and launch these stored objects.



Cross Tab
- Cross Tab 11: Percent Denom for All Patients (with PSC)
- Cross Tab 12: Percent Denom for Patient Subset (with PSC)
- Cross Tab 13: Large Number of Columns and Rows
- Cross Tab 14: Include N (%)
- Cross Tab 15: Descend N (%) Sort
- Cross Tab 16: Descend N (%) Sort, Patient Subset
- Cross Tab 1: General of Reason for D/C with heading
- Cross Tab 2: General of Reason for D/C, Filter out missing

Order by: ● Type ○ Description

# CrossTab Browser types of analysis

## *Select type of crosstab analysis*

The CrossTab Browser allows Multiple study mode in CrossTabs. However, Shift Tables requires the specific study baseline and endpoint definition be entered in ReviewAdmin and does not allow multiple protocol selection.

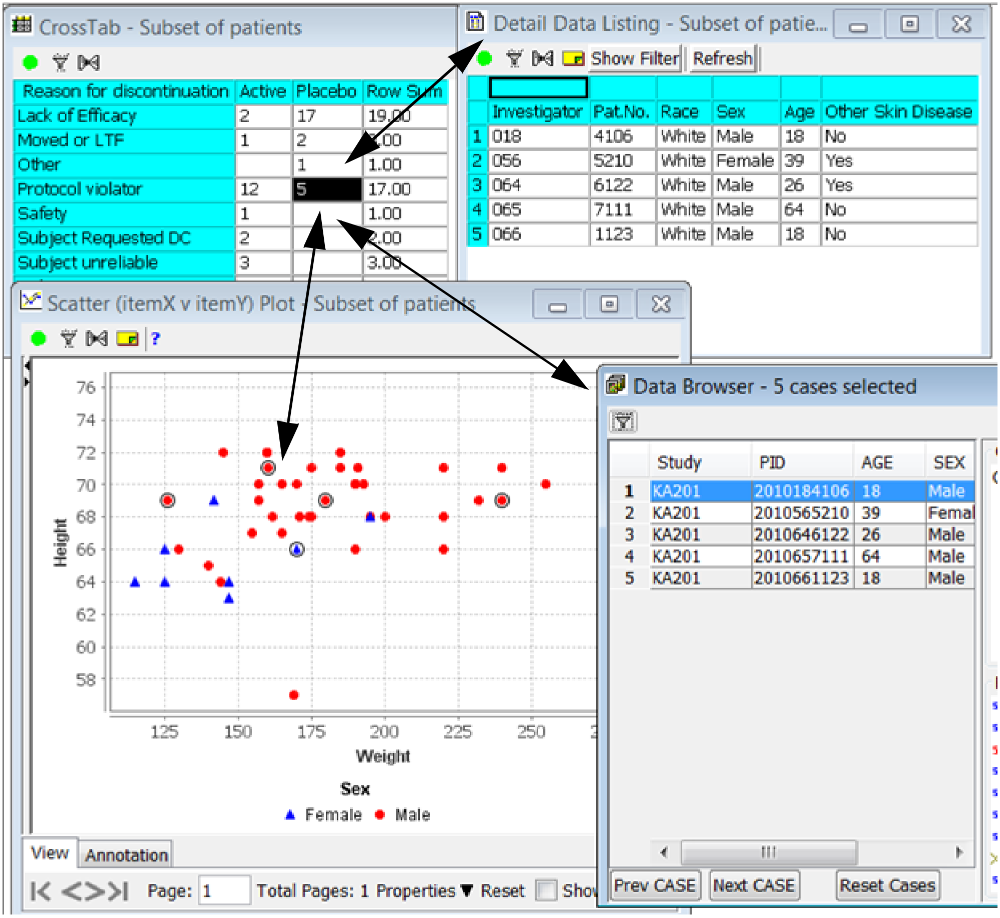
In the CrossTab Browser you can select from four types in the Type List.

- CrossTab: Clinical patient categorization and counts.
- CrossTab Top N, Bottom: displays the top N and bottom N values of a variable in a study for either all patients or the current patient subset.
- CrossTab Side by Side Columns: Individual column categories are displayed as counts side by side to one row variable.
- CrossTab - Combination Explorer: Subject based calculations which displays all permutations of selected data and the number of patients and percentages.
- Shift Table: Clinical patient categorization by defined threshold values segmented over time.

The CrossTab Browser output represents patient counts and not individual record counts. This function facilitates patient identification to all underlying patient data from categorical patient counts, regional graphic selection, and row selections in patient and detail data listings.

Either CrossTab type facilitates browsing patient listings underlying any of the patient counts within the table results. When you click on any of the categorized patient counts, the results table updates the Data Browser and Detail Data Listing Reports to display a listing of patients underlying the table count. Scatter plot graphs highlight the patients underlying the CrossTab Browser table patient count clicked on.

The individual patient counts within the CrossTab and Shift Tables are fully interactive with all patient-level displays of data. If you open the Data Browser and then highlight the patient subset cell count within the CrossTab Browser, those patients are identified. Likewise, a Detail Data Listing or Scatter Plot graph will reflect the patient data for the selected patient subset.



| Reason for discontinuation | Active | Placebo | Row Sum |
|---|---|---|---|
| Lack of Efficacy | 2 | 17 | 19.00 |
| Moved or LTF | 1 | 2 | 3.00 |
| Other | | 1 | 1.00 |
| Protocol violator | 12 | 5 | 17.00 |
| Safety | 1 | | 1.00 |
| Subject Requested DC | 2 | | 2.00 |
| Subject unreliable | 3 | | 3.00 |

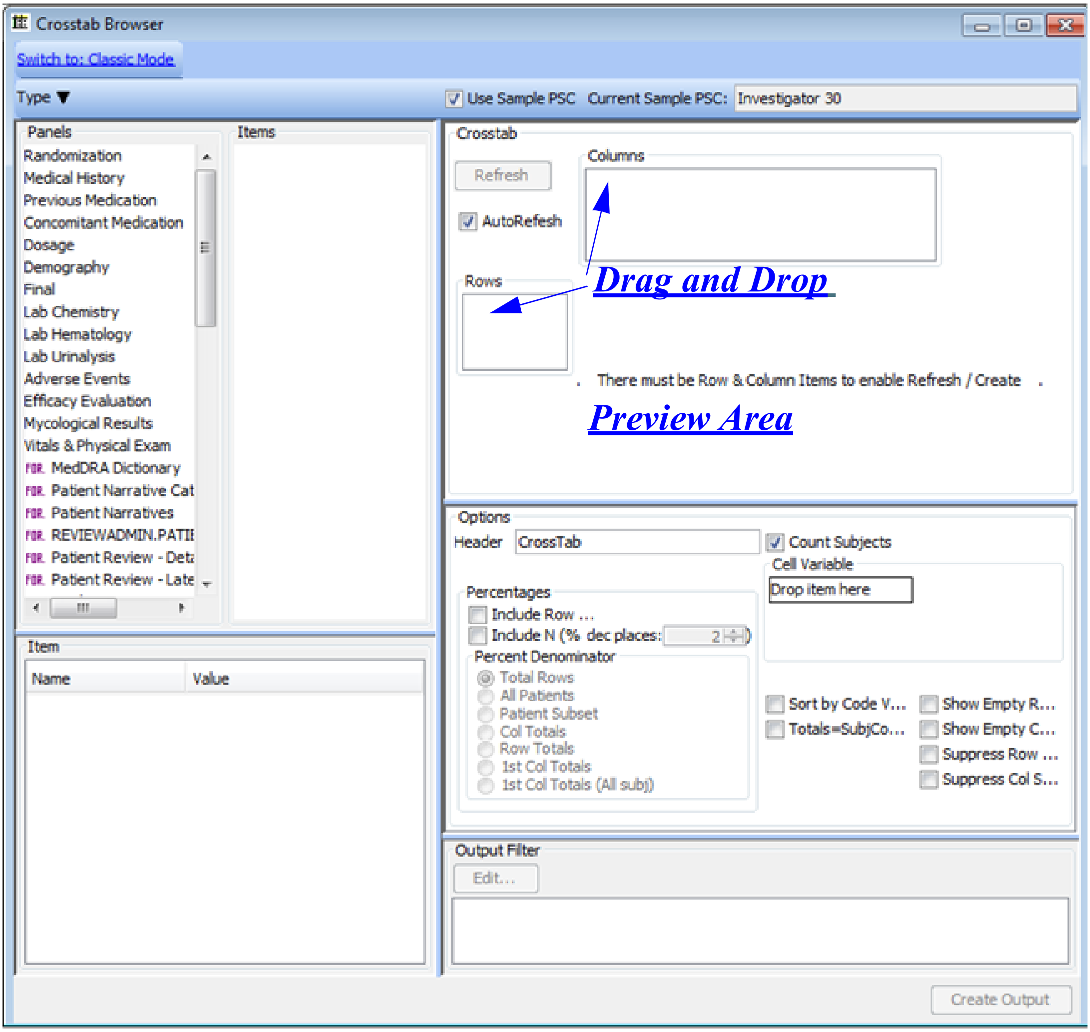
| | Investigator | Pat.No. | Race | Sex | Age | Other Skin Disease |
|---|---|---|---|---|---|---|
| 1 | 018 | 4106 | White | Male | 18 | No |
| 2 | 056 | 5210 | White | Female | 39 | Yes |
| 3 | 064 | 6122 | White | Male | 26 | Yes |
| 4 | 065 | 7111 | White | Male | 64 | No |
| 5 | 066 | 1123 | White | Male | 18 | No |

| | Study | PID | AGE | SEX |
|---|---|---|---|---|
| 1 | KA201 | 2010184106 | 18 | Male |
| 2 | KA201 | 2010565210 | 39 | Femal |
| 3 | KA201 | 2010646122 | 26 | Male |
| 4 | KA201 | 2010657111 | 64 | Male |
| 5 | KA201 | 2010661123 | 18 | Male |

# Defining a CrossTab table - New Mode

## *New Mode versus Classic mode*

New in JReview Version 11 is **Drag and Drop** functionality to define crosstabs with a preview of results. Upon selecting the CrossTab browser build window will open in “**New Mode**” for drag and drop functions.  The browser opens in default crosstab.



☑ Use Sample PSC  Current Sample PSC: Investigator 30

☑ AutoRefesh

There must be Row & Column Items to enable Refresh / Create

Header CrossTab

☑ Count Subjects

Cell Variable: Drop item here

☐ Include Row ...

☐ Include N (% dec places: 2)

● Total Rows
○ All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

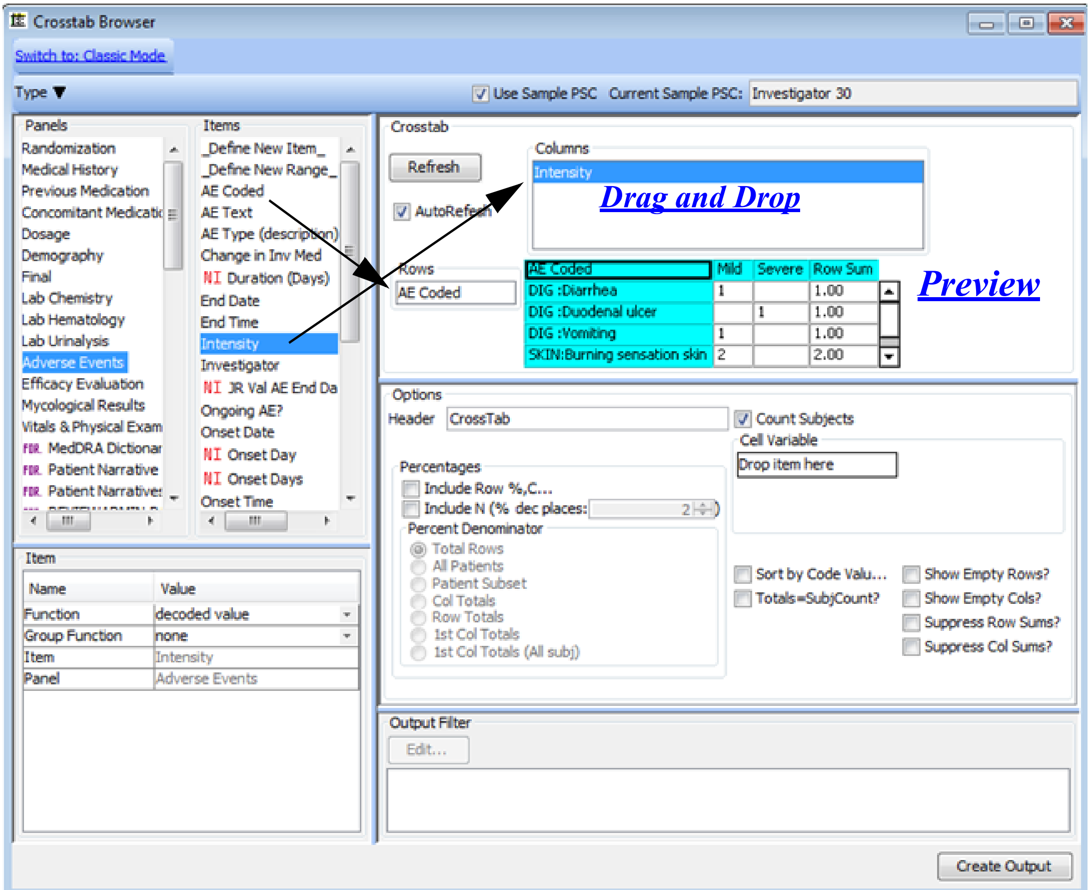
☐ Sort by Code V...
☐ Totals=SubjCo...
☐ Show Empty R...
☐ Show Empty C...
☐ Suppress Row ...
☐ Suppress Col S...

***Drag and Drop***

***Preview Area***

The central area is the crosstab **Preview.** When the row and column variables are defined to construct a crosstab, the Preview populates the Crosstab with **sample** data. As options and percentages are modified, the sample data may be refreshed and the crosstab updated.

Here is an example of a crosstab for AE Coded versus Intensity. The Preview displays data for the **Sample PSC**.



☑ Use Sample PSC  Current Sample PSC: Investigator 30

☑ AutoRefresh

Columns: Intensity

Rows: AE Coded

| AE Coded | Mild | Severe | Row Sum |
|---|---|---|---|
| DIG :Diarrhea | 1 | | 1.00 |
| DIG :Duodenal ulcer | | 1 | 1.00 |
| DIG :Vomiting | 1 | | 1.00 |
| SKIN:Burning sensation skin | 2 | | 2.00 |

Item

| Name | Value |
|---|---|
| Function | decoded value |
| Group Function | none |
| Item | Intensity |
| Panel | Adverse Events |

Options

Header CrossTab

☑ Count Subjects

Cell Variable: Drop item here

Percentages

☐ Include Row %,C...

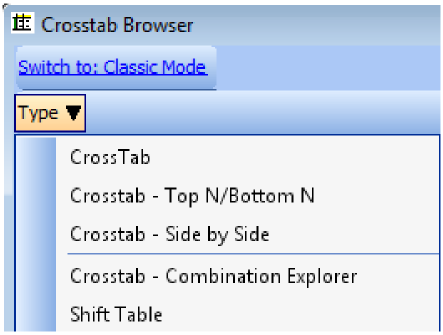
☐ Include N (% dec places: 2 )

Percent Denominator

● Total Rows
○ All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

☐ Sort by Code Valu...
☐ Totals=SubjCount?
☐ Show Empty Rows?
☐ Show Empty Cols?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

Open the CrossTab Browser from the **Browse** menu, or click on the icon in the toolbar. The CrossTab Browser opens in "**New Mode"** to default type **CrossTab.** All the Classic Mode features to define a crosstab are available in New Mode. Click on **Type** to display the drop down list for other crosstab types. When you select a crosstab type listed below the line, the CrossTab Browser will change to Classic Mode. Optionally, the user may click the **Switch to: Classic Mode** button for traditional building of output definitions.

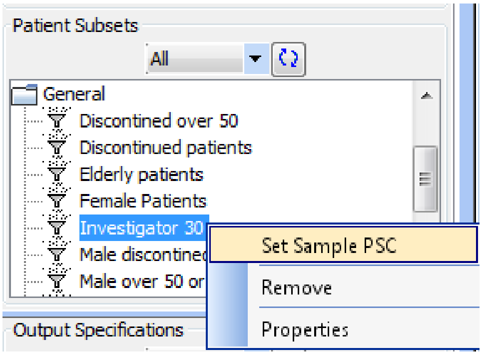


It is assumed that the user is familiar with the previous methods for defining crosstabs in the CrossTab Browser. ***(See section on Defining a CrossTab specification - Classic Mode)***

## *Set Sample PSC*

Users with ReviewAdmin priv63 may assign a "**Sample PSC**" to preview results while building the crosstab definition, to limit the amount of sample data so that the Preview can be refreshed quickly. It is important that the user select a patient subset to serve as a filter on the Preview's sample data. The Sample PSC is saved at the study level as public and the Sample PSC icon is outlined with a **green box**.

1. Right click on a Patient Subset in JReview's Patient Subsets tree; and select "**Set Sample PSC**".

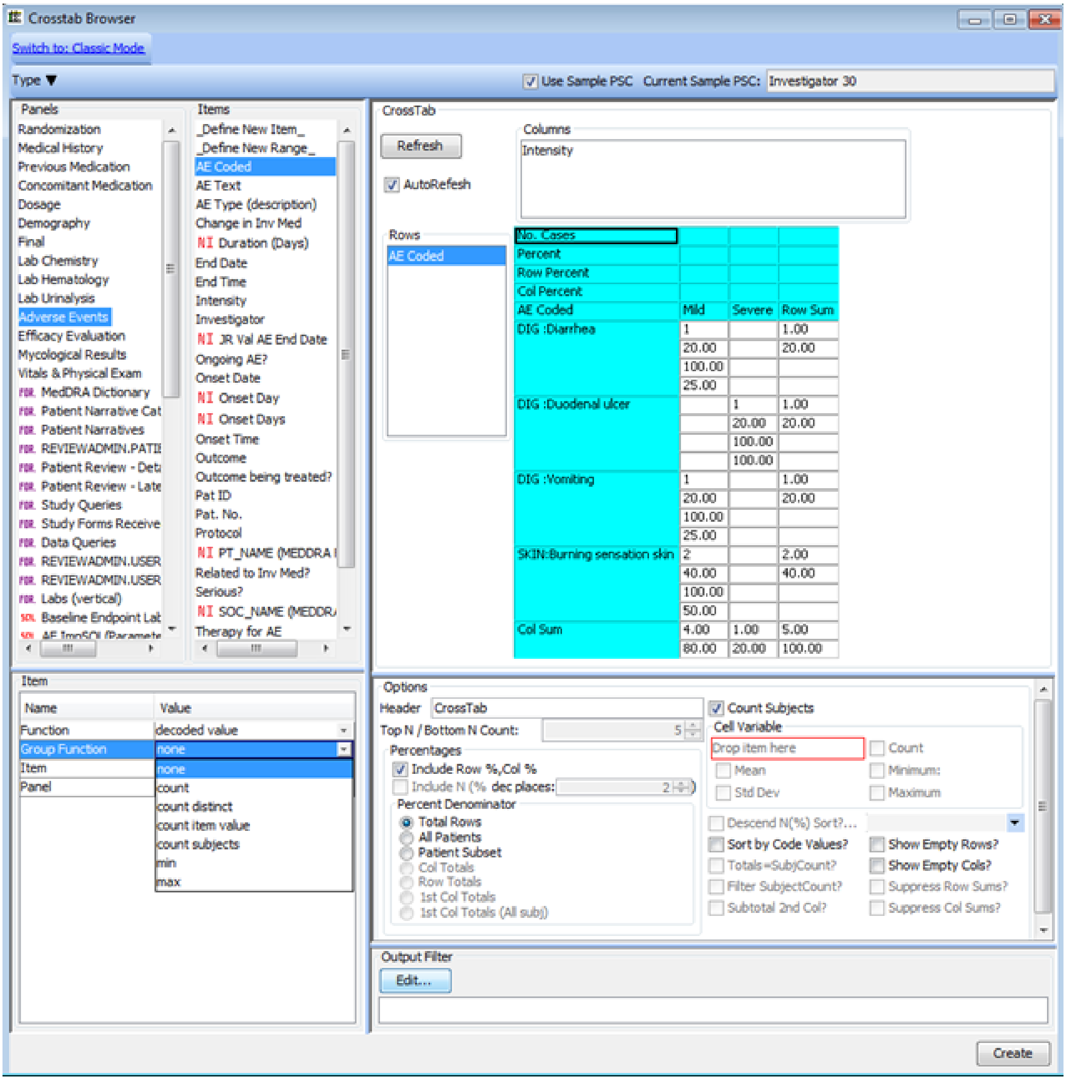


2. The name of the Sample PSC Item is displayed at the right side of the New Mode CrossTab Browser's toolbar.
3. The checkbox "**Use Sample PSC**" is next to the **Current Sample PSC** description to enable/disable the PSC Sample filter for the crosstab Preview. When unchecked all patients or the current selection criteria is applied.

## *Drag & Drop Items*

There are several major components of the New Mode CrossTab Browser. The **DraggablePIFPanel** enables an item to be dragged to a target. The central area is the CrossTab Preview. The users define a crosstab by dropping items on target locations; for example, **Rows** and **Columns**.

The **Item property table** contains the **Group Function** for the active selected item and is displayed in the drop down list.



☑ Use Sample PSC  Current Sample PSC: Investigator 30

☑ AutoRefesh

Columns: Intensity

Rows: AE Coded

| | | | |
|---|---|---|---|
| No. Cases | | | |
| Percent | | | |
| Row Percent | | | |
| Col Percent | | | |
| AE Coded | Mild | Severe | Row Sum |
| DIG :Diarrhea | 1 | | 1.00 |
| | 20.00 | | 20.00 |
| | 100.00 | | |
| | 25.00 | | |
| DIG :Duodenal ulcer | | 1 | 1.00 |
| | | 20.00 | 20.00 |
| | | 100.00 | |
| | | 100.00 | |
| DIG :Vomiting | 1 | | 1.00 |
| | 20.00 | | 20.00 |
| | 100.00 | | |
| | 25.00 | | |
| SKIN:Burning sensation skin | 2 | | 2.00 |
| | 40.00 | | 40.00 |
| | 100.00 | | |
| | 50.00 | | |
| Col Sum | 4.00 | 1.00 | 5.00 |
| | 80.00 | 20.00 | 100.00 |

Item

| Name | Value |
|---|---|
| Function | decoded value |
| Group Function | none |
| Item | none<br>count<br>count distinct<br>count item value<br>count subjects<br>min<br>max |
| Panel | |

Header: CrossTab

Top N / Bottom N Count: 5

Percentages

☑ Include Row %,Col %
☐ Include N (% dec places: 2)

Percent Denominator

● Total Rows
○ All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

☑ Count Subjects

Cell Variable: Drop item here

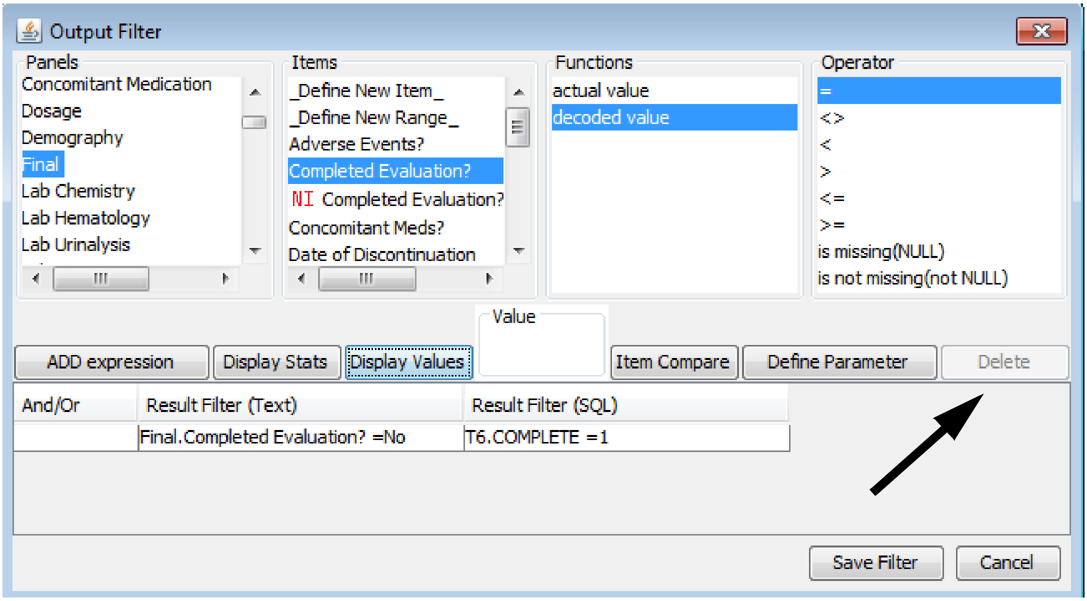
☐ Count
☐ Mean
☐ Minimum:
☐ Std Dev
☐ Maximum

☐ Descend N(%) Sort?...
☐ Sort by Code Values?
☐ Show Empty Rows?
☐ Totals=SubjCount?
☐ Show Empty Cols?
☐ Filter SubjectCount?
☐ Suppress Row Sums?
☐ Subtotal 2nd Col?
☐ Suppress Col Sums?

If the user drops an item on a drop target that is already defined, the newly dropped item replaces the current item. When the item is dropped, the drop target "area", e.g., the row or column box is selected, and its properties are presented in the Item property table. All drop targets are selectable, and certain "**Options**" for percentages may be selected dependent upon the selected crosstab type.

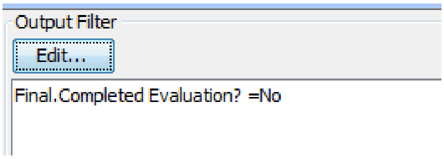
## CrossTab Output Filter

The control for the **Output Filter** differs from that found in the Classic Mode. When the **Output Filter Edit button** is clicked the Output Filter dialog is displayed for editing and creating a filter. A "**Delete**" button is provided at the right side of the dialog's button row.



| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | Final.Completed Evaluation? =No | T6.COMPLETE =1 |

The filter expressions are displayed in a text area in this control (a popup is no longer needed to view the current filter).



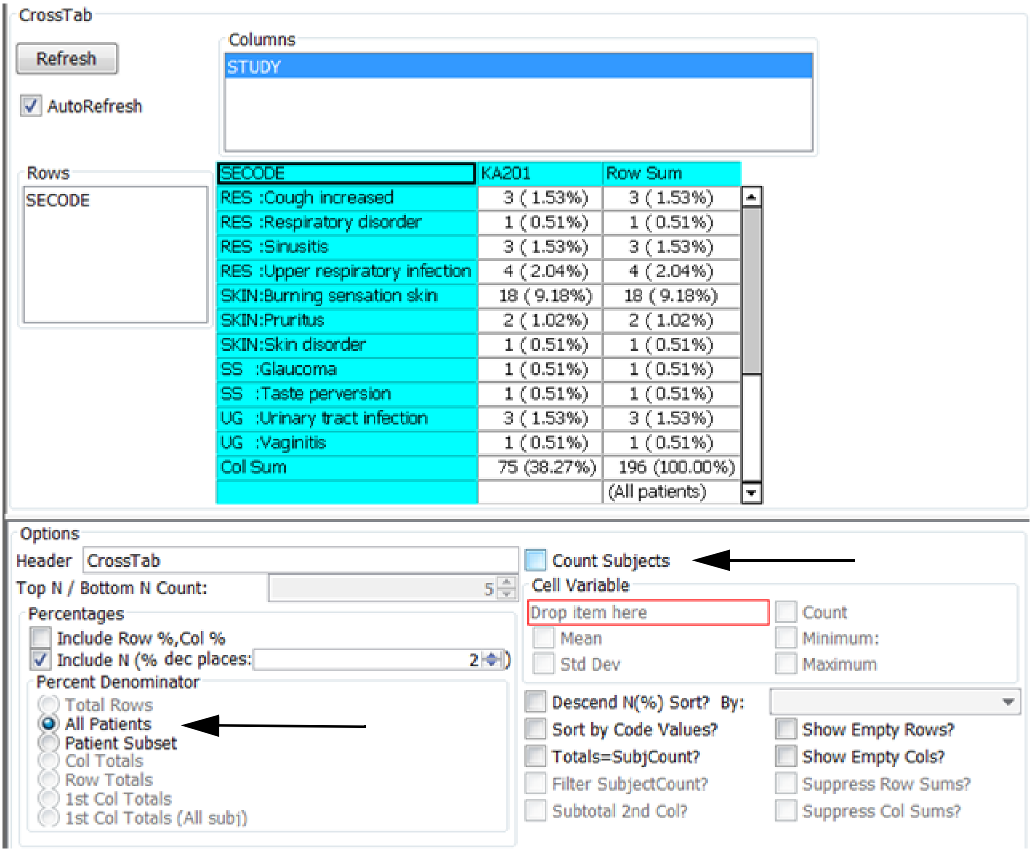
Final.Completed Evaluation? =No

Click **Create** to display the crosstab defined in a CrossTab Viewer. The entire results will display for the crosstab specification and specified selection criteria, if one was used. The **Set Sample PSC *will be ignored*** when the crosstab is created.

## *Incidence tabulations*

Crosstabs now support Incidence tabulations by unchecking ‘Count Subjects’, then adding the row variable also as the Cell Variable then check ‘Count’. The Crosstabs switch to ‘incidence mode’ including % of some denominator which can be either row totals or col totals. Descending Sort is also supported.

The Incidence tabulations is a slightly modified behavior in the crosstab browser to support AE Incidence tables – which are based on Count of AE observations rather than normal default of Count Subjects. Users may check the ‘Include N %’ (so they’ll see that information in the cells – but in this case the N is the count, not subject count). When checking the Include N % checkbox then All Patients and Patient Subset percent denominator are enabled while disabling Percent Denominator - 1st Col Totals as a choice for this option with Include N %.



Columns: STUDY

Rows: SECODE

| SECODE | KA201 | Row Sum |
|---|---|---|
| RES :Cough increased | 3 ( 1.53%) | 3 ( 1.53%) |
| RES :Respiratory disorder | 1 ( 0.51%) | 1 ( 0.51%) |
| RES :Sinusitis | 3 ( 1.53%) | 3 ( 1.53%) |
| RES :Upper respiratory infection | 4 ( 2.04%) | 4 ( 2.04%) |
| SKIN:Burning sensation skin | 18 ( 9.18%) | 18 ( 9.18%) |
| SKIN:Pruritus | 2 ( 1.02%) | 2 ( 1.02%) |
| SKIN:Skin disorder | 1 ( 0.51%) | 1 ( 0.51%) |
| SS :Glaucoma | 1 ( 0.51%) | 1 ( 0.51%) |
| SS :Taste perversion | 1 ( 0.51%) | 1 ( 0.51%) |
| UG :Urinary tract infection | 3 ( 1.53%) | 3 ( 1.53%) |
| UG :Vaginitis | 1 ( 0.51%) | 1 ( 0.51%) |
| Col Sum | 75 (38.27%) | 196 (100.00%) |
| | | (All patients) |

Header: CrossTab

Top N / Bottom N Count: 5

Percentages

☐ Include Row %,Col %

☑ Include N (% dec places: 2

Percent Denominator

○ Total Rows
● All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

☐ Count Subjects

Cell Variable

Drop item here

☐ Count
☐ Mean
☐ Minimum:
☐ Std Dev
☐ Maximum

☐ Descend N(%) Sort? By:

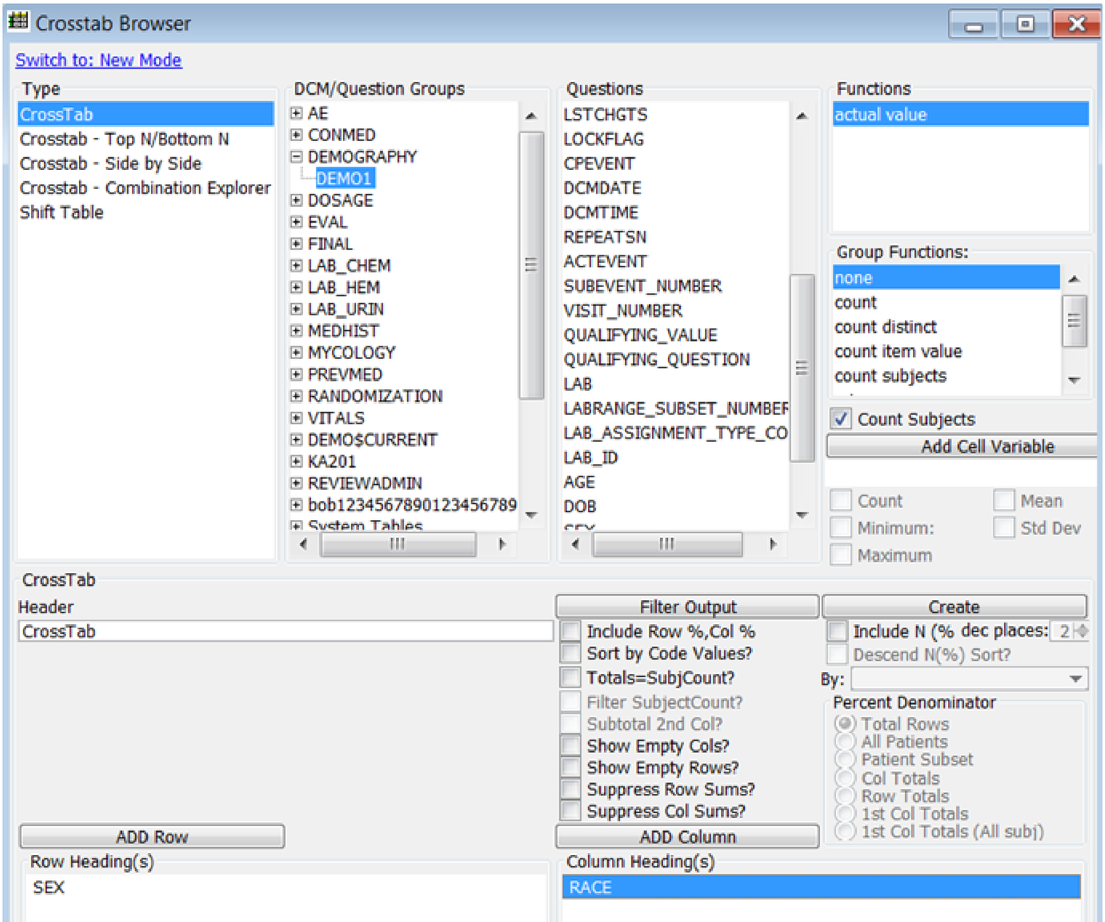
☐ Sort by Code Values?
☐ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Rows?
☐ Show Empty Cols?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

# Defining a CrossTab table - Classic Mode

## *Selecting a panel, item, and function*

You can define the contents of a CrossTab table by applying the same method that you used to build other browser specifications. Clinical groupings of patients who meet the current patient selection criteria can be examined by using the CrossTab Browser.

1. Click the icon from the toolbar, or from the **Browse** menu select **CrossTabs**. Review displays the CrossTab Browser window where you specify the type and contents of your multi-dimensional analysis.



Type: CrossTab
DCM/Question Groups: DEMO1
Functions: actual value
Group Functions: none
☑ Count Subjects
☐ Count ☐ Mean
☐ Minimum: ☐ Std Dev
☐ Maximum

CrossTab
Header: CrossTab

☐ Include Row %,Col %
☐ Sort by Code Values?
☐ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

☐ Include N (% dec places: 2
☐ Descend N(%) Sort?

Percent Denominator
● Total Rows
○ All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s): SEX
Column Heading(s): RACE

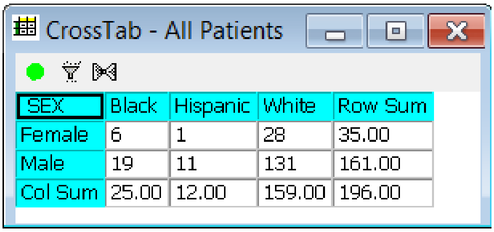
2. Select a panel, an item and the appropriate function or use the default function.
3. Click **ADD Row** or **ADD Column** to add the selected item to the CrossTab content spreadsheet at the bottom of the CrossTab window.

   Multiple rows and/or columns may be added.
4. Edit the default Cross Tab Heading by clicking in the heading box.
5. Click **Create.**

The CrossTab construct is created and displays results in the CrossTab output window containing a spreadsheet of the multi-dimensional analysis you designed.

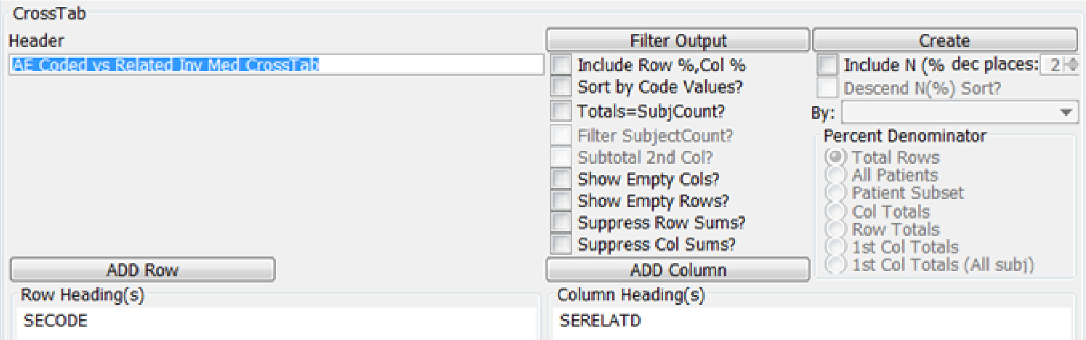
The crosstab heading displays either ‘All Patients’ or ‘Subset’ if a patient selection criteria was entered. If you modify the crosstab heading the patient population status of either ‘All Patients’ or ‘Subset’ still displays.

The individual Column Sum and Row Sum results are calculated with an over all total sum displayed. The CrossTab output represents patient counts and not individual record counts.



| SEX | Black | Hispanic | White | Row Sum |
|---|---|---|---|---|
| Female | 6 | 1 | 28 | 35.00 |
| Male | 19 | 11 | 131 | 161.00 |
| Col Sum | 25.00 | 12.00 | 159.00 | 196.00 |

In this CrossTab example for Adverse Events not all patients reported Adverse Events during the study.



Header: AE Coded vs Related Inv Med CrossTab

☐ Include Row %,Col %
☐ Sort by Code Values?
☐ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

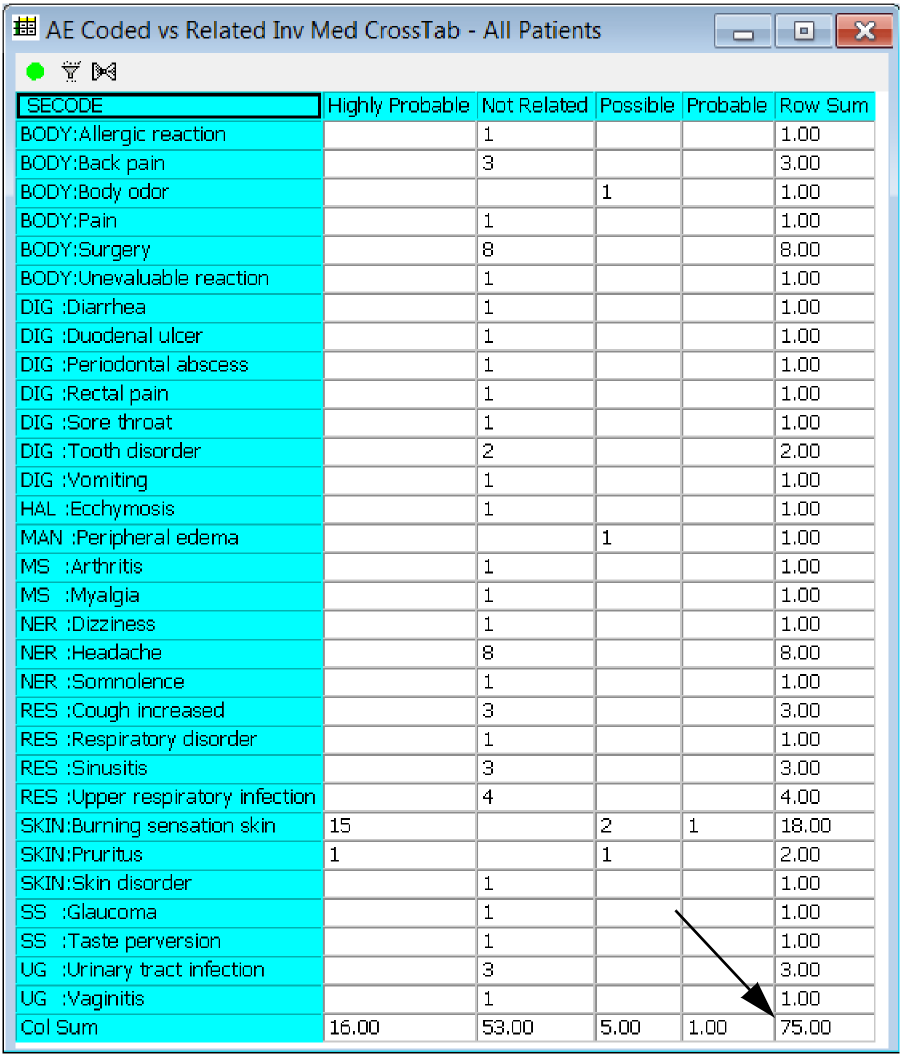
☐ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

Percent Denominator
● Total Rows
○ All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s): SECODE

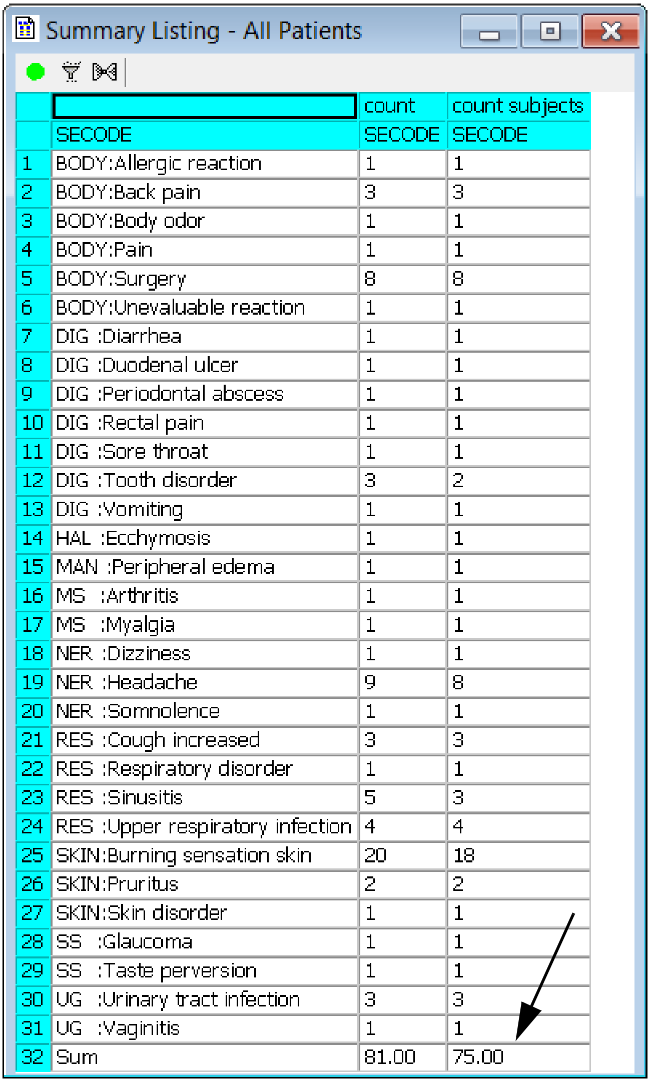
Column Heading(s): SERELATD

The Adverse Events CrossTab data represents patient counts and **not** individual Adverse Events. The CrossTab contains only the data from those patients who meet your current patient selection criteria and output filter criteria. There are 75 patients who reported Adverse Events.



| SECODE | Highly Probable | Not Related | Possible | Probable | Row Sum |
|---|---|---|---|---|---|
| BODY:Allergic reaction | | 1 | | | 1.00 |
| BODY:Back pain | | 3 | | | 3.00 |
| BODY:Body odor | | | 1 | | 1.00 |
| BODY:Pain | | 1 | | | 1.00 |
| BODY:Surgery | | 8 | | | 8.00 |
| BODY:Unevaluable reaction | | 1 | | | 1.00 |
| DIG :Diarrhea | | 1 | | | 1.00 |
| DIG :Duodenal ulcer | | 1 | | | 1.00 |
| DIG :Periodontal abscess | | 1 | | | 1.00 |
| DIG :Rectal pain | | 1 | | | 1.00 |
| DIG :Sore throat | | 1 | | | 1.00 |
| DIG :Tooth disorder | | 2 | | | 2.00 |
| DIG :Vomiting | | 1 | | | 1.00 |
| HAL :Ecchymosis | | 1 | | | 1.00 |
| MAN :Peripheral edema | | | 1 | | 1.00 |
| MS :Arthritis | | 1 | | | 1.00 |
| MS :Myalgia | | 1 | | | 1.00 |
| NER :Dizziness | | 1 | | | 1.00 |
| NER :Headache | | 8 | | | 8.00 |
| NER :Somnolence | | 1 | | | 1.00 |
| RES :Cough increased | | 3 | | | 3.00 |
| RES :Respiratory disorder | | 1 | | | 1.00 |
| RES :Sinusitis | | 3 | | | 3.00 |
| RES :Upper respiratory infection | | 4 | | | 4.00 |
| SKIN:Burning sensation skin | 15 | | 2 | 1 | 18.00 |
| SKIN:Pruritus | 1 | | 1 | | 2.00 |
| SKIN:Skin disorder | | 1 | | | 1.00 |
| SS :Glaucoma | | 1 | | | 1.00 |
| SS :Taste perversion | | 1 | | | 1.00 |
| UG :Urinary tract infection | | 3 | | | 3.00 |
| UG :Vaginitis | | 1 | | | 1.00 |
| Col Sum | 16.00 | 53.00 | 5.00 | 1.00 | 75.00 |

Compare the crosstab results to a summary listing of individual adverse event counts and corresponding patient counts with total sums. The summary listing displays the total sums for 75 patients who reported 81 Adverse Events where some patients reported multiple Adverse Events.



| | | count | count subjects |
|---|---|---|---|
| | SECODE | SECODE | SECODE |
| 1 | BODY:Allergic reaction | 1 | 1 |
| 2 | BODY:Back pain | 3 | 3 |
| 3 | BODY:Body odor | 1 | 1 |
| 4 | BODY:Pain | 1 | 1 |
| 5 | BODY:Surgery | 8 | 8 |
| 6 | BODY:Unevaluable reaction | 1 | 1 |
| 7 | DIG :Diarrhea | 1 | 1 |
| 8 | DIG :Duodenal ulcer | 1 | 1 |
| 9 | DIG :Periodontal abscess | 1 | 1 |
| 10 | DIG :Rectal pain | 1 | 1 |
| 11 | DIG :Sore throat | 1 | 1 |
| 12 | DIG :Tooth disorder | 3 | 2 |
| 13 | DIG :Vomiting | 1 | 1 |
| 14 | HAL :Ecchymosis | 1 | 1 |
| 15 | MAN :Peripheral edema | 1 | 1 |
| 16 | MS :Arthritis | 1 | 1 |
| 17 | MS :Myalgia | 1 | 1 |
| 18 | NER :Dizziness | 1 | 1 |
| 19 | NER :Headache | 9 | 8 |
| 20 | NER :Somnolence | 1 | 1 |
| 21 | RES :Cough increased | 3 | 3 |
| 22 | RES :Respiratory disorder | 1 | 1 |
| 23 | RES :Sinusitis | 5 | 3 |
| 24 | RES :Upper respiratory infection | 4 | 4 |
| 25 | SKIN:Burning sensation skin | 20 | 18 |
| 26 | SKIN:Pruritus | 2 | 2 |
| 27 | SKIN:Skin disorder | 1 | 1 |
| 28 | SS :Glaucoma | 1 | 1 |
| 29 | SS :Taste perversion | 1 | 1 |
| 30 | UG :Urinary tract infection | 3 | 3 |
| 31 | UG :Vaginitis | 1 | 1 |
| 32 | Sum | 81.00 | 75.00 |

## *Access to SAS datasets*

SAS datasets are listed with the panels generated from Oracle tables. Items from SAS datasets can be used like other items for CrossTab. You cannot mix items from SAS datasets and Oracle table generated panels within the same CrossTab.

## *Edit column width*

To edit the column width of the CrossTab results:

a. Click the column heading tabs (labeled A, B, etc.) as you would with any windows spreadsheet package.
b. Move the column boundaries to the position you want.

## *Sort by Code Value*

If you want to sort the CrossTab table by the order of the code values, as opposed to the default alphabetic sort of the descriptive text.

Click “Sort by Code Values”.

## *Output Filter*

Row filtering is carried out by the Output Filter which facilitates the specification of observations and visits from multi-visit data items to include in your CrossTab results.

After you define your CrossTab specifications you can use the output filter as a data exploration tool by row filtering data inclusion, then comparing filtered and unfiltered results.

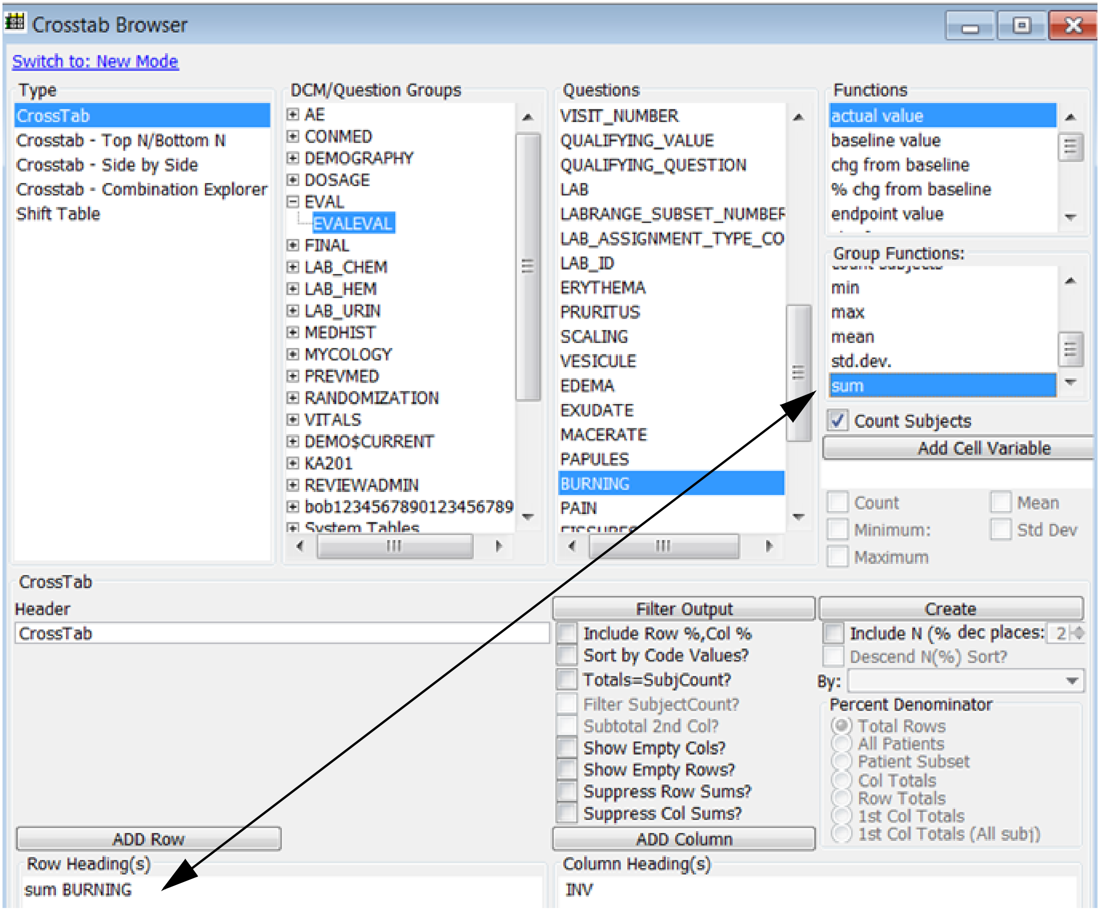
**(*See Chapter 6 Report Browser: Output Filter*)**

6. Click **Filter Output**.
7. Add the filter expressions and click **SAVE**.
8. The **Filter Output** button status toggles to **Filter is ON** when a row filter criteria is active to be applied during the next graph creation.
9. Click **Create.**

***Note: If you save a CrossTab specification with an output filter ON, the same filter will be applied when the CrossTab is recreated.***

## *Apply group function*

You may select the 'Group Function' for a numeric item. Select the group function for either ADD Row or ADD Column within the crosstab.

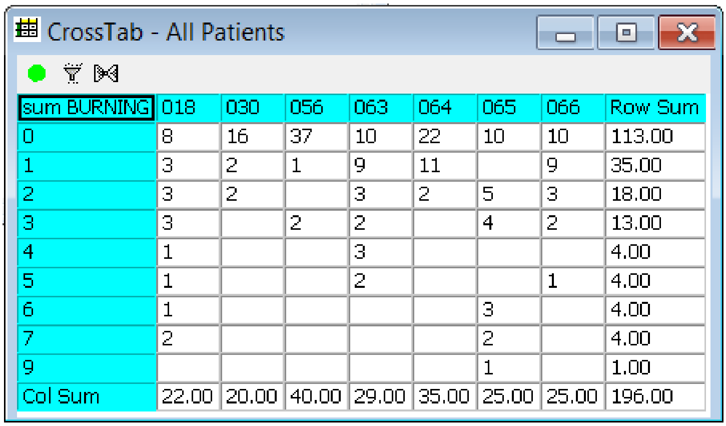


Header: CrossTab

Row Heading(s): sum BURNING

Column Heading(s): INV

The column for ‘sum Burning’ displays the unique sum values with counts by investigator.

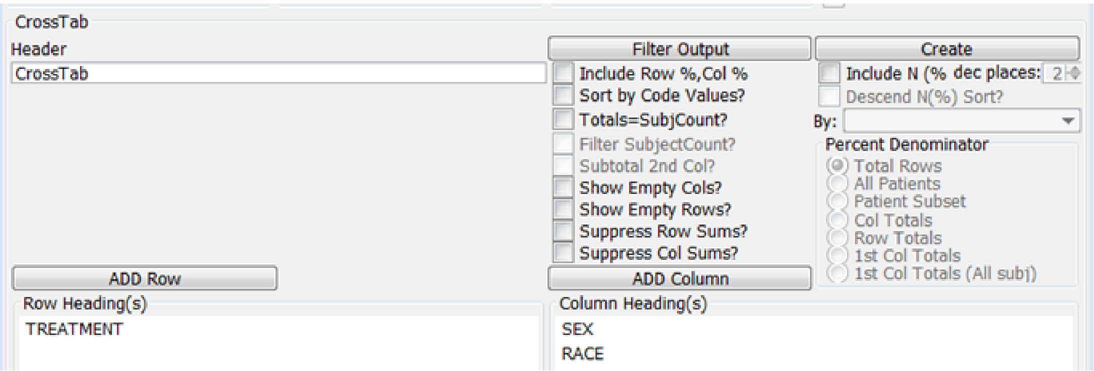


| sum BURNING | 018 | 030 | 056 | 063 | 064 | 065 | 066 | Row Sum |
|---|---|---|---|---|---|---|---|---|
| 0 | 8 | 16 | 37 | 10 | 22 | 10 | 10 | 113.00 |
| 1 | 3 | 2 | 1 | 9 | 11 |  | 9 | 35.00 |
| 2 | 3 | 2 |  | 3 | 2 | 5 | 3 | 18.00 |
| 3 | 3 |  | 2 | 2 |  | 4 | 2 | 13.00 |
| 4 | 1 |  |  | 3 |  |  |  | 4.00 |
| 5 | 1 |  |  | 2 |  |  | 1 | 4.00 |
| 6 | 1 |  |  |  |  | 3 |  | 4.00 |
| 7 | 2 |  |  |  |  | 2 |  | 4.00 |
| 9 |  |  |  |  |  | 1 |  | 1.00 |
| Col Sum | 22.00 | 20.00 | 40.00 | 29.00 | 35.00 | 25.00 | 25.00 | 196.00 |

## *Show empty values*

Click **Show Empty Columns** and/or **Show Empty Rows** if you wish to display a "filler" column and/or row for possible values that never were actually reported in the data. For example, if possible values for race are White, Black, Hispanic, and Oriental, but there are no Orientals in the study, then it would still show a column for Oriental.

In the following example we applied a patient selection criteria for patients who on 'Active' drug in the study. The following crosstabs demonstrate the results when the 'Show Empty' options are checked ON or not.



Header
CrossTab

☐ Include Row %,Col %
☐ Sort by Code Values?
☐ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

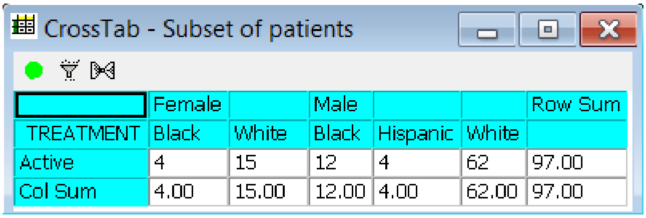
☐ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

Percent Denominator
● Total Rows
○ All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s)
TREATMENT

Column Heading(s)
SEX
RACE

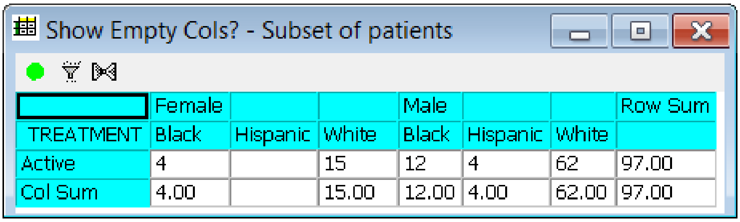
This crosstab shows the normal results when both 'Show Empty Columns' and 'Show Empty Rows' are **not checked ON**.



| | Female | | Male | | | Row Sum |
|---|---|---|---|---|---|---|
| TREATMENT | Black | White | Black | Hispanic | White | |
| Active | 4 | 15 | 12 | 4 | 62 | 97.00 |
| Col Sum | 4.00 | 15.00 | 12.00 | 4.00 | 62.00 | 97.00 |

Observe the different results when empty columns and/or rows are forced to display.

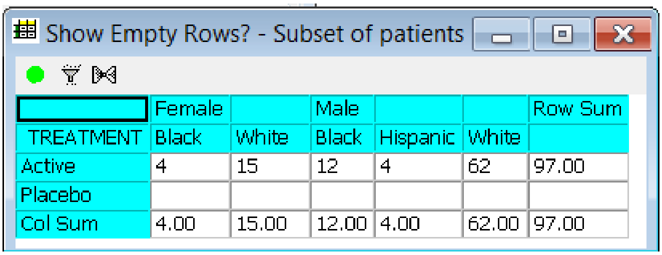
The option to **Show Empty Columns is checked ON** and the empty column for Hispanic is forced to display.



Show Empty Cols? - Subset of patients

| | Female | | | Male | | | Row Sum |
|---|---|---|---|---|---|---|---|
| TREATMENT | Black | Hispanic | White | Black | Hispanic | White | |
| Active | 4 | | 15 | 12 | 4 | 62 | 97.00 |
| Col Sum | 4.00 | | 15.00 | 12.00 | 4.00 | 62.00 | 97.00 |

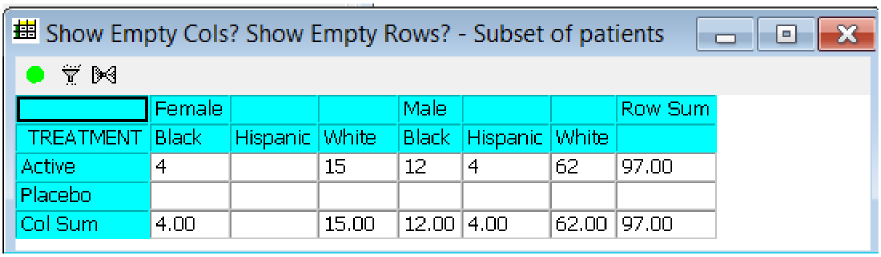
The option to **Show Empty Rows was checked ON** and the empty row for Placebo was forced to display.



Show Empty Rows? - Subset of patients

| | Female | | Male | | | Row Sum |
|---|---|---|---|---|---|---|
| TREATMENT | Black | White | Black | Hispanic | White | |
| Active | 4 | 15 | 12 | 4 | 62 | 97.00 |
| Placebo | | | | | | |
| Col Sum | 4.00 | 15.00 | 12.00 | 4.00 | 62.00 | 97.00 |

**Both options for Show Empty Columns and Show Empty Rows are checked ON** and empty columns and rows are forced to display.



Show Empty Cols? Show Empty Rows? - Subset of patients

| | Female | | | Male | | | Row Sum |
|---|---|---|---|---|---|---|---|
| TREATMENT | Black | Hispanic | White | Black | Hispanic | White | |
| Active | 4 | | 15 | 12 | 4 | 62 | 97.00 |
| Placebo | | | | | | | |
| Col Sum | 4.00 | | 15.00 | 12.00 | 4.00 | 62.00 | 97.00 |

You may ‘suppress row totals’ and ‘suppress col totals’ checkbox preferences even if ‘Totals = SubjCount’ is not checked ON.

## *Add cell variable*

You can optionally generate statistics for a specified cell variable when you create a CrossTab provided the item is numeric.

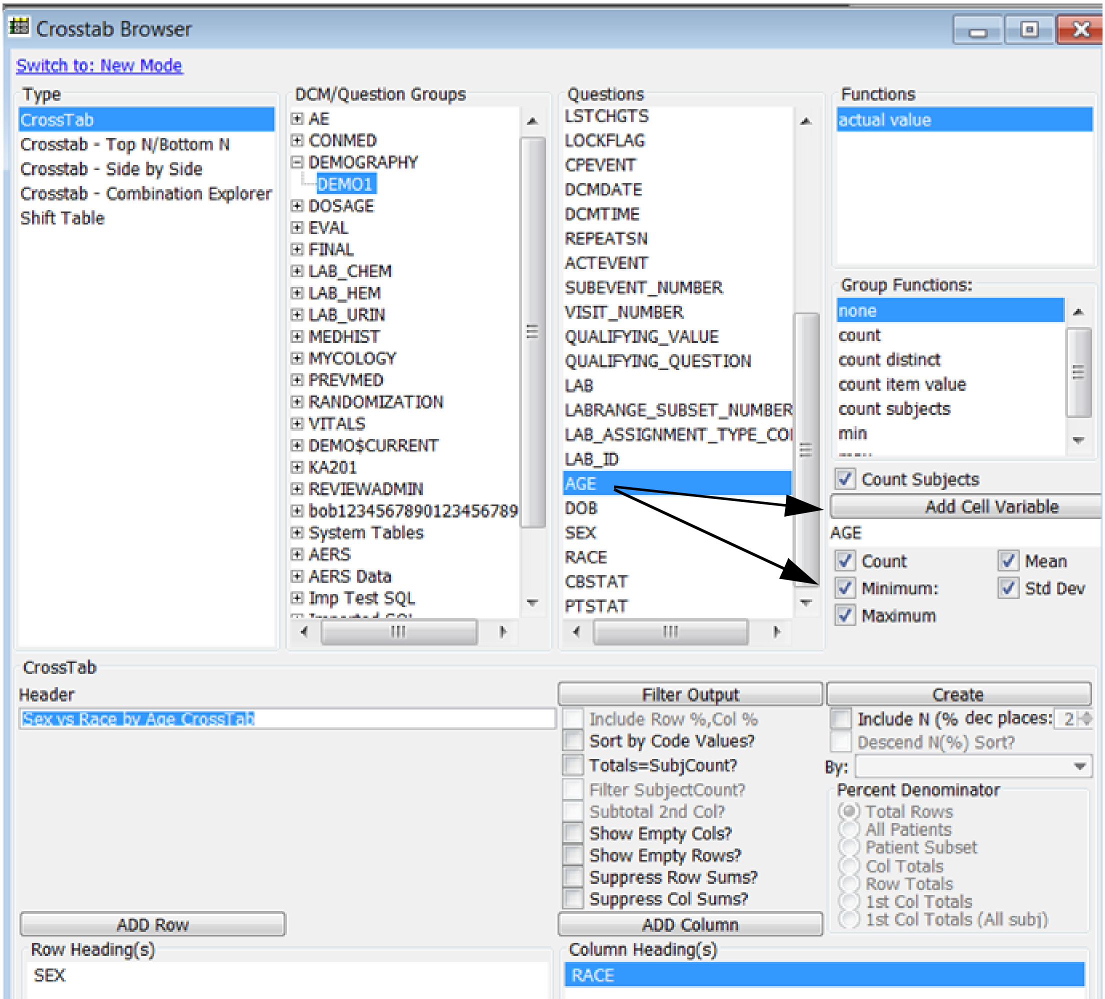
a. Select a panel.

b. Select a numeric item. Optionally click **Count Subjects**.

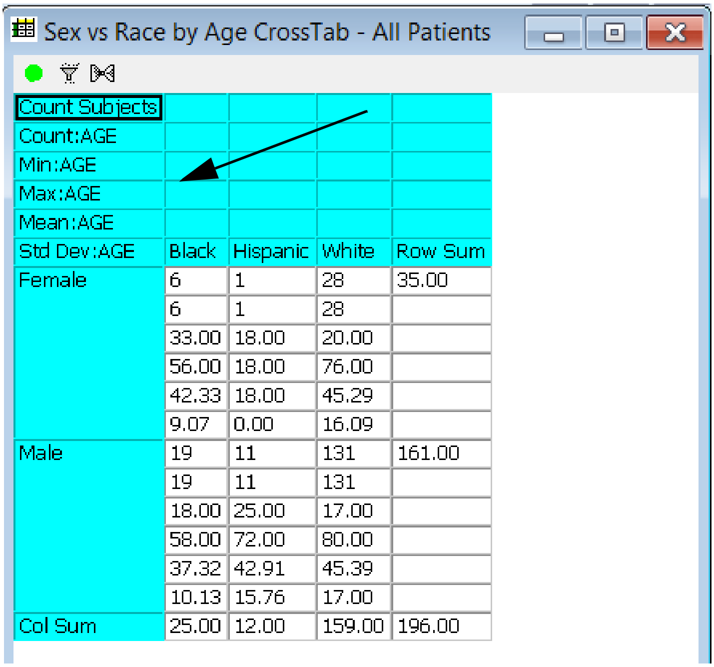
c. Click **Add Cell Variable**.

d. Select one or more **Cell Statistics**. You must select at least one.

***Note: The Add cell variable cannot be used in conjunction with the Optional Include Row%, Col%.***



A legend of the cell statistics displays in the upper left corner. The individual cells display the statistics selected for the cell variable item.



| | | | | |
|---|---|---|---|---|
| Count Subjects | | | | |
| Count:AGE | | | | |
| Min:AGE | | | | |
| Max:AGE | | | | |
| Mean:AGE | | | | |
| Std Dev:AGE | Black | Hispanic | White | Row Sum |
| Female | 6 | 1 | 28 | 35.00 |
| | 6 | 1 | 28 | |
| | 33.00 | 18.00 | 20.00 | |
| | 56.00 | 18.00 | 76.00 | |
| | 42.33 | 18.00 | 45.29 | |
| | 9.07 | 0.00 | 16.09 | |
| Male | 19 | 11 | 131 | 161.00 |
| | 19 | 11 | 131 | |
| | 18.00 | 25.00 | 17.00 | |
| | 58.00 | 72.00 | 80.00 | |
| | 37.32 | 42.91 | 45.39 | |
| | 10.13 | 15.76 | 17.00 | |
| Col Sum | 25.00 | 12.00 | 159.00 | 196.00 |

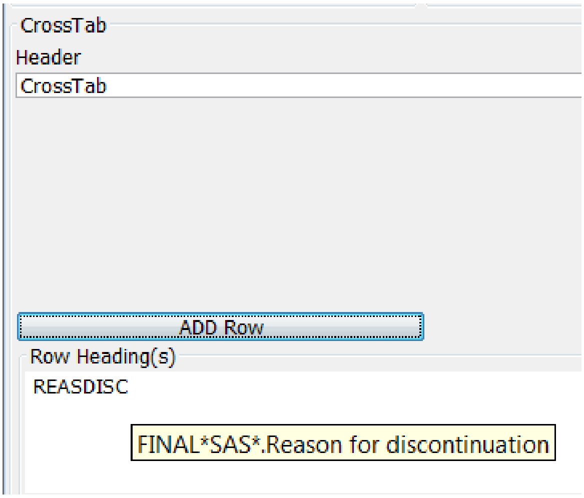
## *Edit the CrossTab specification*

If you want to change the CrossTab specification that you have defined:

1. Click any element in the CrossTab layout to edit. For example, click on any column heading that you want to delete.
2. Click ✂, or from the **Edit** menu, select **Cut.** This deletes the column heading from the CrossTab specification.
3. To modify the corresponding Filter Output, simply change the criteria expressions appropriately
4. Click **Save Filter**.
5. Click **Create** to create a new results window.
6. If you want to clear the entire CrossTab construct, click 🗋.

### Show Details

The **Show Details** feature can be used after you have added items to your crosstab specification. Simply hold the mouse over the item in the crosstab definition to view it’s source contents.



## Display Crosstab with Percentages

### Include Row% Col%

You can optionally calculate cell count percentages for CrossTab or Shift Table with a variety of configurations where row and column percentages are displayed.

Only patient selection criteria and/or a filter can affect the patient counts within the output of a crosstab. However, there are several options that can provide cell percentages, as well as modify the cross tab row and column totals.

Options that provide cell statistics are as follows:

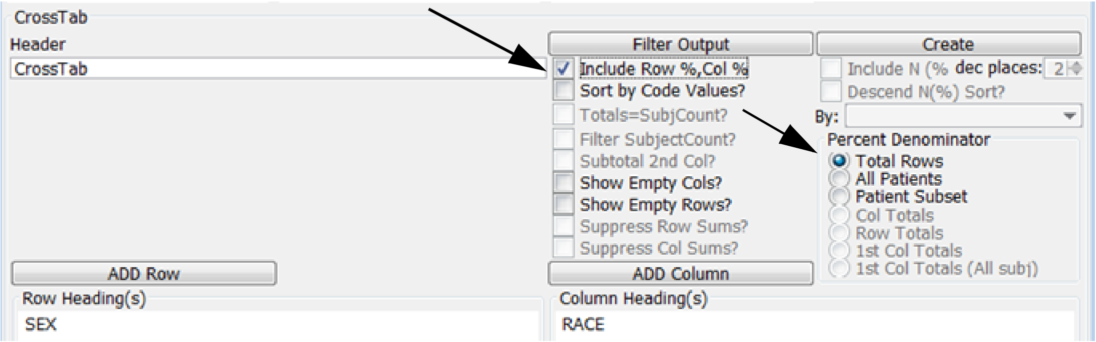
- Include Row%, Col%
- Include N (%)

If either of these percent functions are selected, then choose an option for the Percent Denominator.

- Total Rows
- All Patients
- Patient Subset
- Col Totals
- Row Totals
- 1st Col Totals
- 1st Col Totals (All Sub)

## *Percent Denominator*

When you click the ‘Include Row%, Col%’ check box for cell statistics the **Percent Denominator** default is ‘Total Rows’. Additional options that corresponds with this function are All Patients in the Study or Patient Subset.



Header
CrossTab

☑ Include Row %,Col %
☐ Sort by Code Values?
☐ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

☐ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

Percent Denominator
● Total Rows
○ All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s)
SEX

Column Heading(s)
RACE

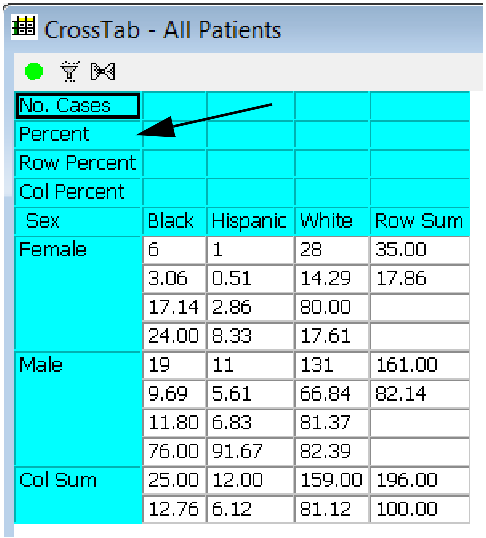
A legend of the cell statistics displays in the upper left corner. The **Include Row% Col%** provides a separate Row Sum with percent and Column Sum with percent including percentages for each cell count. Each row and column is summarized by descriptive statistics.

The example for 6 Female Black patients calculates as:

Percent is 6/default for **Total Rows** where 196 = 3.06%. The option for Total Rows calculates the same results as the All Patients option.

Row Percent is 6/**Row Sum** 35 = 17.14%.

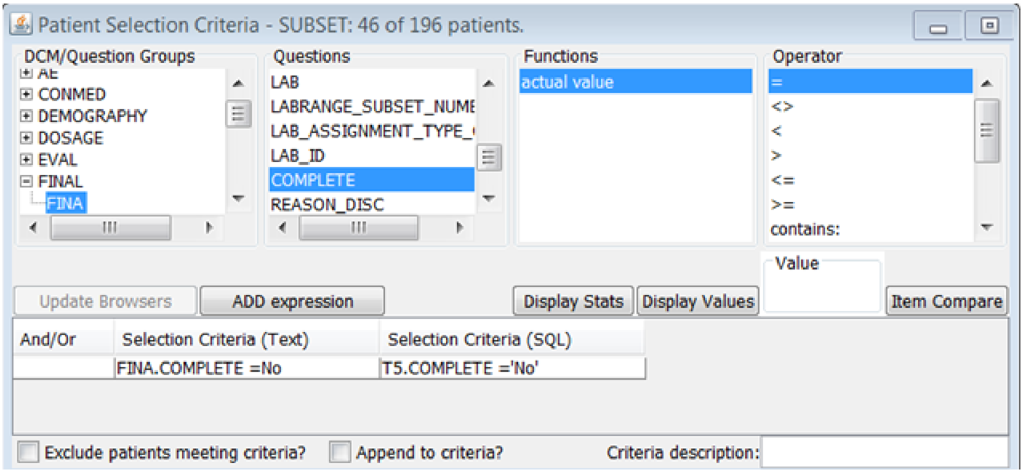
Column Percent is 6/**Col Sum** 25 = 24%.



CrossTab - All Patients

| | | | | |
|---|---|---|---|---|
| No. Cases | | | | |
| Percent | | | | |
| Row Percent | | | | |
| Col Percent | | | | |
| Sex | Black | Hispanic | White | Row Sum |
| Female | 6 | 1 | 28 | 35.00 |
| | 3.06 | 0.51 | 14.29 | 17.86 |
| | 17.14 | 2.86 | 80.00 | |
| | 24.00 | 8.33 | 17.61 | |
| Male | 19 | 11 | 131 | 161.00 |
| | 9.69 | 5.61 | 66.84 | 82.14 |
| | 11.80 | 6.83 | 81.37 | |
| | 76.00 | 91.67 | 82.39 | |
| Col Sum | 25.00 | 12.00 | 159.00 | 196.00 |
| | 12.76 | 6.12 | 81.12 | 100.00 |

To view the differences between the **Percent Denominator** options when the ‘Include Row%,Col%’ function is ON, apply the patient selection criteria for discontinued patients.



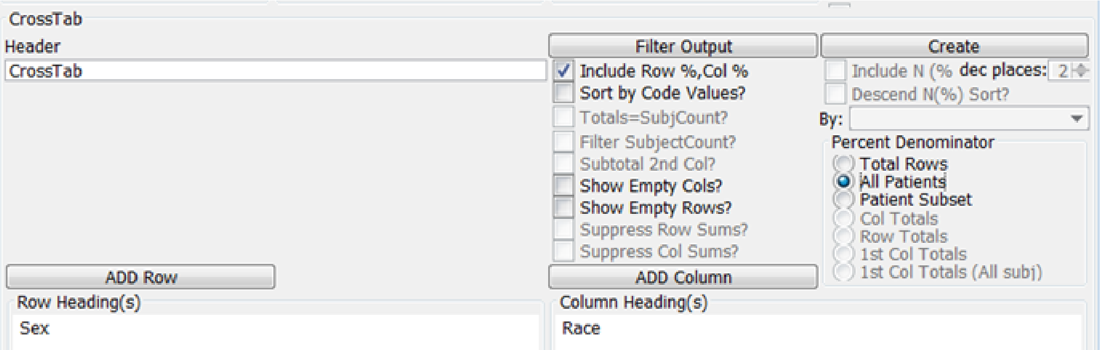
Patient Selection Criteria - SUBSET: 46 of 196 patients.

| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
| | FINA.COMPLETE =No | T5.COMPLETE ='No' |

☐ Exclude patients meeting criteria? ☐ Append to criteria? Criteria description:

The current patient selection criteria calculates the patient count for 46 discontinued cases. All crosstab cell percents are based on result of the patient selection criteria and where the Data Browser shows cases selected is 46. The Row Sum and Col Sum reflect the counts of the patient subset for Discontinued patients.

Next a crosstab is defined for ADD Row for Sex, ADD Column for Race. We will click the **Include Row%,Col%** box **ON** and calculate the different percentages by changing the percent denominator options from the default ‘Total Rows’, then change to ‘All Patients’ and again to ‘Patient Subset’.



CrossTab

Header
CrossTab

☑ Include Row %,Col %
☐ Sort by Code Values?
☐ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

☐ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

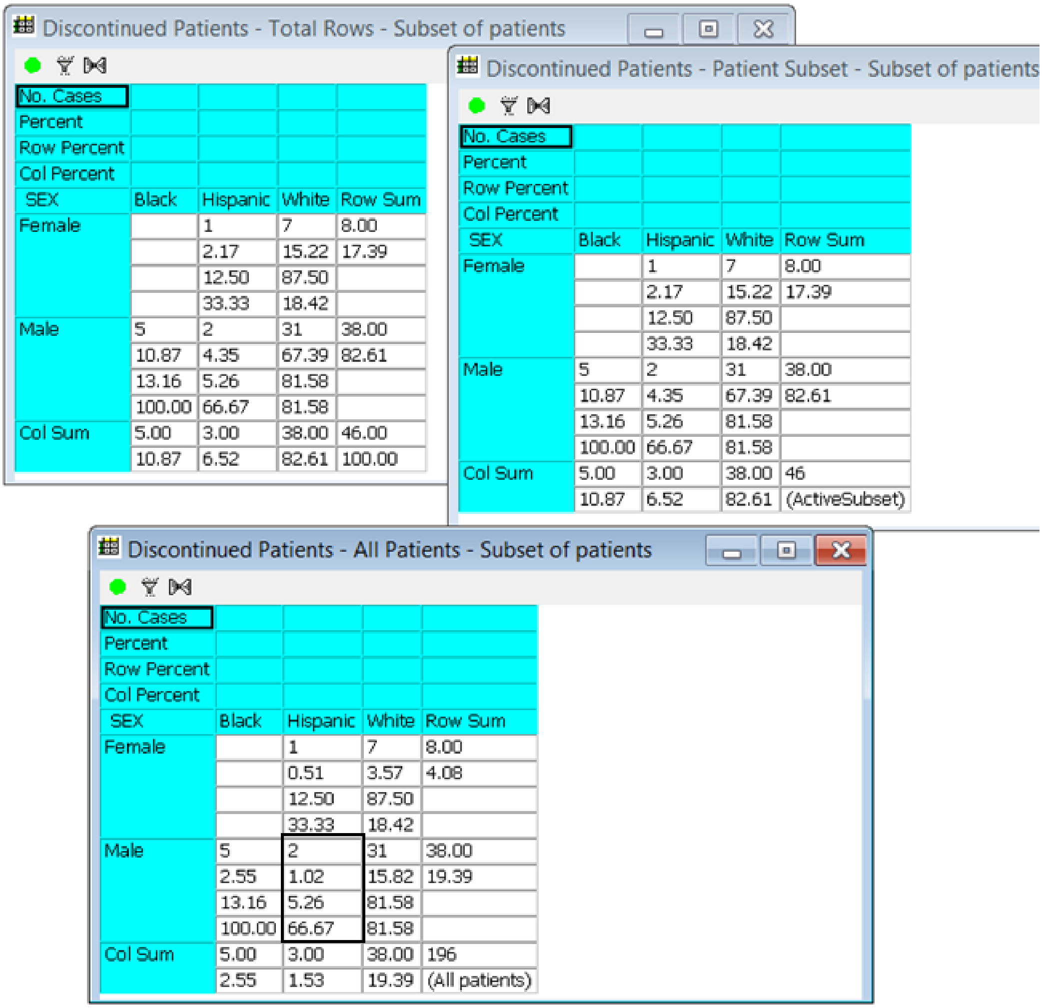
Percent Denominator
○ Total Rows
● All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s)
Sex

Column Heading(s)
Race

By applying the patient selection criteria the patient counts within the output of a crosstab are affected. The following crosstabs show the difference between the Percent Denominator options for ‘Total Rows’, ‘Patient Subset’ and ‘All Patients’. Observe the results for ‘Total Rows’ and ‘Patient Subset’ are the same for the Patient Selection Criteria patient count for 46 because the Demography panel is a single collection panel.

When you have the current patient selection criteria for ‘Discontinued Patients’ and choose the 'All Patients' option as the percent denominator, then the total is 196 patients in the study and all percents are based on that count.



Discontinued Patients - Total Rows - Subset of patients

| | | | | |
|---|---|---|---|---|
| No. Cases | | | | |
| Percent | | | | |
| Row Percent | | | | |
| Col Percent | | | | |
| SEX | Black | Hispanic | White | Row Sum |
| Female | | 1 | 7 | 8.00 |
| | | 2.17 | 15.22 | 17.39 |
| | | 12.50 | 87.50 | |
| | | 33.33 | 18.42 | |
| Male | 5 | 2 | 31 | 38.00 |
| | 10.87 | 4.35 | 67.39 | 82.61 |
| | 13.16 | 5.26 | 81.58 | |
| | 100.00 | 66.67 | 81.58 | |
| Col Sum | 5.00 | 3.00 | 38.00 | 46.00 |
| | 10.87 | 6.52 | 82.61 | 100.00 |

Discontinued Patients - Patient Subset - Subset of patients

| | | | | |
|---|---|---|---|---|
| No. Cases | | | | |
| Percent | | | | |
| Row Percent | | | | |
| Col Percent | | | | |
| SEX | Black | Hispanic | White | Row Sum |
| Female | | 1 | 7 | 8.00 |
| | | 2.17 | 15.22 | 17.39 |
| | | 12.50 | 87.50 | |
| | | 33.33 | 18.42 | |
| Male | 5 | 2 | 31 | 38.00 |
| | 10.87 | 4.35 | 67.39 | 82.61 |
| | 13.16 | 5.26 | 81.58 | |
| | 100.00 | 66.67 | 81.58 | |
| Col Sum | 5.00 | 3.00 | 38.00 | 46 |
| | 10.87 | 6.52 | 82.61 | (ActiveSubset) |

Discontinued Patients - All Patients - Subset of patients

| | | | | |
|---|---|---|---|---|
| No. Cases | | | | |
| Percent | | | | |
| Row Percent | | | | |
| Col Percent | | | | |
| SEX | Black | Hispanic | White | Row Sum |
| Female | | 1 | 7 | 8.00 |
| | | 0.51 | 3.57 | 4.08 |
| | | 12.50 | 87.50 | |
| | | 33.33 | 18.42 | |
| Male | 5 | 2 | 31 | 38.00 |
| | 2.55 | 1.02 | 15.82 | 19.39 |
| | 13.16 | 5.26 | 81.58 | |
| | 100.00 | 66.67 | 81.58 | |
| Col Sum | 5.00 | 3.00 | 38.00 | 196 |
| | 2.55 | 1.53 | 19.39 | (All patients) |

The example above for 2 Male Hispanic patients calculates as:

Percent within ‘All Patients’ is 2/196 = 1.02%.

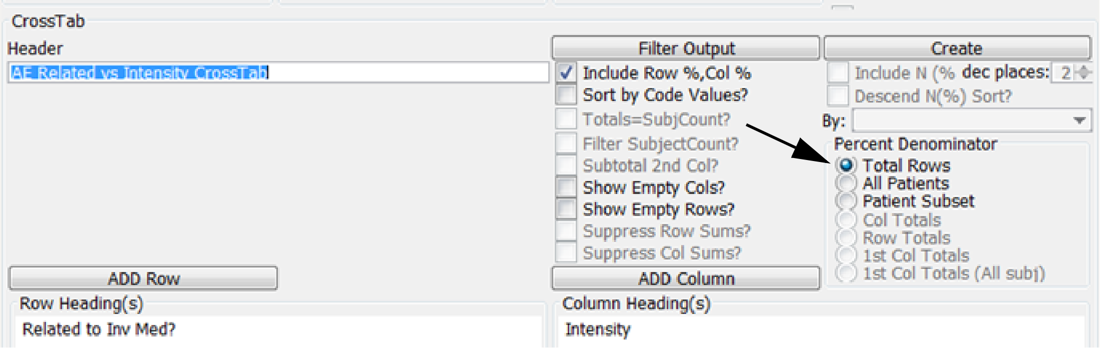
Row Percent is 2/Row Sum 38 = 5.26%.

Column Percent is 2/Col Sum 3 = 66.67%.

The Percent Denominator options become more evident if not all patients have entries in the CrossTab, for example not all patients reported Adverse Events. The percentages are based on the patients reported.

Then when you apply ‘Total Rows’ from all Adverse Events you wouldn't get a grand total of all patients but the total number of patients who had data in the CrossTab.

***No patient selection criteria was applied.***



CrossTab

Header
AE Related vs Intensity CrossTab

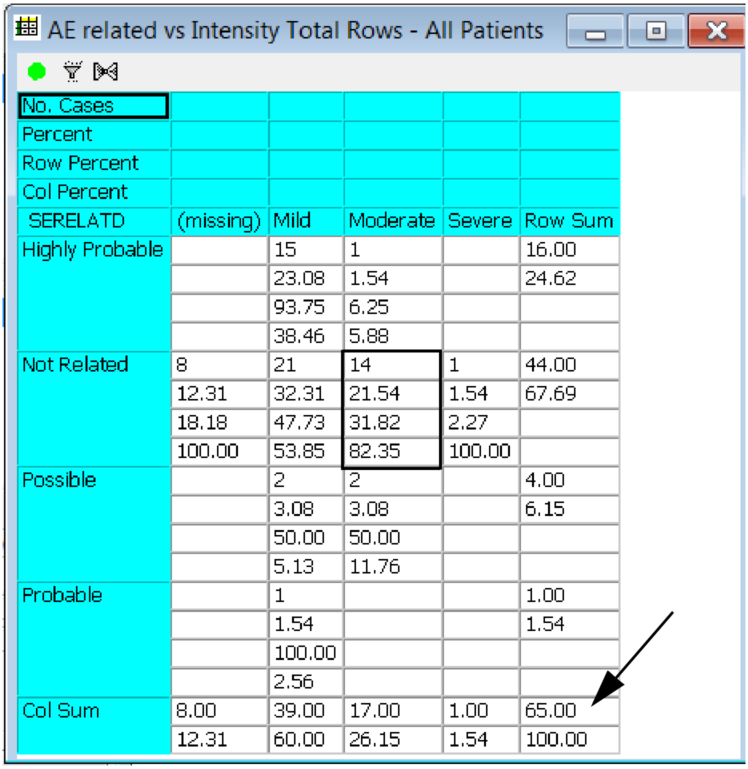
☑ Include Row %,Col %
☐ Sort by Code Values?
☐ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

☐ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

Percent Denominator
● Total Rows
○ All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s): Related to Inv Med?

Column Heading(s): Intensity



| No. Cases | | | | | |
|---|---|---|---|---|---|
| Percent | | | | | |
| Row Percent | | | | | |
| Col Percent | | | | | |
| SERELATD | (missing) | Mild | Moderate | Severe | Row Sum |
| Highly Probable | | 15 | 1 | | 16.00 |
| | | 23.08 | 1.54 | | 24.62 |
| | | 93.75 | 6.25 | | |
| | | 38.46 | 5.88 | | |
| Not Related | 8 | 21 | 14 | 1 | 44.00 |
| | 12.31 | 32.31 | 21.54 | 1.54 | 67.69 |
| | 18.18 | 47.73 | 31.82 | 2.27 | |
| | 100.00 | 53.85 | 82.35 | 100.00 | |
| Possible | | 2 | 2 | | 4.00 |
| | | 3.08 | 3.08 | | 6.15 |
| | | 50.00 | 50.00 | | |
| | | 5.13 | 11.76 | | |
| Probable | | 1 | | | 1.00 |
| | | 1.54 | | | 1.54 |
| | | 100.00 | | | |
| | | 2.56 | | | |
| Col Sum | 8.00 | 39.00 | 17.00 | 1.00 | 65.00 |
| | 12.31 | 60.00 | 26.15 | 1.54 | 100.00 |

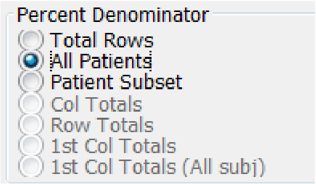
There are 65 patients who reported Adverse Events in the study. If we review the cell for 14 patients who reported Adverse Events as ‘Not Related’ and ‘Moderate’ the calculations are:

**Percent** is 14/**Total Row Sum** 65 = 21.54% patients with Moderate Adverse Events reported as Not Related.

**Row Percent** is 14/**Row Sum** 44 = 31.82%.

**Column Percent** is 14/**Total Col Sum** 17 = 82.35%.

Now compare the same crosstab with the percent denominator set for ‘All Patients’. The percentages are based on all patients in the study.



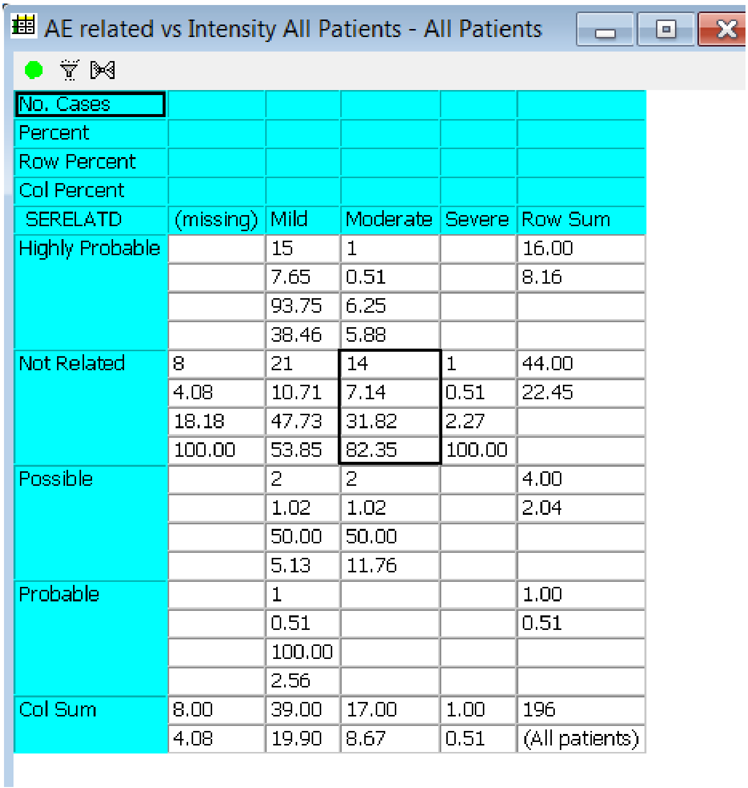
Percent Denominator

○ Total Rows
● All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

The percentages are based on all patients in the study which is 196. If we review the cell for 14 patients who reported Adverse Events as ‘Not Related’ and ‘Moderate’ the calculations are:

**Percent** is 14/**Total Row Sum** 196 = 7.14% patients with Moderate Adverse Events reported as Not Related.
**Row Percent** is 14/**Total Row Sum** 44 = 31.82%.
**Column Percent** is 14/**Total Col Sum** 17 = 82.35%.

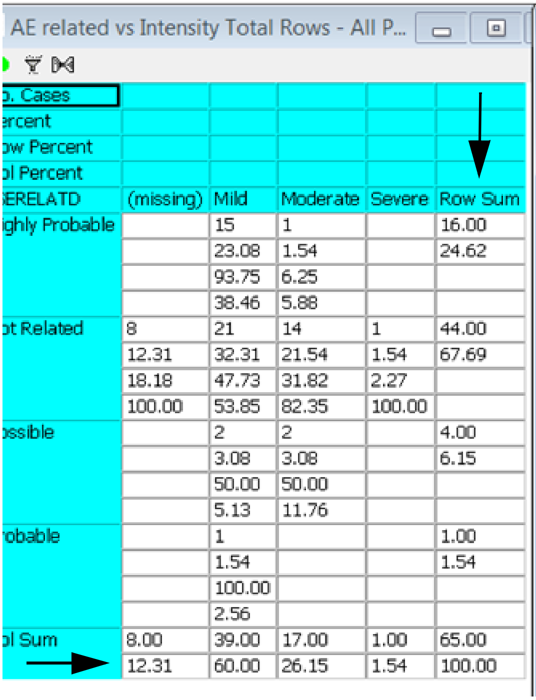
So within the cell the Percent result changes and Row Percent and Column Percent remain the same as the ‘Total Rows’ option.



AE related vs Intensity All Patients - All Patients

| | | | | | |
|---|---|---|---|---|---|
| No. Cases | | | | | |
| Percent | | | | | |
| Row Percent | | | | | |
| Col Percent | | | | | |
| SERELATD | (missing) | Mild | Moderate | Severe | Row Sum |
| Highly Probable | | 15 | 1 | | 16.00 |
| | | 7.65 | 0.51 | | 8.16 |
| | | 93.75 | 6.25 | | |
| | | 38.46 | 5.88 | | |
| Not Related | 8 | 21 | 14 | 1 | 44.00 |
| | 4.08 | 10.71 | 7.14 | 0.51 | 22.45 |
| | 18.18 | 47.73 | 31.82 | 2.27 | |
| | 100.00 | 53.85 | 82.35 | 100.00 | |
| Possible | | 2 | 2 | | 4.00 |
| | | 1.02 | 1.02 | | 2.04 |
| | | 50.00 | 50.00 | | |
| | | 5.13 | 11.76 | | |
| Probable | | 1 | | | 1.00 |
| | | 0.51 | | | 0.51 |
| | | 100.00 | | | |
| | | 2.56 | | | |
| Col Sum | 8.00 | 39.00 | 17.00 | 1.00 | 196 |
| | 4.08 | 19.90 | 8.67 | 0.51 | (All patients) |

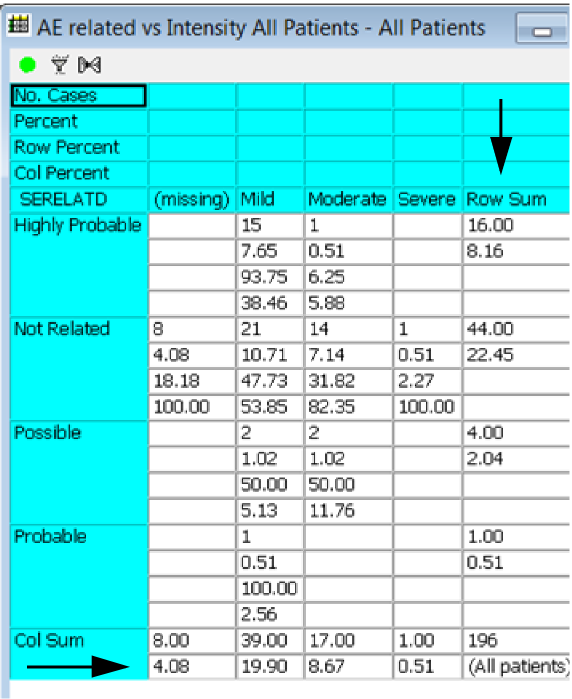
However, what changes significantly are the Total Row Sum percents and the Total Col Sum percents when you compare the crosstab options.



AE related vs Intensity Total Rows - All P...

o. Cases
ercent
ow Percent
ol Percent

| ERELATD | (missing) | Mild | Moderate | Severe | Row Sum |
|---|---|---|---|---|---|
| ighly Probable |  | 15 | 1 |  | 16.00 |
|  |  | 23.08 | 1.54 |  | 24.62 |
|  |  | 93.75 | 6.25 |  |  |
|  |  | 38.46 | 5.88 |  |  |
| ot Related | 8 | 21 | 14 | 1 | 44.00 |
|  | 12.31 | 32.31 | 21.54 | 1.54 | 67.69 |
|  | 18.18 | 47.73 | 31.82 | 2.27 |  |
|  | 100.00 | 53.85 | 82.35 | 100.00 |  |
| ossible |  | 2 | 2 |  | 4.00 |
|  |  | 3.08 | 3.08 |  | 6.15 |
|  |  | 50.00 | 50.00 |  |  |
|  |  | 5.13 | 11.76 |  |  |
| obable |  | 1 |  |  | 1.00 |
|  |  | 1.54 |  |  | 1.54 |
|  |  | 100.00 |  |  |  |
|  |  | 2.56 |  |  |  |
| ol Sum | 8.00 | 39.00 | 17.00 | 1.00 | 65.00 |
|  | 12.31 | 60.00 | 26.15 | 1.54 | 100.00 |



AE related vs Intensity All Patients - All Patients

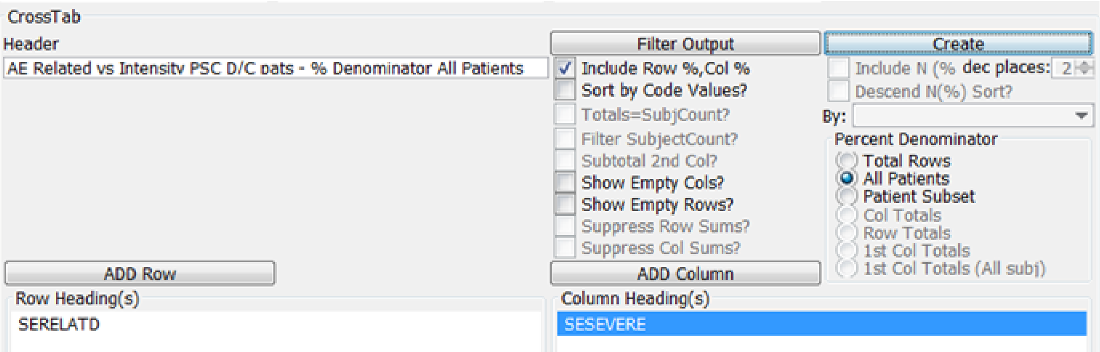
No. Cases
Percent
Row Percent
Col Percent

| SERELATD | (missing) | Mild | Moderate | Severe | Row Sum |
|---|---|---|---|---|---|
| Highly Probable |  | 15 | 1 |  | 16.00 |
|  |  | 7.65 | 0.51 |  | 8.16 |
|  |  | 93.75 | 6.25 |  |  |
|  |  | 38.46 | 5.88 |  |  |
| Not Related | 8 | 21 | 14 | 1 | 44.00 |
|  | 4.08 | 10.71 | 7.14 | 0.51 | 22.45 |
|  | 18.18 | 47.73 | 31.82 | 2.27 |  |
|  | 100.00 | 53.85 | 82.35 | 100.00 |  |
| Possible |  | 2 | 2 |  | 4.00 |
|  |  | 1.02 | 1.02 |  | 2.04 |
|  |  | 50.00 | 50.00 |  |  |
|  |  | 5.13 | 11.76 |  |  |
| Probable |  | 1 |  |  | 1.00 |
|  |  | 0.51 |  |  | 0.51 |
|  |  | 100.00 |  |  |  |
|  |  | 2.56 |  |  |  |
| Col Sum | 8.00 | 39.00 | 17.00 | 1.00 | 196 |
|  | 4.08 | 19.90 | 8.67 | 0.51 | (All patients) |

## *Include Row%,Col% with selection criteria*

The percent denominator allows you to see the percents relative to the entire population (All Patients) or a particular patient selection criteria (Patient Subset). You are able to see the 'incidence' percentage relative to the entire population.

In following example, the same crosstab definition is created with the patient selection criteria applied for ‘Discontinued Patients’.



Header: AE Related vs Intensitv PSC D/C pats - % Denominator All Patients

☑ Include Row %,Col %
☐ Sort by Code Values?
☐ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

☐ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

Percent Denominator
○ Total Rows
● All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s): SERELATD

Column Heading(s): SESEVERE

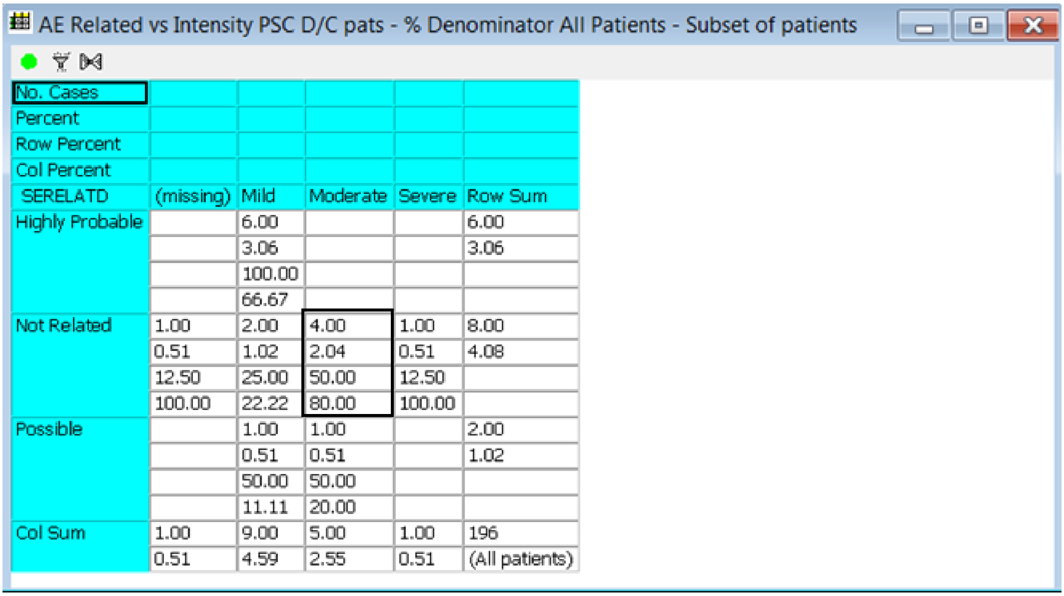
When ‘All Patients’ is selected for the **Percent Denominator** the following results display for the active patient selection criteria of ‘Discontinued Patients’. There are 16 patients who reported Adverse Events and discontinued from the study. The CrossTab for ‘Include Row%, Col%’ results will change dependent upon the percent denominator option selected.

Now if we review the patients who reported Adverse Events as ‘Not Related’ and ‘Moderate’, there are 4 patients as a result of the current patient selection criteria and the results are as follows:

**Percent** is 4/**Total Row Sum** 196 = 2.04% patients with Moderate Adverse Events reported as Not Related.

**Row Percent** is 4/**Row Sum** 8 = 50%.

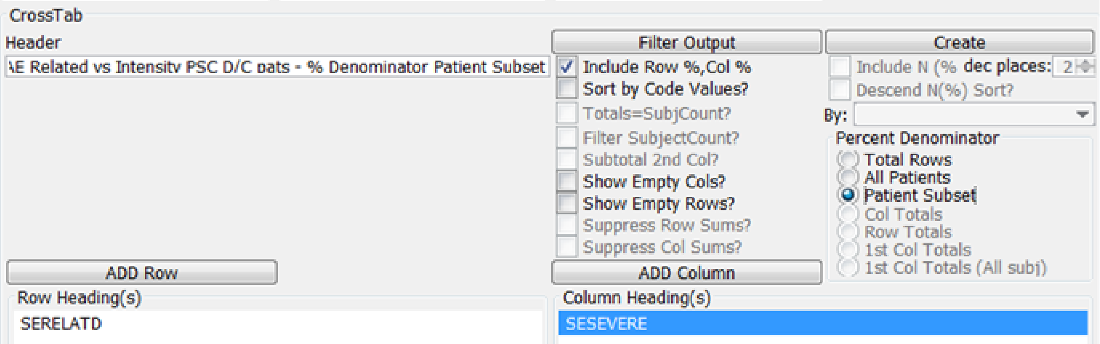
**Column Percent** is 4/**Col Sum** 5 = 80%.



AE Related vs Intensity PSC D/C pats - % Denominator All Patients - Subset of patients

| No. Cases | | | | | |
|---|---|---|---|---|---|
| Percent | | | | | |
| Row Percent | | | | | |
| Col Percent | | | | | |
| SERELATD | (missing) | Mild | Moderate | Severe | Row Sum |
| Highly Probable | | 6.00 | | | 6.00 |
| | | 3.06 | | | 3.06 |
| | | 100.00 | | | |
| | | 66.67 | | | |
| Not Related | 1.00 | 2.00 | 4.00 | 1.00 | 8.00 |
| | 0.51 | 1.02 | 2.04 | 0.51 | 4.08 |
| | 12.50 | 25.00 | 50.00 | 12.50 | |
| | 100.00 | 22.22 | 80.00 | 100.00 | |
| Possible | | 1.00 | 1.00 | | 2.00 |
| | | 0.51 | 0.51 | | 1.02 |
| | | 50.00 | 50.00 | | |
| | | 11.11 | 20.00 | | |
| Col Sum | 1.00 | 9.00 | 5.00 | 1.00 | 196 |
| | 0.51 | 4.59 | 2.55 | 0.51 | (All patients) |

If ‘Patient Subset’ is selected for the **Percent Denominator**, the following results display where the current patient selection criteria for discontinued patients is 46.



Header

E Related vs Intensity PSC D/C pats - % Denominator Patient Subset

☑ Include Row %,Col %
☐ Sort by Code Values?
☐ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

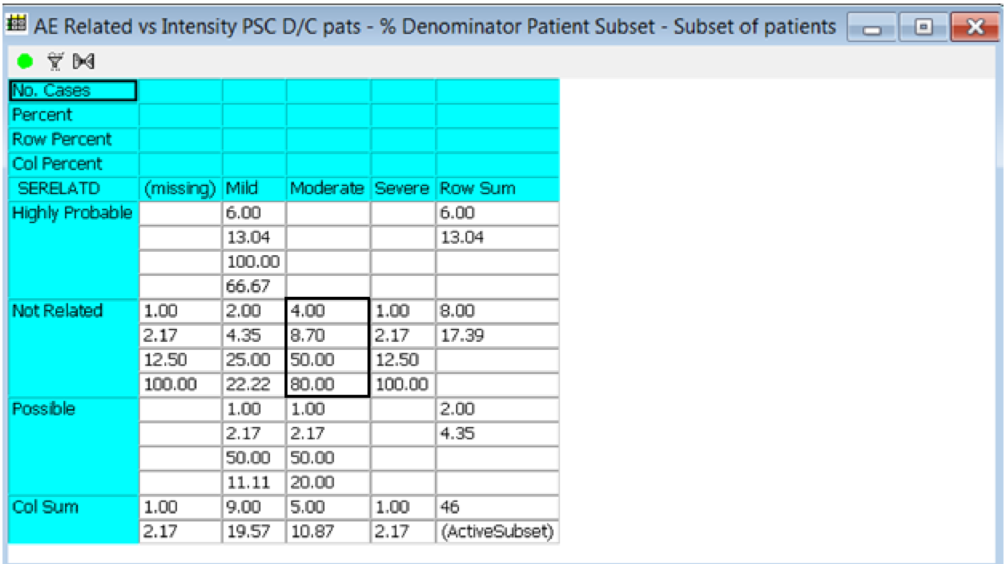
☐ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

Percent Denominator
○ Total Rows
○ All Patients
● Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s): SERELATD

Column Heading(s): SESEVERE

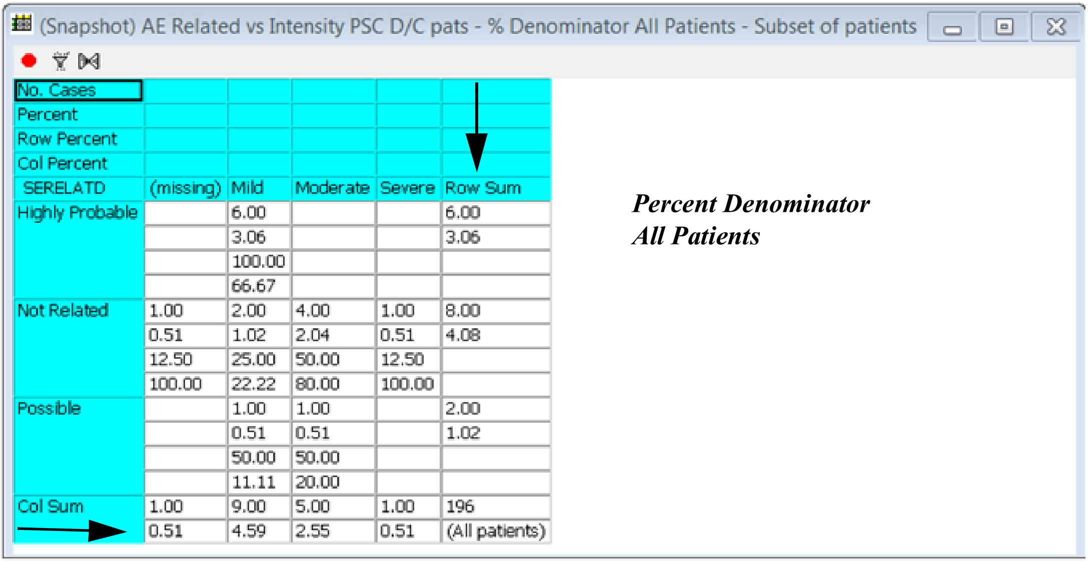
The cell the Percent result changes for 4/46 = 8.70% and Row Percent and Column Percent remain the same.



AE Related vs Intensity PSC D/C pats - % Denominator Patient Subset - Subset of patients

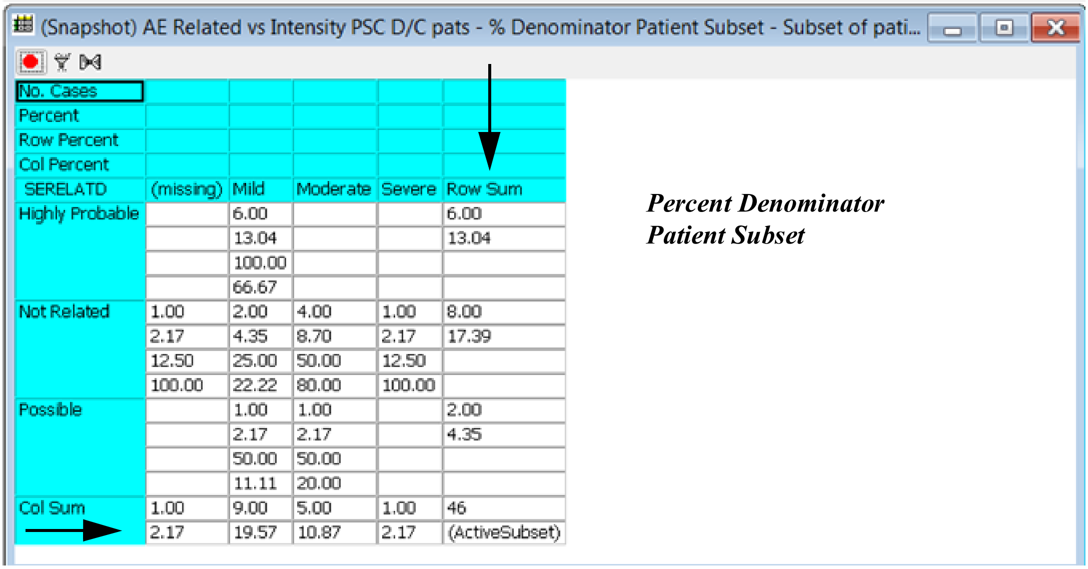
| | | | | | |
|---|---|---|---|---|---|
| No. Cases | | | | | |
| Percent | | | | | |
| Row Percent | | | | | |
| Col Percent | | | | | |
| SERELATD | (missing) | Mild | Moderate | Severe | Row Sum |
| Highly Probable | | 6.00 | | | 6.00 |
| | | 13.04 | | | 13.04 |
| | | 100.00 | | | |
| | | 66.67 | | | |
| Not Related | 1.00 | 2.00 | 4.00 | 1.00 | 8.00 |
| | 2.17 | 4.35 | 8.70 | 2.17 | 17.39 |
| | 12.50 | 25.00 | 50.00 | 12.50 | |
| | 100.00 | 22.22 | 80.00 | 100.00 | |
| Possible | | 1.00 | 1.00 | | 2.00 |
| | | 2.17 | 2.17 | | 4.35 |
| | | 50.00 | 50.00 | | |
| | | 11.11 | 20.00 | | |
| Col Sum | 1.00 | 9.00 | 5.00 | 1.00 | 46 |
| | 2.17 | 19.57 | 10.87 | 2.17 | (ActiveSubset) |

However, what changes significantly are the Total Row Sum percents and the Total Col Sum percents when you compare the crosstab options.


(Snapshot) AE Related vs Intensity PSC D/C pats - % Denominator All Patients - Subset of patients

| No. Cases | | | | | |
|---|---|---|---|---|---|
| Percent | | | | | |
| Row Percent | | | | | |
| Col Percent | | | | | |
| SERELATD | (missing) | Mild | Moderate | Severe | Row Sum |
| Highly Probable | | 6.00 | | | 6.00 |
| | | 3.06 | | | 3.06 |
| | | 100.00 | | | |
| | | 66.67 | | | |
| Not Related | 1.00 | 2.00 | 4.00 | 1.00 | 8.00 |
| | 0.51 | 1.02 | 2.04 | 0.51 | 4.08 |
| | 12.50 | 25.00 | 50.00 | 12.50 | |
| | 100.00 | 22.22 | 80.00 | 100.00 | |
| Possible | | 1.00 | 1.00 | | 2.00 |
| | | 0.51 | 0.51 | | 1.02 |
| | | 50.00 | 50.00 | | |
| | | 11.11 | 20.00 | | |
| Col Sum | 1.00 | 9.00 | 5.00 | 1.00 | 196 |
| | 0.51 | 4.59 | 2.55 | 0.51 | (All patients) |

***Percent Denominator***
***All Patients***


(Snapshot) AE Related vs Intensity PSC D/C pats - % Denominator Patient Subset - Subset of pati...

| No. Cases | | | | | |
|---|---|---|---|---|---|
| Percent | | | | | |
| Row Percent | | | | | |
| Col Percent | | | | | |
| SERELATD | (missing) | Mild | Moderate | Severe | Row Sum |
| Highly Probable | | 6.00 | | | 6.00 |
| | | 13.04 | | | 13.04 |
| | | 100.00 | | | |
| | | 66.67 | | | |
| Not Related | 1.00 | 2.00 | 4.00 | 1.00 | 8.00 |
| | 2.17 | 4.35 | 8.70 | 2.17 | 17.39 |
| | 12.50 | 25.00 | 50.00 | 12.50 | |
| | 100.00 | 22.22 | 80.00 | 100.00 | |
| Possible | | 1.00 | 1.00 | | 2.00 |
| | | 2.17 | 2.17 | | 4.35 |
| | | 50.00 | 50.00 | | |
| | | 11.11 | 20.00 | | |
| Col Sum | 1.00 | 9.00 | 5.00 | 1.00 | 46 |
| | 2.17 | 19.57 | 10.87 | 2.17 | (ActiveSubset) |

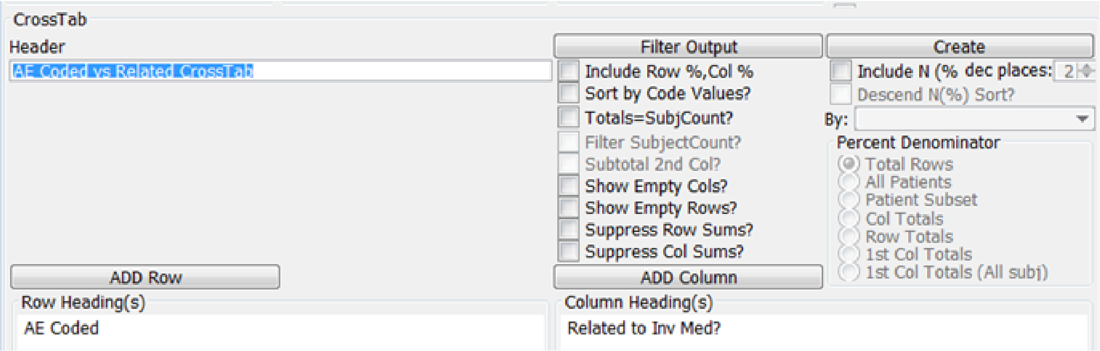
***Percent Denominator***
***Patient Subset***

## *Totals Subject Count*

The **Totals Subject Count** option calculates row and column sums by the number of subjects and not the number of records. It can be demonstrated if not all patients have Adverse Events reported or where patients had multiple occurrences of the same events.

The **Totals Subject Count** may be used in conjunction with **Include N(%)** cell statistics function where additional **Percent Denominator** options for ‘Col Totals’ and ‘Row Totals’ become available.

In the following examples, there is **no** patient selection criteria applied and the default is all current patients. First, we will view the crosstab results when the **Totals Subject Count** option is set OFF (not checked).



Header: AE Coded vs Related CrossTab

☐ Include Row %,Col %
☐ Sort by Code Values?
☐ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

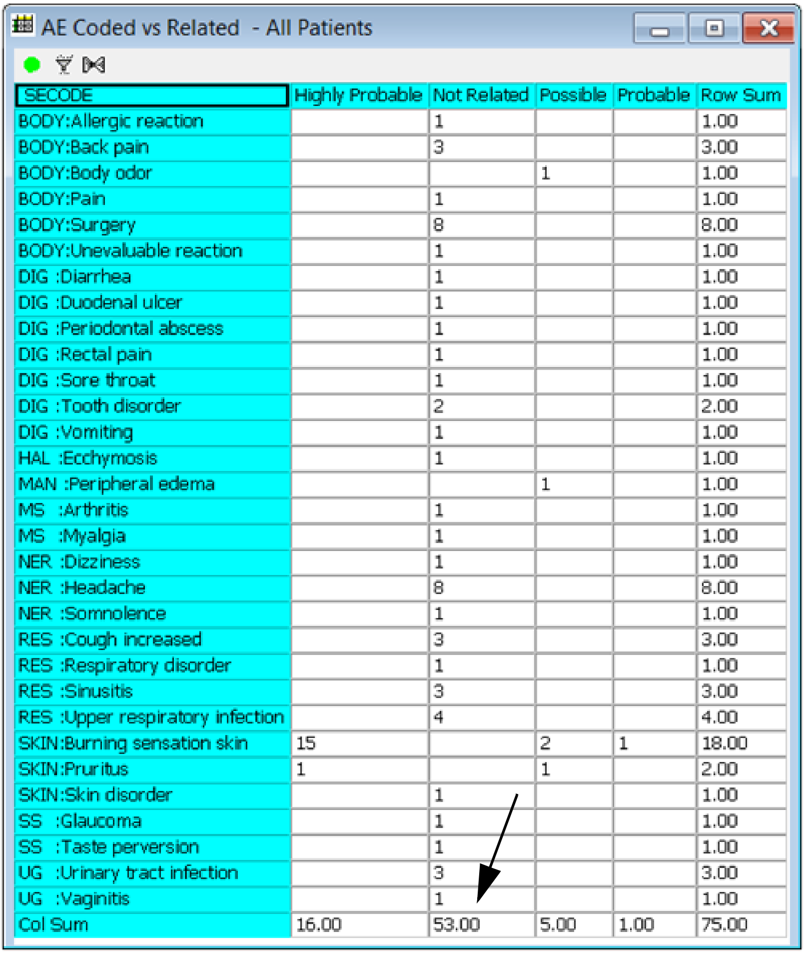
☐ Include N (% dec places: 2
☐ Descend N(%) Sort?

● Total Rows
○ All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s): AE Coded

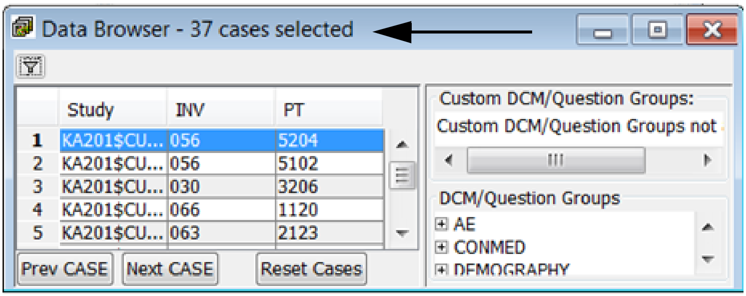
Column Heading(s): Related to Inv Med?

The crosstab results show individual column counts for ‘Related to Inv Med?’. If you open the Data Browser and select the *Col Sum of 53* for ‘Not Related’, the Data Browser updates to 37 cases meaning some patients reported the same Adverse Events multiple times.



AE Coded vs Related - All Patients

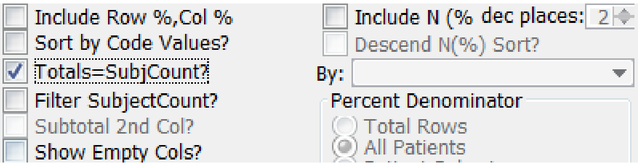
| SECODE | Highly Probable | Not Related | Possible | Probable | Row Sum |
|---|---|---|---|---|---|
| BODY:Allergic reaction | | 1 | | | 1.00 |
| BODY:Back pain | | 3 | | | 3.00 |
| BODY:Body odor | | | 1 | | 1.00 |
| BODY:Pain | | 1 | | | 1.00 |
| BODY:Surgery | | 8 | | | 8.00 |
| BODY:Unevaluable reaction | | 1 | | | 1.00 |
| DIG :Diarrhea | | 1 | | | 1.00 |
| DIG :Duodenal ulcer | | 1 | | | 1.00 |
| DIG :Periodontal abscess | | 1 | | | 1.00 |
| DIG :Rectal pain | | 1 | | | 1.00 |
| DIG :Sore throat | | 1 | | | 1.00 |
| DIG :Tooth disorder | | 2 | | | 2.00 |
| DIG :Vomiting | | 1 | | | 1.00 |
| HAL :Ecchymosis | | 1 | | | 1.00 |
| MAN :Peripheral edema | | | 1 | | 1.00 |
| MS :Arthritis | | 1 | | | 1.00 |
| MS :Myalgia | | 1 | | | 1.00 |
| NER :Dizziness | | 1 | | | 1.00 |
| NER :Headache | | 8 | | | 8.00 |
| NER :Somnolence | | 1 | | | 1.00 |
| RES :Cough increased | | 3 | | | 3.00 |
| RES :Respiratory disorder | | 1 | | | 1.00 |
| RES :Sinusitis | | 3 | | | 3.00 |
| RES :Upper respiratory infection | | 4 | | | 4.00 |
| SKIN:Burning sensation skin | 15 | | 2 | 1 | 18.00 |
| SKIN:Pruritus | 1 | | 1 | | 2.00 |
| SKIN:Skin disorder | | 1 | | | 1.00 |
| SS :Glaucoma | | 1 | | | 1.00 |
| SS :Taste perversion | | 1 | | | 1.00 |
| UG :Urinary tract infection | | 3 | | | 3.00 |
| UG :Vaginitis | | 1 | | | 1.00 |
| Col Sum | 16.00 | 53.00 | 5.00 | 1.00 | 75.00 |



Data Browser - 37 cases selected

| | Study | INV | PT |
|---|---|---|---|
| 1 | KA201$CU... | 056 | 5204 |
| 2 | KA201$CU... | 056 | 5102 |
| 3 | KA201$CU... | 030 | 3206 |
| 4 | KA201$CU... | 066 | 1120 |
| 5 | KA201$CU... | 063 | 2123 |

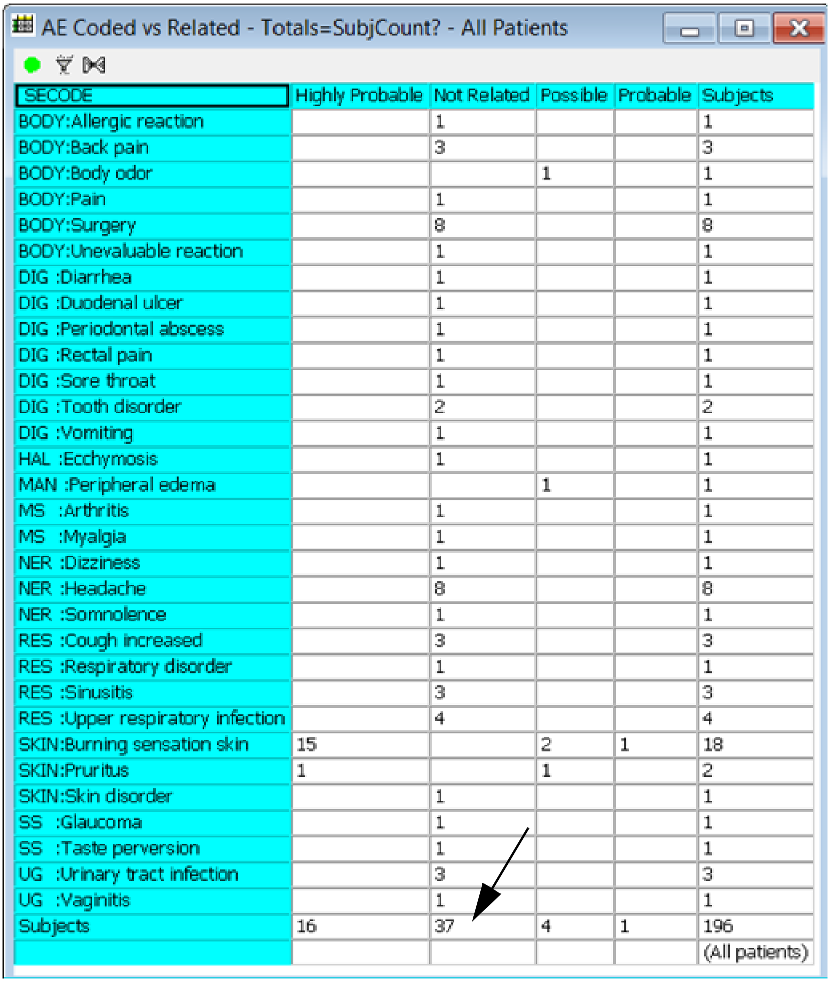
When the ‘Totals=SubjCount?’ is turned **ON**, the updated results show the actual number of patients who reported Adverse Events.



☐ Include Row %,Col %
☐ Sort by Code Values?
☑ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?

☐ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:
Percent Denominator
○ Total Rows
● All Patients

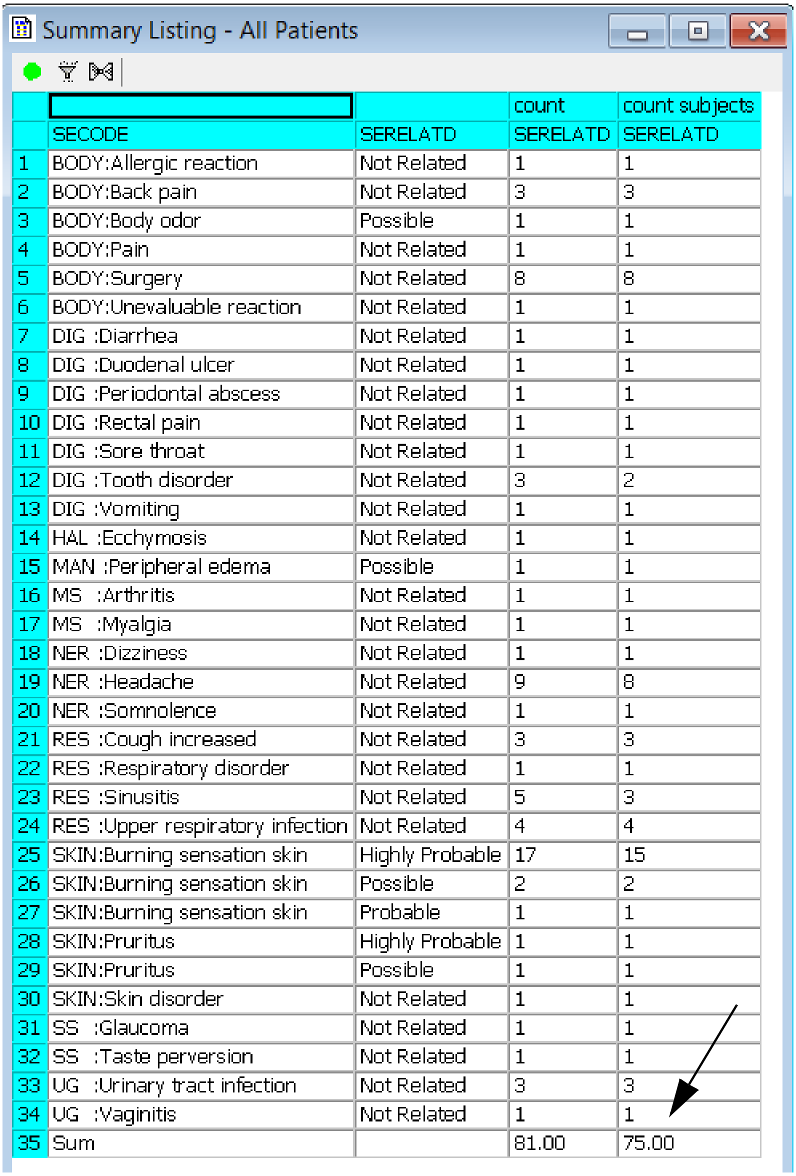
This function consolidates the patient counts where the same patient reported multiple occurrences for the same Adverse Event. The ‘Totals=SubjCount?’ subject count matches the 37 Cases Selected in the Data Browser.



AE Coded vs Related - Totals=SubjCount? - All Patients

| SECODE | Highly Probable | Not Related | Possible | Probable | Subjects |
|---|---|---|---|---|---|
| BODY:Allergic reaction | | 1 | | | 1 |
| BODY:Back pain | | 3 | | | 3 |
| BODY:Body odor | | | 1 | | 1 |
| BODY:Pain | | 1 | | | 1 |
| BODY:Surgery | | 8 | | | 8 |
| BODY:Unevaluable reaction | | 1 | | | 1 |
| DIG :Diarrhea | | 1 | | | 1 |
| DIG :Duodenal ulcer | | 1 | | | 1 |
| DIG :Periodontal abscess | | 1 | | | 1 |
| DIG :Rectal pain | | 1 | | | 1 |
| DIG :Sore throat | | 1 | | | 1 |
| DIG :Tooth disorder | | 2 | | | 2 |
| DIG :Vomiting | | 1 | | | 1 |
| HAL :Ecchymosis | | 1 | | | 1 |
| MAN :Peripheral edema | | | 1 | | 1 |
| MS :Arthritis | | 1 | | | 1 |
| MS :Myalgia | | 1 | | | 1 |
| NER :Dizziness | | 1 | | | 1 |
| NER :Headache | | 8 | | | 8 |
| NER :Somnolence | | 1 | | | 1 |
| RES :Cough increased | | 3 | | | 3 |
| RES :Respiratory disorder | | 1 | | | 1 |
| RES :Sinusitis | | 3 | | | 3 |
| RES :Upper respiratory infection | | 4 | | | 4 |
| SKIN:Burning sensation skin | 15 | | 2 | 1 | 18 |
| SKIN:Pruritus | 1 | | 1 | | 2 |
| SKIN:Skin disorder | | 1 | | | 1 |
| SS :Glaucoma | | 1 | | | 1 |
| SS :Taste perversion | | 1 | | | 1 |
| UG :Urinary tract infection | | 3 | | | 3 |
| UG :Vaginitis | | 1 | | | 1 |
| Subjects | 16 | 37 | 4 | 1 | 196 |
| | | | | | (All patients) |

If you had defined a Summary listing for AE coded with ‘count’ and ‘count subjects’, the ‘event count’ is 81 and the ‘count subjects’ is 75 where the patient identifier is counted multiple times for multiple Adverse Events reported.

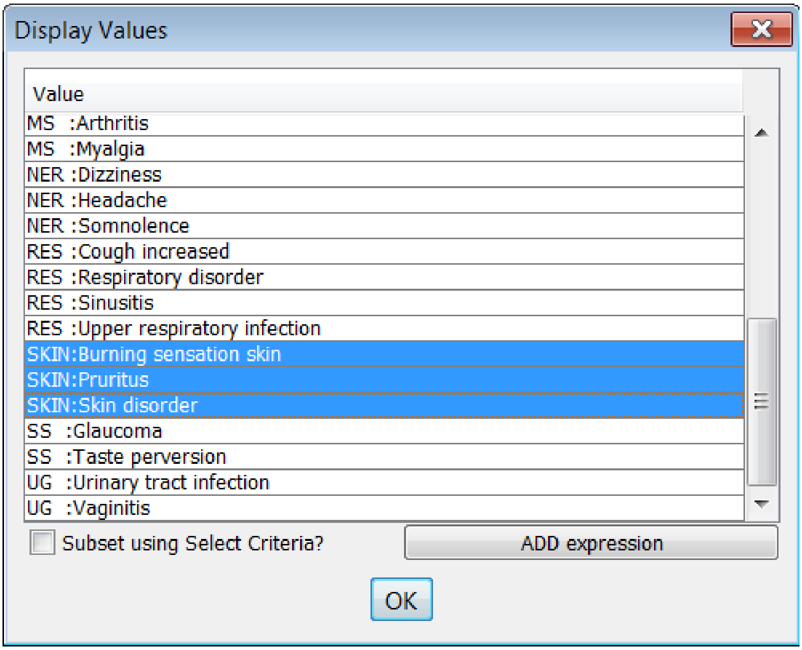


| | | | count | count subjects |
|---|---|---|---|---|
| | SECODE | SERELATD | SERELATD | SERELATD |
| 1 | BODY:Allergic reaction | Not Related | 1 | 1 |
| 2 | BODY:Back pain | Not Related | 3 | 3 |
| 3 | BODY:Body odor | Possible | 1 | 1 |
| 4 | BODY:Pain | Not Related | 1 | 1 |
| 5 | BODY:Surgery | Not Related | 8 | 8 |
| 6 | BODY:Unevaluable reaction | Not Related | 1 | 1 |
| 7 | DIG :Diarrhea | Not Related | 1 | 1 |
| 8 | DIG :Duodenal ulcer | Not Related | 1 | 1 |
| 9 | DIG :Periodontal abscess | Not Related | 1 | 1 |
| 10 | DIG :Rectal pain | Not Related | 1 | 1 |
| 11 | DIG :Sore throat | Not Related | 1 | 1 |
| 12 | DIG :Tooth disorder | Not Related | 3 | 2 |
| 13 | DIG :Vomiting | Not Related | 1 | 1 |
| 14 | HAL :Ecchymosis | Not Related | 1 | 1 |
| 15 | MAN :Peripheral edema | Possible | 1 | 1 |
| 16 | MS :Arthritis | Not Related | 1 | 1 |
| 17 | MS :Myalgia | Not Related | 1 | 1 |
| 18 | NER :Dizziness | Not Related | 1 | 1 |
| 19 | NER :Headache | Not Related | 9 | 8 |
| 20 | NER :Somnolence | Not Related | 1 | 1 |
| 21 | RES :Cough increased | Not Related | 3 | 3 |
| 22 | RES :Respiratory disorder | Not Related | 1 | 1 |
| 23 | RES :Sinusitis | Not Related | 5 | 3 |
| 24 | RES :Upper respiratory infection | Not Related | 4 | 4 |
| 25 | SKIN:Burning sensation skin | Highly Probable | 17 | 15 |
| 26 | SKIN:Burning sensation skin | Possible | 2 | 2 |
| 27 | SKIN:Burning sensation skin | Probable | 1 | 1 |
| 28 | SKIN:Pruritus | Highly Probable | 1 | 1 |
| 29 | SKIN:Pruritus | Possible | 1 | 1 |
| 30 | SKIN:Skin disorder | Not Related | 1 | 1 |
| 31 | SS :Glaucoma | Not Related | 1 | 1 |
| 32 | SS :Taste perversion | Not Related | 1 | 1 |
| 33 | UG :Urinary tract infection | Not Related | 3 | 3 |
| 34 | UG :Vaginitis | Not Related | 1 | 1 |
| 35 | Sum | | 81.00 | 75.00 |

## *Filter Subject Count*

In addition, you can use the **Filter Subject Count** feature to calculate Row and Column Sums by the number of subjects based on the current output filter and obtain subject counts.

The next example defines a Filter Output for Adverse Events coded for SKIN body system as a multiple selection filter definition. There is **no** patient selection criteria applied to the following examples.

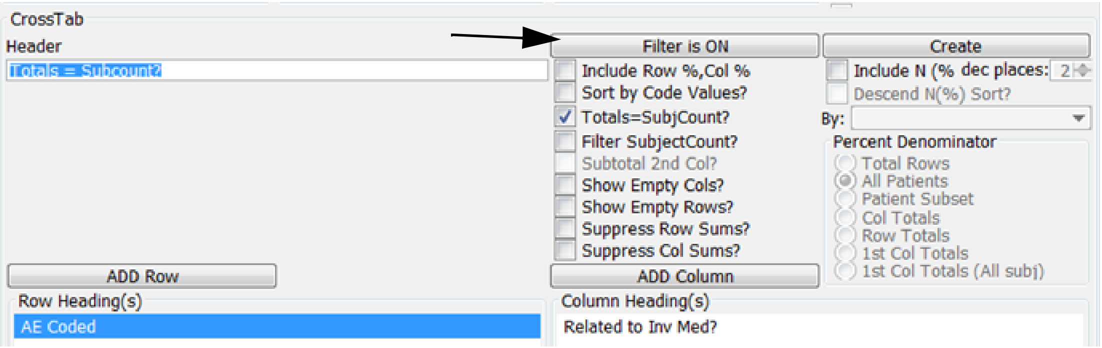


Display Values

| Value |
|---|
| MS :Arthritis |
| MS :Myalgia |
| NER :Dizziness |
| NER :Headache |
| NER :Somnolence |
| RES :Cough increased |
| RES :Respiratory disorder |
| RES :Sinusitis |
| RES :Upper respiratory infection |
| SKIN:Burning sensation skin |
| SKIN:Pruritus |
| SKIN:Skin disorder |
| SS :Glaucoma |
| SS :Taste perversion |
| UG :Urinary tract infection |
| UG :Vaginitis |

☐ Subset using Select Criteria?

The Filter Output button status is now updated to ‘Filter is ON’ with the ‘Filter SubjectCount?’ left unchecked.



CrossTab

Header
Totals = Subcount?

☐ Include Row %,Col %
☐ Sort by Code Values?
☑ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

☐ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

Percent Denominator
○ Total Rows
● All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s): AE Coded

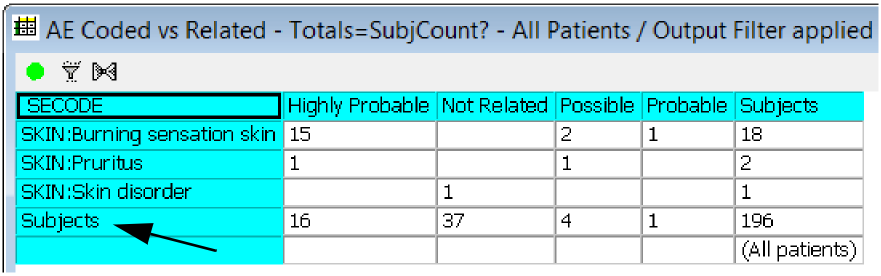
Column Heading(s): Related to Inv Med?

Next compare the subject row results when ‘Filter SubjectCount?’ feature is checked ON/OFF.

The Crosstab results with the ‘Filter is ON’ and ‘Filter SubjectCount?’ unchecked displays only the Adverse Events included in the SKIN body system.

Observe that the ‘Subjects’ counts display for all available patients who reported Adverse Events. The output filter hasn’t been applied yet to the ‘Subjects’ counts.

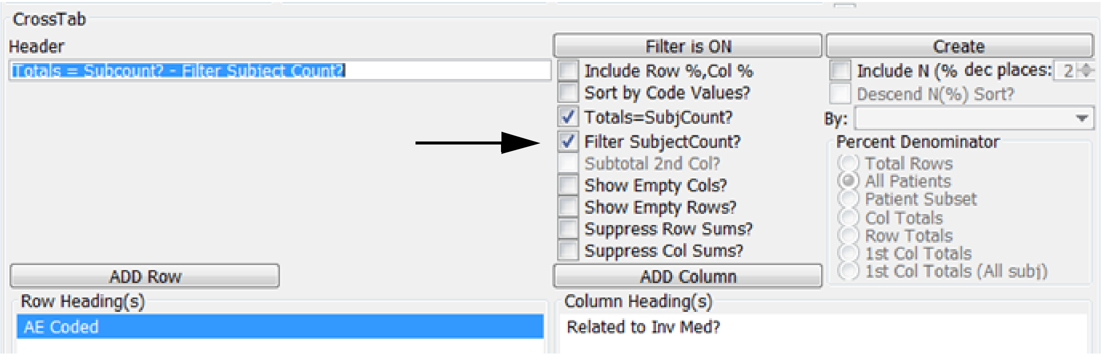
The crosstab heading defaults the current patient population status as ‘All Patients’ and the filter status as ‘Output Filter applied’. This information is an automatic heading default to assist in describing the crosstab contents.



AE Coded vs Related - Totals=SubjCount? - All Patients / Output Filter applied

| SECODE | Highly Probable | Not Related | Possible | Probable | Subjects |
|---|---|---|---|---|---|
| SKIN:Burning sensation skin | 15 | | 2 | 1 | 18 |
| SKIN:Pruritus | 1 | | 1 | | 2 |
| SKIN:Skin disorder | | 1 | | | 1 |
| Subjects | 16 | 37 | 4 | 1 | 196 |
| | | | | | (All patients) |

Next we will view the subject row results when the ‘Filter Subject Count?’ check box is turned ON.



Header: Totals = Subcount? - Filter Subject Count?

☐ Include Row %,Col %
☐ Sort by Code Values?
☑ Totals=SubjCount?
☑ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

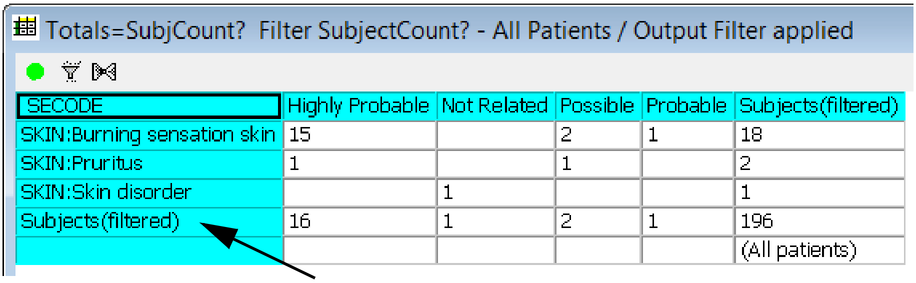
☐ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

Percent Denominator
○ Total Rows
● All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s): AE Coded

Column Heading(s): Related to Inv Med?

Now the results display the actual number of patients who reported Adverse Events for SKIN. See the **Subjects (filtered)** row is updated with new subject counts where the filter is now applied to the subject counts.

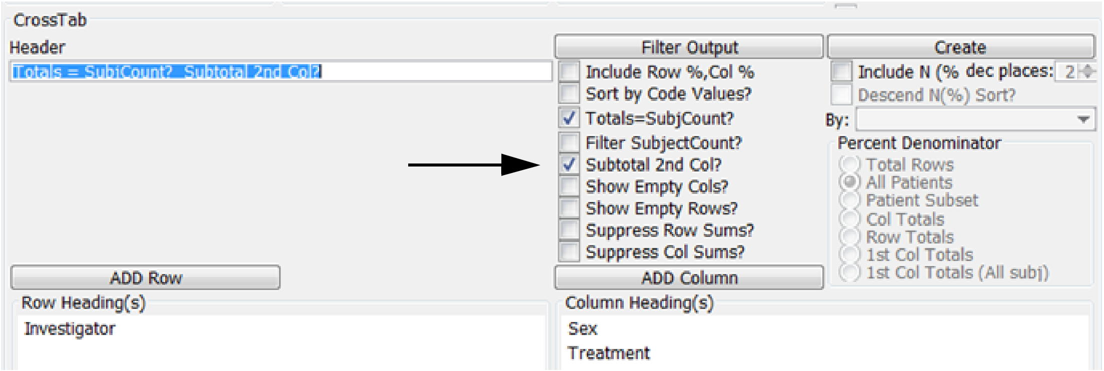

Totals=SubjCount?  Filter SubjectCount? - All Patients / Output Filter applied

| SECODE | Highly Probable | Not Related | Possible | Probable | Subjects(filtered) |
|---|---|---|---|---|---|
| SKIN:Burning sensation skin | 15 | | 2 | 1 | 18 |
| SKIN:Pruritus | 1 | | 1 | | 2 |
| SKIN:Skin disorder | | 1 | | | 1 |
| Subjects(filtered) | 16 | 1 | 2 | 1 | 196 |
| | | | | | (All patients) |

## *Subtotal 2nd column*

You can have multiple headers by selecting another item and clicking ADD Column, where the item is added as a “sub-column” of the first column item. When using multiple column headings there are additional options available for ‘**Subtotals 2nd Column**’.

To use the ‘Subtotal 2nd Col?’ option, you must have two columns added to your crosstab. Selecting the **Subtotals 2nd Column** calculates the subtotal for the first column header and places it as an additional header in the 2nd column. This count is best used in conjunction with the ‘Totals=Subjcount?’ option. When checked, an intermediate ‘Total’ column for the 2nd column item values is added.


CrossTab

Header
Totals = SubjCount?  Subtotal 2nd Col?

☐ Include Row %,Col %
☐ Sort by Code Values?
☑ Totals=SubjCount?
☐ Filter SubjectCount?
☑ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

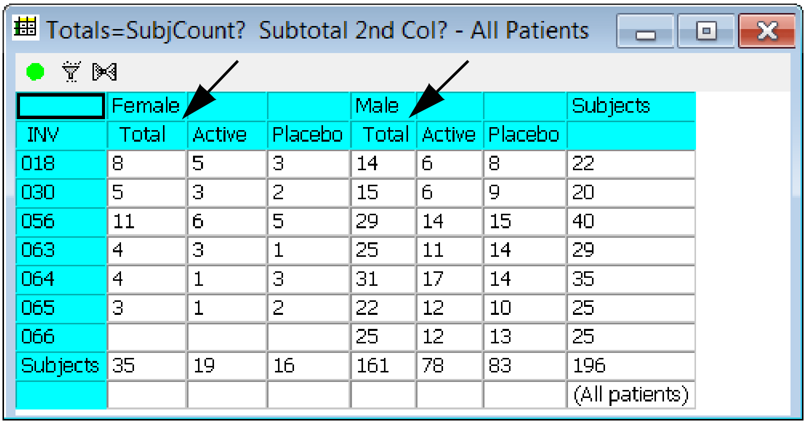
☐ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

Percent Denominator
○ Total Rows
● All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s)
Investigator

Column Heading(s)
Sex
Treatment

In this example, notice that under the Female and Male first column values there is a 'Total' column showing the total number of Female patients in each investigator. If you don't check the 'Subtotal 2nd Col?' option you will see the 'No' and 'Yes' nested values under each sex data item. The 'Subtotal 2nd Col?' option adds the 'Total' column.



|  | Female |  |  | Male |  |  | Subjects |
|---|---|---|---|---|---|---|---|
| INV | Total | Active | Placebo | Total | Active | Placebo |  |
| 018 | 8 | 5 | 3 | 14 | 6 | 8 | 22 |
| 030 | 5 | 3 | 2 | 15 | 6 | 9 | 20 |
| 056 | 11 | 6 | 5 | 29 | 14 | 15 | 40 |
| 063 | 4 | 3 | 1 | 25 | 11 | 14 | 29 |
| 064 | 4 | 1 | 3 | 31 | 17 | 14 | 35 |
| 065 | 3 | 1 | 2 | 22 | 12 | 10 | 25 |
| 066 |  |  |  | 25 | 12 | 13 | 25 |
| Subjects | 35 | 19 | 16 | 161 | 78 | 83 | 196 |
|  |  |  |  |  |  |  | (All patients) |

When 'Subtotal 2nd Col?' option is used in conjunction with **Include N(%) function** there is an option for selecting the sort value by the first column with the 'Descend Sort'. The Percent Denominator allows for using the First Column or just the Column Totals as well as the standard options.

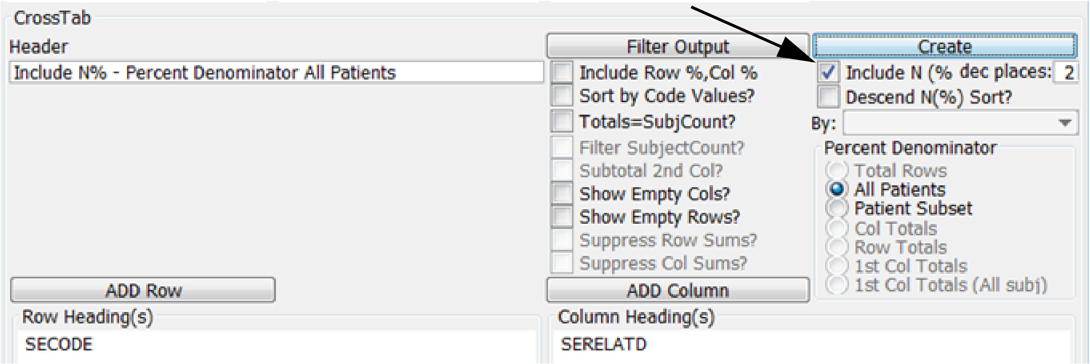
## *Include N% function*

The **Include N(%)** function only uses the total patient population as the **Percent Denominator** based on ‘All Patients or ‘Patient Subset’ where the default is ‘All Patients’.

The default number of decimal places for percentages is 1 rather than the prior default of 2.

Newly-built Crosstabs will now start out with 1/one N (%) decimal place. **This change does not impact any saved Crosstabs**, their Include N (%) decimal places will be whatever they were saved with.

Also, the Include N(%) function is mutually exclusive from the Include Row%, Col% function, so it is an either/or condition.



CrossTab

Header
Include N% - Percent Denominator All Patients

☐ Include Row %,Col %
☐ Sort by Code Values?
☐ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

☑ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

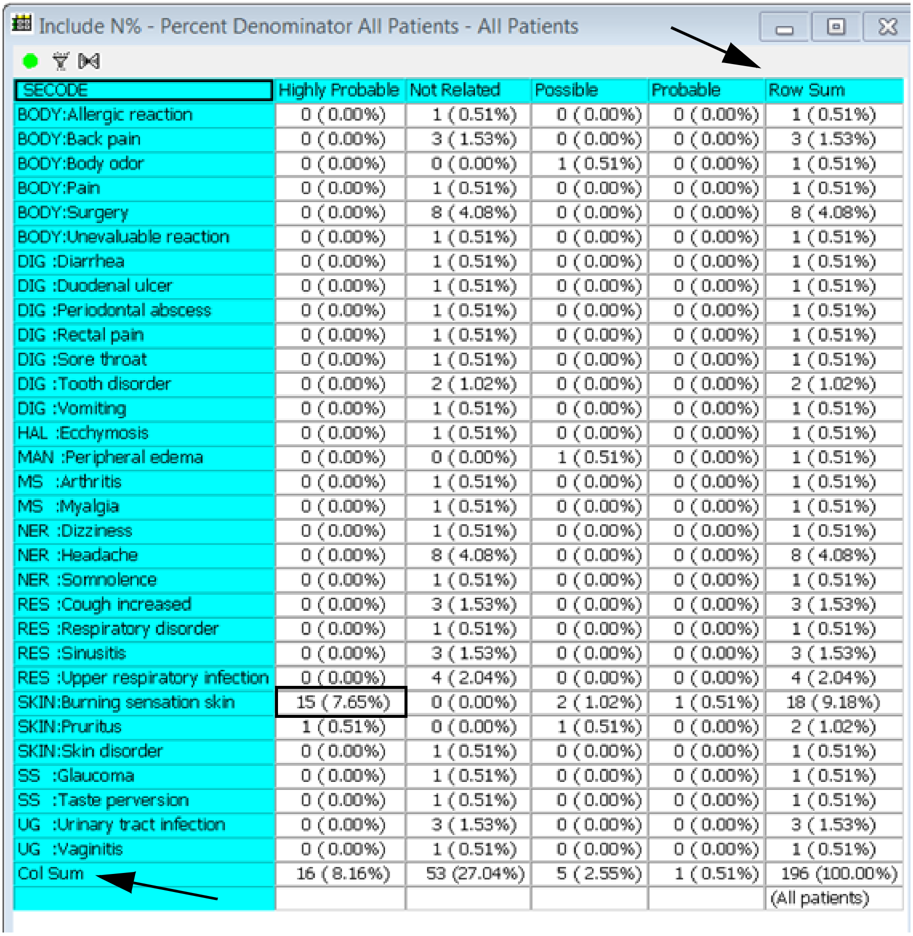
Percent Denominator
○ Total Rows
● All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s)
SECODE

Column Heading(s)
SERELATD

In this crosstab example for AE Coded versus Related to Inv Med, there was **no** patient selection criteria applied. The CrossTab displays only the percent result for each cell count against the current patient population.

The cell statistics for the 15 patients who reported ‘Burning sensation skin’ as ‘Highly Probable’ against ‘All Patients’ calculates as 15/196 = 7.65% against all of the adverse events reported.

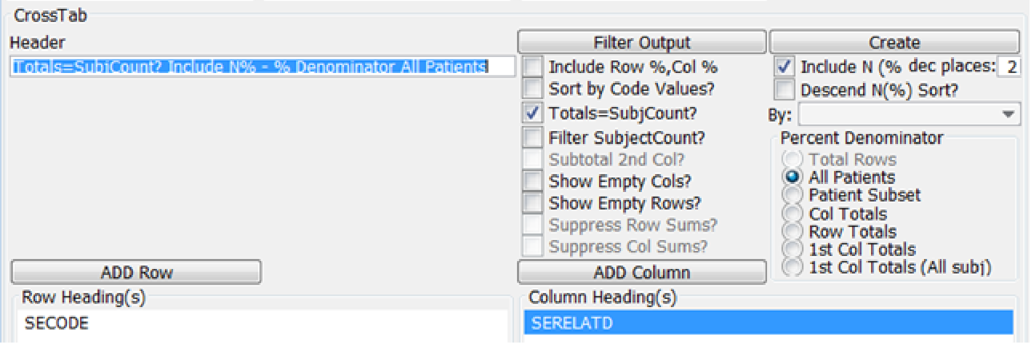


| SECODE | Highly Probable | Not Related | Possible | Probable | Row Sum |
|---|---|---|---|---|---|
| BODY:Allergic reaction | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| BODY:Back pain | 0 ( 0.00%) | 3 ( 1.53%) | 0 ( 0.00%) | 0 ( 0.00%) | 3 ( 1.53%) |
| BODY:Body odor | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 1 ( 0.51%) |
| BODY:Pain | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| BODY:Surgery | 0 ( 0.00%) | 8 ( 4.08%) | 0 ( 0.00%) | 0 ( 0.00%) | 8 ( 4.08%) |
| BODY:Unevaluable reaction | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| DIG :Diarrhea | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| DIG :Duodenal ulcer | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| DIG :Periodontal abscess | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| DIG :Rectal pain | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| DIG :Sore throat | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| DIG :Tooth disorder | 0 ( 0.00%) | 2 ( 1.02%) | 0 ( 0.00%) | 0 ( 0.00%) | 2 ( 1.02%) |
| DIG :Vomiting | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| HAL :Ecchymosis | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| MAN :Peripheral edema | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 1 ( 0.51%) |
| MS :Arthritis | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| MS :Myalgia | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| NER :Dizziness | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| NER :Headache | 0 ( 0.00%) | 8 ( 4.08%) | 0 ( 0.00%) | 0 ( 0.00%) | 8 ( 4.08%) |
| NER :Somnolence | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| RES :Cough increased | 0 ( 0.00%) | 3 ( 1.53%) | 0 ( 0.00%) | 0 ( 0.00%) | 3 ( 1.53%) |
| RES :Respiratory disorder | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| RES :Sinusitis | 0 ( 0.00%) | 3 ( 1.53%) | 0 ( 0.00%) | 0 ( 0.00%) | 3 ( 1.53%) |
| RES :Upper respiratory infection | 0 ( 0.00%) | 4 ( 2.04%) | 0 ( 0.00%) | 0 ( 0.00%) | 4 ( 2.04%) |
| SKIN:Burning sensation skin | 15 ( 7.65%) | 0 ( 0.00%) | 2 ( 1.02%) | 1 ( 0.51%) | 18 ( 9.18%) |
| SKIN:Pruritus | 1 ( 0.51%) | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 2 ( 1.02%) |
| SKIN:Skin disorder | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| SS :Glaucoma | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| SS :Taste perversion | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| UG :Urinary tract infection | 0 ( 0.00%) | 3 ( 1.53%) | 0 ( 0.00%) | 0 ( 0.00%) | 3 ( 1.53%) |
| UG :Vaginitis | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| Col Sum | 16 ( 8.16%) | 53 (27.04%) | 5 ( 2.55%) | 1 ( 0.51%) | 196 (100.00%) |
| | | | | | (All patients) |

Observe the labels for ‘Col Sum’ and ‘Row Sum’. When you check ON the option for ‘Totals=SubjCount?’ only the unique patients are counted who reported Adverse Events. This option removes counting the same patients multiple times if they reported multiple adverse events. If you click the column cell for 53 patients with the Data Browser open, the actual patient count is 37 unique patients identified.

## *Include N% and Totals subject count*

If you select the **Include N(%)** function in conjunction with the 'Totals=Subjcount?' function there are more options available for the **Percent Denominator**. The following crosstab has selected both the 'Include (N)%' and 'Totals=SubCount?' functions as checked On with the Percent Denominator set for 'All Patients'. There is no patient selection criteria applied.


CrossTab

Header: Totals=SubjCount? Include N% - % Denominator All Patients

☐ Include Row %,Col %
☐ Sort by Code Values?
☑ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

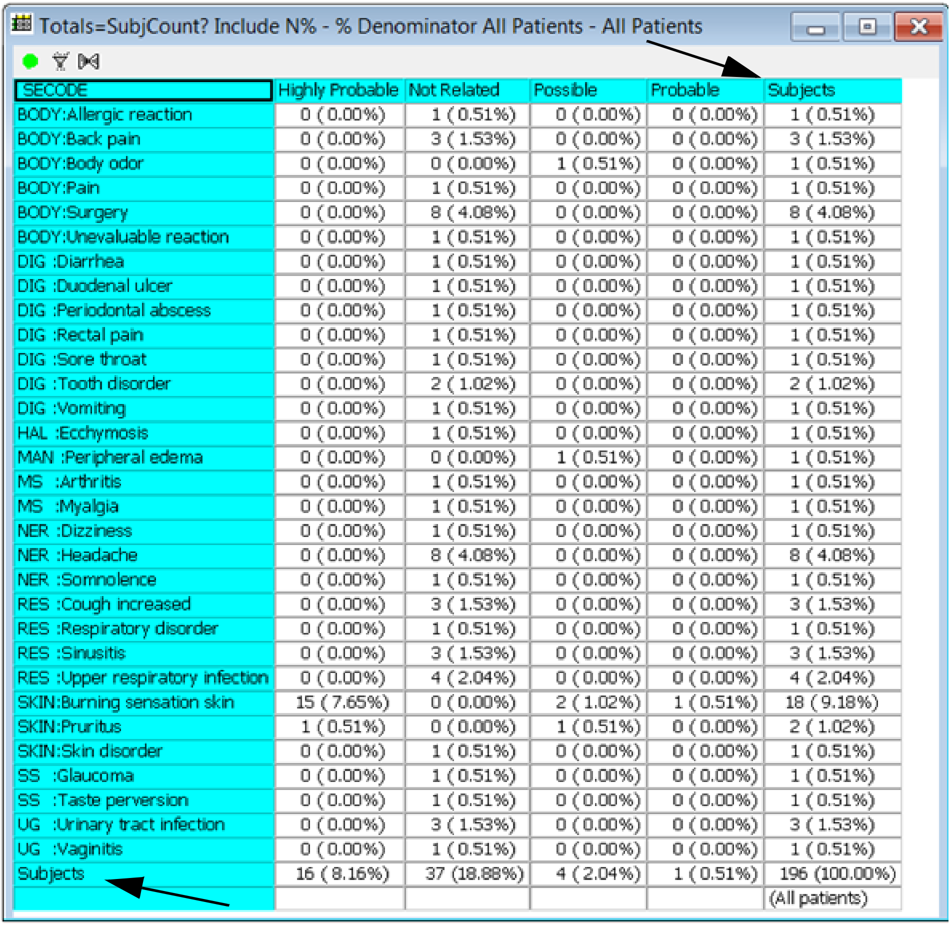
☑ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

Percent Denominator
○ Total Rows
● All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s): SECODE

Column Heading(s): SERELATD

Now the labels display as ‘Subjects’ when the ‘Totals=SubjCount?’ is checked ON. If you click the highlighted subject cell for 37 patients with the Data Browser open, the actual patient count is 37 which matches the actual number of patients who reported Adverse Events.

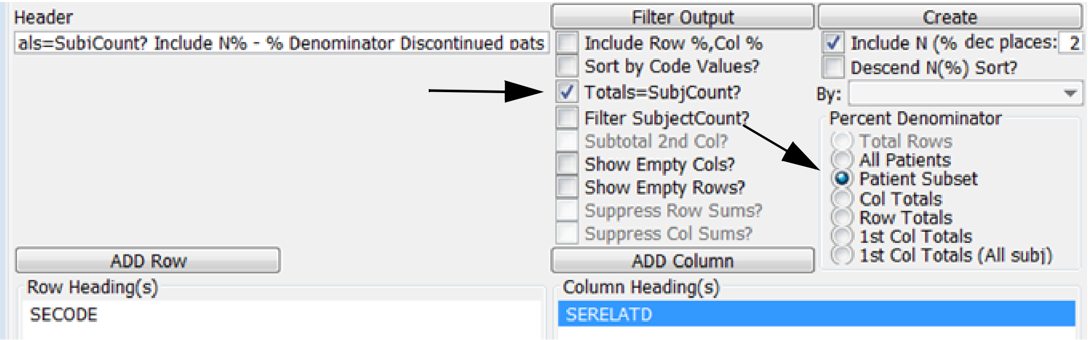


Totals=SubjCount? Include N% - % Denominator All Patients - All Patients

| SECODE | Highly Probable | Not Related | Possible | Probable | Subjects |
|---|---|---|---|---|---|
| BODY:Allergic reaction | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| BODY:Back pain | 0 ( 0.00%) | 3 ( 1.53%) | 0 ( 0.00%) | 0 ( 0.00%) | 3 ( 1.53%) |
| BODY:Body odor | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 1 ( 0.51%) |
| BODY:Pain | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| BODY:Surgery | 0 ( 0.00%) | 8 ( 4.08%) | 0 ( 0.00%) | 0 ( 0.00%) | 8 ( 4.08%) |
| BODY:Unevaluable reaction | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| DIG :Diarrhea | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| DIG :Duodenal ulcer | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| DIG :Periodontal abscess | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| DIG :Rectal pain | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| DIG :Sore throat | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| DIG :Tooth disorder | 0 ( 0.00%) | 2 ( 1.02%) | 0 ( 0.00%) | 0 ( 0.00%) | 2 ( 1.02%) |
| DIG :Vomiting | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| HAL :Ecchymosis | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| MAN :Peripheral edema | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 1 ( 0.51%) |
| MS :Arthritis | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| MS :Myalgia | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| NER :Dizziness | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| NER :Headache | 0 ( 0.00%) | 8 ( 4.08%) | 0 ( 0.00%) | 0 ( 0.00%) | 8 ( 4.08%) |
| NER :Somnolence | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| RES :Cough increased | 0 ( 0.00%) | 3 ( 1.53%) | 0 ( 0.00%) | 0 ( 0.00%) | 3 ( 1.53%) |
| RES :Respiratory disorder | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| RES :Sinusitis | 0 ( 0.00%) | 3 ( 1.53%) | 0 ( 0.00%) | 0 ( 0.00%) | 3 ( 1.53%) |
| RES :Upper respiratory infection | 0 ( 0.00%) | 4 ( 2.04%) | 0 ( 0.00%) | 0 ( 0.00%) | 4 ( 2.04%) |
| SKIN:Burning sensation skin | 15 ( 7.65%) | 0 ( 0.00%) | 2 ( 1.02%) | 1 ( 0.51%) | 18 ( 9.18%) |
| SKIN:Pruritus | 1 ( 0.51%) | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 2 ( 1.02%) |
| SKIN:Skin disorder | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| SS :Glaucoma | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| SS :Taste perversion | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| UG :Urinary tract infection | 0 ( 0.00%) | 3 ( 1.53%) | 0 ( 0.00%) | 0 ( 0.00%) | 3 ( 1.53%) |
| UG :Vaginitis | 0 ( 0.00%) | 1 ( 0.51%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 0.51%) |
| Subjects | 16 ( 8.16%) | 37 (18.88%) | 4 ( 2.04%) | 1 ( 0.51%) | 196 (100.00%) |
|  |  |  |  |  | (All patients) |

### *Include N% Patient Subset*

Next the same crosstab is created with the patient selection criteria for 'Discontinued Patients' applied. Both the 'Include (N)%' and 'Totals=SubCount?' functions are selected with the **Percent Denominator** set for 'Patient Subset' which results in 46 cases.



Header
als=SubjCount? Include N% - % Denominator Discontinued pats

☐ Include Row %,Col %
☐ Sort by Code Values?
☑ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

☑ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

Percent Denominator
○ Total Rows
○ All Patients
● Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

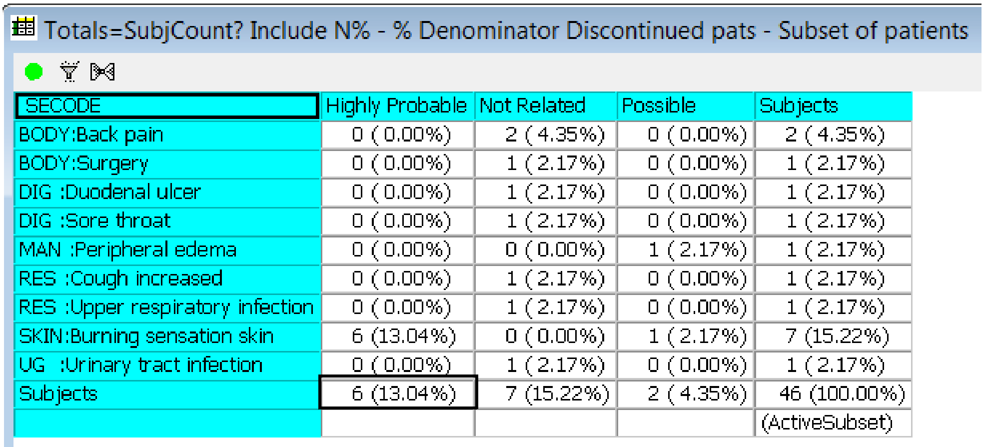
Row Heading(s)
SECODE

Column Heading(s)
SERELATD

The Active Subset count for 46 is displayed and percentages are now based on the revised counts in a single cell to the patient subset.

The individual cell statistics are calculated for the Active Subset as discontinued patients. The subject counts represent unique patients

The revised cell statistics are now 6 patients in the patient subset who discontinued the study and reported 'Burning sensation skin' as 'Highly Probable'. The cell statistic is calculated against 'Active Subset' as 6/46 = 13.04% against the adverse events reported in the 'Active Subset'.



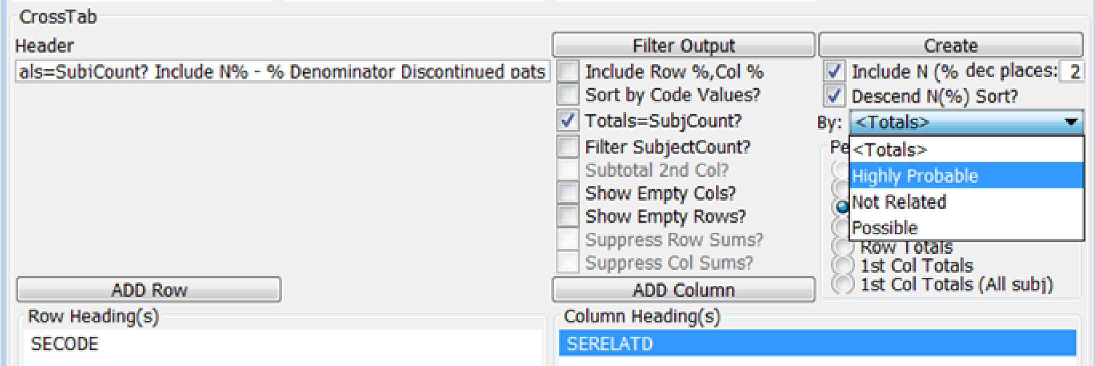
Totals=SubjCount? Include N% - % Denominator Discontinued pats - Subset of patients

| SECODE | Highly Probable | Not Related | Possible | Subjects |
|---|---|---|---|---|
| BODY:Back pain | 0 ( 0.00%) | 2 ( 4.35%) | 0 ( 0.00%) | 2 ( 4.35%) |
| BODY:Surgery | 0 ( 0.00%) | 1 ( 2.17%) | 0 ( 0.00%) | 1 ( 2.17%) |
| DIG :Duodenal ulcer | 0 ( 0.00%) | 1 ( 2.17%) | 0 ( 0.00%) | 1 ( 2.17%) |
| DIG :Sore throat | 0 ( 0.00%) | 1 ( 2.17%) | 0 ( 0.00%) | 1 ( 2.17%) |
| MAN :Peripheral edema | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 2.17%) | 1 ( 2.17%) |
| RES :Cough increased | 0 ( 0.00%) | 1 ( 2.17%) | 0 ( 0.00%) | 1 ( 2.17%) |
| RES :Upper respiratory infection | 0 ( 0.00%) | 1 ( 2.17%) | 0 ( 0.00%) | 1 ( 2.17%) |
| SKIN:Burning sensation skin | 6 (13.04%) | 0 ( 0.00%) | 1 ( 2.17%) | 7 (15.22%) |
| UG :Urinary tract infection | 0 ( 0.00%) | 1 ( 2.17%) | 0 ( 0.00%) | 1 ( 2.17%) |
| Subjects | 6 (13.04%) | 7 (15.22%) | 2 ( 4.35%) | 46 (100.00%) |
| | | | | (ActiveSubset) |

## *Descend N(%) Sort*

The **Descend N(%) Sort** option can be used with the **Include N(%)** function to sort the column percentages in descending order. Use the **By** drop down to choose and control which column for the descending sort column. When selected the First Column Item Values (plus the <total> entry) is the descending sort column.

By selecting the **Sort by Code Values** the row and column headings are sorted by their coded value. By default they are sorted by their description.



Header
als=SubjCount? Include N% - % Denominator Discontinued pats

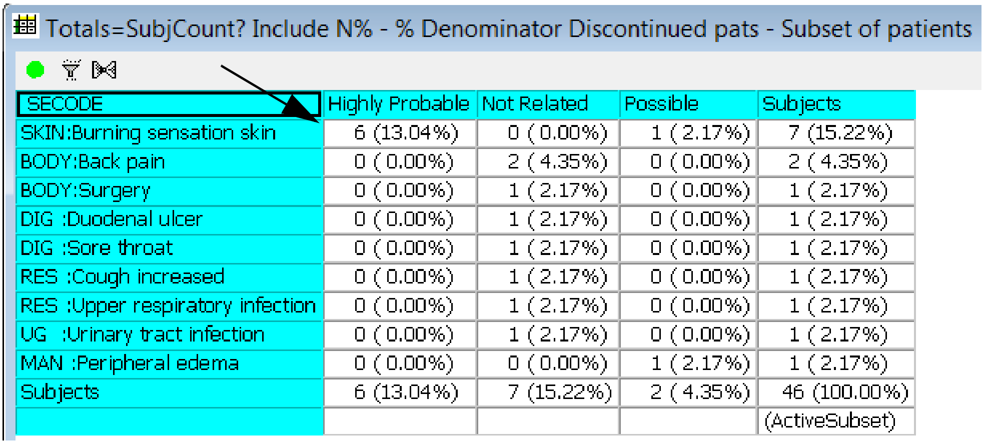
☐ Include Row %,Col %
☐ Sort by Code Values?
☑ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

☑ Include N (% dec places: 2
☑ Descend N(%) Sort?
By: <Totals>
<Totals>
Highly Probable
Not Related
Possible
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s)
SECODE

Column Heading(s)
SERELATD

The previous example shows ‘SKIN: Burning sensation skin’ as ‘Highly Probable’ located at row 9. Now the result sorts to the top of the list when the **Descend N% Sort** option is turned ON and the column sort item is selected for ‘Highly Probable’.



Totals=SubjCount? Include N% - % Denominator Discontinued pats - Subset of patients

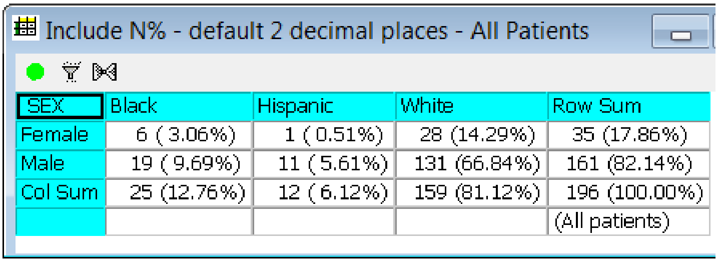
| SECODE | Highly Probable | Not Related | Possible | Subjects |
|---|---|---|---|---|
| SKIN:Burning sensation skin | 6 (13.04%) | 0 ( 0.00%) | 1 ( 2.17%) | 7 (15.22%) |
| BODY:Back pain | 0 ( 0.00%) | 2 ( 4.35%) | 0 ( 0.00%) | 2 ( 4.35%) |
| BODY:Surgery | 0 ( 0.00%) | 1 ( 2.17%) | 0 ( 0.00%) | 1 ( 2.17%) |
| DIG :Duodenal ulcer | 0 ( 0.00%) | 1 ( 2.17%) | 0 ( 0.00%) | 1 ( 2.17%) |
| DIG :Sore throat | 0 ( 0.00%) | 1 ( 2.17%) | 0 ( 0.00%) | 1 ( 2.17%) |
| RES :Cough increased | 0 ( 0.00%) | 1 ( 2.17%) | 0 ( 0.00%) | 1 ( 2.17%) |
| RES :Upper respiratory infection | 0 ( 0.00%) | 1 ( 2.17%) | 0 ( 0.00%) | 1 ( 2.17%) |
| UG :Urinary tract infection | 0 ( 0.00%) | 1 ( 2.17%) | 0 ( 0.00%) | 1 ( 2.17%) |
| MAN :Peripheral edema | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 2.17%) | 1 ( 2.17%) |
| Subjects | 6 (13.04%) | 7 (15.22%) | 2 ( 4.35%) | 46 (100.00%) |
| | | | | (ActiveSubset) |

## *Select decimal places*

You may optionally select the number of decimal places to display with the ‘dec places’ click box. The decimal place default is 2 with options for 0, 1 and 2 where the results are rounded up. When you save the crosstab specification with Include N% option checked ON and selected decimal places; these settings are saved within the crosstab specification.

☑ Include N (% dec places: 2

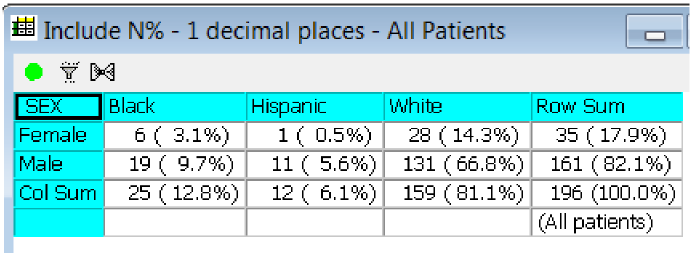
Crosstab with decimal places set to 2.



Include N% - default 2 decimal places - All Patients

| SEX | Black | Hispanic | White | Row Sum |
|---|---|---|---|---|
| Female | 6 ( 3.06%) | 1 ( 0.51%) | 28 (14.29%) | 35 (17.86%) |
| Male | 19 ( 9.69%) | 11 ( 5.61%) | 131 (66.84%) | 161 (82.14%) |
| Col Sum | 25 (12.76%) | 12 ( 6.12%) | 159 (81.12%) | 196 (100.00%) |
| | | | | (All patients) |

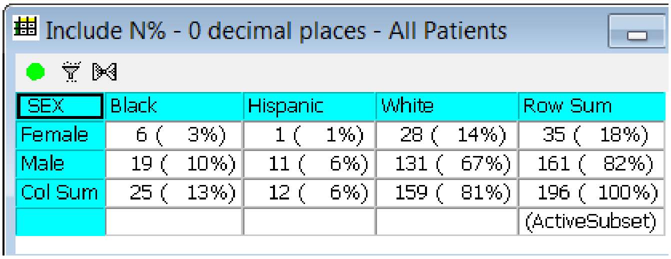
Crosstab with decimal places set to 1.



Include N% - 1 decimal places - All Patients

| SEX | Black | Hispanic | White | Row Sum |
|---|---|---|---|---|
| Female | 6 ( 3.1%) | 1 ( 0.5%) | 28 ( 14.3%) | 35 ( 17.9%) |
| Male | 19 ( 9.7%) | 11 ( 5.6%) | 131 ( 66.8%) | 161 ( 82.1%) |
| Col Sum | 25 ( 12.8%) | 12 ( 6.1%) | 159 ( 81.1%) | 196 (100.0%) |
| | | | | (All patients) |

Crosstab with decimal places set to 0.

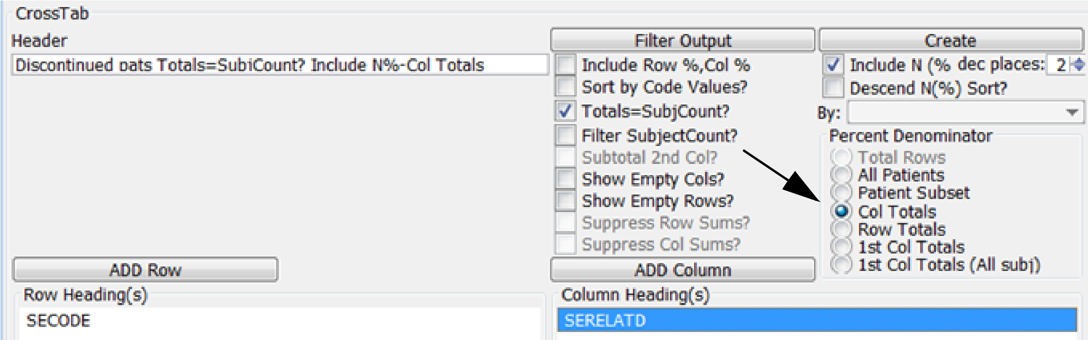


Include N% - 0 decimal places - All Patients

| SEX | Black | Hispanic | White | Row Sum |
|---|---|---|---|---|
| Female | 6 ( 3%) | 1 ( 1%) | 28 ( 14%) | 35 ( 18%) |
| Male | 19 ( 10%) | 11 ( 6%) | 131 ( 67%) | 161 ( 82%) |
| Col Sum | 25 ( 13%) | 12 ( 6%) | 159 ( 81%) | 196 ( 100%) |
| | | | | (ActiveSubset) |

## *Include N% Col Totals*

The following crosstab has selected both the ‘Include (N)%’ and ‘Totals=SubCount?’ functions checked ON with the Percent Denominator set for ‘Col Totals’. Patient selection criteria was applied for discontinued patients.



Header
Discontinued pats Totals=SubjCount? Include N%-Col Totals

☐ Include Row %,Col %
☐ Sort by Code Values?
☑ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

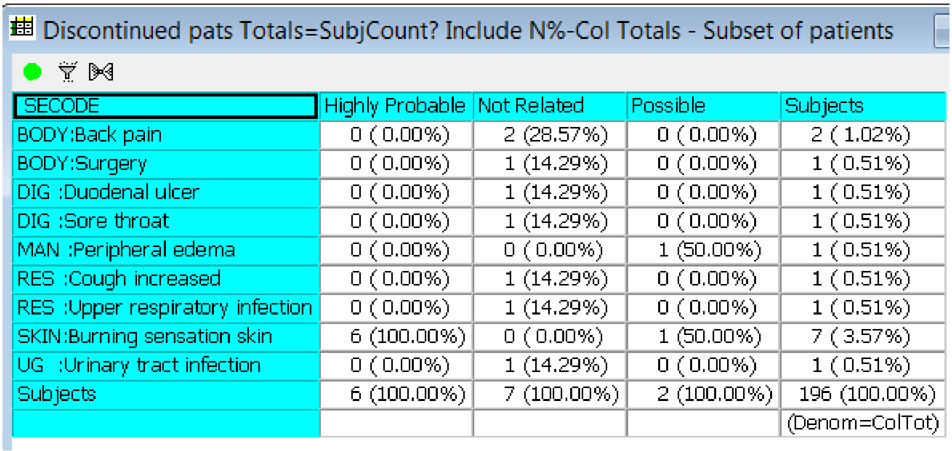
☑ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

Percent Denominator
○ Total Rows
○ All Patients
○ Patient Subset
● Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s): SECODE

Column Heading(s): SERELATD

The individual cell statistics are calculated for the individual column categories ‘Related to Inv Med?’. For example, cell statistic for ‘Back Pain’ as ‘Not Related’ calculates as 2/7 = 2(28.57%) against the ‘Not Related’ column total.

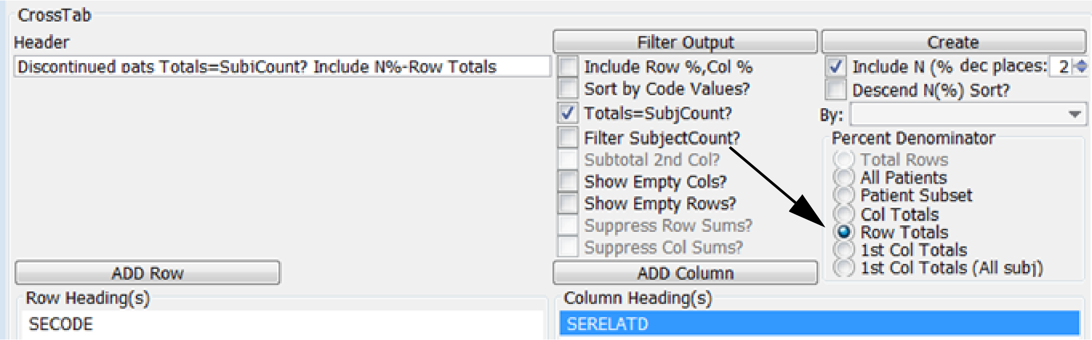


Discontinued pats Totals=SubjCount? Include N%-Col Totals - Subset of patients

| SECODE | Highly Probable | Not Related | Possible | Subjects |
|---|---|---|---|---|
| BODY:Back pain | 0 ( 0.00%) | 2 (28.57%) | 0 ( 0.00%) | 2 ( 1.02%) |
| BODY:Surgery | 0 ( 0.00%) | 1 (14.29%) | 0 ( 0.00%) | 1 ( 0.51%) |
| DIG :Duodenal ulcer | 0 ( 0.00%) | 1 (14.29%) | 0 ( 0.00%) | 1 ( 0.51%) |
| DIG :Sore throat | 0 ( 0.00%) | 1 (14.29%) | 0 ( 0.00%) | 1 ( 0.51%) |
| MAN :Peripheral edema | 0 ( 0.00%) | 0 ( 0.00%) | 1 (50.00%) | 1 ( 0.51%) |
| RES :Cough increased | 0 ( 0.00%) | 1 (14.29%) | 0 ( 0.00%) | 1 ( 0.51%) |
| RES :Upper respiratory infection | 0 ( 0.00%) | 1 (14.29%) | 0 ( 0.00%) | 1 ( 0.51%) |
| SKIN:Burning sensation skin | 6 (100.00%) | 0 ( 0.00%) | 1 (50.00%) | 7 ( 3.57%) |
| UG :Urinary tract infection | 0 ( 0.00%) | 1 (14.29%) | 0 ( 0.00%) | 1 ( 0.51%) |
| Subjects | 6 (100.00%) | 7 (100.00%) | 2 (100.00%) | 196 (100.00%) |
| | | | | (Denom=ColTot) |

## *Include N% Row Totals*

The option for ‘Row Totals’ works the same as ‘Col Totals’. The next crosstab has selected both the ‘Include (N)%’ and ‘Totals=SubCount?’ functions with the Percent Denominator set for ‘Row Totals’. Patient selection criteria is applied for discontinued patients.



CrossTab

Header

Discontinued pats Totals=SubjCount? Include N%-Row Totals

Filter Output
- ☐ Include Row %,Col %
- ☐ Sort by Code Values?
- ☑ Totals=SubjCount?
- ☐ Filter SubjectCount?
- ☐ Subtotal 2nd Col?
- ☐ Show Empty Cols?
- ☐ Show Empty Rows?
- ☐ Suppress Row Sums?
- ☐ Suppress Col Sums?

Create
- ☑ Include N (% dec places: 2
- ☐ Descend N(%) Sort?

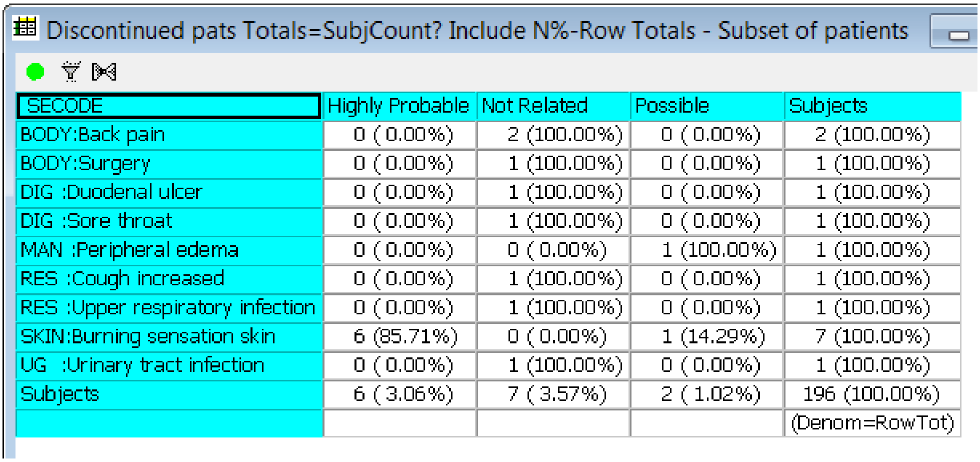
By:

Percent Denominator
- ○ Total Rows
- ○ All Patients
- ○ Patient Subset
- ○ Col Totals
- ● Row Totals
- ○ 1st Col Totals
- ○ 1st Col Totals (All subj)

Row Heading(s): SECODE

Column Heading(s): SERELATD

The individual cell statistics are calculated for the individual row categories ‘AE Coded’. For example, cell statistic for ‘Burning sensation skin’ as ‘Highly Probable’ calculates as 6/7 = 6(85.71%) against the ‘Burning sensation skin’ row total.

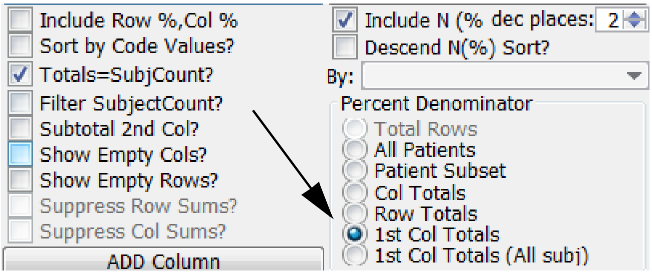


Discontinued pats Totals=SubjCount? Include N%-Row Totals - Subset of patients

| SECODE | Highly Probable | Not Related | Possible | Subjects |
|---|---|---|---|---|
| BODY:Back pain | 0 ( 0.00%) | 2 (100.00%) | 0 ( 0.00%) | 2 (100.00%) |
| BODY:Surgery | 0 ( 0.00%) | 1 (100.00%) | 0 ( 0.00%) | 1 (100.00%) |
| DIG :Duodenal ulcer | 0 ( 0.00%) | 1 (100.00%) | 0 ( 0.00%) | 1 (100.00%) |
| DIG :Sore throat | 0 ( 0.00%) | 1 (100.00%) | 0 ( 0.00%) | 1 (100.00%) |
| MAN :Peripheral edema | 0 ( 0.00%) | 0 ( 0.00%) | 1 (100.00%) | 1 (100.00%) |
| RES :Cough increased | 0 ( 0.00%) | 1 (100.00%) | 0 ( 0.00%) | 1 (100.00%) |
| RES :Upper respiratory infection | 0 ( 0.00%) | 1 (100.00%) | 0 ( 0.00%) | 1 (100.00%) |
| SKIN:Burning sensation skin | 6 (85.71%) | 0 ( 0.00%) | 1 (14.29%) | 7 (100.00%) |
| UG :Urinary tract infection | 0 ( 0.00%) | 1 (100.00%) | 0 ( 0.00%) | 1 (100.00%) |
| Subjects | 6 ( 3.06%) | 7 ( 3.57%) | 2 ( 1.02%) | 196 (100.00%) |
| | | | | (Denom=RowTot) |

## *Include N% First column totals*

The Percent Denominator has two ‘1st Col totals’ options. The difference between the two last denominator choices is whether to reference the patient selection criteria or not in the ‘1’$^{st}$ Col Totals’ total values.

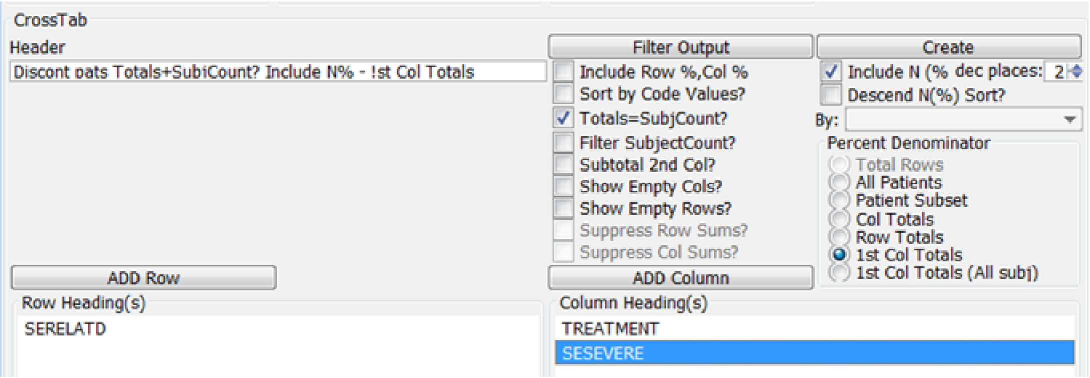


☐ Include Row %,Col %
☐ Sort by Code Values?
☑ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?
☑ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:
Percent Denominator
○ Total Rows
○ All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
● 1st Col Totals
○ 1st Col Totals (All subj)

The first option always calculates the statistics based on a patient selection criteria if present. The second option (All Sub) never uses the patient selection criteria and always show the total population numbers.

The ‘First Column Totals’ option is used when you have more than one column item selected and add a second column total line representing the Subjects for only the first column item values. For example, treatment arm as the first column item and then another item as a subgroup.

The following crosstab has functions turned ON for ‘Include (N)%’ and ‘Totals=SubCount?’ with Percent Denominator set for ‘First Col Totals’.

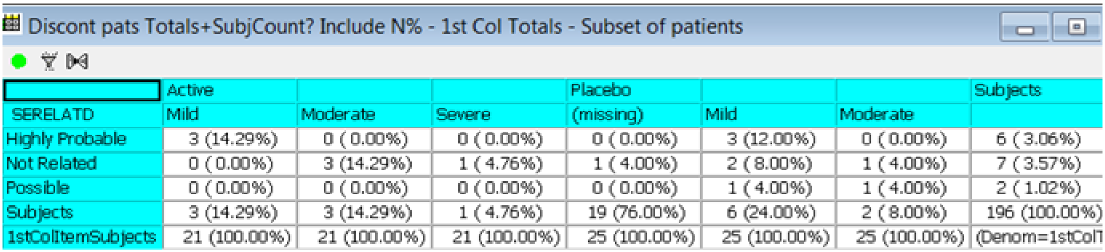


CrossTab
Header
Discont pats Totals+SubjCount? Include N% - !st Col Totals
☐ Include Row %,Col %
☐ Sort by Code Values?
☑ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?
☑ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:
Percent Denominator
○ Total Rows
○ All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
● 1st Col Totals
○ 1st Col Totals (All subj)
Row Heading(s): SERELATD
Column Heading(s): TREATMENT, SESEVERE

For the example, a patient selection criteria was entered for patients who discontinued from the study and the results are 46 discontinued patients. These 46 patients are further split into 21 patients who took ‘Active’ drug and 25 patients who took ‘Placebo’ drug.

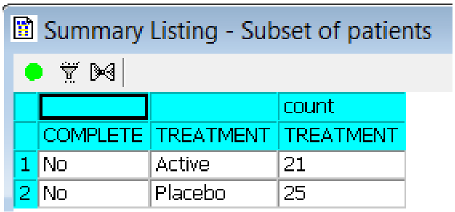
Observe the row results for ‘1st ColItemSubjects’. The statistical percents in the individual cells are calculated from the individual subject count divided by this treatment count.

Observe the ‘Placebo’ treatment column for ‘Mild’. The statistics for the Subjects calculate as 6/25 = 6(24.00%), and for ‘Highly Probable’ by the 3 individual subjects for 3/25 = 3(12.00%). Looking across the ‘Highly Probable’ row are 6 subjects out of 196 total subjects for 6/196 = 6(3.06%).



Discont pats Totals+SubjCount? Include N% - 1st Col Totals - Subset of patients

| | Active | | | Placebo | | | Subjects |
|---|---|---|---|---|---|---|---|
| SERELATD | Mild | Moderate | Severe | (missing) | Mild | Moderate | |
| Highly Probable | 3 (14.29%) | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) | 3 (12.00%) | 0 ( 0.00%) | 6 ( 3.06%) |
| Not Related | 0 ( 0.00%) | 3 (14.29%) | 1 ( 4.76%) | 1 ( 4.00%) | 2 ( 8.00%) | 1 ( 4.00%) | 7 ( 3.57%) |
| Possible | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 4.00%) | 1 ( 4.00%) | 2 ( 1.02%) |
| Subjects | 3 (14.29%) | 3 (14.29%) | 1 ( 4.76%) | 19 (76.00%) | 6 (24.00%) | 2 ( 8.00%) | 196 (100.00%) |
| 1stColItemSubjects | 21 (100.00%) | 21 (100.00%) | 21 (100.00%) | 25 (100.00%) | 25 (100.00%) | 25 (100.00%) | (Denom=1stColI |



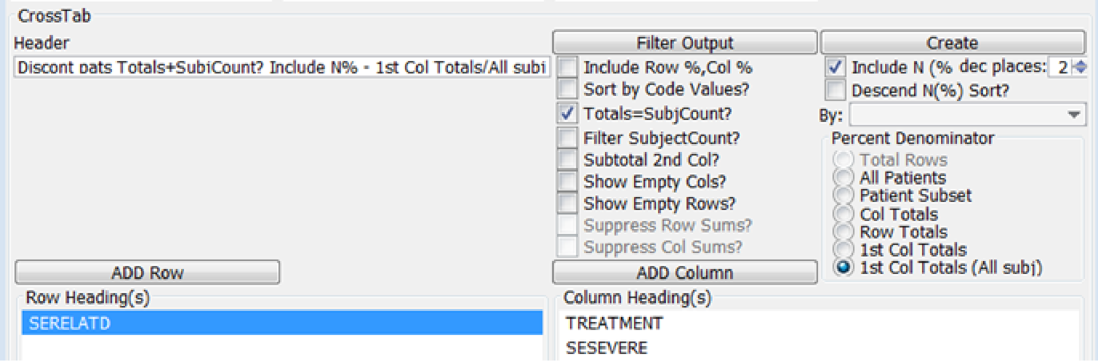
Summary Listing - Subset of patients

| | | | count |
|---|---|---|---|
| | COMPLETE | TREATMENT | TREATMENT |
| 1 | No | Active | 21 |
| 2 | No | Placebo | 25 |

## Include N% First column totals (All sub)

The ‘First Column Totals (All sub)’ option is also used when you have more than one column item selected and add a second column total line representing the Subjects. However, this option **never** uses the patient selection criteria if present, and always shows the total population numbers.

The following crosstab has functions turned ON for ‘Include (N)%’ and ‘Totals=SubCount?’ with Percent Denominator set for ‘First Col Totals (All sub)’.


CrossTab

Header
Discont pats Totals+SubjCount? Include N% - 1st Col Totals/All subj

- ☐ Include Row %,Col %
- ☐ Sort by Code Values?
- ☑ Totals=SubjCount?
- ☐ Filter SubjectCount?
- ☐ Subtotal 2nd Col?
- ☐ Show Empty Cols?
- ☐ Show Empty Rows?
- ☐ Suppress Row Sums?
- ☐ Suppress Col Sums?
- ☑ Include N (% dec places: 2
- ☐ Descend N(%) Sort?

By:

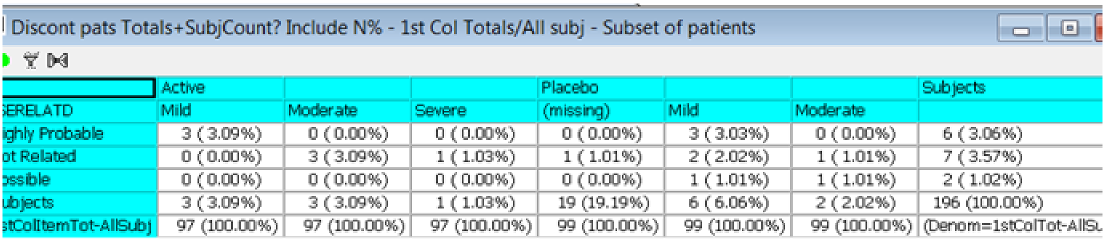
Percent Denominator
- ○ Total Rows
- ○ All Patients
- ○ Patient Subset
- ○ Col Totals
- ○ Row Totals
- ○ 1st Col Totals
- ● 1st Col Totals (All subj)

Row Heading(s)
SERELATD

Column Heading(s)
TREATMENT
SESEVERE

For the example, a patient selection criteria was entered for patients who discontinued from the study and the results are 46 discontinued patients. However, for the total patient population in the study is 196 where there are 97 patients who took ‘Active’ drug and 99 patients who took ‘Placebo’ drug.

The crosstab results calculate the statistics based upon the total patient population for the item column added. See the ‘Placebo’ treatment column for ‘Highly Probable’ as ‘Mild’. The statistics for the Subjects calculate as 6/99 = 6(6.06%), and for ‘Highly Probable’ by the 3 individual subjects for 3/99 = 3(3.03%). Looking across the ‘Highly Probable’ row are 6 subjects out of 196 total subjects for 6/196 = 6(3.06%).

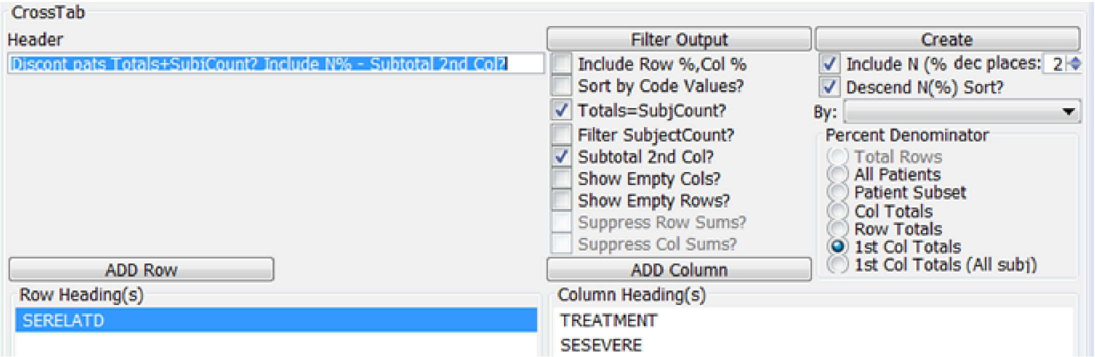

Discont pats Totals+SubjCount? Include N% - 1st Col Totals/All subj - Subset of patients

| | Active | | | Placebo | | | Subjects |
|---|---|---|---|---|---|---|---|
| ERELATD | Mild | Moderate | Severe | (missing) | Mild | Moderate | |
| ighly Probable | 3 ( 3.09%) | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) | 3 ( 3.03%) | 0 ( 0.00%) | 6 ( 3.06%) |
| ot Related | 0 ( 0.00%) | 3 ( 3.09%) | 1 ( 1.03%) | 1 ( 1.01%) | 2 ( 2.02%) | 1 ( 1.01%) | 7 ( 3.57%) |
| ssible | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) | 1 ( 1.01%) | 1 ( 1.01%) | 2 ( 1.02%) |
| ubjects | 3 ( 3.09%) | 3 ( 3.09%) | 1 ( 1.03%) | 19 (19.19%) | 6 ( 6.06%) | 2 ( 2.02%) | 196 (100.00%) |
| stColItemTot-AllSubj | 97 (100.00%) | 97 (100.00%) | 97 (100.00%) | 99 (100.00%) | 99 (100.00%) | 99 (100.00%) | (Denom=1stColTot-AllSu |

## *Include N% with Subtotal 2nd column*

This option is used when you have two or more column items selected and when checked, an intermediate 'Total' column for the 2nd column item values is added. This option is useful in conjunction with the 'Descend Sort - by a selected 1st column item value'.

In the following example, when 'Subtotal 2nd Column' is used with the 'Include N(%)' and 'Descend N(%) Sort' and selecting one of the values of the first column item from the dropdown list box. If you pick 'Active' for example, then it will do a descending sort on the 'Active' column.



Header
Discont pats Totals+SubjCount? Include N% - Subtotal 2nd Col?

☐ Include Row %,Col %
☐ Sort by Code Values?
☑ Totals=SubjCount?
☐ Filter SubjectCount?
☑ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

☑ Include N (% dec places: 2
☑ Descend N(%) Sort?
By:

Percent Denominator
○ Total Rows
○ All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
● 1st Col Totals
○ 1st Col Totals (All subj)

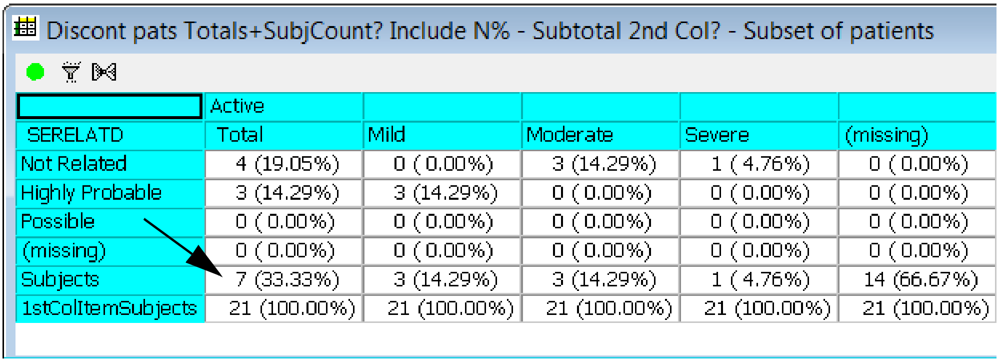
Row Heading(s)
SERELATD

Column Heading(s)
TREATMENT
SESEVERE

A patient selection criteria was entered for patients who discontinued from the study and the results are 46 discontinued patients. These 46 patients are further split into 21 patients who took 'Active' drug and 25 patients who took 'Placebo' drug.

Observe the row results for ‘1st ColItemSubjects’. The results for the ‘Active’ total column calculates the Subjects statistics as 7/21= 7(33.33%). The statistical percents in the individual cells can be calculated from this total column statistic.

*(This screen is a split crosstab example.)*

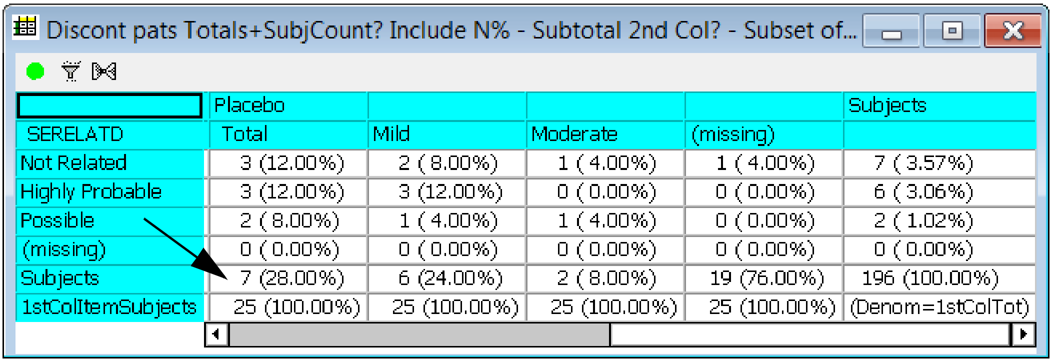


Discont pats Totals+SubjCount? Include N% - Subtotal 2nd Col? - Subset of patients

| | Active | | | | |
|---|---|---|---|---|---|
| SERELATD | Total | Mild | Moderate | Severe | (missing) |
| Not Related | 4 (19.05%) | 0 ( 0.00%) | 3 (14.29%) | 1 ( 4.76%) | 0 ( 0.00%) |
| Highly Probable | 3 (14.29%) | 3 (14.29%) | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) |
| Possible | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) |
| (missing) | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) |
| Subjects | 7 (33.33%) | 3 (14.29%) | 3 (14.29%) | 1 ( 4.76%) | 14 (66.67%) |
| 1stColItemSubjects | 21 (100.00%) | 21 (100.00%) | 21 (100.00%) | 21 (100.00%) | 21 (100.00%) |

The results for the ‘Placebo’ total column calculates the Subjects statistics as 7/25= 7(28.00%).

*(Continuation from previous crosstab.)*



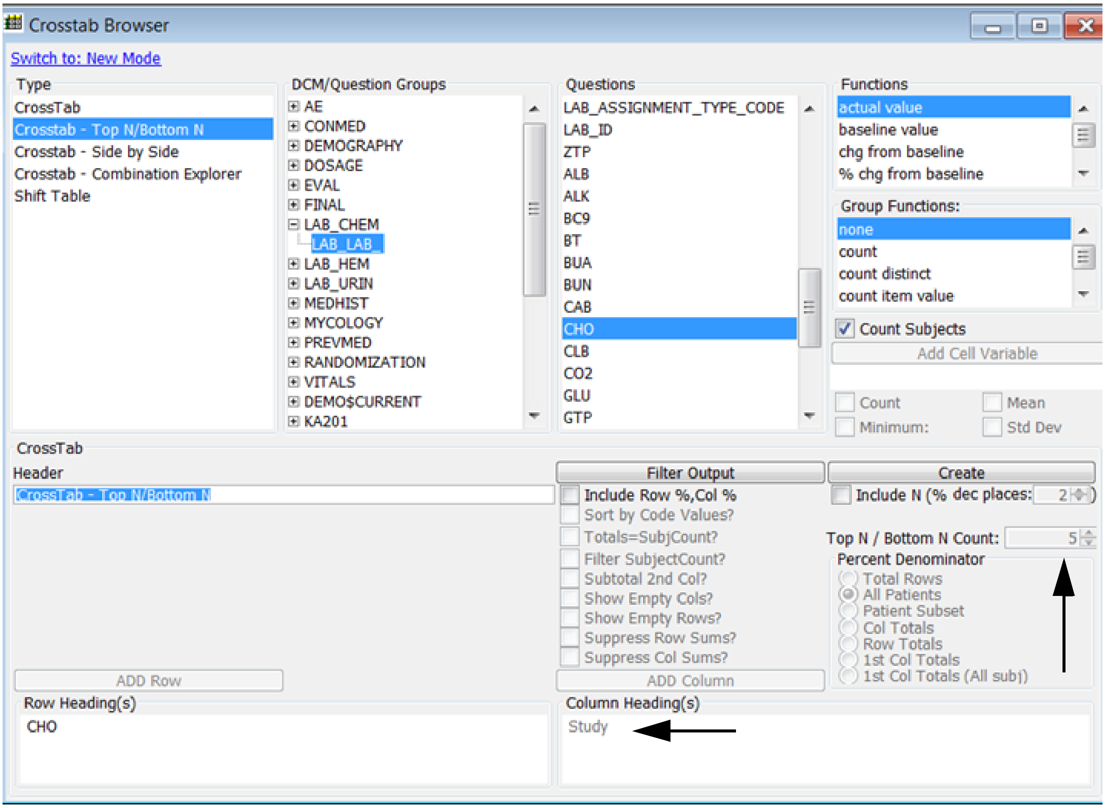
Discont pats Totals+SubjCount? Include N% - Subtotal 2nd Col? - Subset of...

| | Placebo | | | | Subjects |
|---|---|---|---|---|---|
| SERELATD | Total | Mild | Moderate | (missing) | |
| Not Related | 3 (12.00%) | 2 ( 8.00%) | 1 ( 4.00%) | 1 ( 4.00%) | 7 ( 3.57%) |
| Highly Probable | 3 (12.00%) | 3 (12.00%) | 0 ( 0.00%) | 0 ( 0.00%) | 6 ( 3.06%) |
| Possible | 2 ( 8.00%) | 1 ( 4.00%) | 1 ( 4.00%) | 0 ( 0.00%) | 2 ( 1.02%) |
| (missing) | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) | 0 ( 0.00%) |
| Subjects | 7 (28.00%) | 6 (24.00%) | 2 ( 8.00%) | 19 (76.00%) | 196 (100.00%) |
| 1stColItemSubjects | 25 (100.00%) | 25 (100.00%) | 25 (100.00%) | 25 (100.00%) | (Denom=1stColTot) |

# CrossTab Top N - Bottom N

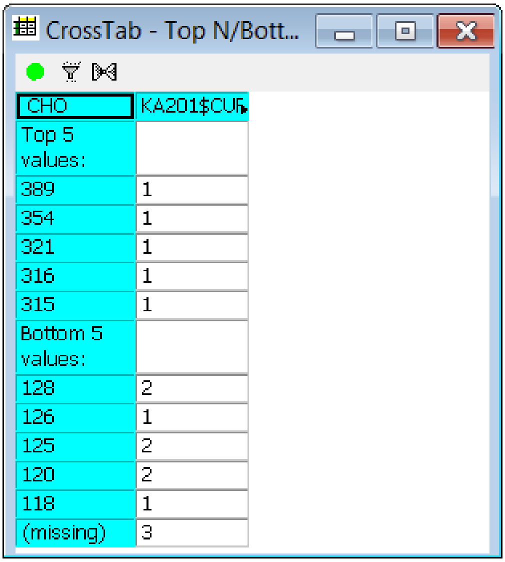
## *Display Top N Bottom N*

The CrossTab Top N, Bottom N is used when you wish to display the top N and bottom N values of a variable in a study for either all patients or the current patient subset. After selecting which variable is to be analyzed, the column heading default is set to' Study' and the Top N / Bottom N count is set to '5'.



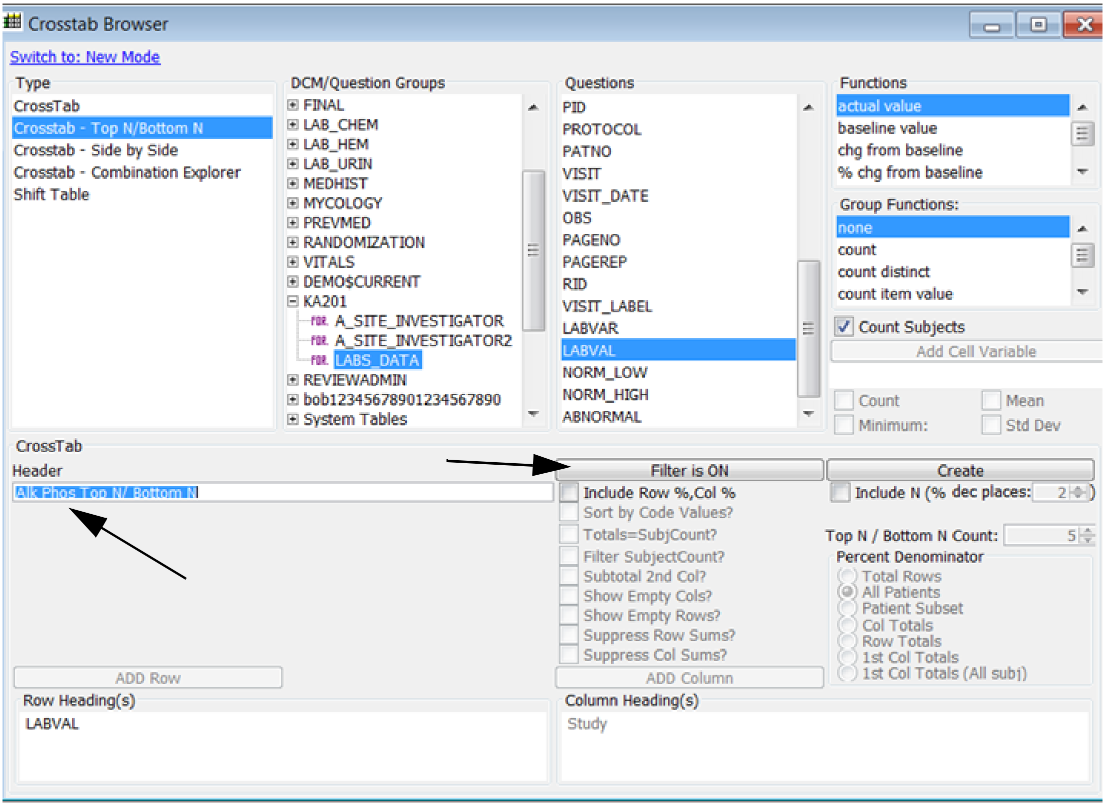
Type: Crosstab - Top N/Bottom N
DCM/Question Groups: LAB_CHEM / LAB_LAB_
Questions: CHO
Functions: actual value
Group Functions: none
☑ Count Subjects
Header: CrossTab - Top N/Bottom N
☐ Include N (% dec places: 2)
Top N / Bottom N Count: 5
Percent Denominator: ● All Patients
Row Heading(s): CHO
Column Heading(s): Study

Once the TopN/Bottom N crosstab is displayed, each cell is clickable as with any crosstab results, to highlight/select the patients in the cell – in any other displayed output, such as lab listings, etc.



| CHO | KA201$CUF |
|---|---|
| Top 5 values: | |
| 389 | 1 |
| 354 | 1 |
| 321 | 1 |
| 316 | 1 |
| 315 | 1 |
| Bottom 5 values: | |
| 128 | 2 |
| 126 | 1 |
| 125 | 2 |
| 120 | 2 |
| 118 | 1 |
| (missing) | 3 |

When using a vertical lab table, you must define a **Filter Output** for the specific lab test of interest. Then enter the item that contains the lab value result as **ADD Row**. In this example, the output filter for Lab Variable was selected for ‘ALK’.



Type: Crosstab - Top N/Bottom N

DCM/Question Groups: KA201 – LABS_DATA

Questions: LABVAL

Functions: actual value

Group Functions: none

☑ Count Subjects

Header: Alk Phos Top N/ Bottom N

Include N (% dec places: 2)

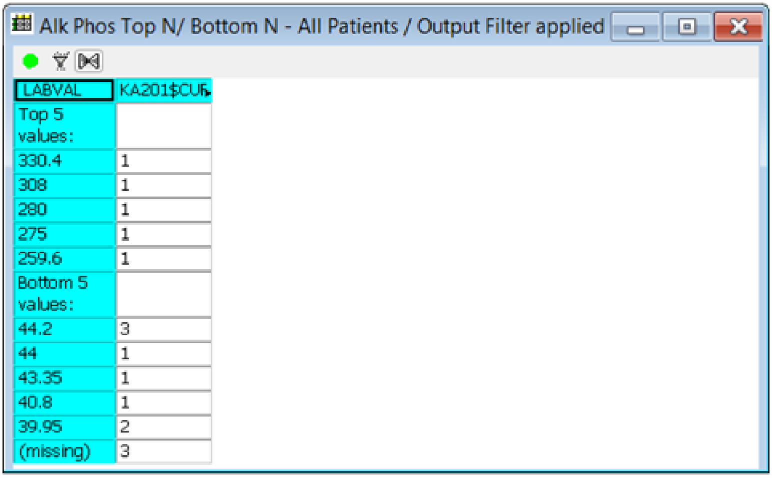
Top N / Bottom N Count: 5

Percent Denominator: ● All Patients

Row Heading(s): LABVAL

Column Heading(s): Study

Make sure to enter the lab test description into the CrossTab Header.


Alk Phos Top N/ Bottom N - All Patients / Output Filter applied

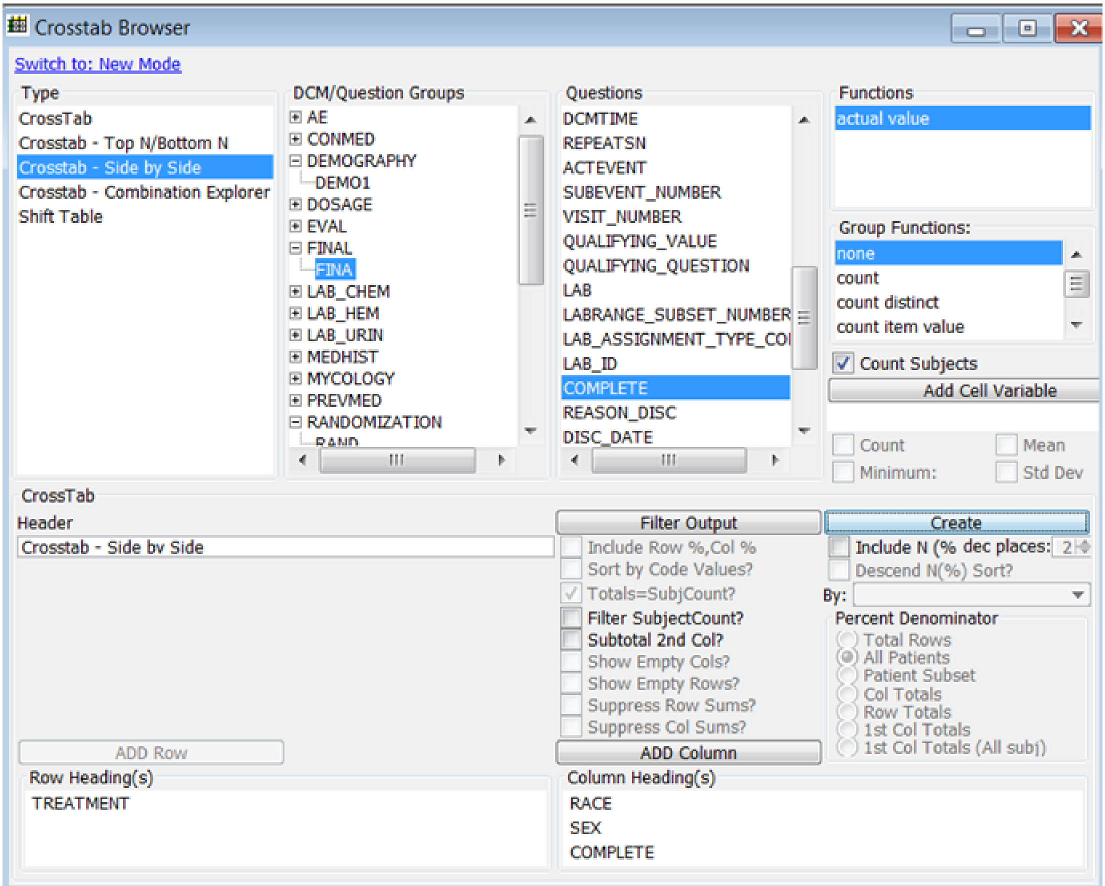
| LABVAL | KA201$CUR |
|---|---|
| Top 5 values: | |
| 330.4 | 1 |
| 308 | 1 |
| 280 | 1 |
| 275 | 1 |
| 259.6 | 1 |
| Bottom 5 values: | |
| 44.2 | 3 |
| 44 | 1 |
| 43.35 | 1 |
| 40.8 | 1 |
| 39.95 | 2 |
| (missing) | 3 |

# CrossTab Side by Side

## *What is CrossTab Side by Side Columns?*

The CrossTab Side by Side Columns allows you to display multiple crosstab columns in a side by side format against one row variable.

This crosstab type displays selected columns across (not nested) where each column (by selected row items) is retrieved separately without intermediate joins. Therefore, the statistics from each column are independent of each other.



Type: Crosstab - Side by Side

DCM/Question Groups: FINAL / FINA

Questions: COMPLETE

Functions: actual value

Group Functions: none

☑ Count Subjects

☐ Count ☐ Mean
☐ Minimum: ☐ Std Dev

CrossTab

Header: Crosstab - Side by Side

☐ Include Row %,Col %
☐ Sort by Code Values?
☑ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

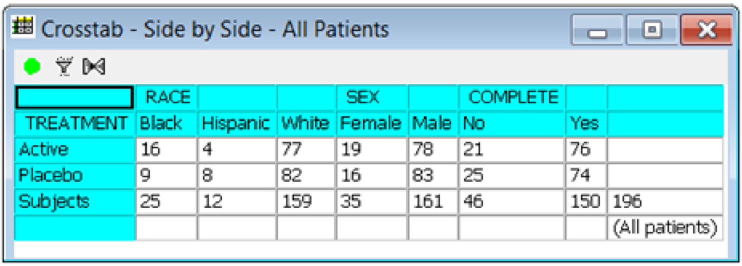
☐ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

Percent Denominator
○ Total Rows
● All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s):
TREATMENT

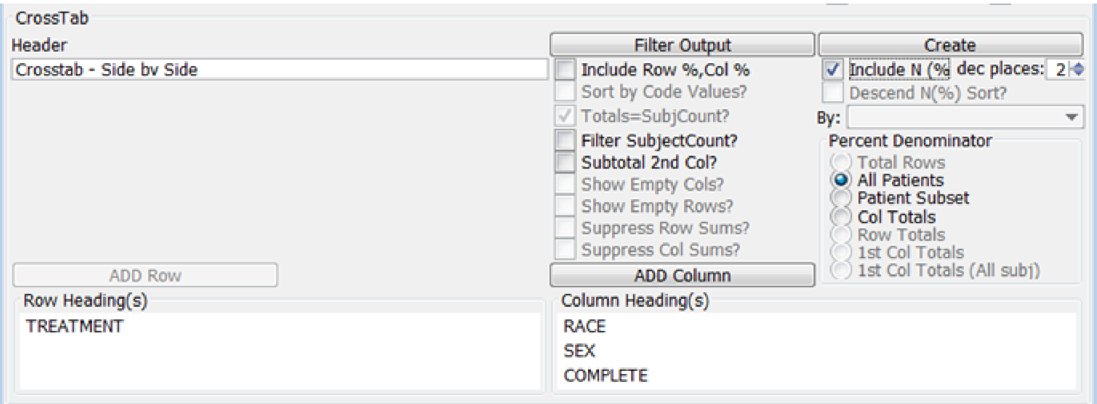
Column Heading(s):
RACE
SEX
COMPLETE

Observe for the selected columns Race, Sex and Complete the individual category counts total 196.



| | RACE | | | SEX | | COMPLETE | | |
|---|---|---|---|---|---|---|---|---|
| TREATMENT | Black | Hispanic | White | Female | Male | No | Yes | |
| Active | 16 | 4 | 77 | 19 | 78 | 21 | 76 | |
| Placebo | 9 | 8 | 82 | 16 | 83 | 25 | 74 | |
| Subjects | 25 | 12 | 159 | 35 | 161 | 46 | 150 | 196 |
| | | | | | | | | (All patients) |

You may optionally apply the **Include N(%)** function for total patient population as the **Percent Denominator** and the default is 'All Patients'.



Header
Crosstab - Side bv Side

☐ Include Row %,Col %
☐ Sort by Code Values?
☑ Totals=SubjCount?
☐ Filter SubjectCount?
☐ Subtotal 2nd Col?
☐ Show Empty Cols?
☐ Show Empty Rows?
☐ Suppress Row Sums?
☐ Suppress Col Sums?

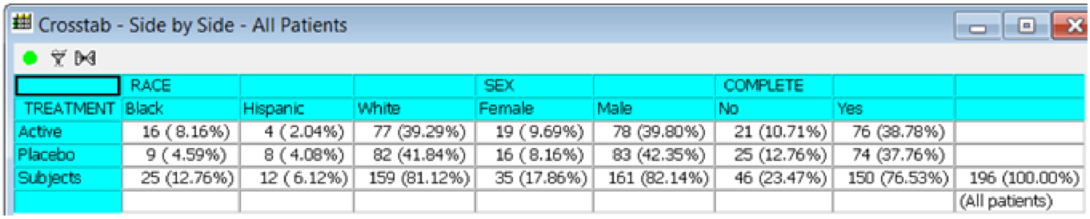
☑ Include N (% dec places: 2
☐ Descend N(%) Sort?
By:

Percent Denominator
○ Total Rows
● All Patients
○ Patient Subset
○ Col Totals
○ Row Totals
○ 1st Col Totals
○ 1st Col Totals (All subj)

Row Heading(s)
TREATMENT

Column Heading(s)
RACE
SEX
COMPLETE

The **Include N(%)** function only uses the total patient population as the **Percent Denominator** based on 'All Patients or 'Patient Subset' where the default is 'All Patients'. ***(See section - Include N(%))***



| | RACE | | | SEX | | COMPLETE | | |
|---|---|---|---|---|---|---|---|---|
| TREATMENT | Black | Hispanic | White | Female | Male | No | Yes | |
| Active | 16 ( 8.16%) | 4 ( 2.04%) | 77 (39.29%) | 19 ( 9.69%) | 78 (39.80%) | 21 (10.71%) | 76 (38.78%) | |
| Placebo | 9 ( 4.59%) | 8 ( 4.08%) | 82 (41.84%) | 16 ( 8.16%) | 83 (42.35%) | 25 (12.76%) | 74 (37.76%) | |
| Subjects | 25 (12.76%) | 12 ( 6.12%) | 159 (81.12%) | 35 (17.86%) | 161 (82.14%) | 46 (23.47%) | 150 (76.53%) | 196 (100.00%) |
| | | | | | | | | (All patients) |

# Interactive CrossTab - Combination Explorer

### *View patient counts*

The CrossTab - Combination Explorer is designed for ***interactive*** data exploration to evaluate subjects based on calculations which display all permutations of the selected data displaying the number of patients and percentages. The **Include N%** and the corresponding **Percent Denominator** selections are the only permitted percentage calculations.

Patient Selection Criteria or Filter Output may be applied to the CrossTab - Combination Explorer if desired.

***Note: The Combination Explorer is not typically saved as a CrossTab Object due to the interactive design.***

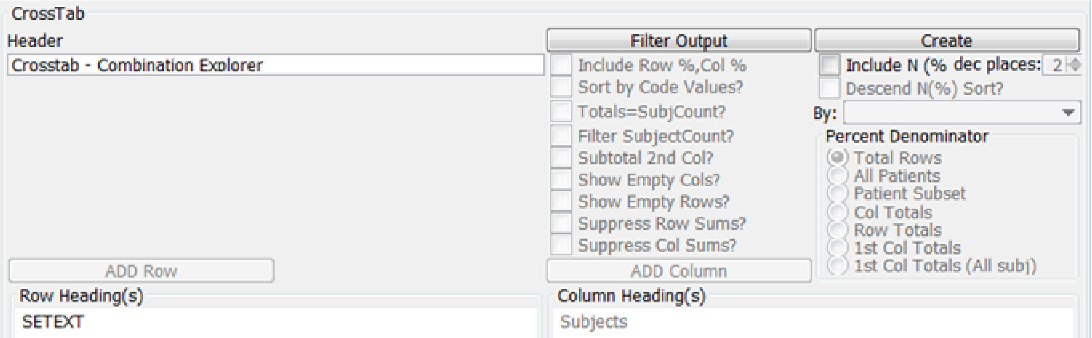
This function is particularly useful when analyzing relationships and trends between Adverse Events or Concomitant Medications within patients. To define the CrossTab – Combination Explorer:

1. Select Type for **CrossTab - Combination Explorer**.

   The Column is automatically set to ‘Subjects’ as required. Multiple rows and/or columns cannot be added.
2. Select a panel, an item and the appropriate function or use the default function.
3. Click **ADD Row**.

   For example, add ‘AE Text’ as the Row item to be analyzed/explored.

   Only one row variable is allowed.
4. Click Create.



CrossTab

Header: Crosstab - Combination Explorer

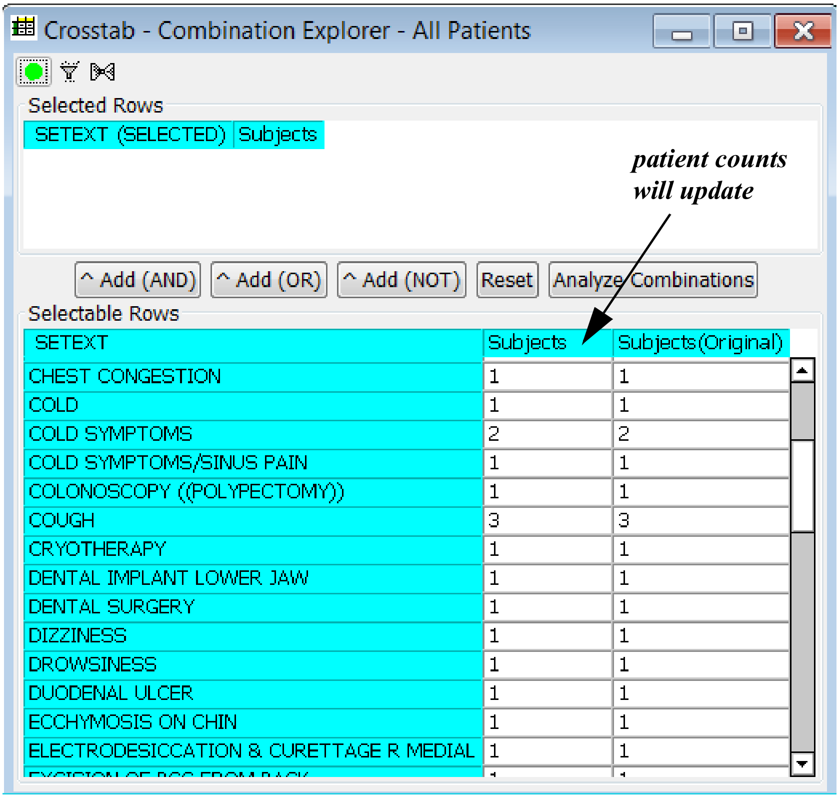
Percent Denominator: ● Total Rows

Row Heading(s): SETEXT

Column Heading(s): Subjects

The CrossTab - Combination Explorer window is generated with a list of Adverse Events for the patients in the current population (or subset) with patient counts for each. The right most column **Subjects (Original)** preserves the original (initial) patient counts for each adverse event for reference during the next exploration phase.

As selected rows are added to the top, the center column for **Subjects** will update patient counts.



***patient counts will update***

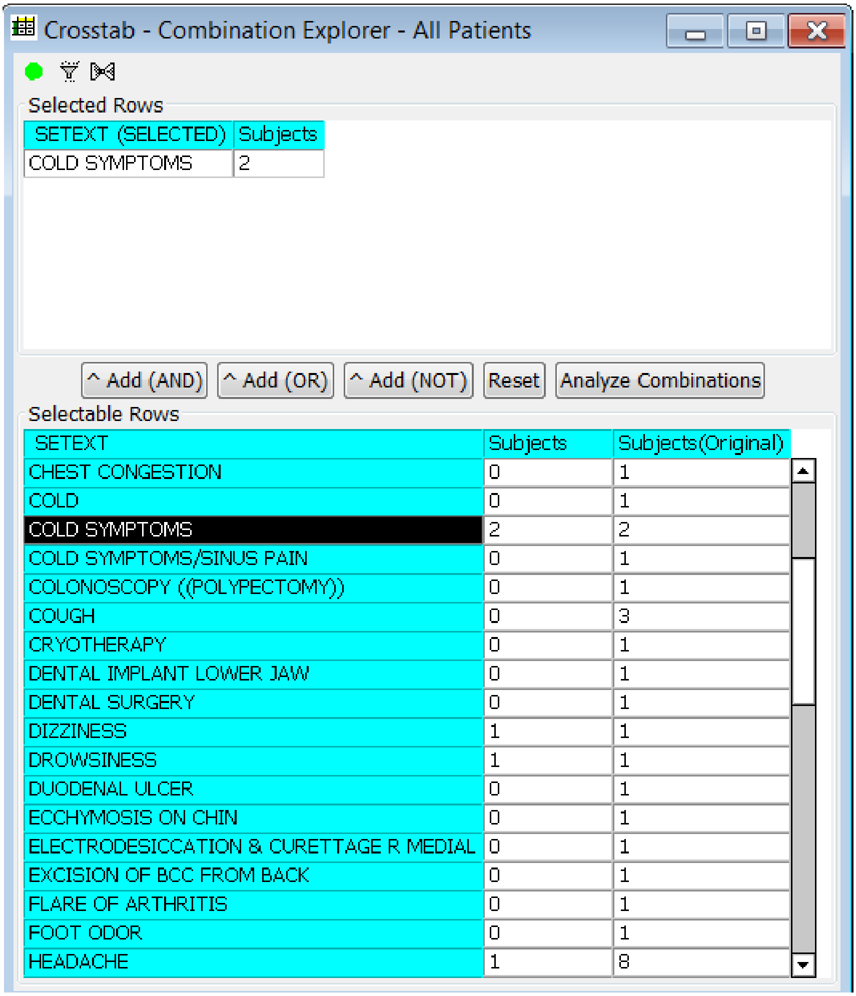
| SETEXT (SELECTED) | Subjects |
|---|---|

| SETEXT | Subjects | Subjects(Original) |
|---|---|---|
| CHEST CONGESTION | 1 | 1 |
| COLD | 1 | 1 |
| COLD SYMPTOMS | 2 | 2 |
| COLD SYMPTOMS/SINUS PAIN | 1 | 1 |
| COLONOSCOPY ((POLYPECTOMY)) | 1 | 1 |
| COUGH | 3 | 3 |
| CRYOTHERAPY | 1 | 1 |
| DENTAL IMPLANT LOWER JAW | 1 | 1 |
| DENTAL SURGERY | 1 | 1 |
| DIZZINESS | 1 | 1 |
| DROWSINESS | 1 | 1 |
| DUODENAL ULCER | 1 | 1 |
| ECCHYMOSIS ON CHIN | 1 | 1 |
| ELECTRODESICCATION & CURETTAGE R MEDIAL | 1 | 1 |

5. Select the first Value to add for exploration to the SELECT list.

   For example, select ‘Cold Symptoms’ and click any of the Add buttons to add it to the list of Adverse Events of interest. The other spreadsheet for information (traditional spreadsheet) shows the Adverse Event counts by individual patient (column) to verify correctness of counts at each step.

   After adding ‘Cold Symptoms’ to the SELECTED set, the lower spreadsheet’s ‘Subjects’ column is updated to reflect the patient counts for those patients who have ‘Cold Symptoms’ and the counts of the other Adverse Events that they have.



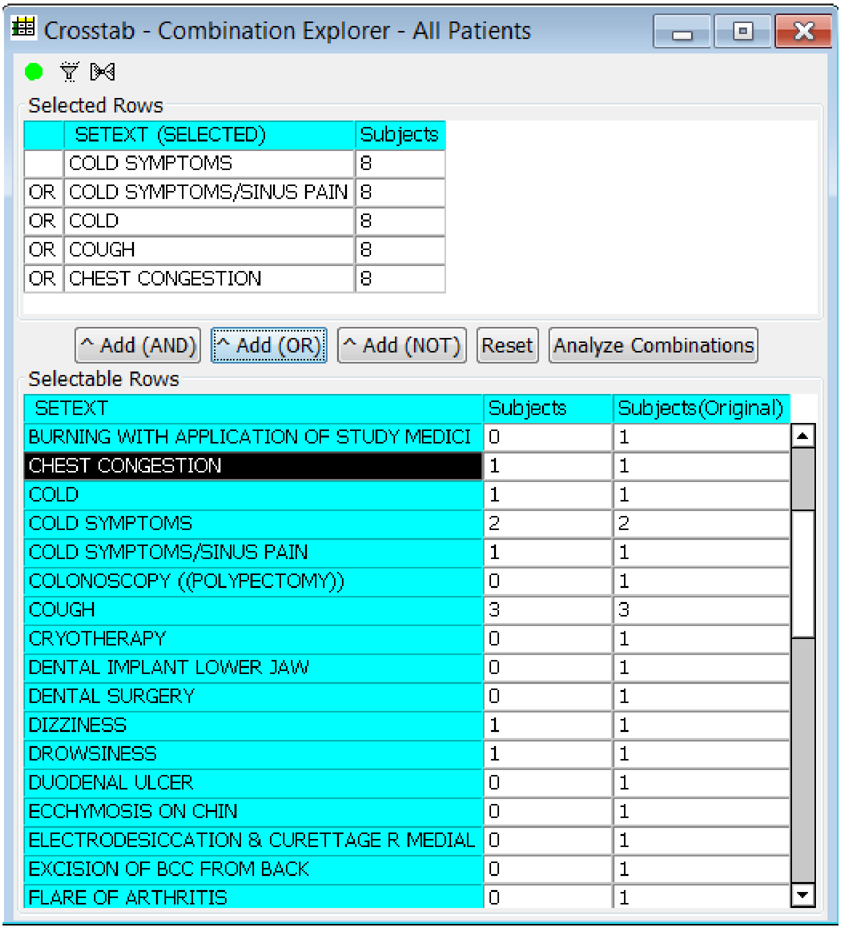
| SETEXT (SELECTED) | Subjects |
|---|---|
| COLD SYMPTOMS | 2 |

| SETEXT | Subjects | Subjects(Original) |
|---|---|---|
| CHEST CONGESTION | 0 | 1 |
| COLD | 0 | 1 |
| COLD SYMPTOMS | 2 | 2 |
| COLD SYMPTOMS/SINUS PAIN | 0 | 1 |
| COLONOSCOPY ((POLYPECTOMY)) | 0 | 1 |
| COUGH | 0 | 3 |
| CRYOTHERAPY | 0 | 1 |
| DENTAL IMPLANT LOWER JAW | 0 | 1 |
| DENTAL SURGERY | 0 | 1 |
| DIZZINESS | 1 | 1 |
| DROWSINESS | 1 | 1 |
| DUODENAL ULCER | 0 | 1 |
| ECCHYMOSIS ON CHIN | 0 | 1 |
| ELECTRODESICCATION & CURETTAGE R MEDIAL | 0 | 1 |
| EXCISION OF BCC FROM BACK | 0 | 1 |
| FLARE OF ARTHRITIS | 0 | 1 |
| FOOT ODOR | 0 | 1 |
| HEADACHE | 1 | 8 |

6. Select the additional values for exploration to the SELECT list. You ***must*** select a between two to six values before you click Analyze Combinations.

   For example, we're interested in patients who had 'Cold Symptoms' OR 'Cough' then click on the 'Add (OR)' button to add it to the list of selected Adverse Events with the OR between them. The selected values update the lower spreadsheet counts under **Subjects** for the patients in that set ('Cold Symptoms' OR 'Cough') and which other Adverse Events that they had. See the updated counts for Dizziness and Drowsiness.

   There are 2 patients who reported 'Cold Symptoms' OR there is 1 patient who reported 'Cold Symptoms/Sinus Pain', and 3 patients who reported 'Cough', etc., for a total of 8 patients. Each of the 8 patients reported one OR more of the selected Adverse Events.



|  | SETEXT (SELECTED) | Subjects |
|---|---|---|
|  | COLD SYMPTOMS | 8 |
| OR | COLD SYMPTOMS/SINUS PAIN | 8 |
| OR | COLD | 8 |
| OR | COUGH | 8 |
| OR | CHEST CONGESTION | 8 |

| SETEXT | Subjects | Subjects(Original) |
|---|---|---|
| BURNING WITH APPLICATION OF STUDY MEDICI | 0 | 1 |
| CHEST CONGESTION | 1 | 1 |
| COLD | 1 | 1 |
| COLD SYMPTOMS | 2 | 2 |
| COLD SYMPTOMS/SINUS PAIN | 1 | 1 |
| COLONOSCOPY ((POLYPECTOMY)) | 0 | 1 |
| COUGH | 3 | 3 |
| CRYOTHERAPY | 0 | 1 |
| DENTAL IMPLANT LOWER JAW | 0 | 1 |
| DENTAL SURGERY | 0 | 1 |
| DIZZINESS | 1 | 1 |
| DROWSINESS | 1 | 1 |
| DUODENAL ULCER | 0 | 1 |
| ECCHYMOSIS ON CHIN | 0 | 1 |
| ELECTRODESICCATION & CURETTAGE R MEDIAL | 0 | 1 |
| EXCISION OF BCC FROM BACK | 0 | 1 |
| FLARE OF ARTHRITIS | 0 | 1 |

The selected values update the lower spreadsheet counts under **Subjects** to reflect the patient counts for patients with any of these Adverse Events and others they have.

You can view the individual patients by opening the Data Browser and clicking on any numeric cell value. The Data Browser updates to the included patients.

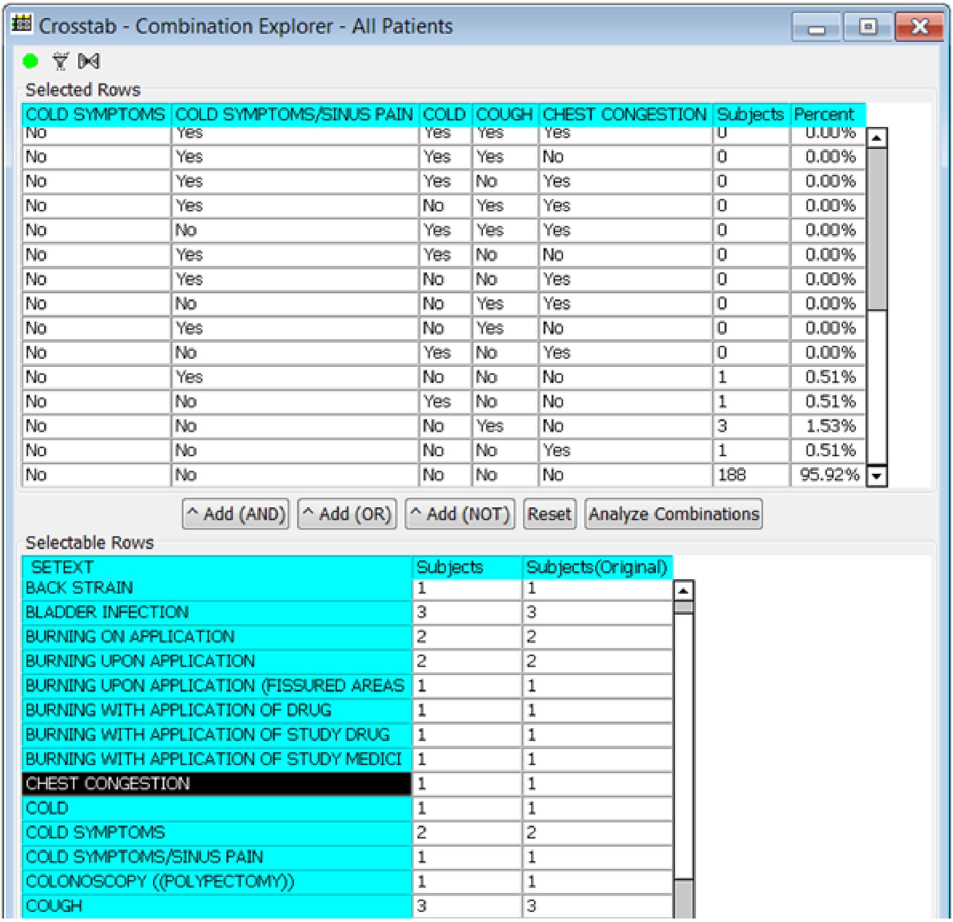
When adding Adverse Events to the SELECTED list, they can be added using ‘Add (AND)’, ‘Add (OR)’, ‘Add (NOT)’ to determine combinations such as patients who had Headache, but not Cold Symptoms, etc. If you had clicked the ‘Add (AND)’ button the Boolean selection would be restrictive where the same patients had to report both Adverse Events.

## *Analyze Combinations*

Once you have added the selected values to the SELECT list, you can display all permutations of the selected values (Adverse Events) and the number of patients and percent in each.

The previously selected Boolean operators *do NOT* affect the results of Analyze Combinations. The spreadsheet generated shows all subject combinations for the selected values.

7. Click **Analyze Combinations** to view statistics of the selected rows..



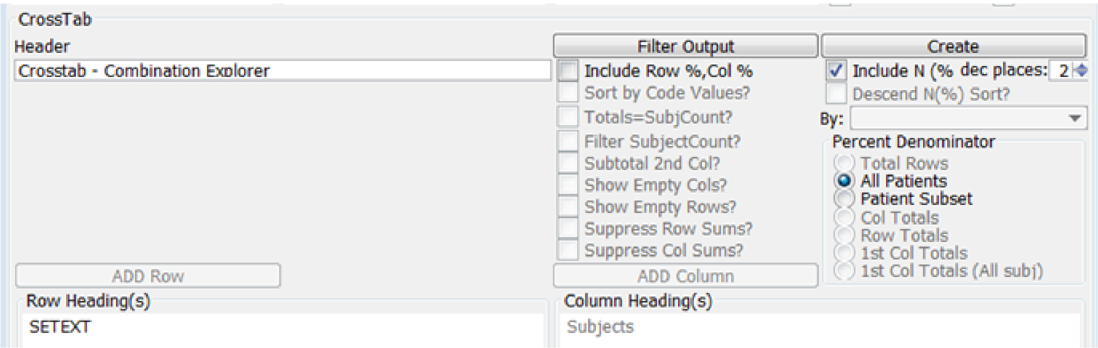
| COLD SYMPTOMS | COLD SYMPTOMS/SINUS PAIN | COLD | COUGH | CHEST CONGESTION | Subjects | Percent |
|---|---|---|---|---|---|---|
| No | Yes | Yes | Yes | Yes | 0 | 0.00% |
| No | Yes | Yes | Yes | No | 0 | 0.00% |
| No | Yes | Yes | No | Yes | 0 | 0.00% |
| No | Yes | No | Yes | Yes | 0 | 0.00% |
| No | No | Yes | Yes | Yes | 0 | 0.00% |
| No | Yes | Yes | No | No | 0 | 0.00% |
| No | Yes | No | No | Yes | 0 | 0.00% |
| No | No | No | Yes | Yes | 0 | 0.00% |
| No | Yes | No | Yes | No | 0 | 0.00% |
| No | No | Yes | No | Yes | 0 | 0.00% |
| No | Yes | No | No | No | 1 | 0.51% |
| No | No | Yes | No | No | 1 | 0.51% |
| No | No | No | Yes | No | 3 | 1.53% |
| No | No | No | No | Yes | 1 | 0.51% |
| No | No | No | No | No | 188 | 95.92% |

| SETEXT | Subjects | Subjects(Original) |
|---|---|---|
| BACK STRAIN | 1 | 1 |
| BLADDER INFECTION | 3 | 3 |
| BURNING ON APPLICATION | 2 | 2 |
| BURNING UPON APPLICATION | 2 | 2 |
| BURNING UPON APPLICATION (FISSURED AREAS | 1 | 1 |
| BURNING WITH APPLICATION OF DRUG | 1 | 1 |
| BURNING WITH APPLICATION OF STUDY DRUG | 1 | 1 |
| BURNING WITH APPLICATION OF STUDY MEDICI | 1 | 1 |
| CHEST CONGESTION | 1 | 1 |
| COLD | 1 | 1 |
| COLD SYMPTOMS | 2 | 2 |
| COLD SYMPTOMS/SINUS PAIN | 1 | 1 |
| COLONOSCOPY ((POLYPECTOMY)) | 1 | 1 |
| COUGH | 3 | 3 |

8. Click the printer icon to print the spreadsheet results in the active window.
9. Click **Reset** to clear selected values.

## *Include N% to Analyze Combinations*

You can apply Include N% to selected Adverse Events values to view subject percentages.



CrossTab

Header

Crosstab - Combination Explorer

- ☐ Include Row %,Col %
- ☐ Sort by Code Values?
- ☐ Totals=SubjCount?
- ☐ Filter SubjectCount?
- ☐ Subtotal 2nd Col?
- ☐ Show Empty Cols?
- ☐ Show Empty Rows?
- ☐ Suppress Row Sums?
- ☐ Suppress Col Sums?

- ☑ Include N (% dec places: 2
- ☐ Descend N(%) Sort?

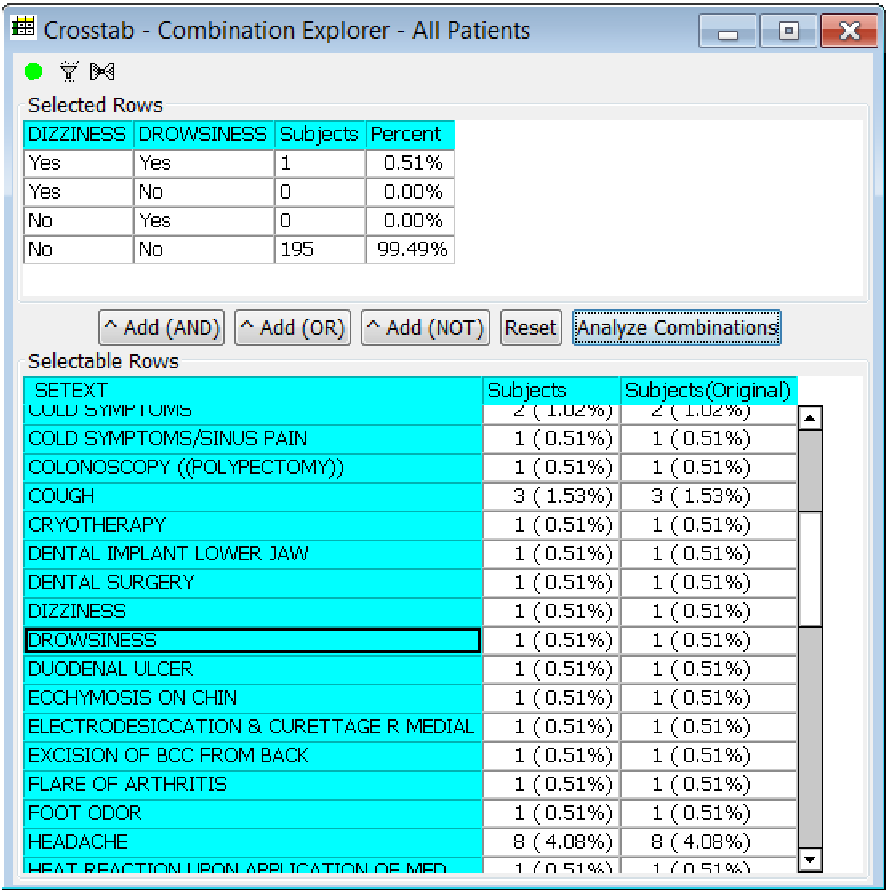
By:

Percent Denominator
- ○ Total Rows
- ● All Patients
- ○ Patient Subset
- ○ Col Totals
- ○ Row Totals
- ○ 1st Col Totals
- ○ 1st Col Totals (All subj)

Row Heading(s): SETEXT

Column Heading(s): Subjects

The percentages are applied to the **Subjects (Original)** column. Click **Analyze Combinations** to view percentages.



Crosstab - Combination Explorer - All Patients

Selected Rows

| DIZZINESS | DROWSINESS | Subjects | Percent |
|---|---|---|---|
| Yes | Yes | 1 | 0.51% |
| Yes | No | 0 | 0.00% |
| No | Yes | 0 | 0.00% |
| No | No | 195 | 99.49% |

Selectable Rows

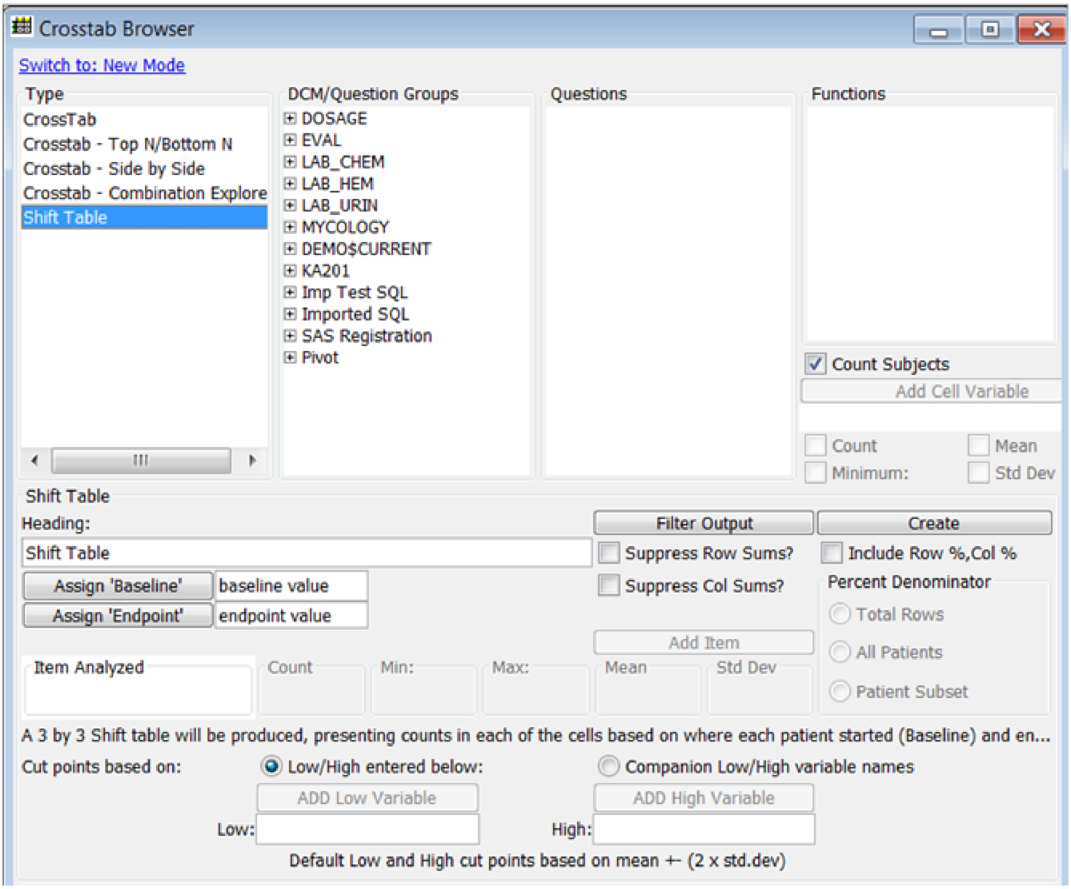
| SETEXT | Subjects | Subjects(Original) |
|---|---|---|
| COLD SYMPTOMS | 2 ( 1.02%) | 2 ( 1.02%) |
| COLD SYMPTOMS/SINUS PAIN | 1 ( 0.51%) | 1 ( 0.51%) |
| COLONOSCOPY ((POLYPECTOMY)) | 1 ( 0.51%) | 1 ( 0.51%) |
| COUGH | 3 ( 1.53%) | 3 ( 1.53%) |
| CRYOTHERAPY | 1 ( 0.51%) | 1 ( 0.51%) |
| DENTAL IMPLANT LOWER JAW | 1 ( 0.51%) | 1 ( 0.51%) |
| DENTAL SURGERY | 1 ( 0.51%) | 1 ( 0.51%) |
| DIZZINESS | 1 ( 0.51%) | 1 ( 0.51%) |
| DROWSINESS | 1 ( 0.51%) | 1 ( 0.51%) |
| DUODENAL ULCER | 1 ( 0.51%) | 1 ( 0.51%) |
| ECCHYMOSIS ON CHIN | 1 ( 0.51%) | 1 ( 0.51%) |
| ELECTRODESICCATION & CURETTAGE R MEDIAL | 1 ( 0.51%) | 1 ( 0.51%) |
| EXCISION OF BCC FROM BACK | 1 ( 0.51%) | 1 ( 0.51%) |
| FLARE OF ARTHRITIS | 1 ( 0.51%) | 1 ( 0.51%) |
| FOOT ODOR | 1 ( 0.51%) | 1 ( 0.51%) |
| HEADACHE | 8 ( 4.08%) | 8 ( 4.08%) |
| HEAT REACTION UPON APPLICATION OF MED | 1 ( 0.51%) | 1 ( 0.51%) |

# Defining a Shift Table

*Item analyzed*

The Shift Table is a patient count of any numeric multi-visit patient data, providing patient categorization by defined threshold values segmented over time. The panels and items available are limited to data that is multi-visit or multi-measure. You must use numeric data.

When the Shift Table is selected, not all panels listed may contain data suitable for Shift Table calculation. For example, Laboratory and Vital Signs data is meaningful as data values with normal ranges to reference.



Type: Shift Table

Heading: Shift Table

Assign 'Baseline': baseline value

Assign 'Endpoint': endpoint value

☑ Count Subjects

☐ Count ☐ Mean

☐ Minimum: ☐ Std Dev

☐ Suppress Row Sums? ☐ Include Row %,Col %

☐ Suppress Col Sums?

○ Total Rows

○ All Patients

○ Patient Subset

A 3 by 3 Shift table will be produced, presenting counts in each of the cells based on where each patient started (Baseline) and en...

Cut points based on: ● Low/High entered below: ○ Companion Low/High variable names

Low:

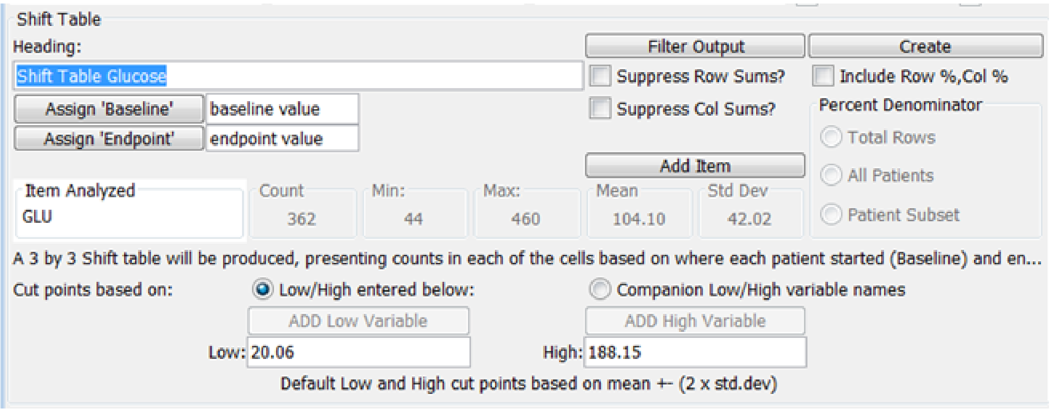
High:

Default Low and High cut points based on mean +- (2 x std.dev)

## Create Shift Table

Define the contents of a Shift Table by applying the same method that you used to build all other browser constructs:

1. Select a panel.
2. Select the item to be analyzed.
3. Click the **ADD Item** button and the item is added into the Item Analyzed box. Basic descriptive statistics are displayed and default cutoff values are assigned.
4. Optionally Assign Baseline and Endpoint values from the Functions list box. The system default for the Shift Table is the 'Baseline value' and 'Endpoint value' definitions entered in ReviewAdmin.
5. Click **Create**. Review opens the Shift Table results.



Shift Table

Heading: Shift Table Glucose

Assign 'Baseline': baseline value

Assign 'Endpoint': endpoint value

☐ Suppress Row Sums?

☐ Suppress Col Sums?

☐ Include Row %,Col %

Percent Denominator

○ Total Rows

○ All Patients

○ Patient Subset

| Item Analyzed | Count | Min: | Max: | Mean | Std Dev |
|---|---|---|---|---|---|
| GLU | 362 | 44 | 460 | 104.10 | 42.02 |

A 3 by 3 Shift table will be produced, presenting counts in each of the cells based on where each patient started (Baseline) and en...

Cut points based on: ● Low/High entered below: ○ Companion Low/High variable names

Low: 20.06

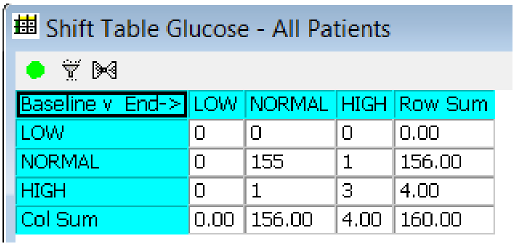
High: 188.15

Default Low and High cut points based on mean +- (2 x std.dev)

A 3 by 3 Shift table will be produced, representing counts in each of the cells based on where each patient started (Baseline) and ended (Endpoint) for the selected item. The Cut Points are based on either Low/High entered range or optionally select Companion Low/High Variable names available in vertical lab tables.

The CrossTab Browser defaults the table type as the heading, however, you can edit the default Shift Table heading in the results window. The heading displays on the Shift Table output, as well as on any printouts.

Read the Baseline values as rows versus Endpoint values as columns. For example, the lab Glucose had 1 patient normal at baseline and high at endpoint of the study.

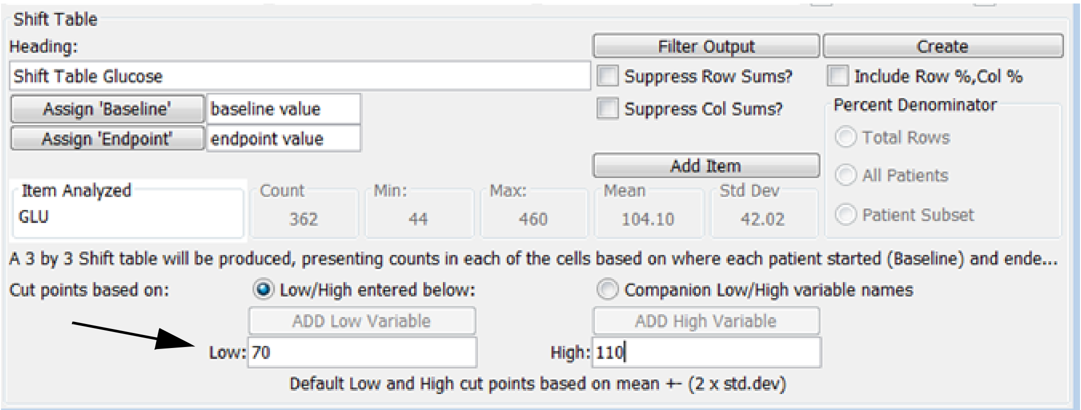

Shift Table Glucose - All Patients

| Baseline v End-> | LOW | NORMAL | HIGH | Row Sum |
|---|---|---|---|---|
| LOW | 0 | 0 | 0 | 0.00 |
| NORMAL | 0 | 155 | 1 | 156.00 |
| HIGH | 0 | 1 | 3 | 4.00 |
| Col Sum | 0.00 | 156.00 | 4.00 | 160.00 |

## *Range values*

Use the default Low/High range values. The Shift Table type presents basic statistics and default boundary values of normal range for the selected item. The normal range by default is +/- two times the standard deviation.

Or, you can edit the default Low/High range values by typing in the values you want to apply.



Shift Table

Heading: Shift Table Glucose

Assign 'Baseline': baseline value

Assign 'Endpoint': endpoint value

☐ Suppress Row Sums?

☐ Suppress Col Sums?

☐ Include Row %,Col %

Percent Denominator: ○ Total Rows ○ All Patients ○ Patient Subset

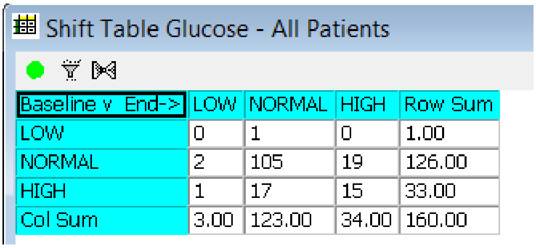
| Item Analyzed | Count | Min: | Max: | Mean | Std Dev |
|---|---|---|---|---|---|
| GLU | 362 | 44 | 460 | 104.10 | 42.02 |

A 3 by 3 Shift table will be produced, presenting counts in each of the cells based on where each patient started (Baseline) and ende...

Cut points based on: ● Low/High entered below: ○ Companion Low/High variable names

Low: 70 High: 110

Default Low and High cut points based on mean +- (2 x std.dev)


Shift Table Glucose - All Patients

| Baseline v End-> | LOW | NORMAL | HIGH | Row Sum |
|---|---|---|---|---|
| LOW | 0 | 1 | 0 | 1.00 |
| NORMAL | 2 | 105 | 19 | 126.00 |
| HIGH | 1 | 17 | 15 | 33.00 |
| Col Sum | 3.00 | 123.00 | 34.00 | 160.00 |

Use the **Companion Low/High variable names** to select the reference laboratory normal ranges for the item analyzed.

***Note: Define New Ranges is not applicable for use as the Companion Low/High variable names. You must use the reference laboratory ranges.***

## *Assign Baseline and Endpoint*

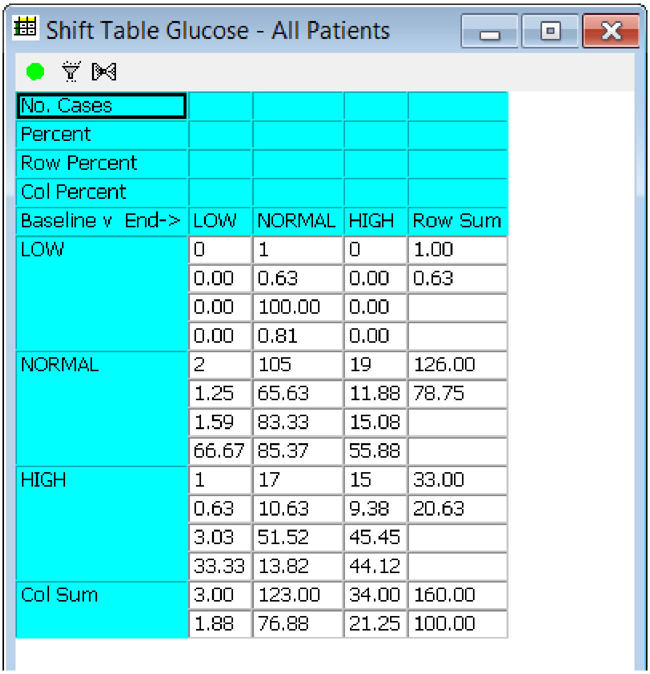
The system default for the Shift Table is the ‘Baseline value’ and ‘Endpoint value’ definitions entered in ReviewAdmin. Instead you can use Assign Baseline”or “Assign Endpoint” buttons to pick user defined ‘New Event’ for either of these time points. The user may define New Event functions. Select the event function from the Functions list box and click either Assign Baseline or Assign Endpoint to replace the system default. The resulting Shift Table uses the New Event descriptions as labels instead of the usual “Baseline v Endpoint ->” at the top of the shift table. **(See *Chapter 12: Advanced Topics: New Events function*)**

## *Apply Filter Output*

The output filter looks and operates similar to the patient selection criteria window. You select the panel item and value or range value to create a row filtering criteria. The selection of the values or range values are supported by Display Stats and Display Values. **(See *Chapter 6: Report Browser: Output Filter*)**

## *Include Row% and Col%*

You can optionally create a Shift Table with row and column percentages displayed by checking **Include Row%, Col%**. Each row and column will be summarized by the following data:



| | | | | |
|---|---|---|---|---|
| No. Cases | | | | |
| Percent | | | | |
| Row Percent | | | | |
| Col Percent | | | | |
| Baseline v End-> | LOW | NORMAL | HIGH | Row Sum |
| LOW | 0 | 1 | 0 | 1.00 |
| | 0.00 | 0.63 | 0.00 | 0.63 |
| | 0.00 | 100.00 | 0.00 | |
| | 0.00 | 0.81 | 0.00 | |
| NORMAL | 2 | 105 | 19 | 126.00 |
| | 1.25 | 65.63 | 11.88 | 78.75 |
| | 1.59 | 83.33 | 15.08 | |
| | 66.67 | 85.37 | 55.88 | |
| HIGH | 1 | 17 | 15 | 33.00 |
| | 0.63 | 10.63 | 9.38 | 20.63 |
| | 3.03 | 51.52 | 45.45 | |
| | 33.33 | 13.82 | 44.12 | |
| Col Sum | 3.00 | 123.00 | 34.00 | 160.00 |
| | 1.88 | 76.88 | 21.25 | 100.00 |

# Multiple CrossTab/Shift Tables

## *Multiple CrossTabs*

You can have multiple CrossTabs active at the same time. After you define and create one CrossTab:

1. Click 🗋, or from the **File** menu, select **New** to refresh your screen. While creating a new CrossTab you can add to the specifications of the existing CrossTab.
2. Click **Create** to execute the new CrossTab. There will be a CrossTab Browser output window for each CrossTab created. There is no limitation within Review as to how many CrossTabs you create and leave open. Each open CrossTab output window is fully interactive with all patient level browser displays, to identify and characterize the underlying patient data. You can optionally create a CrossTab or Shift Table with row and column percentages displayed.

   ***Note: If you enter a patient selection criteria, all currently open crosstab output windows will refresh to display the new results with the patient selection criteria applied.***

# Snapshot output

## *Multiple population mode*

Review has an optional multiple-population mode available in the CrossTab Browser. The Snapshot output allows you to change the patient selection criteria and view the different output within the CrossTab browser at the same time. When the results are executed and displayed from the CrossTab browser output window, two icons are displayed for “Snapshot Output” and “Who?”. **(See *Chapter 6 Report Browser: Snapshot Output*)**

# Printing and exporting CrossTab/Shift Tables

## *Print Preview*

To display a print preview of your output:

1. Click on the generated output window to make it the active window.
2. Click 🔍, or from the **File** menu, select **Print Preview**.

   Review displays a screen shot of the selected active screen. The Study Name is automatically added to the CrossTab header.
3. Click either **Print** or **Close.**

   The Print Preview function is applicable to all browsers with output results.

## *Print the CrossTab/Shift Tables*

To print the CrossTab/Shift Table:

1. Click 🖨 , or from the **File** menu, select **Print**. Review displays the standard print dialog box.
2. Click **OK** on the printer. The CrossTab/Shift Table prints on the specified printer.

The default printed CrossTab/Shift Table contains the CrossTab/Shift Table heading as you entered it as a header, the study name, the current patient selection criteria, and a page number as the footer.

## *Page Setup*

Page setup can be accessed by selecting page setup from the **File** menu. Review displays a standard spreadsheet page setup dialog box, allowing you to make changes.

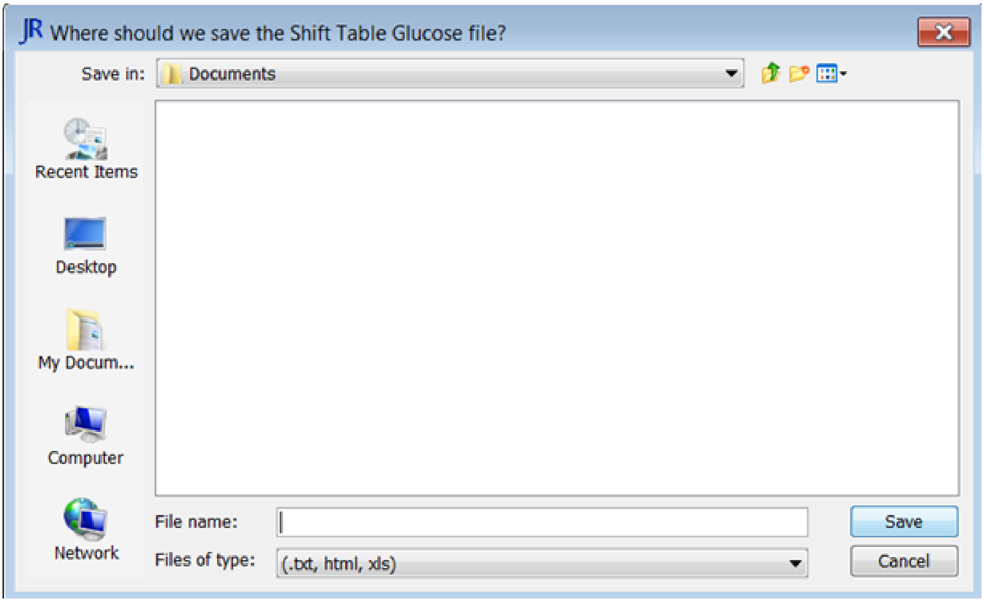
## *Exporting the CrossTab/Shift Tables*

Export of CrossTab spreadsheet includes Excel 4, 5 and 7, tab delimited files, HTML format and PDF files.

To export your tables:

1. From the **File** menu, select **Export**.

   Review displays the Export **Save As** window.



2. Enter the storage location, and Click **OK**.

   Your tables are exported to the currently selected disk directory.

   **(See *Chapter 12: Advanced Topics: Shared Object Storage- Location*.)**

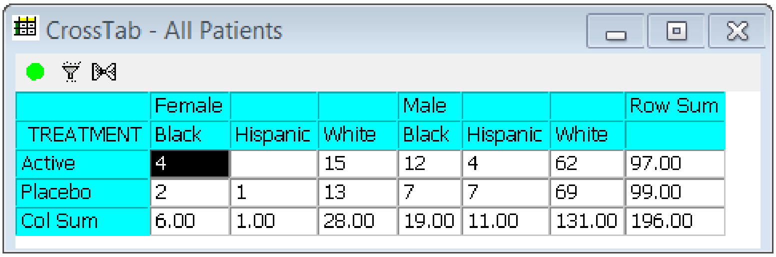
# Interactive patient-level displays

## Crosstab cell select

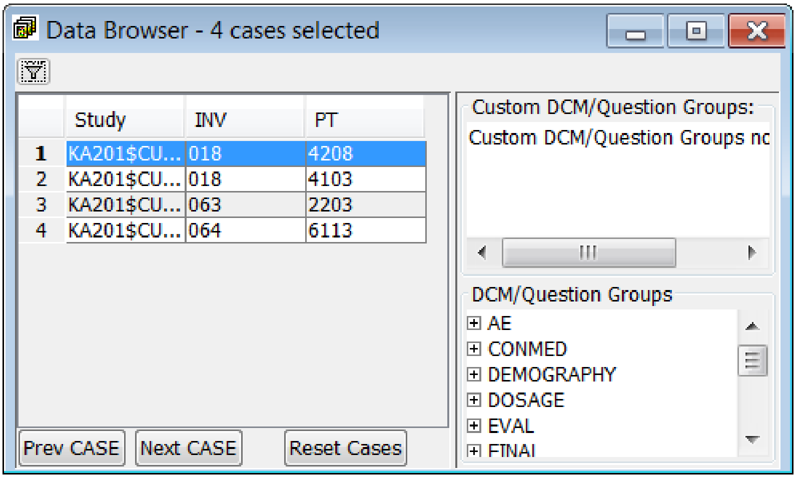
You can identify patients within a crosstab with the Data Browser while viewing your crosstab results. Open the Data Browser and click on any cell count within the crosstab. The Data Browser updates to identify those patients selected in the crosstab cell.

## Crosstab multiple cell select

Selecting multiple cells within the crosstab to identify those patients works similar to selecting a single crosstab cell. Open the Data Browser then hold down the CTRL key and click on multiple cells within the crosstab. The Data Browser result adds the patients in the crosstab cells.



|  | Female |  |  | Male |  |  | Row Sum |
|---|---|---|---|---|---|---|---|
| TREATMENT | Black | Hispanic | White | Black | Hispanic | White |  |
| Active | 4 |  | 15 | 12 | 4 | 62 | 97.00 |
| Placebo | 2 | 1 | 13 | 7 | 7 | 69 | 99.00 |
| Col Sum | 6.00 | 1.00 | 28.00 | 19.00 | 11.00 | 131.00 | 196.00 |



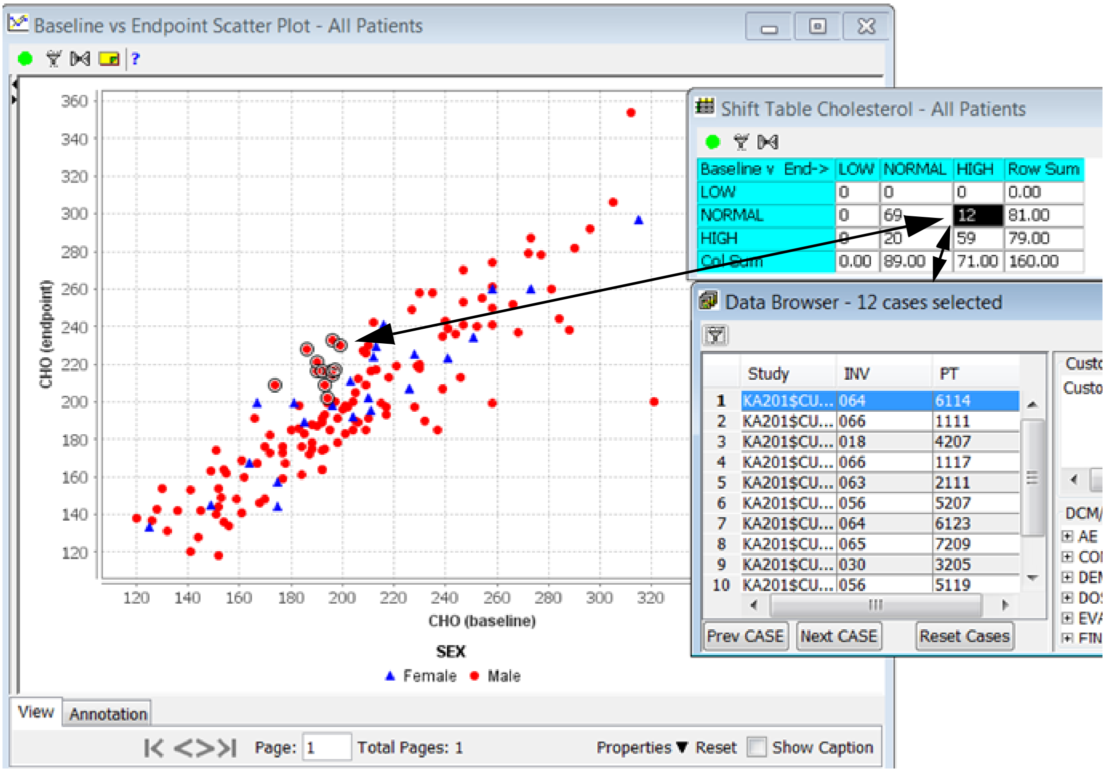
|  | Study | INV | PT |
|---|---|---|---|
| 1 | KA201$CU... | 018 | 4208 |
| 2 | KA201$CU... | 018 | 4103 |
| 3 | KA201$CU... | 063 | 2203 |
| 4 | KA201$CU... | 064 | 6113 |

The patient counts are fully interactive with all patient-level displays of data. Data Browser and Detail Data Listing reports update to identify and describe only the patients underlying the patient counts clicked on.

If you have created a Detail Patient Listing report, Scatter Plot graph, or have the Data Browser open, you can click on any table values in one of the CrossTab/Shift Table windows to view a patient listing of the selected table value in all open patient-level displays of data.

Scatter plot graphs update to highlight only the patients underlying the patient count selected in the Shift Table, against the patient population subset by the current patient selection criteria.

***Note: Use categorical counts for low, normal and high. Do not use total counts.***



| Baseline v End-> | LOW | NORMAL | HIGH | Row Sum |
|---|---|---|---|---|
| LOW | 0 | 0 | 0 | 0.00 |
| NORMAL | 0 | 69 | 12 | 81.00 |
| HIGH | 0 | 20 | 59 | 79.00 |
| Col Sum | 0.00 | 89.00 | 71.00 | 160.00 |

|  | Study | INV | PT |
|---|---|---|---|
| 1 | KA201$CU... | 064 | 6114 |
| 2 | KA201$CU... | 066 | 1111 |
| 3 | KA201$CU... | 018 | 4207 |
| 4 | KA201$CU... | 066 | 1117 |
| 5 | KA201$CU... | 063 | 2111 |
| 6 | KA201$CU... | 056 | 5207 |
| 7 | KA201$CU... | 064 | 6123 |
| 8 | KA201$CU... | 065 | 7209 |
| 9 | KA201$CU... | 030 | 3205 |
| 10 | KA201$CU... | 056 | 5119 |

# Object storage

For detailed instructions on how to save, retrieve, schedule output and remove object specifications (reports, graphs, crosstabs, etc.), ***See Chapter 11: Saving and Manage Objects, Scheduling plus Alerts Browser***.

If you save a CrossTab specification with a patient selection criteria and/or the output filter on, they are saved with the CrossTab or Shift Table output specification. **(*See Chapter 11: Saving and Manage Objects, Scheduling plus Alerts Browser*)**

You cannot schedule a saved Shift Table specification, however, you can schedule a saved CrossTab specification.

# Exploring data

## *Changing the patient selection criteria*

After you define the specifications of your CrossTab\Shift Table, and create it by clicking **Create CrossTab**, you can use the CrossTab\Shift Table(s) that are currently displayed as data exploration views:

1. Change the patient selection criteria, redefining it by adding additional criteria expressions, or removing existing criteria expressions.
2. Clicking **Update Browsers** in the Patient Selection Criteria window to update all active browsers according to the new Criteria.

   CrossTabs or other browser objects that are opened will be updated according to your new patient selection criteria.

### *CrossTab output filter*

Row filtering is carried out by the Output Filter Criteria window. The output filter facilitates specification of observations and visits, from multi-visit data items, to include in your focused presentations.

After you define the specifications of your CrossTab, you can use the output filter as a data exploration tool by row filtering data inclusion, then comparing filtered and unfiltered results. Open filtered and non-filtered Scatter Plot graphs can be very informative when Review's complementary browsers, such as the CrossTab browser, are utilized in the multiple patient-mode to identify and characterize subsets of patients:

1. Click **Filter Output**, and create a new filter by adding or removing filter criteria expressions.
2. Click **Save Filter** in the CrossTab output filter window to apply it against the next created CrossTab. The **Filter Output** button in the CrossTab Browser window toggles to **Filter is ON**.

   ***Note*****:** ***If you save the CrossTab specification with an output filter on, the same filter will be applied when the CrossTab is recreated.***

## Closing the CrossTab Browser

### *Closing a CrossTab Window*

If you are finished reviewing the data in a CrossTab or Shift Table, double-click the window's close box.

### *Closing the CrossTab Browser*

If you are finished with the CrossTab Browser and do not want to define any other constructs, double-click the close box of the CrossTab Browser window. Review closes all CrossTab Browser windows currently opened.

# 9 Generating Statistics

# SAS Proc types

## *Selection set*

In JReview, you can select a previously saved Patient Subset, Dynamic PSC or define your own selection criteria by using the Statistics Browser (SAS Proc Browser). After launching the saved patient subset or building your own patient selection criteria, you can explore stored statistical reports of items for each of the patients who meet the selection criteria. These stored statistical report objects were created in the SAS Proc Browser.

## *Selecting a SAS Proc*

The following types of **SAS Procs** are available in **IReview:**

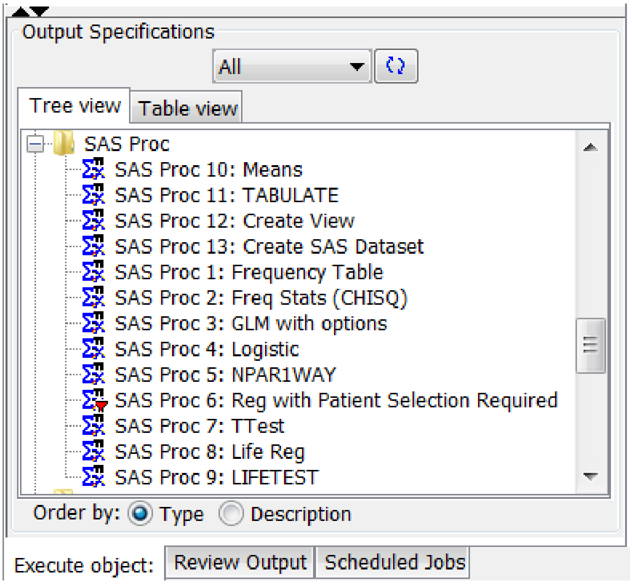
- **Create SAS View*** - generates a SAS view of the items selected.
- **Create SAS DataSet*** - generates a SAS dataset of the items selected for the patient population currently selected.
- **FREQ*** - generates a frequency distribution matrix of the items specified.
- **FREQ*** with Statistics - generates a frequency distribution matrix with additional statistics ‘Options’.
- **TTEST*** - one of a number of hypothesis tests looks at the t-statistic, t-distribution and degrees of freedom to determine a p value (probability) that can be used to determine whether the population means differ.
- **LIFETEST*** - is a nonparametric procedure for estimating survival.
- **MEANS*** - generates a report of basic statistics for each of the items for the population currently selected.
- **TABULATE*** - generates a cross-tabulation of the items for the population currently selected.

# Execute a SAS Proc specification

## *Quick execute*

JReview displays a list of categorical folders for stored patient subsets and output specifications at the selected storage location. Simply select one of the storage locations to display it's specific folders and contents.

Icons are displayed along with the stored object to identify the source as report, graph, registered SAS program, etc. When a patient selection criteria is saved with the stored object; the filter icon displays with the specific browser icon. JReview aids users to quickly locate and launch these stored objects.



SAS Proc
- SAS Proc 10: Means
- SAS Proc 11: TABULATE
- SAS Proc 12: Create View
- SAS Proc 13: Create SAS Dataset
- SAS Proc 1: Frequency Table
- SAS Proc 2: Freq Stats (CHISQ)
- SAS Proc 3: GLM with options
- SAS Proc 4: Logistic
- SAS Proc 5: NPAR1WAY
- SAS Proc 6: Reg with Patient Selection Required
- SAS Proc 7: TTest
- SAS Proc 8: Life Reg
- SAS Proc 9: LIFETEST

Order by: ● Type ○ Description

## *Retrieve a saved output specification*

To retrieve a saved output specification:

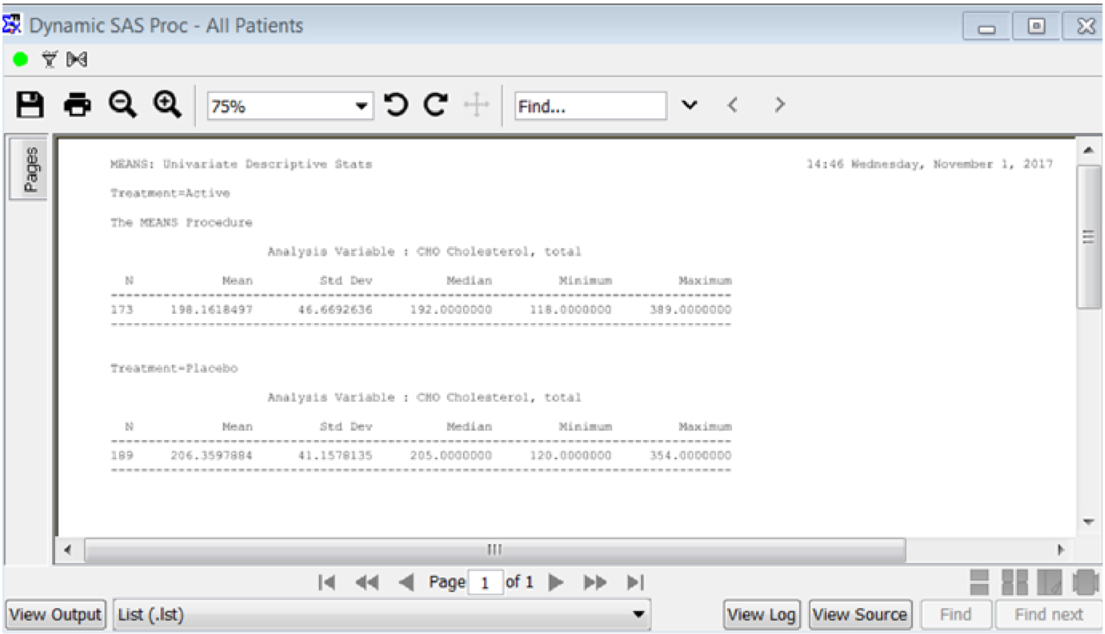
1. Double click to open a folder in Output Specifications.
2. The SAS Proc icon , displays next to the SAS Proc specification description.

   Double click on the object to launch in a single step. The stored output specification will be launched.

# SAS Proc results display

## *SAS Proc output*

When you select the SAS Proc specification which contains the information you want, JReview sends your request to be processed by SAS on your server computer, and displays the results in View Output window. The data in your report contains only data from those patients who meet your current patient selection criteria and/or SAS Proc output filter.



```
MEANS: Univariate Descriptive Stats                                              14:46 Wednesday, November 1, 2017

Treatment=Active

The MEANS Procedure

                    Analysis Variable : CHO Cholesterol, total

  N           Mean         Std Dev          Median         Minimum         Maximum
------------------------------------------------------------------------------------
173    198.1618497      46.6692636     192.0000000     118.0000000     389.0000000
------------------------------------------------------------------------------------


Treatment=Placebo

                    Analysis Variable : CHO Cholesterol, total

  N           Mean         Std Dev          Median         Minimum         Maximum
------------------------------------------------------------------------------------
189    206.3597884      41.1578135     205.0000000     120.0000000     354.0000000
------------------------------------------------------------------------------------
```

## *Displaying the SAS output, source, or log*

Notice the three buttons at the bottom of the Output display window. By default, the SAS output has been displayed; however, if you want to review the SAS log click **View SAS Log**. If you want to review the SAS source used to create the SAS output click **View SAS Source**. To review the SAS output again, after reviewing the SAS log or SAS source click **View Output**.

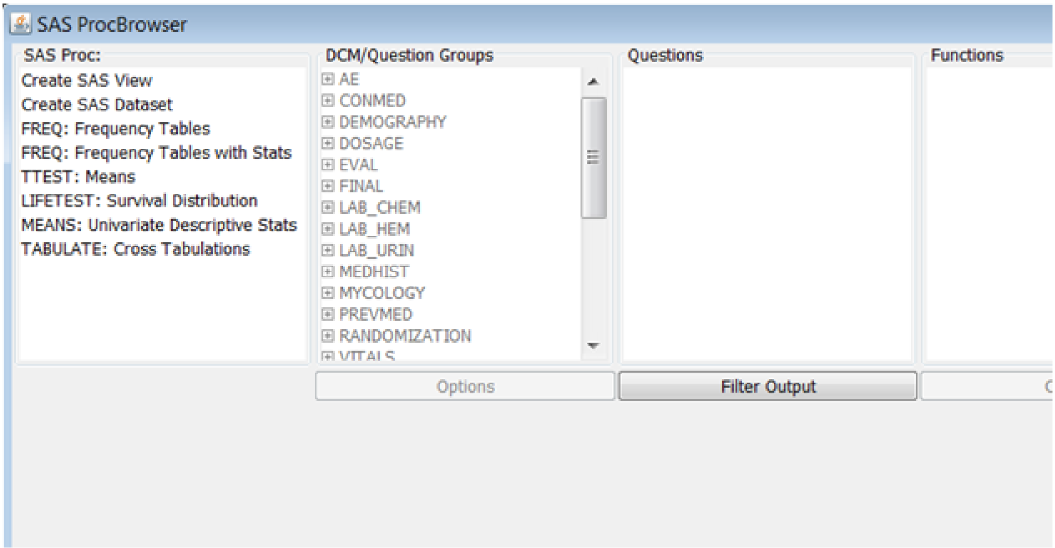
If multiple SAS Proc results are active at the same time, each functions independently. That is, you can review the source, log or output of each independently by clicking the appropriate results button in the respective windows.

# Defining a SAS View and Dataset

## *Opening the SAS Proc Browser*

Full or restricted access to the SAS Proc Browser is enabled/disabled based on the SAS user-level setting made by the administrator. By default, access to all SAS Procs is enabled.

Click , or from the **Browse** menu, select **SAS Procs**. Review displays a new window where you can specify the panels and items to be included for the execution of SAS procedures.

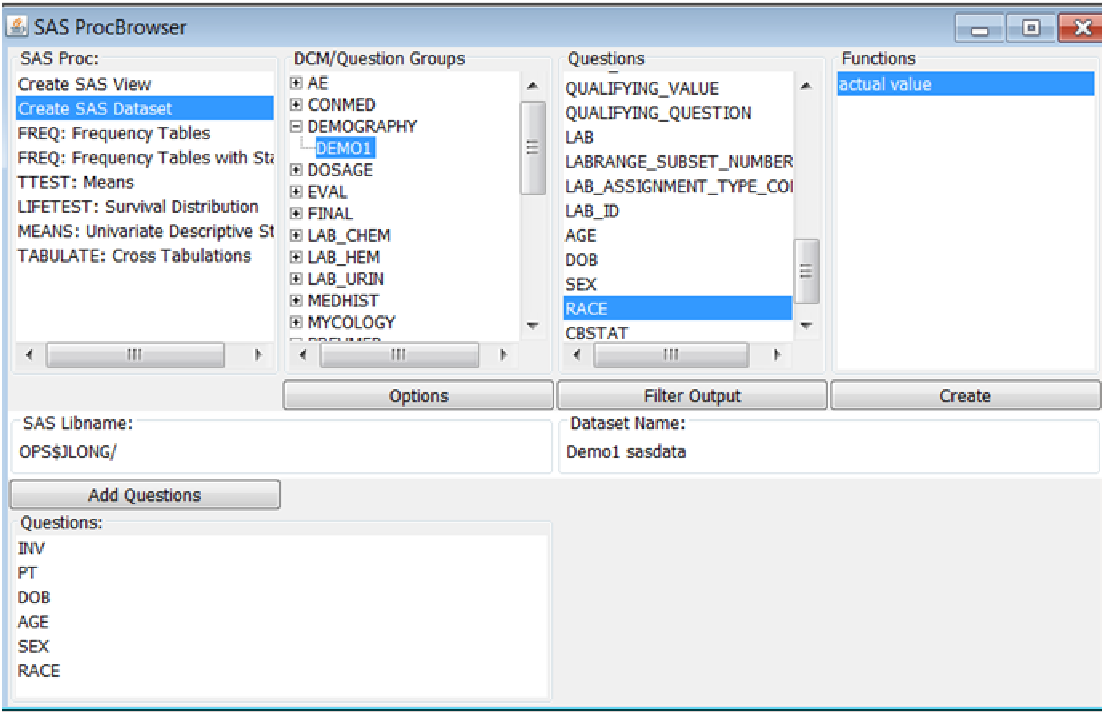


## *Create SAS View and Dataset*

Define the specifications of the SAS View or Dataset by applying the same method that you used to build the patient selection criteria:

1. Select **Create SAS View** or **Create SAS Dataset**.
2. Select a panel.
3. Select each item of interest.
4. When using the Create SAS View, and Create SAS Dataset you may use the **Add Questions** to select and add single items. Or, click on the SHIFT key to select a particular panel for **Add DCM/Question Groups** to default all items for the selected panel. This method of selecting individual items, or all items from multiple panels will create a single SAS View or Dataset.

   When selecting individual items from one or more datasets where you have not used the Shift, or CTRL key is referred to as ‘Single Dataset mode’. Essentially you can pick any items from any panels  to be combined into a single dataset.



SAS Libname: OPS$JLONG/

Dataset Name: Demo1 sasdata

Questions:
INV
PT
DOB
AGE
SEX
RACE

5. You can create multiple SAS Views or Datasets by selecting multiple panels in the following ways:

   For contiguous panels (panels listed next to each other):

   a. Click the first panel.
   b. Hold the **shift** key and mouse click and drag the cursor over the next panel(s).

   For non-contiguous panels (panels not listed next to each other):

   a. Select the panels you want while holding down the **CTRL** key.
   b. Click each panel you want to select.

   When you use the Shift or CTRL key, you enter into Multi-Dataset mode where you can pick one, or more panels. In that case, it will create one dataset per selected panel, where all items for each selected dataset will be included.

   Each panel that was selected is assigned an individual SAS View or Dataset name with all items included.

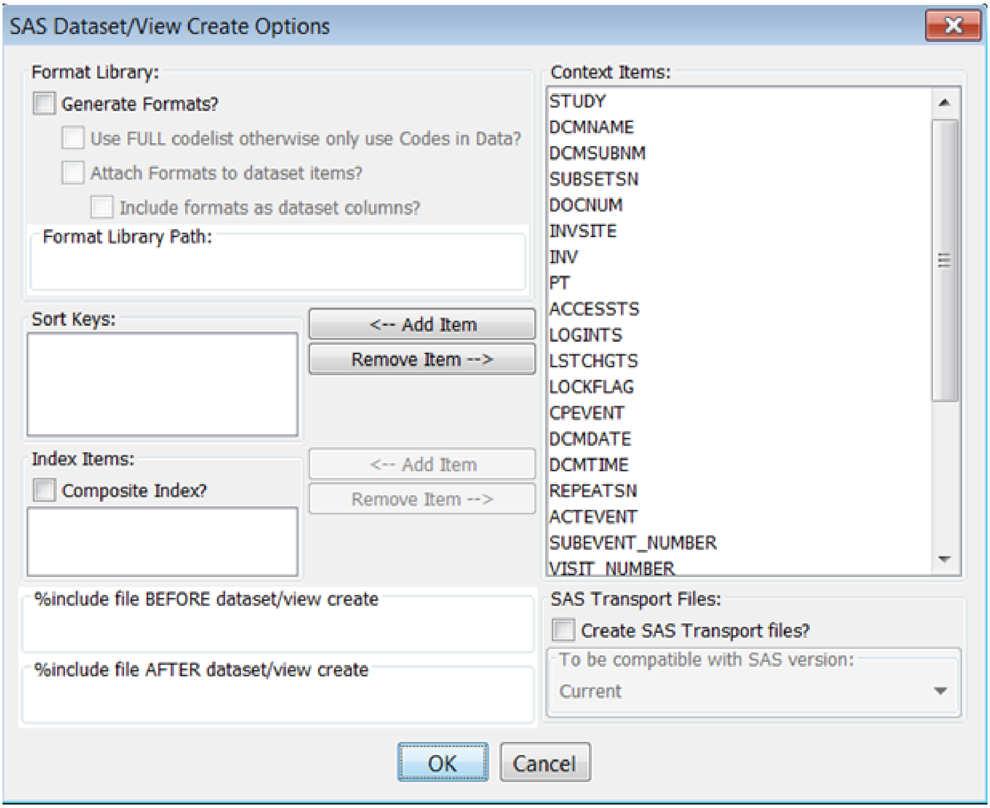
   *Note:* ***If multiple panels are selected, and item names are repeated, Review automatically forces unique names to be used in the creation of the SAS View or the SAS Dataset***.

## *Select format library options*

The SAS Dataset/View Create Options window allows you to specify format library options such as generate formats, use FULL codelist, attach formats to dataset items and include formats as dataset columns. In addition, you can define dataset sorting, index items and enter %include files to be added before and after the dataset or view is created. When you create a SAS Dataset all the settings are enabled including Index Items and the option to create SAS Transport files and PDF files.

You must select ‘Generate Formats?’ in order to ‘Use FULL codelist’ or to ‘Attach Formats’. Likewise, in order to ‘Include formats as dataset columns’, you must first select the ‘Attach Formats’ in order to create those columns.

6. Click **Options. The** SAS Dataset/View Create window opens.
7. Enter your options.
8. Create SAS Transport Files?



SAS Dataset/View Create Options

Format Library:
☐ Generate Formats?
☐ Use FULL codelist otherwise only use Codes in Data?
☐ Attach Formats to dataset items?
☐ Include formats as dataset columns?
Format Library Path:

Sort Keys:

Index Items:
☐ Composite Index?

Context Items:
STUDY
DCMNAME
DCMSUBNM
SUBSETSN
DOCNUM
INVSITE
INV
PT
ACCESSTS
LOGINTS
LSTCHGTS
LOCKFLAG
CPEVENT
DCMDATE
DCMTIME
REPEATSN
ACTEVENT
SUBEVENT_NUMBER
VISIT_NUMBER

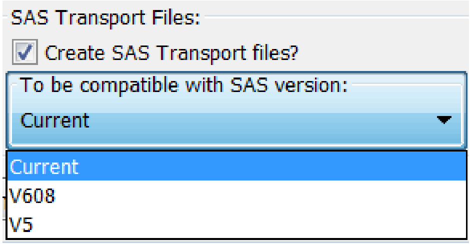
%include file BEFORE dataset/view create

%include file AFTER dataset/view create

SAS Transport Files:
☐ Create SAS Transport files?
To be compatible with SAS version: Current

## *SAS Transport Files*

You must click Create SAS Transport Files in order to select the type of transport file.


SAS Transport Files:

☑ Create SAS Transport files?

To be compatible with SAS version: Current

The SAS Views you create are dynamic, i.e., whenever accessed by SAS return the current Oracle data. The SAS Dataset created contains the selected items of the current patient population.

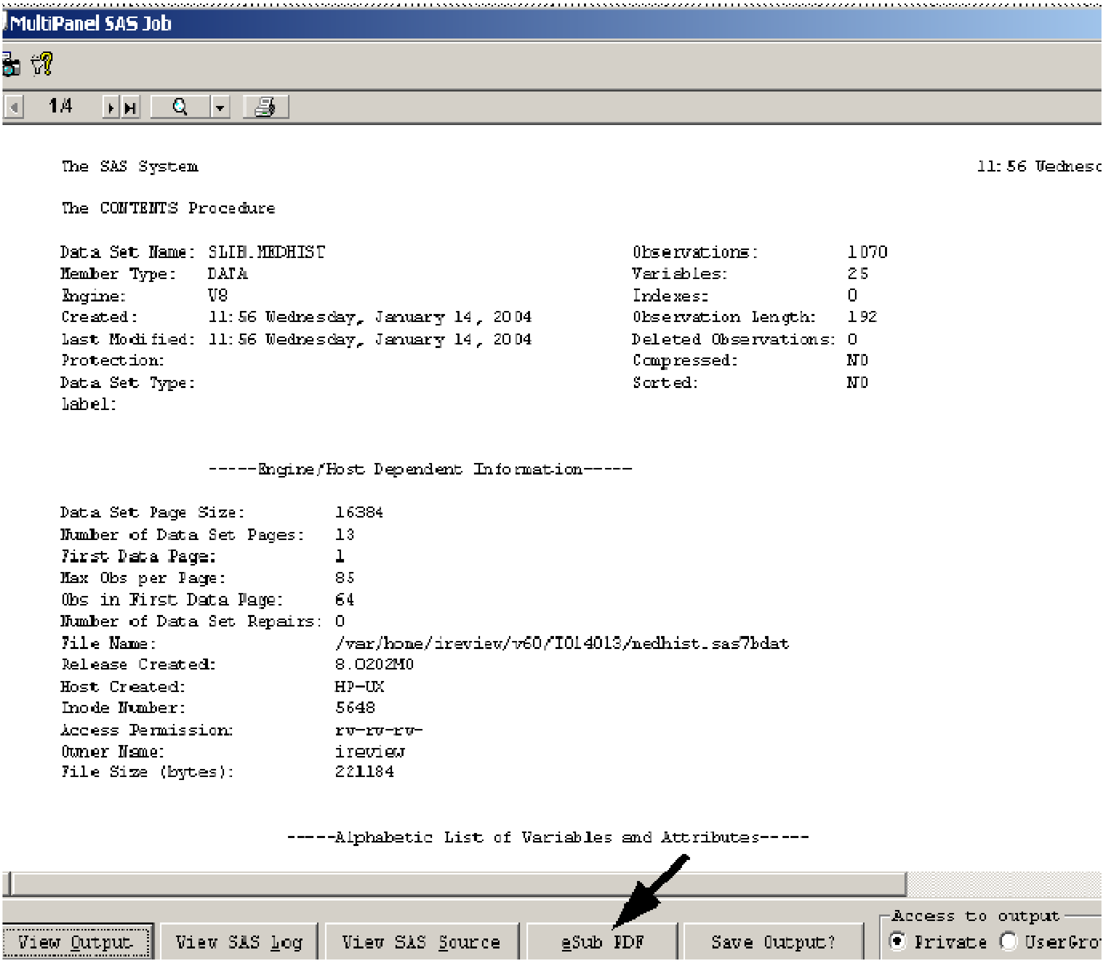
This feature allows you to take snapshots of the data while the study is ongoing. Simply select panels and items to add to the dataset, and export if desired. ***(See Chapter 12 for information about the pseudo-items '_Define New Item_' and '_Define New Range_' on the pseudo-function, '_New Event Function_'.)***

9. Click **OK.**
10. Click **Create to generate SAS Output**.

## *V5 (FDA Guidelines) option*

When you create SAS Transport Files as V5 (FDA Guidelines) this option is the only one which requires format settings. You must generate format catalogs and attach the formats to the variables in the datasets. It is not mandatory to 'Include formats as dataset columns'.

***Note: When you click the V5 option the two required options are selected for you and you cannot change it.***

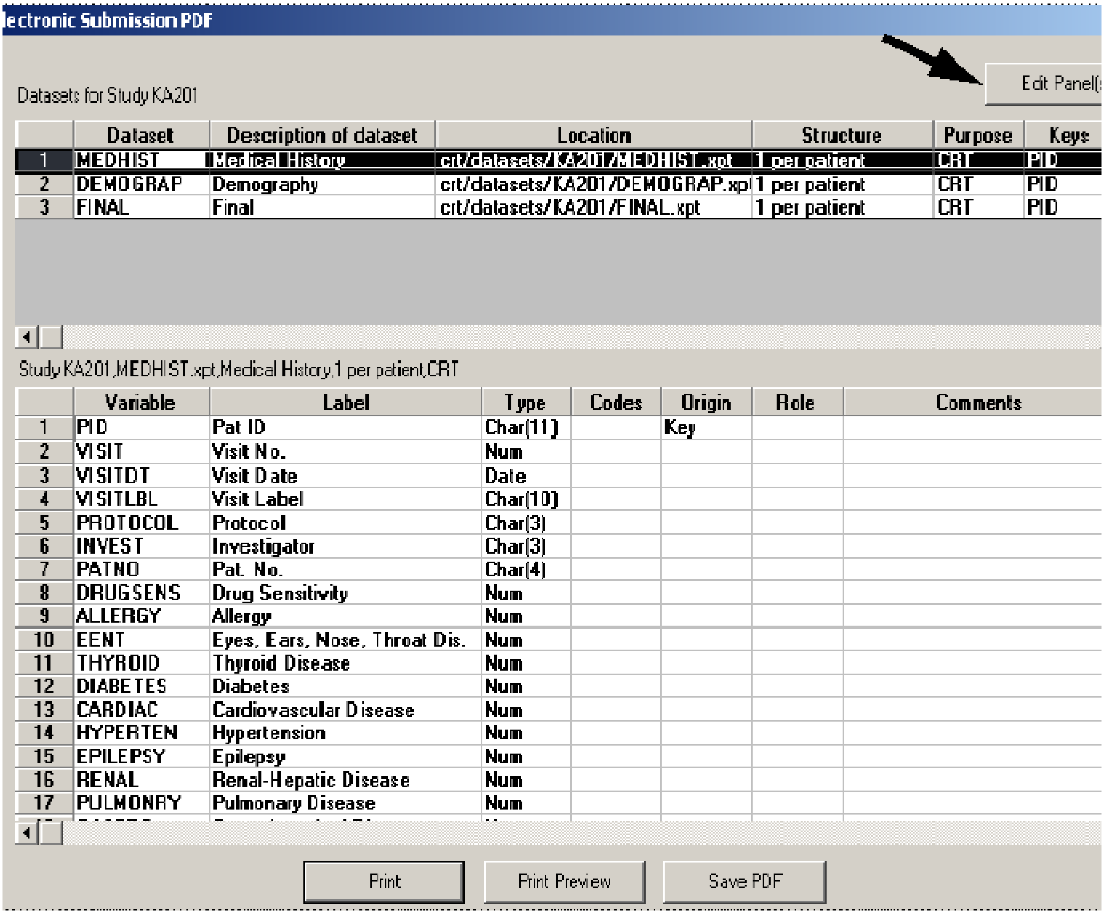


```
The SAS System                                                          11:56 Wednesc

The CONTENTS Procedure

Data Set Name:  SLIB.MEDHIST                            Observations:          1070
Member Type:    DATA                                    Variables:             25
Engine:         V8                                      Indexes:               0
Created:        11:56 Wednesday, January 14, 2004       Observation Length:    192
Last Modified:  11:56 Wednesday, January 14, 2004       Deleted Observations:  0
Protection:                                             Compressed:            NO
Data Set Type:                                          Sorted:                NO
Label:


             -----Engine/Host Dependent Information-----

Data Set Page Size:          16384
Number of Data Set Pages:    13
First Data Page:             1
Max Obs per Page:            85
Obs in First Data Page:      64
Number of Data Set Repairs:  0
File Name:                   /var/home/ireview/v60/T014013/medhist.sas7bdat
Release Created:             8.0202M0
Host Created:                HP-UX
Inode Number:                5648
Access Permission:           rw-rw-rw-
Owner Name:                  ireview
File Size (bytes):           221184


                  -----Alphabetic List of Variables and Attributes-----
```

## *Edit panels*

When you select the V5 (FDA Guidelines) option and create the SAS Dataset/View, you can edit the panels by clicking the **eSub PDF** button. The Electronic Submission PDF window displays as a panels spreadsheet. The primary function of the panels spreadsheet is to display format details.

1. Click **Edit Panel**(s) to convert the panels spreadsheet into edit mode. The button status changes to save Panel(s).
2. Select a row variable to edit specific fields in the items spreadsheet.
3. Click **Save Panels**.
4. Click **Save PDF**. Print Preview and Print buttons can be selected.



Datasets for Study KA201

| | Dataset | Description of dataset | Location | Structure | Purpose | Keys |
|---|---|---|---|---|---|---|
| 1 | MEDHIST | Medical History | crt/datasets/KA201/MEDHIST.xpt | 1 per patient | CRT | PID |
| 2 | DEMOGRAP | Demography | crt/datasets/KA201/DEMOGRAP.xp | 1 per patient | CRT | PID |
| 3 | FINAL | Final | crt/datasets/KA201/FINAL.xpt | 1 per patient | CRT | PID |

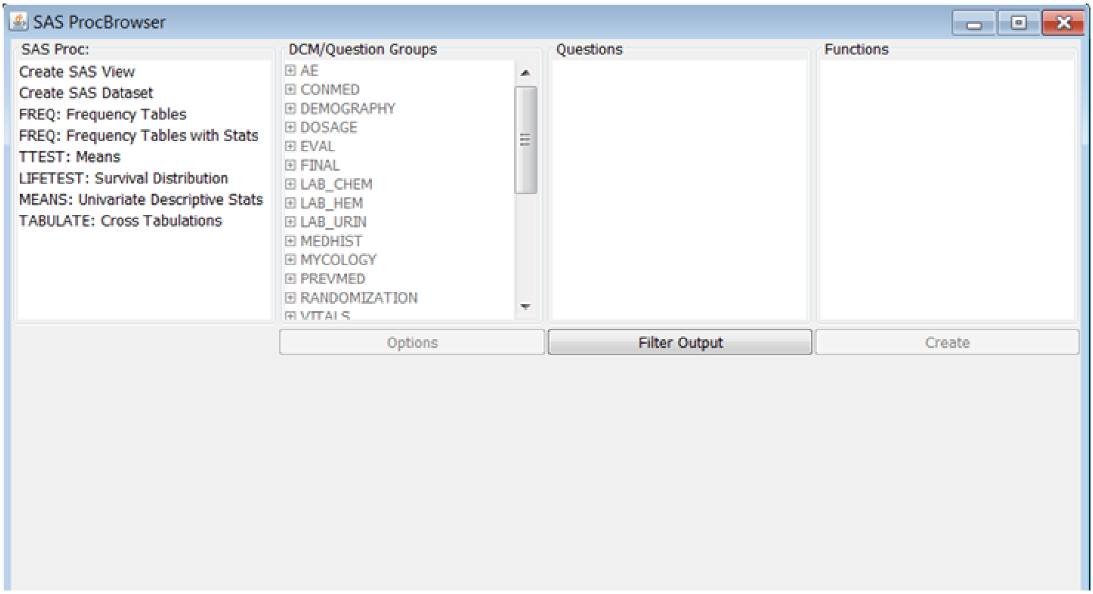
Study KA201,MEDHIST.xpt,Medical History,1 per patient,CRT

| | Variable | Label | Type | Codes | Origin | Role | Comments |
|---|---|---|---|---|---|---|---|
| 1 | PID | Pat ID | Char(11) | | Key | | |
| 2 | VISIT | Visit No. | Num | | | | |
| 3 | VISITDT | Visit Date | Date | | | | |
| 4 | VISITLBL | Visit Label | Char(10) | | | | |
| 5 | PROTOCOL | Protocol | Char(3) | | | | |
| 6 | INVEST | Investigator | Char(3) | | | | |
| 7 | PATNO | Pat. No. | Char(4) | | | | |
| 8 | DRUGSENS | Drug Sensitivity | Num | | | | |
| 9 | ALLERGY | Allergy | Num | | | | |
| 10 | EENT | Eyes, Ears, Nose, Throat Dis. | Num | | | | |
| 11 | THYROID | Thyroid Disease | Num | | | | |
| 12 | DIABETES | Diabetes | Num | | | | |
| 13 | CARDIAC | Cardiovascular Disease | Num | | | | |
| 14 | HYPERTEN | Hypertension | Num | | | | |
| 15 | EPILEPSY | Epilepsy | Num | | | | |
| 16 | RENAL | Renal-Hepatic Disease | Num | | | | |
| 17 | PULMONRY | Pulmonary Disease | Num | | | | |

# Defining a SAS Proc Specification

## *Define SAS Proc specification*

Define the specifications of the SAS Proc run by applying the same method that you used to build the patient selection criteria.



1. Select a SAS Proc.
2. Select a panel.
3. Select each item of interest and an appropriate function, or use the default function.
4. Select a BY Variable(s) to categorize the data if applicable.
5. Click Create.

## *Adding items to be analyzed*

Select the individual item(s) to be analyzed, and click **ADD Item** to add the item to the SAS Proc specification.

The following SAS Procs share the same display window for the selections ADD By Var and ADD Item.

- FREQ
- MEANS
- TABULATE
- FREQ with Statistics

## *Adding BY variables*

You can further process the data with the use of BY categorical variables. Click **ADD By Var** to add the selected Item to the list of By Variables for the SAS Proc run.

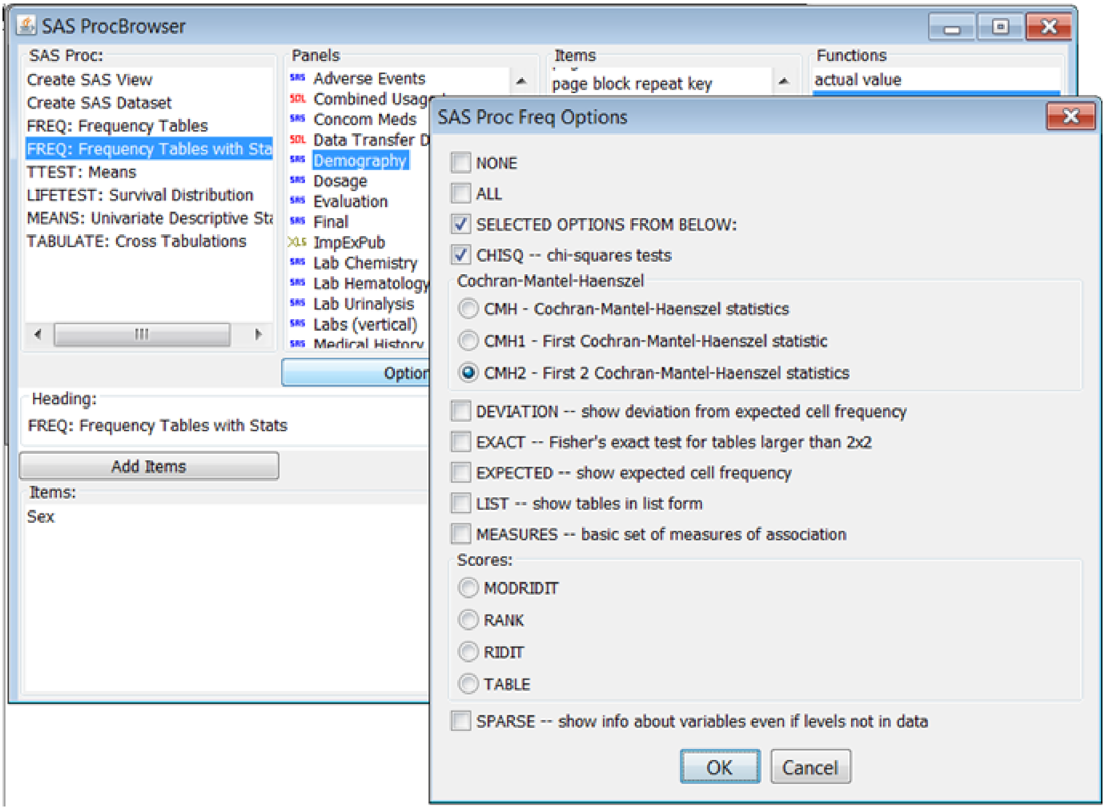
A BY variable is a variable by which the data sets are ordered according to the BY statement variable. Statistical observations on BY variables are carried out on ordered, grouped, or indexed values of one or more variables.

## *Statistics options*

Some of the more complex SAS Procs have additional options available to further analyze the data. The statistic options are specific to the SAS Proc selected. You will see the OPTIONS button enabled for those specific SAS Procs; otherwise, the OPTIONS button is not highlighted. Click Options if available.

The Frequency tables with Stats has an Options button to further analyze the data with additional statistical testing as follows:

1. Click **Frequency tables with Stats** as the SAS Proc type. The Options button is enabled when this SAS Proc type is selected.
2. Select a panel.
3. Select each item of interest.
4. Click **Options** to display the SAS Proc Freq Options window.
5. Select the statistical test(s) for analysis and click **OK**.



Heading:
FREQ: Frequency Tables with Stats

☐ NONE
☐ ALL
☑ SELECTED OPTIONS FROM BELOW:
☑ CHISQ -- chi-squares tests

Cochran-Mantel-Haenszel
○ CMH - Cochran-Mantel-Haenszel statistics
○ CMH1 - First Cochran-Mantel-Haenszel statistic
● CMH2 - First 2 Cochran-Mantel-Haenszel statistics

☐ DEVIATION -- show deviation from expected cell frequency
☐ EXACT -- Fisher's exact test for tables larger than 2x2
☐ EXPECTED -- show expected cell frequency
☐ LIST -- show tables in list form
☐ MEASURES -- basic set of measures of association

Scores:
○ MODRIDIT
○ RANK
○ RIDIT
○ TABLE

☐ SPARSE -- show info about variables even if levels not in data

## *Output filter*

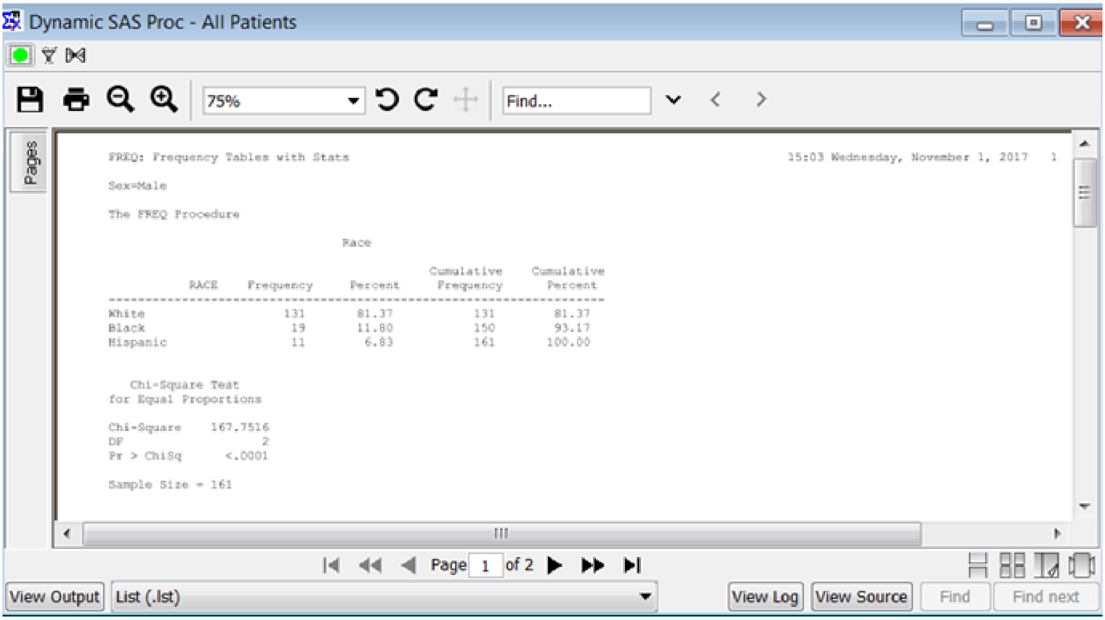
**(See *Chapter 6 Report Browser: Output Filter*)**

## *Defining a SAS Proc title*

Enter a title for the SAS Proc that will be displayed as the caption of the resulting SAS Proc output window, as well as on any printouts. Enter the title text in the “Heading” field.

## Creating the SAS Proc output

When your SAS Proc specification contains the information you want, click **Create**. Review sends your request to be processed by SAS on your server computer, and displays the results in View Output window. The data in your report contains only data from those patients who meet your current patient selection criteria and/or SAS Proc output filter:



```
FREQ: Frequency Tables with Stats                                        15:03 Wednesday, November 1, 2017   1

Sex=Male

The FREQ Procedure

                                 Race

                                                Cumulative    Cumulative
            RACE    Frequency     Percent        Frequency       Percent
-------------------------------------------------------------------------
White                     131       81.37              131         81.37
Black                      19       11.80              150         93.17
Hispanic                   11        6.83              161        100.00


   Chi-Square Test
for Equal Proportions

Chi-Square    167.7516
DF                   2
Pr > ChiSq      <.0001

Sample Size = 161
```

## Change a SAS Proc specification

To change the SAS Proc Run specification that you define:

1. Click anywhere in either the **By Variables** or the **Item(s) analyzed** list.
2. Click on the item that you want to delete.
3. Click ✂ or from the **Edit** menu, select **Cut**. This deletes the highlighted row from the SAS Proc specification.
4. To clear the entire SAS specification, click 🗋.

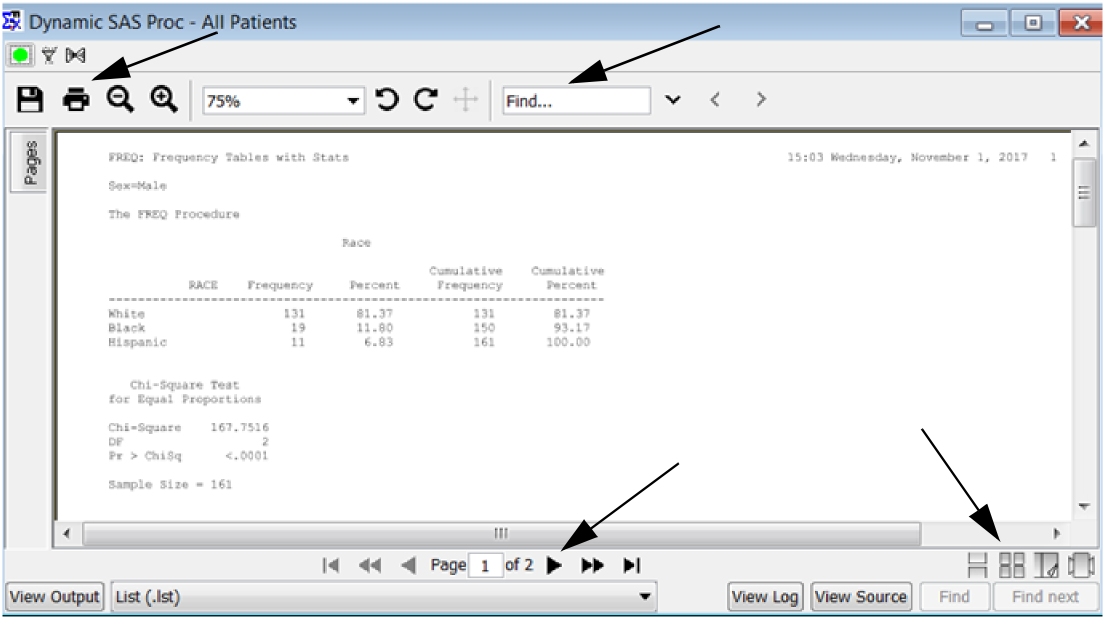
# SAS Proc results display

## *Toolbar*

The PDF viewer not only provides quite a few viewing options – like continuous stream of pages, or two at a time – like a magazine, four up, etc. – but also has built in ‘bookmark’ access (really nice in formatted reports or formatted patient profiles – which both generate bookmarks), plus a built in Search function.

Use the tool bar buttons to scroll through the pages or change the image scale with the plus and minus signs.

Use the **Printer icon** to print the output results.



```
FREQ: Frequency Tables with Stats                                   15:03 Wednesday, November 1, 2017   1

Sex=Male

The FREQ Procedure

                                Race

                                                  Cumulative    Cumulative
           RACE    Frequency     Percent     Frequency      Percent
-------------------------------------------------------------------
White                    131       81.37           131        81.37
Black                     19       11.80           150        93.17
Hispanic                  11        6.83           161       100.00


   Chi-Square Test
for Equal Proportions

Chi-Square     167.7516
DF                    2
Pr > ChiSq       <.0001

Sample Size = 161
```

## *Find menu command*

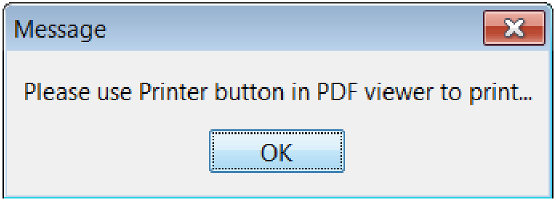
You can perform a ‘Find’/’Find Next’ for text search in ASCII type SAS output (.SAS,.LOG). Click on the **Find** button to enter text search.

# Exporting and printing results

## *Printing the SAS Proc results*

The Print function is applicable to all browsers with output results. To get a printed copy of your output:

1. Click on the generated output window to make it the active window.
2. Click 🖨 icon. (***See previous section on Toolbar)***



Please use Printer button in PDF viewer to print...

The SAS results (output, source, or log) prints on the currently selected printer.

SAS Program / SAS Proc Output display converts .LST file to PDF in the JRServer, then displaying the converted PDF in the PDF viewer in the JReview client. This offers better control over font sizes, lines per inch, etc. This .LST file is exportable directly as a PDF file.

## *Exporting the result*

Export your result to PDF files.

1. From the **File** menu, select **Export**. The created output window must be the active window.

   Review displays the **Export** dialog box.
2. Enter the storage location.
3. Enter the storage type.
4. Click OK.

   The result is exported to the currently selected disk directory.

***(See Chapter 6: Report Browser for Exporting Results)***

# Multiple SAS Proc outputs

## *Opening multiple SAS Proc results*

You can have multiple SAS Proc result windows active at the same time. After you execute one SAS Proc output, you can minimize the results and execute another saved SAS Proc specification.

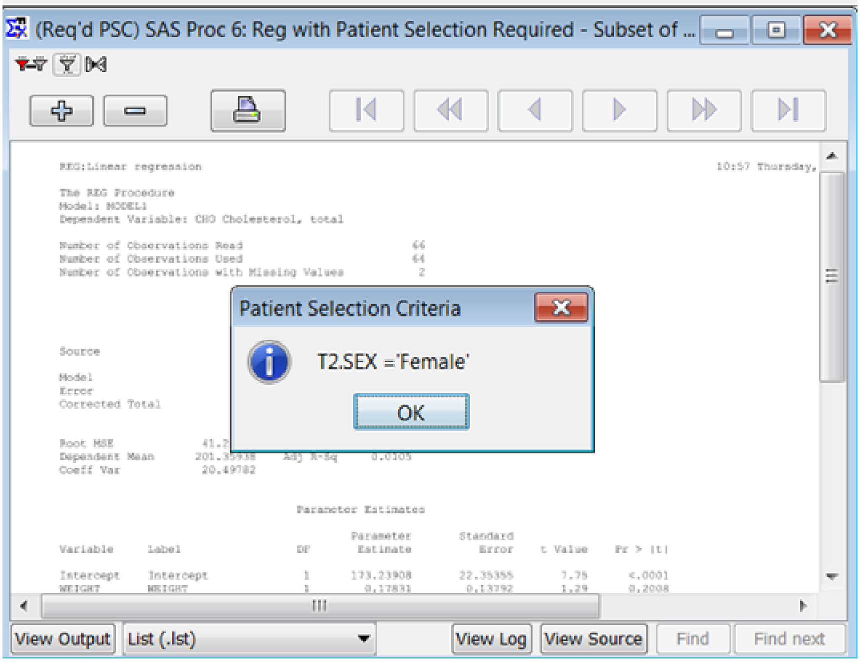
JReview displays a new window for each new SAS statistical analysis. You can have several output windows active at the same time. (The suggested procedure is to minimize the output windows, and open them as needed to help manage window space. The only limitation that an end-user may experience in the number of SAS Proc result windows opened at once is window space).

After you define and create one SAS Proc output, you can minimize the results and/or activate the SAS Proc Browser. Once the SAS Proc Browser is the active window:

1. Click 🗋 or from the **File** menu, select **New** to refresh the screen. (You can open saved SAS Proc specification.)
2. You add variables to an active or saved SAS Proc specification, and click **Create SAS Output** to run the SAS Proc request.

## *Snapshot output*

JReview has an optional multiple-population mode available within the individual browsers output window. When the results are executed and displayed from the browser output window, three icons are displayed for “Snapshot Output”, “Selection Criteria” and “Output Filter”. The Selection Criteria button opens a message box to display the current patient selection criteria. The Snapshot output allows you to freeze the current output window and then change the patient selection criteria and view the different output within the browser at the same time.



```
REG:Linear regression                                                   10:57 Thursday,

The REG Procedure
Model: MODEL1
Dependent Variable: CHO Cholesterol, total

Number of Observations Read                      66
Number of Observations Used                      64
Number of Observations with Missing Values        2




Source

Model
Error
Corrected Total


Root MSE               41.2
Dependent Mean        201.35938    Adj R-Sq      0.0105
Coeff Var              20.49782


                                   Parameter Estimates

                                           Parameter       Standard
Variable      Label                 DF      Estimate          Error    t Value    Pr > |t|

Intercept     Intercept              1     173.23908       22.35355       7.75      <.0001
WEIGHT        WEIGHT                 1       0.17831        0.13792       1.29      0.2008
```

T2.SEX ='Female'

***Note: If the stored object definition already has a required patient selection criteria defined, you will not be allowed to change it.***

When you click the Snapshot button in the output window, the output heading will display “Snapshot” in the title and the button changes color. This output window is now ‘frozen’. You can apply a selection criteria or change a non-required selection criteria and execute new output for display next to the ‘Snapshot’.

# Save a SAS Proc specification

## *Save a SAS Proc specification*

You can save the SAS Proc specification for later use or validation of results. All saved SAS Procs with output filters ON are saved with the filters. **(See *Chapter 11: Saving and Managing Objects, plus Alerts Browser)***

*Note:* ***However, SAS PROC is currently* NOT supported *by Job Scheduling (as the message indicates).***

# Close SAS Proc Browser and results

## *Closing a SAS Proc output window*

If you are finished reviewing the output of a SAS Proc, and do not need to use the output to review any other patient populations: Double-click the window's close box.

## *Closing the SAS Proc Browser*

If you are finished with all SAS Proc outputs, and do not need to define any other reports: Double-click the close box of the SAS Proc Browser window. Review also closes all SAS Proc results windows currently opened.

# Exploring data

## *Changing the patient selection criteria*

After you have executed a stored object, you can use the object(s) that are currently displayed as data exploration views by doing the following:

1. Change the patient selection criteria, redefining it by adding additional expressions, or removing existing expressions.
2. Click **Update Browsers** in the Patient Selection Criteria window to update all active browsers according to the new criteria.

   Any SAS Procs, or other browser objects that are open update according to your new criteria. Each report generated with a filter on will update with the same filter criteria with which it was created.

## *SAS Proc output filter*

After you define the specifications of your graph, you can use the output filter as a data exploration tool by row filtering data inclusion and comparing filtered and unfiltered results. Row filtering is carried out by the Output Filter Criteria window. The output filter functionality allows specified observations and visits, from multi-visit items, to focus reporting presentations on clinically specific requisites.

Open filtered scatter plot graphs can be very informative when Review's patient-level interactive browsers are utilized in the multiple-patient mode to identify and characterize a subset of patients.

1. Change the output filter criteria by adding additional expressions, or removing existing expressions.
2. Click **Save Filter** in the SAS Proc Output Filter window to apply it against the next created SAS Proc.

## *Pivot panels*

Pivot Panels provide a powerful display of data, and provides a data structure that can be uniquely utilized by the SAS Proc Browser in producing clinically pertinent presentations of data “on the fly”.

***Note: Saved specifications using a pivot panel will only work with the pivot panel it was created with. If the same pivot panel is recreated with the same name, the objects using the original panel will not work because the system naming convention iterates with each created panel. (*****See** ***Chapter 12: Common Topics: Define Pivot Panel.*****)**

## *Join logic*

The pseudo-panel ‘_Define Join Logic_’ provides an opportunity to investigate relations within the clinical data defined by medical investigators “on the fly”. Join logic defined for the Clintrial type 0 panel is required to utilize the items within Clintrial type 0 panels. **(See *Chapter 12: Common Topics: Define Join Logic*.)**

## *Clintrial tags*

Clintrial tags are accessible to be used in SAS Proc specifications. When the pseudo-panel Clintrial tags is clicked on:

- Clintrial tags are listed as a pseudo-panel.
- Definitions, and Categorizations of tags are listed in the items list. **(See *Chapter 12: Common Topics: Clintrial tags*.)**

## *Protocol comparison*

Use of the pseudo-item <Study ID> in SAS Proc specifications, facilitates comparisons between protocols. **(See *Chapter 12: Common Topics: <Study ID> pseudo Item*.)**

## *New Event Function*

Utilizing the pseudo-function “_New Event Function_” allows you to create and define new landmark events to be evaluated and applied to your selected patient populations. (**See *Chapter 2: Selecting Patients: _New Event Function*.)**

# 10 STAT Program Registration Browser

# STAT Program Registration Browser

## *General*

Your SAS Programmers can register SAS programs and SAS Data Sets used in the formal analysis of the protocol(s) of interest. SAS programs can be registered as study-specific, project-specific or global. These programs and datasets can be made available and registered to Review, typically after the completion of the protocol and cleaning of the database. Your SAS programs can be run against existing SAS datasets, or SAS views that are generated by Review at runtime. Thereafter, you can access these programs and datasets by using the STAT Program Registration Browser.

STAT programs and program groups can be executed from the Object Explorer like other JReview objects. From the output window, the user has the ability to change the output format from lst to htm, pdf, csv, txt, etc.

A privilege setting [P19] is required to run the STAT Program Browser (and to view and run SAS and R programs in the Object Explorer), and a separate privilege setting [P29] controls access to the STAT Program Registration Browser. Users who have access to the STAT Program Registration Browser also have access to the STAT Program Browser, and to STAT programs in the Object Explorer.

In addition, access to STAT programs and their output can be controlled by User Group membership and User Level settings.

Access the STAT Program Registration Browser from Browse menu; or click on the icon in the tool bar.

## *Registered SAS programs*

SAS program registrations can be viewed, added, edited and deleted using the STAT Program Registration Browser window. A separate window, the STAT Program Registration Browser, is used to execute individual SAS programs and to execute groups of programs in a single batch run.

SAS programs and program groups can also be executed from the Object Explorer like other Review objects.

A privilege setting is required to run the STAT Program Browser, and a separate privilege setting controls access to the STAT Program Registration Browser. Users who have access to the STAT Program Registration Browser also have access to the STAT Program Registration Browser. These privileges are defined in ReviewAdmin.

In addition, access to SAS programs and their output can be controlled by User Group membership and User Level settings.

Sub-dialogs are available from the STAT Program Registration Browser to handle program groups, print formats, and patient selection subsets, and also to manage libraries, categories, status codes, etc. and SAS program memberships in these areas.

The following sections describe the various dialogs and windows and their functions for SAS program registration and the execution of SAS programs and groups.

# Interactively register SAS programs

## *Converted SAS programs*

SAS Programs previously registered with ReviewAdmin are converted into the STAT Program Registration Browser during the release upgrade. A conversion script converts earlier SAS program registrations into the new table structures without affecting any of the existing tables used by Review. Converted SAS programs will be included with a STATUS of "CONVERTED." These previously registered SAS programs are listed when you view the STAT Program Registration Browser window. If no SAS programs were previously registered through ReviewAdmin, the STAT Program Registration Browser displays a message in the Programs list for "No programs are registered." When you register new SAS programs the default STATUS is "DEFAULT."

***(See the ReviewAdmin manual for Review configuration descriptions of tables.)***

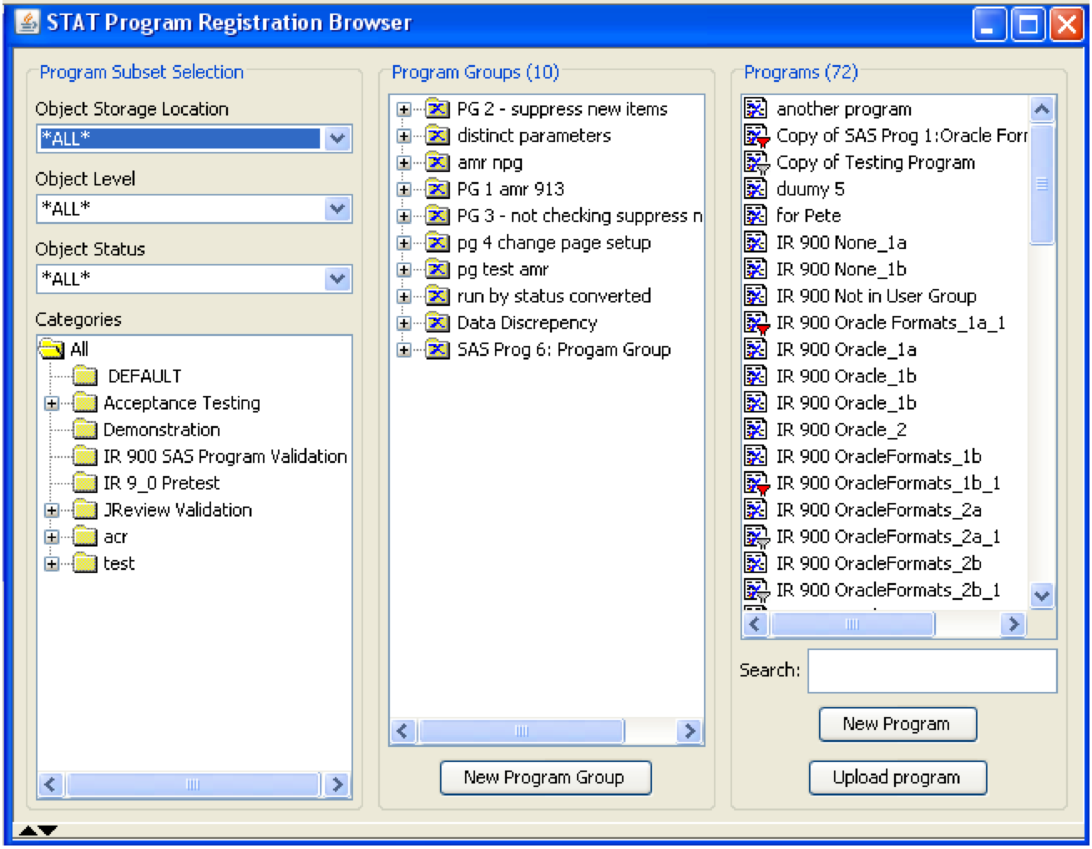
During the conversion, messages are produced if it encounters print formats with missing line size, page size values or inconsistencies between the data origin type and the libname/datalib fields. For example, if the data source is NONE and there are values in either the libname or datalib fields, they will be blanked out. Likewise, if a problem with an invalid data source is encountered then the data source is changed to "None". The messages report the number of adjustments that were made, if any.

## STAT Program Registration window

The STAT Program Registration Browser main window displays lists of all available User Groups, Categories, Program Groups and already registered SAS Programs. A count of the contents for each list is  displayed to assist in the registration management.

The Programs list displays all programs belonging to the currently selected User Group, Category and Program Group(s). You can select multiple program groups with the CTRL key to display all the programs that belong to the selected multiple program groups.

*Note:  You can only access the STAT Program Registration Browser in single protocol mode.*



Object Storage Location: *ALL*

Object Level: *ALL*

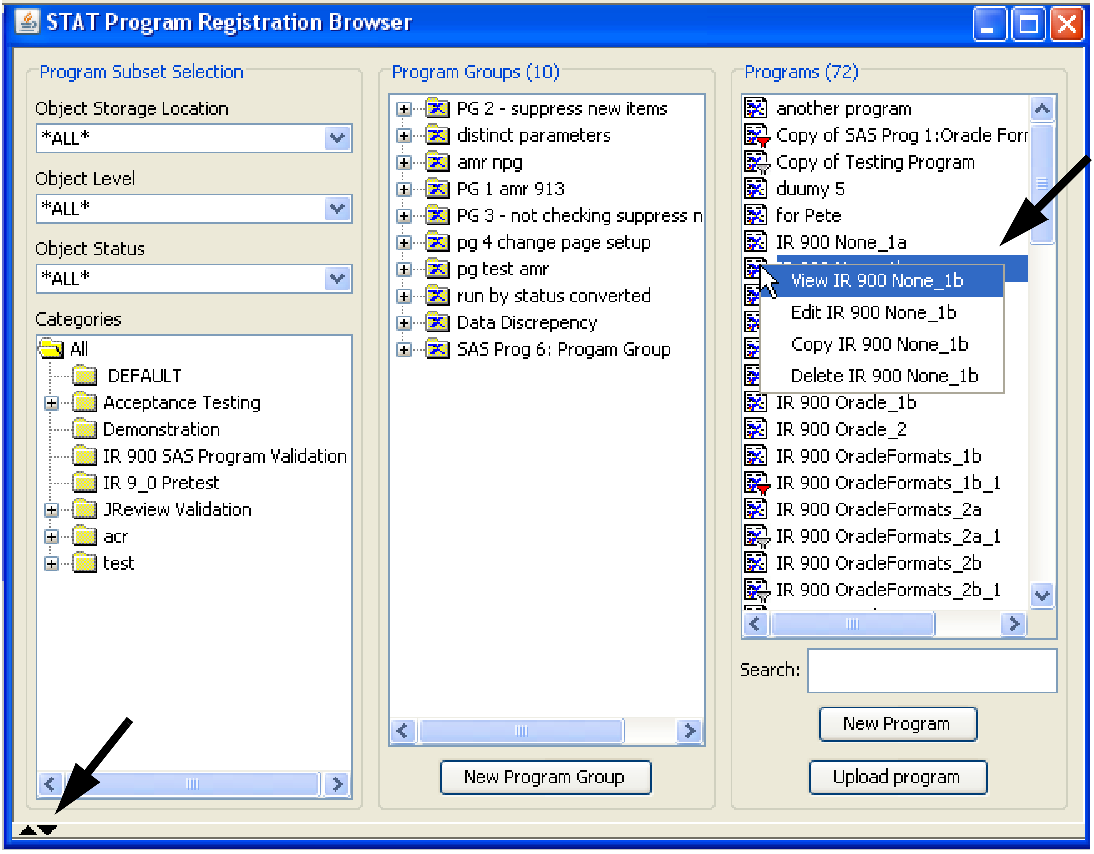
Object Status: *ALL*

Categories:
- All
  - DEFAULT
  - Acceptance Testing
  - Demonstration
  - IR 900 SAS Program Validation
  - IR 9_0 Pretest
  - JReview Validation
  - acr
  - test

Program Groups (10):
- PG 2 - suppress new items
- distinct parameters
- amr npg
- PG 1 amr 913
- PG 3 - not checking suppress n
- pg 4 change page setup
- pg test amr
- run by status converted
- Data Discrepency
- SAS Prog 6: Progam Group

Programs (72):
- another program
- Copy of SAS Prog 1:Oracle Forr
- Copy of Testing Program
- duumy 5
- for Pete
- IR 900 None_1a
- IR 900 None_1b
- IR 900 Not in User Group
- IR 900 Oracle Formats_1a_1
- IR 900 Oracle_1a
- IR 900 Oracle_1b
- IR 900 Oracle_1b
- IR 900 Oracle_2
- IR 900 OracleFormats_1b
- IR 900 OracleFormats_1b_1
- IR 900 OracleFormats_2a
- IR 900 OracleFormats_2a_1
- IR 900 OracleFormats_2b
- IR 900 OracleFormats_2b_1

You may select a Program or Program Group and right mouse click, to display a floating menu of functions for View, Edit, Copy or Delete.



Object Storage Location: *ALL*

Object Level: *ALL*

Object Status: *ALL*

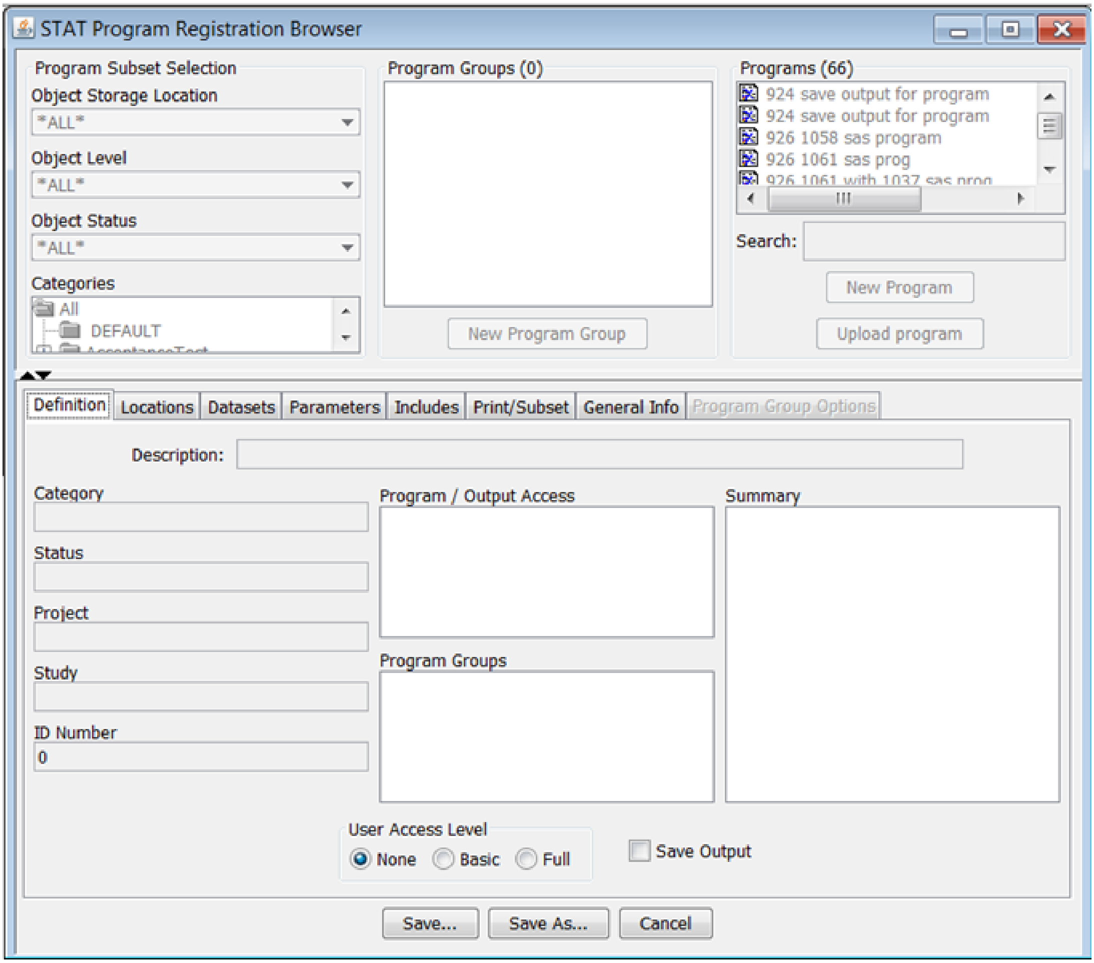
Click the expand arrow in the lower left corner. The STAT Program Registration Browser window expands for access to the function tabs for viewing and registering SAS program information.

The function for **View** was selected. The STAT Program Registration Browser window splits into two viewing areas; detailed information about the currently registered SAS program displays below.

Clicking on a registered SAS program displays information about the program in fields on the tab pages. Clicking on a Program Group displays information about the group in the registration fields below. The program group status code is displayed along with checkbox for the “Run by Status” and “Distinct Parms” options.

Clicking on a particular tab displays a set of related fields. Taken together, the fields on all of the tab pages display all of the information for a particular SAS program.

Observe in View mode that the **Save**, **Save As** and **Edit** buttons located at the bottom are shaded and disabled.



STAT Program Registration Browser

Program Subset Selection

Object Storage Location: *ALL*

Object Level: *ALL*

Object Status: *ALL*

Categories:
- All
  - DEFAULT

Program Groups (0)

Programs (66)
- 924 save output for program
- 924 save output for program
- 926 1058 sas program
- 926 1061 sas prog

Description:

Category:

Status:

Project:

Study:

ID Number: 0

User Access Level: ● None ○ Basic ○ Full

☐ Save Output

## *Register a new SAS program*

The next sections describe each of the tab windows in detail for registering a new SAS program or editing an existing program.

The cursor arrows located at the left midway allow you to expand the top window and toggle between viewing and registration details. Refer back to listed programs and program groups above, or register a new SAS program with the registration function tabs below.

Click the **New Program** or **New Program Group** button to register a new SAS program or program group.

***Note: Currently in JReview version 9.12, you can only register a SAS Program and not a SAS Program Group. The ability to register a New Program Group will be made available in a future release.***

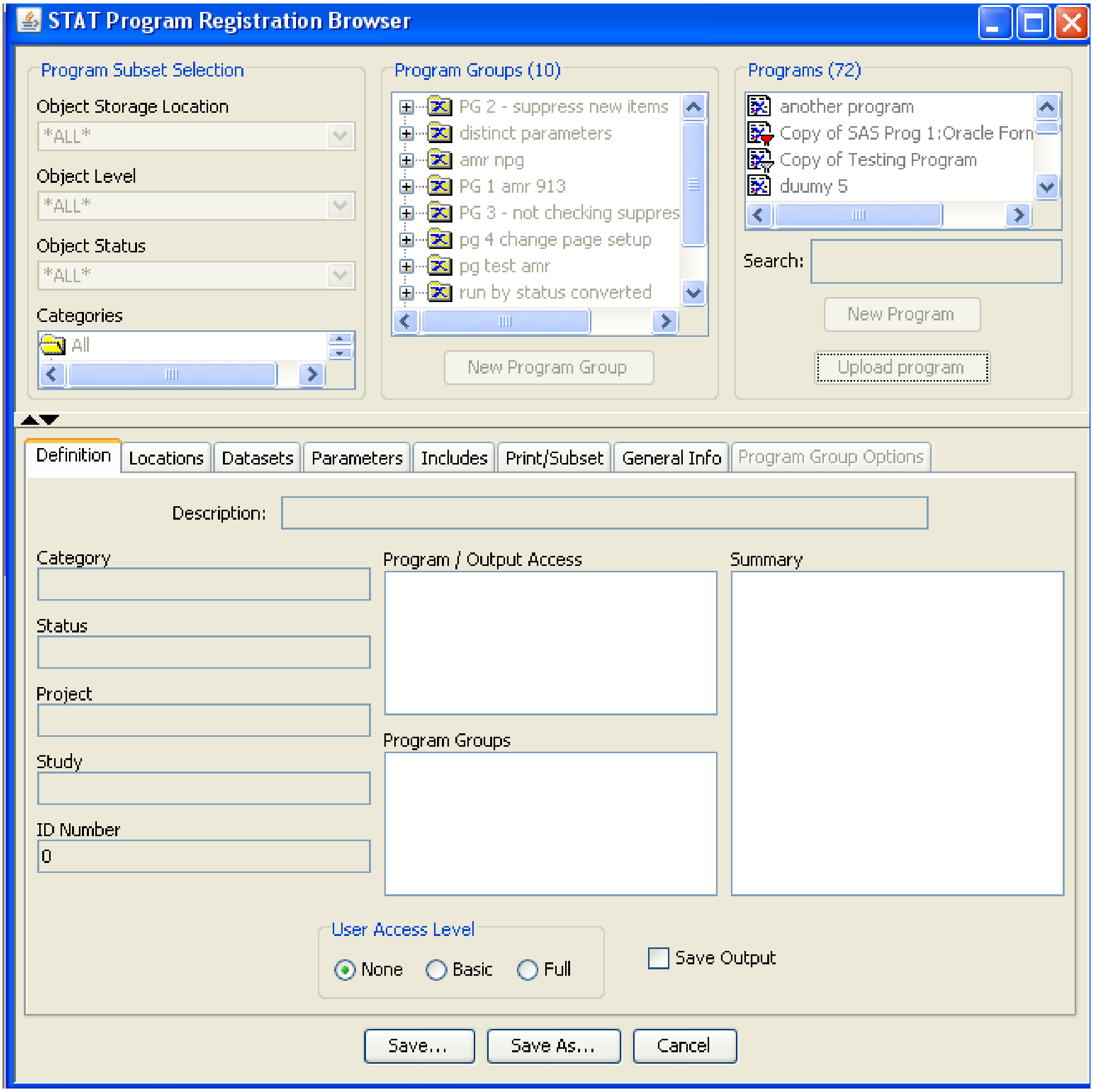
The following functions are enabled when you select **New Program** or **New Program Group** for **Edit** mode.

- **Cancel** - discards the changes (after a "Cancel changes?" dialog confirms this).
- **Save** - opens the Save Object dialog, and clicking on the **Save** button here saves the program changes. Clicking **Cancel** on the Save Object dialog returns to the STAT Program Registration Browser in the same state as before the **Save** button was clicked.
- **Save As** - opens the Save As Object dialog, and clicking on the **Save** button here saves the program changes as a new SAS program.

Right mouse click for functions to **View**, **Copy**, **Edit**, and **Delete** are available.

- **View** - Displays the contents of the fields on the tab pages to view characteristics of a SAS program.
- **Edit** - enables editing the contents of the fields on the tab pages to change characteristics of a SAS program.
- **Copy** - makes a duplicate of the entire current SAS program registration, adding the words "Copy of" to the front of the description.
- **Delete** - deletes the currently selected SAS program registration. A confirmation window always displays where the text indicates if the program belongs to one or more program groups and/or has saved output.

Click **New Program** or **New Program Group** to register SAS programs and to register new program groups. The STAT Program Registration Browser splits into two viewing areas with the registration function tabs below. Use the cursor arrows to expand the top window and toggle between viewing and registration details.



Object Storage Location: *ALL*

Object Level: *ALL*

Object Status: *ALL*

ID Number: 0

User Access Level: ● None ○ Basic ○ Full

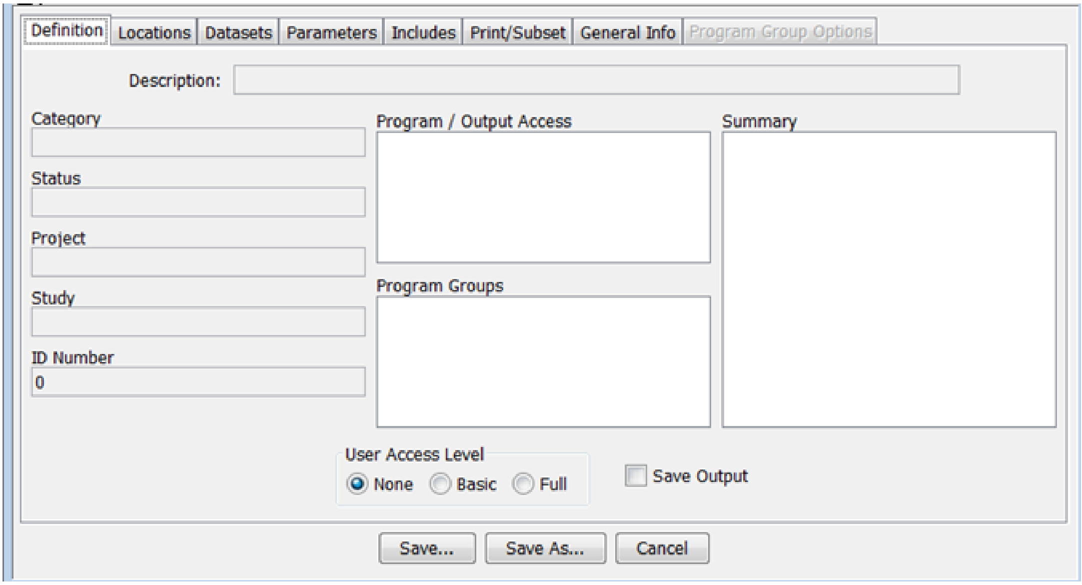
☐ Save Output

The STAT Program Registration Browser facilitates the entry and registration of SAS programs into JReview. This tool visually organizes the supporting files, datasets, panels, studies, and SAS program parameters where appropriate.

Initially, prior to registering any SAS programs only the **New Program** button is enabled. Once you have registered or converted SAS programs and select a SAS program from the Programs list, then the functions to **View**, **Copy**, **Edit** and **Delete** are available.

When you click the **New Program** button the registration tabs become available for entry. The '*Definition*' tab is the first entry in sequence to enter details for registering a new SAS program. Some information is entered directly through the '*Definition*' tab. Other information is displayed and determined by the way the program was saved.

The minimal amount of information required to register a new SAS program is the *Description*, *Category* and *Status*. Therefore, you can save a SAS program registration without the actual source code reference. The minimal information entered creates a registration slot for the SAS program where additional runtime information can be entered in the future. If you attempt to run a SAS program registration with a missing source code reference, there are runtime checks for source code and datasets. An error message displays alerting you to the incomplete SAS registration.



ID Number
0

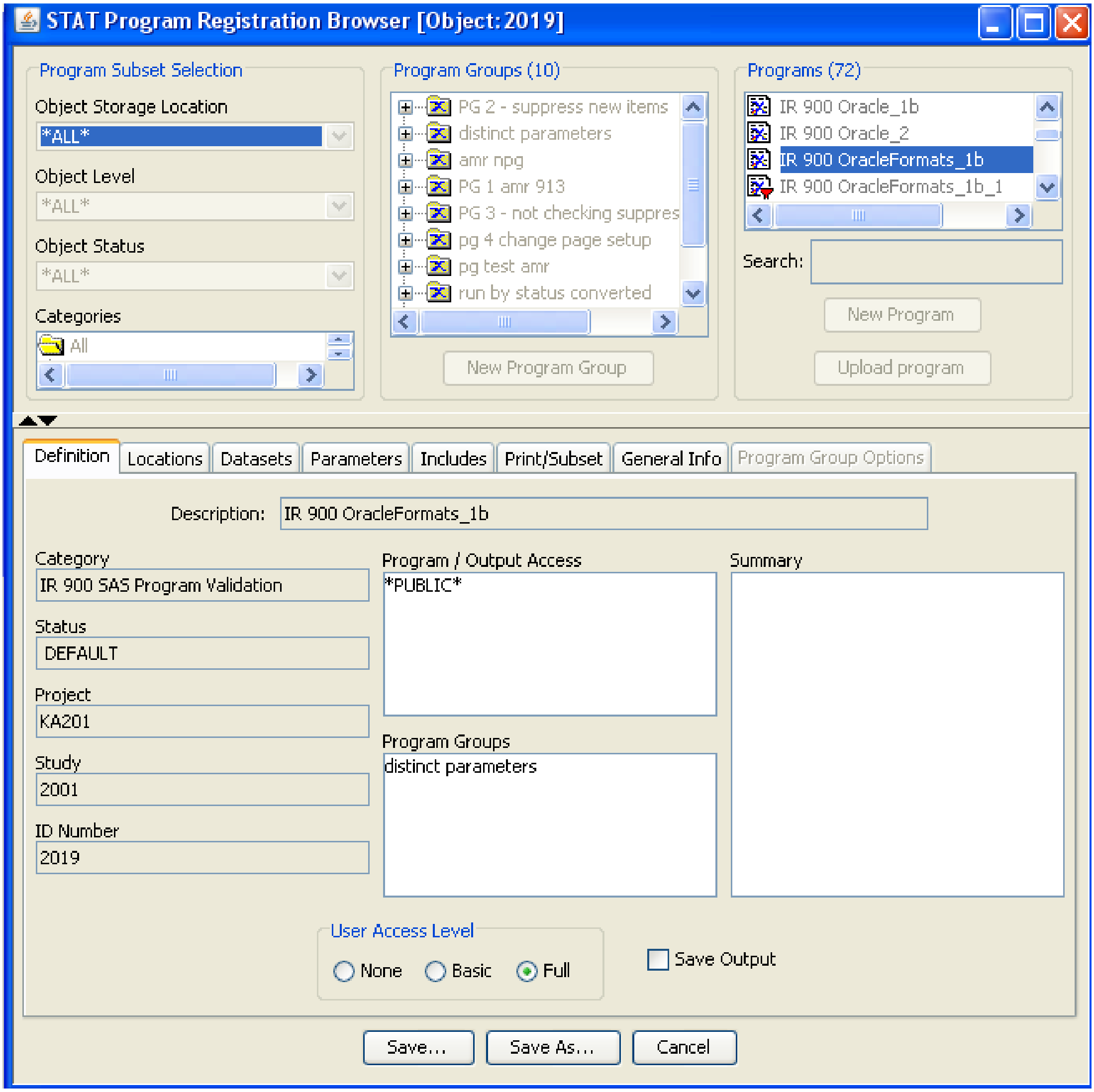
User Access Level
● None ○ Basic ○ Full

☐ Save Output

## *Definition tab*

When you register a SAS program in the system with the Review STAT Program Registration Browser; you add an entry specifying the appropriate Project and Study, description of the SAS program to appear in the STAT Program Registration Browser list box, category location where the SAS program is located and status. These details are entered in the Definition and Locations tabs.

This example shows a SAS program selected from the Programs list in **Edit** mode, and displays the available information.



Object Storage Location: *ALL*

Object Level: *ALL*

Object Status: *ALL*

Categories: All

Search:

Description: IR 900 OracleFormats_1b

Category: IR 900 SAS Program Validation

Status: DEFAULT

Project: KA201

Study: 2001

ID Number: 2019

Program / Output Access: *PUBLIC*

Program Groups: distinct parameters

User Access Level: ○ None ○ Basic ● Full

☐ Save Output

***Hint: Prior to registering new SAS programs you may need to first create a New Category if the folder destination does not already exist. (See System Management: Category.)***

When you click the **New Program** button some program values are defaulted.

- **Project** and **Study** indicate what project and study(ies) the program belongs to. The project and study is selected by choosing the level in the "Save Object" window and not on the tab. *ALL* in the **Study** field indicates a project-level program. *ALL* in the **Project** and **Study** fields indicates a global program.
- **User Access Level** indicates the level of user that can access the program.

Other item values are modifiable in new or edit modes. Use the dropdown listboxes to enter new item values or edit existing values from converted SAS programs in the **Definition** tab.

- **Description** is the descriptive name for the SAS program to appear in the Program list box.
- **Category** is the folder where the SAS program is to be located (folder hierarchy within Review).
- **Status** is the assigned status code for the program (from a list of pre-defined statuses). Converted SAS programs have a default status of "CONVERTED".
- **Save Output** indicates whether or not the program output will be automatically saved upon execution to the Review Output Tab.
- **Program / Output Access** shows either a list of user groups or *PUBLIC*, indicating what users can access the program and its output.
- **Program Groups** information displays if the program is added to a program group.
- **Summary** is a longer text describing the program.

***Hint: When registering a new SAS program, enter the information in all the SAS registration tabs and then click the SAVE button in the last tab window. If you click the SAVE button on an individual tab window during a NEW registration before completing all the tab entries, the SAS program registration is saved and any incomplete entries must be added or changed in EDIT mode.***

## *Locations tab*

Users can type entries in any of these fields, or, if the IR Server version supports browsing, the **Browse** button next to each entry opens the Browse Server window that displays lists of directories and files on the server. Directories can be navigated to select directories and files. If the server version does not support browsing, the **Browse** buttons are disabled. ***(See Auxiliary Windows: Browse Server.)***

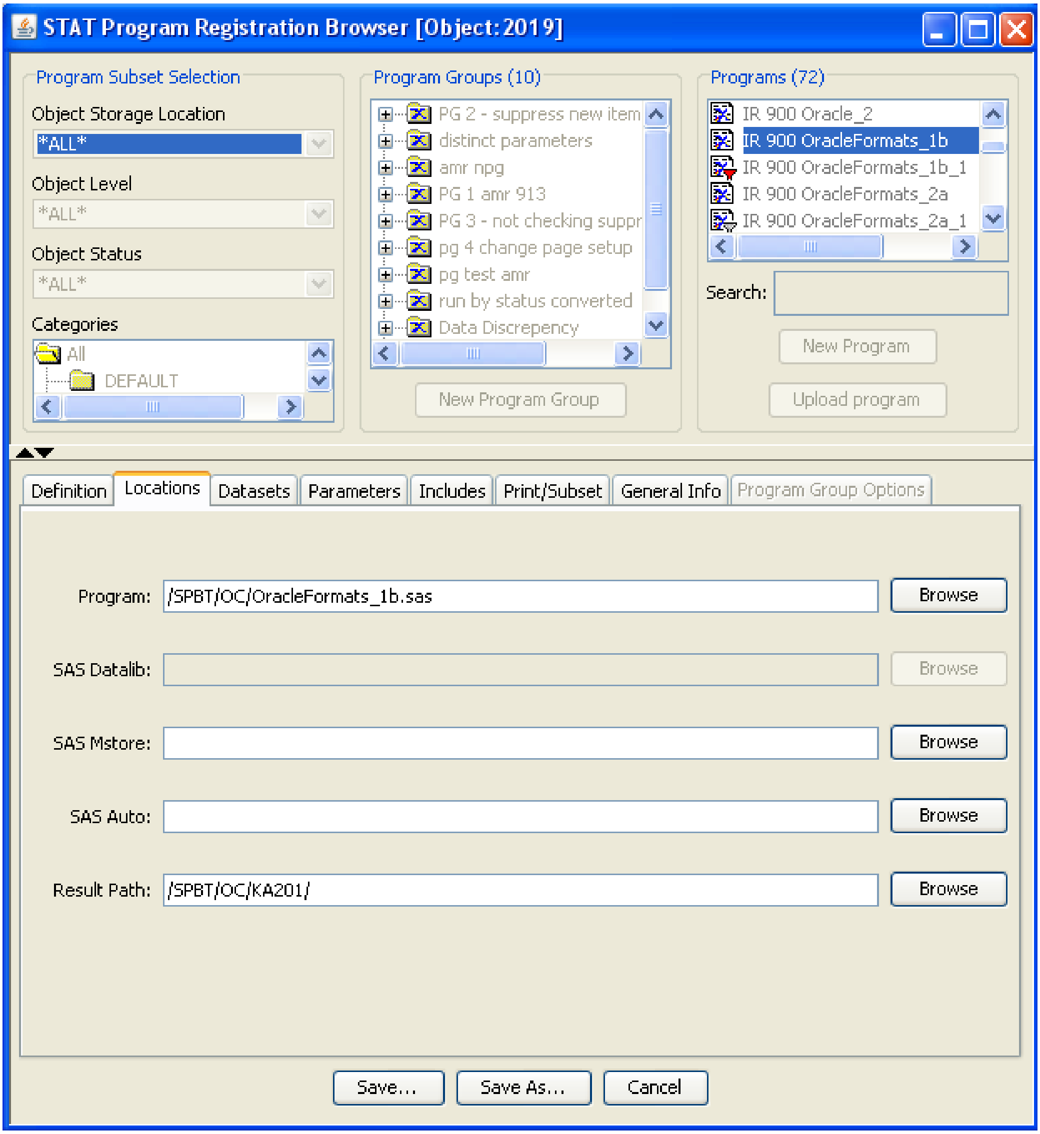
Enter or select the following information in the '*Locations*' tab:

- **Program** - File location for the program source code.
- **SAS Datalib** - Directory location for any datasets that are accessed in the program code. (Required and used only if the data origin is SAS.)
- **SAS Mstore** - Location of a MACRO library for the program to use.
- **SAS Auto -** Location of a SAS Autocall library.
- **Result Path** - Directory where output from the program will be stored. If this is left empty, the sever home directory is used.

If you check '*Save Output*' on the Definition tab, the output from the SAS program will automatically get saved to the location specified in your 'Result Path' on the Locations tab.

If you do not check '*Save Output*' , once the program is run, the user will have the option at that time of saving the output.

The window displays default to SAS.



Object Storage Location: *ALL*

Object Level: *ALL*

Object Status: *ALL*

Program: /SPBT/OC/OracleFormats_1b.sas

SAS Datalib:

SAS Mstore:

SAS Auto:

Result Path: /SPBT/OC/KA201/

## *Substitution parameter tokens*

Several configuration items that refer to directory paths or files can contain substitution parameter tokens which get replaced at runtime with values from the current environment. These tokens are as follows:

<proj> - references the current Review Project

<prot> - references the current Review Study

<sysroot> - refers to the IR Server root directory

<user> - refers to the current user logon ID (limited to the Result Path directory only under the Locations tab)

The tokens <proj>,<prot>, and <sysroot> can be used with the following configuration items:

Locations tab:

- Program source code file
- Data library
- Result path
- Macro library
- Autocall library

Includes tab: ***(See section for Includes Tab)***

- Study Include files
- Program Include files

In addition, the <user> token can be used in the Result path configuration item.

For example, a data library path might be specified as C:\test\<proj>\<prot>\sasdata when registering a program. Assuming the current project is KA and the current study is KA201, when the program is run, the path would resolve to C:\test\KA\KA201\sasdata. This allows, for example, a Global registered program to run against different studies and use the SAS datasets for the current study without having to change the data library location path.

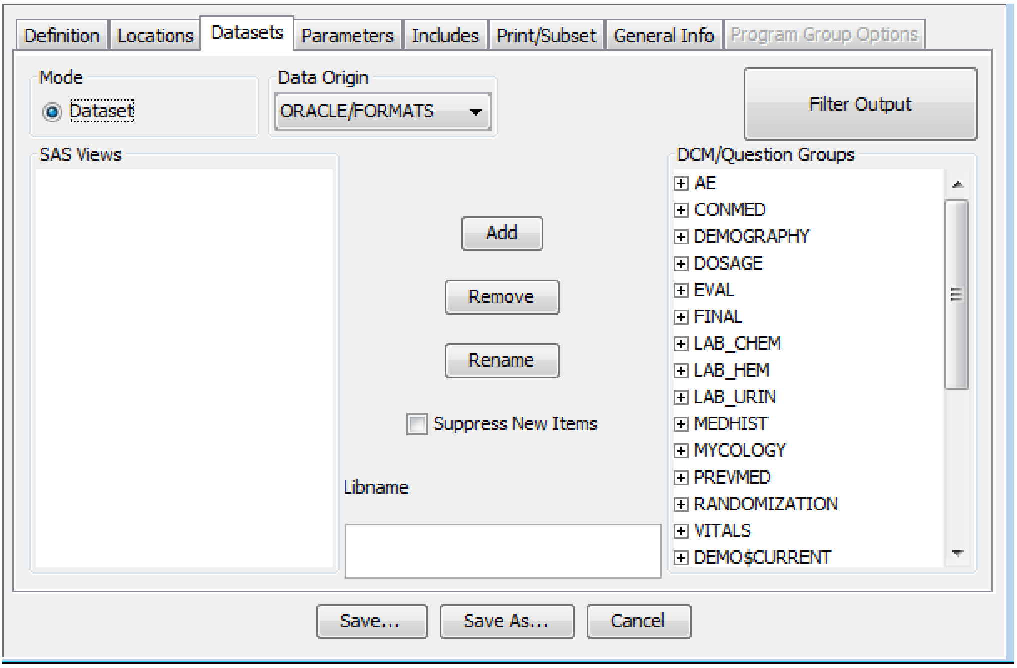
## *Datasets tab*

Click the **Datasets** tab, select the **Data Origin** from the list to indicate where the data for the program originates.

- **NONE** - No SAS or Oracle data source is required (program is self contained and no patient selection criteria can be applied).
- **ORACLE** - Review generates SAS views from specified Oracle tables prior to SAS Program execution.
- **ORACLE/FORMATS** - Review generates SAS Views and SAS Formats for specified Oracle tables prior to SAS Program execution.
- **PATIENTSET** - Review generates a SAS View of the patients. The resulting SAS View of the patients meeting the selection criteria is then used by the registered SAS Program (program is self contained, but patient selection criteria can be applied).
- **SAS** - Runs SAS program against pre-existing SAS Datasets. Enter user named SAS datasets.

***Note: When changing the data origin, if datasets are currently assigned, a confirmation message displays to indicate that the current dataset assignments will be removed.***

Datasets Tab has added **Filter Output** for use with SAS Programs or R scripts for data prepared by JReview for use in SAS/R as SAS views or R data frames (from tab;es/datasets or composites).

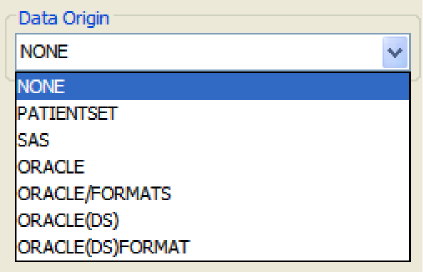


Mode: ● Dataset

Data Origin: ORACLE/FORMATS

☐ Suppress New Items

Your SAS programs can be run against existing SAS datasets, or SAS views that are generated by JReview at runtime. The Review Program Registration Browser lets you specify your preference in the Data Origin.



PATIENTSET *Data Origin*:

- Review generates a standard named SAS View of the patients meeting any defined patient selection criteria.
- This SAS view can then be utilized within the program.

SAS *Data Origin:*

- If no Patient Selection Criteria is defined, JReview will use the existing SAS datasets you define directly.
- If a Patient Selection Criteria is defined, Review will generate a subsetted version of each of the existing SAS datasets to include only those patients meeting the criteria.

ORACLE or ORACLE/FORMATS *Data Origin:*

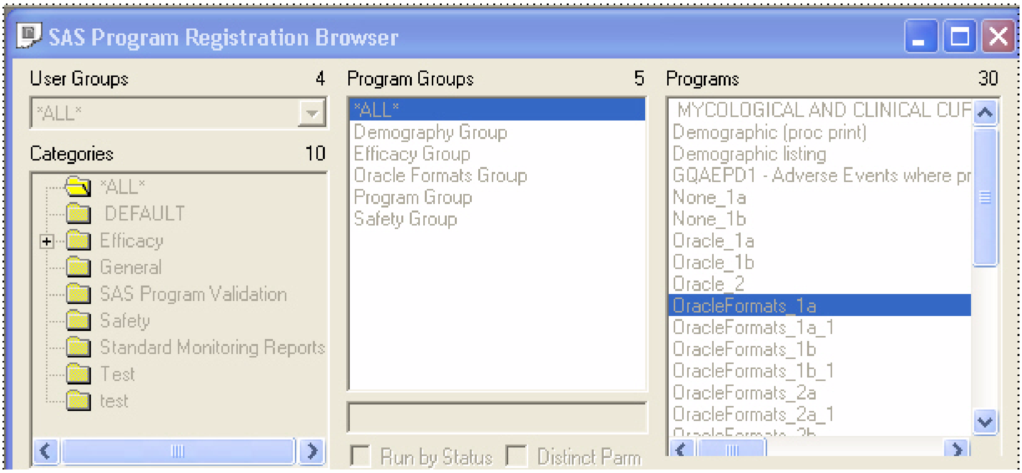
- Review will generate SAS views for each panel you define.
- You must specify the panel name and the SAS dataset name that your program expects to see for the panel.

ORACLE(DS) or ORACLE(DS)FORMATS *Data Origin:*

- JReview will generate SAS views for each Oracle table selected.
- JReview proceeds to create a corresponding SAS dataset for each view prior to %including the registered SAS program.

If a patient selection criteria is active at the time the end user requests running of an existing SAS program, Review generates SAS code to invoke SAS Proc SQL to create a SAS view containing a list of patients who meet the current subset criteria. This same SAS code then creates new versions of the current SAS datasets referenced by the selected program, using a SAS match merge technique, including only those patients who are in the patient selection criteria subset.

*Note:* ***When the data origin is SAS, Oracle or Oracle Formats then saving requires that at least one dataset or Oracle table has been selected.***



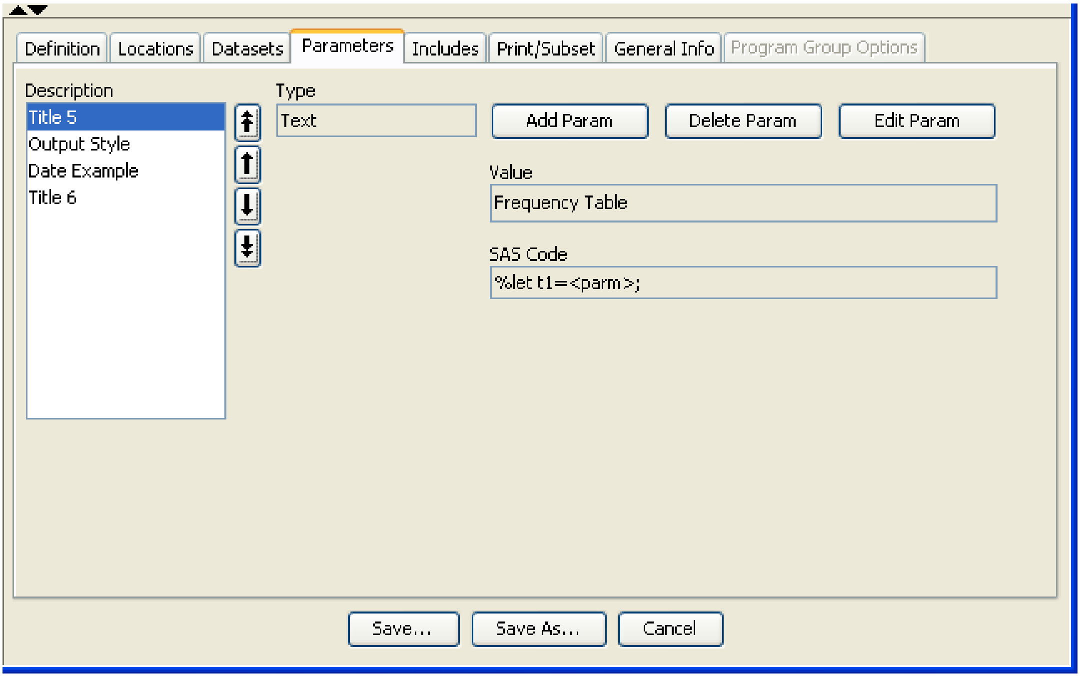
- **Libname** is the reference name for the library of SAS datasets that are accessed by the program. This can only be entered, and is required, if the D*ata Origin* is other than NONE or PATIENTSET. (The reserved words SLIB, BASEOS and OS are not allowed here.)
- **SAS Views or Datasets** is the list of datasets that will be accessed by the program. For ORACLE and ORACLE/FORMATS data origins, the dataset and panel names will be listed, and only the dataset name can be changed. For SAS data origin, the names are user-defined.(The reserved words PATSET and SASVIEW are not allowed as dataset names.)
- **Panels** is a list of panel names that can be selected as datasets. For ORACLE and ORACLE/FORMATS data origins, SAS views are created from the panels. For SAS data origin, the panel names are provided as a convenience and do not directly relate to SAS datasets. The default dataset name is the SAS name associated in the Clinical Data Management system.
- **Add** / **Remove** / **Rename** buttons are used to add, remove and rename datasets in the list on the left. For SAS data origin, the item "_Client Defined DataSet_" allows typing in an arbitrary name.
- The **Suppress New Items** checkbox controls whether new items added to panels are included in the SAS views created for processing.

## *Parameters tab*

The ‘*Parameters*’ tab allows you to enter runtime parameters to modify the behavior for the selected SAS program. Review prompts you for runtime parameter values to be selected and passed to your program.

Click the **Parameters** tab to add or edit parameter information. Use the **Add Param**, **Delete Param**, and **Edit Param** buttons to add, delete or edit parameter information.

The Parameter # lists existing parameters by sequence number. The number is both for display purposes and for order of parameter inclusion in the SAS job. Click on the parameter number to view information about the parameter. In this example, a previously registered SAS Program was selected from the Programs list and for the **Edit** function.



Description
- Title 5
- Output Style
- Date Example
- Title 6

Type: Text

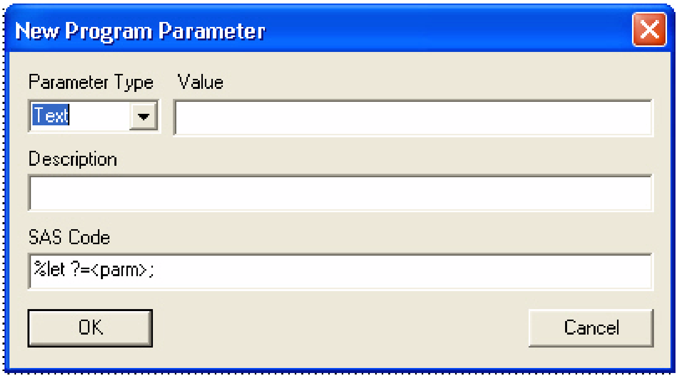
Value: Frequency Table

SAS Code: %let t1=<parm>;

If there are no parameters registered, the Review Program Registration Browser assigns a SeqNo (1) to the first row to add new program parameter information or edit existing parameters.

**Param #** lists the parameters by sequence number. The parameters for a specific program are sequenced by this value, for display purposes and order of inclusion into the SAS job. Click on a parameter number to see information about that parameter.

1. Click the **Add Param** button and the New Program Parameter window opens.



Parameter Type: Text

SAS Code: %let ?=<parm>;

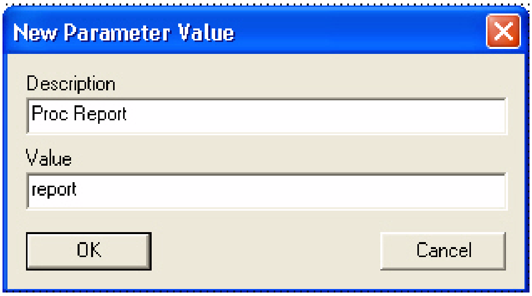
2. **Parameter Type** indicates **Date**, **Directory**, **File, List** or **Text**.
3. For **Text** and **Date** parameters:

   **Value** is the default text value for the parameter.

   For **List** parameters:

   Values must be added when you select the List parameter type. Use the **Add Value**, **Delete Value**, and **Edit Value** buttons on the Parameters tab to add, delete and edit values in the list.

   **Values** is a list of possible values for the parameter.



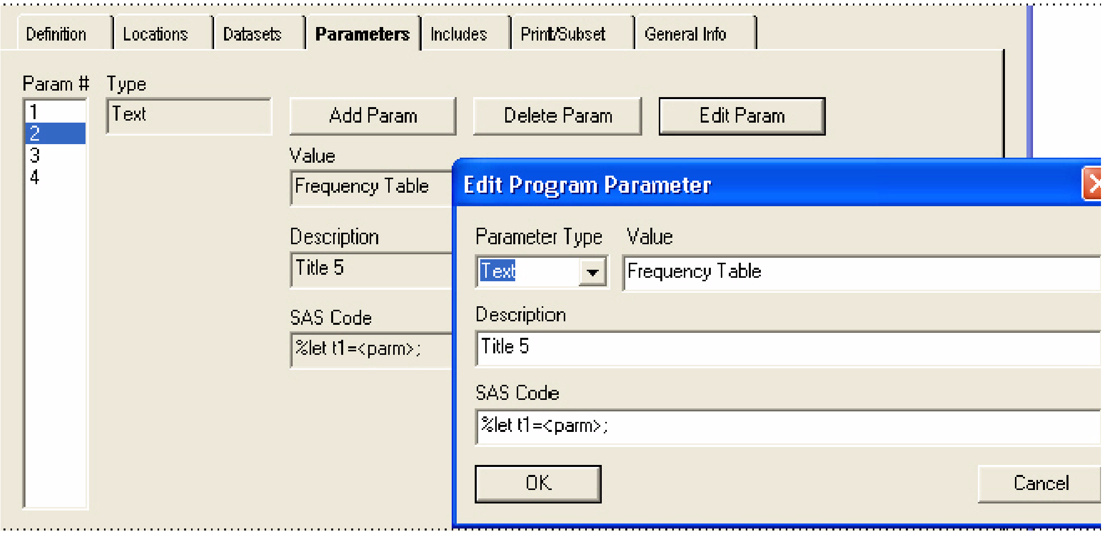
Description: Proc Report

Value: report

4. **Description** is a descriptive name for the parameter.
5. **SAS Code** is the code used to set the parameter value into a MACRO variable in the SAS program code. This is usually of the form “%let ?=<parm>;” where ‘?’ is the name of the MACRO variable used in the SAS program. Replace the question mark with the MACRO variable.
6. Click **OK** to save. Click **Cancel** to discard changes.

   Multiple parameters can be included for each SAS program, and the SASCode can include as many <parm> substitution tokens as desired. Each instance is substituted with the value of the user’s selection.

Example of the parameter type for **Text**.



Param #: 1, 2, 3, 4

Type: Text

Value: Frequency Table

Description: Title 5

SAS Code: %let t1=<parm>;

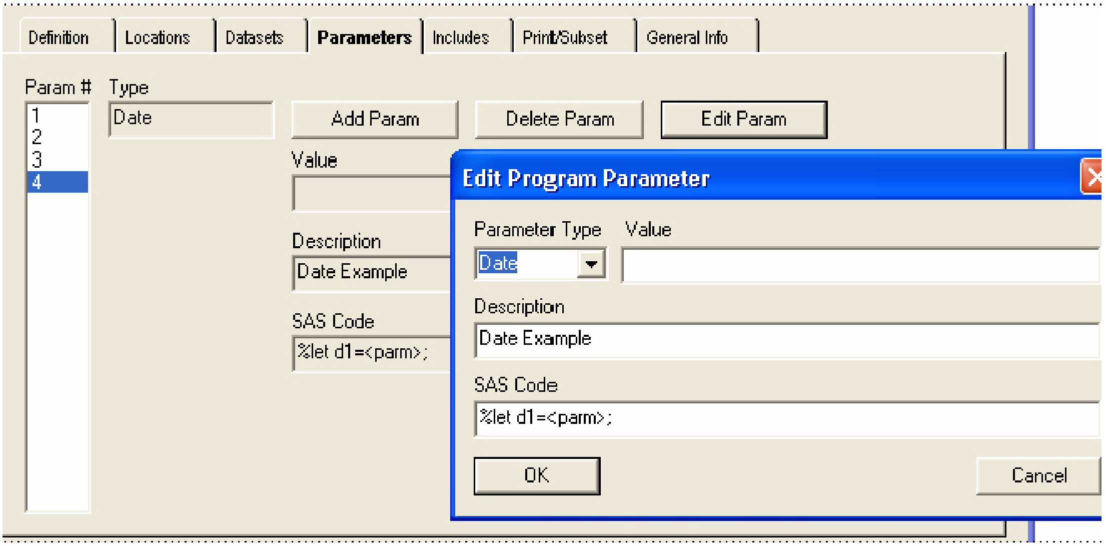
Parameter Type: Text

Value: Frequency Table

Description: Title 5

SAS Code: %let t1=<parm>;

Example of the parameter type for **Date**.



Param #: 1, 2, 3, 4

Type: Date

Value:

Description: Date Example

SAS Code: %let d1=<parm>;

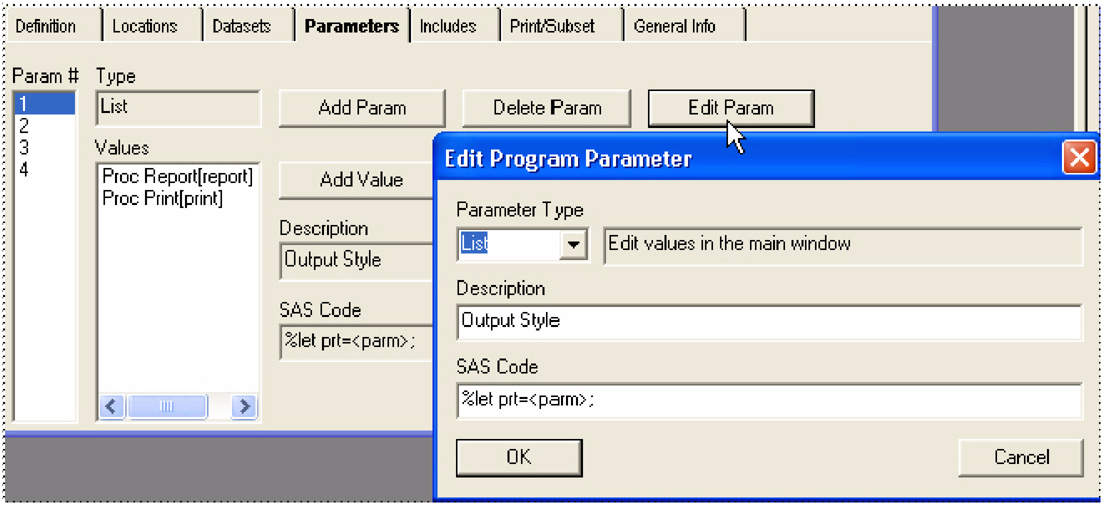
Parameter Type: Date

Value:

Description: Date Example

SAS Code: %let d1=<parm>;

Example of the **List** parameter type where **Values** is a list of the possible choices for the parameter.



Type: List

Values:
Proc Report[report]
Proc Print[print]

Description: Output Style

SAS Code: %let prt=<parm>;

Edit Program Parameter

Parameter Type: List — Edit values in the main window

Description: Output Style

SAS Code: %let prt=<parm>;

The List parameter type is a specifically formatted list of possible parameter values. You must add the values when you select the List parameter type. Each entry consists of parameter text description and parameter value. This is presented in the form of a list with the following entries:

Detail report[1]

Summary report[2]

In this example, if you select the Summary report[2] entry, then <parm> in the **SAS Code** will be substituted with the value 2. Note that the value being substituted is a character value, you need to include any required quotes in the **SAS Code** expression.

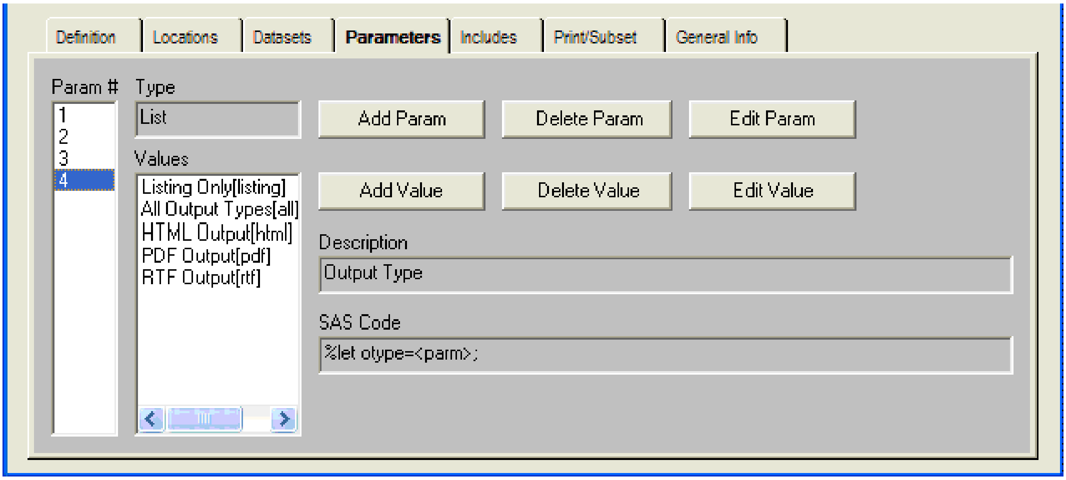
An example is:

%let REPSTYLE=<parm>;

If you choose 'Summary report[2]' as described above, then <parm> is substituted with 2, yielding:

%let REPSTYLE = 2;

This SAS program shows the parameter type for *List* with multiple values added and listed.



Type: List

Values:
- Listing Only[listing]
- All Output Types[all]
- HTML Output[html]
- PDF Output[pdf]
- RTF Output[rtf]

Description: Output Type

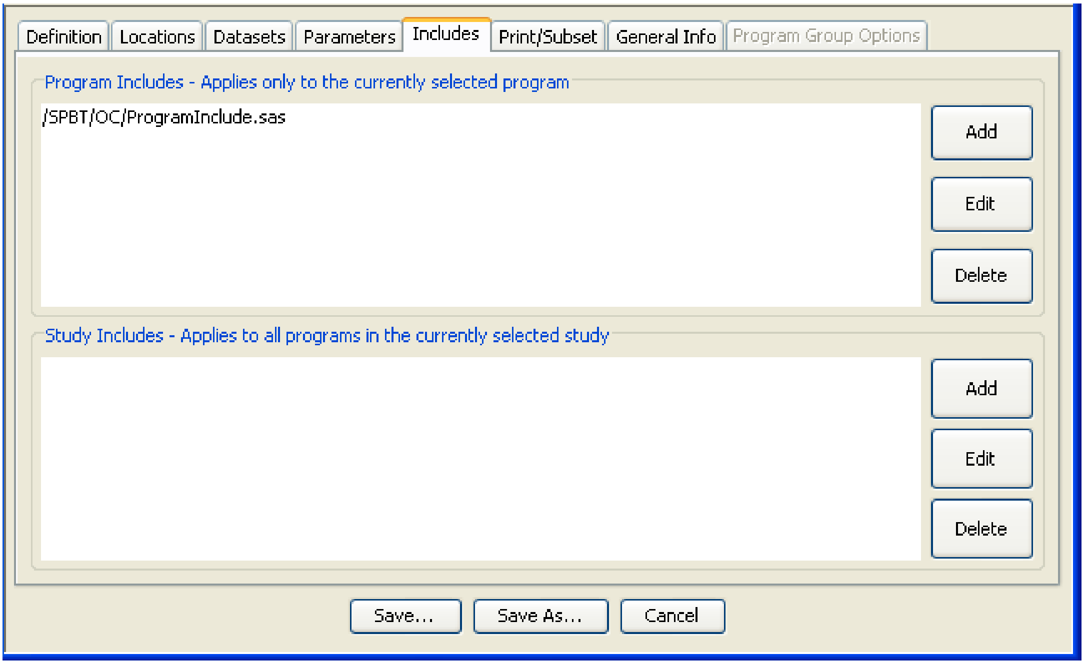
SAS Code:

```
%let otype=<parm>;
```

## *Includes tab*

Click the '*Includes'* tab to enter associated source files program to automatically insert include file references in the SAS code that it creates. The system will add a '%include' for each entry. Use the **Add**, **Edit** and **Delete** buttons to add, edit and delete files in the list. *(See Auxiliary Windows: Browse Server.)*

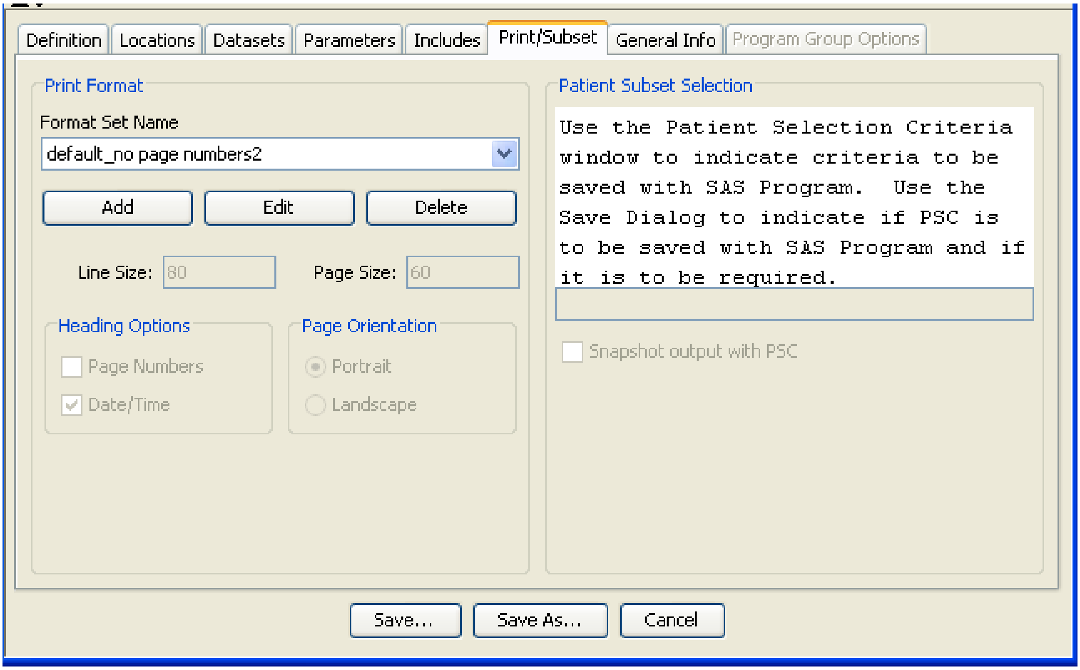
- **Program Includes** contains a list of source files to be included for the selected ***individual program***.
- **Study Includes** is a list of source files to be included for ***all programs*** in the currently selected study.



/SPBT/OC/ProgramInclude.sas

### *Print/Subset tab*

Use the Print/Subset tab to enter print format options and to apply a patient subset selection if required.



Format Set Name: default_no page numbers2

Line Size: 80

Page Size: 60

☐ Page Numbers

☑ Date/Time

● Portrait

○ Landscape

Use the Patient Selection Criteria window to indicate criteria to be saved with SAS Program. Use the Save Dialog to indicate if PSC is to be saved with SAS Program and if it is to be required.

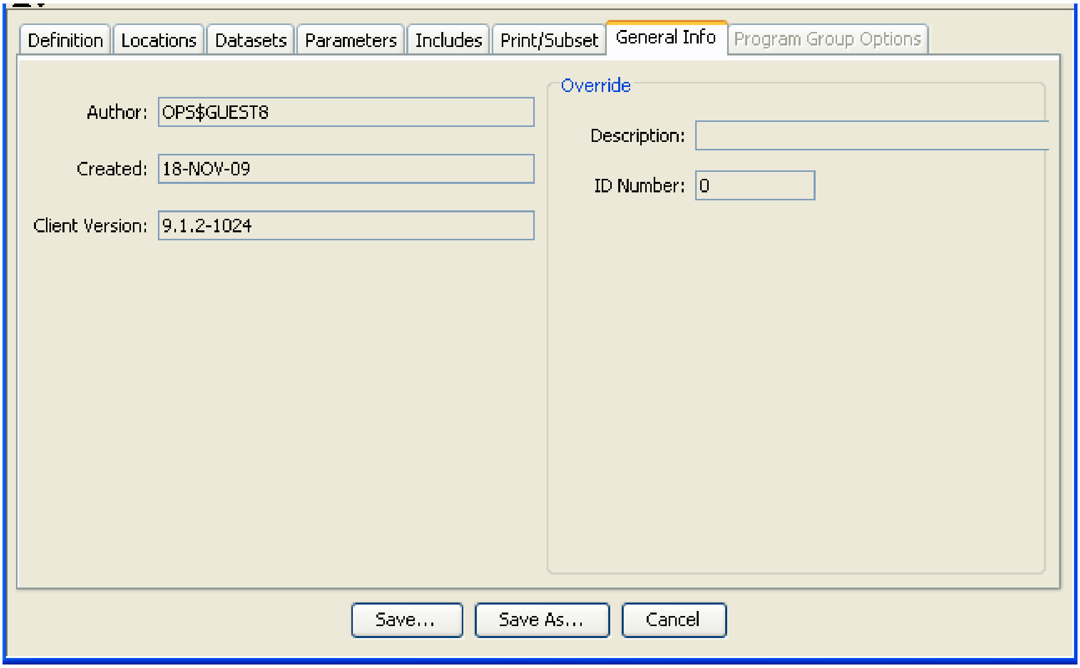
☐ Snapshot output with PSC

- **Print Format** – shows the current print format assigned for the program. Print Format '_Default_' print format can only be modified by a '***SuperUser***'. *(See Auxiliary Windows: Print Format.)*
  - **Format Set Name** - displays a drop down list to select changes for the print format. You can also define a new *Format Set* to use for many registered programs and program groups.
  - **Heading options** for Page Numbers and Date/Time are available in addition to setting the Page Orientation.
  - **Page Orientation** for portrait or landscape.
- **Patient Subset Selection** – can be assigned to programs or programs groups. *(See Auxiliary Windows: Select Subset.)*
  - **Current Subset** - defined means the SAS program will automatically execute against the defined patient subset.
  - If a program has no subset assigned and one is active in the Patient Selection Criteria window at runtime, the active patient selection criteria is used in execution.
  - **Select Subset** - opens a dialog window to enter changes or clear the patient subset selection for a SAS program. ***If the Data Origin is set to NONE, the Select Subset button is disabled.***

## *General Info tab*

The ‘*General Info*’ tab displays general information about the registered program.

- **Author** - UserID of the person who added the program registration into the system.
- **Created** - Date the program registration was added.
- **Client Version** - Review client version used to add the program registration.
- **Override** – What program, if any, the program is overriding at the study level. Displays the **Description** and **ID Number** - an internal object ID number for the SAS program (determined by Review).



Author: OPS$GUEST8

Created: 18-NOV-09

Client Version: 9.1.2-1024

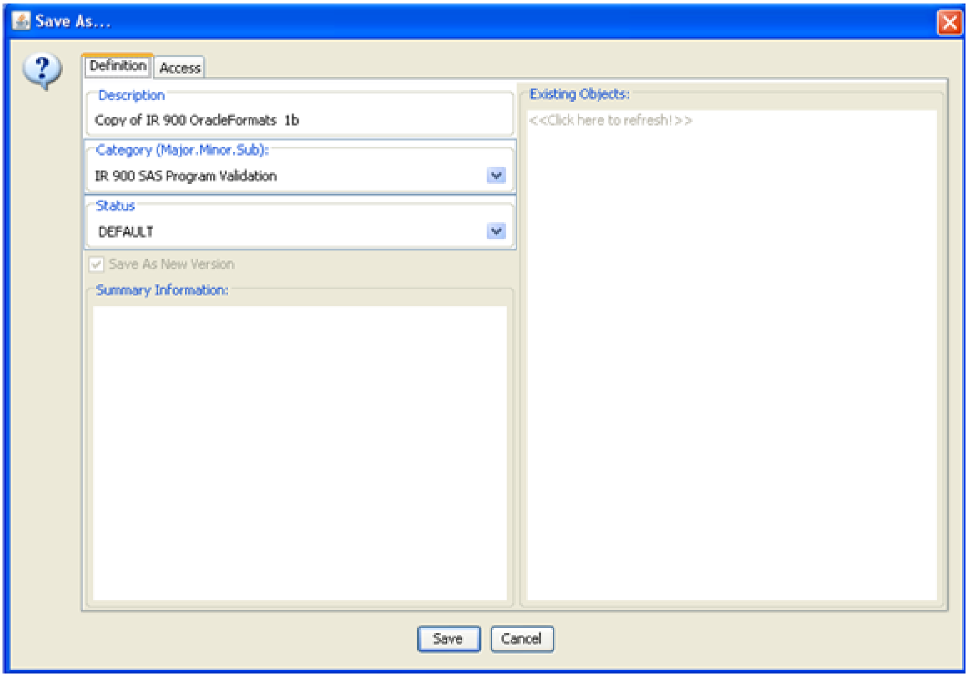
Description:

ID Number: 0

## *Save STAT Program Registration*

Once you have entered the STAT Program Registration information in **New** or **Edit** mode from the tabs, click the **Save or SAS As** button on the main STAT Program Registration Browser window. Review displays the Save As window.

**(See *Chapter 11: Saving and Managing Objects, plus Alerts Browser)***



Description: Copy of IR 900 OracleFormats 1b

Category (Major.Minor.Sub): IR 900 SAS Program Validation

Status: DEFAULT

☑ Save As New Version

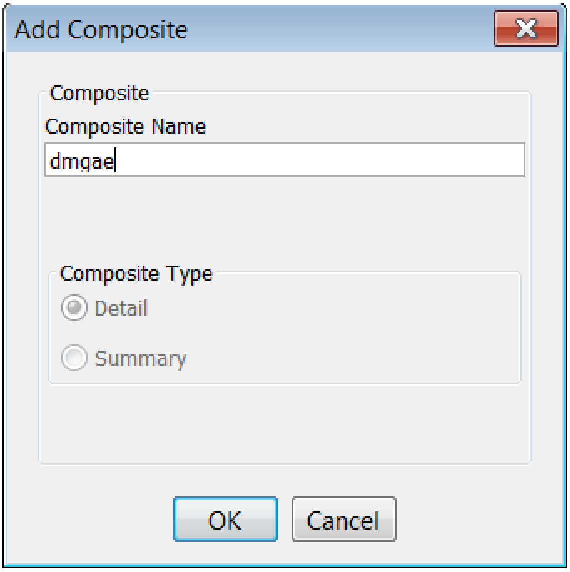
## *Enable Composites*

Enable Composites in SAS program registration is supported when accessing a database data source (Oracle, SQLServer, PostgreSQL). This feature has been supported for R scripts previously. Essentially this functions much like defining a 'report', i.e., specifying which items from which tables are of interest – to be combined into a single SAS view made available to the registered SAS program. **(See Interactively register R programs)**

The SAS composites may be defined either in a SAS environment or database environment. The composites are created on the fly when the SAS job runs - creating the composites as temporary SAS views.

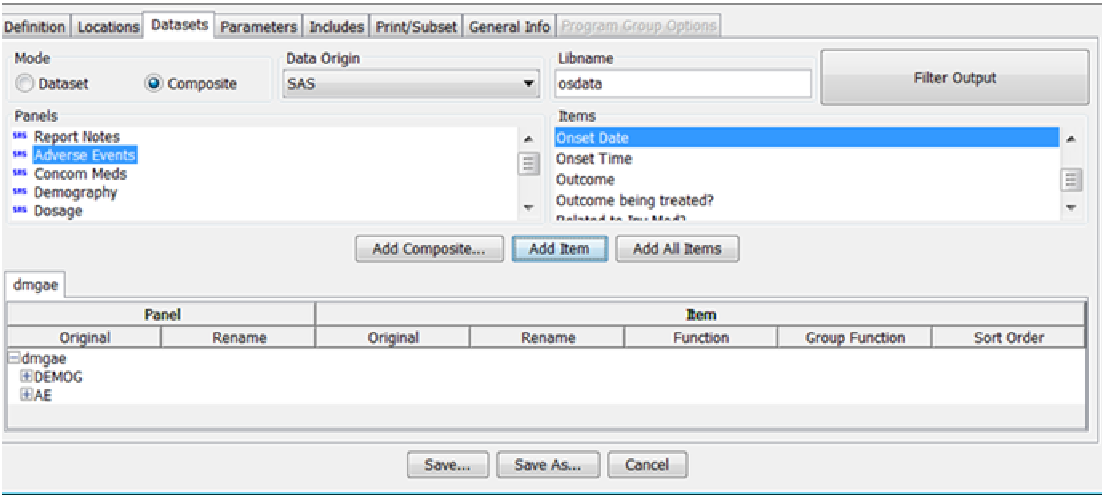
The steps are as follows:

1. Go into the SAS program registration, 'New SAS Program', then under 'Locations Tab' for 'Program' then 'Browse' to the location of the saved SAS job on the server.
2. Select as the program to be executed and make sure 'SAS' is selected (not 'R').
3. Then under the 'Datasets' tab, select 'Composites' for 'Mode'.
4. Enter the Libname entry (that matches the SAS program's libname reference).
5. Then click 'Add Composite' and type the composite name – that's the name of the generated SAS view – as is being referenced in the SAS program.



Composite Name: dmgae

6. Next, add contents to the composite. In the list of Panels and Items, select panel first, then select an item, and click ‘Add Item’. Do the same for any other items from a selected panel.



Mode: ○ Dataset ● Composite

Data Origin: SAS

Libname: osdata

7. Lastly, click ‘Save As..’ and complete the save dialog which will save the specifications.
8. Execute the SAS program from the output explorer.

# Interactively register R programs

## *R scripts overview*

JReview supports the ability to ‘register’ any R scripts stored on the server side to be executed from any JReview user’s session thereafter. The integration of JReview and R programs is intended to support use of standard R scripts from many different studies, even if the study dataset and column names are different.

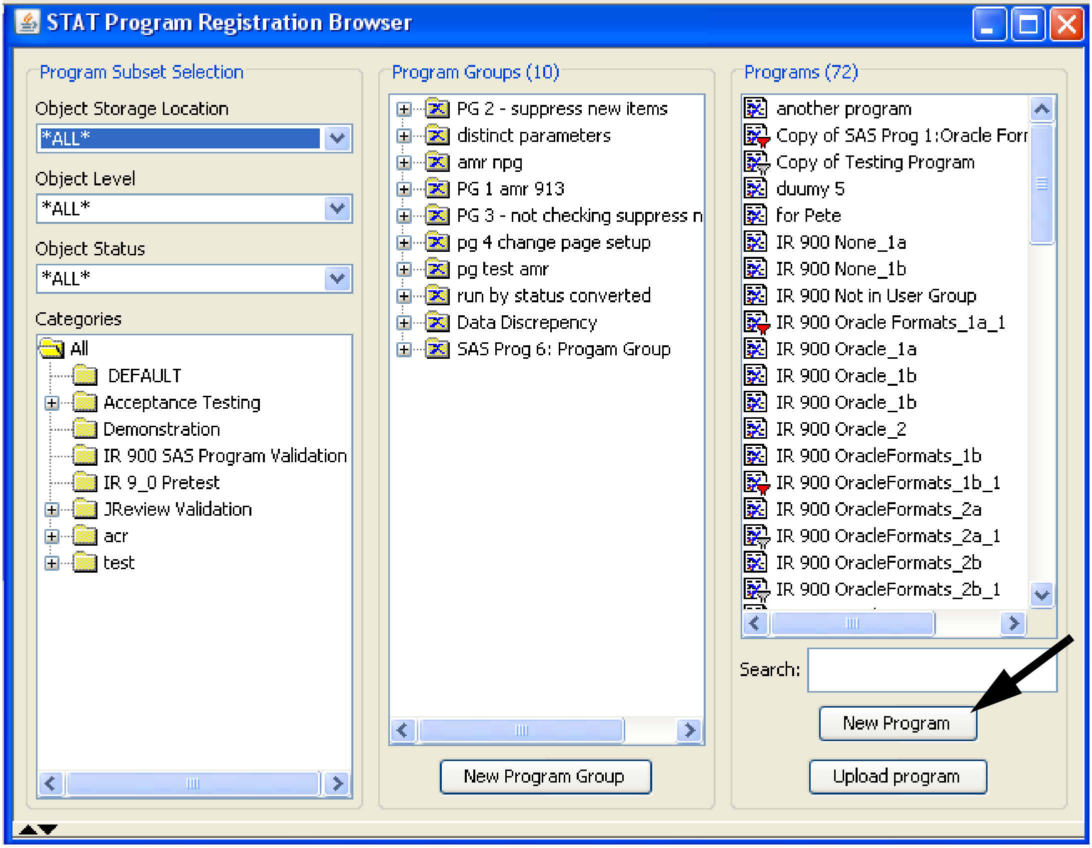
Variable name remapping is supported, as well as forming R dataframe ‘composites’ from different SAS datasets where join logic has already been determined and implemented by JReview. The benefit is that the user registering the R script can select different items from different datasets, all of which can be presented to the R script as an already prepared R data frame, without any other processing needed within the R script.

## *Register R programs*

The following steps details the R script registration process.

1. Launch the ‘STAT Program Registration’ browser (for either SAS or R) by clicking in the icon toolbar, or select ‘Browse’ menu item, then ‘Stat Programs’ submenu item.

   The STAT Program Registration Browser window is displayed which lists the currently registered programs, along with several buttons which allow registering new programs/scripts New Program or Upload Program (to move a program from your PC to the server).



Object Storage Location: *ALL*

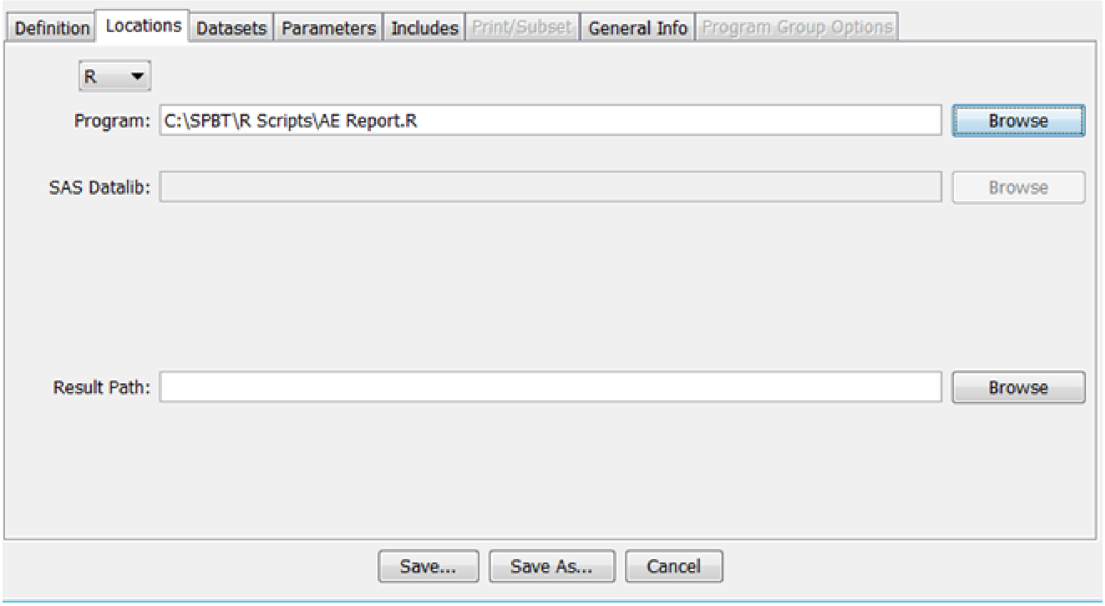
Object Level: *ALL*

Object Status: *ALL*

2. Click on the ‘New Program’ button, (assuming the SAS or R program has already been uploaded to the server); the following dialog window is displayed.

The Locations tabs displays in default SAS settings.  When R program” is not installed, or not enabled on the Locations tab; then only information for SAS programs is displayed. If “R program”  is installed and enabled, another dropdown listbox appears in the Locations tab. The user can select either a SAS or R program to be registered.  Other settings are also conditionally enabled, or disabled based on “R program”  status, such as the ‘Composite’ mode button in the Datasets tab.

To register an “R program”, the user selects the R option on the Locations tab. Once the R option is selected, a number of tabs become disabled which aren’t relevant for registering an “R program”.



R

Program: C:\SPBT\R Scripts\AE Report.R

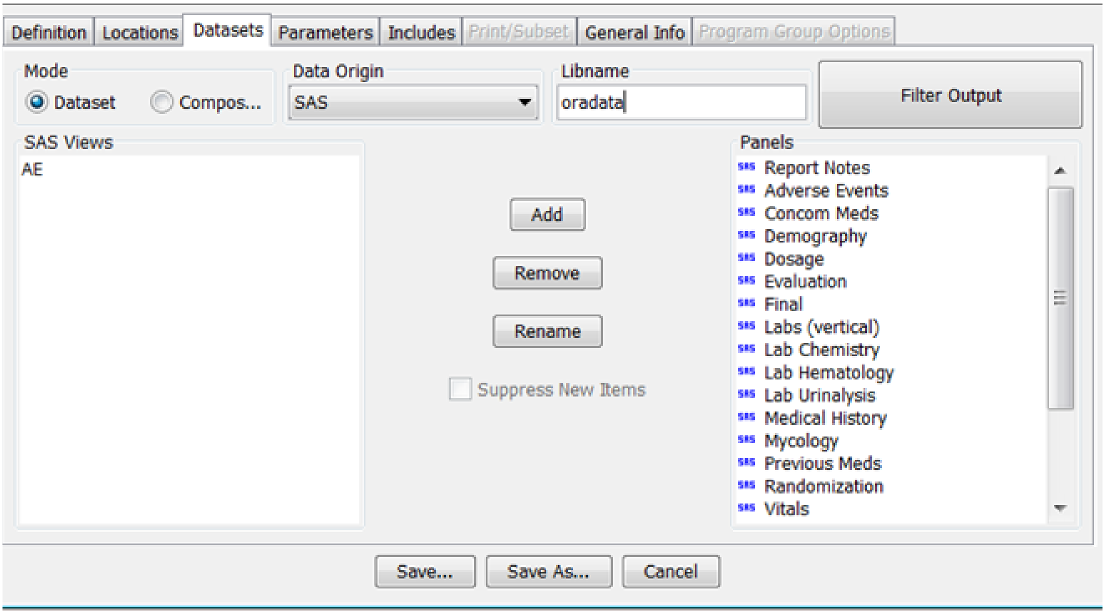
3. The user can select either SAS or R in the dropdown listbox, telling the system what type of program is being registered. Use use the ‘Browse’ button to locate the program on the server side, to fill in the ‘Program:’ entry for the fully qualified location/name of the program.

4. The next most important task is to tell JReview which SAS datasets should be provided to the SAS or R program. Click on the ‘Datasets’ tab.

   Two main choices are available: ‘Dataset’ or ‘Composites’.

   - **Datasets** provides complete datasets (subsetted to only include the current Patient Selection Criteria patients), as R dataframes (from R scripts), or subsetted SAS datasetsfor a SAS program.

Dataset example: Full datasets are provided as R data frames (for R scripts), or SAS datasets (for SAS programs):



Mode: ● Dataset ○ Compos...

Data Origin: SAS

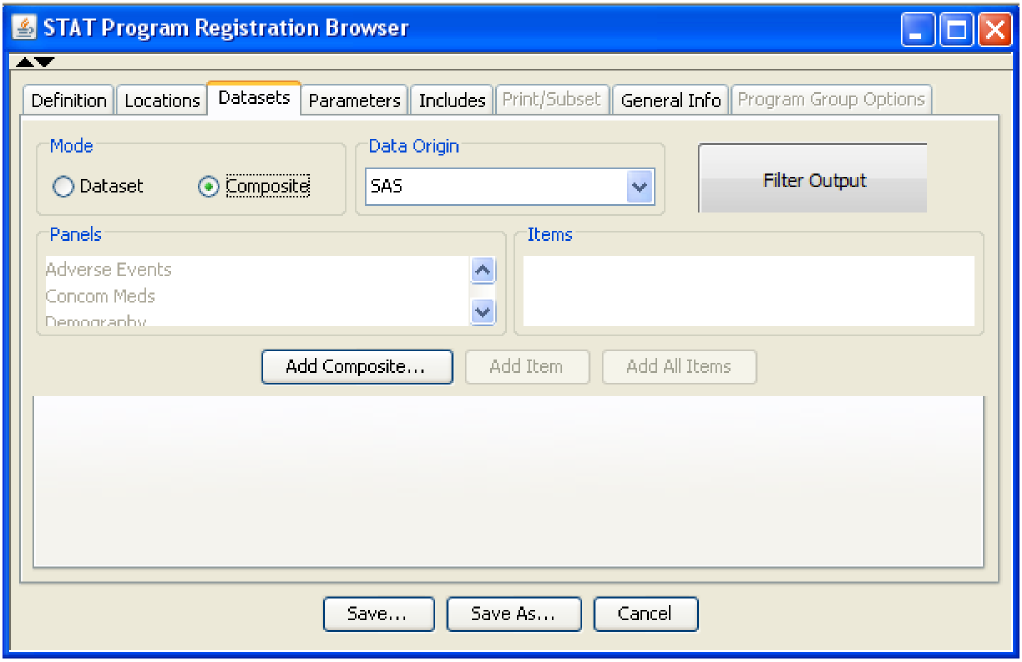
Libname: oradata

SAS Views: AE

☐ Suppress New Items

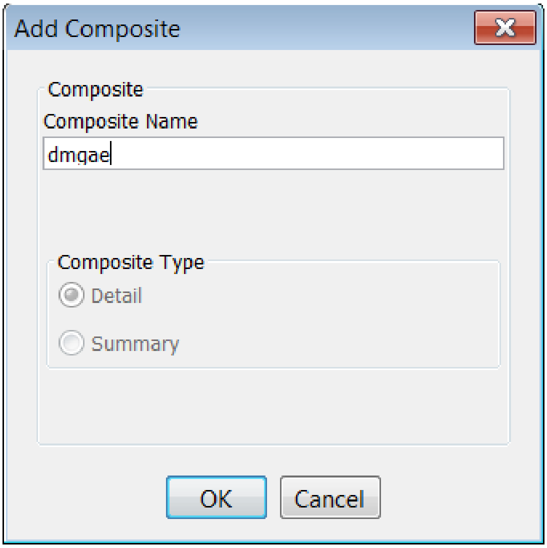
- **Composites** allows the user to select different items from different datasets. This is similar to constructing a detail report in JReview, but the result is a named R dataframe (based on the composite name you provide); and the items from different datasets – with individual variable name renaming supported.

When the R option is selected on the Locations tab, the ‘Composite’ mode button in the Datasets tab is also conditonally enabled, or disabled based on “R program” status.



When Composite mode is selected, click the **Add Composite** button to enter a descriptive label for a Composite.

Adding multiple Composite tabs is supported. The selected panels and items are added in a tree display.



Composite Name: dmgae

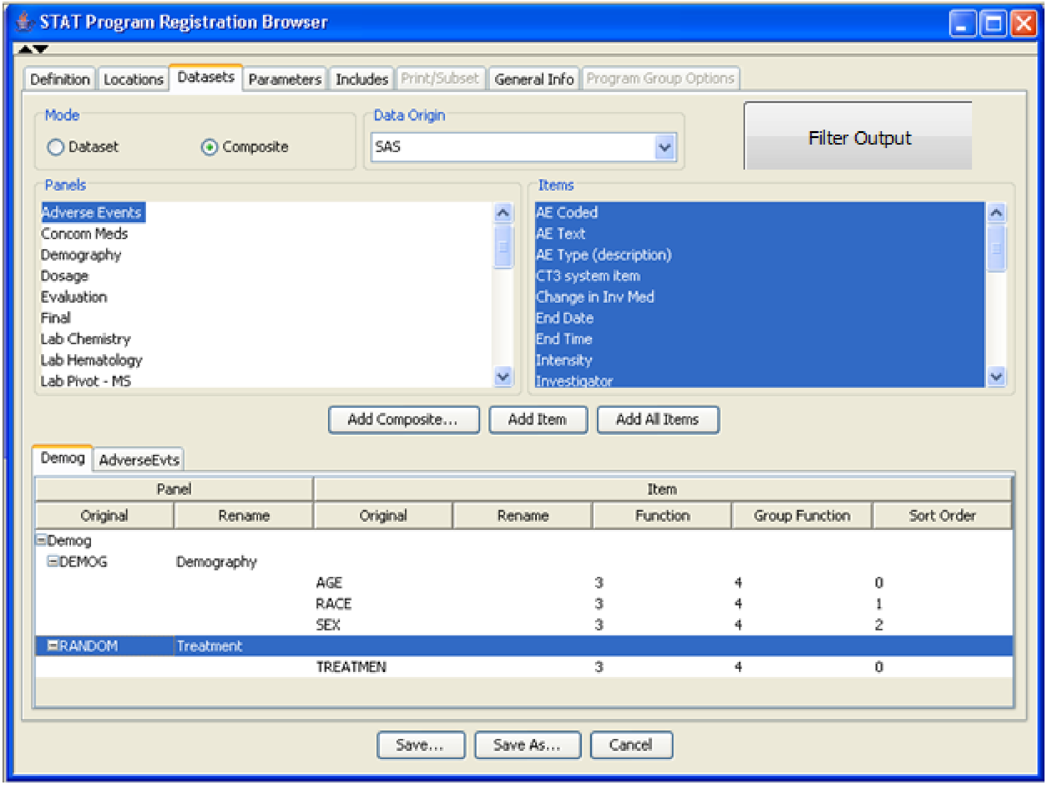
Composite names have a couple of restrictions.

- The name of a composite must be from 1 to 36 characters.
- The name cannot contain spaces.
- There is no limit to the number of composites. However, each composite must have a unique name.

Then select the individual panels and items to add to the defined composite for panels and items of interest.

You may double click on a particular panel or item“Rename” column to change the description. Likewise, to remove a renamed description, double click on the column to select and delete.

Composites Example: The User selects items from various datasets resulting in an already joined R dataframe, with just the items selected. Any item name may be RENAMED as desired, so the DataFrame and ItemNames will match the called R script:



Mode: ○ Dataset ● Composite

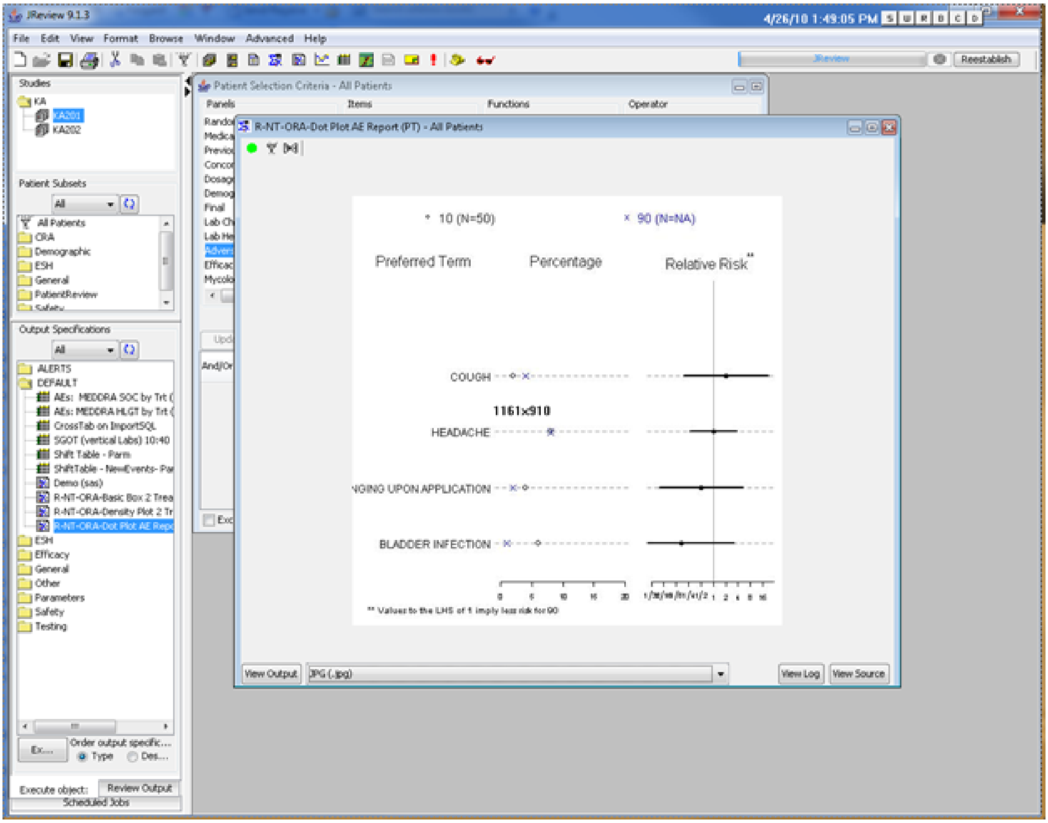
Data Origin: SAS

| Panel | | Item | | | | |
|---|---|---|---|---|---|---|
| Original | Rename | Original | Rename | Function | Group Function | Sort Order |
| ⊟Demog | | | | | | |
| ⊟DEMOG | Demography | | | | | |
| | | AGE | | 3 | 4 | 0 |
| | | RACE | | 3 | 4 | 1 |
| | | SEX | | 3 | 4 | 2 |
| ⊟RANDOM | Treatment | | | | | |
| | | TREATMEN | | 3 | 4 | 0 |

Datasets Tab has added **Filter Output** for use with SAS Programs or R scripts for data prepared by JReview for use in SAS/R as SAS views or R data frames (from tab;es/datasets or composites).

5. After completing the registration information, telling JReview where to find the R script, what SAS datasets (or composites) are required., click Save.
6. Save the R registration the same as with any JReview object, either Private, UserGroup or Public. Specify the definition scope for Study, Project, StudyGroup or Global. Thereafter, the object specification appears in the Output Explorer, along with any report, graph, patient profile, etc. These can also be included in Dashboard Views.

An example of a R script executions, displaying generated plots. The R script output that can be displayed/retrieved includes a variety of graph output types, plus PDF, RTF, table (Excel like output).

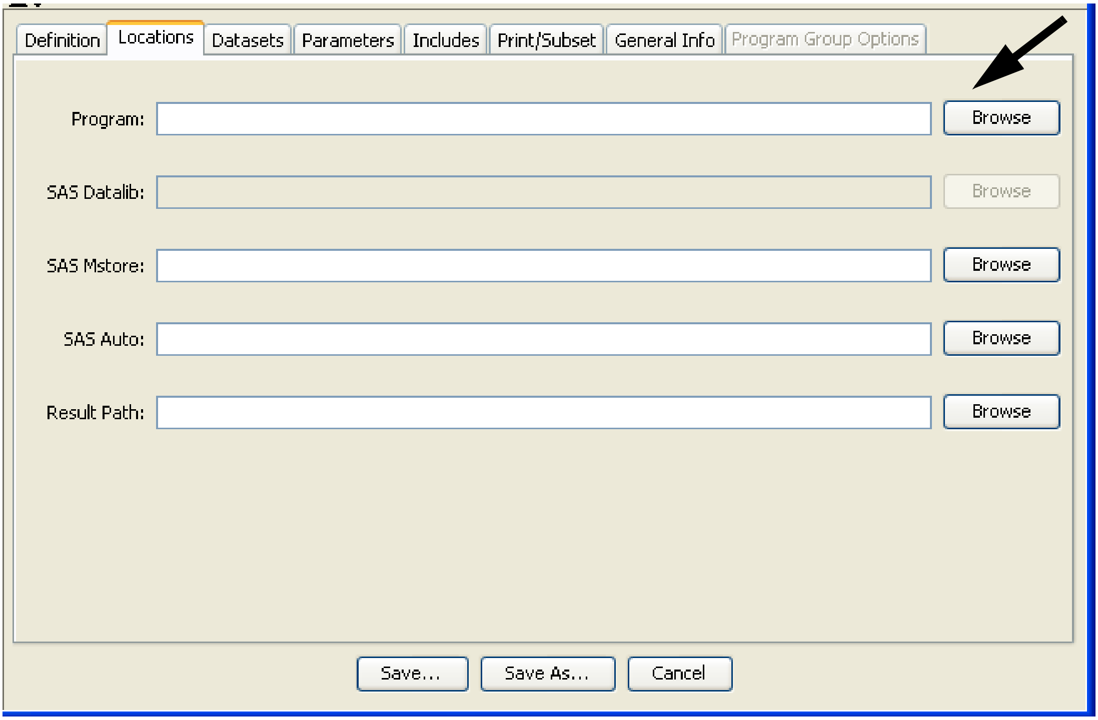


# Auxiliary Windows

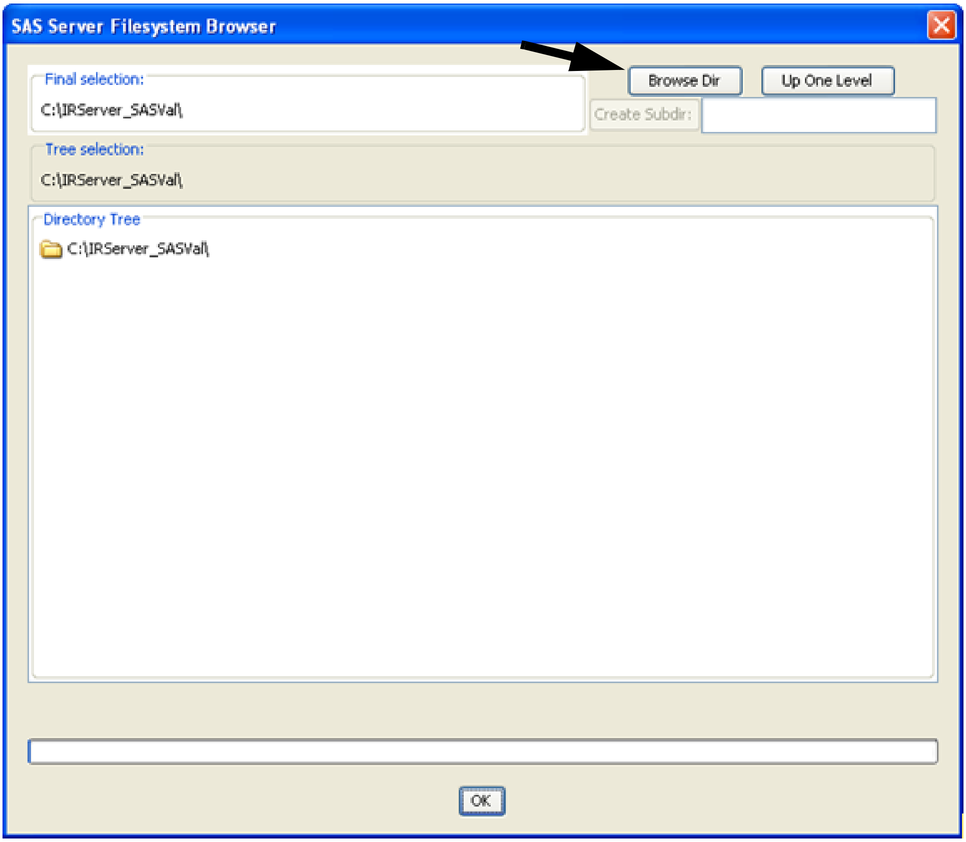
## *Browse Server*

If the Review Server version supports browsing, the **Browse** and **Add** buttons open a Browse Server window that displays lists of directories and files on the server. Directories can be navigated and files can be selected for inclusion in these lists. Access to browse directories is available throughout the SAS Program Registration functions. If the server version does not support browsing, a window opens to allow you to type in a new entry.

You can type entries in any of these fields in the Locations tab, or, if the Review Server version supports browsing, clicking the **Browse** button next to each entry opens a Browse Server window.



Click the **Browse Directory** button to display and select subdirectories and files.

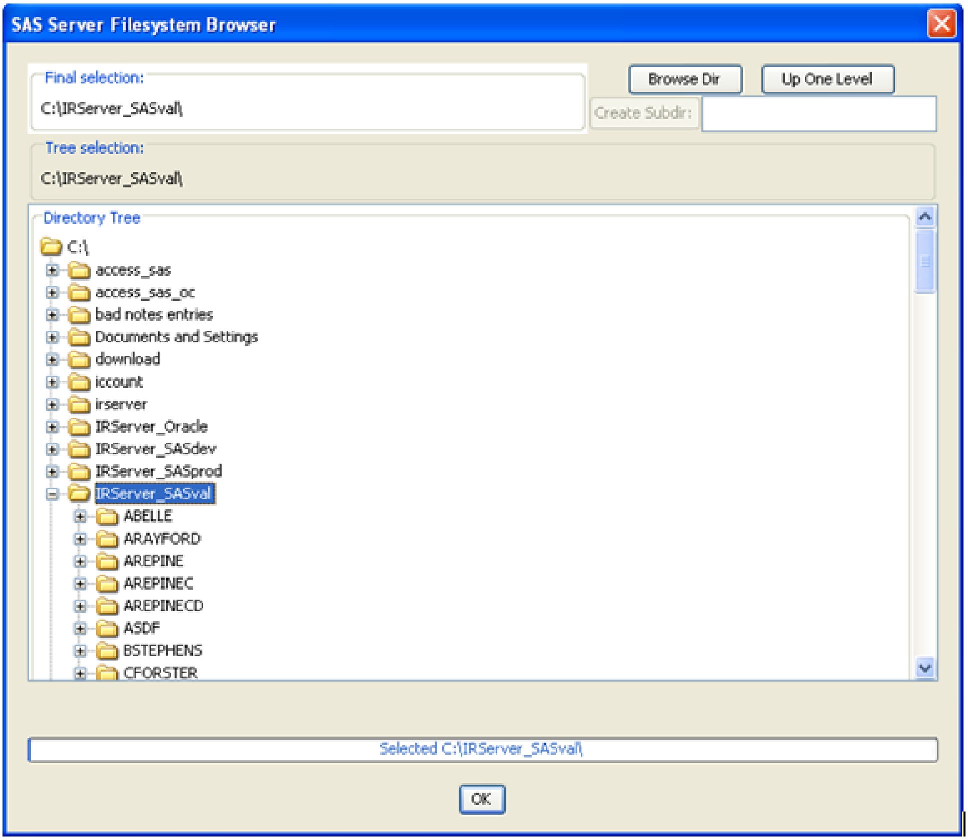


Final selection: C:\IRServer_SASVal\

Tree selection: C:\IRServer_SASVal\

Directory Tree: C:\IRServer_SASVal\

The Browse Server window allows users to browse directories and files on the server. This avoids typing errors and also prevents users from typing paths and/or file names that do not exist.



Final selection: C:\IRServer_SASval\

Tree selection: C:\IRServer_SASval\

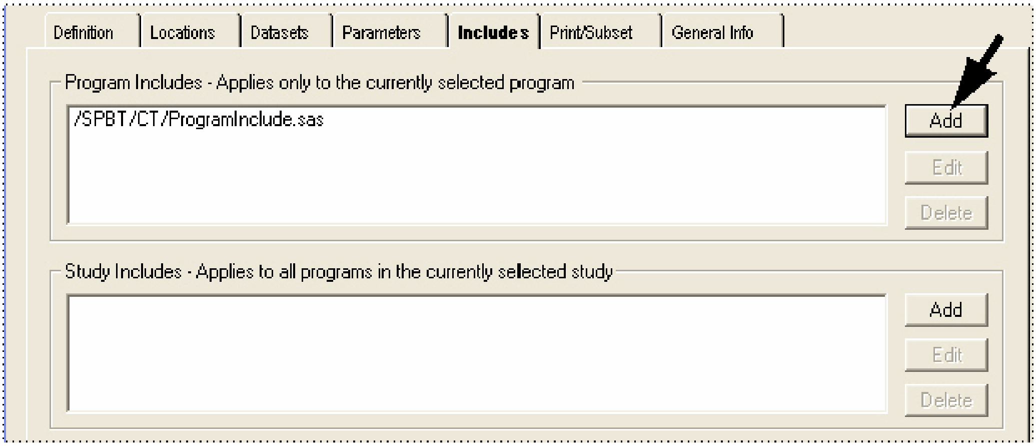
Selected C:\IRServer_SASval\

The “Browsing:” text area initially contains the server home directory where you can also type a path here. Clicking the **Browse Directory** button displays directories and files that exist in that directory. Double-clicking on a directory selects it to be the current browsing directory.

Clicking on a directory in the list displays files in that directory. The “Current selection:” text area displays the path/file that will be returned when you click the **OK** button. The dialog also knows if the required return is a directory or a file and will only allow the correct selection type to be returned.

The Includes tab in the STAT Program Registration Browser window displays the **Add** button. When the **Add** button is clicked for Program Includes or Study Includes, the **Browse Server** window opens for the SAS Program Include file.

You *must* click the **Add** button to enter the Program Includes or Study Includes directory and file information and cannot type the information.

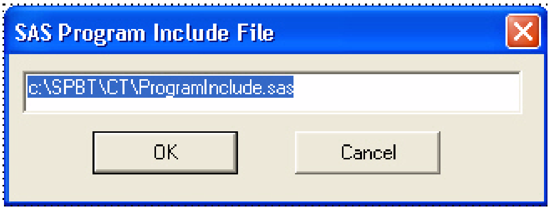


Program Includes - Applies only to the currently selected program

/SPBT/CT/ProgramInclude.sas

Study Includes - Applies to all programs in the currently selected study

You can edit an entry from either list in the Includes tab by selecting it and clicking the **Edit** button, which opens a window where the text of the entry can be changed. Use the same steps and click the **Delete** button to delete an entry from either list.



c:\SPBT\CT\ProgramInclude.sas

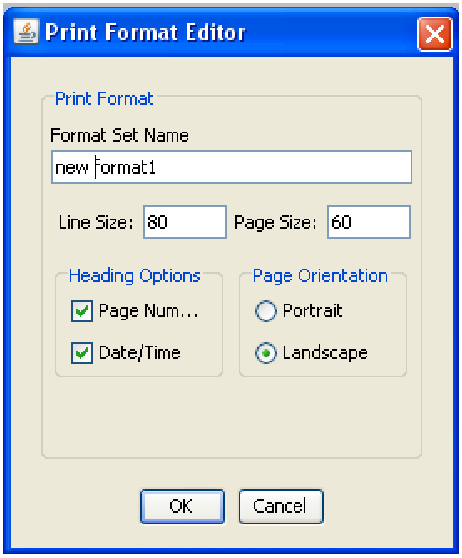
## *Print Format*

When you click the **Change Print Format** button on either the SAS program Print/Subset tab or on the Add Program Group dialog, the Print Format window opens. This dialog allows adding, editing and deleting print format sets as well as choosing a print format for a particular SAS program or program group.

The _default_ format is applied to every new SAS program and program group when it is created.

1. Click the **New** button to create a new Format Set.

   When you open the Print Format window from a program group, the number of programs within the group is displayed at the upper right.
2. Enter a Format Set description.  Format set names can be up to 40 characters long.
3. Change the Line Size and Page Size.
4. Check Heading options for Page Numbers and Date/Time.
5. Select the Page Orientation.
6. Click **Save**.



Format Set Name: new format1

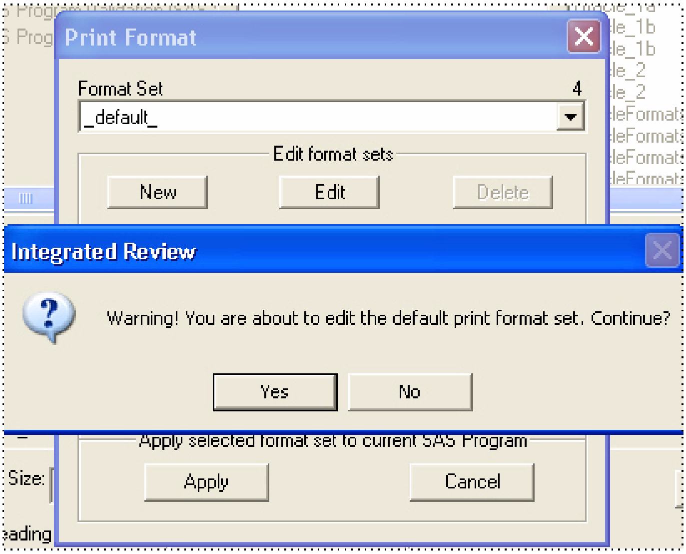
Line Size: 80
Page Size: 60

☑ Page Num...
☑ Date/Time

○ Portrait
● Landscape

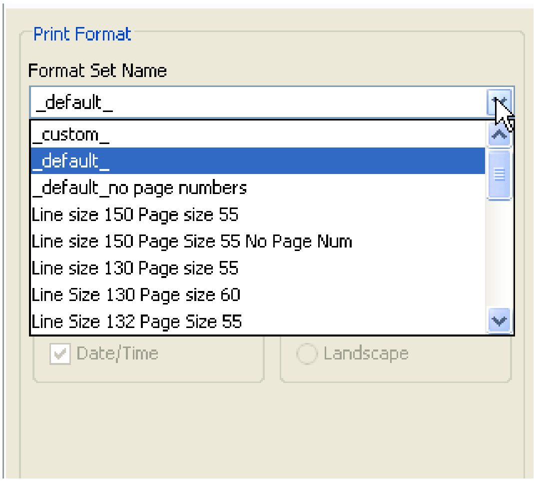
*Note:  A print format cannot be deleted if it is currently assigned to a SAS program or program group.*

To edit a Format Set, click the **Edit** button. Follow the same steps used to add a new Format Set. If you select to edit the _default_ format, a warning message displays. Click **Yes** to continue to edit the _default_ format set.



Warning! You are about to edit the default print format set. Continue?

Print format sets can be defined and named so that the same format settings can be used for many SAS programs and program groups. Two special names, _default_ and _custom_, are also defined.



The _custom_ format allows any SAS program or program group to have its own unique print format settings. When the _custom_ format is selected, the fields on the dialog become editable for you to enter their own format parameters. Click **Apply** to save format changes.

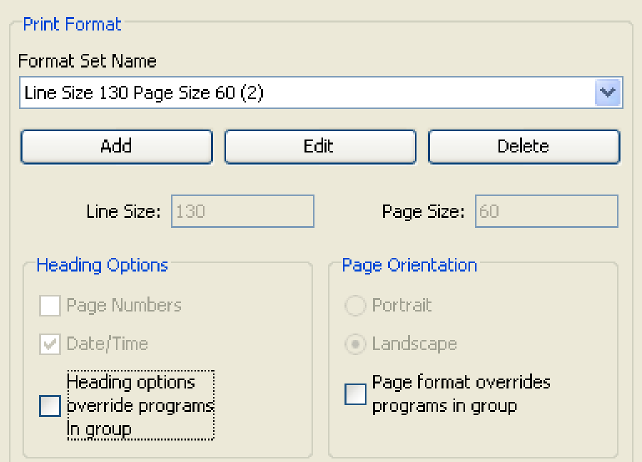
## *Program Format options*

**Print Format Overrides Programs** causes the program group's print format to be used for the entire output. "Heading Options Override Programs in Group" and "Page Format Overrides Programs in Group" are unique to program groups.

These options are set when adding or editing a program group. If a program group has a print format assigned and the "**Page Format Overrides Programs**" box was checked when the program group was saved, all output from the entire batch run will be formatted according to the program group's print format settings. Otherwise, the output from the batch will be formatted using the maximum line size and page size used by any of the programs in the group.

For example, if a program group is run without any print format overrides set for the program group, the display format is determined by taking the maximum page size and maximum line size of all of the programs within the group. For example, if one program has LS=80 PS=60 and another has LS=132 PS=50, the display format will be LS=132 PS=60.

Likewise, if a program group has a heading options assigned and the "**Heading Options Override Programs**" box was checked when the program group was saved, all output from the entire batch run will be formatted according to the program group's heading options. Otherwise, the output from the batch will be formatted using the individual heading options used by the programs in the group.



Print Format

Format Set Name: Line Size 130 Page Size 60 (2)

Line Size: 130

Page Size: 60

Heading Options

☐ Page Numbers

☑ Date/Time

☐ Heading options override programs In group

Page Orientation

○ Portrait

● Landscape

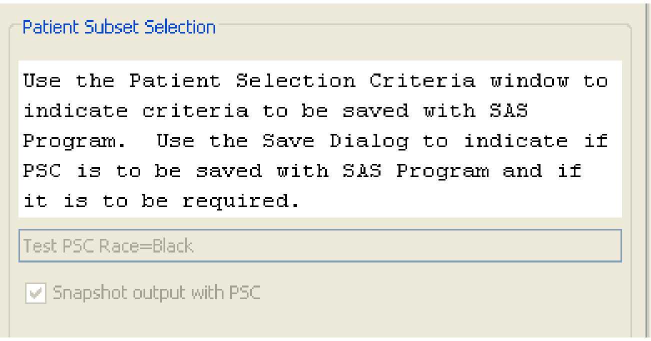
☐ Page format overrides programs in group

*Note: (See System Management: New Program Group.)*

## Patient Subset selection

If a program or group has no subset selection assigned and one is active in the Patient Selection Criteria window, the active subset selection will be used in the program or group execution.

The active patient selection criteria may be appended and saved to a SAS Program or Program Group during registration. The patient subset is entered in the Patient Selection Criteria window to be saved with the SAS Program or Program Group. Use the SAVE dialog to indicate if the selection criteria is to be required.



Use the Patient Selection Criteria window to indicate criteria to be saved with SAS Program. Use the Save Dialog to indicate if PSC is to be saved with SAS Program and if it is to be required.

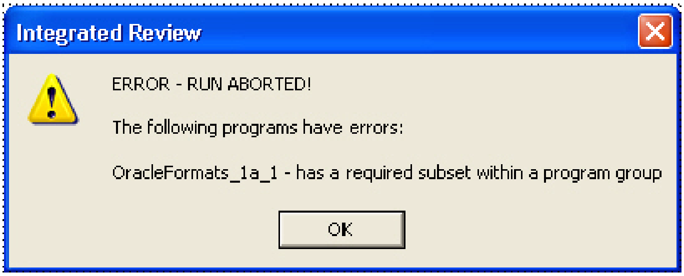
Test PSC Race=Black

☑ Snapshot output with PSC

When accessing View or Edit modes for registered SAS Programs or Program Groups previously saved with patient selection criteria; go to the patient selection criteria window to view patient subset details. A filter icon displays next to the object description indicating the program or program group has an appended patient subset. The red filter icon indicates the “Store Required Patient Selection Criteria” option was checked on either for the SAS program or the Program Group dialog.

Forcing “All Patients” can be applied during the registration SAVE diaog by checking the “Store Required Patient Selection Criteria” option on, to disallow changing the patient subset selection for a program or group.

Program group subset selections override all subset selections that may have been assigned to the SAS programs in that group. An exception is that if a program in a program group has a *required* subset, the program group will not run and displays an error message.



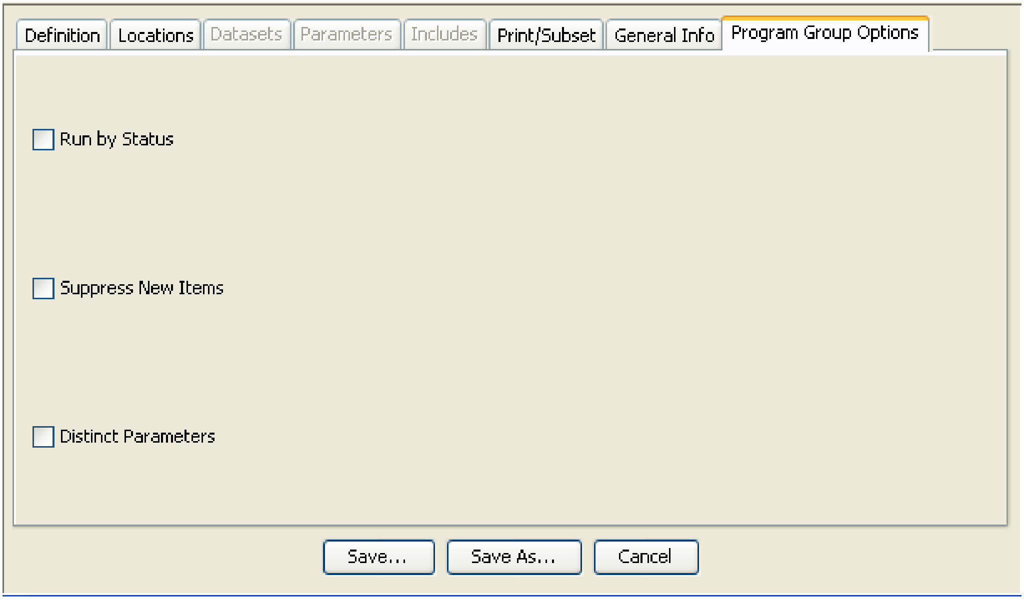
ERROR - RUN ABORTED!

The following programs have errors:

OracleFormats_1a_1 - has a required subset within a program group

## *Program group options*

Program group options may be selected for the following functions:



☐ Run by Status

☐ Suppress New Items

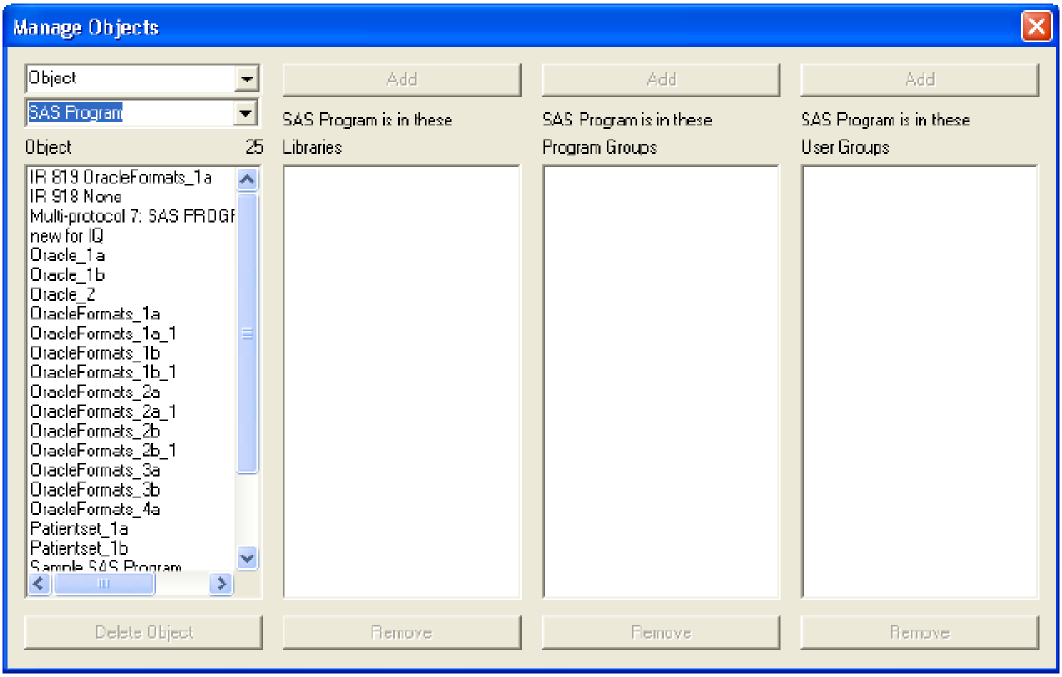
☐ Distinct Parameters

- **Run By Status** will result in only those programs that have the same status code as the program group to display and run as part of the group. If the “Run By Status” is not checked, programs and program group can have different status and all programs will run.
- **Distinct Parameters** displays parameters only once at runtime if they appear in more than one program in a program group.
- **Suppress New Items** overrides the settings for the programs in the group.

# Manage SAS objects

## *Manage SAS programs*

Click the **Manage** option in the tool bar for Advanced menu, to access the Manage Objects window.



Object

SAS Program

Object 25

IR 819 OracleFormats_1a
IR 918 None
Multi-protocol 7: SAS PROG
new for IQ
Oracle_1a
Oracle_1b
Oracle_2
OracleFormats_1a
OracleFormats_1a_1
OracleFormats_1b
OracleFormats_1b_1
OracleFormats_2a
OracleFormats_2a_1
OracleFormats_2b
OracleFormats_2b_1
OracleFormats_3a
OracleFormats_3b
OracleFormats_4a
Patientset_1a
Patientset_1b
Sample SAS Program

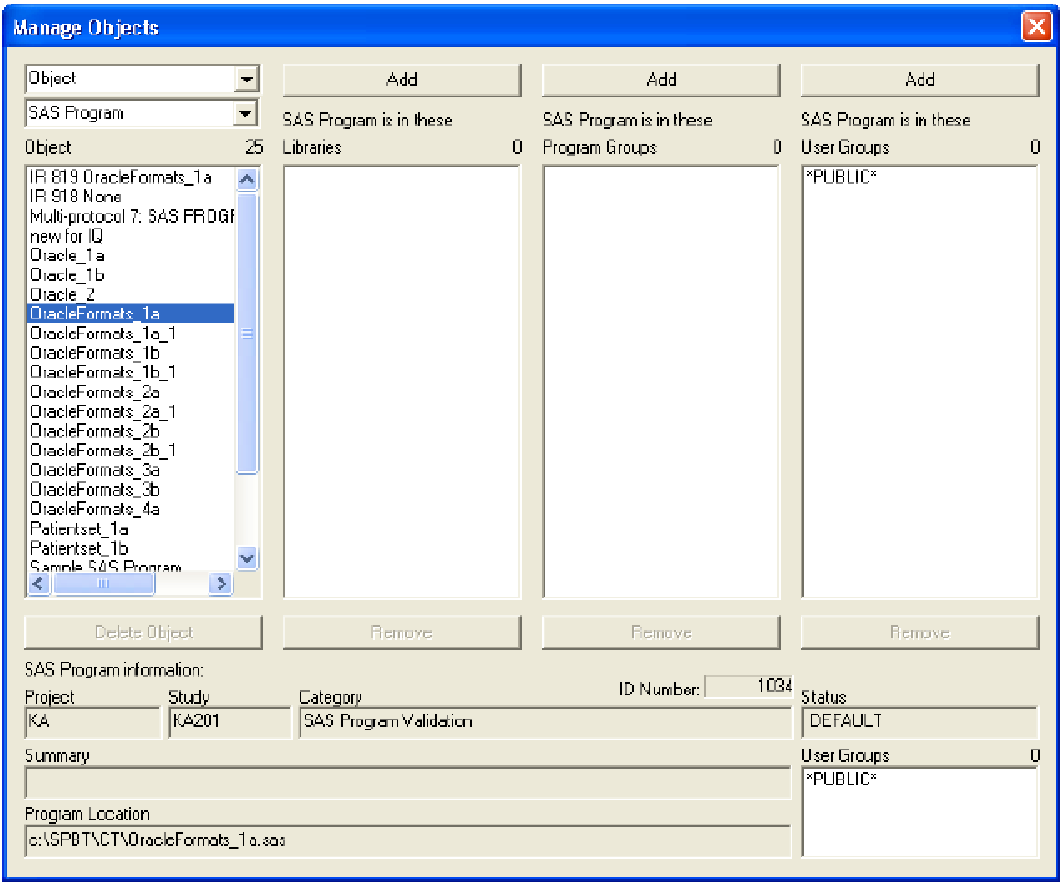
A drop down list displays the available system management options where you can manage the membership of registered SAS programs within the following areas:

- **Object (SAS Program)** - Manage SAS program registrations.
- **Library** - Manage libraries.
- **Category** - Manage categories.
- **Status** - Manage status codes.
- **Program Group** - Manage SAS programs within Program Groups and pertains ONLY to SAS programs. Other object types are excluded.
- **Object Group** - Manages non-SAS program objects within Object Groups and includes SAS Procs.
- **User Group** - Manages objects belonging to User Groups.

## *SAS Program*

You can select a SAS program from the Program list on the SAS Program Registration window, then click the **Manage** button to view the Manage Objects window with the SAS program registration details displayed.

Likewise, you can click the **Manage** button on the SAS Program Registration window to open the Manage Objects window and click SAS Program. Select a SAS program from the list to view detailed information fields displayed at the bottom for that item.



Object

SAS Program

Object 25

IR 819 OracleFormats_1a
IR 918 None
Multi-protocol 7: SAS PROGF
new for IQ
Oracle_1a
Oracle_1b
Oracle_2
OracleFormats_1a
OracleFormats_1a_1
OracleFormats_1b
OracleFormats_1b_1
OracleFormats_2a
OracleFormats_2a_1
OracleFormats_2b
OracleFormats_2b_1
OracleFormats_3a
OracleFormats_3b
OracleFormats_4a
Patientset_1a
Patientset_1b
Sample SAS Program

User Groups: *PUBLIC*

SAS Program information:

Project: KA
Study: KA201
Category: SAS Program Validation
ID Number: 1034
Status: DEFAULT
Summary:
User Groups 0: *PUBLIC*
Program Location: c:\SPBT\CT\OracleFormats_1a.sas

The following functions are available to assist you in managing the membership of SAS programs within Program Groups, Libraries and User Groups.

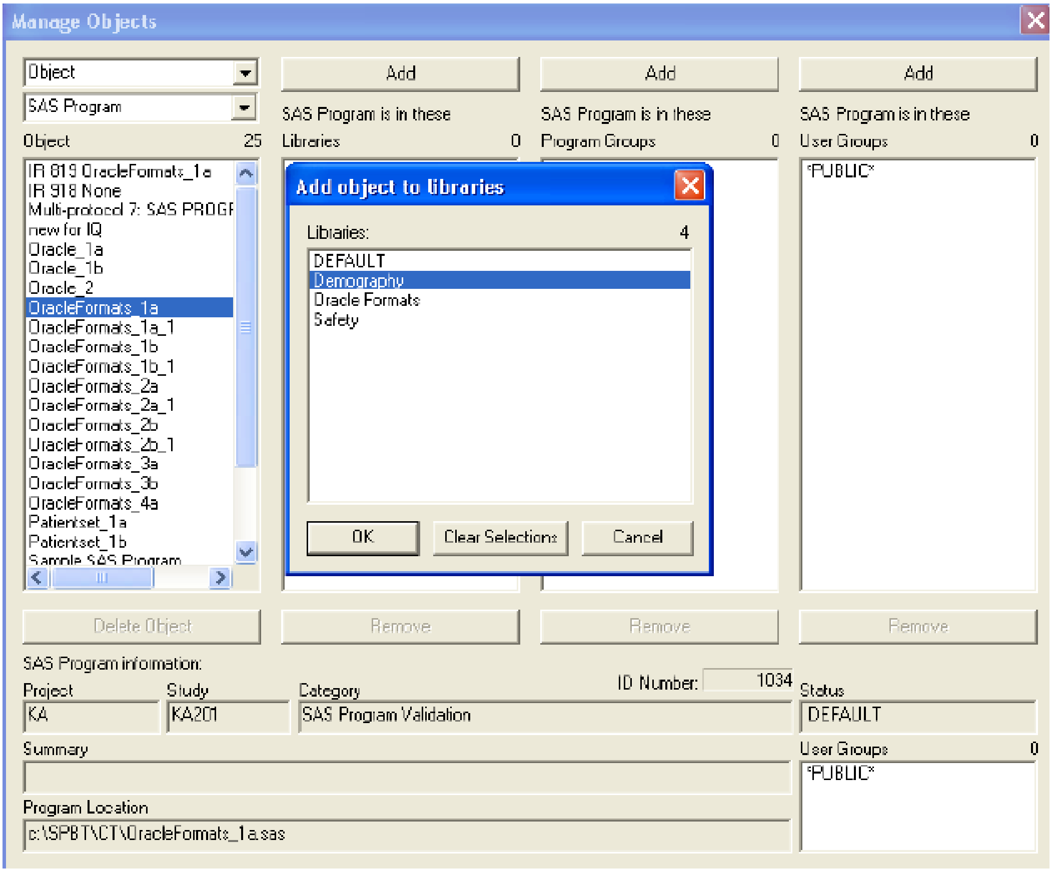
1. Click on **SAS Program** to display the registered SAS programs.
2. Select a SAS program from the list. You can only select one SAS program at a time.

   Detailed information about the SAS program displays at bottom.

   The Libraries, Program Groups, User Groups display for the SAS program showing current membership status.
3. Click **Add/Remove Libraries** to change a SAS program's membership in a library.

   You can select multiple libraries with the CTRL or SHIFT key to add or remove the SAS program's membership in multiple libraries.

   Click **OK** to save.



SAS Program information:

Project: KA

Study: KA201

Category: SAS Program Validation

ID Number: 1034

Status: DEFAULT

Summary:

User Groups 0: *PUBLIC*

Program Location: c:\SPBT\CT\OracleFormats_1a.sas

4. Click **Add/ Remove Program Groups** to change a SAS program's membership in program groups.

   You can select multiple program groups with the CTRL or SHIFT key to add or remove the SAS program's membership in multiple program groups.

   Click **OK** to save.

5. Click **Add/ Remove User Groups** to change a SAS program's membership in user groups.

   You can select multiple user groups with the CTRL or SHIFT key to add or remove the SAS program's membership in multiple user groups.

   Click **OK** to save.

   If you click **Remove all User Groups** the SAS program changes to *PUBLIC*.

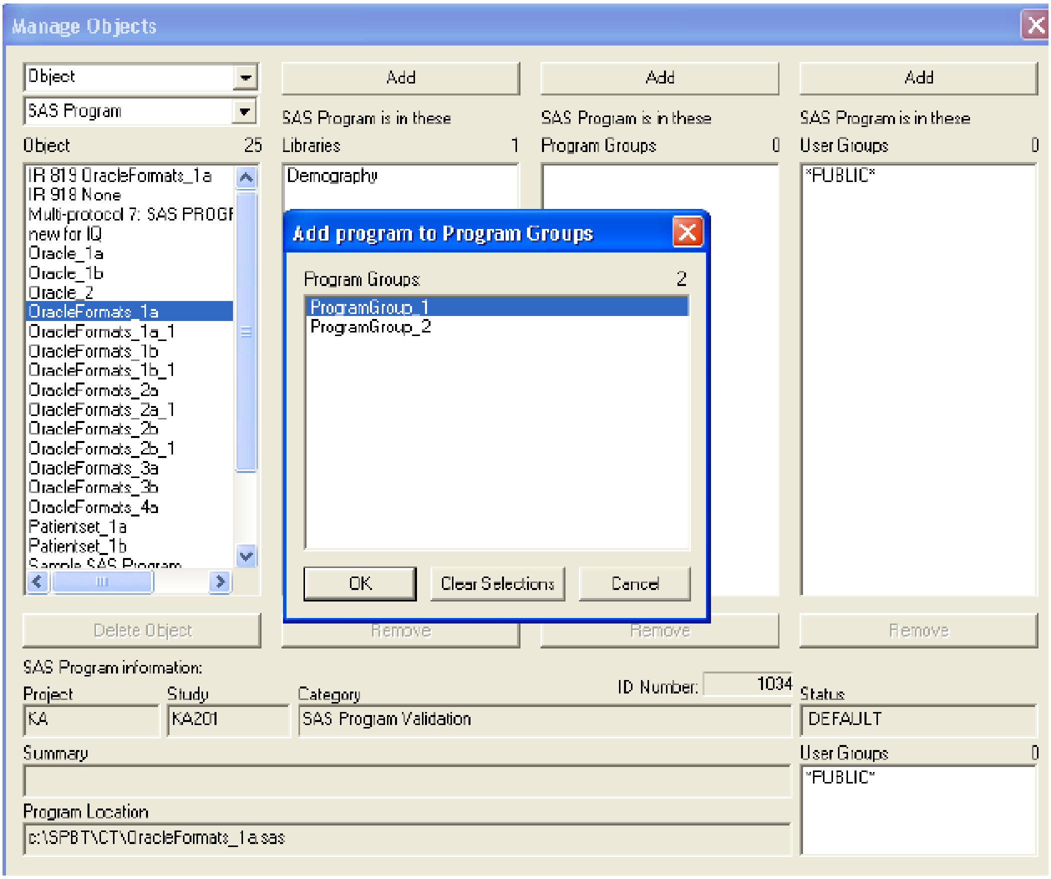
6. Click **Delete SAS Program** and the SAS program registration and all references are deleted from the database tables.

   If the SAS program to be deleted belongs to one or more program groups, an "**Are you sure?**" warning message *always* displays, with additional text if belongs to a program group and/or has saved output.

## *Program Group*

Open the Manage Objects window and select Program Group. The following functions are available to assist you in managing Program Groups and the membership of SAS programs within Program Groups.

1. Click on **Program Group** to display the existing programs groups.



Object
SAS Program

Object 25
IR 819 OracleFormats_1a
IR 918 None
Multi-protocol 7: SAS PROG
new for IQ
Oracle_1a
Oracle_1b
Oracle_2
OracleFormats_1a
OracleFormats_1a_1
OracleFormats_1b
OracleFormats_1b_1
OracleFormats_2a
OracleFormats_2a_1
OracleFormats_2b
OracleFormats_2b_1
OracleFormats_3a
OracleFormats_3b
OracleFormats_4a
Patientset_1a
Patientset_1b

SAS Program is in these Libraries 1
Demography

SAS Program is in these Program Groups 0

SAS Program is in these User Groups 0
*PUBLIC*

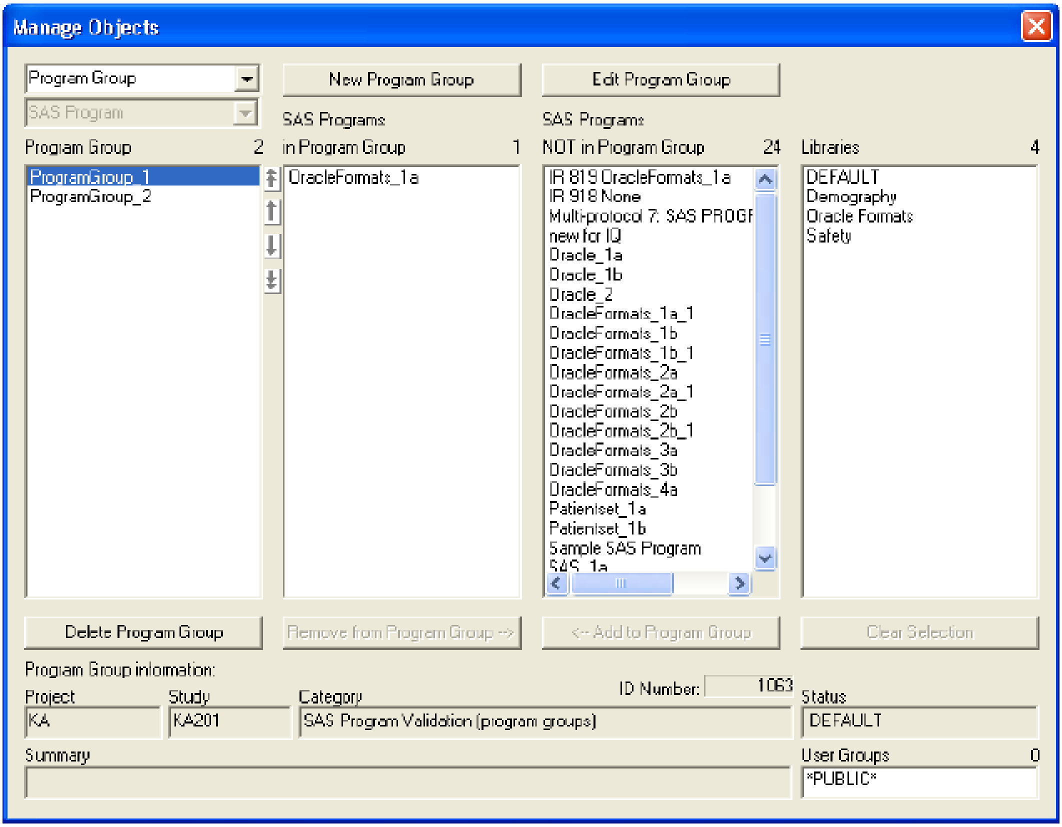
Program Groups 2
ProgramGroup_1
ProgramGroup_2

SAS Program information:
ID Number: 1034
Project: KA
Study: KA201
Category: SAS Program Validation
Status: DEFAULT
Summary:
User Groups 0
*PUBLIC*
Program Location: c:\SPBT\CT\OracleFormats_1a.sas

2. Select a program group from the list. You can only select one program group at a time.

   Detailed information about the program group displays at bottom.

   The SAS program lists identify which SAS programs are in or NOT in the selected program group.



Program Group 2
- ProgramGroup_1
- ProgramGroup_2

SAS Programs in Program Group 1
- OracleFormats_1a

SAS Programs NOT in Program Group 24
- IR 819 OracleFormats_1a
- IR 918 None
- Multi-protocol 7: SAS PROG
- new for IQ
- Oracle_1a
- Oracle_1b
- Oracle_2
- OracleFormats_1a_1
- OracleFormats_1b
- OracleFormats_1b_1
- OracleFormats_2a
- OracleFormats_2a_1
- OracleFormats_2b
- OracleFormats_2b_1
- OracleFormats_3a
- OracleFormats_3b
- OracleFormats_4a
- Patientset_1a
- Patientset_1b
- Sample SAS Program
- SAS_1a

Libraries 4
- DEFAULT
- Demography
- Oracle Formats
- Safety

Program Group information:

Project: KA

Study: KA201

Category: SAS Program Validation (program groups)

ID Number: 1063

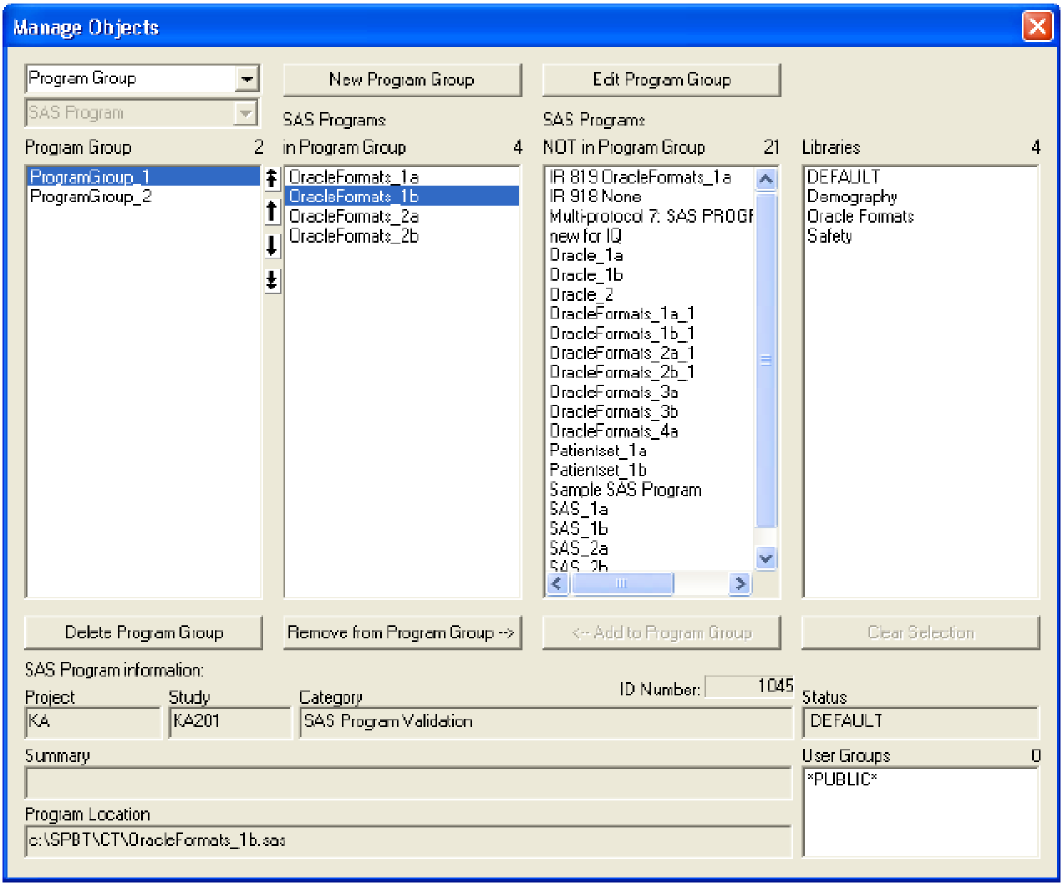
Status: DEFAULT

Summary:

User Groups 0: *PUBLIC*

3. Select a SAS program to display program information in fields at bottom.
4. Click the **Add to Program Group** or **Remove from Program Group** buttons to move SAS programs in and out of the selected program group. The Add and Remove feature changes which programs belong to a program group.

5. The **Arrow** buttons become active when a SAS program in the program group is selected. Arrows can be used to move a program up or down one place in the list (middle buttons) or to the top or bottom of the list (top and bottom double-arrow buttons).



Program Group 2
- ProgramGroup_1
- ProgramGroup_2

SAS Programs in Program Group 4
- OracleFormats_1a
- OracleFormats_1b
- OracleFormats_2a
- OracleFormats_2b

SAS Programs NOT in Program Group 21
- IR 819 OracleFormats_1a
- IR 918 None
- Multi-protocol 7: SAS PROGI
- new for IQ
- Oracle_1a
- Oracle_1b
- Oracle_2
- OracleFormats_1a_1
- OracleFormats_1b_1
- OracleFormats_2a_1
- OracleFormats_2b_1
- OracleFormats_3a
- OracleFormats_3b
- OracleFormats_4a
- Patientset_1a
- Patientset_1b
- Sample SAS Program
- SAS_1a
- SAS_1b
- SAS_2a
- SAS_2b

Libraries 4
- DEFAULT
- Demography
- Oracle Formats
- Safety

ID Number: 1045

Project: KA

Study: KA201

Category: SAS Program Validation

Status: DEFAULT

Summary:

User Groups 0: *PUBLIC*

Program Location: c:\SPBT\CT\OracleFormats_1b.sas

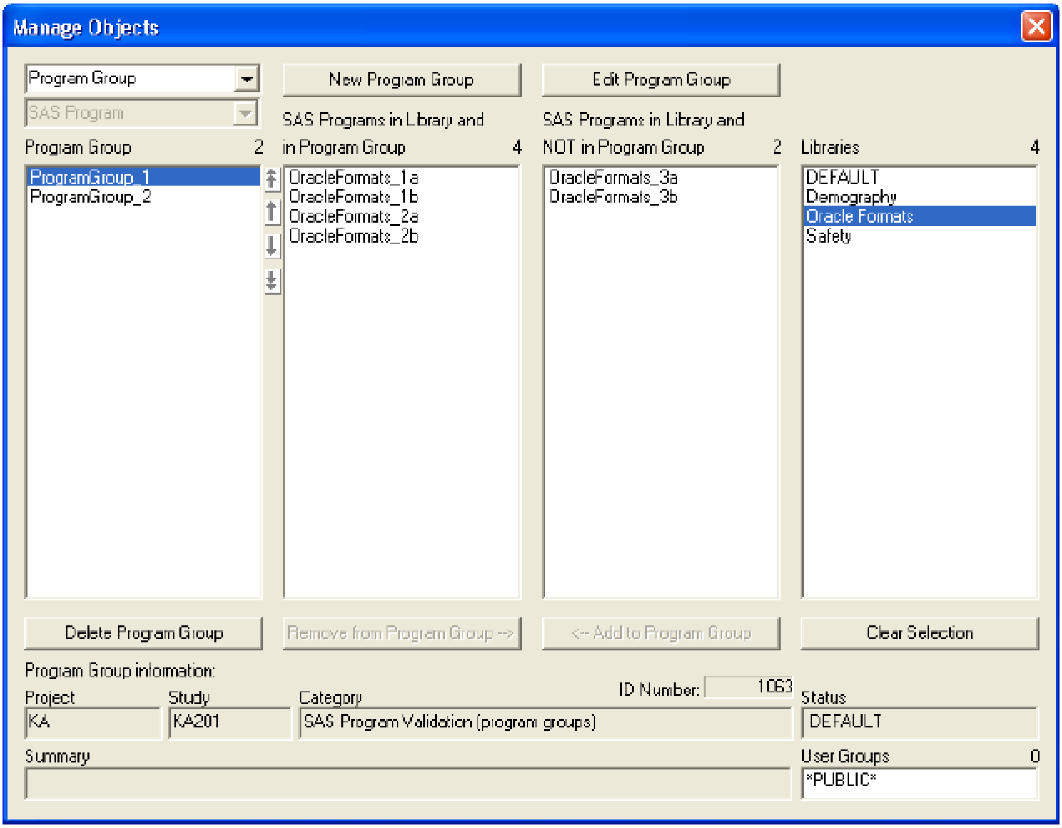
***Note: Review does not allow ANY mixing of data origins with same-name datasets even for Oracle versus Oracle/Formats. The reason is Review generates the SAS view of an Oracle table only once, regardless of how many programs in a program group use the dataset. If the data origin is Oracle/Formats, the format is applied directly in the view to the SAS dataset, otherwise, it is plain SAS variables with no formats applied. Which one gets generated would depend on the order of programs in the group.***

6. Click on a **Library** from the Libraries list.

   You can select multiple libraries with the CTRL or SHIFT key to view the SAS programs membership in multiple libraries.

   The SAS programs lists identifies which SAS programs are in or NOT in the selected library(ies) for the program group.

   Click **Clear Selection** to clear selection(s) in the library list.



Program Group

SAS Program

| Program Group 2 | SAS Programs in Library and in Program Group 4 | SAS Programs in Library and NOT in Program Group 2 | Libraries 4 |
|---|---|---|---|
| ProgramGroup_1 | OracleFormats_1a | OracleFormats_3a | DEFAULT |
| ProgramGroup_2 | OracleFormats_1b | OracleFormats_3b | Demography |
| | OracleFormats_2a | | Oracle Formats |
| | OracleFormats_2b | | Safety |

Program Group information:

Project: KA

Study: KA201

Category: SAS Program Validation (program groups)

ID Number: 1063

Status: DEFAULT

Summary:

User Groups 0: *PUBLIC*

## *New Program Group*

Program groups are a convenient way to define a number of programs that are to be executed together as a group, in a specific sequence. Program groups are considered objects, and have the characteristics of other objects such as belonging to a category.

1. Click the **New Program Group** button to open the SAS Program Group window.
2. Required fields for entry are *Name, Category* and *Status*.

***Note: A Program Group can belong to only one CATEGORY and have only one STATUS assigned to it.***

***Note: A program group can only be saved at User Group or Public locations.***

Defaults are supplied (e.g., study-level group, print format = _default_) and you can select or type in the various fields.

3. You can specify a Patient Selection Criteria be applied to the program group at runtime. Click **Select Subset** for choices. *(See Auxiliary Windows: Select Subset.)*
4. Click the **Browse** button to define a Result Path to save output. *(See Auxiliary Windows: Browse Server.)*
5. **Print Format Overrides Programs** causes the program group's print format to be used for the entire output. "Heading Options Override Programs in Group" and "Page Format Overrides Programs in Group" are unique to program groups. *(See Auxiliary Windows: Print Format.)*

   If a program group does NOT have a Print Format Overrides Programs box checked, individual program setting apply for page numbers and date/time. Order of programs will determine page numbers printed unless one of the programs resets the page numbering. If the Print Format Overrides Programs IS checked, the program group settings will be applied at the beginning of the run. *Still, any program may have an OPTIONS statement that may change these settings.*
6. Options available to program groups are:
   - **Save Output** stores all program output files in the group's Result Path. If Save Output is checked then output is automatically saved.
   - **Run By Status** will result in only those programs that have the same status code as the program group to display and run as part of the group. If the "Run By Status" is not checked, programs and program group can have different status and all programs will run.
   - **Subset Required** overrides the settings for the programs in the group.
   - **Distinct Parameters** displays parameters only once at runtime if they appear in more than one program in a program group.

- **Suppress New Items** overrides the settings for the programs in the group.

7. Clicking the **Save** button verifies that required fields are filled (e.g., Description, Category, Status) and opens the Save Object window.
8. Clicking the **Cancel** button discards changes after a confirmation dialog is displayed.
9. Select a program group and click the **Edit Program Group** button. The SAS Program Group window opens with the details of the selected program group for you to edit.
10. Select a program group and click the **Delete Program Group** button to delete a program group and all references in database tables. The SAS program registrations are NOT deleted.

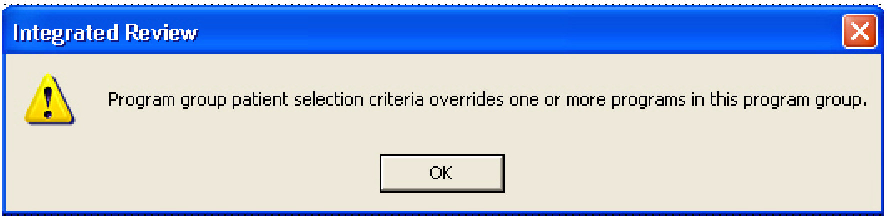
## *Program Group Restrictions*

***Program groups may not run for any of the following reasons:***

1. A program has no program source location defined (can't run a program if there is no source code!).
2. Data origin for a program requires datasets (e.g. SAS or ORACLE) but no datasets are defined for the program.
3. Programs within a group have a dataset / data origin conflict. Specifically, two or more programs with different data origins (SAS/ORACLE) or different physical locations (datalib directories) have datasets defined with the same name. Since the collection of datasets for all programs in a group are processed together prior to running the actual programs, this means we have a dataset that comes from two different sources.
4. A program within a group has a required patient subset selection. Since program groups always override patient subset selections for the programs, required subset selections are not allowed in programs within a program group.
5. Distinct parameters have a conflict (e.g. LIST-type parameters with the same name and different possible values in two or more programs). Since the Distinct option means that parameters for all programs are collapsed by name prior to running the programs, LIST parameters with the same name must have the same list of possible values in order for them to be processed together.

***Informational and other messages:***

1. One or more programs have a (non-required) patient subset selection that is overridden by the program group. This is true even if the program group has no subset selected – the program's subset selection will be ignored in this case and "All Patients" will be applied to the program group.



Program group patient selection criteria overrides one or more programs in this program group.

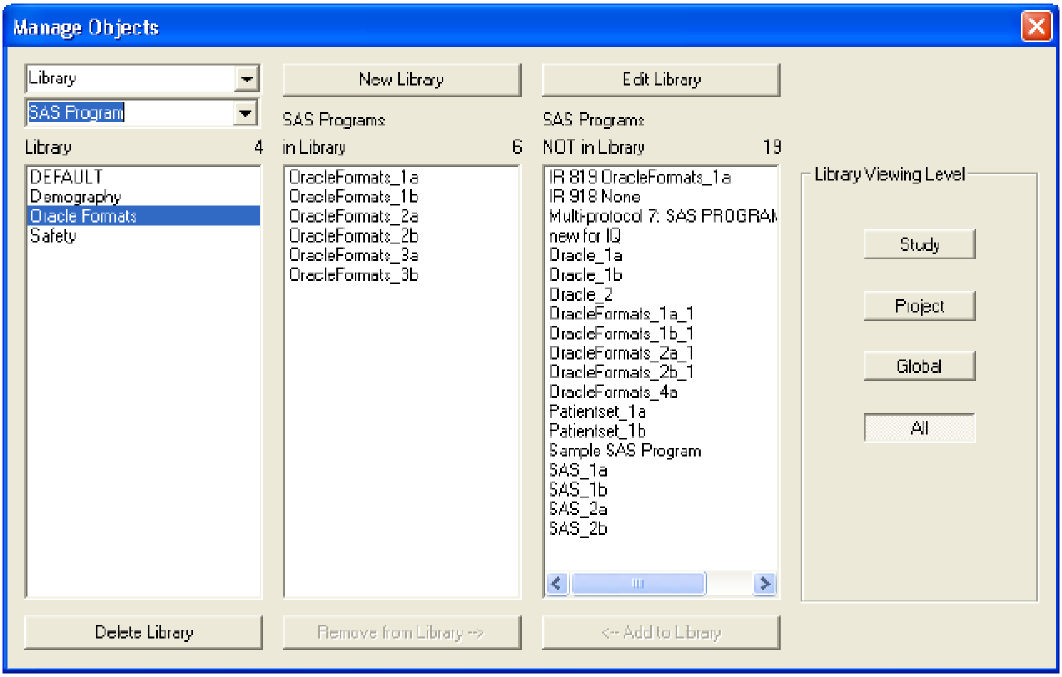
2. Incomplete print formats were fixed (LS=0, PS=0). This could be for a program or program group depending on the Print Format Overrides checkbox.
3. When a study level override is assigned or removed and the target program belongs to a program group, a message is displayed indicating that the overriding program was added or removed from the program group(s) that the overridden program belongs to.
4. If the "_default_" print format is edited, a warning message displays – "About to edit default print format" – since this format is automatically assigned to new programs/groups when they are first created.

## Library

Open the Manage Objects window and select Library. The Library functions assist you to manage the SAS programs’ membership within the Libraries.

1. Click on a **Library** to display the SAS program lists for that library.

   The SAS program lists identify which SAS programs are in or NOT in the selected library.



Library

SAS Program

Library 4

DEFAULT
Demography
Oracle Formats
Safety

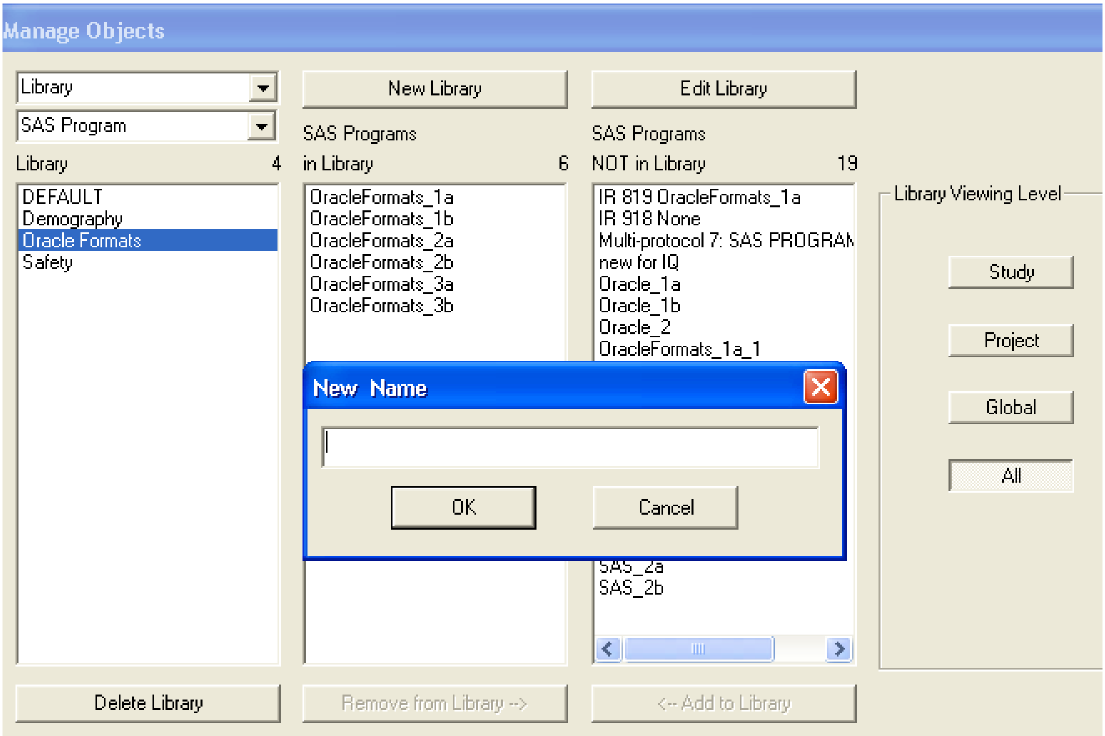
SAS Programs in Library 6

OracleFormats_1a
OracleFormats_1b
OracleFormats_2a
OracleFormats_2b
OracleFormats_3a
OracleFormats_3b

SAS Programs NOT in Library 19

IR 819 OracleFormats_1a
IR 918 None
Multi-protocol 7: SAS PROGRAM
new for IQ
Oracle_1a
Oracle_1b
Oracle_2
OracleFormats_1a_1
OracleFormats_1b_1
OracleFormats_2a_1
OracleFormats_2b_1
OracleFormats_4a
Patientset_1a
Patientset_1b
Sample SAS Program
SAS_1a
SAS_1b
SAS_2a
SAS_2b

2. Click on a SAS program to display program information in fields at bottom.
3. Click the **Add to Library** or **Remove from Library** buttons to move SAS programs in and out of the selected library. The Add and Remove feature changes which programs belong to a library.
4. Click **New Library** to open a window to enter a new library name and click **OK**.Select a library and click **Edit Library** to open a window to edit a library name.

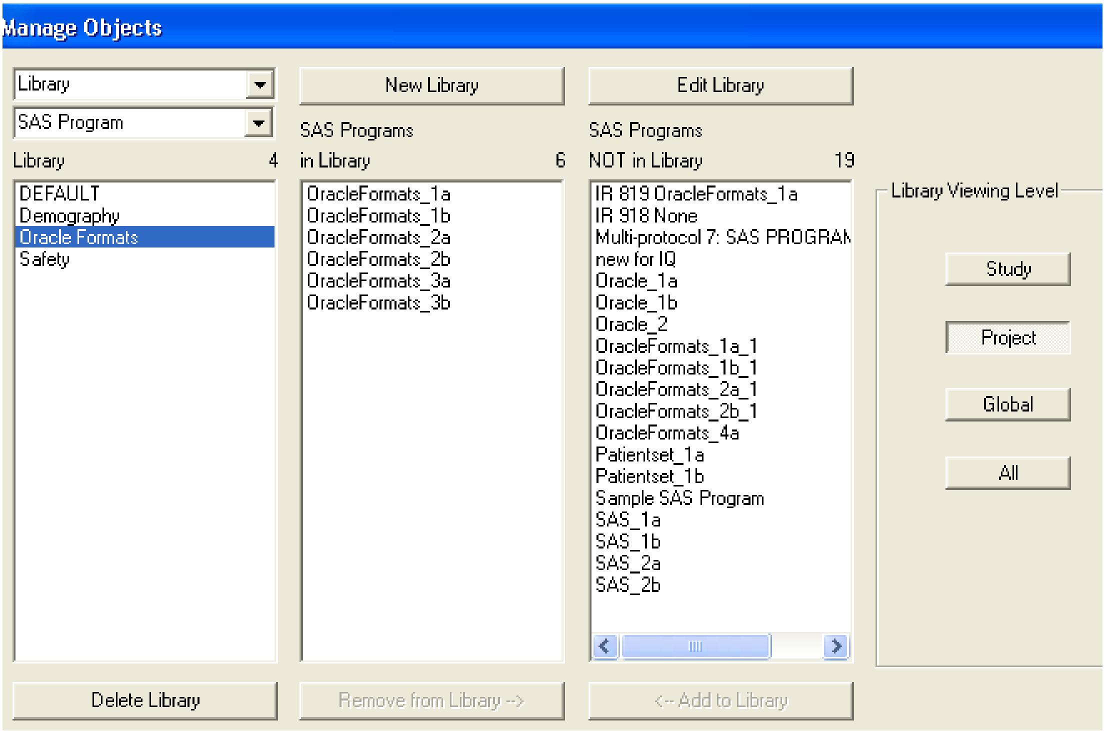


5. Select a library and click **Delete Library** to delete a library and all references in database tables. The SAS program registrations are NOT deleted.

6. The **Library Viewing Level** restricts the lists of SAS program registrations displayed to only show the selected level(s) of programs.

   Multiple levels can be selected by clicking more than one button.

   The default view is for **All** levels.



## *Category*

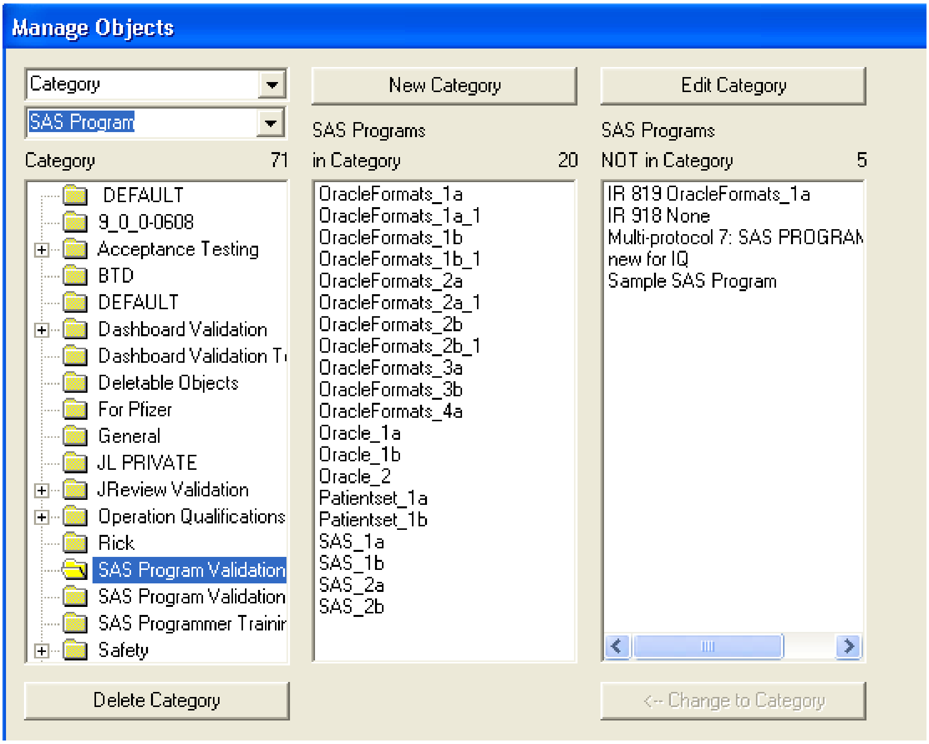
The Category functions assist you to manage the SAS programs membership within Categories. Open the Manage Objects window and select **Category** to access the following functions.

1. Click on a **Category** to display the SAS program lists for that category.

   The SAS program lists identify which SAS programs are in or NOT in the selected category.

   All available categories are listed with the options to create **New**, **Edit**, **Delete** a selected category or **Change** programs to the category.

*Hint:* ***Prior to registering new SAS programs you may need to first create a New category if the folder destination does not already exist.***



Category
SAS Program

Category 71

DEFAULT
9_0_0-0608
Acceptance Testing
BTD
DEFAULT
Dashboard Validation
Dashboard Validation T
Deletable Objects
For Pfizer
General
JL PRIVATE
JReview Validation
Operation Qualifications
Rick
SAS Program Validation
SAS Program Validation
SAS Programmer Trainir
Safety

SAS Programs in Category 20

OracleFormats_1a
OracleFormats_1a_1
OracleFormats_1b
OracleFormats_1b_1
OracleFormats_2a
OracleFormats_2a_1
OracleFormats_2b
OracleFormats_2b_1
OracleFormats_3a
OracleFormats_3b
OracleFormats_4a
Oracle_1a
Oracle_1b
Oracle_2
Patientset_1a
Patientset_1b
SAS_1a
SAS_1b
SAS_2a
SAS_2b

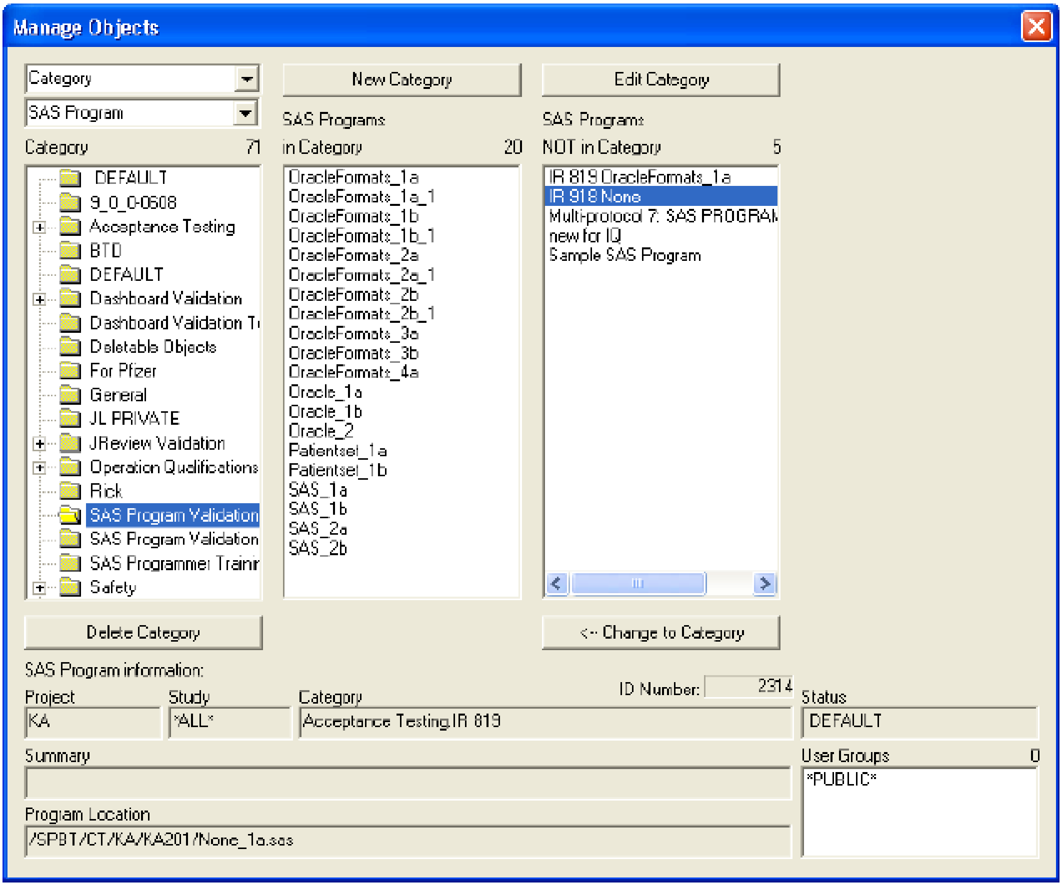
SAS Programs NOT in Category 5

IR 819 OracleFormats_1a
IR 918 None
Multi-protocol 7: SAS PROGRAM
new for IQ
Sample SAS Program

2. Click on a SAS program to display program information in fields at bottom.
3. Select a SAS program from the NOT in Category list. You can select multiple SAS programs with the CTRL or SHIFT key.

***Note: A SAS program can belong to only one CATEGORY and have only one STATUS assigned to it. These items are required for SAS registration on the Definition tab.***

4. Click the **Change to Category** button to change the category that the program(s) belong to.



Category
SAS Program

Category 71
- DEFAULT
- 9_0_0-0608
- Acceptance Testing
- BTD
- DEFAULT
- Dashboard Validation
- Dashboard Validation T
- Deletable Objects
- For Pfizer
- General
- JL PRIVATE
- JReview Validation
- Operation Qualifications
- Rick
- SAS Program Validation
- SAS Program Validation
- SAS Programmer Trainr
- Safety

SAS Programs in Category 20
- OracleFormats_1a
- OracleFormats_1a_1
- OracleFormats_1b
- OracleFormats_1b_1
- OracleFormats_2a
- OracleFormats_2a_1
- OracleFormats_2b
- OracleFormats_2b_1
- OracleFormats_3a
- OracleFormats_3b
- OracleFormats_4a
- Oracle_1a
- Oracle_1b
- Oracle_2
- Patientsel_1a
- Patientsel_1b
- SAS_1a
- SAS_1b
- SAS_2a
- SAS_2b

SAS Programs NOT in Category 5
- IR 819 OracleFormats_1a
- IR 918 None
- Multi-protocol 7: SAS PROGRAM
- new for IQ
- Sample SAS Program

SAS Program information:

ID Number: 2314

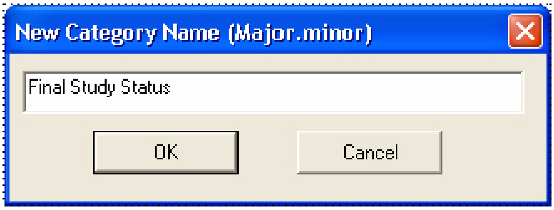
| Project | Study | Category | Status |
|---|---|---|---|
| KA | *ALL* | Acceptance Testing.IR 819 | DEFAULT |

Summary:

User Groups 0: *PUBLIC*

Program Location: /SPBT/CT/KA/KA201/None_1a.sas

5. Click **New Category** and enter a New Category Name. You can add multiple levels (first.second.third). Duplicate names or blank levels are not allowed. Click **OK**.



Final Study Status

The new folder category is now available for you to assign SAS programs when you register a new SAS program.

6. Click **Edit Category** to edit at any level (first, middle, end nodes). Duplicate names are not allowed or blank levels. Click **OK**.

7. Click **Delete Category** which will NOT delete a category if any programs are assigned to it. The SAS program registrations are NOT deleted.

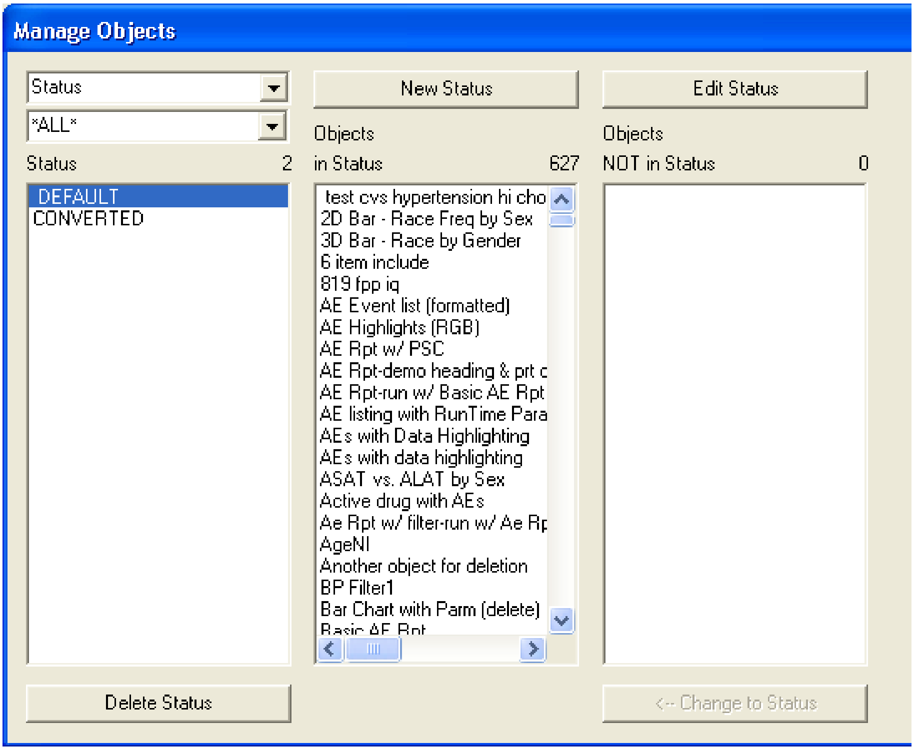
   You can only delete end nodes (e.g. for category “Safety.Labs.Reports” you have to delete the end node “Reports” before you can delete the next node ‘Labs”, etc.).

## *Status*

The Status functions assist you to manage the SAS programs membership within a Status. Open the Manage Objects window and click **Status.** The following functions are available:

1. Select a **Status**. The SAS program lists identify which SAS programs are in or NOT in the selected status.

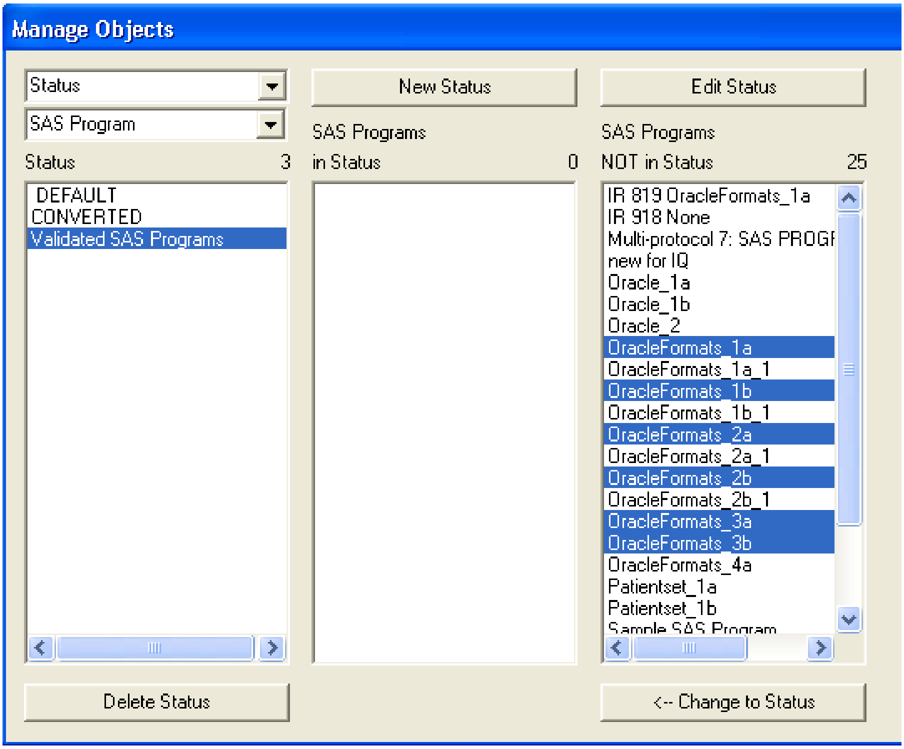
   All available statuses are listed with the options to create **New**, **Edit**, **Delete** or **Change** programs to the status.
2. Click on a SAS program to display program information in fields at bottom.



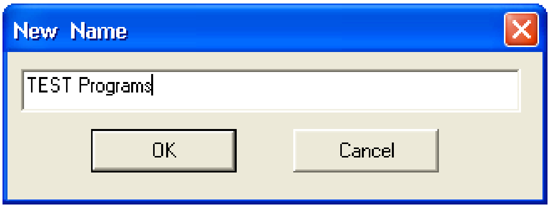
***Note: A SAS program can belong to only one CATEGORY and have only one STATUS assigned to it. These items are required for SAS registration on the Definition tab.***

3. Select a SAS program from the NOT in Status list. You can select multiple SAS programs with the CTRL or SHIFT key.

   Click the **Change to Status** button to change the status that the program(s) belong to.



4. Click **New Status** and enter a New Status Name. Click **OK**.



TEST Programs

The new status is now available for you to assign SAS programs when you register a new SAS program.

5. Click **Edit Status** to open a text dialog to edit a status name.

6. Click **Delete Status** which will NOT delete a status if any programs are assigned to it. The SAS program registrations are NOT deleted.

## *User Group - SAS Program*

By default all programs are available to view in *PUBLIC*. You can manage the user's access by assigning a User Group. Therefore, the User Group will determine what programs or program groups a particular user sees in the Object Explorer categories. The STAT Program Registration Browser and Manage Objects windows always show all programs and program groups so users can manage them.

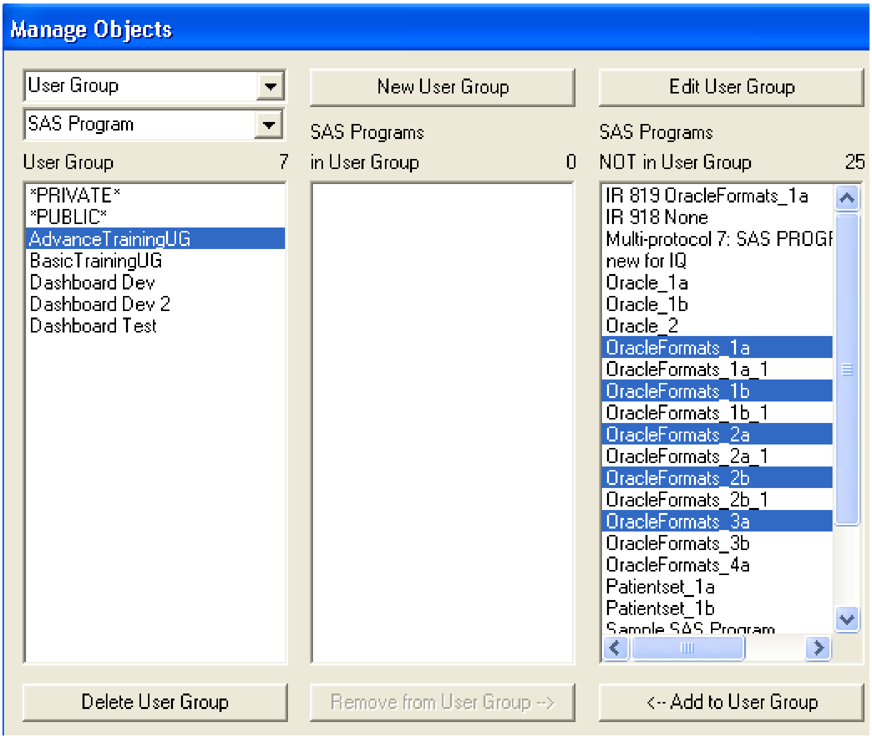
The User Group - SAS Program option assists you to manage the SAS programs membership within a User Group. Open the Manage Objects window and click **User Group** and select SAS Program. The following functions are available:

1. Click on a **User Group** (or *PUBLIC*) to display SAS program lists for user group (or *PUBLIC*).
2. Click on a SAS program to display program information in fields at bottom.

3. Click the **Add to User Group** and **Remove from User Group** buttons to change which programs belong to a User Group.

   You can select multiple SAS programs with the CTRL or SHIFT key.

   Adding to *PUBLIC* removes all user group assignments.

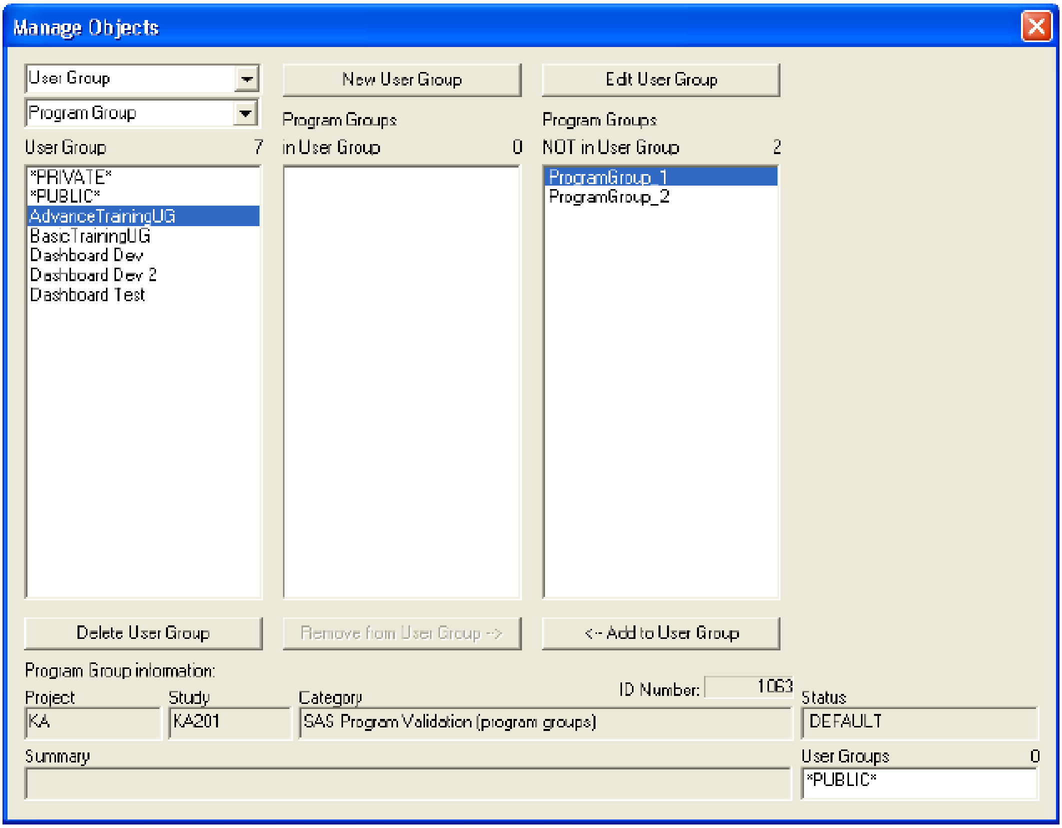


## User Group - Program Group

The User Group - Program Group option assists you to manage the SAS Program Groups within a User Group. A Program Group can belong to multiple User Groups. Open the Manage Objects window and click **User Group** and select Program Group.

1. Click on a **User Group** (or *PUBLIC*) to display program group lists for user group (or *PUBLIC*).
2. Click on a SAS program group to display program information in fields at bottom.

3. Click the **Add to User Group** and **Remove from User Group** buttons to change which program groups belong to a User Group.



User Group
Program Group

User Group 7
*PRIVATE*
*PUBLIC*
AdvanceTrainingUG
BasicTrainingUG
Dashboard Dev
Dashboard Dev 2
Dashboard Test

Program Groups in User Group 0

Program Groups NOT in User Group 2
ProgramGroup_1
ProgramGroup_2

Program Group information:

ID Number: 1063

Project: KA
Study: KA201
Category: SAS Program Validation (program groups)
Status: DEFAULT
Summary:
User Groups 0
*PUBLIC*

# STAT Program Registration Browser

## Selection criteria

You can use the STAT Program Registration Browser to execute registered SAS programs, with the original complete patient population, or to execute the programs with only those patients who meet the current patient selection criteria.

In addition, you can schedule a SAS program to run now or at a later scheduled date/time as a batch job. The actual output can be saved in the designated folder with the creation date/time stamp for future reference. A brief description of the patient subset criteria used to generate the output will display along side the creation date/time stamp. **(See *section: Schedule SAS program jobs)***

## Opening the STAT Program Registration Browser

The STAT Program Registration Browser is useful in exploring patient subpopulation statistical responses to the clinical trials. After defining your patient selection criteria, click or from the **Browse** menu, select **SAS Programs**. Review opens the STAT Program Registration Browser window to display the categorical folders containing additional subfolder and all registered SAS programs for the current protocol. Groups of SAS programs can also be defined and executed.

## Registered SAS programs

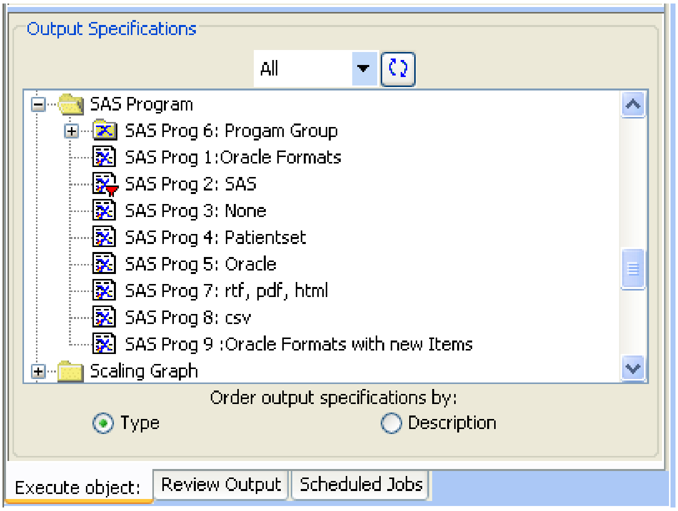
Your System Administrator can register SAS programs and SAS Data Sets used in the formal analysis of the protocol(s) of interest. They can be current Global and Study Specific SAS programs or Project global SAS programs. These programs and datasets can be made available and registered to Review, typically after the completion of the protocol and cleaning of the database. Thereafter, you can access these programs and datasets by using the STAT Program Registration Browser.

## *Quick execute*

JReview displays a list of categorical folders for stored patient subsets and output specifications at the selected storage location. Simply select one of the storage locations to display it’s specific folders and contents. Icons are displayed along with the stored object to identify the source as report, graph, registered SAS program, etc.

The **SAS Programs** icons is .

When a patient selection criteria is saved with the stored object; the filter icon displays with the specific browser icon.



Order output specifications by:
● Type ○ Description

You may apply a previously stored patient selection criteria to the output specification or define a new selection criteria prior to creating output. To retrieve a saved output specification:

1. Double click to open a folder in Output Specifications.
2. Double click on the object to launch in a single step. The stored output specification will be launched.

JReview aids users to quickly locate and launch these stored objects. This shortcut allows users to bypass opening the individual browsers to launch saved objects.

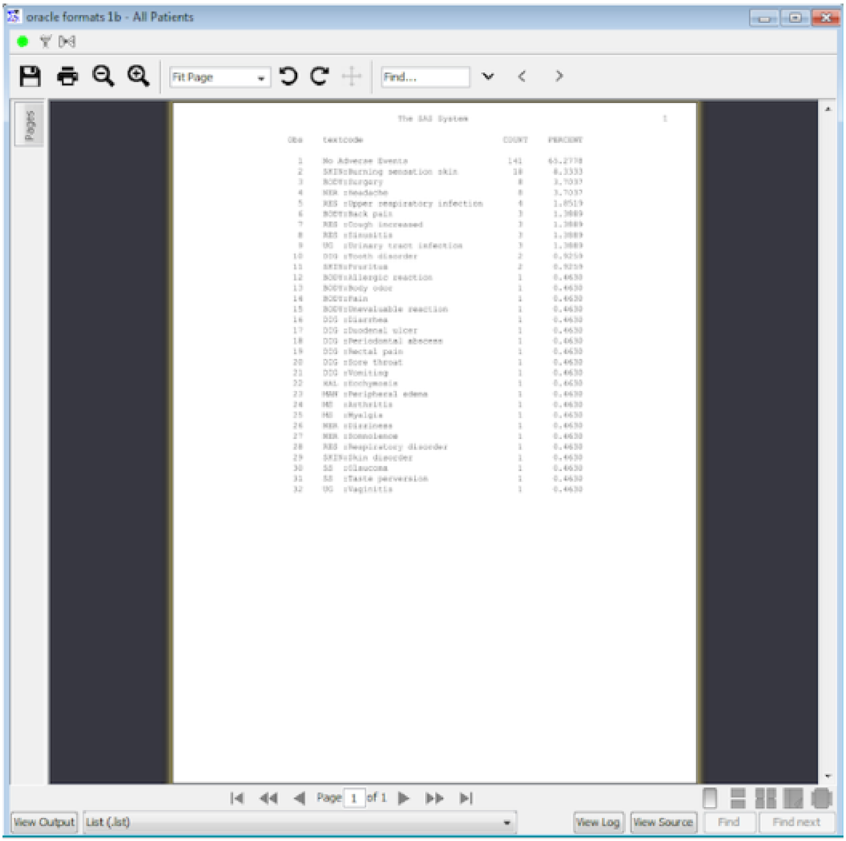
The STAT Program Registration Browser is useful in exploring patient subpopulation statistical responses to the clinical trials. After defining your patient selection criteria, select and click from a list of **SAS Programs** production tables registered by your System Administrator for the current protocol. Groups of SAS programs can also be selected and executed.

# SAS program results and log files

## Creating the table output

When you regenerate the SAS production table, JReview sends your request to be processed by SAS on your server computer, and displays the results on your PC in a Table Output window.

SAS Program .LST and any .PDF will use the PDF viewer (.lst output as shown). Empty/no reply/no return PDF output will display "**PDF file unavailable**" in PDF viewer.



The PDF viewer not only provides several viewing options for continuous stream of pages, or two at a time like a book, four up, etc. – but also has built in ‘bookmark’ access, plus a built in Search function.

> ***Note*: *The data in your report contains only data from those patients who meet your current selection criteria.***

### *Displaying the SAS log or source*

Three display options are at the bottom of the output display window.

Click **View SAS log**, to view the SAS log.

Click **View SAS Source**, to view the SAS source used to create the SAS output.

Click **View Output**, to view the SAS output again.  JReview supports HTML display output.

### *Error Lists*

Importing SAS dataset based ‘error reports’ is supported bringing them into a single ‘neutral’ table for each study, but adding a ‘virtual’ reference to each original dataset with SAS labels, etc.  So all ‘error lists’ can be reviewed separately (editable status/comment columns), but a common table can be summarized with number Open, Closed, etc.

### *Multiple table outputs*

There can be multiple table outputs active at the same time. After you have generated one SAS Production table, you can select another.

Each output is displayed in its own window. Each table output remains active and updates to reflect the current patient selection criteria when **Update Browser** is used.

If there are multiple SAS Proc outputs active at the same time, each functions independently, that is, you can review the source, log, or output of each independently by clicking the appropriate buttons in the respective windows.

## Snapshot output

**(See *Chapter 9: Generating Statistics - SnapShot with SAS Procs*)**

# Schedule SAS program jobs

Scheduled SAS Procs and SAS Programs are listed directly in their respective folder in the **Review Output** tab and pending jobs bypass the **Schedule** tab. Since they're stored in different tables in the ReviewAdmin account they don't have the same information as the ObjectCatalog entries for the other object types.

Unlike the other browser objects (reports, graphs, crosstabs), scheduled SAS jobs cannot be changed or removed from the scheduler. SAS Procs and SAS Programs are placed on the schedule queue of the operating system (of the SAS Server) so it's not possible to remove or change the schedule of these object types.

SAS Program scheduling for repetitive scheduling is now supported.

***(See Chapter 11: Saving and Manage Objects, Scheduling plus Alerts Browser)***

# Printing SAS program results

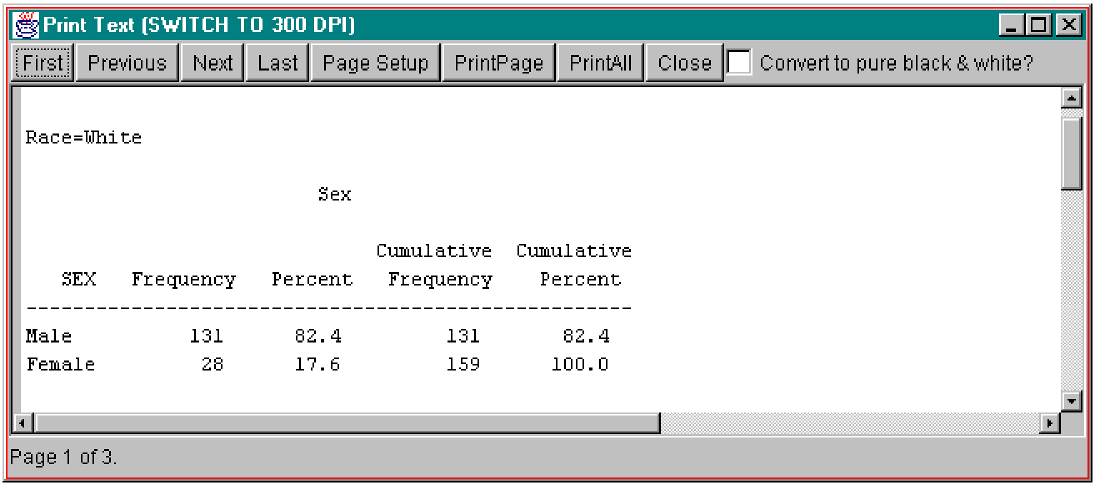
## Print table output

The Print function is applicable to all browsers with output results. To get a printed copy of your output:

1. Click on the generated output window to make it the active window.
2. Click 🖨 , or from the JReview **File** menu, select **Print**.

***Caution: Do not select the Internet Browser's FILE menu Print option. This will cause a system error.***

JReview displays a screen shot of the selected active screen.



```
Race=White

                         Sex

                              Cumulative  Cumulative
   SEX   Frequency   Percent   Frequency    Percent
----------------------------------------------------
Male          131      82.4         131       82.4
Female         28      17.6         159      100.0
```

3. Click either **PrintPage**, **PrintAll** or **Close**. The PrintPage option will print only the first page of your output. The PrintAll option will print the entire output.

The SAS results (output, source, or log) prints on the currently selected printer.

*Note: The **Convert to pure black & white?** option is only applicable to graphs where multiple colors are displayed. If you have a non-color printer, click this option for better print resolution of graphs.*

***(See Chapter 6: Report Browser for Exporting Results)***

# Exploring data

## *Opened SAS production table results*

After you have selected a SAS Production table to be executed, click **Execute**, and repeat as desired.

Each output remains active in its own window. You can use the output(s) that are displayed as data exploration views.

### *Update patient selection criteria*

Change the selection criteria by adding additional expressions or removing existing expressions.

Click **Update Browsers** on the selection criteria window to update all active browsers according to the new criteria.

# 11

# Saving and Manage Objects, Scheduling plus Alerts Browser

# Object Storage

## *Finalize object specification*

All objects in JReview can be saved which includes patient selection criteria, reports, graphs, patient profile and crosstab. The steps to save these objects are all done in the same way.

When the object layout contains the necessary information and all editing is complete, you can save the object specification for future use. You are not saving the output of the object but the specification you defined for building the object. The data or retrieved output represents the database at the time the object is executed, providing access to live data. Your object contains only data from those patients who meet your current patient selection criteria and/or output filter criteria.

All saved objects with output filters turned ON are saved with the filter specifications respectively. If you have an active filter ON when the object specifications are saved, you will have that same active filter turned ON when the saved specifications are relaunched.

The saved patient selection criteria is saved in the Patient Subset section of the Object Explorer, and other objects are saved in the Output Specifications section.

Any changes applied to the graph properties are saved, if you click on **Save** with the graph output window open.  The **Save** window opens and the changed properties are saved with the graph.

# Save the object specification

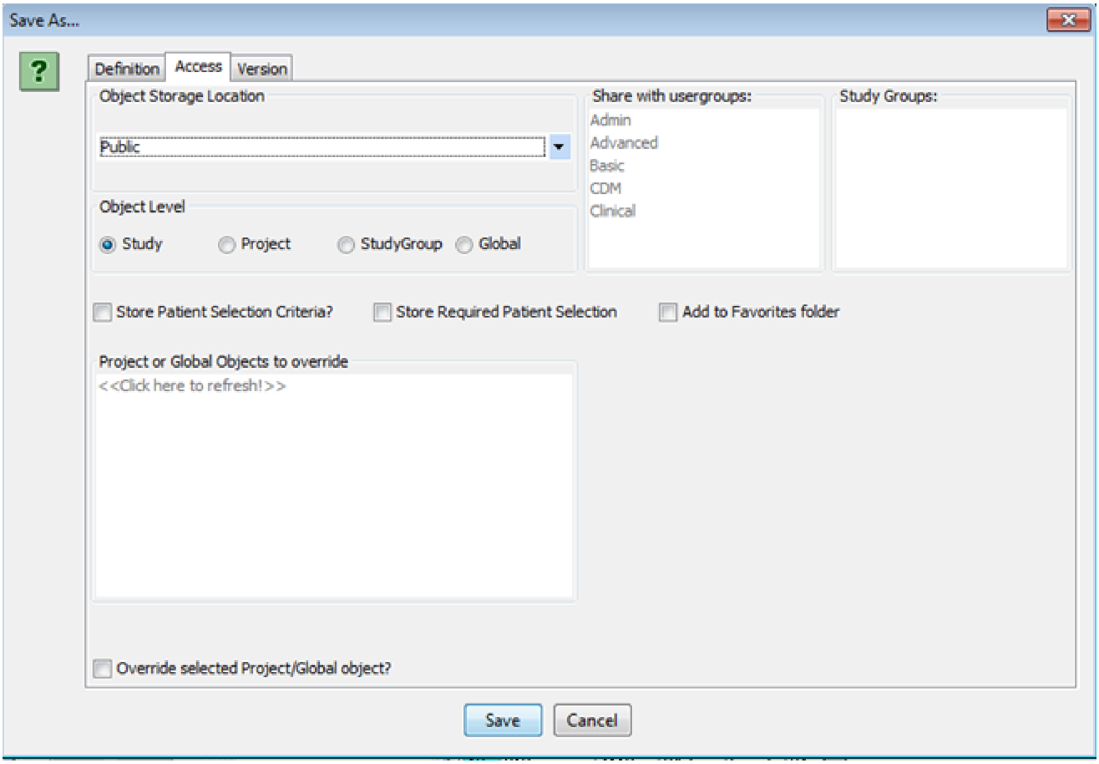
## Access tab

The Browser build window defining your object specification (report, graph, crosstab, patient profile, etc.) must be the active open window when you are ready to save your object specification for later use. In addition, there are two ways to save Graph specifications, either from the browser window which does not save any changed graph properties or from the output window where it saves the changed properties.

1. Click 💾, or from the **File** menu select **Save.**

   JReview displays the **Save window** organized by tabs associated with saving an object:

2. In the **Access tab,** select an **Object Storage Location**.



Object Storage Location: Public

Object Level: ● Study ○ Project ○ StudyGroup ○ Global

Share with usergroups:
Admin
Advanced
Basic
CDM
Clinical

Study Groups:

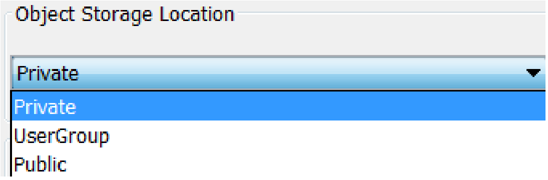
☐ Store Patient Selection Criteria? ☐ Store Required Patient Selection ☐ Add to Favorites folder

Project or Global Objects to override
<<Click here to refresh!>>

☐ Override selected Project/Global object?

## *Object storage location*

Saving on database object storage sites, requires the author to have “Publishing Authorization” defined in the configuration tables. **(See *ReviewAdmin Users Manual*)**



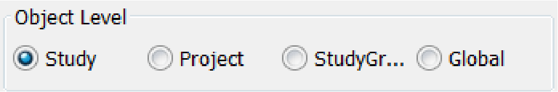
There are three user access levels to store the object specification: Private (db), User Group (db) and Public (db). User access levels designated as ‘db’ for database makes the object available for scheduling. Objects may be saved at the study, user group or global level

- **Private** is a database object storage for sole access by the user. IRAdmin review privilege for Protected_Category at UserID level.
- **User Group** is a database object storage for defined User Groups in the configuration tables. Object storage in User Group level allows you to specify sharing with multiple User Groups. When you are a member in a User Group and click User Group, the ‘Share with usergroups’ list box is made available for selection. Click on a usergroup to share the object, use the CTRL or SHIFT key to make multiple selections.

  IRAdmin review privilege for User Group Save where users in a usergroup can update and delete other user group member objects. The privilege is set at either the UserID or User Group level. Also, IRAdmin review privilege for Protected_Category at User Group level.
- **Public** also has shared network drive for storage where all users have access to public objects, but authorization is required to save an object as public.

## *Object level*

3. Select an **Object Level**. The object may be stored at four levels: Study, Project, StudyGroup or Global.



When you select either Private, User Group or Public for shared network drive storage location, you can assign an object level to restrict access to a specific study level or share access between multiple studies at Project or Global levels.

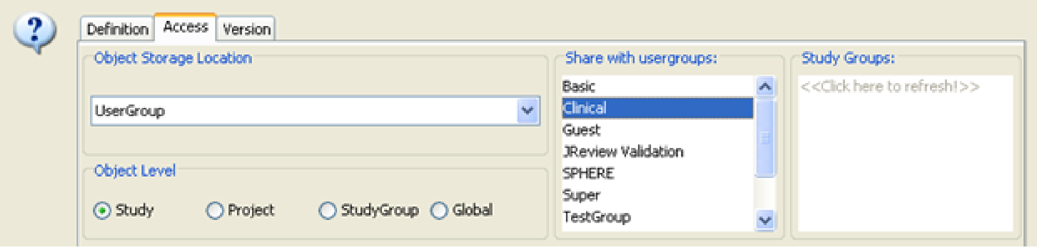
## Study Override

You can override a previously saved object at the Project or Global level with a Study level object. When you select Study level, the ‘Override selected Project/Global object?’ check box is made available for selection.

Save at the Study Object Level, when you can choose to override a previously saved Project or Global level object. Select the previously saved project or global level object from the ‘Projects or Global Objects to override’ list. The chosen Project or Global level object will be replaced by the new Study level object when you click SAVE. The original Project/Global object is still available for selection in other studies, but is overridden for the selected study.

## Share with user groups

When UserGroup is selected the ‘Share with usergroups:’ box is enabled allowing you to select other usergroups to share access with the object specification. Use the CTRL or SHIFT key to make multiple selections.



Object Storage Location: UserGroup

Object Level: ● Study ○ Project ○ StudyGroup ○ Global

Share with usergroups:
- Basic
- Clinical
- Guest
- JReview Validation
- SPHERE
- Super
- TestGroup

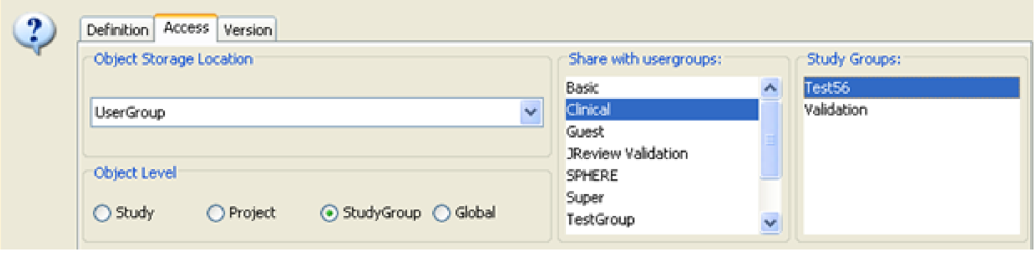
Study Groups: <<Click here to refresh!>>

## *Publish for study groups*

Saving at the Study Group level, makes an object only available to studies, who are part of the same group and are not project specific.  Study groups are setup in Review Admin.  They are non-visual groupings of studies.

The study group save privilege allows the user to save objects to Study Groups and selected in the 'Publish for Study Groups' list. They can, and are intended to cross projects. Users can create a study group from within Review Admin, assign studies when this option is turned ON, objects can be saved to the study group. These groups are not visible in JReview (like project and study are), but rather help group studies of common architecture.

For example, you may create a study group for Therapeutic Areas such as Oncology trials, or a group for versions of database standards. Such as,  if three ongoing projects were built on one database standard and each may have two studies. The "Standards Committee" decides on new standards which will affect all future studies. So, the next studies that each of the projects start up will use a new standard. This is a good place to create two study groups. The first study group will have the initial six studies (two from each of the three projects) and another study group will contain all future new studies. The user within JReview does not see the study groups until he/she goes to save an object. This option allows the user to be able to save objects as a global report, but only to a subset of studies that could be across protocols.



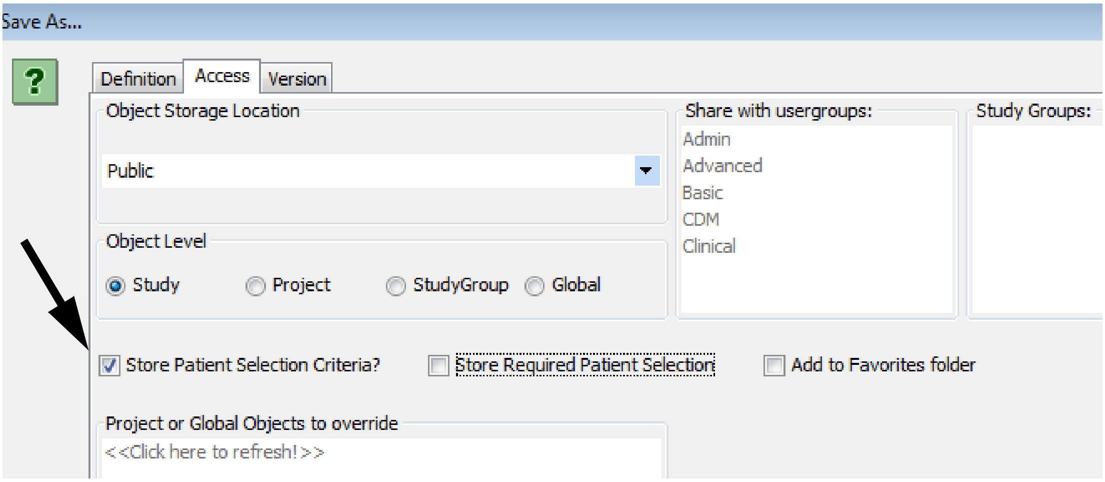
Object Storage Location: UserGroup

Object Level: ○ Study ○ Project ● StudyGroup ○ Global

Share with usergroups:
- Basic
- Clinical
- Guest
- JReview Validation
- SPHERE
- Super
- TestGroup

Study Groups:
- Test56
- Validation

4. Click the '**Store Patient Selection Criteria**' box if you choose to save the current patient selection criteria with the output specification. When a user selects the stored object specification they can modify the selection criteria and still run the output.



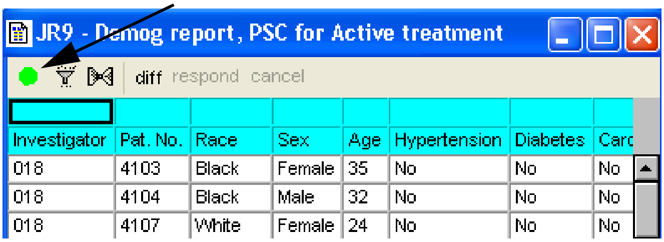
Object Storage Location: Public

Object Level: ● Study ○ Project ○ StudyGroup ○ Global

Share with usergroups: Admin, Advanced, Basic, CDM, Clinical

☑ Store Patient Selection Criteria? ☐ Store Required Patient Selection ☐ Add to Favorites folder

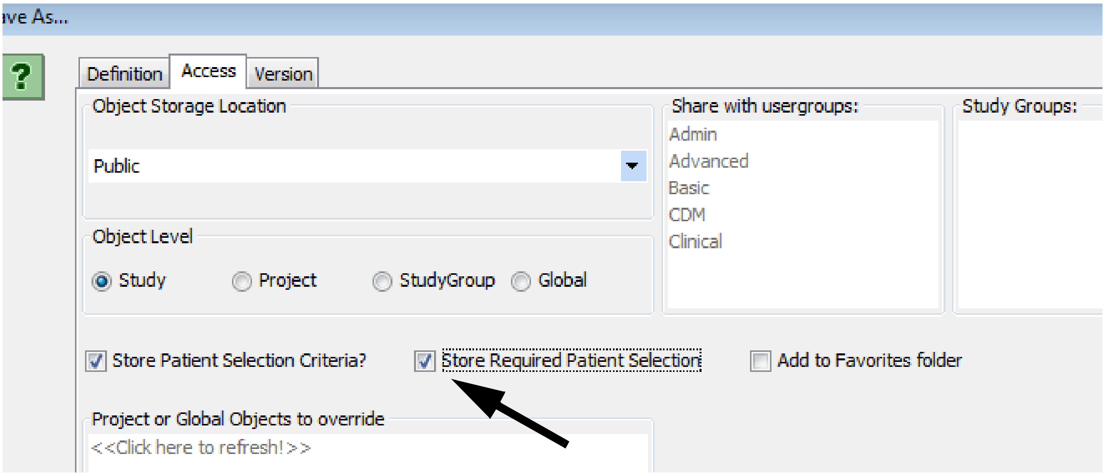
Objects saved without or with a patient selection criteria NOT required allow you to remove or change the current patient selection criteria and refresh the output window. See the first icon in the output toolbar set to green.



| Investigator | Pat. No. | Race | Sex | Age | Hypertension | Diabetes | Card |
|---|---|---|---|---|---|---|---|
| 018 | 4103 | Black | Female | 35 | No | No | No |
| 018 | 4104 | Black | Male | 32 | No | No | No |
| 018 | 4107 | White | Female | 24 | No | No | No |

If the particular patient selection criteria is specific for the output, click the '**Store Required Patient Selection**' box. In this instance, the output opens in snapshot mode and the patient selection criteria is required for the output and cannot be cleared. Both check boxes display as checked ON to make the PSC required for the saved object.

Optionally, you may check on the '**Store Required Patient Selection**' box, if you require that all patients to be included - then 'All Patients' are required for the saved object.



Object Storage Location: Public

Object Level: ● Study ○ Project ○ StudyGroup ○ Global

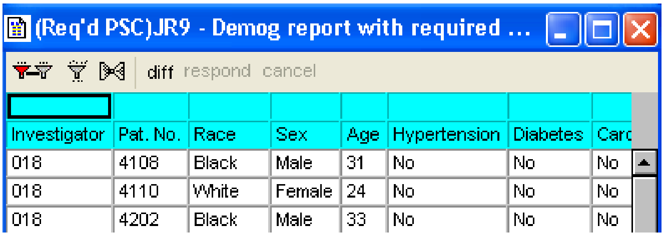
Share with usergroups: Admin, Advanced, Basic, CDM, Clinical

Study Groups:

☑ Store Patient Selection Criteria? ☑ Store Required Patient Selection ☐ Add to Favorites folder

Project or Global Objects to override: <<Click here to refresh!>>

Objects saved with a REQUIRED patient selection criteria do NOT allow you to remove or change the patient selection criteria. See the first icon in the output toolbar set to red.

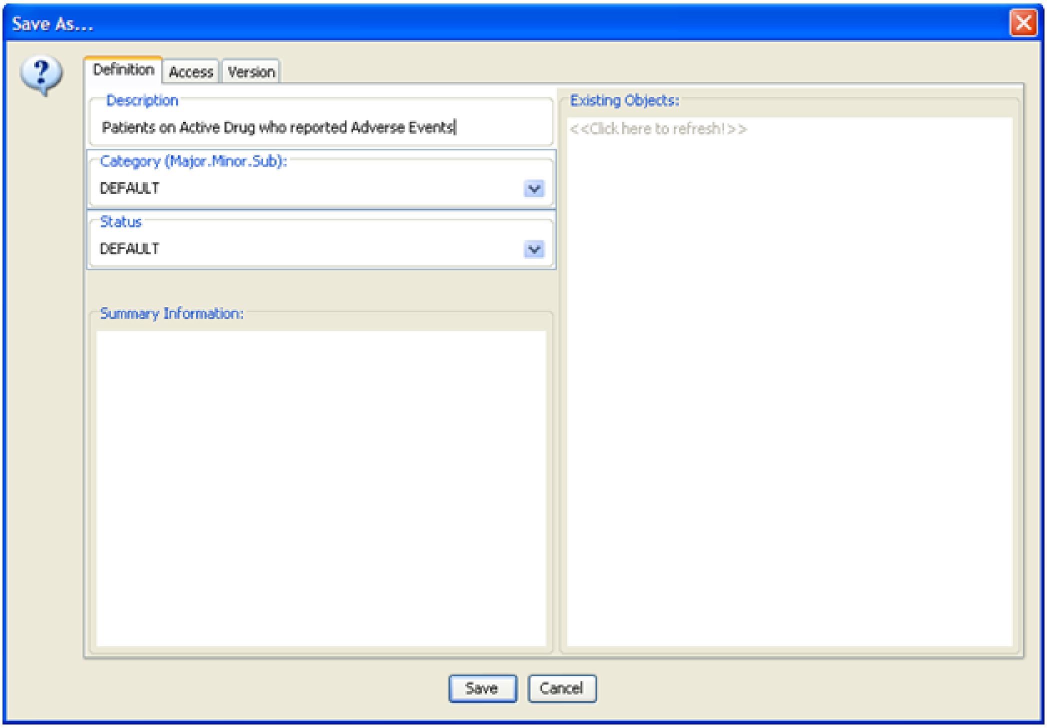


| Investigator | Pat. No. | Race | Sex | Age | Hypertension | Diabetes | Carc |
|---|---|---|---|---|---|---|---|
| 018 | 4108 | Black | Male | 31 | No | No | No |
| 018 | 4110 | White | Female | 24 | No | No | No |
| 018 | 4202 | Black | Male | 33 | No | No | No |

Also when saving a new object or Re-Saving an existing one you have the option of tagging the object as a Favorite. ***(See section on Object Explorer window: Favorite saved objects)***

## *Definition tab*

5. In the **Definition tab**, enter an appropriate **Description**. The Description is the name displayed in the **Object Explorer window**, used to retrieve the object.



Description: Patients on Active Drug who reported Adverse Events

Category (Major.Minor.Sub): DEFAULT

Status: DEFAULT

6. Enter the folder(s) information in the **Category** box. The Category defines the folder hierarchy, for the saved object in the Object Explorer.

   Each folder (major, minor and subfolder) is separated by a period where folder titles can consist of more than one word separated by a space. For example, the major folder for ‘Safety’ has two minor folders ‘Safety.AEs’ and ‘Safety.Labs’.

   Folder names are **case-sensitive** and after the folder(s) are initially created, they are selected from the dropdown list box.

7. Enter a **Status** for the object. The Status may be used when managing objects to create Object Groups for launching groups of objects with the same status.

8. You can include **Summary Information** for future reference to be viewed by yourself or others later (optional).

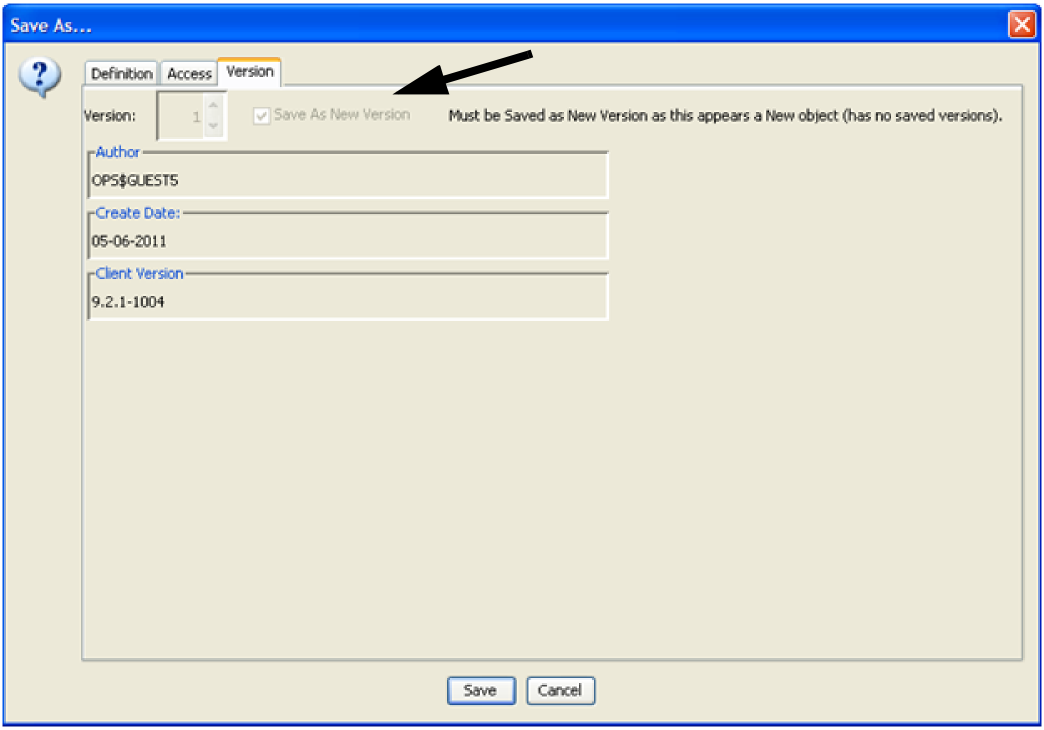
   An ID Number is assigned and used internally by Review to track the object.

***Note: The Existing Objects display only objects according to level – Private, UserGroup, Public when selected on in the Access tab.***

## *Version tab*

JReview has the following “Allow Updates” privilege settings apply to Save and Update an object.  A new object must be saved as New Version as there are no prior saved versions.

Click on **Save,** to save the object specification or defined patient selection criteria to the Object Explorer window.



Version: 1
☑ Save As New Version
Must be Saved as New Version as this appears a New object (has no saved versions).

Author
OPS$GUEST5

Create Date:
05-06-2011

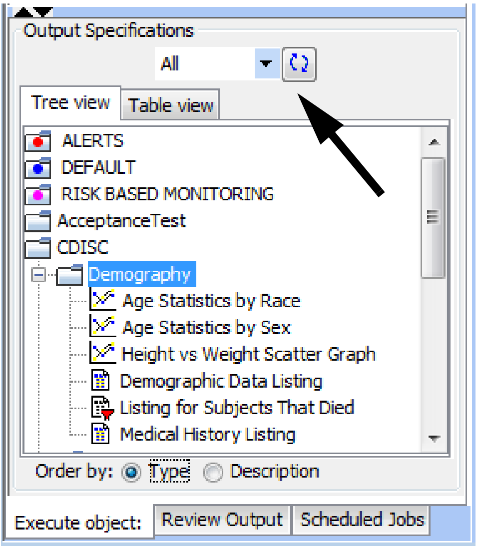
Client Version
9.2.1-1004

When an initial/new object is saved it is not necessary to close the output specification to create output. The ObjectID is assigned automatically to a new output specification so that the step of closing and re-opening is not necessary.

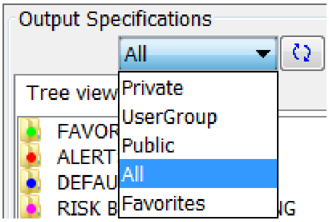
# Object Explorer window

## *Saved output specification*

Once you have saved your output specification and assigned folder information, your stored object will display in the Object Explorer window under Output Specifications. Review displays a list of folders for previously saved output specifications at the selected storage location.

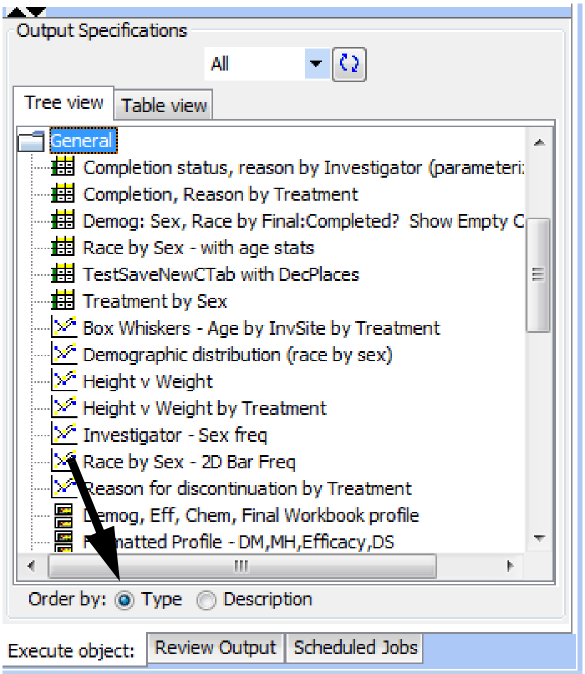


Select one of the storage locations as Private, UserGroup, Public or Favorites to display it’s specific folders and contents. The circular arrows icon refreshes the displayed folders when you toggle between storage locations.



JReview system generated folders will display at the top with a colored dot when these specific objects are defined for ALERTS, DEFAULT and RISK BASED MONITORING. These folders are NOT added by the end user.

Icons are displayed along with the stored object to identify the source as report, graph, registered SAS program, etc. When a patient selection criteria is saved with the stored object; the funnel icon displays with the specific browser icon. A red color funnel indicates the patient selection criteria is required for the object.



General
- Completion status, reason by Investigator (parameteri
- Completion, Reason by Treatment
- Demog: Sex, Race by Final:Completed? Show Empty C
- Race by Sex - with age stats
- TestSaveNewCTab with DecPlaces
- Treatment by Sex
- Box Whiskers - Age by InvSite by Treatment
- Demographic distribution (race by sex)
- Height v Weight
- Height v Weight by Treatment
- Investigator - Sex freq
- Race by Sex - 2D Bar Freq
- Reason for discontinuation by Treatment
- Demog, Eff, Chem, Final Workbook profile
- Formatted Profile - DM,MH,Efficacy,DS

Saved objects and their associated icons can be sorted to display in their folders by icon type or description. See ‘Order output specifications by’ and simply click sort by **Type** or **Description**.

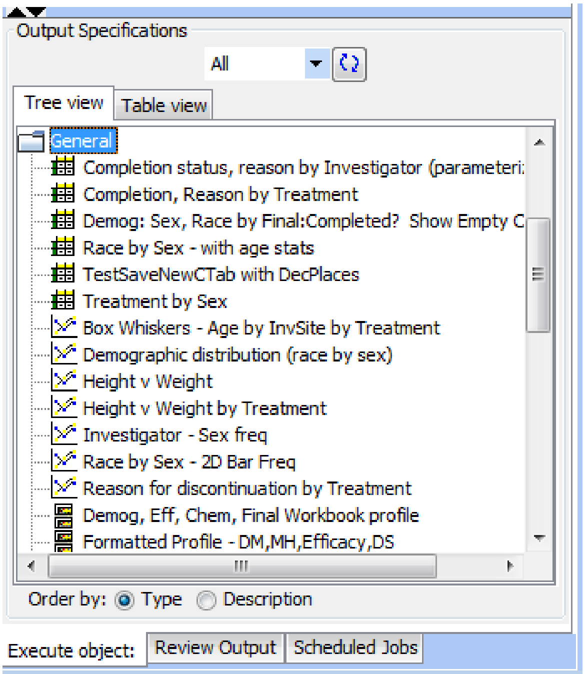
## *Object Explorer quick execute*

The Object Explorer window aids users to quickly locate and immediately launch previously saved objects stored within organized folders. This shortcut allows users to bypass opening the individual browsers to launch saved objects. Simply select one of the storage locations to display it’s specific folders and contents. When you select All (db) then all database stored objects are displayed from Private (db), Usergroup (db) and Public (db).

If you select Private (db), then only private objects and the FAVORITE folder objects will be listed.

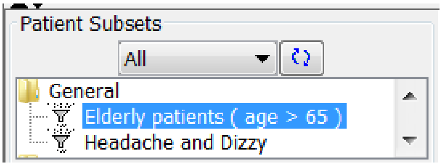
If you want to retrieve a saved output specification:

1. Select the object storage location from the drop down list.
2. Double click to open a folder.
3. Double click on the object. Your stored object specification is launched.



To apply a saved patient selection criteria to your object specification:

1. Double click to open a folder in Patient Subsets.



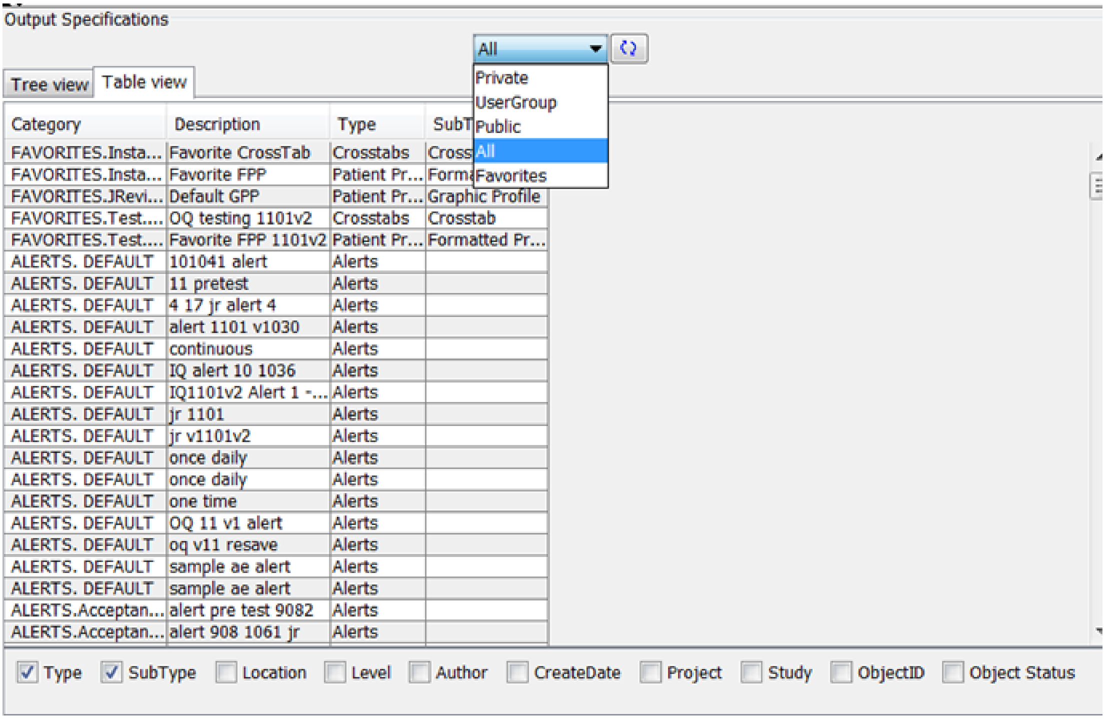
2. Double click to paste the selected patient selection criteria into the Patient Selection Criteria Window. Then follow the previous steps to retrieve and execute a stored output specification or create your own selection criteria for a stored output specification.

## *Object Explorer Table view*

The ‘**Table view**’ in the Output Specifications/Object Explorer is as alternative to the familiar ‘**Tree view**’. The Output Explorer ‘**Table view**’ is used to display the contents of the Output Specifications in a table, which is sortable (like reports) up to 3 levels deep.

Select to display stored objects for **All, Private, UserGroup, Public or Favorites.**

Checkboxes are available to include/not include certain values from the Object Catalog along with the ‘Object Status’. There is also a Find/Search capability similar to detailed data listings.

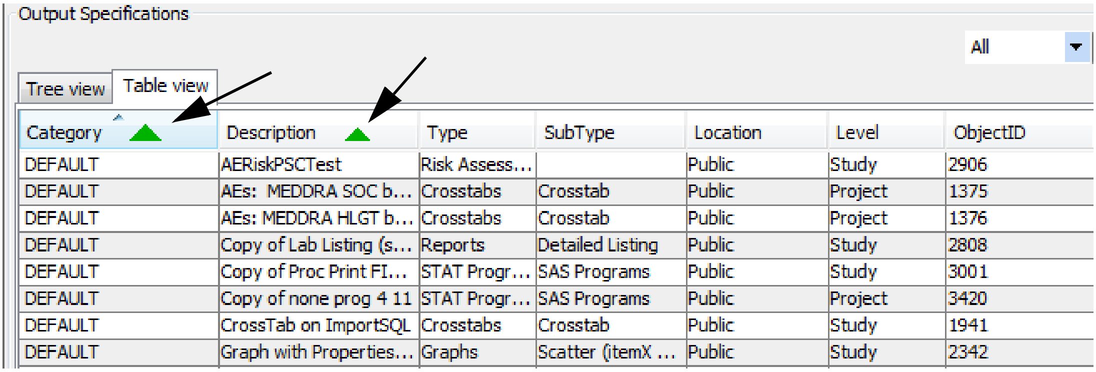


| Category | Description | Type | SubT |
|---|---|---|---|
| FAVORITES.Insta... | Favorite CrossTab | Crosstabs | Cross |
| FAVORITES.Insta... | Favorite FPP | Patient Pr... | Forma |
| FAVORITES.JRevi... | Default GPP | Patient Pr... | Graphic Profile |
| FAVORITES.Test.... | OQ testing 1101v2 | Crosstabs | Crosstab |
| FAVORITES.Test.... | Favorite FPP 1101v2 | Patient Pr... | Formatted Pr... |
| ALERTS. DEFAULT | 101041 alert | Alerts | |
| ALERTS. DEFAULT | 11 pretest | Alerts | |
| ALERTS. DEFAULT | 4 17 jr alert 4 | Alerts | |
| ALERTS. DEFAULT | alert 1101 v1030 | Alerts | |
| ALERTS. DEFAULT | continuous | Alerts | |
| ALERTS. DEFAULT | IQ alert 10 1036 | Alerts | |
| ALERTS. DEFAULT | IQ1101v2 Alert 1 -... | Alerts | |
| ALERTS. DEFAULT | jr 1101 | Alerts | |
| ALERTS. DEFAULT | jr v1101v2 | Alerts | |
| ALERTS. DEFAULT | once daily | Alerts | |
| ALERTS. DEFAULT | once daily | Alerts | |
| ALERTS. DEFAULT | one time | Alerts | |
| ALERTS. DEFAULT | OQ 11 v1 alert | Alerts | |
| ALERTS. DEFAULT | oq v11 resave | Alerts | |
| ALERTS. DEFAULT | sample ae alert | Alerts | |
| ALERTS. DEFAULT | sample ae alert | Alerts | |
| ALERTS.Acceptan... | alert pre test 9082 | Alerts | |
| ALERTS.Acceptan... | alert 908 1061 jr | Alerts | |

☑ Type ☑ SubType ☐ Location ☐ Level ☐ Author ☐ CreateDate ☐ Project ☐ Study ☐ ObjectID ☐ Object Status

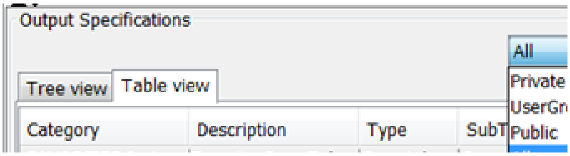
The Output Explorer Table view supports these features:

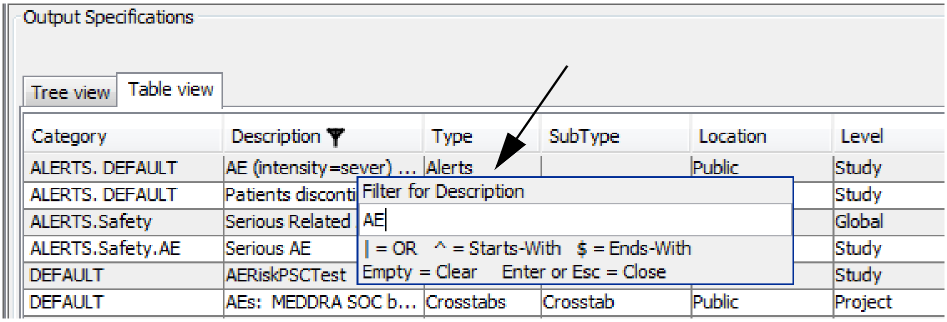
- Sorting (to 3 levels) through left mouse click on column headers, and ANDed column filtering through right mouse click on column headers.



| Category | Description | Type | SubType | Location | Level | ObjectID |
|---|---|---|---|---|---|---|
| DEFAULT | AERiskPSCTest | Risk Assess... | | Public | Study | 2906 |
| DEFAULT | AEs: MEDDRA SOC b... | Crosstabs | Crosstab | Public | Project | 1375 |
| DEFAULT | AEs: MEDDRA HLGT b... | Crosstabs | Crosstab | Public | Project | 1376 |
| DEFAULT | Copy of Lab Listing (s... | Reports | Detailed Listing | Public | Study | 2808 |
| DEFAULT | Copy of Proc Print FI... | STAT Progr... | SAS Programs | Public | Study | 3001 |
| DEFAULT | Copy of none prog 4 11 | STAT Progr... | SAS Programs | Public | Project | 3420 |
| DEFAULT | CrossTab on ImportSQL | Crosstabs | Crosstab | Public | Study | 1941 |
| DEFAULT | Graph with Properties... | Graphs | Scatter (itemX ... | Public | Study | 2342 |

- Regular expressions directives may be used in addition to normal as-you-type case-insensitive, substring-match filtering.





| Category | Description | Type | SubType | Location | Level |
|---|---|---|---|---|---|
| ALERTS. DEFAULT | AE (intensity=sever) ... | Alerts | | Public | Study |
| ALERTS. DEFAULT | Patients disconti | | | | Study |
| ALERTS.Safety | Serious Related | | | | Global |
| ALERTS.Safety.AE | Serious AE | | | | Study |
| DEFAULT | AERiskPSCTest | | | | Study |
| DEFAULT | AEs: MEDDRA SOC b... | Crosstabs | Crosstab | Public | Project |

Filter for Description

AE

| = OR ^ = Starts-With $ = Ends-With

Empty = Clear Enter or Esc = Close

- There is linkage between the traditional tree view and new table view selecting a leaf in the tree view will scroll to and highlight its row in the table view (and vice versa).
- The same right-click popup menu is available on the table row as the tree node, where double-clicking executes the object.
- Column checkboxes choose which columns show (1st two are always shown), where columns can be resized but not drag-reordered.

## *Favorite saved objects*

A "Favorites" object tagging feature is available in JReview. This feature permits users to tag arbitrary objects as favorites to show in their new Favorites top-level pseudo object folder. The new " FAVORITES" folder is not a true storage folder like others in JReview and the object references in it are not copies of their target objects. The Favorites entries are more like shortcuts to objects elsewhere in your saved object folder hierarchy.

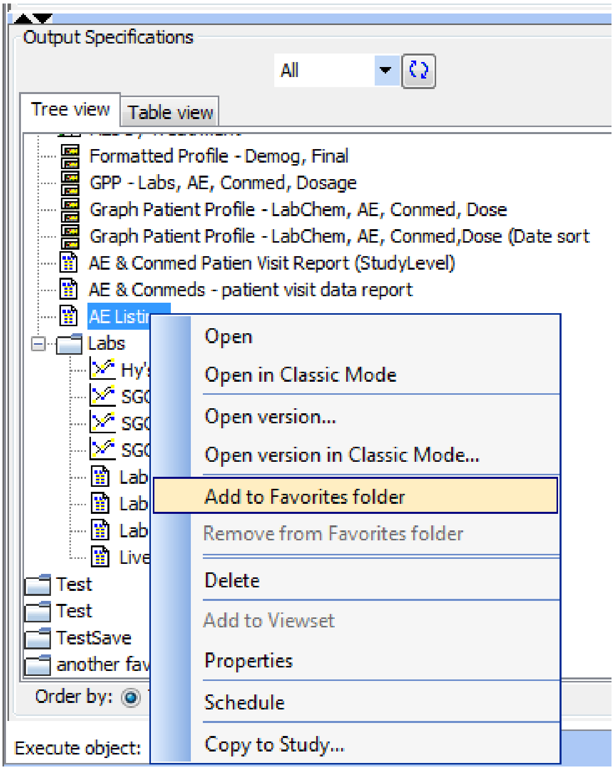
This feature has two benefits:

***Convenience*** - There may be a subset of objects you use on a regular basis, or objects you may be using frequently over the coming days or weeks, that you'd like to be able find quickly.

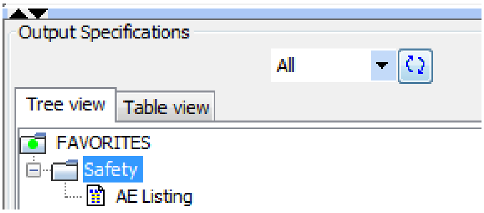
***Performance*** - If your site or project has thousands of saved objects, or complex logic to populate the objects trees, you may add Favorites then turn on User Preference "Favorites Start up Mode" to limit your Object Specifications, Review Output and Scheduled Jobs lists to objects you've tagged as Favorites. This would reduce your JReview desktop - Study selection time by an order of magnitude or more.

**Technical note:** Favorites are managed and stored on a Study and Username/NodeID basis. Favorites are not "shared" across users or studies though each of these levels may have tagged the same objects as Favorites. Also, Favorites mode / storage location selection carries through the object’s Review Output and Scheduled Jobs list entries.

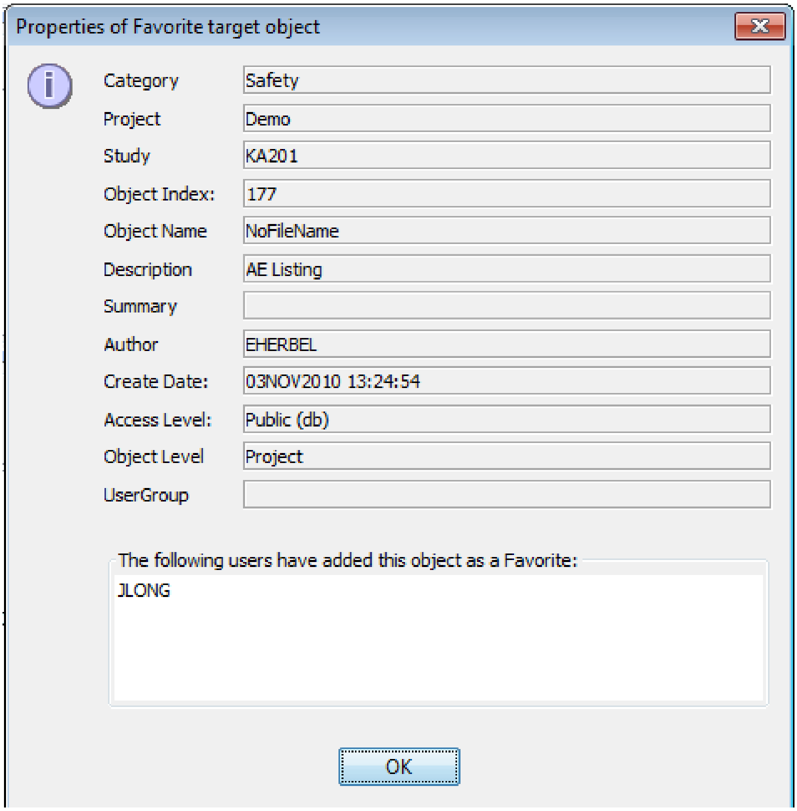
You tag an object as a Favorite by right-clicking on the object and choosing "Add to Favorites folder".



If the object is your first favorite the Favorites folder will be created and shown at top. The object shortcut will be shown in its original folder structure under the FAVORITES name.



You may query the object's Properties through the right-click menu and see all users that have tagged the object as a Favorite.



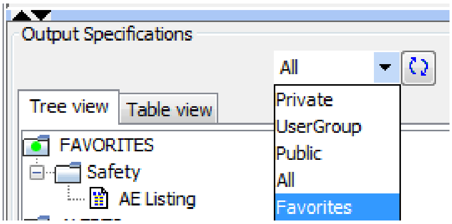
Properties of Favorite target object

| | |
|---|---|
| Category | Safety |
| Project | Demo |
| Study | KA201 |
| Object Index: | 177 |
| Object Name | NoFileName |
| Description | AE Listing |
| Summary | |
| Author | EHERBEL |
| Create Date: | 03NOV2010 13:24:54 |
| Access Level: | Public (db) |
| Object Level | Project |
| UserGroup | |

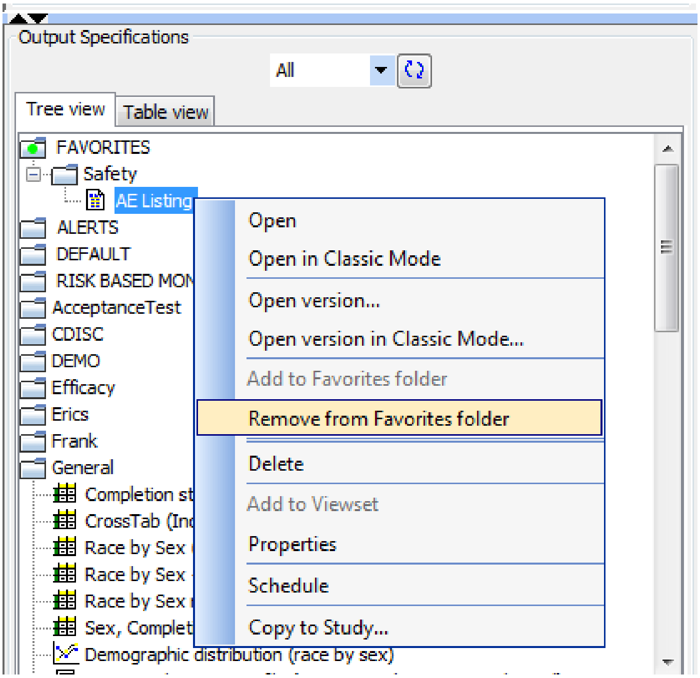
The following users have added this object as a Favorite:

JLONG

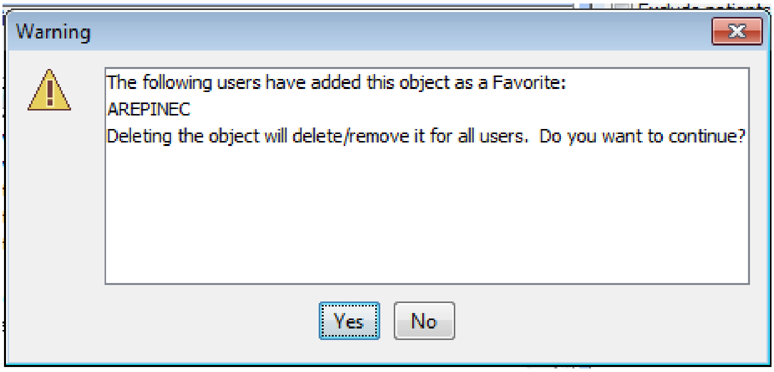
To view only the Favorites objects, their Schedules and their Saved results choose the Favorites location in the Output Specifications drop-down.



If you no longer want the object as a Favorite you may Remove it as a favorite (this does not Delete the object, just removes your short-cut reference to it).

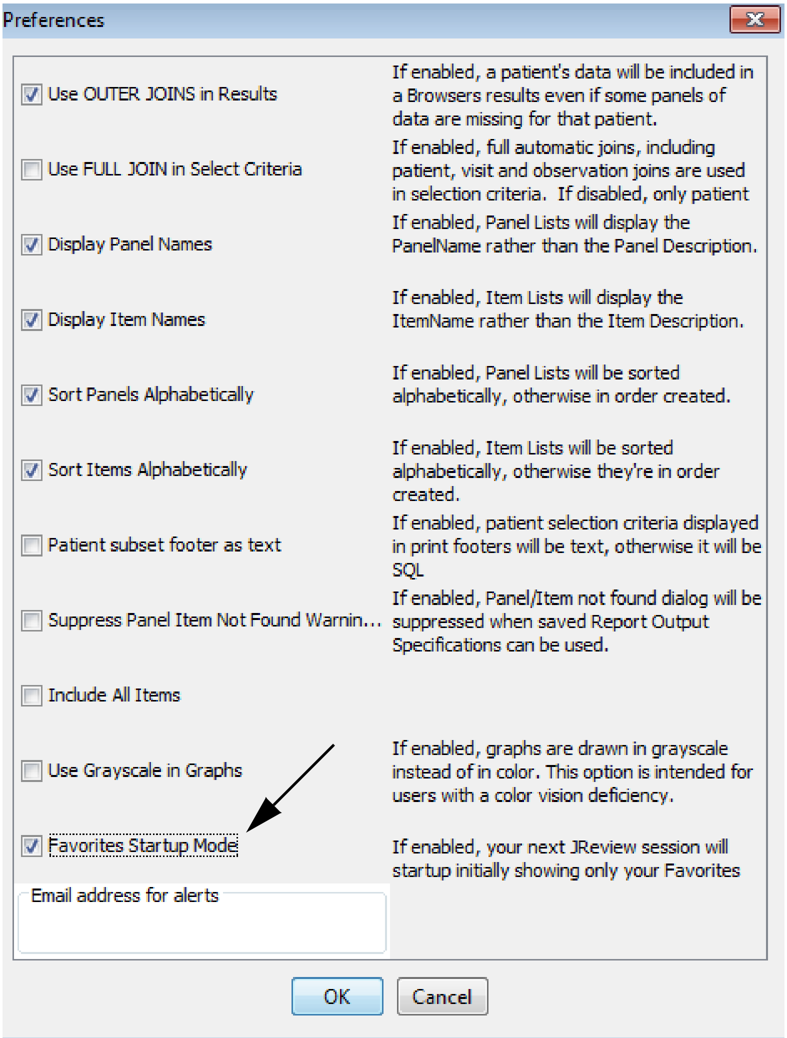


If you try to Delete an object that has been "Favorited", a notice of those that have tagged it as such will be shown.



The following users have added this object as a Favorite:
AREPINEC
Deleting the object will delete/remove it for all users. Do you want to continue?

If you want to start up your future JReview sessions where they initially show only the Favorites entries, set "Favorites Start up Mode" from User Preferences. This will dramatically speed up some key complex queries / displays in JReview.

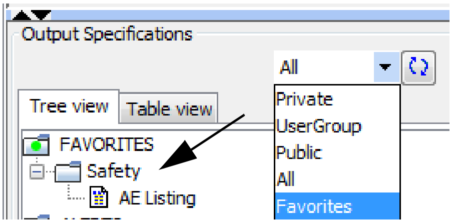


Preferences

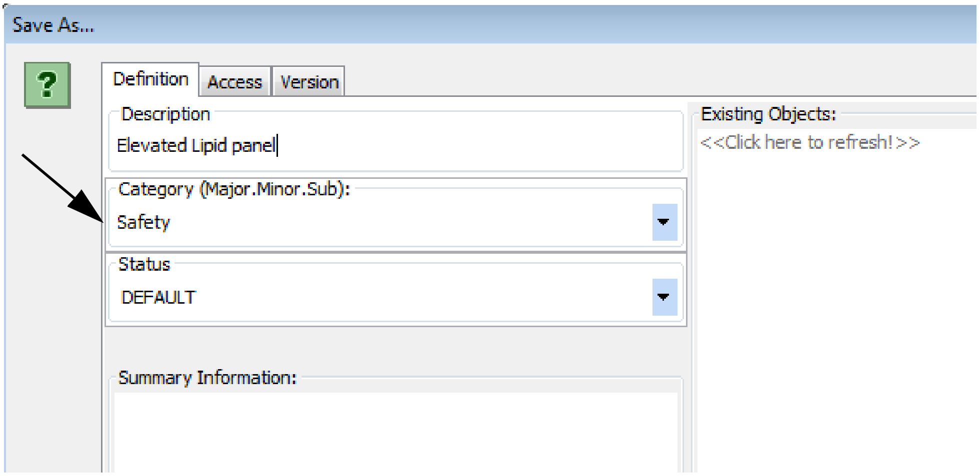
| | |
|---|---|
| ☑ Use OUTER JOINS in Results | If enabled, a patient's data will be included in a Browsers results even if some panels of data are missing for that patient. |
| ☐ Use FULL JOIN in Select Criteria | If enabled, full automatic joins, including patient, visit and observation joins are used in selection criteria. If disabled, only patient |
| ☑ Display Panel Names | If enabled, Panel Lists will display the PanelName rather than the Panel Description. |
| ☑ Display Item Names | If enabled, Item Lists will display the ItemName rather than the Item Description. |
| ☑ Sort Panels Alphabetically | If enabled, Panel Lists will be sorted alphabetically, otherwise in order created. |
| ☑ Sort Items Alphabetically | If enabled, Item Lists will be sorted alphabetically, otherwise they're in order created. |
| ☐ Patient subset footer as text | If enabled, patient selection criteria displayed in print footers will be text, otherwise it will be SQL |
| ☐ Suppress Panel Item Not Found Warnin... | If enabled, Panel/Item not found dialog will be suppressed when saved Report Output Specifications can be used. |
| ☐ Include All Items | |
| ☐ Use Grayscale in Graphs | If enabled, graphs are drawn in grayscale instead of in color. This option is intended for users with a color vision deficiency. |
| ☑ Favorites Startup Mode | If enabled, your next JReview session will startup initially showing only your Favorites |

Email address for alerts

***Note:*** when you are showing only Favorites in the Object Specifications (aka "Favorites mode") you will only be able to save to the Categories/Folders of the objects you've tagged as Favorites. This is necessary for the associated performance improvement. But you may manually enter the Category/Folder or move out of "Favorites Mode".



Remember the FAVORITES folder is a pseudo category/folder, you should not type it in explicitly nor expect it to show in the Categories / Folders drop-downs.

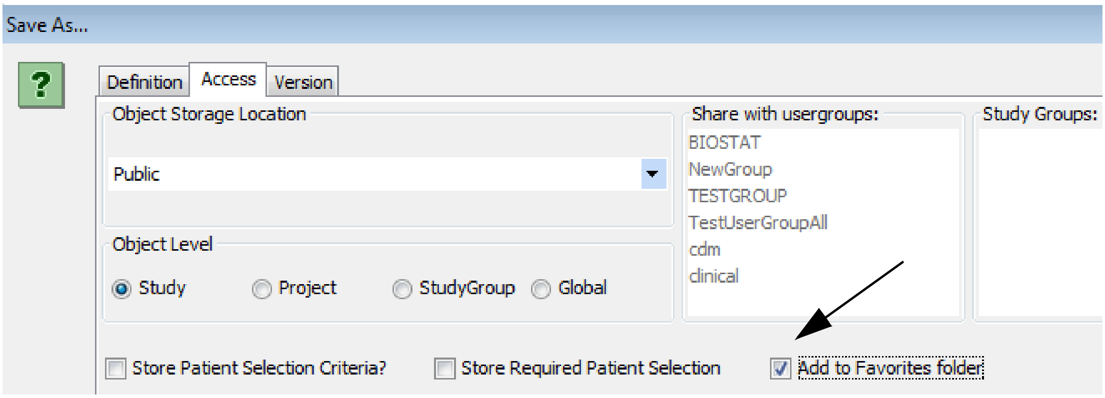


Description: Elevated Lipid panel

Category (Major.Minor.Sub): Safety

Status: DEFAULT

When Saving a new object or Re-Saving an existing one you are offered the option of tagging the object as a Favorite (forced on in Favorites mode).



Object Storage Location: Public

Object Level: ● Study ○ Project ○ StudyGroup ○ Global

BIOSTAT
NewGroup
TESTGROUP
TestUserGroupAll
cdm
clinical

☐ Store Patient Selection Criteria? ☐ Store Required Patient Selection ☑ Add to Favorites folder

There is the auto-addition of one's default Dashboard GPP or WPP to their Favorites. This feature is to support Dashboard users (only) that use Favorites.

If you've Favorites and are a Dashboard user (have Dashboard configured or ever used it) then you may/should notice a GPP or WPP appearing in your Favorites that you didn't add. You also cannot Remove it from Favorites.

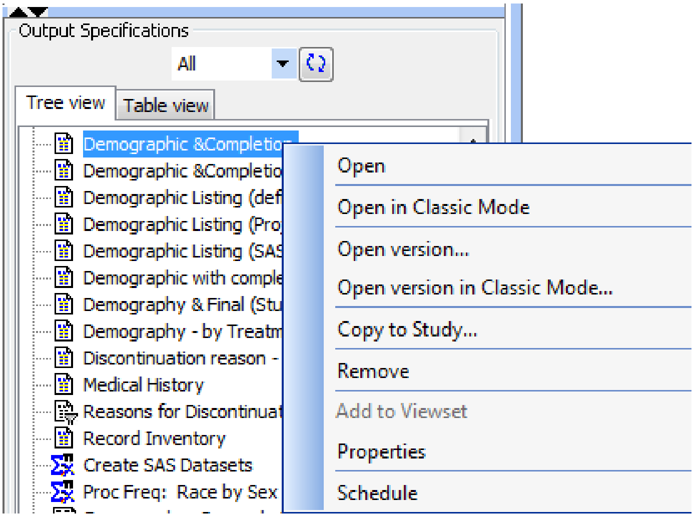
## Retrieve specification from Output Specifications

To view the object specification without executing the results:

1. Select the stored object in Output Specifications window.
2. Right-mouse click to display a floating menu.
3. Click **Open**. The object specification displays in the browser build window where it was defined.

   When you select **Open,** the most recently saved object specification version is opened.

   When selecting a saved graphic patient profile; you have can click **View Template** for details.
4. Enter changes to the object specification to update current version or resave as a new object.



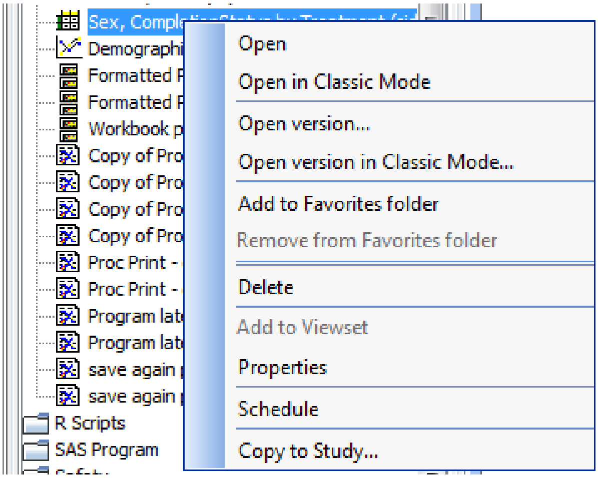
If the user is not the author and attempts to apply changes to the selected object, then a '**Warning**' message will display stating the object was created by someone else and you cannot update it..

## *Open saved new mode object*

The following conditions apply when opening a saved reports, graph, and crosstab object:

- If a saved output object was created in **Classic Mode** and uses the “Vertical Node” for defining the graph, i.e.,, directly uses a vertical panel, then the graph definition is always opened in Classic Mode, and New Mode is not available for the graph.
- If a saved graph object defined in New Mode uses the HRZ (Vertical-to-Horizontal Transform) feature, then the graph definition will always open in New Mode, and Classic Mode is unavailable.
- The JReview version or the Graph Browser mode used when saving the graph object does NOT determine the selection of the initial mode, ***except*** for those graph definitions only available in Classic Mode.
- If the Graph Browser is open and a saved object is then opened, the definition will be opened in whatever is the current Graph Browser mode, ***except*** for those graph definitions only available in Classic Mode.

When the user selects an output object in the Object Explorer and right-click the Classic Mode options only show for ***Reports, Graphs, and Crosstabs***.



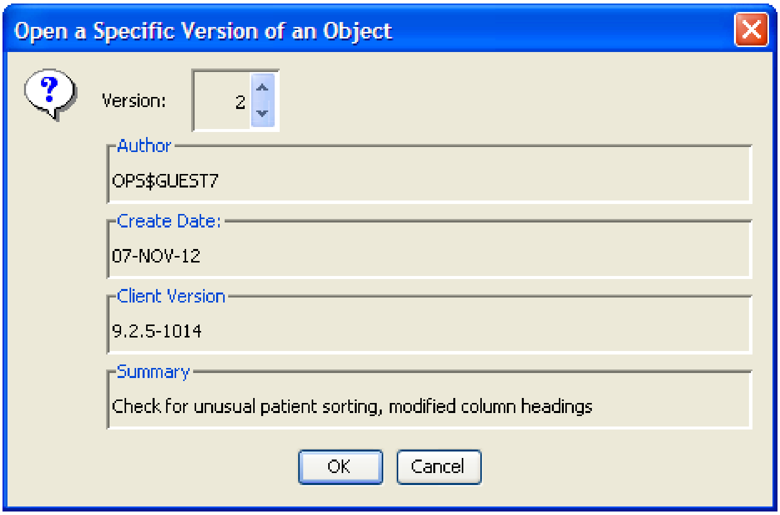
## *Open specific version*

When you right mouse click to display the floating menu, JReview supports **Open Version** on available Output Objects (reports, graphs, etc), to select and access a previously saved version of the output specification.

The user may select a specific object to modify and save by clicking 🖫, or from the **File** menu select **Save.**

When the user opens an existing object and JReview displays the **Save window** with a checkbox for "**Save As New Version**". If you click to uncheck it, then the **Save** button and title changes to **Update**. You can **Save as New Version** or allow updates to previously saved objects dependent upon the privilege settings.

- If the "Allow Updates" privilege (P37) is N, then saving to an existing object always creates a new version.
- If the "Allow Updates" privilege (P37) is Y, then saving to an existing object always overwrites the current object and version.



Open a Specific Version of an Object

Version: 2

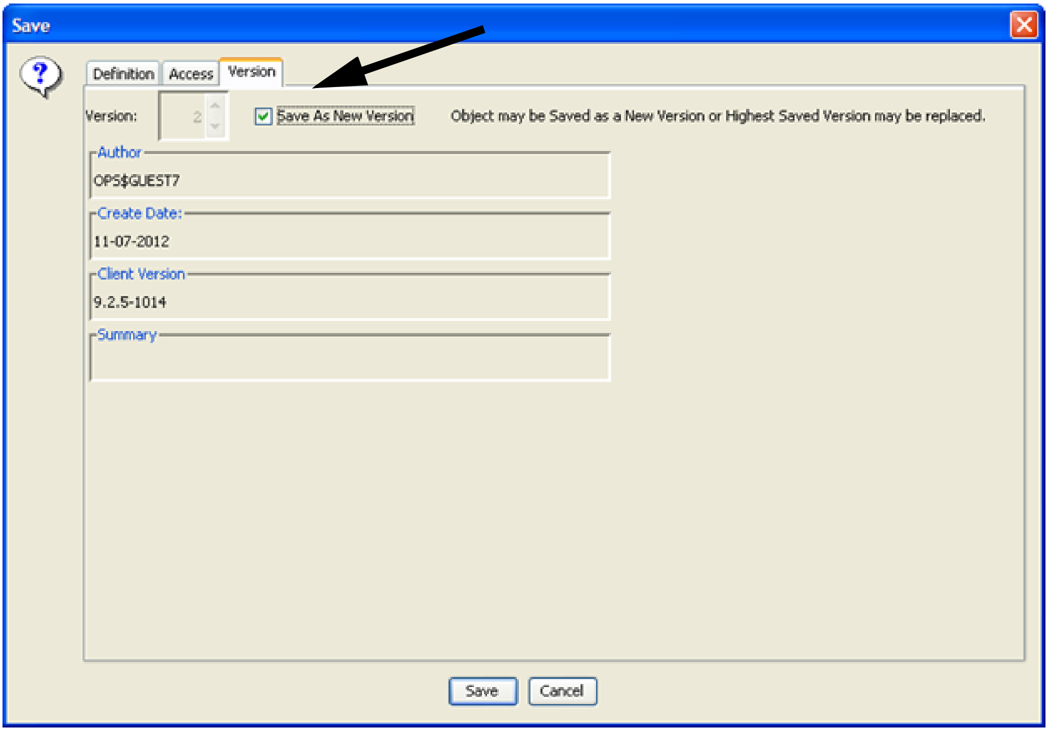
Author: OPS$GUEST7

Create Date: 07-NOV-12

Client Version: 9.2.5-1014

Summary: Check for unusual patient sorting, modified column headings

If Allows Updates is pemitted, you may un-check the Save as New Version checkbox and update the current version. The **Save window** updates the current version. Otherwise, you would **Save As New Version**.



Version: 2

☑ Save As New Version

Object may be Saved as a New Version or Highest Saved Version may be replaced.

Author: OPS$GUEST7

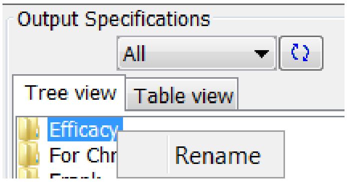
Create Date: 11-07-2012

Client Version: 9.2.5-1014

Summary:

## *Rename Category*

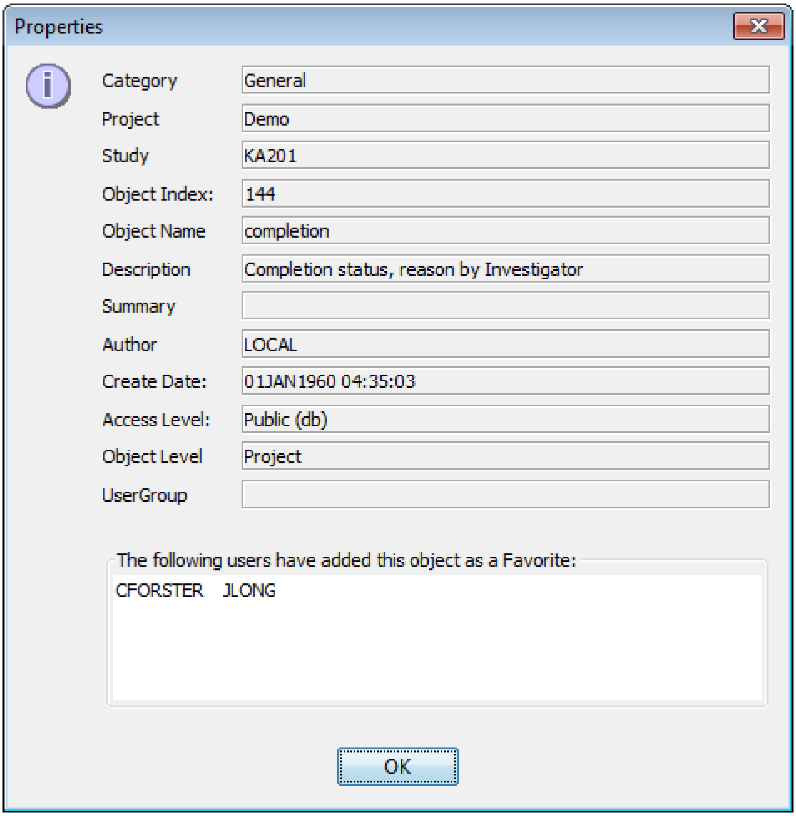
Users with permission in ReviewAdmin may change a Category folder name with right mouse-click on the selected category.



## *Object properties*

You can view information about an object when you select **Properties**.

1. Select the stored object in Output Specifications window with a single click.
2. Right-mouse click to display a floating menu.
3. Click **Properties**. The Properties window opens for the selected object.
4. Click **OK** to close the Properties window.



| | |
|---|---|
| Category | General |
| Project | Demo |
| Study | KA201 |
| Object Index: | 144 |
| Object Name | completion |
| Description | Completion status, reason by Investigator |
| Summary | |
| Author | LOCAL |
| Create Date: | 01JAN1960 04:35:03 |
| Access Level: | Public (db) |
| Object Level | Project |
| UserGroup | |

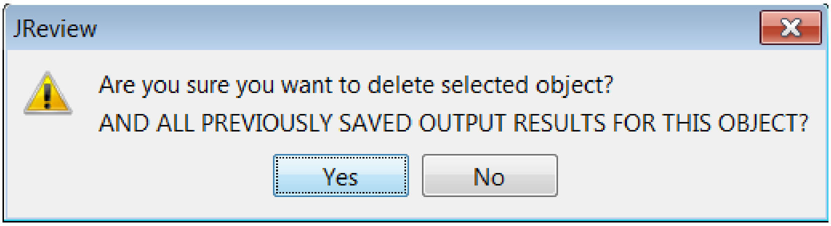
The following users have added this object as a Favorite:

CFORSTER JLONG

## *Remove output specification*

If you wish to delete the object specification select **Remove**:

1. Select the stored object in Output Specifications window with a single click.
2. Right-mouse click to display a floating menu.
3. Click **Remove**. Only the author or Super User has permission to delete an object. A warning message displays to confirm delete object.

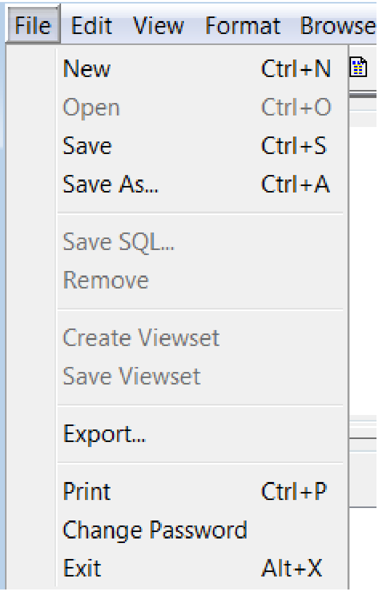

JReview

Are you sure you want to delete selected object?

AND ALL PREVIOUSLY SAVED OUTPUT RESULTS FOR THIS OBJECT?

## *File Export*

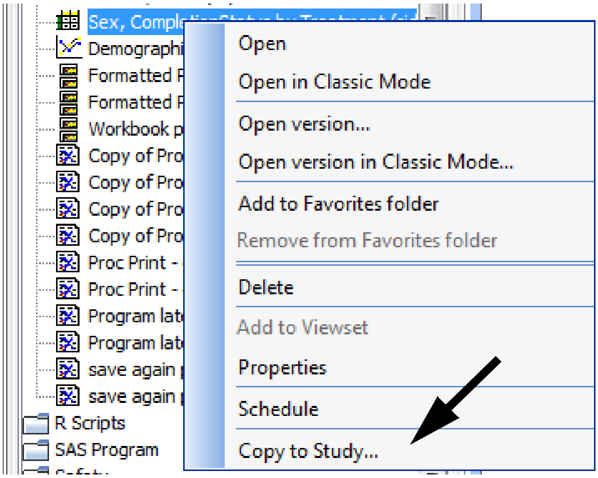
From the **File** menu select **Export** for any file to export. The Save dialog remembers the directory/subdirectory of your last save during the session, and will prepopulate that directory as a starting point.



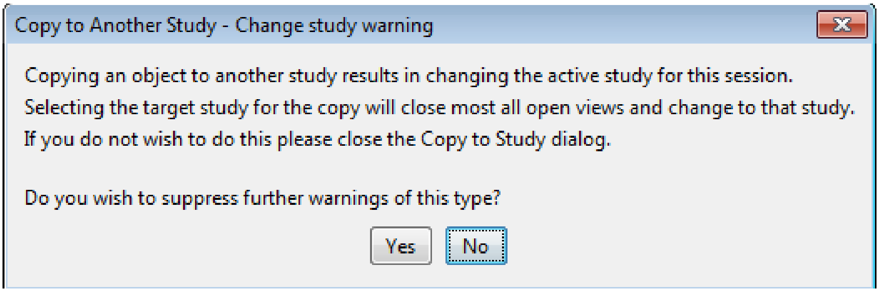
## *Copy to study*

The **Copy to Study** feature will ‘push’ a copy of the selected object to a different Project/Study.

1. Select the stored object in the Output Specifications window.
2. Right-mouse click to display a floating menu.
3. Click **Copy to Study**.



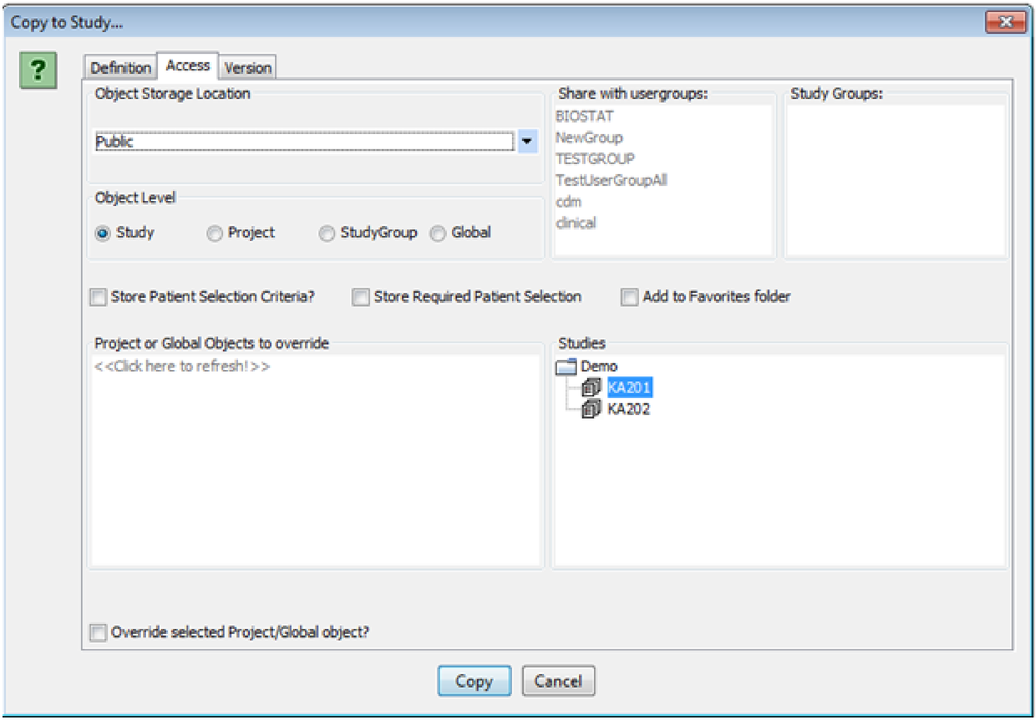
A Change study warning message displays stating this action will change the active study for this session. Click Yes/No for the message.



Copying an object to another study results in changing the active study for this session.
Selecting the target study for the copy will close most all open views and change to that study.
If you do not wish to do this please close the Copy to Study dialog.

Do you wish to suppress further warnings of this type?

4. A **Copy to Study** dialog displays. Enter the necessary Save information for Access and Definition tabs to save a copy of the object to a new study location.



Object Storage Location: Public

Object Level: ● Study

☐ Store Patient Selection Criteria?
☐ Store Required Patient Selection
☐ Add to Favorites folder

Studies: Demo / KA201

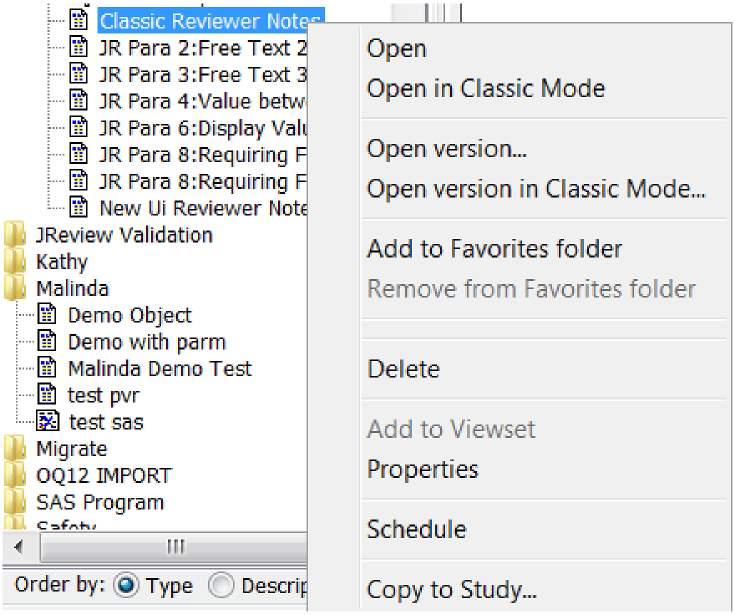
☐ Override selected Project/Global object?

# Schedule output

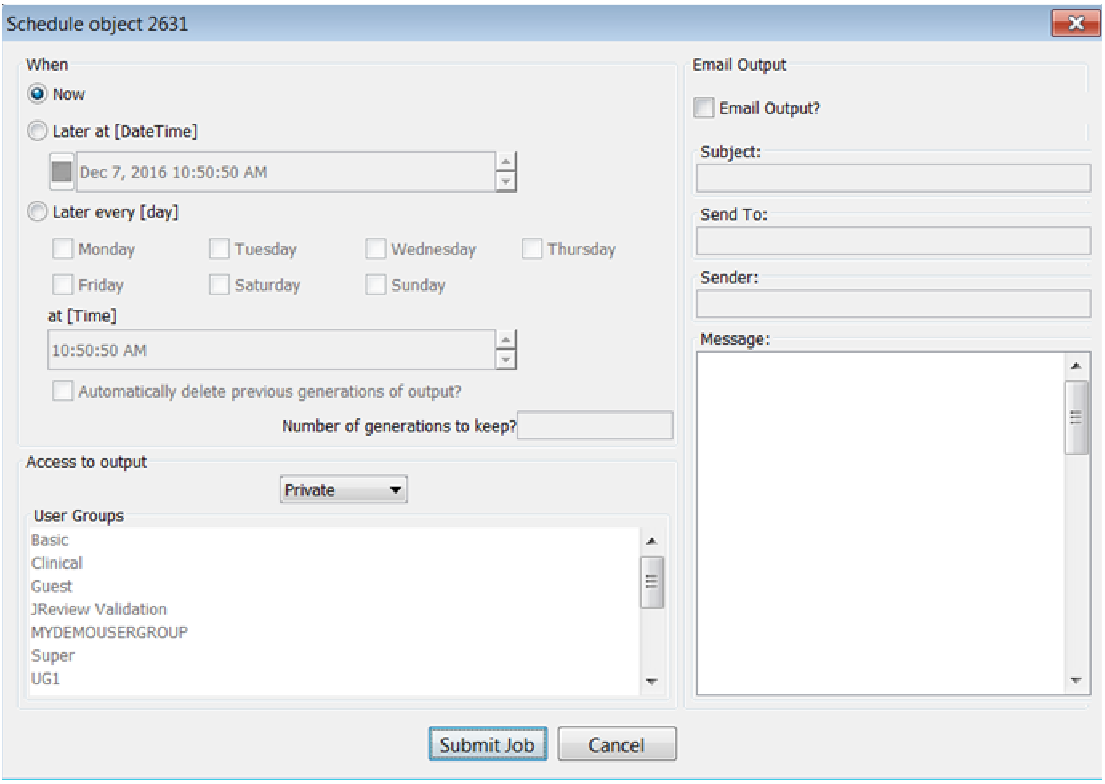
## Object Explorer scheduled output

The Object Explorer window aids users to quickly locate and schedule previously saved objects stored within organized folders. The output scheduler allows users to schedule a job throughout all output browsers in Review. This includes reports, graphs, crosstabs and SAS jobs.  Email attachments (reports, etc.) is supported and requires a print server.

1. Select the stored object in Output Specifications window with a single click.
2. Right-mouse click to display a floating menu.



3. Click **Schedule**. A dialog window displays for Job Scheduling.



Schedule object 2631

When

● Now

○ Later at [DateTime]

Dec 7, 2016 10:50:50 AM

○ Later every [day]

☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday

☐ Friday ☐ Saturday ☐ Sunday

at [Time]

10:50:50 AM

☐ Automatically delete previous generations of output?

Number of generations to keep?

Access to output

Private

User Groups

Basic
Clinical
Guest
JReview Validation
MYDEMOUSERGROUP
Super
UG1

Email Output

☐ Email Output?

Subject:

Send To:

Sender:

Message:

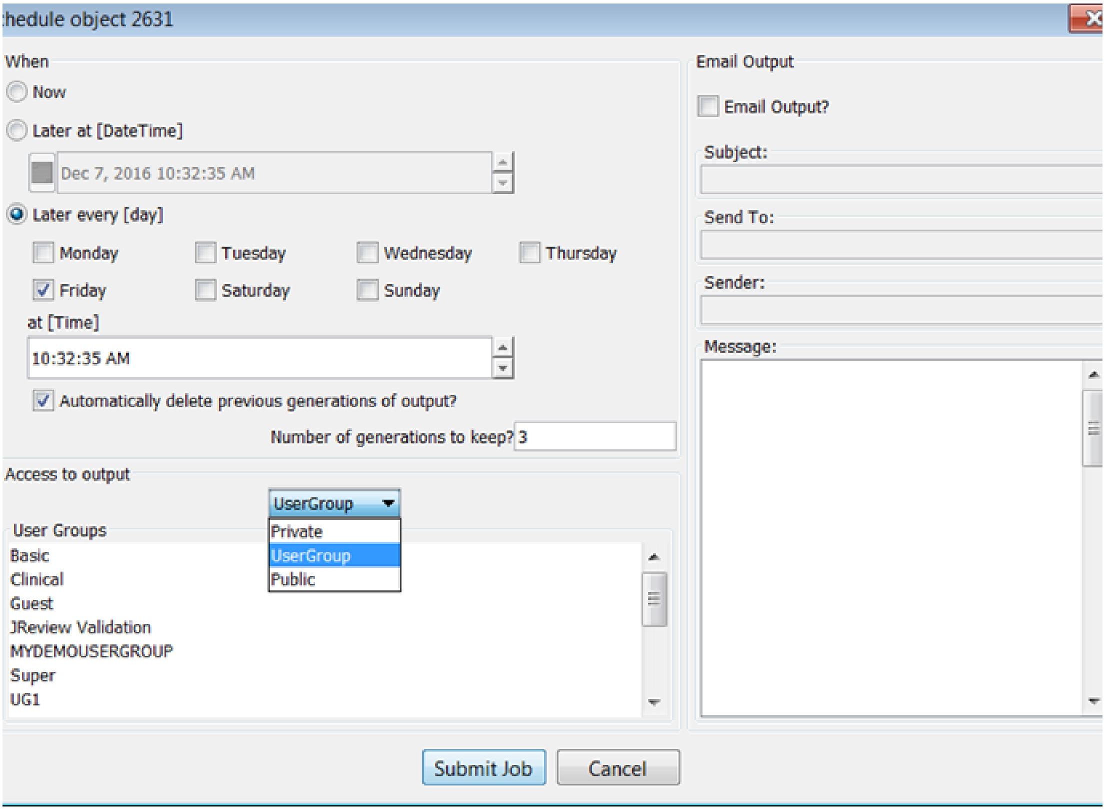
***Note: Scheduling Formatted Patient Profiles requires an optional printer server module.***

4. The schedule default is **Now.** If you select Later at (Date Time), click on the arrow to display a drop down calendar to select a future date and time.

   OR

   Schedule a ***repetitive frequency*** using selected days of the week by selecting Later every (day). This feature allows you to **automatically delete previous generations of output** or enter a **number of generations to keep**.

5. Select who can access the stored output results for Private, UserGroup or Public.



○ Now
○ Later at [DateTime]
Dec 7, 2016 10:32:35 AM
● Later every [day]
☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday
☑ Friday ☐ Saturday ☐ Sunday
at [Time] 10:32:35 AM
☑ Automatically delete previous generations of output?
Number of generations to keep? 3
Access to output: UserGroup
☐ Email Output?

## *Email attachments*

**Email attachments (reports, etc.)** ***(requires print server)*** is supported through expanded scheduling support for the ability to specify list of email recipients for scheduled reports, etc. This feature needs to be configured with outbound email server information, and is a privilege that can be disabled for all, or enabled for specific users or usergroups.

6. To send output as Email attachment, click the checkbox **Email Output**.
7. Enter **Subject, Send To, Sender and Message**.
8. Click **Submit Job**.

   The output results are placed as archives in the object folder with a date time stamp and identify the user who submitted the job run. Only the person who scheduled the job output can delete the stored results. Objects submitted as Email Output are mailed.

## *Greenwich Mean Time (GMT)*

Report scheduling server enhancement now manages the scheduled time based on Greenwich Mean Time (GMT) – displaying users local time in JReview scheduling dialog, but converting to GMT – and running the scheduled report based on the correct GMT. This supports multi-national customers with servers in one time zone, and users in other time zones.

## *Schedule Patient Profiles and Narratives*

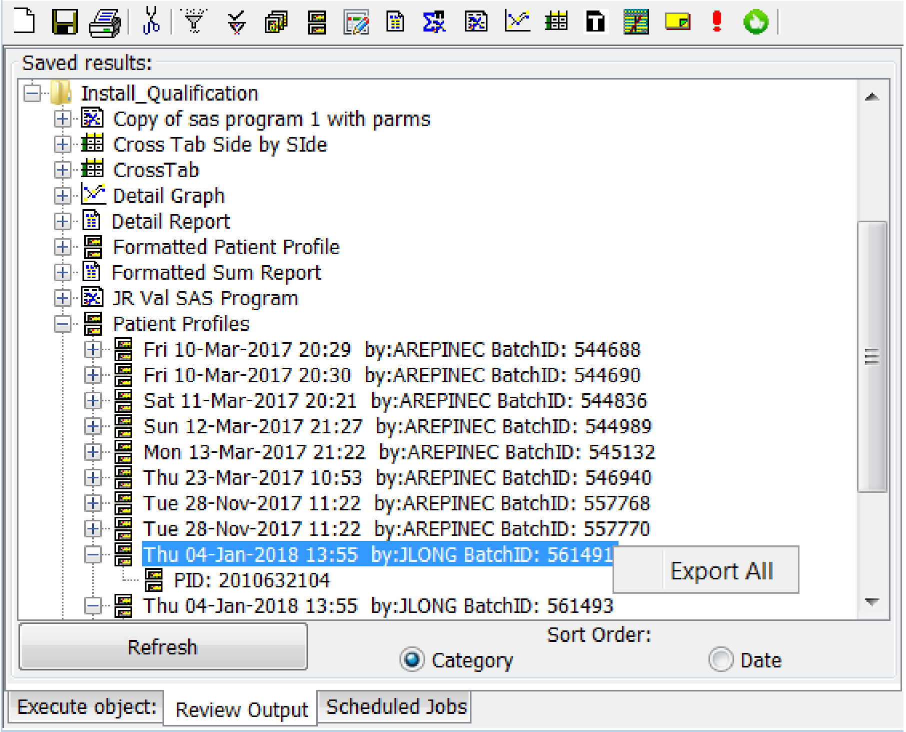
Scheduling Workbook Patient Profiles and Patient Narratives is supported if Patient Profile Scheduling Server is licensed (optional license). Previously, Formatted Patient Profiles could be scheduled as a batch job to generate the PDFs for each of the patients (either selected patients or all patients in a subset). The generated PDFs were accessible directly through the JReview ‘Review Output’ tab, but could also be directed to be saved to a study specific directory which could be externally accessible to users. Now the same functionality for Workbook Patient Profiles is supported generating Excel spreadsheets for each patient – also accessible externally if desired.

Patient Narratives can also be scheduled generating the RTF files for each patient in batch and saving the resulting RTF files for access from within JReview as well as in an externally accessible directory. The print server supports to retrieve/save .rtf and .xls output files as well as previously supported .pdf output.

For defined Patient Narrative and Workbook profile definitions, right mouse click to schedule selected patients for both types of objects. Patient Narratives are stored in configured (PDFJOBDIR= ) directory per study - generated and saved as .rtf files.

Workbook profiles are stored in the configured (PDFJOBDIR= ) directory for the study - generated and saved as completed XLS files.

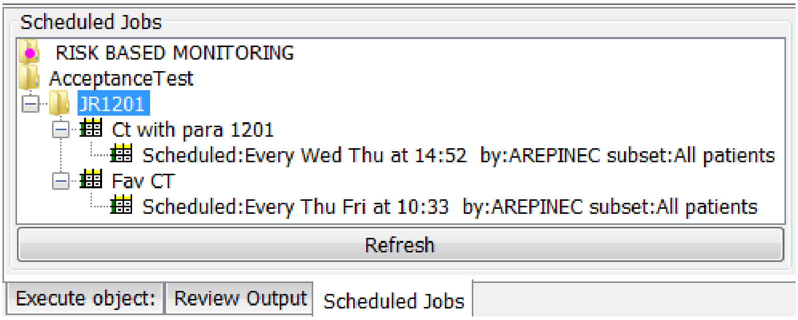
Also, Workbook profiles located the Saved Output for those profiles in the Review Output tab, then right mouse clicked on the batch header for the job. Then select 'Export All' to save the generated spreadsheets to local directory.


Saved results:

- Install_Qualification
  - Copy of sas program 1 with parms
  - Cross Tab Side by SIde
  - CrossTab
  - Detail Graph
  - Detail Report
  - Formatted Patient Profile
  - Formatted Sum Report
  - JR Val SAS Program
  - Patient Profiles
    - Fri 10-Mar-2017 20:29 by:AREPINEC BatchID: 544688
    - Fri 10-Mar-2017 20:30 by:AREPINEC BatchID: 544690
    - Sat 11-Mar-2017 20:21 by:AREPINEC BatchID: 544836
    - Sun 12-Mar-2017 21:27 by:AREPINEC BatchID: 544989
    - Mon 13-Mar-2017 21:22 by:AREPINEC BatchID: 545132
    - Thu 23-Mar-2017 10:53 by:AREPINEC BatchID: 546940
    - Tue 28-Nov-2017 11:22 by:AREPINEC BatchID: 557768
    - Tue 28-Nov-2017 11:22 by:AREPINEC BatchID: 557770
    - Thu 04-Jan-2018 13:55 by:JLONG BatchID: 561491
      - PID: 2010632104
    - Thu 04-Jan-2018 13:55 by:JLONG BatchID: 561493

## View Scheduled Jobs

Click the Scheduled Jobs tab at the bottom of the Object Explorer window to view jobs currently scheduled. The scheduled jobs are organized and listed in the same folder category as the object specification storage folder.


Scheduled Jobs

RISK BASED MONITORING
AcceptanceTest
JR1201
    Ct with para 1201
        Scheduled:Every Wed Thu at 14:52  by:AREPINEC subset:All patients
    Fav CT
        Scheduled:Every Thu Fri at 10:33  by:AREPINEC subset:All patients

***Note:  Scheduled SAS Procs and SAS Programs bypass being listed in the Schedule tab and go directly to the Review Output tab.***

## Remove Scheduled Jobs

If you need to remove a scheduled job, highlight the job description and right-mouse click to display a floating menu, click **Remove**.

## Change Schedule

If you need to change a scheduled job:

1. Click the Scheduled tab at the bottom of the Object Explorer window to view jobs currently scheduled.
2. Select the job description and right-mouse click to display a floating menu.
3. Click **Change Schedule**.
4. The Job Scheduling window opens for you to enter your changes.

   Reports, graphs and crosstabs have their scheduling information saved in the Job Schedule table which is consulted by the Report Scheduling server. This allows you to go back and change the scheduling of these object types.
5. Click Update.

## *Schedule SAS jobs*

**SAS Programs** are placed on the schedule queue of the operating system (of the SAS Server) and are placed directly into the Review Output tab bypassing the Scheduled tab. Therefore, pending SAS jobs are removed from the Review Output tab. The Review server does not use the operating system for scheduling but runs the program using the Review server. The schedule is kept in a file on the server and the Review client does not have access to it.

You can remove a pending SAS job from the Review Output tab, however, the Review server still runs the SAS program, the output is just not accessible through JReview. Therefore, the SAS job is not actually cancelled that is scheduled.

SAS Program scheduling for repetitive scheduling is now supported.

*Note:* ***However, SAS PROC is currently*** **NOT supported** ***by Job Scheduling (as the message indicates).***

## *Manual Schedule Viewset*

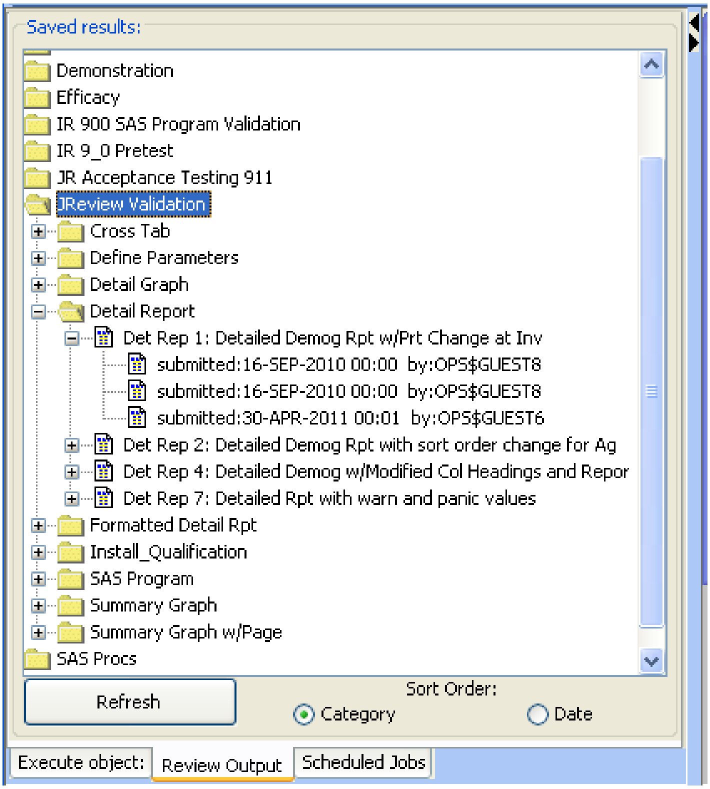
This viewset scheduling option was made for those instances that the viewset did not get scheduled at the time it was saved.  For example, when Live mode only was in effect.

# Review output

## *Locate stored output results*

The Saved Results folders are from the category folder definition for each of the objects that were run. Folders are only displayed if an object has output saved.

1. Click the **Review Output tab** at the bottom of the Object Explorer window to view saved output. The stored output results are saved with the date/time stamp and author who submitted the job.
2. Single click on the folder category to open.
3. Double click on the object description to view output.



Saved results:

- Demonstration
- Efficacy
- IR 900 SAS Program Validation
- IR 9_0 Pretest
- JR Acceptance Testing 911
- JReview Validation
  - Cross Tab
  - Define Parameters
  - Detail Graph
  - Detail Report
    - Det Rep 1: Detailed Demog Rpt w/Prt Change at Inv
      - submitted:16-SEP-2010 00:00 by:OPS$GUEST8
      - submitted:16-SEP-2010 00:00 by:OPS$GUEST8
      - submitted:30-APR-2011 00:01 by:OPS$GUEST6
    - Det Rep 2: Detailed Demog Rpt with sort order change for Ag
    - Det Rep 4: Detailed Demog w/Modified Col Headings and Repor
    - Det Rep 7: Detailed Rpt with warn and panic values
  - Formatted Detail Rpt
  - Install_Qualification
  - SAS Program
  - Summary Graph
  - Summary Graph w/Page
- SAS Procs

Sort Order: ● Category ○ Date

The exception is previously run and saved SAS Proc output results from an earlier Review release. The SAS Proc browser scheduled a job to be run and the output saved. The output would be listed under the specific SAS Proc that was run. Therefore, old SAS Proc jobs are placed in a SAS Proc folder.

## *Export formatted profiles*

Users may export all formatted patient profiles in a given batch to be copied to the users indicated directory location.

In the Review Output List, right click on the formatted patient profile output folder for the job to view menu, and select ‘Export All’ .

## *Quick remove saved output results*

1. Locate and open the output folder.
2. Select the stored object with a single click.
3. Right-mouse click to display a floating menu, click **Remove**.

# Manage and Migrate Objects

## *Manage Migrate operations*

The Manage Migrate feature is available on the Advanced menu. All users have access to use Manage/Migrate; however they are only able to modify the objects they have authored. There are two exceptions; if the user is a “super user” they have access to modify all objects. Also, only a super user has access to manage the available status options. Import Object activity requires the user to have p58 to perform an object import.

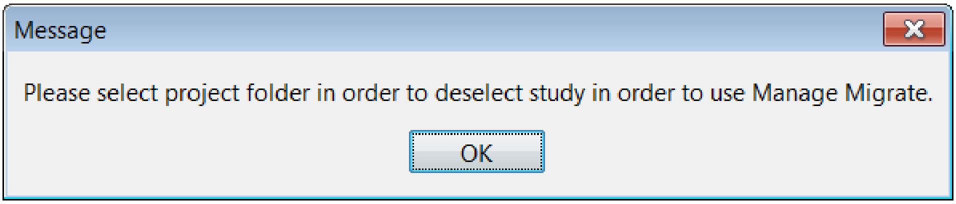
The Manage object functions are used to maintain the object status for add, edit, and delete. Also the ability to change the object location, level, author, status, category, copy to other study, and delete. Saved output may also be selected for deletion. Users initially apply an object filter to filter down to the objects for a selected activity. The Migrate object functions allow users to export and import objects.

The Manage Migrate functions support object management operations to change the object with the current activities:

- Modify Storage Locations (Private, usergroup or public)
- Modify Level (Study, Study Group, Project or Global)
- Modify Status
- Modify Category
- Import objects from a spreadsheet into a database*
- Export – create an xls file of exported objects
- Viewsets are not supported
- Delete objects
- Copy Object from one study, project or study group to another.
- Modify author
- Delete saved output
- Maintain Status – add, edit or delete*
- Document Object stored in an Excel spreadsheet.

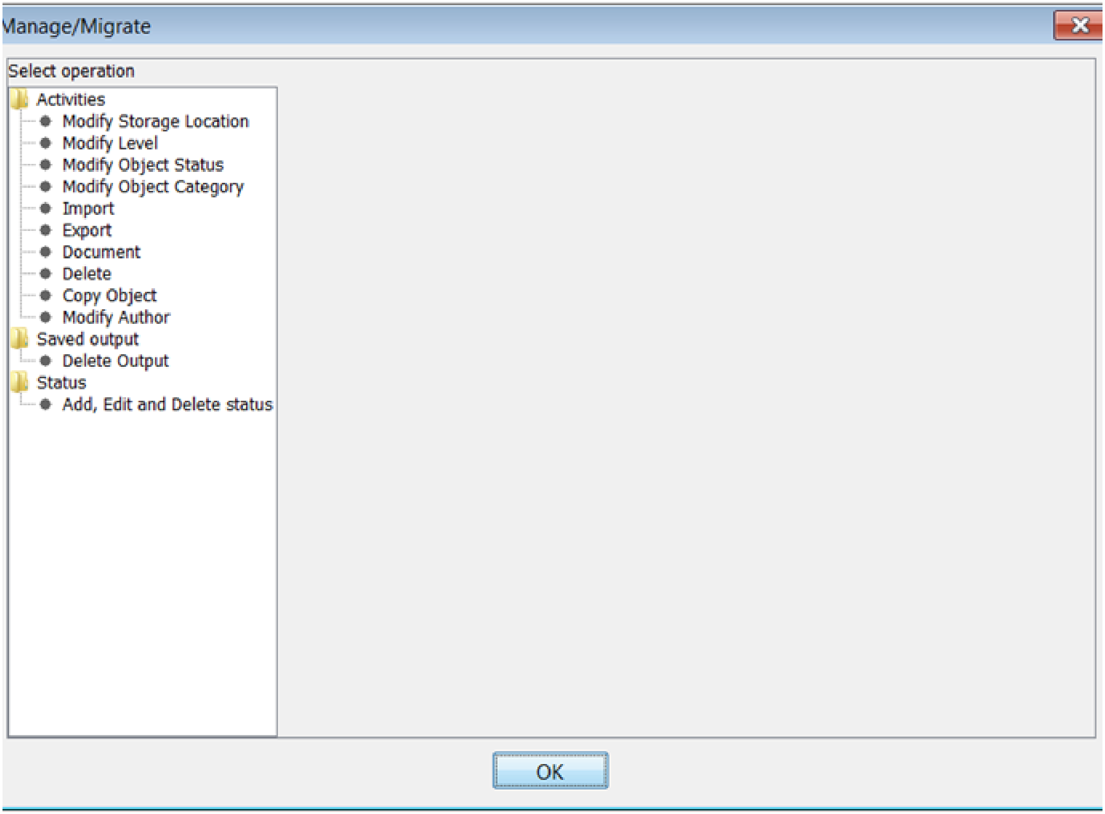
## *Open Manage Migrate*

The User must select a project folder – **not a study** prior to selecting the Manage/Migrate from the **Advanced Menu**. You can only import objects from an “export” that was created with the same version as the target database.



Please select project folder in order to deselect study in order to use Manage Migrate.

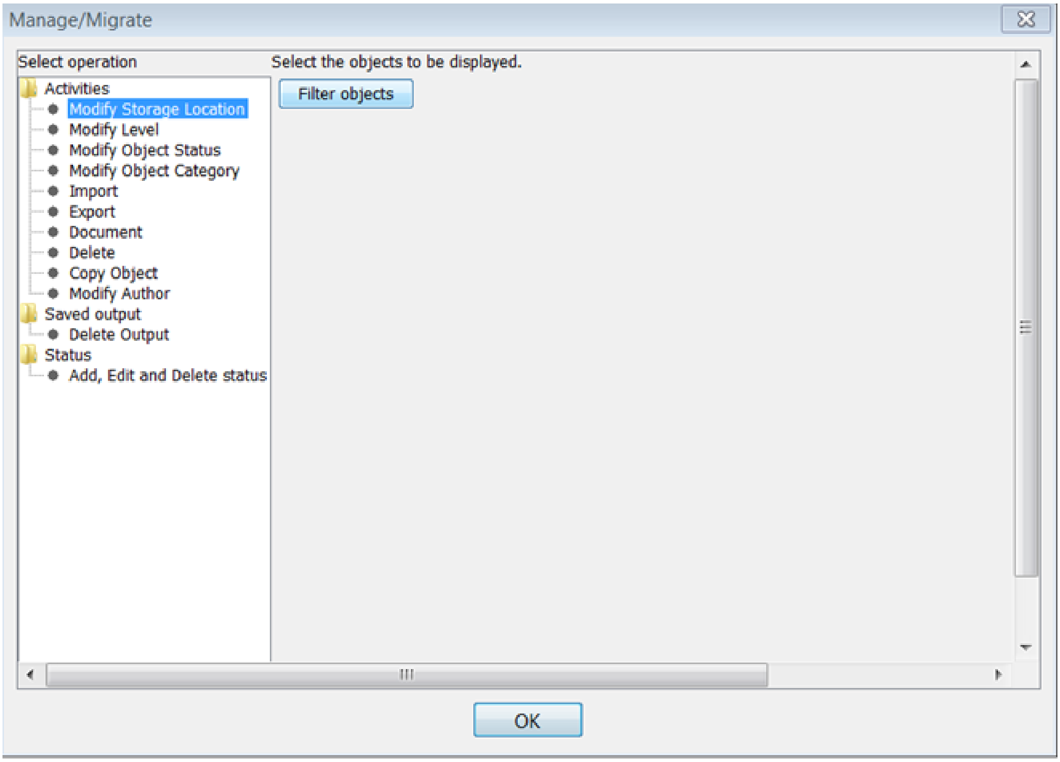
Go to the **Advanced menu** and select Select **Manage/Migrate.** The first step is to select a Manage/Migrate activity.



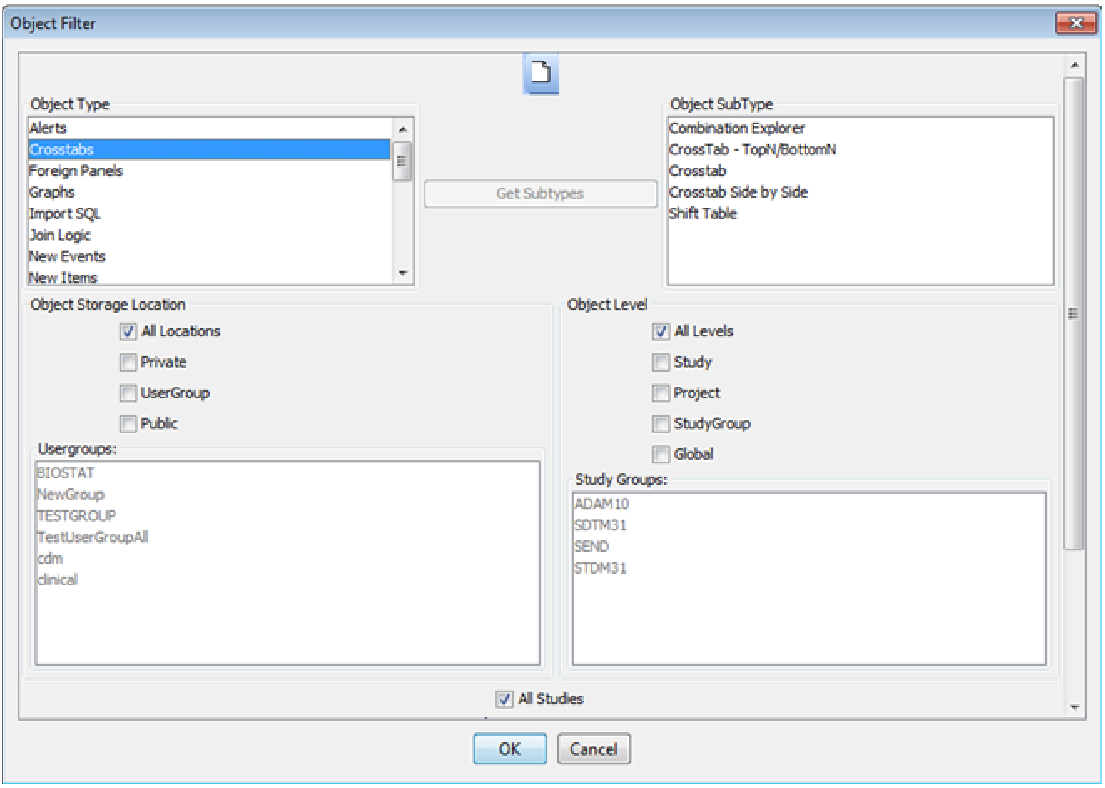
## Select Activity

The **Select Filter Objects** is ***required*** for all activities with the exception of Deletion of saved output and the Add, Edit and Delete Status. The following steps are apply for changing an object to a new location, level, author, status, or category. For example, under the **Activities** folder, select **Modify Storage Location**.

1. Click **Filter objects**. The **Object Type** is the only required item to select for the filter. All other selections are optional to refine the filter results, such as:
   - Object Storage Location
   - Object Level
   - User groups
   - Study Groups
   - Studies
   - Projects



The **Object Filter** window opens. Select an **Object Type** and the **Object SubType** fills with the available object subtypes.



Object Type
Alerts
Crosstabs
Foreign Panels
Graphs
Import SQL
Join Logic
New Events
New Items

Object SubType
Combination Explorer
CrossTab - TopN/BottomN
Crosstab
Crosstab Side by Side
Shift Table

Object Storage Location
☑ All Locations
☐ Private
☐ UserGroup
☐ Public

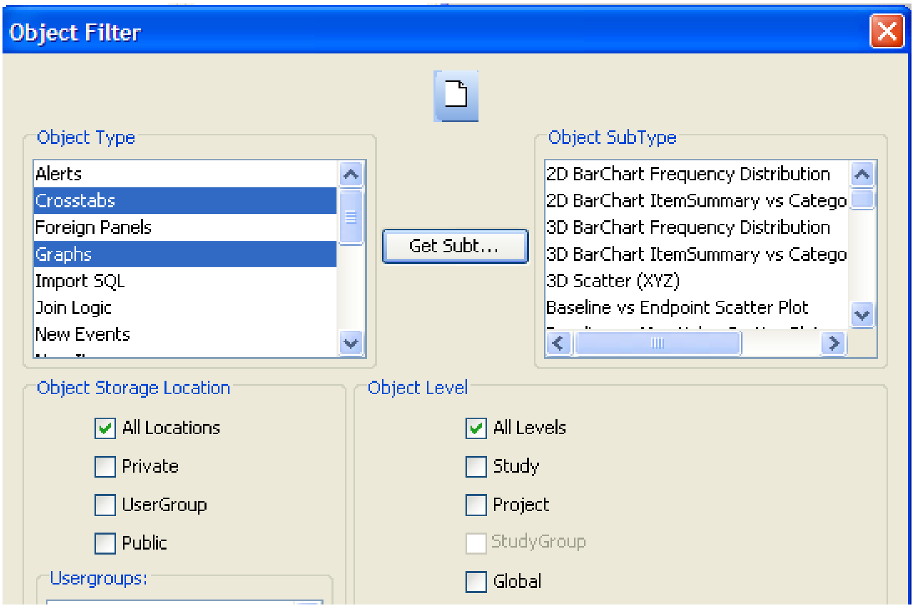
Usergroups:
BIOSTAT
NewGroup
TESTGROUP
TestUserGroupAll
cdm
clinical

Object Level
☑ All Levels
☐ Study
☐ Project
☐ StudyGroup
☐ Global

Study Groups:
ADAM10
SDTM31
SEND
STDM31

☑ All Studies

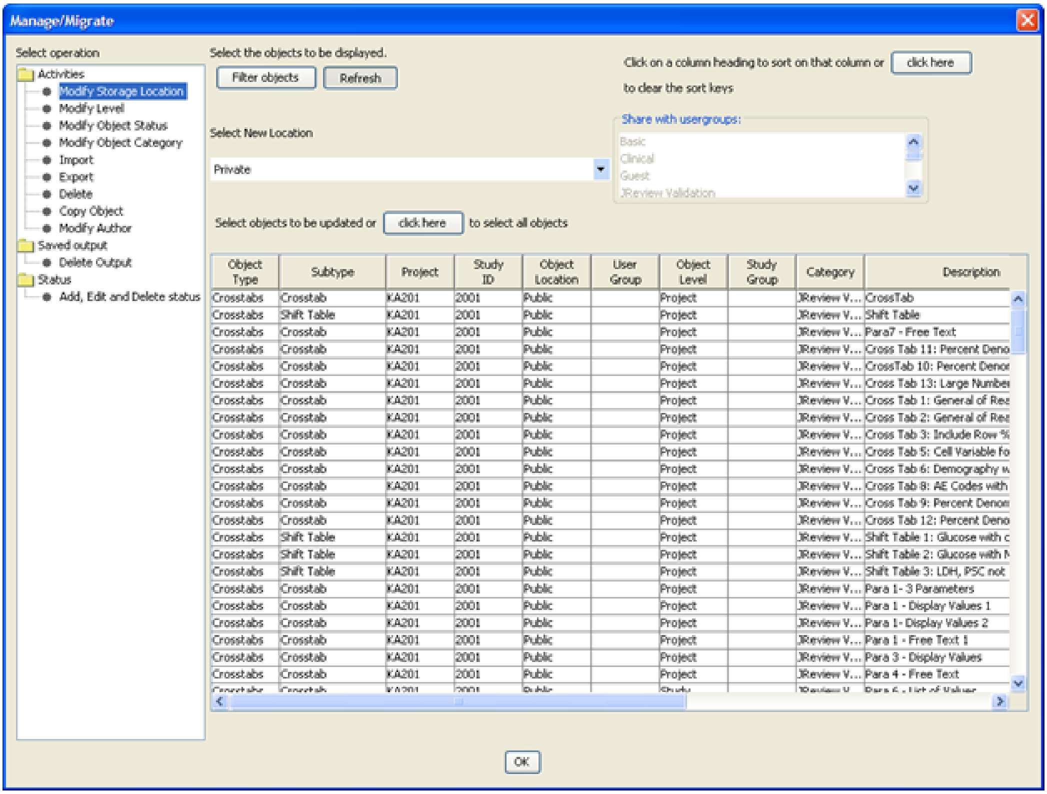
2. If you need to select multiple objects use the Ctrl key or Shift key, then click the **Get Subtype** button. Again, use the Ctrl key to select multiple object subtypes.
3. The **New** button will set the filter selection back to default selections.



4. Click **OK** button to retrieve objects based on filter settings.

This step generates a spreadsheet for the selected filter objects. After you have selected your object filter, use the generated spreadsheet window to apply your activity. The steps are similar between the various activity functions.

5. From the spreadsheet you may sort up to three columns. Click on a column heading to sort the column. A button is available to clear sort.
6. Use the horizontal scroll bar to view more column details within the spreadsheet.
7. A button is available to select all objects.
8. Select a row or select multiple rows with the Ctrl key or Shift Key.



Select the objects to be displayed.

Click on a column heading to sort on that column or click here to clear the sort keys

Select New Location: Private

Select objects to be updated or click here to select all objects

| Object Type | Subtype | Project | Study ID | Object Location | User Group | Object Level | Study Group | Category | Description |
|---|---|---|---|---|---|---|---|---|---|
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | CrossTab |
| Crosstabs | Shift Table | KA201 | 2001 | Public |  | Project |  | JReview V... | Shift Table |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Para7 - Free Text |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Cross Tab 11: Percent Deno |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | CrossTab 10: Percent Denor |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Cross Tab 13: Large Number |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Cross Tab 1: General of Rea |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Cross Tab 2: General of Rea |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Cross Tab 3: Include Row % |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Cross Tab 5: Cell Variable fo |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Cross Tab 6: Demography w |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Cross Tab 8: AE Codes with |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Cross Tab 9: Percent Denon |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Cross Tab 12: Percent Deno |
| Crosstabs | Shift Table | KA201 | 2001 | Public |  | Project |  | JReview V... | Shift Table 1: Glucose with c |
| Crosstabs | Shift Table | KA201 | 2001 | Public |  | Project |  | JReview V... | Shift Table 2: Glucose with N |
| Crosstabs | Shift Table | KA201 | 2001 | Public |  | Project |  | JReview V... | Shift Table 3: LDH, PSC not |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Para 1- 3 Parameters |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Para 1 - Display Values 1 |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Para 1- Display Values 2 |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Para 1 - Free Text 1 |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Para 3 - Display Values |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Project |  | JReview V... | Para 4 - Free Text |
| Crosstabs | Crosstab | KA201 | 2001 | Public |  | Study |  | JReview V... | Para 6 - List of Values |

9. Once a row or rows have been selected, select the activity description such as New Location for the Modify Storage Location.

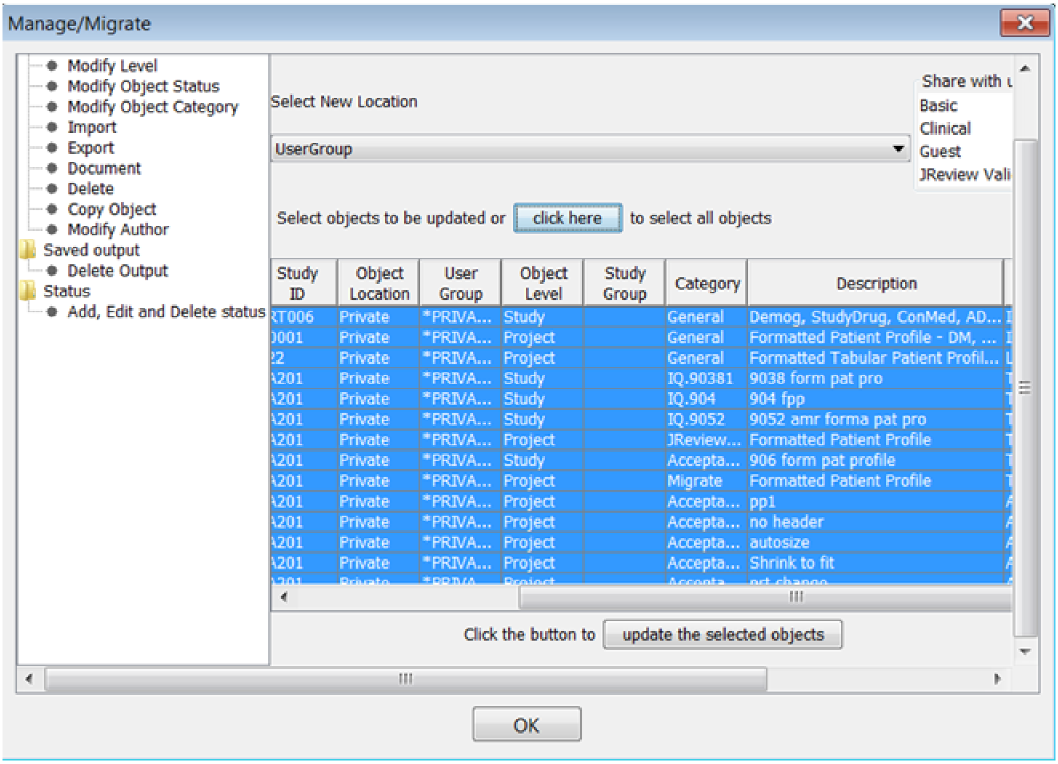
Select New Location

Private

Each Modify Activity feature in the Select operation list allows the user to filter objects then apply either a New Storage Location, New Level, New Object Status, New Object Category, or New Author.

Dependent upon on the Modify Activity selected, click **OK** and the update button is made available. For example, the "**update the selected objects**" button.

10. Click the **update the selected objects** button to apply changes. The changes are applied to the selected objects.



Select New Location

UserGroup

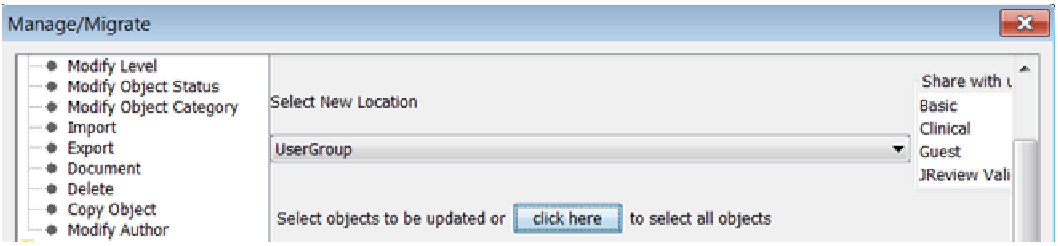
Select objects to be updated or click here to select all objects

| Study ID | Object Location | User Group | Object Level | Study Group | Category | Description |
|---|---|---|---|---|---|---|
| RT006 | Private | *PRIVA... | Study | | General | Demog, StudyDrug, ConMed, AD... |
| 0001 | Private | *PRIVA... | Project | | General | Formatted Patient Profile - DM, ... |
| 22 | Private | *PRIVA... | Project | | General | Formatted Tabular Patient Profil... |
| A201 | Private | *PRIVA... | Study | | IQ.90381 | 9038 form pat pro |
| A201 | Private | *PRIVA... | Study | | IQ.904 | 904 fpp |
| A201 | Private | *PRIVA... | Study | | IQ.9052 | 9052 amr forma pat pro |
| A201 | Private | *PRIVA... | Project | | JReview... | Formatted Patient Profile |
| A201 | Private | *PRIVA... | Study | | Accepta... | 906 form pat profile |
| A201 | Private | *PRIVA... | Project | | Migrate | Formatted Patient Profile |
| A201 | Private | *PRIVA... | Project | | Accepta... | pp1 |
| A201 | Private | *PRIVA... | Project | | Accepta... | no header |
| A201 | Private | *PRIVA... | Project | | Accepta... | autosize |
| A201 | Private | *PRIVA... | Project | | Accepta... | Shrink to fit |

Click the button to update the selected objects

11. Use the **Filter objects** button on the spreadsheet window, to toggle between the Object Filter window and the objects spreadsheet.

    The filter objects button allows the user to go back to the previously defined object filter and make changes.

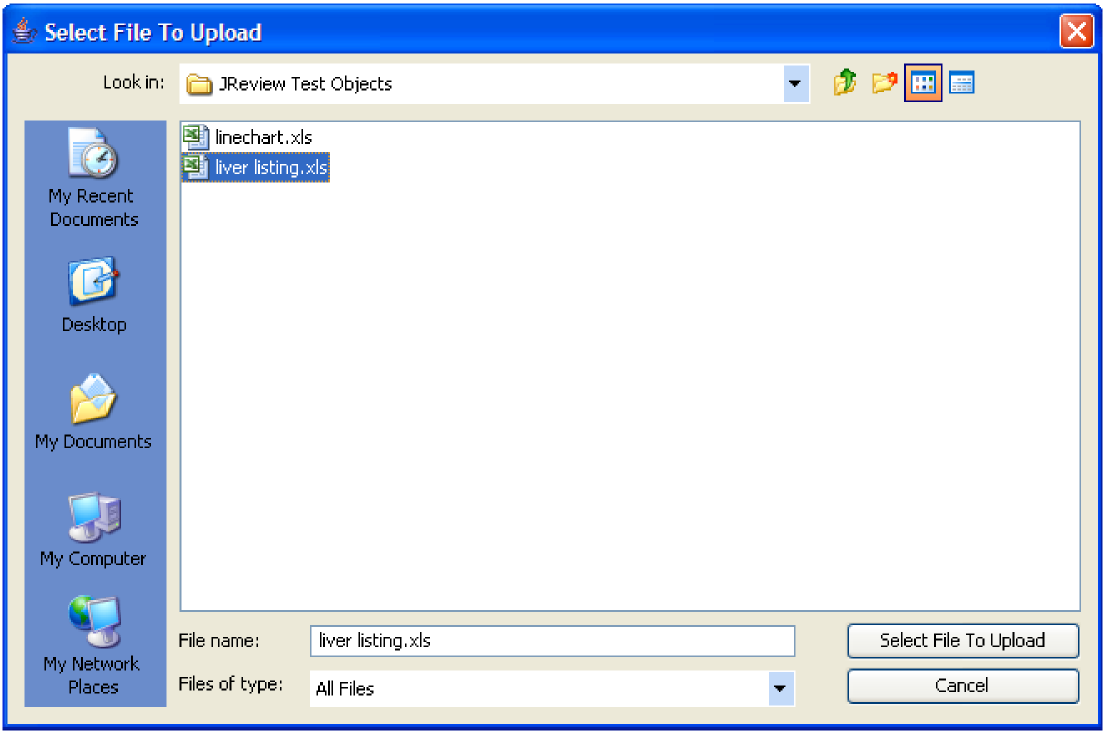


12. The **Refresh** button can be used if changes are made on one activity while a list of objects is displayed, then another activity requires the user to refresh the list after the changes were made.
13. Click **OK** button to close the dialog.

## *Import Object*

The Import Object activity requires user privilege p58 to import.

1. Under the **Activities** folder, select **Import**.
2. The Import window opens for “**Select File to Upload**”.



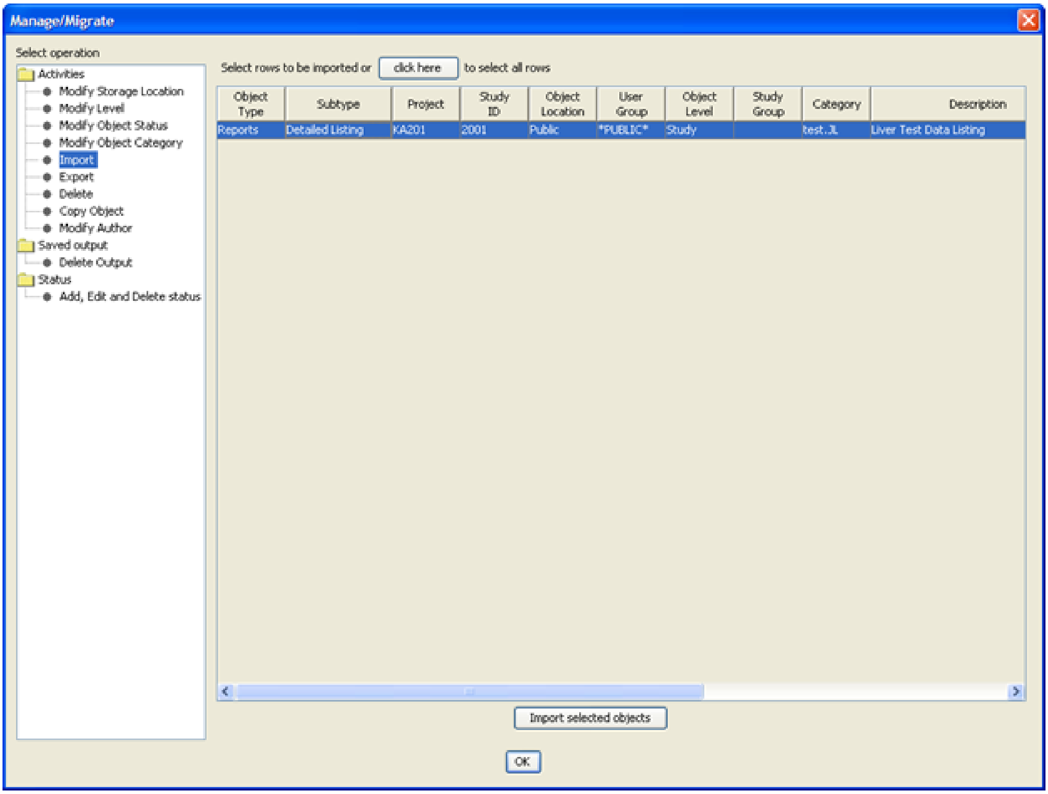
Look in: JReview Test Objects

File name: liver listing.xls

Files of type: All Files

3. Select a file and Click **Select File to Upload** button. The object spreadsheet is generated containing the selected import objects.

4. Select the object row(s) to import.



Select rows to be imported or click here to select all rows

| Object Type | Subtype | Project | Study ID | Object Location | User Group | Object Level | Study Group | Category | Description |
|---|---|---|---|---|---|---|---|---|---|
| Reports | Detailed Listing | KA201 | 2001 | Public | *PUBLIC* | Study | | test..JL | Liver Test Data Listing |

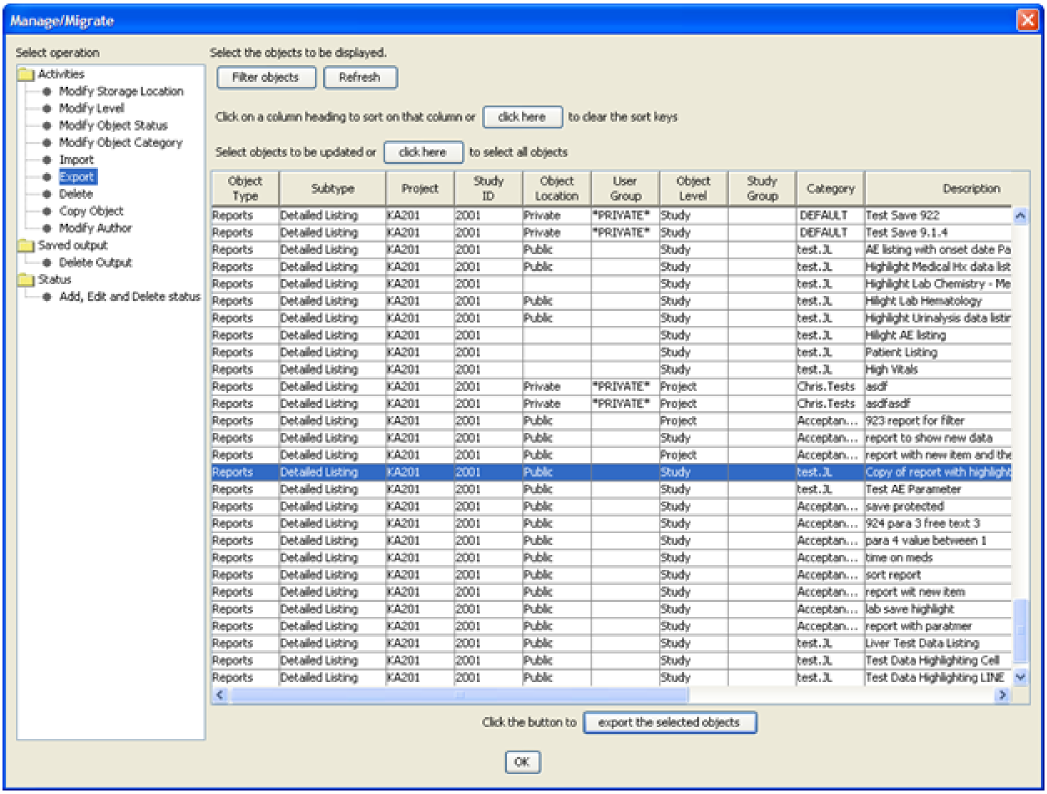
5. Click the **Import selected objects** button. The selected objects are imported.
6. Click **OK** to close.

***Note: If objects are initially saved in a development / sandbox environment and later migrated to a production server - their object index number will change. Also, viewsets within Dashboard cannot be migrated.***

## *Export Object*

Users may export objects as follows:

1. Under the **Activities** folder, select **Export**.
2. Click **Filter objects**. Select objects to filter using any additional information if needed.
3. Click **OK** to generate spreadsheet of filtered objects.
4. Optionally sort columns to locate objects.
5. Select the object row(s) to export.
6. Click the **export selected objects** button.



Select the objects to be displayed.

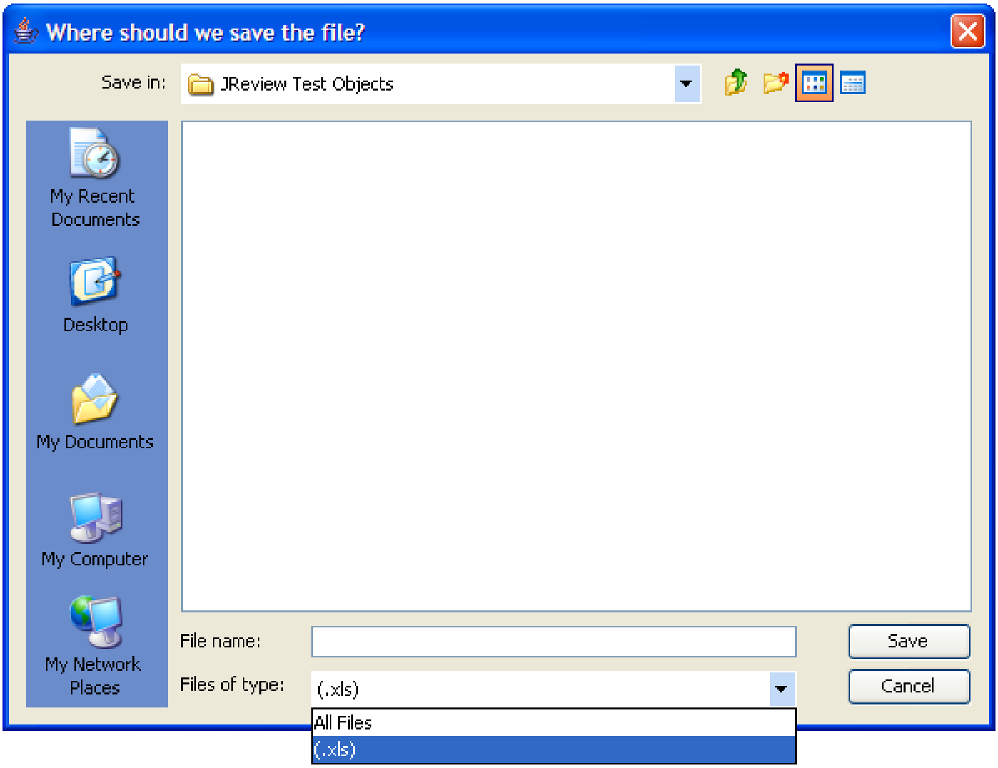
Click on a column heading to sort on that column or click here to clear the sort keys

Select objects to be updated or click here to select all objects

| Object Type | Subtype | Project | Study ID | Object Location | User Group | Object Level | Study Group | Category | Description |
|---|---|---|---|---|---|---|---|---|---|
| Reports | Detailed Listing | KA201 | 2001 | Private | *PRIVATE* | Study | | DEFAULT | Test Save 922 |
| Reports | Detailed Listing | KA201 | 2001 | Private | *PRIVATE* | Study | | DEFAULT | Test Save 9.1.4 |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | test.JL | AE listing with onset date Pa |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | test.JL | Highlight Medical Hx data list |
| Reports | Detailed Listing | KA201 | 2001 | | | Study | | test.JL | Highlight Lab Chemistry - Me |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | test.JL | Hilight Lab Hematology |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | test.JL | Highlight Urinalysis data listir |
| Reports | Detailed Listing | KA201 | 2001 | | | Study | | test.JL | Hilight AE listing |
| Reports | Detailed Listing | KA201 | 2001 | | | Study | | test.JL | Patient Listing |
| Reports | Detailed Listing | KA201 | 2001 | | | Study | | test.JL | High Vitals |
| Reports | Detailed Listing | KA201 | 2001 | Private | *PRIVATE* | Project | | Chris.Tests | asdf |
| Reports | Detailed Listing | KA201 | 2001 | Private | *PRIVATE* | Project | | Chris.Tests | asdfasdf |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Project | | Acceptan... | 923 report for filter |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | Acceptan... | report to show new data |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Project | | Acceptan... | report with new item and the |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | test.JL | Copy of report with highlight |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | test.JL | Test AE Parameter |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | Acceptan... | save protected |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | Acceptan... | 924 para 3 free text 3 |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | Acceptan... | para 4 value between 1 |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | Acceptan... | time on meds |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | Acceptan... | sort report |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | Acceptan... | report wit new item |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | Acceptan... | lab save highlight |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | Acceptan... | report with paratmer |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | test.JL | Liver Test Data Listing |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | test.JL | Test Data Highlighting Cell |
| Reports | Detailed Listing | KA201 | 2001 | Public | | Study | | test.JL | Test Data Highlighting LINE |

Click the button to export the selected objects

Export window opens for “**Where should we save the file?**” Select a destination folder and enter a File Name. The file is exported as **xls**.



## Copy Object

Users may copy objects as follows:

1. Under the **Activities** folder, select **Copy Object**.
2. Click **Filter objects**. Select objects to filter using any additional information if needed.
3. Click OK to generate spreadsheet of filtered objects.
4. Select the object storage level. The default is Study level.
5. Optionally sort columns to locate objects.
6. Select the object row(s) to copy.
7. Click the **copy selected objects** button. An exact copy of the object and description is created and added to the spreadsheet.
8. Optionally, go back to the Activities folder, and modify and activity for the copied object if needed.

## *Document Object*

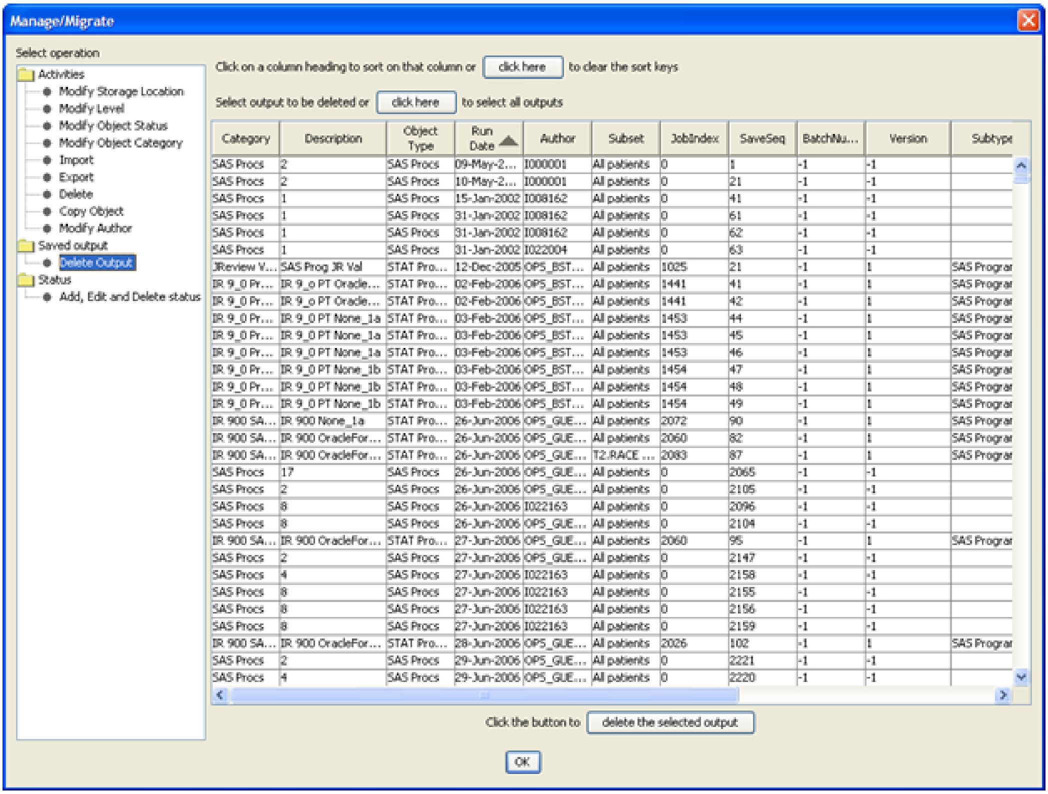
There is the capability accessed from the Manage/Migrate to generate formatted documentation for any JReview reporting object (graphs, crosstabs, reports, patient profiles, RBM definitions). The documentation is stored in an Excel spreadsheet and downloaded to the user's PC.

## *Delete Output*

Users may delete saved output as follows:

1. Under the **Saved Output** folder, select **Delete Output**.

   The spreadsheet displays with the saved output scheduled information.
2. Optionally sort columns to locate objects.
3. Select the object row(s) to delete.
4. Click **delete the selected output** button.
5. Click **OK** to close activity.



Click on a column heading to sort on that column or click here to clear the sort keys

Select output to be deleted or click here to select all outputs

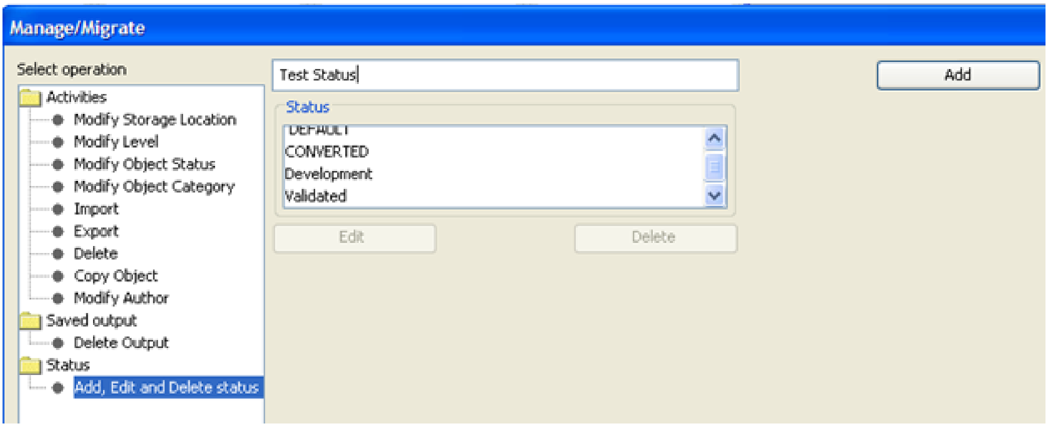
| Category | Description | Object Type | Run Date | Author | Subset | JobIndex | SaveSeq | BatchNu... | Version | Subtype |
|---|---|---|---|---|---|---|---|---|---|---|
| SAS Procs | 2 | SAS Procs | 09-May-2... | I000001 | All patients | 0 | 1 | -1 | -1 | |
| SAS Procs | 2 | SAS Procs | 10-May-2... | I000001 | All patients | 0 | 21 | -1 | -1 | |
| SAS Procs | 1 | SAS Procs | 15-Jan-2002 | I008162 | All patients | 0 | 41 | -1 | -1 | |
| SAS Procs | 1 | SAS Procs | 31-Jan-2002 | I008162 | All patients | 0 | 61 | -1 | -1 | |
| SAS Procs | 1 | SAS Procs | 31-Jan-2002 | I008162 | All patients | 0 | 62 | -1 | -1 | |
| SAS Procs | 1 | SAS Procs | 31-Jan-2002 | I022004 | All patients | 0 | 63 | -1 | -1 | |
| JReview V... | SAS Prog JR Val | STAT Pro... | 12-Dec-2005 | OPS_BST... | All patients | 1025 | 21 | -1 | 1 | SAS Progra |
| IR 9_0 Pr... | IR 9_o PT Oracle... | STAT Pro... | 02-Feb-2006 | OPS_BST... | All patients | 1441 | 41 | -1 | 1 | SAS Progra |
| IR 9_0 Pr... | IR 9_o PT Oracle... | STAT Pro... | 02-Feb-2006 | OPS_BST... | All patients | 1441 | 42 | -1 | 1 | SAS Progra |
| IR 9_0 Pr... | IR 9_0 PT None_1a | STAT Pro... | 03-Feb-2006 | OPS_BST... | All patients | 1453 | 44 | -1 | 1 | SAS Progra |
| IR 9_0 Pr... | IR 9_0 PT None_1a | STAT Pro... | 03-Feb-2006 | OPS_BST... | All patients | 1453 | 45 | -1 | 1 | SAS Progra |
| IR 9_0 Pr... | IR 9_0 PT None_1a | STAT Pro... | 03-Feb-2006 | OPS_BST... | All patients | 1453 | 46 | -1 | 1 | SAS Progra |
| IR 9_0 Pr... | IR 9_0 PT None_1b | STAT Pro... | 03-Feb-2006 | OPS_BST... | All patients | 1454 | 47 | -1 | 1 | SAS Progra |
| IR 9_0 Pr... | IR 9_0 PT None_1b | STAT Pro... | 03-Feb-2006 | OPS_BST... | All patients | 1454 | 48 | -1 | 1 | SAS Progra |
| IR 9_0 Pr... | IR 9_0 PT None_1b | STAT Pro... | 03-Feb-2006 | OPS_BST... | All patients | 1454 | 49 | -1 | 1 | SAS Progra |
| IR 900 SA... | IR 900 None_1a | STAT Pro... | 26-Jun-2006 | OPS_GUE... | All patients | 2072 | 90 | -1 | 1 | SAS Progra |
| IR 900 SA... | IR 900 OracleFor... | STAT Pro... | 26-Jun-2006 | OPS_GUE... | All patients | 2060 | 82 | -1 | 1 | SAS Progra |
| IR 900 SA... | IR 900 OracleFor... | STAT Pro... | 26-Jun-2006 | OPS_GUE... | T2.RACE ... | 2083 | 87 | -1 | 1 | SAS Progra |
| SAS Procs | 17 | SAS Procs | 26-Jun-2006 | OPS_GUE... | All patients | 0 | 2065 | -1 | -1 | |
| SAS Procs | 2 | SAS Procs | 26-Jun-2006 | OPS_GUE... | All patients | 0 | 2105 | -1 | -1 | |
| SAS Procs | 8 | SAS Procs | 26-Jun-2006 | I022163 | All patients | 0 | 2096 | -1 | -1 | |
| SAS Procs | 8 | SAS Procs | 26-Jun-2006 | OPS_GUE... | All patients | 0 | 2104 | -1 | -1 | |
| IR 900 SA... | IR 900 OracleFor... | STAT Pro... | 27-Jun-2006 | OPS_GUE... | All patients | 2060 | 95 | -1 | 1 | SAS Progra |
| SAS Procs | 2 | SAS Procs | 27-Jun-2006 | OPS_GUE... | All patients | 0 | 2147 | -1 | -1 | |
| SAS Procs | 4 | SAS Procs | 27-Jun-2006 | I022163 | All patients | 0 | 2158 | -1 | -1 | |
| SAS Procs | 8 | SAS Procs | 27-Jun-2006 | I022163 | All patients | 0 | 2155 | -1 | -1 | |
| SAS Procs | 8 | SAS Procs | 27-Jun-2006 | I022163 | All patients | 0 | 2156 | -1 | -1 | |
| SAS Procs | 8 | SAS Procs | 27-Jun-2006 | I022163 | All patients | 0 | 2159 | -1 | -1 | |
| IR 900 SA... | IR 900 OracleFor... | STAT Pro... | 28-Jun-2006 | OPS_GUE... | All patients | 2026 | 102 | -1 | 1 | SAS Progra |
| SAS Procs | 2 | SAS Procs | 29-Jun-2006 | OPS_GUE... | All patients | 0 | 2221 | -1 | -1 | |
| SAS Procs | 4 | SAS Procs | 29-Jun-2006 | OPS_GUE... | All patients | 0 | 2220 | -1 | -1 | |

Click the button to delete the selected output

## *Manage Status*

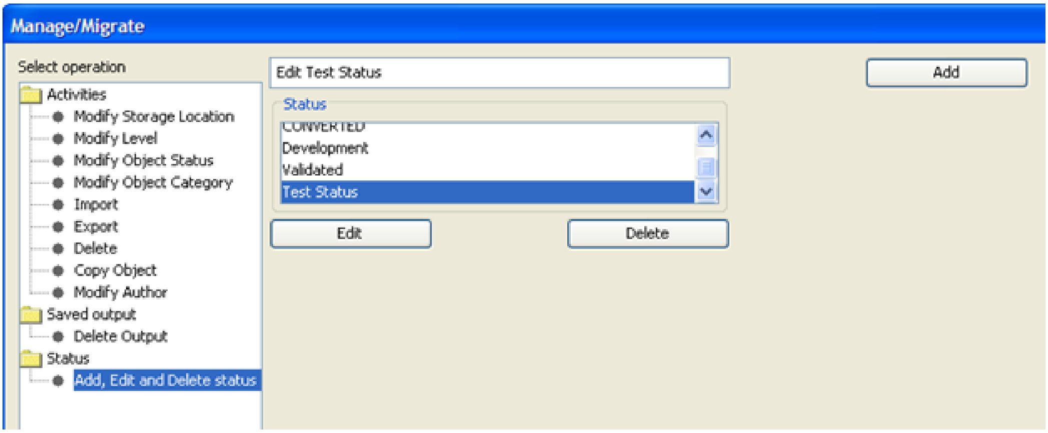
Only Super Users are allowed access to change an object status and add, edit, or delete available status options. A watermark may be entered into ReviewAdmin associated to a particular status. The watermark may only be applied to a PDF, such as formatted reports and formatted patient profiles.

1. Under the **Status folder**, select Add, Edit, and Delete status.
2. In the text box, enter a new Status. Click **Add**. The status is added.



Test Status

3. To edit an existing status, select it from the Status list and enter the changed description in the text box. Click **Edit**. The changed status description is applied to the Status list.



Edit Test Status

4. To delete a status, select it from the Status list. Click **Delete**. The status is removed from the Status list.
5. Click **OK** to close the activity window.

# Alerts Browser

## *What are alerts?*

An alert is an object that checks data for a specific condition using an output filter. Alerts are scheduled to execute like other objects and check the data. When the alert executes and the condition is true (the filter produces output), the alert is said to be “triggered” and produces a message. This message can be viewed in Integrated Review and can also be E-mailed to Integrated Review users.

Alerts are created and saved using the Alerts Browser window and are displayed in the Object Explorer in a special category named “ Alerts” located first in the list.

Alerts are scheduled from the Object Explorer like other objects and are displayed in the Schedule tab in a special category named “ Alerts”.

The output from alerts and objects executed by alerts can be accessed in the Review Output tab, once again in the “ Alerts” category.

A privilege setting [P36] is required to run the Alerts Browser, to view and schedule alerts in the Object Explorer, and to view the output from alerts in the Review Output tab.

In addition, access to alerts and their output can be controlled by User Group membership.

The Alerts Browser contains tab pages to define an alert and its characteristics. Alerts consist of an alert filter, an operation mode setting, a text message and optionally, an JReview object to execute. The following sections describe the various tab pages and their functions for defining alerts.

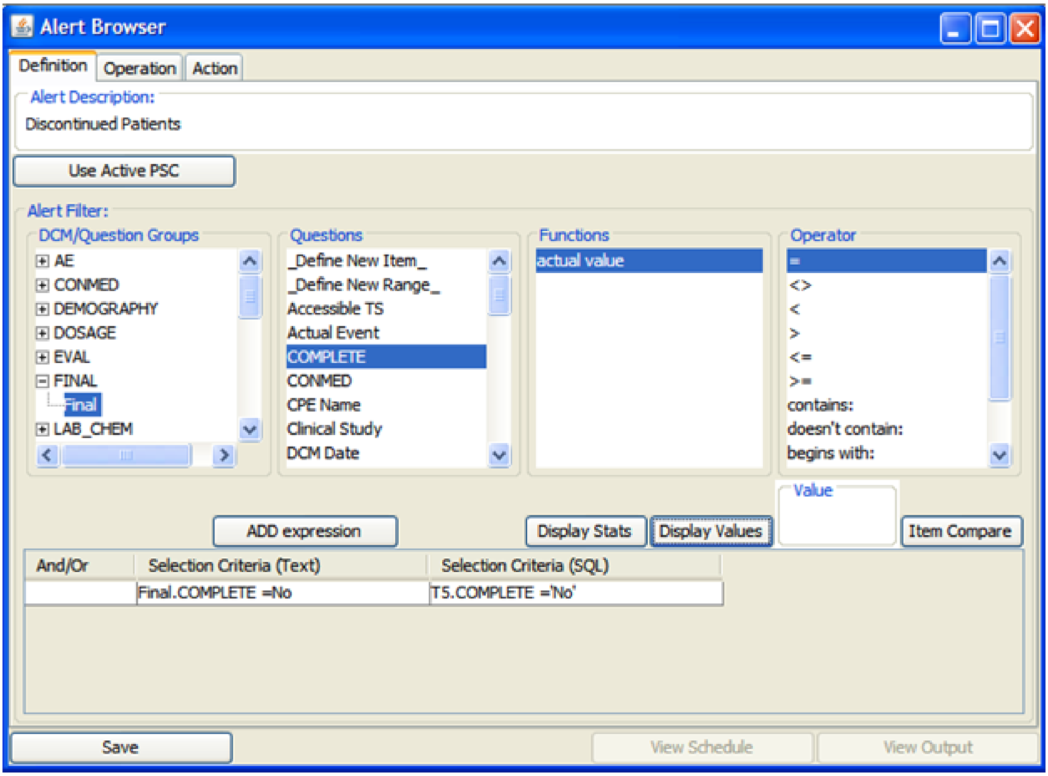
## *Definition tab*

Each tab displays a set of related fields which contain all of the information for a particular alert. In addition to the tabs, the Alerts Browser has four buttons which functions as follows:

- **Save** button opens the Save Object dialog.
- **Filter** button opens the Alert Filter window.
- **View Schedule** button opens the Alert Schedule window.
- **View Output** button opens the Alert Output window.

1. To open the **Alerts Browser**, click ! in the toolbar, or from the **Browse** menu, select **Alerts**.

   The **Alert Registration window** opens displaying three tabs.
2. Enter a **Description** for the Alert as the descriptive name. This can be up to 60 characters.
3. You can either use the current selection criteria in the PSC window and click **Use Active PSC** button. It allows the user to use the active Patient Selection Criteria as the alert filter. The current PSC will be copied into the Alert Filter Criteria Defintion window. Or the user can define a filter criteria directly within the Alert Definiton window.



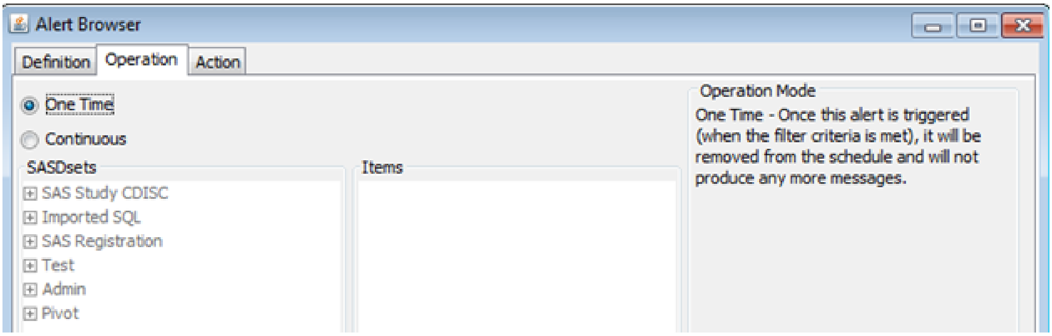
Alert Description:
Discontinued Patients

| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
|  | Final.COMPLETE =No | T5.COMPLETE ='No' |

## *Operation tab*

4. Next click the **Operation tab**. You need to determine the **Frequency** to run the alert. The **Frequency** determines if the alert will only be triggered once, or will continue to remain in the schedule each time after it is triggered.

   **One Time mode** means that the first time the alert is triggered. It will be removed from the schedule.



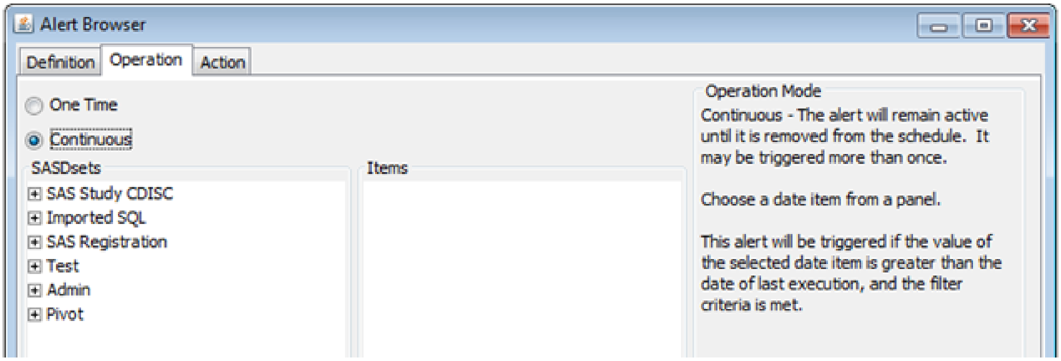
● One Time

○ Continuous

Operation Mode

One Time - Once this alert is triggered (when the filter criteria is met), it will be removed from the schedule and will not produce any more messages.

**Continuous mode** means that in addition to the criteria specified in the alert filter, the alert will not be triggered unless the date item chosen is later than the last date the alert was executed. The alert remains active until it is deactivated on the Schedule tab.



○ One Time

● Continuous

Operation Mode

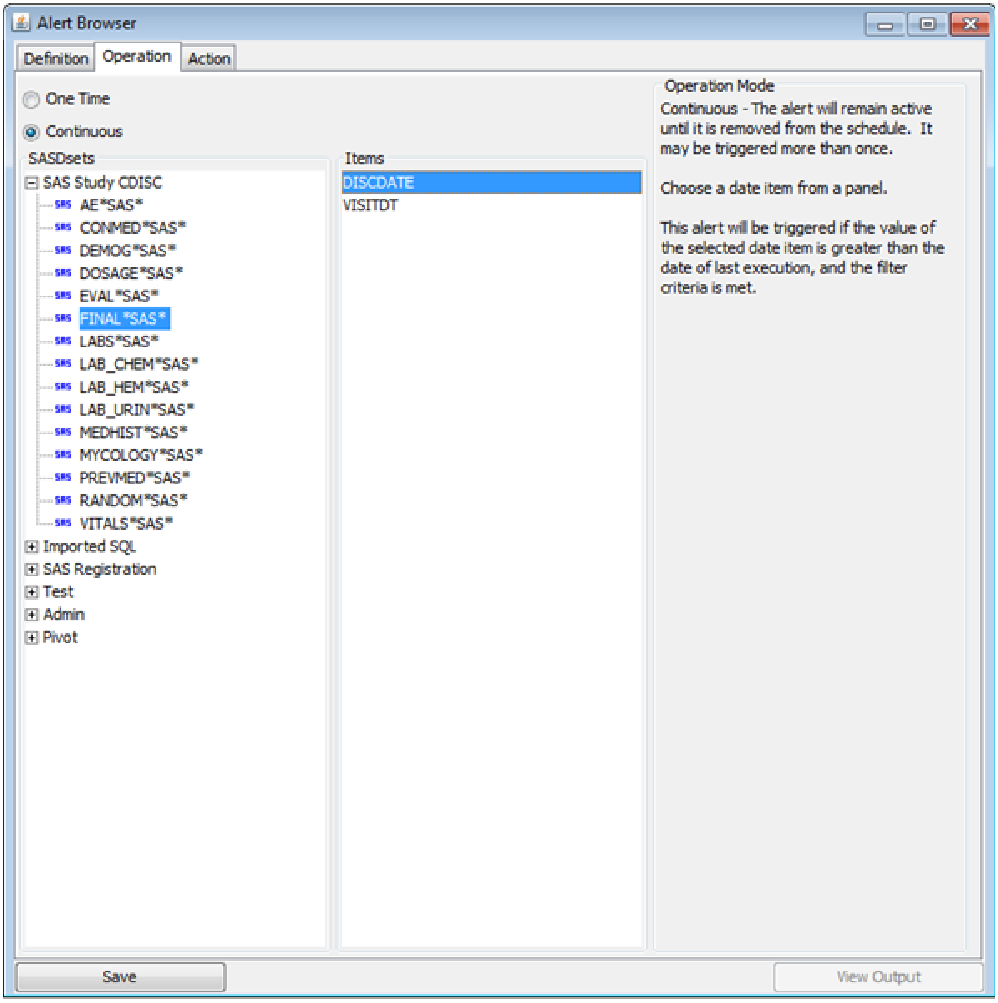
Continuous - The alert will remain active until it is removed from the schedule. It may be triggered more than once.

Choose a date item from a panel.

This alert will be triggered if the value of the selected date item is greater than the date of last execution, and the filter criteria is met.

5. Select a **Frequency mode**. If you select Continuous mode, a date item is required to trigger the alert.
   - **Panel** indicates the panel name for the date item to be used for Continuous mode.
   - **Item** is the date item in the panel to be used for Continuous mode.
   - **Operation Mode** describes the selected operation mode.

6. Select a panel and item for date.



○ One Time

● Continuous

Operation Mode

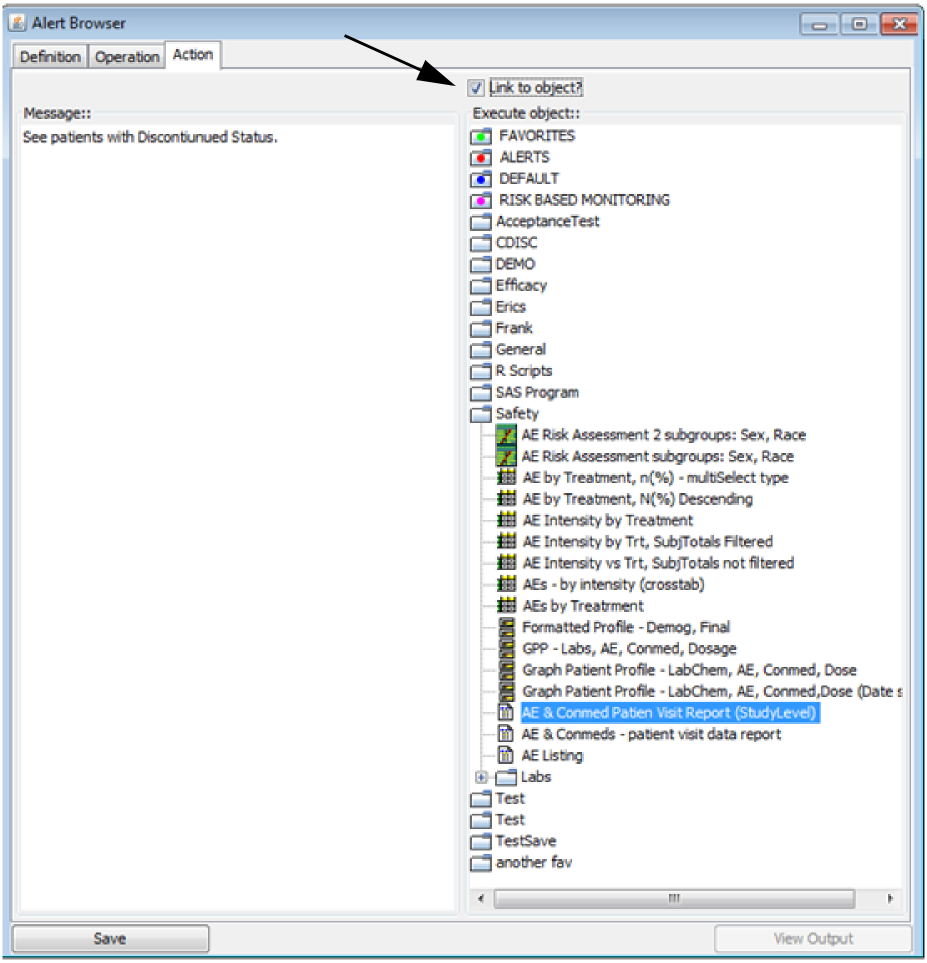
Continuous - The alert will remain active until it is removed from the schedule. It may be triggered more than once.

Choose a date item from a panel.

This alert will be triggered if the value of the selected date item is greater than the date of last execution, and the filter criteria is met.

## *Action tab*

7. Click the **Action tab**.
8. Enter a text **Message** that is produced when the alert is triggered.
9. Click **Link to object** box (optional), when checked indicates that a stored object will be executed when the alert is triggered.
10. Select an **Execute object** when **Link to object** is checked ON. The list displays available objects to be executed.

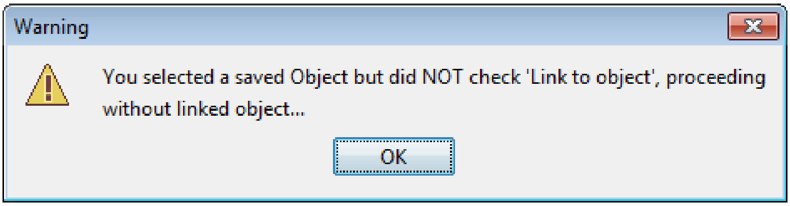


Message:: See patients with Discontiunued Status.

☑ Link to object?

Execute object:: AE & Conmed Patien Visit Report (StudyLevel)

A warning message will display if you select a saved object but did not check 'Link to object' check box ON.


Warning

You selected a saved Object but did NOT check 'Link to object', proceeding without linked object...

The following Object types are excluded from the list of choices for **Link to Object:**

- Alerts
- Patient Selection Criteria
- Visual Subsets
- Patient Profiles
- Object Groups
- SAS Programs
- SAS Program Groups

Objects that are checked and excluded at save-time (because they are sub-types of another object type) are:

- Patient Visit Reports
- Shift Tables

**All other objects are allowed to be linked to an alert including reports with runtime parameters.**

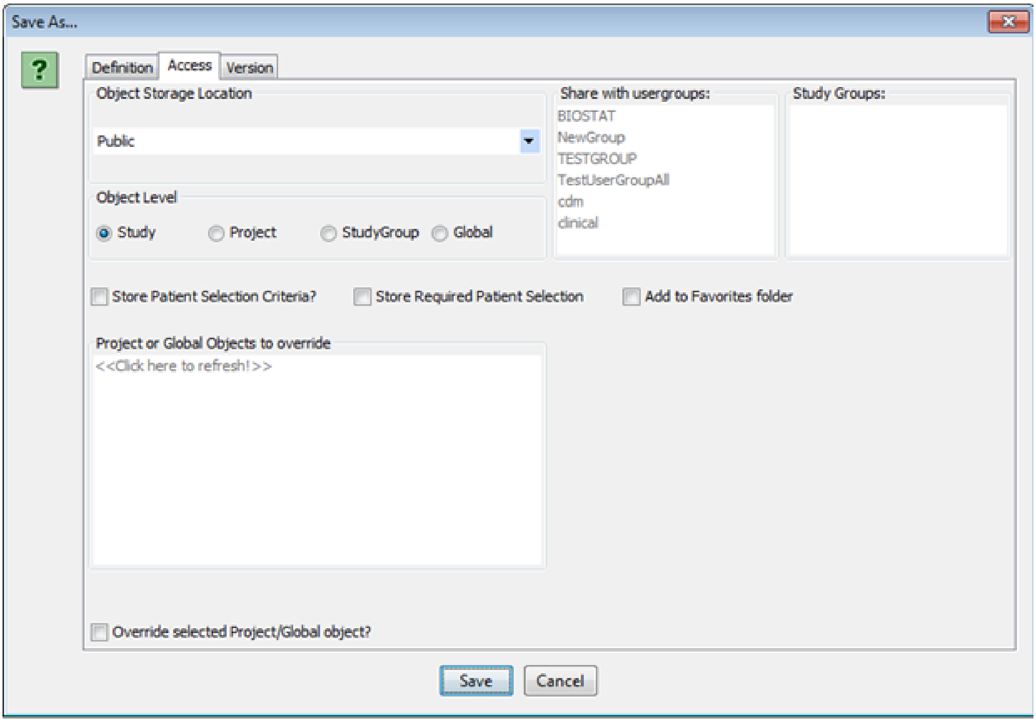
If you click **Save** before entering a text message the following message window displays.


Integrated Review

Please provide a message text

11. Click **Save**. The Save window opens for you to enter the alert object specifications. *(See previous section: Save the object specification)*

The alert object is saved to the Alerts category in the **Object Explorer** window. If you enter another category on the **Definition tab,** this category is added as a subcategory under the default Alerts category.



Object Storage Location: Public

Object Level: ● Study ○ Project ○ StudyGroup ○ Global

Share with usergroups:
BIOSTAT
NewGroup
TESTGROUP
TestUserGroupAll
cdm
clinical

Study Groups:

☐ Store Patient Selection Criteria? ☐ Store Required Patient Selection ☐ Add to Favorites folder

Project or Global Objects to override
<<Click here to refresh!>>

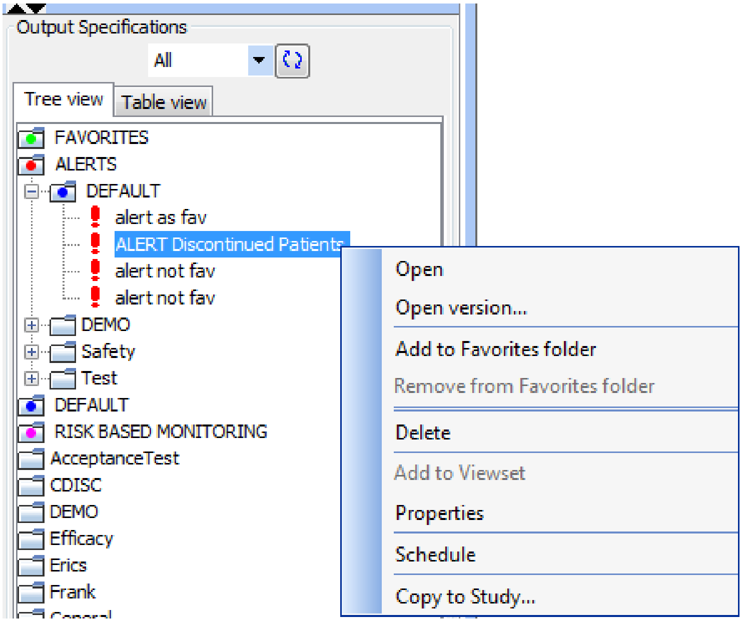
☐ Override selected Project/Global object?

## *Alert activation*

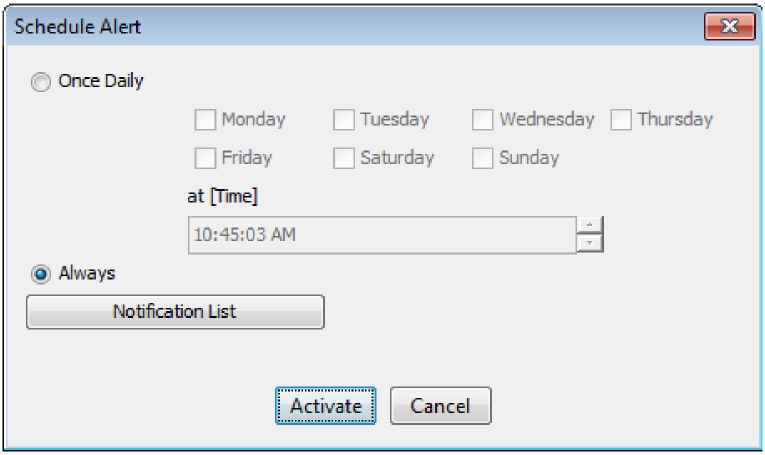
Once the alert object is saved, you can activate it with your defined operation settings by scheduling the alert. The Alert **View Schedule** window displays the current schedule entries for an alert. If there are no schedule entries, the View Schedule button is disabled.

You activate the alert object by scheduling it the same as other objects.

1. Select the alert object in ALERTS in the **Object Explorer window**.
2. Right-mouse click to display a floating menu.

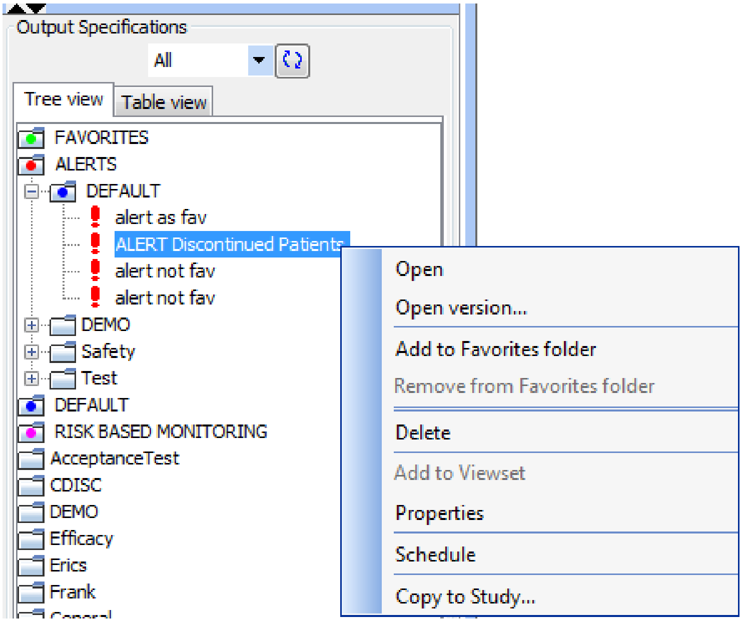


3. Click **Schedule**. The **Schedule Alert** window displays for Job Scheduling.

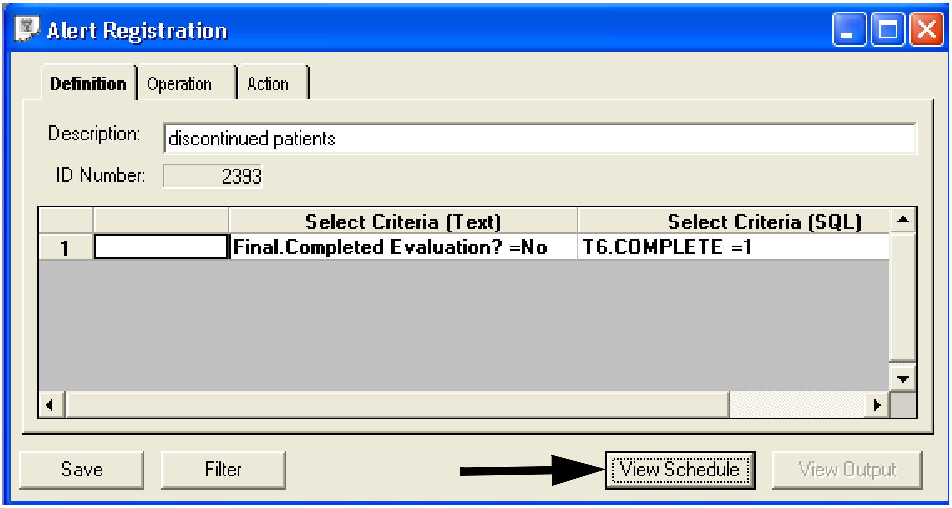


4. Enter when to activate the alert as **Once Daily** with a time or **Always**.
5. Click the **Notification List** and select users to notify.
6. Click **Activate** to schedule the alert.

7. You may enter an Email address from the **Edit** menu when you select **Preferences.**
8. To view the alert schedule, select the alert object in the Alerts category in the **Object Explorer** window.
9. Right-mouse click to display a floating menu and click **Open**.



The **Alert Registration** window opens and the **View Schedule** button is now enabled.

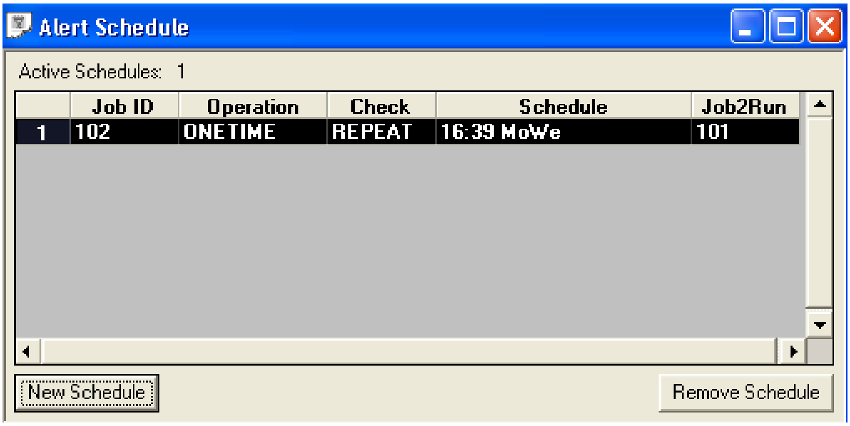


Description: discontinued patients

ID Number: 2393

|  |  | Select Criteria (Text) | Select Criteria (SQL) |
|---|---|---|---|
| 1 |  | Final.Completed Evaluation? =No | T6.COMPLETE =1 |

10. Click the **View Schedule** button to open the **Alert Schedule** window.



|  | Job ID | Operation | Check | Schedule | Job2Run |
|---|---|---|---|---|---|
| 1 | 102 | ONETIME | REPEAT | 16:39 MoWe | 101 |

11. Select an alert job entry and click the **Remove Schedule** button to remove the alert job, or click the **New Schedule** button to change the alert job schedule.

## *Alert output*

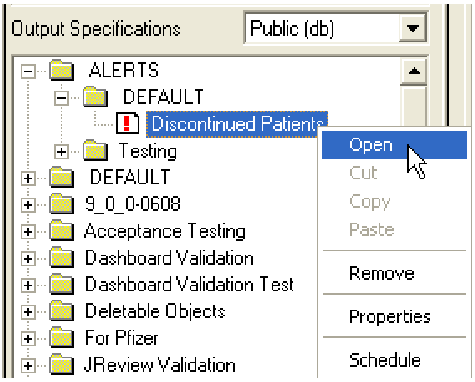
If any new alerts were triggered since your last login, the following message displays.

Integrated Review

New Alerts since last login

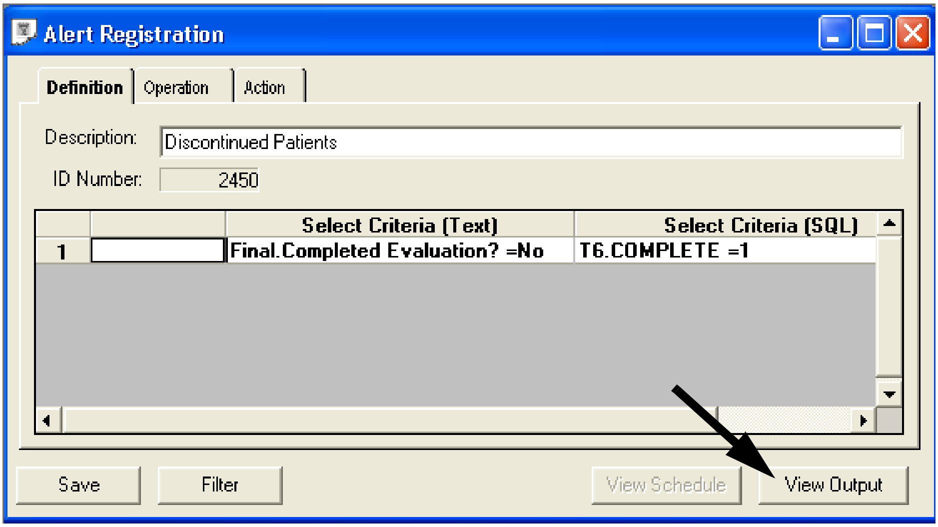
You view an alert object the same as other objects.

1. Select the alert object in the Alerts category in the **Object Explorer window**.
2. Right-mouse click to display a floating menu and click **Open**.



Output Specifications: Public (db)

The **Alert Registration** window displays for Job Scheduling.



Description: Discontinued Patients

ID Number: 2450

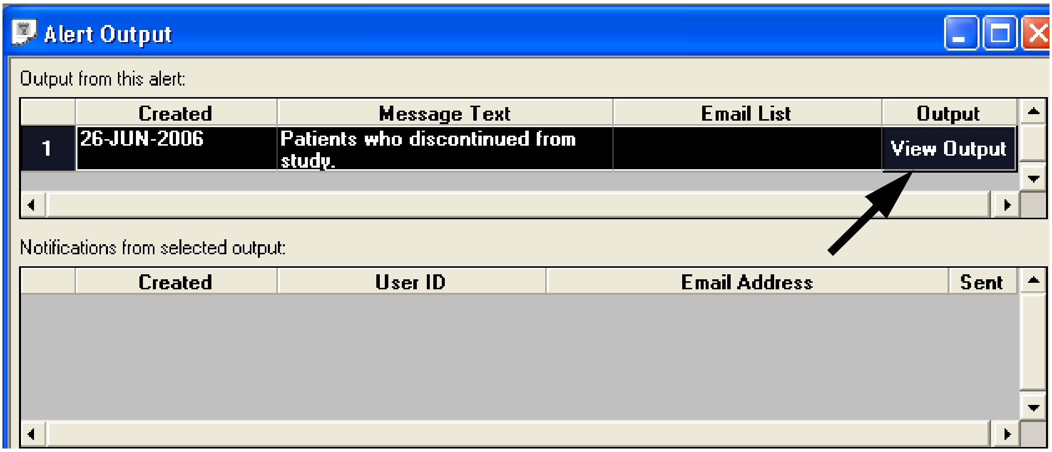
|  |  | Select Criteria (Text) | Select Criteria (SQL) |
|---|---|---|---|
| 1 |  | Final.Completed Evaluation? =No | T6.COMPLETE =1 |

3. Click the **View Output** button.

   The **Alert Output** window displays any messages produced by an alert. If another object was linked to the alert that produced output, a **View Output** button displays in the last column.

   When an output line is highlighted, if any E-mail notifications were attempted, they are displayed in the lower part of the window. The last columns, labeled “Sent” indicates whether or not the E-mail was successfully sent.

4. Click on the **View Output** button to view that object’s output.



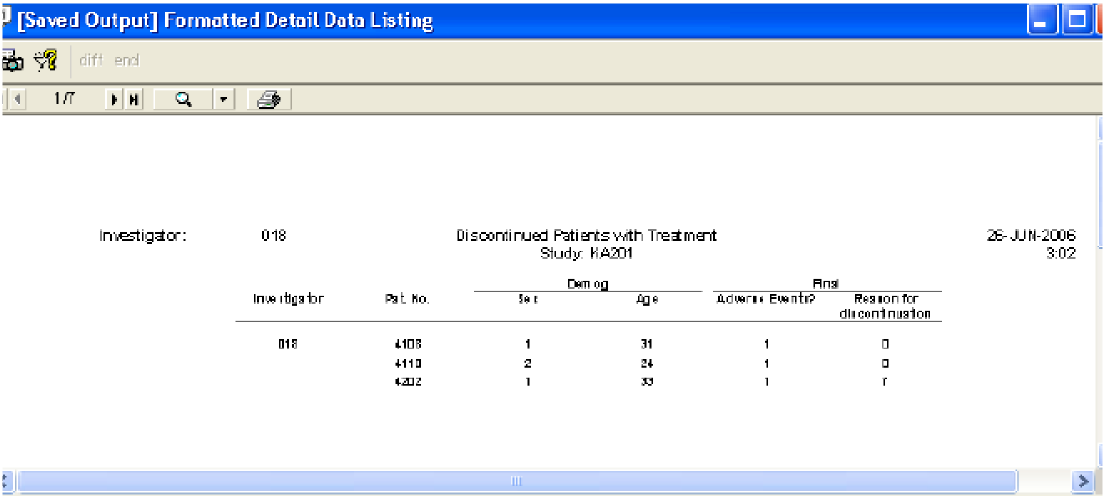
Output from this alert:

|  | Created | Message Text | Email List | Output |
|---|---|---|---|---|
| 1 | 26-JUN-2006 | Patients who discontinued from study. |  | View Output |

Notifications from selected output:

|  | Created | User ID | Email Address | Sent |
|---|---|---|---|---|

The object output which was linked to the alert trigger opens.



Investigator: 018

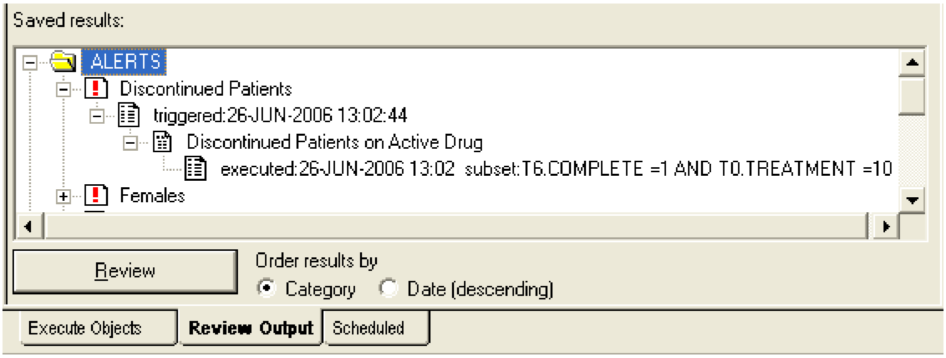
Discontinued Patients with Treatment
Study: KA201

26-JUN-2006
3:02

| Investigator | Pat. No. | Demog<br>Sex | Age | Final<br>Adverse Event? | Reason for discontinuation |
|---|---|---|---|---|---|
| 018 | 4108 | 1 | 31 | 1 | 0 |
|  | 4110 | 2 | 24 | 1 | 0 |
|  | 4202 | 1 | 33 | 1 | 7 |

Another way to view the alert object output, particularly when there are multiple output results from an alert activated as continuous:

1. Click the **Review Output tab** at the bottom of the Object Explorer window to view saved output. The stored output results are saved with the date/time stamp and author who submitted the job.
2. Single click to open the Alerts category and open the particular alert trigger object.
3. Either highlight the output description and click the **Review** button or double click on the description to view output.



# 12 Advanced functions

# Define Join Logic

## *User-defined logical joins*

If the default join logic used by JReview is not appropriate for a pair of tables, you can specify the join logic  between the tables.

A common usage of this utility is to define join logic between the Dosage panel’s Start Date item as “>=” the Adverse Event panel’s Onset Date item. This, and any logical join can be defined by the end-user at any time. Thus, the end-user can define joins 'on the fly'.

The Define Join Logic works with only two tables at a time defining the join logic between those two tables only. The system can then pick up the join pairs as needed.

## *Logical joins with Clintrial Type 0*

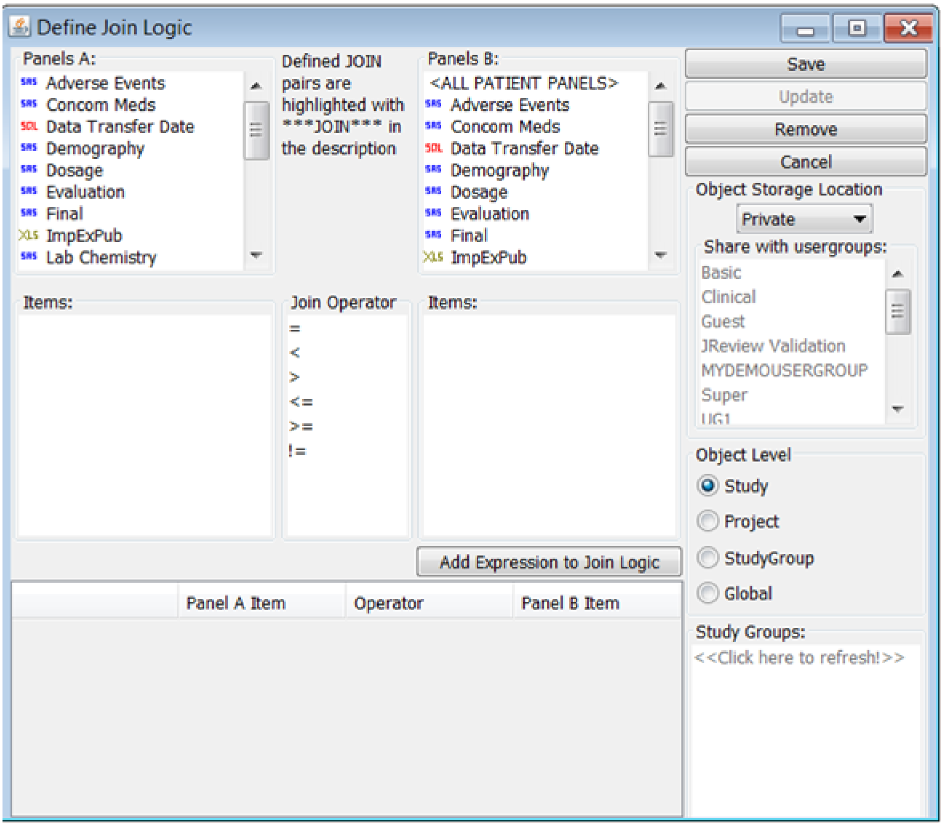
This is a necessary utility in the join logic and utilization of a Clintrial Type 0 panel. The Type 0 panels don't have typical context items, and are typically non-patient data.

## *BaselineKey*

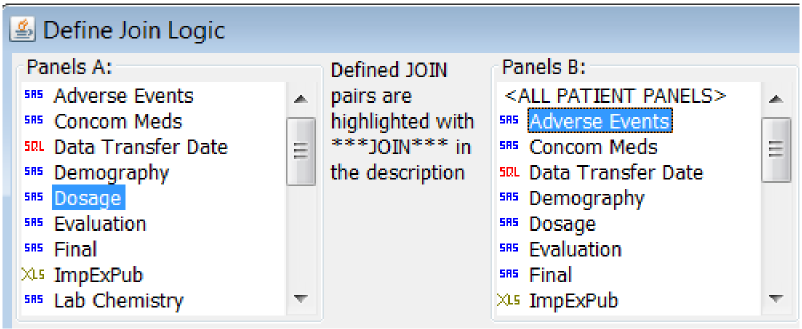
Baseline join logic has added ability to specify additional ‘BLKEY’ (BaselineKey) for any table in a study, also a expected Frequency=4, when adding config.options BLJOIN; keyword parameter.  Then the additional BaselineKey item is added to the join logic when the baseline view of the table is self joined to itself for baseline, chg from baseline, etc.  This is necessary for multiple rows per visit, such as Labs, Scales, etc.

## *Creating logical joins*

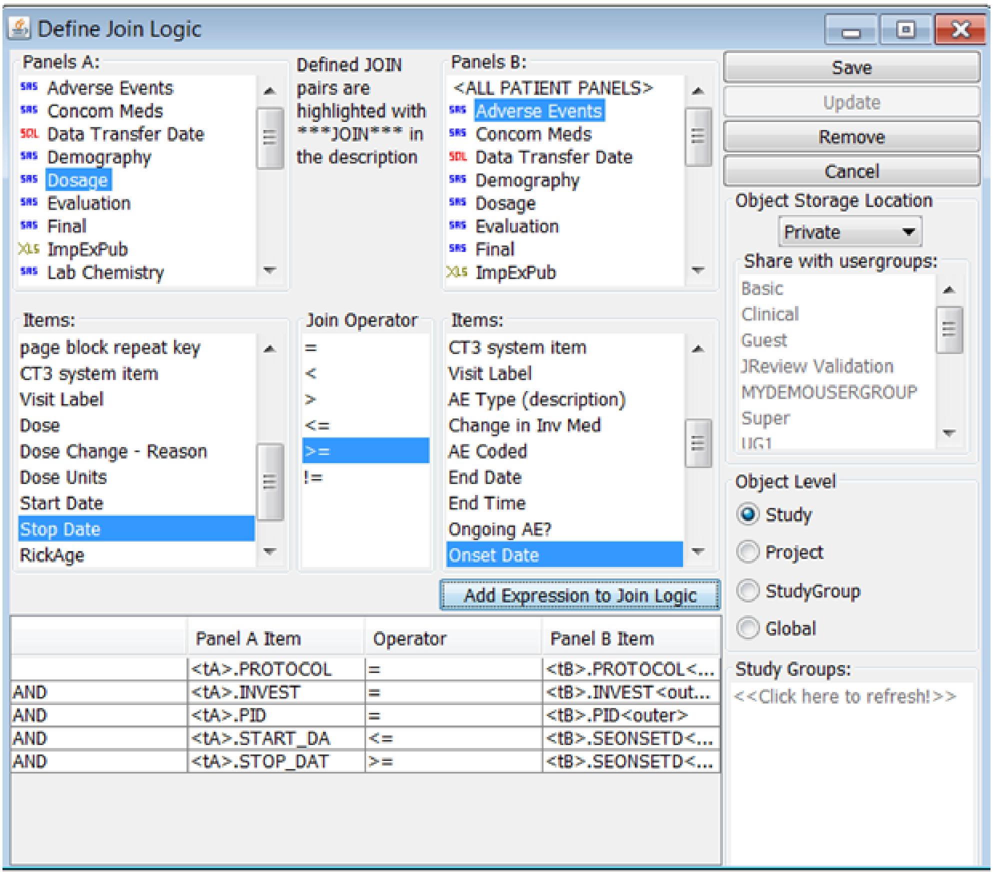
1. From the Advanced menu in the tool bar, select **Define Join Logic**. The Define Join Logic window opens listing all panels in lists A and B.



2. Select and click on the panels that you would like to join.



3. Select and click on items and join operators, defining relational joins.
4. Then click **Add Expression to Join Logic** to build the logic for the join between the selected panels.



Defined JOIN pairs are highlighted with ***JOIN*** in the description

| | Panel A Item | Operator | Panel B Item |
|---|---|---|---|
| | <tA>.PROTOCOL | = | <tB>.PROTOCOL<... |
| AND | <tA>.INVEST | = | <tB>.INVEST<out... |
| AND | <tA>.PID | = | <tB>.PID<outer> |
| AND | <tA>.START_DA | <= | <tB>.SEONSETD<... |
| AND | <tA>.STOP_DAT | >= | <tB>.SEONSETD<... |

Object Storage Location: Private

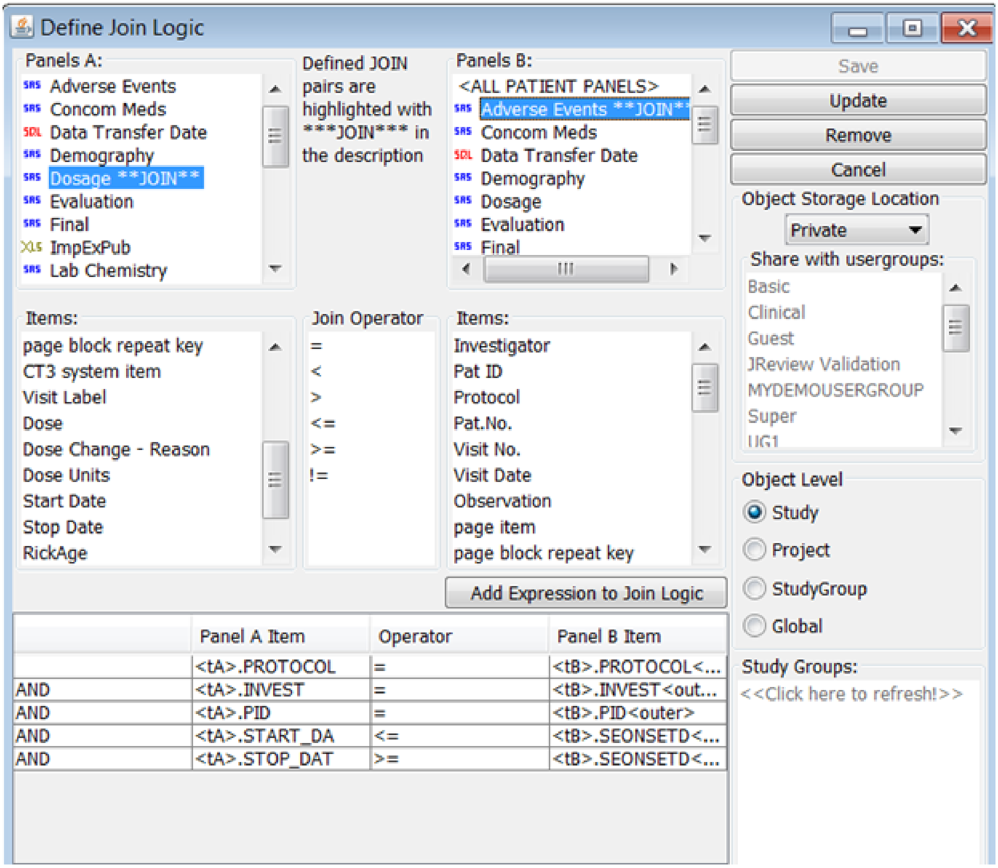
Object Level:
● Study
○ Project
○ StudyGroup
○ Global

## *Global object storage of join logic*

5. Define the **Object Store** as Private, UserGroup or Public. Select UserGroup and optionally share with multiple UserGroups is supported. The default is private and will allow access only to the author.
6. **Object Level** supports Study, Project, StudyGroup, and Global. Optionally, select 'All Studies' for a Public or UserGroup level join definition as a 'Global Join Define' all studies definition. Multiple StudyGroups may be selected.

7. Click **Save** and view message for ‘Join saved’. Click **OK**.

   Once the Define Join Logic has been saved, the defined JOIN pairs are highlighted in the description with ‘***JOIN***’. You must click on the ‘A’ panel with ‘***JOIN***’ description to list corresponding ‘B’ panel.



Defined JOIN pairs are highlighted with ***JOIN*** in the description

Object Storage Location: Private

Object Level: ● Study ○ Project ○ StudyGroup ○ Global

| | Panel A Item | Operator | Panel B Item |
|---|---|---|---|
| | <tA>.PROTOCOL | = | <tB>.PROTOCOL<... |
| AND | <tA>.INVEST | = | <tB>.INVEST<out... |
| AND | <tA>.PID | = | <tB>.PID<outer> |
| AND | <tA>.START_DA | <= | <tB>.SEONSETD<... |
| AND | <tA>.STOP_DAT | >= | <tB>.SEONSETD<... |

## *Update or Remove Join Logic*

8. From the Advanced menu in the tool bar, select **Define Join Logic**
9. Select the joined panels pair. Enter changes if needed.
10. Click **Update** or **Remove**.

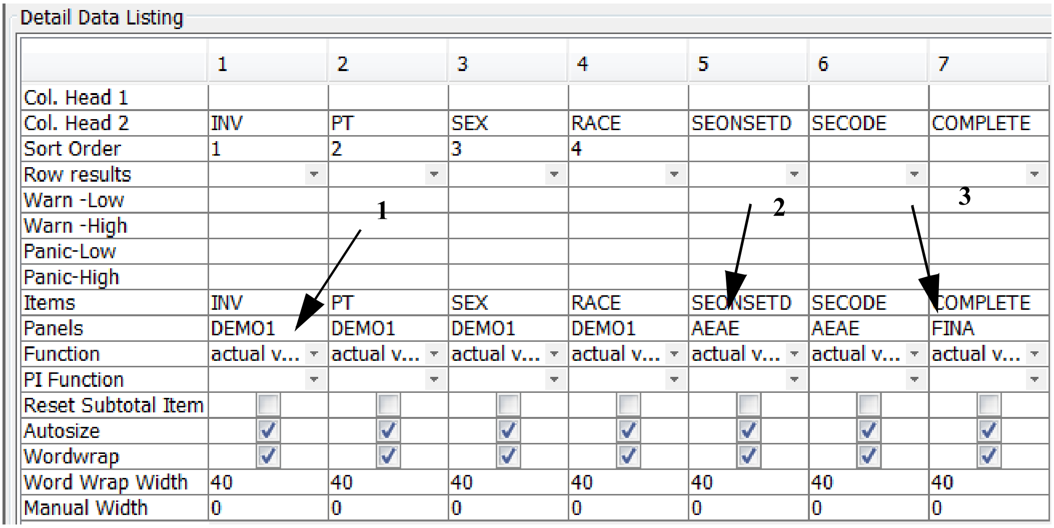
# Join Order

## *Join order in multi-panel reports*

By default, the Join Order of a multi-panel detail data listing report is ordered by the sequence in which you selected panels and items. The patient records displayed in the report are determined by the first panel selected, for example a head to tail linkage.

Instead of creating multiple reports to obtain different patients in the output, simply change the Join Order of the report and save for your different output requirements.

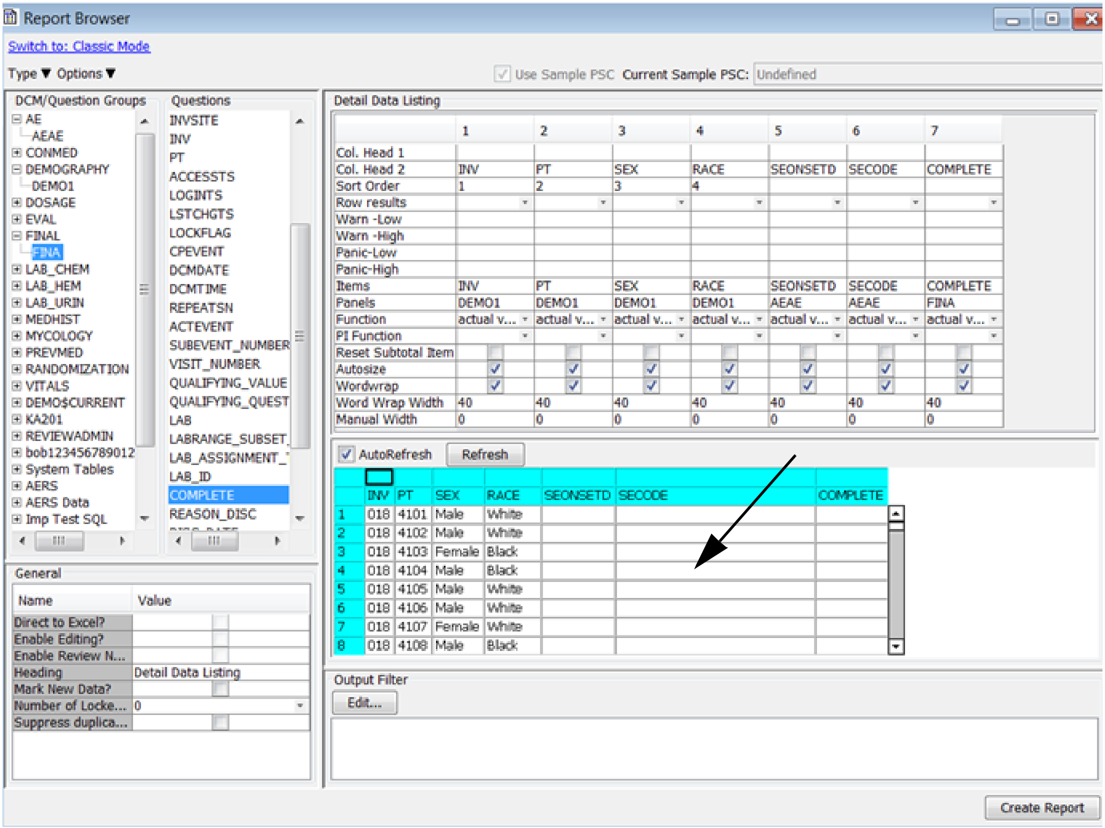
For example, if you create a multi-panel detail data listing with panels selected in the order first *Demography* and second *Adverse Events* then *Final*, the join order will default in the same sequence.



Detail Data Listing

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | | |
| Col. Head 2 | INV | PT | SEX | RACE | SEONSETD | SECODE | COMPLETE |
| Sort Order | 1 | 2 | 3 | 4 | | | |
| Row results | | | | | | | |
| Warn -Low | | | | | | | |
| Warn -High | | | | | | | |
| Panic-Low | | | | | | | |
| Panic-High | | | | | | | |
| Items | INV | PT | SEX | RACE | SEONSETD | SECODE | COMPLETE |
| Panels | DEMO1 | DEMO1 | DEMO1 | DEMO1 | AEAE | AEAE | FINA |
| Function | actual v... | actual v... | actual v... | actual v... | actual v... | actual v... | actual v... |
| PI Function | | | | | | | |
| Reset Subtotal Item | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Autosize | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Wordwrap | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Word Wrap Width | 40 | 40 | 40 | 40 | 40 | 40 | 40 |
| Manual Width | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

When the report is created, all patients with demography panels will display in the report even if they do not have Adverse Events records.



☑ Use Sample PSC **Current Sample PSC:** Undefined

Detail Data Listing

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | | |
| Col. Head 2 | INV | PT | SEX | RACE | SEONSETD | SECODE | COMPLETE |
| Sort Order | 1 | 2 | 3 | 4 | | | |
| Row results | | | | | | | |
| Warn -Low | | | | | | | |
| Warn -High | | | | | | | |
| Panic-Low | | | | | | | |
| Panic-High | | | | | | | |
| Items | INV | PT | SEX | RACE | SEONSETD | SECODE | COMPLETE |
| Panels | DEMO1 | DEMO1 | DEMO1 | DEMO1 | AEAE | AEAE | FINA |
| Function | actual v... | actual v... | actual v... | actual v... | actual v... | actual v... | actual v... |
| PI Function | | | | | | | |
| Reset Subtotal Item | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Autosize | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Wordwrap | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Word Wrap Width | 40 | 40 | 40 | 40 | 40 | 40 | 40 |
| Manual Width | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

☑ AutoRefresh Refresh

| | INV | PT | SEX | RACE | SEONSETD | SECODE | COMPLETE |
|---|---|---|---|---|---|---|---|
| 1 | 018 | 4101 | Male | White | | | |
| 2 | 018 | 4102 | Male | White | | | |
| 3 | 018 | 4103 | Female | Black | | | |
| 4 | 018 | 4104 | Male | Black | | | |
| 5 | 018 | 4105 | Male | White | | | |
| 6 | 018 | 4106 | Male | White | | | |
| 7 | 018 | 4107 | Female | White | | | |
| 8 | 018 | 4108 | Male | Black | | | |

Output Filter

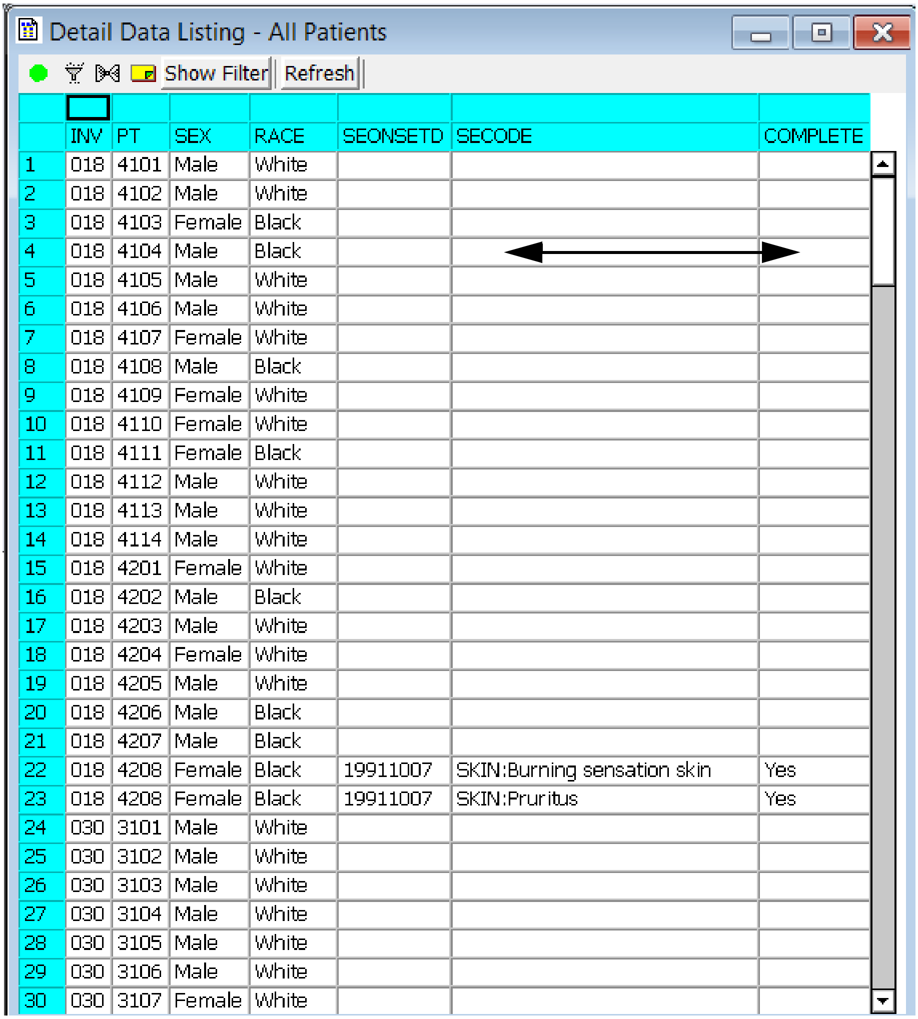
Edit...

General

| Name | Value |
|---|---|
| Direct to Excel? | ☐ |
| Enable Editing? | ☐ |
| Enable Review N... | ☐ |
| Heading | Detail Data Listing |
| Mark New Data? | ☐ |
| Number of Locke... | 0 |
| Suppress duplica... | ☐ |

Had you selected the Adverse Events panel first, then only patients with Adverse Events would display. This report would show fewer patients than when the Demography panel was ordered first. This example assumes all patients have a Demography panel, but not all patients had Adverse Events.

Notice the last column for ‘FINAL Completed?’ displays as a blank row when the Adverse Event record doesn’t exist. The Final panel data is not truly missing, but unable to link in the report due to the previous non-existent record. The patients who show Adverse Events records are able to link and display their Final data.

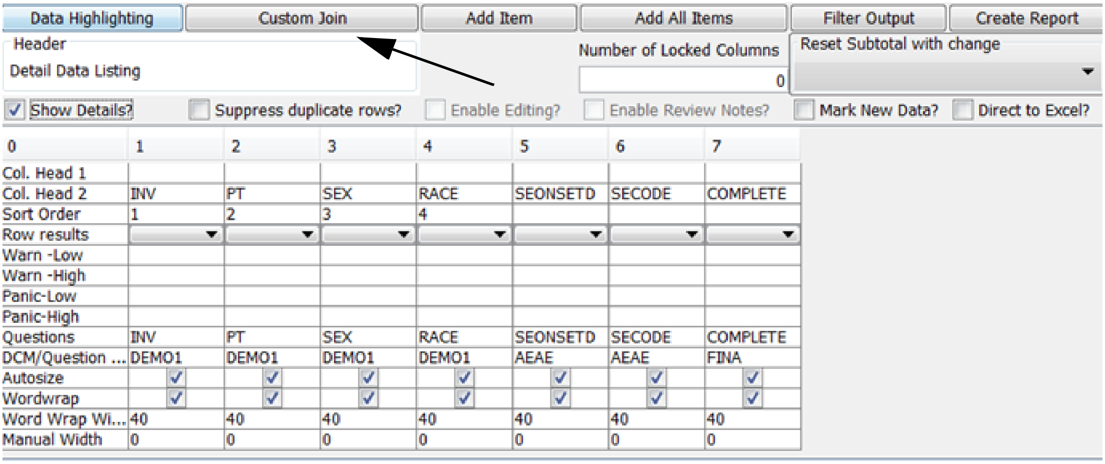


|  | INV | PT | SEX | RACE | SEONSETD | SECODE | COMPLETE |
|---|---|---|---|---|---|---|---|
| 1 | 018 | 4101 | Male | White |  |  |  |
| 2 | 018 | 4102 | Male | White |  |  |  |
| 3 | 018 | 4103 | Female | Black |  |  |  |
| 4 | 018 | 4104 | Male | Black |  |  |  |
| 5 | 018 | 4105 | Male | White |  |  |  |
| 6 | 018 | 4106 | Male | White |  |  |  |
| 7 | 018 | 4107 | Female | White |  |  |  |
| 8 | 018 | 4108 | Male | Black |  |  |  |
| 9 | 018 | 4109 | Female | White |  |  |  |
| 10 | 018 | 4110 | Female | White |  |  |  |
| 11 | 018 | 4111 | Female | Black |  |  |  |
| 12 | 018 | 4112 | Male | White |  |  |  |
| 13 | 018 | 4113 | Male | White |  |  |  |
| 14 | 018 | 4114 | Male | White |  |  |  |
| 15 | 018 | 4201 | Female | White |  |  |  |
| 16 | 018 | 4202 | Male | Black |  |  |  |
| 17 | 018 | 4203 | Male | White |  |  |  |
| 18 | 018 | 4204 | Female | White |  |  |  |
| 19 | 018 | 4205 | Male | White |  |  |  |
| 20 | 018 | 4206 | Male | Black |  |  |  |
| 21 | 018 | 4207 | Male | Black |  |  |  |
| 22 | 018 | 4208 | Female | Black | 19911007 | SKIN:Burning sensation skin | Yes |
| 23 | 018 | 4208 | Female | Black | 19911007 | SKIN:Pruritus | Yes |
| 24 | 030 | 3101 | Male | White |  |  |  |
| 25 | 030 | 3102 | Male | White |  |  |  |
| 26 | 030 | 3103 | Male | White |  |  |  |
| 27 | 030 | 3104 | Male | White |  |  |  |
| 28 | 030 | 3105 | Male | White |  |  |  |
| 29 | 030 | 3106 | Male | White |  |  |  |
| 30 | 030 | 3107 | Female | White |  |  |  |

## *Change Join Order*

You can change the **default Join Order** of the panels entered in your detail data listing specification as follows:

1. Define a detail data listing with data items from multiple panel sources.
2. From the Report Browser Classic Mode window, click **Custom Join**.

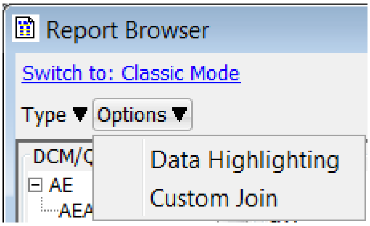


Number of Locked Columns: 0

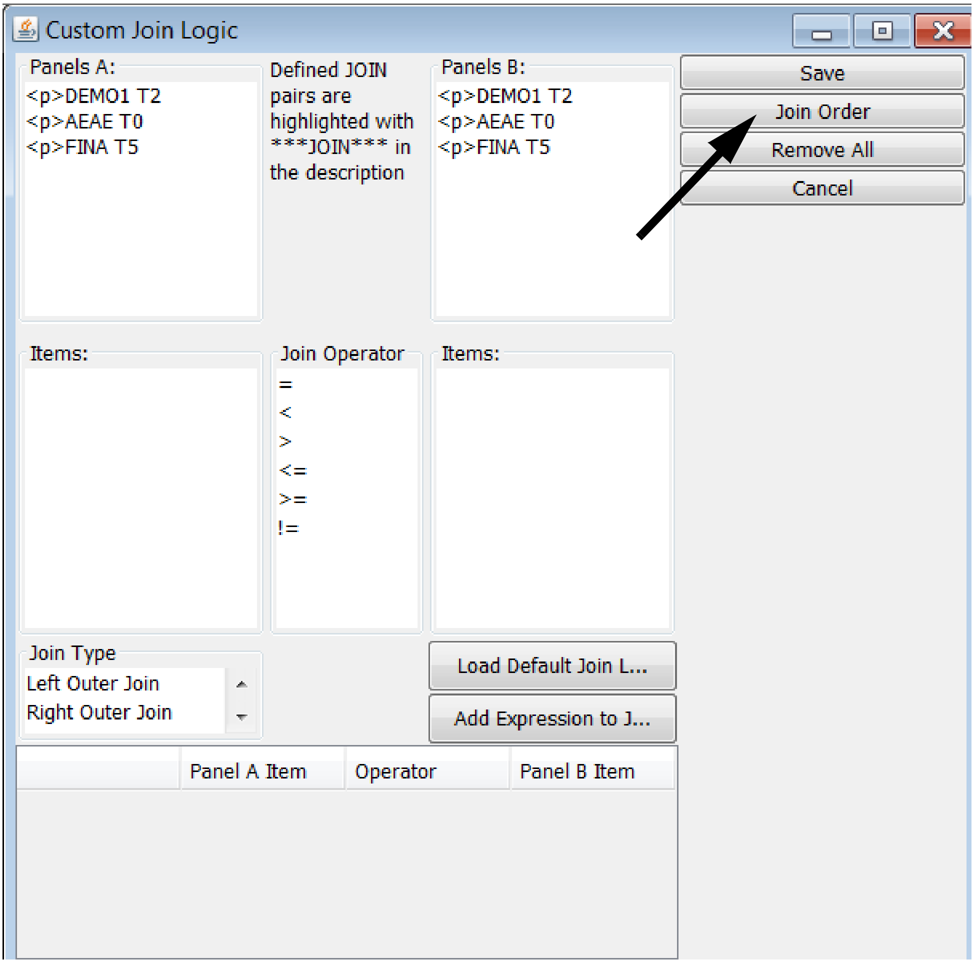
☑ Show Details? ☐ Suppress duplicate rows? ☐ Enable Editing? ☐ Enable Review Notes? ☐ Mark New Data? ☐ Direct to Excel?

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|
| Col. Head 1 | | | | | | | |
| Col. Head 2 | INV | PT | SEX | RACE | SEONSETD | SECODE | COMPLETE |
| Sort Order | 1 | 2 | 3 | 4 | | | |
| Row results | | | | | | | |
| Warn -Low | | | | | | | |
| Warn -High | | | | | | | |
| Panic-Low | | | | | | | |
| Panic-High | | | | | | | |
| Questions | INV | PT | SEX | RACE | SEONSETD | SECODE | COMPLETE |
| DCM/Question ... | DEMO1 | DEMO1 | DEMO1 | DEMO1 | AEAE | AEAE | FINA |
| Autosize | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Wordwrap | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |
| Word Wrap Wi... | 40 | 40 | 40 | 40 | 40 | 40 | 40 |
| Manual Width | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

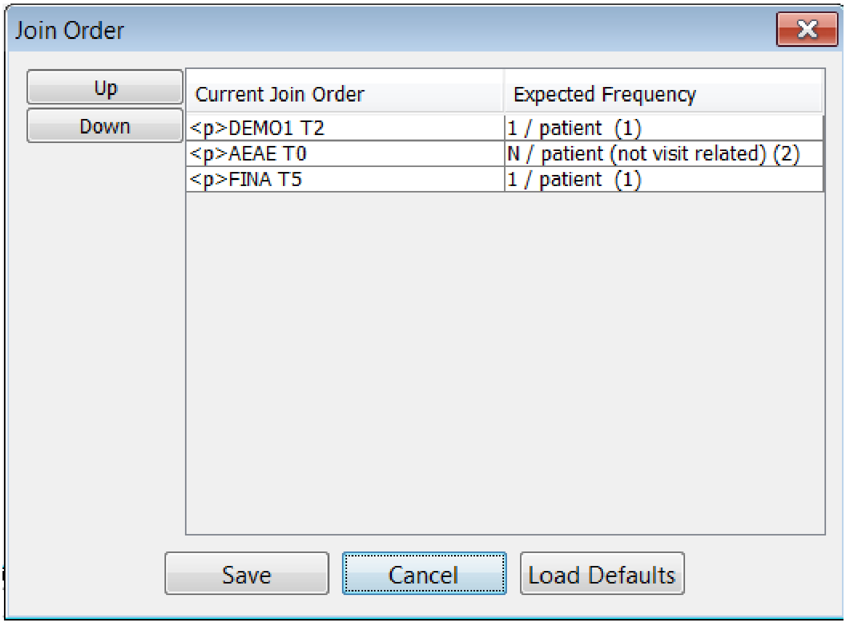
Click on the **Options menu** in Report Browser New Mode to select **Custom Join**.



3. The **Custom Join Logic window** displays. Click **Join Order.**



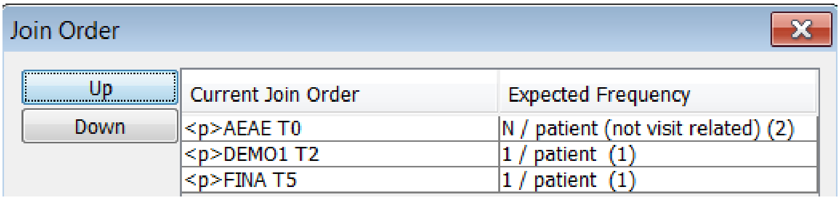
The Join Order Definition window displays with the default Join Order definition.



| Current Join Order | Expected Frequency |
|---|---|
| <p>DEMO1 T2 | 1 / patient (1) |
| <p>AEAE T0 | N / patient (not visit related) (2) |
| <p>FINA T5 | 1 / patient (1) |

4. Click on the panel you want to reorder and use the up/down buttons to the left.

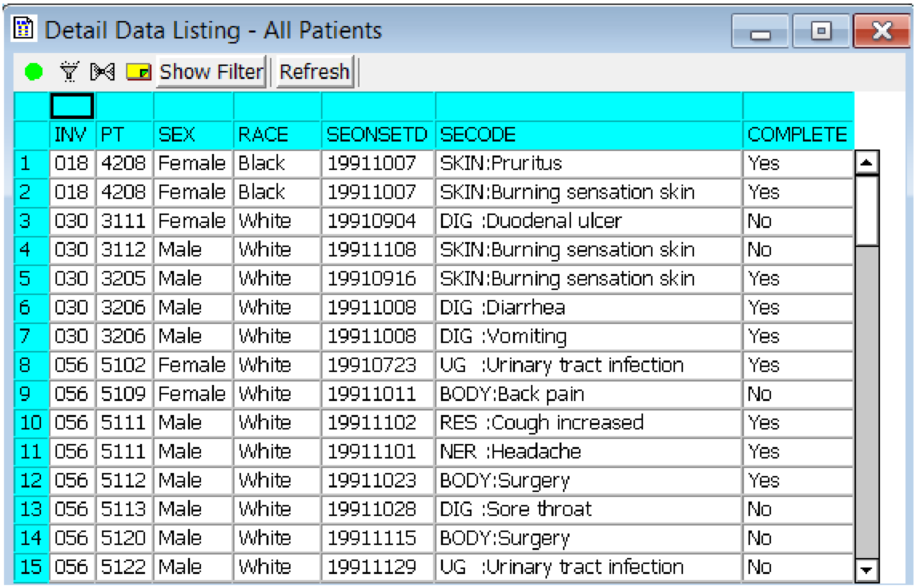
   In the example, Demography is moved to the 2nd order position and Adverse Events is now in the primary or driver position.



| Current Join Order | Expected Frequency |
|---|---|
| <p>AEAE T0 | N / patient (not visit related) (2) |
| <p>DEMO1 T2 | 1 / patient (1) |
| <p>FINA T5 | 1 / patient (1) |

5. Click **Save** in the **Join Order window** to apply the new Join Order to the report. The Join Order window closes and you are returned to the **Custom Join Logic window**.
6. Click **Save** in the **Define Join Logic** window and close the window. The revised custom Join Order is now saved along with your report specifications.

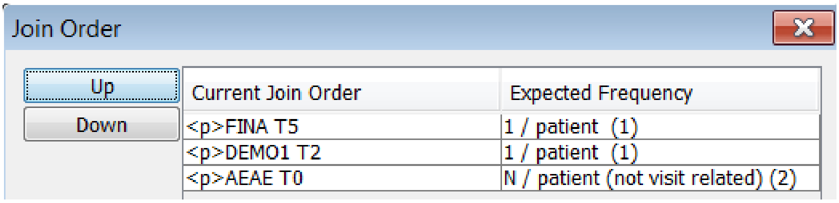
This report shows the revised join order where Adverse Events is assigned the first order position. Any blank records for Adverse Events are dropped from the listing.



Detail Data Listing - All Patients

|  | INV | PT | SEX | RACE | SEONSETD | SECODE | COMPLETE |
|---|---|---|---|---|---|---|---|
| 1 | 018 | 4208 | Female | Black | 19911007 | SKIN:Pruritus | Yes |
| 2 | 018 | 4208 | Female | Black | 19911007 | SKIN:Burning sensation skin | Yes |
| 3 | 030 | 3111 | Female | White | 19910904 | DIG :Duodenal ulcer | No |
| 4 | 030 | 3112 | Male | White | 19911108 | SKIN:Burning sensation skin | No |
| 5 | 030 | 3205 | Male | White | 19910916 | SKIN:Burning sensation skin | Yes |
| 6 | 030 | 3206 | Male | White | 19911008 | DIG :Diarrhea | Yes |
| 7 | 030 | 3206 | Male | White | 19911008 | DIG :Vomiting | Yes |
| 8 | 056 | 5102 | Female | White | 19910723 | UG :Urinary tract infection | Yes |
| 9 | 056 | 5109 | Female | White | 19911011 | BODY:Back pain | No |
| 10 | 056 | 5111 | Male | White | 19911102 | RES :Cough increased | Yes |
| 11 | 056 | 5111 | Male | White | 19911101 | NER :Headache | Yes |
| 12 | 056 | 5112 | Male | White | 19911023 | BODY:Surgery | Yes |
| 13 | 056 | 5113 | Male | White | 19911028 | DIG :Sore throat | No |
| 14 | 056 | 5120 | Male | White | 19911115 | BODY:Surgery | No |
| 15 | 056 | 5122 | Male | White | 19911129 | UG :Urinary tract infection | No |

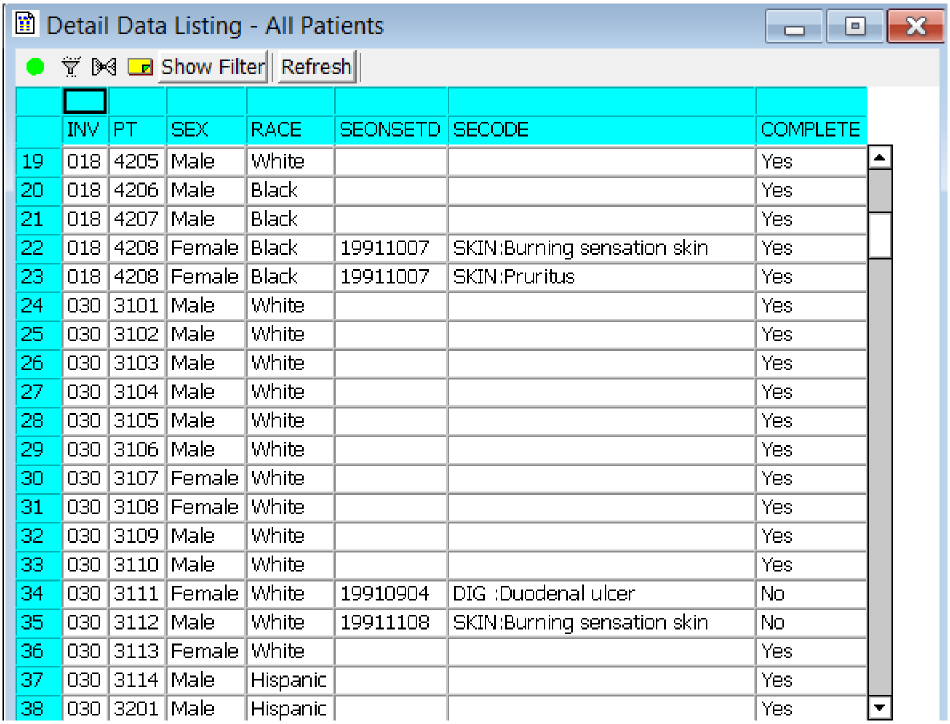
The last example revises the Join Order as the Final panel in the first order, Demography in second and Adverse Events as last.



Join Order

| Current Join Order | Expected Frequency |
|---|---|
| <p>FINA T5 | 1 / patient (1) |
| <p>DEMO1 T2 | 1 / patient (1) |
| <p>AEAE T0 | N / patient (not visit related) (2) |

Notice how the previously blank data for Final panel and completed study contain data. In the first example, where non-existent Adverse Event records displayed the Final panel was unable to link and displayed as blank data.



| | INV | PT | SEX | RACE | SEONSETD | SECODE | COMPLETE |
|---|---|---|---|---|---|---|---|
| 19 | 018 | 4205 | Male | White | | | Yes |
| 20 | 018 | 4206 | Male | Black | | | Yes |
| 21 | 018 | 4207 | Male | Black | | | Yes |
| 22 | 018 | 4208 | Female | Black | 19911007 | SKIN:Burning sensation skin | Yes |
| 23 | 018 | 4208 | Female | Black | 19911007 | SKIN:Pruritus | Yes |
| 24 | 030 | 3101 | Male | White | | | Yes |
| 25 | 030 | 3102 | Male | White | | | Yes |
| 26 | 030 | 3103 | Male | White | | | Yes |
| 27 | 030 | 3104 | Male | White | | | Yes |
| 28 | 030 | 3105 | Male | White | | | Yes |
| 29 | 030 | 3106 | Male | White | | | Yes |
| 30 | 030 | 3107 | Female | White | | | Yes |
| 31 | 030 | 3108 | Female | White | | | Yes |
| 32 | 030 | 3109 | Male | White | | | Yes |
| 33 | 030 | 3110 | Male | White | | | Yes |
| 34 | 030 | 3111 | Female | White | 19910904 | DIG :Duodenal ulcer | No |
| 35 | 030 | 3112 | Male | White | 19911108 | SKIN:Burning sensation skin | No |
| 36 | 030 | 3113 | Female | White | | | Yes |
| 37 | 030 | 3114 | Male | Hispanic | | | Yes |
| 38 | 030 | 3201 | Male | Hispanic | | | Yes |

## Load Default Join Order

Initially the Join Order window displays the default Join Order determined by the panel sequence defined in the report specification. After the report specification and changed Join Order is saved, you have the option of reloading the join order back to the system default.

1. Launch the saved report object from the Object Specifications window.
2. Open the Report Browser window to display the report specification.
3. Follow the previous steps to define a Join Order.
4. Click the **Load Defaults** button.

   The system default join order is reloaded into the Join Order window.
5. Click **Save**.

# Define Custom Joins

## *Creating custom joins*

In the Report Browser, you can specify customized join logic at the individual report level in JReview to use between specified tables. In the define Custom Join, the join logic needs to be complete between all the tables in the report.

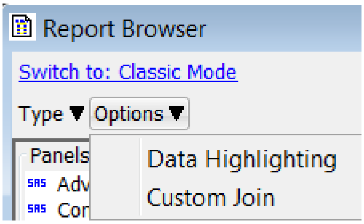
A common usage of this utility is to define custom joins to identify existing versus missing records or entries. The custom join logic is saved with the individual report specification.

***Note: The Define Custom Join Logic supersedes the Join Order.***

***Note: Define Custom Join does not apply to the Patient Visit Data Report type.***

1. First define your detail data listing report specification to identify which tables will utilize the custom join logic.
2. From the Report Browser ***Classic Mode*** window, click on the **Custom Join** button.

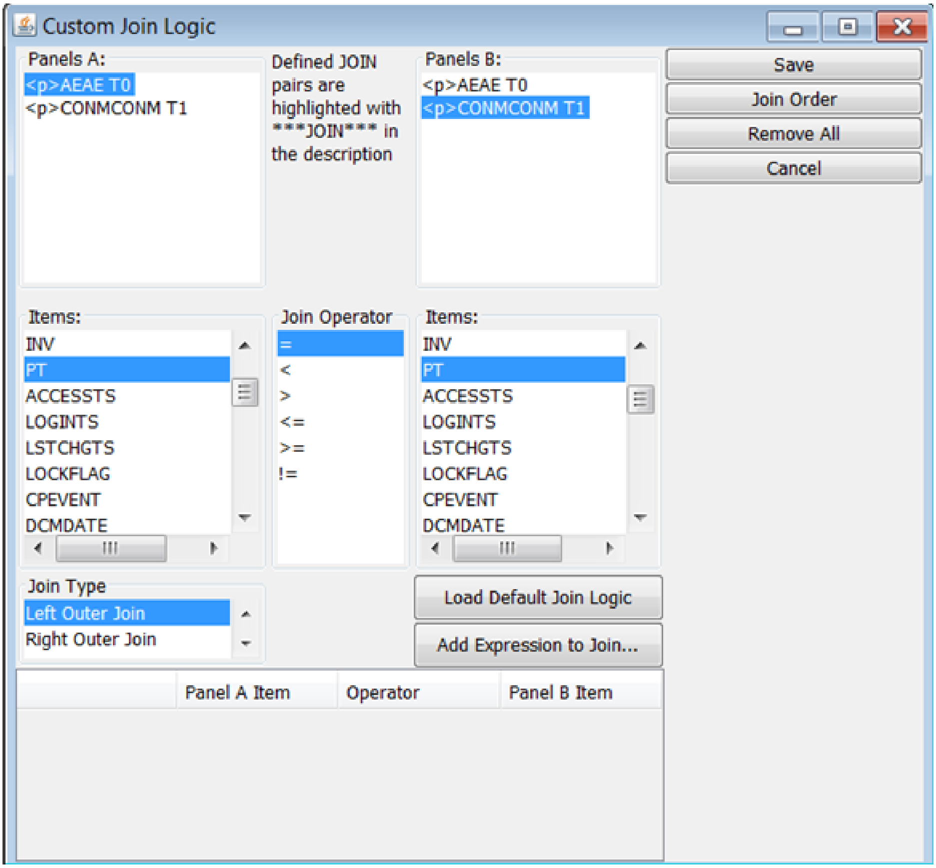
   Or, from the Report Browser ***New Mode*** Mode window, select from the **Options** menu.

   The **Define Join Logic window** opens listing all panels A and B.

   The maximum number of tables for Custom Joins is 15.

3. Point and click on the panels that you would like to join.
4. Point and click on items and join operators, defining relational joins.



## *Join type*

The Define Custom Join Logic supports a ‘tree’ join where the join for each table needs to be defined. Otherwise, results may be meaningless.

5. Select the Join Type.

The Left Outer and Right Outer Join dictate which table is the driver table and are identical in behavior, however, just flip which table is the driver table, i.e., examples:

PanelA = AE     PanelB = CONCOM

**Left outer on PID is: AE.PID = CONCOM.PID (+)**

(meaning – report rows for any patients with at least one AE)

PanelA = AE     PanelB = CONCOM

**Right outer on PID is: AE.PID (+)= CONCOM.PID**

(meaning – report rows for any patients with at least one CONCOM)

An example to show the difference in a report is:

AE.PID  AE.SETEXT  CONCOM.PID  CONCOM.DRUGNAME

The left outer join is the usual results seen but the right outer join will display conmeds at the end of the report with no AE entries.

Inner joins only includes rows in the report if a record exists for each table in the report, i.e.,

DEMOG.PID  DEMOG.AGE  AE.SETEXT

With left outer join on all patients will be listed even if they don’t have an AE.

With Inner joins on only those patients with at least one AE will be listed.

6. Then click **Add Expression to Join Logic** to build the logic for the join between the selected panels.
7. Click **Save**.

## *Update or Remove Custom Join*

After a report specification is saved with Custom Join Logic specified, you can edit or remove the saved custom join logic.

1. Launch the saved report object from the Object Specifications window.
2. Open the Report Browser window to display the report specification.
3. From the Report Browser window, click **Custom Join**.The previously saved Custom Join Logic definition displays.
4. Click the **Remove** to clear the current custom join logic.
5. Use the scissors icon to remove individual join logic rows. Add changes and click **Update** or **Save**.

## *Load Default Join Logic*

After a report specification is saved with Custom Join Logic specified, you have the option of replacing the custom join logic with the system default. This feature is a way to reload the initial system join logic.

1. Launch the saved report object from the Object Specifications window.
2. Open the Report Browser window to display the report specification.
3. From the Report Browser window, click **Custom Join**.The previously saved Custom Join Logic definition displays.
4. Click the **Load Default Join Logic** button. The system default join logic is reloaded into the Custom Join Logic.

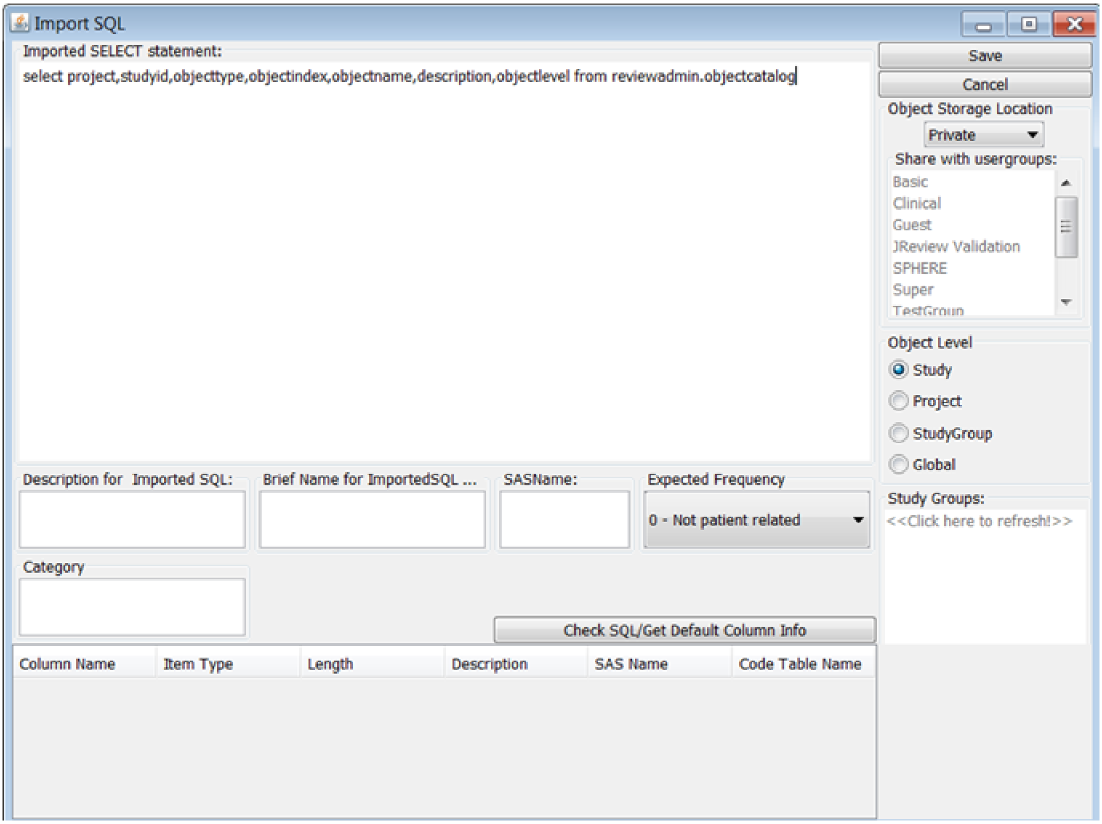
   You can also use the system default to initially define the Custom Join Logic as a starting point.
5. Click **Save**.

# Import SQL

## *Enter Import SQL SELECT statement*

The Import SQL function is another way to create and access foreign panels for data review. It provides a mechanism for creating complex objects along with utilizing queries previously developed outside of JReview.

1. From the **Advanced menu** in the toolbar, select **Import SQL.**



Imported SELECT statement:

```
select project,studyid,objecttype,objectindex,objectname,description,objectlevel from reviewadmin.objectcatalog
```

Object Storage Location: Private

Expected Frequency: 0 - Not patient related

Object Level: ● Study

2. Either type in the desired SELECT Statement or copy a SELECT statement to the clipboard and paste it into the ‘Imported SELECT statement’ edit control.

   The maximum is 28,000 characters and requires the new9082.sql script to ImportSQL.table

3. For an example of a select statement accessing our Object Catalog table in the ReviewAdmin oracle account:

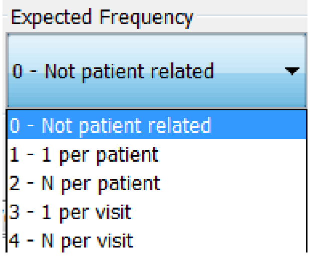
   **select project,studyid,objecttype,objectindex,objectname, description,objectlevel from reviewadmin.objectcatalog**

   You can select and copy this select statement to the clipboard, then paste it into the ‘Import SELECT statement’ edit control. DO NOT end the statement with a semi-colon.

   Additional advanced Select statement syntax such as ‘USING’, as the initial keyword instead of ‘SELECT’ is allowed.

   Supports ‘&’ prefix parameters (&promptName) in addition to <prompt=> syntax. Also, displays parameter references in user prompt dialog - once per parameter - even if included multiple times in SELECT statement.

4. Select the correct ‘Expected Frequency’ from the dropdown list box which are Clintrial panel types. The default is for non-patient data as Type 0.



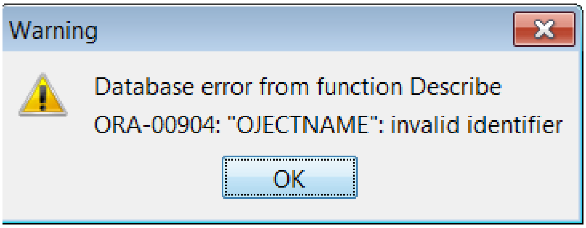
Expected Frequency

0 - Not patient related

***Note: If it’s not patient related, it’s important not to subset using the Patient Selection Criteria. (See ReviewAdmin: Register Foreign Panels)***

***Note: MSSQL database you must type the SELECT statement using all CAPS. It will not return an error message when typed in lower case.***

5. Click the **Check SQL/Get Column Info** button which goes out to the database, and checks the SQL syntax and returns an Oracle error if present.

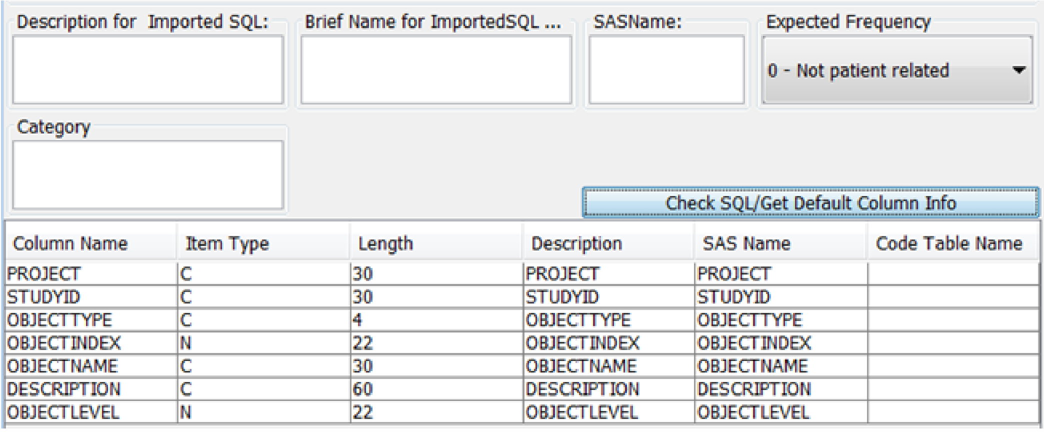


Database error from function Describe

ORA-00904: "OJECTNAME": invalid identifier

If the SQL syntax is correct, than the ‘Column Information in Imported SELECT statement’ spreadsheet is filled with the column information from the select statement (col name, type, length, description, SASName).

There is the ability to attach a codelist or DVG reference to an ImportSQL column with the add ‘code table’definition column.



Expected Frequency: 0 - Not patient related

| Column Name | Item Type | Length | Description | SAS Name | Code Table Name |
|---|---|---|---|---|---|
| PROJECT | C | 30 | PROJECT | PROJECT | |
| STUDYID | C | 30 | STUDYID | STUDYID | |
| OBJECTTYPE | C | 4 | OBJECTTYPE | OBJECTTYPE | |
| OBJECTINDEX | N | 22 | OBJECTINDEX | OBJECTINDEX | |
| OBJECTNAME | C | 30 | OBJECTNAME | OBJECTNAME | |
| DESCRIPTION | C | 60 | DESCRIPTION | DESCRIPTION | |
| OBJECTLEVEL | N | 22 | OBJECTLEVEL | OBJECTLEVEL | |

6. Enter a Description, ‘Brief Name, i.e. PanelName’, SASName (less than 8 characters).
7. Select the appropriate ‘Object Store’ and ‘Object Level’ similar to Saved Objects terminology. The Private Object Store is stored in the database. All definitions are stored in the ‘ImportSQL’ table in the ReviewAdmin account.

   The Import SQL definition can also be saved at Study, StudyGroup (multiples supported) and Global (*ALL*). Save at the Project level is supported.

   Select multiple UserGroups is allowed and selecting multiple StudyGroups.

   ImportSQLs can be hidden from view by not displaying on the list of panels, for other usergroups. This is similar to Foreign Panel hiding if an author defines a report on a Foreign Panel or ImportSQL, they have access through usergroup membership. However, they do not want those Foreign Panels or ImportSQL’s to be visible or availabe to other users in other usergroups, to be used in other definitions.

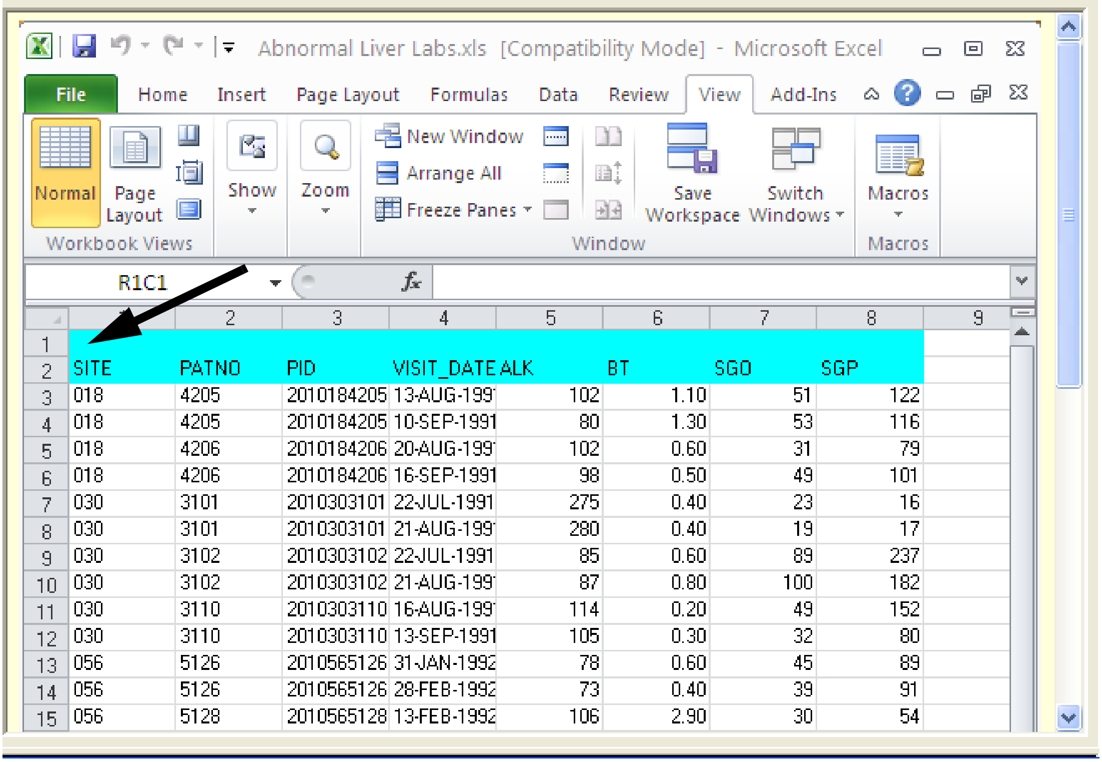
   This allows complex ImportSQL definitions to be saved and used in reporting definitions, but the details of the ImportSQL can thereby be hidden from users in other usergroups.
8. Only the Description and SASName can be modified. You can delete any of the rows in the spreadsheet, if the user didn’t want all the columns to be available for reporting in JReview after registering this SQL statement.
9. Click **SAVE**. The information is saved and added to the list of Panels and will function much like a registered Foreign Panel. You can do reports, graphs, use it in Output Filters, etc.
10. To edit or remove after it has been defined, select Import SQL in the Panel or DCM list, then right mouse click to edit or remove.

# Import Excel

The Import Excel requires a priviledge to be set in ReviewAdmin. This function is used primarily to support Phase One - Pharmacokinetics data. It provides a mechanism to access their spreadsheet data and import up to 100 fields, allowing edits to column names.

Before importing an Excel or Excel-S file, you **must** remove any blank embedded rows above the column header.  See in the example below where row 1 must be deleted. Any blank rows will interfere with importing the column names.

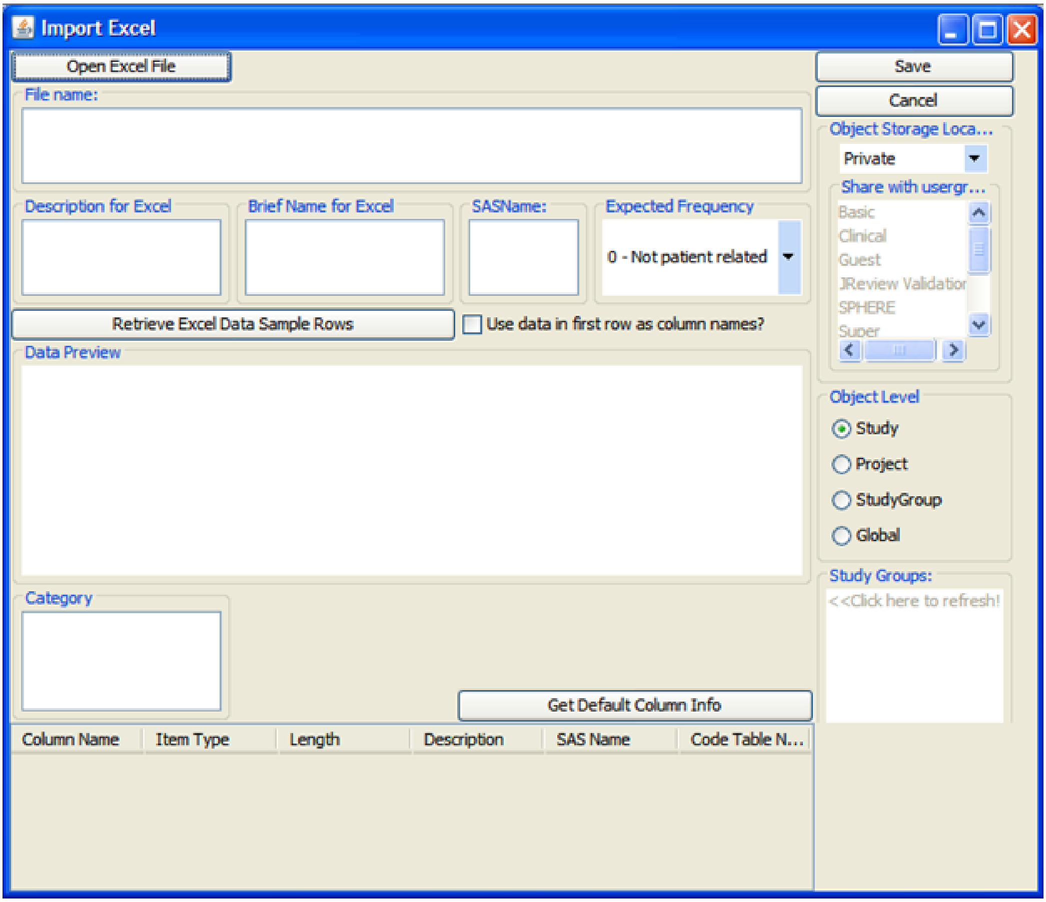
***Note:  When adding an Excel file containing patient data there MUST be a column for PID included. The column name may be changed in the Import Excel function when the data columns are retrieved.***



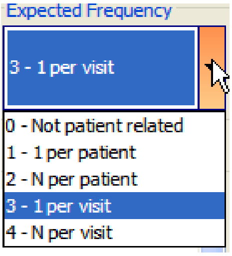
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | |
| 2 | SITE | PATNO | PID | VISIT_DATE | ALK | BT | SGO | SGP | |
| 3 | 018 | 4205 | 2010184205 | 13-AUG-199 | 102 | 1.10 | 51 | 122 | |
| 4 | 018 | 4205 | 2010184205 | 10-SEP-1991 | 80 | 1.30 | 53 | 116 | |
| 5 | 018 | 4206 | 2010184206 | 20-AUG-199 | 102 | 0.60 | 31 | 79 | |
| 6 | 018 | 4206 | 2010184206 | 16-SEP-1991 | 98 | 0.50 | 49 | 101 | |
| 7 | 030 | 3101 | 2010303101 | 22-JUL-1991 | 275 | 0.40 | 23 | 16 | |
| 8 | 030 | 3101 | 2010303101 | 21-AUG-199 | 280 | 0.40 | 19 | 17 | |
| 9 | 030 | 3102 | 2010303102 | 22-JUL-1991 | 85 | 0.60 | 89 | 237 | |
| 10 | 030 | 3102 | 2010303102 | 21-AUG-199 | 87 | 0.80 | 100 | 182 | |
| 11 | 030 | 3110 | 2010303110 | 16-AUG-199 | 114 | 0.20 | 49 | 152 | |
| 12 | 030 | 3110 | 2010303110 | 13-SEP-1991 | 105 | 0.30 | 32 | 80 | |
| 13 | 056 | 5126 | 2010565126 | 31-JAN-1992 | 78 | 0.60 | 45 | 89 | |
| 14 | 056 | 5126 | 2010565126 | 28-FEB-1992 | 73 | 0.40 | 39 | 91 | |
| 15 | 056 | 5128 | 2010565128 | 13-FEB-1992 | 106 | 2.90 | 30 | 54 | |

## *Open Excel File*

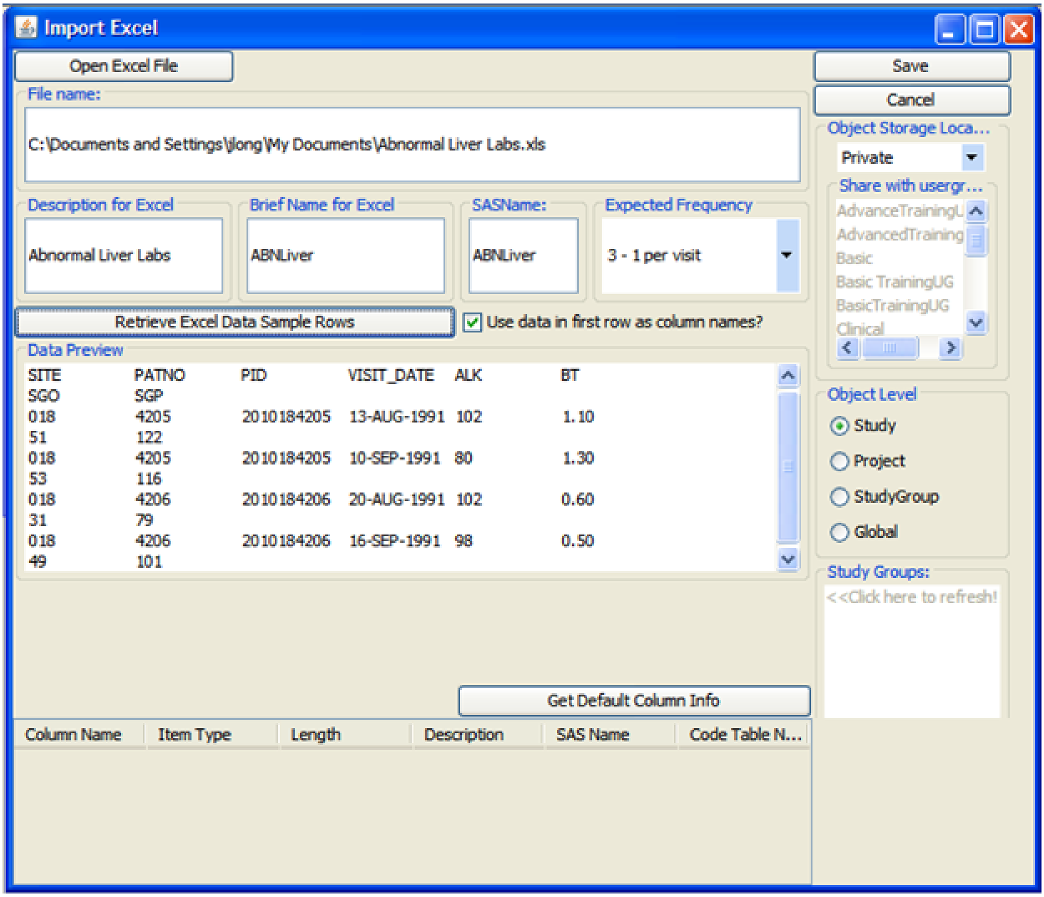
1. From the **Advanced menu** in the toolbar, select **Import Excel.**
2. Click **Open Excel File,** and select the Excel file to import.



3. Enter **Description for Excel, Brief Name for Excel,** and **SASName.**
4. Click drop down list for **Expected Frequency.** Select the correct 'Expected Frequency' which are Clintrial panel types. The default is for non-patient data as Type 0.



5. Optionally, click check box to "**Use data in first row as column names?".**
6. Click **RetrieveExcel Data Sample Rows**.



File name: C:\Documents and Settings\jlong\My Documents\Abnormal Liver Labs.xls

Description for Excel: Abnormal Liver Labs

Brief Name for Excel: ABNLiver

SASName: ABNLiver

Expected Frequency: 3 - 1 per visit

☑ Use data in first row as column names?

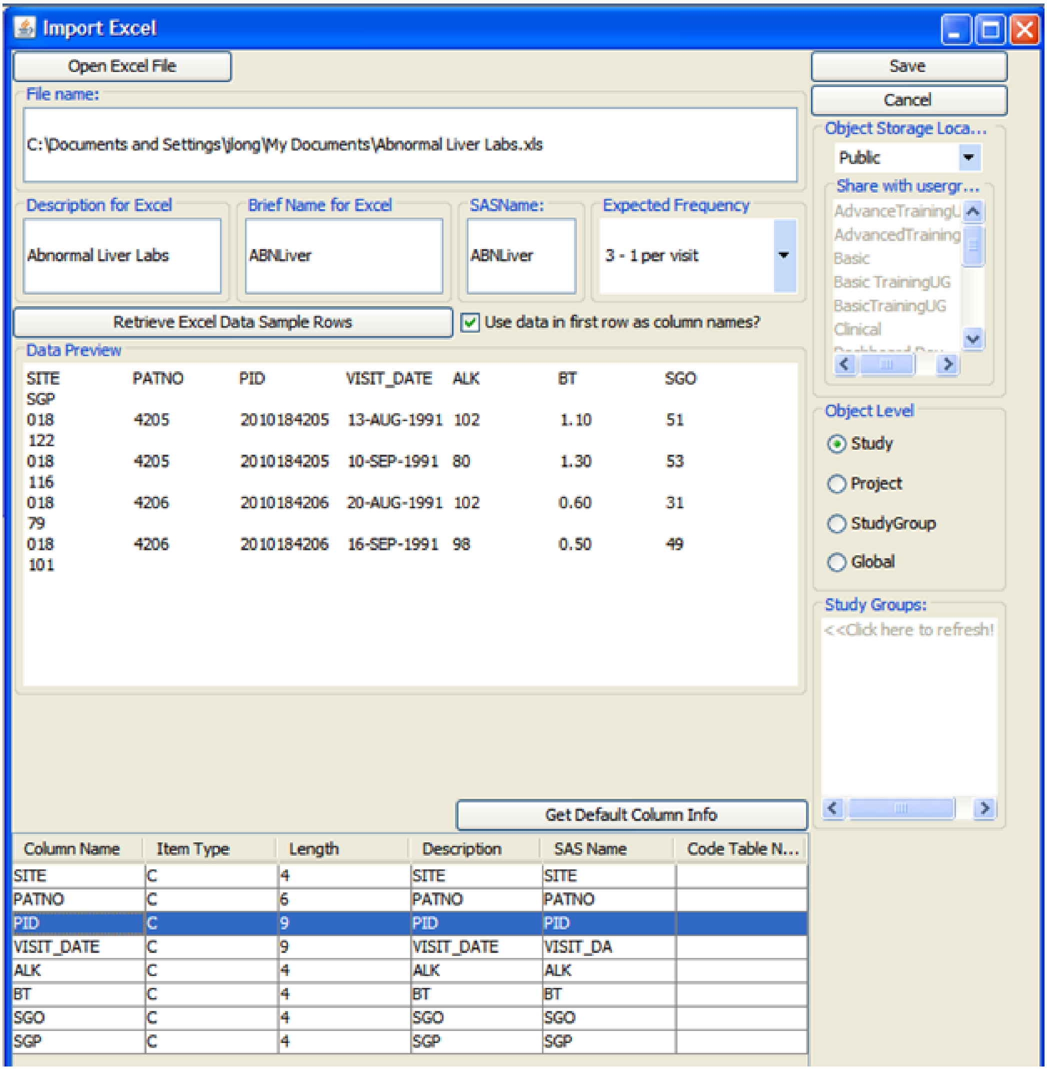
Object Storage Loca...: Private

Object Level: ● Study ○ Project ○ StudyGroup ○ Global

Data Preview

| SITE | PATNO | PID | VISIT_DATE | ALK | BT |
|---|---|---|---|---|---|
| SGO | SGP | | | | |
| 018 | 4205 | 2010184205 | 13-AUG-1991 | 102 | 1.10 |
| 51 | 122 | | | | |
| 018 | 4205 | 2010184205 | 10-SEP-1991 | 80 | 1.30 |
| 53 | 116 | | | | |
| 018 | 4206 | 2010184206 | 20-AUG-1991 | 102 | 0.60 |
| 31 | 79 | | | | |
| 018 | 4206 | 2010184206 | 16-SEP-1991 | 98 | 0.50 |
| 49 | 101 | | | | |

7. Click **Get Default Column Info.** For patient data, make sure there is a **Column Name** for PID. Optionally, change any **Item Type** to character if needed.



File name: C:\Documents and Settings\jlong\My Documents\Abnormal Liver Labs.xls

Description for Excel: Abnormal Liver Labs

Brief Name for Excel: ABNLiver

SASName: ABNLiver

Expected Frequency: 3 - 1 per visit

Object Storage Loca...: Public

☑ Use data in first row as column names?

Object Level: ● Study ○ Project ○ StudyGroup ○ Global

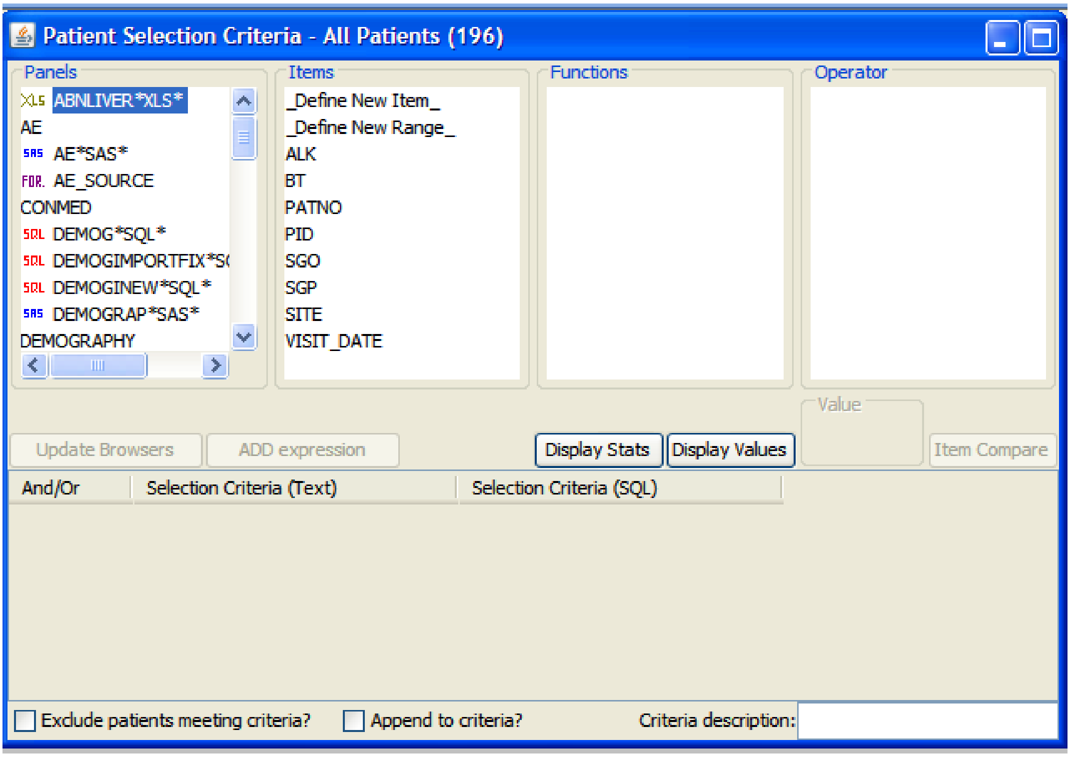
Study Groups: <<Click here to refresh!

Data Preview

```
SITE        PATNO       PID         VISIT_DATE   ALK        BT         SGO
SGP
018         4205        2010184205  13-AUG-1991  102        1.10       51
122
018         4205        2010184205  10-SEP-1991  80         1.30       53
116
018         4206        2010184206  20-AUG-1991  102        0.60       31
79
018         4206        2010184206  16-SEP-1991  98         0.50       49
101
```

| Column Name | Item Type | Length | Description | SAS Name | Code Table N... |
|---|---|---|---|---|---|
| SITE | C | 4 | SITE | SITE | |
| PATNO | C | 6 | PATNO | PATNO | |
| PID | C | 9 | PID | PID | |
| VISIT_DATE | C | 9 | VISIT_DATE | VISIT_DA | |
| ALK | C | 4 | ALK | ALK | |
| BT | C | 4 | BT | BT | |
| SGO | C | 4 | SGO | SGO | |
| SGP | C | 4 | SGP | SGP | |

8. Select the appropriate ‘**Object Store**’ and ‘**Object Level**’ similar to Saved Objects terminology. The Private Object Store is stored in the database. All definitions are stored in the Importexcelcontent table in the ReviewAdmin account. Select multiple UserGroups is allowed and selecting multiple StudyGroups.
9. Click **Save**. The saved object is assigned an object index number with an XLS prefix. The Import Excel file is displayed under the Panels list
10. To edit or remove the saved Excel file in the Panel or DCM list, right mouse click to **Edit** or **Remove**.

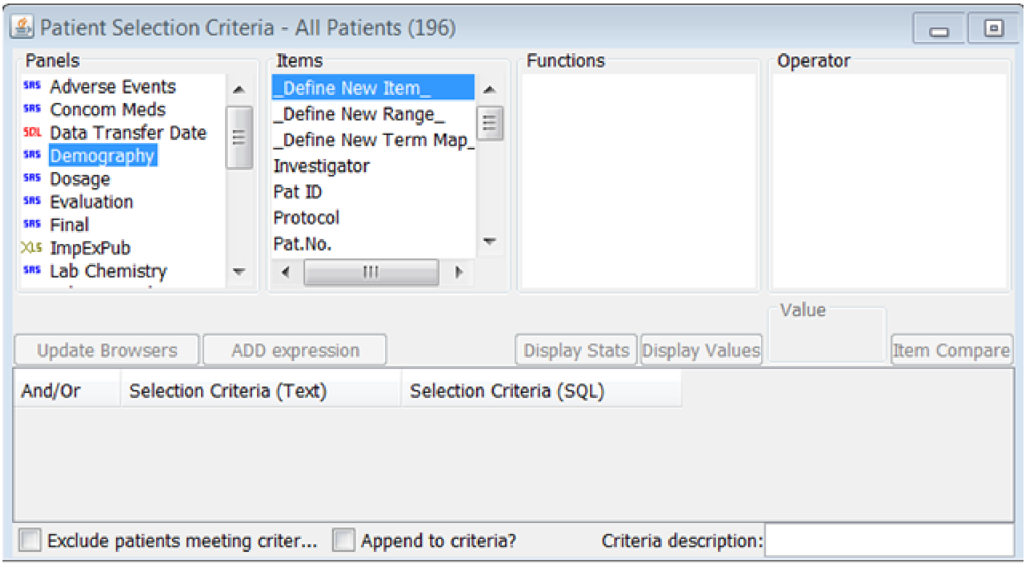


# Define New Item

## *Derived items across panels*

You may find it desirable to select and report a derivation of the original clinical data. For example, derive a total score by summing up several raw data items in the database from within the same panel or across panels and panels types. Deriving items across panels requires no programming. You select the panels and the underlying items, using any mathematics operator to join Item expressions and save the derived item.

1. From the Patient Selection Criteria or any Browser build window, select a panel and then click **Define New Item**.

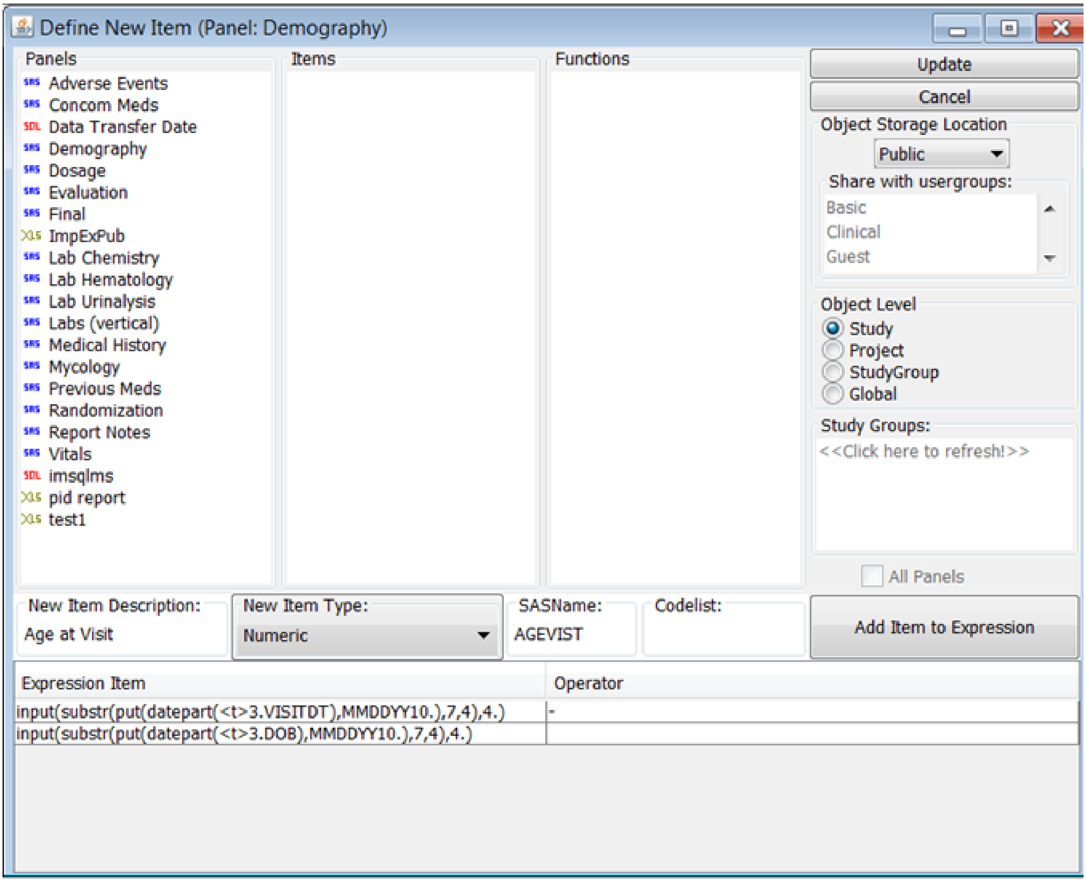


2. Select panel items.
3. Join item expression with mathematical operators.
4. Enter New Item Description.
5. Save New Item.

The newly defined item will be displayed and accessible from the active panel when you clicked on _Defined New Item_.

For example, perhaps in the Demography panel the patient’s age was not collected, but you have the Date of Birth.

You could define a calculated age by doing date arithmetic on the Date of Birth against the Visit Date.  Here is the definition for a saved new item for “Age at Visit”.



Object Storage Location: Public

Object Level: ● Study ○ Project ○ StudyGroup ○ Global

☐ All Panels

New Item Description: Age at Visit

New Item Type: Numeric

SASName: AGEVIST

Codelist:

| Expression Item | Operator |
|---|---|
| input(substr(put(datepart(<t>3.VISITDT),MMDDYY10.),7,4),4.) | - |
| input(substr(put(datepart(<t>3.DOB),MMDDYY10.),7,4),4.) | |

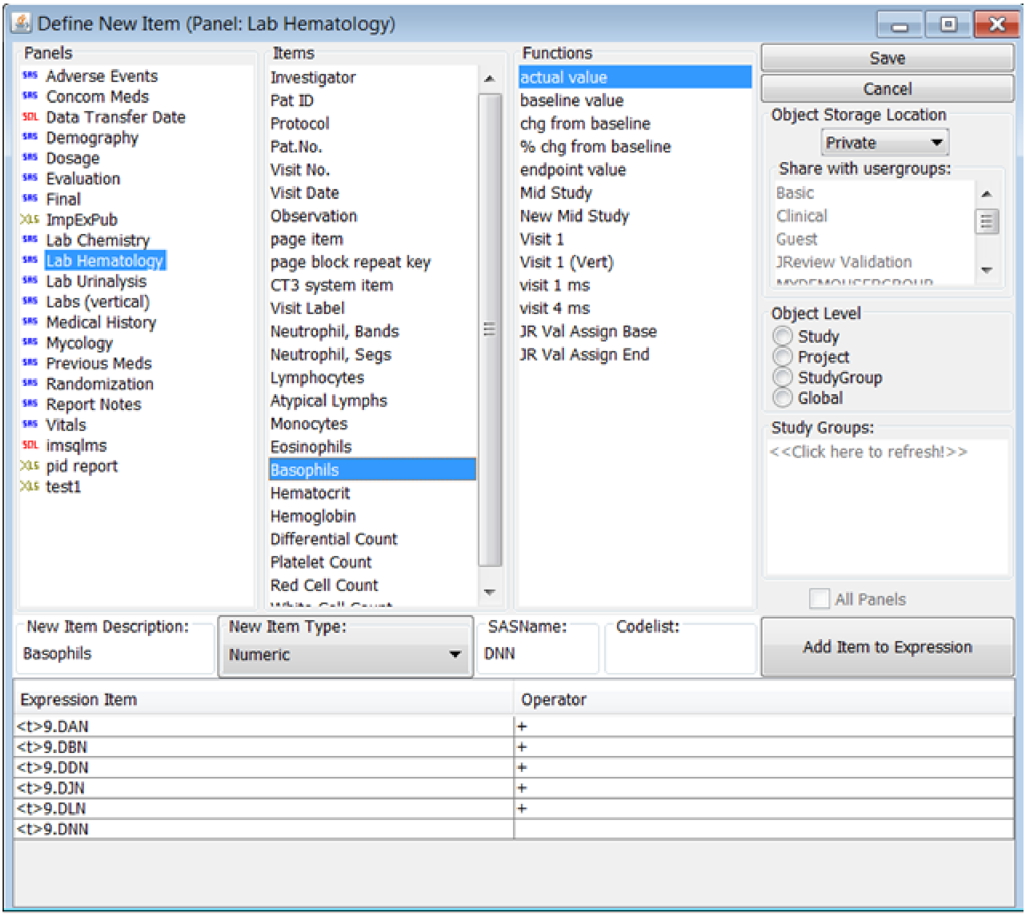
## *Define New Item*

1. The first entry in the Items list for every panel is the pseudo-item; click on '_Define New Item_'.

   JReview displays the Define New Item window where you can define the expression for the derived item.

2. Select the items. Click **Add Item to Expression** to paste the item and function into the expression spreadsheet.  Or double click to add the individual items.

As each item is added, it's description and codelist reference is defaulted into the New Item Description text. This is handy if you want to copy an existing item(s) from one panel to another for convenience in display. The item(s) is than available for use throughout all the browsers.



Object Storage Location: Private

New Item Description: Basophils

New Item Type: Numeric

SASName: DNN

Codelist:

| Expression Item | Operator |
|---|---|
| <t>9.DAN | + |
| <t>9.DBN | + |
| <t>9.DDN | + |
| <t>9.DJN | + |
| <t>9.DLN | + |
| <t>9.DNN | |

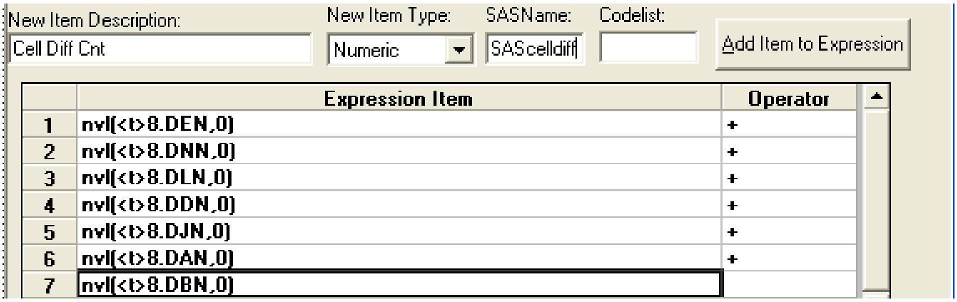
## *Add operators*

By default, the rows are joined by '+' operators; however, you can change the operator. By clicking on the operator field, you can change it to any mathematical operator of choice.

You can also edit more complex mathematical expressions within the Expression Items edit box by editing the SQL to adjust your derived item calculation, as shown in the next example. Double click on the cell row to begin edit. Be sure to hit the **Return** key on the last expression line so all expression items and operators are processed into the calculation.

***Note: You must use parentheses between rows to control operator precedence if it is a complex expression.***

You can edit the SQL within the Expression Item edit box to adjust your derived item calculation, as shown in the next example.



New Item Description: Cell Diff Cnt

New Item Type: Numeric

SASName: SAScelldiff

Codelist:

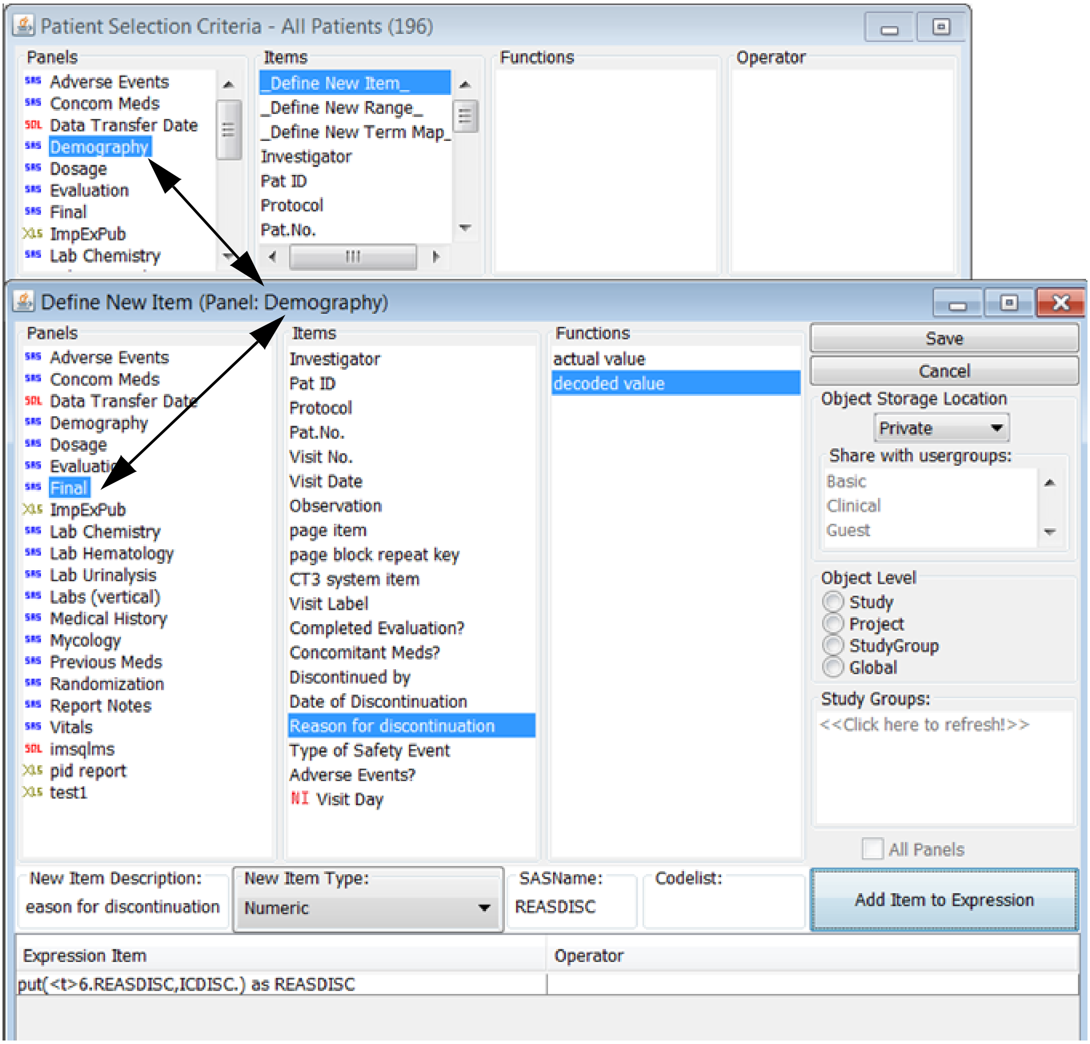
| | Expression Item | Operator |
|---|---|---|
| 1 | nvl(<t>8.DEN,0) | + |
| 2 | nvl(<t>8.DNN,0) | + |
| 3 | nvl(<t>8.DLN,0) | + |
| 4 | nvl(<t>8.DDN,0) | + |
| 5 | nvl(<t>8.DJN,0) | + |
| 6 | nvl(<t>8.DAN,0) | + |
| 7 | nvl(<t>8.DBN,0) | |

***Note: If any items used in a mathematical calculation contain NULL data, the resulting derived item will be NULL per standard Oracle functionality.***

***Note: The overall length of the expression is currently limited to 256 characters. JReview prevents you from exceeding this limit.***

## *Decode reference*

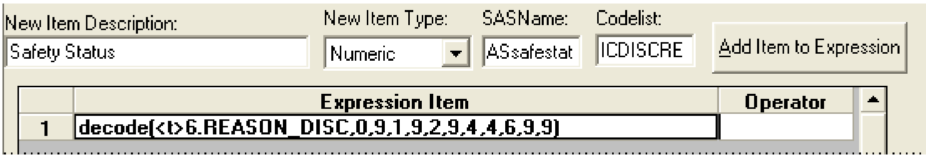
In the next example, you can define a new item to reference an existing decode in one panel and display the new item in a different panel.



New Item Description: eason for discontinuation
New Item Type: Numeric
SASName: REASDISC
Codelist:

| Expression Item | Operator |
|---|---|
| put(<t>6.REASDISC,ICDISC.) as REASDISC | |

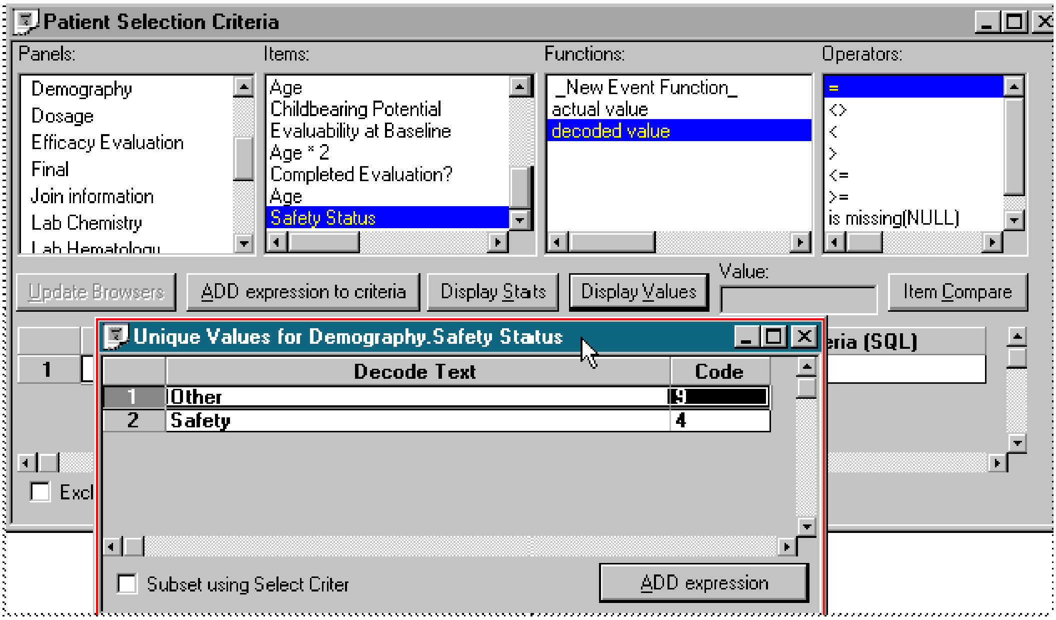
Here the item expression is modified to reference specific decode values.



New Item Description: Safety Status
New Item Type: Numeric
SASName: ASsafestat
Codelist: ICDISCRE

| | Expression Item | Operator |
|---|---|---|
| 1 | decode(<t>6.REASON_DISC,0,9,1,9,2,9,4,4,6,9,9) | |

The New Item is saved and added to the Demography panel, while the decode information is taken from Reason for discontinuation item in the Final panel.



|  | Decode Text | Code |
|---|---|---|
| 1 | Other | 9 |
| 2 | Safety | 4 |

## *Save New Item*

3. Enter a description.

   The “New Item Description” field allows you to enter a description of your expression. This description will be in the item list when you select the panel to which you are adding the new data item.

4. If you need to change your item type from the default value, click the **New Item Type** button to select from the drop list.

5. When you enter a SAS name into the SAS Name field, there is an internal check to prevent duplication of SAS names within the same panel.

6. Select the Object Storage location.

   If you save the new item as **Private,** you must select ‘Private’ in the Object Explorer area for Patient Subsets and Object Specifications to access the new item. In addition, you may need to refresh the window to view the private new item.

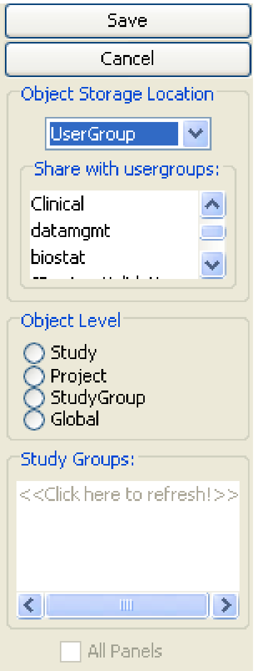
   The saved “New Item” displays in the Items list for the selected panel with the new item prefix for “NI”.

## *Save a Global New Item*

7. Select **UserGroup** or **Public** for Object Storage Location to optionally save as a **Global New Item**.

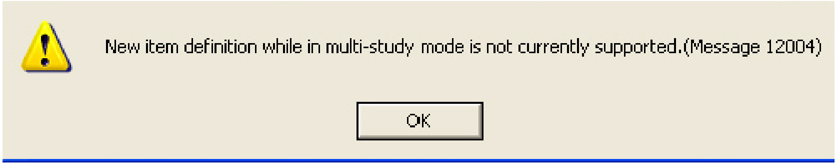
   Selecting multiple UserGroups for save is supported.

   If you are granted “SuperUser” capability through the ReviewAdmin’s Review Privileges and you select **UserGroup** or **Public** you can optionally save as a **Global New Item**.



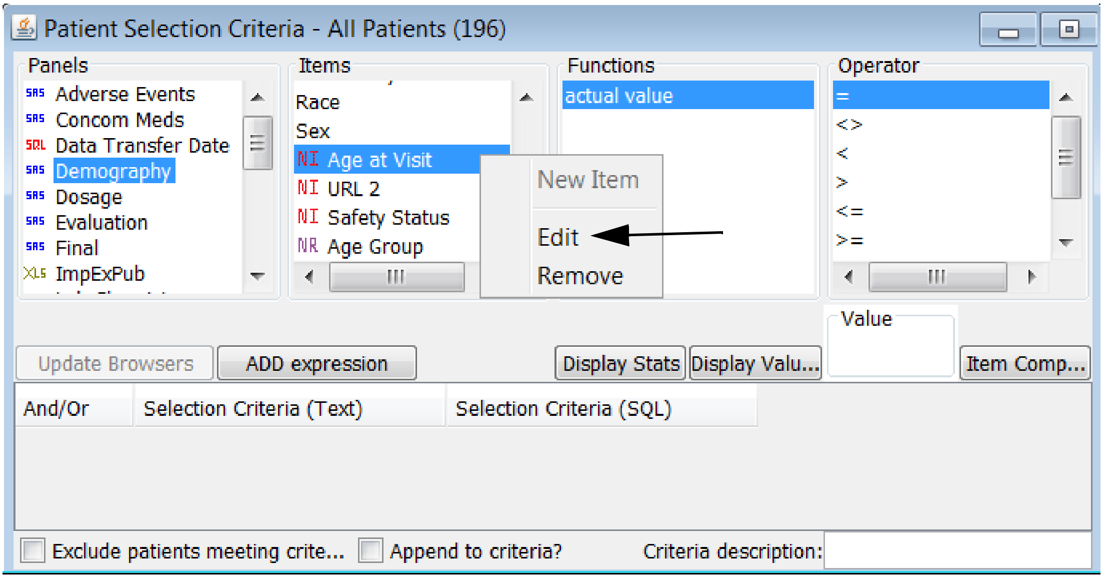
8. Optionally select Global New Item for **All Panels** to display and select the new item across all panels.
9. Click **Save**. JReview saves the definition and the description and posts the New Item from the panel in which it was activated.

   You can select the new item in studies other than the study where it was defined and saved. A message will display if you attempt to define a new item in multi-study mode. Likewise, you cannot access a new item in multi-study mode.


New item definition while in multi-study mode is not currently supported.(Message 12004)

## *Edit defined new item*

When you return to the define New Item dialog box, notice that the description of your newly defined item has been added to the end of the list of items. The saved “New Item” displays in the selected panel with the new item prefix for “NI”.



To change the expression for the new Item that you have defined and saved:

1. Select the panel that it belongs to.
2. Select the New Item's description from the item list.
3. Right mouse click on the item to display a floating menu; select **Edit**.
4. Change any portion of the New Item Expression with Add/edit items, functions and operators.
5. Click **Update** and JReview saves the changes.

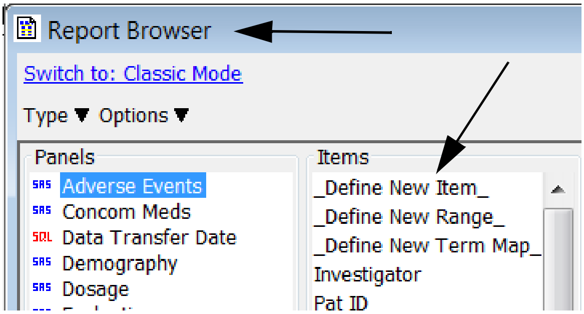
## *Remove saved new item*

To remove the new item that you have previously defined.

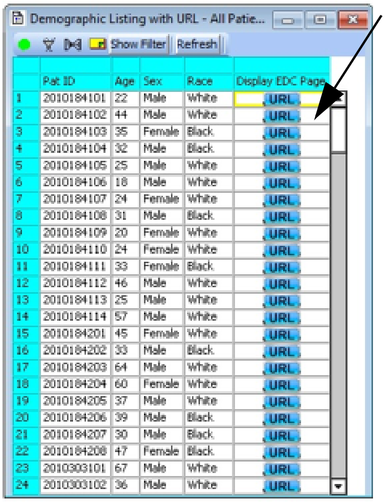
1. Select the panel it belongs to.
2. Select the new item description you would like to remove.
3. Right mouse click on the item to display a floating menu; select **Remove**.

## Define New Item URL type

**Detailed Reports** have the added ability to launch a URL in a JReview managed, embedded Web Browser when a 'URL' type field is clicked in a detailed report. The 'URL' type field can be either a NewItem definition which combines a specified URL lead in string followed by a specific 'page ID' from the data – to launch and display a referenced EDC page data contents, for example. Many other uses are possible such as, displaying scanned images of reference documents, medical images, etc.

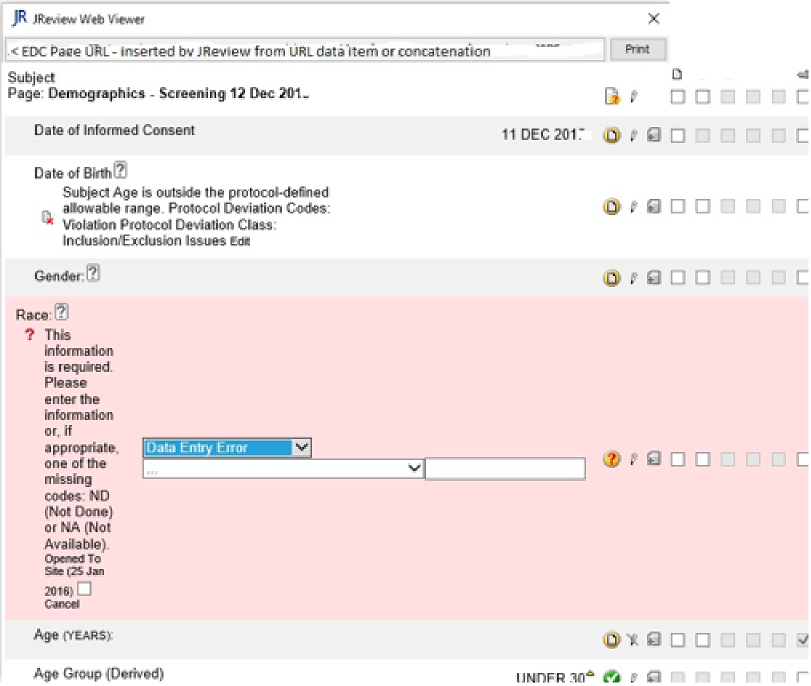


The function to **Define New Item** as a new 'URL' type, or define an existing item in the database as a 'URL' type – via the IRAdmin 'Item Override' capability. Then when the 'URL' data column is added to the report, when the user clicks on the 'URL' symbol in the cell – JReview opens another JReview managed/embedded web browser to display the contents of that URL. This is useful for displaying the contents of an EDC page, or displaying image scans, etc.



| | Pat ID | Age | Sex | Race | Display EDC Page |
|---|---|---|---|---|---|
| 1 | 2010184101 | 22 | Male | White | URL |
| 2 | 2010184102 | 44 | Male | White | URL |
| 3 | 2010184103 | 35 | Female | Black | URL |
| 4 | 2010184104 | 32 | Male | Black | URL |
| 5 | 2010184105 | 25 | Male | White | URL |
| 6 | 2010184106 | 18 | Male | White | URL |
| 7 | 2010184107 | 24 | Female | White | URL |
| 8 | 2010184108 | 31 | Male | Black | URL |
| 9 | 2010184109 | 20 | Female | White | URL |
| 10 | 2010184110 | 24 | Female | White | URL |
| 11 | 2010184111 | 33 | Female | Black | URL |
| 12 | 2010184112 | 46 | Male | White | URL |
| 13 | 2010184113 | 25 | Male | White | URL |
| 14 | 2010184114 | 57 | Male | White | URL |
| 15 | 2010184201 | 45 | Female | White | URL |
| 16 | 2010184202 | 33 | Male | Black | URL |
| 17 | 2010184203 | 64 | Male | White | URL |
| 18 | 2010184204 | 60 | Female | White | URL |
| 19 | 2010184205 | 37 | Male | White | URL |
| 20 | 2010184206 | 39 | Male | Black | URL |
| 21 | 2010184207 | 30 | Male | Black | URL |
| 22 | 2010184208 | 47 | Female | Black | URL |
| 23 | 2010303101 | 67 | Male | White | URL |
| 24 | 2010303102 | 36 | Male | White | URL |

The key part to the URL New Item definition is the number portion must map to a database as an index number to that EDC page. This allows the user to link between JReview and an EDC page without leaving JReview. For example, https://www.mdsol.com?sponsor?study?id=12637845



< EDC Page URL - Inserted by JReview from URL data item or concatenation

Subject
Page: **Demographics - Screening 12 Dec 201**

Date of Informed Consent 11 DEC 201

Date of Birth
Subject Age is outside the protocol-defined allowable range. Protocol Deviation Codes: Violation Protocol Deviation Class: Inclusion/Exclusion Issues Edit

Gender:

Race:
? This information is required. Please enter the information or, if appropriate, one of the missing codes: ND (Not Done) or NA (Not Available). Opened To Site (25 Jan 2016) ☐ Cancel
Data Entry Error

Age (YEARS):

Age Group (Derived) UNDER 30

This functions as a hyperlink with JReview within detailed reports and may be implemented several ways within ReviewAdmin. The patient number is configured to the URL column to open browser by entering in ReviewAdmin.source.

- **URLINT** - internal opens a window within the JReview web viewer application.
- **URLEXT** - opens in local external web browser and offers flexibiltiy to see a new tab in the browser.

## *Substitution Parameter*

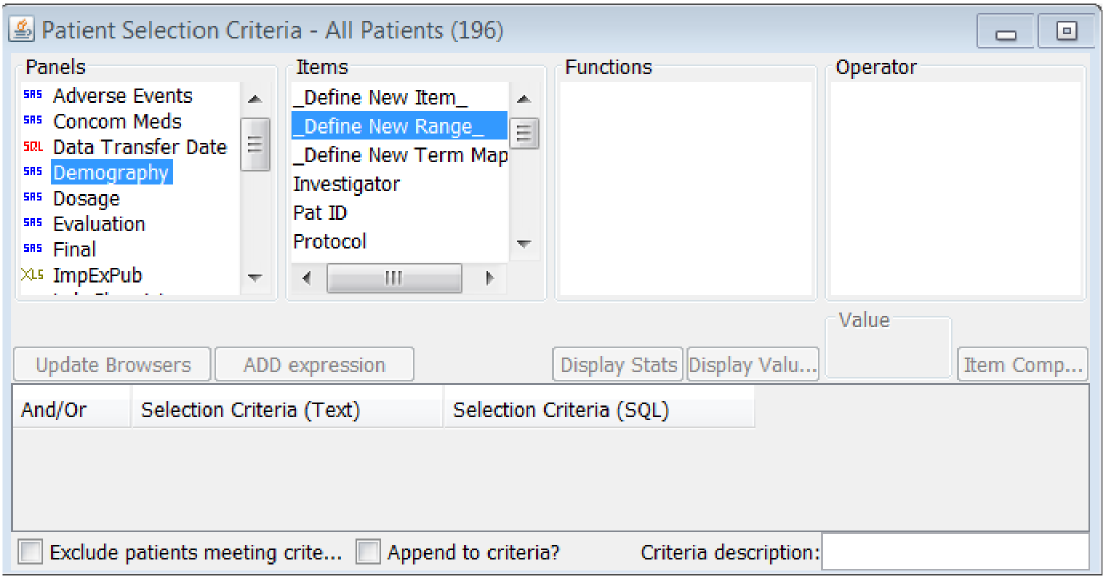
New Items has an added new substitution parameter <tc> - for table alias – which will be resolved to the current panel – so that a NewItem can be added with ‘All Panels’ checked – but changing the default <t>6 (panelIndex number) – which would resolve to the panel it was defined from – changing the <t>6 to <tc> which will resolve to the current panel.

# Define New Range

## User-defined range variables

You can report continuous numerical data as groups of values or categories based upon range variables is often a desirable task. JReview supports user definition of range variables upon numeric data items throughout the Report, CrossTab, Graph Browsers and SAS Proc.

From the Patient Selection Criteria or any Browser build window, select a panel and then click Define New Item. The second entry in the item list is the pseudo-item ”_Define New Range_”.

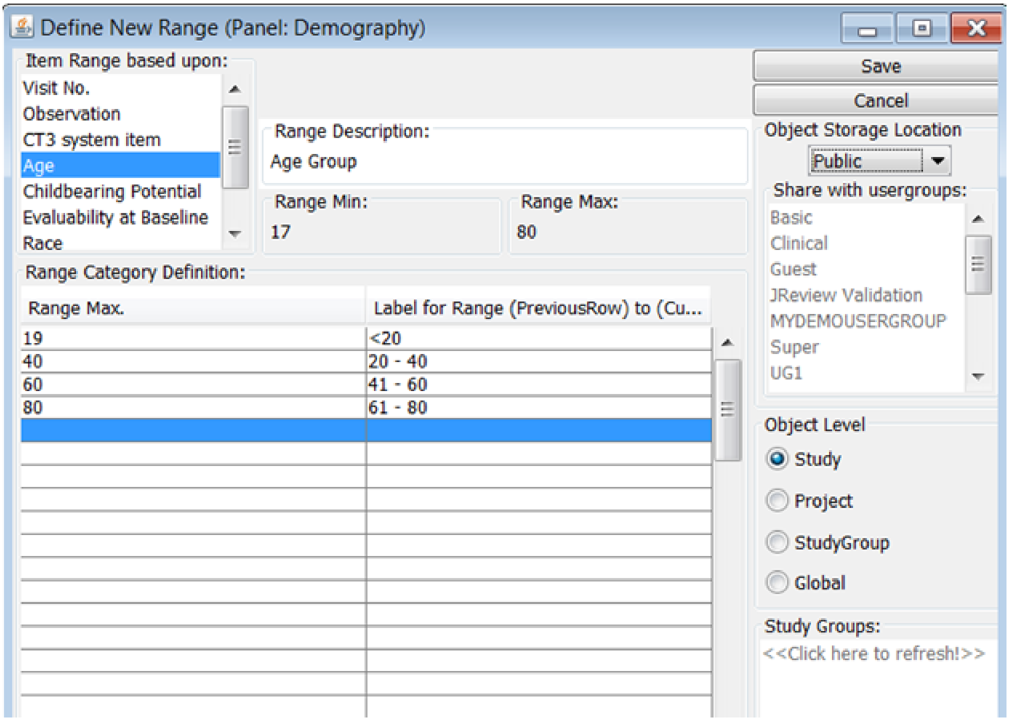


## Define New Range

1. Click on ”_Define New Range_”. JReview displays the **Define New Range Variable** window where you enter the definition of your new range variable.
2. Select the numeric data item upon which to base your new range variable.

   JReview automatically displays the current range of the numeric variable in the database displayed as the Min and Max values.

3. Enter a **Range Description**. Your description will be listed in the Items list when you select the panel in which you added the new range variable.



Item Range based upon: Age

Range Description: Age Group

Range Min: 17

Range Max: 80

Object Storage Location: Public

Object Level: ● Study

Range Category Definition:

| Range Max. | Label for Range (PreviousRow) to (Cu... |
|---|---|
| 19 | <20 |
| 40 | 20 - 40 |
| 60 | 41 - 60 |
| 80 | 61 - 80 |

## *Define range cut points*

4. Double click on each cell in the **Range Max** column, and enter the numeric ‘cut points’ of your ranges .

5. Double click on the cell to enter a **Label for Range** to describe the relation of the previous row to the current row and to Range columns.

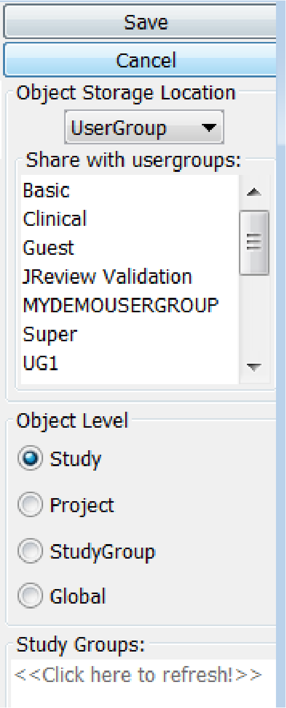
   The definition of ranges are entered as the Maximum value of each range; as opposed to entry of the minimum and maximum values for every range. In essence, you are entering the only the Maximum value of each range; because JReview uses the previous row’s Maximum value as the Minimum value of the following row’s range.

   The first row’s Minimum value is automatically generated by JReview to include all points less than, but not including, the range maximum of the following row.

   Missing item values for a patient or group are automatically assigned to a range noted as a ‘missing’ entry.

6. Select the **Object Store** access as **Private, UserGroup** or **Public**.

   Selecting multiple UserGroups for save is supported.



Object Storage Location
UserGroup ▾

Share with usergroups:
Basic
Clinical
Guest
JReview Validation
MYDEMOUSERGROUP
Super
UG1

Object Level
● Study
○ Project
○ StudyGroup
○ Global

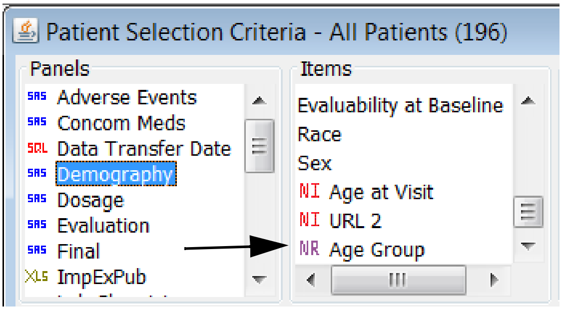
Study Groups:
<<Click here to refresh!>>

   If you save the new item as **Private,** you must select ‘Private’ in the Object Explorer area for Patient Subsets and Object Specifications to access the new range. In addition, you may need to refresh the window to view the private new range.

7. Optionally select **Global New Range**.
8. Click **Save**. JReview saves the definition and the description and posts the New Range from the panel in which it was activated.

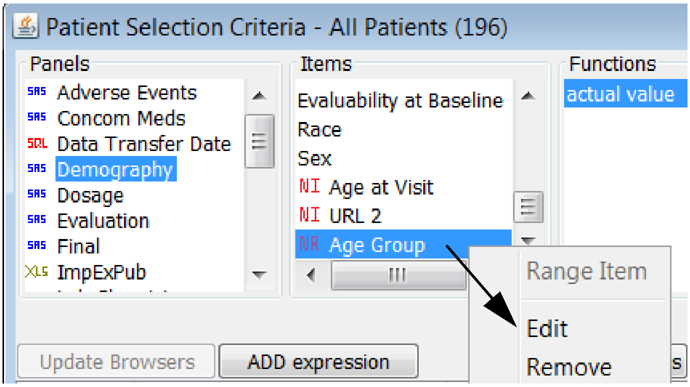
JReview saves the descriptive information about the range within internal tables. The actual set of ranges values will be stored on the database under your User ID, in a new table of the form.

The saved “New Range” displays in the Items list for the selected panel with the new range prefix for “NR”.



## Edit New Range

To apply changes or remove to the range variable that you have defined and saved:



1. Select the panel.
2. Select the range variable description in the **Items list**.
3. Right mouse click on the range variable to display a floating menu; select **Edit** or **Remove**.
4. Change any portion of the New Range Expression.
5. Click **Update** and JReview saves the changes.
6. Enter changes to any of the range value definitions.
7. Click **Update** where JReview saves your changes to **Edit** or **Remove** the range variable from selected panel's Items list.

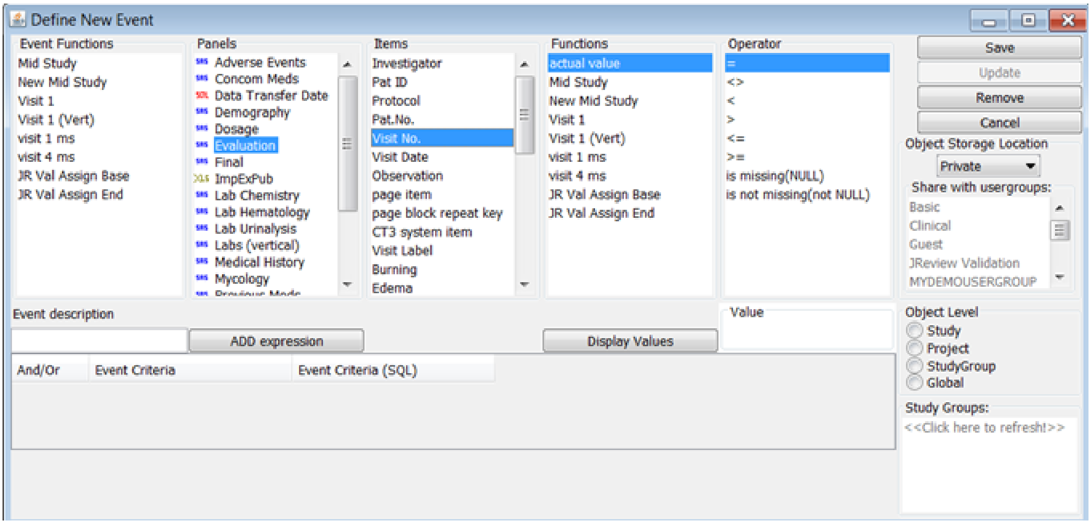
# Define New Event

## User-defined time related milestones

You can define time-related milestones, such as baseline, endpoint, or any description of your choice, for use throughout JReview. From the pseudo-function "_New Event Function_" you can view a current listing of event derived-values and add new event criteria.

## Define New Event

1. From the **Advanced** menu, click **Define New Event**.
2. Select a Panel and item to reference the event you wish to define.



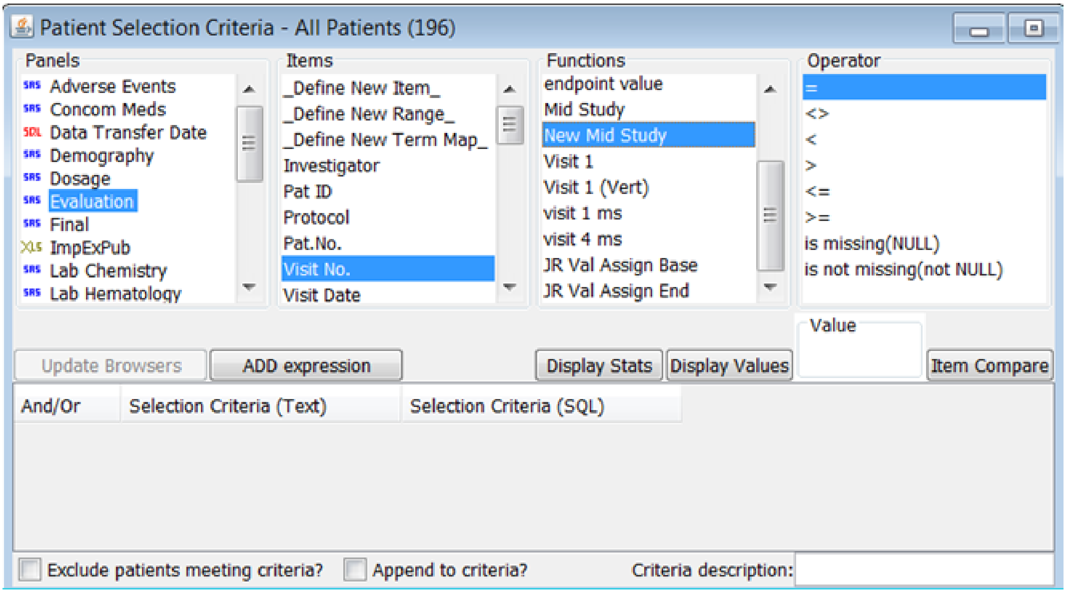
3. Select an existing event function, or define a new event by clicking on a reference **Panel**.
4. Select an **Operator**.
5. Select a value from the **Display Values** list or enter a value in the "Value" field.
6. Click **ADD Expression** to build the new event function value. The values will be entered in the Event Criteria spreadsheet.
7. When you are finished defining the event function value; enter the **Event Description**.

8. Select the **Object Storage Location** access as **Private, UserGroup** or **Public**.

   If you save the new item as **Private,** you must select ‘Private’ in the Object Explorer area for Patient Subsets and Object Specifications to access the new event. In addition, you may need to refresh the window to view the private new event.

9. Select the **Object Level** as **Global**, **Project**, **StudyGroup** or **Study**.
10. Click **SAVE.**

    The New Event function is displayed in the Functions list with the function values.



## *Edit or remove new event function*

1. From the **Advanced** menu, click **Define New Event** list. The **New Event** window opens.
2. Select the Event Function you want to edit or remove.
3. Enter any changes and click **Update** to resave the event function; or click **Remove** to delete.

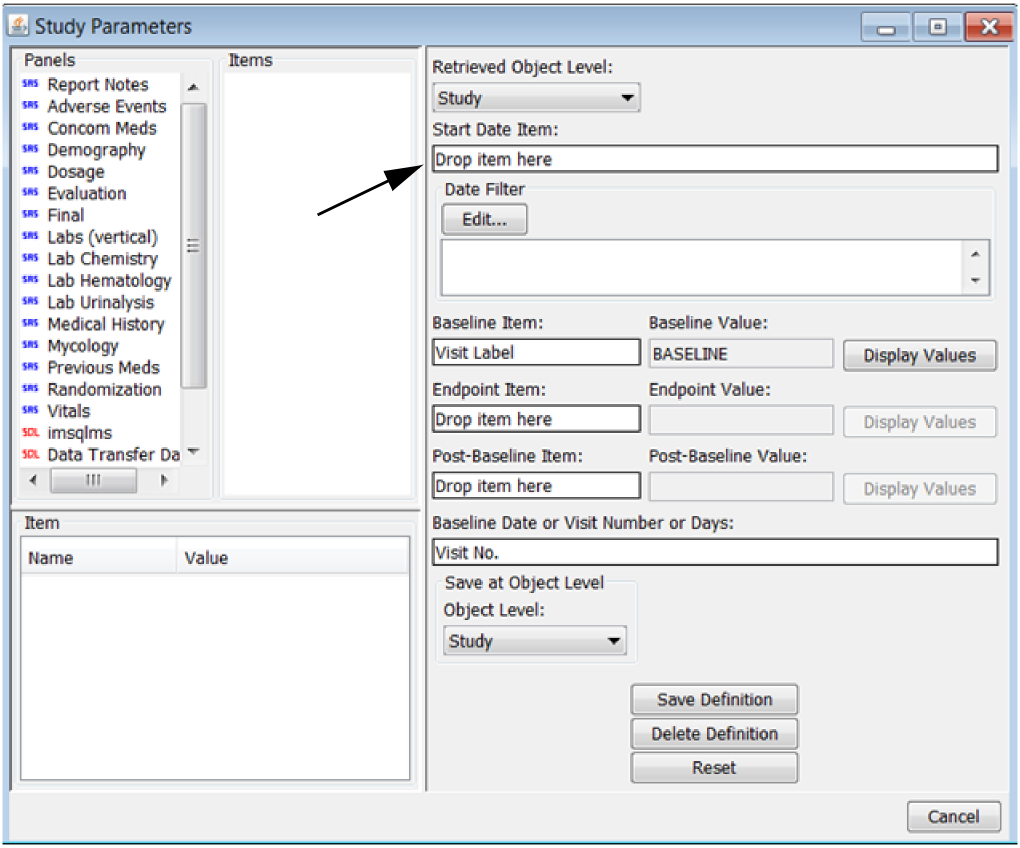
# Study Parameters

## *Define Study Start Date*

The Study Start Date is necessary when defining certain graph types for **Kaplan Meier, Napolean's March, Trellis Plots**, etc. Instead of adding this information into each graph definition the user may enter the Study Start Date once.

Go to the **Advanced Menu** and select '**Study Parameters'** to open the definition dialog. Select the Start Date Item. An optional Date Filter, is available, if needed.

The **Study Parameters** saved locally through the JReview Advanced menu will take precedence over a Baseline Endpoint defined within ReviewAdmin.



Study Parameters

Retrieved Object Level: Study

Start Date Item: Drop item here

Baseline Item: Visit Label

Baseline Value: BASELINE

Endpoint Item: Drop item here

Endpoint Value:

Post-Baseline Item: Drop item here

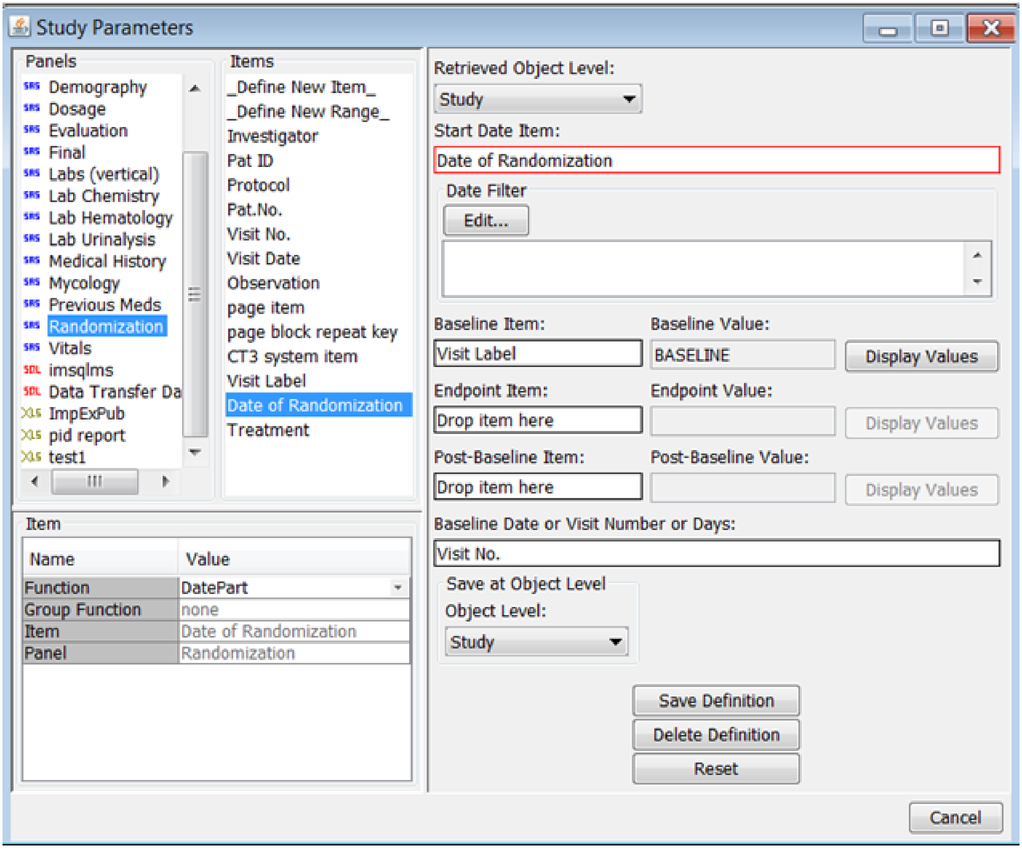
Post-Baseline Value:

Baseline Date or Visit Number or Days: Visit No.

Save at Object Level

Object Level: Study

By doing it once for the study, then it automatically will be available for any of the graphs that need a study start date. When the user defines and saves the study start date for a particular study, for example, Date of Randomization, then goes to the Graph Browser, then select Kaplan Meier under the ‘Other’ graph types – the ‘**Start Date Item**’ will be filled in automatically with the defined study start date item.



Retrieved Object Level: Study

Start Date Item: Date of Randomization

Baseline Item: Visit Label

Baseline Value: BASELINE

Endpoint Item: Drop item here

Endpoint Value:

Post-Baseline Item: Drop item here

Post-Baseline Value:

Baseline Date or Visit Number or Days: Visit No.

Object Level: Study

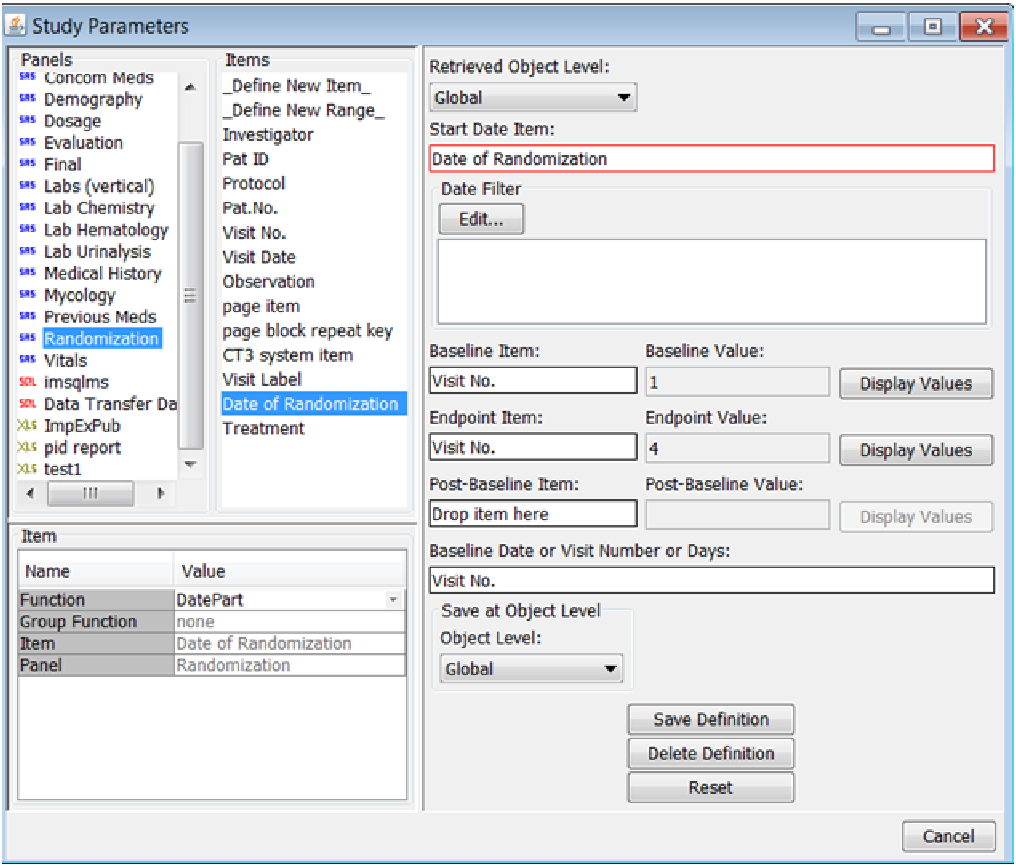
| Name | Value |
|---|---|
| Function | DatePart |
| Group Function | none |
| Item | Date of Randomization |
| Panel | Randomization |

**WARNING:** ***Some graph types will not be listed in the graph menus if the Study Parameters are NOT set. Likewise, if an object that uses these study parameters is saved and the parameters are then deleted - the object will still show up in the Object Explorer but instead displays a message.***

Additional definitions are added to support the **Composite Hy's Law plot** in the 'Study Management' dialog under the Advanced menu, but also useful for other graphs. A 'post baseline' definition is needed for the 'post baseline' max values for this graph.

There are two entries for that definition.  Some studies now not only have a baseline flag (in SDTM – it's LBBLFL='Y' for LB dataset), but also some submissions are coming in with a post baseline flag column.  For example, LBPBFL='Y' for post baseline flag='Y'.  So, if a dataset has a postbaseline flag column, then you'd use the 'Post-Baseline Item:' to select the post baseline flag item, then choose the value for it, i.e., 'Y.

However, if a study doesn't have a Post-Baseline item, then you'd use the 'Baseline Date or Visit Number or Days' definition – to tell the system what item to use to lookup either the visit number, date or day number item – corresponding to the baseline definition value. Then internally the system uses that field and baseline corresponding value to determine post baseline, by using '>',  i.e., in the case of KA201, where the baseline definition would be VISIT_LABEL='BASELINE', we don't have a post baseline flag, but if you select 'VISIT' for the 'Baseline Date or Visit Number or Days' item – then it looks up the visit number for each patient which corresponds to the baseline visit number then uses > to.  So, if patient 4101 has visit=1 for visit_label='BASELINE' – it'll use visit > 1 for post baseline.



Retrieved Object Level: Global

Start Date Item: Date of Randomization

Baseline Item: Visit No.

Baseline Value: 1

Endpoint Item: Visit No.

Endpoint Value: 4

Post-Baseline Item: Drop item here

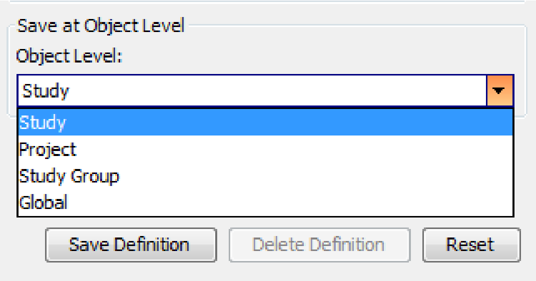
Post-Baseline Value:

Baseline Date or Visit Number or Days: Visit No.

Object Level: Global

| Name | Value |
|---|---|
| Function | DatePart |
| Group Function | none |
| Item | Date of Randomization |
| Panel | Randomization |

Click **Save Definition** at Object Level for either Study, Study Group, Project or Global level. The user saves the StudyStartDate definition for the Vertical Panel at a selected ***Object Level.*** The Object Levels include Study, Project, Study Group, and Global. If the Object Level is Study Group, then a primary study group is used. '**Primary Study Group**' is a configuration setting where if a study belongs to multiple study groups, the ReviewAdmin user can designate one of the study groups to be the primary study group. If the study is only a member of a single study group, then that's the primary study group. Therefore, there is no studygroup dropdown list if the user selects StudyGroup as the level. Instead the saving and retrieving from the **primary study group** always occurs for **StudyStartDate** definitions.



# Vertical to Horizontal Panel

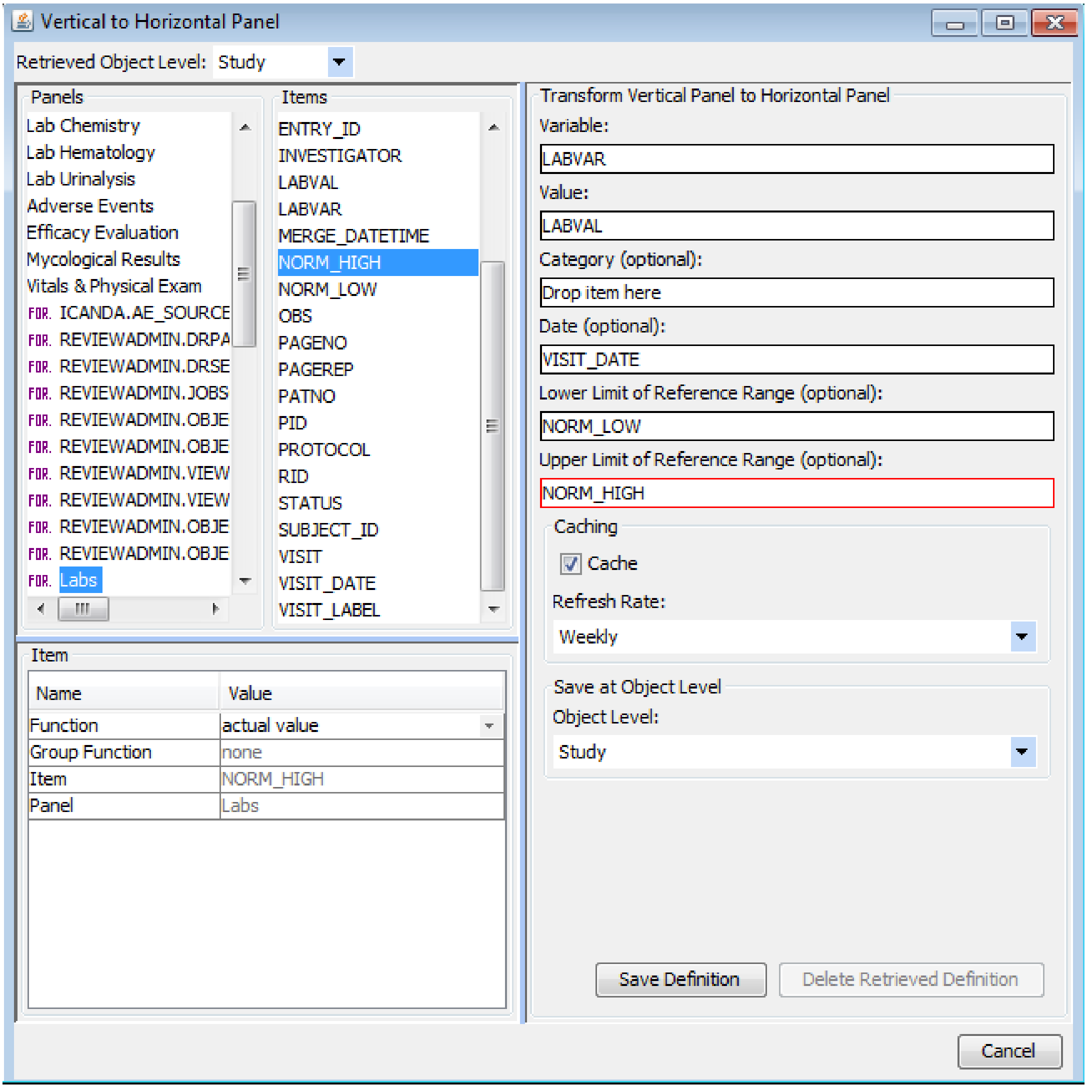
## *Transform Vertical to Horizontal Panel*

The feature to transform **"Vertical to Horizontal Panel"** is to support the use of vertical panels in JReview "New Mode Browsers". The Vertical to Horizontal panel will display in the panels list with the "**HRZ**" prefix to identify as a transformed vertical to horizontal panel.

The HRZ panels (Vertical to Horizontal Panel definitions) are available throughout JReview. They are included in Patient Selection Criteria, Output Filter, and any of the browser definition areas.

A frequently encountered example of a vertical panel is “Lab Chemistry”. A secondary purpose, is to centrally specify often-used variables in the vertical panel so that they can be used as ***default*** items in browsers, and may avoid repetitive specification of the same variables.

Go to the **Advanced menu** in the tool bar to select **Vertical to Horizontal Panel**.



Retrieved Object Level: Study

Item

| Name | Value |
|---|---|
| Function | actual value |
| Group Function | none |
| Item | NORM_HIGH |
| Panel | Labs |

Variable: LABVAR

Value: LABVAL

Category (optional): Drop item here

Date (optional): VISIT_DATE

Lower Limit of Reference Range (optional): NORM_LOW

Upper Limit of Reference Range (optional): NORM_HIGH

☑ Cache

Refresh Rate: Weekly

Object Level: Study

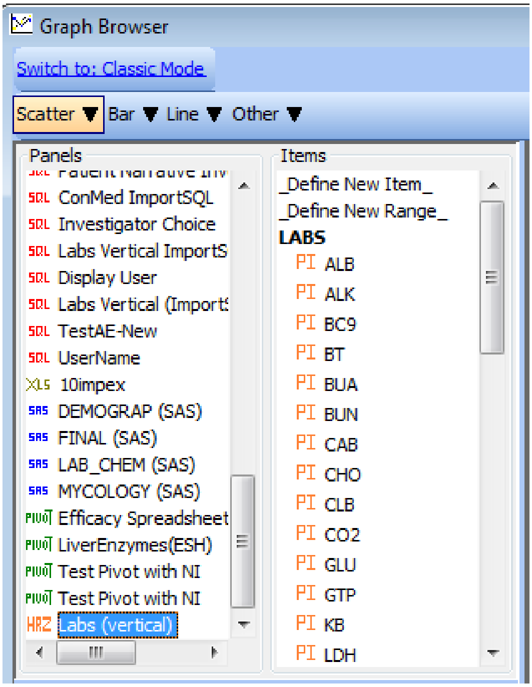
In the Vertical-to-Horizontal Transform dialog, the user selects a Vertical Panel, and then drags items belonging to that panel to the appropriate form fields displayed on the right-side of the dialog. These fields are drop-target components. Like the “drag-and-drop” browsers in JReview, the properties of a “dropped” item can be edited in the Item Property Table. Specifications of “Variable” and “Value” are required. The other variables are optional. The “Date” should only be an item that represents a “date” for this field; a calculated “days” item should NOT be used for this field.

The user saves the specified transformation definition for the Vertical Panel at a selected ***Object Level.*** The Object Levels include Study, Project, Study Group, and Global. If the Object Level is Study Group, then a primary study group is used. ‘**Primary Study Group**’ is a configuration setting where if a study belongs to multiple study groups, the ReviewAdmin user can designate one of the study groups to be the primary study group. If the study is only a member of a single study group, then that’s the primary study group. Therefore, there is no studygroup dropdown list if the user selects StudyGroup as the level. Instead the saving and retrieving from the **primary study group** always occurs for **Horizontal Panel** definitions.

The HRZ definition can be associated only with a ***single*** Study Group name. If the association is changed, i.e., the panel definition is now saved for a different study group, any prior HRZ association between a study group and the panel is removed.

When a “transform” is defined for a Vertical Panel, a “fabricated” panel decorated with an *HRZ* prefix will appear in the panel tree of a browsers that support the use of HRZ panels. When an HRZ panel is selected in the panel tree, its items are hierarchically presented in the associated item display. The “original” items are under the “Original” heading, and fabricated items are under the “Labs” or other subheadings. Note that the individual lab tests appear as separate items, but in actuality they are values in the “Variable” column of the Vertical Panel. From the end-user’s perspective, these fabricated items can be treated in the same way that horizontal panel items are employed.

The saved horizontal panel displays with the **"HRZ"** prefix to identify as a transformed vertical to horizontal panel. The individual laboratory tests are listed for selection with included reference range.

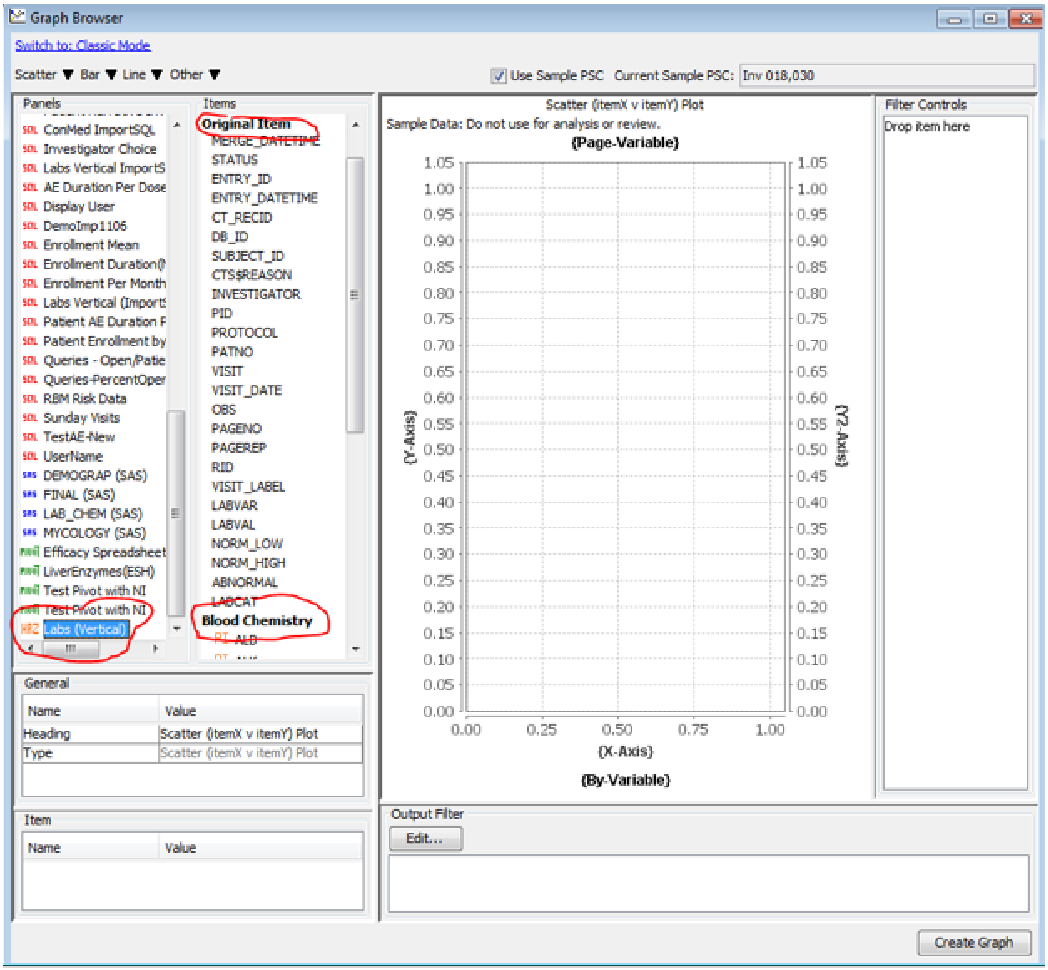


## Define HRZ

Open the **Advanced menu**, to select **"Vertical to Horizontal Panel".** The user selects a Vertical Panel, and then drags items belonging to that panel to the appropriate drop target components on the right-side of the dialog.

1. **Variable** is a ***required item*** that specifies the panel item containing what in a Horizontal Panel would be separate panel items (i.e., database table columns). For a Lab Chemistry Vertical Panel, this item typically contains the names of lab tests (Cholesterol, Bilirubin, Glucose, etc.).
2. **Value** is a ***required item*** that specifies the panel item that contains the value for each instance of a "lab test" value in the Variable item. For a Lab Chemistry Vertical Panel, this item contains the values for the lab test measurements (e.g., the actual lab test result).

3. **Category** is an optional item that specifies the item that contains the "category" of a lab test. It is possible in some datasets that the same lab test name can be associated with different lab test types. (e.g., Lab Chemistry and Urinalysis). While having the same name, the test may involve different procedures and measurements. Fabricated items in different categories within an HRZ panel are associated under different subheadings in the PIFPanel's item display.



General

| Name | Value |
|---|---|
| Heading | Scatter (itemX v itemY) Plot |
| Type | Scatter (itemX v itemY) Plot |

Item

| Name | Value |
|---|---|

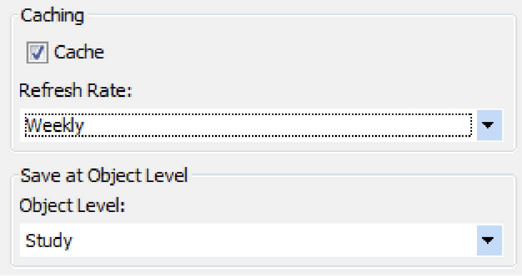
4. **Time** is an optional item that specifies when a measurement or event occurred. Time may be either a "Date" or calculated "Days".
5. **Lower-Limit of the Normal Range** is an optional item that specifies the Lower Limit of the Normal Range.
6. **Upper-Limit of the Normal Range** is an optional item that specifies the Upper Limit of the Normal Range.

A selected item's properties appear in the Item property table, and the user can modify the values of editable properties. Items in selected drop-target components can be deleted using JReview's "cut" operation or pressing the "Delete" key.

The current panel is the panel that is selected in the PIFPanel. In other words, a HRZ definition that is being created or modified is associated with the currently selected panel. If the user selects a different panel, the form is cleared. See Object-Level section for further description.

## *Cache HRZ Definition*

The Caching feature can be turned-on by checking the **Cache checkbox**. The Refresh Rate combo box provides the options for time intervals at which automatic refresh of the cache occur. The combo box is enabled when the Cache checkbox is selected.



Caching

☑ Cache

Refresh Rate: Weekly

Save at Object Level

Object Level: Study

The construction of "fabricated" items requires computer processing, and may cause slower retrievals of panel items. To improve performance, an optional ***Caching*** feature is provided. With caching, the fabricated items are constructed and then stored for reuse; this procedure avoids reconstructing the fabricated items for each retrieval request. However, the fabricated items may become invalid if new data values are loaded into the vertical panel. This may happen periodically in some environments. The Caching feature includes a set of ***Refresh Rate*** options so that the cached items may be automatically regenerated at selected time intervals. The Refresh Rate options are: None, Daily, Weekly, Biweekly, and Monthly.

## HRZ Object-Level

A concise UI design is used to support the Object-Level feature. There are two aspects of Object-Level in the dialog.

The first aspect is the object-level at which panels with HRZ definitions are retrieved when updating the PIFPanel's panel tree. The Retrieved Object Level combo box sets the object level at which the panels are retrieved. When the level is changed the PIFPanel is updated so that any defined Vertical Panels with HRZ definitions at the selected level are decorated with a "**HRZ**" suffix.

When a user selects a panel with an "**HRZ**" decoration", i.e., a vertical panel with an HRZ definition at the currently selected "retrieval" level, the form is populated with items and other values associated with the definition.

The second aspect of Object-Level is the level at which the definition is saved. The "retrieved" level is not necessarily the same level as the "save" level. This independence allows the user to retrieve a predefined definition at one level, and save it with or without modification at a different level. The controls for the Save Object-Level are found in the Save at Object Level subpanel. This subpanel contains a combo box for selecting the object level at which the definition will be saved; a second combo box, which is enabled when the Object-Level combo box's selected value is "Study Group", allows the user to select a Study Group for the Object Level.

## Save HRZ Definition

The **Save** button saves the definition specified in the form for the currently selected panel. ***The Save at Object Level controls determine the object level at which the object is saved.***

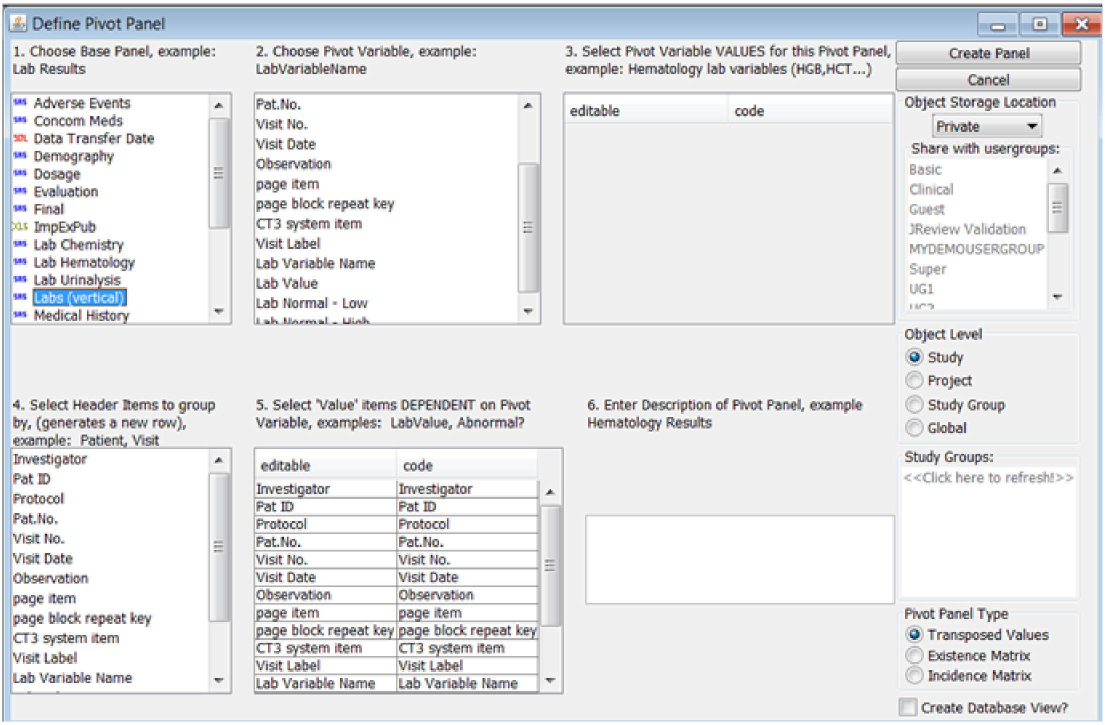
The **Delete Retrieved Definition** deletes the definition associated with the currently selected panel. ***The object-level for the delete operation is determined by the Retrieved Object Level and NOT the Save Object Level.***

# Pivot panels

## *Transposing normalized clinical data*

The Pivot Panel allows the transposing of data from a “vertical” table to a “horizontal” table. The user can choose which variables will make up the “horizontal” table. You can transpose clinical data stored in a normalized manner into a more easily reportable horizontal data structure. From the **Advanced** menu in the tool bar, select **Define Pivot Panel**.

The Define Pivot Panel window opens where you sequentially enter your selections to define the pivot panel.



Define Pivot Panel

1. Choose Base Panel, example: Lab Results

2. Choose Pivot Variable, example: LabVariableName

3. Select Pivot Variable VALUES for this Pivot Panel, example: Hematology lab variables (HGB,HCT...)

4. Select Header Items to group by, (generates a new row), example: Patient, Visit

5. Select 'Value' items DEPENDENT on Pivot Variable, examples: LabValue, Abnormal?

6. Enter Description of Pivot Panel, example Hematology Results

Object Storage Location: Private

Object Level: ● Study ○ Project ○ Study Group ○ Global

Study Groups: <<Click here to refresh!>>

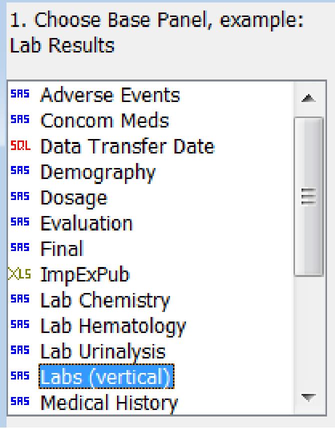
Pivot Panel Type: ● Transposed Values ○ Existence Matrix ○ Incidence Matrix

☐ Create Database View?

## Creating pivot panels

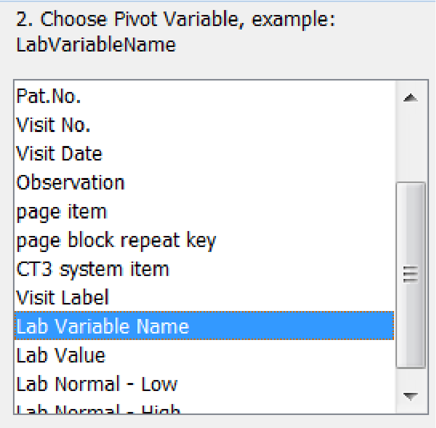
The creation of the pivot panel is a point and click operation. You construct the new data structure by selecting the appropriate items sequentially according to the number of the list box. Each list box is numbered and includes a brief description and instruction:

1. Choose a base panel.



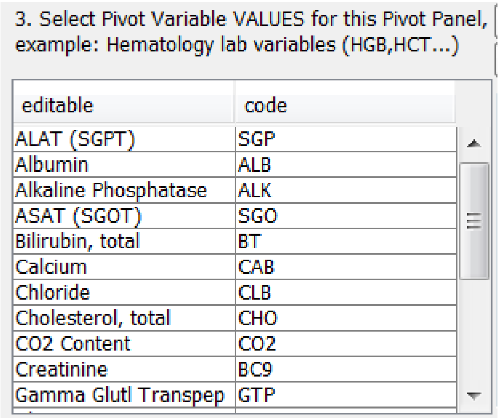
1. Choose Base Panel, example:
Lab Results

2. Choose a pivot variable.



2. Choose Pivot Variable, example:
LabVariableName

3. The left editable column allows you to edit the code description by double clicking in the cell. Next, select the Pivot Variable Values. Hold down **Ctrl key** and click to select multiple values.

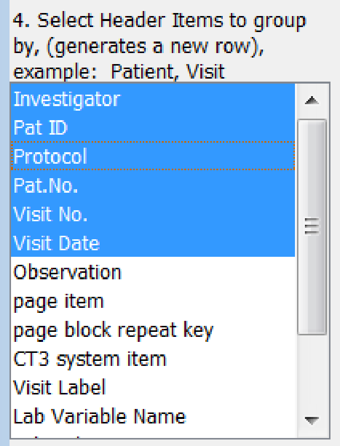


3. Select Pivot Variable VALUES for this Pivot Panel,
example: Hematology lab variables (HGB,HCT...)

| editable | code |
|---|---|
| ALAT (SGPT) | SGP |
| Albumin | ALB |
| Alkaline Phosphatase | ALK |
| ASAT (SGOT) | SGO |
| Bilirubin, total | BT |
| Calcium | CAB |
| Chloride | CLB |
| Cholesterol, total | CHO |
| CO2 Content | CO2 |
| Creatinine | BC9 |
| Gamma Glutl Transpep | GTP |

4. Select header items to group by, generating a new row in the new data structure for each change in the header items. By default, Patient ID is included as one of the header items.

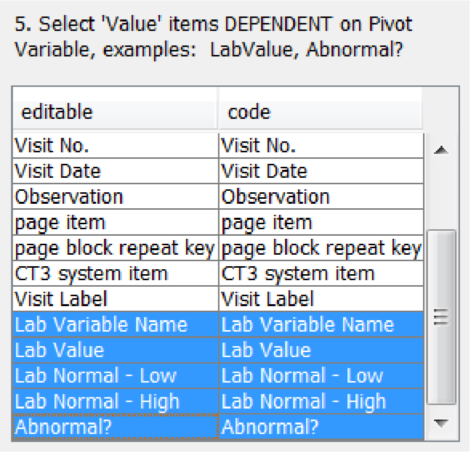
   For example, if you include Patient ID and Visit Number, a new row will be created not only for a change in Patient ID, but also for each Patient Visit Number. You must hold down the **Ctrl** and click to select multiple Values.



4. Select Header Items to group
by, (generates a new row),
example: Patient, Visit

Investigator
Pat ID
Protocol
Pat.No.
Visit No.
Visit Date
Observation
page item
page block repeat key
CT3 system item
Visit Label
Lab Variable Name

5. Select items that are dependent on the pivot variable. This is the data which will be stored for each pivot variable value. Multiple dependent variables can be selected. Optionally use the left editable column to edit the code description by double clicking in the cell.

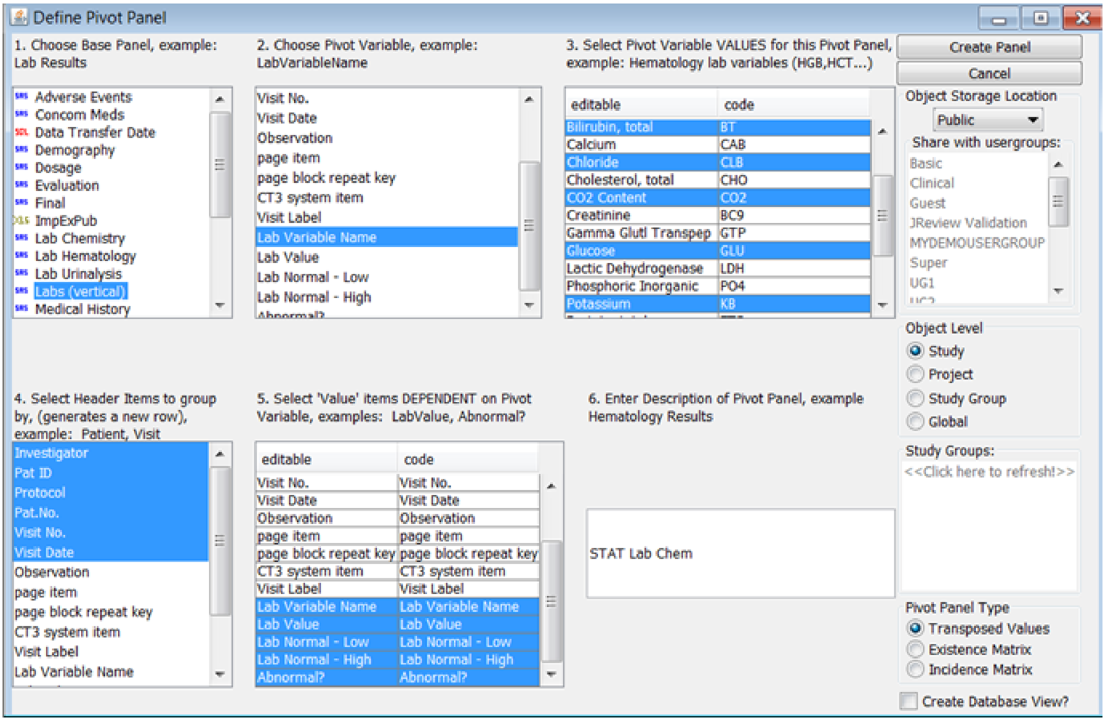


5. Select 'Value' items DEPENDENT on Pivot Variable, examples: LabValue, Abnormal?

| editable | code |
|---|---|
| Visit No. | Visit No. |
| Visit Date | Visit Date |
| Observation | Observation |
| page item | page item |
| page block repeat key | page block repeat key |
| CT3 system item | CT3 system item |
| Visit Label | Visit Label |
| Lab Variable Name | Lab Variable Name |
| Lab Value | Lab Value |
| Lab Normal - Low | Lab Normal - Low |
| Lab Normal - High | Lab Normal - High |
| Abnormal? | Abnormal? |

6. Enter a description for the pivot panel.
7. Select the **Object Store** for Private, UserGroup or Public.
8. Select the **Object Level** for Study, Project, StudyGroup or Global.

   If the selected study belongs to a StudyGroup you have the option to share or **Publish for StudyGroups**. Use the CTRL for multiple selections for studygroups.



1. Choose Base Panel, example: Lab Results

- Adverse Events
- Concom Meds
- Data Transfer Date
- Demography
- Dosage
- Evaluation
- Final
- ImpExPub
- Lab Chemistry
- Lab Hematology
- Lab Urinalysis
- Labs (vertical)
- Medical History

2. Choose Pivot Variable, example: LabVariableName

- Visit No.
- Visit Date
- Observation
- page item
- page block repeat key
- CT3 system item
- Visit Label
- Lab Variable Name
- Lab Value
- Lab Normal - Low
- Lab Normal - High

3. Select Pivot Variable VALUES for this Pivot Panel, example: Hematology lab variables (HGB,HCT...)

| editable | code |
|---|---|
| Bilirubin, total | BT |
| Calcium | CAB |
| Chloride | CLB |
| Cholesterol, total | CHO |
| CO2 Content | CO2 |
| Creatinine | BC9 |
| Gamma Glutl Transpep | GTP |
| Glucose | GLU |
| Lactic Dehydrogenase | LDH |
| Phosphoric Inorganic | PO4 |
| Potassium | KB |

Object Storage Location: Public

Share with usergroups:

- Basic
- Clinical
- Guest
- JReview Validation
- MYDEMOUSERGROUP
- Super
- UG1

Object Level

● Study
○ Project
○ Study Group
○ Global

4. Select Header Items to group by, (generates a new row), example: Patient, Visit

- Investigator
- Pat ID
- Protocol
- Pat.No.
- Visit No.
- Visit Date
- Observation
- page item
- page block repeat key
- CT3 system item
- Visit Label
- Lab Variable Name

5. Select 'Value' items DEPENDENT on Pivot Variable, examples: LabValue, Abnormal?

| editable | code |
|---|---|
| Visit No. | Visit No. |
| Visit Date | Visit Date |
| Observation | Observation |
| page item | page item |
| page block repeat key | page block repeat key |
| CT3 system item | CT3 system item |
| Visit Label | Visit Label |
| Lab Variable Name | Lab Variable Name |
| Lab Value | Lab Value |
| Lab Normal - Low | Lab Normal - Low |
| Lab Normal - High | Lab Normal - High |
| Abnormal? | Abnormal? |

6. Enter Description of Pivot Panel, example Hematology Results

STAT Lab Chem

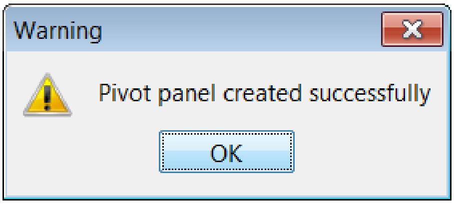
Study Groups: <<Click here to refresh!>>

Pivot Panel Type

● Transposed Values
○ Existence Matrix
○ Incidence Matrix

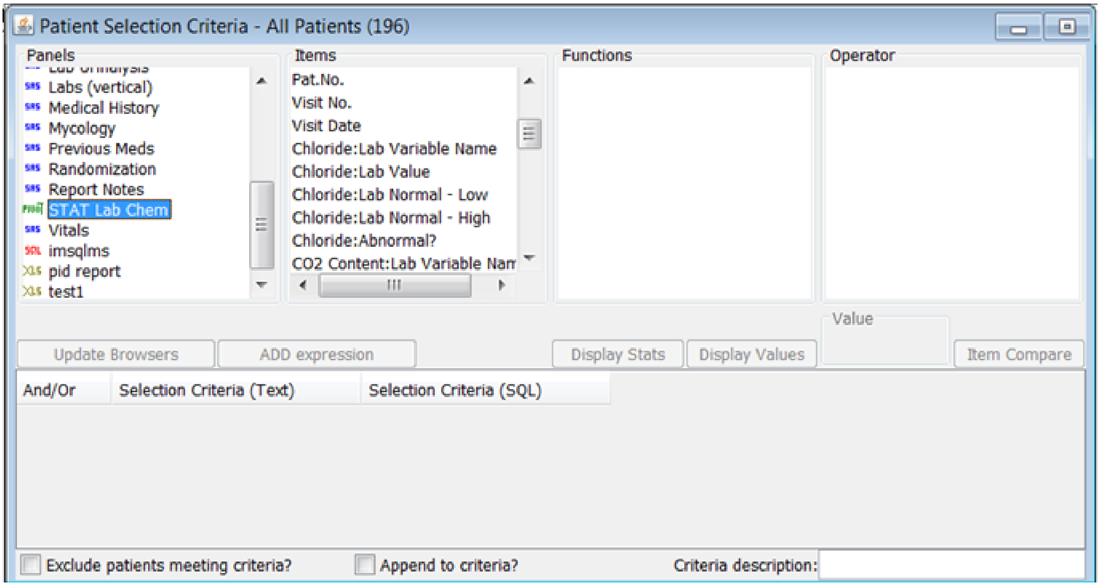
☐ Create Database View?

9. Select the **Pivot Panel Type**.
   - **Transposed Values** - demonstrated with the Lab Hematology example.
   - **Existence Matrix** - will define either a 1 or a 0 when the presence of a value is in the specified field. For example, when used as a method for looking for the existence of a specific Adverse Event (i.e. Headache) per patient; in step 2 choose AE Text and select ‘HEADACHE’ as the value in step 3. Next just use PID as the header field and leave the dependent variable blank. If you use this pivot panel to create a detailed report, then any patient who has a ‘HEADACHE’ value for the field will be 1 and if they did not then it will be 0. Even if the patient had 20 headaches it will only show a 1 (meaning that at least one existed).
   - **Incidence Matrix** - is similar to the Existence matrix, but using the previous example would show the number of headaches per patient. So if a patient had 20 headaches then the value would be 20.
   - **Create Database View** option creates an Oracle view.
10. Click **Create Panel**.


Warning

Pivot panel created successfully

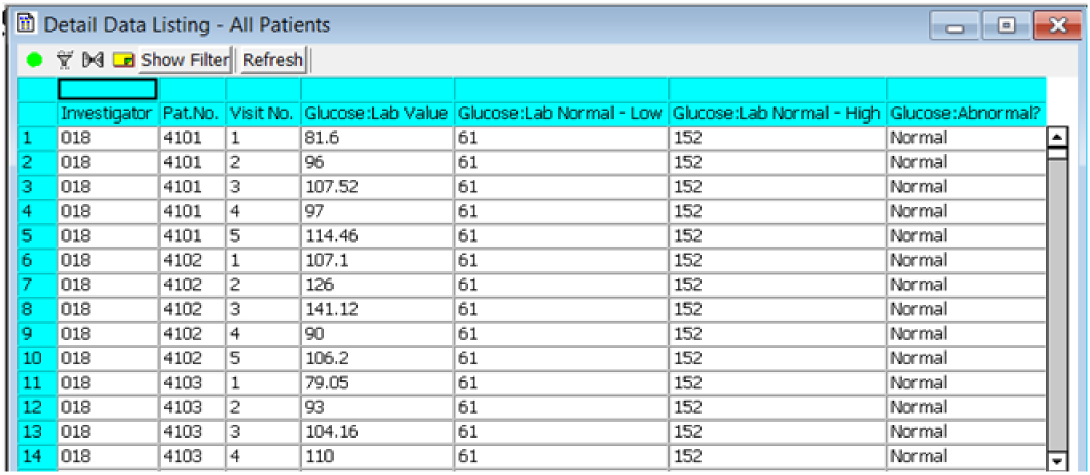
When the pivot panel is created, it is included in the panel listing with a dependent variables listing in the items list box.


Patient Selection Criteria - All Patients (196)

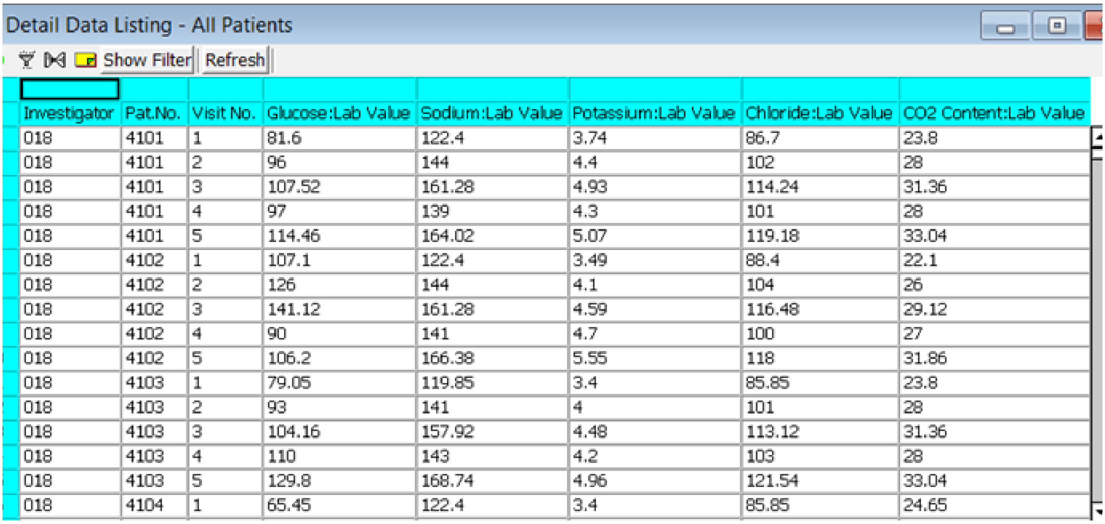
***Note: Saved specifications using a pivot panel will only work with the pivot panel it was created with. If the same pivot panel is recreated with the same name, the objects using the original panel will not work because the system naming convention iterates with each created panel.***

A comparison between the Laboratory Examination Panel and the defined Pivot Panel is best demonstrated by opening the panels with the Data Browser.

The Laboratory Examinations Panel previously stored in a normalized manner is pivoted into a horizontal data structure.



| | Investigator | Pat.No. | Visit No. | Glucose:Lab Value | Glucose:Lab Normal - Low | Glucose:Lab Normal - High | Glucose:Abnormal? |
|---|---|---|---|---|---|---|---|
| 1 | 018 | 4101 | 1 | 81.6 | 61 | 152 | Normal |
| 2 | 018 | 4101 | 2 | 96 | 61 | 152 | Normal |
| 3 | 018 | 4101 | 3 | 107.52 | 61 | 152 | Normal |
| 4 | 018 | 4101 | 4 | 97 | 61 | 152 | Normal |
| 5 | 018 | 4101 | 5 | 114.46 | 61 | 152 | Normal |
| 6 | 018 | 4102 | 1 | 107.1 | 61 | 152 | Normal |
| 7 | 018 | 4102 | 2 | 126 | 61 | 152 | Normal |
| 8 | 018 | 4102 | 3 | 141.12 | 61 | 152 | Normal |
| 9 | 018 | 4102 | 4 | 90 | 61 | 152 | Normal |
| 10 | 018 | 4102 | 5 | 106.2 | 61 | 152 | Normal |
| 11 | 018 | 4103 | 1 | 79.05 | 61 | 152 | Normal |
| 12 | 018 | 4103 | 2 | 93 | 61 | 152 | Normal |
| 13 | 018 | 4103 | 3 | 104.16 | 61 | 152 | Normal |
| 14 | 018 | 4103 | 4 | 110 | 61 | 152 | Normal |



| Investigator | Pat.No. | Visit No. | Glucose:Lab Value | Sodium:Lab Value | Potassium:Lab Value | Chloride:Lab Value | CO2 Content:Lab Value |
|---|---|---|---|---|---|---|---|
| 018 | 4101 | 1 | 81.6 | 122.4 | 3.74 | 86.7 | 23.8 |
| 018 | 4101 | 2 | 96 | 144 | 4.4 | 102 | 28 |
| 018 | 4101 | 3 | 107.52 | 161.28 | 4.93 | 114.24 | 31.36 |
| 018 | 4101 | 4 | 97 | 139 | 4.3 | 101 | 28 |
| 018 | 4101 | 5 | 114.46 | 164.02 | 5.07 | 119.18 | 33.04 |
| 018 | 4102 | 1 | 107.1 | 122.4 | 3.49 | 88.4 | 22.1 |
| 018 | 4102 | 2 | 126 | 144 | 4.1 | 104 | 26 |
| 018 | 4102 | 3 | 141.12 | 161.28 | 4.59 | 116.48 | 29.12 |
| 018 | 4102 | 4 | 90 | 141 | 4.7 | 100 | 27 |
| 018 | 4102 | 5 | 106.2 | 166.38 | 5.55 | 118 | 31.86 |
| 018 | 4103 | 1 | 79.05 | 119.85 | 3.4 | 85.85 | 23.8 |
| 018 | 4103 | 2 | 93 | 141 | 4 | 101 | 28 |
| 018 | 4103 | 3 | 104.16 | 157.92 | 4.48 | 113.12 | 31.36 |
| 018 | 4103 | 4 | 110 | 143 | 4.2 | 103 | 28 |
| 018 | 4103 | 5 | 129.8 | 168.74 | 4.96 | 121.54 | 33.04 |
| 018 | 4104 | 1 | 65.45 | 122.4 | 3.4 | 85.85 | 24.65 |

## *Remove pivot panel*

Right mouse click on the selected pivot panel to display a floating menu; click Remove. Pivot panels can not be edited.

# Mapping Text Terms

## *Remapping terms*

Mapping text terms provides user definition through a remapping definition window. It allows the users to select a text item (for example AE Preferred Term), then defining a 'mapped' term and selecting which of the available existing terms (AE Preferred Term, for example) should belong to that remapped term. An example would be defining a mapped term of 'Hypersensitivity reaction', then selecting each of the preferred term values in the data that you'd like to remap to that general term. Then in reports, graphs, crosstabs, etc., the remapped term can be included in addition to or instead of the original term.

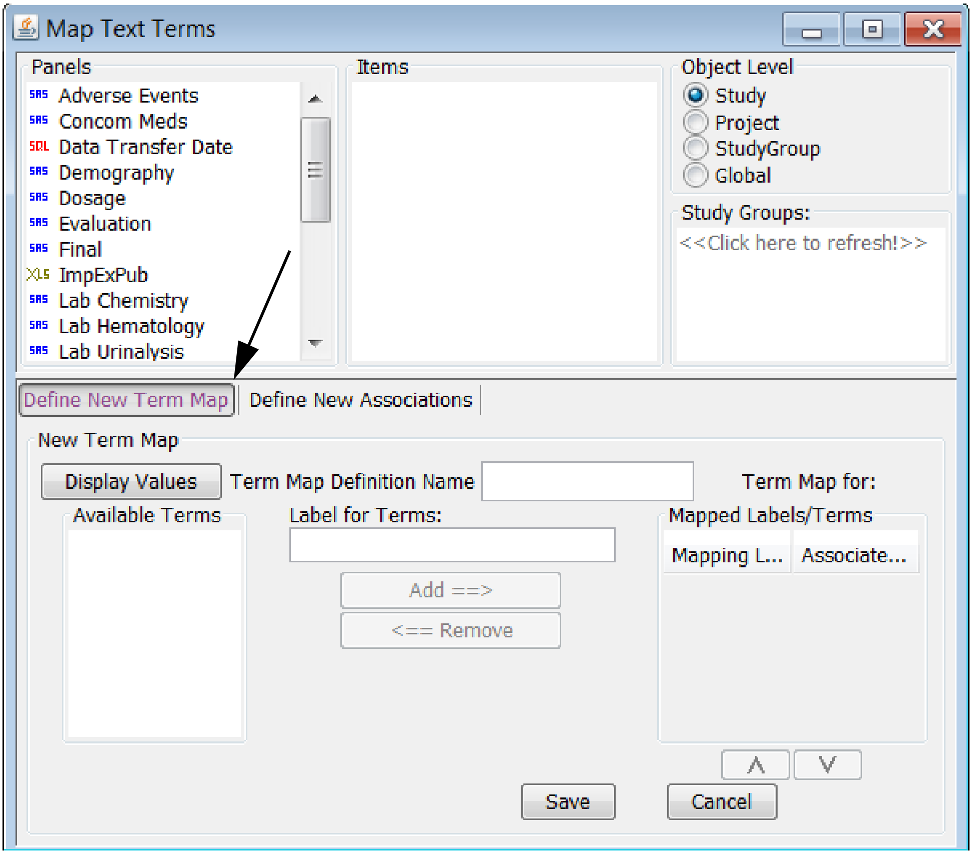
If the original term is not on the mapped list then the original term is displayed in the report. So referencing the mapped term yields either the new mapped categories or the original terms. Also, the named 'mapped terms' definition can be referenced/associated with other terms, i.e., if AE Preferred Terms have been mapped to a new mapped category definition, that mapped category definition can also be reused for Medical History preferred terms with **Define New Associations**.

This function is selected from the **Advanced menu** for users who have permission.

## *Save Initial Remap*

Open the **Advanced** menu to select **Map Text Terms**. The window opens to the **Define New Term Map** tab.

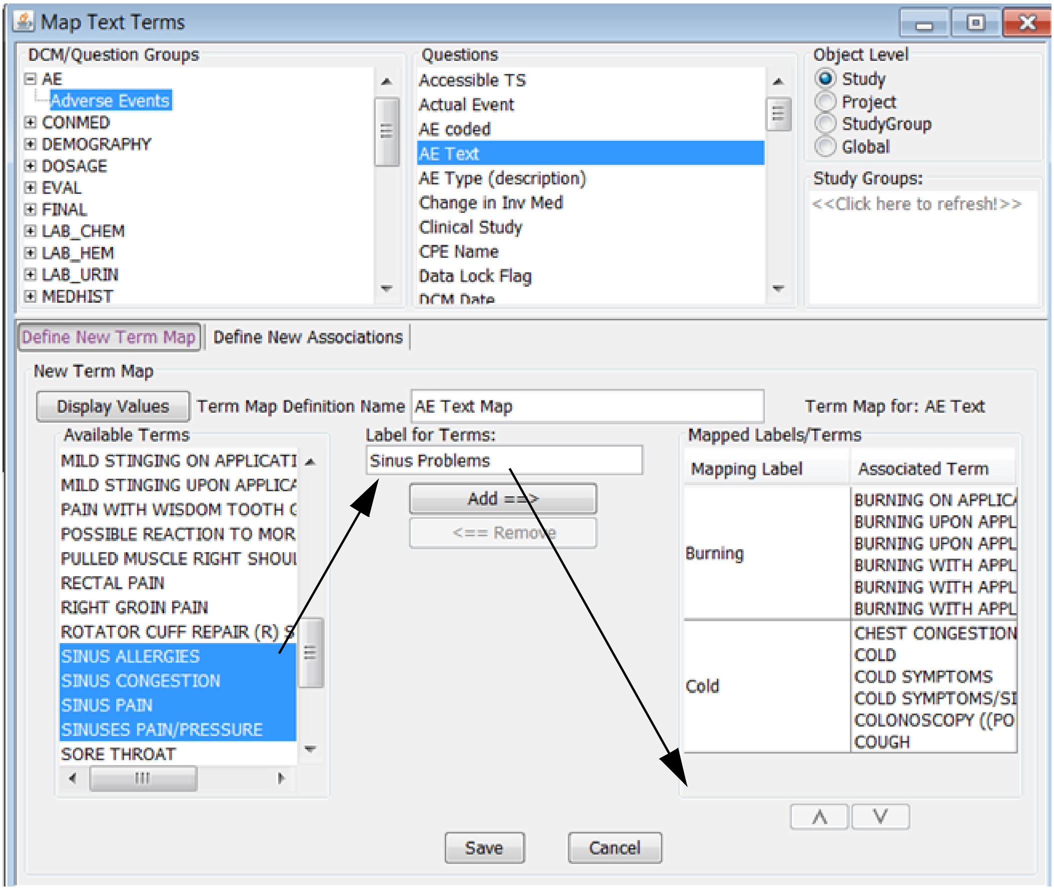
1. Select a panel and item from the upper window.
2. Select the **Object Level** for storage.
3. Click **Display Values** for Available Terms in the bottom window**.**



4. Enter the **Term Map Definition Name** (such as AE Term Map, Concmed Term Map).

   The **Term Map Definition Name** is what you will see in the Items list after it is saved. The **Label for Terms** is for the individual maps. For example, you label all the burning terminology as just “Burning” (this is the label). Then when you use it in a report all the burning terms will show as just “Burning”. You can only use the actual value of an item, not the decoded value as it is meant to be used with character terms like AE text.

5. Enter the **Label for Terms** (such as Burning, Cold, Surgery, etc).
6. Select from the **Available Terms** list and click **Add**. The selected available terms will be added to the **Mapped Labels/Terms** list. Enter a new label and repeat steps to select and add mapping terms.



Object Level: ● Study ○ Project ○ StudyGroup ○ Global

Term Map Definition Name: AE Text Map

Term Map for: AE Text

Label for Terms: Sinus Problems

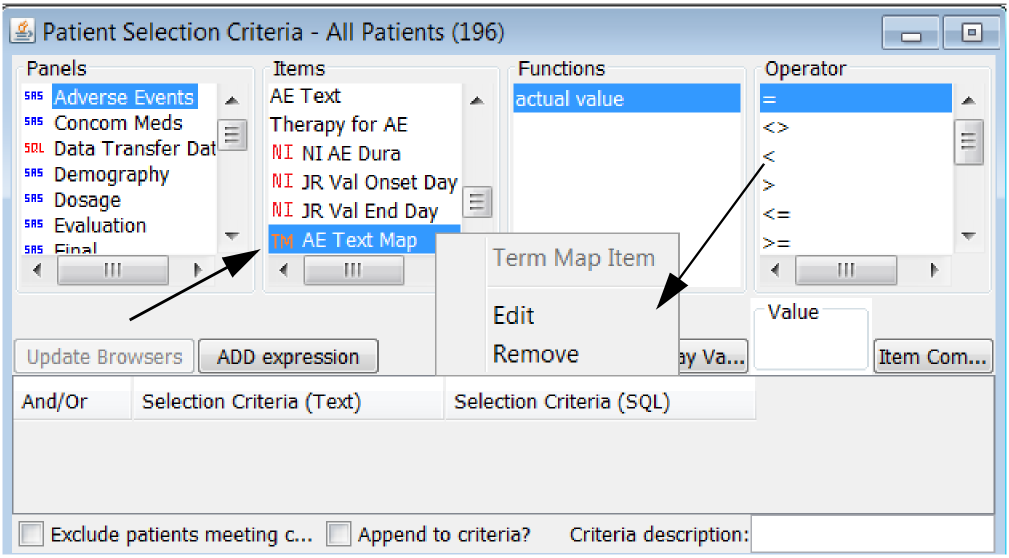
| Mapping Label | Associated Term |
|---|---|
| Burning | BURNING ON APPLICA<br>BURNING UPON APPL<br>BURNING UPON APPL<br>BURNING WITH APPL<br>BURNING WITH APPL<br>BURNING WITH APPL |
| Cold | CHEST CONGESTION<br>COLD<br>COLD SYMPTOMS<br>COLD SYMPTOMS/SI<br>COLONOSCOPY ((PO<br>COUGH |

7. After you have added all labels and mapped terms, click **Save**.

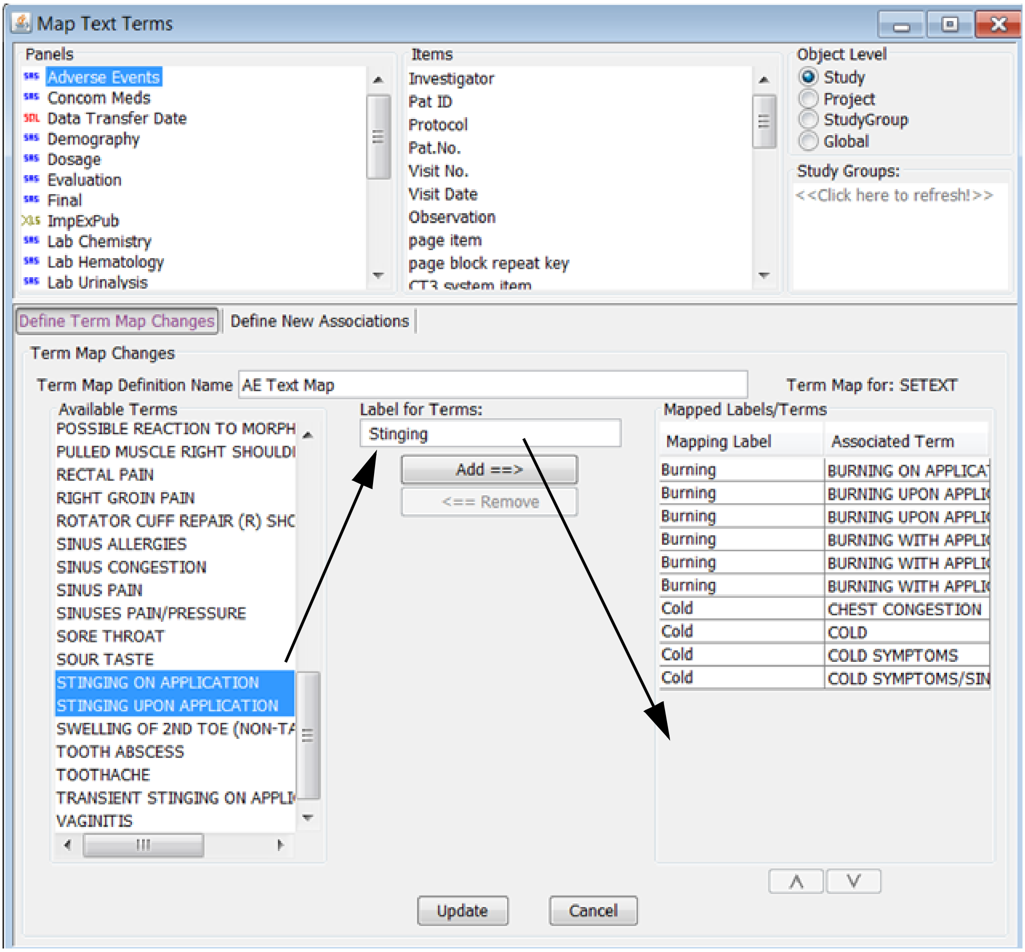
## *Edit a Term Map*

The New Term Map definition is saved with the prefix **TM** in the **Items** list for the panel Adverse Events. The term map item is available in Patient Selection Criteria, Report, CrossTab, Graph Browsers and Patient Narrative Definition. It is not available in Patient Profiles.

If you want to edit a term map item, select it in the items list and **right click** to **Edit or Remove**. Edit is where you add or remove mapping terms. Remove will delete the entire saved Term Map Item definition.



1. Right Click on the Term Map Item in the Items list.
2. Add or Remove Label/Term pairs.
3. Click **Update**.



Panels:
- Adverse Events
- Concom Meds
- Data Transfer Date
- Demography
- Dosage
- Evaluation
- Final
- ImpExPub
- Lab Chemistry
- Lab Hematology
- Lab Urinalysis

Items:
- Investigator
- Pat ID
- Protocol
- Pat.No.
- Visit No.
- Visit Date
- Observation
- page item
- page block repeat key
- CT3 system item

Object Level:
● Study
○ Project
○ StudyGroup
○ Global

Term Map Definition Name: AE Text Map

Term Map for: SETEXT

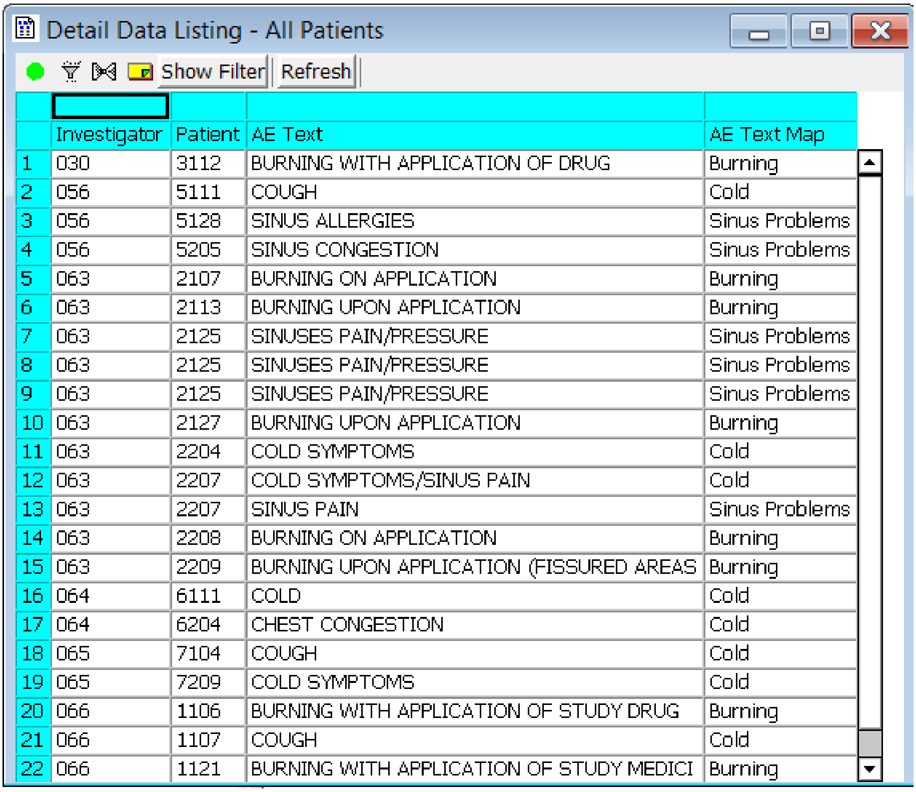
Available Terms:
- POSSIBLE REACTION TO MORPH
- PULLED MUSCLE RIGHT SHOULDI
- RECTAL PAIN
- RIGHT GROIN PAIN
- ROTATOR CUFF REPAIR (R) SHC
- SINUS ALLERGIES
- SINUS CONGESTION
- SINUS PAIN
- SINUSES PAIN/PRESSURE
- SORE THROAT
- SOUR TASTE
- STINGING ON APPLICATION
- STINGING UPON APPLICATION
- SWELLING OF 2ND TOE (NON-TA
- TOOTH ABSCESS
- TOOTHACHE
- TRANSIENT STINGING ON APPLI
- VAGINITIS

Label for Terms: Stinging

Mapped Labels/Terms:

| Mapping Label | Associated Term |
|---|---|
| Burning | BURNING ON APPLICA |
| Burning | BURNING UPON APPLI |
| Burning | BURNING UPON APPLI |
| Burning | BURNING WITH APPLI |
| Burning | BURNING WITH APPLI |
| Burning | BURNING WITH APPLI |
| Cold | CHEST CONGESTION |
| Cold | COLD |
| Cold | COLD SYMPTOMS |
| Cold | COLD SYMPTOMS/SIN |

A detailed data listing was defined in the Report Browser. It shows the initial entry for AE Text to AE Text Map term.



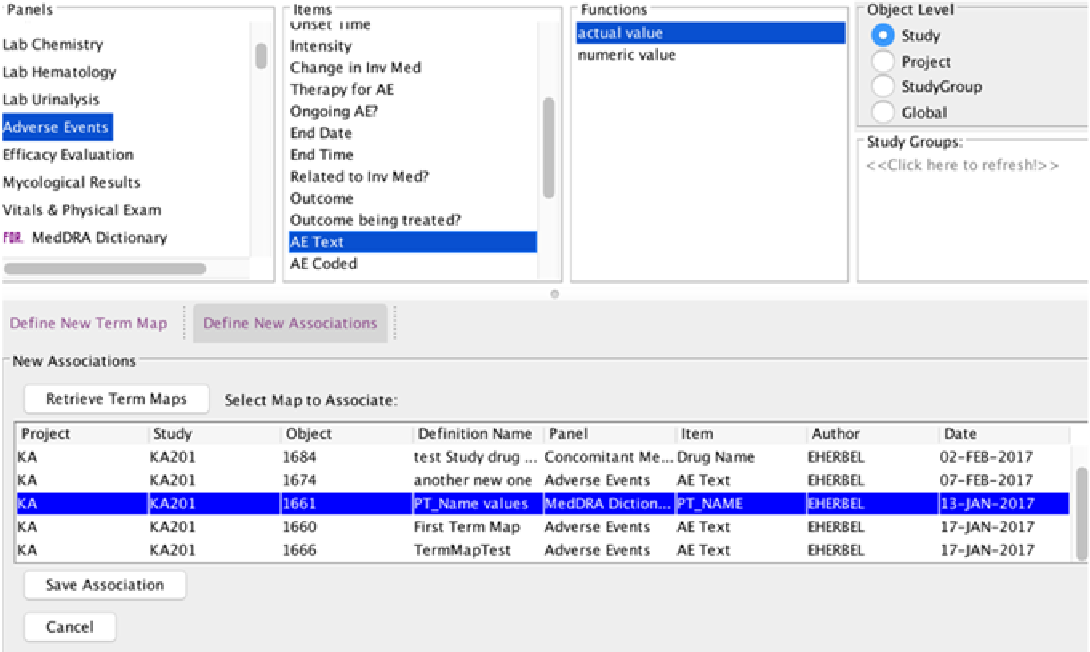
| | Investigator | Patient | AE Text | AE Text Map |
|---|---|---|---|---|
| 1 | 030 | 3112 | BURNING WITH APPLICATION OF DRUG | Burning |
| 2 | 056 | 5111 | COUGH | Cold |
| 3 | 056 | 5128 | SINUS ALLERGIES | Sinus Problems |
| 4 | 056 | 5205 | SINUS CONGESTION | Sinus Problems |
| 5 | 063 | 2107 | BURNING ON APPLICATION | Burning |
| 6 | 063 | 2113 | BURNING UPON APPLICATION | Burning |
| 7 | 063 | 2125 | SINUSES PAIN/PRESSURE | Sinus Problems |
| 8 | 063 | 2125 | SINUSES PAIN/PRESSURE | Sinus Problems |
| 9 | 063 | 2125 | SINUSES PAIN/PRESSURE | Sinus Problems |
| 10 | 063 | 2127 | BURNING UPON APPLICATION | Burning |
| 11 | 063 | 2204 | COLD SYMPTOMS | Cold |
| 12 | 063 | 2207 | COLD SYMPTOMS/SINUS PAIN | Cold |
| 13 | 063 | 2207 | SINUS PAIN | Sinus Problems |
| 14 | 063 | 2208 | BURNING ON APPLICATION | Burning |
| 15 | 063 | 2209 | BURNING UPON APPLICATION (FISSURED AREAS | Burning |
| 16 | 064 | 6111 | COLD | Cold |
| 17 | 064 | 6204 | CHEST CONGESTION | Cold |
| 18 | 065 | 7104 | COUGH | Cold |
| 19 | 065 | 7209 | COLD SYMPTOMS | Cold |
| 20 | 066 | 1106 | BURNING WITH APPLICATION OF STUDY DRUG | Burning |
| 21 | 066 | 1107 | COUGH | Cold |
| 22 | 066 | 1121 | BURNING WITH APPLICATION OF STUDY MEDICI | Burning |

## *Define a New Association*

Define New Associations is meant to associate a particular map with another item. So, for instance if you are mapping a dictionary you can then associate that map with the appropriate AE item or Concmed item, etc. ***You cannot edit anything about the map when defining an association.***

Associations can be used in a report or crosstab, or other objects, the same way Term Maps Items are used. In the Items list Term Maps Items and Associations are indistinguishable. You cannot edit an association, however, you can edit the Term Map Item that the association is based on. The Associations were meant to be used with Dictionaries, so that the mapping could be done once and then the user can associate for example an appropriate AE item, or an appropriate Concmed item with the dictionary mapping. Or, if there is a similar item in two different panels, associations would work as well. The user must aware of the contents of the items they are associating.

1. Select an item to associate with.
2. Open the list of Remap objects.
3. Select an object to associate.
4. Save Association.

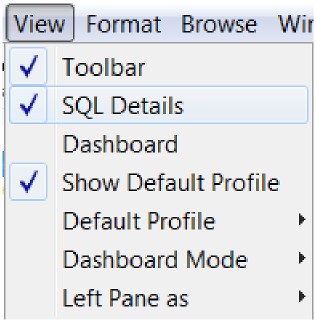


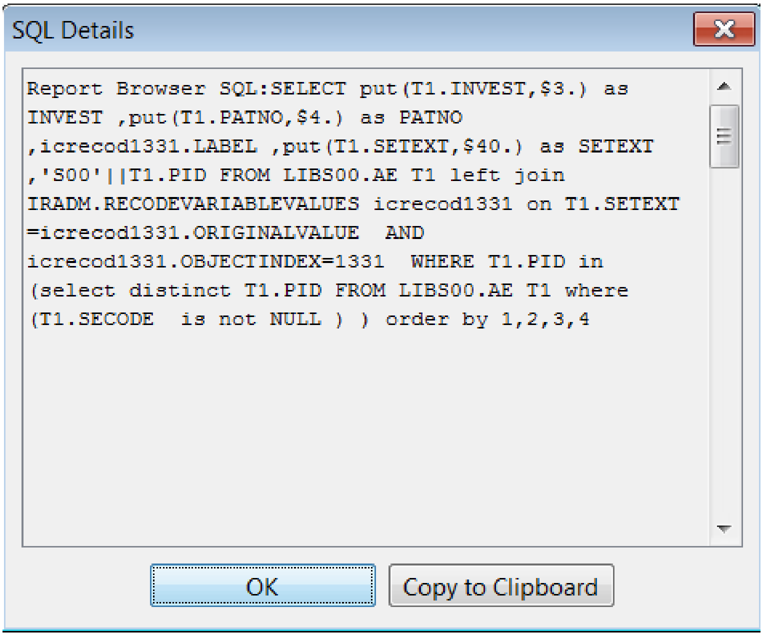
| Project | Study | Object | Definition Name | Panel | Item | Author | Date |
|---|---|---|---|---|---|---|---|
| KA | KA201 | 1684 | test Study drug ... | Concomitant Me... | Drug Name | EHERBEL | 02-FEB-2017 |
| KA | KA201 | 1674 | another new one | Adverse Events | AE Text | EHERBEL | 07-FEB-2017 |
| KA | KA201 | 1661 | PT_Name values | MedDRA Diction... | PT_NAME | EHERBEL | 13-JAN-2017 |
| KA | KA201 | 1660 | First Term Map | Adverse Events | AE Text | EHERBEL | 17-JAN-2017 |
| KA | KA201 | 1666 | TermMapTest | Adverse Events | AE Text | EHERBEL | 17-JAN-2017 |

# Copy to Clipboard

## *View SQL details dialog*

You can view the SQL details dialog from the From the Advanced menu in the tool bar, click **SQL Details**. The various browsers will display the SQL details as you explore the data. JReview allows you to copy the SQL to Clipboard.





```
Report Browser SQL:SELECT put(T1.INVEST,$3.) as
INVEST ,put(T1.PATNO,$4.) as PATNO
,icrecod1331.LABEL ,put(T1.SETEXT,$40.) as SETEXT
,'S00'||T1.PID FROM LIBS00.AE T1 left join
IRADM.RECODEVARIABLEVALUES icrecod1331 on T1.SETEXT
=icrecod1331.ORIGINALVALUE  AND
icrecod1331.OBJECTINDEX=1331  WHERE T1.PID in
(select distinct T1.PID FROM LIBS00.AE T1 where
(T1.SECODE  is not NULL ) ) order by 1,2,3,4
```

# 13 Dashboard Views

# Viewing Patient Data

## *What is Dashboard?*

Dashboard is an easy and user friendly solution to the problem of distributing clinical trial data to a broad base of data review personnel.

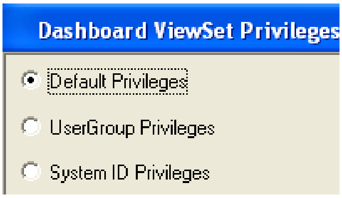
Dashboard leverages the use of JReview™ by enabling a broad range of users to have desktop access to ongoing Clinical Trial patient subsets, reports, multi-dimensional analysis, basic/advanced statistical and graphical objects and results.

Dashboard provides the ability to create viewsets displaying multiple reports, crosstabs and graphs that have been previously defined utilizing IReview™ and JReview™. These reports, crosstabs and graphs may be viewed simultaneously from a high level summary perspective. Or, drill down to individual graphic patient profiles is also provided. Data may be viewed in *LIVE* mode or in *CACHED* mode where it is refreshed on a regular basis.

Users can select previously saved objects to organize and save as viewsets for routine retrieval. Viewsets may be labeled as 'Favorite' for preferred access. Customized viewsets may be kept privately or shared.

## *Dashboard access*

Any user of JReview has access to the Dashboard features through permissions granted in ***ReviewAdmin***. The setting to allow for Dashboard use is in JReview.tx located on the server set by systems personnel to show 'DashboardViewMode=TRUE'. This setting provides a site with wide permission.


Dashboard ViewSet Privileges

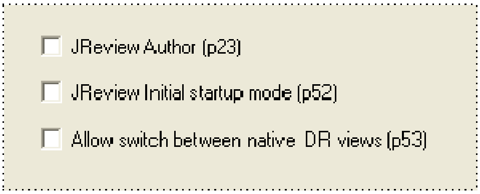
● Default Privileges

○ UserGroup Privileges

○ System ID Privileges

Additional Dashboard access options control direct entry and use of Dashboard only; versus access to JReview to define output specifications.

JReview Dashboard View supports as a preferred start-up mode, the ***ReviewAdmin*** option where the user goes into Dashboard View mode automatically after initial JReview logon.



☐ JReview Author (p23)

☐ JReview Initial startup mode (p52)

☐ Allow switch between native DR views (p53)

ENABLED P52 brings the client into JReview.

DISABLED P52 brings the client into Dashboard viewsets.

If the user chooses ‘Dashboard View’ as their ‘home page’ preference, that is what they will see initially in JReview after they connect, and select a project/study. Alternately, if they leave their preference as native JReview user Interface, the current JReview/IReview user interface is displayed, but they can choose to enable the Dashboard View interface at any time during their session dynamically. Similarly, a ‘Dashboard View’ default user can switch to ‘native JReview’ mode dynamically and switch back and forth if they choose.

The initial display of JReview Dashboard View includes a list of ‘tabs’ across the top corresponding to the users favorite ‘Dashboard Viewsets’.

## *Dashboard functions*

Dashboard users can perform the following functions.

- Simultaneously view results from multiple IReview™ and JReview™ saved output specifications.
- Define a set of saved outputs they wish to view side-by-side. This “ViewSet” may then be displayed in a “dashboard” style view of data outputs.
- Define multiple viewsets for each project/study they have access to.
- Create viewsets for their own private use or for sharing with other users.
- Create ‘Favorite’ viewsets for easy access as tabs.

Dashboard supports the following types of output specifications:

- **Cross Tabs** - cross tabulations and Shift tables.
- **Graphs** - Scatter plots, bar charts, pie charts and multi-page graphs.
- **Reports** - Non-formatted and formatted reports.
- **Parameterized Objects**.

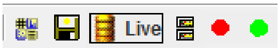
The following object types CANNOT be added to a viewset:

- **Patient Visit Reports**
- **Patient Profiles**
- **Formatted Patient Profiles**
- **Graphic Patient Profiles**

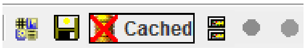
## *Types of data access*

Dashboard provides two types of access to data:

- “***LIVE* Mode** - access to data as it currently exists in the connected database.



- “***CACHED* Mode** - access to data which has been extracted from the connected database via a scheduled job.



***LIVE Mode is used to define and save a viewset. LIVE Mode*** is preferred by Dashboard users who want to apply patient selection criteria to individual views or viewsets. The CACHED Mode is for access to large data files which has been extracted from the connected database via a scheduled job.

The access mode options available in Dashboard are set in ***ReviewAdmin.***

- Switching Mode
  - Live Mode Only
  - Cache Mode Only
- Default Mode
  - Live Mode
  - Cache Mode

Use the **Change mode** icon in the Dashboard tool bar to toggle between CACHE and LIVE mode.

When a viewset is first saved, a scheduled job is created for each view in the viewset. These are repeating jobs where the repetition is specified in the JRServer initialization file. If the user tries to view a viewset before the scheduled jobs have completed, the user needs to change to *LIVE* mode manually to view output results. Once the scheduled jobs have run, *CACHED* mode output results will be available. The *CACHED* mode output will then be refreshed based on the repeating job schedule. The run date/time displays for Cached objects.

Objects marked as “Slow” can be disallowed from executing in Live mode so the effect on the interface is that Slow objects will only show up in Cached mode. Also, there is the ability to disable mode switching between cached and live mode.

## *Schedule Views*

In ReviewAdmin there is a setting for Dashboard Viewset Job Runtimes. In Cached mode the data would reflect the last time the scheduled job was run according to what is set in Dashboard Viewset Job Runtimes. This allows for different runtimes for different studies so multiple jobs are not running at once on the server.

Scheduling of Dashboard can only be done at the time the viewset is saved. During the save process, prior to sending the JSCH command, a check is made. If there is not an entry in the jobs table for the current study, then the "global" job date and time is used. If there is an entry then the study job date and time is used to schedule a viewset as assigned by study. This supports the ability to schedule by study so that different times could be set for different studies. This setting is implemented in ***ReviewAdmin***.

# Create Dashboard Viewsets

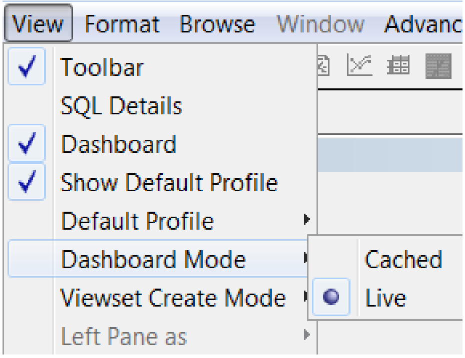
## *Open Dashboard*

After you open a clinical project folder and select a study, you can access Dashboard.

Open Dashboard from the **View** menu and select **Dashboard**.

The default option for '**Show Default Profile**' is checked ON. When this option is ON you are required to assign a 'Default Profile' to save and view your viewset. The option 'Show Default Profile' checked ON allows 4 views as maximum in the viewset because the Patient Profile Browser patient list and 'Default Profile' reserve the last 2 view window positions.

The default **Dashboard Mode** for ***Live*** or ***Cached*** is set in ***ReviewAdmin.***



If you click OFF the option for **'Show Default Profile'** before opening Dashboard then you have access to specify a maximum of 6 views within a viewset when the Default Profile is not required.

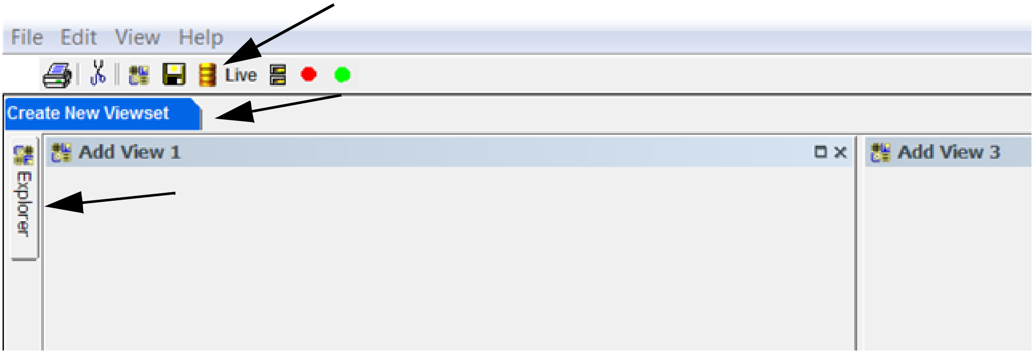
## Dashboard tool bar

Initially upon opening Dashboard, a blank window may display with empty views until someone defines a shared favorite viewset or the user has private favorites. There is no limit to the number of viewsets saved with a favorite status however, only 10 favorite viewsets will be displayed across the header area.

So the header area displays shared **Favorite tabs** created by all users when saved as User Group or Public. Private access would allow you to only view your Favorite tabs.

The header area displays Favorite tabs across the top and the highlighted tab reflects the current viewset displayed. The header area displays a **Create New Viewset** tab until a 'Favorite' default viewset is defined.

Click **Explorer** tab on the side to access the Dashboard category folders of viewsets saved by yourself and shared by others.



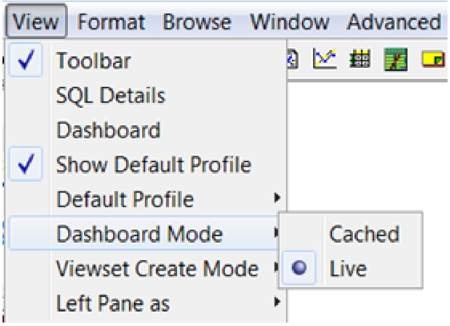
There are several additional icons located at the end of the tool bar, that pertain specifically to Dashboard and only display when in Dashboard.

- **New Viewset** - Adds a new viewset tab for adding views.
- **Save Viewset** - Click to save selected views as viewset.
- **Change mode** - Toggle between CACHE and LIVE mode.
- **Default Profile** - Toggle between Show Default Profile ON/OFF.
- **Snapshot All -** sets all views to snapshot ON in the active viewset.
- **Release All -** releases all views in the active viewset to snapshot OFF.

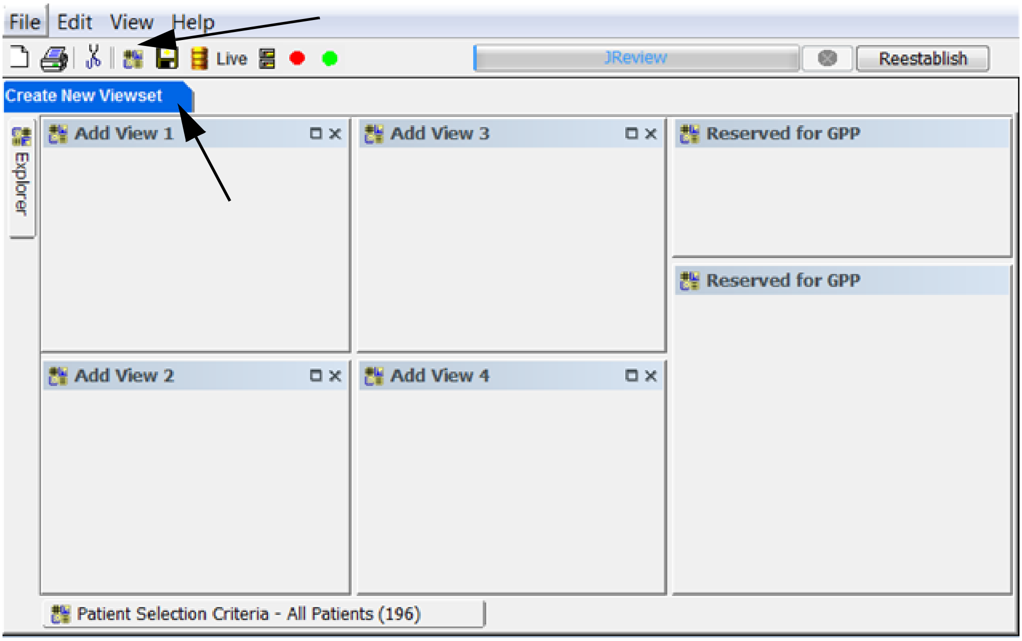
## *Create New Viewset*

***You must use LIVE Mode to define and save a viewset.*** To add a viewset with a Default Profile use the following steps:

1. Open Dashboard, from the **View** menu, select **Dashboard** with defaults as ‘Show Default Profile’ and default mode setting.

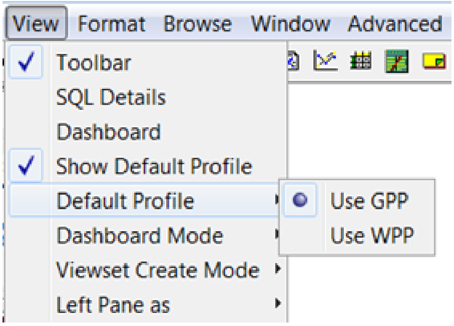


2. The main Dashboard viewing window displays. Dashboard requires at least one viewset tab be displayed in the tab headers. Initially the ‘**Create New Viewset**’ tab displays in the top left corner. Or click the **New Viewset** icon in the tool bar, or select from the File menu **Create Viewset** to add the Create New Viewset tab to the Dashboard window.



## Default Profile levels

If you select to Show Default Profile, a message will display if one has not been selected.



The default profile is either not set or does not exist

A Default Graphic Profile (GPP) and Workbook Profile (WPP) can be saved using public, user group, or private. Only one Default Graphic Profile and one Default Workbook Profile can be set for each profile level (private, user group and public).

Only viewset authors with privileges can save Default Graphic Profile (GPP) and Workbook Profile (WPP), at the public and user group levels. Users may only save default profiles at their private level.

If the PP is saved at Public it would be considered at the study level, (as Public for anyone in that particular study). It can also be saved at the User Group level or Private level. When Dashboard opens the system will check if the user has a Private default and use that one, if not a check is done for User Group level on the user's user groups, if not then the public default is used if one exists. If there is not a PP set then the above message will display so that one can be set.

When a Default Profile is saved, it is applied to any viewsets open in each viewset level (Public, Private or User Group), at the lowest profile level for that user (private being the lowest and then user group and public), regardless who the author was of the particular viewset.

For example, if a profile is set at the user group level and a user belongs to that user group, and this user does not have a private profile, the profile at the user group level will show.

Either the Graphic Profile or the Workbook Profile will show depending on which one is chosen in the View Menu.

The user can change between Graphic Profile or the Workbook Profile, where JReview will remember which one the user was using upon exit (GPP or WPP). The next session will start with the last profile type used.

You must set both default profiles, via right click in Object Explorer when in Dashboard mode. The Object Explorer checks for the profile type before it allows set default to be enabled.

## *Select Default Profile*

After you have added the **Create New Viewset tab** to the Dashboard window, you may proceed to select the Default Profile and add views to the viewset.

***Note: Recommend selecting a Profile without patient selection criteria.***

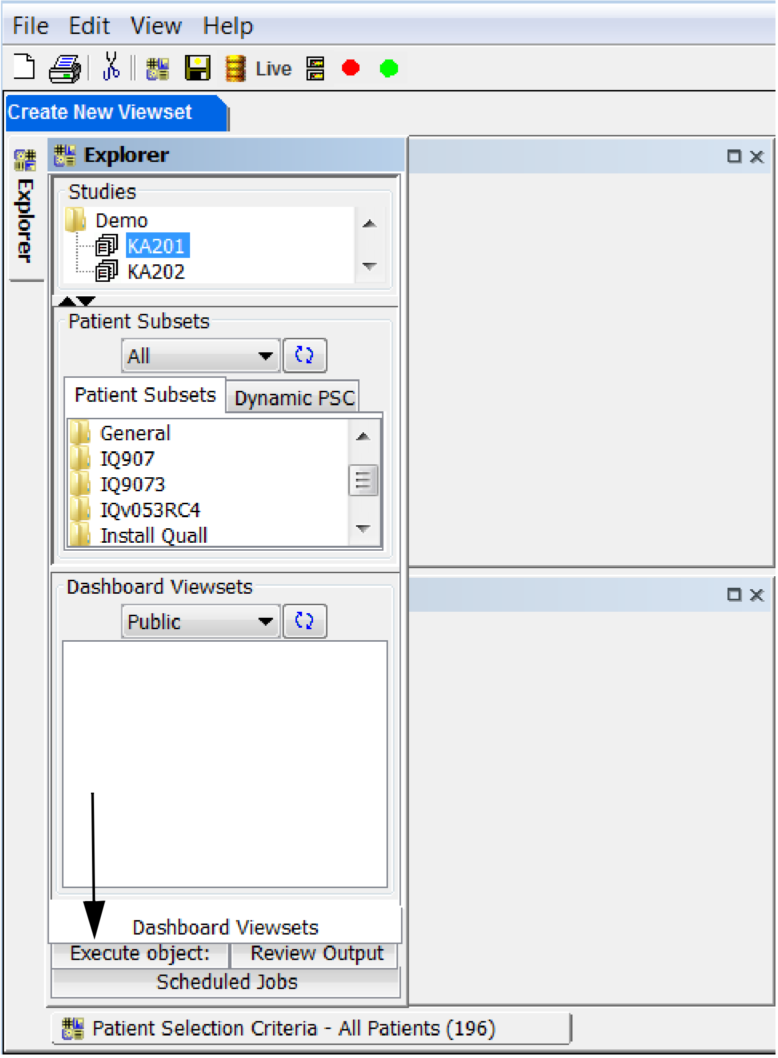
1. Click on the **Explorer** tab (located on the side).

   The **Explorer** tab opens and displays all previously saved viewsets as private or public. Initially the Explorer window shows no previously saved viewsets.

   - The **Execute object** tab is accessed to select objects for views and to save viewsets.
   - The **Dashboard Viewsets** tab is clicked to go back to the Explorer window to view and launch saved viewsets.

2. Click the **Execute object** tab located at bottom, to access the Output Specifications category folders.

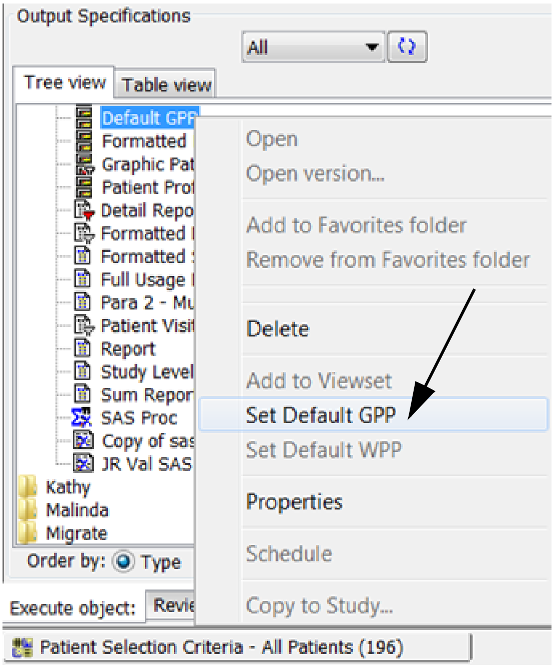
   In the Output Specifications, next select the **Default Profile** and output objects to add as views in the viewset.



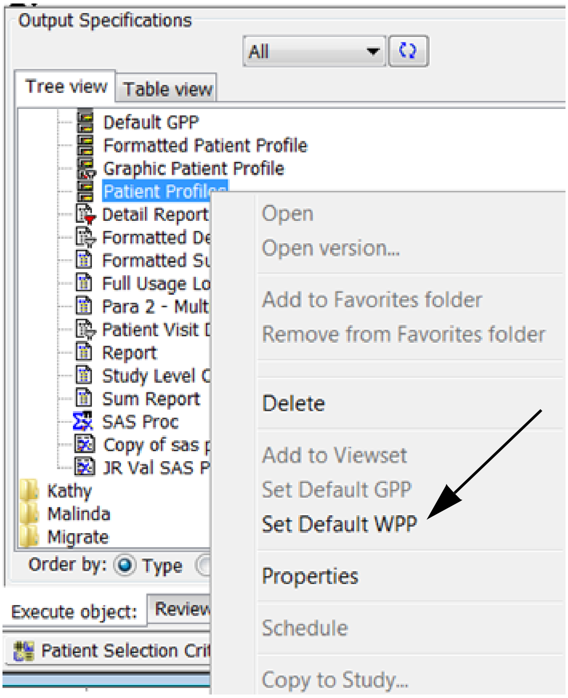
3. Select a Default Profile and right mouse click to display a floating menu for either the selected GPP or WPP.

   After right click a screen with information regarding whether the GPP or WPP is default and if so the level appears.

4. Click **Set Default GPP** for graphic profile type, OR

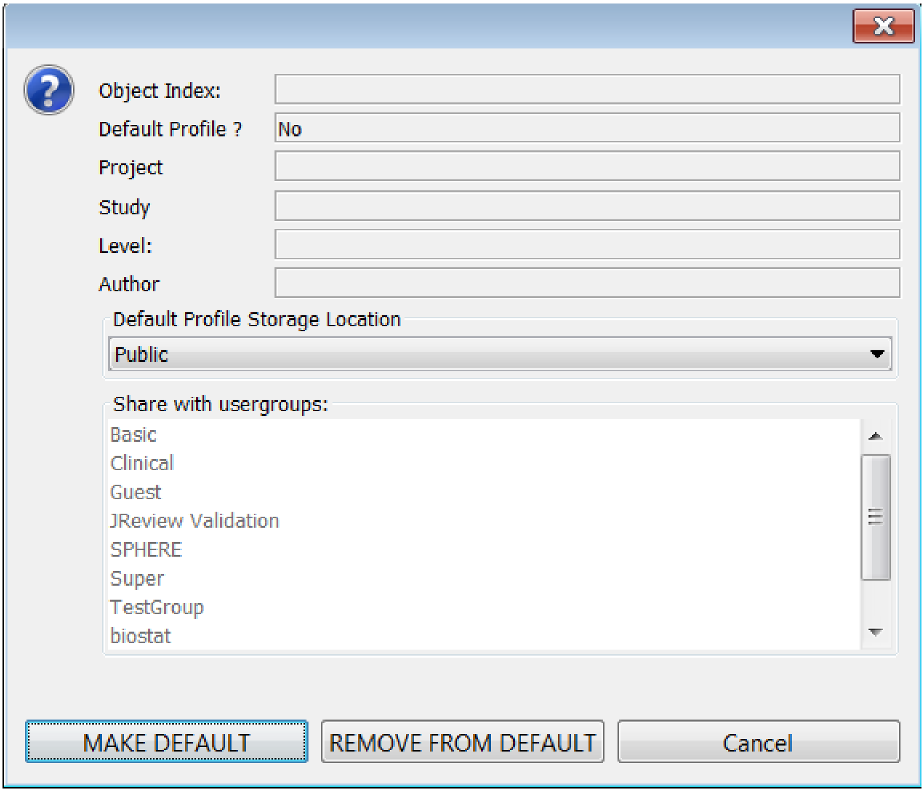


Click **Set Default WPP** to select a workbook profile type.



A window opens to save the selected Default Profile allowing the user to save as private, user group or public.

If the GPP/WPP is set at more than one level the dropdown box at the top of the screen will indicate. The user can remove the GPP/WPP from default based on what is chosen in the drop down box. The user can save the GPP/WPP to default after choosing a Level.



Object Index:

Default Profile ? No

Project

Study

Level:

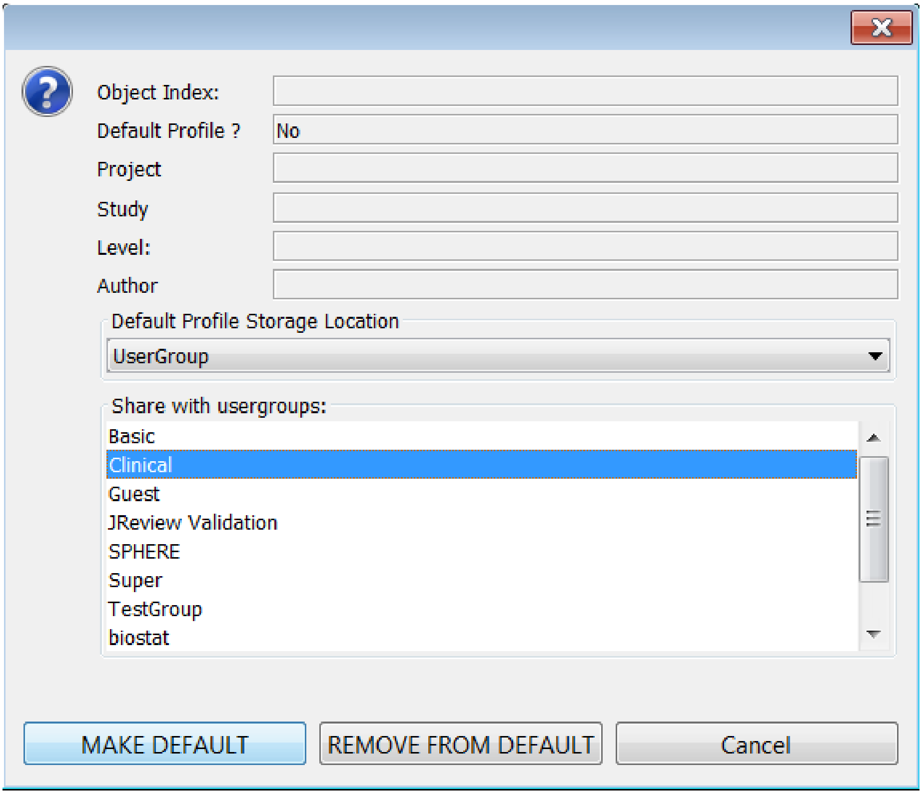
Author

Default Profile Storage Location: Public

Share with usergroups:

- Basic
- Clinical
- Guest
- JReview Validation
- SPHERE
- Super
- TestGroup
- biostat

5. Select the **Default Profile Storage Location**.



Object Index:

Default Profile ? No

Project

Study

Level:

Author

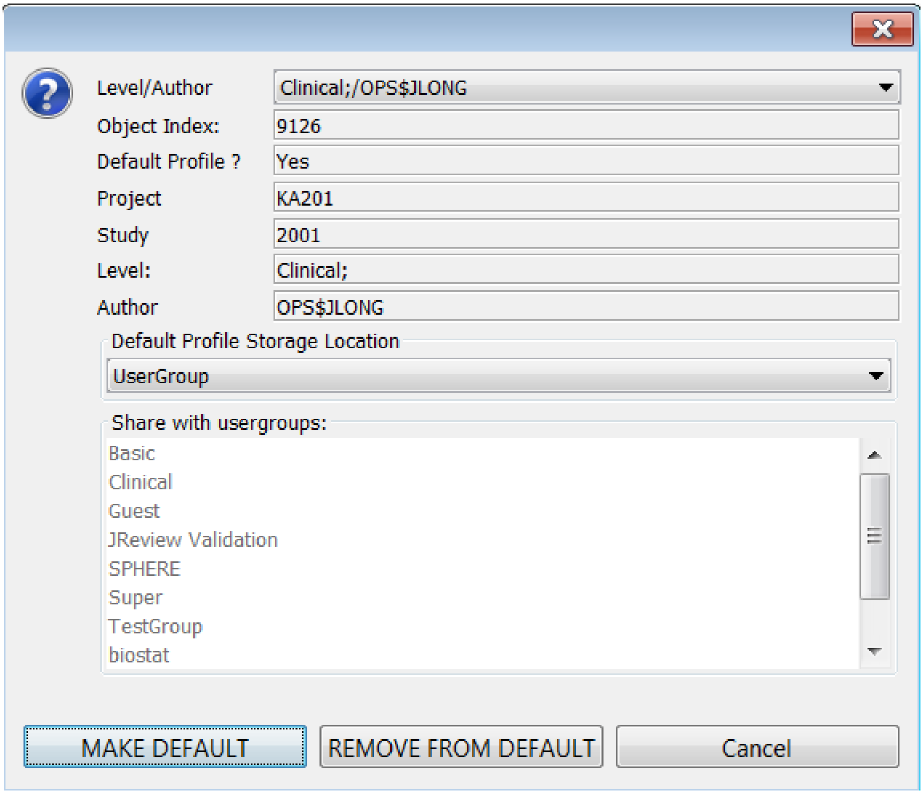
Default Profile Storage Location

UserGroup

Share with usergroups:

- Basic
- Clinical
- Guest
- JReview Validation
- SPHERE
- Super
- TestGroup
- biostat

6. Click **MAKE DEFAULT** to save.



Level/Author: Clinical;/OPS$JLONG

Object Index: 9126

Default Profile ?: Yes

Project: KA201

Study: 2001

Level: Clinical;

Author: OPS$JLONG

Default Profile Storage Location: UserGroup

Share with usergroups:

- Basic
- Clinical
- Guest
- JReview Validation
- SPHERE
- Super
- TestGroup
- biostat

## *Add views to Viewset*

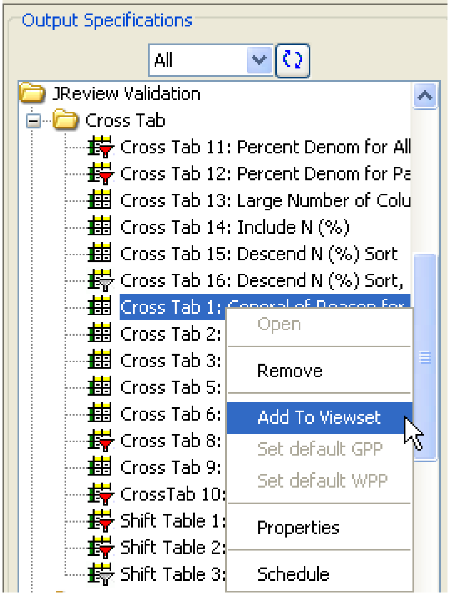
After adding the Default Profile in the open ‘Create New Viewset Tab’, now you may add object views to the viewset. There are 2 ways to add object views to a viewset:

1. In the Object Explorer under Output Specifications, access the category folders and select the objects.
2. Select the object you wish to display then **drag and drop** to the view location. If you wish to change a selected object view, select another object to drag and drop over the current object. It will be replaced by new the object.

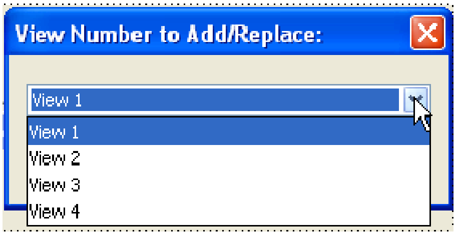
   Parameterized objects that contain runtime or prompting filters are supported in Dashboard Viewsets.

   **OR**

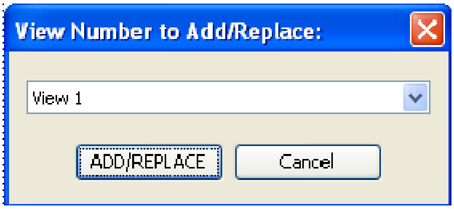
   Right click on the object you wish to display the floating menu to add to the viewset. Click **Add to Viewset** to display the View Number to Add/Replace window.



   The View Number represents the view location in the viewset. Choose the view number from the drop down list, where the object should be placed.

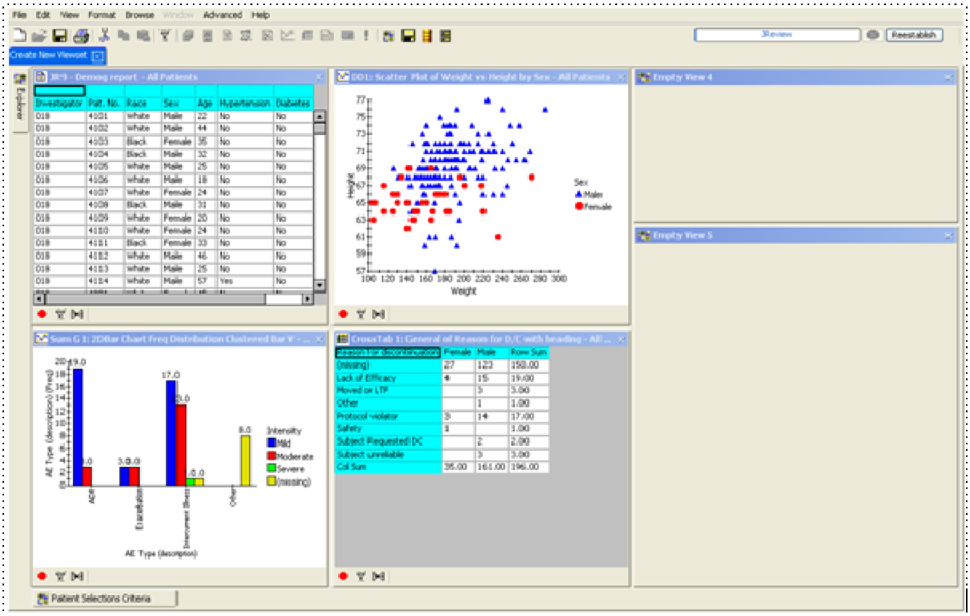


3. Click on **ADD/REPLACE**, and the object will execute and be placed in the **Create New Viewset tab** in the selected position.



4. Click the Explorer tab after each view is added and repeat the steps to add all object Views 1 through 4 to the new viewset. Before saving, you can change any of the objects by choosing the view position.

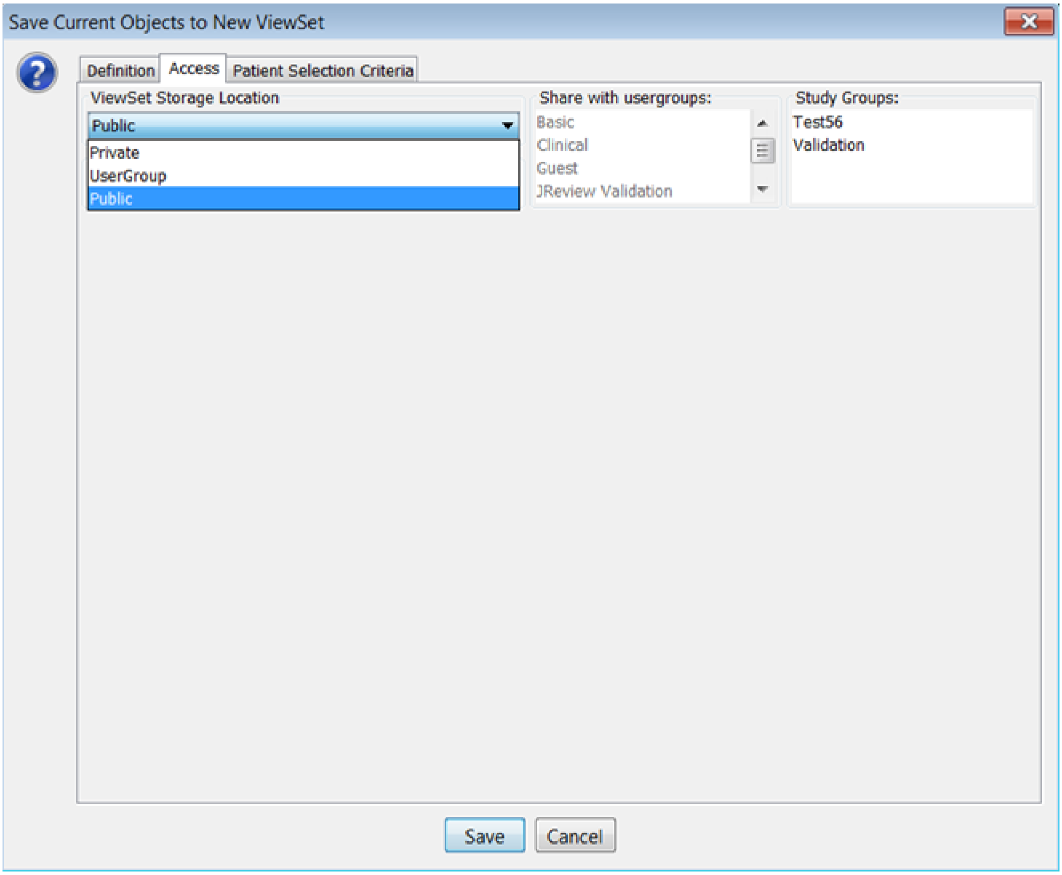
   You may enter up to 4 views, when the **Show Default Profile** option is checked ON. If the **Show Default Profile** option is not checked ON, then you may enter up to 6 views for the viewset.



## Save Viewset

1. When you are finished adding views, click save viewset from the **File menu**, or click the **Save Viewset** icon in the Dashboard tool bar.

2. The **Save Current Objects to New Viewset** window opens. Click the **Access** tab, to enter information for **Viewset Storage Location** and **Object Level.**



3. Select the **Viewset Storage Location** as ***Private***, ***UserGroup,*** or ***Public*** to display folders of saved patient subsets and output specifications. The selected **Viewset Storage Location** determines which folders are displayed for **Create ViewSet**.

   Dependent upon which views are included in the viewset determines how the study, project and global levels are saved. Select the **Object Level**.

- ***Study level*** - If at least one view (object) is study level, the viewset is study level and will only be saved in that study level.
- ***Project level*** - If all views (objects) are project level or a mixture of project and global level, then the viewset is project level and will be available across the entire project.
- ***Global level*** - If all the views (objects) are global, then the viewset is saved as a global viewset and will be available across all studies and projects.

***Study Group level*** is available in Dashboard as an option. However, Dashboard will check if an object is in a study group when creating a viewset. So during create viewset if all objects are study group level or a mixture of study group and global level; then the viewset is study group level, and will be available across all the studies in that study group.

A restriction applies where study group and project level objects are not allowed in the same viewset, as this could cause an object to be run in a study where it does not apply.

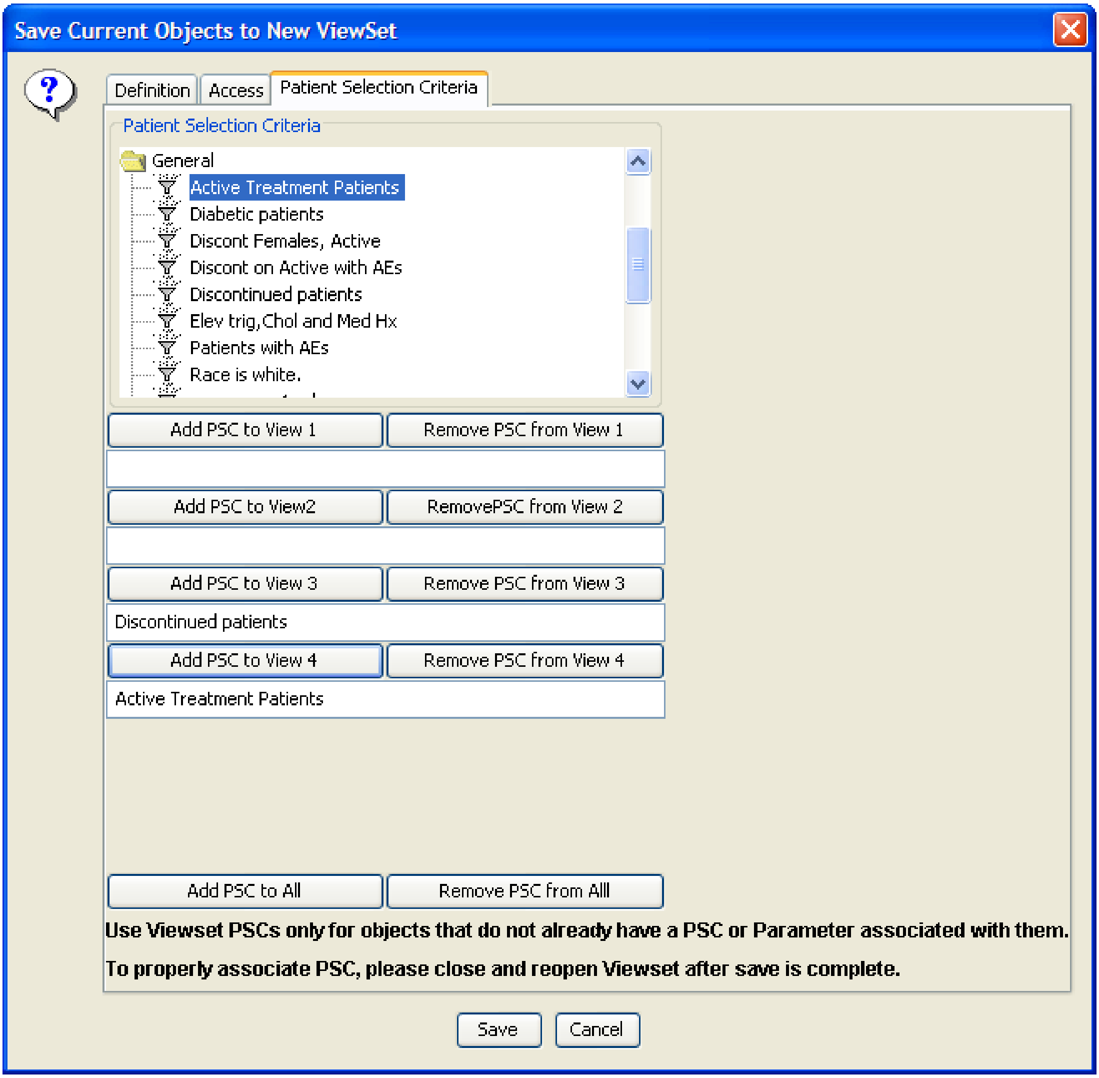
4. Click the **Patient Selection Criteria** tab. Open PSC category folder to select and add individual selection criteria definitions to preferred objects within the viewset, by their designated view location. Use the Add and Remove buttons. The selected PSC may all be the same or different or some combination.

   Use the Viewset PSC only for objects that do not already have a PSC or Parameter associated with them. To properly associate PSC, close and reopen the viewset after the save is complete. It's a safer way to associate a PSC with a view in a viewset. When you use objects that already have PSC's on them, the same behavior will occur as if you were opening multiple objects in JReview one after another, but without the chance to freeze and reset the PSC. The PSC window will set the PSC for other objects that open after. It is recommended that you don't use objects that already have PSC's because it's difficult to control. You need to specifically set the PSC for each view when you are using the PSC tab and then save the viewset that way. It will not change the object itself, just the way in opens in a viewset.

***Note: The Dashboard View interface clearly shows the user when it's busy with the familiar internet spinning wheel while working.***

***Note: Saved Dashboard viewsets cannot be migrated like saved objects.***

After each object opens sequentially within the viewset and gets it's possible PSC, the PSC is cleared before opening the next object, and cleared at the end of opening the viewset. This is only during the opening of the viewset. The Patient Profile is excluded from the PSC on open viewset.



Discontinued patients

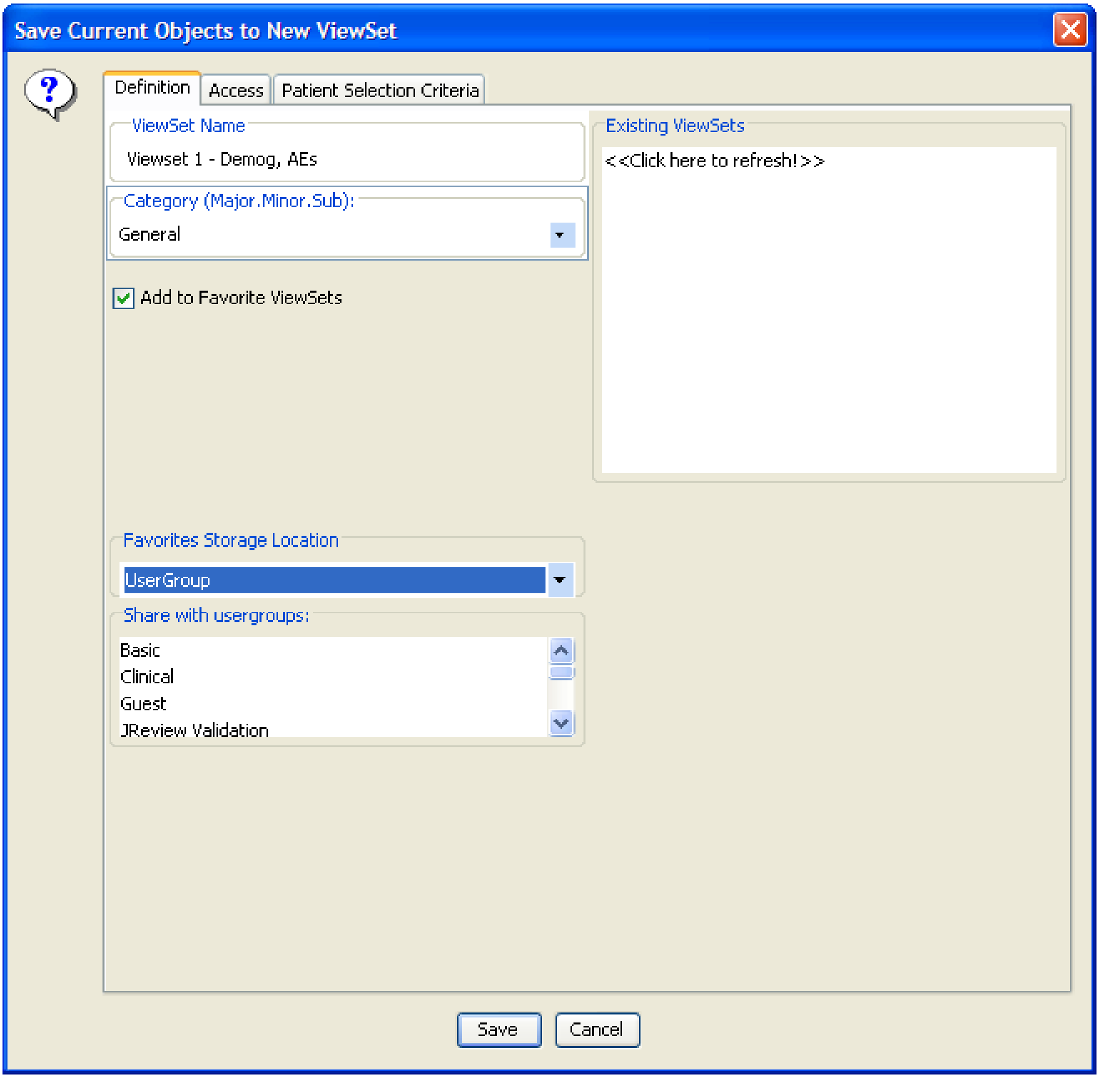
Active Treatment Patients

**Use Viewset PSCs only for objects that do not already have a PSC or Parameter associated with them.**

**To properly associate PSC, please close and reopen Viewset after save is complete.**

5. Click the **Definitions** tab and enter a viewset name in the **ViewSet Name** box.
6. .Enter to create a new folder or select a **Category** from the drop down list box to add the viewset to an existing folder.
7. Optionally click the checkbox **Add to Favorite Viewsets,** to automatically display this viewset tab in the header tabs when you open Dashboard. Or you may add **Add to Favorite Viewsets,** after saving the viewset.

   Multiple favorite viewsets are allowed and the maximum number of Favorite Viewsets is 10.



ViewSet Name: Viewset 1 - Demog, AEs

Category (Major.Minor.Sub): General

☑ Add to Favorite ViewSets

Favorites Storage Location: UserGroup

Share with usergroups:
Basic
Clinical
Guest
JReview Validation

8. Optionally share Favorite Viewsets. Click on the Favorites Storage Location drop down list box.

   This allows the user to save favorites as private or user group when they are in viewsets that are public or user group. However, once a user has private viewsets that is what will take precedence. So the user has the ability to have private favorites and user group favorites for public viewsets that exist.

9. If share with user group location, select from the user groups list. Add multiple user groups with the CTRL or Shift key.

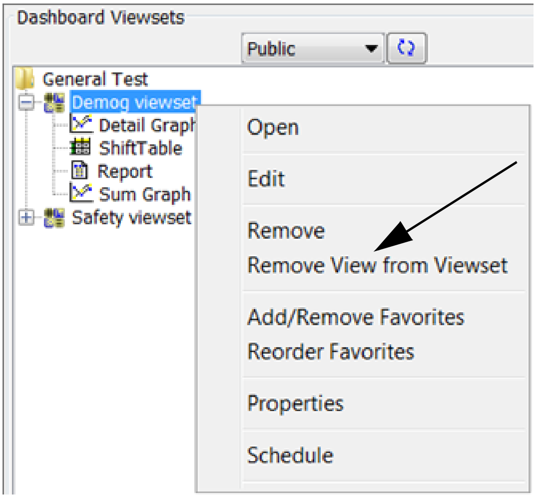
10. Click **Save** and the viewset is added to the selected category and as a favorite viewset to your header tabs. A message displays stating the viewset has been saved.

    If you need to clear the current view entries, click **Cancel** to clear the view windows and start over.

## *Remove object from viewset*

There are two ways to remove an object or objects from a viewset:

- Right click on the object in the Viewset Tree.
- Choose "**Remove this object from Viewset**".



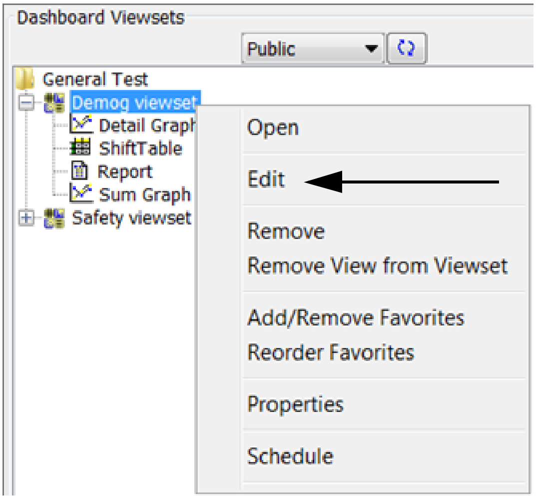
A message displays asking if you are sure, click OK. The object is removed from the viewset. (The object will still be available in the Execute object tree).

- You can also right click on the viewset (in the viewset tree).
- Click **Remove View from Viewset.**
- Select and remove the object by the viewset number.

## *Edit viewset*

Dashboard Viewsets supports editing to add or delete objects from a viewset. To edit an object or objects from a viewset:

1. Either right click on the Viewset in the viewset tree and choose **Edit**, or right click on the Tab and choose **Edit**. This opens the viewset in Edit mode.



2. Go to the Execute object, and right click on an object.
3. Choose the view number you wish to replace. Click add/replace and the object executes in the position you chose.

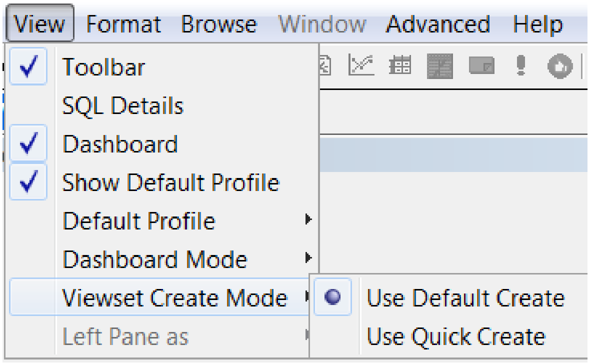
   If the original viewset had less than the maximum number of objects, you can add objects to the open positions in the same manner.
4. When you are satisfied with the objects and arrangement, resave the viewset by clicking the **Save Viewset icon**, or **Save Viewset** from the menu.

   The save dialog window displays populated with the save information. You can make changes in the save dialog or just accept as is. The original viewset will be overwritten with the new information. Once you edit a viewset even if you change the name, the original viewset will no longer exist.

   After the edit/create process is complete and the viewset is saved, the Tab will remain open as the viewset that was just created or edited.

## Quick Create Viewset

When creating a viewset, if the objects have no data, the view will not open and therefore the view cannot be saved to the viewset. In order to provide a way to save objects that currently have no data to a viewset, **Quick Create** was developed.



Go to Dashboard then select the view menu and click on Viewset Create Mode -> Quick Create. Then select Create Viewset. Begin dragging in objects or use the right click Add View method.  Objects that are not allowed in the viewset, were also not allowed using this method and those allowed were allowed. The objects did not execute and an informational panel was placed in the view.

By selecting **Quick Create** Mode from the view menu, objects can be dragged or put into each view without execution. A representation of the object shows in the view. The viewset can be then saved. The create viewset tab will be cleared and ready to create another viewset. There is no automatic opening of the viewset after the save process is complete. Quick Create **cannot** be used to edit viewsets.

Viewsets created with quick create, after being saved, are no different than viewsets created with the original default process. If data is available for the object the view will open, if not the view will be empty and close. This is the behavior in JReview when an object has no data, it does not open. The reason for developing this option for creating viewsets was to allow for viewset setup prior to data being available, or for use with exception report objects when the exceptions have not yet occurred. It can also be used for objects that have data, but will still not execute the object at the time of creation. During Quick Create the viewsets are ***not automatically scheduled*** as they are during the original viewset creation process. If scheduling is desired (for Cached Mode), it must be done as a separate action. Quick Create cannot be used to edit viewsets.

## *Remove viewset*

The user who saved the viewset can remove it.

1. Select the viewset and right mouse click to display the floating menu box.
2. Click **Remove** and the viewset is removed. If a user attempts to remove a viewset and is not the author, a message displays identifying the author.

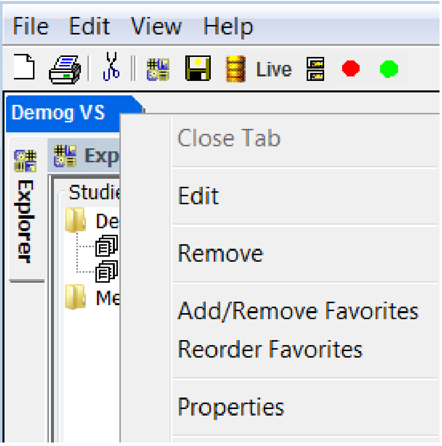
If a particular object was deleted in IReview or JReview and currently belongs to a viewset; the object is automatically removed from the viewset. A message displays '**This object no longer exists!'** for the missing view when the viewset is opened.

When all the objects are removed in IReview or JReview then the viewset is automatically deleted.

## *Add to Favorites*

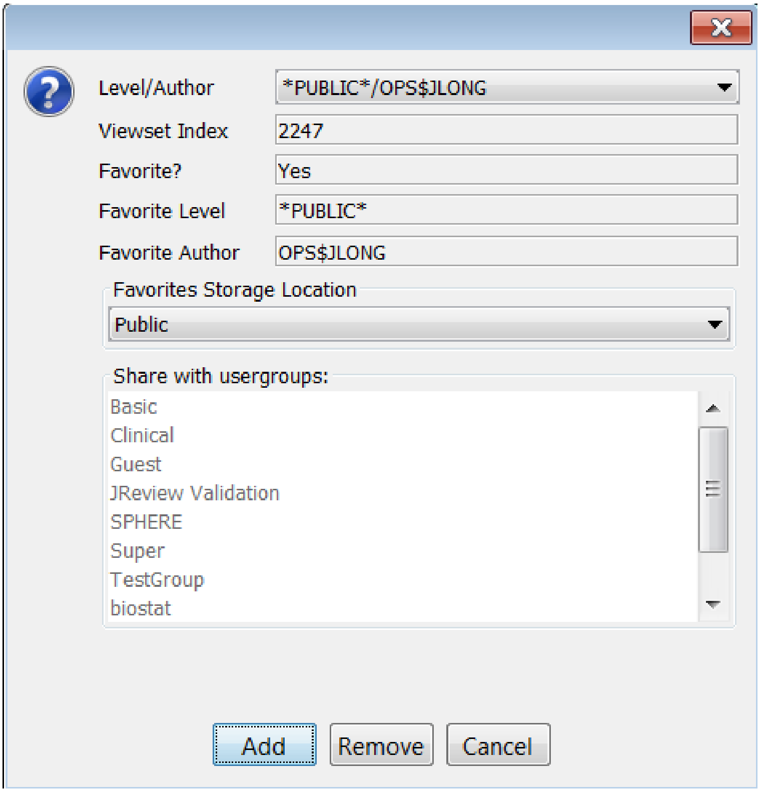
You can add a viewset to your favorites after it has been saved.  It allows add and remove from favorites.

1. Select the viewset and right mouse click to display the floating menu box and choose Add/Remove Favorites.



Level of favorites can be chosen from this screen. Favorites can be saved to private, user group or public level at any viewset level (dependent upon author privileges.)

2. Right click on a viewset and choose **Add/Remove Favorites**.



Level/Author: *PUBLIC*/OPS$JLONG

Viewset Index: 2247

Favorite?: Yes

Favorite Level: *PUBLIC*

Favorite Author: OPS$JLONG

Favorites Storage Location: Public

Share with usergroups:

Basic
Clinical
Guest
JReview Validation
SPHERE
Super
TestGroup
biostat

3. Click **Add** to add viewset to Favorites, or click **Remove** and the selected viewset is removed as a favorite.

   This shows favorite information about the viewset. Also, it allows the user to add to favorites and remove from favorites. The **Favorite Level** can be chosen from this window to save to private, user group or public level at any viewset level.

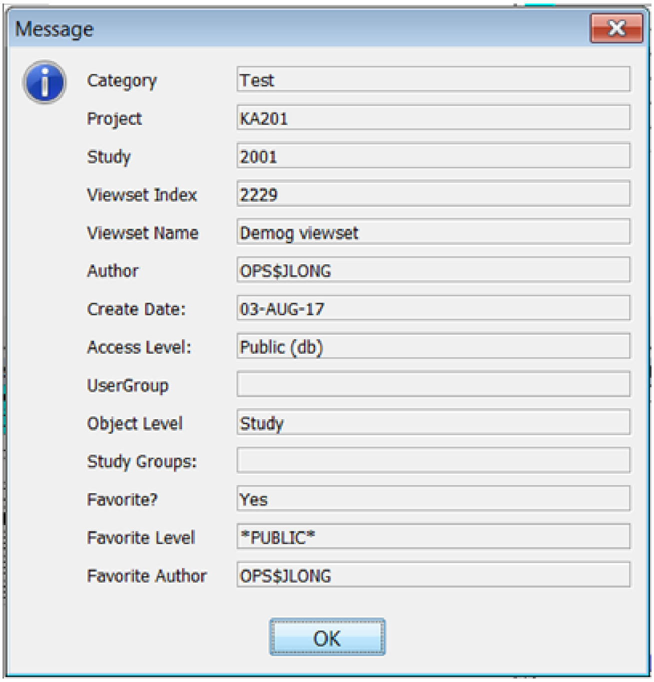
   Saving and removing favorites can occur from the viewset tree, the tabs or during saving of the viewset.

   If a viewset is a favorite at more than one level the drop box at the top of the screen will indicate this, and changing the drop box will facilitate deleting a favorite at the appropriate level.

For example at the public viewset level a favorite can be saved to private or user group. When favorites get retrieved at any viewset level, the first check will be if the user has any private favorites, if so only those will be opened. If no private favorites, the next check is for user group favorites from the user groups the user belongs to. If there are user group favorites and no private for that user, those favorites will be opened. If neither private nor user group favorites are available for that user, the last check is for public favorites. If those exist, those favorites will be opened. Only the first 10 favorites that get returned will be opened.

The user can save favorites as private or user group when they are in viewsets that are public or user group. Once a user has private viewsets that is what will take precedence. So there is the ability to have private favorites and user group favorites for public viewsets.

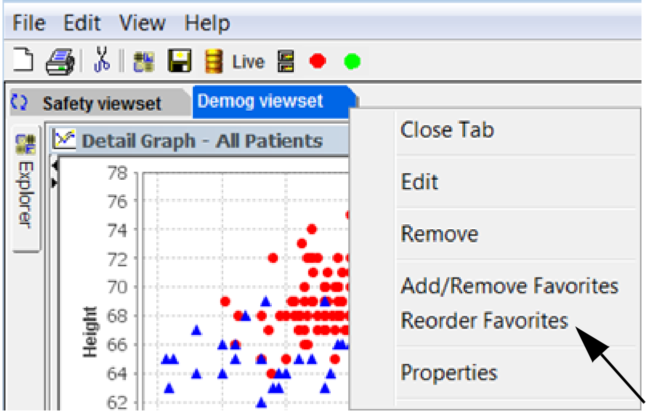
4. Click **Properties** to see how the viewset was saved. This shows favorite information about the viewset.



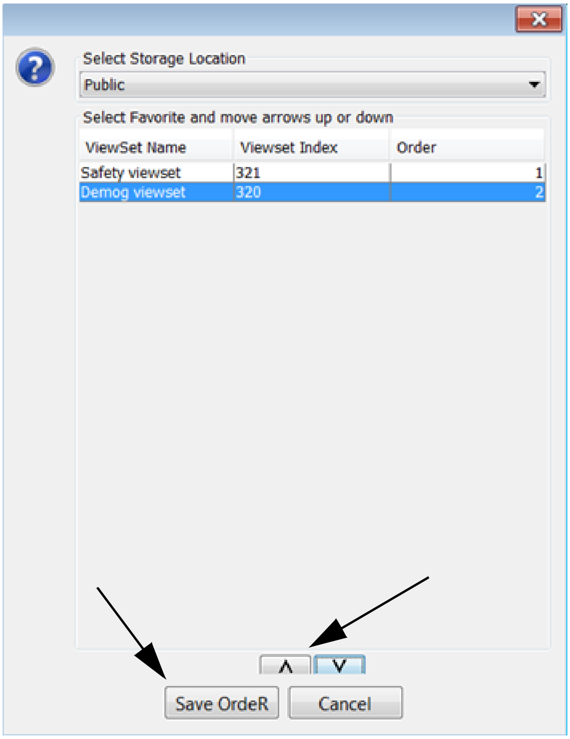
| | |
|---|---|
| Category | Test |
| Project | KA201 |
| Study | 2001 |
| Viewset Index | 2229 |
| Viewset Name | Demog viewset |
| Author | OPS$JLONG |
| Create Date: | 03-AUG-17 |
| Access Level: | Public (db) |
| UserGroup | |
| Object Level | Study |
| Study Groups: | |
| Favorite? | Yes |
| Favorite Level | *PUBLIC* |
| Favorite Author | OPS$JLONG |

## *Reorder Favorites*

Favorite viewset order is from ***right to left***. To reorder favorites, right click on a favorite viewset and select **Reorder Favorites**.



Select the viewset row and use the up/down arrows. Click **Save Order**. There is the option of reloading favorites which will reopen the favorites in the new order. The Favorite View tabs are reordered to the new order from ***right to left***. First favorite viewset will open in the right most tab.



Select Storage Location

Public

Select Favorite and move arrows up or down

| ViewSet Name | Viewset Index | Order |
|---|---|---|
| Safety viewset | 321 | 1 |
| Demog viewset | 320 | 2 |

## *Manual schedule viewset*

This viewset scheduling option was made for those instances that the viewset did not get scheduled at the time it was saved. If the viewset had been created when Live Mode only was in effect, the viewset wasn't scheduled for use for Cache mode. Here is a manual 'schedule' action for a viewset. The way the manual scheduling works is as follows:

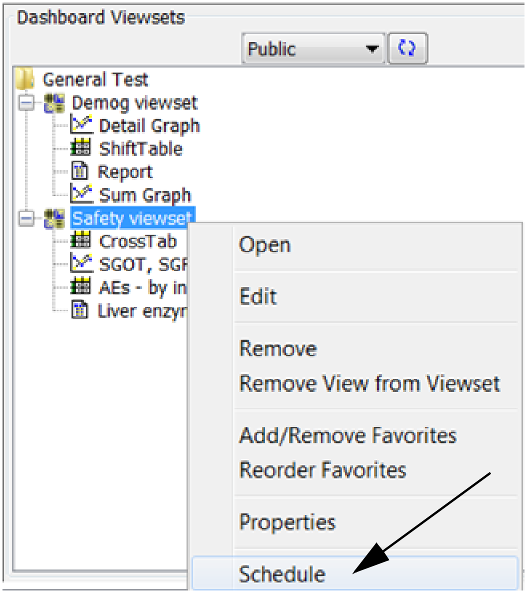
1. Right click on any viewset in Live Mode.
2. At the bottom of the list click on Schedule.

If the objects in the viewset have not been scheduled for Dashboard Cached Mode, they will be schedule according to the settings in IRAdmin

If the object have already been scheduled for Dashboard they will not be rescheduled.

The scheduled jobs do NOT appear in the regular Job Schedule Panel (they cannot be changed or deleted). After the jobs run they will appear in Cached Mode view sets.

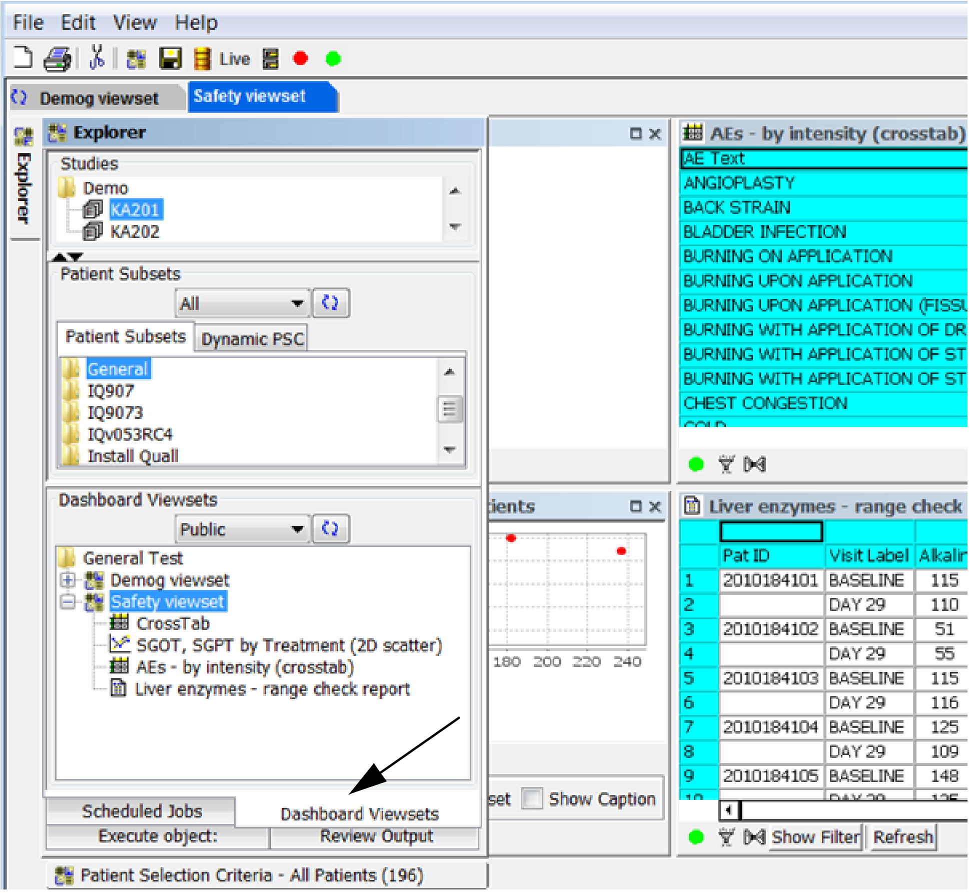
Viewset objects will still be scheduled at the time the viewset is saved, if IRAdmin settings indicate Switch mode or Cached Mode (Not Live only).



# View Viewsets

## *Select a viewset*

When you open Dashboard and favorite viewsets have already been saved; the window will display the default favorite viewset, however, the user can select and view other saved viewsets as follows:

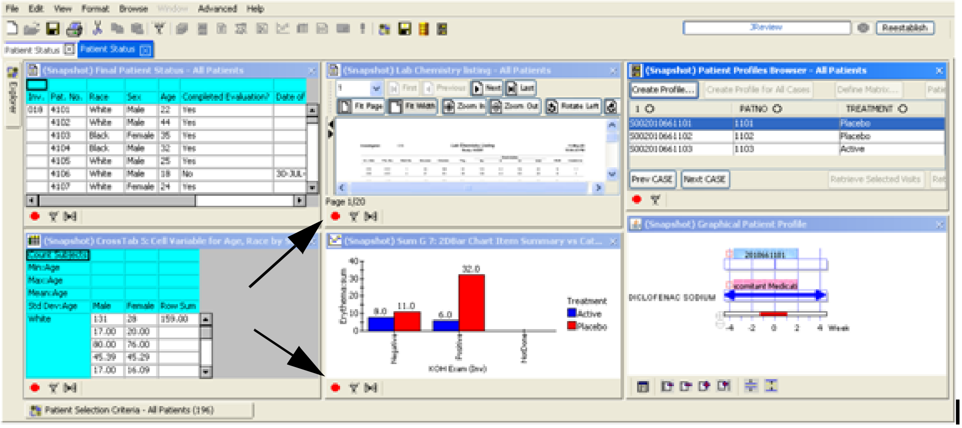


| | Pat ID | Visit Label | Alkali |
|---|---|---|---|
| 1 | 2010184101 | BASELINE | 115 |
| 2 | | DAY 29 | 110 |
| 3 | 2010184102 | BASELINE | 51 |
| 4 | | DAY 29 | 55 |
| 5 | 2010184103 | BASELINE | 115 |
| 6 | | DAY 29 | 116 |
| 7 | 2010184104 | BASELINE | 125 |
| 8 | | DAY 29 | 109 |
| 9 | 2010184105 | BASELINE | 148 |

1. Click on a different favorite viewset already displayed in the header.
2. If the viewset is not a “Favorite’ viewset displayed in the header tab, then click the **Explorer** tab to display the **Dashboard Viewsets** window.
3. Select the user access level as ***Private*, *UserGroup*, *Public or All*.**

   Whatever user access level you select to access will be your default access level the next time you open Dashboard. So, if your preference is ***Private*** access you will not need to reselect it each time you open Dashboard.
4. Select the category folder to display the list of saved viewsets.

   Use the plus + signs to expand the viewset folders and display the contained views.
5. Click on a viewset name to open that viewset on the Dashboard.

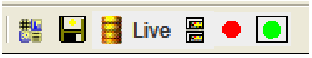


| Inv. | Pat. No. | Race | Sex | Age | Completed Evaluation? | Date of |
|---|---|---|---|---|---|---|
| 018 | 4101 | White | Male | 22 | Yes | |
| | 4102 | White | Male | 44 | Yes | |
| | 4103 | Black | Female | 35 | Yes | |
| | 4104 | Black | Male | 32 | Yes | |
| | 4105 | White | Male | 25 | Yes | |
| | 4106 | White | Male | 18 | No | 30-JUL- |
| | 4107 | White | Female | 24 | Yes | |

| 1 | PATNO | TREATMENT |
|---|---|---|
| S002010661101 | 1101 | Placebo |
| S002010661102 | 1102 | Placebo |
| S002010661103 | 1103 | Active |

| Count Subjects<br>Min:Age<br>Max:Age<br>Mean:Age<br>Std Dev:Age | Male | Female | Row Sum |
|---|---|---|---|
| White | 131 | 28 | 159.00 |
| | 17.00 | 20.00 | |
| | 80.00 | 76.00 | |
| | 45.39 | 45.29 | |
| | 17.00 | 16.09 | |

You may toggle On/Off each individual ‘Snapshot’ icon in the currently active Dashboard View panes. Or use the viewset wide ‘snapshot’/’live’ buttons displayed as red and green to toggle all views within the active Dashboard viewset. These buttons are unavailable as grayed out in Cached mode.



You may double click on any individual view header to enlarge that window, then double click to restore it back within the viewset.

You are allowed to change the size of each individual view in a dashboard viewset to be retained after saving the viewset. Temporary changes to the size of each individual view will be maintained while the viewset is open and revert back to the saved sizes after closing.

## *Apply Selection Criteria to viewset*

Dashboard can apply a patient selection criteria to a viewset if the opened output specification did not have a required subset. The user ***must use LIVE Mode*** to apply different patient subsets to different view selections when saved in the viewset.

To apply a current patient selection criteria to a particular object view you must turn OFF Snapshot mode by clicking the red button. The button will indicate as green the Snapshot is turned OFF.

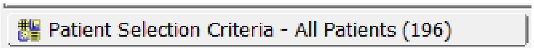
If you have the Default Profile turned ON, you may want to turn OFF the Snapshot mode for the Patient Profile Browser list displayed. Then the patients listed will update the subset applied by the patient selection criteria.

You may select a previously saved patient selection criteria or define your own as follows:

1. Click the **Explorer** tab to display the **Dashboard Viewsets** window.
2. Select the desired viewset and turn OFF Snapshot in the individual object views.
3. Optionally select the Patient Profile Browser patient list and turn OFF Snaphot.
4. Select the category folder to display the list of saved Patient Selection Criteria. Double click to launch the selected criteria and automatically update the displayed viewset objects.

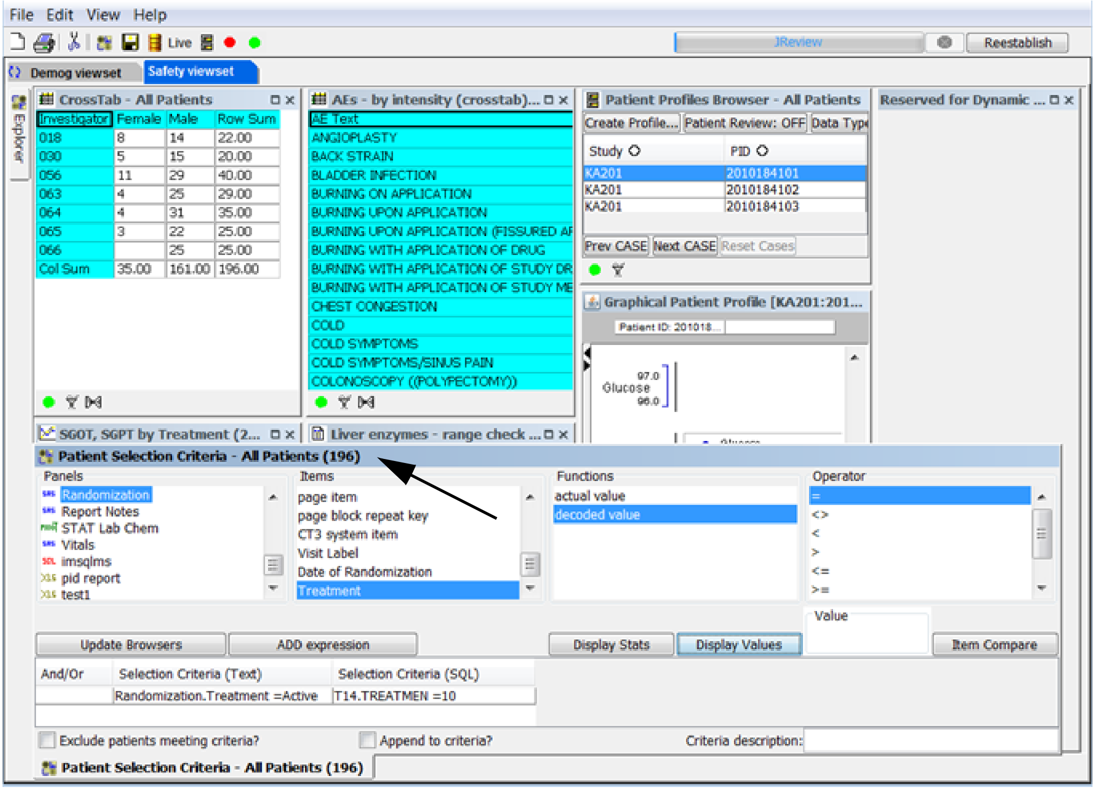
   OR

   Click the **Patient Selection Criteria tab** located at the bottom of the screen.



Patient Selection Criteria - All Patients (196)

The Patient Selection Criteria window opens to enter your own selection criteria. After entering your selection criteria, clicking update browsers; the Patient Selection Criteria window automatically closes after the selection criteria updates the viewset.



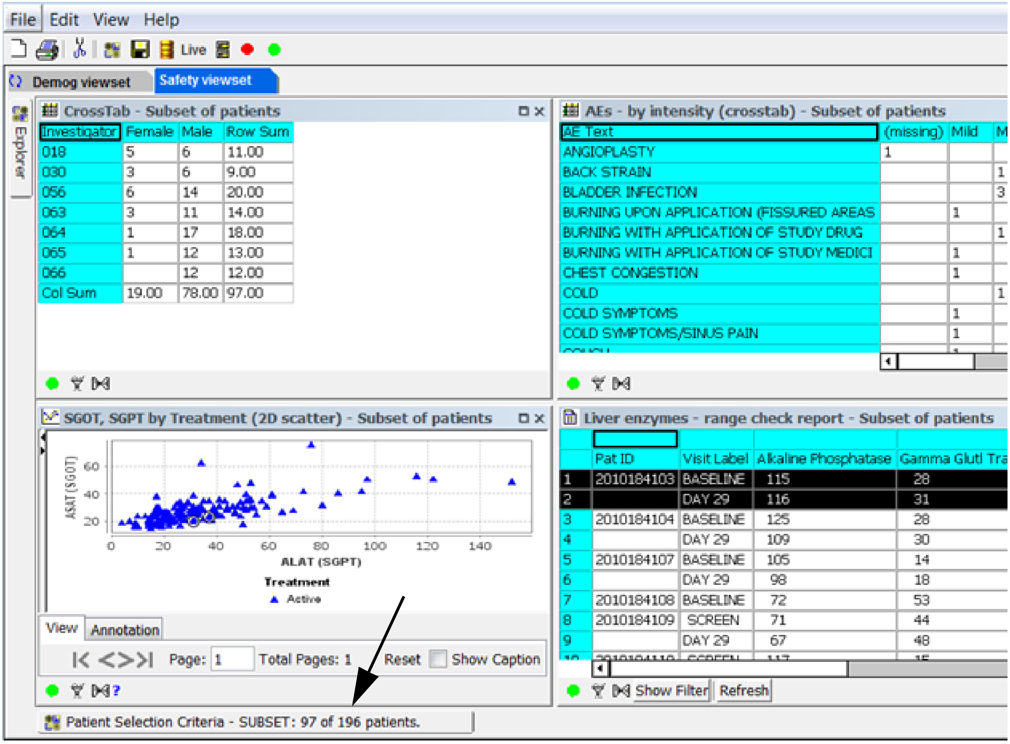
| Investigator | Female | Male | Row Sum |
|---|---|---|---|
| 018 | 8 | 14 | 22.00 |
| 030 | 5 | 15 | 20.00 |
| 056 | 11 | 29 | 40.00 |
| 063 | 4 | 25 | 29.00 |
| 064 | 4 | 31 | 35.00 |
| 065 | 3 | 22 | 25.00 |
| 066 |  | 25 | 25.00 |
| Col Sum | 35.00 | 161.00 | 196.00 |

| AE Text |
|---|
| ANGIOPLASTY |
| BACK STRAIN |
| BLADDER INFECTION |
| BURNING ON APPLICATION |
| BURNING UPON APPLICATION |
| BURNING UPON APPLICATION (FISSURED AF |
| BURNING WITH APPLICATION OF DRUG |
| BURNING WITH APPLICATION OF STUDY DR |
| BURNING WITH APPLICATION OF STUDY ME |
| CHEST CONGESTION |
| COLD |
| COLD SYMPTOMS |
| COLD SYMPTOMS/SINUS PAIN |
| COLONOSCOPY ((POLYPECTOMY)) |

| Study | PID |
|---|---|
| KA201 | 2010184101 |
| KA201 | 2010184102 |
| KA201 | 2010184103 |

| And/Or | Selection Criteria (Text) | Selection Criteria (SQL) |
|---|---|---|
|  | Randomization.Treatment =Active | T14.TREATMEN =10 |

All object views and/or Patient Profile Browser patient list with Snapshot mode OFF update to the applied Patient Selection Criteria subset. The Patient Selection Criteria button shows the subset count.



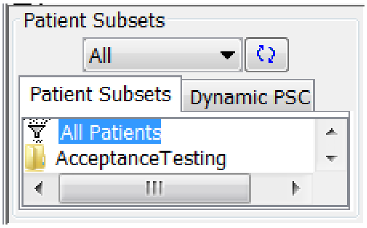
| Investigator | Female | Male | Row Sum |
|---|---|---|---|
| 018 | 5 | 6 | 11.00 |
| 030 | 3 | 6 | 9.00 |
| 056 | 6 | 14 | 20.00 |
| 063 | 3 | 11 | 14.00 |
| 064 | 1 | 17 | 18.00 |
| 065 | 1 | 12 | 13.00 |
| 066 |  | 12 | 12.00 |
| Col Sum | 19.00 | 78.00 | 97.00 |

| AE Text | (missing) | Mild | M |
|---|---|---|---|
| ANGIOPLASTY | 1 |  |  |
| BACK STRAIN |  |  | 1 |
| BLADDER INFECTION |  |  | 3 |
| BURNING UPON APPLICATION (FISSURED AREAS |  | 1 |  |
| BURNING WITH APPLICATION OF STUDY DRUG |  |  | 1 |
| BURNING WITH APPLICATION OF STUDY MEDICI |  | 1 |  |
| CHEST CONGESTION |  | 1 |  |
| COLD |  |  | 1 |
| COLD SYMPTOMS |  | 1 |  |
| COLD SYMPTOMS/SINUS PAIN |  | 1 |  |

|  | Pat ID | Visit Label | Alkaline Phosphatase | Gamma Glutl Tra |
|---|---|---|---|---|
| 1 | 2010184103 | BASELINE | 115 | 28 |
| 2 |  | DAY 29 | 116 | 31 |
| 3 | 2010184104 | BASELINE | 125 | 28 |
| 4 |  | DAY 29 | 109 | 30 |
| 5 | 2010184107 | BASELINE | 105 | 14 |
| 6 |  | DAY 29 | 98 | 18 |
| 7 | 2010184108 | BASELINE | 72 | 53 |
| 8 | 2010184109 | SCREEN | 71 | 44 |
| 9 |  | DAY 29 | 67 | 48 |

Patient Selection Criteria - SUBSET: 97 of 196 patients.

5. Use the **New** icon in the tool bar to clear the patient selection criteria. Apply your own patient selection criteria.
6. Or, select and double-click on ‘**All Patients**’ in the Patient Subsets window, to clear the patient selection criteria and return to all patients.

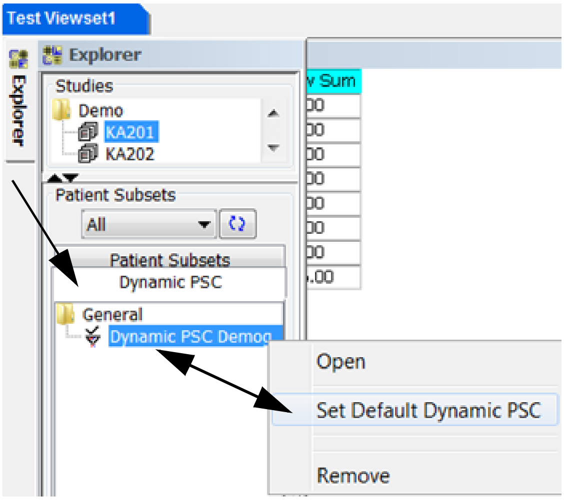


## *Dynamic PSC*

The Dynamic Patient Selection Criteria (DPSC) are first defined and saved as objects in JReview (Patient Subsets), for access in Dashboard. They will be available in the Dashboard Explorer window in the Dynamic PSC tab under the Patient Subsets.

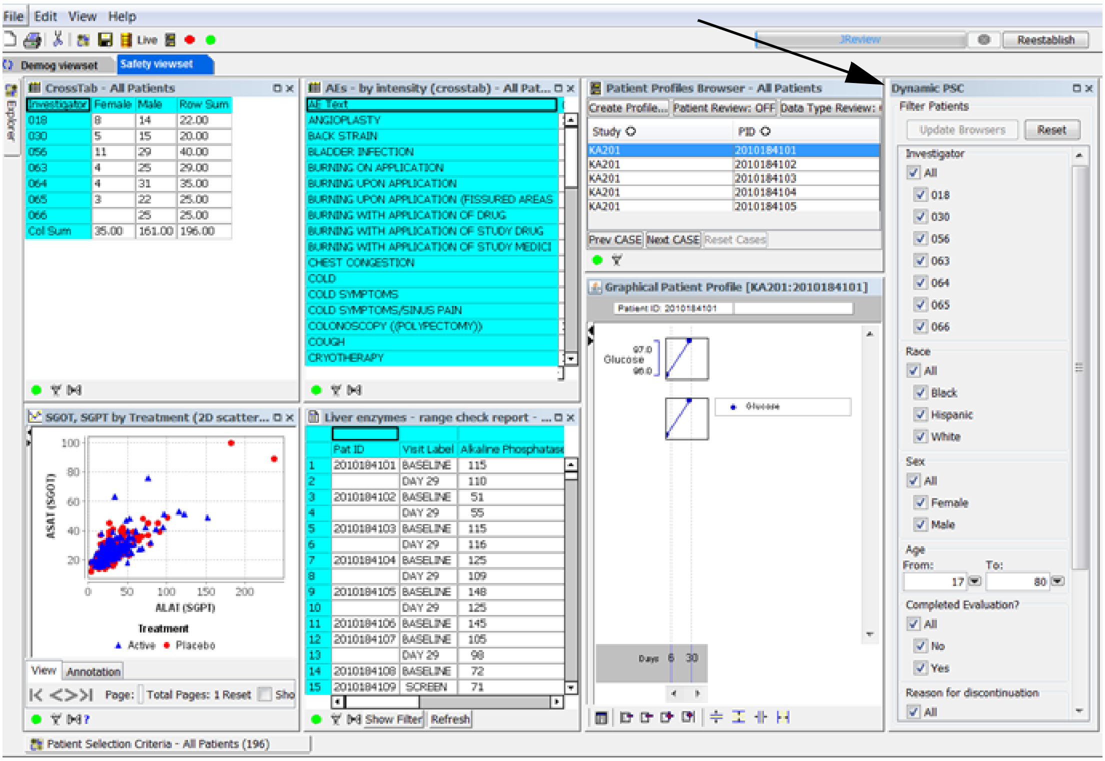
## *Set Default Dynamic PSC*

To set the default DPSC in Dashboard, go to the Dynamic PSC tab under Patient Subsets. Select the DPSC and right mouse click to display the floating menu. Select **Set Default Dynamic PSC**.



In Dashboard View mode – the default Dynamic PSC is displayed automatically to the far right. You can change the default while in Dashboard by opening any DPSC from the list, which is available in Dashboard. Likewise, close any DPSC and reopen another. Once you close the DPSC in Dashboard you will have to manually reopen.

Also, if you left a DPSC open in JReview, it will open in Dashboard. If you want to change the DPSC that's open in Dashboard; click on the one you want in the PSC Explorer in Dashboard.



**CrossTab - All Patients**

| Investigator | Female | Male | Row Sum |
|---|---|---|---|
| 018 | 8 | 14 | 22.00 |
| 030 | 5 | 15 | 20.00 |
| 056 | 11 | 29 | 40.00 |
| 063 | 4 | 25 | 29.00 |
| 064 | 4 | 31 | 35.00 |
| 065 | 3 | 22 | 25.00 |
| 066 |  | 25 | 25.00 |
| Col Sum | 35.00 | 161.00 | 196.00 |

**AEs - by intensity (crosstab) - All Pat...**

| AE Text |
|---|
| ANGIOPLASTY |
| BACK STRAIN |
| BLADDER INFECTION |
| BURNING ON APPLICATION |
| BURNING UPON APPLICATION |
| BURNING UPON APPLICATION (FISSURED AREAS |
| BURNING WITH APPLICATION OF DRUG |
| BURNING WITH APPLICATION OF STUDY DRUG |
| BURNING WITH APPLICATION OF STUDY MEDICI |
| CHEST CONGESTION |
| COLD |
| COLD SYMPTOMS |
| COLD SYMPTOMS/SINUS PAIN |
| COLONOSCOPY ((POLYPECTOMY)) |
| COUGH |
| CRYOTHERAPY |

**Patient Profiles Browser - All Patients**

| Study | PID |
|---|---|
| KA201 | 2010184101 |
| KA201 | 2010184102 |
| KA201 | 2010184103 |
| KA201 | 2010184104 |
| KA201 | 2010184105 |

**Liver enzymes - range check report - ...**

|  | Pat ID | Visit Label | Alkaline Phosphatase |
|---|---|---|---|
| 1 | 2010184101 | BASELINE | 115 |
| 2 |  | DAY 29 | 110 |
| 3 | 2010184102 | BASELINE | 51 |
| 4 |  | DAY 29 | 55 |
| 5 | 2010184103 | BASELINE | 115 |
| 6 |  | DAY 29 | 116 |
| 7 | 2010184104 | BASELINE | 125 |
| 8 |  | DAY 29 | 109 |
| 9 | 2010184105 | BASELINE | 148 |
| 10 |  | DAY 29 | 125 |
| 11 | 2010184106 | BASELINE | 145 |
| 12 | 2010184107 | BASELINE | 105 |
| 13 |  | DAY 29 | 98 |
| 14 | 2010184108 | BASELINE | 72 |
| 15 | 2010184109 | SCREEN | 71 |

**Dynamic PSC**

Investigator
- ☑ All
  - ☑ 018
  - ☑ 030
  - ☑ 056
  - ☑ 063
  - ☑ 064
  - ☑ 065
  - ☑ 066

Race
- ☑ All
  - ☑ Black
  - ☑ Hispanic
  - ☑ White

Sex
- ☑ All
  - ☑ Female
  - ☑ Male

Age
From: 17 To: 80

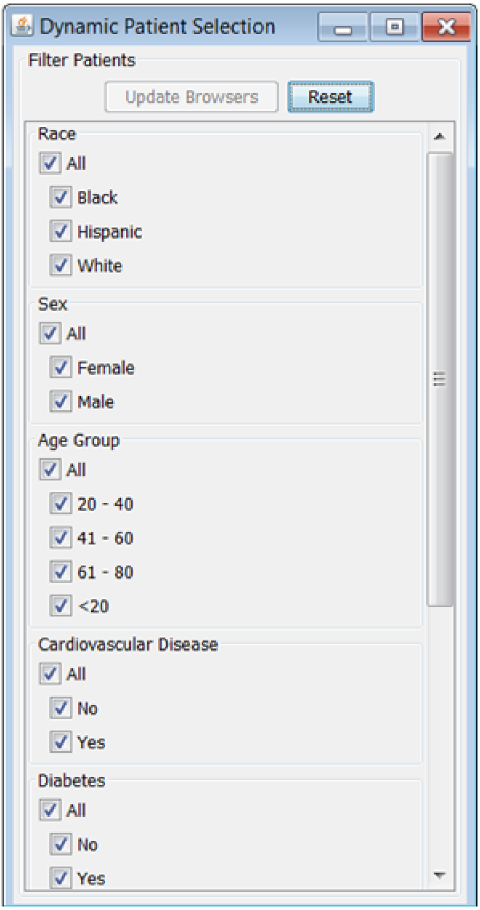
Completed Evaluation?
- ☑ All
  - ☑ No
  - ☑ Yes

Reason for discontinuation
- ☑ All

The patient **Filter Controls** are listed as checkboxes. The default is “All Patients” the same as Patient Selection Criteria window. Select patients to display with checkboxes checked ON for selected versus unchecked as not selected.

Click **Update Browsers** to select patients in graphs, reports and crosstabs.

Click **Reset** to clear any selections. Remember to click **Update Browsers** to return to **All Patients** selected.



Race
- ☑ All
  - ☑ Black
  - ☑ Hispanic
  - ☑ White

Sex
- ☑ All
  - ☑ Female
  - ☑ Male

Age Group
- ☑ All
  - ☑ 20 - 40
  - ☑ 41 - 60
  - ☑ 61 - 80
  - ☑ <20

Cardiovascular Disease
- ☑ All
  - ☑ No
  - ☑ Yes

Diabetes
- ☑ All
  - ☑ No
  - ☑ Yes

# View Patient Data

## *Patient drill down*

The Patient Profile Browser patient list displays on the right side.

You may select a patient to display in the Default Graphic Patient Profile view.

The user can drill down on a selected patient in the Dashboard Views window if the particular view is a detail data listing, crosstab or summary graph. Formatted reports and detail scatter plots do not support individual patient drill down.

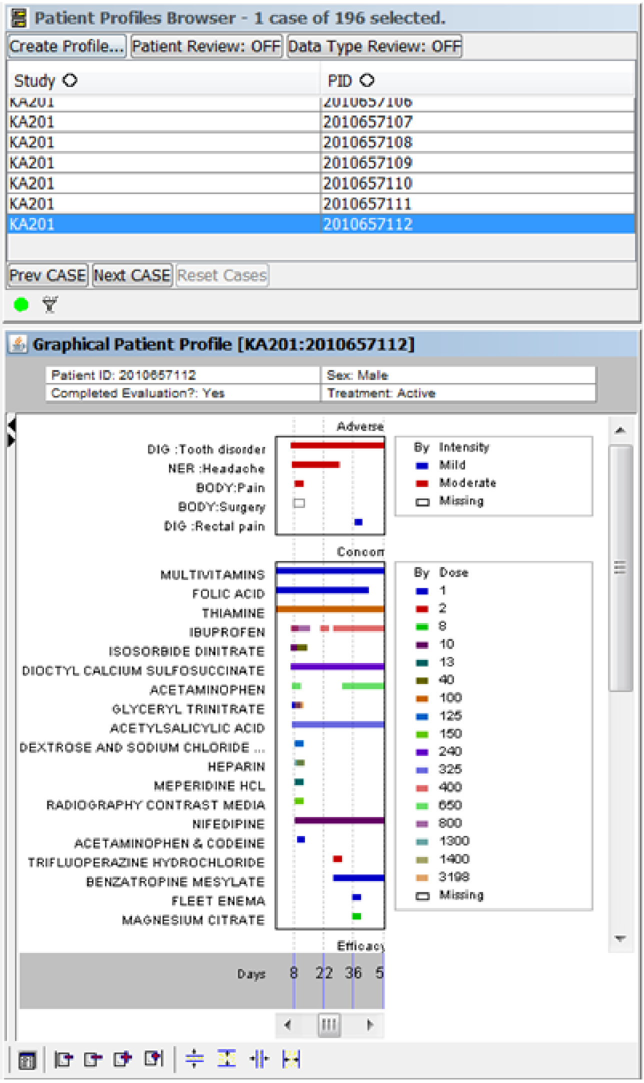
Click **Reset Cases** if needed to refresh the patient list between selections. If you had selected patients from a graph, first click on the graph '**Reset**' button, before clicking the Patient Profile **Reset Cases.** Selecting patients from graphs controls the patients listed in the Patient Profile and data listing. So, you must reset all graphs first before the Patient Profile list can reset. Or, you could simply click on the Explorer tab to go the e Dashboard Viewsets tab to select 'All Patients'. All views and the Patient Profile list are reset or cleared of any graph selections.

When viewing a viewset in the Dashboard Views window and the viewset contains a detail data listing, the user can drill down on a selected patient for more detail just like the Output Explorer window.

The individual object views are interactive with the Patient Profile Browser patient list. Clicking on a bar in a Bar Chart Graph updates the patient list to contain those patients represented in the selected bar. The Graphic Patient Profile updates to display the first patient in the updated list. Selecting a patient row in a detail data listing updates the opens Graphic Patient Profile view window for the selected patient.

You may double click on the Graphic Patient Profile view header to enlarge the window. Then double click on the header again to restore to view size. This feature works on all view windows.

You may click on Patient Review, to turn ON the Patient Review Tracking Tool. (*See Chapter 4 - Patient Profile Browser: Patient Review Tracking Tool)*



| Study | PID |
|---|---|
| KA201 | 2010657106 |
| KA201 | 2010657107 |
| KA201 | 2010657108 |
| KA201 | 2010657109 |
| KA201 | 2010657110 |
| KA201 | 2010657111 |
| KA201 | 2010657112 |

Patient ID: 2010657112
Sex: Male
Completed Evaluation?: Yes
Treatment: Active

# 14 Risk Assessment Browser

# Risk Assessment Analysis

## What is the Risk Assessment Browser?

The Risk Assessment Browser is used to evaluate the 'distribution' of patients when investigating different Adverse Events, as a systematic approach to quantify the burden of disease/injury resulting from major risk factors. Relative Risk (RR) is the risk of an event (or of developing a disease) relative to exposure. The risks are defined as the probability of an adverse event and/or a factor that raises the probability of an adverse event.

Multiple study mode is supported. Patient Selection Criteria may be applied the same as other output browsers, to specify which patients will be included in the Risk Assessment.

## What is Relative Risk Ratio?

Another term for the ***relative risk*** is the ***risk ratio*** because it is the ratio of the risk in the exposed divided by the risk in the unexposed. The relative risk ratio is the probability of the event occurring in the exposed group versus a non-exposed group.

***RR = P exposed / P non-exposed***

Consider an example where in the probability of developing lung cancer among smokers was 20% and among non-smokers 1%. This situation is expressed in the 2_×_2 table to the right.

Here, ***a = 20(%), b = 80, c = 1, and d = 99***. Then the relative risk of cancer associated with smoking is where Smokers would be twenty times as likely as non-smokers to develop lung cancer.

$$RR = \frac{a/(a+b)}{c/(c+d)} = \frac{20/100}{1/100} = 20$$

**RR = 1 )** association between exposure and disease unlikely to exist.

**RR >> 1 )** increased risk of disease among those that have been exposed.

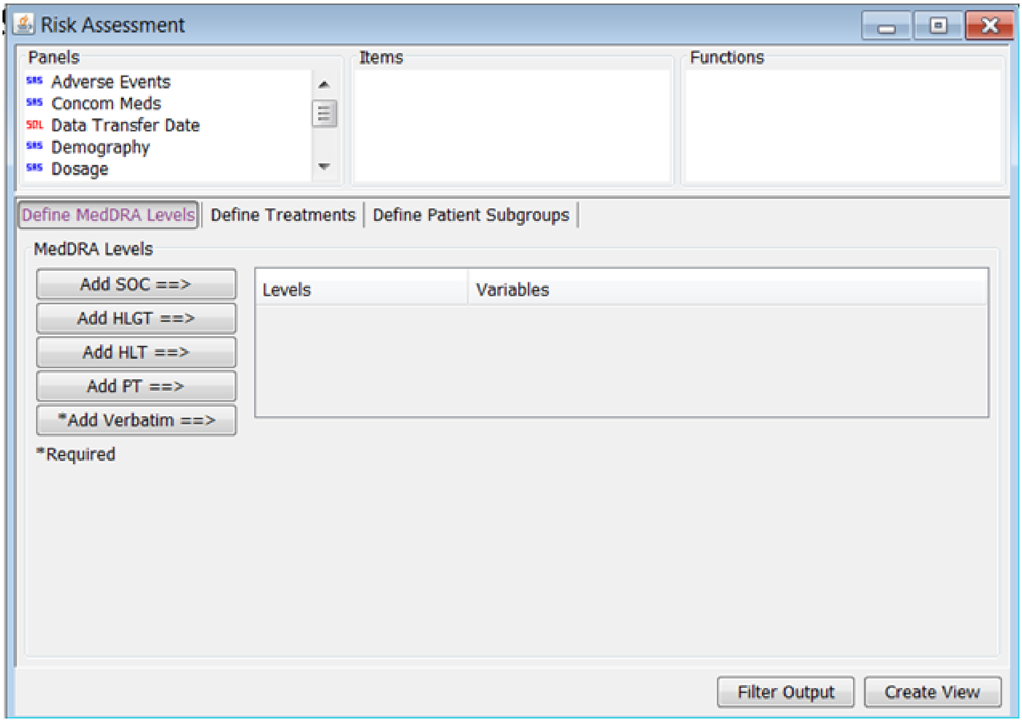
**RR << 1 )** decreased risk of disease among those that have been exposed.

## *Open Risk Assessment Browser*

After selecting single or multi-study mode, users with access privileges set in ***ReviewAdmin*** can click the Risk Assessment icon in the tool bar;

or from the browser menu, select Risk Assessment.

The main Risk Assessment definition window opens where you can enter information captured from either CDISC or Legacy systems.

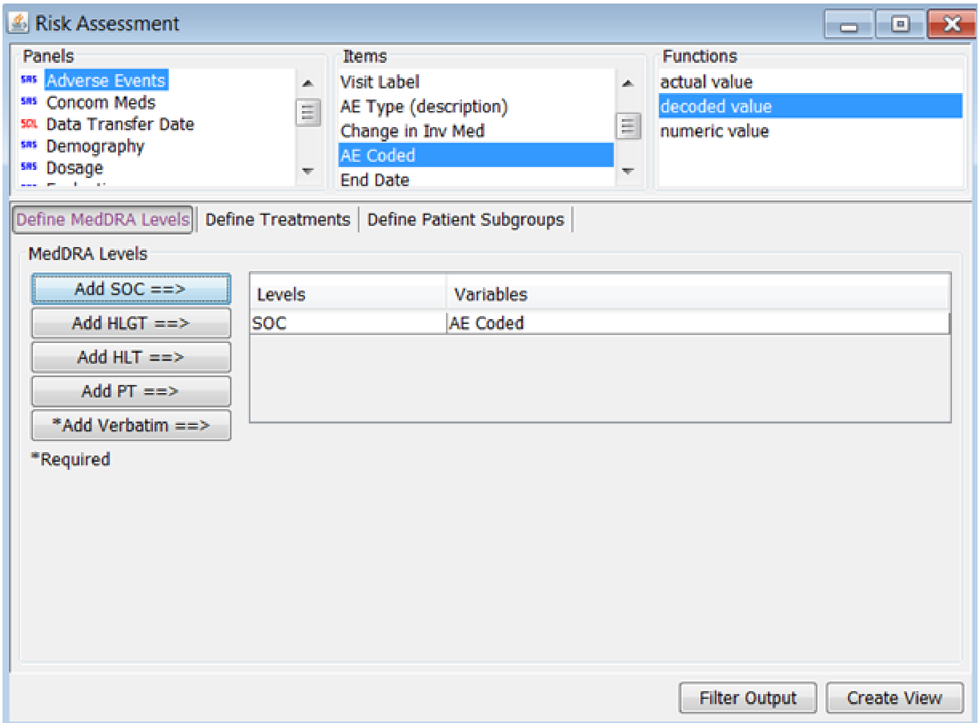


## *Define MedDRA levels*

There are three data functions for entering risk assessment information.

- Define MedDRA levels
- Define Treatments
- Define Patient Subgroups

1. Select the **Define MedDRA levels** option to enter MedDRA terms. You may enter any available MedDRA terms as not all terms are required.
2. Select Adverse Events in the panels list; select SOC data item for System Organ Class.
3. Click on the **Add SOC** button to add System Organ Class.

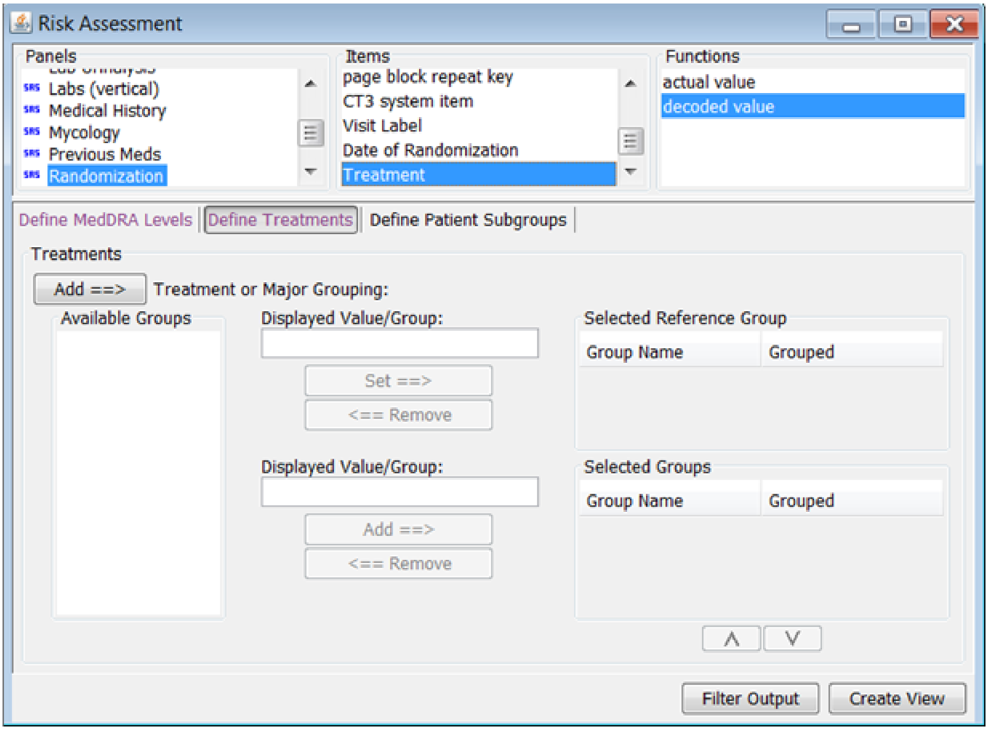


| Levels | Variables |
|---|---|
| SOC | AE Coded |

4. The ‘**Add Verbatim**’ term is required. You may optionally add other MedDRA level terms. Repeat the same steps to add the following data items:
   - Select the High Level Group Term, click on **Add HLGT** button.
   - Select the High Level Term, click on **Add HLT** button.
   - Select the Preferred Term, click on **Add PT** button.
   - Select the Adverse Events Text, click on **Add Verbatim** button.

## *Define Treatments*

5. Select the **Define Treatments** level option. The **Treatments** area displays to enter available treatment groups information.
6. Select the Randomization panel and item for Treatment, click **Add.** The **Available Groups** for Treatments to be analyzed are entered.



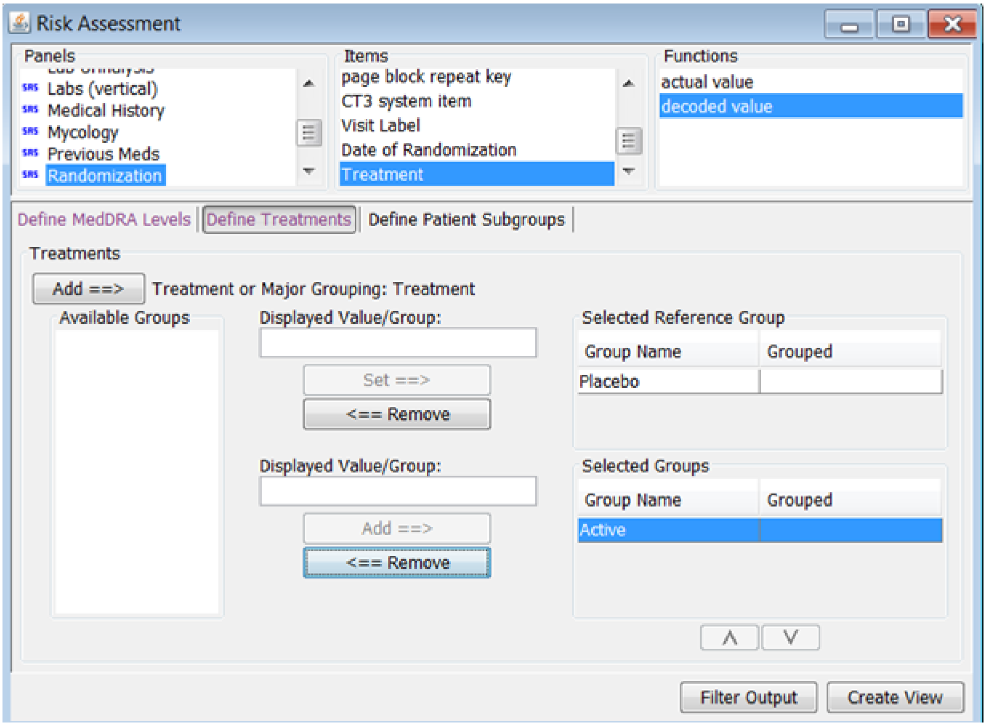
7. Select the treatment group to be applied as the **Reference Group**, and click **Set** button.

   The treatment item selected for the Reference Group is applied as the denominator in the ratio calculation.

8. Select the treatment Item(s) to be added as the **Selected Group**(s) at the bottom, and click **Add** button. The treatment items selected for the ‘Selected Group’ are analyzed against the above ‘Reference Group’.

   If needed, you may select and add multiple treatments, optionally rename a treatment description, or define a treatment group with multiple selections (low, medium, high), and enter a new group name.

   For the example, Placebo is set to ‘Reference Group’ as the denominator in the ratio against the Active’ Selected Group’.



## *Define Patient Subgroups*

9. Select the **Define Patient Subgroups** level option. The **Patient Subgroups** area displays to enter available patient subgroups information.

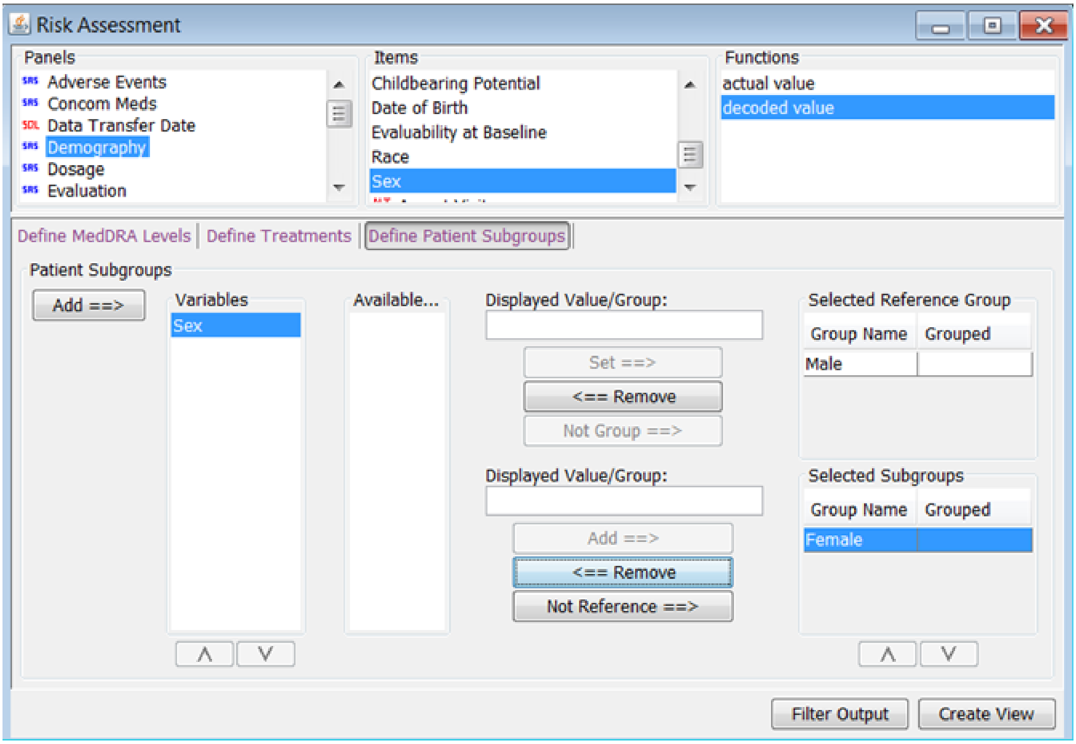
10. For example, select the Demography panel for Sex data item and click **Add**. The item variable for Sex is added with **Available Subgroups** as ‘Female’ and ‘Male’.

11. Select the **Reference Group** data item for the denominator applied in the ratio calculation, and click **Set**.

12. Select the **Selected Subgroups** data item to be analyzed against the Reference Group.

    For the example, the Male ‘Reference Group’ was selected as the denominator in the ratio calculation referenced against Female as the ‘Selected Subgroup’.

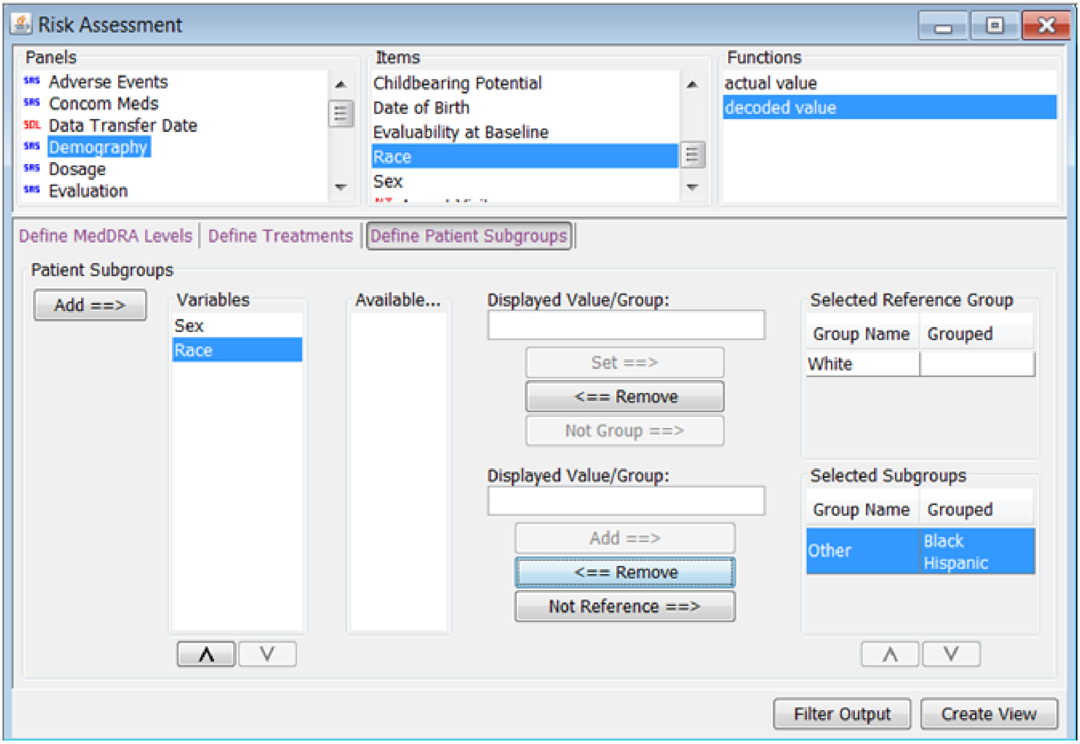
    Use the **Remove** button to select and remove individual variable selections.



You may add multiple variables if needed, optionally rename a subgroup description, or define a subgroup with multiple selections, and enter a new group name.

This example for Patient Subgroups shows white entered as the ‘Reference Group’, and multiple groups selected and renamed with a new group name as the ‘Selected Subgroup’.

When adding multiple variable selections and rename a group, first enter the displayed value/group name. Then multi-select the variables and click either **Set** or **Add,** dependent if you are entering the top **Reference Group** or lower **Subgroups**. The added ‘Group Name’ displays with the multiple ‘Grouped’ variables.



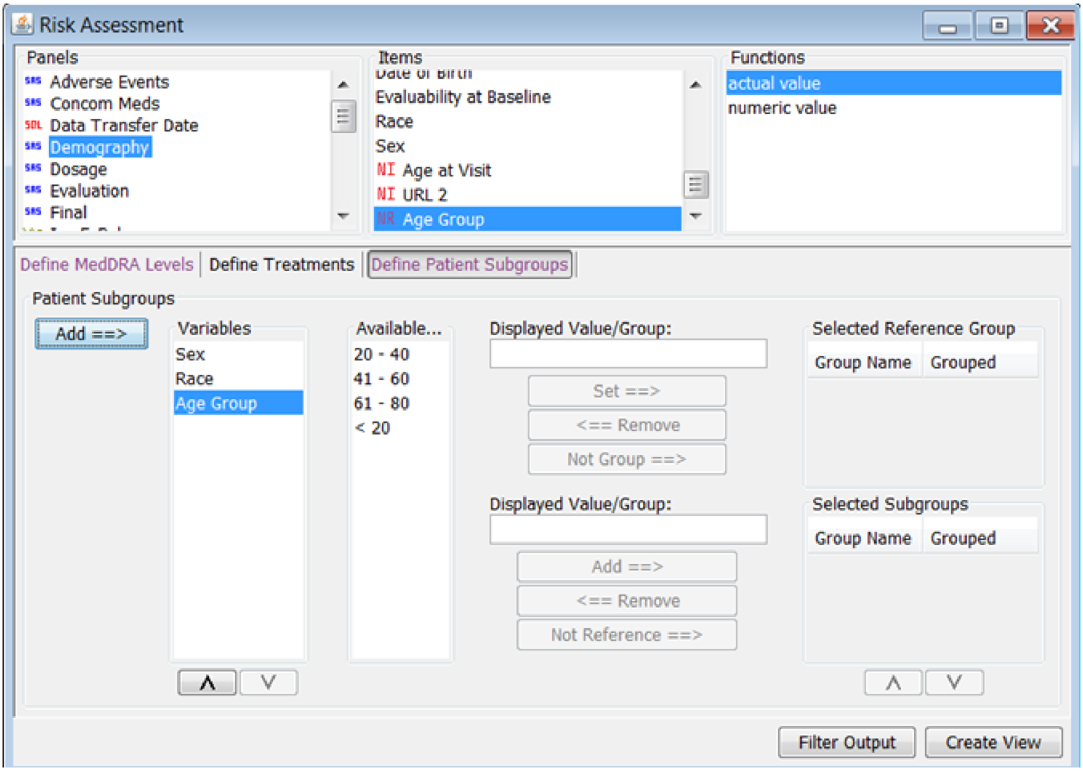
Selected Reference Group

| Group Name | Grouped |
|---|---|
| White | |

Selected Subgroups

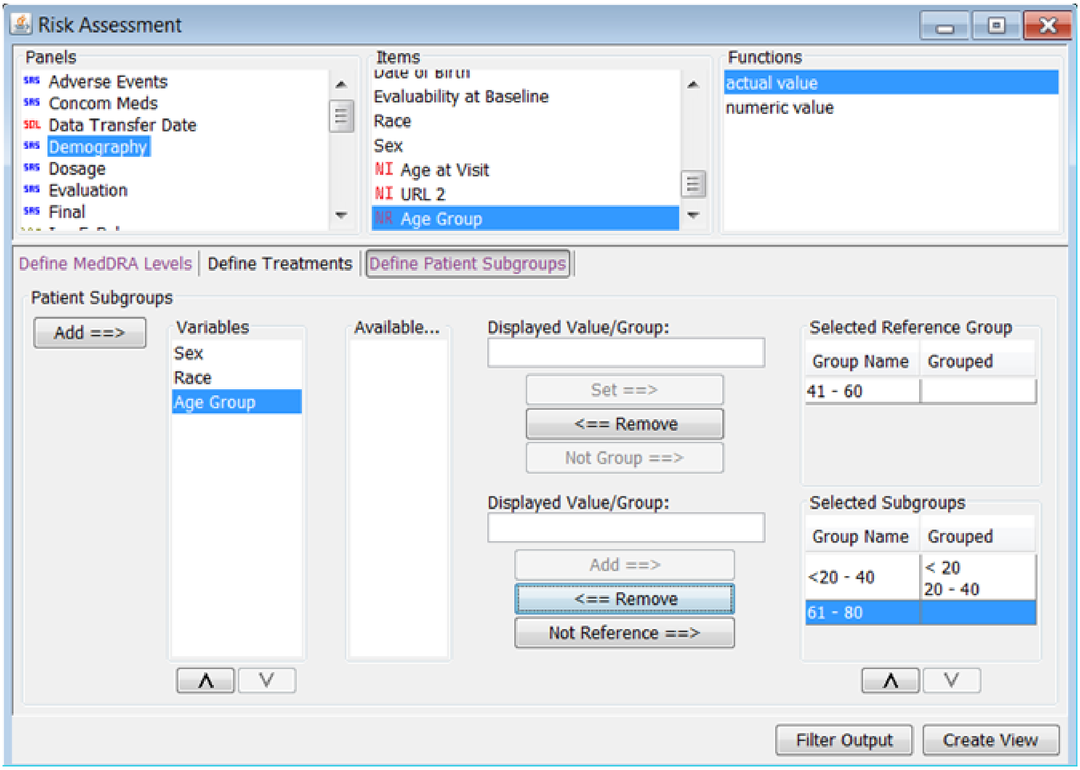
| Group Name | Grouped |
|---|---|
| Other | Black<br>Hispanic |

Another Patient Subgroup example shows the new data range defined for Age Group was added with four available subgroups. Again, you may organize and add as individual subgroups.



The Age Group for 41 - 60 was selected and set as the Reference Group for the denominator in the ratio calculation.

Next the new label for ‘<20 - 40’ was entered in the Displayed Value/Group text box. The two age groups for ‘<20’ and ‘20 - 40’ were selected and click Add. The last age range was added for ‘60 - 80’, to show multiple age groups added to the **Selected Subgroups**.



Selected Reference Group

| Group Name | Grouped |
|---|---|
| 41 - 60 | |

Selected Subgroups

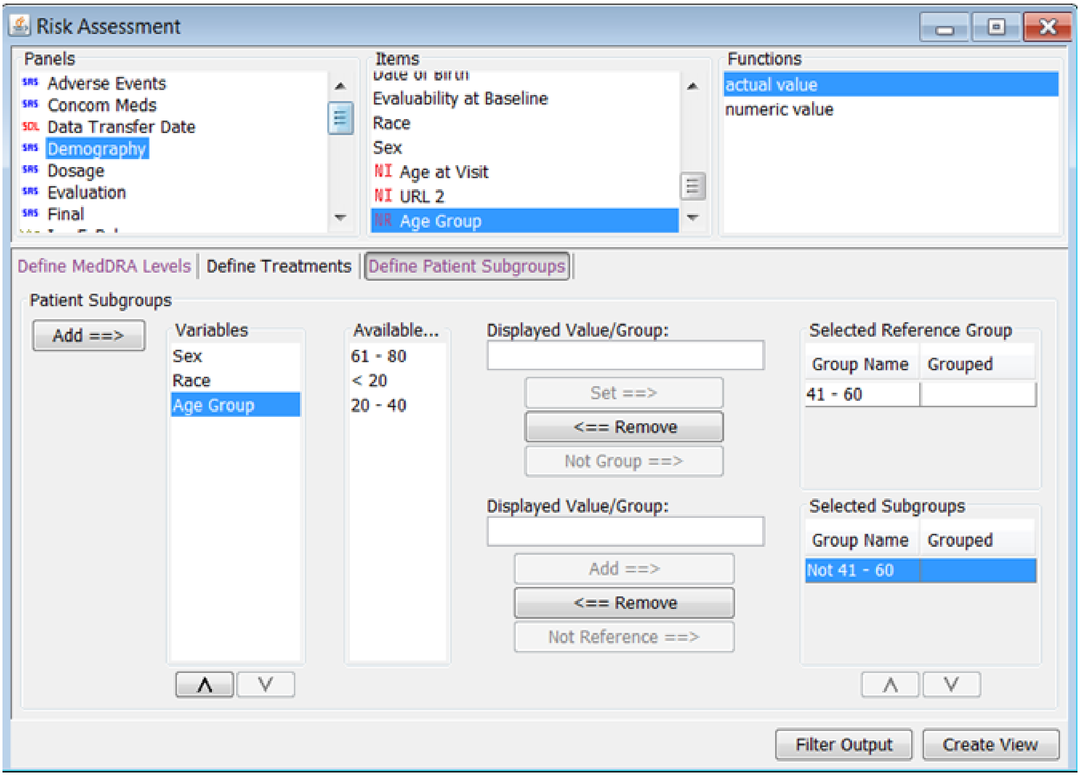
| Group Name | Grouped |
|---|---|
| <20 - 40 | < 20<br>20 - 40 |
| 61 - 80 | |

If you wish to consolidate multiple subgroups instead of entering as individual subgroups, you may use the **Not Group** or **Not Reference** feature.

First the subgroup for ‘41-60’ was entered as **Set** for **Selected Reference Group**.

Next **Not Reference** for **Selected Subgroups** was clicked, the remaining subgroups were consolidated and entered as ‘Not 41-60’.

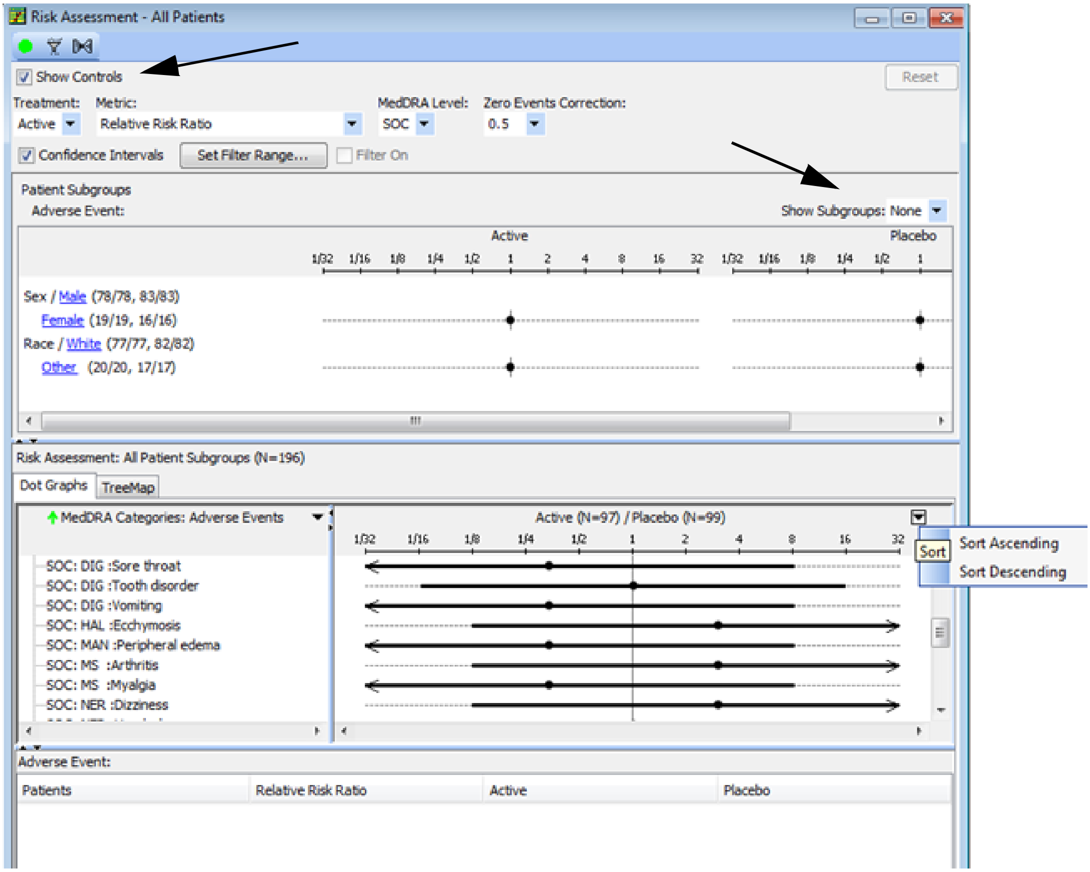
After you have entered the MedDRA levels, Treatments and Patient Subgroups for the Risk Assessment analysis, you may analyze the data results by clicking **Create View.**



# Interact with Risk Assessment Results

## *View Risk Assessment*

The Risk Assessment window opens to display "multi-value" dot plots. Each row in the graph contains a dot plot of a Relative Risk Ratio or Risk Difference for a MedDRA term. The ratio or difference "compares" a treatment group to a reference group. There is a feature that "overlays" values for patient subgroups. The subgroups are defined by a single selected variable (e.g., Sex: Males, Females). The patient group options are the same as those defined in the Risk Assessment Browse window and appear in the Patient Subgroup graphs.



Risk Assessment - All Patients

☑ Show Controls

Treatment: Active

Metric: Relative Risk Ratio

MedDRA Level: SOC

Zero Events Correction: 0.5

☑ Confidence Intervals

☐ Filter On

Patient Subgroups

Adverse Event:

Show Subgroups: None

Sex / Male (78/78, 83/83)

Female (19/19, 16/16)

Race / White (77/77, 82/82)

Other (20/20, 17/17)

Risk Assessment: All Patient Subgroups (N=196)

Active (N=97) / Placebo (N=99)

To save space in the Risk Assessment viewer, a checkbox is provided that allows the user to show or hide the "control panel". The control panel is ***hidden*** when the Risk Assessment frame is opened.

The **Show Controls** check-box shows and hides the control panel of “view options” for **Treatment, Metric**, **MedDRA Level**, and **Zero Events Correction**. There is a **Confidence Intervals** checkbox that determines whether confidence intervals are displayed in the graphs.  If you had entered multiple treatment groups than you would select which reference treatment group to apply for comparison analysis. Metric selections are available for relative risk ratio and various risk difference options.

The default  **Zero Events Correction** measure for “0.5” is enabled. You may toggle to the none corrected presentation which displays all incalculable ratios that have zero incidence in at least one ARM. When the Zero Events Correction (0.5) is turned OFF as disabled then red shows AE’s present in one treatment ARM versus not present in the other ARM when the frequency changes. The Risk Ratio algorithm cannot be calculated if there is a zero in the numerator.

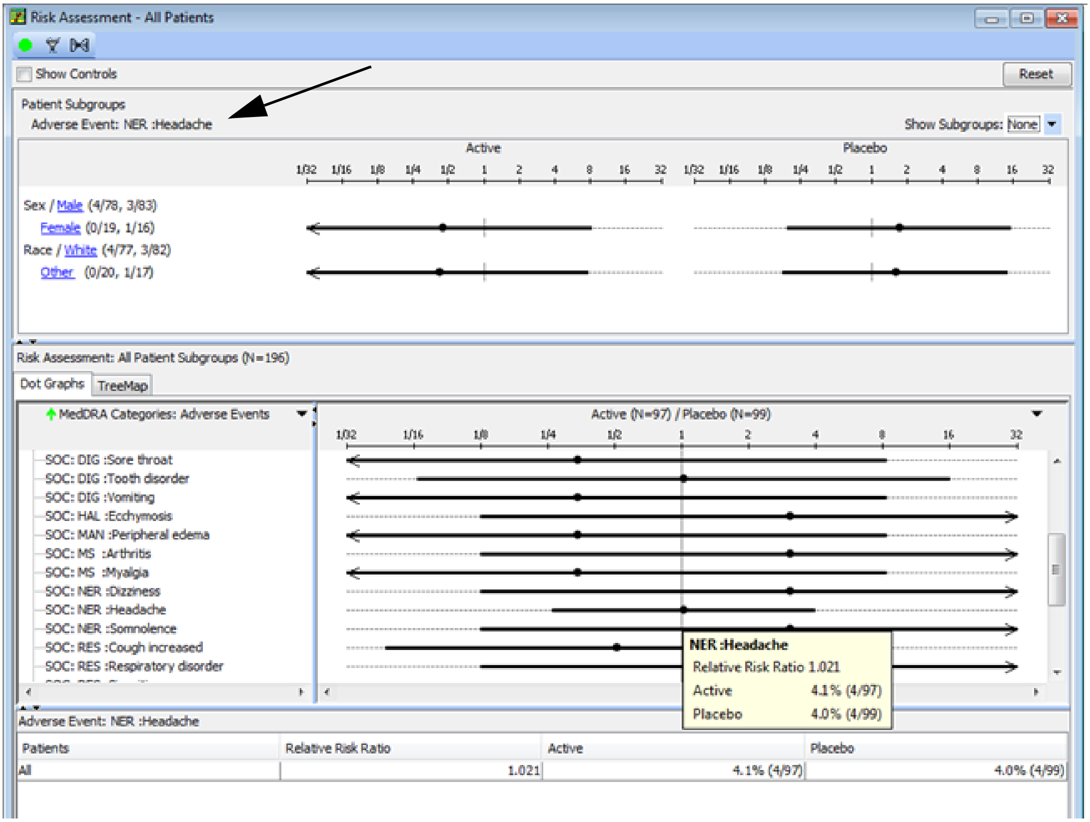
The Risk Assessment analysis plot opens with two tab display options for **Dot Graphs** and **TreeMap**. The Dot Graphs initially opens to display the default MedDRA level for SOC as the top level sort term listed in alpha order. Typically you may prefer to view in descending order, and may change the Risk Assessment default sort by clicking the arrow in the upper right corner. A drop down **Sort** list displays to select for ascending or descending sort. A tab to view as TreeMap display is also available.

In the Risk Assessment, the size of the central dot in the plot analysis corresponds to the importance of the SOC, where a larger dot represents more patients and smaller dot means fewer patients reported the Adverse Event within the SOC. This feature provides a quick visual aide to the importance of the Adverse Event on the patient population.

The top Patient Subgroups plot displays the two treatment group arms with separate ratios displayed at baseline. When an SOC **dot** is selected the treatment arms re calibrate to show ratio differences between treatment arms separated by confidence intervals. Hover over a SOC dot to display a tool tip window of specific details for relative risk ratio and percentages.

Both the table and legend can be resized by dragging separators.

This example shows the SOC was selected for “NER:Headache”.



**NER :Headache**
Relative Risk Ratio 1.021
Active 4.1% (4/97)
Placebo 4.0% (4/99)

Adverse Event: NER :Headache

| Patients | Relative Risk Ratio | Active | Placebo |
|---|---|---|---|
| All | 1.021 | 4.1% (4/97) | 4.0% (4/99) |

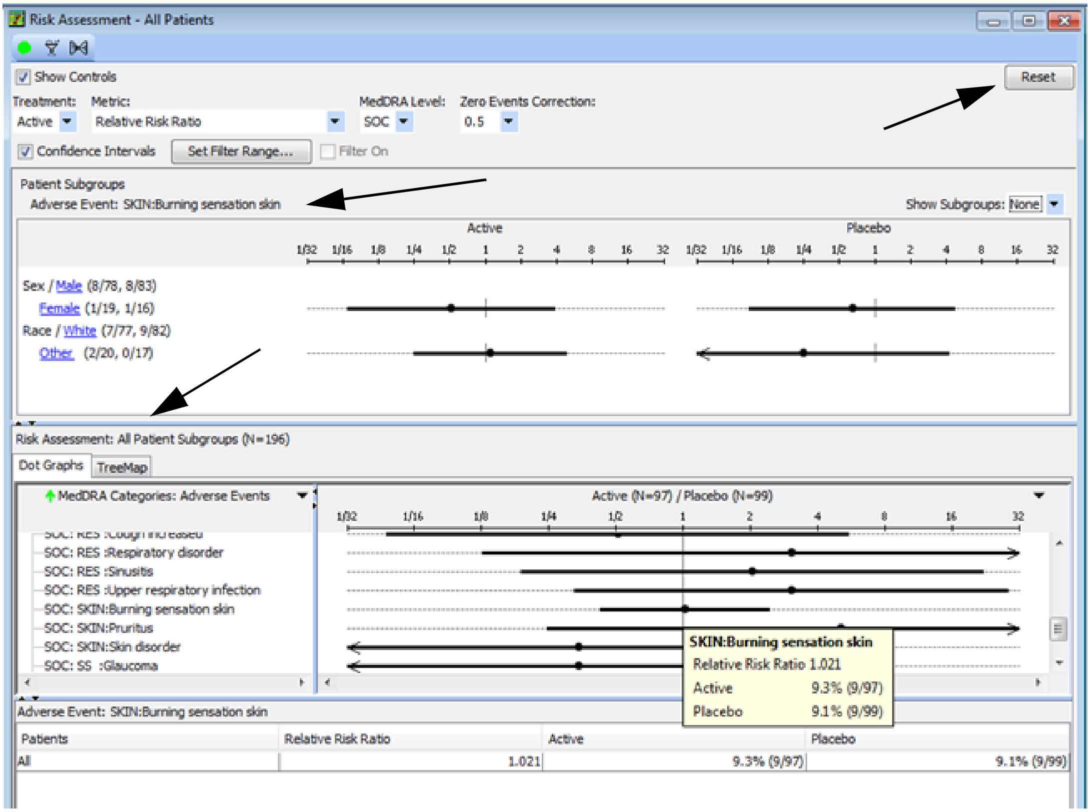
A data table is presented at the bottom of the Risk Assessment window. The data in the table is very similar to the current tooltip data presented when hovering over a row in the AE graph.

## *Select MedDRA level*

Select and click on an SOC dot to modify the upper Patient Subgroup analysis to show the treatment arm distributions. The **Patient Subgroups** label shows the selected SOC description and the ratios show the adjustments for Active versus Placebo. This example shows selected SOC for “SKIN:Burning sensation skin”.

Whenever you select a different SOC level from the Risk Assessment plot; the Patient Subgroups re calibrates for treatment distribution ratios across the entered patient subgroups.

Missing values display at the side in red with ratio details. Click the **Reset** button to return to baseline status and remove any prior sub setting selections.



☑ Show Controls

Treatment: Active

Metric: Relative Risk Ratio

MedDRA Level: SOC

Zero Events Correction: 0.5

☑ Confidence Intervals

☐ Filter On

Patient Subgroups

Adverse Event: SKIN:Burning sensation skin

Show Subgroups: None

Sex / Male (8/78, 8/83)

Female (1/19, 1/16)

Race / White (7/77, 9/82)

Other (2/20, 0/17)

Risk Assessment: All Patient Subgroups (N=196)

Active (N=97) / Placebo (N=99)

SOC: RES :Cough increased

SOC: RES :Respiratory disorder

SOC: RES :Sinusitis

SOC: RES :Upper respiratory infection

SOC: SKIN:Burning sensation skin

SOC: SKIN:Pruritus

SOC: SKIN:Skin disorder

SOC: SS :Glaucoma

**SKIN:Burning sensation skin**

Relative Risk Ratio 1.021

| | |
|---|---|
| Active | 9.3% (9/97) |
| Placebo | 9.1% (9/99) |

Adverse Event: SKIN:Burning sensation skin

| Patients | Relative Risk Ratio | Active | Placebo |
|---|---|---|---|
| All | 1.021 | 9.3% (9/97) | 9.1% (9/99) |

If multiple MedDRA level terms were entered, click on the plus sign for the SOC to display the list for the next MedDRA Level term. Use the same steps to select more detailed level for ratio calculations, and to drill down into the levels below HLT, if these MedDRA details were entered.

## *Select patient subgroup*

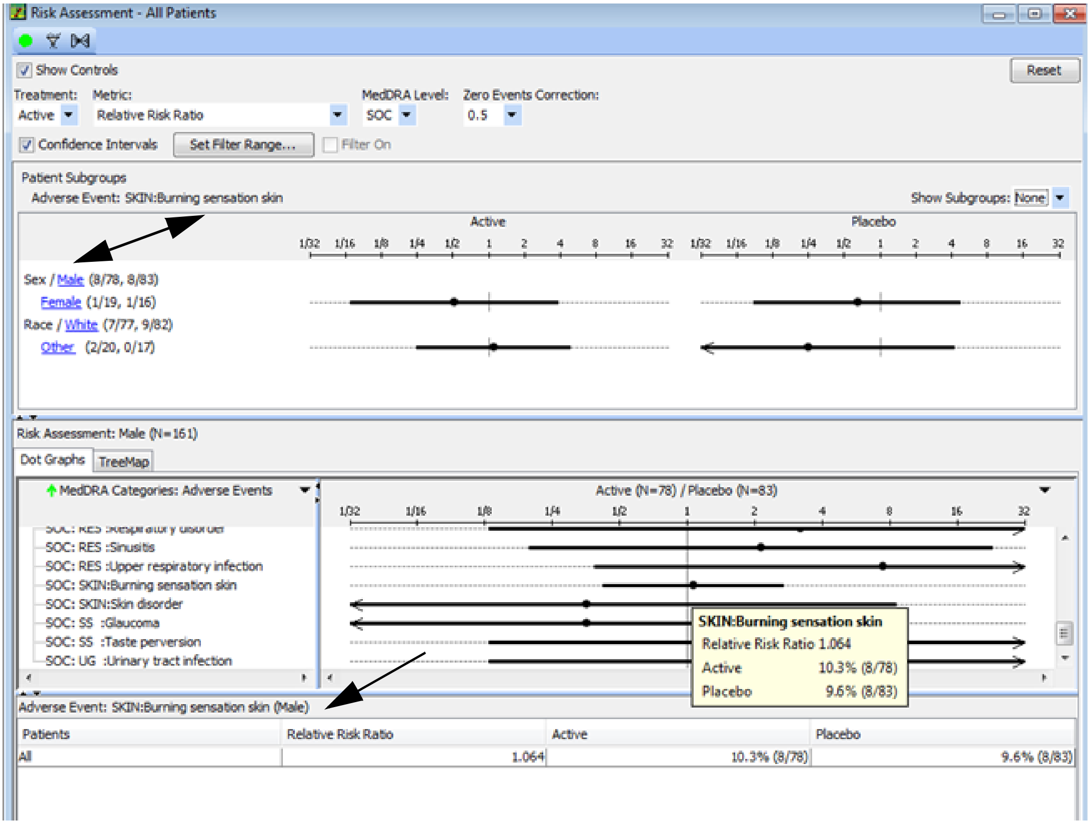
Select a patient subgroup by clicking on the highlighted subgroup, then the Risk Assessment recalculates the distribution and the header updates for the selected patient subgroup. The Risk Assessment difference as different calculation shows for multiple patient population options when applied. Red shows AEs present in one treatment arm versus not present in the other arm when the frequency changes.

The subgroup for ‘Males’ was selected and displays in the Risk Assessment header. The selected Adverse Event for ‘SKIN:Burning sensation skin’ and patient subgroup for males recalculates the relative risk ratio as follows:

Active 8/78 = 10.3%

Placebo 8/83 = 9.6%

0.1025 / 0.0963 = Relative Risk Ratio 1.064



Risk Assessment - All Patients

☑ Show Controls

Treatment: Active

Metric: Relative Risk Ratio

MedDRA Level: SOC

Zero Events Correction: 0.5

☑ Confidence Intervals

☐ Filter On

Patient Subgroups

Adverse Event: SKIN:Burning sensation skin

Show Subgroups: None

Sex / Male (8/78, 8/83)

Female (1/19, 1/16)

Race / White (7/77, 9/82)

Other (2/20, 0/17)

Risk Assessment: Male (N=161)

MedDRA Categories: Adverse Events

Active (N=78) / Placebo (N=83)

SOC: RES :Respiratory disorder

SOC: RES :Sinusitis

SOC: RES :Upper respiratory infection

SOC: SKIN:Burning sensation skin

SOC: SKIN:Skin disorder

SOC: SS :Glaucoma

SOC: SS :Taste perversion

SOC: UG :Urinary tract infection

SKIN:Burning sensation skin

Relative Risk Ratio 1.064

Active 10.3% (8/78)

Placebo 9.6% (8/83)

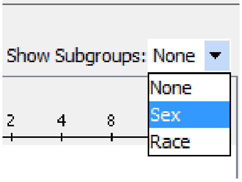
Adverse Event: SKIN:Burning sensation skin (Male)

| Patients | Relative Risk Ratio | Active | Placebo |
|---|---|---|---|
| All | 1.064 | 10.3% (8/78) | 9.6% (8/83) |

In the current example, the ‘covariate/subset’ items are presented in ‘ratio’ manner which is straight forward for two value items such as Gender. It is a little more complex for multi-value items such as Race, Age Groups, where for each of those, the user would choose the ‘base’ or ‘subset value’ of primary interest with each of the other ratios determined relative to that.

## *Apply patient subgroup overlay*

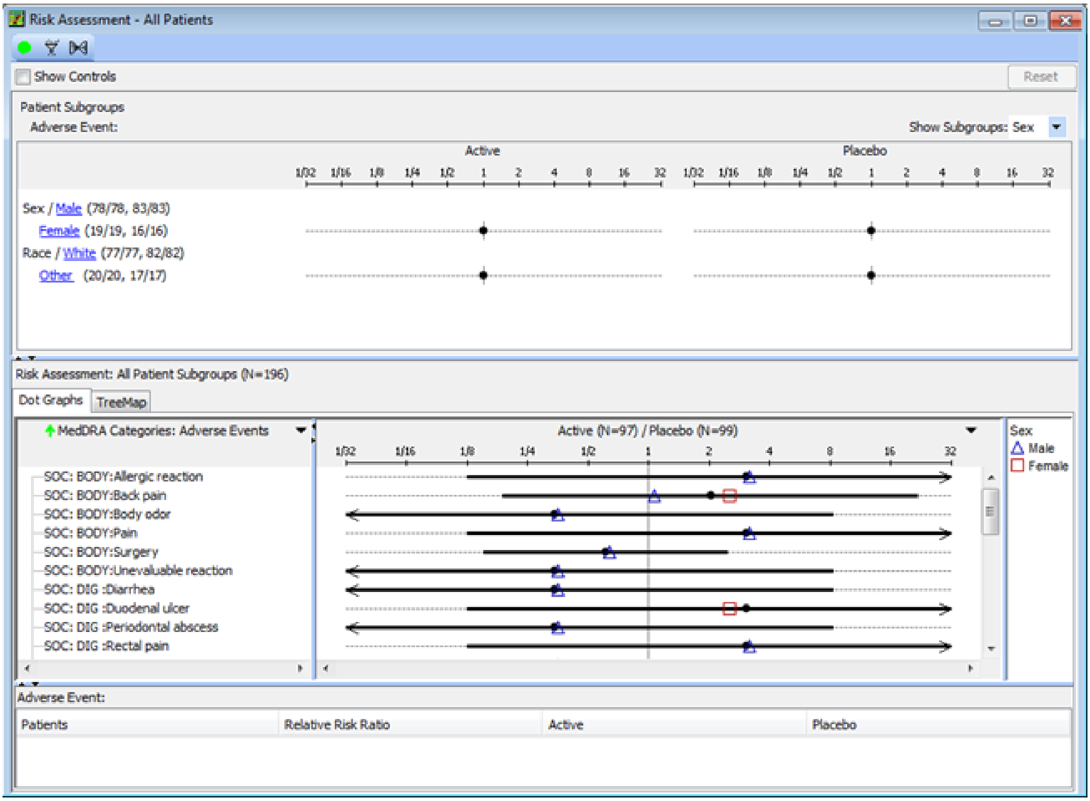
To display an “overlay” of Patient Subgroup values, such as “males” and “females”, “ Sex” is selected from the Show Subgroups combo box.  The options in this combo box are the same as the variables shown in the Patient Subgroups graph panel; in addition, the option “None” is provided.



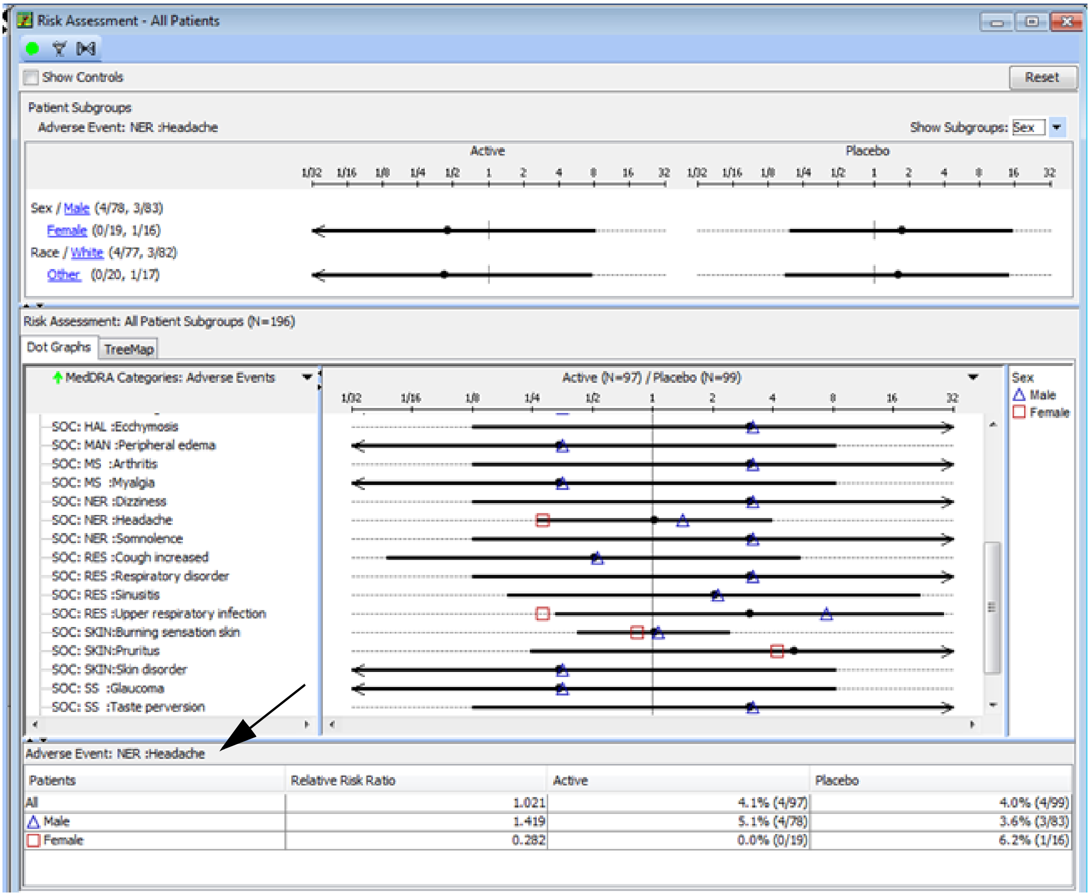
A data table is presented at the bottom of the Risk Assessment window.  The data in the table is very similar to the current tooltip data presented when hovering over a row in the AE graph.  However, in addition, the table contains data for each of the chosen patient subgroups.  Data is presented when the user clicks on a row in the AE graph - the data is associated with the currently selected row.  ***If no row is selected, there is no data in the table.***

When the patient subgroup for “Sex” is selected the overlay shows a different symbol and color is used for each subgroup.  A legend is shown when a subgroup variable is selected in the combo box; it indicates the symbols and colors that are being used.  If “None” is selected, the legend is removed.  A maximum of 10 symbols and colors are available.  The legend can be horizontally resized by dragging a separator that is positioned at the legend’s left side.

The overlay and legend appear in printed output.


Risk Assessment - All Patients
☐ Show Controls
Reset
Patient Subgroups
Adverse Event:
Show Subgroups: Sex
Active
Placebo
1/32 1/16 1/8 1/4 1/2 1 2 4 8 16 32
Sex / Male (78/78, 83/83)
Female (19/19, 16/16)
Race / White (77/77, 82/82)
Other (20/20, 17/17)
Risk Assessment: All Patient Subgroups (N=196)
Dot Graphs
TreeMap
MedDRA Categories: Adverse Events
Active (N=97) / Placebo (N=99)
SOC: BODY:Allergic reaction
SOC: BODY:Back pain
SOC: BODY:Body odor
SOC: BODY:Pain
SOC: BODY:Surgery
SOC: BODY:Unevaluable reaction
SOC: DIG :Diarrhea
SOC: DIG :Duodenal ulcer
SOC: DIG :Periodontal abscess
SOC: DIG :Rectal pain
Sex
△ Male
□ Female
Adverse Event:
Patients
Relative Risk Ratio
Active
Placebo

Next “SOC: NER: Headache was selected. The metrics for the patient subgroups use the total number of patients in the subgroup for either the treatment arm or reference group as denominator values in the ratios, For example, the represented value for “males” for “Headache” would be based on the number of males reporting this AE event relative to the number of males. Remember there are two ratios involved: one for the “treatment” arm and one for the “reference” group.



Show Subgroups: Sex

Adverse Event: NER :Headache

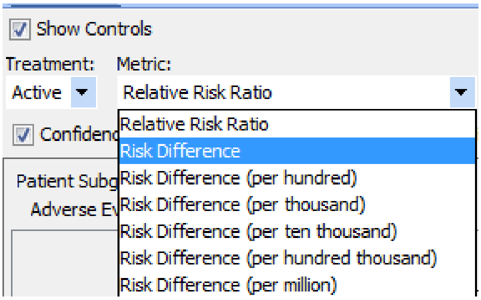
| Patients | Relative Risk Ratio | Active | Placebo |
|---|---|---|---|
| All | 1.021 | 4.1% (4/97) | 4.0% (4/99) |
| △ Male | 1.419 | 5.1% (4/78) | 3.6% (3/83) |
| ☐ Female | 0.282 | 0.0% (0/19) | 6.2% (1/16) |

The table at the bottom of the frame displays values for the currently selected row in the AE graphs where “Headache” is selected. The displayed values in the table are similar to the tooltips: the value of the current metric (e.g., Relative Risk Ratio, Risk Difference), and percentages and patient counts for both “treatment” and “eference” groups. The first row in the table is the same as the tooltip. Subsequent rows will show data for each patient subgroup, if a subgroup overlay variable has been selected in the combo box described. The table can be vertically resized using the separator at the top of the table’s panel. The text at the top of the table shows the name of the currently selected AE.

***Note:*** that values in the table will be updated when “view options” such as the “metric” or “zero correction” are changed. The table data is also updated if a Patient Subgroup is selected as a “filter” by clicking on an underlined item in the Patient Subgroup panel. The data does not automatically change when the viewed MedDRA level is changed: the selected AE term remains the same in this case.

## *Select Metric options*

The ‘Risk Difference’ metric is selected for the same patient subgroup for ‘Males’ and MedDRA Level SOC for ‘SKIN:Burning sensation skin’.



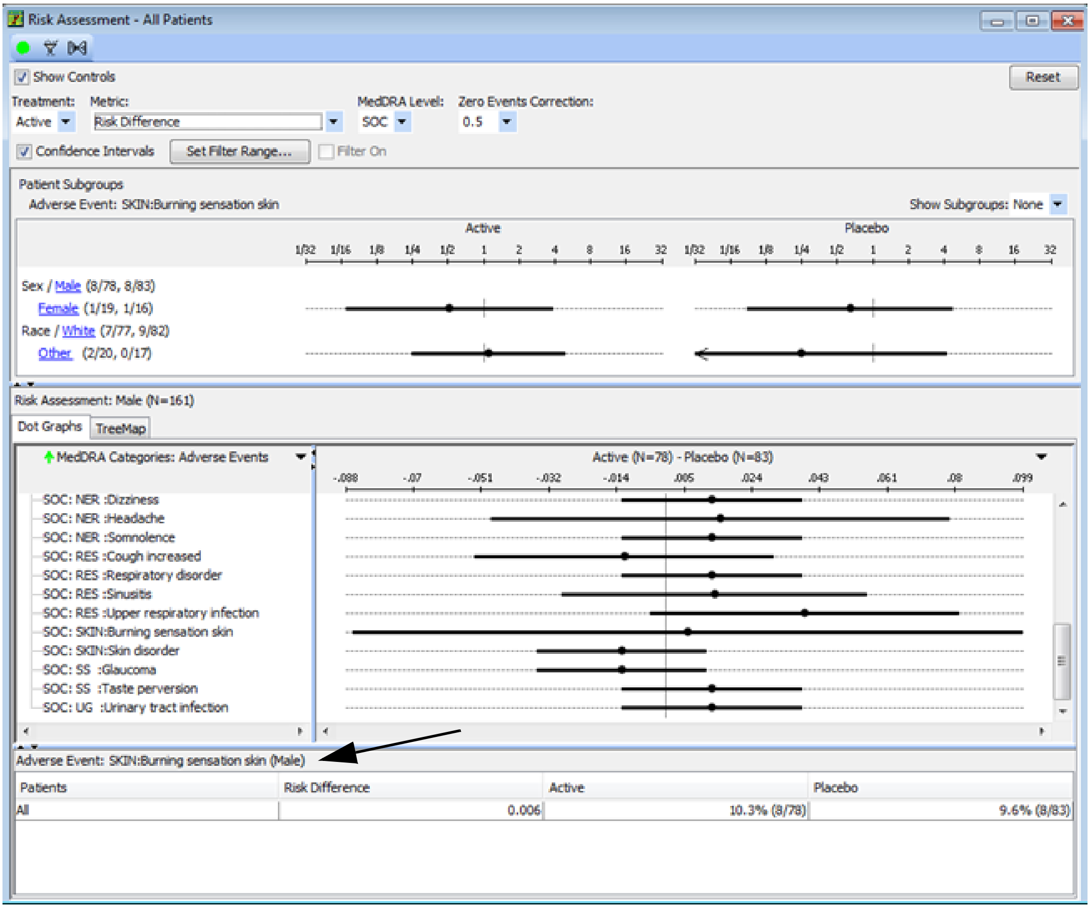
Other risk difference options may be selected for comparison.

The Risk Difference recalculates as follows:

Active 8/78 = 10.3%

Placebo 8/83 = 9.6%

0.1025 - 0.0963 = Risk Difference 0.006



☑ Show Controls

Treatment: Active

Metric: Risk Difference

MedDRA Level: SOC

Zero Events Correction: 0.5

☑ Confidence Intervals

☐ Filter On

Adverse Event: SKIN:Burning sensation skin

Show Subgroups: None

Sex / Male (8/78, 8/83)

Female (1/19, 1/16)

Race / White (7/77, 9/82)

Other (2/20, 0/17)

Adverse Event: SKIN:Burning sensation skin (Male)

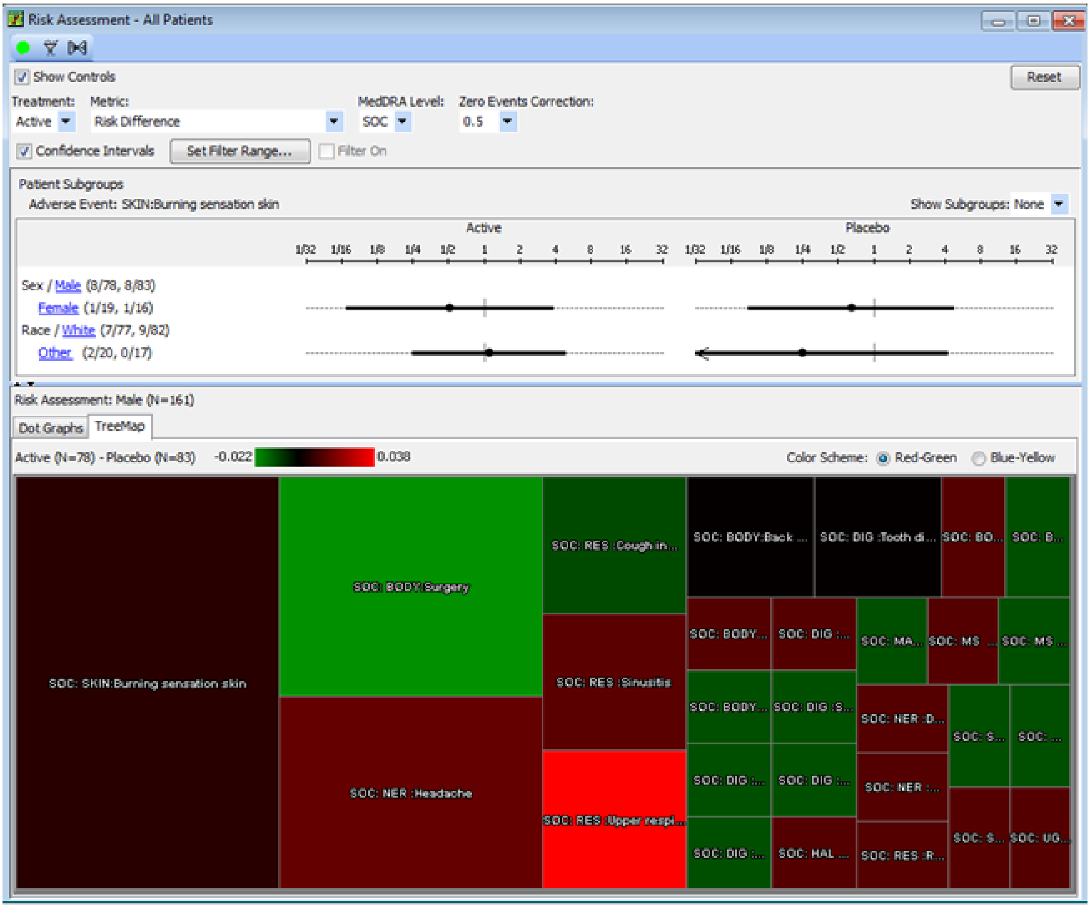
| Patients | Risk Difference | Active | Placebo |
|---|---|---|---|
| All | 0.006 | 10.3% (8/78) | 9.6% (8/83) |

## *Patient Highlighting*

When points are selected in the AE Risk Assessment graphic the patients contained therein generate Patient highlighting in other areas. The selected patients are highlighted in other output display, i.e. other reports, graphs, etc. in the normal manner.

## View TreeMap

Another Risk Assessment viewing option is the TreeMap. Click on the TreeMap tab to display a rectangle presentation of an adverse event.



Risk Assessment - All Patients

☑ Show Controls

Treatment: Active

Metric: Risk Difference

MedDRA Level: SOC

Zero Events Correction: 0.5

☑ Confidence Intervals

☐ Filter On

Patient Subgroups

Adverse Event: SKIN:Burning sensation skin

Show Subgroups: None

Sex / Male (8/78, 8/83)

Female (1/19, 1/16)

Race / White (7/77, 9/82)

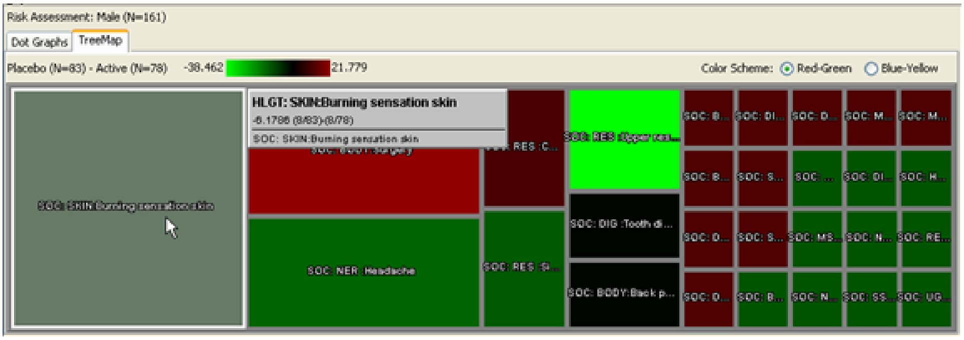
Other (2/20, 0/17)

Risk Assessment: Male (N=161)

Active (N=78) - Placebo (N=83) -0.022 0.038

Color Scheme: ● Red-Green ○ Blue-Yellow

These rectangles can be nested in “higher-order” rectangles, each representing a classification such as an SOC type. The size of the rectangle represents the number of patients showing an adverse event. So, the larger the rectangle, the more patients exhibited the adverse event. You may hover over a SOC rectangle to display a tool tip window of specific details for relative risk ratio and percentages.



Risk Assessment: Male (N=161)

Placebo (N=83) - Active (N=78)

Color Scheme: ● Red-Green ○ Blue-Yellow

HLGT: SKIN:Burning sensation skin
-6.1786 (8/83)-(8/78)
SOC: SKIN:Burning sensation skin

The colors relate to the metric’s value (e.g., Relative Risk Ratio, Risk Difference) for an adverse event. When the color is “black”, the difference between the treatment groups (e.g., “Placebo” vs. “Active”) is small or nonexistent. When the color is red, relatively more adverse events appeared in the Placebo group. When the color is green, relatively more adverse events appeared in the Active group. The degree of reddishness or greenness (the luminosity) indicates the magnitude of the metric’s value. For example, a “dark” red means that relatively more adverse events appeared in the Placebo group, but the “difference” or “ratio” is small.

Clicking on an SOC in the TreeMap affects the patient subgroup data in the upper panel. This operation is similar to what happens when clicking on a row in the dot-plot graphs.

The range for the Risk Ratios is fixed: it is always 1/32 to 32. However, the range for the Risk Differences is determined by the actual minimum and maximum values in the data.

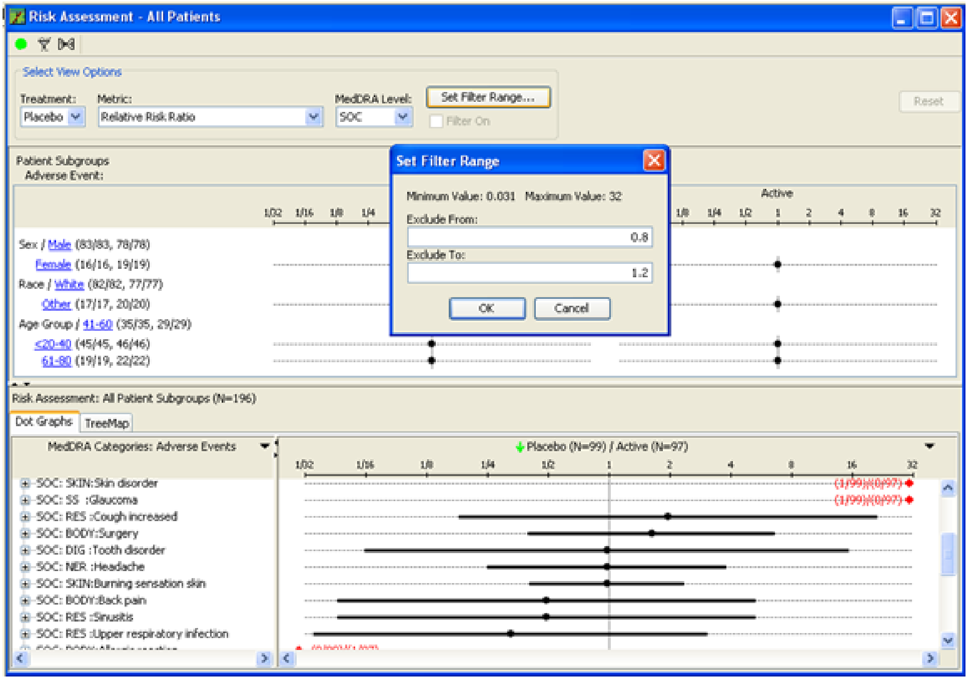
Double clicking on a rectangle allows the user to zoom-in to a lower level in the MedDRA hierarchy.

# Filtering visual results

## *Set Filter Range*

The “Filter Range” feature allows the user to exclude rows in the dot plots that may have no or only negligible effect sizes. For example, for the Risk Difference (per thousand) metric, the user might want to hide relatively small differences, say, where the difference is less than 10. In such a case, the user can enter a range of -10 to 10. Any dot plot (row) where the difference is between -10 and 10 will not be shown.

The Set Filter Range may be turned ON or OFF using the checkbox. When the filter is ON, a gray area on the graph shows the range of values that are used for excluding adverse events. In other words, any adverse event where the middle of the dot would fall within the gray area is hidden.



Treatment: Placebo

Metric: Relative Risk Ratio

MedDRA Level: SOC

☐ Filter On

Set Filter Range

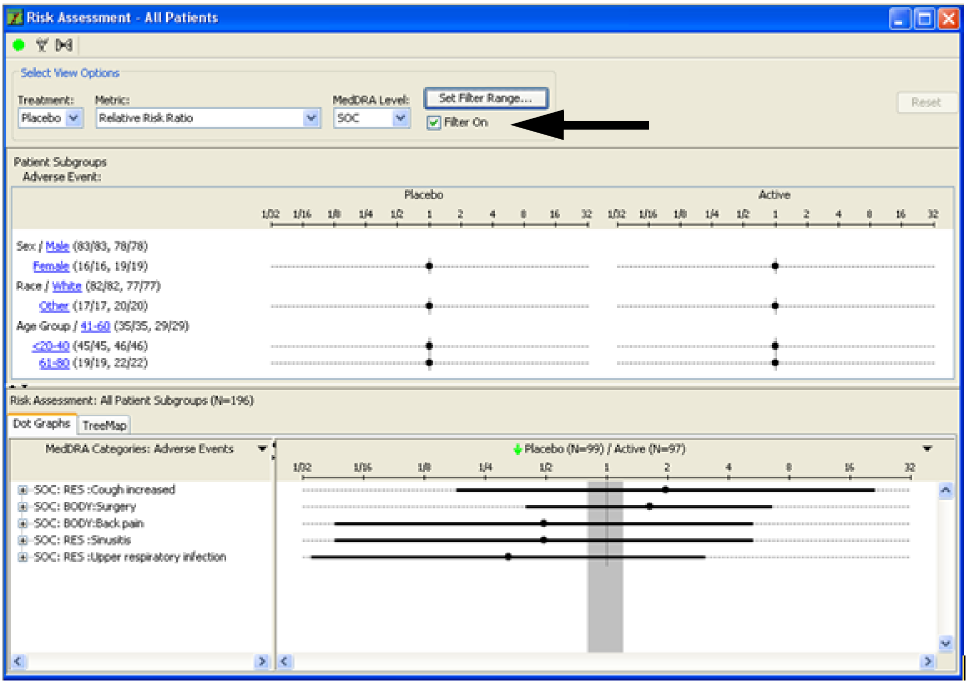
Minimum Value: 0.031 Maximum Value: 32

Exclude From: 0.8

Exclude To: 1.2

Risk Assessment: All Patient Subgroups (N=196)

Similarly, for Risk Ratios, the user might want to hide dot plot rows where the ratio is close to "1", meaning that the treatment groups are almost the same in terms of the relative number of patients showing a particular adverse event. Because the user is looking for "significant" differences between treatment groups, such data is regarded as "clutter." So, the user might enter a range of ".8 to 1.2" to filter out adverse events that have small ratio sizes.



Risk Assessment - All Patients

Select View Options

Treatment: Placebo

Metric: Relative Risk Ratio

MedDRA Level: SOC

☑ Filter On

Patient Subgroups

Adverse Event:

Sex / Male (83/83, 78/78)

Female (16/16, 19/19)

Race / White (82/82, 77/77)

Other (17/17, 20/20)

Age Group / 41-60 (35/35, 29/29)

<20-40 (45/45, 46/46)

61-80 (19/19, 22/22)

Risk Assessment: All Patient Subgroups (N=196)

MedDRA Categories: Adverse Events

SOC: RES :Cough increased

SOC: BODY:Surgery

SOC: BODY:Back pain

SOC: RES :Sinusitis

SOC: RES :Upper respiratory infection

Placebo (N=99) / Active (N=97)

The user can choose any part of the range, and thus could use the filter for somewhat different purposes as well. For example, the user might want to hide adverse effects where a Placebo group showed more adverse effects.

## *Apply output filter*

Risk assessment can be used with an output filter, so only the adverse events of interest will be analyzed. In the main Risk Assessment window, apply an output filter the same as in other output browsers, to remove the 'not related' adverse events or low intensity. The risk factors selected are where there is good quantitative evidence of a dose-response relationship and clear exposure.

## *Save risk assessment*

The risk assessment definition can be saved like other output objects using the same object save steps. The saved risk assessment objects are available in the Object Specifications window for access by other users. You may optionally apply and save patient selection criteria with the risk assessment object specification.

For detailed instructions on how to save, retrieve, schedule output and remove object specifications (reports, graphs, crosstabs, etc.).
***(See Chapter 11: Saving Objects, plus Alerts Browser)***

# Printing and Exporting Graphs

## *Printing the graph*

To get a printed copy of your graph you must access a **Print Preview window** and menu bar.

1. Click on the result window to make it the active window.
2. Click 🖨 , or from the **Browser File** menu, select **Print**.

Click either **PrintPage**, **PrintAll** or **Close**. The PrintPage option will print only the first page of your output. The PrintAll option will print the entire output. The result prints on the currently selected printer.

If the multi-value overlay is selected, the overlay and a legend appear in the printed output.

## *Edit menu Copy*

1. Click on the result window to make it the active window.
2. Select Edit in the menu bar.
3. Select the Copy function, to copy the currently displayed output window to clipboard for pasting into Word, etc.

## *Exporting the graph*

The Export feature exports the data to Excel.  AE data broken down by the chosen patient subgroups (e.g., Male, Female) is exported. For each patient subgroup, the metric (e.g., Risk Ratio) and the number AE occurrences for both treatment and reference arms are presented in separate columns. Each row is an AE type. Total patient counts for each of the chosen subgroups is presented in a header area.

Another is that if the user has unselected the Show Confidence Intervals check-box in the Control Panel, no Confidence Interval columns will presented in any of the sheets.

1. From the menu bar in the **Print Plot window**, click **Export.** The save dialog window opens to export to Excel.
2. Select a folder location and enter a **File Name**.
3. Click **Save** to export the graph results.

## *Export Presentation*

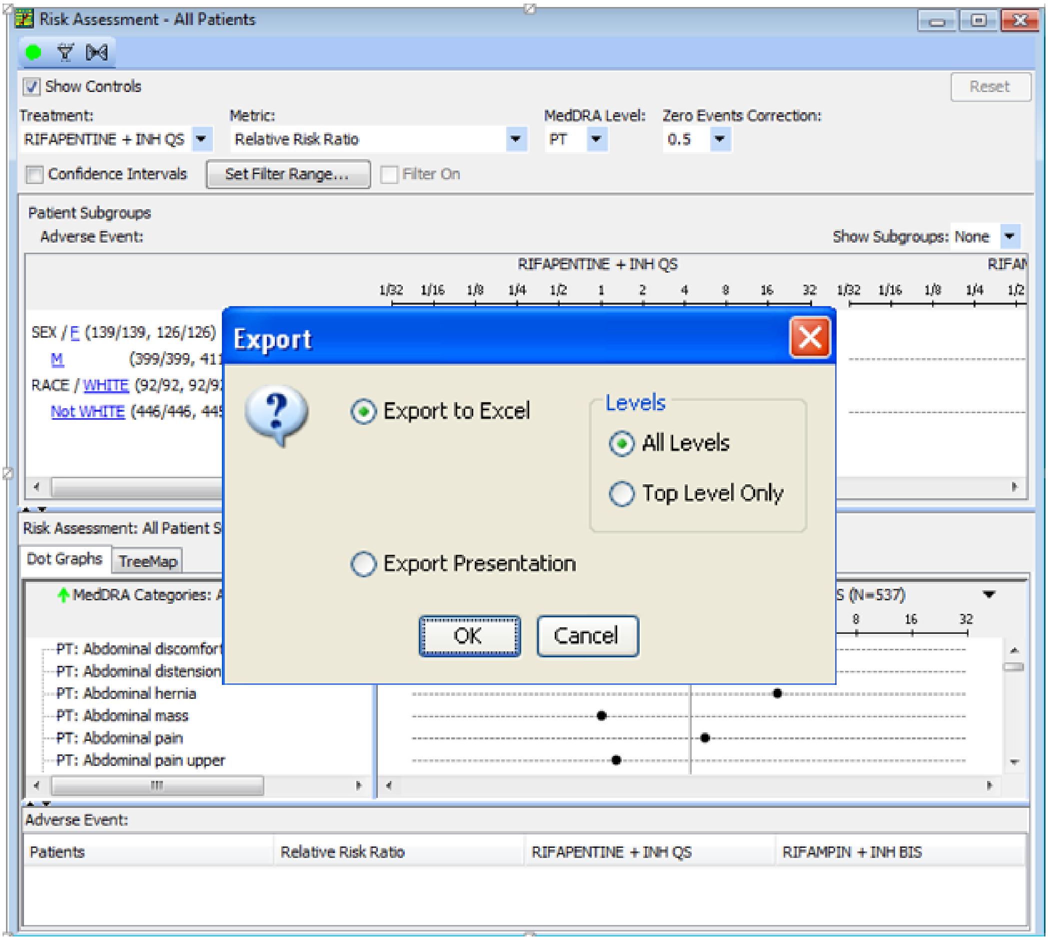
Export Presentation allows the user to create and export a display similar to that found in medical publications. The feature provides a “wizard-like” dialog that allows the user to select a subset of AE types, and to create a “risk data” display for presentation purposes. The display combines tabular data with dot plot graphs in a format similar to that found in medical publications. Each row in the display contains a textual display of risk-related data and a dot plot.  The feature is subsumed under “Export.”

The data presented in the presentation is largely, but not entirely, based on the current Adverse Event/MEDDRA graph data currently shown in the Risk Assessment viewer. As in the viewer, patient subset selection, the current metric, treatment choice, and range filters determine what is contained in the presentation. As in the Export to Excel and Print functions, the presentation displays data only at the selected MEDDRA level (e.g., SOC, PT); it is not a tree display.

Because the number of AE (MEDDRA) terms may be too large to fit on a document page such as Microsoft Word, and only a subset of terms may of interest (e.g., AEs with many observed instances) the user can select a subset of terms to be displayed. Forty is the maximum number of terms that can appear in the presentation. In the dialog, the user can sort a listing of terms.

*Note:* ***The selected sort type in the “wizard” determines the sort order in the presentation.***

For Risk Assessment, choosing Export from the JReview **File menu** results in a modal popup dialog that asks for the type of Export. Select **Export to Excel** with All Levels of MEDDRA terms, or just the Top Level Only. Another option is to select **Export Presentation** (graphics).



Risk Assessment - All Patients

☑ Show Controls

Treatment: RIFAPENTINE + INH QS

Metric: Relative Risk Ratio

MedDRA Level: PT

Zero Events Correction: 0.5

☐ Confidence Intervals

☐ Filter On

Show Subgroups: None

SEX / F (139/139, 126/126)

M (399/399, 41

RACE / WHITE (92/92, 92/9

Not WHITE (446/446, 44

PT: Abdominal discomfort

PT: Abdominal distension

PT: Abdominal hernia

PT: Abdominal mass

PT: Abdominal pain

PT: Abdominal pain upper

Export

● Export to Excel

Levels

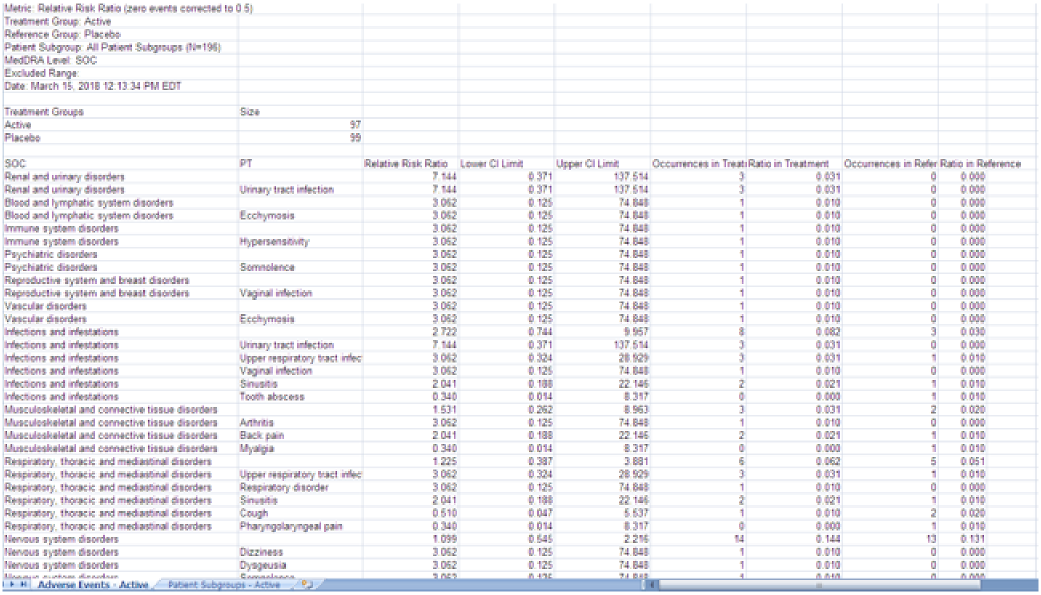
● All Levels

○ Top Level Only

○ Export Presentation

| Patients | Relative Risk Ratio | RIFAPENTINE + INH QS | RIFAMPIN + INH BIS |
|---|---|---|---|

If the user selects ‘Export to Excel … All Levels’ – here’s an example screenshot of the display – which includes a column for each of the MEDDRA levels that were included in the AE Risk Assessment. In this case SOC and PT, with the SOC repeated on each row for each PT.



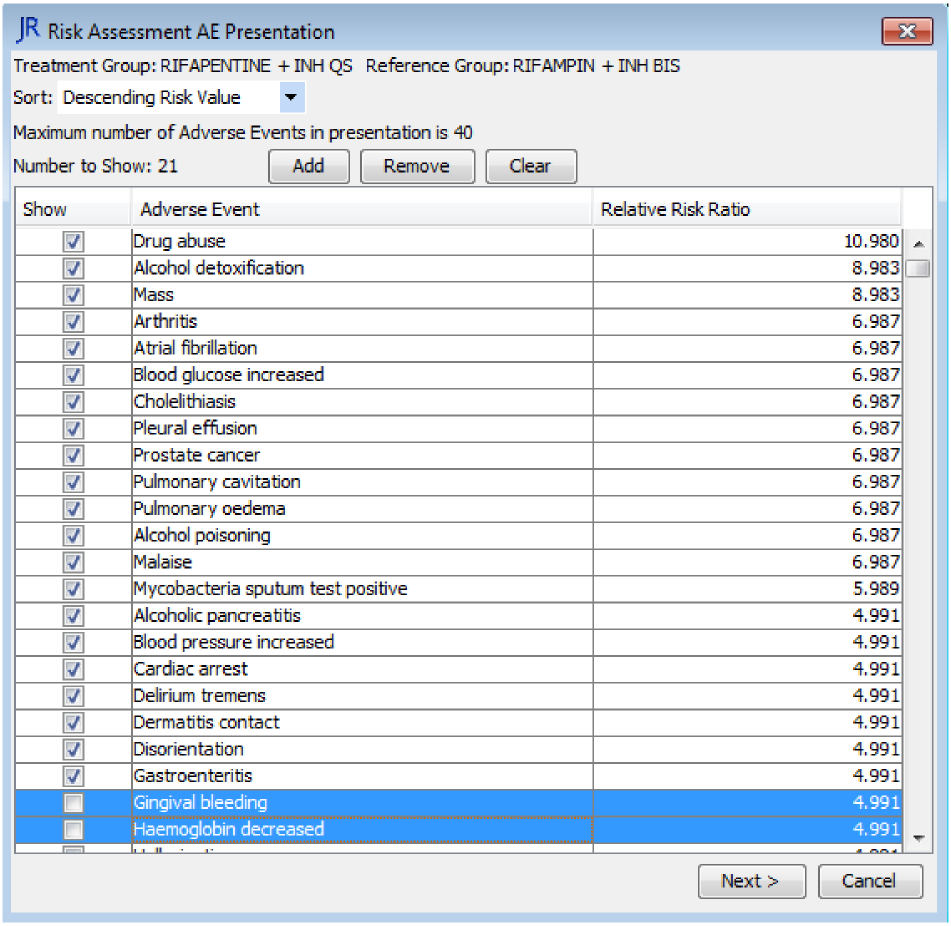
Metric: Relative Risk Ratio (zero events corrected to 0.5)
Treatment Group: Active
Reference Group: Placebo
Patient Subgroup: All Patient Subgroups (N=196)
MedDRA Level: SOC
Excluded Range:
Date: March 15, 2018 12:13:34 PM EDT

| Treatment Groups | Size |
|---|---|
| Active | 97 |
| Placebo | 99 |

| SOC | PT | Relative Risk Ratio | Lower CI Limit | Upper CI Limit | Occurrences in Treat | Ratio in Treatment | Occurrences in Refer | Ratio in Reference |
|---|---|---|---|---|---|---|---|---|
| Renal and urinary disorders | | 7.144 | 0.371 | 137.514 | 3 | 0.031 | 0 | 0.000 |
| Renal and urinary disorders | Urinary tract infection | 7.144 | 0.371 | 137.514 | 3 | 0.031 | 0 | 0.000 |
| Blood and lymphatic system disorders | | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |
| Blood and lymphatic system disorders | Ecchymosis | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |
| Immune system disorders | | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |
| Immune system disorders | Hypersensitivity | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |
| Psychiatric disorders | | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |
| Psychiatric disorders | Somnolence | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |
| Reproductive system and breast disorders | | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |
| Reproductive system and breast disorders | Vaginal infection | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |
| Vascular disorders | | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |
| Vascular disorders | Ecchymosis | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |
| Infections and infestations | | 2.722 | 0.744 | 9.957 | 8 | 0.082 | 3 | 0.030 |
| Infections and infestations | Urinary tract infection | 7.144 | 0.371 | 137.514 | 3 | 0.031 | 0 | 0.000 |
| Infections and infestations | Upper respiratory tract infec | 3.062 | 0.324 | 28.929 | 3 | 0.031 | 1 | 0.010 |
| Infections and infestations | Vaginal infection | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |
| Infections and infestations | Sinusitis | 2.041 | 0.188 | 22.146 | 2 | 0.021 | 1 | 0.010 |
| Infections and infestations | Tooth abscess | 0.340 | 0.014 | 8.317 | 0 | 0.000 | 1 | 0.010 |
| Musculoskeletal and connective tissue disorders | | 1.531 | 0.262 | 8.963 | 3 | 0.031 | 2 | 0.020 |
| Musculoskeletal and connective tissue disorders | Arthritis | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |
| Musculoskeletal and connective tissue disorders | Back pain | 2.041 | 0.188 | 22.146 | 2 | 0.021 | 1 | 0.010 |
| Musculoskeletal and connective tissue disorders | Myalgia | 0.340 | 0.014 | 8.317 | 0 | 0.000 | 1 | 0.010 |
| Respiratory, thoracic and mediastinal disorders | | 1.225 | 0.387 | 3.881 | 6 | 0.062 | 5 | 0.051 |
| Respiratory, thoracic and mediastinal disorders | Upper respiratory tract infec | 3.062 | 0.324 | 28.929 | 3 | 0.031 | 1 | 0.010 |
| Respiratory, thoracic and mediastinal disorders | Respiratory disorder | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |
| Respiratory, thoracic and mediastinal disorders | Sinusitis | 2.041 | 0.188 | 22.146 | 2 | 0.021 | 1 | 0.010 |
| Respiratory, thoracic and mediastinal disorders | Cough | 0.510 | 0.047 | 5.537 | 1 | 0.010 | 2 | 0.020 |
| Respiratory, thoracic and mediastinal disorders | Pharyngolaryngeal pain | 0.340 | 0.014 | 8.317 | 0 | 0.000 | 1 | 0.010 |
| Nervous system disorders | | 1.099 | 0.545 | 2.216 | 14 | 0.144 | 13 | 0.131 |
| Nervous system disorders | Dizziness | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |
| Nervous system disorders | Dysgeusia | 3.062 | 0.125 | 74.848 | 1 | 0.010 | 0 | 0.000 |

If the user chooses “Export Presentation”, a two–page “wizard” dialog is presented. The first page allows the user to select the MEDDRA AE types to include in the presentation. The rows can be sorted either alphabetically or based on the risk value, either in a descending or ascending order. The default order is the same as the current sort type in the main Risk Assessment viewer. However, the sort in the presentation depends on the sort in the wizard, and not the main viewer.

The checkboxes in the first column of the "AE" table allows the user to toggle the choice as to whether the AE should be "shown" in the presentation. However, for more "bulk" selections, the user can select multiple rows in the table and click on the "Add" button: the selected rows will be added to the "Show" set. Similarly, selected rows can be "removed" from the "Show" set. "Clear" removes all items from the "Show " set.  A numeric counter field displays the number of AEs that are in the "Show" set.



Treatment Group: RIFAPENTINE + INH QS  Reference Group: RIFAMPIN + INH BIS

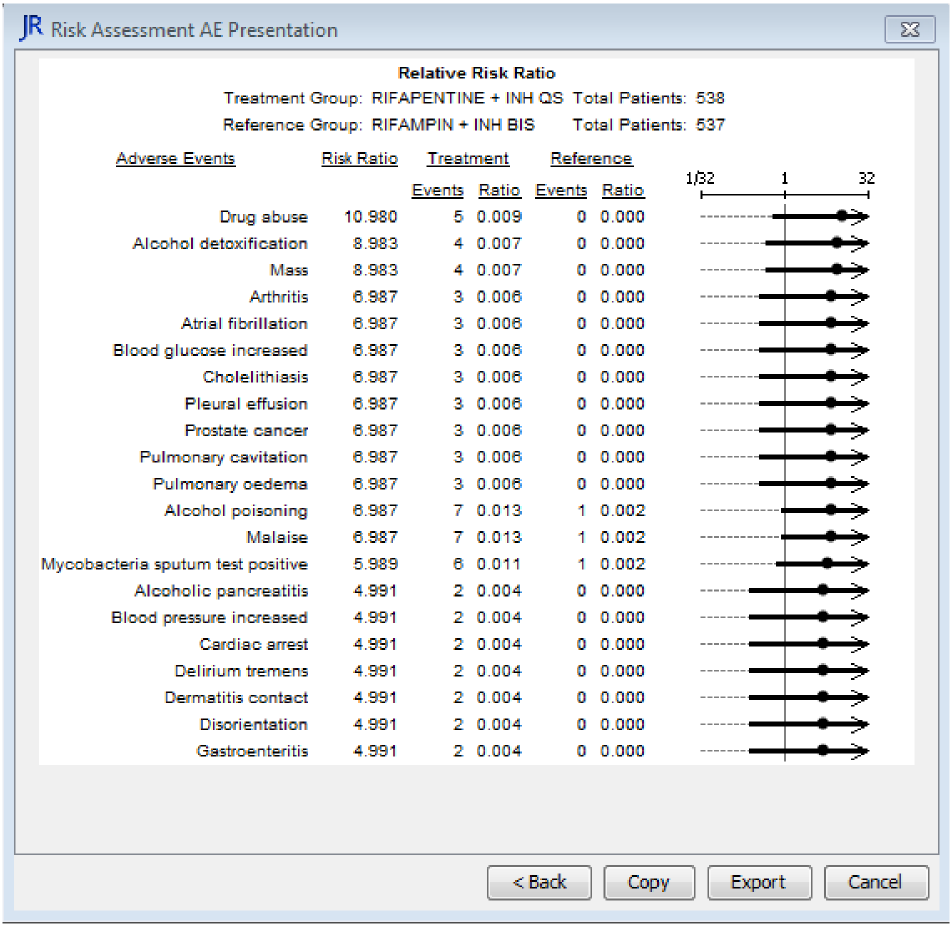
Sort: Descending Risk Value

Maximum number of Adverse Events in presentation is 40

Number to Show: 21

| Show | Adverse Event | Relative Risk Ratio |
|---|---|---|
| ☑ | Drug abuse | 10.980 |
| ☑ | Alcohol detoxification | 8.983 |
| ☑ | Mass | 8.983 |
| ☑ | Arthritis | 6.987 |
| ☑ | Atrial fibrillation | 6.987 |
| ☑ | Blood glucose increased | 6.987 |
| ☑ | Cholelithiasis | 6.987 |
| ☑ | Pleural effusion | 6.987 |
| ☑ | Prostate cancer | 6.987 |
| ☑ | Pulmonary cavitation | 6.987 |
| ☑ | Pulmonary oedema | 6.987 |
| ☑ | Alcohol poisoning | 6.987 |
| ☑ | Malaise | 6.987 |
| ☑ | Mycobacteria sputum test positive | 5.989 |
| ☑ | Alcoholic pancreatitis | 4.991 |
| ☑ | Blood pressure increased | 4.991 |
| ☑ | Cardiac arrest | 4.991 |
| ☑ | Delirium tremens | 4.991 |
| ☑ | Dermatitis contact | 4.991 |
| ☑ | Disorientation | 4.991 |
| ☑ | Gastroenteritis | 4.991 |
| ☐ | Gingival bleeding | 4.991 |
| ☐ | Haemoglobin decreased | 4.991 |

If the “Show” set contains at least one AE and has no more than 40 AEs, the “Next >” button is enabled. The user clicks on this button to change to the second page, which contains the “Preview” display and button controls. The “presentation” itself is displayed in a scrollable pane.  There are four buttons at the bottom of the frame on this page. “< Back” returns the user to the first page of the wizard.  “Copy” copies the presentation to the clipboard so that it can then be pasted into a document (e.g., a Word document).  When “Export” is chosen, the user is presented with a File Chooser dialog that allows the user to specify a file, and to specify an “image” format: the format may be either JPEG or EPS. The image may then be generated in the chosen file.



**Relative Risk Ratio**

Treatment Group:  RIFAPENTINE + INH QS  Total Patients:  538

Reference Group:  RIFAMPIN + INH BIS  Total Patients:  537

| Adverse Events | Risk Ratio | Treatment | | Reference | |
|---|---|---|---|---|---|
| | | Events | Ratio | Events | Ratio |
| Drug abuse | 10.980 | 5 | 0.009 | 0 | 0.000 |
| Alcohol detoxification | 8.983 | 4 | 0.007 | 0 | 0.000 |
| Mass | 8.983 | 4 | 0.007 | 0 | 0.000 |
| Arthritis | 6.987 | 3 | 0.006 | 0 | 0.000 |
| Atrial fibrillation | 6.987 | 3 | 0.006 | 0 | 0.000 |
| Blood glucose increased | 6.987 | 3 | 0.006 | 0 | 0.000 |
| Cholelithiasis | 6.987 | 3 | 0.006 | 0 | 0.000 |
| Pleural effusion | 6.987 | 3 | 0.006 | 0 | 0.000 |
| Prostate cancer | 6.987 | 3 | 0.006 | 0 | 0.000 |
| Pulmonary cavitation | 6.987 | 3 | 0.006 | 0 | 0.000 |
| Pulmonary oedema | 6.987 | 3 | 0.006 | 0 | 0.000 |
| Alcohol poisoning | 6.987 | 7 | 0.013 | 1 | 0.002 |
| Malaise | 6.987 | 7 | 0.013 | 1 | 0.002 |
| Mycobacteria sputum test positive | 5.989 | 6 | 0.011 | 1 | 0.002 |
| Alcoholic pancreatitis | 4.991 | 2 | 0.004 | 0 | 0.000 |
| Blood pressure increased | 4.991 | 2 | 0.004 | 0 | 0.000 |
| Cardiac arrest | 4.991 | 2 | 0.004 | 0 | 0.000 |
| Delirium tremens | 4.991 | 2 | 0.004 | 0 | 0.000 |
| Dermatitis contact | 4.991 | 2 | 0.004 | 0 | 0.000 |
| Disorientation | 4.991 | 2 | 0.004 | 0 | 0.000 |
| Gastroenteritis | 4.991 | 2 | 0.004 | 0 | 0.000 |

# 15 *Patient Narratives Browser*

# Patient Narrative Privileges

## Narratives Access Levels

The Patient Narratives Browser provides a facility to define, generate, edit and manage the patient narrative writing process all from within JReview. The end product of the patient narrative definitions is either a PDF or RTF document which contains the automatically inserted patient overview information (header information), standard boiler plate text with patient specific details inserted, including conditional inclusion of text blocks, as well as area for patient specific narrative text to be written and saved, with selected reports or graphs to illustrate the items of interest for the patient. An example patient narrative after being defined, edited, and ‘created’ is the generated PDF document which can also be exported as an RTF document.

The Patient Narratives Browser is used to define Patient Narrative templates, and support the capability to create and manage the work flow for Patient Narratives. It supports the Medical Writing team functionality to define templates for Patient Narratives, and check out cases to create the patient narratives. Ideally the patient narrative template is defined at the start of the study and then not accessed again unless an update is required.

The Patient Narratives access levels must be setup in ***ReviewAdmin*** under Review Privileges for the Patient Profile/Narrative tab. There are three privilege settings:

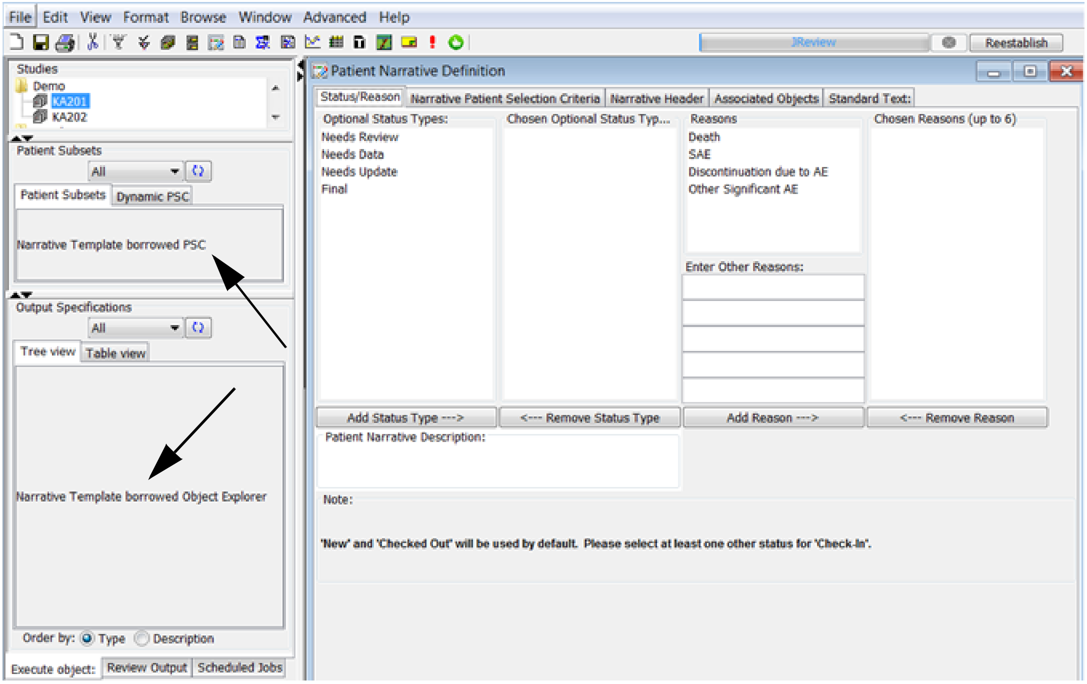
- ***Enable Patient Narrative Template Definition*** **(p55)** – allows for advanced lead medical writers to initially setup a narrative template for access.
- ***Enable Check Out Browser/Patient Narratives*** **(p56)** – allows for medical writers to access created narrative templates to enter and check out patient narratives.
- ***Enable View Check Out Browser/Patient Narrative*** **(p57)** - allows for view only access to other personnel to read the patient narratives.

# Patient Narrative Templates

## *Define Patient Narrative Template*

Once settings and privileges are granted, the next step is the initial setup of a narrative template. From the **Advanced** menu, select **Patient Narrative Definition.**

The **Patient Narrative Definition** window opens showing the Narrative Template borrowed Patient Subsets and Object Explorer.

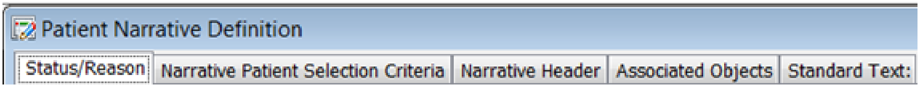


Narrative Template borrowed PSC

Narrative Template borrowed Object Explorer

'New' and 'Checked Out' will be used by default. Please select at least one other status for 'Check-In'.

There are five tabs in the **Patient Narrative Definition** window used to define the patient narrative template.  Enter information in the order of the tabs.



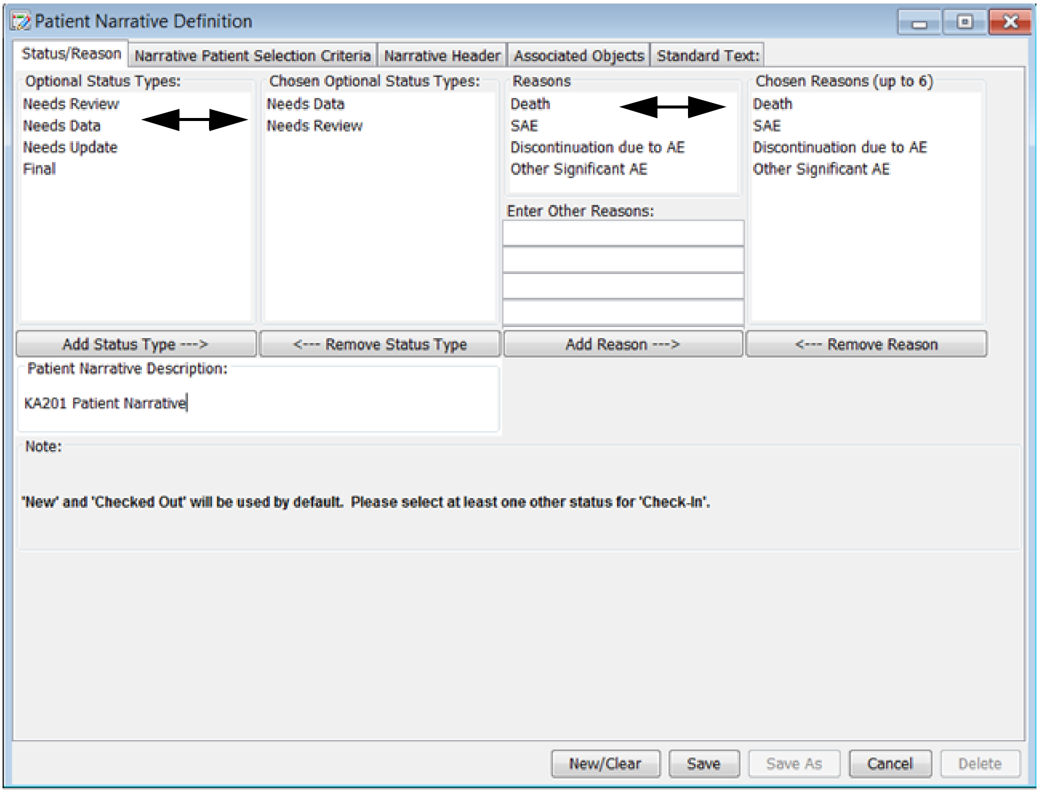
1. ***Status Reason*** – display option status types which can be added as config parameters. The two required status types are: New and Checked Out. Only one user can check out a narrative at a time. The status column tracks the work flow of the patient narratives.
2. ***Narrative Patient Selection Criteria*** – rules to include patients in the narrative based upon existed patient selection criteria, or add new patient subsets. Multiple patient subsets may be selected and included in the narrative definition.
3. ***Narrative Header*** – defines the template content by adding and removing item questions. It is based upon selecting patient information from Type 1 panels. The patient narrative template definition may be saved at the Study, Project, Global, or Study Group level. The narrative supports PDF or RTF display options.
4. ***Associated Objects*** – specific object can be associated or embedded into the patient narrative.
5. ***Standard Text*** – defined narrative header details are displayed in the narrative template along with any additional added data items selected from the DCM/Question Groups.  Embedded objects may be added to the Standard Text in the Patient Narrative Definition.

## *Status Reason tab*

1. Start at the **Status/Reason tab**. Select from the Optional Status Types list box, all appropriate statuses. Use the **Add and Remove Status Type buttons**.

   **'New'** and '**Checked Out'** will be used by default. You must select at least one other status type for '**Check In'** status.

   The Administrator must add the Status Types in the ***ReviewAdmin*** Config Table for NRSTATUSTYPES=Needs Review, Needs Data, Needs Update, Final.



Optional Status Types:
Needs Review
Needs Data
Needs Update
Final

Chosen Optional Status Types:
Needs Data
Needs Review

Reasons
Death
SAE
Discontinuation due to AE
Other Significant AE

Enter Other Reasons:

Chosen Reasons (up to 6)
Death
SAE
Discontinuation due to AE
Other Significant AE

Patient Narrative Description:
KA201 Patient Narrative

Note:
'New' and 'Checked Out' will be used by default. Please select at least one other status for 'Check-In'.

2. Select **Reasons** by clicking **Add Reason** as a definitions/assignments, (the reason why the narrative is being written – 'Death', 'SAE', etc.). Up to 6 reasons may be assigned. Other Reasons may be entered too.

   The **Reasons** are updated in both the patient narrative definition dialog, checkout browser (primary reason displayed), and writers panel.

3. Enter a **Patient Narrative Description *(required)*** to save the patient narrative.

4. Next, in the **Narrative Patient Selection Criteria tab**, you have the options to enter as:

- “All Patient”
- Define new patient subset
- Add existing patient subsets

Multiple patient subsets may be selected and added with the **Add Patient Selection Criteria button**. When multiple subsets are included, the patients selected by the subsets are by “OR” selection criteria to represent each subset. Use the **Remove Patient Selection Criteria button** to select, and remove narrative patient selection criteria.

There is the capability to map each PSC referenced to retrieve a selected group of patients to a ‘reason for narrative’ default setting. This is especially useful when generating patient narratives in batch.

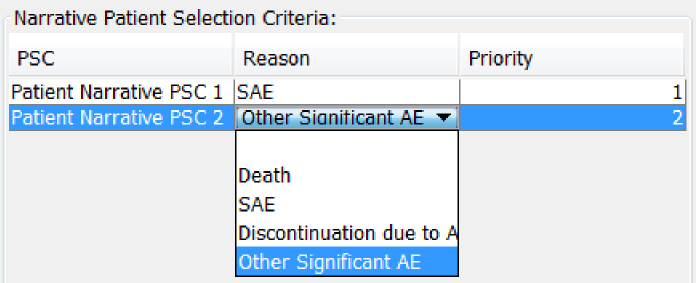
****** This workflow will be decided by the customer to either do narratives with reasons preselected or NOT to have reasons preselected.***

If you use preselected reason they appear on the narrative spreadsheet. If you don’t - only the narratives that have been saved will have reasons. Medical Writer should not be changing their mind mid batch. The reason priority was originally set up so that narratives could be batch processed and files written to some place on the server and then worked outside of JReview. However, it could be used as well in the one-by-one checkout scenario. This process is flexible and set by the customer on how it will be used.

The capability is to map a **Reason** to a PSC. For example, if the PSC selects all patients with Serious AE’s, you would choose a reason from the drop down list for SAE. If the PSC is discontinued due to AE, then you would choose that reason.

When a **Reason** and **Priority** is mapped to a PSC it will be applied to the patient narrative. The medical writer will be unable to change the mapped reason. If PSC are added to the list in the Narrative Patient Selection Criteria tab without reason and priority mapping - the medical writer is required to select a reason(s) in the narrative.

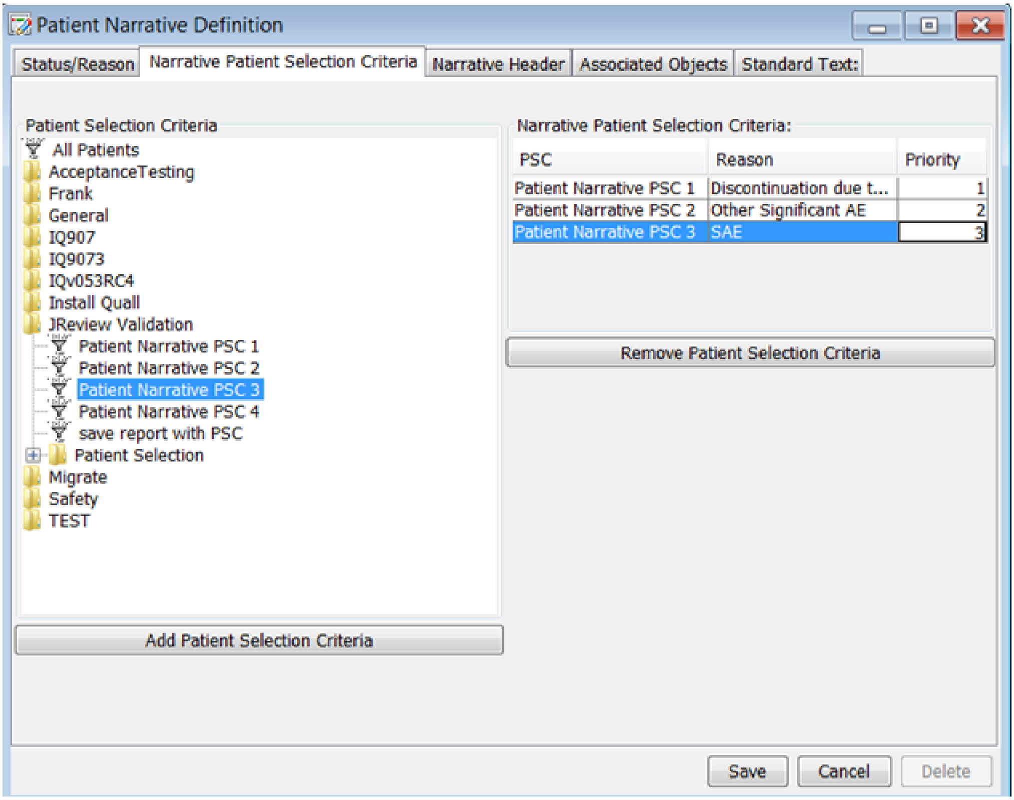
The **Priority** has to do with which reason is more important on the narrative. So if a patient had more than one reason, which one would become the Primary Reason for writing the narrative and then prioritize down. Start with "1" as the highest priority ander the reasons with consecutive numbers. There are maximum 6 allowed reasons, so start with highest priority as 1, second highest 2, etc.



Narrative Patient Selection Criteria:

| PSC | Reason | Priority |
|---|---|---|
| Patient Narrative PSC 1 | SAE | 1 |
| Patient Narrative PSC 2 | Other Significant AE | 2 |

The **Reasons** must first be entered in the **Status/Reason tab**, so that the dropdown list for Reasons displays. Then when you open the narrative the reason will be auto filled.



Narrative Patient Selection Criteria:

| PSC | Reason | Priority |
|---|---|---|
| Patient Narrative PSC 1 | Discontinuation due t... | 1 |
| Patient Narrative PSC 2 | Other Significant AE | 2 |
| Patient Narrative PSC 3 | SAE | 3 |

## *Check missing PSC*

Previously, if after the creation of a Narrative Template, a PSC gets removed or corrupt in some way, it would render the process invalid.

Patient Narratives now checks for missing reporting objects that had been embedded in patient narratives - which existed when they were embedded, but had been subsequently deleted.  There is also the same checking for PSCs that were used to define patient narrative selection criteria.

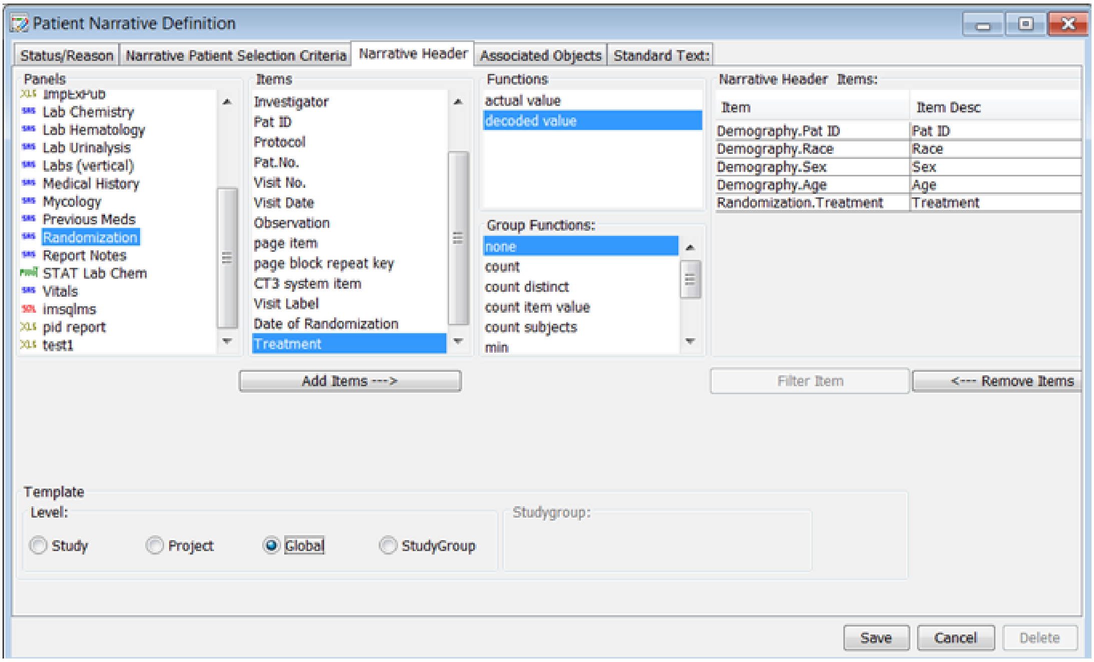
Prior to opening the Checkout Browser, or Narrative Template Definition the PSCs from the Template being opened are checked for validity or missing, and if a problem exists an error message with details is presented. For the checkout browser the error instructions tell the user to go to the definition and update before continuing. The Checkout browser does not open until any issues are fixed. For the Definition the details are again presented, but the Definition opens to allow the user to fix it.  If the PSC is missing, it will automatically be removed, but the Definition must be updated.  If corrupted the user must remove and update.

## *Narrative Header tab*

Typically you would select Narrative Header details for basic patient information collected from Type 1 panels.

5. Click the **Narrative Header** tab. From the list of Panels, select items to be added to the Narrative Header. Use the **Add Questions** and **Remove Questions** buttons.

   If needed, you may edit the **Item Description** in the Narrative Header Items list. Click on the item description to select and edit.



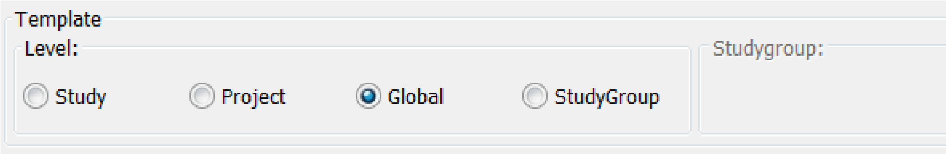
| Item | Item Desc |
|---|---|
| Demography.Pat ID | Pat ID |
| Demography.Race | Race |
| Demography.Sex | Sex |
| Demography.Age | Age |
| Randomization.Treatment | Treatment |

6. Optionally, you may filter on a selected item. Select the item in the Narrative Header Items list. The **Filter Item** button is activated to apply a filter.

   The intention for Filter use is to choose a single value for each header item, if the user knows or expects there might be multiple entries. There is added logic to limit entry of the value for any of the header items to the first one returned, and to note if there are more than one entry being returned – with a trailing ellipsis '…'.

## *Assign Template level*

7. Select the Template **Level** for Study, Project, Global, or Study Group.



Template

Level:

○ Study ○ Project ● Global ○ StudyGroup

Studygroup:

If you select Study Group, a dialog window will display to select the Study Group.

In most instances, Study and Project will be used. The way it works is when the Medical Writer accesses the Checkout Browser at whatever study, it will open at the lowest level template available. So, if a Study level template is available then it would be used. If not, then the access is to the Project level template. When there is no Project level template, then Study Group is next, and if no Study Group template then use the Global template last.

It is probably unlikely to use the same template for all the studies and projects, because header information and standard text may be different between studies or projects. Also, the subset of patients based upon the patient selection criteria applied may be different.

Where a project contains studies that are of similar design, then the Project level template will be used. If some studies within that project are different (in the way you want to define the template), then put them in a Study Group or just define the different ones individually. It will depend upon the specifics required in the Narrative Reporting for those particular studies. The usual reasons are SAE, Death, and Discontinuation due to Adverse Event where these are mandated by an FDA guidance. The Reason for 'Other significant AE' is included but each customer may want to specify reasons asked for by the FDA, such as elevated liver enzymes, etc. This information might also be applied to drive the Patient Selection Criteria for the template.

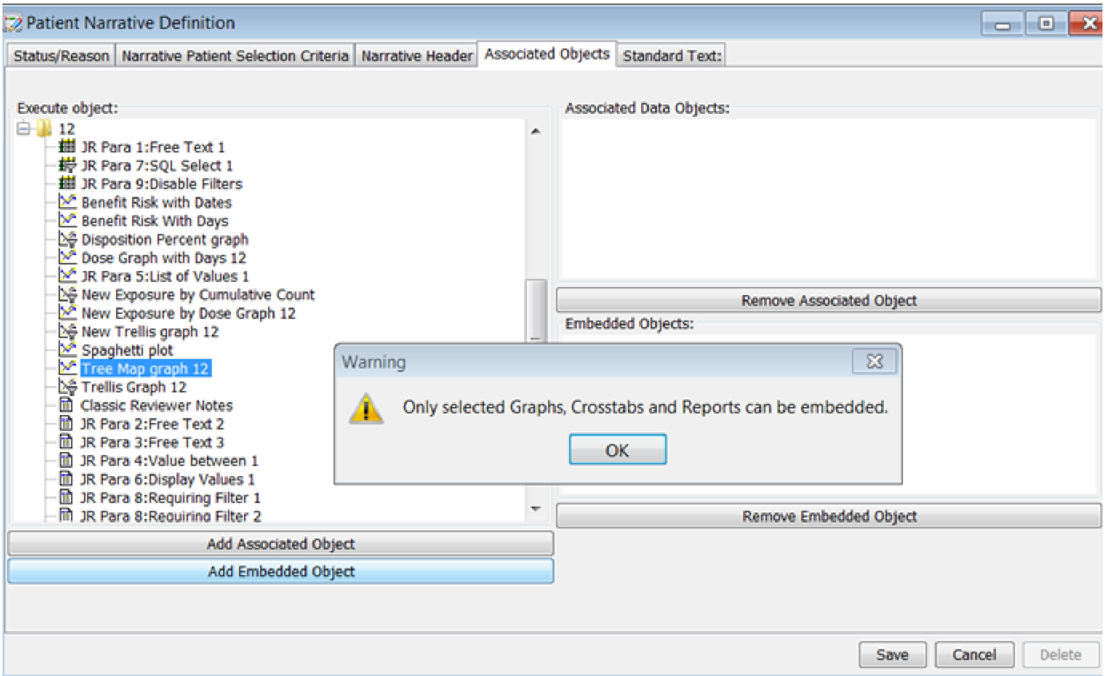
## *Associated Objects tab*

The Associated Objects tab is where you add associated and embedded objects for later use. They must be selected here first to be displayed on the drop list in the Standard Text tab. Next, in the Standard Text tab you put the embedded objects in the standard text at the curser, wherever you want them to appear within the text.

8. Optionally, you may **Add Associated Objects** or **Add Embedded Objects** to the narrative template. Click the **Associated Objects** tab.

   Only basic type scatter plots, crosstabs and reports may be embedded or a warning message will display. Instead, add complex output objects as Associated Objects.

   Select objects from the **Execute Object** category folders. Use the Add and Remove buttons for Associated Data Objects and Embedded Objects. The user chooses the Embedded Objects before entering the standard text details.



Only selected Graphs, Crosstabs and Reports can be embedded.

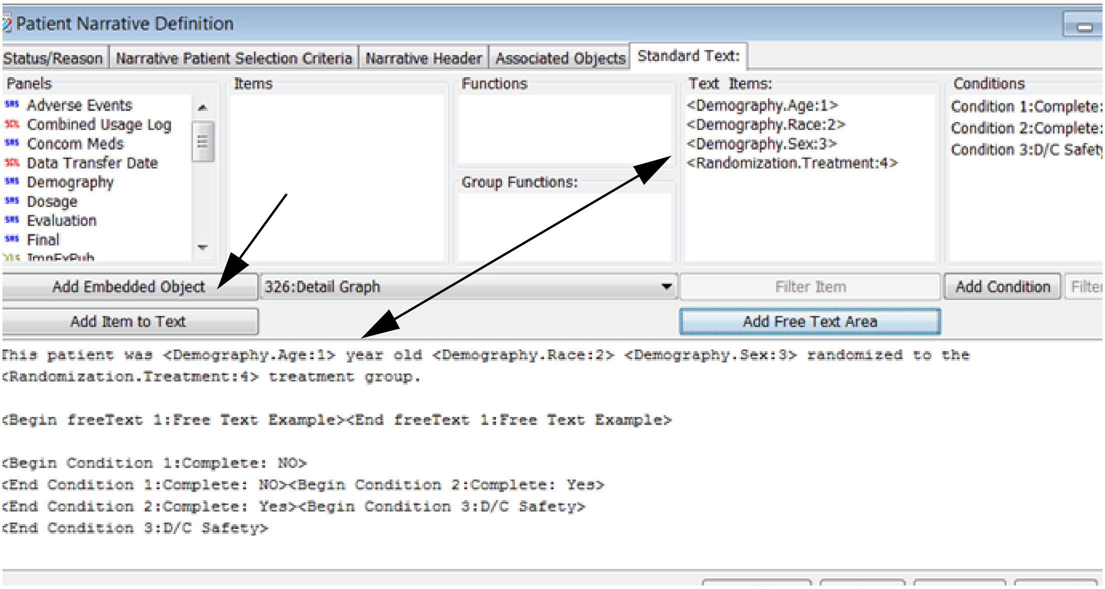
## *Standard Text tab*

The Standard Text tab is where you:

- Add Items to Text,
- Add Embedded Objects,
- Add Conditions,
- Add Free Text Areas.

9. Click the **Standard Text** Tab. Start by including Items in the Standard Text display box by selecting the question group/panel and question/item. Click the **Add Item to Text** button.

   The Text items are added in the Text Items list and displayed in the Standard Text box.

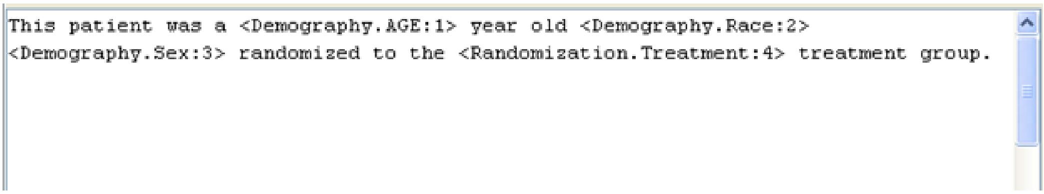


Text Items:
<Demography.Age:1>
<Demography.Race:2>
<Demography.Sex:3>
<Randomization.Treatment:4>

Conditions
Condition 1:Complete:
Condition 2:Complete:
Condition 3:D/C Safety

```
This patient was <Demography.Age:1> year old <Demography.Race:2> <Demography.Sex:3> randomized to the
<Randomization.Treatment:4> treatment group.

<Begin freeText 1:Free Text Example><End freeText 1:Free Text Example>

<Begin Condition 1:Complete: NO>
<End Condition 1:Complete: NO><Begin Condition 2:Complete: Yes>
<End Condition 2:Complete: Yes><Begin Condition 3:D/C Safety>
<End Condition 3:D/C Safety>
```

Edit the Standard Text display for the added text items, by entering information into the template using a combination of added items and typed text.



```
This patient was a <Demography.AGE:1> year old <Demography.Race:2>
<Demography.Sex:3> randomized to the <Randomization.Treatment:4> treatment group.
```

If you need to remove any added Text Item, select and delete the added item in the Standard Text display box. It will be removed from the Text Items list after you click **Save**, or **Update**.

Next, the Standard Text tab allows the ability to choose an already defined embedded object and add it to the standard text at the curser. Select the embedded object from the drop down list and click **Add Embedded Object**.

Then in the writer's panel, when the user chooses Create Narrative, the PDF created at that point displays any Standard Text defined embedded objects.

***Risk:*** This is limited to Patient Narrative Definition and Writer's Panel, where the Embedded objects will show as tags in the standard text (same as they would in the Clinical Summary). Also, when Create Narrative is chosen the embedded object(s) that were defined will display in the PDF. Showing the embedded object is currently not available if the narrative has been scheduled. ***(This will require a JRServer change.)***

10. Optionally, you may filter on a selected text item.

    Select the item in the Text Items list. The **Filter Items** button is activated to apply a filter, to allow selection of specific rows of data for the standard header items.

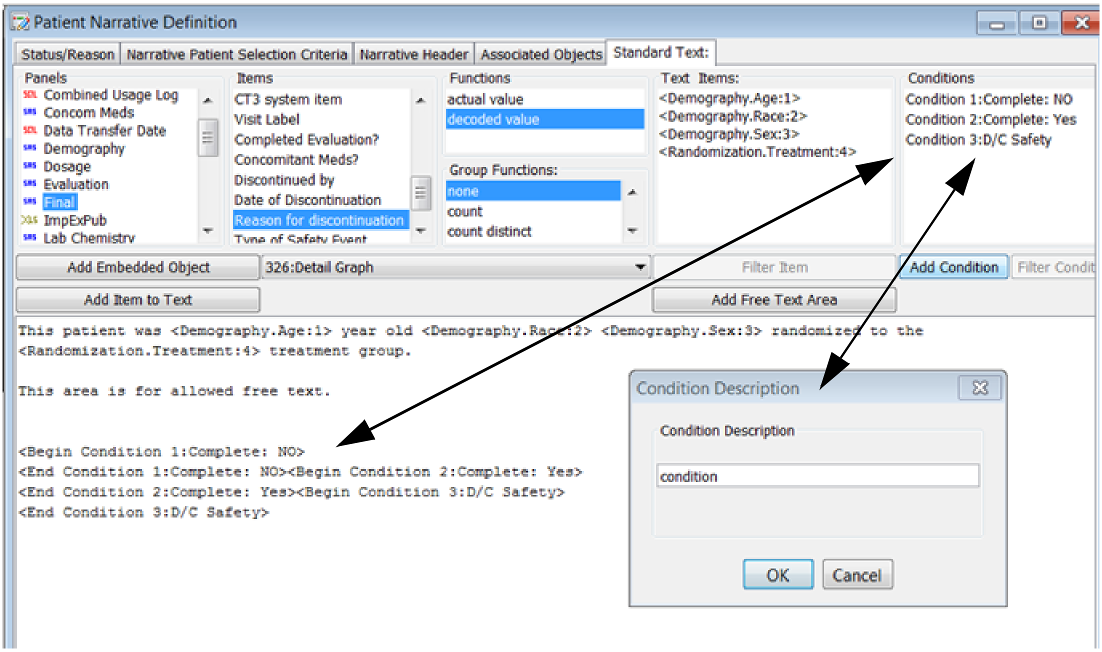
## *Add Conditions*

Optionally, you may add **Conditions**. The Standard Text area includes user modifiable descriptions for the item descriptions included.

11. When you click on **Add Condition,** first the Condition Description box opens to enter your description.

    When you click **OK**, the **Filter Output** window opens to enter an individual filter to apply to your Condition. Each **Condition Description** only works for an individual filter value. It supports the use of conditionals (include text block only if the condition is true), and supports group functions such as 'max blood pressure', etc.

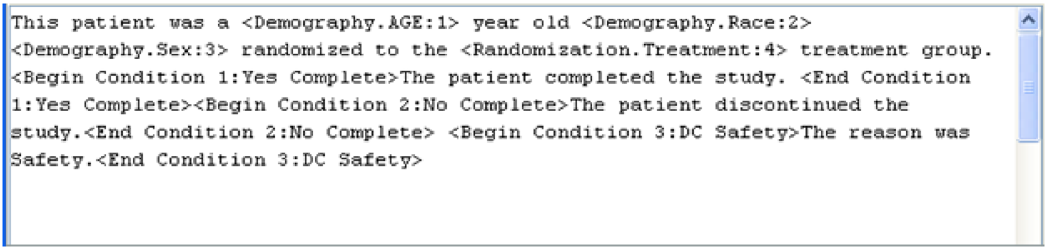
    As the conditions are defined they are automatically added to the Conditions list box and the Standard Text box, where you may edit the added conditions to a readable text format.



```
This patient was <Demography.Age:1> year old <Demography.Race:2> <Demography.Sex:3> randomized to the
<Randomization.Treatment:4> treatment group.

This area is for allowed free text.


<Begin Condition 1:Complete: NO>
<End Condition 1:Complete: NO><Begin Condition 2:Complete: Yes>
<End Condition 2:Complete: Yes><Begin Condition 3:D/C Safety>
<End Condition 3:D/C Safety>
```

Condition Description: condition

12. To remove a condition, delete it from the Standard Text area. It will be removed from the Conditions list box after you click **Save** or **Update**.



This patient was a <Demography.AGE:1> year old <Demography.Race:2> <Demography.Sex:3> randomized to the <Randomization.Treatment:4> treatment group. <Begin Condition 1:Yes Complete>The patient completed the study. <End Condition 1:Yes Complete><Begin Condition 2:No Complete>The patient discontinued the study.<End Condition 2:No Complete> <Begin Condition 3:DC Safety>The reason was Safety.<End Condition 3:DC Safety>

***Note:*** It is not necessary to add a carriage return after the first paragraph to add a blank line before the condition began. Avoid the tendency to hand enter a lot of carriage returns for view ability during the definition of the standard text. This will create a problem caused by the user in the way the conditions are being spaced in the definition. It will generate extra spaces in the final output. The key is to make sure that any extra carriage returns are within the conditional blocks.

For example, if the template is defined as follows, there are a lot of extra spaces in the writers panel:

***Template***

This patient was a <Demography.Age:1> year old <Demography.Race:2> <Demography.Sex:3> randomized to the <Randomization.Treatment:4> treatment group.

<Begin Condition 1:Completer>

The patient completed the trial.

<End Condition 1:Completer>

<Begin Condition 2:Discontinued>

The patient discontinued the trial due to <Final.Reason for discontinuation:5>

<End Condition 2:Discontinued>

***Writers Panel***

This patient was a 66 year old White Female randomized to the Active treatment group.

The patient discontinued the trial due to Safety.

However, if the template is defined instead as follows, the writers panel looks correct:

***Template***

This patient was a <Demography.Age:1> year old <Demography.Race:2> <Demography.Sex:3> randomized to the <Randomization.Treatment:4> treatment group.

<Begin Condition 1:Completer>

The patient completed the trial.

<End Condition 1:Completer><Begin Condition 2:Discontinued>

The patient discontinued the trial due to <Final.Reason for discontinuation:5>

<End Condition 2:Discontinued>

***Writers Panel for patient 3111***

This patient was a 66 year old White Female randomized to the Active treatment group.

The patient discontinued the trial due to Safety.

***Writers Panel for patient 5111***

This patient was a 32 year old White Male randomized to the Active treatment group.

The patient completed the trial.

## *Enter Free Text*

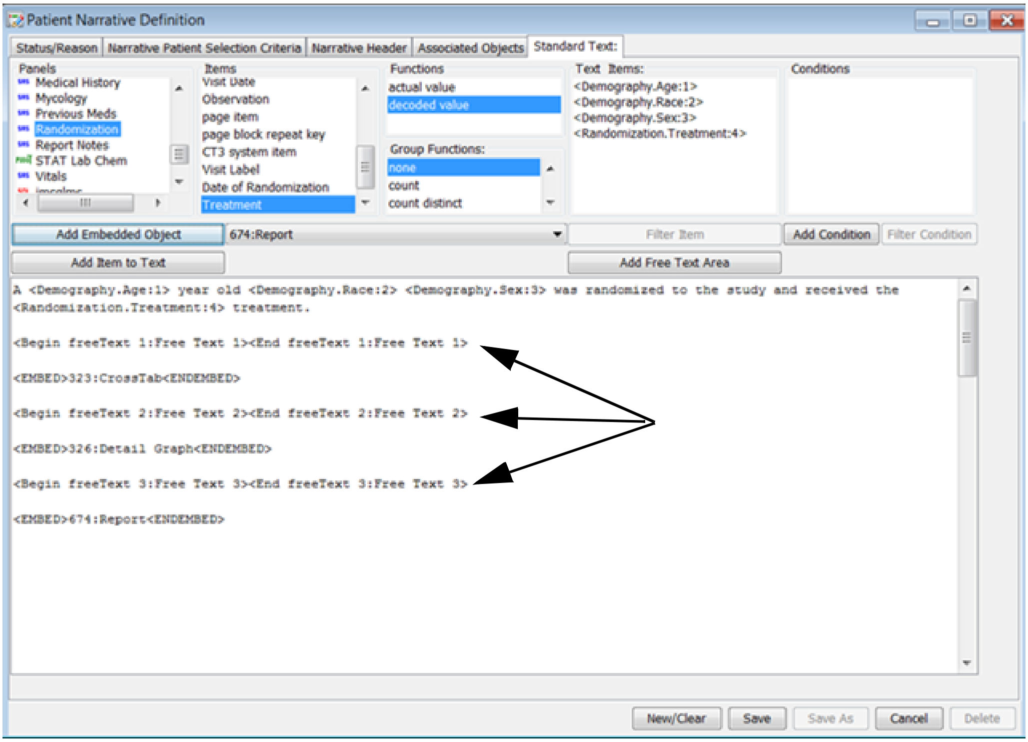
The user is allowed to enter "Free Text" and embedded objects to be interleaved in the Narrative Standard Text. This feature allows interleaving of medical writer text entries between ‘automated text’ sections. The definition of embedded object occurs at the ‘standard text’ definition stage.

13. In the Narrative Definition on the **Standard Text Tab** the **Add Free Text Area button** allows the user to insert free text areas, that will be filled in during each individual narrative creation. Also, the list of embedded objects and a button to insert the embedded object into the standard text at the cursor is present on the Standard Text Tab. These embedded objects will be executed when the **Create Narrative** button is clicked for each individual narrative.

When a pateint is selected during check out, the **Open Standard Text Narrative** button allows for the utilization of the free text areas interleaved in the Standard Text. It presents a PDF with form fields in it where you can fill in some text or not. You would have had to add these areas in the Narrative Definition using add Free Text Area under the Standard Text tab. Then when you Open Standard Text you fill in text in the form fields, Save the text, and then when you Create Narrative it will show a PDF that includes the free text you just entered and of course all of the standard text and embedded objects.

Open Clinical Summary works the same as it used to. However, if you have Free Text Areas you won’t be able to utilize them using this method.

The basic difference is, if you are utilizing Free Text Areas in your standard text, you will need to use the first button **Open Standard Text**. If you are not utilizing Free Text Areas in the Standard Text, you can use open Clinical Summary and then have your Free Text at the end in the Clinical Summary. The Standard text will be implemented as always when you click on “Create Narrative”.



```
A <Demography.Age:1> year old <Demography.Race:2> <Demography.Sex:3> was randomized to the study and received the
<Randomization.Treatment:4> treatment.

<Begin freeText 1:Free Text 1><End freeText 1:Free Text 1>

<EMBED>323:CrossTab<ENDEMBED>

<Begin freeText 2:Free Text 2><End freeText 2:Free Text 2>

<EMBED>326:Detail Graph<ENDEMBED>

<Begin freeText 3:Free Text 3><End freeText 3:Free Text 3>

<EMBED>674:Report<ENDEMBED>
```

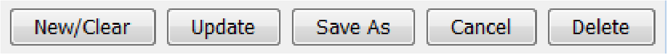
***Risk:*** The Free text area has prompted the use of a new PDF Viewer on both client and server that allows PDF form fields to be inserted into each individual narrative. The user can then enter information into these form fields and save that to each individual patient narrative. After checking out a patient, the user should choose "Open Standard Text Narrative" to enter information into these free text areas for each patient. After saving the information in the fields, the user can then create the narrative and any embedded objects will be executed at that point. The previous way ("Open Free Text Narrative") of working with individual narratives is preserved with the option of just entering free text at the end of the narrative (instead of interleaving with the standard text). The standard text in this method, as before, cannot be edited. When **Create Narrative** is clicked on this screen any embedded objects within the standard text and any embedded objects put in the Clinical Summary will be executed when the PDF is created.

So, free text can be entered anywhere in the standard text in the definition. For example, entering different free text areas after different sentences with items or conditions. The idea is that the user may want to make some free text comments specifically after different occurrences for different patients. (As opposed to inserting all the free text at the end.) So, if you want to interleave free text you must use the New button to open Standard text. If you prefer to put all the free text at the end, use the old method for open clinical summary.

***Warning:*** When you open up standard text and insert free text in the form fields, you must **save** your text first, (with the **Save button** on the top next to create narrative), ***before*** using create narrative or it will be lost.

14. Click **Save.** The ***Patient Narrative Description*** was already entered in the **Status/Reason tab** and the ***Template Level*** was already assigned in the **Narrative Header tab**.

    The Patient Narrative Template is saved. The narratives templates and created patient narratives never display in the Object Explorer. They are only accessible through the Patient Narratives Browser. Reopen the saved narrative to apply changes as **Update** or **Save As**.



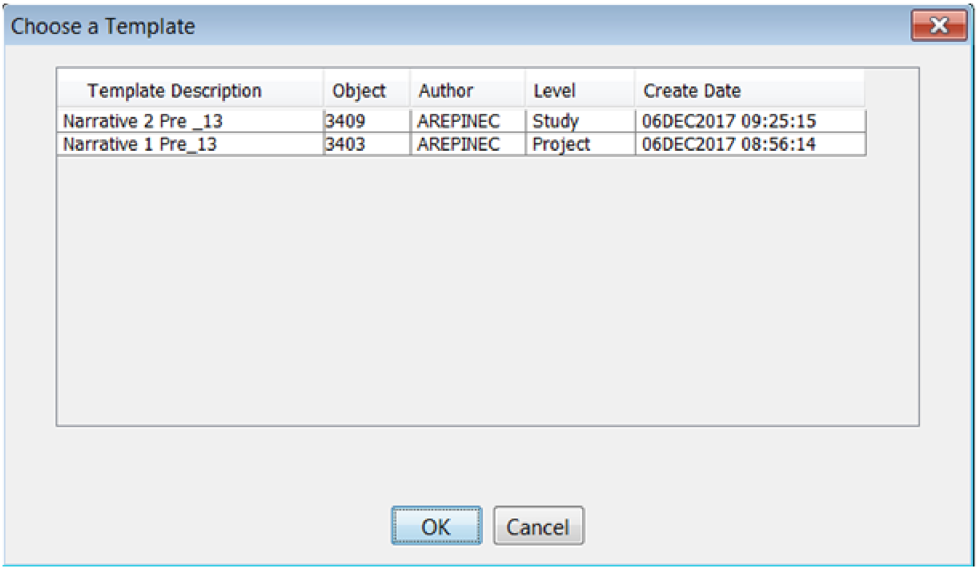
# Patient Narratives Multiple Template Definitions

## *Multiple template definitions*

Multiple narrative template definitions are allowed to be created with a patient list and narratives associated to each one.

***Risk:*** This impacts the entire Patient Narrative process because of created different patient lists for each template.

When entering Patient Narrative Definition, if more than one template exists a template list is presented and the user chooses which template to work with. The same occurs when opening the checkout browser. If more than one template exists the user must choose which patient list to work with. In connection with the update in the Narrative Template Browser, the user can choose to either update the current definition or the new SaveAs which will create a different template using any changes that have been entered. The Narrative Template is given a name so the user will be able to distinguish between narratives easily.



| Template Description | Object | Author | Level | Create Date |
|---|---|---|---|---|
| Narrative 2 Pre _13 | 3409 | AREPINEC | Study | 06DEC2017 09:25:15 |
| Narrative 1 Pre_13 | 3403 | AREPINEC | Project | 06DEC2017 08:56:14 |

# Check Out Patients and Create Patient Narratives

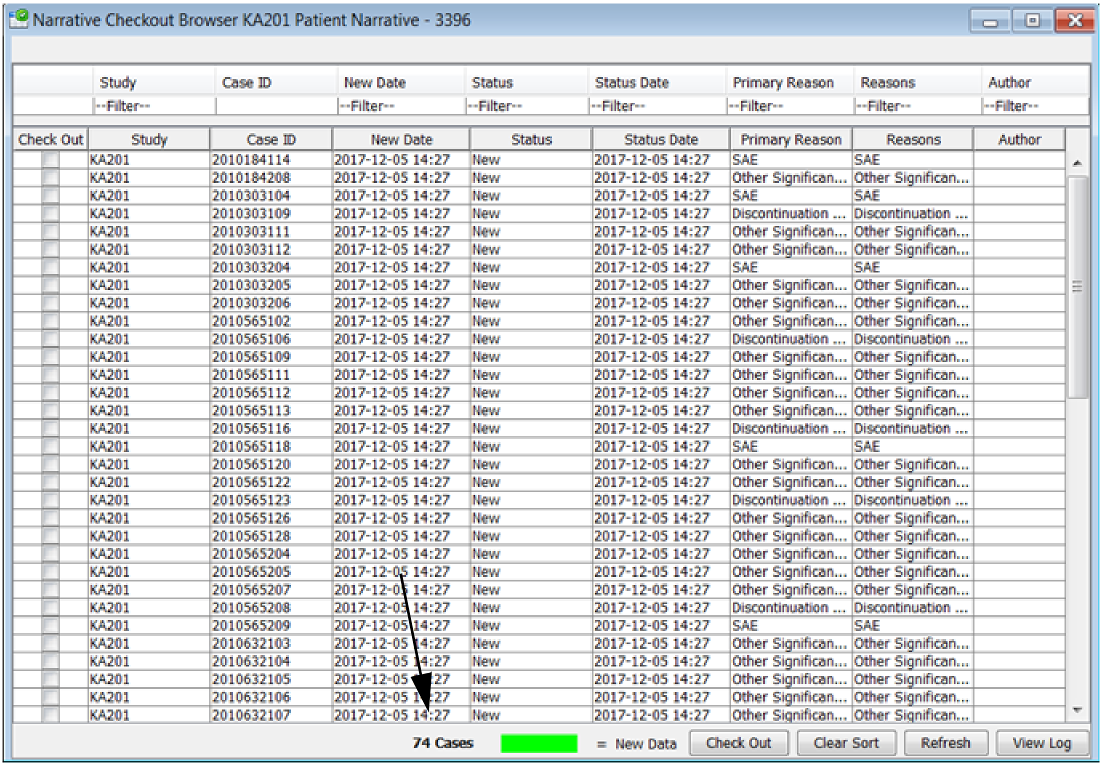
## *Checkout Case*

Once the template is saved then Medical writers with privileges may access the created narrative templates to check out and enter patient narratives. They access the **Narrative Check Out** Browser where the patients who meet the patient selection criteria are displayed, to select cases and checkout.

1. Click on the **Narrative Check Out** icon in the tool bar,

   or select **Narrative Check Out** from the **Browse menu**. The Narrative Checkout Browser window opens.

   The number of patients is displayed who meet all patient selection criteria as defined in the Narrative Patient Selection Criteria tab.



| | Study | Case ID | New Date | Status | Status Date | Primary Reason | Reasons | Author |
|---|---|---|---|---|---|---|---|---|
| | --Filter-- | | --Filter-- | --Filter-- | --Filter-- | --Filter-- | --Filter-- | --Filter-- |

| Check Out | Study | Case ID | New Date | Status | Status Date | Primary Reason | Reasons | Author |
|---|---|---|---|---|---|---|---|---|
| ☐ | KA201 | 2010184114 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | SAE | SAE | |
| ☐ | KA201 | 2010184208 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010303104 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | SAE | SAE | |
| ☐ | KA201 | 2010303109 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Discontinuation ... | Discontinuation ... | |
| ☐ | KA201 | 2010303111 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010303112 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010303204 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | SAE | SAE | |
| ☐ | KA201 | 2010303205 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010303206 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010565102 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010565106 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Discontinuation ... | Discontinuation ... | |
| ☐ | KA201 | 2010565109 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010565111 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010565112 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010565113 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010565116 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Discontinuation ... | Discontinuation ... | |
| ☐ | KA201 | 2010565118 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | SAE | SAE | |
| ☐ | KA201 | 2010565120 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010565122 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010565123 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Discontinuation ... | Discontinuation ... | |
| ☐ | KA201 | 2010565126 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010565128 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010565204 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010565205 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010565207 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010565208 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Discontinuation ... | Discontinuation ... | |
| ☐ | KA201 | 2010565209 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | SAE | SAE | |
| ☐ | KA201 | 2010632103 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010632104 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010632105 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010632106 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |
| ☐ | KA201 | 2010632107 | 2017-12-05 14:27 | New | 2017-12-05 14:27 | Other Significan... | Other Significan... | |

74 Cases 🟩 = New Data

## Open Narrative

For Medical writers with privileges to access created narrative templates to check out and enter patient narratives; the Checkout Browser window is different than for users with **View Only** privilege. The Medical Writer is able to open the narrative, change the status, or return to the Checkout Browser.

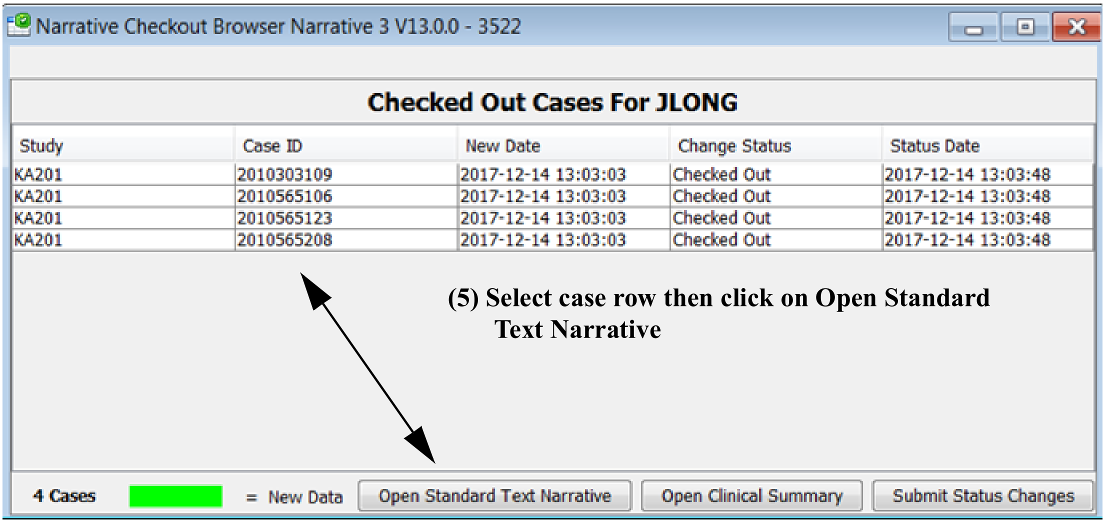
2. To initially checkout a patient, select a case by clicking the **Check Out box** for the patient row. You may select multiple patients for check out.
3. Click on the **Check Out** button.
4. The selected case(s) is added to the **Checked Out Cases** list, for the Medical Writer to access the patient narrative.

   If the Medical Writer currently has No narratives checked out, a message prompts to check out at least one case by selecting a patient and clicking on the **Check Out box**.

   If the Medical Writer had cases previously checked out for patient narrative; the initial window displays the current **Checked Out Cases**.

***There is a basic difference during check out***, if the selected narrative template utilizing Free Text Areas in the standard text. Then you will need to use the first button **Open Standard Text Narrative**. If you are not utilizing Free Text Areas in the Standard Text, you can use **Open Clinical Summary**, and then have your Free Text at the end in the Clinical Summary. The Standard text will be implemented as always when you click on "Create Narrative".

5. Select a case by highlighting the patient row. Click the **Open Narrative** button.



Narrative Checkout Browser Narrative 3 V13.0.0 - 3522

Checked Out Cases For JLONG

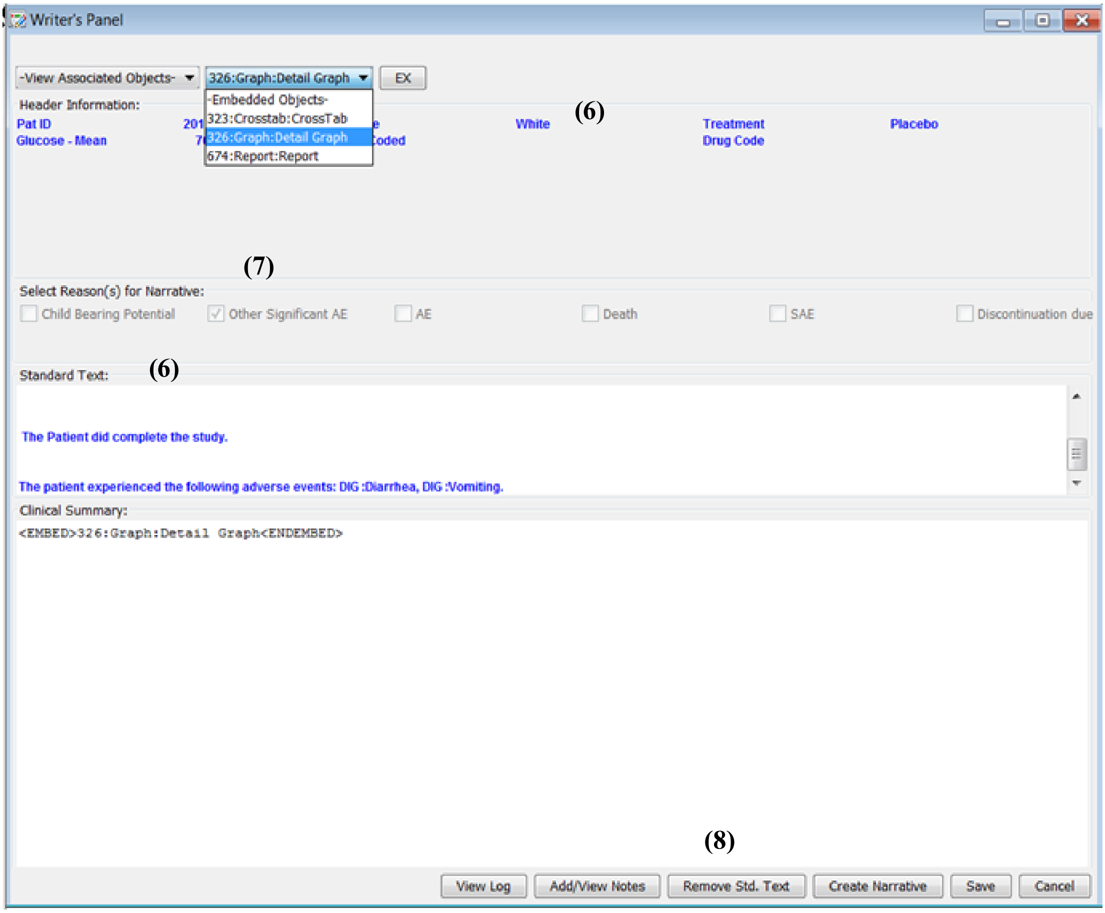
| Study | Case ID | New Date | Change Status | Status Date |
|---|---|---|---|---|
| KA201 | 2010303109 | 2017-12-14 13:03:03 | Checked Out | 2017-12-14 13:03:48 |
| KA201 | 2010565106 | 2017-12-14 13:03:03 | Checked Out | 2017-12-14 13:03:48 |
| KA201 | 2010565123 | 2017-12-14 13:03:03 | Checked Out | 2017-12-14 13:03:48 |
| KA201 | 2010565208 | 2017-12-14 13:03:03 | Checked Out | 2017-12-14 13:03:48 |

**(5) Select case row then click on Open Standard Text Narrative**

4 Cases 🟩 = New Data

*Enter patient narrative*

6. The Writer’s Panel dialog opens for the Medical Writer to enter and/or edit the patient narrative. The defined Narrative Template information displays for the Header Information and Standard Text.



Header Information:

| | | | | | |
|---|---|---|---|---|---|
| Pat ID | 201 | e | White | Treatment | Placebo |
| Glucose - Mean | 7 | Coded | | Drug Code | |

Select Reason(s) for Narrative:

☐ Child Bearing Potential ☑ Other Significant AE ☐ AE ☐ Death ☐ SAE ☐ Discontinuation due

Standard Text:

The Patient did complete the study.

The patient experienced the following adverse events: DIG :Diarrhea, DIG :Vomiting.

Clinical Summary:

```
<EMBED>326:Graph:Detail Graph<ENDEMBED>
```

7. **Reason for Narrative** is ***required.*** If this information was defined in the Narrative Template then it automatically fills in the primary and secondary reason. It cannot be changed on the actual narrative in the writer's panel.

   If Reason for Narrative **is not defined** in the Narrative Template then the medical writer is ***required*** to select a reason(s).

8. Click the **Remove Standard Text** button, if you prefer to replace the template default standard text. Likewise, an **Include Standard Text** button will allow you to replace the removed Standard Text.

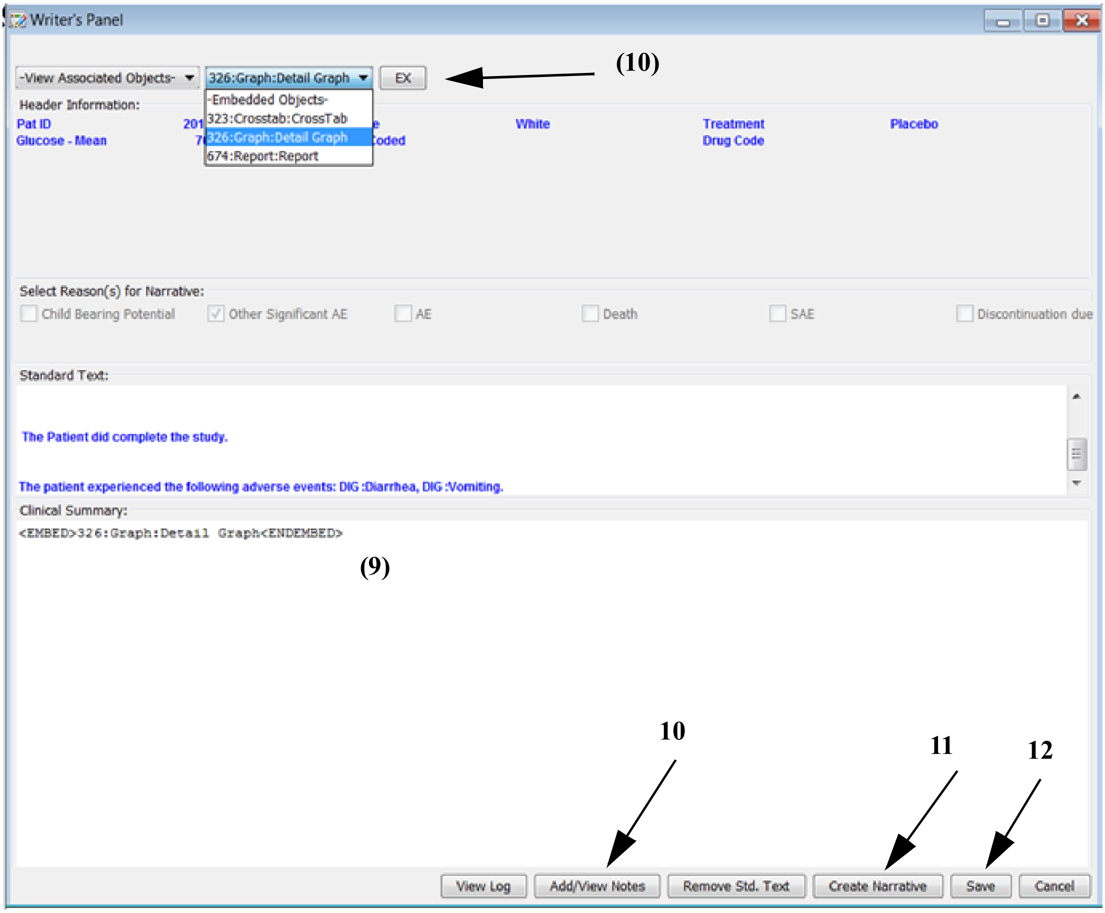
9. Double click in the **Clinical Summary** text box to enter narrative text. Press 'Enter' to start and add new lines in the Clinical Summary box when adding objects. Allow for lines to add text between objects.

   ***Note: It is recommended to enter the Clinical Summary then add any Embedded objects at the end. Add a carriage return.***

10. Use the **Associated Objects** and **Embedded Objects** drop down list to select and add specific objects within the Clinical Summary box.

    Click the **EX button** to execute the selected embedded object to view in another window.

11. Optionally, click on the **Add/View Notes** button. The **Notes Browser** opens to display and reference saved notes for the selected patient.



Select Reason(s) for Narrative:
☐ Child Bearing Potential ☑ Other Significant AE ☐ AE ☐ Death ☐ SAE ☐ Discontinuation due

Standard Text:

The Patient did complete the study.

The patient experienced the following adverse events: DIG :Diarrhea, DIG :Vomiting.

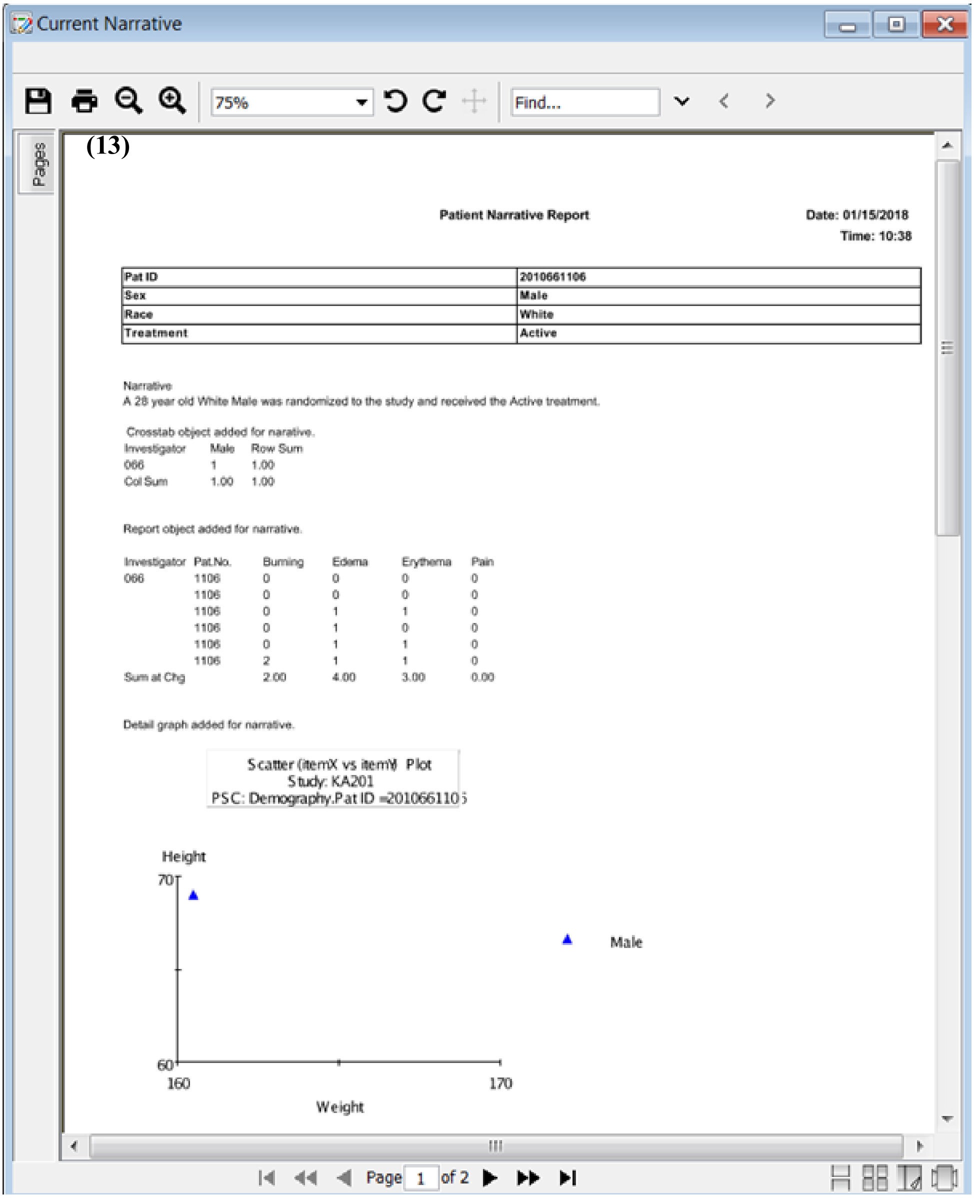
Clinical Summary:

```
<EMBED>326:Graph:Detail Graph<ENDEMBED>
```

12. Click **Create Narrative** to view the **Current Narrative** for that case. The selected embedded objects are executed within the narrative display. The PDF created displays any Standard Text defined with embedded objects.

13. Patient Narratives may be printed in PDF or RTF formats. A print server is required to support the patient narratives print options.  Click on the **Printer icon**.

14. Close the **Current Narrative window** and click **Save,** to save changes to the narrative.  The Narrative Checkout Browser window is displayed.



**Patient Narrative Report**

**Date: 01/15/2018**
**Time: 10:38**

| | |
|---|---|
| **Pat ID** | **2010661106** |
| **Sex** | **Male** |
| **Race** | **White** |
| **Treatment** | **Active** |

Narrative
A 28 year old White Male was randomized to the study and received the Active treatment.

Crosstab object added for narative.

| Investigator | Male | Row Sum |
|---|---|---|
| 066 | 1 | 1.00 |
| Col Sum | 1.00 | 1.00 |

Report object added for narrative.

| Investigator | Pat.No. | Burning | Edema | Erythema | Pain |
|---|---|---|---|---|---|
| 066 | 1106 | 0 | 0 | 0 | 0 |
| | 1106 | 0 | 0 | 0 | 0 |
| | 1106 | 0 | 1 | 1 | 0 |
| | 1106 | 0 | 1 | 0 | 0 |
| | 1106 | 0 | 1 | 1 | 0 |
| | 1106 | 2 | 1 | 1 | 0 |
| Sum at Chg | | 2.00 | 4.00 | 3.00 | 0.00 |

Detail graph added for narrative.

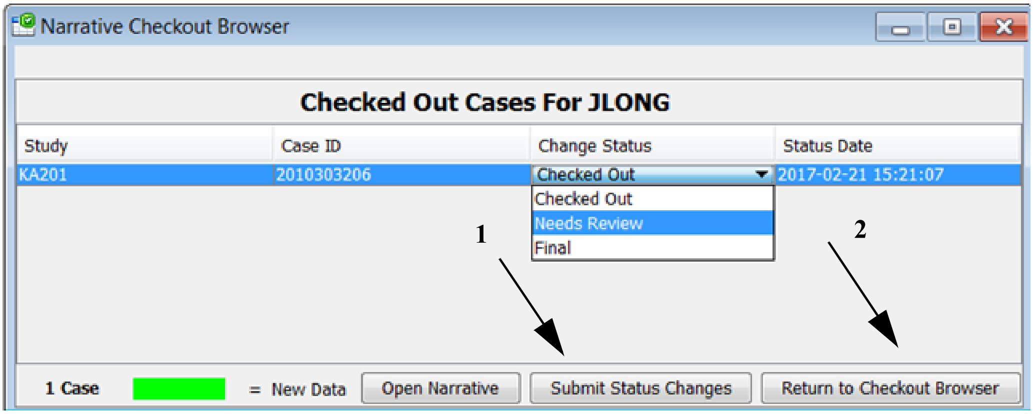
## Change Case ID Status

The Narrative Checkout Browser window is the ***only*** place to **Submit Status Change** for a select patient narrative.

1. Select the patient row and click on the **Change Status** header to display the drop down list. Select a Change Status, then click the **Submit Status Changes** button to ***save***.

   The selected case status is changed from ‘Checked Out’, and the Case ID will be removed from the Checked Out Cases list. The Case ID will display back on the Check Out Browser list.

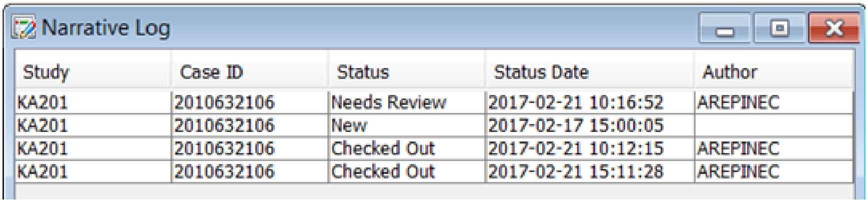
2. Click the **Return to CheckOut Browser** button.



| Study | Case ID | Change Status | Status Date |
|---|---|---|---|
| KA201 | 2010303206 | Checked Out | 2017-02-21 15:21:07 |

## View Log

In the Narrative Checkout Browser window select a ***single patient row*** to highlight and click **View Log**. A message displays if multiple patient rows are selected. The Narrative Log displays with all status changes.



| Study | Case ID | Status | Status Date | Author |
|---|---|---|---|---|
| KA201 | 2010632106 | Needs Review | 2017-02-21 10:16:52 | AREPINEC |
| KA201 | 2010632106 | New | 2017-02-17 15:00:05 | |
| KA201 | 2010632106 | Checked Out | 2017-02-21 10:12:15 | AREPINEC |
| KA201 | 2010632106 | Checked Out | 2017-02-21 15:11:28 | AREPINEC |

## New Data Flag

Upon opening the Narrative Check Out Browser window, cases in the Check Out Browser list will show with green highlighting for ‘New Data’. The patient is highlighted when the date of any data item in the database is greater than the last narrative status date for that patient.

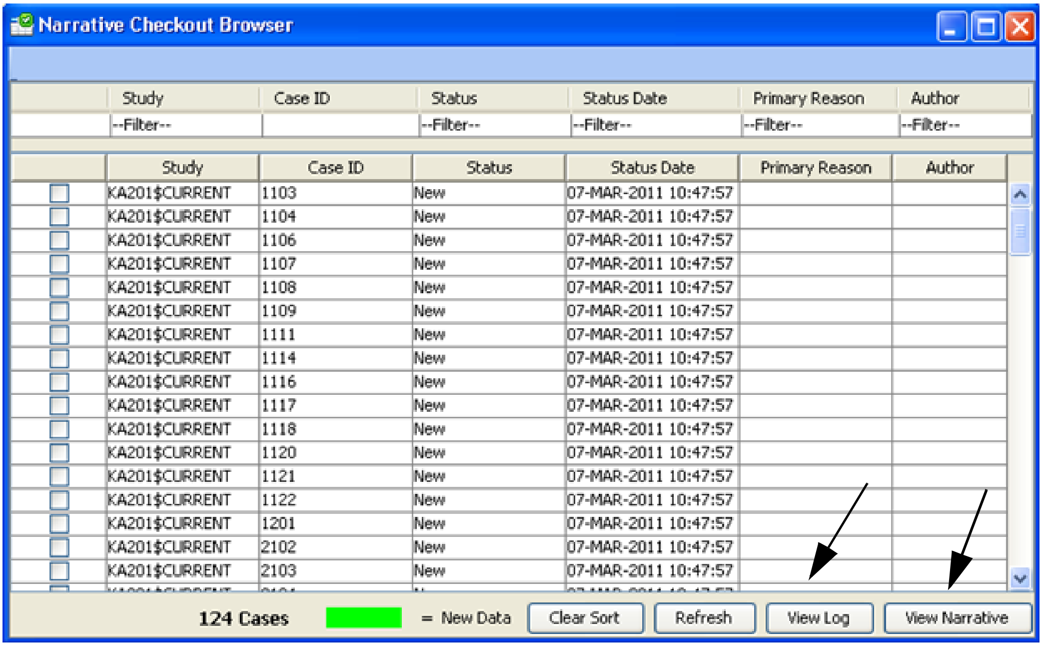
# View Check Out Browser and Patient Narrative

## *View patient narratives*

Users with the privilege to **View Only** narratives that have been created by the Medical Writers, may access the **Narrative Check Out** Browser.

1. Click on the **Narrative Checkout** icon in the tool bar, or select Narrative Check Out from the Browse menu.

   The **Narrative Checkout Browser** window allows users with view privilege to select patients for **View Log,** and **View Narrative**.



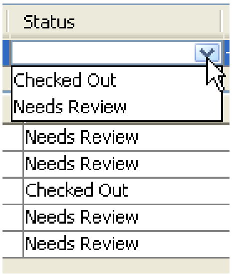
| | Study | Case ID | Status | Status Date | Primary Reason | Author |
|---|---|---|---|---|---|---|
| ☐ | KA201$CURRENT | 1103 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 1104 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 1106 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 1107 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 1108 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 1109 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 1111 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 1114 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 1116 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 1117 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 1118 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 1120 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 1121 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 1122 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 1201 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 2102 | New | 07-MAR-2011 10:47:57 | | |
| ☐ | KA201$CURRENT | 2103 | New | 07-MAR-2011 10:47:57 | | |

2. Click on the **Narrative Checkout** icon in the tool bar, or select Narrative Checkout from the **Browse** menu.
3. Select a case in the list and click the **View Narrative** button.

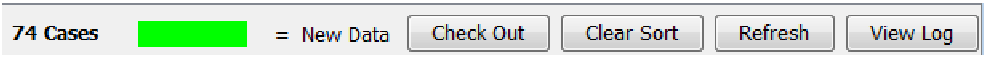
   The **Current Narrative** window displays icons for support features to changing the image size, print narrative, and move between pages.
4. Click on the Printer icon.

## Filter columns

5. The **Narrative Check Out Browser** window allows filtering on the Study, Status, Status Date, Primary Reason, and Author. Click on a filter column to display the drop down filter list.



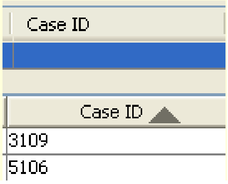
Use the **Refresh** button to remove all filter entries.



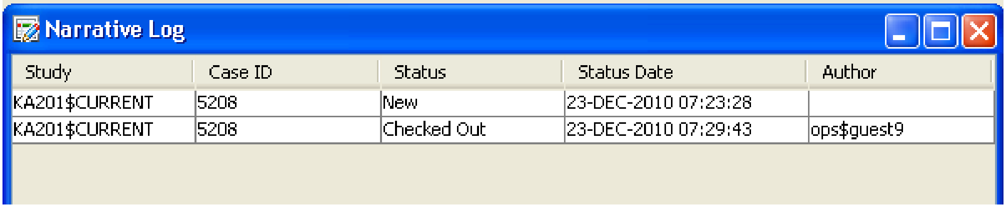
## Sort columns

6. The user is able to sort the various columns within the spreadsheet. Individual columns may be sorted by clicking on the column header to display sort arrows.

   Click the arrow display to change sort from ascending or descending options. Use the **Clear Sort** button to remove all column header sort entries. Use the **Refresh** button to return to initial column displays.



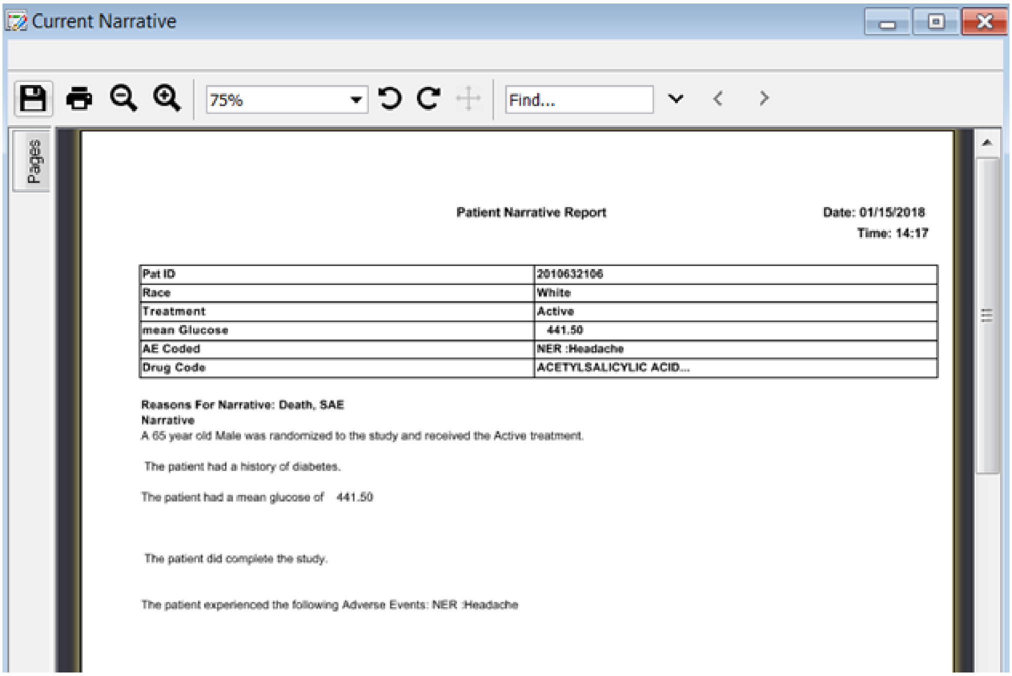
7. Select a case by highlighting the patient row. Click the **View Log** button to view the **Narrative Log** for that case.



| Study | Case ID | Status | Status Date | Author |
|---|---|---|---|---|
| KA201$CURRENT | 5208 | New | 23-DEC-2010 07:23:28 | |
| KA201$CURRENT | 5208 | Checked Out | 23-DEC-2010 07:29:43 | ops$guest9 |

8. Select a case by highlighting the patient row. Click the **View Narrative** button to view the **Current Narrative** for that case. The **Current Narrative** window displays icons for support features to change the image size, print narrative, and move between pages.

The PDF viewer not only provides quite a few viewing options – like continuous stream of pages, or two at a time – like a magazine, four up, etc. – but also has built in 'bookmark' access, plus a built in Search function.



Patient Narrative Report

Date: 01/15/2018
Time: 14:17

| | |
|---|---|
| Pat ID | 2010632106 |
| Race | White |
| Treatment | Active |
| mean Glucose | 441.50 |
| AE Coded | NER :Headache |
| Drug Code | ACETYLSALICYLIC ACID... |

**Reasons For Narrative: Death, SAE**

**Narrative**

A 65 year old Male was randomized to the study and received the Active treatment.

The patient had a history of diabetes.

The patient had a mean glucose of 441.50

The patient did complete the study.

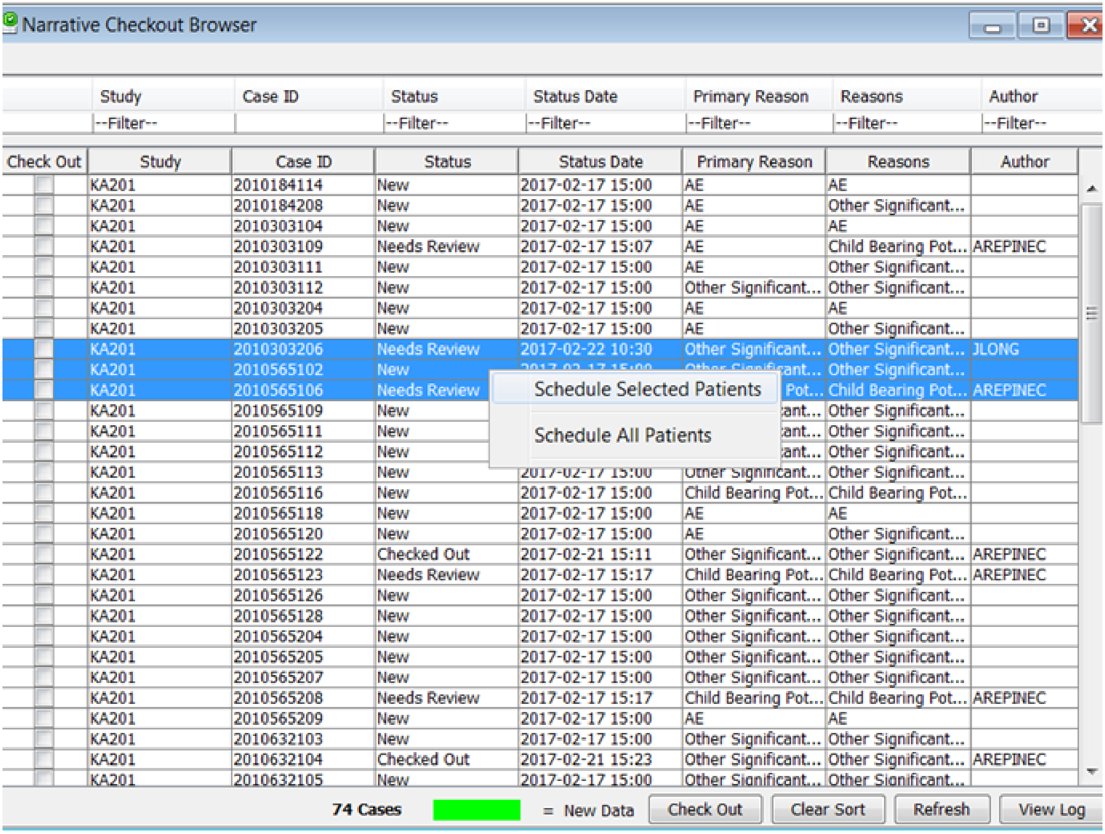
The patient experienced the following Adverse Events: NER :Headache

## *Schedule Patient Narratives*

Scheduling is supported for Workbook Patient Profiles and Patient Narratives, if Patient Profile Scheduling Server is licensed (optional license).

**Patient Narratives** can also be scheduled generating the RTF files for each patient in batch and saving the resulting RTF files for access from within JReview as well as in an **externally accessible directory**.

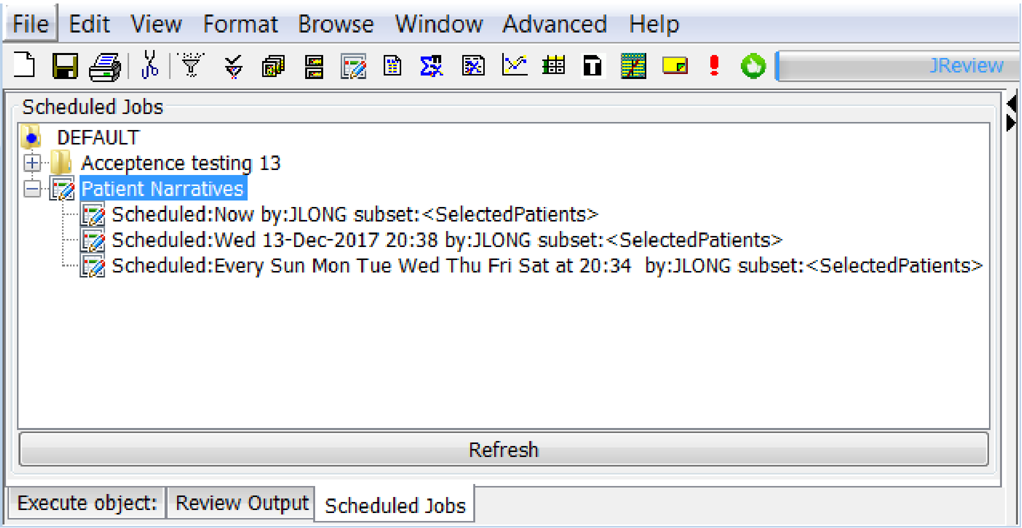
Narratives can be scheduled through the Narrative Checkout Browser with a ***right mouse click*** to display floating menu. Select patient rows to highlight and then right click to either ‘Schedule Selected Patients’ or ‘Schedule All Patients’.



| | Study | Case ID | Status | Status Date | Primary Reason | Reasons | Author |
|---|---|---|---|---|---|---|---|
| | --Filter-- | | --Filter-- | --Filter-- | --Filter-- | --Filter-- | --Filter-- |

| Check Out | Study | Case ID | Status | Status Date | Primary Reason | Reasons | Author |
|---|---|---|---|---|---|---|---|
| ☐ | KA201 | 2010184114 | New | 2017-02-17 15:00 | AE | AE | |
| ☐ | KA201 | 2010184208 | New | 2017-02-17 15:00 | AE | Other Significant... | |
| ☐ | KA201 | 2010303104 | New | 2017-02-17 15:00 | AE | AE | |
| ☐ | KA201 | 2010303109 | Needs Review | 2017-02-17 15:07 | AE | Child Bearing Pot... | AREPINEC |
| ☐ | KA201 | 2010303111 | New | 2017-02-17 15:00 | AE | Other Significant... | |
| ☐ | KA201 | 2010303112 | New | 2017-02-17 15:00 | Other Significant... | Other Significant... | |
| ☐ | KA201 | 2010303204 | New | 2017-02-17 15:00 | AE | AE | |
| ☐ | KA201 | 2010303205 | New | 2017-02-17 15:00 | AE | Other Significant... | |
| ☐ | KA201 | 2010303206 | Needs Review | 2017-02-22 10:30 | Other Significant... | Other Significant... | JLONG |
| ☐ | KA201 | 2010565102 | New | 2017-02-17 15:00 | Other Significant... | Other Significant... | |
| ☐ | KA201 | 2010565106 | Needs Review | | Pot... | Child Bearing Pot... | AREPINEC |
| ☐ | KA201 | 2010565109 | New | | ant... | Other Significant... | |
| ☐ | KA201 | 2010565111 | New | | ant... | Other Significant... | |
| ☐ | KA201 | 2010565112 | New | | ant... | Other Significant... | |
| ☐ | KA201 | 2010565113 | New | 2017-02-17 15:00 | Other Significant... | Other Significant... | |
| ☐ | KA201 | 2010565116 | New | 2017-02-17 15:00 | Child Bearing Pot... | Child Bearing Pot... | |
| ☐ | KA201 | 2010565118 | New | 2017-02-17 15:00 | AE | AE | |
| ☐ | KA201 | 2010565120 | New | 2017-02-17 15:00 | AE | Other Significant... | |
| ☐ | KA201 | 2010565122 | Checked Out | 2017-02-21 15:11 | Other Significant... | Other Significant... | AREPINEC |
| ☐ | KA201 | 2010565123 | Needs Review | 2017-02-17 15:17 | Child Bearing Pot... | Child Bearing Pot... | AREPINEC |
| ☐ | KA201 | 2010565126 | New | 2017-02-17 15:00 | Other Significant... | Other Significant... | |
| ☐ | KA201 | 2010565128 | New | 2017-02-17 15:00 | Other Significant... | Other Significant... | |
| ☐ | KA201 | 2010565204 | New | 2017-02-17 15:00 | Other Significant... | Other Significant... | |
| ☐ | KA201 | 2010565205 | New | 2017-02-17 15:00 | Other Significant... | Other Significant... | |
| ☐ | KA201 | 2010565207 | New | 2017-02-17 15:00 | Other Significant... | Other Significant... | |
| ☐ | KA201 | 2010565208 | Needs Review | 2017-02-17 15:17 | Child Bearing Pot... | Child Bearing Pot... | AREPINEC |
| ☐ | KA201 | 2010565209 | New | 2017-02-17 15:00 | AE | AE | |
| ☐ | KA201 | 2010632103 | New | 2017-02-17 15:00 | Other Significant... | Other Significant... | |
| ☐ | KA201 | 2010632104 | Checked Out | 2017-02-21 15:23 | Other Significant... | Other Significant... | AREPINEC |
| ☐ | KA201 | 2010632105 | New | 2017-02-17 15:00 | Other Significant... | Other Significant... | |

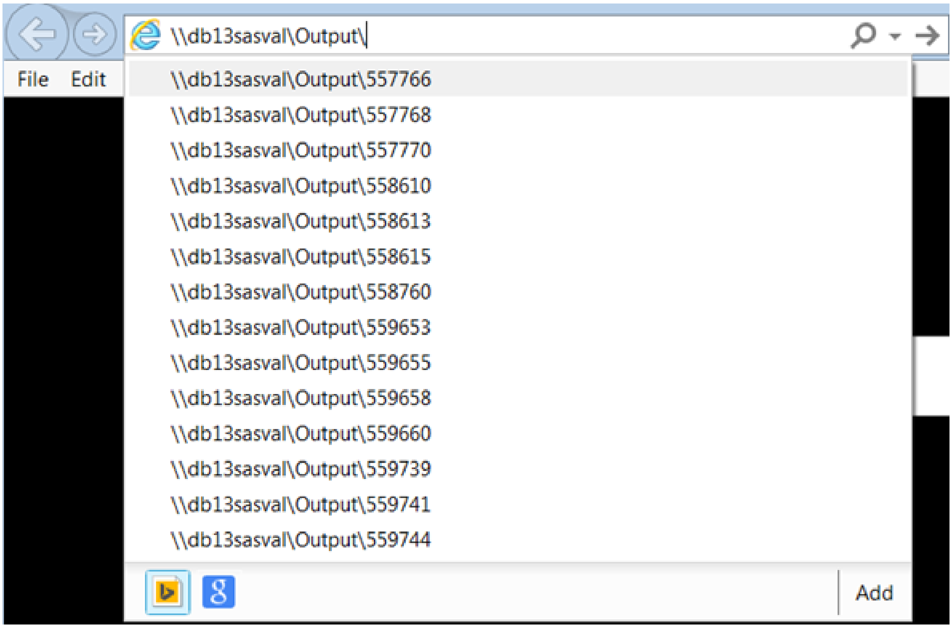
The narratives will appear in the Scheduled Jobs tab (DEFAULT) and they can be deleted or rescheduled there.  Click the Schedule Jobs tab to view and revise scheduled narratives.



DEFAULT
Acceptence testing 13
Patient Narratives
Scheduled:Now by:JLONG subset:<SelectedPatients>
Scheduled:Wed 13-Dec-2017 20:38 by:JLONG subset:<SelectedPatients>
Scheduled:Every Sun Mon Tue Wed Thu Fri Sat at 20:34  by:JLONG subset:<SelectedPatients>

The narratives ***DO NOT*** appear in the Review Output tab currently – only in the ReviewAdmin directory that would be referenced in the Study.Options override keyword:  PDFJOBDIR=<study level output directory>.

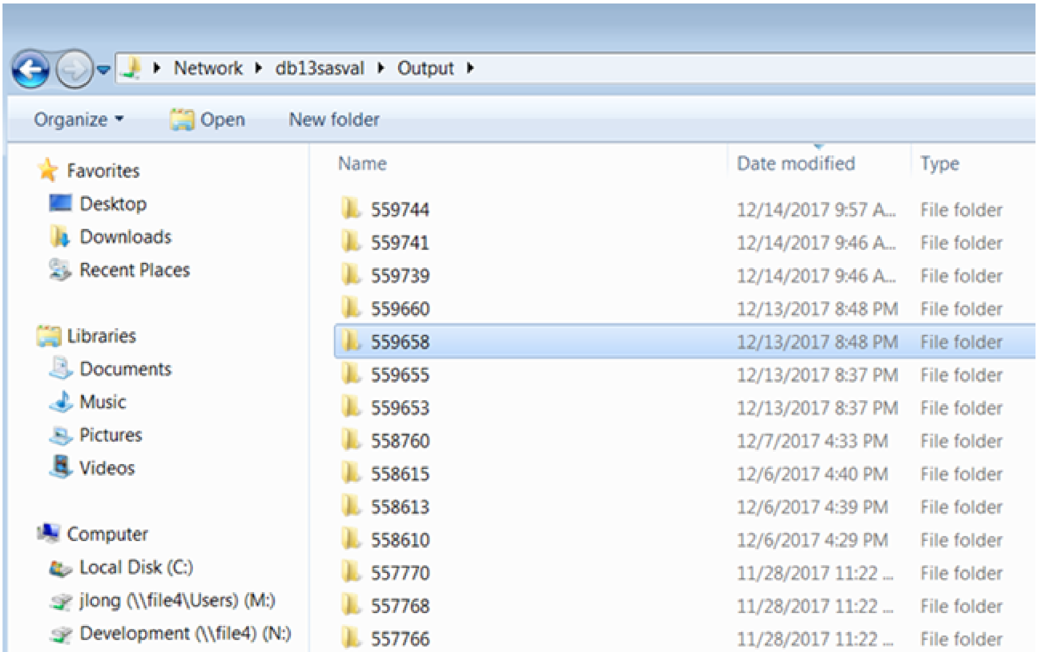
The study level directory is defined in ReviewAdmin – in the Study override table – in the OPTIONS string in the parameter: PDFJOBDIR=; <- where a fully qualified directory is specified.  Then – when either a patient profile WPP or FPP or a patient narrative scheduled job runs, a subdirectory is created in the specified directory – with the 'batch' number as the subdirectory name – with the contents being either XLS files (for WPP), PDF (for FPP) or RTF files for patient narratives – one patient per file.



\\db13sasval\Output\

\\db13sasval\Output\557766
\\db13sasval\Output\557768
\\db13sasval\Output\557770
\\db13sasval\Output\558610
\\db13sasval\Output\558613
\\db13sasval\Output\558615
\\db13sasval\Output\558760
\\db13sasval\Output\559653
\\db13sasval\Output\559655
\\db13sasval\Output\559658
\\db13sasval\Output\559660
\\db13sasval\Output\559739
\\db13sasval\Output\559741
\\db13sasval\Output\559744

Select a file to open one patient narrative.



| Name | Date modified | Type |
|---|---|---|
| 559744 | 12/14/2017 9:57 A... | File folder |
| 559741 | 12/14/2017 9:46 A... | File folder |
| 559739 | 12/14/2017 9:46 A... | File folder |
| 559660 | 12/13/2017 8:48 PM | File folder |
| 559658 | 12/13/2017 8:48 PM | File folder |
| 559655 | 12/13/2017 8:37 PM | File folder |
| 559653 | 12/13/2017 8:37 PM | File folder |
| 558760 | 12/7/2017 4:33 PM | File folder |
| 558615 | 12/6/2017 4:40 PM | File folder |
| 558613 | 12/6/2017 4:39 PM | File folder |
| 558610 | 12/6/2017 4:29 PM | File folder |
| 557770 | 11/28/2017 11:22 ... | File folder |
| 557768 | 11/28/2017 11:22 ... | File folder |
| 557766 | 11/28/2017 11:22 ... | File folder |

# 16

# Risk Based Monitoring Data Browser

# Risk Based Monitoring

## *Overview*

The JReview Risk Based Monitoring Data Browser is designed to facilitate the monitoring of sites within an ongoing study for analysis of Risk Based Monitoring data. The Risk Based Monitoring objects are a group of queries organized into categories.

Indicator queries are defined and then selected to perform one of the following functions:

- Return a count of subjects
- Percent of subjects
- Another type of grouping summarization (item max, mean, etc.)

The indicator queries are then grouped into thresholds – ranging from low risk to high risk. Once a set of indicators have been defined, tested and saved for a study, next you would implement the ongoing data collection of these indicators. The object is scheduled at a required time interval and the results are stored for analysis over the course of the study. Only one RBM object may be run per day which contains multiple indicators defined to monitor risk based data. The results are all grouped and calculated ***by site***.

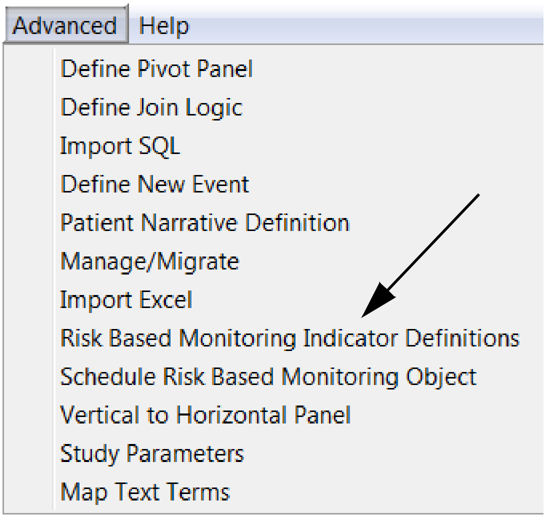
Summary tables as well as detailed graphs are available to review the ongoing results of the indicator queries.

An IPad application is used to visualize/analyze the Risk Based Monitoring data. It allows the user to indicate actions to be taken based on the query results. These actions will be plotted next to the results, thus allowing the user to view any changes after the actions taken.

# Risk Based Monitoring Indicator Definitions

## *Overall requirements*

Access for the **Risk Based Monitoring Indicator Definitions** is located within the **Advanced Menu**. The User must have permission set on for p60 – privilege.

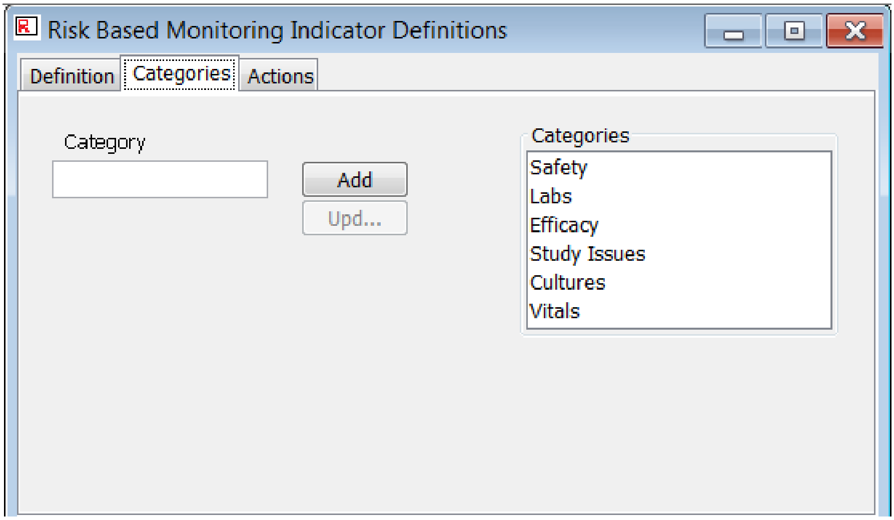


Also, the RBMWEIGHT=1-10 (as an example) must be defined in the ReviewAdmin config options string. This is used to define the range in weights that are available when weighting an individual indicator as well as a specific threshold for an indicator.

A value for SITEID must be set in the source table and possibly for any study overrides in the study table. The value of SITEID is the variable that resides in all of the tables that differentiates a site. For our example, it is the INVESTIGATOR item.

## *Risk Based Monitoring Categories*

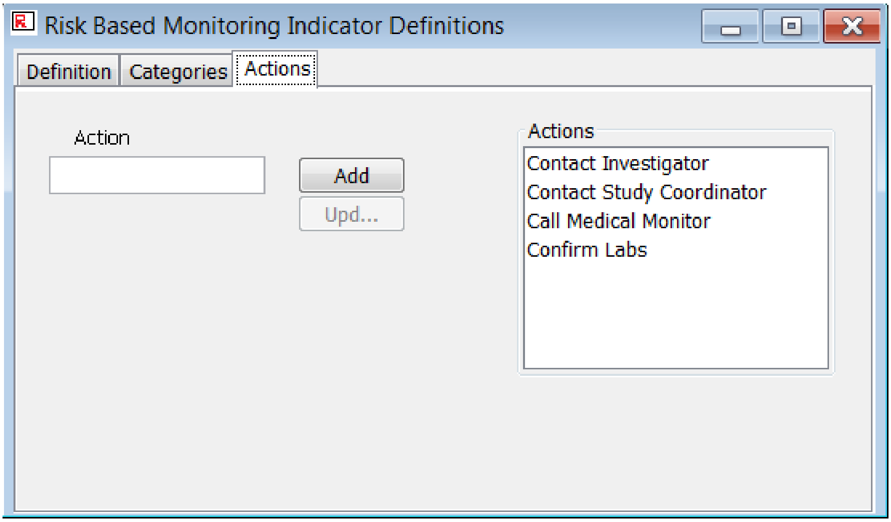
The first step when using the Risk Based Monitoring component is to define the **Categories** that will be used to group all RBM indicators created across all studies in the database. Adding categories is ***mandatory*** before defining queries. Therefore, when first entering the Risk Based Monitoring Indicator Definitions screen when no categories have been defined – you will start in the **Categories tab**. Customers are allowed up to 20 categories as default number. (This value is customizable via an options string in ***ReviewAdmin***.) They should be broad categories to incorporate all possible types of indicators. The categories can be added, updated, but ***not deleted.***



Safety
Labs
Efficacy
Study Issues
Cultures
Vitals

## Risk Based Monitoring Actions

The primary use of RBM **Actions** will be in the IPad application. However, actions can also be associated with a specific threshold as a suggested action to be taken should the results be in that given threshold. The RBM Actions may be added or updated but ***not deleted*** if any action were in use. There is no limit to the number of actions added.

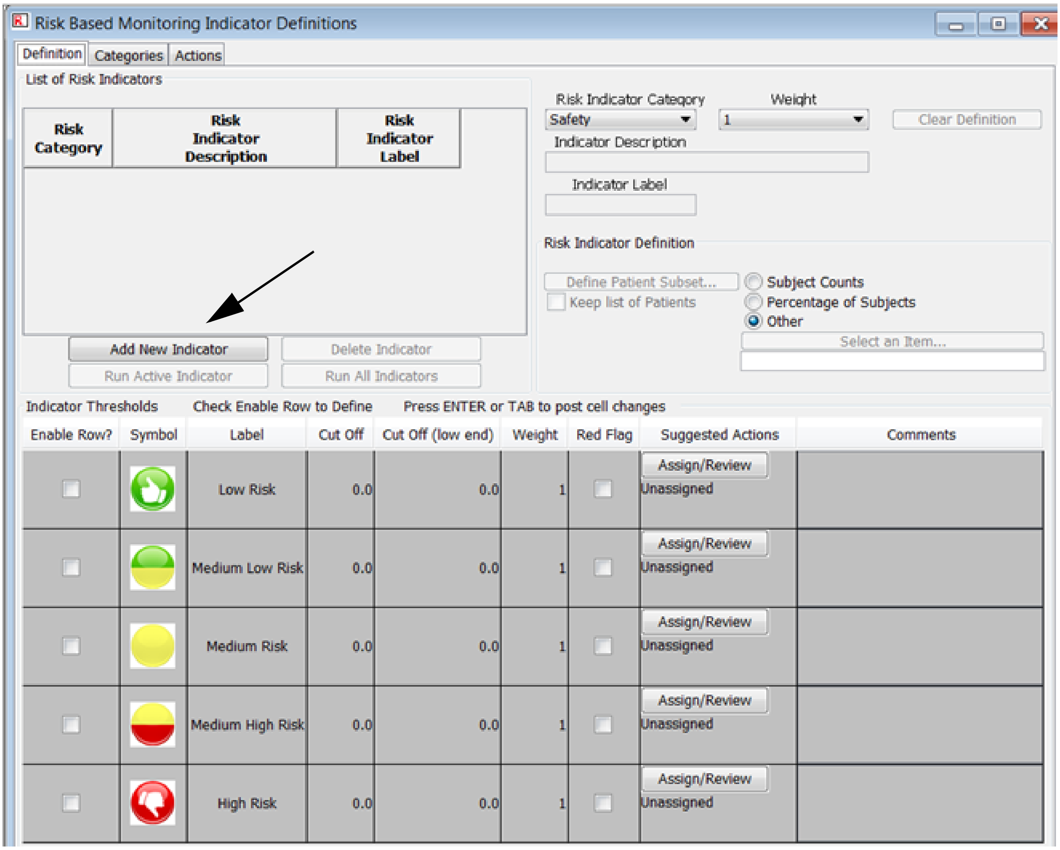


Contact Investigator
Contact Study Coordinator
Call Medical Monitor
Confirm Labs

## Risk Based Monitoring Indicators

Once categories have been created, next indicators (queries) can be defined within the Definition tab.

1. Click on the **Definition tab**.
2. Click on **Add New Indicator**.



Risk Based Monitoring Indicator Definitions

Risk Indicator Category: Safety

Weight: 1

Indicator Description:

Indicator Label:

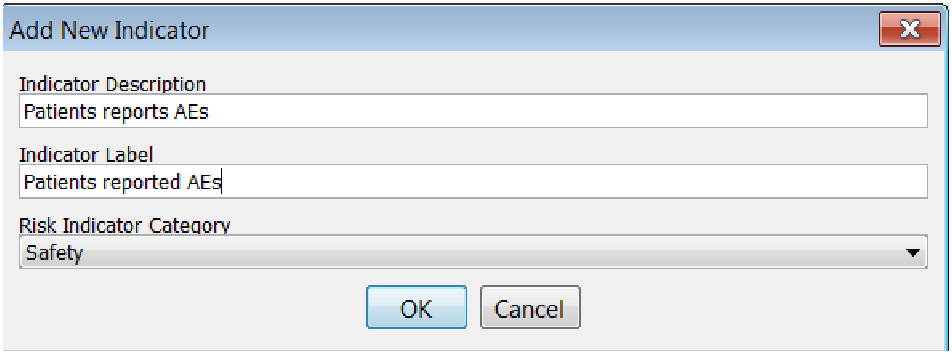
☐ Keep list of Patients

○ Subject Counts
○ Percentage of Subjects
● Other

Indicator Thresholds — Check Enable Row to Define — Press ENTER or TAB to post cell changes

| Enable Row? | Symbol | Label | Cut Off | Cut Off (low end) | Weight | Red Flag | Suggested Actions | Comments |
|---|---|---|---|---|---|---|---|---|
| ☐ | 👍 | Low Risk | 0.0 | 0.0 | 1 | ☐ | Assign/Review<br>Unassigned | |
| ☐ | 🟢 | Medium Low Risk | 0.0 | 0.0 | 1 | ☐ | Assign/Review<br>Unassigned | |
| ☐ | 🟡 | Medium Risk | 0.0 | 0.0 | 1 | ☐ | Assign/Review<br>Unassigned | |
| ☐ | 🔴 | Medium High Risk | 0.0 | 0.0 | 1 | ☐ | Assign/Review<br>Unassigned | |
| ☐ | 👎 | High Risk | 0.0 | 0.0 | 1 | ☐ | Assign/Review<br>Unassigned | |

3. Enter an **Indicator Description** and a shorter **Indicator Label**. If needed, you can change the description or label on the main screen when the Indicator is selected.

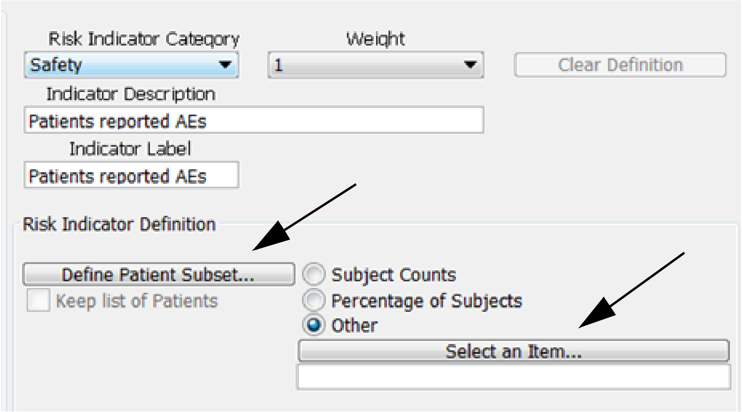


Indicator Description: Patients reports AEs

Indicator Label: Patients reported AEs

Risk Indicator Category: Safety

4. Select the **Risk Indicator Category** which the indicator should be grouped in. A drop down list will display to show available categories.
5. Optionally, select a **Weight** from range 1-10 with default weight of ‘1’. This value will be used later to calculate the Threshold Weight. The RBMWEIGHT=1-10 is set under additional options in IRAdmin >Configuration tables>Config. Or you may specify any range you would prefer.
6. In the Risk Indicator Definition, define the indicator query as either **Define Patient Subset**, **Select an Item**, or a combination of both query types.



Risk Indicator Category: Safety

Weight: 1

Indicator Description: Patients reported AEs

Indicator Label: Patients reported AEs

☐ Keep list of Patients

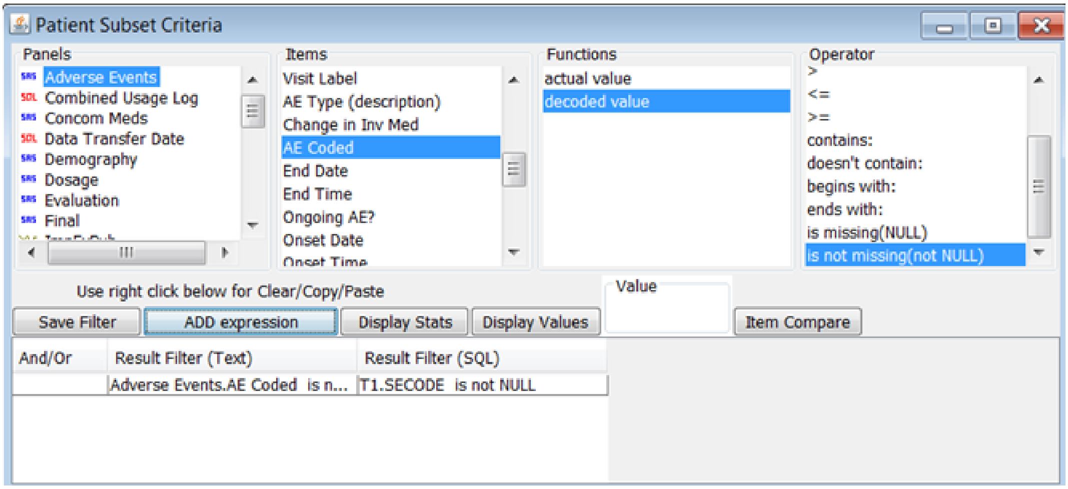
○ Subject Counts
○ Percentage of Subjects
● Other

When you define a specific patient subset as the indicator query, it can be set to calculate as either **Subject Counts** or **Percentage of Subjects**.

If needed, use the **Clear Definition** to clear the entire indicator definition.

## *Define Patient Subset*

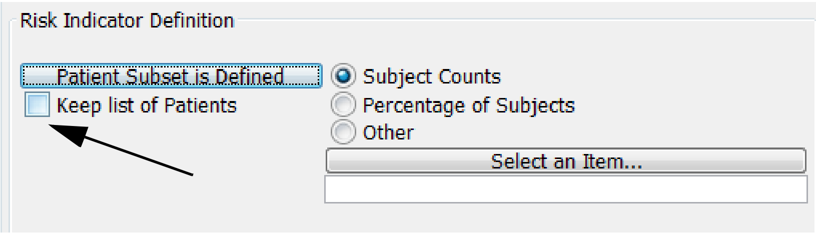
When you click on **Define Patient Subset**, a Patient Subset Criteria window opens to define your preferred patient subset.



| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | Adverse Events.AE Coded is n... | T1.SECODE is not NULL |

Once the patient subset is saved, the button status updates to indicate **Patient Subset is Defined**. Next, select to show either **Subject Counts** or **Percentage of Subjects**. **Other** is used for query type **Select an Item**. If an indicator is created in this way, the user has the option to click the checkbox to **"Keep the list of patients"** that meet those criteria.

The Define Patient subset query is used the majority of the time, as you will need to know which patients have risk concerns. The list of patients is only kept for the last run of the object. For example, the percent of patients with Adverse Events or subject counts of patients with elevated WBC. The patient list is available to view within the **Risk Based Monitoring Data Browser.**



☐ Keep list of Patients

● Subject Counts
○ Percentage of Subjects
○ Other

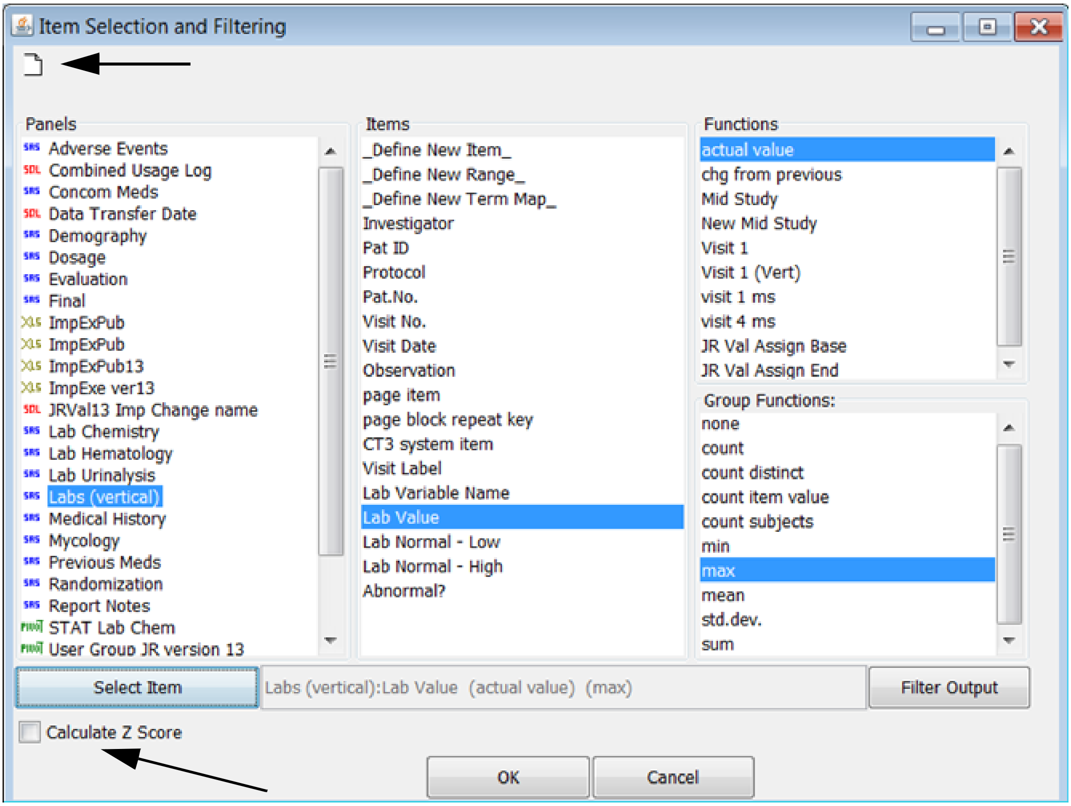
## *Select an Item*

An indicator can also be an item with a group function summarized by site. The **Select an Item** indicator can also have an applied patient subset and/or a filter. This indicator type is used with **Other**. For example, Maximum Cholesterol value per site. This indicator type ***does not*** generate a patient list.

The select an item indicator can be a variable from a site level table that has been registered as a foreign panel or an Import SQL. If the variable is coming from a site level table, there can be no selection of patient subset and no grouping options, since all data is already summarized at the site level.

When the item is selected there is the option to **Calculate Z Score** by clicking on the checkbox.

***Note: Do not use the count group functions. Instead use the Define Patient Subset query to count subjects or percentage of subjects.***



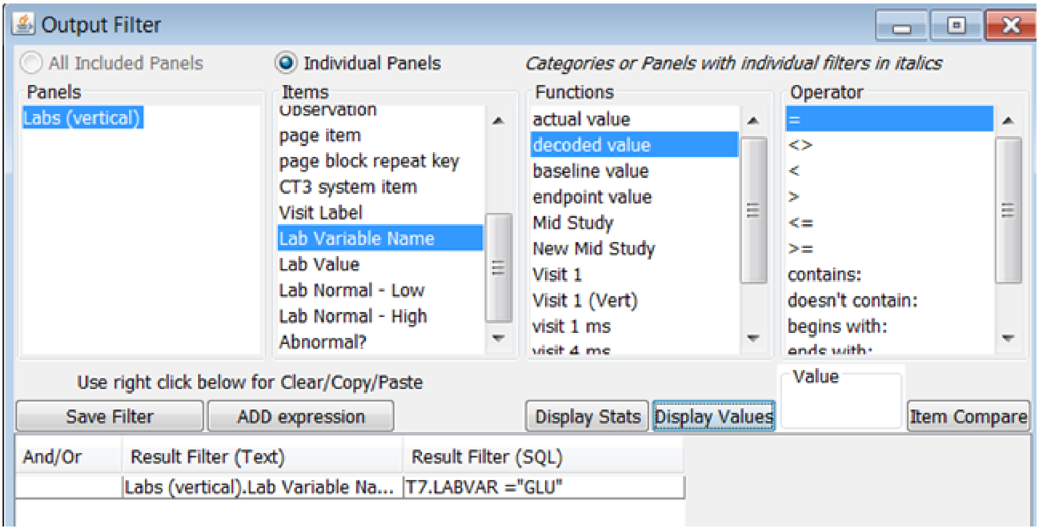
Labs (vertical):Lab Value (actual value) (max)

☐ Calculate Z Score

If needed, use the **New button** in the Item selection and filtering dialog to clear the selected item.

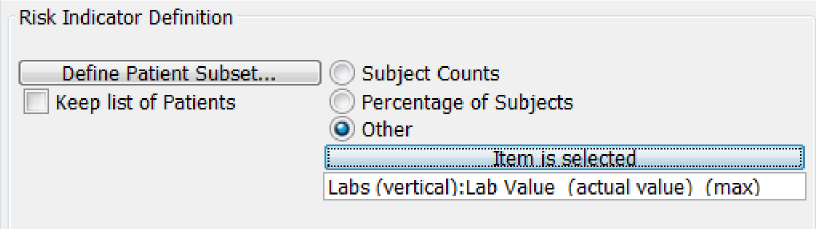
If you use a Vertical Lab table, you will need to use the Filter Output.

1. Start by selecting the LABVAL item which contains the result values.
2. Next, select the **Group Function.**
3. Click **Select Item**. You must click **Select Item** to enable the **Filter Output** button to specify the particular laboratory test.
4. Click **Filter Output** to open the **Output Filter** dialog.
5. Select the LABVAR item for a particular laboratory test and **ADD expression**.
6. Click **Save Filter** in the Output Filter dialog.
7. Click **OK** on the Item Selection and Filtering dialog window.



| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
|  | Labs (vertical).Lab Variable Na... | T7.LABVAR ="GLU" |

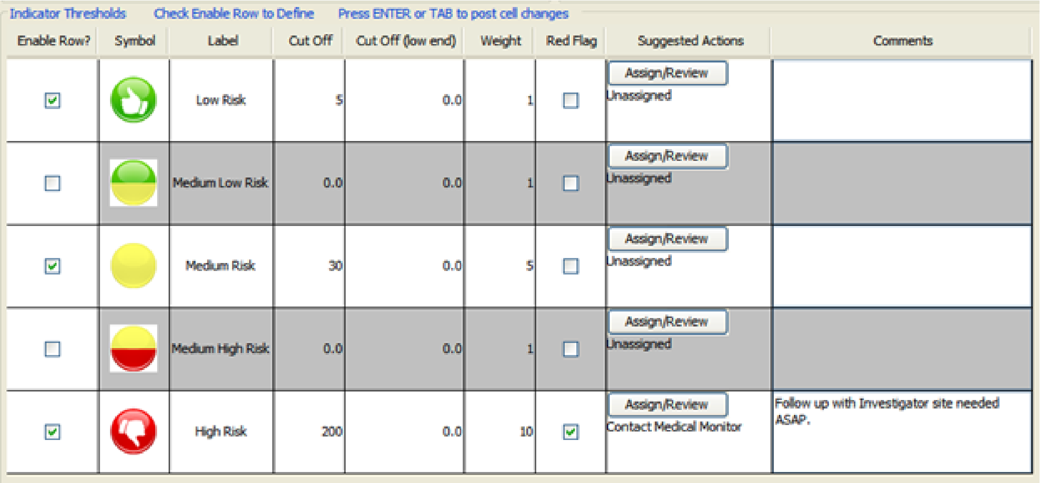
Once the selected item is saved, the button status updates to indicate **Item is selected** associated with **Other** for the calculated function.



Labs (vertical):Lab Value (actual value) (max)

## Define Indicator Thresholds

After an indicator is defined, at least two – preferably 3 or more **Indicator Thresholds** need to be defined to categorize the results of the query.



Indicator Thresholds   Check Enable Row to Define   Press ENTER or TAB to post cell changes

| Enable Row? | Symbol | Label | Cut Off | Cut Off (low end) | Weight | Red Flag | Suggested Actions | Comments |
|---|---|---|---|---|---|---|---|---|
| ☑ | 👍 | Low Risk | 5 | 0.0 | 1 | ☐ | Assign/Review<br>Unassigned | |
| ☐ | 🟢 | Medium Low Risk | 0.0 | 0.0 | 1 | ☐ | Assign/Review<br>Unassigned | |
| ☑ | 🟡 | Medium Risk | 30 | 0.0 | 5 | ☐ | Assign/Review<br>Unassigned | |
| ☐ | 🔴 | Medium High Risk | 0.0 | 0.0 | 1 | ☐ | Assign/Review<br>Unassigned | |
| ☑ | 👎 | High Risk | 200 | 0.0 | 10 | ☑ | Assign/Review<br>Contact Medical Monitor | Follow up with Investigator site needed ASAP. |

1. Select the **Indicator Threshold** levels required for the indicator by clicking the check boxes to **“Enable Row?”**.
2. Next enter the **Cut Off**. Optionally, a threshold can have **Cut Off (low end)**. For example, the **Cutt Off** threshold can look for too many AE’s and the **Cut Off (low end)** for too few or missing AE’s as not reported. The same reasoning applies for laboratory values such as, to find elevated WBC versus depressed WBC values. You may use either Cut Off ranges or use them together.

   Cut Off values are entered in ascending order and Cut Off (low end) values are entered in descending order.

***Hint: When applying ranges make sure all data values fall within the given ranges. Use a summary listing to provide data information on preferred ranges for subject counts, laboratory results, or other data values.***

3. Optionally, assign a **Weight** at a given indicator threshold. Click to display the drop down list within range 1-10. This value will be used later to calculate the T**hreshold Weight**.

   The Weight range is specified under additional options in ReviewAdmin >Configuration tables>Config as:

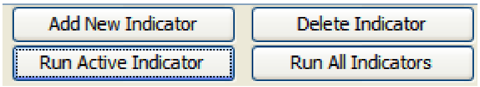
   RBMWEIGHT=1-10; or specify any preferred range.

   A value for SITEID must be set in the source table and possibly for any study overrides in the study table. The value of SITEID is the variable

   that resides in all of the tables that differentiates a site. For our example, it is the INVESTIGATOR item.

   Enter the item that contains the site identifier - in our KA201 example, it is investigator. It is the item that is stored in all of your patient related data that identifies the site.

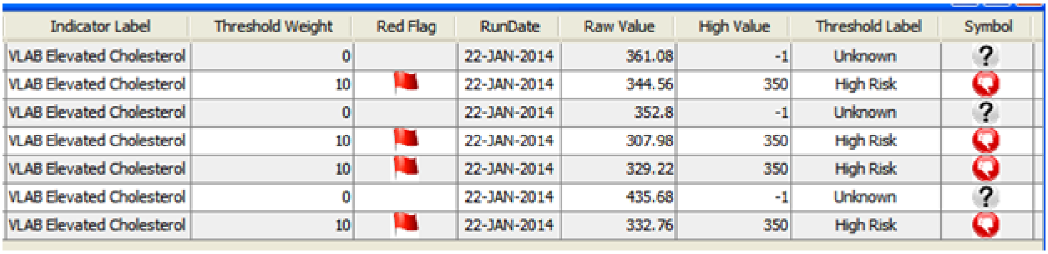
4. Optionally, set on a **Red Flag** to indicate a real concern. The Red Flag will be transmitted to the IPad application and is critical for any site requiring an action to be taken. ***(available in next release)***
5. The **Suggested Action** to be taken can be assigned to a given threshold. The actions available are from the RBM **Actions tab** for primary use in the IPad application. **Comments** can be entered. ***(available in next release)***
6. Test the entered ranges by clicking on **Run Active Indicator**. You may run an individual indicator with **Run the Active Indicator** or **Run All Indicators** to view the entire spreadsheet result.



You may sort on a single column by clicking on the column header.

| Project | Study | Site | Category | Indicator Description | Indicator Label | Threshold Weight | Red Flag | RunDate | Raw Value | High Value | Threshold Label | Symbol | Keep List of Pts. |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| KA | KA201 | 018 | Safety | Patients reported AEs | Patients reported AEs | 0 |  | 16-JAN-2014 | 4.55 | 5 | Low Risk | 🟢 | No |
| KA | KA201 | 030 | Safety | Patients reported AEs | Patients reported AEs | 0 |  | 16-JAN-2014 | 20.00 | 25 | Medium Risk | 🟡 | No |
| KA | KA201 | 056 | Safety | Patients reported AEs | Patients reported AEs | 0 | 🚩 | 16-JAN-2014 | 30.00 | 500 | High Risk | 🔴 | No |
| KA | KA201 | 063 | Safety | Patients reported AEs | Patients reported AEs | 0 | 🚩 | 16-JAN-2014 | 51.72 | 500 | High Risk | 🔴 | No |
| KA | KA201 | 064 | Safety | Patients reported AEs | Patients reported AEs | 0 | 🚩 | 16-JAN-2014 | 37.14 | 500 | High Risk | 🔴 | No |
| KA | KA201 | 065 | Safety | Patients reported AEs | Patients reported AEs | 0 |  | 16-JAN-2014 | 20.00 | 25 | Medium Risk | 🟡 | No |
| KA | KA201 | 066 | Safety | Patients reported AEs | Patients reported AEs | 0 |  | 16-JAN-2014 | 20.00 | 25 | Medium Risk | 🟡 | No |

If you see the ‘**?**’ symbol displayed for a particular indicator description the range needs to be increased.

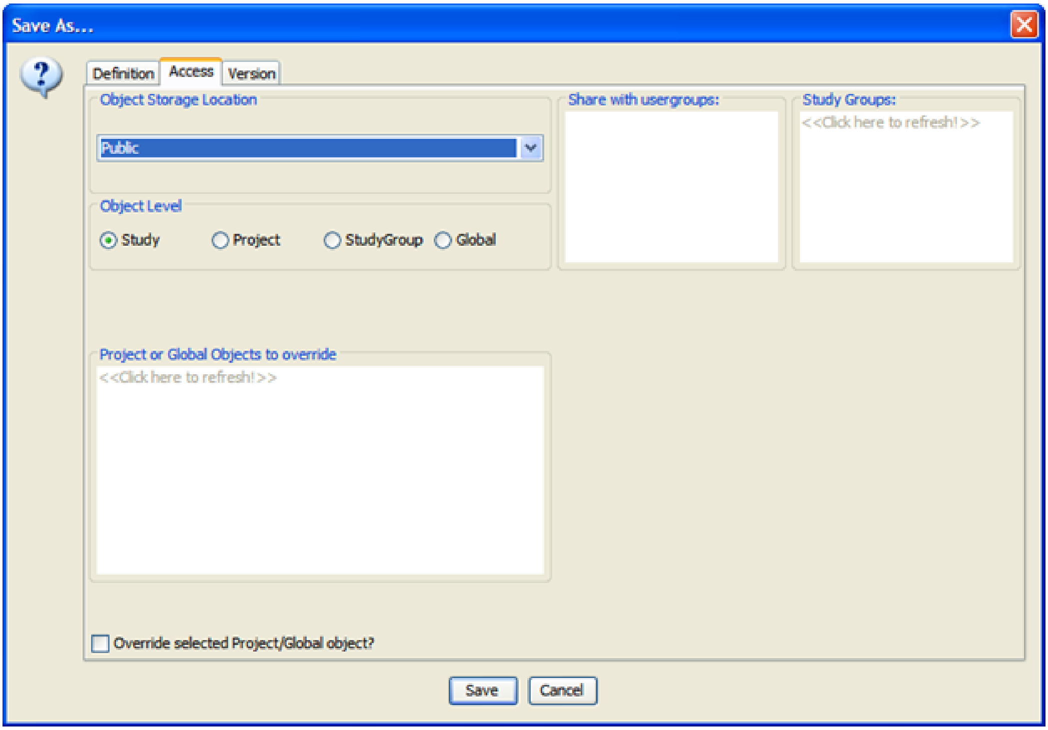


| Indicator Label | Threshold Weight | Red Flag | RunDate | Raw Value | High Value | Threshold Label | Symbol |
|---|---|---|---|---|---|---|---|
| VLAB Elevated Cholesterol | 0 |  | 22-JAN-2014 | 361.08 | -1 | Unknown | ? |
| VLAB Elevated Cholesterol | 10 | 🚩 | 22-JAN-2014 | 344.56 | 350 | High Risk | 👎 |
| VLAB Elevated Cholesterol | 0 |  | 22-JAN-2014 | 352.8 | -1 | Unknown | ? |
| VLAB Elevated Cholesterol | 10 | 🚩 | 22-JAN-2014 | 307.98 | 350 | High Risk | 👎 |
| VLAB Elevated Cholesterol | 10 | 🚩 | 22-JAN-2014 | 329.22 | 350 | High Risk | 👎 |
| VLAB Elevated Cholesterol | 0 |  | 22-JAN-2014 | 435.68 | -1 | Unknown | ? |
| VLAB Elevated Cholesterol | 10 | 🚩 | 22-JAN-2014 | 332.76 | 350 | High Risk | 👎 |

**Threshold Weight** is the Category weight (Safety, Laboratory, etc.) times the assigned **Indicator Weight**. In this example, the **Raw Value** data column displays the maximum cholesterol value for each study site. The **High Value** is the high range entered for **High Risk**.

## *Save RBM Object*

Saving Indicator objects works the same as all other objects in JReview. They can be saved at any level or locations and are stored in the **RISK BASED MONITORING** category in the **Output Specifications**. These objects can be opened, modified and executed.



Public

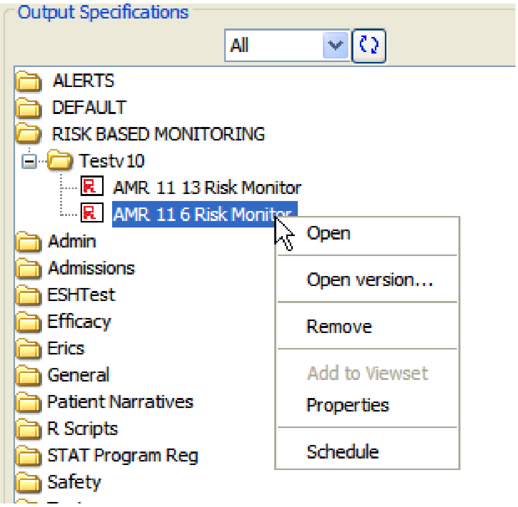
● Study ○ Project ○ StudyGroup ○ Global

<<Click here to refresh!>>

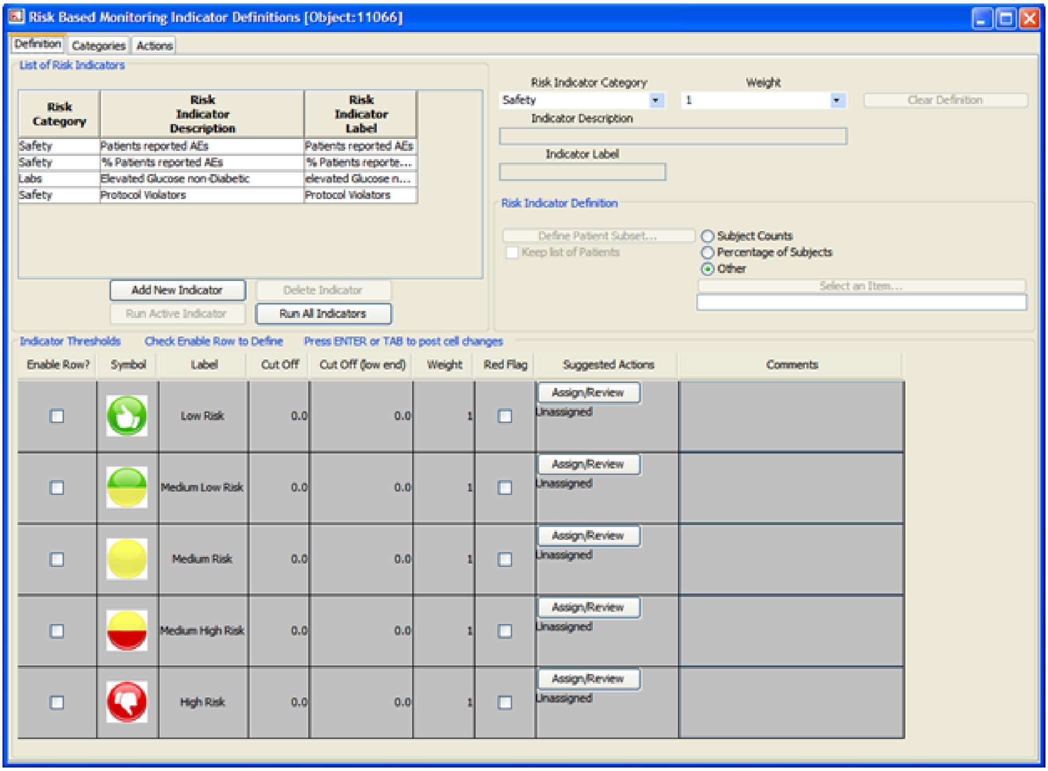
☐ Override selected Project/Global object?

All indicator queries within the object will run when double clicking on the saved RBM object from the Object Explorer.

Right mouse click to display a floating menu to open object, open version, remove (author only), show properties, or schedule.



Here is an example of a previously saved RBM object with numerous indicator queries across multiple Risk Indicator Categories.



| Risk Category | Risk Indicator Description | Risk Indicator Label |
|---|---|---|
| Safety | Patients reported AEs | Patients reported AEs |
| Safety | % Patients reported AEs | % Patients reporte... |
| Labs | Elevated Glucose non-Diabetic | elevated Glucose n... |
| Safety | Protocol Violators | Protocol Violators |

Risk Indicator Category: Safety

Weight: 1

Indicator Description:

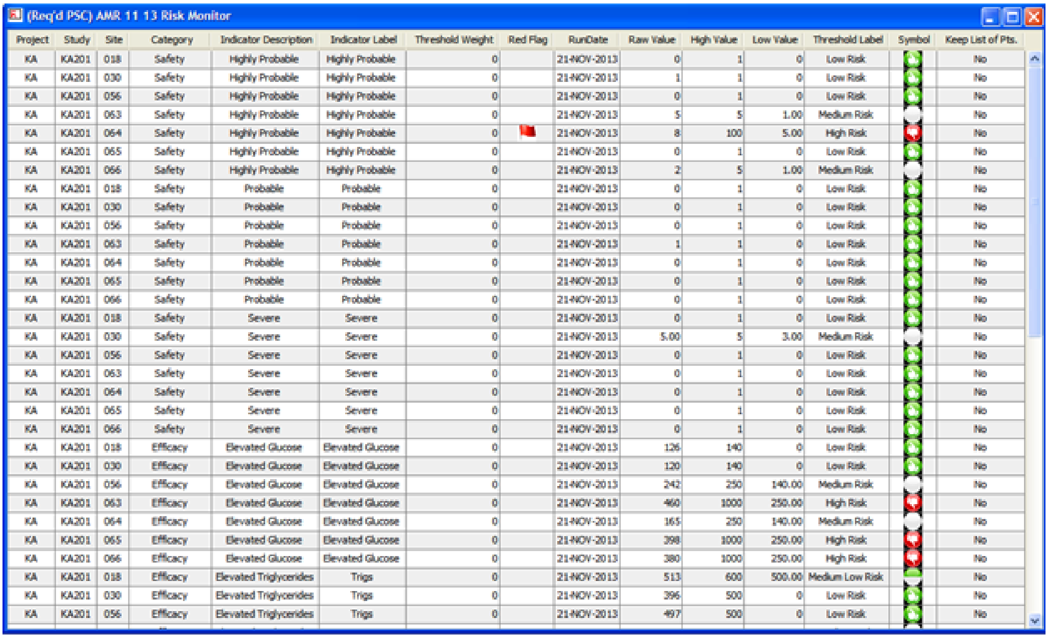
Indicator Label:

☐ Keep list of Patients

○ Subject Counts
○ Percentage of Subjects
● Other

| Enable Row? | Symbol | Label | Cut Off | Cut Off (low end) | Weight | Red Flag | Suggested Actions | Comments |
|---|---|---|---|---|---|---|---|---|
| ☐ | ● | Low Risk | 0.0 | 0.0 | 1 | ☐ | Assign/Review<br>Unassigned | |
| ☐ | ● | Medium Low Risk | 0.0 | 0.0 | 1 | ☐ | Assign/Review<br>Unassigned | |
| ☐ | ● | Medium Risk | 0.0 | 0.0 | 1 | ☐ | Assign/Review<br>Unassigned | |
| ☐ | ● | Medium High Risk | 0.0 | 0.0 | 1 | ☐ | Assign/Review<br>Unassigned | |
| ☐ | ● | High Risk | 0.0 | 0.0 | 1 | ☐ | Assign/Review<br>Unassigned | |

All indicators are run within the RBM object.



(Req'd PSC) AMR 11 13 Risk Monitor

| Project | Study | Site | Category | Indicator Description | Indicator Label | Threshold Weight | Red Flag | RunDate | Raw Value | High Value | Low Value | Threshold Label | Symbol | Keep List of Pts. |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| KA | KA201 | 018 | Safety | Highly Probable | Highly Probable | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 030 | Safety | Highly Probable | Highly Probable | 0 |  | 21-NOV-2013 | 1 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 056 | Safety | Highly Probable | Highly Probable | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 063 | Safety | Highly Probable | Highly Probable | 0 |  | 21-NOV-2013 | 5 | 5 | 1.00 | Medium Risk | ⚪ | No |
| KA | KA201 | 064 | Safety | Highly Probable | Highly Probable | 0 | 🚩 | 21-NOV-2013 | 8 | 100 | 5.00 | High Risk | 🔴 | No |
| KA | KA201 | 065 | Safety | Highly Probable | Highly Probable | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 066 | Safety | Highly Probable | Highly Probable | 0 |  | 21-NOV-2013 | 2 | 5 | 1.00 | Medium Risk | ⚪ | No |
| KA | KA201 | 018 | Safety | Probable | Probable | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 030 | Safety | Probable | Probable | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 056 | Safety | Probable | Probable | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 063 | Safety | Probable | Probable | 0 |  | 21-NOV-2013 | 1 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 064 | Safety | Probable | Probable | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 065 | Safety | Probable | Probable | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 066 | Safety | Probable | Probable | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 018 | Safety | Severe | Severe | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 030 | Safety | Severe | Severe | 0 |  | 21-NOV-2013 | 5.00 | 5 | 3.00 | Medium Risk | ⚪ | No |
| KA | KA201 | 056 | Safety | Severe | Severe | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 063 | Safety | Severe | Severe | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 064 | Safety | Severe | Severe | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 065 | Safety | Severe | Severe | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 066 | Safety | Severe | Severe | 0 |  | 21-NOV-2013 | 0 | 1 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 018 | Efficacy | Elevated Glucose | Elevated Glucose | 0 |  | 21-NOV-2013 | 126 | 140 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 030 | Efficacy | Elevated Glucose | Elevated Glucose | 0 |  | 21-NOV-2013 | 120 | 140 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 056 | Efficacy | Elevated Glucose | Elevated Glucose | 0 |  | 21-NOV-2013 | 242 | 250 | 140.00 | Medium Risk | ⚪ | No |
| KA | KA201 | 063 | Efficacy | Elevated Glucose | Elevated Glucose | 0 |  | 21-NOV-2013 | 460 | 1000 | 250.00 | High Risk | 🔴 | No |
| KA | KA201 | 064 | Efficacy | Elevated Glucose | Elevated Glucose | 0 |  | 21-NOV-2013 | 165 | 250 | 140.00 | Medium Risk | ⚪ | No |
| KA | KA201 | 065 | Efficacy | Elevated Glucose | Elevated Glucose | 0 |  | 21-NOV-2013 | 398 | 1000 | 250.00 | High Risk | 🔴 | No |
| KA | KA201 | 066 | Efficacy | Elevated Glucose | Elevated Glucose | 0 |  | 21-NOV-2013 | 380 | 1000 | 250.00 | High Risk | 🔴 | No |
| KA | KA201 | 018 | Efficacy | Elevated Triglycerides | Trigs | 0 |  | 21-NOV-2013 | 513 | 600 | 500.00 | Medium Low Risk | ◓ | No |
| KA | KA201 | 030 | Efficacy | Elevated Triglycerides | Trigs | 0 |  | 21-NOV-2013 | 396 | 500 | 0 | Low Risk | 🟢 | No |
| KA | KA201 | 056 | Efficacy | Elevated Triglycerides | Trigs | 0 |  | 21-NOV-2013 | 497 | 500 | 0 | Low Risk | 🟢 | No |

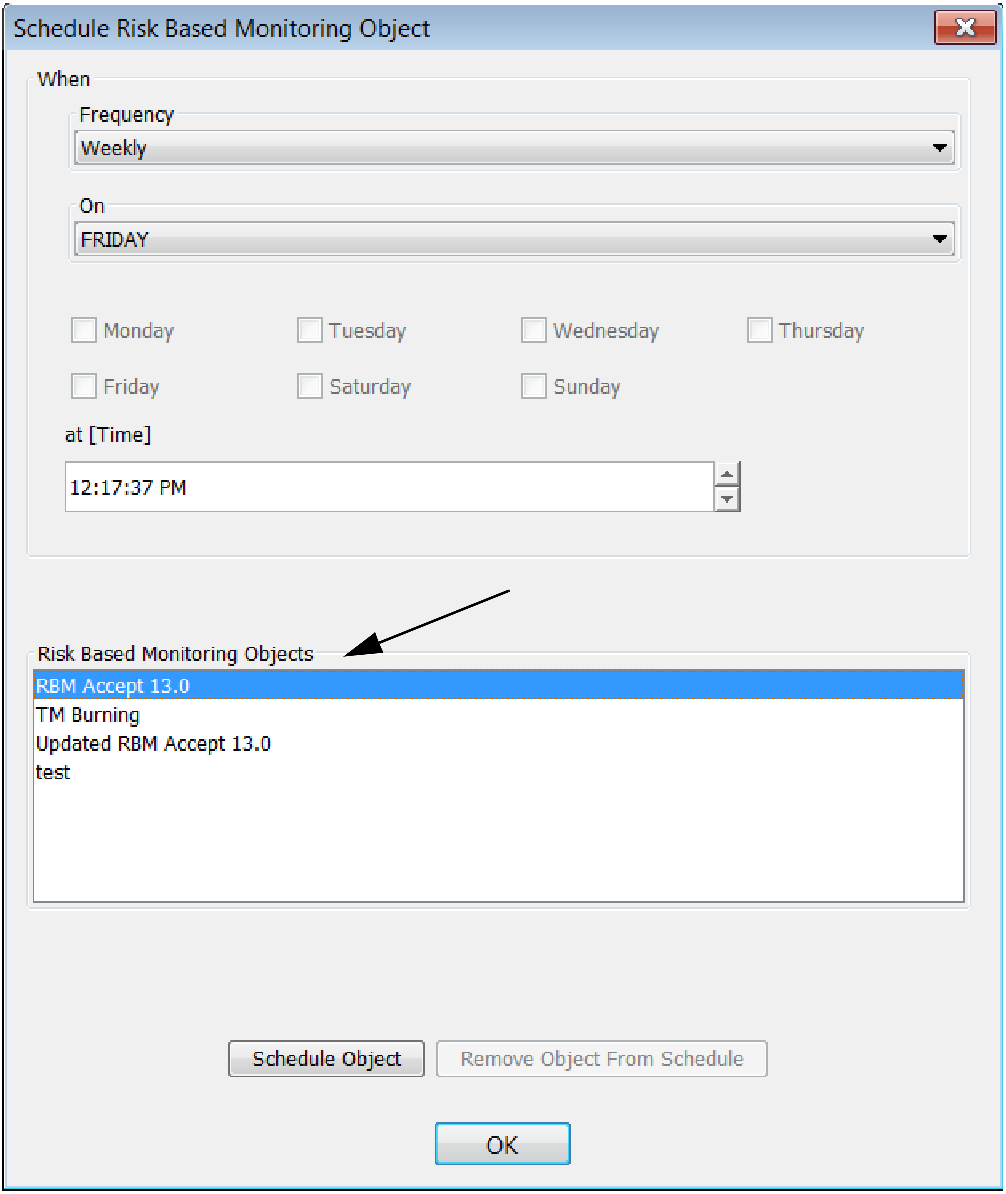
# Schedule Risk Based Monitor Object

## *Schedule RBM object*

Schedule RBM objects off of the **Advanced Menu**, or from right mouse click on selected RBM object to display a floating menu.

You MUST select a saved RBM object from the listbox for Risk Based Monitoring Objects.

***Only one*** RBM object can be scheduled per study per day.



Schedule Risk Based Monitoring Object

When

Frequency: Weekly

On: FRIDAY

☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday

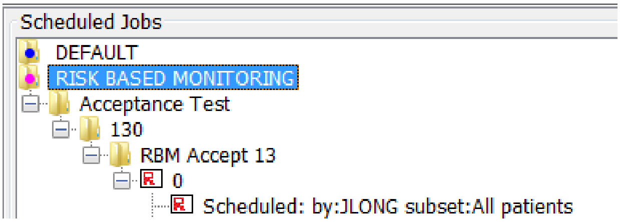
☐ Friday ☐ Saturday ☐ Sunday

at [Time]: 12:17:37 PM

Risk Based Monitoring Objects

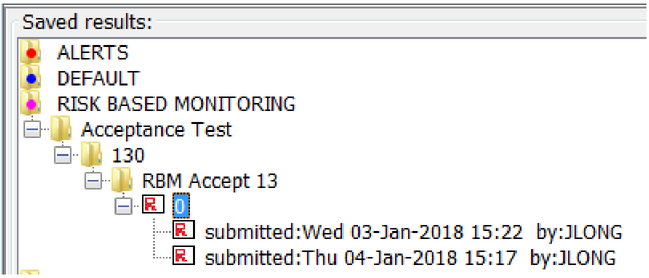
RBM Accept 13.0
TM Burning
Updated RBM Accept 13.0
test

This is an example of a scheduled RBM object in the **Scheduled Jobs tab**.



Scheduled Jobs
DEFAULT
RISK BASED MONITORING
Acceptance Test
130
RBM Accept 13
0
Scheduled: by:JLONG subset:All patients

Once the job is run it displays in the **Saved results tab**. The Risk Based Monitoring analysis runs on a periodic schedule to view the latest data results.



Saved results:
ALERTS
DEFAULT
RISK BASED MONITORING
Acceptance Test
130
RBM Accept 13
0
submitted:Wed 03-Jan-2018 15:22 by:JLONG
submitted:Thu 04-Jan-2018 15:17 by:JLONG

## *Conditions for scheduling*

When running a Project Level RBM object with possible study level differences between items or panels - the following applies:

- Server code is modified to not allow the execution/open of an RBM object where panels or items are not found in any one of the indicators.
- When a project level object is scheduled to a given study it is displayed in the Scheduled Jobs tab. Only the objects that are scheduled for the active study are displayed in the Scheduled Jobs tab. Again, only one RBM object is allowed to be scheduled per study.
- The summarization for same 'weighted average' algorithm is used for all of the aggregations, as less prone to being 'pulled off' by one high risk out of a number of indicators in a category.

# Risk Based Monitoring Data Browser

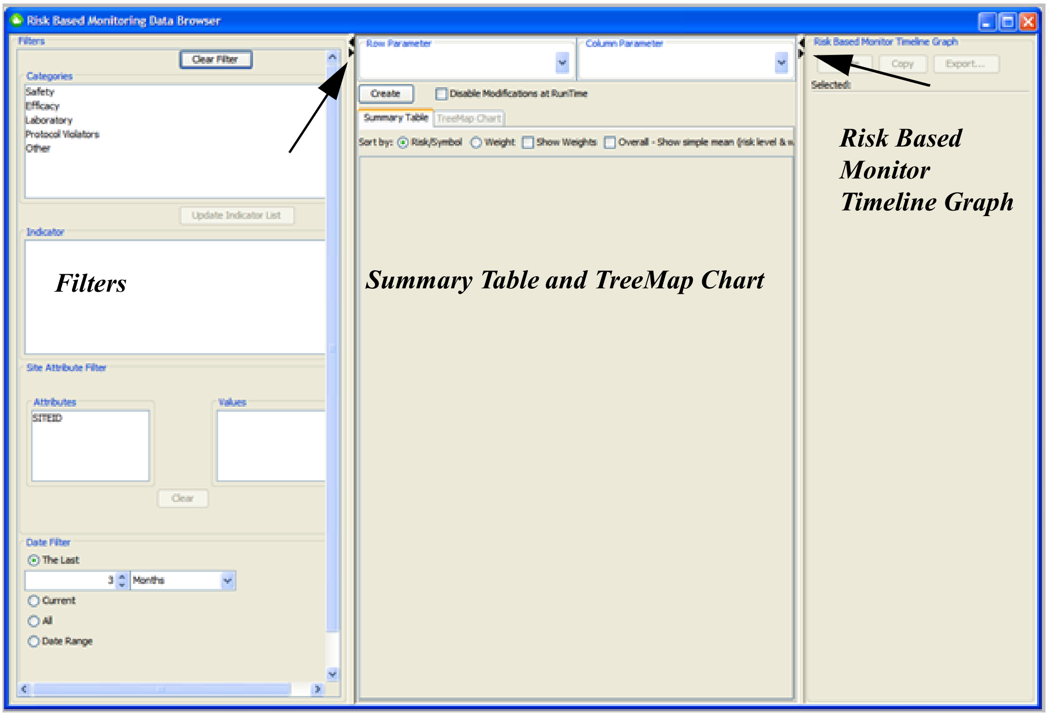
## *Open RBM Data Browser*

After the scheduled RBM object has run, you may view the saved output results. Open the **Risk Based Monitoring Data Browser** from the **Browse** menu, or select the icon in the tool bar. The most recent data results are displayed.

The **Risk Based Monitoring Data Browser** window opens divided into three function areas:

- Filters (left)
- Summary Table and TreeMap Chart (center)
- Risk Based Monitor Timeline Graph (right)

You may minimize any function window by clicking on the black arrows to collapse or expand the view area.



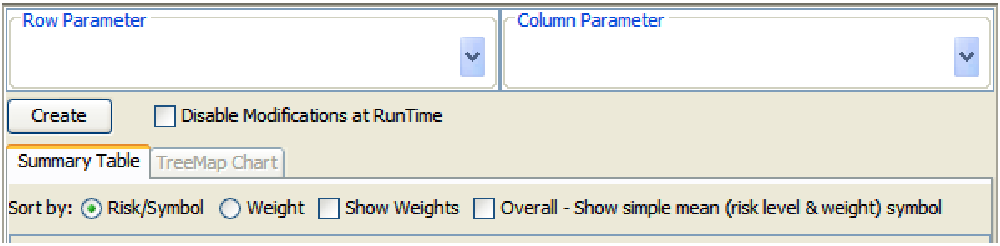
***Filters***

***Summary Table and TreeMap Chart***

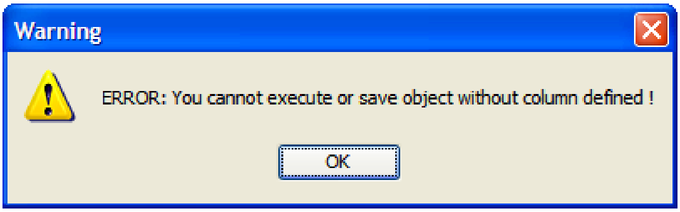
***Risk Based Monitor Timeline Graph***

## *Define RBM Summary Table*

Start in the center window to select what data to display within the tables and graph output. Click on the **Row and Column Parameter** drop down lists for display selections. Filters may be selected before or after clicking **Create** for the output displays.

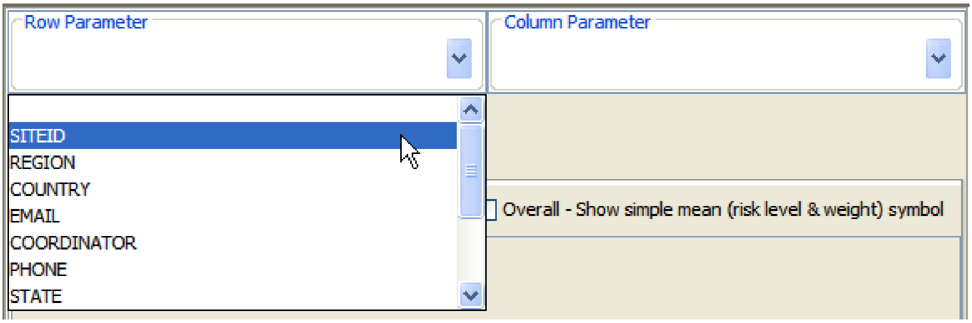


If you click **Create** without defining the **Row and Column Parameters** a warning message displays.

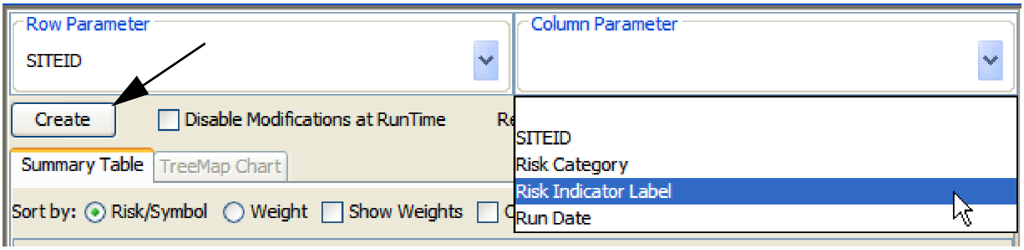


ERROR: You cannot execute or save object without column defined !

Click on the drop down list to select the **Row Parameter**.



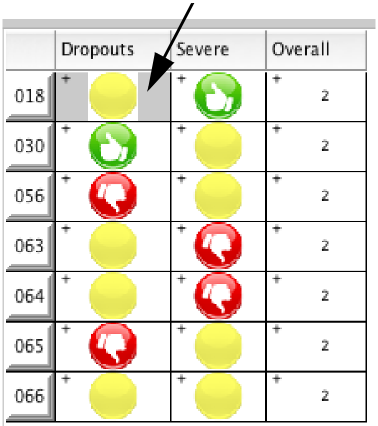
Next, click on the drop down list to select the **Column Parameter**. Then click **Create**



Select from the various display features to show weights, symbols and overall score as the sum of the weights for that row.

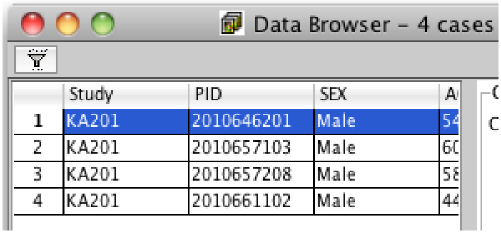
If the Risk Monitoring Indicator was saved with the “Keep List of Patients” checked on, a footnote at the bottom of RBM Summary table states:

**"+ in the cell means a patient list can be broadcast".**



|  | Dropouts | Severe | Overall |
|---|---|---|---|
| 018 | + 🟡 | + 👍 | + 2 |
| 030 | + 👍 | + 🟡 | + 2 |
| 056 | + 👎 | + 🟡 | + 2 |
| 063 | + 🟡 | + 👎 | + 2 |
| 064 | + 🟡 | + 👎 | + 2 |
| 065 | + 👎 | + 🟡 | + 2 |
| 066 | + 🟡 | + 🟡 | + 2 |

Click on a patient cell to display the patient(s).



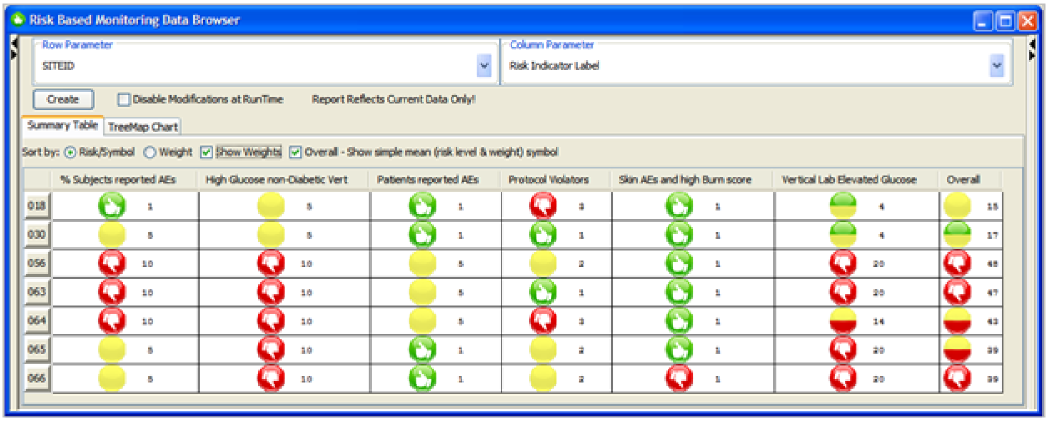
Data Browser – 4 cases

|  | Study | PID | SEX | A |
|---|---|---|---|---|
| 1 | KA201 | 2010646201 | Male | 54 |
| 2 | KA201 | 2010657103 | Male | 6 |
| 3 | KA201 | 2010657208 | Male | 5 |
| 4 | KA201 | 2010661102 | Male | 4 |

**The Report Reflects Current Data Only!**

For RBM Summary table views that return no data, a message will display "**RBM Summary Table returned no data**".

The total weight for a row displays if all cells have weight. However, if any cell in a row has a blank/unassigned weight then the total weight in Overall for the row will be blank/unassigned.



Row Parameter: SITEID

Column Parameter: Risk Indicator Label

Sort by: ● Risk/Symbol ○ Weight ☑ Show Weights ☑ Overall - Show simple mean (risk level & weight) symbol

| | % Subjects reported AEs | High Glucose non-Diabetic Vert | Patients reported AEs | Protocol Violators | Skin AEs and high Burn score | Vertical Lab Elevated Glucose | Overall |
|---|---|---|---|---|---|---|---|
| 018 | 🟢 1 | 🟡 5 | 🟢 1 | 🔴 3 | 🟢 1 | 🟢🟡 4 | 🟡 15 |
| 030 | 🟡 5 | 🟡 5 | 🟢 1 | 🟢 1 | 🟢 1 | 🟢🟡 4 | 🟢🟡 17 |
| 056 | 🔴 10 | 🔴 10 | 🟡 5 | 🟡 2 | 🟢 1 | 🔴 20 | 🔴 48 |
| 063 | 🔴 10 | 🔴 10 | 🟡 5 | 🟢 1 | 🟢 1 | 🔴 20 | 🔴 47 |
| 064 | 🔴 10 | 🔴 10 | 🟡 5 | 🔴 3 | 🟢 1 | 🟡🔴 14 | 🟡🔴 43 |
| 065 | 🟡 5 | 🔴 10 | 🟢 1 | 🟡 2 | 🟢 1 | 🔴 20 | 🟡🔴 39 |
| 066 | 🟡 5 | 🔴 10 | 🟢 1 | 🟡 2 | 🔴 1 | 🔴 20 | 🔴 39 |

The Overall column calculations in the RBM summary view is as follows:

- The user assigns **within-indicator** importance through the Risk Level (1 = High... 5 = Low, 0 = Unassigned).
- The user assigns **across-indicator/across-category** importance by assigning a Weight (1 = Low... 10 = High (based on config'd range), 0 = Unassigned.))

By doing this, the user intends is providing the data to take a fair estimate at what an Overall measure should be. A simple weighted average then will use "divide - half - down"* integer calculation to assign the necessary Risk level symbol integer.

The **Initial Overall column contents is simply the sum of the row's cells weights** (any unassigned in the row invalidates the calculation - shows no/empty weight with no/unassigned symbol.

The calculation will multiply the Risk level/score for a cell * the weight for the cell, sum those values for the row AND then divide by the sum of the weights for the row.

Then **the half-down divide function makes the appropriate pessimistic Symbol assignment for values midway between two integers / Risk Levels** (e.g. an average of 1.5 becomes 1).

The calculations are handled when the weights are used and there are several risk indicators per a category with these Overall Symbol assignment rules:

*Overall Weight per study site is calculated as the Category Weight times Indicator Weight for each Indicator and then the sum score listed in Overall column.

* if a row's weight is not unknown it contributes to the row's total-weight sum (denominator).

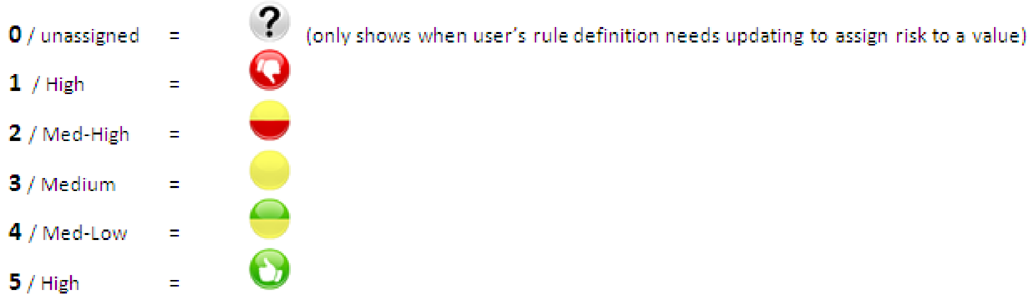
* if a row's weight and Risk Level are not unknown it contributes to the row's total-score (numerator).

* If there are no unknowns in the row the icon assignment is simply based on *"divide half down" of total-score / total-weight - This pushes scores midway between to the "worse" of the two neighboring assignments. E.g. an average of 1.5, precisely between HIGH RISK (1) and MEDIUM-HIGH RISK (2) will slide UP in severity/down in value to (1) HIGH RISK.

* Any UNKNOWN/QUESTION MARK in a row nullifies its Overall calculations & assigns UNKNOWN to Overall.

The Risk level integer value to Risk level symbol mapping is calculated at Risk level plus Weight assigned by the user in the RBM rules definition screen. This means the user expresses their assessment of values for a particular measure in the Risk level assignment (with values 1 through 5, zeros represent rule errors). And the user expresses their assessment across measure importance by assigning Weight (typically, 1 through 10).

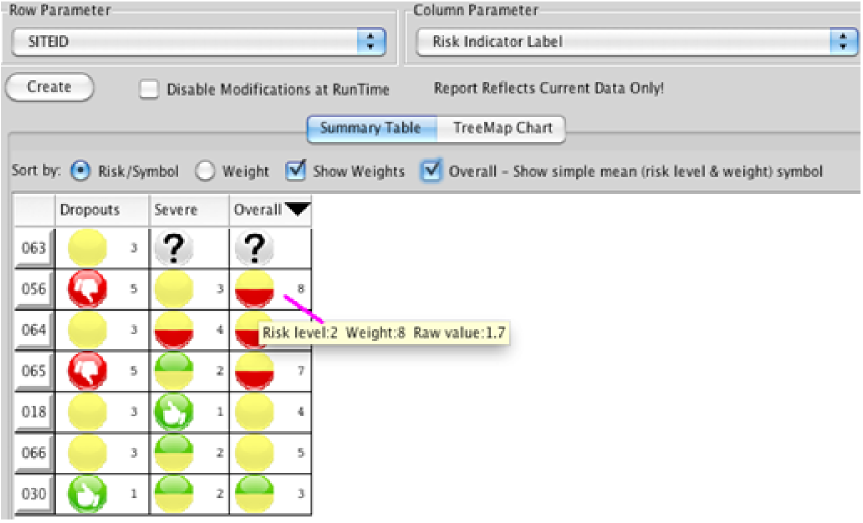
Essentially **the user normalizes the Risk assessment within and across measures through Risk level and Weight assignment**. So the assigned Risk level integer can be used as a comparable measure for all rules.



**0** / unassigned = ? (only shows when user's rule definition needs updating to assign risk to a value)
**1** / High = 👎
**2** / Med-High = ◒
**3** / Medium = ●
**4** / Med-Low = ◓
**5** / High = 👍

Below is a sort by Risk Level display with Overall sorted by descending Risk Level (ascending Risk level integer).

Hovering over **056's** Overall cell we see the raw average as **1.7 which rounds to 2** becoming "Medium High".



Row Parameter: SITEID

Column Parameter: Risk Indicator Label

☐ Disable Modifications at RunTime

Report Reflects Current Data Only!

Sort by: ● Risk/Symbol ○ Weight ☑ Show Weights ☑ Overall - Show simple mean (risk level & weight) symbol

| | Dropouts | Severe | Overall ▼ |
|---|---|---|---|
| 063 | 🟡 3 | ? | ? |
| 056 | 👎 5 | 🟡 3 | ◒ 8 |
| 064 | 🟡 3 | ◒ 4 | ◒ |
| 065 | 👎 5 | ◓ 2 | ◒ 7 |
| 018 | 🟡 3 | 👍 1 | 🟡 4 |
| 066 | 🟡 3 | ◓ 2 | 🟡 5 |
| 030 | 👍 1 | ◓ 2 | ◓ 3 |

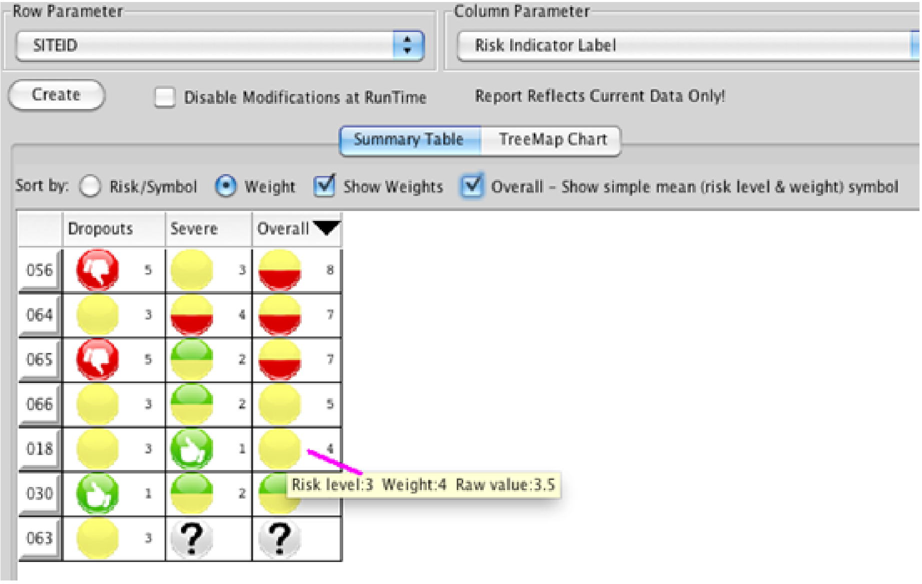
Risk level:2 Weight:8 Raw value:1.7

**The unassigned / ? Risk level value is considered the most serious risk so sorts at the top in this display.**

The yellow tooltip text is shown shifted slightly down from its cell in this screenshot, this is not the case in JReview UI itself where it shows properly aligned.

Below is a sort by Weight display with Overall sorted by descending Weight (descending weight row sum).

Hovering over **018's** Overall cell we see the **raw average as 3.5, which rounds half-down to 3** becoming "Medium Low". So the precisely in-between / middle value moves to the more pessimistic of integer values / Risk levels.



Row Parameter: SITEID

Column Parameter: Risk Indicator Label

☐ Disable Modifications at RunTime

Report Reflects Current Data Only!

Sort by: ○ Risk/Symbol ● Weight ☑ Show Weights ☑ Overall - Show simple mean (risk level & weight) symbol

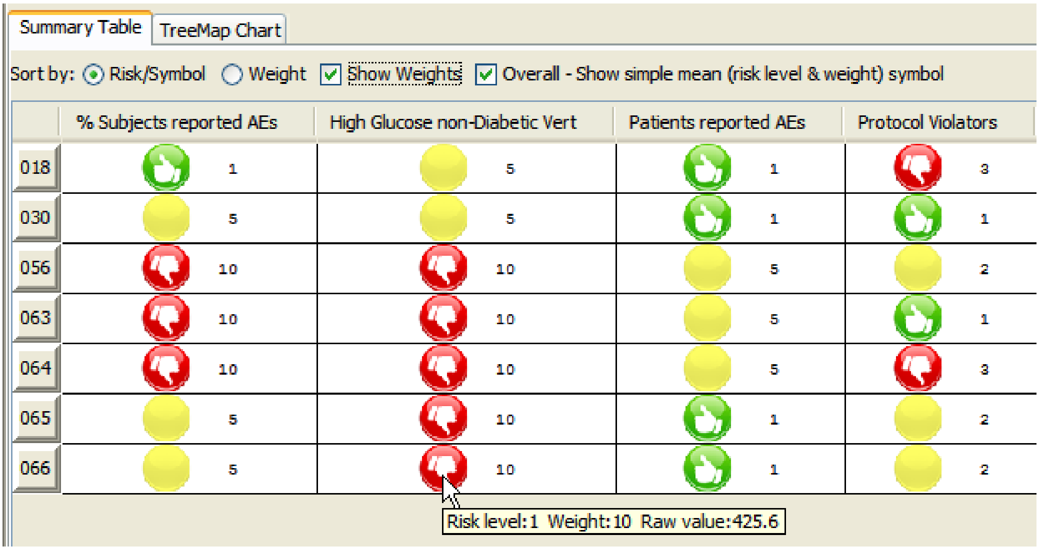
| | Dropouts | Severe | Overall ▼ |
|---|---|---|---|
| 056 | 5 | 3 | 8 |
| 064 | 3 | 4 | 7 |
| 065 | 5 | 2 | 7 |
| 066 | 3 | 2 | 5 |
| 018 | 3 | 1 | 4 |
| 030 | 1 | 2 | |
| 063 | 3 | ? | ? |

Risk level:3 Weight:4 Raw value:3.5

**The unassigned / ? Weight value is considered the lowest weight so sorts at the bottom in this display. This is because the unassigned weight value is lower than all possible legal weight values.**

The yellow tooltip text is shown shifted slightly down from its cell in this screenshot, this is not the case in JReview UI itself where it shows properly aligned.

Hover the mouse over a cell to display a tooltip label for Risk level, Weight and Raw value. Raw data is the result of the metric. The calculated tooltip for Overall Score displays the "Calculated ave:" to show that it is not a raw value like the rest of the columns.



Sort by: ● Risk/Symbol ○ Weight ☑ Show Weights ☑ Overall - Show simple mean (risk level & weight) symbol

|  | % Subjects reported AEs |  | High Glucose non-Diabetic Vert |  | Patients reported AEs |  | Protocol Violators |  |
|---|---|---|---|---|---|---|---|---|
| 018 | 👍 | 1 | ● | 5 | 👍 | 1 | 👎 | 3 |
| 030 | ● | 5 | ● | 5 | 👍 | 1 | 👍 | 1 |
| 056 | 👎 | 10 | 👎 | 10 | ● | 5 | ● | 2 |
| 063 | 👎 | 10 | 👎 | 10 | ● | 5 | 👍 | 1 |
| 064 | 👎 | 10 | 👎 | 10 | ● | 5 | 👎 | 3 |
| 065 | ● | 5 | 👎 | 10 | 👍 | 1 | ● | 2 |
| 066 | ● | 5 | 👎 | 10 | 👍 | 1 | ● | 2 |

Risk level:1 Weight:10 Raw value:425.6

Click on the **TreeMap Chart tab** to display the same data in this format. The cell size is determined by the weight. You can **Copy, Export or Print** the TreeMap Chart from the output tab.

Row Parameter: SITEID

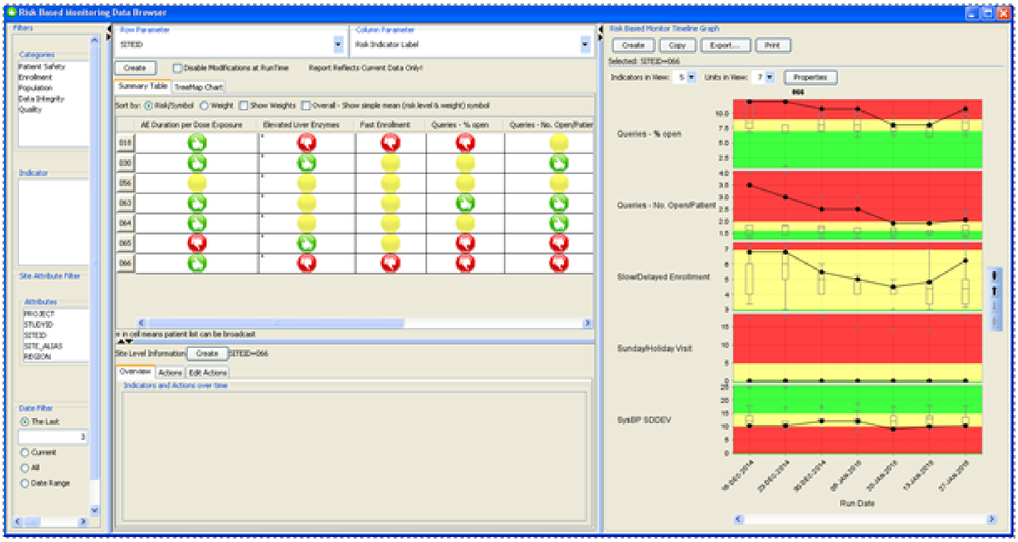
Column Parameter: Risk Indicator Label

☐ Disable Modifications at RunTime

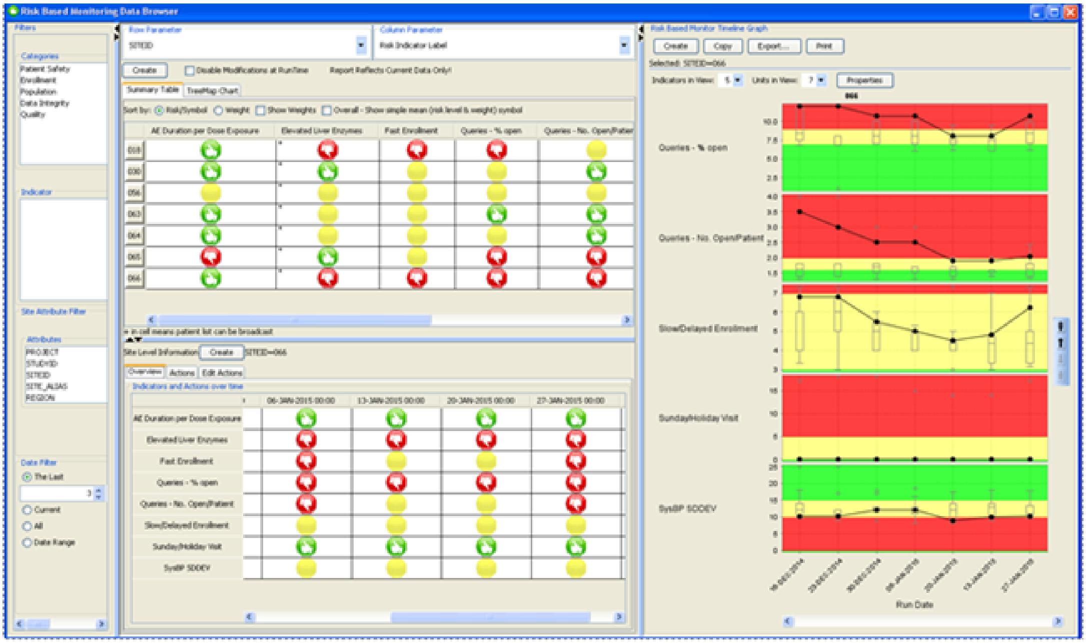
Report Reflects Current Data Only!

After opening the RBM Data Browser, selecting SITEID as the Row Parameter, then either Risk Category or Risk Indicator as a Column Parameter, click Create.

You can click on any site of interest – especially if you, as a CRA or site monitor, are responsible for monitoring the site. Click ‘Create’ in the bottom of the window in the ‘Site Level Information’ area.



After you click ‘Create’, a historical view of the selected site’s indicator results are displayed in the ‘**Overview**’ tab.



Row Parameter: SITEID

Column Parameter: Risk Indicator Label

☐ Disable Modifications at RunTime    Report Reflects Current Data Only!

Sort by: ● Risk/Symbol ○ Weight ☐ Show Weights ☐ Overall - Show simple mean (risk level & weight) symbol

| | AE Duration per Dose Exposure | Elevated Liver Enzymes | Fast Enrollment | Queries - % open | Queries - No. Open/Patier |
|---|---|---|---|---|---|
| 018 | 👍 | * 👎 | 👎 | 👎 | ● |
| 030 | 👍 | * 👍 | ● | ● | 👍 |
| 056 | ● | * ● | ● | ● | ● |
| 063 | 👍 | * ● | ● | 👍 | 👍 |
| 064 | 👍 | * ● | ● | ● | 👍 |
| 065 | 👎 | * 👍 | ● | 👎 | 👎 |
| 066 | 👍 | * 👎 | 👎 | 👎 | 👎 |

* in cell means patient list can be broadcast

Site Level Information: SITEID=066

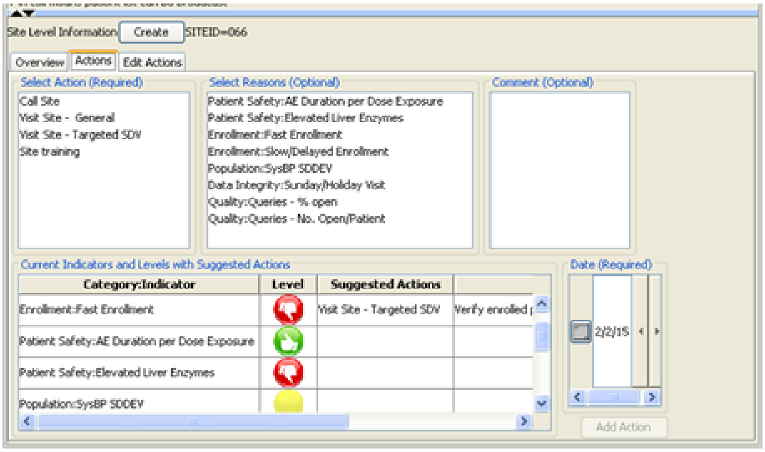
| | 06-JAN-2015 00:00 | 13-JAN-2015 00:00 | 20-JAN-2015 00:00 | 27-JAN-2015 00:00 |
|---|---|---|---|---|
| AE Duration per Dose Exposure | 👍 | 👍 | 👍 | 👍 |
| Elevated Liver Enzymes | 👎 | 👎 | 👎 | 👎 |
| Fast Enrollment | 👎 | ● | ● | 👎 |
| Queries - % open | 👎 | 👎 | 👎 | 👎 |
| Queries - No. Open/Patient | 👎 | ● | ● | 👎 |
| Slow/Delayed Enrollment | ● | ● | ● | ● |
| Sunday/Holiday Visit | 👍 | 👍 | 👍 | 👍 |
| SysBP SDDEV | ● | ● | ● | ● |

Selected: SITEID=066

Indicators in View: 5    Units in View: 7

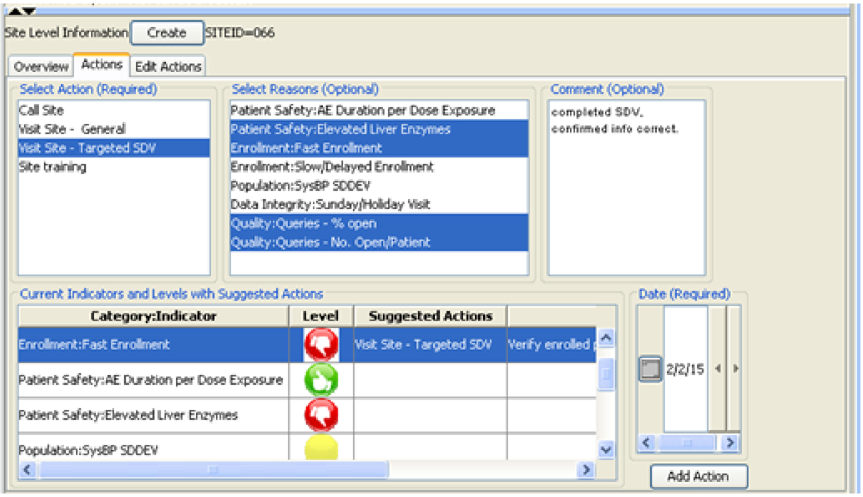
## Suggested Actions

To see a list of ‘**Suggested Actions**’ which have been generated as the result of the Risk Based Monitoring indicators and triggered suggested actions for various indicators and levels, click on the ‘**Actions**’ tab. This displays the list of current indicator, levels and suggested actions, along with additional comments from the RBM definition designer.



| Category:Indicator | Level | Suggested Actions | |
|---|---|---|---|
| Enrollment:Fast Enrollment | 👎 | Visit Site - Targeted SDV | Verify enrolled p |
| Patient Safety:AE Duration per Dose Exposure | 👍 | | |
| Patient Safety:Elevated Liver Enzymes | 👎 | | |
| Population:SysBP SDDEV | 🟡 | | |

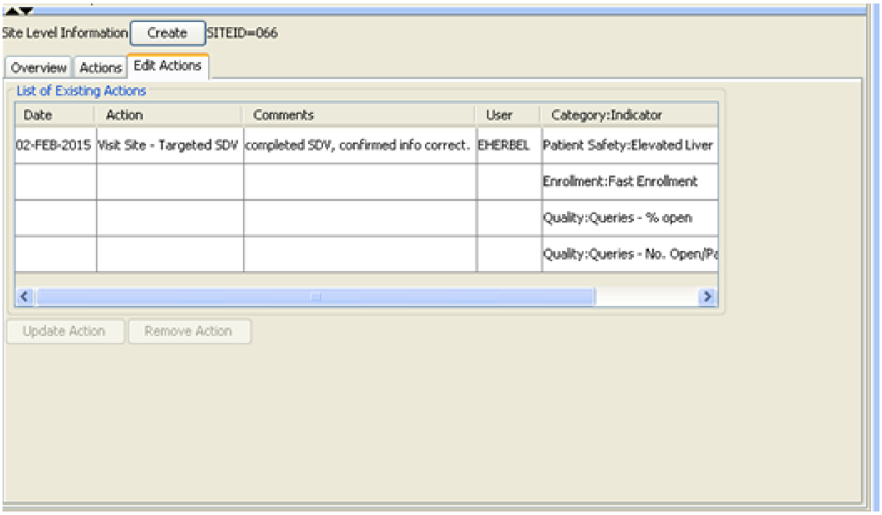
Once you have taken an action regarding the site, select the Action from the first listbox of available actions that have been defined in your environment. Optionally, select as many of the ‘Reasons’, i.e., Indicator descriptions, that apply to the action, and optionally enter a comment, select the ‘Date’, then click ‘Add Action’.



Comment (Optional): completed SDV, confirmed info correct.

| Category:Indicator | Level | Suggested Actions | |
|---|---|---|---|
| Enrollment:Fast Enrollment | 👎 | Visit Site - Targeted SDV | Verify enrolled p |
| Patient Safety:AE Duration per Dose Exposure | 👍 | | |
| Patient Safety:Elevated Liver Enzymes | 👎 | | |
| Population:SysBP SDDEV | 🟡 | | |

If you click on the ‘**Edit Actions**’ tab, you’ll see all actions that you or anyone else have added for the currently selected site.

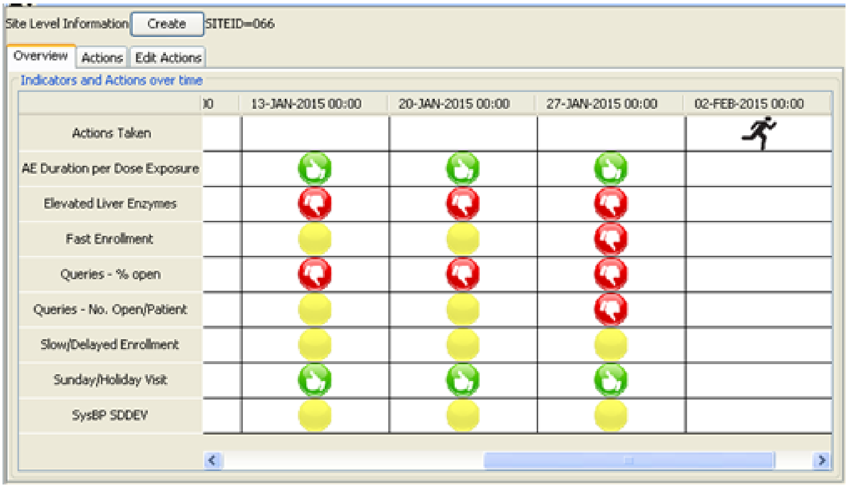


SITEID=066

List of Existing Actions

| Date | Action | Comments | User | Category:Indicator |
|---|---|---|---|---|
| 02-FEB-2015 | Visit Site - Targeted SDV | completed SDV, confirmed info correct. | EHERBEL | Patient Safety:Elevated Liver |
| | | | | Enrollment:Fast Enrollment |
| | | | | Quality:Queries - % open |
| | | | | Quality:Queries - No. Open/Pa |

Lastly, clicking back on the ‘**Overview**’ tab, and scrolling to the right to view the most recent dates, there is an icon in the ‘**Actions**’ row. It allows everyone reviewing the site, when an action was taken, in the context of when the RBM analyses were executed. The assumption would be that after an action has been taken: i.e., either visiting the site, communicating with the site, etc. – to discuss the situation and hopefully resolve the issue. You should see improved indicator results after the action was taken.



SITEID=066

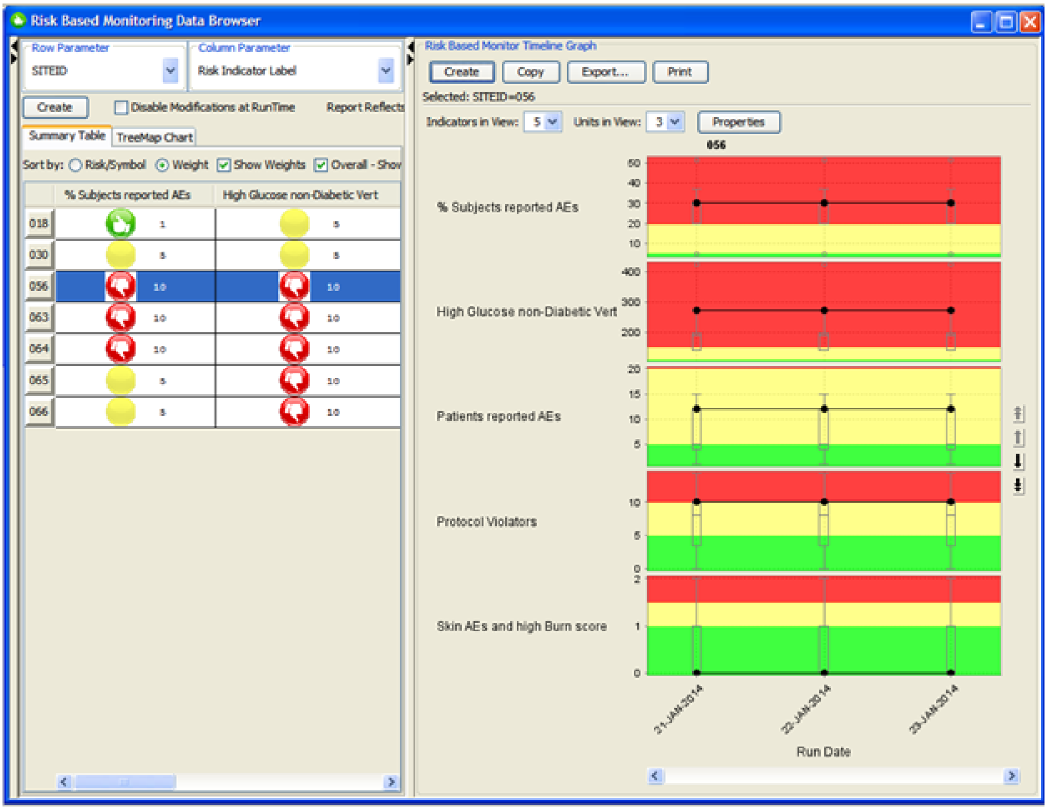
Indicators and Actions over time

| | 00 | 13-JAN-2015 00:00 | 20-JAN-2015 00:00 | 27-JAN-2015 00:00 | 02-FEB-2015 00:00 |
|---|---|---|---|---|---|
| Actions Taken | | | | | 🏃 |
| AE Duration per Dose Exposure | | 👍 | 👍 | 👍 | |
| Elevated Liver Enzymes | | 👎 | 👎 | 👎 | |
| Fast Enrollment | | 🟡 | 🟡 | 👎 | |
| Queries - % open | | 👎 | 👎 | 👎 | |
| Queries - No. Open/Patient | | 🟡 | 🟡 | 👎 | |
| Slow/Delayed Enrollment | | 🟡 | 🟡 | 🟡 | |
| Sunday/Holiday Visit | | 👍 | 👍 | 👍 | |
| SysBP SDDEV | | 🟡 | 🟡 | 🟡 | |

## Create RBM Timeline Graph

You must define the Summary Table first before viewing the Timeline Graph. Click **Create** for **Risk Based Monitor Timeline Graph** to display a Box Whiskers plot by Run Date. ***See Chapter 7: Graph Browser - section for Box Whiskers Plot.***

You can select a particular site from the summary table to view as plotted line on the Box Whiskers plot. This allows viewing where a site falls within the median plot range.



Row Parameter: SITEID

Column Parameter: Risk Indicator Label

Selected: SITEID=056

Indicators in View: 5

Units in View: 3

| | % Subjects reported AEs | High Glucose non-Diabetic Vert |
|---|---|---|
| 018 | 👍 1 | ● 5 |
| 030 | ● 5 | ● 5 |
| 056 | 👎 10 | 👎 10 |
| 063 | 👎 10 | 👎 10 |
| 064 | 👎 10 | 👎 10 |
| 065 | ● 5 | 👎 10 |
| 066 | ● 5 | 👎 10 |

The output window header provides options to **Copy, Export, or Print** the Timeline Graph results.

Use the **Indicators in View** to select how many indicators to display on the graph and use the right scroll arrows to move within the output.

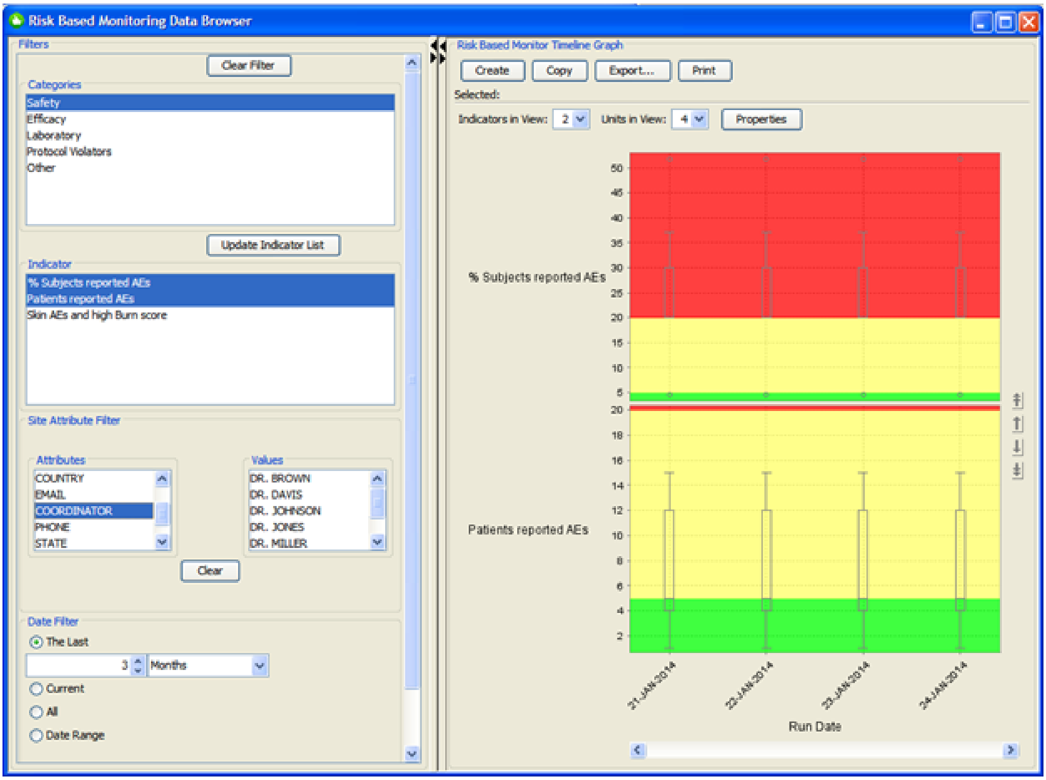
The **Units in View** feature selects how many Run dates to display.

Select **Properties** to change the **Subplot Label Orientation** view from horizontal to vertical.

## Apply RBM Filters

Optionally, apply filters to the Summary Table or Timeline Graph.

1. Select from the Categories list.
2. Click **Update Indicator List** to display Indicators, and select Indicators of interest.
3. Click **Create** for Summary Table and/or Timeline Graph to refresh output results.
4. Optional, select a **Site Attribute Filter** to further specify data results.
5. Optional, select a **Date Filter** may be used to view data within a preferred time range.
6. Click **Clear Filter** to remove all filters. Click **Create,** to return output results to original status.



Indicators in View: 2

Units in View: 4

● The Last 3 Months

## *Save RBM Data Browser object*

Once you define your risk based mointoring data browser parameters and filters, you can save this object to the output specifications. It will launch like any other saved J-Review output object.

In addition, there is an option for **Disable Modifications at Run Time**. If this option is selected when you save the risk based data browser object; then the user cannot change parameters, or filters while viewing. Left un-checked, the user can make adjustments for viewing results, but will not change the saved object specification. This allows you to save a variety of risk based data browser views. The result reflects the current data only.

# 17

# Templates Browser

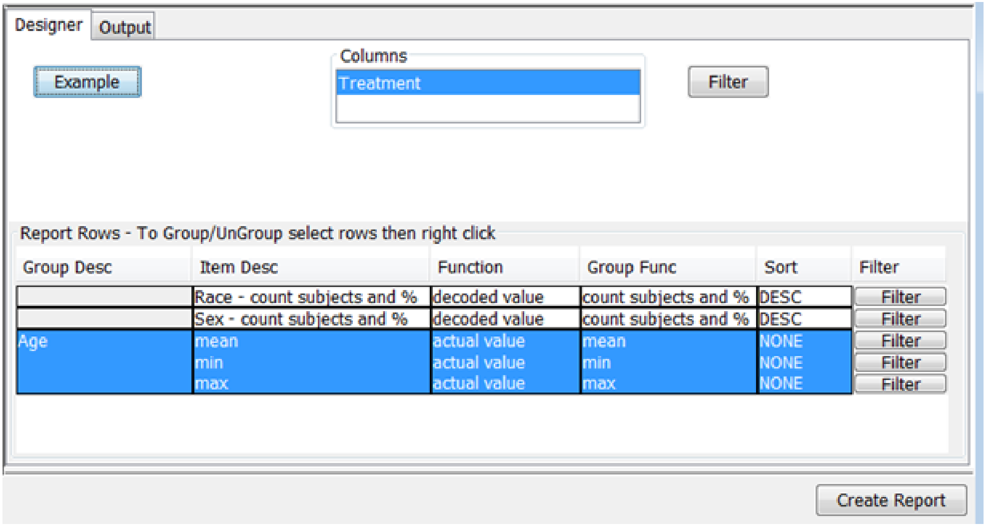
# Templates Browser

## *Report Templates*

The Templates Browser was developed to support the need for a form of template-based summary report generation. The goal is to enable JReview users to create reports resembling the more common summary tables seen in submissions to regulatory agencies. The user interfaces features drag-and-drop style report definition while also permitting some flexibility in presentation. The report output is "grid" style supporting cell selection broadcast to other output. The current “Demographic Summary Report” is the first available template report **Type**.

Report Templates are defined for a number of always used reports in clinical studies, for  Subject demographics and baseline characteristics overview (but can be used for any data items). The definition is easy to use drag & drop items, and select from an extensive list of information/functions, ‘group’ rows as appropriate.

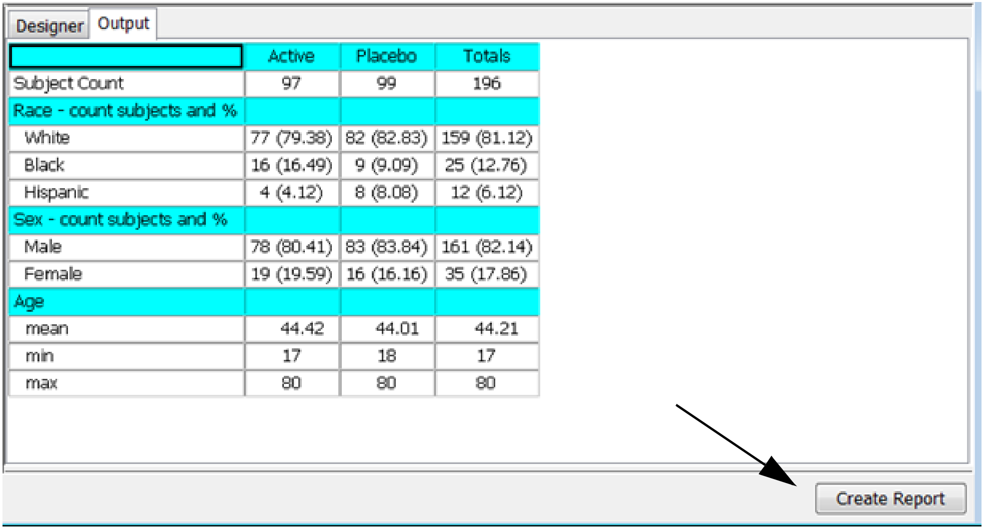
The Templates Reports window opens in **Designer tab** to build the report.



Columns: Treatment

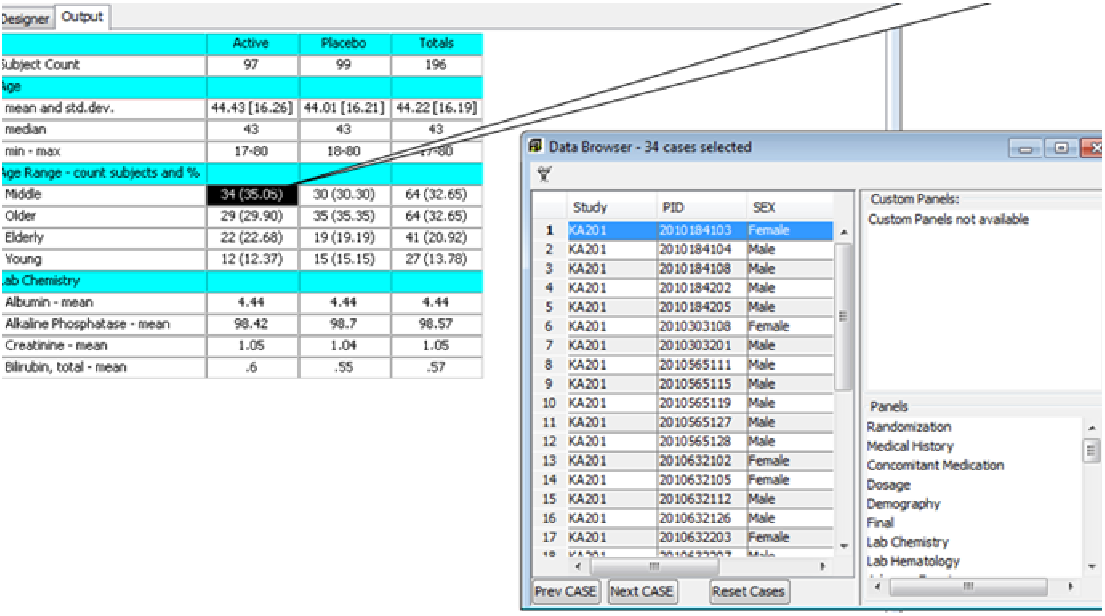
| Group Desc | Item Desc | Function | Group Func | Sort | Filter |
|---|---|---|---|---|---|
| | Race - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| | Sex - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| Age | mean | actual value | mean | NONE | Filter |
| | min | actual value | min | NONE | Filter |
| | max | actual value | max | NONE | Filter |

Use the **Output tab** to generate and view the report. Clicking the **Create Report** button creates the report in a separate window. The same behavior as other New Mode Browsers.



| | Active | Placebo | Totals |
|---|---|---|---|
| Subject Count | 97 | 99 | 196 |
| Race - count subjects and % | | | |
| White | 77 (79.38) | 82 (82.83) | 159 (81.12) |
| Black | 16 (16.49) | 9 (9.09) | 25 (12.76) |
| Hispanic | 4 (4.12) | 8 (8.08) | 12 (6.12) |
| Sex - count subjects and % | | | |
| Male | 78 (80.41) | 83 (83.84) | 161 (82.14) |
| Female | 19 (19.59) | 16 (16.16) | 35 (17.86) |
| Age | | | |
| mean | 44.42 | 44.01 | 44.21 |
| min | 17 | 18 | 17 |
| max | 80 | 80 | 80 |

Drilldown is available for all subject counts.



| | Active | Placebo | Totals |
|---|---|---|---|
| ubject Count | 97 | 99 | 196 |
| ge | | | |
| mean and std.dev. | 44.43 [16.26] | 44.01 [16.21] | 44.22 [16.19] |
| median | 43 | 43 | 43 |
| min - max | 17-80 | 18-80 | 17-80 |
| ge Range - count subjects and % | | | |
| Middle | 34 (35.05) | 30 (30.30) | 64 (32.65) |
| Older | 29 (29.90) | 35 (35.35) | 64 (32.65) |
| Elderly | 22 (22.68) | 19 (19.19) | 41 (20.92) |
| Young | 12 (12.37) | 15 (15.15) | 27 (13.78) |
| ab Chemistry | | | |
| Albumin - mean | 4.44 | 4.44 | 4.44 |
| Alkaline Phosphatase - mean | 98.42 | 98.7 | 98.57 |
| Creatinine - mean | 1.05 | 1.04 | 1.05 |
| Bilirubin, total - mean | .6 | .55 | .57 |

Data Browser - 34 cases selected

| | Study | PID | SEX |
|---|---|---|---|
| 1 | KA201 | 2010184103 | Female |
| 2 | KA201 | 2010184104 | Male |
| 3 | KA201 | 2010184108 | Male |
| 4 | KA201 | 2010184202 | Male |
| 5 | KA201 | 2010184205 | Male |
| 6 | KA201 | 2010303108 | Female |
| 7 | KA201 | 2010303201 | Male |
| 8 | KA201 | 2010565111 | Male |
| 9 | KA201 | 2010565115 | Male |
| 10 | KA201 | 2010565119 | Male |
| 11 | KA201 | 2010565127 | Male |
| 12 | KA201 | 2010565128 | Male |
| 13 | KA201 | 2010632102 | Female |
| 14 | KA201 | 2010632105 | Female |
| 15 | KA201 | 2010632112 | Male |
| 16 | KA201 | 2010632126 | Male |
| 17 | KA201 | 2010632203 | Female |

Custom Panels:
Custom Panels not available

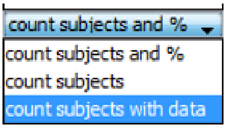
Panels
Randomization
Medical History
Concomitant Medication
Dosage
Demography
Final
Lab Chemistry
Lab Hematology

## *Template Functions*

There are a variety of template functions for grouping, statistics, and sort options that may be applied.

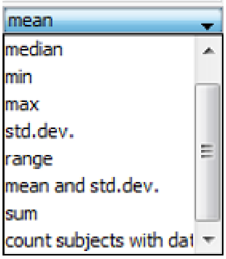
**New grouping functions:**

- For Categorical Data
- Count of subjects and %
- Count of subjects
- Count of subjects with data



**For Continuous Data:**

- Mean
- Median
- Min
- Max
- Std. dev.
- Range
- Mean and Std. Dev.
- Sum
- Count of subjects with data



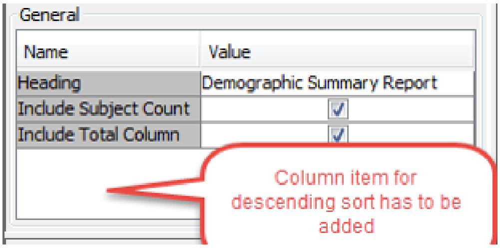
**Sort Options for Categorical Data:**

- Descending (based on first column) is the default.
- Alpha
- Coded

Sort option of NONE is only valid for continuous data rows. Categorical data must have sort set to DESC, ALPHA or CODE.

**Overall Options:**

- Include Subject Count
- Include a Total Count
- Define column to base descending sort.



| Name | Value |
|---|---|
| Heading | Demographic Summary Report |
| Include Subject Count | ☑ |
| Include Total Column | ☑ |

Column item for descending sort has to be added

## *Default decimal places*

The default number of decimal places for percentages is 1 rather than the prior default of 2.

Newly-built Template types (Demog, Incidence) will now start out with 1/one N (%) decimal place. A N (%) decimal place change widget, similar to the one in Crosstab Browsers, has been added to both Template Designers in General Properties.

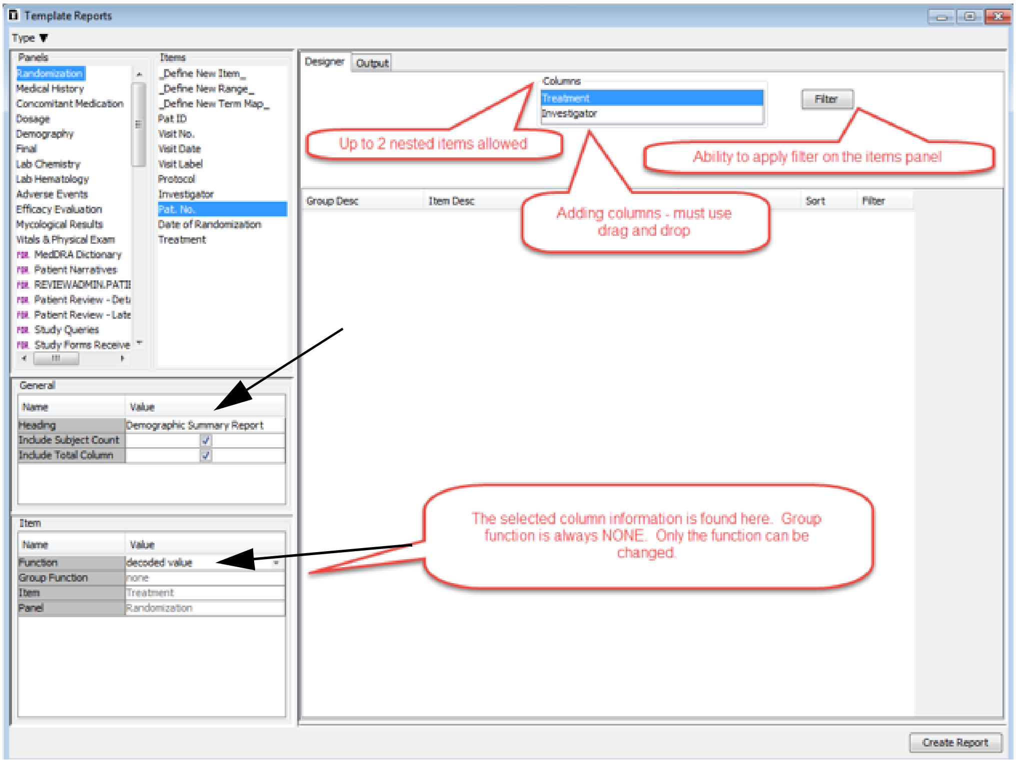
**This change does impact saved Demographic Templates, they will show one/1 N (%) decimal place rather than 2**. This can be changed using a new General N (%) decimal place change property ("Decimal Places (%)").

## *Define Template Report*

Define a template report by clicking on the **Templates icon** in the toolbar , or from the **Browse menu** select **Template Reports**. The Templates Reports definition window opens in the Designer tab.

In this example, **Type**='Demographic Summary Report' is just a description of a very common table/pattern included for most studies.

**Columns** can be defined by up to 2 grouping items (nesting items) with an optional filter. The selected column information is found in the left Items table. Group function is ***always*** NONE. Only the function can be changed.



| Name | Value |
|---|---|
| Heading | Demographic Summary Report |
| Include Subject Count | ✓ |
| Include Total Column | ✓ |

| Name | Value |
|---|---|
| Function | decoded value |
| Group Function | none |
| Item | Treatment |
| Panel | Randomization |

Up to 2 nested items allowed

Ability to apply filter on the items panel

Adding columns - must use drag and drop

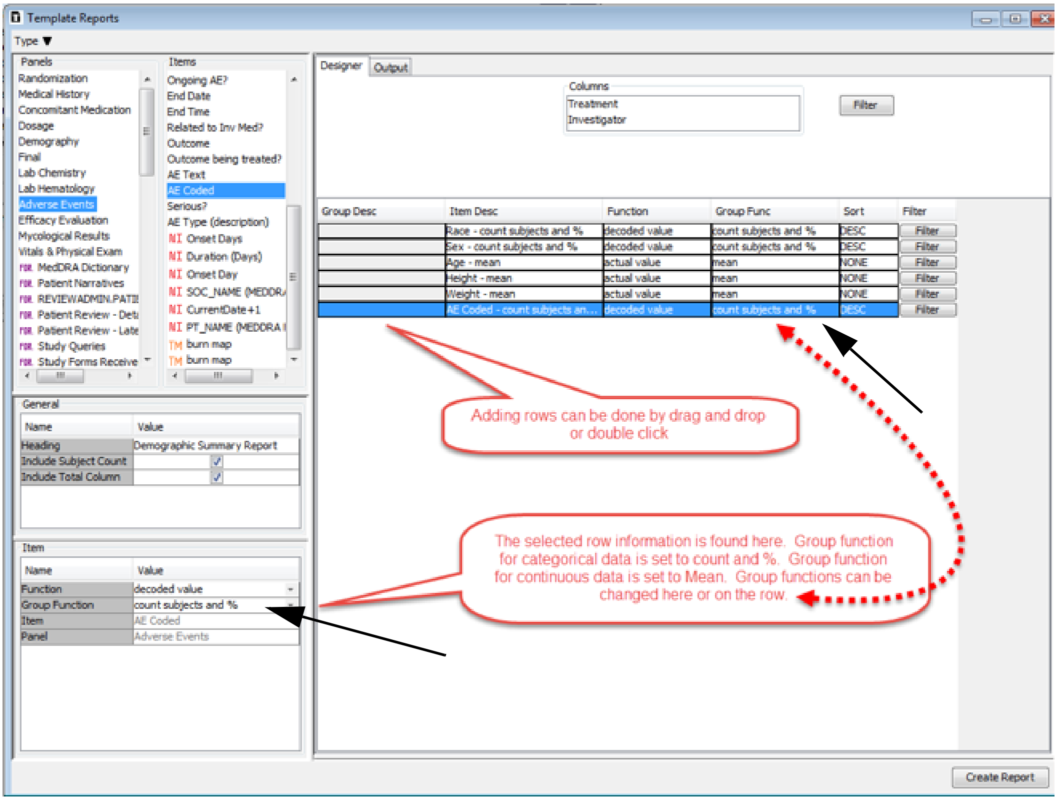
The selected column information is found here. Group function is always NONE. Only the function can be changed.

Add rows by drag and drop or double click.

The selected row information is listed in the Item table to the left.

Group function for ***categorical data*** is set to count and % shown in the rows added in the **Designer tab**.

Group function for ***continuous data*** is set to Mean.  Select the item row to change the Group function from the Item tabel, or in the Group Func column.



General

| Name | Value |
|---|---|
| Heading | Demographic Summary Report |
| Include Subject Count | ✓ |
| Include Total Column | ✓ |

Item

| Name | Value |
|---|---|
| Function | decoded value |
| Group Function | count subjects and % |
| Item | AE Coded |
| Panel | Adverse Events |

| Group Desc | Item Desc | Function | Group Func | Sort | Filter |
|---|---|---|---|---|---|
| | Race - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| | Sex - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| | Age - mean | actual value | mean | NONE | Filter |
| | Height - mean | actual value | mean | NONE | Filter |
| | Weight - mean | actual value | mean | NONE | Filter |
| | AE Coded - count subjects an... | decoded value | count subjects and % | DESC | Filter |

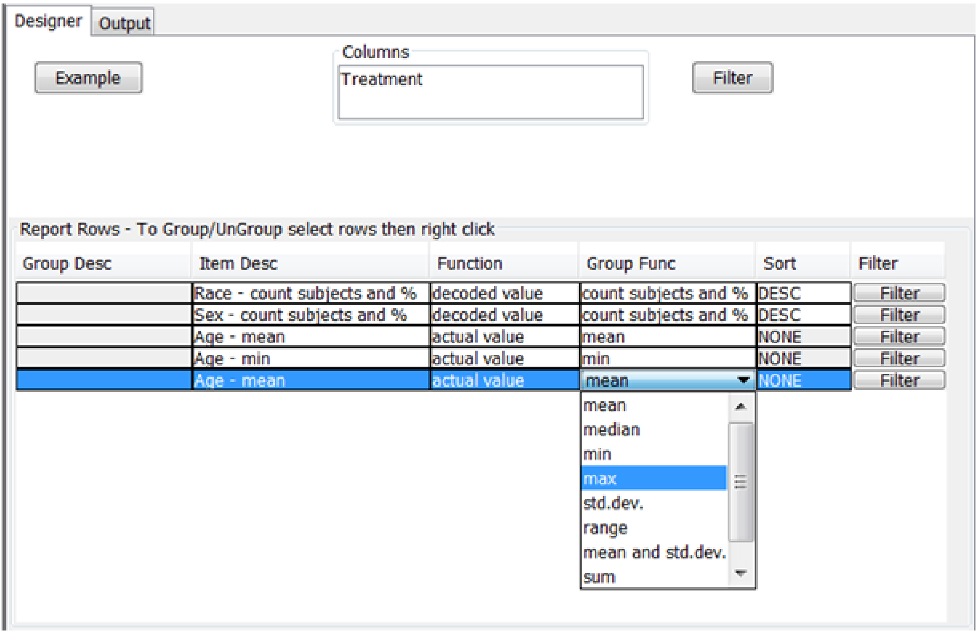
Adding rows can be done by drag and drop or double click

The selected row information is found here.  Group function for categorical data is set to count and %.  Group function for continuous data is set to Mean.  Group functions can be changed here or on the row.

Categorical items default grouping function is **count subjects and %** sorted descending based on first column.

Numeric items default grouping function is **Mean**.

Each row can have an ***optional*** **Filter** applied.



Columns

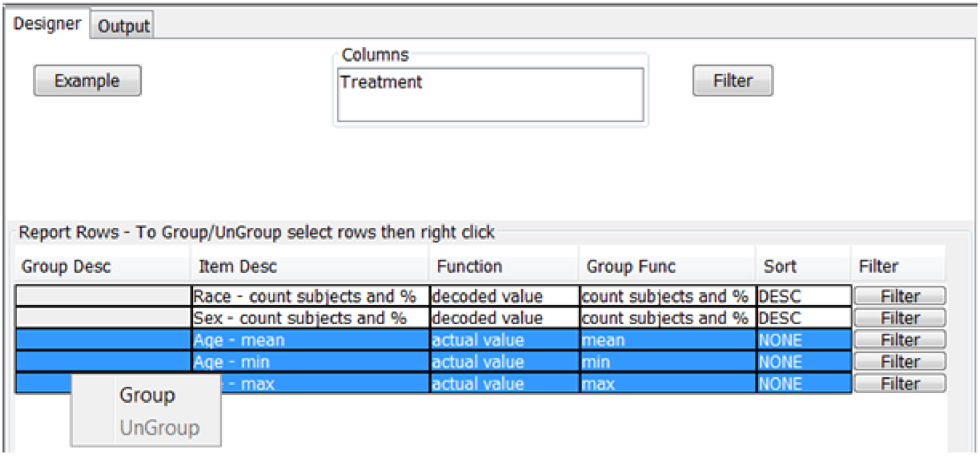
Treatment

Report Rows - To Group/UnGroup select rows then right click

| Group Desc | Item Desc | Function | Group Func | Sort | Filter |
|---|---|---|---|---|---|
| | Race - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| | Sex - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| | Age - mean | actual value | mean | NONE | Filter |
| | Age - min | actual value | min | NONE | Filter |
| | Age - mean | actual value | mean | NONE | Filter |

Shown here are Demographic row items:

- Item descriptions are all editable. Double click within the **Item** Description cell to edit.
- **Group** description is available when two or more rows are grouped allowing for a custom Group description. Highlight cells then right click to display the floating menu to **Group** or **UnGroup**.

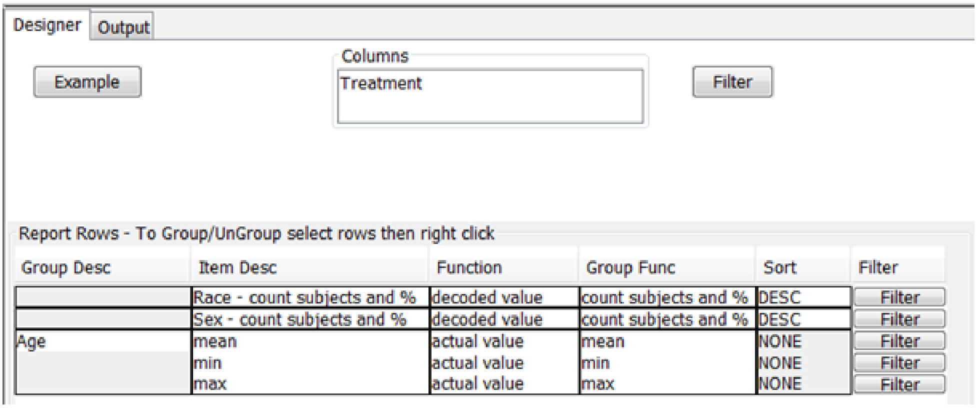


Columns
Treatment

Report Rows - To Group/UnGroup select rows then right click

| Group Desc | Item Desc | Function | Group Func | Sort | Filter |
|---|---|---|---|---|---|
| | Race - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| | Sex - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| | Age - mean | actual value | mean | NONE | Filter |
| | Age - min | actual value | min | NONE | Filter |
| | - max | actual value | max | NONE | Filter |

- Select Group and the group description is automatically added.

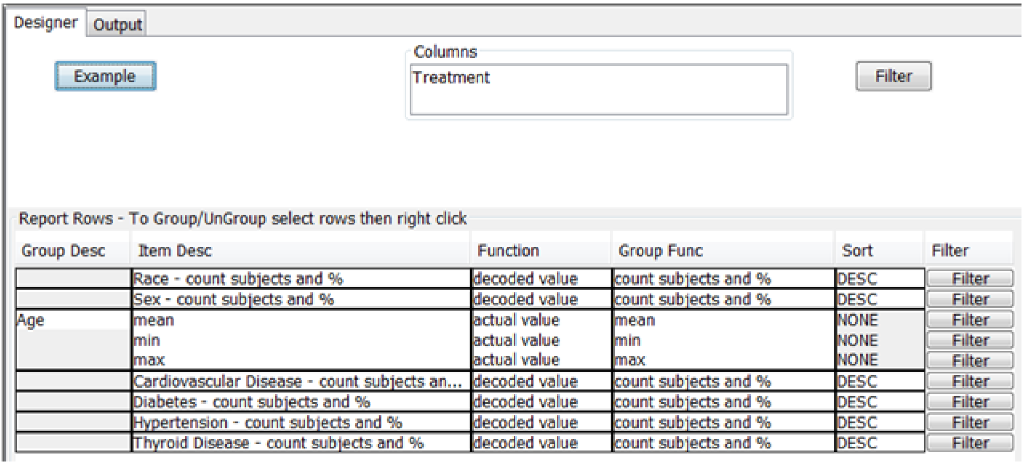


Columns
Treatment

Report Rows - To Group/UnGroup select rows then right click

| Group Desc | Item Desc | Function | Group Func | Sort | Filter |
|---|---|---|---|---|---|
| | Race - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| | Sex - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| Age | mean | actual value | mean | NONE | Filter |
| | min | actual value | min | NONE | Filter |
| | max | actual value | max | NONE | Filter |

- Add more items to report rows.

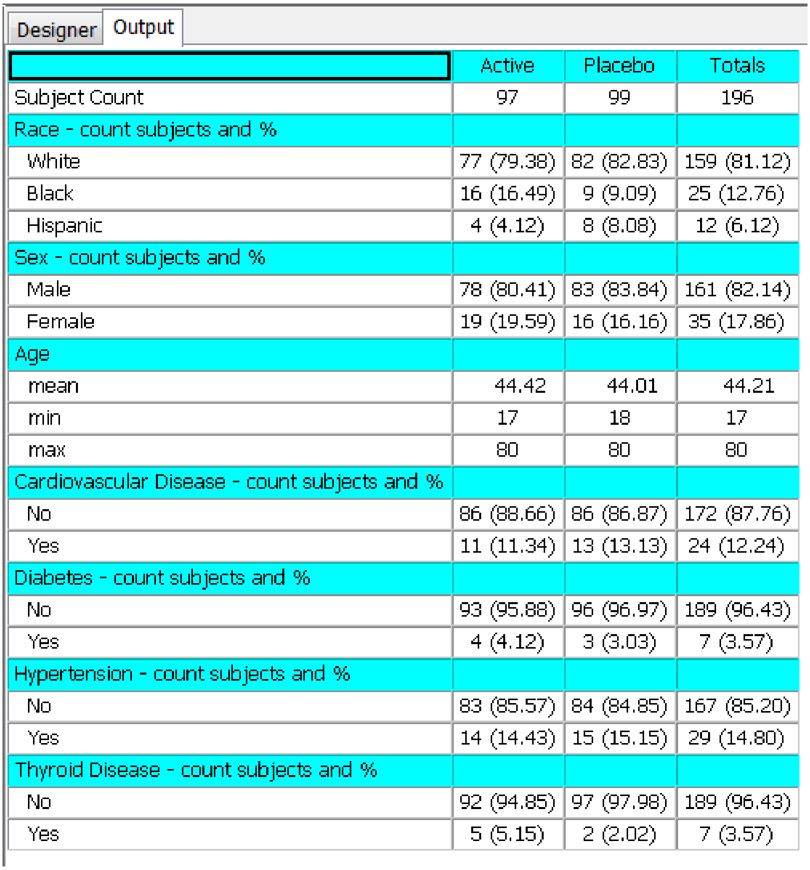


Columns: Treatment

Report Rows - To Group/UnGroup select rows then right click

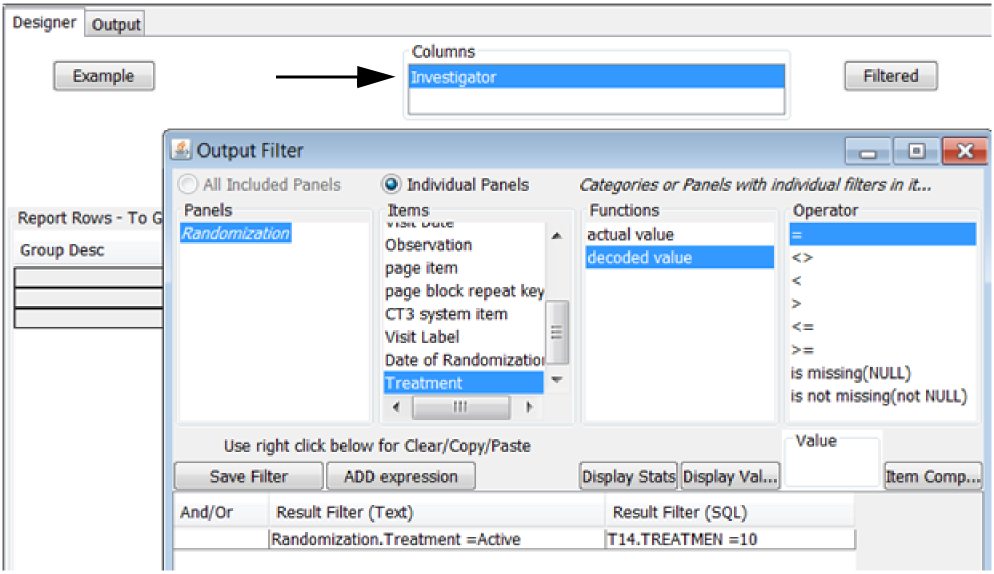
| Group Desc | Item Desc | Function | Group Func | Sort | Filter |
|---|---|---|---|---|---|
| | Race - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| | Sex - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| Age | mean | actual value | mean | NONE | Filter |
| | min | actual value | min | NONE | Filter |
| | max | actual value | max | NONE | Filter |
| | Cardiovascular Disease - count subjects an... | decoded value | count subjects and % | DESC | Filter |
| | Diabetes - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| | Hypertension - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| | Thyroid Disease - count subjects and % | decoded value | count subjects and % | DESC | Filter |

- View Output tab.



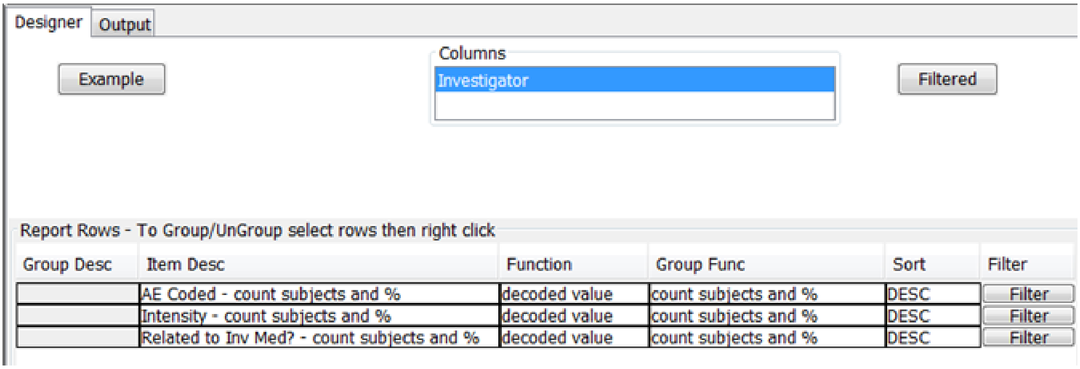
| | Active | Placebo | Totals |
|---|---|---|---|
| Subject Count | 97 | 99 | 196 |
| Race - count subjects and % | | | |
| White | 77 (79.38) | 82 (82.83) | 159 (81.12) |
| Black | 16 (16.49) | 9 (9.09) | 25 (12.76) |
| Hispanic | 4 (4.12) | 8 (8.08) | 12 (6.12) |
| Sex - count subjects and % | | | |
| Male | 78 (80.41) | 83 (83.84) | 161 (82.14) |
| Female | 19 (19.59) | 16 (16.16) | 35 (17.86) |
| Age | | | |
| mean | 44.42 | 44.01 | 44.21 |
| min | 17 | 18 | 17 |
| max | 80 | 80 | 80 |
| Cardiovascular Disease - count subjects and % | | | |
| No | 86 (88.66) | 86 (86.87) | 172 (87.76) |
| Yes | 11 (11.34) | 13 (13.13) | 24 (12.24) |
| Diabetes - count subjects and % | | | |
| No | 93 (95.88) | 96 (96.97) | 189 (96.43) |
| Yes | 4 (4.12) | 3 (3.03) | 7 (3.57) |
| Hypertension - count subjects and % | | | |
| No | 83 (85.57) | 84 (84.85) | 167 (85.20) |
| Yes | 14 (14.43) | 15 (15.15) | 29 (14.80) |
| Thyroid Disease - count subjects and % | | | |
| No | 92 (94.85) | 97 (97.98) | 189 (96.43) |
| Yes | 5 (5.15) | 2 (2.02) | 7 (3.57) |

In this example, a filter was applied to the Investigator column from the Randomization panel.  When the Output Filter is saved the button changes status to ‘**Filtered**’.



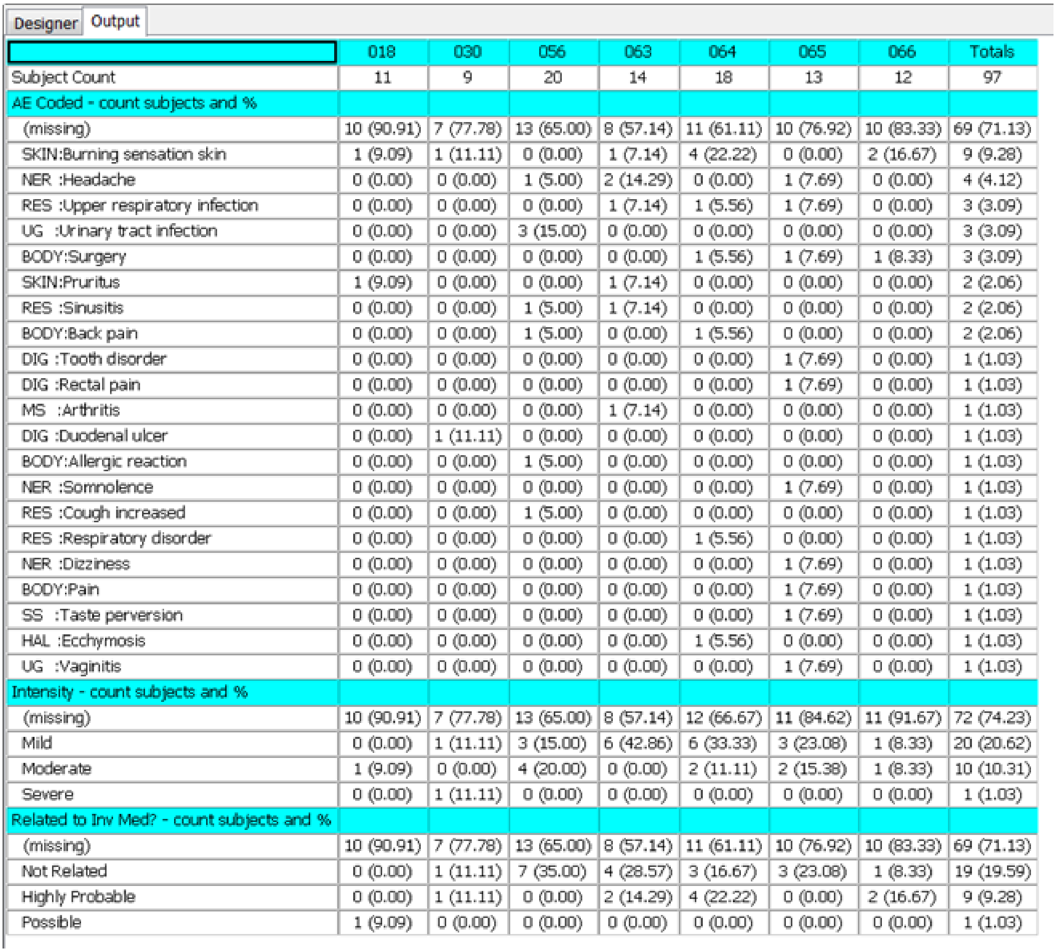
| And/Or | Result Filter (Text) | Result Filter (SQL) |
|---|---|---|
| | Randomization.Treatment =Active | T14.TREATMEN =10 |

**Report Rows** were added from the Adverse Events panel.



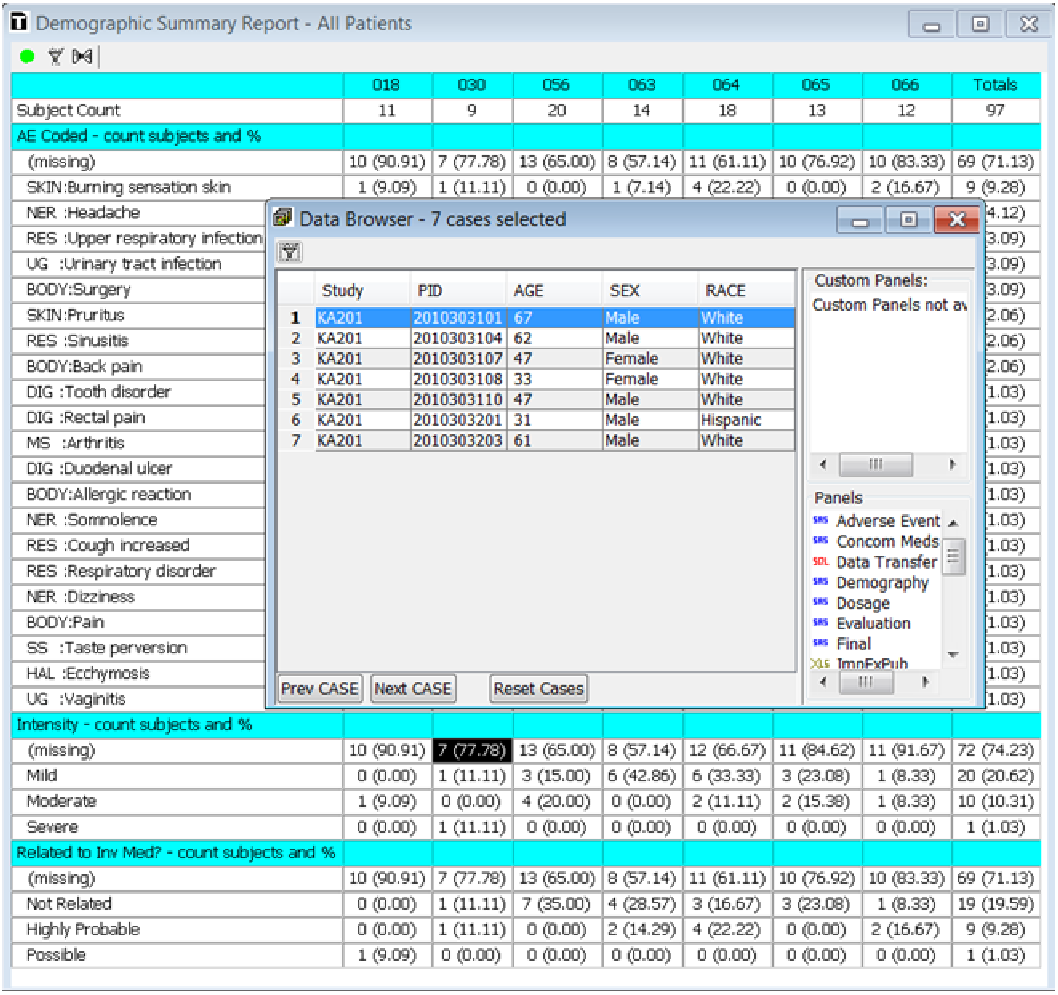
| Group Desc | Item Desc | Function | Group Func | Sort | Filter |
|---|---|---|---|---|---|
| | AE Coded - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| | Intensity - count subjects and % | decoded value | count subjects and % | DESC | Filter |
| | Related to Inv Med? - count subjects and % | decoded value | count subjects and % | DESC | Filter |

Click on the **Output tab** to view.



| | 018 | 030 | 056 | 063 | 064 | 065 | 066 | Totals |
|---|---|---|---|---|---|---|---|---|
| Subject Count | 11 | 9 | 20 | 14 | 18 | 13 | 12 | 97 |
| AE Coded - count subjects and % | | | | | | | | |
| (missing) | 10 (90.91) | 7 (77.78) | 13 (65.00) | 8 (57.14) | 11 (61.11) | 10 (76.92) | 10 (83.33) | 69 (71.13) |
| SKIN:Burning sensation skin | 1 (9.09) | 1 (11.11) | 0 (0.00) | 1 (7.14) | 4 (22.22) | 0 (0.00) | 2 (16.67) | 9 (9.28) |
| NER :Headache | 0 (0.00) | 0 (0.00) | 1 (5.00) | 2 (14.29) | 0 (0.00) | 1 (7.69) | 0 (0.00) | 4 (4.12) |
| RES :Upper respiratory infection | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (7.14) | 1 (5.56) | 1 (7.69) | 0 (0.00) | 3 (3.09) |
| UG :Urinary tract infection | 0 (0.00) | 0 (0.00) | 3 (15.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 3 (3.09) |
| BODY:Surgery | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (5.56) | 1 (7.69) | 1 (8.33) | 3 (3.09) |
| SKIN:Pruritus | 1 (9.09) | 0 (0.00) | 0 (0.00) | 1 (7.14) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 2 (2.06) |
| RES :Sinusitis | 0 (0.00) | 0 (0.00) | 1 (5.00) | 1 (7.14) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 2 (2.06) |
| BODY:Back pain | 0 (0.00) | 0 (0.00) | 1 (5.00) | 0 (0.00) | 1 (5.56) | 0 (0.00) | 0 (0.00) | 2 (2.06) |
| DIG :Tooth disorder | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (7.69) | 0 (0.00) | 1 (1.03) |
| DIG :Rectal pain | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (7.69) | 0 (0.00) | 1 (1.03) |
| MS :Arthritis | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (7.14) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (1.03) |
| DIG :Duodenal ulcer | 0 (0.00) | 1 (11.11) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (1.03) |
| BODY:Allergic reaction | 0 (0.00) | 0 (0.00) | 1 (5.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (1.03) |
| NER :Somnolence | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (7.69) | 0 (0.00) | 1 (1.03) |
| RES :Cough increased | 0 (0.00) | 0 (0.00) | 1 (5.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (1.03) |
| RES :Respiratory disorder | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (5.56) | 0 (0.00) | 0 (0.00) | 1 (1.03) |
| NER :Dizziness | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (7.69) | 0 (0.00) | 1 (1.03) |
| BODY:Pain | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (7.69) | 0 (0.00) | 1 (1.03) |
| SS :Taste perversion | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (7.69) | 0 (0.00) | 1 (1.03) |
| HAL :Ecchymosis | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (5.56) | 0 (0.00) | 0 (0.00) | 1 (1.03) |
| UG :Vaginitis | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (7.69) | 0 (0.00) | 1 (1.03) |
| Intensity - count subjects and % | | | | | | | | |
| (missing) | 10 (90.91) | 7 (77.78) | 13 (65.00) | 8 (57.14) | 12 (66.67) | 11 (84.62) | 11 (91.67) | 72 (74.23) |
| Mild | 0 (0.00) | 1 (11.11) | 3 (15.00) | 6 (42.86) | 6 (33.33) | 3 (23.08) | 1 (8.33) | 20 (20.62) |
| Moderate | 1 (9.09) | 0 (0.00) | 4 (20.00) | 0 (0.00) | 2 (11.11) | 2 (15.38) | 1 (8.33) | 10 (10.31) |
| Severe | 0 (0.00) | 1 (11.11) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (1.03) |
| Related to Inv Med? - count subjects and % | | | | | | | | |
| (missing) | 10 (90.91) | 7 (77.78) | 13 (65.00) | 8 (57.14) | 11 (61.11) | 10 (76.92) | 10 (83.33) | 69 (71.13) |
| Not Related | 0 (0.00) | 1 (11.11) | 7 (35.00) | 4 (28.57) | 3 (16.67) | 3 (23.08) | 1 (8.33) | 19 (19.59) |
| Highly Probable | 0 (0.00) | 1 (11.11) | 0 (0.00) | 2 (14.29) | 4 (22.22) | 0 (0.00) | 2 (16.67) | 9 (9.28) |
| Possible | 1 (9.09) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (1.03) |

Click **Create Report** for results and to interface with other output browsers.



| | 018 | 030 | 056 | 063 | 064 | 065 | 066 | Totals |
|---|---|---|---|---|---|---|---|---|
| Subject Count | 11 | 9 | 20 | 14 | 18 | 13 | 12 | 97 |
| AE Coded - count subjects and % | | | | | | | | |
| (missing) | 10 (90.91) | 7 (77.78) | 13 (65.00) | 8 (57.14) | 11 (61.11) | 10 (76.92) | 10 (83.33) | 69 (71.13) |
| SKIN:Burning sensation skin | 1 (9.09) | 1 (11.11) | 0 (0.00) | 1 (7.14) | 4 (22.22) | 0 (0.00) | 2 (16.67) | 9 (9.28) |
| NER :Headache | | | | | | | | 4.12) |
| RES :Upper respiratory infection | | | | | | | | 3.09) |
| UG :Urinary tract infection | | | | | | | | 3.09) |
| BODY:Surgery | | | | | | | | 3.09) |
| SKIN:Pruritus | | | | | | | | 2.06) |
| RES :Sinusitis | | | | | | | | 2.06) |
| BODY:Back pain | | | | | | | | 2.06) |
| DIG :Tooth disorder | | | | | | | | 1.03) |
| DIG :Rectal pain | | | | | | | | 1.03) |
| MS :Arthritis | | | | | | | | 1.03) |
| DIG :Duodenal ulcer | | | | | | | | 1.03) |
| BODY:Allergic reaction | | | | | | | | 1.03) |
| NER :Somnolence | | | | | | | | 1.03) |
| RES :Cough increased | | | | | | | | 1.03) |
| RES :Respiratory disorder | | | | | | | | 1.03) |
| NER :Dizziness | | | | | | | | 1.03) |
| BODY:Pain | | | | | | | | 1.03) |
| SS :Taste perversion | | | | | | | | 1.03) |
| HAL :Ecchymosis | | | | | | | | 1.03) |
| UG :Vaginitis | | | | | | | | 1.03) |
| Intensity - count subjects and % | | | | | | | | |
| (missing) | 10 (90.91) | 7 (77.78) | 13 (65.00) | 8 (57.14) | 12 (66.67) | 11 (84.62) | 11 (91.67) | 72 (74.23) |
| Mild | 0 (0.00) | 1 (11.11) | 3 (15.00) | 6 (42.86) | 6 (33.33) | 3 (23.08) | 1 (8.33) | 20 (20.62) |
| Moderate | 1 (9.09) | 0 (0.00) | 4 (20.00) | 0 (0.00) | 2 (11.11) | 2 (15.38) | 1 (8.33) | 10 (10.31) |
| Severe | 0 (0.00) | 1 (11.11) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (1.03) |
| Related to Inv Med? - count subjects and % | | | | | | | | |
| (missing) | 10 (90.91) | 7 (77.78) | 13 (65.00) | 8 (57.14) | 11 (61.11) | 10 (76.92) | 10 (83.33) | 69 (71.13) |
| Not Related | 0 (0.00) | 1 (11.11) | 7 (35.00) | 4 (28.57) | 3 (16.67) | 3 (23.08) | 1 (8.33) | 19 (19.59) |
| Highly Probable | 0 (0.00) | 1 (11.11) | 0 (0.00) | 2 (14.29) | 4 (22.22) | 0 (0.00) | 2 (16.67) | 9 (9.28) |
| Possible | 1 (9.09) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (1.03) |

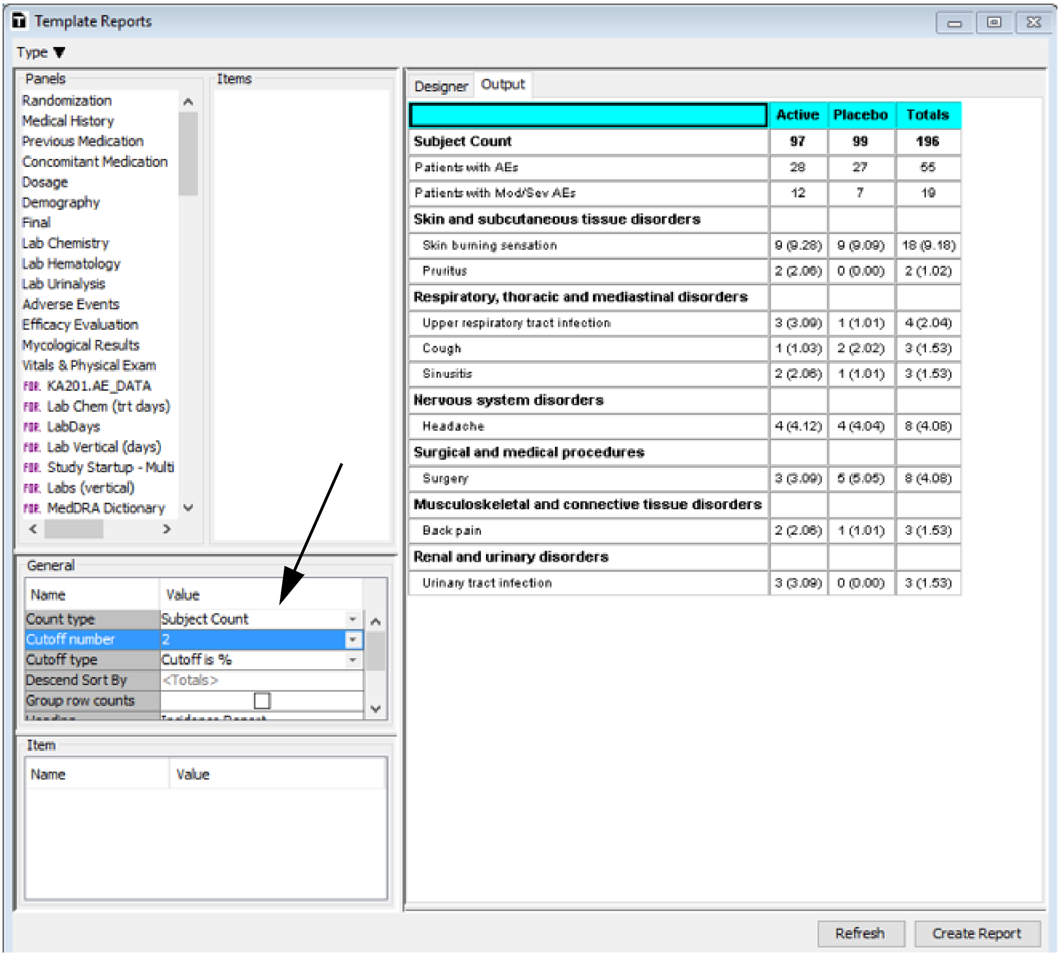
| | Study | PID | AGE | SEX | RACE |
|---|---|---|---|---|---|
| 1 | KA201 | 2010303101 | 67 | Male | White |
| 2 | KA201 | 2010303104 | 62 | Male | White |
| 3 | KA201 | 2010303107 | 47 | Female | White |
| 4 | KA201 | 2010303108 | 33 | Female | White |
| 5 | KA201 | 2010303110 | 47 | Male | White |
| 6 | KA201 | 2010303201 | 31 | Male | Hispanic |
| 7 | KA201 | 2010303203 | 61 | Male | White |

Another example, would be to define an Adverse Event summary table of multiple nested sorts (SOC, then PT within) with ‘cell’ content specified (default n(%)). It has the same user interface, but also supporting traditional ‘nested sorts’ for different AE MedDRA levels (SOC, PT or SMQ, PT, etc.).

As with the ‘Demographic Summary table’, use the drag and drop interface to add AE coded term levels to the definition. Typically added are SOC and PT, as well as a ‘column’ variable either Study, or some other categorical item. Then apply some ‘general overview’ statistics to display number of patients with AEs as well as different subsets, for example, number of patients Serious AEs, etc.

The default presentation is in descending order of most frequent SOC reports with PTs nested below, also in descending order of most frequent PT reports. The other commonly requested feature is to be able to specify a cutoff %, for example - 2, which means that detail levels (PT) entries are only included if at least one of the entries for the PT are at least 2% of the population. And the SOCs are included only if at least one of their PTs meet the cutoff. The cutoff % or cutoff count is also interactive, so users can experiment with the different cutoff % to see the resulting content. If multiple columns, such as treatment group are included, the user can choose which to use for descending sort, or <totals>.

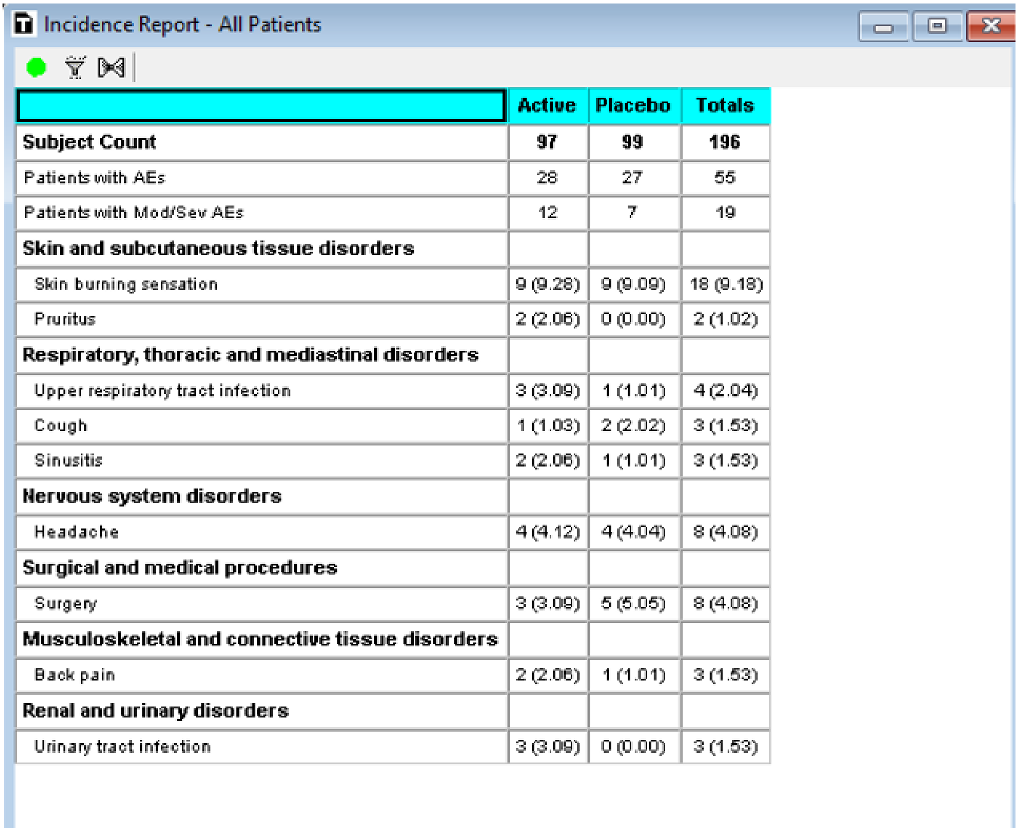
Here is a screenshot of the ‘preview’ display of the Incidence table showing the cutoff % selection. etc.



| Name | Value |
|---|---|
| Count type | Subject Count |
| Cutoff number | 2 |
| Cutoff type | Cutoff is % |
| Descend Sort By | <Totals> |
| Group row counts | ☐ |

| | Active | Placebo | Totals |
|---|---|---|---|
| **Subject Count** | **97** | **99** | **196** |
| Patients with AEs | 28 | 27 | 55 |
| Patients with Mod/Sev AEs | 12 | 7 | 19 |
| **Skin and subcutaneous tissue disorders** | | | |
| Skin burning sensation | 9 (9.28) | 9 (9.09) | 18 (9.18) |
| Pruritus | 2 (2.06) | 0 (0.00) | 2 (1.02) |
| **Respiratory, thoracic and mediastinal disorders** | | | |
| Upper respiratory tract infection | 3 (3.09) | 1 (1.01) | 4 (2.04) |
| Cough | 1 (1.03) | 2 (2.02) | 3 (1.53) |
| Sinusitis | 2 (2.06) | 1 (1.01) | 3 (1.53) |
| **Nervous system disorders** | | | |
| Headache | 4 (4.12) | 4 (4.04) | 8 (4.08) |
| **Surgical and medical procedures** | | | |
| Surgery | 3 (3.09) | 5 (5.05) | 8 (4.08) |
| **Musculoskeletal and connective tissue disorders** | | | |
| Back pain | 2 (2.06) | 1 (1.01) | 3 (1.53) |
| **Renal and urinary disorders** | | | |
| Urinary tract infection | 3 (3.09) | 0 (0.00) | 3 (1.53) |

When the user either saves and executes the saved definition from the Object Explorer, or clicks the ‘Create Report’ button – a window displaying the results is displayed. Observe the results are also clickable – just like a crosstab – so if the user clicks on any of the cells in the table – they’ll see which patients are contained within the count (highlighting those patients in any reports, graphs, patient profiles displayed).



| | Active | Placebo | Totals |
|---|---|---|---|
| **Subject Count** | **97** | **99** | **196** |
| Patients with AEs | 28 | 27 | 55 |
| Patients with Mod/Sev AEs | 12 | 7 | 19 |
| **Skin and subcutaneous tissue disorders** | | | |
| Skin burning sensation | 9 (9.28) | 9 (9.09) | 18 (9.18) |
| Pruritus | 2 (2.06) | 0 (0.00) | 2 (1.02) |
| **Respiratory, thoracic and mediastinal disorders** | | | |
| Upper respiratory tract infection | 3 (3.09) | 1 (1.01) | 4 (2.04) |
| Cough | 1 (1.03) | 2 (2.02) | 3 (1.53) |
| Sinusitis | 2 (2.06) | 1 (1.01) | 3 (1.53) |
| **Nervous system disorders** | | | |
| Headache | 4 (4.12) | 4 (4.04) | 8 (4.08) |
| **Surgical and medical procedures** | | | |
| Surgery | 3 (3.09) | 5 (5.05) | 8 (4.08) |
| **Musculoskeletal and connective tissue disorders** | | | |
| Back pain | 2 (2.06) | 1 (1.01) | 3 (1.53) |
| **Renal and urinary disorders** | | | |
| Urinary tract infection | 3 (3.09) | 0 (0.00) | 3 (1.53) |

# 18

# Data Quality Statistics Analysis

# Data Quality Statistics Summary

## *Centralized Statistical Review*

The Data Quality Statistics Summary provides an ‘unsupervised’ centralized statistical review of data in a trial – on an ongoing basis – directly against the data accessed by JReview. This area runs a battery of tests against the data – including duplicate patient detection, and a wide range of statistical tests, then generates a ‘global score’ for each geographic area (country, for example), and each site within the region. The data to be included in the evaluation, as well as which tests should be included (default is all of the tests provided), plus weighting factors for generating the global score from the contributing tests – can all be selected/modified by the user setting up the definitions.

## *Requirements for setup*

First, the required R scripts need to be added and be in the correct location. Second, there is only one data quality object allowed per level. The definitions can be saved at 3 levels: study, project, and study group. Only the lowest level will be used to generate data for a given study. You can however save multiple versions of the same object as well as save up to 10 generations of data.

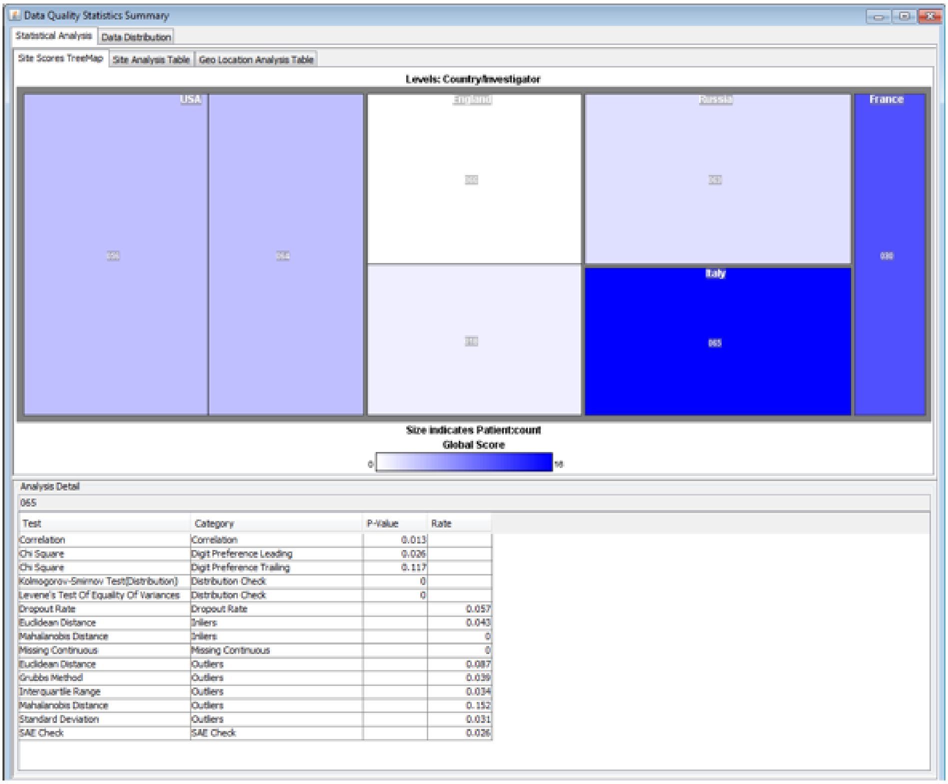
When a definition is deleted all version and generations of data will also be deleted. Anything related to the objects index will be cleared out. The execution of a data quality object can only be done through scheduling due to expected time to execute. Similar to elsewhere in the product the scheduling can be set to run repeatedly on a schedule or run now. Run now means that the next time the print server wakes up this will be run.

Currently, no object for data quality will appear in the object explorer, nor is it available in the dashboard. ***The current implementation does not respect the patient selection criteria, so patient selection criteria will have no effect on this feature at all.*** When the print server executes a data quality object all the generated data is stored in the database. This is to allow for fast searching on the data.

Here’s a walk through of the results – once an analysis has been conducted, followed by an overview of the definition area.

An overview display under the ‘**Statistical Analysis**’ tab, and ‘**Site Score Treemap**’ – shows the coloration of ‘global score’ – sites within country (optional level). When clicking on one of the sites, the darker color represents the higher the ‘global score’. The table below displays the ‘analysis details’ behind the global score.

FIGURE 1 - Site Score Treemap



Analysis Detail

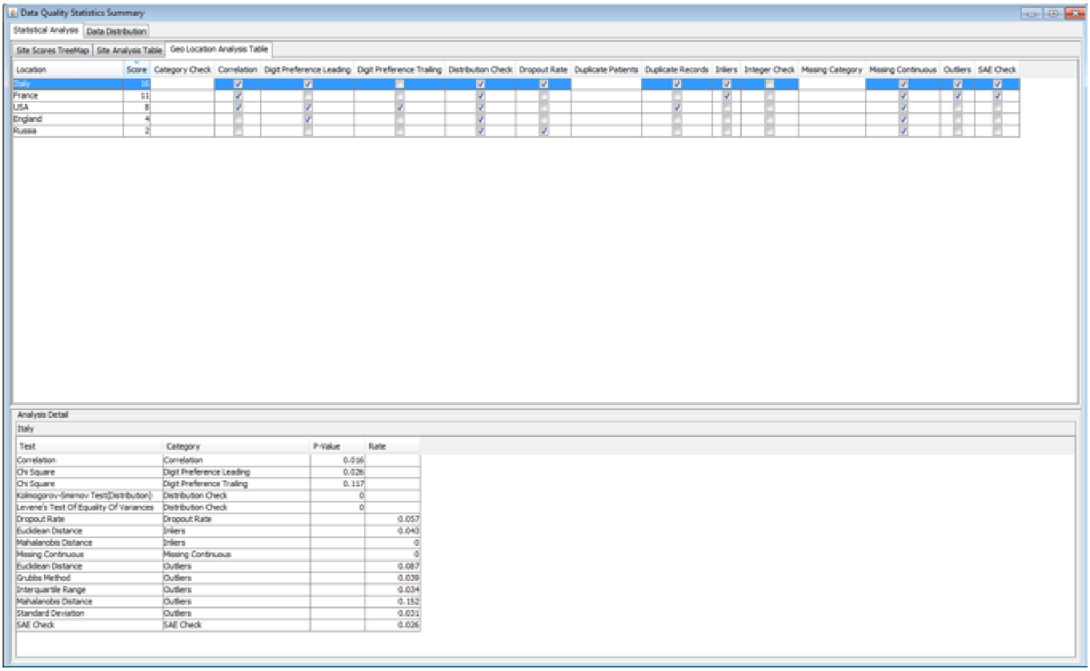
065

| Test | Category | P-Value | Rate |
|---|---|---|---|
| Correlation | Correlation | 0.013 | |
| Chi Square | Digit Preference Leading | 0.026 | |
| Chi Square | Digit Preference Trailing | 0.117 | |
| Kolmogorov-Smirnov Test(Distribution) | Distribution Check | 0 | |
| Levene's Test Of Equality Of Variances | Distribution Check | 0 | |
| Dropout Rate | Dropout Rate | | 0.057 |
| Euclidean Distance | Inliers | | 0.043 |
| Mahalanobis Distance | Inliers | | 0 |
| Missing Continuous | Missing Continuous | | 0 |
| Euclidean Distance | Outliers | | 0.087 |
| Grubbs Method | Outliers | | 0.039 |
| Interquartile Range | Outliers | | 0.034 |
| Mahalanobis Distance | Outliers | | 0.152 |
| Standard Deviation | Outliers | | 0.031 |
| SAE Check | SAE Check | | 0.026 |

## *View Countries*

When you click on the ‘**Site Analysis Table**’ or ‘**Geo Location Analysis Table**’ – you see the countries, and their respective ‘global score’, and the results of each of the specific analyses. A check mark means that country was ‘flagged’ for that analysis … and each of the flagged analyses contribute to the ‘global score’ based on weighting factors that are defined in the definition screen. If one of the analyses is blank (no checkbox) – that means the analysis wasn’t run – due to either not enough information, or the user had asked that the analysis not be included. Clicking on any of the country lines – updates the ‘**Analysis Details**’ table on the bottom of the window.

FIGURE 2 - Geo Location



| Location | Score | Category Check | Correlation | Digit Preference Leading | Digit Preference Trailing | Distribution Check | Dropout Rate | Duplicate Patients | Duplicate Records | Inliers | Integer Check | Missing Category | Missing Continuous | Outliers | SAE Check |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Italy | 16 |  | ☑ | ☑ | ☐ | ☑ | ☑ |  | ☑ | ☑ | ☐ |  | ☑ | ☑ | ☑ |
| France | 11 |  | ☑ | ☐ | ☐ | ☑ | ☐ |  | ☐ | ☑ | ☐ |  | ☑ | ☑ | ☑ |
| USA | 8 |  | ☑ | ☑ | ☑ | ☑ | ☐ |  | ☑ | ☐ | ☐ |  | ☑ | ☐ | ☐ |
| England | 4 |  | ☐ | ☑ | ☐ | ☑ | ☐ |  | ☐ | ☐ | ☐ |  | ☑ | ☐ | ☐ |
| Russia | 2 |  | ☐ | ☐ | ☐ | ☑ | ☑ |  | ☐ | ☐ | ☐ |  | ☑ | ☐ | ☐ |

Analysis Detail

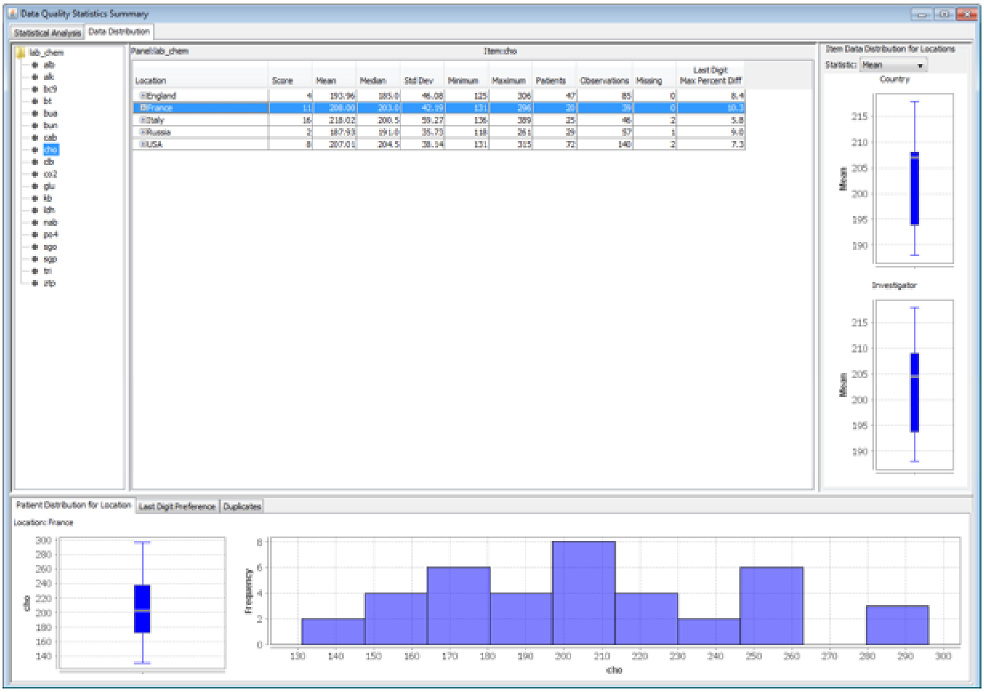
Italy

| Test | Category | P-Value | Rate |
|---|---|---|---|
| Correlation | Correlation | 0.016 |  |
| Chi Square | Digit Preference Leading | 0.026 |  |
| Chi Square | Digit Preference Trailing | 0.117 |  |
| Kolmogorov-Smirnov Test(Distribution) | Distribution Check | 0 |  |
| Levene's Test Of Equality Of Variances | Distribution Check | 0 |  |
| Dropout Rate | Dropout Rate |  | 0.057 |
| Euclidean Distance | Inliers |  | 0.040 |
| Mahalanobis Distance | Inliers |  | 0 |
| Missing Continuous | Missing Continuous |  | 0 |
| Euclidean Distance | Outliers |  | 0.087 |
| Grubbs Method | Outliers |  | 0.038 |
| Interquartile Range | Outliers |  | 0.034 |
| Mahalanobis Distance | Outliers |  | 0.152 |
| Standard Deviation | Outliers |  | 0.031 |
| SAE Check | SAE Check |  | 0.026 |

## *Data Distribution Tab*

Clicking on the '**Data Distribution**' tab displays a list of tables/datasets in the data, and items/columns within each. Clicking on any of the tables -> Items, then displays the details of a variety of statistics for that item – displayed by country, then clicking on '+' opens the country to display the included sites in the country. The Score (global score) column is included for information, but isn't specific to the item selected – the other statistics are … but the score is present for information, and sorting purposes. Clicking on any of the countries or sites – then updates the other graphics on the page – data distribution for the item, histogram of distribution, etc.

FIGURE 3 - Data Distribution



Panel:lab_chem Item:cho

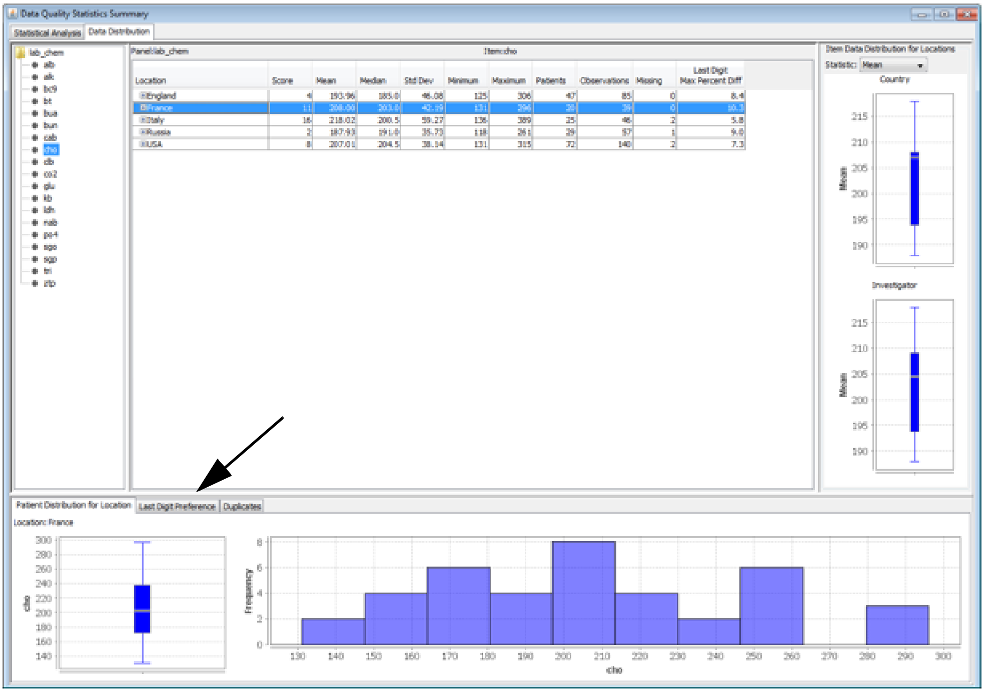
| Location | Score | Mean | Median | Std Dev | Minimum | Maximum | Patients | Observations | Missing | Last Digit Max Percent Diff |
|---|---|---|---|---|---|---|---|---|---|---|
| ⊞England | 4 | 193.96 | 185.0 | 46.08 | 125 | 306 | 47 | 85 | 0 | 8.4 |
| ⊟France | 11 | 208.00 | 203.0 | 42.19 | 131 | 296 | 20 | 39 | 0 | 10.3 |
| ⊞Italy | 16 | 218.02 | 200.5 | 59.27 | 136 | 389 | 25 | 46 | 2 | 5.8 |
| ⊞Russia | 2 | 187.93 | 191.0 | 35.73 | 118 | 261 | 29 | 57 | 1 | 9.0 |
| ⊞USA | 8 | 207.01 | 204.5 | 38.14 | 131 | 315 | 72 | 140 | 2 | 7.3 |

Location: France

## *Last Digit Preference Tab*

Clicking on the ‘**Last Digit Preference**’ tab toward the bottom of the window displays the digit preference for the country or site – compared to all others.

FIGURE 4 - Last Digit Preference



Panel:lab_chem Item:cho

| Location | Score | Mean | Median | Std Dev | Minimum | Maximum | Patients | Observations | Missing | Last Digit Max Percent Diff |
|---|---|---|---|---|---|---|---|---|---|---|
| ⊞England | 4 | 193.96 | 185.0 | 46.08 | 125 | 306 | 47 | 85 | 0 | 8.4 |
| ⊞France | 11 | 208.00 | 203.0 | 42.19 | 131 | 296 | 20 | 39 | 0 | 10.3 |
| ⊞Italy | 16 | 218.02 | 200.5 | 59.27 | 136 | 389 | 25 | 46 | 2 | 5.8 |
| ⊞Russia | 2 | 187.93 | 191.0 | 35.73 | 118 | 261 | 29 | 57 | 1 | 9.0 |
| ⊞USA | 8 | 207.01 | 204.5 | 38.14 | 131 | 315 | 72 | 140 | 2 | 7.3 |

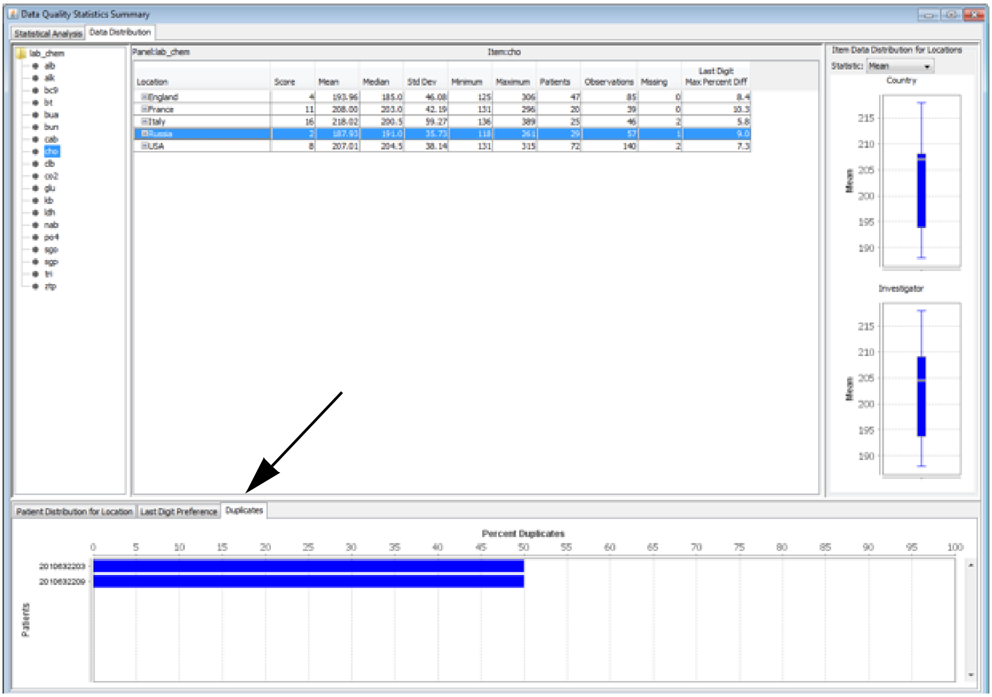
Statistic: Mean

Location: France

## *Duplicates Tab*

Clicking on the **Duplicates** tab toward the bottom displays the possible duplicate patients and 'percent duplicates'.   This info is driven by information provided during the definition step.

FIGURE 5 - Duplicates



Panel:lab_chem

Item:cho

| Location | Score | Mean | Median | Std Dev | Minimum | Maximum | Patients | Observations | Missing | Last Digit Max Percent Diff |
|---|---|---|---|---|---|---|---|---|---|---|
| ⊞England | 4 | 193.96 | 185.0 | 46.08 | 125 | 306 | 47 | 85 | 0 | 8.4 |
| ⊞France | 11 | 208.00 | 203.0 | 42.19 | 131 | 296 | 20 | 39 | 0 | 10.3 |
| ⊞Italy | 16 | 218.02 | 200.5 | 59.27 | 136 | 389 | 25 | 46 | 2 | 5.8 |
| ⊞Russia | 2 | 187.93 | 191.0 | 35.73 | 118 | 261 | 29 | 57 | 1 | 9.0 |
| ⊞USA | 8 | 207.01 | 204.5 | 38.14 | 131 | 315 | 72 | 140 | 2 | 7.3 |

# Data Quality User Interface

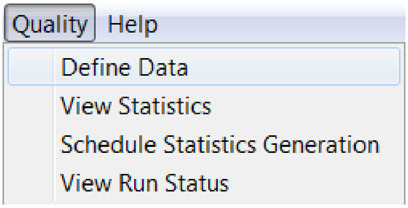
## *Overview of Interface*

The client presents data that is calculated and generated by R scripts and the JRevew server. Both the R scripts and the JReview server are external to the client.

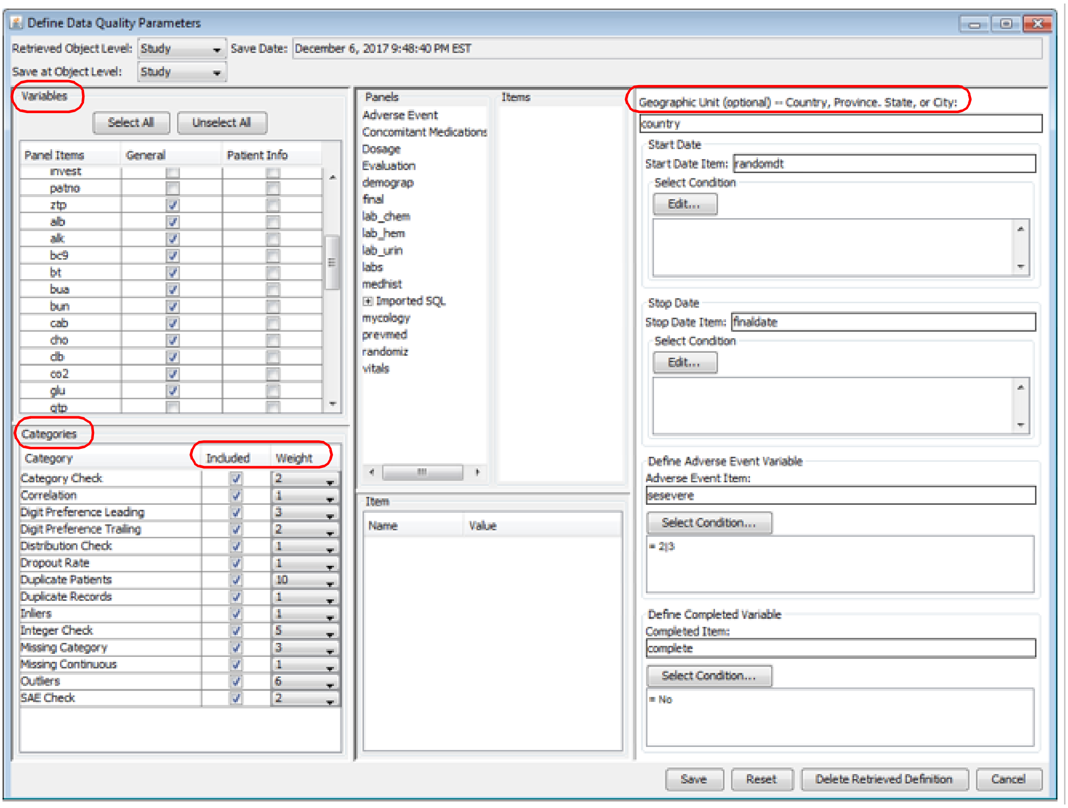
## *Define Analysis*

**Define Data** must be done prior to scheduling analysis to select which **Variables** should be included (checked in the 'general' column), which items should be considered for 'duplicate patient' determination – checking items in the 'Patient Info' column.

Select **Quality** from the menu bar then select **Define Data**.



**Definition step** – The next area is ‘**Categories**’ – those are the types of analyses that will be conducted – all are included by default. The ***weight column*** lets the user change the relative importance of each of the analyses. The definition areas to the right – are for options ‘GeoLocation’ definition (Country – typically), as well as information for Start and Stop dates (used during some of the analyses), location of an Adverse Event variable (with filtering possible), and Patient Completion information. All of these are considered during some of the analyses.



Retrieved Object Level: Study
Save Date: December 6, 2017 9:48:40 PM EST
Save at Object Level: Study

| Panel Items | General | Patient Info |
|---|---|---|
| invest | ☐ | ☐ |
| patno | ☐ | ☐ |
| ztp | ☑ | ☐ |
| alb | ☑ | ☐ |
| alk | ☑ | ☐ |
| bc9 | ☑ | ☐ |
| bt | ☑ | ☐ |
| bua | ☑ | ☐ |
| bun | ☑ | ☐ |
| cab | ☑ | ☐ |
| cho | ☑ | ☐ |
| clb | ☑ | ☐ |
| co2 | ☑ | ☐ |
| glu | ☑ | ☐ |
| gtp | ☐ | ☐ |

Categories

| Category | Included | Weight |
|---|---|---|
| Category Check | ☑ | 2 |
| Correlation | ☑ | 1 |
| Digit Preference Leading | ☑ | 3 |
| Digit Preference Trailing | ☑ | 2 |
| Distribution Check | ☑ | 1 |
| Dropout Rate | ☑ | 1 |
| Duplicate Patients | ☑ | 10 |
| Duplicate Records | ☑ | 1 |
| Inliers | ☑ | 1 |
| Integer Check | ☑ | 5 |
| Missing Category | ☑ | 3 |
| Missing Continuous | ☑ | 1 |
| Outliers | ☑ | 6 |
| SAE Check | ☑ | 2 |

Panels:
Adverse Event
Concomitant Medications
Dosage
Evaluation
demograp
final
lab_chem
lab_hem
lab_urin
labs
medhist
Imported SQL
mycology
prevmed
randomiz
vitals

Geographic Unit (optional) -- Country, Province, State, or City: country

Start Date
Start Date Item: randomdt
Select Condition

Stop Date
Stop Date Item: finaldate
Select Condition

Define Adverse Event Variable
Adverse Event Item: sesevere
= 2|3

Define Completed Variable
Completed Item: complete
= No

## *Classes of Data*

The Data Quality features are invoked from the menu items in the “Quality” menu that is presented in the JReview toolbar. The menu will only be presented if the JNLP property “enableDataQuality” is set to *true*.

There are two classes of data that are presented. The first class is *Data Distribution*, which is a set of tabular and graphical presentations of the data distribution and other descriptive statistics. The data displays are shown for a selected variable. Sites can be (optionally) organized by geographic location, and the data can be presented for geographic locations along with the site specific data. The data distribution data includes descriptive statistics such as mean, median and standard deviation as well as other parameters such minimum and maximum values, patient counts, observation counts, missing data counts, and a “last digit preference” measure. Graphical representations of the data distribution are presented for a site or geographical location by clicking on a row in the tabular presentation.

The second class of presented data is *Statistical Analysis*. This class of presented data is intended to provide composite scores that form a summary view of the data. A summary score for each site (and geographic location) is calculated. A higher score for a site is intended to indicate a greater possibility that the site is “eccentric” in terms of the collected data and is possibly problematic. The summary score is a sum of the number flagged *categories*. Categories can be weighted so that some categories may contribute more “weight” in calculating the “sum” score. For each site, a statistical computation for each category (e.g. outlier, inlier, digit preference, drop-out rate, etc.) is performed. For some categories, a statistical test is run and in others the “suspiciousness” of the site is based on some threshold value. Thus, in some categories a “p-value” is calculated, while in other cases a “rate” (e.g., a proportion of patient values) is calculated. Some categories involve calculations based on multivariate statistics.

To create the Data Quality data, the user first defines what data is to be used. This involves specifying the variables, i.e., the items, and the categories to be included. Some items may define patient characteristics or parameters that can be used for specific analysis categories such as “Duplicate Patients”, and the user interface allows the user to specify this type of item.

The set of categories also needs to be chosen. The user may assign weights to the categories, and these weights are used in calculating the “summary” score for a site or geographic location. The summary score is calculated by summing the weights for categories that have met the criterion of “suspicious”.

For the calculations to be performed, the user must specify: Start Date and End Date items, the item defining Adverse Events, and an item that defines whether the patient completed the study. Optionally, the user can specify a geographic location item.

Analogous to the Study Parameters advanced feature, the definition can be saved at a specified object level. Therefore, the user interface supports retrieving the saved object at one level and saving it at that level or a different level. Saved definitions can be deleted. Earlier *versions* of the saved object (definition) can be retrieved and edited.

To generate resulting Data Quality data, the saved definition must be *run*. A run be may be scheduled or the definition can be run “now”. Each run creates a new version of the results. Earlier runs are saved, but there is a limit on how many versions can be saved. An additional utility allows the user to view the status and history of “runs”.

The Data Quality can only be used if a Study is chosen. ***The feature does not work in multi-study mode.***

Users should be made aware that when specifying the variables to include in the Data Quality definition, the number of variables should be limited by the number of patients in the study. It is suggested that the number of patients be larger than the number of variables. (As a loose nontechnical rule-of-thumb, there should be at least about 10 patients for each variable.)

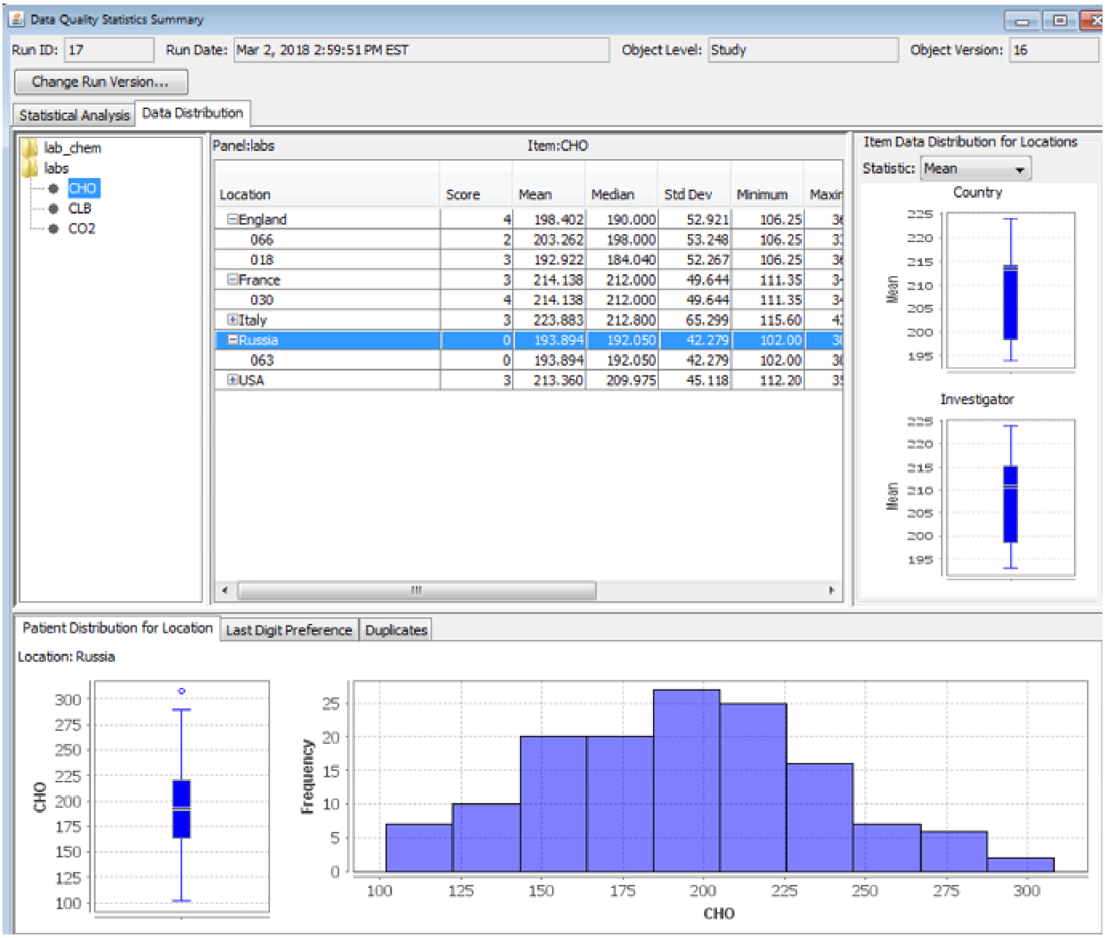
Data Distribution and Statistical Analysis are separate tabs in the Data Quality viewer.

Figures 1 – 3 below show the Data Distribution view. The user selects an item in the tree at the left of the screen. A “tree-table” of the statistics for that item is then presented for the sites and geographic locations. The box plots at the right show the distribution of sites and geographic locations for the chosen measure. A drop down combo-box above the box plots allows the user to choose the measure. The combo-box options correspond to the columns in the tree table containing statistical values.

At the bottom of the viewer are shown graphic presentations of the data distribution. The user clicks on a row in the “tree-table” to populate these graphs. There are three separate tabs for these presentations. The first tab contains a box plot and a histogram showing the distribution of values for the selected site (or geographic location) for the currently selected item. The second tab contains a bar chart showing the percent of values where each digit is found in the values of the selected item. The plot shows the digit preference for the selected site and for all other sites. The third tab contains a scrollable bar graph showing the percent duplicate values for each patient at that site that has duplicate values.

For convenience, there is a column in the tree-table providing the “Statistical Analysis summary score” for each row.

Figure 1



Run ID: 17

Run Date: Mar 2, 2018 2:59:51 PM EST

Object Level: Study

Object Version: 16

Panel:labs

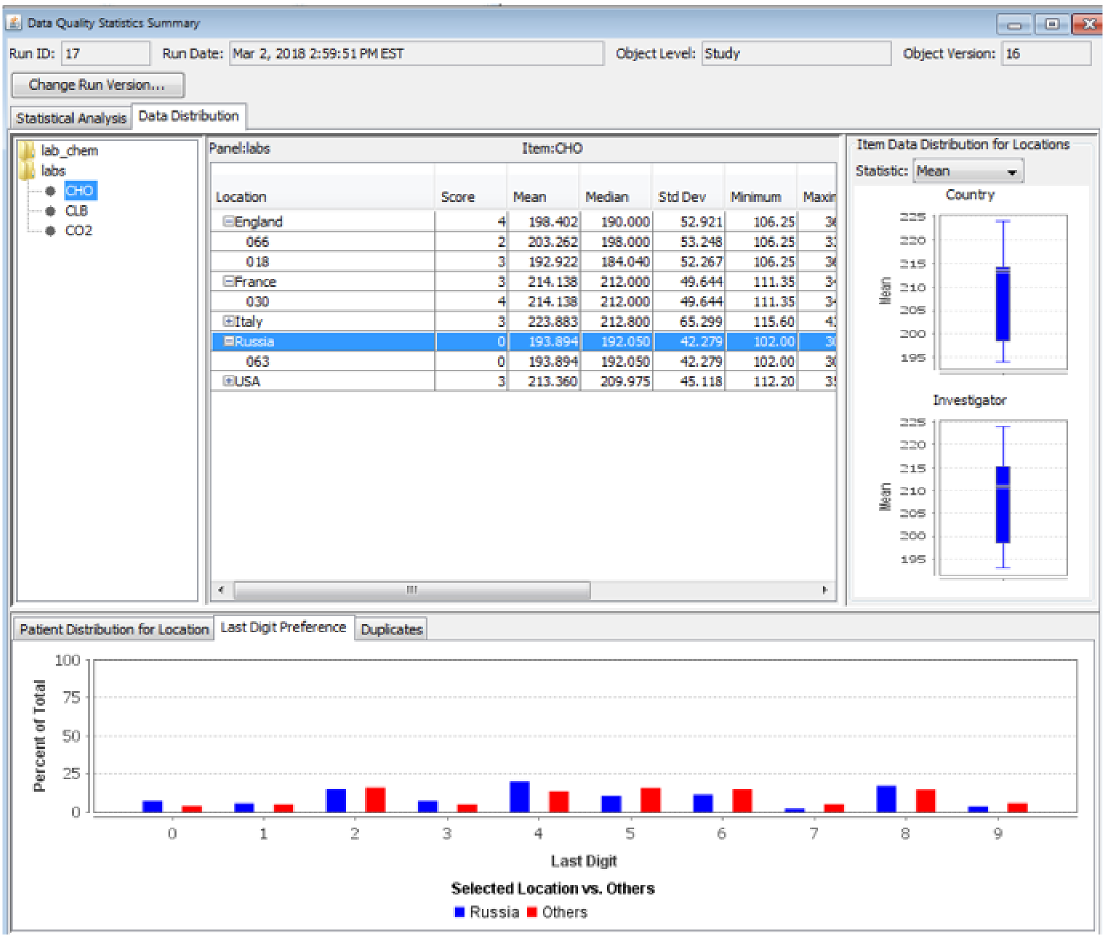
Item:CHO

| Location | Score | Mean | Median | Std Dev | Minimum | Maxi |
|---|---|---|---|---|---|---|
| ⊟England | 4 | 198.402 | 190.000 | 52.921 | 106.25 | 3 |
| 066 | 2 | 203.262 | 198.000 | 53.248 | 106.25 | 3 |
| 018 | 3 | 192.922 | 184.040 | 52.267 | 106.25 | 3 |
| ⊟France | 3 | 214.138 | 212.000 | 49.644 | 111.35 | 3 |
| 030 | 4 | 214.138 | 212.000 | 49.644 | 111.35 | 3 |
| ⊞Italy | 3 | 223.883 | 212.800 | 65.299 | 115.60 | 4 |
| ⊟Russia | 0 | 193.894 | 192.050 | 42.279 | 102.00 | 3 |
| 063 | 0 | 193.894 | 192.050 | 42.279 | 102.00 | 3 |
| ⊞USA | 3 | 213.360 | 209.975 | 45.118 | 112.20 | 3 |

Statistic: Mean

Location: Russia

Figure 2



Data Quality Statistics Summary

Run ID: 17
Run Date: Mar 2, 2018 2:59:51 PM EST
Object Level: Study
Object Version: 16

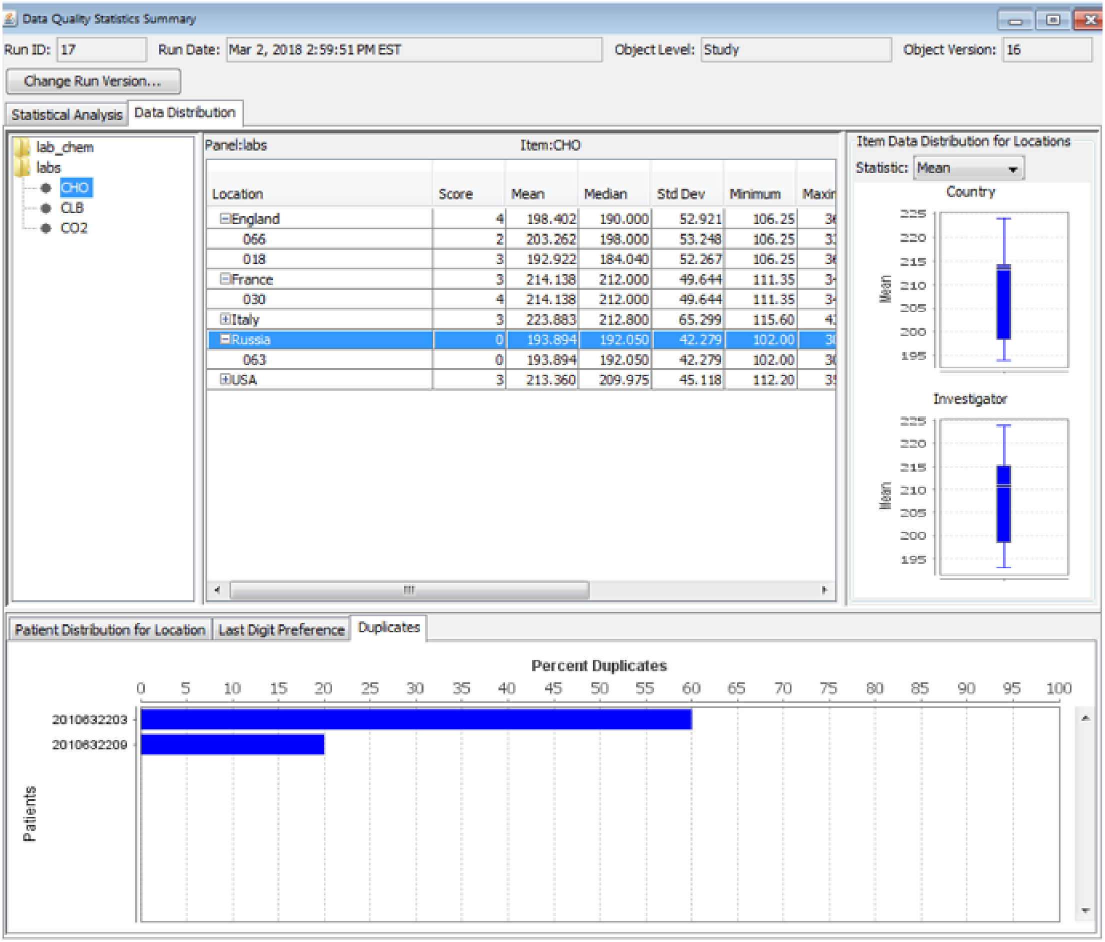
Panel:labs    Item:CHO

| Location | Score | Mean | Median | Std Dev | Minimum | Maxi |
|---|---|---|---|---|---|---|
| ⊟England | 4 | 198.402 | 190.000 | 52.921 | 106.25 | 3 |
| 066 | 2 | 203.262 | 198.000 | 53.248 | 106.25 | 3 |
| 018 | 3 | 192.922 | 184.040 | 52.267 | 106.25 | 3 |
| ⊟France | 3 | 214.138 | 212.000 | 49.644 | 111.35 | 3 |
| 030 | 4 | 214.138 | 212.000 | 49.644 | 111.35 | 3 |
| ⊞Italy | 3 | 223.883 | 212.800 | 65.299 | 115.60 | 4 |
| ⊟Russia | 0 | 193.894 | 192.050 | 42.279 | 102.00 | 3 |
| 063 | 0 | 193.894 | 192.050 | 42.279 | 102.00 | 3 |
| ⊞USA | 3 | 213.360 | 209.975 | 45.118 | 112.20 | 3 |

Item Data Distribution for Locations

Statistic: Mean

Figure 3


Data Quality Statistics Summary

Run ID: 17

Run Date: Mar 2, 2018 2:59:51 PM EST

Object Level: Study

Object Version: 16

Panel:labs Item:CHO

| Location | Score | Mean | Median | Std Dev | Minimum | Maxi |
|---|---|---|---|---|---|---|
| ⊟England | 4 | 198.402 | 190.000 | 52.921 | 106.25 | 3 |
| 066 | 2 | 203.262 | 198.000 | 53.248 | 106.25 | 3 |
| 018 | 3 | 192.922 | 184.040 | 52.267 | 106.25 | 3 |
| ⊟France | 3 | 214.138 | 212.000 | 49.644 | 111.35 | 3 |
| 030 | 4 | 214.138 | 212.000 | 49.644 | 111.35 | 3 |
| ⊞Italy | 3 | 223.883 | 212.800 | 65.299 | 115.60 | 4 |
| ⊟Russia | 0 | 193.894 | 192.050 | 42.279 | 102.00 | 3 |
| 063 | 0 | 193.894 | 192.050 | 42.279 | 102.00 | 3 |
| ⊞USA | 3 | 213.360 | 209.975 | 45.118 | 112.20 | 3 |

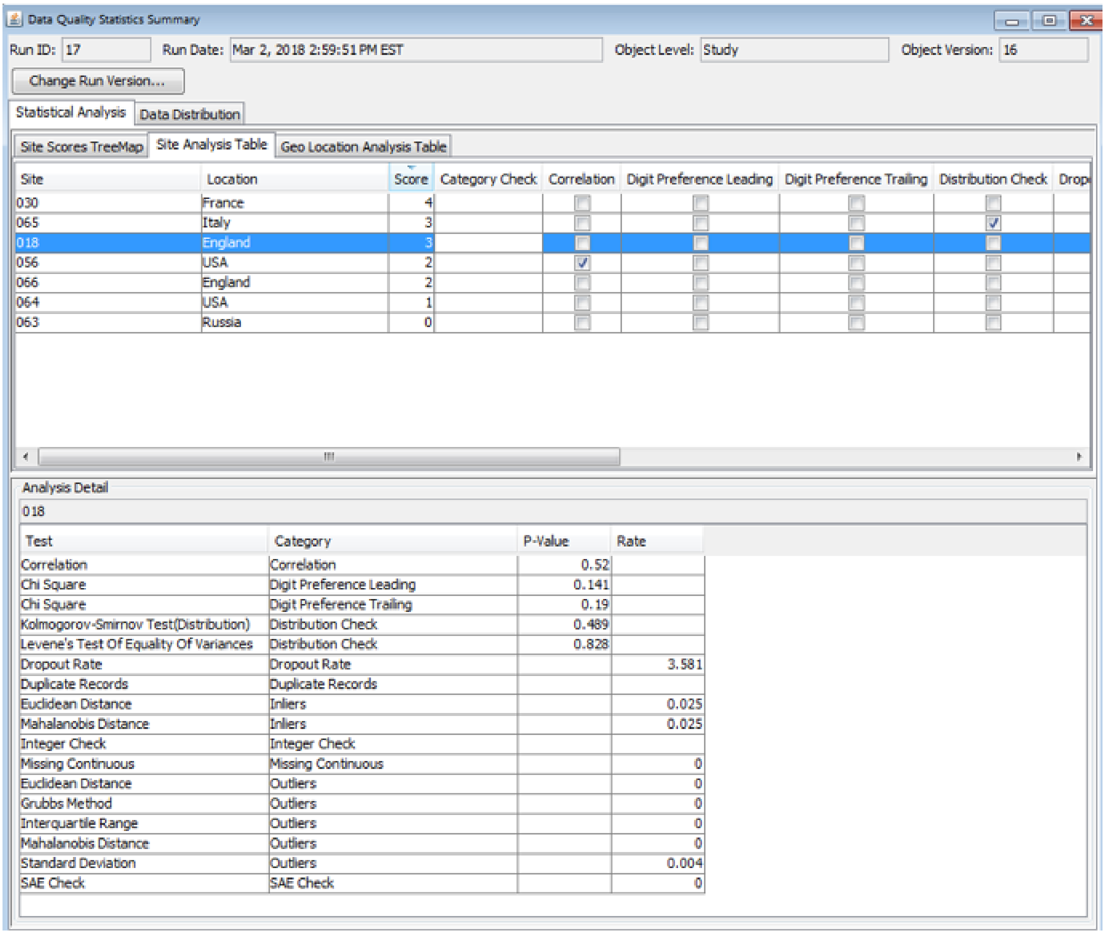
Item Data Distribution for Locations

Statistic: Mean

The Statistical View tab has multiple sub-tabs: a tabular view of the Site data, a tabular view of the Geographical Location data if it exists, and a Tree-Map view of the data. See Figures 4-5.

Figure 4 shows the tabular view of the Statistical Analysis. Each row in the top table is a site (or a geographic location for a geographic location tab). A column contains the overall score for the site. Other columns contain (non-interactive) checkboxes for each "category". If a checkbox is "checked", JReview has found the category to have suspicious data for that site. If a geographical location item is specified, then there is a column identifying the location of the site. The bottom table presents outcomes for the selected row in the top table (i.e., site or geographical location) of the statistical tests used for each of the categories.

Figure 4



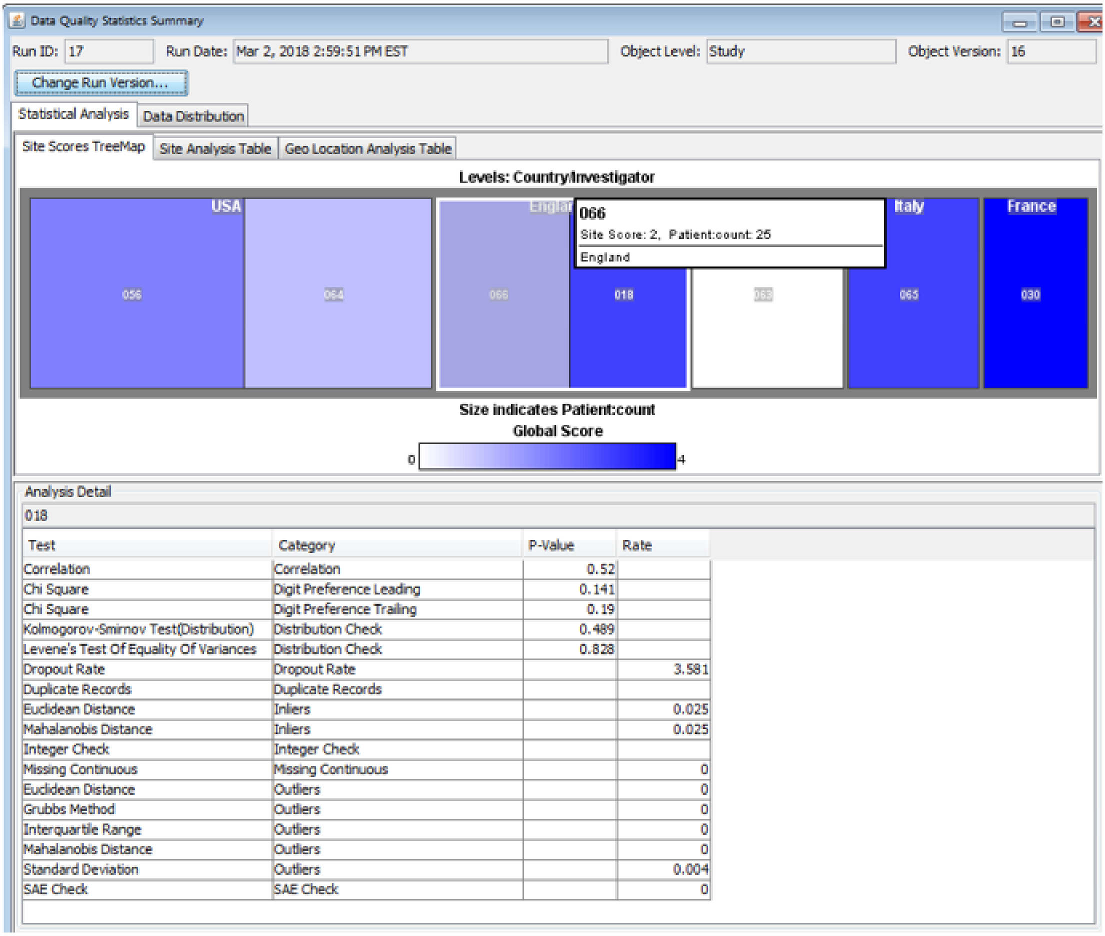
Run ID: 17 Run Date: Mar 2, 2018 2:59:51 PM EST Object Level: Study Object Version: 16

| Site | Location | Score | Category Check | Correlation | Digit Preference Leading | Digit Preference Trailing | Distribution Check | Drop |
|---|---|---|---|---|---|---|---|---|
| 030 | France | 4 | | ☐ | ☐ | ☐ | ☐ | |
| 065 | Italy | 3 | | ☐ | ☐ | ☐ | ☑ | |
| 018 | England | 3 | | ☐ | ☐ | ☐ | ☐ | |
| 056 | USA | 2 | | ☑ | ☐ | ☐ | ☐ | |
| 066 | England | 2 | | ☐ | ☐ | ☐ | ☐ | |
| 064 | USA | 1 | | ☐ | ☐ | ☐ | ☐ | |
| 063 | Russia | 0 | | ☐ | ☐ | ☐ | ☐ | |

018

| Test | Category | P-Value | Rate |
|---|---|---|---|
| Correlation | Correlation | 0.52 | |
| Chi Square | Digit Preference Leading | 0.141 | |
| Chi Square | Digit Preference Trailing | 0.19 | |
| Kolmogorov-Smirnov Test(Distribution) | Distribution Check | 0.489 | |
| Levene's Test Of Equality Of Variances | Distribution Check | 0.828 | |
| Dropout Rate | Dropout Rate | | 3.581 |
| Duplicate Records | Duplicate Records | | |
| Euclidean Distance | Inliers | | 0.025 |
| Mahalanobis Distance | Inliers | | 0.025 |
| Integer Check | Integer Check | | |
| Missing Continuous | Missing Continuous | | 0 |
| Euclidean Distance | Outliers | | 0 |
| Grubbs Method | Outliers | | 0 |
| Interquartile Range | Outliers | | 0 |
| Mahalanobis Distance | Outliers | | 0 |
| Standard Deviation | Outliers | | 0.004 |
| SAE Check | SAE Check | | 0 |

Figure 5 shows the Tree-Map view of the Statistical Analysis.



Run ID: 17 Run Date: Mar 2, 2018 2:59:51 PM EST Object Level: Study Object Version: 16

018

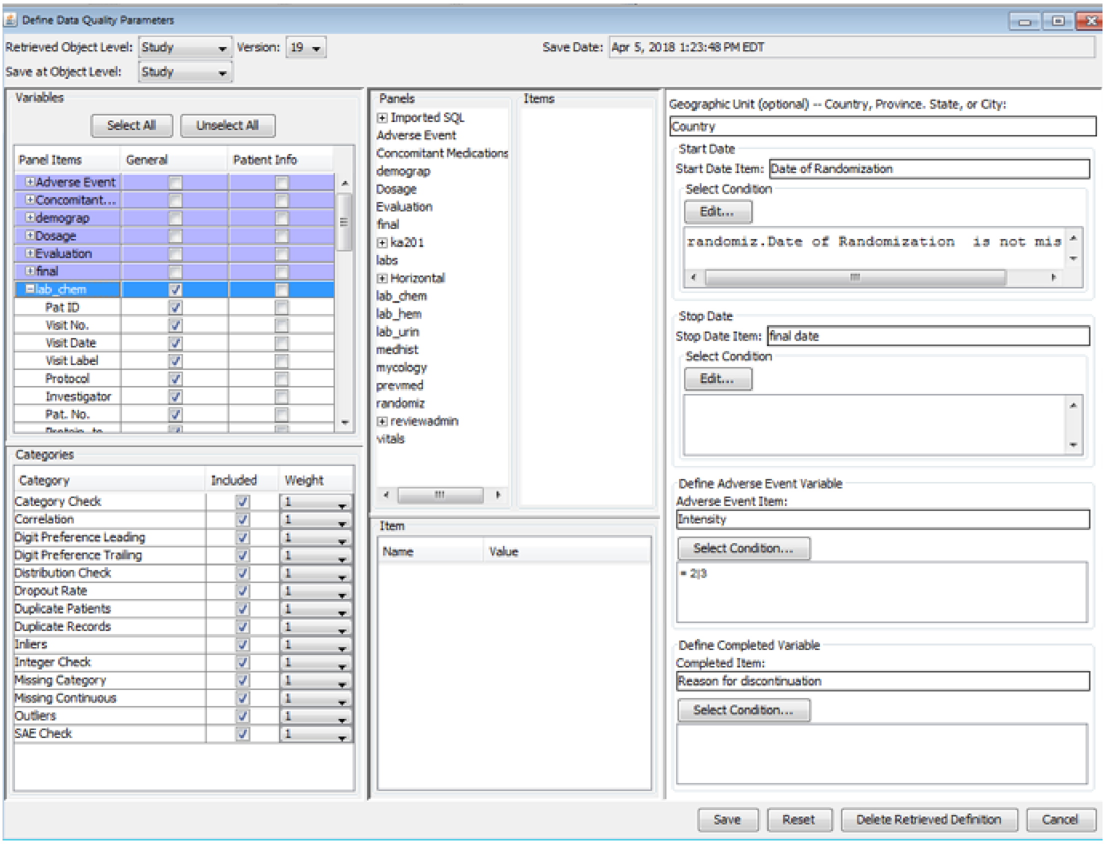
| Test | Category | P-Value | Rate |
|---|---|---|---|
| Correlation | Correlation | 0.52 | |
| Chi Square | Digit Preference Leading | 0.141 | |
| Chi Square | Digit Preference Trailing | 0.19 | |
| Kolmogorov-Smirnov Test(Distribution) | Distribution Check | 0.489 | |
| Levene's Test Of Equality Of Variances | Distribution Check | 0.828 | |
| Dropout Rate | Dropout Rate | | 3.581 |
| Duplicate Records | Duplicate Records | | |
| Euclidean Distance | Inliers | | 0.025 |
| Mahalanobis Distance | Inliers | | 0.025 |
| Integer Check | Integer Check | | |
| Missing Continuous | Missing Continuous | | 0 |
| Euclidean Distance | Outliers | | 0 |
| Grubbs Method | Outliers | | 0 |
| Interquartile Range | Outliers | | 0 |
| Mahalanobis Distance | Outliers | | 0 |
| Standard Deviation | Outliers | | 0.004 |
| SAE Check | SAE Check | | 0 |

At the top of the viewer is text providing identifying information for the run and saved object that define and construct the data. Also, an option to choose a different run to view is provided; clicking on this option's button displays a dialog.

## Data Quality Definition

This is the definition screen. On the left-side tree-map, the user selects which items to include for the data quality calculations. The checkboxes in the tables are interactive. An item may be designated as a “patient info” item (see above). The left-side bottom table allows the user to specify which “categories” to include for the statistical analysis. The third column is used for specifying weights for each category using a combo-box.

Figure 6



Retrieved Object Level: Study

Version: 19

Save Date: Apr 5, 2018 1:23:48 PM EDT

Save at Object Level: Study

Variables

| Panel Items | General | Patient Info |
|---|---|---|
| ⊞ Adverse Event | ☐ | ☐ |
| ⊞ Concomitant... | ☐ | ☐ |
| ⊞ demograp | ☐ | ☐ |
| ⊞ Dosage | ☐ | ☐ |
| ⊞ Evaluation | ☐ | ☐ |
| ⊞ final | ☐ | ☐ |
| ⊟ lab_chem | ☑ | ☐ |
| Pat ID | ☑ | ☐ |
| Visit No. | ☑ | ☐ |
| Visit Date | ☑ | ☐ |
| Visit Label | ☑ | ☐ |
| Protocol | ☑ | ☐ |
| Investigator | ☑ | ☐ |
| Pat. No. | ☑ | ☐ |

Categories

| Category | Included | Weight |
|---|---|---|
| Category Check | ☑ | 1 |
| Correlation | ☑ | 1 |
| Digit Preference Leading | ☑ | 1 |
| Digit Preference Trailing | ☑ | 1 |
| Distribution Check | ☑ | 1 |
| Dropout Rate | ☑ | 1 |
| Duplicate Patients | ☑ | 1 |
| Duplicate Records | ☑ | 1 |
| Inliers | ☑ | 1 |
| Integer Check | ☑ | 1 |
| Missing Category | ☑ | 1 |
| Missing Continuous | ☑ | 1 |
| Outliers | ☑ | 1 |
| SAE Check | ☑ | 1 |

Panels

- ⊞ Imported SQL
- Adverse Event
- Concomitant Medications
- demograp
- Dosage
- Evaluation
- final
- ⊞ ka201
- labs
- ⊞ Horizontal
- lab_chem
- lab_hem
- lab_urin
- medhist
- mycology
- prevmed
- randomiz
- ⊞ reviewadmin
- vitals

| Name | Value |
|---|---|

Geographic Unit (optional) -- Country, Province, State, or City: Country

Start Date

Start Date Item: Date of Randomization

Select Condition

randomiz.Date of Randomization is not mis

Stop Date

Stop Date Item: final date

Select Condition

Define Adverse Event Variable

Adverse Event Item: Intensity

= 2|3

Define Completed Variable

Completed Item: Reason for discontinuation

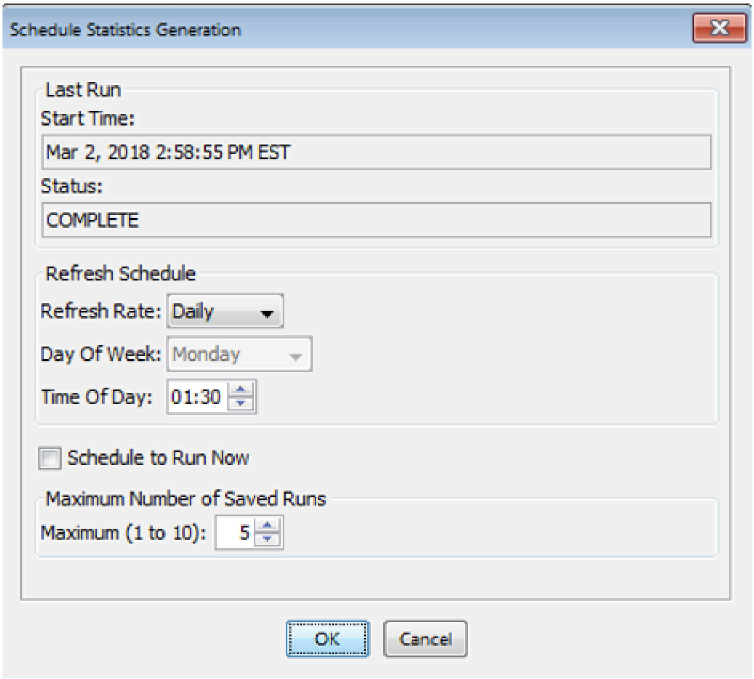
The right-side panel contains fields that are populated by dragging and dropping items on them. Some fields have associated filter controls that may be used to refine the specification.

At the top, there is a combo-box that designates the object level at which to retrieve an object, and a second combo-box that designates at which level to save the definition currently being viewed in the data- definition form. A third combo-box allows the retrieval of a specific version of the saved definition (at the given retrieved object level). Note that changes to the retrieve and version combo-boxes invoke a data retrieval form the server and an update to the data-definition form. Save, Reset, Delete Retrieved Definition, and Cancel buttons are presented at the bottom of the screen. Save saves the current definition in the form at the designated save object level. The version combo-box may be updated on a save if the save and retrieve levels are the same. The Delete button deletes the currently retrieved definition. On delete, the version combo-box is disabled and its items are removed. Reset retrieves the currently retrieved definition and re-populates the form. Cancel closes the window.

## Schedule Statistics Generation

Figure 7 shows the dialog for scheduling a statistical data run. It also contains information about the status of the last run.

Figure 7



Schedule Statistics Generation

Last Run

Start Time: Mar 2, 2018 2:58:55 PM EST

Status: COMPLETE

Refresh Schedule

Refresh Rate: Daily

Day Of Week: Monday

Time Of Day: 01:30

☐ Schedule to Run Now

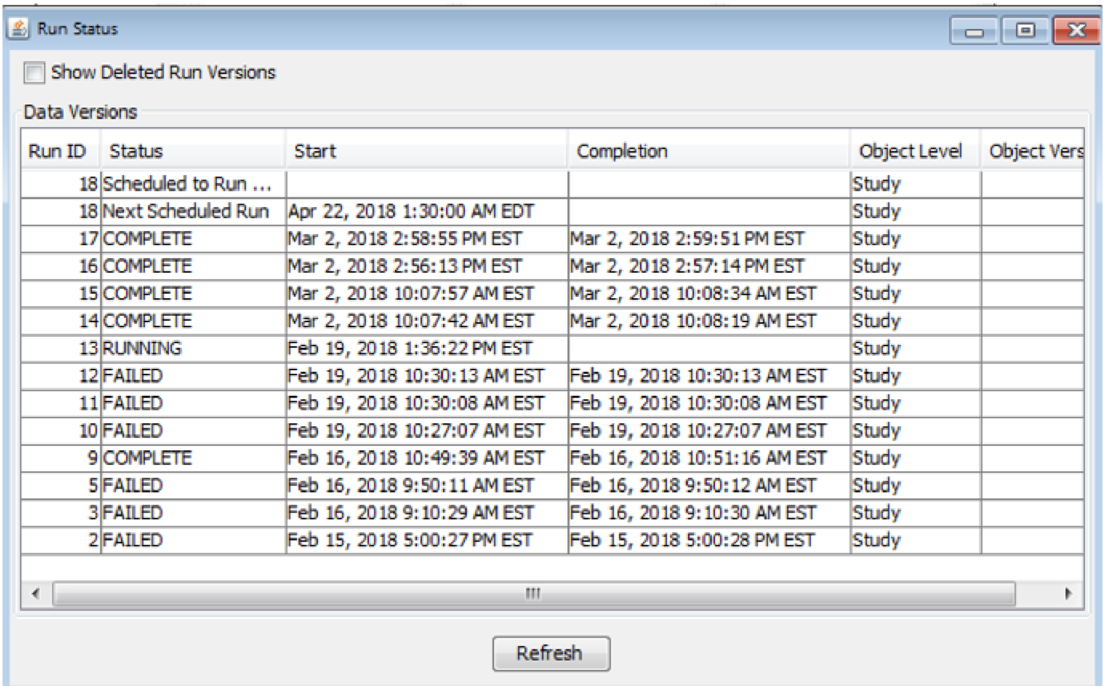
Maximum Number of Saved Runs

Maximum (1 to 10): 5

## *View Run Status*

Figure 8 shows the dialog for the status and history of runs. A checkbox allows the user to optionally include deleted “runs” in the listing. A Refresh button is provided to update the data in the viewer.

Figure 8



☐ Show Deleted Run Versions

| Run ID | Status | Start | Completion | Object Level | Object Vers |
|---|---|---|---|---|---|
| 18 | Scheduled to Run ... | | | Study | |
| 18 | Next Scheduled Run | Apr 22, 2018 1:30:00 AM EDT | | Study | |
| 17 | COMPLETE | Mar 2, 2018 2:58:55 PM EST | Mar 2, 2018 2:59:51 PM EST | Study | |
| 16 | COMPLETE | Mar 2, 2018 2:56:13 PM EST | Mar 2, 2018 2:57:14 PM EST | Study | |
| 15 | COMPLETE | Mar 2, 2018 10:07:57 AM EST | Mar 2, 2018 10:08:34 AM EST | Study | |
| 14 | COMPLETE | Mar 2, 2018 10:07:42 AM EST | Mar 2, 2018 10:08:19 AM EST | Study | |
| 13 | RUNNING | Feb 19, 2018 1:36:22 PM EST | | Study | |
| 12 | FAILED | Feb 19, 2018 10:30:13 AM EST | Feb 19, 2018 10:30:13 AM EST | Study | |
| 11 | FAILED | Feb 19, 2018 10:30:08 AM EST | Feb 19, 2018 10:30:08 AM EST | Study | |
| 10 | FAILED | Feb 19, 2018 10:27:07 AM EST | Feb 19, 2018 10:27:07 AM EST | Study | |
| 9 | COMPLETE | Feb 16, 2018 10:49:39 AM EST | Feb 16, 2018 10:51:16 AM EST | Study | |
| 5 | FAILED | Feb 16, 2018 9:50:11 AM EST | Feb 16, 2018 9:50:12 AM EST | Study | |
| 3 | FAILED | Feb 16, 2018 9:10:29 AM EST | Feb 16, 2018 9:10:30 AM EST | Study | |
| 2 | FAILED | Feb 15, 2018 5:00:27 PM EST | Feb 15, 2018 5:00:28 PM EST | Study | |

# Index