RELEASE 9.1.3

JReview®

Exploring Clinical Data using JReview

Copyright © 1994 - 2010 by Integrated Clinical Systems, Inc. All rights reserved. Printed in the United States of America.

No part of this work covered by the copyrights hereon may be reproduced or copied in any form or by any means — graphic, electronic, or mechanical, including photocopying, recording, taping, or information and retrieval systems — without written permission from the publisher:

Integrated Clinical Systems, Inc.
900 State Highway 12
Frenchtown, NJ 08825

First Printing: October 2006

Restricted Rights Legend

Use, duplication, or disclosure by the Government is subject to restrictions set forth in Section 252.227-7013 (c)(1)(ii) (October 1987) of the U.S. Department of Defense Supplement to the Federal Regulations or other similar regulations of other governmental agencies.

Export Notice

COMPANY agrees not to knowingly export or re-export any Programs or Documentation, or technical data furnished under this Agreement or any part or any direct product thereof, directly or indirectly, into Serbia and Montenegro, Iran, Iraq, the People's Republic of China, Sudan, Syria, or any of those countries listed from time to time in Part 770 to Title 15 of the U.S. Code of Federal Regulations in Country Groups Q, S, W, Y, or Z, which, as of the date of this Agreement, are as follows: Group Q (Romania), Group S (Libya), Group W (Reserved), Group Y (Albania, Armenia, Azerbaijan, Belarus, Bulgaria, Cambodia, Estonia, Georgia, Kazakhstan, Kyrgyztan, Laos, Latvia, Lithuania, Moldova, Mongolia, Russia, Tajikstan, Turkmenistan, Ukraine, Uzbekistan, and Vietnam) and Group Z (Cuba and North Korea), unless prior authorization is obtained from the U.S. Department of Commerce and/or other appropriate governmental agencies. For purposes of this Agreement, the term “direct product” is defined to mean the immediate product (including processes and services) produced directly by use of the technical data.

Integrated Review is a trademark and JReview is a registered trademark of Integrated Clinical Systems, Inc.

All other trademarks are owned by their respective companies.

Contents

1 Getting Started

Introduction 2

What is JReview? 2
Authoring versus Non-Authoring 2
Key features in JReview 4

Installing the application 5

JReview Setup / Install 5

Starting the application 9

Logging on 9
Database and SAS server 12
Choosing an ORACLE database 12
JReview Server 12
NODE UserID 13
Wrong password? 13
Trouble shooting 13

On-line Help 15

On-line Help 15

Quick tour 16

Main window 16
Sort folder contents 19
Launch a saved object 20
Preferences 21
ToolBar and Browser Menu Bar 22
General instructions 24
JReview Settings 29

2 Selecting Patients

Specify Patient Selection Criteria 33

Review sub-populations 33
Focused analysis 33

Steps for Patient Selection Criteria 34

Select a project 34
Single-protocol mode 34
Multi-protocol mode 35
Access to SAS datasets 35

Steps for selection criteria 36
Building criteria expressions 37
Criteria expressions 37
Selecting a panel 37
Selecting an item 38
Supplying a value 39
Displaying item values 40
Selecting multiple values 41
Selecting an operator 42
Building a string expression 43
Joining criteria expressions 43
Boolean operators 43
Additional criteria expressions 44
AND operator 45
OR operator 46
ANDSelect operator 47
Build a complex patient selection criteria 48
Changing the selection criteria 49
Item comparison selector 50
Compare items 50
Exclude patient criteria 51
Display excluded patients 51
Functions 53
Types of function values 53
Decoded value 53
Actual value function 53
Derived function values 53
Date function 54
Item Statistics 55
Display item statistics 55
Displaying subsets of protocol population 57
Object storage: Saving your work 58
Saving the selection criteria 58
Access tab 60
Object storage location 61
Object level 62
Publish for study groups 62
Override selected Project / Global object? 63
Object Explorer window 63
Retrieve a saved selection criteria 64
Append to criteria 64
Object properties 66
Quick remove 67
Create Tabs 68
Create new tab 68
Move objects between tabs 69
Display Data Browser 70

3 Review Patient Data

Data Browser 73
- Subset patients 73
- Opening the Data Browser 74
- Expand spreadsheet columns 74
- Sort columns 75
- Browse patient data 76
- Horizontal data display 78
- Graph format display 79
- View Data Browser 81

Notes Browser 82
- Store patient notes 82
- Add note from Data Browser 82
- Edit note in Notes Browser 86
- Add response in Notes Browser 89
- User defined notes reports 90

Multiple-patient mode 91
- Freezing a case 91

Export and Print listings and panel views 94
- Export a data browser spreadsheet 94
- Print Preview 94

Exploring data 95
- Changing the patient selection criteria 95
- Patient Identification 96
- CrossTab Browser results 97
- Discrepancy reports 98
- Detail Data Listing reports 98
- Scatter plot graphs 98

Closing panel views and the Data Browser 98
- Closing a panel view 98
- Closing the Data Browser window 98

4 Patient Profiles

Types of Patient Profiles 101
- Patient profile types 101
- Access to SAS datasets 101

Execute patient profile 102
- Quick execute 102
- Selection criteria 103
- Retrieve a stored output specification 103

Patient profile features 104
- View saved patient profile 104
- Define patient profile matrix 104
- Show patient profile 106

Define Patient Profile 107
- Select workbook profile 107
- Add profile content 108

Add Subpanel 110
Type of workbook 111
Organize data 111
Single worksheet mode 113
Multiple worksheet mode 115
Modify profile 118
Define Header 119
Customize patient profile output 121
Sort Order 123
Filter Output 124
Patient Profile Filter Output 124
Patient Profile Review Tracking Tool 127
Patient Tracking functions 127
Patient Review Levels 129
Sort columns 129
Define Critical 130
Update Patient Tracking Status 132
Select review level 133
Color coding 133
Filter review 135
Bulk review setting 136
Track selection criteria 136
View Patient Log 137
Highlight patient data 139
User defined tracking reports 140
Study lock 142
Formatted Patient Profile 143
Select formatted profile 143
Activate Page Break 144
Apply Page Header and Footer 145
Format Column Headings 147
Format Columns 148
Preview / Page Setup 149
Page Setup 151
Number of ID items 151
Panel Orientation 152
Column width 153
Print and Export Patient Profiles 154
Print patient profile 154
Export patient profile 154
Object Storage 157
Close Patient Profiles Browser 157
Closing the Patient Profiles windows 157

5 Graphic Patient Profiles
Graphic Patient Profile 161
Access Graphic Patient Profile 161
Show Graphic Patient Profile 162

Missing data 163
Basic graphic user interface 164
Define Graphic Profile Template 166
Open Patient Profiles Browser 166
Open Graphic Profile Template 167
Select template level 169
Define study start date 170
Define Visit 173
Define header items 174
Category types 175
Define Category Information 176
Ongoing Item 177
Time Axis scale 178
Duration Category Type 179
Dosage Category Type 180
Text Category Type 181
Laboratory Category Type 183
Time Point Type category 186
Save template 188
Edit graphic template 188
Define Graphic Profile 189
Select graphic profile 189
Select defined template 190
Change Time Axis 190
Change Limit value 191
Display Time items 191
Select categories for display 192
Select items for display 194
Normal range multiplier 197
Create Graphic Patient Profile 199
Basic graphic user interface 201
Graph settings 204
Select settings 204
Appearance options 204
Printing and PDF output settings 205
Color settings 206
Headers and footers 207
Category settings 207
Formatted Profiles 209
Show formatted patient profile 209
Printing and Exporting Patient Profiles 210
Print Preview 210
Print patient profile 210
Export patient profile 211
Object Storage 212
Close Patient Profiles Browser 212
Closing the Patient Profiles windows 212

6 Report Browser

Execute report 216
Selection set 216
Quick execute 216

Report types and features 217
Type of report 217

Defining Report Specifications 218
Selecting a panel, item, and function 218
Adding items 219
User-defined functions 219
Access to SAS datasets 219
Column autosizing 220
Edit item sort order 220
Change column order 221
Changing the report specifications 221
Edit column heading 222
Defining a report title 222
Show Details 222
Create report 223

Detail Data Listing features 224
Defining row results 224
Reset subtotal in row results 226
Highlighting data check ranges 227
Suppress duplicate rows 229

Summary Listing features 230
Group functions 230
Count distinct 233
Count item value 234
New item with aggregate functions 234

Object toolbar 235
Snapshot output 235
Who icon 235
Output filter icon 236
Multiple population mode 237
Multiple output for required selection criteria 240

Output filter 243
Subset data 243
Creating report output filter 244
Comparing items 245
Adding expressions 245
View output filter 248

Define Runtime filters 249
Runtime parameter 249
Create parameter 250
Enter runtime parameter 255
Reset filter parameters 257

Patient Visit Data Report 258
Select panel visit data report 258
Define patient visit data report 259

Report options 259
Add Patient Info Items 261
Define Date Merge Settings 262
Create Patient Visit Data Report 263
Lookup on existing date 264
Apply output filter 266
Add vertical lab 268
Formatted reports 272
Select formatted listing type 272
Apply Page Header and Footer 273
Enter a Group Header 275
Format Column Headings 277
Format Columns 280
Sort Order 283
Preview / Page Setup 284
Create formatted report 287
Conditional Data Highlighting 288
Define data highlighting 288
Highlighting patients 295
Single patient mode 295
Multiple-patient mode 297
Printing and Exporting Results 299
Printing the result 299
Exporting the result 300
Object Storage 301
Exploring data 301
Changing the patient selection criteria 301
Patient Identification 301

7 Graph Browser
Patient selection criteria 305
Selection set 305
Execute a graph 305
Quick execute 305
Graph types and features 306
Graph features 306
Graph Browser window 306
Detail data graph 307
Summary data graph 307
Bar styles 308
Group functions 308
Graph display results 309
2D Graph Toolbar 309
Display BY variable 311
Graph display keys 312
Graph manipulation keys 312
Data point select 313
Multiple graphs 315

Defining a graph specification 316
Creating a graph specification 316
Change graph specifications 316
Page BY variable 317
X and Y scaling 318
Detail Data Graph Styles 319
Scatter (Item X vs. Item Y) Plot 319
Scatter Plot with Regression Line 324
3-D Scatter Plot 326
Baseline vs. Endpoint Scatter Plot 328
MultiLine Chart Item Value vs. Category by Case 330
MultiLine Chart Item Value vs. Category by ByVar 332
Summary Graph Styles 334
2-D Bar Chart Frequency Distribution 334
3D BarChart Frequency Distribution 338
2-D Bar Chart Item Summary vs. Category 340
3D BarChart Item Summary vs.Category 342
Pareto Chart fFrquency Distribution 344
Pie Chart Item Summary vs. Category 347
Line Chart-item vs. Category 351
Item Mean and Standard Deviation vs. Category 353
Output Filter 354
Filter Controls 355
Snapshot output 362
Multiple population mode 362
Multiple output for required selection criteria 365
Highlighting patients 368
Single patient mode 368
Multiple patient mode 371
Scatter plot graph 371
BarChart graph 375
Pie Chart 376
Graph Editing 377
Graph settings 377
Printing and Exporting Graphs 378
Printing the graph 378
Exporting the graph 379
Object Storage 380
Exploring data 380
Changing the patient selection criteria 380
Patient Identification 380
Closing graphs and the Graph Browser 381
Closing a graph window 381
Closing the Graph Browser 381

8 CrossTab Browser
Patient selection criteria 386

Selection set 386
Execute CrossTab 386
Quick execute 386
CrossTab Browser types of analysis 387
Select type of crosstab analysis 387
Defining a CrossTab table 389
Selecting a panel, item, and function 389
Access to SAS datasets 392
Edit column width 393
Sort by Code Value 393
Output Filter 393
Apply group function 394
Show empty values 395
Add cell variable 397
Edit the CrossTab specification 398
Display Crosstab with Percentages 399
Include Row% Col% 399
Percent Denominator 399
Include Row%,Col% with selection criteria 406
Totals Subject Count 410
Filter Subject Count 414
Subtotal 2nd column 416
Include N% function 417
Include N% and Totals subject count 419
Include N% Patient Subset 420
Descend N(%) Sort 421
Select decimal places 422
Include N% Col Totals 423
Include N% Row Totals 424
Include N% First column totals 425
Include N% First column totals (All sub) 427
Include N% with Subtotal 2nd column 428
CrossTab Side by Side Columns 430
Interactive CrossTab - Combination Explorer 432
View patient counts 432
Analyze Combinations 437
Include N% to Analyze Combinations 438
Defining a Shift Table 440
Item analyzed 440
Create Shift Table 441
Range values 442
Assign Baseline and Endpoint 443
Apply Filter Output 443
Include Row% and Col% 444
Multiple CrossTab/Shift Tables 444
Multiple CrossTabs 444
Snapshot output 445
Multiple population mode 445
Printing and exporting CrossTab/Shift Tables 445

Print Preview 445
Print the CrossTab / Shift Tables 446
Page Setup 446
Exporting the CrossTab / Shift Tables 447
Interactive patient-level displays 448
Crosstab cell select 448
Crosstab multiple cell select 448
Detail data patient listings and graphs 449
Object storage 450
Exploring data 450
Changing the patient selection criteria 450
CrossTab output filter 451
Closing the CrossTab Browser 451
Closing a CrossTab Window 451
Closing the CrossTab Browser 451

9 Generating Statistics
SAS Proc types 455
Selection set 455
Selecting a SAS Proc 455
Execute a SAS Proc specification 456
Quick execute 456
Retrieve a saved output specification 456
SAS Proc results display 457
SAS Proc output 457
Displaying the SAS output, source, or log 457
Print copy of output 458
Defining a SAS View and Dataset (future release) 459
Opening the SAS Proc Browser 459
Create SAS View and Dataset 459
Select format library options 463
SAS Transport Files 464
V5 (FDA Guidelines) option 464
Edit panels 466
Defining a SAS Proc Specification 467
Define SAS Proc specification 467
Adding items to be analyzed 468
Adding BY variables 468
Statistics options 468
Output filter 469
Defining a SAS Proc title 469
Creating the SAS Proc output 470
Change a SAS Proc specification 470
SAS Proc results display 471
Toolbar 471
Find menu command 472
Displaying the SAS output, source, or log 472
Exporting and printing results 473

Print Preview 473
Printing the SAS Proc results 473
Exporting the result 474
Multiple SAS Proc outputs 475
Opening multiple SAS Proc results 475
Snapshot output 475
Save and schedule a SAS Proc specification 478
Save a SAS Proc specification 478
Schedule SAS Proc jobs 478
Review output 478
Advanced SAS Proc options (future release) 479
Select SAS display options 479
Close SAS Proc Browser and results 488
Closing a SAS Proc output window 488
Closing the SAS Proc Browser 488
Exploring data 488
Changing the patient selection criteria 488
SAS Proc output filter 489
Pivot panels 489
Join logic 489
Clintrial tags 489
Protocol comparison 490
New Event Function 490

10 STAT Program Registration Browser
STAT Program Registration Browser 493
General 493
Registered SAS programs 494
Interactively register SAS programs 495
Converted SAS programs 495
STAT Program Registration window 496
Register a new SAS program 499
Definition tab 502
Locations tab 504
Substitution parameter tokens 506
Datasets tab 507
Parameters tab 510
Includes tab 515
Print/Subset tab 516
General Info tab 517
Save STAT Program Registration 518
Interactively register R programs 519
R scripts overview 519
Register R programs 519
Auxiliary Windows 527
Browse Server 527
Print Format 531
Program Format options 533

Patient Subset selection 534
Program group options 535
Manage SAS objects (future release) 536
Manage SAS programs 536
SAS Program 538
Program Group 541
New Program Group 545
Program Group Restrictions 546
Library 548
Category 551
Status 553
User Group - SAS Program 556
User Group - Program Group 557
STAT Program Registration Browser 558
Selection criteria 558
Opening the STAT Program Registration Browser 558
Registered SAS programs 558
Quick execute 559
Retrieve a table 560
SAS program results and log files 561
Creating the table output 561
Displaying the SAS log or source 561
Multiple table outputs 562
Snapshot output 562
Schedule SAS program jobs 562
Printing SAS program results 563
Print table output 563
Exploring data 564
Opened SAS production table results 564
Update patient selection criteria 564

11 Saving Objects, Scheduling plus Alerts Browser
Object Storage 567
Finalize object specification 567
Save the object specification 568
Definition tab 568
Access tab 569
Object storage location 570
Object level 570
Share with user groups 571
Publish for study groups 571
Store Patient selection criteria 572
Object Explorer window 574
Saved output specification 574
Object Explorer quick execute 575
Retrieve specification from Output Specifications 576
Object versions 577
Remove output specification 578

Object properties 579
Schedule output 580
Object Explorer scheduled output 580
View Scheduled Jobs 581
Remove Scheduled Jobs 581
Change Schedule 582
Schedule SAS jobs 582
Review output 583
Locate stored output results 583
Quick remove saved output results 584
Alerts Browser 584
What are alerts? 584
Definition tab 585
Operation tab 587
Action tab 589
Alert activation 591
Alert output 594

12 Advanced functions

Define Join Logic 599
User-defined logical joins 599
Logical joins with Clintrial Type 0 599
Creating logical joins 600
Global object storage of join logic 602
Update or Remove Join Logic 602
Join Order 603
Join order in multi-panel reports 603
Change Join Order 606
Load Default Join Order 610
Define Custom Joins 611
Creating custom joins 611
Join type 613
Update or Remove Custom Join 614
Load Default Join Logic 614
Import SQL 615
Enter Import SQL SELECT statement 615
Define New Item 618
Derived items across panels 618
Define New Item 620
Add operators 622
Decode reference 623
Save New Item 624
Save a Global New Item 625
Edit defined new item 627
Remove saved new item 627
Define New Range 628
User-defined range variables 628
Define New Range 628

Define range cut points 629
Save new range variable 630
Edit New Range 631
Define New Event 632
User-defined time related milestones 632
Define New Event 632
Edit or remove new event function 635
Pivot panels 636
Transposing normalized clinical data 636
Creating pivot panels 637
Remove pivot panel 641
Copy to Clipboard 642
View SQL details dialog 642
642

13Dashboard Views
Viewing Patient Data 644
What is Dashboard? 644
Dashboard access 644
Dashboard functions 645
Types of data access 646
Create Dashboard Viewsets 647
Open Dashboard 647
Dashboard tool bar 648
Create New Viewset 649
Select Default Profile 650
Add views to Viewset 653
Save ViewSet 655
Remove object from Viewset 657
Edit Viewset 657
Remove ViewSet 658
Add to Favorites 658
View Viewsets 659
Select a ViewSet 659
Apply Selection Criteria to viewset 660
View Patient Data 663
Patient drill down 663

14Risk Assessment Browser
Risk Assessment Analysis 666
What is the Risk Assessment Browser? 666
Open Risk Assessment Browser 666
Define MedDRA levels 668
Define Treatments 669
Define Patient Subgroups 671
Interact with Risk Assessment Results 677
View Risk Assessment 677

Select MedDRA level 679
Select patient subgroup 680
Select Metric options 681
Patient Highlighting 682
View TreeMap 683
Filtering visual results 685
Set Filter Range 685
Apply output filter 686
Save risk assessment 687

Index

1 Getting Started

Introduction 2
- What is JReview? 2
- Authoring versus Non-Authoring 2
- Key features in JReview 4

Authoring versus Non-Authoring 2
- JReview Setup / Install 5

Starting the application 9
- Logging on 9
- Database and SAS server 12
- Choosing an ORACLE database 12
- JReview Server 12
- NODE UserID 13
- Wrong password? 13
- Trouble shooting 13

On-line Help 15
- On-line Help 15

Quick tour 16
- Main window 16
- Sort folder contents 19
- Launch a saved object 20
- Preferences 21
- ToolBar and Browser Menu Bar 22
- General instructions 24
- JReview Settings 29

Introduction

What is JReview?

JReview is the web-enabled version of Integrated Review. It allows users to view, create, print, and interact with their Integrated Review 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

Non-authoring mode of JReview presents a run-time, read-only environment for browsing and re-executing IReview objects. While the objects will interact as they would in IReview or 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 most kinds of objects (reports, graphs, crosstabs, patient profiles, etc). Objects are completely compatible across Integrated Clinical Systems' products which currently include Integrated Review (IReview), JReview and DashBoard Review.

JReview authoring mode supports the creation of nonformatted reports, cross tabs, shift tables, graphs, Patient SelectionCriteria, Workbook and Graphical Patient Profiles. Advanced authoring areas were added in version 9.0.3; such as Alerts, New Ranges, New Items, Pivot Panels, Import SQL and Graphic Patient Profile Template authoring have been added with version 9.0.3.

JReview can run as a Java™ 2 applet or Java Webstart application (requiring Sun Java 2 Plug-in version 1.4.2+) and execute under Microsoft Internet Explorer, Mozilla Firefox and other browsers supporting the Java Plug-in. Because of its platform-independent design, JReview also runs under Apple Mac OS X and potentially Sun Solaris, and Linux. The Sun Java Plug-in can be installed such that does not impact the default browser JVM.

Object Type Support	Non-Authoring	Authoring
Patient Profile Workbook	X	X
Formatted Patient Profile	X	X
Graphic Patient Profile	X	X
Detail Data Listing	X	X
Summary Listing	X	X
Formatted Detail Data Listing	X	X
Formatted Summary Listing	X	X
Patient Visit Data Report	X	X
Detail Data Graph	X	X
Summary Graph	X	X
CrossTab	X	X
Shift Table	X	X
SAS Proc	X	Basic
SAS Program	X	X (SAS Program Management – future release)
Alerts	X	X
New Range, New Items, Pivot Panels, Import SQL	X	X
Dashboard	X	X

JReview provides the following features:

Intuitive to use; no programming knowledge required.

Direct and immediate access to data stored in existing clinical database systems.

Patient Selection Criteria; select the project, studies, and data types, and focus on data values, ranges, and populations by clicking on the appropriate clinical trial data, operators, and values in the Patient Selection Criteria window.

Multiple selections of data across different time periods.

Patient Listings, Panel Views of subject data, CRF images and Audit Trail accessible from the **Data Browser**.

Summary and Detail reports, formatted options and Patient Visit Data reports cross panels from the **Report Browser**.

Patient Profiles Browser; generate tabular profiles in spreadsheet and formatted displays available for export to PDF, HTML or Excel spreadsheets.

Create time oriented graphical displays (days on drug) with **Graphic Profiles** with duration bars for AEs, Concomitant Meds, Dosage, etc. Display line and trend plots for Labs and Vitals with normal range color region high/low normal symbols. Generate PDFs directly.

CrossTab Browser of multi-dimensional clinical data analysis capabilities to identify patients underlying patient counts within cells. Specify 'Percent Denominator' for all patients or subset populations with CrossTabs and Shift Tables.

Graph Browser provides line charts, scatter plots, 2 and 3-dimensional bar charts, and frequency distributions.

Patient identification (formerly called Drill-Down) within graphs.

ALERTS Browser: sweeps data for the occurrence of specified event or if specified criteria has been met.

Notes Browser: Post notes on Patient data for private use or to share and interact with colleagues

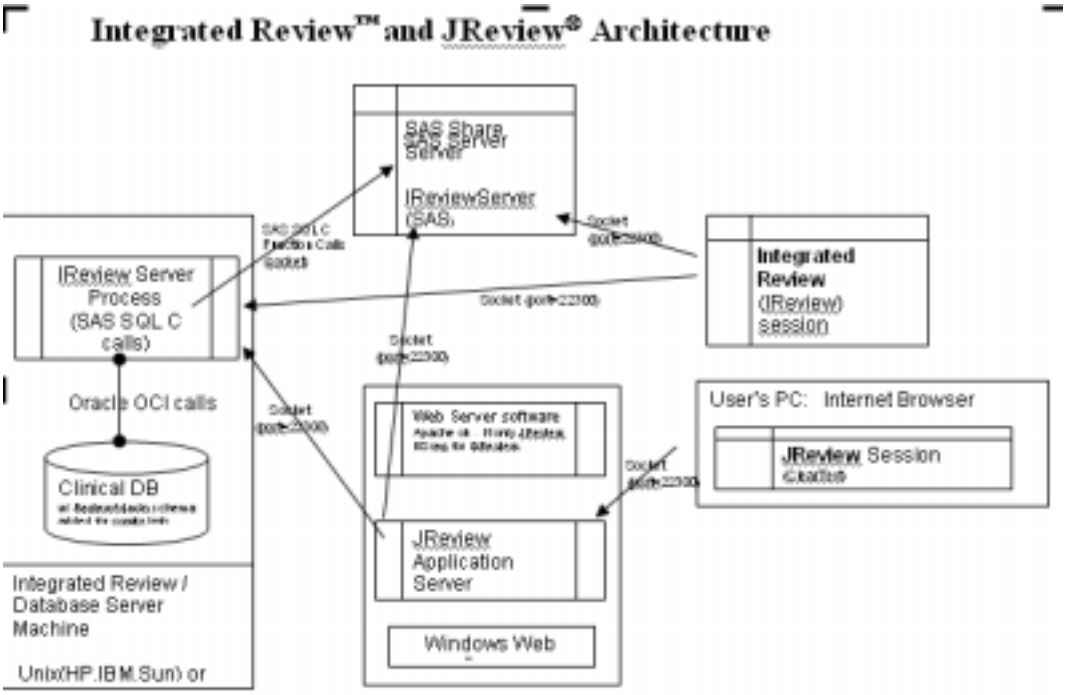
Installing the application

JReview Setup/Install

Refer to the JReview Application Server Installation and Administrator Guide. This document assumes you are the end user and details how to use the application functions.

The setup / install is best executed from Microsoft Internet Explorer (although JReview™ runs equally well under Microsoft and Netscape browsers). Internet Explorer affords better automation of the JRE install through it's ActiveX interface. You may use Internet Explorer to perform the setup / install and subsequently use Netscape to execute JReview™ if you wish.

The setup / install procedure must be performed on any PC or laptop from which JReview™ execution is desired. This procedure may be required once every 6 to 12 months for release updates. This procedure can be invoked from your web server or from CD.



When you are ready to conduct JReview client access tests we recommend progressing from simple access testing to more complex production environment testing. ***Detailed steps are provided in the JReview Application Server Installation and Administrator Guide for Trouble Shooting Client Access.*** There are three phases to these tests:

1. Invoking the JAS as an application on your Web Server desktop and testing JReview client access directly on the Web Server.
2. Invoking the JAS as an application on your Web Server desktop and testing JReview client access from a desktop representative of your JReview user's environment.
3. Optional installation of the JAS as a Windows Service on your Web Server and testing JReview client access from a desktop representative of your JReview user's environment.

Contact your IT support personnel or server administrator for assistance with problems accessing the JReview application.

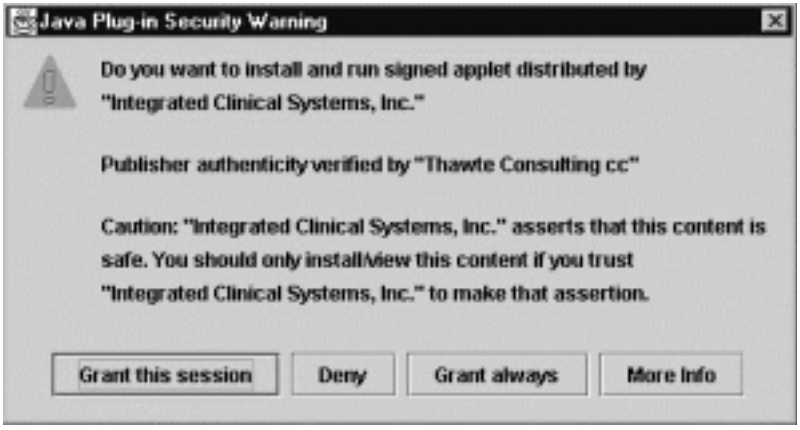
Any other logon / JReview start-up options (e.g. autologon, single-signon) may be provided and are custom to the JReview customer's web portal and the responsibility of the JReview customer to document since they create the portal.

Therefore, the JReview users have 4 possible links and at most TWO at their installation; Auth & non-Auth Plaintext links (aka clear-text) OR Auth & non-Auth SSL links. Most likely, JReview users will only see ONE link depending on whether their JReview admin allows them Authoring or non-Authoring mode.

Note: SSL JReview users only have the "Secure JReview Access over the Internet (1st time Java(tm) Plug-In download from the ICS's site)" link on their JReview Splash pages as the link they use to start JReview.

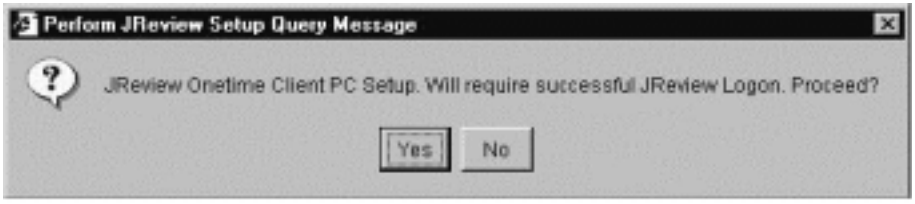
If you need assistance with the JReview Installation, click on the **Troubleshooting page**. Choose defaults or options specified by your PC administrator. (The install process requires 25M free on the C: drive, but results in use of 5 - 7M.)

4. On some machines, a reboot is required after the Java Plug-In install. If that is the case, after reboot, **reload the JReview™ Web page and press the same JReview™ Setup/Install link again**. Once the plug-in install is complete, the process will continue with the install of the JReview™ support JAR. The screen will briefly show:
5. Verify that Integrated Clinical Systems, Inc. is the distributor, then choose **"Grant Always"** to allow JReview™ to install it's components.



If you are installing from your web site, the following dialog box opens. Answer **"Yes"**.

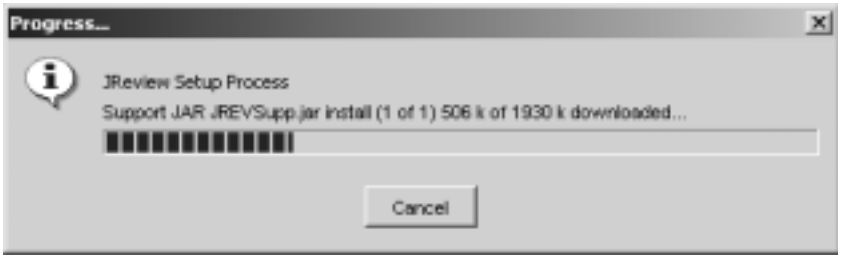
A similar confirmation will occur for installs from CD. The system will check to ensure that the support JAR is indeed necessary



If you are installing from your web site, you will need to successfully login through the JReview Server LOGON window. Enter information provided by your administrator and press **"OK".**

If you are installing from a CD, a JReview™ Setup Progress Bar will appear. Successful execution of the JReview install applet will display showing the progress of the JReview™ Support JAR install. **DO NOT** interrupt the progress.

6. Execute the JReview applet through your Website JReview page. All subsequent access can be through that link.



If you entered incorrect information, or if the JReview™ Server Process is not running or is inaccessible, an error message may display. If such errors occur, see "Trouble Shooting" section and contact your system administrator for assistance.

When the JReview™ setup / install process is complete and successful, the following dialog box will appear. Follow the instructions and exit all of your internet browser sessions. You are now ready to run JReview™ from your link on your web site as directed by your administrator.

Starting the application

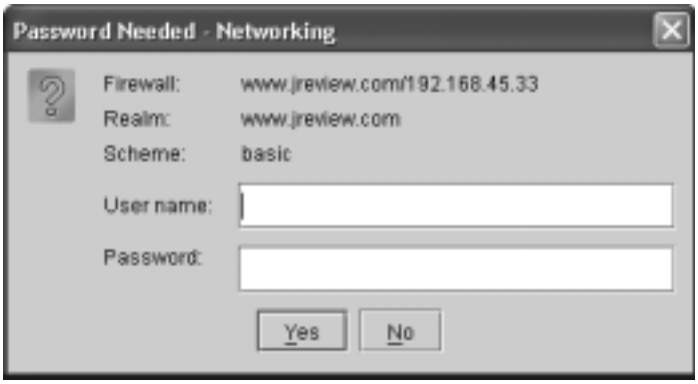
Logging on

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.

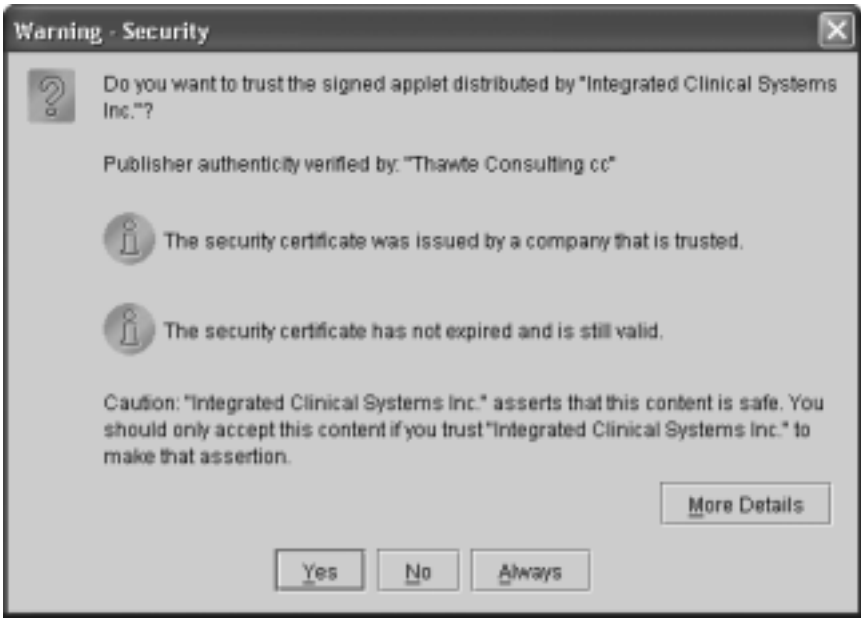
1. Select your JReview link (SSL for normal Internet use, Clear-text for LAN / in-office use). Authoring versions are available if you have permission to create and save objects in JReview™.

2. Enter your web server logon information.

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



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



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.

   The Database UserID and Password are the same as your IReview entries.

6. Click **OK**.

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. They will be the same addresses used in the IReview LOGON screen.

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. Therefore, they are the same as the IReview LOGON settings.

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.

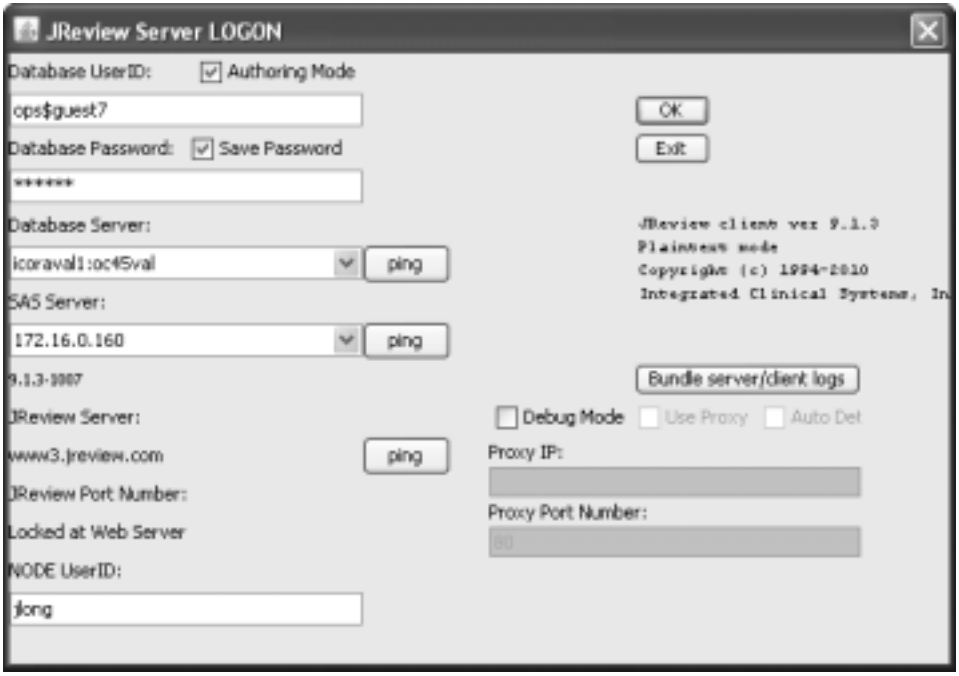
If you want to access an ORACLE database other than the default database that you normally connect to, add the specified database identifier (ORACLE SID) to the end of the ORACLE Server name separated by a colon (:) in the text entry box within the opening Logon dialog box. If the Oracle instance is 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 the each JReview client has a unique NODE UserID. Select the Advance button to designate a unique NODE UserID.



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.

Trouble shooting

This section describes potential difficulties you may initially encounter attempting to use JReview. Please review these suggestions and if problems persist, contact Integrated Clinical Systems Technical Support.

Problem: I pressed the JReview Setup / Install link and I get "Your browser understands the tag but isn't running the applet, for some reason (Java Plug-In 1.4.2 not available?)."

Remedy: The Sun Java 2 Plug-in Version 1.4.2 did not install properly. For LAN / Fast connections choose the link "Press for JReview Setup / Install with Java(tm) Plug-In download from your Web site", for Modem / Slow connections choose the "Press for JReview Setup / Install with Java(tm) Plug-In download from Sun's site", and assure the plugin installs correctly. Reboot if asked to do so.

Problem: I installed the Sun Java 2 Plug-in, rebooted and pressed the "Press here to access JReview" link. I get "Loading Java AppletÖ" then a gray screen and the message "Start: Applet not inited" in the browser status bar.

Remedy: You have not successfully downloaded / installed the JReview Support JAR. JReview client setup is a 2-step process; 1) Java 2 Plug-in install, 2) JReview Support JAR install. Choose the "JReview Setup / Install link" you chose previously and allow JReview to download and install the Support JAR. Assure that you close all browsers after the support JAR download prior to accessing JReview.

Problem: I cannot successfully logon to JReview, I get "Openning SocketÖ", a delay, then a communications warning box. The JReview Logon screen is re-presented.

Remedy: Several conditions can be the cause:

1)The JReview Server process is not running on the web server.

2) You are trying to connect through a proxy server or firewall that prevents the socket connection. JReview installations without the Security Module / SSL and proper proxy server / firewall configuration will prevent JReview communications.

3) An Integrated Review Server process is not running on the host / ip you have entered in the Oracle Server field of the JReview Logon screen.

In all the above cases, contact your Web / JReview administrator. If he / she has difficulty correcting the problem, he / she can contact Integrated Clinical Systems Technical Support.

Problem: I've logged on to JReview and used it for a while when it seemed to freeze and presented a communications warning box.

Remedy: A communications or logic error has caused JReview / JRServer to suspend or abort the JReview client session. Close your browser and restart JReview. If the problem is reproducible, please record the steps to reproduce the problem and contact your Web / JReview administrator On-line Help and Integrated Clinical Systems Technical Support.

On-line Help

On-line Help

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

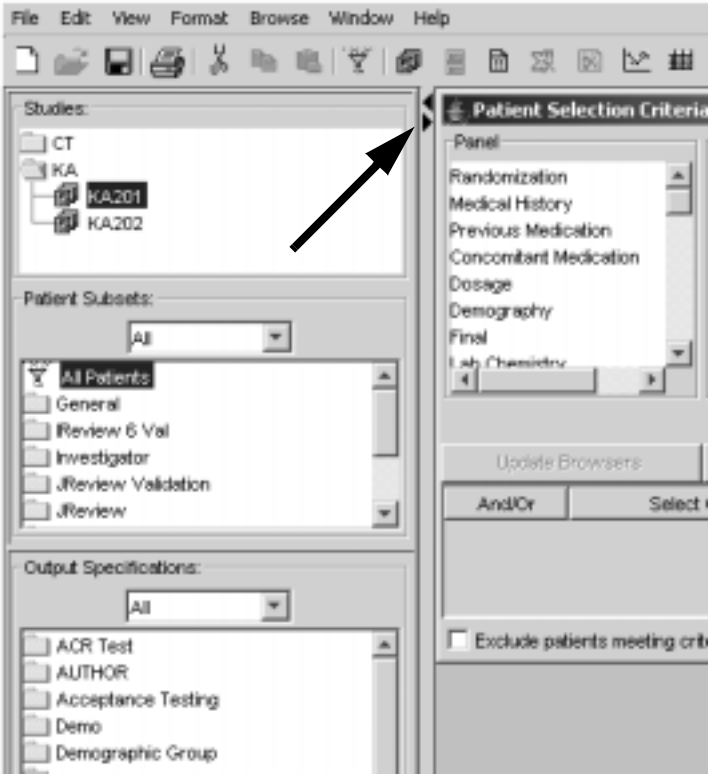
Quick tour

Main window

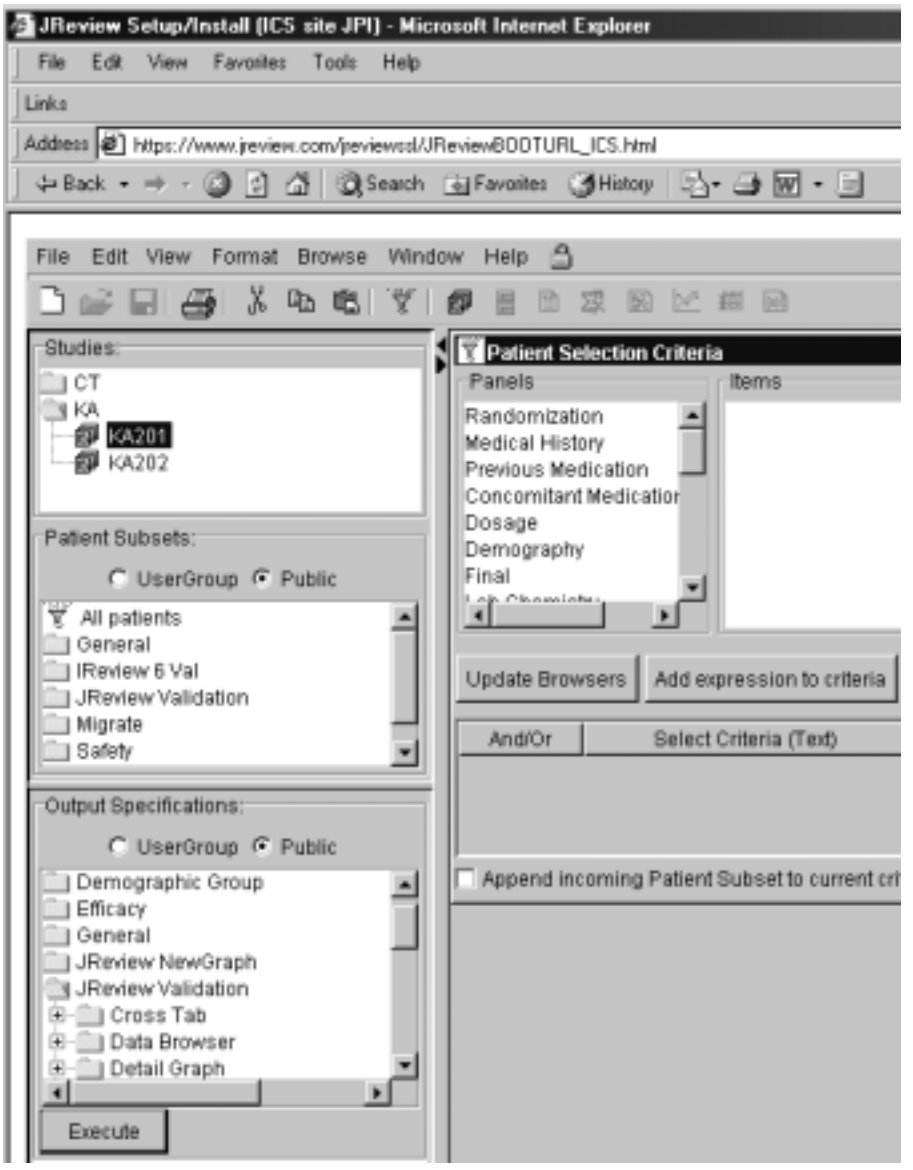
After you successfully log into the ORACLE database (on the computer storing your clinical data), the main window of JReview opens.

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 KA' and protocol 'KA201'. JReview retrieves all previously stored Output Specification objects created and organized in folders from IReview.



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 SAS, SQL or FOR (Foreign).

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 in IReview, they can be quickly located and launched from within these folders in both IReview and JReview. The results are displayed in the Output Specifications window and Patient Subsets window.

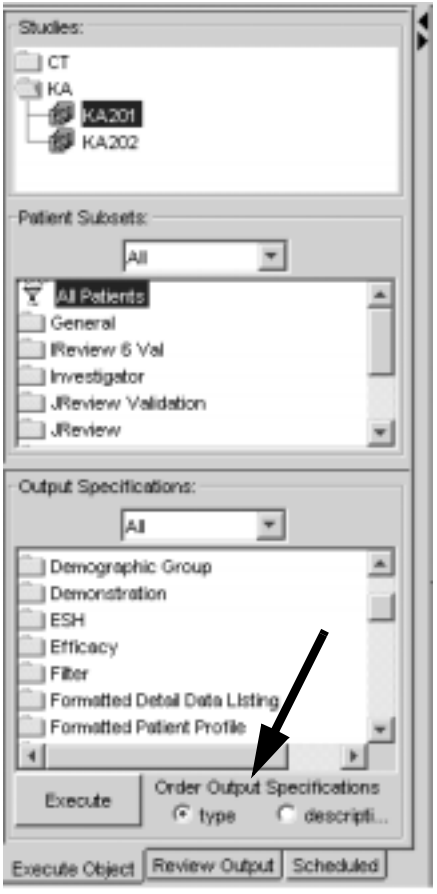
Note: The individual who creates and saves an object definition has sole security to delete or modify it. SuperUsers have extended privileges.

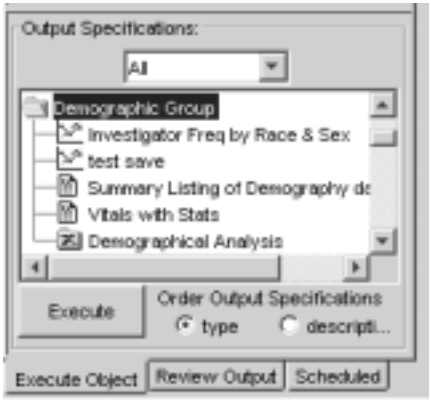
In addition, a browser icon displays along side the object description to quickly identify the various output results, such as Reports, Graphs, CrossTabs, Registered SAS Programs, etc. A filter icon lets you know that a patient selection criteria was saved with the output specification object. A red 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.

In JReview, the saved objects in UserGroup and Public levels are displayed from IReview. The stored Private level objects in IReview are not displayed in JReview.

Sort folder contents

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 sort display.





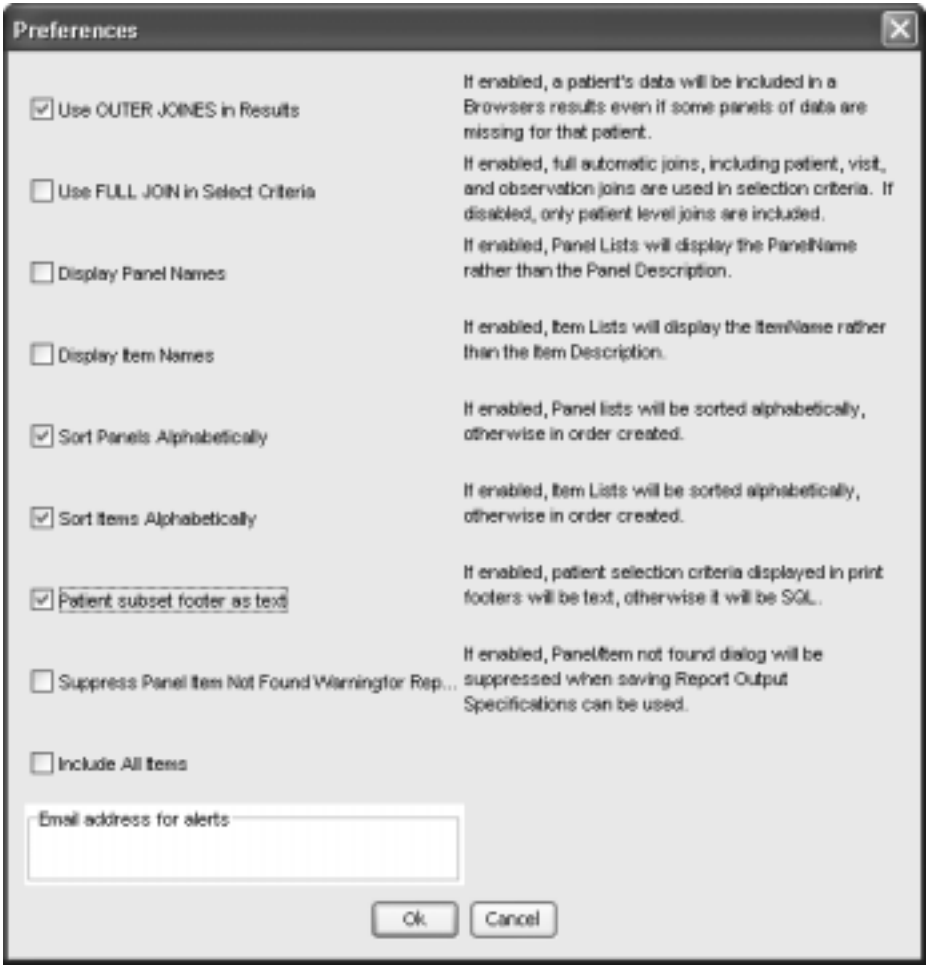
Launch a saved object

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. Use the '**X'** icon to cancel a process. Click **Restablish** if the connection is dropped.

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.



You can access some functions through the Browser Menu Bar. Icons which cannot be accessed in JReview are disabled in the toolbar. For example, select **Print** for **printing** results output display. *(See individual chapters for printing instructions of output display.*

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

The individual browser toolbar buttons are used in IReview for creating and saving object specifications. These are the same browser icons displayed along side the stored object descriptions to identify the object type. The ToolBar buttons are as follows:

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.

Data Browser: Starts the Data Browser.

Patient Profile Browser: Starts the Patient Profile Browser.

Report Browser: Starts the Report Browser.

Graph Browser: Starts the Graph Browser.

CrossTabs Browser: Starts the CrossTabs Browser.

SAS Proc Browser: Starts the Statistics Browser in IReview only.

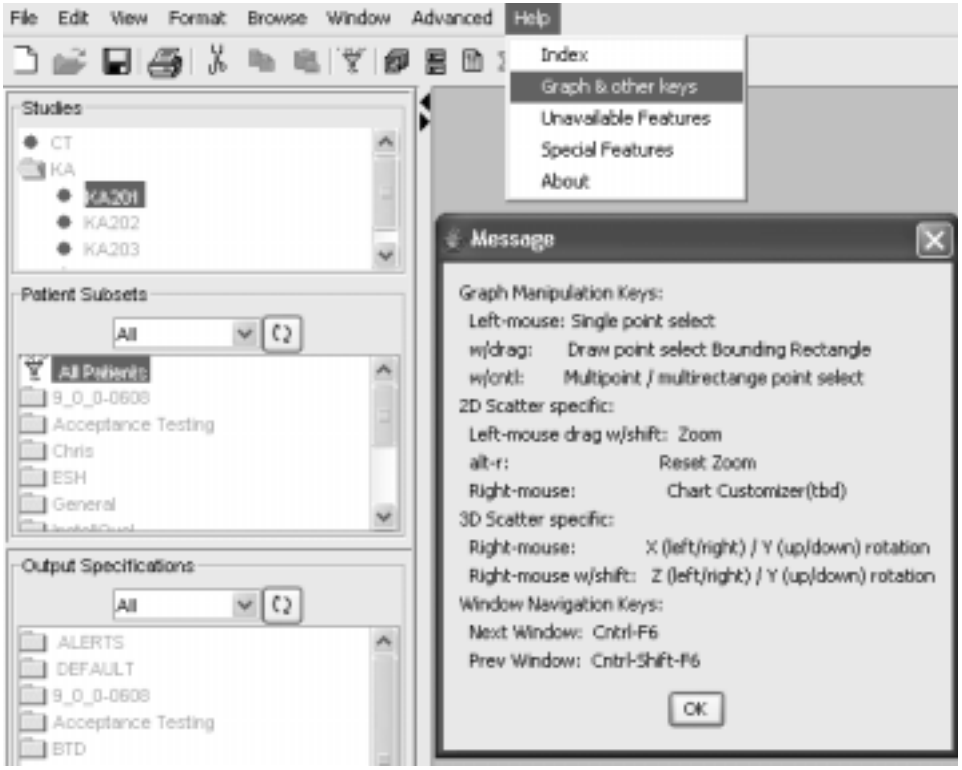
SAS Program Browser: Registered SAS Programs Library for immediate execution against selected patient populations in IReview only.

Notes Browser: Opens the Notes Browser.

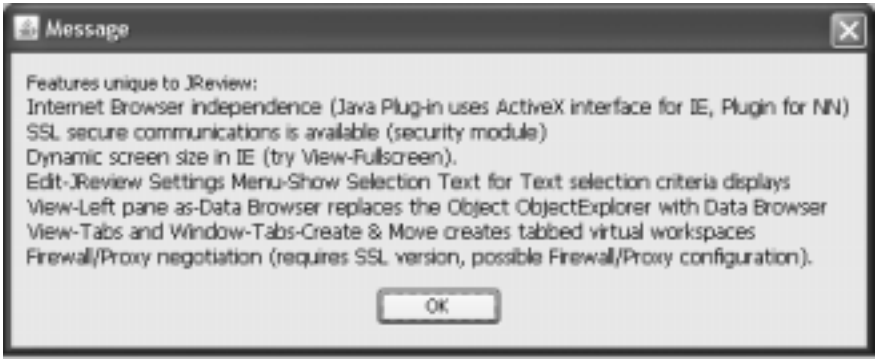
Alerts Browser: Starts the Alerts Browser.

You can view information about features which will be implemented in the near future and user tips.

- Seelct to view information for **Graph Manipulation keys**.



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



- JReview's client version information can be viewed from **Help -> About.**

- JReview's current limitations can be viewed from **Help -> Unavailable Features.**

- Features unique to JReview can be viewed from **Help -> Special Features**.

- 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.

- Printing - 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).

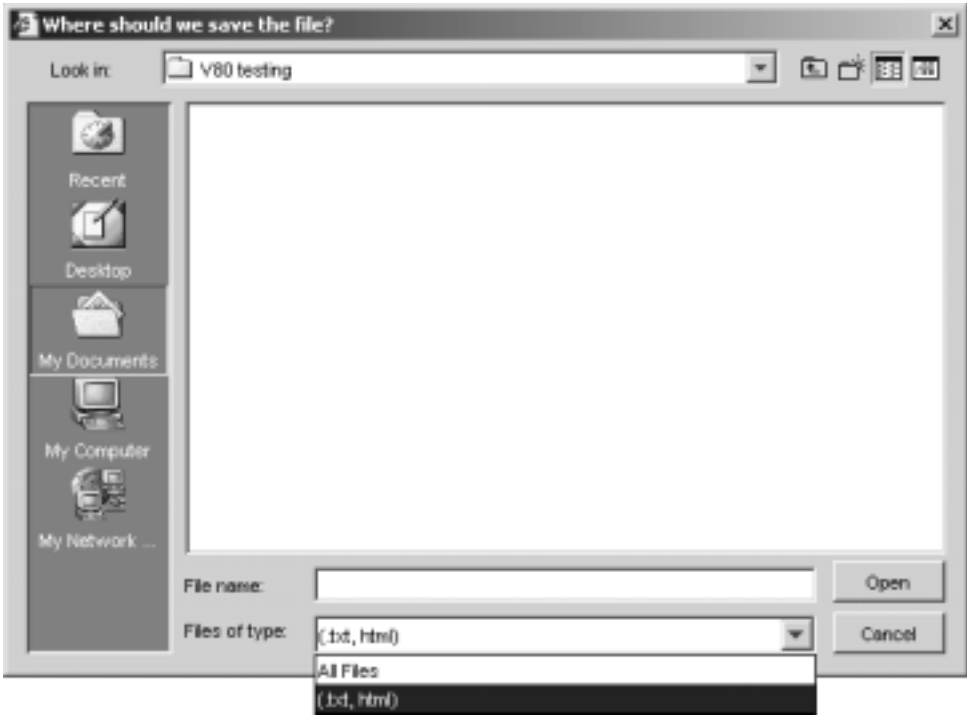
2. If your printer supports reducing the resolution of the printout, we recommend that you reduce the print resolution to 300 dpi. This will significantly speed the printing process.

- 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

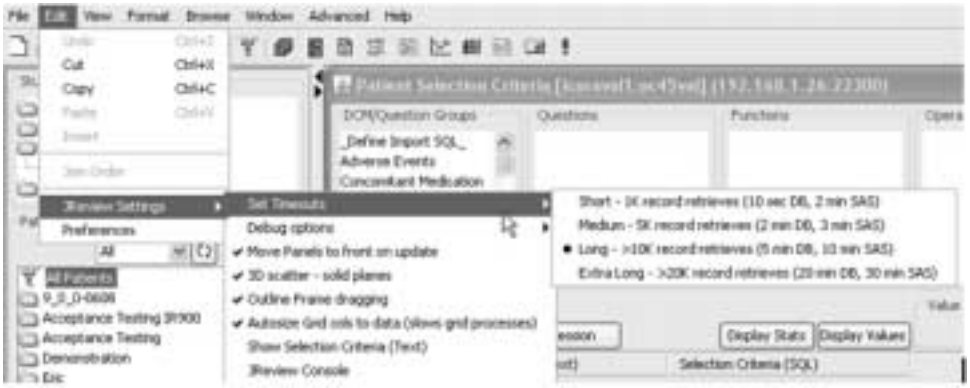
  Use the mouse (click and drag) to highlight a range of grid cells, Select the **Edit** menu and click **Copy**.
- Exporting objects to native file formats is available. To select an object to export, you must select its frame (make the titlebar blue). Select the **File** menu and click **Export**. Based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



- Not all communication requests are processed in a separate thread. This means that JReview may appear to freeze momentarily upon certain requests. See description of the procress bar which will appear for all delayed requests).

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 33
Review sub-populations 33
Focused analysis 33

Steps for Patient Selection Criteria 34
Select a project 34
Single-protocol mode 34
Multi-protocol mode 35
Access to SAS datasets 35
Steps for selection criteria 36

Building criteria expressions 37
Criteria expressions 37
Selecting a panel 37
Selecting an item 38
Supplying a value 39
Displaying item values 40
Selecting multiple values 41
Selecting an operator 42
Building a string expression 43

Joining criteria expressions 43
Boolean operators 43
Additional criteria expressions 44
AND operator 45
OR operator 46
ANDSelect operator 47
Build a complex patient selection criteria 48
Changing the selection criteria 49

Item comparison selector 50
Compare items 50
Exclude patient criteria 51
Display excluded patients 51
Functions 53
Types of function values 53
Decoded value 53
Actual value function 53
Derived function values 53
Date function 54
Item Statistics 55
Display item statistics 55
Displaying subsets of protocol population 57
Object storage: Saving your work 58
Saving the selection criteria 58
Access tab 60
Object storage location 61
Object level 62
Publish for study groups 62
Override selected Project / Global object? 63
Object Explorer window 63
Retrieve a saved selection criteria 64
Append to criteria 64
Object properties 66
Quick remove 67
Create Tabs 68
Create new tab 68
Move objects between tabs 69
Display Data Browser 70

Specify Patient Selection Criteria

Review sub-populations

Review 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 Review 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 focuses Review’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.

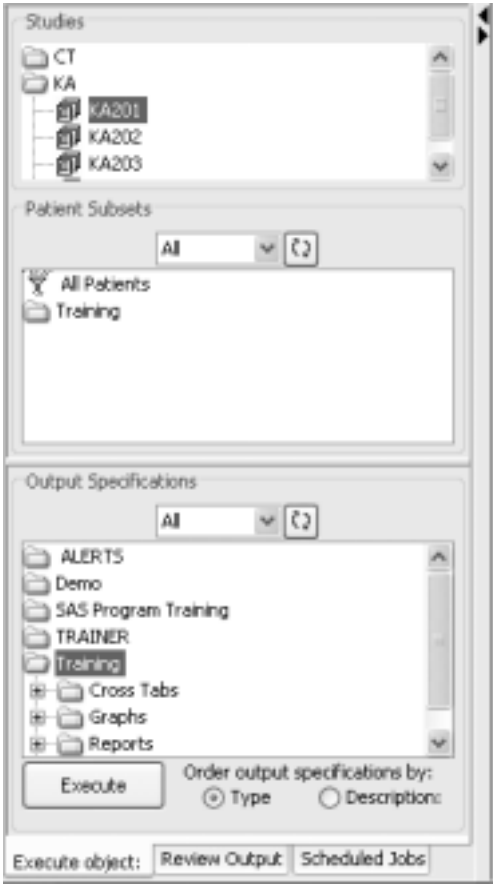
Steps for Patient Selection Criteria

Select a project

In the Object Explorer Window, 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 KA', Review opens that project folder to display the protocols stored in your clinical data base.

Single-protocol mode

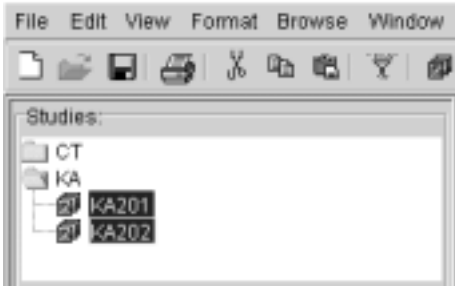
You can click and select a protocol that you want to explore. If you click on one protocol, you are in single-protocol mode. The lists of panels and items that are displayed corresponds to all panels and items in that protocol.



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.

You can select multiple protocols in one of the following ways:



For contiguous protocols (protocols listed next to each other):

1. Click the first protocol.
2. 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):

1. Select the protocols you want while holding the **Ctrl** key.
2. Click each protocol you want to select.

Note: In Browsers, the item StudyID, is used for protocol comparison.

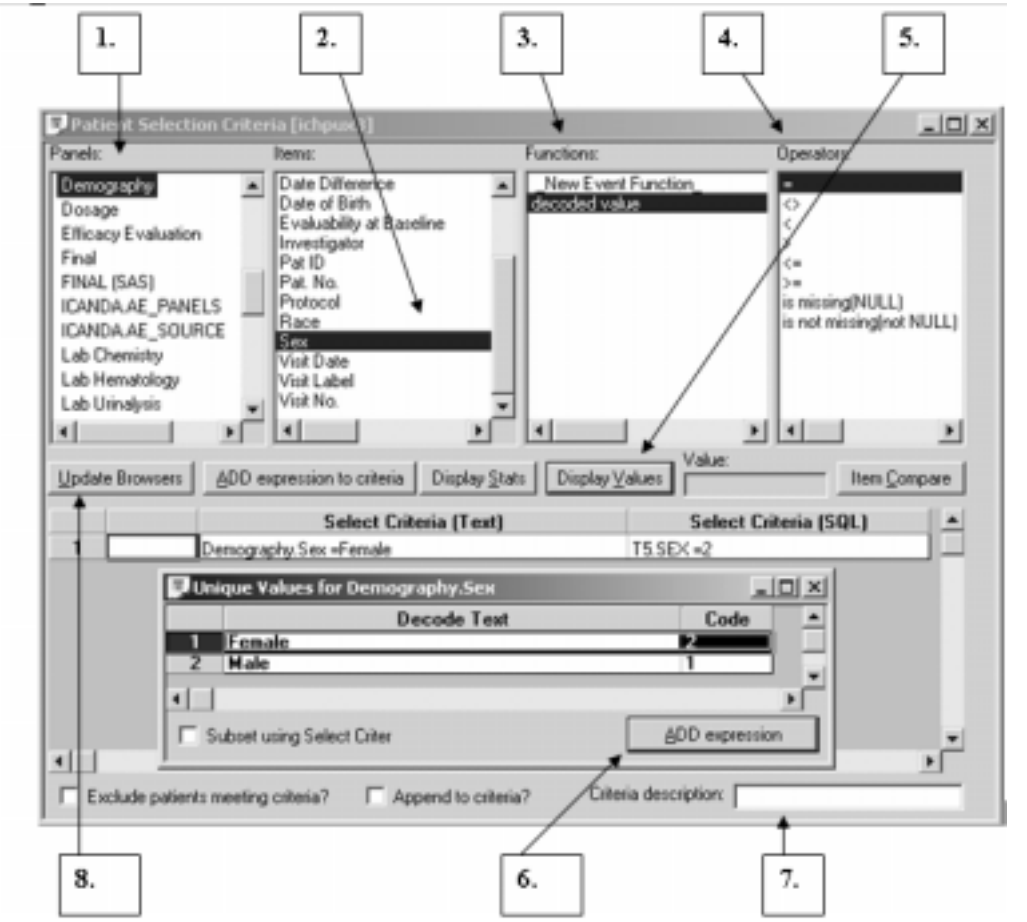
Access to SAS datasets

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.

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.



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

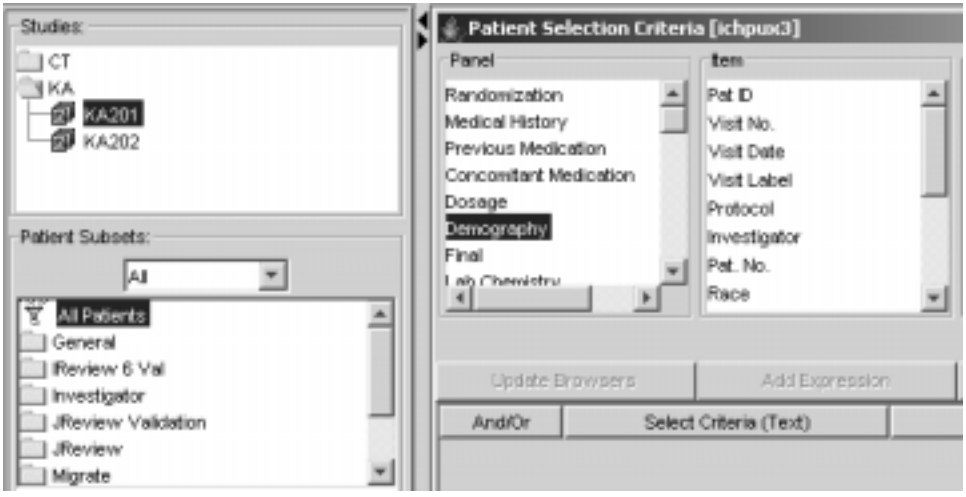
Patient selection criteria are made up of logical expressions, such as '**AGE > 50**', connected by Boolean operators, such as AND, ANDSELECT, or OR. You create these expressions by clicking on various listboxes.

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. They often correspond to Case Report Form (CRF) modules, such as 'Admissions', '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. Your goal is to build a patient selection criteria to describe the patient population that you want to explore.

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**,** Review retrieves and presents a list of all the items stored in the Demography Panel.

2. Select an item.
3. Select an operator.

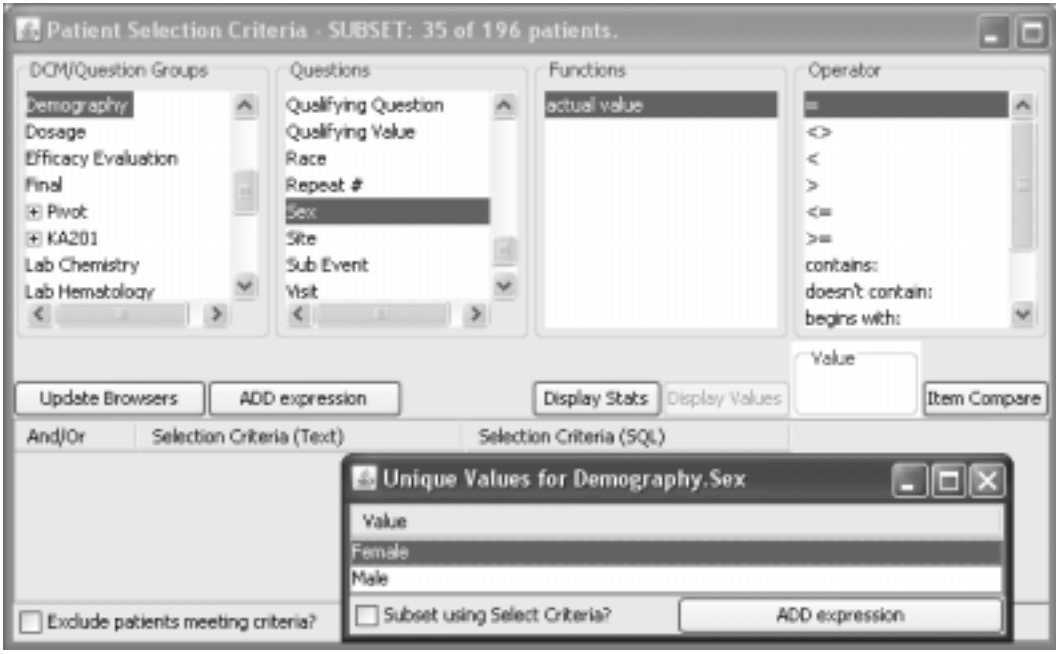
   The list of Functions and Operators displayed will vary dependent upon the item's data type.

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.

   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**.

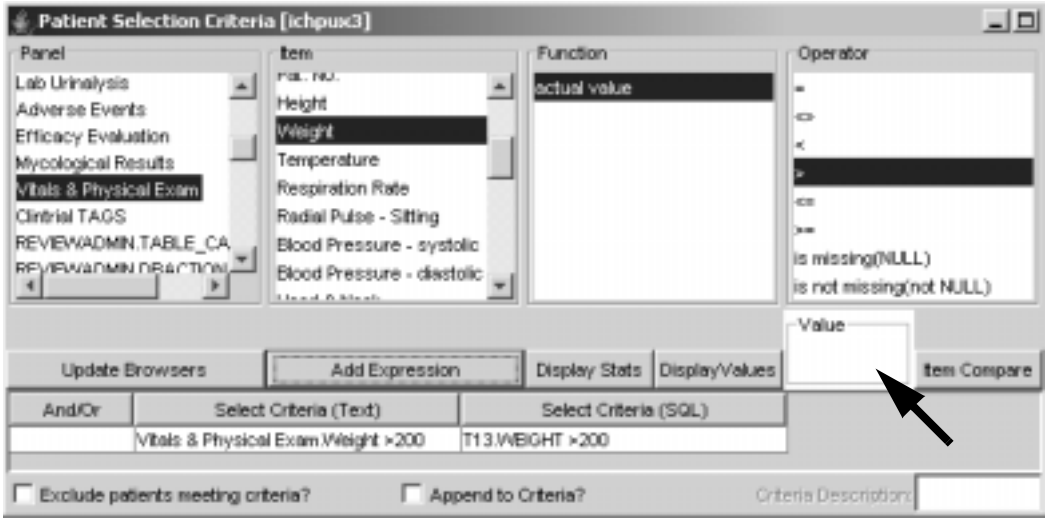


The configuration option for RETREIVEPATIENTCOUNTS, permits the Patient Selection Criteria header display to update, showing the number of patients in the current active selection criteria.

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.



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.

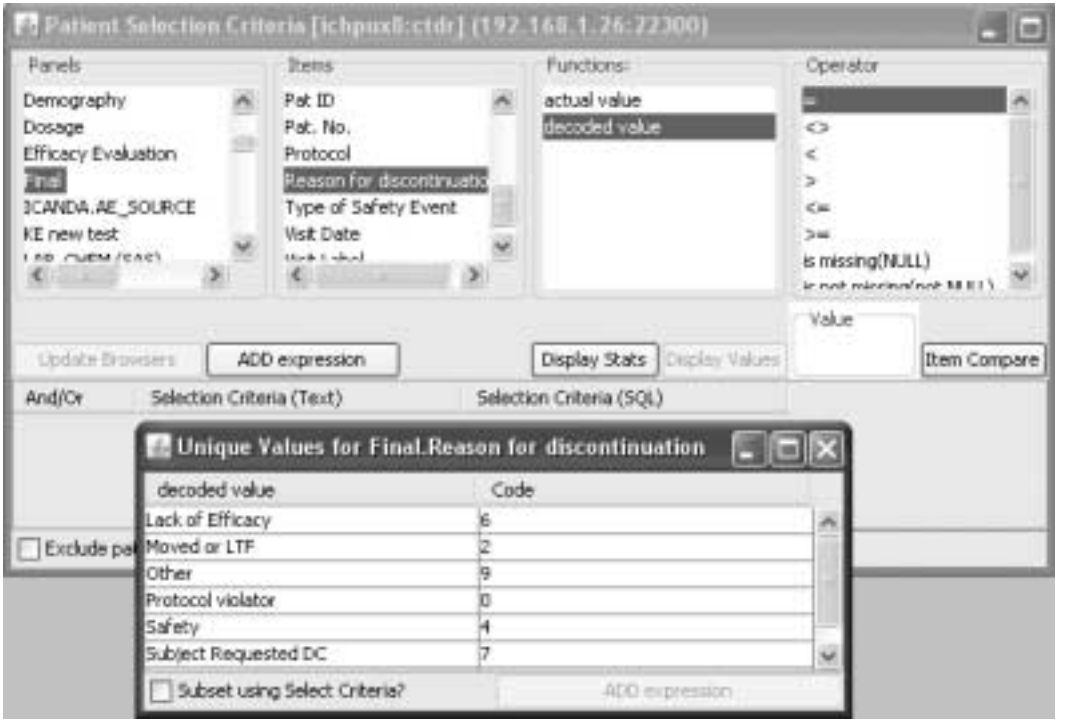
And/Or	Select Criteria (Text)	Select Criteria (SQL)
	Vitals & Physical Exam.Weight >200	T13.WEIGHT >200

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):

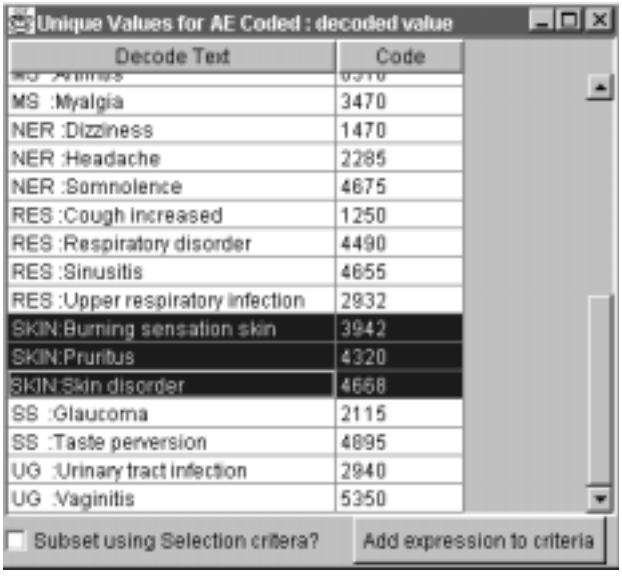
1. Select a panel, such as Final Report.
2. Select an item, such as Reason for Discontinuation.
3. Click **Display Values**. The Dispaly Values window does not automatically open for decode items.

   Review 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.



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.



When you click **ADD expression to criteria**, Review 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	Select Criteria (Text)	Select Criteria (SQL)
	Adverse Events.AE Coded =3942,4320,4668	T10.SECODE IN ('3942','4320','4668')

Review 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', Review 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: Review 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:

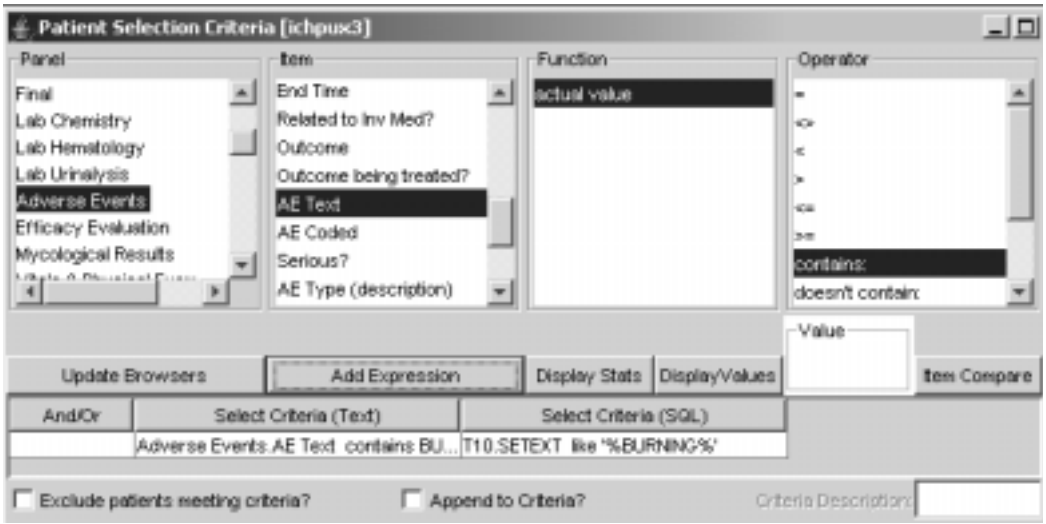
e. is missing (NULL)

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**.



Joining criteria expressions

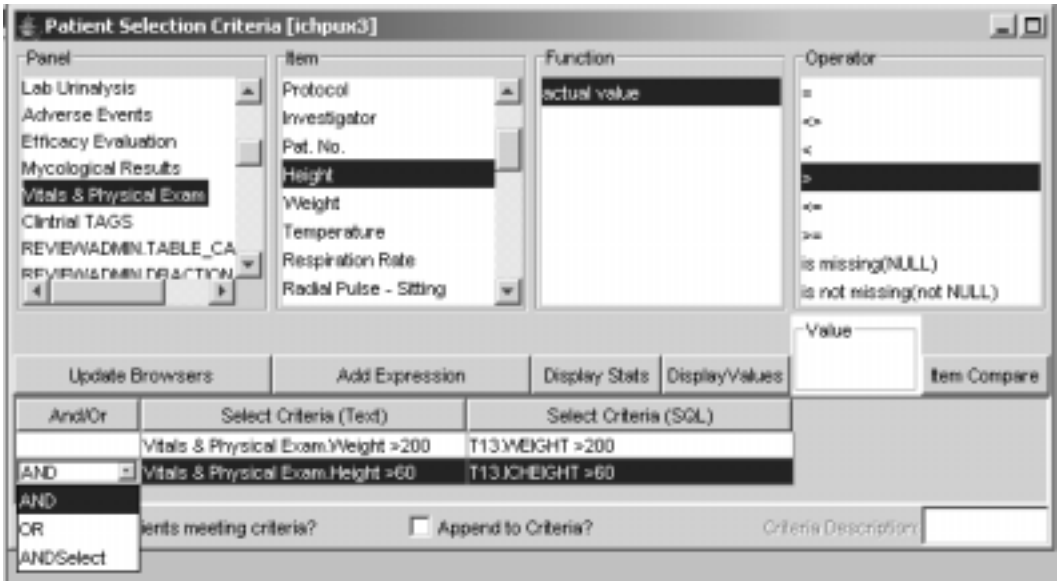
Boolean operators

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.

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. This means that the previous expression and the current expression will be used with an AND between them. The patients selected pass the previous expression Criteria AND the current expression Criteria. If this is not appropriate, you can change the AND to an OR or ANDSelect.



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

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.

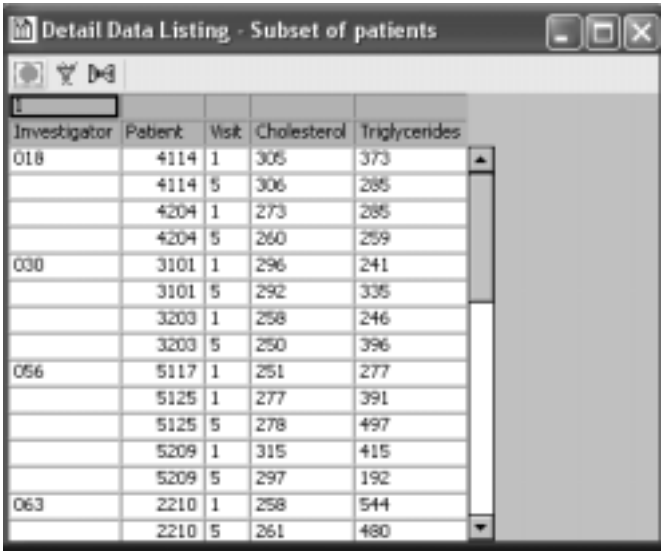
AND operator

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

		Select Criteria (Text)	Select Criteria (SQL)
1		Lab Chemistry Cholesterol, total >=250	T7.CHO >=250
2	AND	Lab Chemistry Triglycerides >=250	T7.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: Viewing 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.

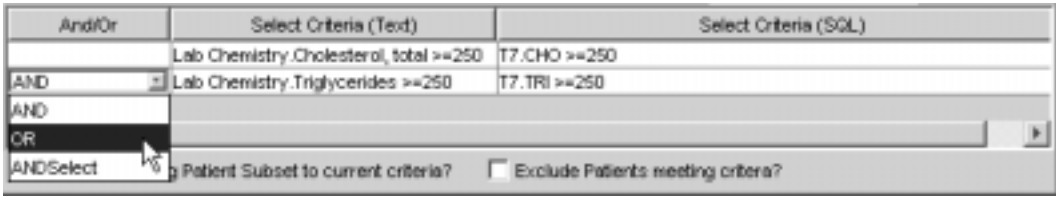


Investigator	Patient	Visit	Cholesterol	Triglycerides
018	4114	1	305	373
	4114	5	306	285
	4204	1	273	285
	4204	5	260	259
030	3101	1	296	241
	3101	5	292	335
	3203	1	258	246
	3203	5	250	396
056	5117	1	251	277
	5125	1	277	391
	5125	5	278	497
	5209	1	315	415
	5209	5	297	192
063	2210	1	258	544
	2210	5	261	480

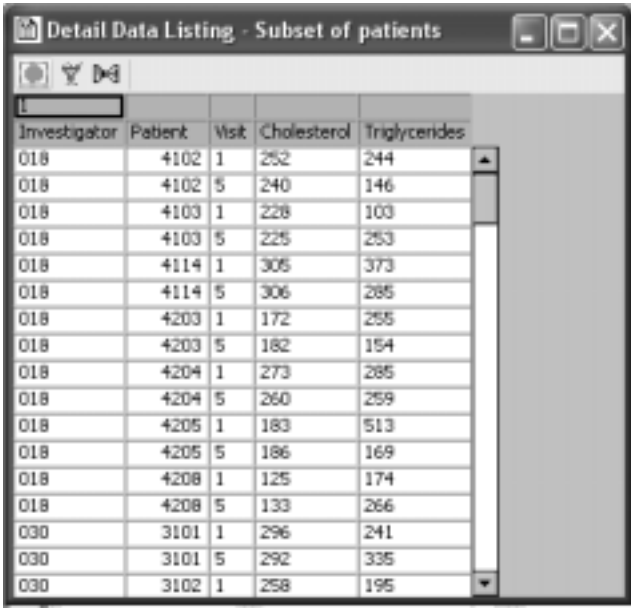
Notice in the detail data listing contains some patient visits which do not meet the selection criteria as show by the arrows. Remember the patient selection criteria is based upon the patient paradigm and all the patient's data is displayed. If you do not want the visits (rows) to display in your output,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



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.



Investigator	Patient	Visit	Cholesterol	Triglycerides
018	4102	1	252	244
018	4102	5	240	146
018	4103	1	228	103
018	4103	5	225	253
018	4114	1	305	373
018	4114	5	306	285
018	4203	1	172	255
018	4203	5	182	154
018	4204	1	273	285
018	4204	5	260	259
018	4205	1	183	513
018	4205	5	186	169
018	4208	1	125	174
018	4208	5	133	266
030	3101	1	296	241
030	3101	5	292	335
030	3102	1	258	195

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.

		Select Criteria (Text)	Select Criteria (SQL)
1		Lab Chemistry.Cholesterol, total >=250	T7.CHO >=250
2	ANDSelect	Lab Chemistry.Triglycerides >=250	T7.TRI >=250

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.

Detail Data Listing - Subset of patients

Investigator	Patient	Visit	Cholesterol	Triglycerides
018	4114	1	305	373
	4114	5	306	285
	4204	1	273	285
	4204	5	260	259
030	3101	1	296	241
	3101	5	292	335
	3203	1	258	246
	3203	5	250	396
056	5117	1	251	277
	5125	1	277	391
	5125	5	278	497
	5209	1	315	415
	5209	5	297	192

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.

		Select Criteria (Text)	Select Criteria (SQL)
1		Lab Chemistry.Cholesterol, total >=250	T7.CHO >=250
2	OR	Lab Chemistry.Triglycerides >=250	T7.TRI >=250
3	ANDSelect	Medical History.Cardiovascular Disease =2	T1.CARDIAC =2
4	OR	Medical History.Hypertension =2	T1.HYPERTEN =2

The ANDSELECT operator partitions the patient selection criteria to be executed into two subqueries. First Review 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.

Detail Data Listing - Subset of patients

Investigator	Patient	Visit	Cholesterol	Triglycerides	Cardiovascular Dx	Hypertension
018	4114	1	305	373	No	Yes
	4114	5	306	285	No	Yes
	4208	1	125	174	No	Yes
	4208	5	133	266	No	Yes
030	3104	1	258	62	Yes	No
	3104	5	199	50	Yes	No
	3109	1	227	341	Yes	Yes
	3109	5	249	355	Yes	Yes
	3111	1	292	199	No	Yes
	3204	1	194	272	Yes	Yes
	3204	5	199	232	Yes	Yes
	3205	1	196	164	Yes	Yes
	3205	5	216	333	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. Review 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

		Select Criteria (Text)	Select Criteria (SQL)
1		Mycological Results:Visit No. =1	T12.VISIT =1
2	AND	Mycological Results:KOH Exam (Inv) =Positive	T12.KOHEXAM ='2'
3	ANDSelect	Mycological Results:Visit No. =6	T12.VISIT =6
4	AND	Mycological Results:KOH Exam (Inv) =Positive	T12.KOHEXAM ='2'

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.

*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

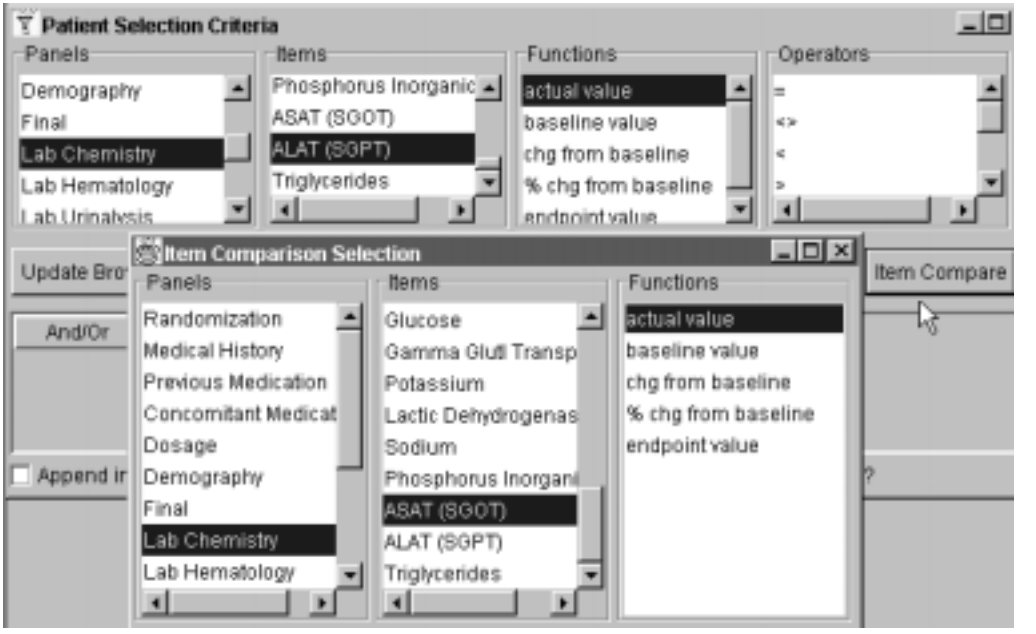
If you want to change the patient selection criteria, click anywhere in the row that you want to change:

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**.

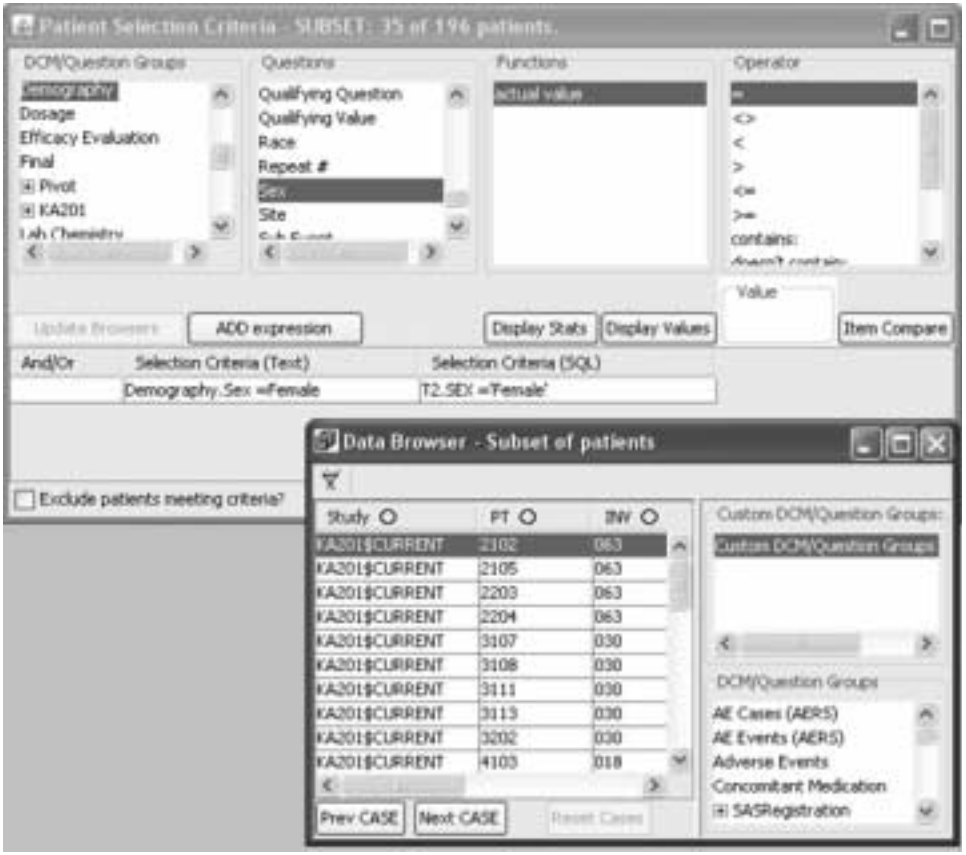
Note: The SQL text that is created when compare Lab Chemistry panel item SGOT > than SGPT actual values:

		Select Criteria (Text)	Select Criteria (SQL)
1		Lab Chemistry.ASAT (SGOT) >Lab Chemistry.ALAT (SGPT)	T7.SGO >T7.SGP

Exclude patient criteria

Display excluded patients

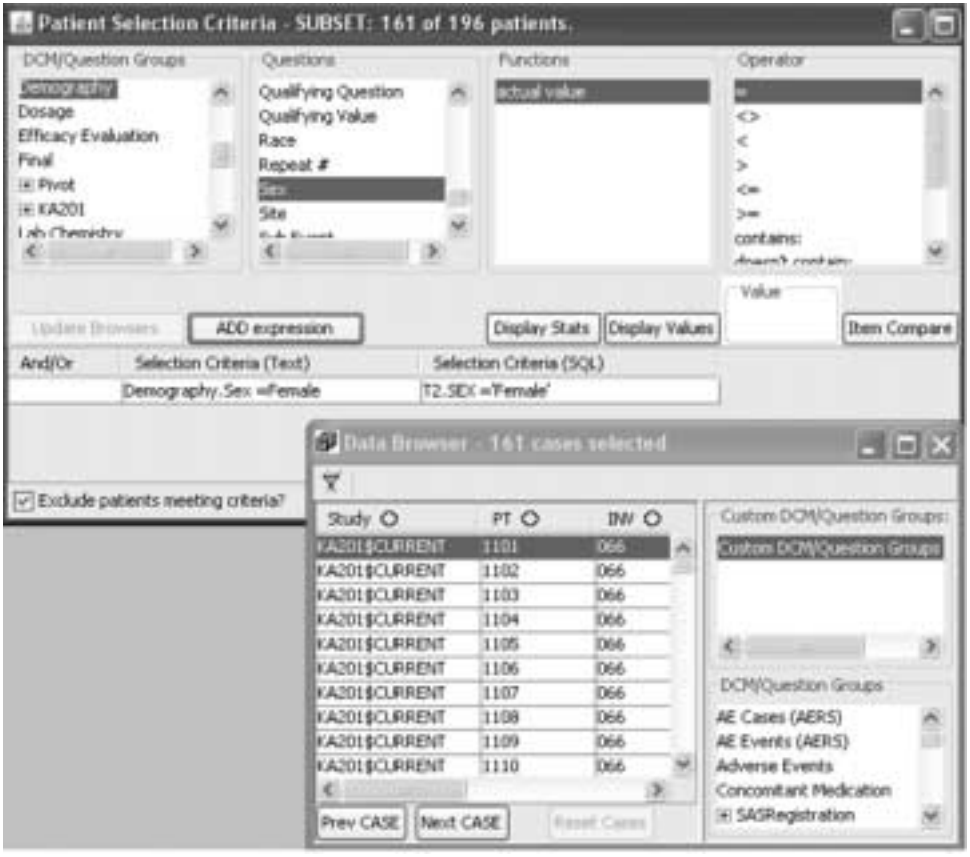
You have the ability to view those patients who are not in your current selection criteria by setting **Exclude patients meets criteria?**. Click the button in the lower right corner of the Patient Selection Criteria Window to set this option on. For example, build a patient selection criteria for female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



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.



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 (see below).

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.

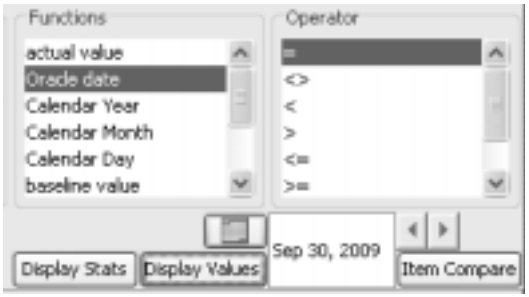
Derived function values

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 in IReview available to select in JReview.

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.

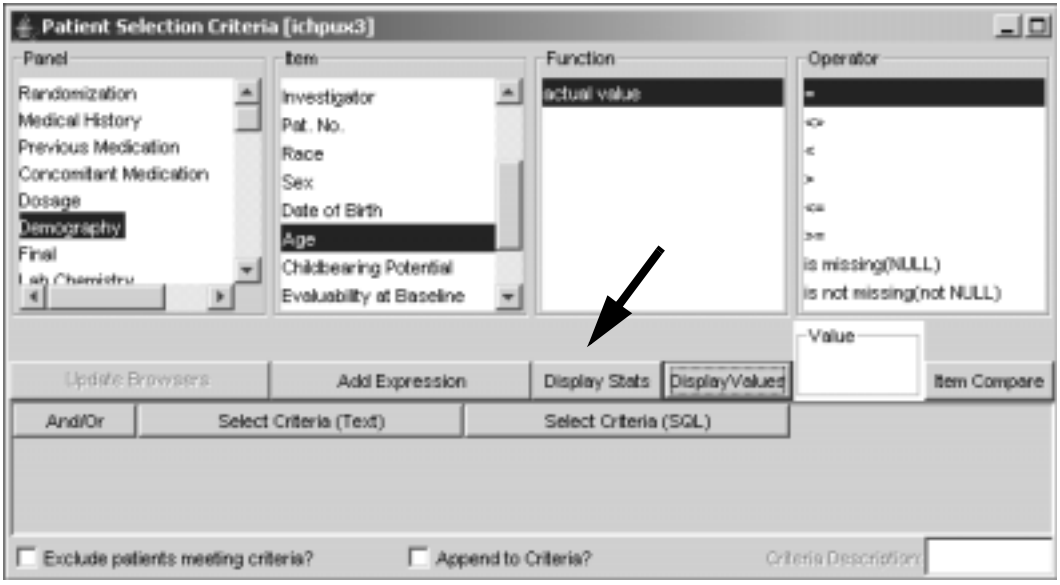
Item Statistics

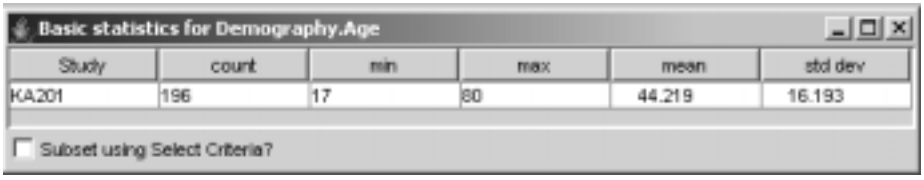
Display item statistics

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

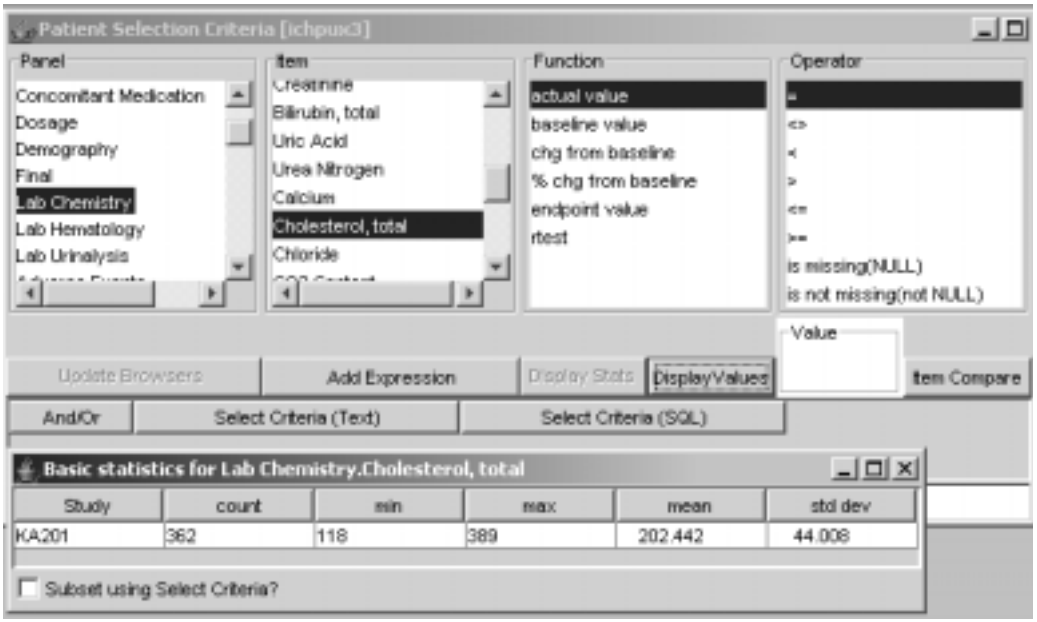
Hint: This function has meaning when applied to numeric data items and may not be significant for other values.

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.





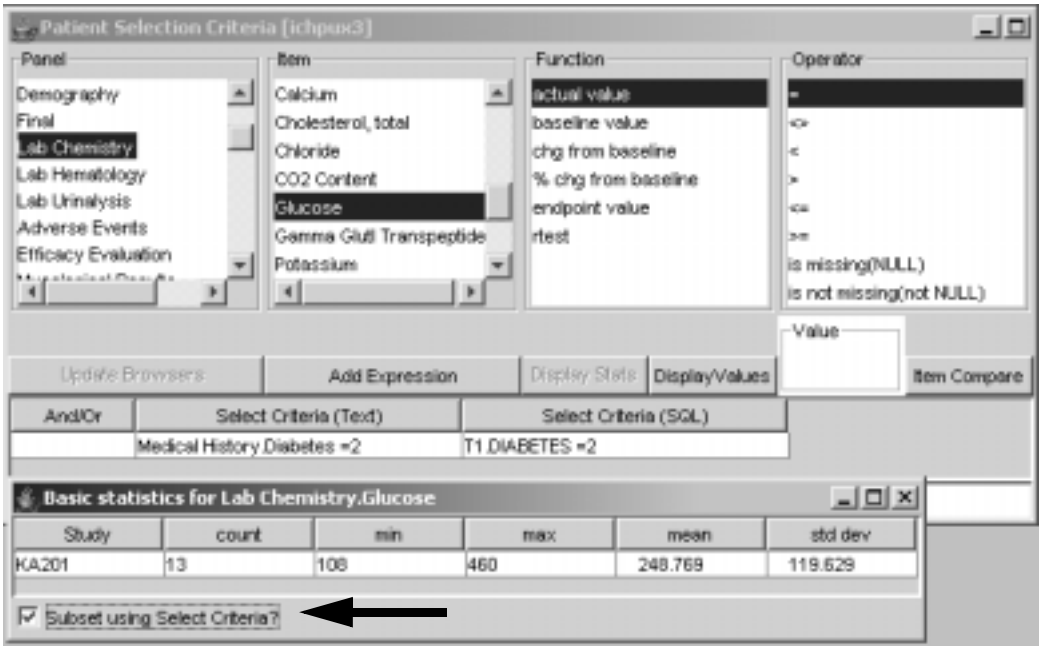
This example for lab item cholesterol counts the individual lab values across multiple visits to display the basic statistics for the lab item.



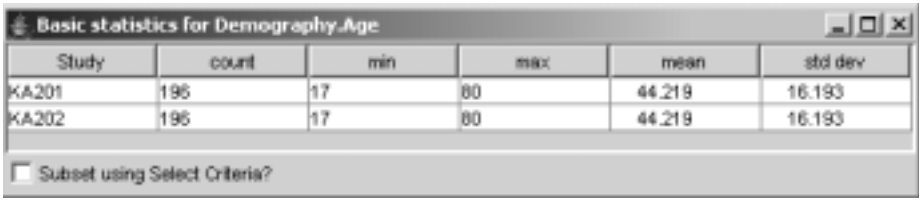
You can limit the displayed statistics for the patients meeting the patient selection criteria by checking "Subset using Select Criteria?". If the checkbox is not checked, the statistics are for the total patient population.

When

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**.



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



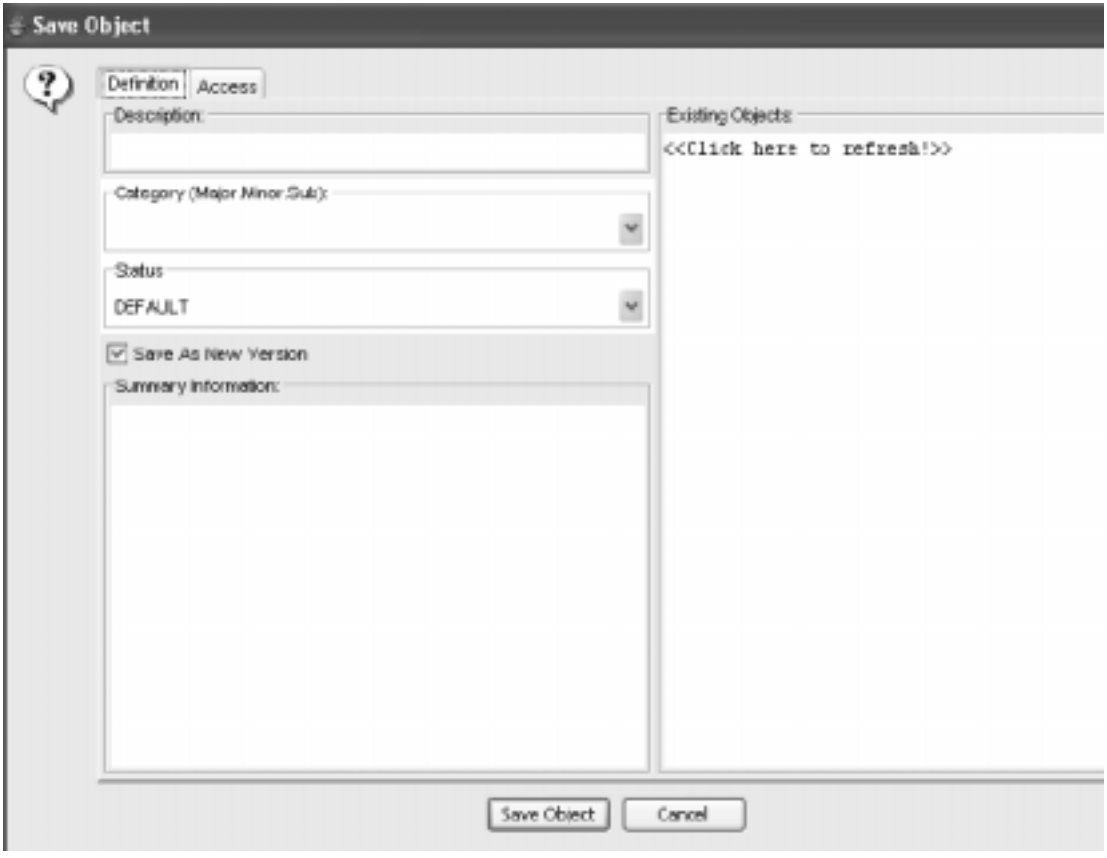
Object storage: Saving your work

Saving the selection criteria

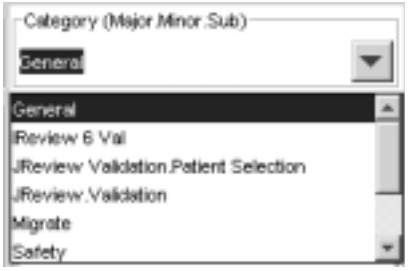
To save the patient selection criteria you have created for later use:

1. Make certain that the Patient Selection Criteria window is the active window by clicking on its title bar.
2. Click , or from the **File** menu select **Save.**

   JReview displays the **Save window** organized by tabs associated with saving an object:
3. In the **Definition tab**, enter an appropriate **Description**. This description is displayed in the **Object Explorer window**.



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'.

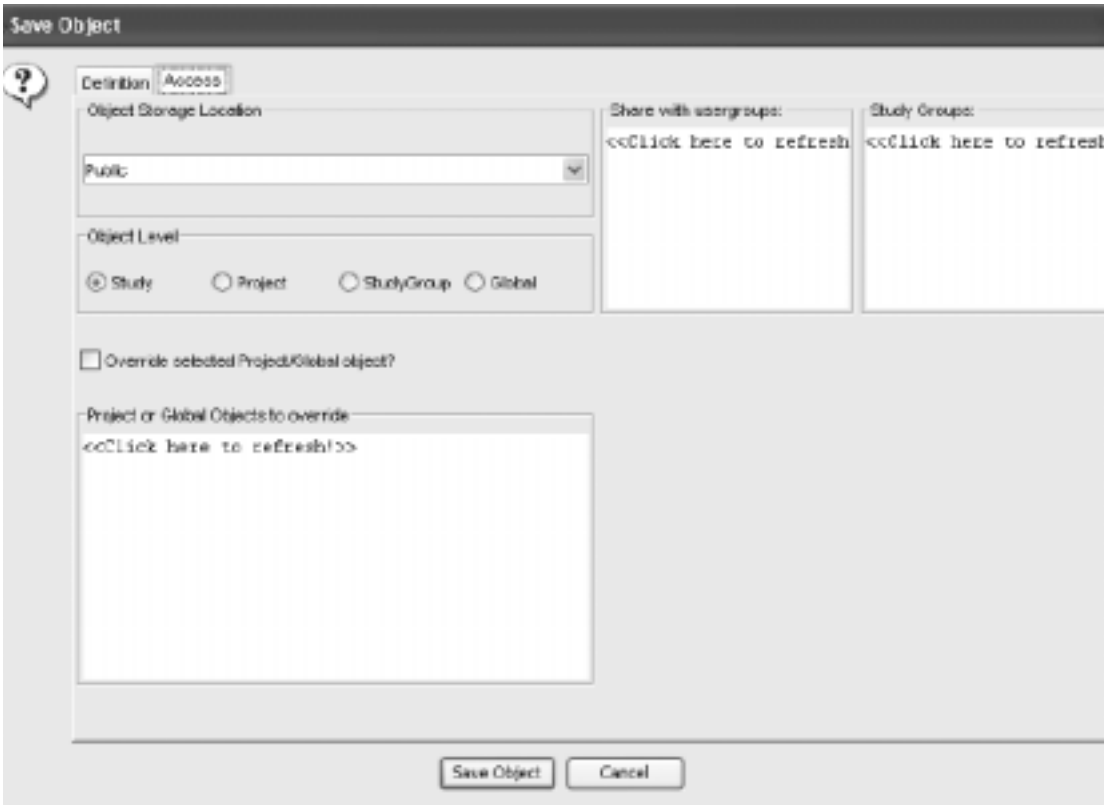
   Folder names are case-sensitive and after the folder(s) are initially created, they are selected from the dropdown list box.

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.

Access tab

7. Click on the **Access tab** to enter object storage location and object level user access.



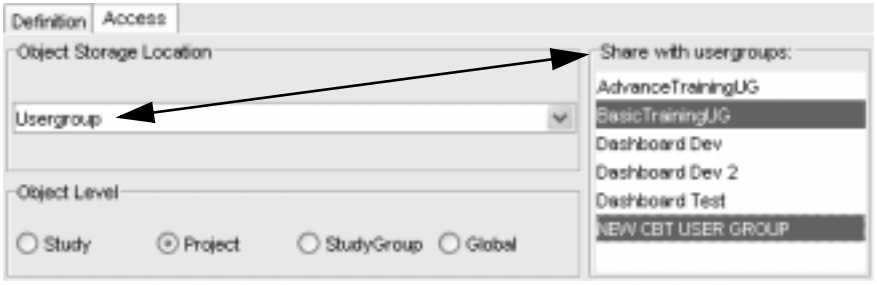
8. Select an **Object Storage Location**.

You can store patient selection criteria in JReview at three user access levels: Private, UserGroup or Public. Saving on database object storage sites, requires the author to have "Publishing Authorization" defined in the configuration tables.

9. Enter the Object Storage Location.

- Private storage is a database object storage. JReview is web based access which allows users to access JReview from different PCs. In addition, you can schedule Private database stored objects.
- UserGroup storage is a database object storage for defined UserGroups in the configuration tables.

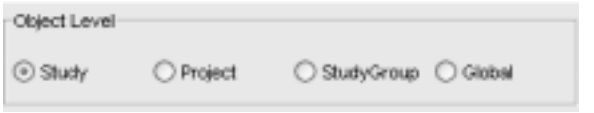
  Object storage in UserGroup level allows you to specify sharing with multiple UserGroups. This works when you click UserGroup and you are a member in a UserGroup, then the UserGroup listbox is enabled. If you want to share the object with multiple UserGroups, simply use the CTRL or SHIFT mouse click for multiple selections.



- Public storage is also a database object storage for all users of Review. There is more user access when designated as Public versus limited access when setup for UserGroup storage.

Object level

10. Select an **Object Level**. You can store your patient selection criteria at four levels: Study, Project, StudyGroup or Global.



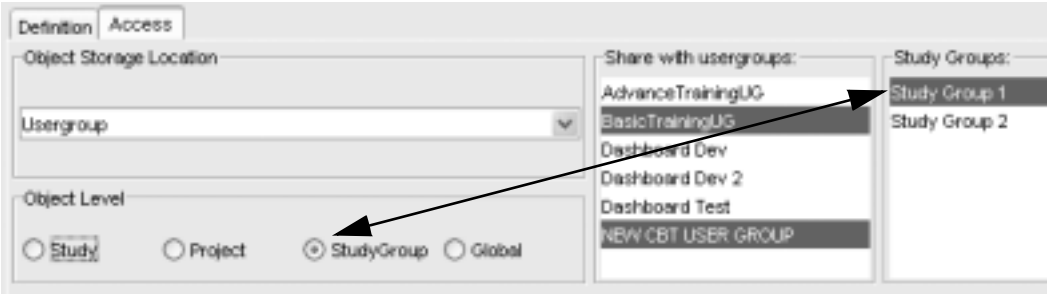
When you select either Private, User Group or Public for shared network drive storage location, you can assign an object level to restrict access to a specific study level or share access between multiple studies at Project or Global levels.

11. Click **Save Object**. JReview stores the Patient Selection Criteria to the designated Private, UserGroup, or Public storage location.

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 IReview (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 IReview 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.



Override selected Project/Global object?

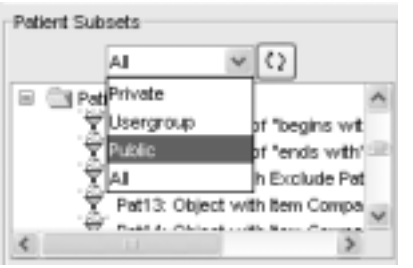
The purpose of the override is to create a study specific version of the standard object, in the non-standard study. For example, you create a set of global or project level objects and assume they should be applicable to all subjects in the study project (for project level) or all studies in the database (global level) based upon your internal standards. This may be true the majority of the time but then you encounter a non-standard study. Therefore, when you are in the non-standard study this object is displayed in your list box and will suppress the project or global version to display the local version instead.

Note: The Override selected Project/Global object question is only available when you select UserGroup or Public for Study object level.

Object Explorer window

Once you have saved your selection criteria and assign folder information, your folder and selection criteria will display as a stored object in the Object Explorer Window under Patient Subsets. Review displays a list of folders for previously saved output specifications at the selected object storage location. Simply select one of the storage locations as Private, UserGroup, Public or All to display it's specific folders and contents. The 'All' option in Output Explorer displays 'All' accessible database saved objects (private(db), usergroup(db) and public(db)) for the user.

Select the object storage location from the drop down list. Use the refresh button on the right to refresh the folder list when moving between user access levels. l



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.

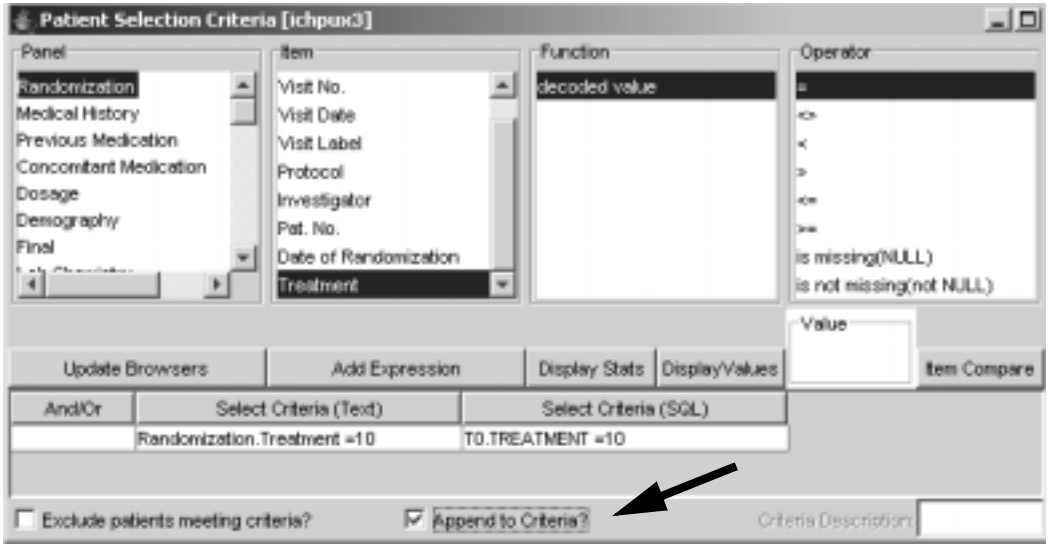
Append to criteria

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.



Object properties

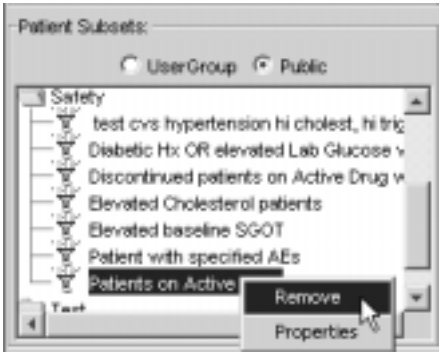
You can view information about an object when you select “Properties”.

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

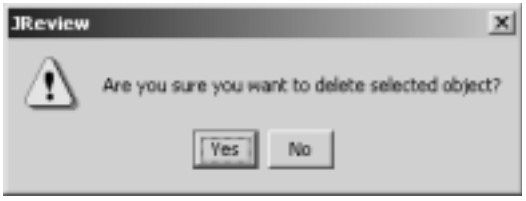
3. Click **Properties** to display details and click **OK** to close window.

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**.



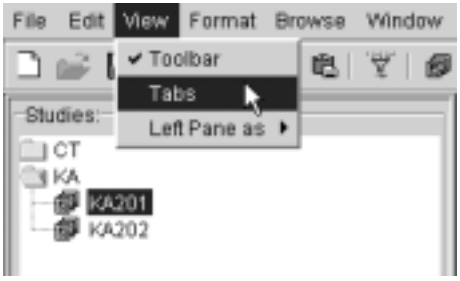
The Remove function is a quick way to delete stored objects provided the user is the creator or a SuperUser. It works for 'UserGroup' or 'Public' objects equally.

Create Tabs

Create new tab

You can open multiple output objects and organize them for display on tabs which you create. The tab is active for the session you are logged on.

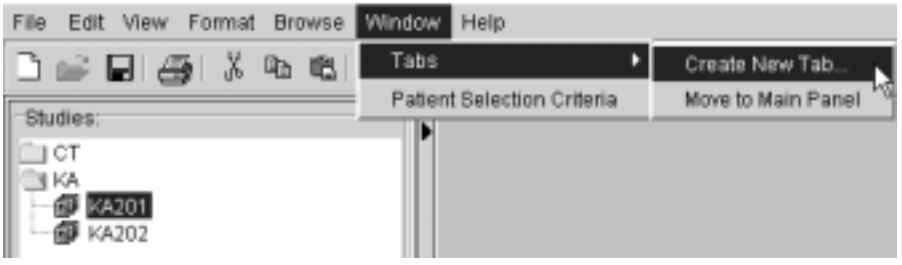
1. From the **Menu Bar**, select **View**.



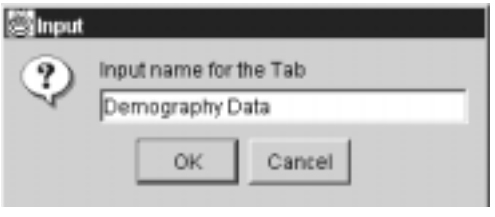
2. Select **Tabs**.

   The Main window displays with a **Main** tab at the bottom of the screen.

3. From the **Menu Bar**, select **Window**.
4. Select **Tabs** and **Create New Tab**.



5. A Tab dialog box opens for you to label the tab. Enter the tab name and click **OK**.

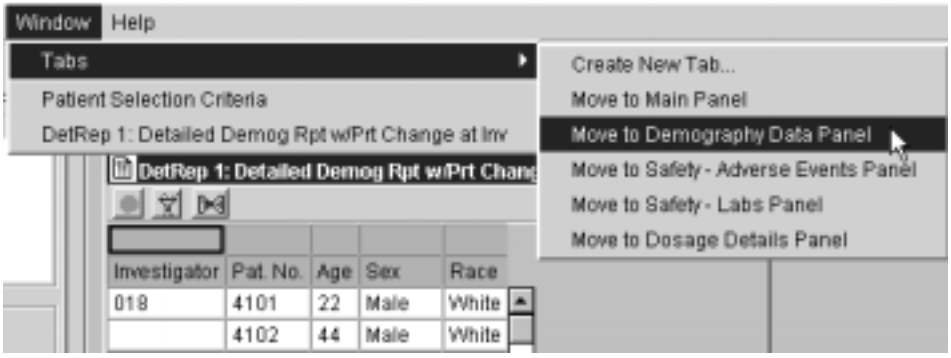


The new tab is created next to the Main tab at the bottom of the screen. Repeat the steps to add additional tabs. At this point you can select a tab and launch multiple output objects of your choosing to organize by tab category. Simply click on the selected tab and open the output objects of choice.

Move objects between tabs

If you wish to move an output object to another tab:

6. Make the object window the active window.
7. From the **Menu Bar**, select **Window**.
8. Select **Tabs** and the target tab location. The output is moved to the selected tab.

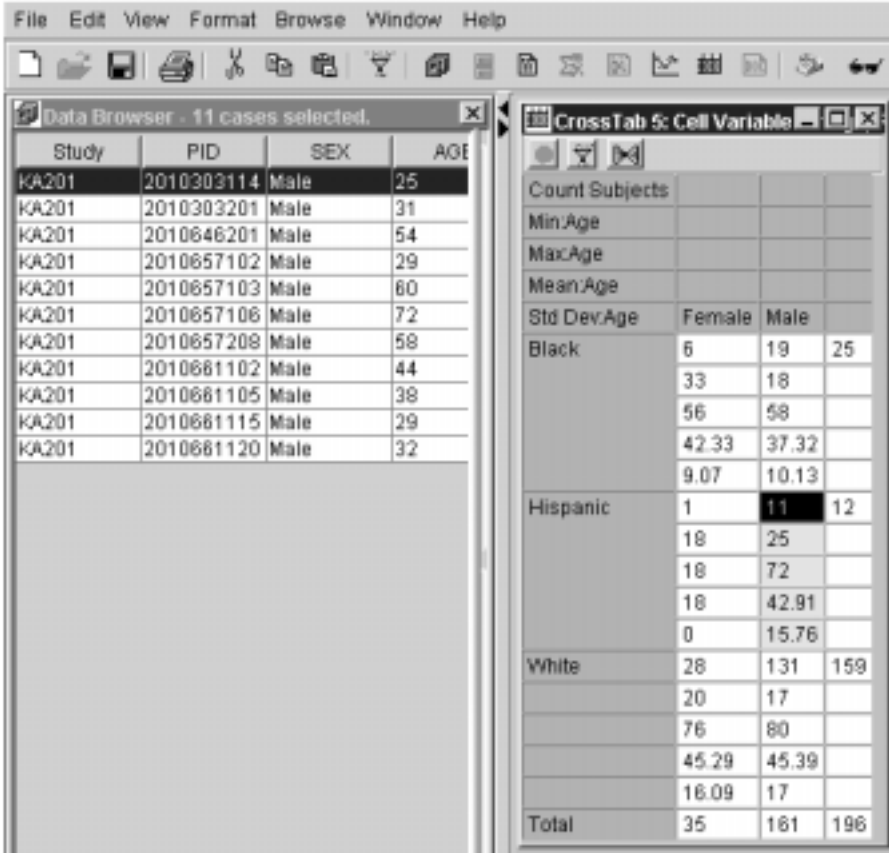


For your convenience while viewing multiple output you can set the left pane of you screen to display the Data Browser.

9. From the **Menu Bar**, select **View**.

10. Select **Tabs** and **Left Pane as Data Browser**.

The left side of the screen displays the Data Browser where previously the Object Explorer area displayed. This feature maximizes your display area for interaction and updates between the Data Browser and patient selection criteria and any open output windows.



Simply close the Data Browser when through and the screen defaults back to the Object Explorer display.

3 Review Patient Data

Data Browser 73
- Opening the Data Browser 74
- Expand spreadsheet columns 74
- Sort columns 75
- Browse patient data 76
- Horizontal data display 78
- Graph format display 79
- View Data Browser 81

Notes Browser 82
- Store patient notes 82
- Add note from Data Browser 82
- Edit note in Notes Browser 86
- Add response in Notes Browser 89
- User defined notes reports 90

Multiple-patient mode 91
- Freezing a case 91

Export and Print listings and panel views 94
- Export a data browser spreadsheet 94
- Print Preview 94

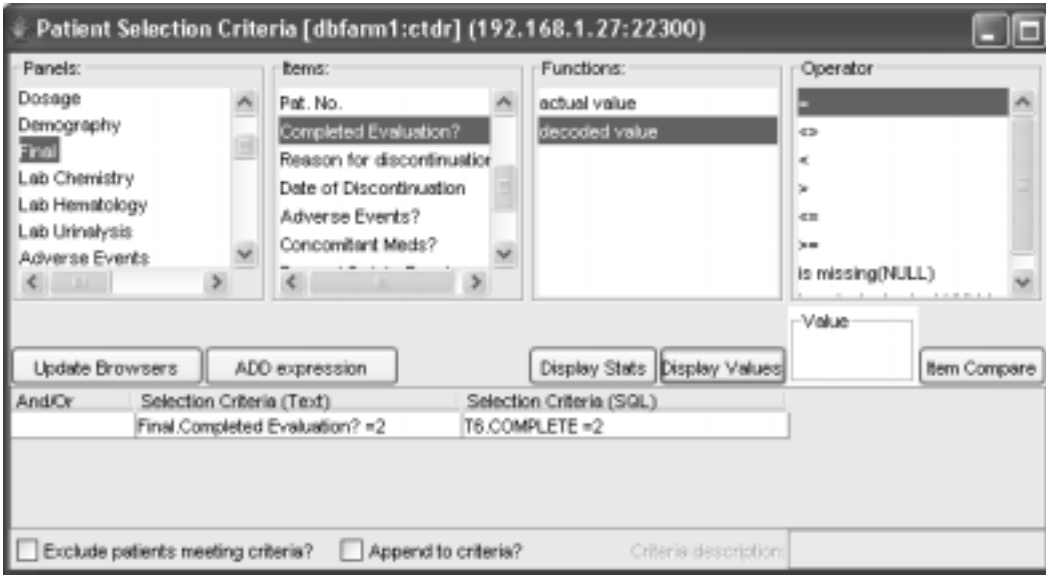
Exploring data 95
- Changing the patient selection criteria 95
- Patient Identification 96
- CrossTab Browser results 97
- Discrepancy reports 98
- Detail Data Listing reports 98
- Scatter plot graphs 98

Exploring data **95**
Closing a panel view 98
Closing the Data Browser window 98

Data Browser

Subset patients

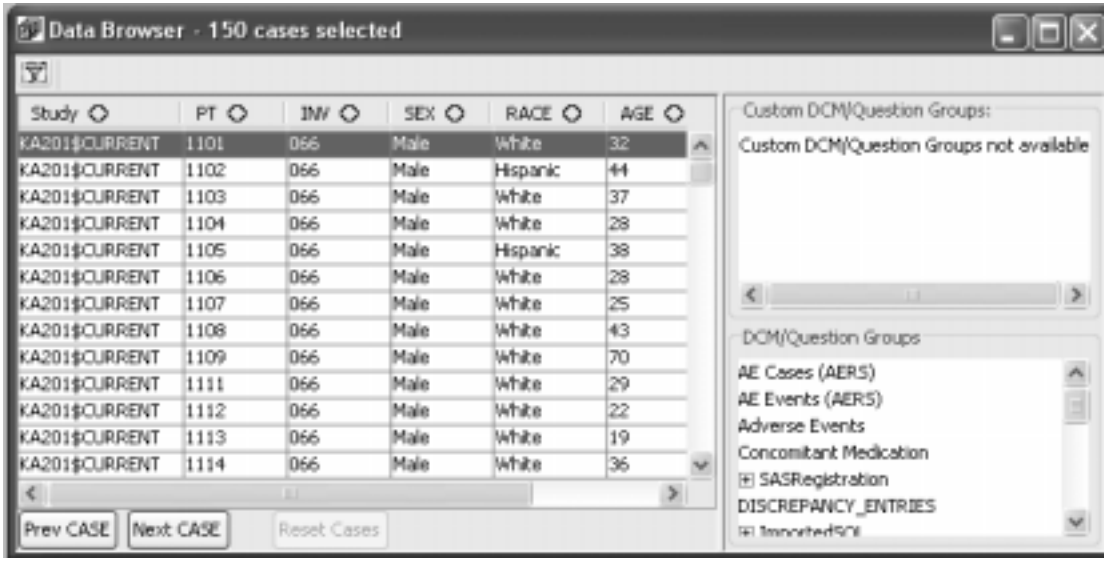
The Data Browser presents a list of patients who meet the current patient selection criteria. It provides the user with the ability to look at data for an individual patient. After building the patient selection criteria, you can quickly view a detailed list of the selected patients by using the Data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



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.



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.

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.

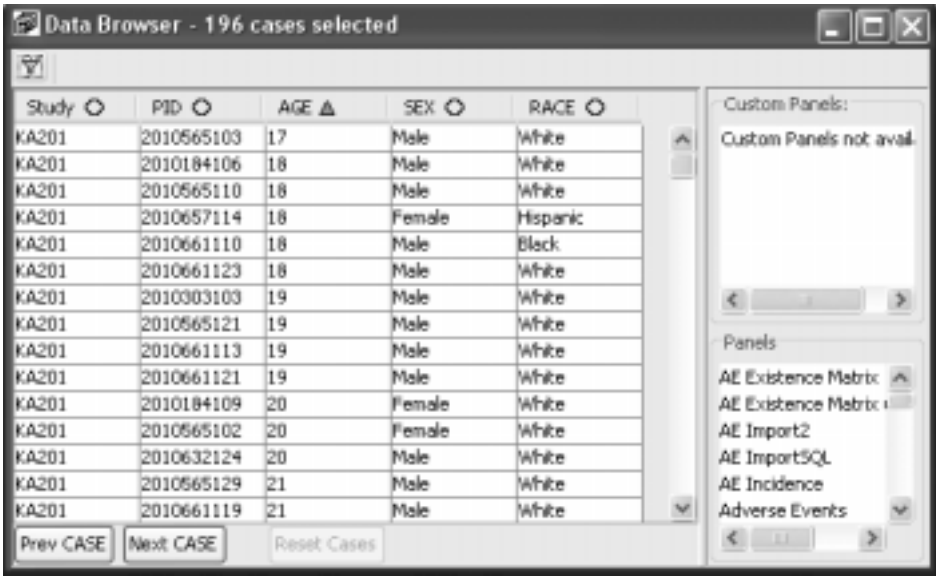
Click and drag the cursor on the line between the column heading tabs to the width desired.

Sort columns

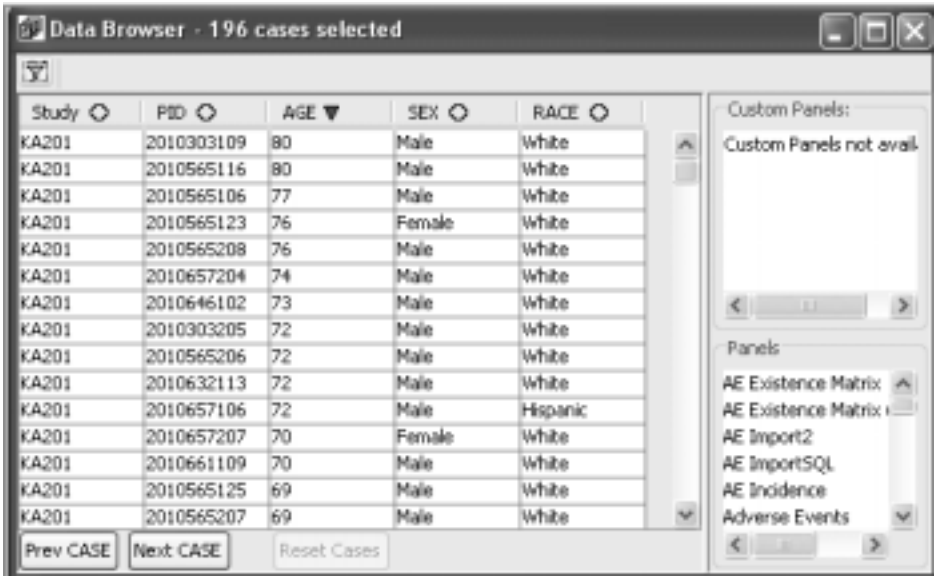
You may select and sort any column in the main Data Browser window where the column header contains the corresponding symbol next to the description.

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.



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



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.

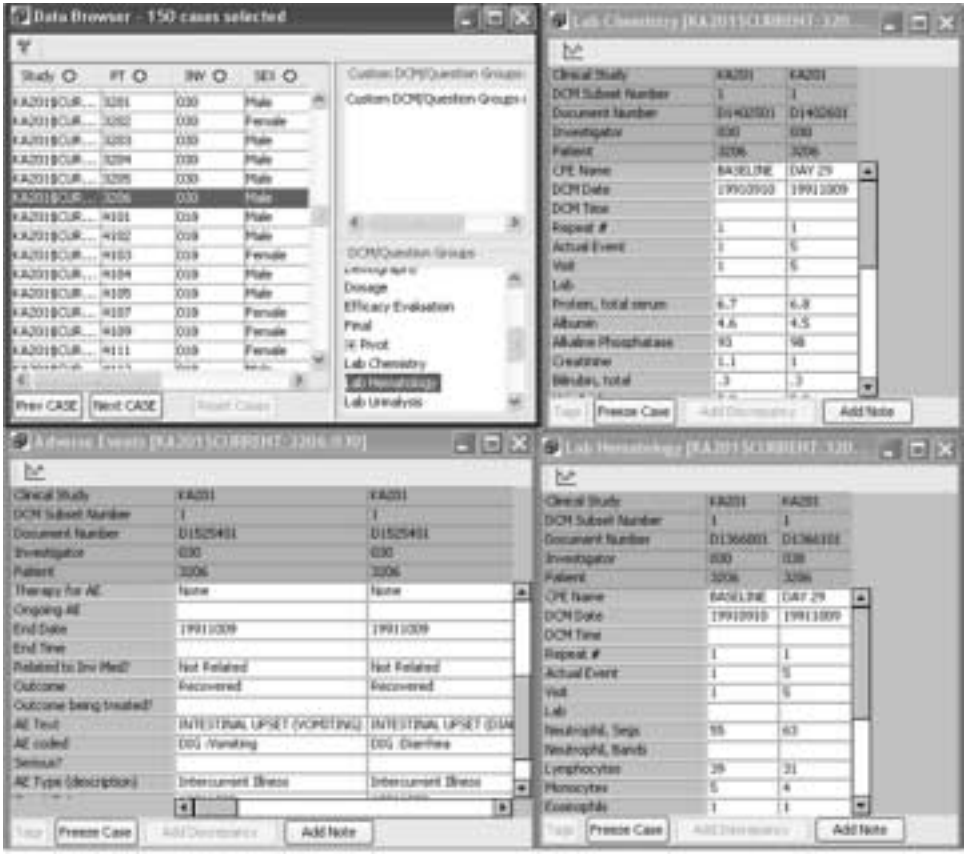
   Each time another patient is selected, each open panel view window is updated to reflect the data for the currently selected patient.
5. If the 'Freeze Case / Case Frozen' function is toggled to **Case Frozen**, the panel view window displayed remains displayed(frozen) with the patient data they were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

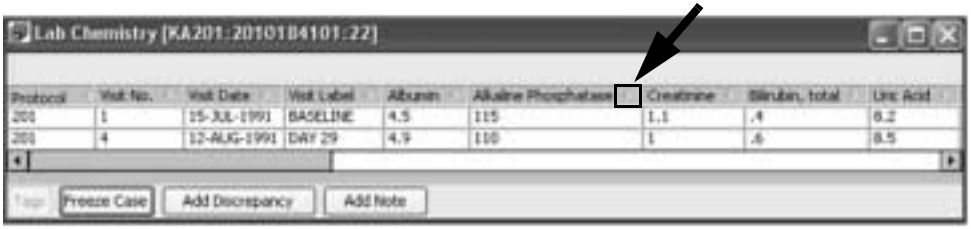
If the panel displayed contains multiple observations, all observations for this patient are displayed in the spreadsheet.

The default vertical panel displays for the data ordered by the Visit Date.

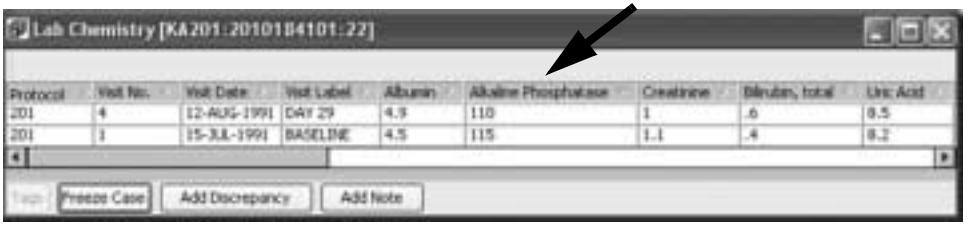


Optional horizontal panel display of the data is supported within ReviewAdmin by a configuration option.

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



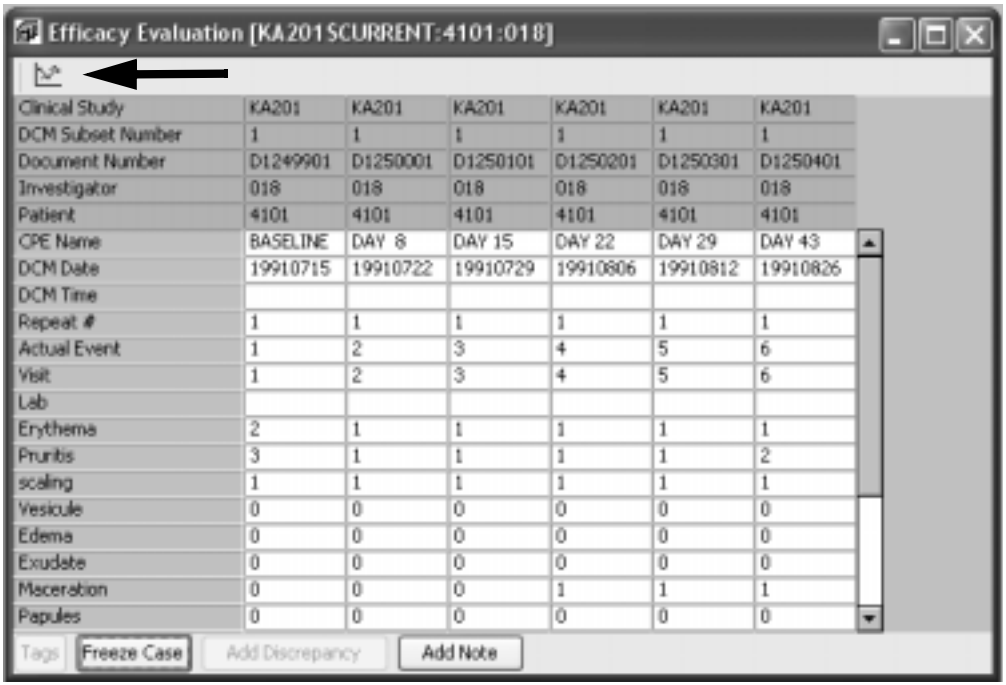
Simply click on the column symbol to change the column sort order.



Graph format display

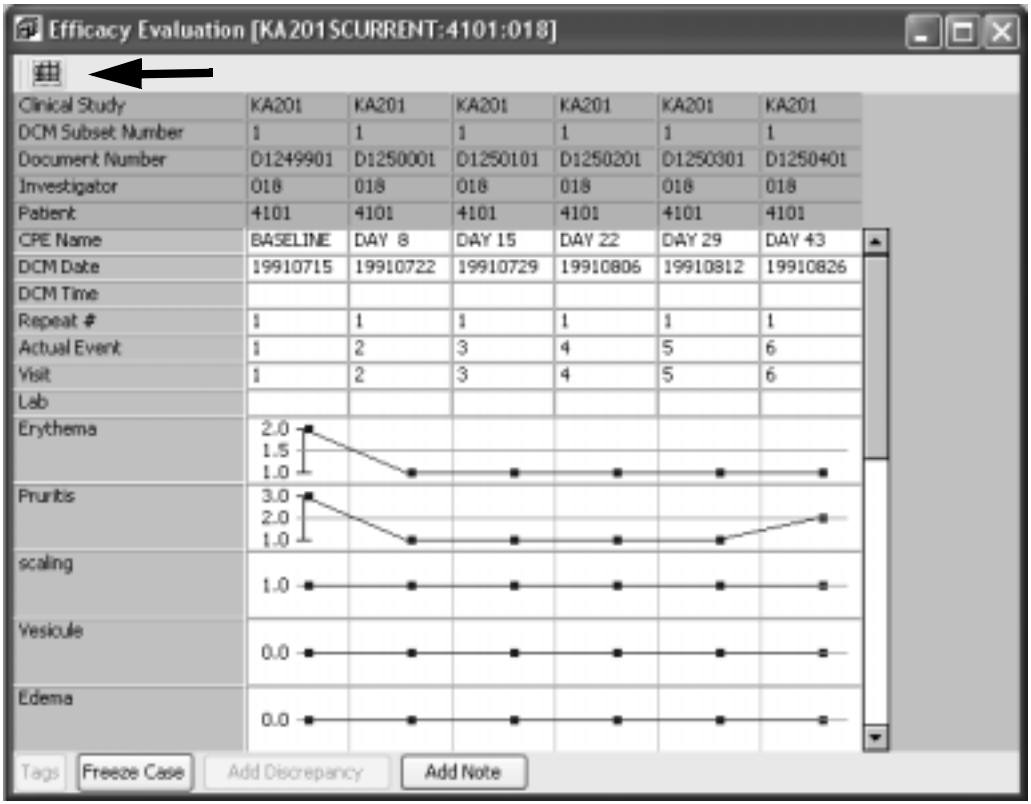
You can view a graph representation of the data from panels collected as multiple visits or observations with numeric data. Initially when you open a panel the default display is the table format

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

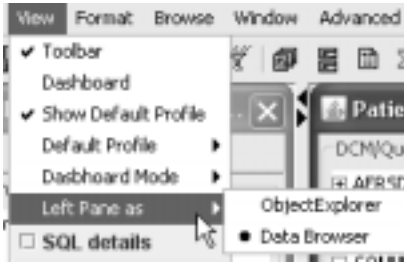


Clinical Study	KA201	KA201	KA201	KA201	KA201	KA201
DCM Subset Number	1	1	1	1	1	1
Document Number	D1249901	D1250001	D1250101	D1250201	D1250301	D1250401
Investigator	018	018	018	018	018	018
Patient	4101	4101	4101	4101	4101	4101
CPE Name	BASELINE	DAY 8	DAY 15	DAY 22	DAY 29	DAY 43
DCM Date	19910715	19910722	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

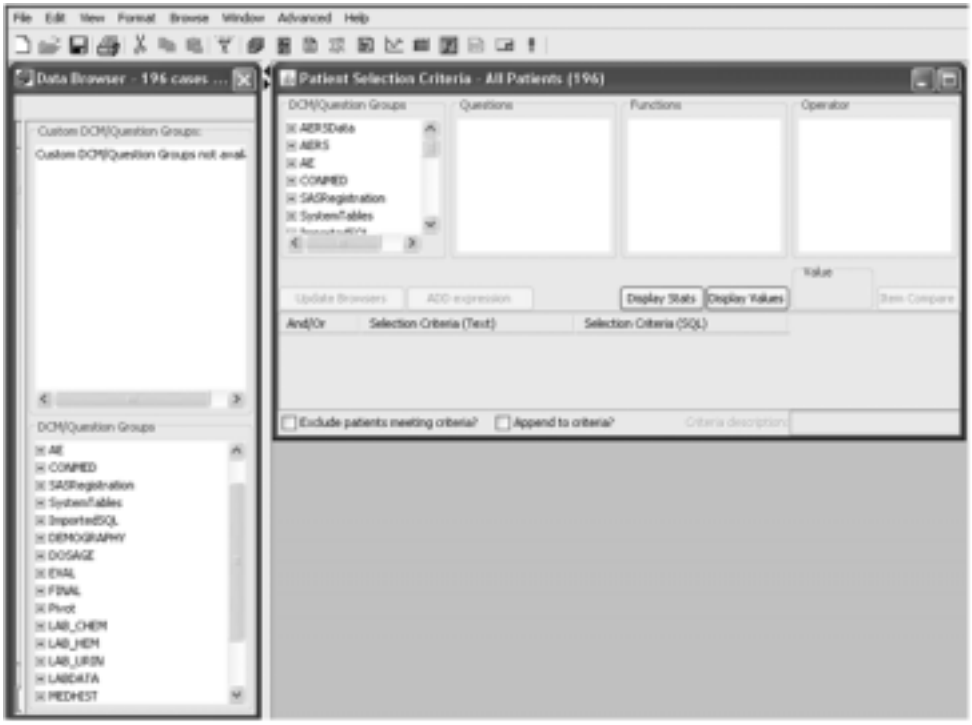
The graph displays as a Trend Plot with the patient's minimum and maximum values listed in the first column. Click the table icon to switch the display back to the spreadsheet format.



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

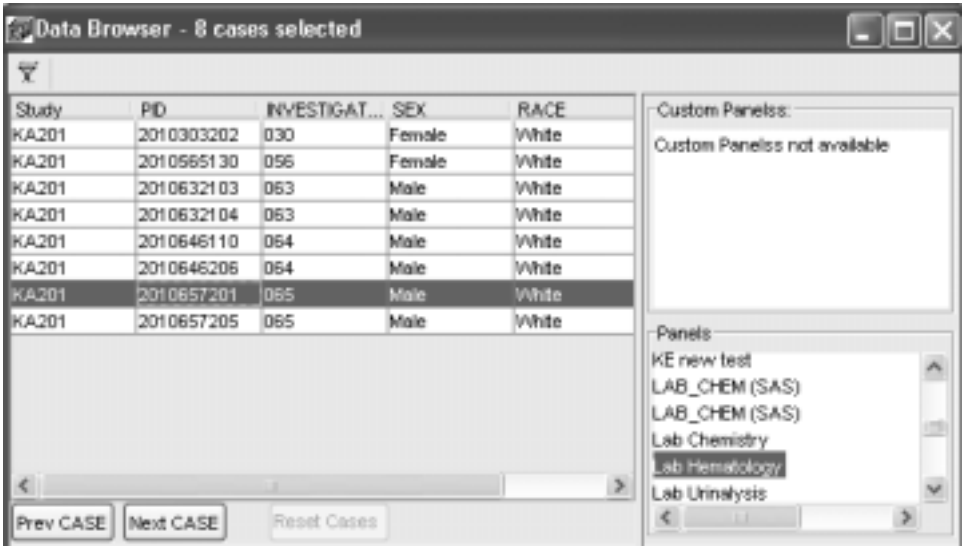
Store patient notes

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)*

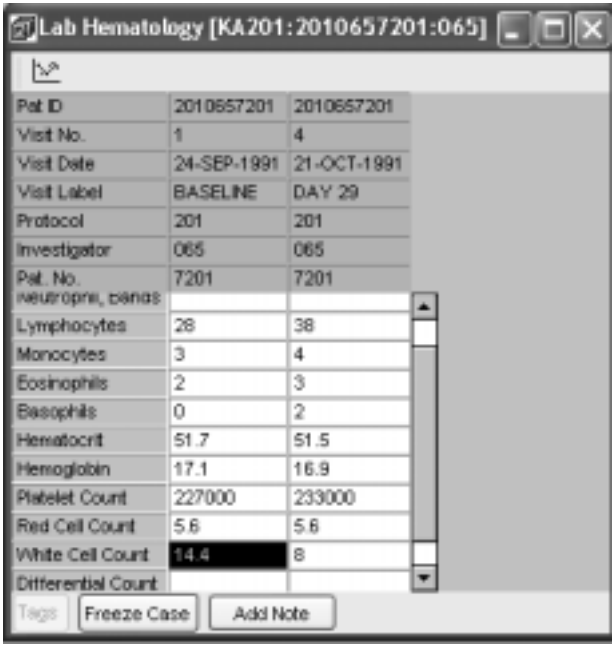
Add note from Data Browser

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.



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

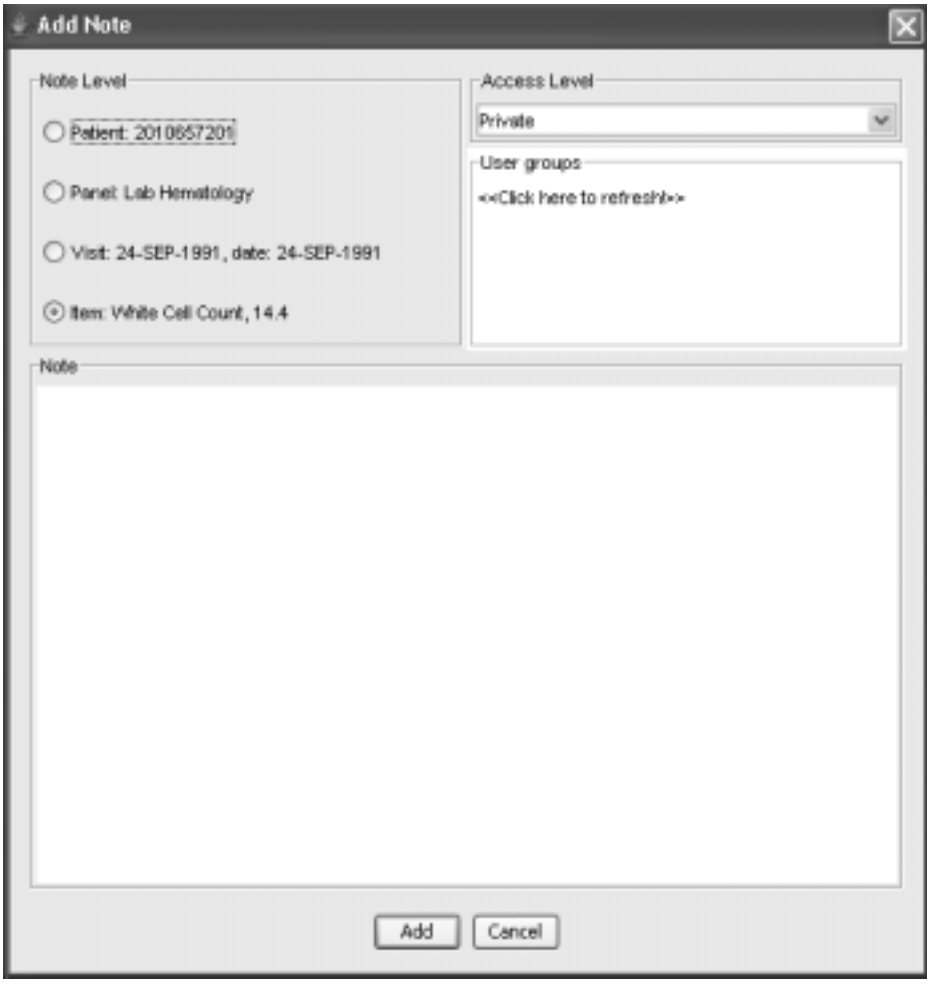


5. Click **Add Note**. The Add Note window opens.

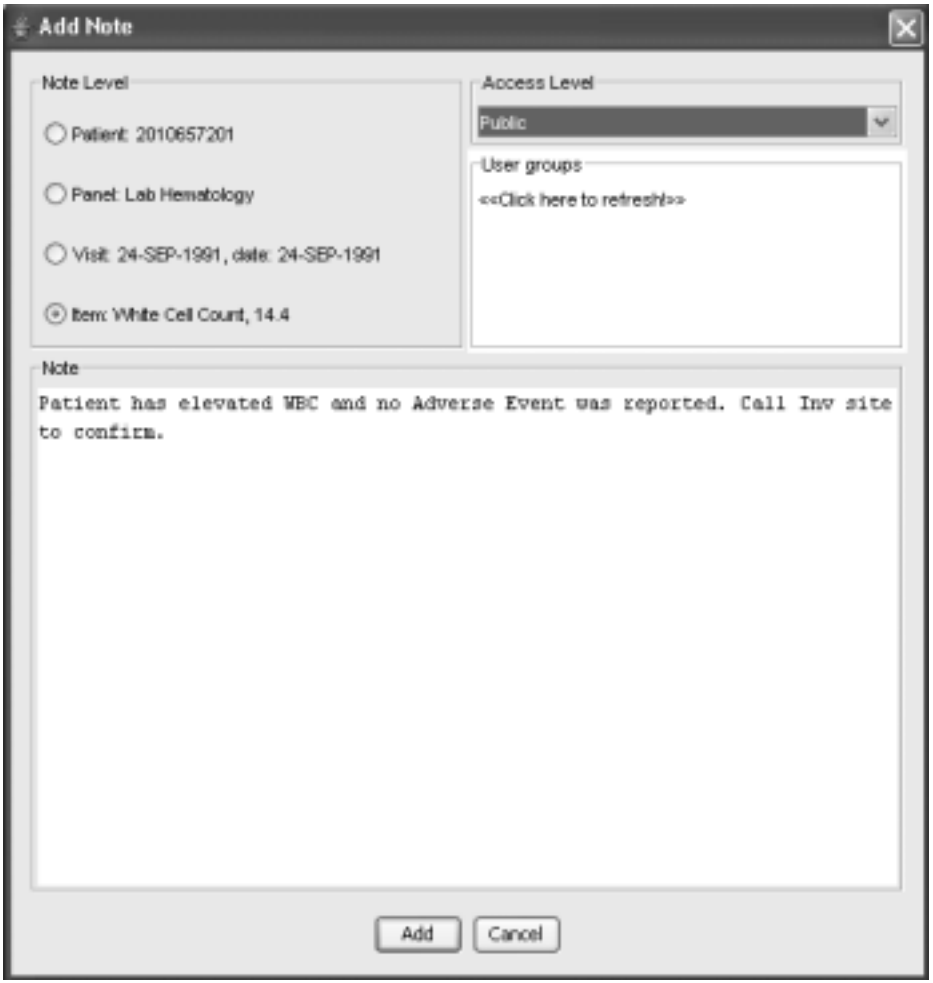
The **Note Level** details display for the selected data column which are later displayed in the Notes Browser spreadsheet after the note is saved. Your note level selection determines if minimal note level details or all note level details are displayed after the note is saved.

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.

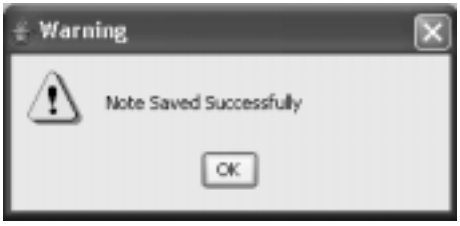
For example, if your note content is general to the patient or panel type you would select patient or panel level. The columns for visit and item would display as blank in the Notes Browser spreadsheet. Item level displays the most detail in the Notes Browser spreadsheet.



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



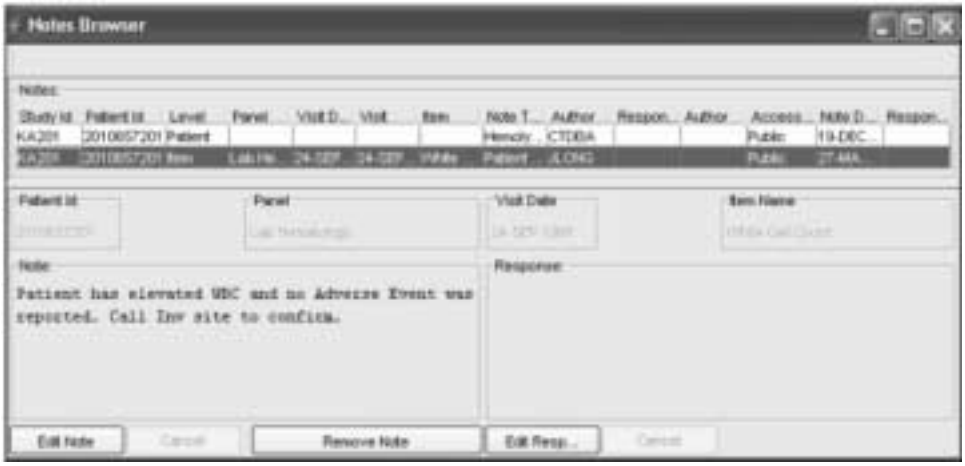
7. Select the **Note Level** to apply the note at either Patient, Panel, Visit or Item level.
8. Select **Note Access Level** for viewing access as Private, UserGroup or Public. Click **Add** to save the note.



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**.

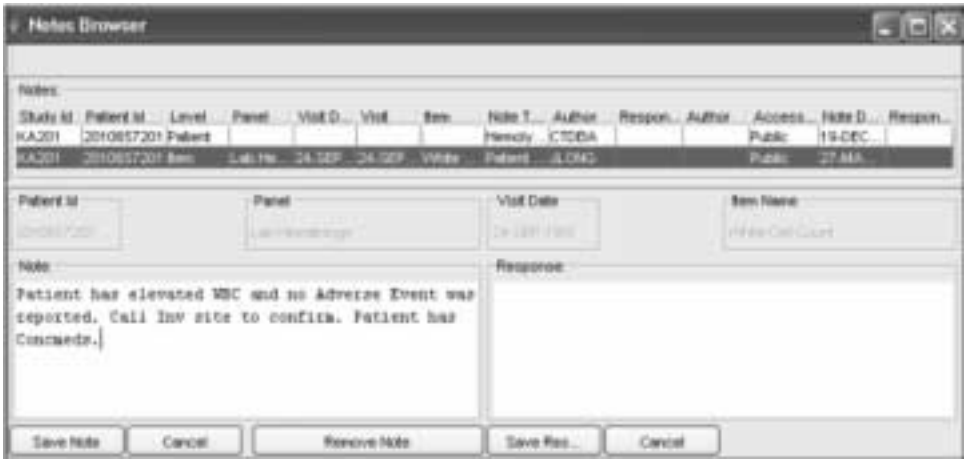
   The Notes Browser window opens. All patients with saved notes are listed. You may enter a patient selection criteria to list specific patients.



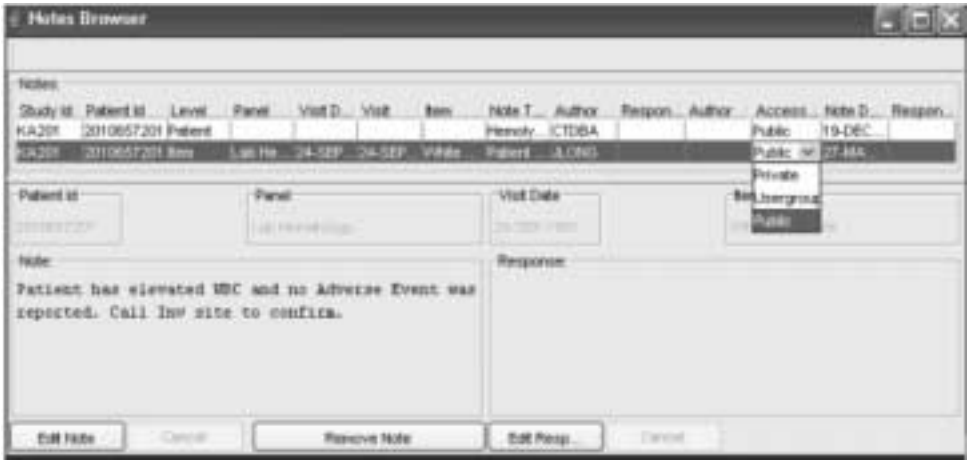
2. Use the scroll bar and select a patient to display the Note text. If the patient has multiple notes you may need to select the specific note.
3. Select and highlight the patient in the patient list in the Notes Browser.
4. Optionally select **Edit Note** or **Remove Note**. You cannot edit or remove 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.

5. 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**.



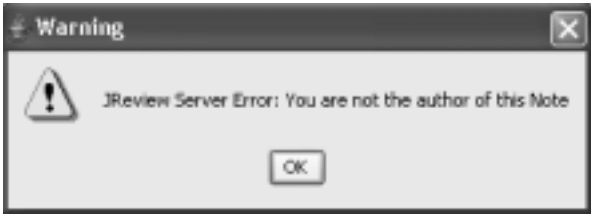
6. In the row for the selected patient, enter the note access level by clicking on **Access** to display the drop down list for Private, UserGroup or Public.



7. 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.



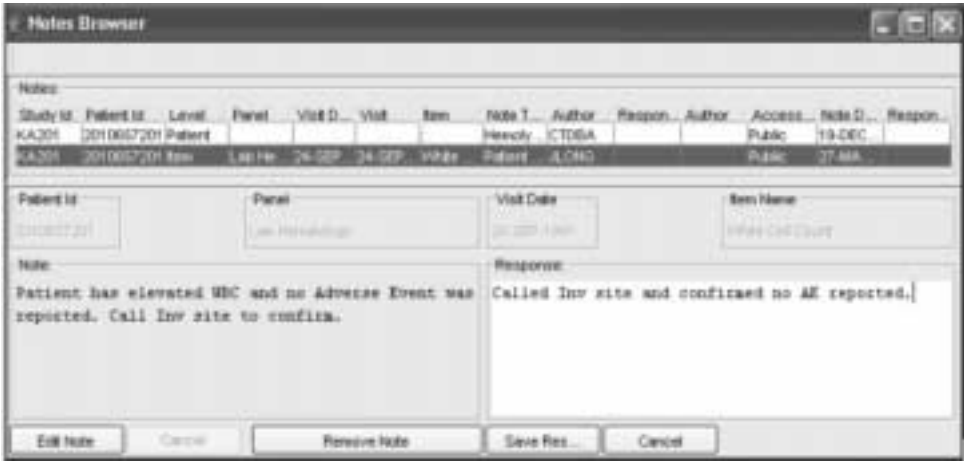
8. Close the Notes Browser window.

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

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. Click the cursor in the Response box to enter up to 2000 characters.



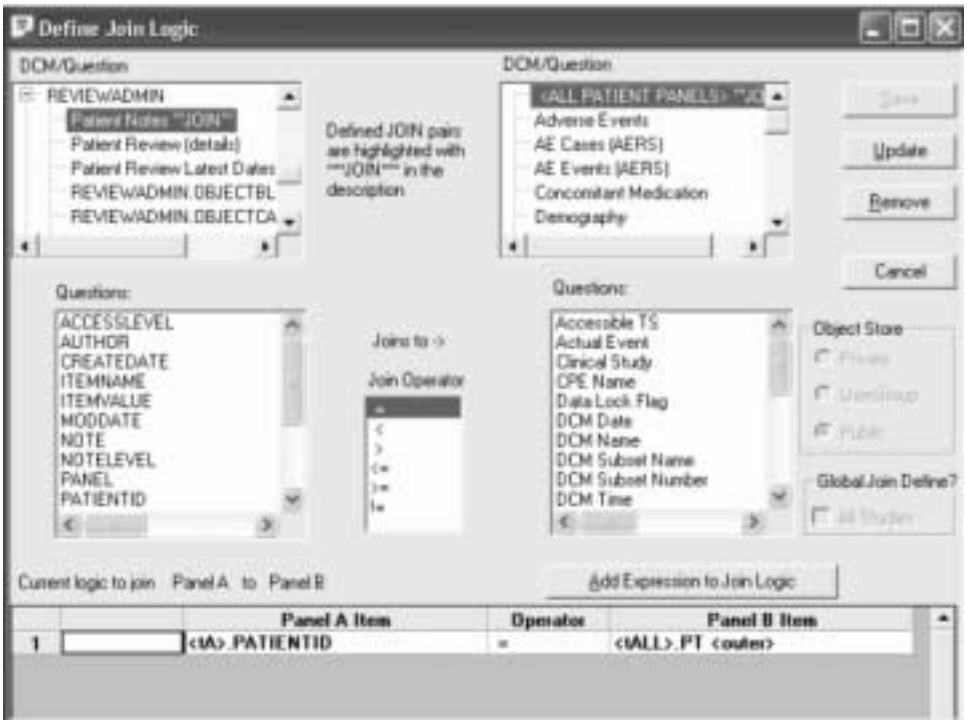
2. Click **Save Response**. The response is saved at the same note level and access level as the original note. If you click **Cancel** before clicking the Save Response button then the response is not added.

   The Response box becomes shaded or inactive after clicking Save Response and the button status changes to **Edit Response**.

3. If you need to delete or remove the response and you are the author; click **Edit Response**, delete the text then click **Save Response**.
4. Close the Notes Browser window.

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.

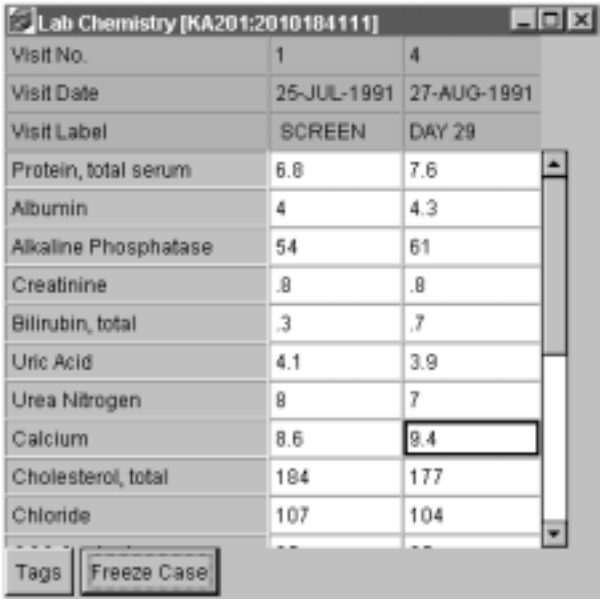


Multiple-patient mode

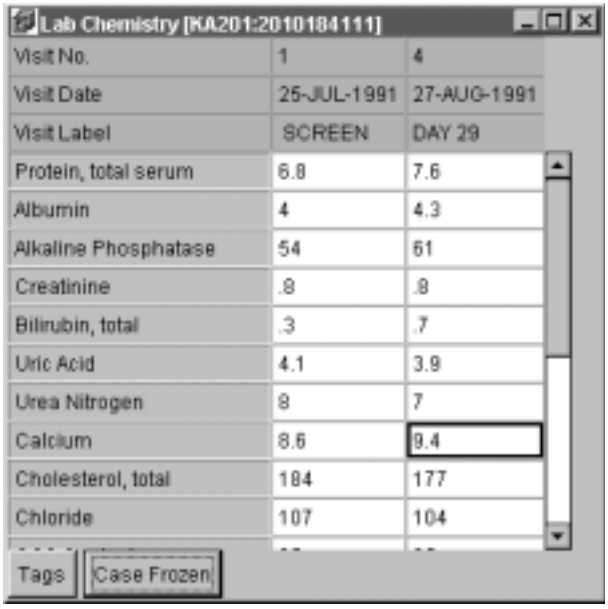
Freezing a case

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.



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

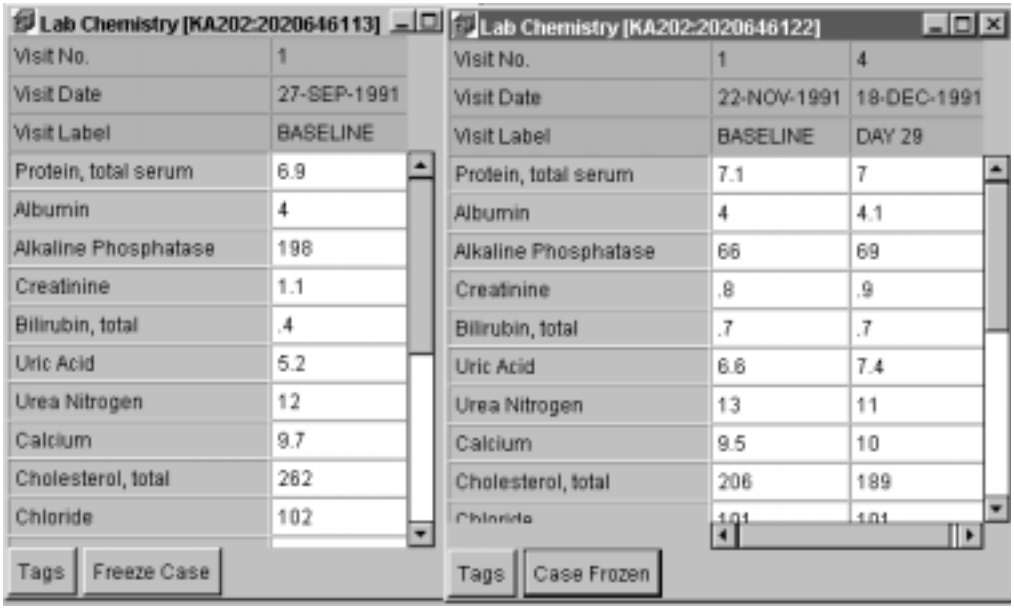


When the **Case Frozen** button is present, data in the panel view is frozen, and will not update when you select another patient.

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.



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.

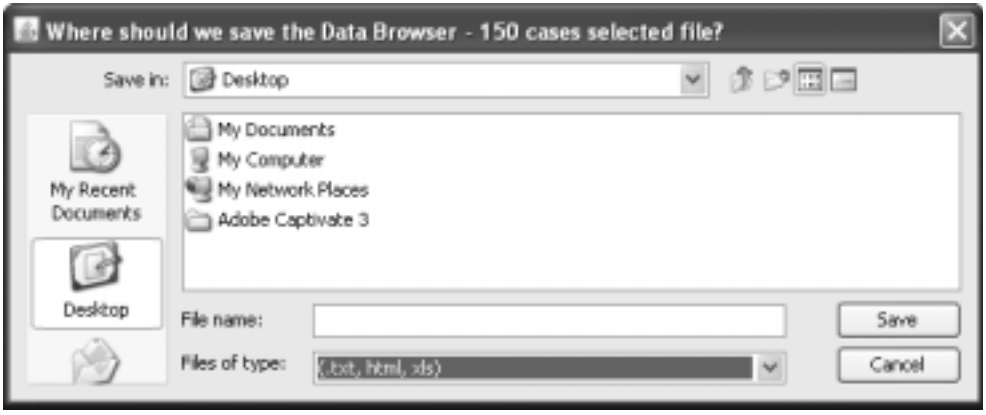
Export and Print listings and panel views

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)*

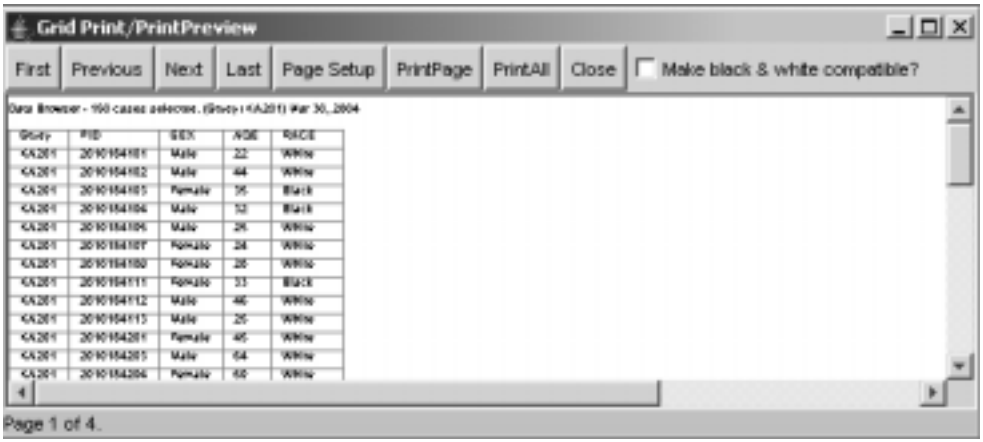
Print Preview

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: 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. You can use the buttons to scroll through the pages of the output.



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.

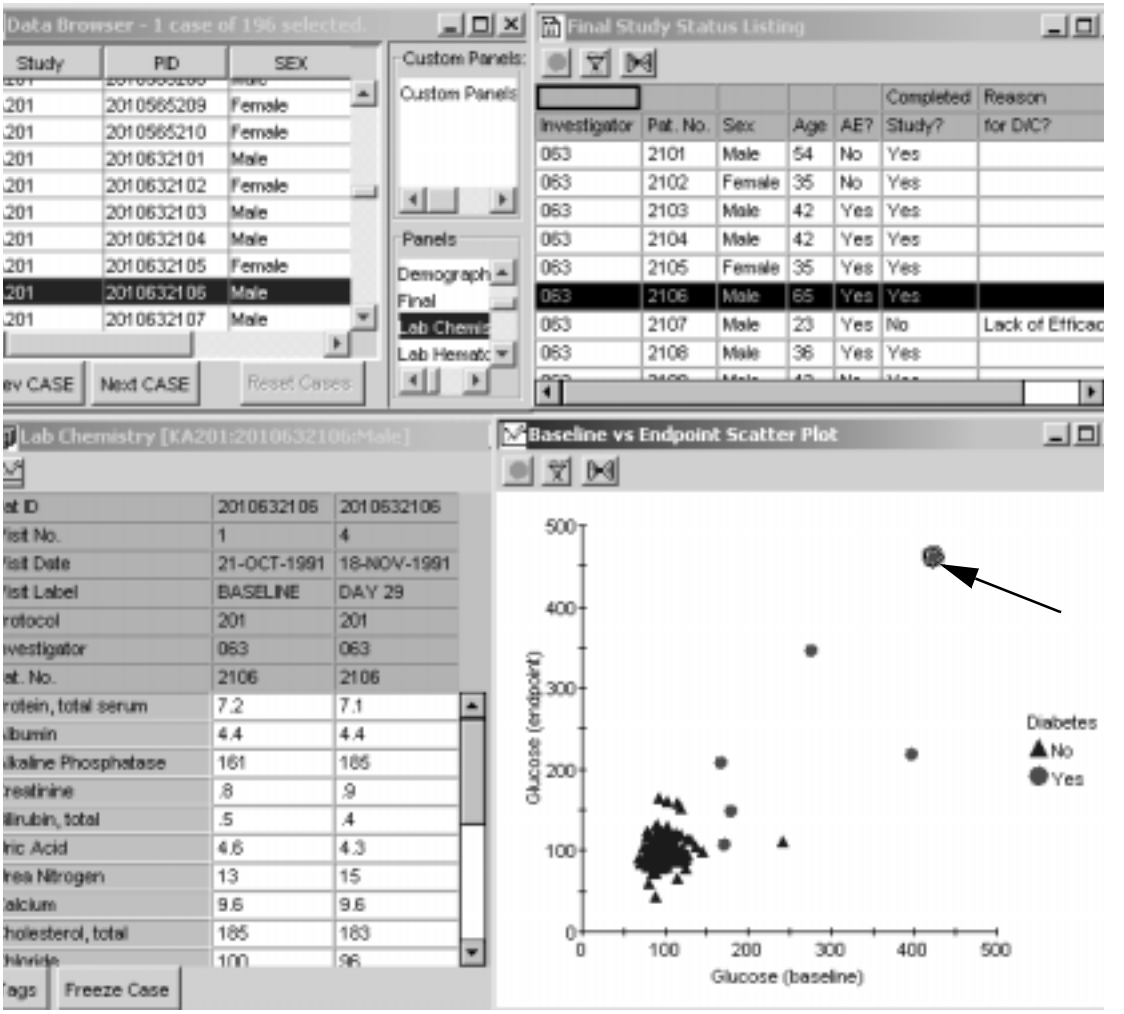
*Note: Use the **Convert to pure black & white?** option is only applicable to graphs where multiple colors are displayed. If your printer is non-color click this feature for better black and white print resolution of graphs.*

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.

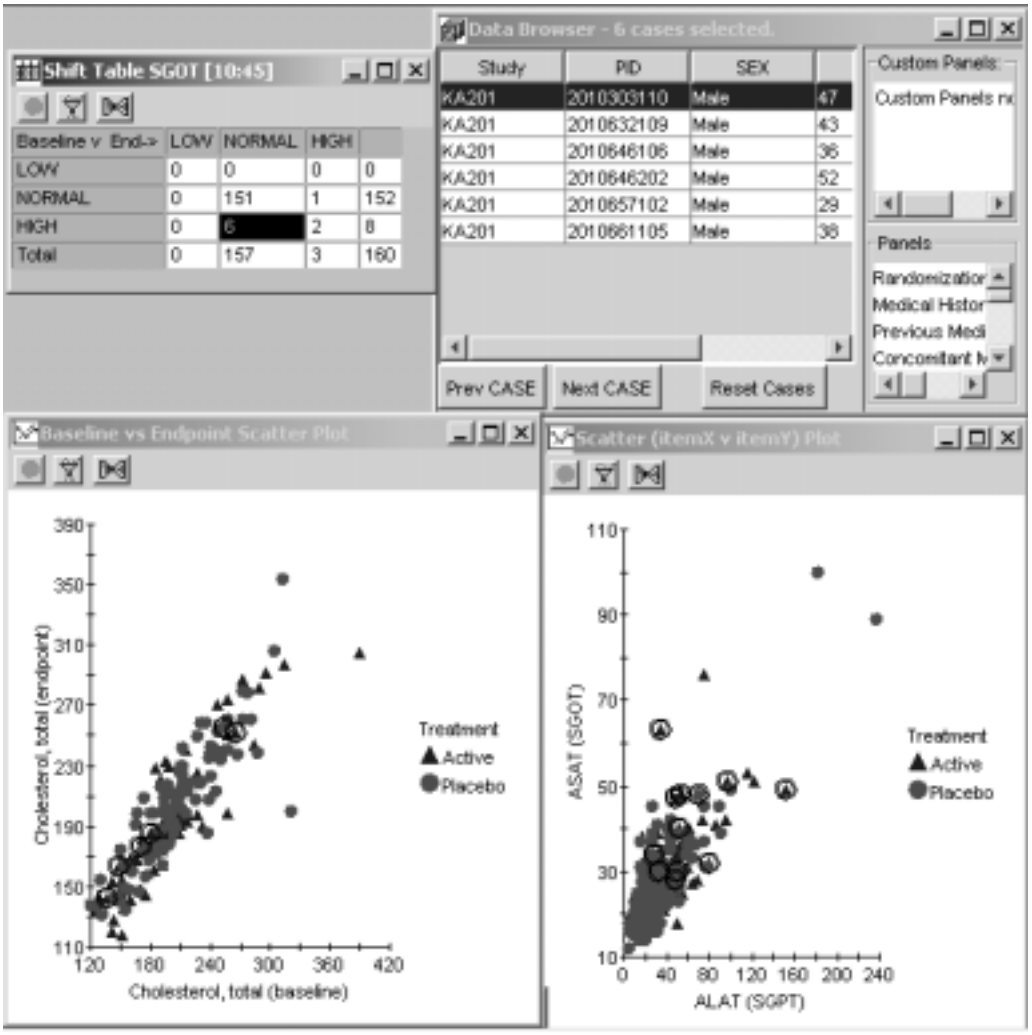
You can select and subset multiple patients from all patient level displays of data and CrossTab result tables, to generate corresponding patient listings in the Data Browser and Detail Data Listing Reports. This facilitates patient identification and detailed patient data review via the reviewing tools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



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.)*



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 101
Patient profile types 101
Access to SAS datasets 101

Execute patient profile 102
Quick execute 102
Retrieve a stored output specification 103

Patient profile features 104
View saved patient profile 104
Define patient profile matrix 104
Show patient profile 106

Define Patient Profile 107
Select workbook profile 107
Add profile content 108
Add Subpanel 110

Type of workbook 111
Organize data 111
Single worksheet mode 113
Multiple worksheet mode 115
Modify profile 118
Customize patient profile output 121
Sort Order 123

Filter Output 124
Patient Profile Filter Output 124

Patient Profile Review Tracking Tool 127
- Patient Tracking functions 127
- Patient Review Levels 129
- Sort columns 129
- Define Critical 130
- Update Patient Tracking Status 132
- Select review level 133
- Color coding 133
- Filter review 135
- Bulk review setting 136
- Track selection criteria 136
- View Patient Log 137
- Highlight patient data 139
- User defined tracking reports 140
- Study lock 142

Formatted Patient Profile 143
- Select formatted profile 143
- Activate Page Break 144
- Apply Page Header and Footer 145
- Format Column Headings 147
- Format Columns 148
- Preview / Page Setup 149
- Page Setup 151
- Number of ID items 151
- Panel Orientation 152
- Column width 153

Print and Export Patient Profiles 154
- Print patient profile 154
- Export patient profile 154

Object Storage 157

Close Patient Profiles Browser 157
- Closing the Patient Profiles windows 157

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** generated 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.

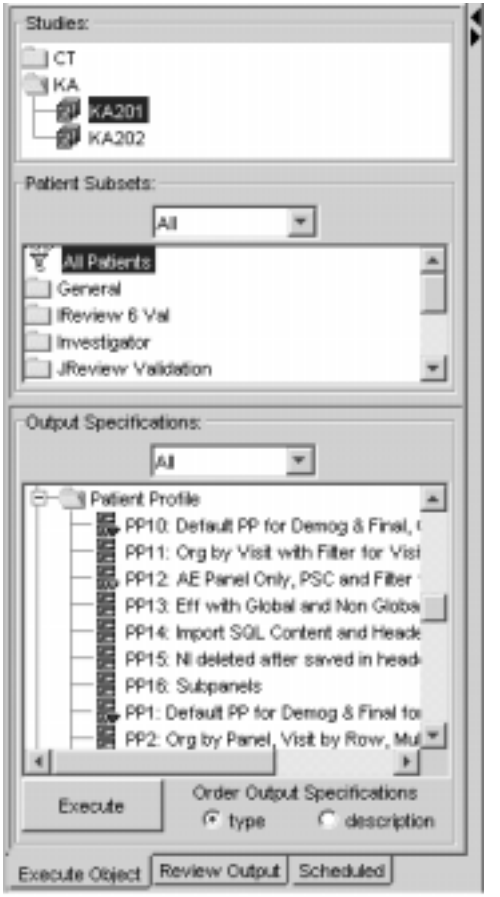
Note:The current restriction is you cannot mix items from SAS datasets and Oracle table generated panels within the same patient profile.

Execute patient profile

Quick execute

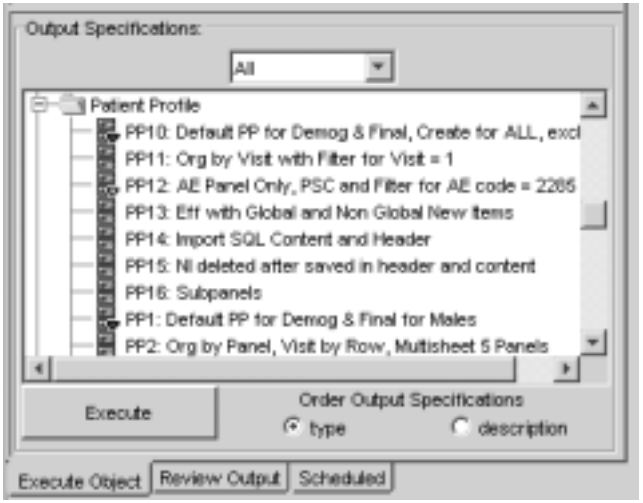
JReview displays a list of categorical folders for stored patient subsets and output specifications at the selected storage location. Simply select one of the storage locations to display it's specific folders and contents.

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.



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 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. Click on the object description and click **Execute**.

   OR
3. 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.

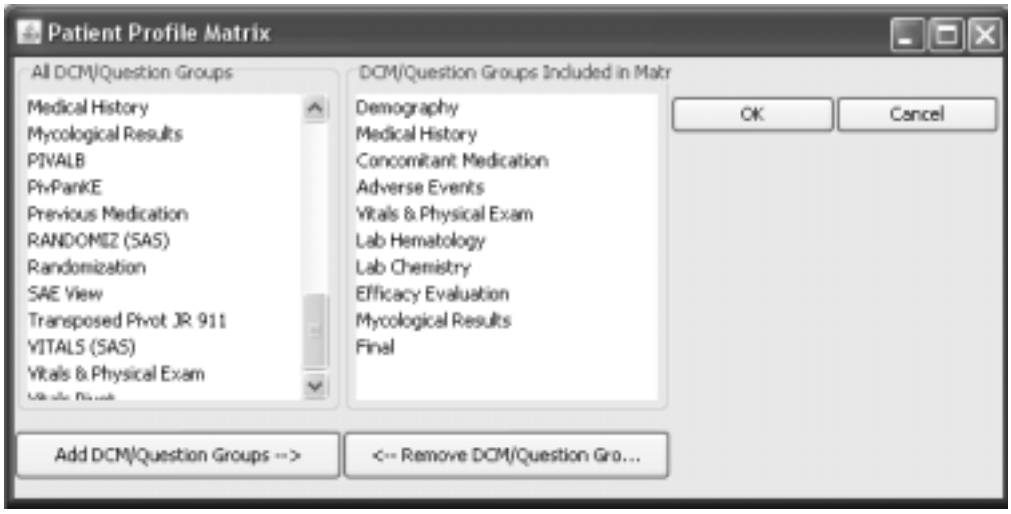
Select a patient from the list and click **Create Profile**. Only one patient profile can be open at a time and gives a specific stored/required patient selection criteria warning. A warning dialog will be present when trying to open a new Patient Profile if a Snapshot/Frozen or "Req'd PSC" for a Patient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

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.

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**.



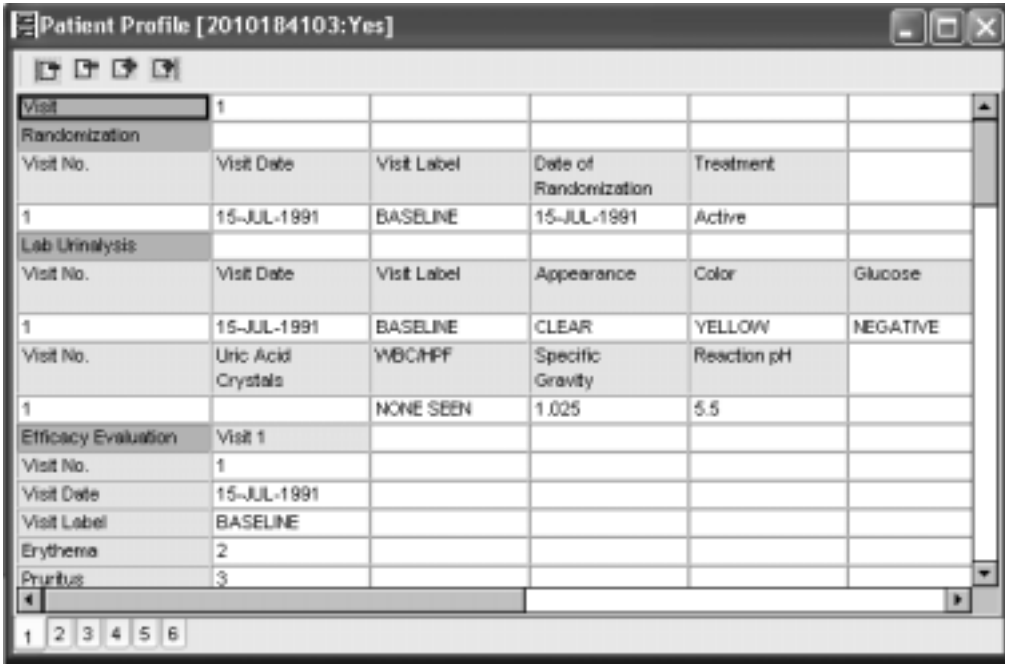
The first 10 patients display all their visit information. All visit numbers are listed for the active patients as a way to track individual patient study status by visit. The remaining patients listed display the message stating 'Not Retrieved'.

4. To retrieve additional patients, highlight multiple patients and click **Retrieve Selected Visits.**
5. Click **Retrieve All Visits** for all remaining patients.

Note: All patient related panels and included items are listed, not foreign panels or pivot panels.

Show patient profile

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



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

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.

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.

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.

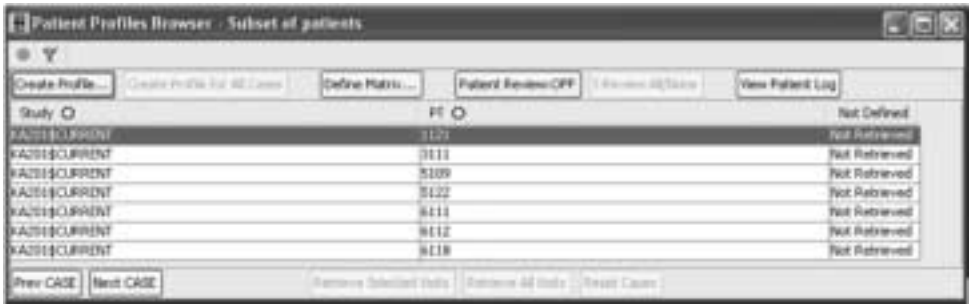
2. Select the panel. When defining a sub panel you can only select a single panel. Multiple visit panels display as vertical or horizontal.
3. Enter a **Sub Panel Description**.
4. Click **Add Sub Panel**. The new sub panel is added to the Panels Included list for selection to add and remove items for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

Type of workbook

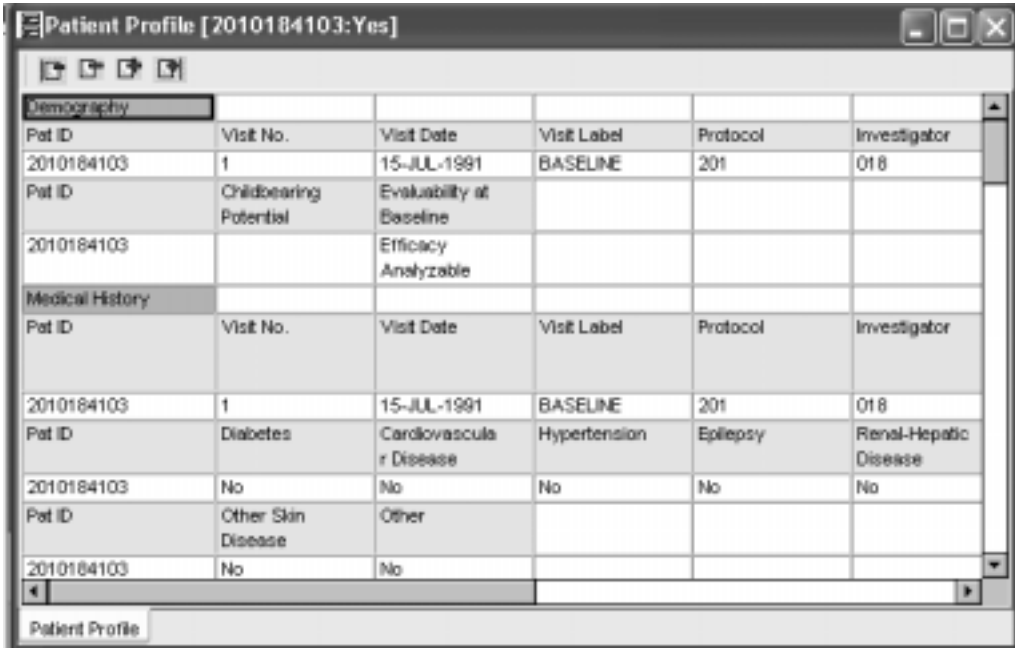
Organize data

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.

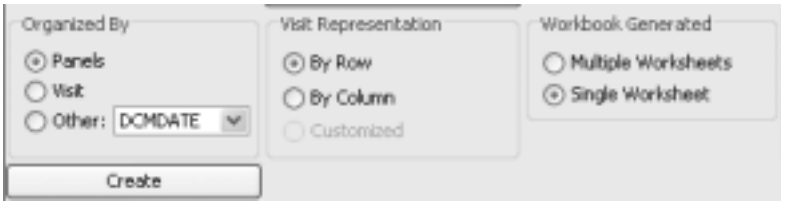
After you define the workbook profile by adding selected panels and items; click **Create** to use the default settings. The Patient Profile Browser window displays the patient list for the selected patients.



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



The next sections cover the workbook profile display options.



The single worksheet mode can be organized by Panels, Visit or Other (i.e., DCM Date).

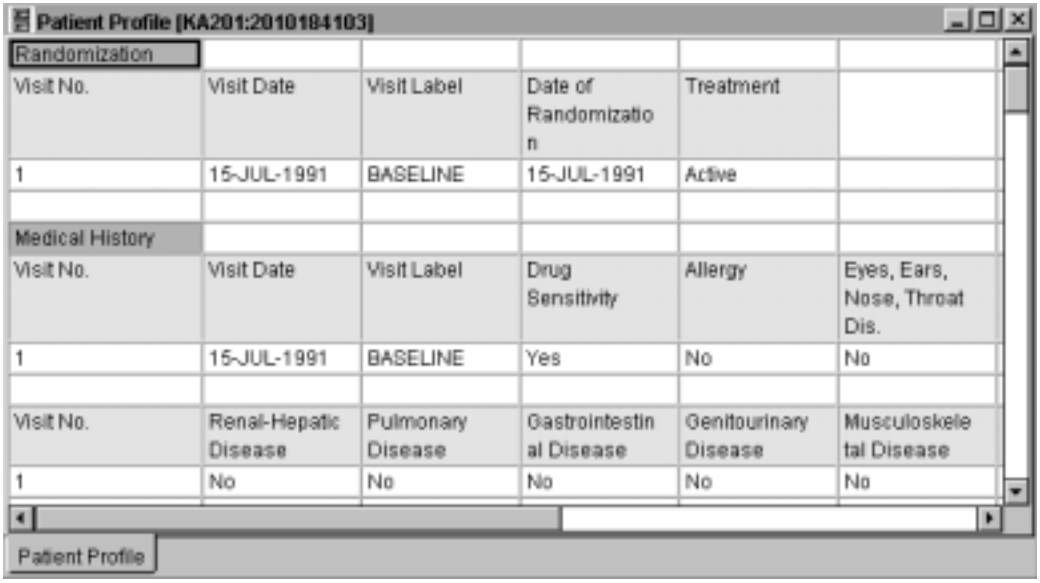
- ***By panel*** lists a single worksheet for all data for all panels included where there is data for the active patient. It will display in the order that has been defined and visits are sorted numerically.
- ***By visit*** lists a single worksheet for all data for all visits for the active patient.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

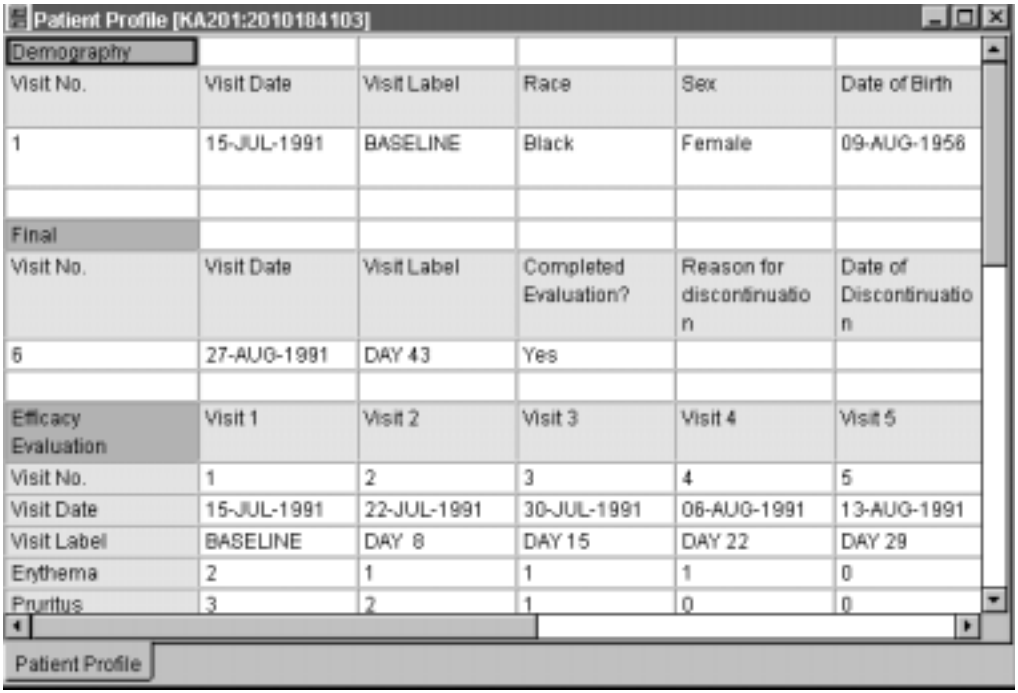
Note:When the worksheet mode for ***by visit*** *is selected then the visit representation options are not available.*

- ***By Other (DCM DATE)*** lists a single worksheet for all data by the other designated date item for the active patient. The dates are sorted. *(This feature is only available in Oracle Clinical DataBase.)*

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



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


Patient Profile [KA201:2010184103]

Demography					
Visit No.	Visit Date	Visit Label	Race	Sex	Date of Birth
1	15-JUL-1991	BASELINE	Black	Female	09-AUG-1956
Final					
Visit No.	Visit Date	Visit Label	Completed Evaluation?	Reason for discontinuation	Date of Discontinuation
6	27-AUG-1991	DAY 43	Yes		
Efficacy Evaluation	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
Visit No.	1	2	3	4	5
Visit Date	15-JUL-1991	22-JUL-1991	30-JUL-1991	06-AUG-1991	13-AUG-1991
Visit Label	BASELINE	DAY 8	DAY 15	DAY 22	DAY 29
Erythema	2	1	1	1	0
Pruritus	3	2	1	0	0

Patient Profile

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

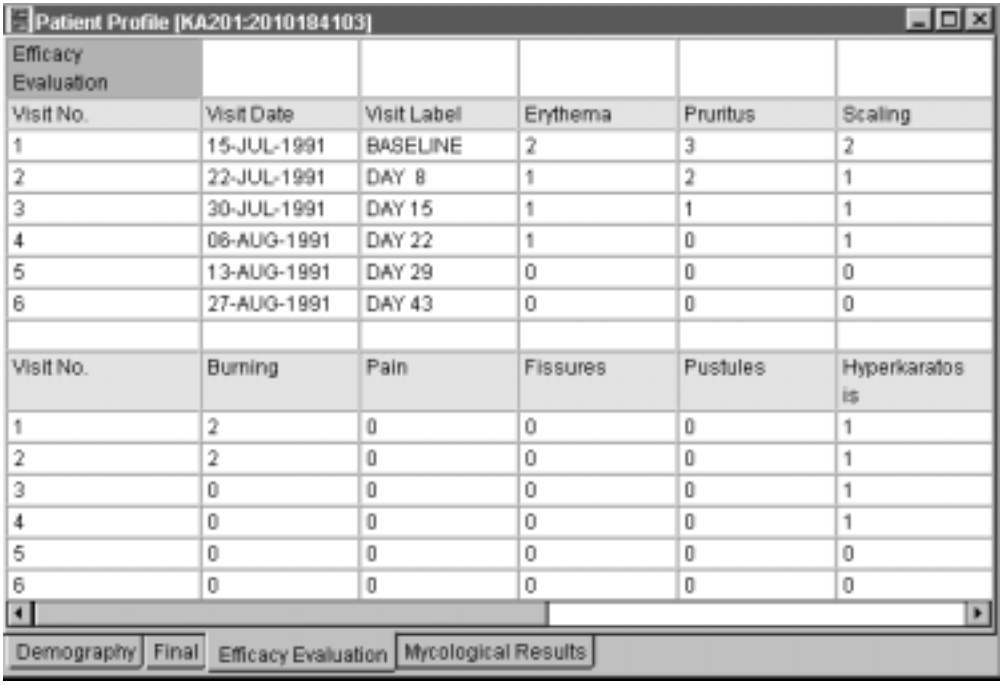
Visit	2				
Efficacy Evaluation					
Visit No.	Visit Date	Visit Label	Erythema	Pruritus	Scaling
2	22-JUL-1991	DAY 8	1	2	1
Visit No.	Burning	Pain	Fissures	Pustules	Hyperkaratosis
2	2	0	0	0	1
Visit	3				
Efficacy Evaluation					
Visit No.	Visit Date	Visit Label	Erythema	Pruritus	Scaling
3	30-JUL-1991	DAY 15	1	1	1
Visit No.	Burning	Pain	Fissures	Pustules	Hyperkaratosis
3	0	0	0	0	1

Multiple worksheet mode

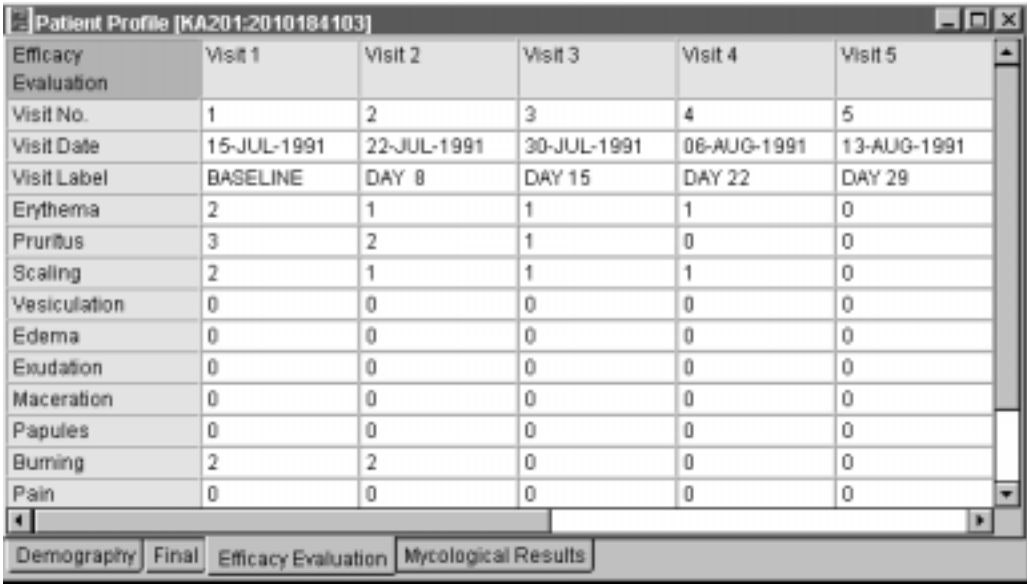
The multiple worksheet mode can be organized by panel or visit.

- 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 options displays the tabs organized by panel label.



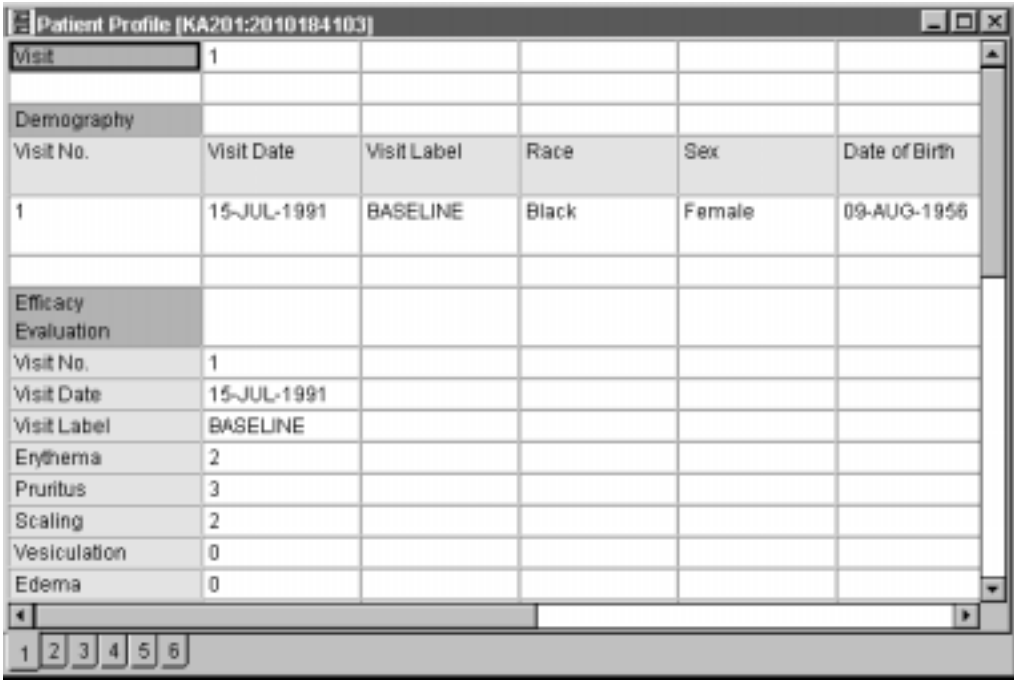
The next example shows the Patient Profiles Browser in multiple worksheet mode for the options ***by panel*** and visit representation as column. The tabs are also organized by panel description.


Patient Profile [KA201:2010184103]

Efficacy Evaluation	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
Visit No.	1	2	3	4	5
Visit Date	15-JUL-1991	22-JUL-1991	30-JUL-1991	06-AUG-1991	13-AUG-1991
Visit Label	BASELINE	DAY 8	DAY 15	DAY 22	DAY 29
Erythema	2	1	1	1	0
Pruritus	3	2	1	0	0
Scaling	2	1	1	1	0
Vesiculation	0	0	0	0	0
Edema	0	0	0	0	0
Exudation	0	0	0	0	0
Maceration	0	0	0	0	0
Papules	0	0	0	0	0
Burning	2	2	0	0	0
Pain	0	0	0	0	0

Demography | Final | Efficacy Evaluation | Mycological Results

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



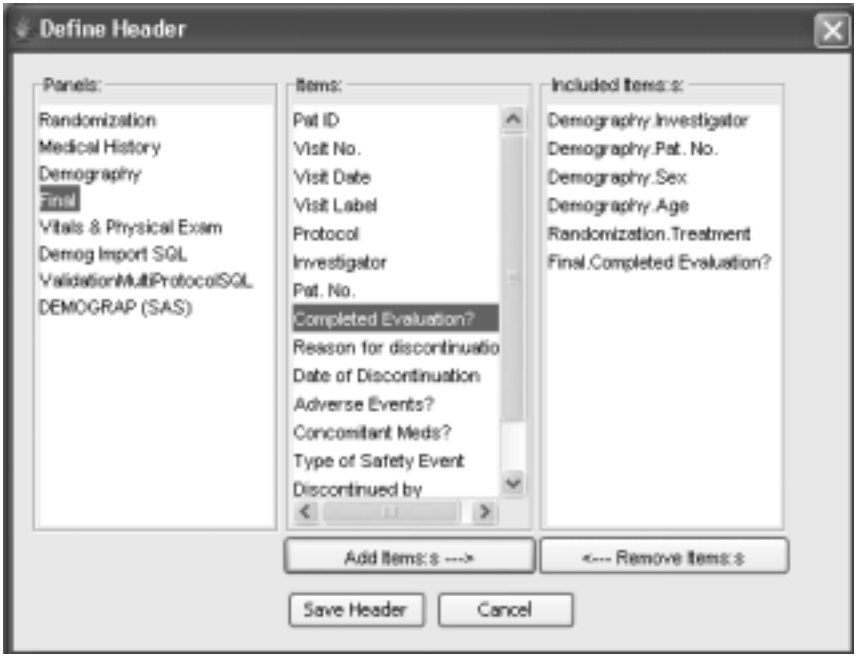
Modify profile

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.

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.

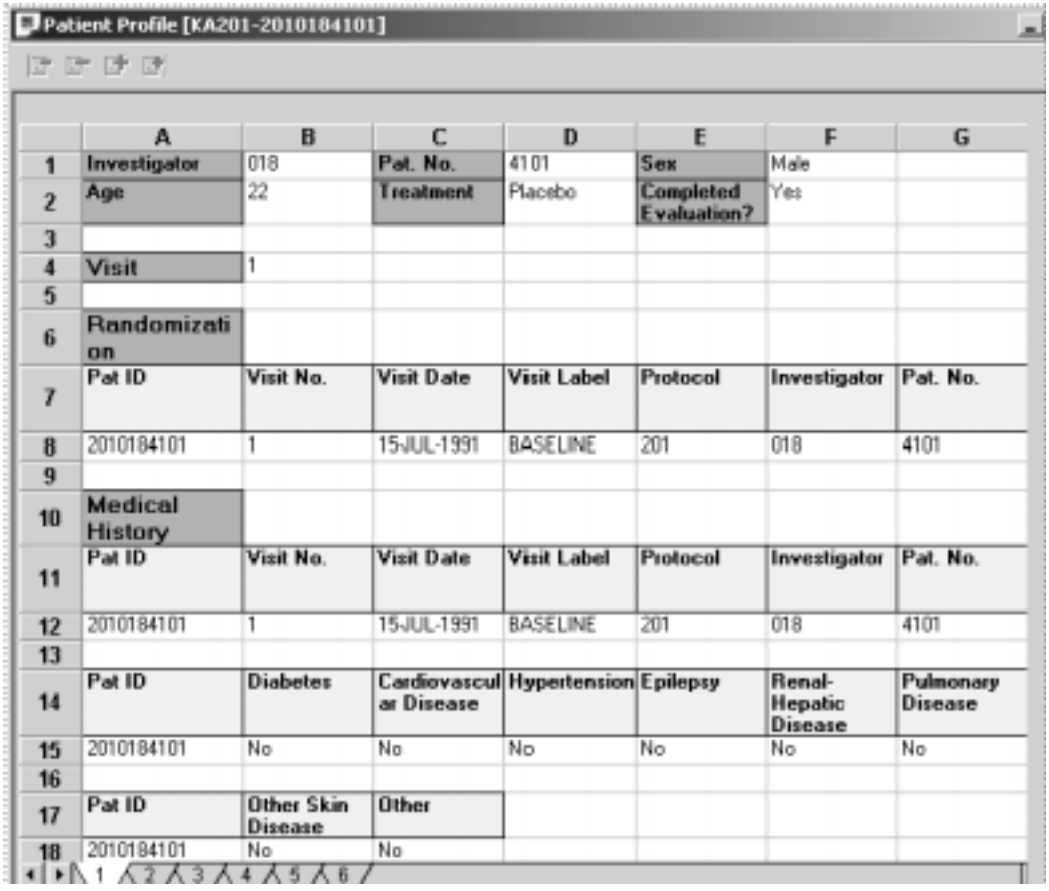
1. Click **Define Header** from the Patient Profiles Browser window.
2. Select a panel.
3. Select the items from the various panels to add as header information. Use the **Add Items** and **Remove Items** buttons to include or remove items from the header definition. As a short cut, you can double click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

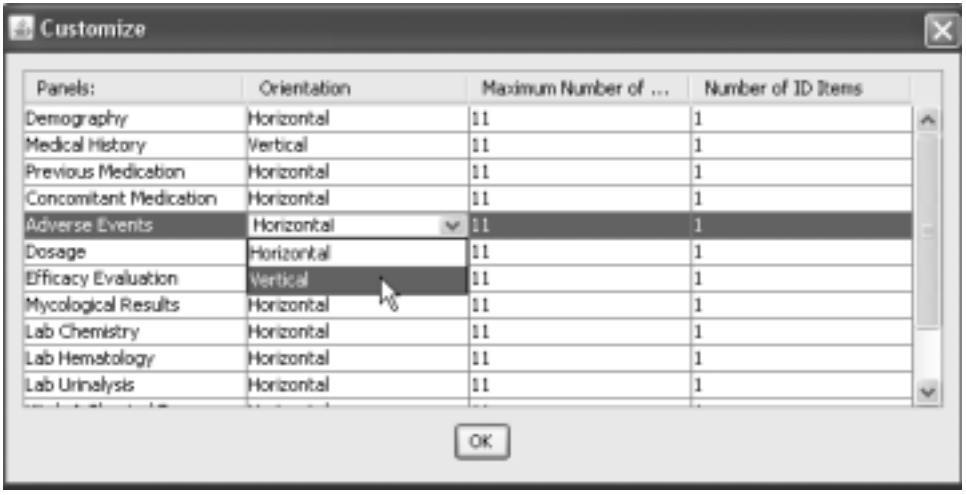

Patient Profile [KA201-2010184101]

	A	B	C	D	E	F	G
1	Investigator	018	Pat. No.	4101	Sex	Male	
2	Age	22	Treatment	Placebo	Completed Evaluation?	Yes	
3							
4	Visit	1					
5							
6	Randomization						
7	Pat ID	Visit No.	Visit Date	Visit Label	Protocol	Investigator	Pat. No.
8	2010184101	1	15-JUL-1991	BASELINE	201	018	4101
9							
10	Medical History						
11	Pat ID	Visit No.	Visit Date	Visit Label	Protocol	Investigator	Pat. No.
12	2010184101	1	15-JUL-1991	BASELINE	201	018	4101
13							
14	Pat ID	Diabetes	Cardiovascular Disease	Hypertension	Epilepsy	Renal-Hepatic Disease	Pulmonary Disease
15	2010184101	No	No	No	No	No	No
16							
17	Pat ID	Other Skin Disease	Other				
18	2010184101	No	No				

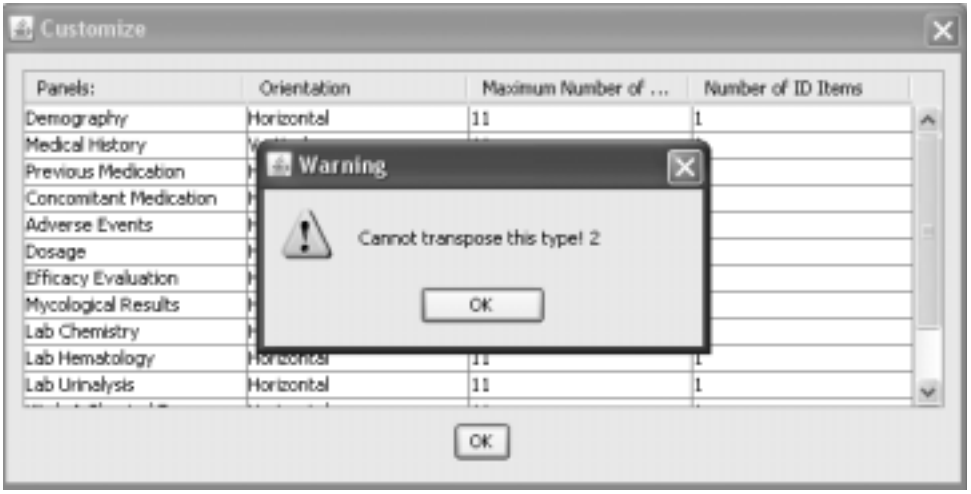
1 2 3 4 5 6

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

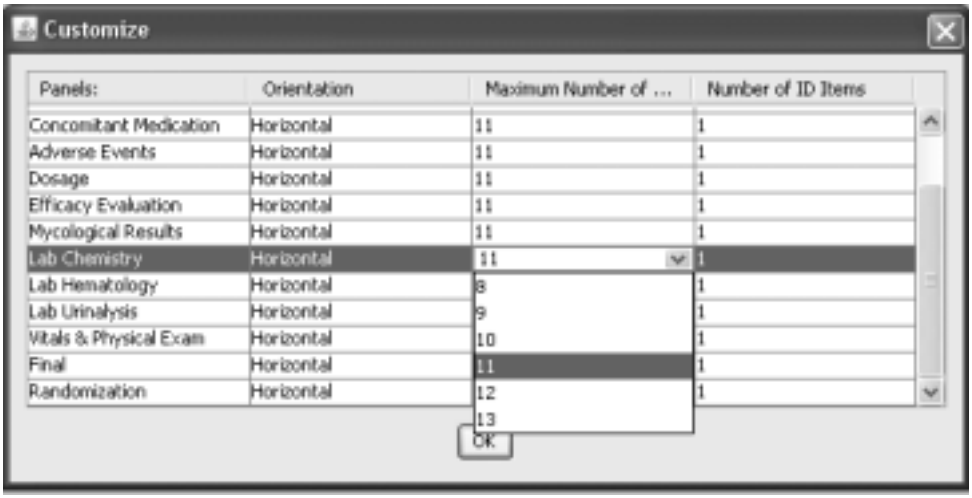
1. Click **Customize** to view the default settings.
2. Click on the panel cell for **Orientation** to access the drop down list to select horizontal or vertical.



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



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.



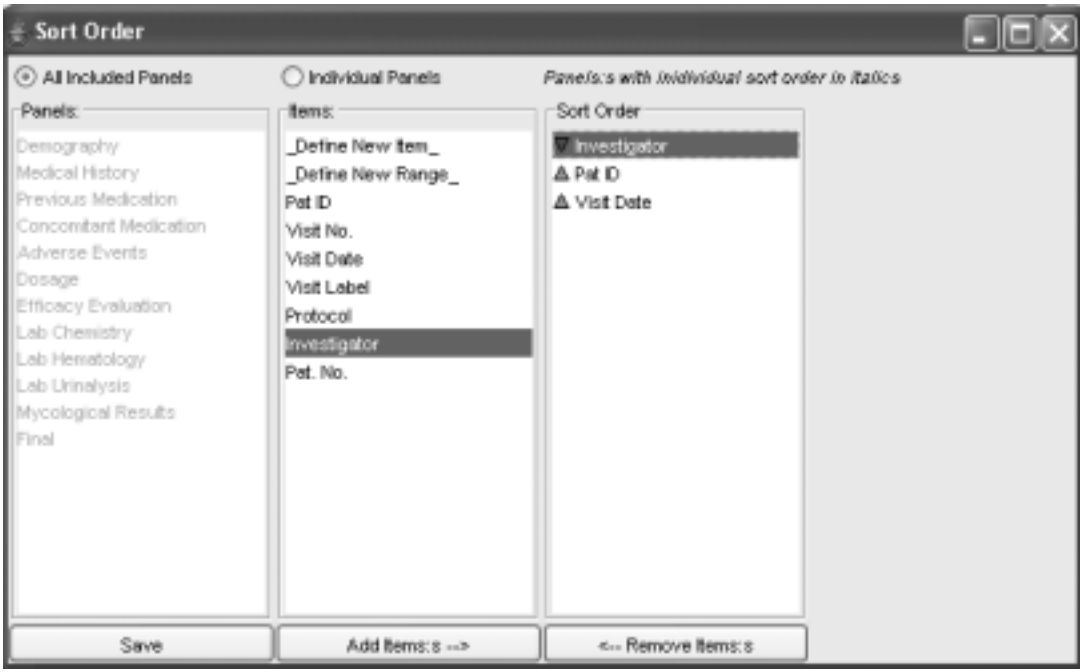
4. Click on the panel cell for **Number of ID Items**. The option to display ID items as represented by the PatientNo and VisitNo are also selected from a drop down list for choices are 0, 1 and 2.

   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.

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.

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.

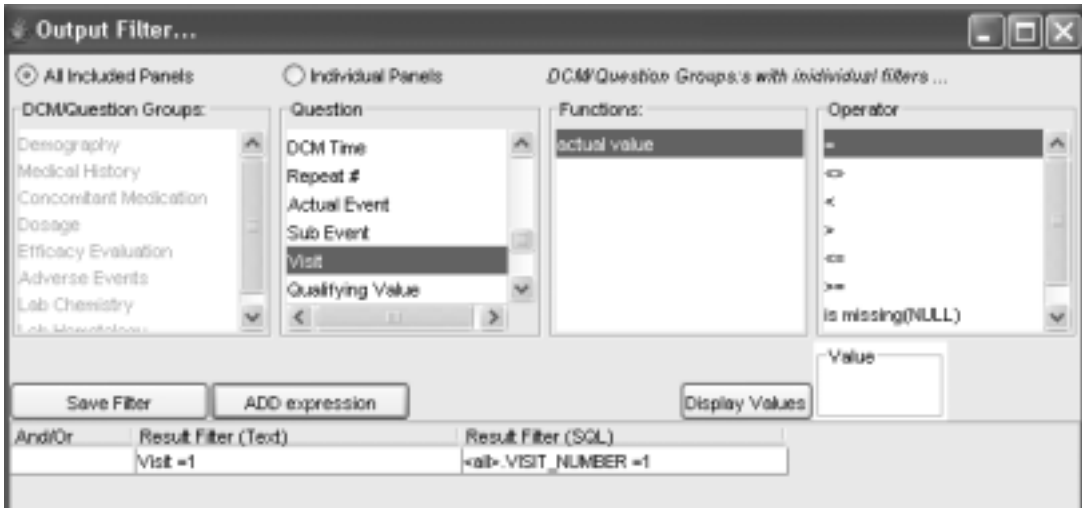
Filter Output works in the Patient Profiles (both workbook and graphic) where only included panels (or panels behind included graphic categories) are viewable and selectable for filtering in the Filter Output window. So if you did not include any panels / categories in your graphic profile, even if they 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.

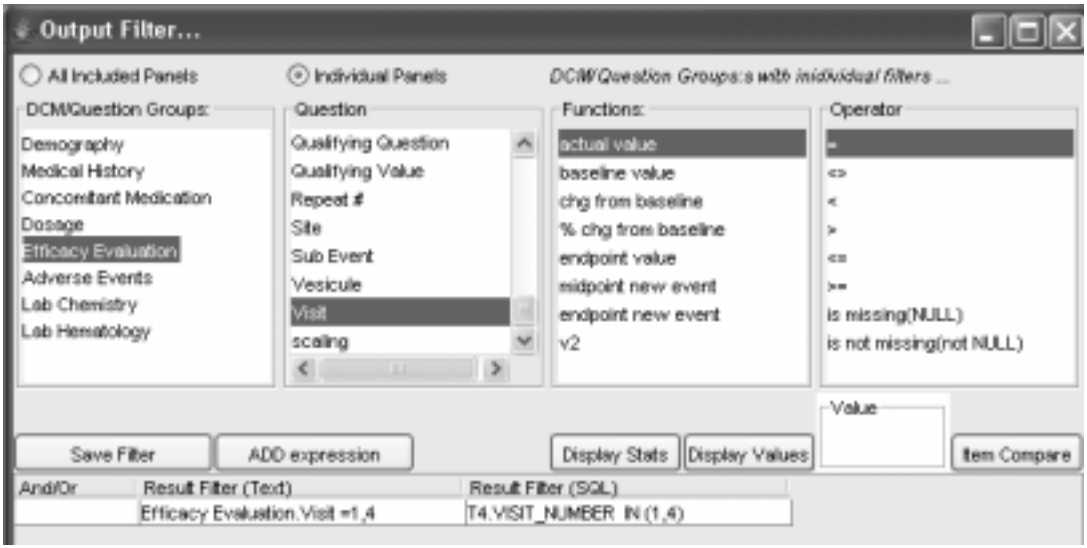
The only exception to this is in Graphic profiles when a category is defined by more than one panel (i.e. dosage and treatment). In this case, both these panels will appear in the Filter Output window and filtering criteria from one panel would affect the other panel.

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 Graphic Profile and filter all graphic displays.



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 graph displays.



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.

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.

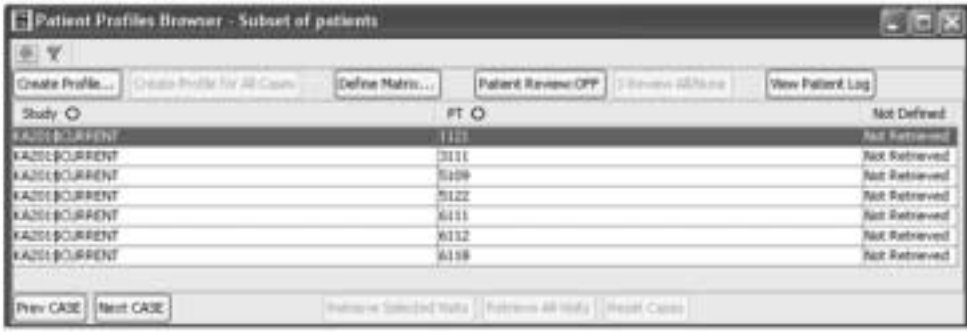
Note: It is highly recommended to subset the patient population when using the Patient Profile Review Tracking functions. The status updating for individual patients and checking for new data may affect response time.

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.

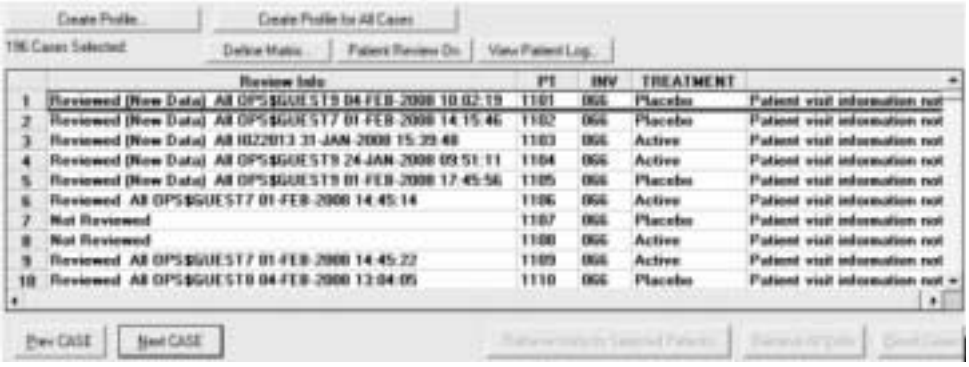
The required column in the Patient Profile Review Tracking window is the “IReviewed” column. Additional columns are available when the Patient Review is turned ON. The configurations for this option are defined in ReviewAdmin where the administrator has the ability to set Yes or No, for the additional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



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.

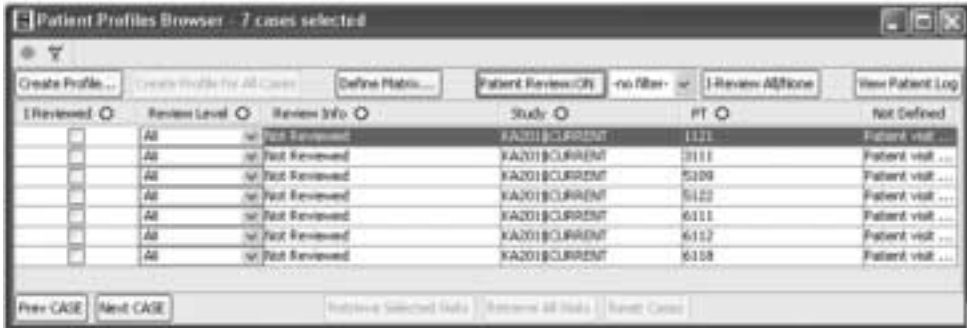


Patient Review Levels

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.



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.

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:

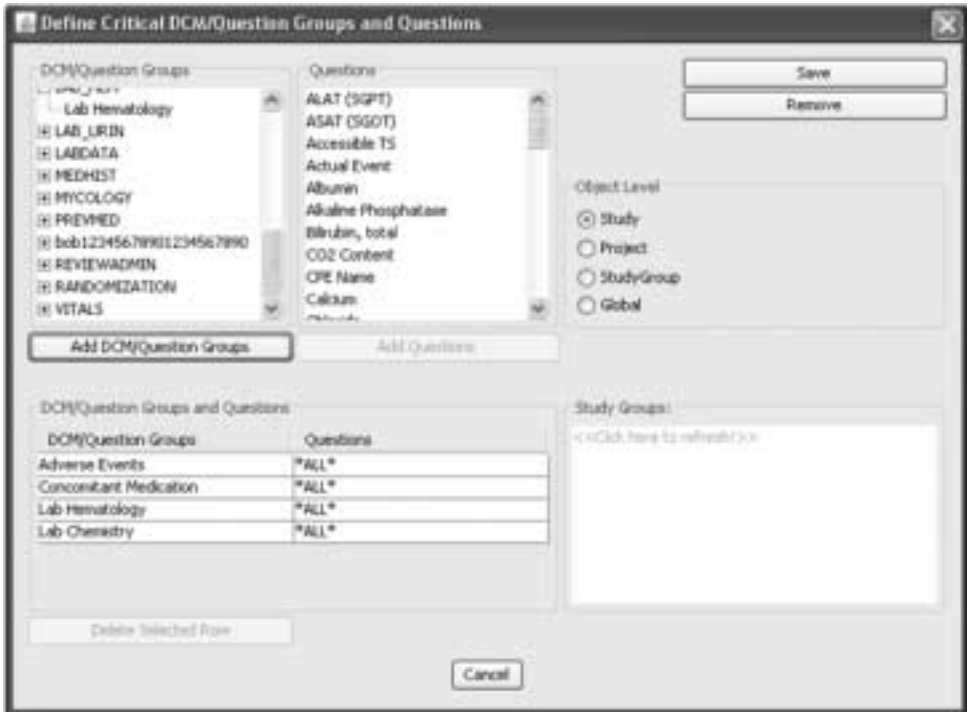
- Critical: Study Level,
- Critical: StudyGroup Level,
- Critical: Project Level,
- Critical: Global Level.

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.

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 order in which you add panels and items to the critical panel, displays in the same order on the Panels Included drop down list box.

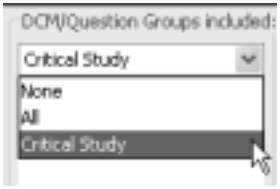


3. If you need to remove an added row, select the row and click **Delete Selected Row.**

   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.

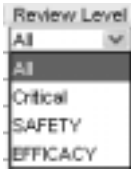
Additional columns are available and optional; Review Level, Review Info, Color Coding, and Comment. The system has sort numbers defined for each column display option, so the column can be ordered.

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.



   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.

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

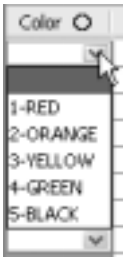
    The configurations for the comments option is defined in ReviewAdmin. The comment field can be viewed in the ***patientpostit table***.

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.

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.

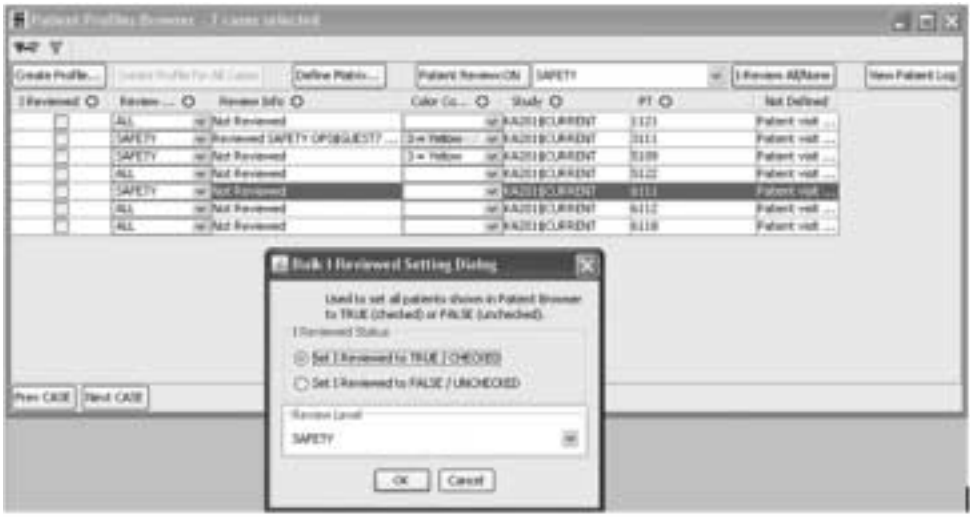
If the user unchecks the "I Reviewed" box for a particular patient review then a DELETE DATE record is generated with the data time stamp in the Patient Log. The default is 24 hours and the amount of time can be defined as an ReviewAdmin config option in REVIEWSTATUSLIMIT=1 where the value can be 1 to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

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.

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.



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.

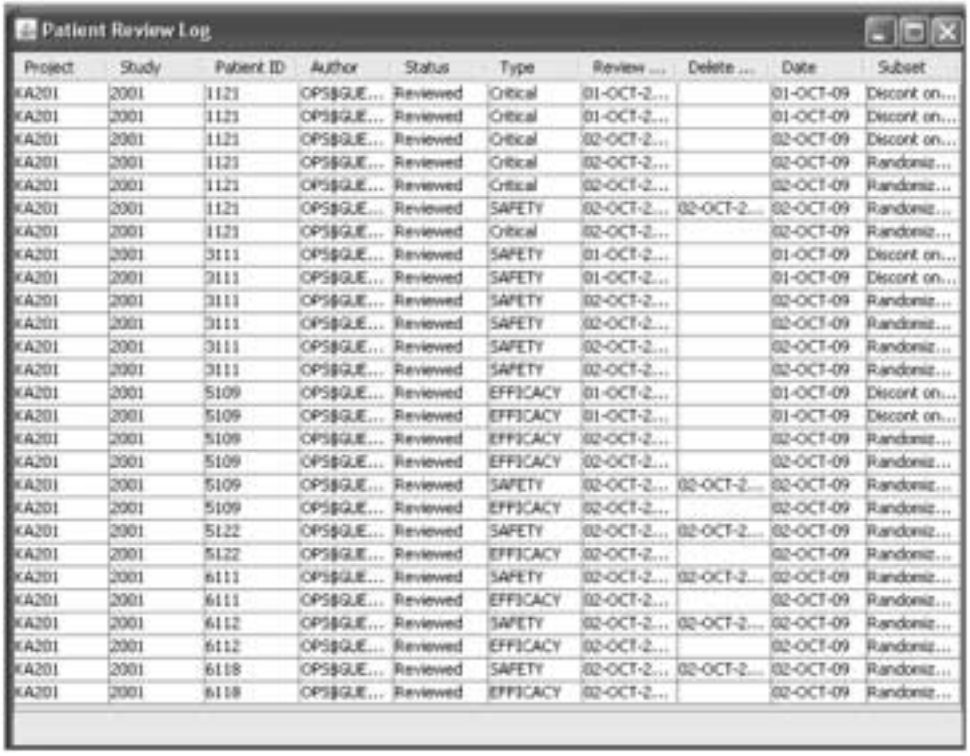
You may view the detailed audit trail of a patient(s) review status by clicking the View Patient Log button.

13. 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.

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	Review ...	Delete ...	Date	Subset
KA201	2001	1121	OPS$GUE...	Reviewed	Critical	01-OCT-2...		01-OCT-09	Discont on...
KA201	2001	1121	OPS$GUE...	Reviewed	Critical	01-OCT-2...		01-OCT-09	Discont on...
KA201	2001	1121	OPS$GUE...	Reviewed	Critical	02-OCT-2...		02-OCT-09	Discont on...
KA201	2001	1121	OPS$GUE...	Reviewed	Critical	02-OCT-2...		02-OCT-09	Randomiz...
KA201	2001	1121	OPS$GUE...	Reviewed	Critical	02-OCT-2...		02-OCT-09	Randomiz...
KA201	2001	1121	OPS$GUE...	Reviewed	SAFETY	02-OCT-2...	02-OCT-2...	02-OCT-09	Randomiz...
KA201	2001	1121	OPS$GUE...	Reviewed	Critical	02-OCT-2...		02-OCT-09	Randomiz...
KA201	2001	3111	OPS$GUE...	Reviewed	SAFETY	01-OCT-2...		01-OCT-09	Discont on...
KA201	2001	3111	OPS$GUE...	Reviewed	SAFETY	01-OCT-2...		01-OCT-09	Discont on...
KA201	2001	3111	OPS$GUE...	Reviewed	SAFETY	02-OCT-2...		02-OCT-09	Randomiz...
KA201	2001	3111	OPS$GUE...	Reviewed	SAFETY	02-OCT-2...		02-OCT-09	Randomiz...
KA201	2001	3111	OPS$GUE...	Reviewed	SAFETY	02-OCT-2...		02-OCT-09	Randomiz...
KA201	2001	3111	OPS$GUE...	Reviewed	SAFETY	02-OCT-2...		02-OCT-09	Randomiz...
KA201	2001	5109	OPS$GUE...	Reviewed	EFFICACY	01-OCT-2...		01-OCT-09	Discont on...
KA201	2001	5109	OPS$GUE...	Reviewed	EFFICACY	01-OCT-2...		01-OCT-09	Discont on...
KA201	2001	5109	OPS$GUE...	Reviewed	EFFICACY	02-OCT-2...		02-OCT-09	Randomiz...
KA201	2001	5109	OPS$GUE...	Reviewed	EFFICACY	02-OCT-2...		02-OCT-09	Randomiz...
KA201	2001	5109	OPS$GUE...	Reviewed	SAFETY	02-OCT-2...	02-OCT-2...	02-OCT-09	Randomiz...
KA201	2001	5109	OPS$GUE...	Reviewed	EFFICACY	02-OCT-2...		02-OCT-09	Randomiz...
KA201	2001	5122	OPS$GUE...	Reviewed	SAFETY	02-OCT-2...	02-OCT-2...	02-OCT-09	Randomiz...
KA201	2001	5122	OPS$GUE...	Reviewed	EFFICACY	02-OCT-2...		02-OCT-09	Randomiz...
KA201	2001	6111	OPS$GUE...	Reviewed	SAFETY	02-OCT-2...	02-OCT-2...	02-OCT-09	Randomiz...
KA201	2001	6111	OPS$GUE...	Reviewed	EFFICACY	02-OCT-2...		02-OCT-09	Randomiz...
KA201	2001	6112	OPS$GUE...	Reviewed	SAFETY	02-OCT-2...	02-OCT-2...	02-OCT-09	Randomiz...
KA201	2001	6112	OPS$GUE...	Reviewed	EFFICACY	02-OCT-2...		02-OCT-09	Randomiz...
KA201	2001	6118	OPS$GUE...	Reviewed	SAFETY	02-OCT-2...	02-OCT-2...	02-OCT-09	Randomiz...
KA201	2001	6118	OPS$GUE...	Reviewed	EFFICACY	02-OCT-2...		02-OCT-09	Randomiz...

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

Click the **Export** button to export your Patient Review Log in Excel files, HTML format or Tabbed Txt files.

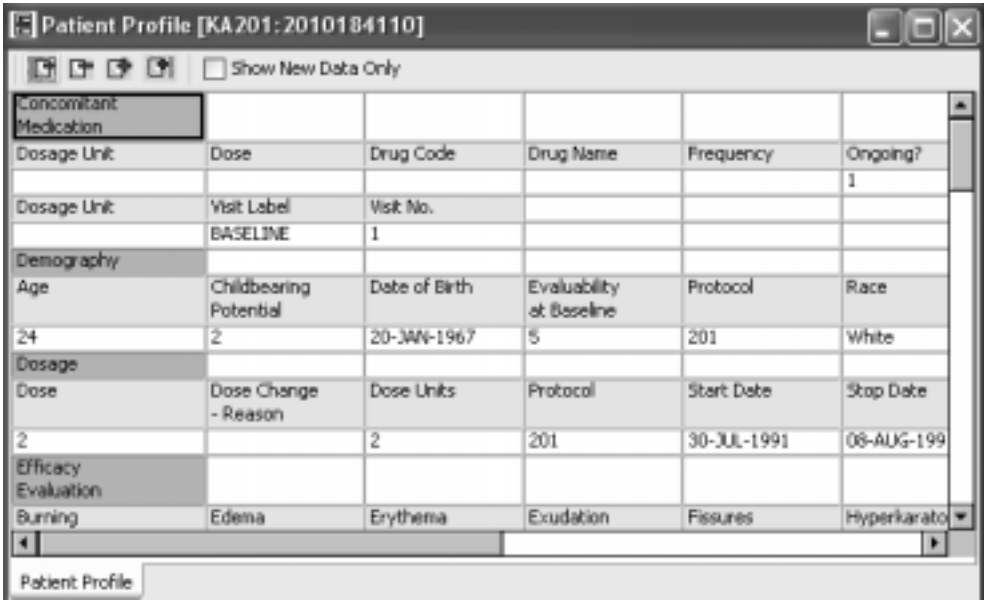
Close the Patient Review Log window.

Highlight patient data

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 but is not available in the Graphic Patient 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**"..



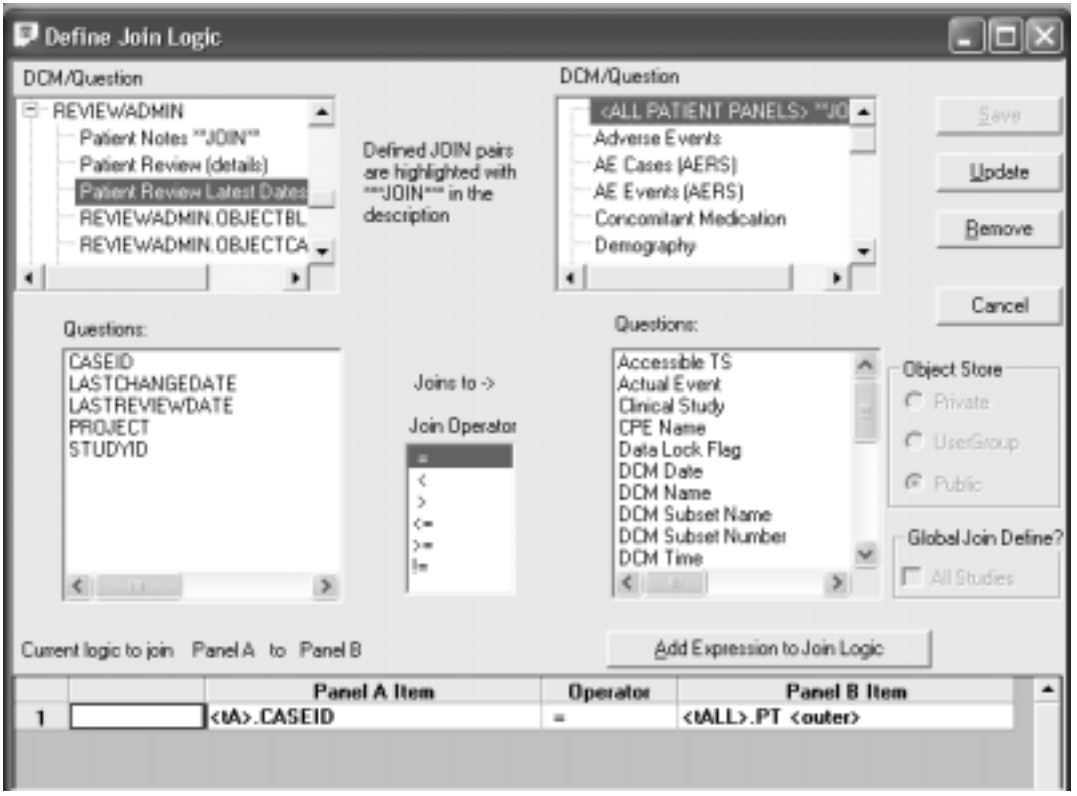
All the panel heading rows are displayed to show they've been checked for new data AND new data rows are displayed highlighted in purple. New Data Columns behave similarly.

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.

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 IReview 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.



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.

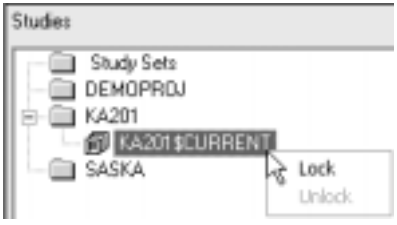
The privilege to lock or unlock a study is a high level manager function enabled in ReviewAdmin which allows the user to display a lock status on an individual study. If a study is not locked, then Review will check for data updates and new data for that study the first time the user turns ON the Patient 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 IReview.

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.

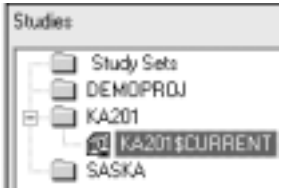
When a selected study is set to Lock mode the following conditions occur in the Patient Profile Review Tracking tool.

- 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.

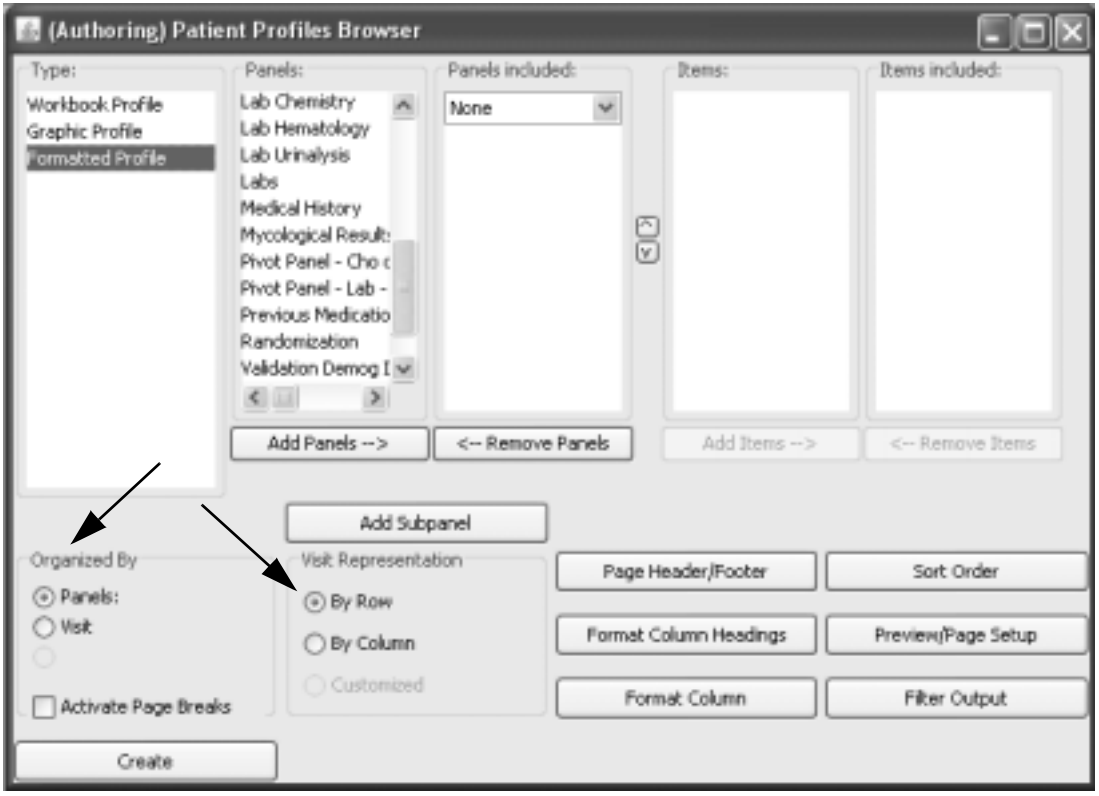


Formatted Patient Profile

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***.



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

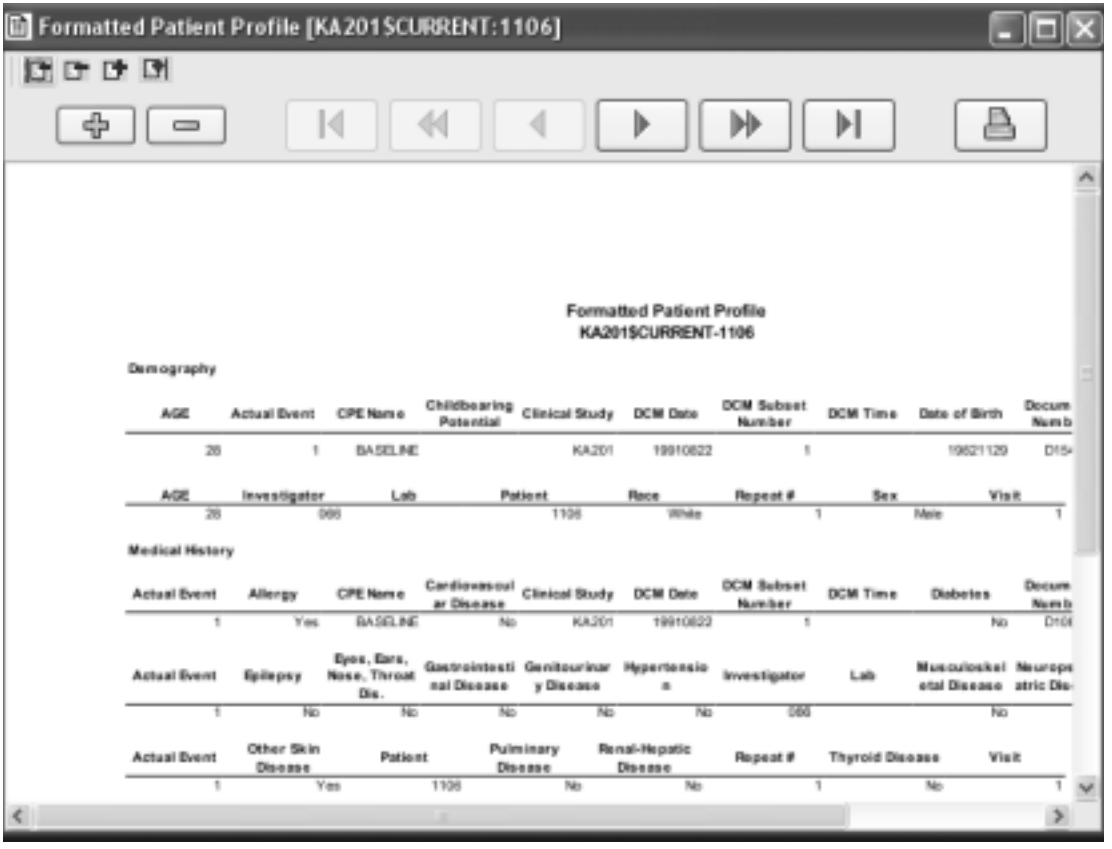
This is a partial view of a formatted profile with default settings.

– At the top upper left corner, use the page by buttons for plus and minus to go to the next or previous patient.

– Use the arrows in the main menu bar to move between pages within a single patient with sliding scroll bar on right.

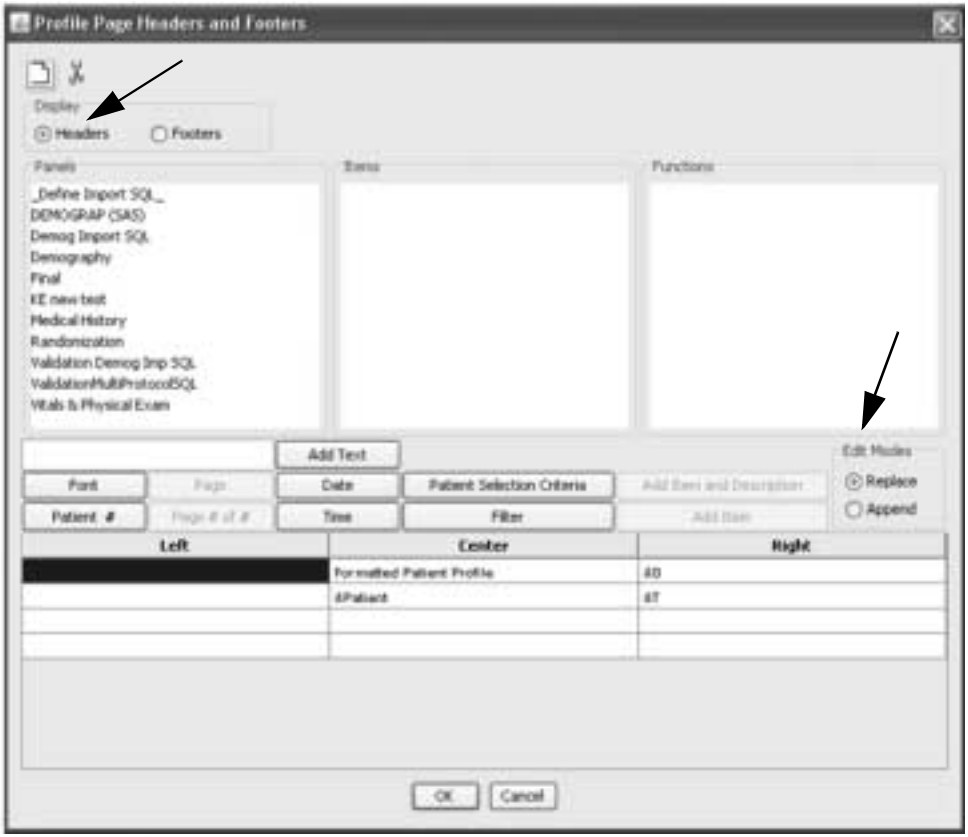
– The plus and minus buttons are available to enlarge or reduce the view.

– The printer icon is located at the far right in the menu bar.



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.



The default settings for Headers are:

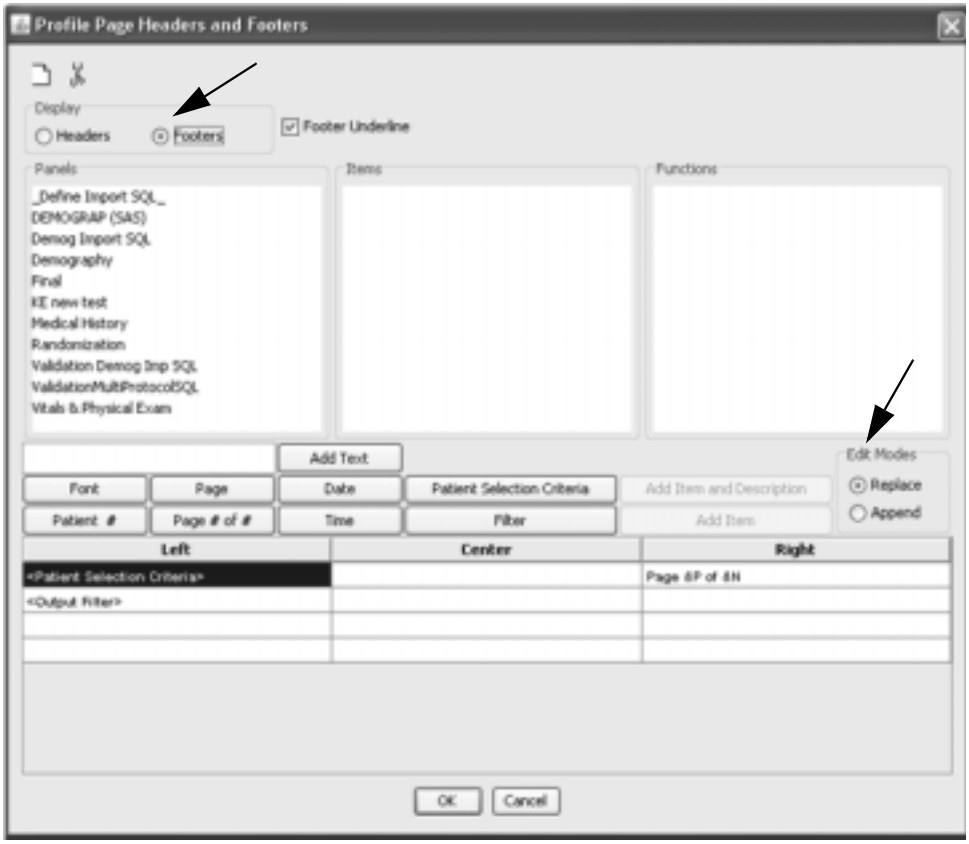
   a. Default title is the profile type displayed in the center cell as Formatted Profile with PatientID below.

   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.

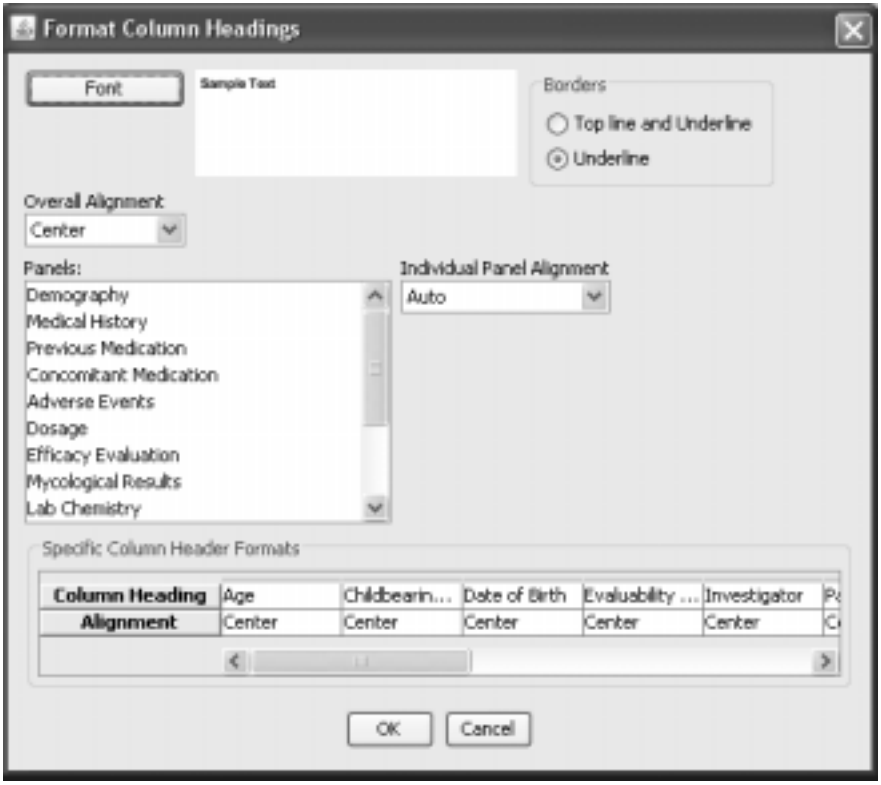
5. Click on a cell and use the **Scissors icon** to delete the selected cell contents or click the **New icon** to clear all cell contents.
6. Click the Font button to change font, style and size.
7. Click Display Footers.



8. 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 apply format changes.

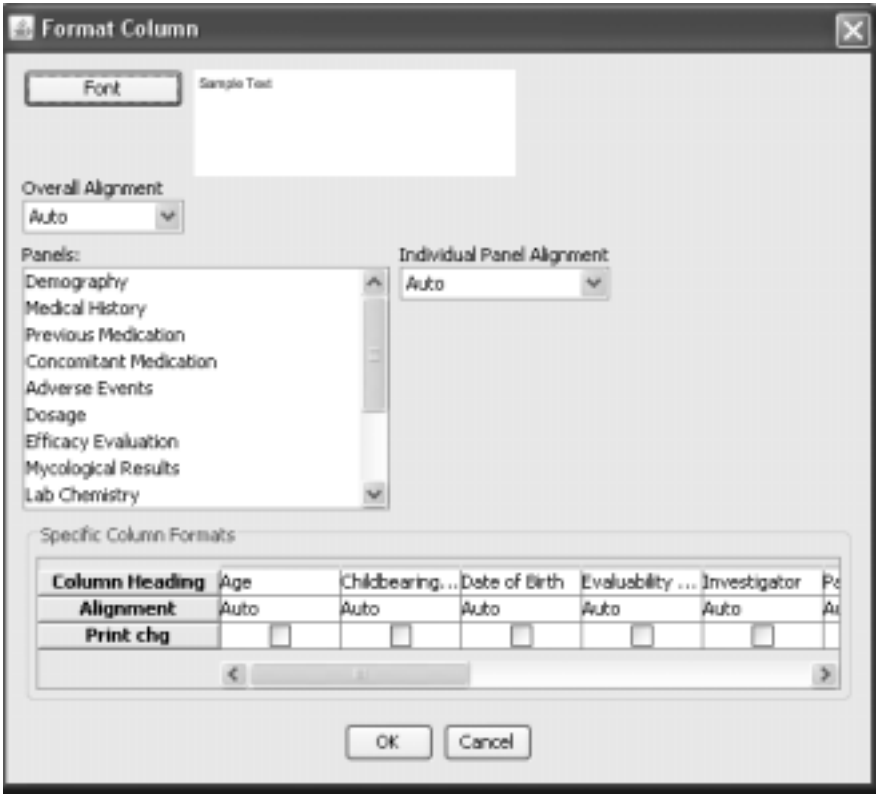
To apply Overall Column Header Formats:

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. Click **OK** to apply format changes.



To apply overall formats to font, style and size:

1. Click on the **Format Column** button to open the Profile Column Formatting 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.



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

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

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.

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.

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.

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. Change the **Maximum Visits Displayed in Row** selecting from the drop down list. The choices are 5 to 9.

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**.

- 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.

Print and Export Patient Profiles

Print patient profile

To print the patient profile of the selected patient:

1. Click on the title bar of the Patient Profile window to make it the active window.
2. Click , or from the **File** menu, select **Print**.

   You can access the printer icon from the tool bar within the formatted patient profile output window to display the Print dialog box.
3. Click **OK**. A signature line with the date is printed at the bottom of the worksheet.

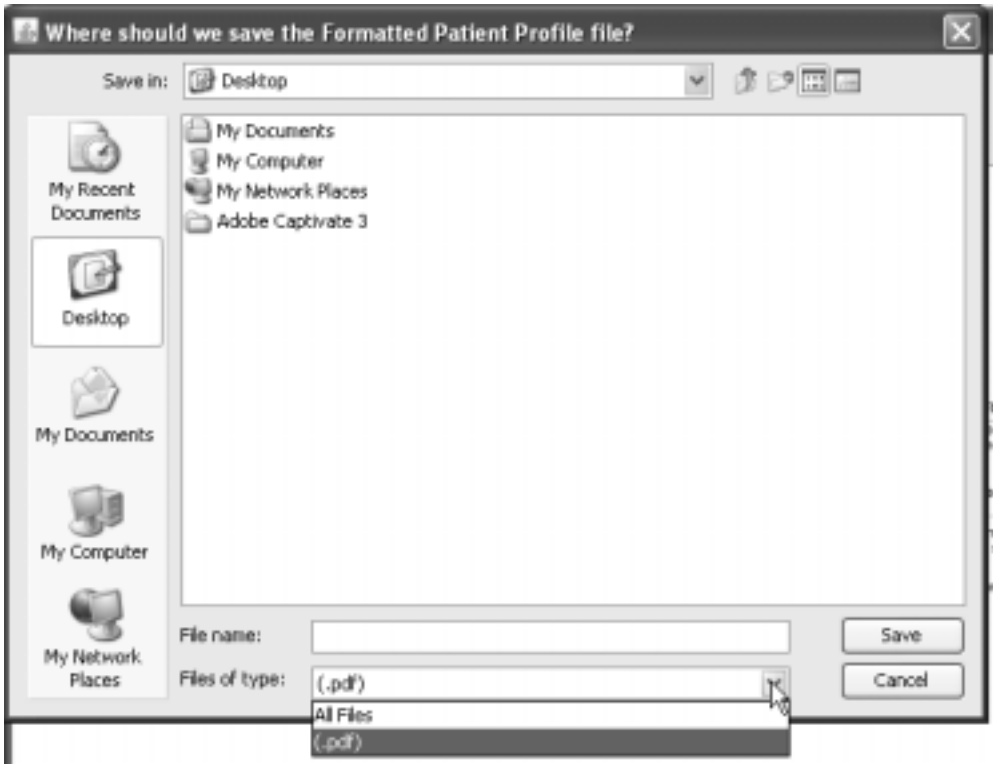
Export patient profile

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.

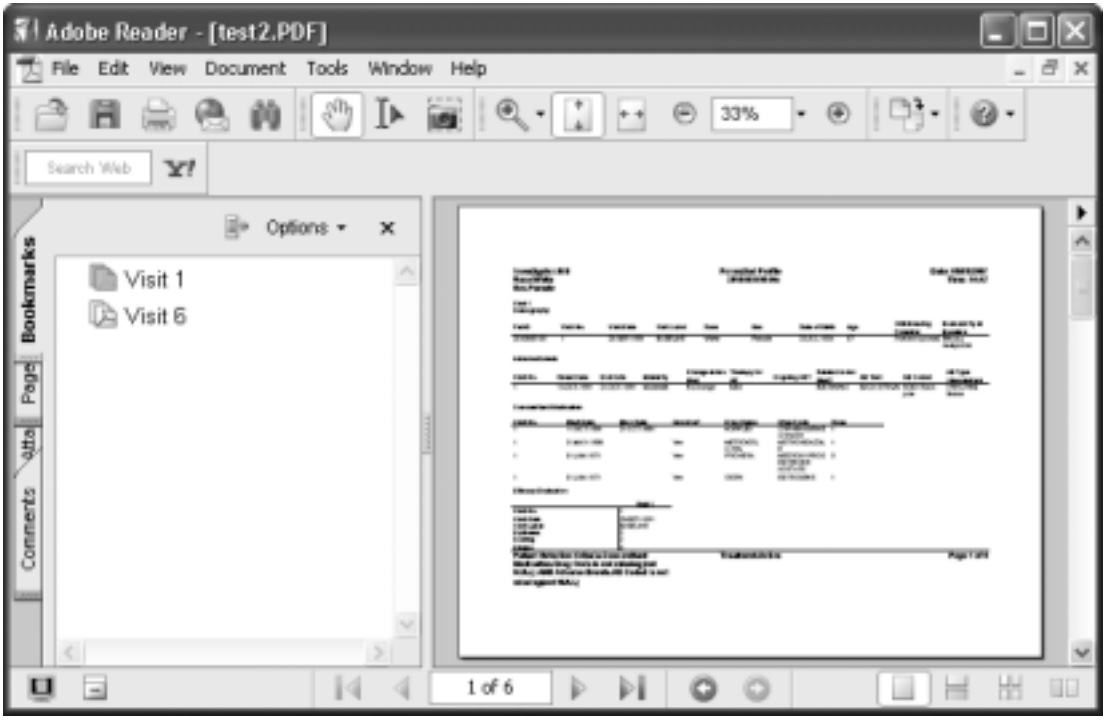
To export your **Workbook Profile** in Excel files, HTML format or Tabbed Txt files:

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.
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.

Formatted Patient Profiles can only be exported as PDF files.



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.).*



Graphic patient profiles require to print / print preview the GPP in the Patient Profile output window.

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: Scheduling Formatted Patient Profiles requires optional printer server module.

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 161

Access Graphic Patient Profile 161
Show Graphic Patient Profile 162
Missing data 163
Basic graphic user interface 164

Define Graphic Profile Template 166

Open Patient Profiles Browser 166
Open Graphic Profile Template 167
Select template level 169
Define study start date 170
Define Visit 173
Define header items 174
Category types 175
Define Category Information 176
Ongoing Item 177
Time Axis scale 178
Duration Category Type 179
Dosage Category Type 180
Text Category Type 181
Laboratory Category Type 183
Time Point Type category 186
Save template 188
Edit graphic template 188

Define Graphic Profile 189

Select graphic profile 189
Select defined template 190
Change Time Axis 190
Change Limit value 191
Display Time items 191

Select categories for display 192
Select items for display 194
Normal range multiplier 197
Create Graphic Patient Profile 199
Basic graphic user interface 201

Graph settings 204
Select settings 204
Appearance options 204
Printing and PDF output settings 205
Color settings 206
Headers and footers 207
Category settings 207

Formatted Profiles 209
Show formatted patient profile 209

Printing and Exporting Patient Profiles 210
Print Preview 210
Print patient profile 210
Export patient profile 211

Object Storage 212

Close Patient Profiles Browser 212
Closing the Patient Profiles windows 212

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.

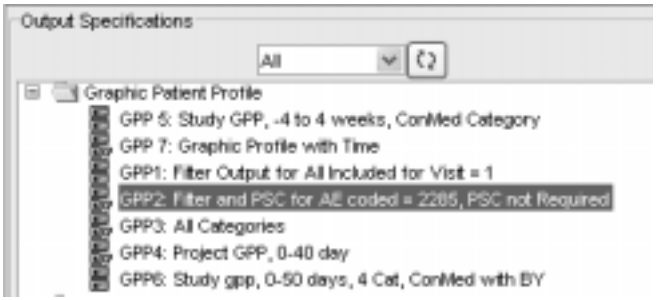
The graphic patient profile specifications are created within the limits set by the currently defined graphic patient profile templates defined in either JReview or IReview.

- 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.

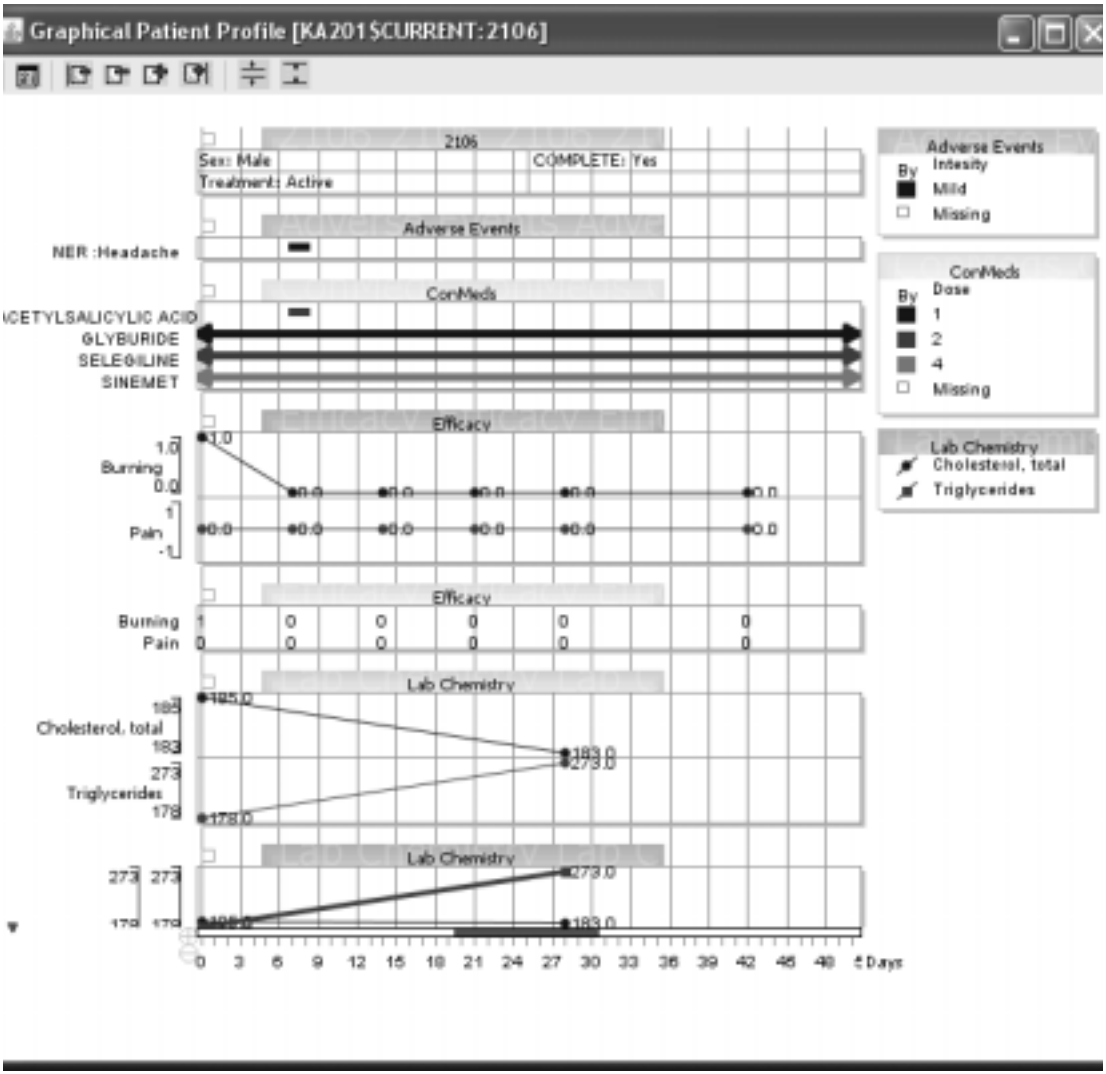
The patient data is displayed from multiple data domains and plotted against a common time axis. The display style for each domain depends upon the kind of data, for example, duration events such as Adverse Events are plotted as horizontal bars showing the duration of the event, from onset date to end date.

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**.

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.

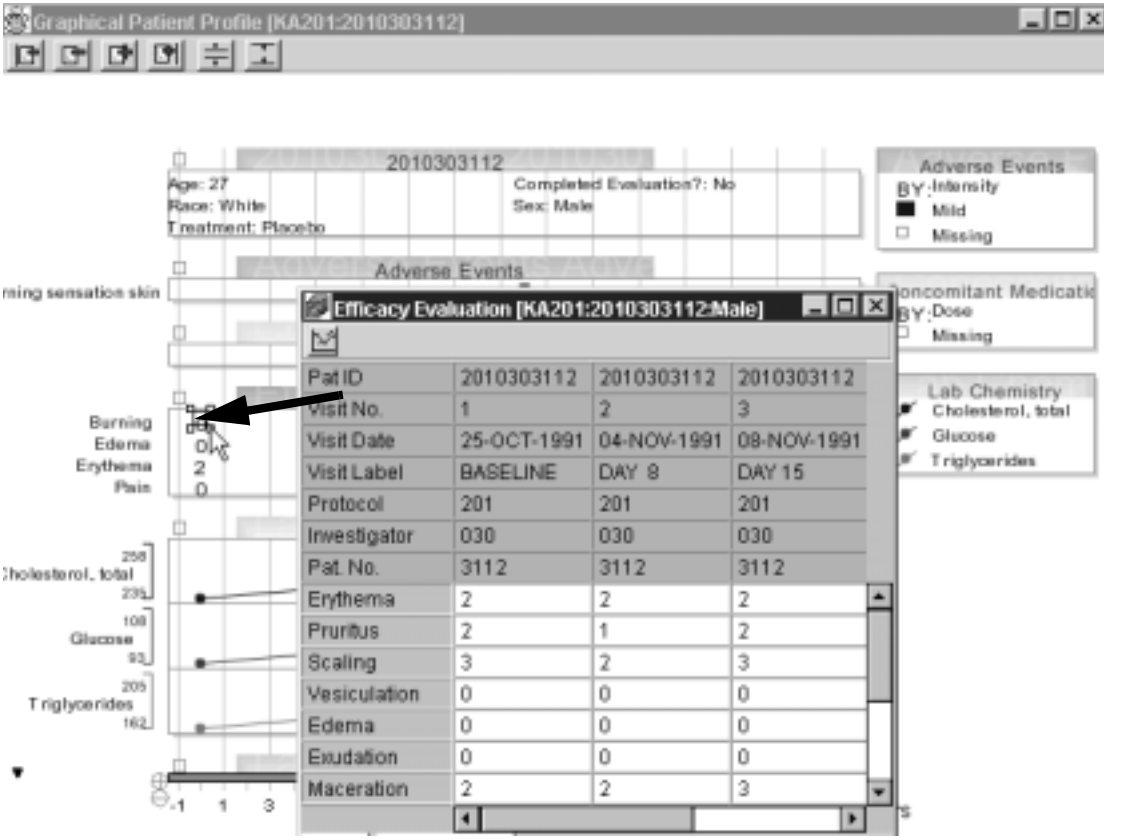


Missing data

Missing data is displayed for line plots and scatter plots as blank. Duration plots as an empty box for missing BY variable value. 'B' if it has a start date but no end date. 'E' if it has a stop date but no start date and no bar if it has no start and stop date. *(See section: Define Graphic Profile Template for 'Ongoing Item')*

Once the graphic patient profile displays, the following functions are available to assist you in further examining each graphic data display.

- Use the keyboard up and down arrows to scroll 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.



Pat ID	2010303112	2010303112	2010303112
Visit No.	1	2	3
Visit Date	25-OCT-1991	04-NOV-1991	08-NOV-1991
Visit Label	BASELINE	DAY 8	DAY 15
Protocol	201	201	201
Investigator	030	030	030
Pat. No.	3112	3112	3112
Erythema	2	2	2
Pruritus	2	1	2
Scaling	3	2	3
Vesiculation	0	0	0
Edema	0	0	0
Exudation	0	0	0
Maceration	2	2	3

- To select multiple points, click and hold the left mouse button, drag the mouse to create a “box” and let go of the left mouse button. This will invoke a drilldown for all the points in the box.
- Click the left mouse button to deselect all previously selected points.
- Zoom in and zoom out with the ‘+’ and ‘-’ icons on the left of side of the time line scroll bar.

- On the Control bar (located at the left side of categories) with the box icon; use the left mouse to minimize and maximize the category.

- To move between patients, in the Toolbar use the icons with the appearance of little pages with + and - signs. The first button always takes you to the first patient. The second button moves you one patient back. The third button moves you one patient forward. The last button always takes you to the last patient.

- The last buttons decrease or increase row size by 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.

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.

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**.**

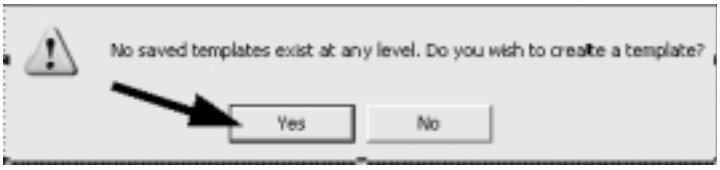
Click on the toolbar or from the **Browse** menu, select **Patient Profiles**.

JReview opens the Patient Profiles Browser window to the default profile type for **Workbook Profile**. Click on the **Graphic Profile** type.

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.



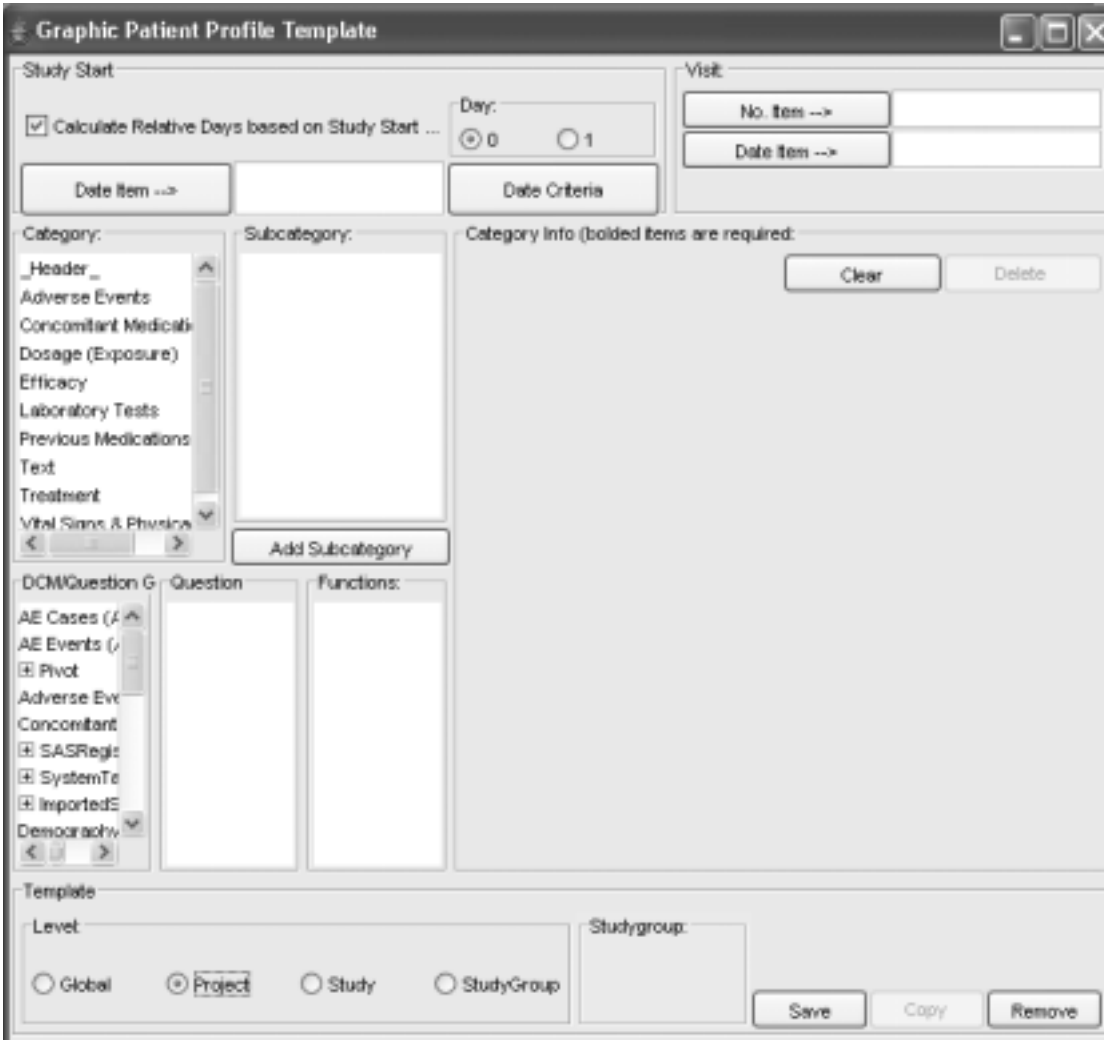
Click **Yes** and the Graphic Patient Profile Template window opens.

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.

Entry of the Study Start Date is **required** unless the database utilizes an item for day calculations.


Graphic Patient Profile Template
Study Start
Calculate Relative Days based on Study Start ...
Day:
0
1
Date Item -->
Date Criteria
Visit:
No. Item -->
Date Item -->
Category:
Header
Adverse Events
Concomitant Medicati
Dosage (Exposure)
Efficacy
Laboratory Tests
Previous Medications
Text
Treatment
Vital Signs & Physica
Subcategory:
Add Subcategory
Category Info (bolded items are required:
Clear
Delete
DCM/Question G
AE Cases (A
AE Events (
Pivot
Adverse Ev
Concomitant
SASRegis
SystemTe
ImportedS
Demographv
Question
Functions:
Template
Level
Global
Project
Study
StudyGroup
Studygroup
Save
Copy
Remove

Select template level

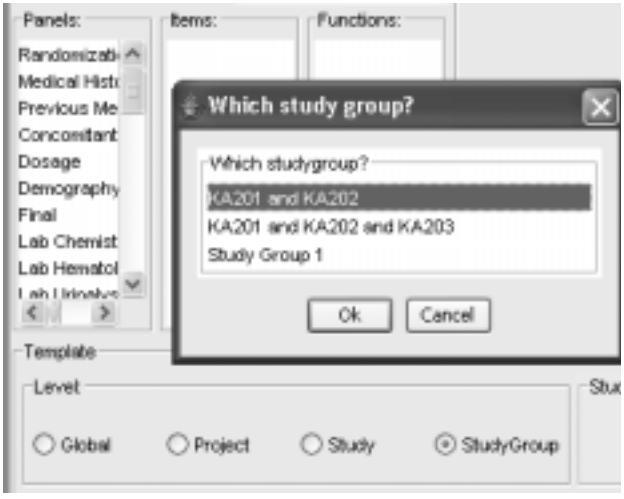
Super Users are able to save templates at the object storage level for global, project and study levels as only one per level. If the study selected belongs to a Study Group previously defined in ReviewAdmin, then the Study Group option is also available. The templates are saved at the object storage location for public only.

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.

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.

1. Select the **Template Level** for Global, Project, Study or Study Group.

If you select Study Group for the Template level then you must also select a study group. Multiple study groups can be selected with the CTRL or SHIFT key.



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.

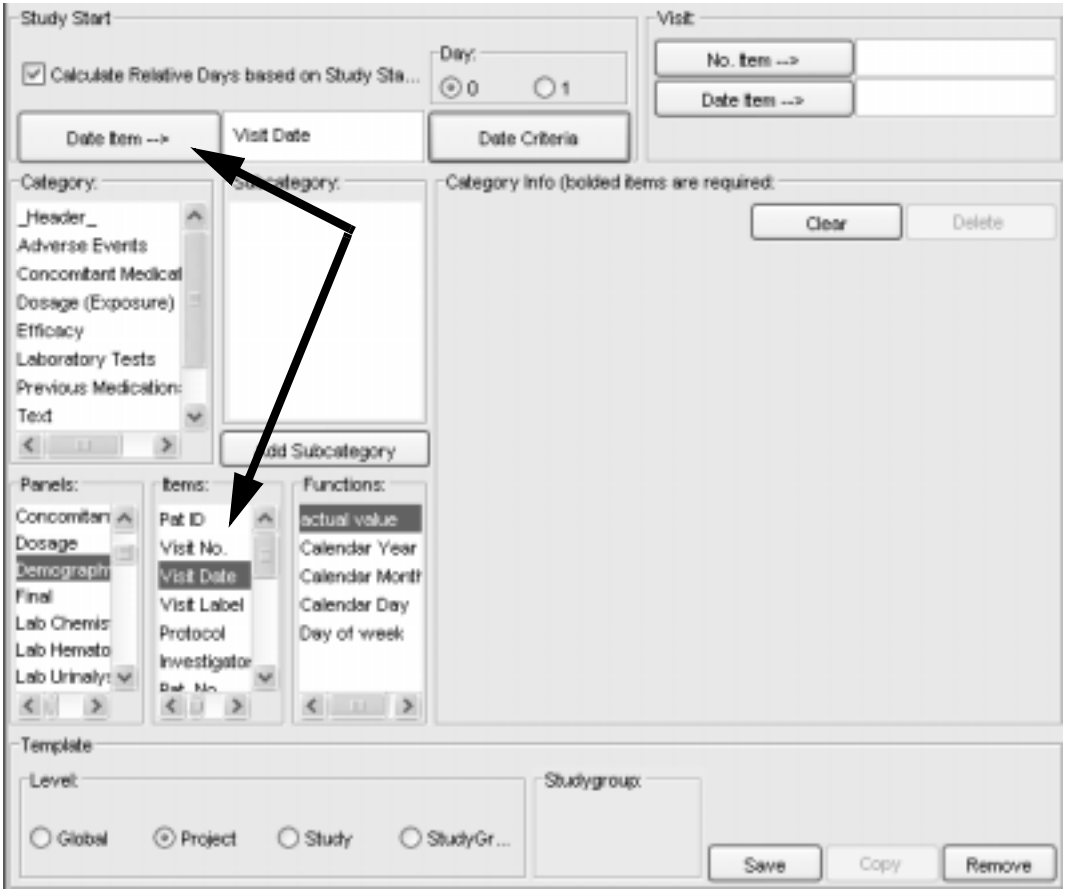
The Study Start Date is **required** to create a Graphic Patient Profile. Therefore, if you forget to enter a study start date you would be **unable** to save the template.

Once a Study Start Date has been entered then the Save and Copy buttons are available.

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.

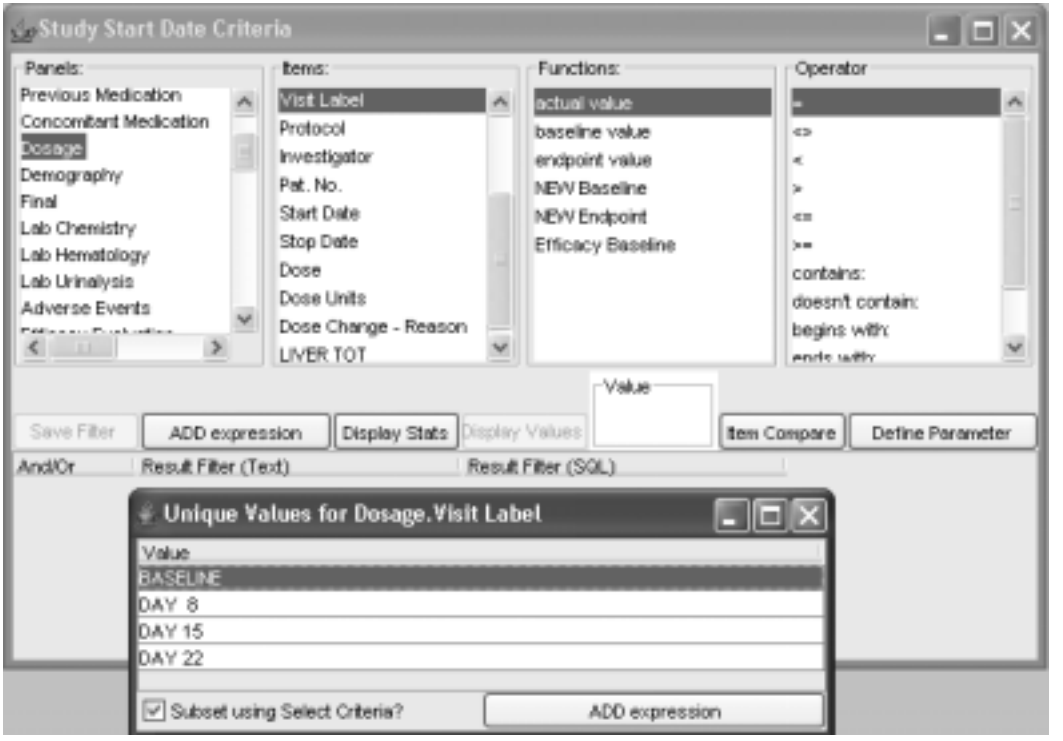
Enter the precalculated Day item created in your database (not Review). You are required to select at least one item per defined category that contains numeric values denoting *relative days from study start* (i.e., for a single event category such as “Laboratory Test” you would enter an item containing 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.

2. To enter the Study Start Date Item, select a panel and date item. Click **Date Item**.
3. Enter the date item as **Day 0** or **Day 1**.



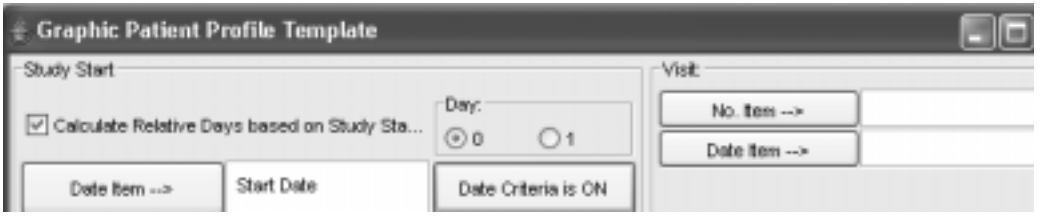
If you had entered a study start date from a multiple record panel then you need to further specify the date by clicking **Date Criteria**. For example, if you had selected the Start Date item from the Dosage Panel, the Date Criteria is **required** for this multiple record panel.

The Study Start Date Criteria window opens for you to specify details such as a visit label or visit number for your selected date.



4. Click **Save Filter** and close the window.

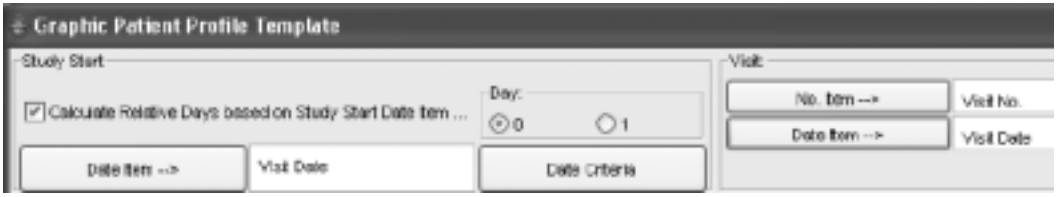
   The **Date Criteria** button status changes to 'Date Criteria ON'.



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.

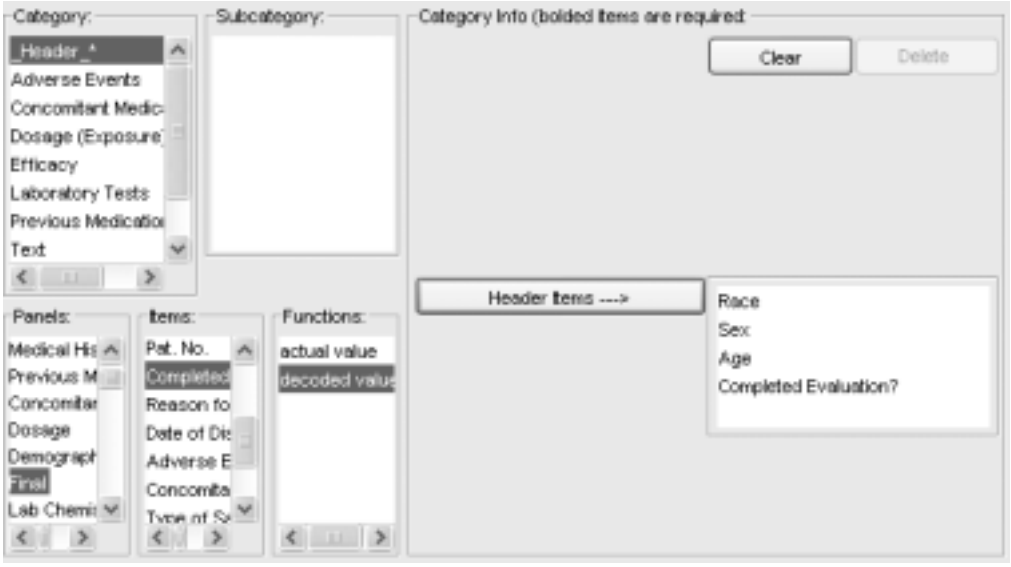
Information entered in the Visit function for "No. Item" and "Date Item" are **required** to come from the same panel source as the entries for Visit Number and Visit Date. The resulting calculation for relative "Days on Drug" is displayed and plotted against the visit number along the X Axis on the 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.



Adding a header is optional. The PatientID defaults if left blank.

5. Click **Header** from the Category list.
6. Go to the Panels list and Items list to select and add header items to display in the graphic patient profile.
7. Click **Header Items** button to add items. Highlight and click scissors in the tool bar to remove items.



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.

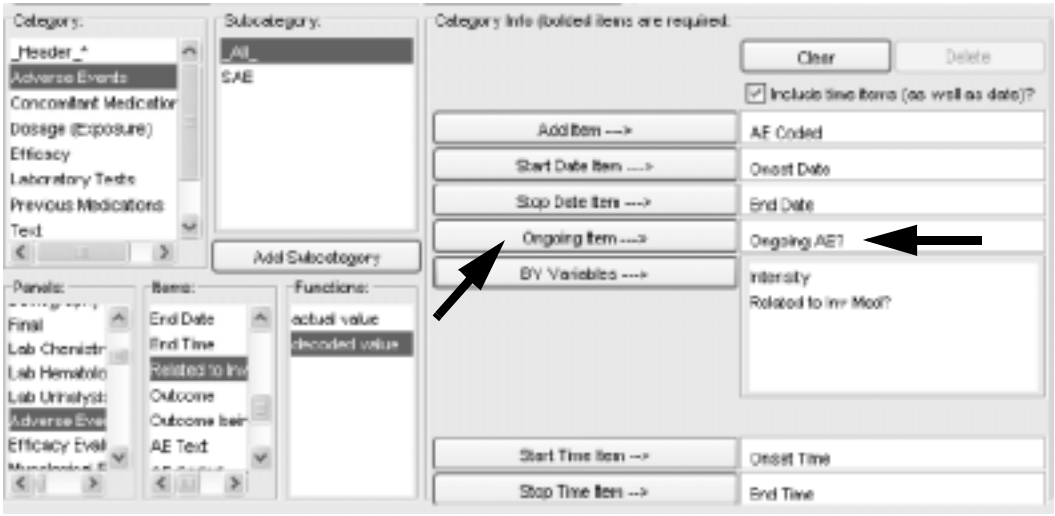
The following table lists the data categories.

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

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. If the category collects time data, click the **Include time items** box to activate the time items to display along 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.



Ongoing Item

The presence of an 'Ongoing Item' collected during the study, will display the following behavior when the graphic patient profile is created.

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

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
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.

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. The **Add Item** is the field to be graphed. **Ongoing Item** and **BY Variables** are optional. The **BY Variables** display details as a legend option.

Dosage Category Type

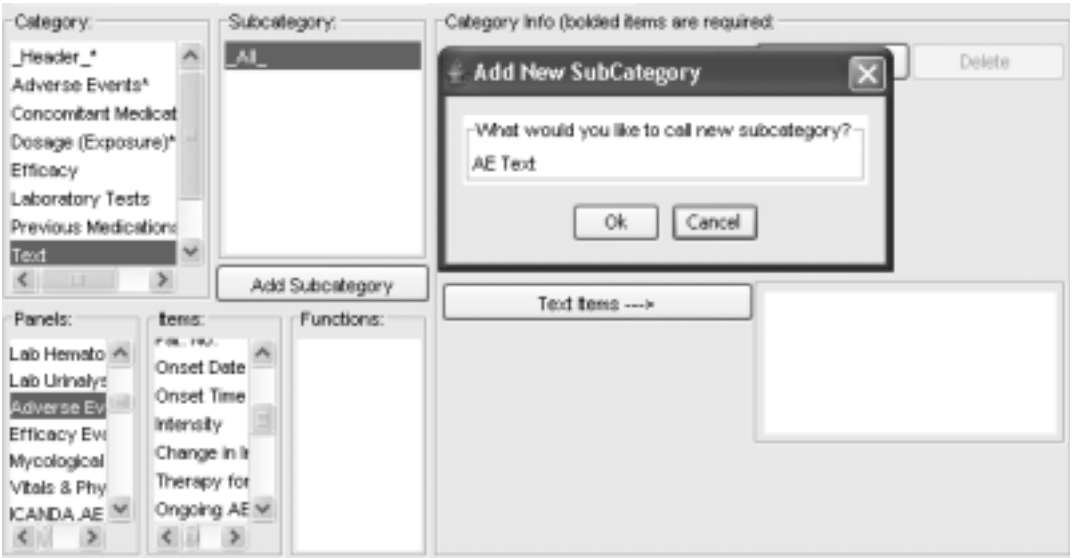
The dosage category is a special case of duration **requiring a numeric** field representing dosage values for the item to graph. The dosage category supports multiple dosing regimens when you add subcategories.

Text Category Type

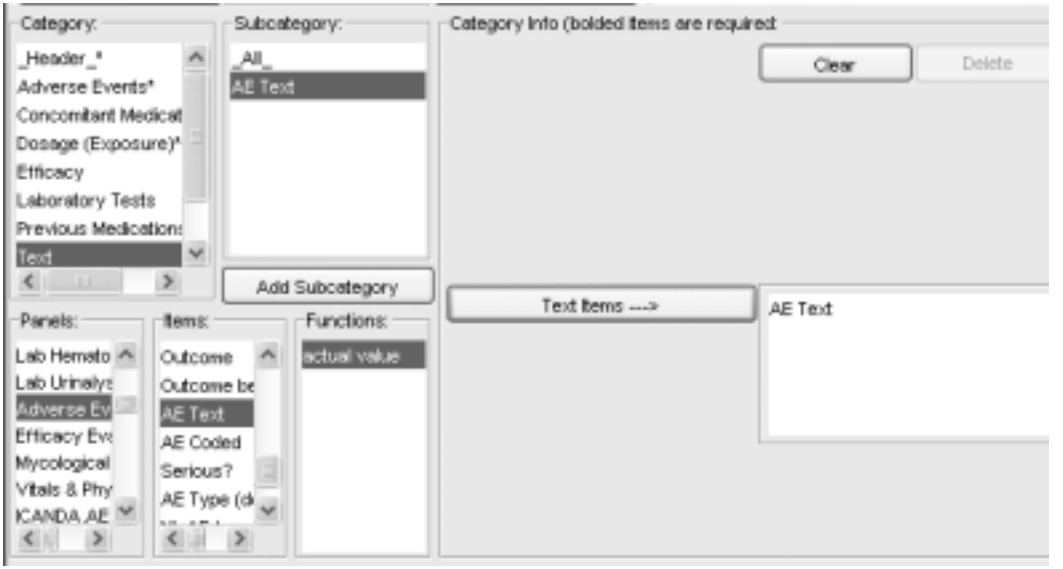
The text category is a text type which initially contains no subcategories. The SuperUser defines subcategories and assigns specific database items / fields from the panels / tables to either categorize itself or a subcategory. The items are displayed as non-time aligned data.

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**.



4. Select the Panel(s) and item(s).
5. Click the **Text Items** button to add.



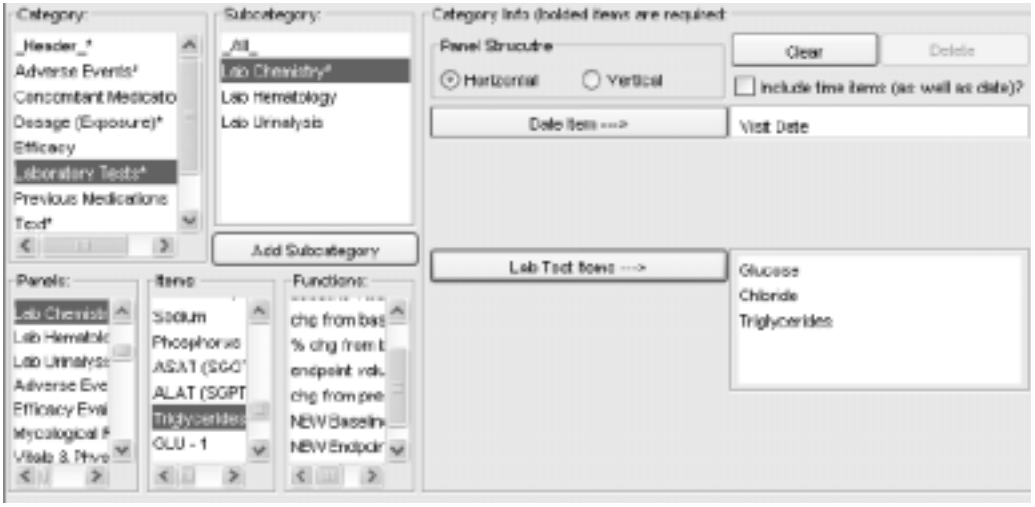
6. The Text subcategory is added. Click the **Delete** button to remove.

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:

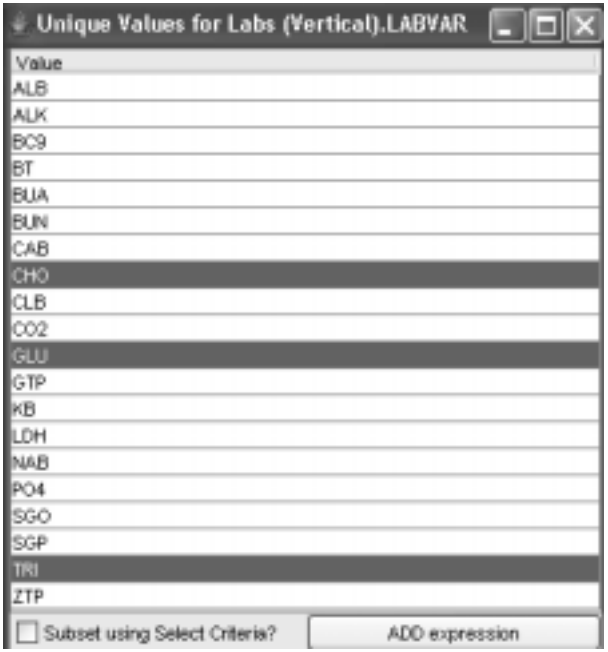
- Date Item - the field containing the date of the event.
- Item(s) - the fields which the user may select for graphing.



Vertical panel structure requires:

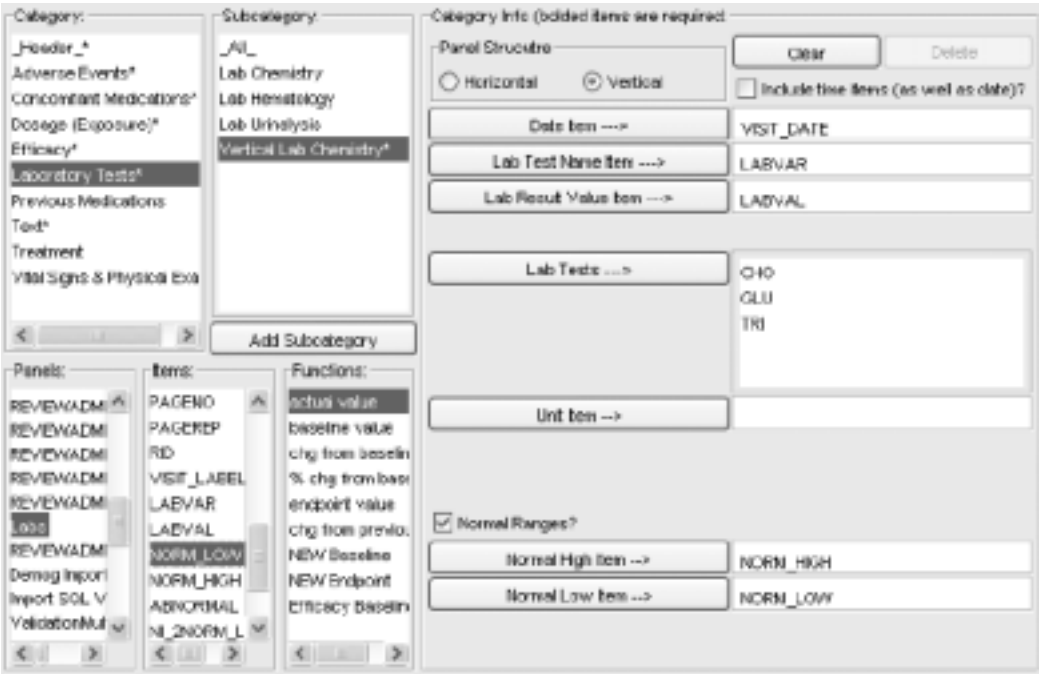
- Date Item - the field containing the date of the event.
- Lab Test Name Item - the field containing the lab test name.
- Lab Result Name Item - the field containing the lab test result or value.
- Lab Test(s) - the list of lab tests which the user may select for graphing. The overall list of lab test 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.



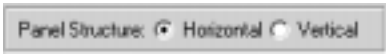
- Unit Item - are the units associated with the lab tests.
- Normal Ranges - are the normal ranges for the lab tests. Click this box to enter the Normal High Item and Normal Low Item.

  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.



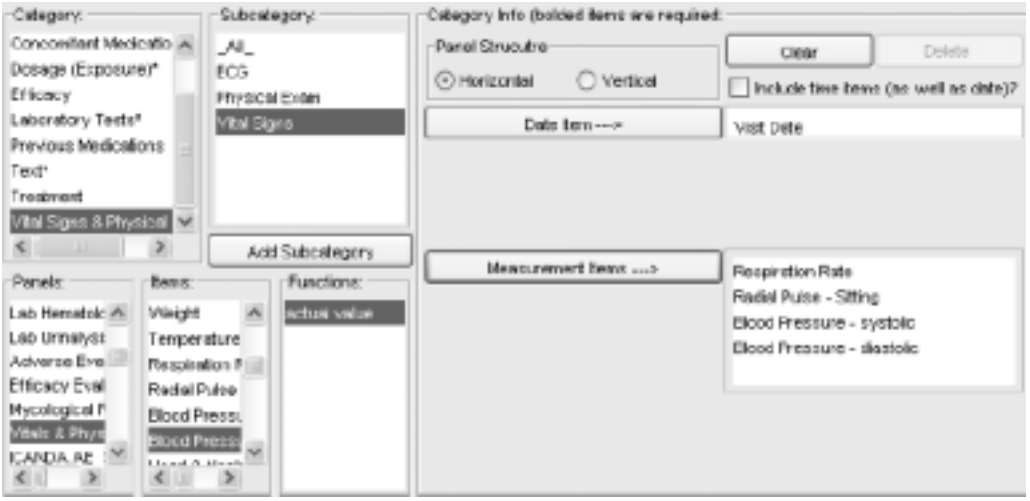
Time Point Type category

Time point type categories also includes Vitals and Efficacy panels and may be either horizontal or vertical.



Horizontal panel structure requires:

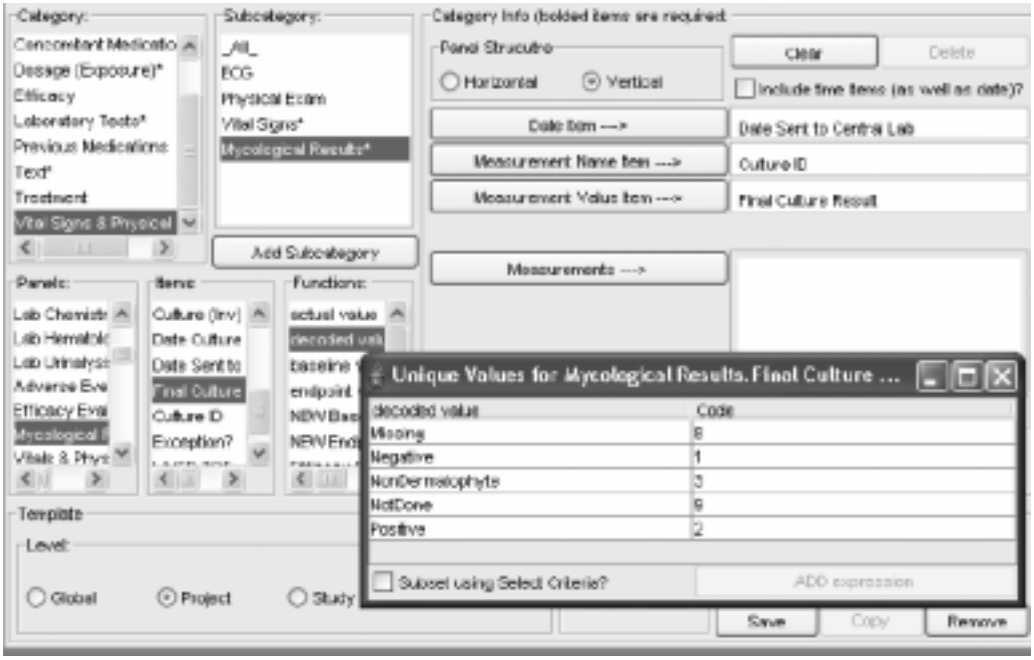
- Date Item - the field containing the date of the event.
- Item(s) - the fields which the user may select for graphing.



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.

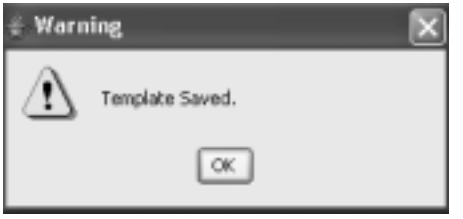
In the example, the Mycological Results Category was added as a subcategory and panel structure selected for vertical format.



Save template

When you have added all categories and subcategories to the template, click **Save**.

A message window displays the template has been saved. Click OK to close the message window.



You can click the **Copy** button to copy category details from a saved template to an undefined template level to save time entering similar categories. The **Remove** button becomes available after a template is saved and is used to remove a saved template if needed.

Close the Graphic Patient Profile Template window.

Edit graphic template

The available template levels are highlighted in the Patient Profiles Browser window in the Template Level list. If no template exists for a level then the template option is shaded as disabled.

The **Edit Graphic Template** button becomes available if you need to **edit** the existing template. Also, use the **Edit Graphic Template** button to **add** a new template not previously defined.

Define Graphic Profile

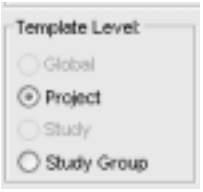
Select graphic profile

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 **Graphical Profile** as the type.

Select defined template

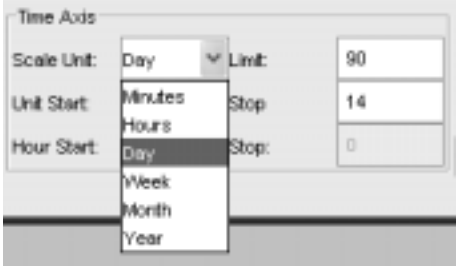
3. Select from the available template levels to define your graphic patient profile. Shaded template levels haven't been defined and saved yet.



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**.

4. 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.



Simply enter the Start and Stop value for the selected time scale.

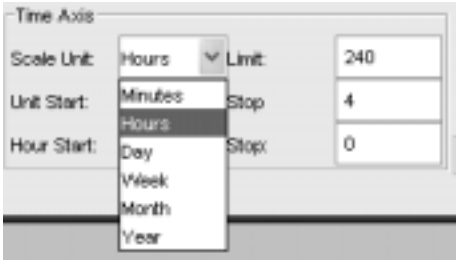
Change Limit value

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.

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.



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

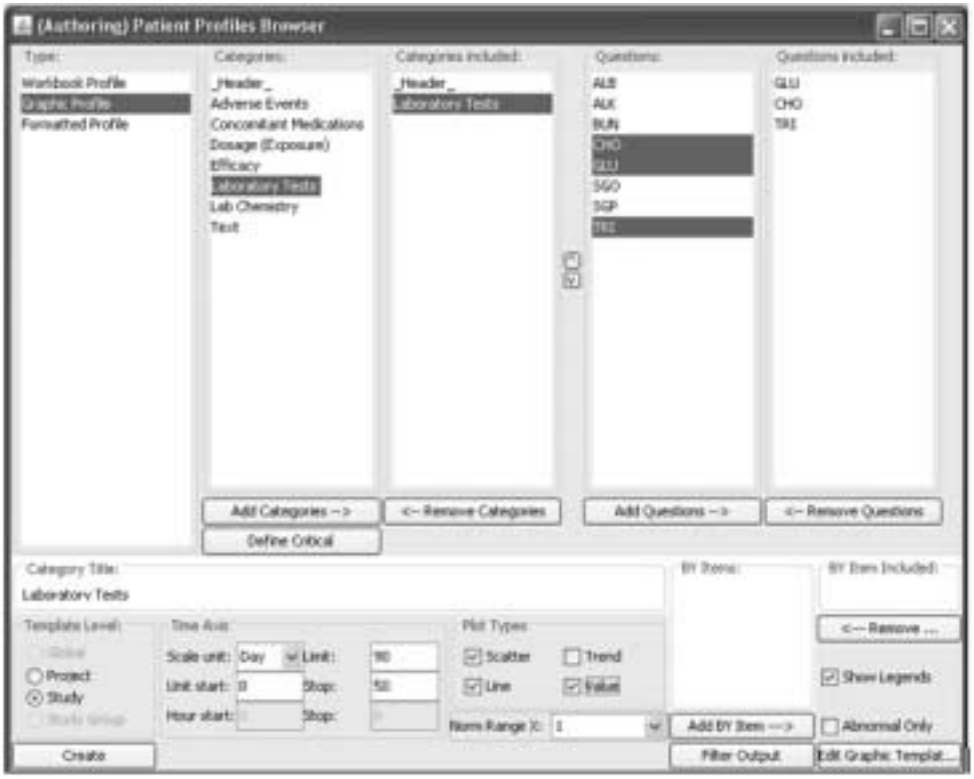
After you select an available template from the template levels you are able to select those categories to be included in the graphic patient profile. Optional header information if available may have been defined for the selected template.

5. 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.

6. Reorder the **Categories Included** with the **up** and **down** arrows.

7. Select each **included category** and view the list of **Items** and **By Items** (where applicable) for the graph plots.



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.

8. 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.
9. Use drag and drop to reorder how the added items are displayed in the **Included Items** list box.

10. 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.

11. You can change the **Category Title** of any included category (except for the header which will always display the PatientID).

12. The **Sort Option** is dependent upon the selected category is only available if the data item selected is alpha, for example adverse events or concomitant medications. The data items are associated with dates so you have the option to sort by alpha or date in the graphic profile.

13. Add or change the default **Plot Types**. The available plot types are dependent on the category type defined.

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.

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 if dropped from the graphic display.

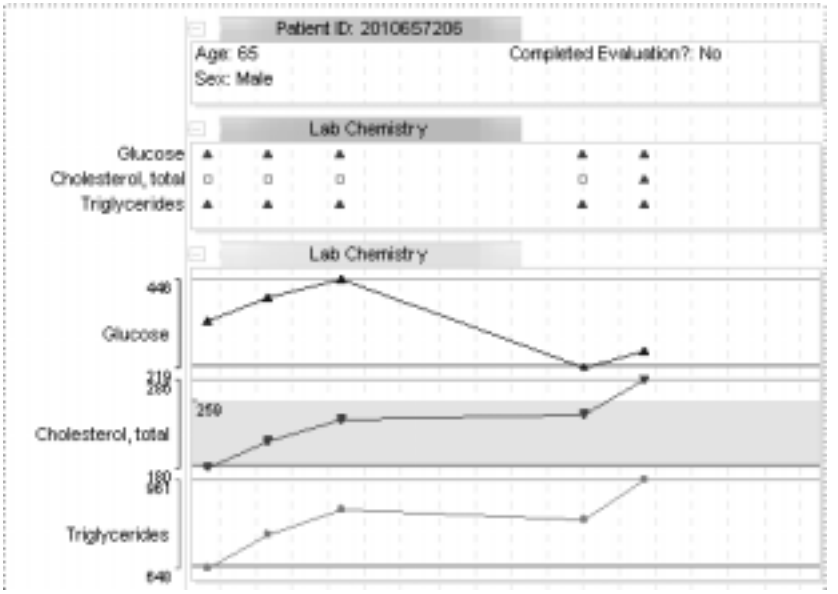
A normal range 'multiplier' option for labs allows you to specify if you only want to 'flag' or mark as low or high, those labs that are outside N times the normal range values. It is implemented as normal high times N versus normal low divided by N.

14. You can only select 1, 2 or 3 for the normal range multipliers with the default set to 1.

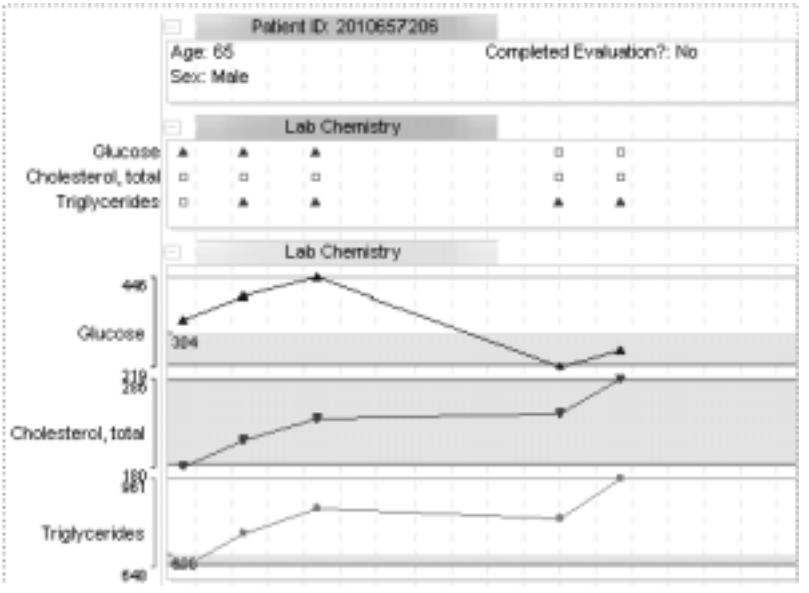
For comparison, first view out of range labs for Normal Range multiplier set to 1 and then change the normal range multiplier to 2. Select Plot Type of "Scatter" for labs and notice some points that were out of range previously changed to in-range from the up / down triangle to box plot point. If you 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 black for normal.

Normal Range set to 1. The scatter plot shows triangles 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.



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.



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:

15. Click **Create**.

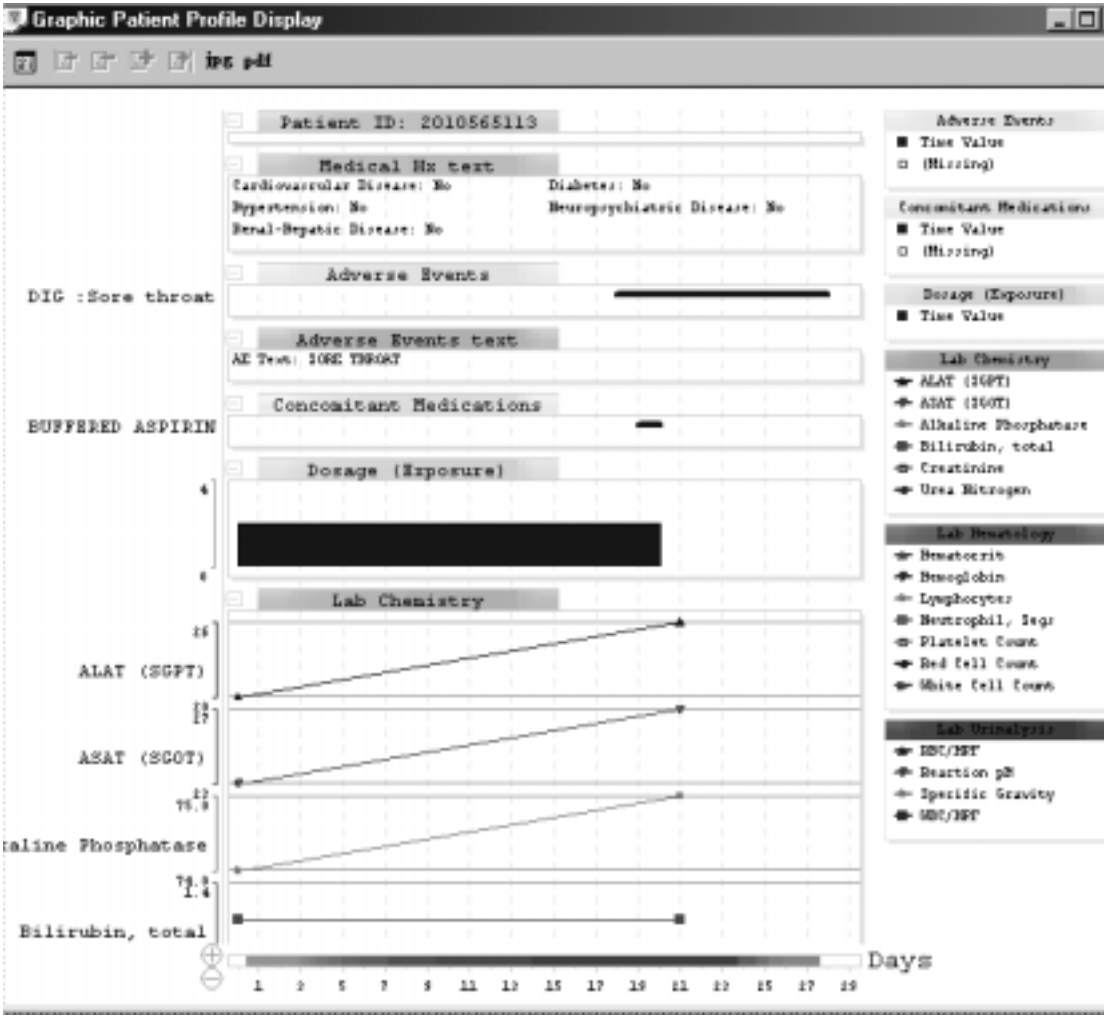
    The Patient Profile Browser window opens to display the list of patients who meet the patient selection criteria or view a list for all patients if no selection criteria was defined. The study and PID (patient id) are listed for identification in the patient list.

16. 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.

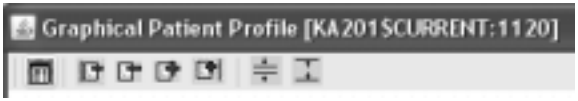
    Red arrows display in the right margin to identify additional graph display if you scroll up or down with the arrow keys.

17. To save to the object specification for your Graphic Patient Profile, see *See Chapter 11: Saving Objects, plus Alerts Browser.*


Graphic Patient Profile Display
jpg pdf
Patient ID: 2010565113
Medical Hx text
Cardiovascular Disease: No
Diabetes: No
Hypertension: No
Neuropsychiatric Disease: No
Renal-Hepatic Disease: No
Adverse Events
DIC :Sore throat
Adverse Events text
AE Term: SORE THROAT
Concomitant Medications
BUFFERED ASPIRIN
Dosage (Exposure)
Lab Chemistry
ALAT (SGPT)
ASAT (SCOT)
aline Phosphatase
Bilirubin, total
Days
Adverse Events
Time Value
(Missing)
Concomitant Medications
Time Value
(Missing)
Dosage (Exposure)
Time Value
Lab Chemistry
ALAT (SGPT)
ASAT (SGOT)
Alkaline Phosphatase
Bilirubin, total
Creatinine
Urea Nitrogen
Lab Hematology
Hematocrit
Hemoglobin
Lymphocytes
Neutrophil, Segs
Platelet Count
Red Cell Count
White Cell Count
Lab Urinalysis
RBC/HPF
Reaction pH
Specific Gravity
WBC/HPF

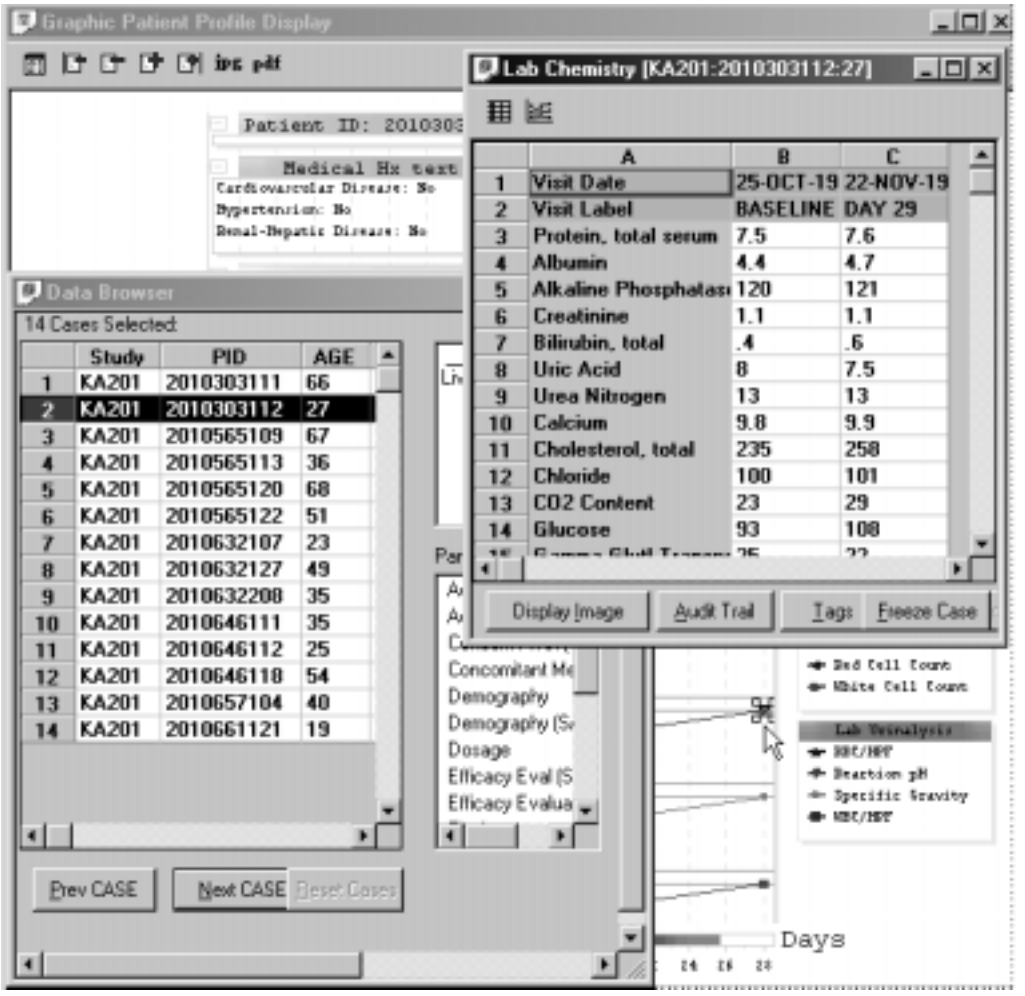
Once the graphic patient profile displays, the following functions are available to assist you in further examining each graphic data display.

- Use the keyboard up and down arrows to scroll through the multiple graphic plots for the patient.
- Use the keyboard left and right arrows to scroll x-axis on the graph across the time scale, or click-and-drag the scroll bar.
- The first icon represents the settings option. *(See section: Graph Settings for Select Settings)*
- In the Toolbar use the icons with the appearance of little pages with + and - signs to move between patients. The first button always takes you to the first patient. The second button moves you one patient back. The third button moves you one patient forward. The last button always takes you to the last patient.



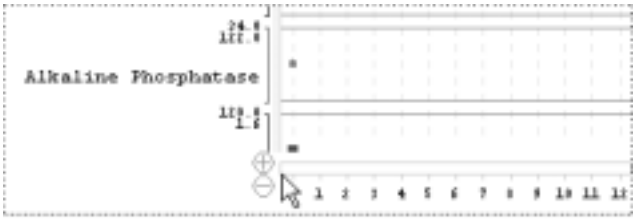
- The last buttons decrease or increase row size by compressing or expanding the rows.

- Select a data point on a graph display and left mouse click to select and invoke drill down.

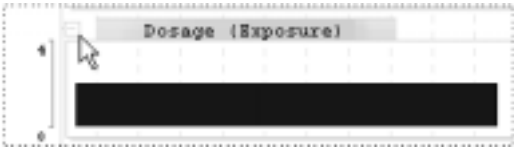


- To select multiple points, click and hold the left mouse button, drag the mouse to create a “box” and let go of the left mouse button. This will invoke a drill down for all the points in the box.
- Click the left mouse button to deselect all previously selected points.

- Zoom in and zoom out with the '+' and '-' icons on the left of side of the scroll bar.



- On the Control bar (left side of categories); use the left mouse to minimize and maximize the category.



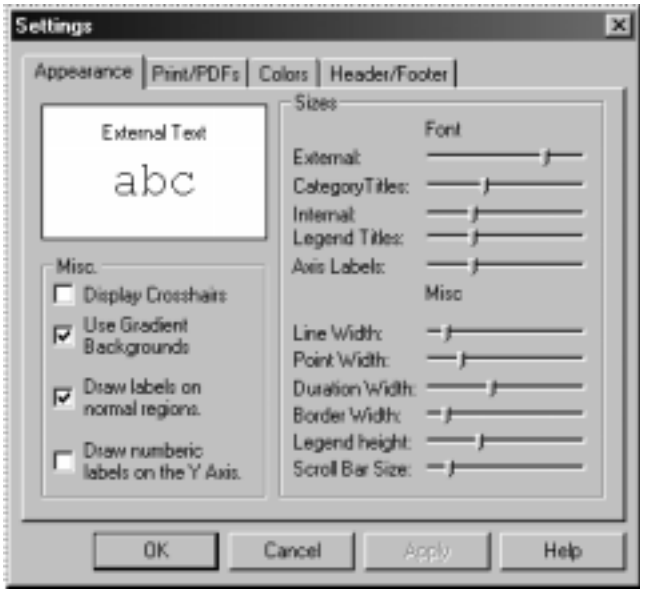
Graph settings

Select settings

On the Toolbar, click the first button to bring up the 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'.

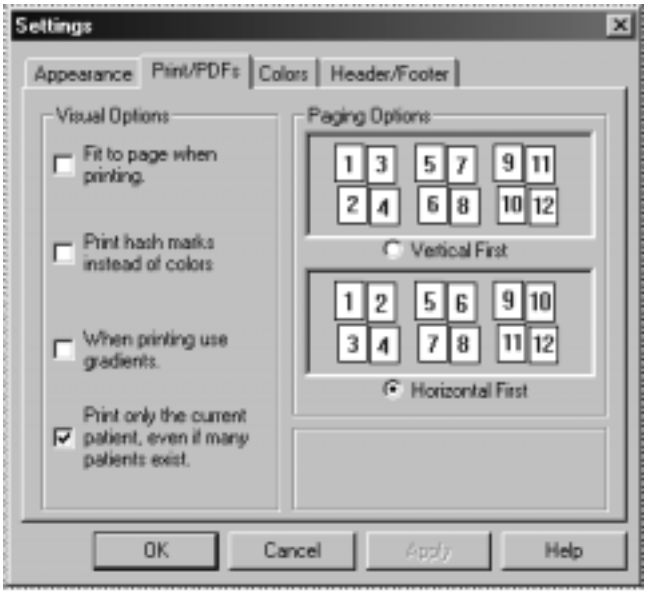


The size of the text “abc” will be the actual size of the text on the graph. The same occurs for the 'Misc.' size settings, except the white box will contain a line of the appropriate width.

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.



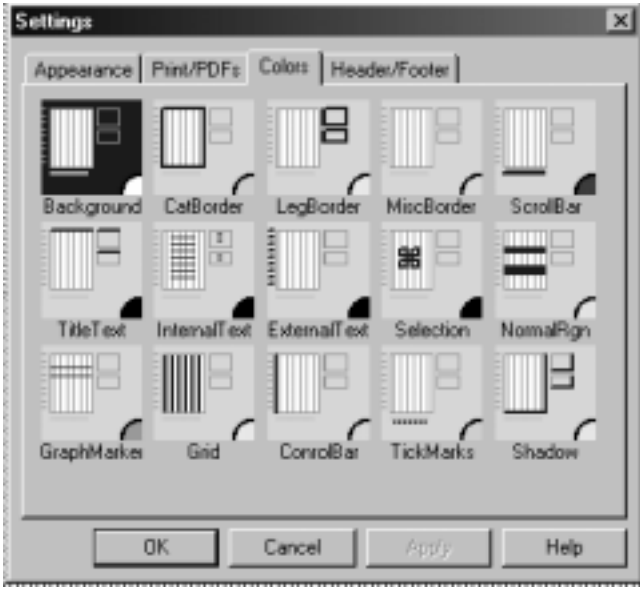
The most important of these options is the first, 'Fit to page when printing'. This option has precedence over all other printing options. If it is selected, then a page will be printed on one page regardless of the view range or the height per row. The default for “fitting” is true. Ideally, it is easiest 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.

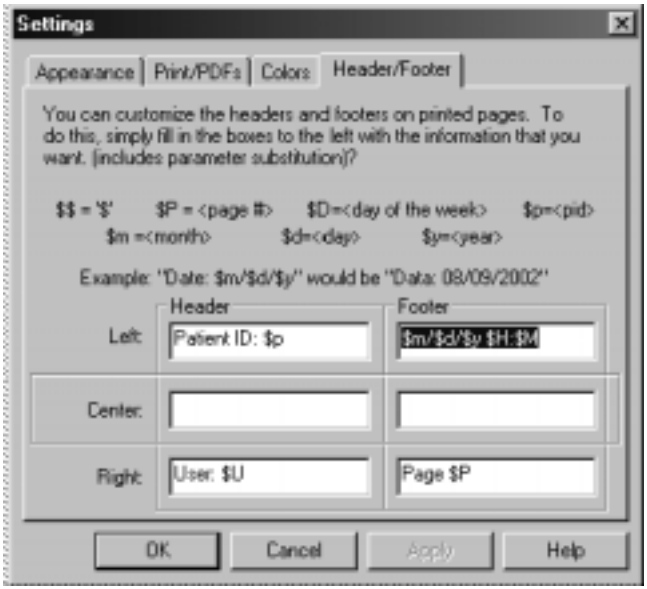


The color of the background is not blue however. The actual color of the background is white, which is shown by the little circle in the bottom right corner. This method of conveying the color clearly distinguishes each part of the graph while at the same time gives you a sense of color. So to change 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.

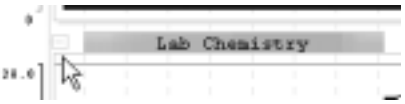
Headers and footers

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.

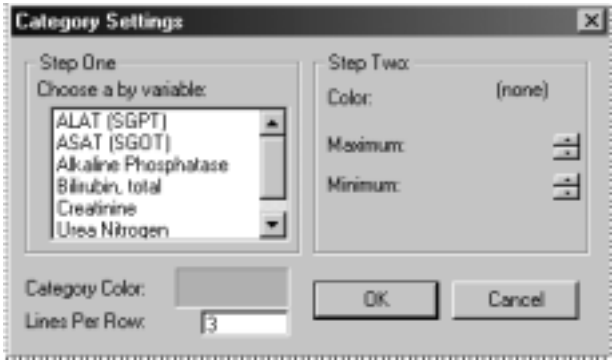


Category settings

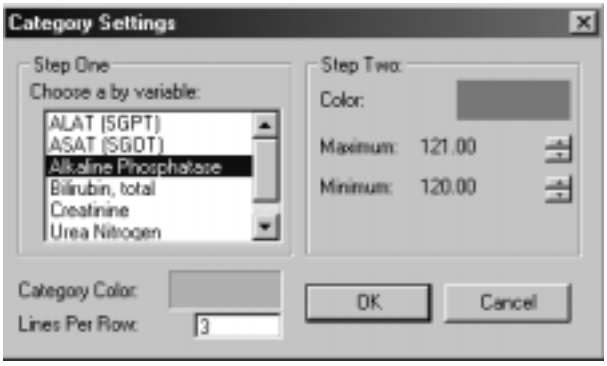
Each category has its own category settings dialog box. In the Graphic Patient Profile window use the right mouse button on the control bar next to the category title.



Each graph's dialog has unique characteristics. Every category contains a category color box, on the bottom left of the dialog box.



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.



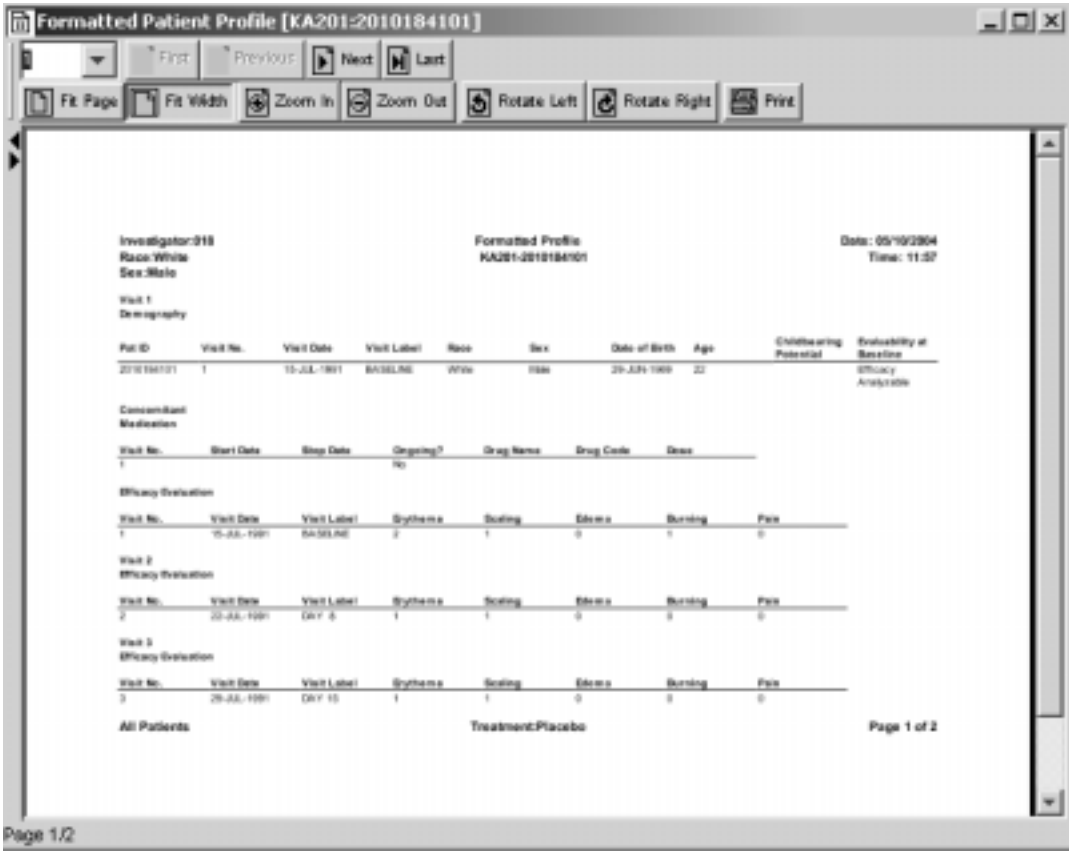
You can change the color of the particular BY variable by clicking on the color with the left mouse button. You also have the ability to modify the maximum and minimum. There are no limits on the minimum and maximum except that the min must be less than the max. The range on 'lines per row' is 1 to 10.

Formatted Profiles

Show formatted patient profile

JReview users with access to the Patient Profiles can execute Formatted Patient Profiles defined in IReview. The saved formatted 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 or all available patients if no selection criteria was defined.

Select a patient and click Show Patient Profile to display a formatted profile similar to the workbook type. Use the tool bar buttons to move between multiple pages or to zoom or print the output.



Printing and Exporting Patient Profiles

Print Preview

To display a print preview of a patient profile in the Patient Profile output window:

1. Click on the title bar of the Patient Profile window to make it the active window.
2. Click , or from the **File** menu, select **Print Preview**.

   JReview displays a screen shot of the selected active screen. The Print Preview function is applicable to all browsers with output results.

   Formatted patient profiles display in print preview mode.

   Print Preview for a graphic patient profile displays a detailed cover page before the graphic profile pages. The following information displays along with the Filter Output definition if applicable.

3. Click either **Print** or **Close.**

Print patient profile

To print the patient profile of the selected patient:

1. Click on the title bar of the Patient Profile window to make it the active window.
2. Click , or from the **File** menu, select **Print**.

   You can access the printer icon from the tool bar within the formatted patient profile output window to display the Print dialog box.

3. Click **OK**.

Note: When you select Print Preview or Print for the selected Patient Profile, a signature line with the date is printed at the bottom of the worksheet.

Export patient profile

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.

Note: Only formatted object types can be exported to PDF files.

1. To select an object to export, it must be the active window. Select the **File** menu and click **Export**.

   JReview displays the **Save File** 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.

Graphic patient profiles require to print / print preview the GPP in the Patient Profile output window.

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 216
- Selection set 216
- Quick execute 216

Report types and features 217
- Type of report 217

Defining Report Specifications 218
- Selecting a panel, item, and function 218
- Adding items 219
- User-defined functions 219
- Access to SAS datasets 219
- Column autosizing 220
- Edit item sort order 220
- Change column order 221
- Changing the report specifications 221
- Edit column heading 222
- Defining a report title 222
- Show Details 222
- Create report 223

Detail Data Listing features 224
- Defining row results 224
- Reset subtotal in row results 226
- Highlighting data check ranges 227
- Suppress duplicate rows 229

Summary Listing features 230
- Group functions 230
- Count distinct 233
- Count item value 234
- New item with aggregate functions 234

Object toolbar 235
Snapshot output 235
Who icon 235
Output filter icon 236
Multiple population mode 237
Multiple output for required selection criteria 240
Output filter 243
Subset data 243
Creating report output filter 244
Comparing items 245
Adding expressions 245
View output filter 248
Define Runtime filters 249
Runtime parameter 249
Create parameter 250
Enter runtime parameter 255
Reset filter parameters 257
Patient Visit Data Report 258
Select panel visit data report 258
Define patient visit data report 259
Click Options and Patient Info. The Report Options and Patient Information window opens. 259
Add Patient Info Items 261
Define Date Merge Settings 262
Create Patient Visit Data Report 263
Lookup on existing date 264
Apply output filter 266
Add vertical lab 268
Formatted reports 272
Select formatted listing type 272
Apply Page Header and Footer 273
Enter a Group Header 275
Format Column Headings 277
Format Columns 280
Sort Order 283

Preview / Page Setup 284
Create formatted report 287

Conditional Data Highlighting 288
Define data highlighting 288

Highlighting patients 295
Single patient mode 295
Multiple-patient mode 297

Printing and Exporting Results 299
Printing the result 299
Exporting the result 300

Object Storage 301

Exploring data 301
Changing the patient selection criteria 301
Patient Identification 301

Execute report

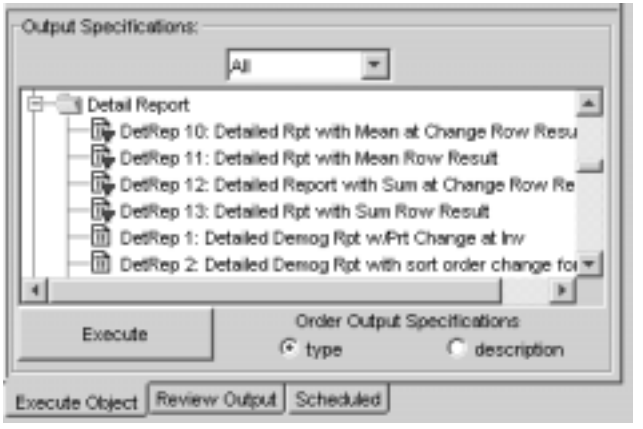
Selection set

In JReview, you can select a previously saved Patient Subset 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. Click on the object description and click **Execute** OR double click on the object 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.

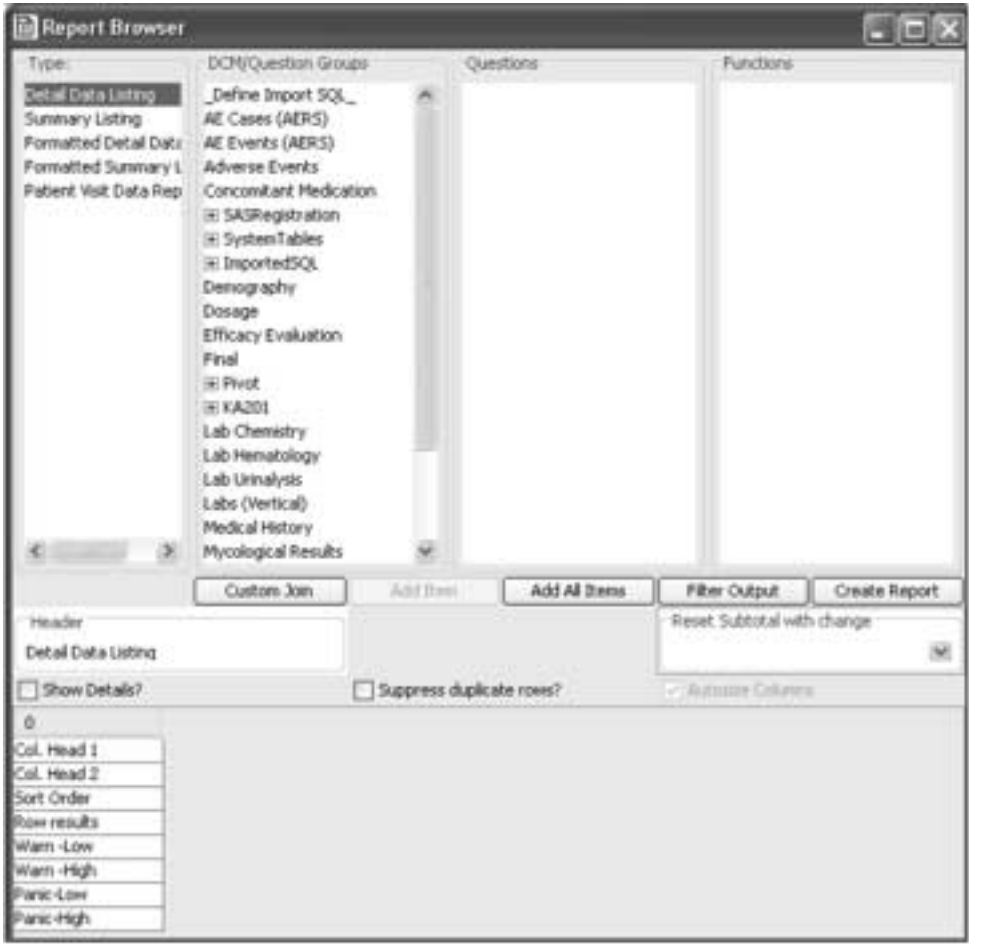
- Detail Data Listing generate one report line for each patient observation.
- Summary Listing generate one report line containing summary information such as summary category, counts, mean, and so on.
- Formatted Detail Data Listing and Formatted Summary Listing provide the same basic functions as Detail 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

Selecting a panel, item, and function

To open the Report Browser, from the **Browse** menu, select **Reports** or click on the toolbar. You define the contents of a report using the same method that you 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 IReview browsers. IReview provides predefined functions where users can select from a function value list. IReview 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 *Review Users Guide 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 in IReview 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.

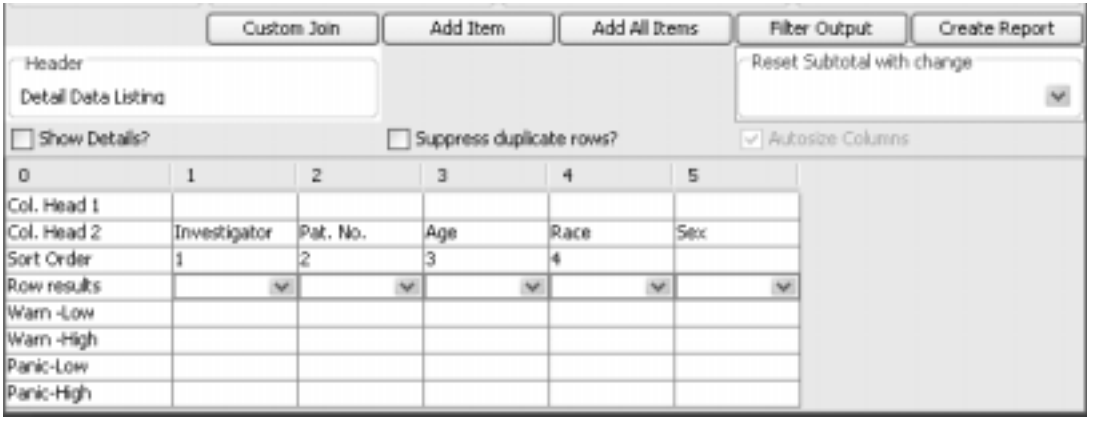
Column autosizing

JReview automatically autosizes the report column widths as shown by **AutoSize Columns on**.

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.



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.

Note: Formatted reports use a different definition for how items are sorted

Change column order

Click on the column you want to move and drag the column to the desired location.

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. To edit a column heading:

1. Click on the text.
2. Edit the text.
3. Press **Enter**.

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.

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

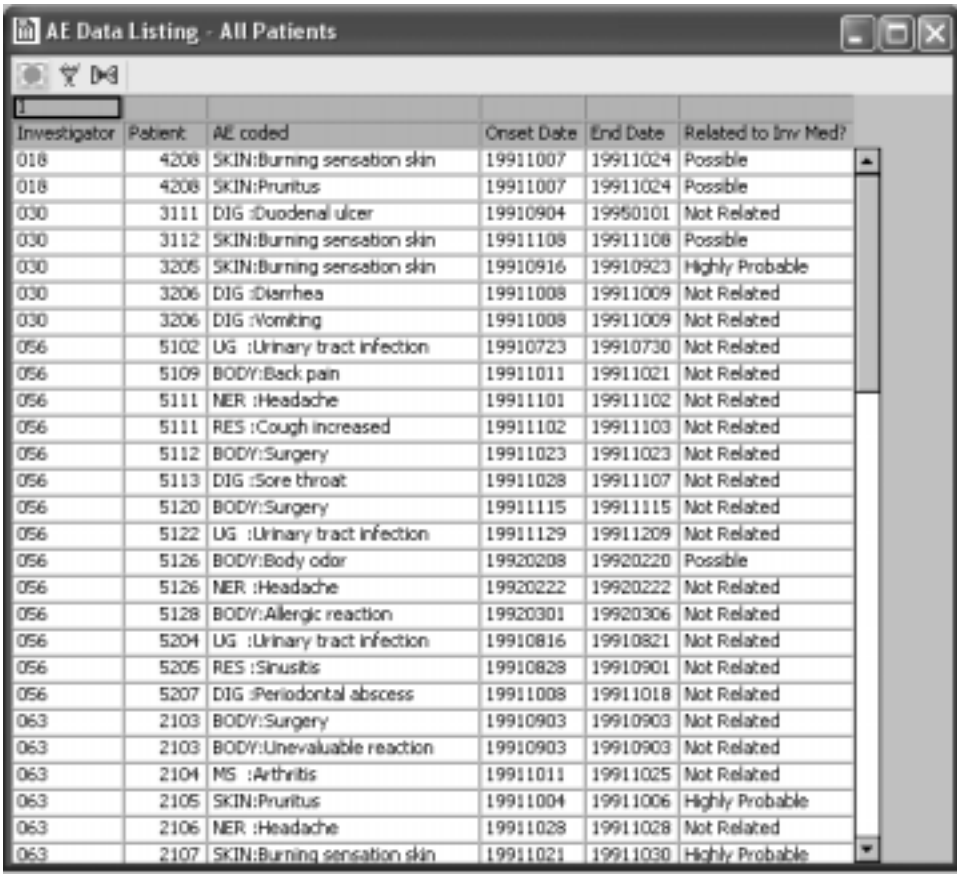
The 'Show Details?' feature can be used after you have added items to your report specification.

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.

Show Details is helpful after you define and save a report definition and look back to view it's source contents.

*Note: The **Items** and **Panels** names are displayed from the Data Dictionary and not the Items and Panels Description.*

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.



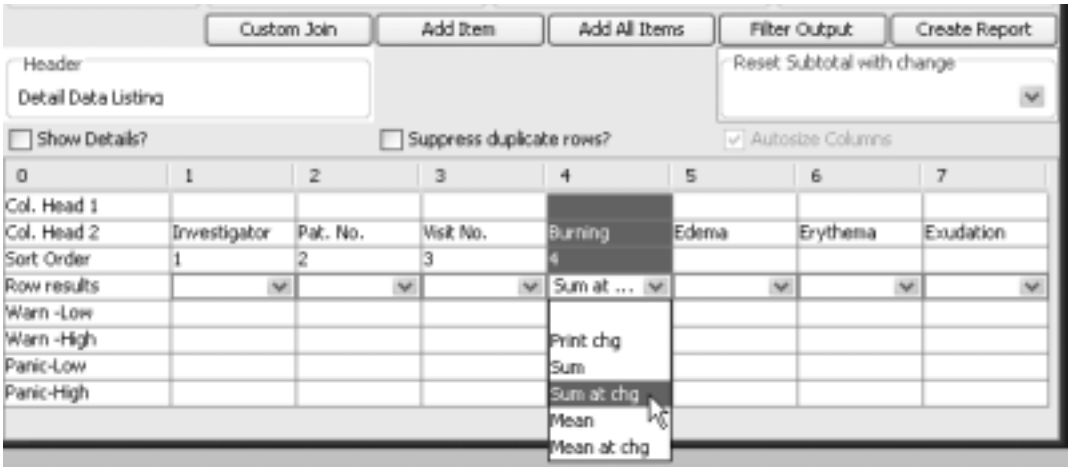
AE Data Listing - All Patients

Investigator	Patient	AE coded	Onset Date	End Date	Related to Inv Med?
018	4208	SKIN:Burning sensation skin	19911007	19911024	Possible
018	4208	SKIN:Pruritus	19911007	19911024	Possible
030	3111	DIG :Duodenal ulcer	19910904	19950101	Not Related
030	3112	SKIN:Burning sensation skin	19911108	19911108	Possible
030	3205	SKIN:Burning sensation skin	19910916	19910923	Highly Probable
030	3206	DIG :Diarrhea	19911008	19911009	Not Related
030	3206	DIG :Vomiting	19911008	19911009	Not Related
056	5102	UG :Urinary tract infection	19910723	19910730	Not Related
056	5109	BODY:Back pain	19911011	19911021	Not Related
056	5111	NER :Headache	19911101	19911102	Not Related
056	5111	RES :Cough increased	19911102	19911103	Not Related
056	5112	BODY:Surgery	19911023	19911023	Not Related
056	5113	DIG :Sore throat	19911028	19911107	Not Related
056	5120	BODY:Surgery	19911115	19911115	Not Related
056	5122	UG :Urinary tract infection	19911129	19911209	Not Related
056	5126	BODY:Body odor	19920208	19920220	Possible
056	5126	NER :Headache	19920222	19920222	Not Related
056	5128	BODY:Allergic reaction	19920301	19920306	Not Related
056	5204	UG :Urinary tract infection	19910816	19910821	Not Related
056	5205	RES :Sinusitis	19910828	19910901	Not Related
056	5207	DIG :Periodontal abscess	19911008	19911018	Not Related
063	2103	BODY:Surgery	19910903	19910903	Not Related
063	2103	BODY:Unevaluable reaction	19910903	19910903	Not Related
063	2104	MS :Arthritis	19911011	19911025	Not Related
063	2105	SKIN:Pruritus	19911004	19911006	Highly Probable
063	2106	NER :Headache	19911028	19911028	Not Related
063	2107	SKIN:Burning sensation skin	19911021	19911030	Highly Probable

Detail Data Listing features

Defining row results

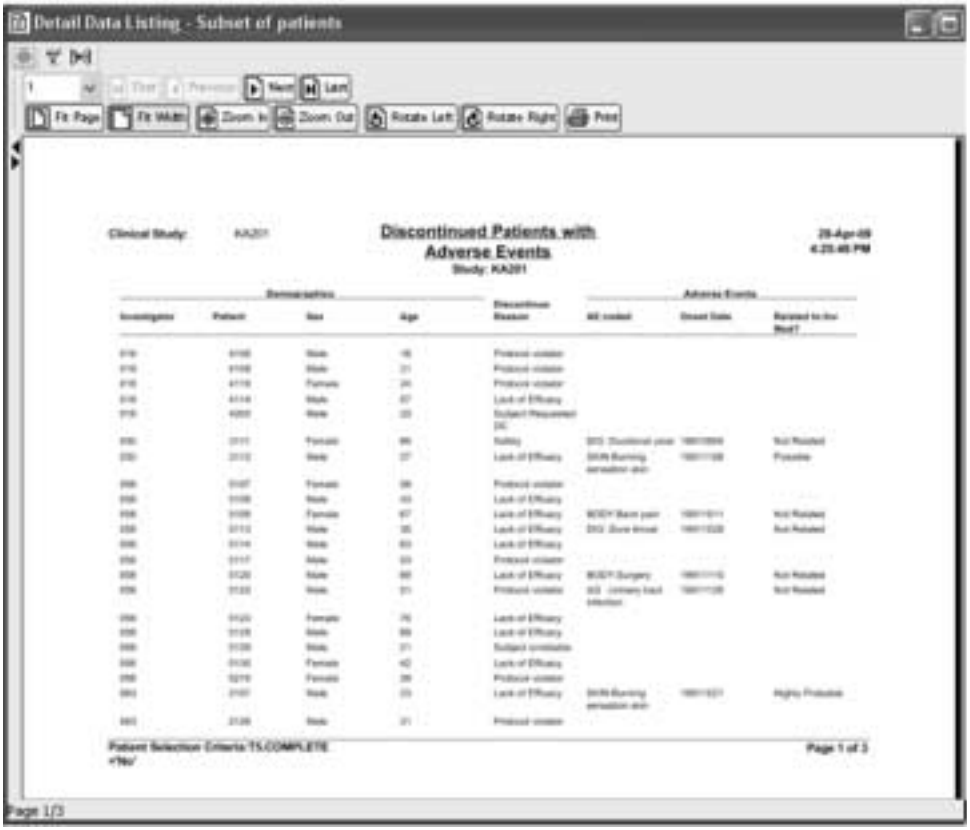
A numeric date type provides clinically pertinent options, such as mean or sum. Numeric row results generate report summations (for example, Selecting Sum or Mean), or break point summations that the report will generate in summation or at break points for example, change in PID, Sum at Change and Mean at Change. The Row Results drop down list below is for non-formatted report types.



Note: Mathematical row results options are different between non-formatted and formatted report types.

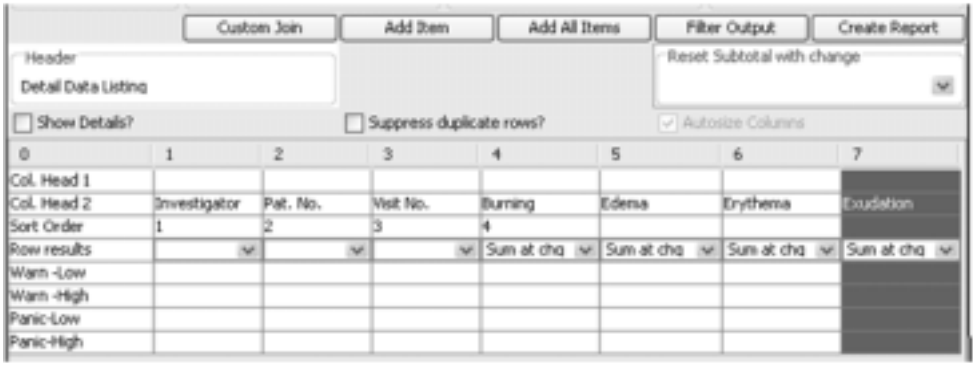
The formatted reports have more mathematical options. In addition, formatted reports support Sum at Change, Mean at Change, Mean at Change and Mean, and Sum at Change and Sum.

The Formatted Report options also apply formats to modify the headers, footer, page breaks, column headings and more.



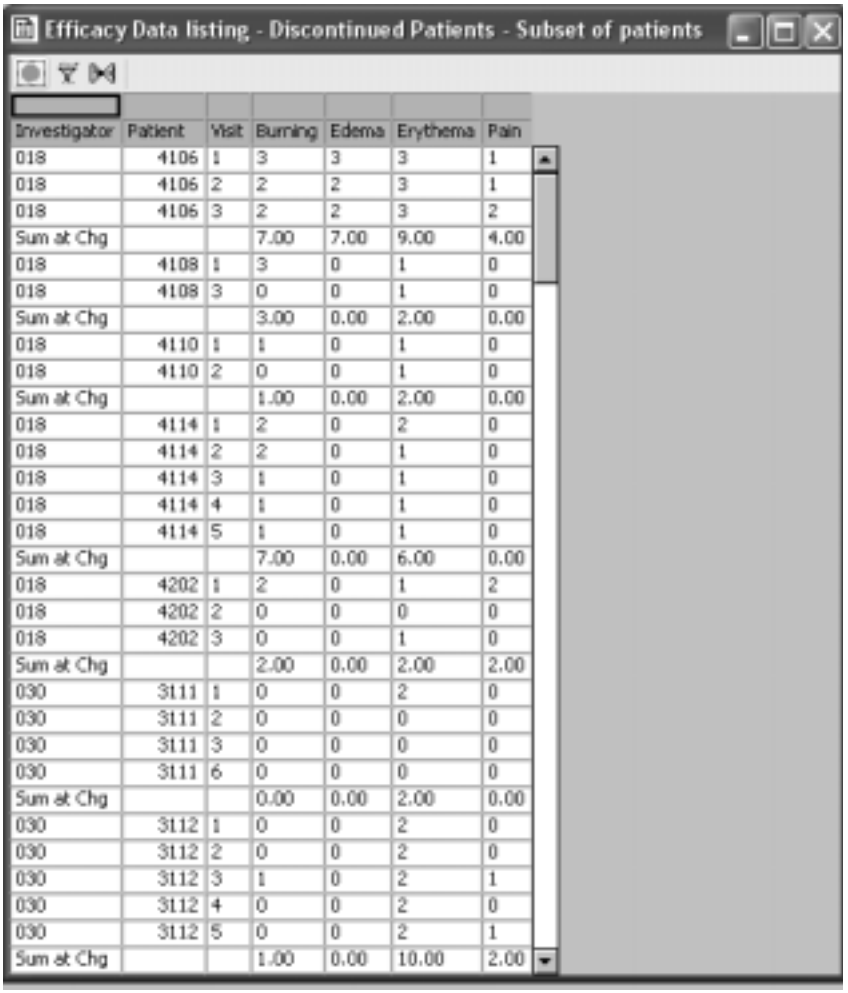
Reset subtotal in row results

The mathematical row results options are available in the Detail Data Listing and Summary Listing.



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.

The mathematical break point is applied to the Pat No. with 'Sum at change' row result selected for Efficacy Evaluation items.



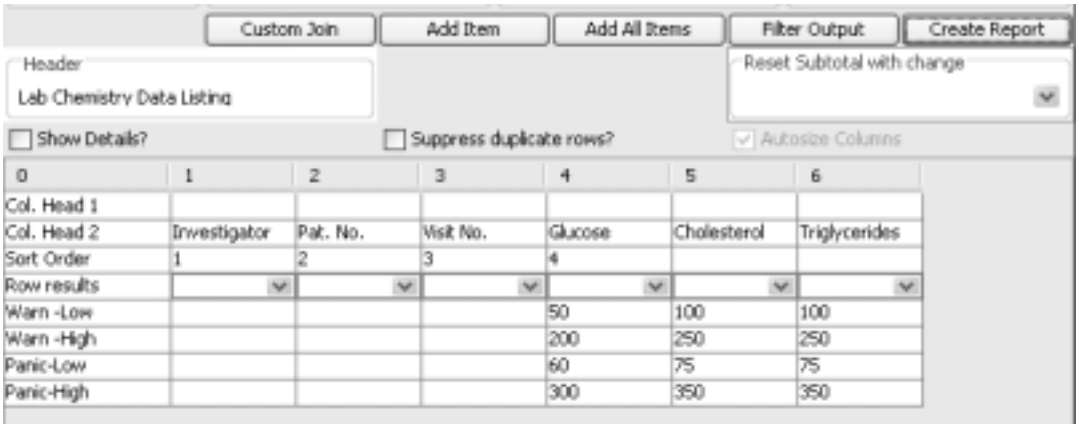
Efficacy Data listing - Discontinued Patients - Subset of patients

Investigator	Patient	Visit	Burning	Edema	Erythema	Pain
018	4106	1	3	3	3	1
018	4106	2	2	2	3	1
018	4106	3	2	2	3	2
Sum at Chg			7.00	7.00	9.00	4.00
018	4108	1	3	0	1	0
018	4108	3	0	0	1	0
Sum at Chg			3.00	0.00	2.00	0.00
018	4110	1	1	0	1	0
018	4110	2	0	0	1	0
Sum at Chg			1.00	0.00	2.00	0.00
018	4114	1	2	0	2	0
018	4114	2	2	0	1	0
018	4114	3	1	0	1	0
018	4114	4	1	0	1	0
018	4114	5	1	0	1	0
Sum at Chg			7.00	0.00	6.00	0.00
018	4202	1	2	0	1	2
018	4202	2	0	0	0	0
018	4202	3	0	0	1	0
Sum at Chg			2.00	0.00	2.00	2.00
030	3111	1	0	0	2	0
030	3111	2	0	0	0	0
030	3111	3	0	0	0	0
030	3111	6	0	0	0	0
Sum at Chg			0.00	0.00	2.00	0.00
030	3112	1	0	0	2	0
030	3112	2	0	0	2	0
030	3112	3	1	0	2	1
030	3112	4	0	0	2	0
030	3112	5	0	0	2	1
Sum at Chg			1.00	0.00	10.00	2.00

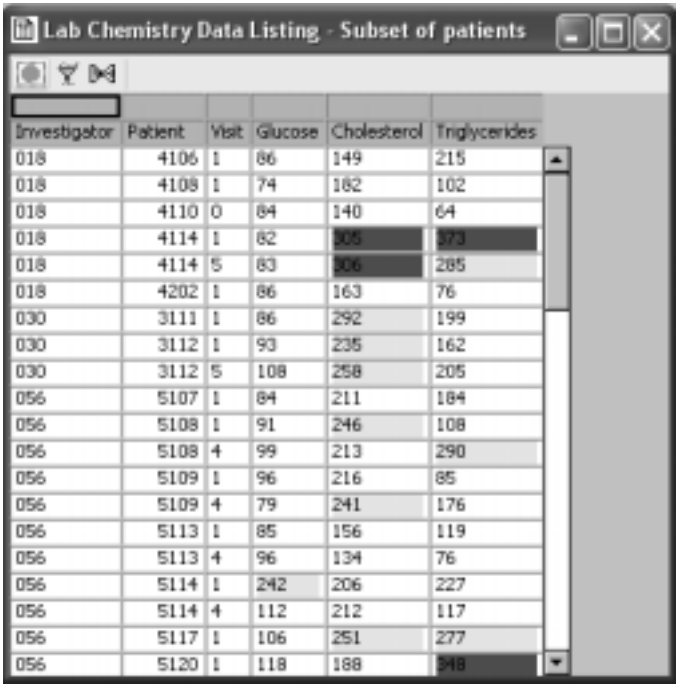
Highlighting data check ranges

When you define a report, for example, 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. Variable values outside the ranges you define will show up in yellow and red. 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".



0	1	2	3	4	5	6
Col. Head 1						
Col. Head 2	Investigator	Pat. No.	Visit No.	Glucose	Cholesterol	Triglycerides
Sort Order	1	2	3	4		
Row results						
Warn -Low				50	100	100
Warn -High				200	250	250
Panic-Low				60	75	75
Panic-High				300	350	350



Investigator	Patient	Visit	Glucose	Cholesterol	Triglycerides
018	4106	1	86	149	215
018	4108	1	74	182	102
018	4110	0	84	140	64
018	4114	1	82	305	373
018	4114	5	83	306	285
018	4202	1	86	163	76
030	3111	1	86	292	199
030	3112	1	93	235	162
030	3112	5	108	258	205
056	5107	1	84	211	184
056	5108	1	91	246	108
056	5108	4	99	213	290
056	5109	1	96	216	85
056	5109	4	79	241	176
056	5113	1	85	156	119
056	5113	4	96	134	76
056	5114	1	242	206	227
056	5114	4	112	212	117
056	5117	1	106	251	277
056	5120	1	118	188	348

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.

The examples show the difference between this report when the suppress duplicate rows is turned off versus on. For example, see PatNo 2125.

(SnapShot) AE Listing - Suppress ...

Investigator	Pat. No.	AE Coded
063	2103	BODY:Unevaluable reaction
063	2103	BODY:Surgery
063	2104	MS :Arthritis
063	2105	SKIN:Pruritus
063	2106	NER :Headache
063	2107	SKIN:Burning sensation skin
063	2108	DIG :Tooth disorder
063	2108	DIG :Tooth disorder
063	2113	SKIN:Burning sensation skin
063	2123	NER :Headache
063	2125	RES :Sinusitis
063	2125	RES :Sinusitis
063	2125	RES :Sinusitis
063	2127	SKIN:Burning sensation skin
063	2201	NER :Headache
063	2201	NER :Headache
063	2204	NER :Headache
063	2204	RES :Upper respiratory infection
063	2207	RES :Upper respiratory infection
063	2207	RES :Sinusitis
063	2208	MAN :Peripheral edema
063	2208	SKIN:Burning sensation skin
063	2209	SKIN:Burning sensation skin

AE Listing - Suppress Duplicate ON

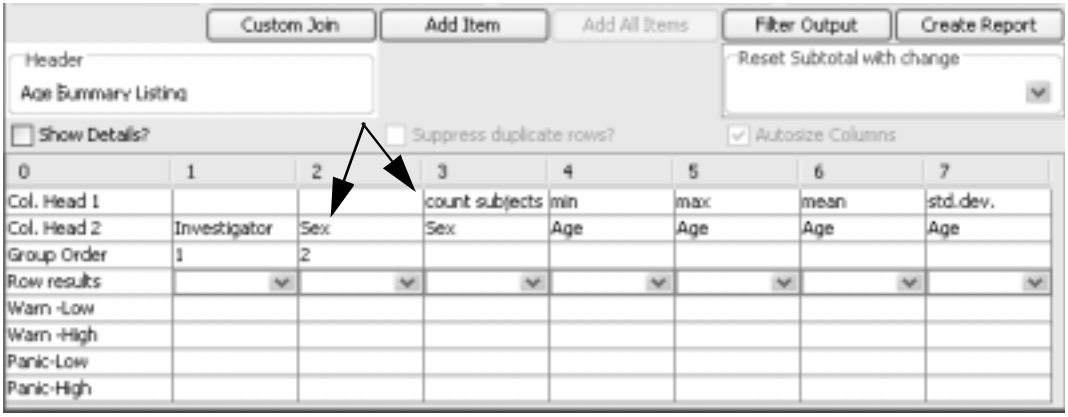
Investigator	Pat. No.	AE Coded
063	2103	BODY:Unevaluable reaction
063	2103	BODY:Surgery
063	2104	MS :Arthritis
063	2105	SKIN:Pruritus
063	2106	NER :Headache
063	2107	SKIN:Burning sensation skin
063	2108	DIG :Tooth disorder
063	2113	SKIN:Burning sensation skin
063	2123	NER :Headache
063	2125	RES :Sinusitis
063	2127	SKIN:Burning sensation skin
063	2201	NER :Headache
063	2204	NER :Headache
063	2204	RES :Upper respiratory infection
063	2207	RES :Upper respiratory infection
063	2207	RES :Sinusitis
063	2208	MAN :Peripheral edema
063	2208	SKIN:Burning sensation skin
063	2209	SKIN:Burning sensation skin

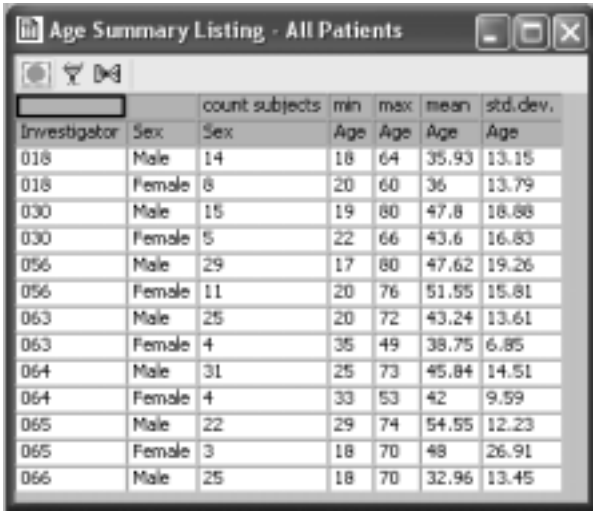
Summary Listing features

Group functions

The Summary Listing have different Group functions available dependent upon the item selected:

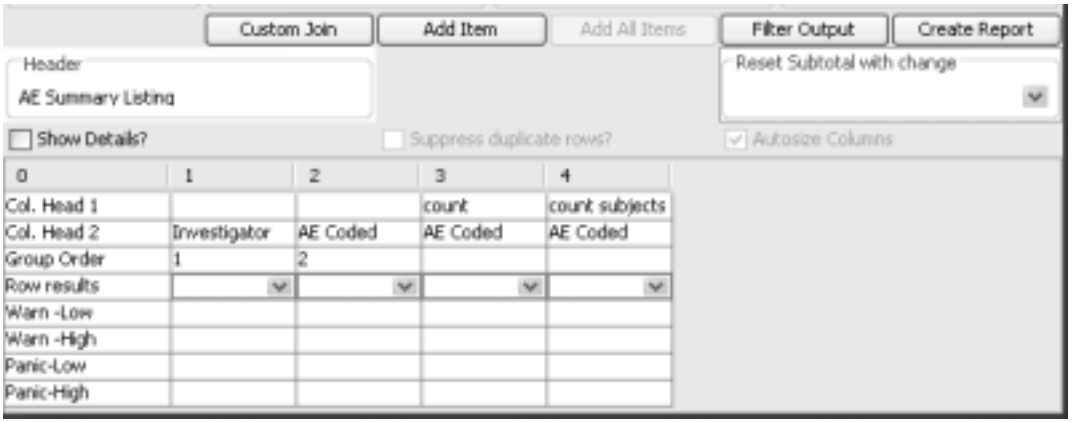
When building a Summary Listing it is typical to first select an item with a group function of 'none' and then follow it by the item with a group function applied. This method displays the item first as a row label followed by the items with group functions applied.

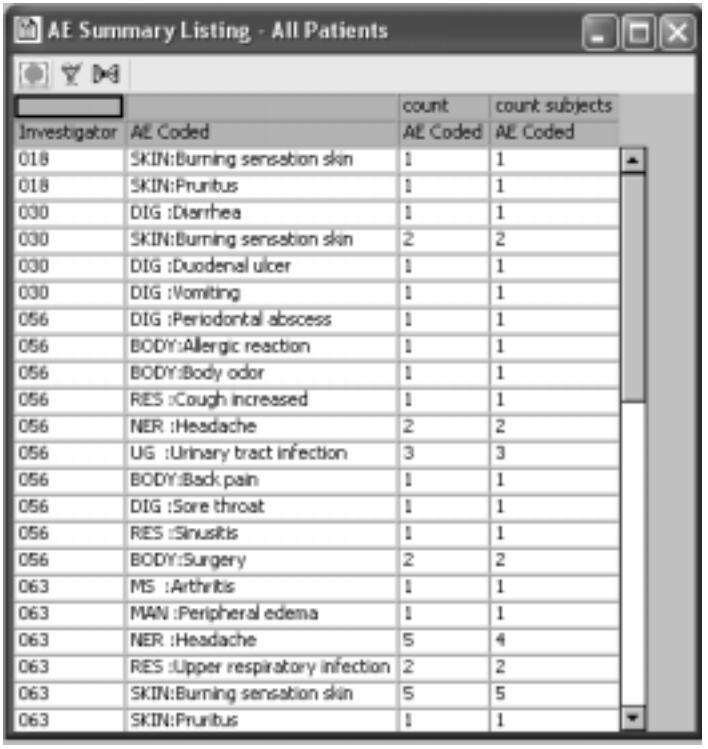




		count subjects	min	max	mean	std.dev.
Investigator	Sex	Sex	Age	Age	Age	Age
018	Male	14	18	64	35.93	13.15
018	Female	8	20	60	36	13.79
030	Male	15	19	80	47.8	18.88
030	Female	5	22	66	43.6	16.83
056	Male	29	17	80	47.62	19.26
056	Female	11	20	76	51.55	15.81
063	Male	25	20	72	43.24	13.61
063	Female	4	35	49	38.75	6.85
064	Male	31	25	73	45.84	14.51
064	Female	4	33	53	42	9.59
065	Male	22	29	74	54.55	12.23
065	Female	3	18	70	48	26.91
066	Male	25	18	70	32.96	13.45

The item ‘AE Coded’ is entered first with a group function of ‘none’ followed by the group functions ‘count’ and ‘count subjects’.



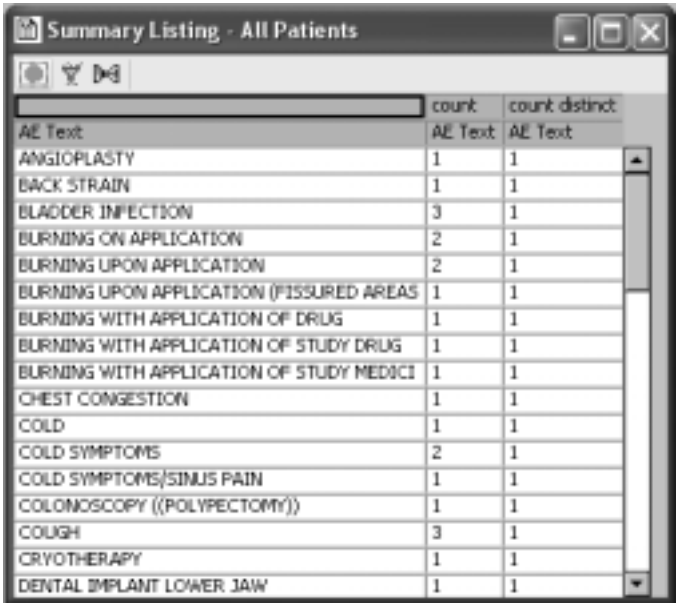


		count	count subjects
Investigator	AE Coded	AE Coded	AE Coded
018	SKIN:Burning sensation skin	1	1
018	SKIN:Pruritus	1	1
030	DIG :Diarrhea	1	1
030	SKIN:Burning sensation skin	2	2
030	DIG :Duodenal ulcer	1	1
030	DIG :Vomiting	1	1
056	DIG :Periodontal abscess	1	1
056	BODY:Allergic reaction	1	1
056	BODY:Body odor	1	1
056	RES :Cough increased	1	1
056	NER :Headache	2	2
056	UG :Urinary tract infection	3	3
056	BODY:Back pain	1	1
056	DIG :Sore throat	1	1
056	RES :Sinusitis	1	1
056	BODY:Surgery	2	2
063	MS :Arthritis	1	1
063	MAN :Peripheral edema	1	1
063	NER :Headache	5	4
063	RES :Upper respiratory infection	2	2
063	SKIN:Burning sensation skin	5	5
063	SKIN:Pruritus	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).

0	1	2	3
Col. Head 1		count	count distinct
Col. Head 2	AE Text	AE Text	AE Text
Group Order	1		
Row results			
Warn -Low			
Warn -High			
Panic-Low			
Panic-High			



	count	count distinct
AE Text	AE Text	AE Text
ANGIOPLASTY	1	1
BACK STRAIN	1	1
BLADDER INFECTION	3	1
BURNING ON APPLICATION	2	1
BURNING UPON APPLICATION	2	1
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	1
COLD SYMPTOMS/SINUS PAIN	1	1
COLONOSCOPY ((POLYPECTOMY))	1	1
COUGH	3	1
CRYOTHERAPY	1	1
DENTAL IMPLANT LOWER JAW	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.

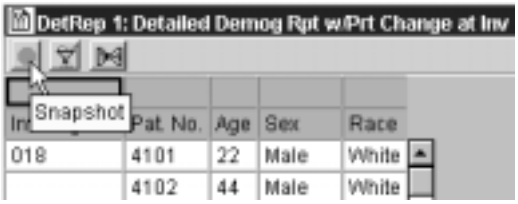
New item with aggregate functions

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.*

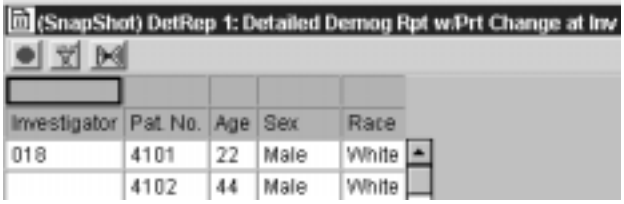
Object toolbar

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).

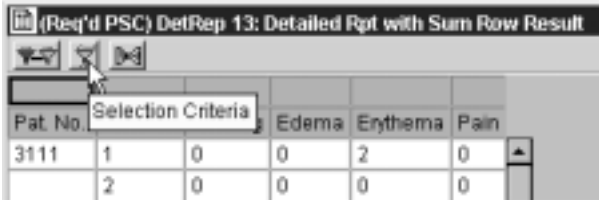


If you click on Snapshot the green button changes to red to indicate the window is frozen and the heading changes to Snapshot' mode. This results window is now blocked to any updates from the patient selection criteria.

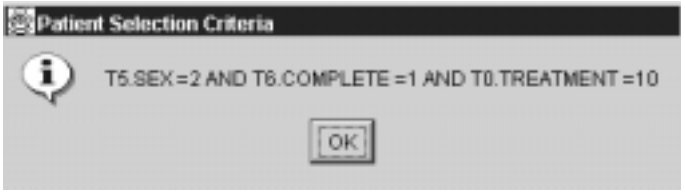


Who icon

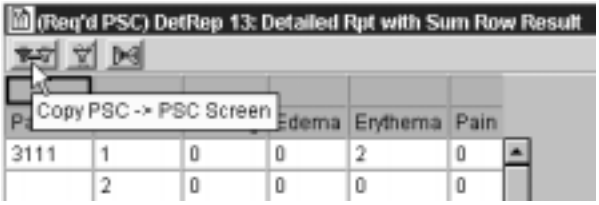
When you click the Selection Criteria icon a message window opens to identify any patient selection criteria active on the output window.



Click OK to close the window.

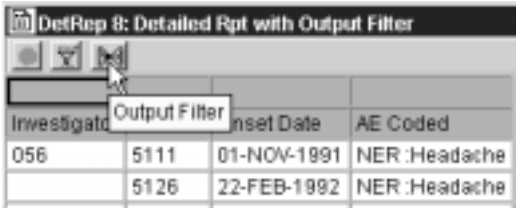


Output objects saved with a required patient selection criteria display with a red filter.

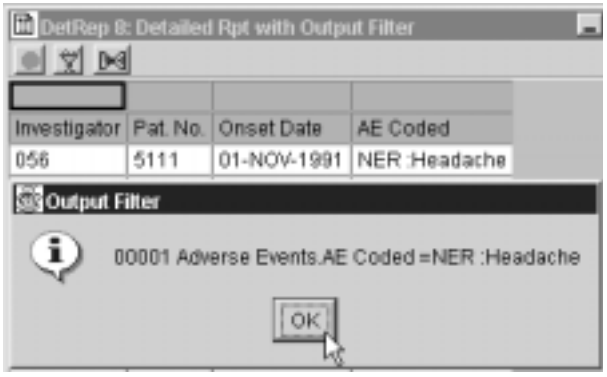


Output filter icon

When you click the Output Filter icon a message window opens to identify any active Output Filters on the output window.

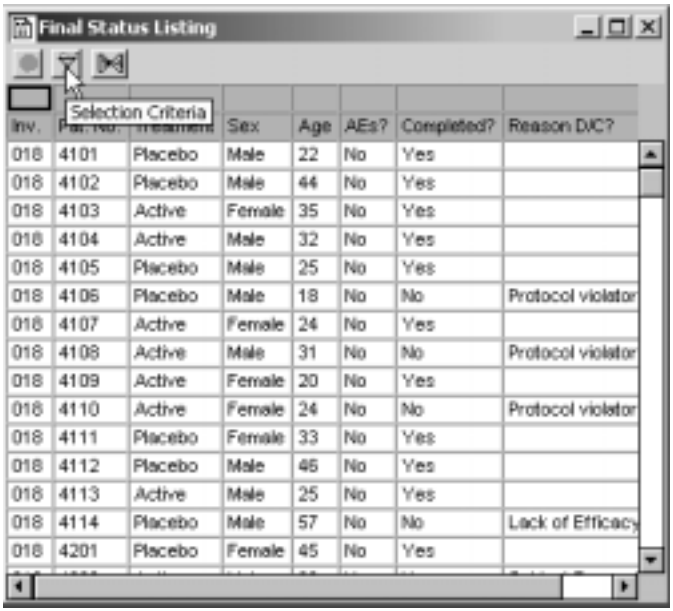


Click **OK** to close the window.



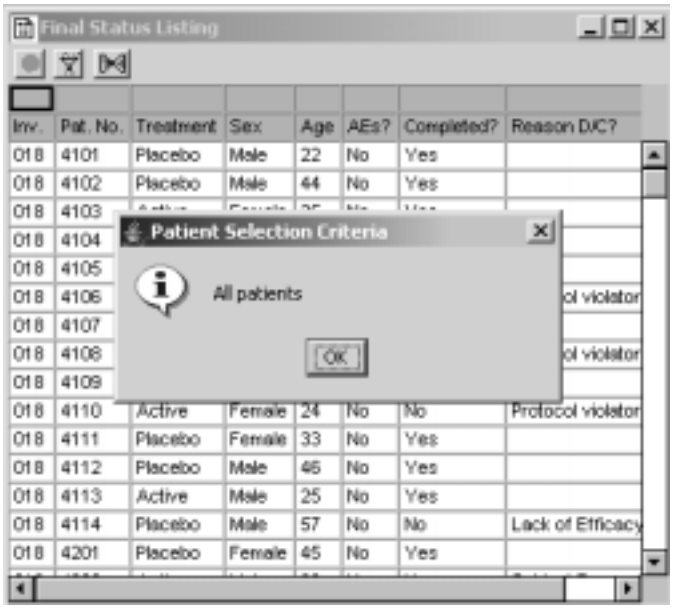
JReview has an optional multiple-population mode available within the individual browsers output window. When the results are executed and displayed from the browser output window, three icons are displayed for “Snapshot”, “Selection Criteria?” and “Output Filter”. The Snapshot output allows you to freeze 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.



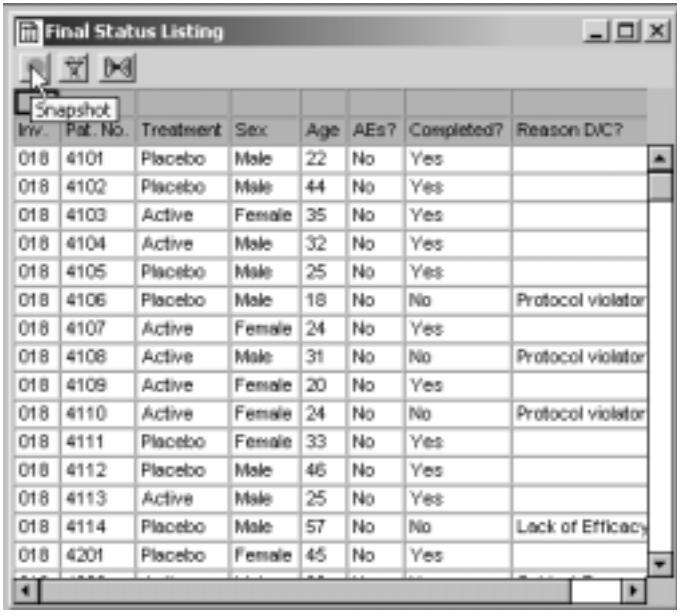
Inv.	Pat.No.	Treatment	Sex	Age	AEs?	Completed?	Reason D/C?
018	4101	Placebo	Male	22	No	Yes	
018	4102	Placebo	Male	44	No	Yes	
018	4103	Active	Female	35	No	Yes	
018	4104	Active	Male	32	No	Yes	
018	4105	Placebo	Male	25	No	Yes	
018	4106	Placebo	Male	18	No	No	Protocol violator
018	4107	Active	Female	24	No	Yes	
018	4108	Active	Male	31	No	No	Protocol violator
018	4109	Active	Female	20	No	Yes	
018	4110	Active	Female	24	No	No	Protocol violator
018	4111	Placebo	Female	33	No	Yes	
018	4112	Placebo	Male	46	No	Yes	
018	4113	Active	Male	25	No	Yes	
018	4114	Placebo	Male	57	No	No	Lack of Efficacy
018	4201	Placebo	Female	45	No	Yes	

The output example shows a stored report object with no patient selection criteria. A snapshot was taken of the current output.



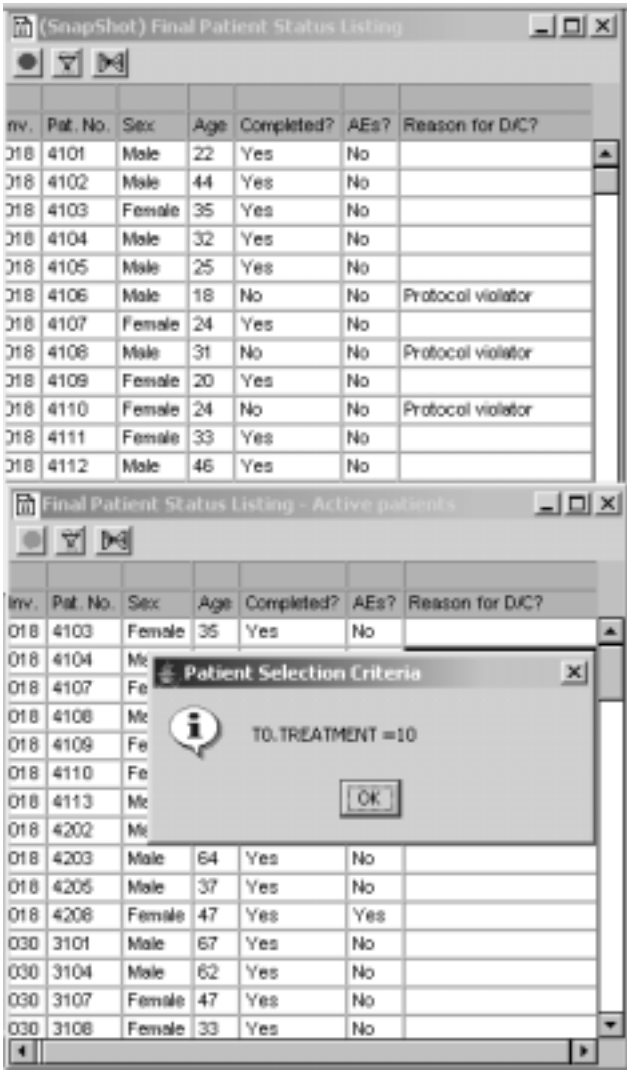
Inv.	Pat. No.	Treatment	Sex	Age	AEs?	Completed?	Reason D/C?
018	4101	Placebo	Male	22	No	Yes	
018	4102	Placebo	Male	44	No	Yes	
018	4103						
018	4104						
018	4105						
018	4106						ol violator
018	4107						
018	4108						ol violator
018	4109						
018	4110	Active	Female	24	No	No	Protocol violator
018	4111	Placebo	Female	33	No	Yes	
018	4112	Placebo	Male	46	No	Yes	
018	4113	Active	Male	25	No	Yes	
018	4114	Placebo	Male	57	No	No	Lack of Efficacy
018	4201	Placebo	Female	45	No	Yes	

Clicking on Snapshot locks the output window.

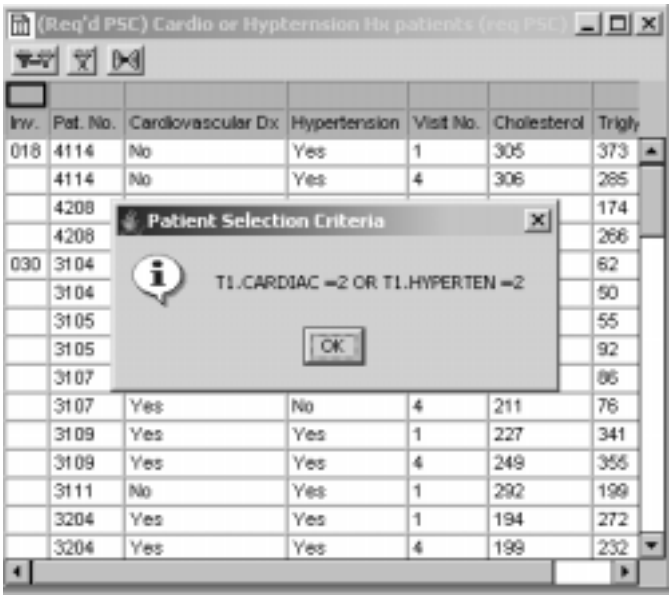


Inv.	Pat. No.	Treatment	Sex	Age	AEs?	Completed?	Reason D/C?
018	4101	Placebo	Male	22	No	Yes	
018	4102	Placebo	Male	44	No	Yes	
018	4103	Active	Female	35	No	Yes	
018	4104	Active	Male	32	No	Yes	
018	4105	Placebo	Male	25	No	Yes	
018	4106	Placebo	Male	18	No	No	Protocol violator
018	4107	Active	Female	24	No	Yes	
018	4108	Active	Male	31	No	No	Protocol violator
018	4109	Active	Female	20	No	Yes	
018	4110	Active	Female	24	No	No	Protocol violator
018	4111	Placebo	Female	33	No	Yes	
018	4112	Placebo	Male	46	No	Yes	
018	4113	Active	Male	25	No	Yes	
018	4114	Placebo	Male	57	No	No	Lack of Efficacy
018	4201	Placebo	Female	45	No	Yes	

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.

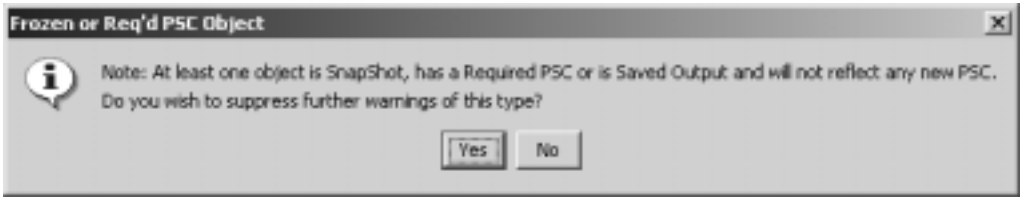


When a stored object definition has a required selection criteria, you are not allowed to modify the selection criteria. The output window displays a notation in the heading "Req'd PSC" with a double filter icon. You can open multiple objects with "Req'd PSC" and toggle between the required selection criteria to update your Data Browser display or other open objects where a selection criteria definition is not required.

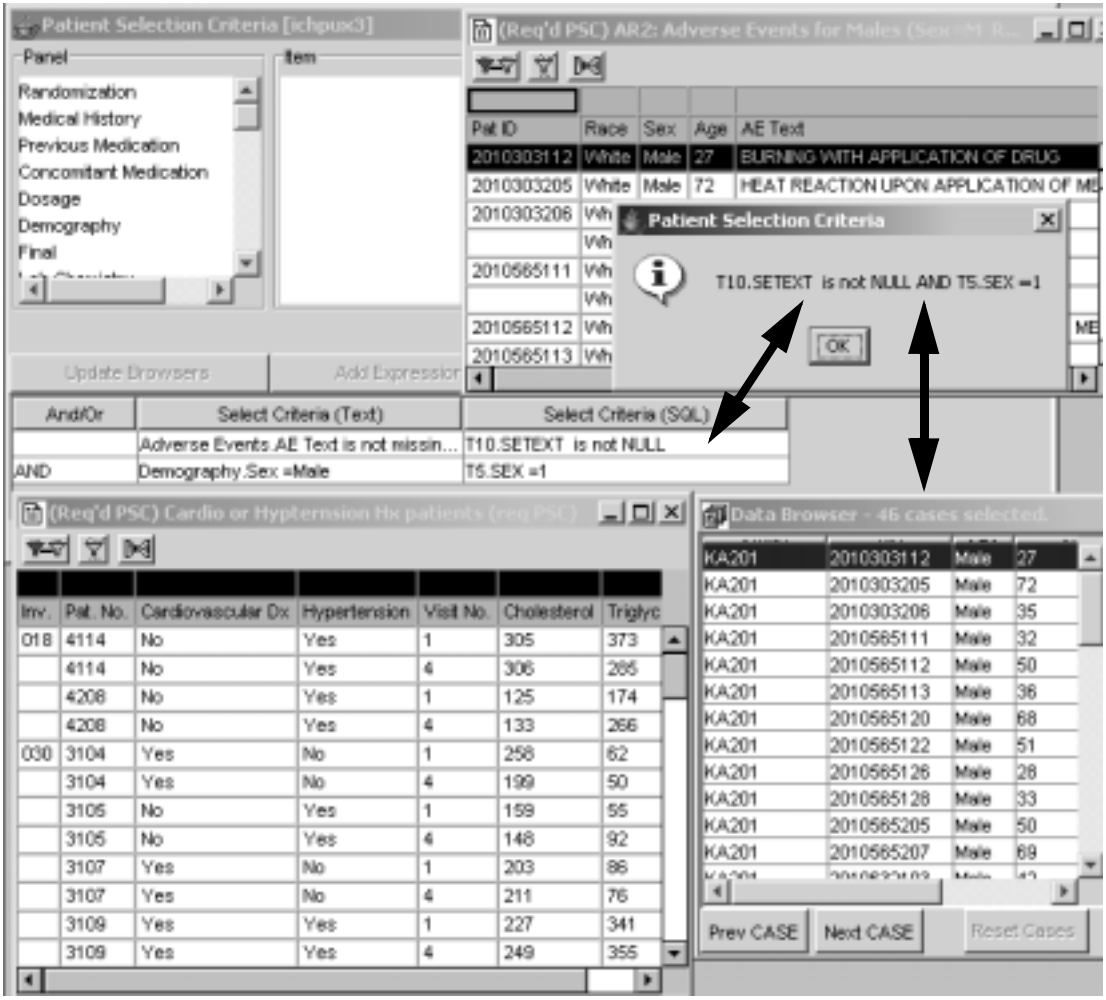


Inv.	Pat. No.	Cardiovascular Dx	Hypertension	Visit No.	Cholesterol	Trigly
018	4114	No	Yes	1	305	373
	4114	No	Yes	4	306	285
	4208					174
	4208					266
030	3104					62
	3104					50
	3105					55
	3105					92
	3107					86
	3107	Yes	No	4	211	76
	3109	Yes	Yes	1	227	341
	3109	Yes	Yes	4	249	355
	3111	No	Yes	1	292	199
	3204	Yes	Yes	1	194	272
	3204	Yes	Yes	4	199	232

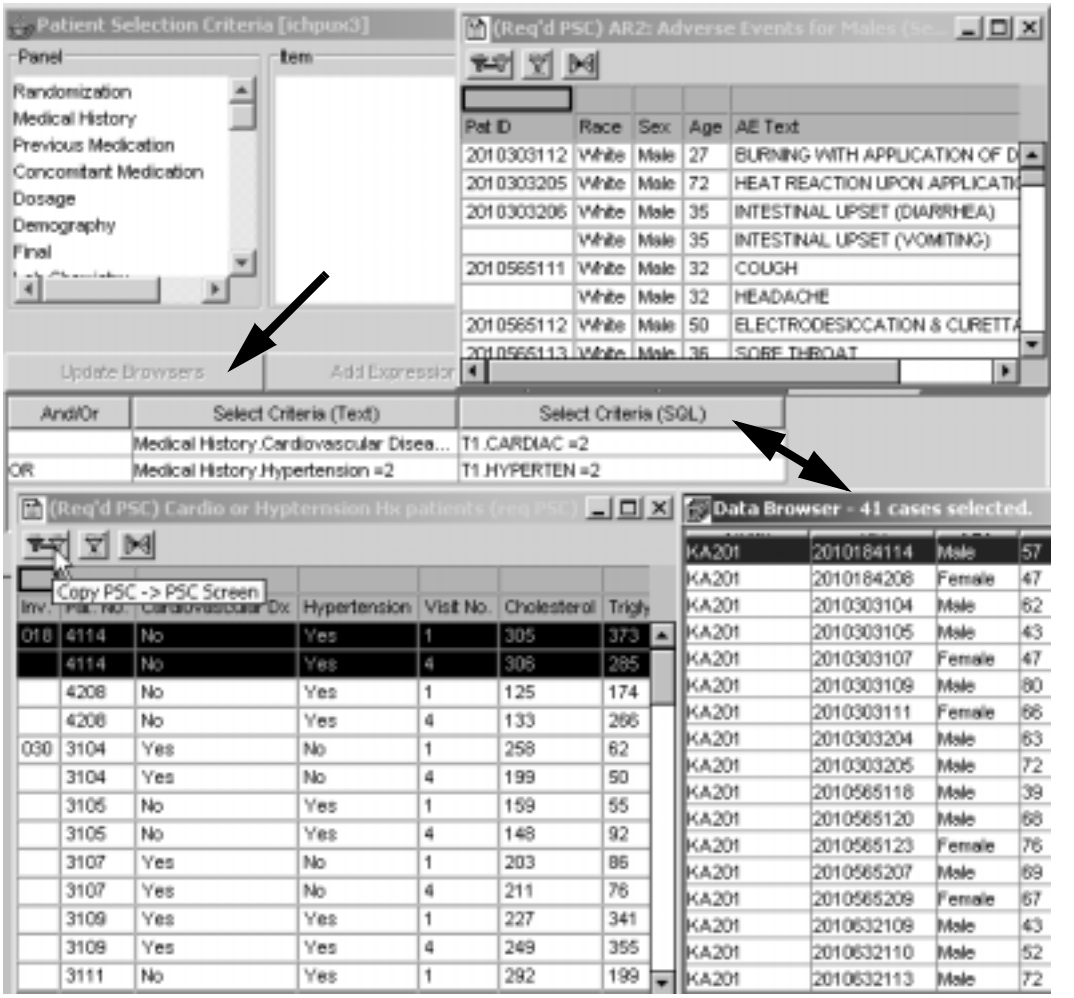
JReview gives a warning when opening a "Stored/Req'd PSC" subset object and allows the user to suppress the warning after the first time. A warning dialog will be presented when trying to update the patient selection criteria if a Snapshot/Frozen or "Req'd PSC" object is open. The warning informs the 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.



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.



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. Click **Update Browsers** to update the Data Browser display.



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.

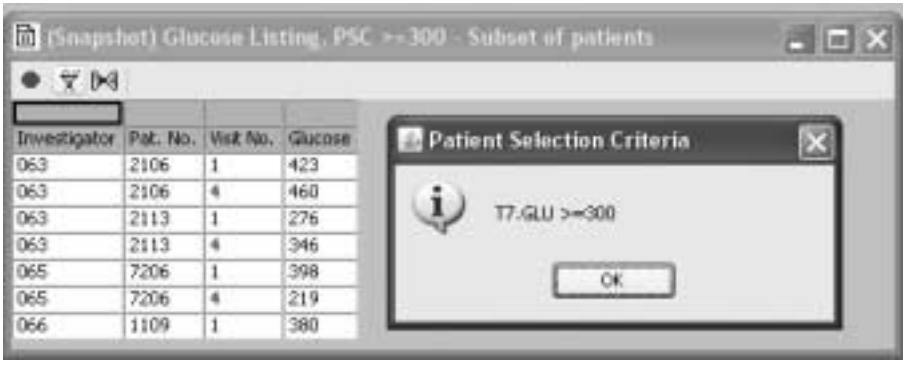
Output filter

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.

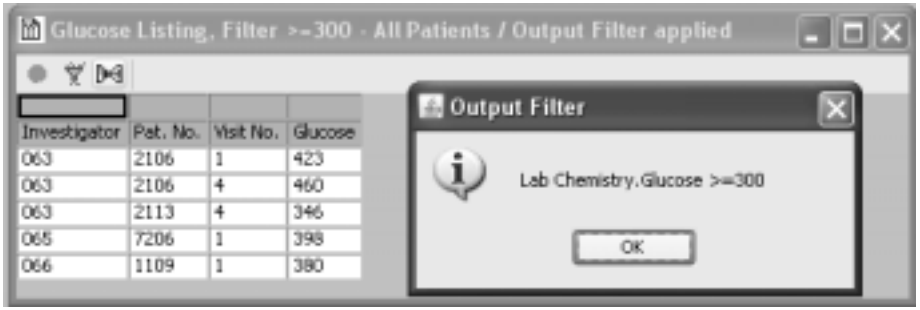
For example, if you want to see all the patients who had Adverse Events with an intensity of 'Serious', you need to decide whether to define the data subset at the patient level or observation / visit level. If you define the data selection with a patient selection criteria and apply it to a detail data 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.



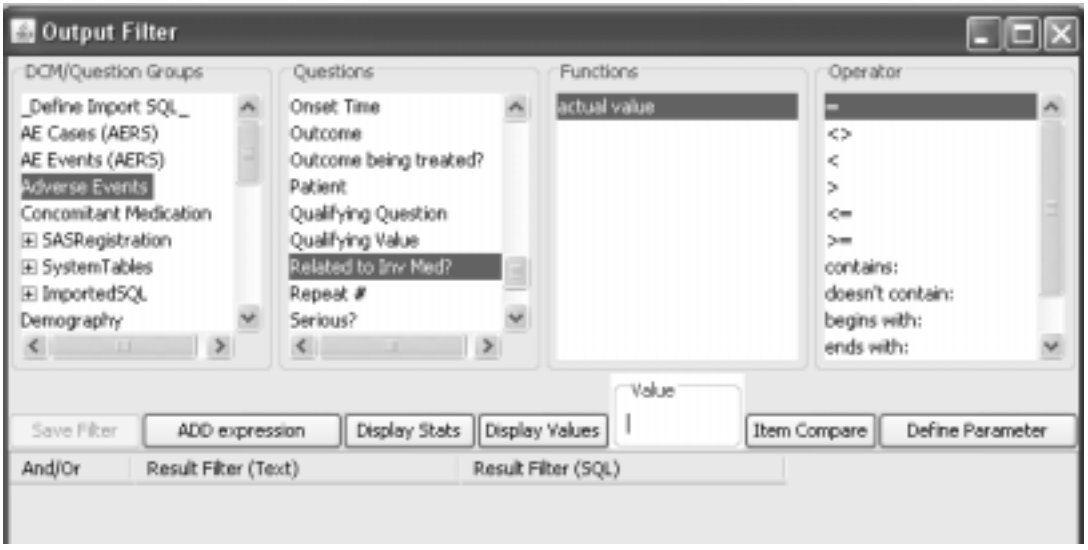
Next the output filter was applied and the previous patient selection criteria was removed. The exact same patients are selected. However, the difference is the patient selection criteria displays all the visits for selected patients, while the output filter selects only those visits with the elevated 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.



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**.

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

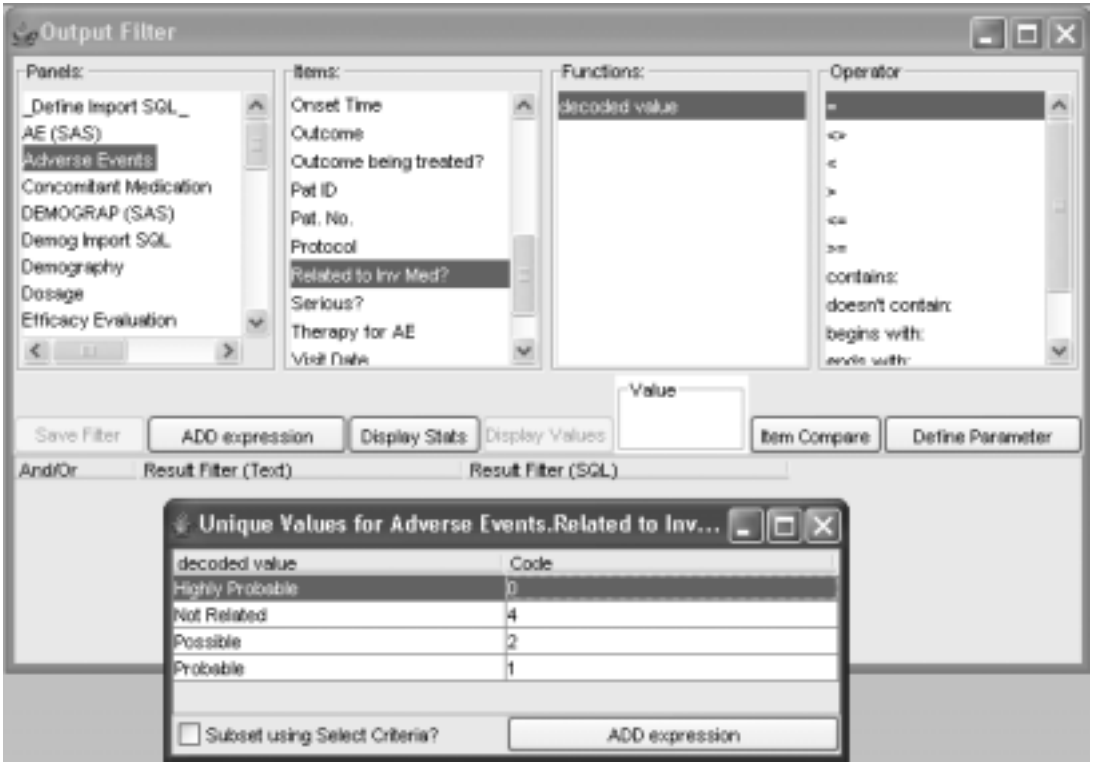
Click **Item Compare** if you want to create a criteria expression that is based on the relationship of two item values. (See *Chapter 2: Selecting Patients: Compare Items*)

Adding expressions

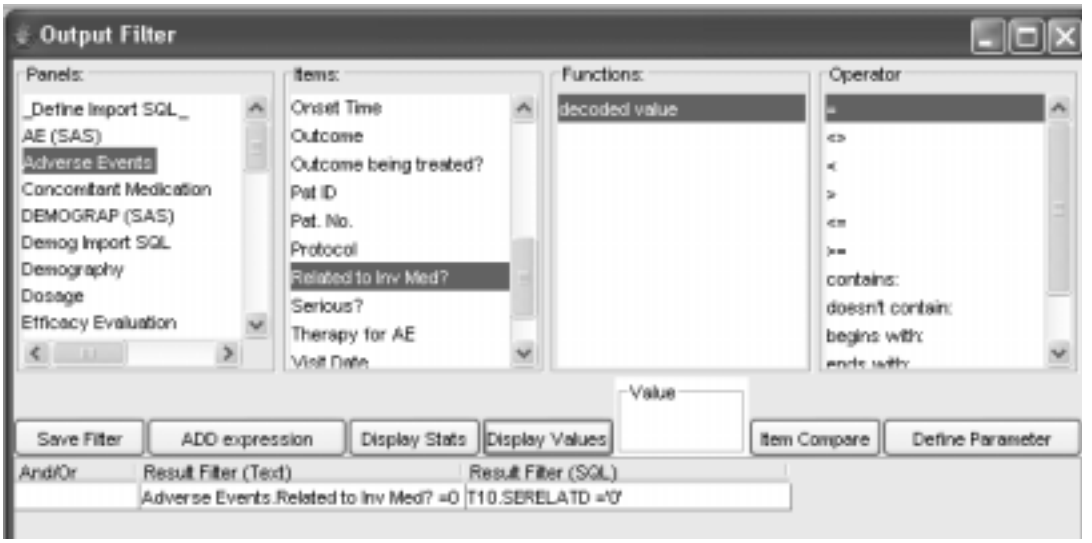
Click **ADD Expression** once a row filtering criteria has been created. The expression is immediately entered in the Result Filter (Text) and Result Filter (SQL) columns.

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

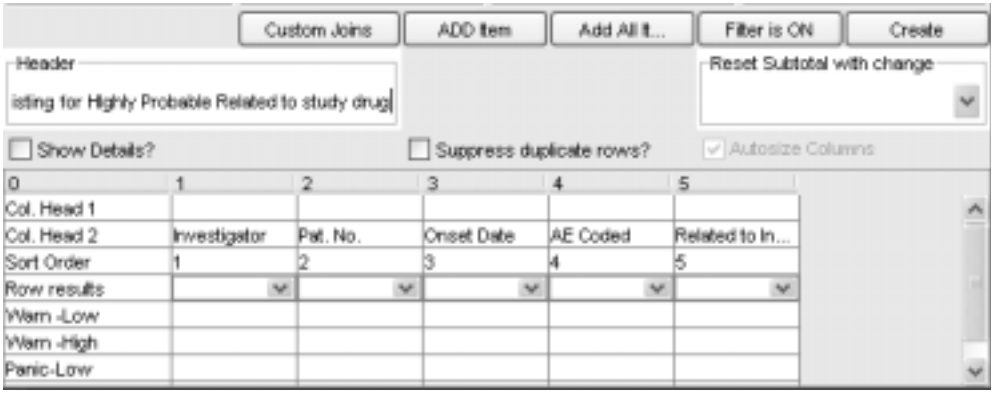
in the patient selection criteria, the operator OR is also available for non-dependent filter expressions. AND Select is not an option in the output filter.



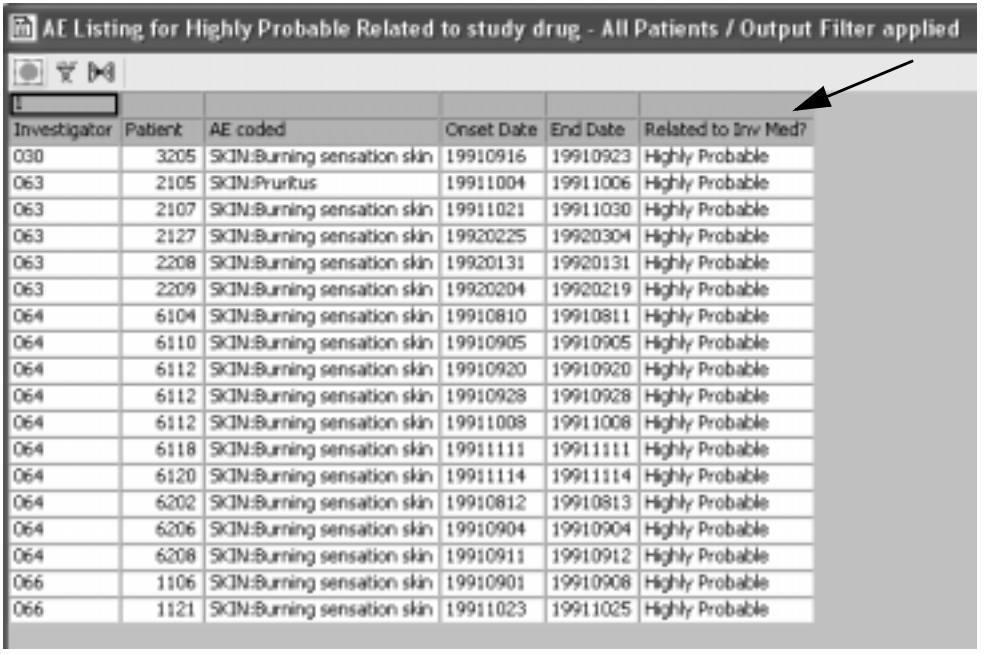
When the output filter is entered, click **Save Filter** to apply to the next generated report.



The Report Browser **Filter Output** button status updates to **Filter is ON.**



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.



AE Listing for Highly Probable Related to study drug - All Patients / Output Filter applied

Investigator	Patient	AE coded	Onset Date	End Date	Related to Inv Med?
030	3205	SKIN:Burning sensation skin	19910916	19910923	Highly Probable
063	2105	SKIN:Pruritus	19911004	19911006	Highly Probable
063	2107	SKIN:Burning sensation skin	19911021	19911030	Highly Probable
063	2127	SKIN:Burning sensation skin	19920225	19920304	Highly Probable
063	2208	SKIN:Burning sensation skin	19920131	19920131	Highly Probable
063	2209	SKIN:Burning sensation skin	19920204	19920219	Highly Probable
064	6104	SKIN:Burning sensation skin	19910810	19910811	Highly Probable
064	6110	SKIN:Burning sensation skin	19910905	19910905	Highly Probable
064	6112	SKIN:Burning sensation skin	19910920	19910920	Highly Probable
064	6112	SKIN:Burning sensation skin	19910928	19910928	Highly Probable
064	6112	SKIN:Burning sensation skin	19911008	19911008	Highly Probable
064	6118	SKIN:Burning sensation skin	19911111	19911111	Highly Probable
064	6120	SKIN:Burning sensation skin	19911114	19911114	Highly Probable
064	6202	SKIN:Burning sensation skin	19910812	19910813	Highly Probable
064	6206	SKIN:Burning sensation skin	19910904	19910904	Highly Probable
064	6208	SKIN:Burning sensation skin	19910911	19910912	Highly Probable
066	1106	SKIN:Burning sensation skin	19910901	19910908	Highly Probable
066	1121	SKIN:Burning sensation skin	19911023	19911025	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.

To turn the Filter Output off:

1. Click **Filter is ON** and the CrossTab Output Filter window opens.
2. Click **New**.
3. Click **Save Filter** to save the cleared filter status before closing the Output Filter window.
4. The Report Browser window updates the button to **Filter Output** indicating NO Output Filter is defined.

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).

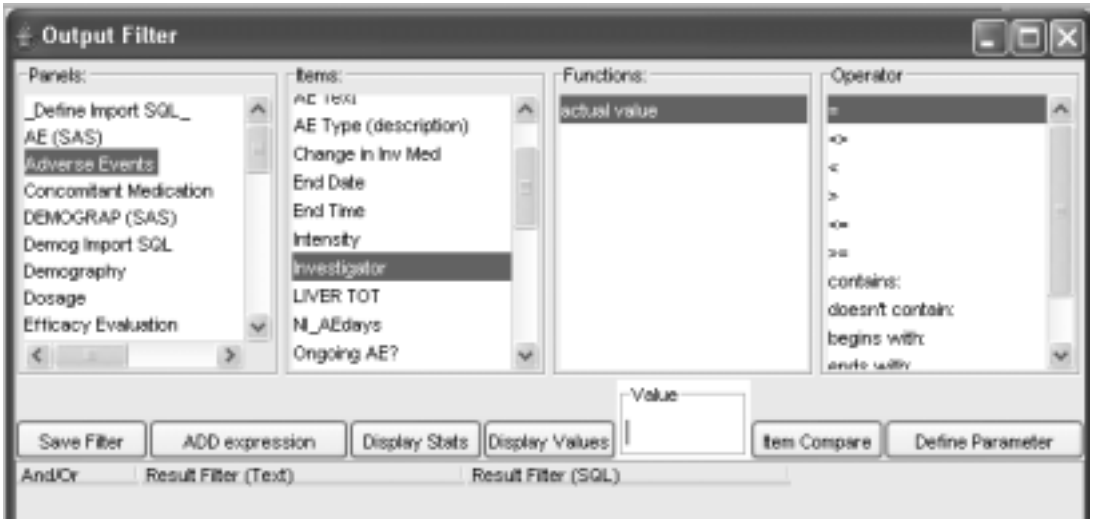
The defaulted parameter text can be edited to an end-user prompt or question.

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 containing different patients or data values.

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 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. You may replace the default text in the End User Prompt for field value(s) by typing over the description.

6. Select one of the **Parameter Value Choices.**

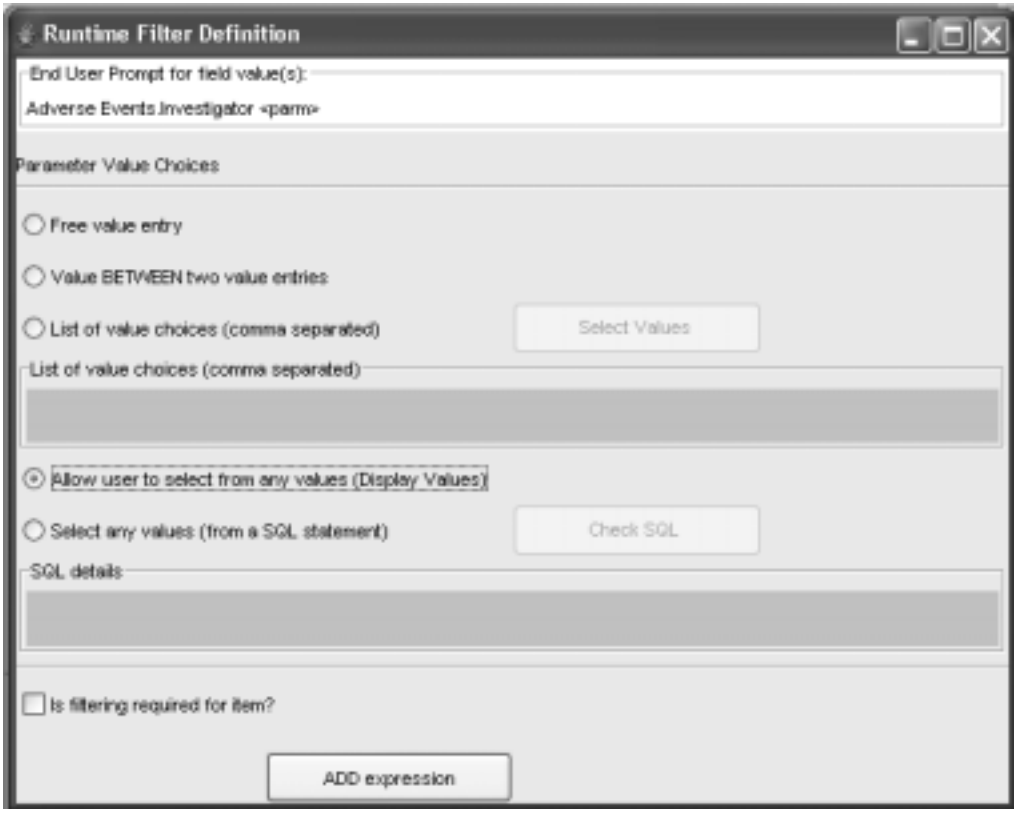
When selecting which parameter value choice to apply to your data you must consider the data type. For example, whether the data is date, numeric, free text or references a data dictionary file.

The free value entry can be used for free text data such as Adverse Event Text or Concomitant Medication Text.

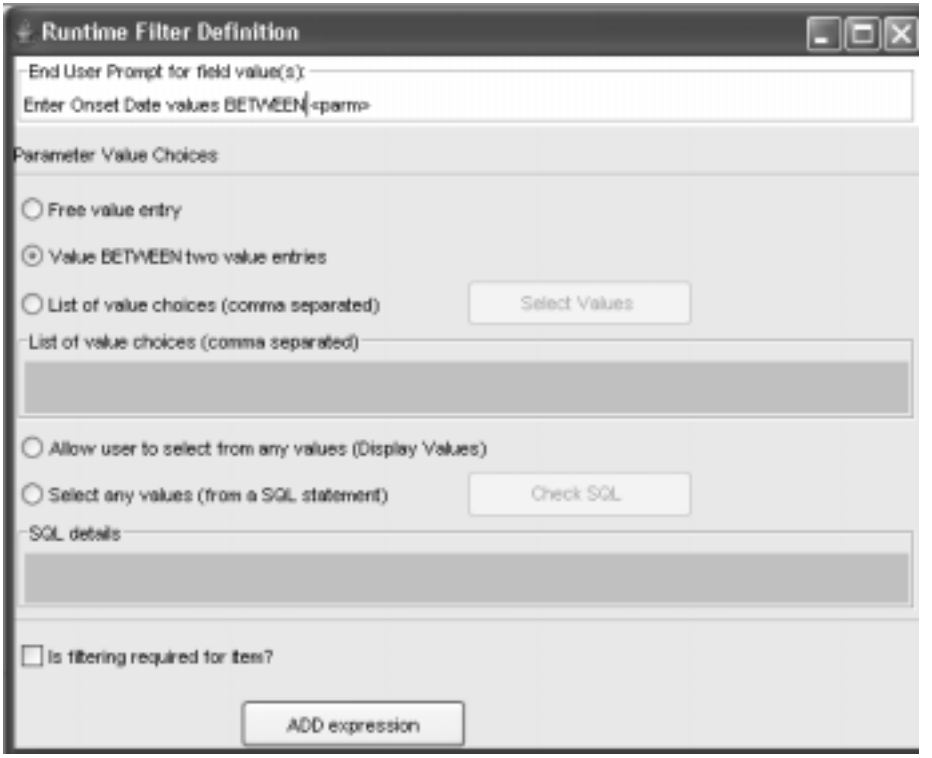
The option to select a value between two value entries can be applied for date ranges or numeric laboratory and vital signs data.

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.

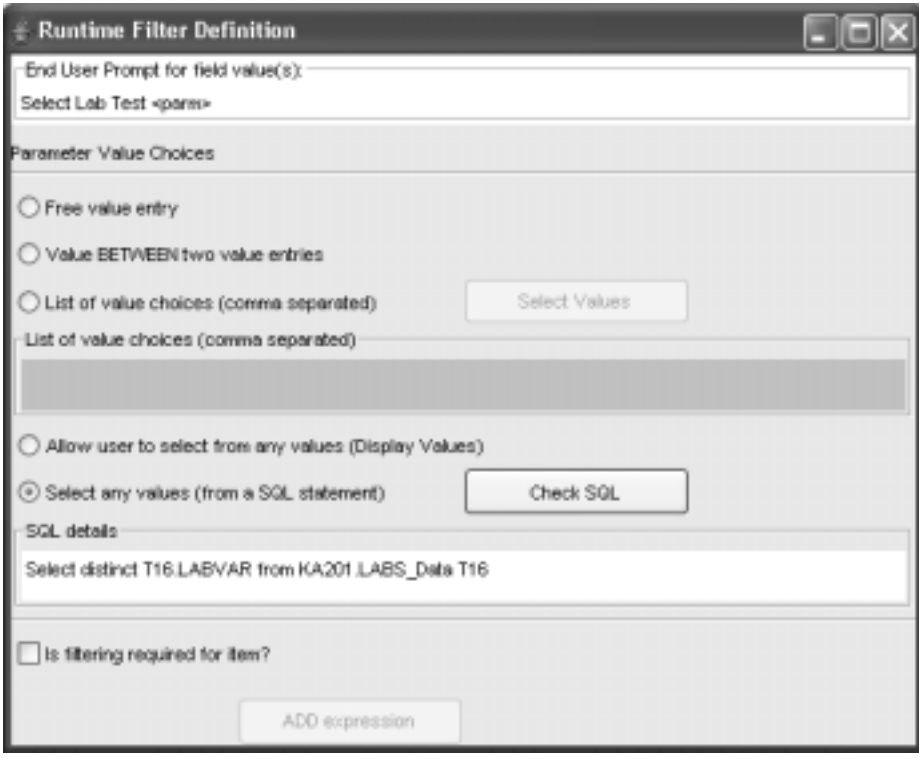


7. Check if filtering is required for item? (optional)
8. Click **ADD expression**.
9. Repeat the steps to add another parameter.

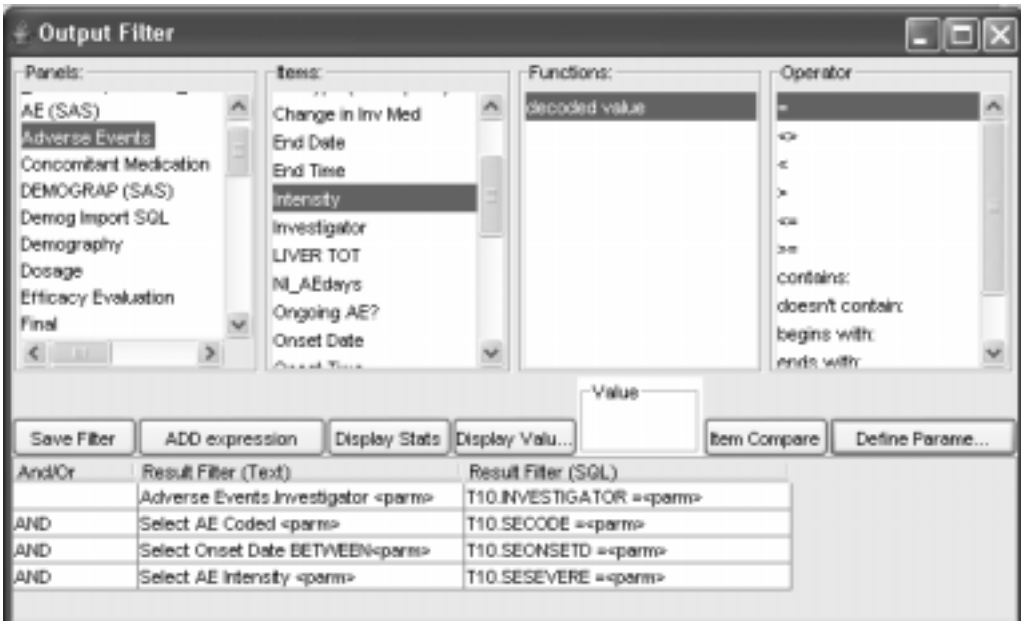


If you select the parameter option for '**Select any values (from a SQL statement)',** enter the SQL statement.

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.



10. Change the Boolean Operators in the Output Filter window if needed then click **Save Filter**.



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.

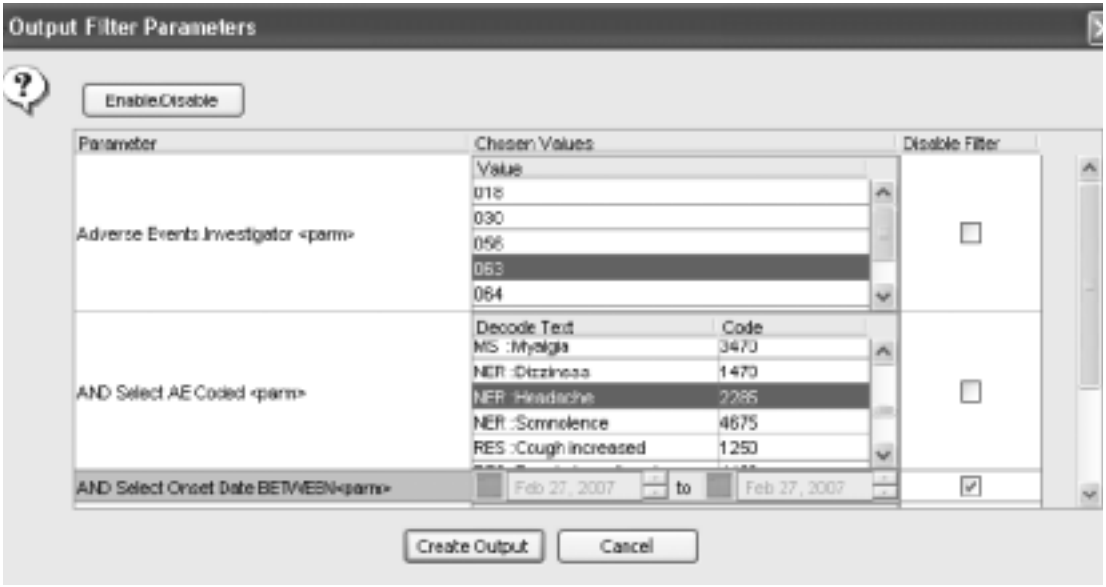
Use the scroll bar to the right to view multiple parameters within the window.

The user may select multiple parameters with the CTRL or SHIFT key in the Display Values option.

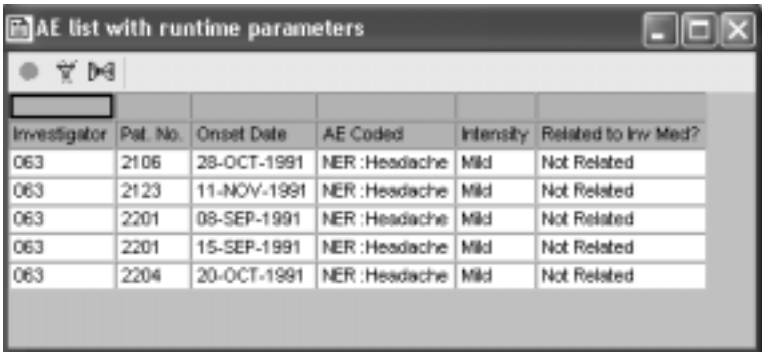
The 'Disable Filter' checkbox allows the user the flexibility to 'turn off' filtering for a particular item. If the 'Disable Filter' checkbox is grayed out then you cannot disable the runtime filter parameter as it was defined as required by the author in the output specification.

Click the 'Enable / Disable' button to enable or disable all the filters.

Note: If the Parameter description appears truncated you can stretch the column width by dragging the header border.



After making parameter selections, click **Create Output** to generate the results.



Investigator	Pat. No.	Onset Date	AE Coded	Intensity	Related to Inv Med?
063	2106	28-OCT-1991	NER :Headache	Mild	Not Related
063	2123	11-NOV-1991	NER :Headache	Mild	Not Related
063	2201	08-SEP-1991	NER :Headache	Mild	Not Related
063	2201	15-SEP-1991	NER :Headache	Mild	Not Related
063	2204	20-OCT-1991	NER :Headache	Mild	Not Related

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.

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.

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

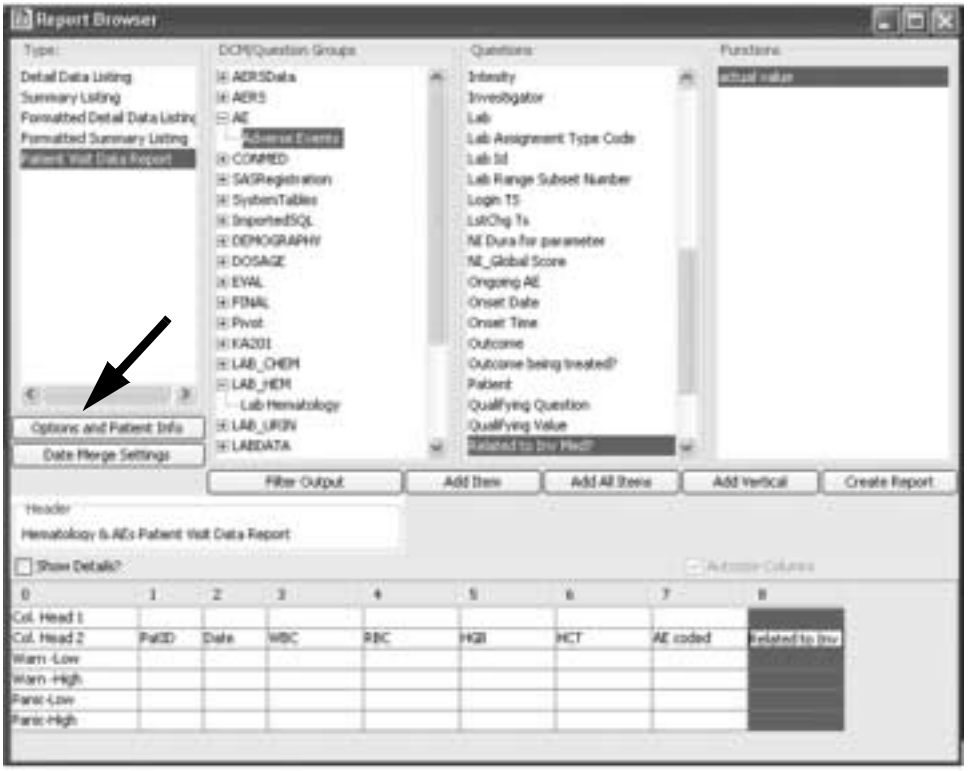
The patient visit data report supports joining multiple visit data into a single report without the usual problems encountered with multiple joins. You can select data from different panels containing multiple visit data and the records are linked by the Visit Date.

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 Visit Date are hard coded into the report and are required.

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:

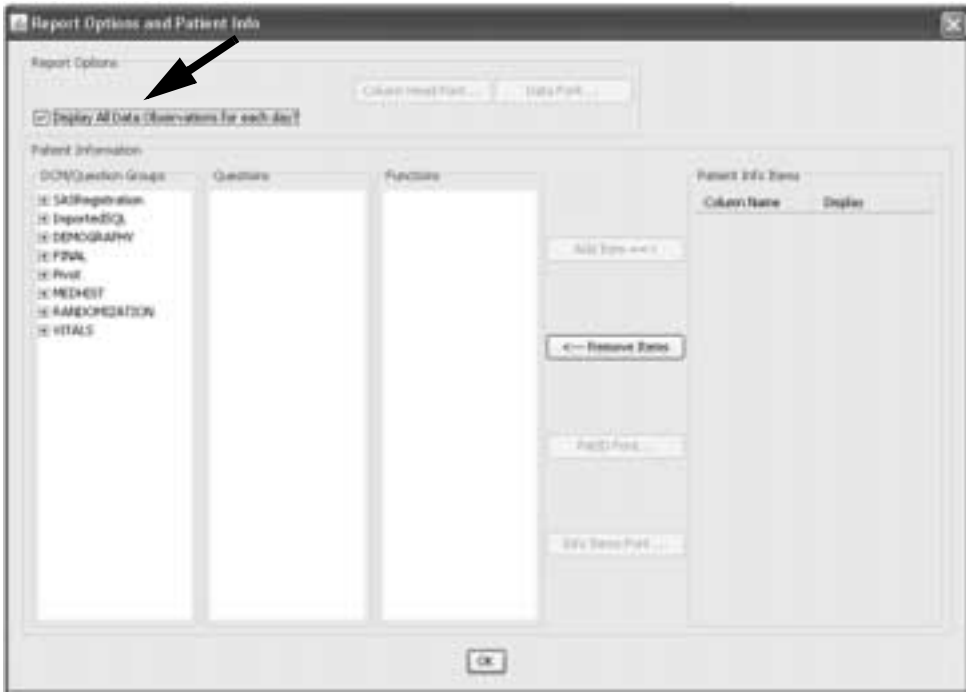
1. Select a panel.
2. Select each item of interest.
3. For each item, select an appropriate function or use the default function type for the type of item selected.



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.



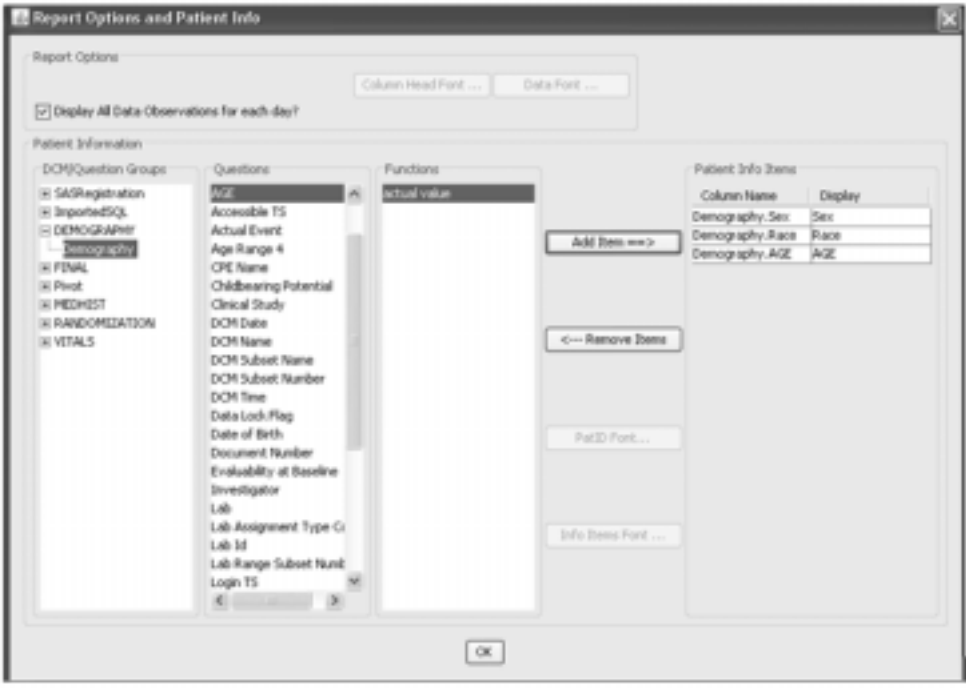
5. **Report Options** supports multiple observations with the default set to ON for '**Display All Data Observations for each day?**'. For example, if there are multiple Adverse Events with the same Onset Date, they'll be listed on separate report rows as floating for that patient. The first Adverse 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.

6. Optionally, click **Column Head Font** and **Data Font** to change fonts for Column Headers and Report Data. ***(Future enhancement)***

You can add patient information items to display as a column under the PatientID. For example, demographic or medical history information.

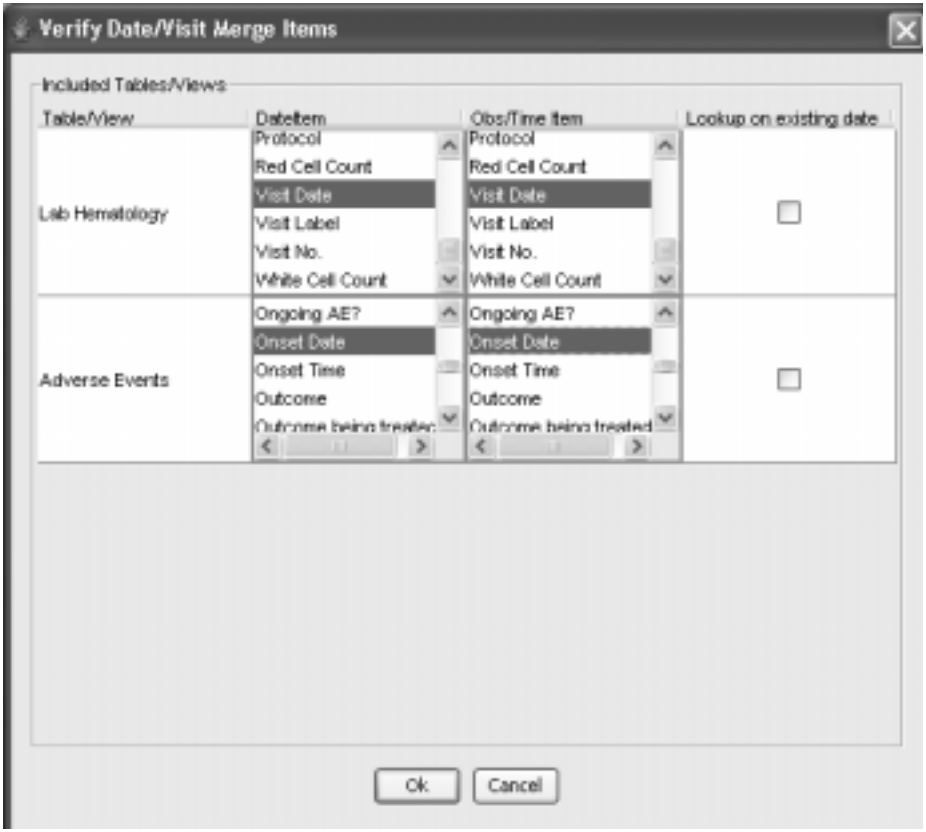
7. Select the panel and item.
8. Click **Add Item** and **Remove Item** to add or remove items from the Patient Info Items list.



9. Optionally, click **PatID Font** and **Info Item Font** to apply fonts for PatID and Info Items. ***(Future enhancement)***
10. Click **OK.**

When you add items to your report specification the Visit Date is defaulted for all selected panels. 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.

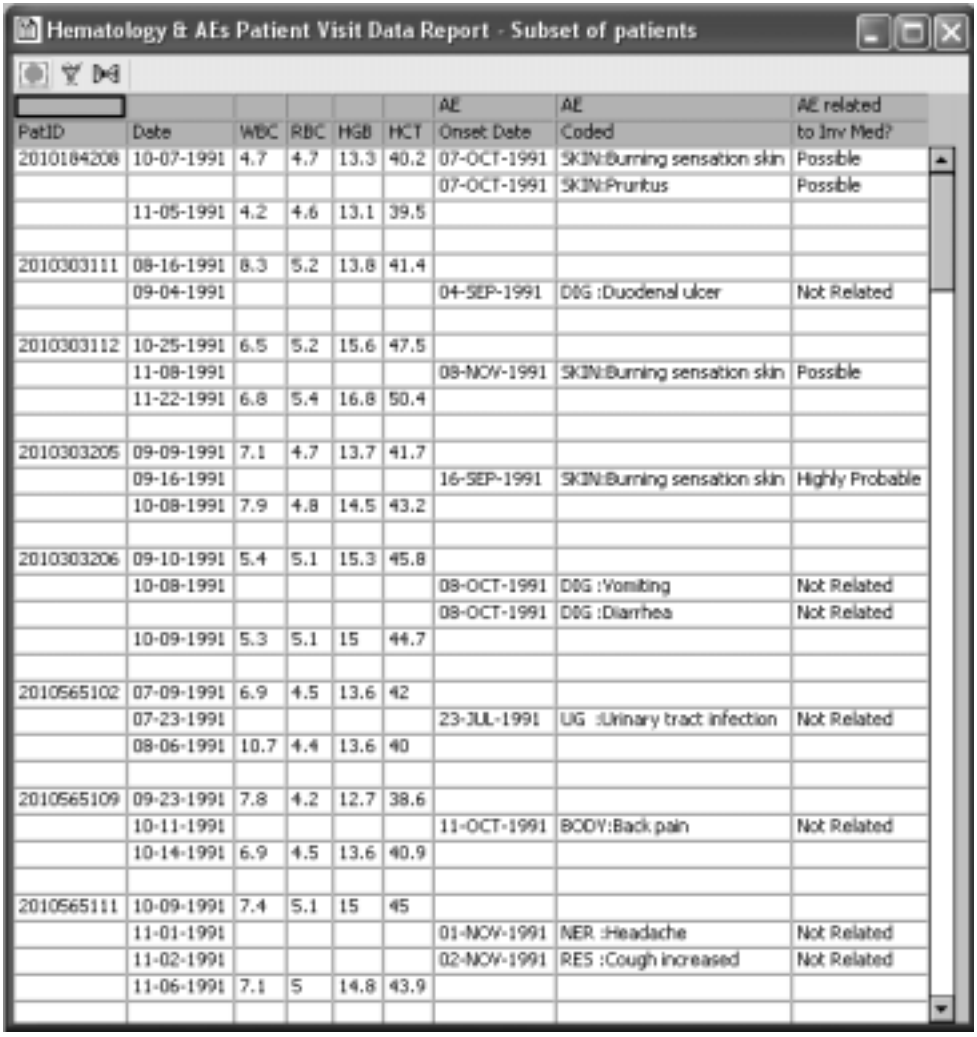
11. Click **Date Merge Settings**. The Verify Date / Visit Merge Items window opens.



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 Onset Date	AE Coded	AE related to Inv Med?
2010184208	10-07-1991	4.7	4.7	13.3	40.2	07-OCT-1991	SKIN:Burning sensation skin	Possible
						07-OCT-1991	SKIN:Pruritus	Possible
	11-05-1991	4.2	4.6	13.1	39.5			
2010303111	08-16-1991	8.3	5.2	13.8	41.4			
	09-04-1991					04-SEP-1991	DIG :Duodenal ulcer	Not Related
2010303112	10-25-1991	6.5	5.2	15.6	47.5			
	11-08-1991					08-NOV-1991	SKIN:Burning sensation skin	Possible
	11-22-1991	6.8	5.4	16.8	50.4			
2010303205	09-09-1991	7.1	4.7	13.7	41.7			
	09-16-1991					16-SEP-1991	SKIN:Burning sensation skin	Highly Probable
	10-08-1991	7.9	4.8	14.5	43.2			
2010303206	09-10-1991	5.4	5.1	15.3	45.8			
	10-08-1991					08-OCT-1991	DIG :Vomiting	Not Related
						08-OCT-1991	DIG :Diarrhea	Not Related
	10-09-1991	5.3	5.1	15	44.7			
2010565102	07-09-1991	6.9	4.5	13.6	42			
	07-23-1991					23-JUL-1991	UG :Urinary tract infection	Not Related
	08-06-1991	10.7	4.4	13.6	40			
2010565109	09-23-1991	7.8	4.2	12.7	38.6			
	10-11-1991					11-OCT-1991	BODY:Back pain	Not Related
	10-14-1991	6.9	4.5	13.6	40.9			
2010565111	10-09-1991	7.4	5.1	15	45			
	11-01-1991					01-NOV-1991	NER :Headache	Not Related
	11-02-1991					02-NOV-1991	RES :Cough increased	Not Related
	11-06-1991	7.1	5	14.8	43.9			

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.

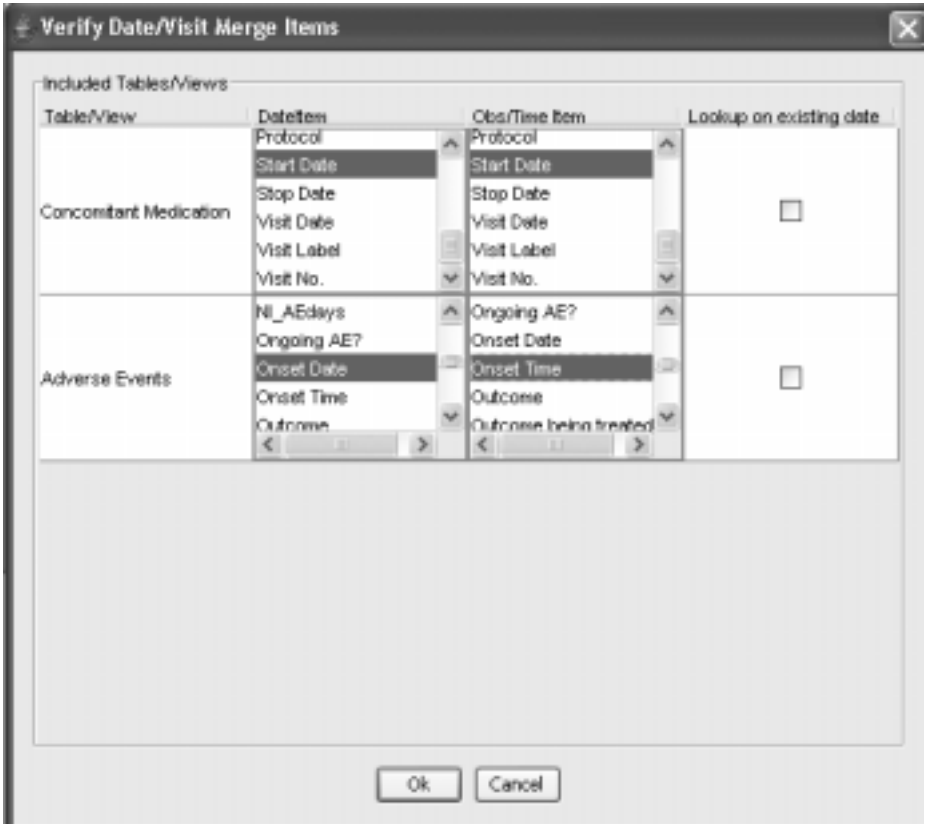
Header

Conmed & AE Patient Visit Data Report

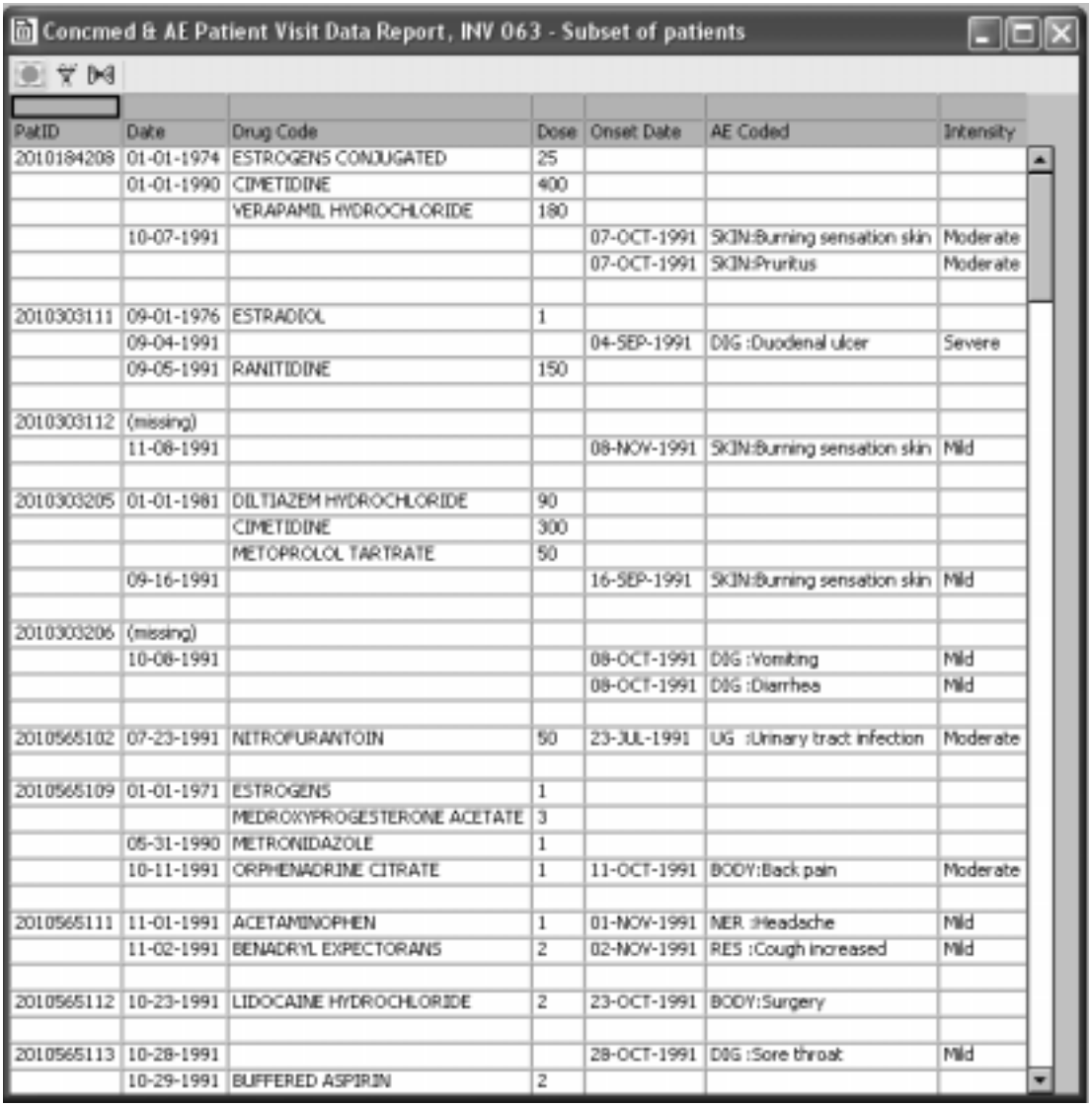
Show Details? Autosize Columns

0	1	2	3	4	5	6	7
Col. Head 1	1						
Col. Head 2	PatID	Date	Drug Code	Dose	Onset Date	AE Coded	Intensity
Warn -Low							
Warn -High							
Panic-Low							
Panic-High							

The first listing shows the DateMerge lookup questions with the default settings for 'NO'.



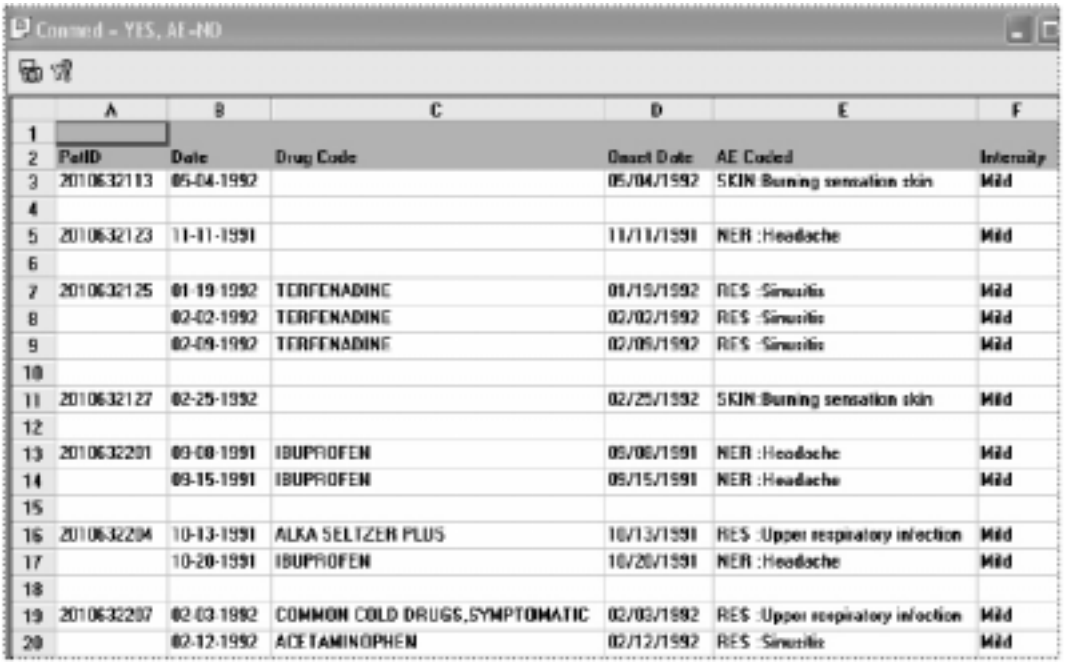
A patient selection criteria was applied to select only the patients for Investigator 063. The listing shows all records are displayed if present for Conmeds and Adverse Events.



Concmed & AE Patient Visit Data Report, INV 063 - Subset of patients

PatID	Date	Drug Code	Dose	Onset Date	AE Coded	Intensity
2010184208	01-01-1974	ESTROGENS CONJUGATED	25			
	01-01-1990	CIMETIDINE	400			
		VERAPAMIL HYDROCHLORIDE	180			
	10-07-1991			07-OCT-1991	SKIN:Burning sensation skin	Moderate
				07-OCT-1991	SKIN:Pruritus	Moderate
2010303111	09-01-1976	ESTRADIOL	1			
	09-04-1991			04-SEP-1991	DIG :Duodenal ulcer	Severe
	09-05-1991	RANITIDINE	150			
2010303112	(missing)					
	11-08-1991			08-NOV-1991	SKIN:Burning sensation skin	Mild
2010303205	01-01-1981	DILTIAZEM HYDROCHLORIDE	90			
		CIMETIDINE	300			
		METOPROLOL TARTRATE	50			
	09-16-1991			16-SEP-1991	SKIN:Burning sensation skin	Mild
2010303206	(missing)					
	10-08-1991			08-OCT-1991	DIG :Vomiting	Mild
				08-OCT-1991	DIG :Diarrhea	Mild
2010565102	07-23-1991	NITROFURANTOIN	50	23-JUL-1991	UG :Urinary tract infection	Moderate
2010565109	01-01-1971	ESTROGENS	1			
		MEDROXYPROGESTERONE ACETATE	3			
	05-31-1990	METRONIDAZOLE	1			
	10-11-1991	ORPHENADRINE CITRATE	1	11-OCT-1991	BODY:Back pain	Moderate
2010565111	11-01-1991	ACETAMINOPHEN	1	01-NOV-1991	NER :Headache	Mild
	11-02-1991	BENADRYL EXPECTORANS	2	02-NOV-1991	RES :Cough increased	Mild
2010565112	10-23-1991	LIDOCAINE HYDROCHLORIDE	2	23-OCT-1991	BODY:Surgery	
2010565113	10-28-1991			28-OCT-1991	DIG :Sore throat	Mild
	10-29-1991	BUFFERED ASPIRIN	2			

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.



Conmed - YES, AE-NO

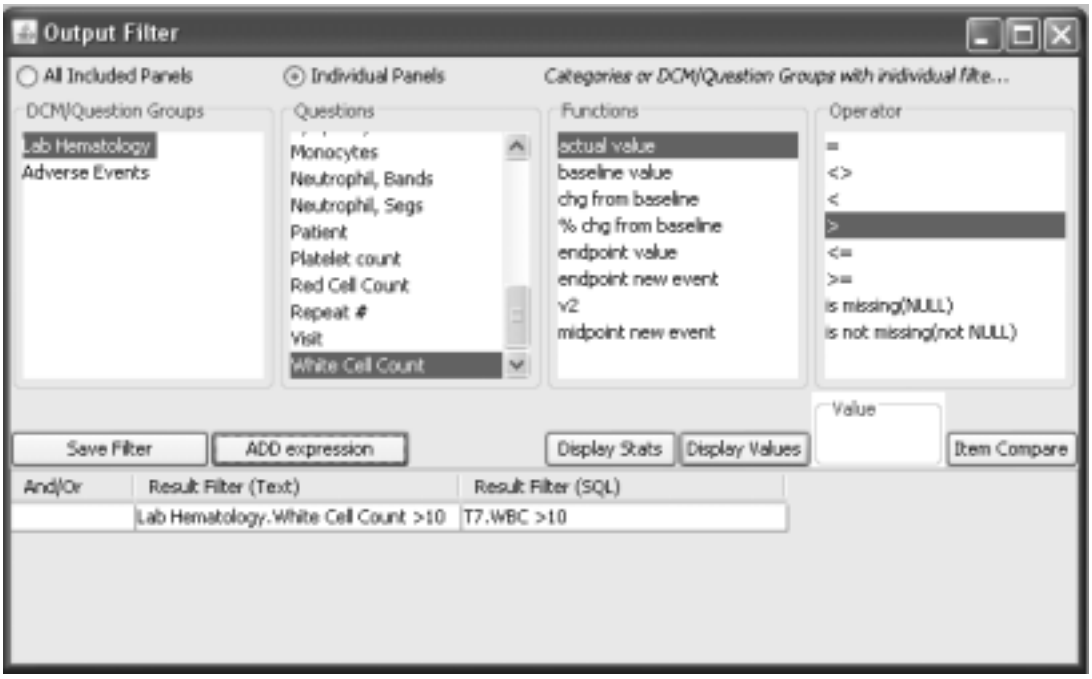
	A	B	C	D	E	F
1						
2	PatID	Date	Drug Code	Onset Date	AE Coded	Intensity
3	2010632113	05-04-1992		05/04/1992	SKIN:Burning sensation skin	Mild
4						
5	2010632123	11-11-1991		11/11/1991	NER :Headache	Mild
6						
7	2010632125	01-19-1992	TERFENADINE	01/19/1992	RES :Sinusitis	Mild
8		02-02-1992	TERFENADINE	02/02/1992	RES :Sinusitis	Mild
9		02-09-1992	TERFENADINE	02/09/1992	RES :Sinusitis	Mild
10						
11	2010632127	02-25-1992		02/25/1992	SKIN:Burning sensation skin	Mild
12						
13	2010632201	09-08-1991	IBUPROFEN	09/08/1991	NER :Headache	Mild
14		09-15-1991	IBUPROFEN	09/15/1991	NER :Headache	Mild
15						
16	2010632204	10-13-1991	ALKA SELTZER PLUS	10/13/1991	RES :Upper respiratory infection	Mild
17		10-20-1991	IBUPROFEN	10/20/1991	NER :Headache	Mild
18						
19	2010632207	02-03-1992	COMMON COLD DRUGS,SYMPTOMATIC	02/03/1992	RES :Upper respiratory infection	Mild
20		02-12-1992	ACETAMINOPHEN	02/12/1992	RES :Sinusitis	Mild

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**.



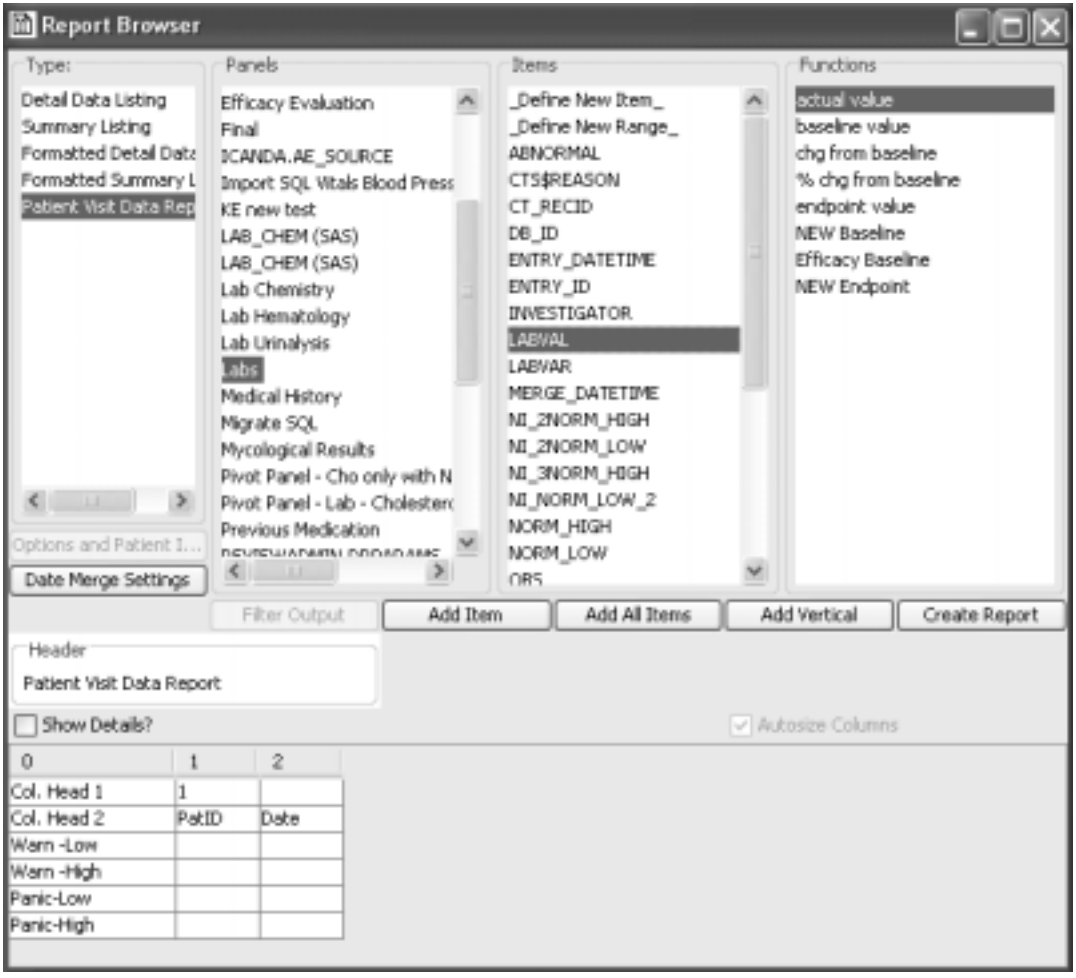
5. Click **Save Filter.**

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.

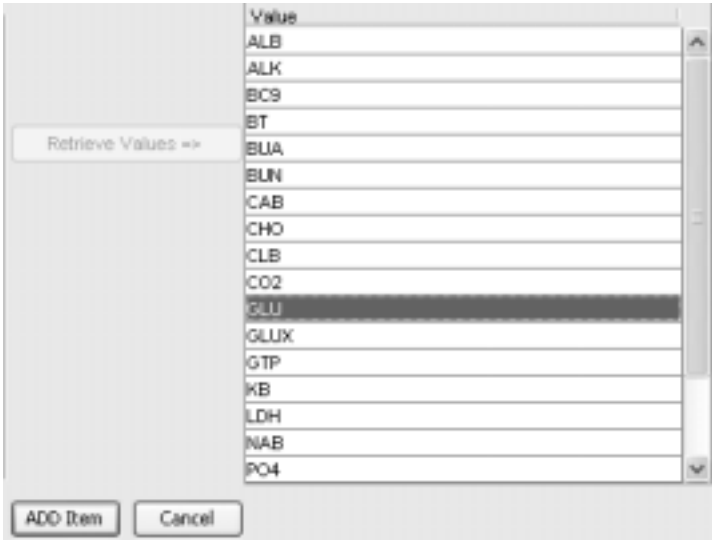
1. Select a vertical lab panel.
2. Select the 'Lab Value' and click **ADD Vertical**.



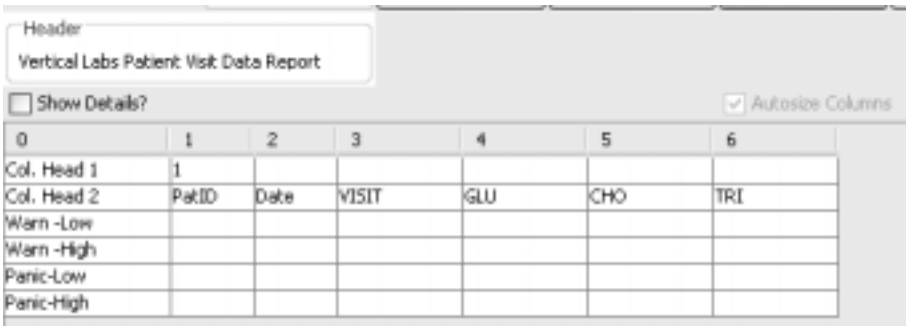
The **Vertical Item Information** window opens. The instructions explain how to select the data item which represents the individual lab tests.

3. Select the Pivot Item Value,i.e., the item which contains the test name or description.
4. Click **Retrieve Values**.

5. Select the **Pivot Item Value** and click **ADD Item**.

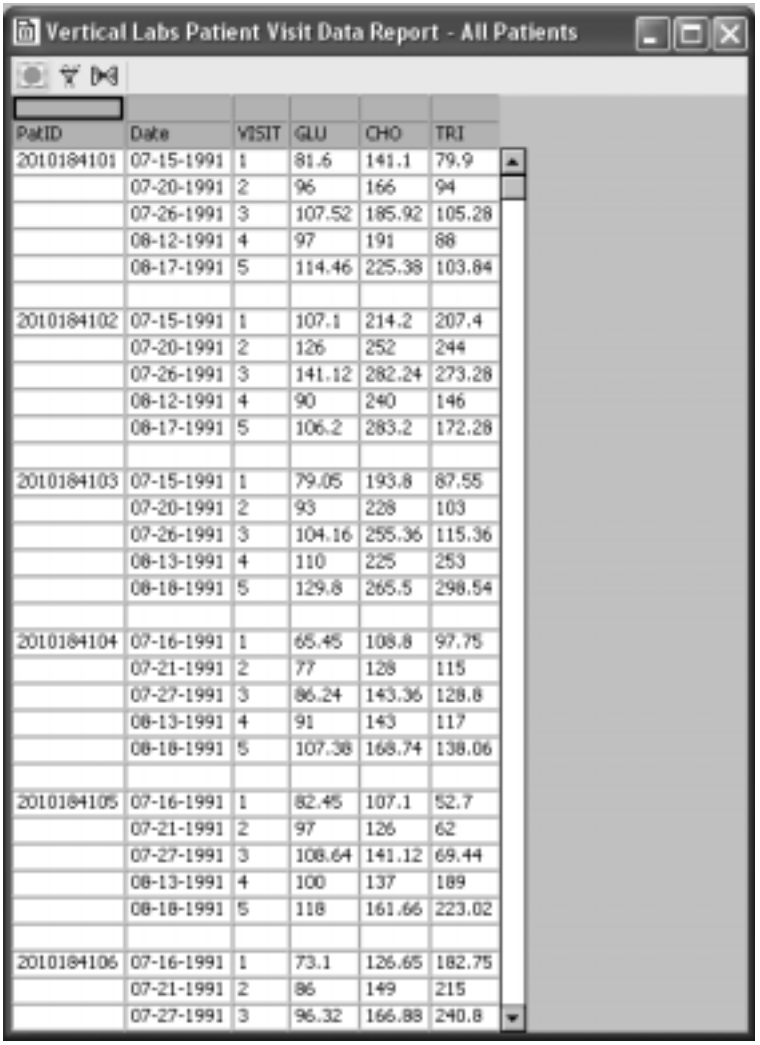


6. Repeat the steps to add additional lab parameters to the report.



0	1	2	3	4	5	6
Col. Head 1	1					
Col. Head 2	PatID	Date	VISIT	GLU	CHO	TRI
Warn -Low						
Warn -High						
Panic-Low						
Panic-High						

7. Add report options for patient information and apply formats *(optional)*.
8. Enter Date Merge Settings (required).
9. Enter a report Heading.
10. Click **Create Report**.



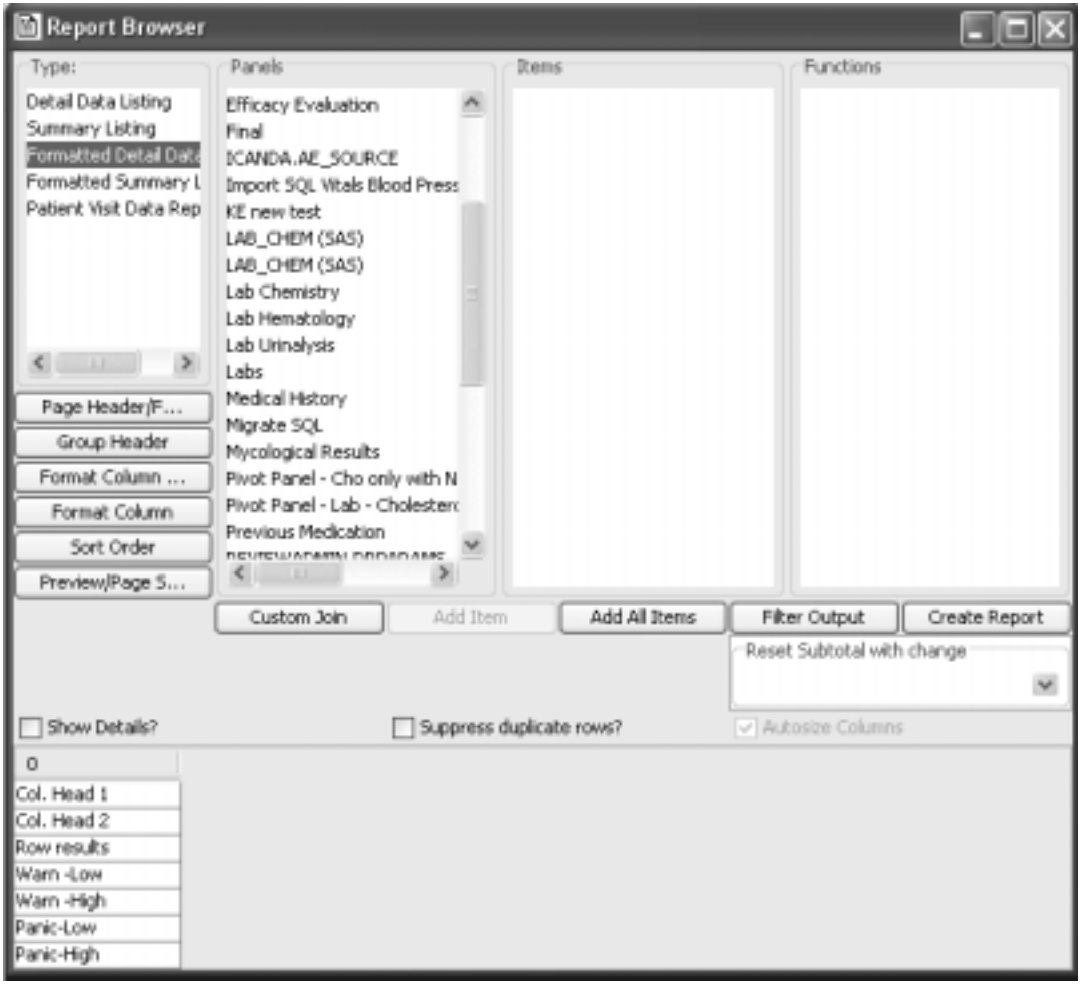
PatID	Date	VISIT	GLU	CHO	TRI
2010184101	07-15-1991	1	81.6	141.1	79.9
	07-20-1991	2	96	166	94
	07-26-1991	3	107.52	185.92	105.28
	08-12-1991	4	97	191	88
	08-17-1991	5	114.46	225.38	103.84
2010184102	07-15-1991	1	107.1	214.2	207.4
	07-20-1991	2	126	252	244
	07-26-1991	3	141.12	282.24	273.28
	08-12-1991	4	90	240	146
	08-17-1991	5	106.2	283.2	172.28
2010184103	07-15-1991	1	79.05	193.8	87.55
	07-20-1991	2	93	228	103
	07-26-1991	3	104.16	255.36	115.36
	08-13-1991	4	110	225	253
	08-18-1991	5	129.8	265.5	298.54
2010184104	07-16-1991	1	65.45	108.8	97.75
	07-21-1991	2	77	128	115
	07-27-1991	3	86.24	143.36	128.8
	08-13-1991	4	91	143	117
	08-18-1991	5	107.38	168.74	138.06
2010184105	07-16-1991	1	82.45	107.1	52.7
	07-21-1991	2	97	126	62
	07-27-1991	3	108.64	141.12	69.44
	08-13-1991	4	100	137	189
	08-18-1991	5	118	161.66	223.02
2010184106	07-16-1991	1	73.1	126.65	182.75
	07-21-1991	2	86	149	215
	07-27-1991	3	96.32	166.88	240.8

Formatted reports

Select formatted listing type

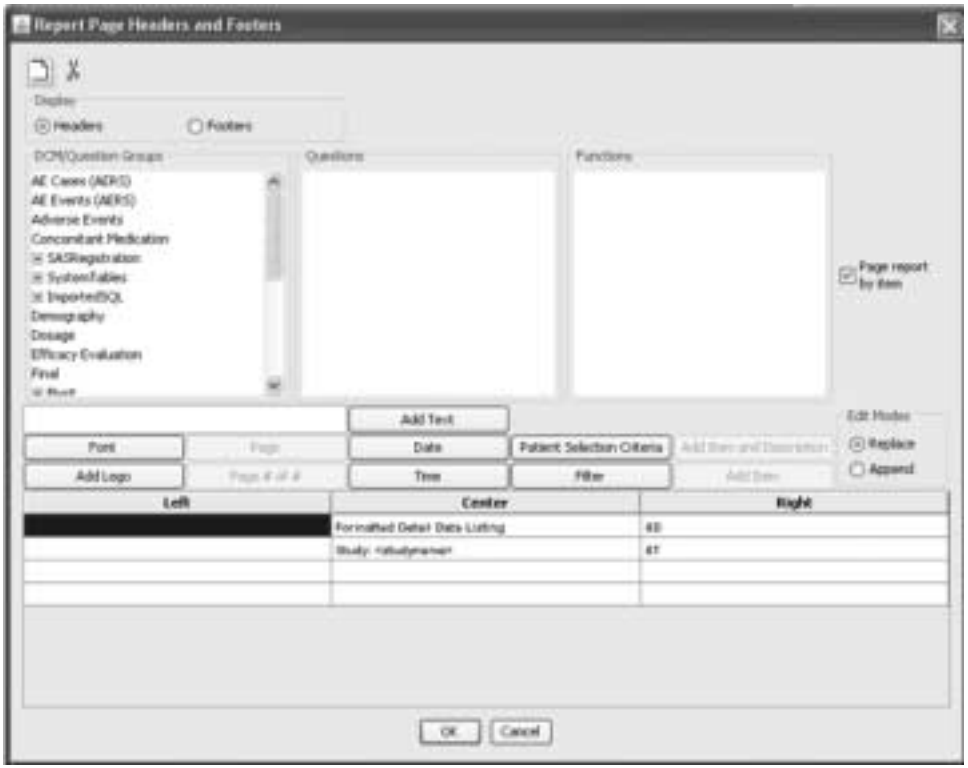
When you select the report type for Formatted Detail Data Listing or Formatted Summary Listing the associated function buttons are displayed. Overall report default settings are:

- Font is Arial.
- Page Setup for landscape with one inch margins.



To enter descriptive information to the Header and Footer area:

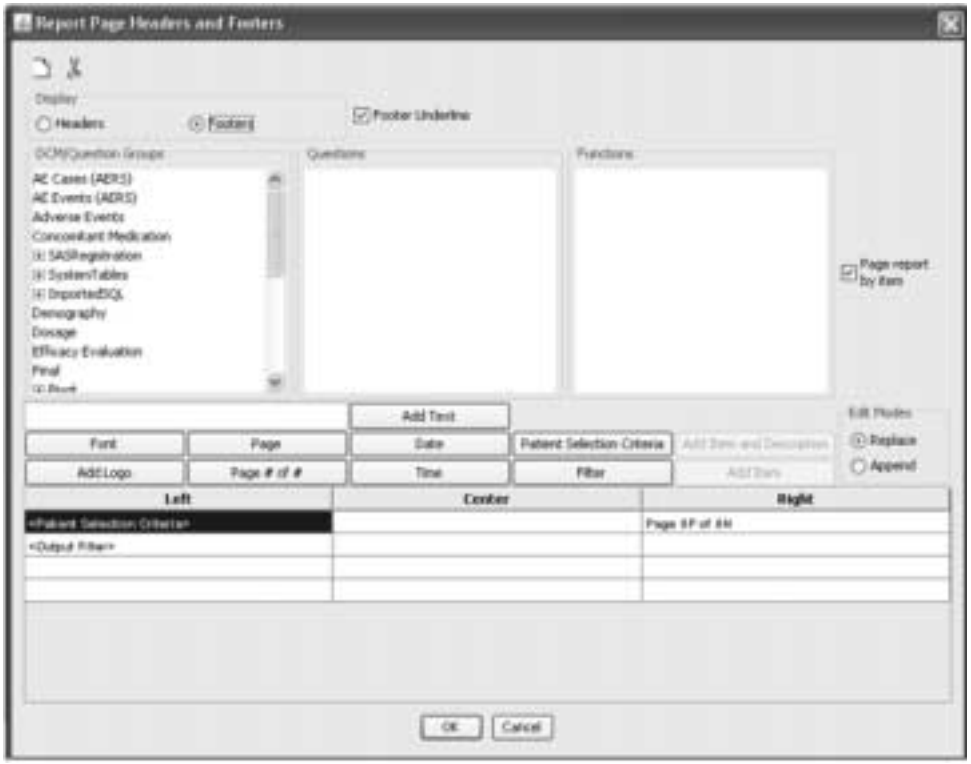
1. Click on the Page Header / Footer button to open Report Page Headers and Footers window. The default settings for headers are:
   a. Default title is the report type displayed in the center cell as Formatted Detail Data Listing or Formatted Summary Listing.
   b. Date and Time on the right.
   c. Font is BOLD **10.**
   d. Page Report By Item.



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**.

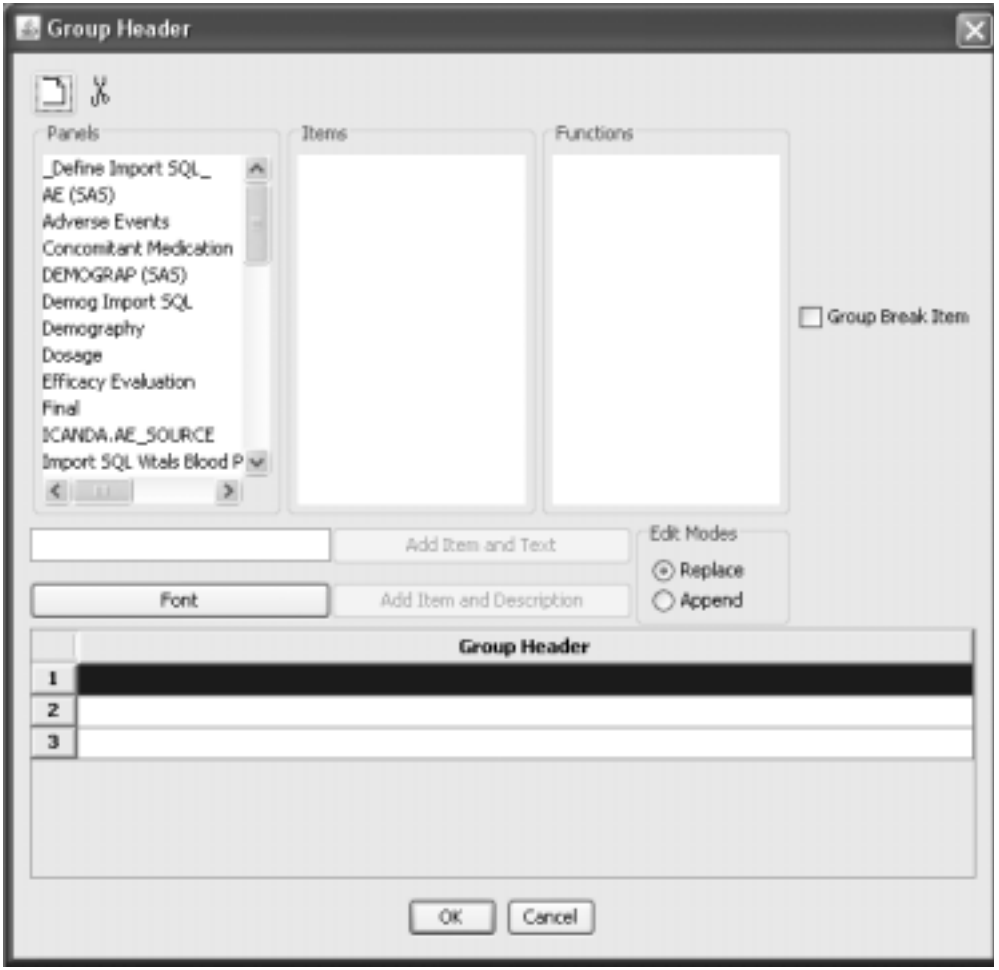
Note:It is not required to have an item be defined as a page by item, and more than one item can be defined.

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.



Enter a Group Header

1. Click on the Group Header button to open the Report 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.

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.

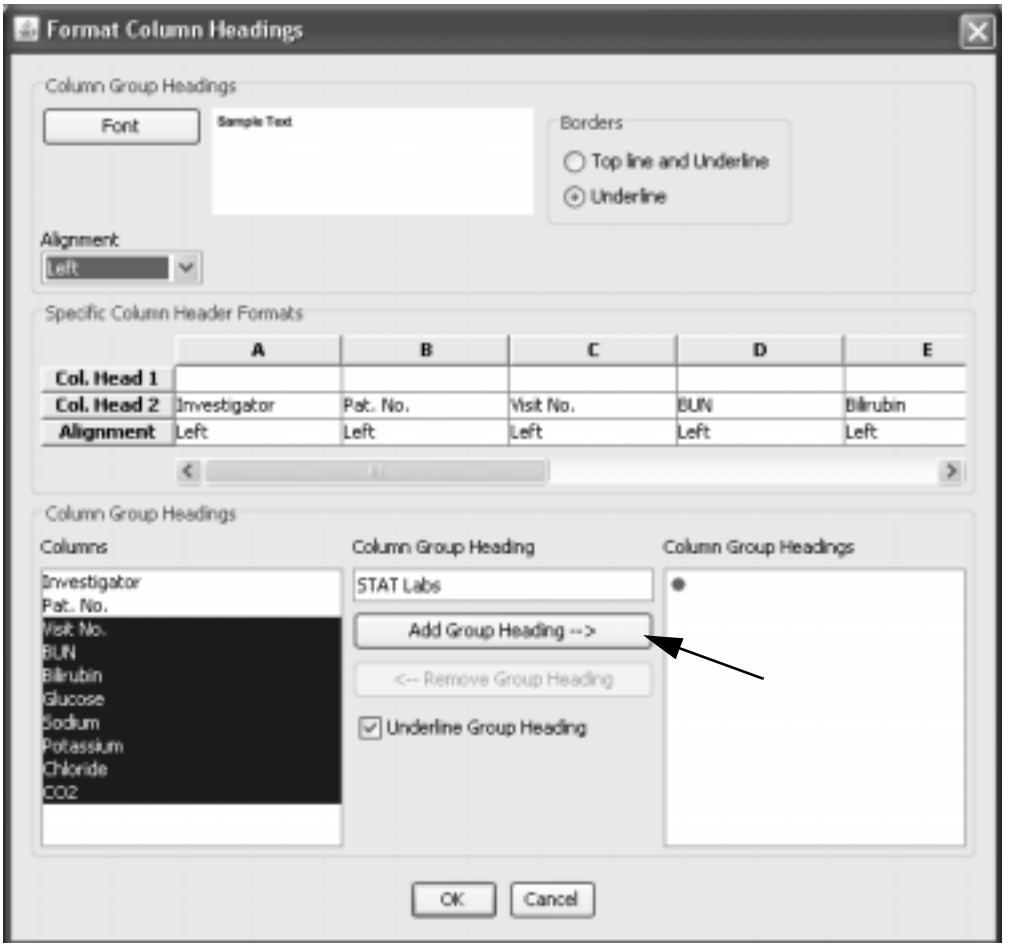
To apply Overall Column Header Formats:

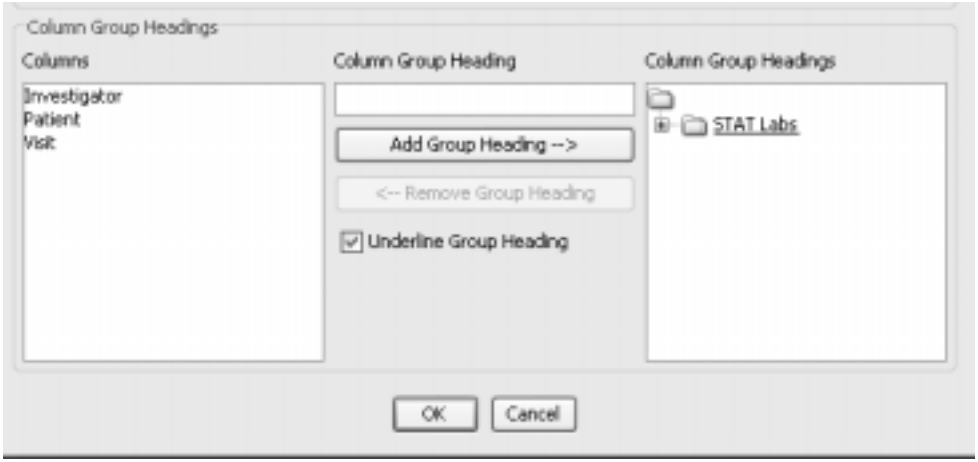
1. Click the Font button to change font, style and size.
2. Change the borders.
3. Apply a Specific Column Header Format by clicking the drop down list for alignment. Change from default center to auto, left, or right.

   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.





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.

1. To open the Report Column Formatting window, click on the F**ormat Column** button.

   The default setting alignment is automatic based on the data type.

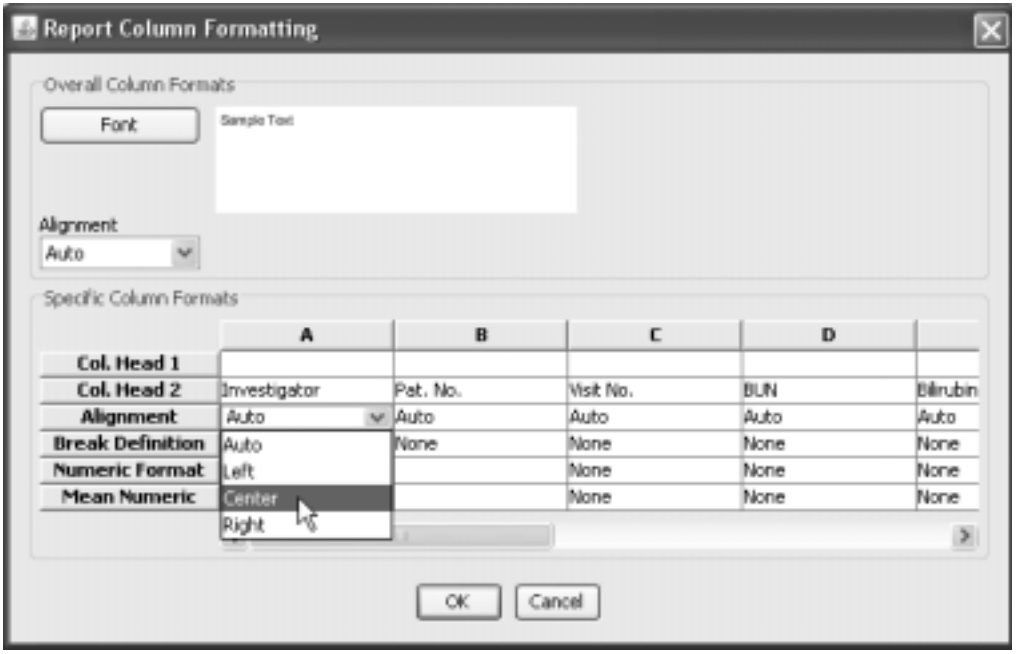
   Break definition is set to none and font is regular **8.**

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.

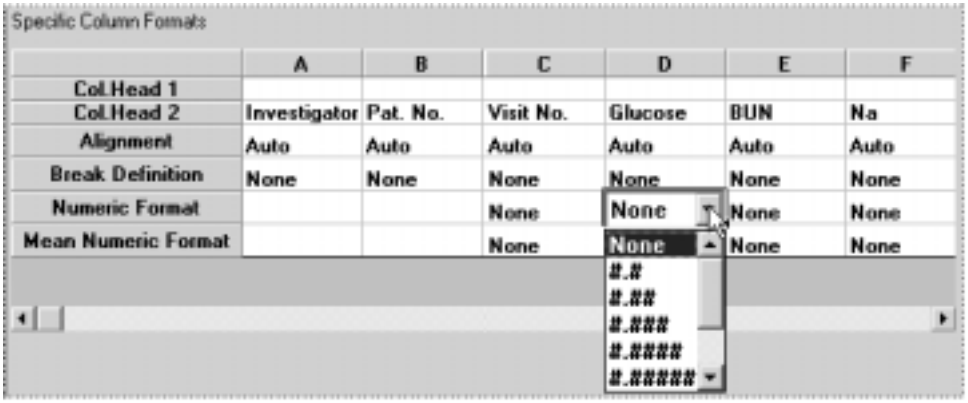
4. Click the **Break Definition** drop down list for None, Skip line, Underline, Page.

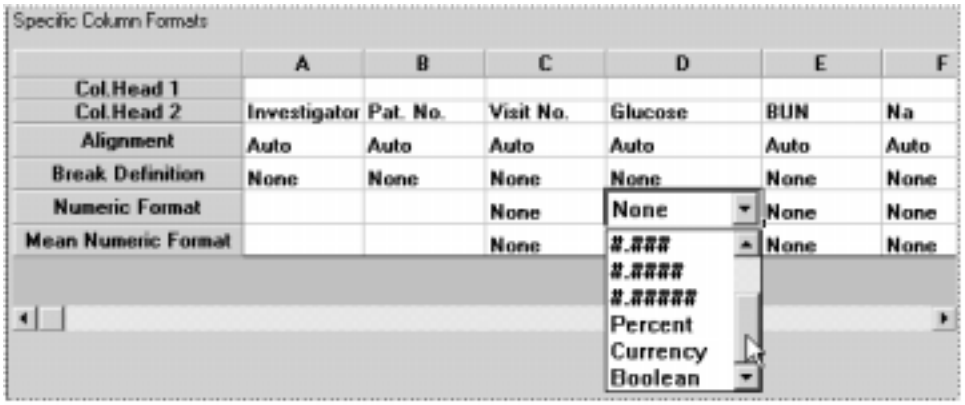


5. Click the **Numeric Format** drop down list for any numeric item included as a column in the report.

   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%.

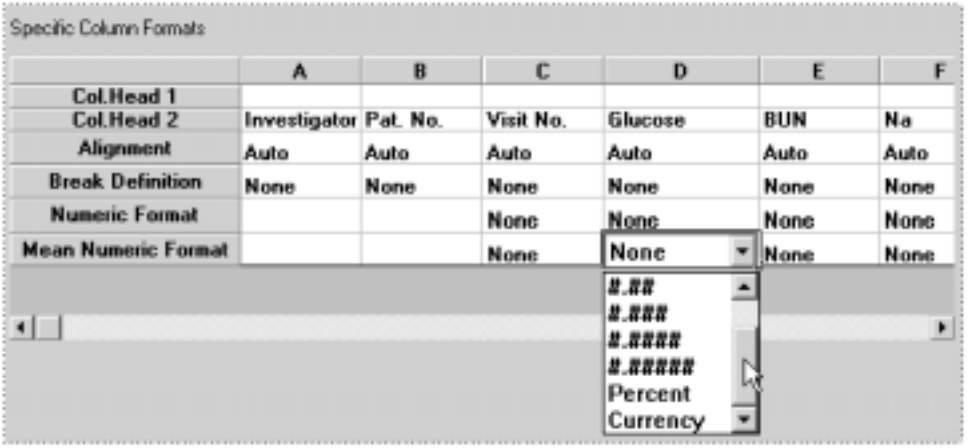
   The Boolean numeric format would be used on a calculated field where '0=False' and all other numeric values will display as 'True'.





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.



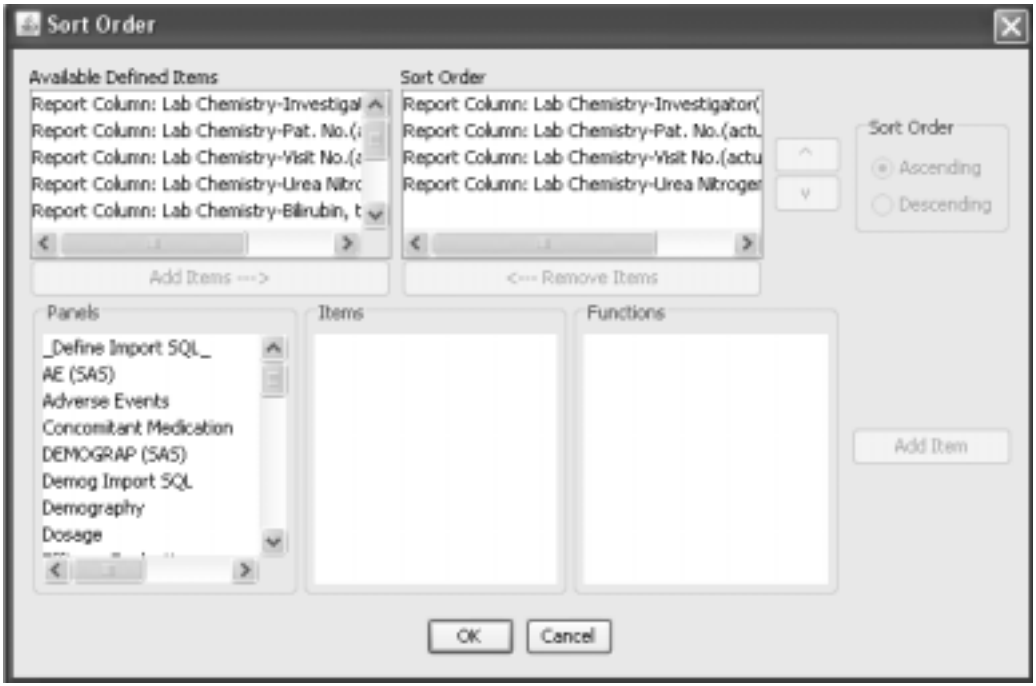
7. Click **OK**, to save Report Column Formatting.

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.

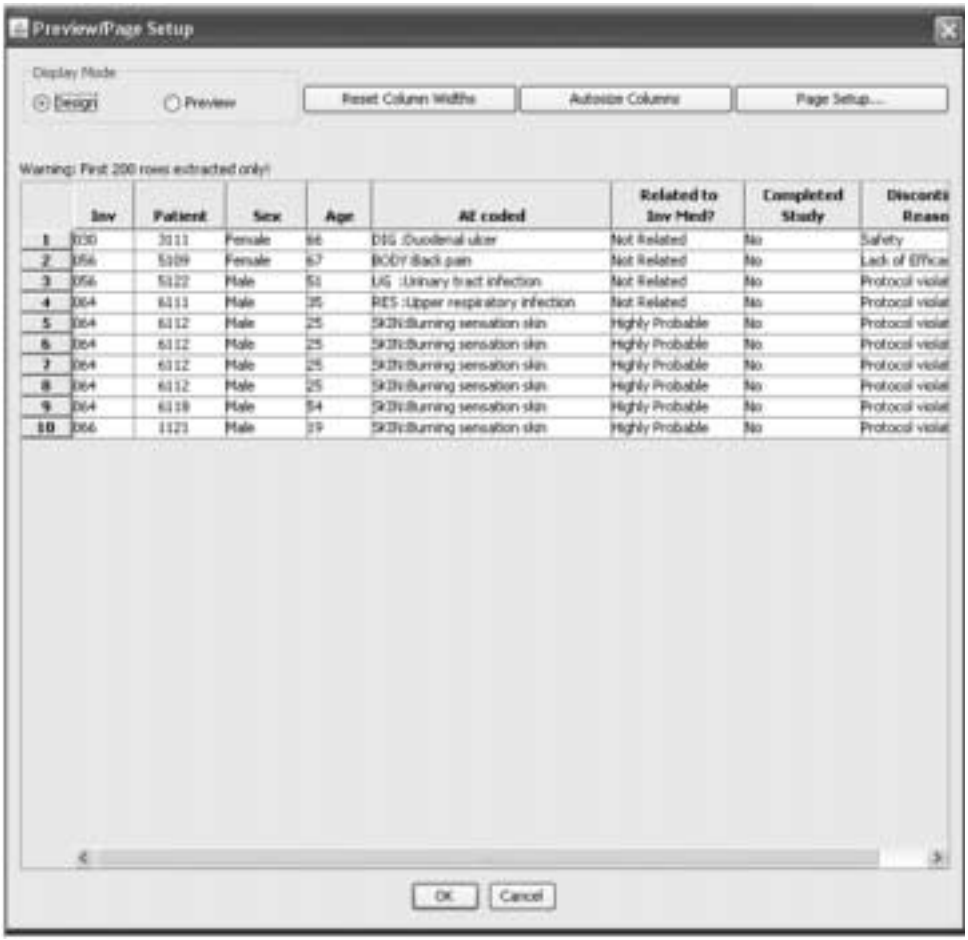
Note: It is advised to define all areas of the report prior to defining the sort.



- 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.

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'.



Note: See Print Preview function from the File menu for non-formatted reports.

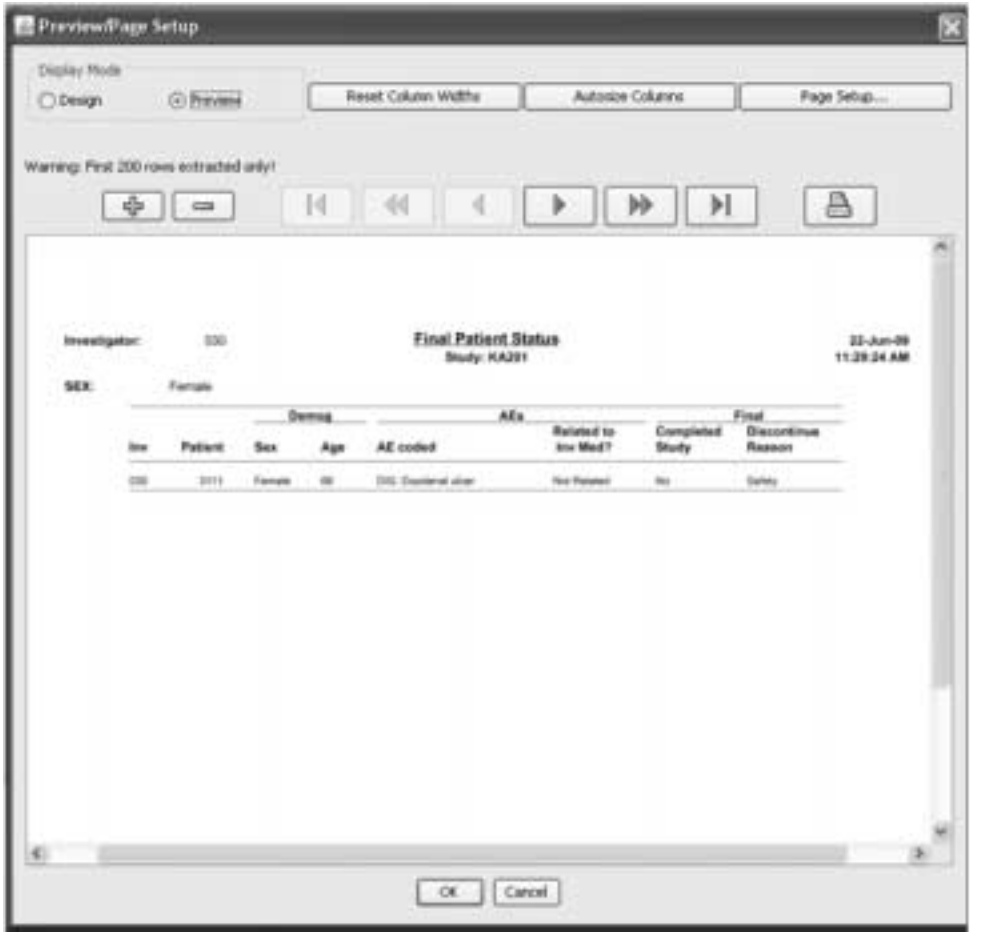
The default display is landscape and the settings are maximum column width of one inch. The width is set to fit all columns on a page depending upon the number of columns in the report.

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.

3. Select Display Mode for 'Preview'.



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.

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.

You must create the report to view and print the entire records contained in the report.

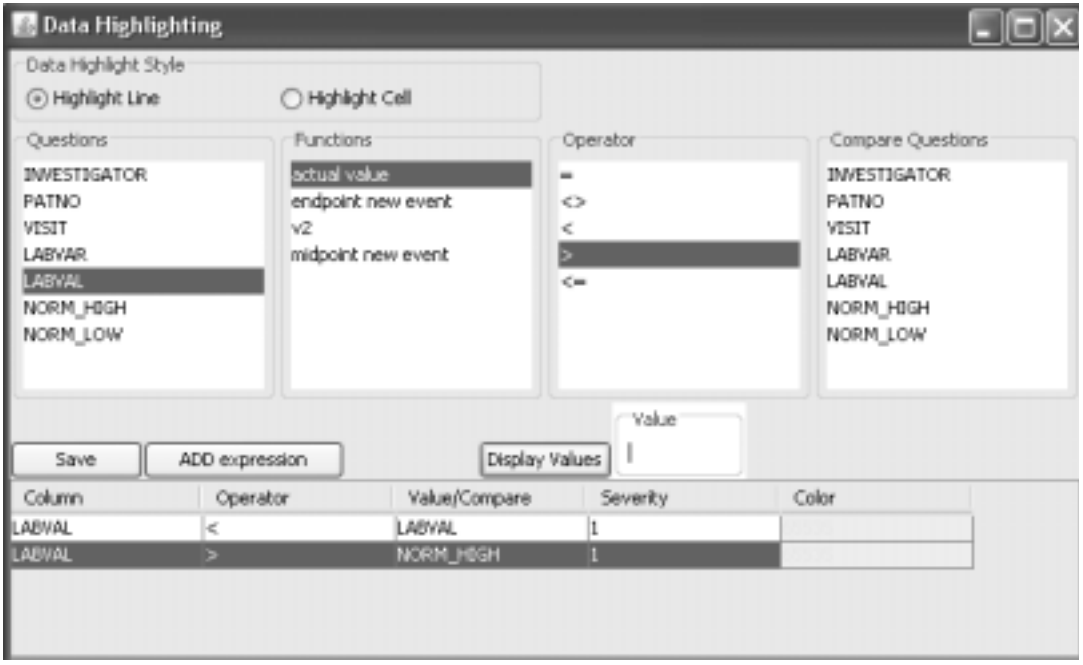
1. Click **OK** in the Preview window and return to the Report Browser window.
2. Click **Create Report**.
3. Use the tool bar buttons to scroll through the pages or change the image scale with the plus and minus signs.

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. 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. The data highlights can be applied to both regular reports (Detail Data Listing and Summary Listing) and formatted reports. The following example is a detail data listing for the vertical lab data table (Labs panel) with lab reference ranges included to compare to the actual lab values.

1. After adding items to the report specification, click the **Data Highlighting** button to open the Data Highlighting window which looks and operates similar to the output filter window.



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.

   The Data Highlighting button on the Report Browser changes status to show 'Data Highlighting ON'.

8. Click the **Create Report** button in the Report Browser.

This report displays with the option set to Highlight Line.

Detail Data Listing

	A	B	C	D	E	F	G	H
1								
2	INVESTIGATOR	PATNO	VISIT	VISIT_DATE	LABVAR	LABVAL	NORM_LOW	NORM_HIGH
3	018	4101	1	15-JUL-1991	ALB	3.83	3	5
4		4101	1	15-JUL-1991	ALK	97.75	67	135
5		4101	1	15-JUL-1991	BT	.34	.3	1
6		4101	1	15-JUL-1991	BUN	13.6	10	18
7		4101	1	15-JUL-1991	CHO	141.1	157	259
8		4101	1	15-JUL-1991	CO2	23.8	24	32
9		4101	1	15-JUL-1991	GTP	23.8	3	62
10		4101	1	15-JUL-1991	LDH	107.1	119	194
11		4101	1	15-JUL-1991	PO4	2.64	3	4
12		4101	1	15-JUL-1991	ZTP	5.87	6	8
13		4101	1	15-JUL-1991	SGP	21.25	8	57
14		4101	1	15-JUL-1991	SGO	20.4	16	37
15		4101	1	15-JUL-1991	NAB	122.4	128	161

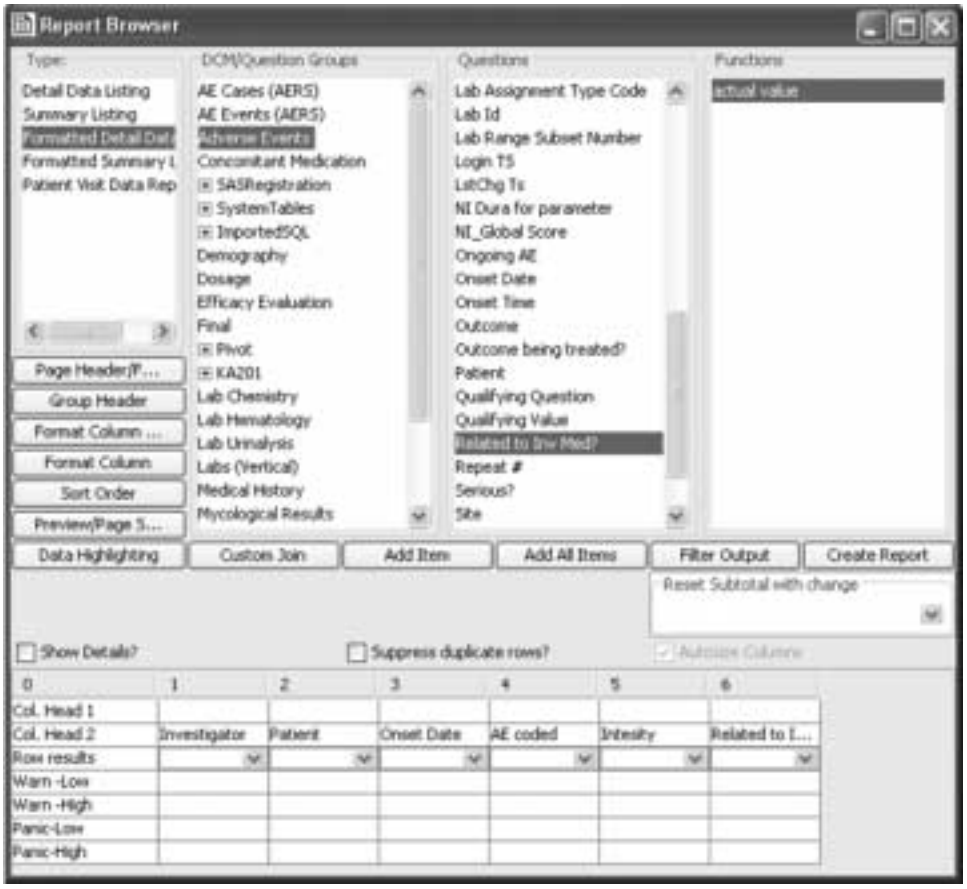
This is the same report displayed with the option set to Highlight Cell.

Detail Data Listing

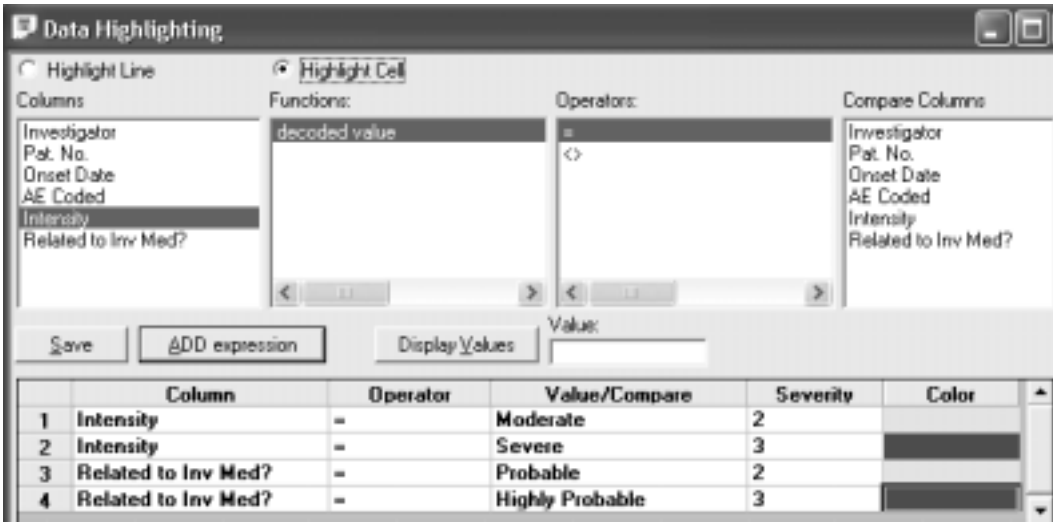
	A	B	C	D	E	F	G	H
1								
2	INVESTIGATOR	PATNO	VISIT	VISIT_DATE	LABVAR	LABVAL	NORM_LOW	NORM_HIGH
3	018	4101	1	15-JUL-1991	ALB	3.83	3	5
4		4101	1	15-JUL-1991	ALK	97.75	67	135
5		4101	1	15-JUL-1991	BT	.34	.3	1
6		4101	1	15-JUL-1991	BUN	13.6	10	18
7		4101	1	15-JUL-1991	CHO	141.1	157	259
8		4101	1	15-JUL-1991	CO2	23.8	24	32
9		4101	1	15-JUL-1991	GTP	23.8	3	62
10		4101	1	15-JUL-1991	LDH	107.1	119	194
11		4101	1	15-JUL-1991	PO4	2.64	3	4
12		4101	1	15-JUL-1991	ZTP	5.87	6	8
13		4101	1	15-JUL-1991	SGP	21.25	8	57
14		4101	1	15-JUL-1991	SGO	20.4	16	37
15		4101	1	15-JUL-1991	NAB	122.4	128	161

*Note: Data Highlighting is **not applicable** in the Patient Data Visit Report.*

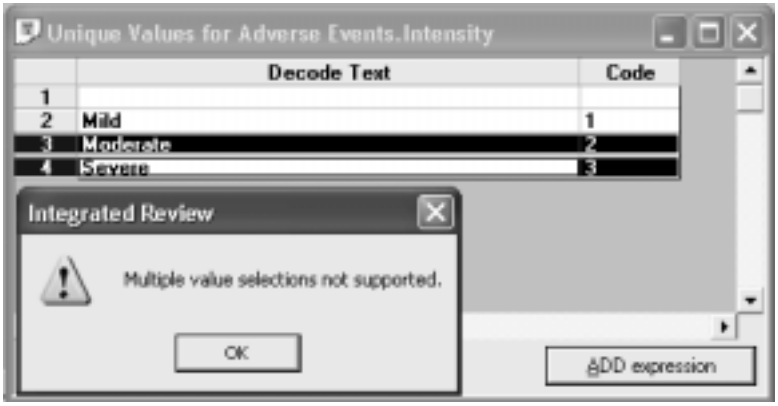
The following example is a formatted detail data listing of Adverse Events highlighting character data from a decode file.



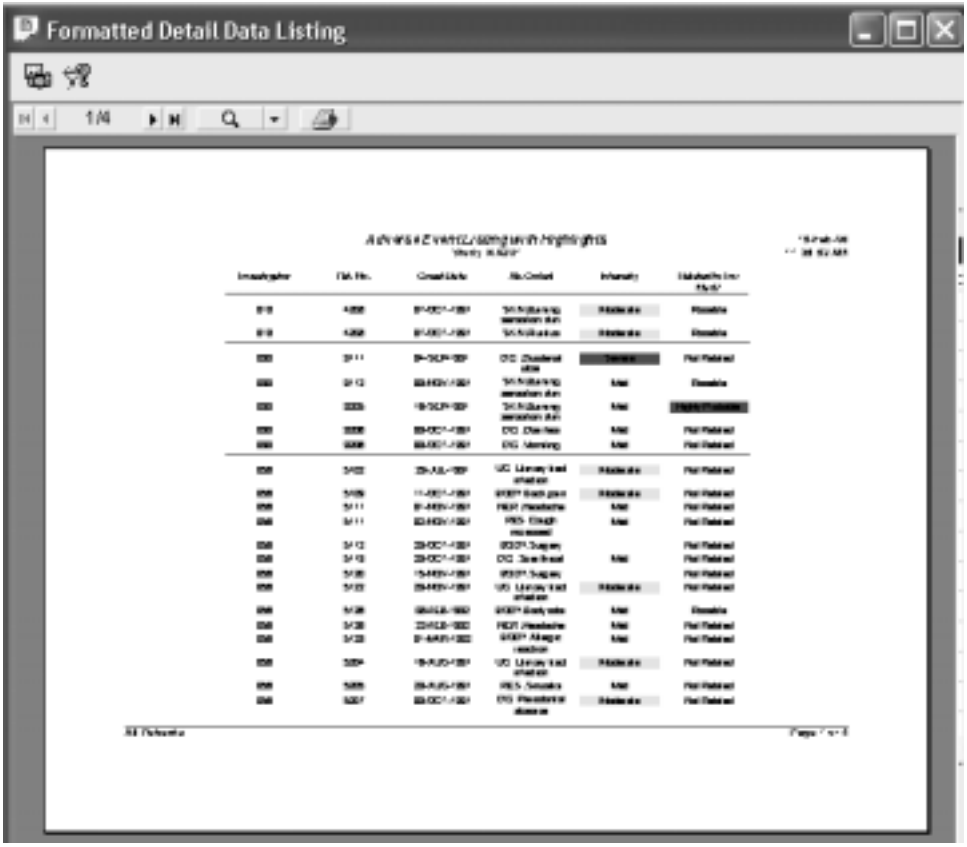
Data highlighting was applied to character decode values for 'Intensity' and 'Related to Inv Med?'. Severity levels and color were entered and data highlighting set to 'Highlight Cell'.



Selecting multiple items from the Unique Values list is not allowed. Each item must be an individual selection to assign a Severity and Color.



Individual data items are highlighted for ‘Intensity’ and ‘Related to Inv Med?’ based on the saved data highlighting criteria.

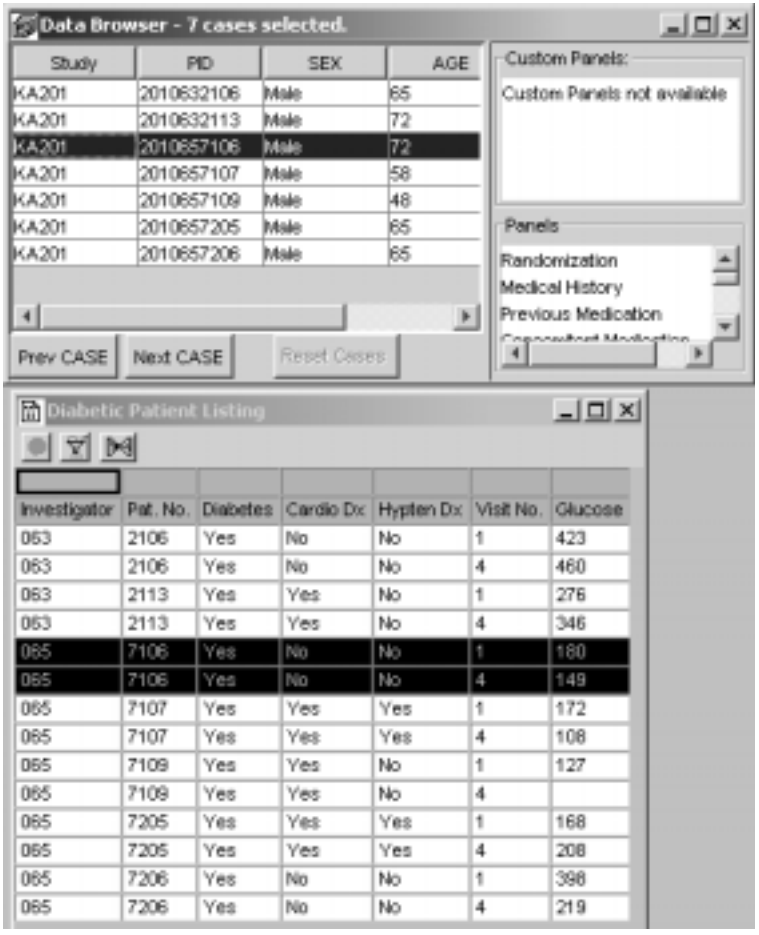


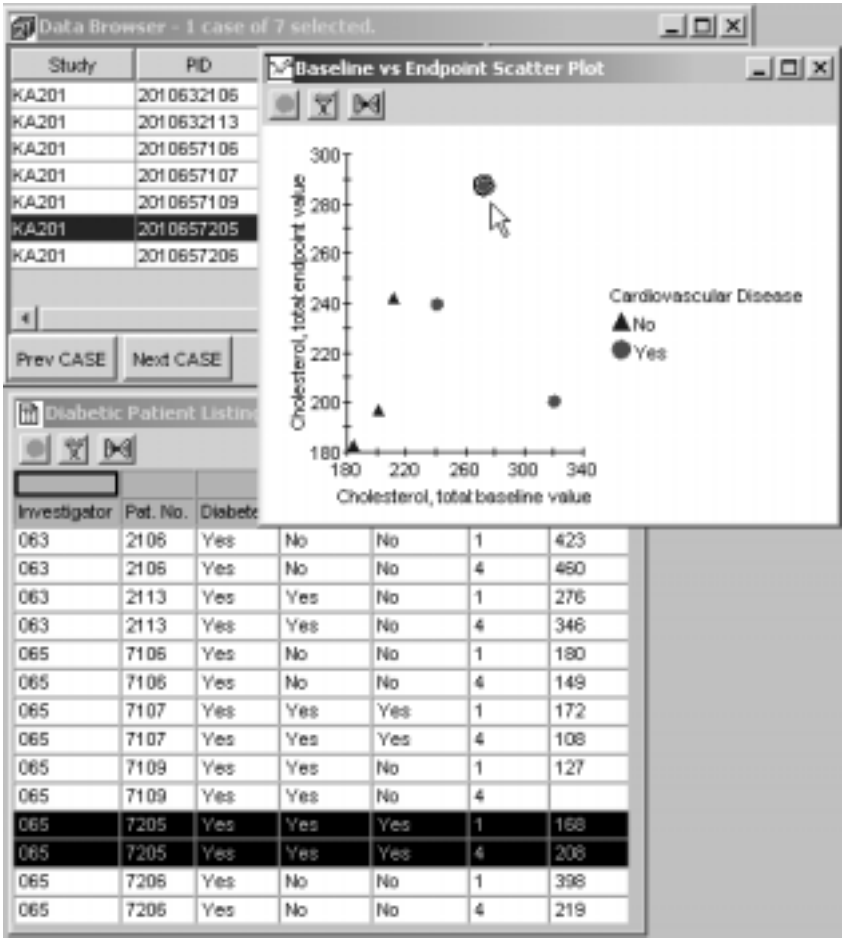
Highlighting patients

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.

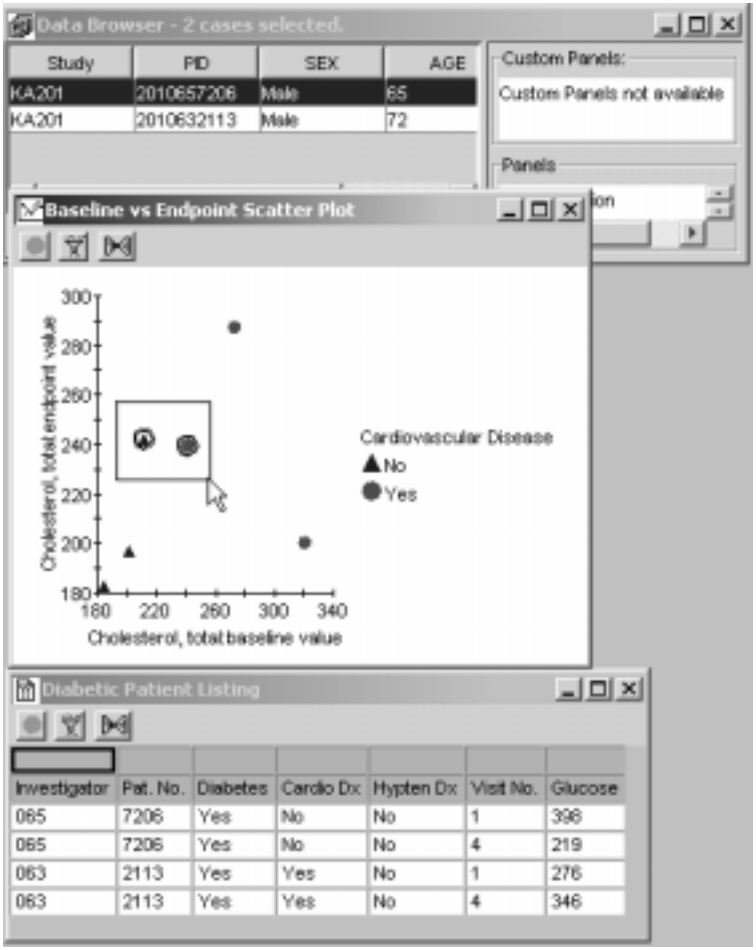
Click on one patient row instantly highlights the corresponding patient and data in any other active patient-level reports, patient listings, and Scatter Plot graphs. In an active scatter graph, the selected patient's data point is highlighted.





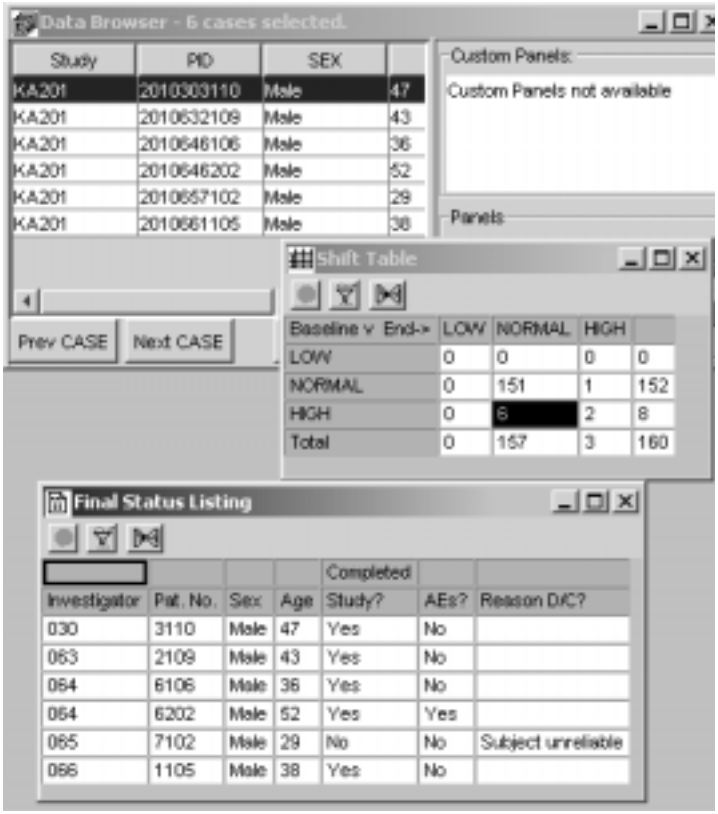
Multi-Line Chart not yet supported by JReview. In an active Multi-Line Chart Item Value vs. Category by Case graph, a highlighted line within the graph will update all patient-level displays of data to highlight the patient underlying the case data.

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.*)



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.


Data Browser - 6 cases selected.
Study
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
Custom Panels:
Custom Panels not available
Panels
Prev CASE
Next CASE
Shift Table
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
Final Status Listing
Investigator Pat. No. Sex Age Completed Study? AEs? Reason D/C?
030 3110 Male 47 Yes No
063 2109 Male 43 Yes No
064 6106 Male 36 Yes No
064 6202 Male 52 Yes Yes
065 7102 Male 29 No No Subject unreliable
066 1105 Male 38 Yes No

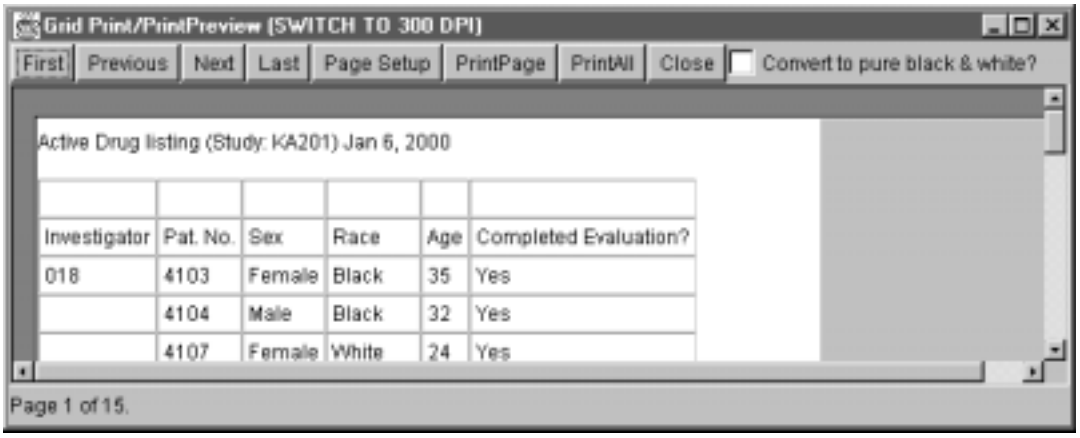
Printing and Exporting Results

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.



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.*

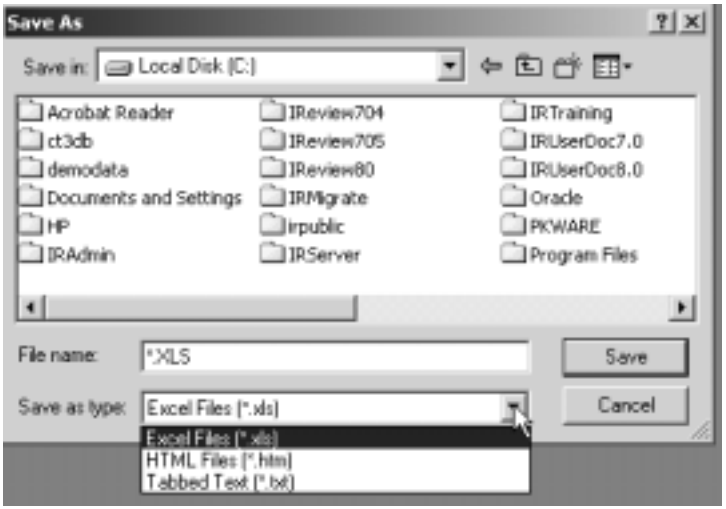
Caution: Do not select the Internet Browser's FILE menu Print option. This will cause a system error.

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 As** 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.*

Object Storage

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.*

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 **305**
Selection set 305
Execute a graph **305**
Quick execute 305
Graph types and features **306**
Graph features 306
Graph Browser window 306
Detail data graph 307
Summary data graph 307
Bar styles 308
Group functions 308
2D Graph Toolbar 309
Display BY variable 311
Graph manipulation keys 312
Data point select 313
Multiple graphs 315
Defining a graph specification **316**
Creating a graph specification 316
Change graph specifications 316
Page BY variable 317
X and Y scaling 318
Detail Data Graph Styles **319**
Scatter (Item X vs. Item Y) Plot 319
Scatter Plot with Regression Line 324
3-D Scatter Plot 326
Baseline vs. Endpoint Scatter Plot 328
MultiLine Chart Item Value vs. Category by Case 330
MultiLine Chart Item Value vs. Category by ByVar 332

Summary Graph Styles **334**
2-D Bar Chart Frequency Distribution 334
3D BarChart Frequency Distribution 338
2-D Bar Chart Item Summary vs. Category 340
3D BarChart Frequency Distribution 338
Pareto Chart fFrquency Distribution 344
Pie Chart Item Summary vs. Category 347
Line Chart-item vs. Category 351
Item Mean and Standard Deviation vs. Category 353

Output Filter **354**
Filter Controls 355

Snapshot output **362**
Multiple population mode 362
Multiple output for required selection criteria 365

Highlighting patients **368**
Single patient mode 368

Multiple patient mode **371**
Scatter plot graph 371
BarChart graph 375
Pie Chart 376

Graph Editing **377**
Graph settings 377

Printing and Exporting Graphs **378**
Printing the graph 378
Exporting the graph 379

Object Storage **380**

Exploring data **380**
Changing the patient selection criteria 380
Patient Identification 380

Closing graphs and the Graph Browser **381**
Closing a graph window 381
Closing the Graph Browser 381

Patient selection criteria

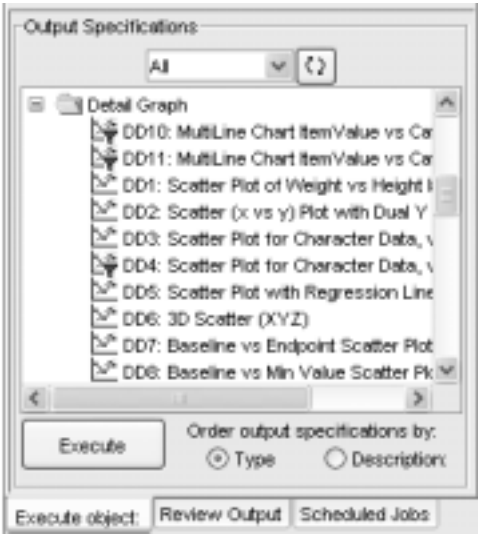
Selection set

In JReview, you can explore selected data items of the selected patients graphically by using the Graph Browser. After launching the saved patient subset 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 IReview or JReview.

Execute a graph

Quick execute

Both IReview and 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.)*



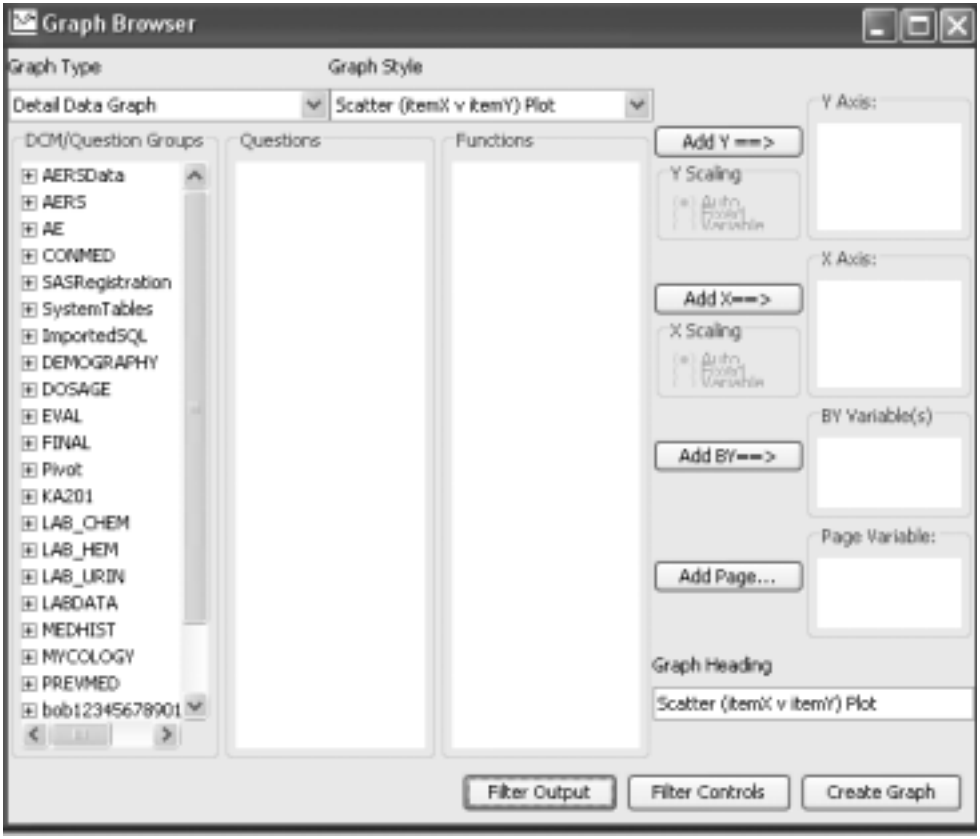
Graph types and features

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.

Graph Browser window

To open the Graph Browser window you can either select Graphs from the Browse menu, or click the Graph icon in the tool bar.

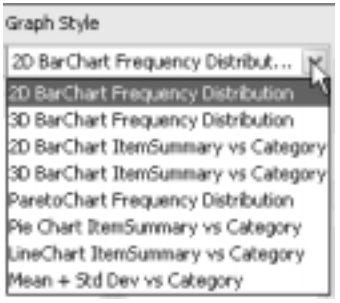


Detail data graph

Detail Data Graphs display individual patient data points for each patient observation. In JReview you can create the following Detail Data Graphs:

Summary data graph

Summary Data Graphs display summary information such as summary category, counts, means, and so on. In JReview you can create the following Summary Graphs:



Note: IReview supports some additional graph types.

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 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

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.

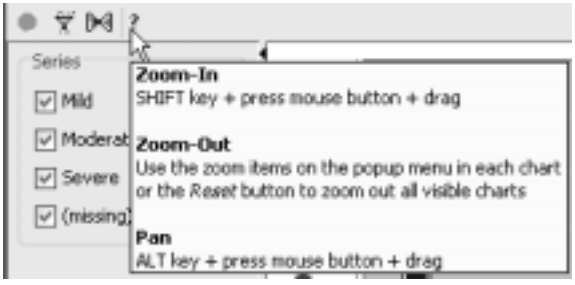
If you generate a graph without the multi-page option enabled the toolbar displays the buttons for 'Snapshot', 'Who?' and 'Output Filter'.

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.

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.

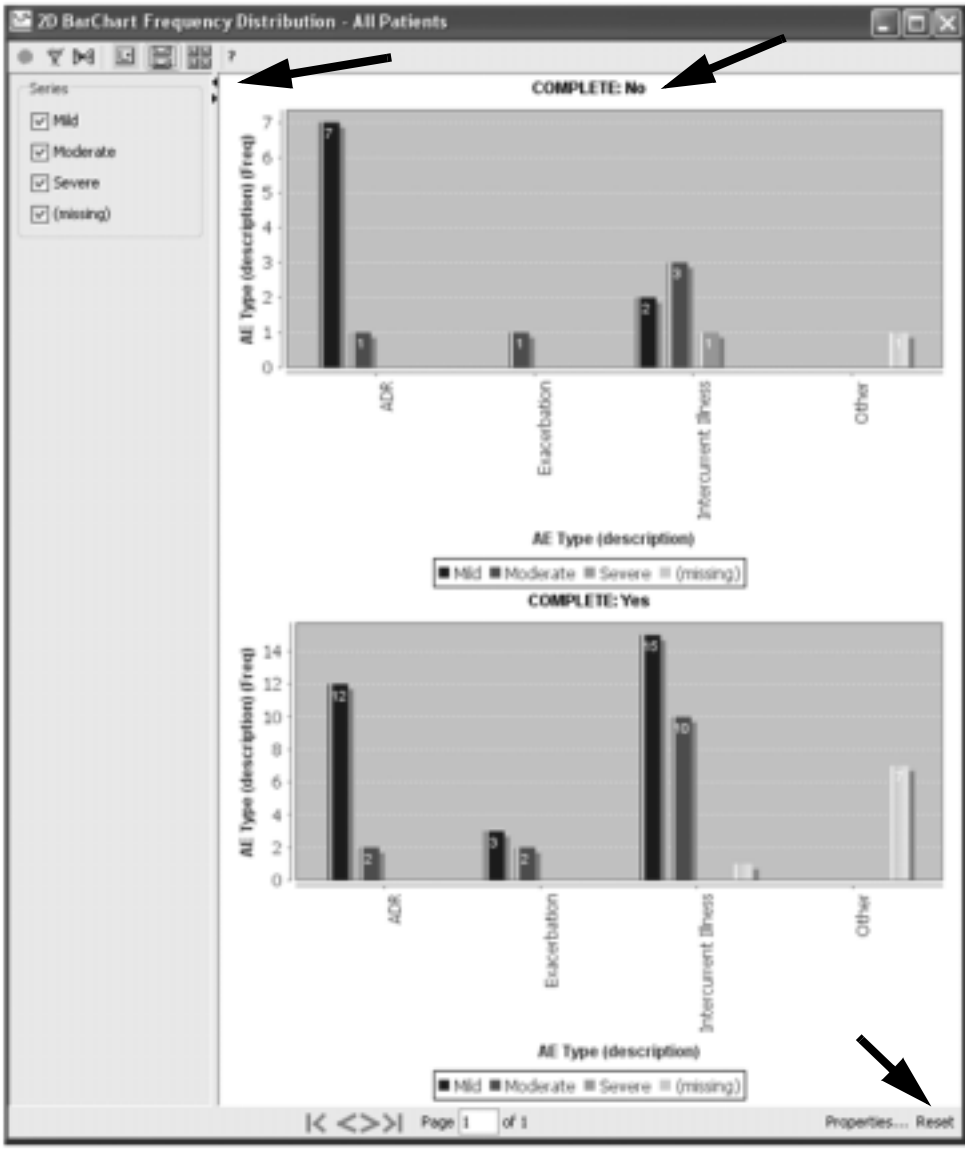
The "Question Mark" displays a graph manipulation key.



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 “Completed”, is displayed at the top of each graph. The page number is displayed at the bottom.

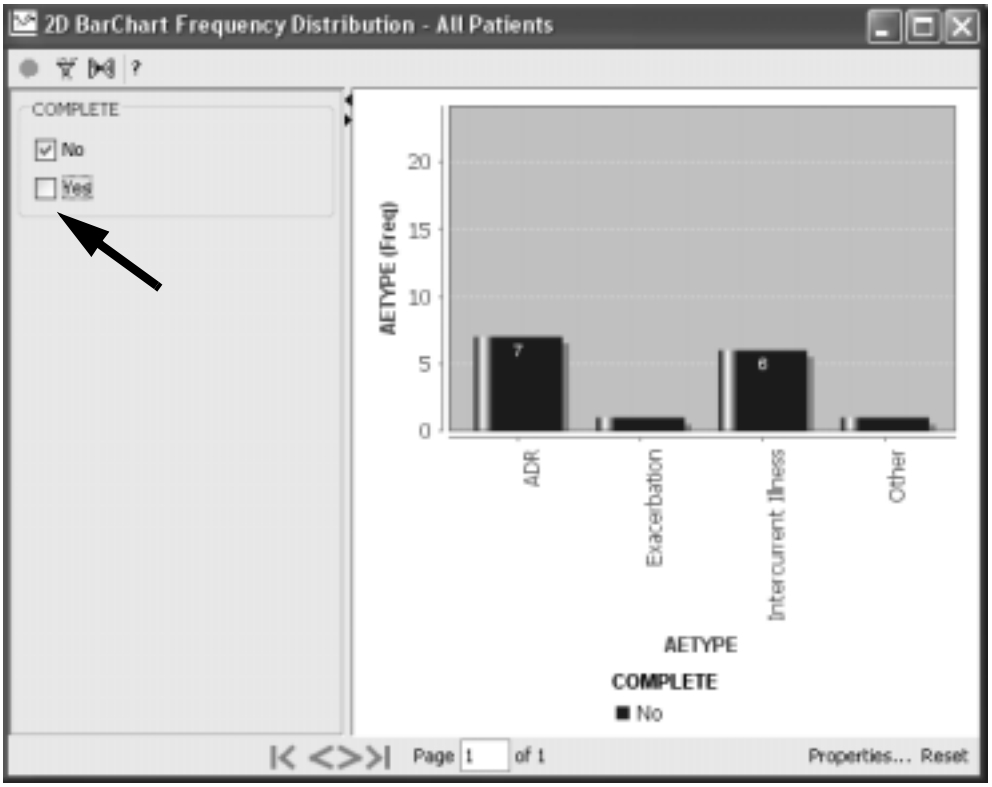
Use the top left black arrows to minimize, or display the legend **Series**.



Display BY variable

You may select which BY variable to display in the graph. Initally 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.

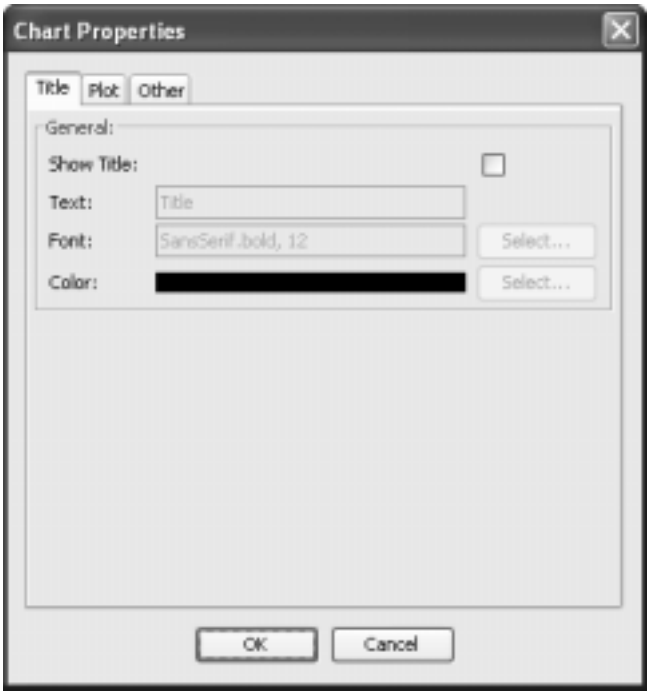
In this example, we turned off the patients who completed the study from displaying in the barchart (un-checked “Yes”).



Graph display keys

Graph manipulation keys

Click on “Properties” located in the graph footer, to display the Chart Properties window.



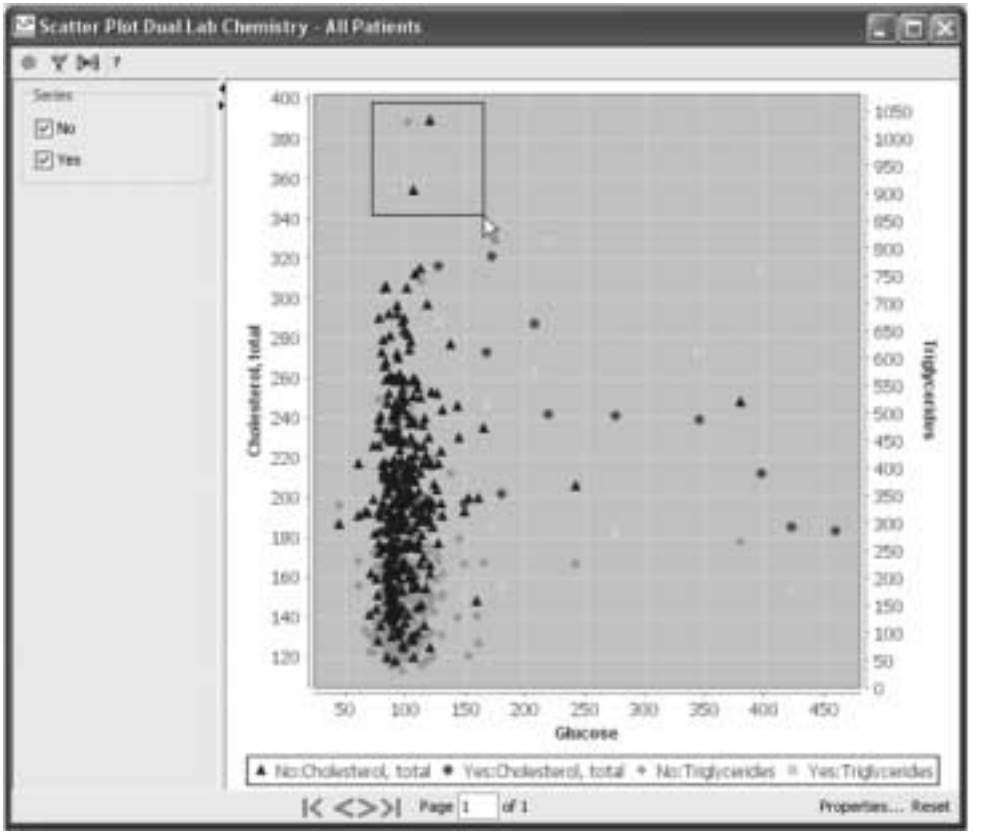
Click on the **HELP** menu in the tool bar and select **Graph & other keys**.

The message window displays outlining directions for the various graph manipulation keys.

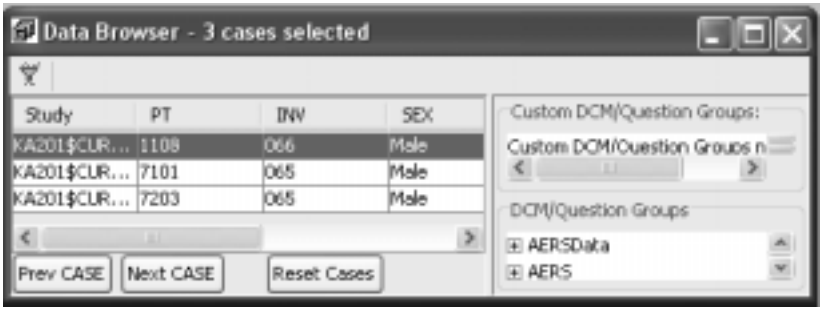
Data point select

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.

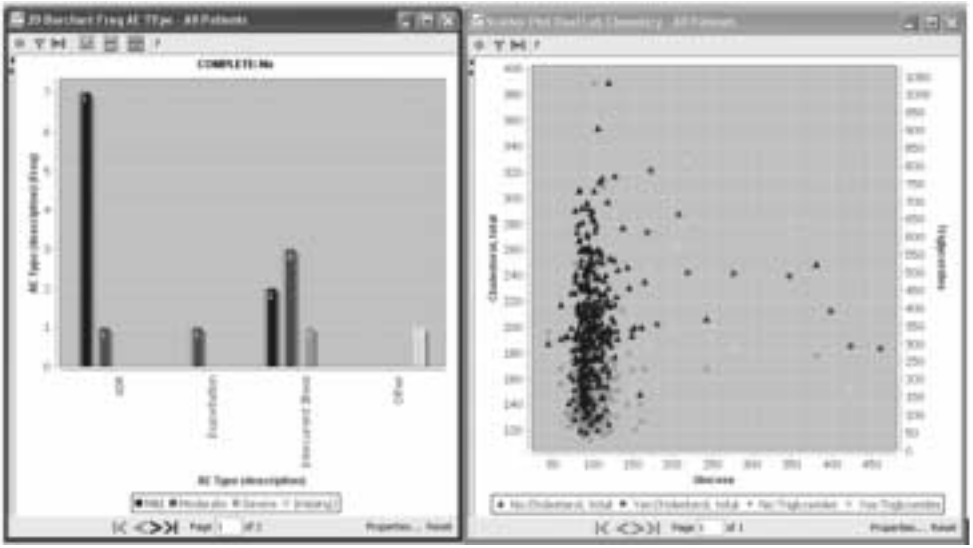


The Data Browser updates to display the selected cases.



Multiple graphs

You can have multiple graphs active at the same time by executing multiple graph objects.



Defining a graph specification

Creating a graph specification

Specify the contents of a graph by applying the same method that you used to build the patient selection criteria.

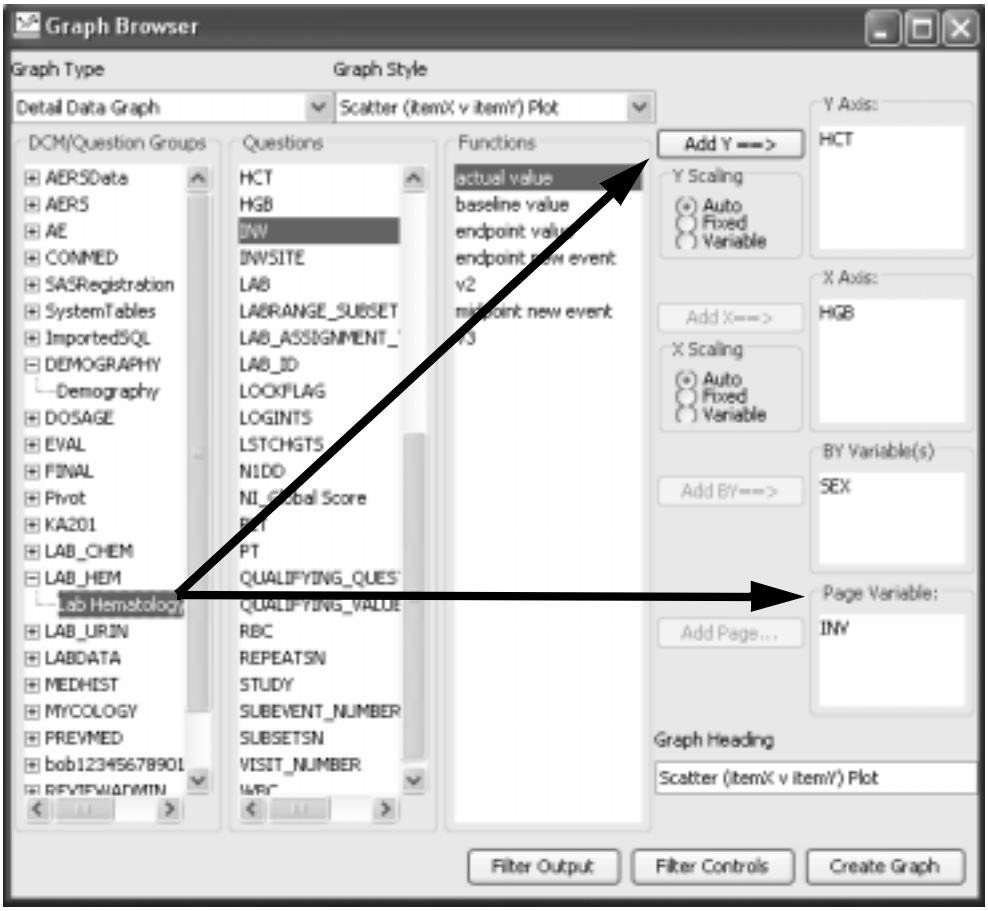
1. Select a Graph Type.
2. Select a Graph Style.
3. Select a panel and item with the appropriate function for the item.
4. Depending on the graph type and style selected, click the appropriate graph axis button to add the item to the graph specification.

   For example, click to add the selected item to the Y-axis on the right side of the Graph Browser window.
5. Enter a Add BY variable to group the data (optional).
6. Enter a Page BY variable (optional).
7. 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.
8. Click Create Graph.

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 .



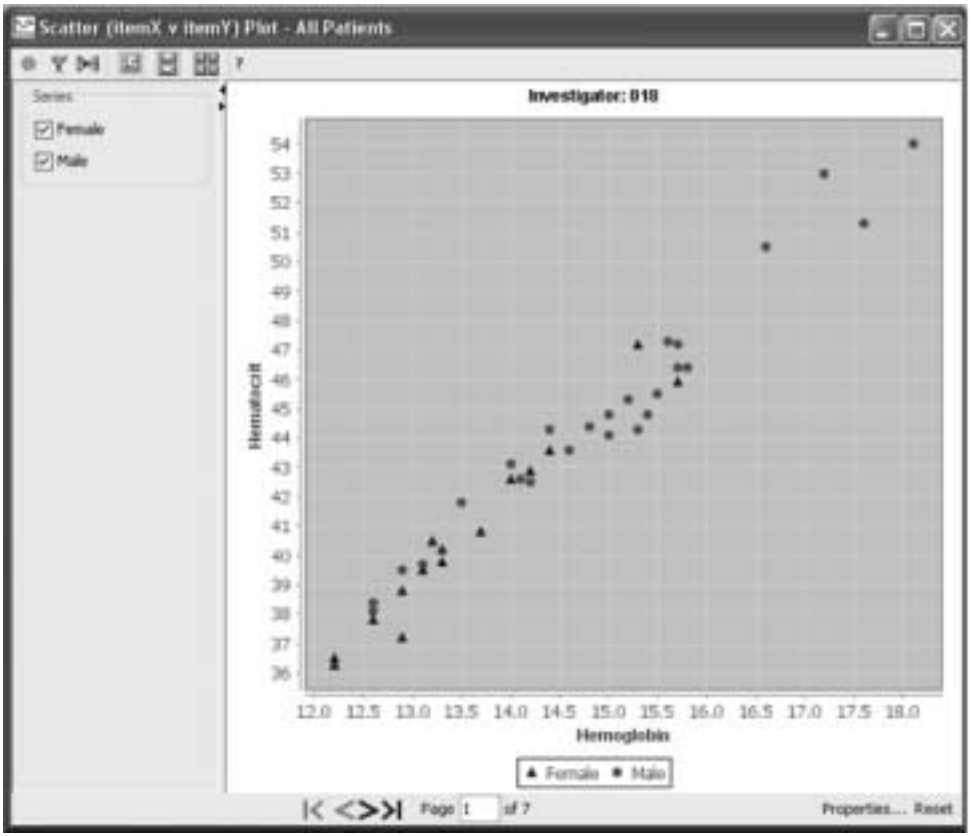
Page BY variable

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.

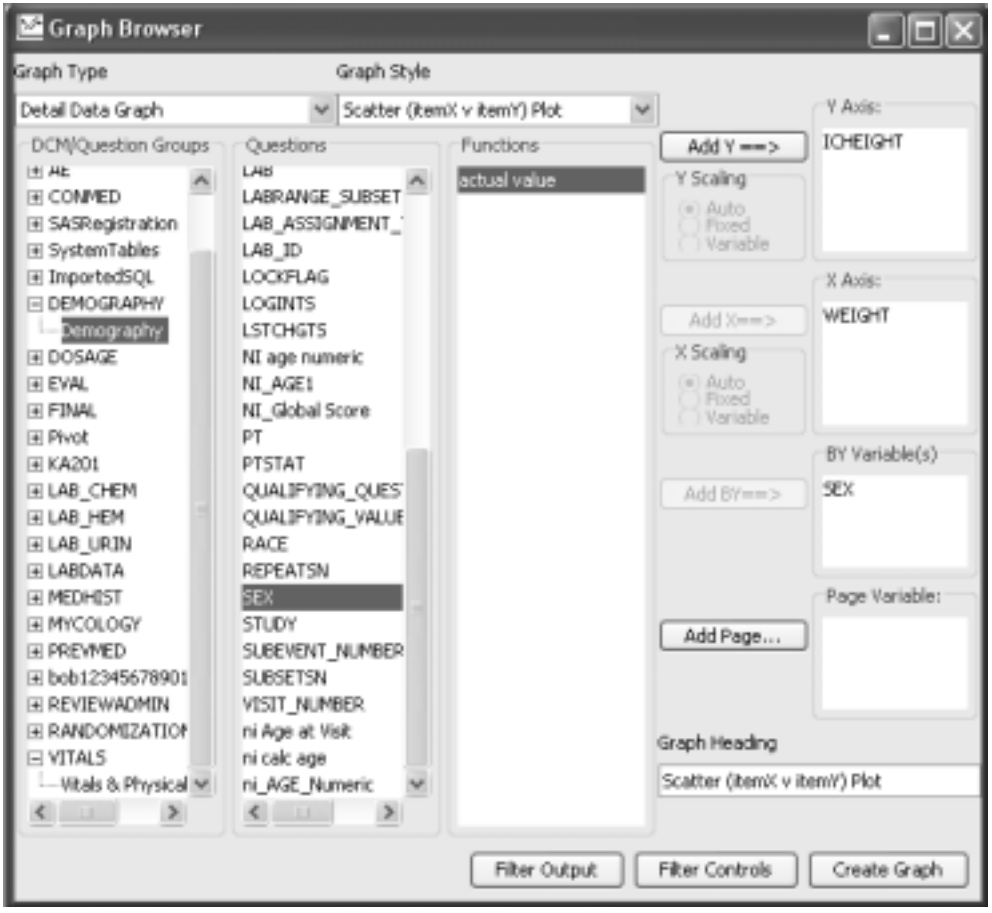
Detail Data Graph Styles

Scatter (Item X vs. Item Y) Plot

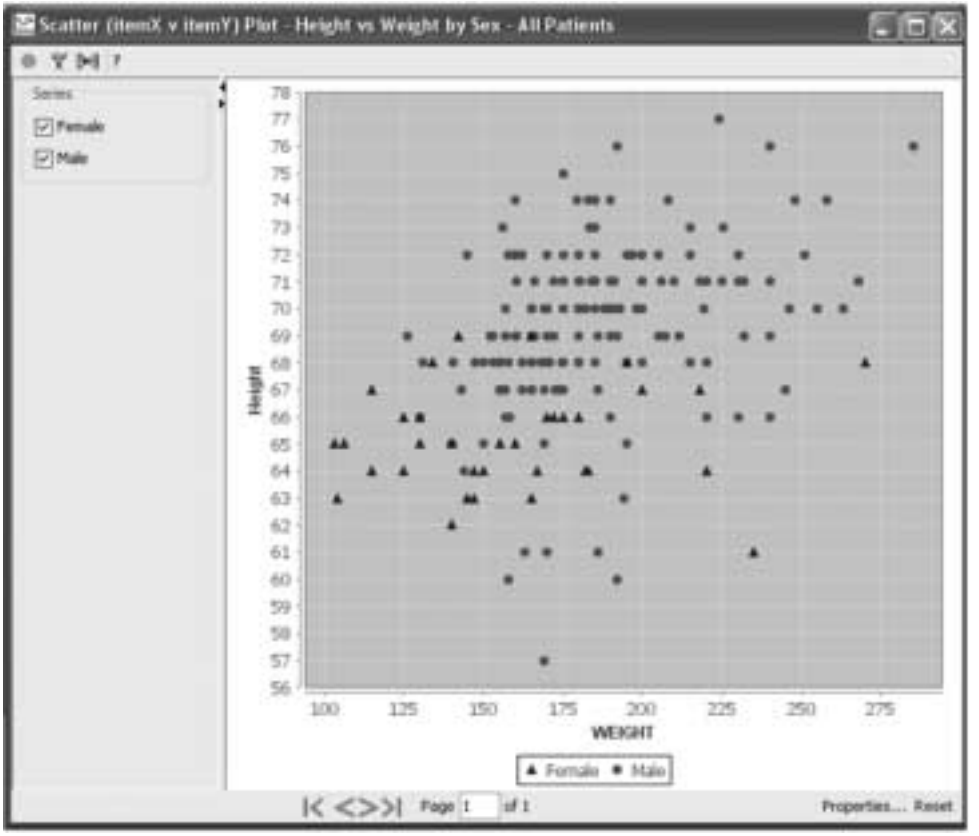
In a Scatter (Item X vs. Item Y) Plot graph, each data point corresponds to each patient's observation for item X and item Y.

Use the BY variable to subset graphic displays.

Optionally, change the default graph style for the graph header.



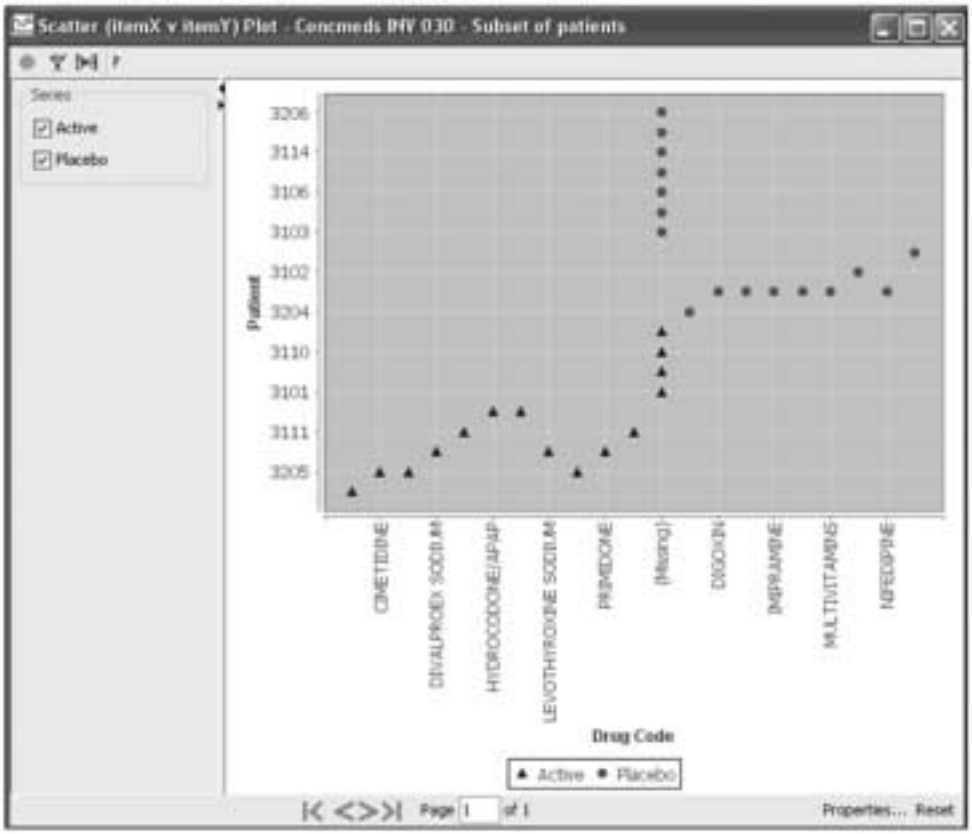
This scatter plot example displays numeric data. There is no restriction on the data type used.



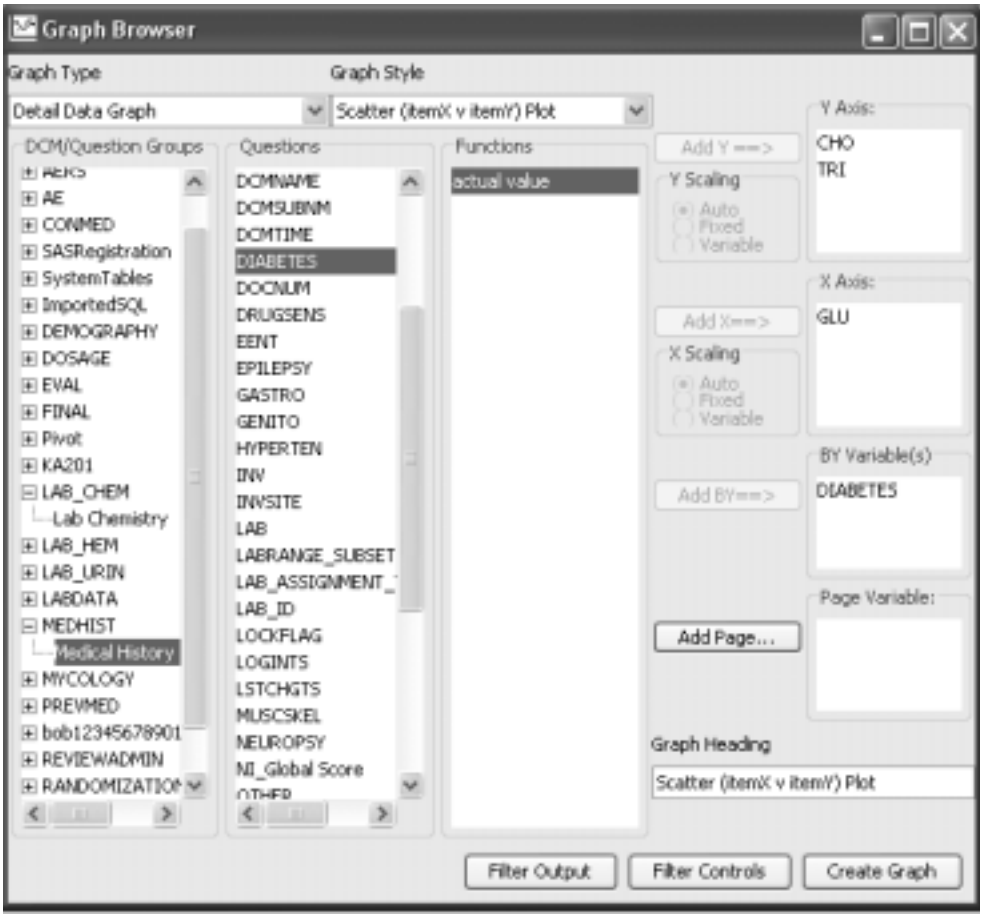
Character data is also supported. This example of the same graph type Scatter (Item X vs. Item Y) Plot with character data shows concomitant medications for individual patients.

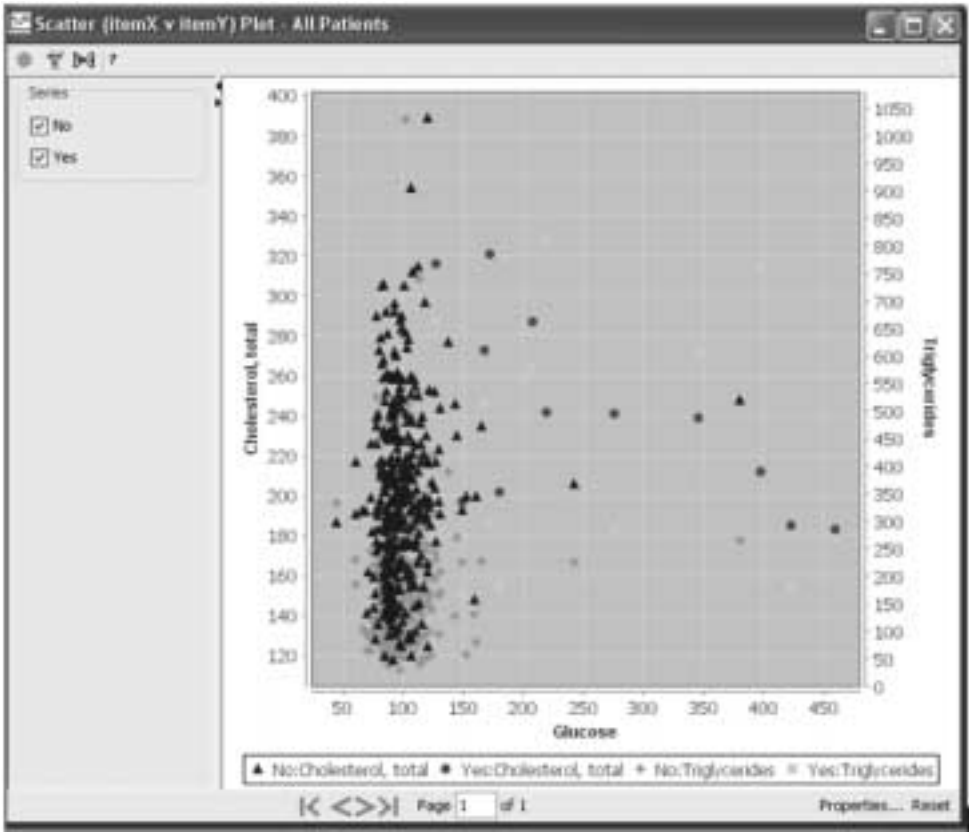
For this example, the data was subset for manageable size in viewing (approximately 20 values maximum on either the X-axis or Y-axis).

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).

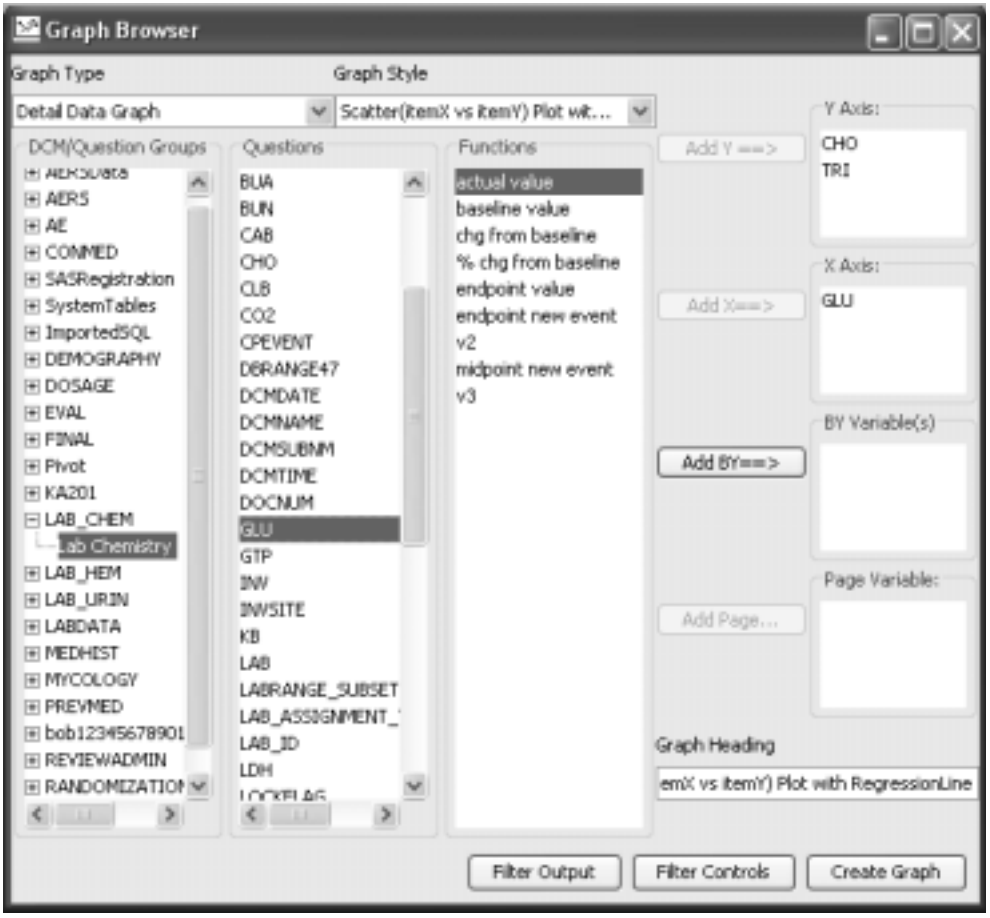


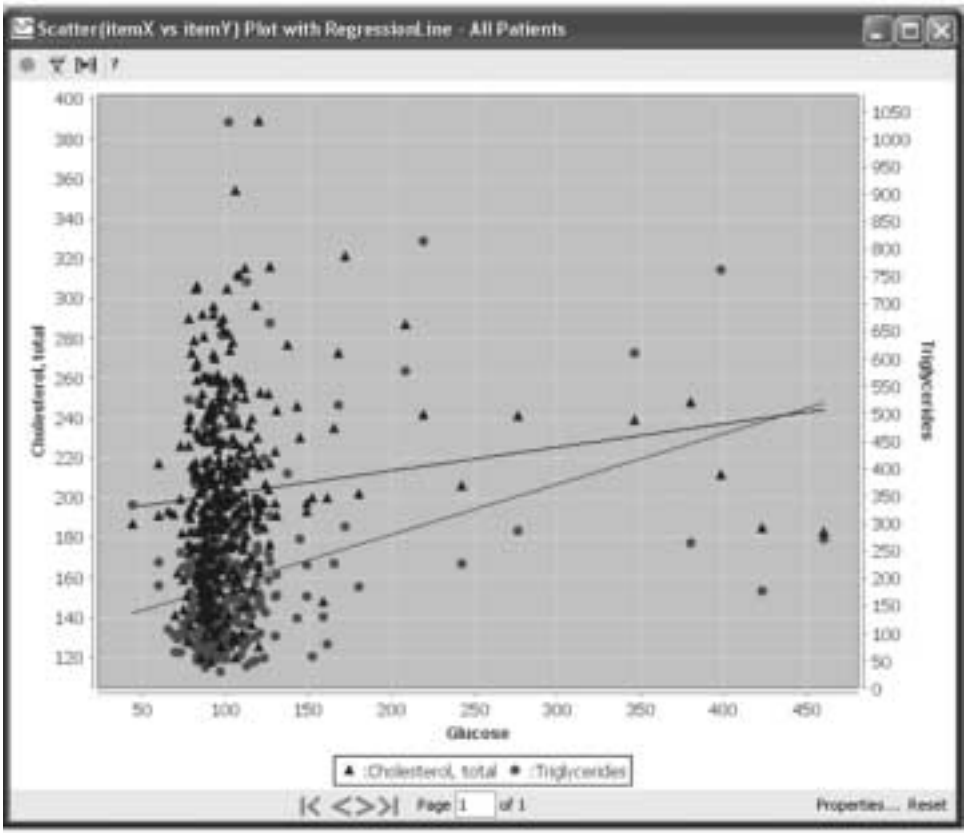

Scatter (itemX v itemY) Plot - All Patients
Series
No
Yes
Cholesterol, total
Triglycerides
Glucose
No:Cholesterol, total
Yes:Cholesterol, total
No:Triglycerides
Yes:Triglycerides
Page 1 of 1
Properties...
Reset

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)

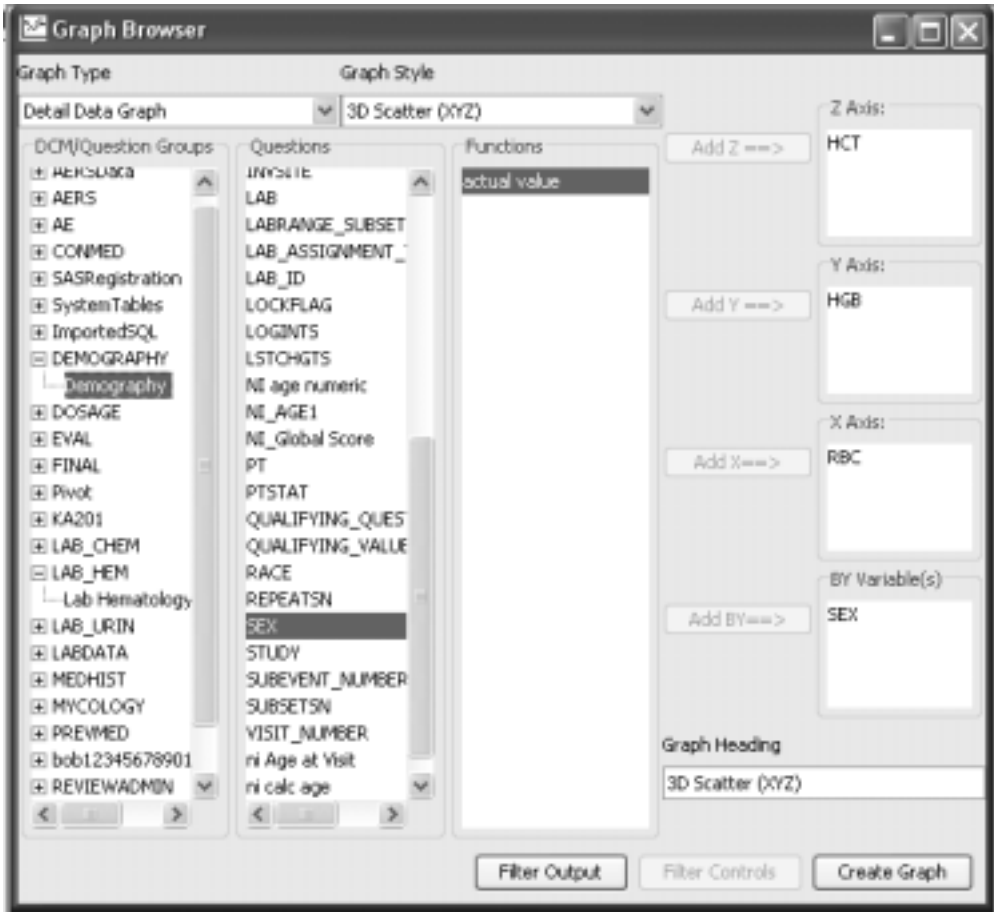
The Scatter Plot with Regression Line can also be plotted as two variables on the Y axis (dual Y axis mode).

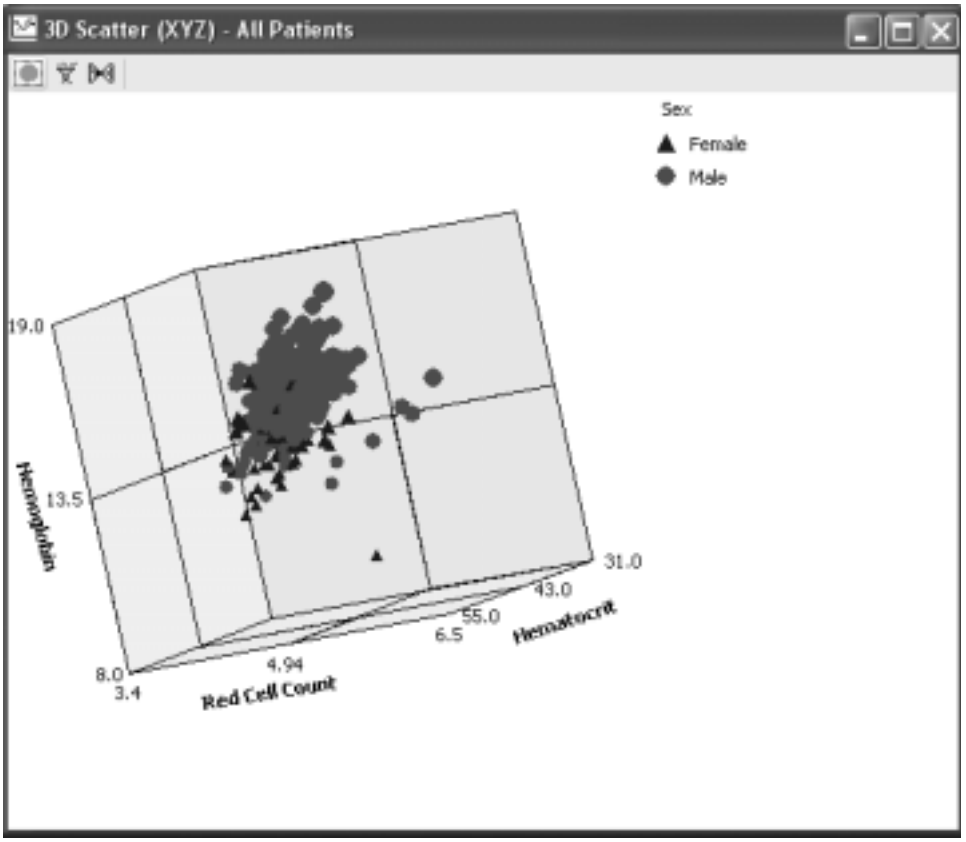



Scatter(itemX vs itemY) Plot with RegressionLine - All Patients
Cholesterol, total
Triglycerides
Glucose
:Cholesterol, total
:Triglycerides
Page 1 of 1
Properties...
Reset

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.

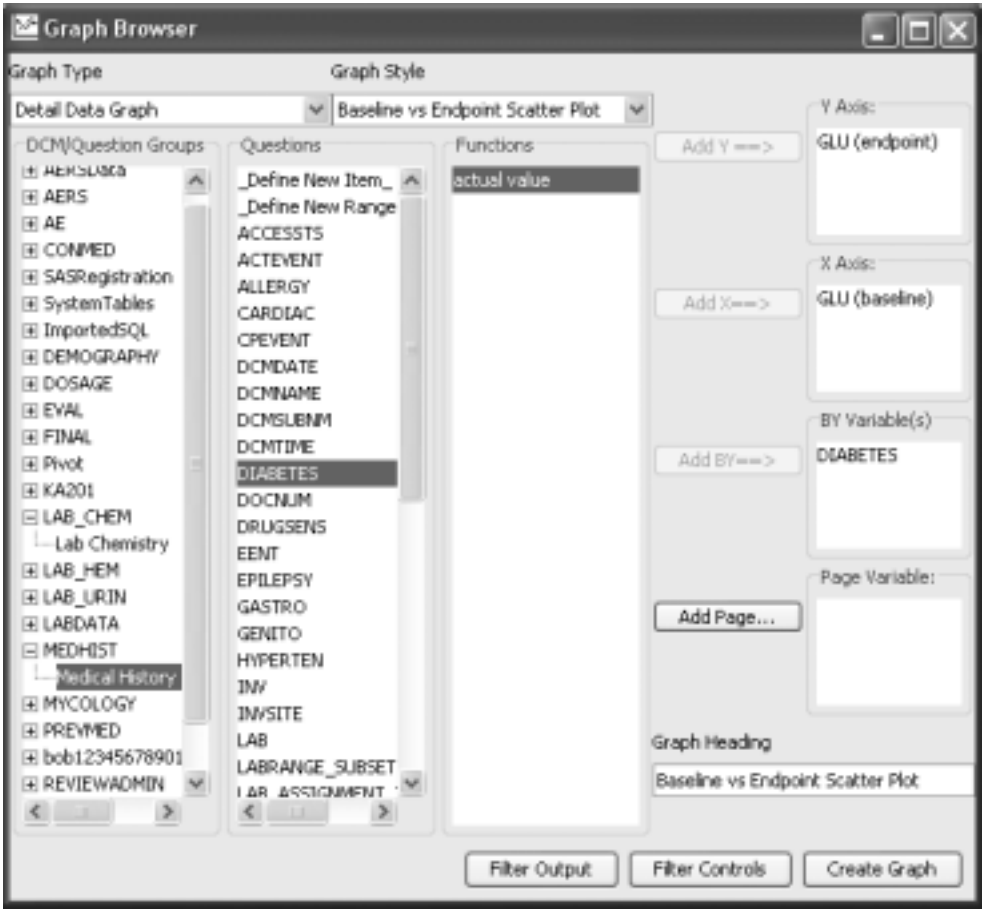



3D Scatter (XYZ) - All Patients
Sex
Female
Male
19.0
13.5
8.0
Hemoglobin
3.4
4.94
Red Cell Count
6.5
55.0
43.0
31.0
Hematocrit

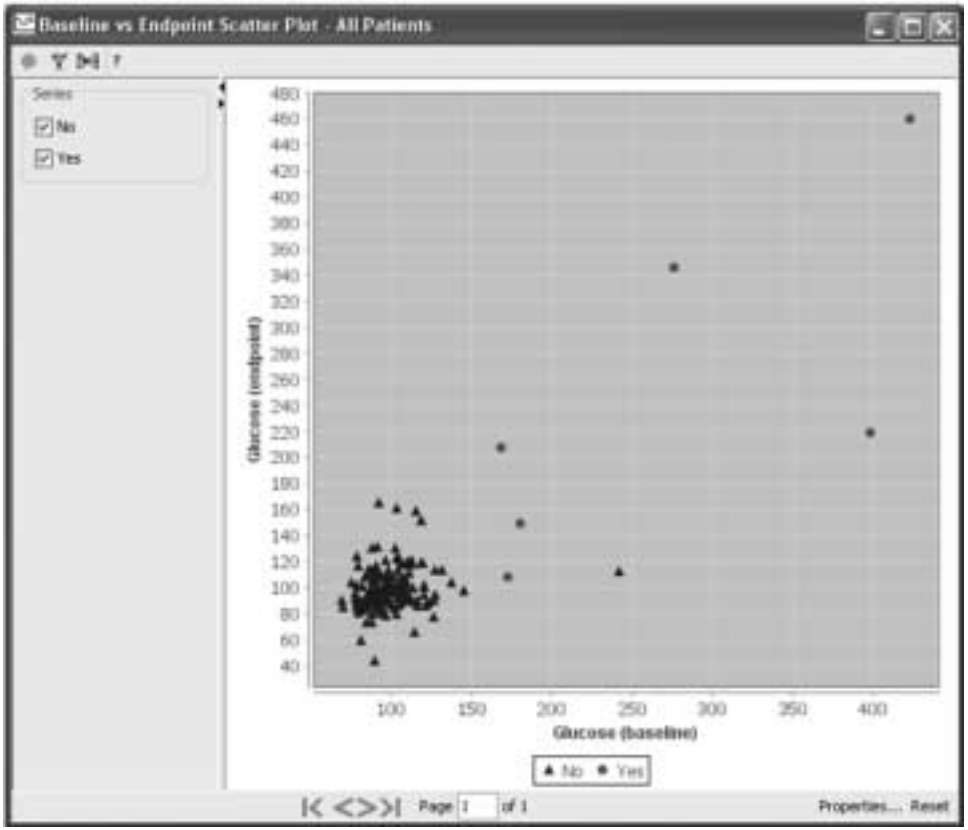
Baseline vs. Endpoint Scatter Plot

In a Baseline vs. Endpoint scatter plot each data point represents a patient's baseline (X-axis) and endpoint (Y-axis) for the item.

Use the **BY variable** to subset graphic displays.



Review also provides graphing formats for Baseline vs. Min Value Scatter Plot, as well as Baseline vs. Max Value Scatter Plot of selected items.

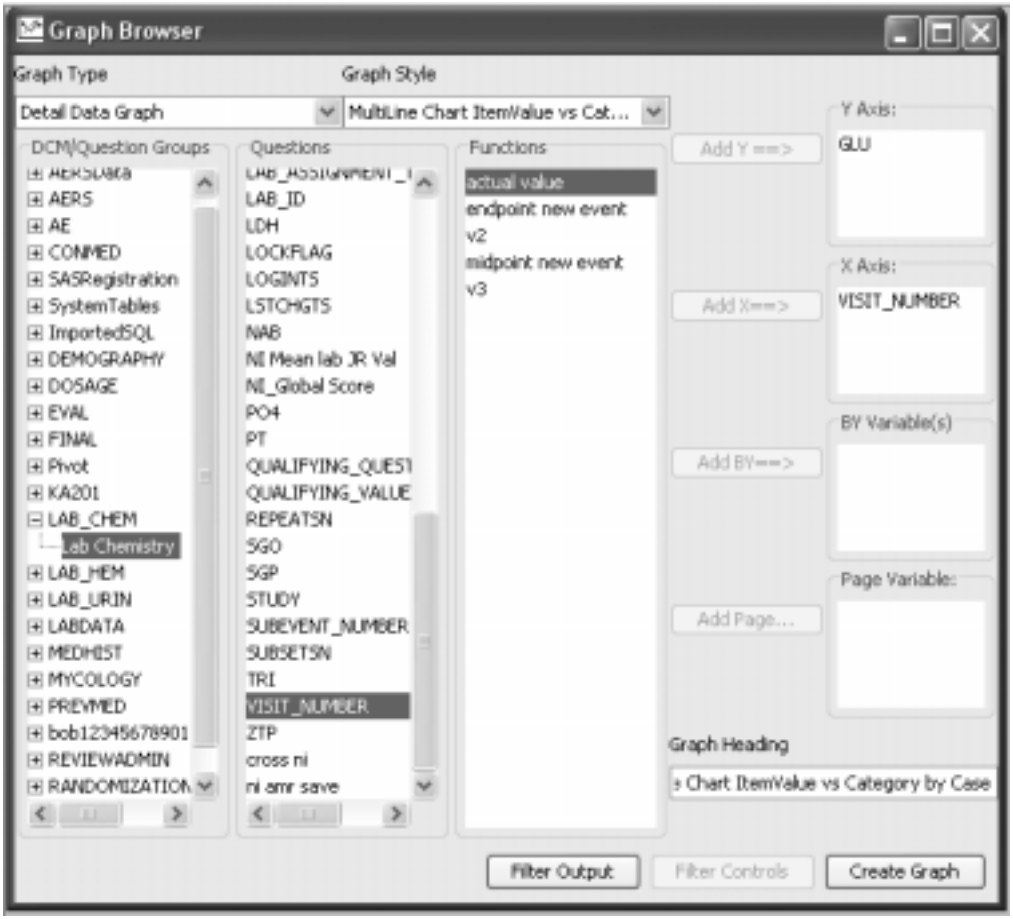


In a MultiLine Chart Item Value vs. Category by Case graph, each patient is represented by a line.

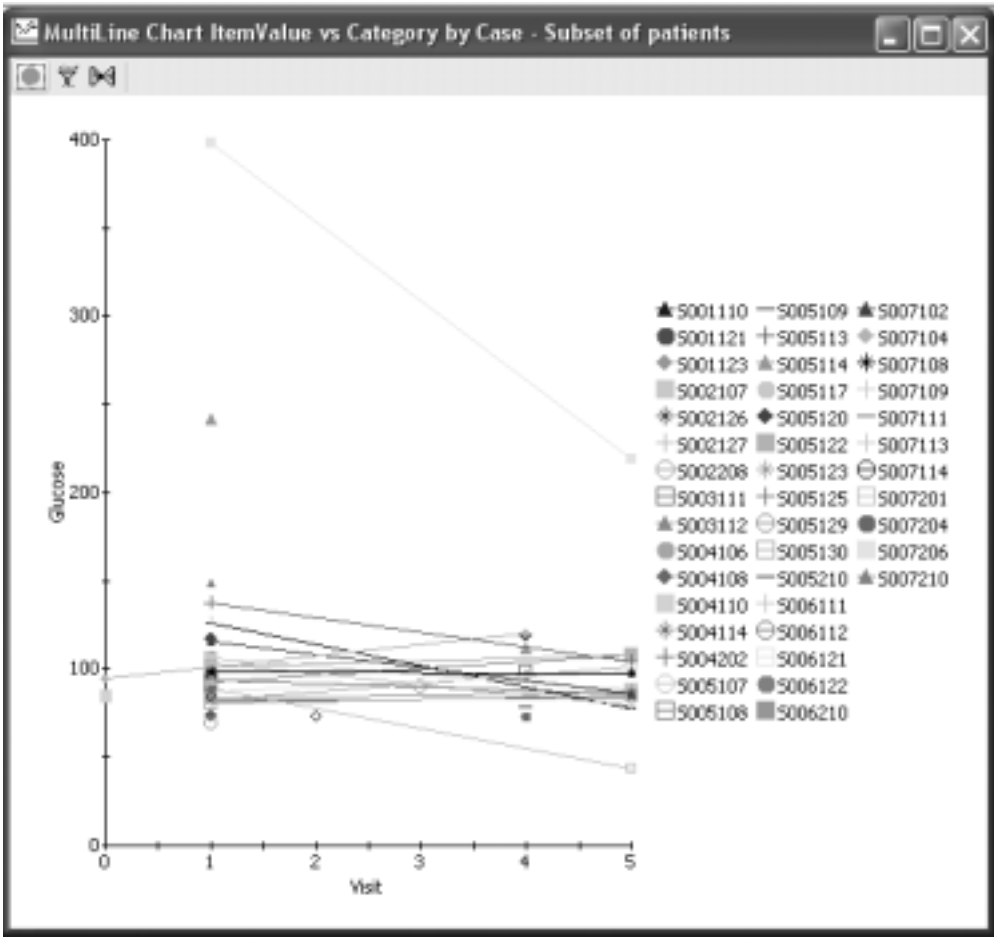
PID is defaulted for the patient identification. The Page variable is not allowed.

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.



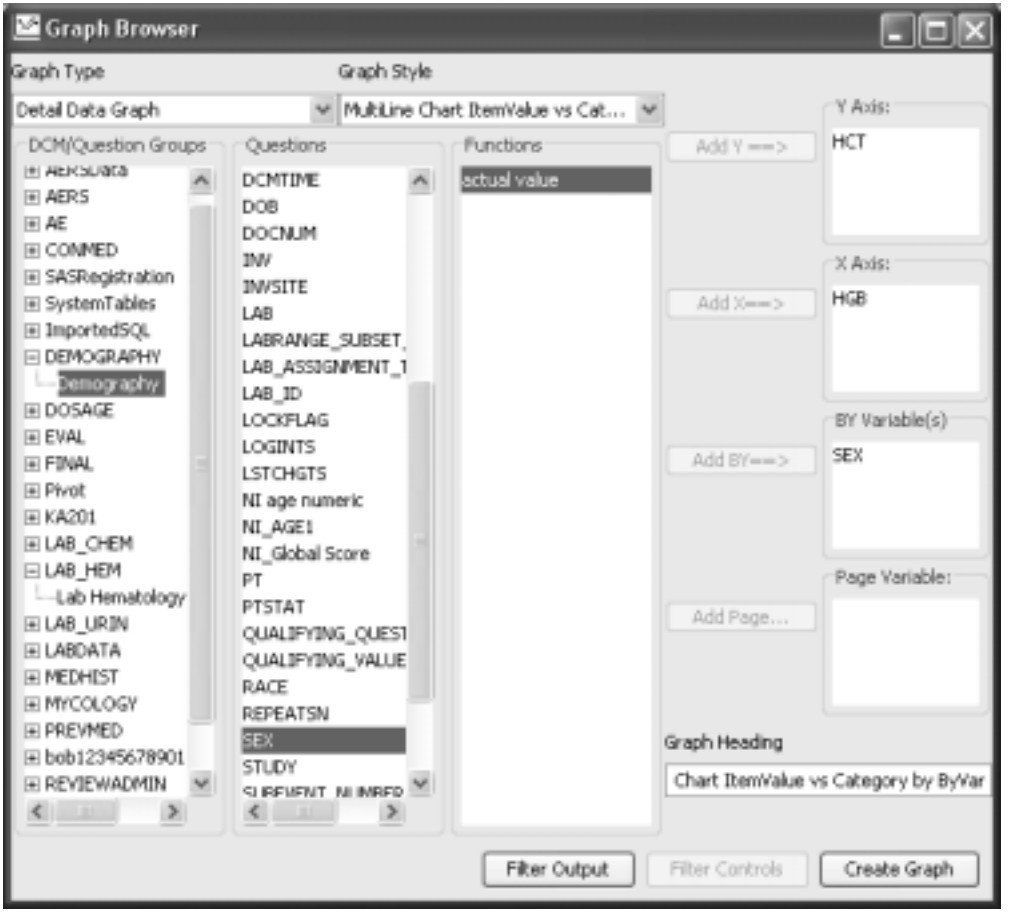
In this example, a Patient selection criteria was applied for discontinued patients.



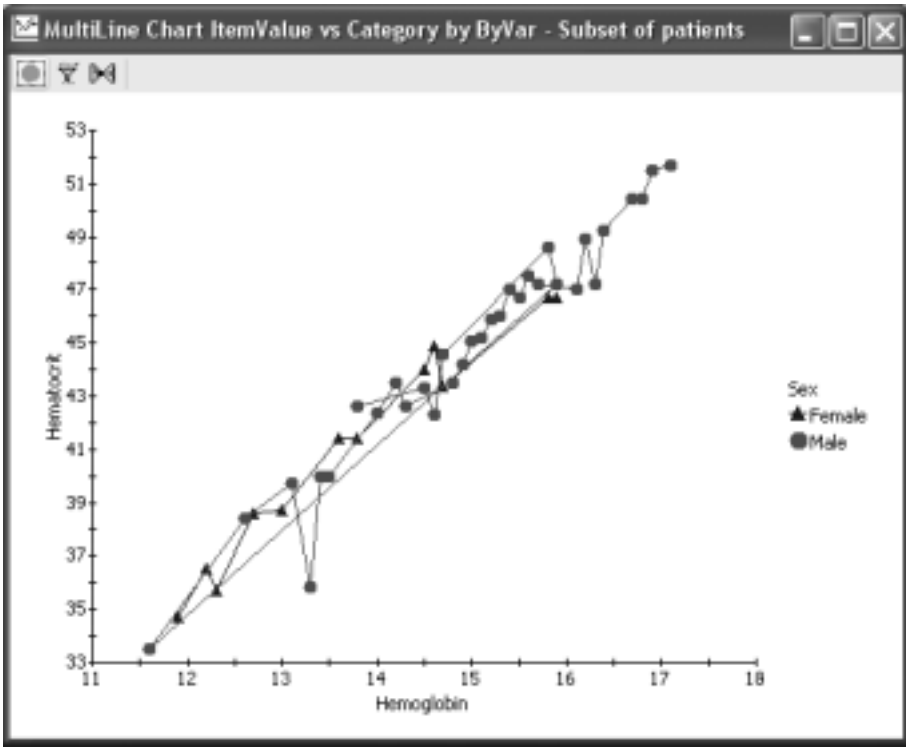
The MultiLine Chart Item Value vs. Category by ByVar graph, provides the same functionality as the MultiLine Chart item Value vs. Category by Case graph. However, you select the patient identification item.

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.



In this example, a Patient selection criteria was applied for discontinued patients.



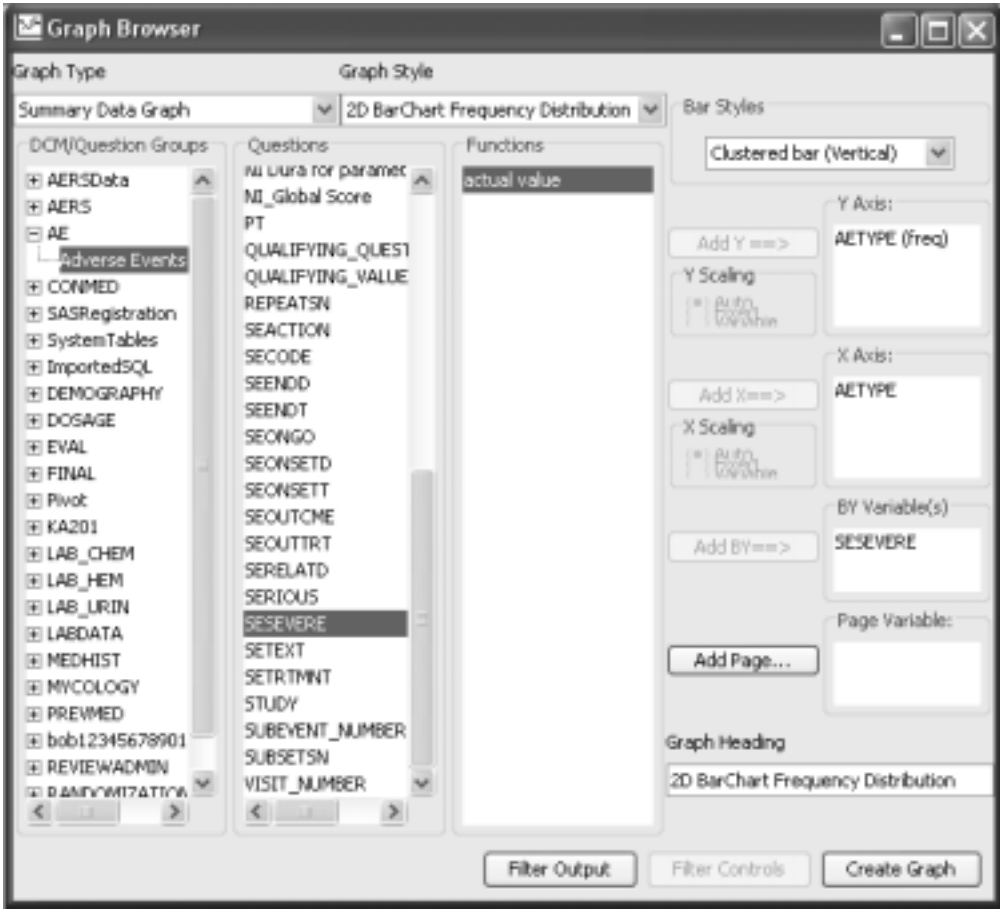
Summary Graph Styles

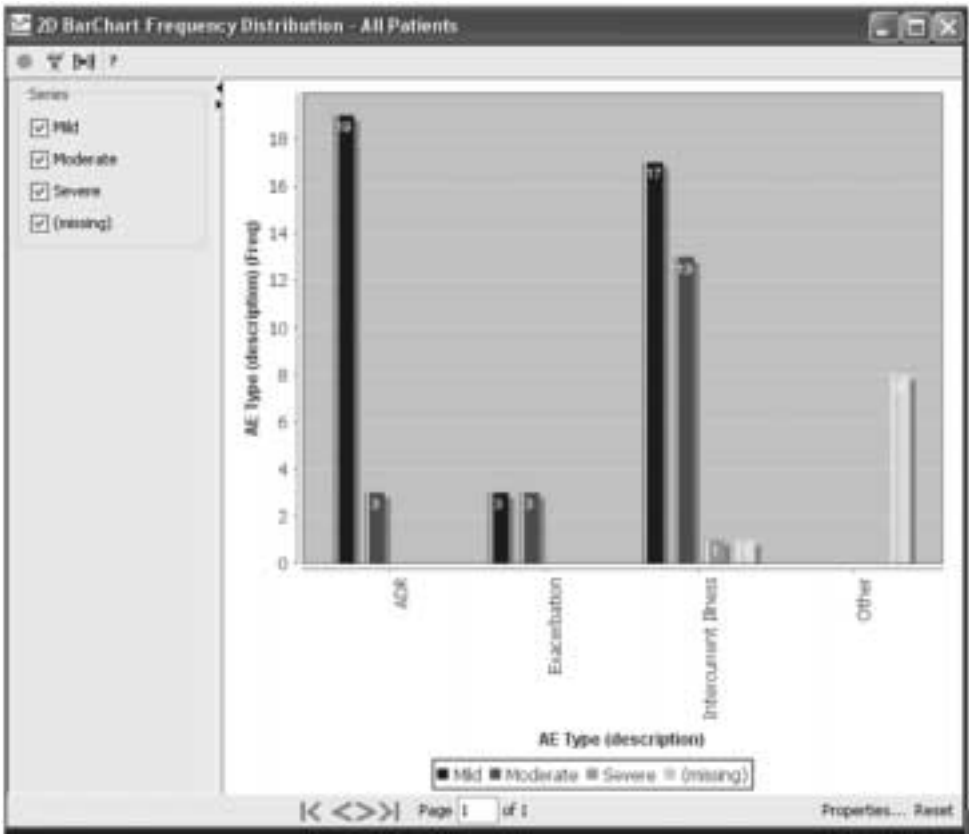
2-D Bar Chart Frequency Distribution

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.

Use the **BY variable** to subset graphic displays.



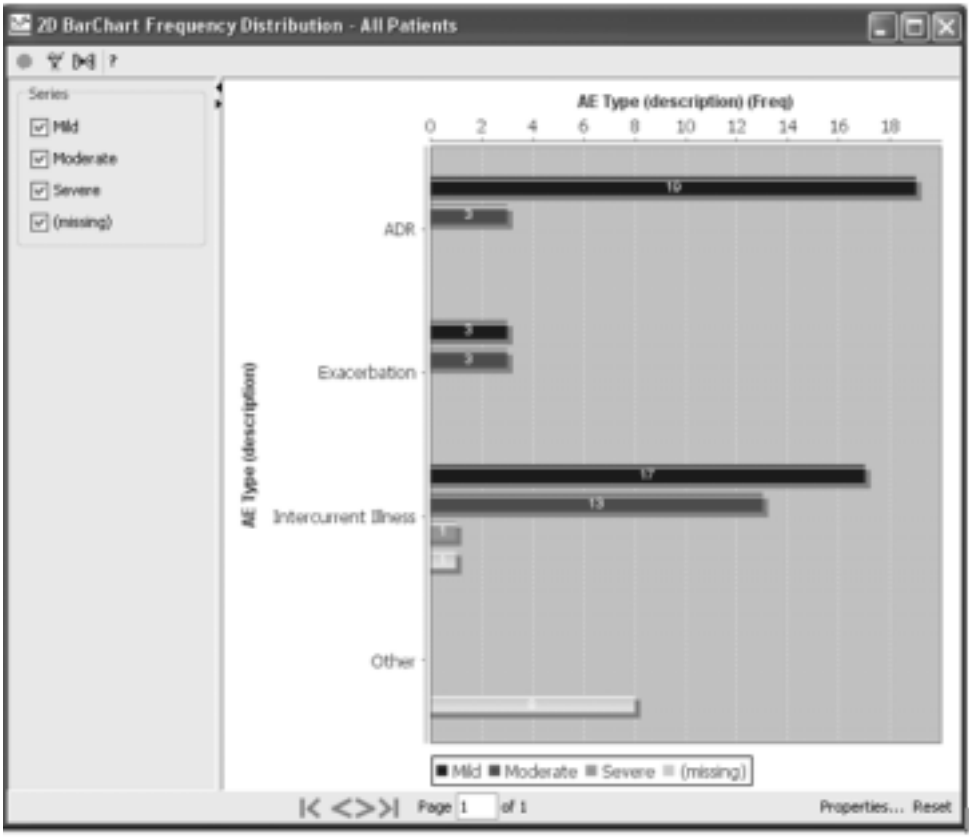


The frequency bar counts represent patients as compared to a Summary Listing showing patient counts versus item counts.

AE Type Summary Listing

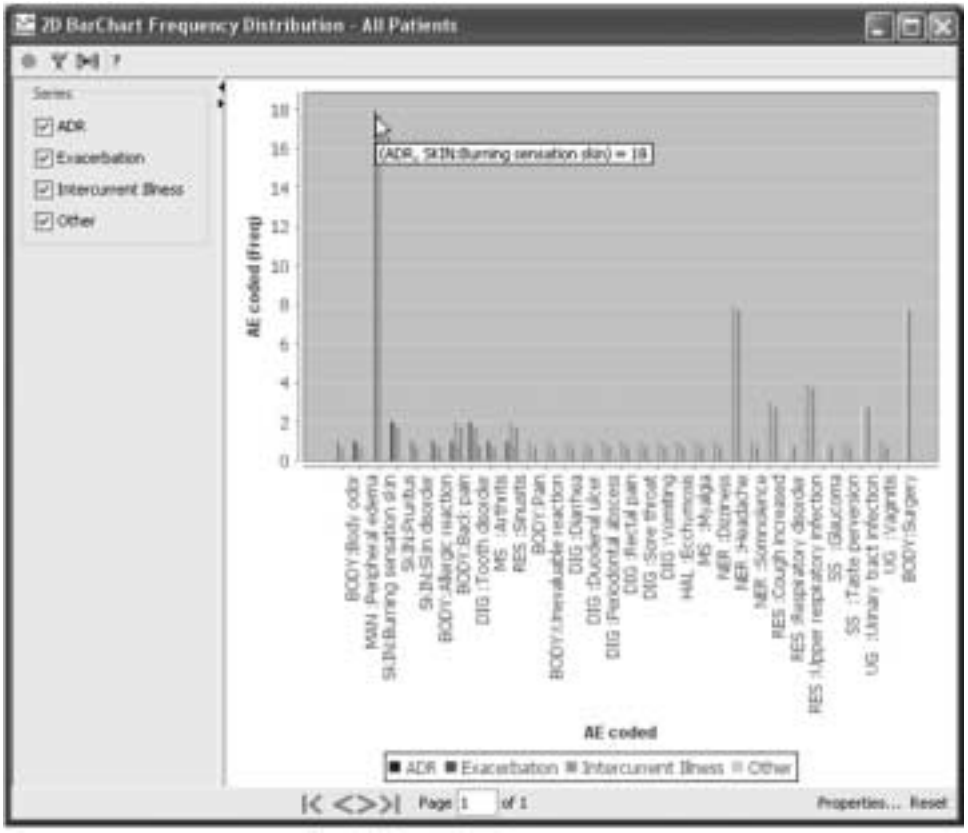
		count subjects	count
AE Type (description)	Intensity	AE Type	AE Type
Exacerbation	Mild	3	5
Exacerbation	Moderate	3	3
Intercurrent Illness	Mild	17	24
Intercurrent Illness	Moderate	13	14
Intercurrent Illness	Severe	1	1
Intercurrent Illness		1	1
ADR	Mild	19	21
ADR	Moderate	3	4
Other		8	8

This example shows the same graph type and style, but with a different Bar style option.



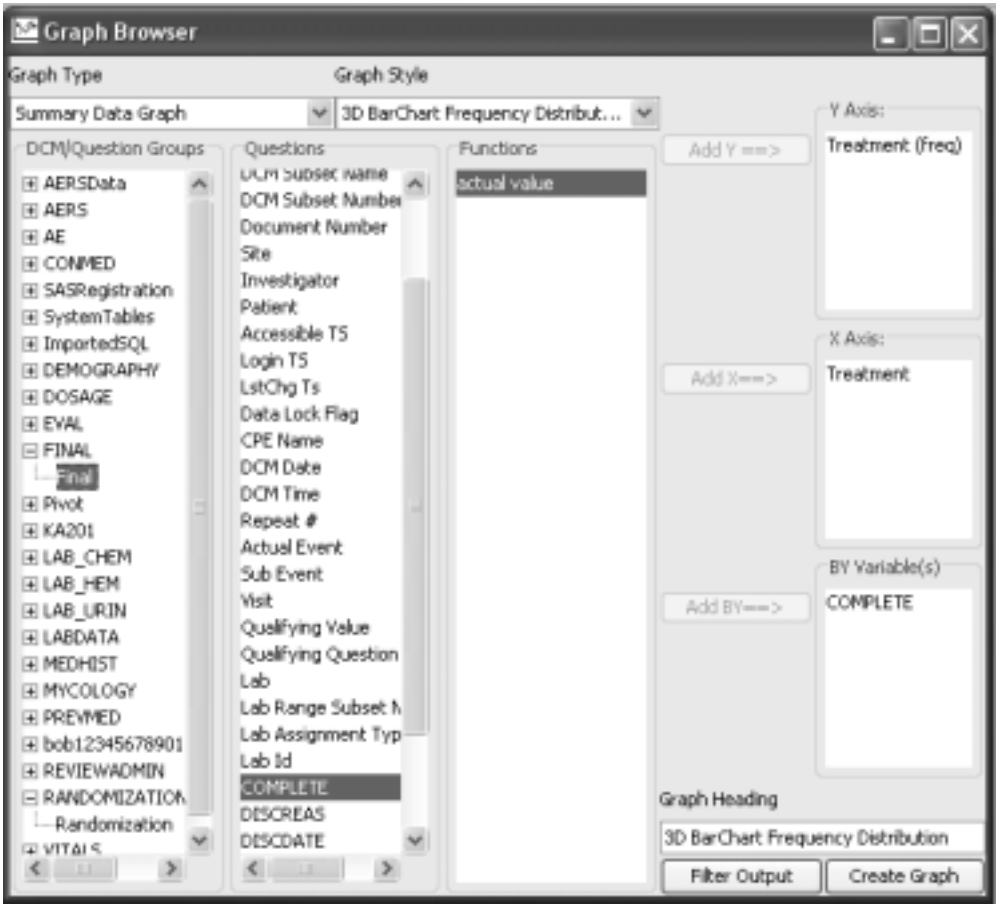
This example of a 2D Barchart Frequency Distribution plots Adverse Event data. The counts represent patient counts and the individual adverse events.

Hint: ***Place mouse over bar to view description and count.***

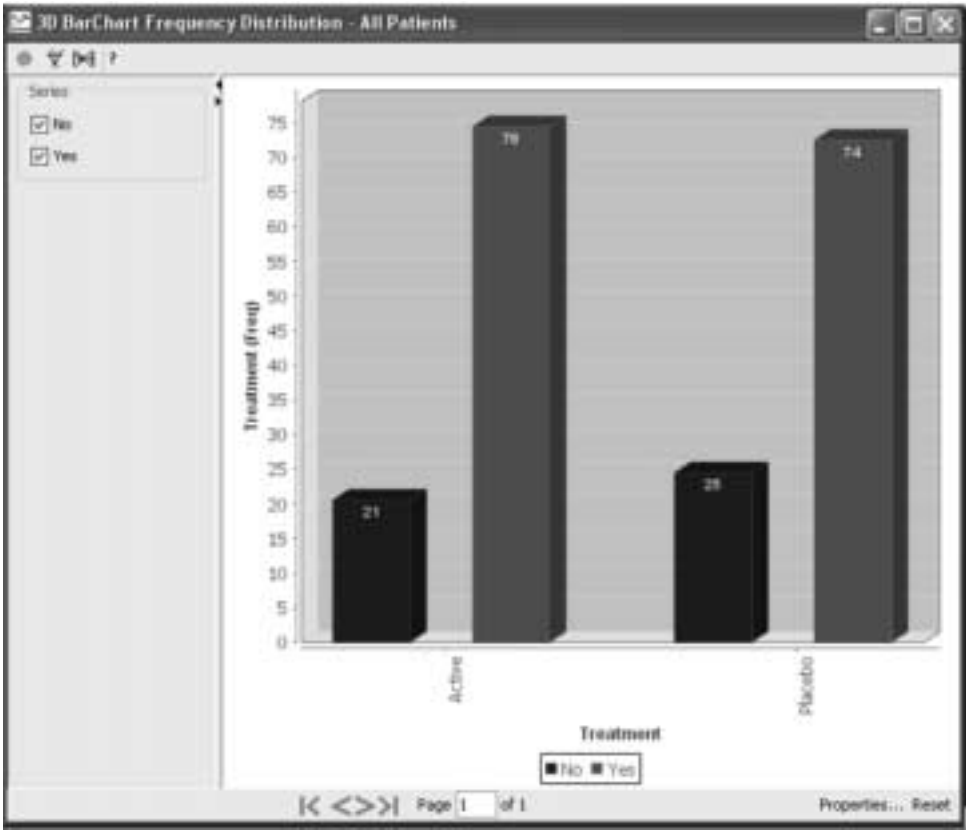


3D BarChart Frequency Distribution

In a 3D BarChart Frequency Distribution graph, each bar represents the category value of the item with the Y-axis representing the frequency.



Use the BY variable to subset graphic displays.



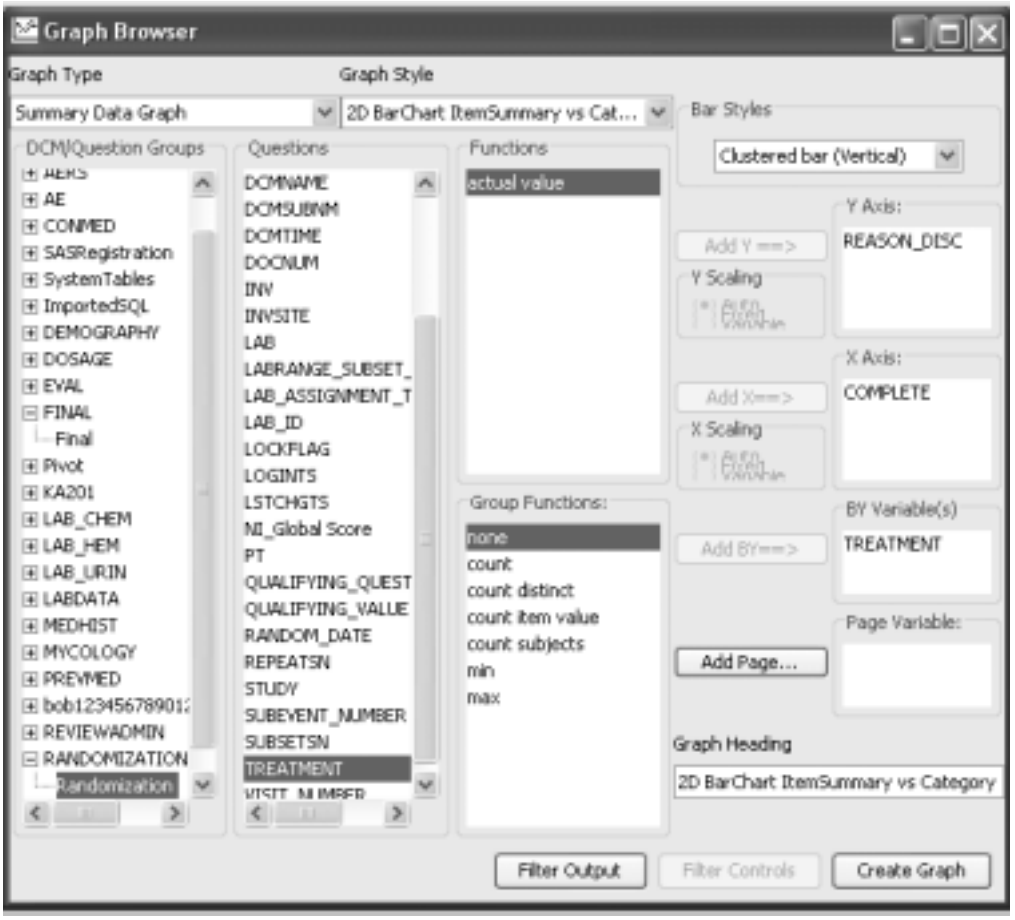
Note: This not a true 3D bar chart; it is a 3D style that makes the bars look solid rather than flat. JReview currently does not have a true 3D bar chart.

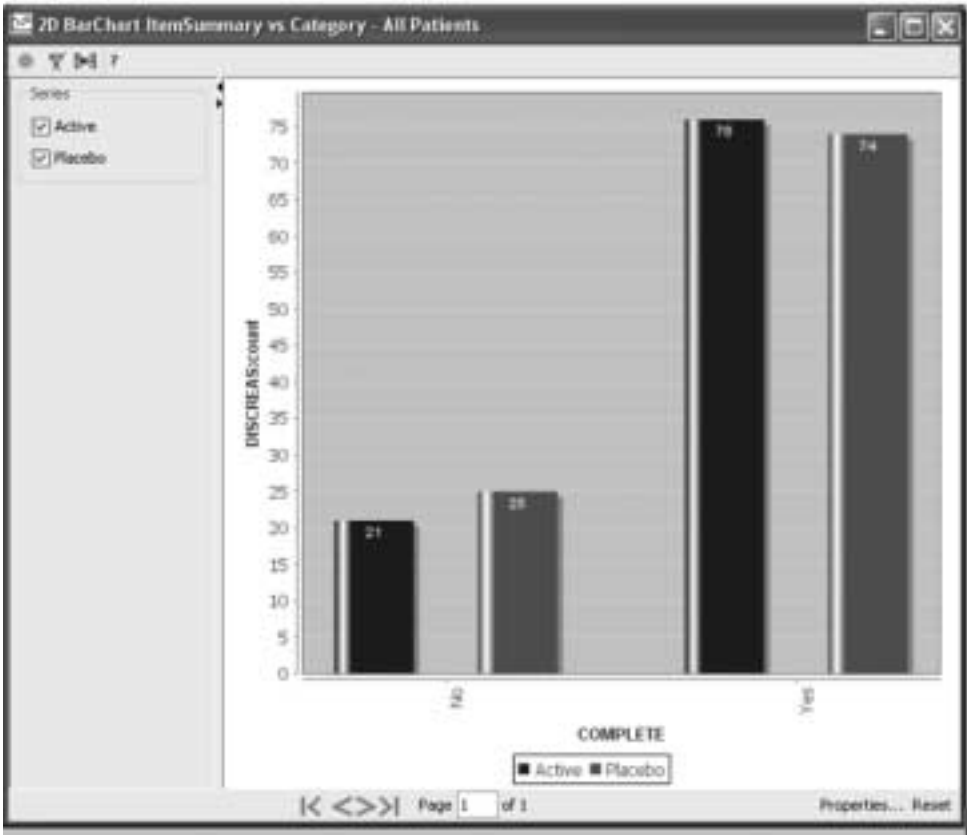
In a 2D BarChart item Summary vs. Category, each bar represents a category value X-axis versus a summary statistic (mean, count, sum) Y-axis.

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 as “Reason Discontinued:Count”.

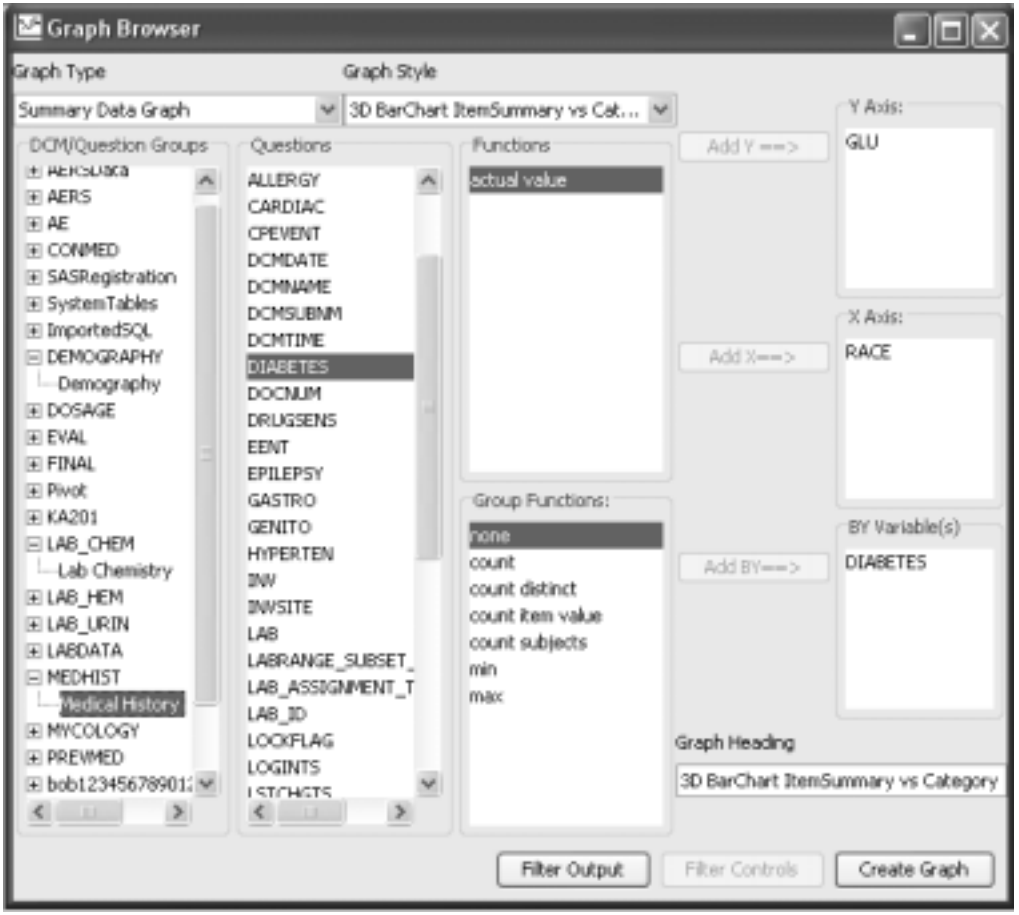


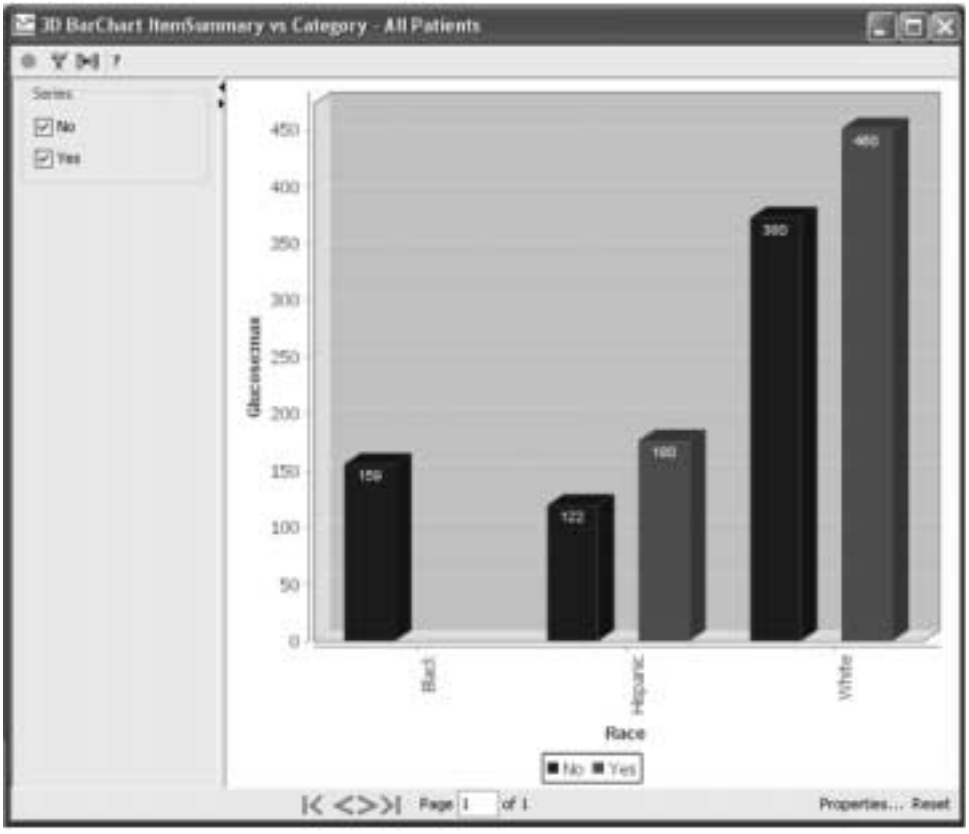

2D BarChart ItemSummary vs Category - All Patients
Series
Active
Placebo
DISCREAS:count
75
70
65
60
55
50
45
40
35
30
25
20
15
10
5
0
21
25
76
74
COMPLETE
Active
Placebo
Page 1 of 1
Properties...
Reset

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.

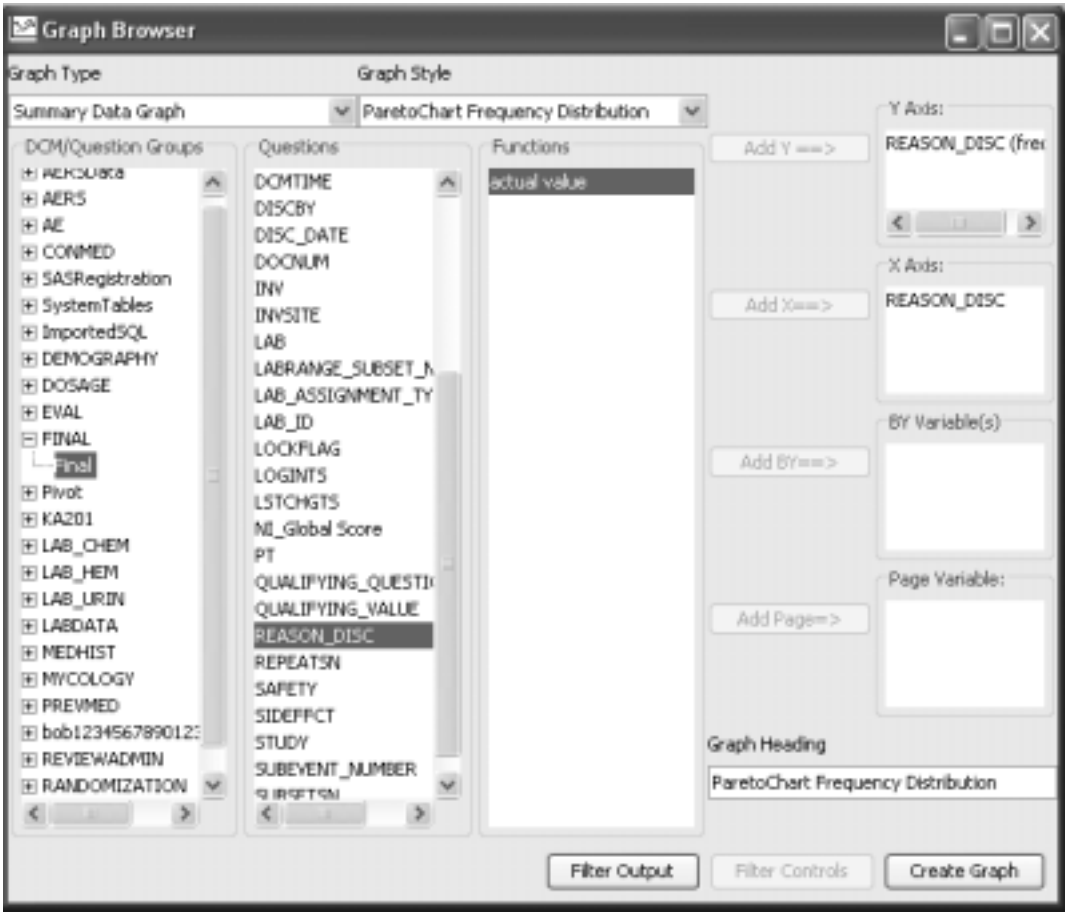
In this example, the Y-axis was added as “Glucose:Max”.





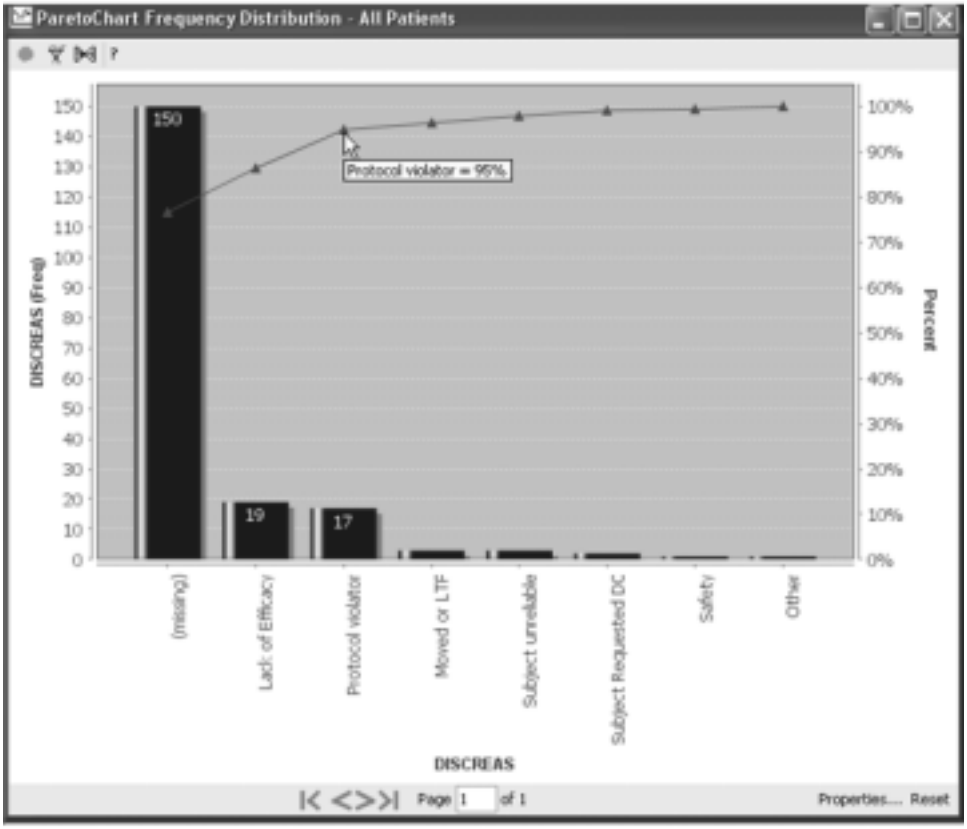
Note: This not a true 3D bar chart; it is a 3D style that makes the bars look solid rather than flat. JReview currently does not have a true 3D bar chart.

In a Pareto chart frequency Distribution, each bar represents a category value that corresponds to the plotted Y-axis.

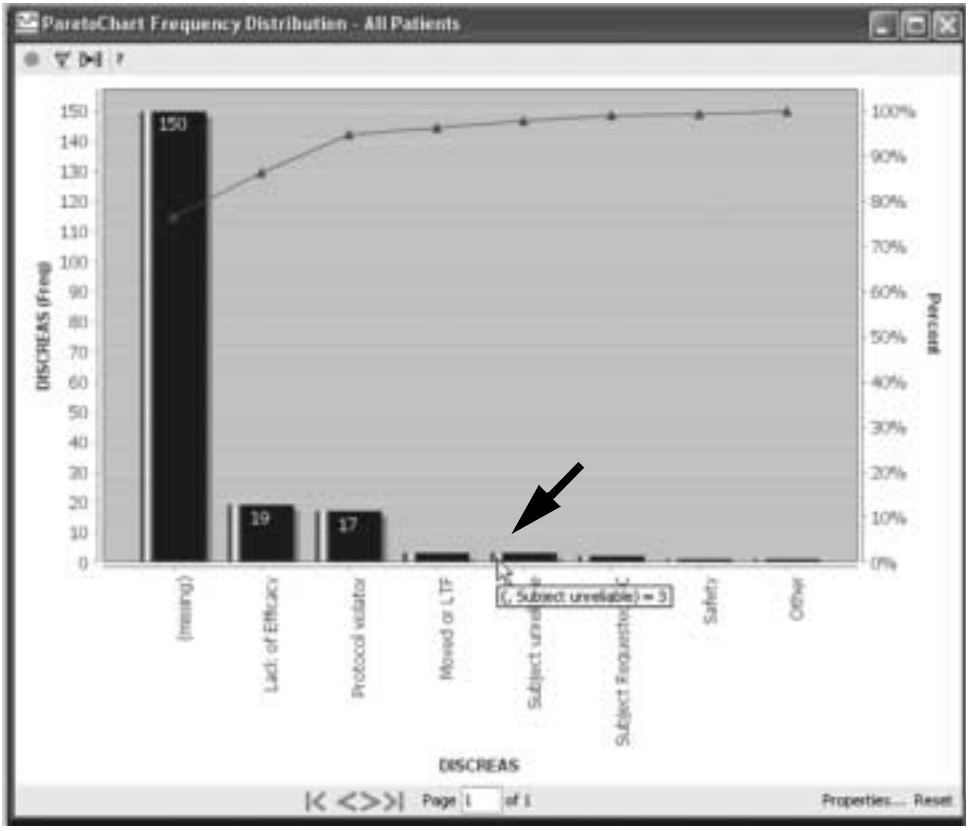


The line above the bars shows the cumulative percentage.

Pareto charts display the Y-axis bars in descending order of frequency.



Hint: ***Place the mouse over a bar to view description and count.***

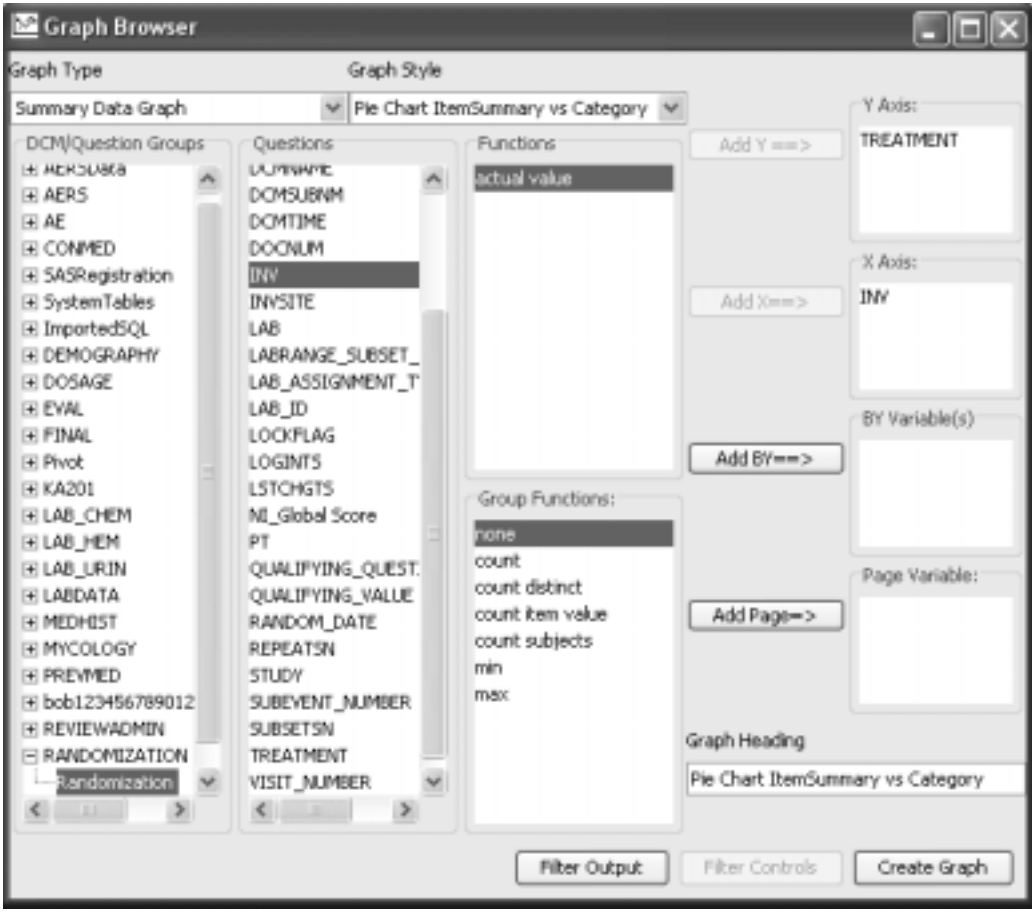


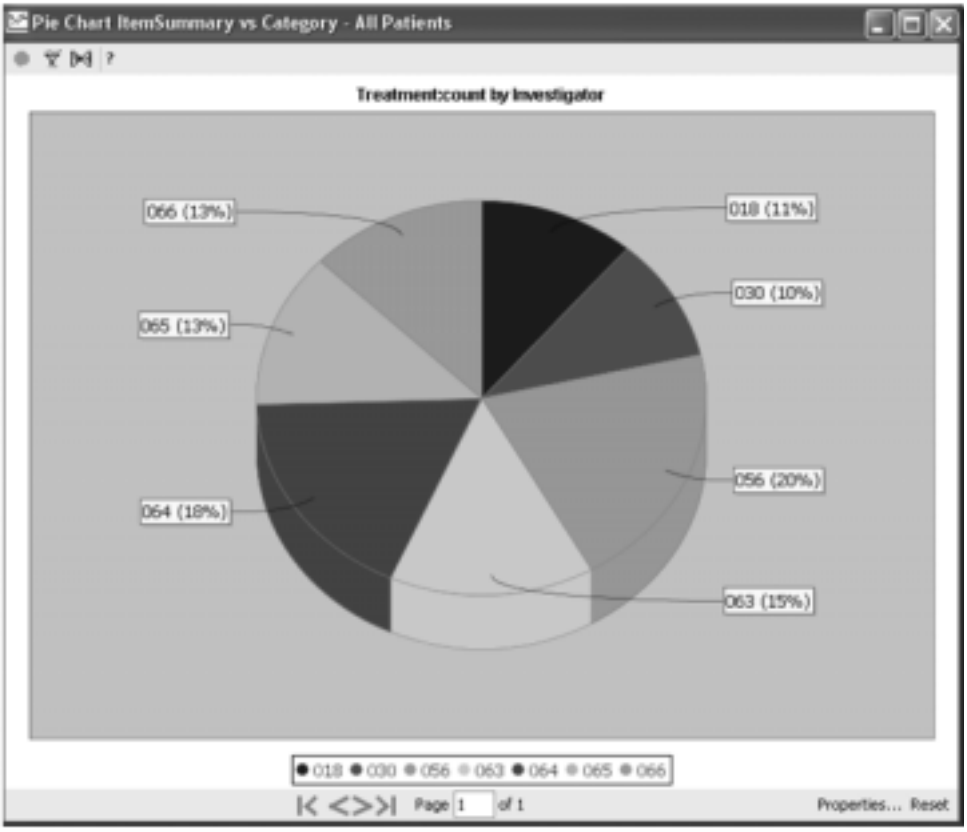
Pie Chart Item Summary vs. Category

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).

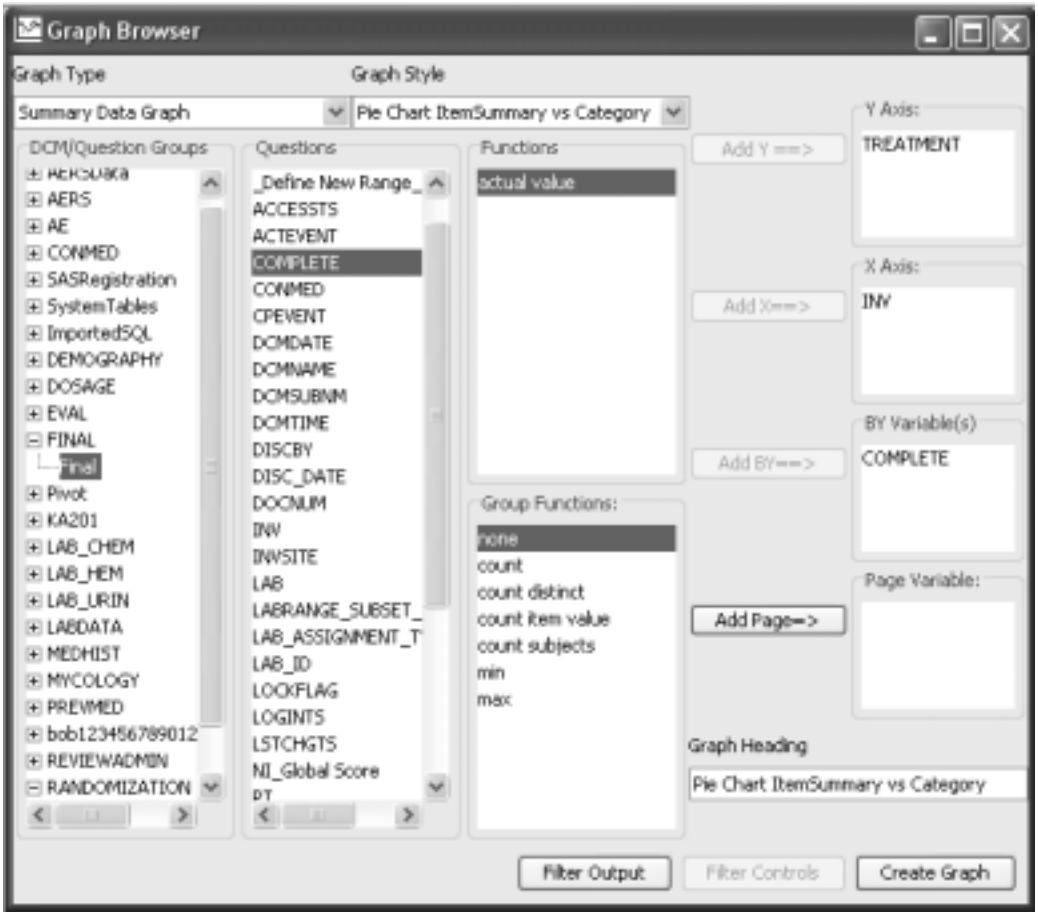
The Graph Browser window provides a separate list of group functions for the Y-axis. Use the **BY variable** to display multiple pie charts of grouped data.

For this example, the Y-axis Treatment was entered for 'Count'.

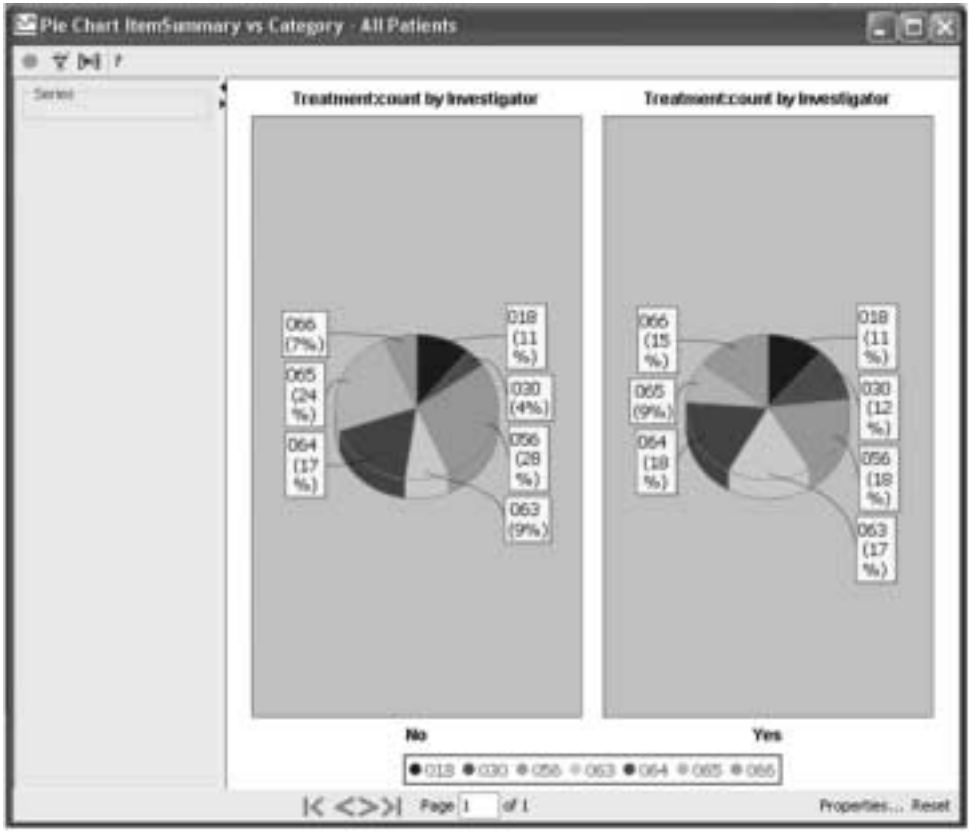



Pie Chart ItemSummary vs Category - All Patients
Treatment:count by Investigator
066 (13%)
018 (11%)
030 (10%)
065 (13%)
056 (20%)
064 (18%)
063 (15%)
018 030 056 063 064 065 066
Page 1 of 1
Properties... Reset

Same Pie chart with **BY variable** added for completed study.



The **BY variable** displays multiple pie charts of grouped data.

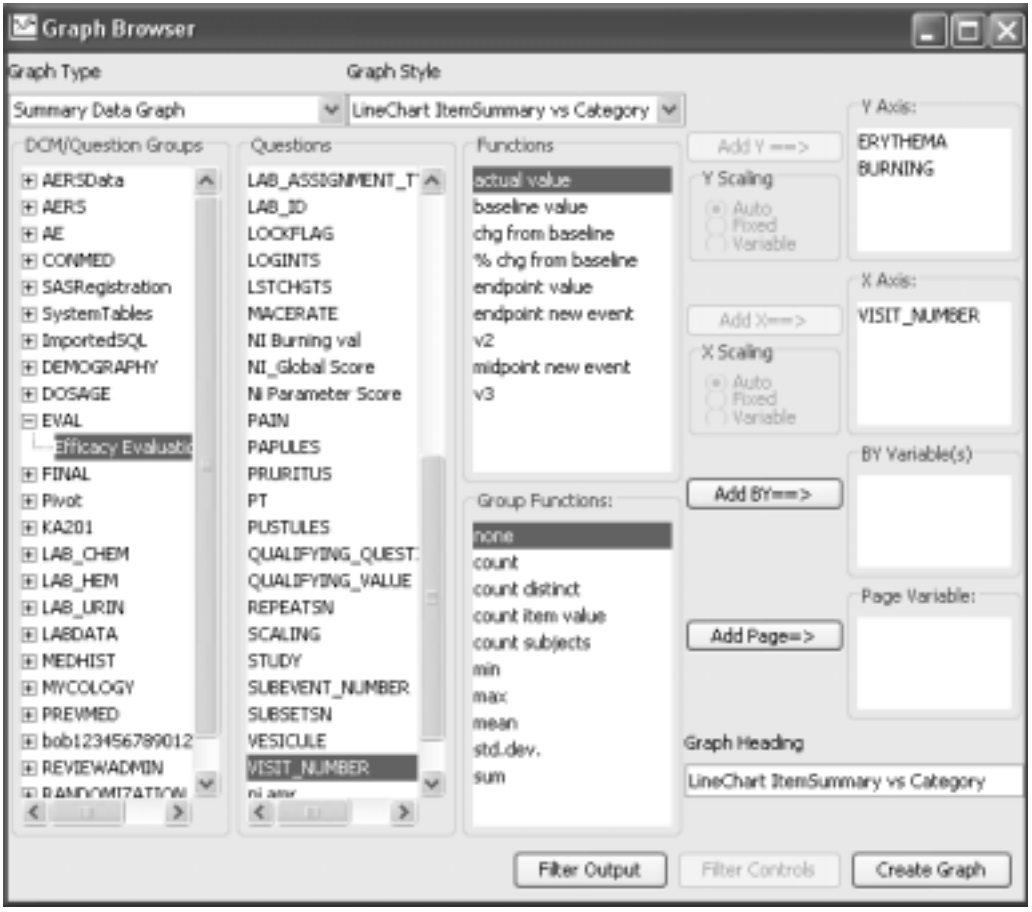


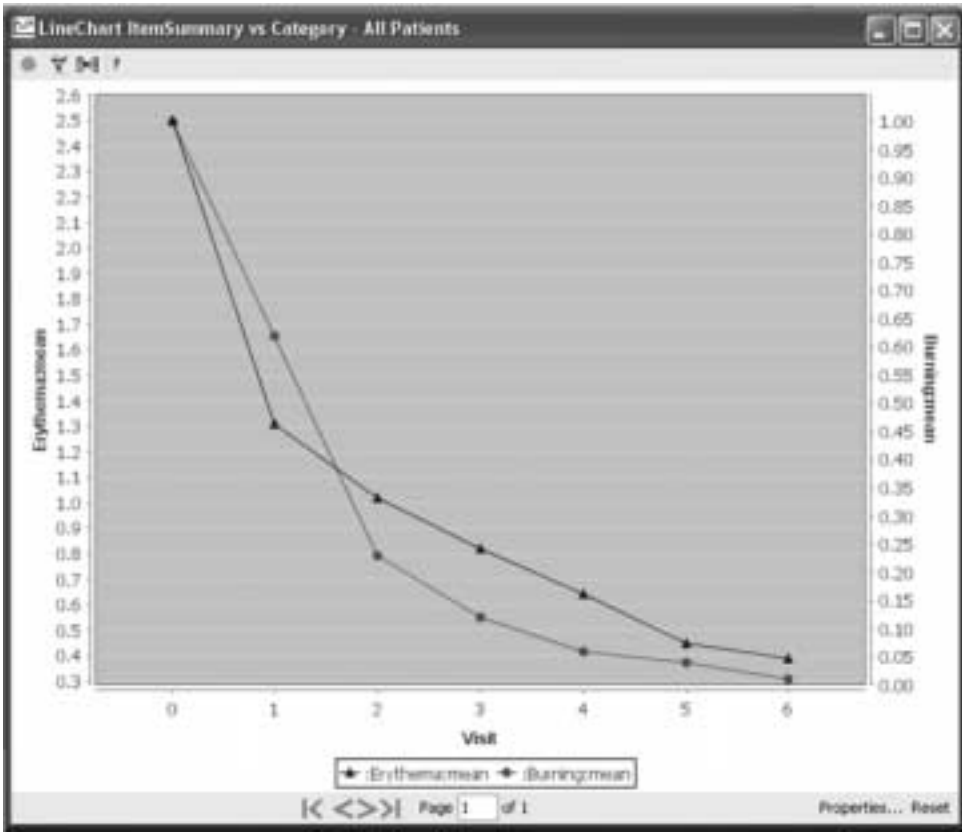
Line Chart-item vs. Category

In a Line Chart-item 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”.

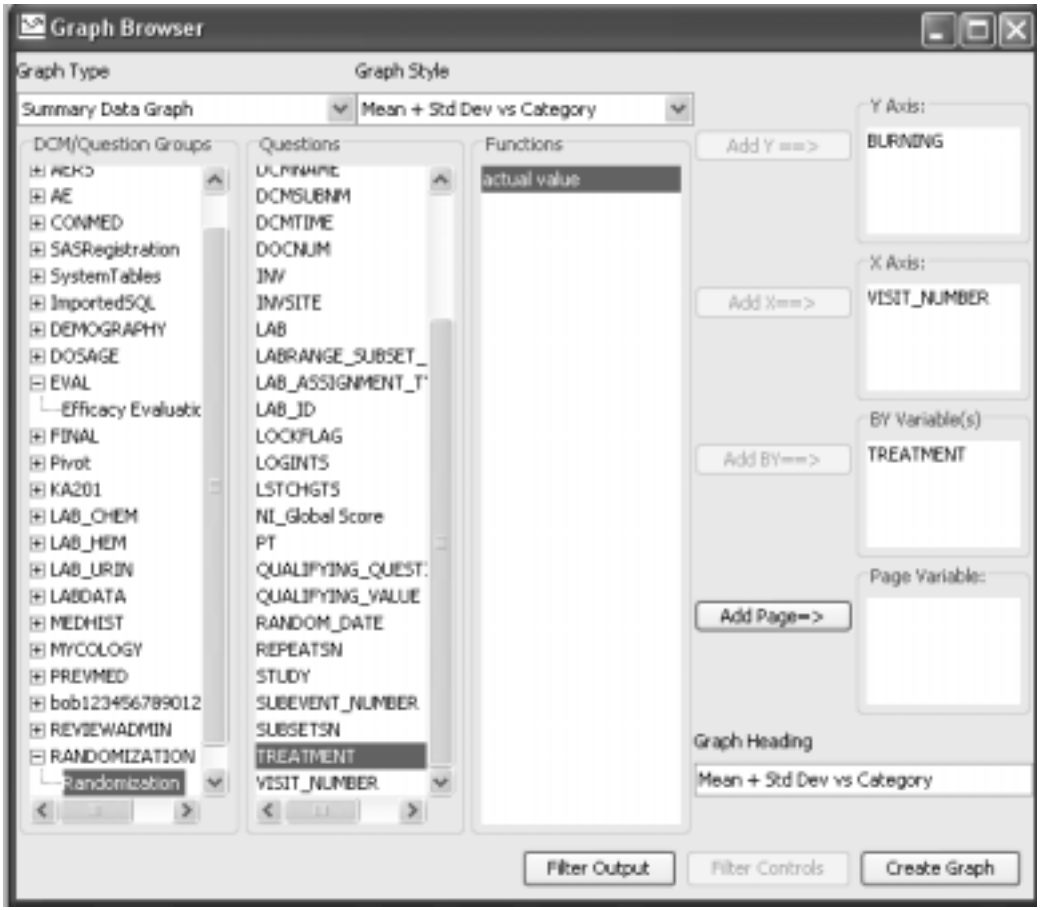


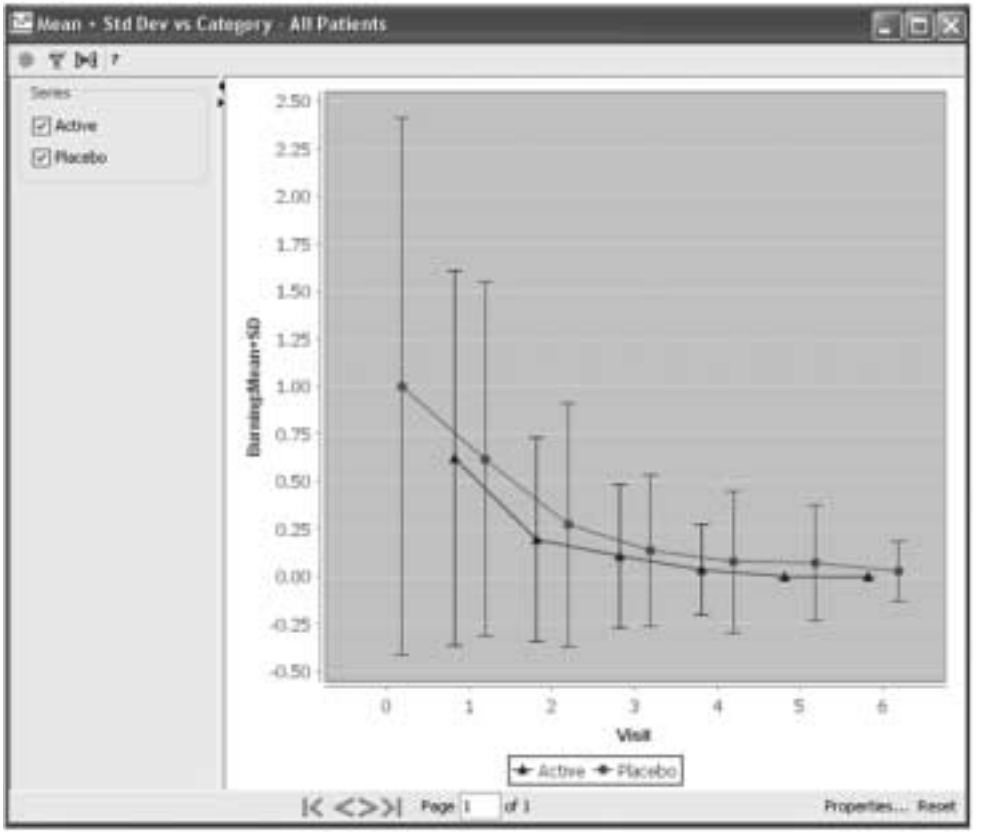

LineChart ItemSummary vs Category - All Patients
Erythemamean
Burningmean
Visit
Erythemamean
Burningmean
Page 1 of 1
Properties... Reset

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, chg from baseline, etc.

In this example, the Y-axis was added as “Burning Mean + SD”.





Output Filter

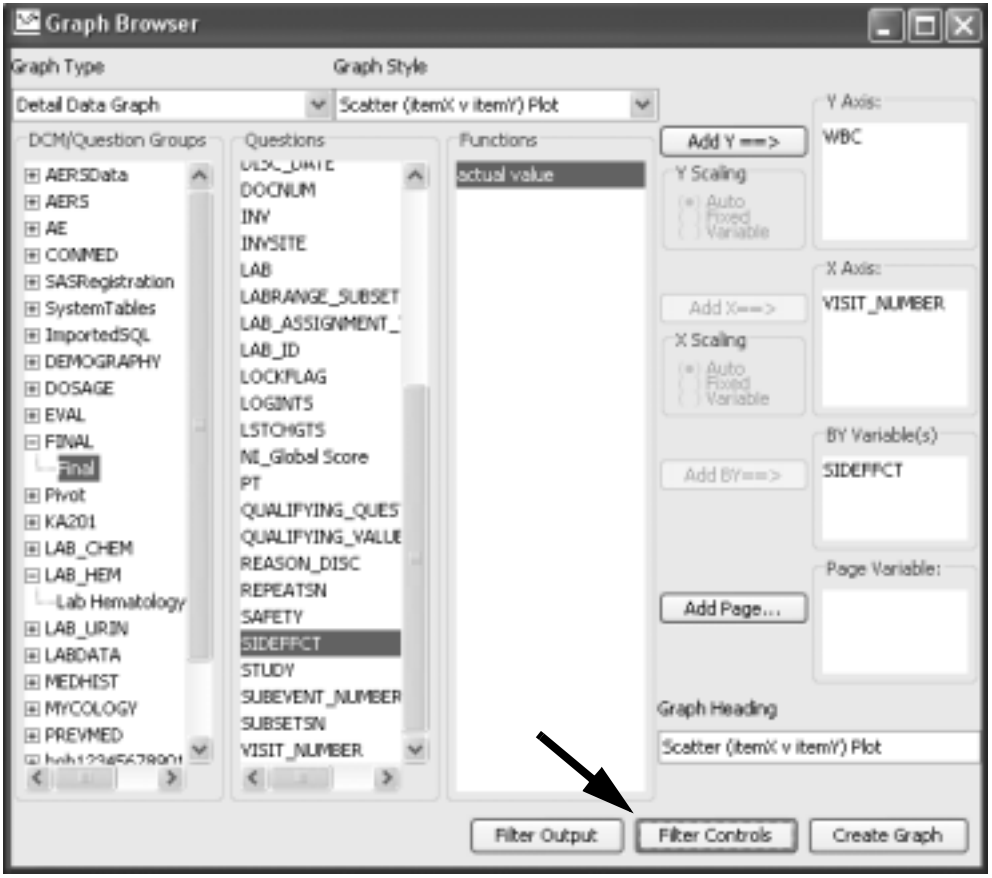
The output filter is designed to focus in on particular observations and visits; it is not designed to be used for the patient selection criteria. (*See Chapter 6: Report Browser for Output Filter and Run Time Parameters. The same instructions apply for the Graph Browser.)*

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: checkboxes for category type data, and sliders for numeric range type data. When the number of categories is large for a variable, the checkboxes are presented as a scrolling list.

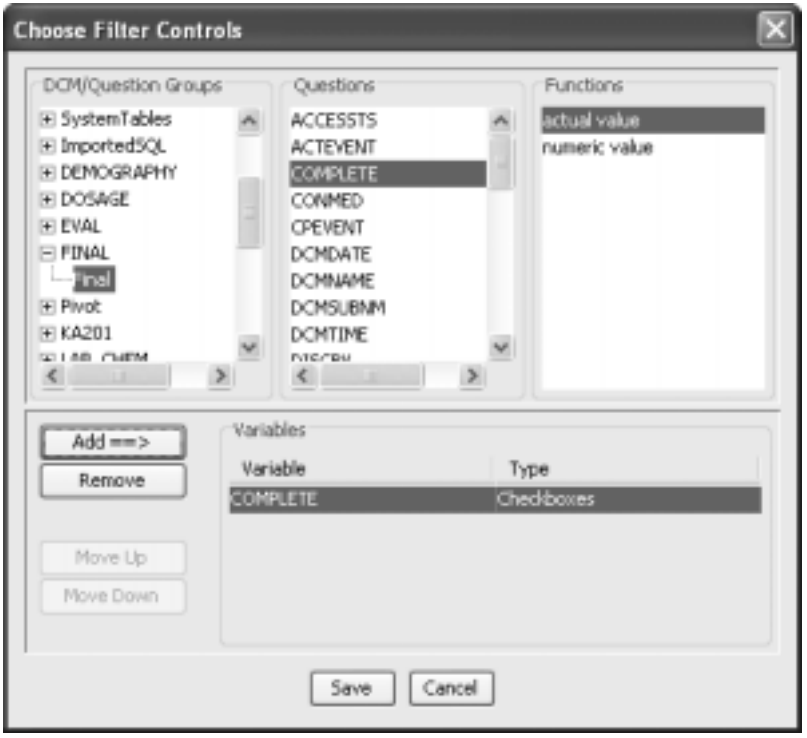
For example, for a Scatter plot with Y-Axis for "WBC", and "VISIT" on the X-Axis, and Side Effects as the BY variable was defined. After defining the scatter plot, you may add filter controls to the graph.

1. Click on the **Filters Control** button.



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. Checkboxes 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.



The variable for “Completed Study” is added as checkboxes.

The numeric variable for “WBC” is added and Numeric Range is selected.

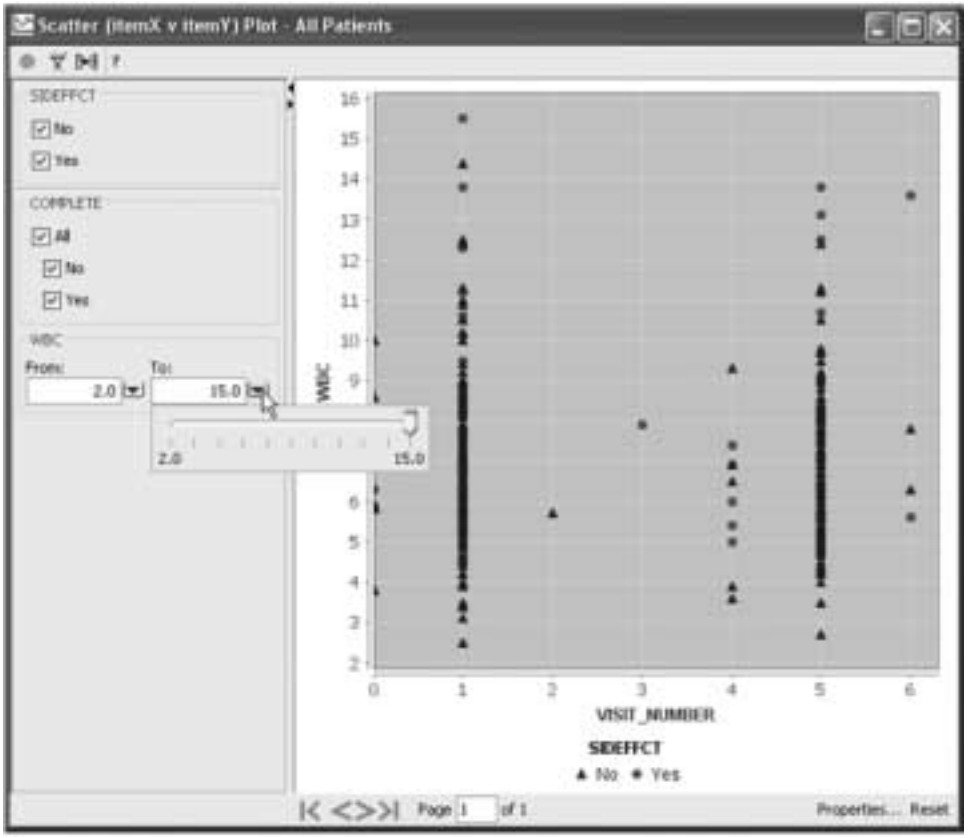
4. Click **Save**. The Filter Contols are saved. The button status changes to Filter Controls ON.
5. Click **Create Graph**.

The saved Filter Controls are listed with the BY variable if added. Initially the graph displays with all values.

6. Click on the checkboxes 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.

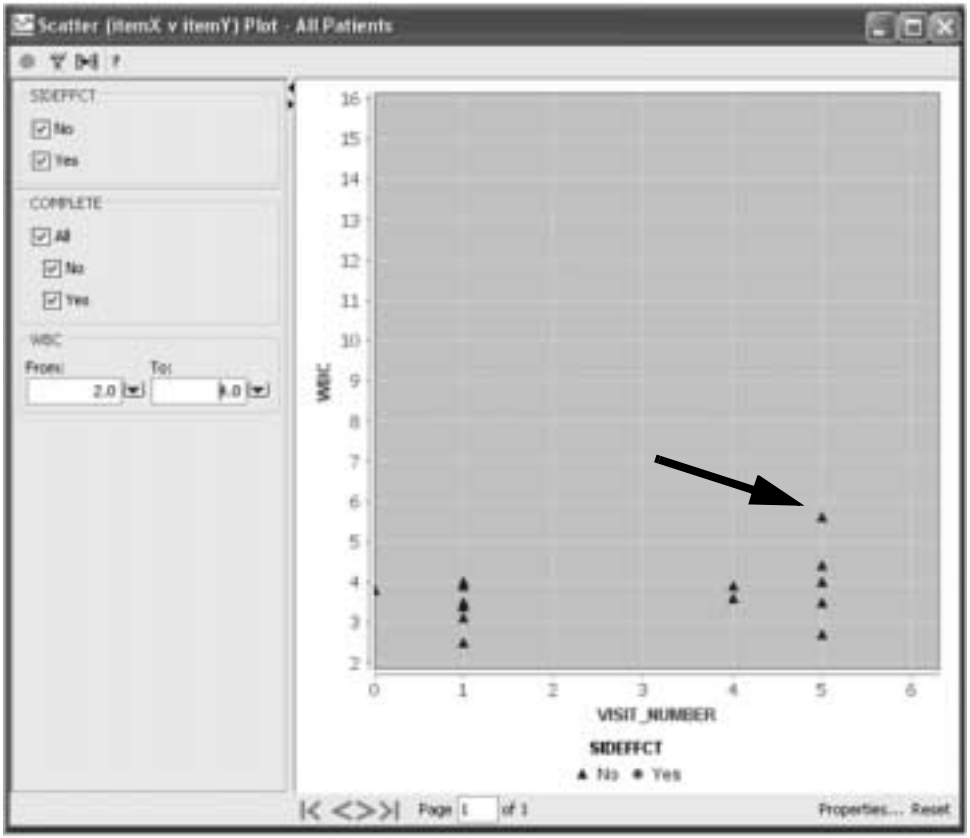
   Numeric Ranges initially display the minimal and maximum values.

   You must click **Enter**, to update the graph display.

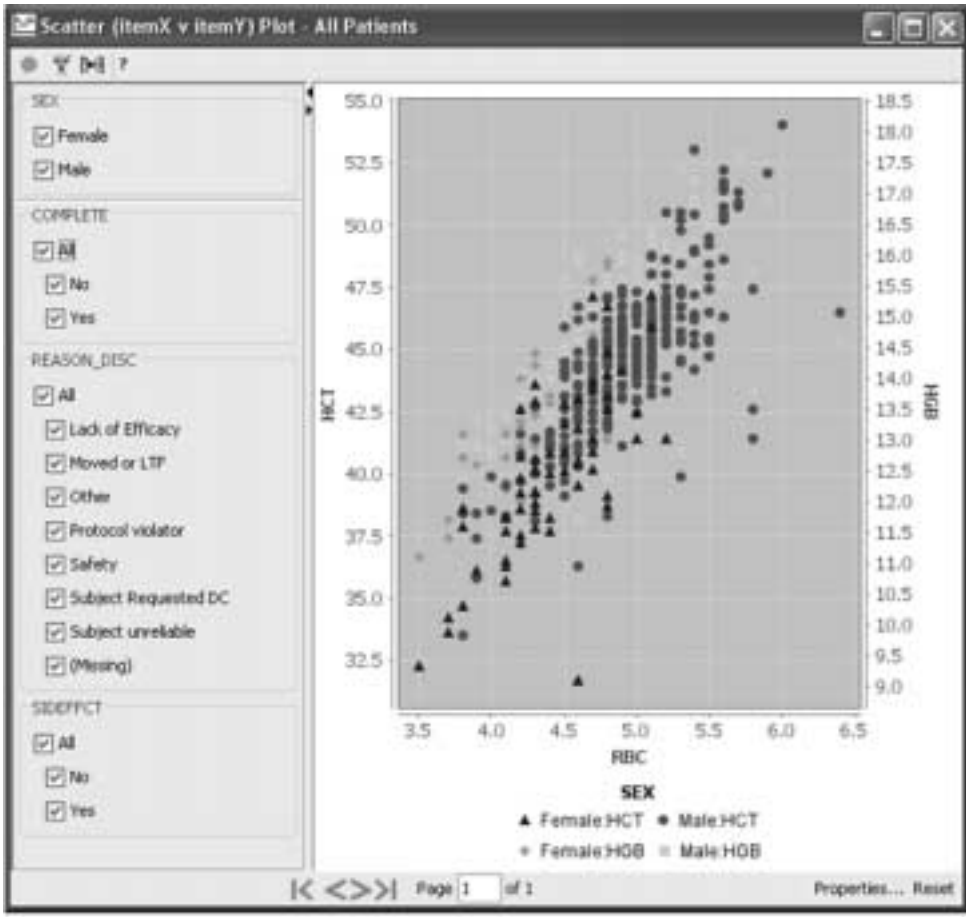


The WBC range was changed to a maximum value of “4.0”. Observe some values may still display if higher than maximum value entered. This same patient had multiple visits with WBC values of “5.6” and “3.4”.

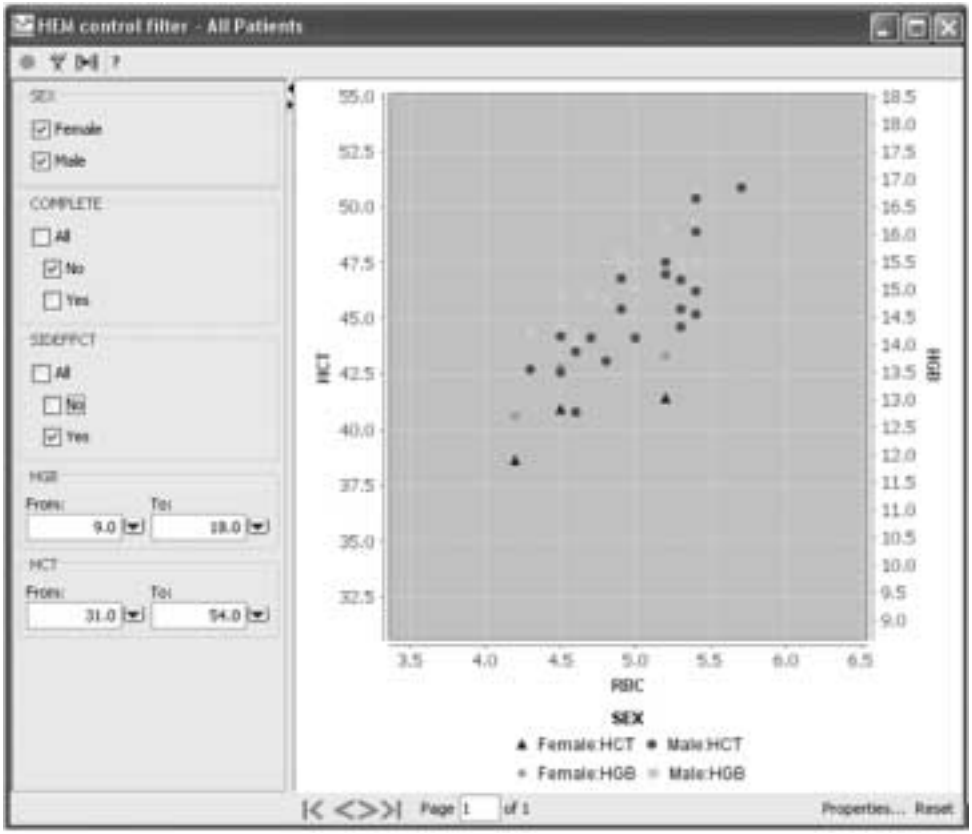
With category filters, a patient is shown if they fall into any of the checked categories. Essentially, the categories for a variable have an “OR” relationship. In this case, the patient is shown because their WBC value at another visit is “3.4”, and out of range.



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.



Now 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.



To edit or remove Filter Controls:

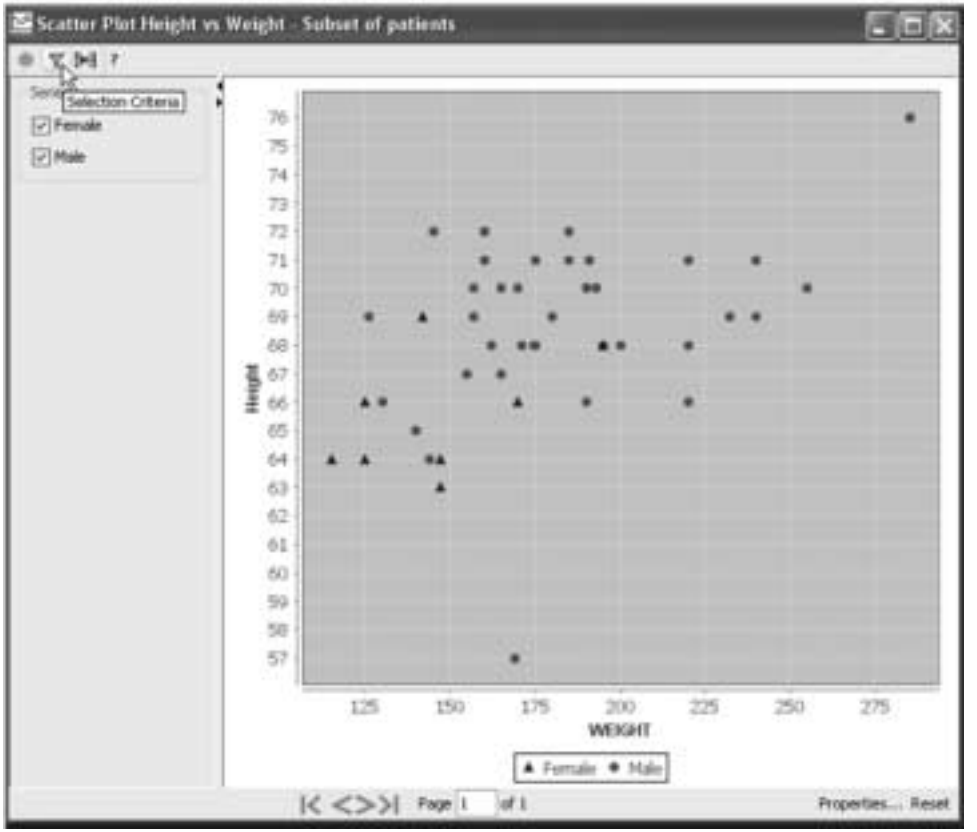
1. Click on the **Filters Control** button.
2. Select the Filter Control variable, then click on the **Remove** button.
3. You must remove each individual filter control variable, to turn off the entire function.
4. Click **Save**.

Snapshot output

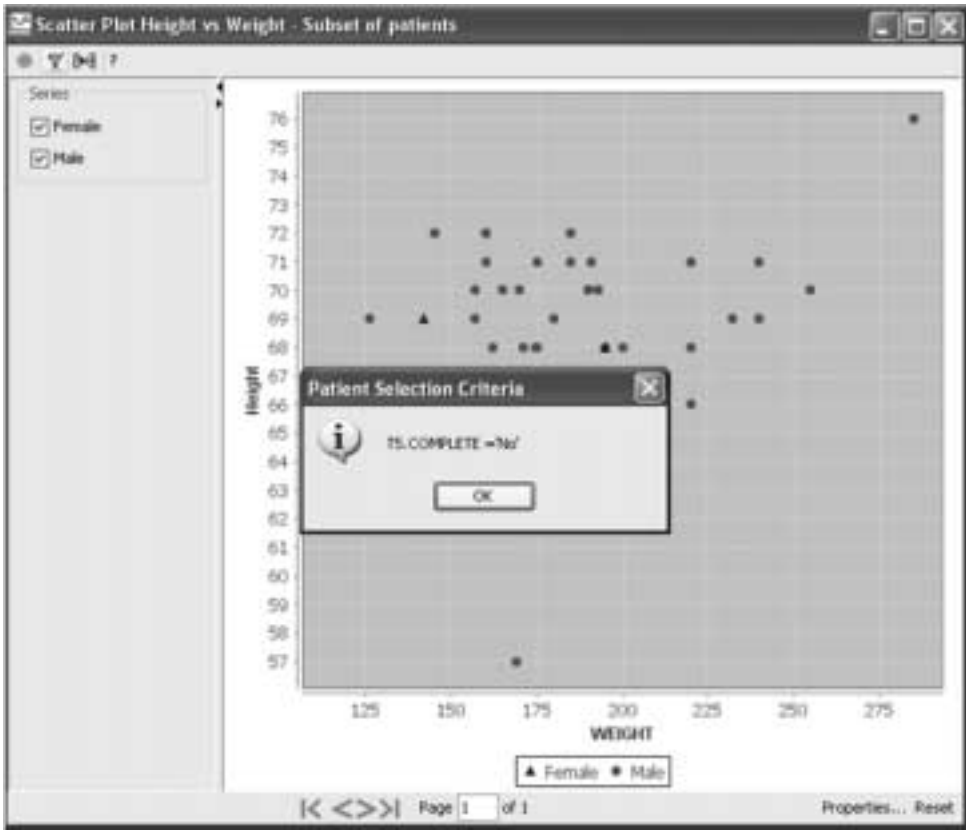
Multiple population mode

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.



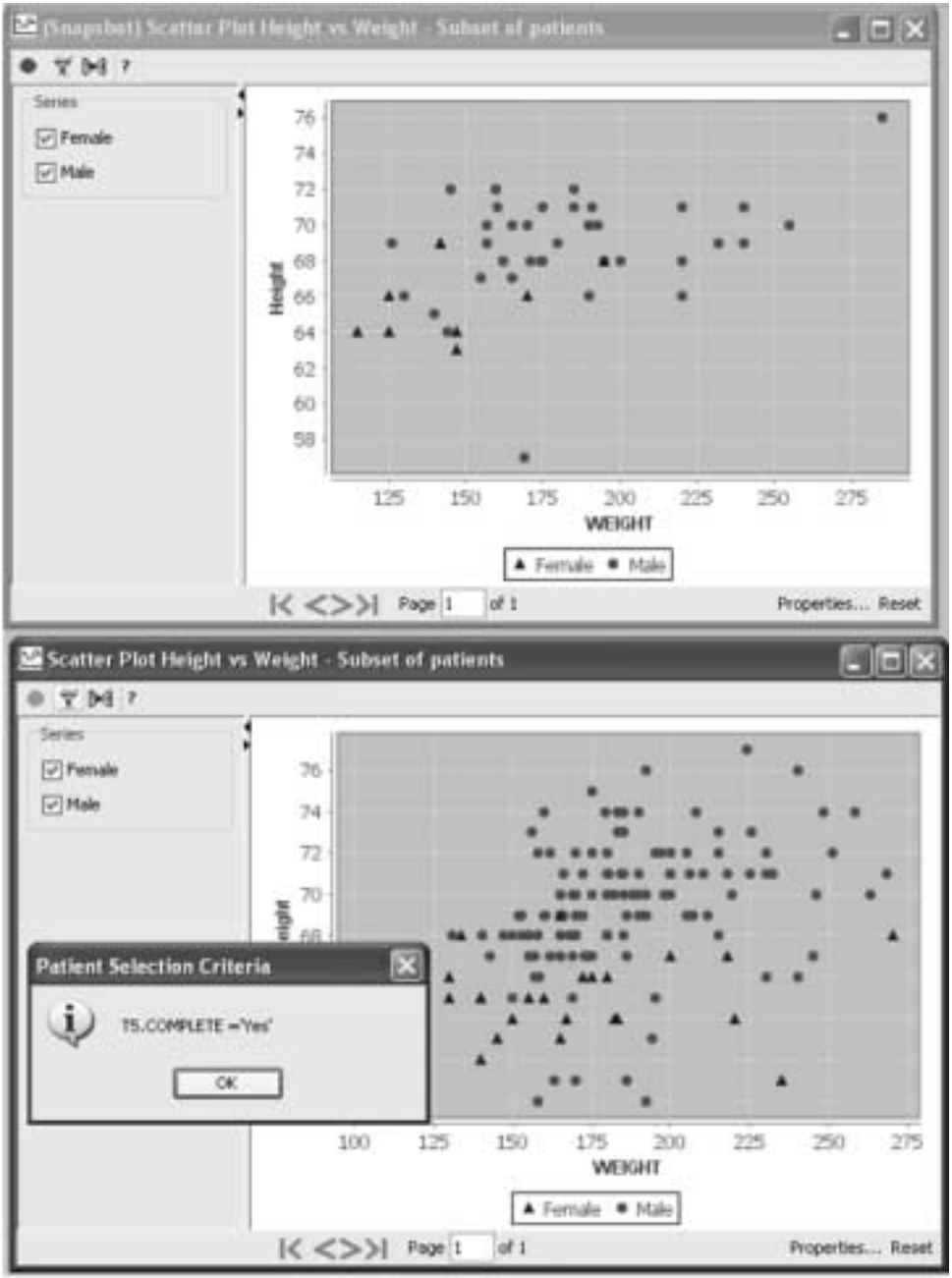
The output example shows a stored graph object with previous patient selection criteria defined.



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.

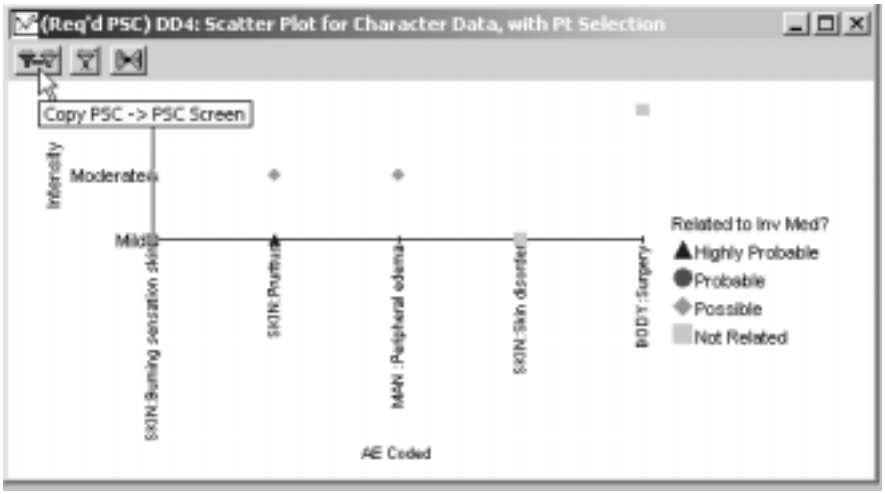
A patient selection criteria was applied and then the same graph object re-executed to display the two output windows together for comparison. The selection criteria message box shows the new graph output window has a selection criteria for “Completed Study”.



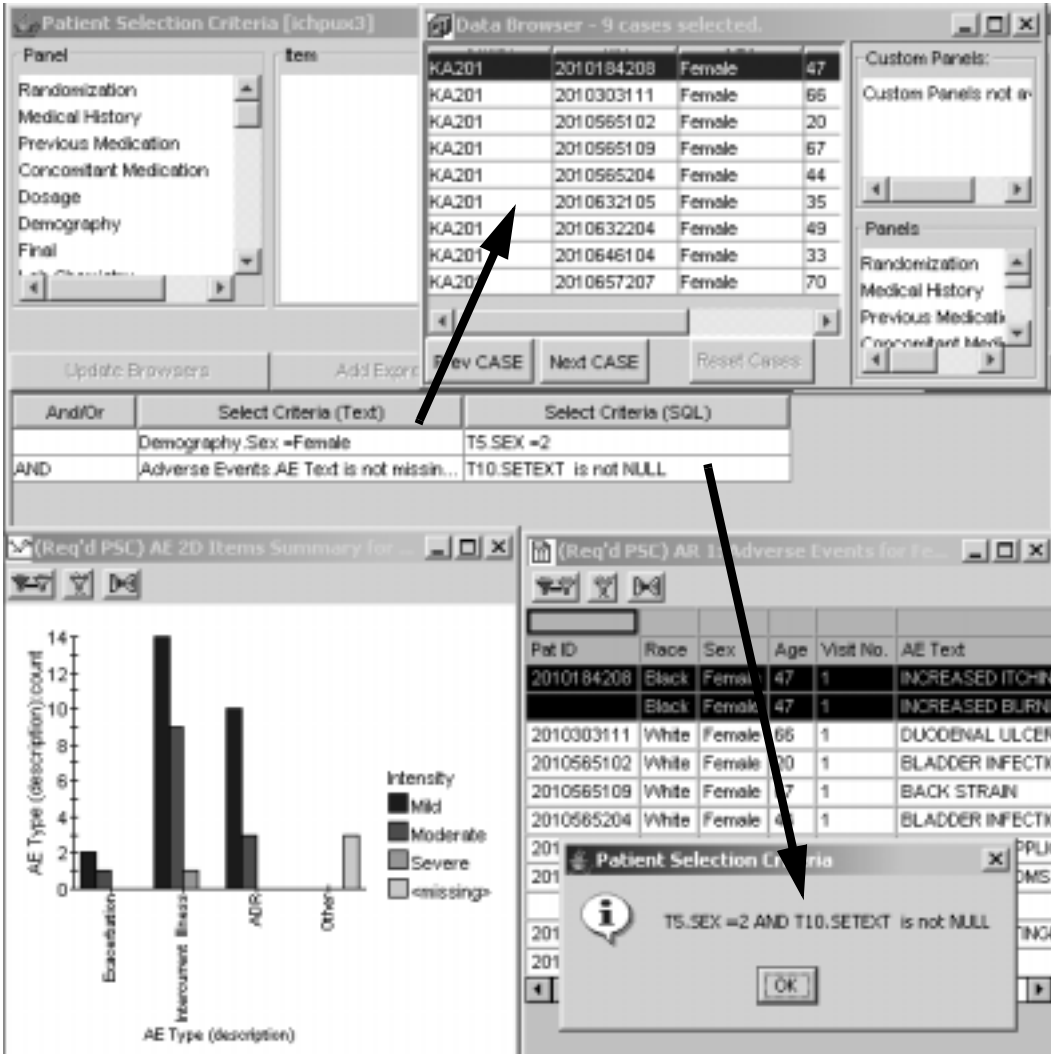
Multiple output for required selection criteria

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.

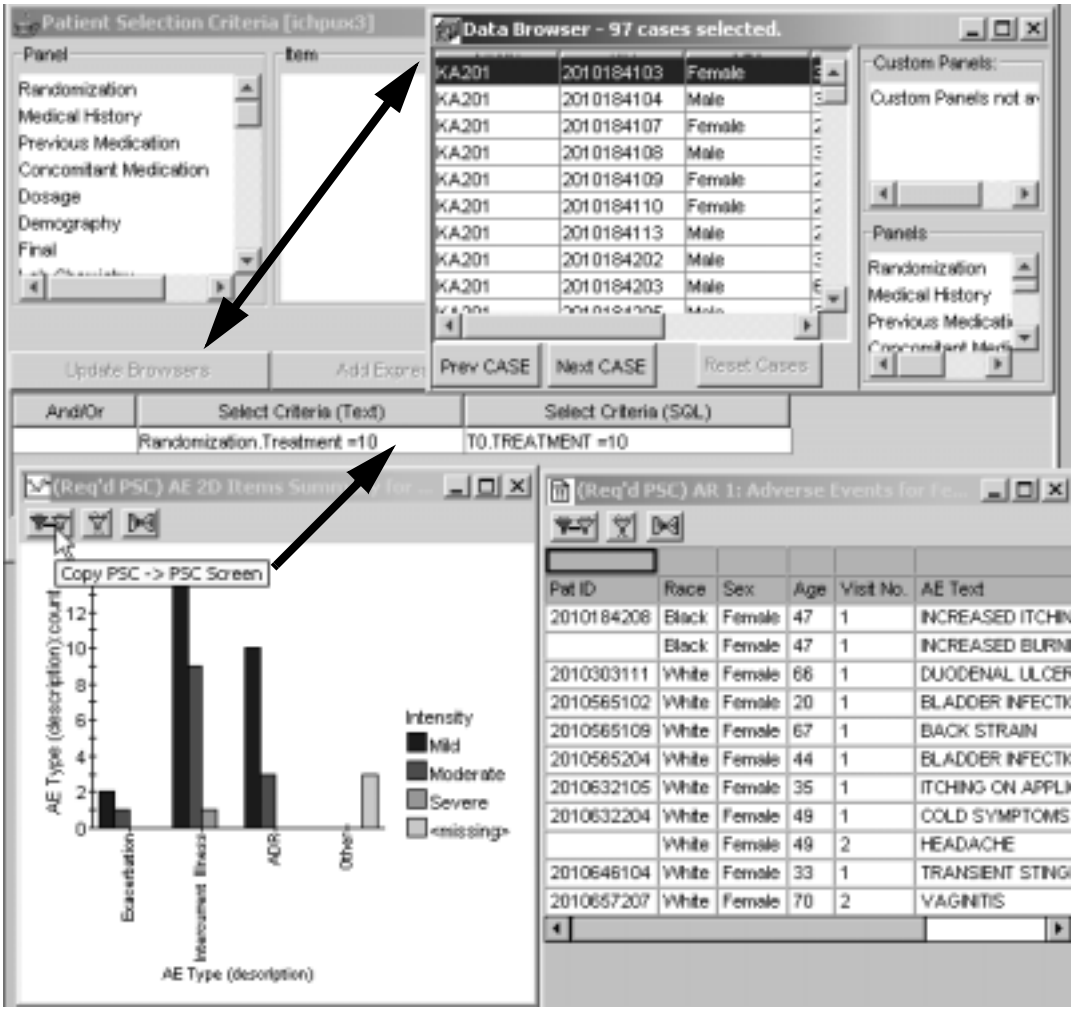
You can open multiple objects with “Req’d PSC” and toggle between the required selection criteria to update your Data Browser display or other objects where a selection criteria definition isn’t required.



The last launched object with a required selection criteria is loaded into the Patient Selection Criteria window.


Patient Selection Criteria [ichpux3]
Panel
Item
Randomization
Medical History
Previous Medication
Concomitant Medication
Dosage
Demography
Final
Update Browsers
Add Expr
Data Browser - 9 cases selected.
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
KA20 2010657207 Female 70
Prev CASE
Next CASE
Reset Cases
Custom Panels:
Custom Panels not a
Panels
Randomization
Medical History
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
(Req'd PSC) AE 2D Items Summary for ...
AE Type (description) count
AE Type (description)
Intensity
Mild
Moderate
Severe
<missing>
Pat ID
Race
Sex
Age
Visit No.
AE Text
2010184208 Black Female 47 1 INCREASED ITCHIN
Black Female 47 1 INCREASED BURN
2010303111 White Female 66 1 DUODENAL ULCE
2010565102 White Female 20 1 BLADDER INFECTI
2010565109 White Female 67 1 BACK STRAIN
2010565204 White Female 44 1 BLADDER INFECTI
Patient Selection Criteria
T5.SEX =2 AND T10.SETEXT is not NULL
OK

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.



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

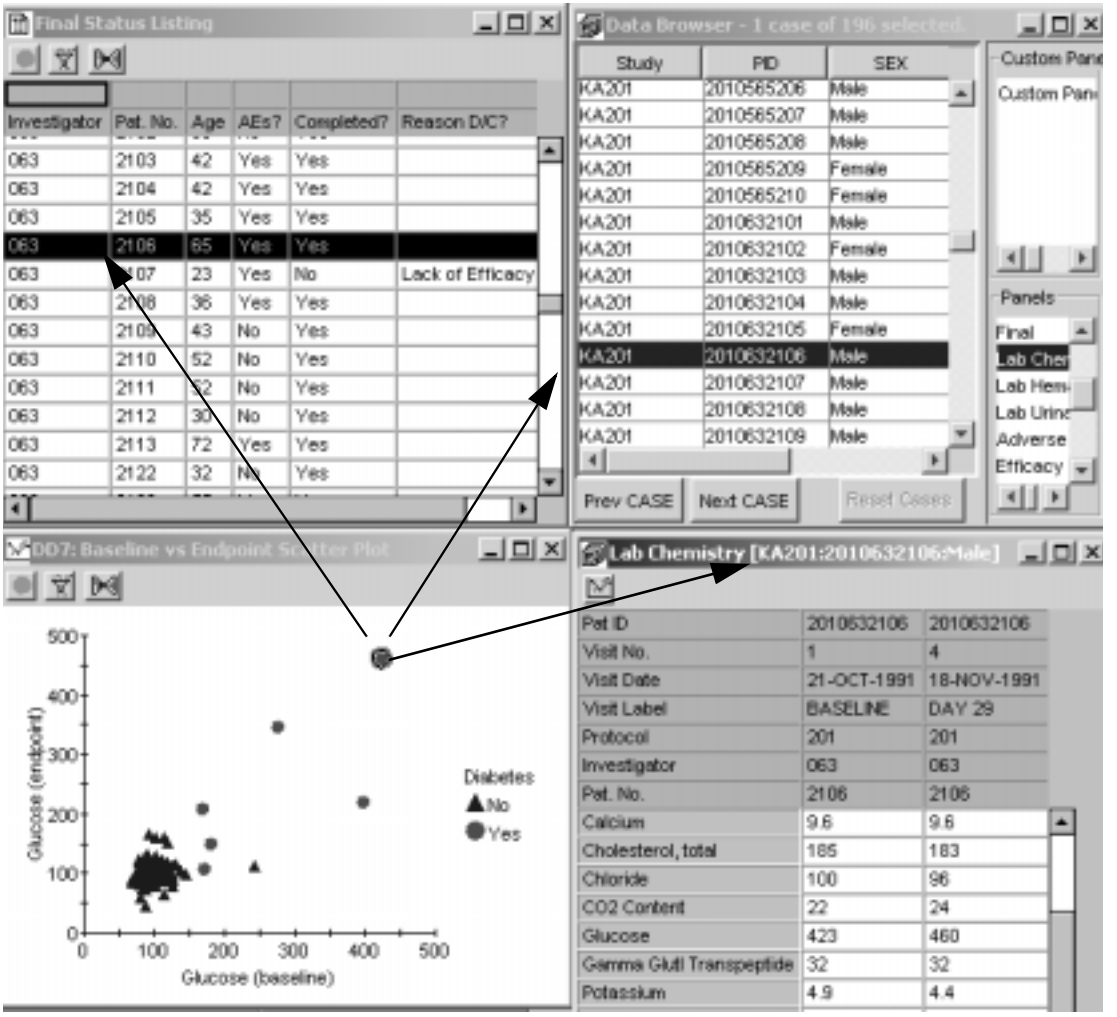
Single patient mode

Scatter Plot graphs are patient-level graphs, and each data point represents an individual patient's data value for the respective variables.

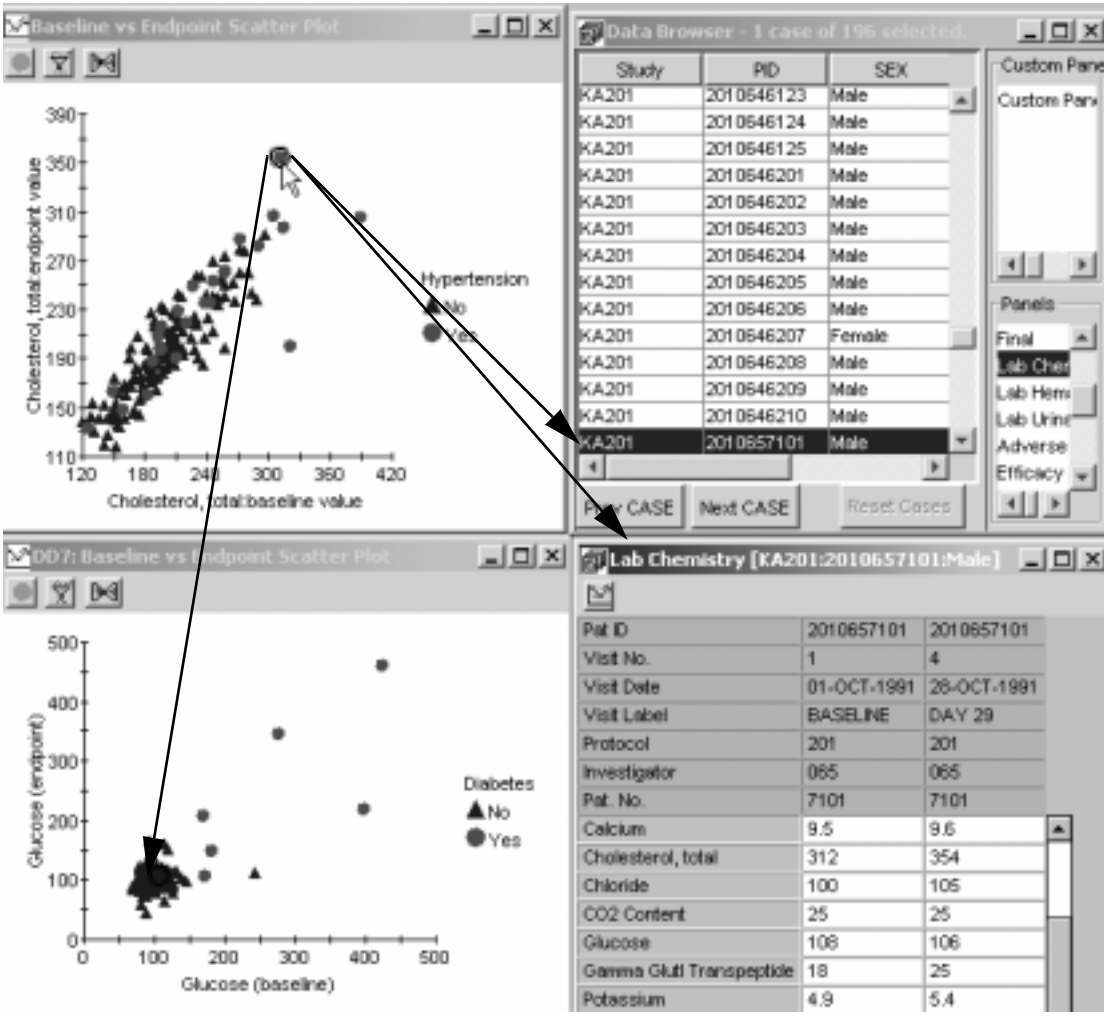
A click on any data point facilitates identification of the underlying patient and access to all respective patient data in the single patient mode.

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.



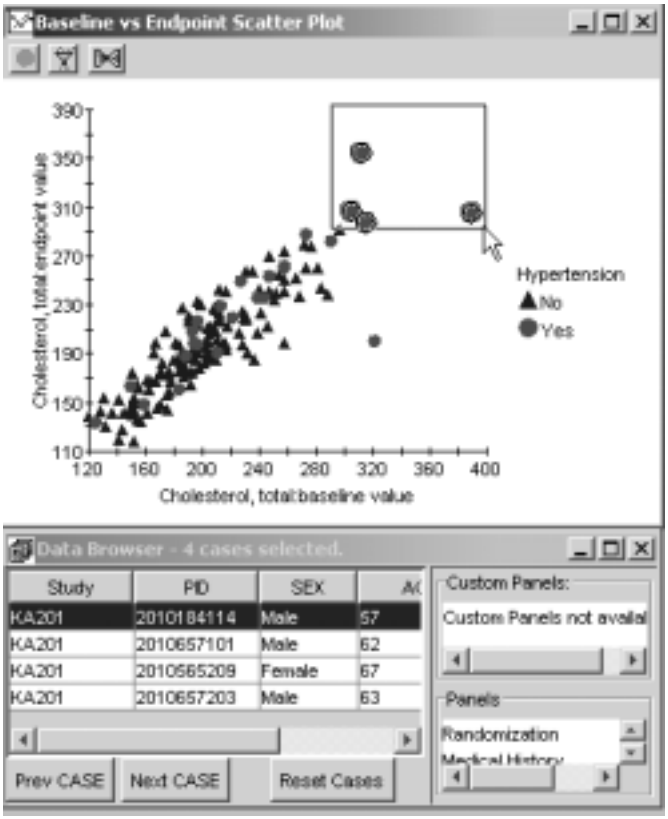
4. If there are multiple scatter plots or Baseline vs. Endpoint plots active, each plot highlights the selected patient's data point. Click on a patient's data point in one graph, to see where that patient's data point is displayed in other graphs.


Baseline vs Endpoint Scatter Plot
Cholesterol, total:endpoint value
Cholesterol, total:baseline value
Hypertension
No
Yes
Data Browser - 1 case of 196 selected.
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
Next CASE
Reset Cases
Custom Panel
Panels
Final
Adverse
Efficacy
DD7: Baseline vs Endpoint Scatter Plot
Glucose (endpoint)
Glucose (baseline)
Diabetes
No
Yes
Lab Chemistry [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

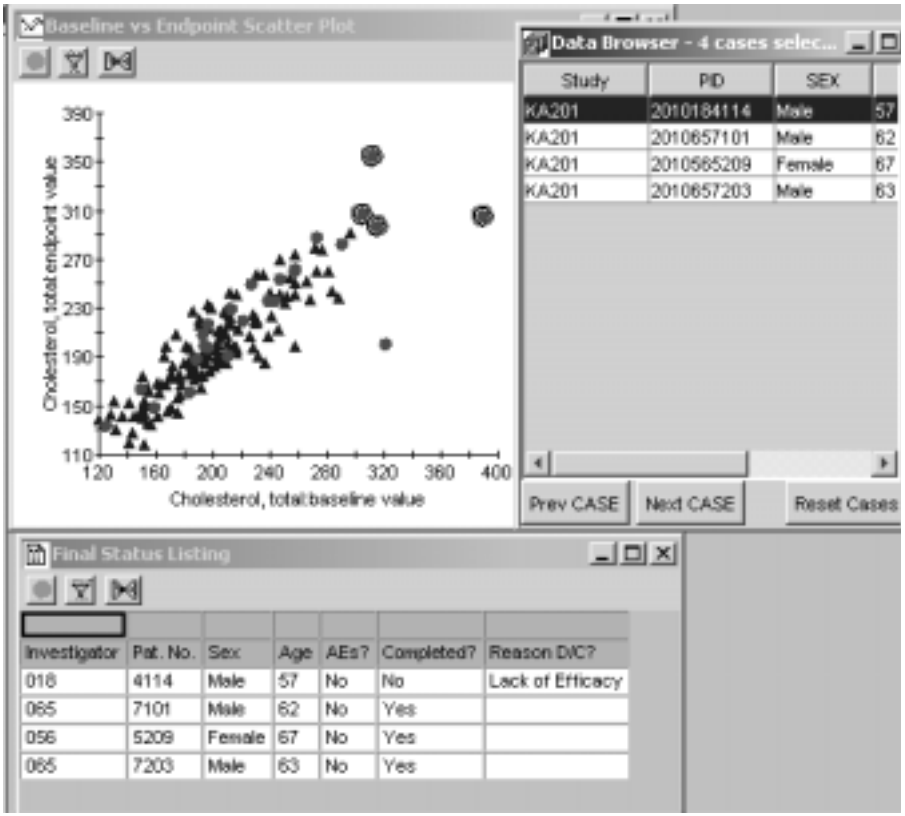
Multiple patient mode

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.

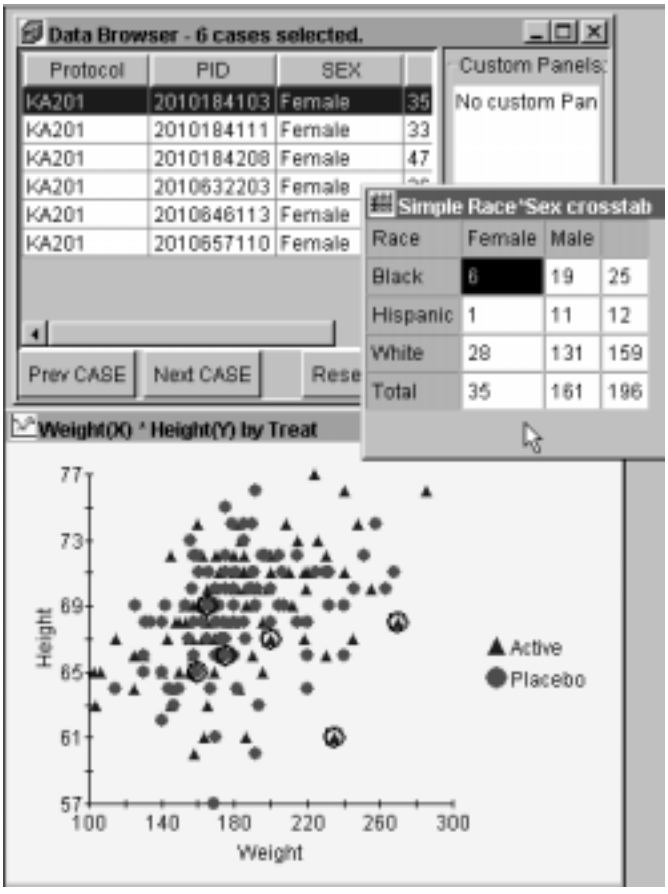


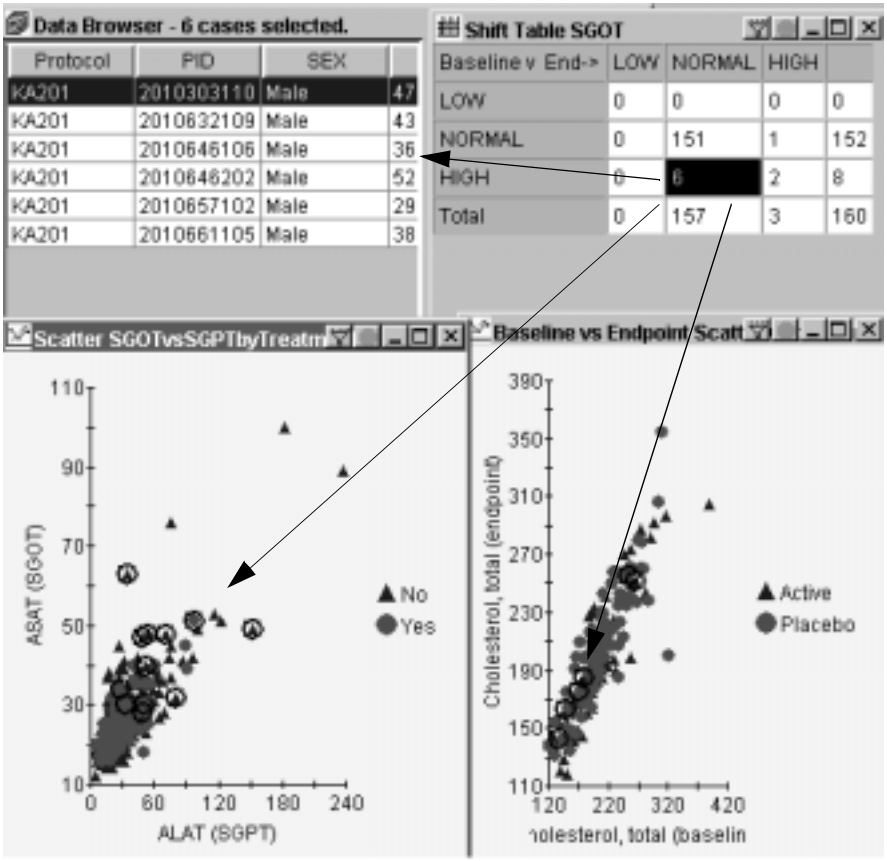
Detail Data Listing Reports, the Data Browser patient listing, and other Scatter Plot graphs are updated to display only the patients that are highlighted in a active Scatter Plot graph in multiple-patient mode.



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.

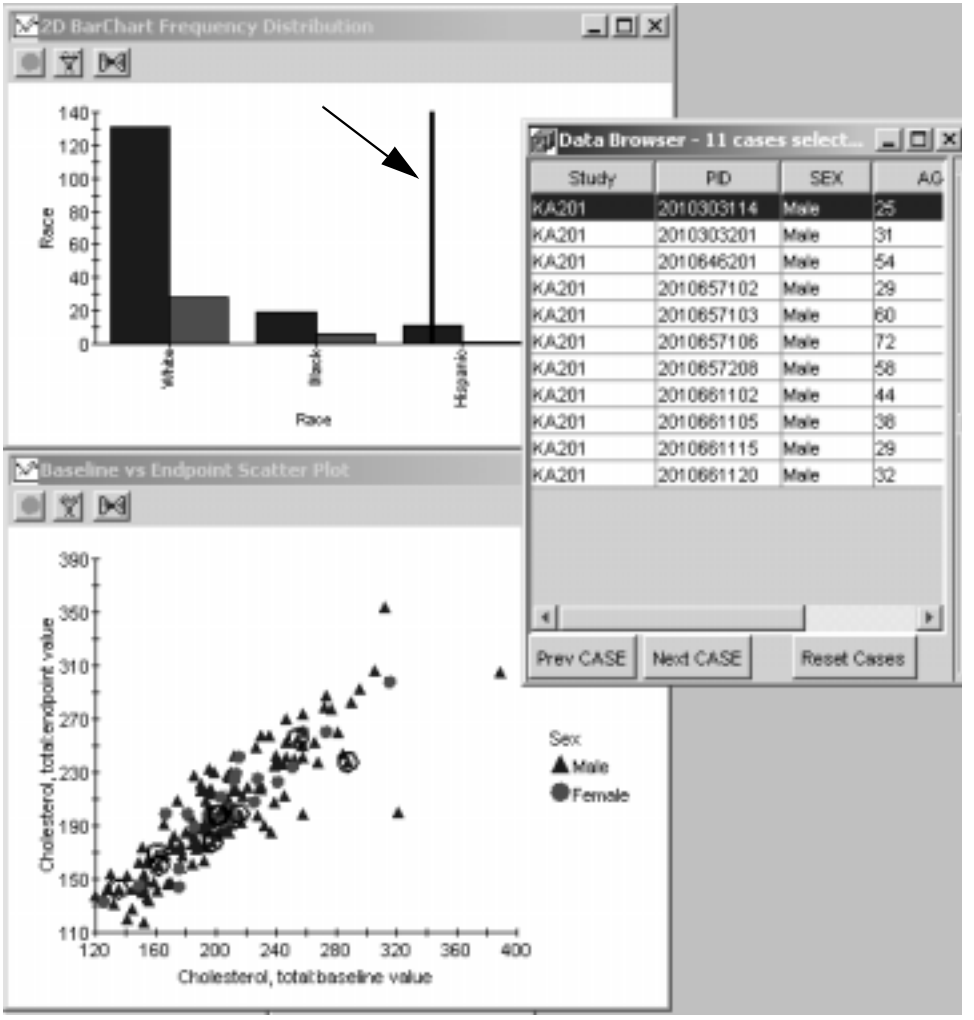
When a patient count is highlighted in the CrossTab results window, instantly all Detail Data Listings, Reports, Scatter Plot graphs, and the Data Browsers patient listing are updated with only the patients underlying the patient count highlighted from the CrossTab Browser results table.


Data Browser - 6 cases selected.
Protocol
PID
SEX
KA201 2010184103 Female 35
KA201 2010184111 Female 33
KA201 2010184208 Female 47
KA201 2010632203 Female
KA201 2010646113 Female
KA201 2010657110 Female
Custom Panels:
No custom Pan
Prev CASE
Next CASE
Rese
Simple Race*Sex crosstab
Race Female Male
Black 6 19 25
Hispanic 1 11 12
White 28 131 159
Total 35 161 196
Weight(X) * Height(Y) by Treat
Height
77
73
69
65
61
57
100 140 180 220 260 300
Weight
Active
Placebo

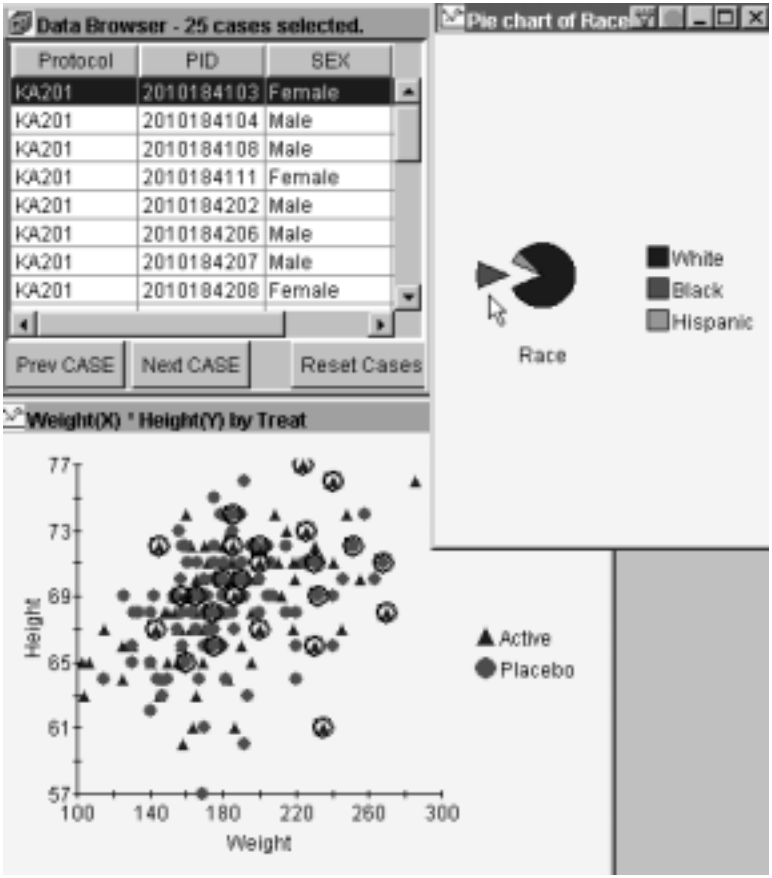

Data Browser - 6 cases selected.
Protocol PID SEX
KA201 2010303110 Male 47
KA201 2010632109 Male 43
KA201 2010646106 Male 36
KA201 2010646202 Male 52
KA201 2010657102 Male 29
KA201 2010661105 Male 38
Shift Table SGOT
Baseline v End-> LOW NORMAL HIGH
LOW 0 0 0 0
NORMAL 0 151 1 152
HIGH 0 6 2 8
Total 0 157 3 160
Scatter SGOTvsSGPTbyTreatm
ASAT (SGOT)
ALAT (SGPT)
No
Yes
Baseline vs Endpoint Scatt
Cholesterol, total (endpoint)
Active
Placebo

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.



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.



Graph Editing

Graph settings

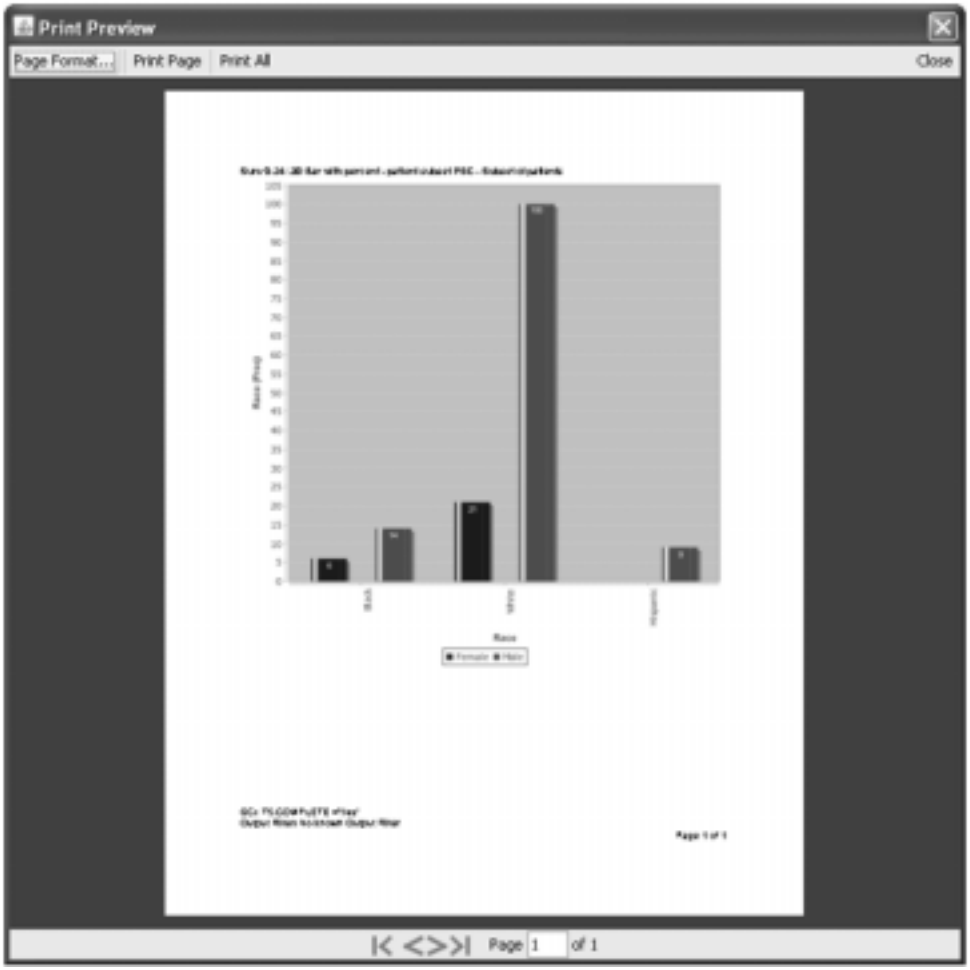
Once you create your graph, you can right-mouse click anywhere on the graph to open the **Chart Properties** window. You can apply a variety of graph format changes with the setting options available.

Printing and Exporting Graphs

Printing the graph

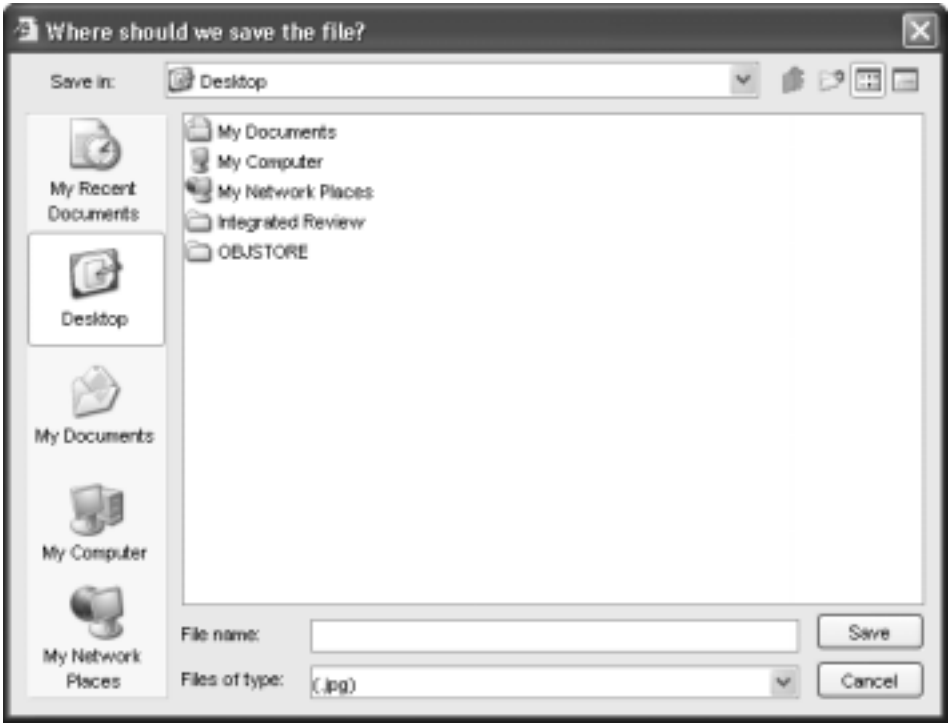
To get a printed copy of your graph you must access a **Print Preview window** and menu bar.

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.



Object Storage

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.*

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 **386**
Selection set 386
Execute CrossTab **386**
Quick execute 386
CrossTab Browser types of analysis **387**
Select type of crosstab analysis 387
Defining a CrossTab table **389**
Selecting a panel, item, and function 389
Access to SAS datasets 392
Edit column width 393
Sort by Code Value 393
Output Filter 393
Apply group function 394
Show empty values 395
Add cell variable 397
Edit the CrossTab specification 398
Display Crosstab with Percentages **399**
Include Row% Col% 399
Percent Denominator 399
Include Row%,Col% with selection criteria 406
Totals Subject Count 410
Filter Subject Count 414
Subtotal 2nd column 416
Include N% function 417
Include N% and Totals subject count 419
Include N% Patient Subset 420
Descend N(%) Sort 421
Select decimal places 422

Include N% Col Totals 423
Include N% Row Totals 424
Include N% First column totals 425
Include N% First column totals (All sub) 427
Include N% with Subtotal 2nd column 428
CrossTab Side by Side Columns 430

Interactive CrossTab - Combination Explorer 432
View patient counts 432
Analyze Combinations 437
Include N% to Analyze Combinations 438
Item analyzed 440

Defining a Shift Table 440
Item analyzed 440
Create Shift Table 441
Range values 442
Assign Baseline and Endpoint 443
Apply Filter Output 443
Include Row% and Col% 444

Multiple CrossTab/Shift Tables 444
Multiple CrossTabs 444

Snapshot output 445
Multiple population mode 445

Printing and exporting CrossTab/Shift Tables 445
Print Preview 445
Print the CrossTab / Shift Tables 446
Page Setup 446
Exporting the CrossTab / Shift Tables 447

Interactive patient-level displays 448
Crosstab cell select 448
Crosstab multiple cell select 448
Detail data patient listings and graphs 449

Object storage 450

Exploring data 450
Changing the patient selection criteria 450

CrossTab output filter 451

Closing the CrossTab Browser 451

Closing a CrossTab Window 451

Closing the CrossTab Browser 451

Patient selection criteria

Selection set

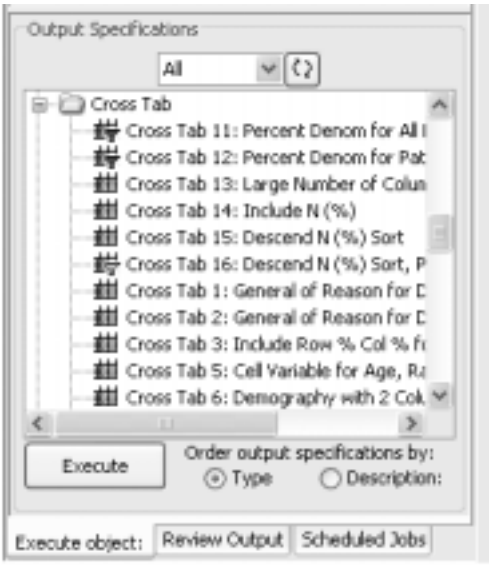
In JReview, you can select a previously saved Patient Subset or define your own selection criteria for use in the CrossTab Browser. After launching the saved patient subset or building your own patient selection criteria, you can explore CrossTab objects created in the CrossTab Browser.

Execute CrossTab

Quick execute

Both IReview and 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.



CrossTab Browser types of analysis

Select type of crosstab analysis

In the CrossTab Browser you can select from four types in the Type List.

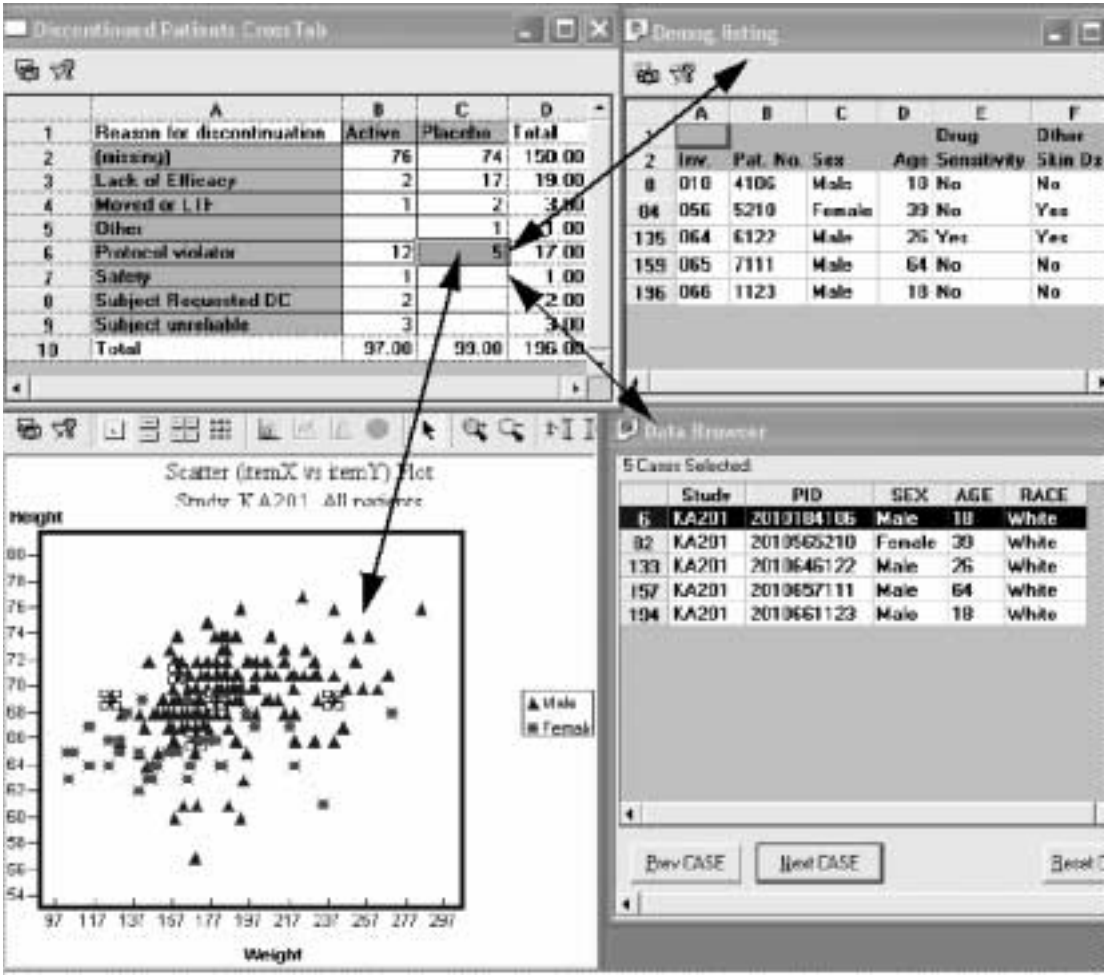
- CrossTab: Clinical patient categorization and counts.
- CrossTab Side by Side Columns: Individual column categories are displayed as counts side by side to one row variable.
- CrossTab - Combination Explorer: Subject based calculations which displays all permutations of selected data and the number 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.

Note: The CrossTab Browser allows Multiple study mode in CrossTabs. However, Shift Tables requires the specific study baseline and endpoint definitions be entered in ReviewAdmin and does not allow multiple protocol selection.

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.



Defining a CrossTab table

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.

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.

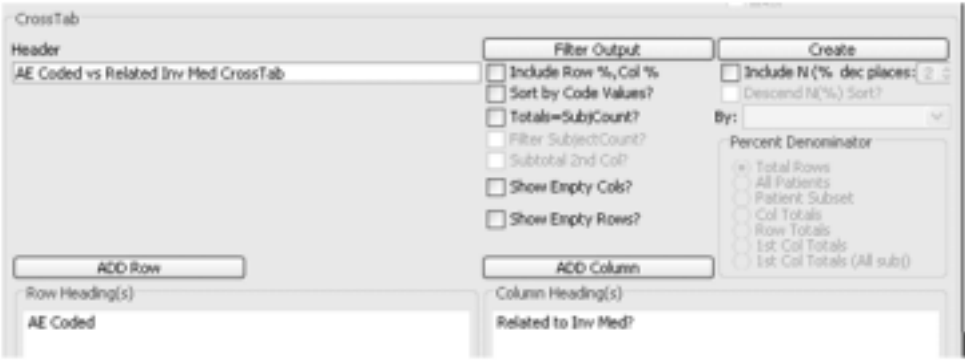
The crosstab heading displays either 'All Patients' or 'Subset' if a patient selection criteria was entered. If you modify the crosstab heading the patient population status of either 'All Patients' or 'Subset' still displays.

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 vs Race CrossTab - All Patients

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.



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.

AE Coded vs Related Inv Med CrossTab - All Patients

AE coded	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.

Summary Listing

1	count	count subjects
AE coded	AE coded	AE coded
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	3	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	9	8
NER :Somnolence	1	1
RES :Cough increased	3	3
RES :Respiratory disorder	1	1
RES :Sinusitis	5	3
RES :Upper respiratory infection	4	4
SKIN:Burning sensation skin	20	18
SKIN:Pruritus	2	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
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.

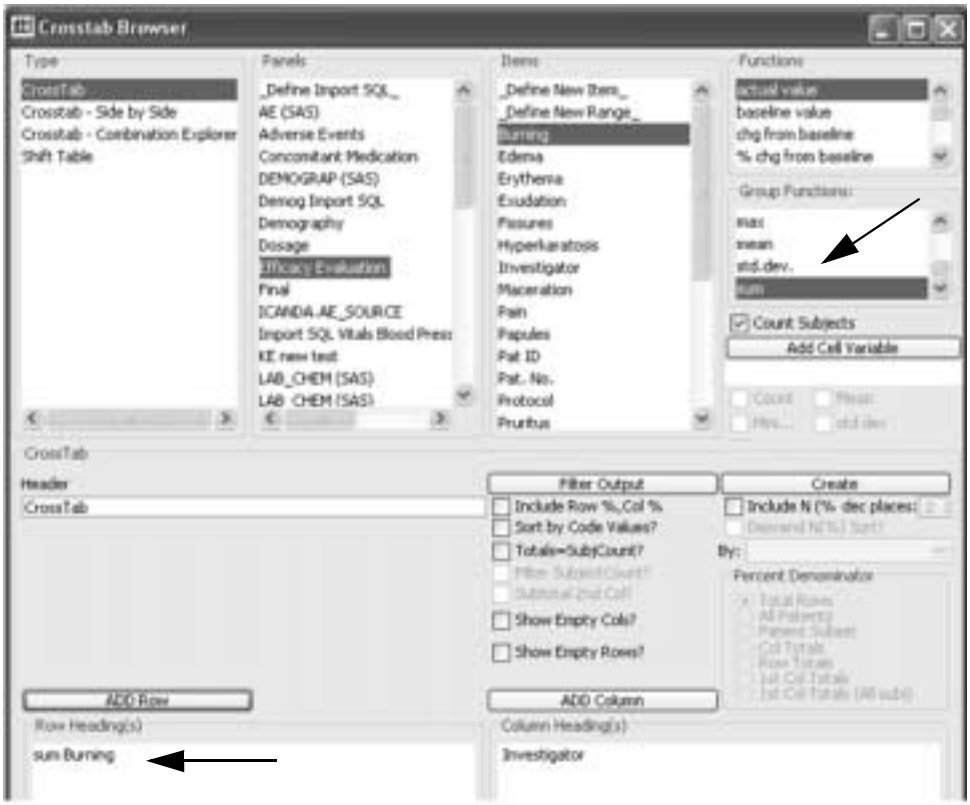
After you define your CrossTab specifications you can use the output filter as a data exploration tool by row filtering data inclusion, then comparing filtered and unfiltered results. (*See Chapter 6 Report Browser: Output Filter*)

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.



The column for 'sum Burning' displays the unique sum values with counts by investigator.

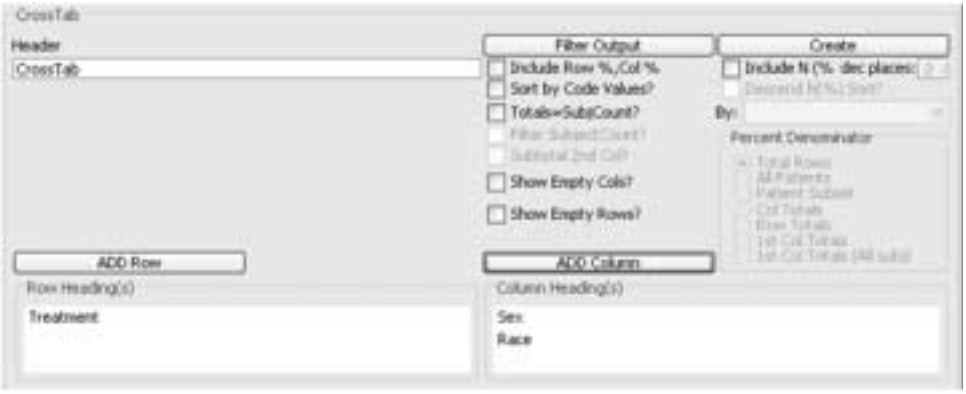
CrossTab - All Patients

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.



This crosstab shows the normal results when both 'Show Empty Columns' and 'Show Empty Rows' are not checked ON.

CrossTab - Subset of patients

	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.

CrossTab - 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.

CrossTab - Show Empty Rows? - Subset of patients

	(missing)	Female		Male			Row Sum
Treatment	(missing)	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.

CrossTab - Show Empty Rows?, 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
Placebo							
Col Sum	4.00		15.00	12.00	4.00	62.00	97.00

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.

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 .

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:

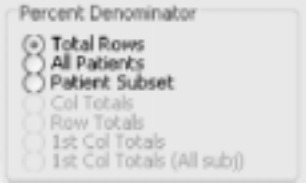
- Include Row%, Col%
- Include N (%)

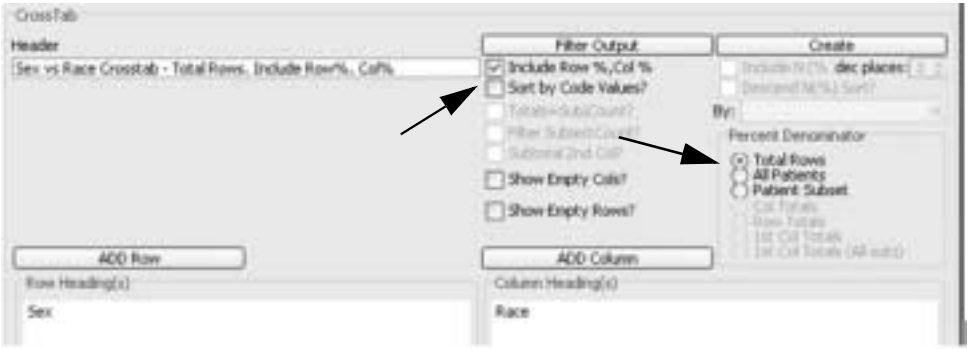
If either of these percent functions are selected, then choose an option for the Percent Denominator.

- 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.





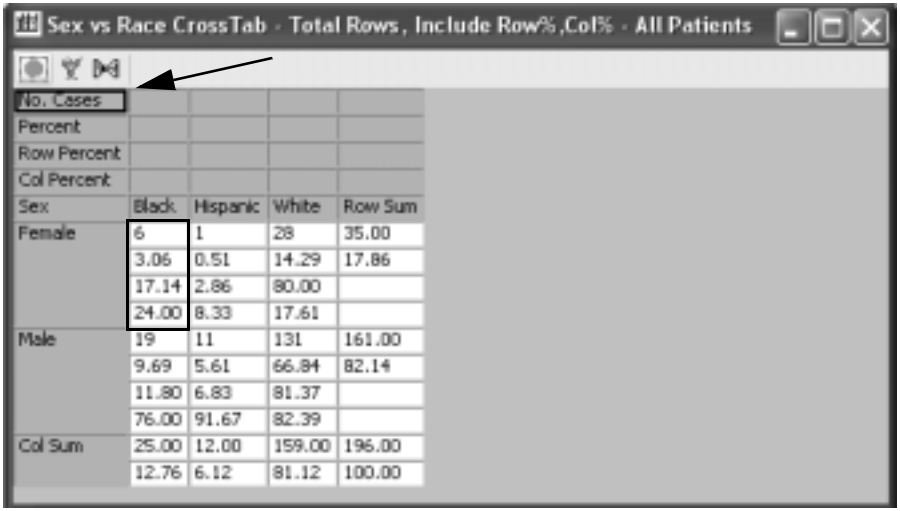
A legend of the cell statistics displays in the upper left corner. The **Include Row% Col%** provides a separate Row Sum with percent and Column Sum with percent including percentages for each cell count. Each row and column is summarized by descriptive statistics.

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.

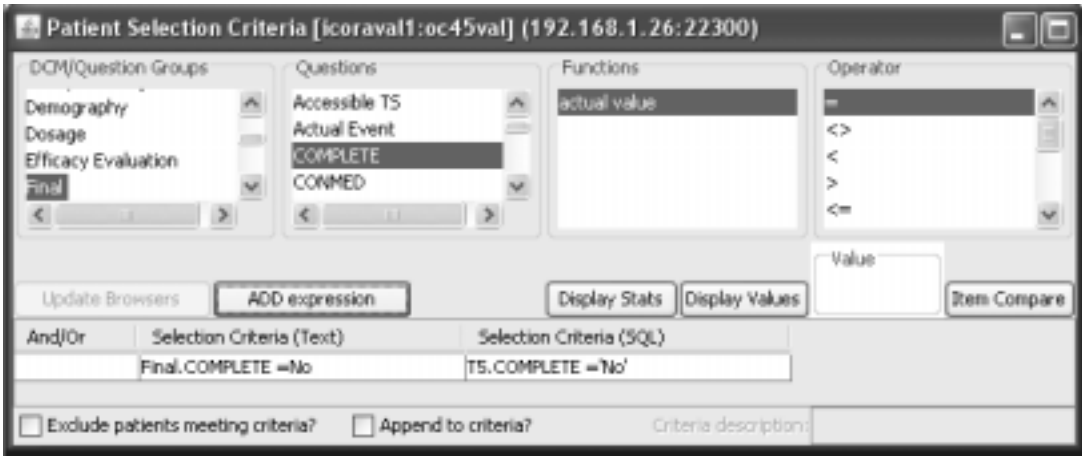
Row Percent is 6/**Row Sum** 35 = 17.14%.

Column Percent is 6/**Col Sum** 25 = 24%.



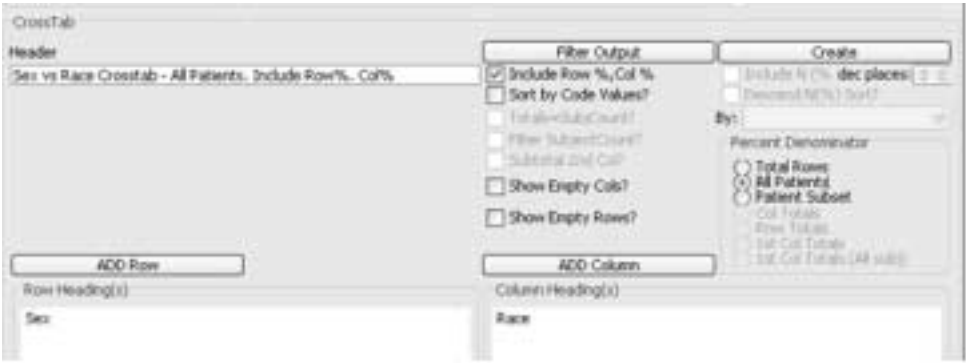
No. Cases				
Percent				
Row Percent				
Col Percent				
Sex	Black	Hispanic	White	Row Sum
Female	6	1	28	35.00
	3.06	0.51	14.29	17.86
	17.14	2.86	80.00	
	24.00	8.33	17.61	
Male	19	11	131	161.00
	9.69	5.61	66.84	82.14
	11.80	6.83	81.37	
	76.00	91.67	82.39	
Col Sum	25.00	12.00	159.00	196.00
	12.76	6.12	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.



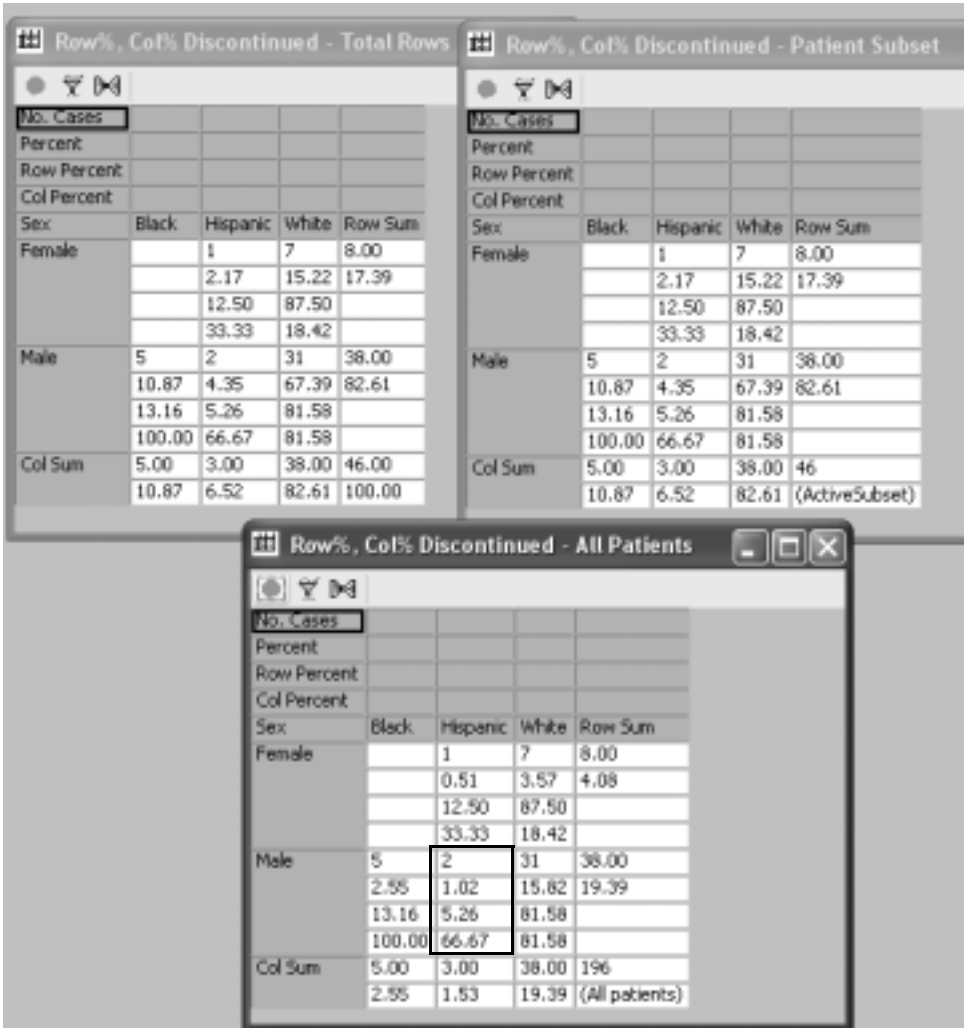
The current patient selection criteria calculates the patient count for 46 discontinued cases. All crosstab cell percents are based on result of the patient selection criteria and where the Data Browser shows cases selected is 46. The Row Sum and Col Sum reflect the counts of the patient subset for Discontinued 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'.



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.



Row%, Col% Discontinued - Total Rows

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

Row%, Col% Discontinued - Patient Subset

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)

Row%, Col% Discontinued - All 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%.

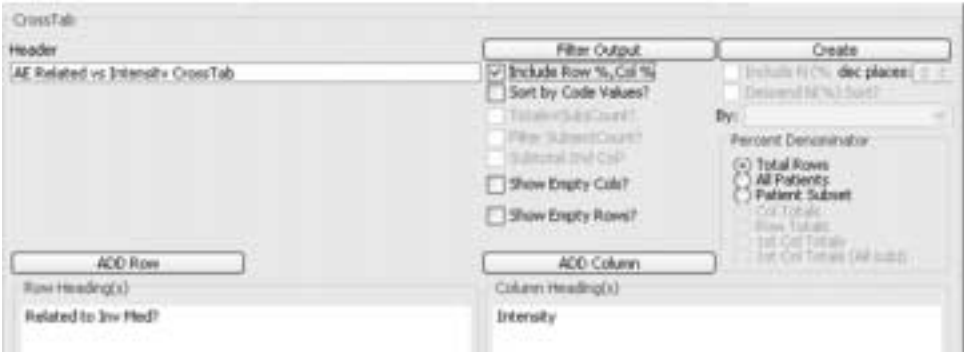
Row Percent is 2 / Row Sum 38 = 5.26%.

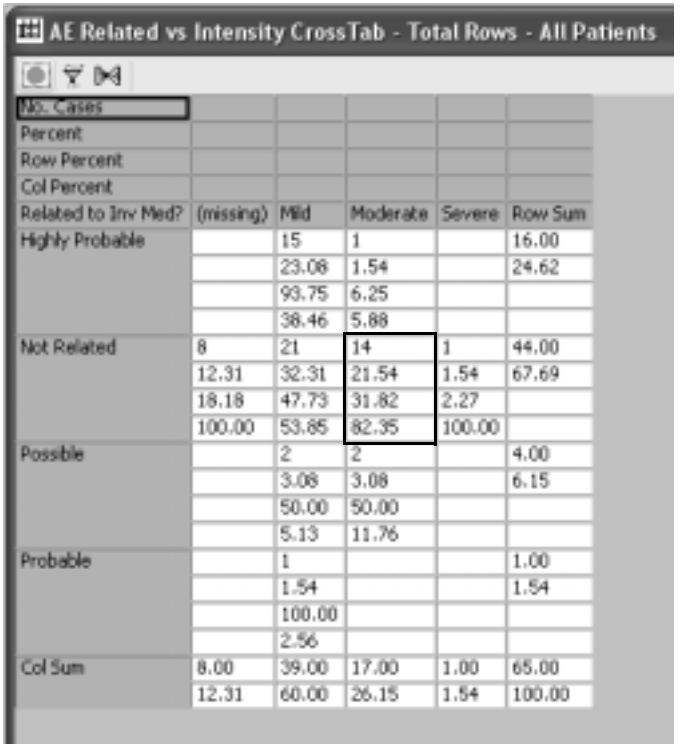
Column Percent is 2 / Col Sum 3 = 66.67%.

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.





No. Cases					
Percent					
Row Percent					
Col Percent					
Related to Inv Med?	(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

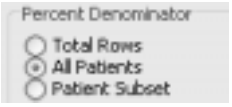
There are 65 patients who reported Adverse Events in the study. If we review the cell for 14 patients who reported Adverse Events as 'Not Related' and 'Moderate' the calculations are:

Percent is 14 / **Total Rows** 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 / **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.



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 Rows** 196 = 7.14% patients with Moderate Adverse Events reported as Not Related.

Row Percent is 14 / **Row Sum** 44 = 31.82%.

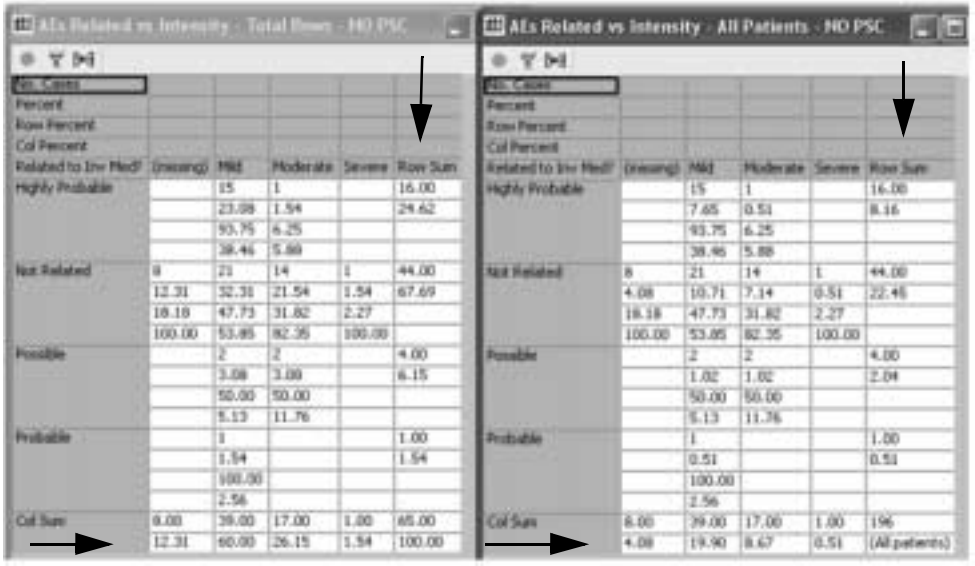
Column Percent is 14 / **Col Sum** 17 = 82.35%.

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 CrossTab - All Patients Percent Denominator - All Patients

No. Cases					
Percent					
Row Percent					
Col Percent					
Related to Inv Med?	(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)

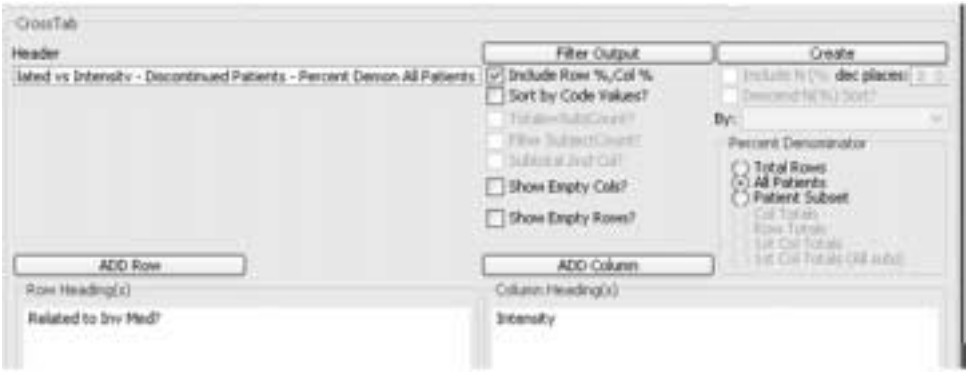
However, what changes significantly are the Total Row Sum percents and the Total Col Sum percents when you compare the crosstab options.



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’.



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 Rows** 196 = 2.04% patients with Moderate Adverse Events reported as Not Related.

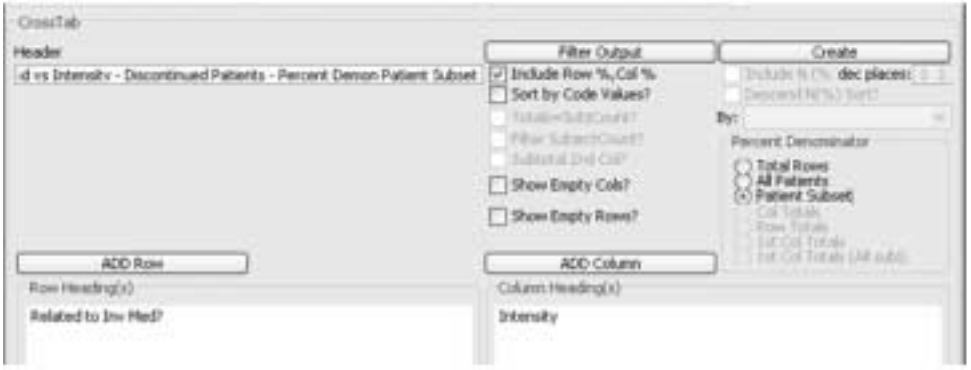
Row Percent is 4 / **Row Sum** 8 = 50%.

Column Percent is 4 / **Col Sum** 5 = 80%.

AE Related vs Intensity - Discontinued Patients - Percent Demon All Patients - Subset of patients

No. Cases					
Percent					
Row Percent					
Col Percent					
Related to Inv Med?	(missing)	Mild	Moderate	Severe	Row Sum
Highly Probable		6			6.00
		3.06			3.06
		100.00			
		66.67			
Not Related	1	2	4	1	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	1		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.

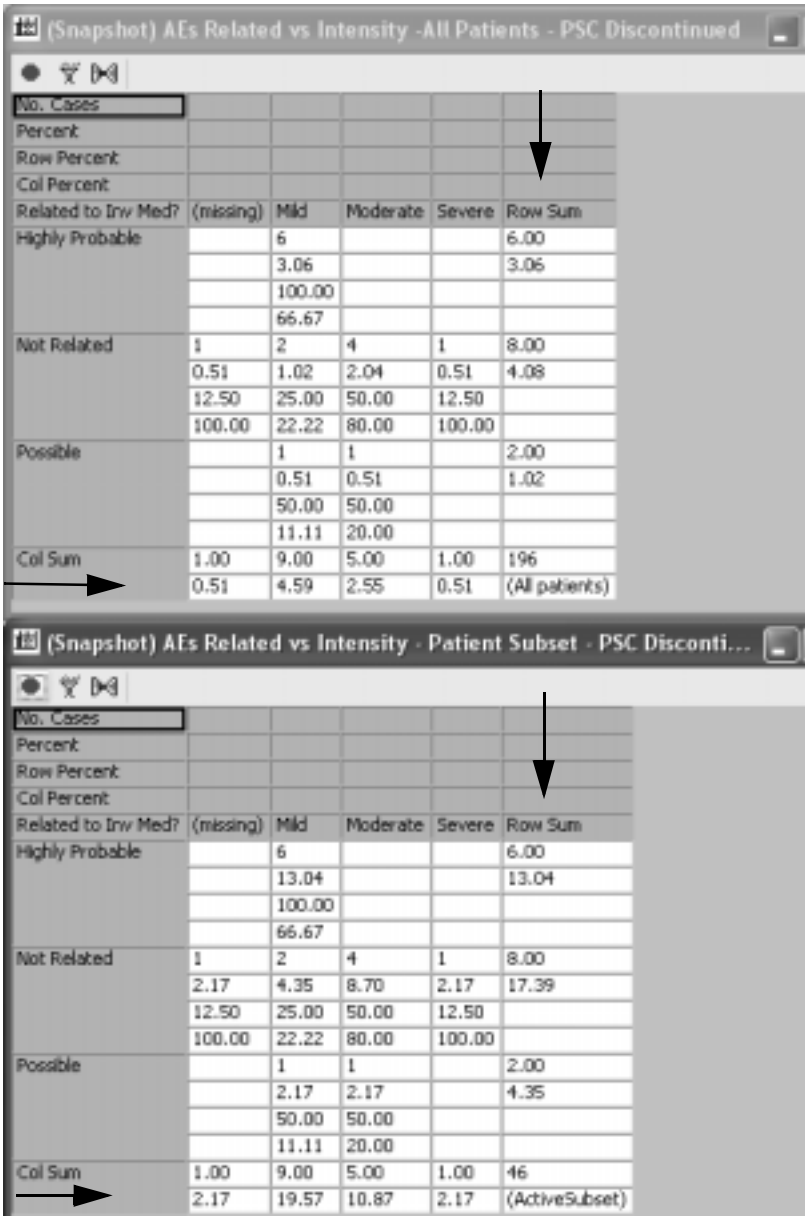


The cell the Percent result changes for 4 / 46 = 8.70% and Row Percent and Column Percent remain the same.

AE Related vs Intensity - Discontinued Patients - Percent Demon Patient Subset - Subset of patients

No. Cases					
Percent					
Row Percent					
Col Percent					
Related to Inv Med?	(missing)	Mild	Moderate	Severe	Row Sum
Highly Probable		6			6.00
		13.04			13.04
		100.00			
		66.67			
Not Related	1	2	4	1	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	1		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) AEs Related vs Intensity -All Patients - PSC Discontinued

No. Cases Percent Row Percent Col Percent					
Related to Inv Med?	(missing)	Mild	Moderate	Severe	Row Sum
Highly Probable		6			6.00
		3.06			3.06
		100.00			
		66.67			
Not Related	1	2	4	1	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	1		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)

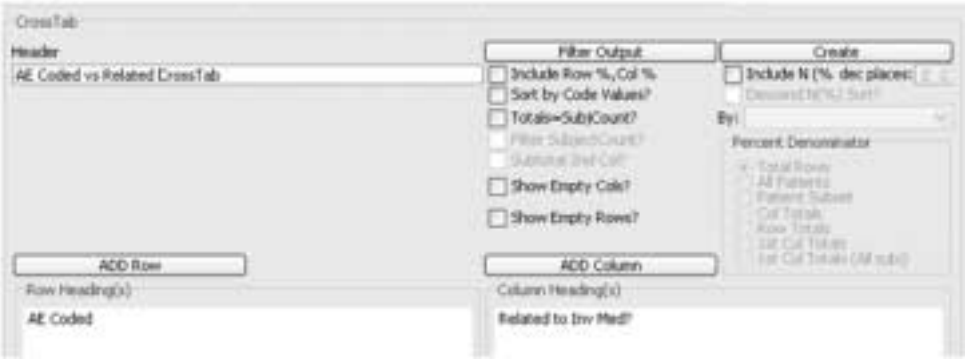
(Snapshot) AEs Related vs Intensity - Patient Subset - PSC Disconti...

No. Cases Percent Row Percent Col Percent					
Related to Inv Med?	(missing)	Mild	Moderate	Severe	Row Sum
Highly Probable		6			6.00
		13.04			13.04
		100.00			
		66.67			
Not Related	1	2	4	1	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	1		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)

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).



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 CrossTab - All Patients

AE coded	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

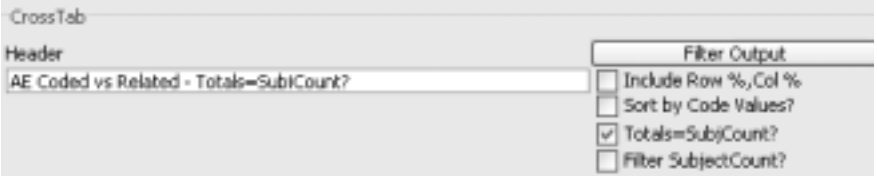
Data Browser - 37 cases selected

Study	PT	INV
KA201$CURRENT	5204	056
KA201$CURRENT	1120	066
KA201$CURRENT	3206	030

Custom DCM/Question Groups:

Custom DCM/Question Groups not available

When the 'Totals=SubjCount?' is turned **ON**, the updated results show the actual number of patients who reported Adverse Events.



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

AE coded	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)

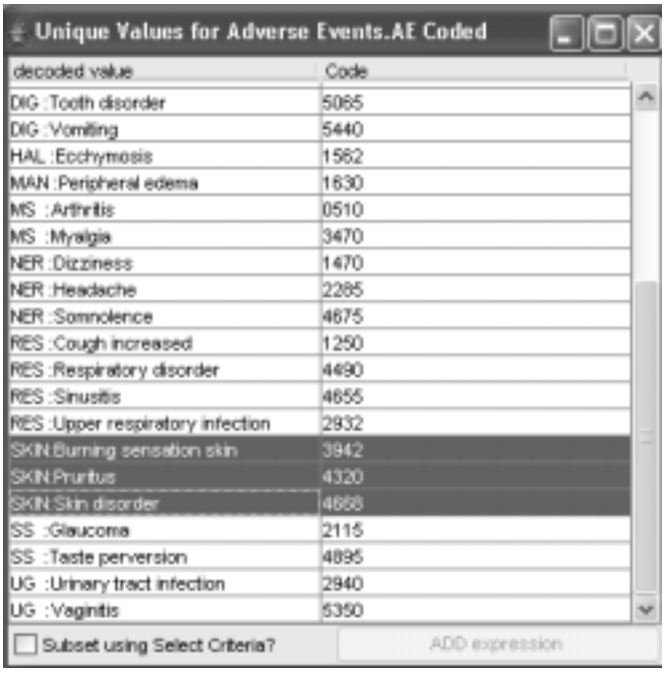
If you had defined a Summary listing for AE coded with ‘count’ and ‘count subjects’, the ‘event count’ is 81 and the ‘count subjects’ is 75 where the patient identifier is counted multiple times for multiple Adverse Events reported.

Summary Listing

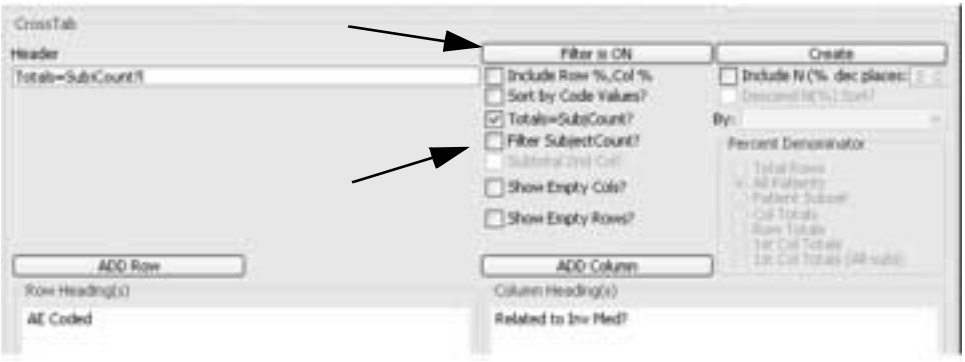
AE		count	count subjects
coded	Related to Inv Med?	Related to Inv Med?	Related to Inv Med?
BODY:Allergic reaction	Not Related	1	1
BODY:Back pain	Not Related	3	3
BODY:Body odor	Possible	1	1
BODY:Pain	Not Related	1	1
BODY:Surgery	Not Related	8	8
BODY:Unevaluable reaction	Not Related	1	1
DIG :Diarrhea	Not Related	1	1
DIG :Duodenal ulcer	Not Related	1	1
DIG :Periodontal abscess	Not Related	1	1
DIG :Rectal pain	Not Related	1	1
DIG :Sore throat	Not Related	1	1
DIG :Tooth disorder	Not Related	3	2
DIG :Vomiting	Not Related	1	1
HAL :Ecchymosis	Not Related	1	1
MAN :Peripheral edema	Possible	1	1
MS :Arthritis	Not Related	1	1
MS :Myalgia	Not Related	1	1
NER :Dizziness	Not Related	1	1
NER :Headache	Not Related	9	8
NER :Somnolence	Not Related	1	1
RES :Cough increased	Not Related	3	3
RES :Respiratory disorder	Not Related	1	1
RES :Sinusitis	Not Related	5	3
RES :Upper respiratory infection	Not Related	4	4
SKIN:Burning sensation skin	Highly Probable	17	15
SKIN:Burning sensation skin	Possible	2	2
SKIN:Burning sensation skin	Probable	1	1
SKIN:Pruritus	Highly Probable	1	1
SKIN:Pruritus	Possible	1	1
SKIN:Skin disorder	Not Related	1	1
SS :Glaucoma	Not Related	1	1
SS :Taste perversion	Not Related	1	1
UG :Urinary tract infection	Not Related	3	3
UG :Vaginitis	Not Related	1	1
Sum		81.00	75.00

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.



The Filter Output button status is now updated to 'Filter is ON' with the 'Filter SubjectCount?' left unchecked.

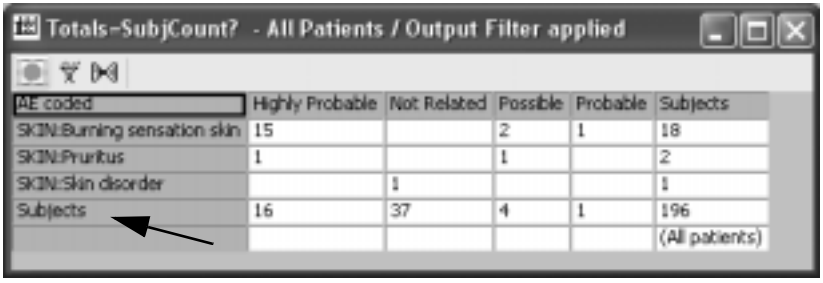


Next compare the subject row results when 'Filter SubjectCount?' feature is checked ON / OFF.

The Crosstab results with the 'Filter is ON' and 'Filter SubjectCount?' unchecked displays only the Adverse Events included in the SKIN body system.

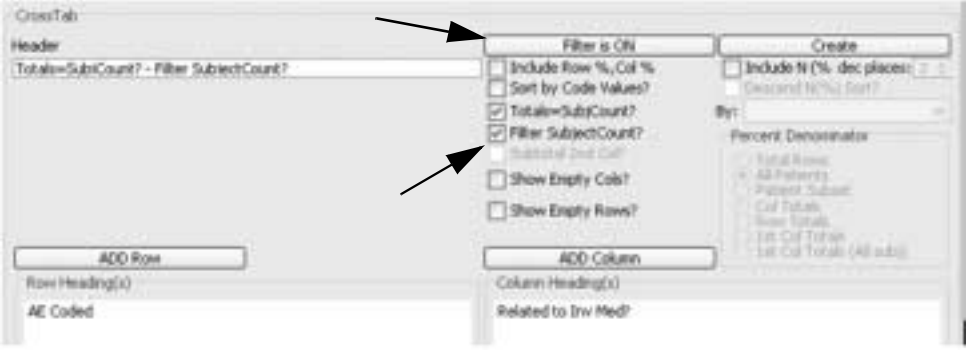
Observe that the 'Subjects' counts display for all available patients who reported Adverse Events. The output filter hasn't been applied yet to the 'Subjects' counts.

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.

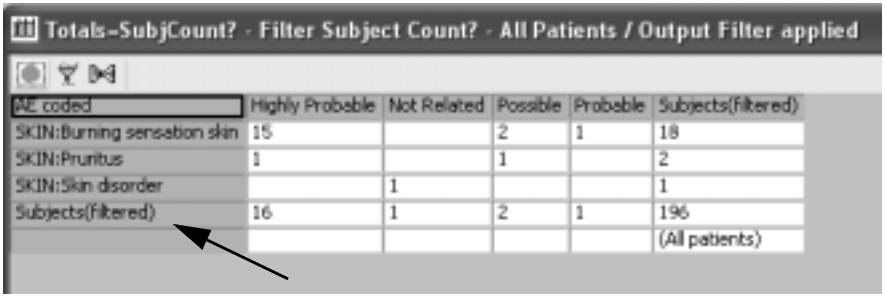


AE coded	Highly Probable	Not Related	Possible	Probable	Subjects
SKIN:Burning sensation skin	15		2	1	18
SKIN:Pruritus	1		1		2
SKIN:Skin disorder		1			1
Subjects	16	37	4	1	196
					(All patients)

Next we will view the subject row results when the 'Filter Subject Count?' check box is turned ON.



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.

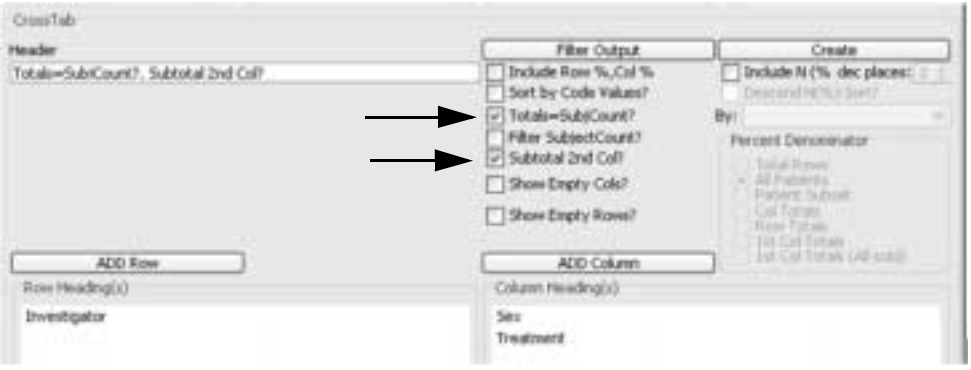


AE coded	Highly Probable	Not Related	Possible	Probable	Subjects(filtered)
SKIN:Burning sensation skin	15		2	1	18
SKIN:Pruritus	1		1		2
SKIN:Skin disorder		1			1
Subjects(filtered)	16	1	2	1	196
					(All patients)

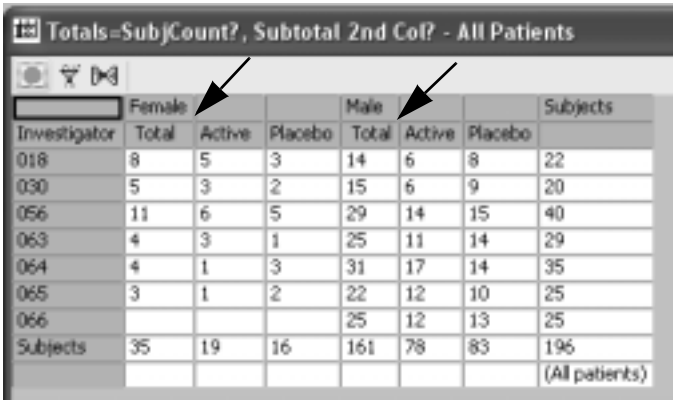
Subtotal 2nd column

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.



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.



Totals=SubjCount?, Subtotal 2nd Col? - All Patients

	Female			Male			Subjects
Investigator	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.

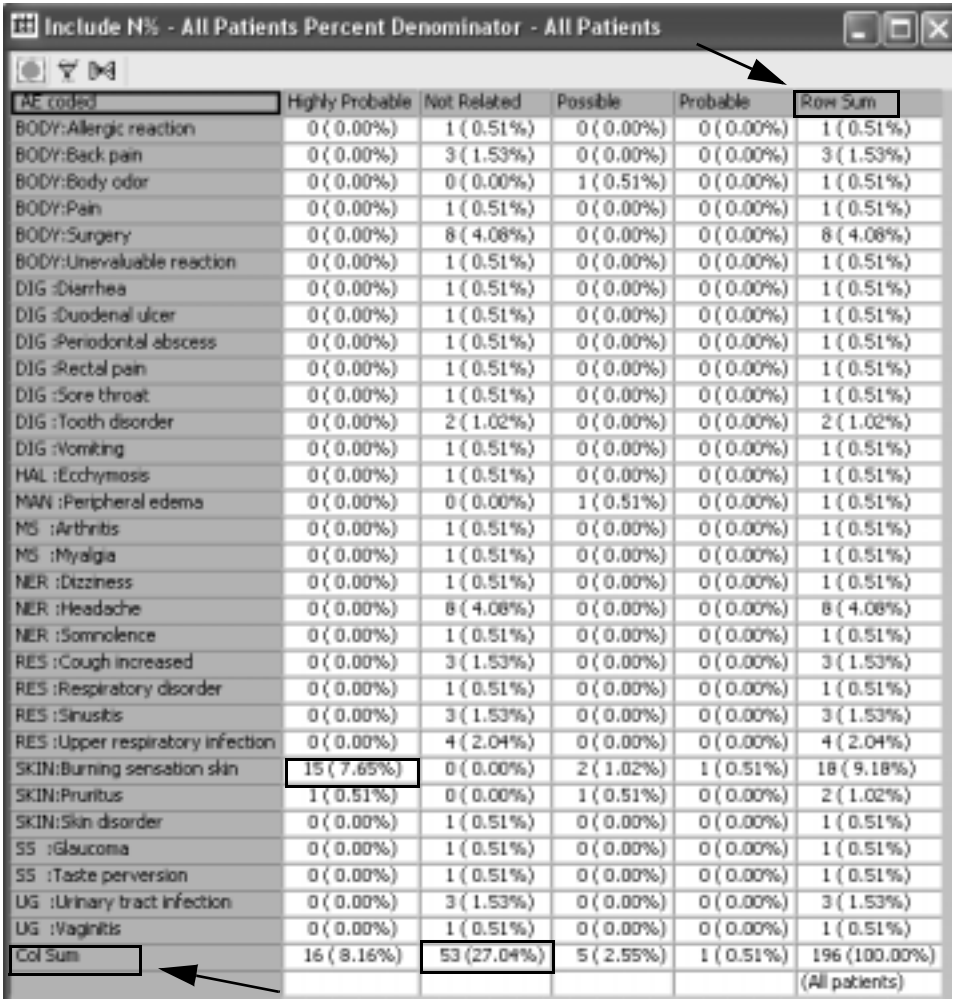
Include N% function

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'.

Also, the Include N(%) function is mutually exclusive from the Include Row%, Col% function, so it is an either / or condition.

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.



Include N% - All Patients Percent Denominator - All Patients

AE coded	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

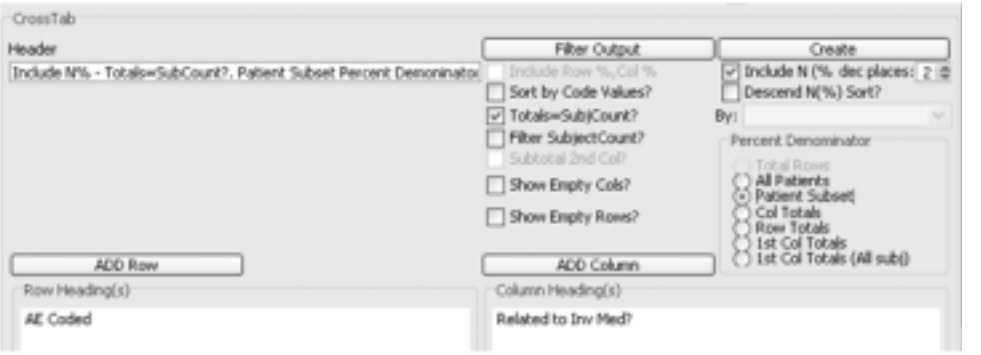
If you select the **Include N(%)** function in conjunction with the 'Totals=Subjcount?' function there are more options available for the **Percent Denominator**. The following crosstab has selected both the 'Include (N)%' and 'Totals=SubCount?' functions as checked On with the Percent Denominator set for 'All Patients'. There is no patient selection criteria applied.

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.

Include N%, Totals=SubjCount? - All Patients Percent Denominator - All Patients

AE coded	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)

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.



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'.

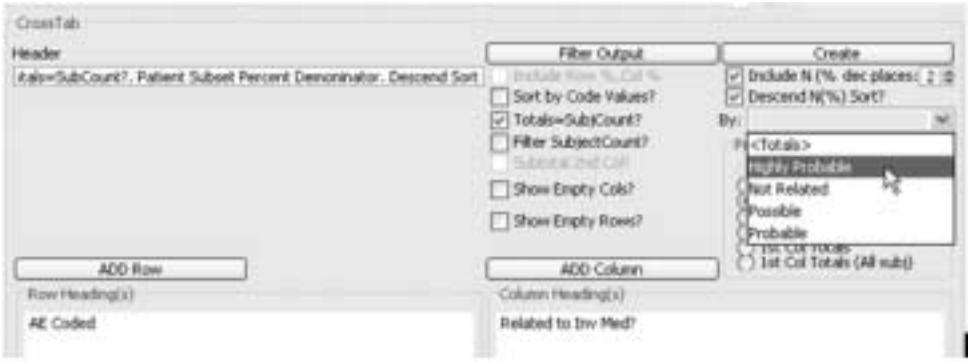
Include N%, Totals=SubjCount? - Patient Subset Denominator - Subset of patients

AE coded	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)

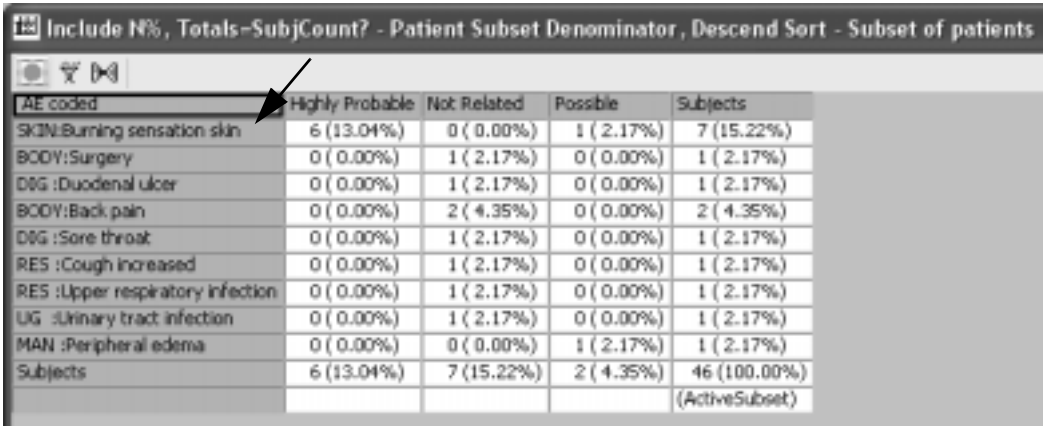
Descend N(%) Sort

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.



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'.

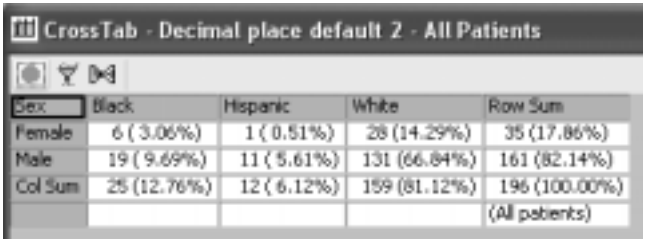


AE coded	Highly Probable	Not Related	Possible	Subjects
SKIN:Burning sensation skin	6 (13.04%)	0 (0.00%)	1 (2.17%)	7 (15.22%)
BODY:Surgery	0 (0.00%)	1 (2.17%)	0 (0.00%)	1 (2.17%)
DIG :Duodenal ulcer	0 (0.00%)	1 (2.17%)	0 (0.00%)	1 (2.17%)
BODY:Back pain	0 (0.00%)	2 (4.35%)	0 (0.00%)	2 (4.35%)
DIG :Sore 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

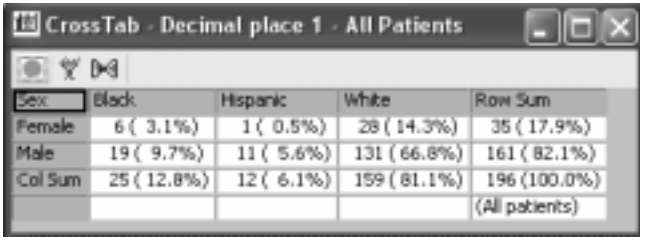
You may optionally select the number of decimal places to display with the 'dec places' click box. The decimal place default is 2 with options for 0, 1 and 2 where the results are rounded up. When you save the crosstab specification with Include N% option checked ON and selected decimal places; these settings are saved within the crosstab specification.

Crosstab with decimal places set to 2.



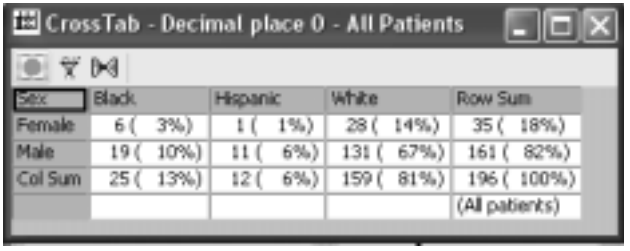
Sex	Black	Hispanic	White	Row Sum
Female	6 (3.06%)	1 (0.51%)	28 (14.29%)	35 (17.86%)
Male	19 (9.69%)	11 (5.61%)	131 (66.84%)	161 (82.14%)
Col Sum	25 (12.76%)	12 (6.12%)	159 (81.12%)	196 (100.00%)
				(All patients)

Crosstab with decimal places set to 1.



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)

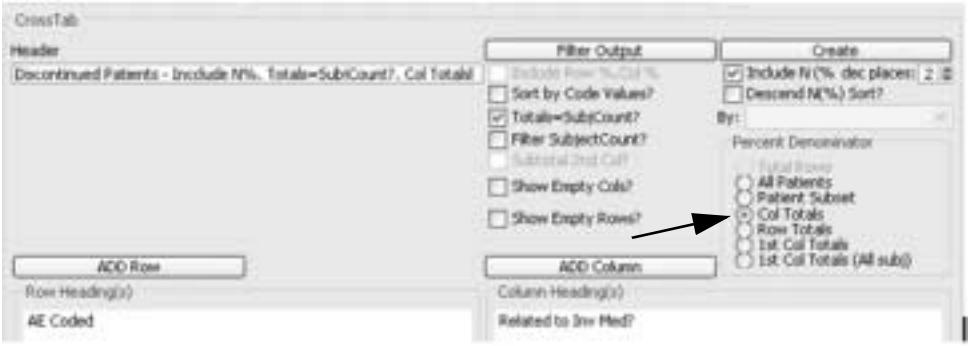
Crosstab with decimal places set to 0.



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%)
				(All patients)

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.

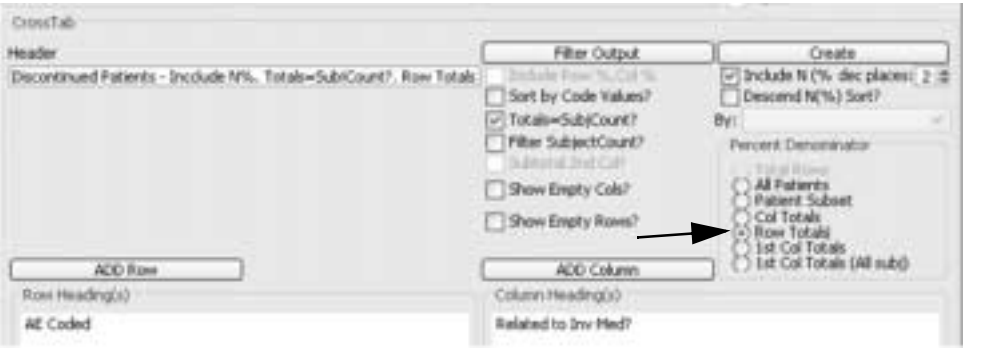


The individual cell statistics are calculated for the individual column categories 'Related to Inv Med?'. For example, cell statistic for 'Back Pain' as 'Not Related' calculates as 2 / 7 = 28.57% against the 'Not Related' column total.

Discontinued Patients - Include N%, Totals=SubjCount?, Col Totals - Subset of patients

AE coded	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)

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.



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 = 85.71% against the 'Burning sensation skin' row total.

Discontinued Patients - Include N%, Totals=SubjCount?,Row Totals - Subset of patients

AE coded	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.

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.

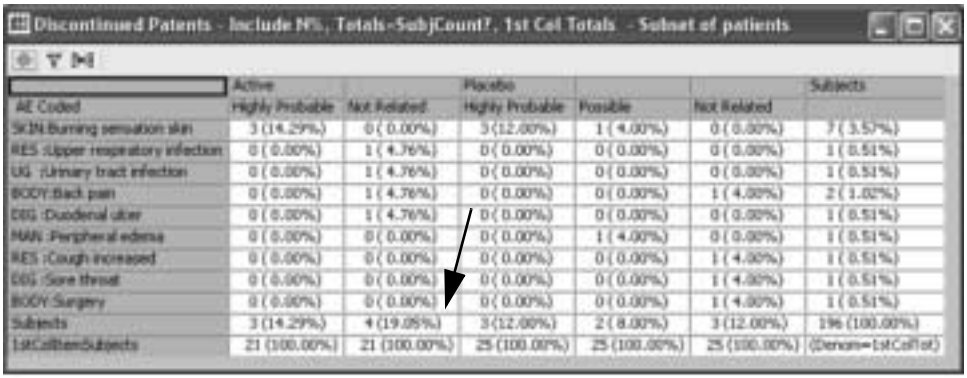
The 'First Column Totals' option is used when you have more than one column item selected and add a second column total line representing the Subjects for only the first column item values. For example, treatment arm as the first column item and then another item as a subgroup.

The following crosstab has functions turned ON for 'Include (N)%' and 'Totals=SubCount?' with Percent Denominator set for 'First Col Totals'.

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 'Active' treatment column for 'Not Related'. The statistics for the subjects calculate as 4 / 21 = 19.05%, then divide this percent by the 4 individual subjects for 1(4.76%).

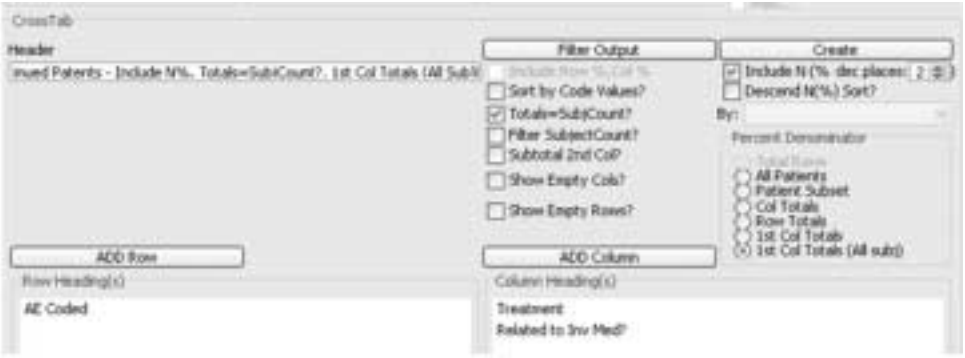


	Active		Placebo			Subjects
AE Coded	Highly Probable	Not Related	Highly Probable	Possible	Not Related	
SKIN:Burning sensation skin	3 (14.29%)	0 (0.00%)	3 (12.00%)	1 (4.00%)	0 (0.00%)	7 (3.57%)
RES :Upper respiratory infection	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
UG :Urinary tract infection	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
BODY:Back pain	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	2 (1.02%)
DIG :Duodenal ulcer	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
MAN :Peripheral edema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	1 (0.51%)
RES :Cough increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (0.51%)
DIG :Sore throat	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (0.51%)
BODY:Surgery	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (0.51%)
Subjects	3 (14.29%)	4 (19.05%)	3 (12.00%)	2 (8.00%)	3 (12.00%)	196 (100.00%)
1stColItemSubjects	21 (100.00%)	21 (100.00%)	25 (100.00%)	25 (100.00%)	25 (100.00%)	(Denom=1stColTot)

Include N% First column totals (All sub)

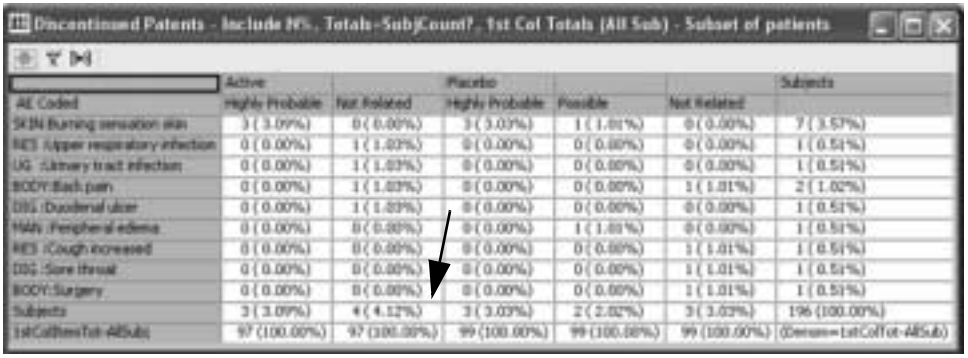
The 'First Column Totals (All sub)' option is also used when you have more than one column item selected and add a second column total line representing the Subjects. However, this option never uses the patient selection criteria if present and always shows the total population numbers.

The following crosstab has functions turned ON for 'Include (N)%' and 'Totals=SubCount?' with Percent Denominator set for 'First Col Totals (All sub)'.



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 there were 97 patients who took 'Active' drug and 99 patients who took 'Placebo' drug.

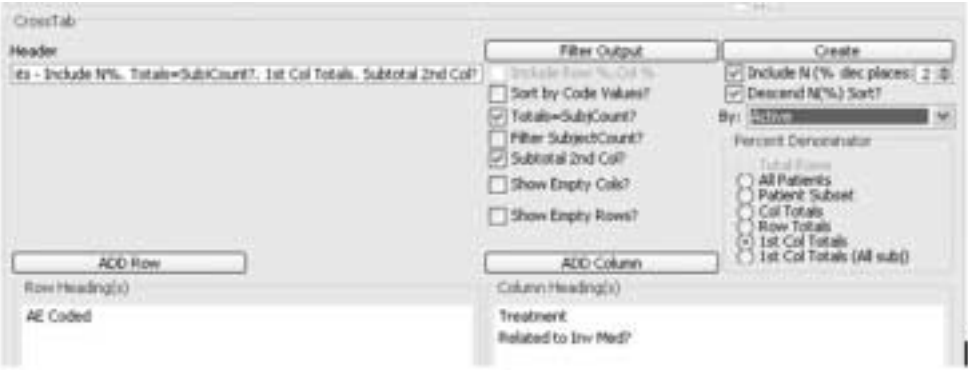
The crosstab results calculate the statistics based upon the total patient population for the item column added. See the 'Active' treatment column for 'Not Related'. The statistics for the subjects calculate as 4 / 97 = 4.12%, then divide this percent by the 4 individual subjects for 1(1.03%).



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.



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.)

Discontinued Patients - Include N%, Totals-SubjCount?, 1st Col

	Active		
AE Coded	Total	Highly Probable	Not Related
SKIN:Burning sensation skin	3 (14.29%)	3 (14.29%)	0 (0.00%)
BODY:Back pain	1 (4.76%)	0 (0.00%)	1 (4.76%)
UG :Urinary tract infection	1 (4.76%)	0 (0.00%)	1 (4.76%)
DIG :Duodenal ulcer	1 (4.76%)	0 (0.00%)	1 (4.76%)
RES :Upper respiratory infection	1 (4.76%)	0 (0.00%)	1 (4.76%)
MAN :Peripheral edema	0 (0.00%)	0 (0.00%)	0 (0.00%)
DIG :Sore throat	0 (0.00%)	0 (0.00%)	0 (0.00%)
BODY:Surgery	0 (0.00%)	0 (0.00%)	0 (0.00%)
RES :Cough increased	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subjects	7 (33.33%)	3 (14.29%)	4 (19.05%)
1stColItemSubjects	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.)

Totals, Subtotal 2nd Col? - Subset of patients

Placebo				Subjects
Total	Highly Probable	Possible	Not Related	
4 (16.00%)	3 (12.00%)	1 (4.00%)	0 (0.00%)	7 (3.57%)
1 (4.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	2 (1.02%)
0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.51%)
1 (4.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	1 (0.51%)
1 (4.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (0.51%)
1 (4.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (0.51%)
1 (4.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (0.51%)
7 (28.00%)	3 (12.00%)	2 (8.00%)	3 (12.00%)	196 (100.00%)
25 (100.00%)	25 (100.00%)	25 (100.00%)	25 (100.00%)	(Denom=1stColTot)

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.

Observe for the selected columns Race, Sex and Complete the individual category counts total 196.

CrossTab - Side by Side - All Patients

	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'.

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(%)*

CrossTab - Side by Side - All Patients

	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.

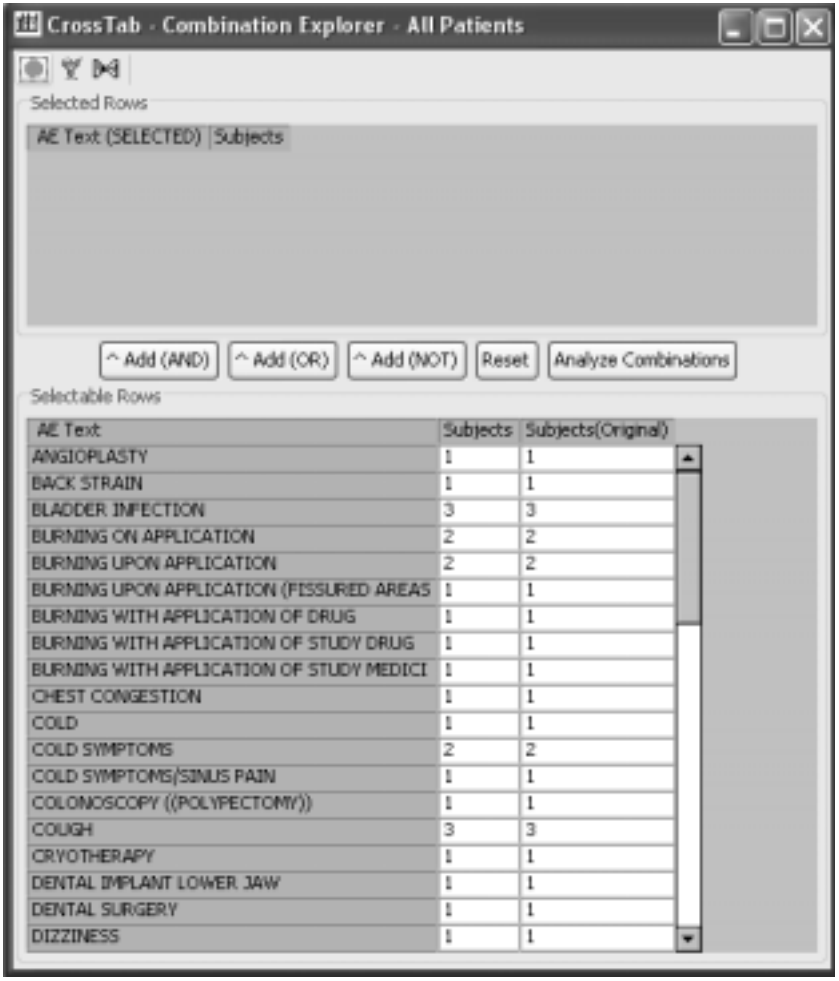
2. Select a panel, an item and the appropriate function or use the default function.
3. Click **ADD Row**.

   For example, add 'AE Text' as the Row item to be analyzed / explored.

   Only one row variable is allowed.

4. Click Create.

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.

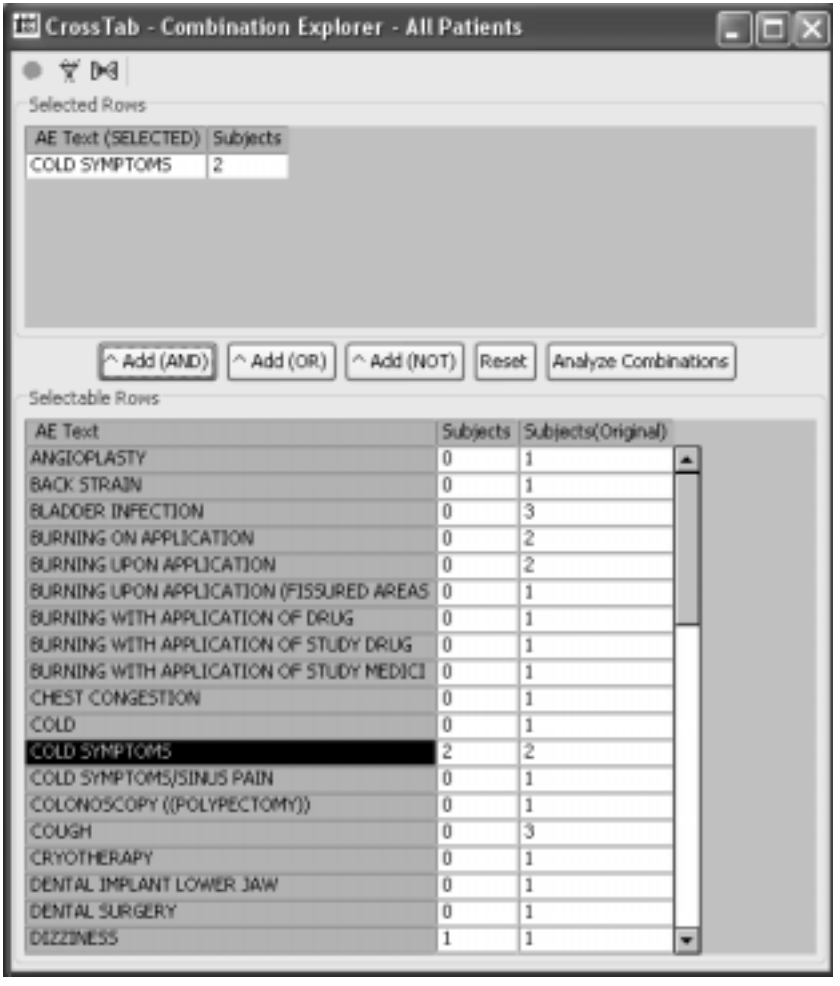


5. Select the first Value to add for exploration to the SELECT list.

   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.

   You ***must*** select a between two to six values for exploration to the SELECT list before you click Analyze Combinations.

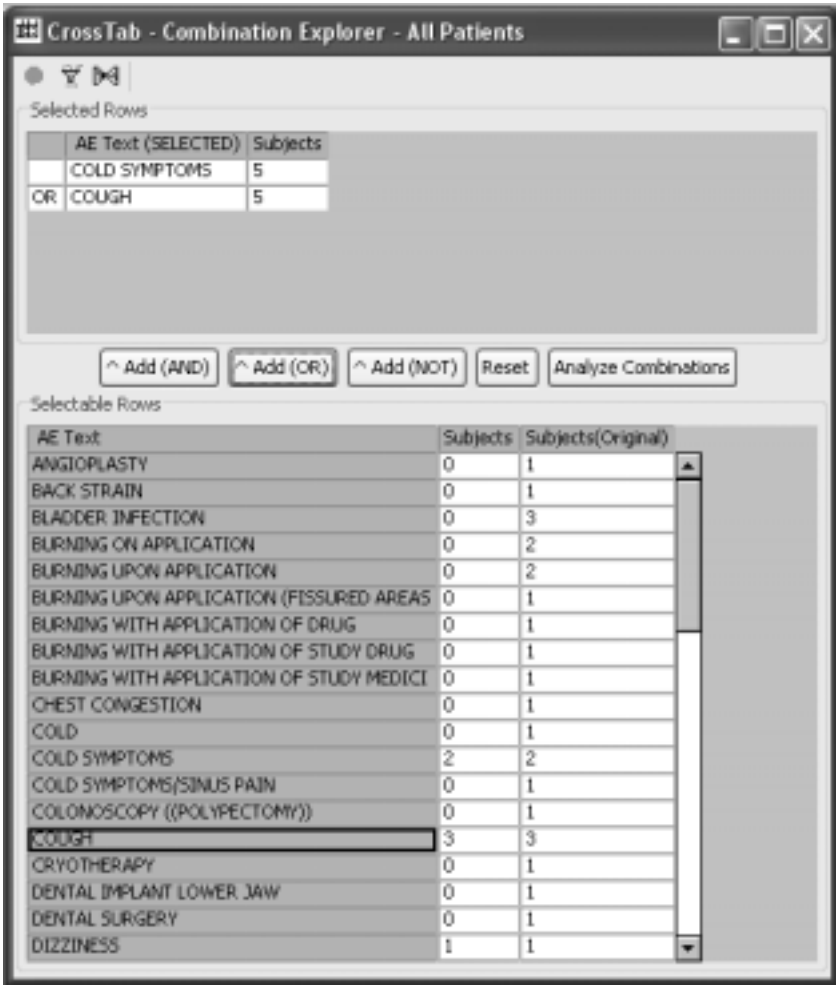


6. Select the second value for exploration to the SELECT list.

   For example, select 'Cough' in the value list then click on the 'Add (OR)' button to add it to the list of selected Adverse Events with the OR between them, i.e., we're interested in patients who had 'Cold Symptoms' OR 'Cough'.

   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.

   There are 2 patients who reported 'Cold Symptoms' OR there are 3 patients who reported 'Cough' for a total of 5 patients. Each of the 5 patients reported one OR both of the selected Adverse Events.

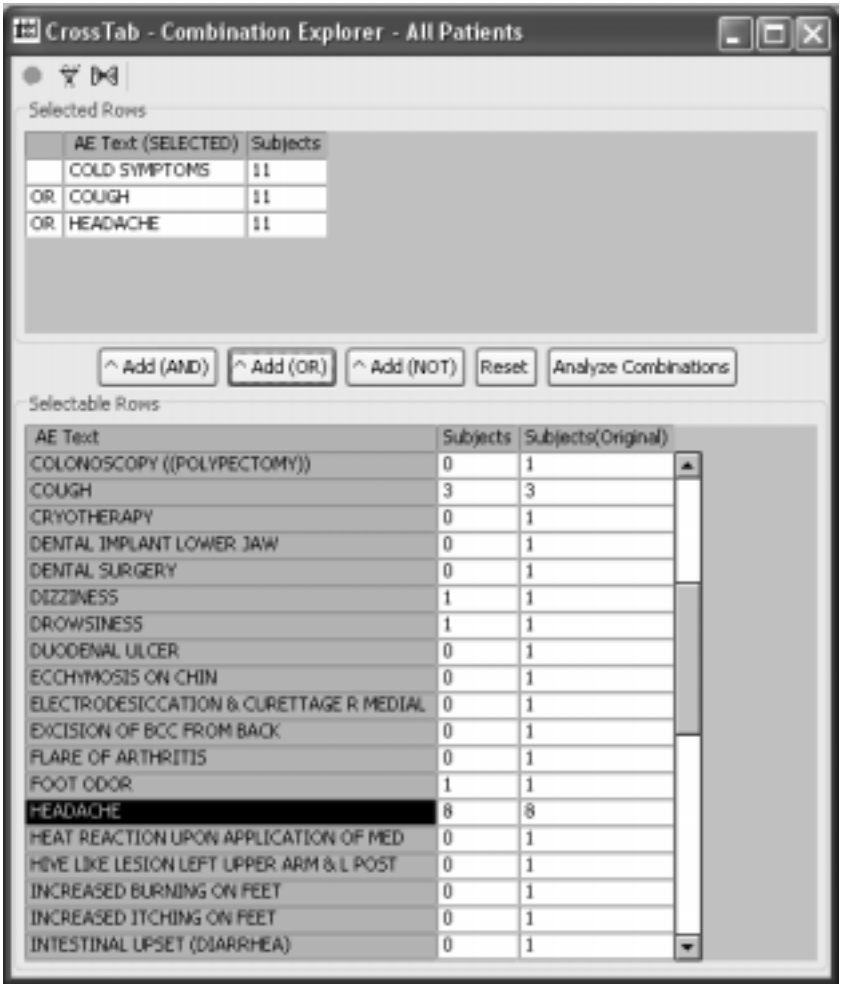


7. Select the third value for exploration to the SELECT list.

   For example, select 'Headache' and click on 'Add (OR)' again to add 'Headache' to the mix where we are interested in any patients who had 'Cold Symptoms' OR 'Cough' OR 'Headache'.

   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.

   Now the results show 2 patients who reported 'Cold Symptoms' OR 3 patients who reported 'Cough' OR 8 patients who reported Headache for a total of 11 patients. Each of the 11 patients reported one OR more of the selected Adverse Events.



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.

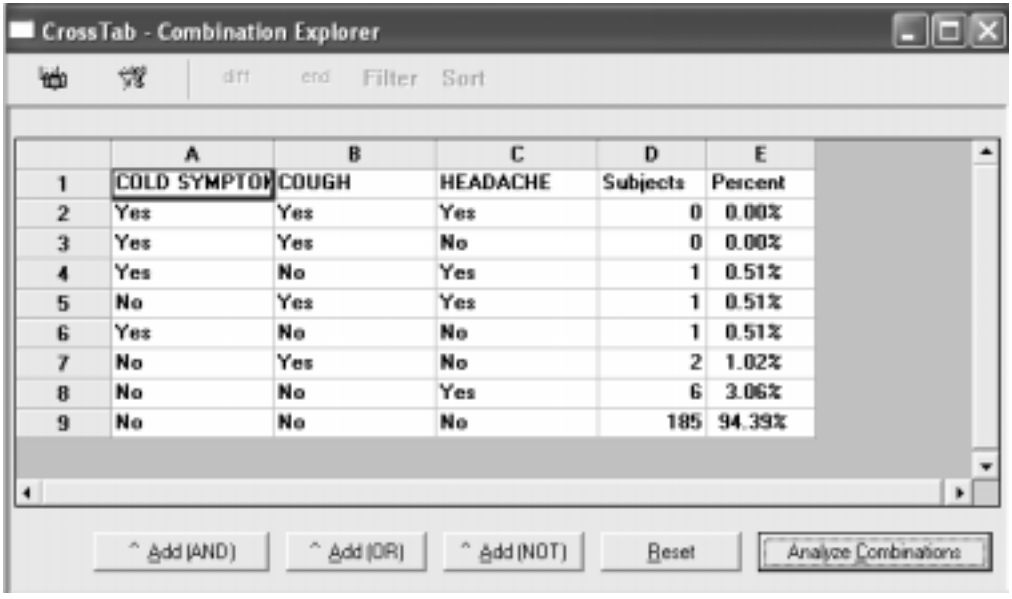
When adding Adverse Events to the SELECTED list, they can be added using 'Add (AND)', 'Add (OR)', 'Add (NOT)' to determine combinations such as patients who had Headache, but not Cold Symptoms, etc. If you had clicked the 'Add (AND)' button the Boolean selection would be restrictive where the same patients had to report both Adverse Events.

Analyze Combinations

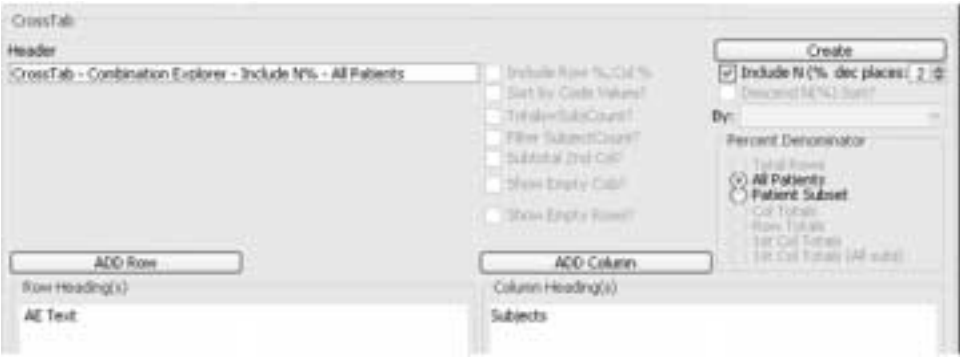
Once you have added the selected values to the SELECT list, you can display all permutations of the selected values (Adverse Events) and the number of patients and percent in each.

The previously selected Boolean operators *do NOT* affect the results of Analyze Combinations. The spreadsheet generated shows all subject combinations for the selected values.

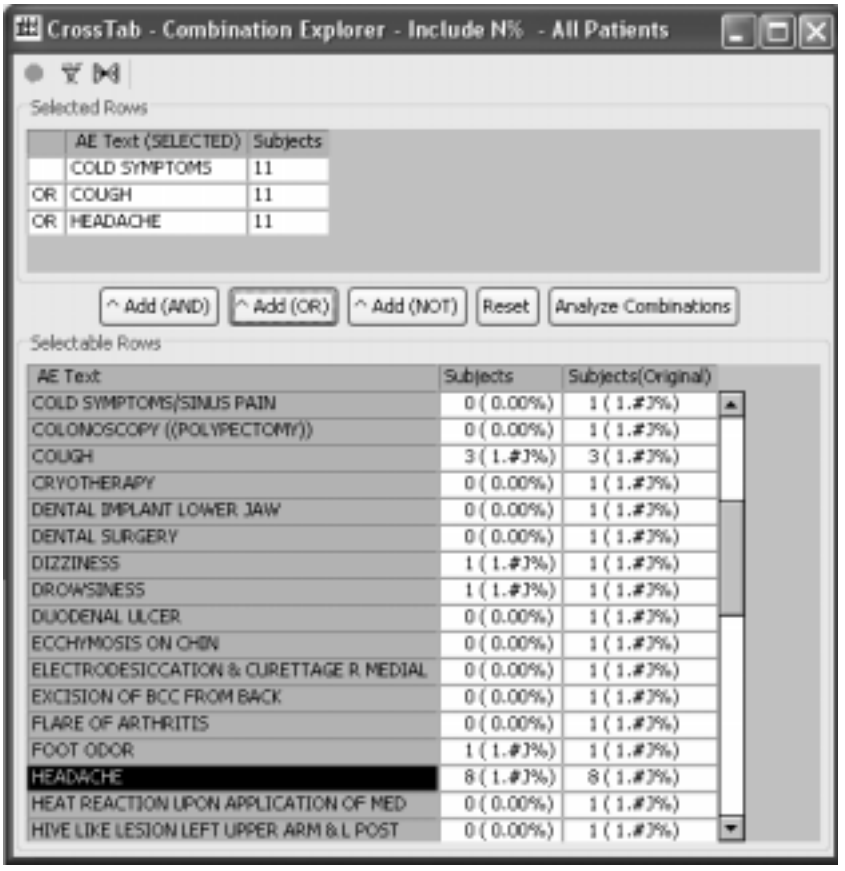
8. Click **Analyze Combinations.**
9. Click the printer icon to print the spreadsheet results in the active window.
10. Click **Reset** to clear selected values.



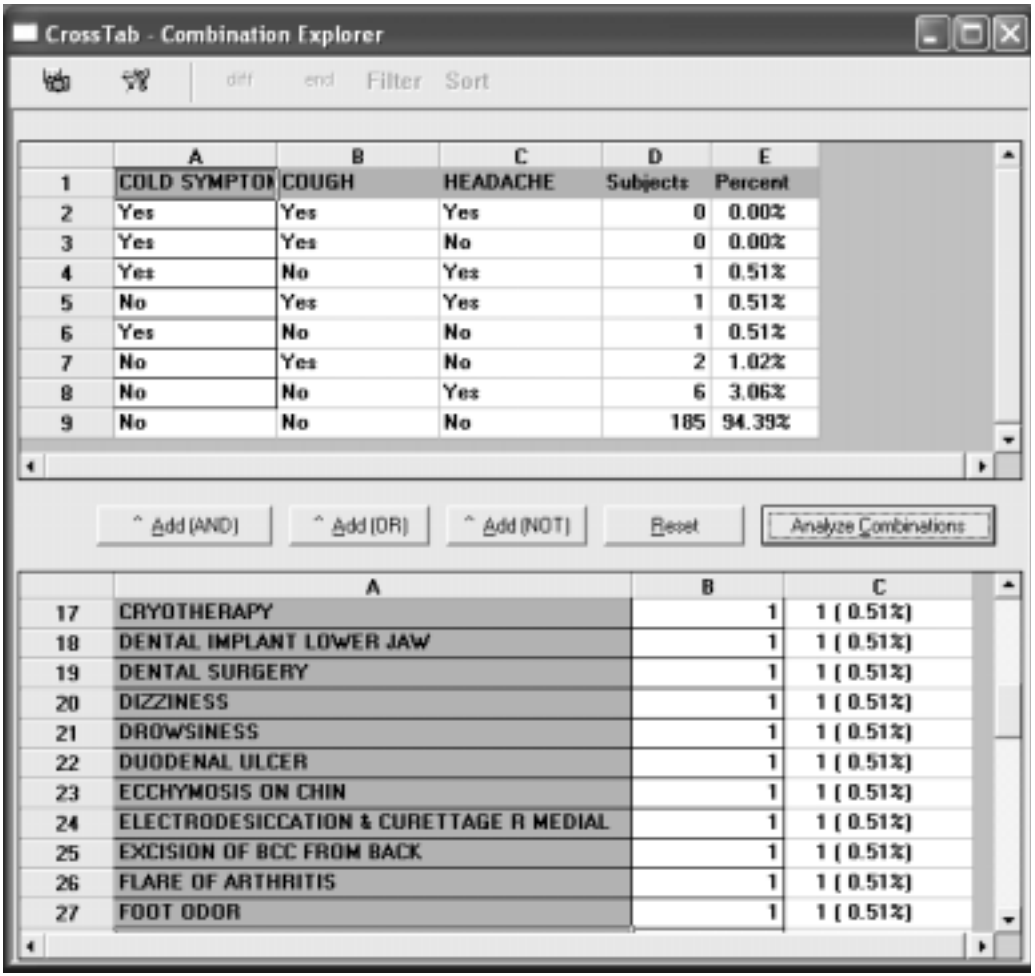
You can apply Include N% to the previous selected Adverse Events values to view subject percentages.



The percentages are applied to the **Subjects(Original)** column.



Click **Analyze Combinations** to view percentages.



Defining a Shift Table

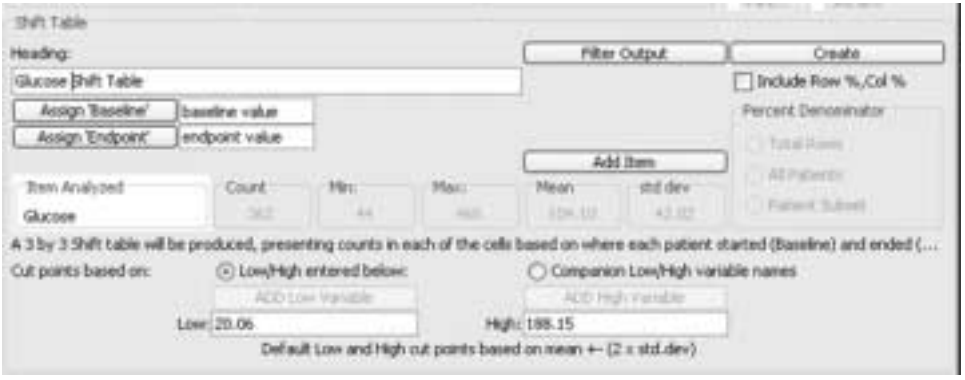
Item analyzed

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.

Define the contents of a Shift Table by applying the same method that you used to build all other browser constructs:

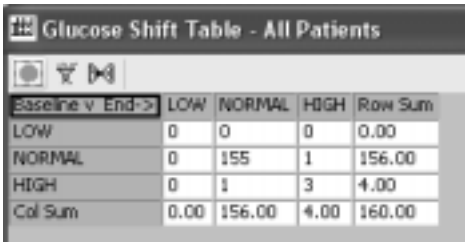
1. Select a panel.
2. Select the item to be analyzed.
3. Click the **ADD Item** button and the item is added into the Item Analyzed box. Basic descriptive statistics are displayed and default cutoff values are assigned.
4. Optionally Assign Baseline and Endpoint values from the Functions list box. The 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.



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.

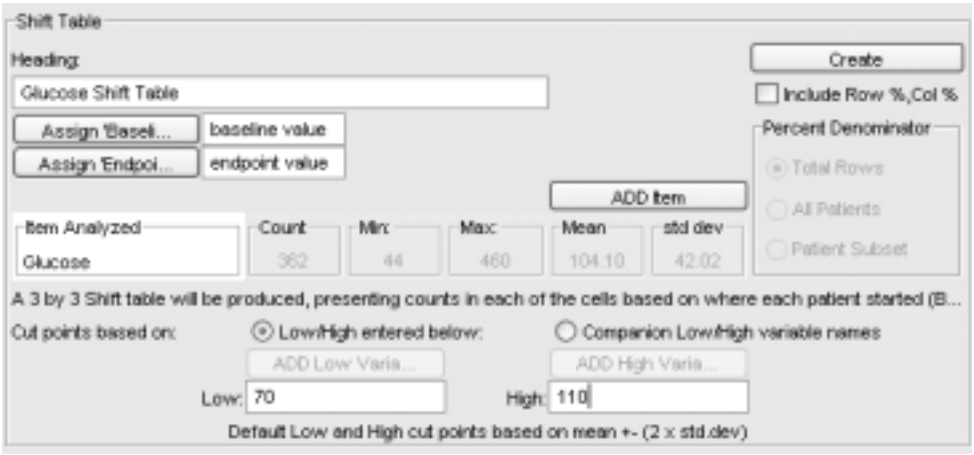


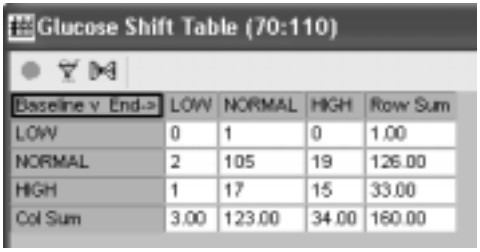
Baseline v End->	LOW	NORMAL	HIGH	Row Sum
LOW	0	0	0	0.00
NORMAL	0	155	1	156.00
HIGH	0	1	3	4.00
Col Sum	0.00	156.00	4.00	160.00

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.





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

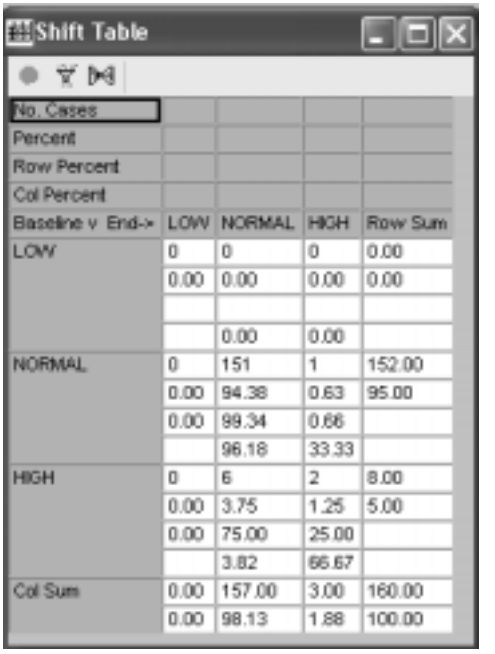
The system default for the Shift Table is the 'Baseline value' and 'Endpoint value' definitions entered in ReviewAdmin. Instead you can use Assign Baseline"or "Assign Endpoint" buttons to pick user defined 'New Event' for either of these time points. The user may define New Event functions. Select the 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	0	0	0.00
	0.00	0.00	0.00	0.00
		0.00	0.00	
NORMAL	0	151	1	152.00
	0.00	94.38	0.63	95.00
	0.00	99.34	0.66	
		96.18	33.33	
HIGH	0	6	2	8.00
	0.00	3.75	1.25	5.00
	0.00	75.00	25.00	
		3.82	66.67	
Col Sum	0.00	157.00	3.00	160.00
	0.00	98.13	1.88	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

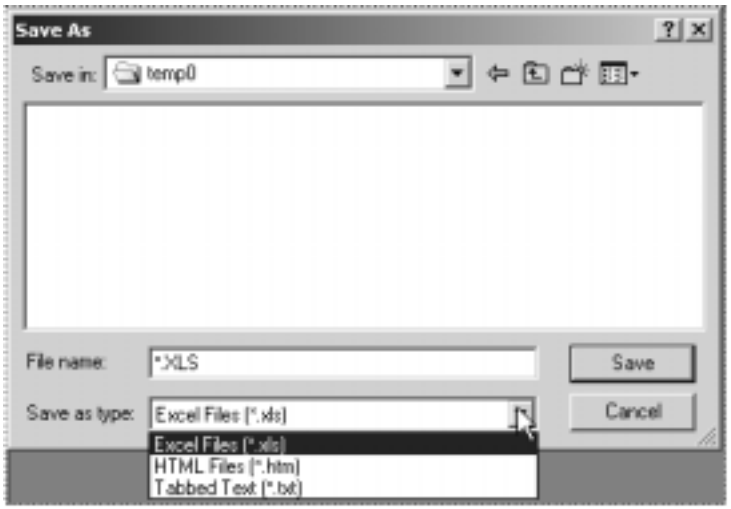
Page setup can be accessed by selecting page setup from the **File** menu. Review displays a standard spreadsheet page setup dialog box, allowing you to make changes.

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*.)

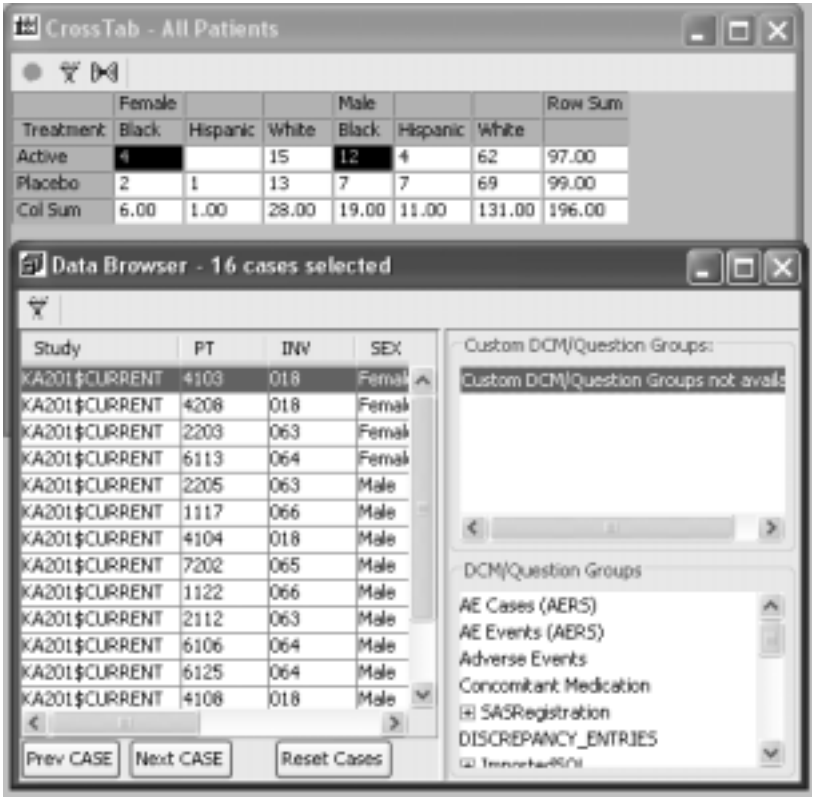
Interactive patient-level displays

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.

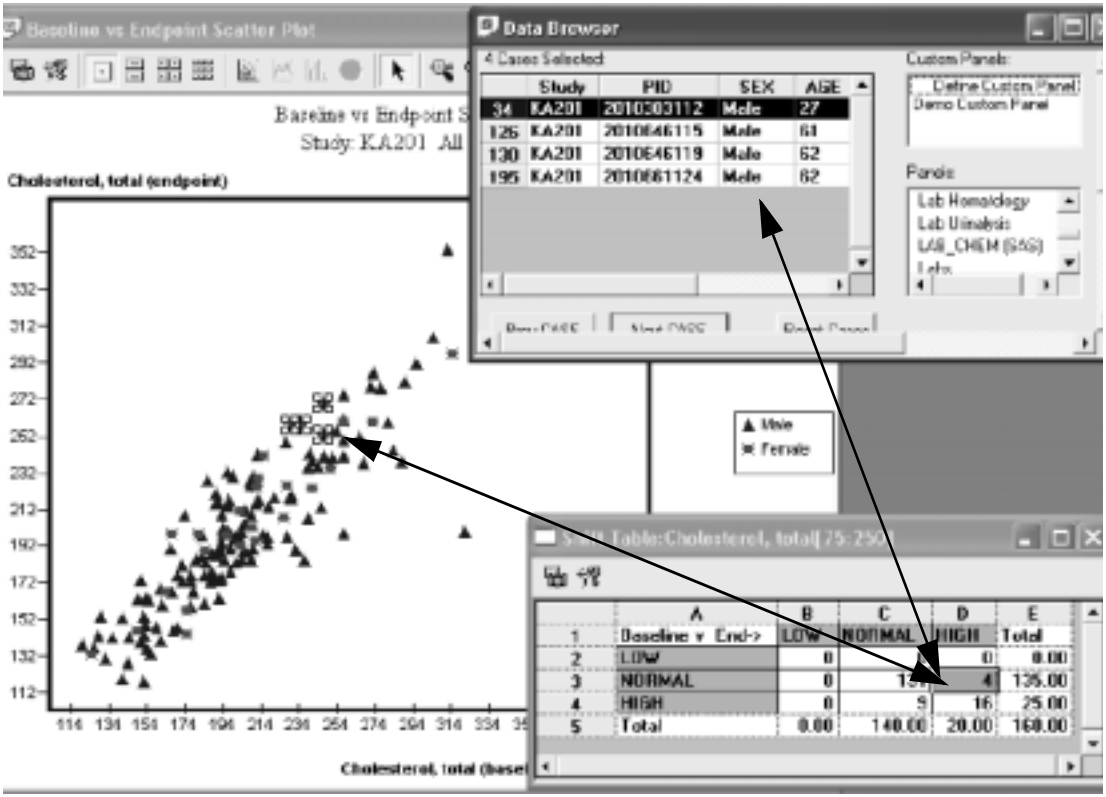


The patient counts are fully interactive with all patient-level displays of data. Data Browser and Detail Data Listing reports update to identify and describe only the patients underlying the patient counts clicked on.

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.



Object storage

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)*

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 Objects, plus Alerts Browser)*

Note: 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 **455**
Selection set 455
Selecting a SAS Proc 455
Execute a SAS Proc specification **456**
Quick execute 456
Retrieve a saved output specification 456
SAS Proc results display **457**
SAS Proc output 457
Displaying the SAS output, source, or log 457
Print copy of output 458
Defining a SAS View and Dataset (future release) **459**
Opening the SAS Proc Browser 459
Create SAS View and Dataset 459
Select format library options 463
SAS Transport Files 464
V5 (FDA Guidelines) option 464
Edit panels 466
Defining a SAS Proc Specification **467**
Define SAS Proc specification 467
Adding items to be analyzed 468
Adding BY variables 468
Statistics options 468
Output filter 469
Defining a SAS Proc title 469
Creating the SAS Proc output 470
Change a SAS Proc specification 470
SAS Proc results display **471**
Toolbar 471

Find menu command 472
Displaying the SAS output, source, or log 472

Exporting and printing results 473
Print Preview 473
Printing the SAS Proc results 473
Exporting the result 474

Multiple SAS Proc outputs 475
Opening multiple SAS Proc results 475
Snapshot output 475

Save and schedule a SAS Proc specification 478
Save a SAS Proc specification 478
Schedule SAS Proc jobs 478
Review output 478

Advanced SAS Proc options (future release) 479
Select SAS display options 479

Close SAS Proc Browser and results 488
Closing a SAS Proc output window 488
Closing the SAS Proc Browser 488

Exploring data 488
Changing the patient selection criteria 488
SAS Proc output filter 489
Pivot panels 489
Join logic 489
Clintrial tags 489
Protocol comparison 490
New Event Function 490

SAS Proc types

Selection set

In JReview, you can select a previously saved Patient Subset 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. ***See below the IReview SAS Proc options; a limited list of options are available for creating in the JReview SAS PROC Browser as noted *.***

Selecting a SAS Proc

The following types of **SAS Procs** are available in **IReview:**

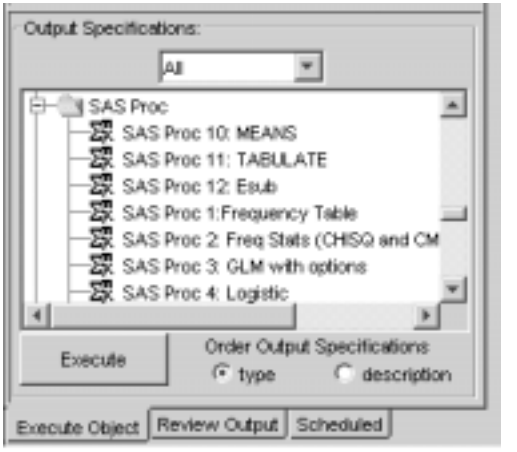
- **Create SAS View** - generates a SAS view of the items selected.
- **Create SAS DataSet** - generates a SAS dataset of the items selected for the patient population currently selected.
- **FREQ*** - generates a frequency distribution matrix of the items specified.
- **FREQ*** with Statistics - generates a frequency distribution matrix with additional statistics 'Options'.
- **GLM** - supports many different analyses including regression, ANOVA, covariance, multivariate and partial correlation are available in 'Options'.
- **LOGISTIC** - supports linear logistic regression analyses for subsets.
- **NPAR1WAY** - performs analysis of variance on ranks.
- **REG** - supports general-purpose linear regression models by least-squares. The various model-selection methods are available in 'Options'.
- **TTEST*** - performs a two sample t-test for testing the hypothesis.
- **LIFEREG** - is a parametric regression procedure for modeling the distribution of survival or failure time data.
- **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

Both IReview and 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.



Retrieve a saved output specification

To retrieve a saved output specification:

1. Double click to open a folder in Output Specifications.
2. Click on the object description and click **Execute**.

   The SAS Proc icon , displays next to the SAS Proc specification description.

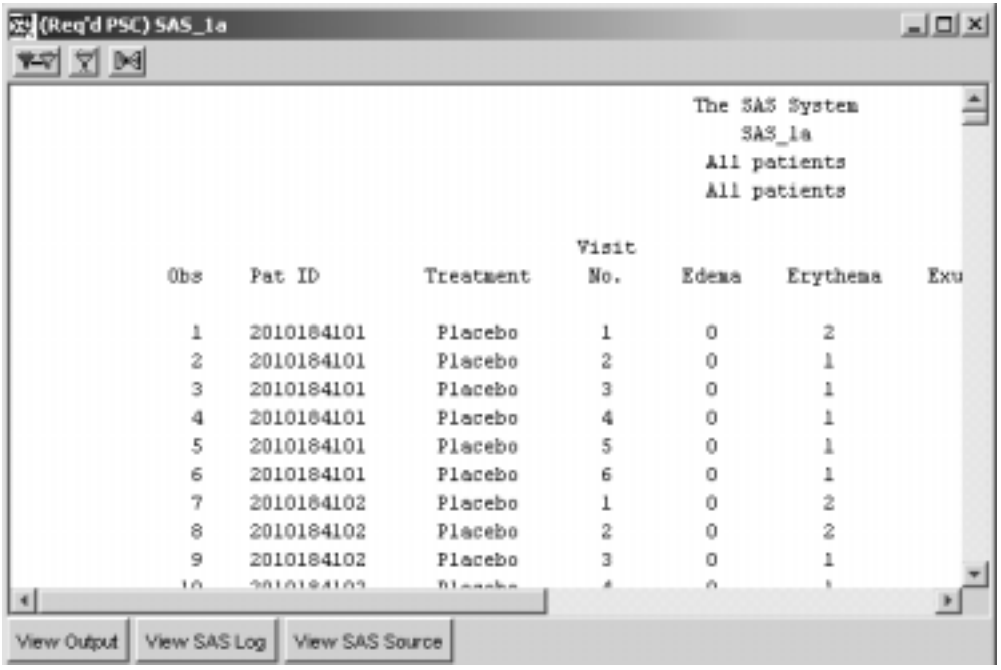
OR

3. 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.



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.

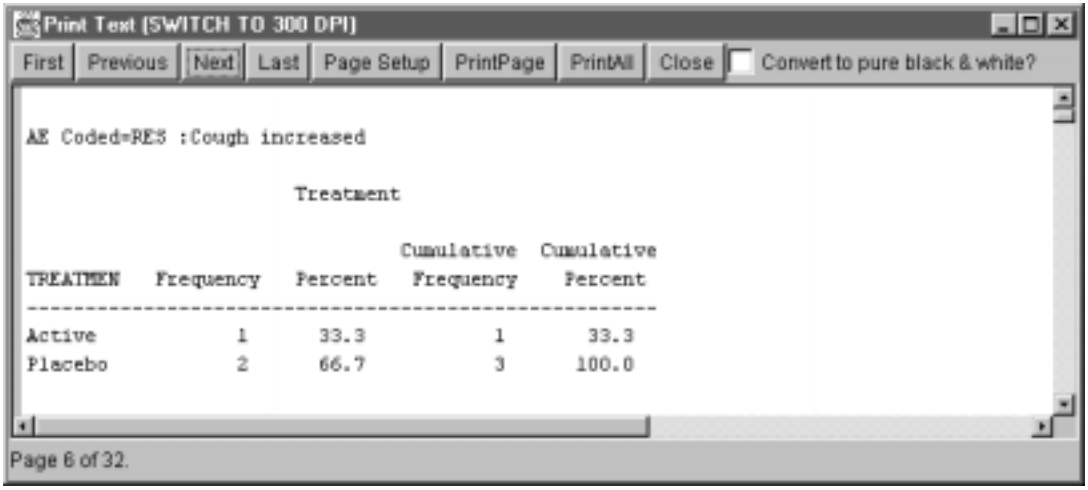
Print copy of output

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.



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.

The SAS results (output, source, or log) 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.*

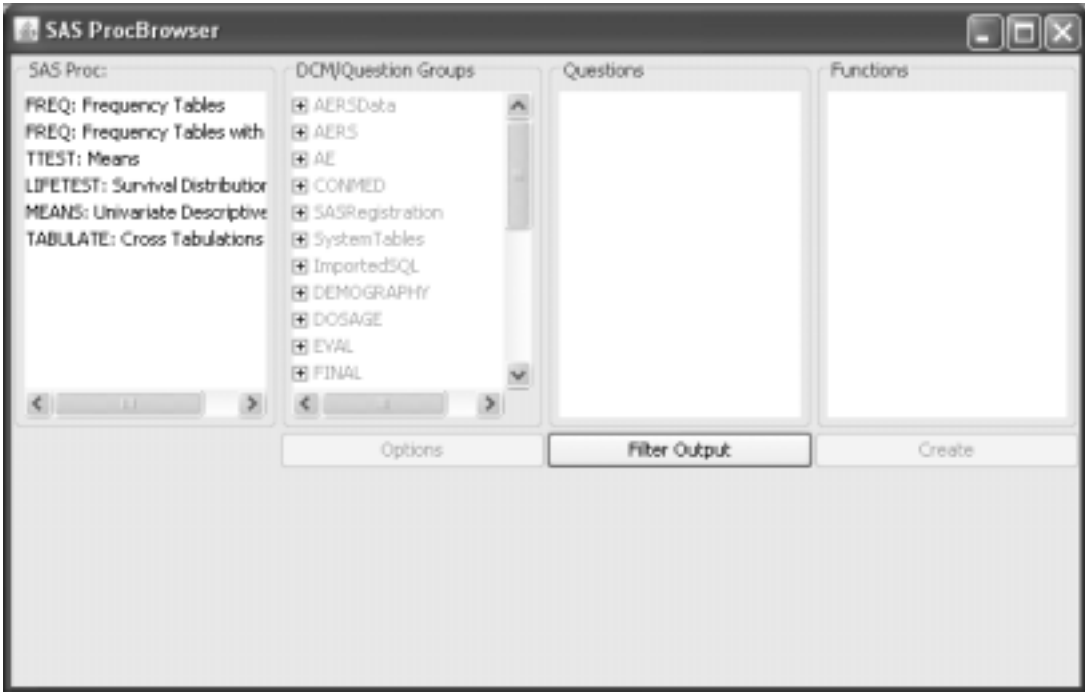
(See Chapter 6: Report Browser for Exporting Results)

Defining a SAS View and Dataset *(future release)*

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.

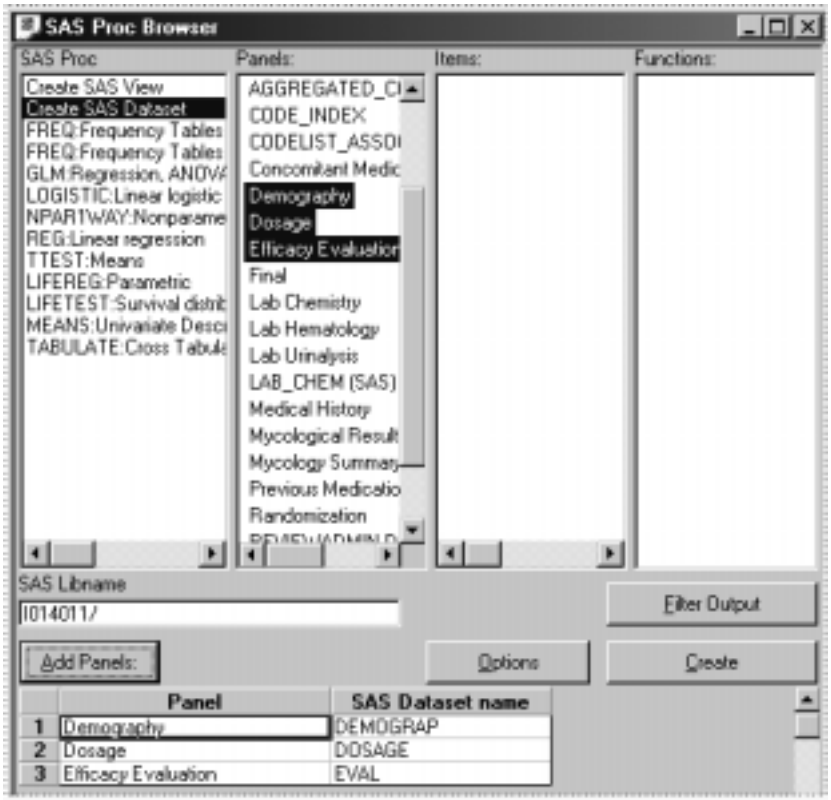
3. Select each item of interest.
4. When using the Create SAS View and Create SAS Dataset you may use the **Add Item** to add single items or **Add ALL Items** to default all items for the selected panel. This method of selecting individual items or all items from multiple panels will create a single SAS View or Dataset.

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).



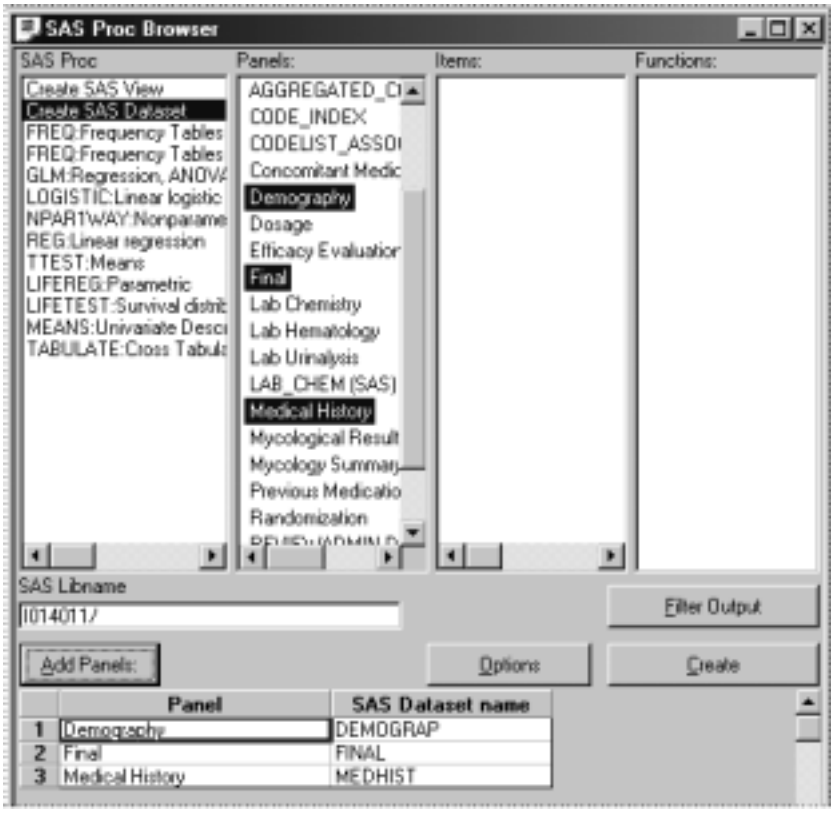
For non-contiguous panels (panels not listed next to each other):

a. Select the panels you want while holding down the **CTRL** key.

b. Click each panel you want to select.

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.

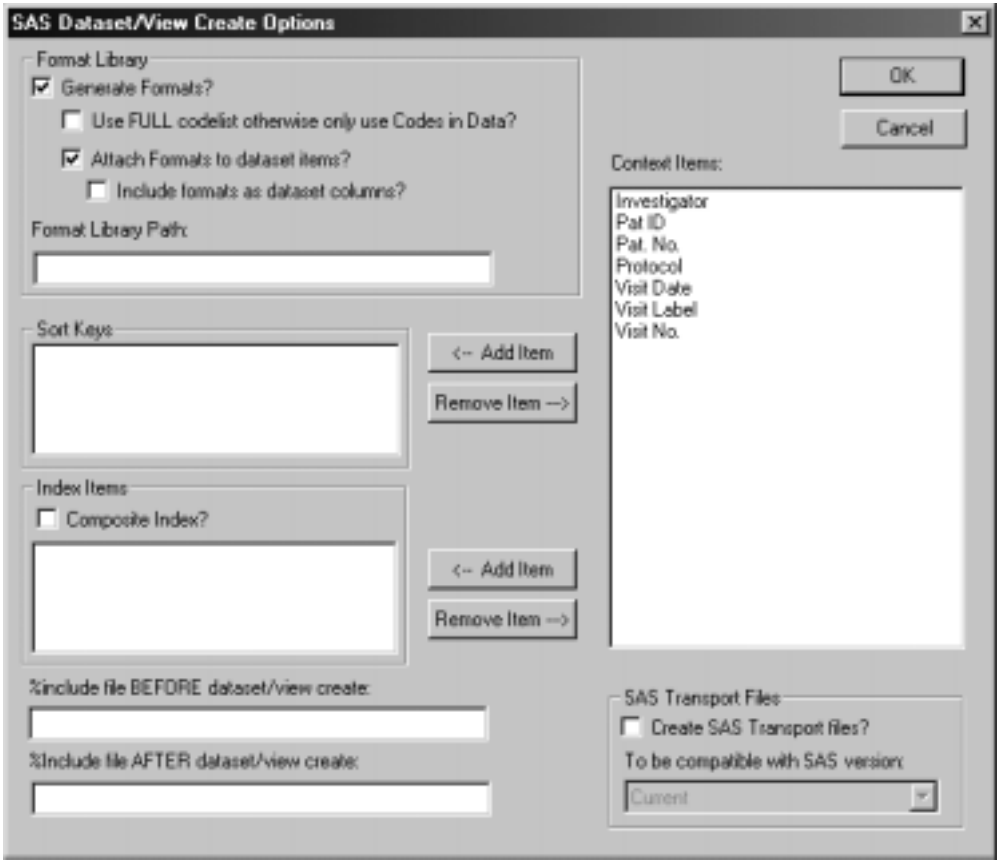


Select format library options

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.

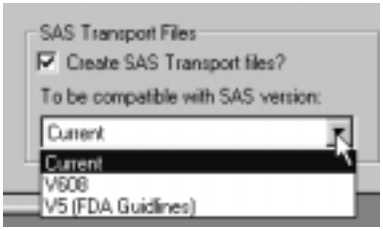
You must select 'Generate Formats?' in order to 'Use FULL codelist' or to 'Attach Formats'. Likewise, in order to 'Include formats as dataset columns', you must first select the 'Attach Formats' in order to create those columns.

6. Click **Options. The** SAS Dataset / View Create window opens.
7. Enter your options.
8. Create SAS Transport Files?



SAS Transport Files

You must click Create SAS Transport Files in order to select the type of transport file.



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_'.)*

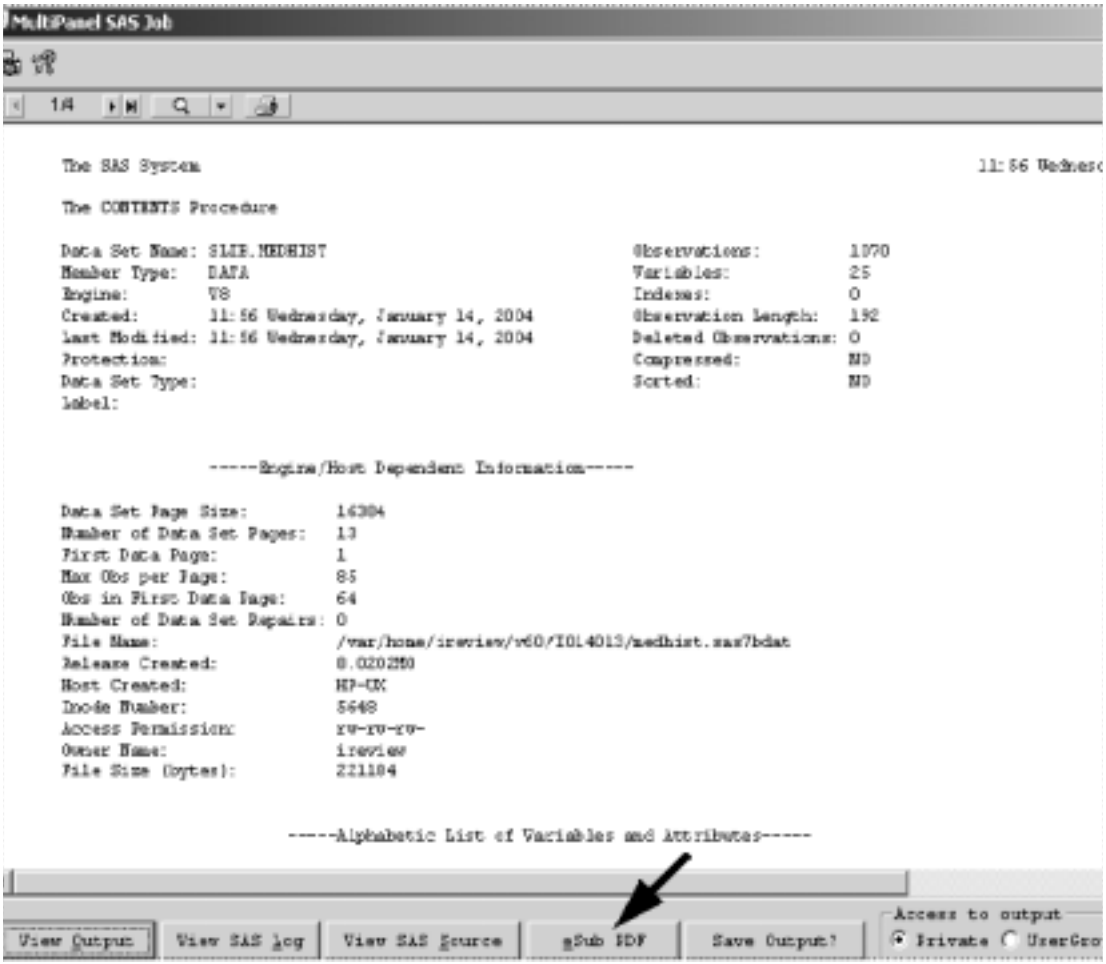
9. Click **OK.**

10. Click **Create to generate SAS Output**.

V5 (FDA Guidelines) option

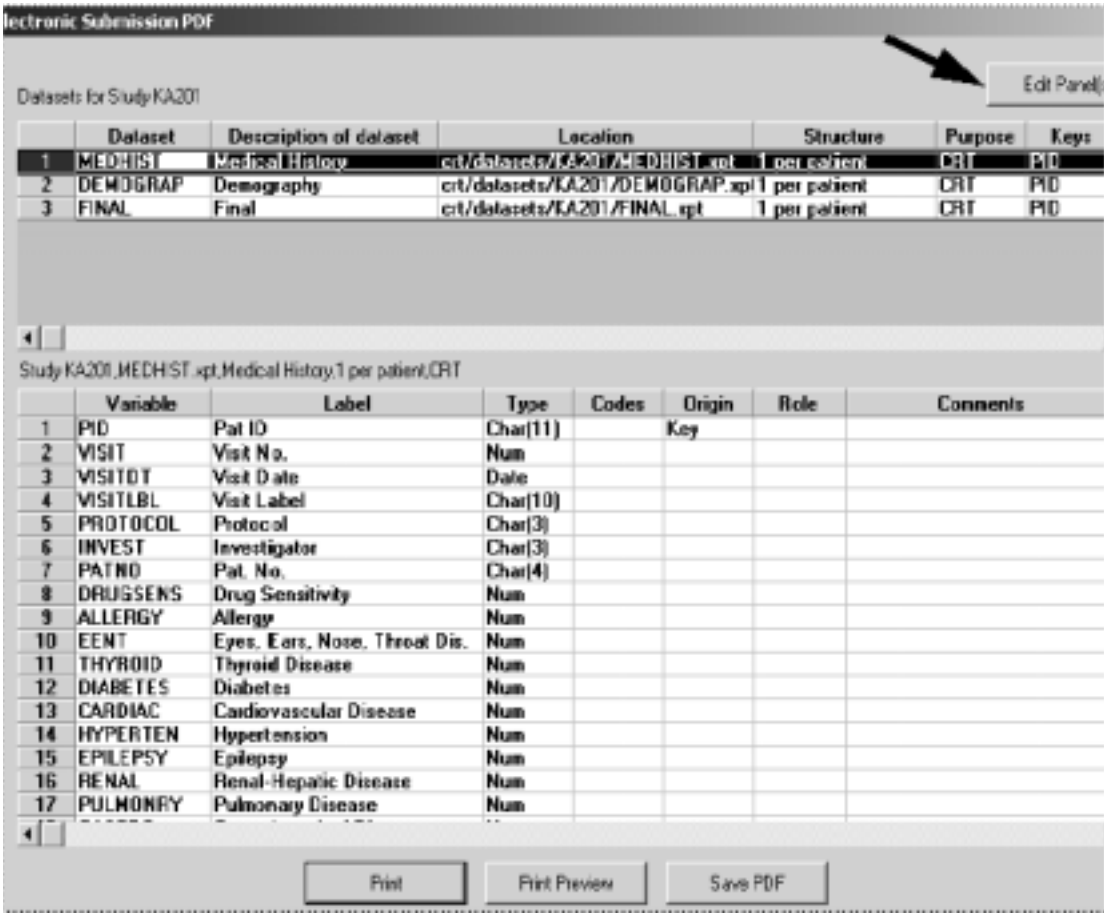
When you create SAS Transport Files as V5 (FDA Guidelines) this option is the only one which requires format settings. You must generate format catalogs and attach the formats to the variables in the datasets. It is not mandatory to 'Include formats as dataset columns'.

Note: When you click the V5 option the two required options are selected for you and you cannot change it.


MultiPanel SAS Job
The SAS System
The CONTENTS Procedure
Data Set Name: SLIB.MEDHIST
Member Type: DATA
Engine: V8
Created: 11:56 Wednesday, January 14, 2004
Last Modified: 11:56 Wednesday, January 14, 2004
Protection:
Data Set Type:
Label:
Observations: 1970
Variables: 25
Indexes: 0
Observation Length: 192
Deleted Observations: 0
Compressed: NO
Sorted: NO
-----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/irsview/v60/I014013/medhist.sas7bdat
Release Created: 8.020250
Host Created: HP-UX
Inode Number: 5648
Access Permission: rw-rw-rw-
Owner Name: irsview
File Size (bytes): 221184
-----Alphabetic List of Variables and Attributes-----
View Output
View SAS Log
View SAS Source
gSub PDF
Save Output?
Access to output
Private

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.

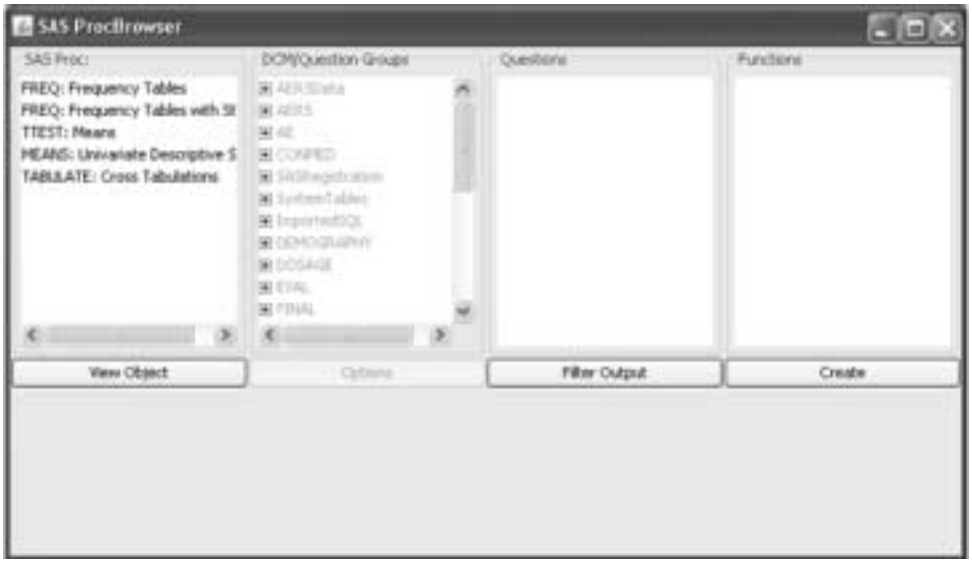
1. Click **Edit Panel**(s) to convert the panels spreadsheet into edit mode. The button status changes to save Panel(s).
2. Select a row variable to edit specific fields in the items spreadsheet.
3. Click **Save Panels**.
4. Click **Save PDF**. Print Preview and Print buttons can be selected.



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.

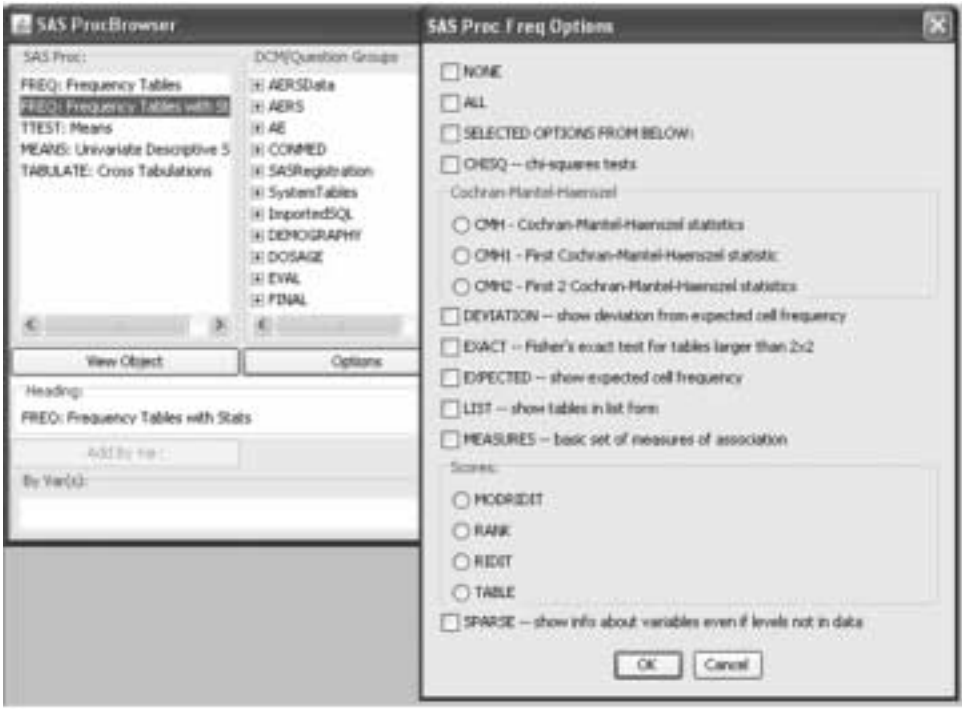
A BY variable is a variable by which the data sets are ordered according to the BY statement variable. Statistical observations on BY variables are carried out on ordered, grouped, or indexed values of one or more variables.

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**.



Output filter

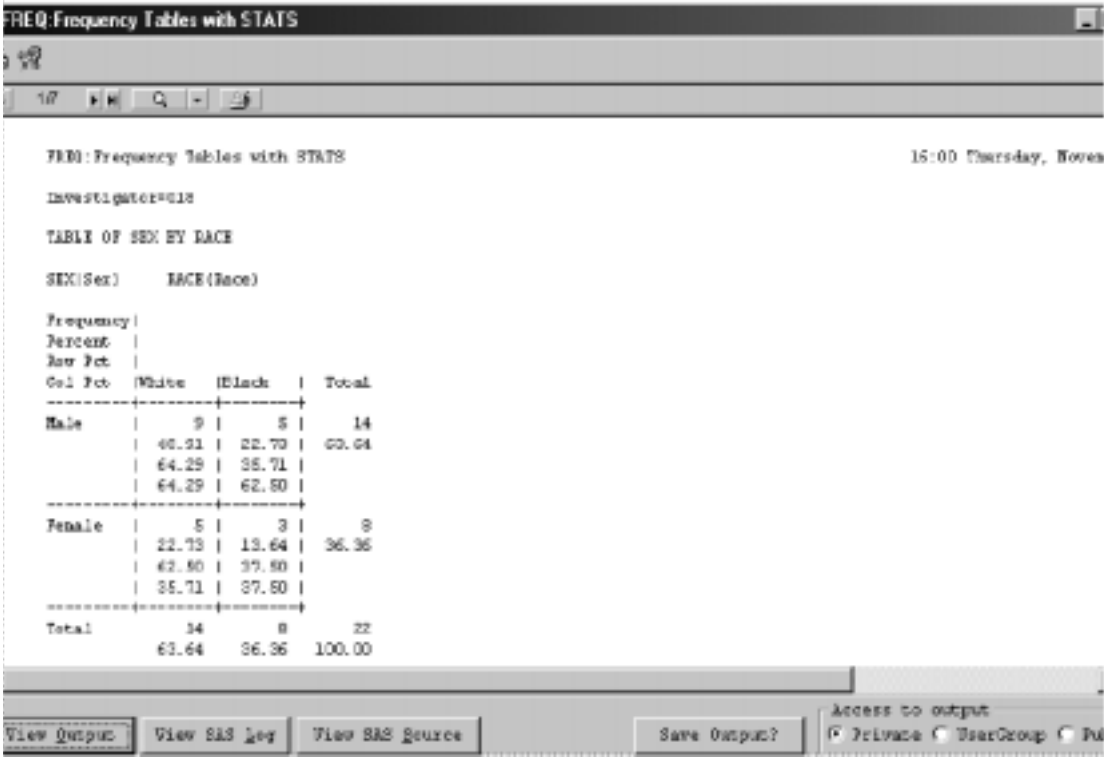
*(*See *Chapter 6 Report Browser: Output Filter.)*

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:



Change a SAS Proc specification

To change the SAS Proc Run specification that you define:

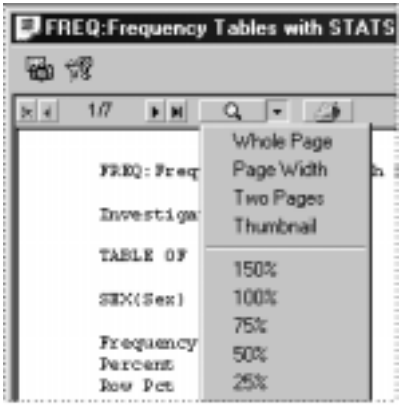
1. Click anywhere in either the **By Variables** or the **Item(s) analyzed** list.
2. Click on the item that you want to delete.
3. Click or from the **Edit** menu, select **Cut**. This deletes the highlighted row from the SAS Proc specification.
4. To clear the entire SAS specification, click .

SAS Proc results display

Toolbar

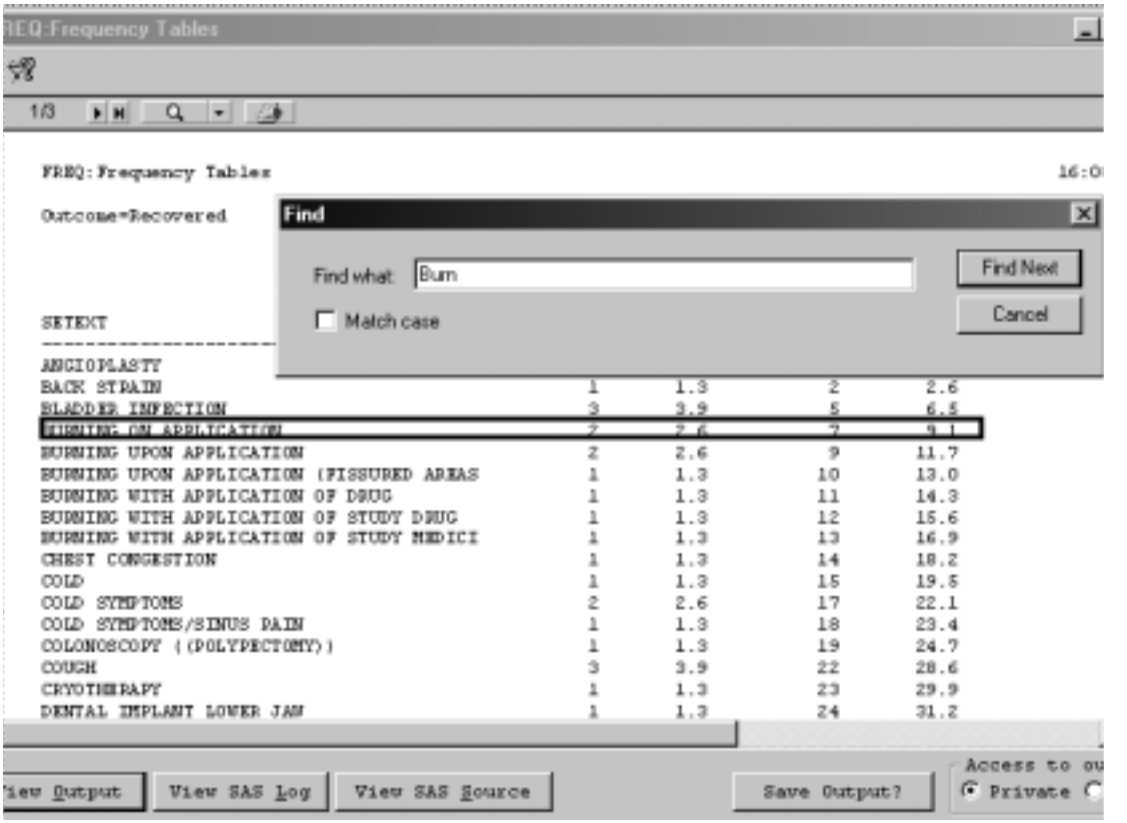
The toolbar at the top of the output display window allows you to page through the output. The paging feature is necessary to view listings where ADD BY Var is applied to create the output. For example, if investigator is the BY Var then a page break by investigator is applied to the output display.

In addition, the magnify button drop down list has percent scale sizing and multiple page display options for you to select.



Find menu command

You can perform a text search which supports case sensitive or not searches and find next. Select the Edit menu and click Find.



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.

Exporting and printing results

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.
3. Click either **Print** or **Close.**

   The Print Preview function is applicable to all browsers with output results.

Printing the SAS Proc results

To get a printed copy of your output:

1. From the Toolbar in the output display window, click the Printer button. Review displays the Print window dialog.
2. Enter printing selections and click Print**.**

OR

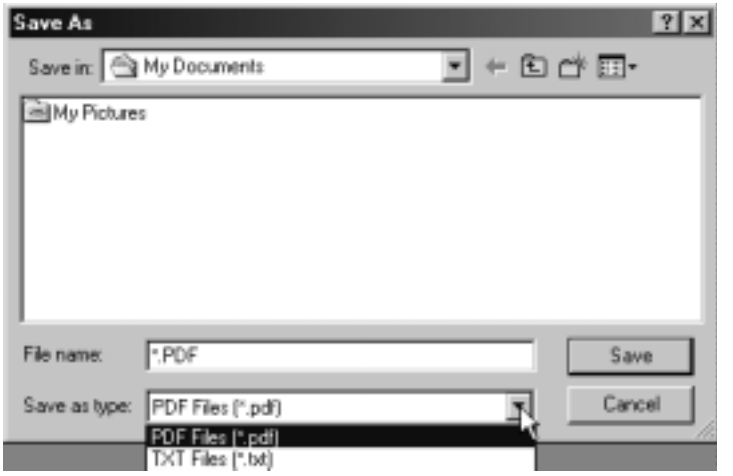
1. Click , or from **File** menu, select **Print**. Review displays the Print window dialog.
2. Enter printing selections and click Print**.**

   The SAS results (output, source, or log) prints on the currently selected printer.

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.

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).

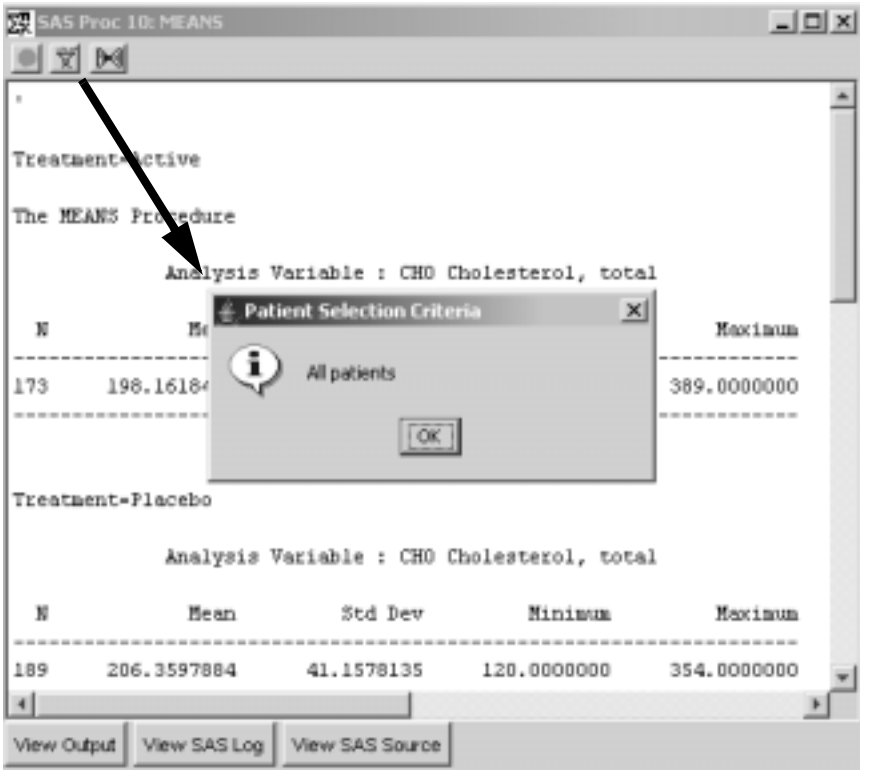
After you define and create one SAS Proc output, you can minimize the results and/or activate the SAS Proc Browser. Once the SAS Proc Browser is the active window:

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

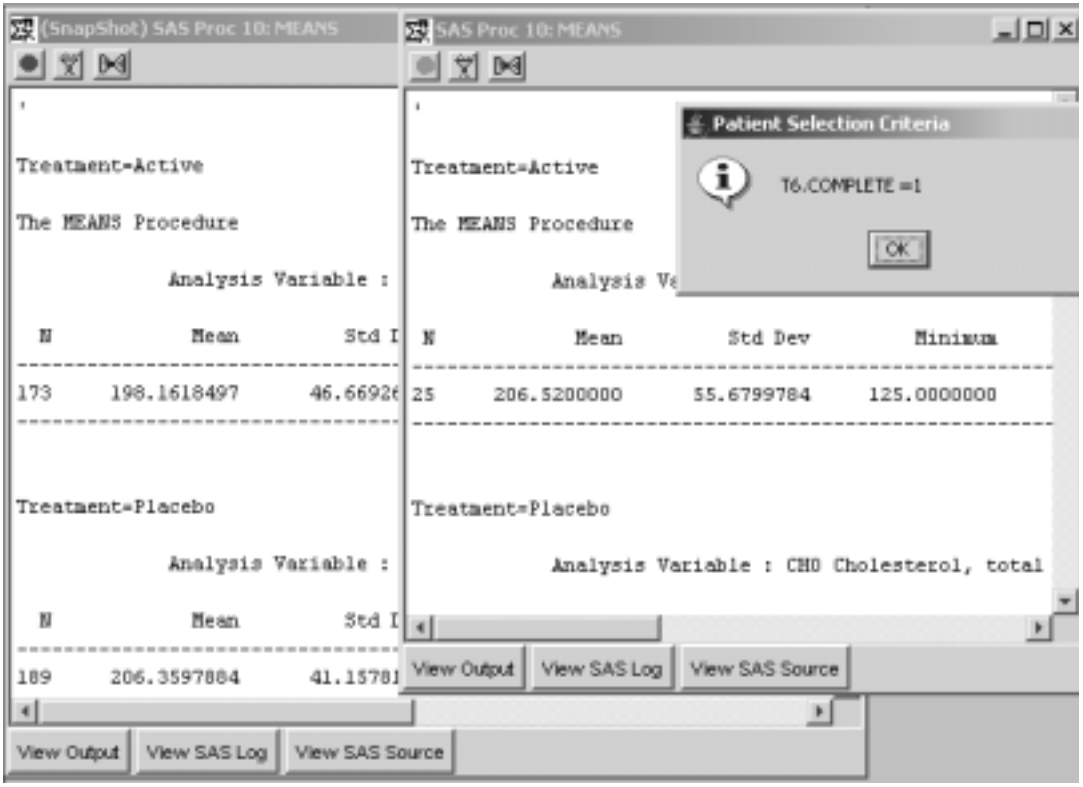
JReview has an optional multiple-population mode available within the individual browsers output window. When the results are executed and displayed from the browser output window, three icons are displayed for “Snapshot Output”, “Selection Criteria” and “Output Filter”. The Selection Criteria button 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.

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’.

A patient selection criteria was applied and then the same stored object re-executed to display the two output windows together for comparison. The selection criteria message box shows the new output window has a selection criteria for “COMPLETE = 1”.



Save and schedule 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. All output specification functions for saving, exporting, scheduling, retrieving and removing are covered in a separate chapter.(See *Chapter 11: Saving and Managing Objects, plus Alerts Browser)*

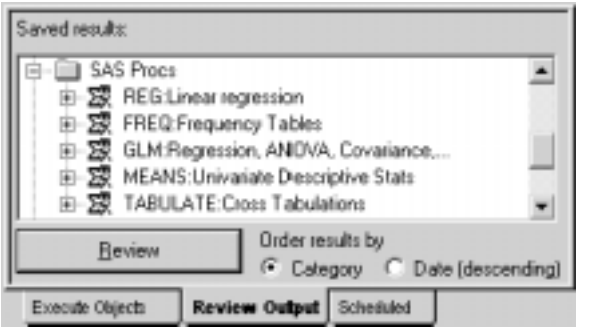
Schedule SAS Proc jobs

An object specification must be saved before it can be scheduled. The output is saved automatically when a job is scheduled. The Review Output option only displays lists of outputs previously stored. Otherwise, a message will state no output is stored.

There is one difference in scheduling SAS Procs and SAS Programs from other browser objects (reports, graphs, crosstabs). Scheduled SAS Procs and SAS Programs go directly to their respective storage folder in the **Review Output** tab and pending jobs bypass the **Schedule** tab.

Review output

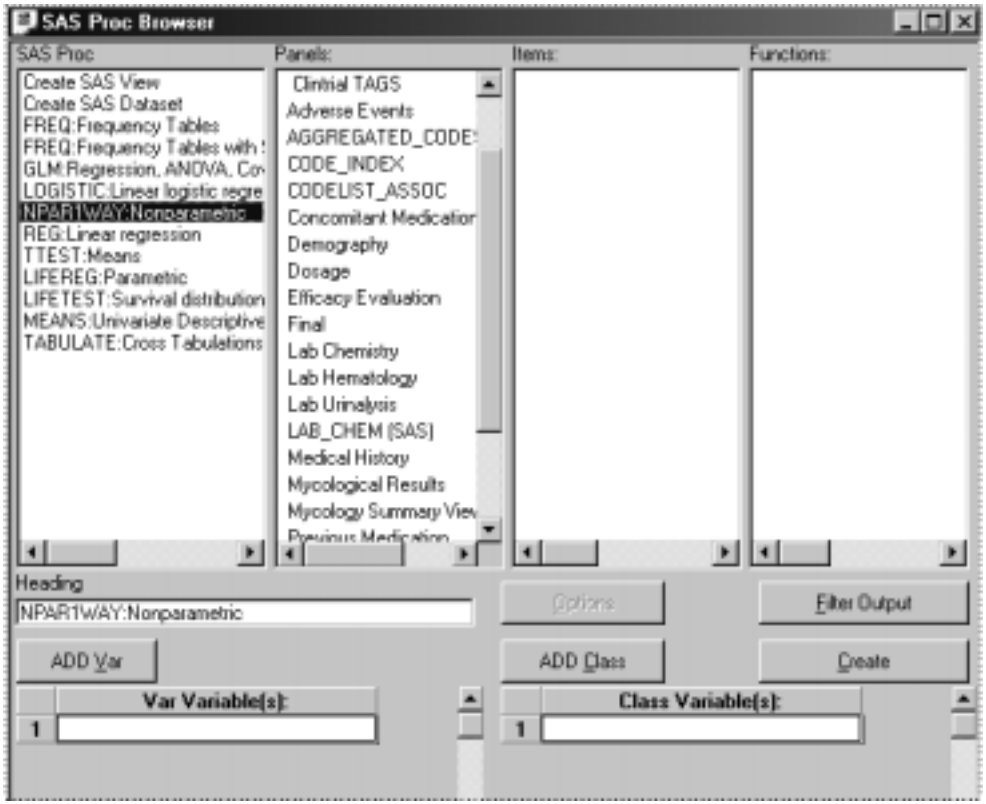
All scheduled SAS Procs objects with saved output are listed in the 'SAS Procs' folder within the **Review Output** tab. They are listed under the major SAS Proc type 'FREQ:Frequency Tables', etc. The reason is that these results are stored differently (run on the SAS server) than the other object types (reports, graphs, crosstabs).



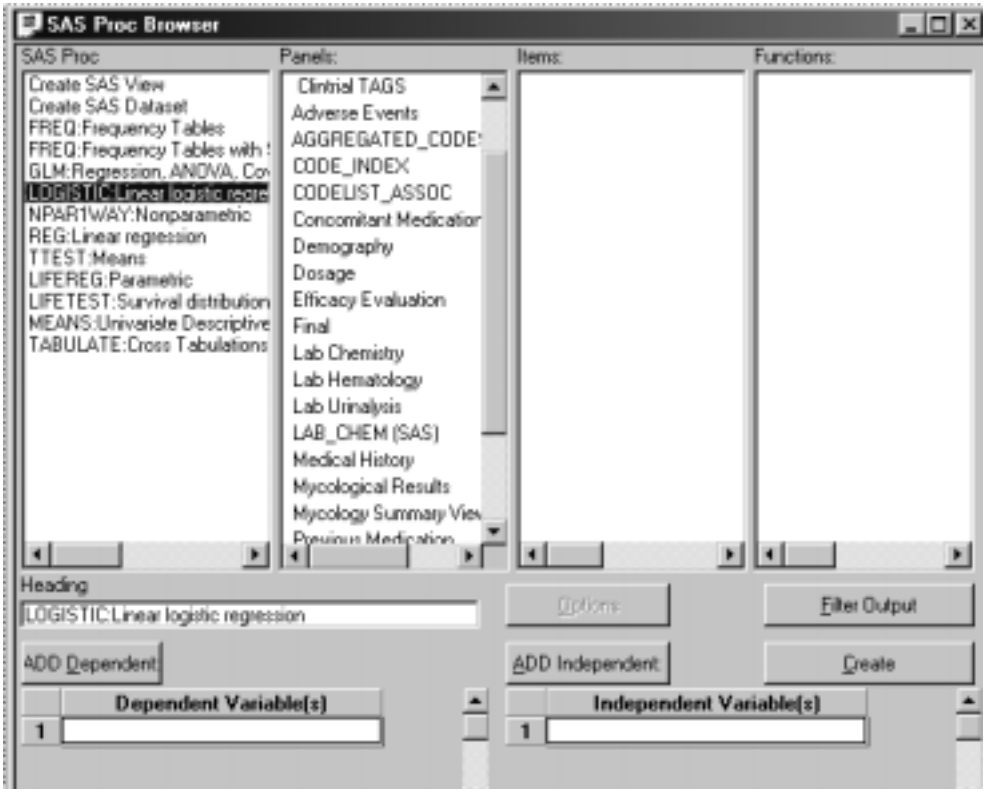
Advanced SAS Proc options *(future release)*

Select SAS display options

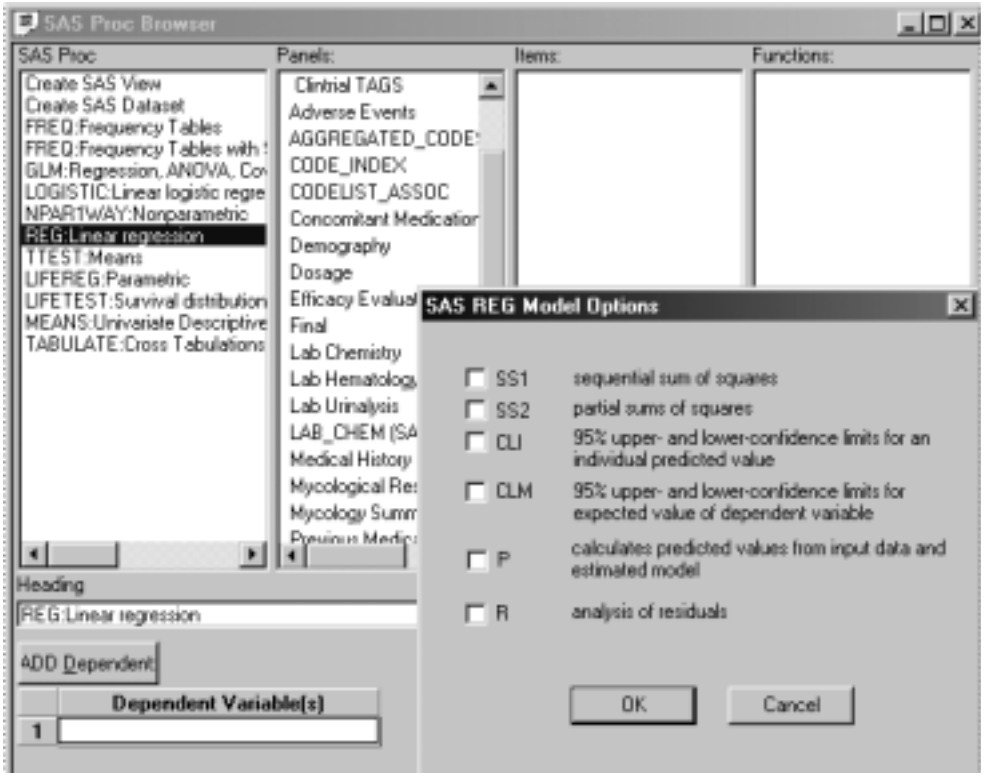
The following SAS Procs: NPAR1WAY and TTEST share the same display window for selections ADD Var and ADD Class. Select panel and item, then click **ADD Var** and **ADD Class** buttons for data items to be analyzed.



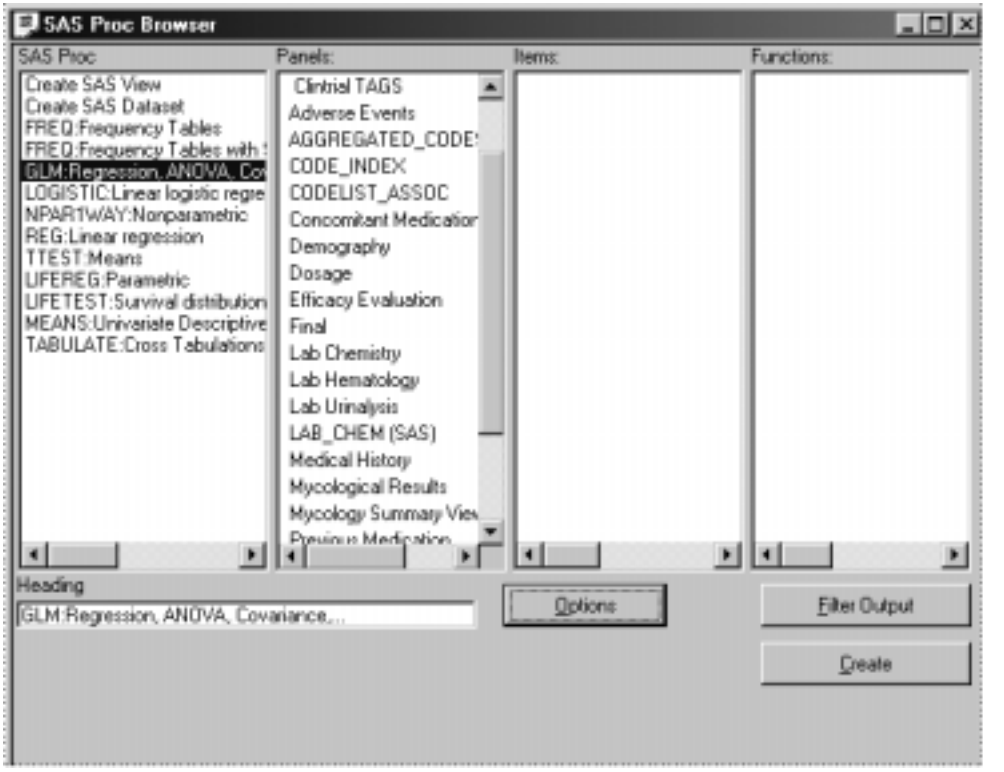
The following SAS Procs LOGISTIC and REG share the same display window for selections ADD Dependent and ADD Independent. Select panel and item, click **ADD Dependent** and **ADD Independent** buttons for data items to be analyzed.

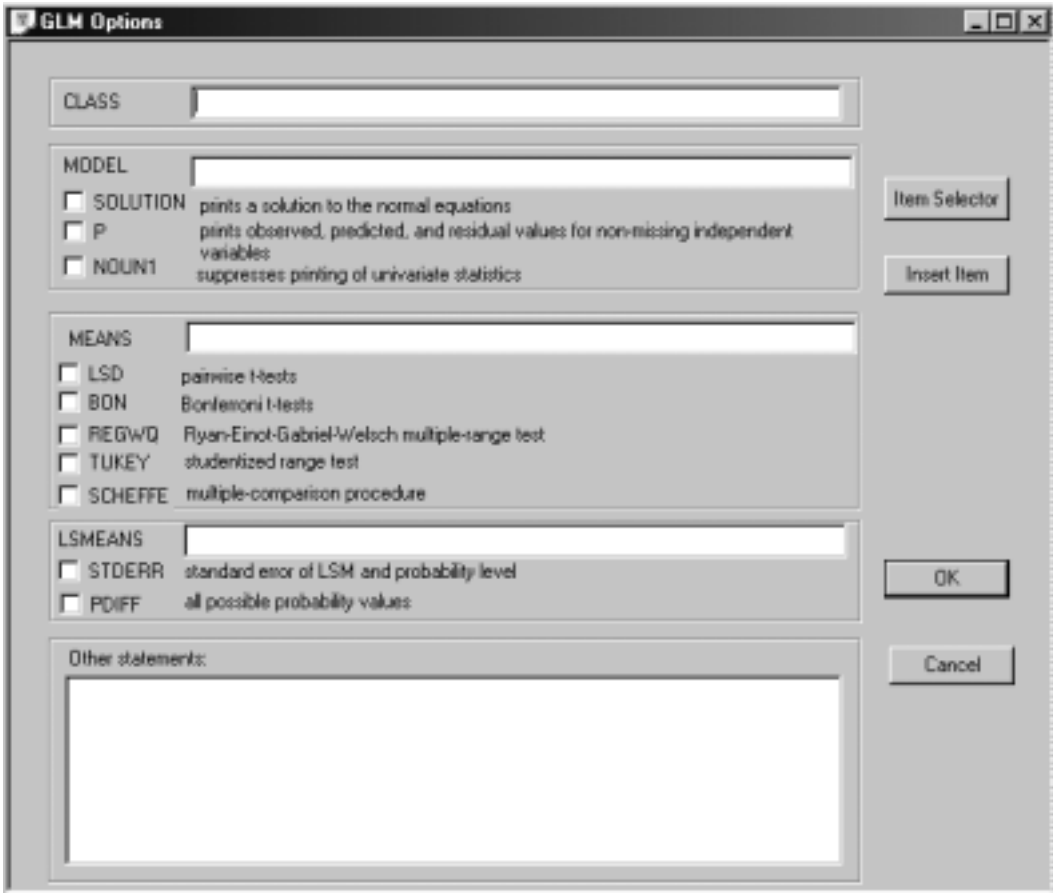


When you select SAS Proc REG, the 'Options' button is automatically enabled for selection of REG Model Options. Click selection boxes desired and click **OK**. The click **Create to generate SAS output**.

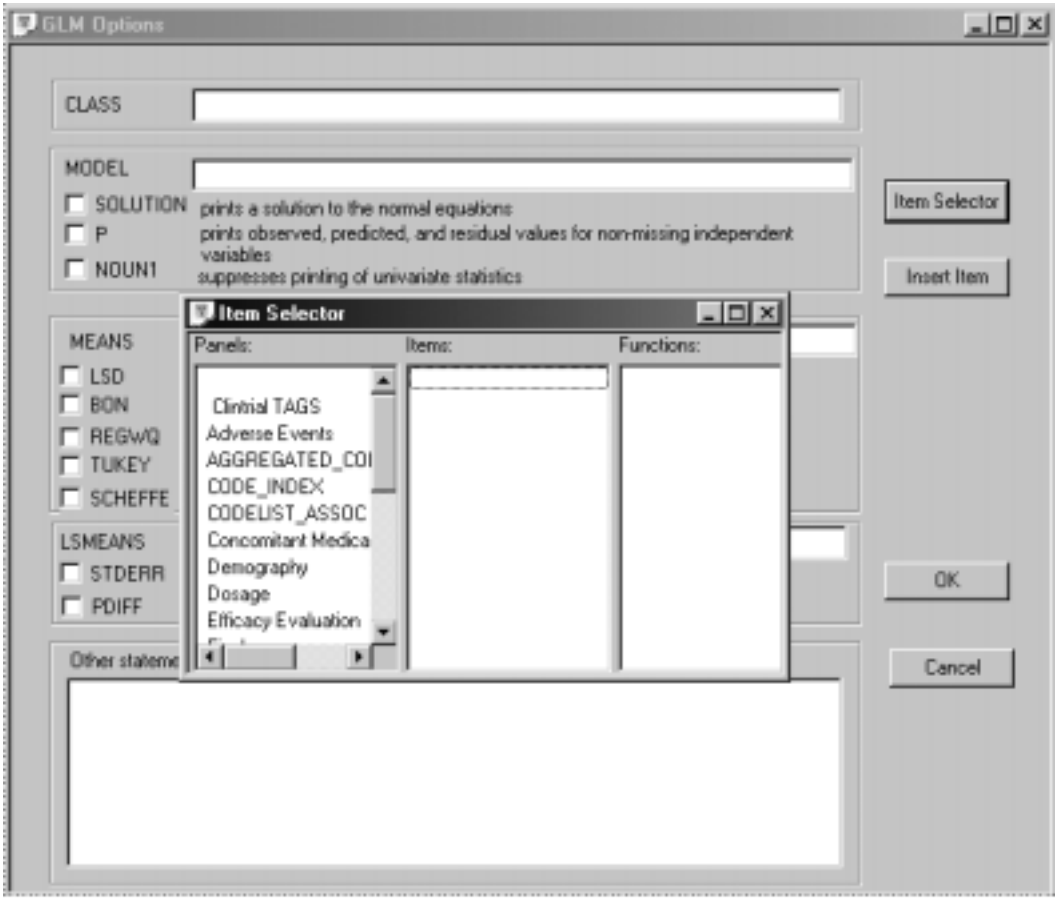


When you select the SAS Proc GLM, the browser window only displays the 'Options' button. Click **Options** to display the GLM Options and define your analysis definitions.

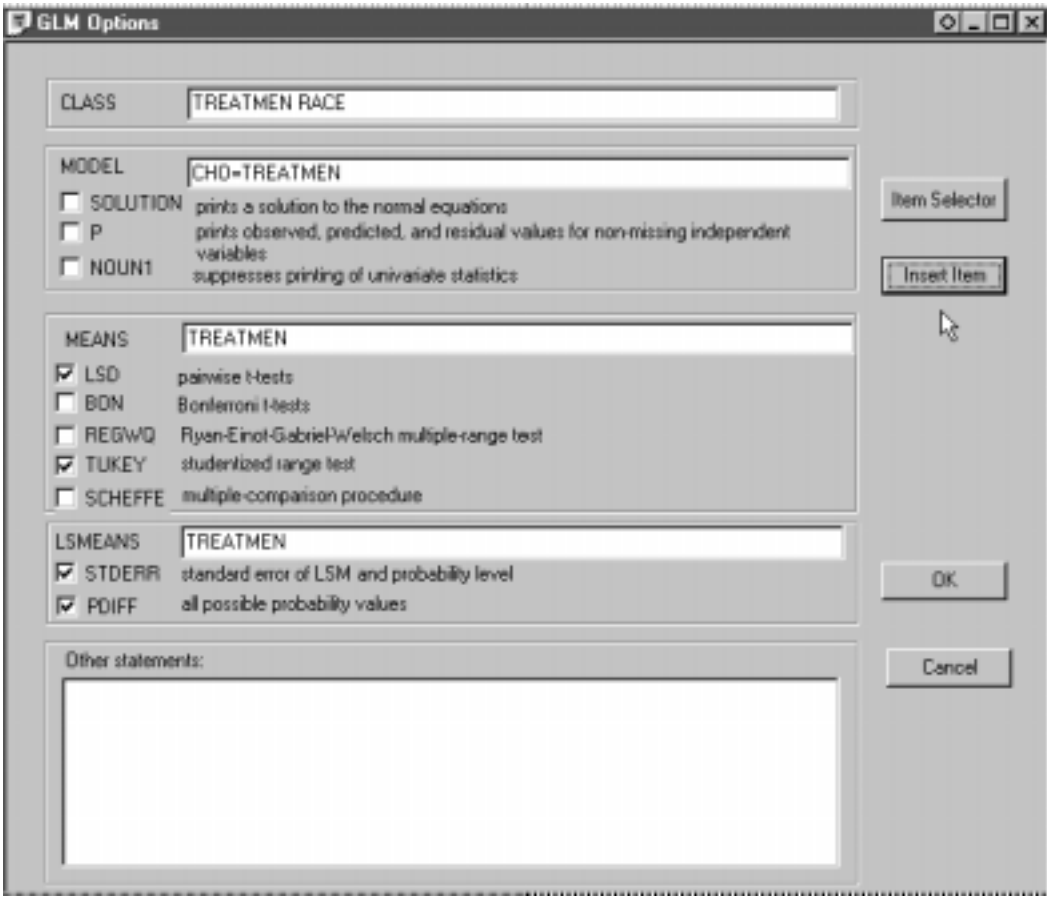



GLM Options
CLASS
MODEL
SOLUTION
prints a solution to the normal equations
P
prints observed, predicted, and residual values for non-missing independent variables
NOUNI
suppresses printing of univariate statistics
Item Selector
Insert Item
MEANS
LSD
pairwise t-tests
BON
Bonferroni t-tests
REGWQ
Ryan-Einot-Gabriel-Welsch multiple-range test
TUKEY
studentized range test
SCHEFFE
multiple-comparison procedure
LSMEANS
STDERR
standard error of LSM and probability level
PDIFF
all possible probability values
OK
Other statements:
Cancel

Click **Item Selector** to display and select panels and items. You can double-click on the desired item or click **Insert Item** to add items to the various edit areas.



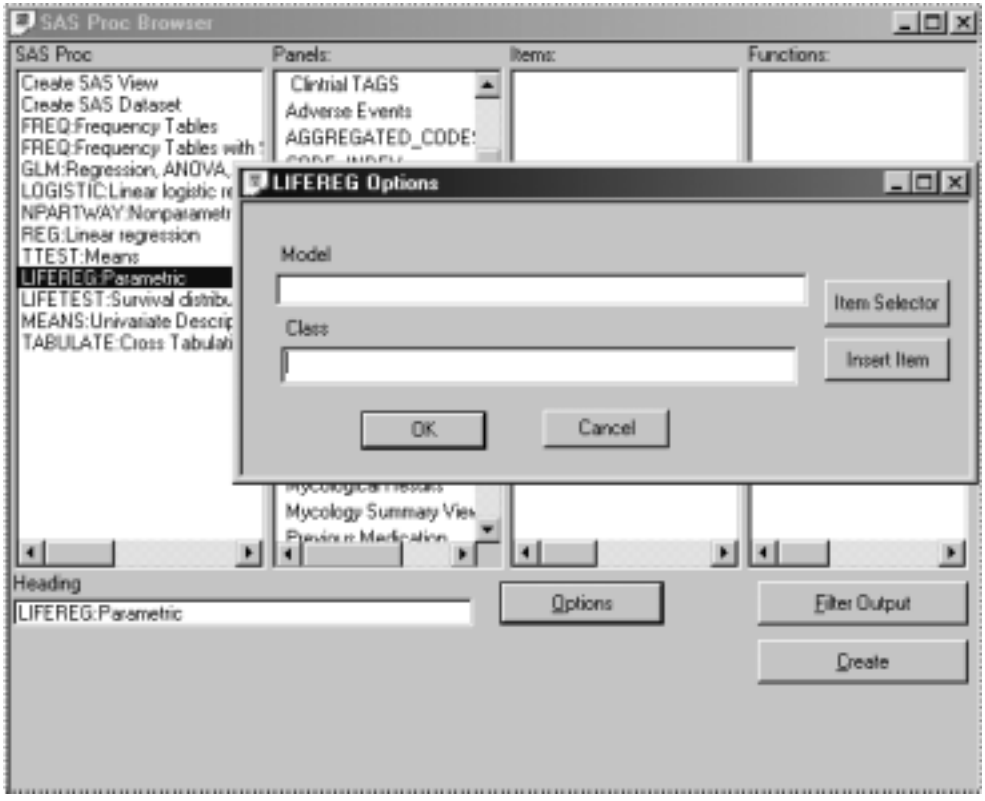
*Note: Do not type text items into the edit areas. You must select items by clicking **Item Selector** and make selections from the panels and items displayed in the Item Selector window. Insert a space between each item selected if you add multiple items within the same edit area.*



You can enter additional valid statements in the GLM procedure by typing in the edit area called 'Other statements'.

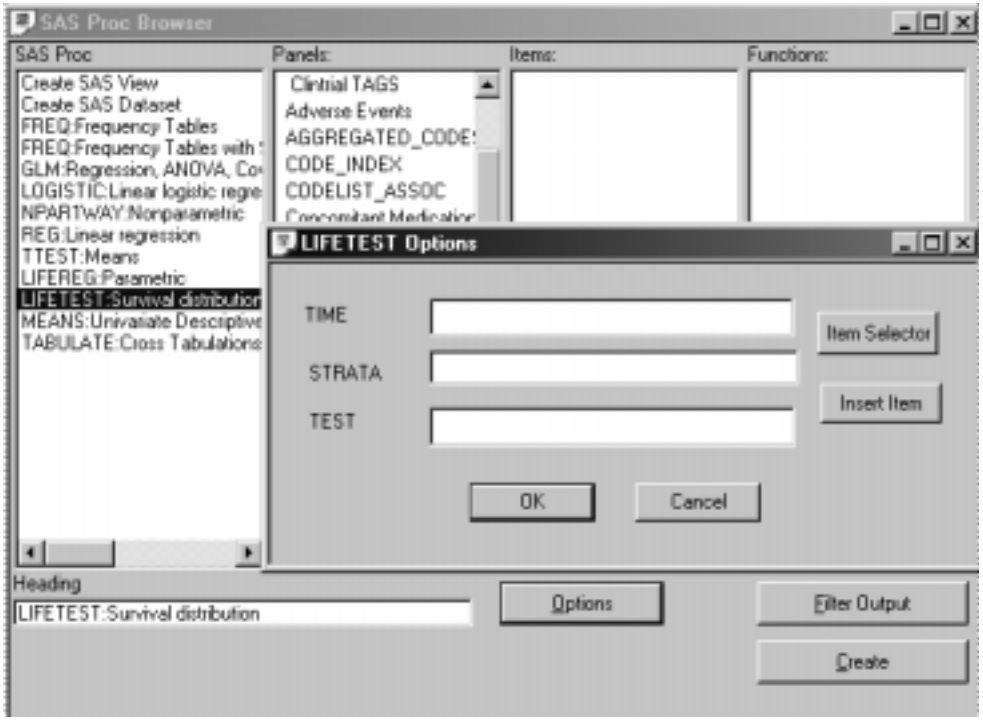
Click **OK** to submit the GLM Options. Click **Create.**

When you select the SAS Proc for LIFEREG: Parametric, click **Options** to display the LIFEREG Options and define your analysis definitions for Model and Class. You must follow the same instructions for the Item Selector and Insert Item as described above.



Click **OK** to submit the LIFEREG Options. Click **Create.**

Select the SAS Proc for LIFETEST: Survival distribution, and click **Options** to display the LIFETEST Options and define your analysis definitions for TIME, STRATA and TEST. Again, use the same steps for Item Selector and Insert Item.



Click **OK** to submit the LIFETEST Options. Click **Create.**

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 Pane*l.)

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 493
General 493
Registered SAS programs 494
Interactively register SAS programs 495
Converted SAS programs 495
STAT Program Registration window 496
Register a new SAS program 499
Definition tab 502
Locations tab 504
Substitution parameter tokens 506
Datasets tab 507
Parameters tab 510
Includes tab 515
Print / Subset tab 516
General Info tab 517
Save STAT Program Registration 518
Interactively register R programs 519
R scripts overview 519
Register R programs 519
Auxiliary Windows 527
Browse Server 527
Print Format 531
Program Format options 533
Patient Subset selection 534
Program group options 535
Manage SAS objects (future release) 536
Manage SAS programs 536
SAS Program 538

Program Group 541
New Program Group 545
Program Group Restrictions 546
Library 548
Category 551
Status 553
User Group - SAS Program 556
User Group - Program Group 557

STAT Program Registration Browser 558
Selection criteria 558
Opening the STAT Program Registration Browser 558

Registered SAS programs 558
Registered SAS programs 558
Quick execute 559
Retrieve a table 560

SAS program results and log files 561
Creating the table output 561
Displaying the SAS log or source 561

Snapshot output 562
Multiple table outputs 562

Schedule SAS program jobs 562

Printing SAS program results 563
Print table output 563

Exploring data 564
Opened SAS production table results 564
Update patient selection criteria 564

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.

Note: Requires IRServer version 8.10)

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.

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.)

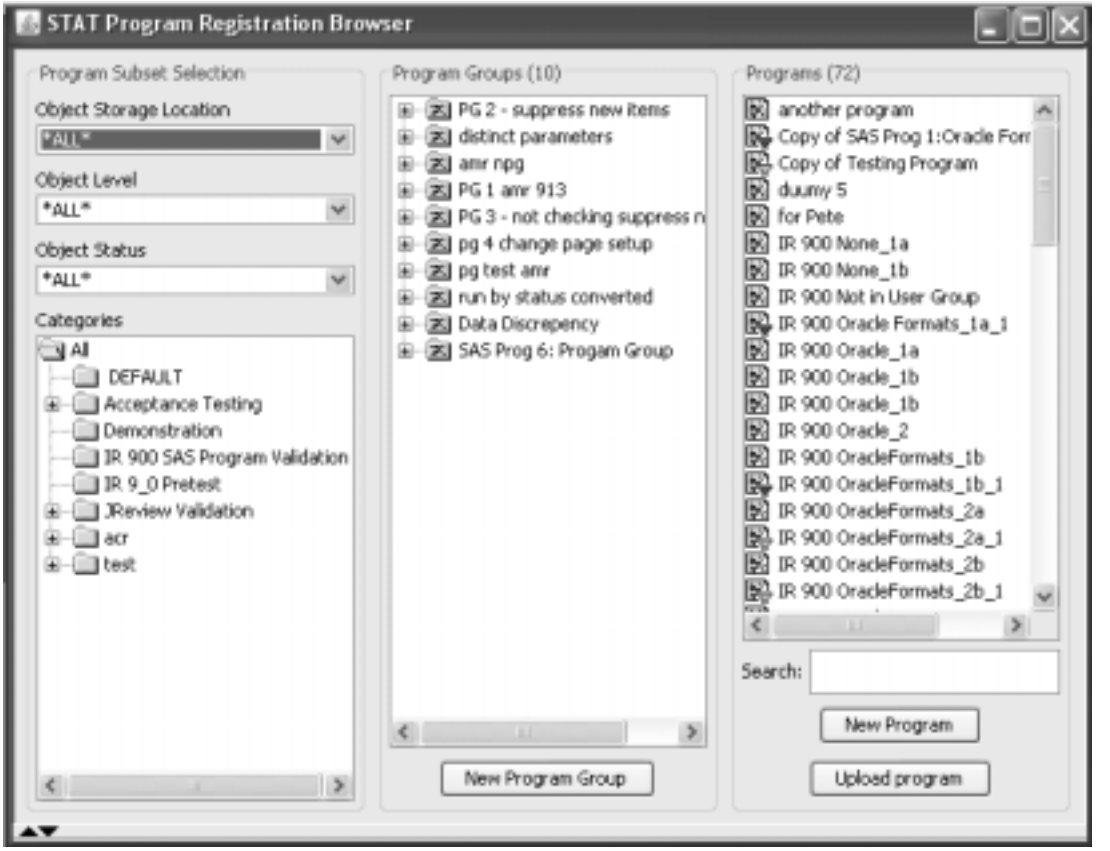
During the conversion, messages are produced if it encounters print formats with missing line size, page size values or inconsistencies between the data origin type and the libname / datalib fields. For example, if the data source is NONE and there are values in either the libname or datalib fields, 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

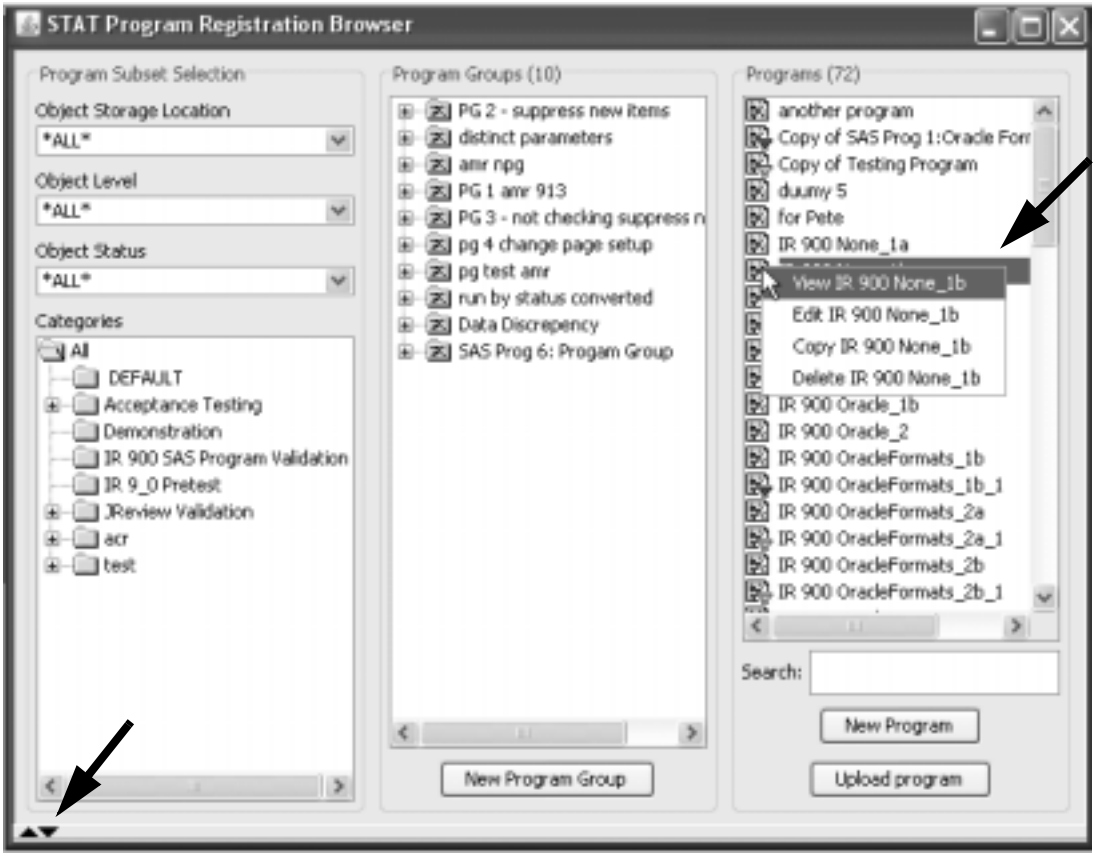
The STAT Program Registration Browser main window displays lists of all available User Groups, Categories, Program Groups and already registered SAS Programs. A count of the contents for each list is displayed to assist in the registration management.

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.



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.



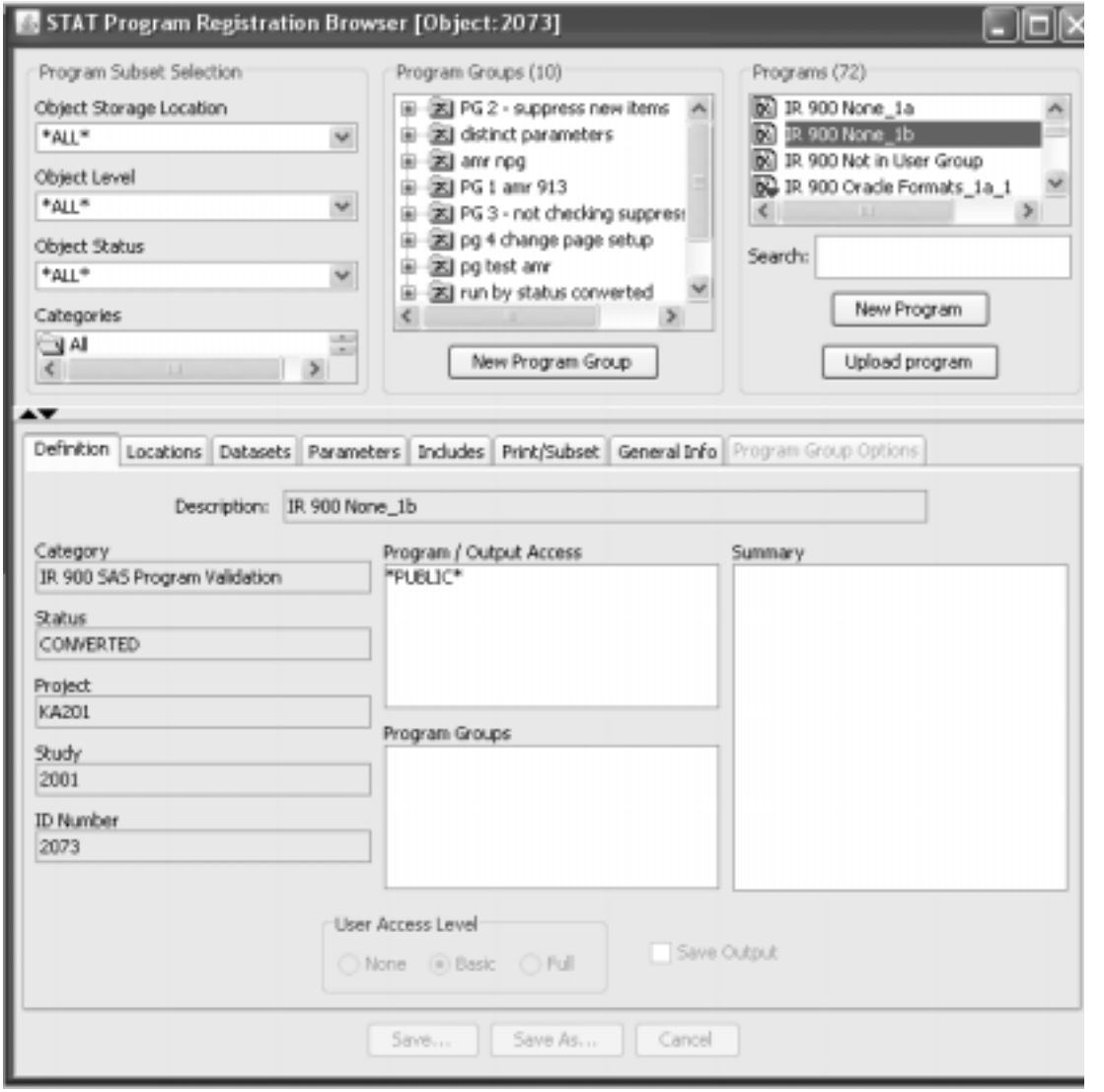
Click the expand arrow in the lower left corner. The STAT Program Registration Browser window expands for access to the function tabs for viewing and registering SAS program information.

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.



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.

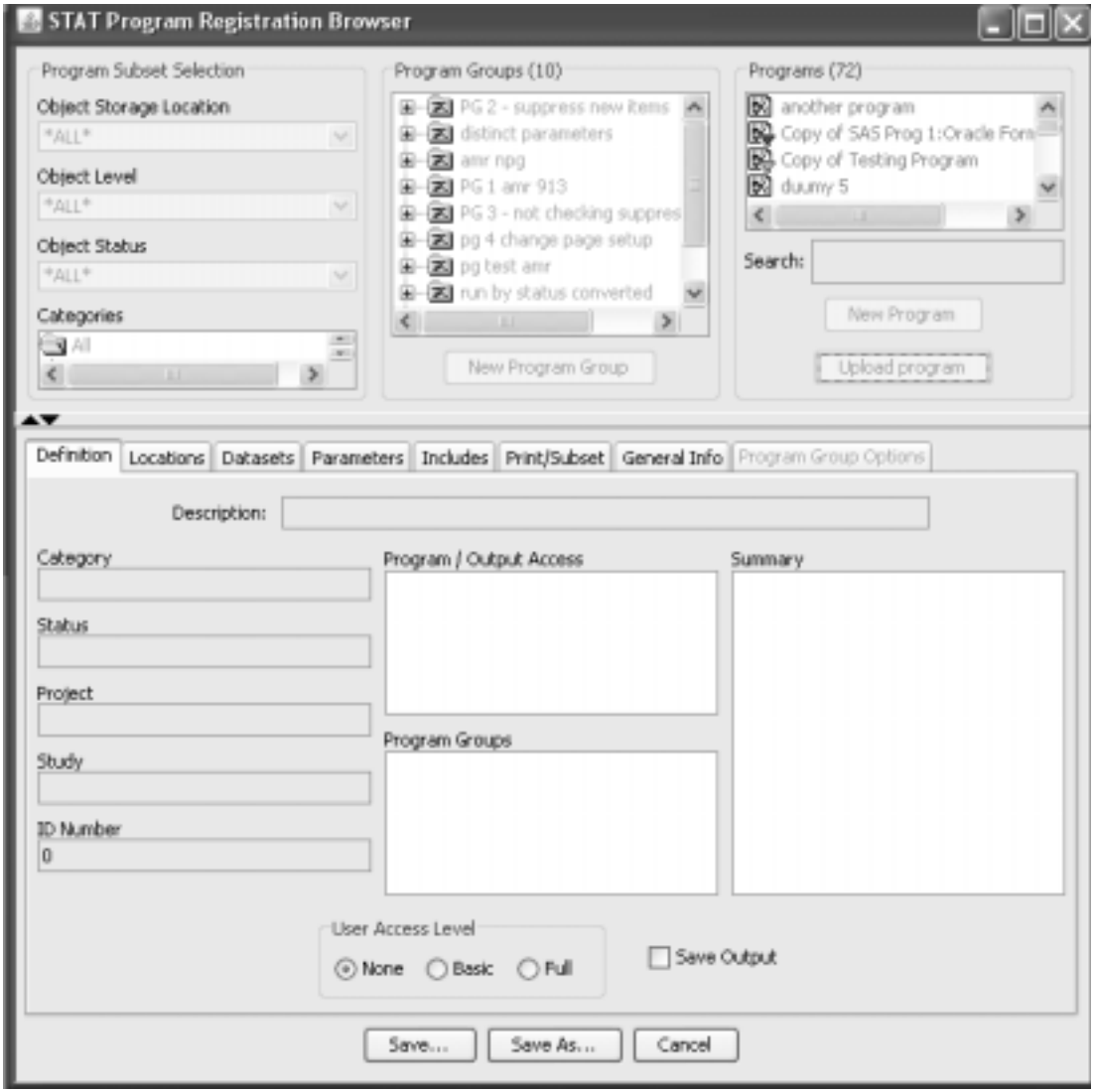
The following functions are enabled when you select **New Program** or **New Program Group** for **Edit** mode.

- **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.



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.

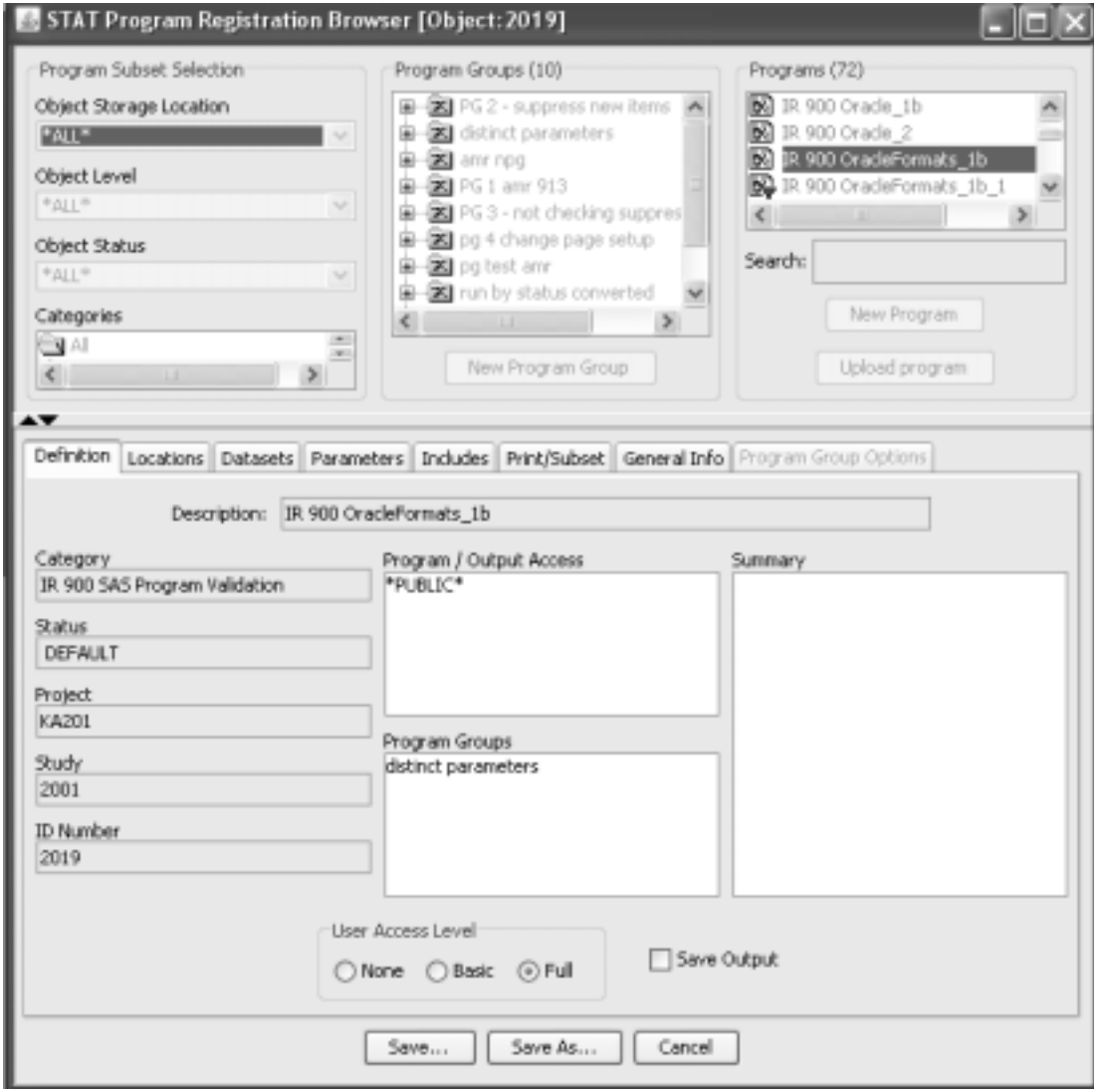
When you click the **New Program** button the registration tabs become available for entry. The '*Definition*' tab is the first entry in sequence to enter details for registering a new SAS program. Some information is entered directly through the '*Definition*' tab. Other information is displayed and 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.

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.



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 predefined 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.

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.)*

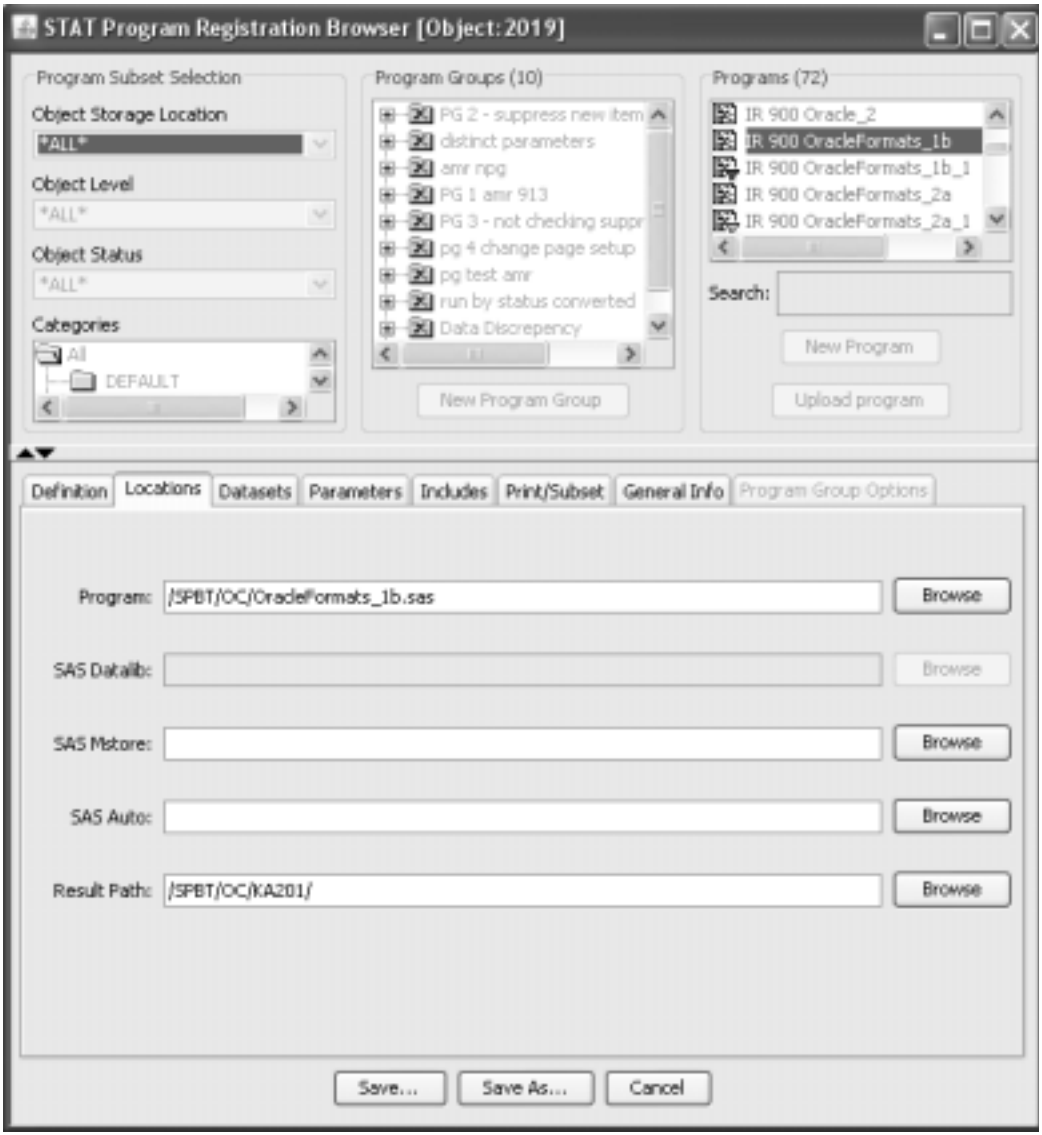
Enter or select the following information in the '*Locations*' tab:

- **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 - L**ocation 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.



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

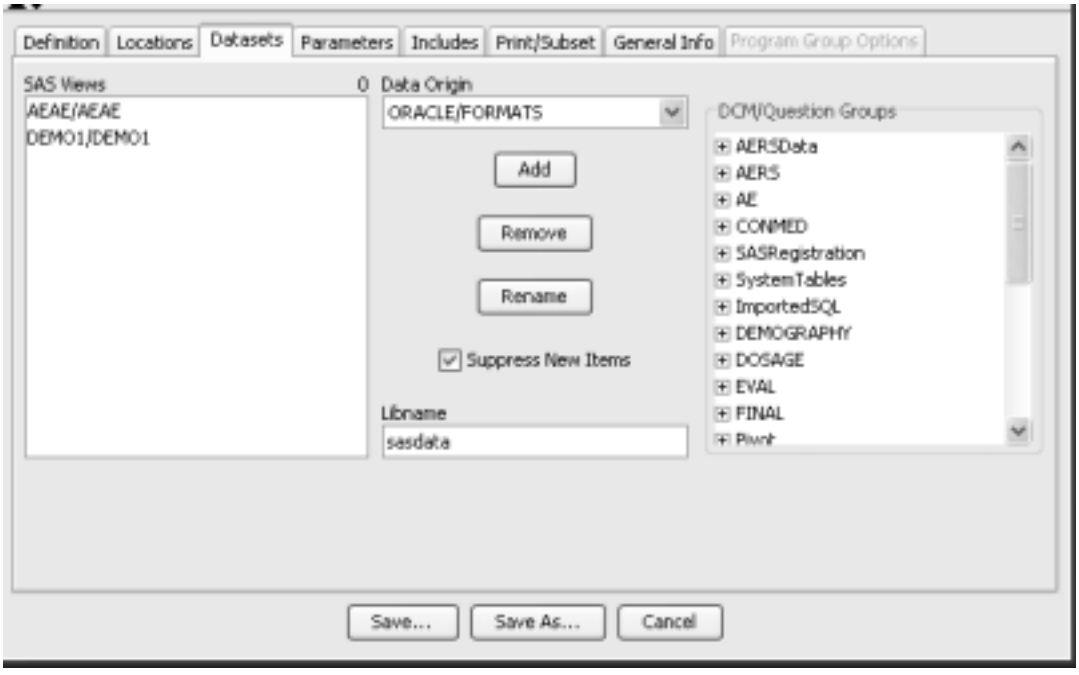
In addition, the <user> token can be used in the Result path configuration item.

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.

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.



Your SAS programs can be run against existing SAS datasets, or SAS views that are generated by Review at runtime. The Review Program Registration Browser lets you specify your preference in the Data Origin.

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.
- SAS Views are recreated each time the Patient Selection Criteria changes.

PATIENTSET *Data Origin*:

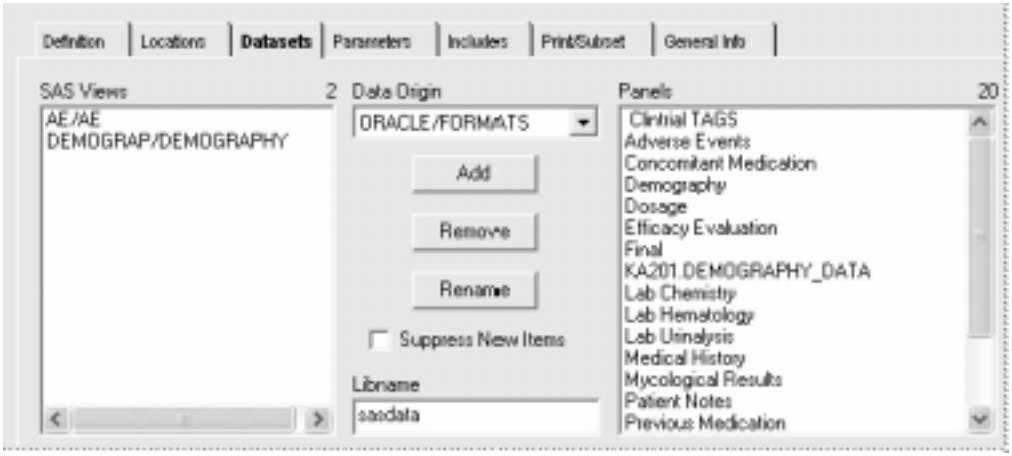
- Review generates a standard named SAS View of the patients meeting any defined patient selection criteria.
- This SAS view can then be utilized within the program.

SAS *Data Origin:*

- If no Patient Selection Criteria is defined, Review 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.

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.***



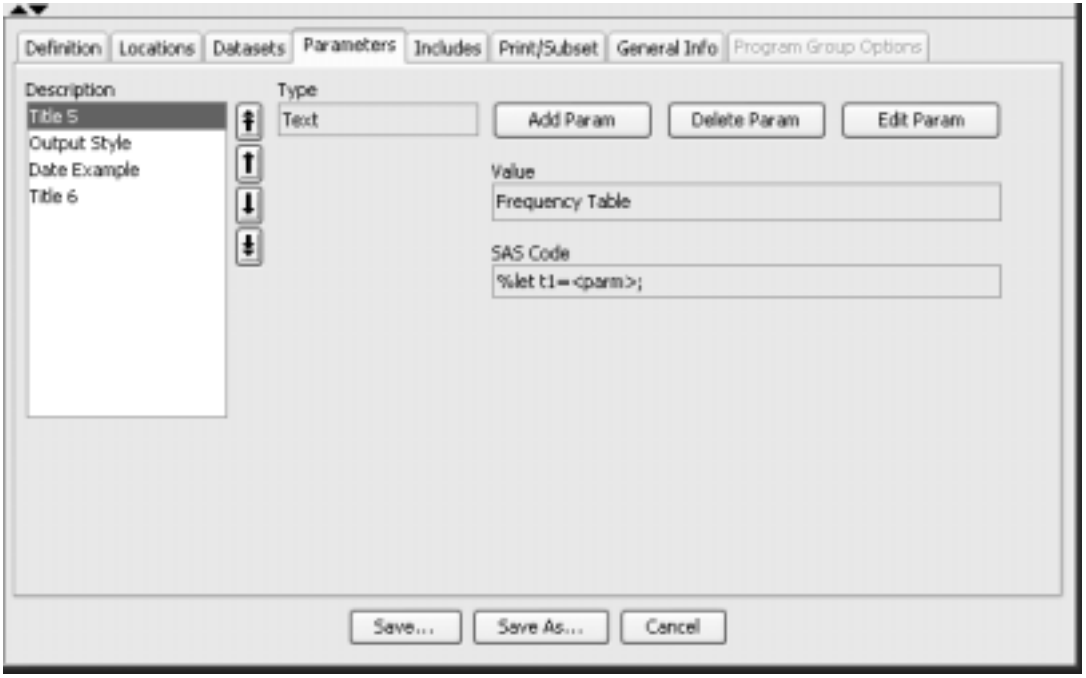
- **Libname** is the reference name for the library of SAS datasets that are accessed by the program. This can only be entered, and is required, if the D*ata Origin* is other than NONE or PATIENTSET. (The reserved words SLIB, BASEOS and OS are not allowed here.)
- **SAS Views or Datasets** is the list 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.

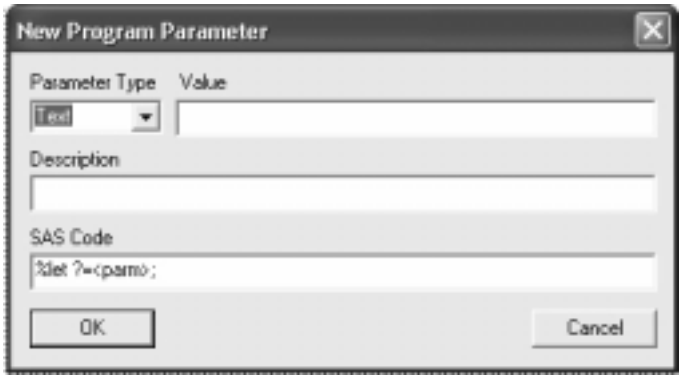
The Parameter # lists existing parameters by sequence number. The number is both for display purposes and for order of parameter inclusion in the SAS job. Click on the parameter number to view information about the parameter. In this example, a previously registered SAS Program was selected from the Programs list and for the **Edit** function.



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.



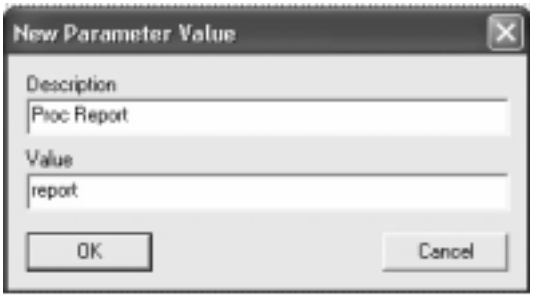
2. **Parameter Type** indicates **Date**, **Directory**, **File, List** or **Text**.
3. For **Text** and **Date** parameters:

   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.

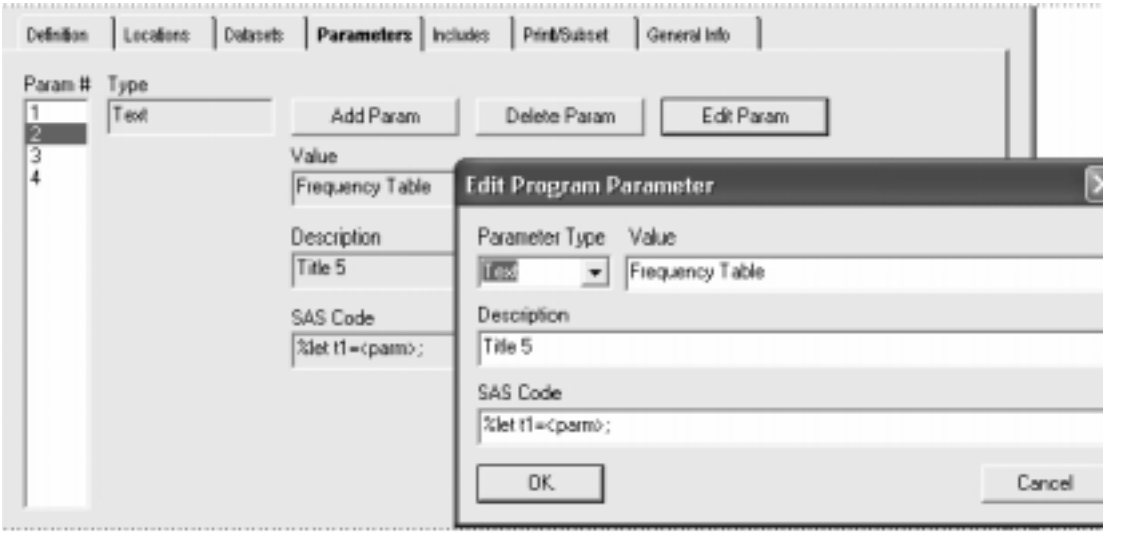
   Values is a list of possible values for the parameter.



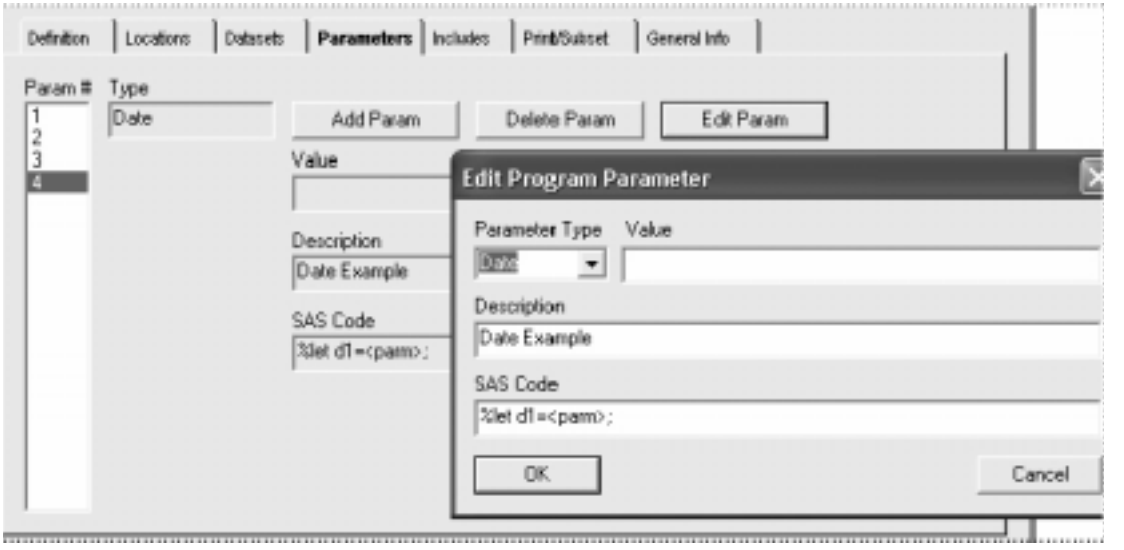
4. **Description** is a descriptive name for the parameter.
5. **SAS Code** is the code used to set the parameter value into a MACRO variable in the SAS program code. This is usually of the form "%let ?=<parm>;" where '?' is the name of the MACRO variable used in the SAS program. Replace the question 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.

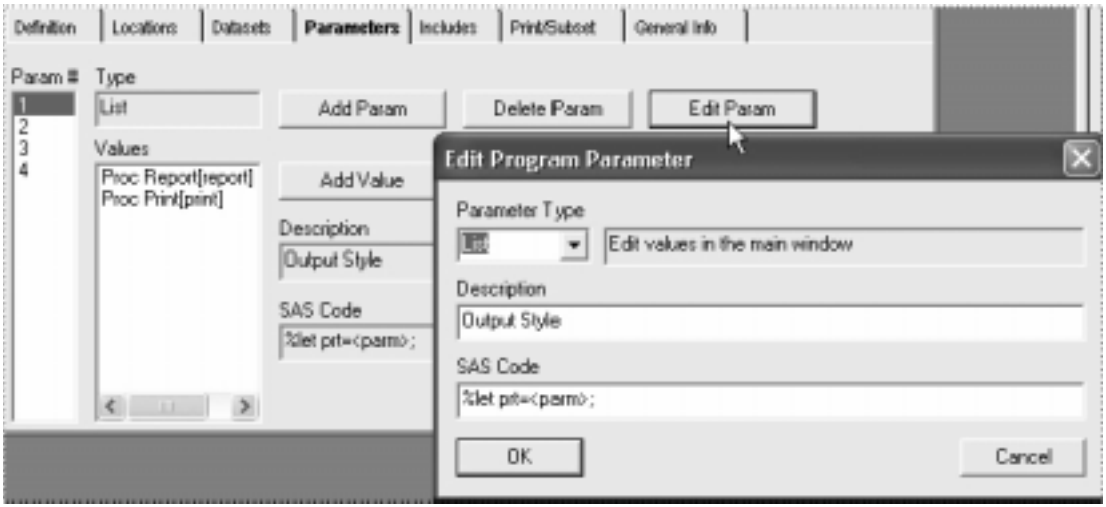
Example of the parameter type for **Text**.



Example of the parameter type for **Date**.



Example of the **List** parameter type where **Values** is a list of the possible choices for the parameter.



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.

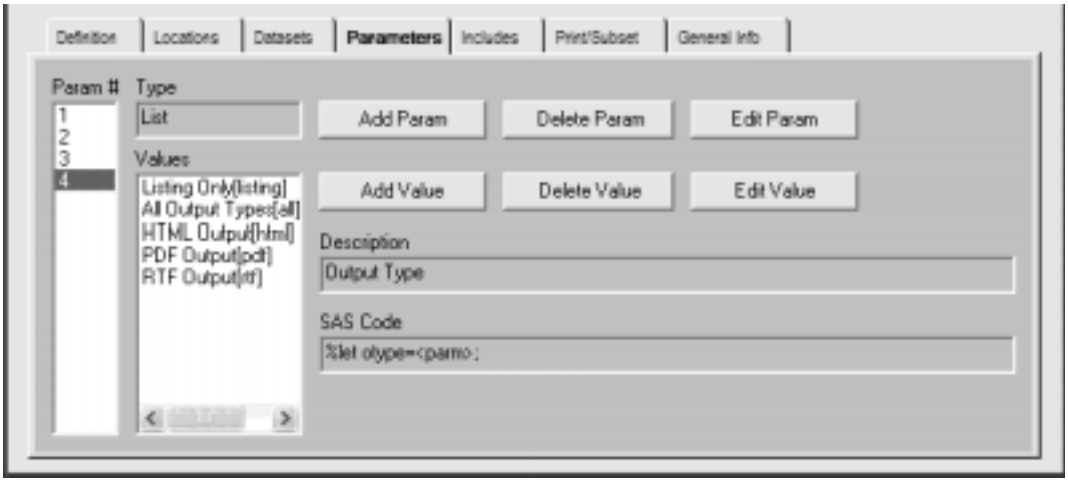
An example is:

%let REPSTYLE=<parm>;

If you choose 'Summary report[2]' as described above, then <parm> is substituted with 2, yielding:

%let REPSTYLE = 2;

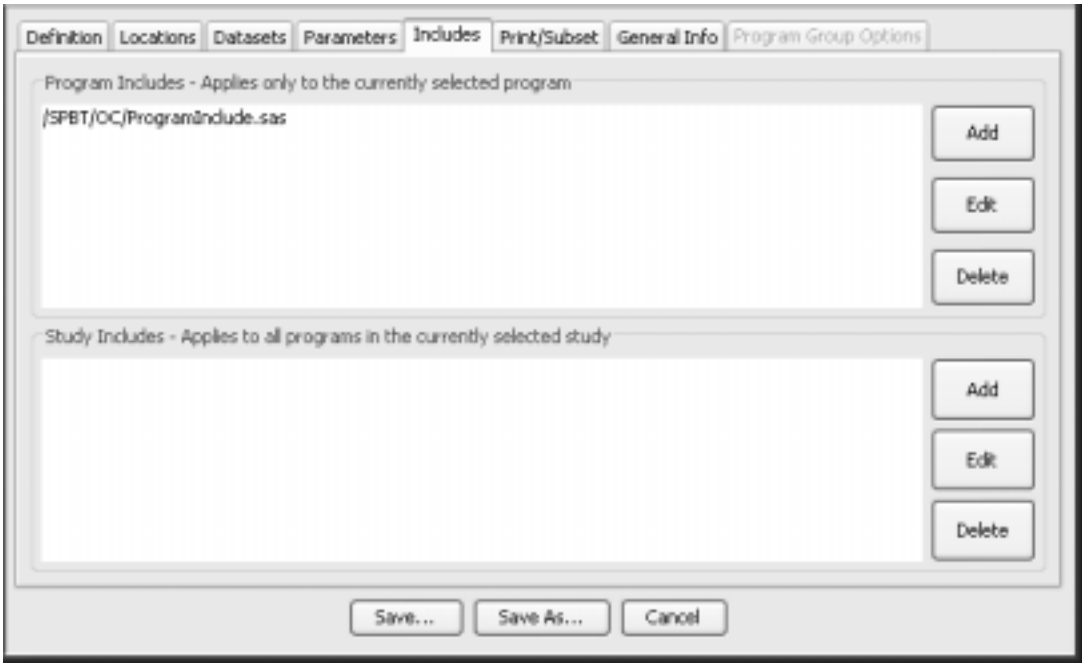
This SAS program shows the parameter type for *List* with multiple values added and listed.



Includes tab

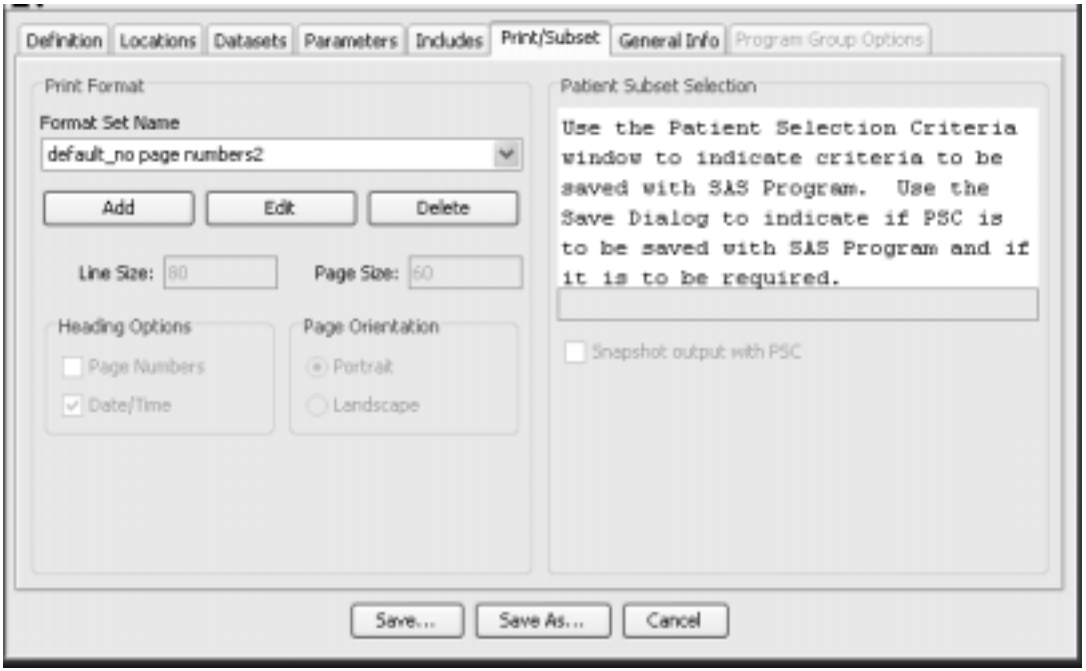
Click the '*Includes*' tab to enter associated source files program to automatically insert include file references in the SAS code that it creates. The system will add a '%include' for each entry. Use the **Add**, **Edit** and **Delete** buttons to add, edit and delete files in the list. *(See Auxiliary 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.



Print/Subset tab

Use the Print / Subset tab to enter print format options and to apply a patient subset selection if required.

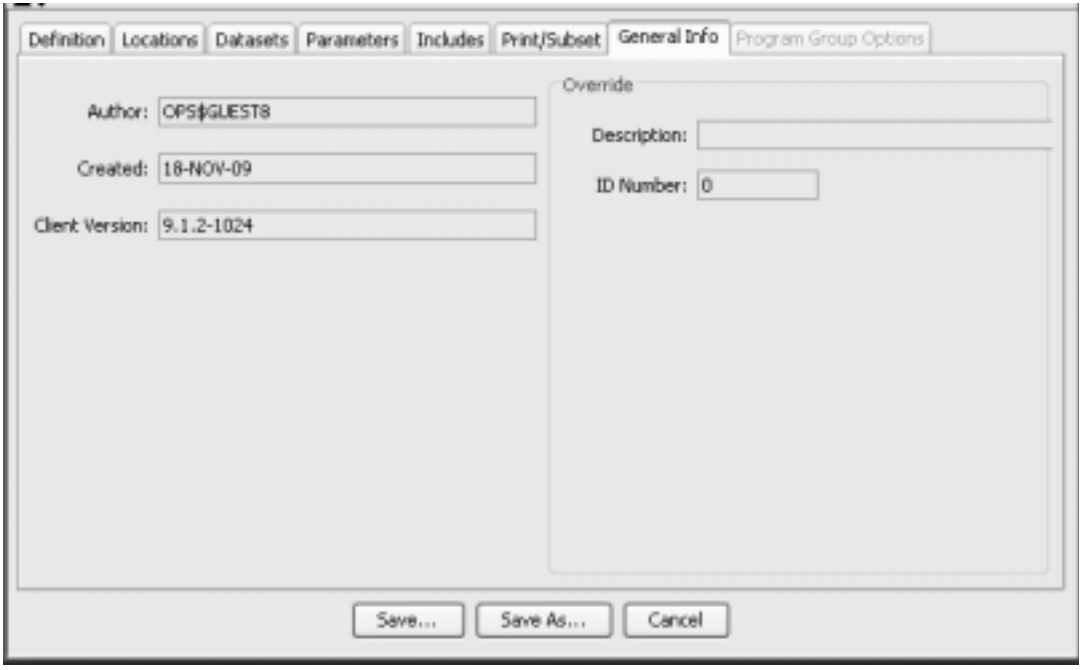


- **Print Format** – shows the current print format assigned for the program. *(See Auxiliary Windows: Print Format.)*
  - **Format Set Name** - displays a drop down list to select changes for the print format. You can also define a new *Format Set* to use for many registered programs and program groups.
  - **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

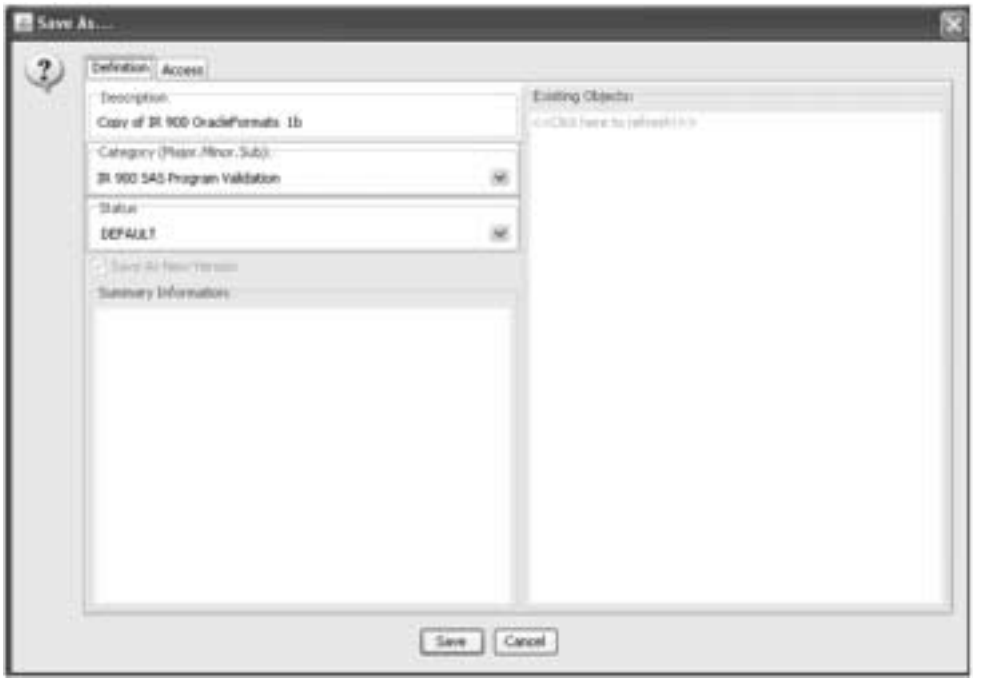
The '*General Info*' tab displays general information about the registered program.

- **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).



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)*



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.

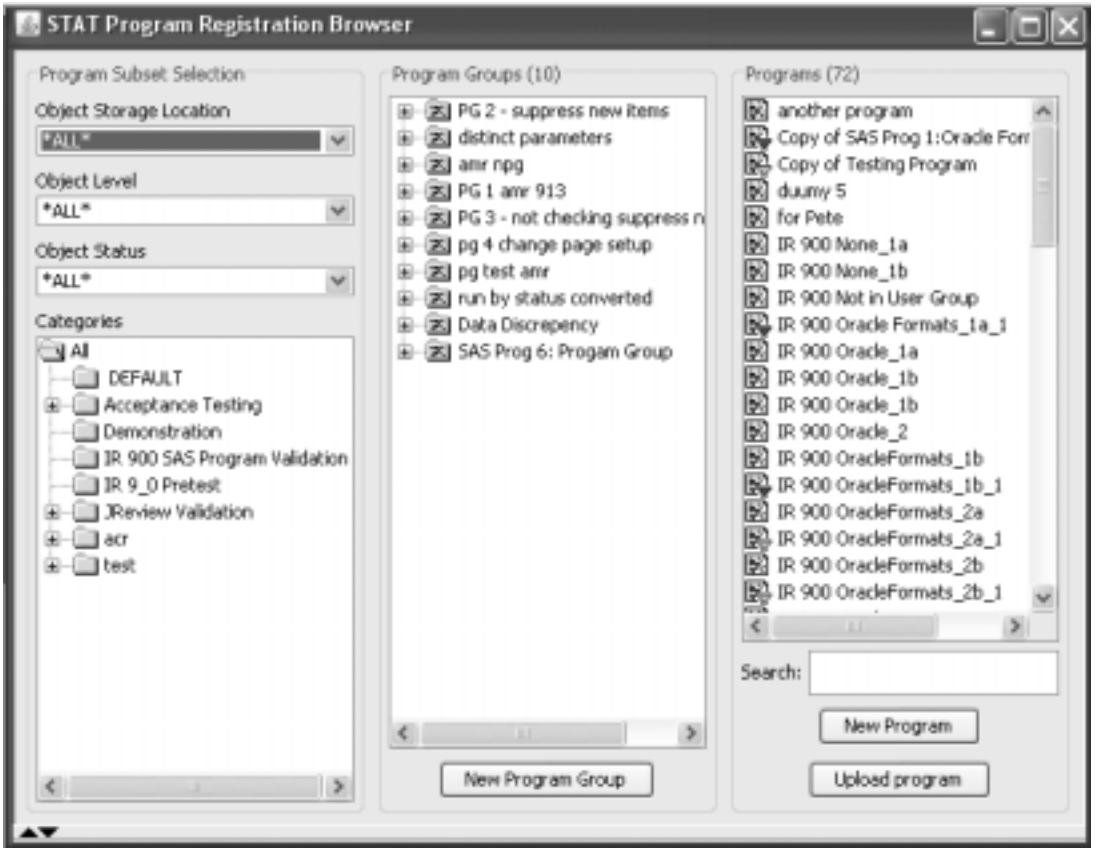
Variable name remapping is supported, as well as forming R dataframe 'composites' from different SAS datasets where join logic has already been determined and implemented by JReview. The benefit is that the user registering the R script can select different items from different datasets, all of which 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 the icon toolbar, or select 'Browse' menu item, then 'Stat Programs' submenu item.

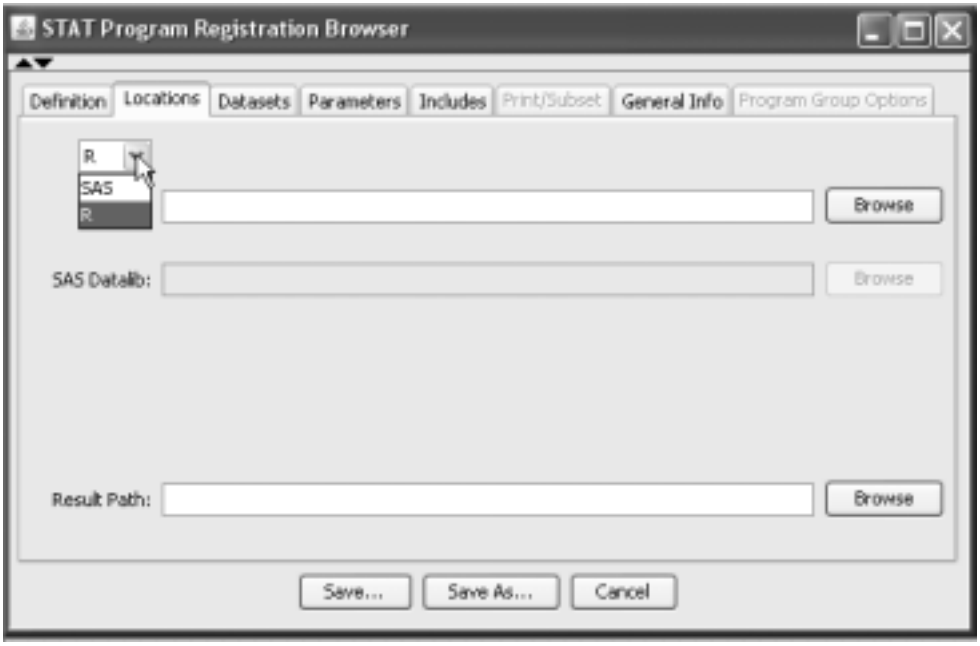
   The STAT Program Registration Browser window is displayed which lists the currently registered programs, along with several buttons which allow registering new programs/scripts New Program or Upload Program (to move a program from your PC to the server).



2. Click on the 'New Program' button, (assuming the SAS or R program has already been uploaded to the server); the following dialog 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 conditonally enabled, or disabled based on “R program” status, such as the ‘Composite’ mode radio 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”.



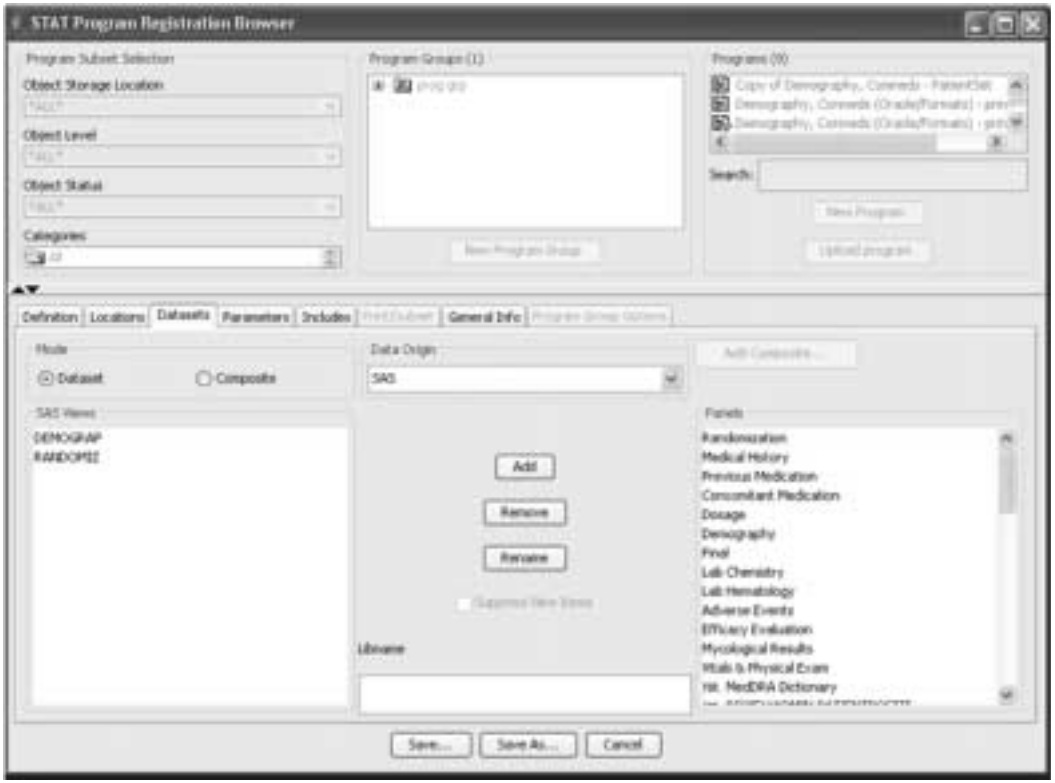
3. The user can select either SAS or R in the dropdown listbox, telling the system what type of program is being registered. Use use the ‘Browse’ button to locate the program on the server side, to fill in the ‘Program:’ entry for the fully qualified location / name of the program.

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.

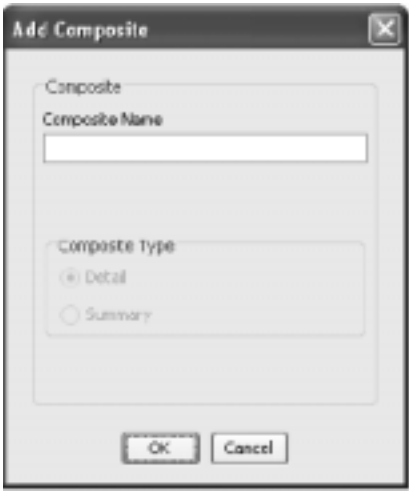
Dataset example: Full datasets are provided as R data frames (for R scripts), or SAS datasets (for SAS programs):



- 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 radio button in the Datasets tab is also conditonally enabled, or disabled based on "R program" status.

When Composite is selected, click **Add Composite** to enter a descriptive label for a Composite. Then select the individual panels and items to add to the defined composite for panels and items of interest.



Adding multiple Composite tabs is supported. The selected panels and items are added in a tree display. You may double click on a particular panel or iitme “Rename” column to change the description. Likewise, to remove a renamed description, double click on the column to select and delete.

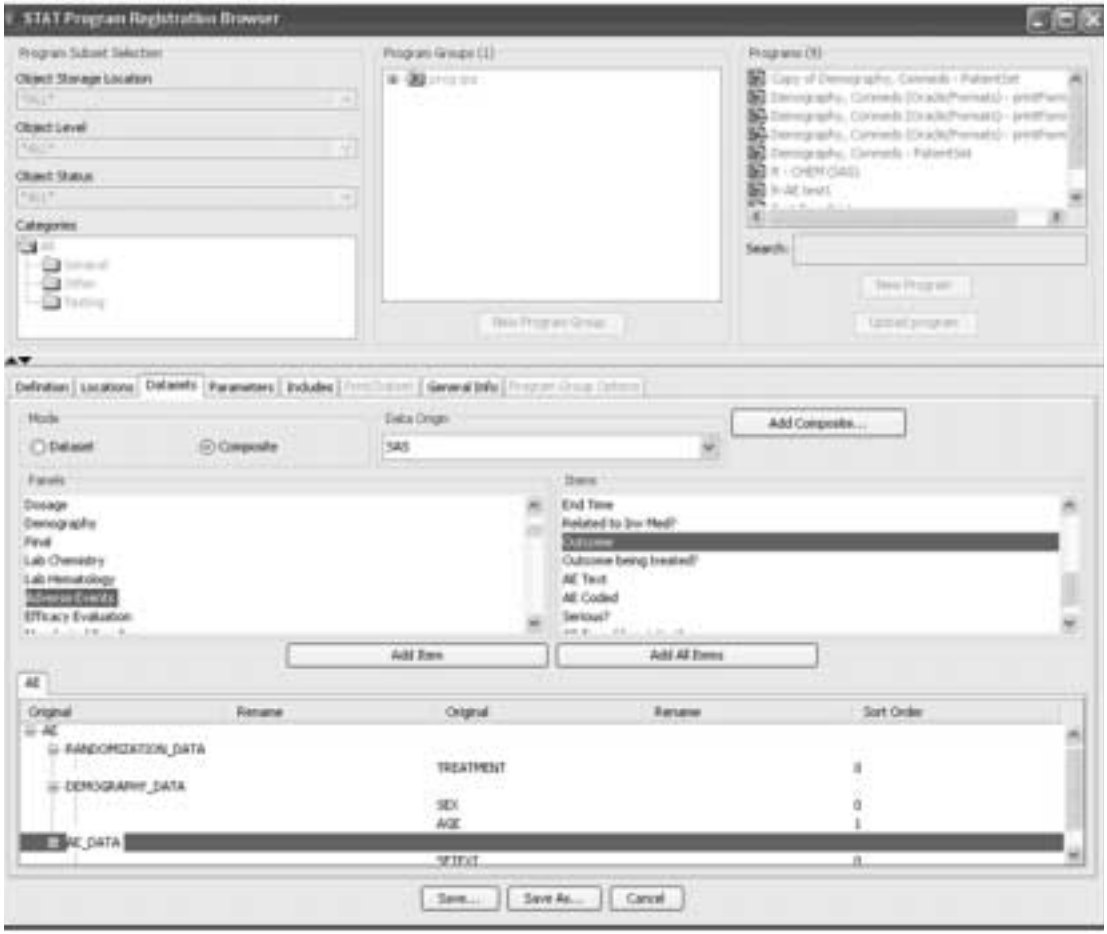
Composite names have a couple of restrictions.

1) The name of a composite must be from 1 to 36 characters.

2) The name cannot contain spaces.

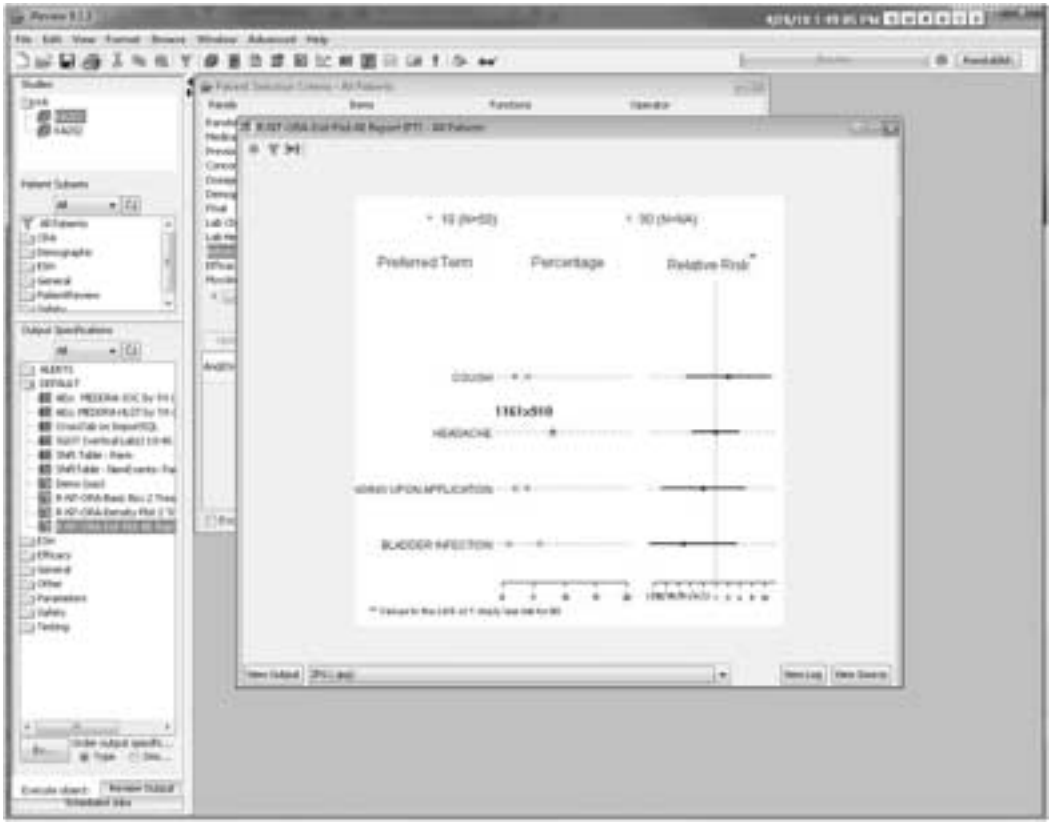
3) There is no limit to the number of composites. However, each composite must have a unique name.

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:



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).

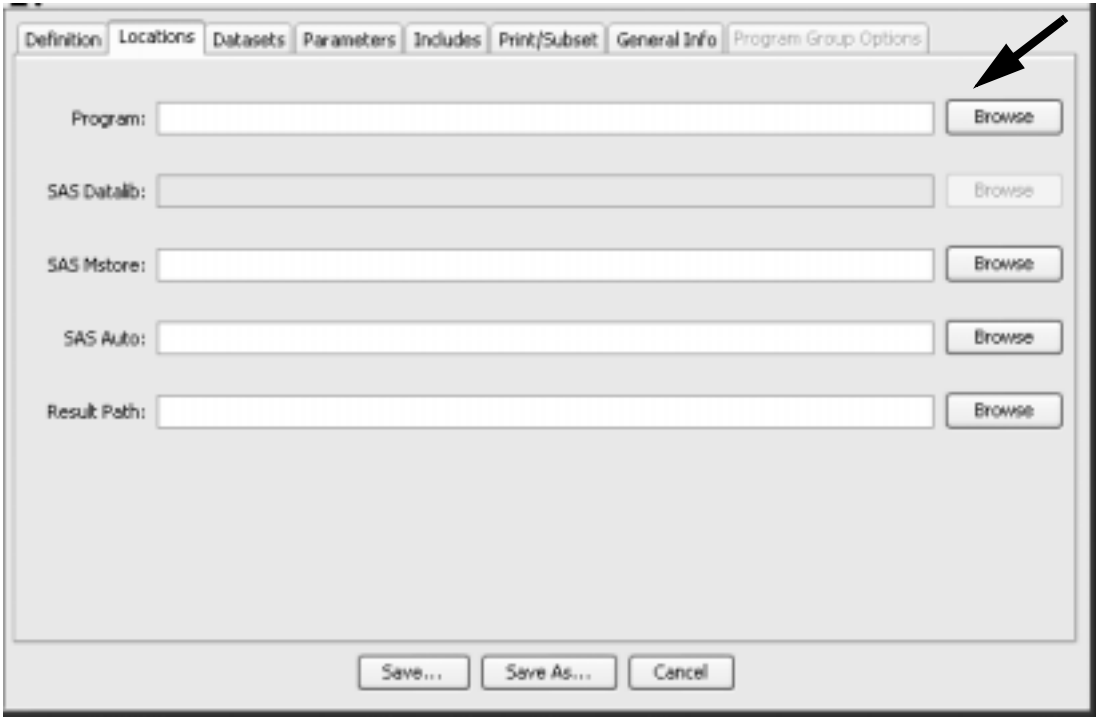


Auxiliary Windows

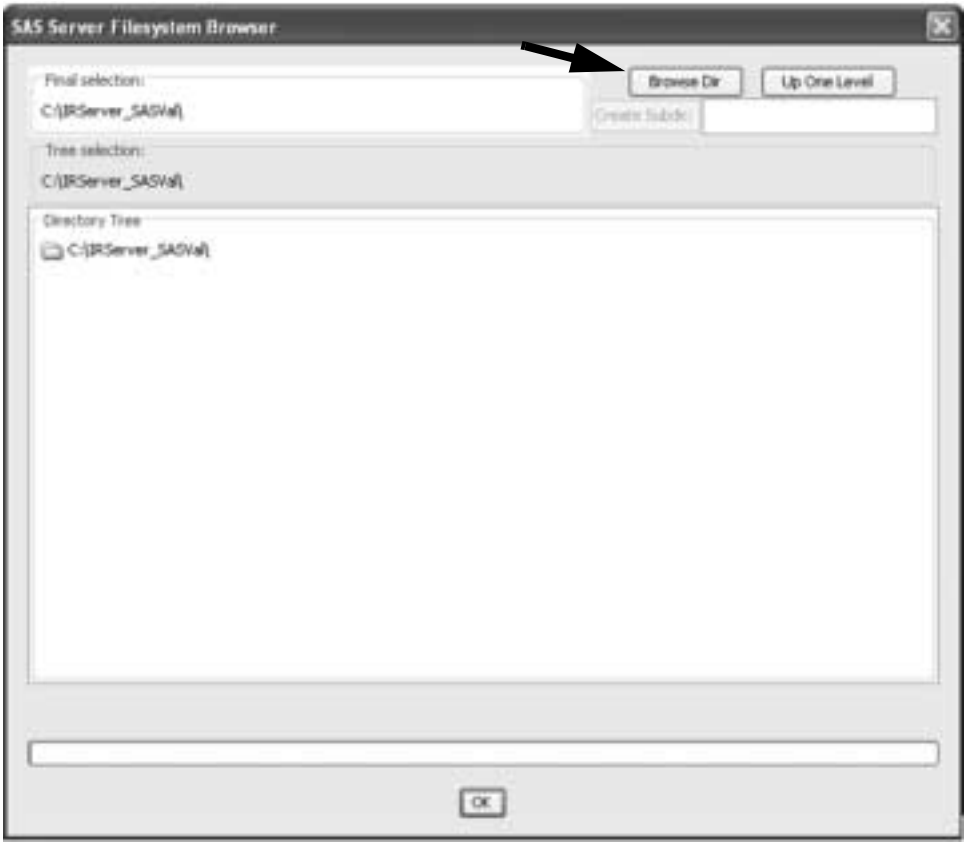
Browse Server

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.



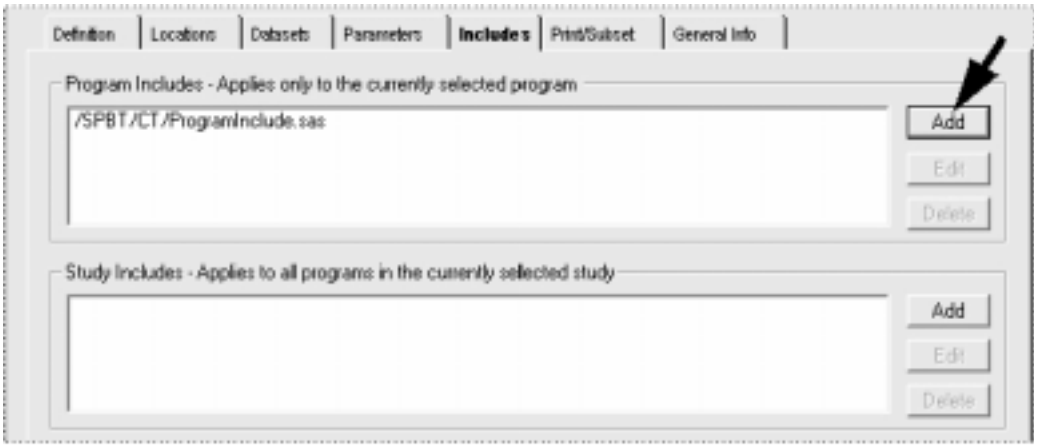
The Browse Server window allows users to browse directories and files on the server. This avoids typing errors and also prevents users from typing paths and/or file names that do not exist.

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.

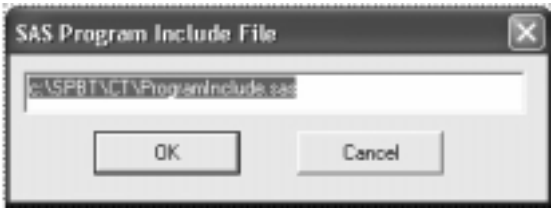
Clicking on a directory in the list displays files in that directory. The "Current selection:" text area displays the path/file that will be returned when you click the **OK** button. The dialog also knows if the required return is a directory or a file and will only allow the correct selection type 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.



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.



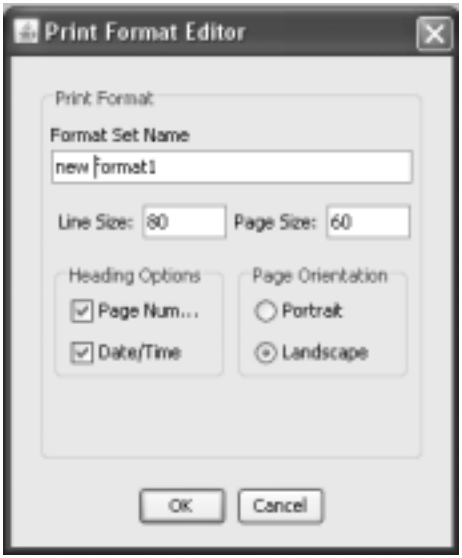
Print Format

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.

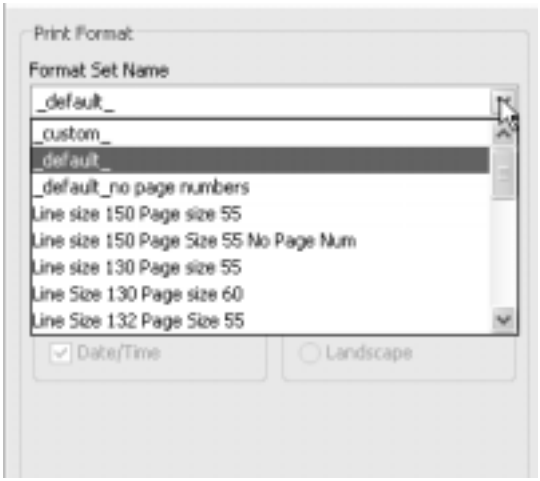
   When you open the Print Format window from a program group, the number of programs within the group is displayed at the upper right.
2. Enter a Format Set description. Format set names can be up to 40 characters long.
3. Change the Line Size and Page Size.
4. Check Heading options for Page Numbers and Date/Time.
5. Select the Page Orientation.
6. Click **Save**.



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.

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.



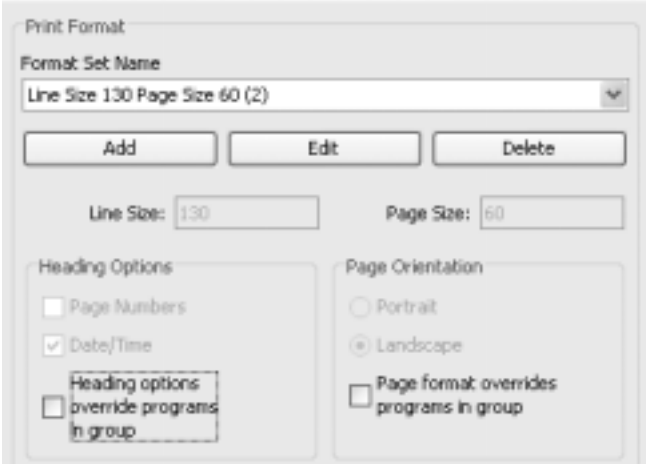
The _custom_ format allows any SAS program or program group to have its own unique print format settings. When the _custom_ format is selected, the fields on the dialog become editable for you to enter their own format parameters. Click **Apply** to save format changes.

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.

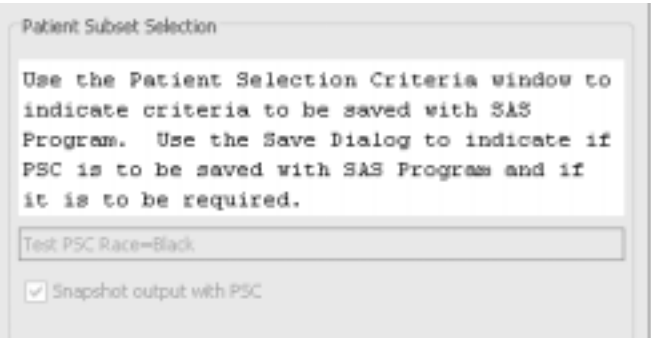
Likewise, if a program group has a heading options assigned and the "**Heading Options Override Programs**" box was checked when the program group was saved, all output from the entire batch run will be formatted according to the program group's heading options. Otherwise, the output from the batch will be formatted using the individual heading options used by the programs in the group.



Note: (See System Management: New Program Group.)

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.



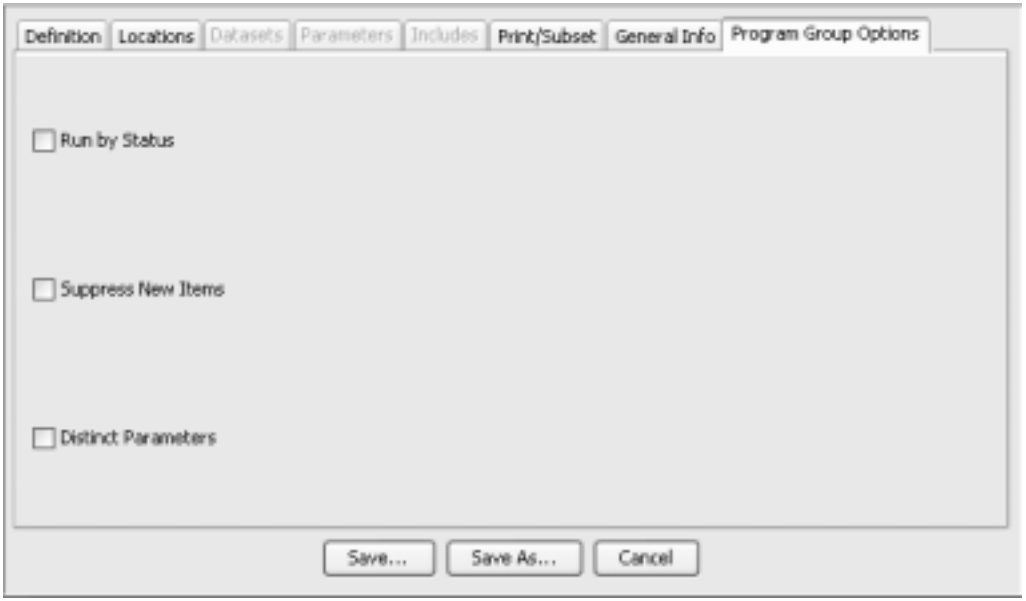
When accessing View or Edit modes for registered SAS Programs or Program Groups previously saved with patient selection criteria; go to the patient selection criteria window to view patient subset details. A filter icon displays next to the object description indicating the program or program group has 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.

Program group options

Program group options may be selected for the following functions:

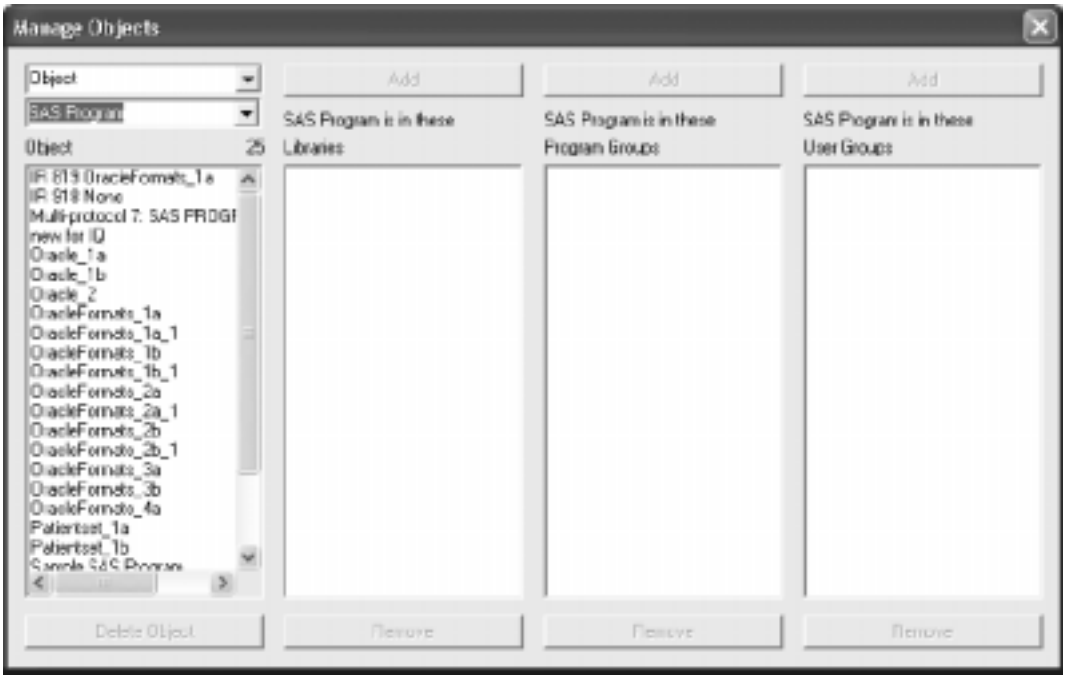


- **Run By Status** will result in only those programs that have the same status code as the program group to display and run as part of the group. If the "Run By Status" is not checked, programs and program group can have different status and all programs will run.
- **Distinct Parameters** displays 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.

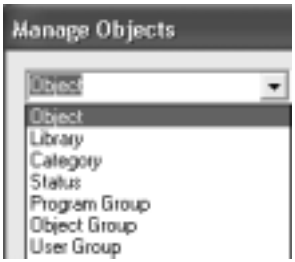
Manage SAS objects *(future release)*

Manage SAS programs

Click the **Manage** option in the tool bar for Advanced menu, to access the Manage Objects window.



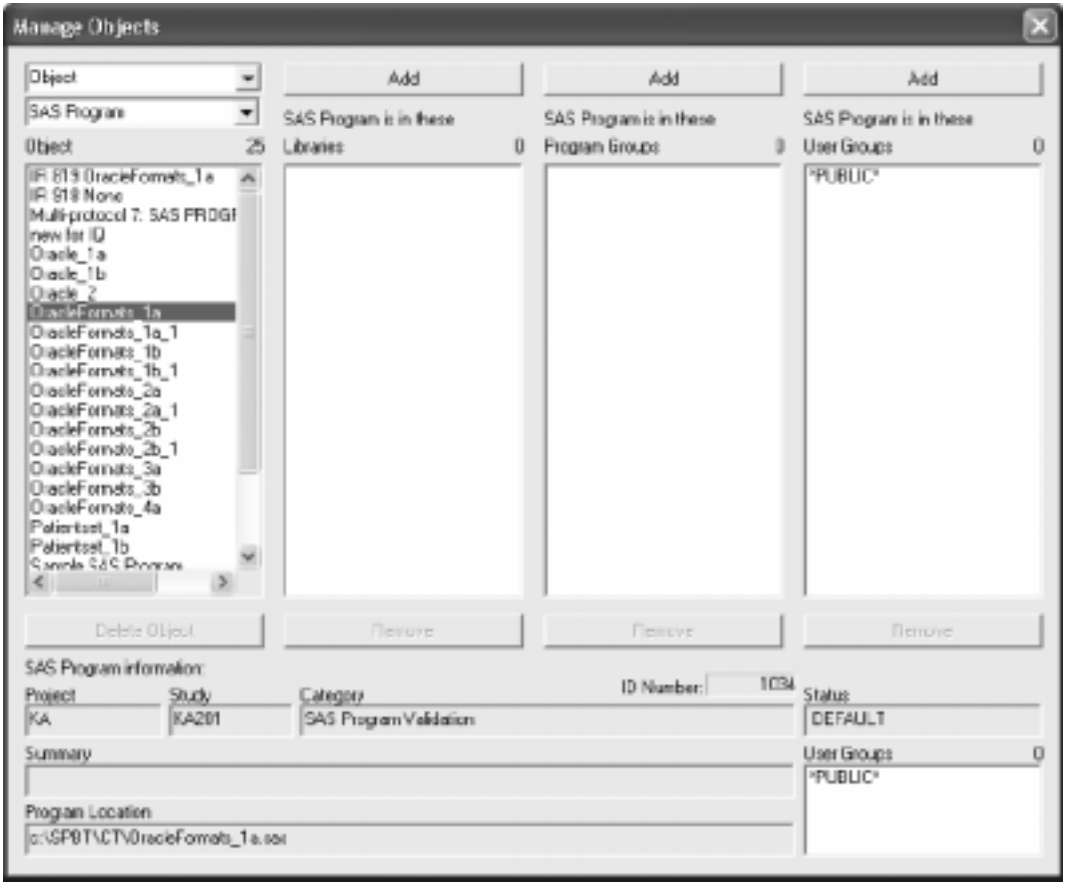
A drop down list displays the available system management options where you can manage the membership of registered SAS programs within the following areas:



- **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.

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.



The following functions are available to assist you in managing the membership of SAS programs within Program Groups, Libraries and User Groups.

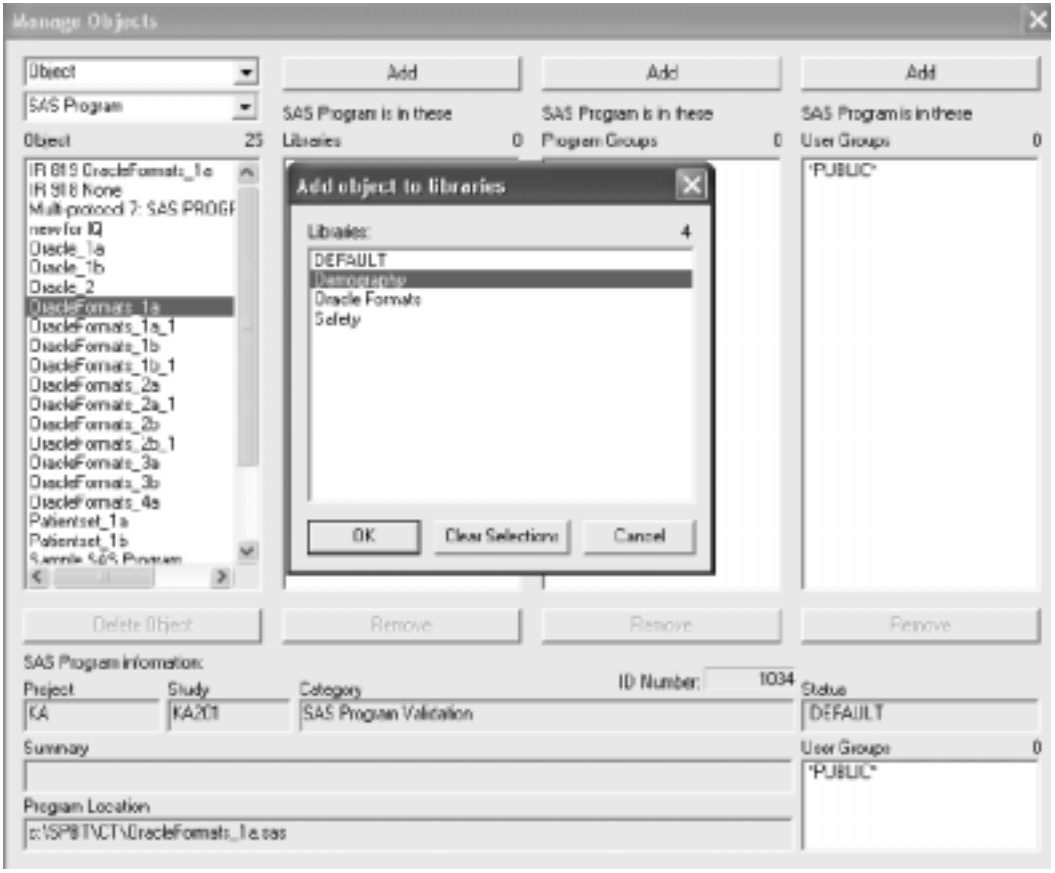
1. Click on **SAS Program** to display the registered SAS programs.
2. Select a SAS program from the list. You can only select one SAS program at a time.

   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.



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.

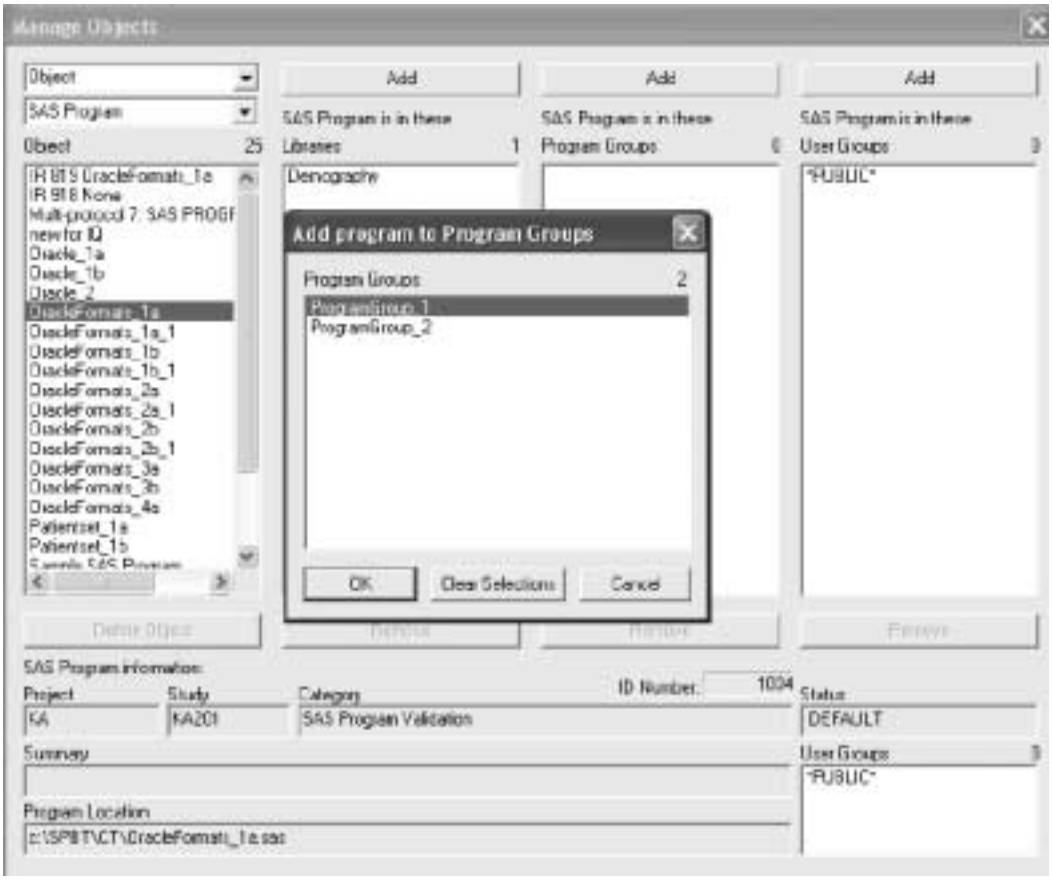
   If you click **Remove all User Groups** the SAS program changes to *PUBLIC*.

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.

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.

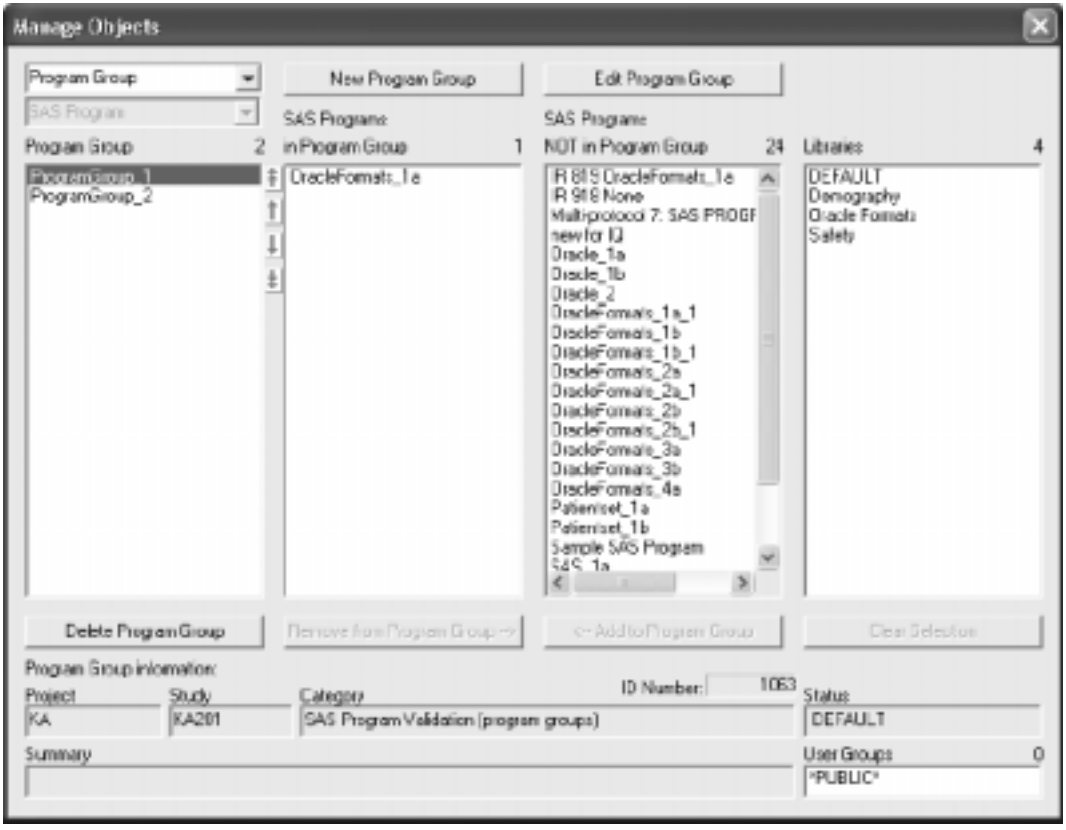
1. Click on **Program Group** to display the existing programs groups.



2. Select a program group from the list. You can only select one program group at a time.

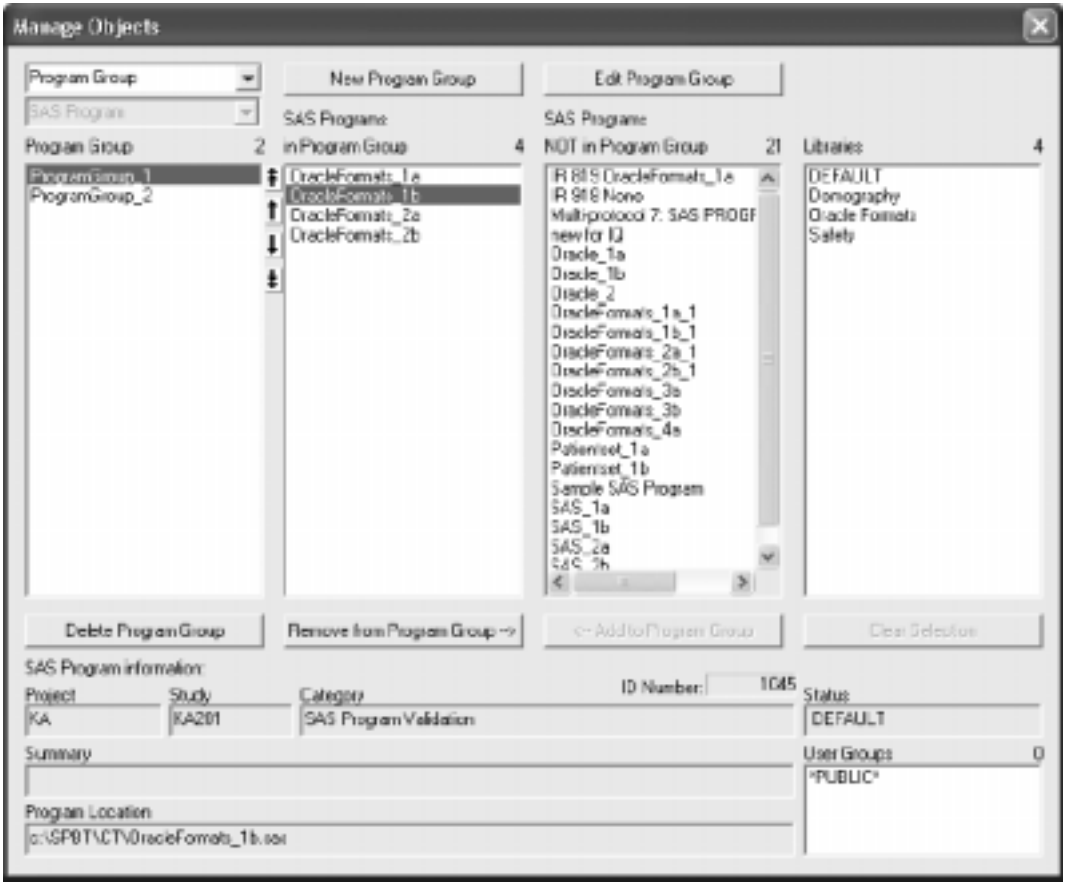
   Detailed information about the program group displays at bottom.

   The SAS program lists identify which SAS programs are in or NOT in the selected program group.



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).



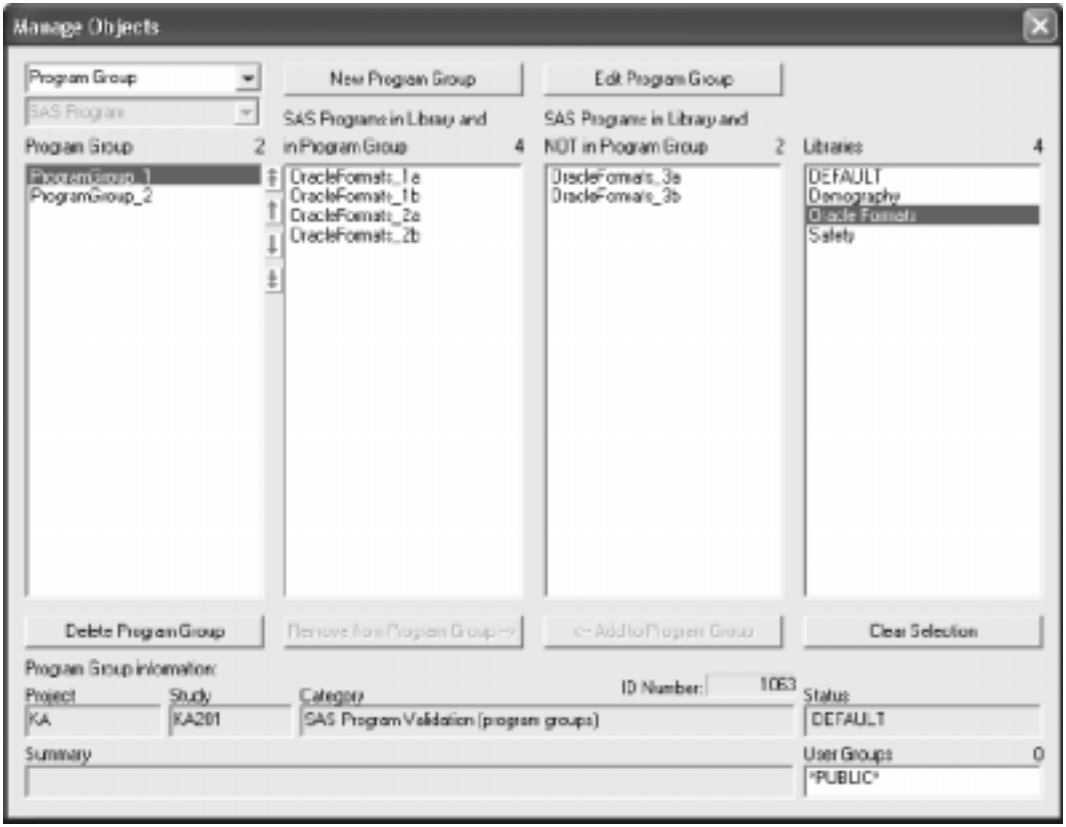
Note: Review does not allow ANY mixing of data origins with same-name datasets even for Oracle versus Oracle/Formats. The reason is Review generates the SAS view of an Oracle table only once, regardless of how many programs in a program group use the dataset. If the data origin is Oracle/Formats, the 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 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.

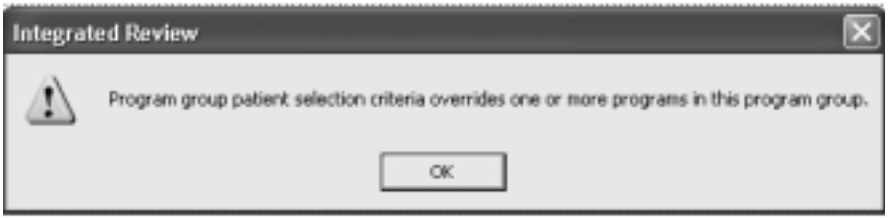
Program Group Restrictions

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.

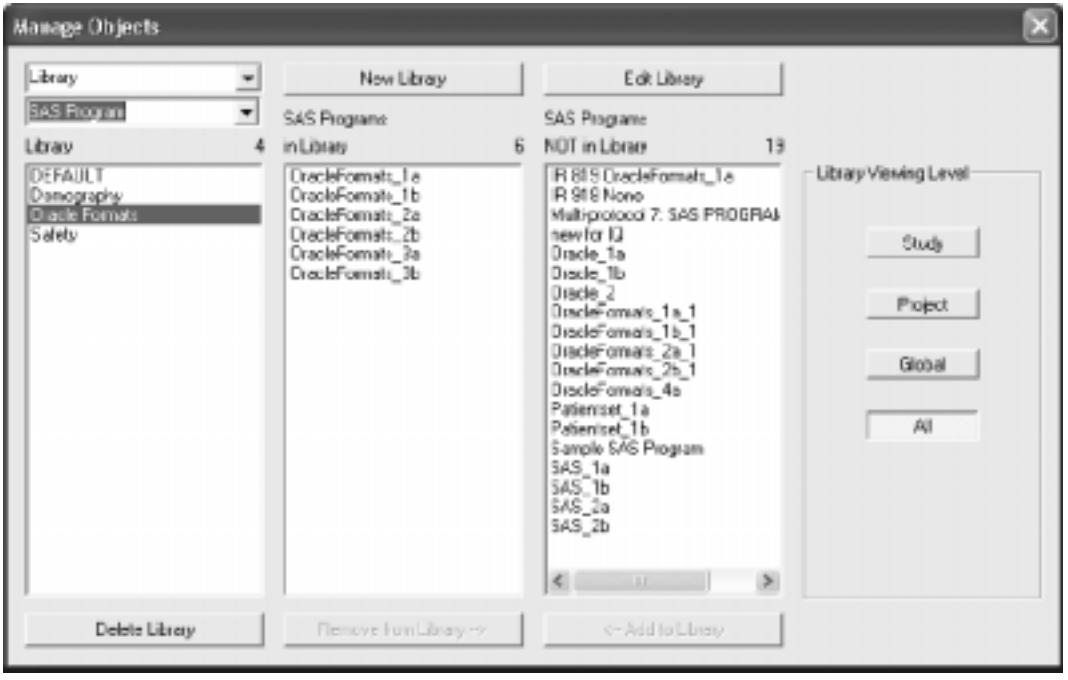


2. Incomplete print formats were fixed (LS=0, PS=0). This could be for a program or program group depending on the Print Format Overrides checkbox.
3. When a study level override is assigned or removed and the target program belongs to a program group, a message is displayed indicating that the overriding 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.

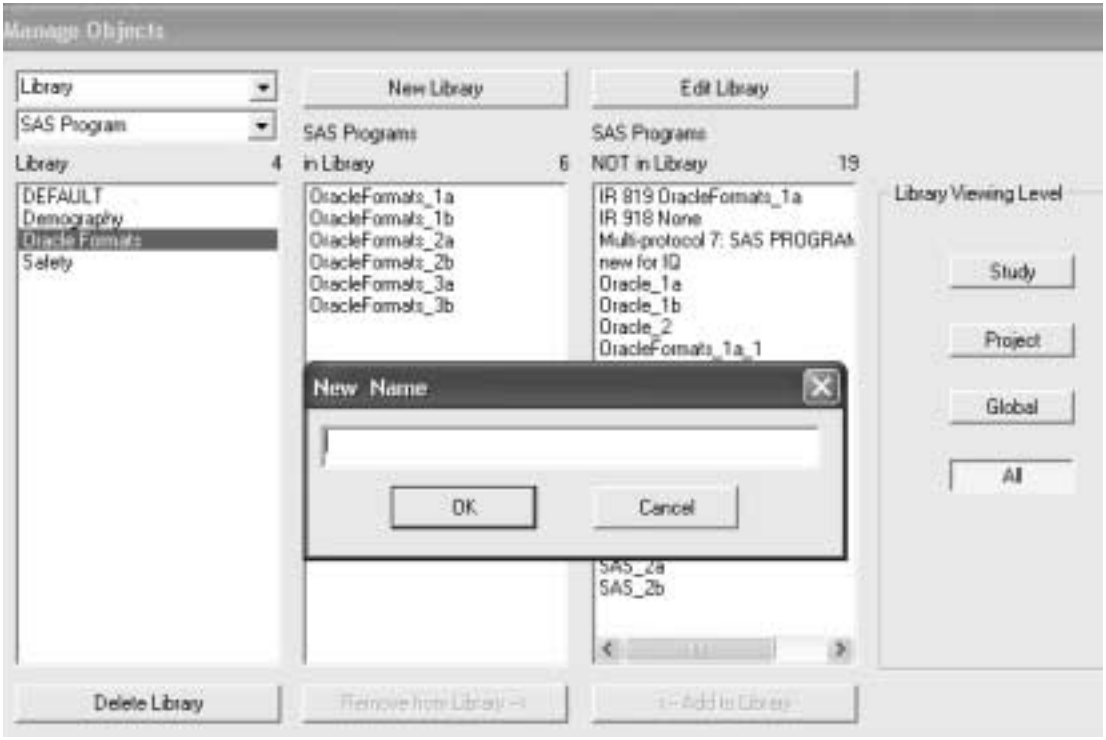
Open the Manage Objects window and select Library. The Library functions assist you to manage the SAS programs' membership within the Libraries.

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.



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.

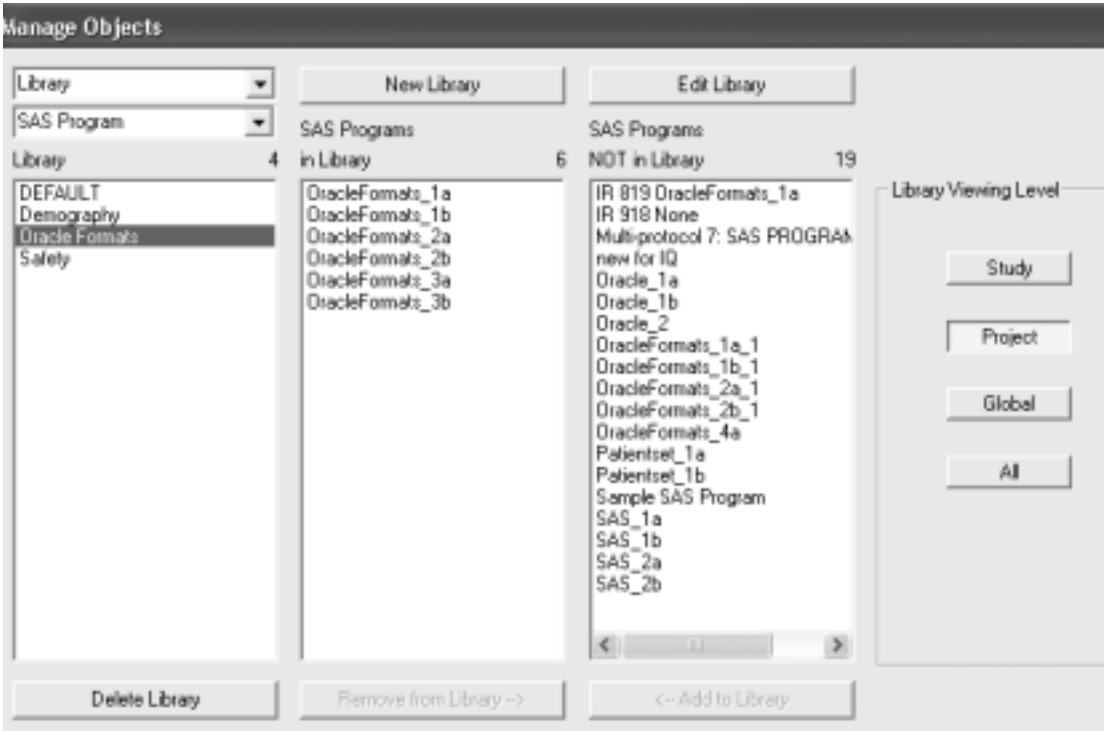


5. Select a library and click **Delete Library** to delete a library and all references in database tables. The SAS program registrations are NOT deleted.

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.



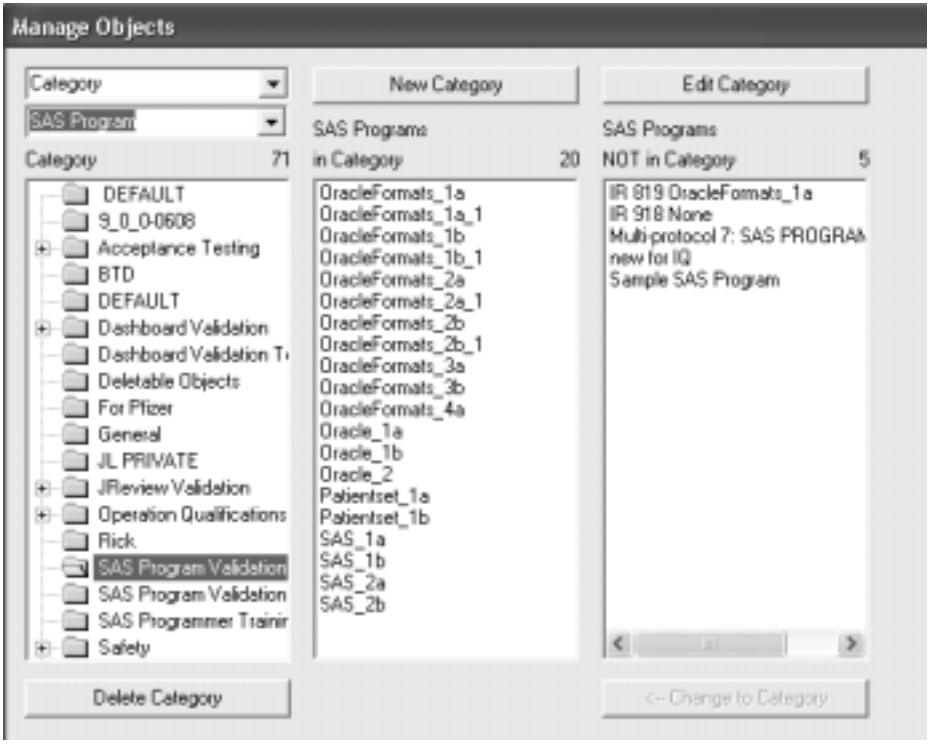
The Category functions assist you to manage the SAS programs membership within Categories. Open the Manage Objects window and select **Category** to access the following functions.

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.

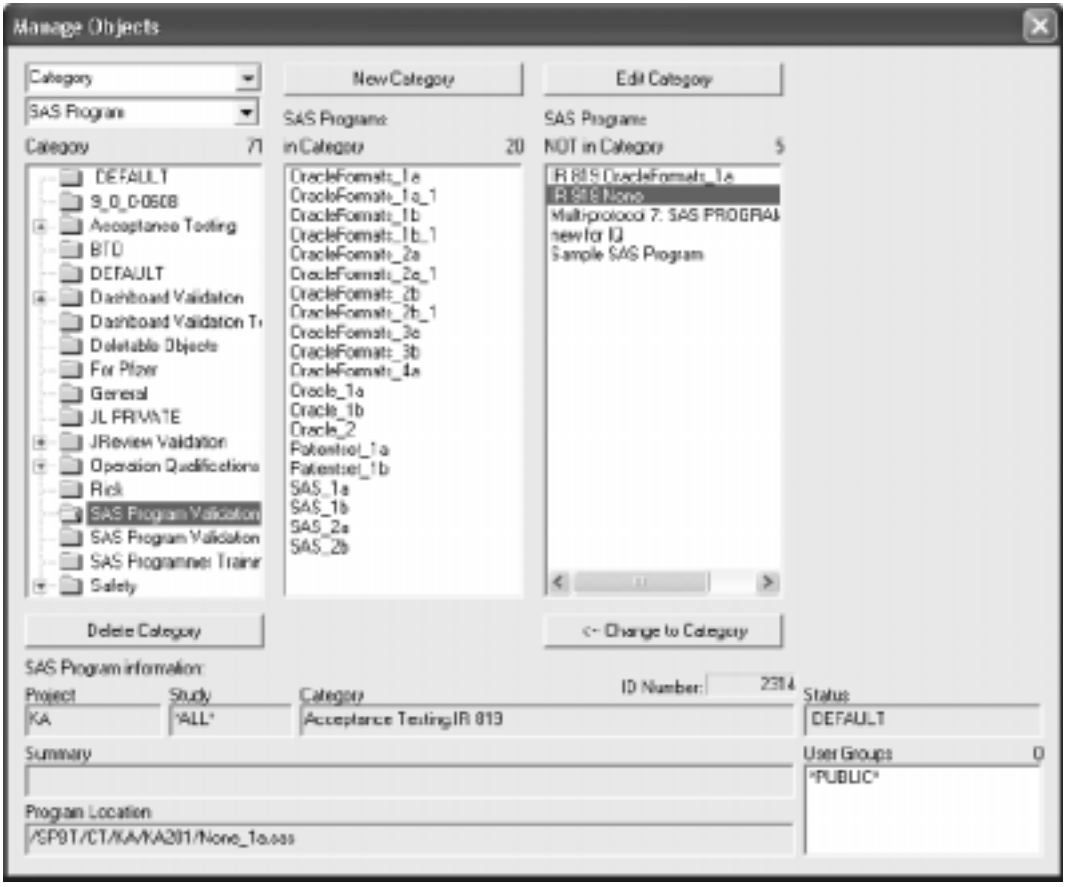
Hint: Prior to registering new SAS programs you may need to first create a New category if the folder destination does not already exist.



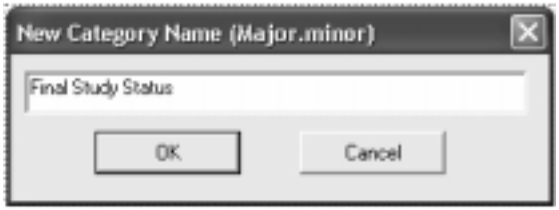
2. Click on a SAS program to display program information in fields at bottom.
3. Select a SAS program from the NOT in Category list. You can select multiple SAS programs with the CTRL or SHIFT key.

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.



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**.



   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.).

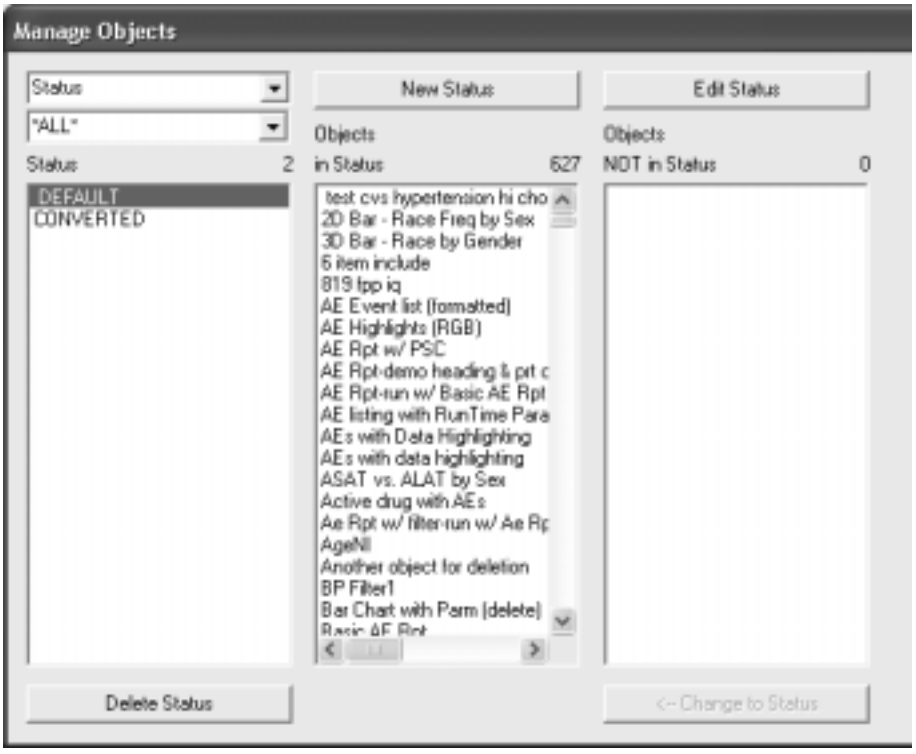
Status

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.

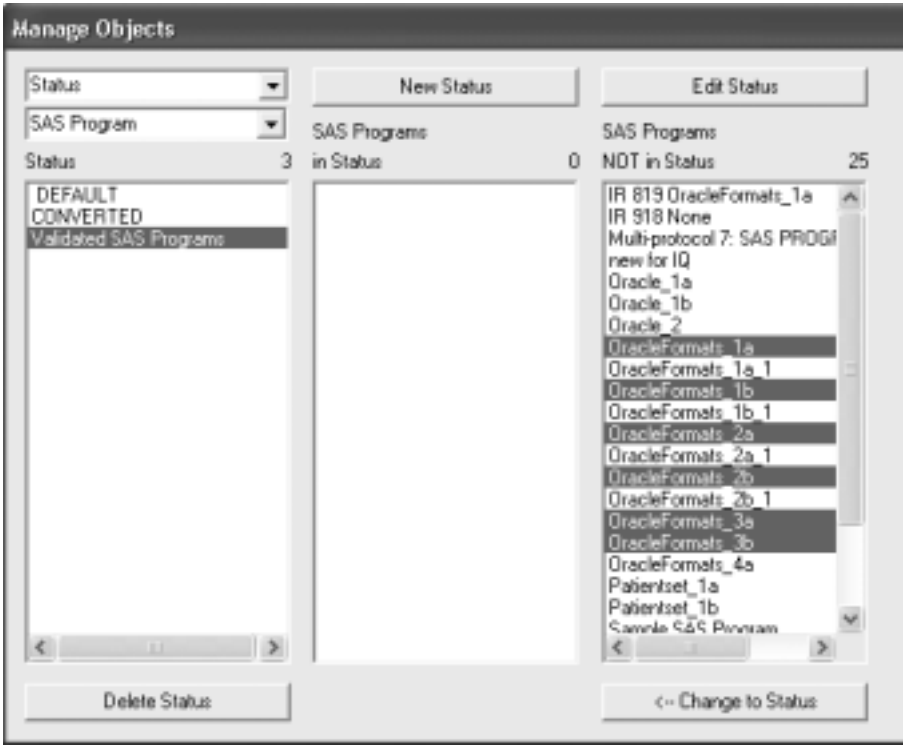
2. Click on a SAS program to display program information in fields at bottom.



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**.

   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

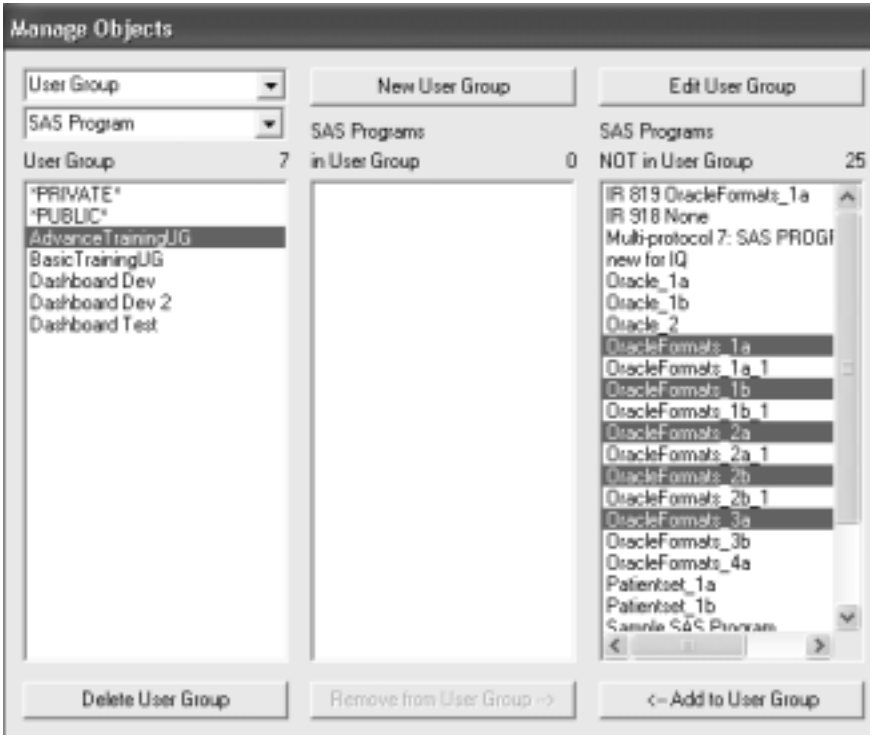
By default all programs are available to view in *PUBLIC*. You can manage the user's access by assigning a User Group. Therefore, the User Group will determine what programs or program groups a particular user sees in the Object Explorer categories. The STAT Program Registration Browser and Manage Objects 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.

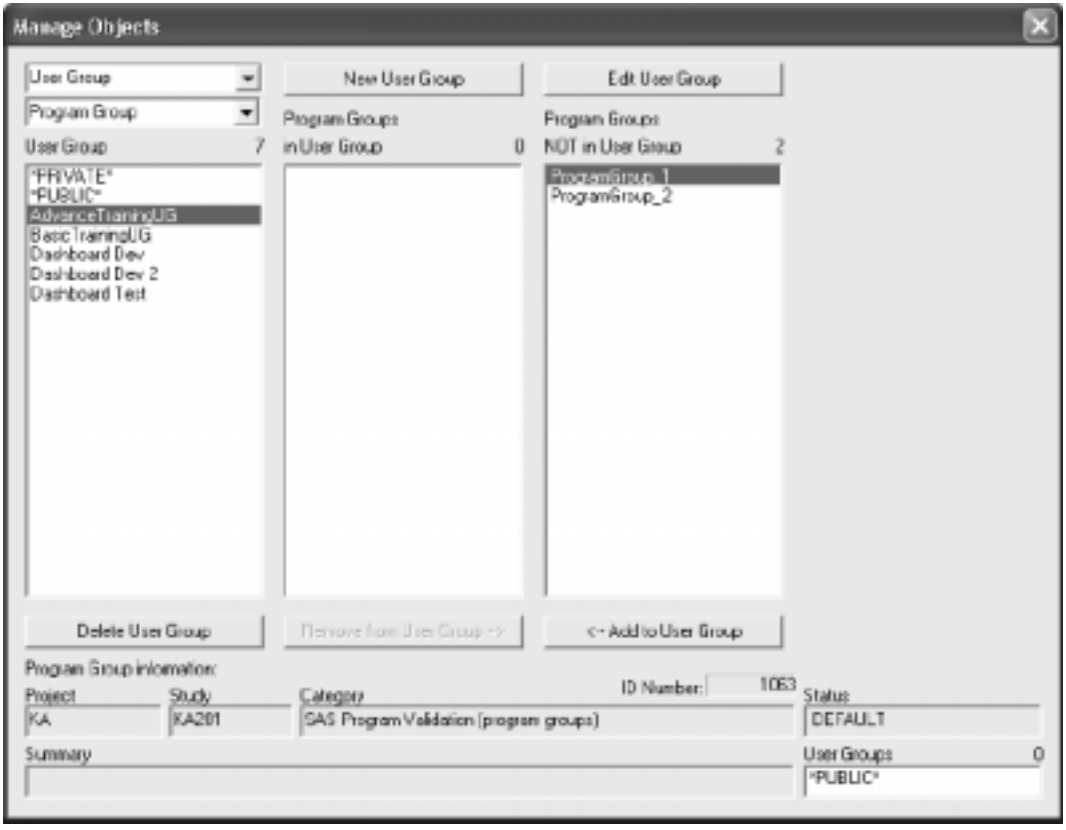
   Adding to *PUBLIC* removes all user group assignments.



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.



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 sub-population 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

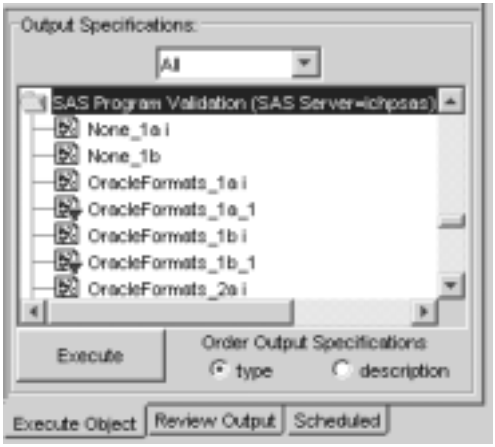
Both IReview and JReview displays a list of categorical folders for stored patient subsets and output specifications at the selected storage location. Simply select one of the storage locations to display it's specific folders and contents.

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. This shortcut allows users to bypass opening the individual browsers to launch saved objects.

The STAT Program Registration Browser is useful in exploring patient sub-population 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. The **SAS Programs** icons is .

Retrieve a table



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:

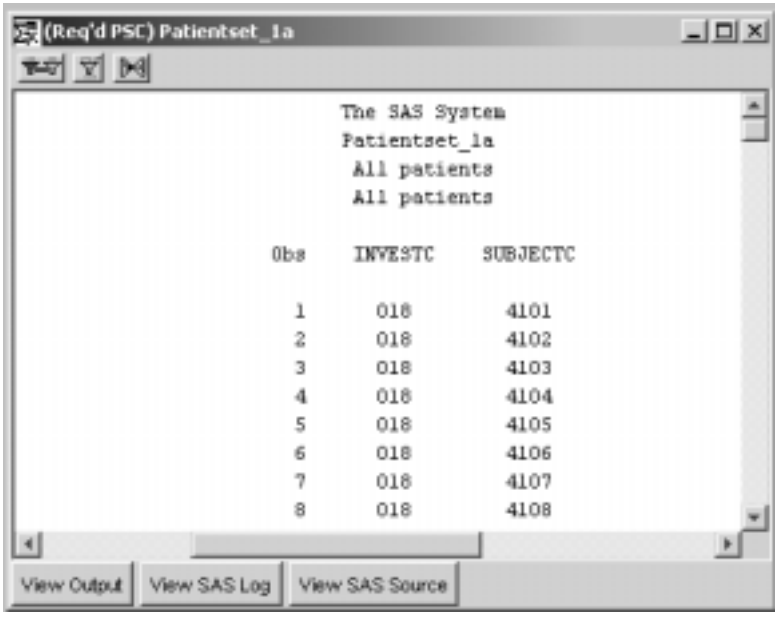
1. Double click to open a folder in Output Specifications.
2. Click on the object description and click **Execute**.

   OR
3. Double click on the object to launch in a single step. The stored output specification will be launched.

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.



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.

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

All output specification functions for saving, exporting, scheduling, retrieving and removing output are covered in the Report Browser.

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.

(See *Chapter 11: Saving Objects, plus Alerts Browser)*

Printing SAS program results

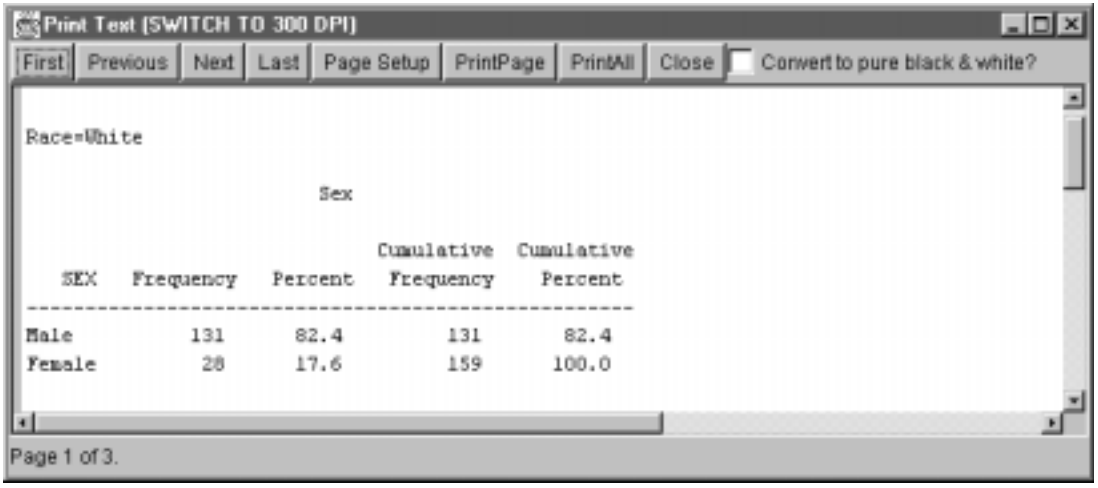
Print table output

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.



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 Objects, Scheduling plus Alerts Browser

Object Storage 567

Finalize object specification 567

Save the object specification 568

Definition tab 568

Access tab 569

Object storage location 570

Object level 570

Share with user groups 571

Publish for study groups 571

Store Patient selection criteria 572

Object Explorer window 574

Saved output specification 574

Object Explorer quick execute 575

Retrieve specification from Output Specifications 576

Object versions 577

Remove output specification 578

Object properties 579

Schedule output 580

Object Explorer scheduled output 580

View Scheduled Jobs 581

Remove Scheduled Jobs 581

Change Schedule 582

Schedule SAS jobs 582

Review output 583

Locate stored output results 583

Quick remove saved output results 584

Alerts Browser **584**
What are alerts? 584
Definition tab 585
Operation tab 587
Action tab 589
Alert activation 591
Alert output 594

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.

Save the object specification

Definition tab

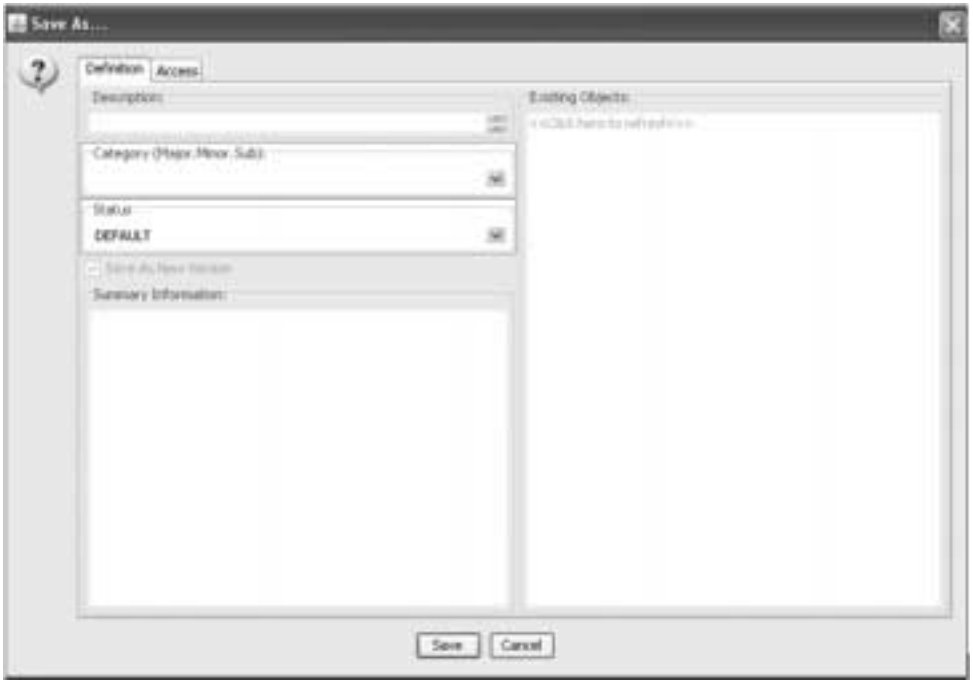
The Browser build window defining your object specification (report, graph, crosstab, patient profile, etc.) must be the active open window when you are ready to save your object specification for later use. In addition, there are two ways to save Graph specifications, either from the browser window 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:

   - **Definition**
   - **Access**

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



3. 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.

4. 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.

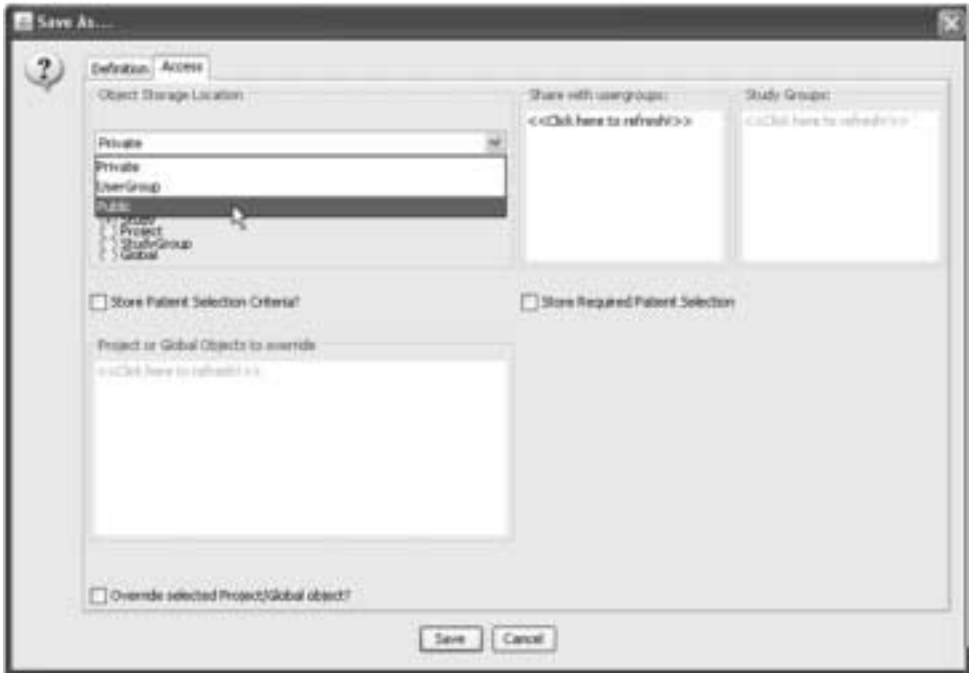
5. You can include **Summary Information** for future reference to be viewed by yourself or others later (optional).

   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.

Access tab

6. Click the **Access tab** and select an **Object Storage Location**.



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)*

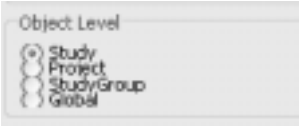
There are three user access levels to store the object specification: Private (db), User Group (db) and Public (db). User access levels designated as 'db' for database makes the object available for scheduling. Objects may be saved at the study, user group or global level

- **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

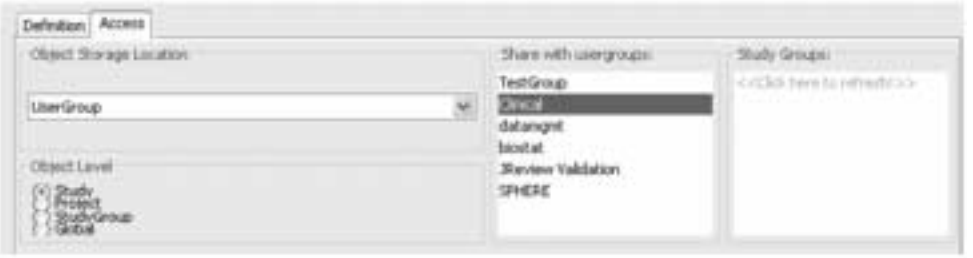
7. Select an **Object Level**. The object may be stored at four levels: Study, Project, StudyGroup or Global.



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.

Share with user groups

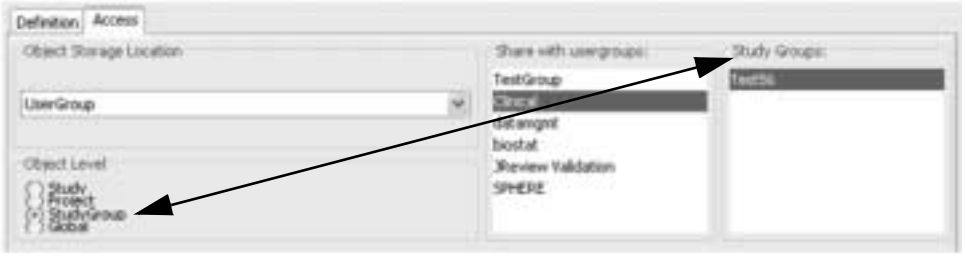
When UserGroup is selected the 'Share with usergroups:' box is enabled allowing you to select other usergroups to share access with the object specification. Use the CTRL or SHIFT key to make multiple selections.



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 IReview (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 IReview 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.



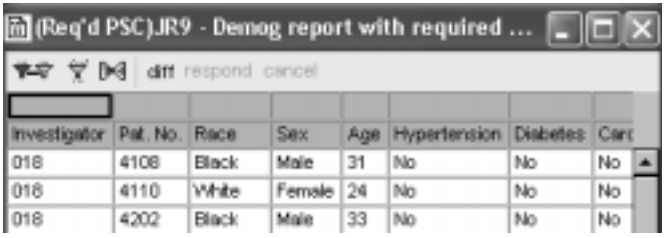
Store Patient selection criteria

8. 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.

   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.

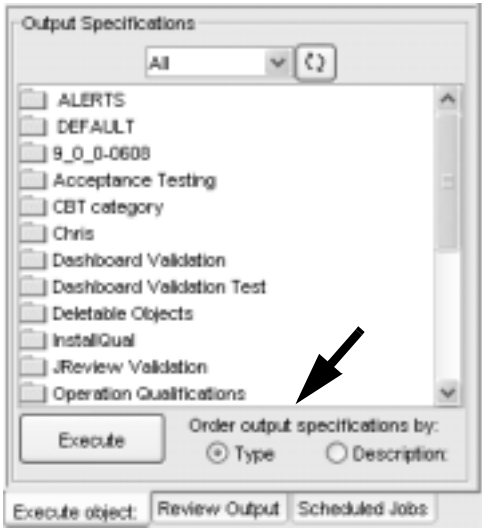
If the particular patient selection criteria is specific for the output, click the '**Store Required Patient Selection**' box. In this instance, the output opens in snapshot mode and the patient selection criteria is required for the output and cannot be cleared.

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.



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. Simply select one of the storage locations as Private, UserGroup or Public to display it's specific folders and contents. The circular arrows icon refreshes the displayed folders when you toggle between storage locations.

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. A red color filter indicates the patient selection criteria is required for the object.

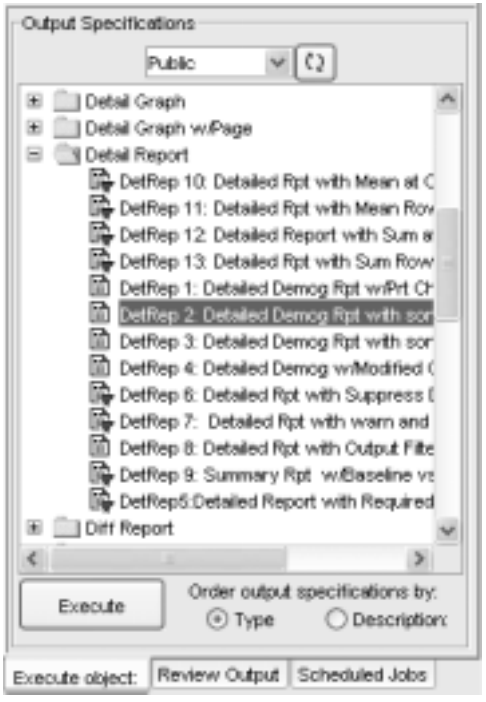
Saved objects and their associated icons can be sorted to display in their folders by icon type or description. See 'Order output specifications by' and simply click sort by **Type** or **Description**.

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 want to retrieve a saved output specification:

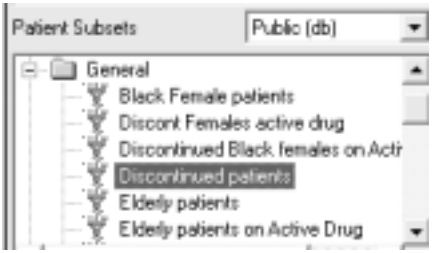
1. Select the object storage location from the drop down list.

2. Double click to open a folder.
3. Click on the object specification and click **Execute,** or 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.



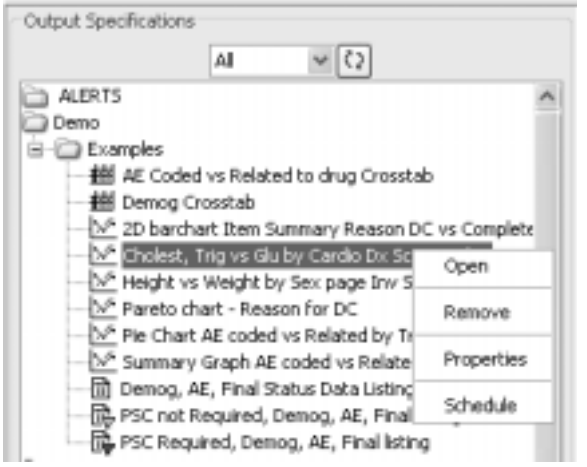
2. Double click to paste the selected patient selection criteria into the Patient Selection Criteria Window. Then follow the previous steps to retrieve and execute a stored output specification or create your own selection criteria for a stored output specification.

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 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.

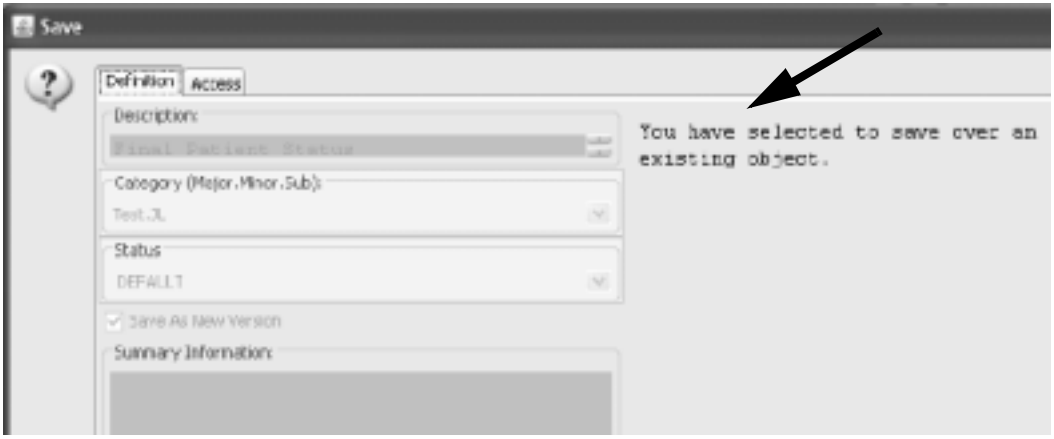


IReview has the following "Allow Updates" privilege settings apply to Save and Update an object. When the user clicks on an existing object, a checkbox appears "Save as new version". If you click to uncheck it, then the **Save** button and title changes to **Update**. You can **Save as New Version** or allow updates to previously saved objects dependent upon 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.

Note: Currently multiple saved versions are accessed in IReview via the Version Tab. The version behavior is supported in JReview.

When you open the object in JReview and enter changes you can either click the **Save icon** or select **Save** from the **File menu**. The **Save window** opens and updates the current version. A message displays to alert you when you are overwriting the current object and version.



If you are not the author and attempt to modify and save over an existing object this message displays.

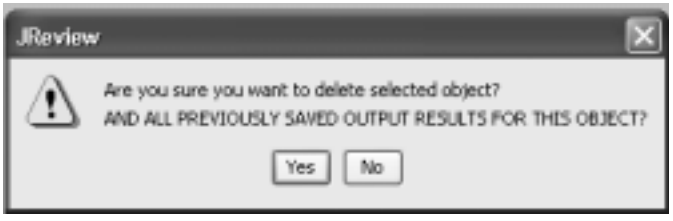
If you want to save as new version, select **Save As** from the **File Menu** to resave as a new object.

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 the Remove command.



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.

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.

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.

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**.

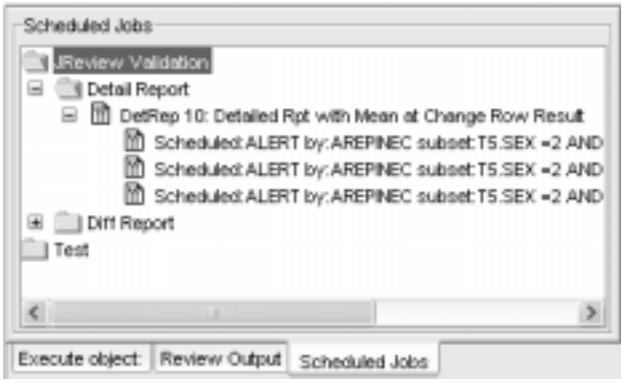
5. Select who can access the stored output results for Private, UserGroup or Public.

6. 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.

View Scheduled Jobs

Click the Scheduled 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.



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

Both SAS Procs and 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 Review. Therefore, the SAS job is not actually cancelled that is scheduled.

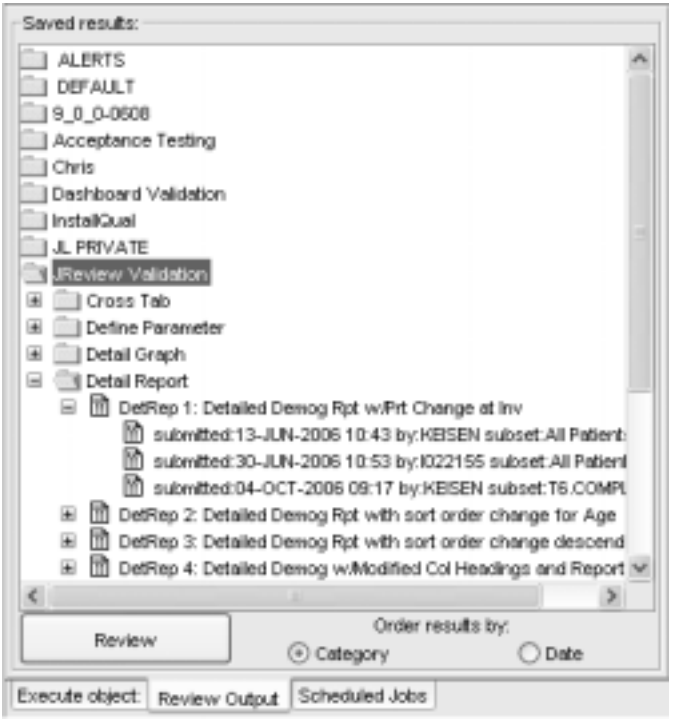
Note: In Review version 8.0, the output record cannot be removed from the Review Output tab and a message displays that the job has not run yet if you try to remove it.

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. Either highlight the output description and click the **Review** button or double click on the description to view output.



Note: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.

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**.

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 IReview 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.

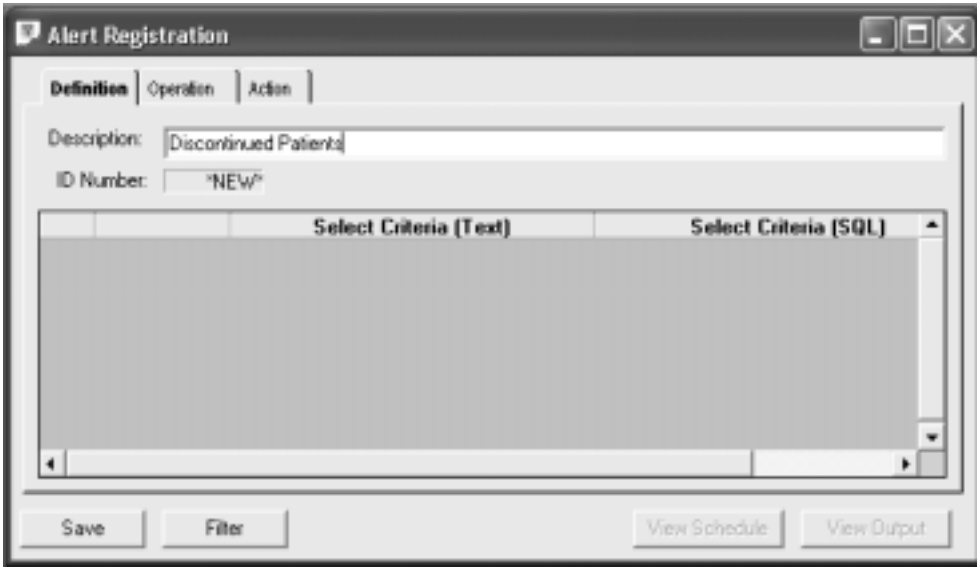
1. To open the **Alerts Browser**, click in the toolbar, or from the **Browse** menu, select **Alerts**.

   The **Alert Registration window** opens displaying three tabs.

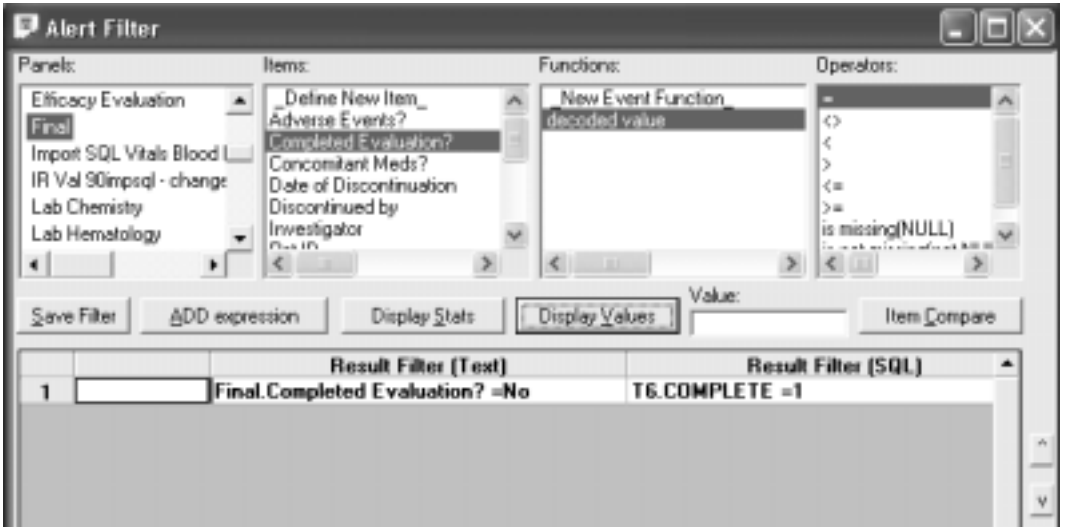
2. Enter a **Description** for the Alert as the descriptive name. This can be up to 60 characters.

   The **ID Number** displays the internal object ID number for an existing alert, or *NEW* for a new alert being defined.

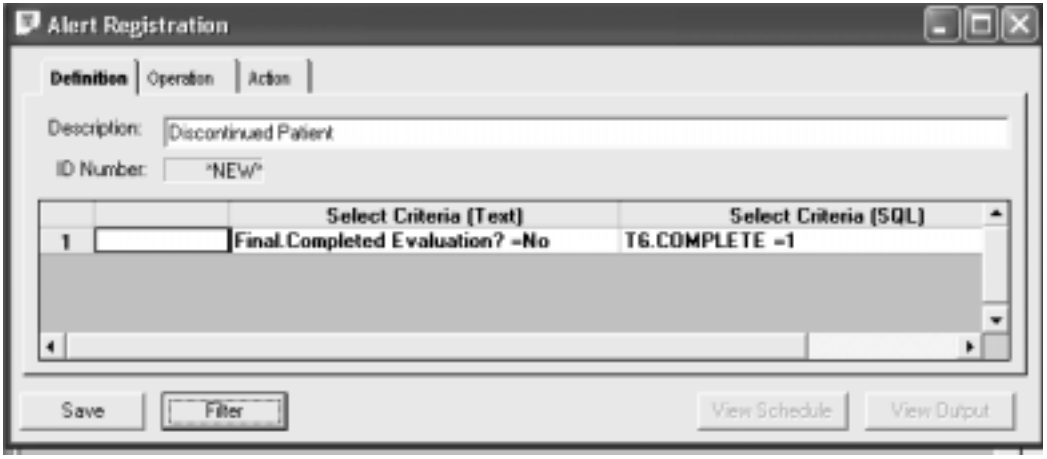
3. Click the **Filter** button.



4. The **Alert Filter window** opens to define the criteria that must be met for the alert to produce its output message. This is similar to the output filter window used when defining other objects like reports. (*See Chapter 6: Reporting: Output Filters*)



5. Click the **Save Filter button** and the alert filter criteria displays in the Alert Registration window in the Definition tab.

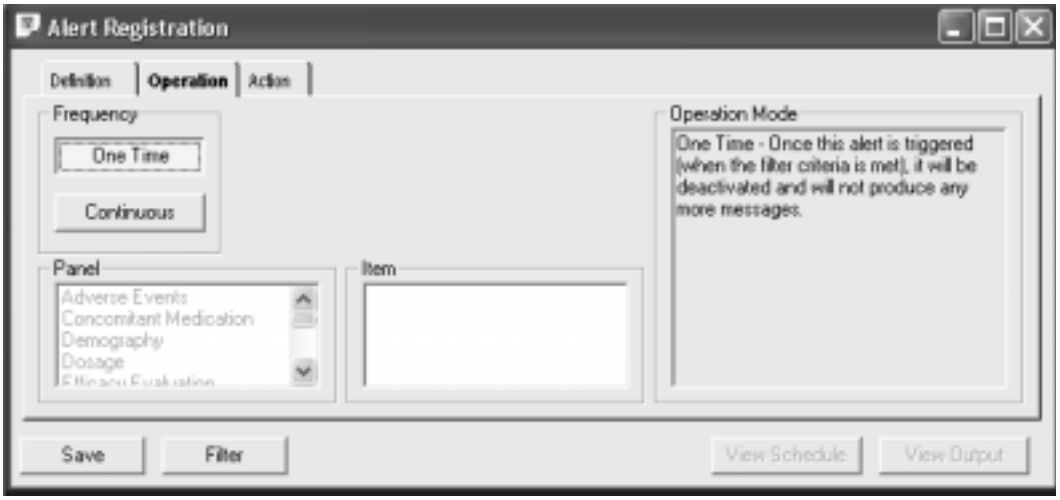


6. Click the **Operation tab**.

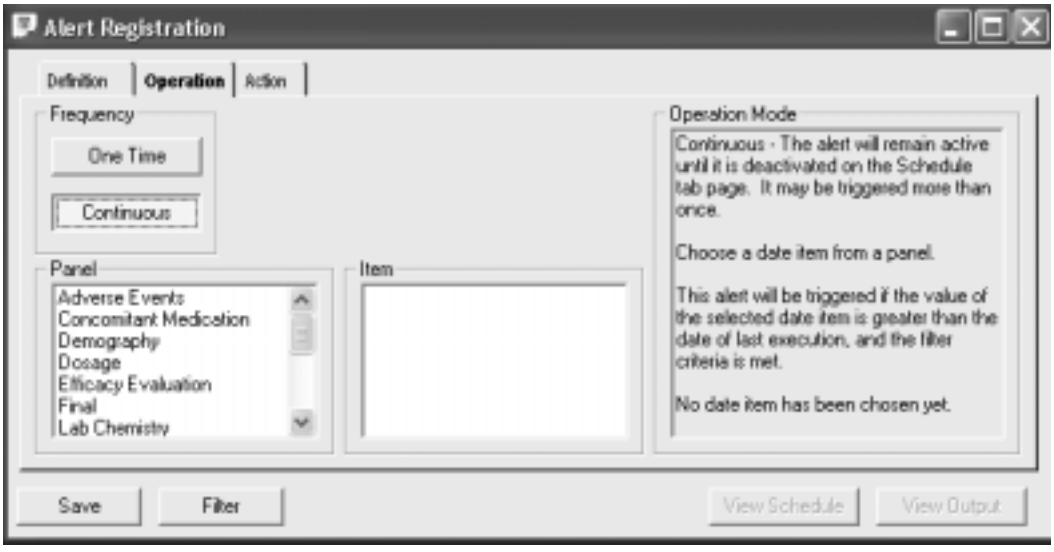
Operation tab

Next 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.

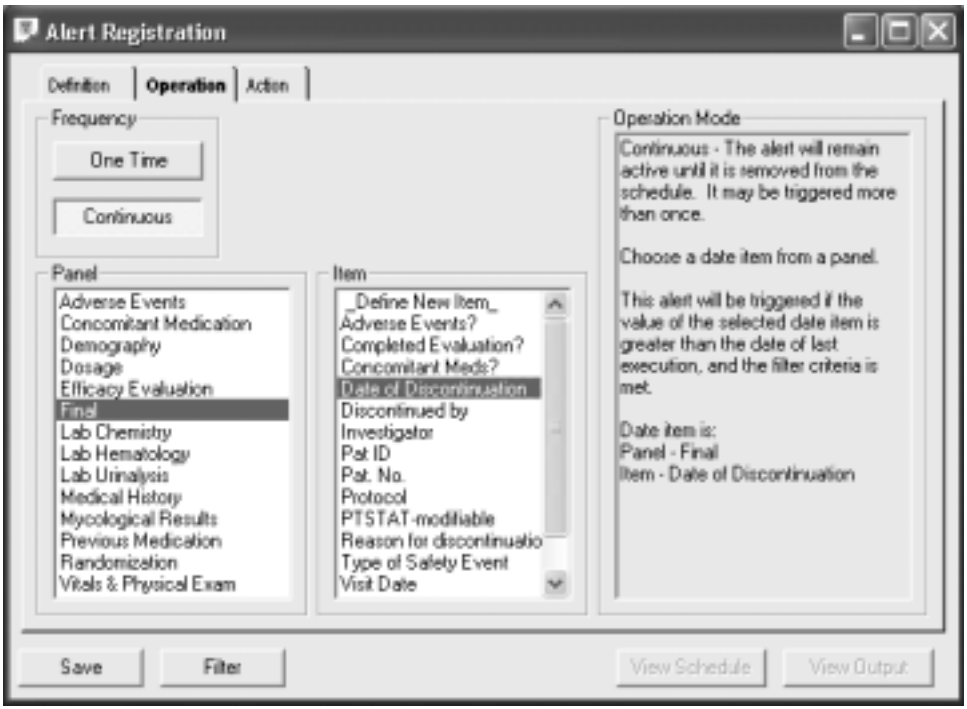
One Time mode means that the first time the alert is triggered. It will be removed from the schedule.



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.

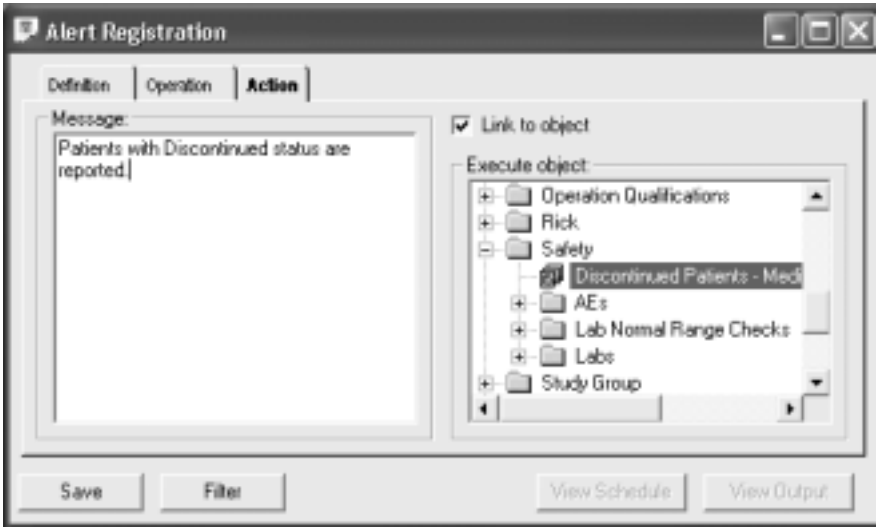


7. Select a **Frequency mode**. If you select Continuous mode, a date item is required to trigger the alert.
   - **Panel** indicates the panel name for the date item to be used for Continuous mode.
   - **Item** is the date item in the panel to be used for Continuous mode.
   - **Operation Mode** describes the selected operation mode.
8. Select a panel and item for date.



Action tab

9. Click the **Action tab**.
10. Enter a text **Message** that is produced when the alert is triggered.
11. Click **Link to object** box (optional), when checked indicates that a stored object will be executed when the alert is triggered.
12. Select an **Execute object** when **Link to object** is checked. The list displays available objects to be executed.



The following Object types are excluded from the list of choices for **Link to Object:**

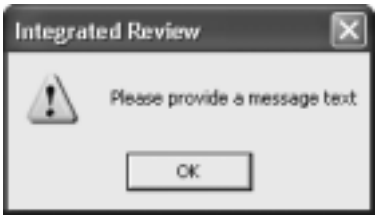
- Alerts
- Patient Selection Criteria
- Visual Subsets
- Patient Profiles
- Object Groups
- SAS Programs
- SAS Program Groups

Objects that are checked and excluded at save-time (because they are sub-types of another object type) are:

- Patient Visit Reports
- Shift Tables

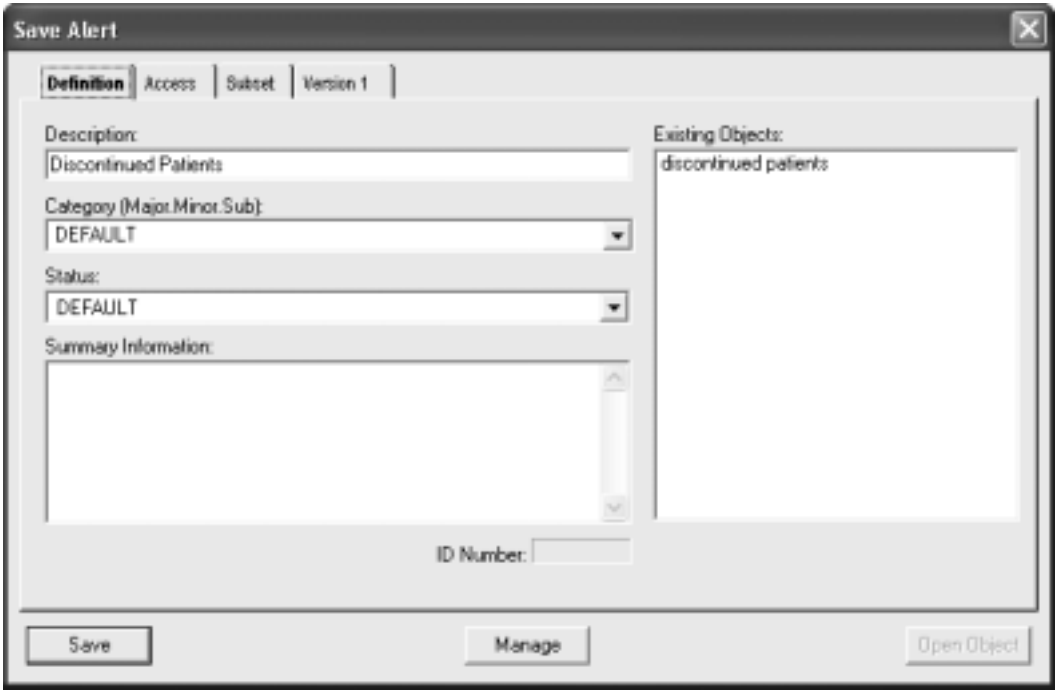
All other objects are allowed to be linked to an alert including reports with runtime parameters.

If you click **Save** before entering a text message the following message window displays.



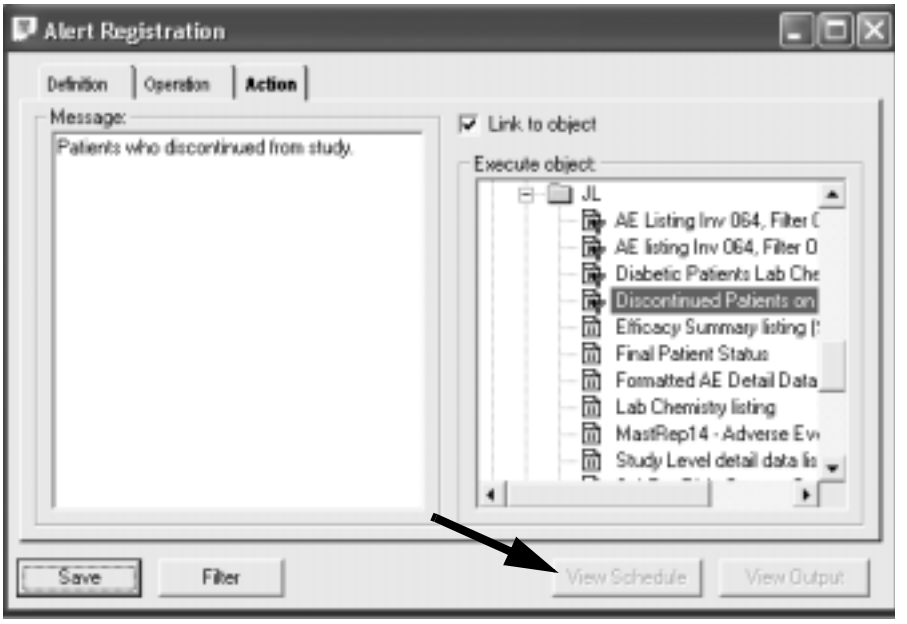
13. Click **Save**. The Save Alert window opens for you to enter the alert object specifications. *(See previous section: Save the object specification)*

    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.



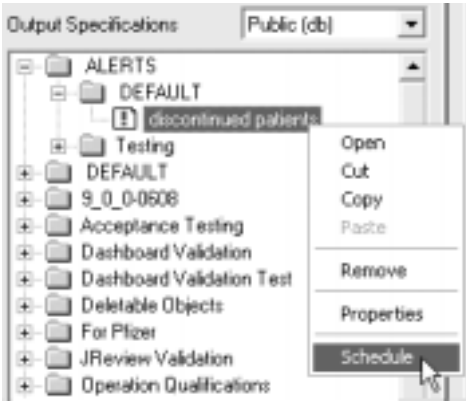
Alert activation

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.

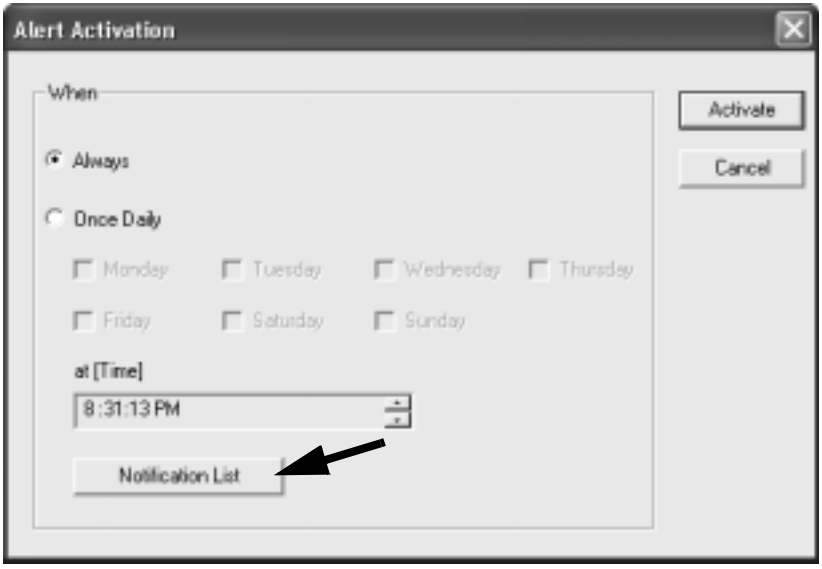


You activate the alert object by scheduling it the same as other objects.

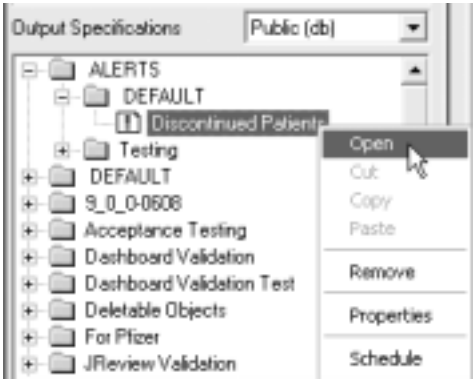
1. Select the alert object in the Alerts category in the **Object Explorer window**.
2. Right-mouse click to display a floating menu.



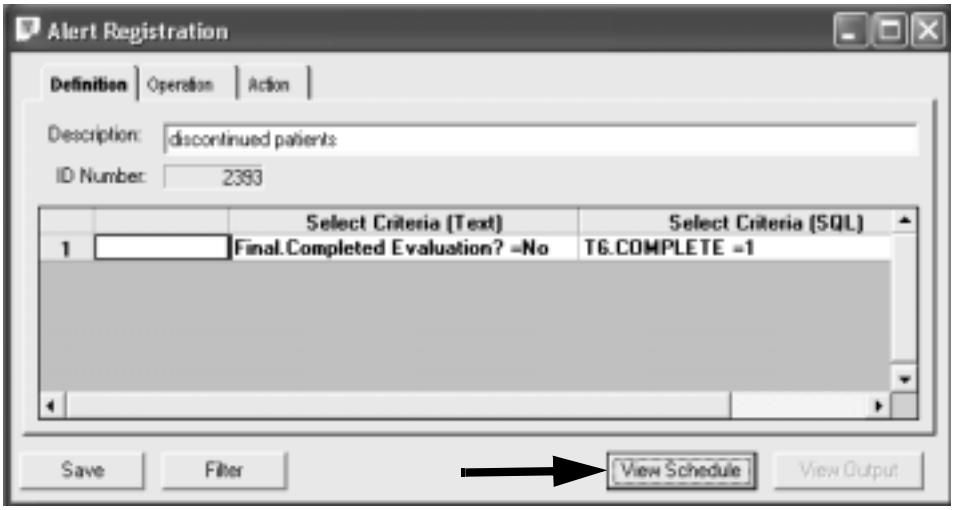
3. Click **Schedule**. The **Alert Activation** window displays for Job Scheduling.
4. Enter when to activate the alert as **Always** or **Once Daily** with a time.



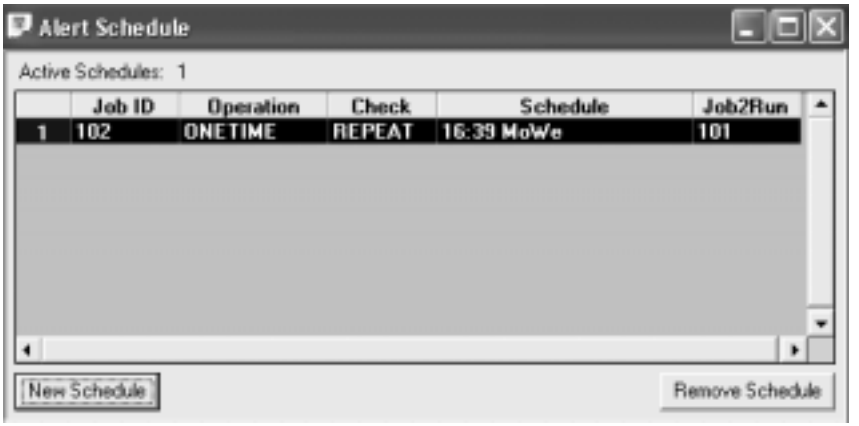
5. Click the **Notification List** and select users to notify.
6. Click **Activate** to schedule the alert.
7. You may enter an Email address from the **Edit** menu when you select **Preferences.**
8. To view the alert schedule, select the alert object in the Alerts category in the **Object Explorer** 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.



10. Click the **View Schedule** button to open the **Alert Schedule** window.



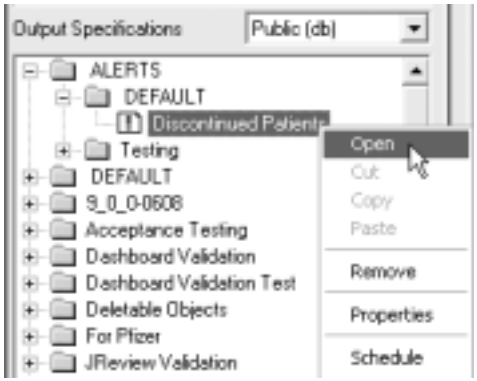
11. Select an alert job entry and click the **Remove Schedule** button to remove the alert job, or click the **New Schedule** button to change the alert job schedule.

Alert output

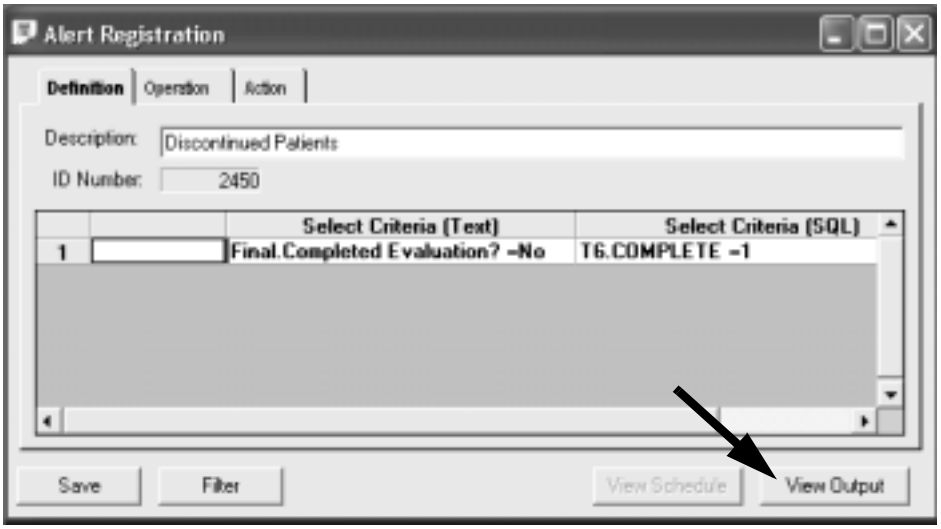
If any new alerts were triggered since your last login, the following message displays.

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**.



The **Alert Registration** window displays for Job Scheduling.

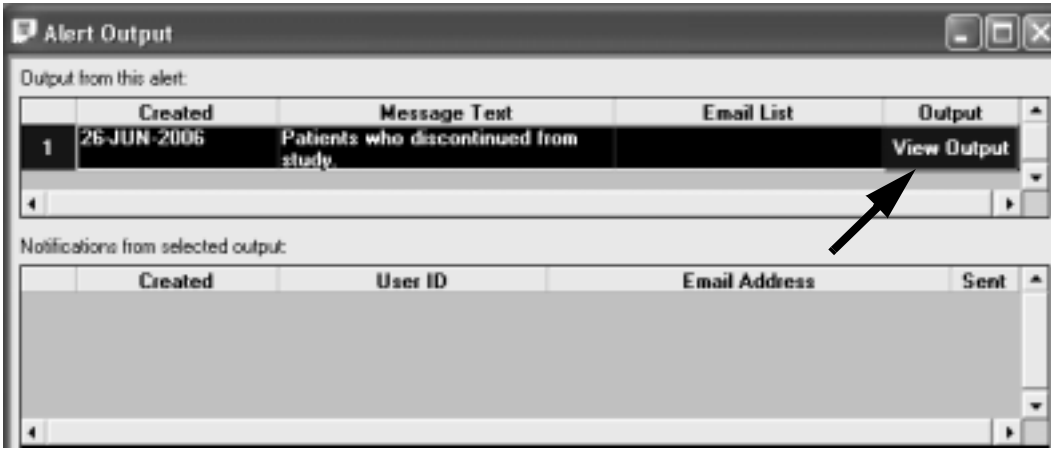


3. Click the **View Output** button.

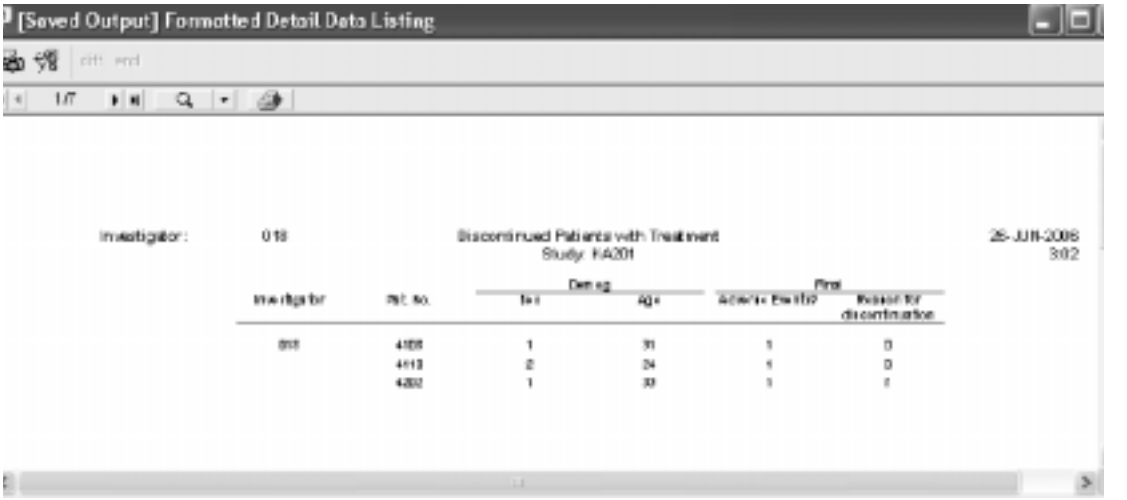
   The **Alert Output** window displays any messages produced by an alert. If another object was linked to the alert that produced output, a **View Output** button displays in the last column.

   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.

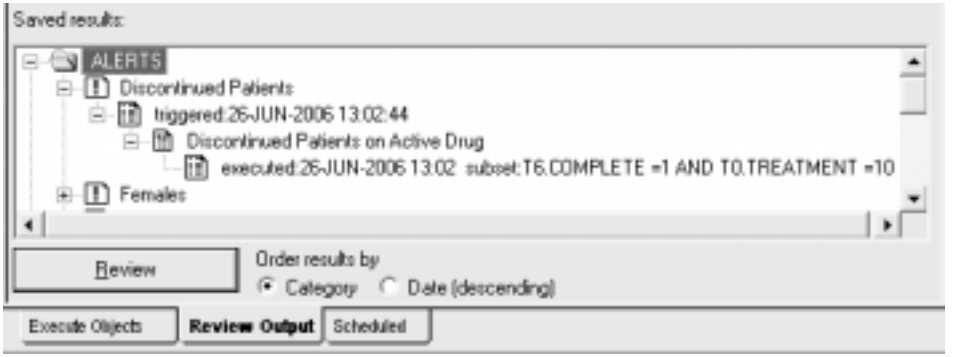


The object output which was linked to the alert trigger opens.



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 599
- User-defined logical joins 599
- Logical joins with Clintrial Type 0 599
- Creating logical joins 600
- Global object storage of join logic 602
- Update or Remove Join Logic 602

Join Order 603
- Join order in multi-panel reports 603
- Change Join Order 606
- Load Default Join Order 610

Define Custom Joins 611
- Creating custom joins 611
- Join type 613
- Update or Remove Custom Join 614
- Load Default Join Logic 614

Import SQL 615
- Enter Import SQL SELECT statement 615

Define New Item 618
- Derived items across panels 618
- Define New Item 620
- Add operators 622
- Decode reference 623
- Save New Item 624
- Save a Global New Item 625
- Edit defined new item 627
- Remove saved new item 627

Define New Range **628**
User-defined range variables 628
Define New Range 628
Define range cut points 629
Save new range variable 630
Edit New Range 631
Define New Event **632**
Define New Event 632
Edit or remove new event function 635
Pivot panels **636**
Transposing normalized clinical data 636
Creating pivot panels 637
Remove pivot panel 641
Copy to Clipboard **642**
View SQL details dialog 642

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'.

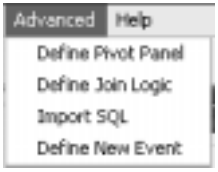
The Define Join Logic works with only two tables at a time defining the join logic between those two tables only. The system can then pick up the join pairs as needed.

Logical joins with Clintrial Type 0

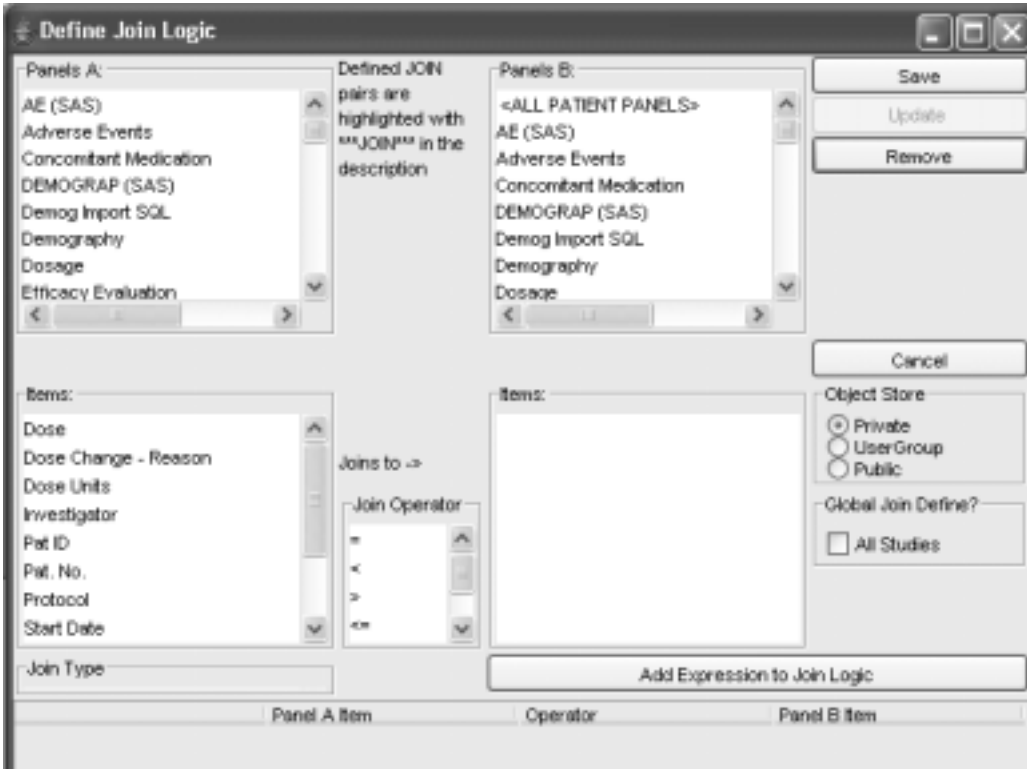
This is a necessary utility in the join logic and utilization of a Clintrial Type 0 panel. The Type 0 panels don't have typical context items, and are typically non-patient data.

Creating logical joins

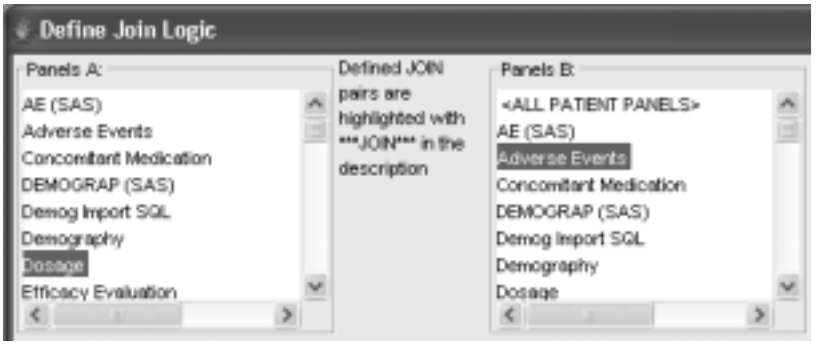
1. From the Advanced menu in the tool bar, select **Define Join Logic**.



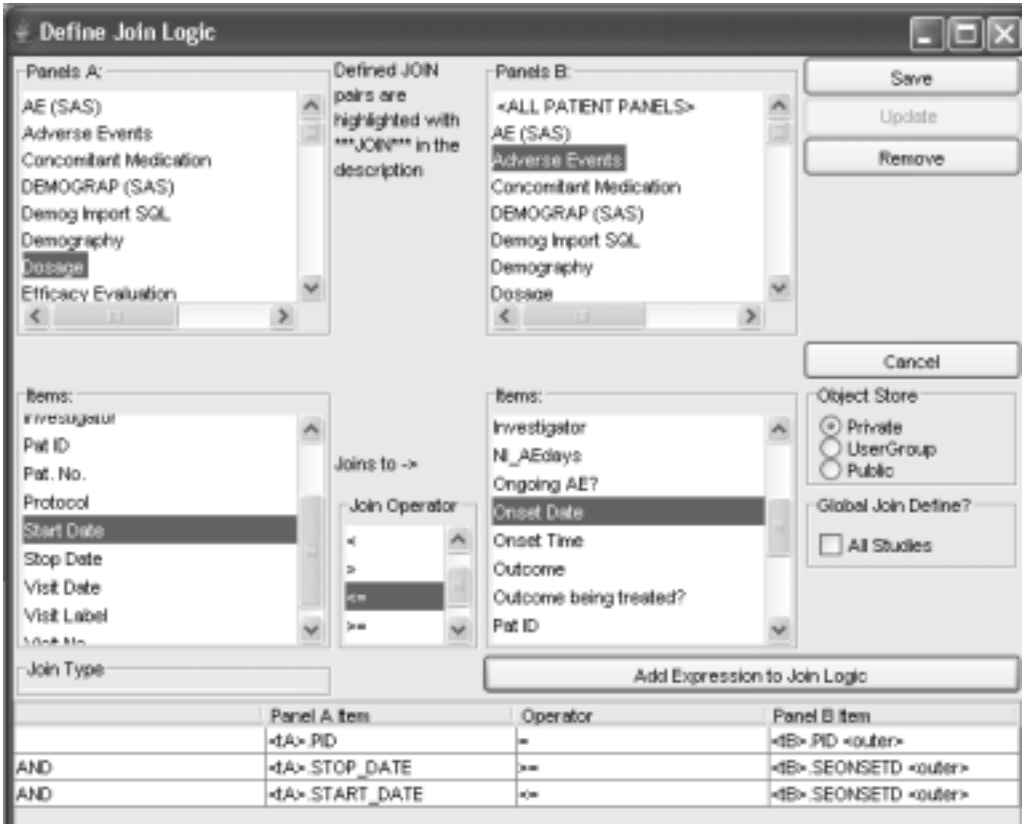
The Define Join Logic window opens listing all panels in lists A and B.



2. Point 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.



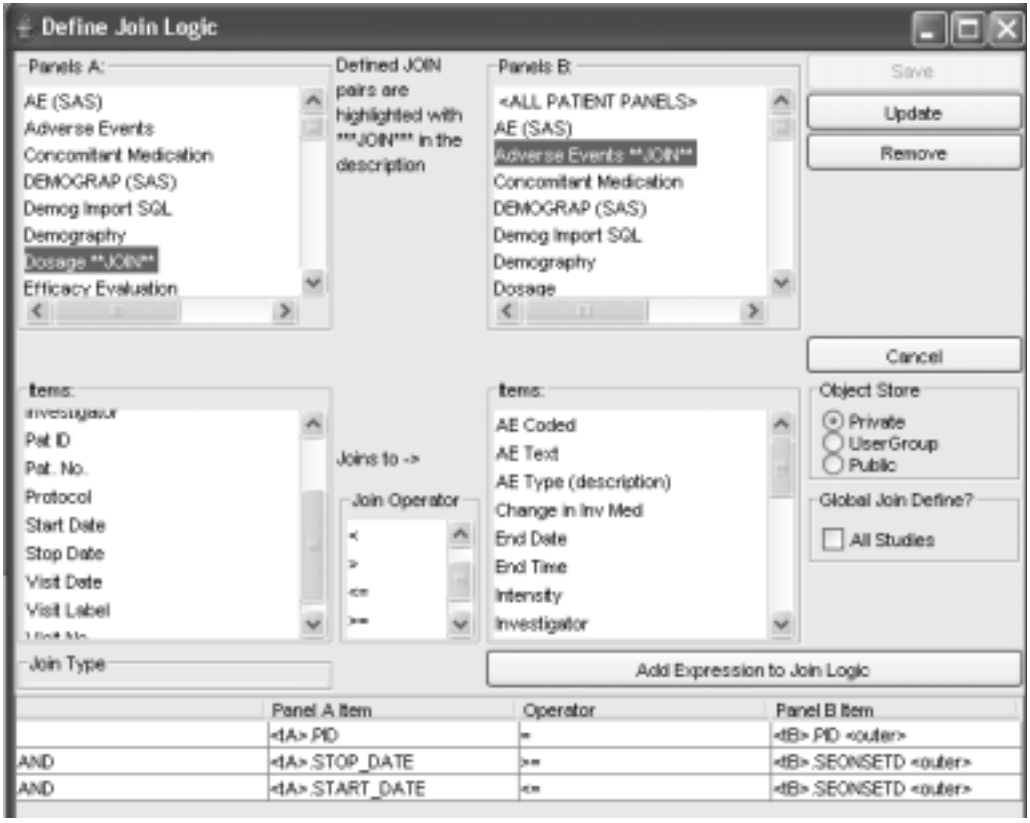
Global object storage of join logic

5. Define the **Object Store** as Private, UserGroup or UserGroup to share the defined Join Logic. The default is private and will allow access only to the author.
6. Optionally, select 'All Studies' for a Public or UserGroup level join definition as a 'Global Join Define' all studies definition.
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.

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.

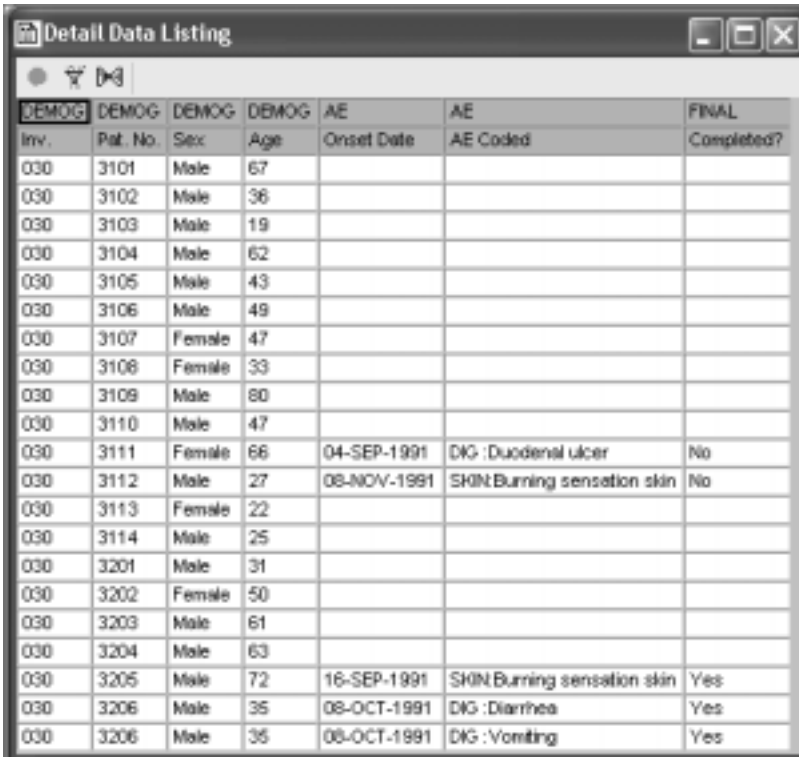
Instead of creating multiple reports to obtain different patients in the output, simply change the Join Order of the report and save for your different output requirements.

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.

When the report is created, all patients with demography panels will display in the report even if they do not have Adverse Events records.

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.

Report Browser
Type:
Detail Data Listing
Summary Listing
Patient Visit Data Report
Panels:
Define Import SQL
AE (SAS)
Adverse Events
Concomitant Medication
DEMOGRAP (SAS)
Demog Import SQL
Demography
Dosage
Efficacy Evaluation
Frank Existence Test - IR
Frank Incidence Test - IR
Frank Pivot Test 1 - IR
ICANDA.AE_SOURCE
Import SQL Vitals Blood Press
KExistanceMatrix
LAB_CHEM (SAS)
LAB_CHEM (SAS)
Items:
Define New Item
Define New Range
Adverse Events?
Completed Evaluation?
Concomitant Meds?
Date of Discontinuation
Discontinued by
Investigator
PTSTAT-modifiable
Pat ID
Pat. No.
Protocol
Reason for discontinuation
Type of Safety Event
Visit Date
Visit Label
Visit No.
Functions:
actual value
decoded value
Custom Join
ADD Item
Add All It...
Filter Output
Create
Header
Detail Data Listing
Reset Subtotal with change
Show Details?
Suppress duplicate rows?
0 1 2 3 4 5 6 7
Col Head 1 DEMOG DEMOG DEMOG DEMOG AE AE FINAL
Col Head 2 Inv. Pat. No. Sex Age Onset Date AE Coded Completed?
Sort Order 1 2 3 4 5 6 7
Row results
Warn -Low
Warn -High
Panic-Low



Detail Data Listing

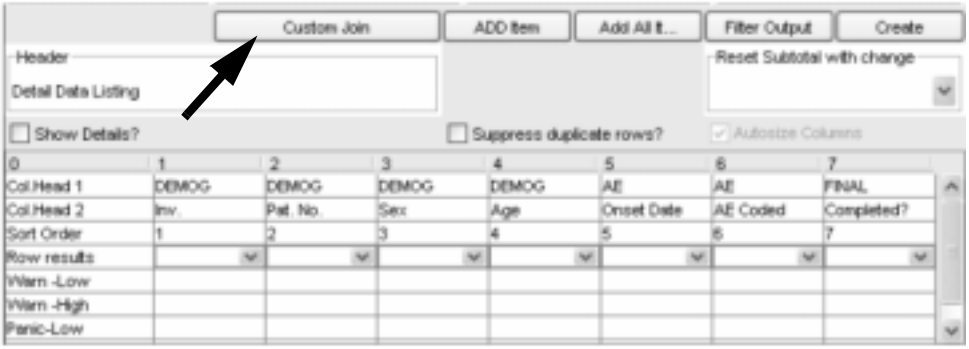
DEMOG Inv.	DEMOG Pat. No.	DEMOG Sex	DEMOG Age	AE Onset Date	AE AE Coded	FINAL Completed?
030	3101	Male	67			
030	3102	Male	36			
030	3103	Male	19			
030	3104	Male	62			
030	3105	Male	43			
030	3106	Male	49			
030	3107	Female	47			
030	3108	Female	33			
030	3109	Male	80			
030	3110	Male	47			
030	3111	Female	66	04-SEP-1991	DIG :Duodenal ulcer	No
030	3112	Male	27	08-NOV-1991	SKIN:Burning sensation skin	No
030	3113	Female	22			
030	3114	Male	25			
030	3201	Male	31			
030	3202	Female	50			
030	3203	Male	61			
030	3204	Male	63			
030	3205	Male	72	16-SEP-1991	SKIN:Burning sensation skin	Yes
030	3206	Male	35	08-OCT-1991	DIG :Diarrhea	Yes
030	3206	Male	35	08-OCT-1991	DIG :Vomiting	Yes

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.

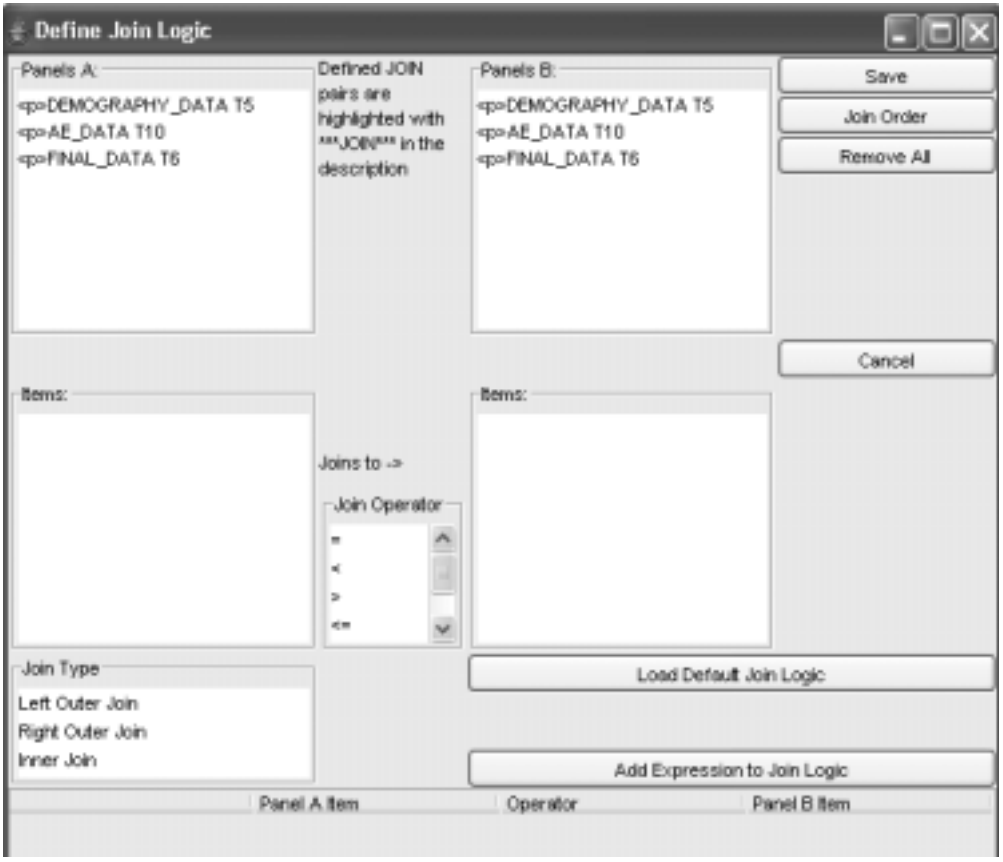
Change Join Order

You can change the default Join Order of the panels entered in your detail data listing specification as follows:

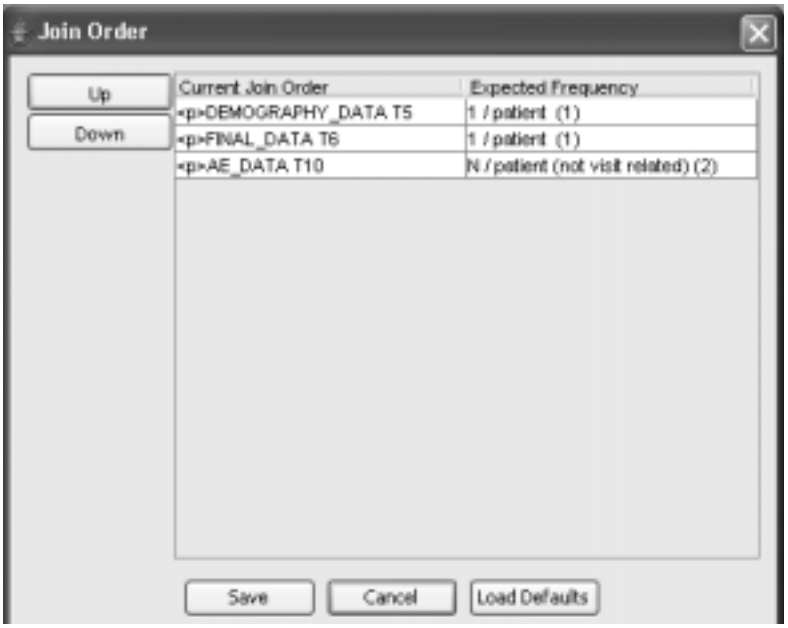
1. Define a detail data listing with data items from multiple panels sources.
2. From the Report Browser window, click **Custom Join**.



3. The Define Join Logic window displays. Click **Join Order.**

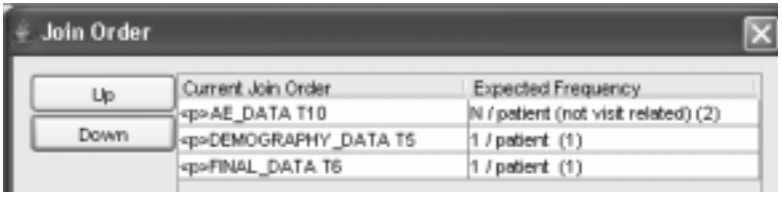


The Join Order Definition window displays with the default Join Order definition.



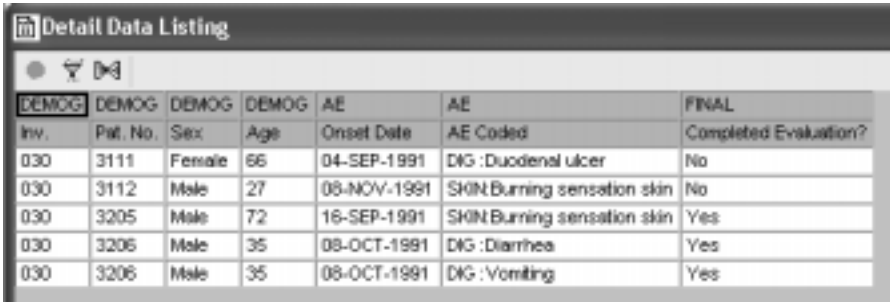
4. Click on the panel you want to reorder and use the arrows to the left.

   In the example, Demography is moved to the 2nd order position and Adverse Events is now in the primary or driver position.



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 Define 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.

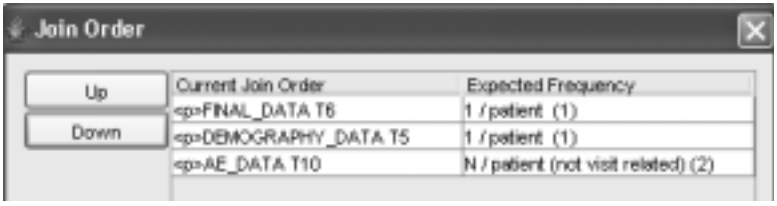
This report shows the revised join order where Adverse Events is assigned the first order position. Any blank records for Adverse Events are dropped from the listing.



Detail Data Listing

DEMOG	DEMOG	DEMOG	DEMOG	AE	AE	FINAL
Inv.	Pat. No.	Sex	Age	Onset Date	AE Coded	Completed Evaluation?
030	3111	Female	66	04-SEP-1991	DIG :Duodenal ulcer	No
030	3112	Male	27	08-NOV-1991	SKIN:Burning sensation skin	No
030	3205	Male	72	16-SEP-1991	SKIN:Burning sensation skin	Yes
030	3206	Male	35	08-OCT-1991	DIG :Diarrhea	Yes
030	3206	Male	35	08-OCT-1991	DIG :Vomiting	Yes

The last example revises the Join Order as the Final panel in the first order, Demography in second and Adverse Events as last.



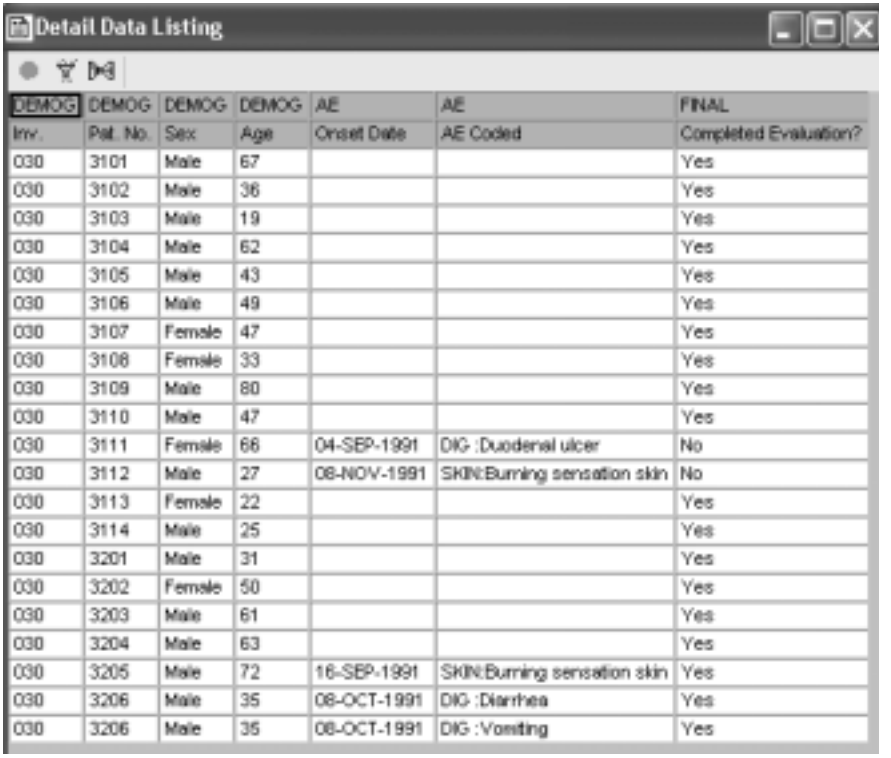
Join Order

Up

Down

Current Join Order	Expected Frequency
<p>FINAL_DATA T6	1 / patient (1)
<p>DEMOGRAPHY_DATA T5	1 / patient (1)
<p>AE_DATA T10	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.


Detail Data Listing

DEMOG	DEMOG	DEMOG	DEMOG	AE	AE	FINAL
Inv.	Pat. No.	Sex	Age	Onset Date	AE Coded	Completed Evaluation?
030	3101	Male	67			Yes
030	3102	Male	36			Yes
030	3103	Male	19			Yes
030	3104	Male	62			Yes
030	3105	Male	43			Yes
030	3106	Male	49			Yes
030	3107	Female	47			Yes
030	3108	Female	33			Yes
030	3109	Male	80			Yes
030	3110	Male	47			Yes
030	3111	Female	66	04-SEP-1991	DIG :Duodenal ulcer	No
030	3112	Male	27	08-NOV-1991	SKIN:Burning sensation skin	No
030	3113	Female	22			Yes
030	3114	Male	25			Yes
030	3201	Male	31			Yes
030	3202	Female	50			Yes
030	3203	Male	61			Yes
030	3204	Male	63			Yes
030	3205	Male	72	16-SEP-1991	SKIN:Burning sensation skin	Yes
030	3206	Male	35	08-OCT-1991	DIG :Diarrhea	Yes
030	3206	Male	35	08-OCT-1991	DIG :Vomiting	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.

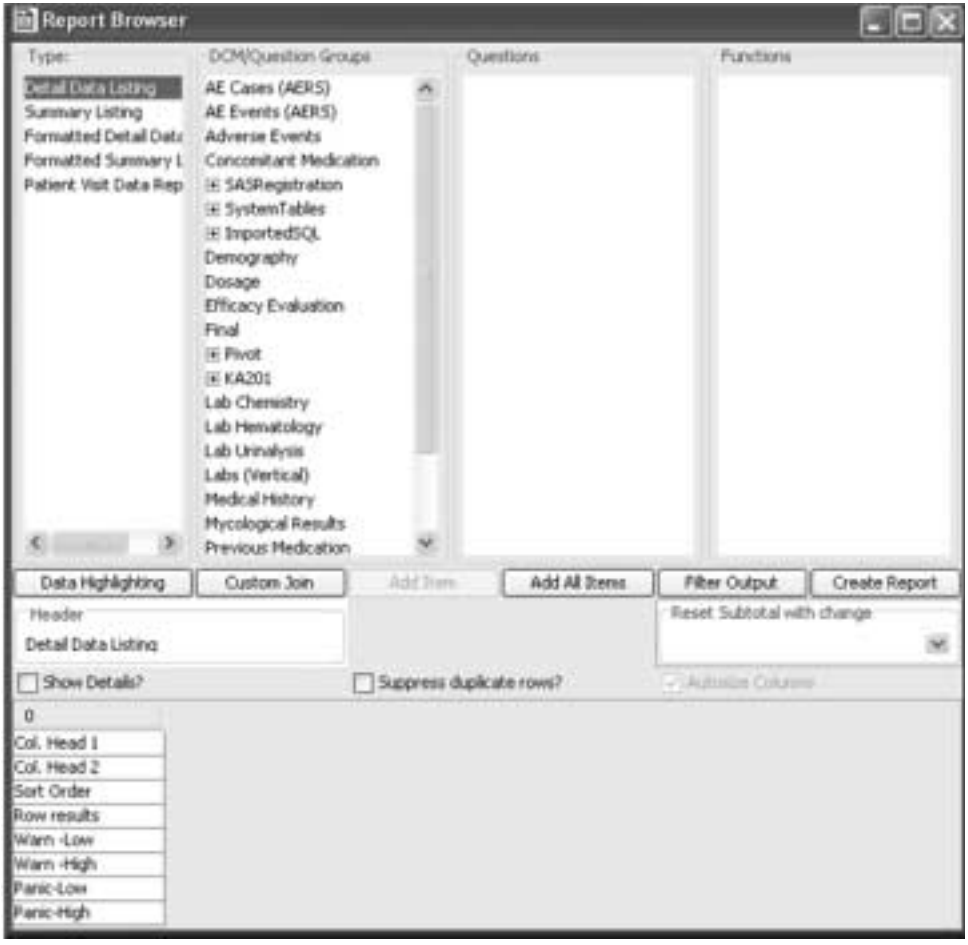
   The system default join order is reloaded into the Join Order window.
5. Click **Save**.

Define Custom Joins

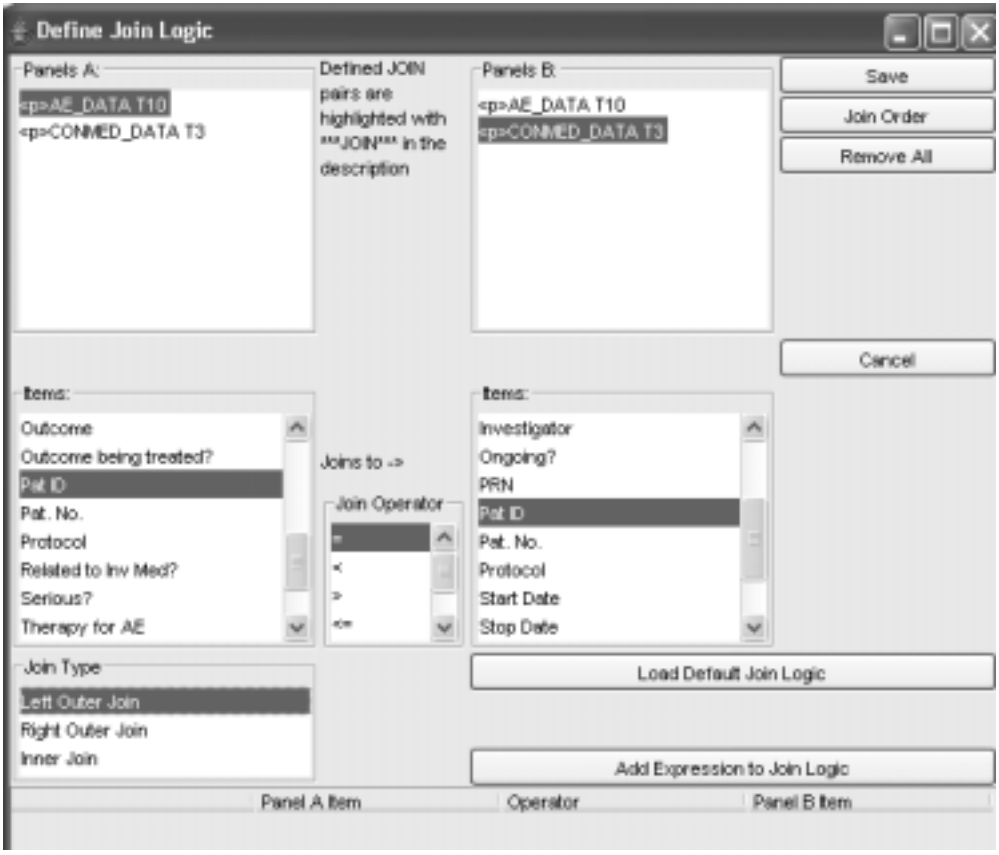
Creating custom joins

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.

1. First define your detail data listing report specification to identify which tables will utilize the custom join logic.



2. From the Report Browser window, click **Custom Join**.
   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.



Note: Define Custom Join does not apply to the Patient Visit Data Report type.

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**.

Note: The Define Custom Join Logic supersedes the Join Order.

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.

5. Click **Yes**. The system default join logic is reloaded into the Custom Join Logic.

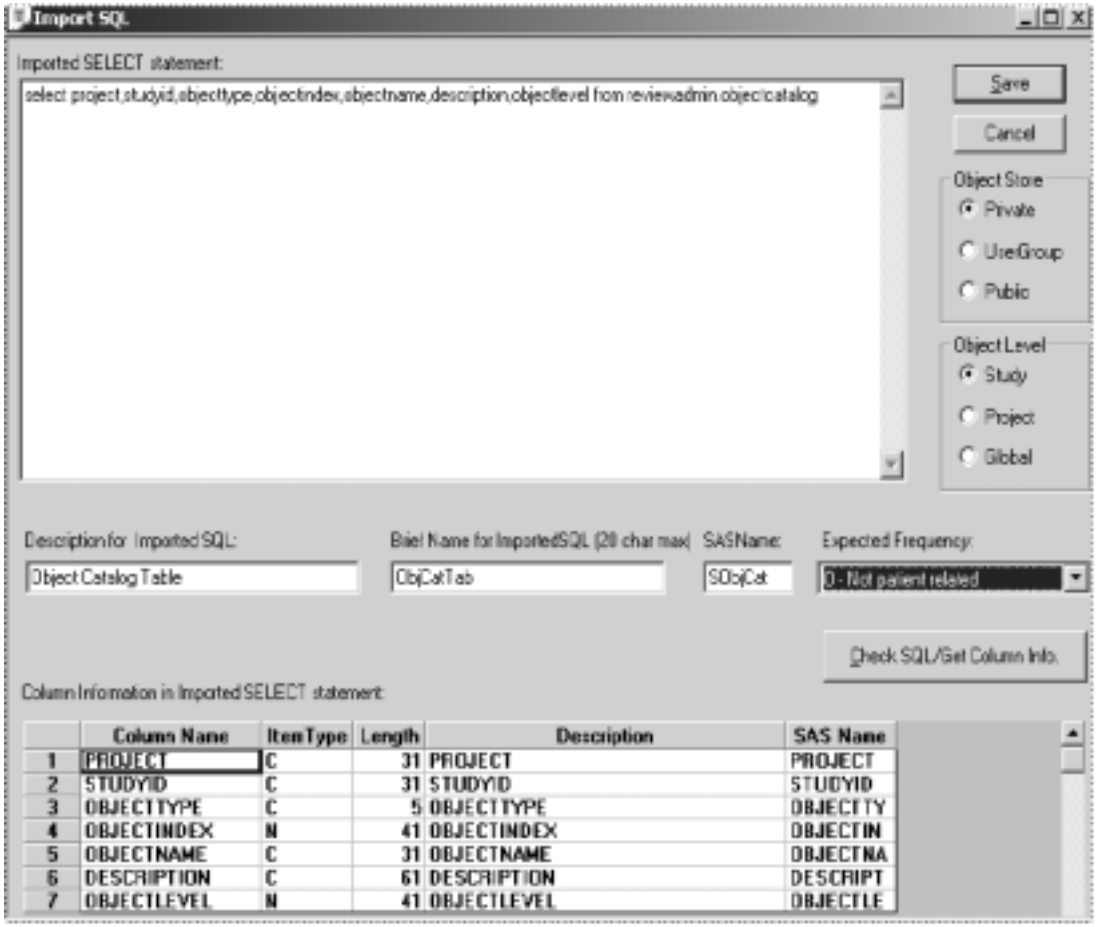
   You can also use the system default to initially define the Custom Join Logic as a starting point.
6. Click **Save**.

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 Review.

1. From the **Advanced menu** in the toolbar, select **Import SQL.**
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:

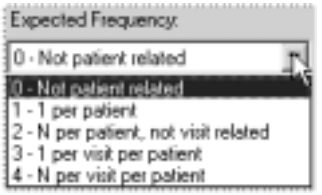
   select project,studyid,objecttype,objectindex,objectname, description,objectlevel from reviewadmin.objectcatalog

   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.



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.

   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).

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 new 'ImportSQL' table in the ReviewAdmin account.

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 Review 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.

   The Import SQL definition can also be saved at Study, StudyGroup (multiples supported) and Global (*ALL*).

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.

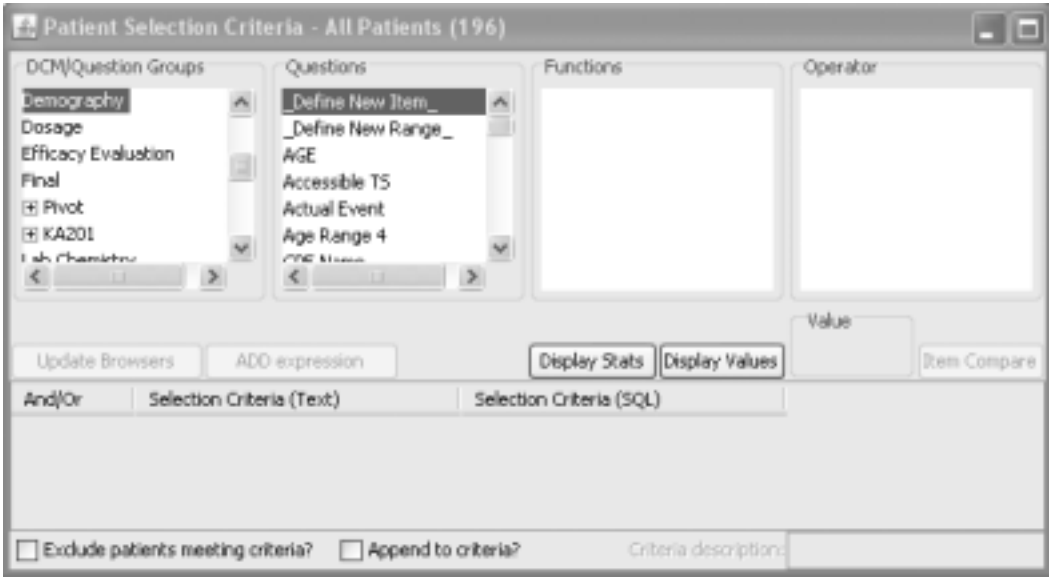
Note: If it's not patient related, it's important not to subset using the Patient Selection Criteria. (See ReviewAdmin: Register Foreign Panels)

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.

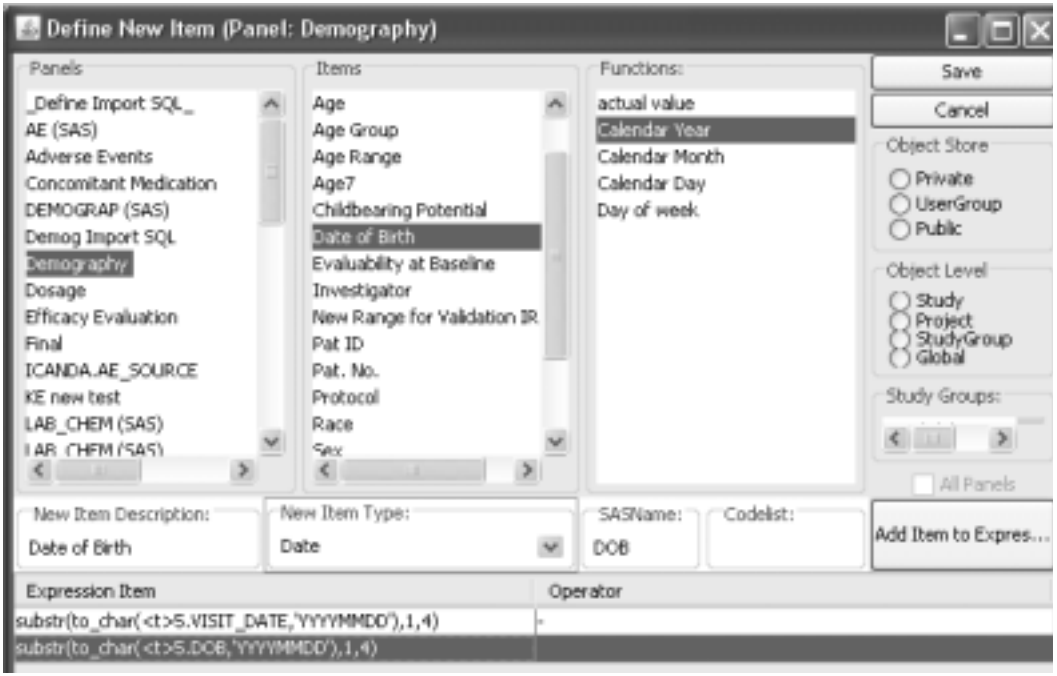


2. Select panel items.
3. Join item expression with mathematical operators.
4. Enter New Item Description.
5. Save New Item.

The newly defined item will be displayed and accessible from the active panel when you clicked on _Defined New Item_.

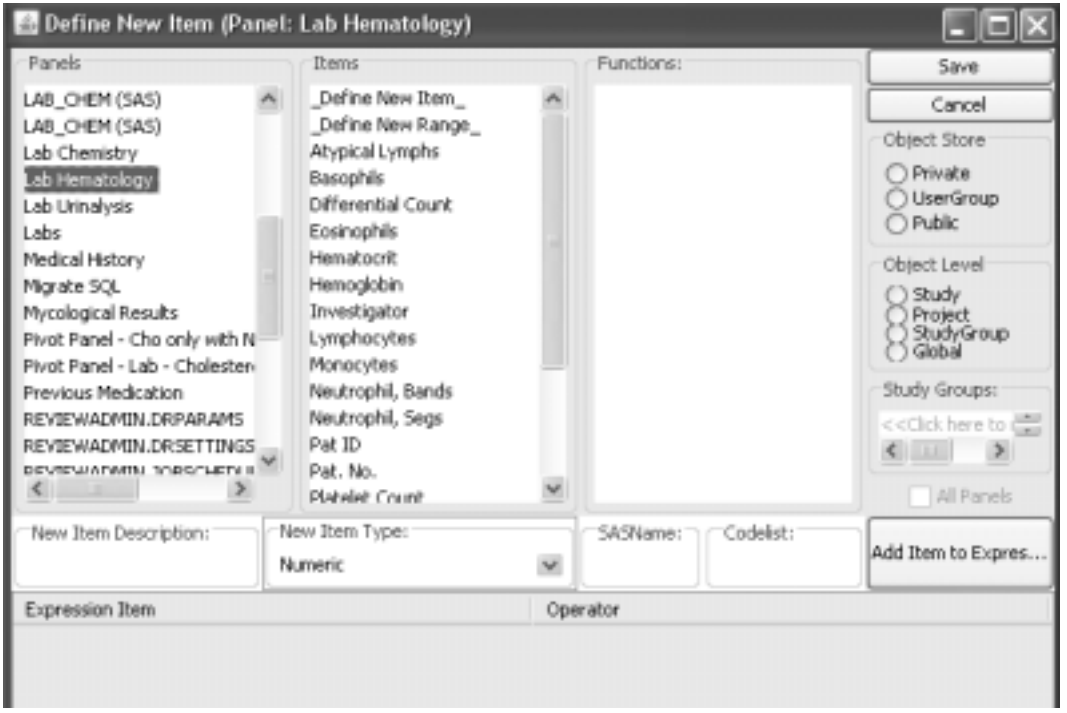
For example, perhaps in the Demography panel the patient's age was not collected, but you have the Date of Birth.

You could define a calculated age by doing date arithmetic on the Date of Birth against the Visit Date.



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.

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.

Note: If any items used in a mathematical calculation contain NULL data, the resulting derived item will be NULL per standard Oracle functionality.

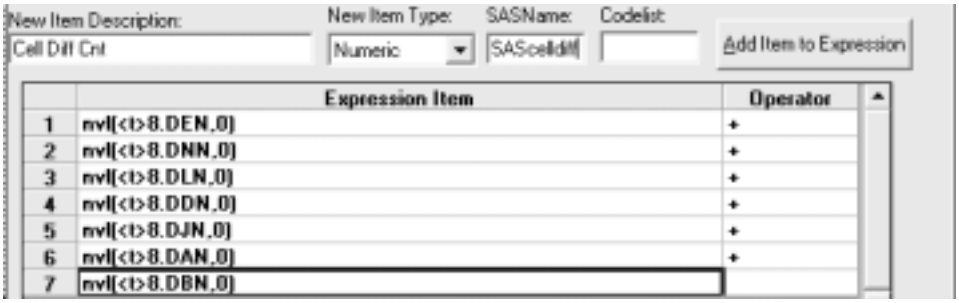
Add operators

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.

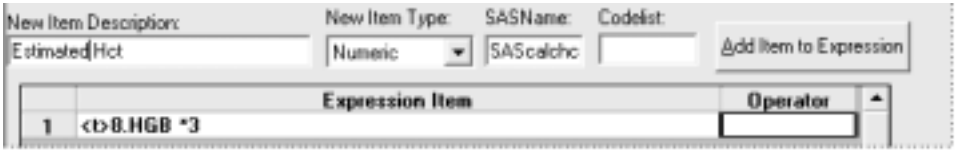
You can also edit more complex mathematical expressions within the Expression Items edit box by editing the SQL to adjust your derived item calculation, as shown in the next example. Double click on the cell row to begin edit. Be sure to hit the **Return** key on the last expression line so all expression 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.

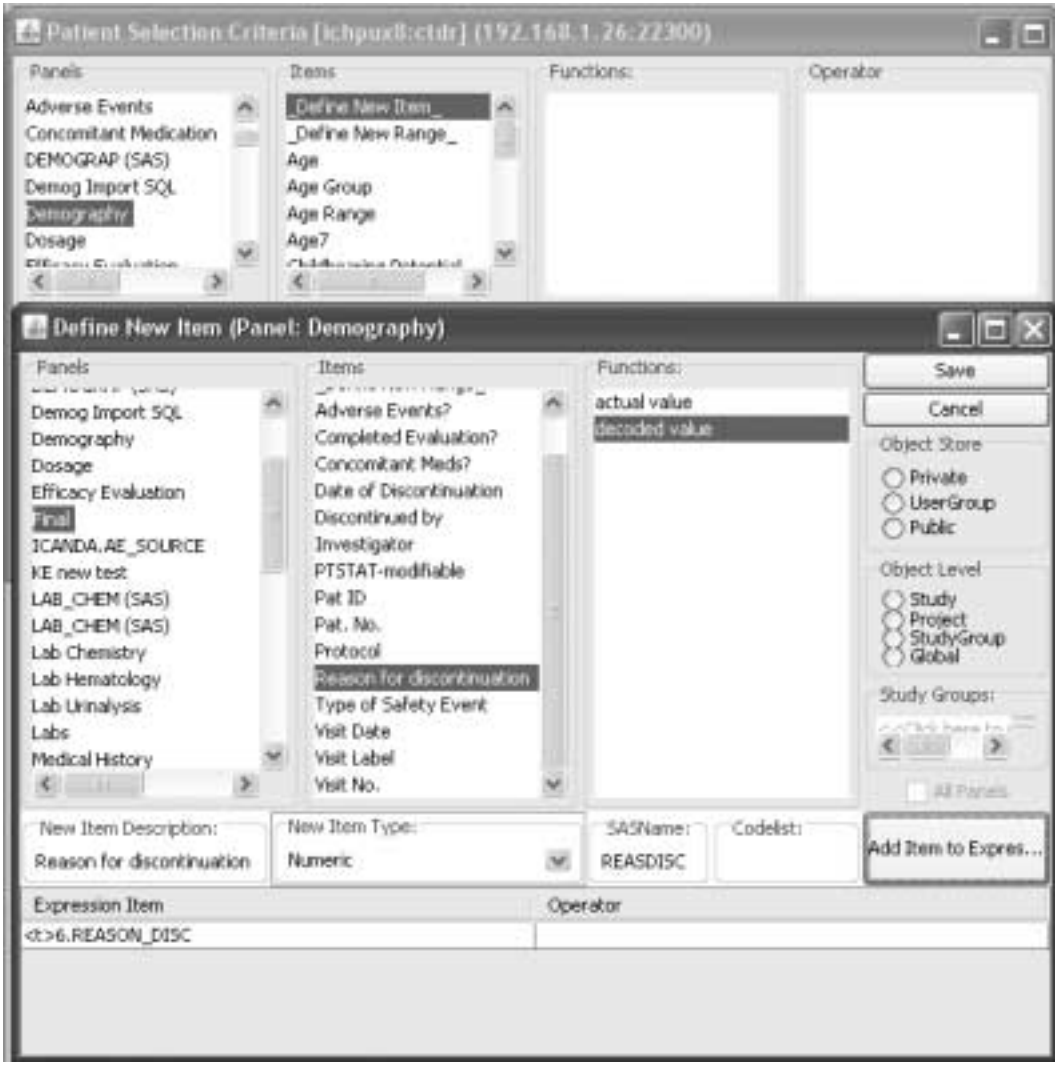
You can edit the SQL within the Expression Item edit box to adjust your derived item calculation, as shown in the next example.



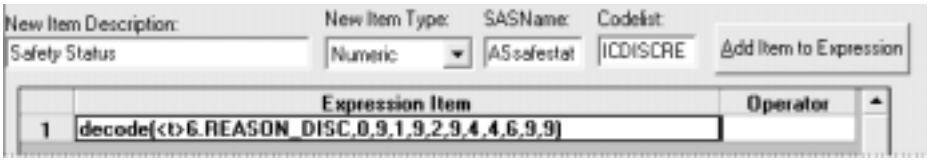
Note: The overall length of the expression is currently limited to 256 characters. Review prevents you from exceeding this limit.



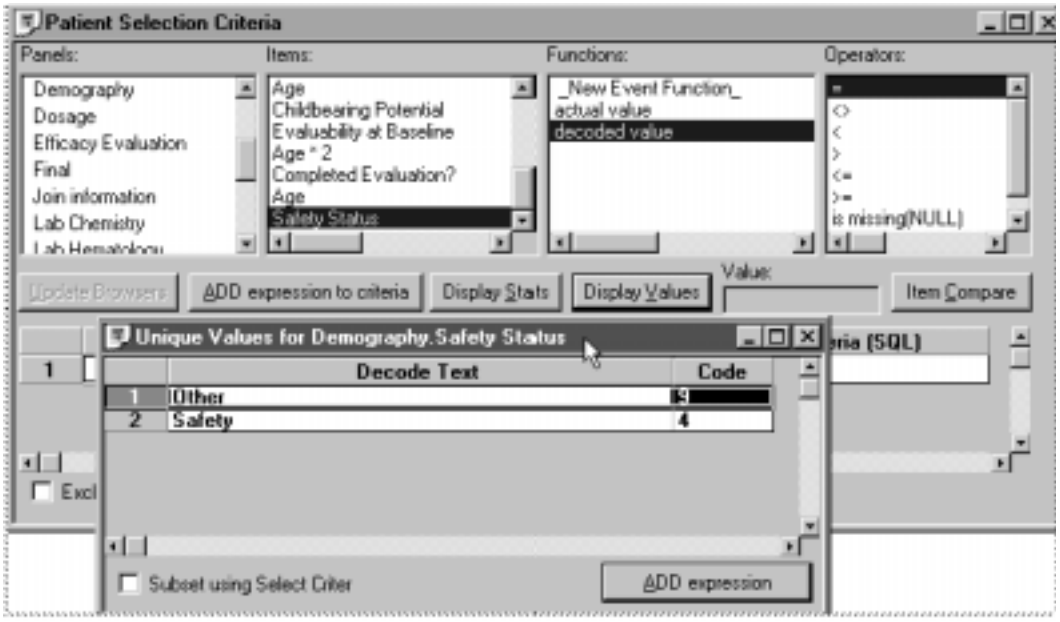
In the next example, you can define a new item to reference an existing decode in one panel and display the new item in a different panel.



The Expression Item is modified to reference specific decode values.



When the New Item is saved and added to the Demography panel, while decode information is taken from Reason for discontinuation item in the Final panel.



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.

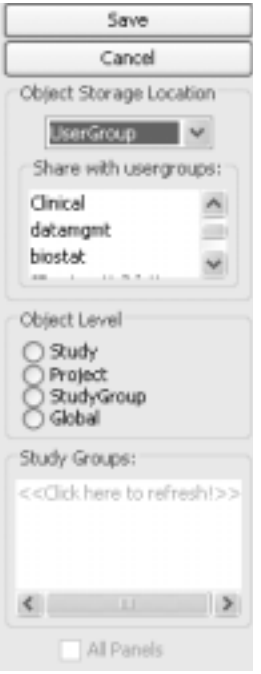
   If you save the new item as **Private,** you must select 'Private' in the Object Explorer area for Patient Subsets and Object Specifications to access the new item. In addition, you may need to refresh the window to view the private new item.

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.

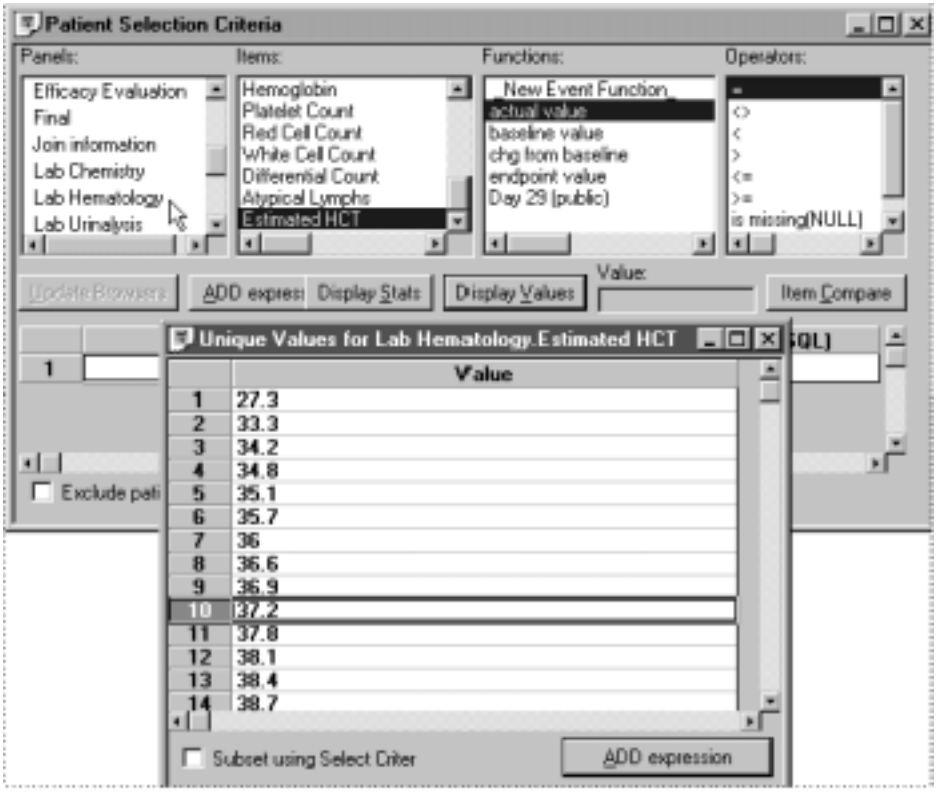
   If you are granted "SuperUser" capability through the ReviewAdmin's Review Privileges and you select **UserGroup** or **Public** you can optionally save as a **Global New Item**.



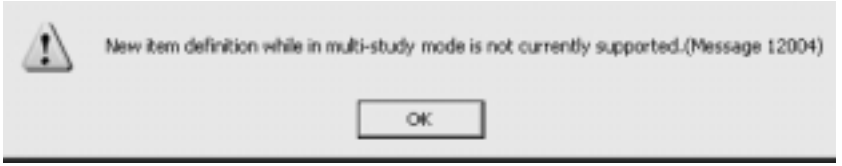
8. Optionally select Global New Item for **All Panels** to display and select the new item across all panels.

9. Click **Save**.

   Review saves the definition and the description and posts the New Item from the panel in which it was activated.

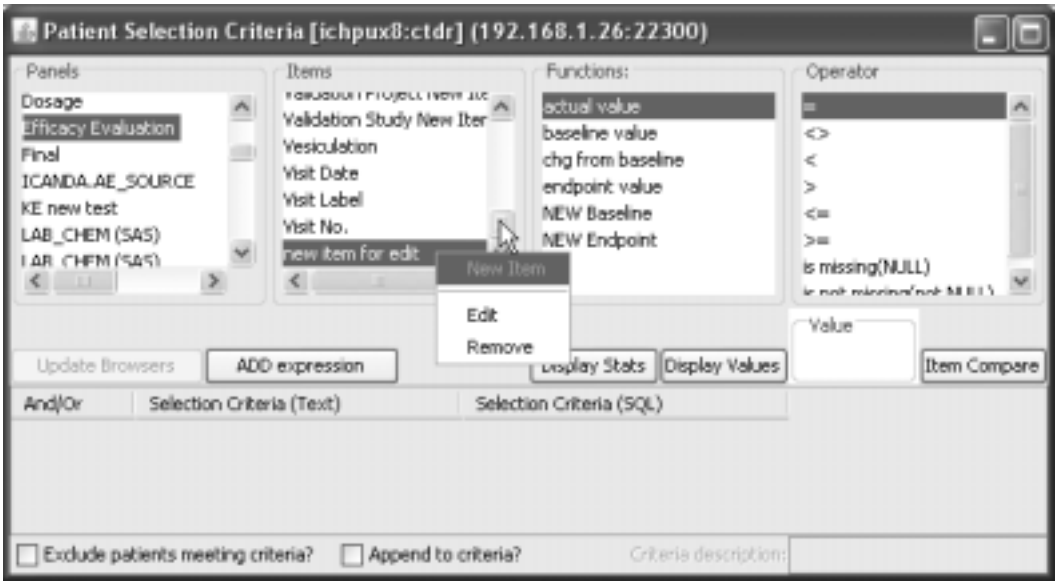


You can select the new item in studies other than the study where it was defined and saved. A message will display if you attempt to define a new item in multi-study mode. Likewise, you cannot access a new item in multi-study mode.



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.



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.

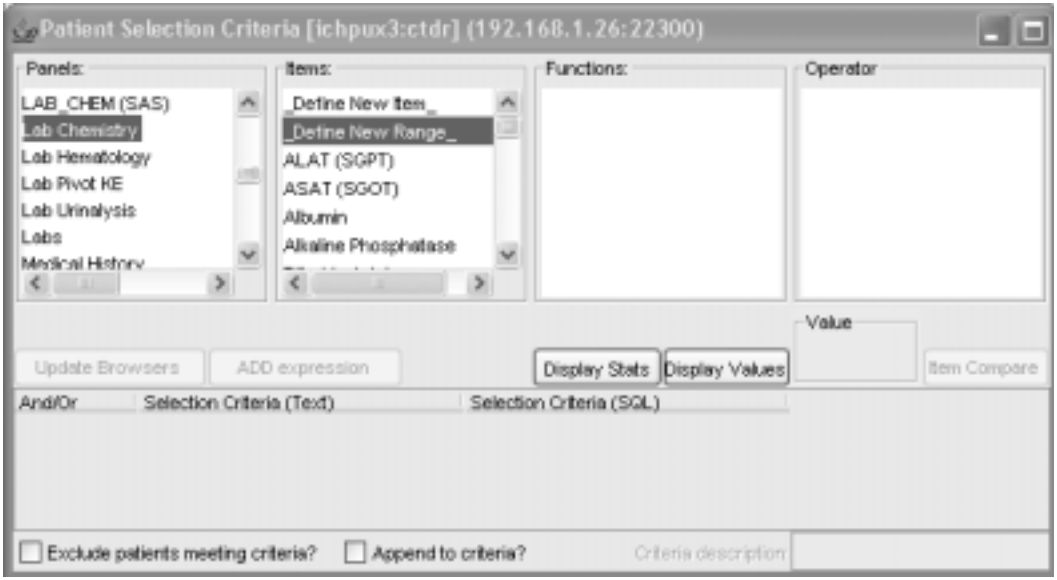
1. Select the panel it belongs to.
2. Select the new item description you would like to remove.
3. Right mouse click on the item to display a floating menu; select **Remove**.

Define New 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_".

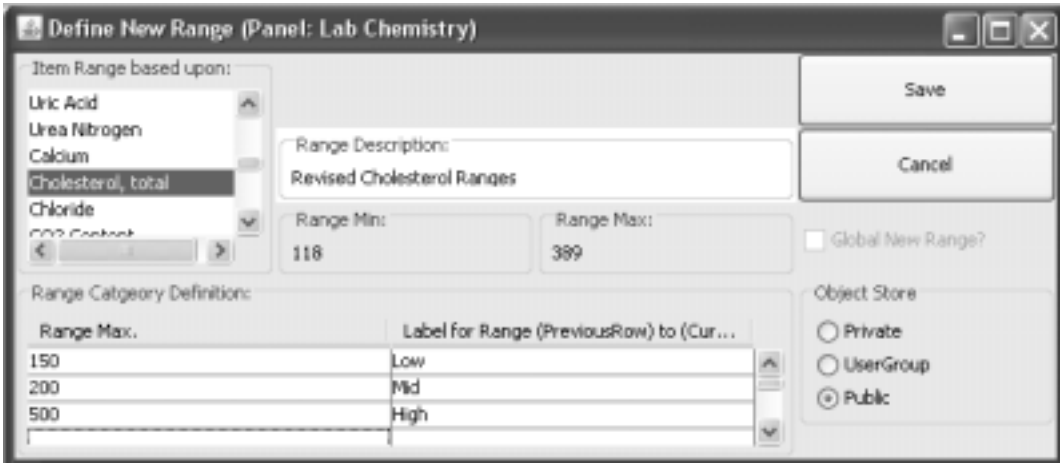


Define New Range

1. Click on "_Define New Range_". Review 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.



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 Review uses the previous row's Maximum value as the Minimum value of the following row's range.

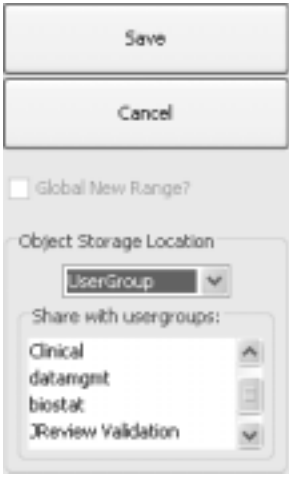
   The first row's Minimum value is automatically generated by Review to include all points less than, but not including, the range maximum of the following row.

   Missing item values for a patient or group are automatically assigned to a range noted as a 'missing' entry.

Save new range variable

6. Select the **Object Store** access as **Private, UserGroup** or **Public**.

   Selecting multiple UserGroups for save is supported.

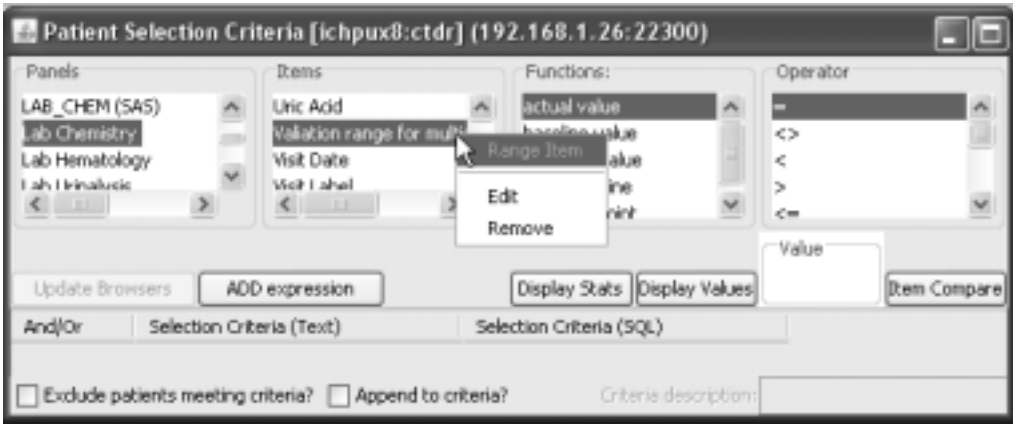


   If you save the new item as **Private,** you must select 'Private' in the Object Explorer area for Patient Subsets and Object Specifications to access the new range. In addition, you may need to refresh the window to view the private new range.

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.

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.

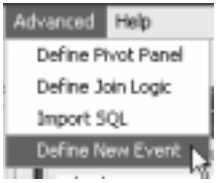
Define New Event

User-defined time related milestones

You can define time-related milestones, such as baseline, endpoint, or any description of your choice, for use throughout Review. From the pseudo-function "_New Event Function_" you can view a current listing of event derived-values and add new event criteria.

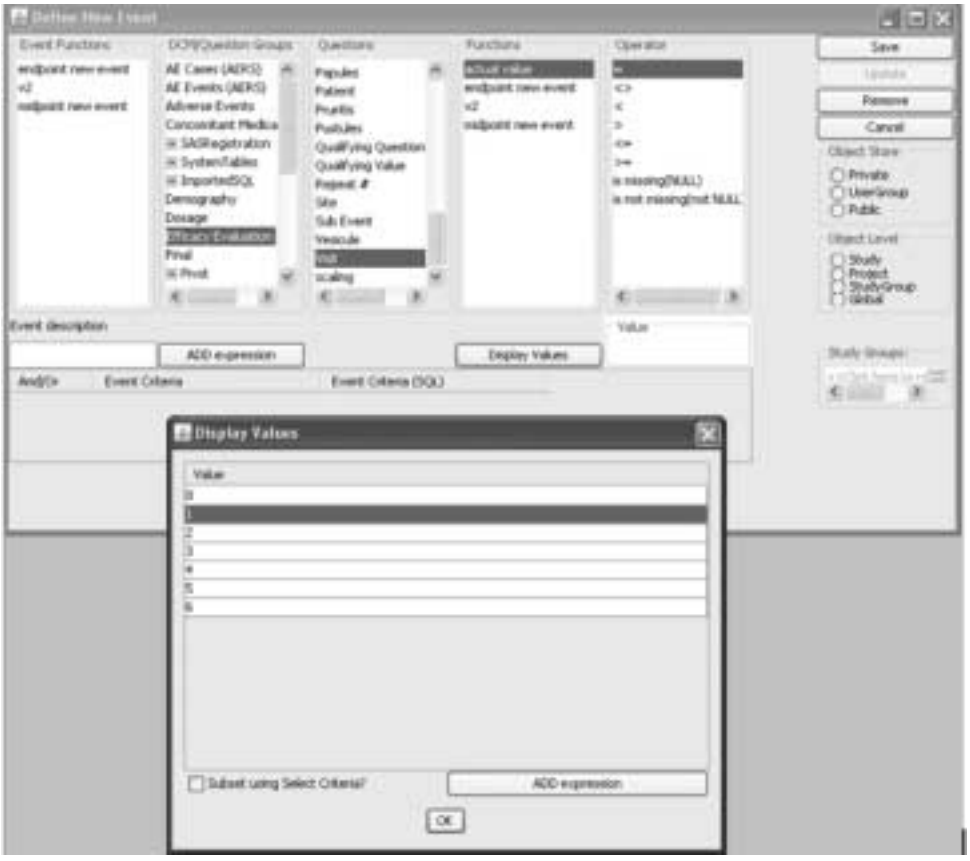
Define New Event

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**.

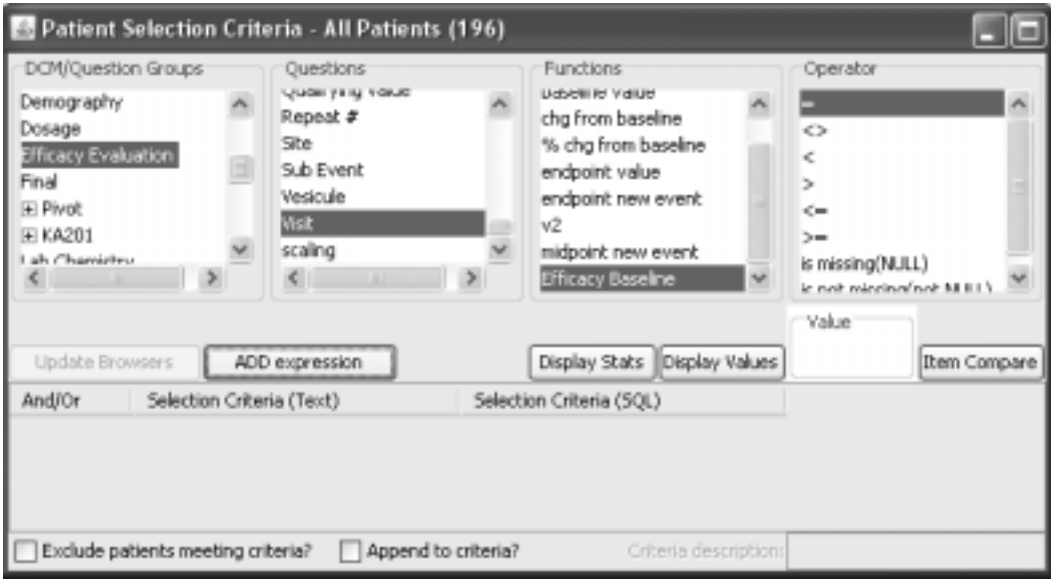


4. Select an **Operator**.
5. Select a value from the **Display Values** list or enter a value in the "Value" field.
6. Click **ADD Expression** to build the new event function value. The values will be entered in the Event Criteria spreadsheet.
7. When you are finished defining the event function value; 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.

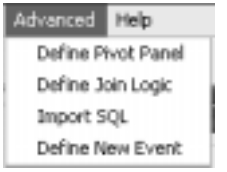
Pivot panels

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**.



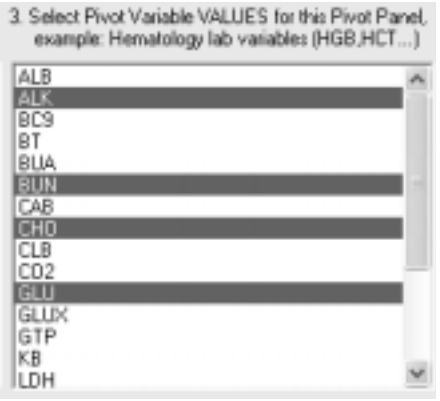
The Define Pivot Panel window opens where you sequentially enter your selections to define the pivot panel.

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.

2. Choose a pivot variable.

3. Select pivot variable Values. Hold down **Ctrl** and click to select multiple values.



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.

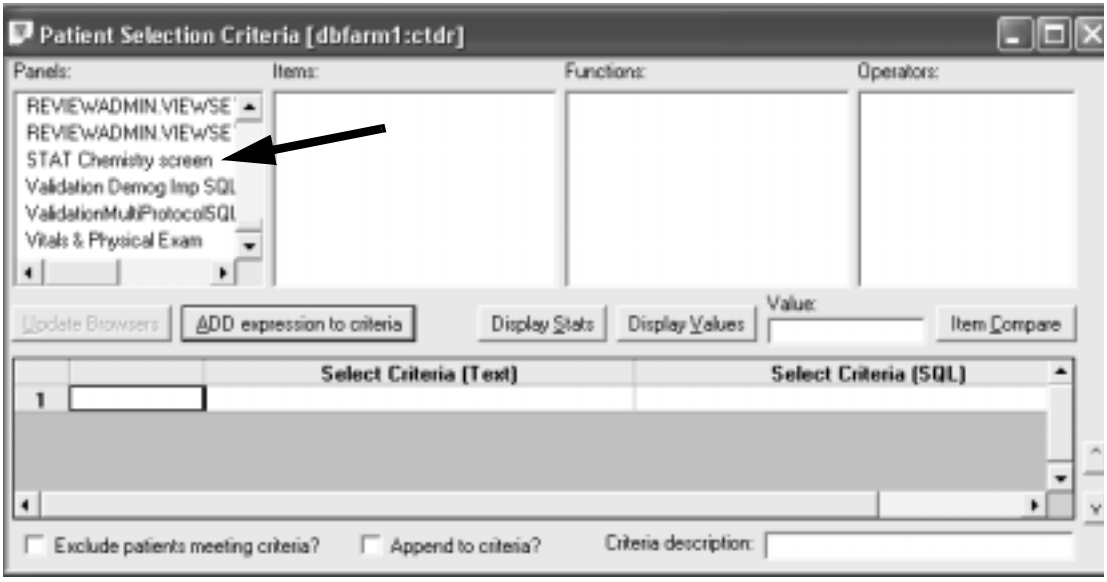
5. Select items that are dependent on the pivot variable. This is the data which will be stored for each pivot variable value. Multiple dependent variables can be selected.

6. Enter a description of 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.

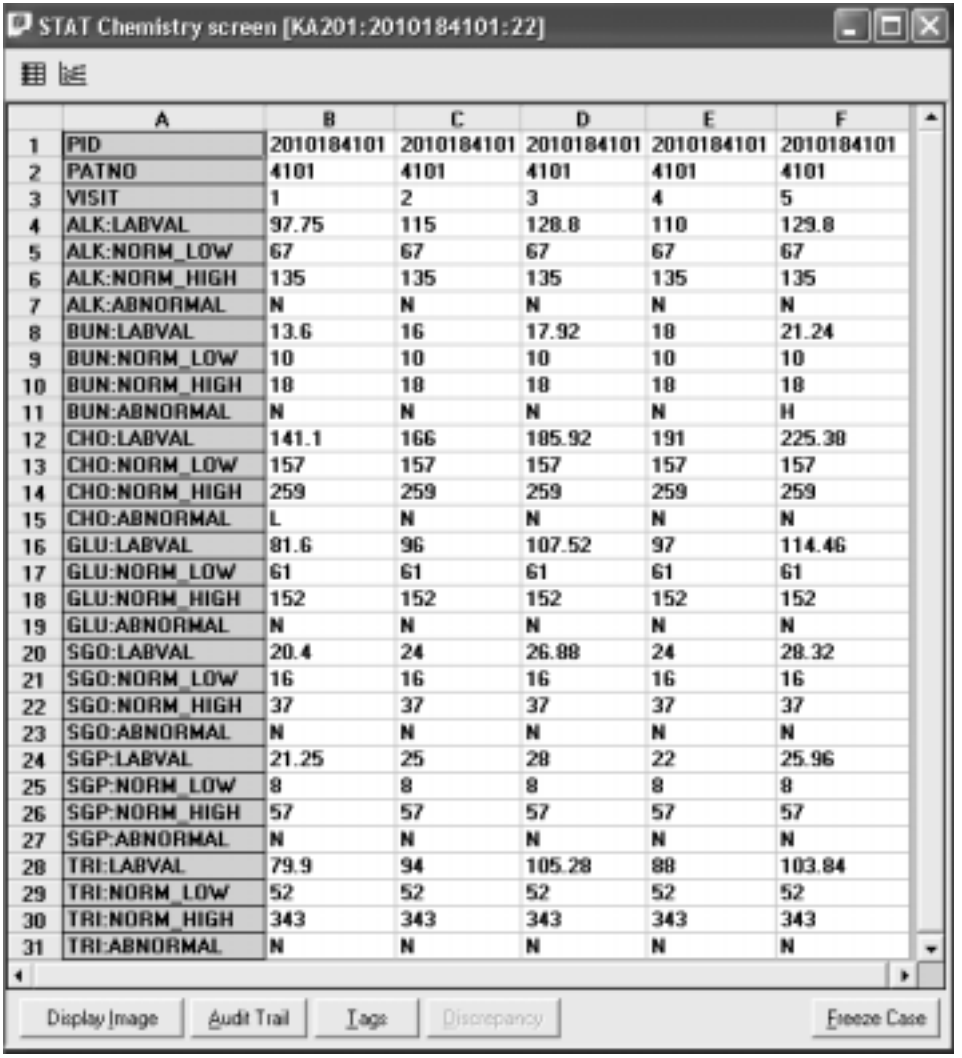
9. Select the **Pivot Panel Type**.
   - **Transposed Values** - demonstrated with the Lab Hematology example.
   - **Existence Matrix** - will define either a 1 or a 0 when the presence of a value is in the specified field. For example, when used as a method for looking for the existence of a specific 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.
10. Create Database View option creates an Oracle view.
11. Click **Create Panel**. When the pivot panel is created, it is included in the panel listing with a dependent variables listing in the items list box.



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.



	A	B	C	D	E	F
1	PID	2010184101	2010184101	2010184101	2010184101	2010184101
2	PATNO	4101	4101	4101	4101	4101
3	VISIT	1	2	3	4	5
4	ALK:LABVAL	97.75	115	128.8	110	129.8
5	ALK:NORM_LOW	67	67	67	67	67
6	ALK:NORM_HIGH	135	135	135	135	135
7	ALK:ABNORMAL	N	N	N	N	N
8	BUN:LABVAL	13.6	16	17.92	18	21.24
9	BUN:NORM_LOW	10	10	10	10	10
10	BUN:NORM_HIGH	18	18	18	18	18
11	BUN:ABNORMAL	N	N	N	N	H
12	CHO:LABVAL	141.1	166	185.92	191	225.38
13	CHO:NORM_LOW	157	157	157	157	157
14	CHO:NORM_HIGH	259	259	259	259	259
15	CHO:ABNORMAL	L	N	N	N	N
16	GLU:LABVAL	81.6	96	107.52	97	114.46
17	GLU:NORM_LOW	61	61	61	61	61
18	GLU:NORM_HIGH	152	152	152	152	152
19	GLU:ABNORMAL	N	N	N	N	N
20	SGO:LABVAL	20.4	24	26.88	24	28.32
21	SGO:NORM_LOW	16	16	16	16	16
22	SGO:NORM_HIGH	37	37	37	37	37
23	SGO:ABNORMAL	N	N	N	N	N
24	SGP:LABVAL	21.25	25	28	22	25.96
25	SGP:NORM_LOW	8	8	8	8	8
26	SGP:NORM_HIGH	57	57	57	57	57
27	SGP:ABNORMAL	N	N	N	N	N
28	TRI:LABVAL	79.9	94	105.28	88	103.84
29	TRI:NORM_LOW	52	52	52	52	52
30	TRI:NORM_HIGH	343	343	343	343	343
31	TRI:ABNORMAL	N	N	N	N	N

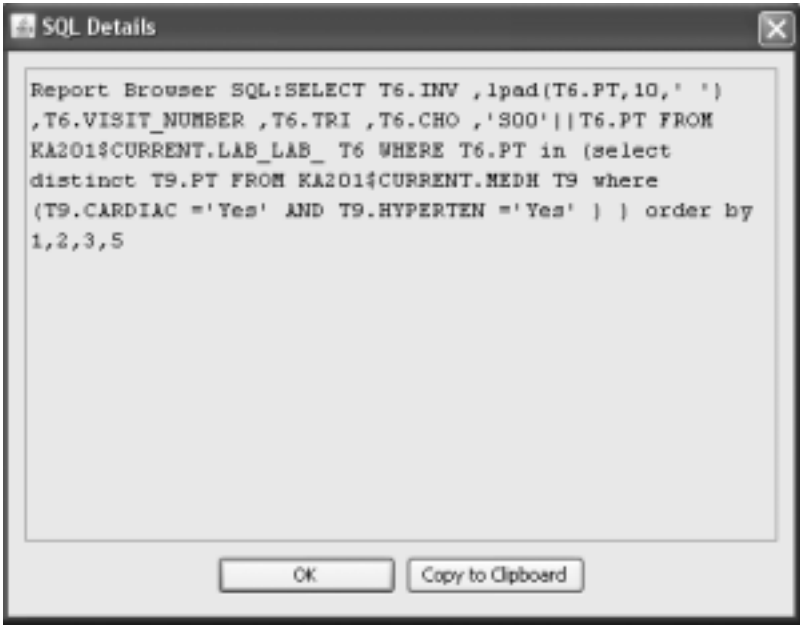
Remove pivot panel

12. Right mouse click on the selected pivot panel to display a floating menu; click Remove. Pivot panels can not be edited.

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.



13 Dashboard Views

Viewing Patient Data 644
- What is Dashboard? 644
- Dashboard access 644
- Dashboard functions 645
- Types of data access 646

Create Dashboard Viewsets 647
- Open Dashboard 647
- Dashboard tool bar 648
- Create New Viewset 649
- Select Default Profile 650
- Add views to Viewset 653
- Save ViewSet 655
- Remove object from Viewset 657
- Edit Viewset 657
- Remove ViewSet 658
- Add to Favorites 658

View Viewsets 659
- Select a ViewSet 659
- Apply Selection Criteria to viewset 660

View Patient Data 663
- Patient drill down 663

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.

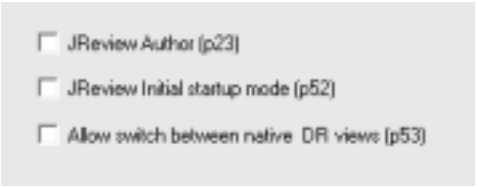
Users can select previously saved objects to organize and save as viewsets for routine retrieval. Viewsets may be labeled as 'Favorite' for preferred access. Customized viewsets may be kept privately or shared.

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.

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 option where the user goes into Dashboard View mode automatically after initial JReview logon.



ENABLED P52 brings the client into JReview.

DISABLED P52 bring the client into 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 and pie charts. Multi-page graphs are supported.
- **Reports** - Non-formatted and formatted reports.

The following object types CANNOT be added to a viewset:

- **Patient Visit Reports**
- **Patient Profiles**
- **Formatted Patient Profiles**
- **Graphic Patient Profiles**

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.

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.

Create Dashboard Viewsets

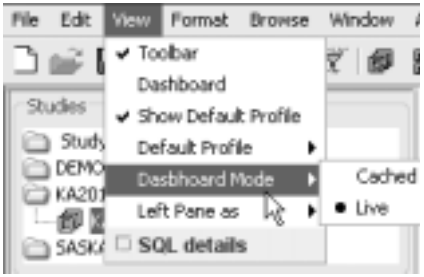
Open Dashboard

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.***



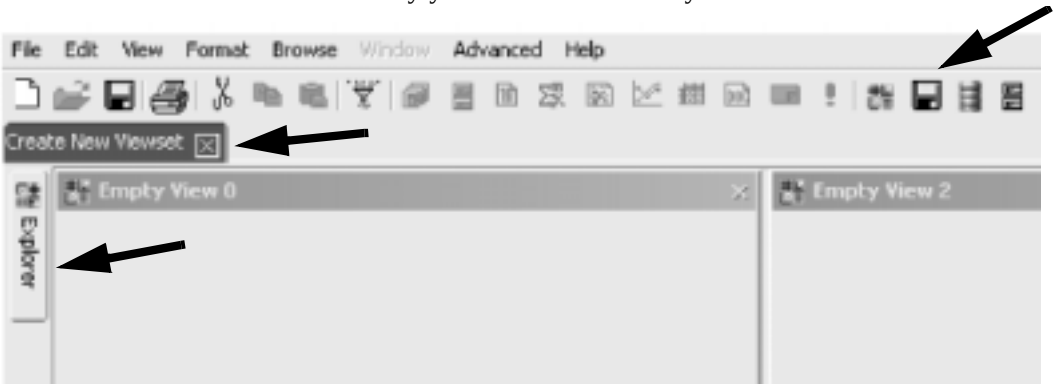
If you click OFF the option for 'Show Default Profile' before opening Dashboard then you have access to specify a maximum of 6 views within a viewset when the Default Profile is not required.

Initially upon opening Dashboard, a blank window may display with empty views until someone defines a shared favorite viewset. All shared viewsets saved with a 'Favorite' status display as tabs across the header. There is no limit to the number of viewsets saved with a favorite status however, the first 10 favorite viewsets saved sequentially are the ones displayed across the header area. The first shared favorite viewset saved is the default seen by all users when they initially open Dashboard.

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.



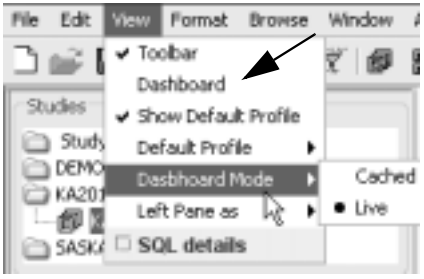
There are four additional icons located at the end of the tool bar, that pertain specifically to Dashboard and only display when in Dashboard.

- **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.

Create New Viewset

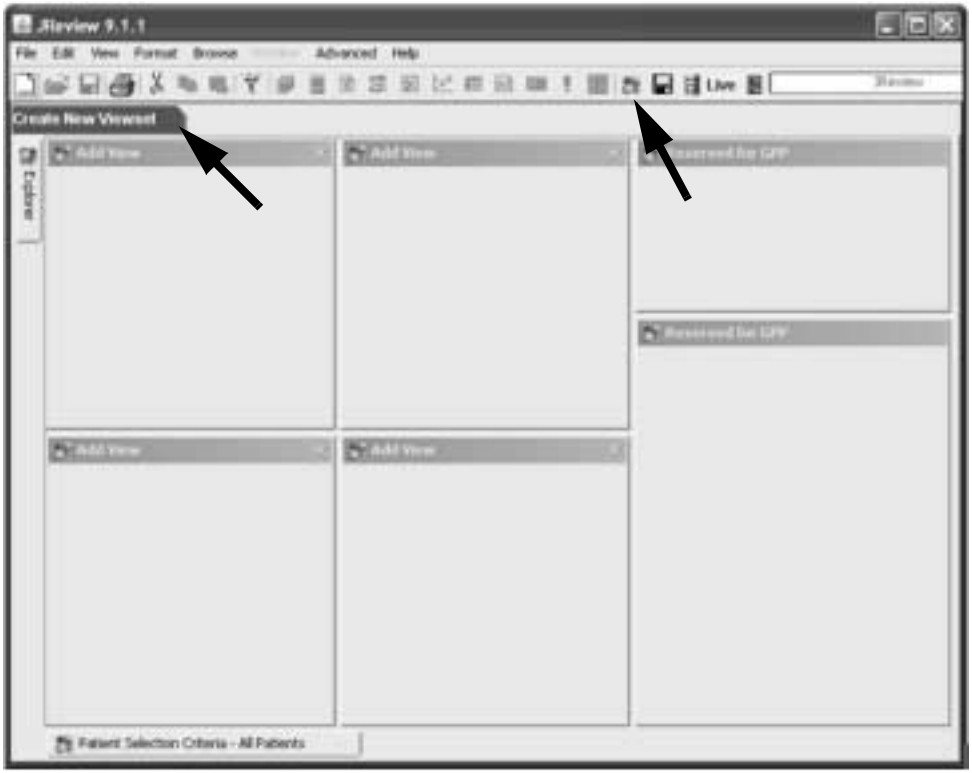
The following steps define how to add a viewset with a Default Profile.

1. Open Dashboard, from the **View** menu, select **Dashboard** with defaults as 'Show Default Profile' and default mode setting.

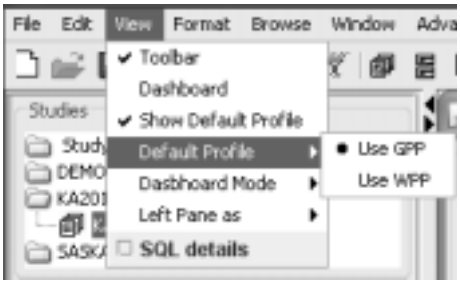


2. The main Dashboard viewing window displays. Dashboard requires at least one viewset tab be displayed in the tab headers.

   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.



The option to select and save a Default Profile is specific to the individual user. Select the **View menu,** to select the profile type.



Only one Default Graphic Profile and one Default Workbook Profile can be set per individual user for each level (Private, UserGroup and Public).

When you save a Default Profile, it is applied to any viewsets you open in each level (Public, Private or User Group), regardless who the author was of the particular viewset.

The Default Profiles are specified by the user viewing the viewsets. 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), and start the next session 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.

Note: Recommend selecting a Profile without a patient selection criteria.

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.

3. Click on the **Explorer** tab (located on the side).

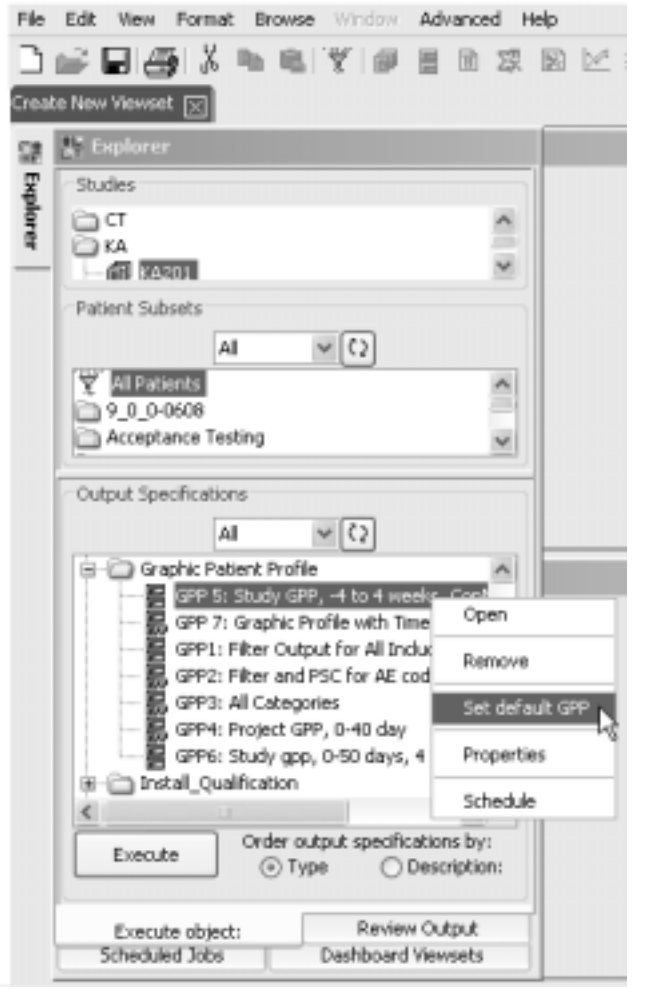
The **Explorer** tab opens and displays all previously saved viewsets as private or public. Initially the Explorer window shows no previously saved viewsets.

- 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.

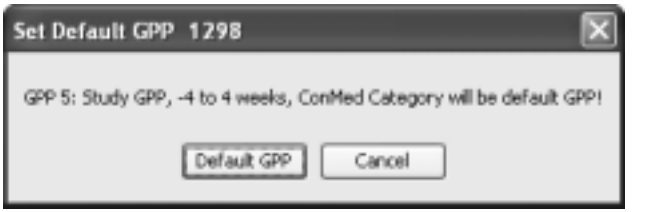
4. Click the **Execute object** tab located at bottom, to access the Output Specifications category folders.

   In the Output Specifications, next select the Default Profile and output objects to add as views in the viewset.

5. Select a Default Profile and right mouse click to display a floating menu. Click **Set Default Profile** for either GPP or WPP.



6. The **Set Default Profile** message window opens for confirmation of the selected GPP. Click **Default Profile** to save.

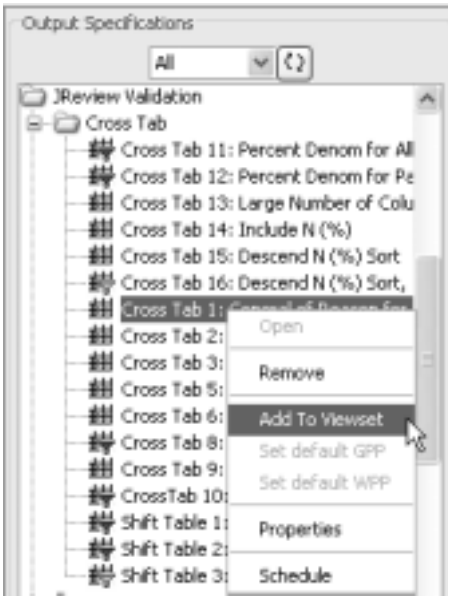


Add views to Viewset

After adding the Default Profile in the open 'Create New Viewset Tab', now you may add object views to the viewset.

7. In the Object Explorer under Output Specifications, access the category folders and select the objects.
8. Right click on the object you wish to display the floating menu to add to the viewset.

   Parameterized objects that contain runtime or prompting filters are supported in Dashboard Viewsets.

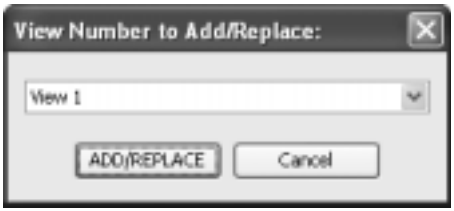


9. Click **Add to Viewset** to display the View Number to Add/Replace window.

   The View Number represents the view location in the viewset.

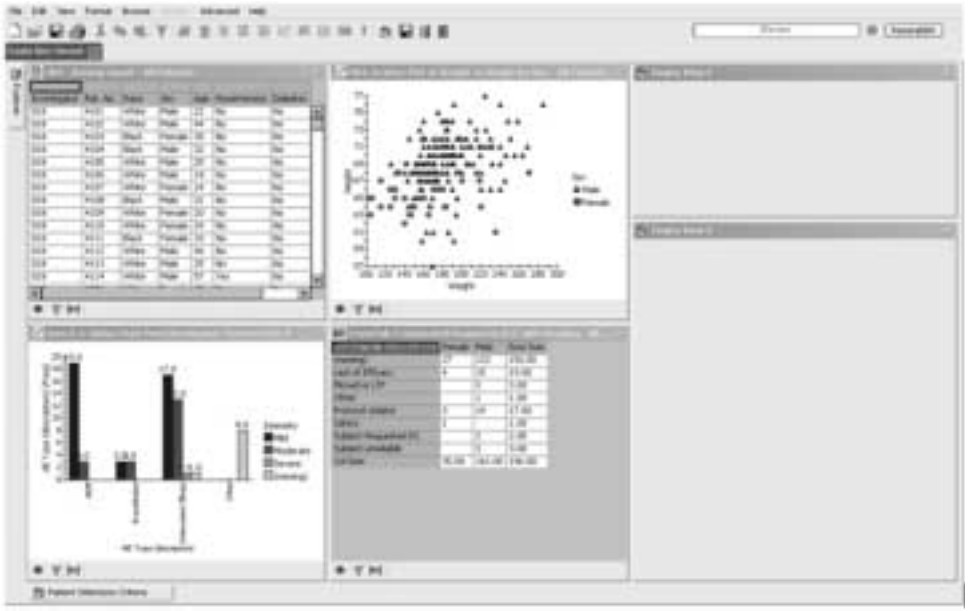
   Choose the view number from the drop down list, where the object should be placed.

10. Click on **ADD/REPLACE**, and the object will execute and be placed in the **Create New Viewset tab** in the selected position.



11. Click the Explorer tab after each view is added. Repeat the steps to add all object choices as Views 1 through 4 to the new viewset. Before saving, you can change any of the objects by choosing the view position.

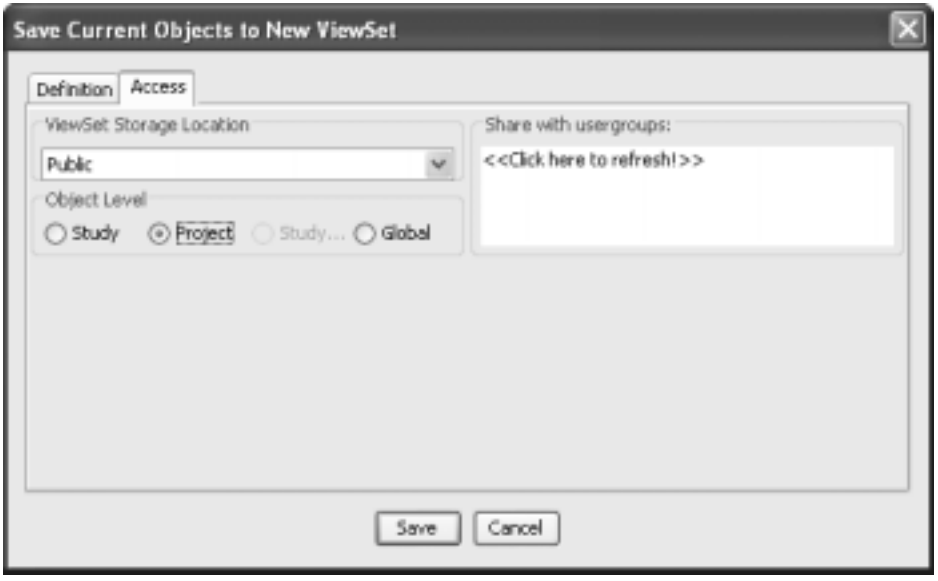
    You may enter up to 4 views, when the **Show Default Profile** option is checked ON. If the **Show Default Profile** option is not checked ON, then you may enter up to 6 views for the viewset.



Note: You cannot <u>append and save</u> a patient selection criteria to a viewset.

12. When finished adding views, click save viewset from the **File menu**, or click the **Save Viewset** icon in the Dashboard tool bar.

13. The **Save Current Objects to New Viewset** window opens. Click the **Access** tab, to enter information for **Viewset Storage Location** and **Object Level.**



14. 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**.

15. 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 does not appear 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.

16. Click the **Definitions** tab and enter a viewset name in the **ViewSet Name** box.

17. ..Enter to create a new folder or select a **Category** from the drop down list box to add the viewset to an existing folder.

18. 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.

19. 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

To remove an object or objects from a viewset:

1. Right click on the object in the Viewset Tree.

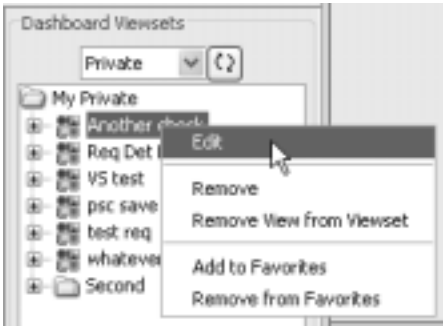
2. Choose “Remove this object from Viewset”.

   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), and remove the object by the viewset number.

Edit 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.

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

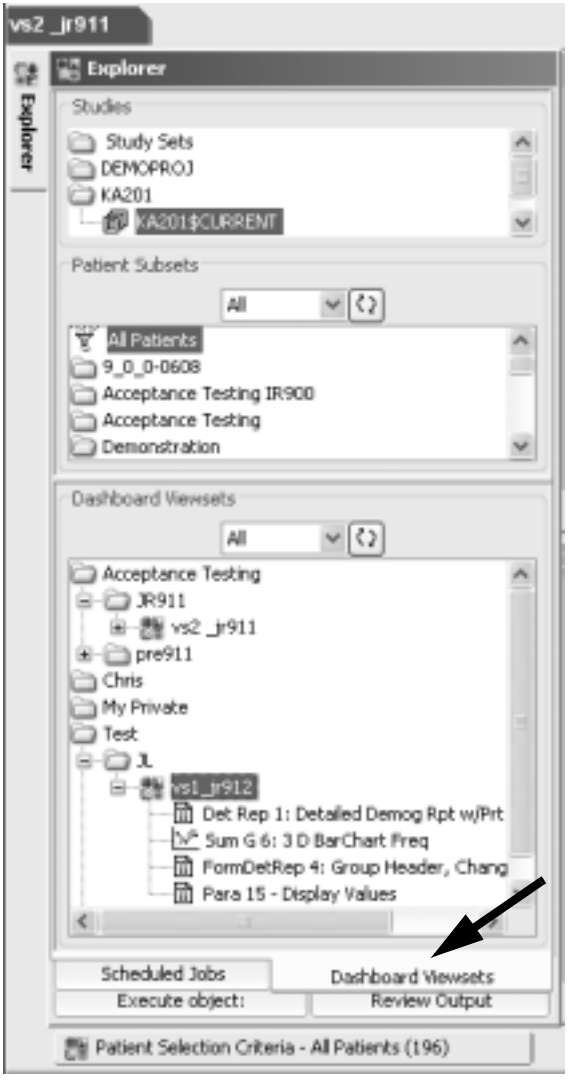
You can add a view set to your favorites after it has been saved.

1. Select the viewset and right mouse click to display the floating menu box.
2. Click **Add to Favorites** and the selected viewset is added as a favorite.
3. Click **Remove from Favorites** and the selected viewset is removed as a favorite.

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:



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.

The viewset opens with the views in ‘Snapshot’ mode as indicated by the red button in the lower left corner of each view window. Double click on any view header to enlarge the window, then double click to restore..

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 can 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.

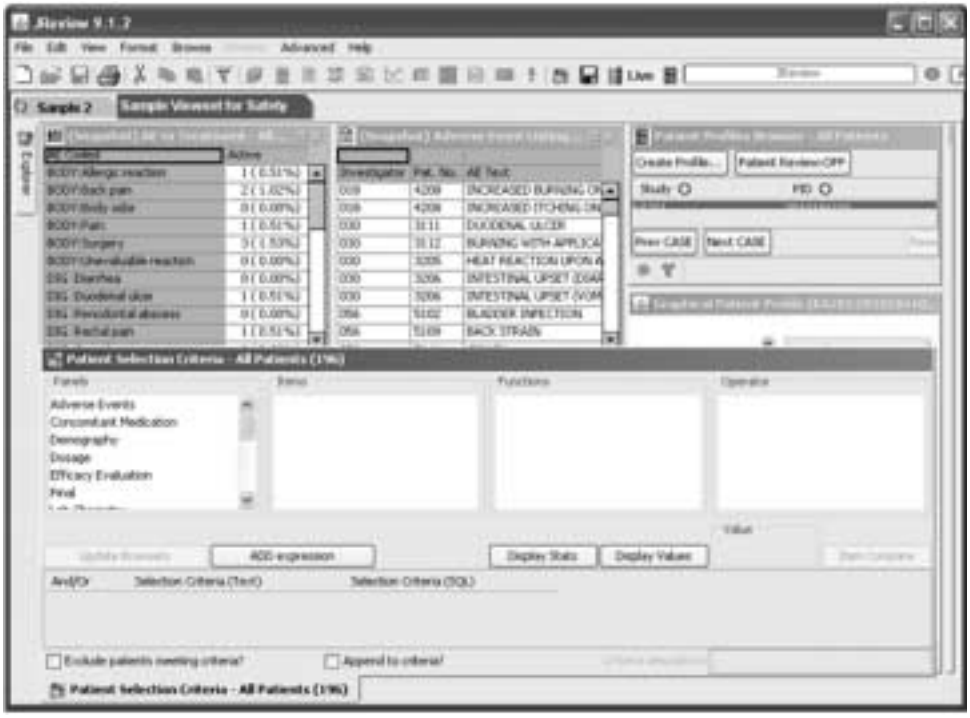
If you have the Default Profile turned ON, you may want to turn OFF the Snapshot mode for the Patient Profile Browser list displayed. Then the patients listed will update the subset applied by the patient selection criteria.

You may select a previously saved patient selection criteria or define your own as follows:

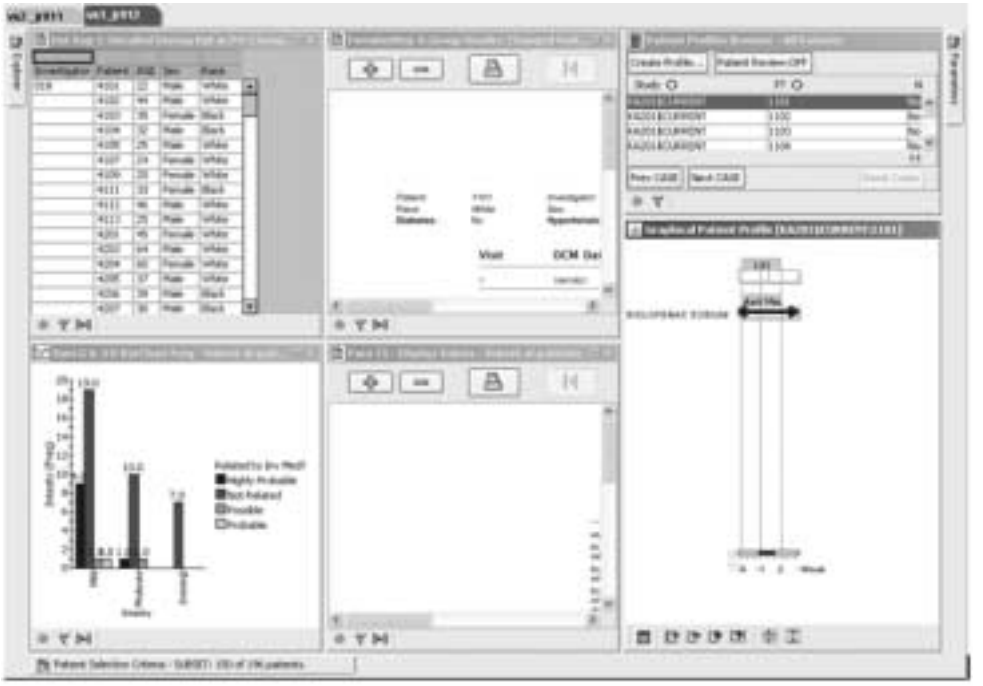
1. Click the **Explorer** tab to display the **Dashboard Viewsets** window.
2. Select the desired viewset and turn OFF Snapshot in the individual object views.
3. Optionally select the Patient Profile Browser patient list and turn OFF Snaphot.
4. Select the category folder to display the list of saved Patient Selection Criteria. Double click to launch the selected criteria and automatically **Update Browsers**.

   OR

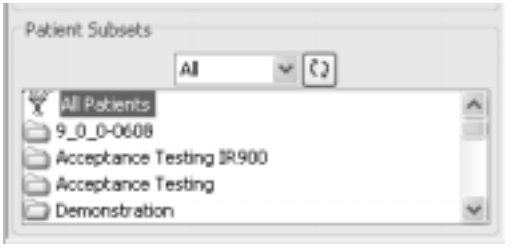
   Click the **Patient Selection Criteria tab** located at the bottom, where the Patient Selection Criteria window opens to enter your own selection criteria. After entering your selection criteria, clicking update browsers; the Patient Selection Criteria window automatically closes after the selection criteria updates the viewset..



All object views and / or Patient Profile Browser patient list with Snap-shot mode OFF update to the applied Patient Selection Criteria subset. The Patient Selection Criteria button shows the subset count.



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..



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.

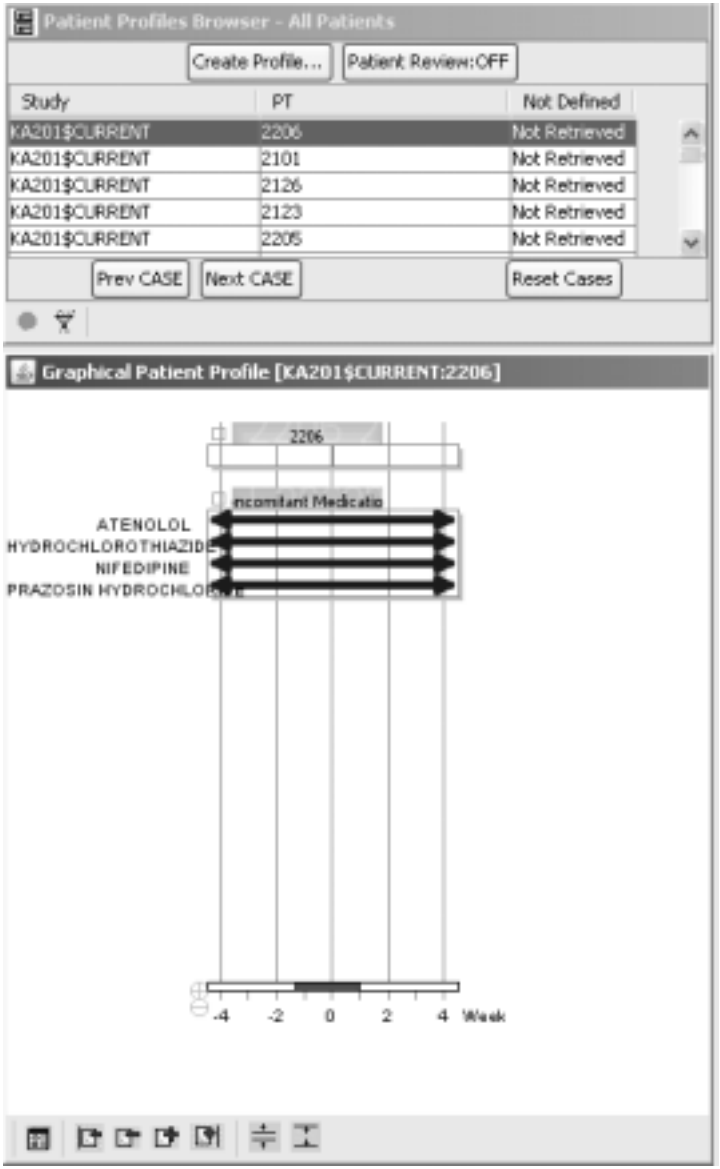
Click **Reset Cases** if needed to refresh the patient list between selections. If you had selected patients from a graph, first click on the graph '**Reset**' button, before clicking the Patient Profile **Reset Cases.** Selecting patients from graphs controls the patients listed in the Patient Profile 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 th 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)***



14 Risk Assessment Browser

Risk Assessment Analysis **666**
- What is the Risk Assessment Browser? 666
- Open Risk Assessment Browser 666
- Define MedDRA levels 668
- Define Treatments 669
- Define Patient Subgroups 671

Interact with Risk Assessment Results **677**
- View Risk Assessment 677
- Select MedDRA level 679
- Select patient subgroup 680
- Select Metric options 681
- Patient Highlighting 682
- View TreeMap 683

Filtering visual results **685**
- Set Filter Range 685
- Apply output filter 686
- Save risk assessment 687

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. 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

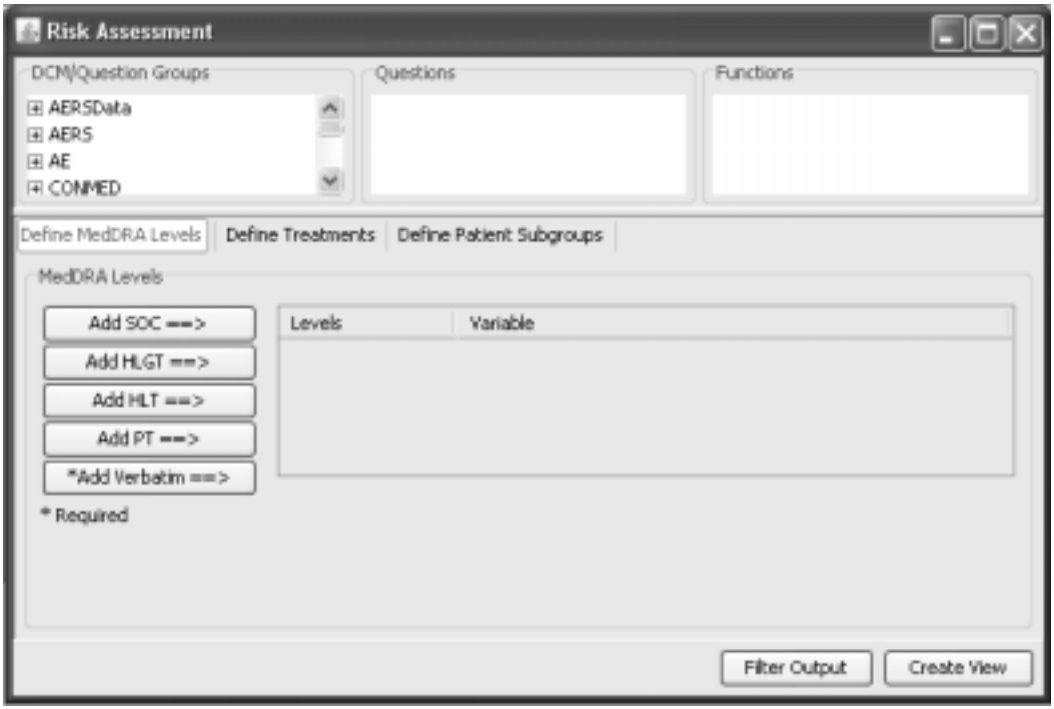
Patient Selection Criteria may be applied the same as other output browsers, to specify which patients will be included in the Risk Assessment.

Open Risk Assessment Browser

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.

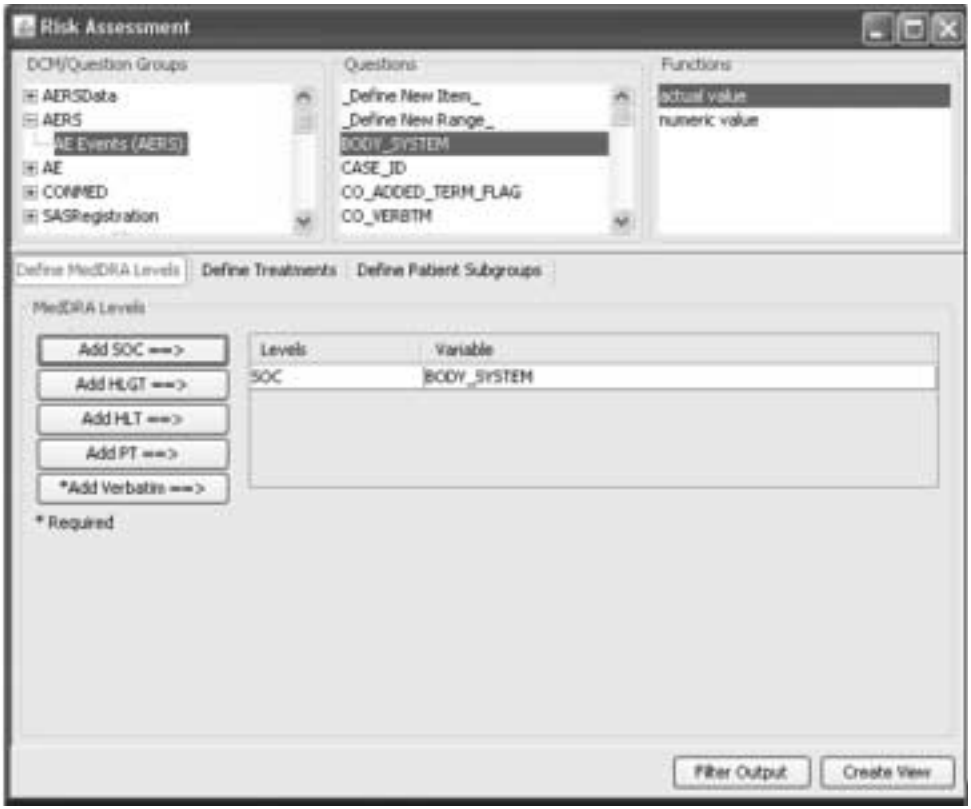
The main Risk Assessment definition window opens where you can enter information captured from either CDISC or Legacy systems.



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.

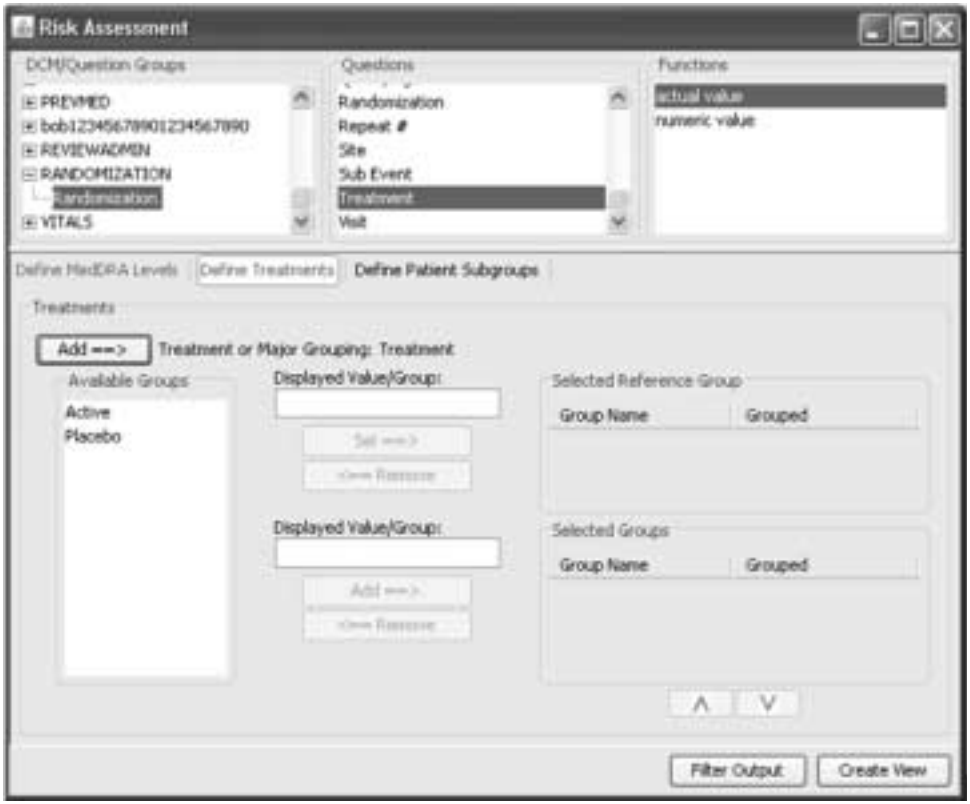


4. Repeat the same steps to add the following data items:
   - Select the High Level Group Term, click on **Add HLGT** button.
   - Select the High Level Term, click on **Add HLT** button.
   - Select the Preferred Term, click on **Add PT** button.
   - Select the Adverse Events Text, click on **Add Verbatim** button.

The 'Add Verbatim' term is required where you may optionally add other MedDRA level terms.

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.



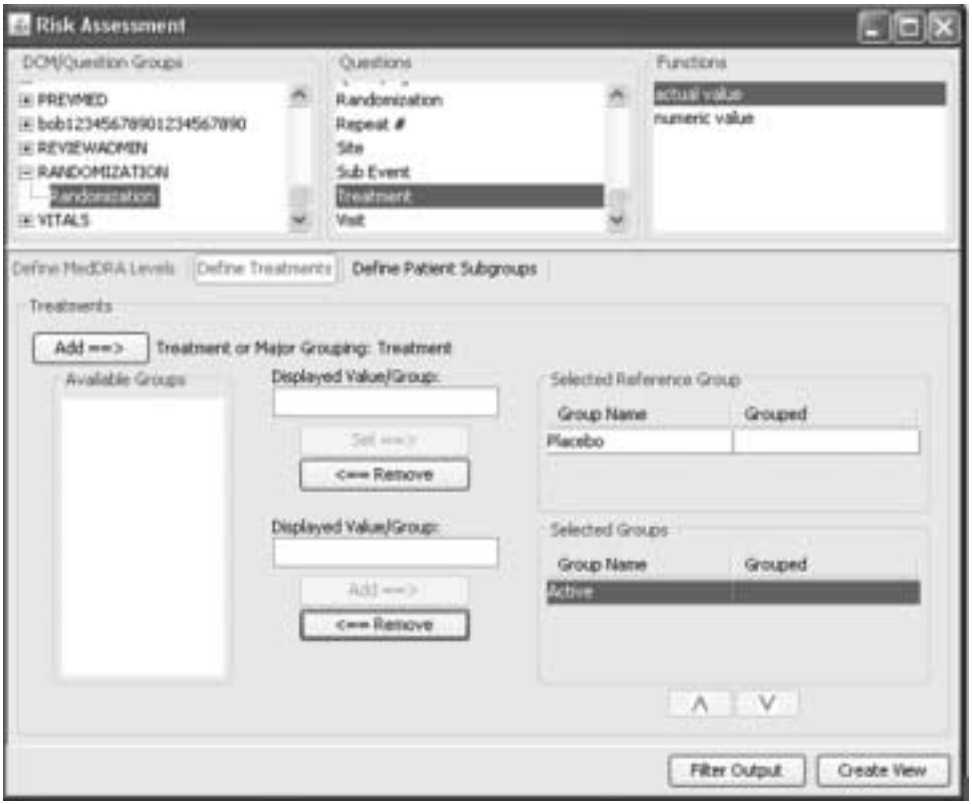
7. Select the treatment group to be applied as the **Reference Group**, and click **Set** button.

   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.

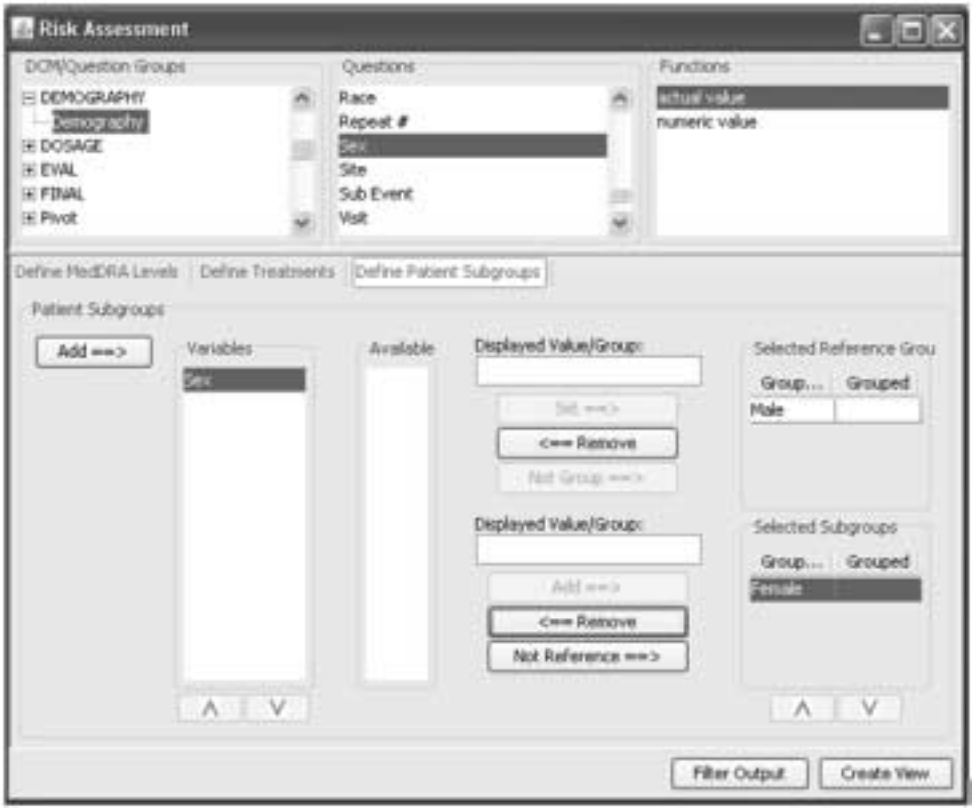
   For the example, Placebo is set to 'Reference Group' as the denominator in the ratio against the Active' Selected Group'.



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'.

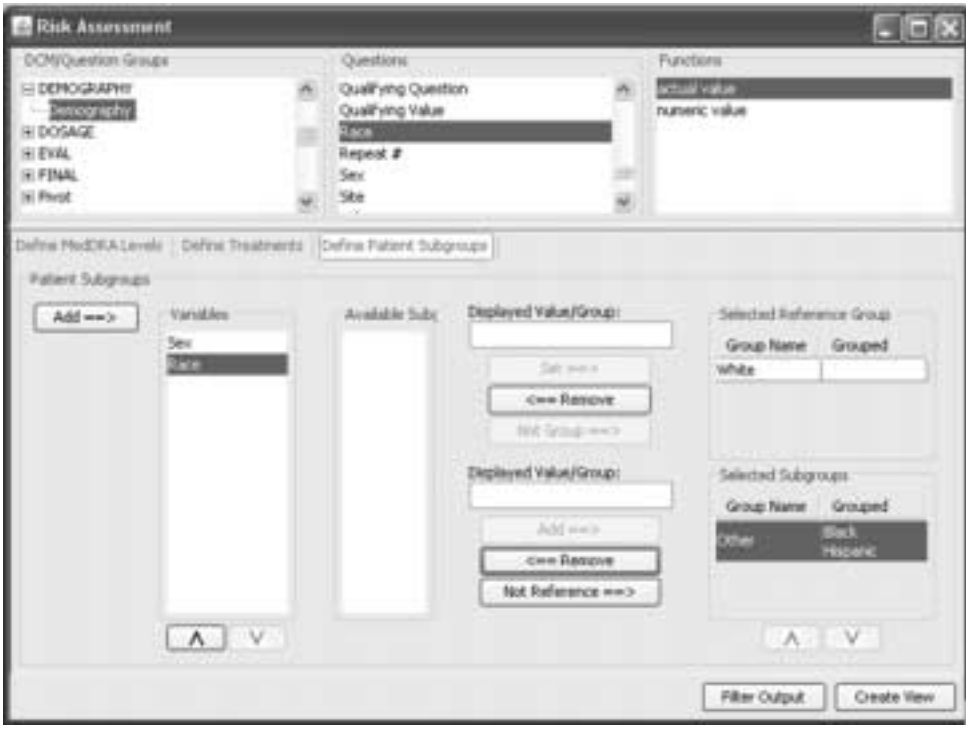
    Use the **Remove** button to select and remove individual variable selections.



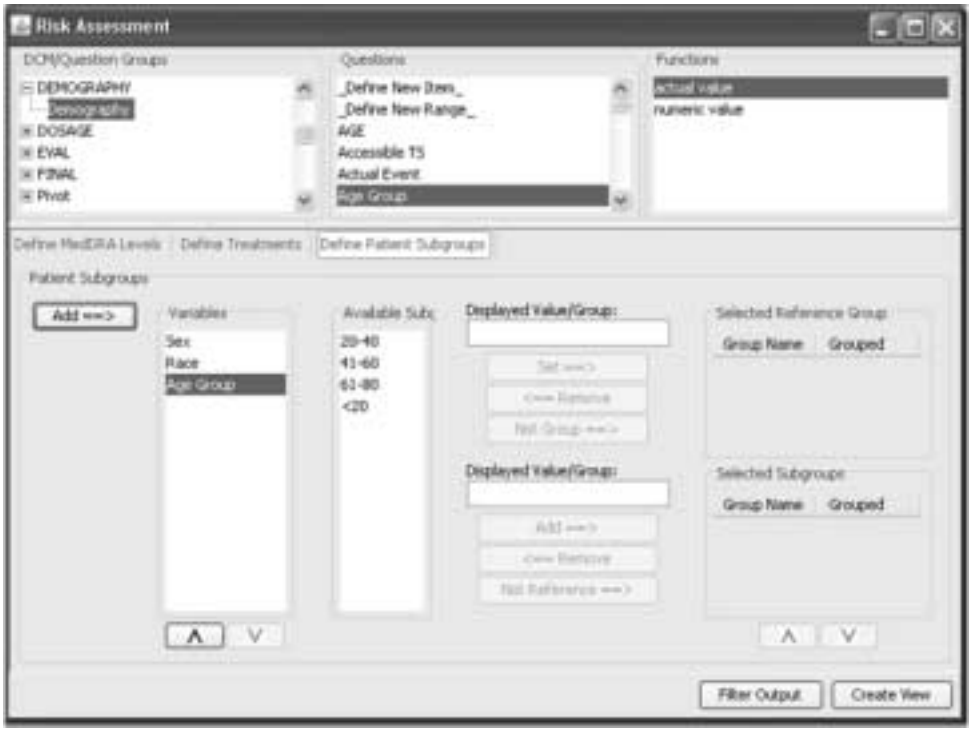
You may add multiple variables if needed, optionally rename a subgroup description, or define a subgroup with multiple selections, and enter a new group name.

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.

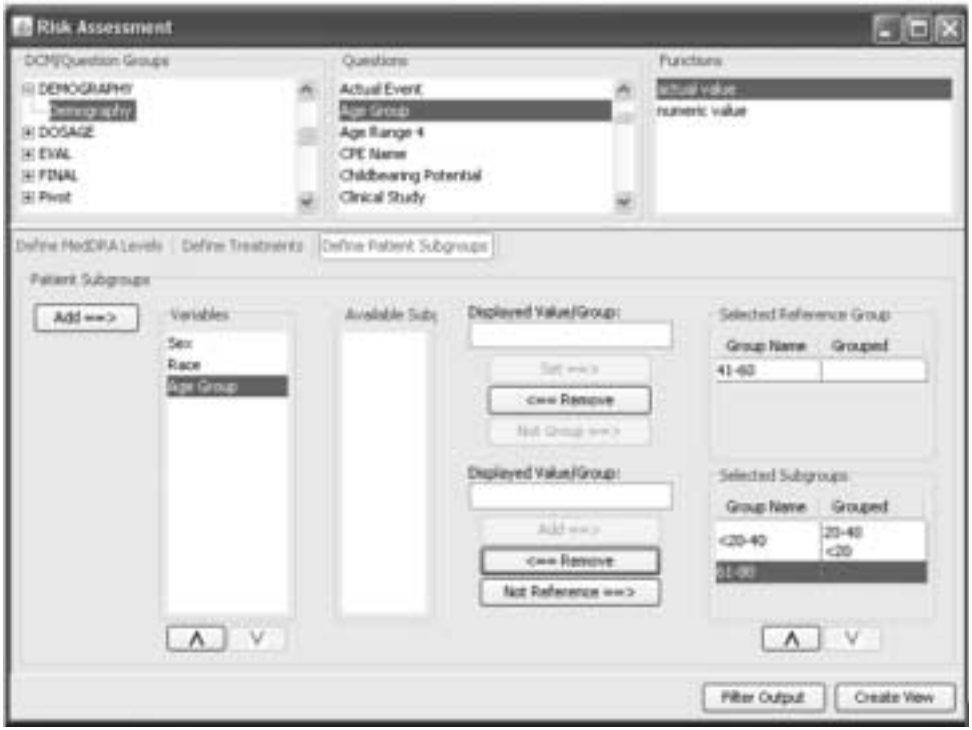


Another Patient Subgroup example shows the new data range defined for Age Group was added with four available subgroups. Again, you may organize and add as individual subgroups.

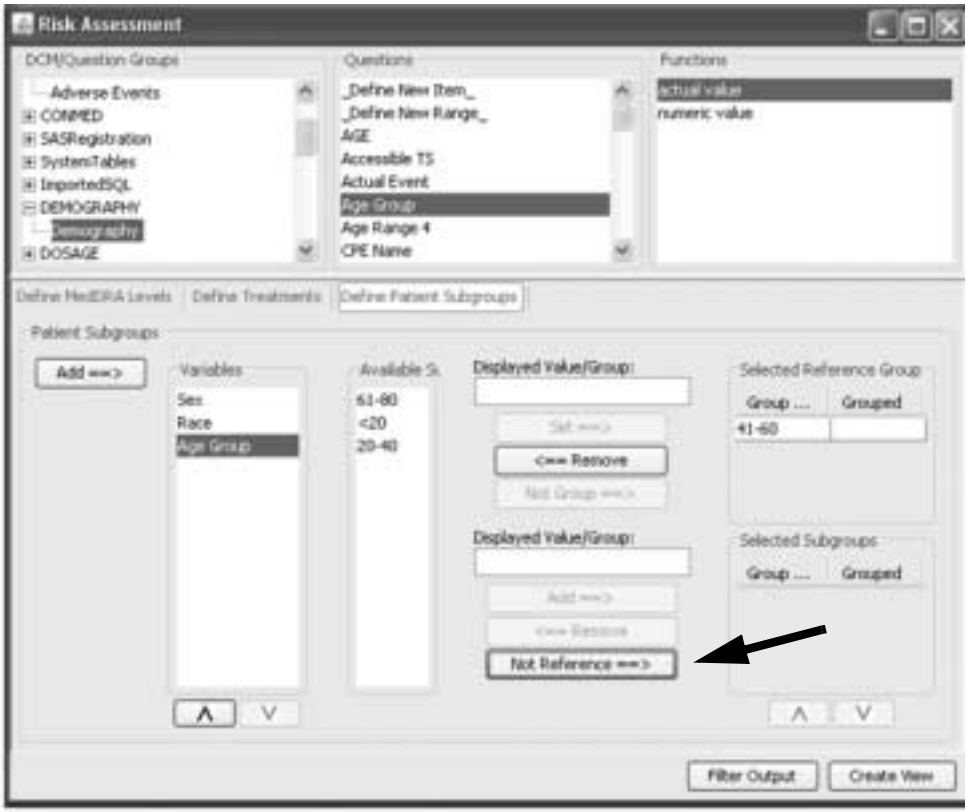


The Age Group for 41 - 60 was selected and set as the Reference Group for the denominator in the ratio calculation.

Next the new label for '<20 - 40' was entered in the Dispalyed 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**.

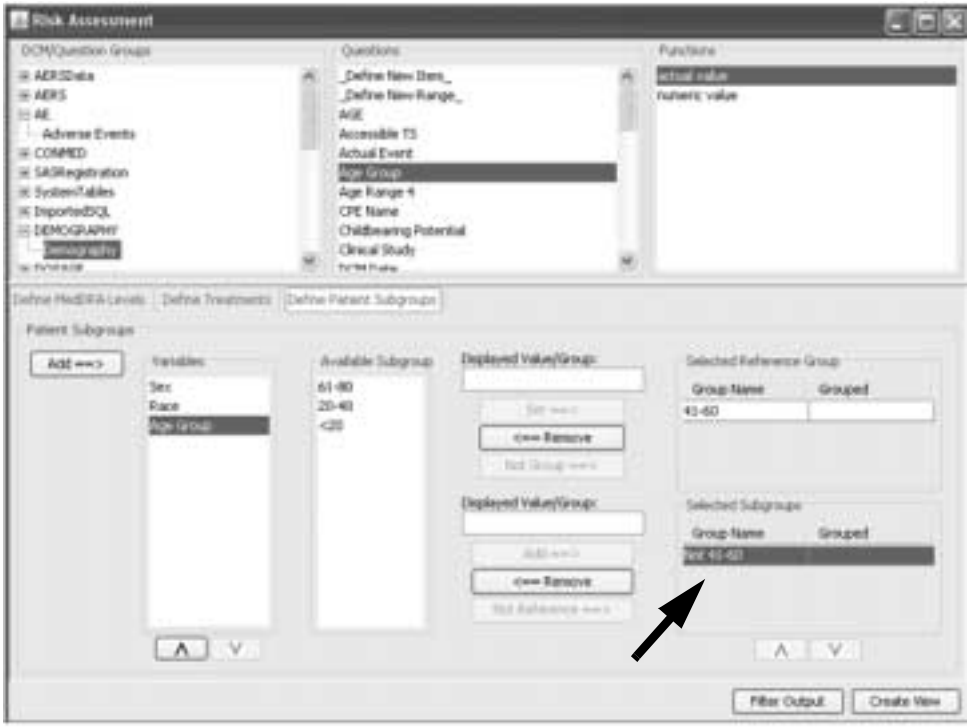


If you wish to consolidate multiple subgroups instead of entering as individual subgroups, you may use the **Not Group** or **Not Reference** feature.



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'.



Interact with Risk Assessment Results

View Risk Assessment

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.**

The Risk Assessment window opens organized with the **Select View Options** located at the top for **Treatment, Metric**, and **MedDRA Level**. 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 Risk Assessment analysis plot below 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.

The top Patient Subgroups plot displays the two treatment group arms with separate ratios displayed at baseline. When an SOC is selected the treatment arms re calibrate to show ratio differences between treatment arms separated by confidence intervals.

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.

You may hover over a SOC dot to display a tool tip window of specific details for relative risk ratio and percentages.

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.

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.

If you click on the plus sign for the SOC, you can display the list for the next MedDRA Level term entered for HLT. Use the same steps to select more detailed level for ratio calculations, and to drill down into the levels below HLT, if they were entered in the MedDRA details.

Select patient subgroup

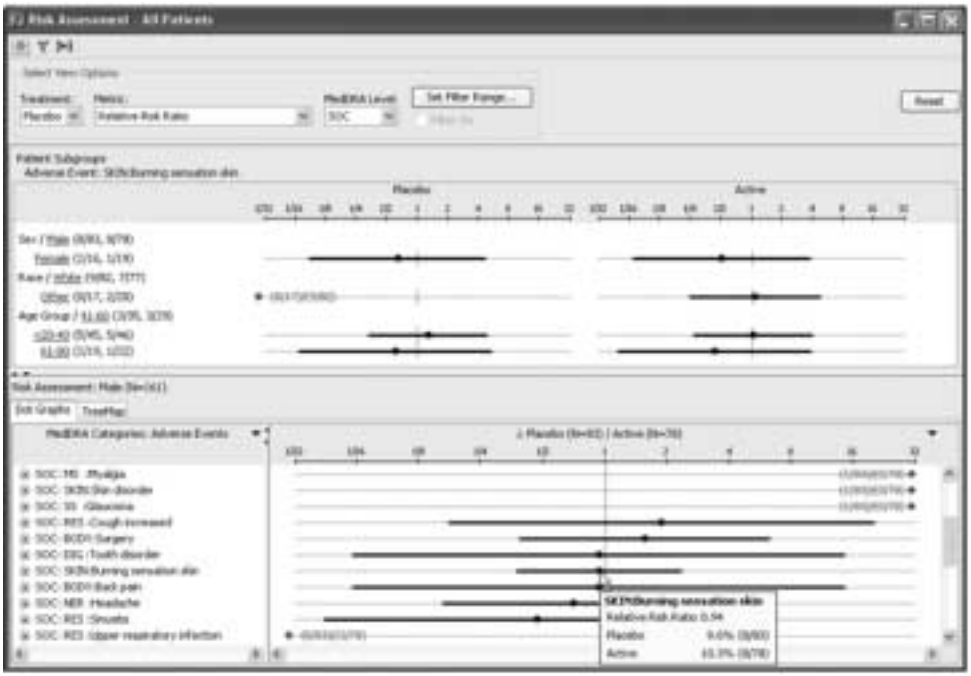
Select a patient subgroup by clicking on the highlighted subgroup, then the Risk Assessment recalculates the distribution and the header updates for the selected patient subgroup. The Risk Assessment difference as different calculation shows for multiple patient population options when applied. Red shows 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 = 0.1025 = 10.3%

Placebo 8 / 83 = 0.0963 = 9.6%

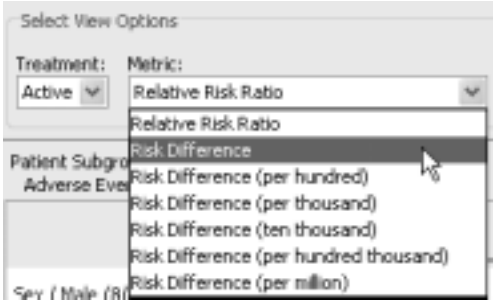
0.1025 / 0.0963 = Relative Risk Ratio 1.064



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.

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'.

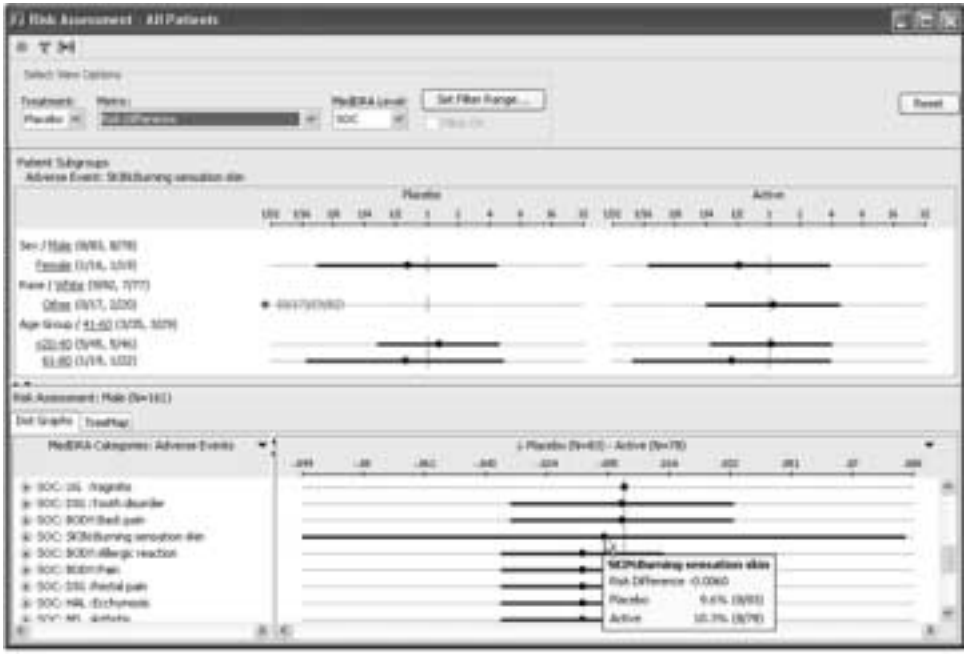


The Risk Difference recalculates as follows:

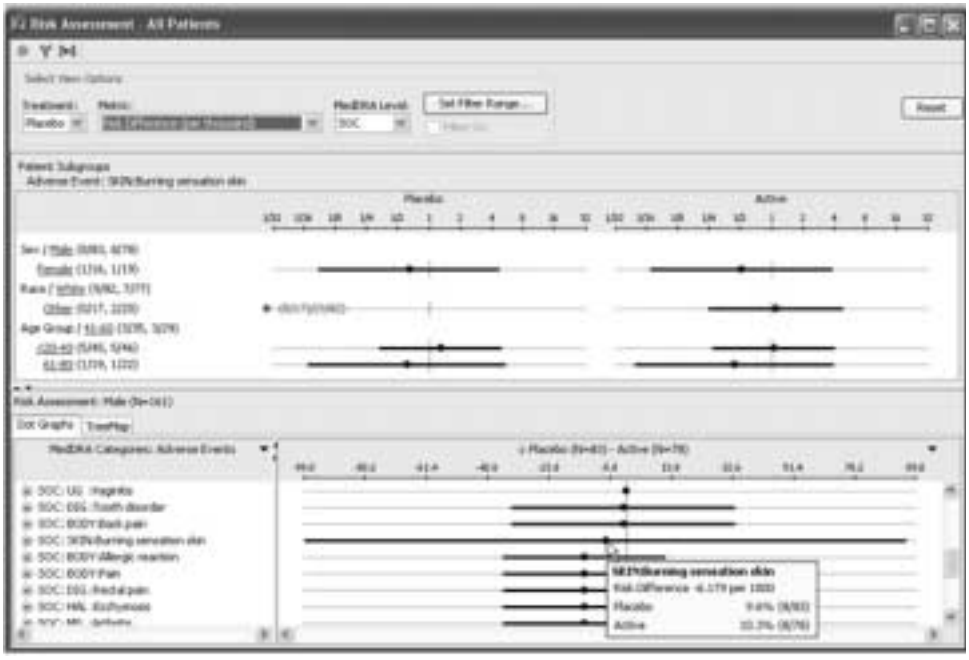
Active 8 / 78 = 0.1025 = 10.3%

Placebo 8 / 83 = 0.0963 = 9.6%

0.1025 - 0.0963 = Risk Difference 0.006



Other risk difference options may be selected for comparison.

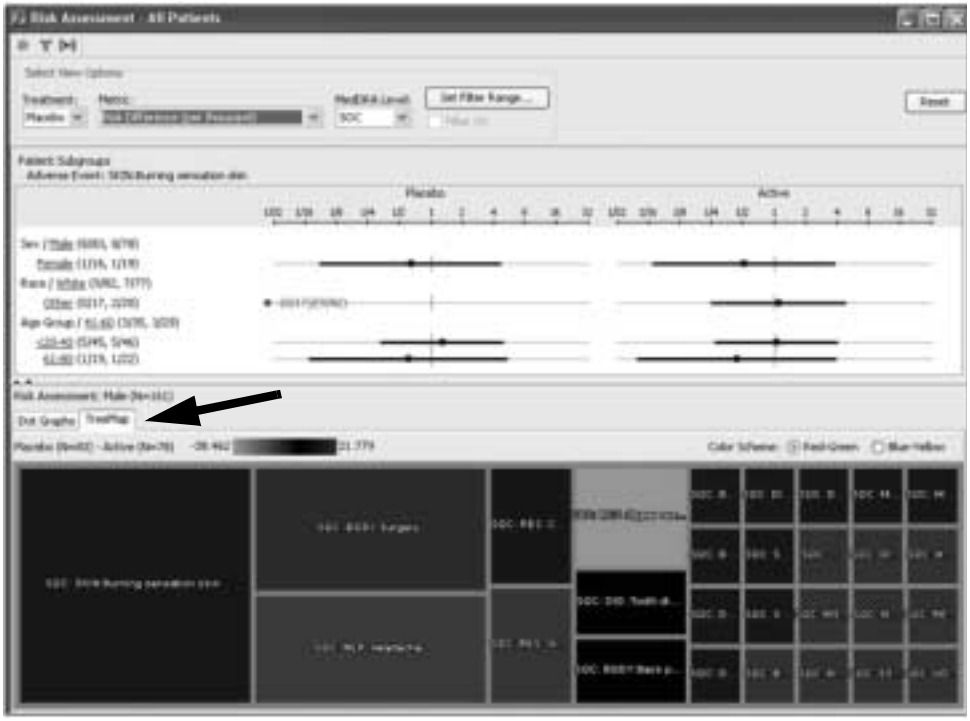


Patient Highlighting

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

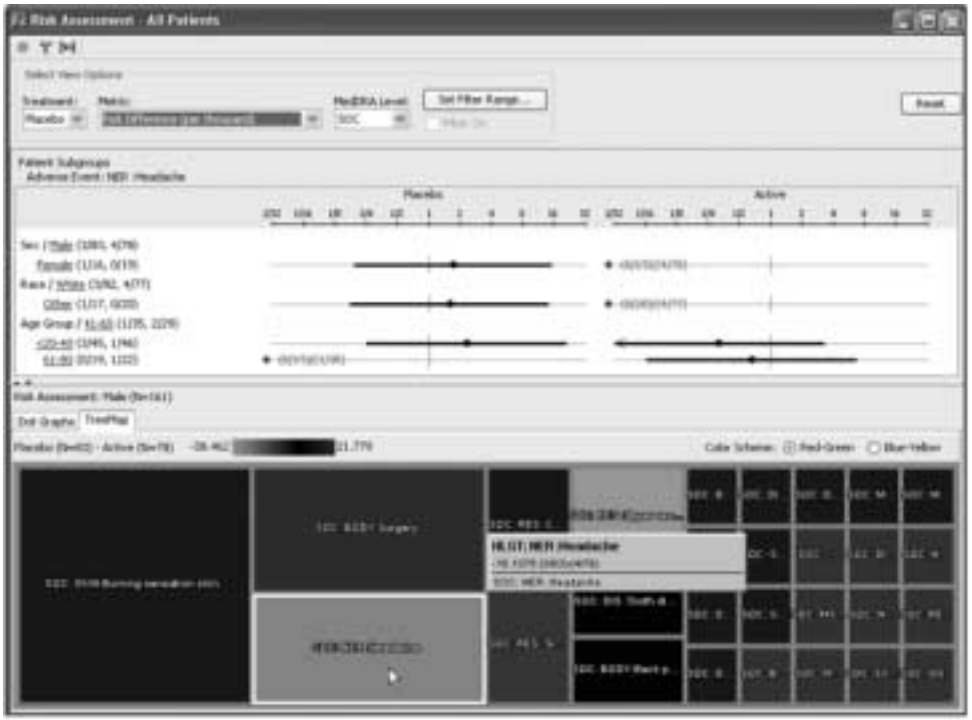
Another Risk Assessement viewing option is the TreeMap. Click on the TreeMap tab to display a rectangle presentation of an adverse event.



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.

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.

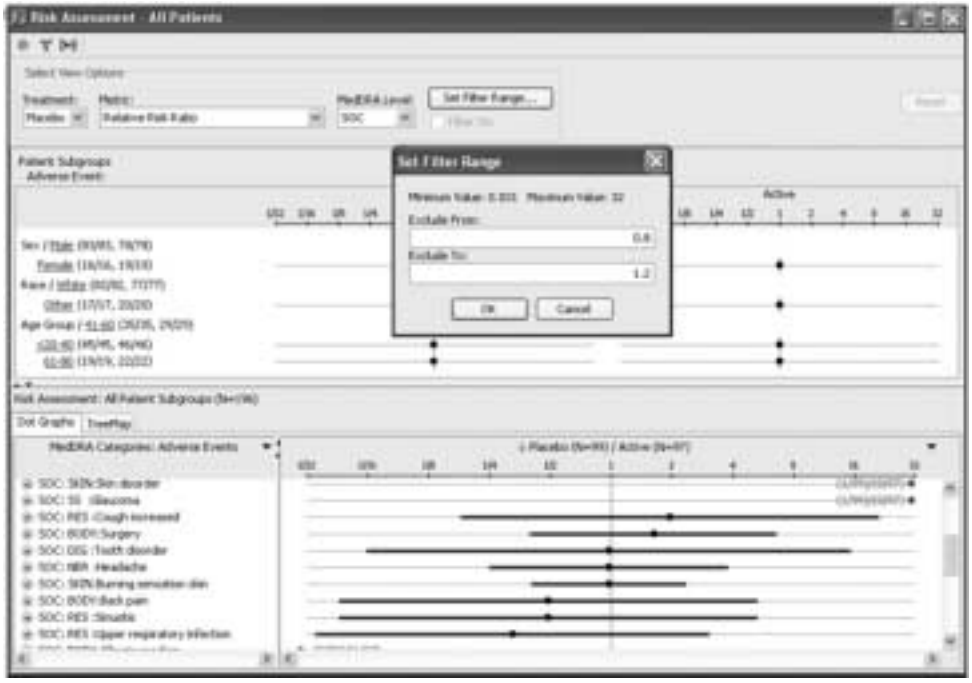
Double clicking on a rectangle allows the user to zoom-in to a lower level in the MedDRA hierarchy.

Filtering visual results

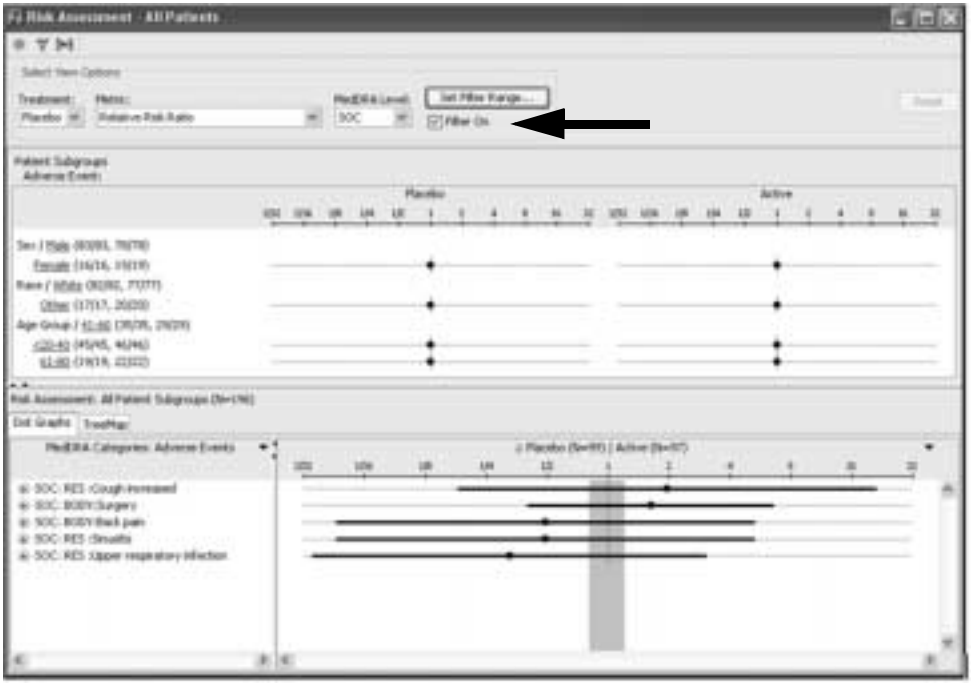
Set Filter Range

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.



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.



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.

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.*

Note: The ability to schedule saved Risk Assessment objects will be available in a future release.

Index

A

Abnormal Only 197
Access Import SQL 615
Access tab 60, 569
Access to SAS datasets 101, 219
Actual value function 53
ADD Class 479
ADD Dependent 480
ADD Expression 245
ADD Independent 480
Add Logo 274
Add to Favorite Viewsets 656
Add to Favorites 658
Add to Viewset 653
ADD Var 479
Add vertical lab 268
Adding BY variables 468
Adding criteria expression 44
Adding expressions 245
Adding items 219
Adding items to be analyzed 468
Adding operators 624
Additional criteria expressions 44
Alert activation 591
Alerts Browser 584
Alignment 280
Analyze Combinations 437
AND 37
ANDSELECT 37
Appearance options 204
Apply Page Header and Footer 273
Assign Baseline 443
Assign Endpoint 443
Autosize Columns 285
Auxiliary Windows 527
Available Groups 669

B

BarChart Frequency Distribution graph 338
BarChart Graph 375
BarChart item Summary vs. Category 340
BarChart Item Summary vs.Category 342
Baseline vs. Endpoint scatter plot 328
Baseline vs. Max Value Scatter Plot 329
Baseline vs. Min Value Scatter Plot 329
Break Definition 280
Browse 527
Browse menu 74, 218, 585
Browse Server 527
Browsing saved selection criteria 66
Building a string expression 55
BY Item 195
By Var 468
BY variable 328

C

CACHED Mode 646
Calendar Year 54
Case Froze 76
Case Frozen 92
Case Frozen Panel View 76
categorical patient counts 372
Categories Included 193
Category 537, 551
Category Colors 207
Category settings 207
cell variable 397
Change graph specifications 319
Change mode 646, 648
Change Schedule 582
change the report 221
Change Time Axis 190
Changing a SAS Proc specification 470
Changing the patient selection criteria 96, 301, 380, 488
Changing the report specifications 221
Changing the selection criteria 51
Character (Text) type data 54
Check SQL 253
chg. from baseline 54
chg. from previous 54
Choose Filter Control 356
click and drag function 371
Clintrial tags 489
Clintrial Type 0 panel 599
Closing a graph window 381
Closing a panel view 98
Closing a report window 157, 212
Closing a SAS Proc output window 488
Closing report browser and reports 301
Closing the Data Browser window 98
Closing the Graph Browser 381
Closing the Report Browser 157, 212
Closing the SAS Proc Browser 488
Col Totals 423
Color 293
color highlight 227
Column Group Headings 278

Combination Explorer 432
common panels 35
complex expression 622
Composites 522
Conditional Data Highlighting 288
configuration tables 61, 570
contiguous protocols 35
Continuous mode 587
control operator precedence 622
Converted SAS programs 495
COPY 188
count distinct 233
Count item value 234, 235
Create New Viewset 648
Create Options window 463
Create paramete 224
Create Patient Visit Data Report 263
Create Profile 199
Create SAS DataSet 455
Create SAS View 455
Create ViewSet 655
Creating a SAS Proc output filter 457
Creating the SAS Proc output 457, 470
Creating the table output 561
CrossTab 387
CrossTab - Combination Explorer 387
CrossTab Browser results 94
CrossTab Side by Side 430
CrossTab Side by Side Columns 387, 430
CrossTab Side by Side columns 430
CrossTab table results 98
Custom 606
Custom Join 606
Customize 121
customized patient profiles 107

D

Dashboard tool bar 648
Dashboard Viewsets 660
Dashboard Viewsets tab 651
data access 646
Data Browser 73
data categories 175
Data Highlighting 288
Data Highlighting button 289
Data Review 76, 113
Dataset 522
Datasets tab 507
date formats 54
Date function 54
Date type 54
decimal places 422
Default and new events 219
default function 54
Default GPP 648
default join logic 599
Define Critical Panels and Items 127, 130
Define Custom Joins 611
Define Date Merge Settings 262
Define Graphic Profile 189
Define Header 118, 161
Define Join Logic 600
Define MedDRA levels 668
Define New Event 632
Define New Item 618
Define New Range 628
Define Parameter 224, 250
Define Patient Subgroups 671
Define patient visit data report 259
Define Treatments 669
Defined New Item 619
Defining a CrossTab table 389
Defining a report title 222
Defining a SAS Proc specification 457
Defining a Shift table 440
Defining range cut points 629
Defining Report Specifications 218
Defining row results 224
Definition tab 58, 502, 568
derived values 53
Descend N(%) Sort 421
Detail Data Listing 217
Detail Data Listing reports 98
Disable Filtering 249
Discrepancy records 91
Discrepancy reports 98
Display all studies 66
Display excluded patients 51
Display multiple pages 309
Display Stats 55, 245, 267, 289
Display Time items 189, 191
Display Values 245, 267, 289
Displaying item statistics 55
Displaying subsets of protocol population 57
Dosage Category Type 180
drill down 663
Duration Category Type 178, 179

E

Edit a saved SAS Proc specification 470
Edit graphic template 189
Edit reports sort order 220
Editing a CrossTab specification 444
Editing or deleting a new event function 635
Enter Import SQL SELECT statement 615
exclude option 52

Exclude patient criteria 51
Execute object tab 651
Expanding spreadsheet columns 74
Explorer tab 648
Exporting a patient profile 143, 209
Exporting the report 211, 300
Exporting the result 474
Expression Items editbox 622

F

Filter Controls 355
Filter is ON 247
Filter Output 393
Filter Range 685
Filter Subject Count 414, 417
Find menu command 91
First Column Totals 425
First Column Totals (All sub) 427
Font 273
Footer 273
Format Column 280
Format Column Headings 277
Format Columns 148, 280
format library options 463
Formatted Detail Data Listing 217, 272
Formatted Summary Listing 217
Freeze Case 76
freeze multiple panel views 92
Freezing a case 91
FREQ 455

G

General Info tab 517
GLM 455, 482
Global level 655
Global New Item 625
Global object storage 602
graph format 79
Graph settings 204
graph specification 316
Graph Toolbar 309
Graphic Patient Profile template 167
Graphic Profile Filter Output 124, 143, 209
Graphic Profile Template 167
Graphic regional patient selection 371
graphic user interface 164, 201
Group Function 394
group functions 340
Group Header 275

H

Header 273
Header Items 174
Headers and footers 207
Heading Options Override Programs 533
Highlight Cell 289
Highlight Line 289
Highlight patient data 139
Highlighting data check ranges 227
Highlighting patients 257
horizontal panel display 78

I

Import SQL 615
Include N(%) 417, 419, 431
Include Row% Col% 400
Insert Item 484
instance ID 11
Interactive patient-level displays 448
invalid ORACLE user ID 13
Item Analyzed box 441
Item comparison selector 50
Item Mean and Standard Deviation vs. Category 353
Item Selector 484, 485
Item Statistics 55

J

Join logic 489
Join Order 224, 603, 607
Join type 613
Joining criteria expressions 43
JReview Console 30

L

Legend 195
Legend option 197
Library 537, 548
LIFEREG 455
LIFEREG Options 486
LIFETEST 455
LIFETEST Options 487
LIVE Mode 646
Load Defaults 610
Lock mode 142
LOGISTIC 455, 480

M

main window 16
Manage SAS objects 536
Manage SAS programs 536
mathematical break point 227
mathematics operator 618
Maximum Number of Columns 122
Maximum value 629
Mean at change 226
Mean at Change and Mean 226
Mean Numeric Format 282
MEANS 455
MedDRA Level 679
Missing data 163
mode options 646
Modify profile content 124
multi-dimensional analysis 389
Multi-Line graph 375
multiple contiguous values 41, 184
Multiple CrossTabs 444
Multiple graphs 315
multiple non-contiguous values 41, 184
Multiple SAS Proc outputs 490
multiple SAS Proc outputs 562
multiple SAS Proc results 458
multiple worksheet mode 115
Multiple-patient mode 91, 297, 371
multi-protocol mode 35
multi-visit 440

N

New Event Function 53, 490, 632
New Item dialog box 627
New Viewset 648
non-contiguous protocols 35
Normal Range 197
Normal range multiplier 197
NPAR1WAY 455, 479
Number of ID Items 122
Numeric Format 281
Numeric type data 54

O

Object 63, 537, 570
Object Explorer quick execute 102, 216, 305, 386, 456, 575
Object Explorer Window 34
Object Explorer window 63, 102, 216, 305, 386, 456, 574
Object Group 537
Object level 60, 63, 569
Object properties 66, 579
Object storage 450
Object storage location 63, 570
Object versions 574
One Time mode 587
On-line help 15
Open 576
Opened SAS production table results 564
Opening multiple SAS Proc results 475
Opening the Table Browser 558, 559
Operation tab 587
operator field 622
Operators 42
Optional output filter 393
OR 37
ORACLE database 12
Orientation 121
Output filter 249, 318
Output filter icon 236
Overall Column Formats 280

P

Page Format Overrides Programs 533
Page Header 273
Page Report By Item 273
Page Setup 285
Parameter Value Choices 251
Parameters tab 510
partial strings 42
password 11
patient counts 387, 449
Patient Drill Down 301, 380
Patient Drilldown 96
Patient Info Items 261, 299
Patient level notes 91
Patient Profile Browser 104, 199
Patient Profile Review Tracking Tool 127
Patient Profiles Browser 166
Patient Review Levels 129
Patient Review Log 138
Patient selection criteria 216
Patient Selection Criteria tab 661
Patient Subgroups 679
Patient Tracking functions 127
Patient Visit Report 217
Percent Denominator 399
Pivot Panel Type 640
Pivot panels 489, 636
Preferences 592
Print Format 531
Print Format Overrides Programs 533
Print Preview 94, 161, 210, 299, 378, 445, 563

Print / PDFs 205
Print / Subset tab 516
Printing a patient listing 154, 210
Printing the CrossTab specifications 451
Printing the report 299
Printing the report specifications 451, 575
Printing the SAS Proc results 458, 473, 563
Private (db) 570
Program Group 537, 541
Program Includes 515
Project level 655
Properties 312, 579
Protocol comparison 301, 490
Public (db) 570
Public storage 61
Publishing Authorization 61, 570

Q

Question Mark 309

R

R program 521
range bars 353
Range Max 629
Range values 442
red colored filter icon 18
Reference Group 670
REG 455, 480
register SAS programs 493, 558
Registered production tables 493, 558
Registered SAS programs 494
Remove 578
Remove a stored object specification 301
Remove Scheduled Jobs 581
Remove ViewSet 658
Removing a saved report specification 301
Removing a saved selection criteria 301
Removing logical join 603
Report Column Formatting 280, 282
report heading 222
Report output filter 301, 380
Report types 217
Reset 310
Reset Columns Widths 285
Retrieve stored specification from file menu 576
Retrieving a saved report specifications 576
Review Levels 129
REVIEWSTATUSLIMIT 142
Risk Assessment 666
Risk Difference 681
Row Totals 424
runtime parameters 249

S

SAS datasets 35, 101, 219, 392
SAS log 457, 472, 561
SAS Name field 624
SAS output 457, 472, 561
SAS Proc FREQ with Statistics 455
SAS Proc output filter 471, 489
SAS Procs 459
SAS Program 538
SAS Program Registration Browser 496
SAS Program Registration window 496
SAS source 457, 472, 561
SAS user-level setting 459
Save Filter 247
Save SAS Program Registration 518
Save template 188
Save Viewset 648, 655
Saved output specification 574
Saving Data Browser specifications 95, 154
Saving the new item 624
Saving the new range variable 630
scatter (Item X vs Item Y) Plot graph 319
Scatter Plot graph 371
Scatter plot graphs 98
Schedule output 580
Schedule SAS Proc jobs 478
Select defined template 190
Selected Group 670
Selecting a panel 37
Selecting a panel, item, and function 218, 389
Selecting a project 34
Selecting a table 561
Selecting an operator 55
Selection set 216, 305, 386, 456, 558
server names 11
Set Default GPP 652
Set Filter Range 685
Severity 293
Shift Table 387
Show Default GPP 647
Show Details 222
Show Empty Columns 395
Show Empty Rows 395
Show New Data Only 139
Show Only New data 139
Single Patient Mode 368
Single patient mode 295
single worksheet mode 113
single-protocol mode 34
Snapshot 309
Sort by Code Value 393

Sort by Code Values 393
Sort Option 196
Sort Order 283
sort order 283
SQL details 642
SQL statement 253
standard deviation 353
Statistics options 468
Status 537, 553
string expression 43
study group 62, 571
Study Includes 515
Study level 655
Study lock 142
Study Override 572
study start date 170
StudyID 35
Sub Panel 110
sub-population of patients 57
sub-population statistical responses 559
sub-populations 33
Subquery 49
Subset on observation and/or visit 243, 319
subset patient populations 375, 376
Subset using Select Criteria 57
Substitution parameter tokens 506
Subtotal 2nd Column 428
Subtotals 2nd Column 416
Sum at change 226
Summary Listing 217
Summary Listing features 230
summary statistic 342
Supplying a value 55
Suppress duplicate rows 229
System Administrator 559

T

TABULATE 455
Test JPUT 30
Text Category Type 181
Text data type 42
text string operators 42
Time Axis scale 178
Time point type 186
time-related milestones 632
Toolbar 471
ToolBar buttons 22
Totals Subject Count 410
Totals=Subjcount? 419
Transposing normalized clinical Data 636
TreeMap 683
TTEST 455, 479

U

unfreeze a panel view 93
Unique Values 41
Update Browsers 301, 380, 488
Update patient selection criteria 564
Update Patient Tracking 127
Update Patient Tracking Status 132
Updating Browsers 44, 55
User Group - Program 556, 557
User Group – Program 537
User-defined logical joins 599
user-defined time-related milestone 53
UserGroup (db) 570
Usergroup storage 61
Using Clintrial tags 243

V

Version tab 574
vertical panel display 77
View Number 653
View patient counts 432
View Patient Log 137
View Patient Tracking 127
View Scheduled Jobs 581
Viewset Storage Location 655
ViewSets 643, 665

W

Watermark 286
Who 309
Who icon 235
Wrong password 13