RELEASE 8.0

Integrated™ Review

Guide to Exploring Clinical Data

Copyright © 1994 - 2004 by Integrated Clinical Systems. 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.
38 Milltown Rd
Stockton, NJ 08559

First Printing: January 2004

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 of Integrated Clinical Systems, Inc..

All other trademarks are owned by their respective companies.

Contents

1 Getting Started

Introduction 23

What is Review 23

Features 23

Starting the application 25

Logging on 25

Choosing an ORACLE database 25

Using an ORACLE connect string 26

Using Personal Oracle7 26

Wrong password? 26

On-line Help 27

On-line Help 27

Terminology for Oracle Clinical users 29

Oracle Clinical terms 29

What are Oracle Clinical keys? 29

What are Oracle Clinical Data Structures? 30

What are Data Extract Views? 32

How does Oracle Clinical pass files to Review? 33

Terminology for Clintrial users 34

What is metadata? 34

What is a project? 34

What is a protocol? 34

What are database tables? 35

What are panels? 35

What are panel types? 36

What is a context panel? 36

What are context items? 37

What are items? 37

What are Database table types? 38

What are records? 38

Quick tour 39

Main window 39

Selecting a patient population 41

Menu bar and windows 42

Toolbar 44

Review workflow 46

2 Selecting Patients
Selecting a project 50
Selecting a project 50
Selecting protocols 50
Single-protocol mode 50
Multi-protocol mode 51
Specify Patient selection criteria 52
Review sub-populations 52
Focused analysis 52
Steps for selection criteria 53
Access to SAS datasets 54
Building and Joining Criteria Expressions 55
Logical expressions 55
Selecting a panel 55
Selecting an item 56
Panel item profiles 57
Supplying a item value 57
Displaying item values 58
Selecting multiple values 59
Selecting an operator 60
Building a string expression 60
Additional criteria expressions 61
Boolean operators 62
AND operator 63
OR operator 64
ANDSelect operator 65
Build a complex patient selection criteria 66
Changing the selection criteria 67
Updating Browsers 68
Criteria description 68
Item comparison selector 69
Compare items 69
Exclude patient criteria 70
Display excluded patients 70
Functions 72
Types of function values 72
'Actual value' function 72
Derived function values 72
Date function 72
New Event Function 73
Displaying item statistics 74
Display stats 74
Displaying subsets of protocol population 75
Clintrial tags 77
Clintrial tags as pseudo-panel 77
Optional user-defined panels and joins 78
Pivot Panels 78
Join Logic 78

Object storage: saving your work 79
Object storage location 79
Object level 80
Saving the selection criteria 81
Override selected Project / Global object? 82
Object Explorer window 83
Retrieve a saved selection criteria 84
Append to criteria 84
Display all studies 87
Browsing saved selection criteria 88
Object properties 89
Printing the selection criteria 90
Quick remove 91
Exploring data 92
Reviewing preferences 92
Outer join in Results 92
Display panel names 93
Display item names 93
Sort panels alphabetically 93
Sort items alphabetically 93
Reviewing with browsers 93

3 Reviewing Patient Data
Patient selection criteria 98
Subset patients 98
Open the Data Browser 99
Listing of patients 99
Data Review 99
Graph format display 102
Browsing through patient data 103
Displaying CRF images 104
Audit trail 104
Reviewing tags (flags and notes) 105
Discrepancy records 106
Discrepancy record panel view 106
Creating discrepancy records 106
Selecting data for discrepancy record 107
Avoid duplicate discrepancy records 109
Patient level notes 110
Store and retrieve patient notes 110
Find menu command 112
Remove note 112
Multiple-patient mode 113
Freezing a case 113
CrossTab Browser results 116
Patient listings and panel views 117
Expanding spreadsheet columns 117
Print Preview 117

Printing a patient listing 117
Printing a panel view 118
Exporting a patient list or panel view 118
Custom panels 119
Define custom panels 119
Custom panel output filter 121
Update or remove custom panel 123
Modifiable items 124
Defining modifiable items 124
Modifying data 126
Modifying coded data 128
Reset items content 129
Saving Data Browser specifications 130
Object storage location 130
Object level 131
Store a selection of panel views 131
Override selected Project / Global object? 133
Object Explorer Window 133
Retrieve a saved Data Browser object 134
Open saved Data Browser settings 134
Quick remove 136
Object properties 137
Updating the Data Browser 138
Closing panel views and the Data Browser 139
Closing a panel view 139
Closing the Data Browser window 139
Exploring data 139
Changing the patient selection criteria 139
Patient identification 139
Discrepancy reports 140
Detail Data Listing reports 140
Scatter plot graphs 140
CrossTab table results 140
Data Browser and pivot panels 140
Data Browsers and join logic 141

4 Patient Profiles
Patient Profiles Browser 145
Selection set 145
Open Patient Profiles Browser 145
Define patient profile matrix 146
Selecting a workbook type 147
Initial default settings 147
Single worksheet mode 148
Multiple worksheet mode 152
Defining a patient profile 155
Modify profile content 155
Access to SAS datasets 155

Define Sub Panel 156
Define Header 156
Customize patient profile output 159
Sort Order 161
Filter Output 162
Patient Profile Filter Output 162
Patient Profile display 163
Expanding spreadsheet columns 163
Print Preview 164
Printing a patient profile 164
Exporting a patient profile 165
Formatted Patient Profile 166
Select formatted profile 166
Activate Page Break 168
Apply Page Header and Footer 168
Format Column Headings 170
Format Columns 171
Preview / Page Setup 172
Page Setup 173
Number of ID items 173
Panel Orientation 174
Column width 175
Object Storage: saving your work 177
Object storage location 177
Object level 178
Saving Patient Profile specifications 179
Object Explorer window 180
Object Explorer quick execute 181
Retrieving a saved Patient Profiles specifications 182
Object properties 183
Quick remove 184
Removing a saved Patient Profiles specification 184
Printing the Patient Profiles specifications 185
Closing Patient Profiles Browser 185
Closing the Patient Profiles Browser 185

5 Graphic Patient Profiles
Patient Profiles Browser 189
Open Patient Profiles Browser 189
Graphic Patient Profile 190
Access Graphic Patient Profile 190
Define Graphic Profile Template 190
Graphic Profile Template 190
Define study start date 192
Define header items 195
Category types 196
Define Category Information 197
Time Axis scale 198

Duration Category Type 199
Dosage Category Type 200
Text Category Type 201
Laboratory Category Type 203
Time Point Type category 205
Save template 208
Edit graphic template 208
Define Graphic Profile 209
Select defined template 209
Change Time Axis 209
Change Limit value 210
Display Time items 210
Select categories for display 211
Select Items for display 211
Normal range multiplier 214
Create Graphic Patient Profile 217
Missing data 218
Basic graphic user interface 218
Filter Output 221
Patient Profile Filter Output 221
Graph settings 223
Select settings 223
Appearance options 224
Printing and PDF output settings 225
Color settings 226
Headers and footers 227
Category settings 227
Graphic Patient Profile display 229
Print Preview 229
Printing a patient profile 229
Exporting a patient profile 230
Object Storage: saving your work 231
Object storage location 231
Object level 232
Saving Patient Profile specifications 233
Object Explorer window 234
Object Explorer quick execute 235
Retrieving a saved Patient Profiles specifications 236
Object properties 237
Quick remove 238
Removing a saved Patient Profiles specification 238
Printing the Patient Profiles specifications 239
Closing Patient Profiles Browser 239
Closing the Patient Profiles Browser 239

6 Reporting
Patient Selection Criteria 245
Selection set 245

Report types 246
Selecting a report type 246
Steps for report building 248
Defining Report Specifications 249
Selecting a panel, item, and function 249
Adding items 250
Default and new events 250
Access to SAS datasets 250
Column autosizing 251
Edit report sort order 251
Edit report column order 251
Changing the report specifications 252
Edit column heading 252
Defining a report title 252
Create report 253
Find menu command 253
Detail Data Listing features 254
Defining row results 254
Using mathematical row results 255
Highlighting data check ranges 258
Suppress duplicate rows 260
Include? prompt 262
Summary Listing features 263
Count distinct 265
Count item value 266
Snapshot output 270
Multiple population mode 270
Join Order 272
Join order in multi-panel reports 272
Output filter 277
Subset on observation and / or visit 277
Creating report output filter 278
Comparing items 279
Adding expressions 279
Apply report output filter 281
Define Parameter 282
Runtime parameter 282
Create parameter 282
Enter runtime parameter 285
Patient Visit Report 286
Select panel visit report 286
Define patient visit report 287
Report options 287
Add Patient Info Items 289
Define Date Merge Settings 290
Create Patient Visit Report 292
Add vertical lab 293
Formatted reports 295
Select formatted listing type 295

Apply Page Header and Footer 296
Enter a Group Header 298
Format Column Headings 299
Format Columns 301
Sort Order 304
Preview / Page Setup 305
Create formatted report 307
Exporting and printing report results 308
Exporting the report 308
Print Preview 309
Printing the report 309
Page Setup 309
Highlighting patients 311
Single patient mode 311
Multiple-patient mode 313
Object Storage: saving your work 315
Finalize output specification 315
Object storage location 315
Object level 316
Save the object specification 317
Object Explorer window 319
Object properties 320
Print stored object specification 321
Object Explorer quick execute 322
Retrieve stored specification from file menu 323
Schedule output 324
Object Explorer scheduled output 324
View Scheduled Jobs 327
Remove Scheduled Jobs 327
Change Schedule 328
Review output 329
Locate stored output results 329
Quick remove saved output results 330
Delete multiple output 330
Quick remove a stored object specification 331
Remove a stored object specification 331
Closing report browser and reports 332
Closing a report window 332
Closing the Report Browser 332
Exploring data 333
Changing the patient selection criteria 333
Pivot panel presentations 333
Report output filter 334
Patient identification 334
Define Join Logic 334
Clintrial tags 334
Protocol comparison 335
New Event Function 335
Outer Joins 335

FULL JOIN 335

7 Graphing

Patient selection criteria 340
Selection set 340
Opening the Graph Browser 340
Access to SAS datasets 341

Selecting a graph type 341
Detail Data Graph 341
Summary Data Graph 341
Bar Styles 342
Group Functions 343

Defining a graph specification 344
Creating a graph specification 344
Change graph specifications 346
Graph Browser output filter 347

Graph display results 347
2D Graph Toolbar 347
Display multiple pages 348
Change graph style 349
Highlight the graph 351
Zoom the graph 354
Resize graph image 355
Multiple graphs 355

Snapshot output 355
Multiple population mode 355

Patient subset by graph 356
Subset by graphic regional selection 356
Save Visual Subset 357
Remove Visual Subset 359

Types of Detail Data Graphs 360
Scatter (Item X vs. Item Y) Plot 360
Scatter Plot with Regression Line 365
3D Scatter Plot 367
Baseline vs. Endpoint Scatter Plot 369
MultiLine Chart Item Value vs. Category by Case 371
MultiLine Chart Item Value vs. Category by ByVar 373

Types of Summary Data Graphs 375
2D Bar Chart Frequency Distribution 375
X and Y scaling 380
3D BarChart Frequency Distribution 384
2D Bar Chart Item Summary vs. Category 386
3D BarChart Item Summary vs.Category 388
Pareto Chart Frequency Distribution 390
Pie Chart Item Summary vs. Category 392
Polar Chart Item Summary vs. Category 394
Radar Chart Item Summary vs. Category 396
Filled Radar Chart Item Summary vs. Category 398

Line Chart Item vs. Category 400
Item Mean and Standard Deviation vs. Category 402
Highlighting patients 404
Single patient mode 404
Multiple patient mode 407
Scatter plot graph 407
Multi-Line graph 407
BarChart graph 407
Pie Chart 407
Graph editing 409
Graph settings 409
General Setup 410
Display Setup 410
Axis Setup 411
Title Setup 411
Legend Setup 412
Printing Graphs 412
Print Preview 412
Printing the graph 413
Object storage: saving your work 413
Schedule output 413
Closing graphs and the Graph Browser 413
Closing a graph window 413
Closing the Graph Browser 413
Exploring Data 414
Changing the patient selection criteria 414
Multiple protocols 414
Graph output filter 414

8 CrossTab Browser
Patient selection criteria 419
Selection set 419
Open the CrossTab Browser 419
CrossTab Browser types of analysis 420
Selecting a CrossTab Browser type of analysis 420
Defining a CrossTab table 422
Selecting a panel, item, and function 422
Access to SAS datasets 424
Optional Include Row% Col% 424
Sort by Code Value 424
Output Filter 425
Edit column width 425
Add cell variable 425
Editing a CrossTab specification 427
Changing the CrossTab specification 427
Defining a Shift Table 428
Item analyzed 428

Create Shift Table 429
Range values 430
Include Row% and Col% 432
Multiple CrossTab/Shift Tables 433
Multiple CrossTabs 433
Snapshot output 433
Multiple population mode 433
Printing and exporting CrossTab/Shift Tables 434
Print Preview 434
Print the CrossTab / Shift Tables 434
Page Setup 434
Exporting the CrossTab / Shift Tables 435
Interactive patient-level displays 436
Detail data patient listings and graphs 436
Object storage: saving your work 438
Schedule output 438
Closing CrossTab tables and the CrossTab Browser 438
Closing a CrossTab Window 438
Closing the CrossTab Browser 438
Exploring data 439
Changing the patient selection criteria 439
CrossTab output filter 439
Pivot panels 440
Join logic 440
Clintrial tags 440
New Event Function 440

9 Generating Statistics
Patient selection criteria 443
Selection set 443
Opening the SAS Proc Browser 443
Selecting a SAS Proc type 444
Selecting a SAS Proc 444
Defining a SAS View and Dataset 445
Create SAS View and Dataset 445
Select format library options 448
SAS Transport Files 449
V5 (FDA Guidelines) option 449
Edit panels 451
Defining a SAS Proc Specification 452
Define SAS Proc specification 452
Adding items to be analyzed 452
Adding BY variables 454
Statistics options 454
Defining a SAS Proc title 455
Creating the SAS Proc output 456
Change a SAS Proc specification 456

Output filter 457
SAS Proc results display 457
Toolbar 457
Find menu command 458
Displaying the SAS output, source, or log 458
Exporting and printing results 459
Print Preview 459
Printing the SAS Proc results 459
Exporting the result 460
Other SAS Proc displays 461
Multiple SAS Proc outputs 470
Opening multiple SAS Proc results 470
Snapshot output 470
Multiple population mode 470
Saving a SAS Proc specification 471
Schedule SAS Proc jobs 471
Review output 471
Close SAS Proc Browser and results 472
Closing a SAS Proc output window 472
Closing the SAS Proc Browser 472
Exploring data 472
Changing the patient selection criteria 472
SAS Proc output filter 472
Pivot panels 473
Join logic 473
Clintrial tags 473
Protocol comparison 474
New Event Function 474

10 Registered SAS Programs
Selection criteria 476
Selection set 476
SAS program browser 476
Registered SAS programs 476
Opening the SAS Program Browser 476
Selecting a table 477
Schedule SAS Program jobs 478
SAS program results and log files 478
Multiple table outputs 479
Snapshot output 479
Multiple population mode 479
Exporting and printing SAS program results 480
Print Preview 480
Printing the table output 480
Exporting the result 481
Close SAS Program results window and SAS Program Browser 482
Closing the table output window 482

Closing the SAS Program Browser 482
Exploring data 482
Opened SAS production table results 482
Update patient selection criteria 482

11 Accessing Documents
Data source (protocol) 484
Selecting a data source 484
Open the Document Browser 484
Displaying a document 485
Closing the Document Browser 485

12 Common Topics
Shared object storage 490
Exploring interpretative consensus 490
Consensus of data interpretation 490
PC Based Object Storage 490
Private object storage 490
WorkGroup object storage 491
UserGroup object storage 491
Public object storage sites 491
SuperUser 492
Server-based global object storage 492
Global object storage 492
Sharing objects 492
Object level 492
Change User Password 493
Change password 493
Snapshot output 493
Multiple population mode 493
Snapshot output 494
Who is the patient population? 494
Pivot panels 495
Transposing normalized clinical data 495
Creating pivot panels 496
Defining logical joins 501
User-defined logical joins 501
Logical joins with Clintrial Type 0 501
Creating logical joins 502
Global object storage of join logic 503
Removing logical join 505
Import SQL 506
Access Import SQL 506
Enter Import SQL SELECT statement 507
Using Clintrial tags 509
Tags for selection and reporting 509
Access Clintrial tags items listing 509

Exploring clinical data with derived item values 510
Derived data item values 510
Derived items across panels 510
"_Define New Item_" 512
Adding operators 515
Saving the new item 517
Saving a Global new item 520
Editing defined new items 521
Removing saved new item definitions 522
Exploring clinical data with range variables 523
User-defined range variables 523
"_Define New Range_" 523
Defining range cut points 524
Saving the new range variable 525
Editing a defined range variable 525
Removing saved range variables 526
New event function 527
User-defined time related milestones 527
"_Define New Event_" 527
Editing or deleting a new event function 528
Exploring clinical data in multi-protocol mode by StudyID 529
Multi-protocol mode: protocol comparisons 529
Using the <StudyID> 529
Reviewing preferences 530
Open preferences 530
Automatic Outer joins 531
Optional Outer joins in Results 531
Use full joins in Selection Criteria 531
Displaying panel names 531
Displaying item names 531
Sort panels alphabetically 532
Sort items alphabetically 532
Patient subset footer as text 532
Clintrial Data Source 532
Single patient mode 532
Identify Patients with interactive browsing design 532
Patient-level results interact 532
Multiple patient mode 533
Patient-level and summary displays interact 533
Browsers interact 533
Summary results and patient level results 534
Displaying spreadsheets 534
Exporting browser spreadsheets 534
Browsers export spreadsheets 535
Copy to Clipboard 535
View SQL details dialog 535
Copying and pasting browser results 536
Browsers copy and paste 536

Index

1 Getting Started

Introduction **23**
- What is Review 23
- Features 23

Starting the application **25**
- Logging on 25
- Choosing an ORACLE database 25
- Using an ORACLE connect string 26
- Using Personal Oracle7 26
- Wrong password? 26

On-line Help **27**
- On-line Help 27

Terminology for Oracle Clinical users **29**
- Oracle Clinical terms 29
- What are Oracle Clinical keys? 29
- What are Oracle Clinical Data Structures? 30
- What are Data Extract Views? 32
- How does Oracle Clinical pass files to Review? 33

Terminology for Clintrial users **34**
What is metadata? 34
What is a project? 34
What is a protocol? 34
What are database tables? 35
What are panels? 35
What are panel types? 36
What is a context panel? 36
What are context items? 37
What are items? 37
What are Database table types? 38
What are records? 38
Quick tour **39**
Main window 39
Selecting a patient population 41
Menu bar and windows 42
Toolbar 44

Introduction

What is Review

Review is a fully integrated client/server data review tool that makes it easy to access, review, report and graph clinical data residing in your clinical or regulatory database (management) system. This powerful, user-friendly Windows application supports data review with interactive and integrated patient listings, reports (detailed, summary and formatted), graphical and statistical modeling of patient subsets and patient populations through multi-dimensional analysis. Review was specifically designed for the pharmaceutical industry to review clinical data and adverse events.

Features

In addition to supporting ongoing monitoring of patient safety and data quality, Review provides the following features:

- Review allows you to explore your data **visually to identify trends**.
- **Intuitive** and easy to use; **no programming knowledge required.**
- Direct and **immediate access to data** stored in existing clinical database (management) systems.
- The **data selection pathways mirror the organization of clinical trial data** and data selection processes are based on a "patient" paradigm.
- Easy assembly of Patient Selection Criteria to select Project, Protocols, and Data types. Focus on data values, ranges, and populations by **point and click creation of criteria expressions.**
- Multiple selections of data across different time periods may be viewed to identify trends and outlyers.
- Point and click utilities for creating and defining Pivot Panels, additional Join Logic, Clintrial 0 Type Panel Joins, New Derived Items, and user-defined Event Function Values such as baseline or endpoint.
- **Data Browser**; instant **Patient Listings** and **Panel Views (data lists) of subject data** of patients meeting current selection criteria. Use to view details of individual patient data, **CRF images**, **Audit Trails** and electronic **Notes**, accessible for all data values. View patient level trend graphs for multi-visit numeric data.
- **Discrepancy reporting**; point and click on patient data value(s) or data column in Data Browser Panel Views and create automatic discrepancy reports. Manually enter an appropriate message and optional priority status by clicking the **Create Discrepancy** button.

Automatically your discrepancy record is documented and entered into the Discrepancy Report Panel.

- **Patient Profile Browser**; defaults all panels / question groups of patient data into the generated patient profile spreadsheet. Or you can create a custom patient profile easily organized by panels / question groups or visit. Display results as single or multiple spreadsheets and print or export as a workbook by study site.
- **Graphical Profiles**; display time oriented graphical displays (days on drug): duration bars for AEs, Concmed, etc., trend plots with normal range color region, high / low normal symbols for labs, vitals, etc. Generate PDFs directly for all selected patients.
- **Report Browser**; mouse clicks on data panels and reporting functions; such as **Means**, **Baseline**, **Endpoint**, **Change from Baseline**, and **Change from Previous** to produce Summary and Detail Data Listing Reports. **Report formatting** may be applied. Color highlighting of out of range data based on ranges specified. Features for count distinct column, count item value, suppress duplicate rows is supported.
- **Multiple Panel reports** are supported by **Automatic Joins** (including outer joins) and run time (end-user) defined joins on any panel including type 0 panels used independently or 'Shared with others'.
- **CrossTab Browser**; multi-dimensional data analysis and Baseline / Endpoint Shift tables for cell statistics allows you to drill down to the patient data behind each cell.
- **Graph Browser**; choose from a variety of graphs including line charts displaying standard deviation with means (display selection), scatter plots, 2 and 3 dimensional bar charts, and frequency distributions. Multi page graphing capability for selected 2D graph types providing multiple graphs on the same page.
- Review provides **powerful 3 dimensional bar chart editing**, and complete display editing of all graphs for **dynamic presentations of clinical data**.
- **Drill-down capabilities within graphs** for exploring the details of graphical patient level data displays. Highlight data in scatter plots or bar chart and identify patients in the Data Browser to view patient level displays.
- SAS Proc (Statistical Analysis System Procedures) Browser; provides access to a powerful statistical engine for **versatile adhoc statistical queries** and provides the **creation of SAS Data Sets** and **SAS Data Views**.
- SAS Program Browser; a list of SAS (Statistical Analysis System Procedures) programs extending Review's analytical depiction of patient populations meeting your defined and applied Patient Selection Criteria. Optional usage of **parameterized SAS (Statistical Analysis System Procedures) programs.**

Starting the application

Logging on

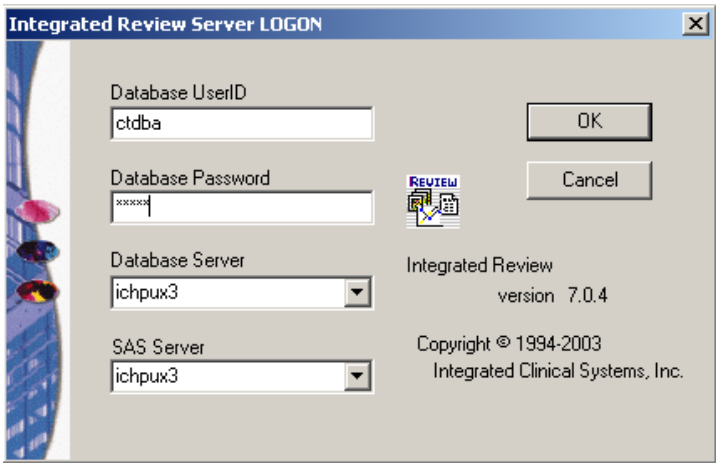
To log on:

1. Double-click on the Review icon:

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

   You can select Oracle Server and SAS Server from the drop down listbox for both.

3. Click **OK**.



Choosing an ORACLE database

By default, Review 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.

Using an ORACLE connect string

Alternatively you can access to an ORACLE database by the use of an ORACLE connect string, preceded by @.

Using Personal Oracle7

When you are using Personal Oracle7, you can access the ORACLE database by entering the word LOCAL.

Wrong password?

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

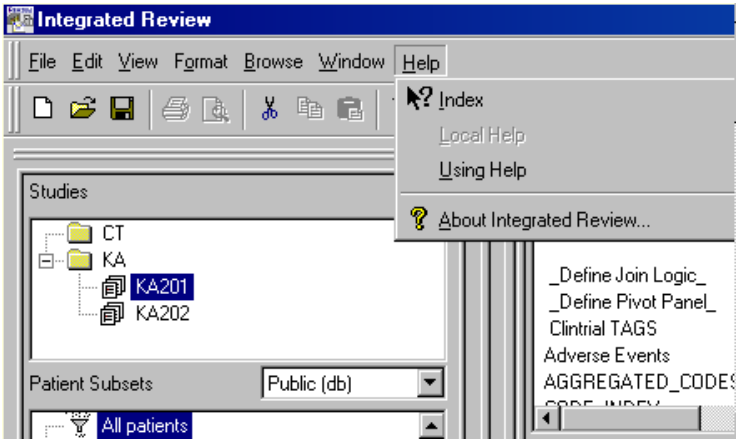
You are allotted three incorrect entries before the application denies access.

On-line Help

On-line Help

Our system of **On-line Help** can be accessed by clicking **Help** from the Menu Bar or the Tool Bar. Select **Index** to display a list of contents explaining how to use the functions for the various browsers.

In addition, your site administrator can enable a Local Help for a site customized help file which can be launched from within Review. If the Local Help file is enabled at your site, click **Help** from the menu bar, and from the display window select **Local Help**.



Terminology for Oracle Clinical users

Oracle Clinical terms

- *Variable names* used by Oracle Clinical are an eight character name which is unique within a view but not unique across views within the same study. The dynamic views are directly related to the study data definition of the DCM which the user has defined.
- *Text Description* as a 40 character SAS label is provided as defined within the DCM_QUESTIONS table.
- *Unique Numeric Identifier* - The DCM_QUESTION_ID is study specific and unique across views.
- *Non-Unique Numeric Identifier* - The QUESTION_ID is non-study specific and also is not unique within a study.

What are Oracle Clinical keys?

The *key* is an identifier which can be used to relate one piece of data to another. Oracle Clinical has the following fixed hierarchy to define a *parent key:*

STUDY

INVESTIGATOR

SITE

VISIT

QUALIFYING VALUE (optional)

SAS_REPEAT_NAME (optional)

The general key names are consistent within a study. Qualifying values are treated as keys and are named by the qualifying question. Repeat Sequence Numbers are named using the eight character SAS_REPEAT_NAME. This attribute is added to the DCM_QUESTION_GROUPS table and is unique within a study. Constant numeric identifiers are provided for each key with the exception of qualifying value and repeat.

Patient	10
Site	20
Investigator	30
Visit	40

For qualifying questions, the QUESTION_ID is used as an identifier. For the repeat number, a numbering seqence based upon the DCM_QUESTION_GROUP_ID is used to ensure the key is unique.

The *Oracle Notation* for DCM_QUESTIONS.DCM_QUESTION_ID refers to the column DCM_QUESTION_ID in the DCM_QUESTIONS.

In addition, a SAS variable is a set of data values that describes a specific characteristic such as weight and would be the equivalent of an Oracle Clinical question.

What are Oracle Clinical Data Structures?

Listed are some of the basic data structures which Oracle uses for data management.

- *Domains* are unique for the various Oracle Clinical objects such as Questions, Question Groups, DCMs, Data Extract Views and Queries. An object name is required to be unique only within a Domain. At the study level, the Domain is the study and within a study parent object names are unique. Child object names, such as DCM questions and DCM Question Groups have different domain uniqueness constraints described below.
- *Questions* are the building blocks of collected data and are defined at the library level.
- *Question Groups* are a collection of one or more questions and are defined at the library level.
- *DCMs (Data Collection Modules)* are defined at the study level and is made up of one or more question groups.

  *Note:*The Oracle clinical data structure nomenclature for DCM, Question Groups and Questions will display as title headings in the Patient Selection Criteria window.

DCM question names are not unique within a study or a DCM under different conditions. For example, BLOOD_PRESSURE can appear as a DCM question in two different DCMs within the same study. Also, DCM questions can occur multiple times within the same DCM question group and differentiated by an Occurrence Sequence Number. The same DCM question can also be repeated multiple times within a DCM question group. The Repeat Sequence Number indicates the repeat of a Question Response Value. To summarize the three situations of multiple occurrences of a question within a study:

- A DCM question can occur two or more times within the same DCM Question Group.

- A DCM question can repeat within a DCM Question Group.
- A DCM question can occur within different DCM's of the same study.

At the library level, Question Names and Question SAS Names are non-unique across Domains. For Questions with multiple Occurrences in a single Question Group, the Occurrence Sequence Number is part of the Question Name. The Repeat Sequence Number (SN) is part of the key, so within a given DCM, DCM Questions can be uniquely identified. However, this is not true with multiple DCMs as across multiple repeating DCM Question Groups in the same DCM which collect the same Questions. In the example below, the question BLOOD PRESSURE (BP) is collected in the DCM ADVERSE_EVENTS and the DCM VITALS, where it appears in both Question Groups of the DCM.

In this STUDY example, the data is collected by two DCMs: VITALS and ADVERSE_EVENTS. The first DCM VITALS has two Question Groups. The first DCM Question Group INITBP, is non-repeating and collects the Question BLOOD_PRESSURE twice. The second DCM Question Group VITALS, repeats three times. The second DCM ADVERSE_EVENTS has one DCM Question Group which is non-repeating.

Table 1: Example of DCM, Question Groups and Questions

DCM, Question Group	Question short name	Occurrence SN	Repeat
DCM: Vitals (short name VITAL) **Question Group: InitBp (short name IBP)** **Initial Blood Pressure _____** **Date of Initial Blood Pressure _____** **Blood Pressure at end of Visit _____**	 **BP** **TimeBP** **BP2**	 **1** **1** **2**	 **1** **1** **1**
DCM: Vitals (short name VITAL) **Question Group: Vitals (short name VITAL)** **Blood Pressure Time of Blood Pressure** **_____ _____** **_____ _____** **_____ _____**	 **BP** **BP** **BP**	 **1** **1** **1**	 **1** **2** **3**
DCM: Adverse Events (short name ADV) **Question Group: Adverse Events (short name ADV)** **AE Date _____** **AE Time _____** **AE Description _____** **Blood Pressure _____**	 **AEDate1** **AETime1** **AEDesc** **BP**	 **1** **1** **1** **1**	 **1** **1** **1** **1**

Oracle Clinical data extract views are of two kinds, standard and custom. The standard views extract data in a fixed way into the STUDY ACCESS ACCOUNT selected for types TEST, CURRENT, STABLE, and SNAPSHOT. The variables in a standard view are unique across the view and non-unique between views in a given study. The custom views can be defined by a user with the query builder or by loading view creation text from a SQL file.

Standard views include both static views and dynamic views. The static views are the same in every access account. The dynamic views are directly related to the study data definition. Examples of static views could be NORMLAB or NORMDATA.

The dynamic views also generated from a standard view are dependent upon the nature of the DCMs which the user defined. These dynamic data extract views are created in Oracle accounts in the following manner:

1. In a study, a view is created for each repeating DCM Question Group in a DCM. It's name is the DCM short name concatenated with the DCM Question Group short name of the repeating Question Group.
2. All non-repeating Question Groups in the DCM are included in a single view with the DCM short name.

When data extract views are created for the above example, the following dynamic views are generated:

- VITALVITAL
- VITAL and
- ADV

These standard views are created together with any custom views defined where the builder can combine data from multiple DCMs. This data can also be aggregated. The same variable can occur multiple times within the same row with various aggregate functions applied.

How does Oracle Clinical pass files to Review?

Following is a brief description of the steps of the process of passing Oracle Clinical project and study information to Review.

1. When Oracle Clinical first connects to Review, the list of projects displays from the Oracle Clinical standard table: RXA_DES.OCL_PROJECTS
2. When you click on a folder, review then presents a list of 'Study Access Accounts' available for that project. These are a combination of STUDY and the 'type' of access ($CURRENT, $STABLE, etc.).
3. When you click on one of the Study Access Accounts, the list of DCM / Question Groups displays:

   All default views created for the study. These are organized by DCM, if there are multiple question groups per DCM (data collection module), otherwise, if a Question Group is the only one as a DCM, it will be 'promoted' to the top level, not listed under it's DCM:

   (+) dcmNameA

   questionGroupA

   questionGroupB

   (-) questionGroupC (only 1 questiongroup in it's DCM)

   (+) dcmNameC

   questionGroupD

   questionGroupE

   (+) Custom Views (list of custom views if any exist)

   (+) System Tables (list of registered Foreign Panels meaning any other Oracle tables or view registered using ReviewAdmin utility).

   By default, the PATIENT_POSITIONS table is registered which displays patient information into the Data Browser list of patients.

Terminology for Clintrial users

What is metadata?

Metadata is data that define Clintrial objects and other structures. The tables that store metadata are called data dictionary tables. Data dictionary tables store reference information about the database and its structures.

Metadata is stored in the data dictionary tables when you 'Create a protocol'.

Clintrial stores the metadata (the protocol attributes) in a data dictionary table that stores protocol metadata for all protocols.

When you create or modify a panel or an item, and when you install a panel, Clintrial stores the metadata in tables in ORACLE accounts that are either system-wide data dictionary accounts, or protocol-specific accounts that can contain both data dictionary and clinical data information.

What is a project?

Typically a drug development project, is where a number of grouped protocols are conducted for a given project.

What is a protocol?

A protocol account (or protocol) is an ORACLE account that serves as a logical container to organize the objects and data for a clinical study. Protocols may contain clinical data for a single study or for multiple related studies.

When you browse clinical data with Review, you specify the protocol(s) that contains the data you want to review by selecting the protocol(s) under the selected project from the Studies folders.

What are database tables?

Clinical data in Clintrial is stored in ORACLE database tables. These database tables contain clinical data in columns and rows:

A column in the table corresponds to an item, or piece of data.

A row in the table corresponds to a record, or group of related data.

What are panels?

In Clintrial, the ORACLE database tables are defined by panels. A panel is a collection of logically or clinically related items.

A panel groups together a set of logically or clinically related items from a CRF page. Panels contain items. For example, a panel might store physical examination results for a subject.

After a protocol is created, panels are created within the protocol, and items within each panel.

Panels define the ORACLE database tables that store the records created when clinical data is entered during data-entry.

Each panel has three associated tables in the ORACLE database: an update table, a data table, and an audit table.

You can associate a panel with specified derivations and rules, which are applied to records in the panel when the records are validated in Clintrial Manage.

Note: In Clintrial, the data structure nomenclature for Panels and Items will display as title headings in the Patient Selection Criteria window.

What are panel types?

The panel type (0 through 5) that determines which context items are required, and the number of records for each set of context items.

Panel type 0: Non-patient data not related to a particular patient or visit. For example, laboratory normal ranges.

Panel type 1: Data collected only once for each patient in a clinical study. For example, demographic data or eligibility data.

Panel type 2: Data that is collected multiple times for each patient. The data is not related to a particular visit. For example, a panel describing previous medications or medical history could contain items that have multiple values entered on the single occasion that data is collected. The panel can be used for repeating items.

Panel type 3: One record is collected once for each patient visit. For example, vital signs or laboratory results may be collected once for the patient at each visit.

Panel type 4: More than one record is collected multiple times for each patient visit. For example, a panel describing adverse events or concomitant medications could contain items that would have multiple values entered at each patient visit.

Panel type 5: Subject enrollment ensures that each subject can be uniquely identified in the database. The system design automatically creates an empty enrollment panel when you create a protocol.

What is a context panel?

A context panel is a special panel containing context items. Context items are associated with each record in a clinical data table for type 1, 2, 3, 4, or 5 panels.

A context panel is always named CONTEXT and there is only one context panel for each protocol.

What are context items?

Special context items are used as keys (either alone, in combination with each other, or in combination with items in the non-context panels) to uniquely identify a record. There are 4 types of context items:

1. Subject-related: Items that identify the subject, such as a subject identifier.
2. Visit-related: Items that identify the visit, such as a visit number or a date.
3. Page-related: Items that identify a study page, such as a page name or page number.
4. Other: Items not related to the subject, the visit, or the page, such as the investigator name.

What are items?

An item stores the data collected by a single field in a study page or by a single field in a batch-loaded file. For example, the PHY_EXAM panel might define items for storing physical examination results.

An item stores the data collected by a single field in a study page. Items are defined within panels, and correspond to one column in a clinical data table. For example, the DEMOG panel might contain the items AGE and SEX or the PHY_EXAM panel might define items for storing physical examination results.

There are 3 types of items:

1. Context items which associate each record in the database with data that uniquely identifies the record, such as a particular subject or subject visit.
2. Data items which represent collected data, for example height or weight.
3. System items which Clintrial uses to identify and manage records.

Note: The data-entry area for an item on a study page is referred to as a field. Field names may differ from the name of the actual item.

What are Database table types?

Each panel in a protocol defines three ORACLE database tables for the storage of clinical data. The items in each panel correspond to the columns of the database tables. The three database tables have the same structure, but contain data in different states:

1. The update table stores clinical data when it is first entered in Clintrial, and is a holding area for clinical data while it is being cleaned.
2. The data table stores clinical data that has passed validation and has been merged.
3. The audit table contains copies of original clinical data records as they existed before modification or deletion.

What are records?

A record corresponds to one row in a database table. The clinical data interactively entered in a study page is stored in one or more records in the database.

Records can also be batch-loaded into the database tables.

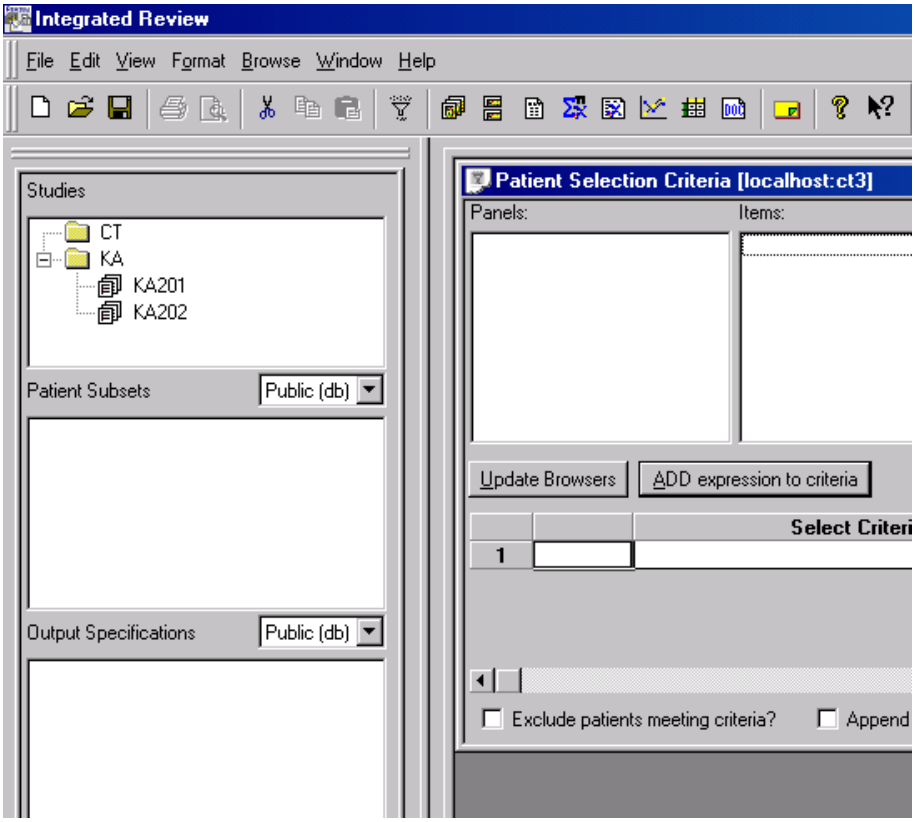
Depending on the panel type, the data collected in a study page is stored in one or more records in the database table. For example, a database table can contain:

- One record per subject
- Multiple records per subject
- One record per subject visit
- Multiple records per subject visit

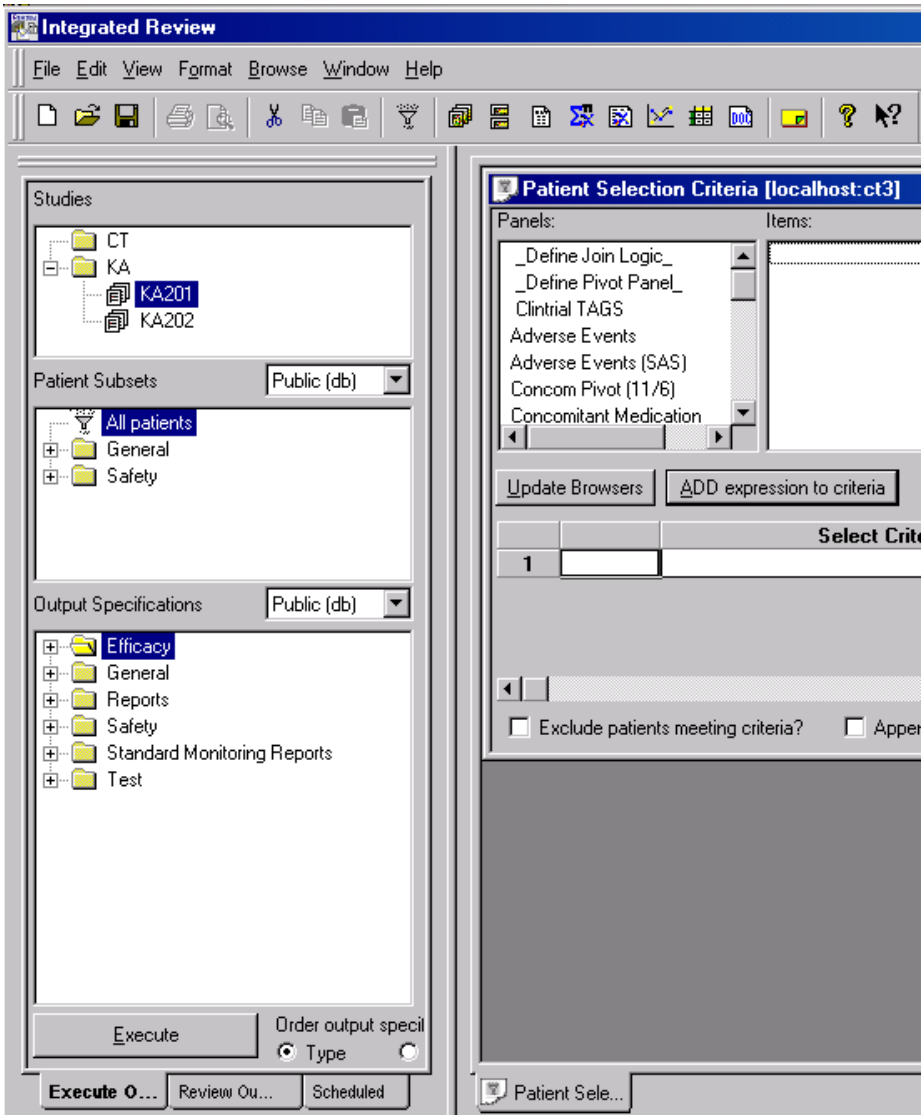
Quick tour

Main window

After you successfully log into the ORACLE database (on the computer storing your clinical data), the main window of Review opens. The left side contains the Object Explorer Window, under studies select a project folder, for example 'Drug KA' and protocol 'KA201'.



Review retrieves all previously stored Patient Subsets and Output Specification objects organized in folders.



The individual browsers covered in the following chapters, are used for building, modifying and saving your Output Specification objects into folders you define. Once the objects are saved, they can be quickly located and launched from within the folders displayed in the Output Specifications window and Patient Subsets window.

The individual who creates and saves an object definition has sole security to delete or modify it. SuperUsers have extended privileges. (See *Chapter 12: Common Topics: SuperUser 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. Patient Selection Criteria may also be saved as separate objects in the Patient Subsets window. The output specification objects stored within their folders can be sorted to display by icon type or by object description. Simply click **by Type** or **by Description**.

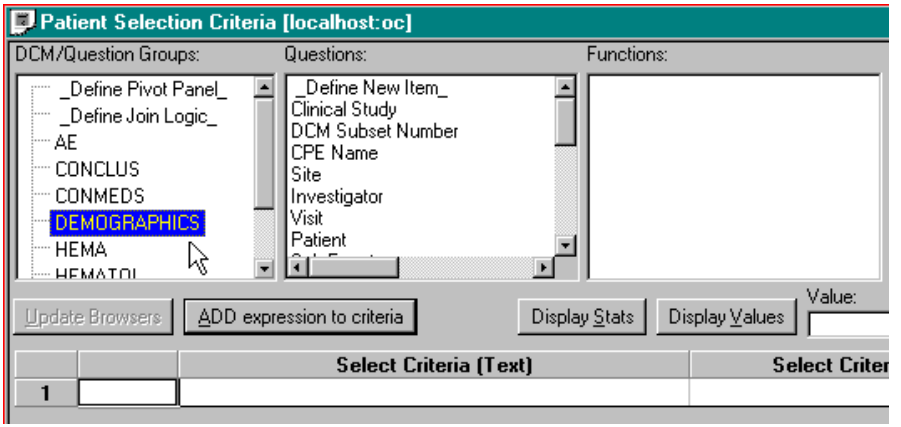
The saved objects can be stored at three levels: Private, UserGroup, or Public. (See *Chapter 12: Common Topics: Shared Object Storage-Locations.)*

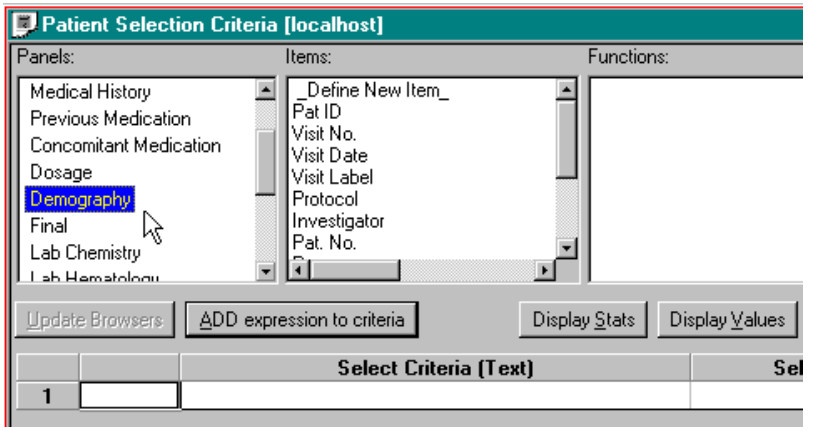
Once an output specification has been saved you can use job scheduling to generate and save the output at a later date and time or select repetitive frequency to generate output results. The Review Output tab located at the bottom of the window allows you to view the archive of output results organized within folders with date and time stamps applied. (See *Chapter 6: Report Browser: Schedule Output.)*

Selecting a patient population

Once the application has started and you have selected the study or studies you wish to explore; you select your patient population by subsetting. 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. If you choose not to enter a Patient Selection Criteria, Review will default to access the whole patient population. Before you select a patient population, you should be familiar with the important regions of the main application window.

Note: The Patient Selection Criteria window displays the section headings as DCM/Question Groups and Questions for Oracle Clinical, or Panels and Items for Clintrial. The headings display as such to be consistent with the site Clinical Data Management system. All other windows within Review use the terms panel and items and there is no functional difference. Therefore, these terms are interchanged throughout this text to imply similar meaning and function.

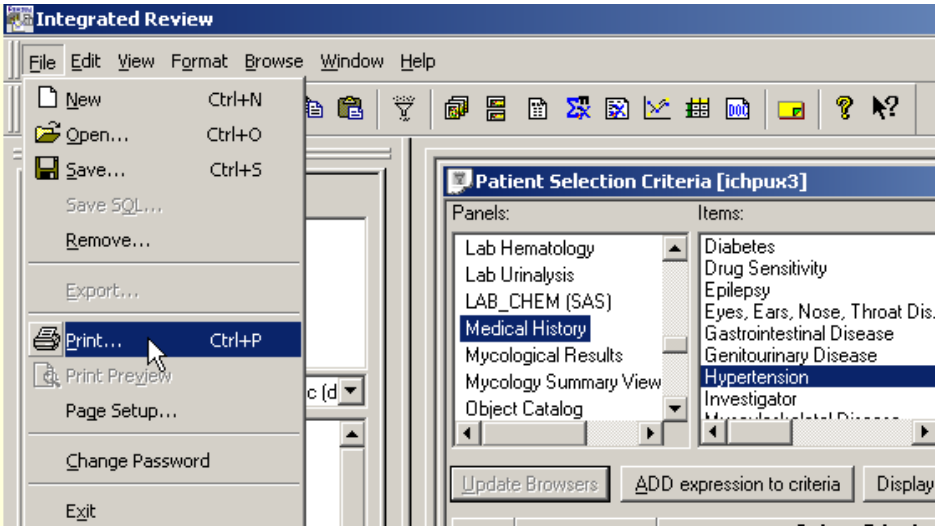




Menu bar and windows

You can access any of the functions available in Review:

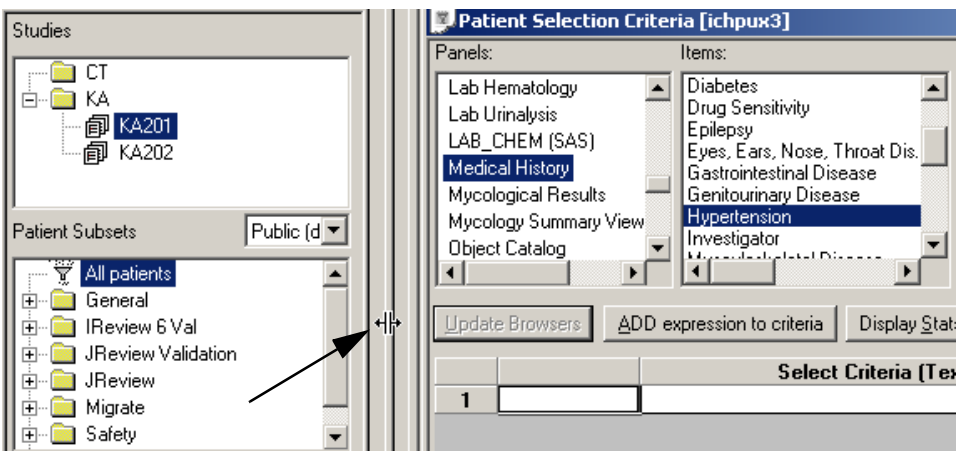
1. Click a menu from the Menu Bar, for example, **File:**
2. Click on one of the submenu Items of the main menu that would be applicable to select, for example **Print**.



Note: Many of the menu commands can be run by clicking on the corresponding Toolbar Icon.

The Menu Bar and Toolbar can be relocated to other areas of the screen. Simply click and drag to the new location.

The Object Explorer Window is docked at the left side and can be re-sized by dragging the right side. This allows you to decrease or increase the window area as needed.



Toolbar

The most commonly used items in Review can be accessed quickly by clicking on one of the Toolbar buttons:

New: Clears the current specifications in the active area.

Open: Retrieves a previously saved set of specifications into the active area.

Save: Saves the specifications of the currently active area.

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

Print Preview: Displays a screen shot of the output result. Applicable to all browsers with output results.

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.

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

Document Browser: Starts the Document Browser.

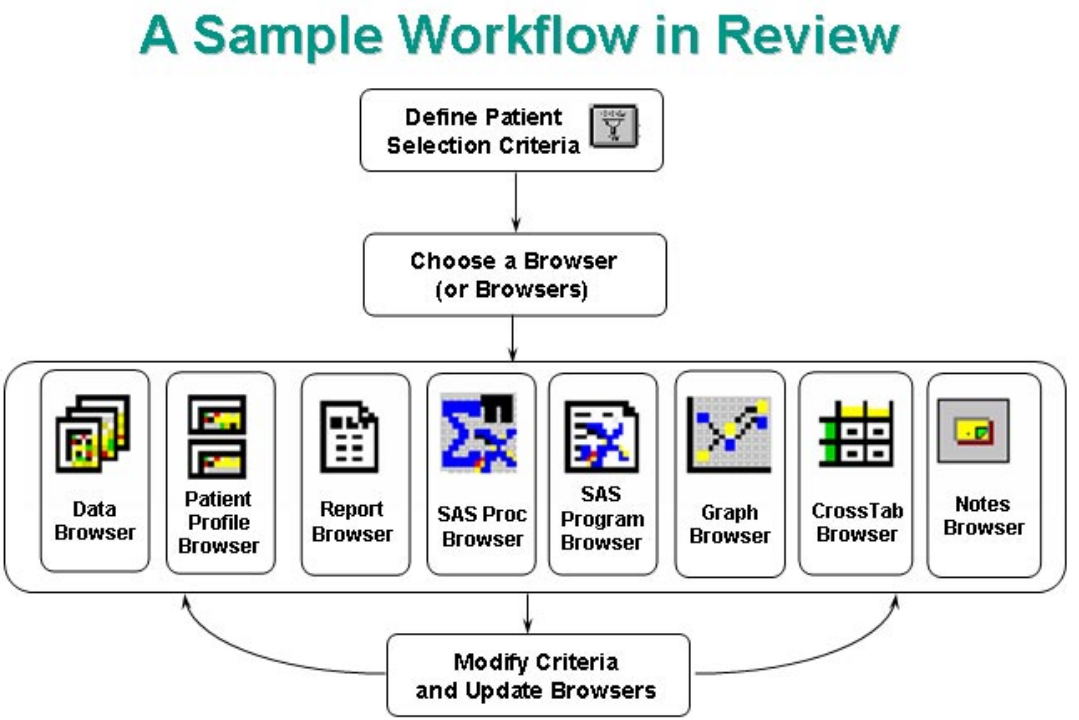
Note Browser: Starts the Patient Level Note Browser.

Gets information about the Review client/server version, and licensee.

Help: Displays a Help contents for Review.

Review workflow

Explore and monitor your clinical data by selecting from the various browsers. Optionally subset the patient population with the Patient Selection Criteria or view all available patients by default.



2 Selecting Patients

Selecting a project 50

Selecting a project 50

Selecting protocols 50

Single-protocol mode 50

Multi-protocol mode 51

Specify Patient selection criteria 52

Review sub-populations 52

Focused analysis 52

Access to SAS datasets 54

Building and Joining Criteria Expressions 55

Logical expressions 55

Selecting a panel 55

Selecting an item 56

Panel item profiles 57

Supplying a item value 57

Displaying item values 58

Selecting multiple values 59

Selecting an operator 60

Building a string expression 60

Additional criteria expressions 61

Boolean operators 62

AND operator 63

OR operator 64

ANDSelect operator 65

Build a complex patient selection criteria 66

Changing the selection criteria 67

Updating Browsers 68

Criteria description 68

Item comparison selector 69
Compare items 69
Exclude patient criteria 70
Display excluded patients 70
Functions 72
Types of function values 72
'Actual value' function 72
Derived function values 72
Date function 72
New Event Function 73
Displaying item statistics 74
Display stats 74
Displaying subsets of protocol population 75
Clintrial tags 77
Clintrial tags as pseudo-panel 77
Optional user-defined panels and joins 78
Pivot Panels 78
Join Logic 78
Object storage: saving your work 79
Object storage location 79
Object level 80
Saving the selection criteria 81
Override selected Project/Global object? 82
Object Explorer window 83
Retrieve a saved selection criteria 84
Append to criteria 84
Display all studies 87
Browsing saved selection criteria 88
Object properties 89
Printing the selection criteria 90
Quick remove 91

Exploring data **92**
Reviewing preferences 92
Outer join in Results 92
Display panel names 93
Display item names 93
Sort panels alphabetically 93
Sort items alphabetically 93
Reviewing with browsers 93

Selecting a project

Selecting a project

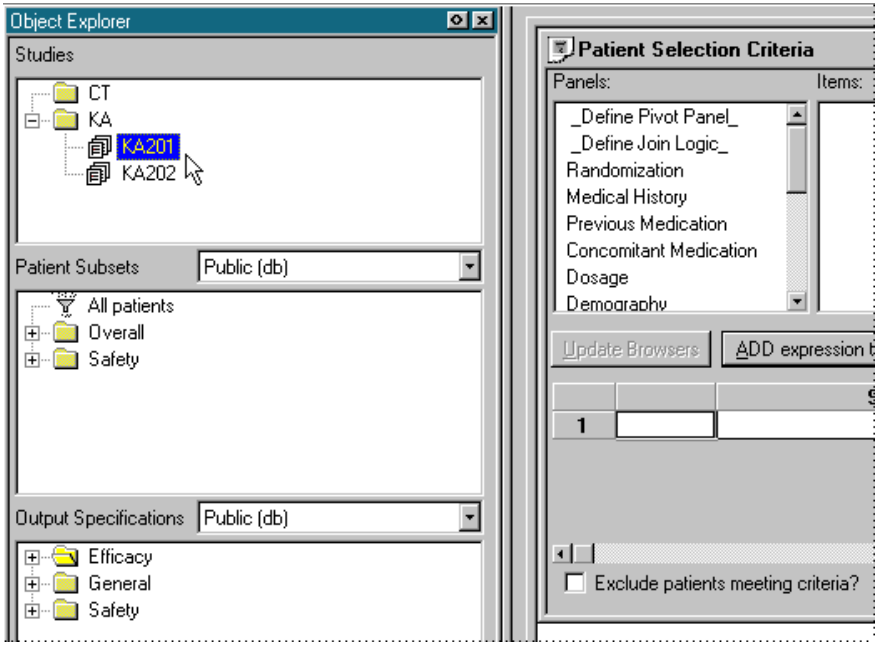
In the Object Explorer window under **Studies**, select a project from the list of project folders.

As soon as you have selected one of the Projects, for example 'Drug KA', Review opens that project folder to display the protocols that are stored in your clinical data base.

Selecting protocols

Single-protocol mode

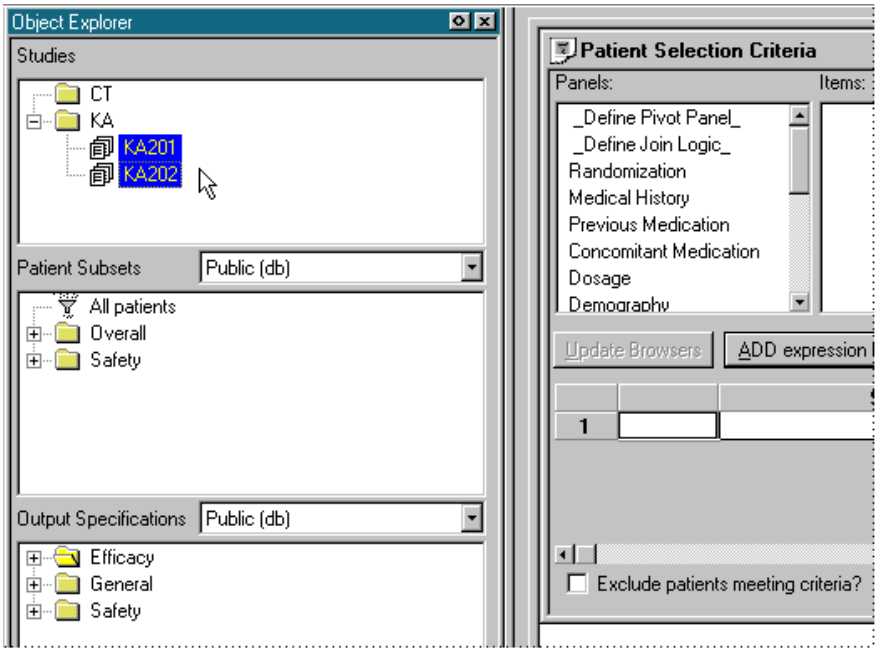
You can click and select a protocol that you want to explore. If you click on one protocol, you are in single-protocol mode. The lists of panels and items that are displayed corresponds to all panels and items in that protocol.



Multi-protocol mode

If you select multiple protocols, you are in multi-protocol mode. The lists of panels and items that you see correspond to common panels and items between the protocols selected. In addition, Review confirms the common items match by data type. Unique panels or items are not displayed for selection.

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.*

Specify Patient selection criteria

Review sub-populations

Using the patient selection criteria, you are able to filter the available patient population from the selected protocols into sub-populations. 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.

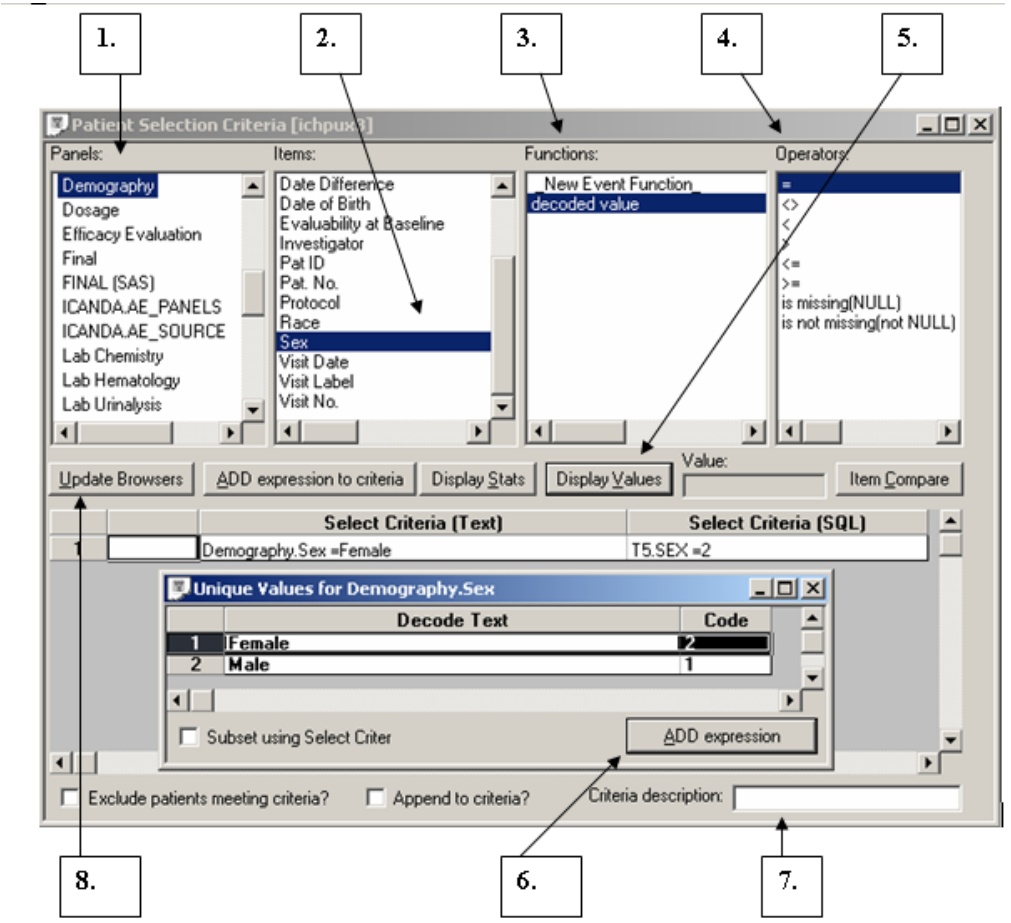
Focused analysis

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 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. Supply a value or select a value from Display Values.
   - Display Values (optional).
   - Display Statistics (optional).
   - Compare Items (optional).
6. Add expression to criteria.
7. Add criteria description (optional).
8. Update Browsers.

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.

Building and Joining Criteria Expressions

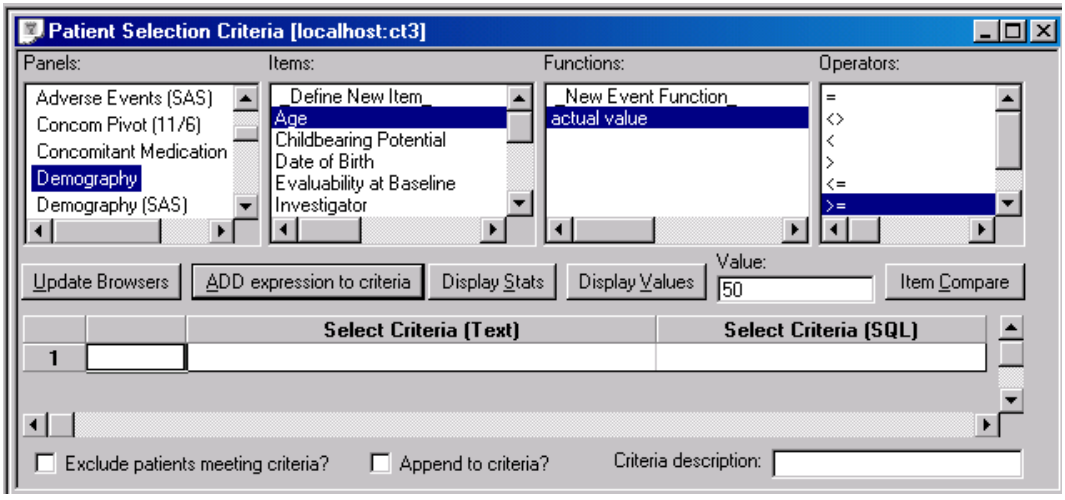
Logical expressions

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

Your clinical data has been collected and entered into meaningful groups of items, referred to as panels. 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, such as '**AGE > 50**', 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.



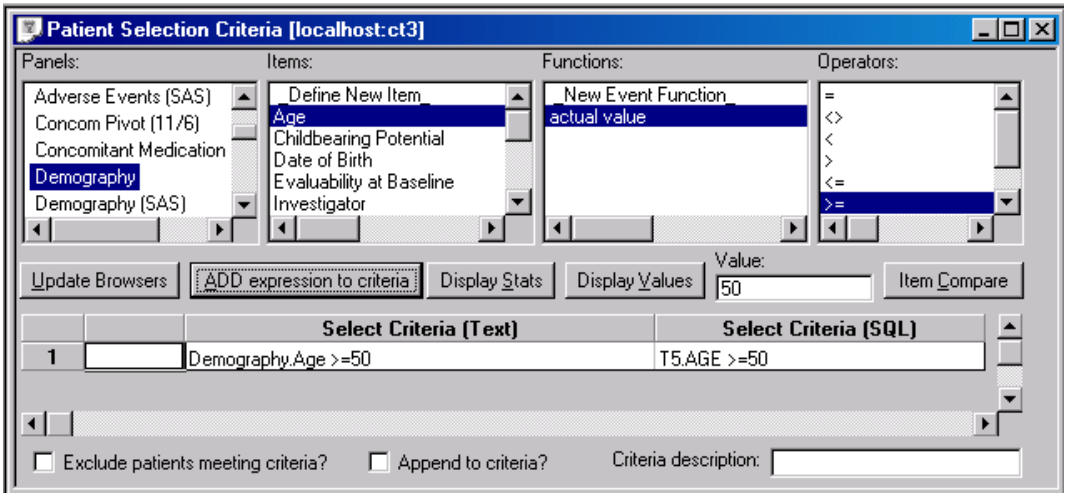
After you have selected the Demography panel**,** Review retrieves and presents a list of all the items stored in the Demography Panel.

Select an item.

Select an operator.

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

If you know the value, you can enter it in the value box or click **Display Values**.

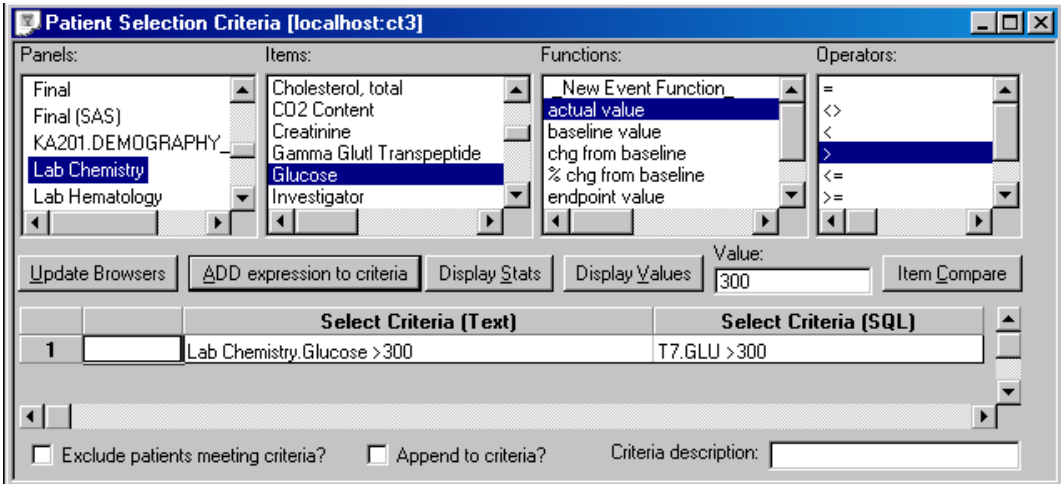


Panel item profiles

Supplying a item value

You can enter a item value for an expression as follows:

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. If you know the value that you want to specify in the expression, enter the value in the Value field.



After you are finished selecting all parts of the expression you are building, click **ADD expression to criteria.** 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.

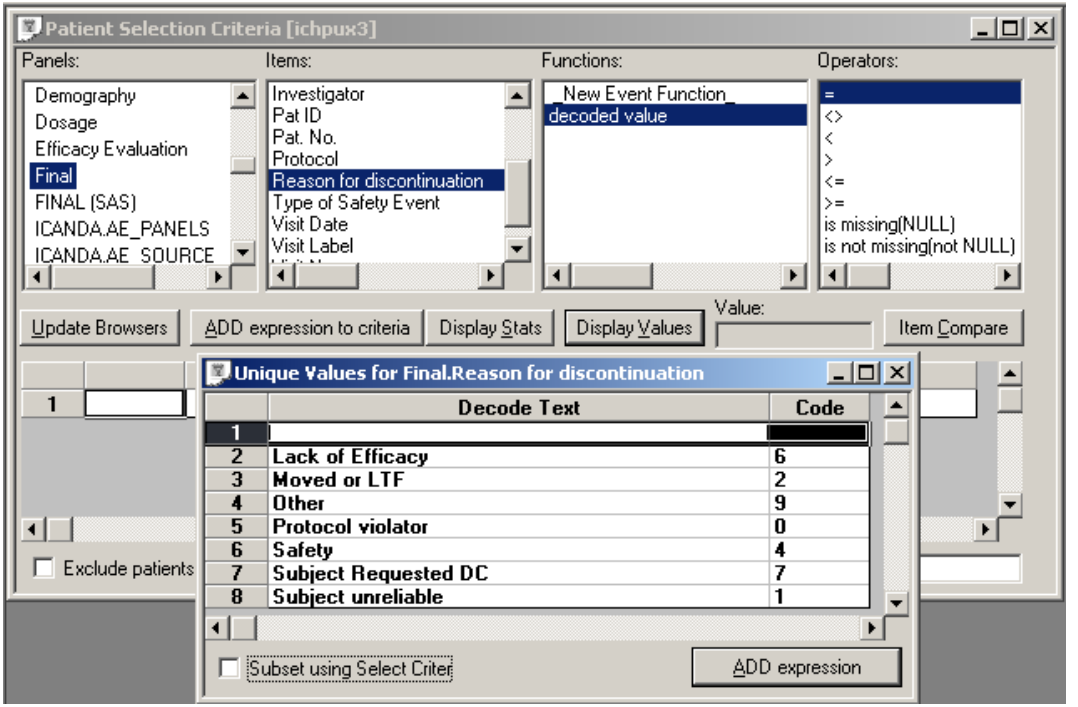
Another way to add select criteria expressions besides directly entering a value is to open the **Display Values** window. Once you have added expressions by entering a value, you can capture perspectives of your data that are uniquely informative. Suppose you are interested in exploring patients who 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.

Note: Display Values window does not automatically open for decode items, allowing the user to specify a code value if already known.

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**.

   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**.

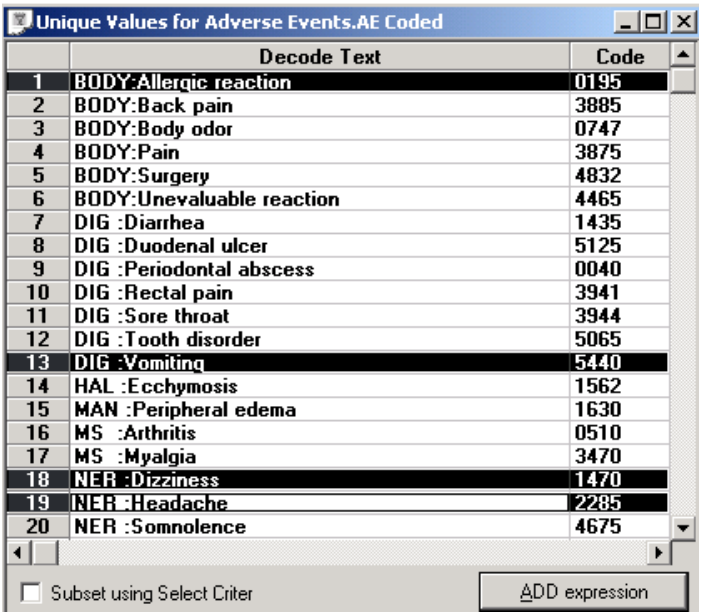


***Shortcut**: If you double-click on the single value of interest in the Unique Values spreadsheet, the expression is automatically added to the next available row in the Patient Selection Criteria window.*

Selecting multiple values

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

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



When you click **ADD expression**, 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.

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.

		Select Criteria (Text)	Select Criteria (SQL)
1		Adverse Events.AE Coded =BODY:Allergic reaction, ...	T10.SECODE IN ('0195','0195','5440','1470','2285')

Selecting an operator

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.
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:

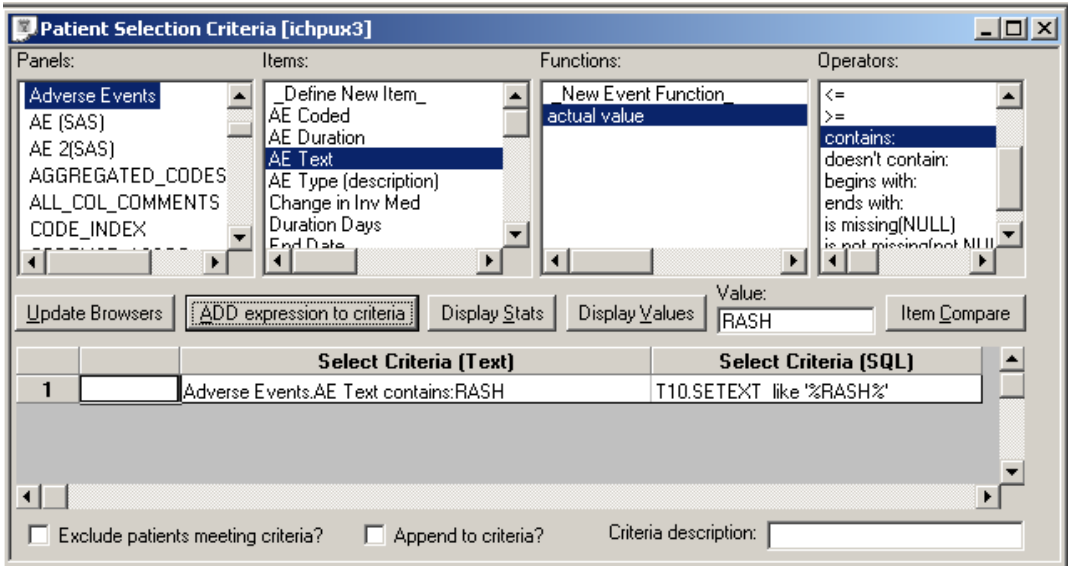
e. is missing (NULL)

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

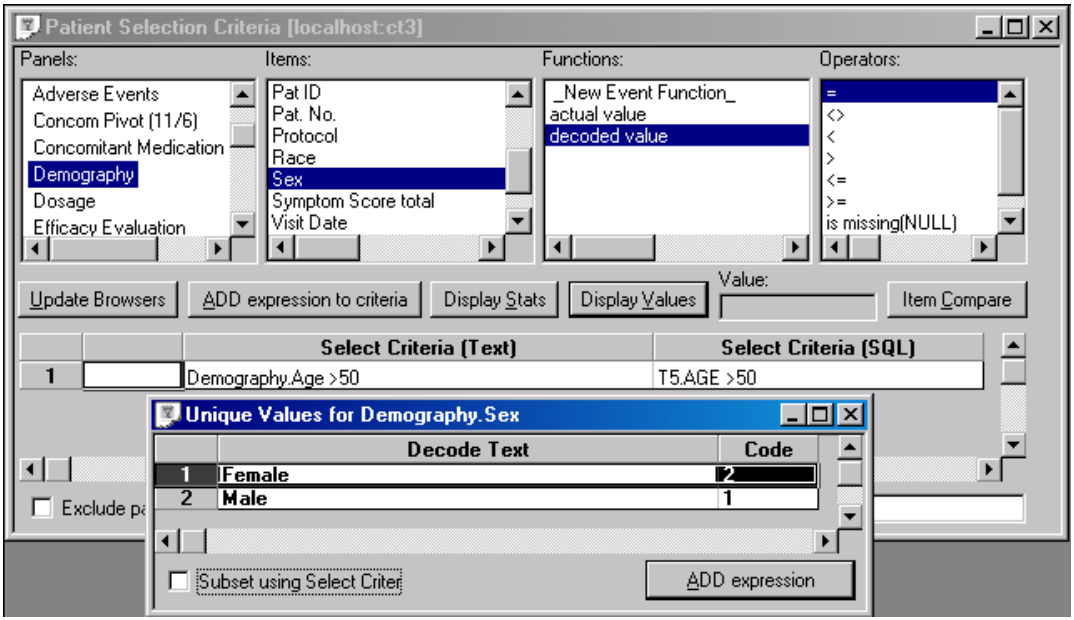
If you are building a string expression, (for example, patients whose 'Adverse Drug Event' field contains the string 'RASH' anywhere in the text of the item), click the 'contains' operator and enter the string 'RASH' in the **'**Value**'** field. The string search is case sensitive and you can determine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



Additional criteria expressions

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

1. Select a panel.
2. Select an item.
3. Select an operator.
4. Either enter a value or click Display Values.
5. Click ADD expression to criteria and close the Unique Values window.
6. Click Update Browsers when you have added all criteria expressions to your patient selection criteria.



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.

		Select Criteria (Text)	Select Criteria (SQL)
1		Demography.Age >50	T5.AGE >50
2	AND	Demography.Sex =Female	T5.SEX =2

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.

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.

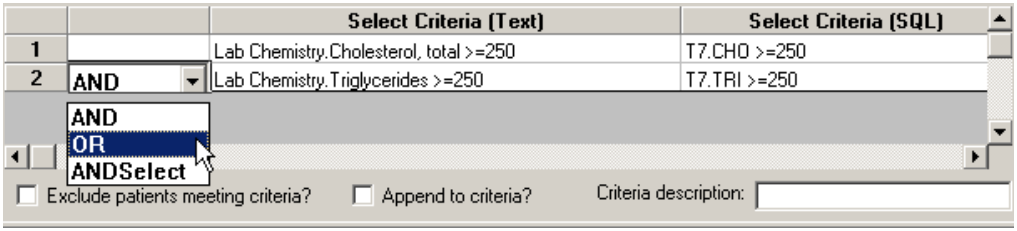
Detail Data Listing

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

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.

Detail Data Listing

	A	B	C	D	E
1					
2	Investigator	Pat. No.	Visit No.	Cholesterol	Triglycerides
3	018	4102	1	252	244
4		4102	4	240	146
5		4103	1	228	103
6		4103	4	225	253
7		4114	1	305	373
8		4114	4	306	285
9		4203	1	172	255
10		4203	4	182	154
11		4204	1	273	285
12		4204	4	260	259
13		4205	1	183	513
14		4205	4	186	169
15		4208	1	125	174
16		4208	4	133	266

When you change the boolean operator to ANDSELECT, the patient selection criteria is partitioned into two segments executed in succession. SELECT 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

	A	B	C	D	E
1					
2	Investigator	Pat. No.	Visit No.	Cholesterol	Triglycerides
3	018	4114	1	305	373
4		4114	4	306	285
5		4204	1	273	285
6		4204	4	260	259
7	030	3101	1	296	241
8		3101	4	292	335
9		3203	1	258	246
10		3203	4	250	396
11	056	5117	1	251	277
12		5125	1	277	391
13		5125	4	278	497
14		5209	1	315	415
15		5209	4	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

	A	B	C	D	E	F	G
1			Cardiovascular				
2	Investigator	Pat. No.	Disease	Hypertension	Visit No.	Cholesterol	Triglycerides
3	018	4114	No	Yes	1	305	373
4		4114	No	Yes	4	306	285
5		4208	No	Yes	1	125	174
6		4208	No	Yes	4	133	266
7	030	3104	Yes	No	1	258	62
8		3104	Yes	No	4	199	50
9		3109	Yes	Yes	1	227	341
10		3109	Yes	Yes	4	249	355
11		3111	No	Yes	1	292	199
12		3204	Yes	Yes	1	194	272
13		3204	Yes	Yes	4	199	232
14		3205	Yes	Yes	1	196	164
15		3205	Yes	Yes	4	216	333

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.

Changing the selection criteria

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

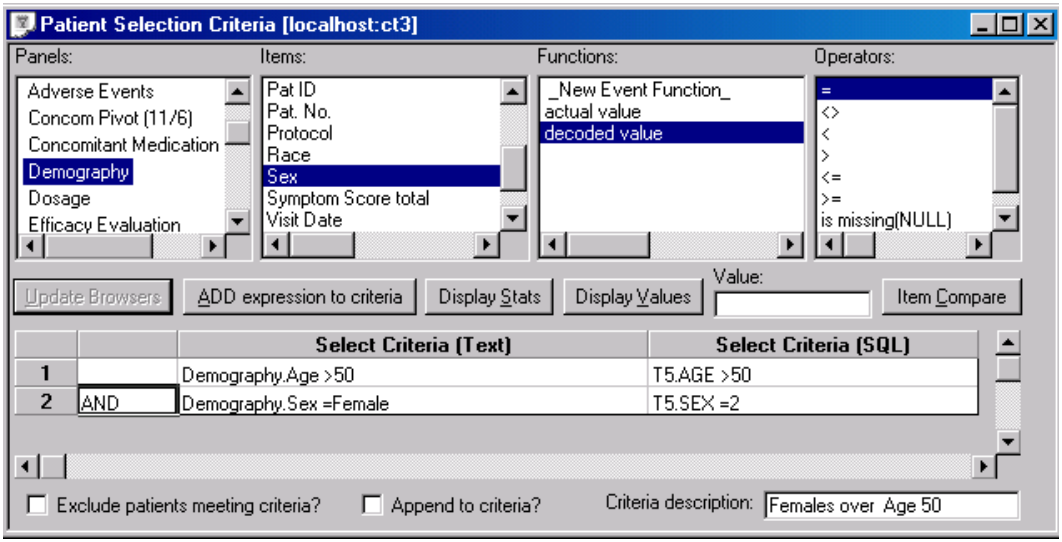
1. To modify the patient selection criteria, you can click on the row and edit it.
2. To remove a row, click or from the **Edit** menu, select **Cut**. This will delete the highlighted row from the expression.
3. To remove all rows, click .

Updating Browsers

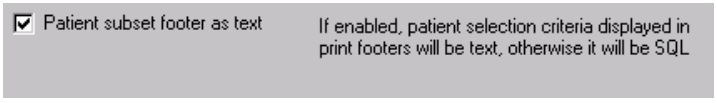
If browser windows are open when you revise patient selection criteria, click **Update Browsers** to apply the updated patient selection criteria to the browser windows.

Criteria description

You can enter a criteria description to display in the print footers as text to override the default SQL.



This option is enabled in Preferences. (See *Chapter 12: Common Topics: Reviewing Preferences*)

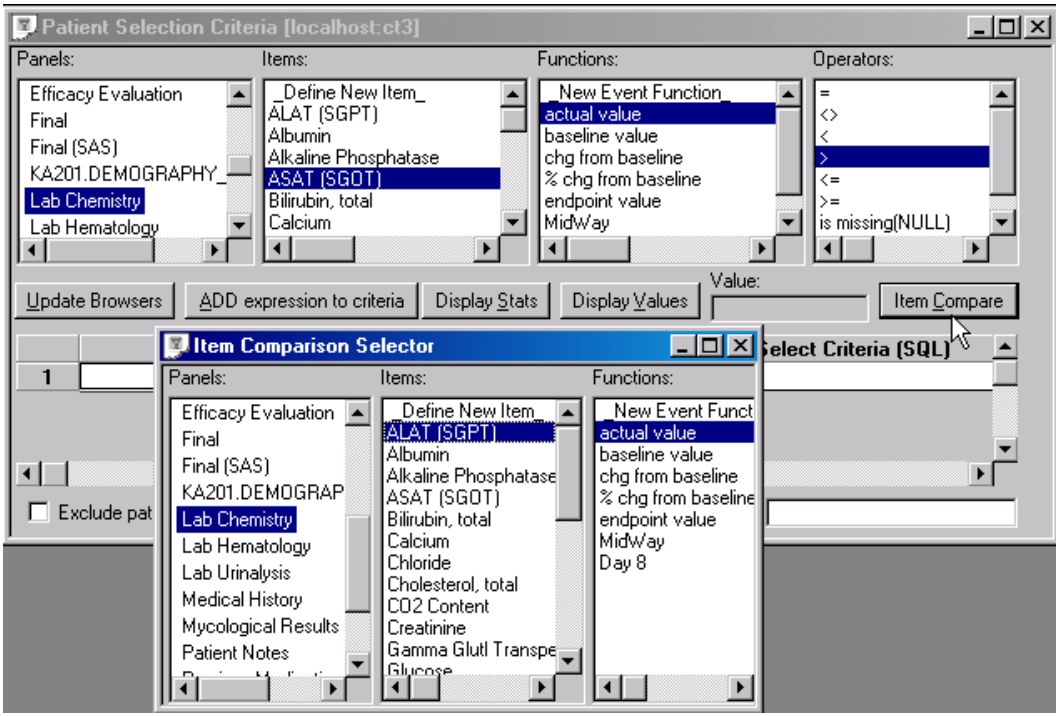


Item comparison selector

Compare items

An alternative mechanism to the basic patient selection criteria is the item comparison selector. This mechanism provides the functionality to base the 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.



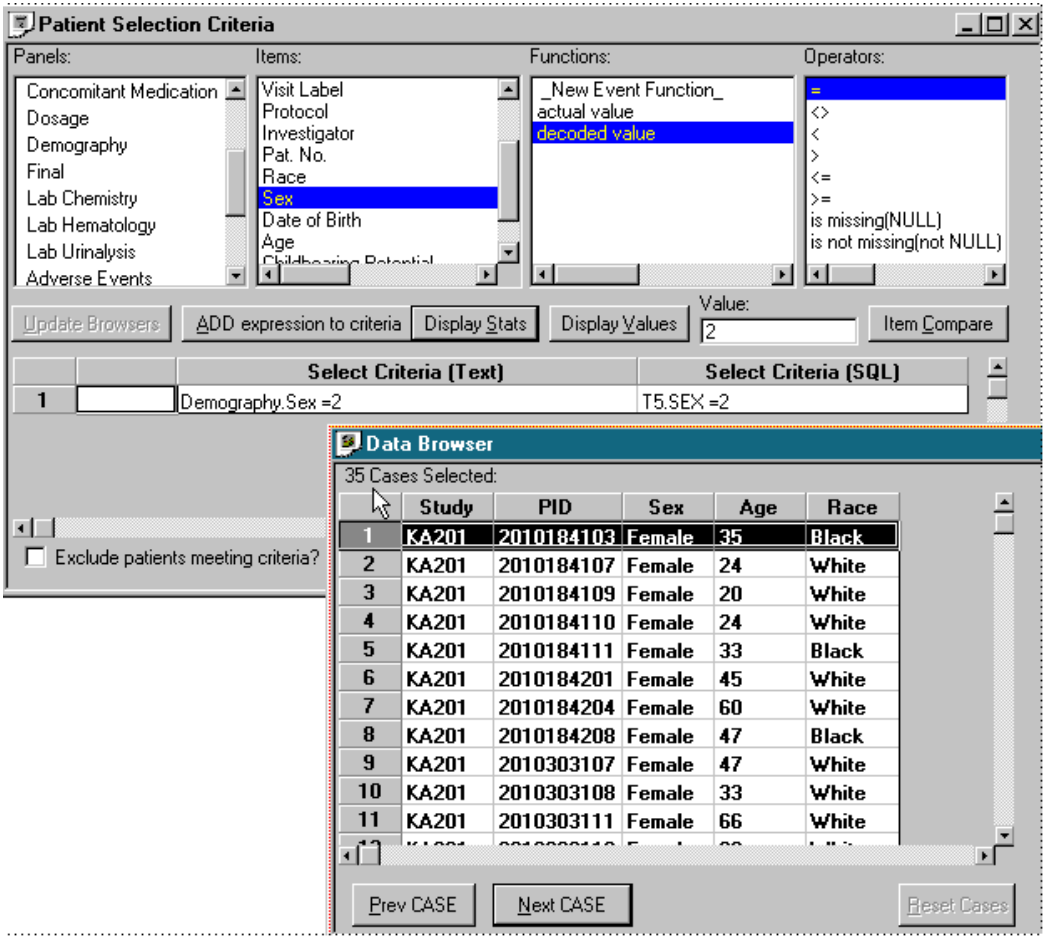
3. Click **ADD expression to criteria**.
4. Close the Item Comparison window.
5. Click **Update Browsers**. See the SQL text created when for compare Lab Chemistry panel item SGOT > than SGPT actual values:

		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

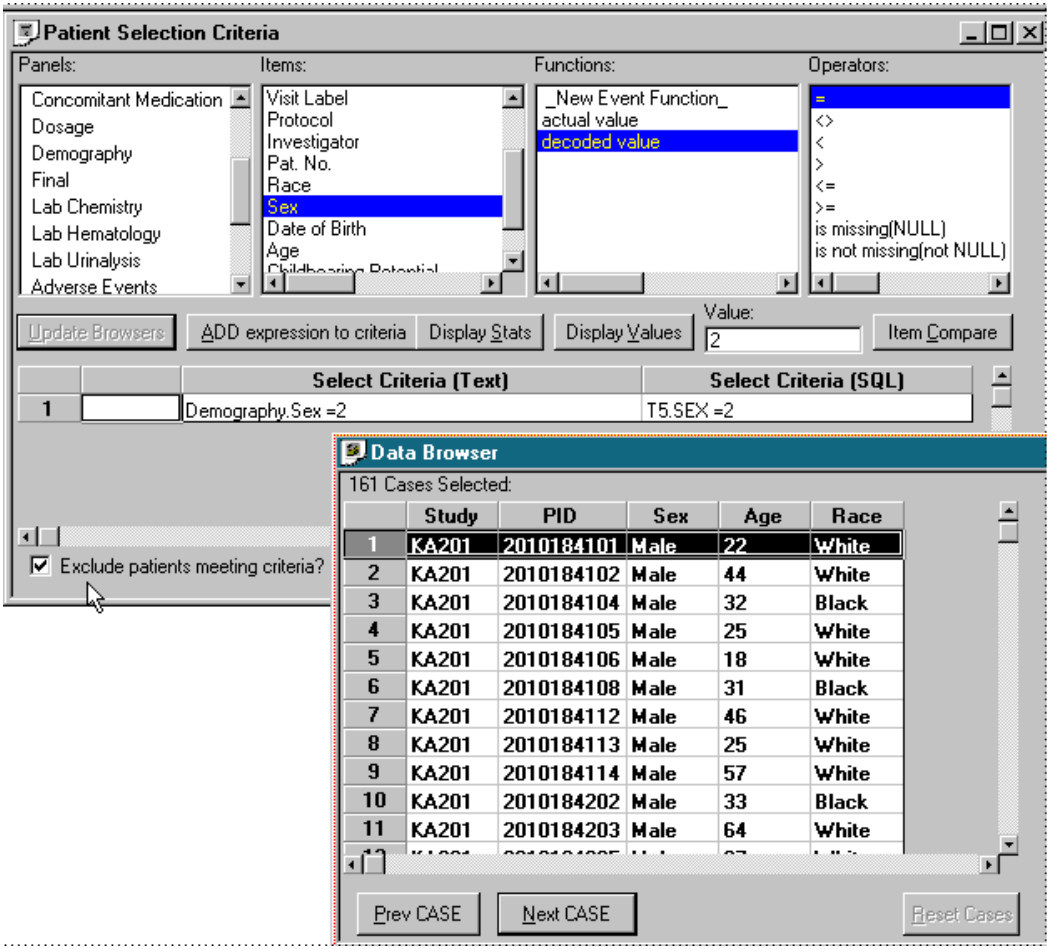
You have the ability to view those patients who are not in your current selection criteria by setting ☐ Exclude patients meeting criteria? . Click the button in the lower left corner of the Patient Selection Criteria Window to set this option on. For example, build a patient selection criteria for female 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 described below.

‘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

Derived forms of the functions, such as Baseline or Endpoint, can also be selected. Review provides default derived values, however the _New Event Function_ allows you to define a variety of time-related milestone functions. *(*See *Chapter 12: Common Topics: New Events Function)*

Date function

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

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

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.

New Event Function

Select the pseudo-function _New Event Function_ and Review allows the user to define run-time related milestones that work like the baseline and endpoint values. The user-defined new events can be applied throughout the application, in patient selections, as well as reporting and graphing. (See *Chapter 12: Common Topics: New Event Function*)

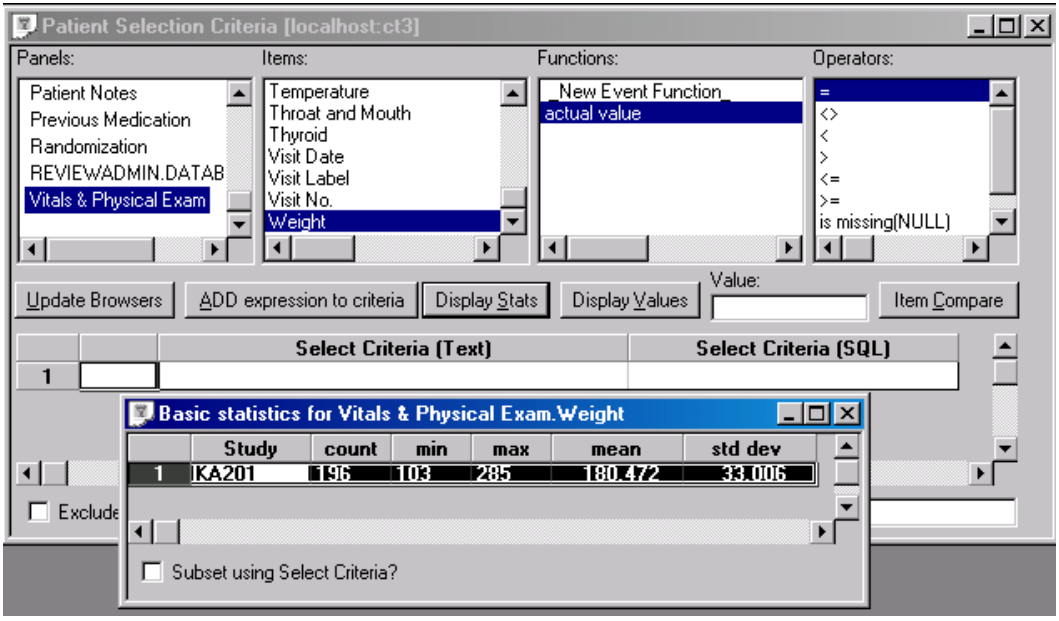
Displaying item statistics

Display stats

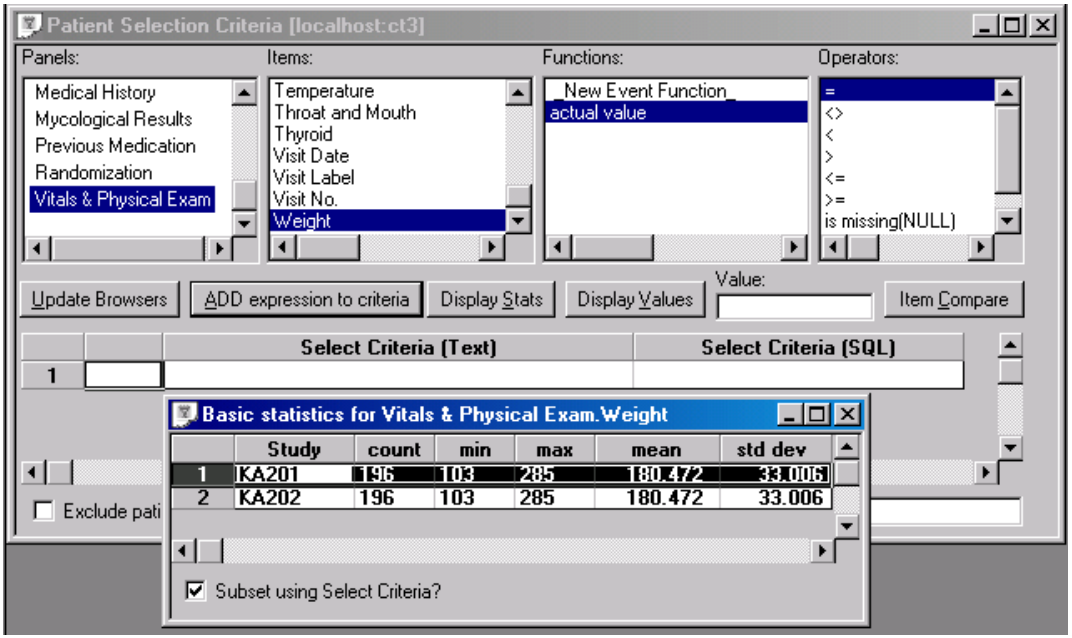
You can display the range and other basic statistics of the item by selecting an item and clicking **Display Stats**.

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

The example for patient weight 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 display represents the total population of patients within the protocols selected and the selected function.

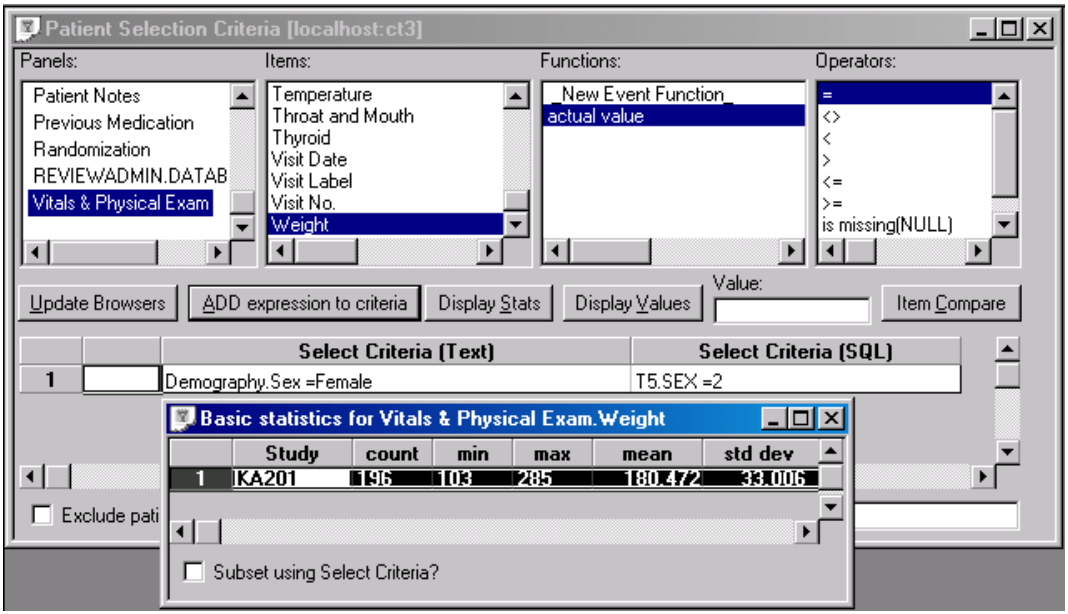


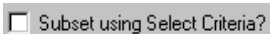
Note: In multi-protocol mode, there is one row for each protocol.

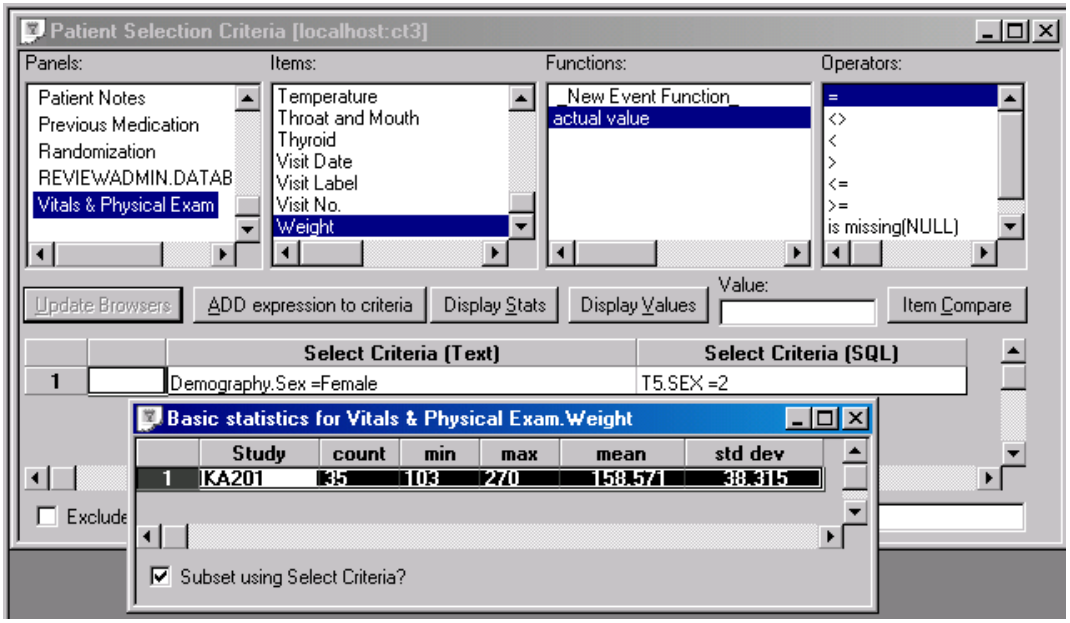


Displaying subsets of protocol population

You can limit the displayed statistics for the patients meeting the patient selection criteria by checking “Subset using Select Criteria?”. If the checkbox is not checked, the statistics are for the total population. If the statistics are displayed when you update patient selection criteria, click Update Browsers to apply the updated patient selection criteria to the displayed statistics.



If  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 **Update Browsers** 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**.



Clintrial tags

Clintrial tags as pseudo-panel

Clintrial tags are accessible as selection criteria and reportable elements. For the pseudo-panel Clintrial tags, the items list shows registered tags when the pseudo-panel Clintrial tags is selected.

Optional user-defined panels and joins

Pivot Panels

If you select the pseudo-panel item '_Define Pivot Panel_', Review provides a point and click mechanism to transpose clinical data stored in a normalized manner, into a more easily reportable horizontal data structure. The created pivot panel objects are accessible throughout all Review browsers.

The '_Define Pivot Panel_' mechanism provides a method of storing such definitions centrally in Review's server-based global object storage site. (See *Chapter 12: Common Topics: Server Based Global Object Storage Site* and *Chapter 12: Common Topics: Defining Pivot Panels*)

Join Logic

Review provides automatic join logic. (See *Chapter 12: Common Topics: Automatic Join Logic*)

In addition Review provides a mechanism, through the pseudo-panel '_Define Join Logic_', to configure complex join rules and force a join definition.

This mechanism is required to access Clintrial Type 0 panels that can be related to patient data, such as laboratory normal values. This tool provides a lookup capability on such Type 0 panels when selecting or reporting patient-level data. An example is to report patient level lab data and lookup for reporting purposes, the corresponding lab normal entry (typically stored in a type 0 panel). (For more information and instruction, (See *Chapter 12: Common Topics: _Define Logical Joins*)

Note: Your site administrator can set site and user configuration to enable or disable '_Define Pivot Panel_' and '_Define Join Logic_'. Therefore, your patient selection criteria window for the panels listbox may appear different dependent upon the configuration setup.

Object storage: saving your work

Object storage location

You can store patient selection criteria at four user access levels: Private, WorkGroup, UserGroup, or Public.

- Private storage is at the local PC level. The private objects are saved on the user's home drive in a directory (folder) called "irpat". Review handles all creation, access and deletion of the private objects in this folder. Therefore, the user should not be concerned with the contents of the irprivat folder.
- WorkGroup storage is PC based and stored at a shared network drive, to which a select group of personnel would have access.

Note: The WorkGroup storage location was supported in earlier Review releases. UserGroup storage location is extensively used for later releases.

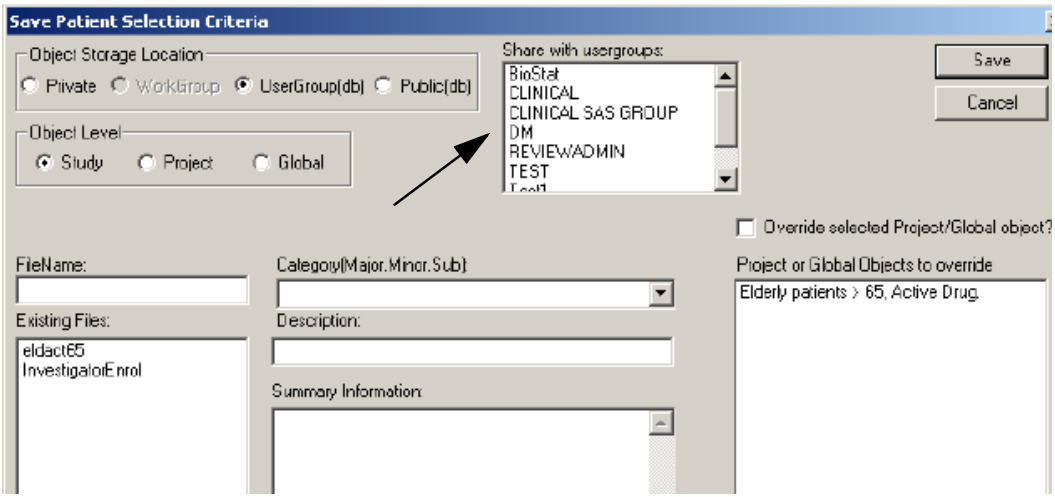
- UserGroup storage is a database object storage for defined UserGroups in the configuration tables.

  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 WorkGroup or UserGroup storage.

  Saving on database object storage sites, requires the author to have "Publishing Authorization" defined in the configuration tables. (See *Chapter 12: Common Topics: Shared Object Storage- Locations)*

When you select UserGroup object storage location, the ‘Share with usergroups’ listbox is made available for selection.



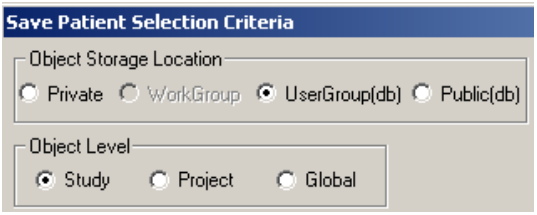
Object level

You can store your patient selection criteria at three levels: Study, Project, or Global. The Object Level box is only enabled and highlighted when you select an Object Storage Location designated as ‘db’ for database. Therefore, when you select either UserGroup or Public for database object 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.

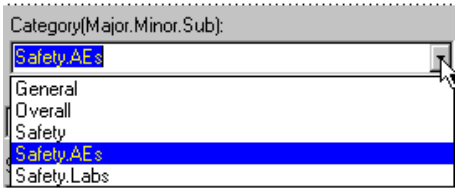
Saving the selection criteria

To save the patient selection criteria (the rows of Criteria Expressions) you have created for later use:

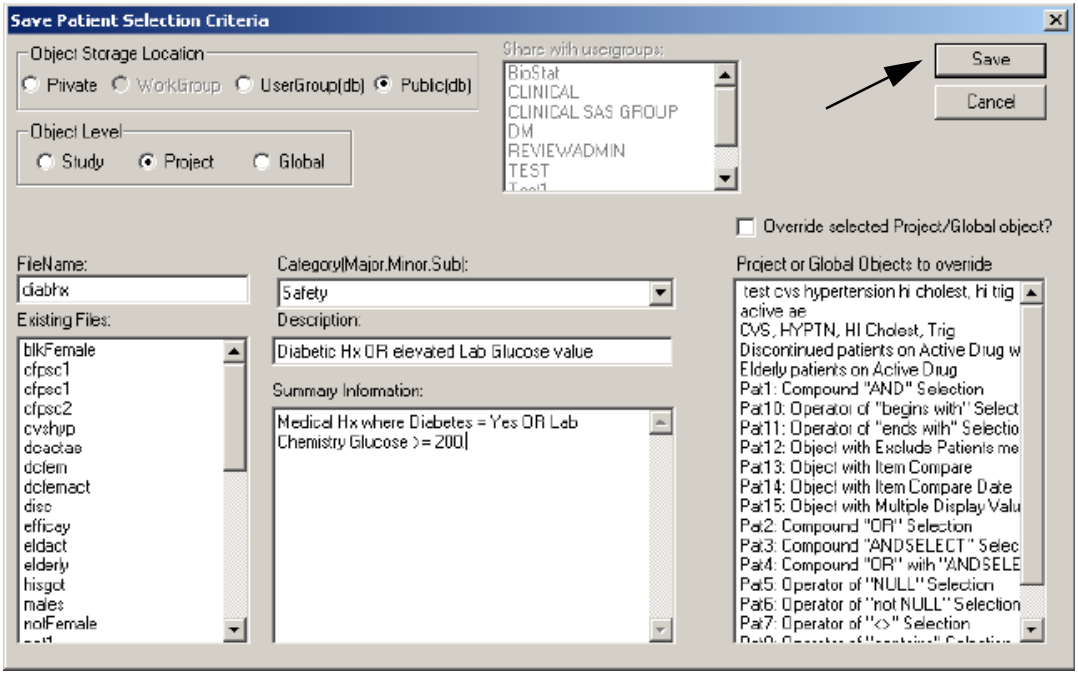
1. Make certain that the Patient Selection Criteria window is the active window by clicking on its title bar.
2. Click , or from the **File** menu select **Save.**
3. Review displays the Save Patient Selection Criteria dialog box where you can specify the storage location.
4. Enter the Object Storage Location and Object Level.



5. Enter a FileName for future reference to be displayed in the list box for Existing Files.
6. 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 listbox.



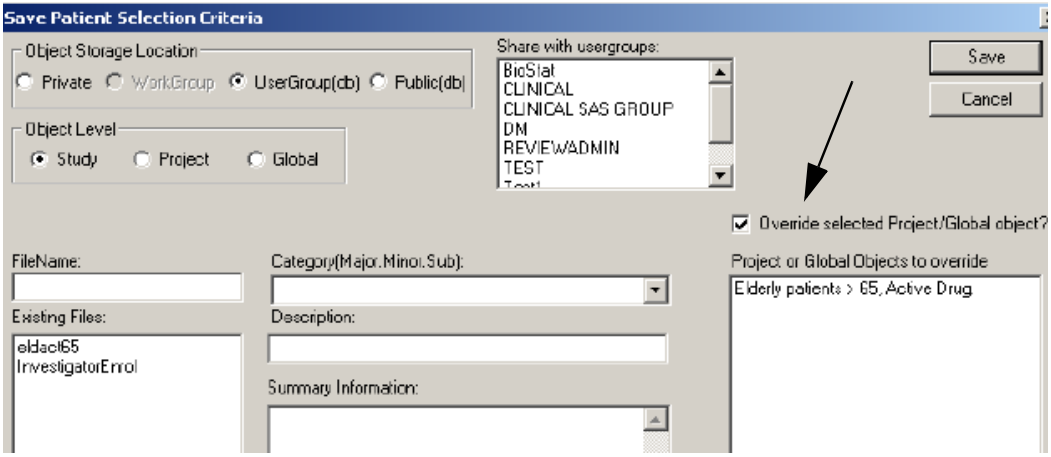
7. Next enter the description including a summary paragraph for additional information to be viewed by yourself or others later.
8. Click **Save**. Review stores the Patient Selection Criteria to the designated PC, UserGroup, or Public storage location.



Override selected Project/Global object?

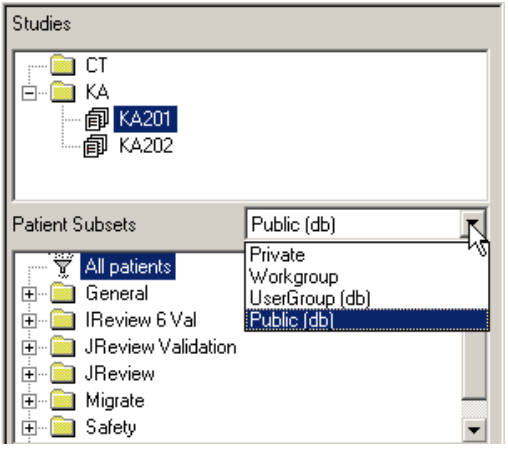
The purpose of the override is to create a study specific version of the standard object, in the non-standard study. For example, you create a set of global or project level objects and assume they should be applicable to all subjects in the study project (for project level) or all studies in the database (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. Otherwise, the question is disabled when you select other object locations and levels.



Object Explorer window

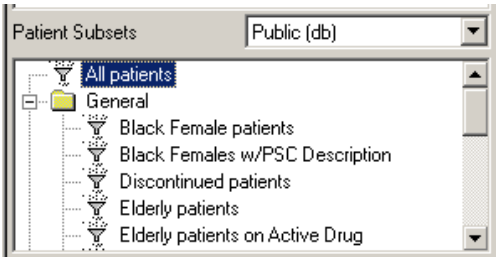
Once you have saved your selection criteria and assign folder information, your folder(s) and selection criteria will display as a stored object in the Object Explorer Window under Patient Subsets. Review displays a list of folders for previously saved output specifications at the selected object storage location. Simply select one of the storage locations as Private, UserGroup or Public to display it's specific folders and contents. Select the object storage location from the drop down list.



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.

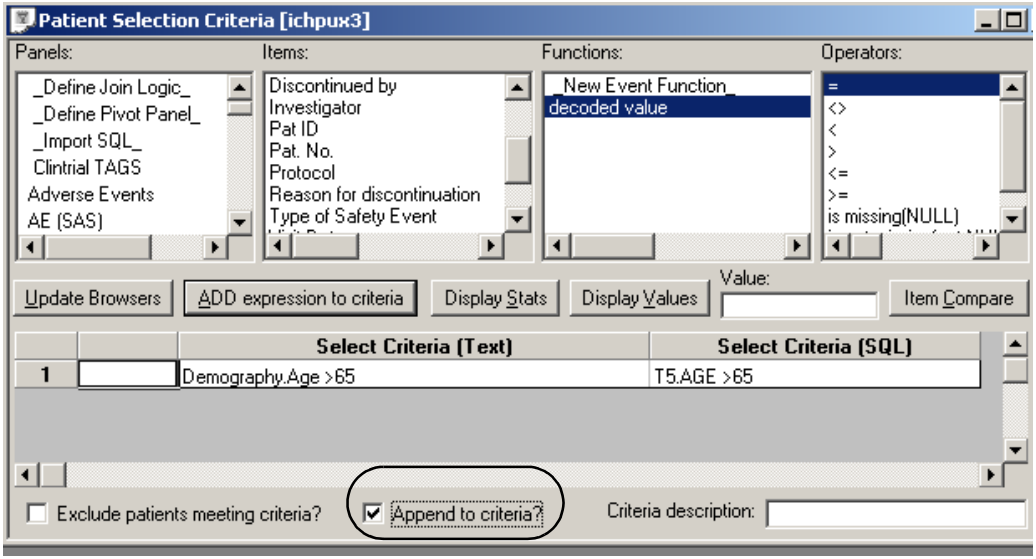
Append to criteria

At this point, you can either click Update Browsers to enable your selection criteria, or continue to add more criteria 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.

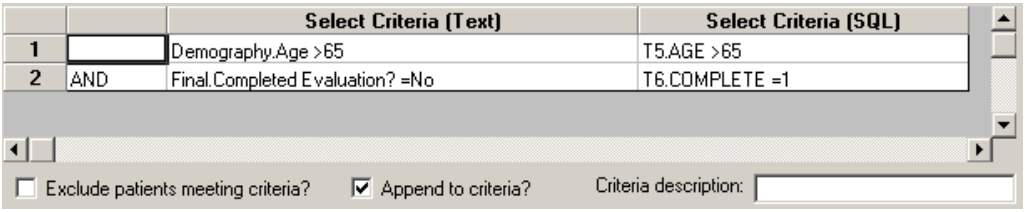
Note: To save time, you can launch and paste previously saved patient selection criteria from the Object Explorer Window to edit and resave as new stored objects. However, you must load the previously stored object first into the Patient Selection Criteria Window then append to or modify it.

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

1. Select and double click to add the first patient selection criteria.
2. Click .

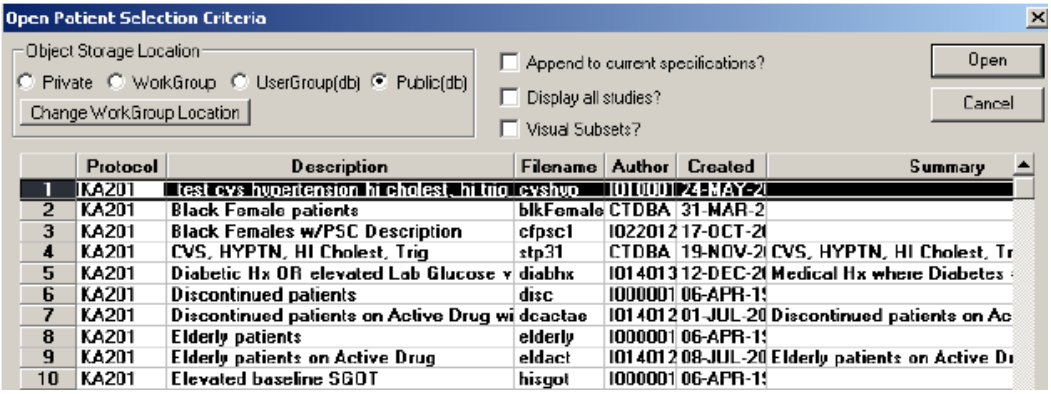


3. Select and double click another selection criteria to append.



Another way to retrieve saved patient selection criteria is to make the patient selection criteria window the active window:

1. Click , or from the **File** menu, select **Open**.
2. Click on the object storage location and the available files display.
3. To retrieve the saved patient selection criteria, select a selection criteria and click **Open;** or double click on the description.
4. You can click the Change WorkGroup Location to browse various object storage sites.

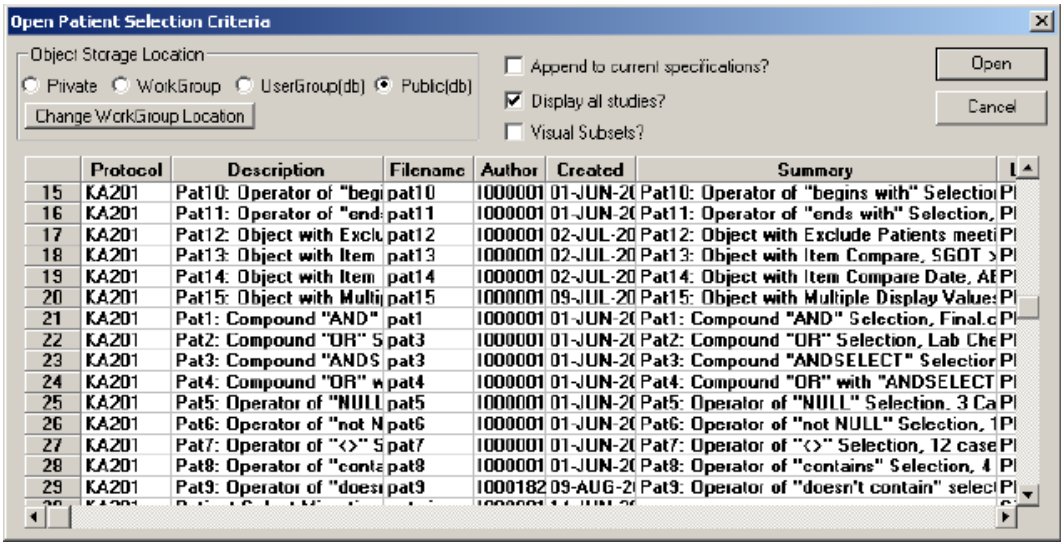


Display all studies

By default, the Display all studies? is not checked, and the displayed list of objects is limited to the selection criteria objects created in the current Study Protocol(s).

If you want to select a saved selection criteria object created and saved from another protocol:

1. Click **Display all studies?**.



2. You then can select from any saved selection criteria object created.
3. Select a foreign object and click **Open**.

The internal data structure between the corresponding protocols is checked and validated and is immediately added to the current patient selection criteria as a new or appended criteria expression.

Note: By default, the stored patient selection criteria is only accessible on the project(s) it was created on. You can click on the Display all studies? *to import foreign objects.*

You can browse through the saved patient selection criteria at the four object storage locations to review the summary text. When you find the one you are looking for:

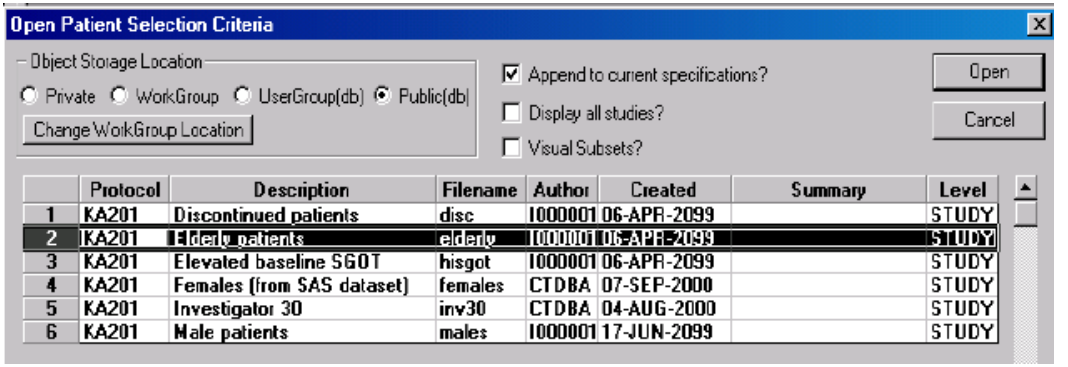
1. Click on the entry.
2. Then click **Open**.

   Review pastes the saved patient selection criteria into the Patient Selection Criteria spreadsheet clearing the current spreadsheet contents.

Another way to append previously saved patient selection criteria is:

1. Select a saved patient selection criteria and enter into the Patient Selection Criteria Window.
2. Click the **Open** icon or from the **File** menu, select **Open**. The Open Patient Selection Criteria window displays.
3. Select the Object Storage Location to display previously saved objects.
4. Select the specification description you want to append.
5. Click

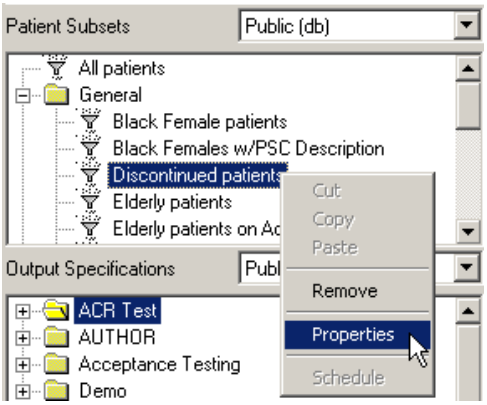
, then click **Open**.
6. The saved specification is added to the current Criteria Expressions.
7. Click **Update Browsers** to apply the new patient selection criteria against the protocol patient population.



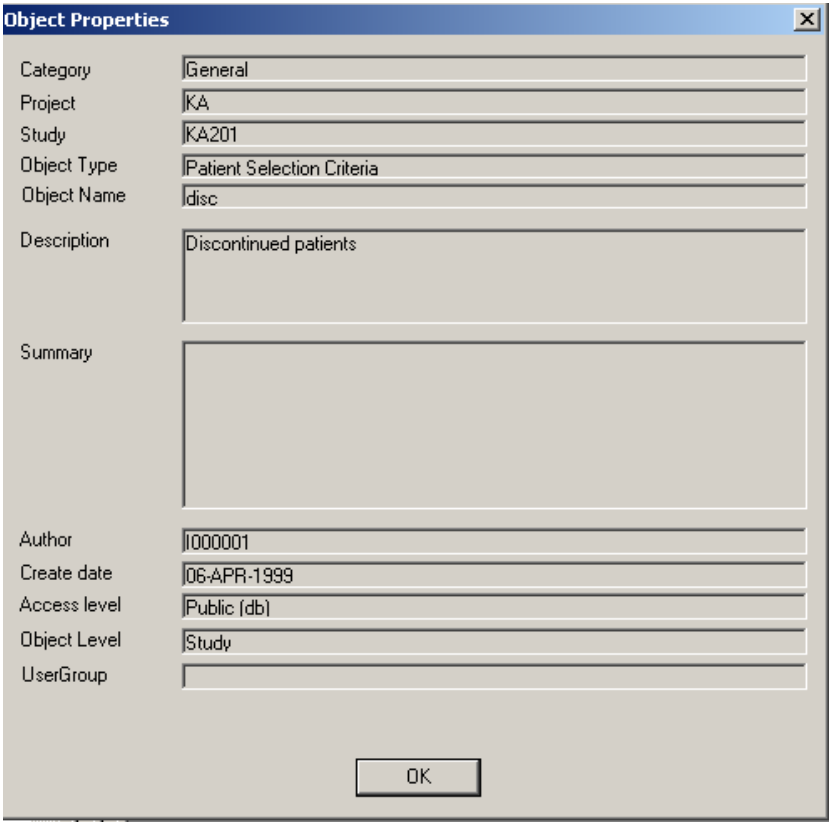
Object properties

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. Then click **Properties**. A dialog window displays whether the object is a patient selection criteria or an output object.



Printing the selection criteria

To print the currently active patient selection criteria:

1. Make certain that the patient selection criteria window is active by clicking on its title bar.
2. Click , or from the **File** menu, select **Print**.

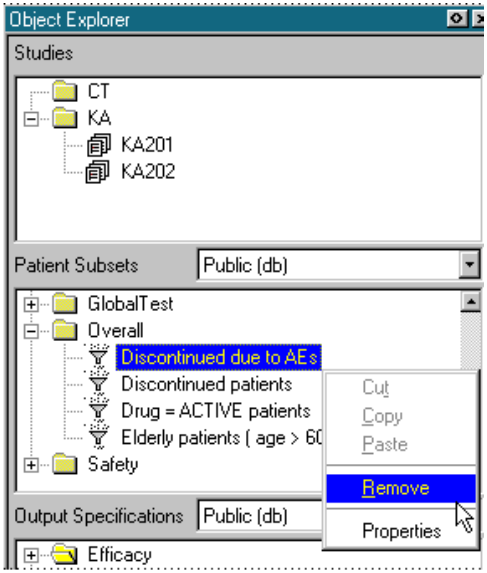
   Review displays the standard Print dialog box.
3. Click **OK**. The patient selection criteria prints on the specified printer. To change the printer, from the **File** menu, select **Print Setup**.

Quick remove

You can quickly delete a saved patient selection criteria (or visual subset) 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?".

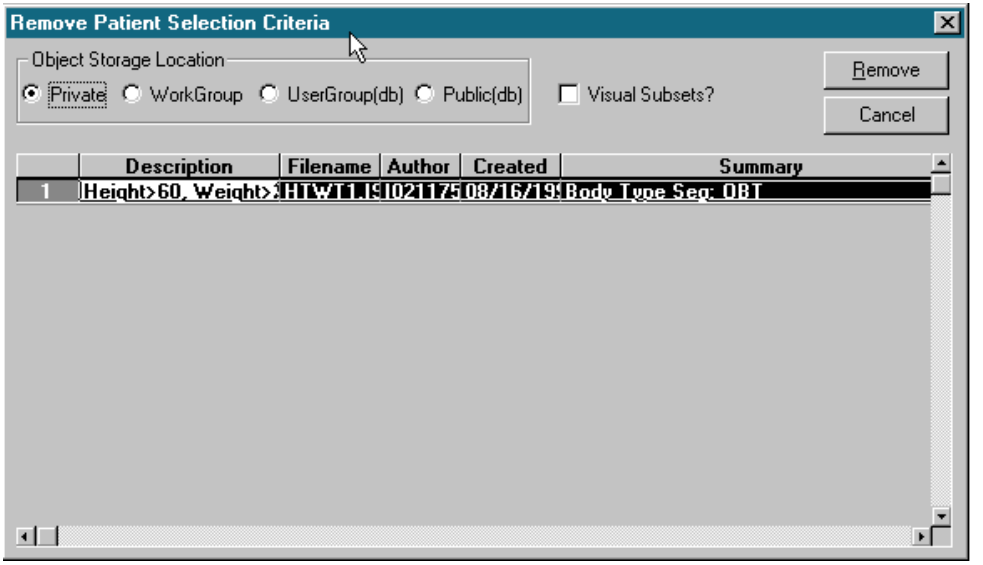
The Remove function is a quick way to delete stored objects provided the user is the creator or a SuperUser. It works for 'Private', 'Workgroup', 'UserGroup' or 'Public' objects equally. (See *Chapter 12: Common Topics: SuperUser Privileges)*



Another way to remove one of the saved patient selection criteria (or visual subset):

1. Make the Patient Selection Criteria the active window.
2. From the **File** menu, click **Remove**.
3. Review displays the Remove Patient Selection Criteria window.
4. Click on the object storage location. The stored patient selection criteria specifications are listed. Click '**Visual Subsets?**', if the object is a visual subset.
5. Select the stored object description you want to remove.
6. Click **Remove**.

Review deletes the selection criteria from the designated local PC, WorkGroup, UserGroup or Public storage location if you have security clearance to do so.



Exploring data

Reviewing preferences

At any time, you can modify Review's preference by selecting the **Edit** menu from the Patient Selection Criteria window, and selecting **Preferences from**.

Outer join in Results

If enabled, a patient's data is included in browser results even if some panels of data are missing for that patient. (See *Chapter 12: Common Topics: Reviewing Preferences*)

Display panel names

If enabled, panel lists display the panel name rather than the panel description. (See *Chapter 12: Common Topics: Reviewing Preference*)

Display item names

If enabled, item lists display the panel name rather than the panel description. (See *Chapter 12: Common Topics: Reviewing Preference)*

Sort panels alphabetically

If enabled, panel lists are sorted alphabetically; otherwise, panels are listed in the order in which they were created. (See *Chapter 12: Common Topics: Reviewing Preferences*)

Sort items alphabetically

If enabled, item lists are sorted alphabetically; otherwise, items are listed in the order in which they were created. (See *Chapter 12: Common Topics: Reviewing Preferences*)

Reviewing with browsers

After you specify the patient selection criteria to be used to retrieve patients, you can explore the patient population you selected using the browsers.

Activate the Detail Data Browser**.** You can display a list of patients who meet the patient selection criteria specified and look at their detail data. (For more information, see *Chapter 3: Reviewing Patient Data.*)

Activate the Patient Profiles Browser. You can organize the selected patients into various Workbook Report types as single worksheet mode or multiple worksheet mode. (For more information, see *Chapter 4: Patient Profiles*.)

Activate the Report Browser. You can create a quick report to list items of interest for each of the patients and patient populations meeting the patient selection criteria. (For more information, see *Chapter 6: Reporting*.)

Activate the Graph Browser. You can look at items of interest graphically for patient populations meeting the patient selection criteria. (For more information, see *Chapter 7: Graphing*.)

Activate the CrossTab Browser. You can create CrossTab and Shift Tables for patient populations meeting the patient selection criteria. (For more information, see *Chapter 8: CrossTab*.)

Activate the Statistics Browser. You can look at a variety of statistics and other reports for items of interest for patient populations meeting the patient selection criteria. (For more information, see *Chapter 9: Generating Statistics*.)

Activate the SAS Program Browser. You can review preprogrammed SAS Production Tables against original SAS datasets used in the analysis for patient populations meeting the patient selection criteria. (For more information, see *Chapter 10: Production Tables*.)

Activate the Note Browser. You can review patient-level notes saved by yourself and others stored in Object Storage Levels for Private, UserGroup and Public. (For more information, see *Chapter 3: Reviewing Patient Data.)*

Activate the Document Browser. You can review documents for the selected protocol. (For more information, see *Chapter 11: Accessing Documents*.)

3 Reviewing Patient Data

Patient selection criteria 98
- Subset patients 98

Open the Data Browser 99
- Listing of patients 99
- Data Review 99
- Graph format display 102
- Browsing through patient data 103
- Displaying CRF images 104
- Audit trail 104
- Reviewing tags (flags and notes) 105

Discrepancy records 106
- Discrepancy record panel view 106
- Creating discrepancy records 106
- Selecting data for discrepancy record 107
- Avoid duplicate discrepancy records 109

Patient level notes 110
- Store and retrieve patient notes 110
- Find menu command 112
- Remove note 112

Multiple-patient mode 113
- Freezing a case 113
- CrossTab Browser results 116

Patient listings and panel views 117
- Expanding spreadsheet columns 117
- Print Preview 117
- Printing a patient listing 117
- Printing a panel view 118
- Exporting a patient list or panel view 118

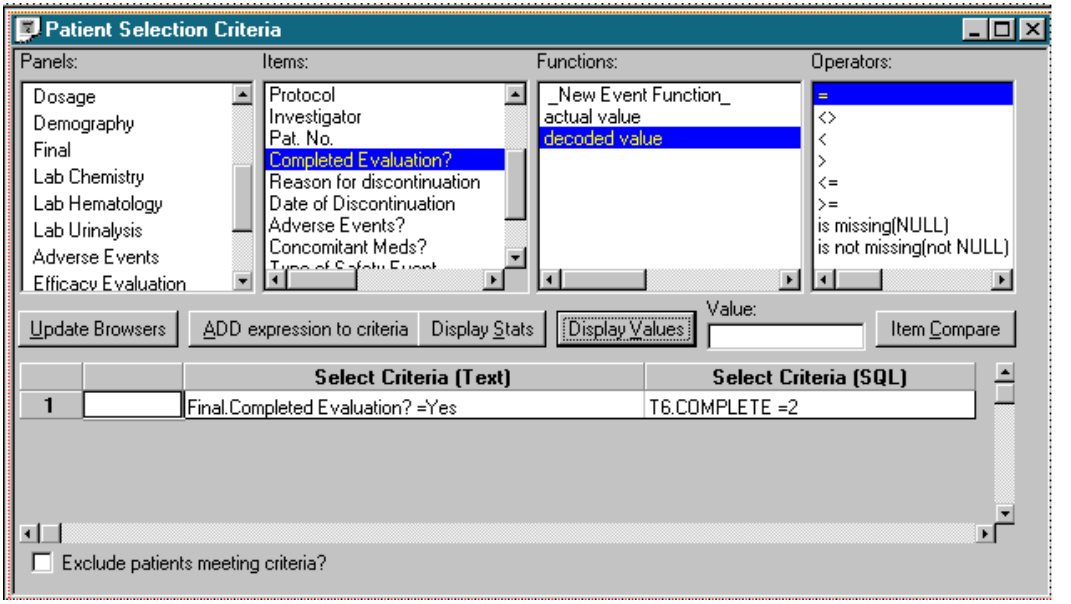
Custom panels 119
Define custom panels 119
Custom panel output filter 121
Update or remove custom panel 123
Modifiable items 124
Defining modifiable items 124
Modifying data 126
Modifying coded data 128
Reset items content 129
Saving Data Browser specifications 130
Object storage location 130
Object level 131
Store a selection of panel views 131
Override selected Project/Global object? 133
Object Explorer Window 133
Retrieve a saved Data Browser object 134
Retrieve a saved Data Browser object 134
Quick remove 136
Object properties 137
Updating the Data Browser 138
Closing panel views and the Data Browser 139
Closing a panel view 139
Closing the Data Browser window 139

Exploring data 139
Changing the patient selection criteria 139
Patient identification 139
Discrepancy reports 140
Detail Data Listing reports 140
Scatter plot graphs 140
CrossTab table results 140
Data Browser and pivot panels 140
Data Browsers and join logic 141

Patient selection criteria

Subset patients

After building the patient selection criteria, you can quickly view a detailed list of patients who meet the patient selection criteria, by using the Data Browser.

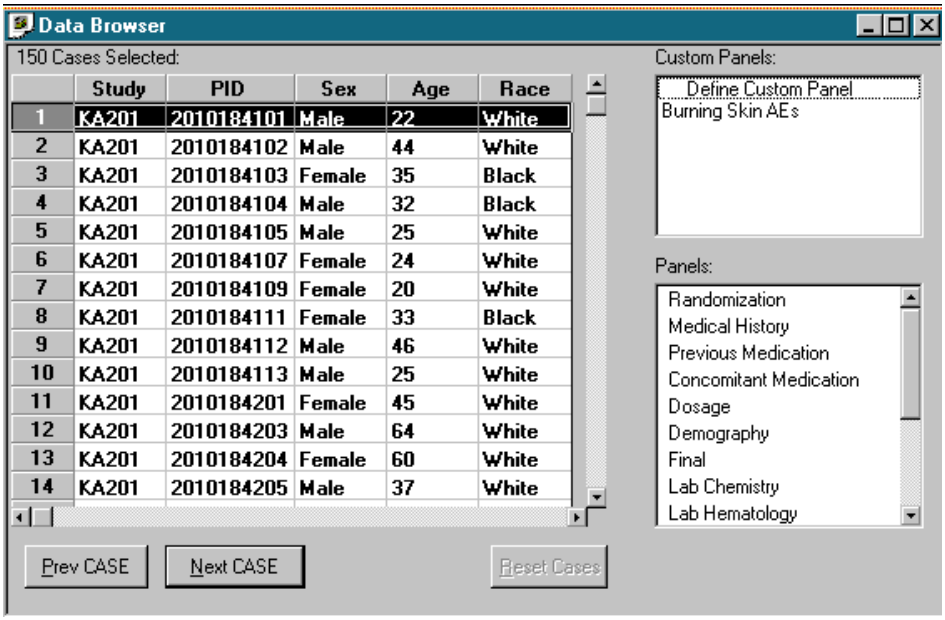


Open the Data Browser

Listing of patients

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

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

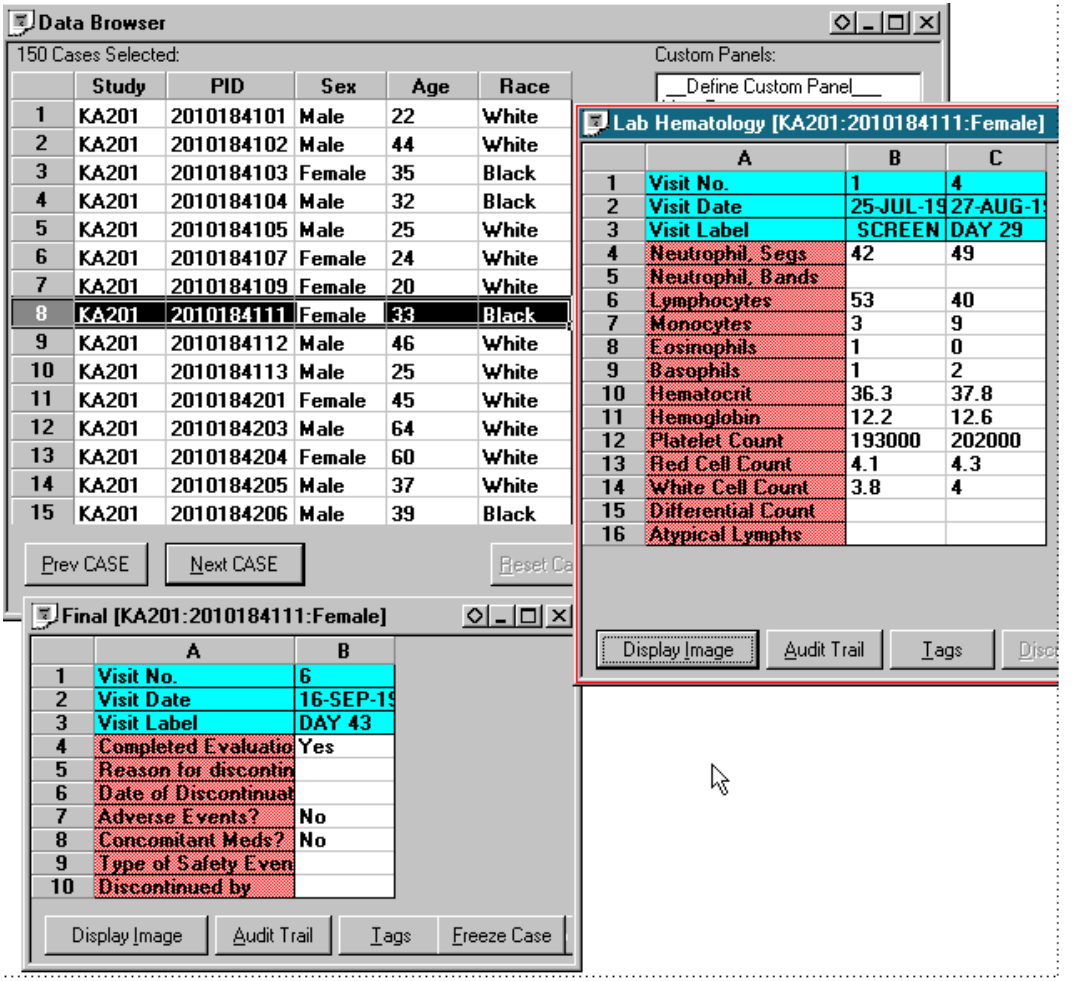


Note: Review displays the number of cases selected before the list of patients. The key clinical information for each patient, such as treatment group, case ID, sex, age, and so on, are also displayed and are custom-configurable through ReviewAdmin.

Data Review

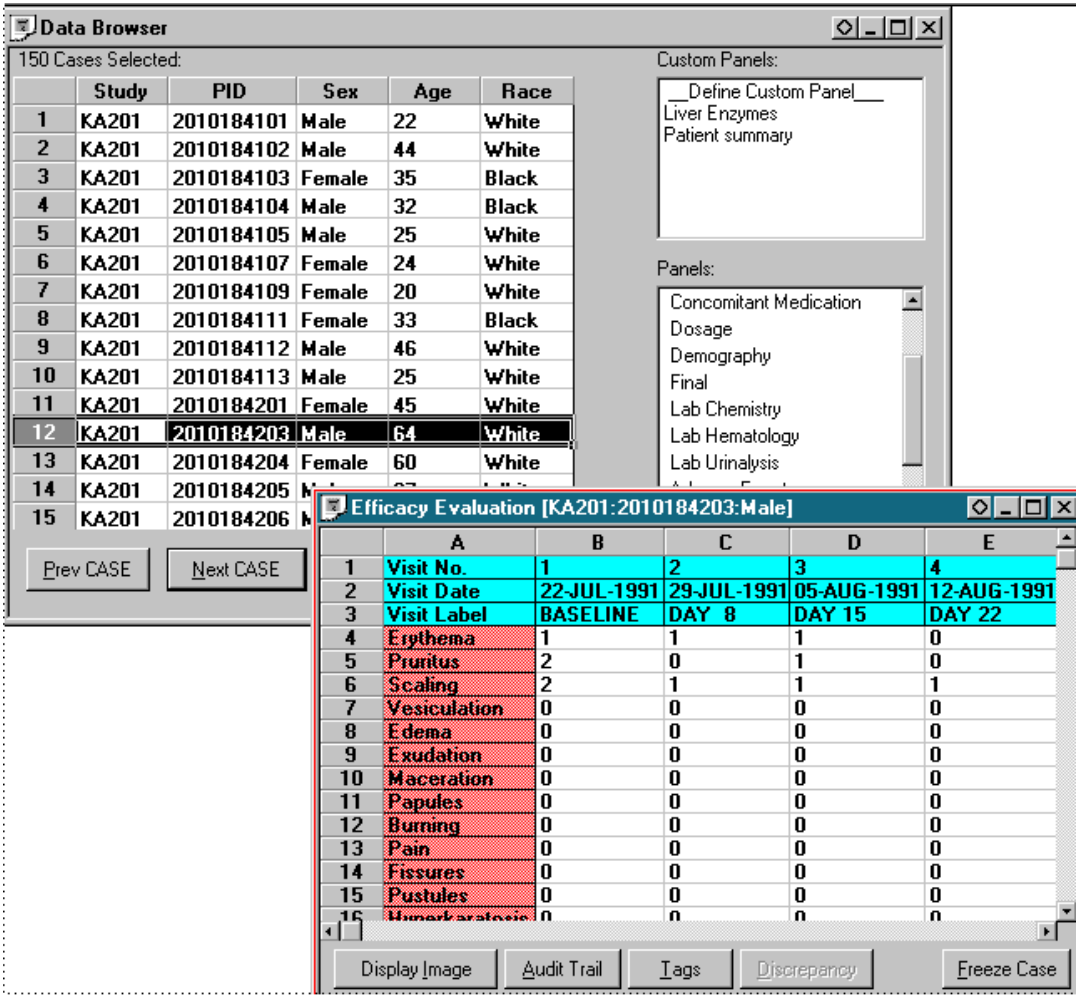
To see more data for each patient selected:

1. 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.
2. Select a panel.



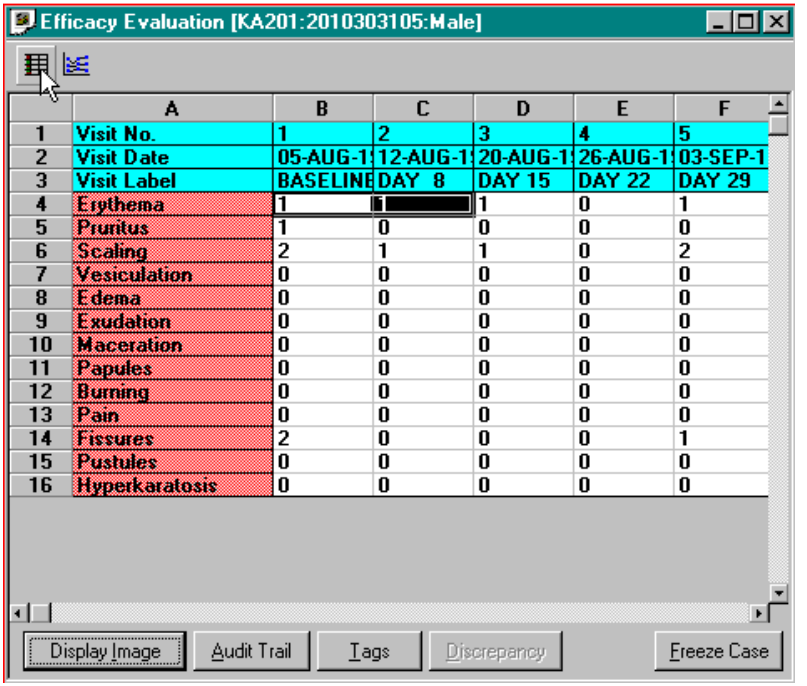
You can select several panels from the list of available panels in the protocol. Each panel selected displays a new window with a spreadsheet containing descriptions and data for the selected patient.

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


Data Browser
150 Cases Selected:
Study PID Sex Age Race
1 KA201 2010184101 Male 22 White
2 KA201 2010184102 Male 44 White
3 KA201 2010184103 Female 35 Black
4 KA201 2010184104 Male 32 Black
5 KA201 2010184105 Male 25 White
6 KA201 2010184107 Female 24 White
7 KA201 2010184109 Female 20 White
8 KA201 2010184111 Female 33 Black
9 KA201 2010184112 Male 46 White
10 KA201 2010184113 Male 25 White
11 KA201 2010184201 Female 45 White
12 KA201 2010184203 Male 64 White
13 KA201 2010184204 Female 60 White
14 KA201 2010184205
15 KA201 2010184206
Prev CASE
Next CASE
Custom Panels:
__Define Custom Panel___
Liver Enzymes
Patient summary
Panels:
Concomitant Medication
Dosage
Demography
Final
Lab Chemistry
Lab Hematology
Lab Urinalysis
Efficacy Evaluation [KA201:2010184203:Male]
A B C D E
1 Visit No. 1 2 3 4
2 Visit Date 22-JUL-1991 29-JUL-1991 05-AUG-1991 12-AUG-1991
3 Visit Label BASELINE DAY 8 DAY 15 DAY 22
4 Erythema 1 1 1 0
5 Pruritus 2 0 1 0
6 Scaling 2 1 1 1
7 Vesiculation 0 0 0 0
8 Edema 0 0 0 0
9 Exudation 0 0 0 0
10 Maceration 0 0 0 0
11 Papules 0 0 0 0
12 Burning 0 0 0 0
13 Pain 0 0 0 0
14 Fissures 0 0 0 0
15 Pustules 0 0 0 0
Display Image
Audit Trail
Tags
Discrepancy
Freeze Case

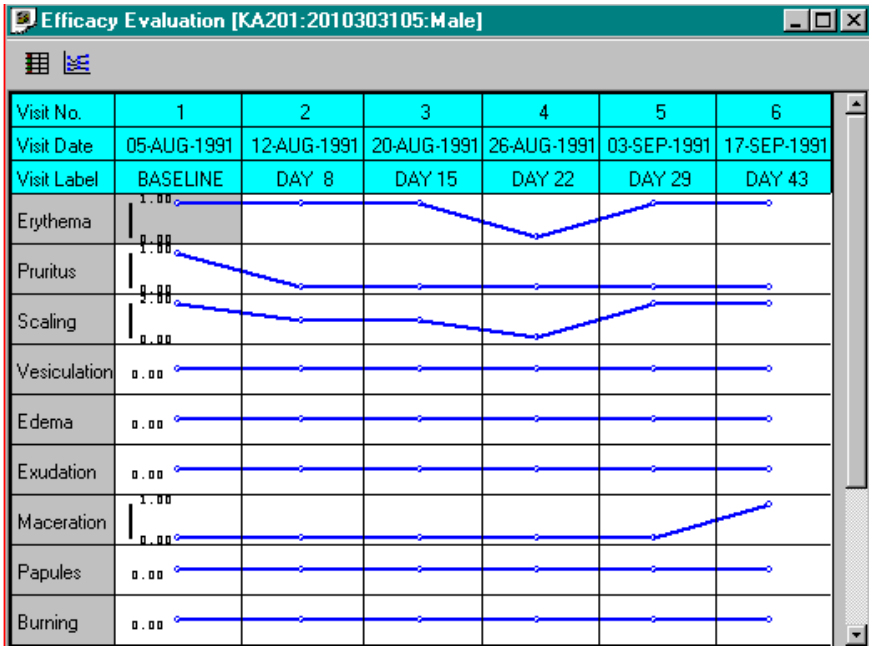
Graph format display

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



	A	B	C	D	E	F
1	Visit No.	1	2	3	4	5
2	Visit Date	05-AUG-1	12-AUG-1	20-AUG-1	26-AUG-1	03-SEP-1
3	Visit Label	BASELINE	DAY 8	DAY 15	DAY 22	DAY 29
4	Erythema	1	1	1	0	1
5	Pruritus	1	0	0	0	0
6	Scaling	2	1	1	0	2
7	Vesiculation	0	0	0	0	0
8	Edema	0	0	0	0	0
9	Exudation	0	0	0	0	0
10	Maceration	0	0	0	0	0
11	Papules	0	0	0	0	0
12	Burning	0	0	0	0	0
13	Pain	0	0	0	0	0
14	Fissures	2	0	0	0	1
15	Pustules	0	0	0	0	0
16	Hyperkaratosis	0	0	0	0	0

If you click the graph icon, the data is converted to a graph format with the patient's minimum and maximum values listed in the first column.



Browsing through patient data

To browse patient data:

1. Select a patient.
2. Select the panels that you are interested in reviewing.
3. Position and size the panel view windows.
4. Click each patient in succession or use **Prev CASE** or **Next CASE**. Each time another patient is selected, each open panel view window is updated to reflect the data for the currently selected patient. 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. (See *Chapter 12: Common Topics; Tags: Clintrial Tags.*)

Displaying CRF images

If your CRF imaging system is configured into Review and you want to review an image of the original Case Report Form (CRF) behind the data displayed:

1. Click on the column heading of the data observation of interest.
2. Click **Display Image**.

   The CRF Image Viewer and the image corresponding to this data is displayed (if it is available in the CRF image archive database, which is not part of Review).

   *Note: If the CRF imaging system is not configured in Review, the **Display Image** is not available.*

Audit trail

To review the historical editing of the original Case Report Form items, in reference to any of the panels:

1. Click on the column heading of the data observation of interest,
2. Click **Audit Trail**.

   The Audit trail window displays the data chronologically; the most recent editing of the original data input is in the left column and moves chronologically to the right. The last column is the original data entered. The Audit Trail documents the dates on which the data was edited, and saves a copy of the data before it was changed.

AUDIT:Demography [KA201:2010184103:Female]

	A	B	C	D	E	F
1	Modification Date/Ti	1995-12-18 11	1995-12-18 11	1995-11-10 0:	1995-11-10 03:	1995-07-26 1:
2	Entry ID	CTDBA	CTDBA	CTDBA	CTDBA	
3	Visit No.	1	1	1	1	1
4	Visit Date	15-JUL-1991	15-JUL-1991	15-JUL-1991	15-JUL-1991	15-JUL-1991
5	Visit Label	BASELINE	BASELINE	BASELINE	BASELINE	BASELINE
6	Race	Black	Black	Black	Black	White
7	Sex	Female	Female	Female	Female	Male
8	Date of Birth	09-AUG-1956	09-AUG-1956	09-AUG-1956	09-AUG-1956	09-AUG-1956
9	Age	35	35	34	35	34
10	Childbearing Potenti					
11	Evaluability at Baseli	Efficacy Analy	Safety Analyza	Efficacy Analy	Efficacy Analyz	Efficacy Analy

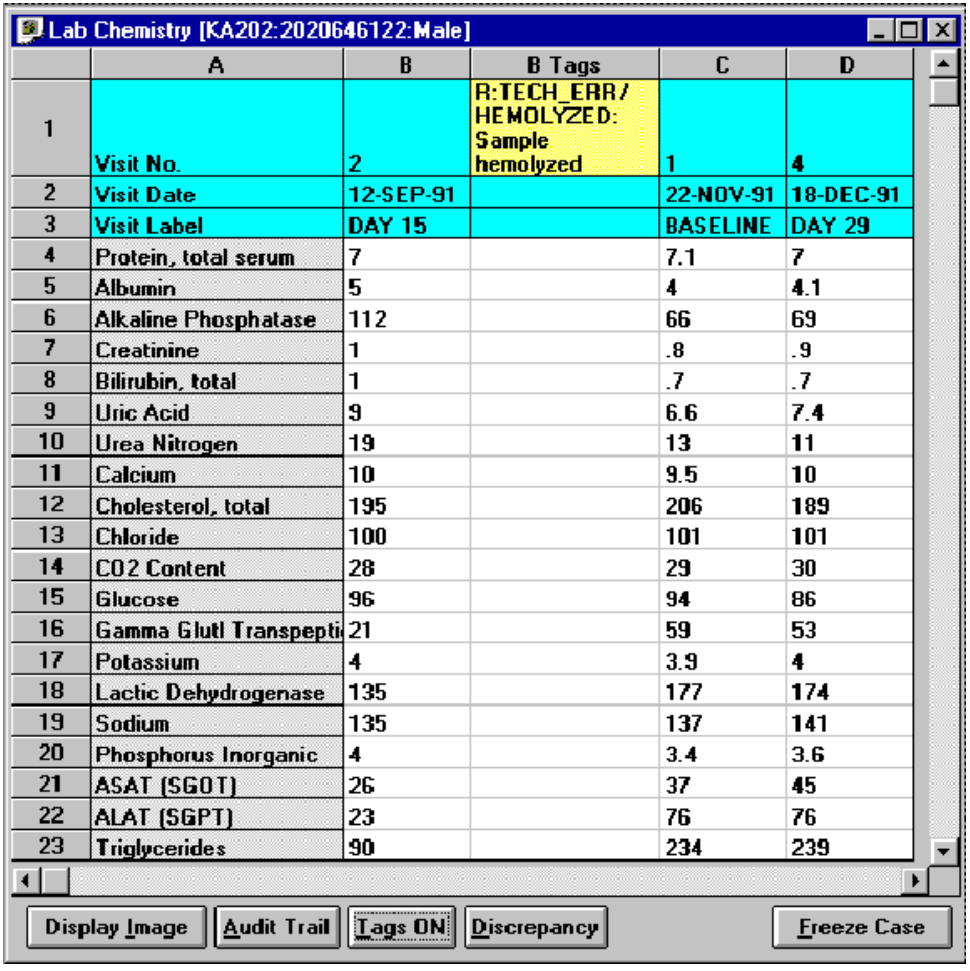
Note: Where any editing has taken place, the new values are highlighted from the previous values. This function is available for Oracle Clinical and Clintrial data.

Reviewing tags (flags and notes)

You can view all Clintrial tags (that is, flags and notes) about your clinical data (Clintrial 3 and 4 only). All labels and monitors of data quality issues, and discrepancies within your clinical data (data that is, not part of the case report forms or matching clinical data forms) are displayed in columns adjacent to the data columns.

To view tags:

1. Open the panel view you are interested in reviewing.
2. Click **Tags**, which will toggle to **Tags ON**.
3. Browse through the patient listing and review the tags.



	A	B	B Tags	C	D
1	Visit No.	2	R:TECH_ERR/ HEMOLYZED: Sample hemolyzed	1	4
2	Visit Date	12-SEP-91		22-NOV-91	18-DEC-91
3	Visit Label	DAY 15		BASELINE	DAY 29
4	Protein, total serum	7		7.1	7
5	Albumin	5		4	4.1
6	Alkaline Phosphatase	112		66	69
7	Creatinine	1		.8	.9
8	Bilirubin, total	1		.7	.7
9	Uric Acid	9		6.6	7.4
10	Urea Nitrogen	19		13	11
11	Calcium	10		9.5	10
12	Cholesterol, total	195		206	189
13	Chloride	100		101	101
14	CO2 Content	28		29	30
15	Glucose	96		94	86
16	Gamma Glutl Transpepti	21		59	53
17	Potassium	4		3.9	4
18	Lactic Dehydrogenase	135		177	174
19	Sodium	135		137	141
20	Phosphorus Inorganic	4		3.4	3.6
21	ASAT (SGOT)	26		37	45
22	ALAT (SGPT)	23		76	76
23	Triglycerides	90		234	239

4. Click **Tags ON** to return the panel view to its default display.

Within each observation, there can be tags attached to the entire observation (record) or to a specified item. The observation tags are displayed in the upper row of the adjacent Tags column (within the context data items.) The specified item tags are displayed in the corresponding data item row of the adjacent tags column.

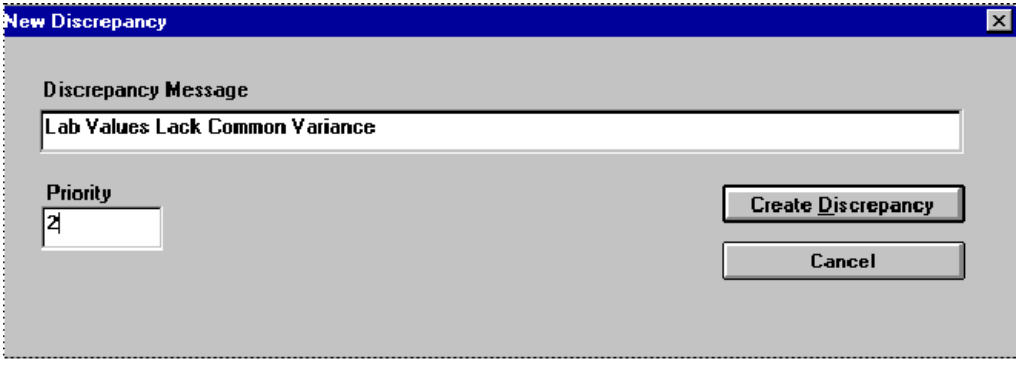
Discrepancy records

Discrepancy record panel view

You can review the discrepancies (Clintrial 4.x only) occurring in a protocol by clicking on the Discrepancy Record panel in the Data Browser panel listing.

Creating discrepancy records

You can create discrepancy records (Clintrial 4.x only) for discrepancies observed during a review of patient data. For example, you might observe that the vital signs data collected for a subject over several visits is unusually consistent, with none of the normal, expected variations. Before you investigate further, you can create a new discrepancy record to document your research.

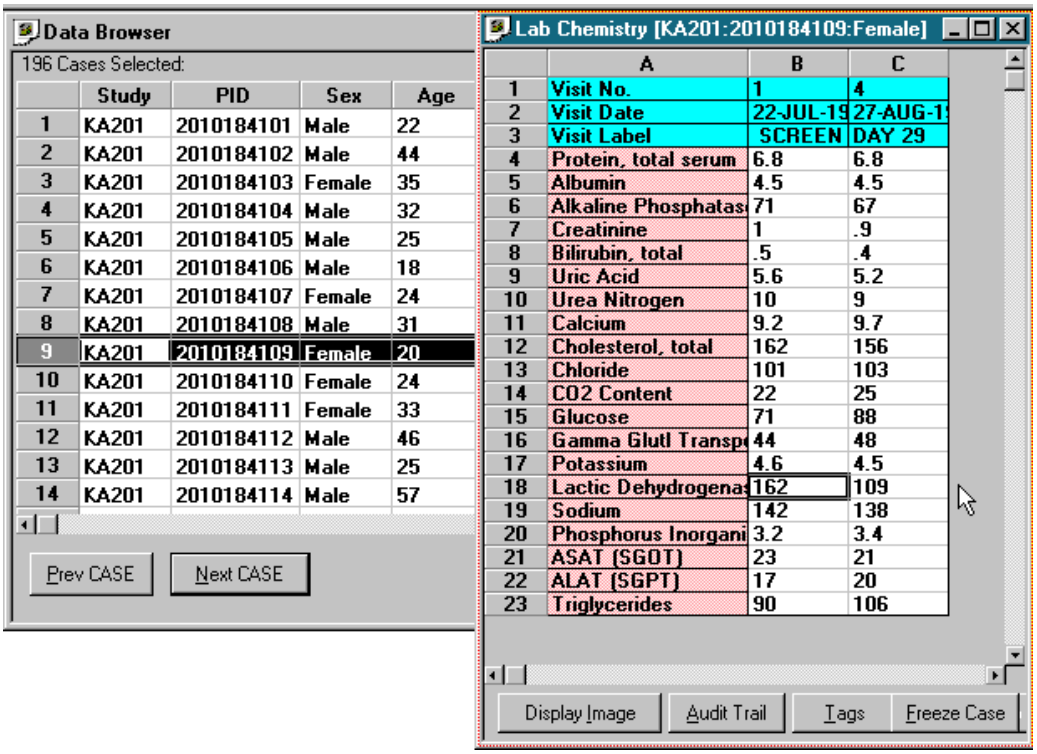


Selecting data for discrepancy record

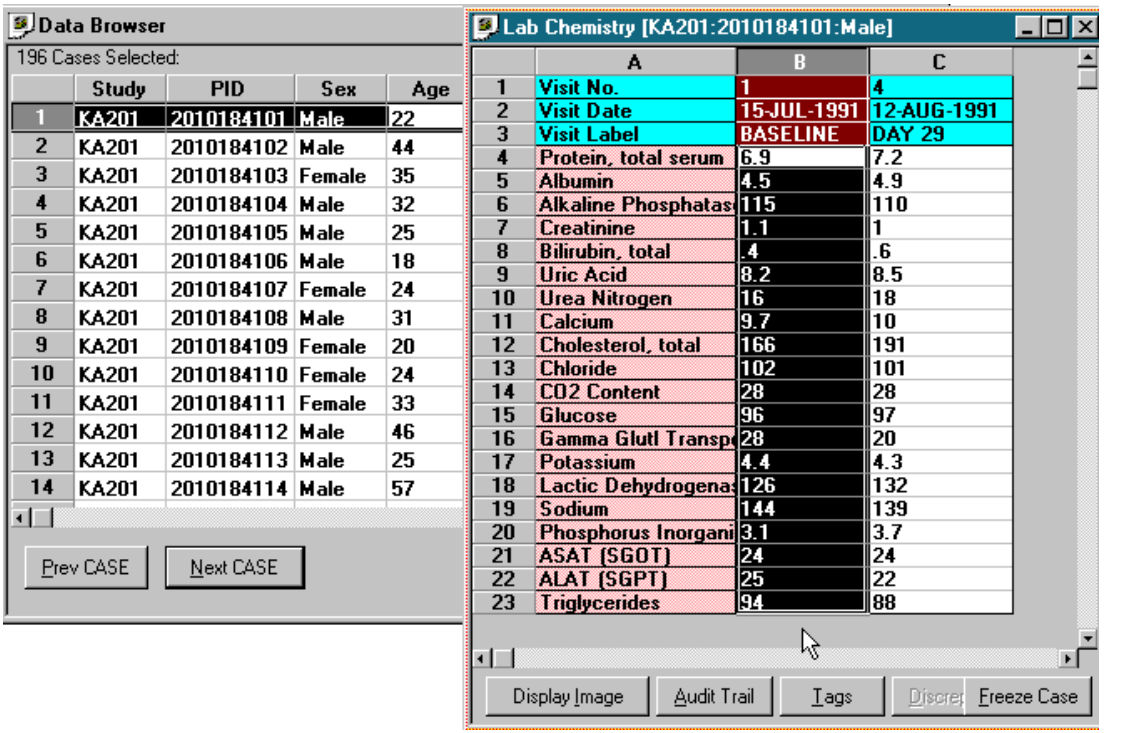
The end user (with the 'Create Access in Resolve') can highlight a patients data value or data values from a Data Browser panel view, and instantly create a discrepancy record, by clicking **Discrepancy**.

To select data values for the discrepancy record:

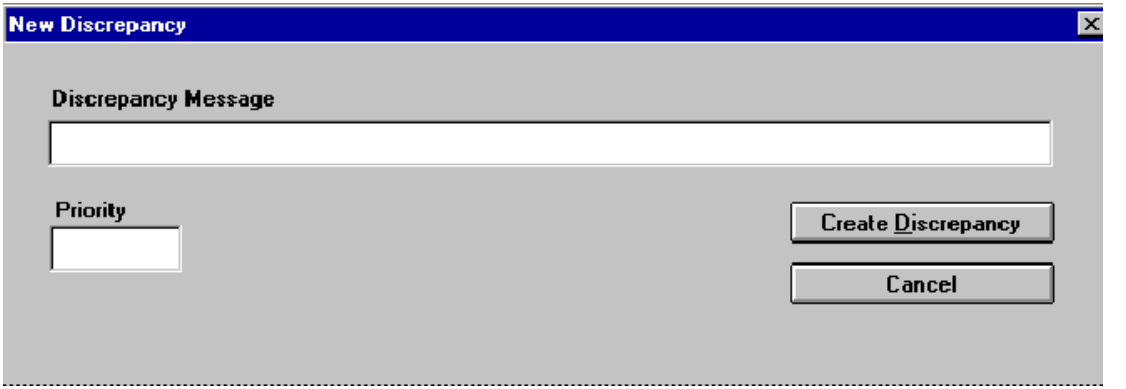
1. Click on data value or values.
2. When selecting non-contiguous data values, hold the **Ctrl** key while clicking on the values of interest.



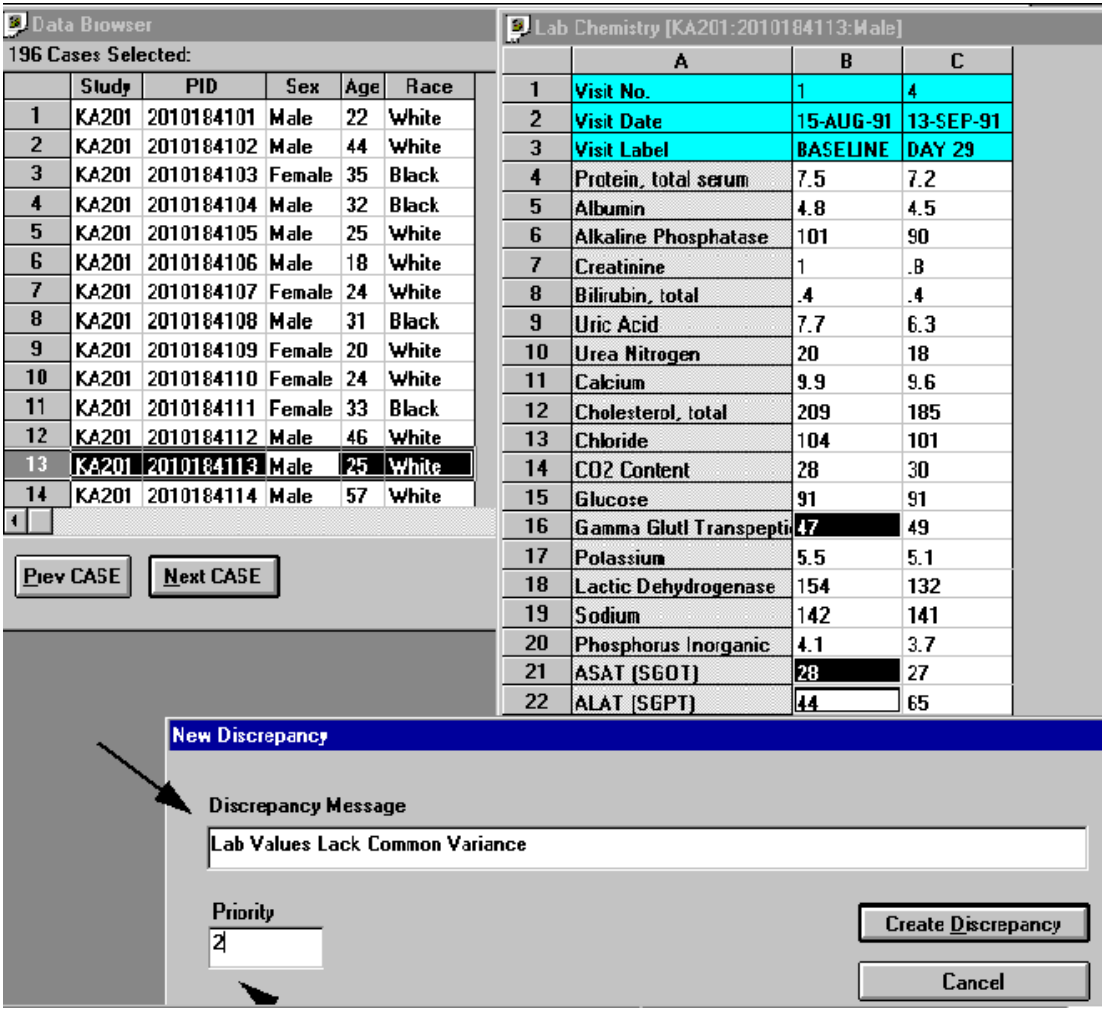
3. You can also select a column of data, by clicking on the header of the appropriate column.



4. Click **Discrepancy**, and the New Discrepancy dialog box opens. The highlighted data value or values are automatically included in the discrepancy record.
5. Enter a message in the discrepancy message field.



6. Optionally assign a priority value to the record in the “Priority” field.
7. Click **Create Discrepancy**, and your discrepancy record is automatically created and accessible in the Discrepancy Log panel.



Avoid duplicate discrepancy records

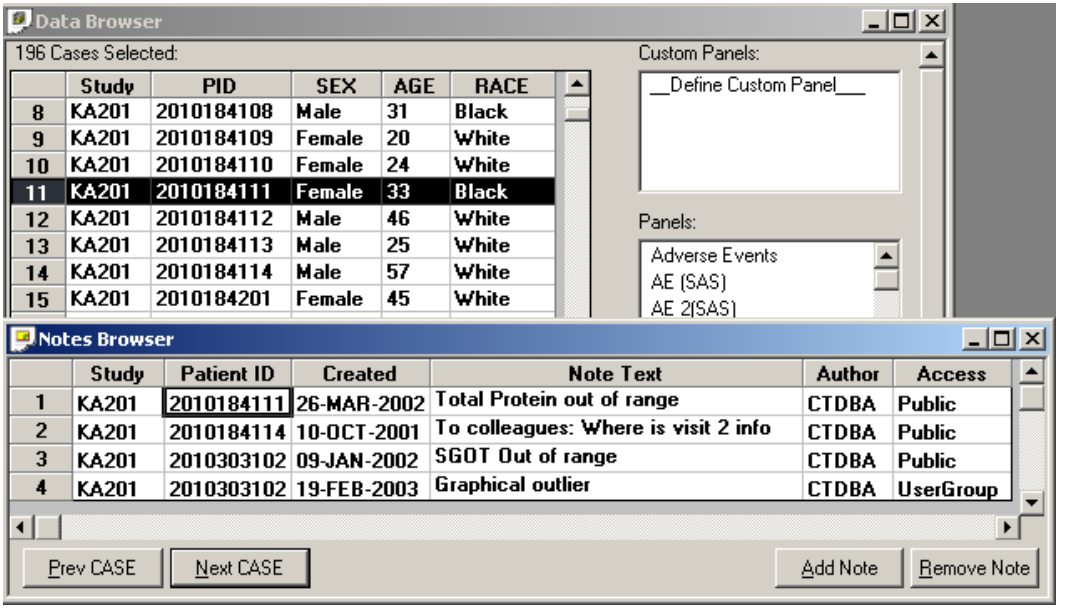
All discrepancies are contained in a Discrepancy Record panel. To avoid creating a duplicate discrepancy record, you can first open the panel view of the Discrepancy Record panel to review existing discrepancy records.

Patient level notes

Store and retrieve patient notes

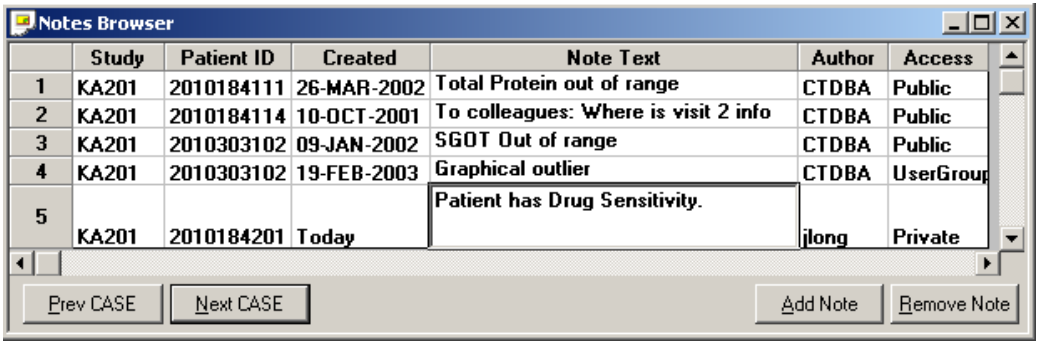
You can store and retrieve patient level notes observed during data review within the Notes Browser. For example, you might validate information and make a note for future reference. The notes can be stored at Object Storage Levels as Private, UserGroup and Public. The author of the note has sole security to edit or remove the note(s), unless the individual has SuperUser privileges. (See *Chapter 12: Common Topics: SuperUser Privileges)*

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

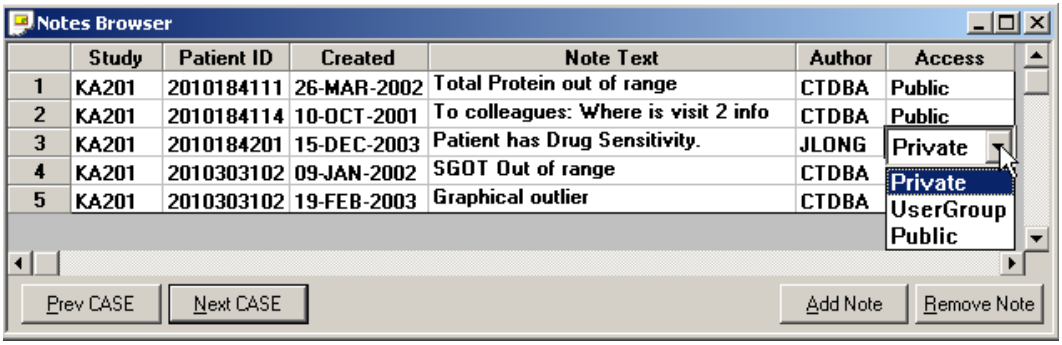


2. Select a patient to highlight in the Data Browser, active patient-level reports, patient listings, or Scatter Plot graphs.

3. Click **Add Note** to open a new note for the selected patient. Click the cursor in the Note Text box to enter up to 256 characters. The text will word wrap to display the note. Hit **Enter** to end note.



4. Enter the Object Storage Location by selecting from the 'Access' drop-down list for Private, UserGroup and Public.



You can enter multiple notes per patient which display sorted by patient ID and date created. The spreadsheet can be exported or copied to clipboard with the same features as a report.

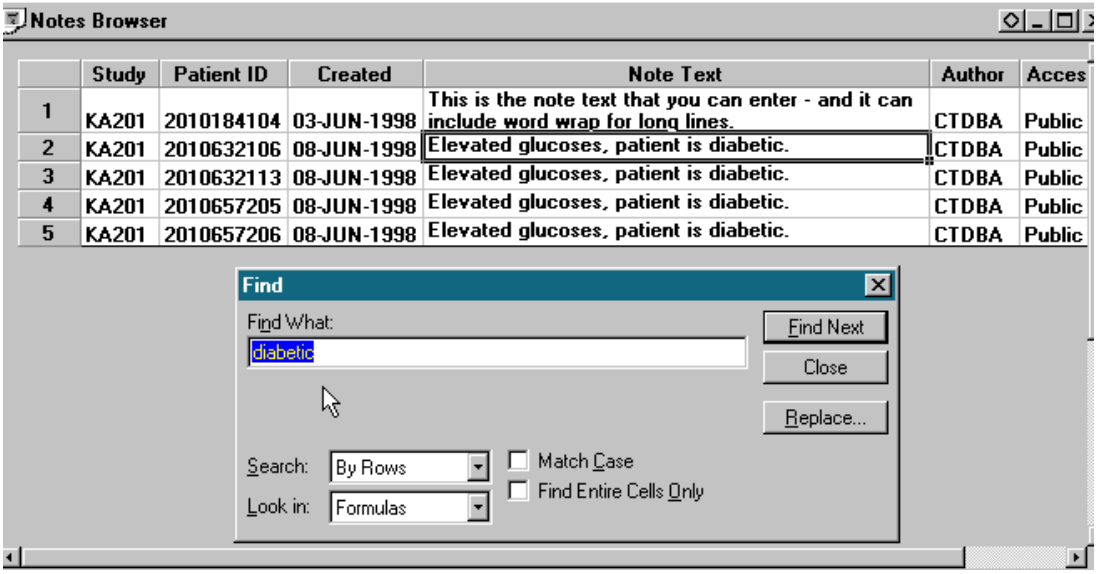
Movement between patients within the spreadsheet can be accomplished with the buttons for **Prev Case** and **Next Case**.

Find menu command

You can perform a search for a key word in the Notes Browser.

1. Click the **Edit** menu, select **Find**.
2. Enter the search criteria and Review will locate the first occurrence.

The find function can also be used on any report results.



Remove note

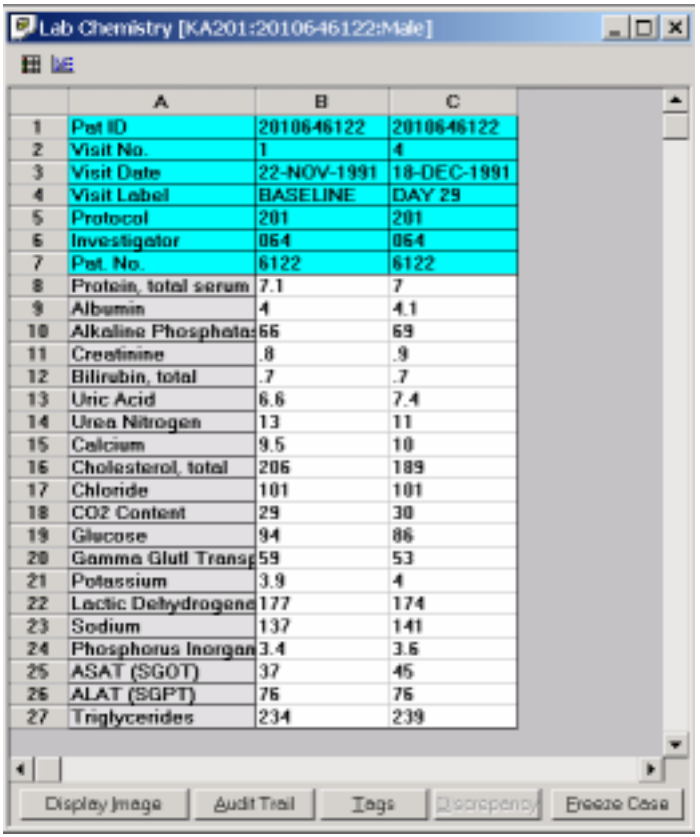
To remove a note:

1. Click , or from the **Browse** menu, select **Notes.**
2. Highlight the note to delete, click **Remove Note**.

Multiple-patient mode

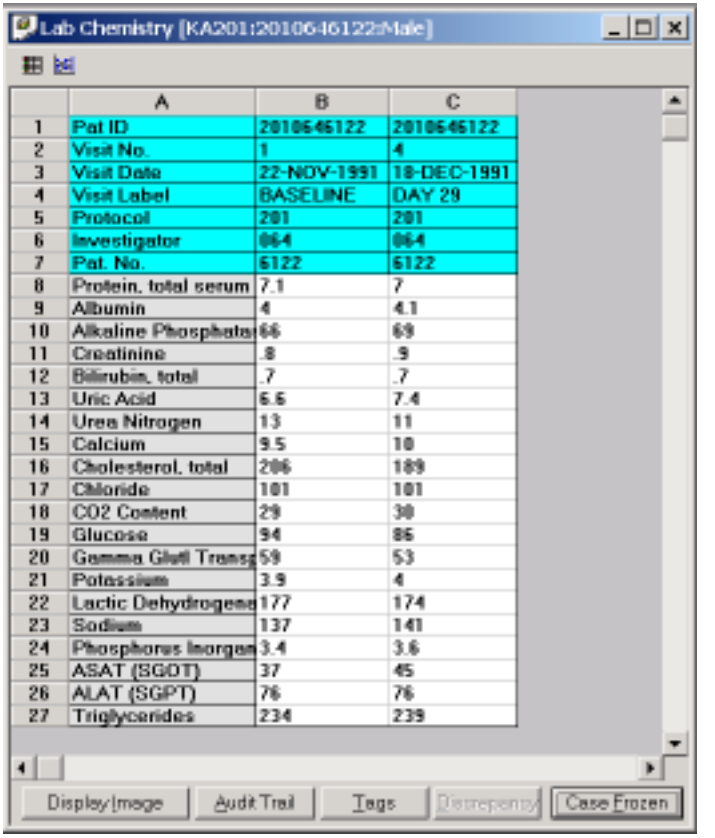
Freezing a case

As you browse through patient data in the Data Browser, you notice that each patient selection updates the open panel views. Review 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.



	A	B	C
1	Pat ID	2010646122	2010646122
2	Visit No.	1	4
3	Visit Date	22-NOV-1991	18-DEC-1991
4	Visit Label	BASELINE	DAY 29
5	Protocol	201	201
6	Investigator	064	064
7	Pat. No.	6122	6122
8	Protein, total serum	7.1	7
9	Albumin	4	4.1
10	Alkaline Phosphata	66	69
11	Creatinine	.8	.9
12	Bilirubin, total	.7	.7
13	Uric Acid	6.6	7.4
14	Urea Nitrogen	13	11
15	Calcium	9.5	10
16	Cholesterol, total	206	189
17	Chloride	101	101
18	CO2 Content	29	30
19	Glucose	94	86
20	Gamma Glutl Transp	59	53
21	Potassium	3.9	4
22	Lactic Dehydrogena	177	174
23	Sodium	137	141
24	Phosphorus Inorgan	3.4	3.6
25	ASAT (SGOT)	37	45
26	ALAT (SGPT)	76	76
27	Triglycerides	234	239

Click the Freeze Case button and 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.



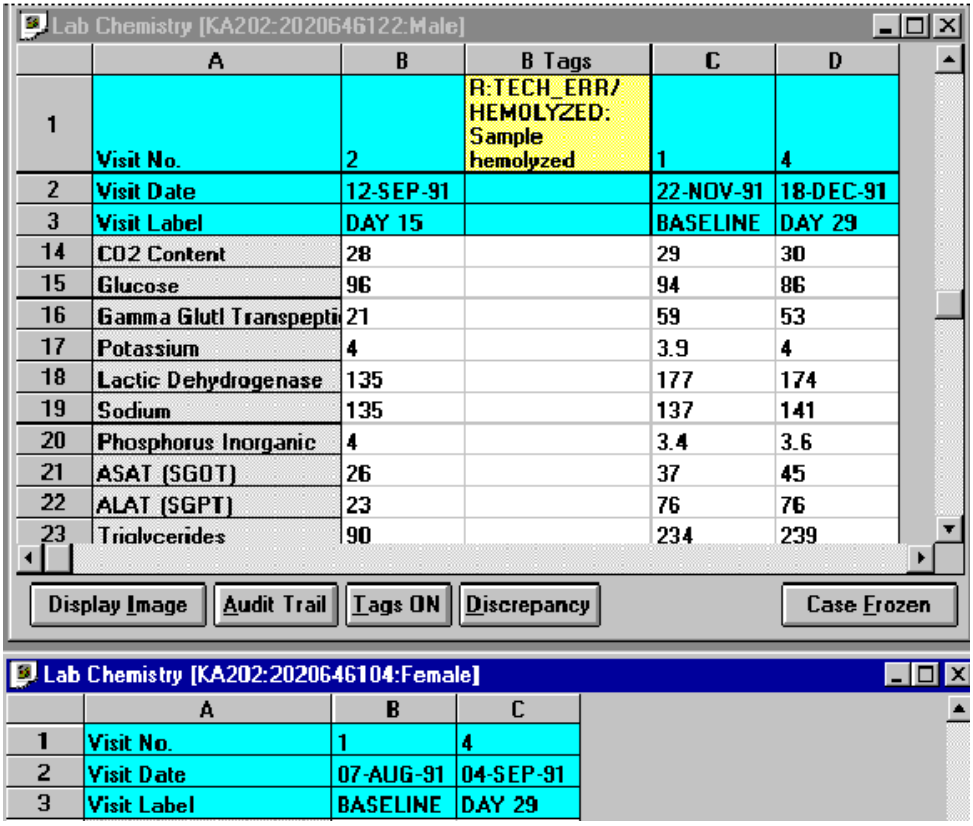
	A	B	C
1	Pat ID	2010646122	2010646122
2	Visit No.	1	4
3	Visit Date	22-NOV-1991	18-DEC-1991
4	Visit Label	BASELINE	DAY 29
5	Protocol	201	201
6	Investigator	064	064
7	Pat. No.	6122	6122
8	Protein, total serum	7.1	7
9	Albumin	4	4.1
10	Alkaline Phosphatase	66	69
11	Creatinine	.8	.9
12	Bilirubin, total	.7	.7
13	Uric Acid	6.6	7.4
14	Urea Nitrogen	13	11
15	Calcium	9.5	10
16	Cholesterol, total	206	189
17	Chloride	101	101
18	CO2 Content	29	30
19	Glucose	94	86
20	Gamma Glutl Transf	59	53
21	Potassium	3.9	4
22	Lactic Dehydrogena	177	174
23	Sodium	137	141
24	Phosphorus Inorgan	3.4	3.6
25	ASAT (SGOT)	37	45
26	ALAT (SGPT)	76	76
27	Triglycerides	234	239

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.

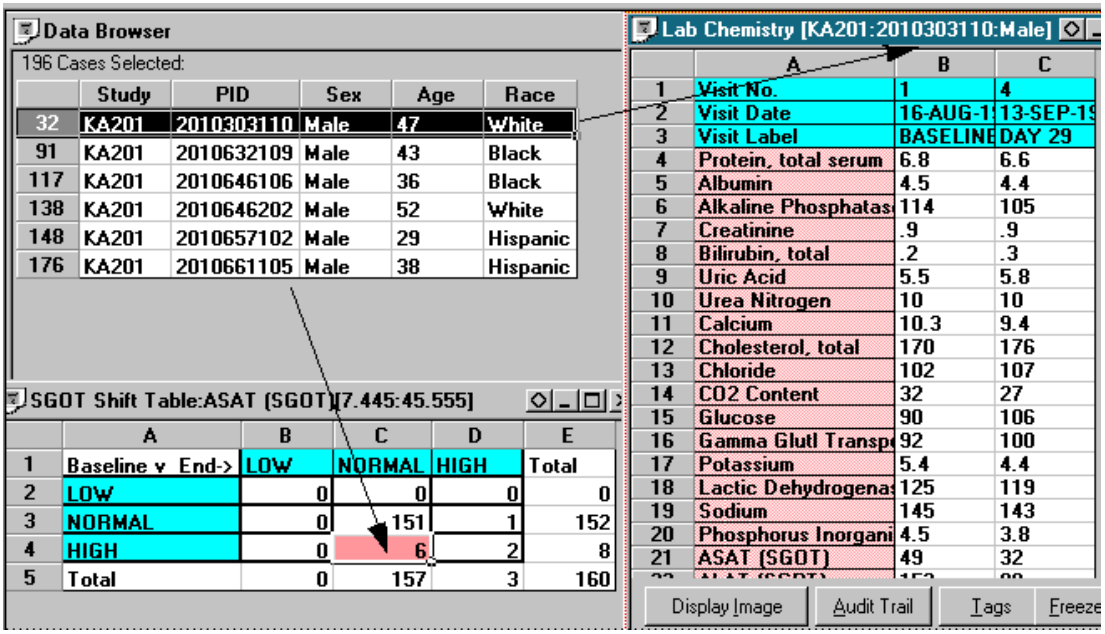
The panel view updates to the selected patient and you can proceed to freeze that view for a new comparative exercise.

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.

This feature facilitates patient identification down from the CrossTab categorical patient counts, to the underlying patient data via the Data Browser.

Clicking on a patient categorical count in the results CrossTab tables subsets and updates the open patient listing in the Data Browser, and opens Detail Data Listing reports to display those patients underlying the selected patient count.

Note: The CrossTab Browser does not allow multiple protocol selection. (See *Chapter 8: CrossTab Browser: Patient selection criteria)*



Patient listings and panel views

Expanding spreadsheet columns

When Review 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.

1. Click and drag the cursor on the line between the column heading tabs (between B and C if you're expanding column B in the example below), and drag the cursor to the width desired.
2. If you want to size all the columns in the spreadsheet, you can highlight the entire spreadsheet by clicking on the upper left spreadsheet column tab, and then size column B and each of the subsequent columns will then be the same width as column B.

Print Preview

To display a print preview of 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 **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 a patient listing

To print the list of patients meeting the current patient selection criteria:

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

   Review displays the standard Print dialog box.
3. Click **OK**.

Printing a panel view

To print the data from a patient's data panel:

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

   Review displays the standard Print dialog box.
3. Click **OK**.

Exporting a patient list or panel view

To export your table in Excel 4, 5 and 7, tab delimited files , HTML format or PDF files:

1. From the **File** menu, select **Export**.

   Review displays the Export dialog box.
2. Enter the storage location.
3. Enter the storage type.
4. Click **OK.**

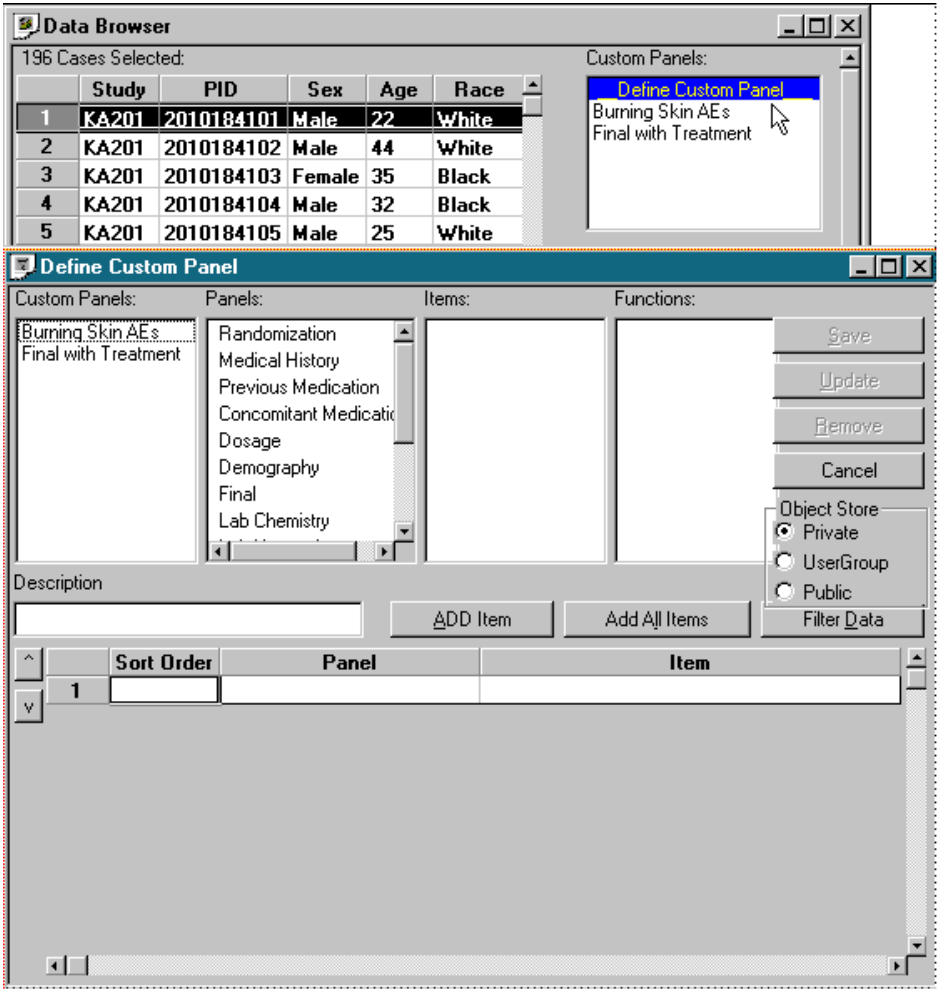
Your patient list or panel view is exported to the currently selected disk directory. (See *Chapter 12: Common Topics: Export Browser Display Spreadsheets; Copy and Paste Browser Results; Copying to Clipboard)*

Custom panels

Define custom panels

You can design your own custom panels for use within the Data Browser with _Define_Custom_Panel_. This feature allows you to select data items from a variety of panels, then save your custom panel with a description.

1. Click **_Define_Custom_Panel_** to open the Define Custom Panel window.

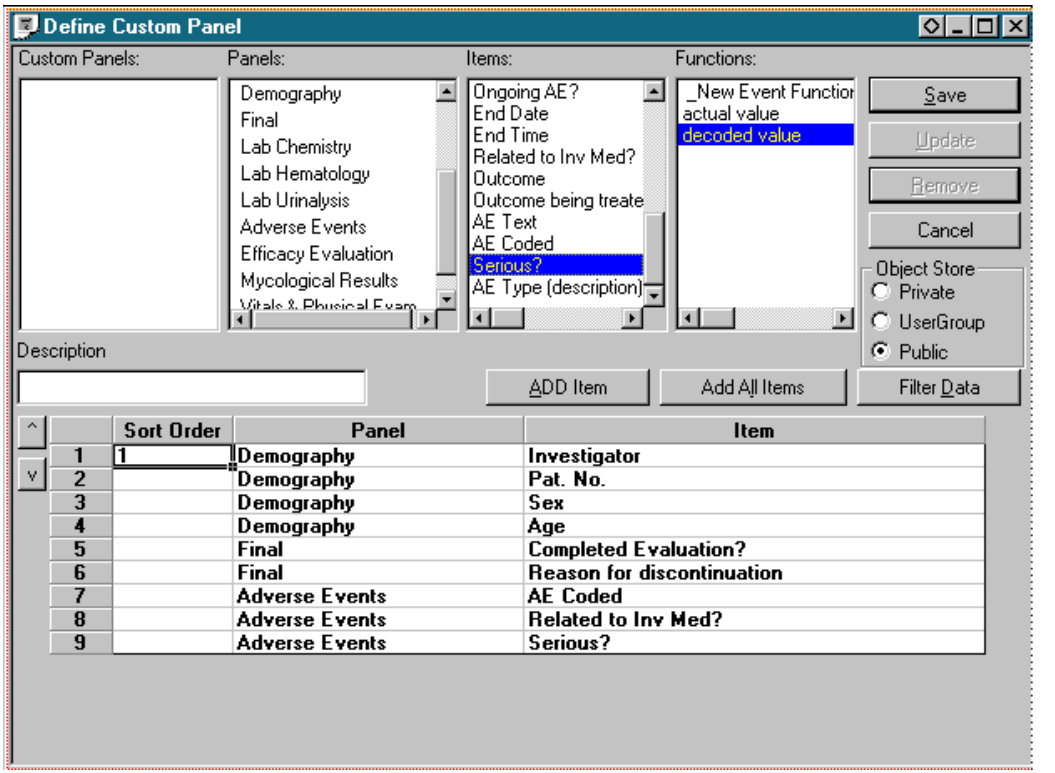


2. From the Panels list, select the various data items you want included in your custom panel. You can double-click on the individual items or click **ADD Item** or **ADD All Items**.

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

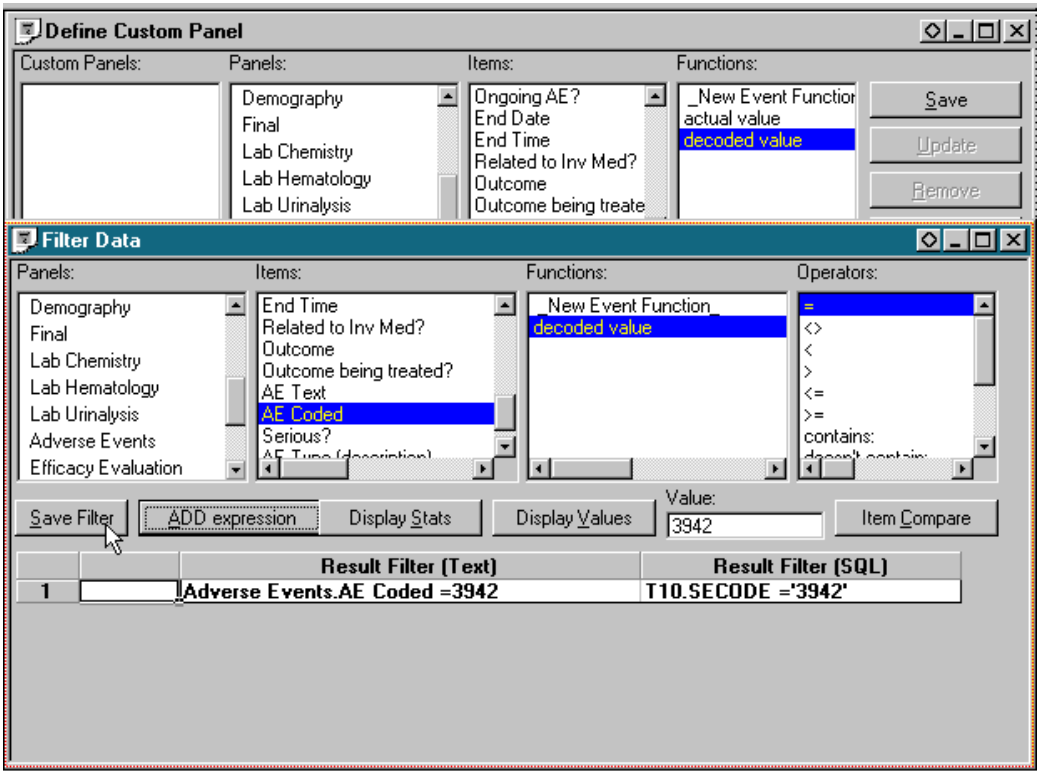
   Note:The current restriction is you cannot mix items from SAS datasets and Oracle table generated panels within the same custom panel.

3. The **Sort Order** can be adjusted by clicking the arrows in this edit box.
4. Before saving your custom panel, you may want to apply an output filter criteria.



The operating features of the output filter are identical to the patient selection criteria window. You have access to all panels and underlying data items when creating an 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.

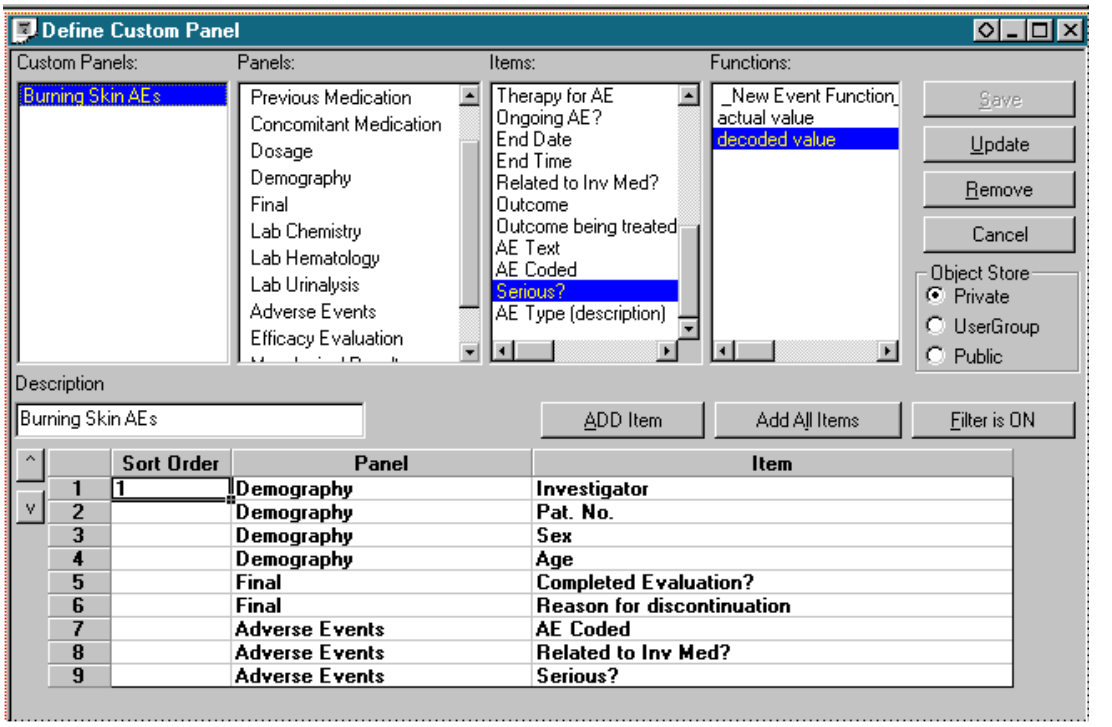
5. Click Filter Data.
6. Select your output filter criteria from the panels and items lists.



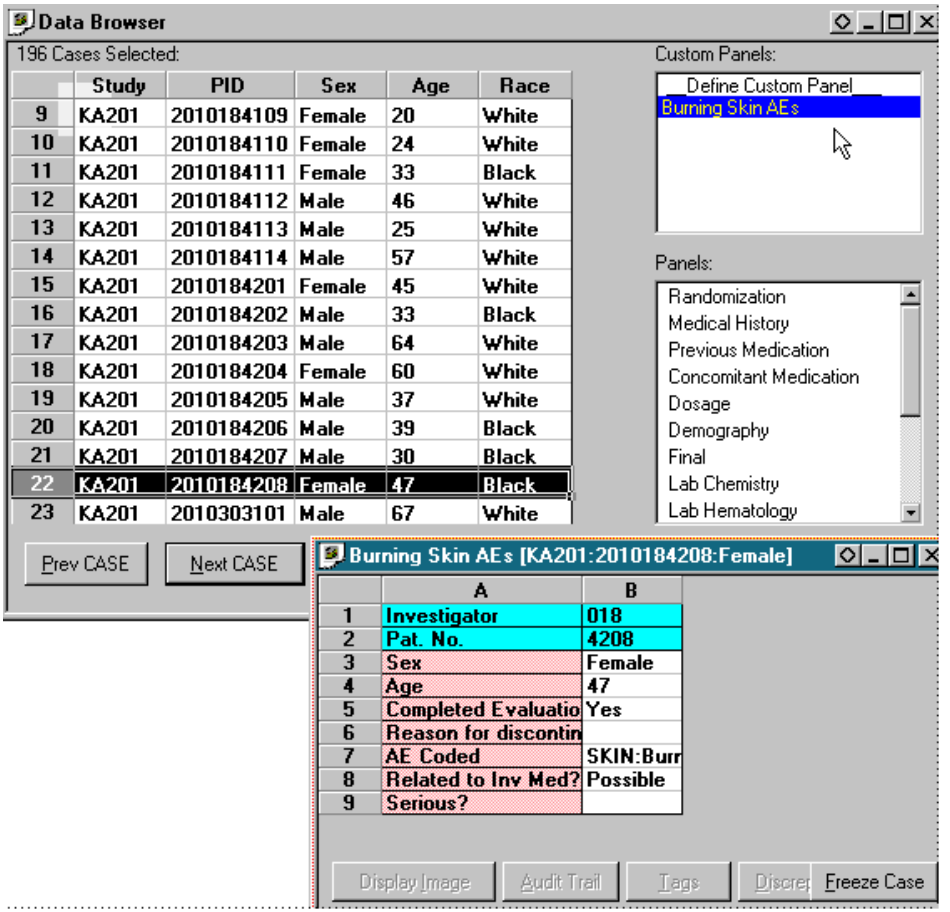
7. Click **Save Filter** and close the Filter Data window. The Define Custom Panel window will reset and display Filter is ON.
8. Enter a description to reference your custom panel and click **Save**.

The output filter looks and operates similarly 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*)



You can now select your custom panels in Data Browser to view individual patients.



Update or remove custom panel

If you need to update or remove any custom panel:

1. Click **_Define Custom Panel_** to open the Define Custom Panel window.
2. Select a panel from the Custom Panels list.
3. You can make changes to the custom panel and click **Update** or click **Remove** to delete from the custom panes list.

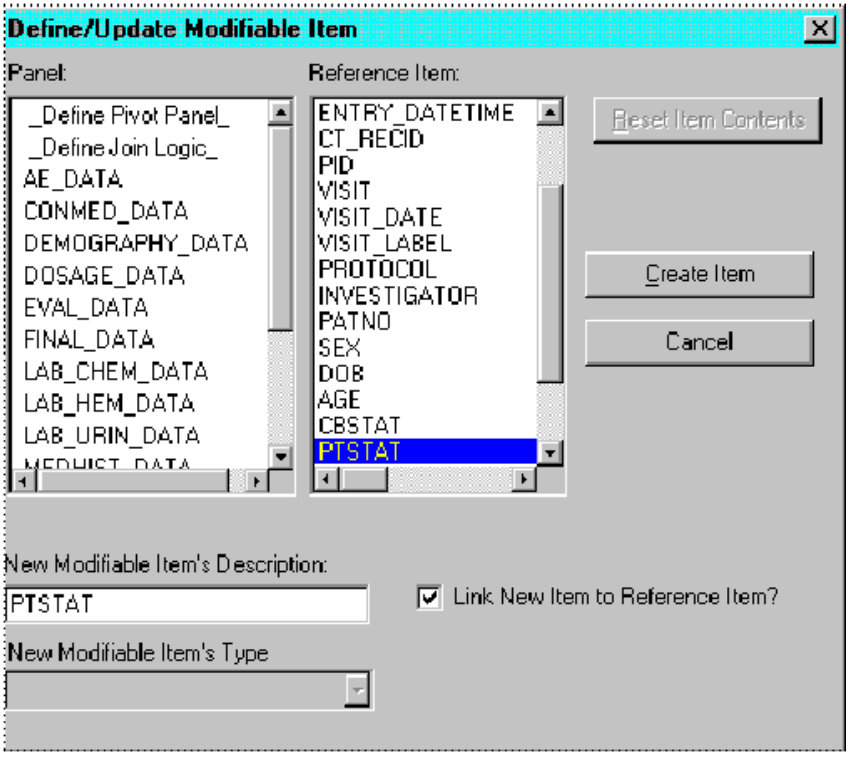
Modifiable items

Defining modifiable items

If your data management system supports this feature, the Define Modifable Items is displayed in the Data Browser window.

Caution: Once you create a modified item, it is permanently a part of your database, and only one modified item can be generated per parent item. **The modified item name can not be changed, nor can the modified item be deleted.** However, the data can always be modified by this pseudo Item from the source parent item.

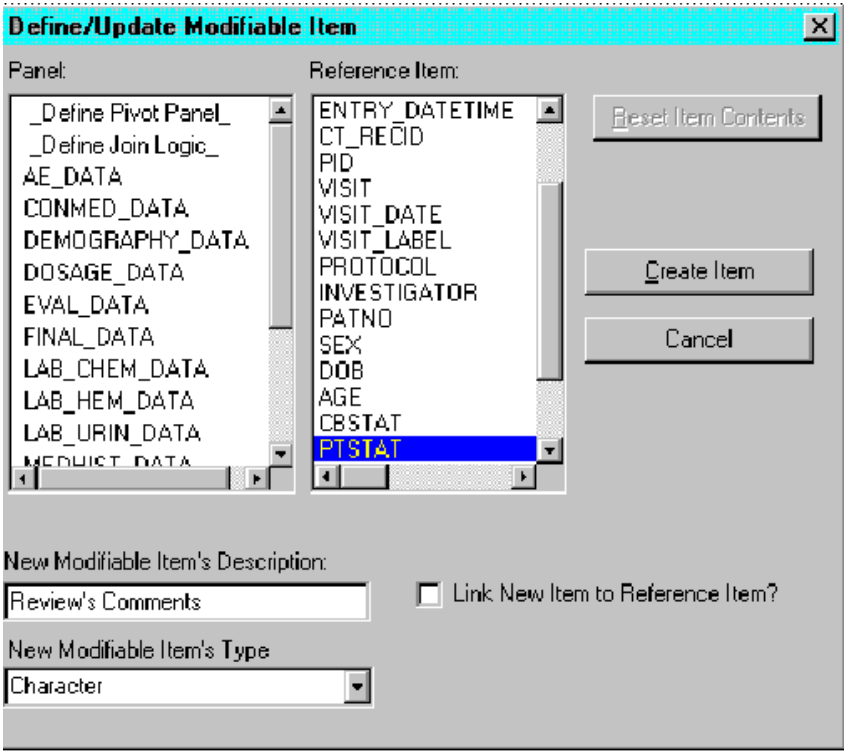
Your ORACLE user ID must be authorized to define parallel modifiable items, and your underlying clinical data management system must support defining parallel modifiable items. You can define modifiable items at run-time. In the Data Browser, click **Define Modifiable Items**. Review displays a dialog box to allow the definition of a modifiable item:



If you can select “Link New Item to Reference Item?”, the new item is tied to an existing item. The new modifiable item created becomes a parallel field using the same decode file (if applicable) and contains the identical values as the existing item.

If

is left unchecked, the new item is not tied to an existing item and no values are duplicated into it.



1. Select the panel in which you want to define the modifiable item.
2. Select the reference item upon which to base the item. Review fills in the description field with the description of the reference item. You should change the description slightly to better distinguish your version of the field.

Note: If you do not alter the new item’s description, it will display the same description as the reference item but flagged as the “modifiable version”.

3. Select **New Modifiable Item’s Type**.
4. Select whether to “Link New Item to Reference Item?”.
5. Click **Create Item**.

Review creates the new Item in the database on the server, and initializes the Item with the value of its reference Item for each patient's observation. The modifiable item updates can be viewed through the custom panels.

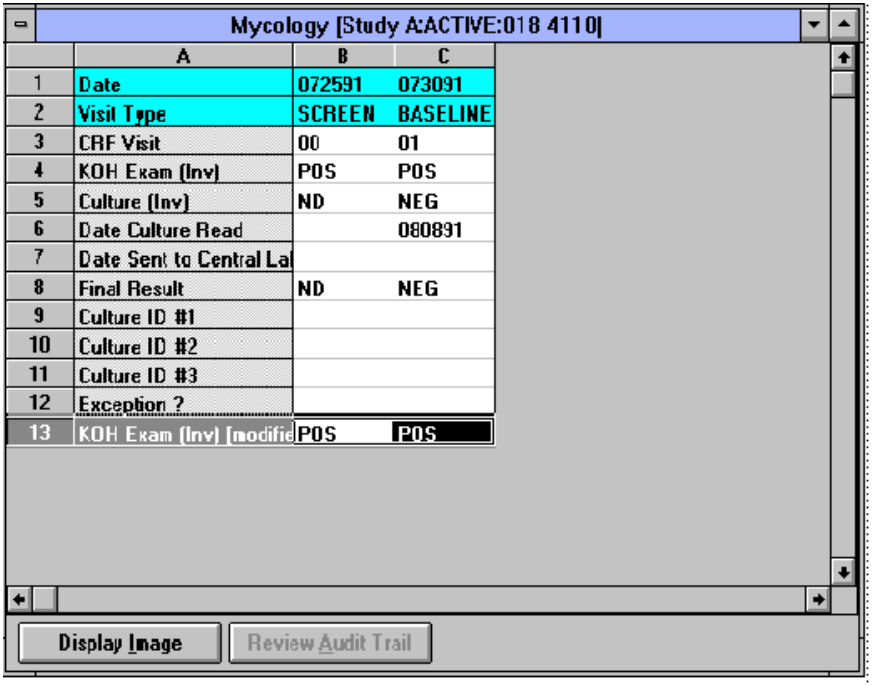
Modifying data

If you have defined a modifiable data item, you can change the values of that item for any individual patient by using the Data Browser.

1. Select the patient of interest.
2. Select the Panel of interest.

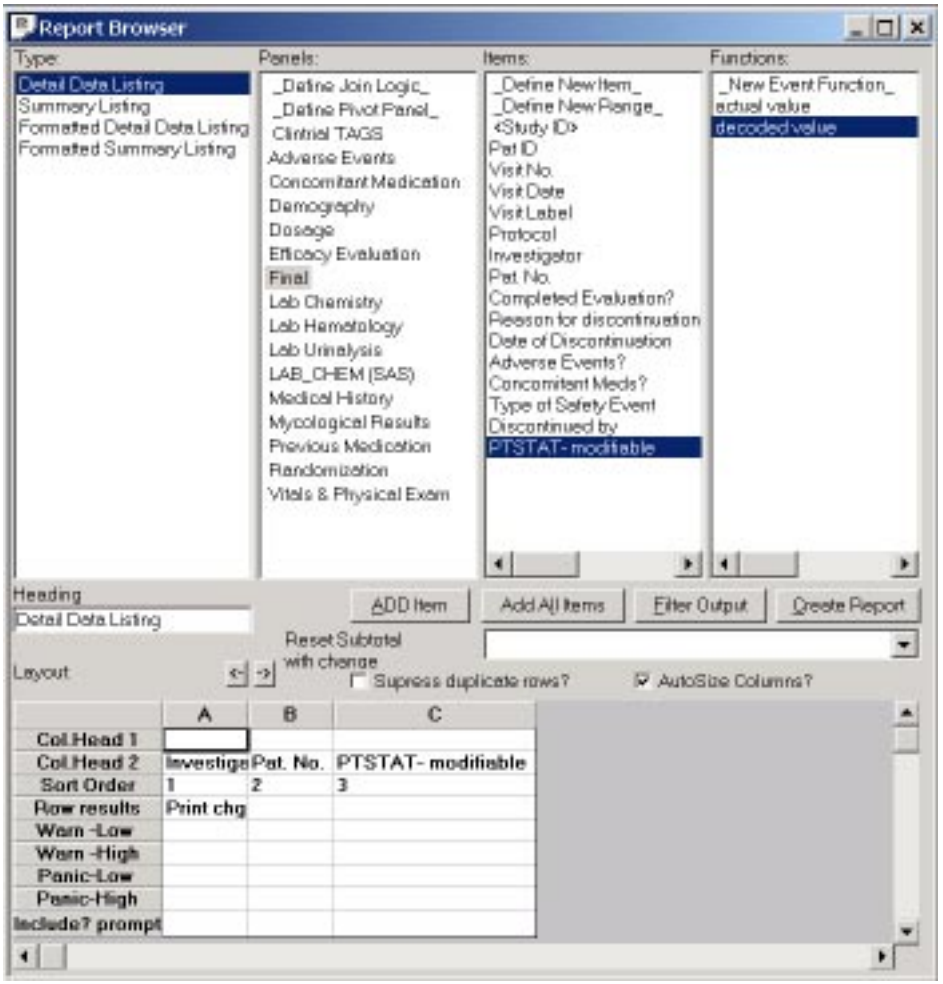
   The modifiable data Item is displayed at the end of the list of items in the panel. The modifiable data items are highlighted as shown in the KOH Exam (Inv) row below:

3. You can make changes directly in the cell of the modifiable data item. Your changes are stored in the database automatically.

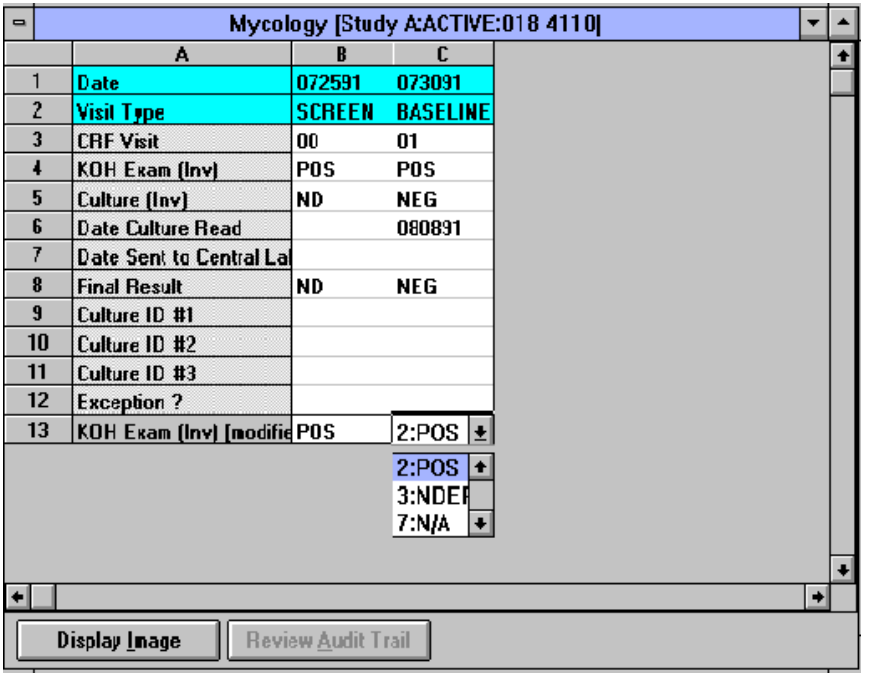


If you have multiple patients or modifiable data items, you can change the values of the item using the Report Browser. The modifiable data items are listed for reporting and can be updated from report window. (See *Chapter 6: Reporting: Defining Report Specifications*)

1. Select the panel(s) of interest.
2. Select the item(s) of interest.
3. Click ☑ Enable modifiable item updating? to edit the items from the created report. If left unchecked you are unable to modify the modifiable item from the report.
4. Click **Create Report**.
5. Click on the column for the modifiable item and edit the value.

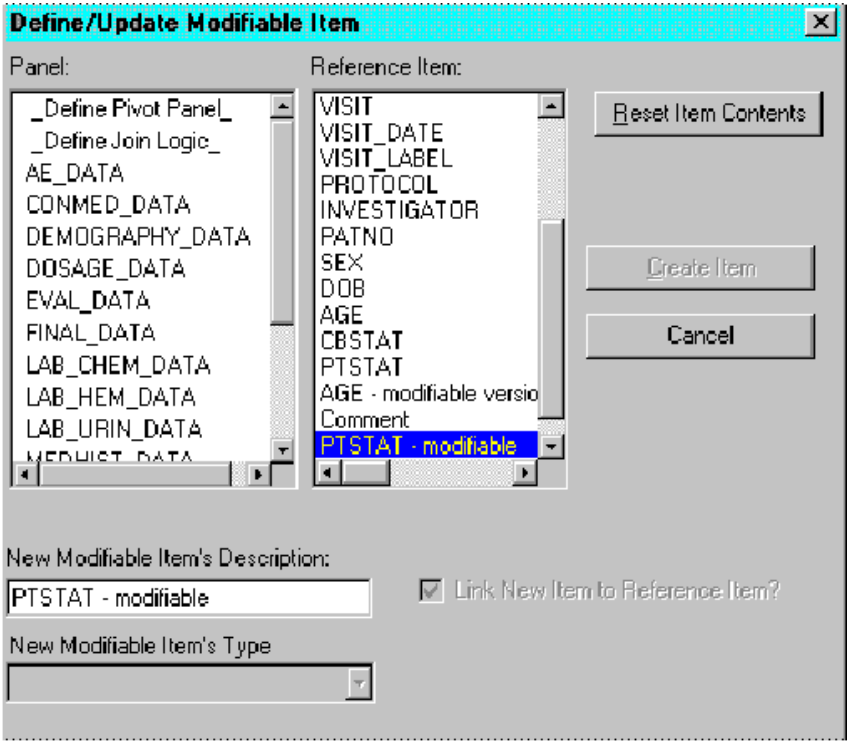


If the reference item for the modifiable data item is a coded data item (its values are decoded using a **code list**), when you click on the item to be modified, it changes to a drop down list. Select one of the possible values from the list:



Reset items content

If you need to reset item contents after you have changed the defaulted values in the modifiable item, click **Reset Item Contents**. All values changes will be reset to the values of the reference item. This button is only enabled when the new modifiable item is linked to a reference item.



Saving Data Browser specifications

Object storage location

You can store patient selection criteria at four user access levels: Private, WorkGroup, UserGroup, or Public.

- Private storage is at the local PC level. The private objects are saved on the user's home drive in a directory (folder) called "irpat". Review handles all creation, access and deletion of the private objects in this folder. Therefore, the user should not be concerned with the contents of the irprivat folder.
- WorkGroup storage is PC based and stored at a shared network drive, to which a select group of personnel would have access.

Note: The WorkGroup storage location was supported in earlier Review releases. UserGroup storage location is extensively used for later releases.

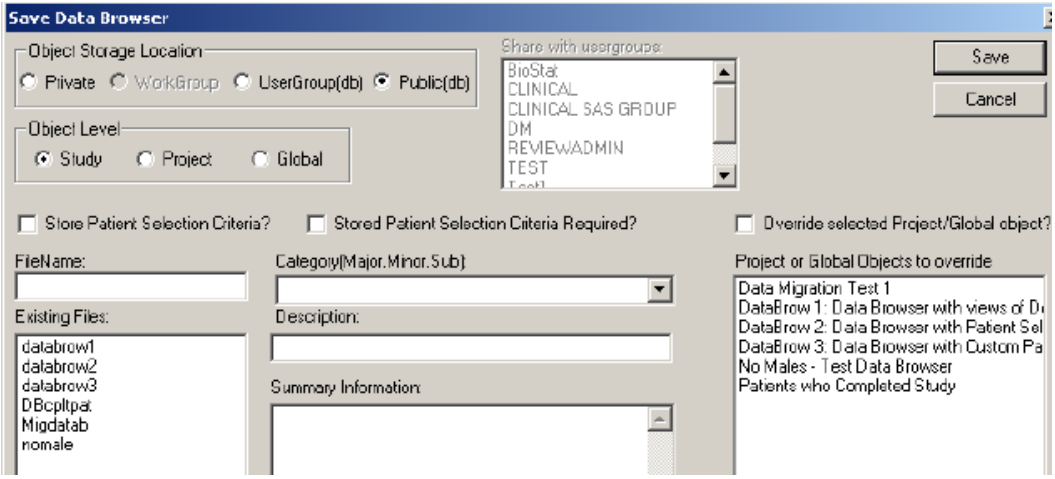
- UserGroup storage is a database object storage for defined UserGroups in the configuration tables.

  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 WorkGroup or UserGroup storage.

  Saving on database object storage sites, requires the author to have "Publishing Authorization" defined in the configuration tables. (See *Chapter 12: Common Topics: Shared Object Storage- Locations)*

When you select the UserGroup object storage location, teh ‘Share with usergroups’ listbox is made available for selection.



Object level

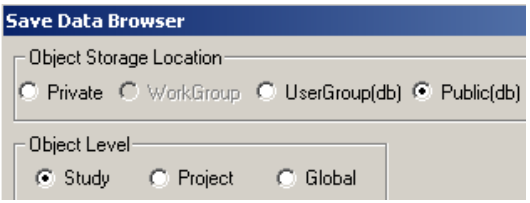
You can store your Data Browser specification at three levels: Study, Project, or Global. The Object Level box is only enabled and highlighted when you select an Object Storage Location designated as ‘db’ for database. Therefore, when you select either UserGroup or Public for database object storage 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.

Store a selection of panel views

The Data Browser's patient listing, and the subsequent panel view windows, are provided for instantaneous data exploration and browsing. Selections of multiple open panel views can be saved as Data Browser objects.

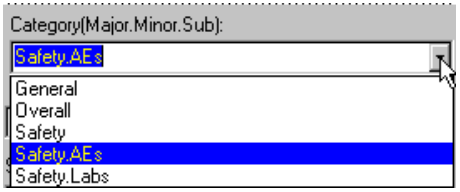
1. Open the panel views and size and position them in the locations to be saved. Make sure the Data Browser window is active.
2. From the **FILE** menu, select **SAVE**.

3. Review displays the Save Data Browser window where you can specify the storage location. Select an object storage location.



4. Select object level type. The default is Study.
5. Click '**Store Patient Selection Criteria?'** 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. If the particular patient selection criteria is specific and required for the output, click '**Stored Patient Selection Criteria Required?'**. In this instance, the patient selection criteria cannot be modified when this stored object specification is selected. If none are selected, then no patient selection criteria is saved with the output specification.

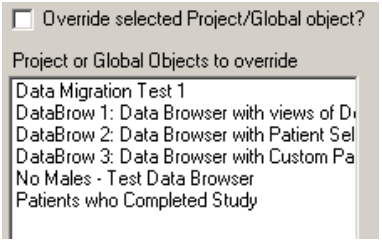
6. Enter a FileName for future reference to be displayed in the list box for Existing Files. The Filename is for internal use and is not displayed in the Object Explorer window.
7. Enter the folder(s) information in the Category box. Each folder (major, minor and subfolder) is separated by a period where folder titles can consist of more than one word separated by a space. For example, the major folder for 'Safety' has two minor folders created as 'Safety.AEs' and 'Safety.Labs'. Folder names are case-sensitive. After the folder(s) are initially created, they are selected from the dropdown listbox.



8. Next enter the appropriate description which is displayed in the Object Explorer window.
9. You can include summary information for future reference to be viewed by yourself or others later.
10. Click **Save**. Review stores the Data Browser Specification to the designated PC, WorkGroup, UserGroup, or Public storage location.

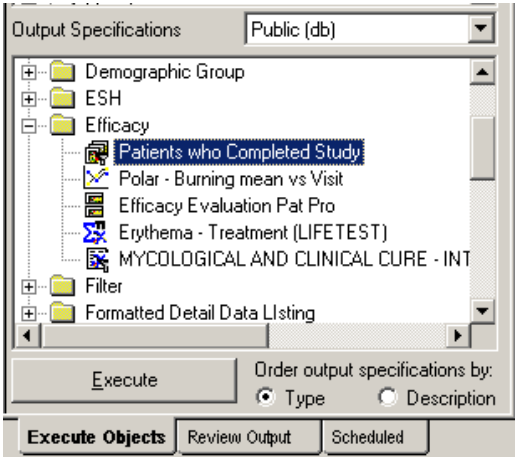
Override selected Project/Global object?

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.



Object Explorer Window

Once you have saved your Data Browser specification and assign folder information, your folder(s) and output specification will display as a stored object in the Object Explorer Window under Output Specifications. A Data Browser icon will display next to your output description. If you saved a patient selection criteria with your output specification, then a filter icon would display next to the browser icon.

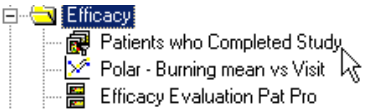


Retrieve a saved Data Browser object

If you want to retrieve a saved Data Browser object:

1. Double click to open a folder.

   The Data Browser icon displays next to the description. If a filter icon displays along side the description it indicates the object was saved along with a patient selection criteria.

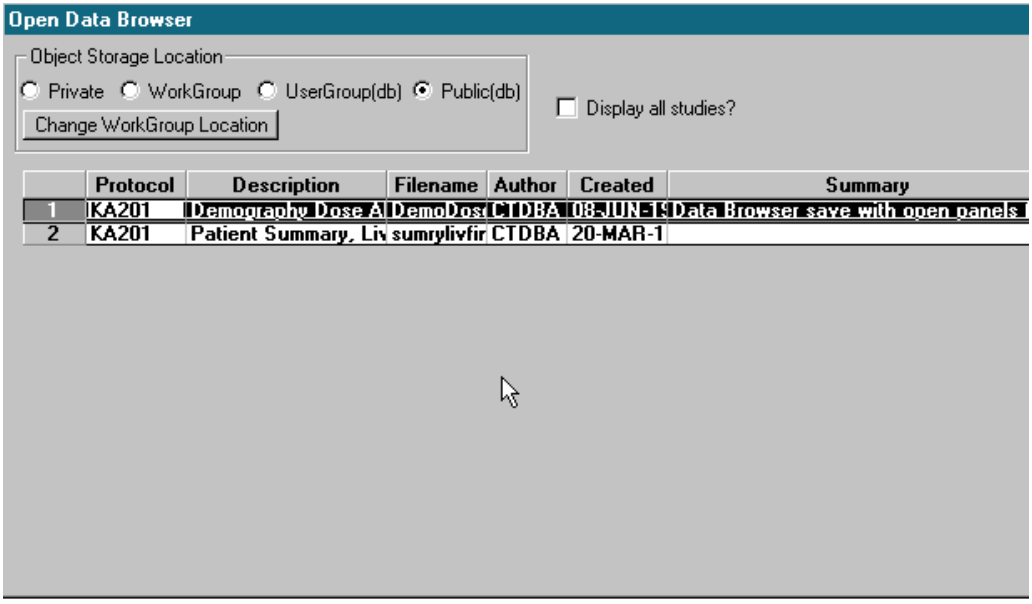


2. Double click to open the stored Data Browser object, or high light the seelcted object and click **Execute**.

Open saved Data Browser settings

Another way to retrieve saved Data Browser specifications is:

1. Make the Data Browser the active window.
2. From the **File** menu, click **Open**. Review displays the Open Data Browser window.
3. Select the object storage location to list stored data browser specifications.
4. Select a data browser description and click the **Open** button or double click on the report description.



5. You can select the Data Browser storage locations.

a. Click Change WorkGroup Location to browse various Data Browser object storage locations.

   By default, Display all studies? is inactive and the display of saved objects is limited to those created while reviewing the current study protocol.

b. Check **Display all studies?**

   All saved Data Browser specifications for all study protocols are displayed. If you open Data Browser specifications created in a different study protocol(s) than the one you are currently reviewing, Review validates all corresponding Data Configurations. If there is any variance in data descriptions and / or data structure, Review notifies the end user of the incompatibility and flags the items that are variant.

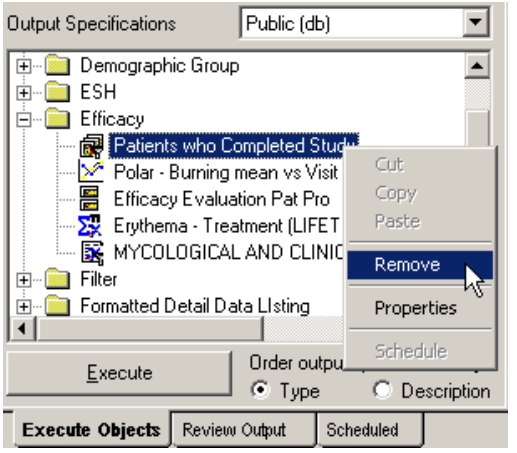
Note: Saved specifications using a pivot panel will only work with the pivot panel it was created with. If the same pivot panel is recreated with the same name, the objects using the original panel will not work because the system naming convention iterates with each created panel. (See Chapter 12*: Common Topics: Pivot Panels*)

Quick remove

You can quickly delete a saved Data Browser object under the Output Specifications window.

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?".

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

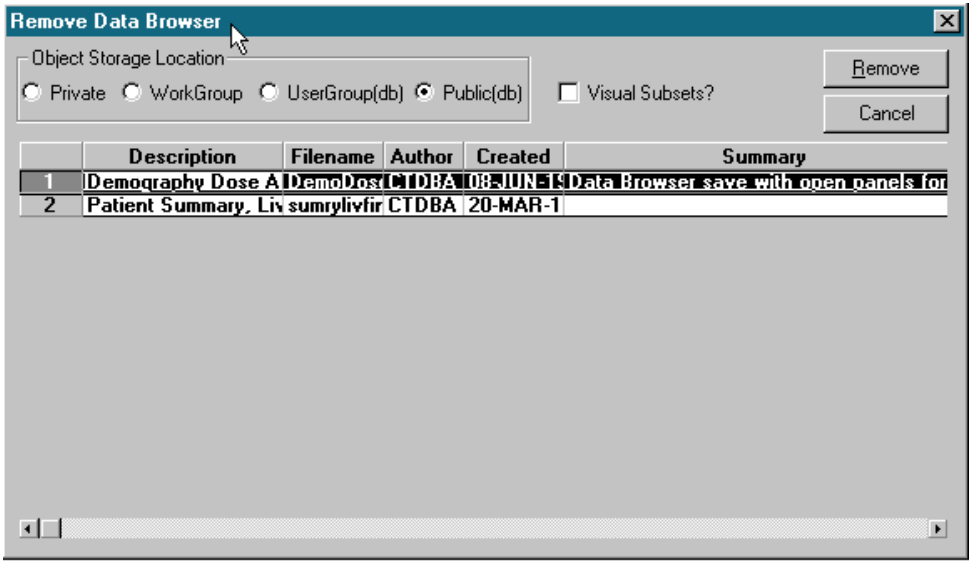


Note: You cannot schedule a saved Data Browser specification.

Another way to remove a stored Data Browser specification:

1. Open the Data Browser to make it the active window.
2. From the **File** menu, click **Remove**. Review displays the Remove Data Browser window.
3. Click on the object storage location. A list of the stored data browser specifications display.
4. Select the stored Data Browser description you want to remove. Click **Remove**.

Review deletes the Data Browser settings from the designated local PC, WorkGroup, UserGroup or Public storage location if you have security clearance to do so. (See *Chapter 12: Common Topics: SuperUser Privileges)*

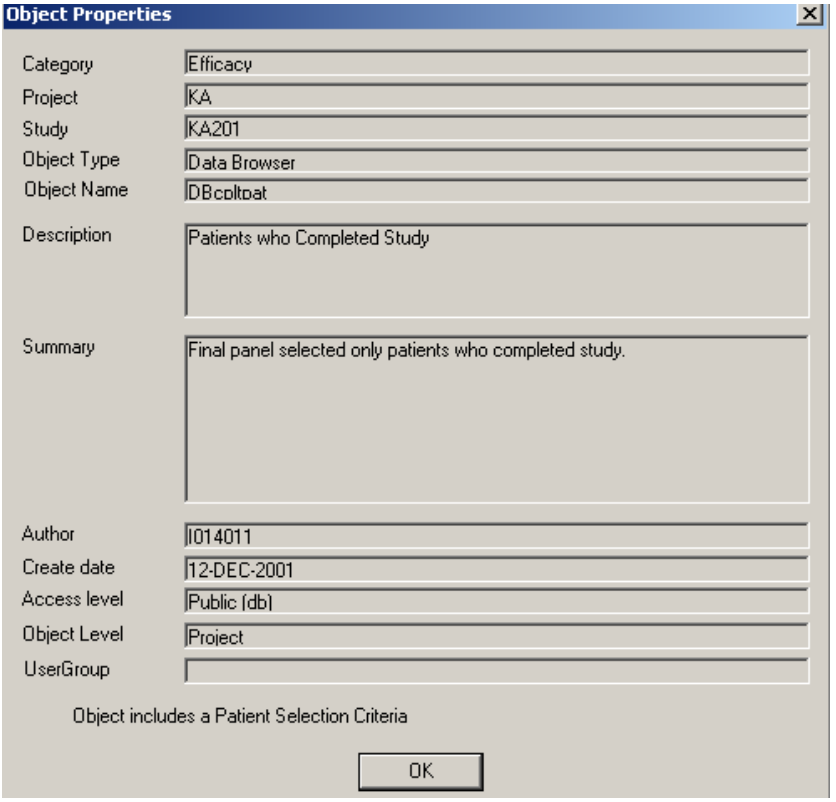


Object properties

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**. A dialog window displays the object properties for the output object.

It works for ‘Private’, ‘Workgroup’, ‘UserGroup’ or ‘Public’ objects equally.



Updating the Data Browser

The Data Browser's patient listing and the subsequent panel view windows enable instantaneous data exploration and browsing.

1. Change the patient selection criteria, refining 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.

   The Data Browser, patient listing, panels, and active browser specifications (objects) are displayed and updated according to the implementations of new patient selection criteria.

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. Review closes all panel views currently opened.

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.

Patient identification

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.

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.

CrossTab table results

Clicking on the patient counts in CrossTab result tables instantly updates the Data Browser, the Detail Data Listing reports, and Scatter Plot graphs to identify and characterize all underlying patients.

Data Browser and pivot panels

Pivot panels provide a powerful display of data, and provide a data structure that can be uniquely utilized by the Data Browser in producing clinically pertinent presentations of data “on the fly.” Using the Data Browser Panel View, you instantly are provided views of the created Pivot Panel. Such views make viewing relational clinical data results easy and dynamic. (See *Chapter 12: Common Topics: Define Pivot Panel*.)

Data Browsers and join logic

The Data Browser provides instantaneous viewing of all panels within a protocol or common between multiple protocols. This includes Clintrial Type 0 panels. The Data Browser's panel view facilitates the viewing of all panel items within each panel. The panel view is a companion utility to the pseudo-panel 'Defining Join Logic_' utility. '_ Define Join Logic_' provides an opportunity to investigate relations within the clinical data defined by medical investigators. Join Logic defined for the Clintrial Type 0 panel is required to utilize the data items within Clintrial Type 0 panels. However, joins can be defined using any panel available. (See *Chapter 12: Common Topics: Define Join Logic*.)

4 Patient Profiles

Patient Profiles Browser 145

Selection set 145

Open Patient Profiles Browser 145

Define patient profile matrix 146

Selecting a workbook type 147

Initial default settings 147

Single worksheet mode 148

Multiple worksheet mode 152

Defining a patient profile 155

Modify profile content 155

Access to SAS datasets 155

Define Sub Panel 156

Define Header 156

Customize patient profile output 159

Sort Order 161

Filter Output 162

Patient Profile Filter Output 162

Patient Profile display 163

Expanding spreadsheet columns 163

Print Preview 164

Printing a patient profile 164

Exporting a patient profile 165

Formatted Patient Profile 166

Select formatted profile 166

Activate Page Break 168

Apply Page Header and Footer 168

Format Column Headings 170

Format Columns 171

Preview/Page Setup 172
Page Setup 173
Number of ID items 173
Panel Orientation 174
Column width 175

Object Storage: saving your work 177

Object storage location 177
Object level 178
Saving Patient Profile specifications 179
Object Explorer window 180
Object Explorer quick execute 181
Retrieving a saved Patient Profiles specifications 182
Object properties 183
Quick remove 184
Removing a saved Patient Profiles specification 184
Printing the Patient Profiles specifications 185

Closing Patient Profiles Browser 185

Closing the Patient Profiles Browser 185

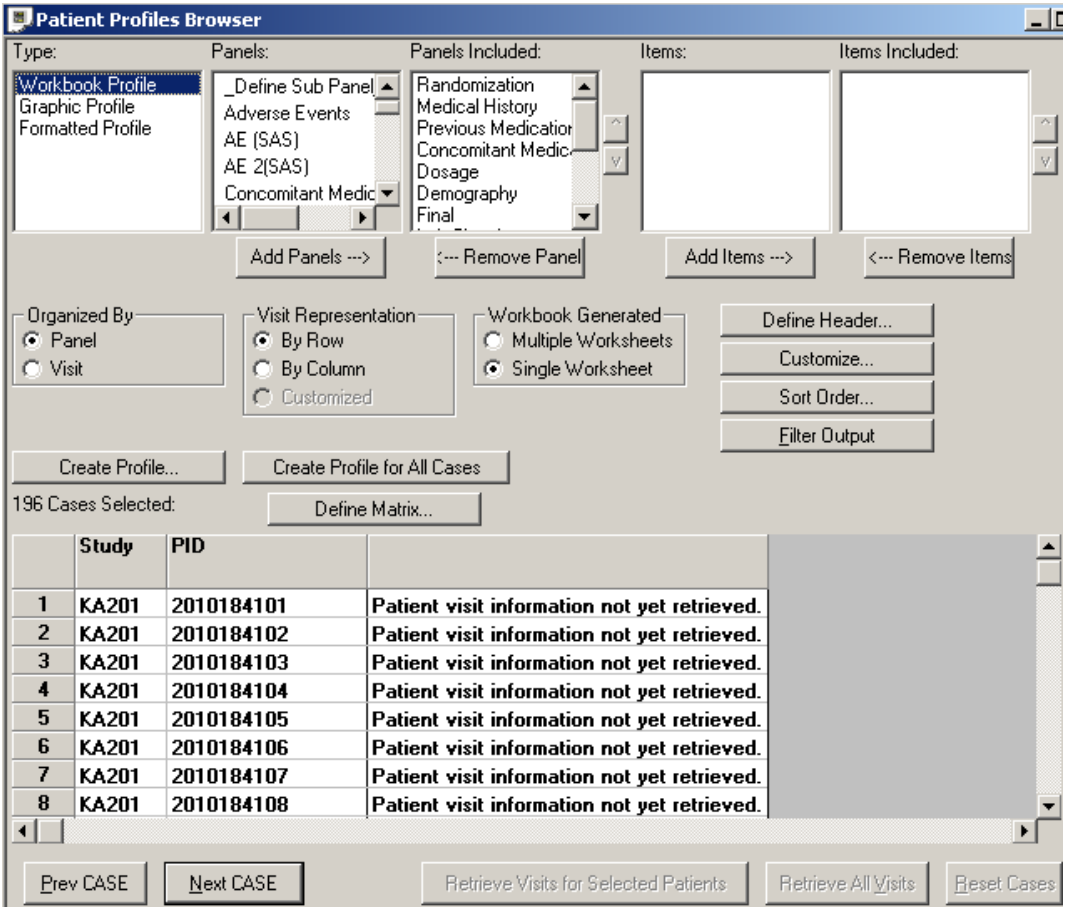
Patient Profiles Browser

Selection set

You can quickly capture a subset of the patient population that you wish to view by building the patient selection criteria.

Open Patient Profiles Browser

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

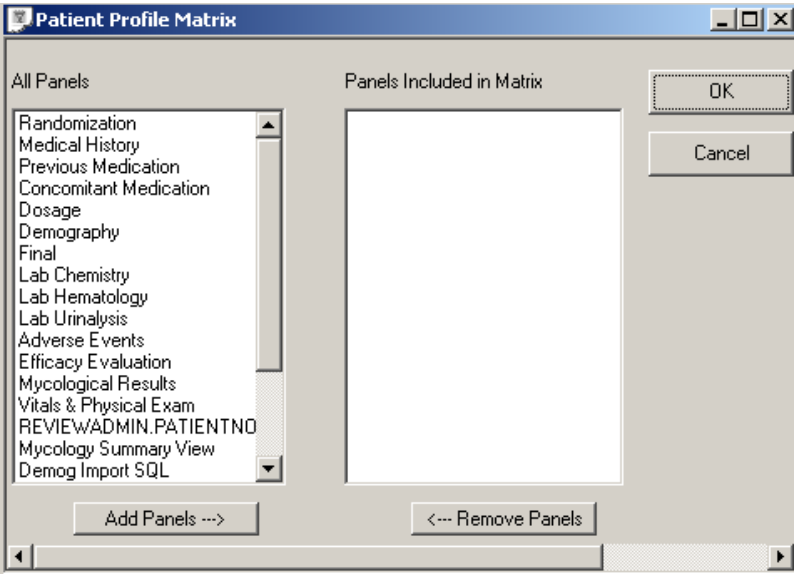


Review opens the Patient Profiles Browser window which displays a list of patients who meet the patient selection criteria or all patients if no selection criteria was defined. The study and PID (patient id) are listed for identification.

Define patient profile matrix

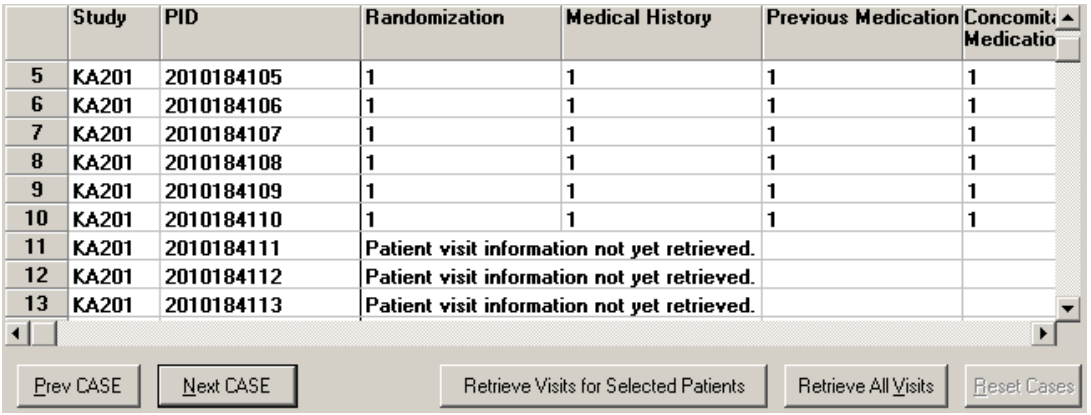
When the Patient Profiles Browser window initially opens the patient visit information is not yet retrieved until you define the patient profile matrix. The patients listed display a message stating 'Patient visit information not yet retrieved'. This allows for faster retrieval of detailed patient visit 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 'Patient visit information not yet retrieved'.

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



	Study	PID	Randomization	Medical History	Previous Medication	Concomit… Medicatio…
5	KA201	2010184105	1	1	1	1
6	KA201	2010184106	1	1	1	1
7	KA201	2010184107	1	1	1	1
8	KA201	2010184108	1	1	1	1
9	KA201	2010184109	1	1	1	1
10	KA201	2010184110	1	1	1	1
11	KA201	2010184111	Patient visit information not yet retrieved.			
12	KA201	2010184112	Patient visit information not yet retrieved.			
13	KA201	2010184113	Patient visit information not yet retrieved.			

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

Selecting a workbook type

Initial default settings

Initially the Patient Profiles Browser opens for Workbook Report type and default settings for the data is organized by panel, and visit related data is represented by rows and single worksheet display. The autosize column is turned ON and the header information is left blank for you to define.

At this point, you can select a patient from the patient list by using the **Prev Case** or **Next Case** buttons to scroll. When you click **Create Patient Profile**, a single worksheet mode with the default settings will be created.

Once you have opened Patient Profiles Browser, you can organize the selected patients into various Workbook Report types as single worksheet mode or multiple worksheet mode. In addition, you can change the sort by visit or panel and the visit representation as row or column in the spreadsheet display.

Single worksheet mode

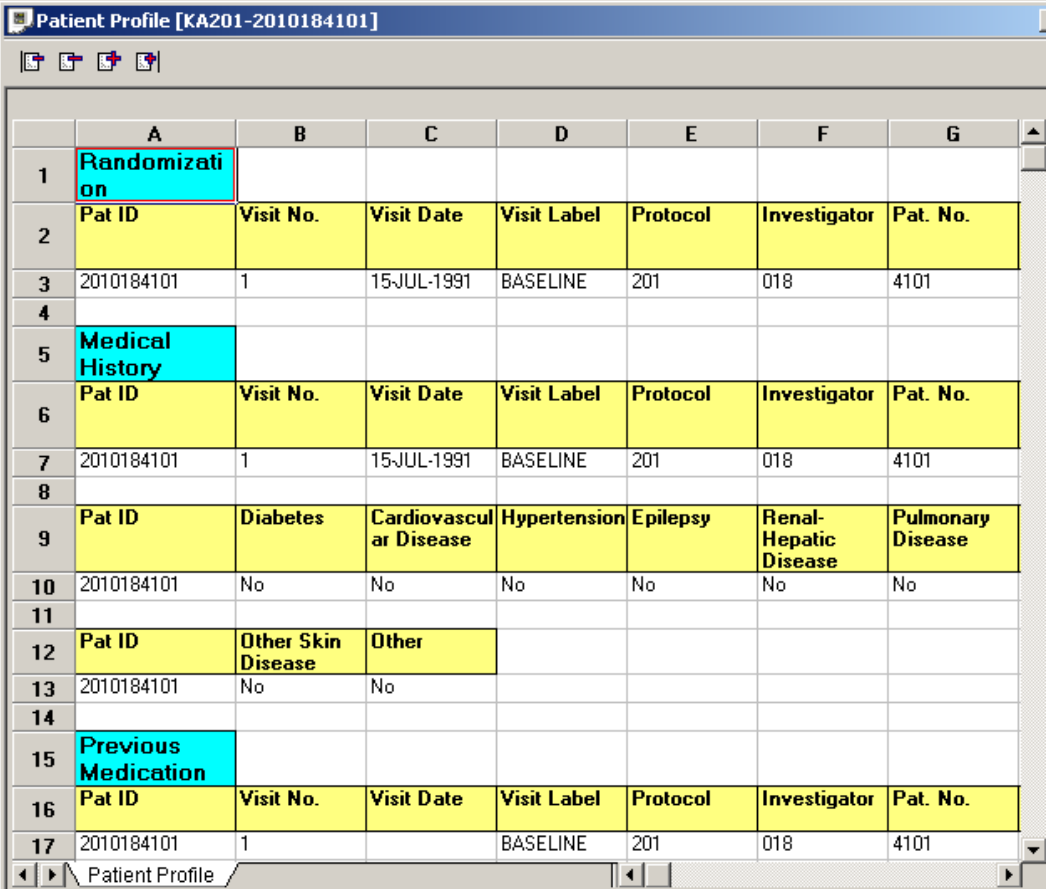
The single worksheet mode can be organized by panel or visit.

- ***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 and 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.*

The example below shows the Patient Profiles Browser in single worksheet mode for the options ***by panel*** and visit representation as row. When the single worksheet mode is generated a single tab displays at the bottom as 'Patient Profile'.



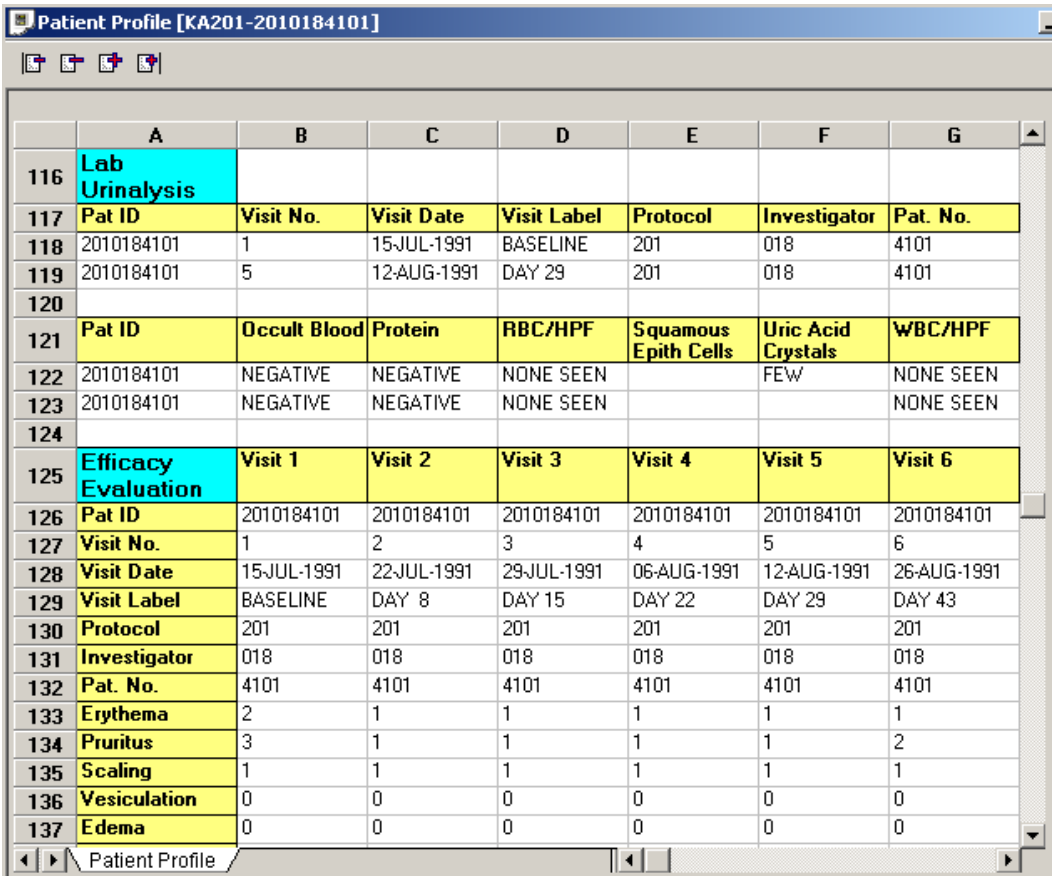
Patient Profile [KA201-2010184101]

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

Patient Profile

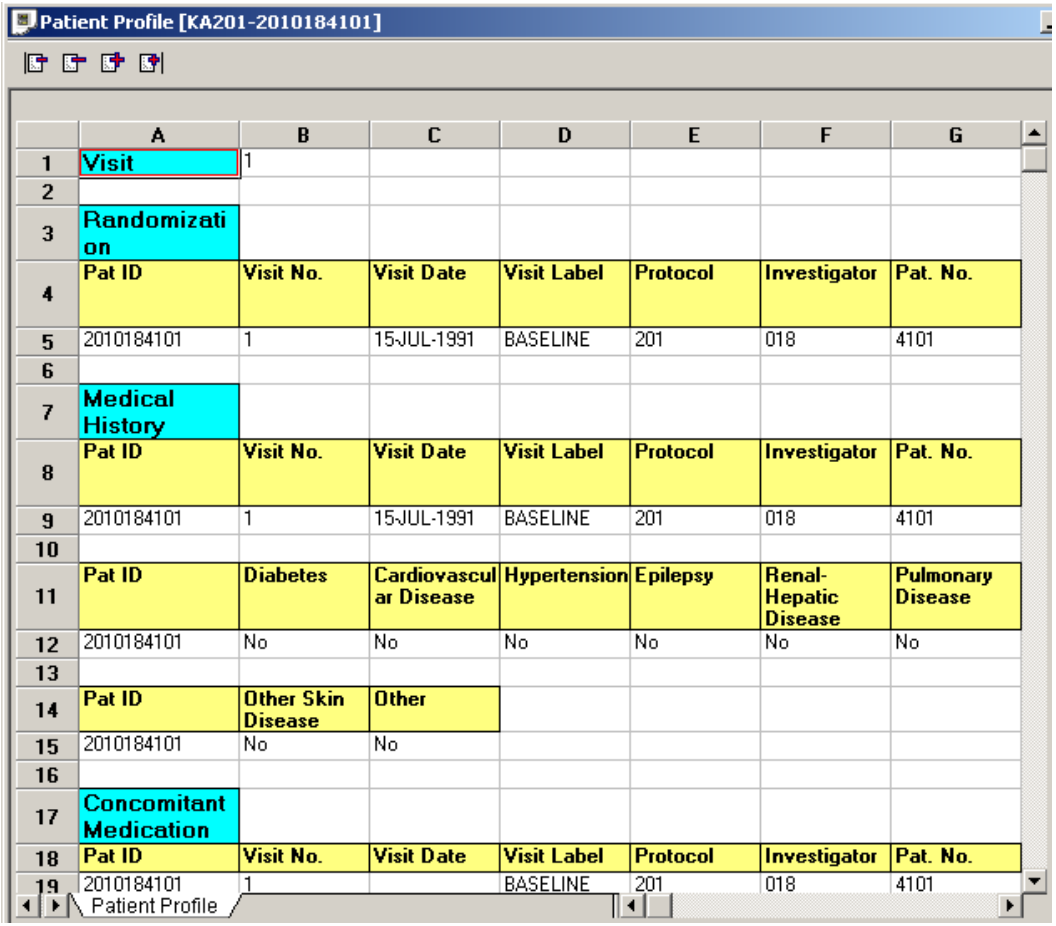
The Toolbar displays the + and - signs to move between patients and to jump to the first or last patient.

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



	A	B	C	D	E	F	G
116	Lab Urinalysis						
117	Pat ID	Visit No.	Visit Date	Visit Label	Protocol	Investigator	Pat. No.
118	2010184101	1	15-JUL-1991	BASELINE	201	018	4101
119	2010184101	5	12-AUG-1991	DAY 29	201	018	4101
120							
121	Pat ID	Occult Blood	Protein	RBC/HPF	Squamous Epith Cells	Uric Acid Crystals	WBC/HPF
122	2010184101	NEGATIVE	NEGATIVE	NONE SEEN		FEW	NONE SEEN
123	2010184101	NEGATIVE	NEGATIVE	NONE SEEN			NONE SEEN
124							
125	Efficacy Evaluation	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
126	Pat ID	2010184101	2010184101	2010184101	2010184101	2010184101	2010184101
127	Visit No.	1	2	3	4	5	6
128	Visit Date	15-JUL-1991	22-JUL-1991	29-JUL-1991	06-AUG-1991	12-AUG-1991	26-AUG-1991
129	Visit Label	BASELINE	DAY 8	DAY 15	DAY 22	DAY 29	DAY 43
130	Protocol	201	201	201	201	201	201
131	Investigator	018	018	018	018	018	018
132	Pat. No.	4101	4101	4101	4101	4101	4101
133	Erythema	2	1	1	1	1	1
134	Pruritus	3	1	1	1	1	2
135	Scaling	1	1	1	1	1	1
136	Vesiculation	0	0	0	0	0	0
137	Edema	0	0	0	0	0	0

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



	A	B	C	D	E	F	G
1	Visit	1					
2							
3	Randomization						
4	Pat ID	Visit No.	Visit Date	Visit Label	Protocol	Investigator	Pat. No.
5	2010184101	1	15-JUL-1991	BASELINE	201	018	4101
6							
7	Medical History						
8	Pat ID	Visit No.	Visit Date	Visit Label	Protocol	Investigator	Pat. No.
9	2010184101	1	15-JUL-1991	BASELINE	201	018	4101
10							
11	Pat ID	Diabetes	Cardiovascular Disease	Hypertension	Epilepsy	Renal-Hepatic Disease	Pulmonary Disease
12	2010184101	No	No	No	No	No	No
13							
14	Pat ID	Other Skin Disease	Other				
15	2010184101	No	No				
16							
17	Concomitant Medication						
18	Pat ID	Visit No.	Visit Date	Visit Label	Protocol	Investigator	Pat. No.
19	2010184101	1		BASELINE	201	018	4101

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.

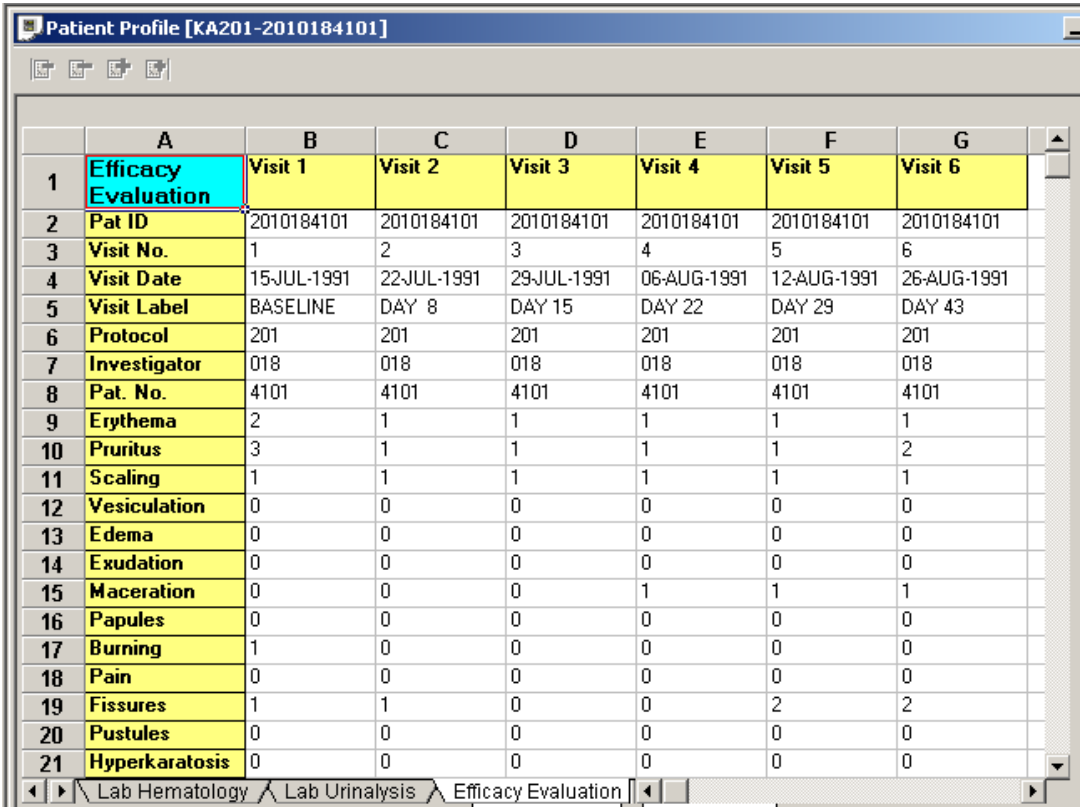
This example shows the Patient Profiles Browser in multiple worksheet mode for the options ***by panel*** and visit representation as row. This options displays the tabs organized by panel label.

Patient Profile [KA201-2010184101]

	A	B	C	D	E	F	G	H
1	Efficacy Evaluation							
2	Pat ID	Visit No.	Visit Date	Visit Label	Protocol	Investigator	Pat. No.	Erythema
3	2010184101	1	15-JUL-1991	BASELINE	201	018	4101	2
4	2010184101	2	22-JUL-1991	DAY 8	201	018	4101	1
5	2010184101	3	29-JUL-1991	DAY 15	201	018	4101	1
6	2010184101	4	06-AUG-1991	DAY 22	201	018	4101	1
7	2010184101	5	12-AUG-1991	DAY 29	201	018	4101	1
8	2010184101	6	26-AUG-1991	DAY 43	201	018	4101	1
9								
10	Pat ID	Edema	Exudation	Maceration	Papules	Burning	Pain	Fissures
11	2010184101	0	0	0	0	1	0	1
12	2010184101	0	0	0	0	0	0	1
13	2010184101	0	0	0	0	0	0	0
14	2010184101	0	0	1	0	0	0	0
15	2010184101	0	0	1	0	0	0	2
16	2010184101	0	0	1	0	0	0	2

Efficacy Evaluation | Mycological Results | Vitals_Physical E

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.



	A	B	C	D	E	F	G
1	Efficacy Evaluation	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
2	Pat ID	2010184101	2010184101	2010184101	2010184101	2010184101	2010184101
3	Visit No.	1	2	3	4	5	6
4	Visit Date	15-JUL-1991	22-JUL-1991	29-JUL-1991	06-AUG-1991	12-AUG-1991	26-AUG-1991
5	Visit Label	BASELINE	DAY 8	DAY 15	DAY 22	DAY 29	DAY 43
6	Protocol	201	201	201	201	201	201
7	Investigator	018	018	018	018	018	018
8	Pat. No.	4101	4101	4101	4101	4101	4101
9	Erythema	2	1	1	1	1	1
10	Pruritus	3	1	1	1	1	2
11	Scaling	1	1	1	1	1	1
12	Vesiculation	0	0	0	0	0	0
13	Edema	0	0	0	0	0	0
14	Exudation	0	0	0	0	0	0
15	Maceration	0	0	0	1	1	1
16	Papules	0	0	0	0	0	0
17	Burning	1	0	0	0	0	0
18	Pain	0	0	0	0	0	0
19	Fissures	1	1	0	0	2	2
20	Pustules	0	0	0	0	0	0
21	Hyperkaratosis	0	0	0	0	0	0

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

Patient Profile [KA201-2010184101]

	A	B	C	D	E	F	G	H
1	Visit	1						
2								
3	Randomization							
4	Pat ID	Visit No.	Visit Date	Visit Label	Protocol	Investigator	Pat. No.	Date of Randomization
5	2010184101	1	15-JUL-1991	BASELINE	201	018	4101	15-JUL-1991
6								
7	Medical History							
8	Pat ID	Visit No.	Visit Date	Visit Label	Protocol	Investigator	Pat. No.	Drug Sensitivity
9	2010184101	1	15-JUL-1991	BASELINE	201	018	4101	Yes
10								
11	Pat ID	Diabetes	Cardiovascular Disease	Hypertension	Epilepsy	Renal-Hepatic Disease	Pulmonary Disease	Gastrointestinal Disease
12	2010184101	No	No	No	No	No	No	No
13								
14	Pat ID	Other Skin Disease	Other					
15	2010184101	No	No					

1 2 3 4 5 6

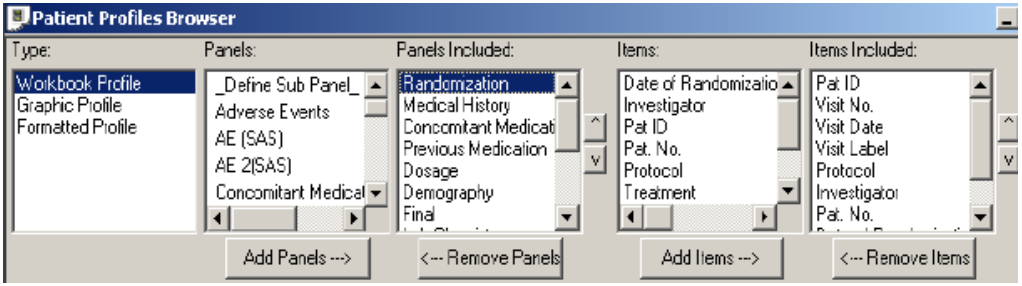
Defining a patient profile

Modify profile content

Up to this point you have selected the single worksheet or multiple worksheet mode with the display settings for panel versus visit. When you clicked **Create Patient Profile** all panels and items would be included in the patient profile generated. The display order of the panels defaults from the list of panels available.

To modify the panels and items displayed in a patient profile:

1. Use the **Add Panels** and **Remove Panels** buttons to select panels defining the patient profile.



2. Use the **Up** and **Down arrows** located next to the **Panels Included** list box to change the sort order of the panels displayed.
3. Use the **Add Items** and **Remove Items** buttons to select specific items for display.
4. Use the **Up** and **Down arrows** located next to the **Items Included** list box to change the sort order of the items displayed.
5. Click **Create Patient Profile**. The modified panel and item contents of the patient profile displays.

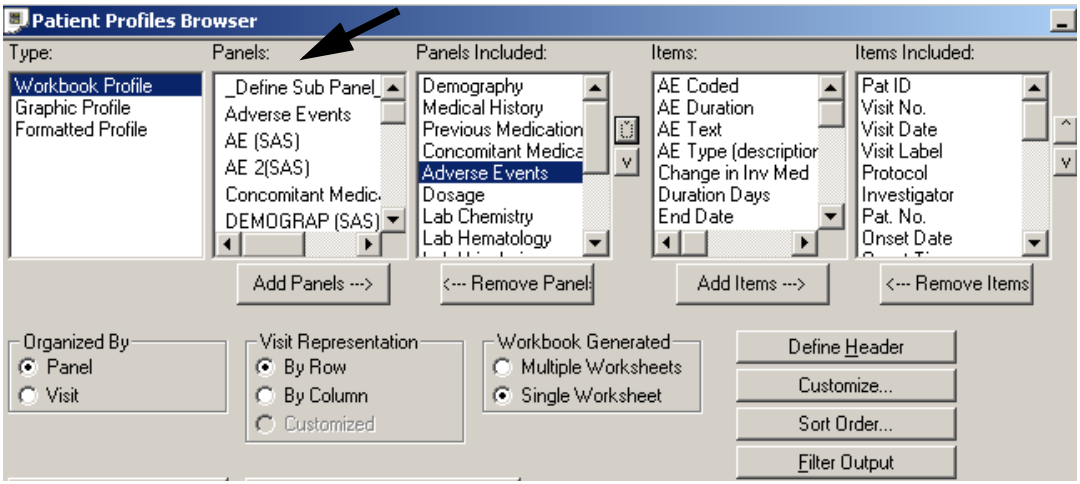
Access to SAS datasets

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.

Define Sub Panel

The **_Define Sub Panel_** function is selected from the panels list box. When you define a sub panel the 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. Simply select the panel and enter a sub panel description. The new sub panel is added to the Panels Included list for selection to add and remove items for display. When defining a sub panel you can only select a single panel. Multiple visit panels display as vertical or horizontal.

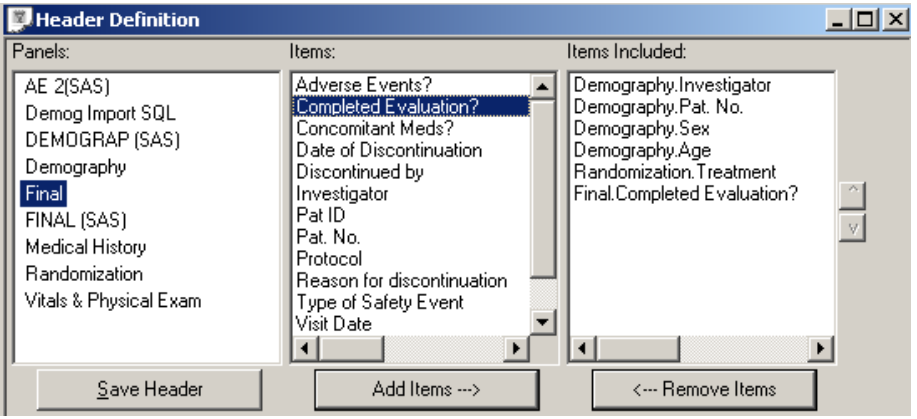


Define Header

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

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

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

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

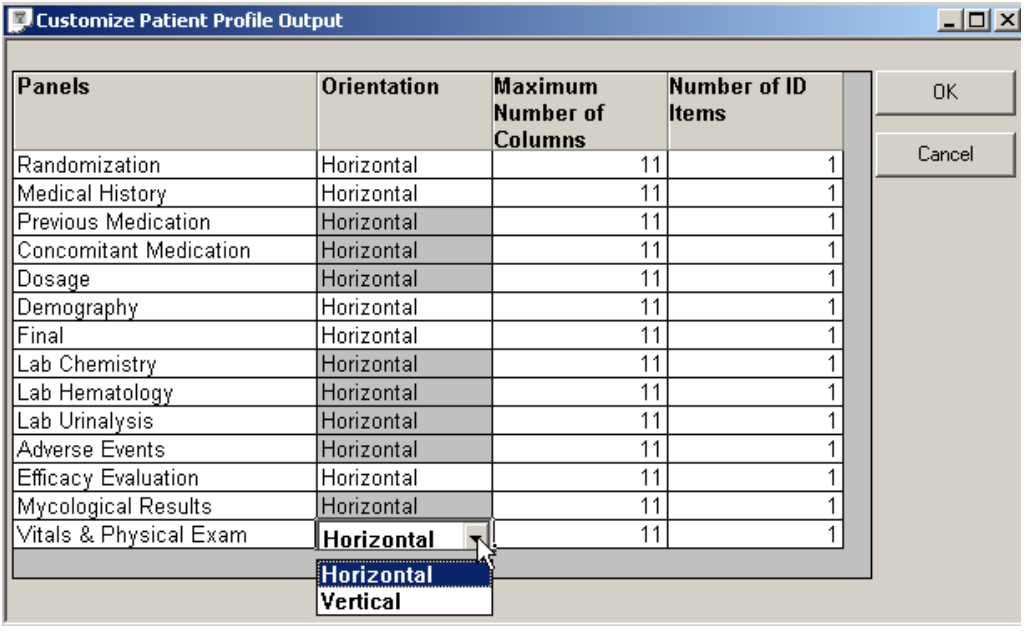
The defined header information will appear only once at the top in the single worksheet mode. In the multiple worksheet mode, it will display at the top of each worksheet whether organized by panel or visit.

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.

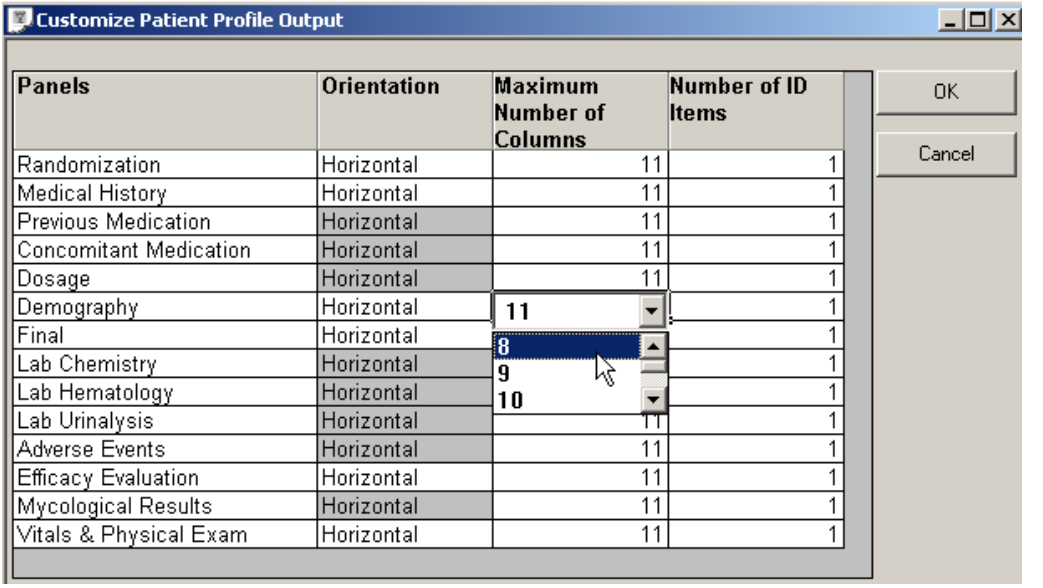
Customize patient profile output

Click **Customize** to view the default settings for all panels regarding display orientation, maximum number of columns and number of ID items. You can make changes to these options on a individual panel basis.

1. Panels shaded in gray have a locked orientation. Panels displayed in white are unlocked and you can on the cell to access the orientation drop down list to select horizontal or vertical.



2. The maximum number of columns displayed per row can also be changed. The range is 8 through 13 selected from the drop down list.

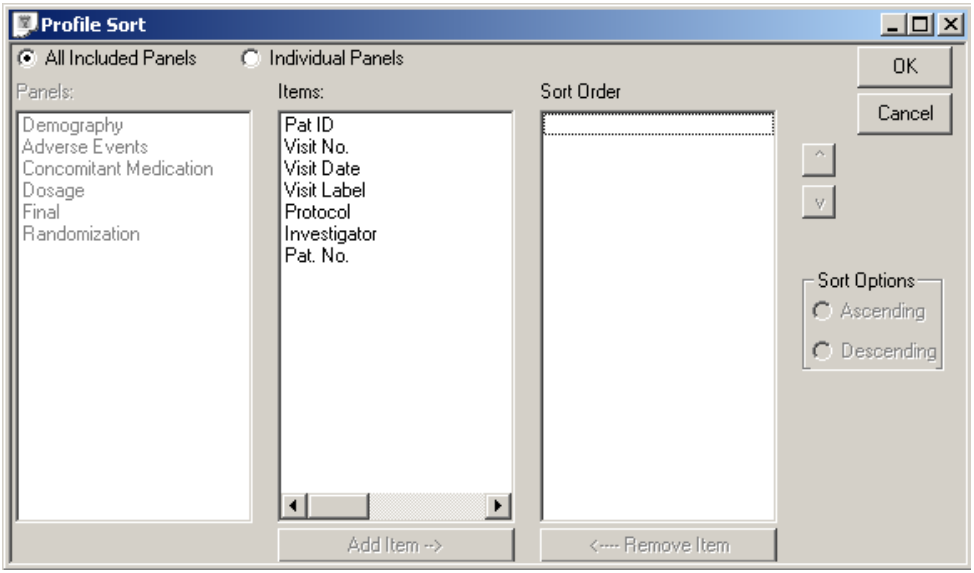


3. The option to display ID items as represented by the PatientNo and VisitNo are also selected from a drop down list for choices are 0, 1 and 2. If a panel row wraps beyond the maximum number of columns defined, you can repeat the display of '1' or '2' ID items onto the next row. If you select '0' ID items then only the initial row contains ID items.
4. 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.

*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.*



- 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.
- 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.
- When you select multiple 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.

Filter Output

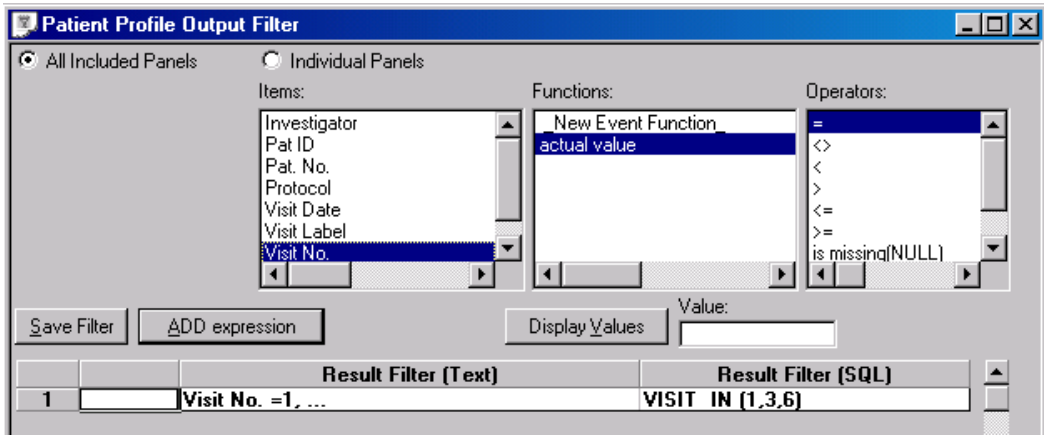
Patient Profile Filter Output

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 where only included panels are viewable and selectable for filtering in the Filter Output window.

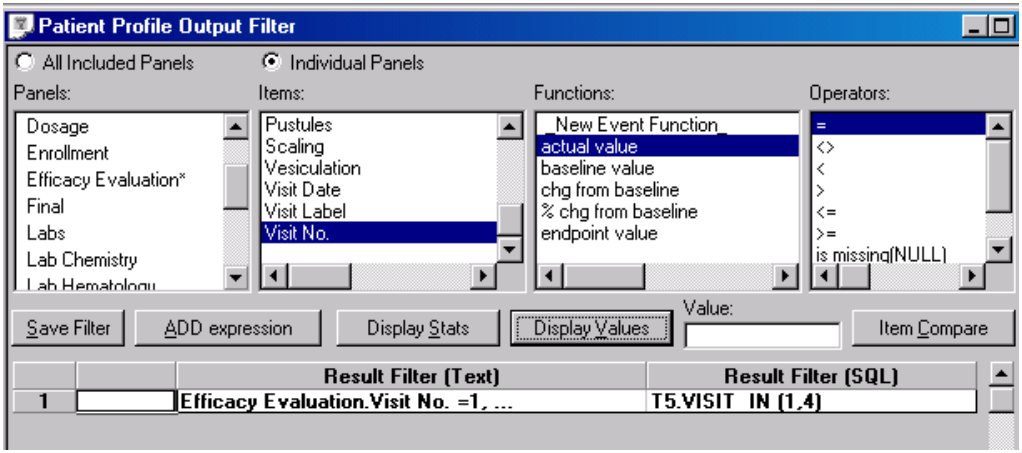
The reason behind this is that in a patient profile, each panel is displayed individually and is not joined with any other panel. Therefore, filtering criteria from any other panel would not apply to a panel used in profiles.

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



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

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



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

   For each individual panel selected and a result filter entered, an asterisk displays next to the panel name flagging the panel has an active output filter.

Patient Profile display

Expanding spreadsheet columns

When Review 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.

1. Click and drag the cursor on the line between the column heading tabs (between B and C if you're expanding column B in the example below), and drag the cursor to the width desired.
2. If you want to size all the columns in the spreadsheet, you can highlight the entire spreadsheet by clicking on the upper left spreadsheet column tab, and then size column B and each of the subsequent columns will then be the same width as column B.

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**.

   Review displays a screen shot of the selected active screen.
3. Click either **Print** or **Close.**

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

Printing a 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**.

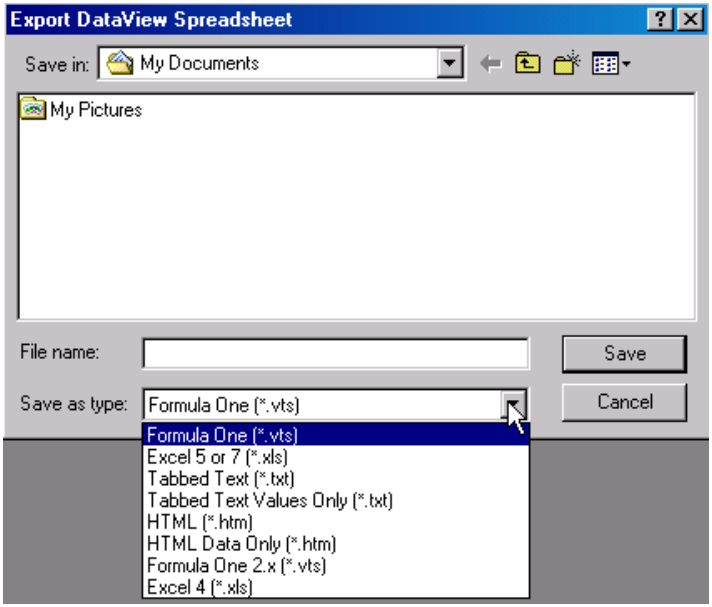
   Review displays the standard Print dialog box.
3. Click **OK**.

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.

To export your table in Excel 4, 5 and 7, tab delimited files, HTML format or PDF files:

1. From the **File** menu, select **Export**.

   Review displays the Export dialog box.



2. Enter the storage location.
3. Enter the storage type.
4. Click **OK.**

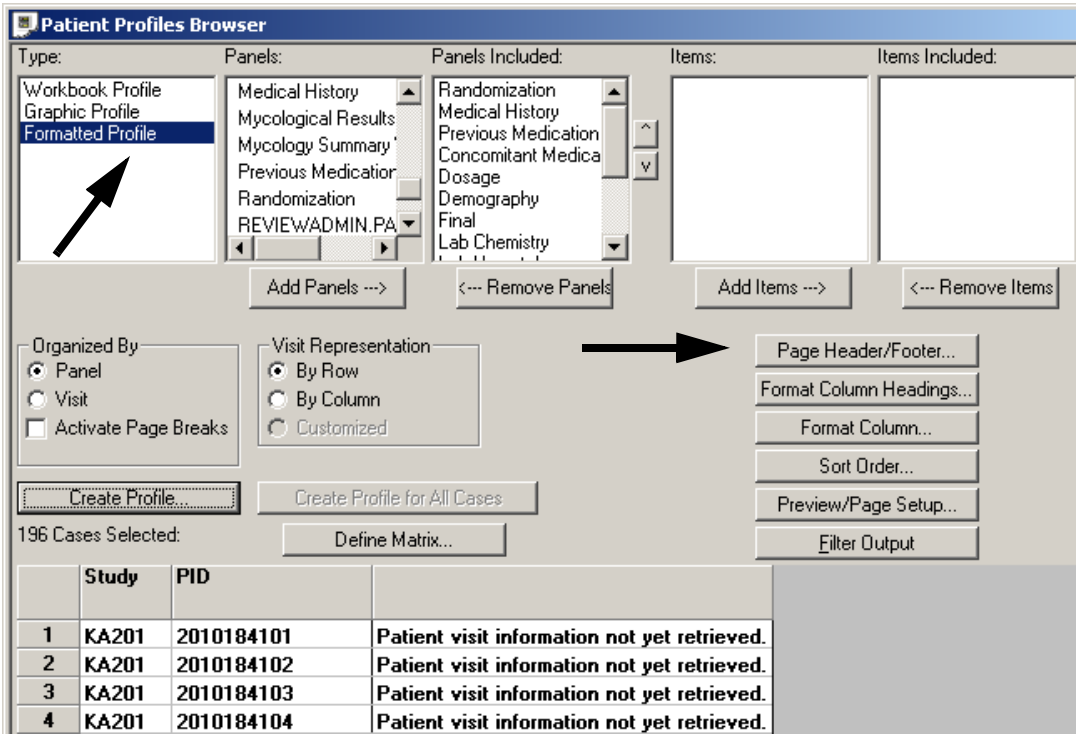
Your patient profile is exported to the currently selected disk directory. (See *Chapter 12: Common Topics: Export Browser Display Spreadsheets; Copy and Paste Browser Results; Copying to Clipboard.)*

Formatted Patient Profile

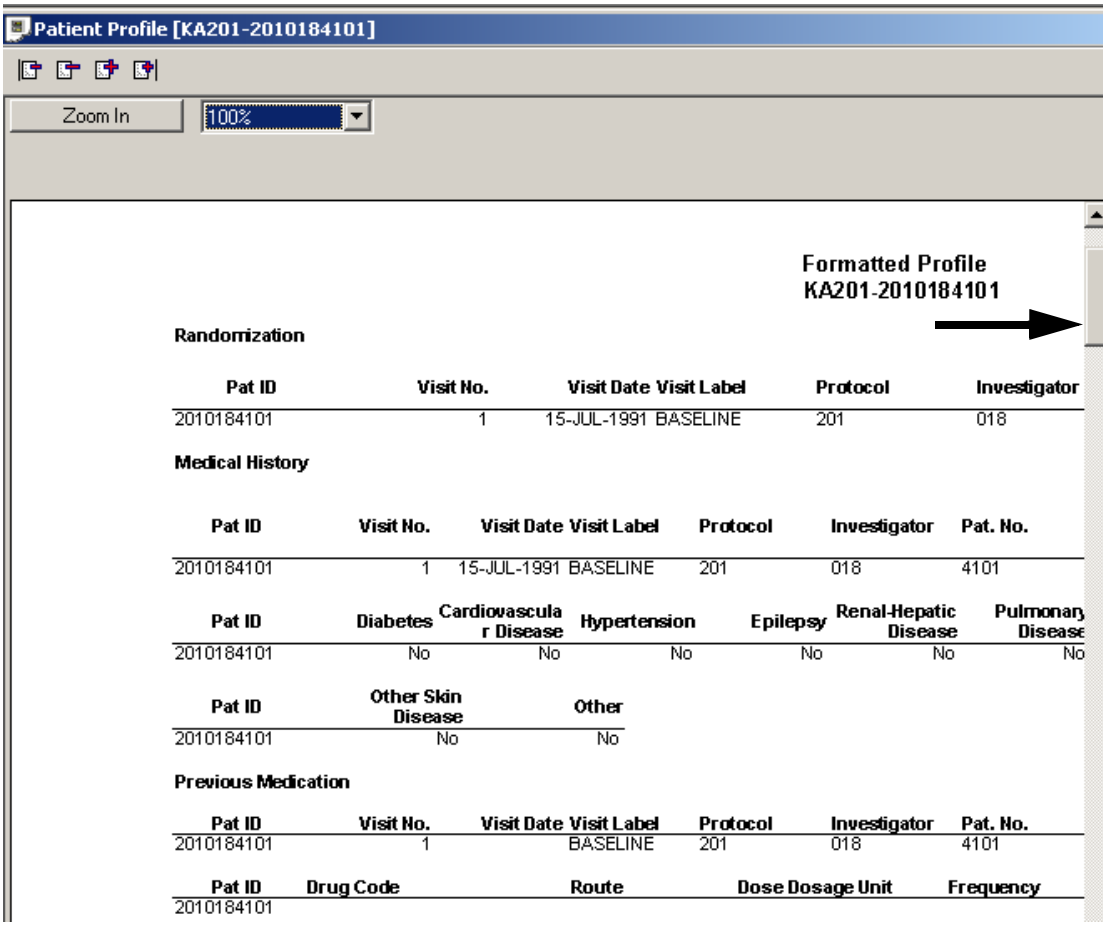
Select formatted profile

When you select the **Formatted Profile** type the format options menu displays for you to apply setting changes. Initially if you click create profile the default settings are organized by ***panel*** and visit representation as ***by row***. The formatted profile default is generated with all panels including all items for a single selected patient.

.

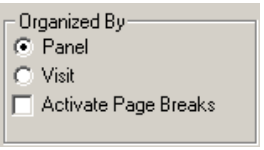


This example is a partial enlarged view of a formatted profile with default settings. There is a scroll bar located on the right to move between pages for a single patient. To move between patients use the page by buttons for plus and minus to go to the next or previous patient. A **Zoom In** button is available and a scale to enlarge or reduce the view.



Activate Page Break

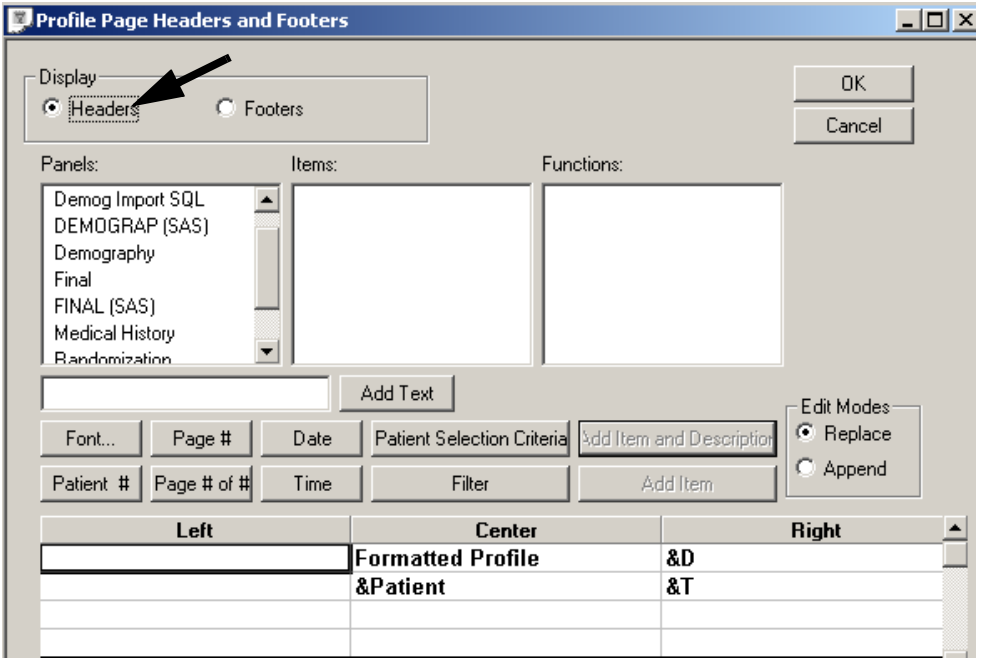
The activate page break default is set to OFF. However, you can select to turn ON page breaks for **Organized By Panel** or **Visit**.



Apply Page Header and Footer

To enter descriptive information to the Header and Footer area:

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



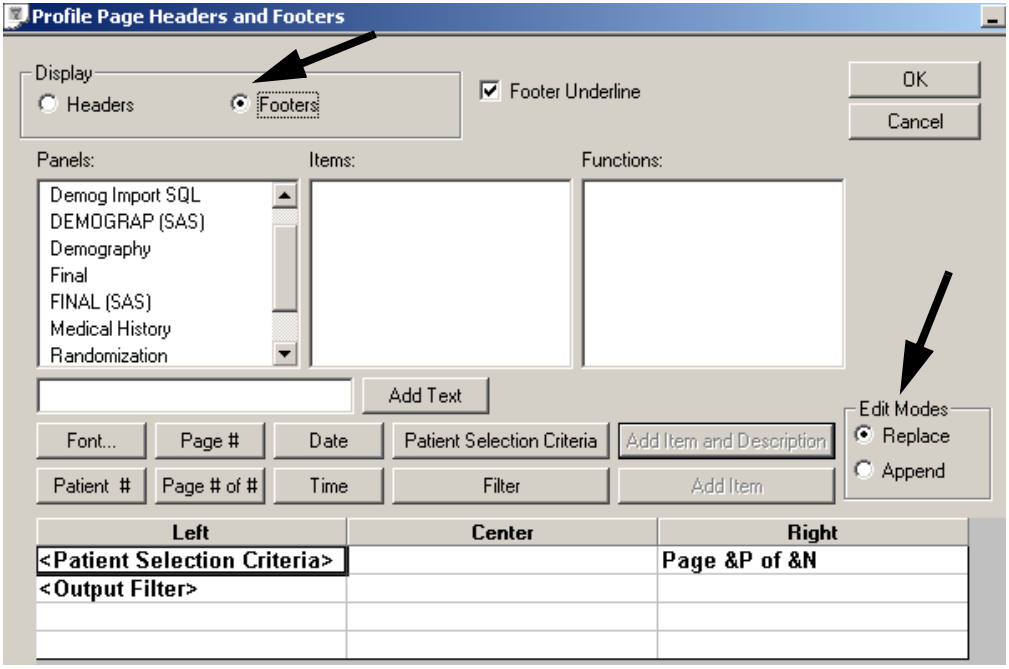
The default settings for headers are:

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. You may click on a cell and use the scissors icon to delete the contents.
5. Click the Font button to change font, style and size.
6. Click Display Footers.



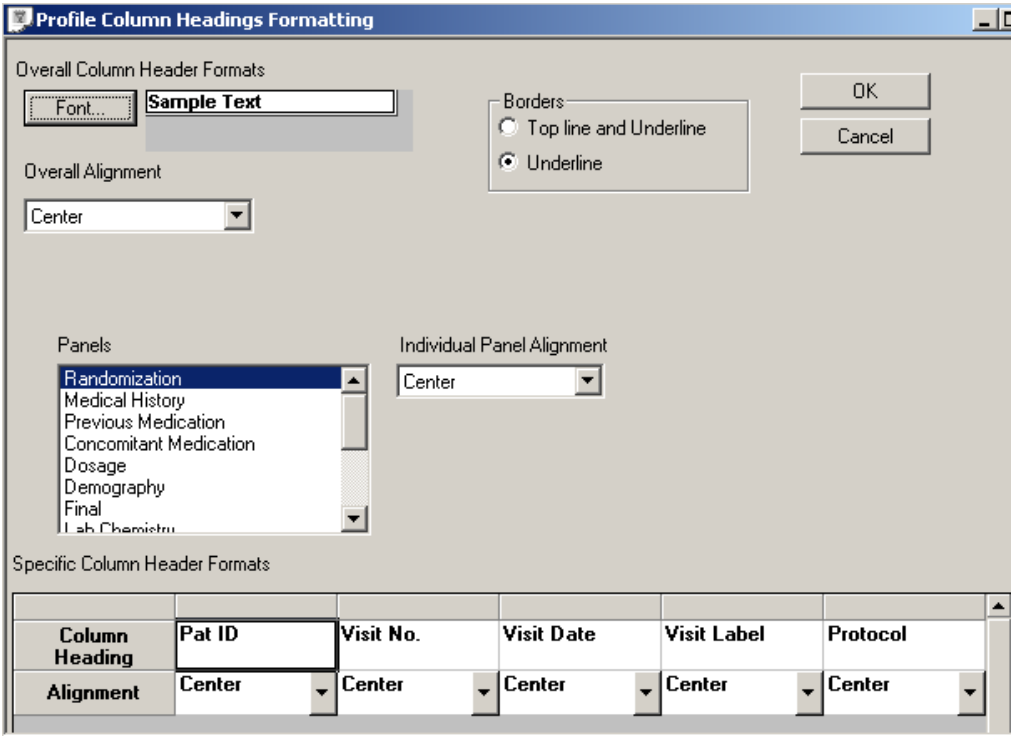
7. Follow the same steps to enter and make changes to the footer. The default settings for footers are:
   a. Patient Selection Criteria and Output Filter on the Left.
   b. Page number on the right.
   c. Underline above the footer.
   d. Font is BOLD **10**.
8. Turn the Footer Underline ON or OFF.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

To open the Profile Column Headings Formatting window click on the **Format Column Headings** button. The default settings for all column headings are:

- Font is **BOLD 8.**
- Overall Alignment - Center.
- Individual Panel Alignment - Center.
- Borders set to Underline is ON.

To apply Overall Column Header Formats:

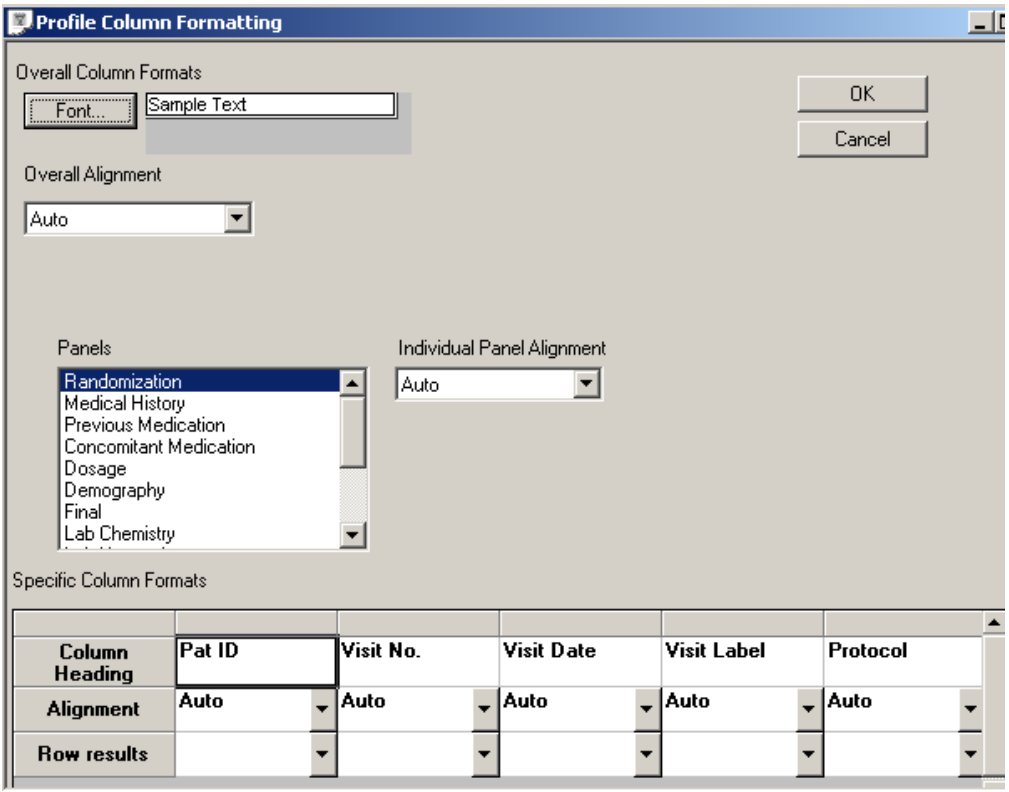
1. Click the Font button to change font, style and size.
2. Change the borders.
3. Apply a Specific Column Header Format by clicking the drop down list for alignment. Change from default center to auto, left, or right.
4. Change Overall Alignment or Individual Panel Alignment.
5. Click **OK** to apply format changes.



To open the Profile Column Formatting window click on the **Format Column** button.

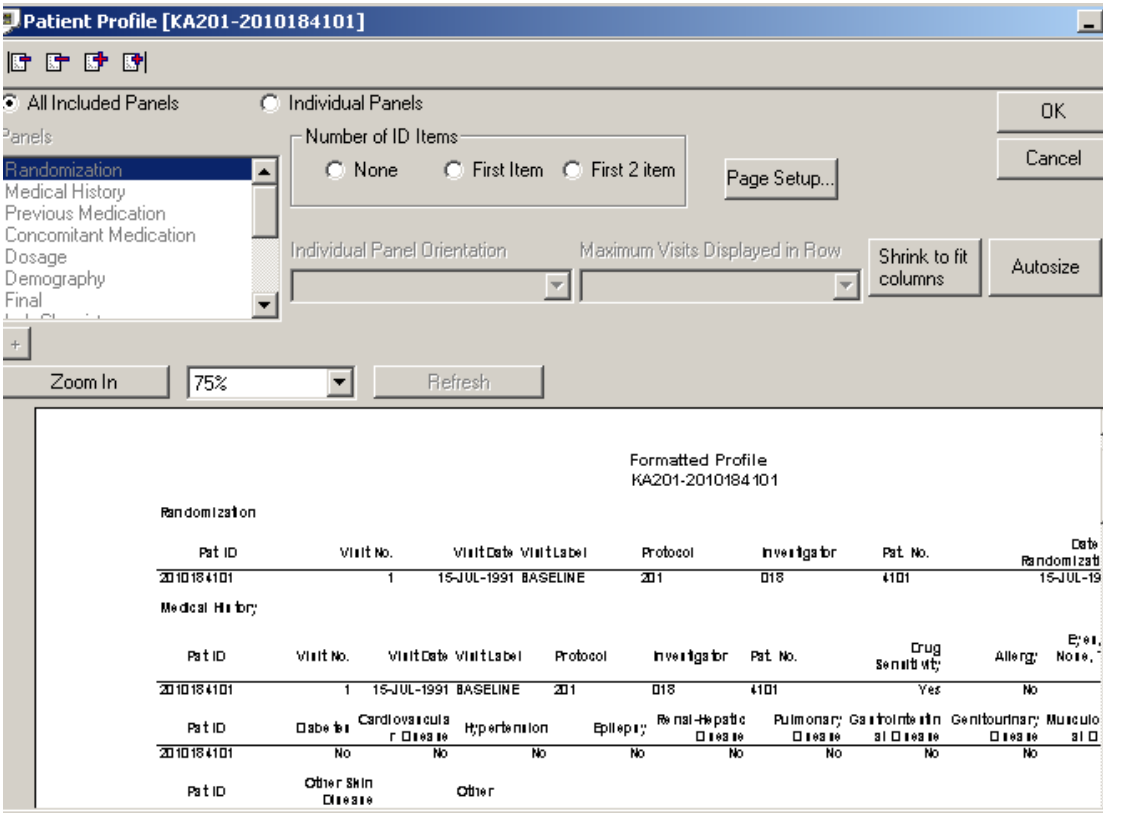
- Font is Regular 8**.**
- Overall Alignment - Auto.
- Individual Panel Alignment - Auto.

1. Click Overall Column Formats to apply overall formats to font, style and size.
2. Change Overall Alignment or Individual Panel Alignment from auto to left, center or right.
3. Click the 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.



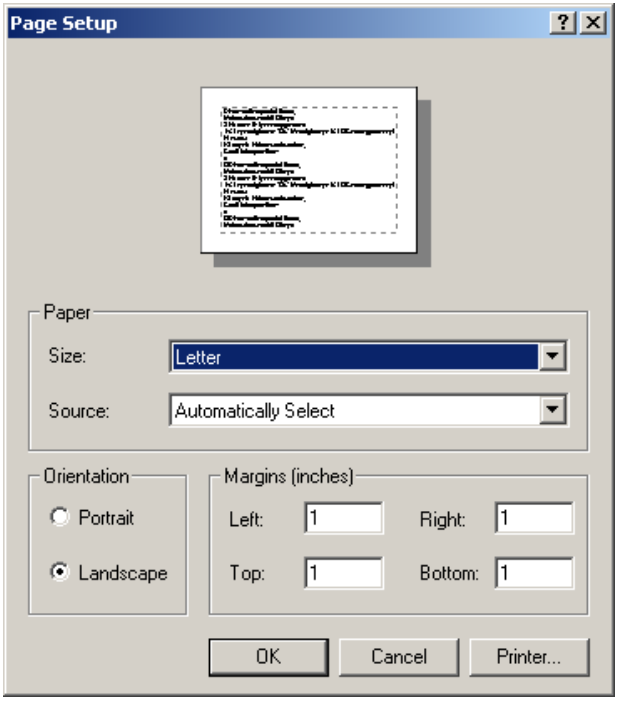
Click **Preview/Page Setup** to view the Preview window of the formatted profile. It is recommended to apply any settings in the following sequence since sizing of the individual columns on the grid in design mode will change the column widths. It is advised to set **Page Setup** before the setting of 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.



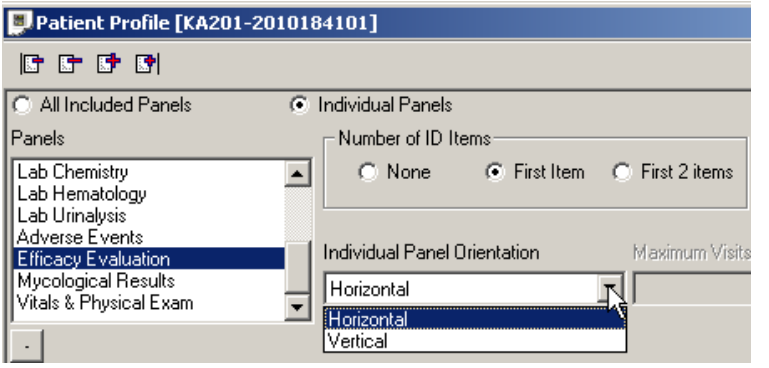
Number of ID items

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.

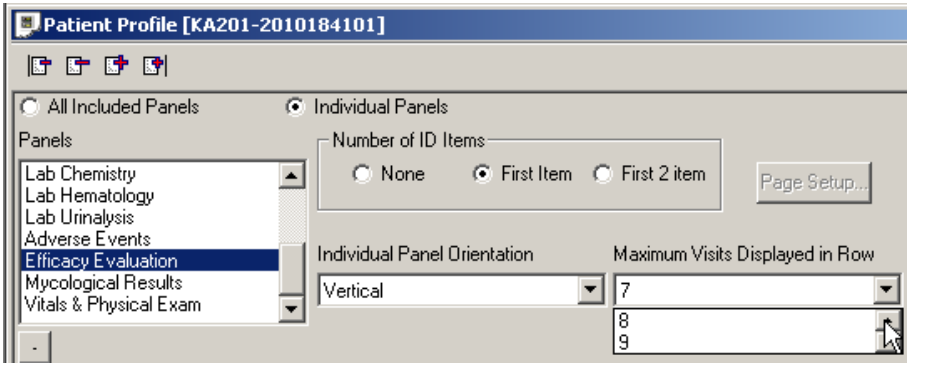
The default setting is for ‘First Item’ where the first row of all panels always displays the PatientID and VisitNo with any wrapped row displaying the PatientID.

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. Click the individual Panel Orientation drop down list to change the panel orientation.



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

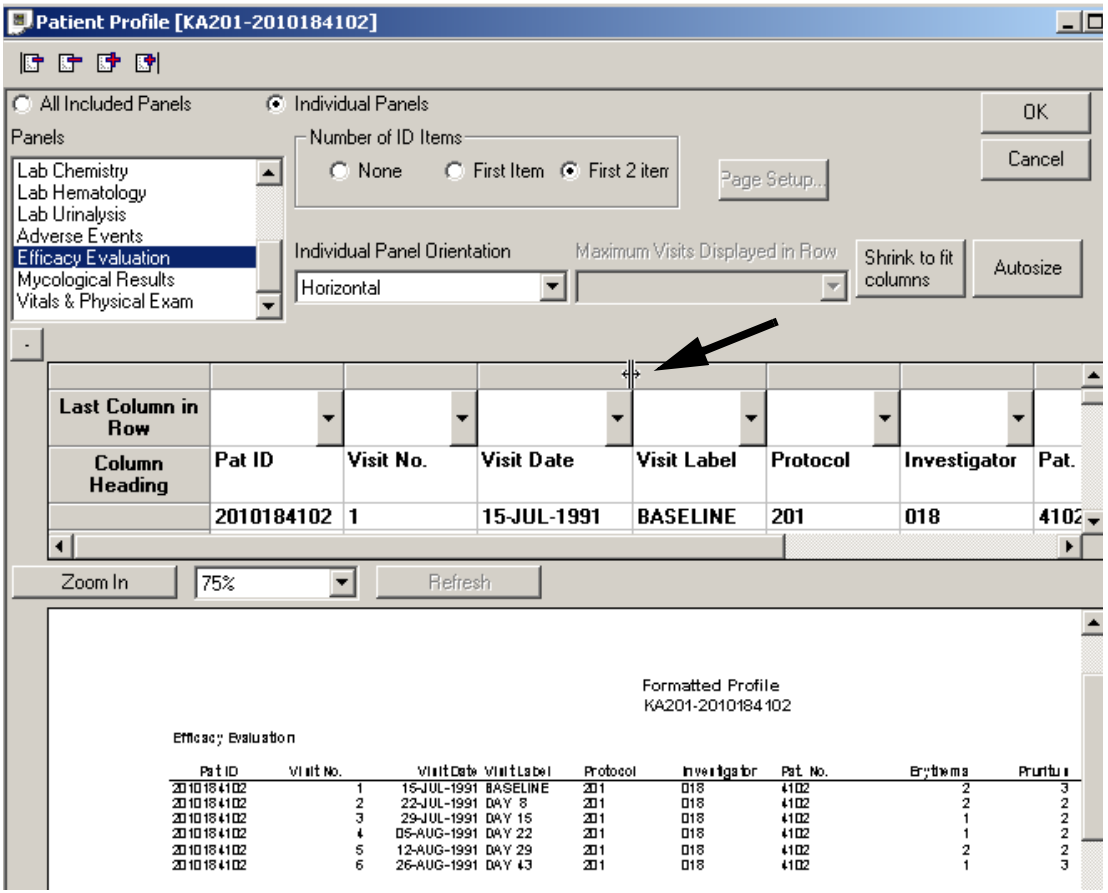


5. Click **Refresh** to view panel orientation change.

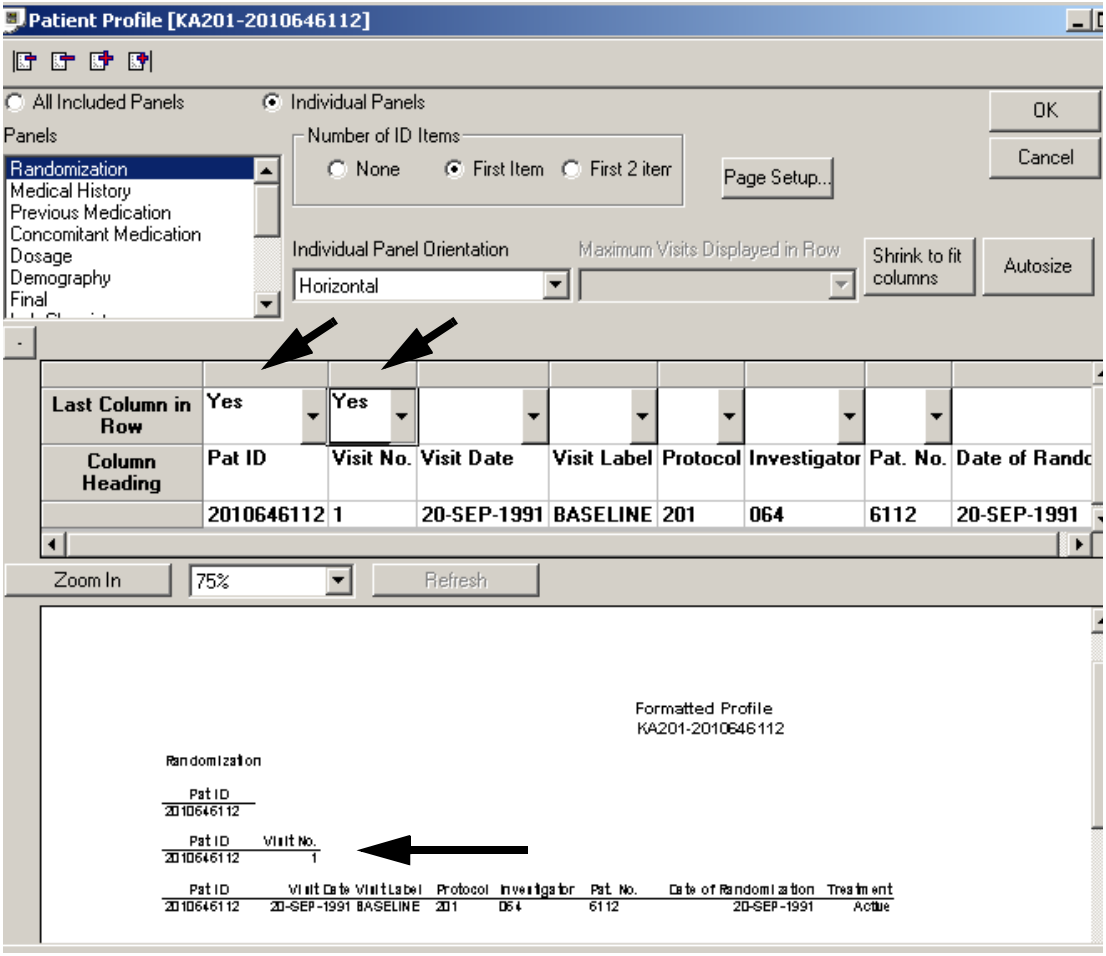
Note: The grid in design mode only displays when you select Individual Panels.

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 selecting 'Yes' for **Last Column in Row.** Click **Refresh** to view your changes.



Object Storage: saving your work

Object storage location

You can store patient selection criteria at four user access levels: Private, WorkGroup, UserGroup, or Public.

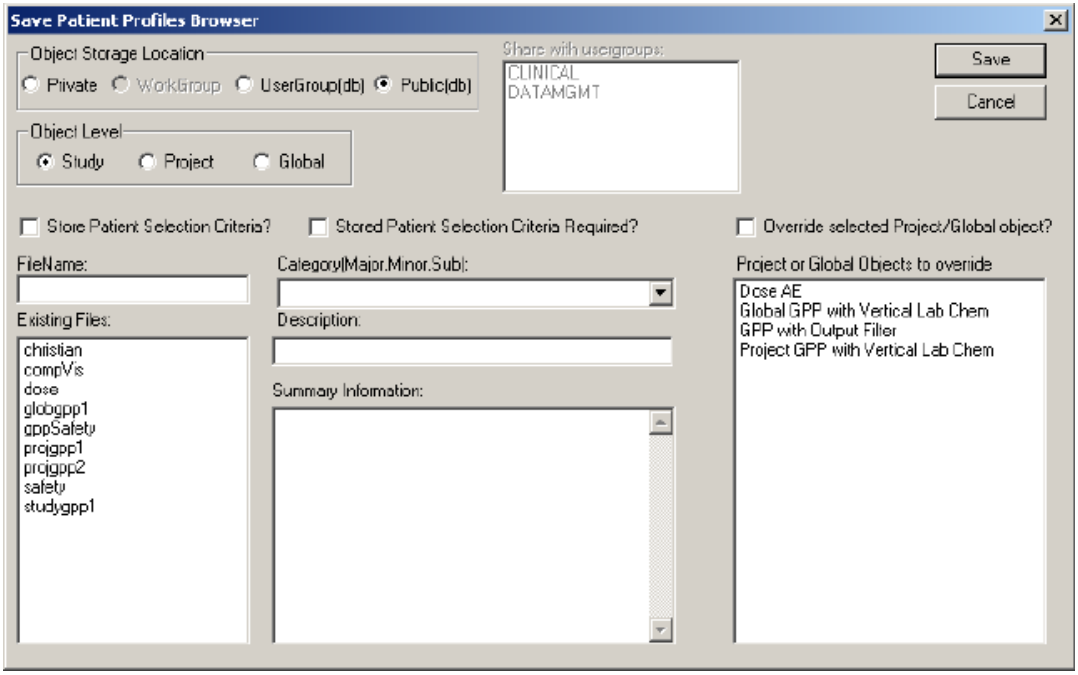
- Private storage is at the local PC level. The private objects are saved on the user's home drive in a directory (folder) called "irpat". Review handles all creation, access and deletion of the private objects in this folder. Therefore, the user should not be concerned with the contents of the irprivat folder.
- WorkGroup storage is PC based and stored at a shared network drive, to which a select group of personnel would have access.

Note: The WorkGroup storage location was supported in earlier Review releases. UserGroup storage location is extensively used for later releases.

- 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 WorkGroup or UserGroup storage.

  Saving on database object storage sites, requires the author to have "Publishing Authorization" defined in the configuration tables. (See *Chapter 12: Common Topics: Shared Object Storage- Locations)*



When you select the UserGroup object storage location, the ‘Share with usergroups’ ListBox is made available for selection.

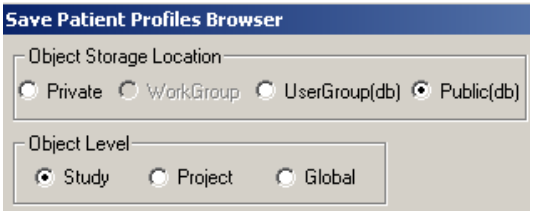
Object level

You can store your output specification at three levels: Study, Project, or Global. The Object Level box is only enabled and highlighted when you select an Object Storage Location designated as ‘db’ for database. Therefore, when you select either UserGroup or Public for database object 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.

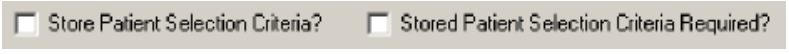
Saving Patient Profile specifications

To save the patient profile specification you have defined for later use:

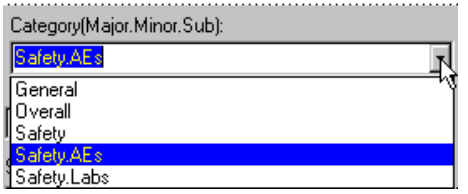
1. Make certain that the Patient Profiles Browser window is the active window by clicking on its title bar.
2. Click , or from the **File** menu select **Save.**
3. Review displays the Save Patient Profiles Browser dialog box where you can specify the storage location.



4. Select object level type. The default is Study.
5. Click **Store Patient Selection Criteria** 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. If the particular patient selection criteria is specific and required for the output, click **Patient Selection Criteria required**. In this instance, the patient selection criteria cannot be modified when this stored object specification is selected. If none selected, then no patient selection criteria is saved with the output specification.



6. Enter a FileName for future reference to be displayed in the list box for Existing Files. The Filename is for internal use and not displayed in the Object Explorer window.
7. 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 drop down listbox.

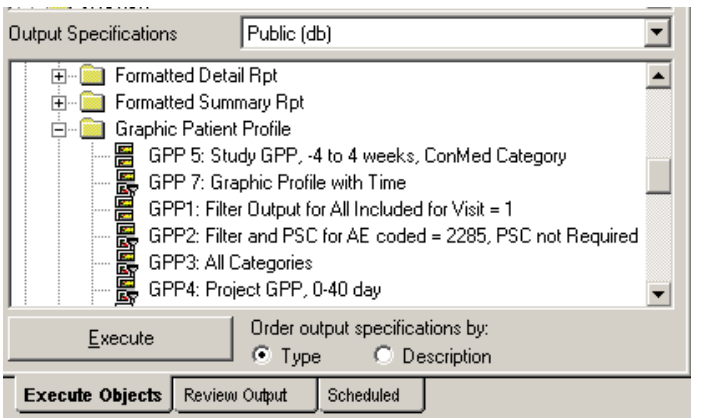


8. Next enter the appropriate description which is displayed in the Object Explorer window.
9. You can include summary information for future reference to be viewed by yourself or others later.
10. Click **Save**.

Review stores the output specification to the designated PC, WorkGroup, UserGroup, or Public storage location.

Object Explorer window

Once you have saved your patient profile specification and assign 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.

Note: Graphic Patient Profiles can not be scheduled or the output saved.

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.

Saved objects and their associated icons can be sorted to display in the their folders by icon type or description. Simply click sort **by Type** or **by Description**.

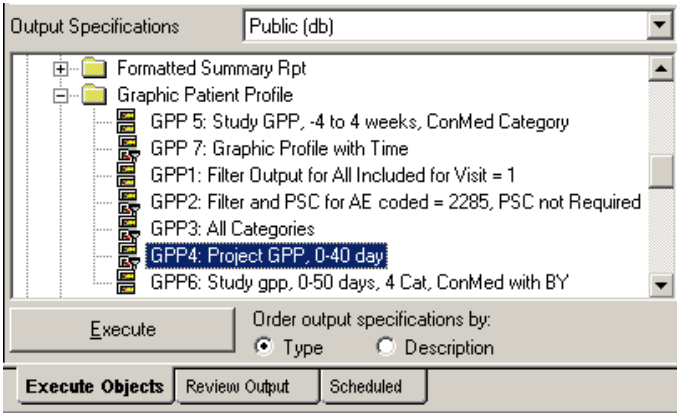
Object Explorer quick execute

The Object Explorer window aids users to quickly locate and launch previously saved objects stored within organized folders. This shortcut allows users to bypass opening the individual browsers to launch saved objects.

If you want to retrieve a saved output specification:

1. Double click to open a folder.
2. Click on the output specification and click **Execute**.

   Your stored output specification will be launched.



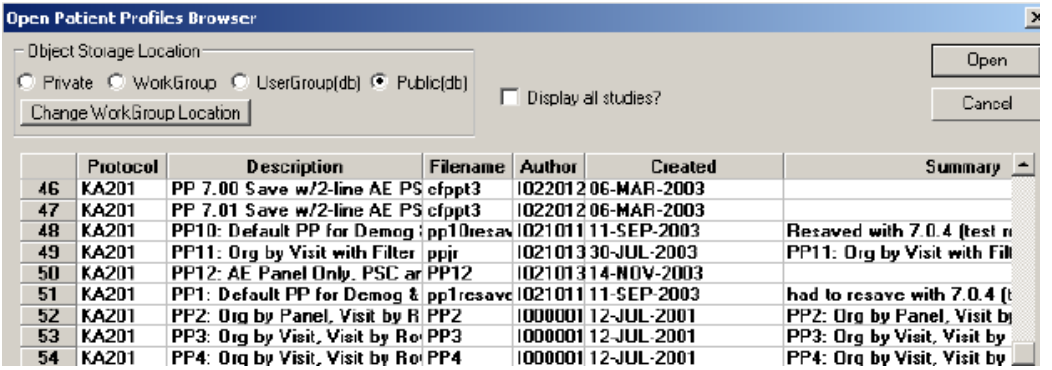
If you want to apply a saved patient selection criteria to your output specification:

1. Double click to open a folder.
2. Double click to paste the selected patient selection criteria into the Patient Selection Criteria Window. Then follow the above steps to retrieve and execute a stored output specification. Or create your own selection criteria for a stored output specification.

Another way to retrieve a previously saved Patient Profiles specifications from the Patient Profiles Browser:

1. Make the Patient Profiles Browser window as the active window.
2. Click **Open**, or from the **File** menu. The Open Patient Profiles Browser window displays.
3. Select the object storage location. Review displays a list of stored Patient Profiles Specifications.
4. Select a Patient Profiles description and click the **Open** button or double click on the description.

Note: You must use the Open Patient Profiles Browser window to access the object storage location for 'WorkGroup'.



   a. If you want to browse and / or select a file from the WorkGroup, UserGroup or Public storage sites, click on the site and the files available to you are displayed in the following window.

   b. Click **Change WorkGroup Location**, and you are enabled to browse various Patient Profiles object storage sites.

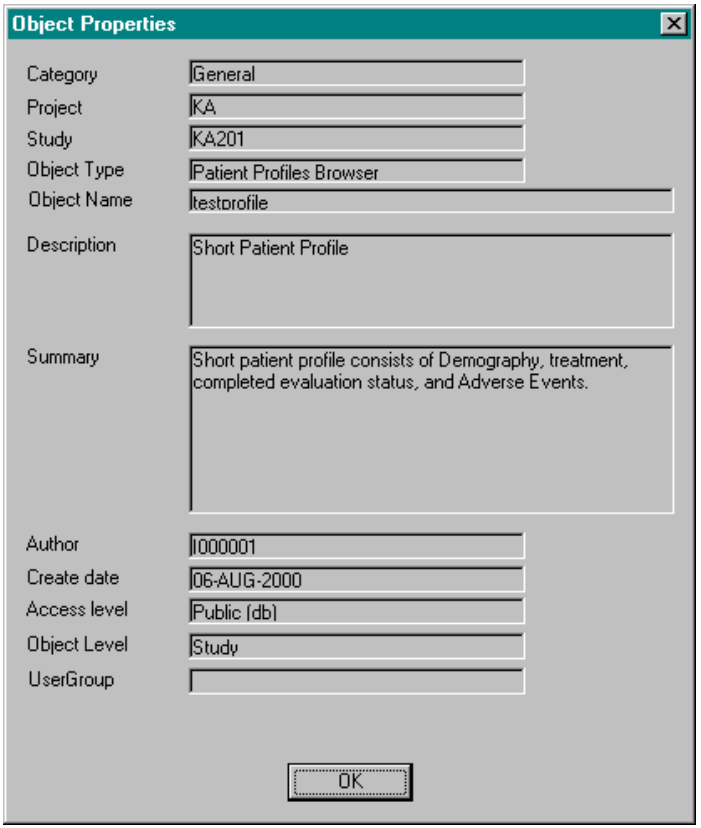
5. You can browse through the Patient Profiles specification by reviewing the summary text. Click on the Patient Profiles specification, and click **Open**. Review pastes the Patient Profiles layout specifications into the layout spreadsheet, clearing the current spreadsheet contents.
6. By default, Review displays only saved Patient Profiles specifications created while reviewing the current Study Protocol(s). You may also import Patient Profiles specification created for other Study Protocol(s). Check **"**Display all studies?" and open any available Patient Profiles Browser specification. Review will validate the data structure to verify that the foreign Patient Profiles specification is compatible with the current study protocol(s).

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. Then click **Properties**. A dialog window displays the object properties for the output object. It works for ‘Private’, ‘Workgroup’, ‘UserGroup’ or ‘Public’ objects equally.

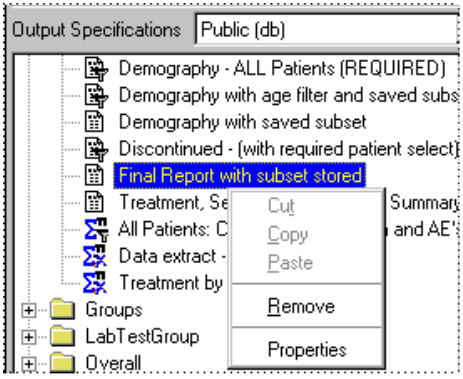


Quick remove

You can quickly delete a saved Patient Profiles Browser object under the Output Specifications window.

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?".

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

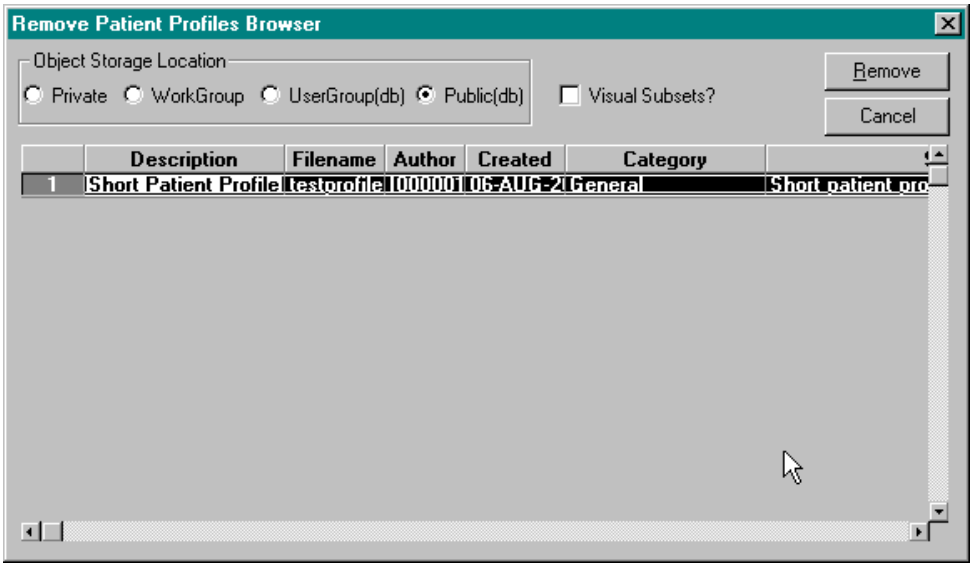


Removing a saved Patient Profiles specification

Another way to remove one of the saved Patient Profiles specifications if you decide it should be deleted:

1. Open the Patient Profiles Browser to make it the active window.
2. From the **File** menu, click **Remove**.
3. Review displays the Remove Patient Profiles Browser window.
4. Click on the object storage location.
5. Select the stored Patient Profiles description you want to remove.
6. Click **Remove**.

Review deletes it from your local PC, WorkGroup, UserGroup or Public storage sites as you designate and have security clearance to do so.



Printing the Patient Profiles specifications

To print the currently active Patient Profiles specification, make certain that the Patient Profiles Browser window is active by clicking on.

1. Click **Print**, or from the **File** menu, select **Print**. Review displays the standard print dialog box.
2. Click **OK**. Repeat column headers are printed on each page in the printout.
3. To change the printer, select **Print Setup** from the **File** menu.

Closing Patient Profiles Browser

Closing the Patient Profiles Browser

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

Patient Profiles Browser **189**

Open Patient Profiles Browser 189

Graphic Patient Profile **190**

Access Graphic Patient Profile 190

Define Graphic Profile Template **190**

Graphic Profile Template 190
Define study start date 192
Define header items 195
Category types 196
Define Category Information 197
Time Axis scale 198
Duration Category Type 199
Dosage Category Type 200
Text Category Type 201
Laboratory Category Type 203
Time Point Type category 205
Save template 208
Edit graphic template 208

Define Graphic Profile **209**

Select defined template 209
Change Time Axis 209
Change Limit value 210
Display Time items 210
Select categories for display 211
Select Items for display 211
Normal range multiplier 214
Create Graphic Patient Profile 217
Missing data 218

Basic graphic user interface 218

Filter Output 221

Patient Profile Filter Output 221

Graph settings 223

Select settings 223
Appearance options 224
Printing and PDF output settings 225
Color settings 226
Headers and footers 227
Category settings 227

Graphic Patient Profile display 229

Print Preview 229
Printing a patient profile 229
Exporting a patient profile 230

Object Storage: saving your work 231

Object storage location 231
Object level 232
Saving Patient Profile specifications 233
Object Explorer window 234
Object Explorer quick execute 235
Retrieving a saved Patient Profiles specifications 236
Object properties 237
Quick remove 238
Removing a saved Patient Profiles specification 238
Printing the Patient Profiles specifications 239

Closing Patient Profiles Browser 239

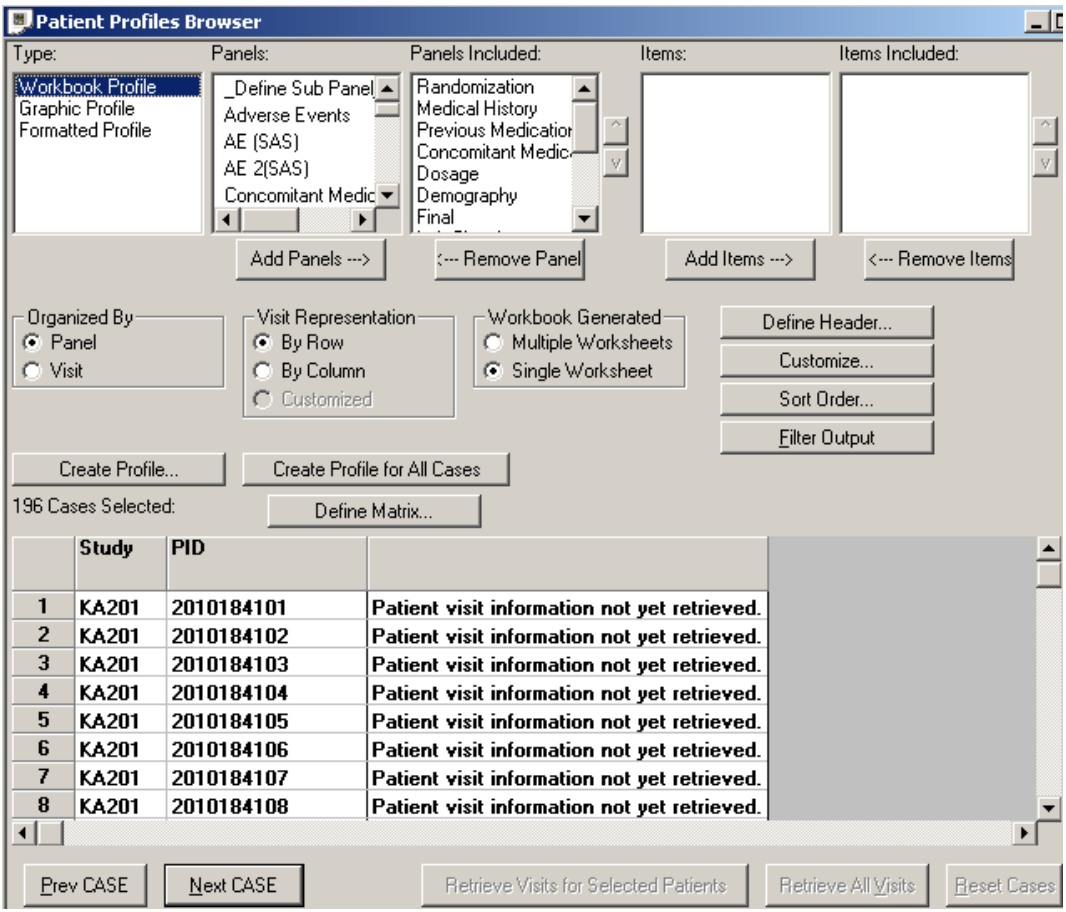
Closing the Patient Profiles Browser 239

Patient Profiles Browser

Open Patient Profiles Browser

Optionally define a patient selection criteria to quickly capture a subset of the patient population that you wish to view.

Click , or from the **Browse** menu, select **Patient Profiles**. Review 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 defined. The study and PID (patient id) are listed for identification. The default profile opens in **Workbook Profile** type.



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 and study levels and in either local, usergroup or public object locations. The user can create graphic patient profile specifications within the limits set by the currently defined graphic patient profile templates.

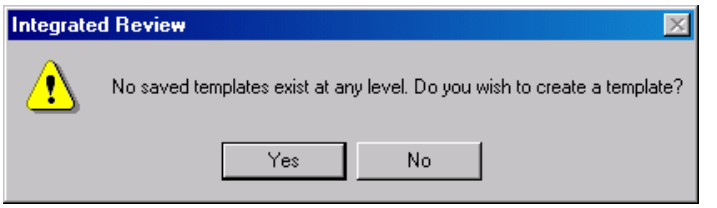
The patient data is displayed from multiple data domains and plotted against a common time axis. The display style for each domain depends upon the kind of data, for example, duration events such as Adverse Events are plotted as horizontal bars showing the duration of the event, from onset date to end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

Define Graphic Profile Template

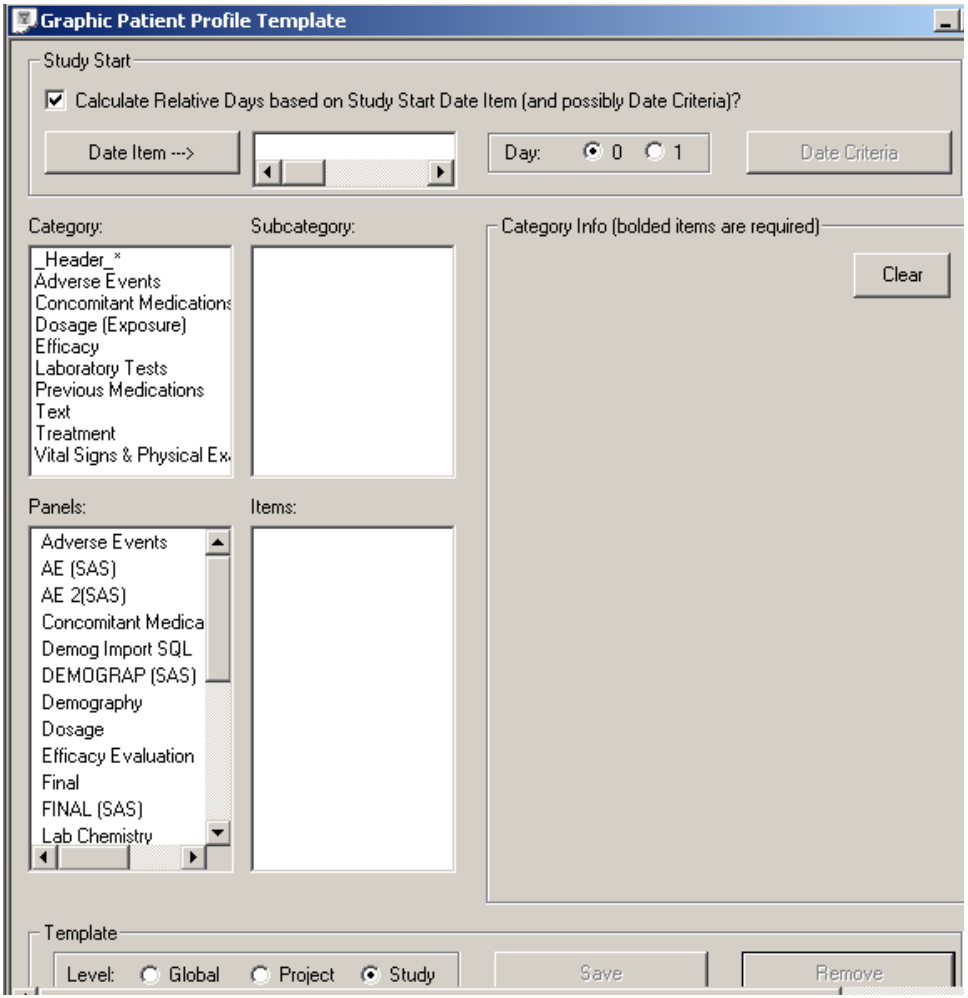
Graphic Profile Template

A Graphic Patient Profile template must be defined first before users can create graphic patient profile specifications. SuperUsers with the privilege to “Create Graphic Patient Profile Templates” access the Graphic Patient Profile template feature from the Patient Profiles Browser window and create a graphic patient profile template. If none exists, a message displays and the user is exited from the graphic patient profile option.

If you have privileges to define a graphic template; this message box displays asking if you wish to create a template now. Click **Yes** and the Graphic Patient Profiles Template window opens.



Note: The Review Administrator application must be updated to allow the granting of these privileges to specific users or groups.



Super Users are able to save templates at the object storage level for global, project 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.

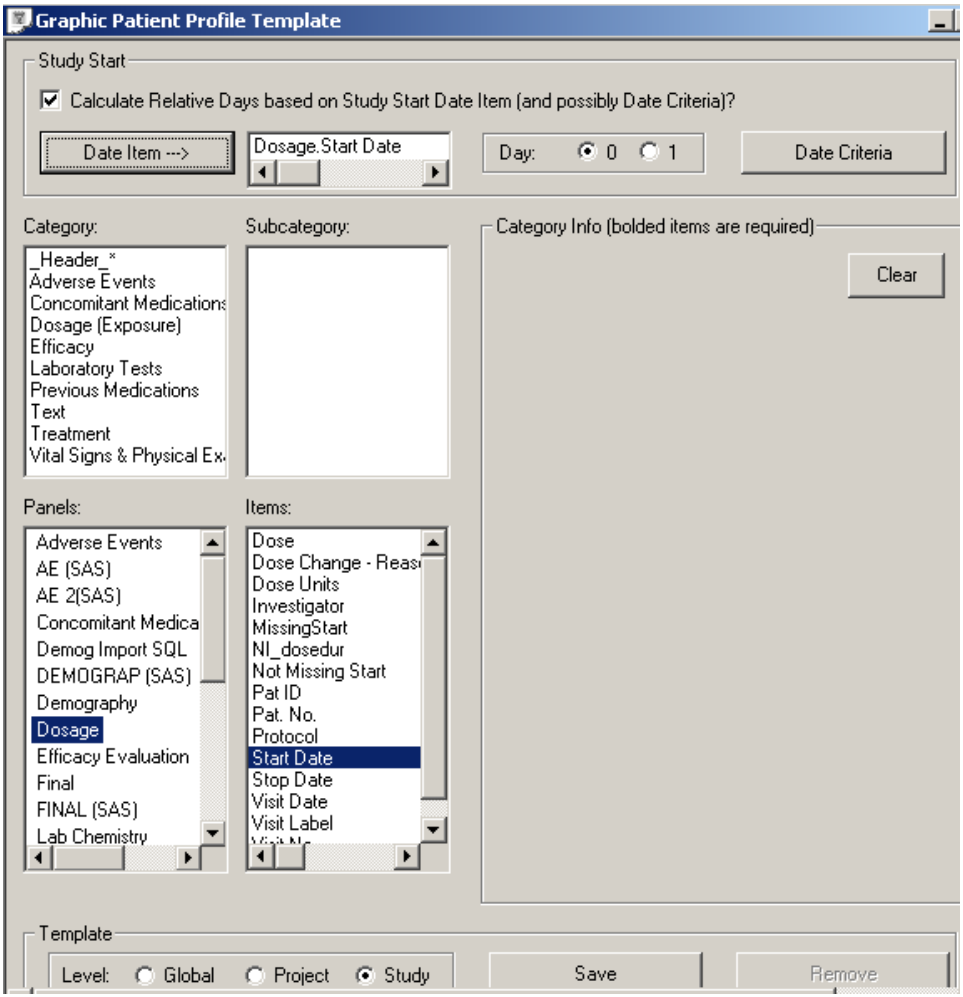
Graphic patient profiles are very complex due to the different types of data can best be represented by different types of graphs. The individual graphs are aligned along a similar time axis, however, each graph may consist of a different plot type based upon the type of data "event" that is depicted. Each graph may be based on data from multiple tables in the underlying database.

Define study start date

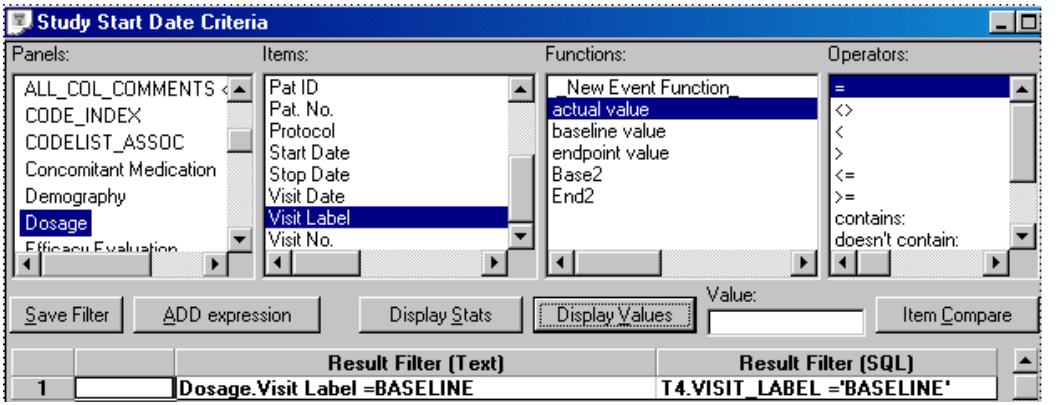
The Study Start check box is defaulted ON for "Calculate Relative days based on Study Start Item (and possibly Date Criteria)?". When checked, you must define an item that contains a unique single value for each patient's study start date as Day 1 or Day 0. For example, a date item located on a single 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 applied to filter down to a unique patient study start date such as visit label is baseline, visit number is 1, etc.

When the Study Start box is unchecked, then all other items in the Study Start box are disabled and buttons previously labeled as "Date" display as "Day". 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.

1. Select the Template level for global, project or study.
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**.
4. If you need to further specify the date, click **Date Criteria**. The Date Criteria is required if you had selected a multiple record data panel for your selection of date.



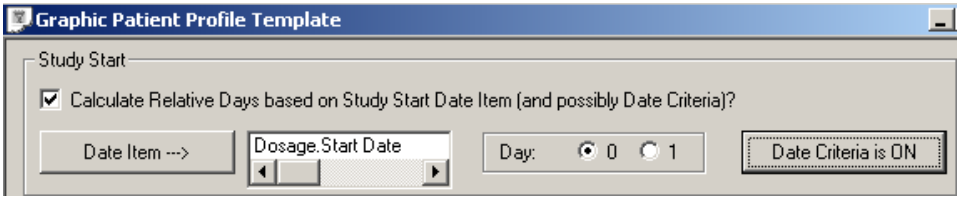
The Study Start Date Criteria window opens for you to specify details such as a visit label.



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

   The **Date Criteria** button status changes to

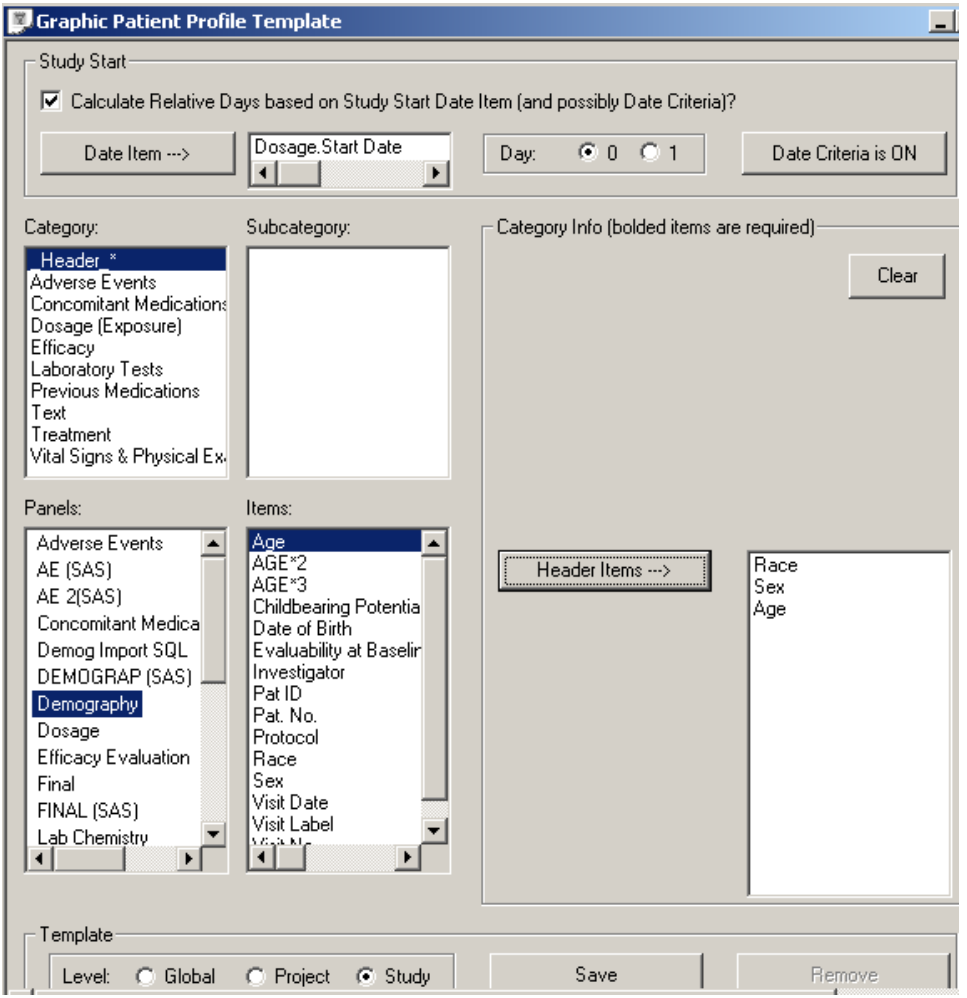
.



Define header items

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

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



Category types

Different types of data can be best represented by different types of graphs. Data with start and stop dates (i.e., duration events) are graphed as horizontal bar charts over time. Data collected on a given date(s) as time point events (i.e., labs, vitals) are graphed as scatter plot graphs. Data with no date associated are displayed as text.

Different information about data panels / tables and items / fields are needed in order to create each type of graph (bar, line or scatter). This database information may come from multiple database panels / tables and are organized into a data category. The data category "bucket" contains the type of data (or event) to be graphed; the type of graphs to be plotted for this type of data (or event); and additional necessary information on panels / tables and items / fields to get the correct data from the database to generate the desired graphs (i.e., lab normals).

- A data category contains specifications about the data for a specific type of data "event".
- Allows for these specifications to be based on multiple database tables restricting that only one-to-one or one-to-many table relationships be allowed.
- Associates the type of data event to be graphed with the appropriate types of plots.

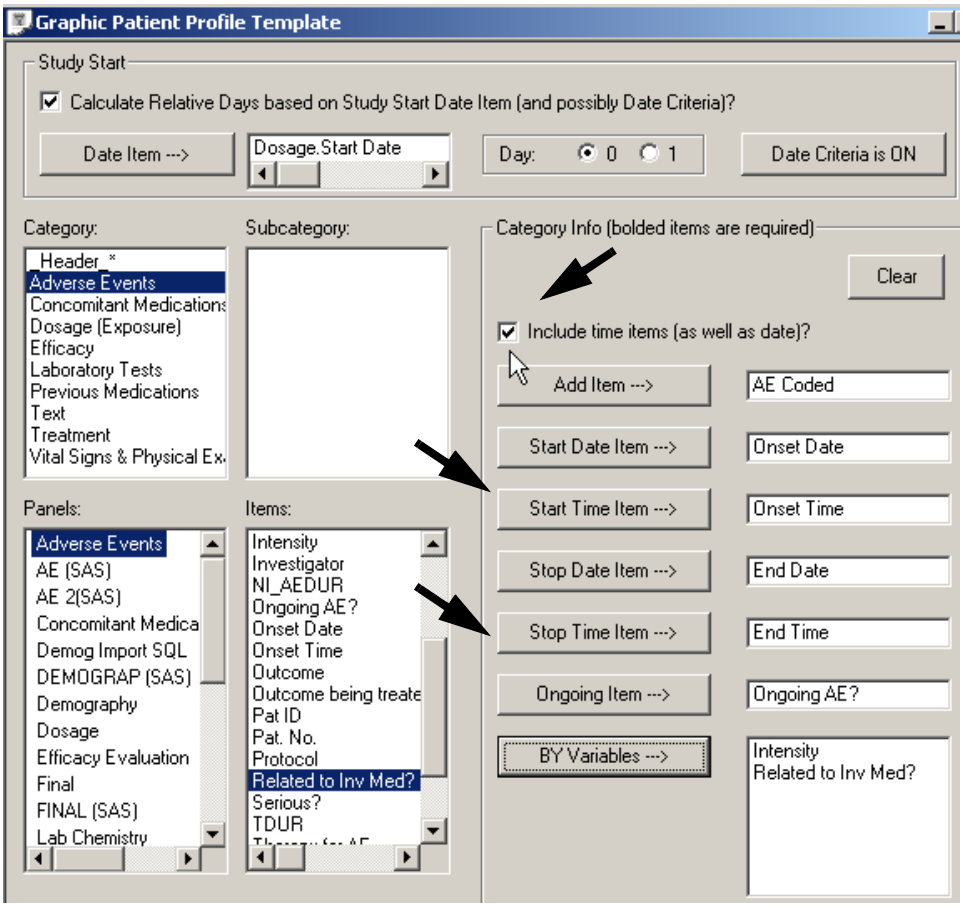
The following table lists the data categories.

Category Type	Definition	Plot Type(s)
Duration	Data collection event that has a start and stop time point.	Horizontal Bar
Time Plot	Data collection event that occurred at a specific point in time.	Data Value Line Plot
Lab	Lab test data collection event that can be compared to normal range values if they are defined in the data.	Scatter Plot Line Plot Trend Plot Data Value
Dosage	Dosage data collection event that has a standardized dose value and start and stop time points.	Vertical Bar
Non-Time Aligned or Text	Data not associated with a specific point in time (i.e., gender, sex)	Free form text

Define Category Information

The SuperUser specifies the category information from a pre-defined categories list and can further specify subcategories for laboratory tests, text, Vitals Signs and Physical Exam.

1. Select a category to display the corresponding template for entering category information.
2. If the category collects time data, click the check 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.
4. Repeat the steps to add another category. An asterisk displays next to the category in the category list noting it has been defined.



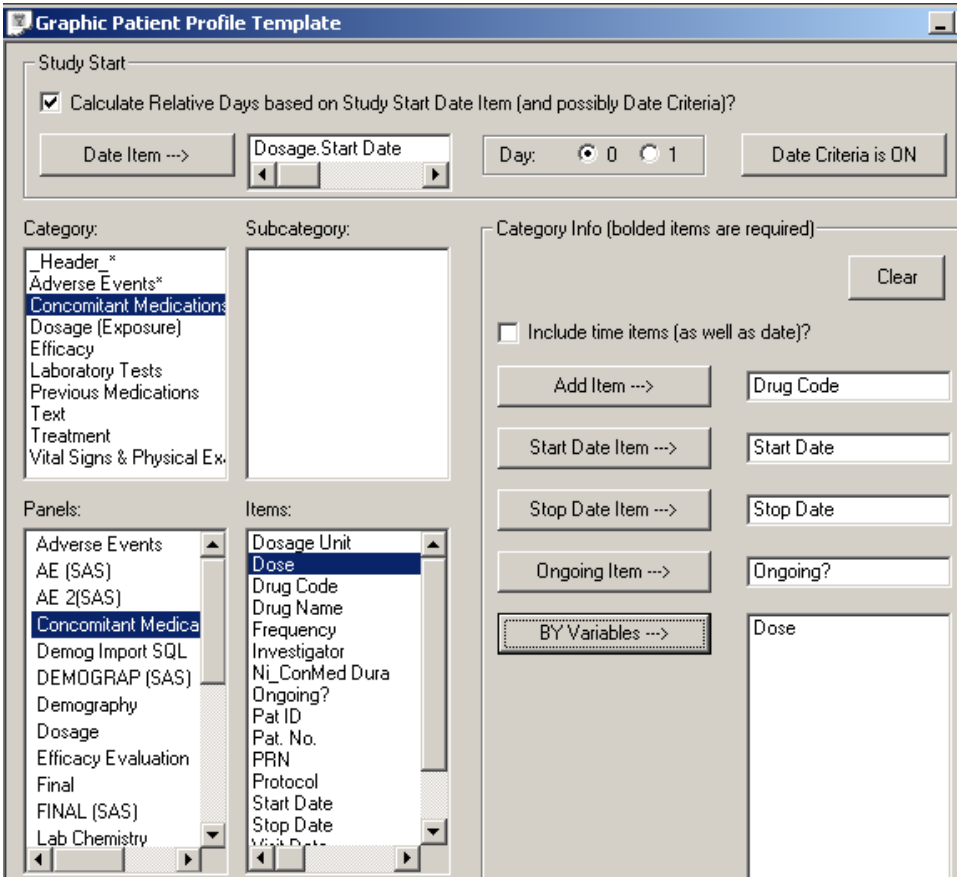
If you include time data items in any category definition by clicking the 'Include time items' checkbox, then Start and Stop Time Items will display for entry. In addition, the Time Axis scale in the graphic patient profile will include hours. The default displays the date items and 'Include time items' 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 are included in the Time Axis scale if the time item was included in the opened template and graphic patient profile object.
- Hours 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.

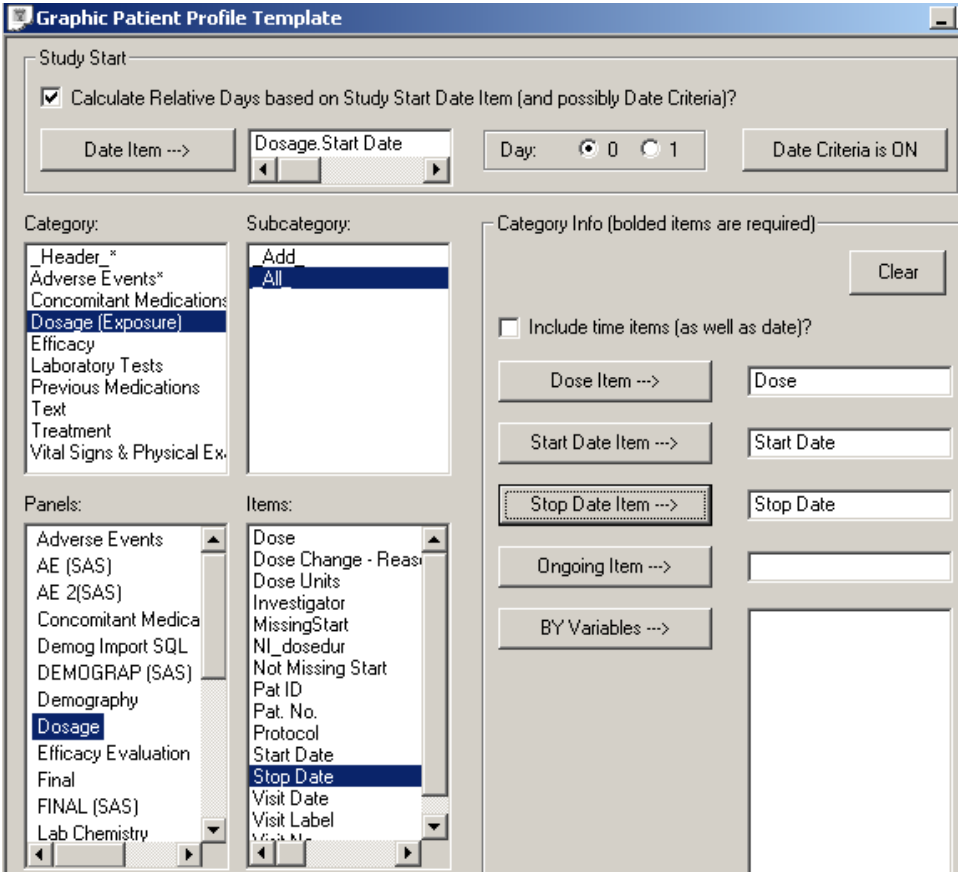
Duration Category Type

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.



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.

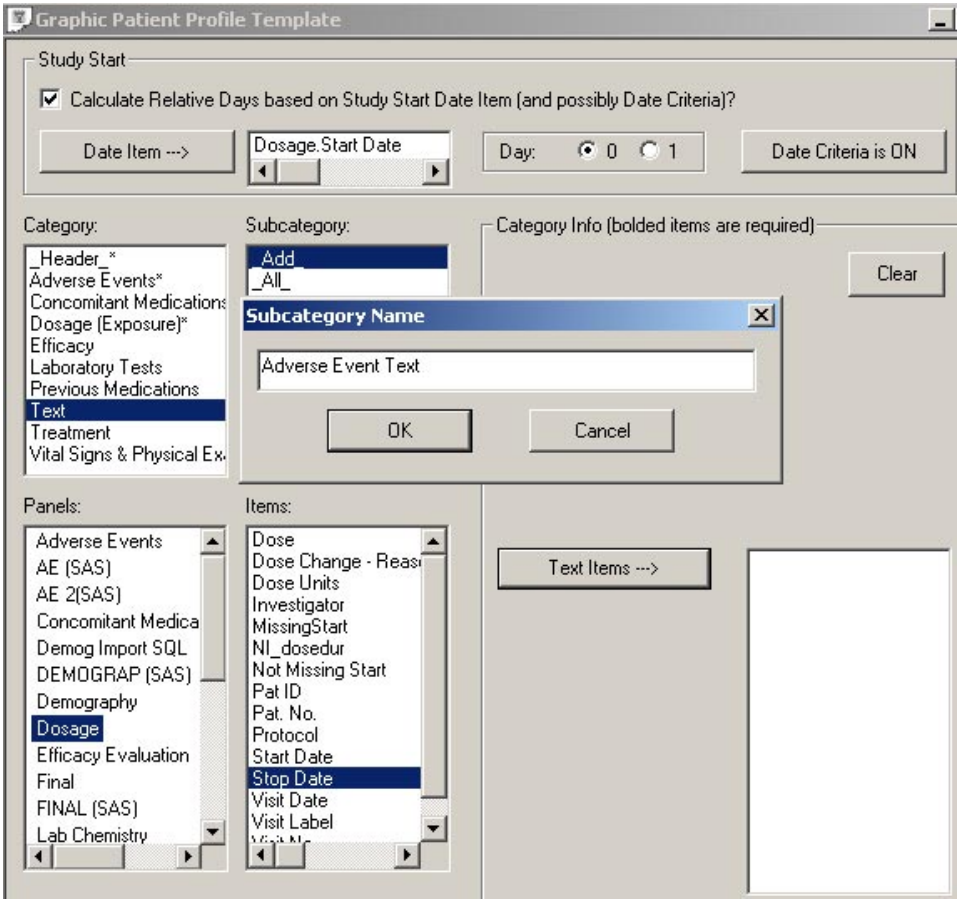


Text Category Type

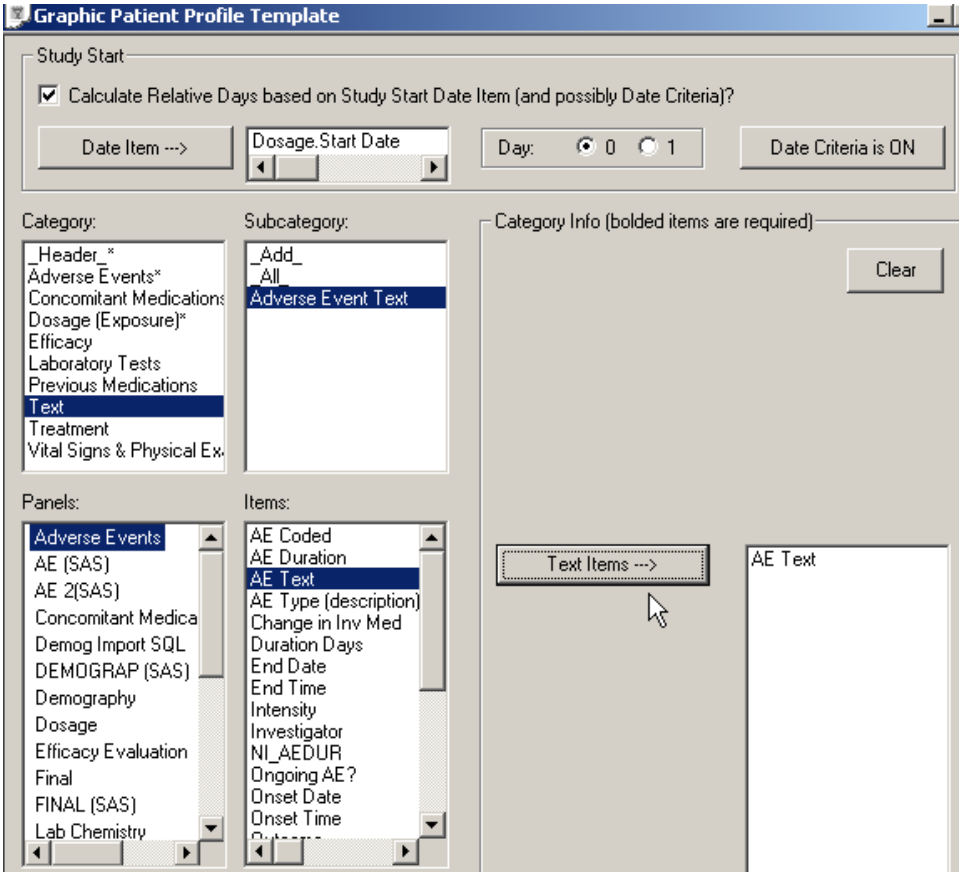
The text category is a text type which initially contains no subcategories. The SuperUser defines subcategories and assigns specific database items / fields from the panels / tables to either categorize itself or a subcategory. The items are displayed as non-time aligned data.

To add a Text Category:

1. Select **Text** in the **Category** list and click **Add** under Subcategory.
2. The **Subcategory Name** 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.



Text subcategory is added.

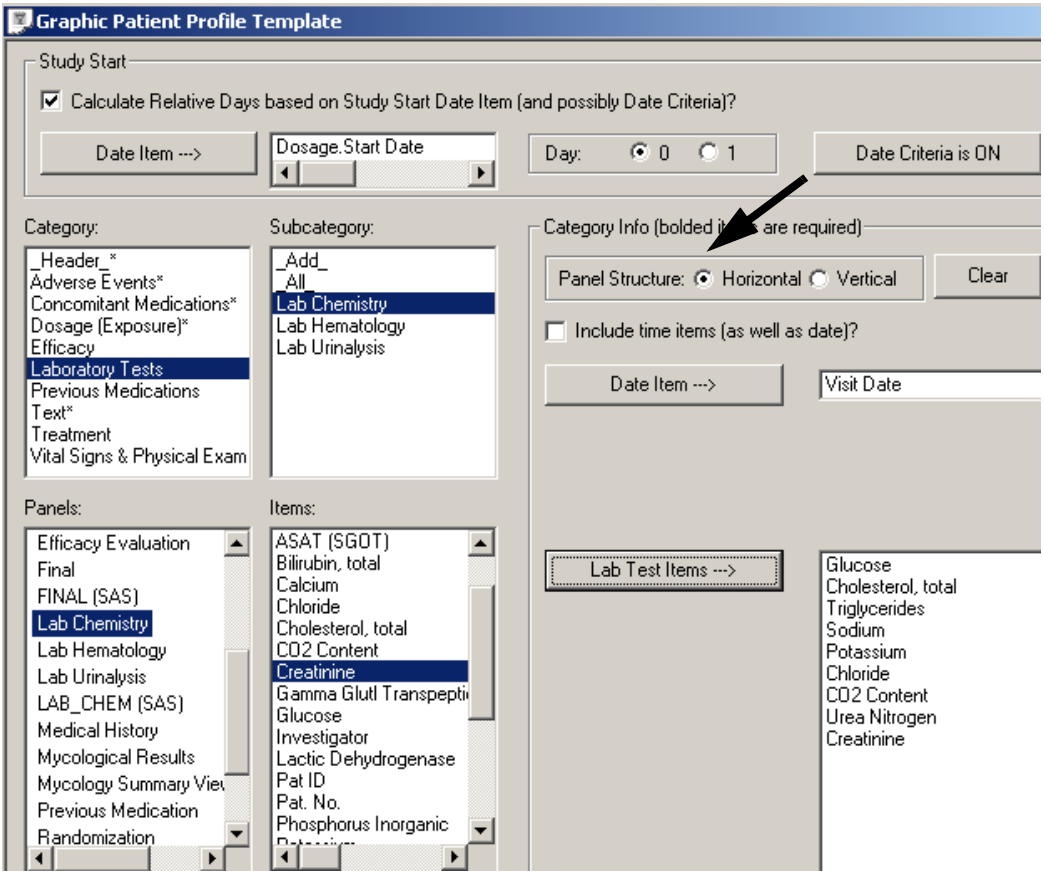


Laboratory Category Type

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 which may or may not be in another table.

Horizontal panel structure requires:

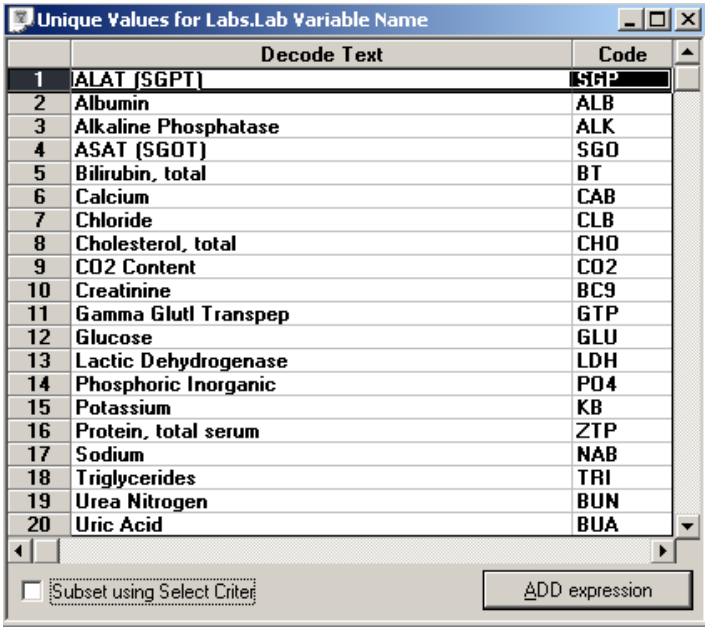
- Date Item - the field containing the date of the event.
- Item(s) - the fields which the user may select for graphing.



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 field.

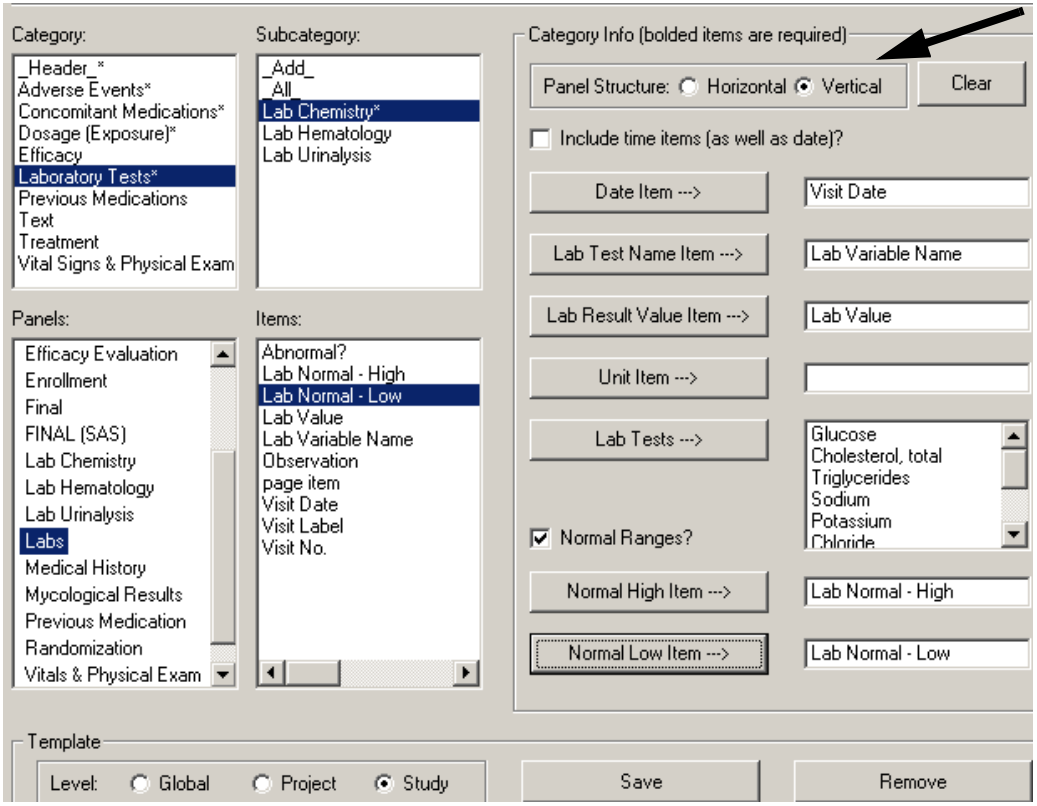
  To select multiple contiguous values, click on a value and drag over the other values. To select multiple non-contiguous values, click on a value and hold down the **Ctrl** key when clicking the other values.



- 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.

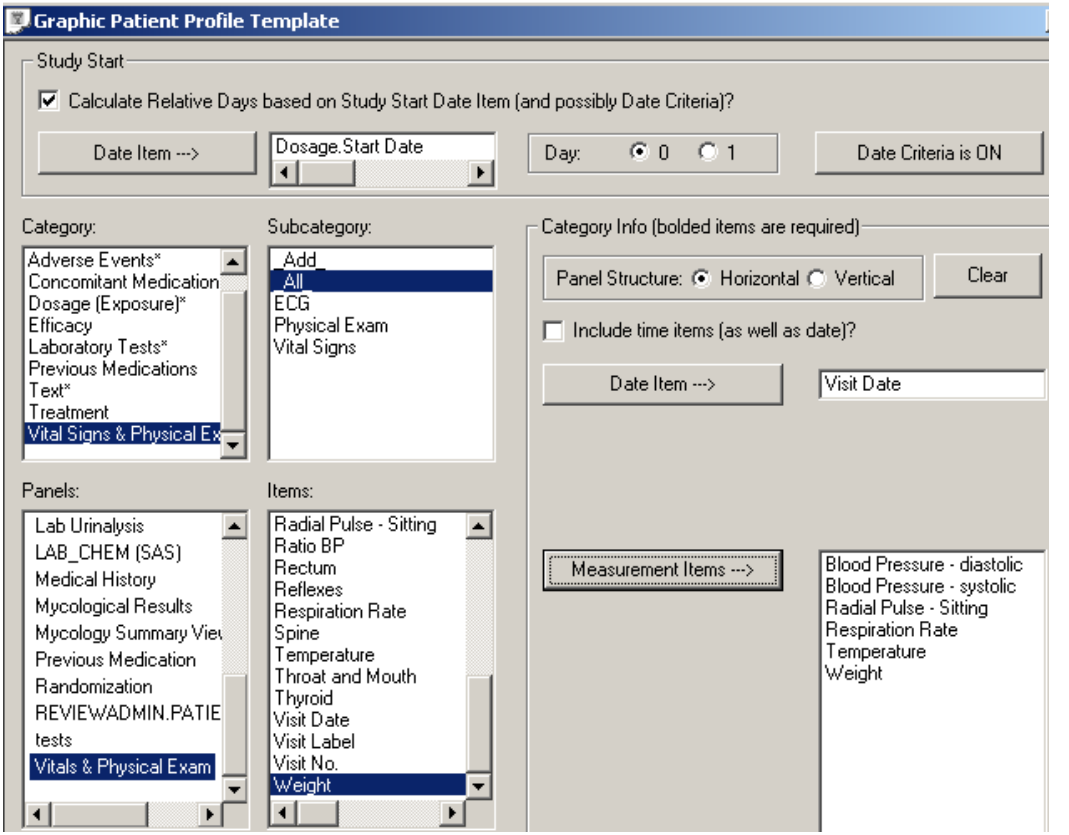


Time Point Type category

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

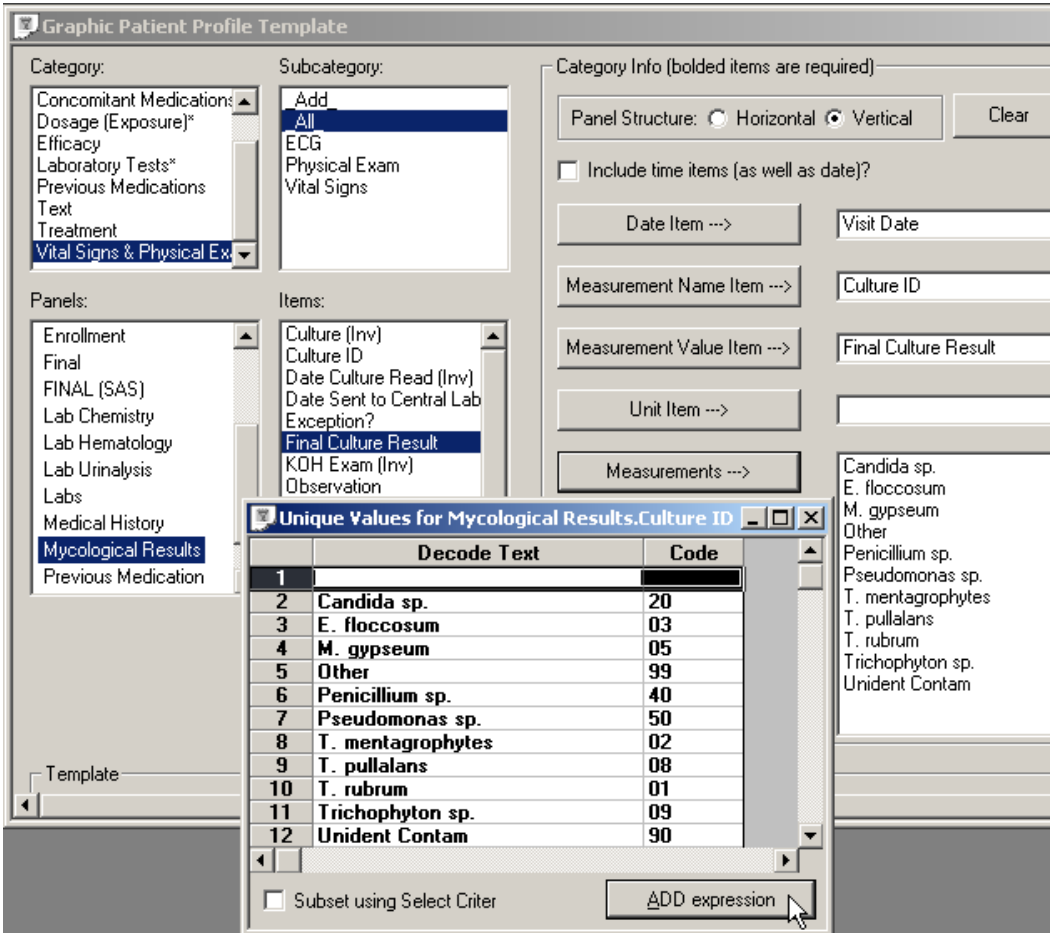
Horizontal panel structure requires:

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


Graphic Patient Profile Template
Study Start
Calculate Relative Days based on Study Start Date Item (and possibly Date Criteria)?
Date Item --->
Dosage.Start Date
Day: 0 1
Date Criteria is ON
Category:
Adverse Events*
Concomitant Medication
Dosage (Exposure)*
Efficacy
Laboratory Tests*
Previous Medications
Text*
Treatment
Vital Signs & Physical Ex
Subcategory:
Add
_All
ECG
Physical Exam
Vital Signs
Category Info (bolded items are required)
Panel Structure: Horizontal Vertical
Clear
Include time items (as well as date)?
Date Item --->
Visit Date
Panels:
Lab Urinalysis
LAB_CHEM (SAS)
Medical History
Mycological Results
Mycology Summary Vie
Previous Medication
Randomization
REVIEWADMIN.PATIE
tests
Vitals & Physical Exam
Items:
Radial Pulse - Sitting
Ratio BP
Rectum
Reflexes
Respiration Rate
Spine
Temperature
Throat and Mouth
Thyroid
Visit Date
Visit Label
Visit No.
Weight
Measurement Items --->
Blood Pressure - diastolic
Blood Pressure - systolic
Radial Pulse - Sitting
Respiration Rate
Temperature
Weight

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.



Note: In this example we used the Vital Signs & Physical Exam category for a Mycology panel because the category format best fitted our data model. Later when you create the graphic patient profile you can modify the category name for display purposes.

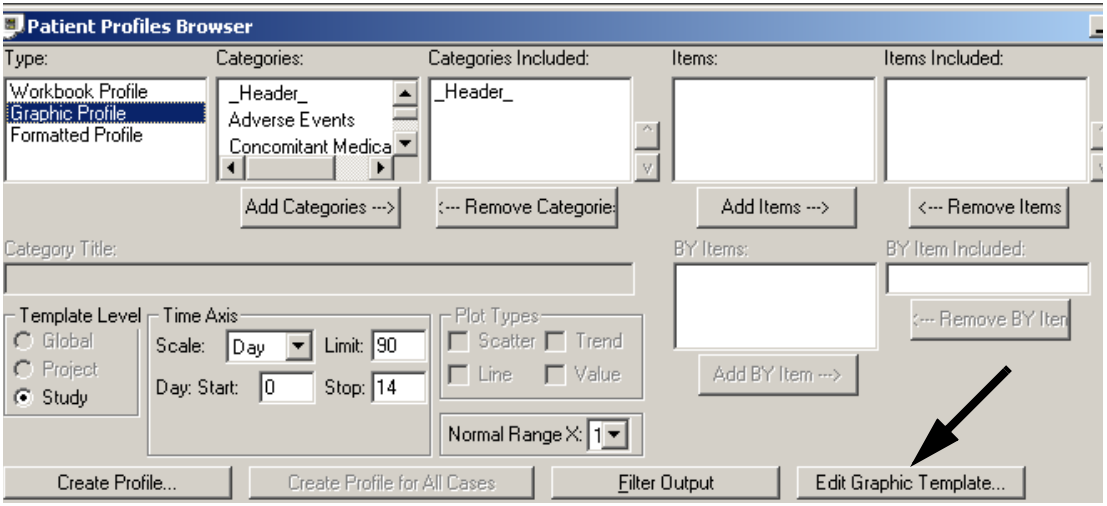
Save template

When you have added all categories and subcategories to the template, click **Save**. A message window displays the template has been saved.

The template is saved at the level selected. 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 selection is shaded as disabled.

Edit graphic template

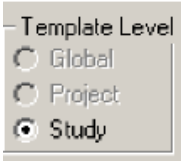
The **Edit Graphic Template** button becomes available if you need to edit the existing template.



Define Graphic Profile

Select defined template

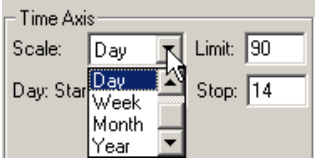
Once a template is saved you can select from the available template levels to define your graphic patient profile. Shaded template levels haven't been defined and saved yet.



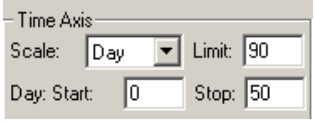
Change Time Axis

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.

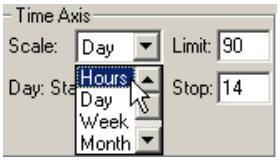
1. You can change the **Time Axis** defaults for the graph plots by selecting from the dropdown **Scale** list and entering the **Start** and **Stop** range.



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



If time items are included in any of the defined categories then the Time Axis will include hours.



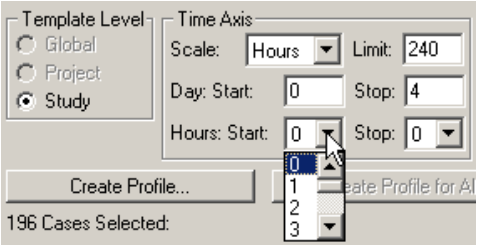
Change Limit value

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

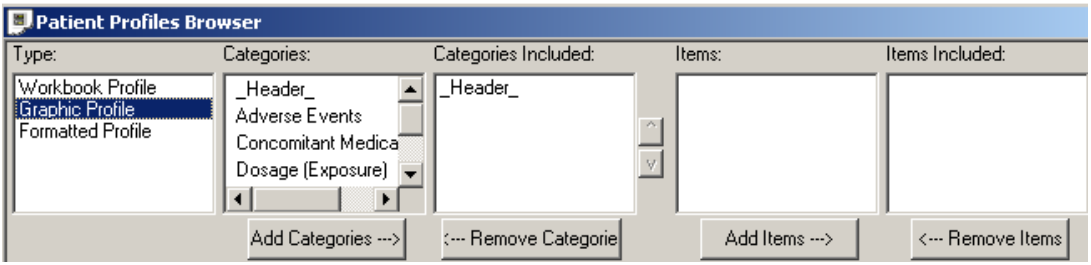
If you had defined a template category to display time items you may set the scale to **Hours**. The Start and Stop Hours scale displays with a dropdown list to select within a 23 hour range before changing to the next day.



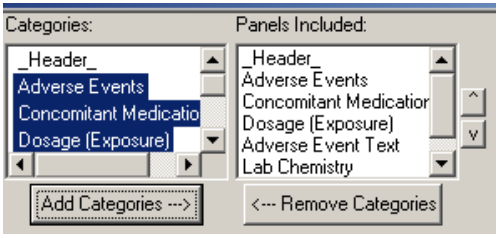
Note: When selecting the Hours Scale it is best to applied to a minimal day range duration of not more than 4 days for meaningful results.

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. The header is defaulted as the first category and is required.

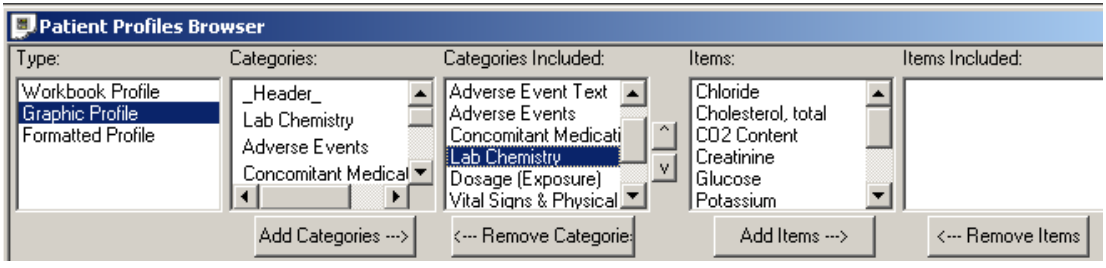


2. Highlight the categories to be included in the graphic profile and click **Add Categories.** Use the **Remove Categories** button to remove. You can highlight and move single or multiple categories with the **SHIFT** or **CTRL** key for multiple selections.
3. Reorder the **Categories Included** with the **up** and **down** arrows.

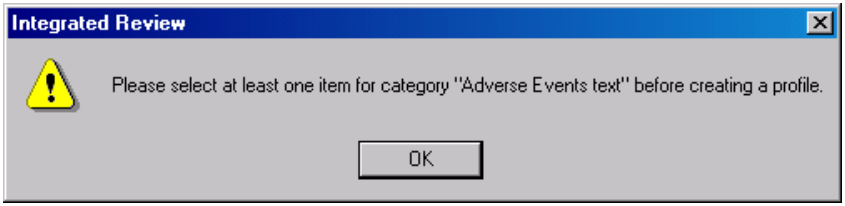


Select Items for display

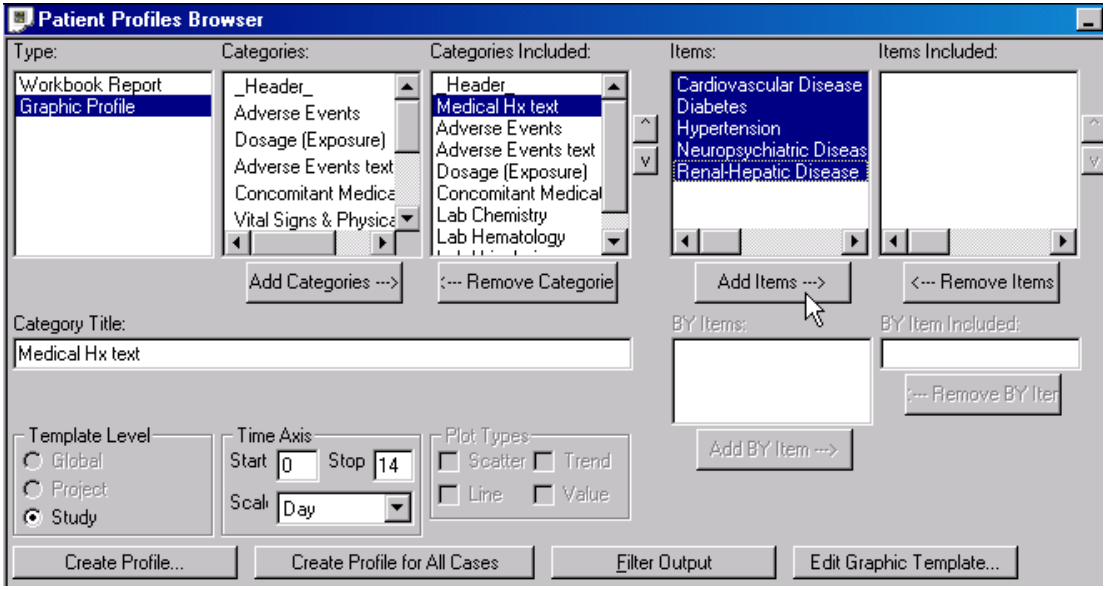
4. Select each **included category** and view the list of items and by items (where applicable) for the graph plots.



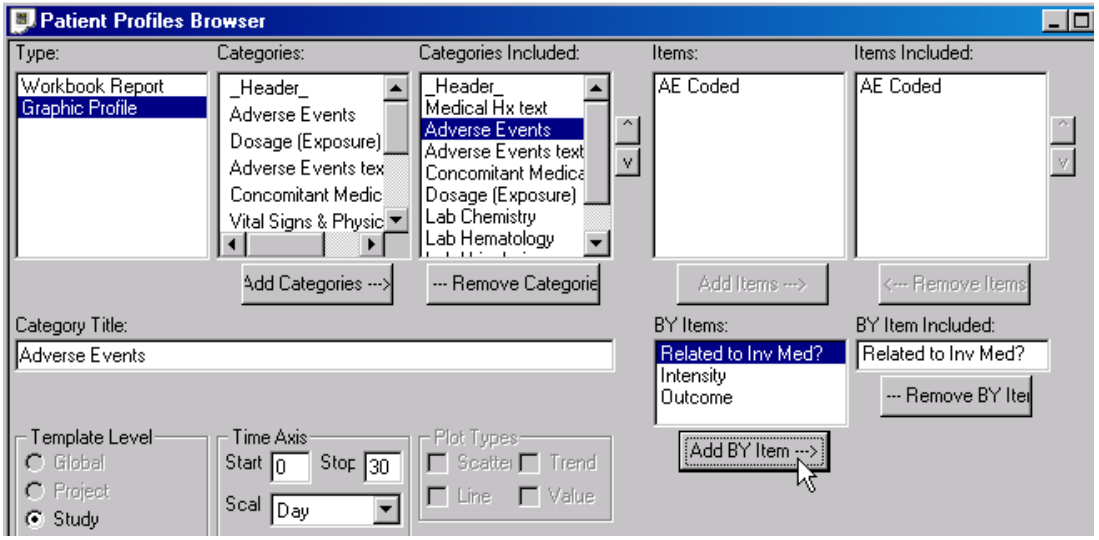
You must go through the entire list of **Categories Included** and select each category and the items(s) you want included in the graphic profile. Otherwise, a message displays alerting you of an included category without items or BY items included.



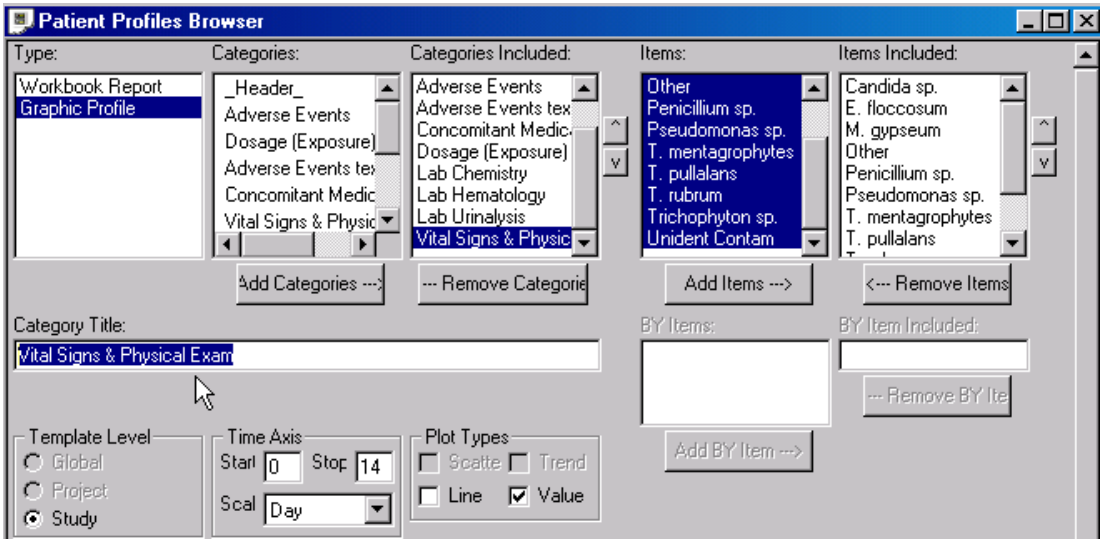
5. Highlight the item(s) and click **Add Items** button to select from available items to be included in the graphic profile.
6. Reorder the **Items Included** with the **up** and **down** arrows.

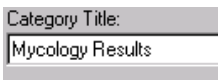


7. Enter the **BY Item** (if applicable) for the selected category.

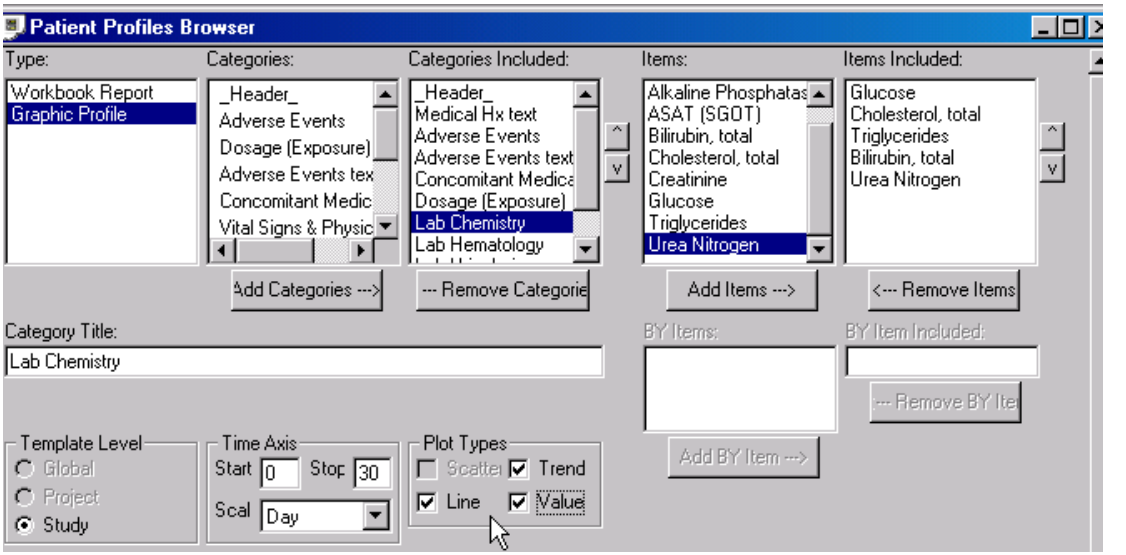


8. You can change the title of any included category (except for the header which will always display the PatientID).





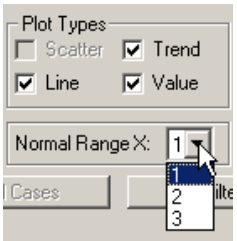
9. You can add or change the default Plot Types. The available plot types are dependent on the category type defined.



Normal range multiplier

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.

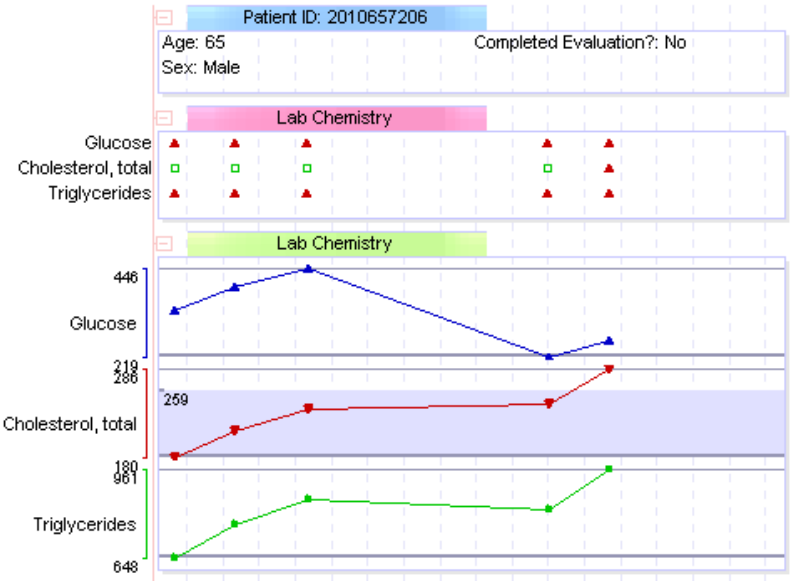
10. You can only select 1, 2 or 3 for the normal range multipliers with the default set to 1.



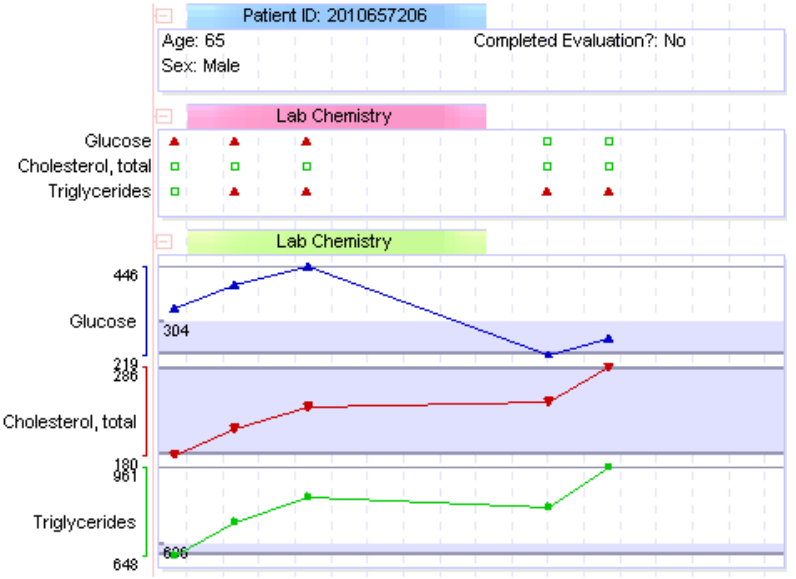
Note: The Multiplier feature applies to Vertical Labs only where Lab Normals may be entered.

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.

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.

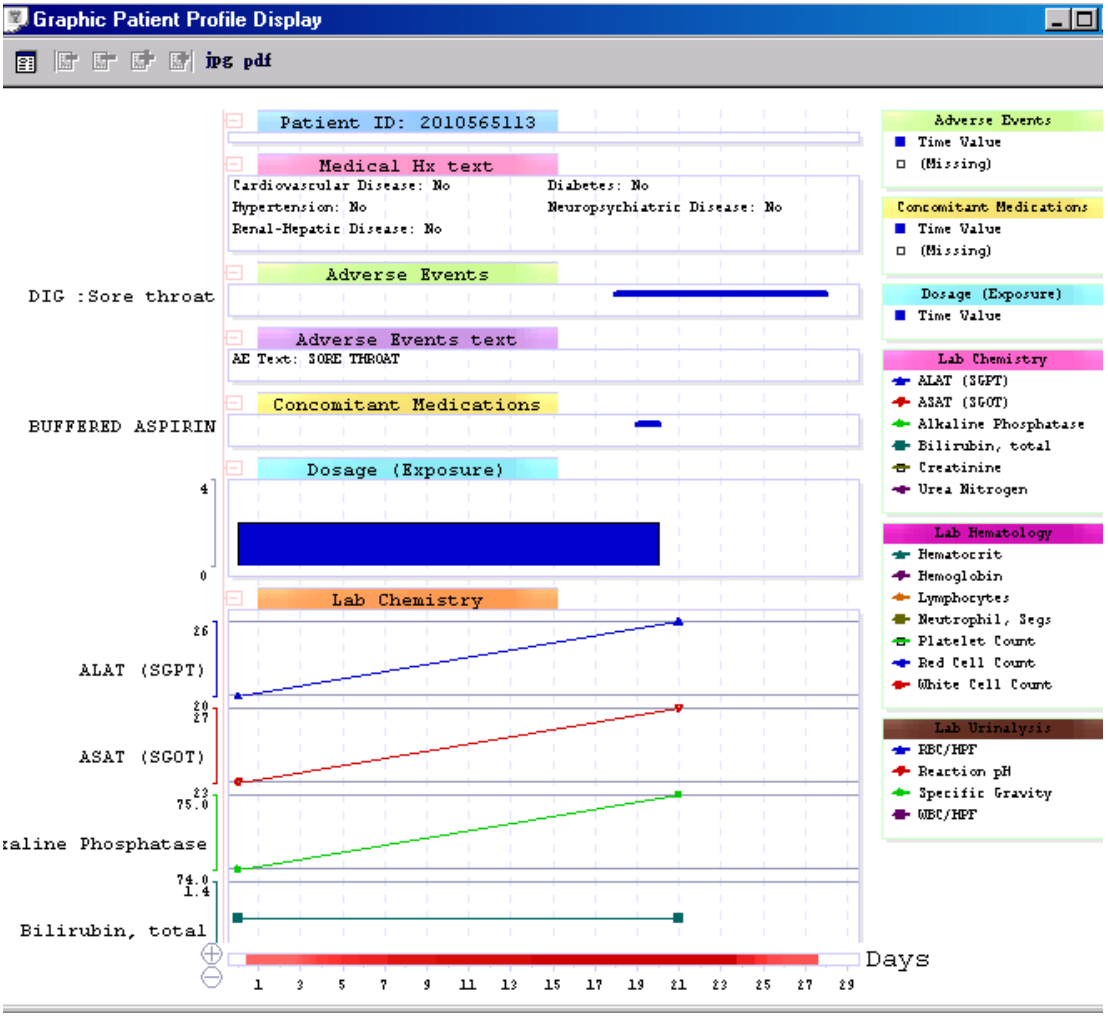


After you have defined all included categories and items included:

11. Select a patient and click **Create Profile**.

The Graphic Patient Profile 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.



12. Once you have finalized the design of your Graphic Patient Profile, you can save your object specifications. (See *Chapter 4: Patient Profiles Browser: Object Storage: saving your work.)*

Missing data

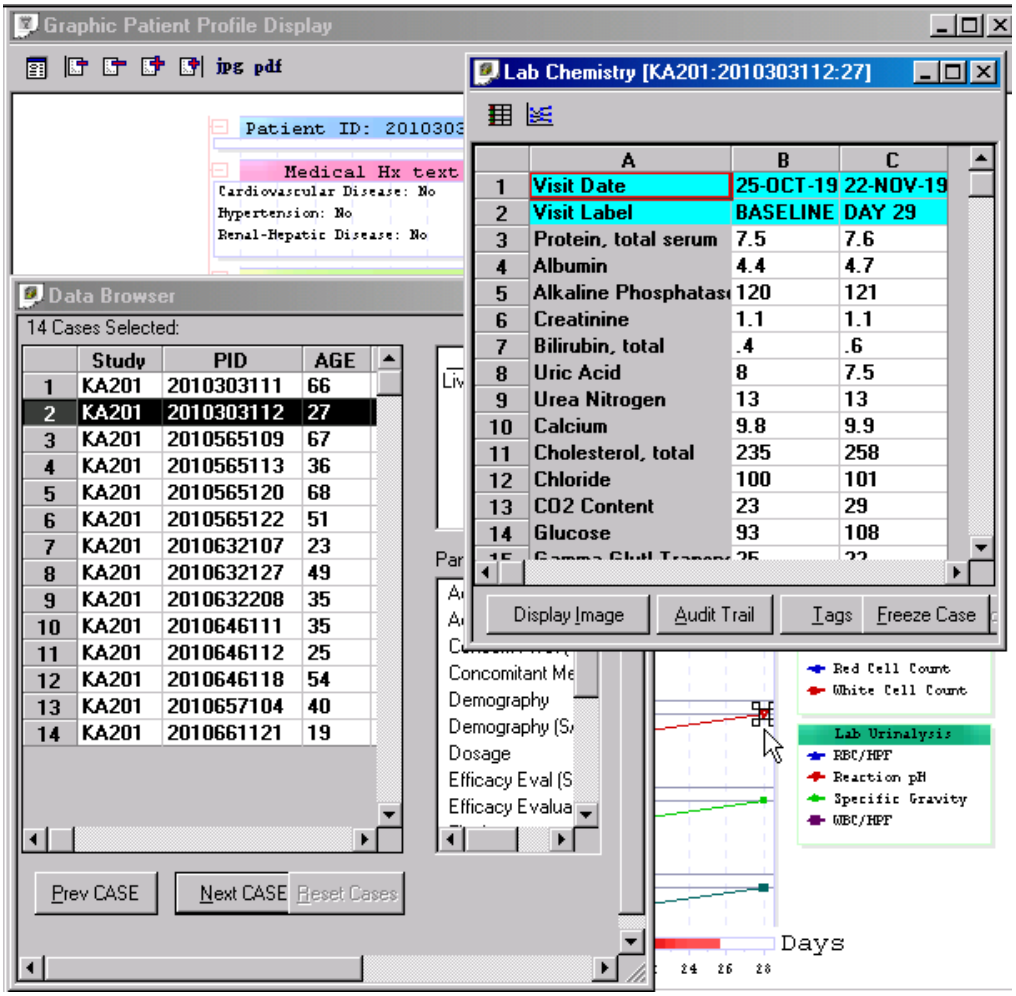
Missing data is displayed for line plots and scatter plots as blank. Duration plots as an empty box for missing BY variable value. 'B' if it has a start date but no end date. 'E' if it has a stop date but no start date and no bar if it has no start and stop date.

Basic graphic user interface

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

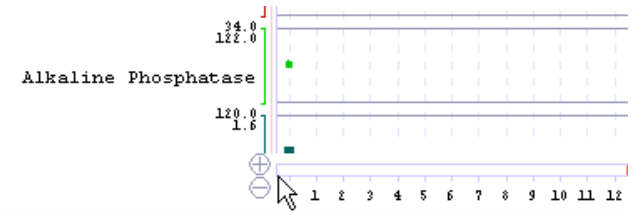
- Use the keyboard up and down arrows to scroll through the multiple graphic plots for the patient.
- Use the keyboard left and right arrows to scroll x-axis on the graph across the time scale, or click-and-drag the scroll bar.
- Use the Next Case and Prev Case button on the Patient Profiles Browser window to move between patient profiles.

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

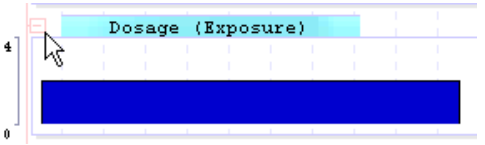


- To select multiple points, click and hold the left mouse button, drag the mouse to create a “box” and let go of the left mouse button. This will invoke a drilldown for all the points in the box.
- Click the left mouse button to deselect all previously selected points.

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



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



- When you create a workbook for multiple case, 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.

- You can save the graph image to JPG or PDF from the Toolbar. Simply click the file icon to open the save window.
- The last buttons decrease or increase row size by compressing or expanding the rows.

Filter Output

Patient Profile Filter Output

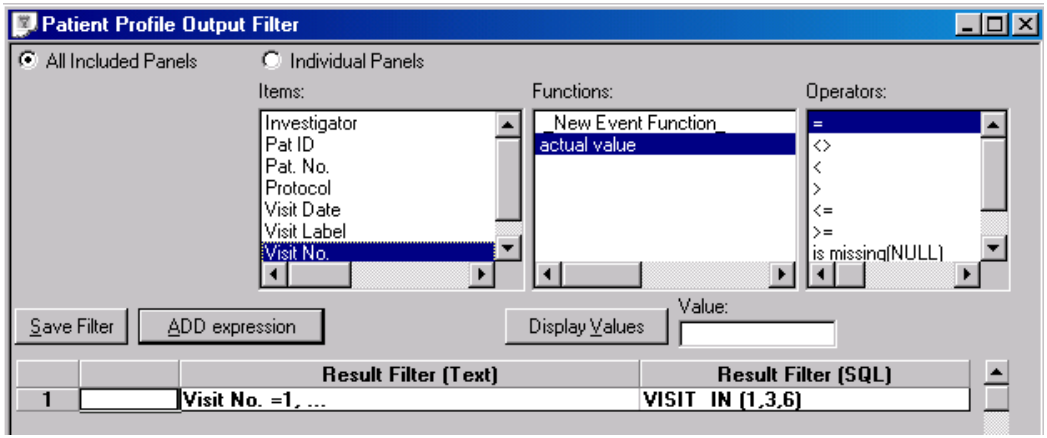
After you define the specifications of your Graphic Patient Profile, you can use the Filter Output as a data exploration tool by filtering data inclusion, then comparing filtered and unfiltered results.

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.

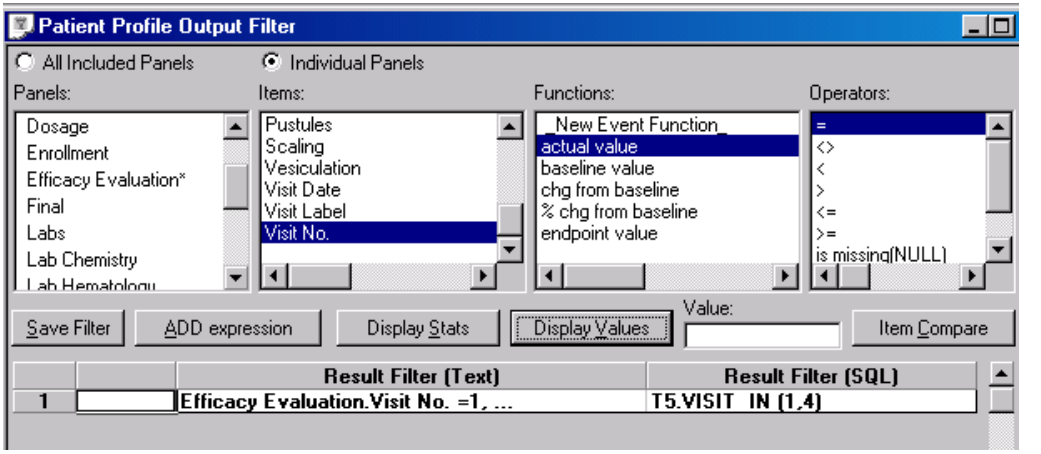
The only exception to this is in Graphic profiles when a category is defined by more than one panel (i.e. dosage and treatment). In this case, both these panels will appear in the Filter Output window and filtering criteria from one panel would affect the other panel.

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



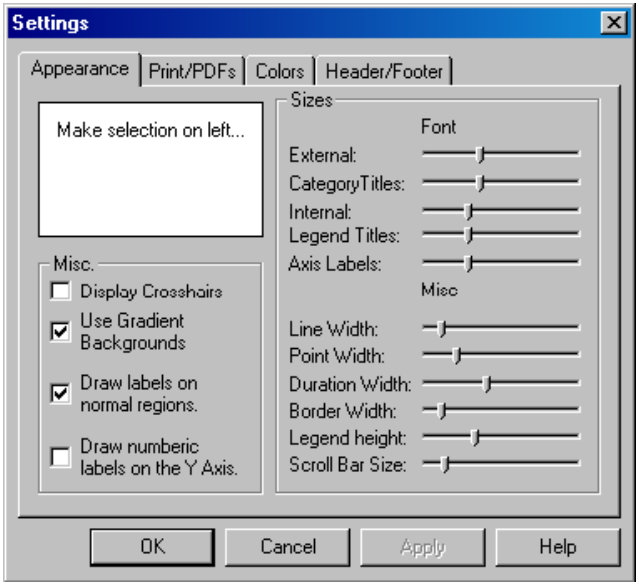
4. Click **Save Filter.** The **Filter Output** button in the Patient Profile Output Filter window toggles to **Filter is ON**. The output filter is applied to the graphic profile when you click **Create Profile**.

   For each individual panel selected and a result filter entered, an asterisk displays next to the panel name flagging the panel has an active output filter.

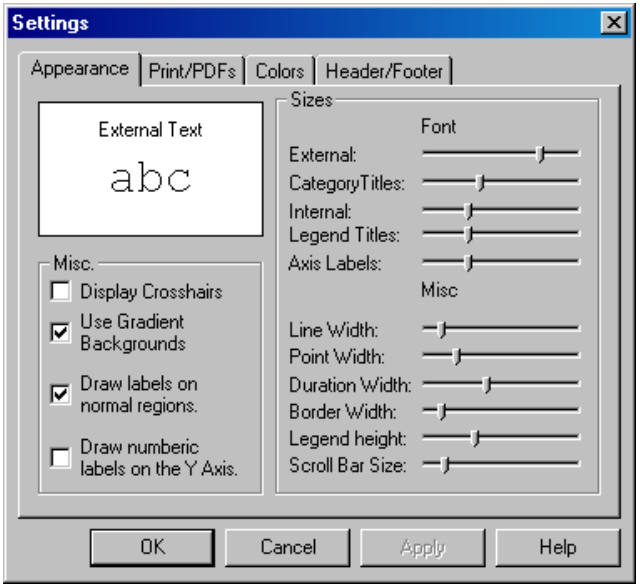
Graph settings

Select settings

On the Toolbar, click the first button to bring up the settings options.



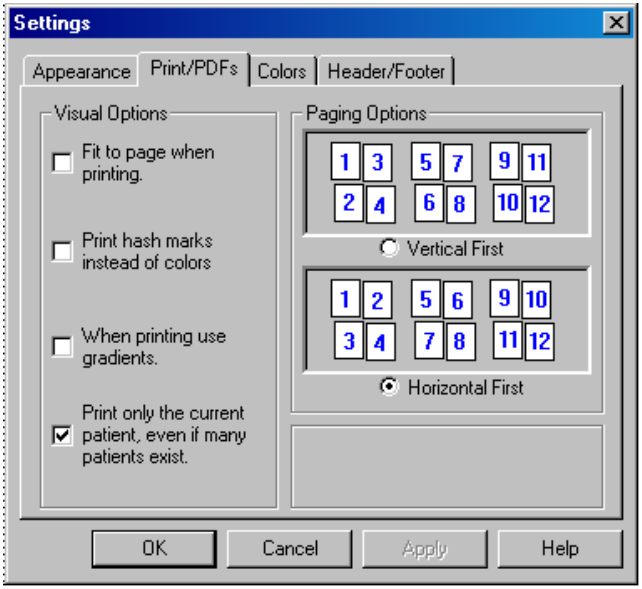
Each of the sliders, when moved with the mouse, will change the contents of the white box to help the you visualize the setting. For example, when you click and move the 'External' slider under 'Fonts'.



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 crosshair 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.

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.

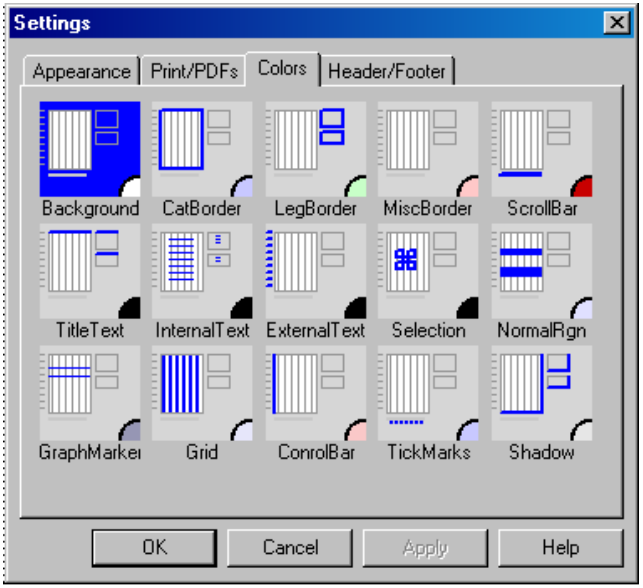


The most important of these options is the first, 'Fit to page when printing'. This option has precedence over all other printing options. If it is selected, then a page will be printed on one page regardless of the view range or the height per row. The default for "fitting" is true. Ideally, it is easiest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

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.

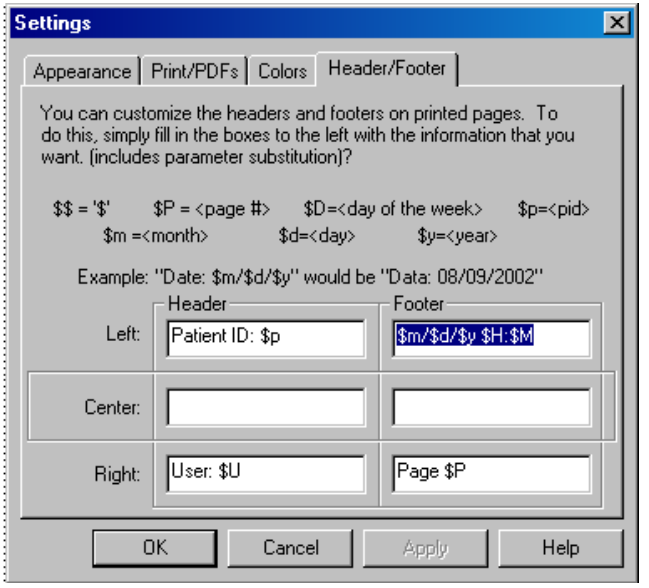


The color of the background is not blue however. The actual color of the background is white, which is shown by the little circle in the bottom right corner. This method of conveying the color clearly distinguishes each part of the graph while at the same time gives you a sense of color. So to change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

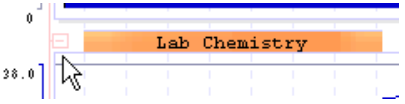
Headers and footers

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.

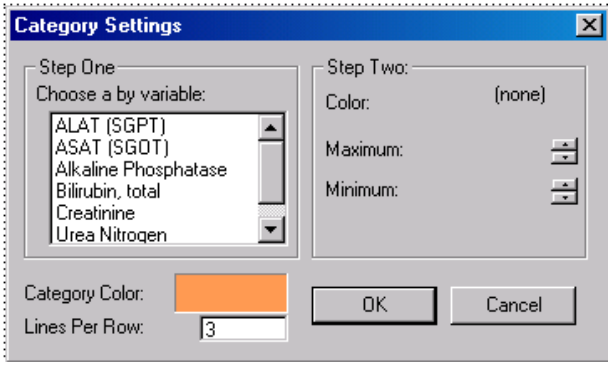


Category settings

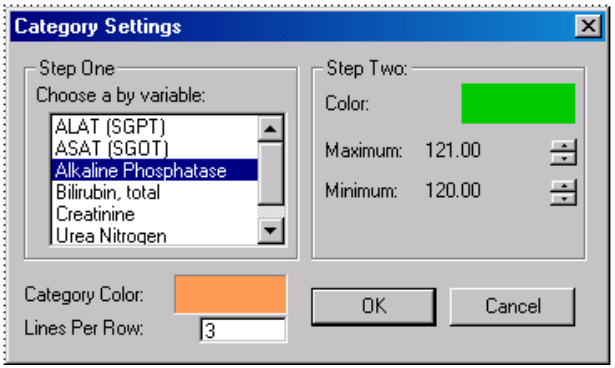
Each category has its own category settings dialog box. In the Graphic Patient Profile window use the right mouse button on the control bar next to the category title.



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.

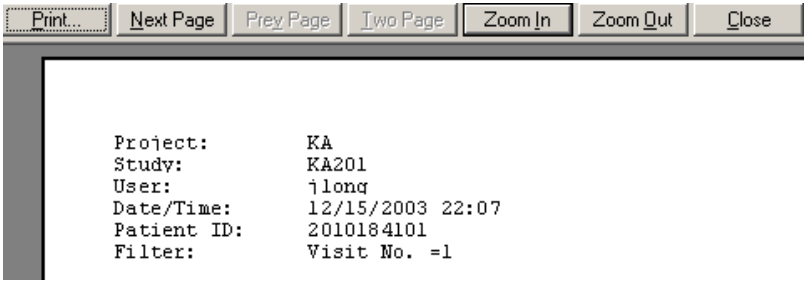
Graphic Patient Profile display

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**.

   Review displays a screen shot of the selected active screen. 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.**

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

Printing a 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**.

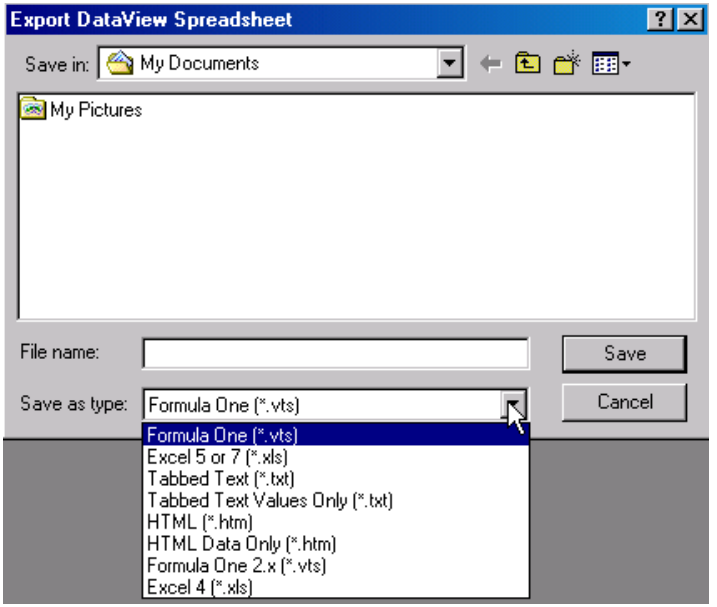
   Review displays the standard Print dialog box.
3. Click **OK**.

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.

To export your table in Excel 4, 5 and 7, tab delimited files, HTML format or PDF files:

1. From the **File** menu, select **Export**.

   Review displays the Export dialog box.



2. Enter the storage location.
3. Enter the storage type.
4. Click **OK.**

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

Object Storage: saving your work

Object storage location

You can store patient selection criteria at four user access levels: Private, WorkGroup, UserGroup, or Public.

- Private storage is at the local PC level. The private objects are saved on the user's home drive in a directory (folder) called "irpat". Review handles all creation, access and deletion of the private objects in this folder. Therefore, the user should not be concerned with the contents of the irprivat folder.
- WorkGroup storage is PC based and stored at a shared network drive, to which a select group of personnel would have access.

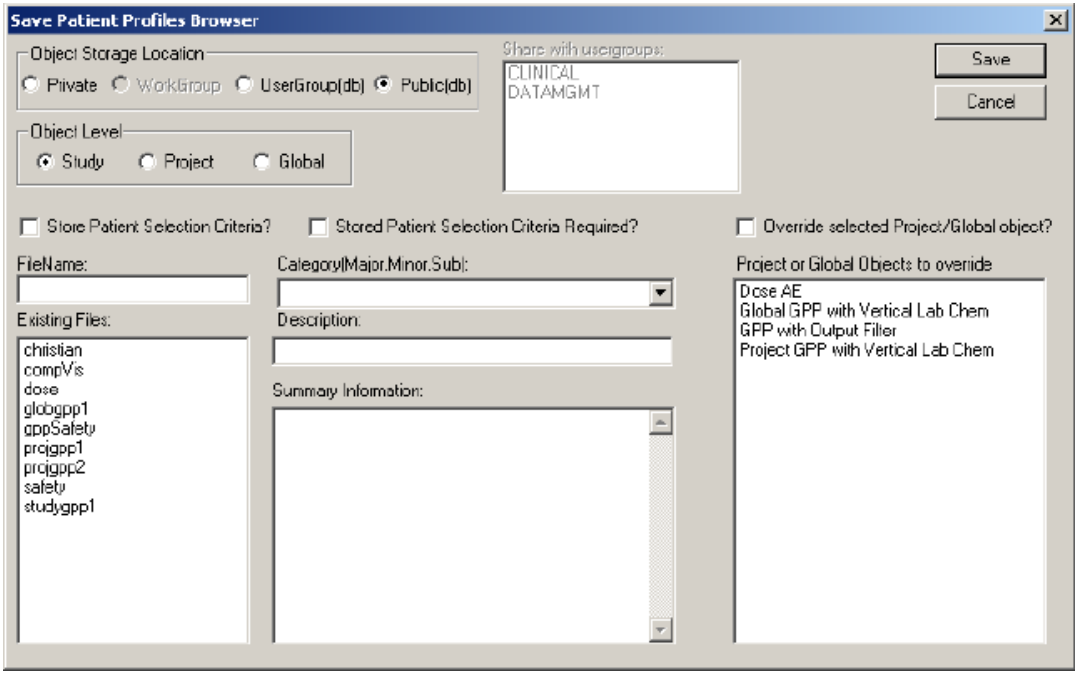
Note: The WorkGroup storage location was supported in earlier Review releases. UserGroup storage location is extensively used for later releases.

- 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 WorkGroup or UserGroup storage.

  Saving on database object storage sites, requires the author to have "Publishing Authorization" defined in the configuration tables. (See *Chapter 12: Common Topics: Shared Object Storage- Locations)*



When you select the UserGroup object storage location, the ‘Share with usergroups’ ListBox is made available for selection.

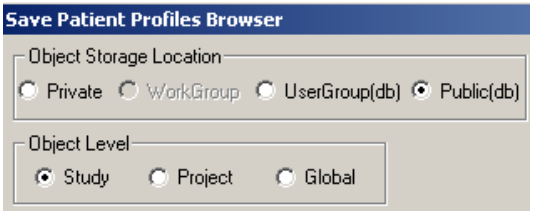
Object level

You can store your output specification at three levels: Study, Project, or Global. The Object Level box is only enabled and highlighted when you select an Object Storage Location designated as ‘db’ for database. Therefore, when you select either UserGroup or Public for database object 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.

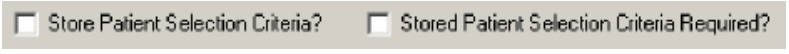
Saving Patient Profile specifications

To save the patient profile specification you have defined for later use:

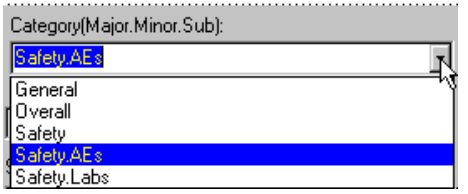
1. Make certain that the Patient Profiles Browser window is the active window by clicking on its title bar.
2. Click , or from the **File** menu select **Save.**
3. Review displays the Save Patient Profiles Browser dialog box where you can specify the storage location.



4. Select object level type. The default is Study.
5. Click **Store Patient Selection Criteria** 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. If the particular patient selection criteria is specific and required for the output, click **Patient Selection Criteria required**. In this instance, the patient selection criteria cannot be modified when this stored object specification is selected. If none selected, then no patient selection criteria is saved with the output specification.



6. Enter a FileName for future reference to be displayed in the list box for Existing Files. The Filename is for internal use and not displayed in the Object Explorer window.
7. 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 drop down listbox.

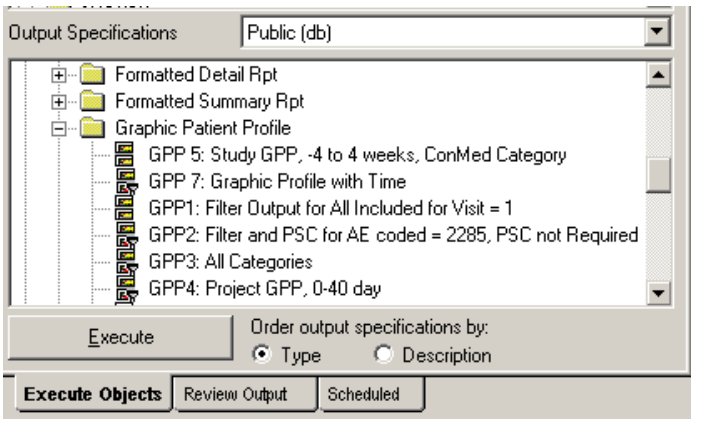


8. Next enter the appropriate description which is displayed in the Object Explorer window.
9. You can include summary information for future reference to be viewed by yourself or others later.
10. Click **Save**.

Review stores the output specification to the designated PC, WorkGroup, UserGroup, or Public storage location.

Object Explorer window

Once you have saved your patient profile specification and assign 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.

Note: Graphic Patient Profiles can not be scheduled or the output saved.

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.

Saved objects and their associated icons can be sorted to display in the their folders by icon type or description. Simply click sort **by Type** or **by Description**.

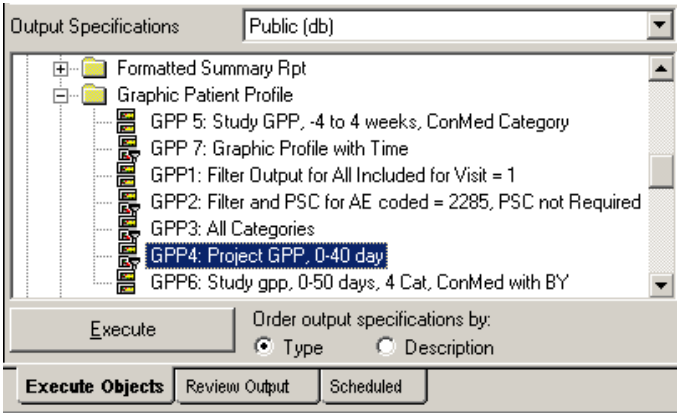
Object Explorer quick execute

The Object Explorer window aids users to quickly locate and launch previously saved objects stored within organized folders. This shortcut allows users to bypass opening the individual browsers to launch saved objects.

If you want to retrieve a saved output specification:

1. Double click to open a folder.
2. Click on the output specification and click **Execute**.

   Your stored output specification will be launched.



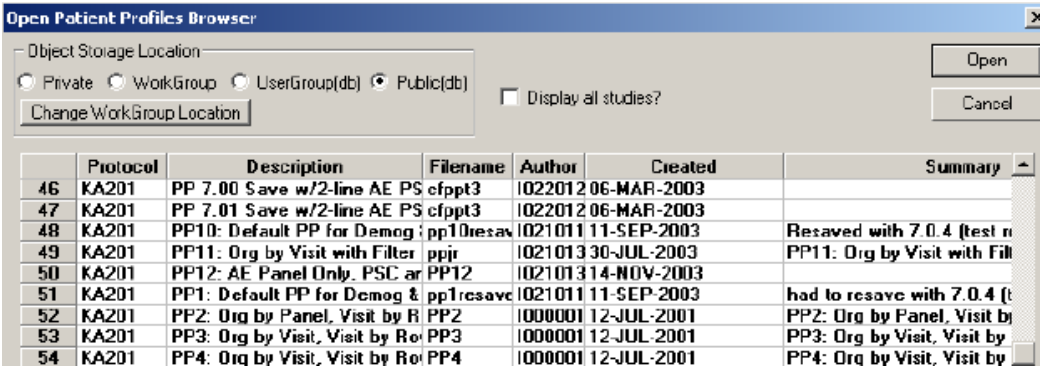
If you want to apply a saved patient selection criteria to your output specification:

1. Double click to open a folder.
2. Double click to paste the selected patient selection criteria into the Patient Selection Criteria Window. Then follow the above steps to retrieve and execute a stored output specification. Or create your own selection criteria for a stored output specification.

Another way to retrieve a previously saved Patient Profiles specifications from the Patient Profiles Browser:

1. Make the Patient Profiles Browser window as the active window.
2. Click **Open**, or from the **File** menu. The Open Patient Profiles Browser window displays.
3. Select the object storage location. Review displays a list of stored Patient Profiles Specifications.
4. Select a Patient Profiles description and click the **Open** button or double click on the description.

Note: You must use the Open Patient Profiles Browser window to access the object storage location for 'WorkGroup'.



   a. If you want to browse and / or select a file from the WorkGroup, UserGroup or Public storage sites, click on the site and the files available to you are displayed in the following window.

   b. Click **Change WorkGroup Location**, and you are enabled to browse various Patient Profiles object storage sites.

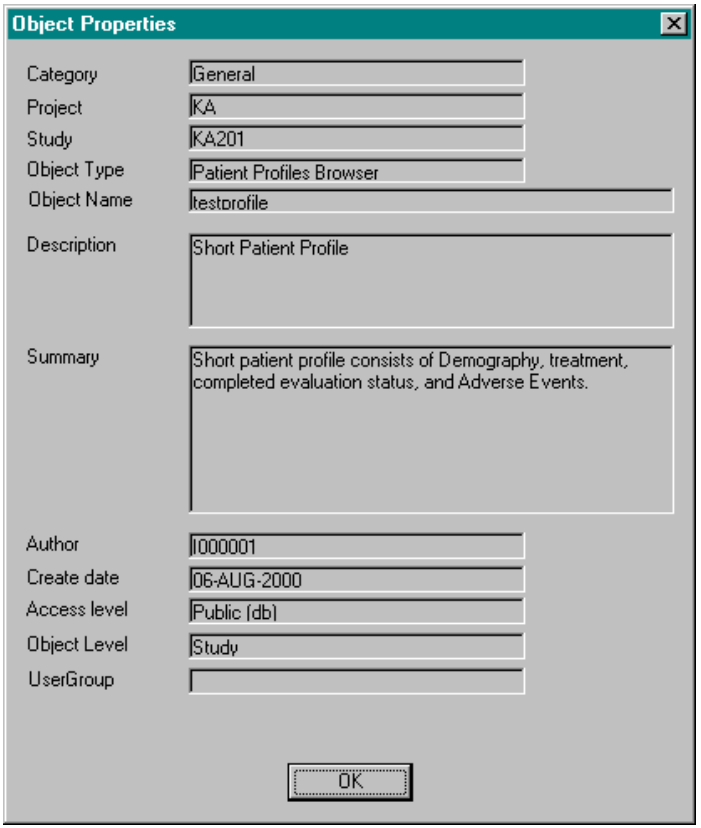
5. You can browse through the Patient Profiles specification by reviewing the summary text. Click on the Patient Profiles specification, and click **Open**. Review pastes the Patient Profiles layout specifications into the layout spreadsheet, clearing the current spreadsheet contents.
6. By default, Review displays only saved Patient Profiles specifications created while reviewing the current Study Protocol(s). You may also import Patient Profiles specification created for other Study Protocol(s). Check **"**Display all studies?" and open any available Patient Profiles Browser specification. Review will validate the data structure to verify that the foreign Patient Profiles specification is compatible with the current study protocol(s).

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. Then click **Properties**. A dialog window displays the object properties for the output object. It works for ‘Private’, ‘Workgroup’, ‘UserGroup’ or ‘Public’ objects equally.

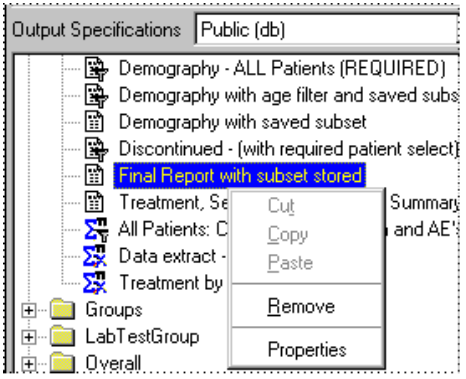


Quick remove

You can quickly delete a saved Patient Profiles Browser object under the Output Specifications window.

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?”.

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

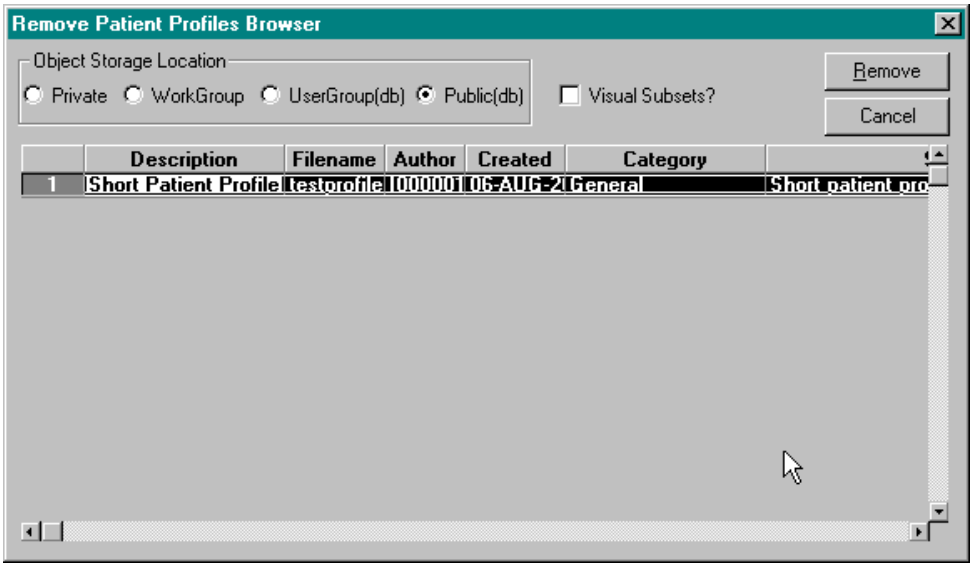


Removing a saved Patient Profiles specification

Another way to remove one of the saved Patient Profiles specifications if you decide it should be deleted:

1. Open the Patient Profiles Browser to make it the active window.
2. From the **File** menu, click **Remove**.
3. Review displays the Remove Patient Profiles Browser window.
4. Click on the object storage location.
5. Select the stored Patient Profiles description you want to remove.
6. Click **Remove**.

Review deletes it from your local PC, WorkGroup, UserGroup or Public storage sites as you designate and have security clearance to do so.



Printing the Patient Profiles specifications

To print the currently active Patient Profiles specification, make certain that the Patient Profiles Browser window is active by clicking on.

1. Click **Print**, or from the **File** menu, select **Print**. Review displays the standard print dialog box.
2. Click **OK**. Repeat column headers are printed on each page in the printout.
3. To change the printer, select **Print Setup** from the **File** menu.

Closing Patient Profiles Browser

Closing the Patient Profiles Browser

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 Reporting

Patient Selection Criteria **245**
- Selection set 245

Report types **246**
- Selecting a report type 246
- Steps for report building 248

Defining Report Specifications **249**
- Selecting a panel, item, and function 249
- Adding items 250
- Default and new events 250
- Access to SAS datasets 250
- Column autosizing 251
- Edit report sort order 251
- Edit report column order 251
- Changing the report specifications 252
- Edit column heading 252
- Defining a report title 252
- Create report 253
- Find menu command 253

Detail Data Listing features **254**
- Defining row results 254
- Using mathematical row results 255
- Highlighting data check ranges 258
- Suppress duplicate rows 260

Summary Listing features **263**
- Include? prompt 262
- Count distinct 265
- Count item value 266

Snapshot output **270**
- Multiple population mode 270

Join Order 272
Join order in multi-panel reports 272
Output filter 277
Subset on observation and/or visit 277
Creating report output filter 278
Comparing items 279
Adding expressions 279
Apply report output filter 281
Define Parameter 282
Runtime parameter 282
Create parameter 282
Enter runtime parameter 285
Patient Visit Report 286
Select panel visit report 286
Define patient visit report 287
Report options 287
Add Patient Info Items 289
Define Date Merge Settings 290
Add vertical lab 293
Formatted reports 295
Select formatted listing type 295
Apply Page Header and Footer 296
Enter a Group Header 298
Format Column Headings 299
Format Columns 301
Sort Order 304
Preview/Page Setup 305
Create formatted report 307
Exporting and printing report results 308
Exporting the report 308
Print Preview 309
Printing the report 309
Page Setup 309

Highlighting patients 311
Single patient mode 311
Multiple-patient mode 313
Object Storage: saving your work 315
Finalize output specification 315
Object storage location 315
Object level 316
Save the object specification 317
Object Explorer window 319
Object properties 320
Print stored object specification 321
Object Explorer quick execute 322
Retrieve stored specification from file menu 323
Schedule output 324
Object Explorer scheduled output 324
View Scheduled Jobs 327
Remove Scheduled Jobs 327
Change Schedule 328
Review output 329
Locate stored output results 329
Quick remove saved output results 330
Delete multiple output 330
Quick remove a stored object specification 331
Remove a stored object specification 331
Closing report browser and reports 332
Closing a report window 332
Closing the Report Browser 332
Exploring data 333
Changing the patient selection criteria 333
Pivot panel presentations 333
Report output filter 334
Patient identification 334
Define Join Logic 334
Clintrial tags 334
Protocol comparison 335

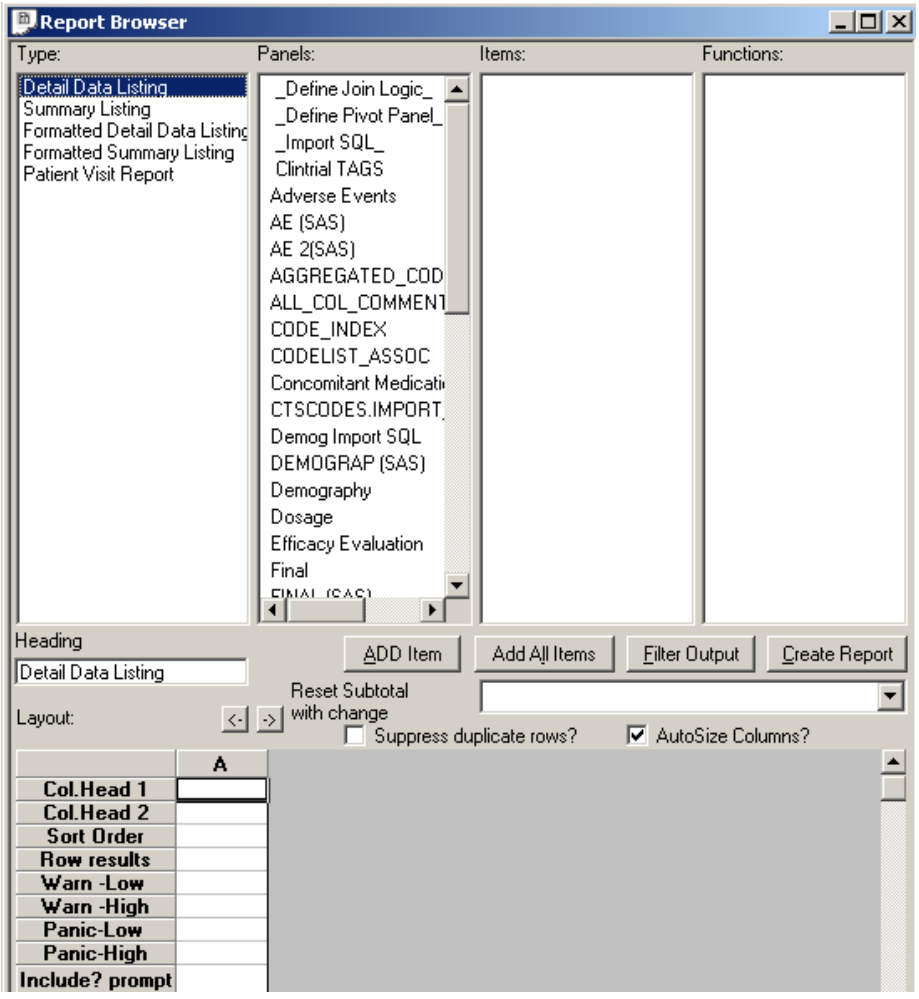
New Event Function 335
Outer Joins 335
FULL JOIN 335

Patient Selection Criteria

Selection set

After building the patient selection criteria, you can explore customized groupings of items for each of the patients who meet the criteria by using the Report Browser. To open the Report Browser, click , or from the **Browse** menu, select **Reports**. Opening the Report Browser

Review displays a new window where you can specify the type, contents, and presentation of your report(s):

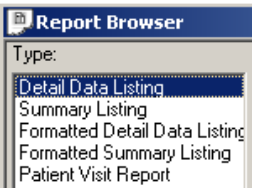


Report types

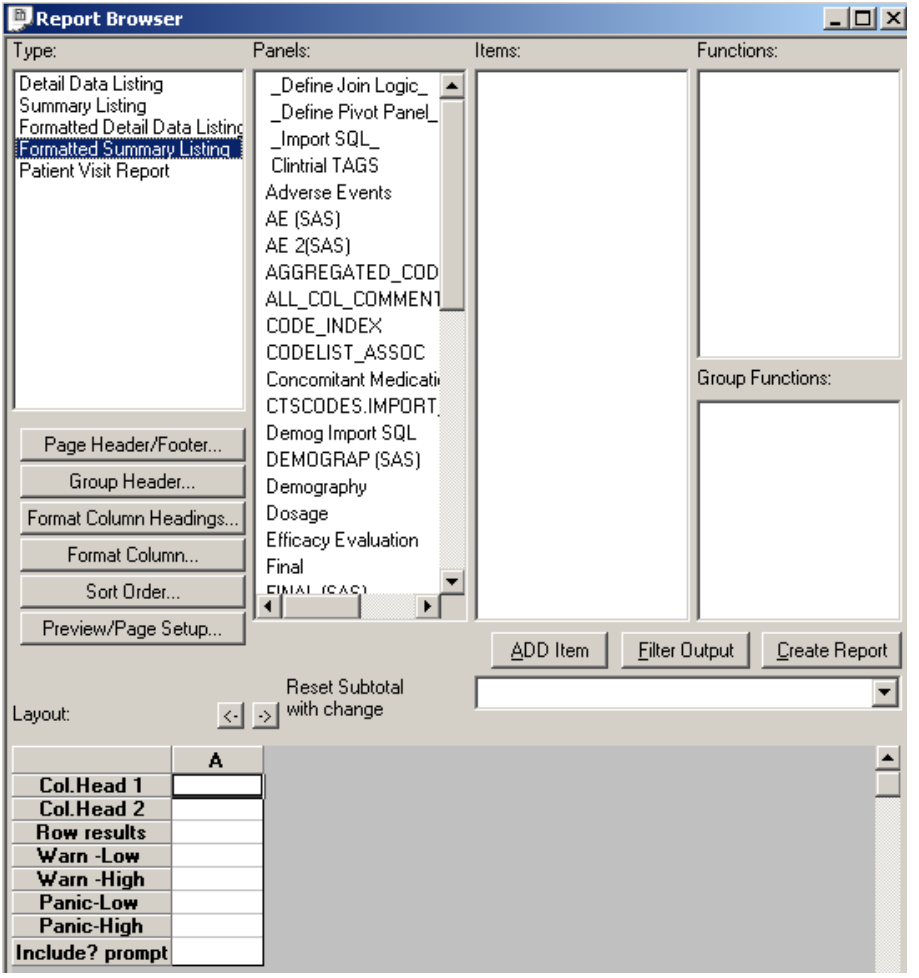
Selecting a report type

The Report Browser facilitates customized groupings of item values for patients currently included in the patient selection criteria. Review provides point and click report creation, without panel join limitations. Multiple study reporting is supported in each of the report types.

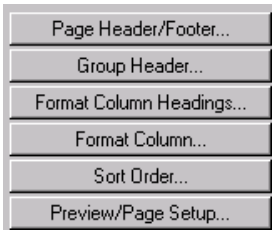
You select a Type of report from the Report Type ListBox by choosing one of the following:

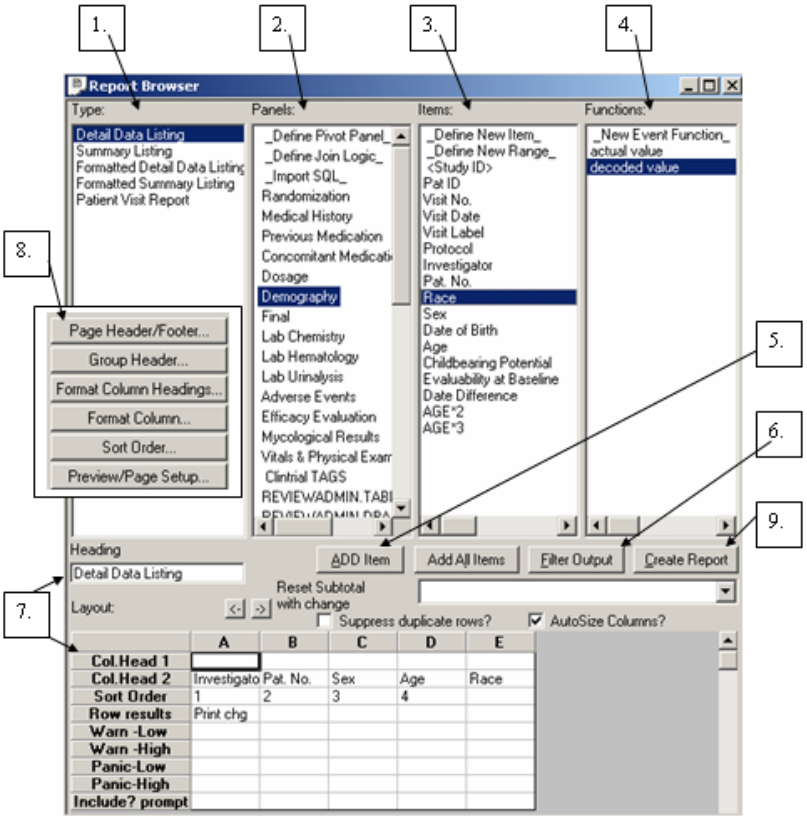


- Detail Data Listing generate one report line for each patient observation.
- Summary Listing generate one report line containing summary information such as summary category, counts, mean, and so on.
- Formatted Detail Data Listing and Formatted Summary Listing provide the same basic functions as Detail Data Listing and Summary Listing. In addition, extensive formatting features are available for you to make changes over default settings which are initialized when you select a formatted listing. Refer to the section in this chapter on **Formatting Reports** when you select Formatted Detail Data Listing or Formatted Summary Listing.
- Patient Visit Report contains patient results organized by patientid and visit where multiple visit panels are easily joined and displayed per row.



The setting changes can be applied to:





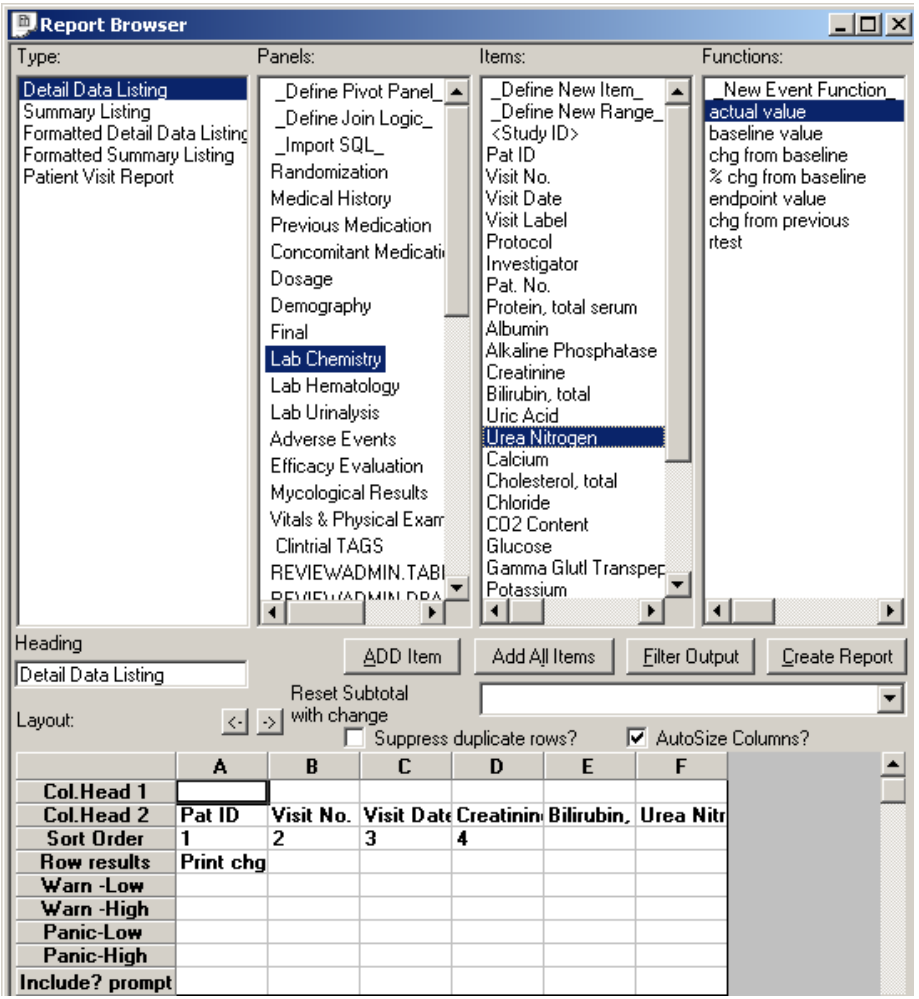
1. Select a Report type.
2. Select a Panel.
3. Select an Item(s).
4. Select a Function.
5. Click ADD Item or double-click on the item to add. (Repeat steps 1-4 as needed to add items.)
6. Optionally, create an Output Filter.
7. For unformatted reports - Edit the column order, column headings, report heading, sort order, row results or range checks.
8. For formatted reports - Edit the column order, column headings and row results or range checks. Apply detailed formats with menu.
9. Click Create Report.

Defining Report Specifications

Selecting a panel, item, and function

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** and Review adds the items 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.

Default and new events

Review provides predefined functions, and you can select from any function value listed. You can utilize the '_New Event_' function that facilitates the creation of new user-defined functions. (See *Chapter 12: Common Topics: _New Events*)

The predefined function 'Chg from previous', calculates the change from the last measure. All other default functions are pre-configured in the Review Administrative Configuration Tables. (See *Review Configuration Guide*)

New item, new ranges, and new events are fully supported in the Report Browser. (See *Chapter 12: Common Topics: Derived Items and New Range Variables*)

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

Optional column autosizing is available, click '**AutoSize Columns?'**. When the report is created the columns will default to the width of the column heading. The default is **AutoSize Columns on**.

Edit report sort order

To make changes to the sort order:

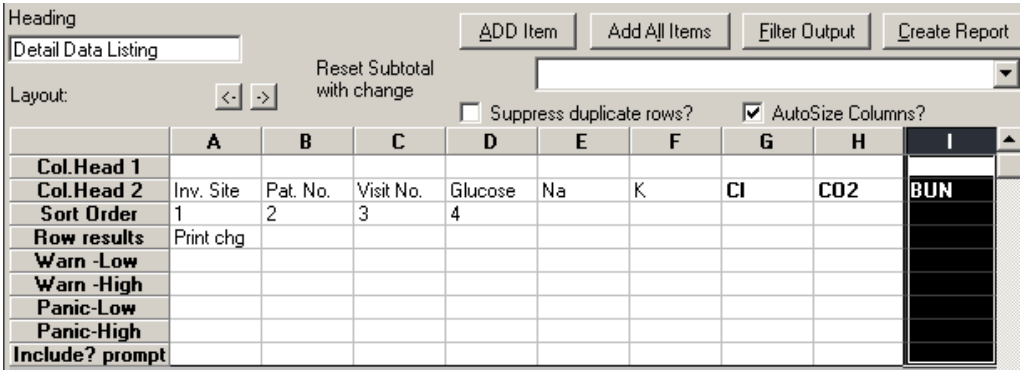
1. Click on the default sort order values.
2. Delete, replace, edit or add sort order values.
   The sort order 1 will be the item in which the primary sort will take place, sub-sorted by sort order 2, and so on.
3. Optional descending sort is specified by a trailing 'D' after the sort order number.

Note: Formatted reports use a different definition for how items are sorted. See sort order for Formatted Reports.

Edit report column order

To move a column:

1. Click on the column you want to move, or click and drag to highlight over the columns you want to move.
2. Use the **directional arrow** buttons to place the highlighted column in the columnar position(s) you would like.



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:

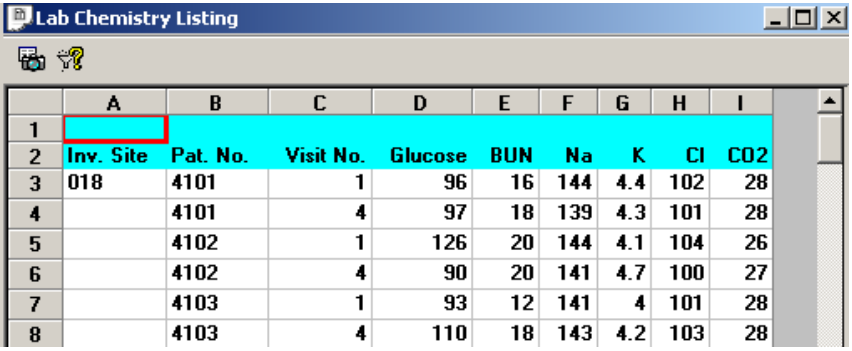
1. Click on the text.
2. Edit the text.
3. Press **Enter**.

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.

Create report

When all report specifications have been entered click **Create Report.** The report is displayed in a Report Browser window containing a spreadsheet of your report.

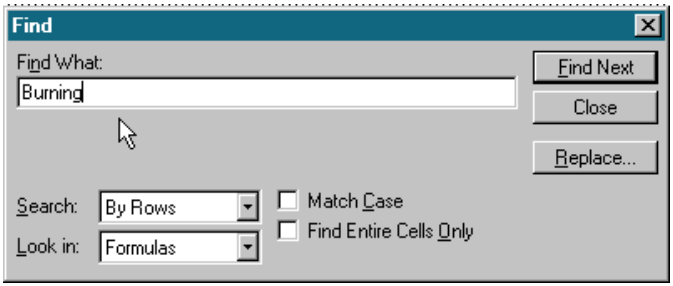


	A	B	C	D	E	F	G	H	I
1									
2	Inv. Site	Pat. No.	Visit No.	Glucose	BUN	Na	K	Cl	CO2
3	018	4101	1	96	16	144	4.4	102	28
4		4101	4	97	18	139	4.3	101	28
5		4102	1	126	20	144	4.1	104	26
6		4102	4	90	20	141	4.7	100	27
7		4103	1	93	12	141	4	101	28
8		4103	4	110	18	143	4.2	103	28

Find menu command

You can perform a search for a key word in the Report Browser. Non-formatted reports use the dialog box below.

1. Click the **Edit** menu, select **Find**.
2. Enter the search criteria and Review will locate the first occurrence. If you select search by column, highlight the column in the spreadsheet.



Formatted Reports do not require the column to be highlighted. Simply enter the search criteria in the dialog box.

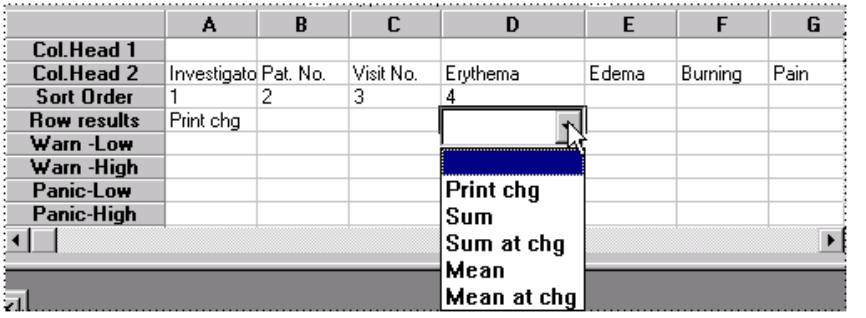
Detail Data Listing features

Defining row results

By default, the first sorted item's 'Row results' is set to the 'Print change', which means that the row will only print on a change in that item value. The row results options vary with each item type. 'Row results' for a non-numeric item type is limited to 'Print change'.

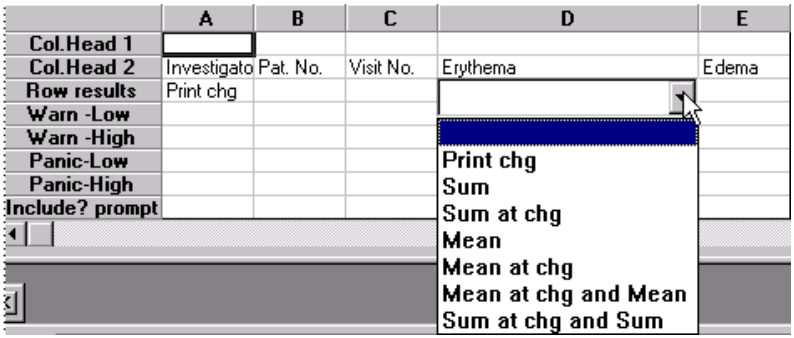
	A	B
Col.Head 1		
Col.Head 2	Investigato	Pat. No.
Sort Order	1	2
Row results	Print chg	
Warn -Low		
Warn -High		
Panic-Low		
Panic-High		
Include? prompt		

A numeric 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 downlist below is for non-formatted report types.



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

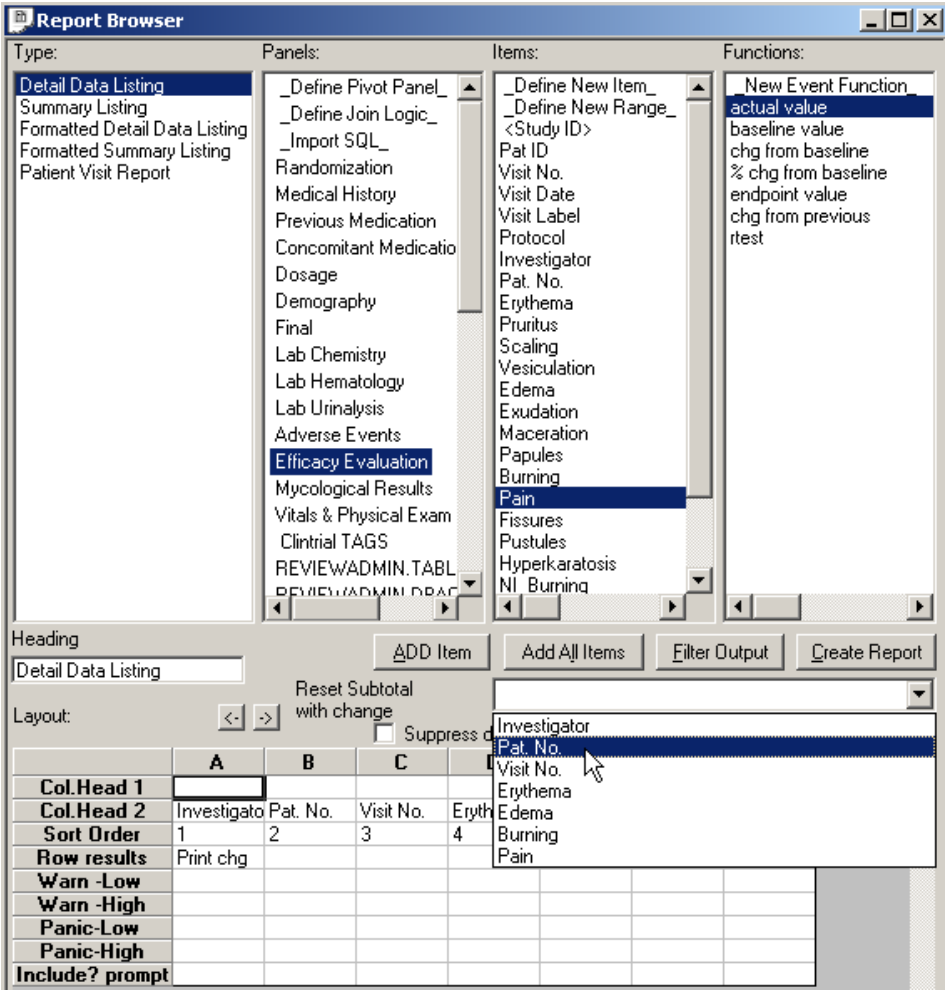
Formatted reports have more mathematical options. In addition, formatted reports support Sum at Change, Mean at Change, Mean at Change and Mean, and Sum at Change and Sum.



Using mathematical row results

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


Report Browser
Type:
Detail Data Listing
Summary Listing
Formatted Detail Data Listing
Formatted Summary Listing
Patient Visit Report
Panels:
Define Pivot Panel
Define Join Logic
Import SQL
Randomization
Medical History
Previous Medication
Concomitant Medicatio
Dosage
Demography
Final
Lab Chemistry
Lab Hematology
Lab Urinalysis
Adverse Events
Efficacy Evaluation
Mycological Results
Vitals & Physical Exam
Clintrial TAGS
REVIEWADMIN.TABL
Items:
Define New Item
Define New Range
<Study ID>
Pat ID
Visit No.
Visit Date
Visit Label
Protocol
Investigator
Pat. No.
Erythema
Pruritus
Scaling
Vesiculation
Edema
Exudation
Maceration
Papules
Burning
Pain
Fissures
Pustules
Hyperkaratosis
NI_Burning
Functions:
New Event Function
actual value
baseline value
chg from baseline
% chg from baseline
endpoint value
chg from previous
rtest
Heading
Detail Data Listing
ADD Item
Add All Items
Filter Output
Create Report
Layout:
Reset Subtotal with change
Investigator
Pat. No.
Visit No.
Erythema
Edema
Burning
Pain
A
B
C
Col.Head 1
Col.Head 2
Investigato
Pat. No.
Visit No.
Eryth
Sort Order
1
2
3
4
Row results
Print chg
Warn -Low
Warn -High
Panic-Low
Panic-High
Include? prompt

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

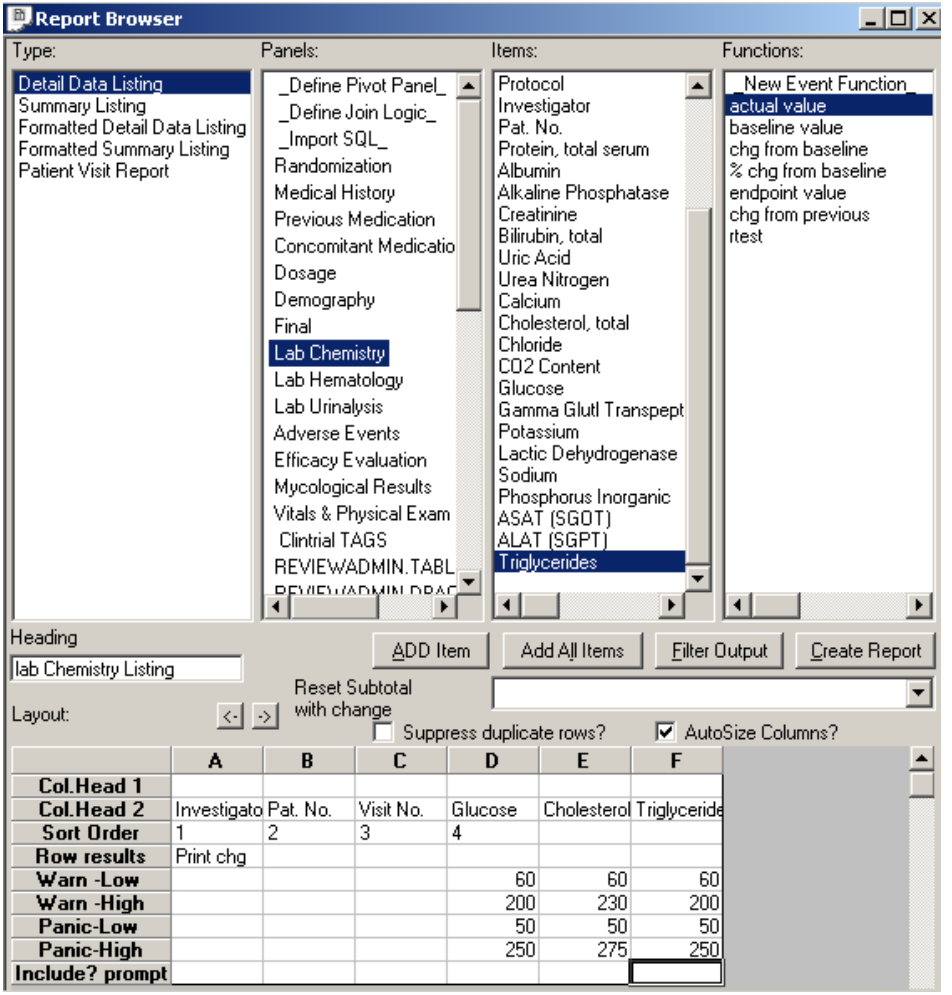
Symptoms Scores Detail Data Listing

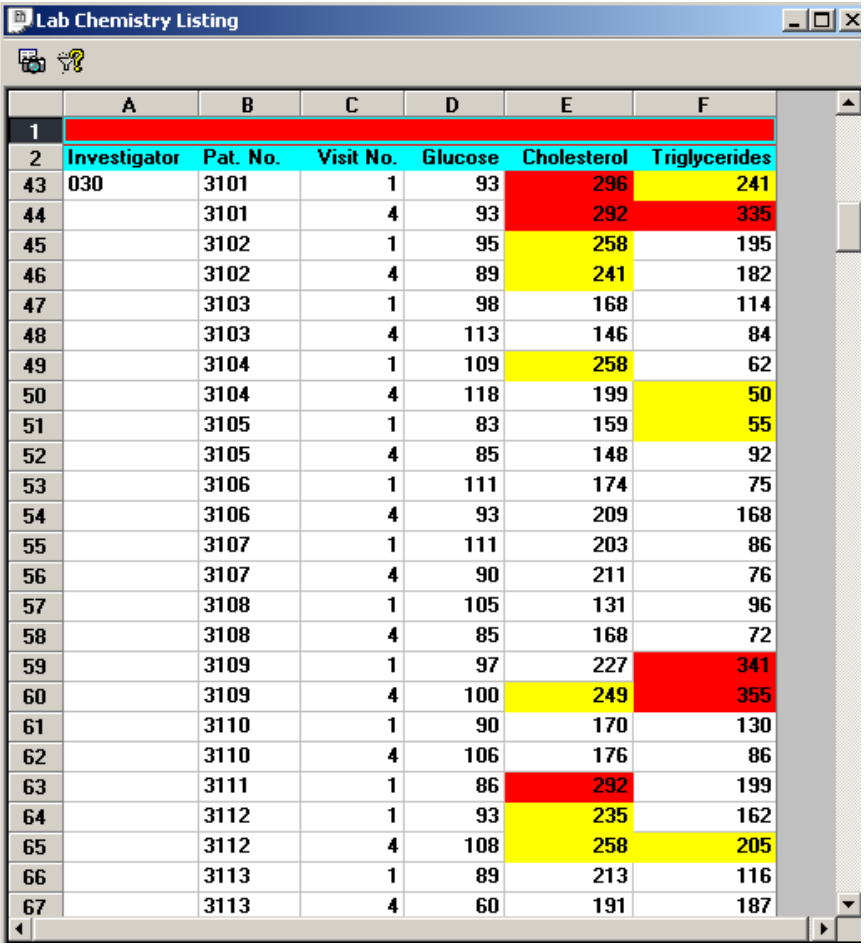
	A	B	C	D	E	F	G
1							
2	Investigator	Pat. No.	Visit No.	Erythema	Edema	Burning	Pain
3	018	4101	1	2	0	1	0
4		4101	2	1	0	0	0
5		4101	3	1	0	0	0
6		4101	4	1	0	0	0
7		4101	5	1	0	0	0
8		4101	6	1	0	0	0
9	Subtotal			7.00	0.00	1.00	0.00
10	018	4102	1	2	0	0	0
11		4102	2	2	0	0	0
12		4102	3	1	0	0	0
13		4102	4	1	0	0	0
14		4102	5	2	0	0	0
15		4102	6	1	0	0	0
16	Subtotal			9.00	0.00	0.00	0.00
17	018	4103	1	2	0	2	0
18		4103	2	1	0	2	0
19		4103	3	1	0	0	0
20		4103	4	1	0	0	0
21		4103	5	0	0	0	0
22		4103	6	0	0	0	0
23	Subtotal			5.00	0.00	4.00	0.00

Highlighting data check ranges

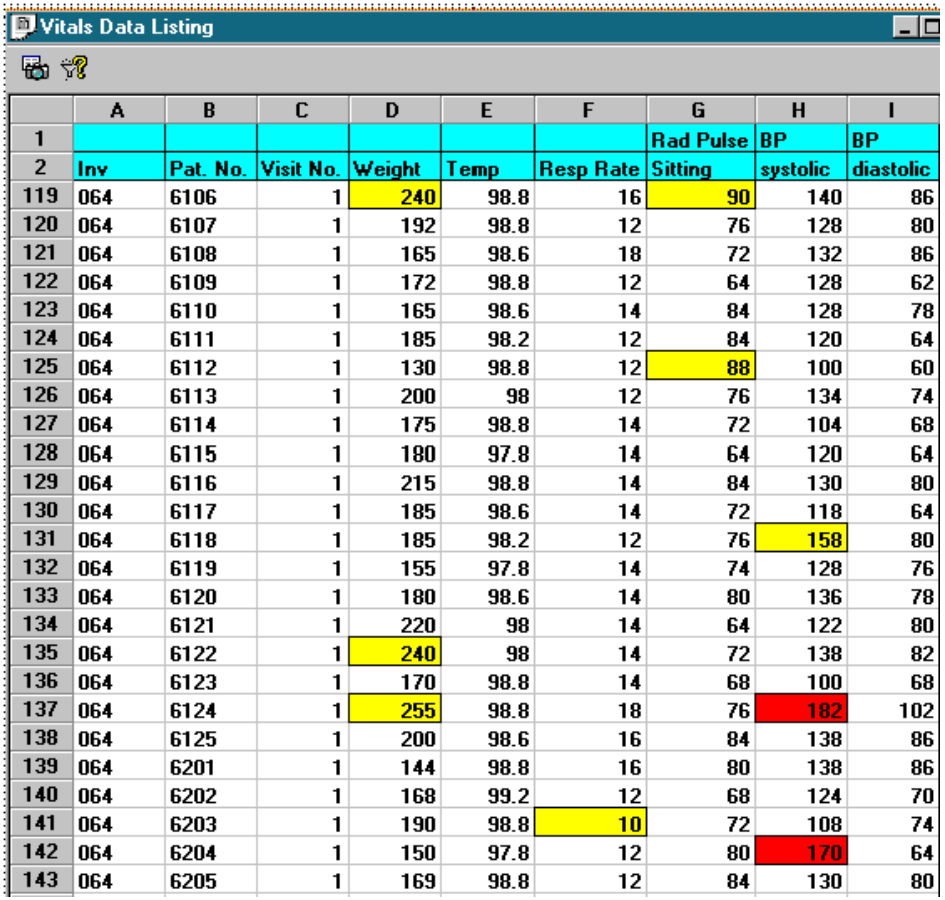
When you define a report, for example, which includes numeric parameters such as laboratory data, vital signs or scores, you can enter warning and panic ranges that will be used to color highlight the data in the report display. Variable values outside the ranges you define will show up in yellow and 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”.





	A	B	C	D	E	F
1						
2	Investigator	Pat. No.	Visit No.	Glucose	Cholesterol	Triglycerides
43	030	3101	1	93	296	241
44		3101	4	93	292	335
45		3102	1	95	258	195
46		3102	4	89	241	182
47		3103	1	98	168	114
48		3103	4	113	146	84
49		3104	1	109	258	62
50		3104	4	118	199	50
51		3105	1	83	159	55
52		3105	4	85	148	92
53		3106	1	111	174	75
54		3106	4	93	209	168
55		3107	1	111	203	86
56		3107	4	90	211	76
57		3108	1	105	131	96
58		3108	4	85	168	72
59		3109	1	97	227	341
60		3109	4	100	249	355
61		3110	1	90	170	130
62		3110	4	106	176	86
63		3111	1	86	292	199
64		3112	1	93	235	162
65		3112	4	108	258	205
66		3113	1	89	213	116
67		3113	4	60	191	187



Vitals Data Listing

	A	B	C	D	E	F	G	H	I
1							Rad Pulse	BP	BP
2	Inv	Pat. No.	Visit No.	Weight	Temp	Resp Rate	Sitting	systolic	diastolic
119	064	6106	1	240	98.8	16	90	140	86
120	064	6107	1	192	98.8	12	76	128	80
121	064	6108	1	165	98.6	18	72	132	86
122	064	6109	1	172	98.8	12	64	128	62
123	064	6110	1	165	98.6	14	84	128	78
124	064	6111	1	185	98.2	12	84	120	64
125	064	6112	1	130	98.8	12	88	100	60
126	064	6113	1	200	98	12	76	134	74
127	064	6114	1	175	98.8	14	72	104	68
128	064	6115	1	180	97.8	14	64	120	64
129	064	6116	1	215	98.8	14	84	130	80
130	064	6117	1	185	98.6	14	72	118	64
131	064	6118	1	185	98.2	12	76	158	80
132	064	6119	1	155	97.8	14	74	128	76
133	064	6120	1	180	98.6	14	80	136	78
134	064	6121	1	220	98	14	64	122	80
135	064	6122	1	240	98	14	72	138	82
136	064	6123	1	170	98.8	14	68	100	68
137	064	6124	1	255	98.8	18	76	182	102
138	064	6125	1	200	98.6	16	84	138	86
139	064	6201	1	144	98.8	16	80	138	86
140	064	6202	1	168	99.2	12	68	124	70
141	064	6203	1	190	98.8	10	72	108	74
142	064	6204	1	150	97.8	12	80	170	64
143	064	6205	1	169	98.8	12	84	130	80

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 turned on.

INV 063 AElist, SUPPRESS DUP OFF

	A	B	C
1			
2	INV	PatNo	AE Coded
3	063	2103	BODY:Unevaluable reaction
4	063	2103	BODY:Surgery
5	063	2104	MS :Arthritis
6	063	2105	SKIN:Pruritus
7	063	2106	NER :Headache
8	063	2107	SKIN:Burning sensation skin
9	063	2108	DIG :Tooth disorder
10	063	2108	DIG :Tooth disorder
11	063	2113	SKIN:Burning sensation skin
12	063	2123	NER :Headache
13	063	2125	RES :Sinusitis
14	063	2125	RES :Sinusitis
15	063	2125	RES :Sinusitis
16	063	2127	SKIN:Burning sensation skin
17	063	2201	NER :Headache
18	063	2201	NER :Headache
19	063	2204	NER :Headache
20	063	2204	RES :Upper respiratory infection
21	063	2207	RES :Upper respiratory infection
22	063	2207	RES :Sinusitis
23	063	2208	MAN :Peripheral edema
24	063	2208	SKIN:Burning sensation skin
25	063	2209	SKIN:Burning sensation skin

[Snapshot] INV 063 AElist, SUPPRESS DUP ON

	A	B	C
1			
2	INV	PatNo	AE Coded
3	063	2103	BODY:Unevaluable reaction
4	063	2103	BODY:Surgery
5	063	2104	MS :Arthritis
6	063	2105	SKIN:Pruritus
7	063	2106	NER :Headache
8	063	2107	SKIN:Burning sensation skin
9	063	2108	DIG :Tooth disorder
10	063	2113	SKIN:Burning sensation skin
11	063	2123	NER :Headache
12	063	2125	RES :Sinusitis
13	063	2127	SKIN:Burning sensation skin
14	063	2201	NER :Headache
15	063	2204	NER :Headache
16	063	2204	RES :Upper respiratory infectio
17	063	2207	RES :Upper respiratory infectio
18	063	2207	RES :Sinusitis
19	063	2208	MAN :Peripheral edema
20	063	2208	SKIN:Burning sensation skin
21	063	2209	SKIN:Burning sensation skin

Include? prompt

The 'Include? Prompt' allows you to facilitate a 'generalized' version of a report where the data items are collected in English or Metric units, and recorded in the database in separate fields corresponding to the collection unit. For example, create a demographic listing with height and weight fields included for height-metric, height-english, etc. If this is the case, you can create a 'general' report, using the include prompt as follows:

	A	B	C	D	E
Col.Head 2	Pat ID	Height	Height	Weight	Weight
Sort Order	1	metric	english	metric	english
Row results	Print chg				
Warn -Low					
Warn -High					
Panic-Low					
Panic-High					
Include? prompt		metric	english	metric	english

When the report is created you will see a spreadsheet with the following:

Include? Yes / No

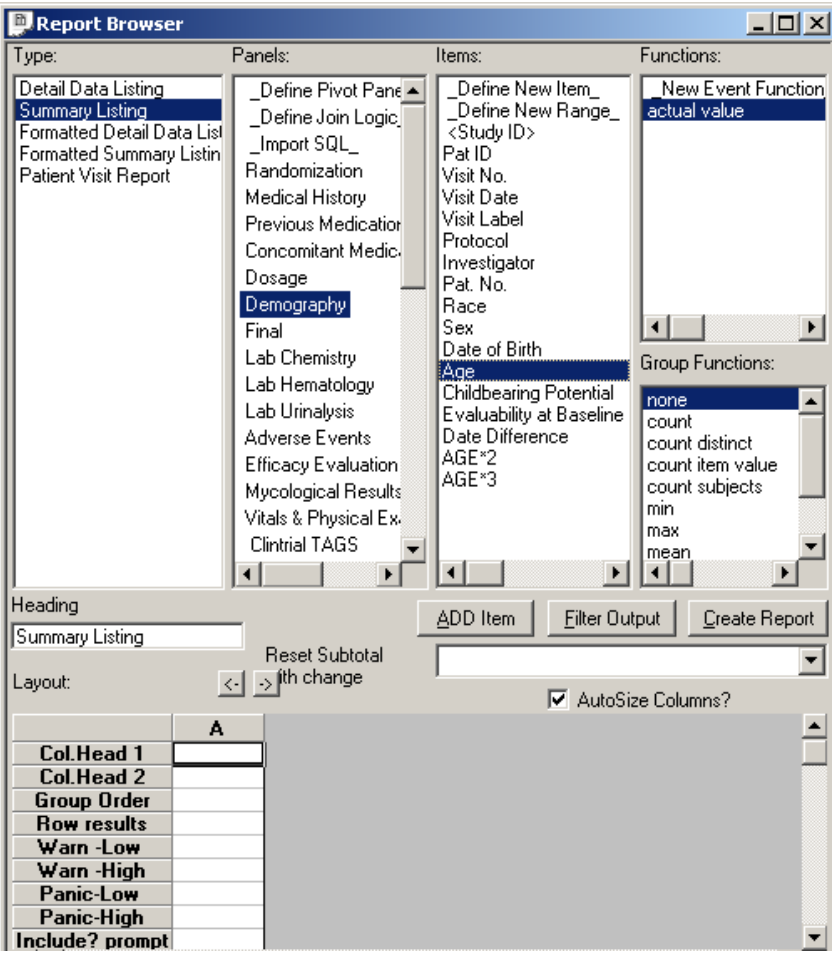
Metric Yes / No

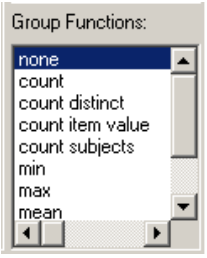
English Yes / No

If you toggle 'YES' for Metric and 'NO' for English and click Create report, you will see a 'Metric' version of the report which includes only the set columns for Metric as the 'Include Prompt'.

Summary Listing features

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.

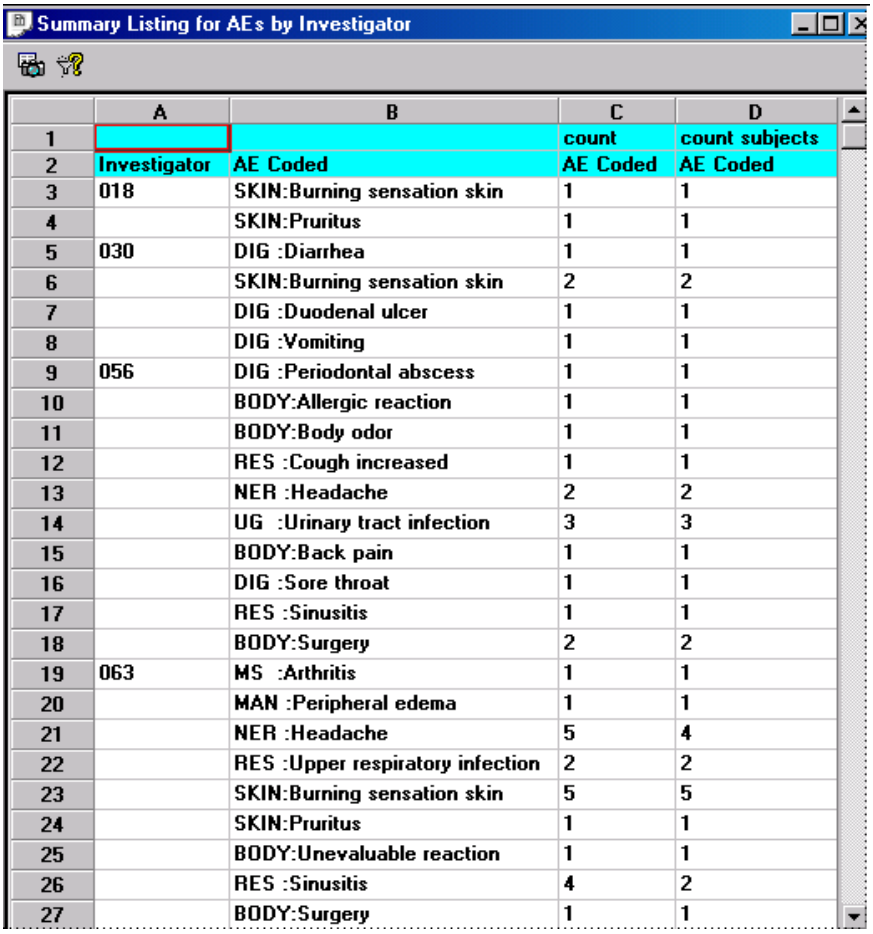
	A	B	C	D	E	F	G
Col.Head 1			count subje	min	max	mean	std dev
Col.Head 2	Investigato	Sex	Sex	Age	Age	Age	Age
Group Order	1	2					
Row results	Print chg	Print chg					
Warn -Low							
Warn -High							
Panic-Low							
Panic-High							
Include? prompt							

Summary Listing by Investigator for Sex/Age

	A	B	C	D	E	F	G
1			count subjects	min	max	mean	std dev
2	Investigator	Sex	Sex	Age	Age	Age	Age
3	018	Male	14	18	64	35.93	13.15
4		Female	8	20	60	36	13.79
5	030	Male	15	19	80	47.8	18.88
6		Female	5	22	66	43.6	16.83
7	056	Male	29	17	80	47.62	19.26
8		Female	11	20	76	51.55	15.81
9	063	Male	25	20	72	43.24	13.61
10		Female	4	35	49	38.75	6.85
11	064	Male	31	25	73	45.84	14.51
12		Female	4	33	53	42	9.59
13	065	Male	22	29	74	54.55	12.23
14		Female	3	18	70	48	26.91
15	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'.

	A	B	C	D
Col.Head 1			count	count subjects
Col.Head 2	Investigator	AE Coded	AE Coded	AE Coded
Group Order	1	2		
Row results	Print chg	Print chg		
Warn -Low				
Warn -High				
Panic-Low				
Panic-High				
Include? prompt				

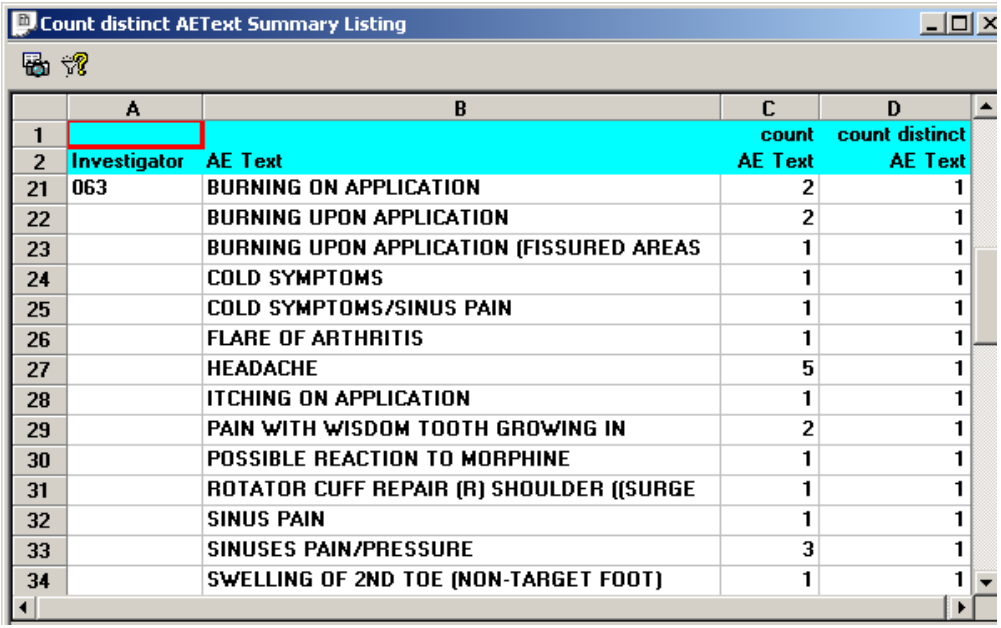


Summary Listing for AEs by Investigator

	A	B	C	D
1			count	count subjects
2	Investigator	AE Coded	AE Coded	AE Coded
3	018	SKIN:Burning sensation skin	1	1
4		SKIN:Pruritus	1	1
5	030	DIG :Diarrhea	1	1
6		SKIN:Burning sensation skin	2	2
7		DIG :Duodenal ulcer	1	1
8		DIG :Vomiting	1	1
9	056	DIG :Periodontal abscess	1	1
10		BODY:Allergic reaction	1	1
11		BODY:Body odor	1	1
12		RES :Cough increased	1	1
13		NER :Headache	2	2
14		UG :Urinary tract infection	3	3
15		BODY:Back pain	1	1
16		DIG :Sore throat	1	1
17		RES :Sinusitis	1	1
18		BODY:Surgery	2	2
19	063	MS :Arthritis	1	1
20		MAN :Peripheral edema	1	1
21		NER :Headache	5	4
22		RES :Upper respiratory infection	2	2
23		SKIN:Burning sensation skin	5	5
24		SKIN:Pruritus	1	1
25		BODY:Unevaluable reaction	1	1
26		RES :Sinusitis	4	2
27		BODY:Surgery	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).



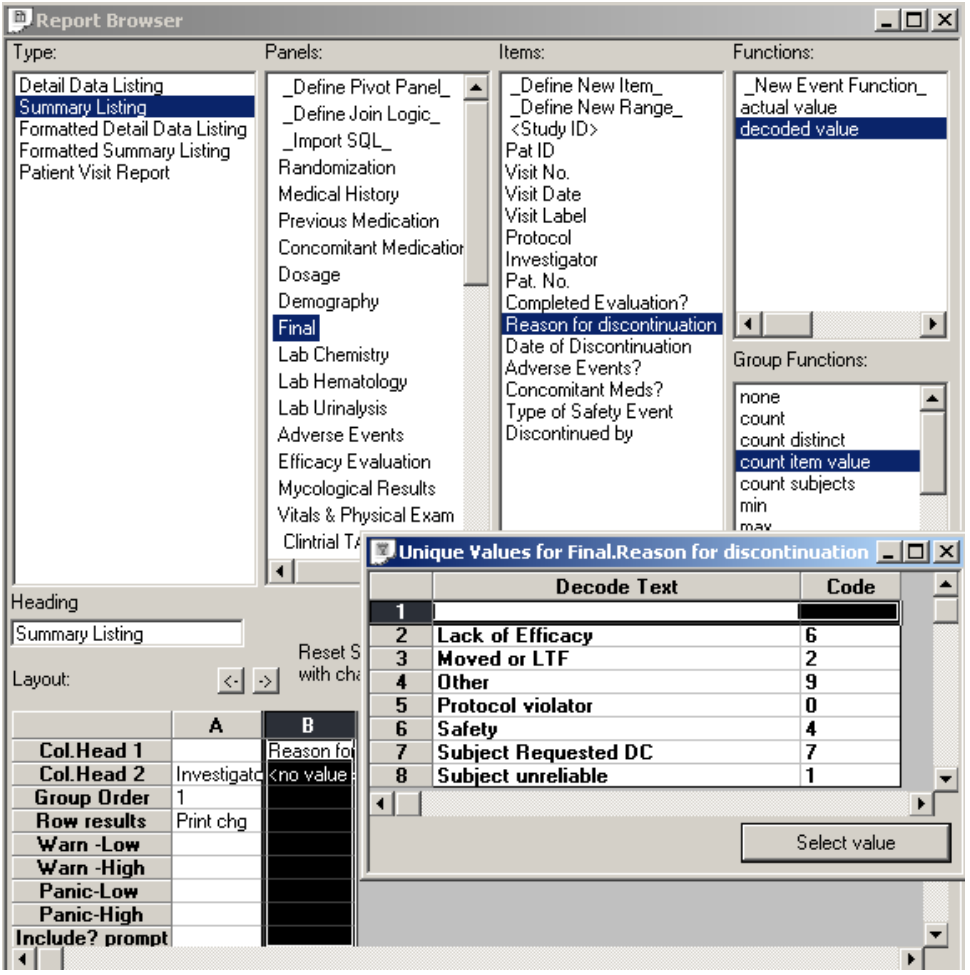
Count distinct AEText Summary Listing

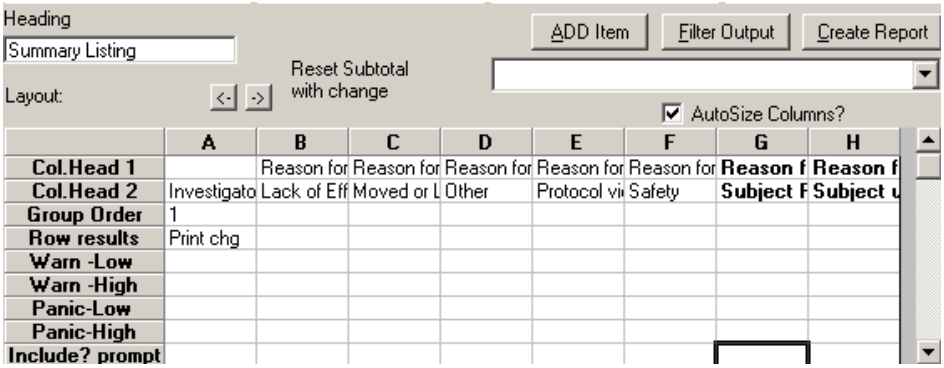
	A	B	C	D
1			count	count distinct
2	Investigator	AE Text	AE Text	AE Text
21	063	BURNING ON APPLICATION	2	1
22		BURNING UPON APPLICATION	2	1
23		BURNING UPON APPLICATION (FISSURED AREAS	1	1
24		COLD SYMPTOMS	1	1
25		COLD SYMPTOMS/SINUS PAIN	1	1
26		FLARE OF ARTHRITIS	1	1
27		HEADACHE	5	1
28		ITCHING ON APPLICATION	1	1
29		PAIN WITH WISDOM TOOTH GROWING IN	2	1
30		POSSIBLE REACTION TO MORPHINE	1	1
31		ROTATOR CUFF REPAIR (R) SHOULDER ((SURGE	1	1
32		SINUS PAIN	1	1
33		SINUSES PAIN/PRESSURE	3	1
34		SWELLING OF 2ND TOE (NON-TARGET FOOT)	1	1

Count item value

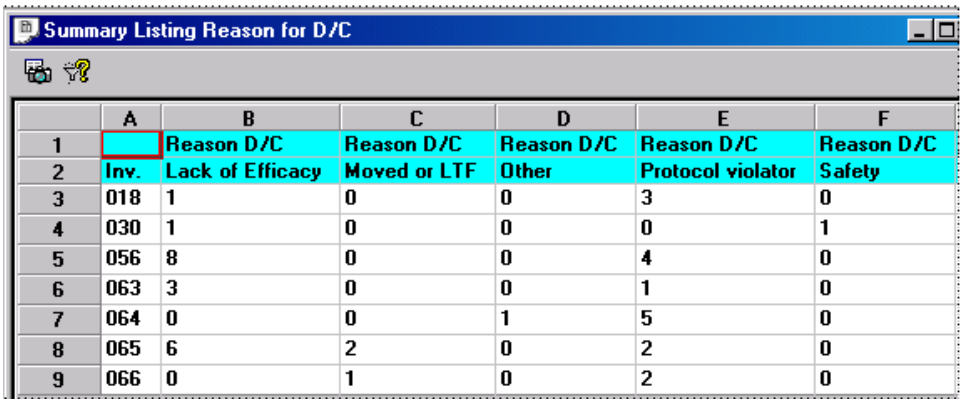
The group function for ‘count item value’ counts the number of entries of a particular item, which has a particular value. This feature is especially useful for reports counting patients having different categories. It enables you to select items from ‘Unique Values’ as a column to count the item.

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.


Report Browser
Type:
Detail Data Listing
Summary Listing
Formatted Detail Data Listing
Formatted Summary Listing
Patient Visit Report
Panels:
Define Pivot Panel
Define Join Logic
Import SQL
Randomization
Medical History
Previous Medication
Concomitant Medicatior
Dosage
Demography
Final
Lab Chemistry
Lab Hematology
Lab Urinalysis
Adverse Events
Efficacy Evaluation
Mycological Results
Vitals & Physical Exam
Items:
Define New Item
Define New Range
<Study ID>
Pat ID
Visit No.
Visit Date
Visit Label
Protocol
Investigator
Pat. No.
Completed Evaluation?
Reason for discontinuation
Date of Discontinuation
Adverse Events?
Concomitant Meds?
Type of Safety Event
Discontinued by
Functions:
New Event Function
actual value
decoded value
Group Functions:
none
count
count distinct
count item value
count subjects
min
Heading
Summary Listing
Layout:
Reset S
with cha
A
B
Col.Head 1
Col.Head 2
Group Order
Row results
Warn -Low
Warn -High
Panic-Low
Panic-High
Include? prompt
Reason for
<no value
Investigato
1
Print chg
Unique Values for Final.Reason for discontinuation
Decode Text
Code
1
2 Lack of Efficacy 6
3 Moved or LTF 2
4 Other 9
5 Protocol violator 0
6 Safety 4
7 Subject Requested DC 7
8 Subject unreliable 1
Select value



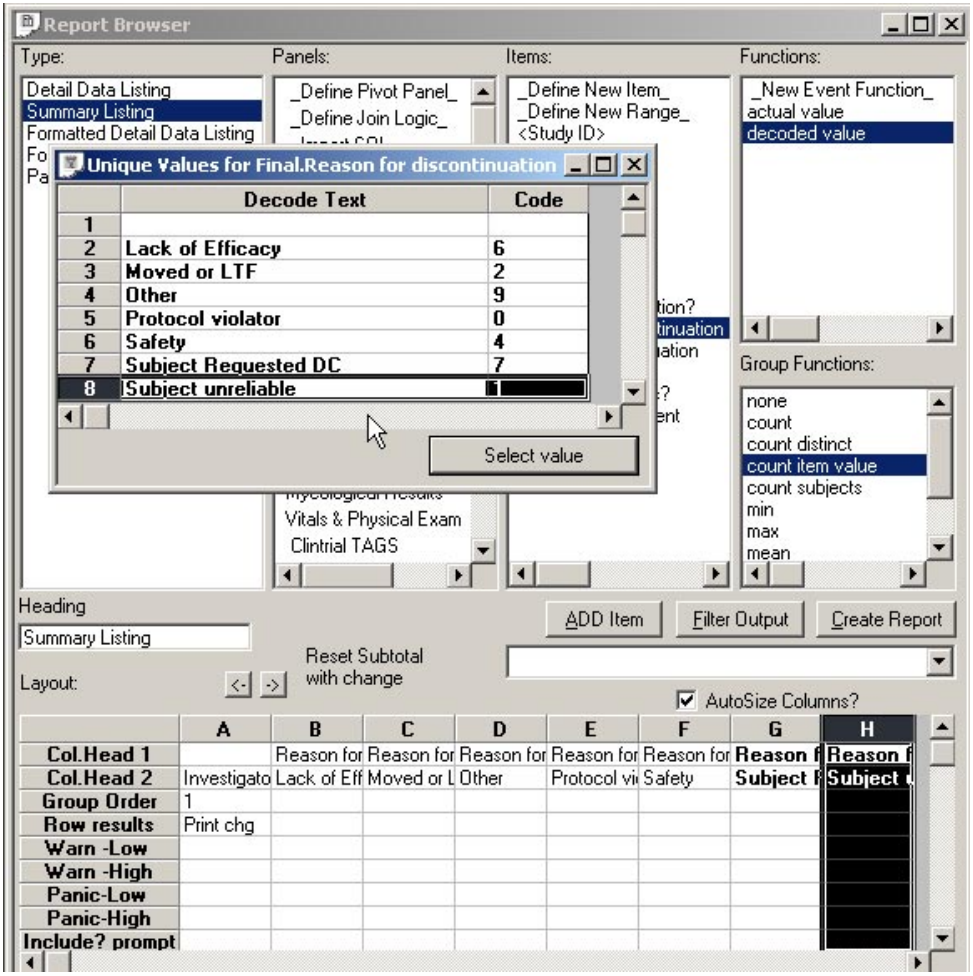
The results are the patient counts for the various Reasons for Discontinuation from the decode file.



Summary Listing Reason for D/C

	A	B	C	D	E	F
1		Reason D/C	Reason D/C	Reason D/C	Reason D/C	Reason D/C
2	Inv.	Lack of Efficacy	Moved or LTF	Other	Protocol violator	Safety
3	018	1	0	0	3	0
4	030	1	0	0	0	1
5	056	8	0	0	4	0
6	063	3	0	0	1	0
7	064	0	0	1	5	0
8	065	6	2	0	2	0
9	066	0	1	0	2	0

5. To change an existing value, double click on the column in the Report Browser window and the unique values window display for that column. Then change your value selected.

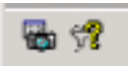


Snapshot output

Multiple population mode

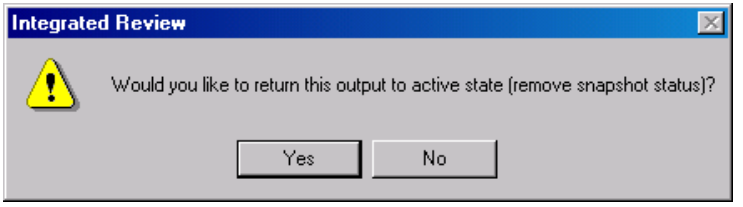
Review has an optional multiple-population mode available in throughout all the output browsers. The Snapshot output function allows you to lock the results window and make changes to the patient selection criteria, output filter and / or report definition contents. Then create and view the different output within the report browser at the same time. The Snapshot function allows you to view multiple open results within the same output browser. (See *Chapter 12: Common Topics: Snapshot output)*

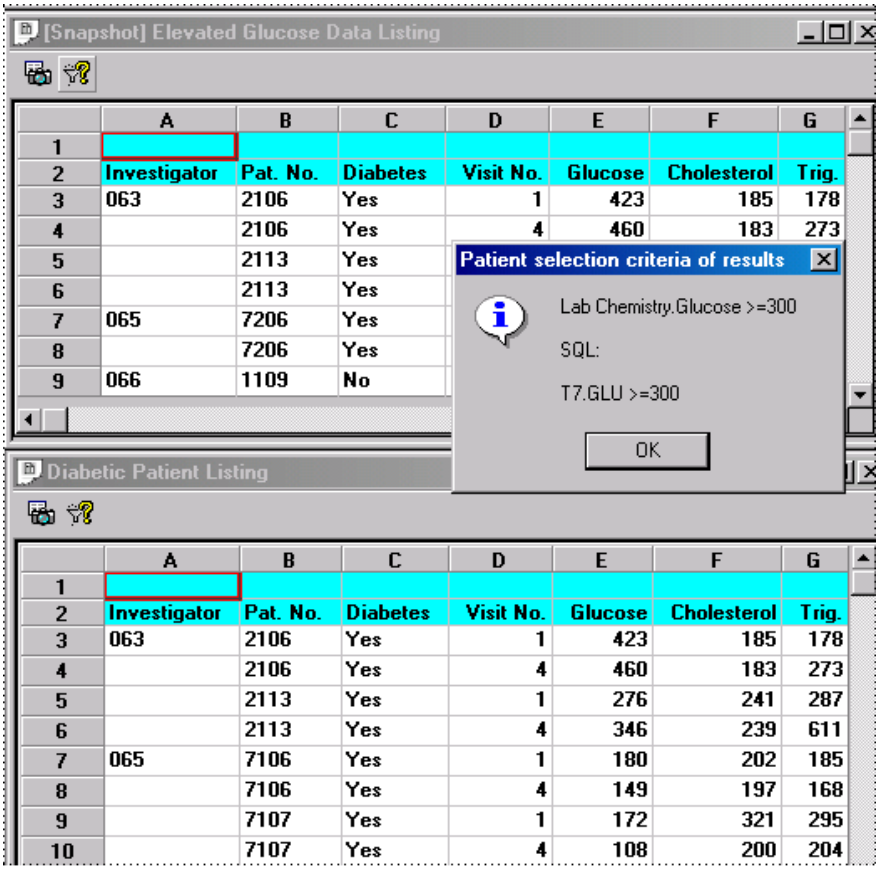
When the results are executed and displayed from the browser output window, two icons are displayed in the toolbar at the top for “Snapshot Output” and “Who?”. Simply click the Snapshot button to lock the current results output window. The report heading changes to display Snapshot for the current window status.



Click the Who button to display a message box showing the current patient selection executed if any.

To reverse the results window snapshot status simply click on the Snapshot button to display the message box.





	A	B	C	D	E	F	G
1							
2	Investigator	Pat. No.	Diabetes	Visit No.	Glucose	Cholesterol	Trig.
3	063	2106	Yes	1	423	185	178
4		2106	Yes	4	460	183	273
5		2113	Yes				
6		2113	Yes				
7	065	7206	Yes				
8		7206	Yes				
9	066	1109	No				

	A	B	C	D	E	F	G
1							
2	Investigator	Pat. No.	Diabetes	Visit No.	Glucose	Cholesterol	Trig.
3	063	2106	Yes	1	423	185	178
4		2106	Yes	4	460	183	273
5		2113	Yes	1	276	241	287
6		2113	Yes	4	346	239	611
7	065	7106	Yes	1	180	202	185
8		7106	Yes	4	149	197	168
9		7107	Yes	1	172	321	295
10		7107	Yes	4	108	200	204

Join Order

Join order in multi-panel reports

By default, the Join Order of a multi-panel 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.

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 report 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.

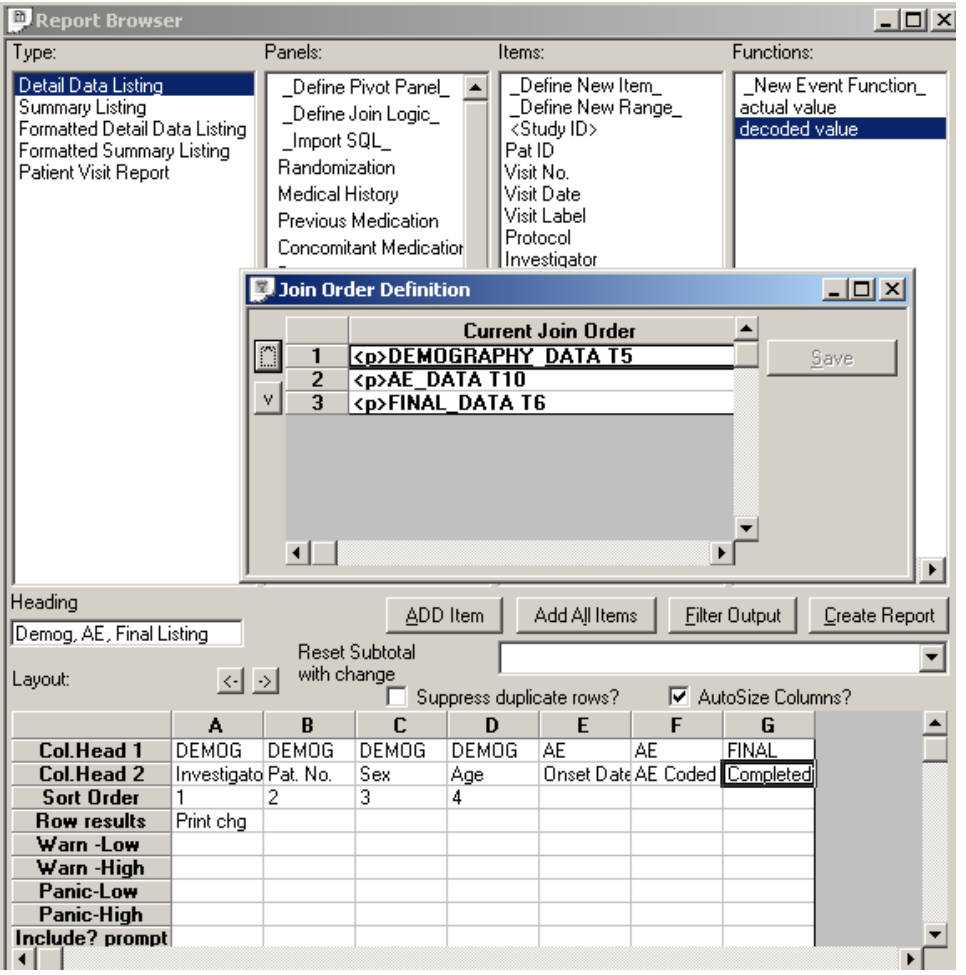
	A	B	C	D	E	F	G
Col.Head 1	DEMOG	DEMOG	DEMO	DEMO	AE	AE	FINAL
Col.Head 2	Inv.	Pat. No.	Sex	Age	Onset Date	AE Coded	Completed?
Sort Order	1	2	4	3			
Row results	Print chg						
Warn -Low							
Warn -High							
Panic-Low							
Panic-High							
Include? prompt							

Demog, AE, Final Listing

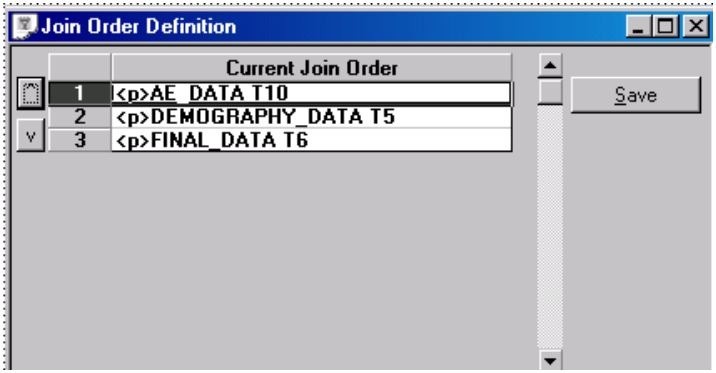
	A	B	C	D	E	F	G
1	DEMOG	DEMOG	DEMOG	DEMOG	AE	AE	FINAL
2	Inv.	Pat. No.	Sex	Age	Onset Date	AE Coded	Completed?
3	030	3101	Male	67			
4		3102	Male	36			
5		3103	Male	19			
6		3104	Male	62			
7		3105	Male	43			
8		3106	Male	49			
9		3107	Female	47			
10		3108	Female	33			
11		3109	Male	80			
12		3110	Male	47			
13		3111	Female	66	04-SEP-1991	DIG :Duodenal ulcer	No
14		3112	Male	27	08-NOV-1991	SKIN:Burning sensation skin	No
15		3113	Female	22			
16		3114	Male	25			
17		3201	Male	31			
18		3202	Female	50			
19		3203	Male	61			
20		3204	Male	63			
21		3205	Male	72	16-SEP-1991	SKIN:Burning sensation skin	Yes
22		3206	Male	35	08-OCT-1991	DIG :Diarrhea	Yes
23		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.

You can change the Join Order by selecting **Edit menu** and click **Join Order**.



The Join Order Definition window displays. Click on the panel you want to reorder and use the arrows to the left. Click **Save** to apply the new Join Order to the report. The revised Join Order is saved along with your report specifications.

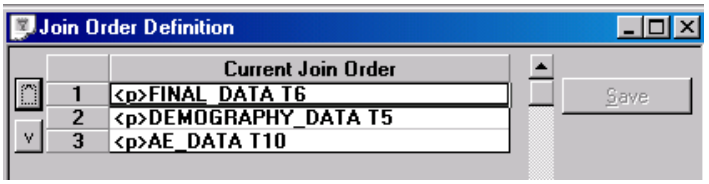


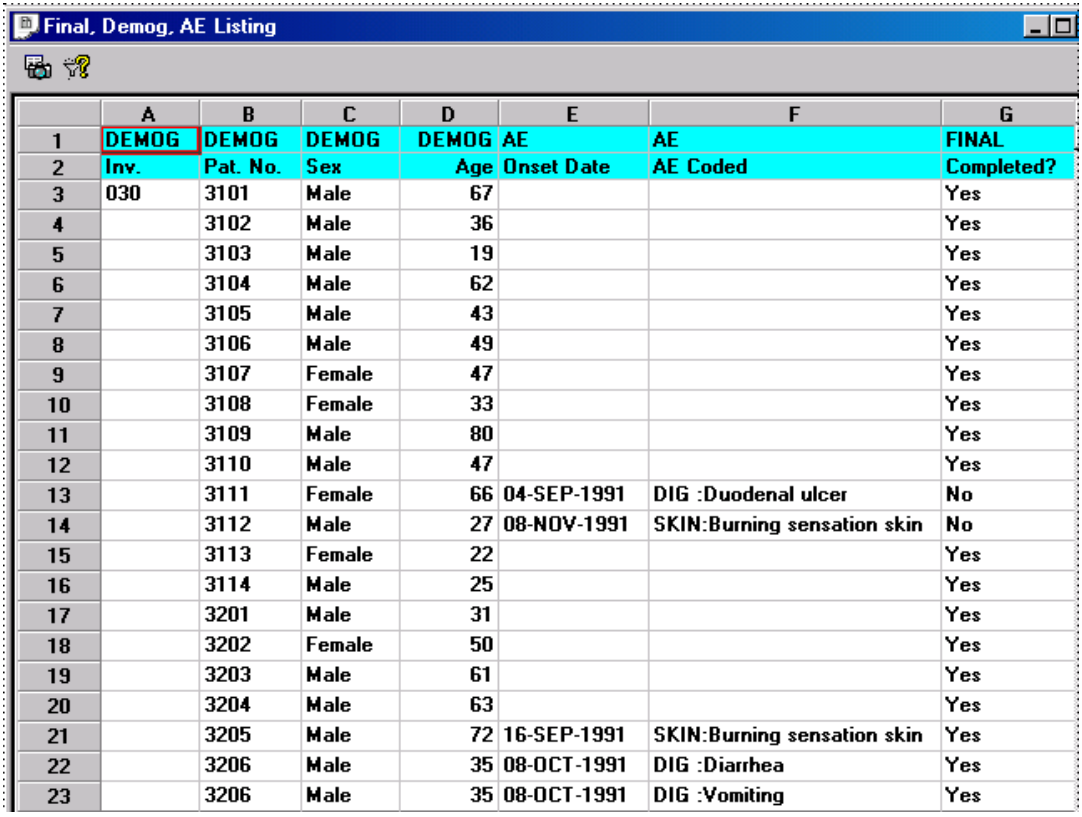
This report shows the revised join order where Adverse Events is assigned the first order position. Any blank records for Adverse Events are dropped from the listing.

AE, Demog, Final Listing

	A	B	C	D	E	F	G
1	DEMOG	DEMOG	DEMOG	DEMOG	AE	AE	FINAL
2	Inv.	Pat. No.	Sex	Age	Onset Date	AE Coded	Completed?
3	030	3111	Female	66	04-SEP-1991	DIG :Duodenal ulcer	No
4		3112	Male	27	08-NOV-1991	SKIN:Burning sensation skin	No
5		3205	Male	72	16-SEP-1991	SKIN:Burning sensation skin	Yes
6		3206	Male	35	08-OCT-1991	DIG :Diarrhea	Yes
7		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. Notice how the previously blank data for Final panel and completed study contain data. In the first example, the Final panel was unable to link to the non-existent Adverse Event panels and displayed as blank data.





Final, Demog, AE Listing

	A	B	C	D	E	F	G
1	DEMOG	DEMOG	DEMOG	DEMOG	AE	AE	FINAL
2	Inv.	Pat. No.	Sex	Age	Onset Date	AE Coded	Completed?
3	030	3101	Male	67			Yes
4		3102	Male	36			Yes
5		3103	Male	19			Yes
6		3104	Male	62			Yes
7		3105	Male	43			Yes
8		3106	Male	49			Yes
9		3107	Female	47			Yes
10		3108	Female	33			Yes
11		3109	Male	80			Yes
12		3110	Male	47			Yes
13		3111	Female	66	04-SEP-1991	DIG :Duodenal ulcer	No
14		3112	Male	27	08-NOV-1991	SKIN:Burning sensation skin	No
15		3113	Female	22			Yes
16		3114	Male	25			Yes
17		3201	Male	31			Yes
18		3202	Female	50			Yes
19		3203	Male	61			Yes
20		3204	Male	63			Yes
21		3205	Male	72	16-SEP-1991	SKIN:Burning sensation skin	Yes
22		3206	Male	35	08-OCT-1991	DIG :Diarrhea	Yes
23		3206	Male	35	08-OCT-1991	DIG :Vomiting	Yes

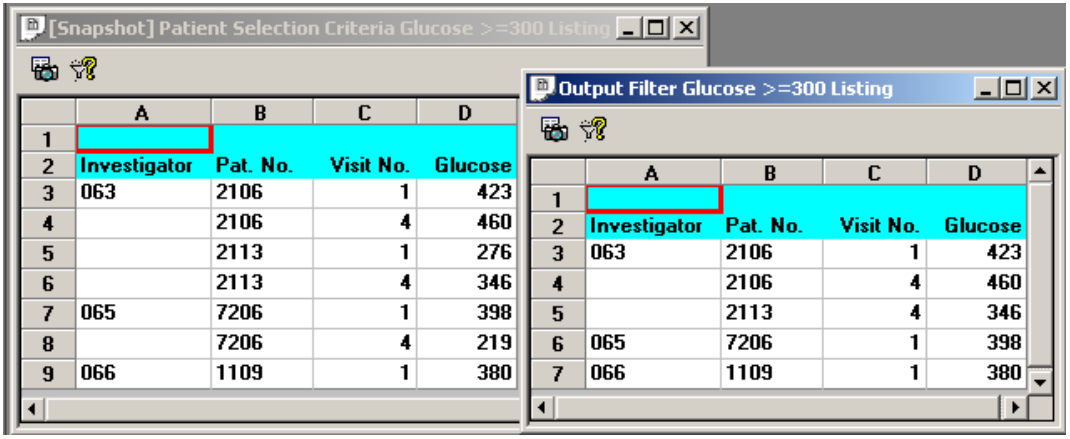
Output filter

Subset on observation and/or visit

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 in addition to 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" on the left. The same glucose selection was defined instead as an output filter on the right.



	A	B	C	D
1				
2	Investigator	Pat. No.	Visit No.	Glucose
3	063	2106	1	423
4		2106	4	460
5		2113	1	276
6		2113	4	346
7	065	7206	1	398
8		7206	4	219
9	066	1109	1	380

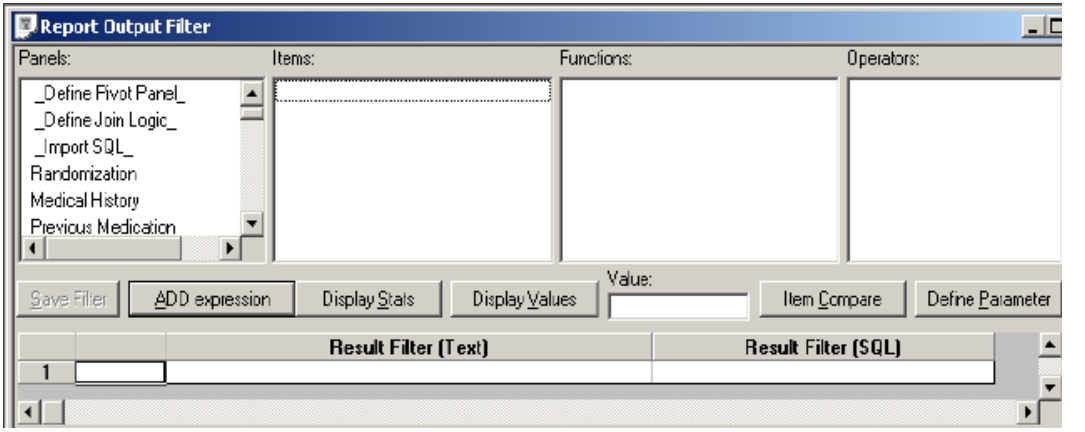
	A	B	C	D
1				
2	Investigator	Pat. No.	Visit No.	Glucose
3	063	2106	1	423
4		2106	4	460
5		2113	4	346
6	065	7206	1	398
7	066	1109	1	380

The exact same patients are selected. The difference is the patient selection criteria displays all the visits for selected patients, while the output filter selected only the visits with the elevated values as defined.

You may apply patient selection criteria and output filters to a report 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*)

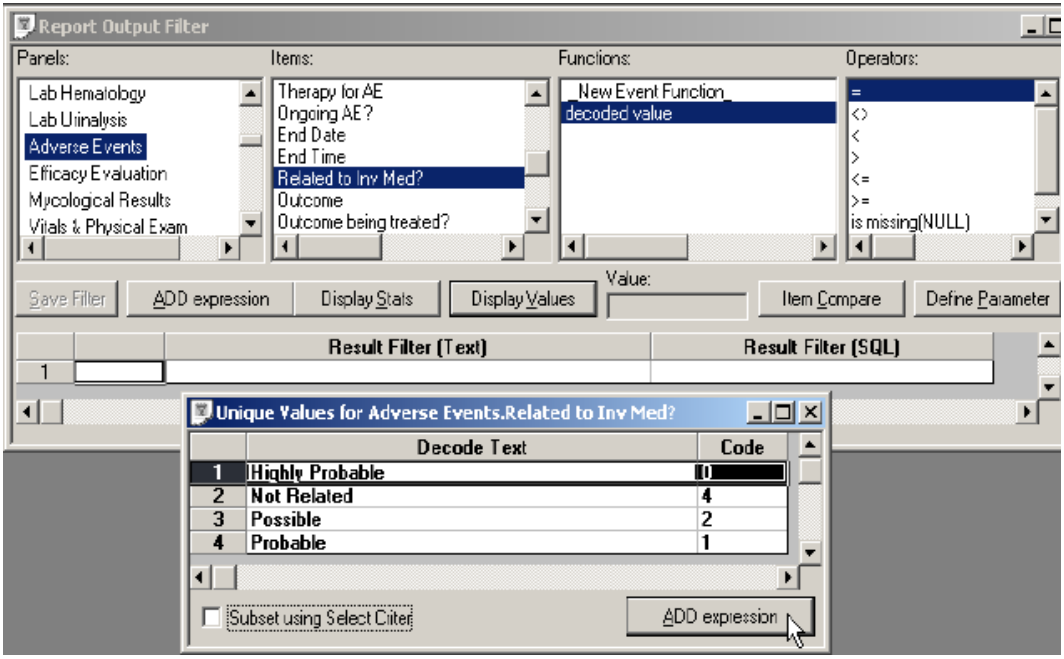
Comparing items

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*)

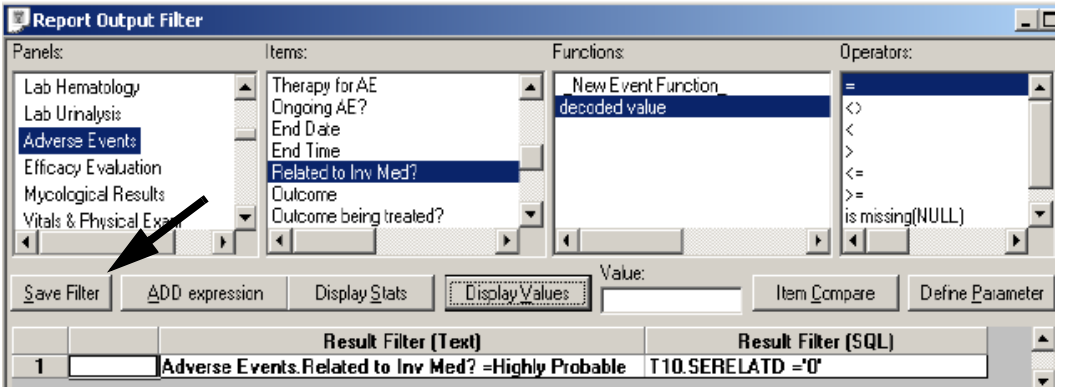
Adding expressions

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.

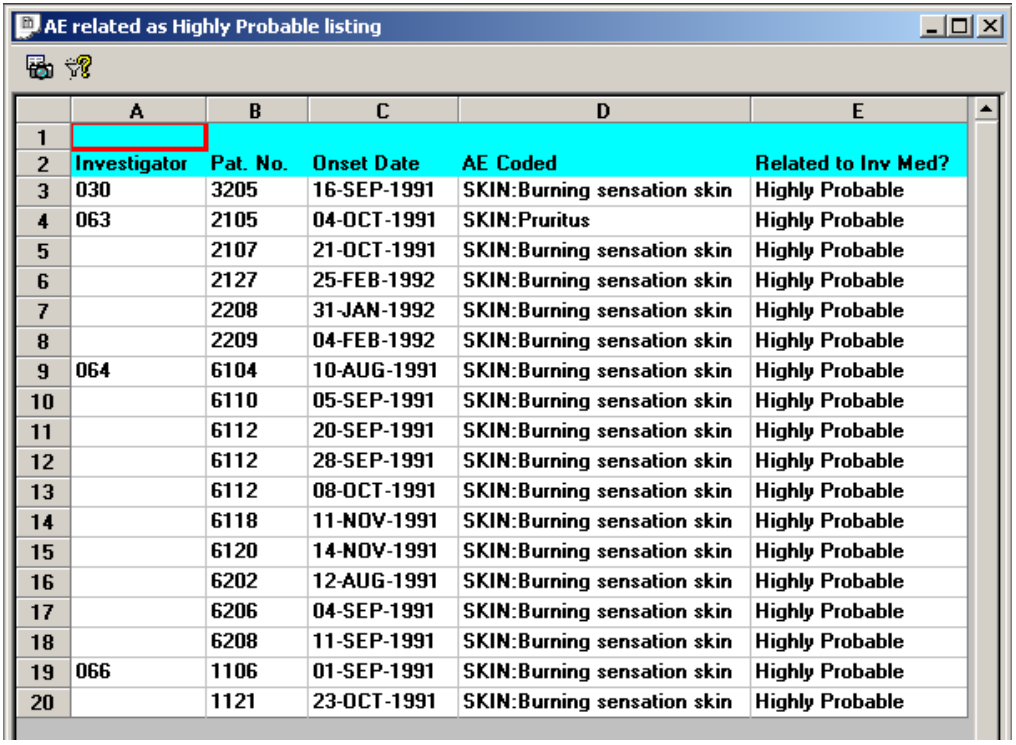
Add as many row filter criteria as needed to limit the rows of observations and visits included in the report analysis. Each result filter expression is automatically joined by the AND operator. However, just as in the patient selection criteria, the operator OR is also available for non-dependent filter expressions. ANDSelect is not available in the output filter.



When the output filter is complete, apply it to the next report creation by clicking **Save Filter**.



The report window's **Filter Output** toggles to **Filter is ON**. The resulting report is for patients meeting the patient selection criteria and the output filter criteria(s).



AE related as Highly Probable listing

	A	B	C	D	E
1					
2	Investigator	Pat. No.	Onset Date	AE Coded	Related to Inv Med?
3	030	3205	16-SEP-1991	SKIN:Burning sensation skin	Highly Probable
4	063	2105	04-OCT-1991	SKIN:Pruritus	Highly Probable
5		2107	21-OCT-1991	SKIN:Burning sensation skin	Highly Probable
6		2127	25-FEB-1992	SKIN:Burning sensation skin	Highly Probable
7		2208	31-JAN-1992	SKIN:Burning sensation skin	Highly Probable
8		2209	04-FEB-1992	SKIN:Burning sensation skin	Highly Probable
9	064	6104	10-AUG-1991	SKIN:Burning sensation skin	Highly Probable
10		6110	05-SEP-1991	SKIN:Burning sensation skin	Highly Probable
11		6112	20-SEP-1991	SKIN:Burning sensation skin	Highly Probable
12		6112	28-SEP-1991	SKIN:Burning sensation skin	Highly Probable
13		6112	08-OCT-1991	SKIN:Burning sensation skin	Highly Probable
14		6118	11-NOV-1991	SKIN:Burning sensation skin	Highly Probable
15		6120	14-NOV-1991	SKIN:Burning sensation skin	Highly Probable
16		6202	12-AUG-1991	SKIN:Burning sensation skin	Highly Probable
17		6206	04-SEP-1991	SKIN:Burning sensation skin	Highly Probable
18		6208	11-SEP-1991	SKIN:Burning sensation skin	Highly Probable
19	066	1106	01-SEP-1991	SKIN:Burning sensation skin	Highly Probable
20		1121	23-OCT-1991	SKIN:Burning sensation skin	Highly Probable

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**.

   or

1. Click all of the Result Filter Rows.
2. From the **Edit** menu, select **Cut**. This deletes the rows from the output filter specification. Clearing the output filter turns it off.
3. Click **Save Filter** to save the cleared filter status before closing the Output Filter window.

Define Parameter

Runtime parameter

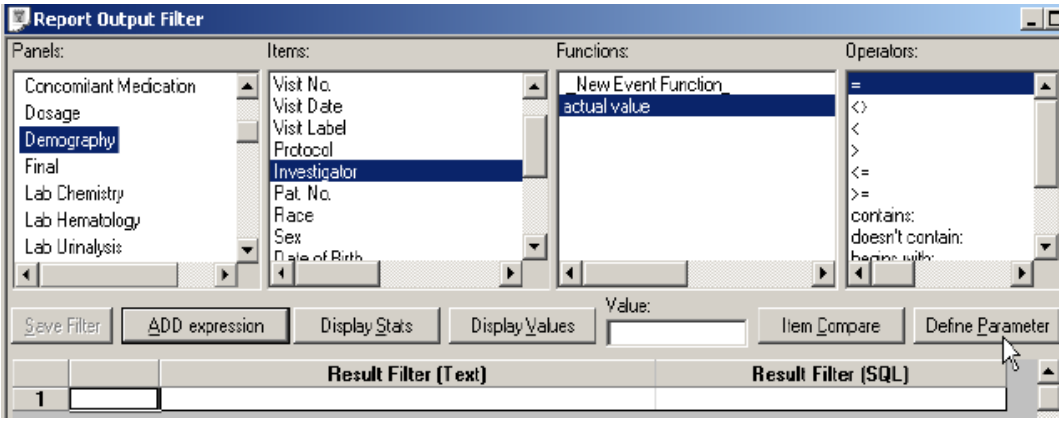
Defining runtime parameters is another way to select Output Filters to subset your patients and data observations. The object specification (reports, graphs, crosstabs) are first saved with the defined parameters. When the object specifications is executed the Output Filter View Choices window with the 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.

Create parameter

The Define Parameter function is accessed within the Filter Output window in the various browsers (reports, graphs, crosstabs). You may combine standard output filter definitions along with defining parameters when you click Save Filter. The operating features of the 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.

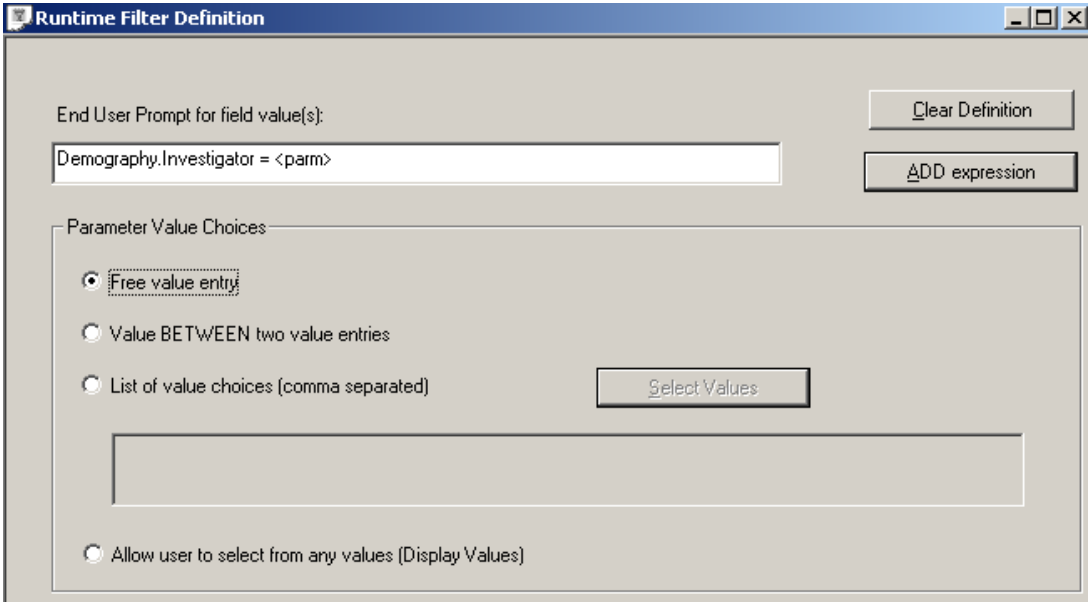
1. Click **Filter Output** from the browser window.
2. Select a panel.
3. Select an item.
4. Select the operator.



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.

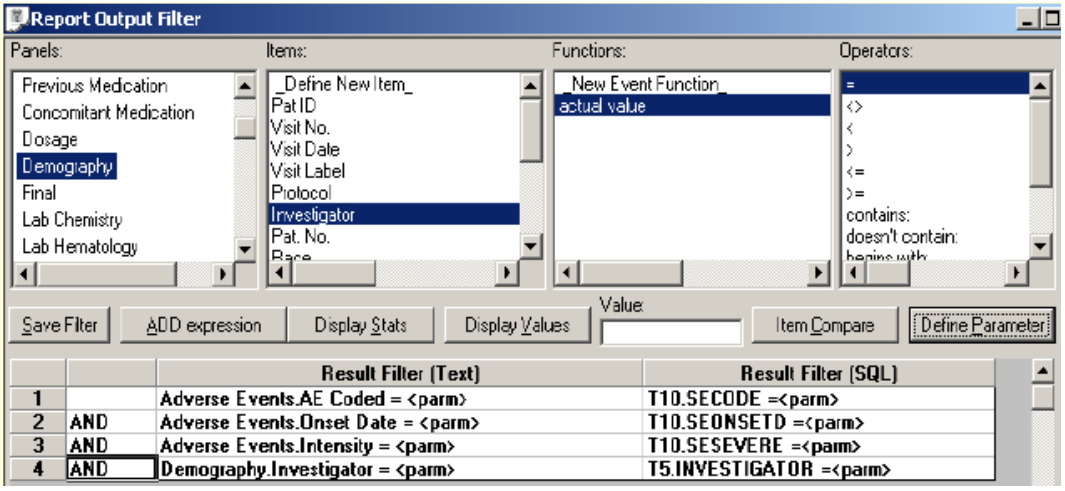
6. Select one of the **Parameter Value Choices**.



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 ore references a data dictionary file. 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. The free value entry can be used for free text data such as Adverse Event Text or Concomitant Medication Text.

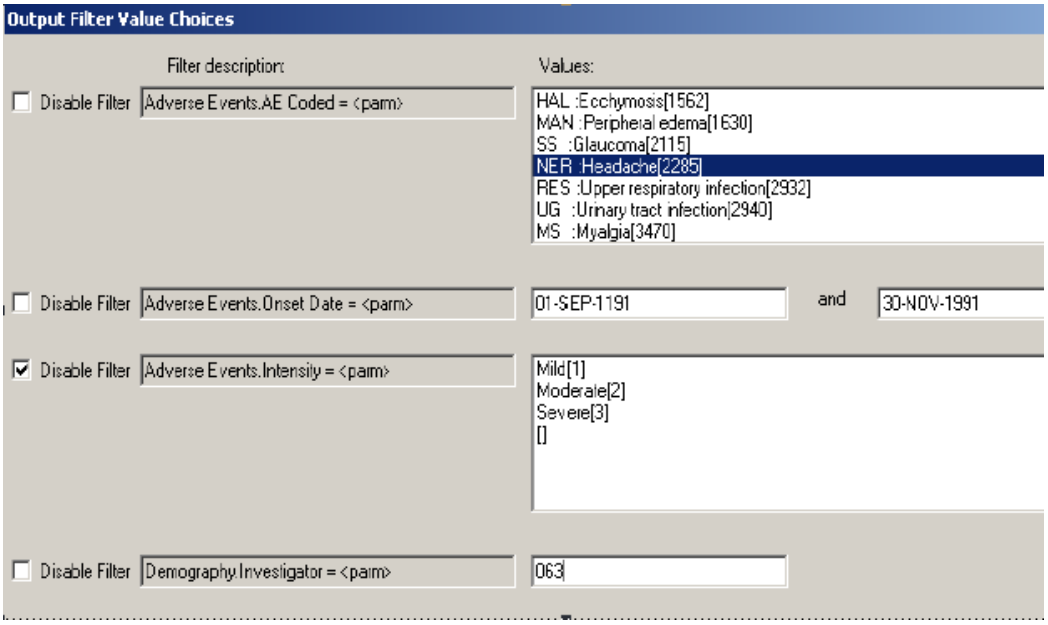
7. Check if filtering is required for item? (optional)
8. Click **ADD expression** and close the window.
9. Repeat the steps to add another parameter.
10. Change the Boolean Operators in the Output Filter window if needed. Click **Save Filter**.

Note: You MUST save the Output Specification first in order to enter parameter selections and create output.



Enter runtime parameter

When the user executes a report, graph or crosstab object with runtime parameter prompts define, first they see the Output Filter Value Choices window prompting for all parameters. 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.



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

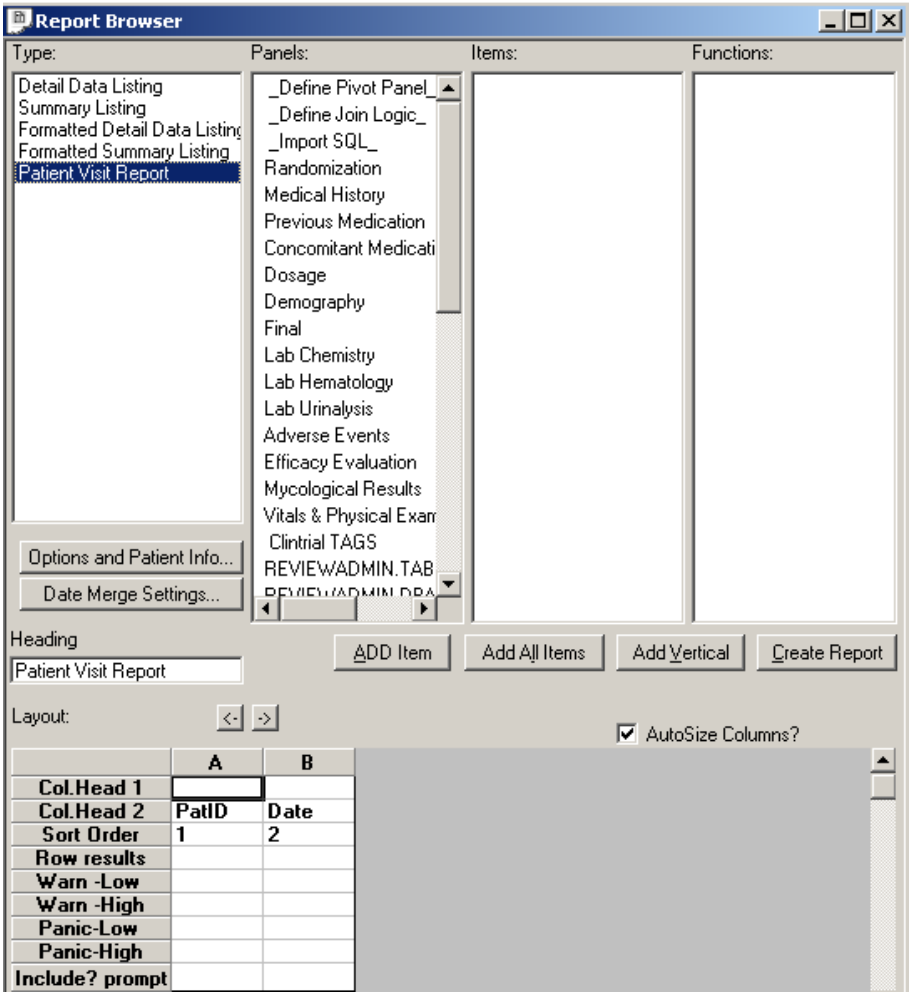
Demography with AEs Data Listing

	A	B	C	D	E	F	G	H	I
1									Related to
2	Inv.	Pat. No.	Sex	Age	Onset Date	End Date	AE Coded	Intensity	Inv Med?
3	063	2106	Male	65	28-OCT-1991	28-OCT-1991	NER :Headache	Mild	Not Related
4		2123	Male	55	11-NOV-1991	11-NOV-1991	NER :Headache	Mild	Not Related
5		2201	Male	27	08-SEP-1991	08-SEP-1991	NER :Headache	Mild	Not Related
6		2201	Male	27	15-SEP-1991	15-SEP-1991	NER :Headache	Mild	Not Related
7		2204	Female	49	20-OCT-1991	21-OCT-1991	NER :Headache	Mild	Not Related

Patient Visit Report

Select panel visit report

The patient visit 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 report

You define the contents of a patient visit 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.

	A	B	C	D	E	F	G	H	I	J	K	L
Col.Head 1												
Col.Head 2	PatID	Date	Visit No.	Glucose	Cholesterol	Triglyc	White Cell	Hemogl	Hemato	Onset Date	Onset Time	AE Coded
Sort Order	1	2										
Row results												
Warn -Low												
Warn -High												
Panic-Low												
Panic-High												
Include? prompt												

Report options

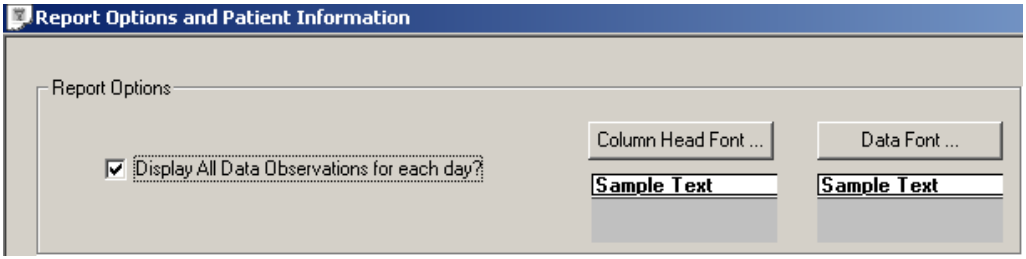
After adding all your items to the report template you can apply additional report options, patient information, formats and date merge settings.

4. Click **Options and Patient Info**. The Report Options and Patient Information window opens.

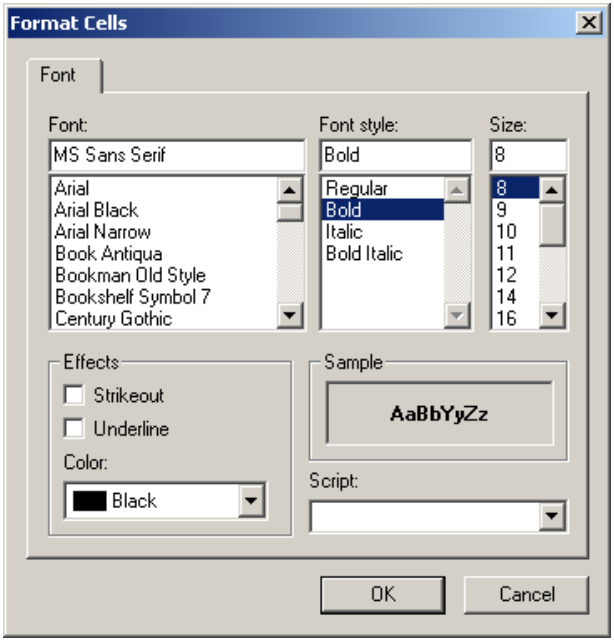
(The image has been split for display purposes.)

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.



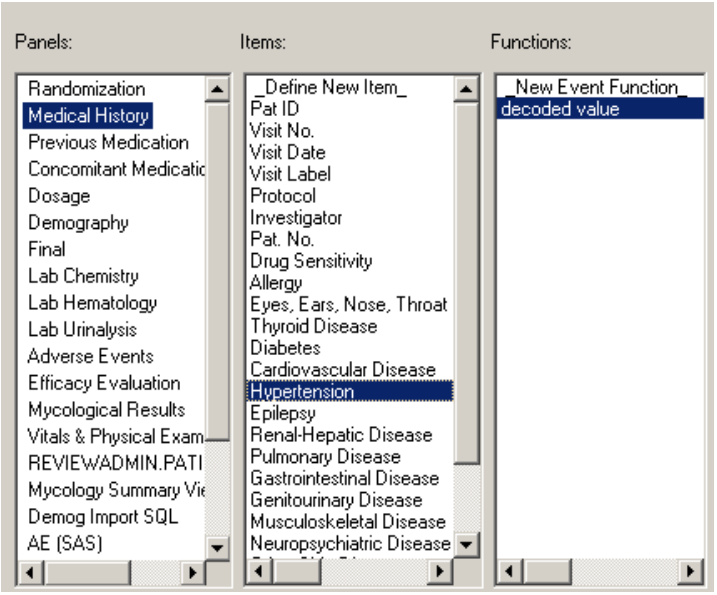
6. **Column Head Font** and **Data Font** are available to control fonts for Column Headers and Report Data.



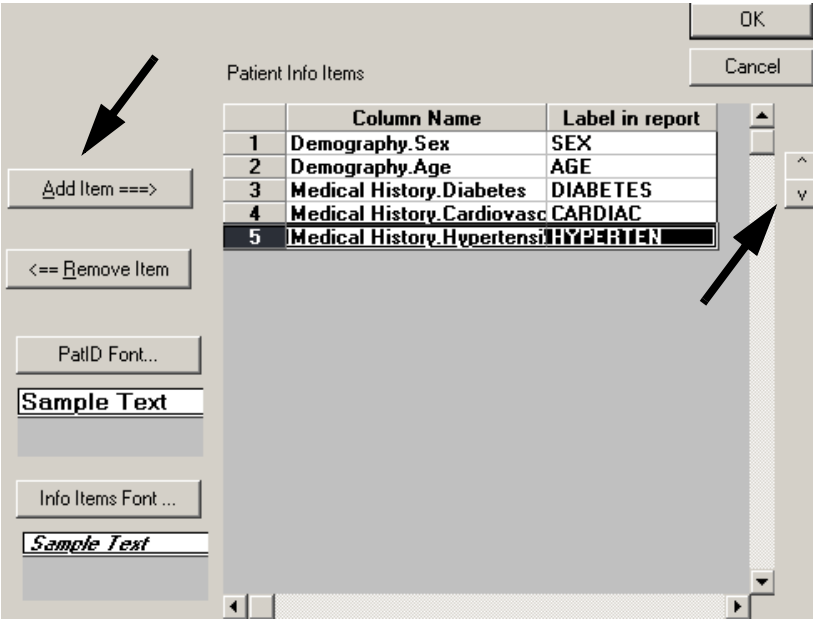
Add Patient Info Items

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

7. Select the panel and item.



8. Click **Add Item** and **Remove Item** to add or remove items from the Patient Info Items list. Use the arrows to change the sort display.
9. Click **PatID Font** and **Info Item Font** to apply fonts for PatID and Info Items.
10. Click **OK.**



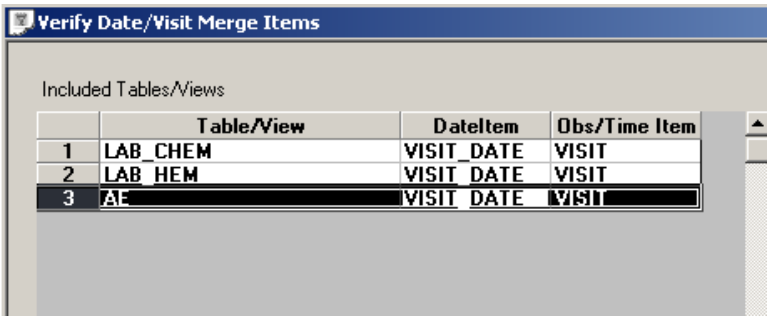
Define Date Merge Settings

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.

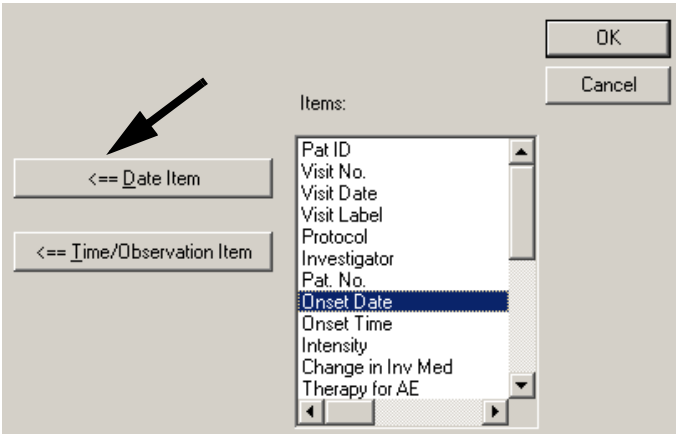
11. Click **Date Merge Settings**.

(This image has been split for display purposes.)

12. Click on the **DateItem** cell. If the panel contains multiple date items the Items list displays.

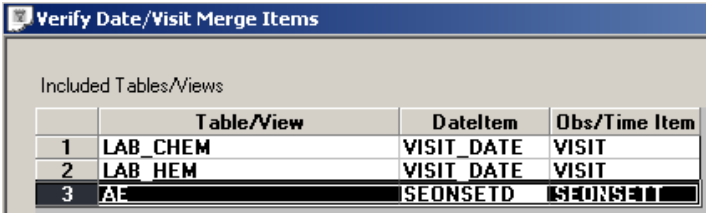


13. Select the preferred date item and click **Date Item** to replace the default Visit Date.



14. If you need to report by an observation or time item, click on the **Obs/Time Item** cell.

15. Select the preferred item. Click **Time/Observation Item** to replace.



16. Click **OK**.

17. Enter a report Heading.

18. Click **Create Report**. *(The image has been split for display purposes.)*

tient Visit Report

	A	B	C	D	E	F	G
	PatID	Date	Visit No.	Glucose	Cholesterol, total	Triglycerides	White Cell C
	2010632201	08-19-1991	1	95	204	149	
	SEX: Male	09-08-1991					
	AGE: 27	09-15-1991					
	DIABETES: No	09-16-1991	4	93	185	184	
	CARDIAC: No						
	HYPERTEN: No						
	2010632204	09-30-1991	1	78	226	125	
	SEX: Female	10-13-1991					
	AGE: 49	10-20-1991					
	DIABETES: No	10-28-1991	4	124	207	139	
	CARDIAC: No						
	HYPERTEN: No						

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.

Patient Visit Report

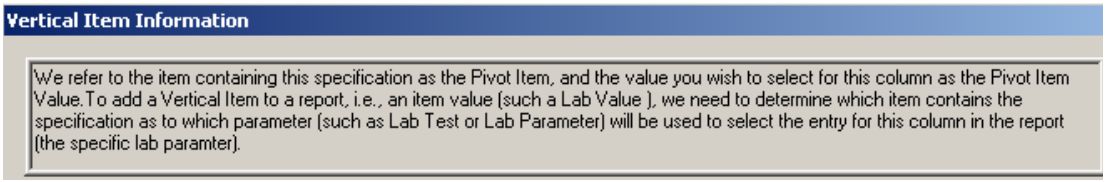
	A	B	H	I	J	K
1						
2	PatID	Date	Hematocrit	Onset Date	Onset Time	AE Coded
165	2010632201	08-19-1991	43.6			
166	SEX: Male	09-08-1991		08-SEP-1991		NER :Headache
167	AGE: 27	09-15-1991		15-SEP-1991	01-JUL-1995 08:00:00	NER :Headache
168	DIABETES: No	09-16-1991	43.6			
169	CARDIAC: No					
170	HYPERTEN: No					
171	2010632204	09-30-1991	41.4			
172	SEX: Female	10-13-1991		13-OCT-1991	01-JUL-1995 07:00:00	RES :Upper respiratory infection
173	AGE: 49	10-20-1991		20-OCT-1991		NER :Headache
174	DIABETES: No	10-28-1991	40.1			
175	CARDIAC: No					
176	HYPERTEN: No					

Add vertical lab

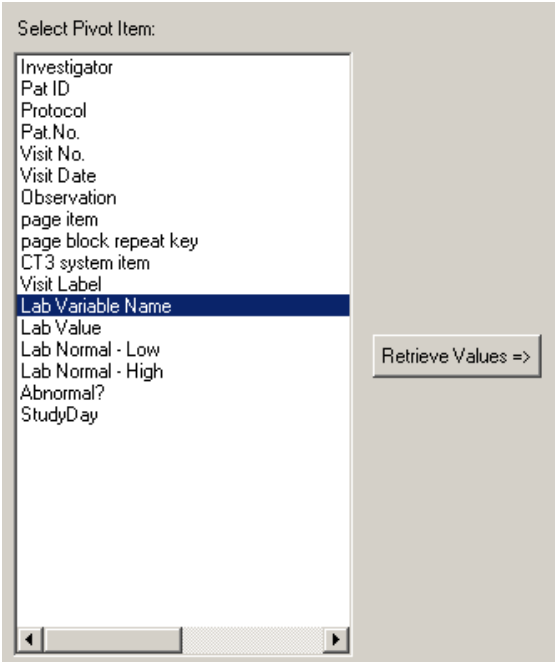
If you have a vertical lab panel and need to access a 'Lab Value' item the 'Add Vertical' button functions to pivot the item. You are able to display a list of all the lab variable names and select the item of interest. The lab item will display a column for the selected lab test to the report while the data is being pulled dynamically from the vertical lab table. Simply repeat the steps to add more lab parameters to the report display.

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

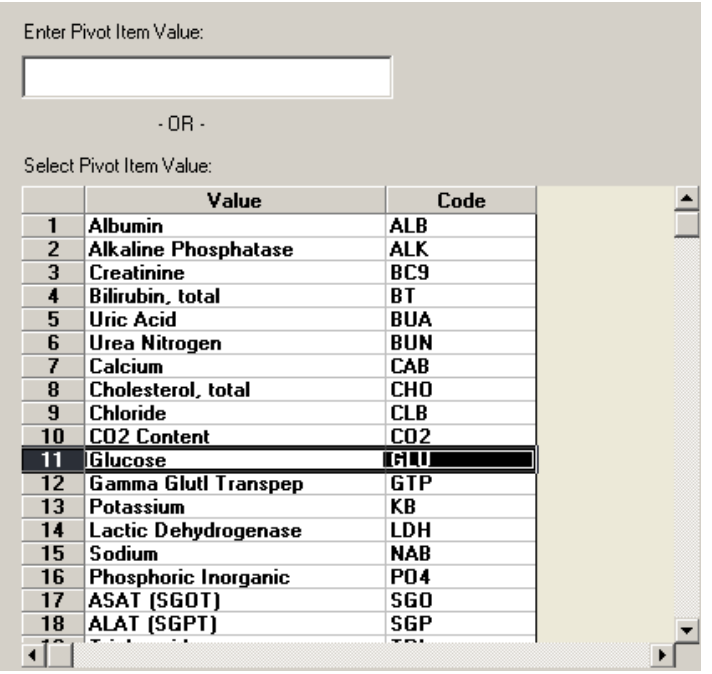
   (The image has been split for display purposes.)



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



4. Select the Pivot Item Value and click ADD Item.



	Value	Code
1	Albumin	ALB
2	Alkaline Phosphatase	ALK
3	Creatinine	BC9
4	Bilirubin, total	BT
5	Uric Acid	BUA
6	Urea Nitrogen	BUN
7	Calcium	CAB
8	Cholesterol, total	CHO
9	Chloride	CLB
10	CO2 Content	CO2
11	Glucose	GLU
12	Gamma Glutl Transpep	GTP
13	Potassium	KB
14	Lactic Dehydrogenase	LDH
15	Sodium	NAB
16	Phosphoric Inorganic	PO4
17	ASAT (SGOT)	SGO
18	ALAT (SGPT)	SGP

5. Repeat steps to add more lab parameters to the report.

	A	B	C	D	E	F	G	H
Col.Head 1								
Col.Head 2	PatID	Date	Glucose	Cholesterol	Sodium	Potassium	Chloride	CO2 Conte
Sort Order	1	2						
Row results								
Warn -Low								
Warn -High								
Panic-Low								
Panic-High								
Include? prompt								

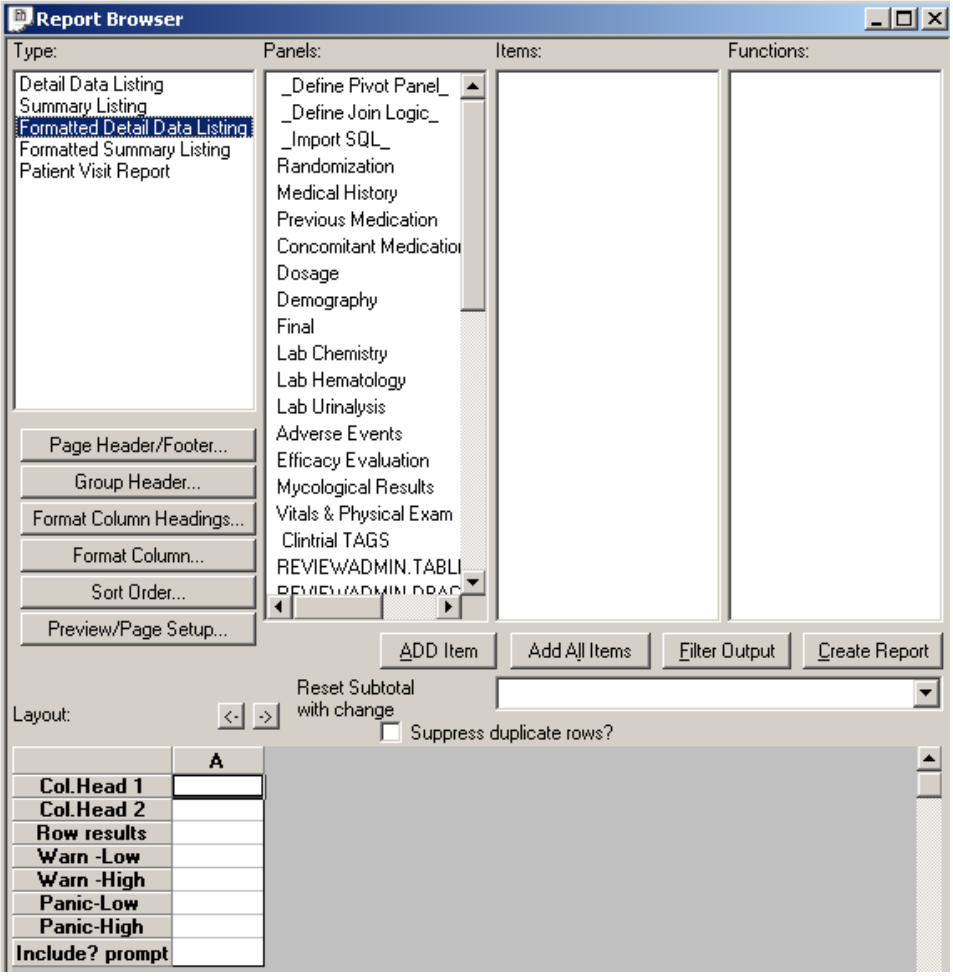
6. After adding all your items to the report template, apply additional report options for patient information, formats and date merge settings.
7. Enter a report Heading.
8. Click **Create Report**.

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:

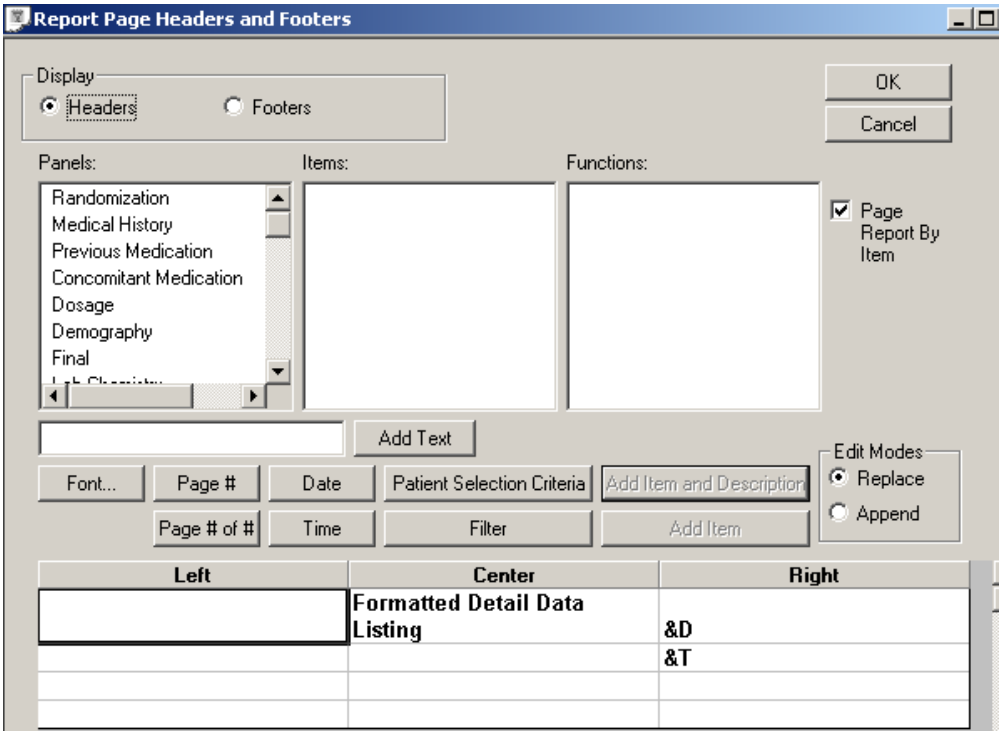
- Font is Arial.
- Page Setup for landscape with one inch margins.



Apply Page Header and Footer

To enter descriptive information to the Header and Footer area:

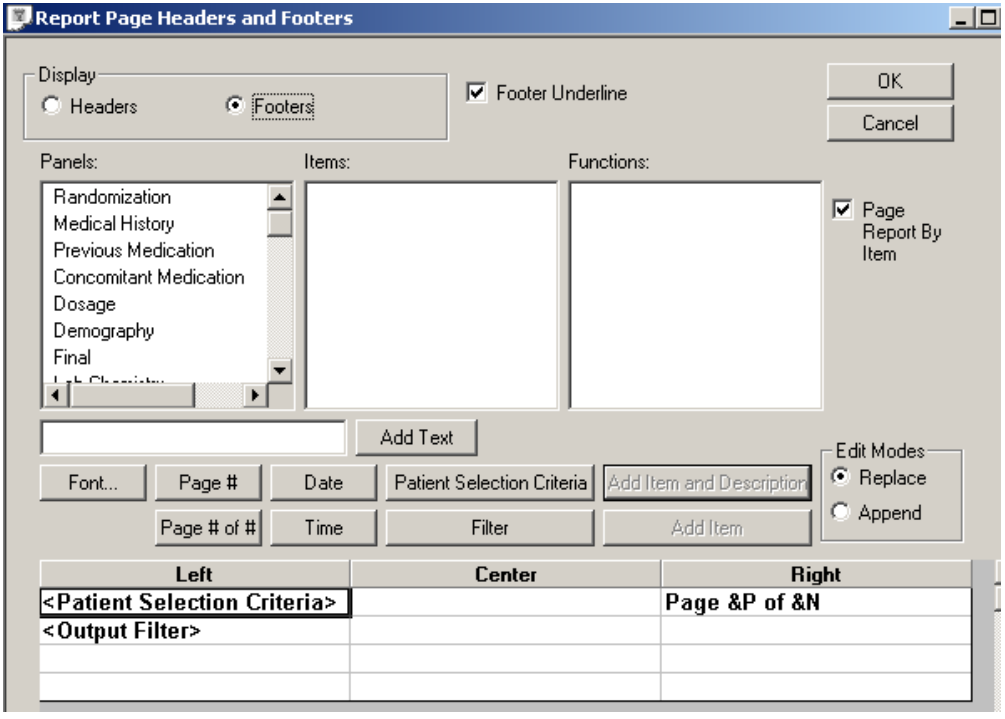
1. Click on the Page Header / Footer button to open Report Page Headers and Footers window. The default settings for headers are:
   a. Default title is the report type displayed in the center cell as Formatted Detail Data Listing or Formatted Summary Listing.
   b. Date and Time on the right.
   c.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



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.

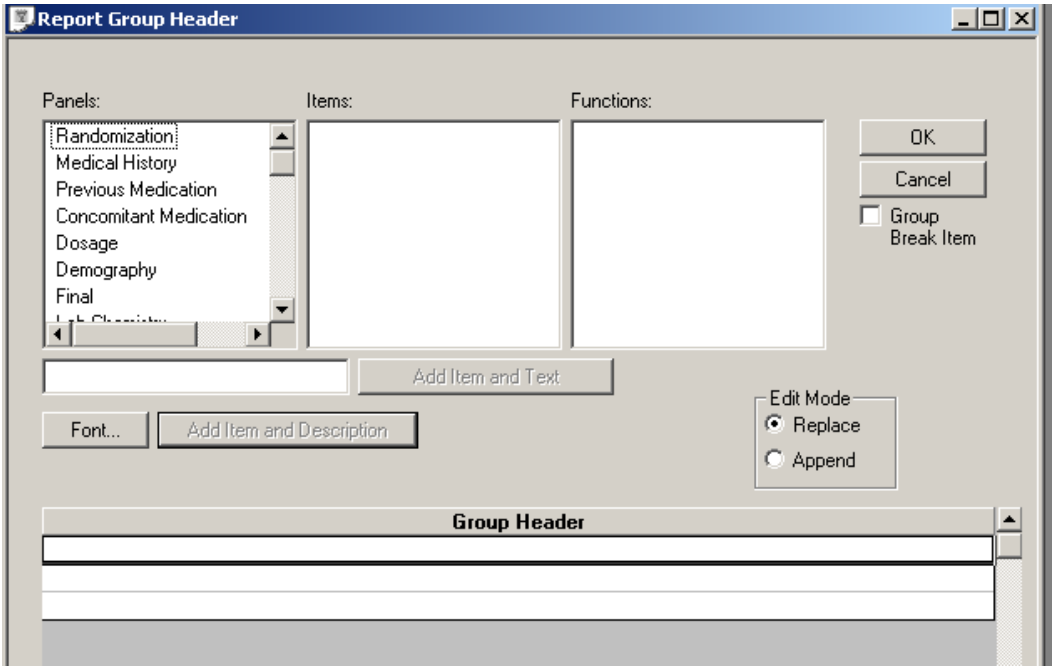
6. Click the Font button to change font, style and size.
7. Click Display Footers. Follow the same steps to enter and make changes to the footer. The default settings for footers are:
   a. Patient Selection Criteria and Output Filter on the Left.
   b. Page number on the right.
   c. Underline above the footer.
   d. Font is BOLD **10**.
8. Turn the Footer Underline ON or OFF.



Enter a Group Header

The default setting for this function is font BOLD 10. There is a maximum of 4 group headers consisting of 3 rows each.

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



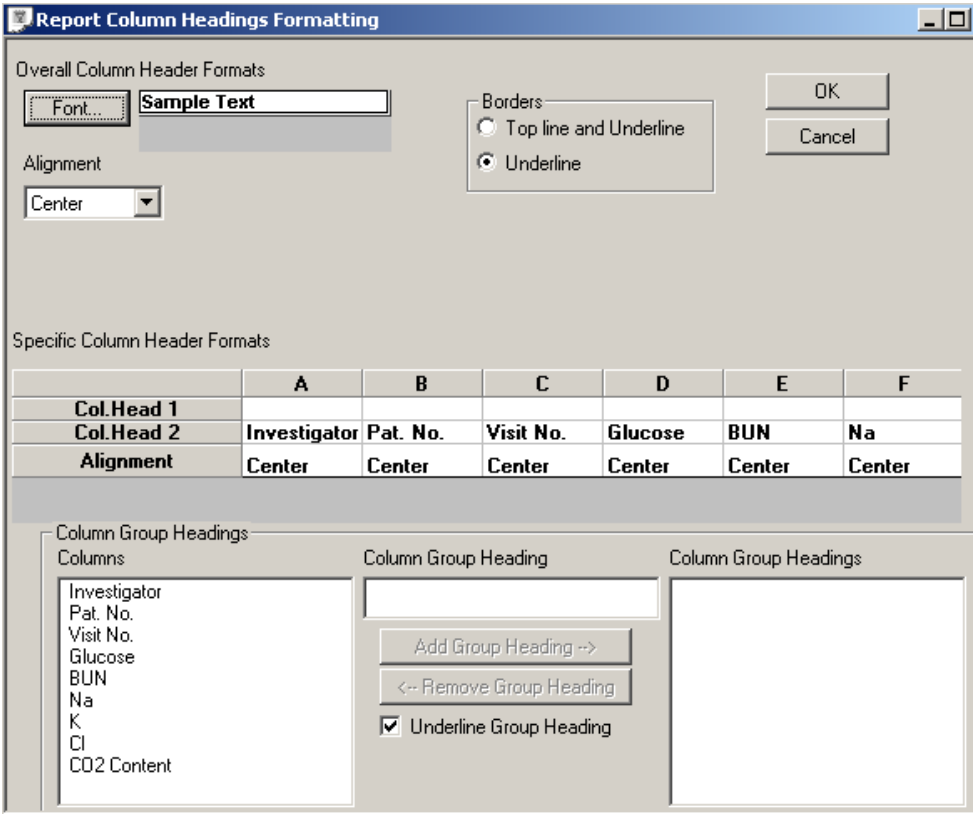
2. Click the Font button to change font, style and size.
3. Use the Add Item and Text button to enter items. If you do not enter a free text description, the item will be added alone without text or description. Text cannot be added alone without an item. You may click on a row and use the scissors icon to delete the contents.
4. Enter panel and item selection to the Group Header with the Edit Mode buttons to Replace or Append changes.

   Note:One item must defined as the Group Break item.

Format Column Headings

To open the Report Column Headings Formatting window click on the Format Column Headings button. The default settings for all column headings are:

- Font is BOLD **8.**
- Alignment - Center.
- Borders set to Underline and Underline Group Heading is ON.



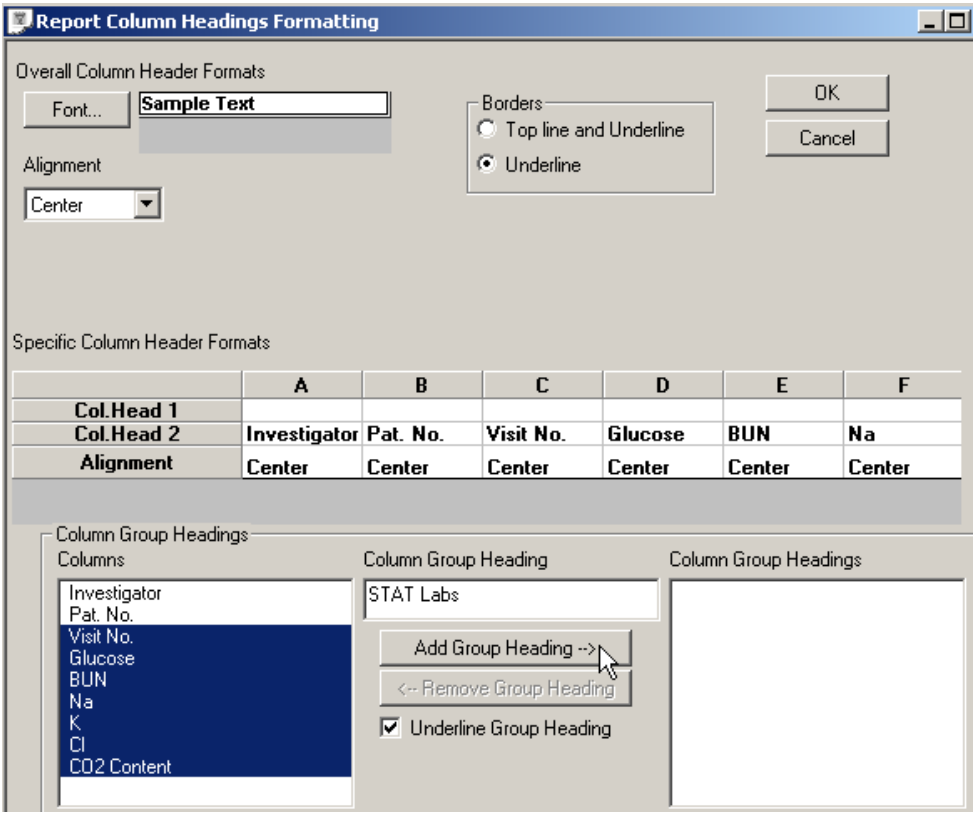
To apply Overall Column Header Formats:

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

Note: 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:

1. Highlight the items you want included in the group.
2. Click Add Group Heading.
3. 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.
4. Enter a Column Group Heading.
5. Click box to Underline the Group Heading.

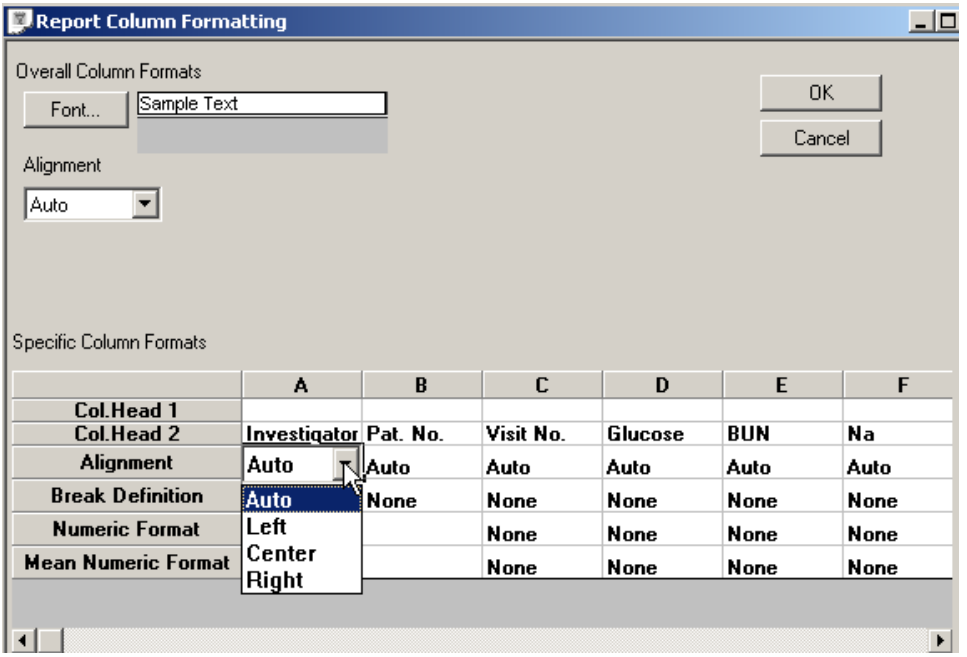


To open the Report Column Formatting window click on the Format Column button. The default setting alignment is automatic based on the data type. Break definition is set to none and font is regular **8.**

- 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.

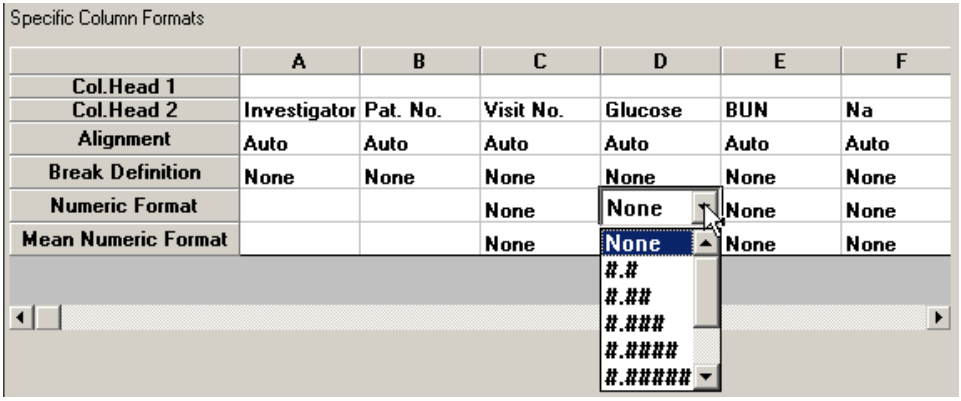
- Click the Alignment drop down list to align the item display for auto, left, center, or right.
- Click the Break Definition drop down list for None, Skip line, Underline, Page.

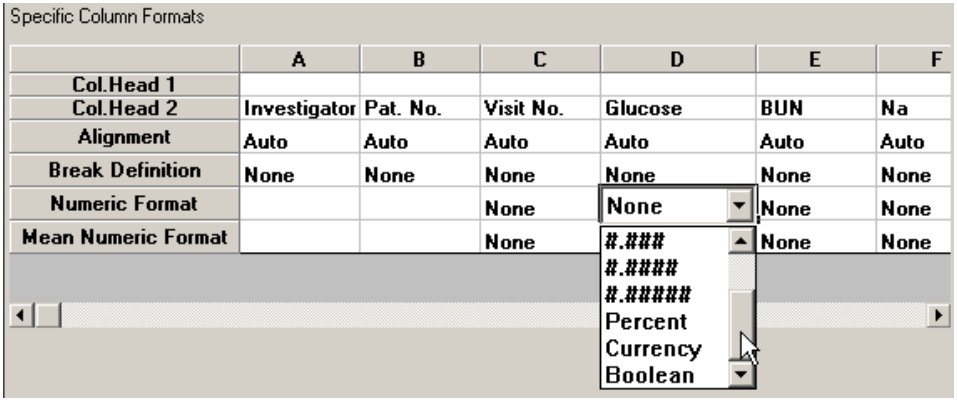


- Click the Numeric Format drop down list for any numeric item included as a column in the report.

  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%.

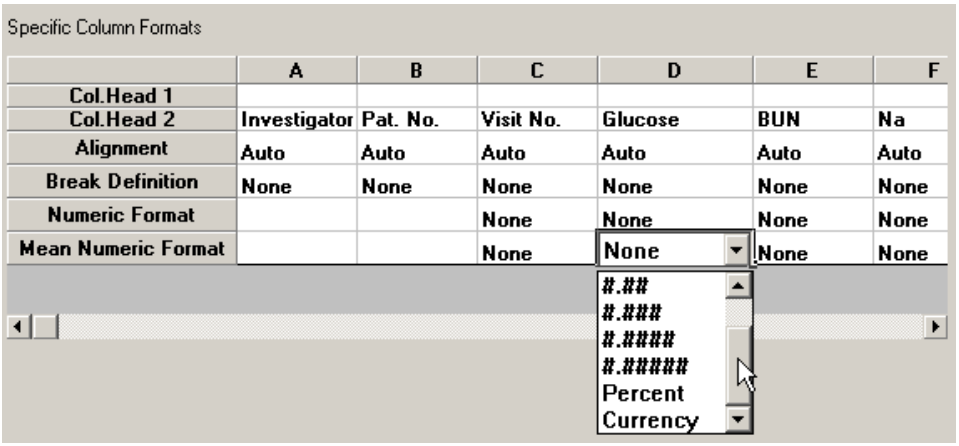
  The Boolean numeric format would be used on a calculated field where '0=False' and all other numeric values will display as 'True'.





The numeric formatting is also available for Change from Baseline and %Change from Baseline items.

- Click the Mean Numeric Format drop down list for any row result defined as Mean, Mean at Change or Mean at Change and Mean.

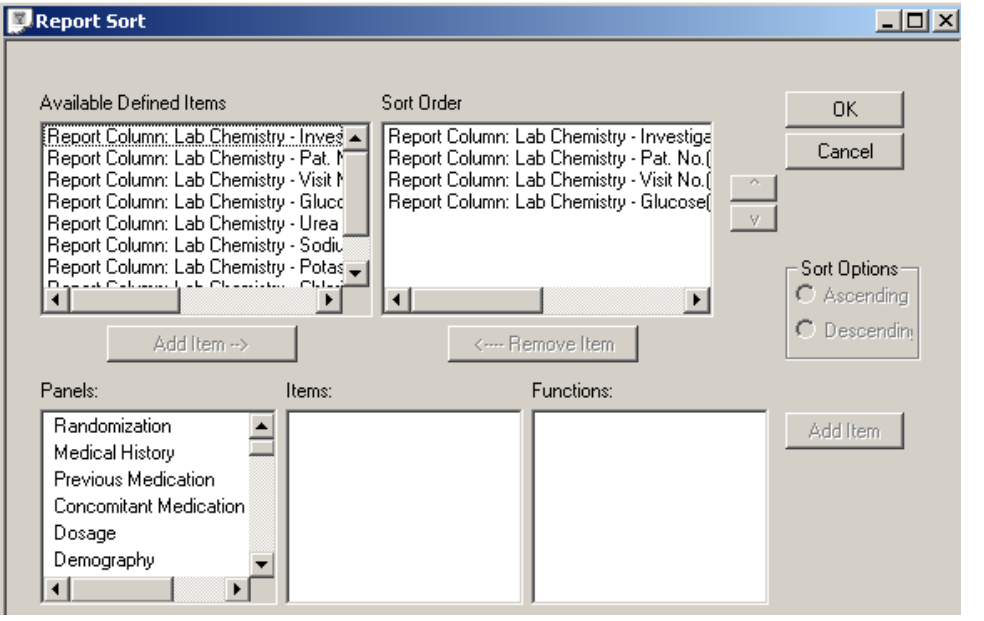


Sort Order

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.

Preview/Page Setup

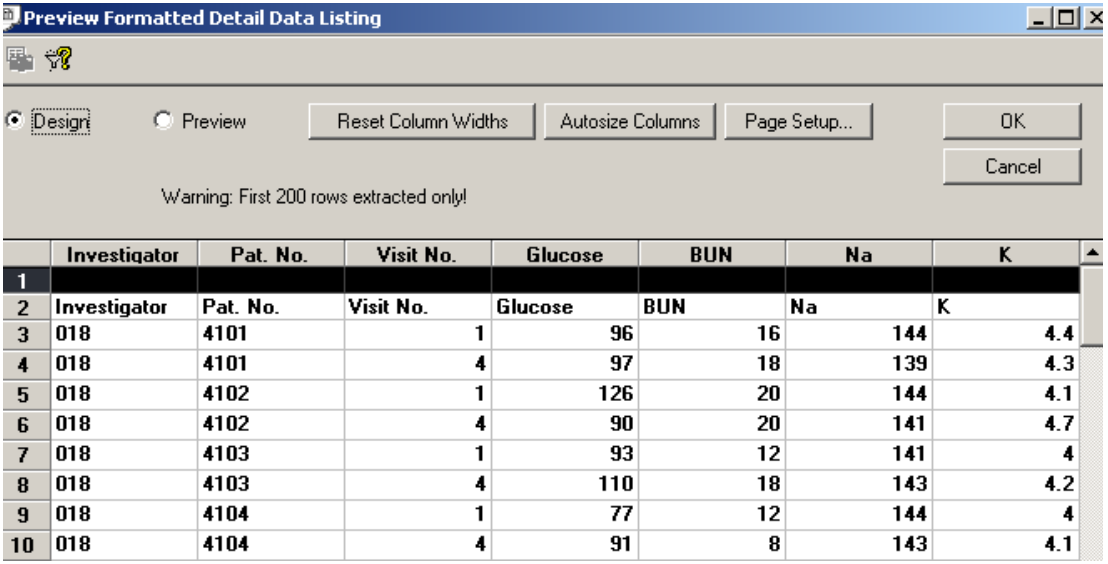
Click Preview / Page Setup to view the Design window or to Preview the report. Both the Design and Preview functions allow you to view the first 200 records only from the database to determine column widths and page setup for orientation and margins. This function is specific to formatted reports only.

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

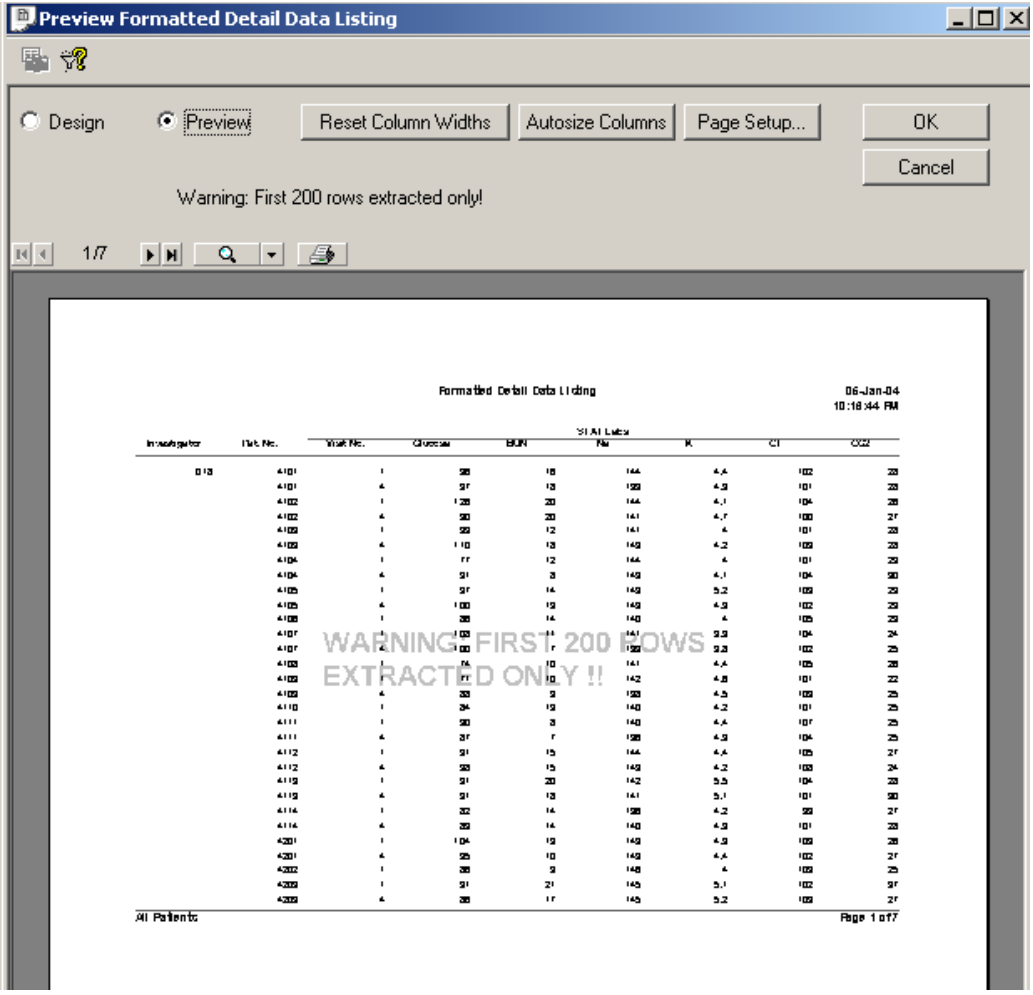
The default display is landscape and the settings are maximum column width of one inch. The width is set to fit all columns on a page depending upon the number of columns in the report.

- 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.

Note: 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.



	Investigator	Pat. No.	Visit No.	Glucose	BUN	Na	K
1							
2	Investigator	Pat. No.	Visit No.	Glucose	BUN	Na	K
3	018	4101	1	96	16	144	4.4
4	018	4101	4	97	18	139	4.3
5	018	4102	1	126	20	144	4.1
6	018	4102	4	90	20	141	4.7
7	018	4103	1	93	12	141	4
8	018	4103	4	110	18	143	4.2
9	018	4104	1	77	12	144	4
10	018	4104	4	91	8	143	4.1

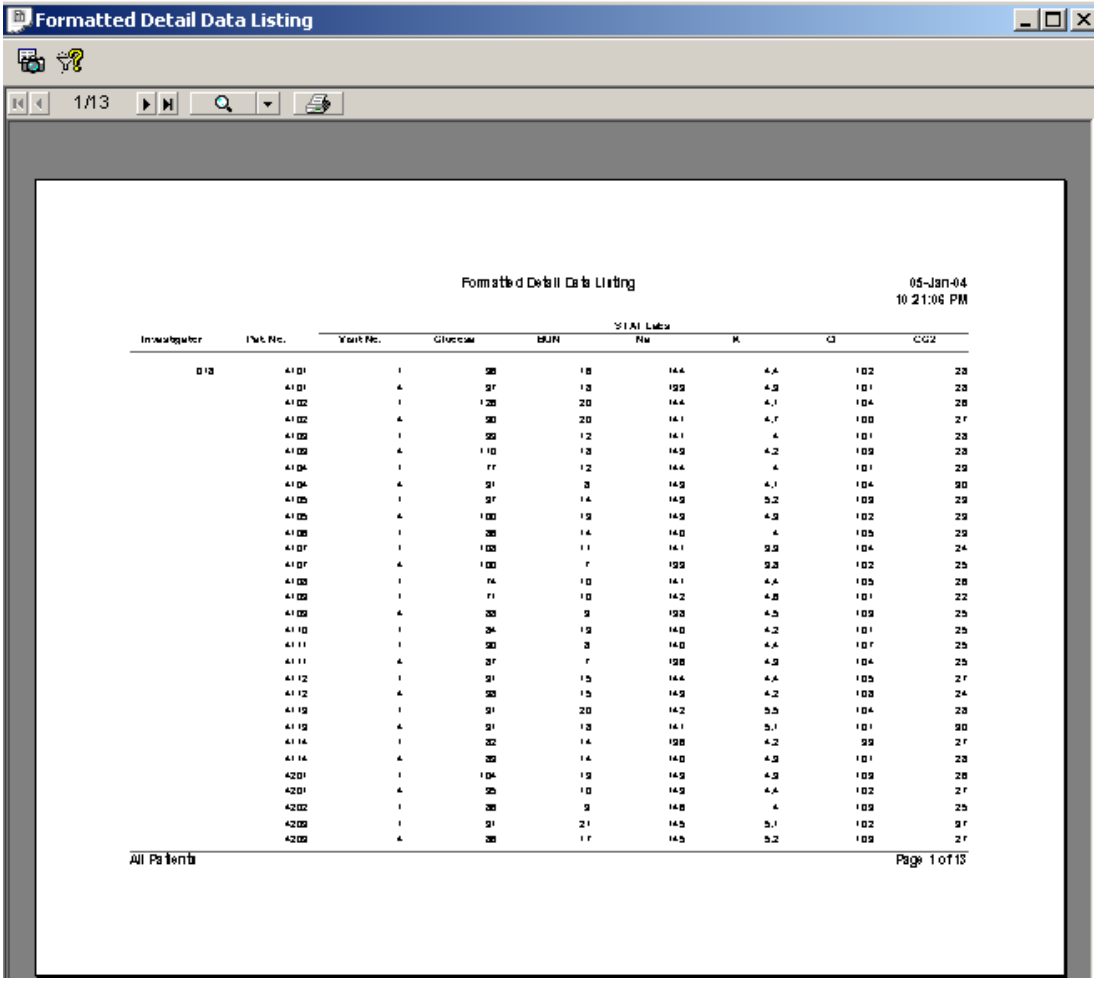


The page you are currently viewing and the total number of pages for the first 200 records in the report are displayed with arrows to move through the listing. Use the magnify button to enlarge the report preview display. You may use the Printer icon to print a sample of the first 200 records of the report from the Preview window.

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.

Create formatted report

You must Create Report to view and print the entire records contained in you report. Click **OK** in the Preview window and return to the Report Browser window. Click **Create Report**. Use the tool bar buttons to scroll through the pages or change the image scale.



Exporting and printing report results

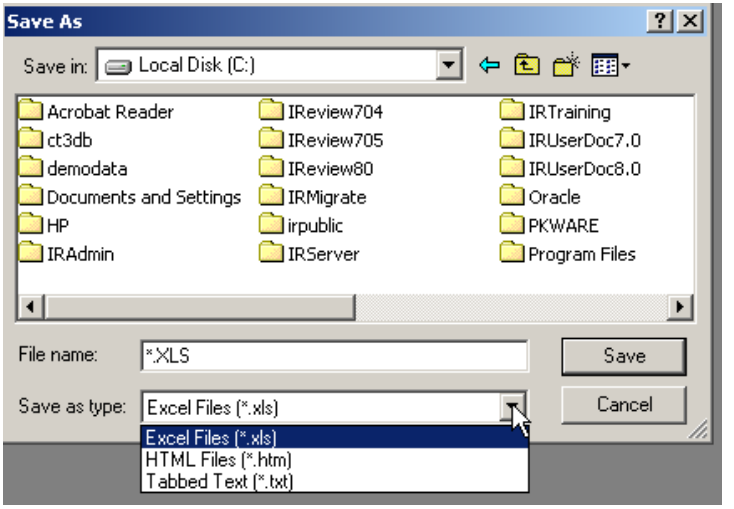
Exporting the report

Export your report in Excel 4, 5 and 7, tab delimited files, HTML format and PDF files.

1. The created report window must be the active window. From the **File** menu, select **Export**.

   Review displays the **Export Save As** window.

Note: Only Formatted Report types can be exported to PDF files. Non-formatted reports can only be exported to Excel and HTML.



2. Enter the storage location.
3. Enter the File name.
4. Enter the format type.
5. Click **Save**.

   The report is exported to the currently selected disk directory. (See *Chapter 12: Common Topics: Export Browser Display Spreadsheets; Copy and Paste Browser Results; Copying to Clipboard*)

Print Preview

You can use the Print Preview for the Detail Data Listing and Summary Listing only.

Note: Formatted Reports must use the Preview/Page Setup button under the formatting functions.

To display a print preview of your non-formatted 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 report

To print your report:

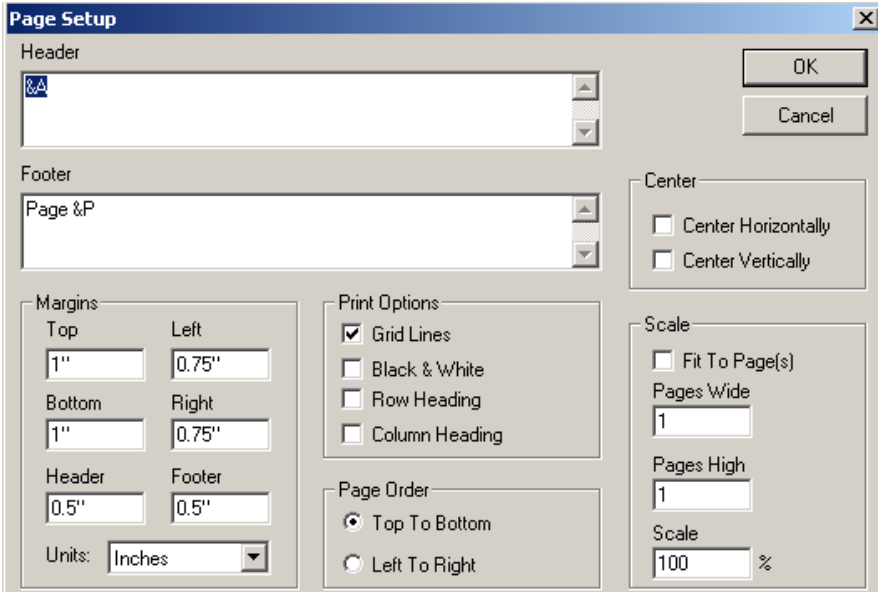
1. Click , or from the **File** menu, select **Print**.

   Review displays the standard print dialog box.
2. Click **OK**. The report prints on the currently selected printer.

Page Setup

The default printed report contains the report heading as you entered it, the current Filter Condition, the current patient selection criteria, and a page number as the footer.

Page setup can be accessed by going to the **File** menu, and selecting **Page Setup**. Review displays a standard page setup dialog box option for you to make changes.

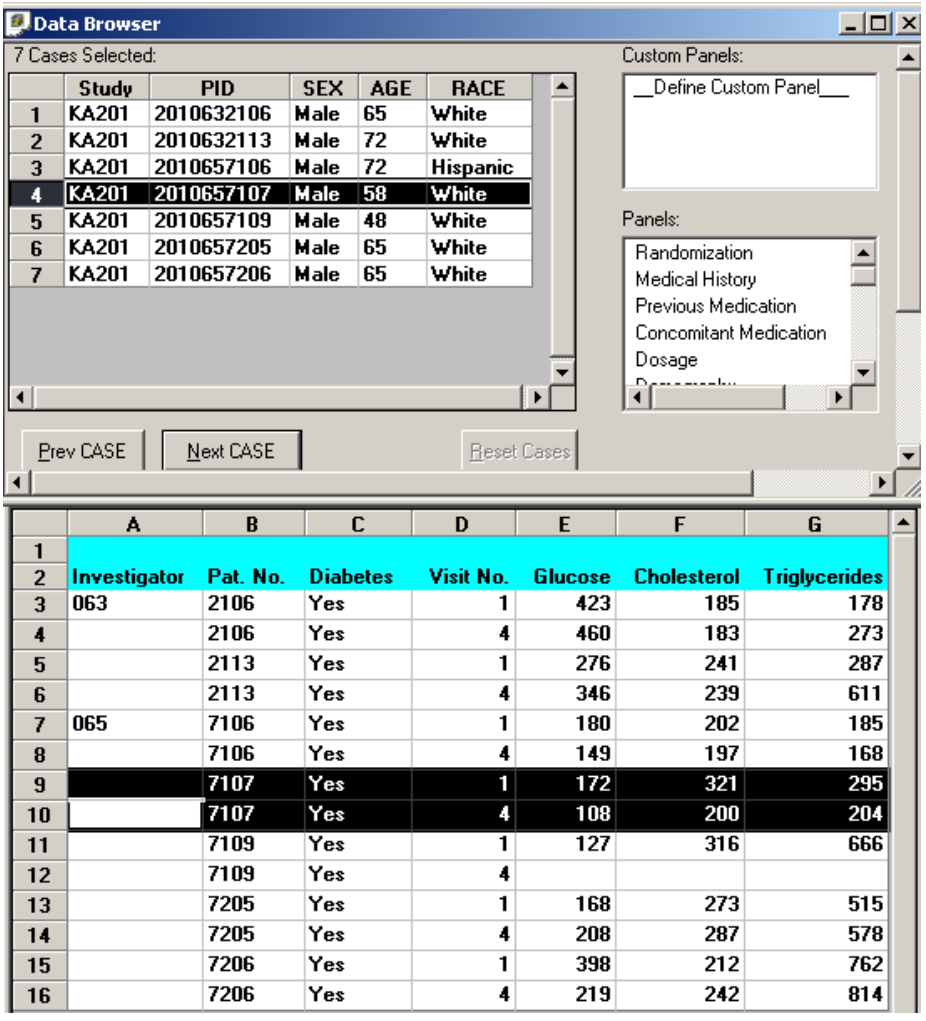


Highlighting patients

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.

Note: Formatted reports are not interactive with the Data Browser and do not highlight and support drilldown links with other browsers.

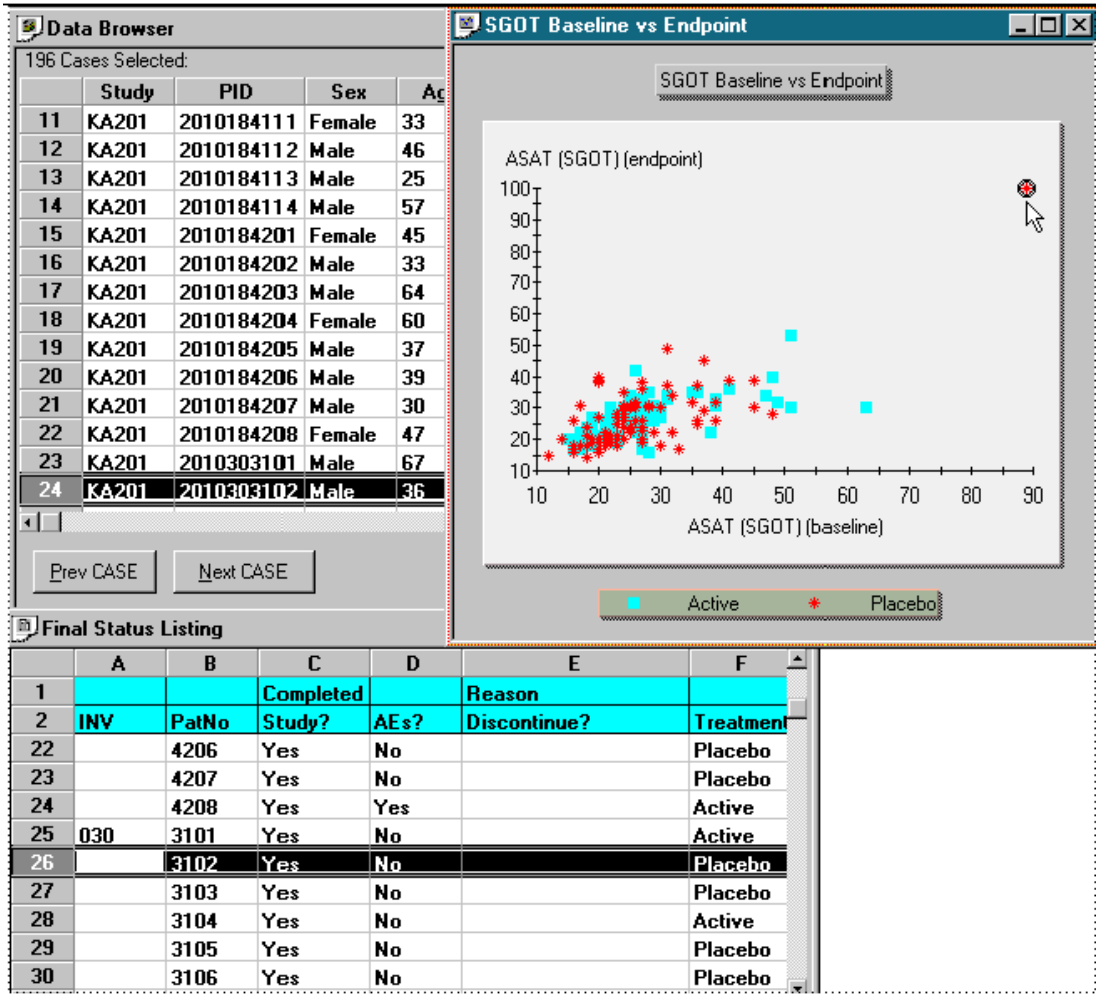


	Study	PID	SEX	AGE	RACE
1	KA201	2010632106	Male	65	White
2	KA201	2010632113	Male	72	White
3	KA201	2010657106	Male	72	Hispanic
4	KA201	2010657107	Male	58	White
5	KA201	2010657109	Male	48	White
6	KA201	2010657205	Male	65	White
7	KA201	2010657206	Male	65	White

	A	B	C	D	E	F	G
1							
2	Investigator	Pat. No.	Diabetes	Visit No.	Glucose	Cholesterol	Triglycerides
3	063	2106	Yes	1	423	185	178
4		2106	Yes	4	460	183	273
5		2113	Yes	1	276	241	287
6		2113	Yes	4	346	239	611
7	065	7106	Yes	1	180	202	185
8		7106	Yes	4	149	197	168
9		7107	Yes	1	172	321	295
10		7107	Yes	4	108	200	204
11		7109	Yes	1	127	316	666
12		7109	Yes	4			
13		7205	Yes	1	168	273	515
14		7205	Yes	4	208	287	578
15		7206	Yes	1	398	212	762
16		7206	Yes	4	219	242	814

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:

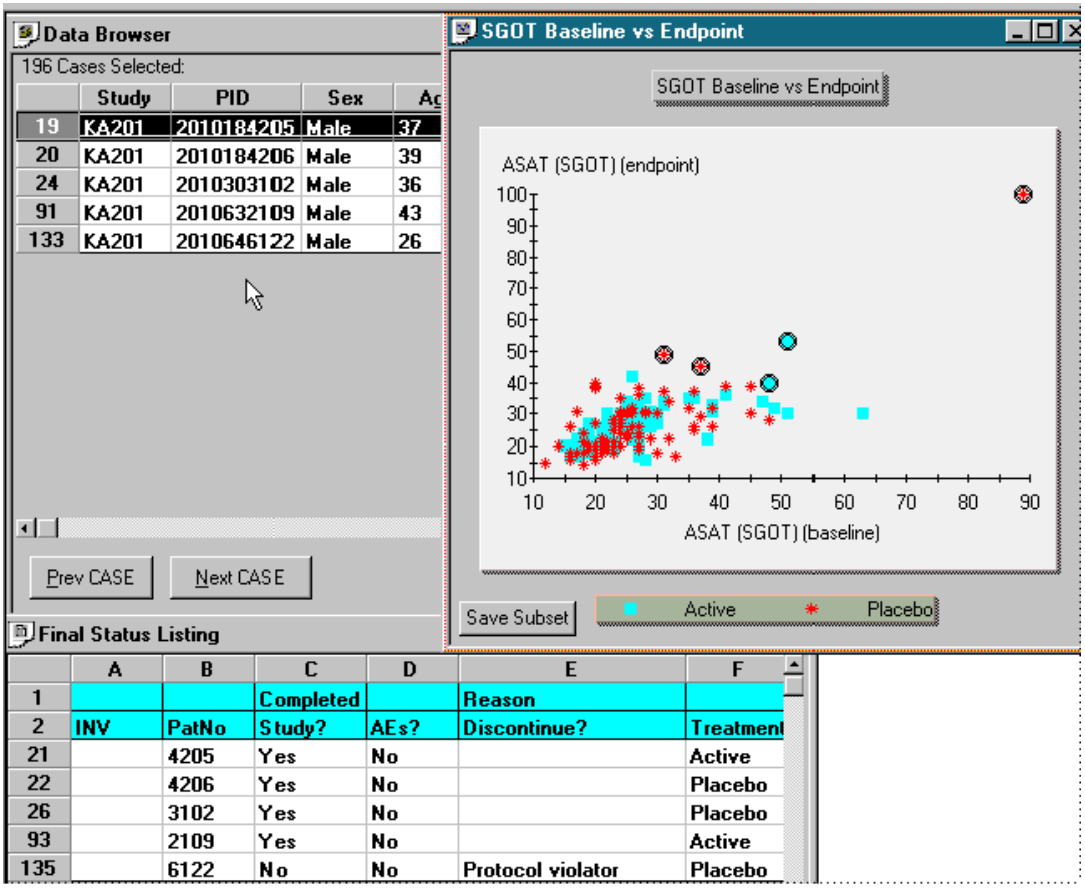
In an active scatter graph the selected patient's data point is highlighted.



In an active Multi-Line Chart Item Value vs. Category by Case graph, a highlighted line within the graph will update all patient-level displays of data to highlight the patient underlying the case data.

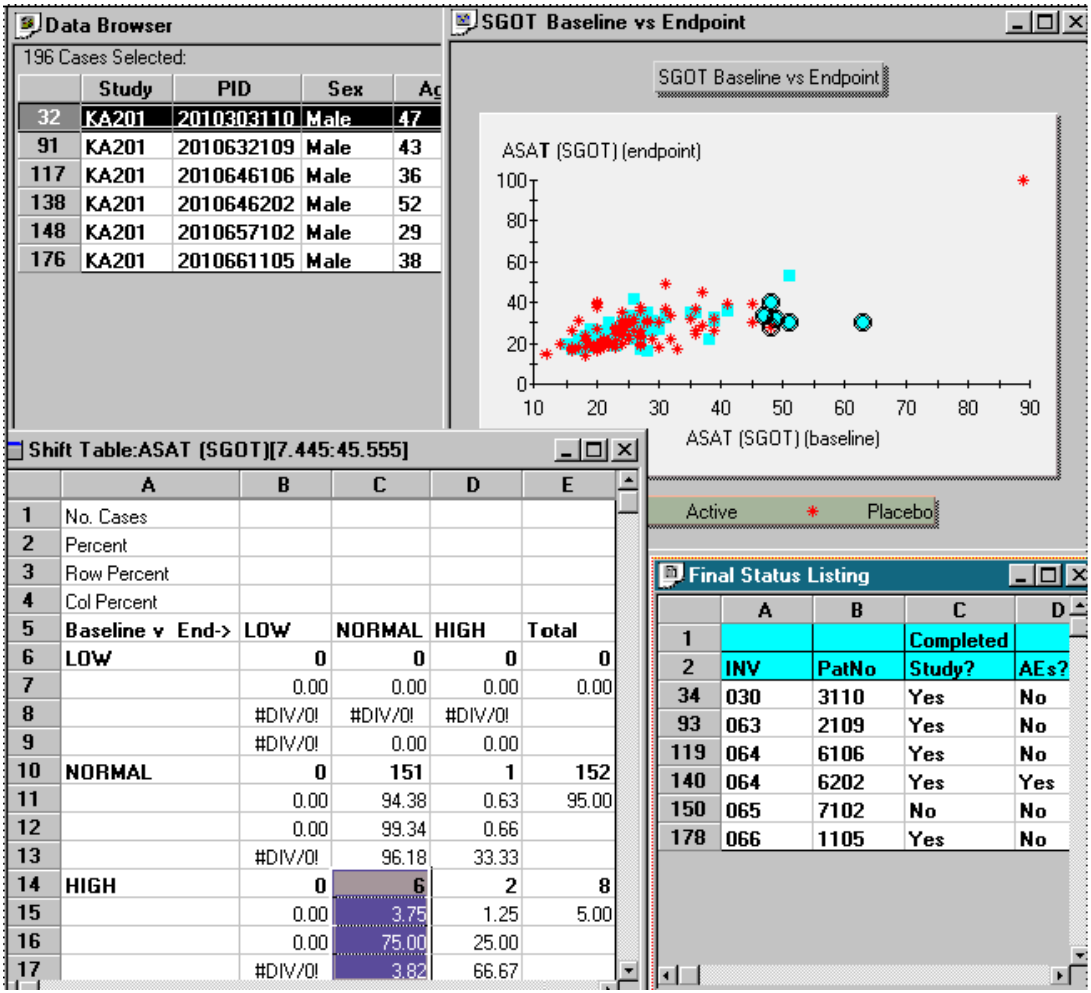
Multiple-patient mode

When multiple patients are highlighted and selected from any patient-level display of data, the Detail Data Listing Reports are updated to display only the patients that are highlighted and selected. (See *Chapter 6 Graph: 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
196 Cases Selected:
Study PID Sex Ag
32 KA201 2010303110 Male 47
91 KA201 2010632109 Male 43
117 KA201 2010646106 Male 36
138 KA201 2010646202 Male 52
148 KA201 2010657102 Male 29
176 KA201 2010661105 Male 38
SGOT Baseline vs Endpoint
SGOT Baseline vs Endpoint
ASAT (SGOT) (endpoint)
100
80
60
40
20
0
10 20 30 40 50 60 70 80 90
ASAT (SGOT) (baseline)
Active
Placebo
Shift Table:ASAT (SGOT)[7.445:45.555]
A B C D E
1 No. Cases
2 Percent
3 Row Percent
4 Col Percent
5 Baseline v End-> LOW NORMAL HIGH Total
6 LOW 0 0 0 0
7 0.00 0.00 0.00 0.00
8 #DIV/0! #DIV/0! #DIV/0!
9 #DIV/0! 0.00 0.00
10 NORMAL 0 151 1 152
11 0.00 94.38 0.63 95.00
12 0.00 99.34 0.66
13 #DIV/0! 96.18 33.33
14 HIGH 0 6 2 8
15 0.00 3.75 1.25 5.00
16 0.00 75.00 25.00
17 #DIV/0! 3.82 66.67
Final Status Listing
A B C D
1 Completed
2 INV PatNo Study? AEs?
34 030 3110 Yes No
93 063 2109 Yes No
119 064 6106 Yes No
140 064 6202 Yes Yes
150 065 7102 No No
178 066 1105 Yes No

Object Storage: saving your work

Finalize output specification

When the report layout contains the necessary information and all editing is complete, you can save the report specification for future use.

Note: The data in your report contains only data from those patients who meet your current patient selection criteria and/or report output filter criteria.

All saved reports with output filters on are saved with the filter specifications respectively. If you have an active filter on when the report specifications are saved, you will have that same active filter on when the saved specifications are relaunched.

Object storage location

The output specification can be stored at four user access levels: Private, WorkGroup, UserGroup, or Public.

- Private storage is at the local PC level.
- WorkGroup storage is PC based and stored at a shared network drive, to which a select group of personnel would have access.

Note: The WorkGroup storage location was supported in earlier Review releases. UserGroup storage location is used extensively for later releases.

- UserGroup storage is a database object storage for defined UserGroups in the configuration tables.

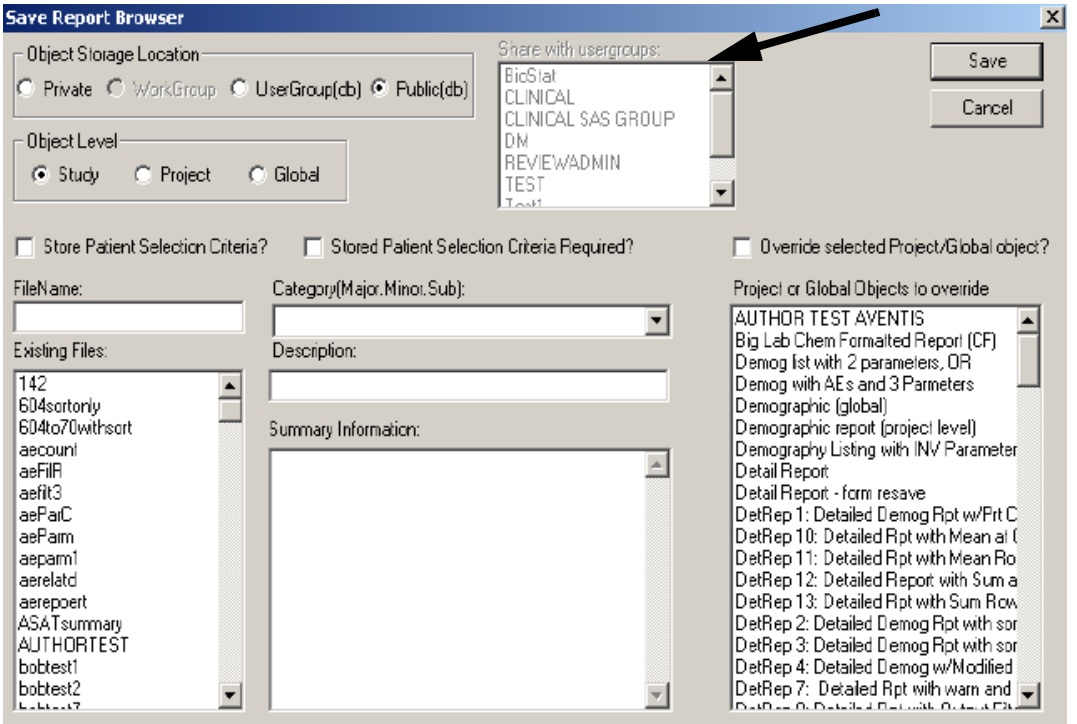
  Object storage in UserGroup level allows you to specify sharing with multiple UserGroups. This works when you click UserGroup and you are a member in a UserGroup, then the UserGroup listbox is enabled. If you want to share the object with multiple UserGroups, simply use the CTRL or SHIFT mouse click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

Saving on database object storage sites, requires the author to have "Publishing Authorization" defined in the configuration tables. (See *Chapter 12: Common Topics: Shared Object Storage- Locations)*

Object level

You can store your output specification at three levels: Study, Project, or Global. The Object Level box is only enabled and highlighted when you select an Object Storage Location designated as 'db' for database. Therefore, when you select either UserGroup or Public for database object 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.



When you select the UserGroup object storage location, the 'Share with usergroups' listbox is made available for selection.

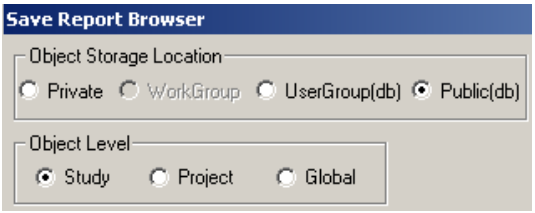
Save the object specification

To save the report specification you have created for later use:

1. You can save your report specification with either the Report Browser window or the Report Output window as the active window.

   If the Report Output window is the active window, then the font, color, alignment, borders and shading will be stored with the report specification.

2. Click , or from the **File** menu select **Save.**
3. Review displays the Save Report Browser window where you can specify the storage location. Select an object storage location.

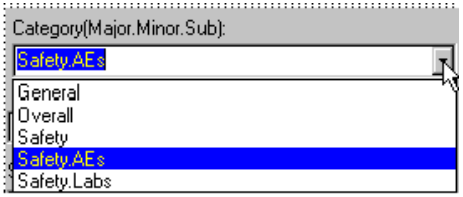


Note: In the example, when UserGroup is selected the 'Share with usergroups:' box is enabled allowing you to select other usergroups to share access with the object specification. Use the CTRL or SHIFT key to make multiple selections.

4. Select object level type. The default is Study.
5. Click **Store Patient Selection Criteria** 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. If the particular patient selection criteria is specific and required for the output, click **Patient Selection Criteria required**. In this instance, the patient selection criteria cannot be modified when this stored object specification is selected. If none selected, then no patient selection criteria is saved with the output specification.

6. Enter a FileName for future reference to be displayed in the list box for Existing Files. The Filename is for internal use and not displayed in the Object Explorer window.

7. 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 listbox.

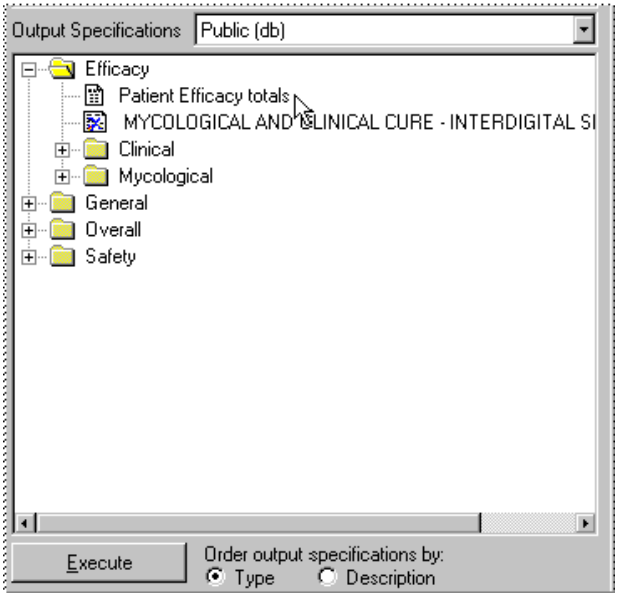


8. Next enter the appropriate description which is displayed in the Object Explorer window.
9. You can include summary information for future reference to be viewed by yourself or others later.
10. Click **Save**.

Review stores the output specification to the designated PC, WorkGroup, UserGroup, or Public storage location.

Note: Any place where the output filter is turned on, the output filter criteria is saved with the browser specifications and will be active when the saved output specification is opened at a later date.

Once you have saved your output specification and assigned folder information, your stored object will display in the Object Explorer window under Output Specifications.



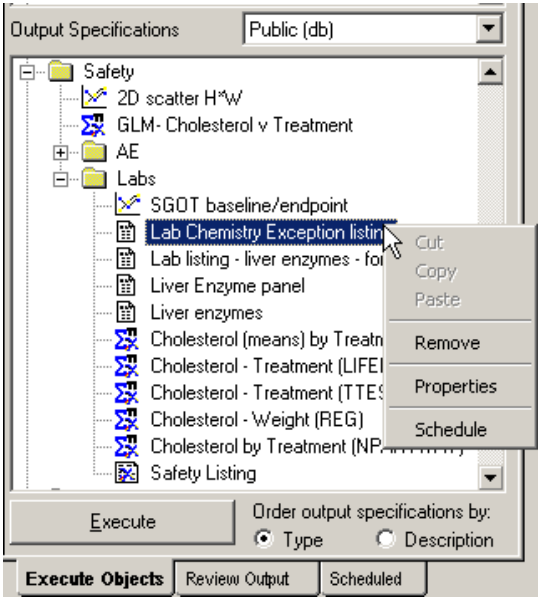
Review displays a list of folders for previously saved output specifications at the selected storage location. Simply select one of the storage locations as Private, UserGroup or Public to display it's specific folders and contents.

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.

Saved objects and their associated icons can be sorted to display in their folders by icon type or description. Simply click sort **by Type** or **by Description**.

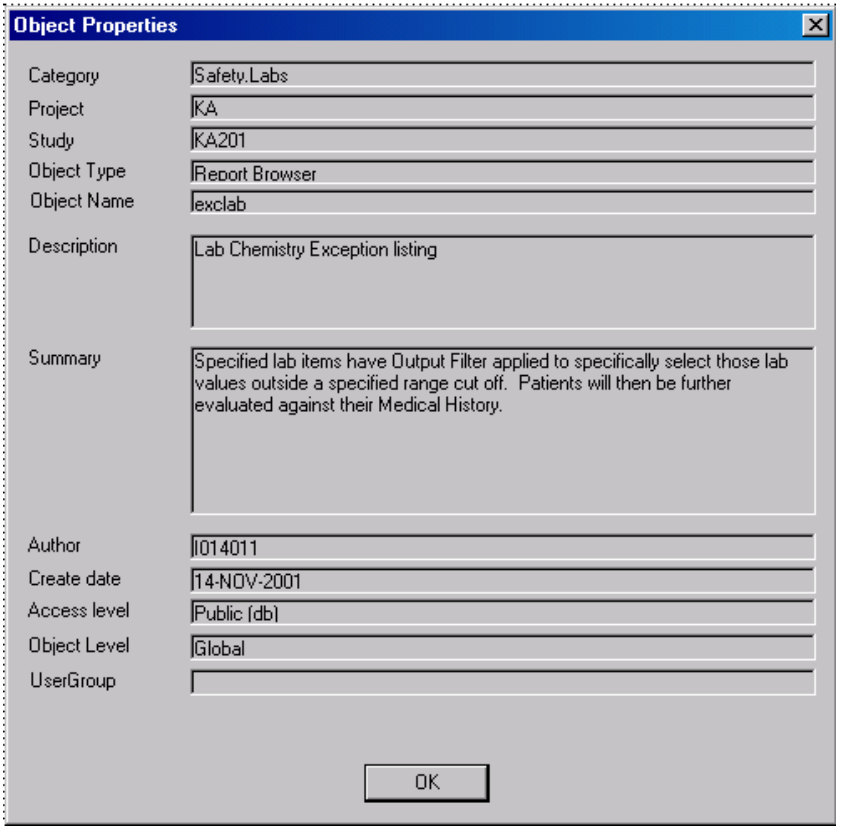
You can view information about an object when you select “Properties”.

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



3. Then click **Properties**. The Object Properties window displays the object properties for the output object.

   It works for ‘Private’, ‘Workgroup’, ‘UserGroup’ or ‘Public’ objects equally.



Print stored object specification

To print the currently active report specification, make certain that the Report Browser window is active by clicking on.

1. Click **Print**, or from the **File** menu, select **Print**. Review displays the standard print dialog box.
2. Click **OK**.
3. To change the printer, select **Print Setup** from the **File** menu.

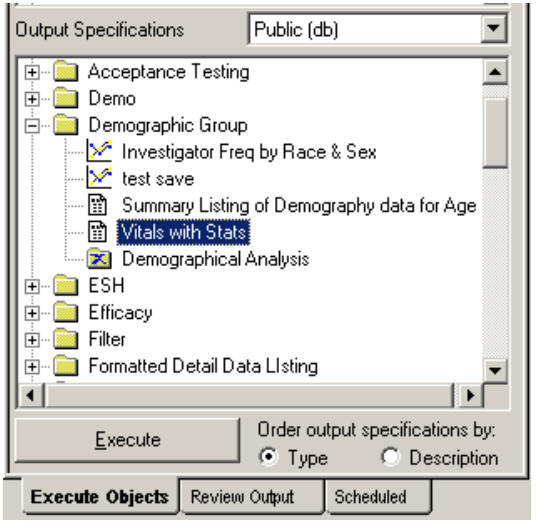
Repeat column headers are printed on each page in printout.

Object Explorer quick execute

The Object Explorer window aids users to quickly locate and immediately launch previously saved objects stored within organized folders. This shortcut allows users to bypass opening the individual browsers to launch saved objects.

If you want to retrieve a saved output specification:

1. Double click to open a folder.
2. Click on the output specification and click **Execute**. Your stored output specification is launched.



If you want to apply a saved patient selection criteria to your output specification:

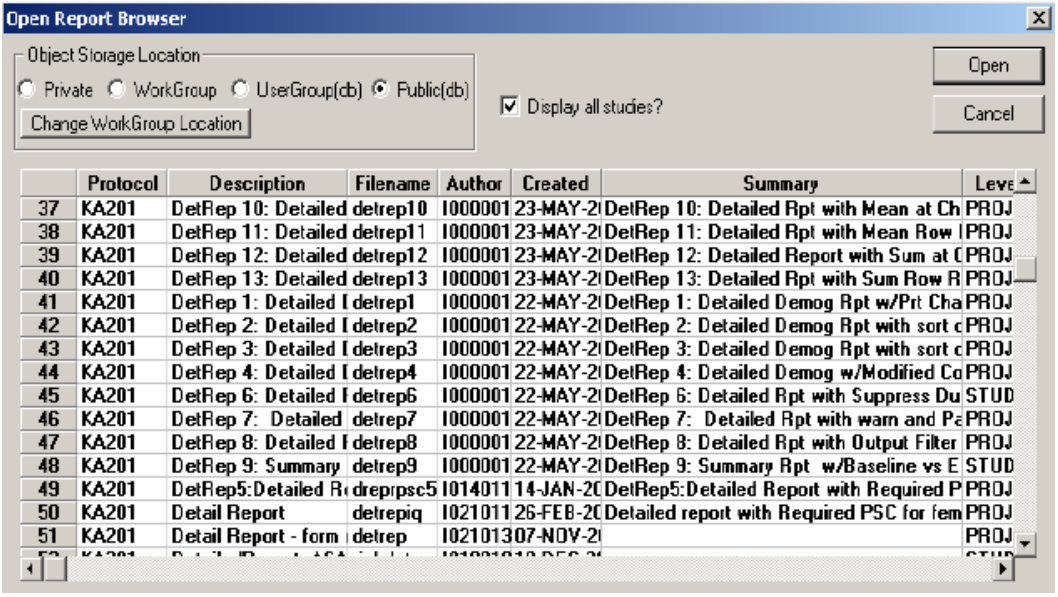
1. Double click to open a folder.
2. Double click to paste the selected patient selection criteria into the Patient Selection Criteria Window. Then follow the above steps to retrieve and execute a stored output specification. Or create your own selection criteria for a stored output specification.

Retrieve stored specification from file menu

Another way to retrieve previously saved object specification from the Report Browser:

1. Make the Report Browser the active window.
2. Select the File menu, click **Open**. Review displays the Open Report Browser window.
3. Select the object storage location to list stored report specifications.
4. Select a report description and click the **Open** button or double click on the report description.

Note: You must use the Open Report Browser window to access the object storage location for 'WorkGroup'.



   a. If you want to browse and / or select a file from the WorkGroup, UserGroup or Public storage sites, click on the site and the files available to you are displayed in the following window.

   b. Click **Change WorkGroup Location**, and you are enabled to browse various report object storage sites.

5. You can browse through the report specification by reviewing the summary text. Click on the report specification, and click **Open**. Review pastes the report layout specifications into the layout spreadsheet, clearing the current spreadsheet contents.

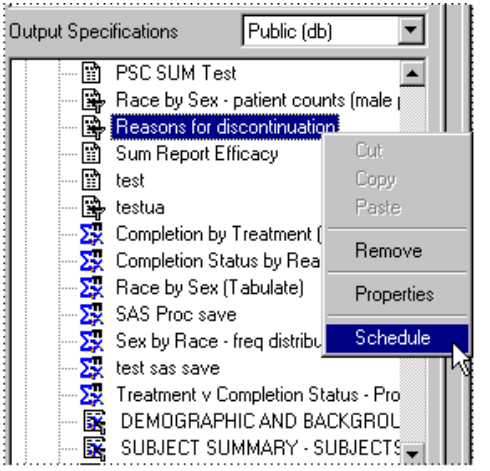
6. By default, Review displays only saved report specifications created while reviewing the current Study Protocol(s). You may also import report specifications created for other Study Protocol(s). Check **"**Display all studies?" and open any available Report Browser specification. Review will validate the data structure to verify that the foreign report specification is compatible with the current study protocol(s).
7. If a filter criteria was on when the report specification was saved, the filter has been saved with the report and will be active upon reopening.

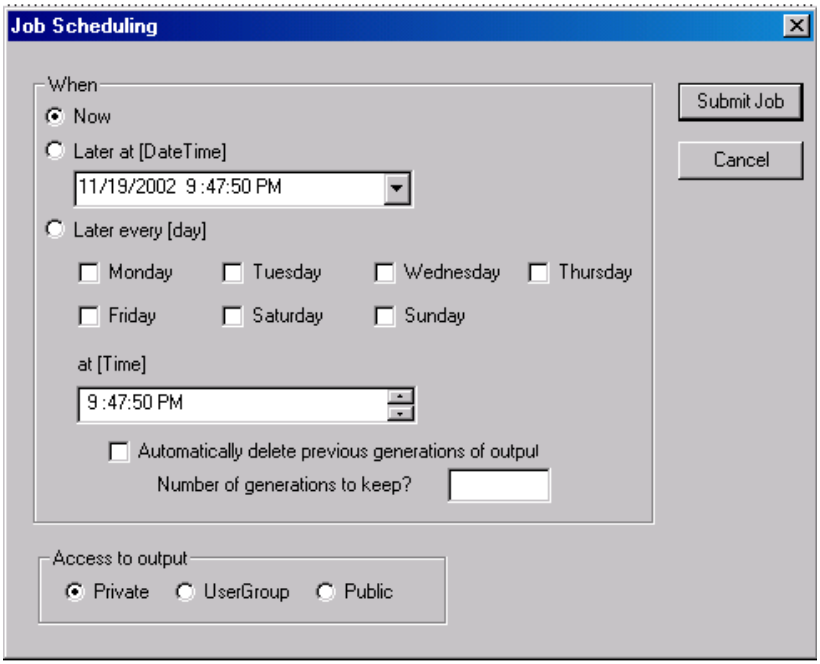
Schedule output

Object Explorer scheduled output

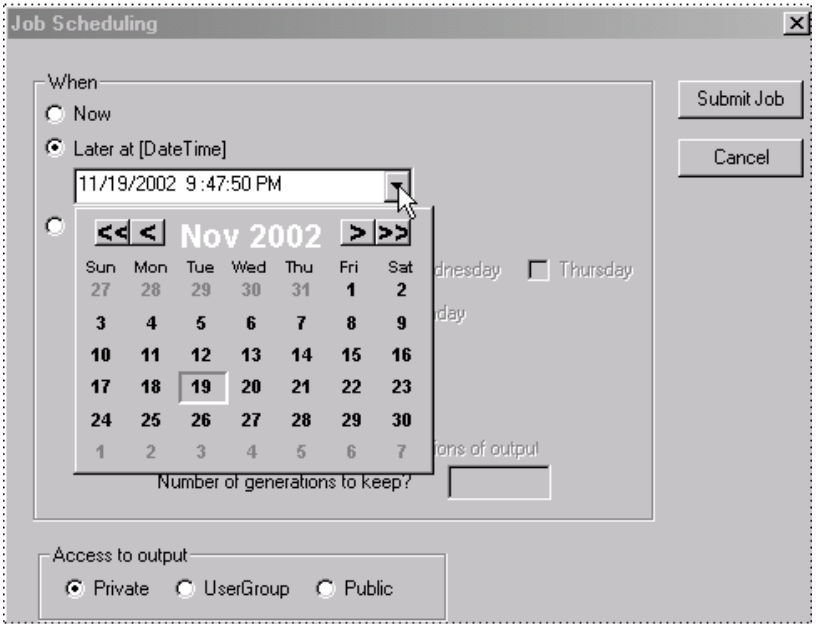
The Object Explorer window aids users to quickly locate and schedule previously saved objects stored within organized folders. The output scheduler allows users to schedule a job throughout all output browsers in Review. This includes reports, graphs, crosstabs and SAS jobs.

1. Select the stored object with a single click.
2. Right-mouse click to display a floating menu.
3. Click **Schedule**. A dialog window displays for Job Scheduling.




Job Scheduling
When
Now
Later at [DateTime]
11/19/2002 9:47:50 PM
Later every [day]
Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday
at [Time]
9:47:50 PM
Automatically delete previous generations of output
Number of generations to keep?
Access to output
Private
UserGroup
Public
Submit Job
Cancel

4. 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

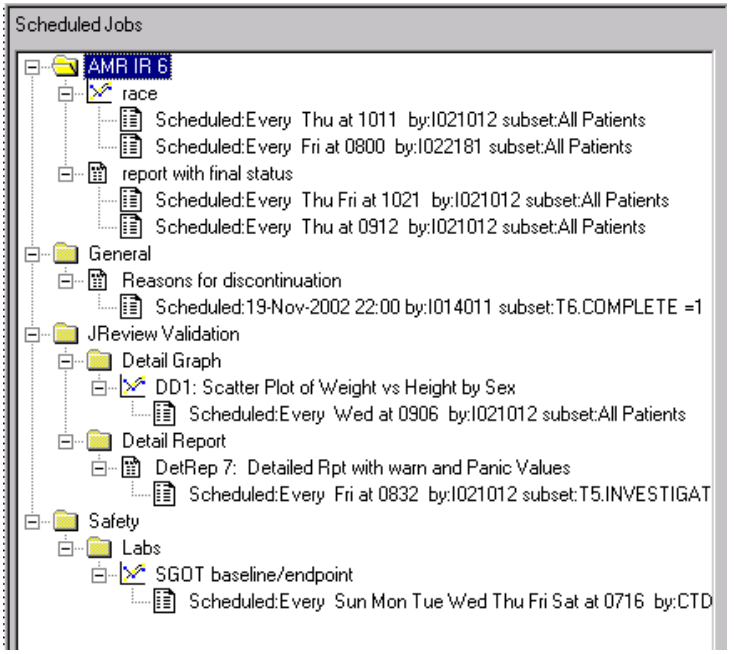
Schedule a repetitive frequency using selected days of the week by selecting Later every (day). This feature allows you to automatically delete previous generations of the output or enter a number of generations to keep.

5. Select who can access the stored output results for Private, UserGroup or Public.
6. Click Submit Job.

The output results are archived 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.

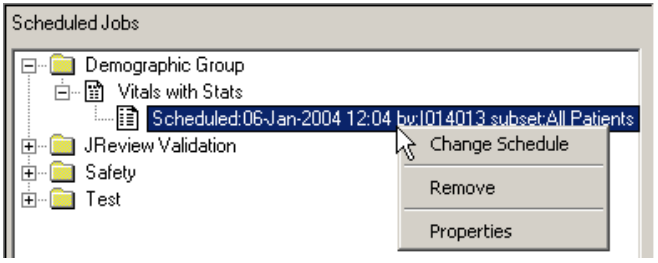
View Scheduled Jobs

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.



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**.

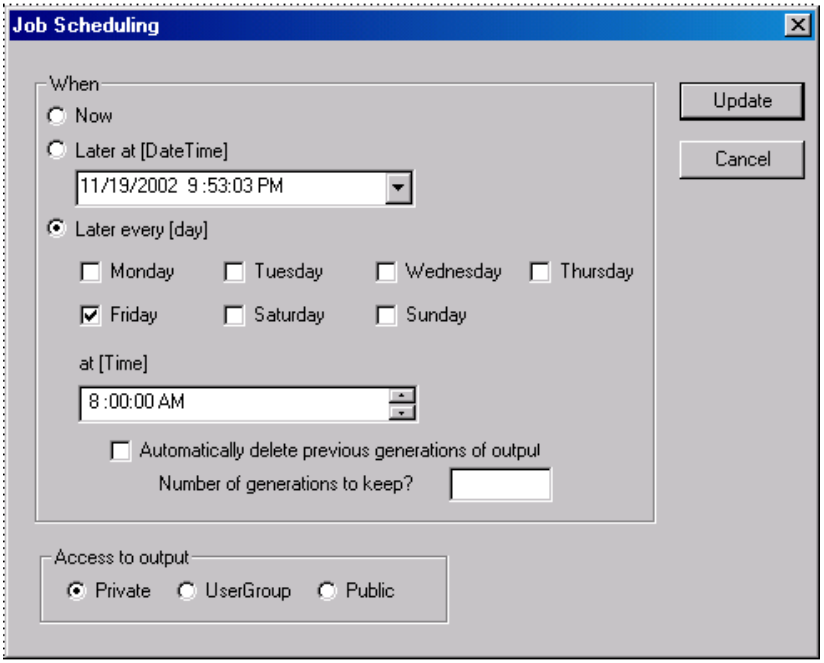


Change Schedule

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.

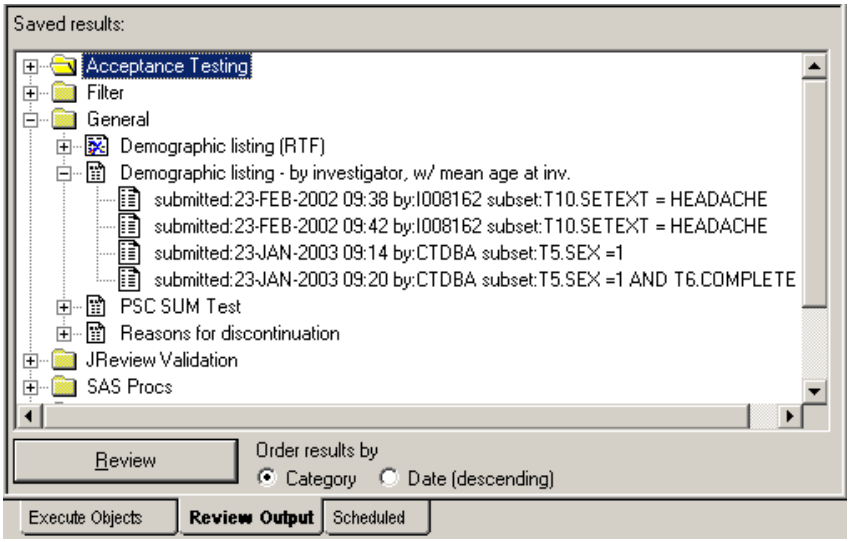
3. Click **Change Schedule**.
4. The Job Scheduling window opens for you to enter your changes.
5. Click Update.



Review output

Locate stored output results

The Review Output folders are from the category folder definition for each of the objects that were run. You only see folders in the Review Output if an object has output saved.



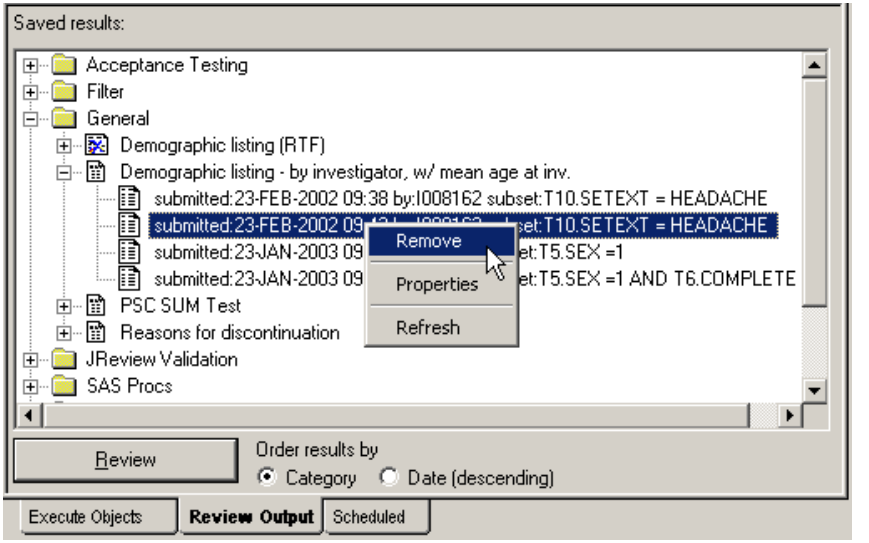
Note:The exception is previously run and saved SAS Proc output results from an earlier Review release. The SAS Proc browser scheduled a job to be run and the output saved. The output would be listed under the specific SAS Proc that was run. Therefore, old SAS Proc jobs are placed in a SAS Proc folder.

You can quickly locate stored output results run from the different Review output browsers for reports, graphs, crosstabs and SAS jobs.

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.

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**.



Delete multiple output

You can delete multiple output results in one of the following ways:

For contiguous output listed next to each other:

1. Click the first output.
2. Hold the **shift key** and mouse click and drag the cursor over the output tables you would like to delete.
3. Click **Delete output**.

For non-contiguous output tables not listed next to each other:

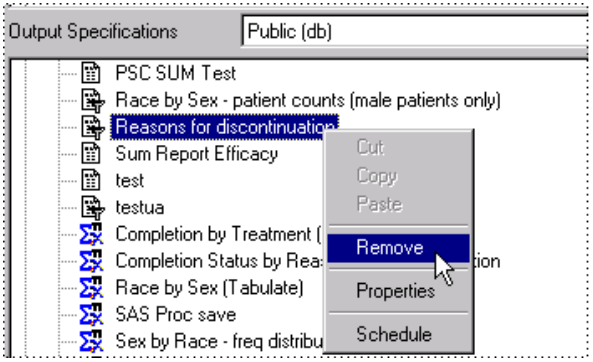
1. Select the output tables you want while holding the **Ctrl key**.
2. Click each output table you would like to delete.
3. Click **Delete output**.

Quick remove a stored object specification

You can quickly delete any saved Output Specification in the Output Specifications window located on the Execute Objects tab.

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?".

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



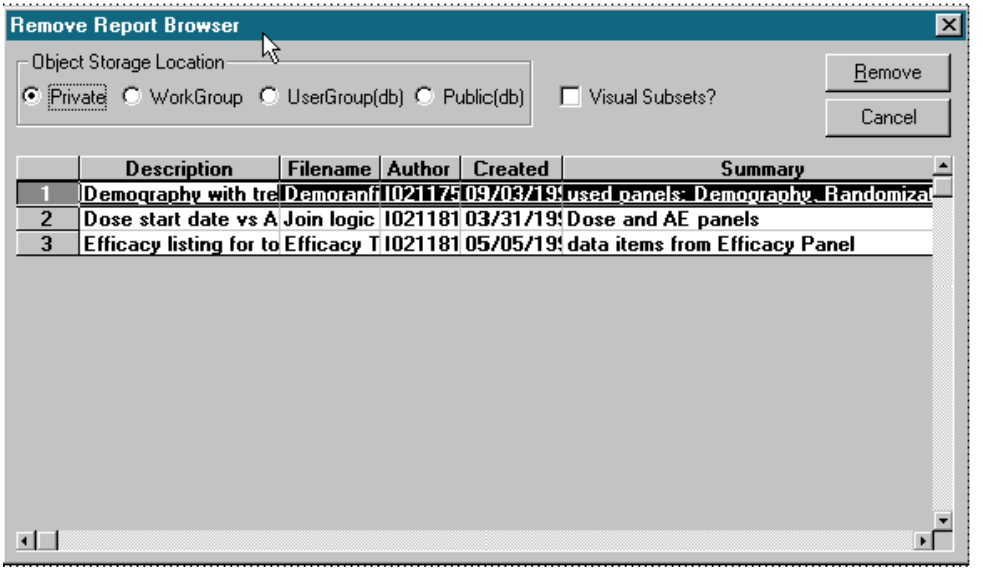
Note:If output has been saved for the object specification, then a message displays stating saved output exists for this object. Therefore, the object specification cannot be deleted at this time.

Remove a stored object specification

Another way to remove a saved object specification:

1. Open the browser to make it the active window.
2. From the **File** menu, click **Remove**.
3. Review displays the Remove Report Browser window.
4. Click on the object storage location.
5. Select the stored report specification you want to remove.
6. Click **Remove.**

Review deletes it from your local PC, WorkGroup, UserGroup or Public storage sites as you designate and have security clearance to do so.



Closing report browser and reports

Closing a report window

If you are finished reviewing the data in a report, double-click the window's close box, as you would with any other window.

Closing the Report Browser

If you are finished with all reports, and do not want to define any other reports: double-click on the close box of the Report Browser window.

Review also closes all report windows currently opened.

Exploring data

Changing the patient selection criteria

After you have defined the specifications of your report, and have created it by clicking **Create Report,** you can use the report(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.

Reports or other browser objects that are displayed will be updated according to your new criteria. Each report generated with a filter on will update with the same filter criteria with which it was created.

Pivot panel presentations

You can create a pivot panel from any of the Review browsers. All pivot panels can be shared, if they are created and registered with the 'Shared with Others' option.

Pivot Panels offer a powerful opportunity to transpose the data structure at the database into a clinically pertinent structured views of the actual data in the data management system.

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: Pivot Panels*)

Report output filter

After you have defined the specifications of your report, you can extend your data exploration by row filter data inclusion. Row filtering is carried out by the output filter criteria window. The output filter function specifies observations and visits, presumably from multi-visit items, to focus reporting presentations on clinically specified item values. Filtered and non-filtered Scatter Plot graphs can be very informative when Review's patient-level interactive browsers are utilized interactively in the multiple-patient mode to identify and characterize a subset of patients:

1. Create an output filter or edit by adding, editing, or removing existing expressions.
2. Click **Save Filter** in the Report Output Filter window to apply it against the next created Report.

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. (See *Chapter 12: Common Topics: Multi-Patient Mode*)

Define 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. Custom join logic for Clintrial type 0 panel can be used anywhere in a report. *(See Chapter 12: Common Topics: Define Join Logic*)

Clintrial tags

Clintrial tags are accessible to be used in Report Browser constructs. Clintrial tags are listed as a pseudo-panel, and definition and categorizations of tags are listed as items. (See *Chapter 12: Common Topics: Clintrial TAGS*)

Protocol comparison

Utilizing the pseudo-item <Study ID> in CrossTab constructs facilitates comparisons between protocols. (See *Chapter 12: Common Topics: <Study ID> pseudo Item*)

New Event Function

Utilizing the pseudo-function '_New Event_' allows you to create and define new landmark events to be evaluated and applied to your selected patient populations as function values. (See *Chapter 12: Common Topics: _New Event Function_*)

Outer Joins

If enabled, a patient's data is included in a browser's results even if some panels of data are missing for that patient. (See *Chapter 12: Common Topics: Reviewing Preferences*)

FULL JOIN

By default, full joins is enabled, which sets selection criteria against each row per patient. By default the FULL Automatic JOINS, tests by row restricting criteria application to Visit and / or Observation, depending on the type of Panel.

An optional join preference is to disable the full joins, this facilitates the selection criteria to be applied throughout all patient data rows. The criteria applied would test by Patient ID and not consider Visit and / or Observation, thus broadening the scope of the patients meeting set criteria. (See *Chapter 12: Common Topics: Reviewing Preferences*)

7 Graphing

Patient selection criteria **340**
- Selection set 340
- Opening the Graph Browser 340
- Access to SAS datasets 341

Selecting a graph type **341**
- Detail Data Graph 341
- Summary Data Graph 341
- Bar Styles 342
- Group Functions 343

Defining a graph specification **344**
- Creating a graph specification 344
- Change graph specifications 346
- Graph Browser output filter 347

Graph display results **347**
- 2D Graph Toolbar 347
- Display multiple pages 348
- Change graph style 349
- Highlight the graph 351
- Zoom the graph 354

Snapshot output **355**
- Multiple graphs 355
- Multiple population mode 355

Types of Detail Data Graphs **360**
- Scatter (Item X vs. Item Y) Plot 360
- Scatter Plot with Regression Line 365
- 3D Scatter Plot 367
- Baseline vs. Endpoint Scatter Plot 369
- MultiLine Chart Item Value vs. Category by Case 371
- MultiLine Chart Item Value vs. Category by ByVar 373

Types of Summary Data Graphs 375
2D Bar Chart Frequency Distribution 375
X and Y scaling 380
3D BarChart Frequency Distribution 384
2D Bar Chart Item Summary vs. Category 386
3D BarChart Item Summary vs.Category 388
Pareto Chart Frequency Distribution 390
Pie Chart Item Summary vs. Category 392
Polar Chart Item Summary vs. Category 394
Radar Chart Item Summary vs. Category 396
Filled Radar Chart Item Summary vs. Category 398
Line Chart Item vs. Category 400
Item Mean and Standard Deviation vs. Category 402
Highlighting patients 404
Single patient mode 404
Multiple patient mode 407
Subset by graphic regional selection 356
Save Visual Subset 357
Remove Visual Subset 359
Multiple patient mode 407
Scatter plot graph 407
Multi-Line graph 407
BarChart graph 407
Pie Chart 407
Graph editing 409
Graph settings 409
General Setup 410
Display Setup 410
Axis Setup 411
Title Setup 411
Legend Setup 412
Printing Graphs 412
Print Preview 412
Printing the graph 413

Object storage: saving your work **413**

Schedule output **413**

Closing graphs and the Graph Browser **413**

Closing a graph window 413

Closing the Graph Browser 413

Exploring Data **414**

Changing the patient selection criteria 414

Multiple protocols 414

Graph output filter 414

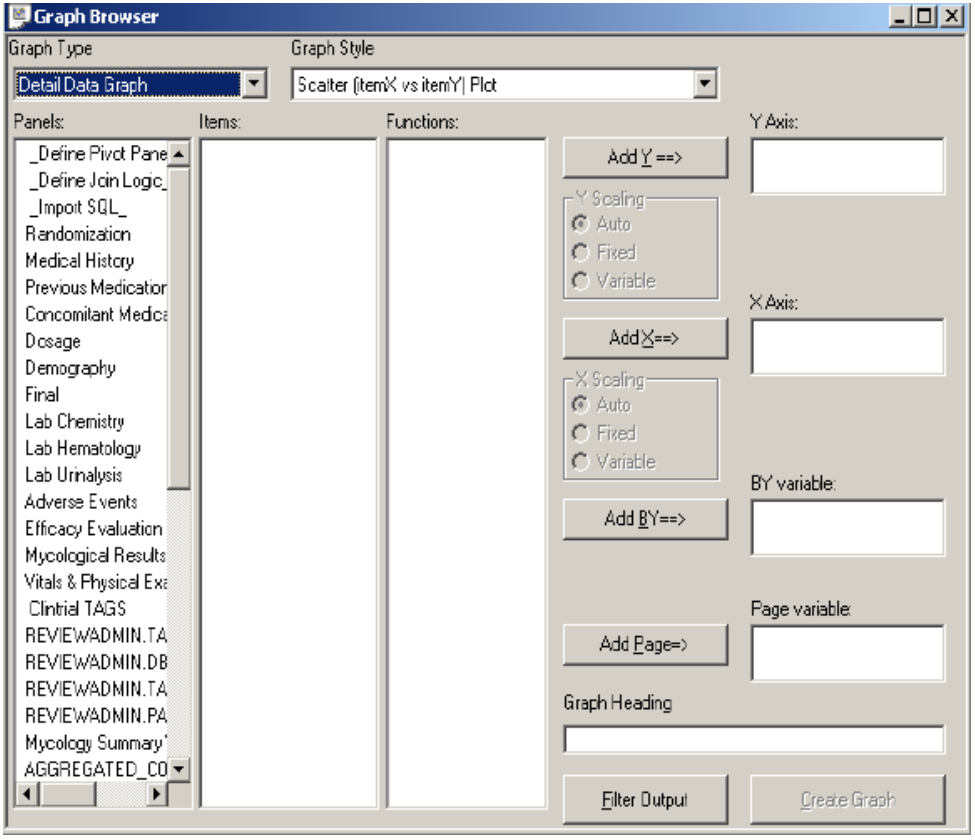
Patient selection criteria

Selection set

You can explore data items of selected patients graphically after defining the patient selection criteria and by using the Graph Browser.

Opening the Graph Browser

Click , or from the **Browse** menu, select **Graphs**. Review displays the Graph Browser window where you specify the type and contents of your graph. The Graph Type listbox offers two options for displaying data graphs at detail patient level or summary data. The Graph Style listbox displays selections dependent upon the graph type you selected.



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 graphs.

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

Selecting a graph type

Detail Data Graph

Click Detail Data Graph option in the Graph Type listbox. Click the Graph Style button to display a drop-down listbox of graph types for Detail Data Graph:

- Scatter (item X vs. item Y) Plot with dual Y axis mode option
- Scatter with Regression Line with dual Y axis mode option
- 3D Scatter (item X vs. item Y vs. item Z) Plot
- Baseline vs. Endpoint Scatter Plot
- Baseline vs. Min value Scatter Plot
- Baseline vs. Max Value Scatter Plot
- MultiLine Chart Item Value vs. Category by Case
- MultiLine Chart Item Value vs. Category by ByVar

Summary Data Graph

Click Summary Data Graph option in the Graph Type listbox. Click the Graph Style button to display a drop-down listbox of graph types for Summary Data Graph:

- 2D BarChart Frequency Distribution
- 3D BarChart Frequency Distribution
- 2D BarChart Item Summary vs. Category
- 3D BarChart Item Summary vs. Category
- Pareto Chart Frequency Distribution
- Pie Chart Item Summary vs. Category
- Line Chart Item Summary vs. Category with dual Y axis mode option

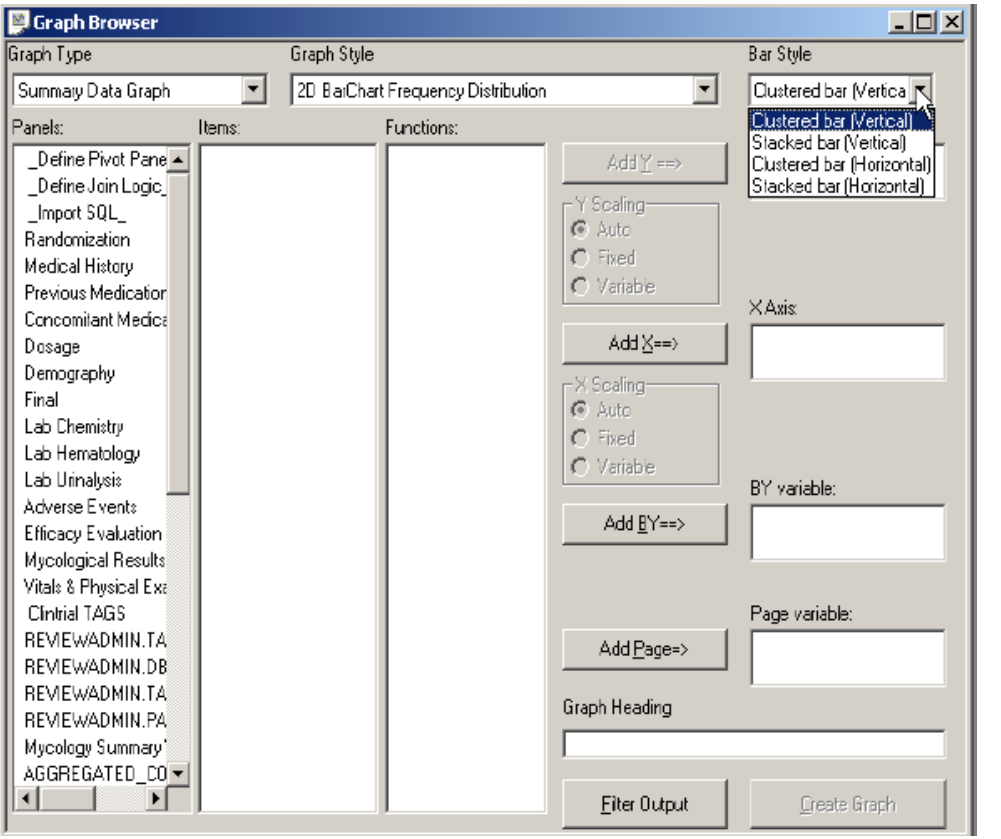
- Multiple Variable MultiLine chart
- Polar Chart Item Summary vs. Category
- Radar Chart Item Summary vs. Category
- Filled Radar Chart Item Summary vs. Category
- Multiple Variable Radar
- Mean + Standard Deviation vs. Category

Note: Multiple studies are supported with Summary Data Graphs.

Bar Styles

The Bar Style listbox displays when the Summary Data Graph type is selected. The following Bar Styles are available for 2D BarCharts only:

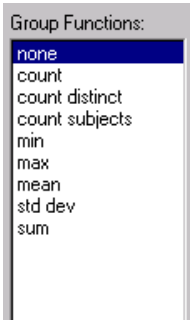
- Clustered bar (Vertical and Horizontal)
- Stacked bar (Vertical and Horizontal)



Group Functions

All general purpose graph types (2D Scatter, Line Chart, and BarChart) allow all normal data function selections displayed in the Functions list-box. 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
- Multiple Variable MultiLine chart
- Polar Chart Item Summary vs. Category
- Radar Chart Item Summary vs. Category
- Filled Radar Chart Item Summary vs. Category
- Multiple Variable Radar



Defining a graph specification

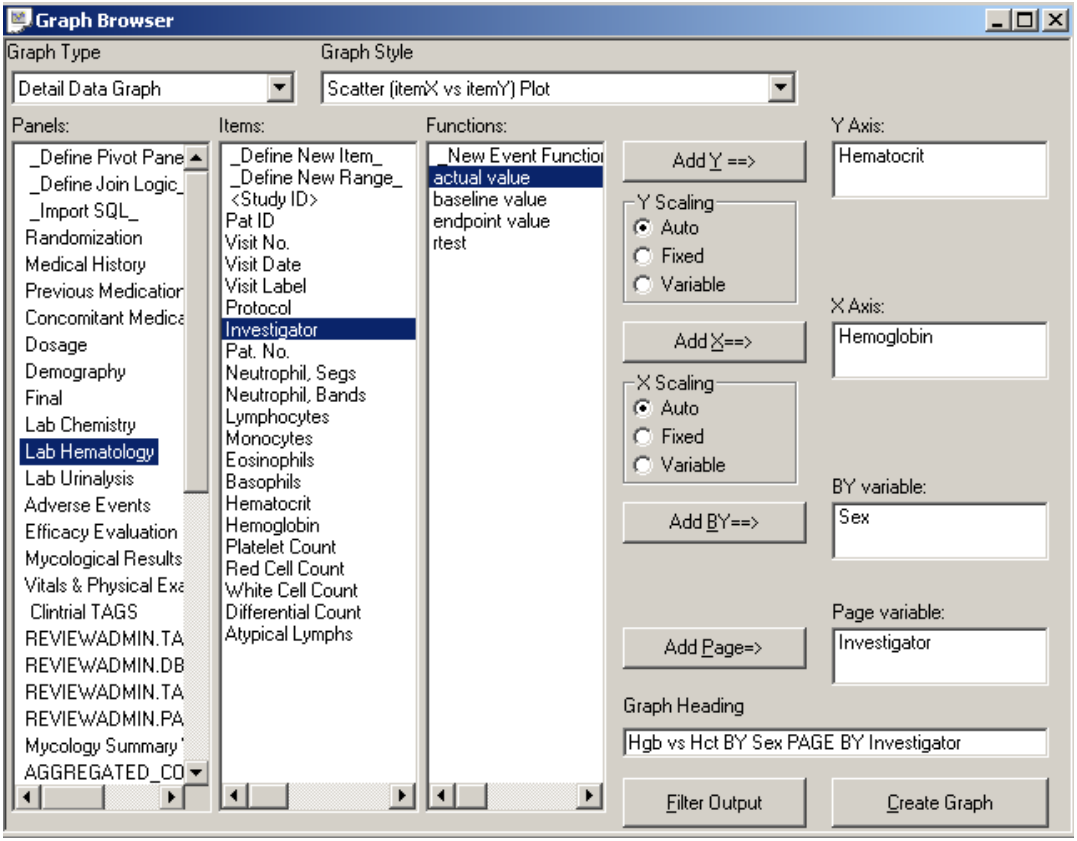
Creating a graph specification

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

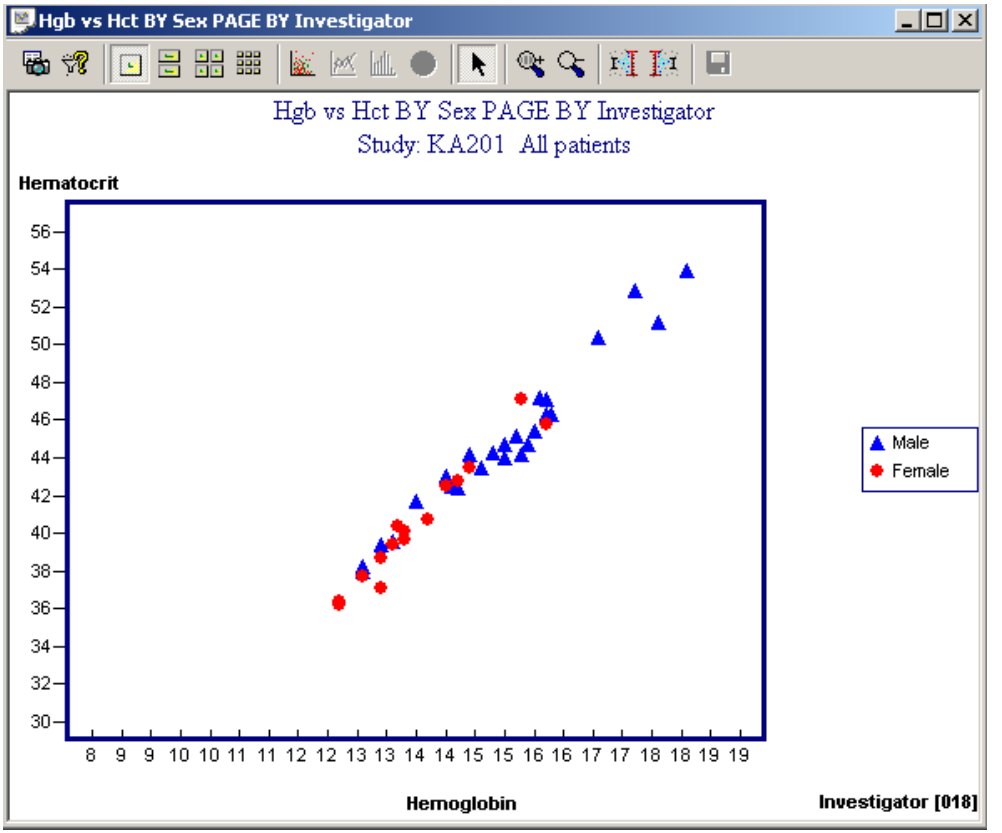
1. Select a panel.
2. Select each item of interest and the appropriate function for the item.
3. Depending on the graph type and style selected, click the appropriate graph axis button to add the item to the graph specification.

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

Note: Selected 2D graphs in Detail Data Graphs for Scatter Plots and Summary Graphs for 2D Barcharts support the Add Page variable.



When you apply a Page variable item such as investigator which may be common to most to 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: The Page By item variable selected in this example for Investigator is displayed in the lower right corner along side the page number.

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 .

Note: You may use the pseudo-function '_New Event Function_' to define your own function as well as new items and new ranges are supported throughout the Graph Browser. (See *Chapter 12 Common Topics: Derived items and New Range Variables and New Event Function*.)

Graph Browser output filter

2. Optionally, create an output filter:

   a. Click **Filter Output**, to row filter the observations and/or date values of choice.

   b. After you build the output filter criteria and save it, the **Filter Output** button toggles to

.

3. When you are satisfied with the contents of the graph specification, click **Create Graph.** The filter criteria is applied during the next graph creation. (See *Chapter 6: Report Browser: Output Filter.*)

Graph display results

2D Graph Toolbar

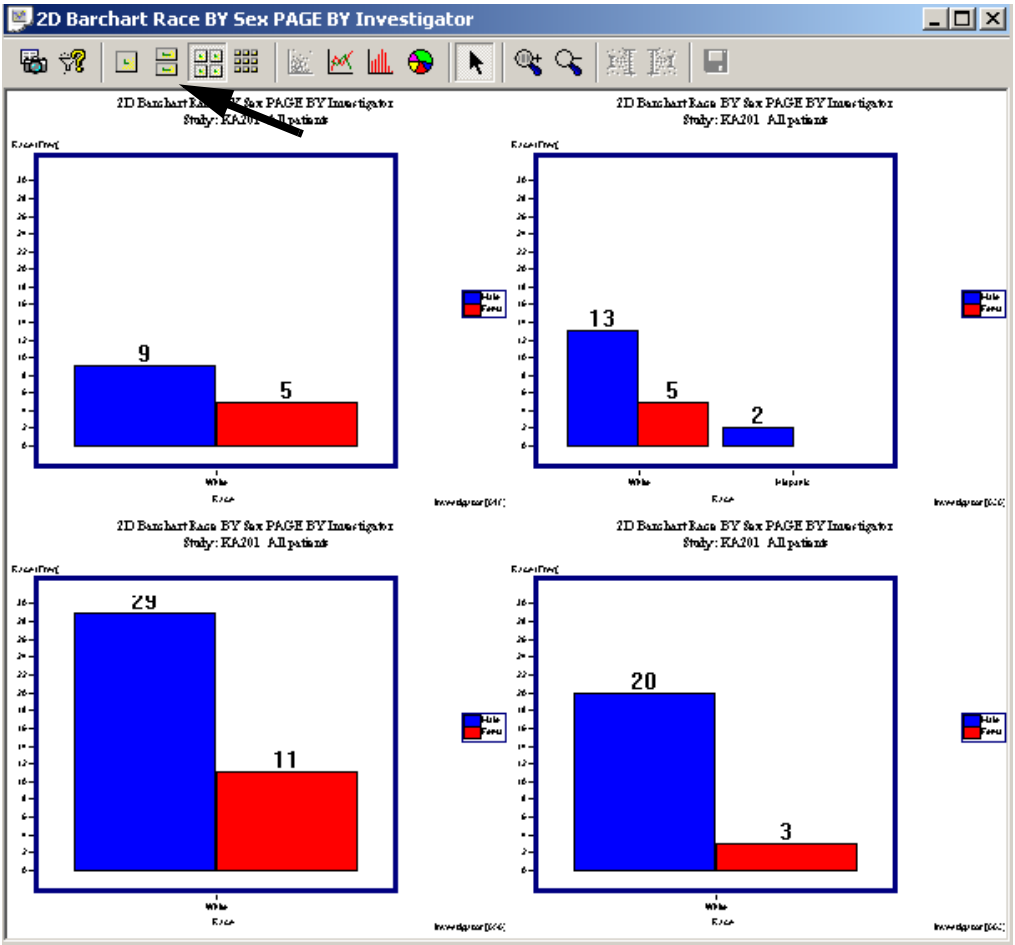
The toolbar displayed in your graph results window is dependent upon the graph you specified. Select 2D graphs have additional features available from the toolbar and the buttons activated are dependent upon the graph style selected for the graph specification. Some 2D graphs have optional multi-page graph display buttons enabled when the Page By item variable is defined in the graph specification. In addition, the 2D Summary Data Graphs have graph style buttons so you can change the current graph style without replacing the graph specification.

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

The next four buttons apply 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.

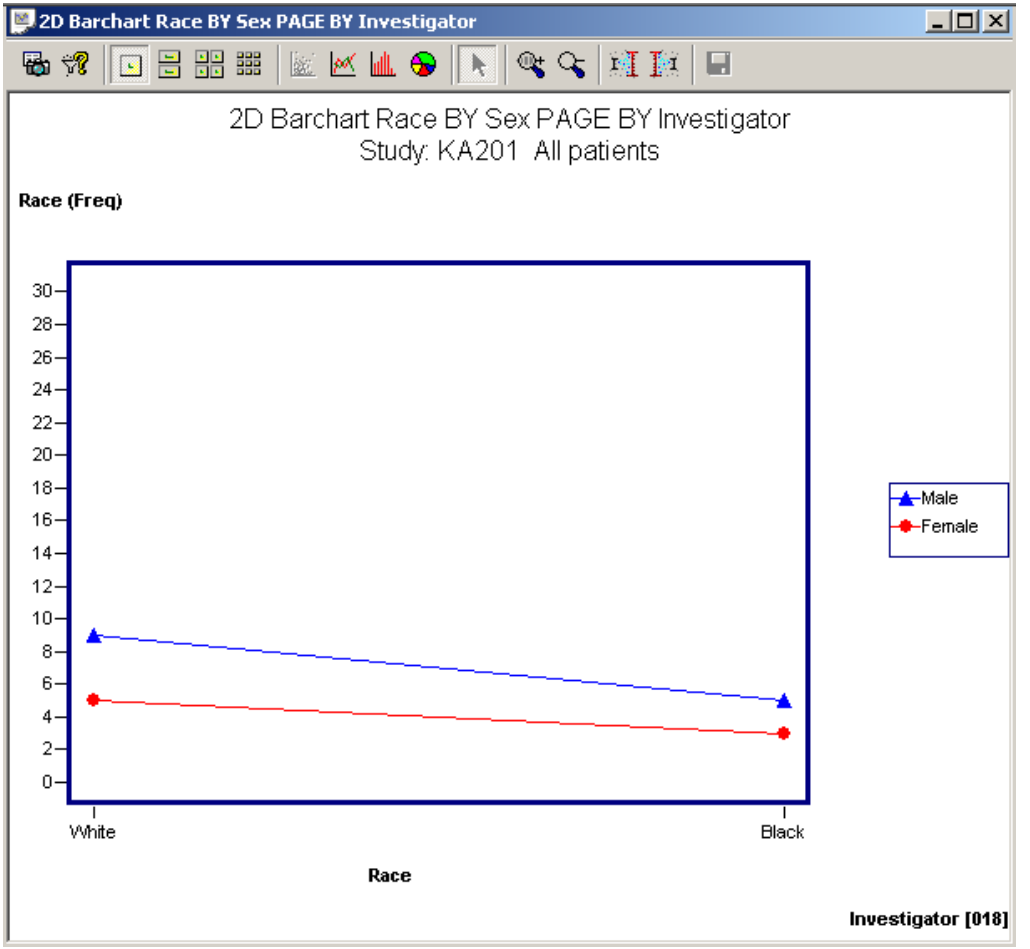
The Page By item variable for Investigator in this example is displayed in the lower right corner of each graph display along side the actual page number.

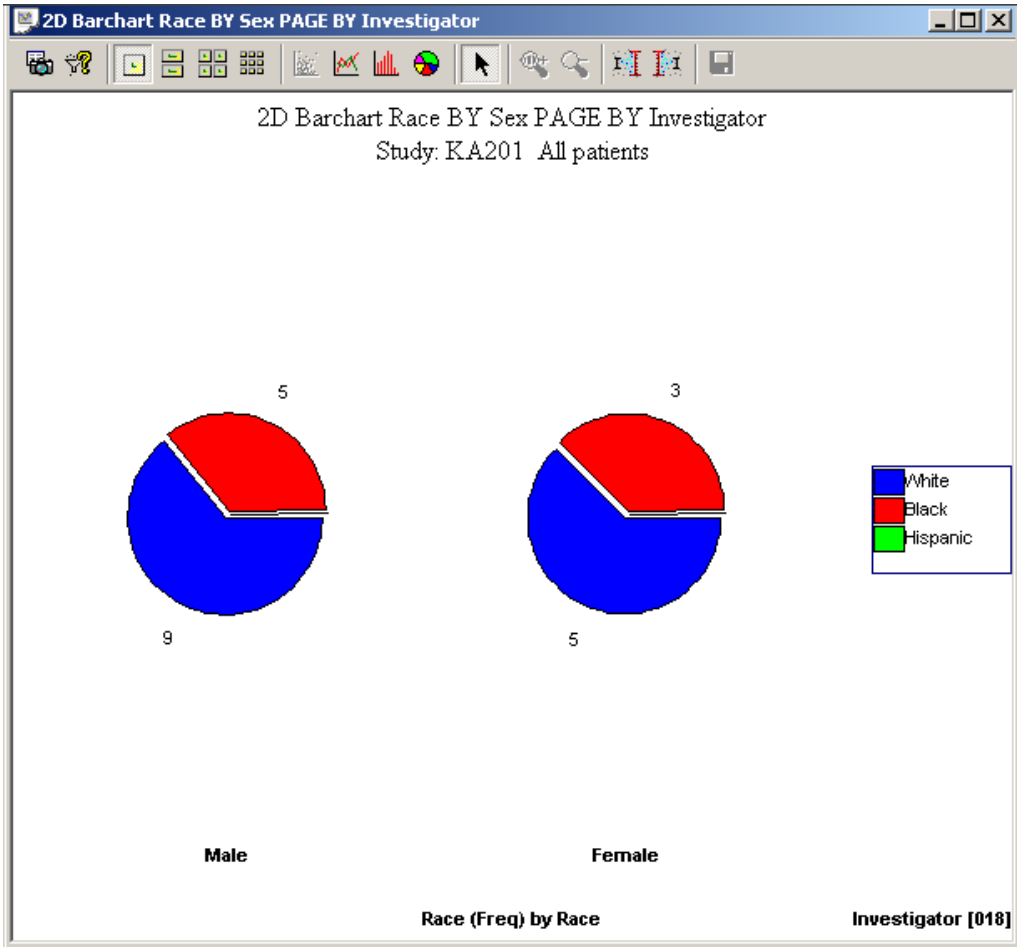


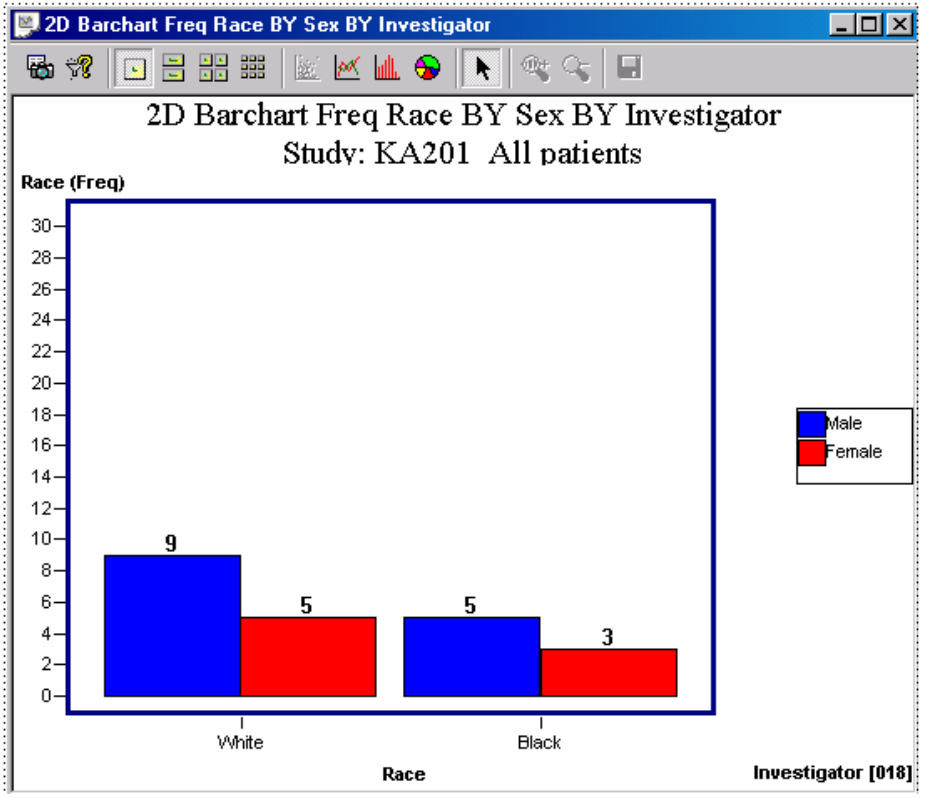
Change graph style

Select 2D Summary Data Graphs have the ability to change the graph type after the graph has been generated. Create your 2D Summary Graph to view the results, then click the graph style buttons to change the graph style view.

Note: The same graph header is displayed between all selected graph styles.




2D Barchart Race BY Sex PAGE BY Investigator
2D Barchart Race BY Sex PAGE BY Investigator
Study: KA201 All patients
5
9
3
5
White
Black
Hispanic
Male
Female
Race (Freq) by Race
Investigator [018]

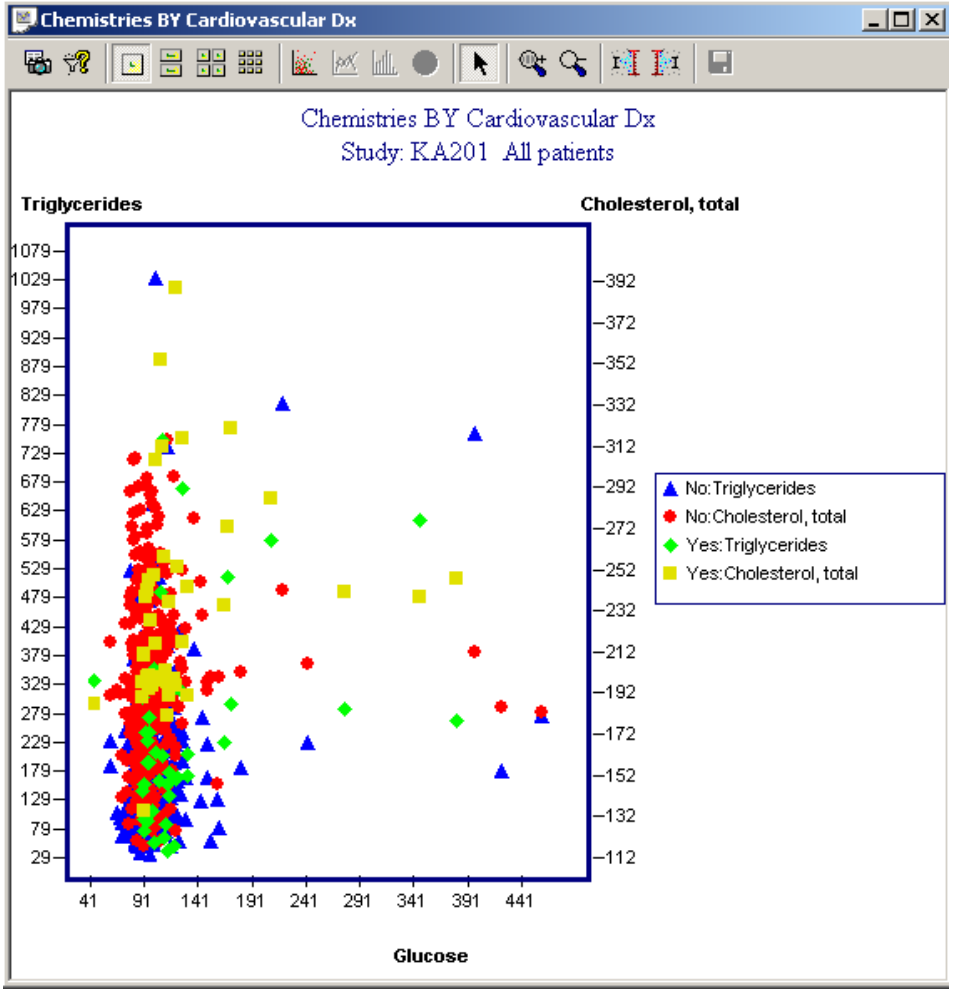


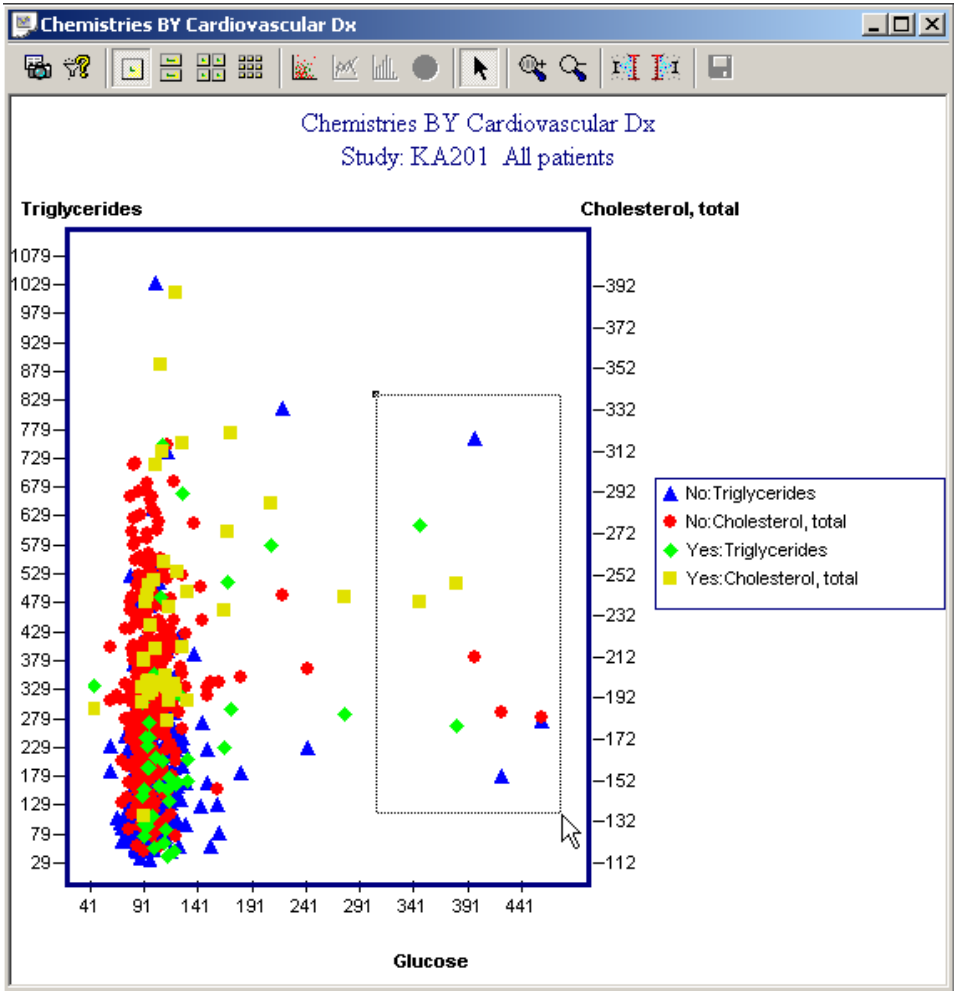
Highlight the graph

The 2D and 3D graphs display a different graph toolbar. Therefore, slightly different steps are used to highlight data points or bars between the graph styles.

- Initially when you create and view a select 2D graph type the arrow icon is active for highlighting and defaulted ON.
- To highlight data points in any 2D Scatter Plot Graph, click and drag the mouse over the selected area in the graph. Start the mouse drag from the upper left corner down and across to the lower right corner.
- The 3D Scatter Plot displays a minimal toolbar without the arrow icon. Simply click and drag the mouse over the selected area in the graph.
- A 2D or 3D Summary Data Graph only requires a click on the selected bar to highlight.

Note: Scatter Plot graphs allow you to save a visual subset of selected data points. (See Graph Browser: Patient subset by graph)

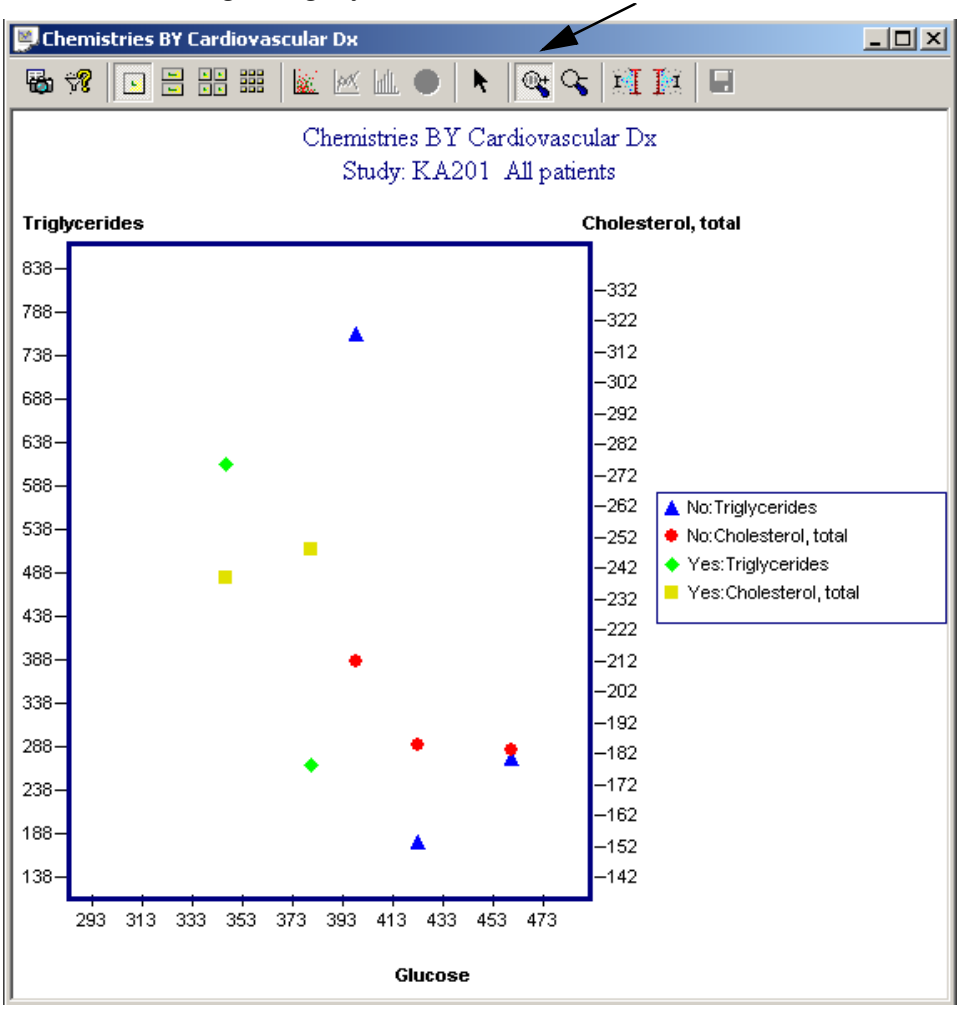



Chemistries BY Cardiovascular Dx
Chemistries BY Cardiovascular Dx
Study: KA201 All patients
Triglycerides
Cholesterol, total
1079
1029
979
929
879
829
779
729
679
629
579
529
479
429
379
329
279
229
179
129
79
29
392
372
352
332
312
292
272
252
232
212
192
172
152
132
112
41
91
141
191
241
291
341
391
441
Glucose
No:Triglycerides
No:Cholesterol, total
Yes:Triglycerides
Yes:Cholesterol, total

Zoom the graph

To use the graph zoom feature on 2D Scatter Plot graphs:

1. Create your 2D Scatter Plot.
2. Click the left magnify button to turn ON the zoom. Click and drag the mouse over the selected area in the graph. A new view of the select zoom area of your graph is displayed.
3. If you choose to highlight any data points while in zoom mode, click the arrow icon to highlight those data points.
4. To exit out of zoom mode and reset to the original display, click the right magnify button.



Resize graph image

The last two buttons increase or decrease the size of the graph image.

Multiple graphs

You can have multiple graphs active at the same time. After you have defined and created one graph:

1. Define and create the first graph and leave the results window open.
2. Go back to the Report Browser window. Click ,or from the **File** menu, select **New** to refresh your screen.
3. Define and create the new graph. Review displays a new window and displays your graph within it.

Note: If you make changes to the patient selection criteria it will refresh the open graph results window.

Snapshot output

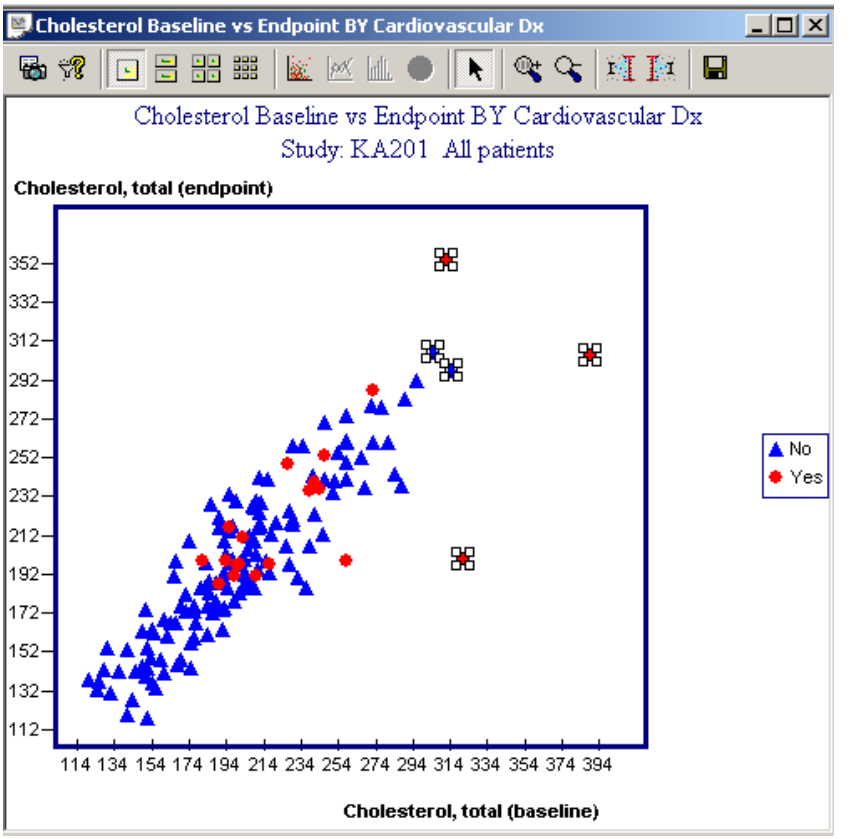
Multiple population mode

Review has an optional multiple-population mode available in the Graph Browser. The Snapshot output allows you to change the patient selection criteria and view the different output within the graph browser at the same time. When the results are executed and displayed from the graph browser output window, two icons are displayed for “Snapshot Output” and “Who?”. (See *Chapter 6: Report Browser: Snapshot Output and Chapter 12 Common Topics: Snapshot output)*

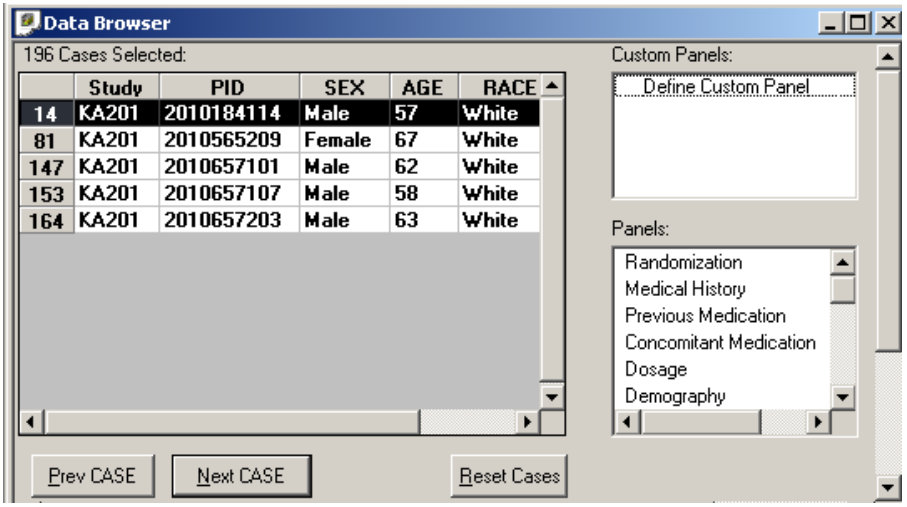
Patient subset by graph

Subset by graphic regional selection

The click and drag windows region selection convention used for highlighting or outlining a region of data, is used in the Graph Browser for Scatter Plots to create a instantaneous subset of patients within the boundary created. (See *Graph Browser: Highlight the graph)*

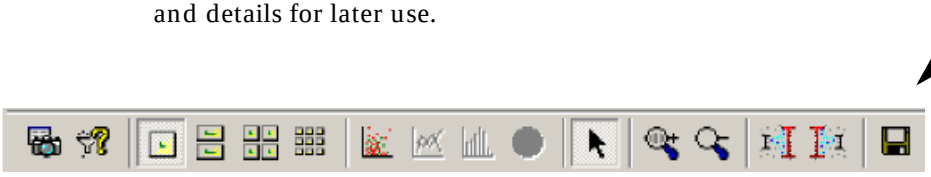


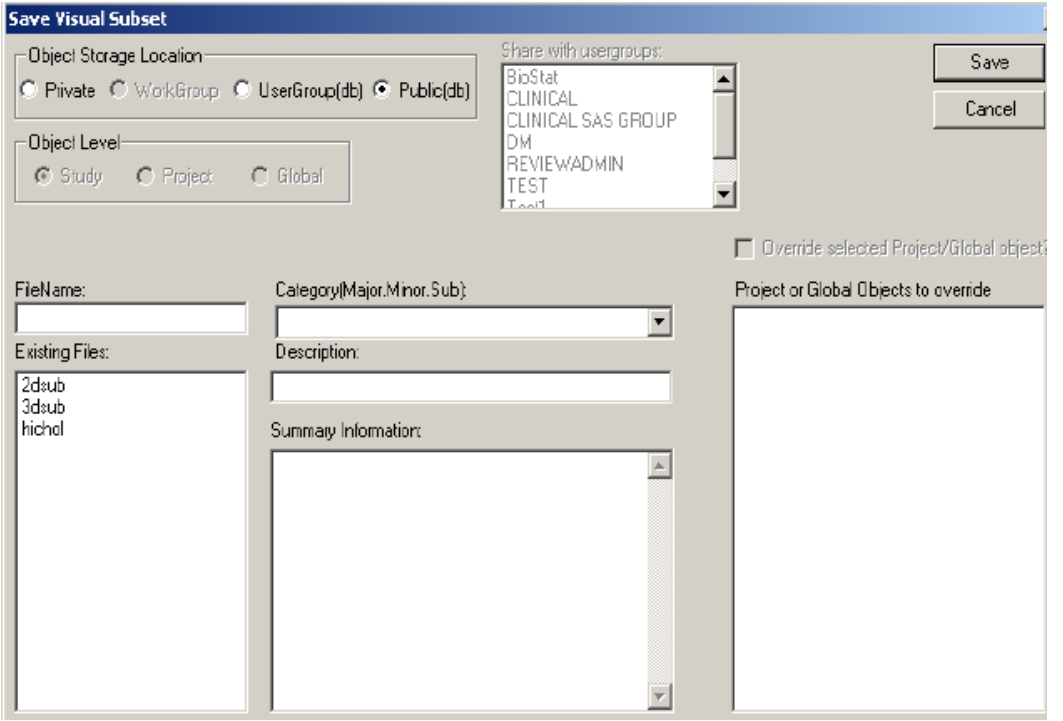
When you open the Data Browser and then select a region from any scatter plot in the multiple-patient mode, the Data Browser instantly updates the current patient listing and all data browsing features for the selected patients within the region selected in the scatter plot graph. *(See Graph Browser: Multiple-Patient Mode)*



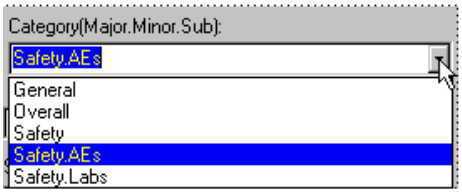
Save Visual Subset

You can save patient subsets from patient-level graphs when you highlight data points. The Save Subset icon is activated and located as the last button in the toolbar. When you click Save Subset Review displays the Save Visual Subset window where you specify the storage location and details for later use.





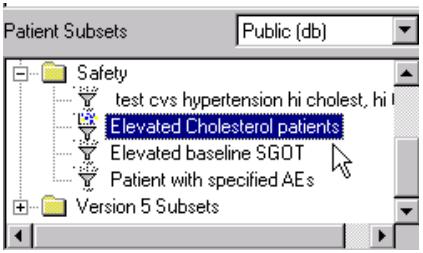
1. Enter the Object Storage Location and Object Level.
2. Enter a FileName.
3. Enter the folder(s) information in the Category box. Each folder (major, minor and subfolder) is separated by a period where folder titles can consist of more than one word separated by a space. Folder names are case-sensitive and after the folder(s) are initially created, they are selected from the dropdown listbox.



4. Enter a description and summary information for display and future reference.
5. Click Save.

The stored patients represented in a visual subset from the Graph Browser can be used in regenerating reports and other analyses.

The saved Visual Subset object stores the highlighted patients in the designated folder of the Object Explorer window under Patient Subsets. The visual subset description is listed with a double icon as a filter with a scatter plot graph on top. The double icon distinguishes the stored visual subset object from the stored patient selection criteria objects which display a single filter icon.



Note: The saved patient subset is NOT A DYNAMIC SAVE. If the data points change in the future, selecting the saved object will display the original subset of data points.

Remove Visual Subset

You can do a quick remove of the stored visual subset.

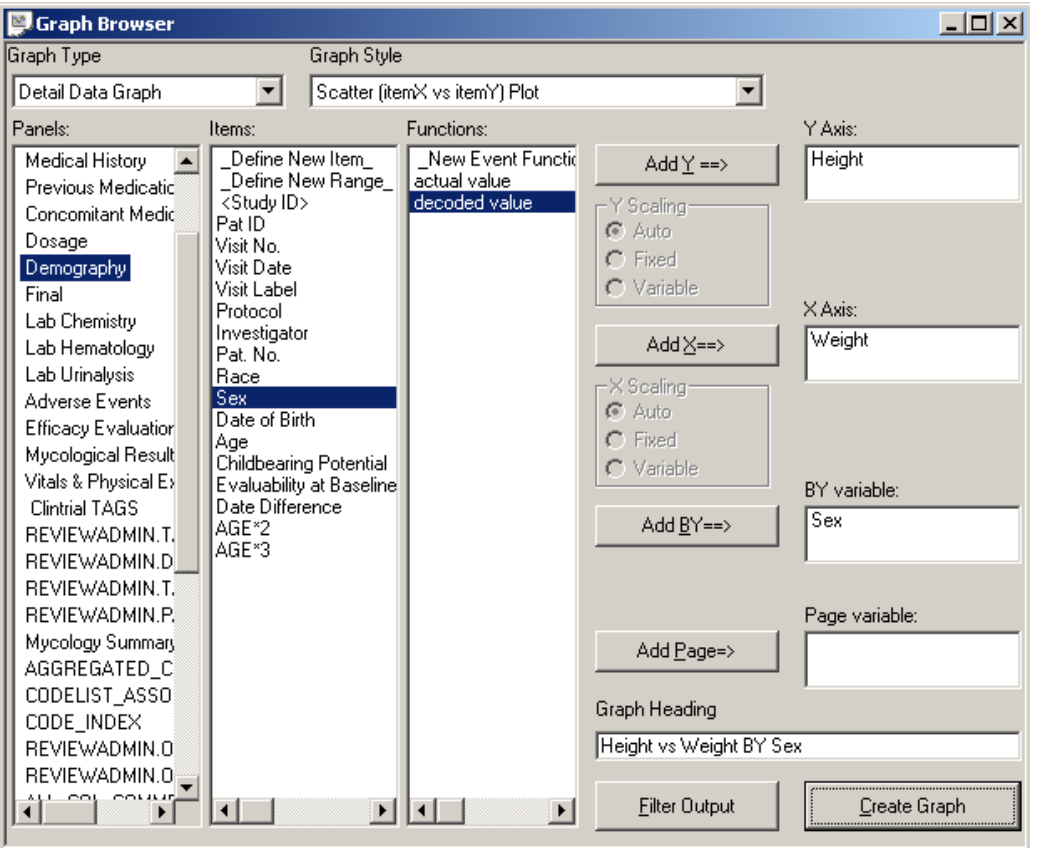
1. Click on the stored object under the Patient Subsets window.
2. From the **File** menu, click **Remove**. You will see a message display asking you to confirm the deletion.

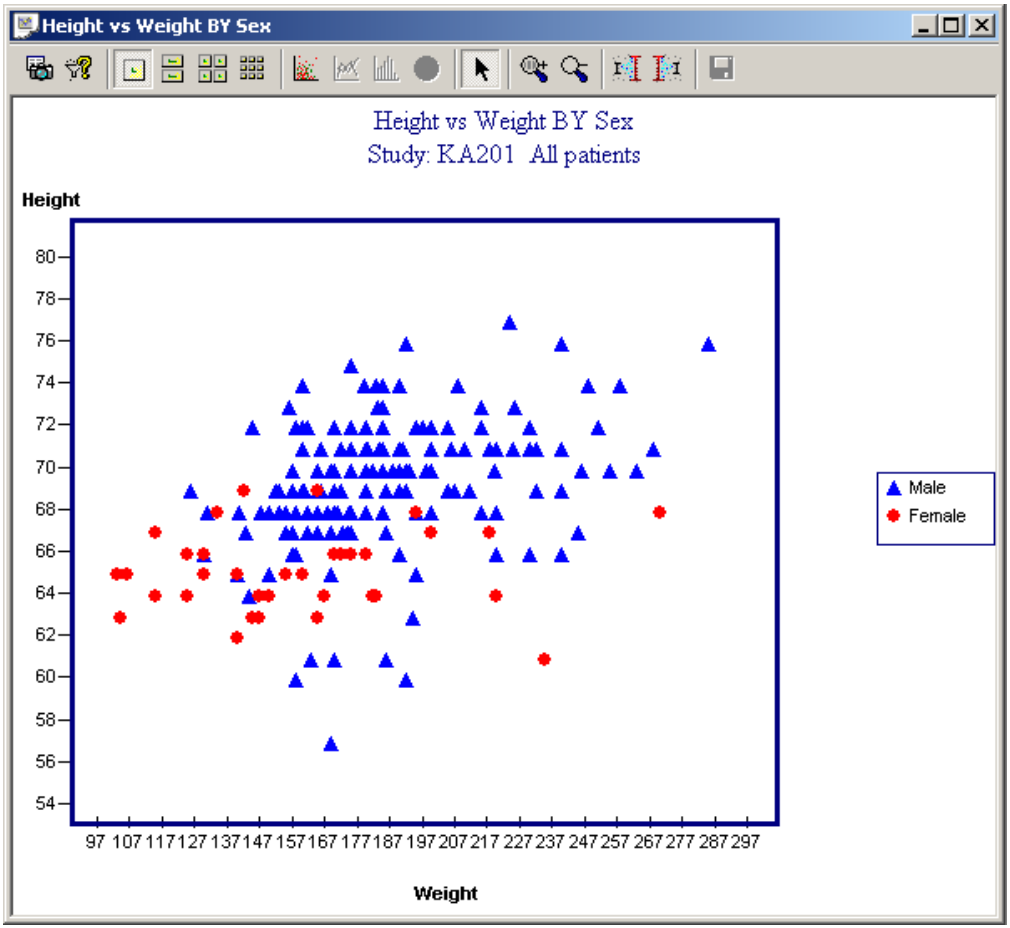
Review deletes the visual subset from the designated local PC, WorkGroup, UserGroup or Public storage location if you have security clearance to do so. (See *Chapter 12: Common Topics: SuperUser Privileges)*

Types of Detail Data Graphs

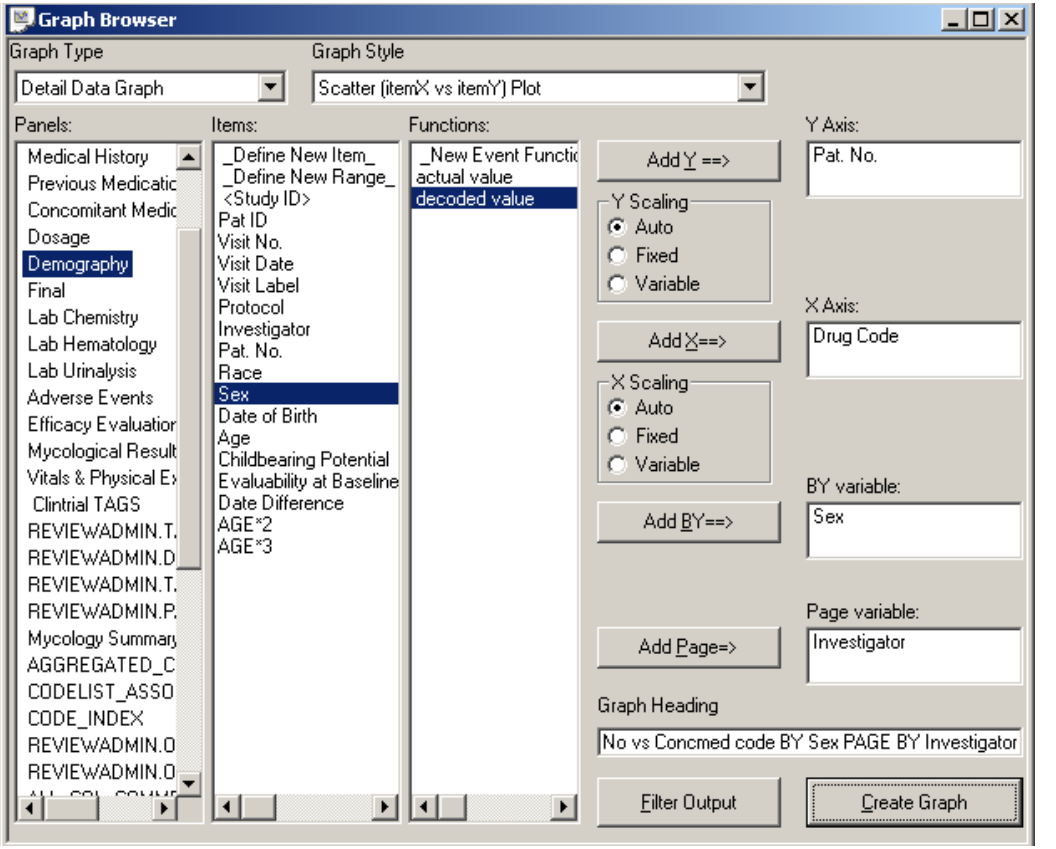
Scatter (Item X vs. Item Y) Plot

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 and BY variable to subset graphic displays.

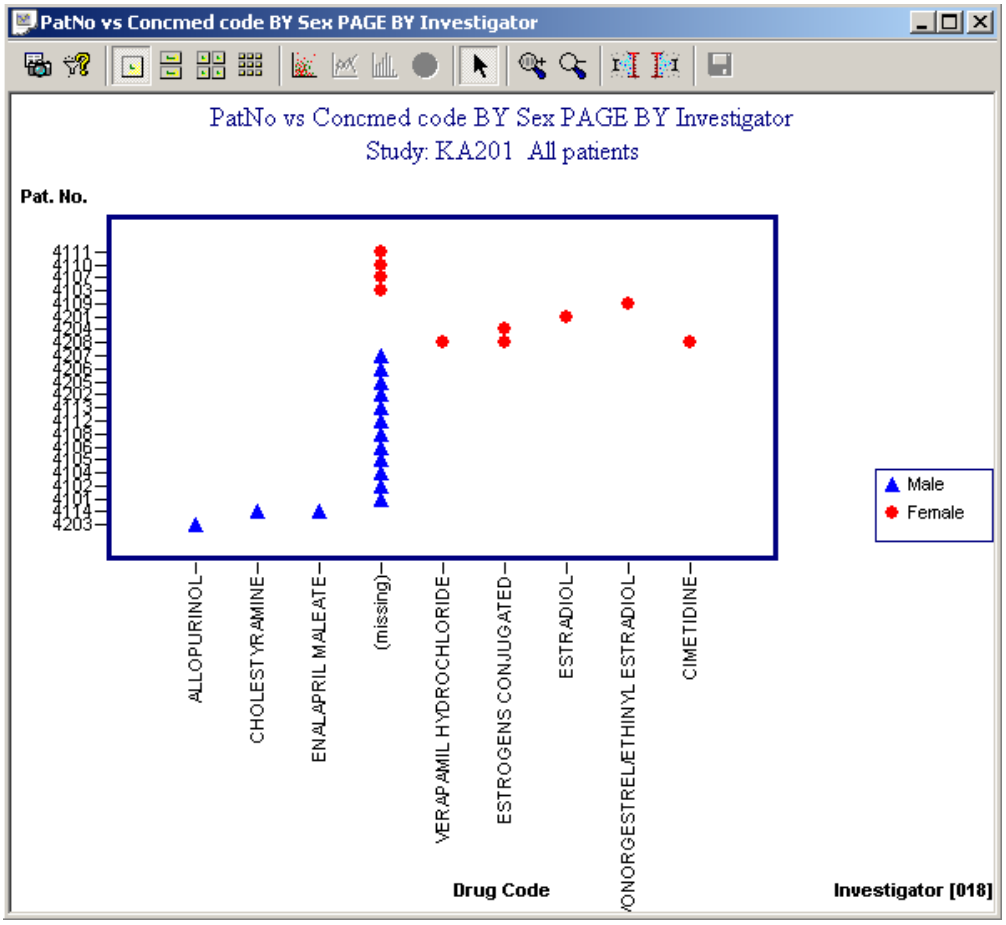



Height vs Weight BY Sex
Height vs Weight BY Sex
Study: KA201 All patients
Height
80
78
76
74
72
70
68
66
64
62
60
58
56
54
97 107 117 127 137 147 157 167 177 187 197 207 217 227 237 247 257 267 277 287 297
Weight
Male
Female

There is no restriction on the data type and character data is also supported. This example demonstrates the Page variable where the data item Investigator was taken from the Concomitant Medication panel along with the X and Y Axis data items.

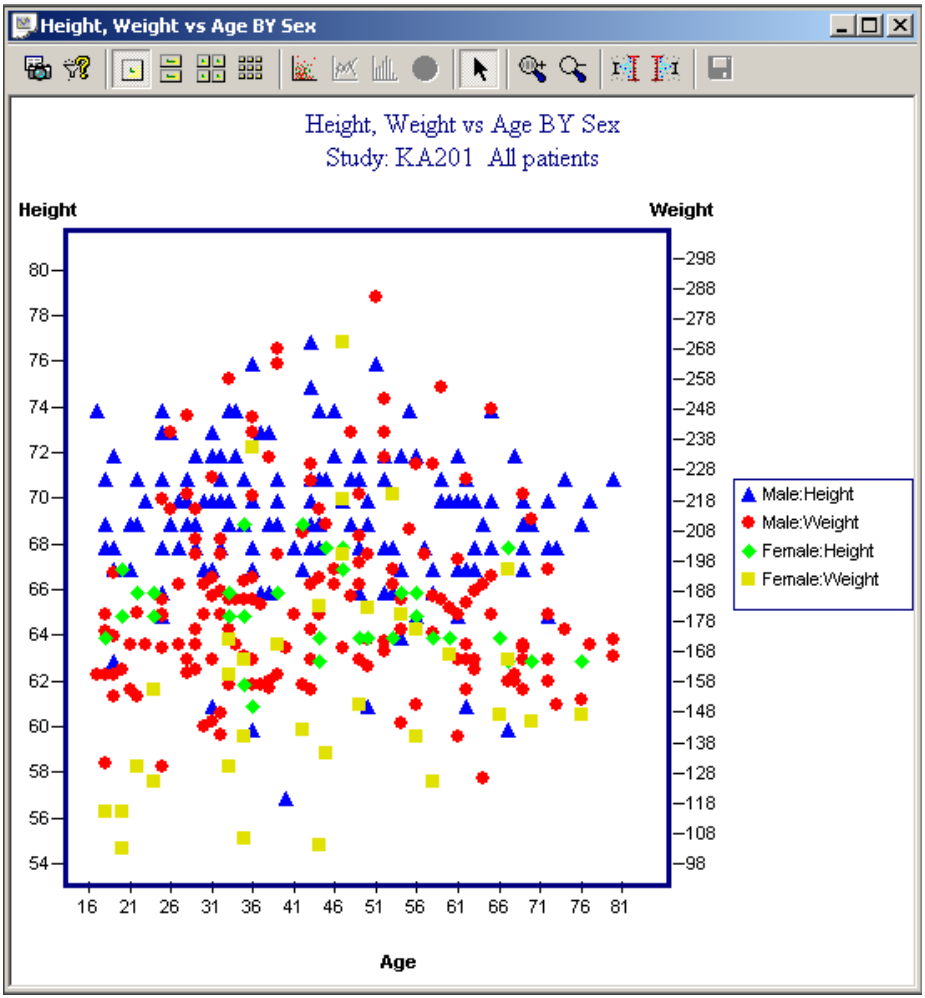


Use the **Page Up** and **Page Down** buttons on your keyboard to move between Investigator pages.



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).

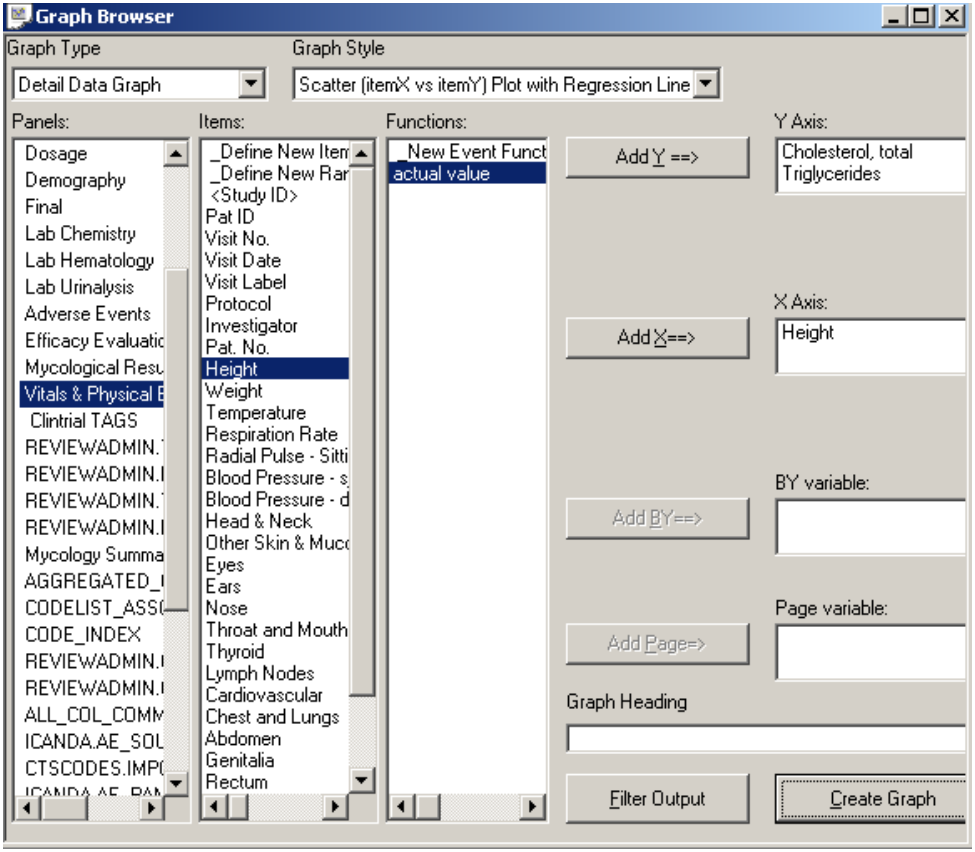


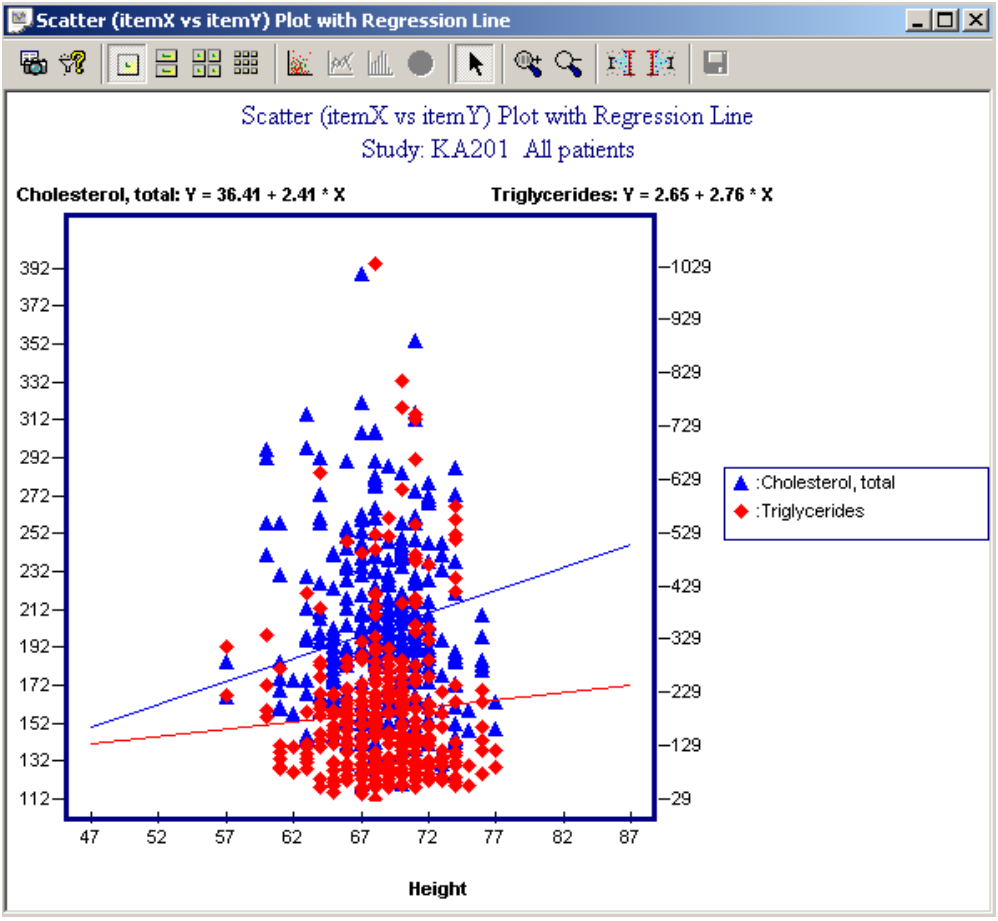
Scatter Plot with Regression Line

In a Scatter (Item X vs. Item Y) Plot with Regression Line (least mean square algorithm), each data point corresponds to each patient's observation for item X and item Y. There is no restriction on the data type used.

*Testing of Regression formula of Y on X: (y = a + b * x)*

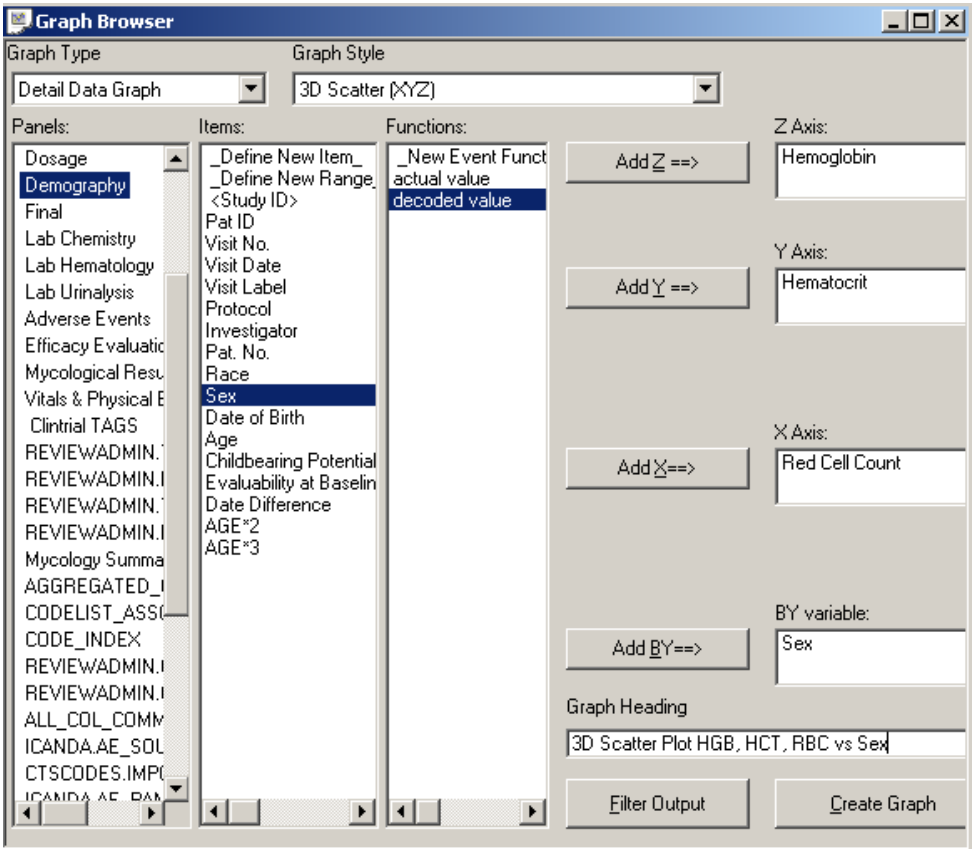
The Scatter Plot with Regression Line can also be plotted as two variables on the Y axis (dual Y axis mode).



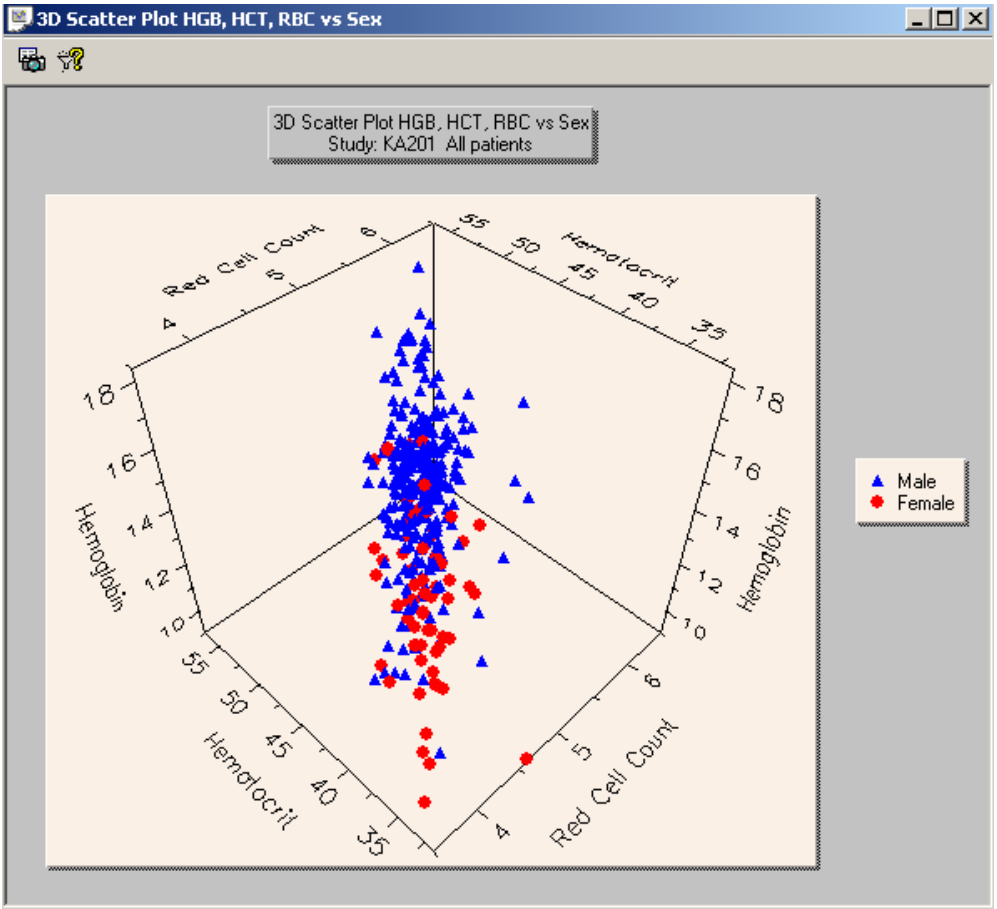

Scatter (itemX vs itemY) Plot with Regression Line
Scatter (itemX vs itemY) Plot with Regression Line
Study: KA201 All patients
Cholesterol, total: Y = 36.41 + 2.41 * X
Triglycerides: Y = 2.65 + 2.76 * X
392
372
352
332
312
292
272
252
232
212
192
172
152
132
112
1029
929
829
729
629
529
429
329
229
129
29
47
52
57
62
67
72
77
82
87
Height
:Cholesterol, total
:Triglycerides

3D Scatter Plot

The 3D Scatter (Item X vs. Item Y vs. Item Z) Plot displays three-dimensional data. Each patient's data points for X and Y coordinates are plotted against the Z elevation value. Use the BY variable to subset graphic displays.

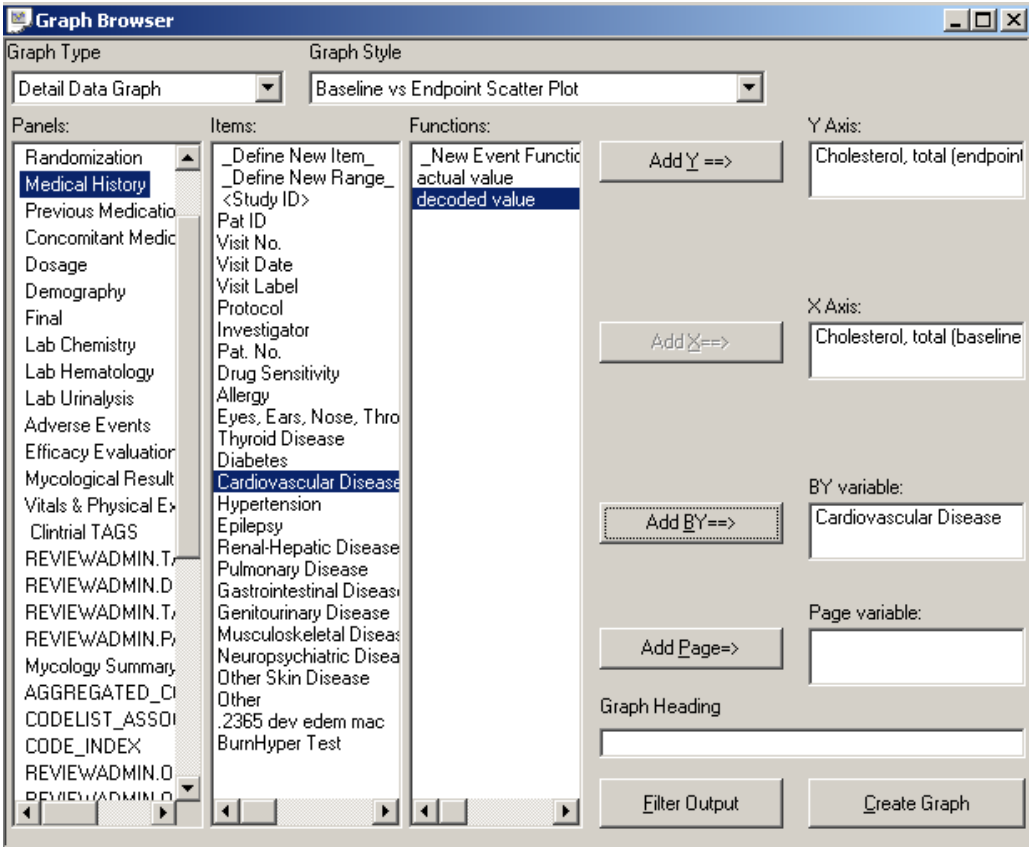


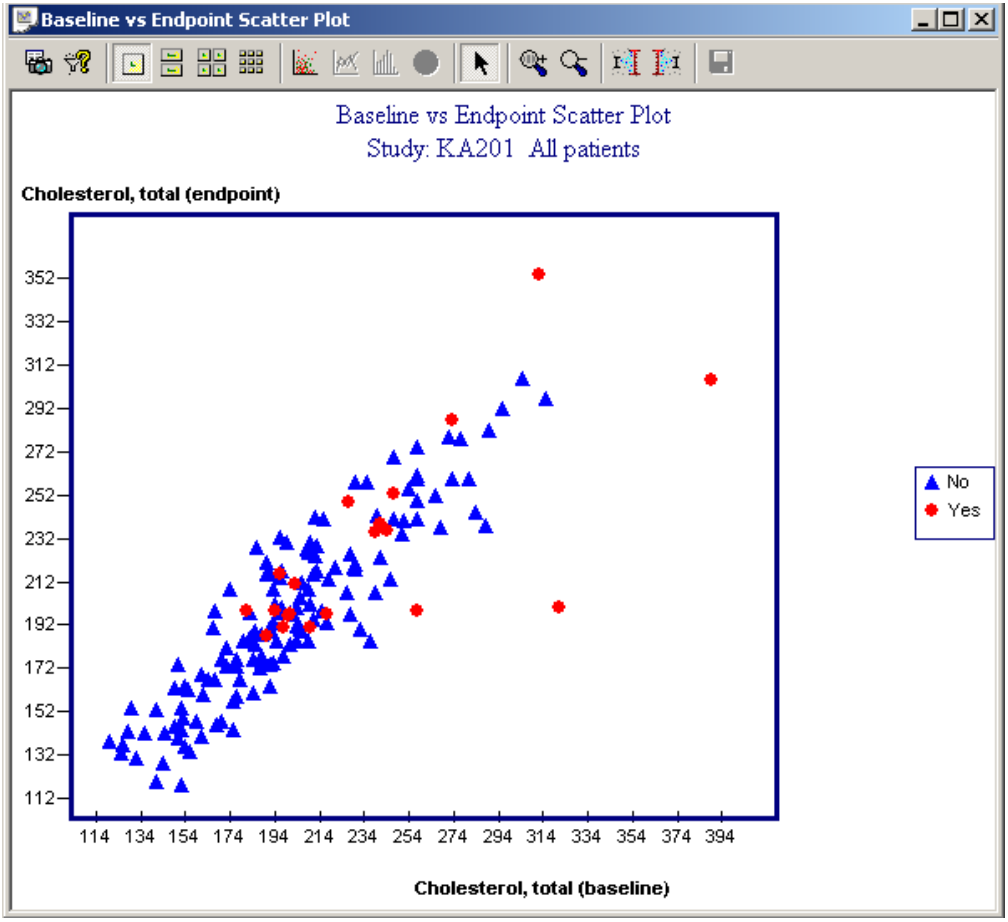
You can rotate a 3D graph image. Click on the left mouse key and then the right mouse key while holding down both keys at the same time, rotate the graph image.



Baseline vs. Endpoint Scatter Plot

In a Baseline vs. Endpoint scatter plot each data point represents a patient's baseline (X axis) and endpoint (Y axis) for the item. The Baseline vs. Endpoint Scatter Plot have only "Y axis" button enabled. When you add the item to the Y axis, it is automatically added to the X axis, and both axis titles are modified with 'Baseline' or 'Endpoint' after the description. 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.

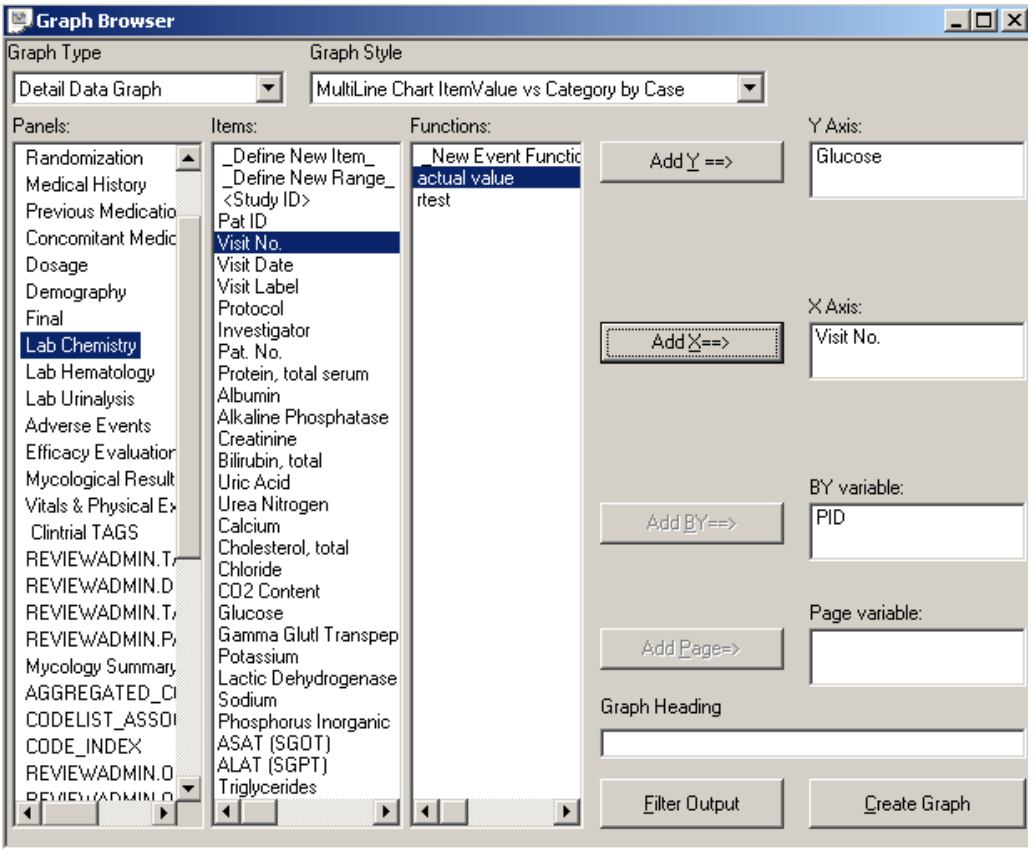



Baseline vs Endpoint Scatter Plot
Baseline vs Endpoint Scatter Plot
Study: KA201 All patients
Cholesterol, total (endpoint)
352
332
312
292
272
252
232
212
192
172
152
132
112
114 134 154 174 194 214 234 254 274 294 314 334 354 374 394
Cholesterol, total (baseline)
No
Yes

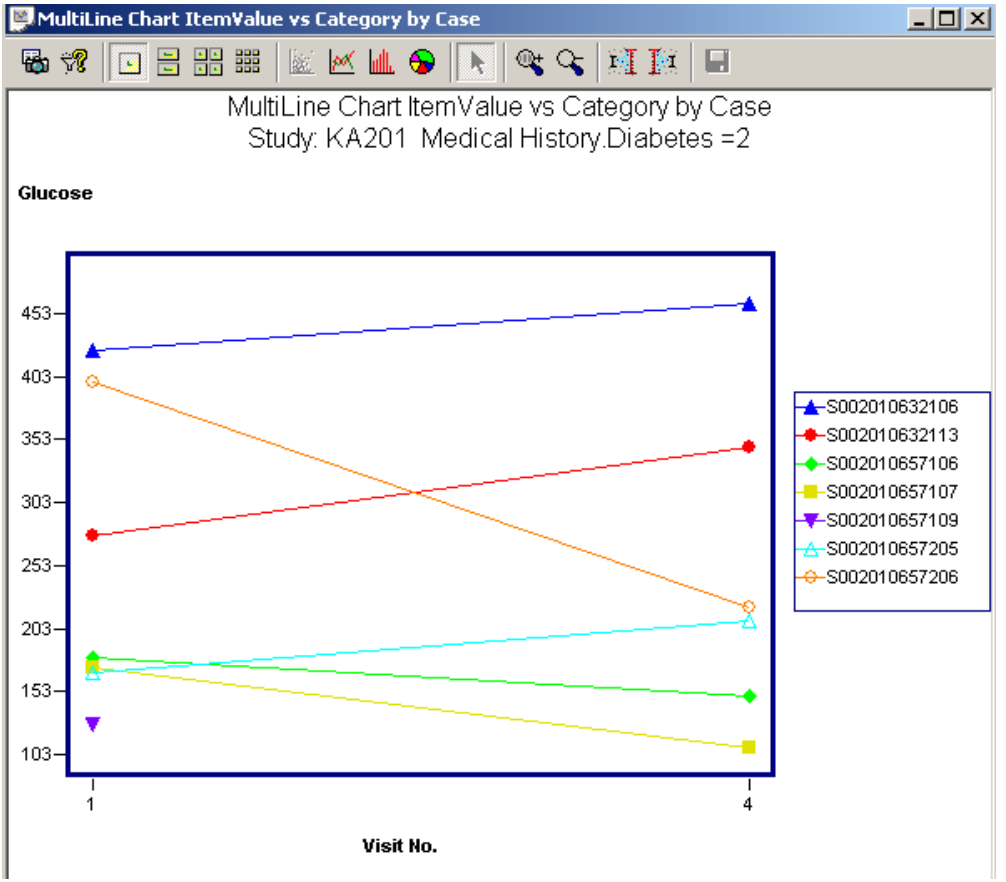
MultiLine Chart Item Value vs. Category by Case

In a MultiLine Chart Item Value vs. Category by Case graph, each patient is represented by a line. PID is defaulted for the patient identification. The Page variable is not allowed. Click on a line and the underlying patient will be highlighted in all patient-level displays of data.

Note: You may need to limit the number of patients displayed.



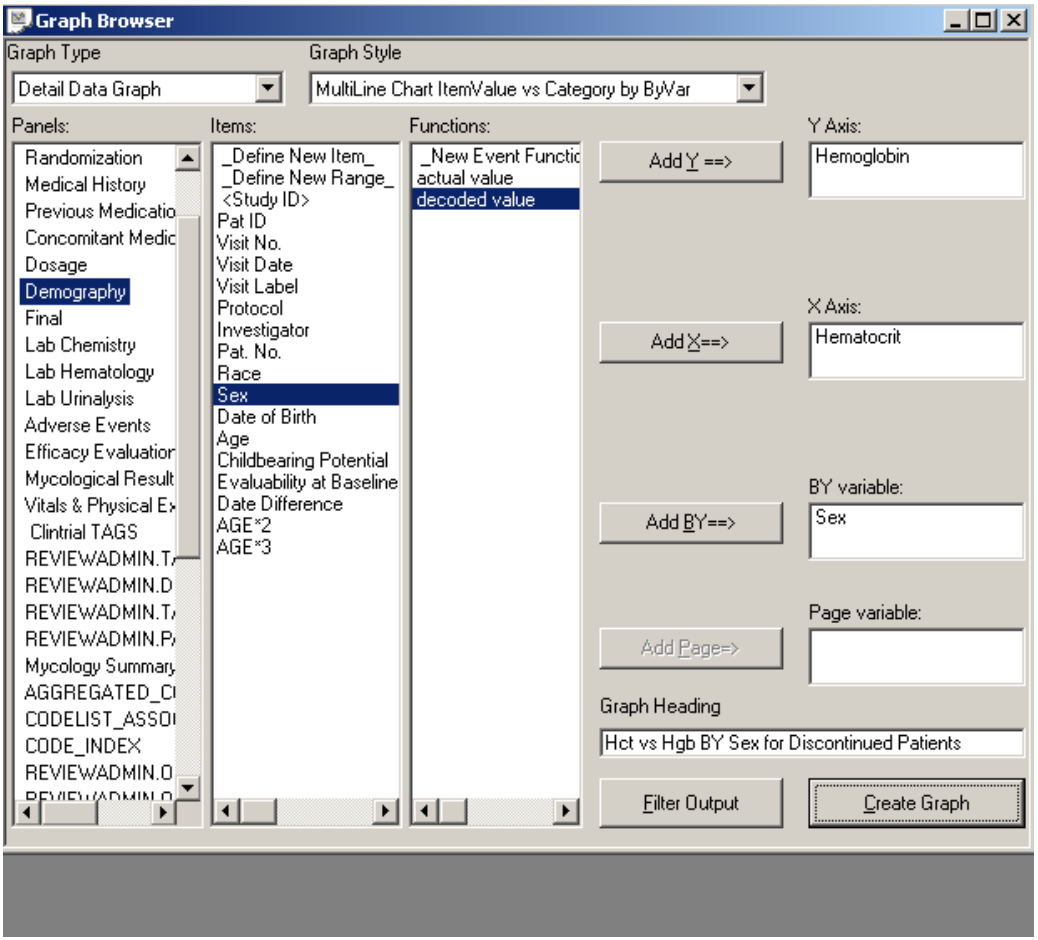
In this example, a patient selection criteria was applied to the graph output for Medical History if Diabetes was ‘Yes’ and displays in the graph heading.

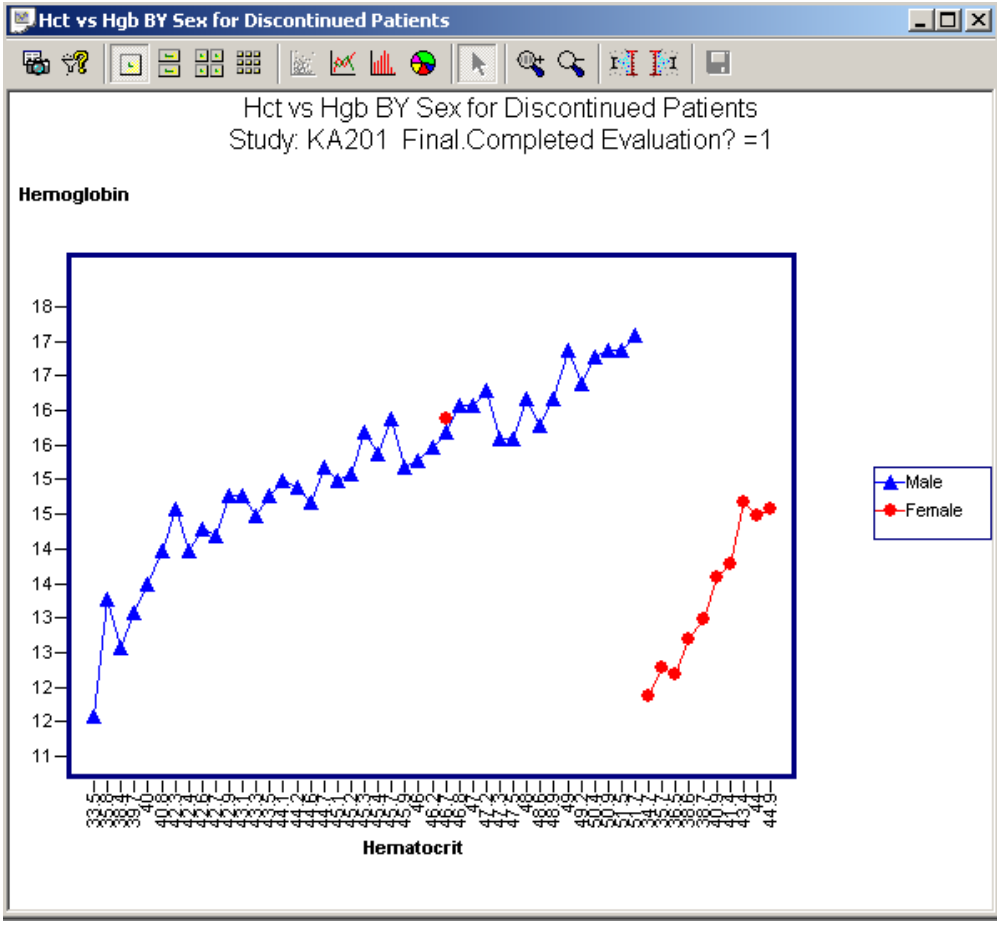


MultiLine Chart Item Value vs. Category by ByVar

The MultiLine Chart Item Value vs. Category by ByVar graph, provides the same functionality as the MultiLine Chart item Value vs. Category by Case graph. However, you select the patient identification item. Each patient is represented by a line. Click on a line and the underlying patient will be highlighted in all patient-level displays of data.

Note: You may need to limit the number of patients displayed.

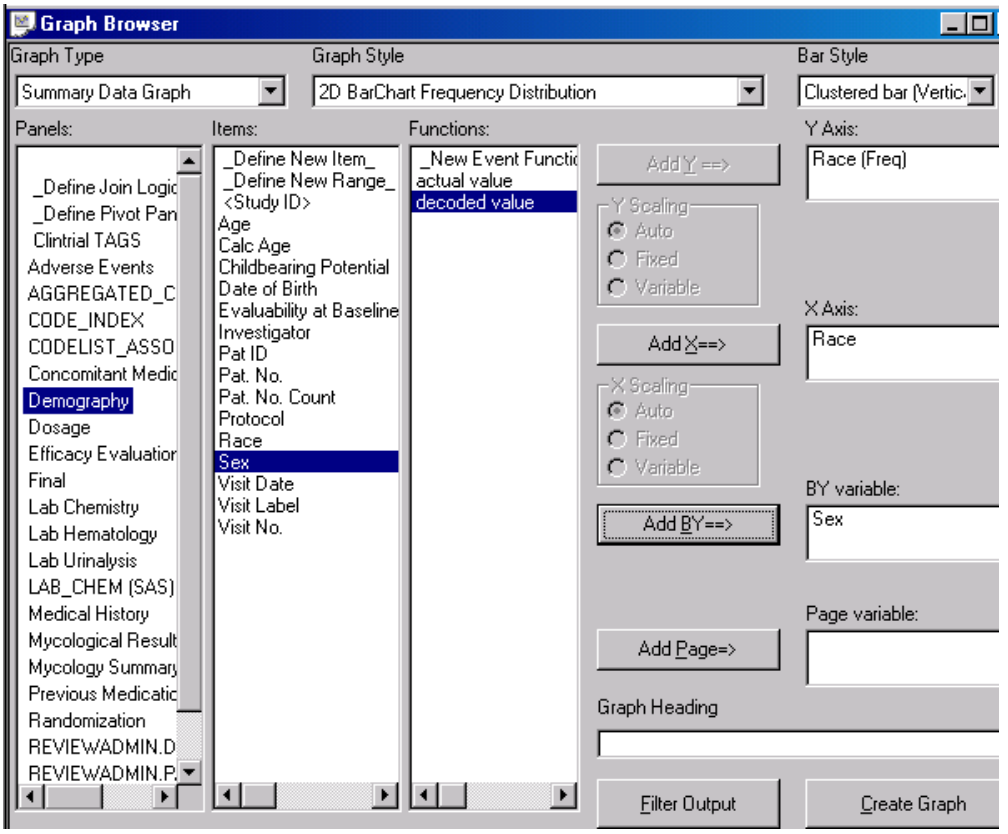


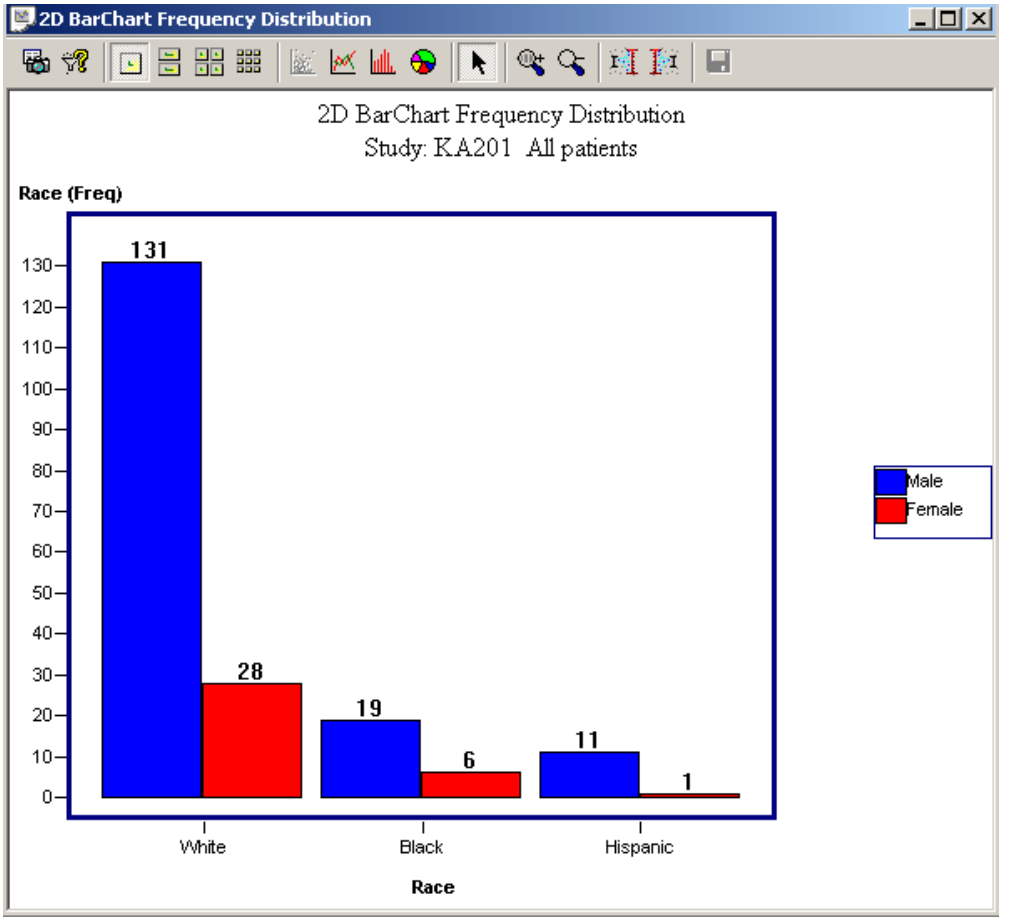

Hct vs Hgb BY Sex for Discontinued Patients
Hct vs Hgb BY Sex for Discontinued Patients
Study: KA201 Final.Completed Evaluation? =1
Hemoglobin
18
17
17
16
16
15
15
14
14
13
13
12
12
11
Hematocrit
Male
Female

Types of Summary Data Graphs

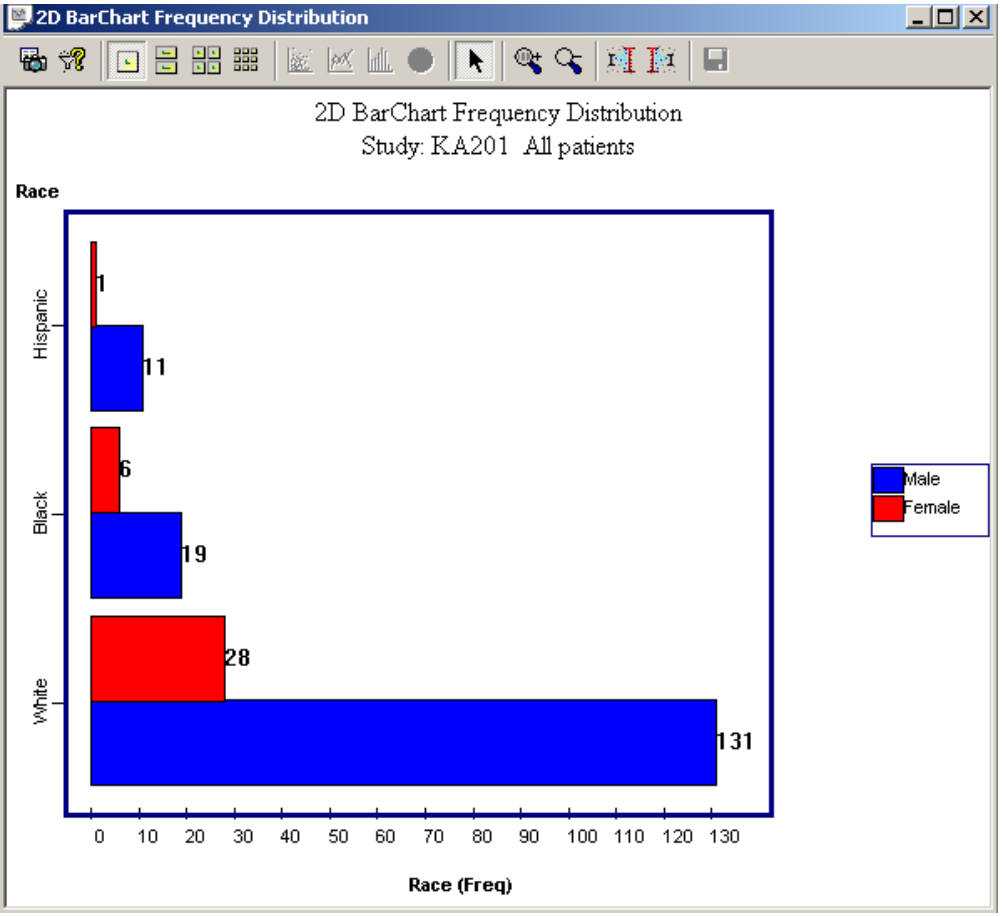
2D Bar Chart Frequency Distribution

In a 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.

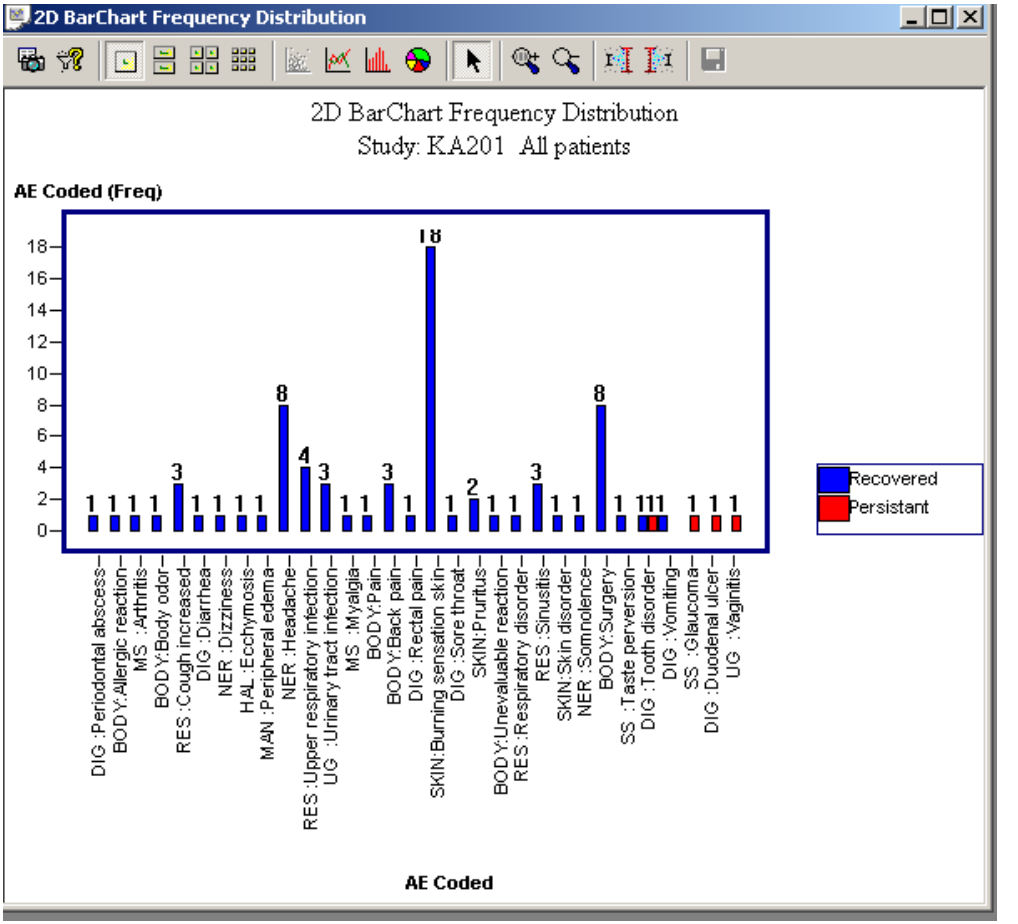



2D BarChart Frequency Distribution
2D BarChart Frequency Distribution
Study: KA201 All patients
Race (Freq)
131
28
19
6
11
1
White
Black
Hispanic
Race
Male
Female

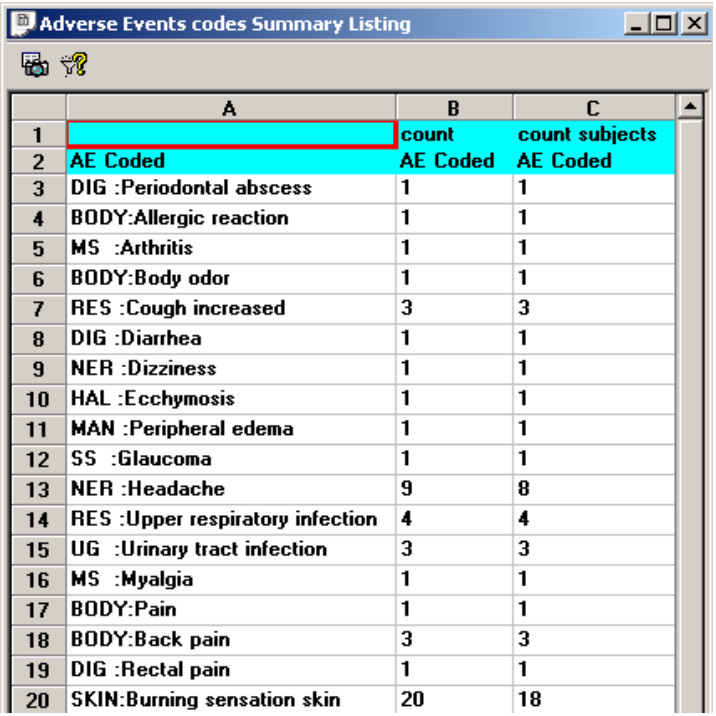
This example shows the same graph type and style, but with a different Bar style option for clustered horizontal.



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



(partial screen display)

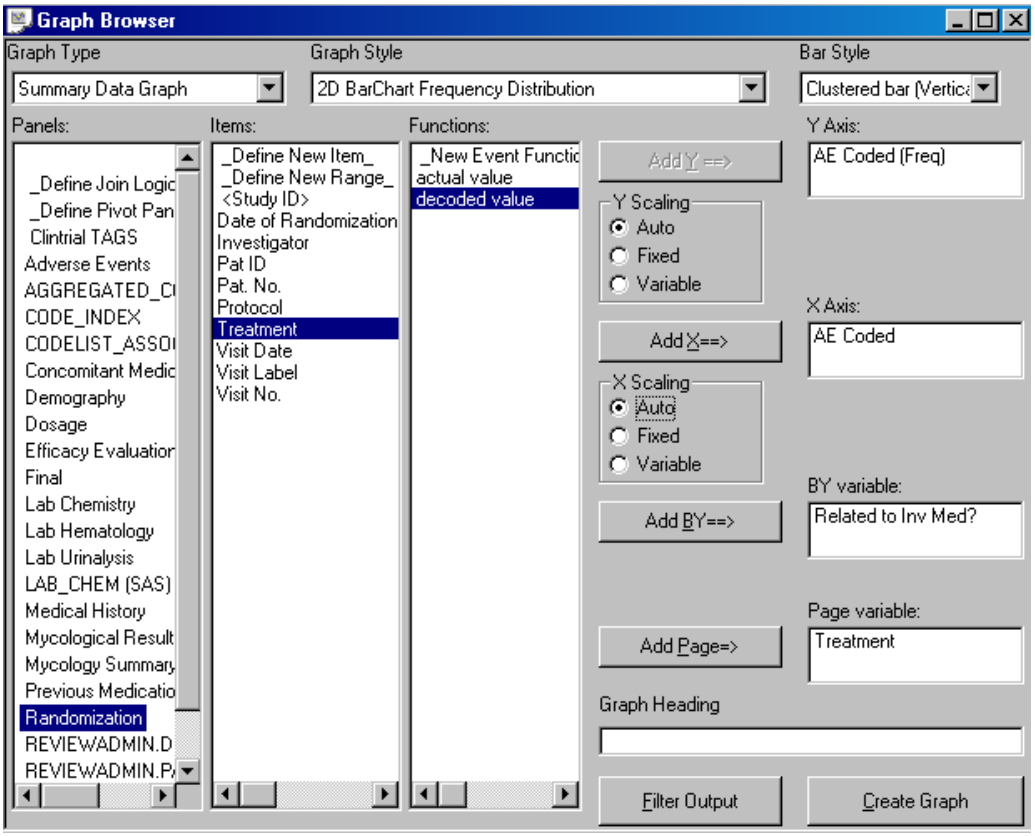


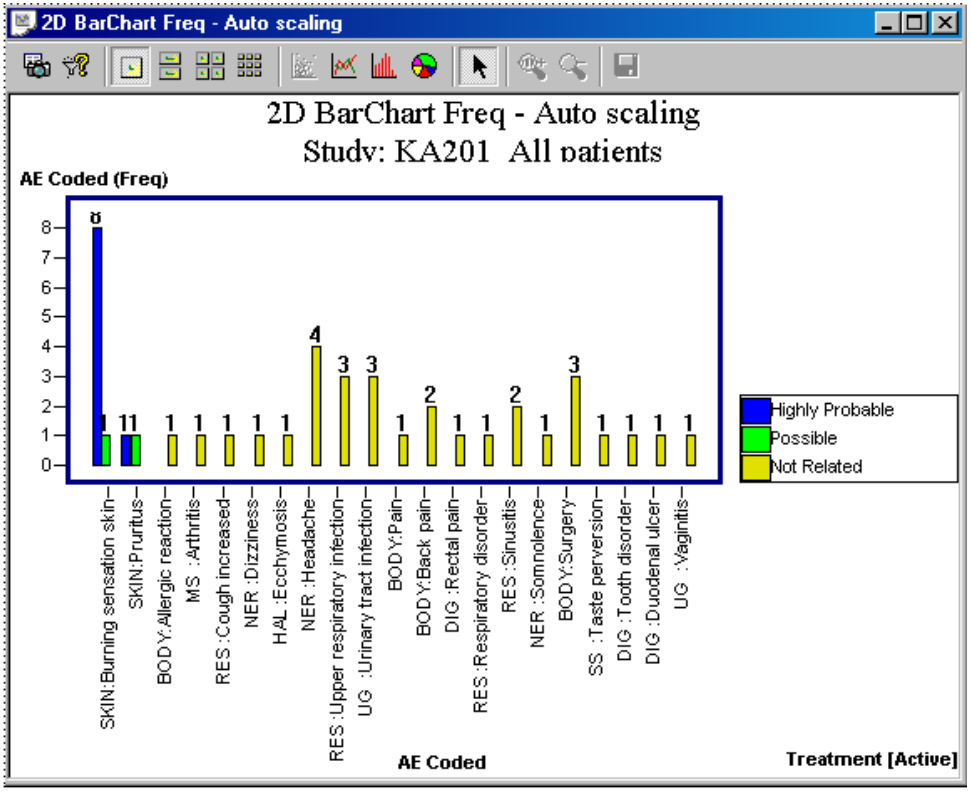
Adverse Events codes Summary Listing

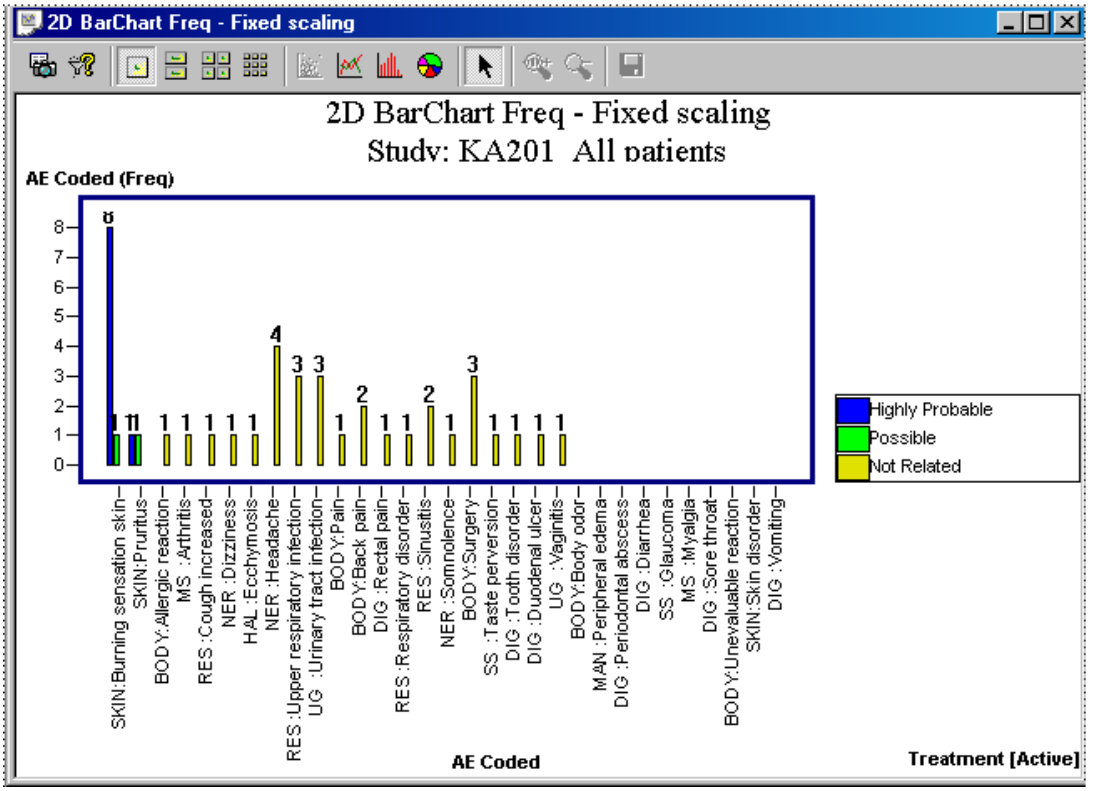
	A	B	C
1		count	count subjects
2	AE Coded	AE Coded	AE Coded
3	DIG :Periodontal abscess	1	1
4	BODY:Allergic reaction	1	1
5	MS :Arthritis	1	1
6	BODY:Body odor	1	1
7	RES :Cough increased	3	3
8	DIG :Diarrhea	1	1
9	NER :Dizziness	1	1
10	HAL :Ecchymosis	1	1
11	MAN :Peripheral edema	1	1
12	SS :Glaucoma	1	1
13	NER :Headache	9	8
14	RES :Upper respiratory infection	4	4
15	UG :Urinary tract infection	3	3
16	MS :Myalgia	1	1
17	BODY:Pain	1	1
18	BODY:Back pain	3	3
19	DIG :Rectal pain	1	1
20	SKIN:Burning sensation skin	20	18

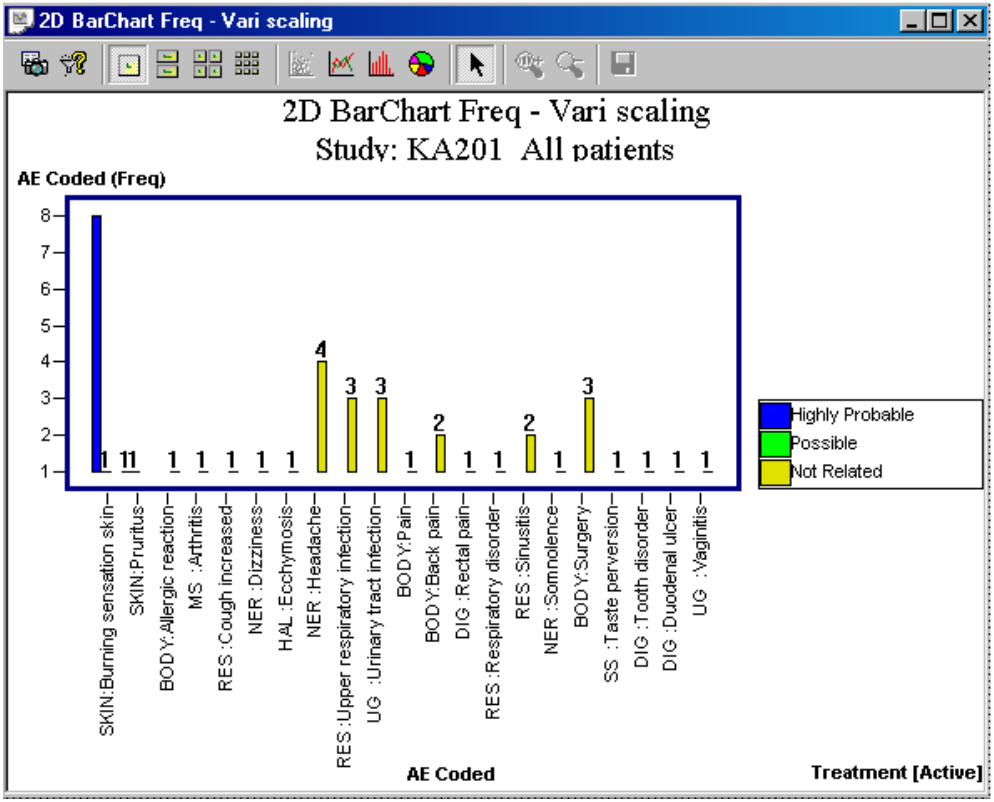
X and Y scaling

The X 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.



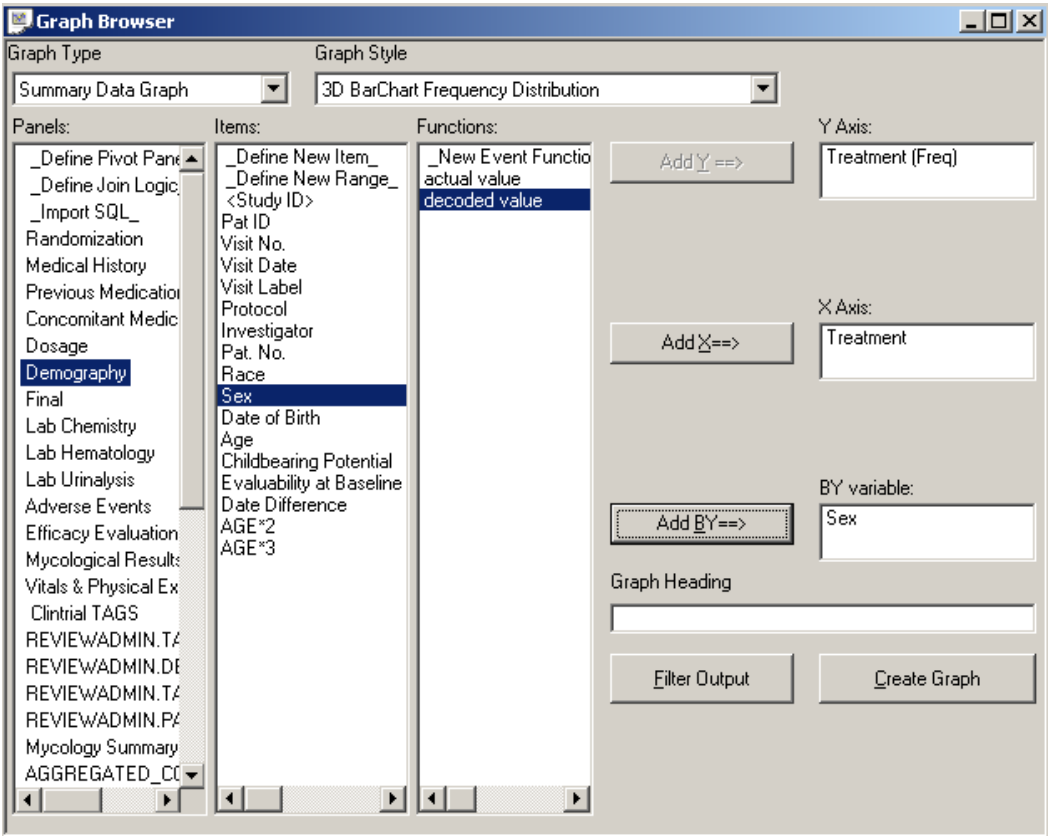

2D BarChart Freq - Auto scaling
2D BarChart Freq - Auto scaling
Study: KA201 All patients
AE Coded (Freq)
8
7
6
5
4
3
2
1
0
1
11
1
1
1
1
1
4
3
3
1
2
1
1
2
1
3
1
1
1
1
SKIN:Burning sensation skin
SKIN:Pruritus
BODY:Allergic reaction
MS :Arthritis
RES :Cough increased
NER :Dizziness
HAL :Ecchymosis
NER :Headache
RES :Upper respiratory infection
UG :Urinary tract infection
BODY:Pain
BODY:Back pain
DIG :Rectal pain
RES :Respiratory disorder
RES :Sinusitis
NER :Somnolence
BODY:Surgery
SS :Taste perversion
DIG :Tooth disorder
DIG :Duodenal ulcer
UG :Vaginitis
AE Coded
Treatment [Active]
Highly Probable
Possible
Not Related


2D BarChart Freq - Fixed scaling
2D BarChart Freq - Fixed scaling
Study: KA201 All patients
AE Coded (Freq)
8
7
6
5
4
3
2
1
0
6
1
1
1
1
1
1
4
3
3
1
2
1
1
2
1
3
1
1
1
1
SKIN:Burning sensation skin
SKIN:Pruritus
BODY:Allergic reaction
MS :Arthritis
RES :Cough increased
NER :Dizziness
HAL :Ecchymosis
NER :Headache
RES :Upper respiratory infection
UG :Urinary tract infection
BODY:Pain
BODY:Back pain
DIG :Rectal pain
RES :Respiratory disorder
RES :Sinusitis
NER :Somnolence
BODY:Surgery
SS :Taste perversion
DIG :Tooth disorder
DIG :Duodenal ulcer
UG :Vaginitis
BODY:Body odor
MAN :Peripheral edema
DIG :Periodontal abscess
DIG :Diarrhea
SS :Glaucoma
MS :Myalgia
DIG :Sore throat
BODY:Unevaluable reaction
SKIN:Skin disorder
DIG :Vomiting
AE Coded
Highly Probable
Possible
Not Related
Treatment [Active]

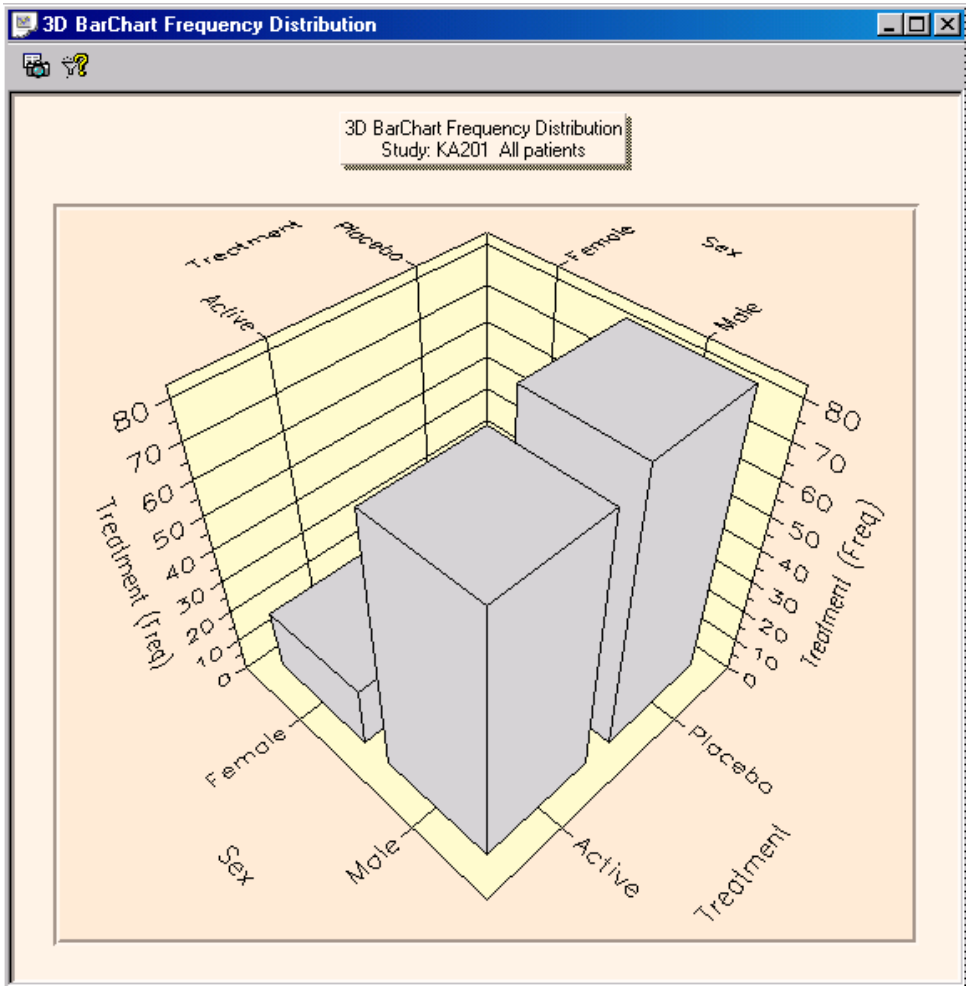

2D BarChart Freq - Vari scaling
2D BarChart Freq - Vari scaling
Study: KA201 All patients
AE Coded (Freq)
8
7
6
5
4
3
2
1
1 11 1 1 1 1 1 4 3 3 1 2 1 1 2 1 3 1 1 1 1
SKIN:Burning sensation skin
SKIN:Pruritus
BODY:Allergic reaction
MS :Arthritis
RES :Cough increased
NER :Dizziness
HAL :Ecchymosis
NER :Headache
RES :Upper respiratory infection
UG :Urinary tract infection
BODY:Pain
BODY:Back pain
DIG :Rectal pain
RES :Respiratory disorder
RES :Sinusitis
NER :Somnolence
BODY:Surgery
SS :Taste perversion
DIG :Tooth disorder
DIG :Duodenal ulcer
UG :Vaginitis
AE Coded
Highly Probable
Possible
Not Related
Treatment [Active]

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.

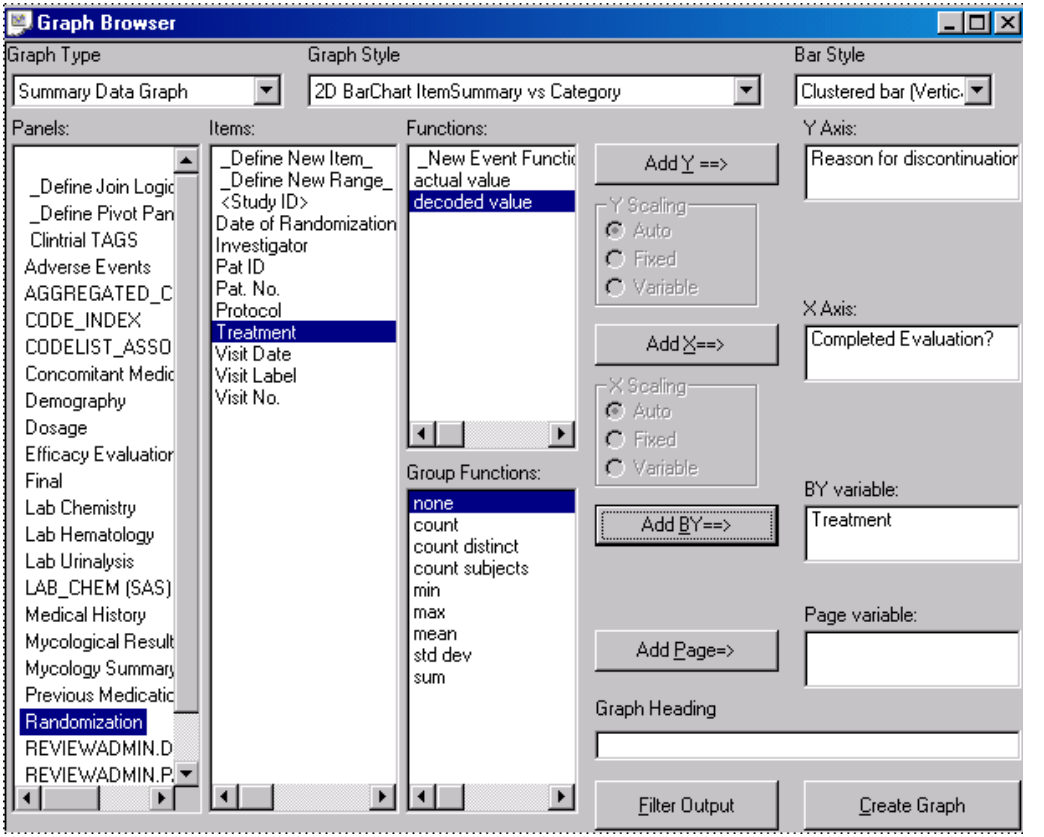


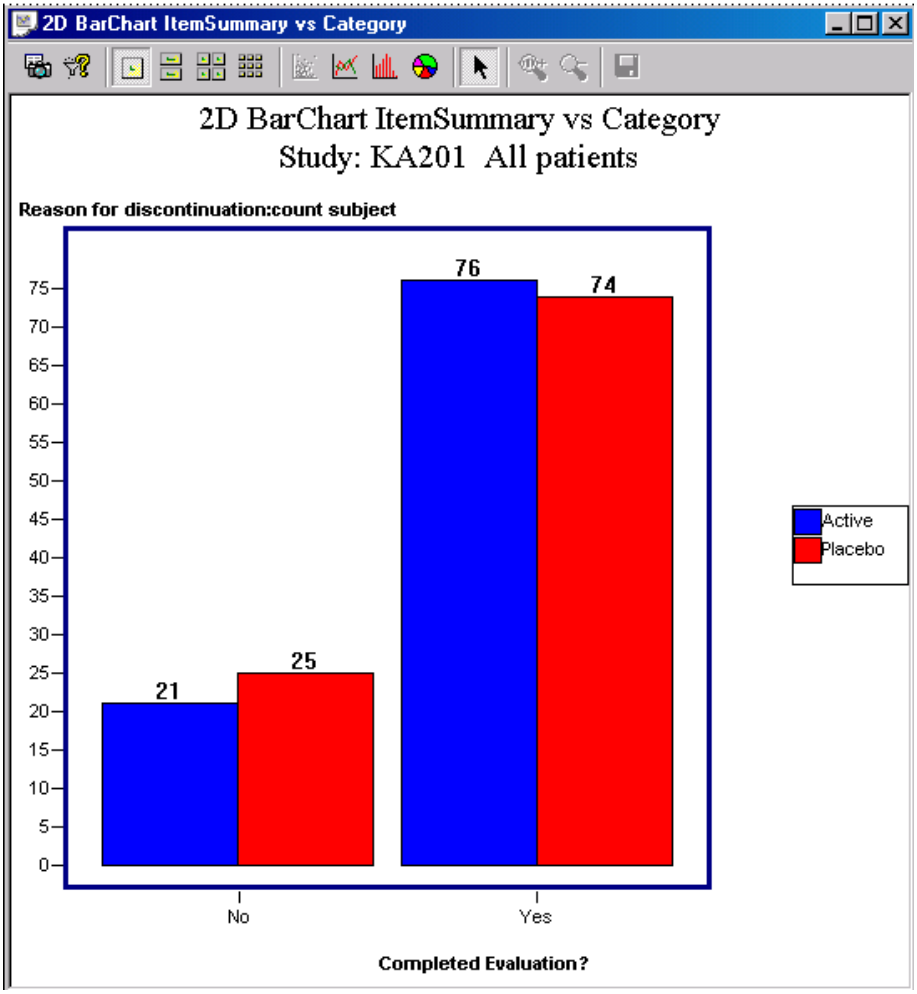
Use the BY variable to subset graphic displays.



2D Bar Chart Item Summary vs. Category

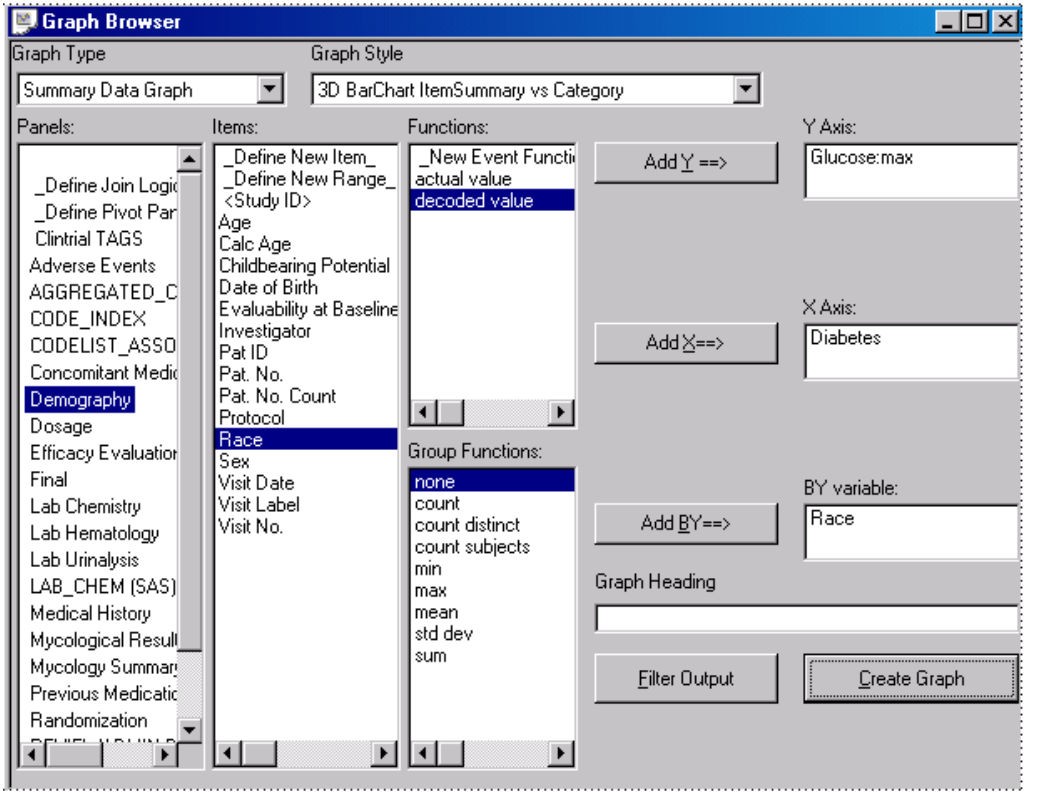
In a 2D BarChart Item Summary vs. Category, each bar represents a category value X axis versus a summary statistic (mean, count, sum) Y axis. The Graph Browser window provides a list of group functions for the Y axis. Use the BY variable to subset graphic displays.

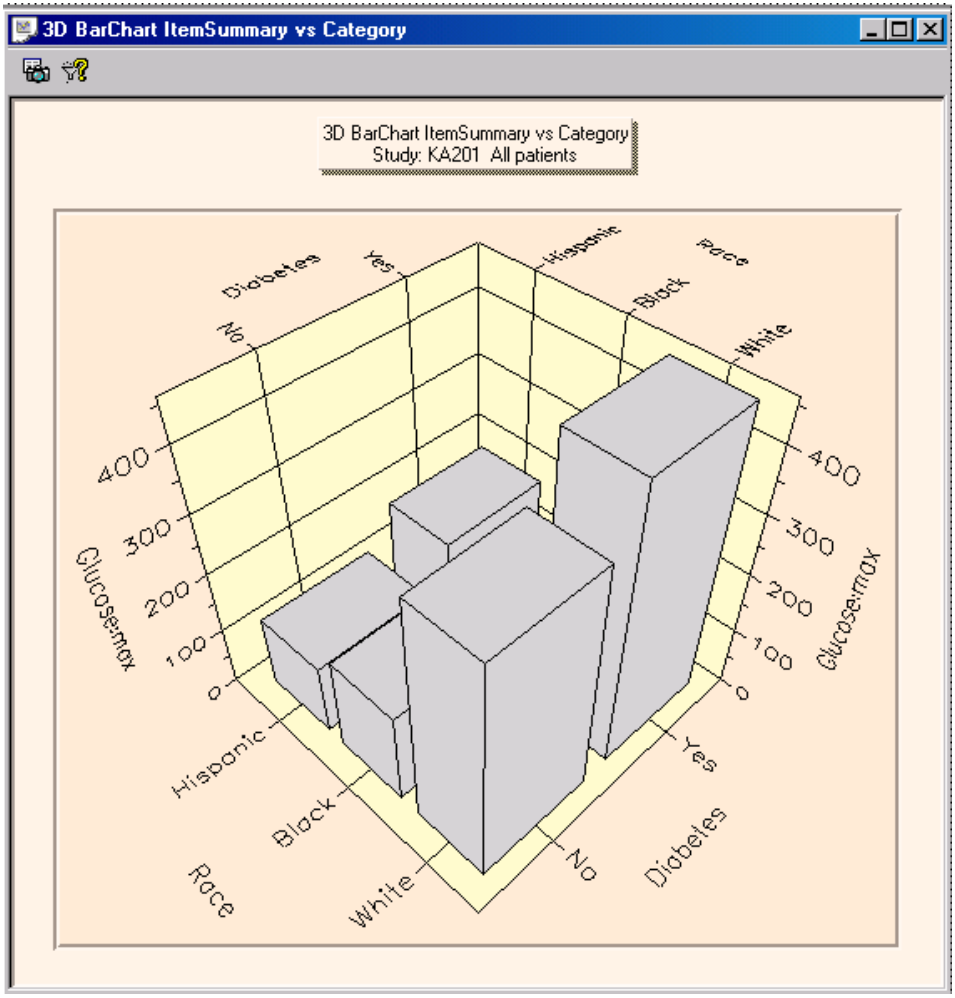



2D BarChart ItemSummary vs Category
2D BarChart ItemSummary vs Category
Study: KA201 All patients
Reason for discontinuation:count subject
75
70
65
60
55
50
45
40
35
30
25
20
15
10
5
0
21
25
76
74
No
Yes
Completed Evaluation?
Active
Placebo

3D BarChart Item Summary vs.Category

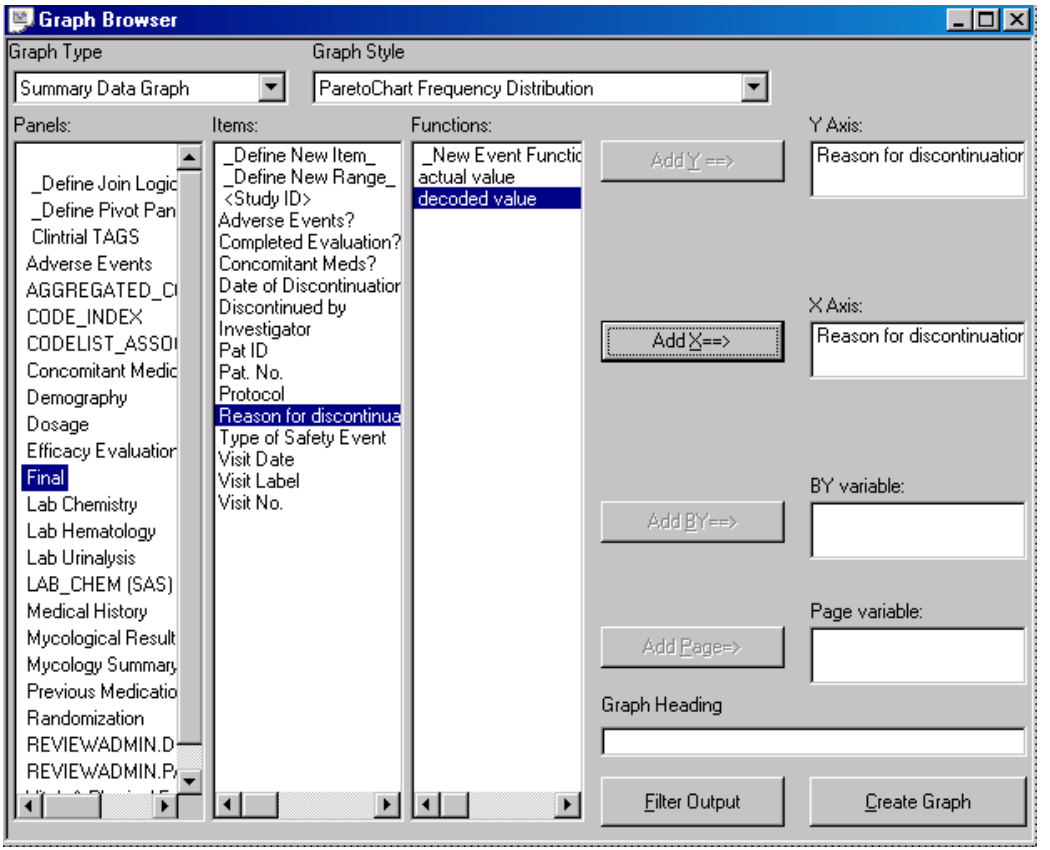
In a 3D BarChart Item Summary vs. Category, each bar represents a category value X axis versus a summary statistic (mean, count, sum) Y axis. The Graph Browser window provides a separate list of group functions for the Y axis. Use the BY variable to subset graphic displays.

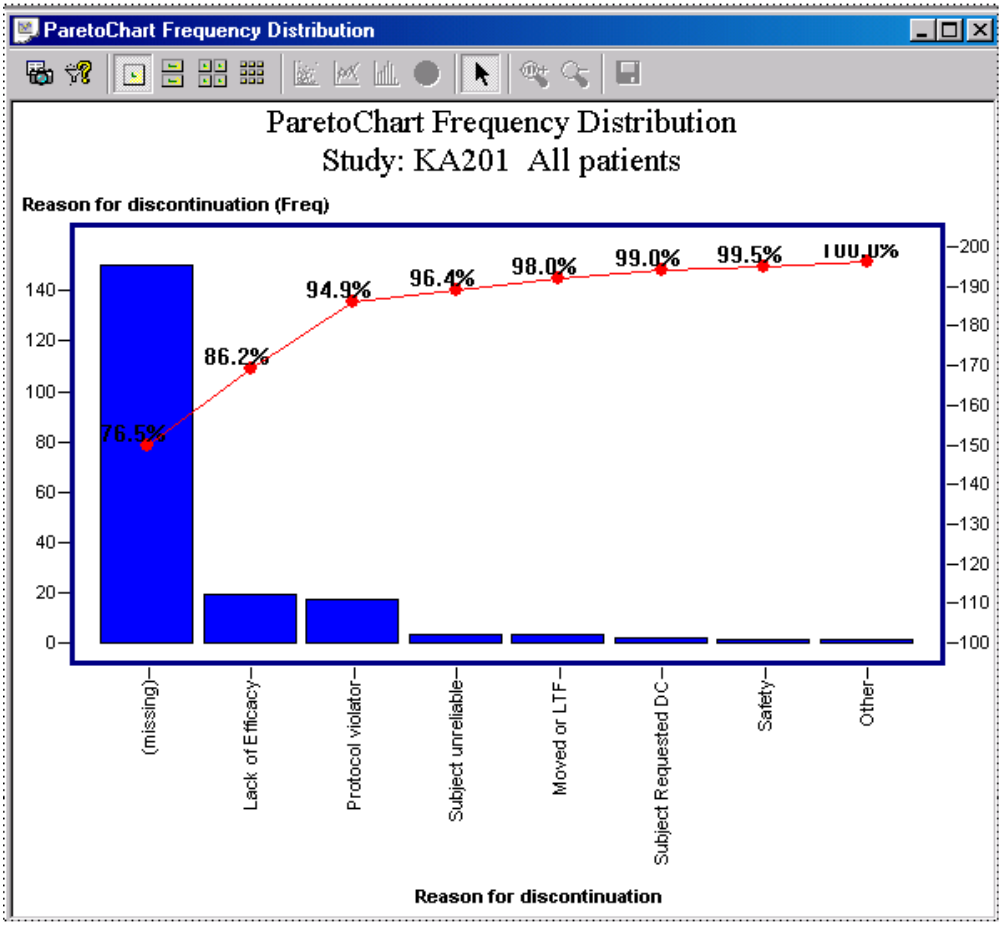



3D BarChart ItemSummary vs Category
3D BarChart ItemSummary vs Category
Study: KA201 All patients
Diabetes
Yes
No
Race
Hispanic
Black
White
Glucosemax
400
300
200
100
0
Hispanic
Black
White
Race
Yes
No
Diabetes

Pareto Chart Frequency Distribution

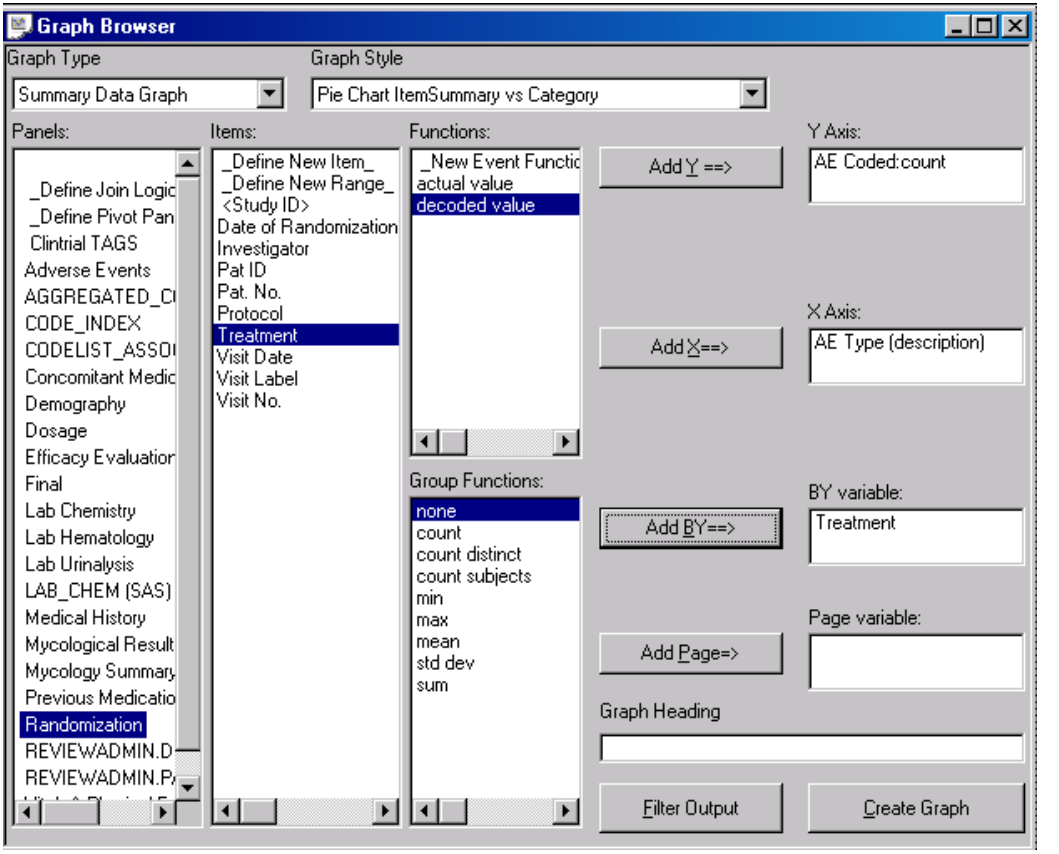
In a Pareto chart frequency Distribution, each bar represents a category value that corresponds to the plotted Y axis. The line above the bars shows the cumulative percentage. Pareto charts display the Y axis bars in descending order of frequency.

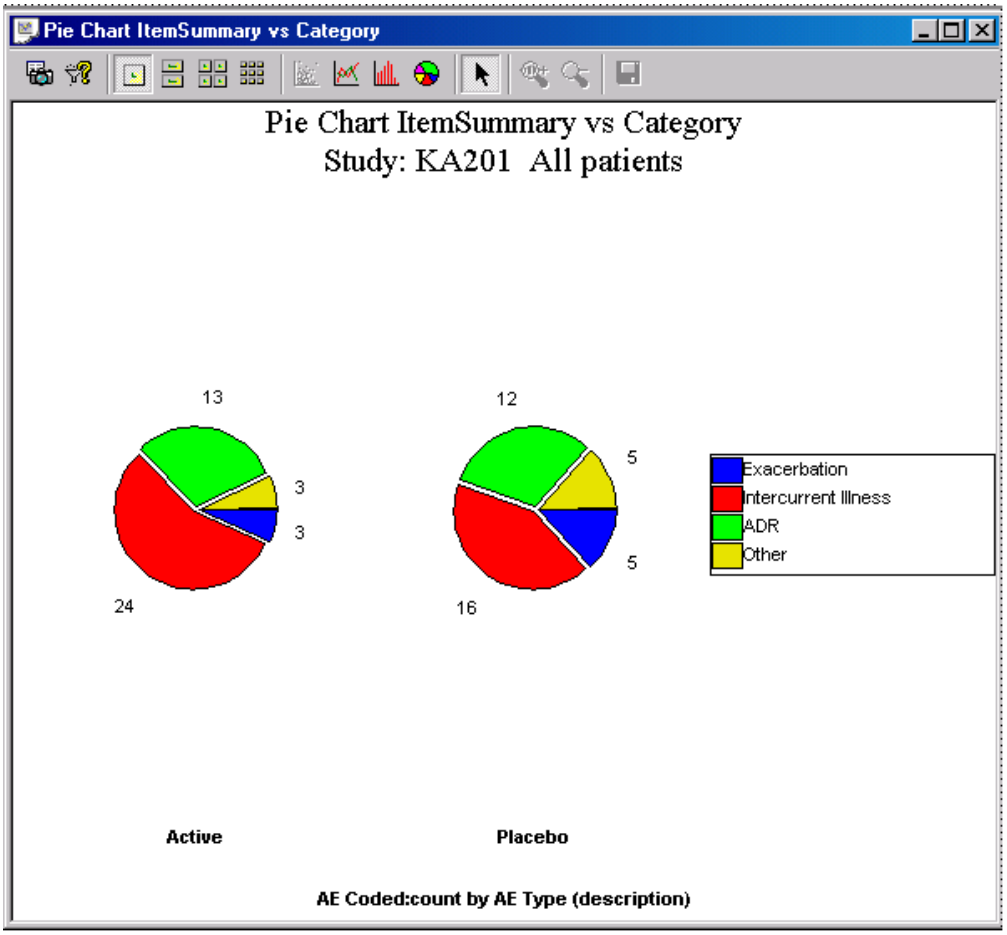



ParetoChart Frequency Distribution
ParetoChart Frequency Distribution
Study: KA201 All patients
Reason for discontinuation (Freq)
140
120
100
80
60
40
20
0
200
190
180
170
160
150
140
130
120
110
100
76.5%
86.2%
94.9%
96.4%
98.0%
99.0%
99.5%
100.0%
(missing)
Lack of Efficacy
Protocol violator
Subject unreliable
Moved or LTF
Subject Requested DC
Safety
Other
Reason for discontinuation

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.

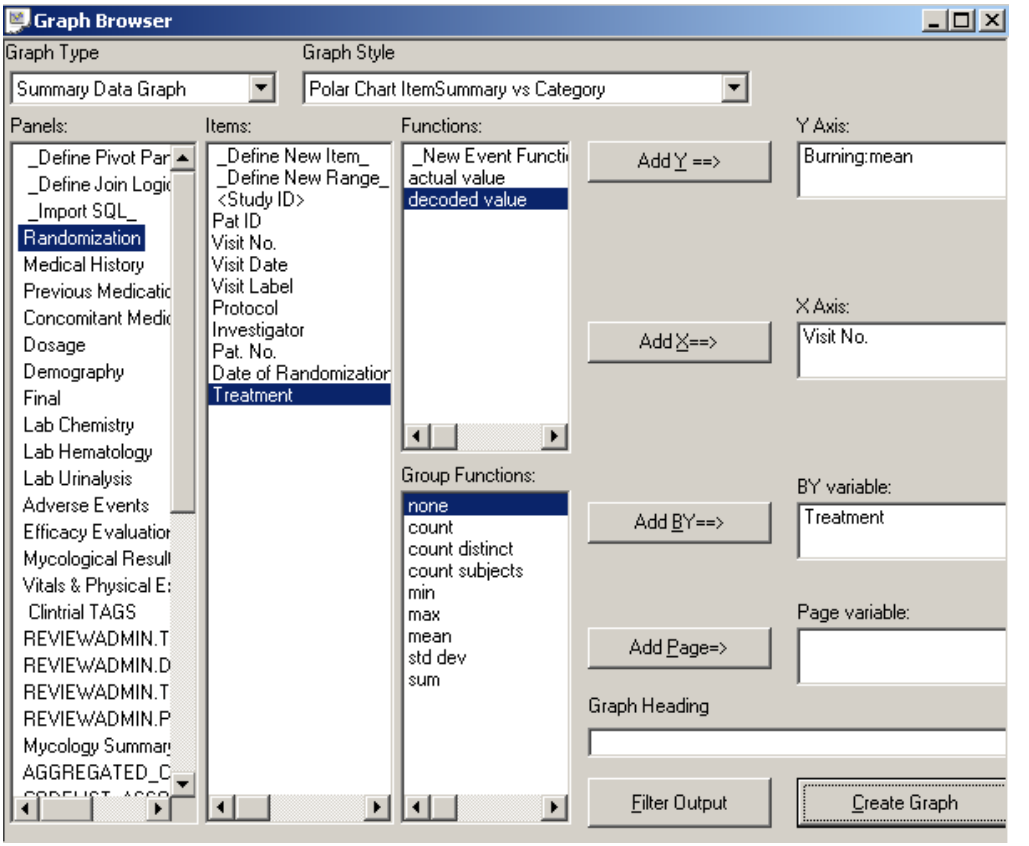


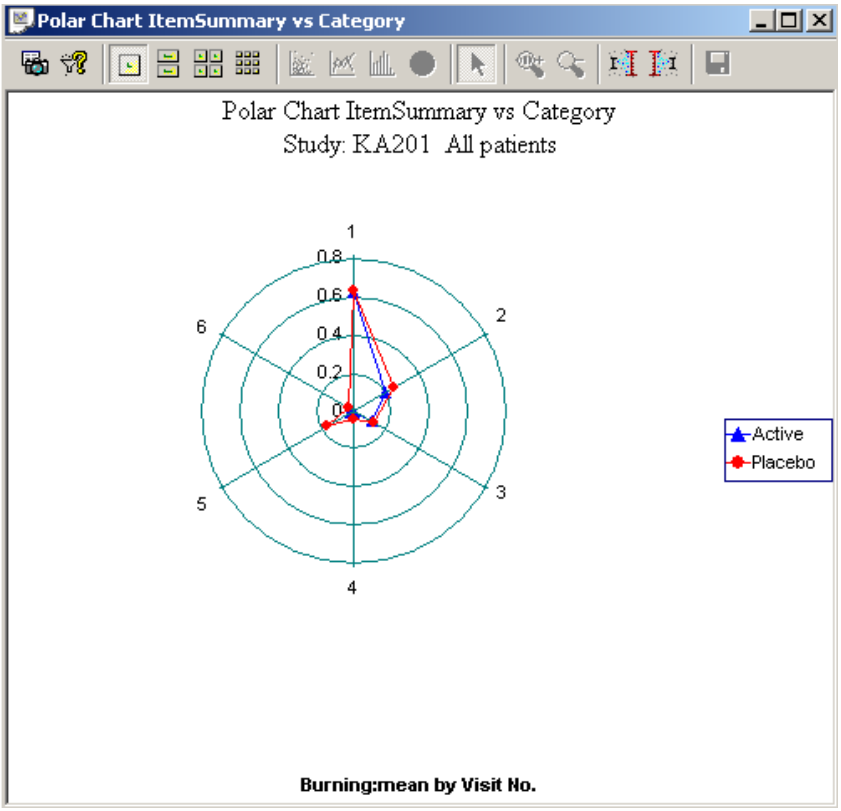

Pie Chart ItemSummary vs Category
Pie Chart ItemSummary vs Category
Study: KA201 All patients
13
3
3
24
12
5
5
16
Exacerbation
Intercurrent Illness
ADR
Other
Active
Placebo
AE Coded:count by AE Type (description)

Polar Chart Item Summary vs. Category

In a Polar Chart Item Summary vs. Category, each data set is draw as connected points on a polar coordinate system (theta, r). The X axis values (theta) are drawn as a circle to represent the amount of rotation and Y axis values (r) are the distance from the origin.

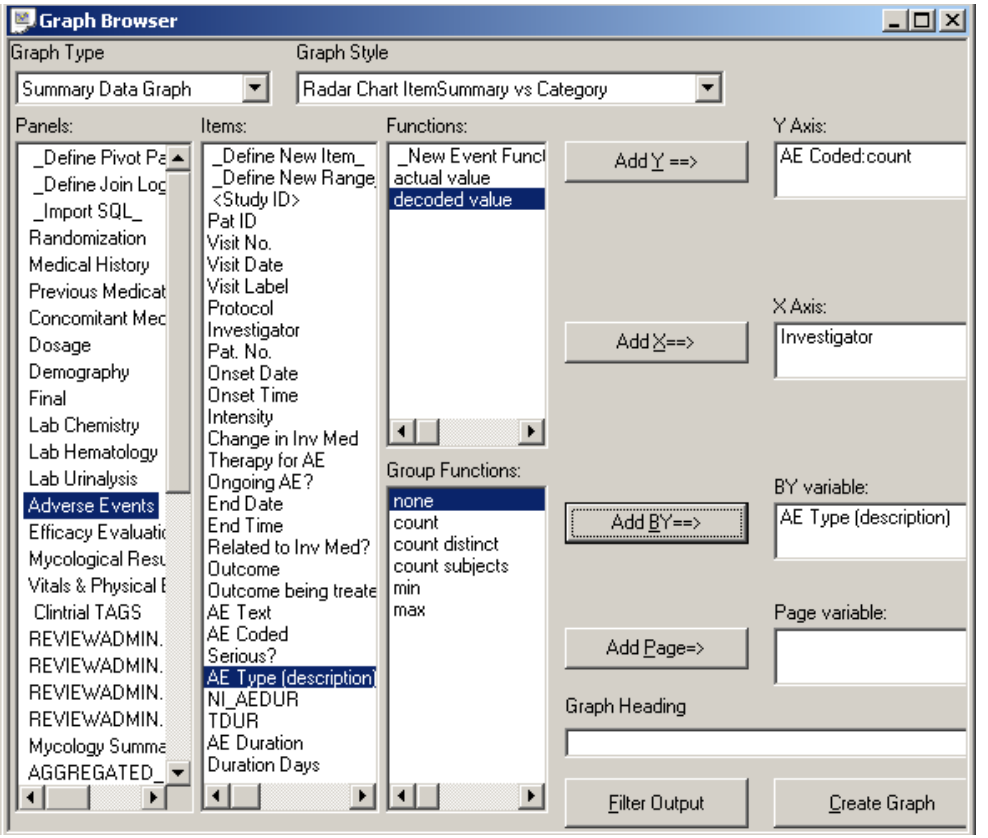
The Graph Browser window provides a separate list of group functions for the Y axis. Use the BY variable to display multiple sets.



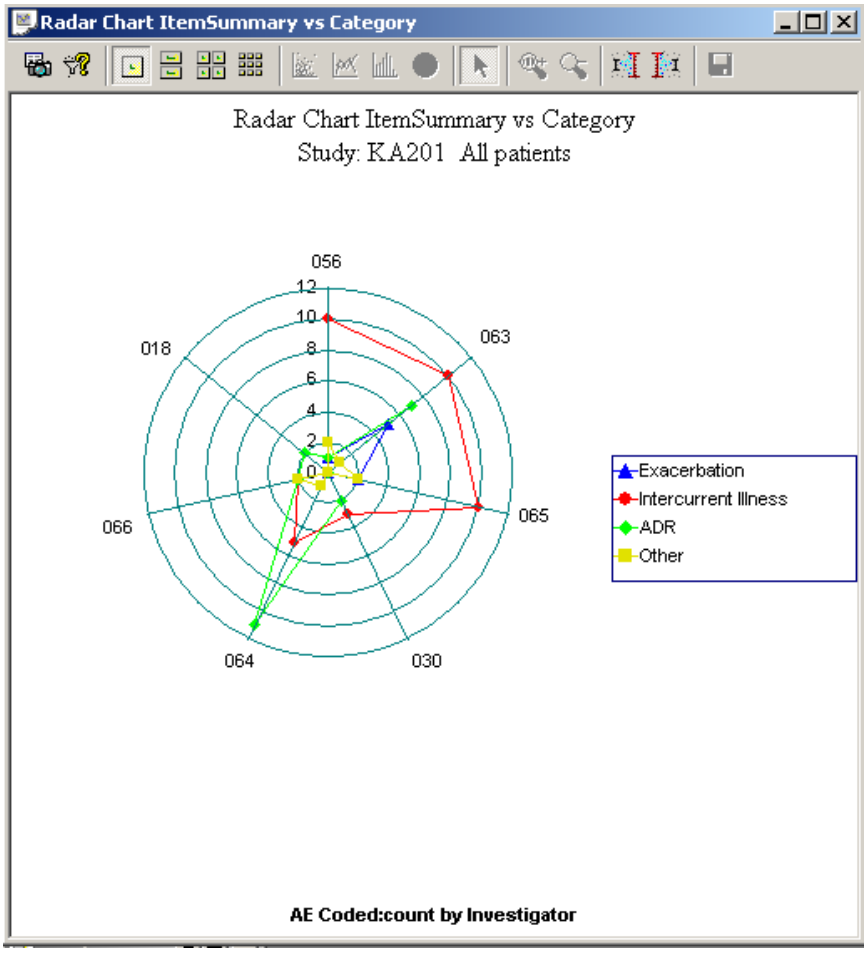

Polar Chart ItemSummary vs Category
Polar Chart ItemSummary vs Category
Study: KA201 All patients
1
2
3
4
5
6
0.8
0.6
0.4
0.2
0
Active
Placebo
Burning:mean by Visit No.

The Radar Chart Item Summary vs. Category, draws the Y axis value in each data set along a radar line (where the X value is ignored). The chart plane is equally divided into angle segments (each point represented at n / 360 degree increments) with the X axis showing Point-labels. The radial gridlines are spaced equally apart. By default, the radar line representing the first point is drawn vertically at 90 degrees. Each data set is drawn as connected points along the radar lines.

The Graph Browser window provides a separate list of group functions for the Y axis. Use the BY variable to subset graphic displays.



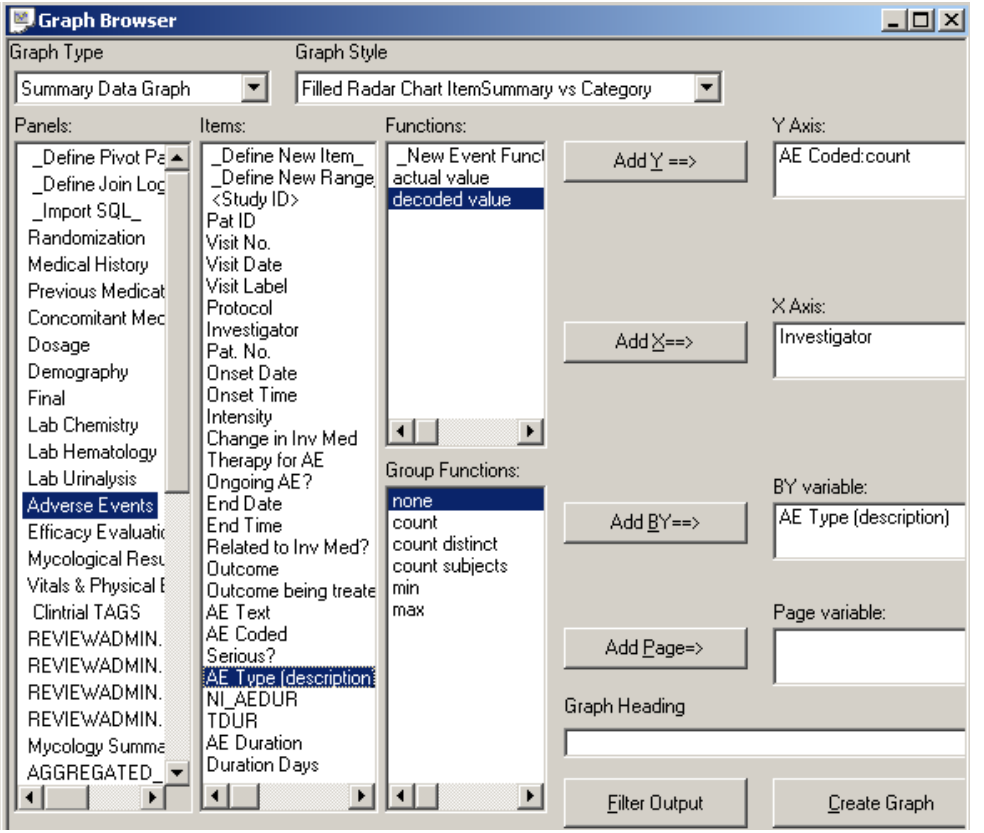
For polar and radar charts, circular gridlines are a property of the Y axis and radial gridlines are a property of the X axis.

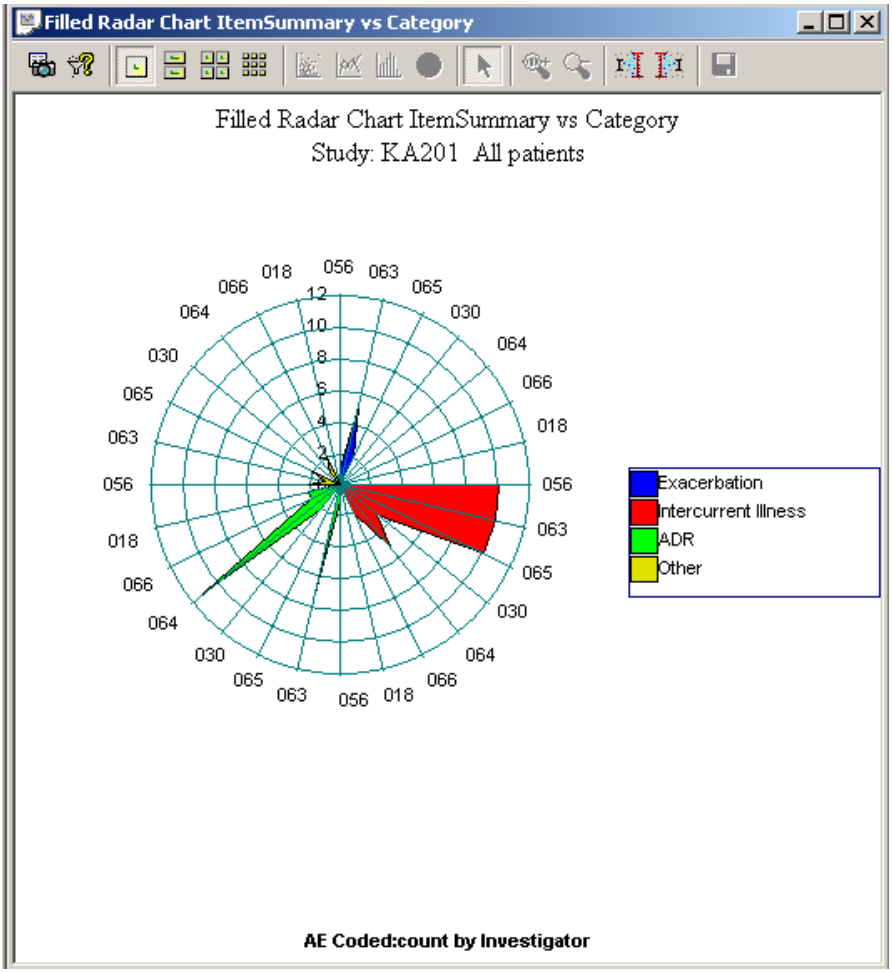


Filled Radar Chart Item Summary vs. Category

The Filled Radar Chart Item Summary vs. Category, shares the same chart definition as the Radar Chart Item Summary vs. Category. The difference is each data set is drawn as connected points along the radar lines with the area filled inside the points.

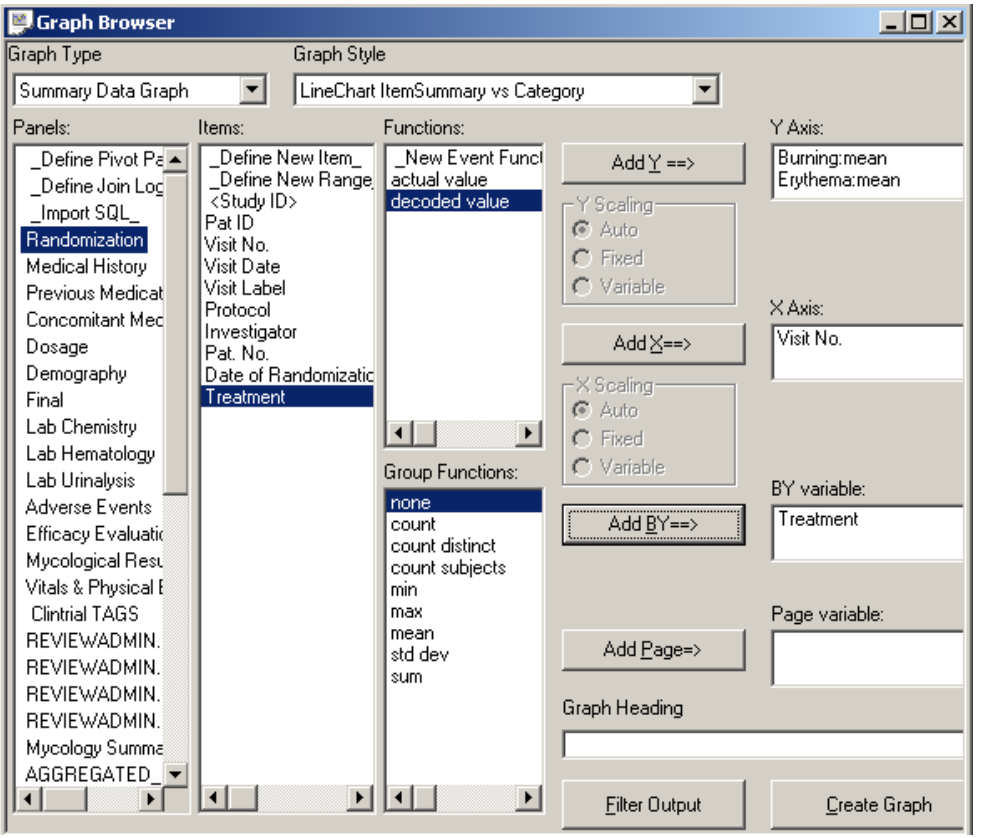
The Graph Browser window provides a separate list of group functions for the Y axis. Use the BY variable to subset graphic displays. Multiple sets are drawn “on top” of the preceding set.

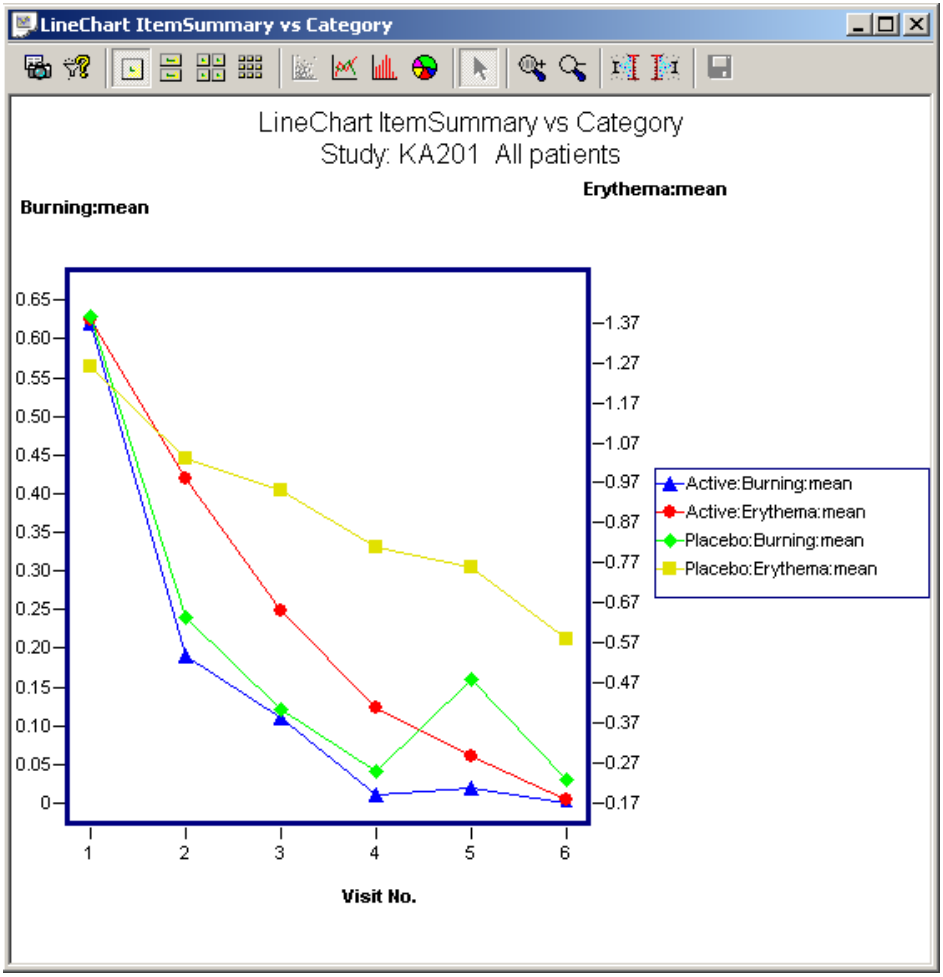



Filled Radar Chart ItemSummary vs Category
Filled Radar Chart ItemSummary vs Category
Study: KA201 All patients
056
063
065
030
064
066
018
12
10
8
6
4
2
Exacerbation
Intercurrent Illness
ADR
Other
AE Coded:count by Investigator

Line Chart Item vs. Category

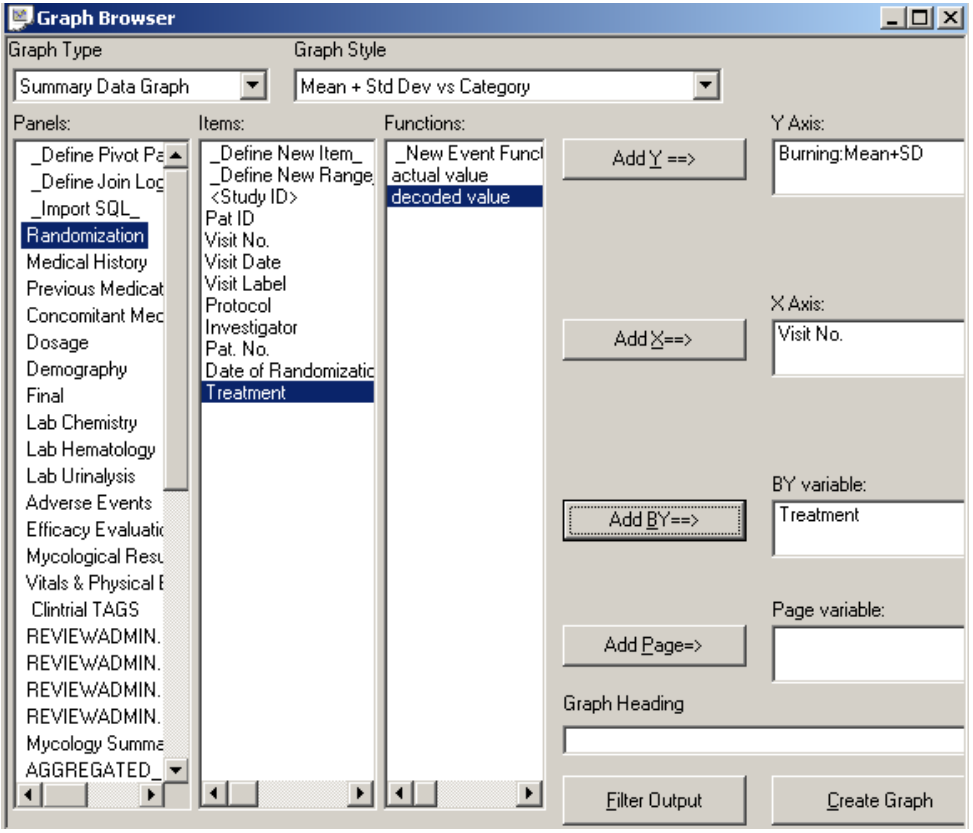
In a Line Chart Item vs. Category, trends over time or other categorical items can be presented. With the use of a categorical BY variable, two or more populations can be represented, and comparatively viewed. The Graph Browser window provides a separate list of group functions for the Y axis. Line Chart Item vs. Category allows you to plot up to 2 variables on the Y axis (dual Y axis mode).

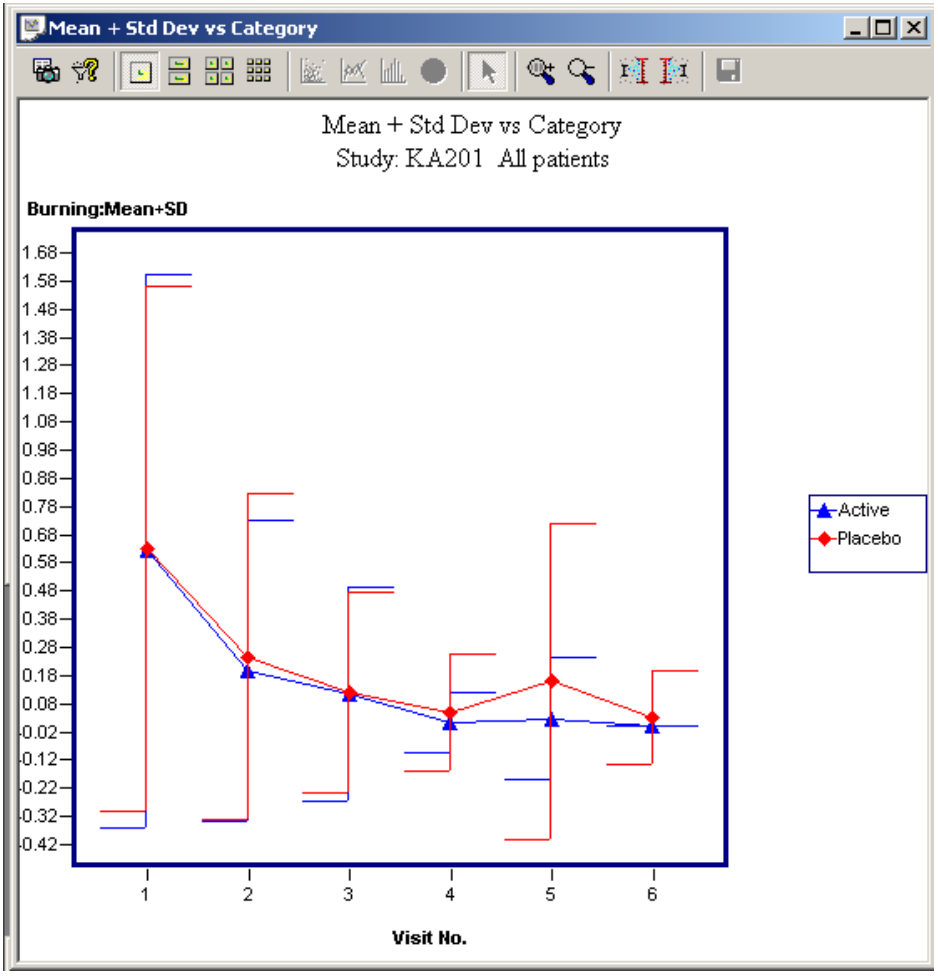



LineChart ItemSummary vs Category
LineChart ItemSummary vs Category
Study: KA201 All patients
Burning:mean
Erythema:mean
0.65
0.60
0.55
0.50
0.45
0.40
0.35
0.30
0.25
0.20
0.15
0.10
0.05
0
1.37
1.27
1.17
1.07
0.97
0.87
0.77
0.67
0.57
0.47
0.37
0.27
0.17
1
2
3
4
5
6
Visit No.
Active:Burning:mean
Active:Erythema:mean
Placebo:Burning:mean
Placebo:Erythema:mean

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.




Mean + Std Dev vs Category
Mean + Std Dev vs Category
Study: KA201 All patients
Burning:Mean+SD
1.68
1.58
1.48
1.38
1.28
1.18
1.08
0.98
0.88
0.78
0.68
0.58
0.48
0.38
0.28
0.18
0.08
-0.02
-0.12
-0.22
-0.32
-0.42
1
2
3
4
5
6
Visit No.
Active
Placebo

Highlighting patients

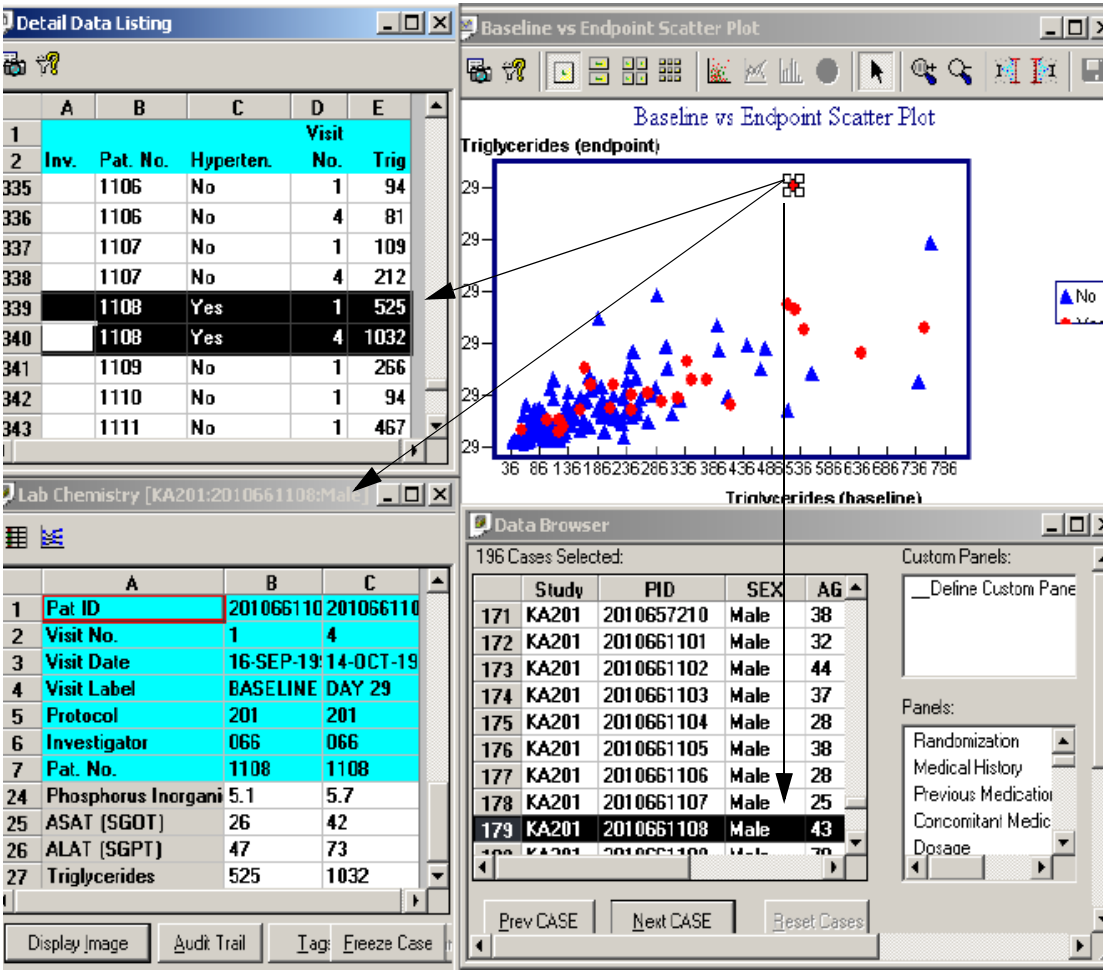
Single patient mode

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.

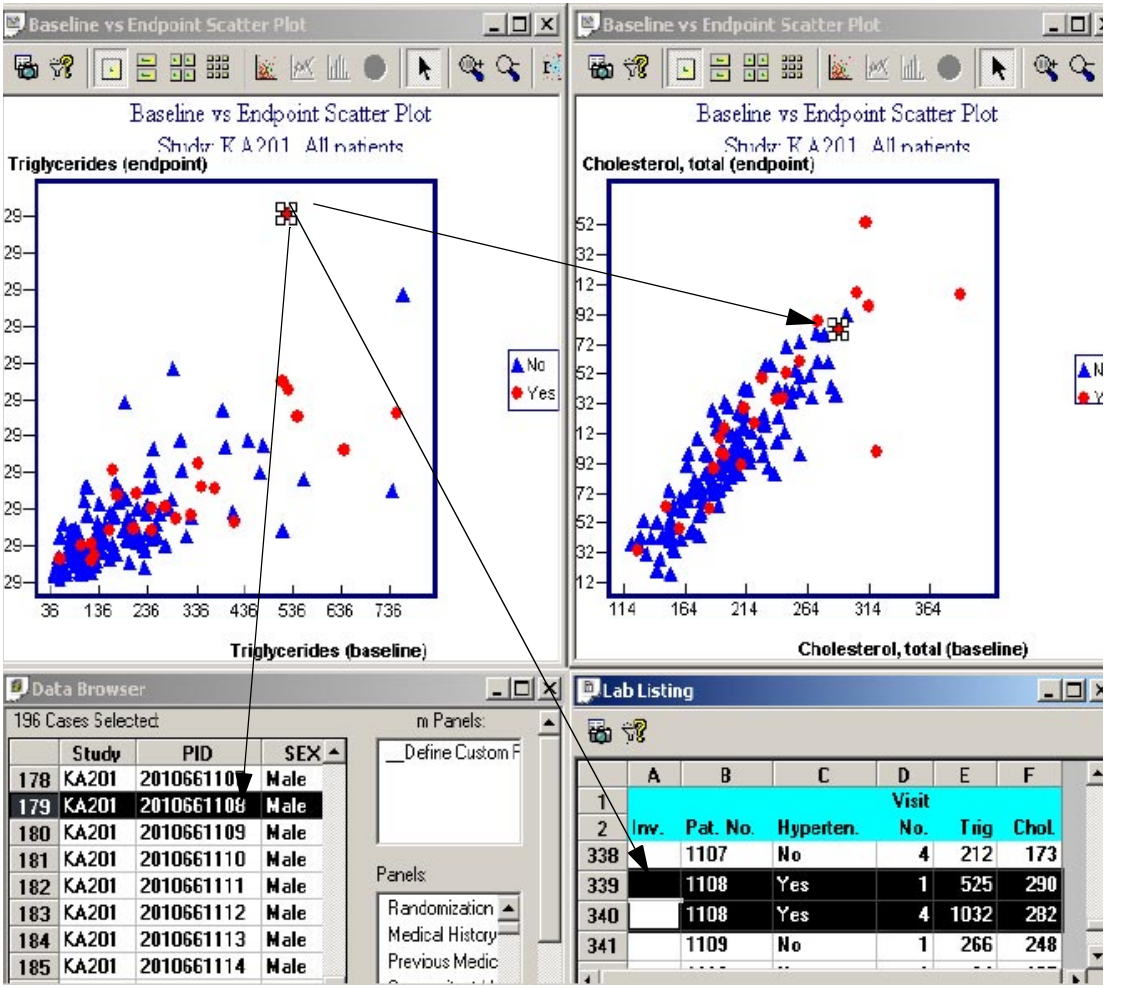
1. Activate the Data Browser to display a list of patients in the current patient selection, or activate the Report Browser to create and display any Detail Data Report (a list of patient data with customized data item groupings).

   Note:The highlighting feature does not apply to formatted reports. (See Chapter 6: Report Browser: Formatted Reports)

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. You can 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
Triglycerides (endpoint)
Triglycerides (baseline)
No
Yes
Cholesterol, total (endpoint)
Cholesterol, total (baseline)
Data Browser
196 Cases Selected
Study
PID
SEX
KA201
Male
Define Custom F
Panels:
Randomization
Medical History
Previous Medic
Lab Listing
Visit
Inv.
Pat. No.
Hyperten.
No.
Trig
Chol.

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 an 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.

Multi-Line graph

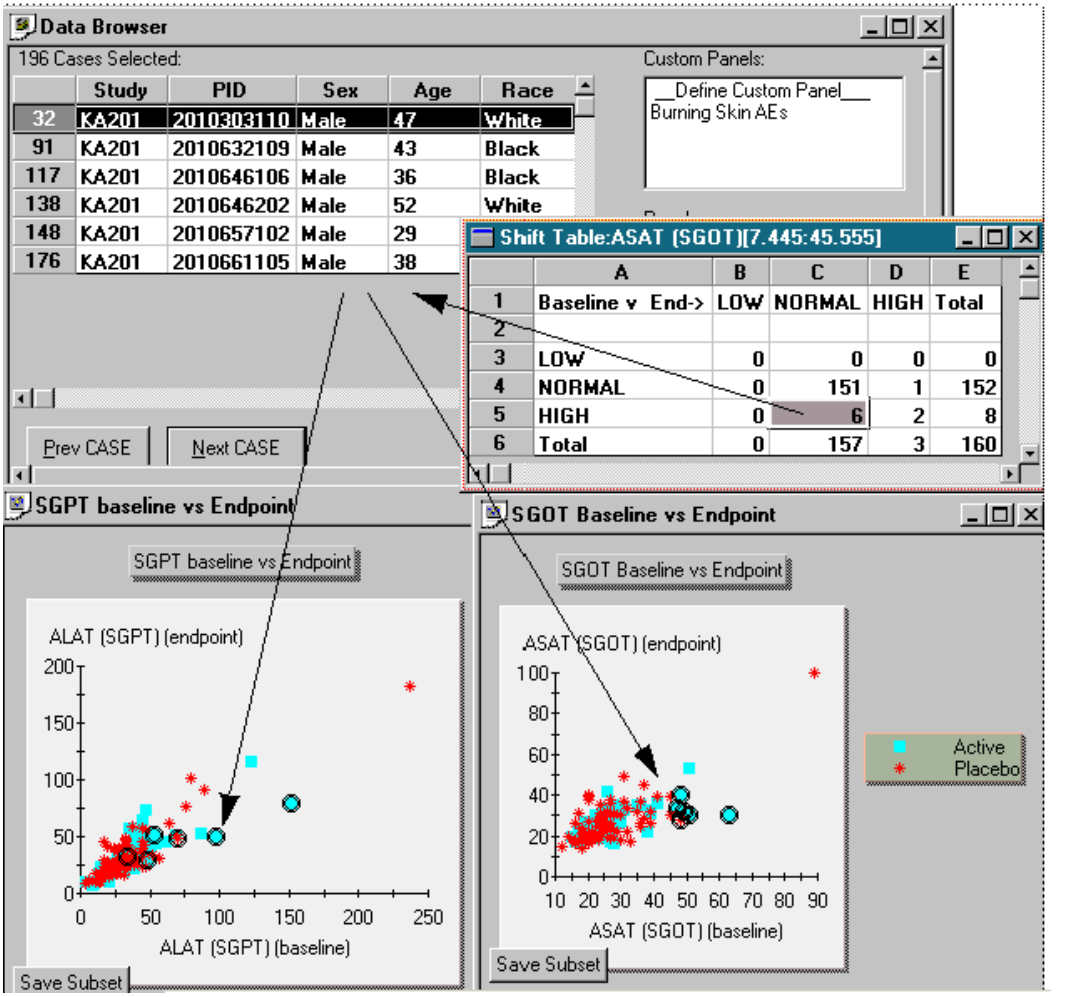
All lines within a multi-line graph, will immediately highlight the underlying patient throughout all open patient-level displays of data.

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.

Pie Chart

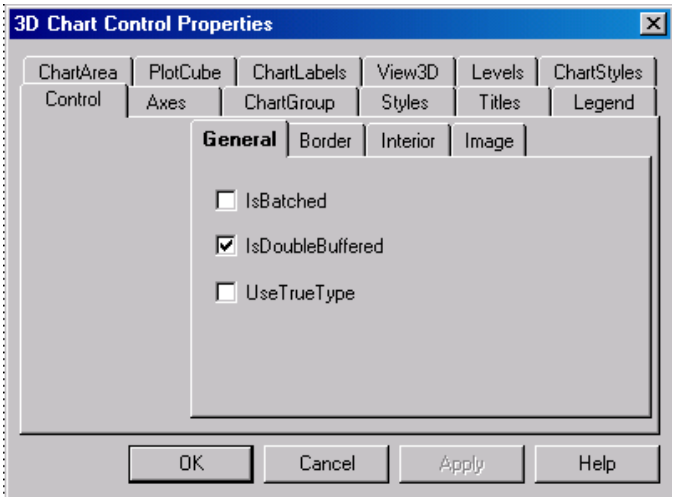
All slices depict a subset patient populations in the Pie Chart. Click on a slice within a Pie Chart and all underlying patients will be subset in all open patient-level displays of data.


Data Browser
196 Cases Selected:
Custom Panels:
__Define Custom Panel___
Burning Skin AEs
Study PID Sex Age Race
32 KA201 2010303110 Male 47 White
91 KA201 2010632109 Male 43 Black
117 KA201 2010646106 Male 36 Black
138 KA201 2010646202 Male 52 White
148 KA201 2010657102 Male 29
176 KA201 2010661105 Male 38
Prev CASE
Next CASE
Shift Table:ASAT (SGOT)[7.445:45.555]
A B C D E
1 Baseline v End-> LOW NORMAL HIGH Total
2
3 LOW 0 0 0 0
4 NORMAL 0 151 1 152
5 HIGH 0 6 2 8
6 Total 0 157 3 160
SGPT baseline vs Endpoint
SGPT baseline vs Endpoint
ALAT (SGPT) (endpoint)
200
150
100
50
0
0 50 100 150 200 250
ALAT (SGPT) (baseline)
Save Subset
SGOT Baseline vs Endpoint
SGOT Baseline vs Endpoint
ASAT (SGOT) (endpoint)
100
80
60
40
20
0
10 20 30 40 50 60 70 80 90
ASAT (SGOT) (baseline)
Active
Placebo
Save Subset

Graph editing

Graph settings

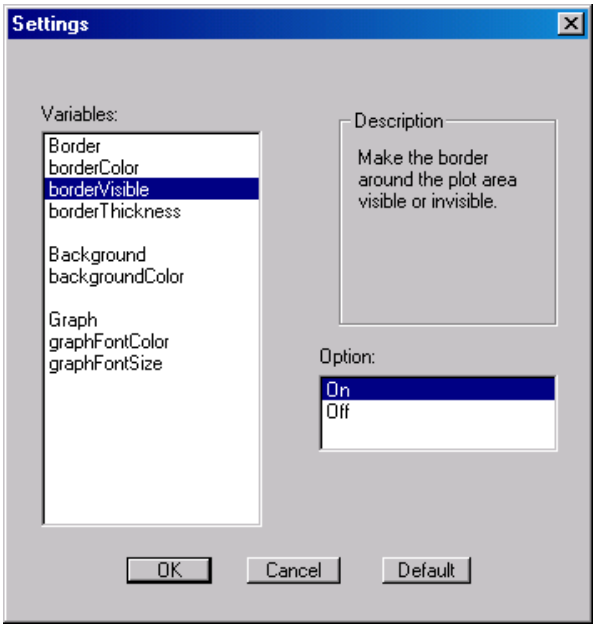
Once you create your graph, you can right-mouse click anywhere on the graph to open the graph settings window. All 3D graph styles display a specific 3D Chart Control Properties window to select the tab and edit graph properties.



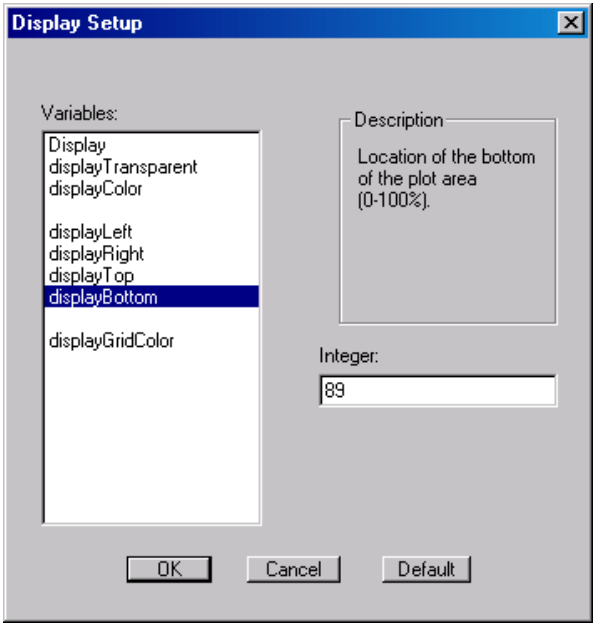
All other graph styles utilize the graph settings window. You can apply a variety of graph format changes with the setting options available.

Each graph setup has it's own selection window with default settings and setting options for you to select. When you select a variable setting in the Variable listbox, the description of the setting function is displayed. The available choices are listed in the Option listbox. A Default button allows you to return to the default setting.

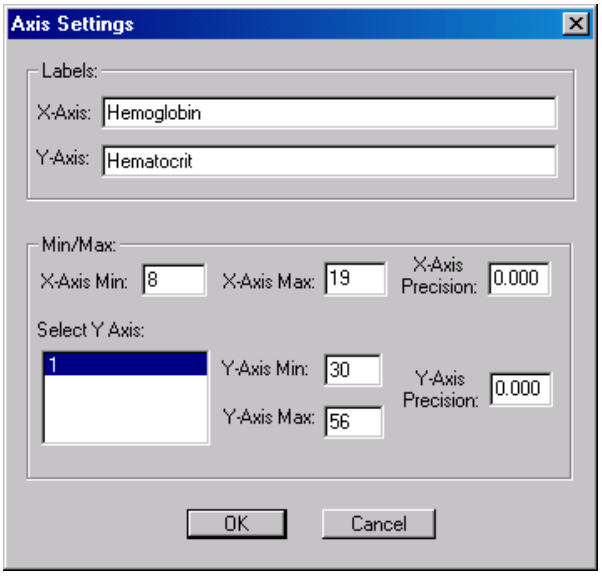
General Setup



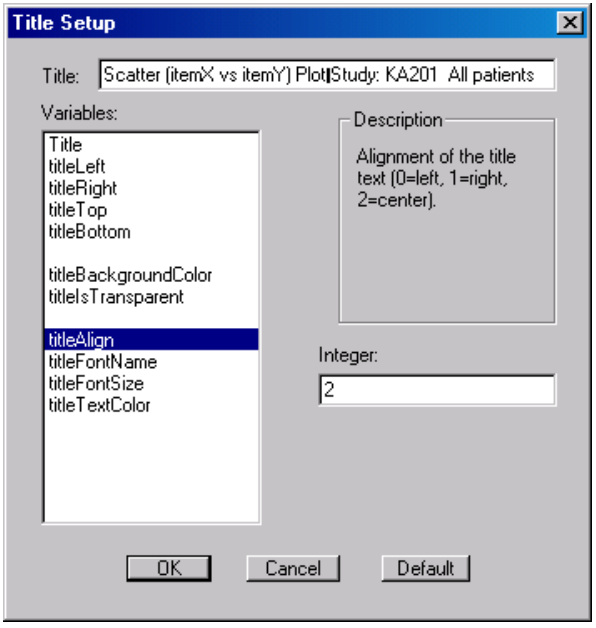
Display Setup



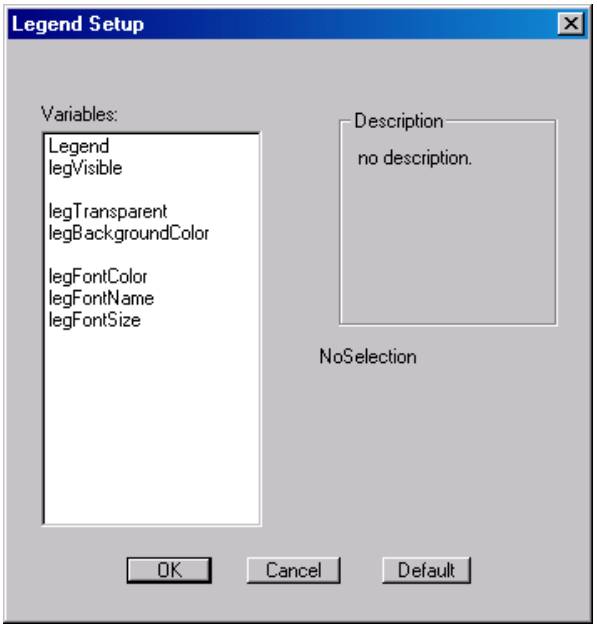
Axis Setup



Title Setup



Legend Setup



Printing Graphs

Print Preview

The default setting for all graphs is portrait and full screen display. Use the Page Setup to select landscape and to adjust height and width. All graph displays are for a single plot.

To display a print preview of your graph:

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 **Print** or **Close from the Print Preview window.**

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

Printing the graph

Another way to print with the graph output window open:

1. Click , or from the **File** menu, select **Print**.

   Review displays the standard print dialog box.

2. Click **OK**. The graph prints on the selected printer.

Object storage: saving your work

(See Chapter 6: Report Browser: Object storage: saving your work)

Schedule output

(See Chapter 6: Report Browser: Schedule output)

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.

Exploring Data

Changing the patient selection criteria

After you define the specifications of your graph, and create it by clicking **Create Graph**, you can use the graph currently displayed as a data exploration view by doing the following:

1. Change the patient selection criteria, 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.

Graphs or other browser objects that are displayed will be updated according to your new criteria. Each graph generated with a filter on will update with the same filter criteria with which it was created.

Multiple protocols

Utilizing the pseudo-item <Study ID> in Graph Browser constructs, within summary graphs and as a BY variable, facilitates comparisons between studies. *(See Chapter 12: Common Topics: <Study ID> pseudo item*.)

Graph output filter

After you define the specifications of your graph, and create it, you can use the output filter facility as a data exploration tool by row filtering data inclusion, then comparing filtered and unfiltered results. Row filtering is carried out by the Output Filter Criteria window. The output filter function allows specified observations and visits, from multi-visit data items, to focus graphical presentations on clinically specific item values (numeric and / or categorical) and ranges.

Open filtered Scatter Plot graphs can be very informative when Review's patient-level browsers interact in the multi-patient mode. In this mode Review facilitates the ability to identify and characterize a subset of patients:

1. Create the output filter criteria or edit it by adding additional expressions, or removing existing ones.
2. Click **Save Filter** in the Graph Output Filter window to apply it against the next created graph. The **Output Filter** button in the Graph Browser window toggles to

.

   Note: *If you save the graph with an output filter ON, the same filter will be used when the graph is recreated.*

8 CrossTab Browser

Patient selection criteria **419**

Selection set 419

Open the CrossTab Browser 419

CrossTab Browser types of analysis **420**

Selecting a CrossTab Browser type of analysis 420

Defining a CrossTab table **422**

Selecting a panel, item, and function 422

Access to SAS datasets 424

Optional Include Row% Col% 424

Sort by Code Value 424

Output Filter 425

Edit column width 425

Add cell variable 425

Changing the CrossTab specification 427

Defining a Shift Table **428**

Item analyzed 428

Create Shift Table 429

Range values 430

Include Row% and Col% 432

Multiple CrossTab/Shift Tables **433**

Multiple CrossTabs 433

Snapshot output **433**

Multiple population mode 433

Printing and exporting CrossTab/Shift Tables 434
Print Preview 434
Print the CrossTab/Shift Tables 434
Page Setup 434
Exporting the CrossTab/Shift Tables 435
Interactive patient-level displays 436
Detail data patient listings and graphs 436
Object storage: saving your work 438
Schedule output 438
Closing CrossTab tables and the CrossTab Browser 438
Closing a CrossTab Window 438
Closing the CrossTab Browser 438
Exploring data 439
Changing the patient selection criteria 439
CrossTab output filter 439
Pivot panels 440
Join logic 440
Clintrial tags 440
New Event Function 440

Patient selection criteria

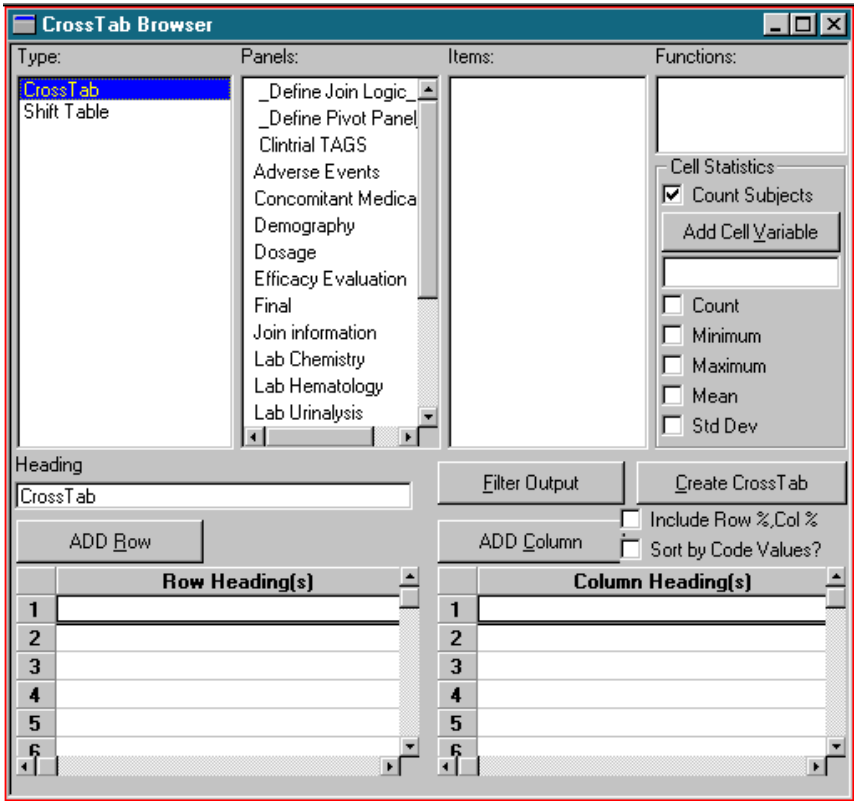
Selection set

You can explore clinical groupings of patients within a single protocol who meet the current patient selection criteria by using the CrossTab Browser.

Note: The CrossTab Browser allows Multistudy mode in CrossTabs. However, Shift Tables does not allow multiple protocol selection.

Open the CrossTab Browser

Click , or from the **Browse** menu, select **CrossTabs**. Review displays a new window where you can specify the type and contents of your multi-dimensional analysis:



CrossTab Browser types of analysis

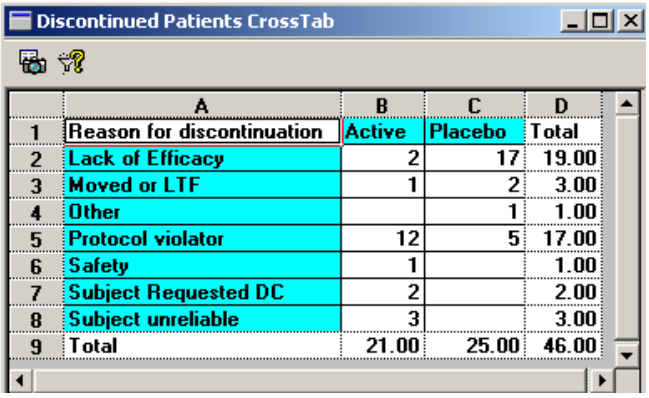
Selecting a CrossTab Browser type of analysis

Select a Type of CrossTab / Shift Table from the Type List by clicking on one of the following:

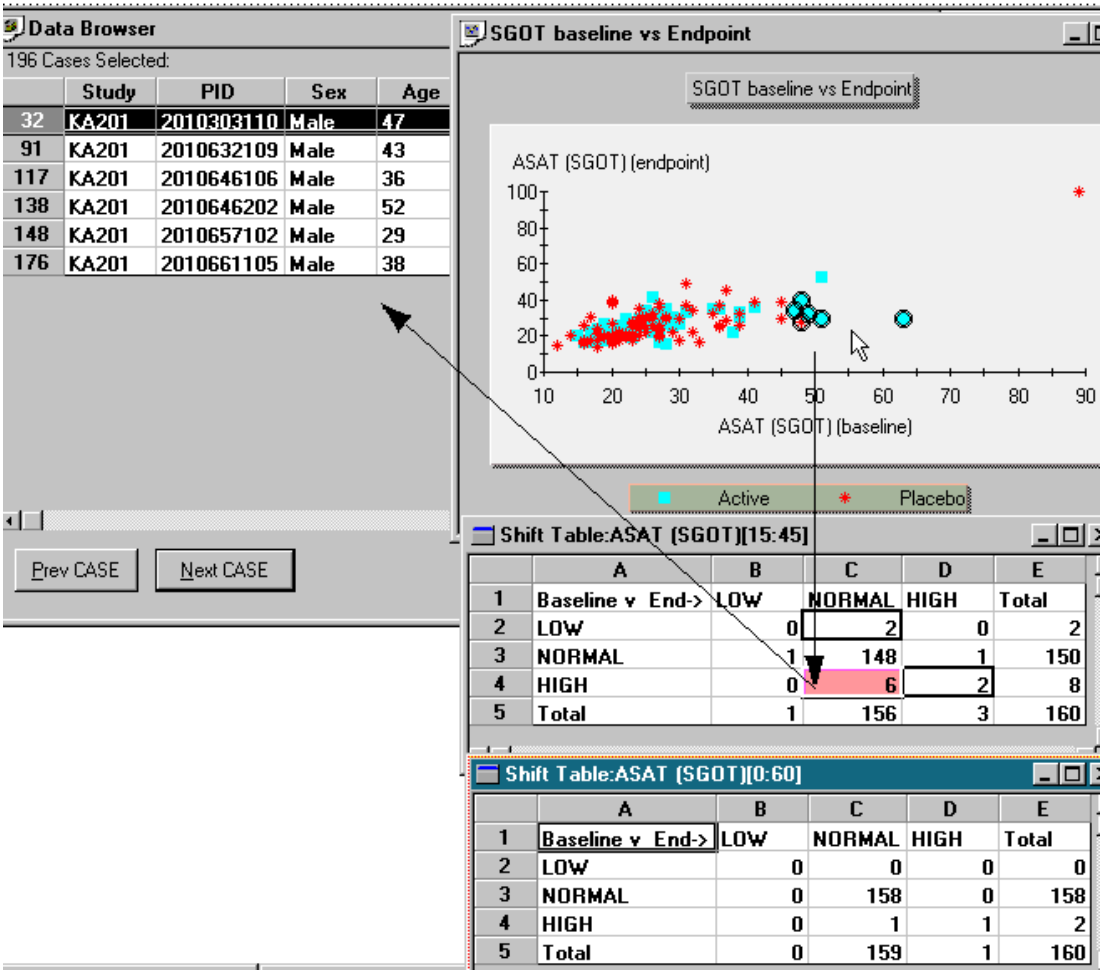
CrossTab: Clinical patient categorization and counts.

Shift Table: Clinical patient categorization by defined threshold values segmented over time.

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. 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.



	A	B	C	D
1	Reason for discontinuation	Active	Placebo	Total
2	Lack of Efficacy	2	17	19.00
3	Moved or LTF	1	2	3.00
4	Other		1	1.00
5	Protocol violator	12	5	17.00
6	Safety	1		1.00
7	Subject Requested DC	2		2.00
8	Subject unreliable	3		3.00
9	Total	21.00	25.00	46.00

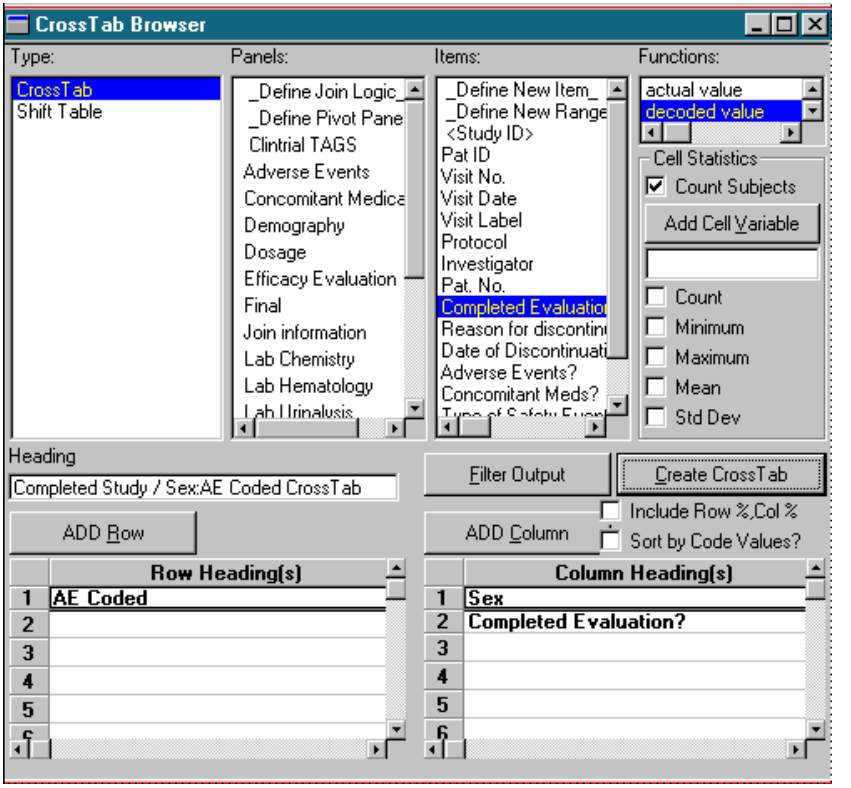

Data Browser
196 Cases Selected:
Study PID Sex Age
32 KA201 2010303110 Male 47
91 KA201 2010632109 Male 43
117 KA201 2010646106 Male 36
138 KA201 2010646202 Male 52
148 KA201 2010657102 Male 29
176 KA201 2010661105 Male 38
Prev CASE
Next CASE
SGOT baseline vs Endpoint
SGOT baseline vs Endpoint
ASAT (SGOT) (endpoint)
ASAT (SGOT) (baseline)
Active
Placebo
Shift Table:ASAT (SGOT)[15:45]
A B C D E
1 Baseline v End-> LOW NORMAL HIGH Total
2 LOW 0 2 0 2
3 NORMAL 1 148 1 150
4 HIGH 0 6 2 8
5 Total 1 156 3 160
Shift Table:ASAT (SGOT)[0:60]
A B C D E
1 Baseline v End-> LOW NORMAL HIGH Total
2 LOW 0 0 0 0
3 NORMAL 0 158 0 158
4 HIGH 0 1 1 2
5 Total 0 159 1 160

Defining a CrossTab table

Selecting a panel, item, and function

You can define the contents of a CrossTab table by applying the method that you used to build all other browser specifications.

1. Select a panel.
2. Select each item of interest.
3. For each item, select the appropriate functions or use the default functions.



4. Click **ADD Row** or **ADD Column** to add the selected Items to the CrossTab content spreadsheet at the bottom of the CrossTab window.
5. You can edit the default Cross Tab Heading by clicking in the heading box.
6. Click **Create.**

The CrossTab construct is created and instantly displays results in the CrossTab output window containing a spreadsheet of the multi-dimensional analysis you designed.

Note: The data in teh CrossTab contains only the data from those patients who meet your current patient selection criteria and output filter criteria.

In the exampe, the CrossTab data represents patient counts and **not** individual Adverse Events.

AEs vs Related to Inv. Med/Treatment CrossTab

	A	B	C	D	E	F	G	H	I
1		Highly Probable		Not Related		Possible		Probable	Total
2	AE Coded	Active	Placebo	Active	Placebo	Active	Placebo		
3	BODY:Allergic reaction			1					1.00
4	BODY:Back pain			2	1				3.00
5	BODY:Body odor						1		1.00
6	BODY:Pain			1					1.00
7	BODY:Surgery			3	5				8.00
8	BODY:Unevaluable reaction				1				1.00
9	DIG :Diarrhea				1				1.00
10	DIG :Duodenal ulcer			1					1.00
11	DIG :Periodontal abscess				1				1.00
12	DIG :Rectal pain			1					1.00
13	DIG :Sore throat				1				1.00
14	DIG :Tooth disorder			1	1				2.00
15	DIG :Vomiting				1				1.00
16	HAL :Ecchymosis			1					1.00
17	MAN :Peripheral edema						1		1.00
18	MS :Arthritis			1					1.00
19	MS :Myalgia				1				1.00
20	NER :Dizziness			1					1.00
21	NER :Headache			4	4				8.00
22	NER :Somnolence			1					1.00
23	RES :Cough increased			1	2				3.00
24	RES :Respiratory disorder			1					1.00
25	RES :Sinusitis			2	1				3.00
26	RES :Upper respiratory infection			3	1				4.00
27	SKIN:Burning sensation skin	8	7			1	1	1	18.00
28	SKIN:Pruritus	1				1			2.00
29	SKIN:Skin disorder				1				1.00

Access to SAS datasets

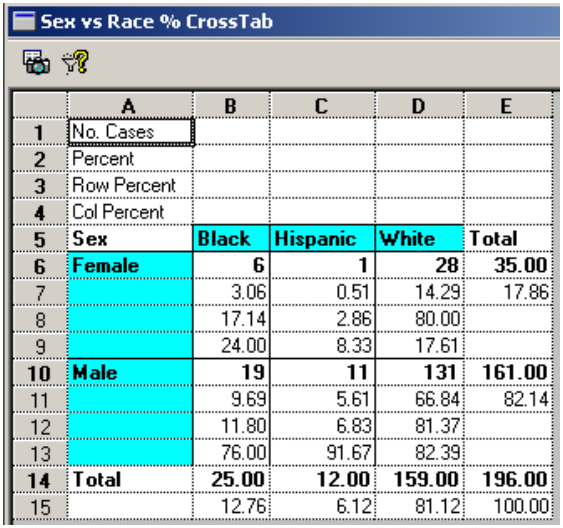
SAS datasets are listed with the panels generated from Oracle tables. Items from SAS datasets can be used like other items for CrossTab.

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

Optional Include Row% Col%

You can optionally create a CrossTab or Shift Table with row and column percentages displayed.

7. Click ☒ Include Row %,Col %. Each row and column is summarized by the following descriptive statistics:



	A	B	C	D	E
1	No. Cases				
2	Percent				
3	Row Percent				
4	Col Percent				
5	**Sex**	**Black**	**Hispanic**	**White**	**Total**
6	**Female**	**6**	**1**	**28**	**35.00**
7		3.06	0.51	14.29	17.86
8		17.14	2.86	80.00	
9		24.00	8.33	17.61	
10	**Male**	**19**	**11**	**131**	**161.00**
11		9.69	5.61	66.84	82.14
12		11.80	6.83	81.37	
13		76.00	91.67	82.39	
14	**Total**	**25.00**	**12.00**	**159.00**	**196.00**
15		12.76	6.12	81.12	100.00

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*)

8. Click **Filter Output**.
9. Add the filter expressions and click **SAVE**.
10. 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. Click **Create Graph.**

Note: If you save a CrossTab specification with an output filter ON, the same filter will be applied when teh CrossTab is recreated.

Edit column width

To edit the column width of the CrossTab results:

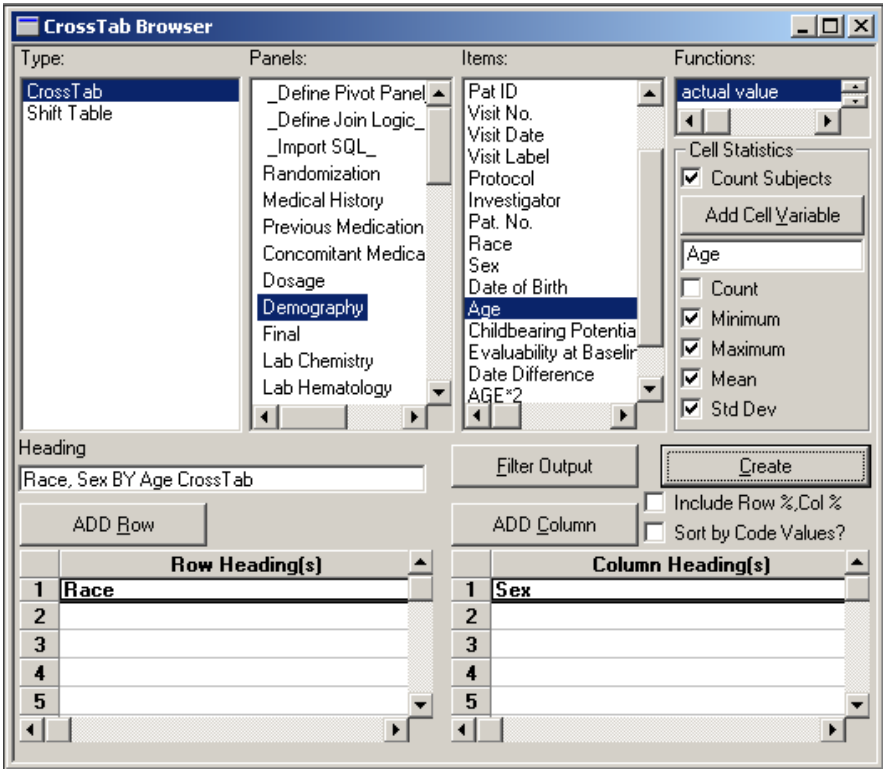
a. Click the column heading tabs (labeled A, B, etc.) as you would with any windows spreadsheet package.
b. Move the column boundaries to the position you want.

Add cell variable

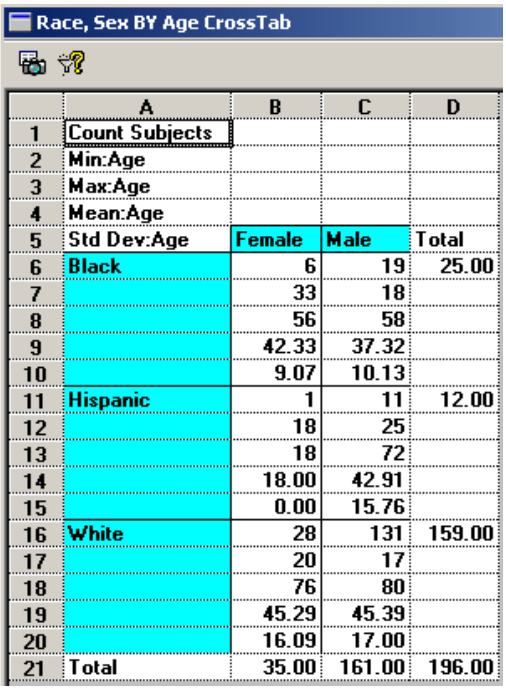
You can optionally generate statistics for a specified cell variable when you create a CrossTab.

a. Select a panel.
b. Select a numeric item. Click **Add Cell Variable**.
c. Select one or more **Cell Statistics**. You must select at least one.

*Note: The Cell Statistics default for Count Subjects must be on. If you choose to use the **Add cell variable** to optionally generate statistics for a specified cell variable, it cannot be used in conjunction with Optional Include Row%, Col%.*


CrossTab Browser
Type:
CrossTab
Shift Table
Panels:
_Define Pivot Panel
Define Join Logic
Import SQL
Randomization
Medical History
Previous Medication
Concomitant Medica
Dosage
Demography
Final
Lab Chemistry
Lab Hematology
Items:
Pat ID
Visit No.
Visit Date
Visit Label
Protocol
Investigator
Pat. No.
Race
Sex
Date of Birth
Age
Childbearing Potentia
Evaluability at Baselir
Date Difference
AGE*2
Functions:
actual value
Cell Statistics
Count Subjects
Add Cell Variable
Age
Count
Minimum
Maximum
Mean
Std Dev
Heading
Race, Sex BY Age CrossTab
Filter Output
Create
Include Row %,Col %
Sort by Code Values?
ADD Row
ADD Column
Row Heading(s)
Column Heading(s)
1 Race
1 Sex

The individual cells display the statistics you selected with the cell variable item.



	A	B	C	D
1	Count Subjects			
2	Min:Age			
3	Max:Age			
4	Mean:Age			
5	Std Dev:Age	Female	Male	Total
6	Black	6	19	25.00
7		33	18	
8		56	58	
9		42.33	37.32	
10		9.07	10.13	
11	Hispanic	1	11	12.00
12		18	25	
13		18	72	
14		18.00	42.91	
15		0.00	15.76	
16	White	28	131	159.00
17		20	17	
18		76	80	
19		45.29	45.39	
20		16.09	17.00	
21	Total	35.00	161.00	196.00

Editing a CrossTab specification

Changing the CrossTab specification

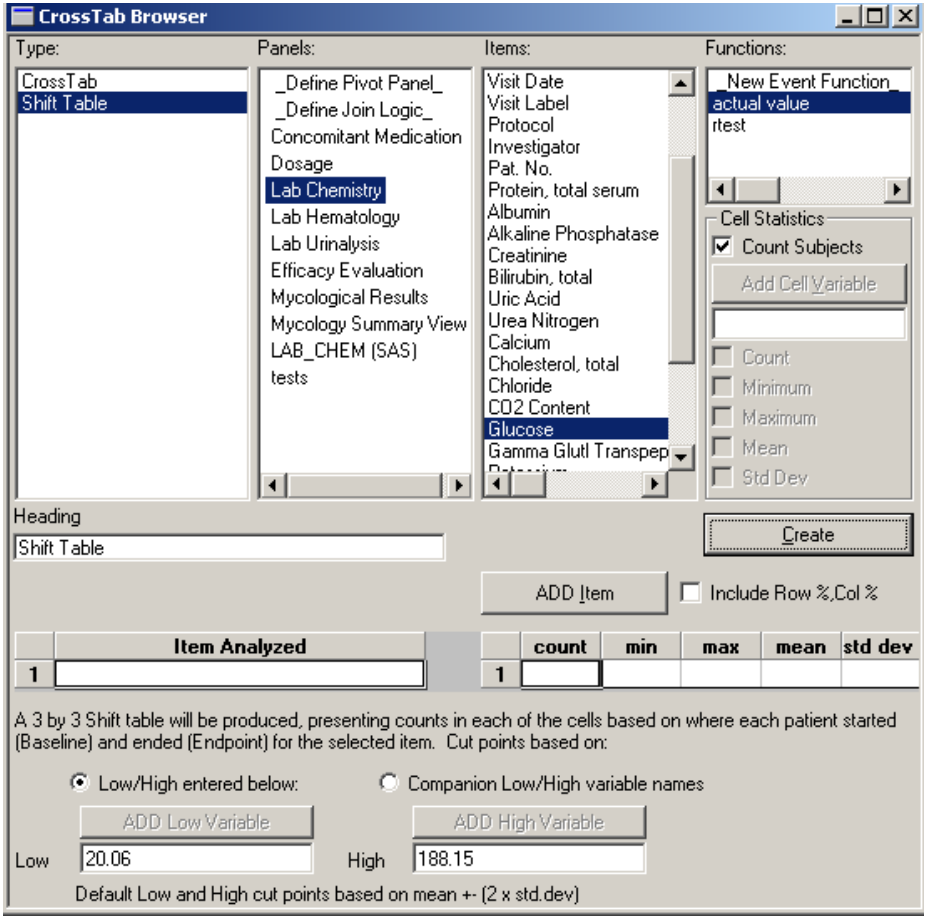
If you want to change the CrossTab specification that you have defined:

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 CrossTab** to create a new results window.
6. If you want to clear the entire CrossTab construct, click .

Defining a Shift Table

Item analyzed

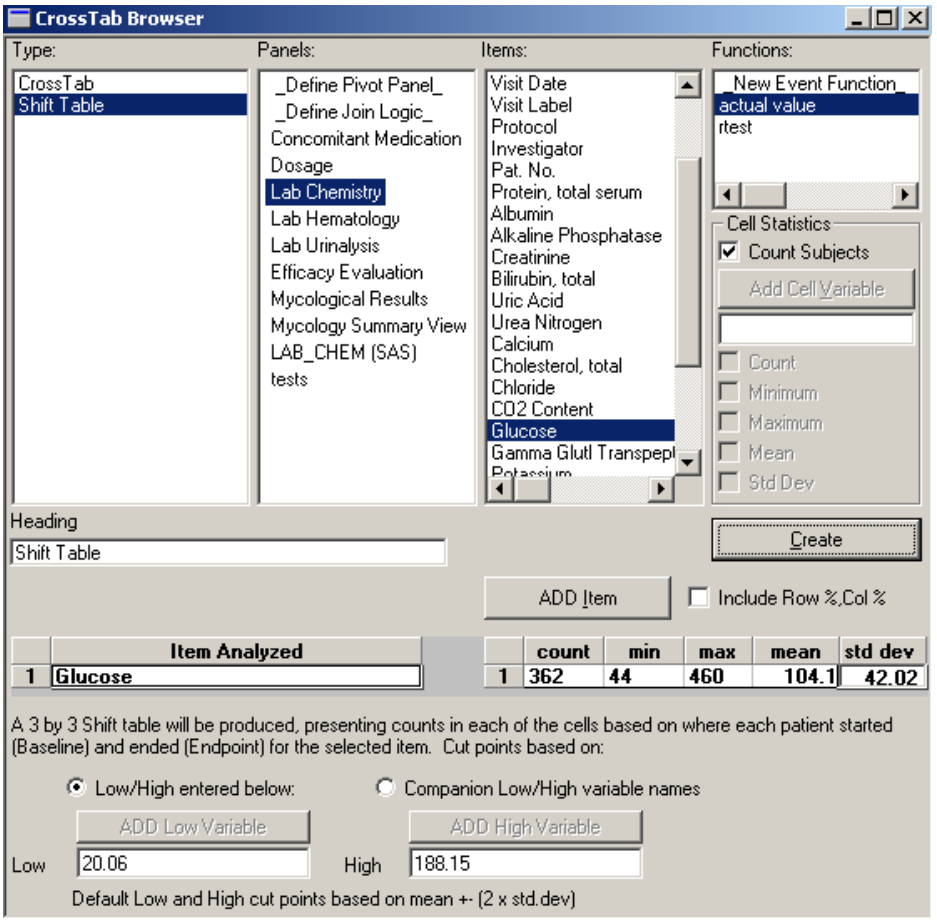
The Shift Table is a patient count of any numeric multi-visit patient data, providing patient categorization by defined threshold values segmented over time. The panels and items available are limited to data that is multi-visit or multi-measure. You must use numeric data. When the Shift Table is selected, not all panels listed contain data suitable for Shift Table calculation. For example, Dose and Concomitant Medication is not as meaningful as data values with normal ranges to reference.



Create Shift Table

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

1. Select a panel.
2. Select the item to be analyzed.
3. Click **ADD Item** to the Item Analyzed box. Basic descriptive statistics are displayed and default cutoff values are assigned.
4. By default, the CrossTab Browser assigns the table type as the heading. Edit the default Shift Table heading to easily identify the Shift Table results window. The heading displays as the caption of the Shift Table output, as well as on any printouts.
5. Click **Create**. Review opens the Shift Table results.



Read Baseline values as rows versus Endpoint values as columns. For example, the lab Glucose had 1 patient normal at baseline and high at endpoint of the study.

Shift Table:Glucose[20.06:188.15]

	A	B	C	D	E
1	Baseline v End->	LOW	NORMAL	HIGH	Total
2	LOW	0	0	0	0.00
3	NORMAL	0	155	1	156.00
4	HIGH	0	1	3	4.00
5	Total	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.

	Item Analyzed
1	Glucose

	count	min	max	mean	std dev
1	362	44	460	104.1	42.02

A 3 by 3 Shift table will be produced, presenting counts in each of the cells based on where each patient started (Baseline) and ended (Endpoint) for the selected item. Cut points based on:

(•) Low/High entered below: ( ) Companion Low/High variable names

ADD Low Variable ADD High Variable

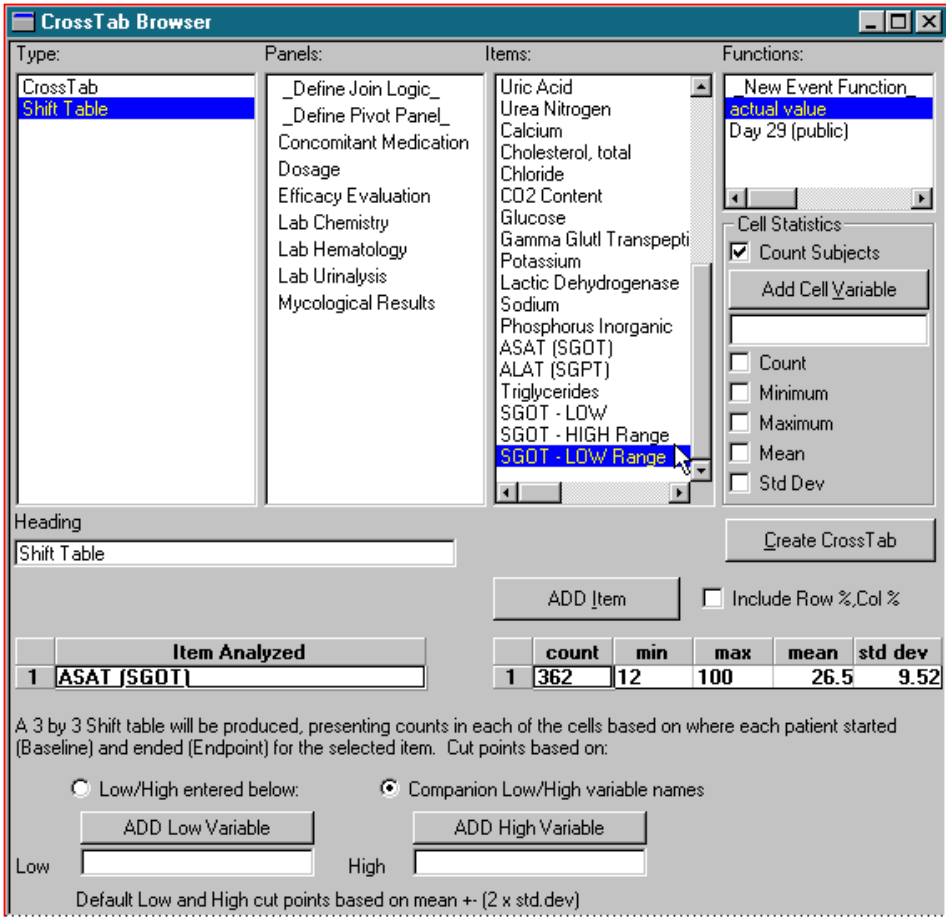
Low 70 High 110

Default Low and High cut points based on mean +- (2 x std.dev)

Shift Table:Glucose[70:110]

	A	B	C	D	E
1	Baseline v End->	LOW	NORMAL	HIGH	Total
2	LOW	0	1	0	1.00
3	NORMAL	2	105	19	126.00
4	HIGH	1	17	15	33.00
5	Total	3.00	123.00	34.00	160.00

Use the Companion Low / High variable names to select the laboratory normal ranges for the item analyzed.



Include Row% and Col%

You can optionally create a Shift Table with row and column percentages displayed.

Check ☒ Include Row %,Col % . Each row and column will be summarized by the following data:

Shift Table:ASAT (SGOT)[7.445:45.555]

	A	B	C	D	E
1	No. Cases				
2	Percent				
3	Row Percent				
4	Col Percent				
5	**Baseline v End->**	**LOW**	**NORMAL**	**HIGH**	**Total**
6	**LOW**	**0**	**0**	**0**	**0**
7		0.00	0.00	0.00	0.00
8		#DIV/0!	#DIV/0!	#DIV/0!	
9		#DIV/0!	0.00	0.00	
10	**NORMAL**	**0**	**151**	**1**	**152**
11		0.00	94.38	0.63	95.00
12		0.00	99.34	0.66	
13		#DIV/0!	96.18	33.33	
14	**HIGH**	**0**	**6**	**2**	**8**
15		0.00	3.75	1.25	5.00
16		0.00	75.00	25.00	
17		#DIV/0!	3.82	66.67	
18	**Total**	**0**	**157**	**3**	**160**
19		0.00	98.13	1.88	100.00

Note: When you include the calculations for row and column percent, you may see text '#DIV/0!' for values where zero cannot be divided by zero.

If you save a CrossTab construct with a patient selection criteria and / or the output filter on, they are saved with the CrossTab or Shift Table output specification. (See *Chapter 6: Report Browser: Object Storage: saving your work)*

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 and Chapter 12: Common Topics: 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.
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 current patient selection criteria, and a page number as the footer.

Page Setup

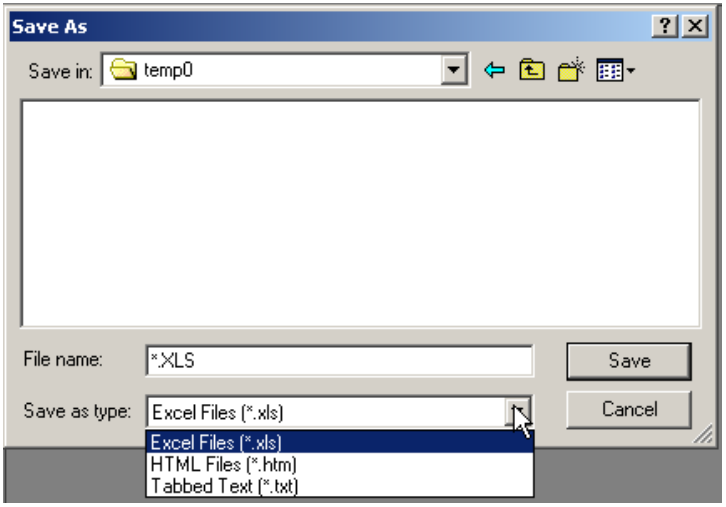
Page setup can be accessed by selecting page setup from the **File** menu. Review displays a standard spreadsheet page setup dialog box, allowing you to make changes.

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.



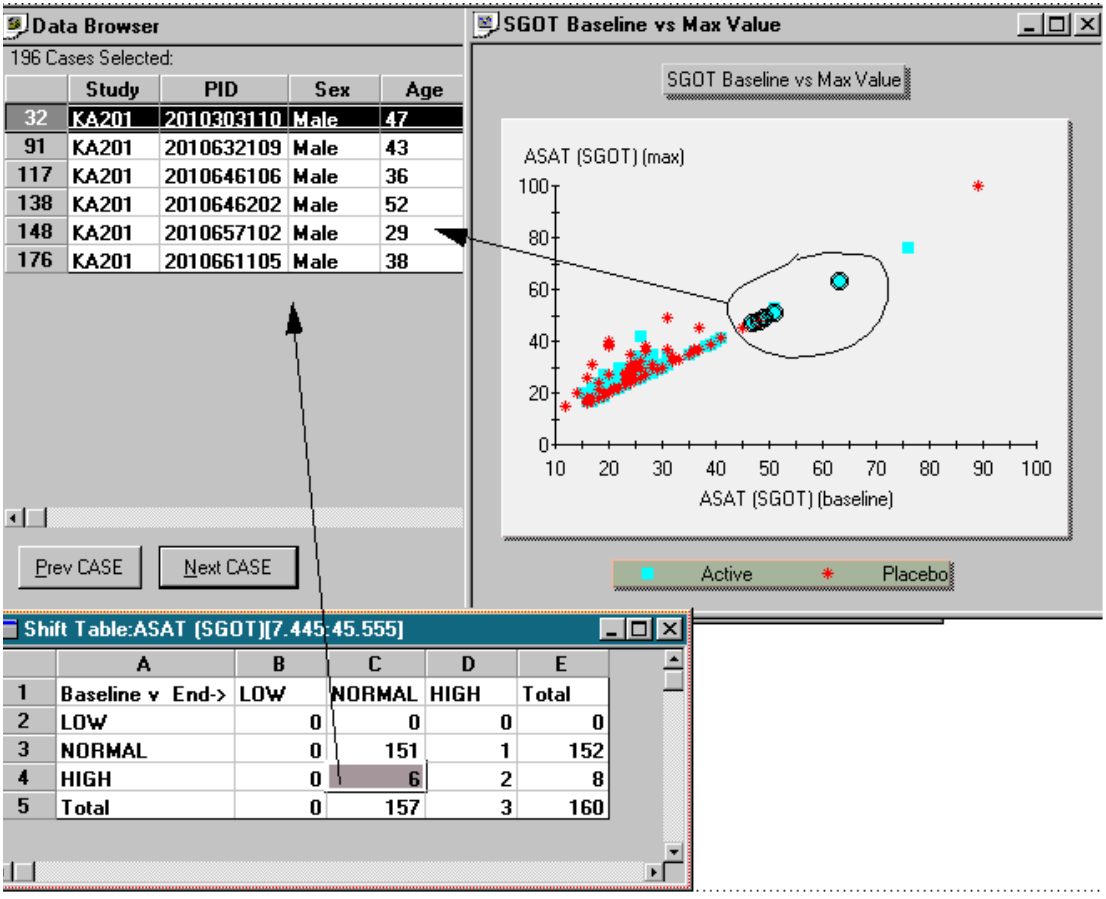
2. Enter the storage location, and Click **OK**.

   Your tables are exported to the currently selected disk directory. (See *Chapter 12: Common Topics: Shared Object Storage- Location*.)

Interactive patient-level displays

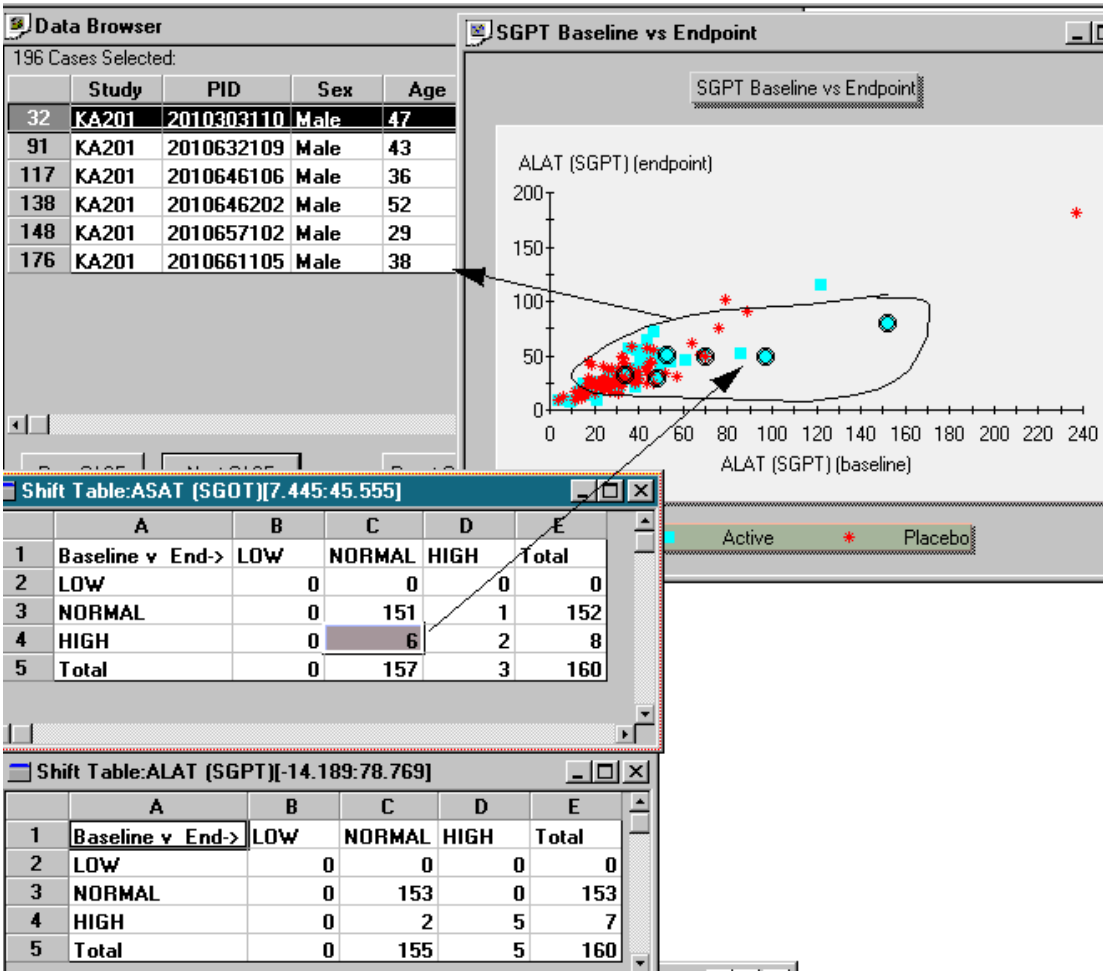
Detail data patient listings and graphs

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. You automatically highlight and subset the patients underlying CrossTab / Shift Table values in any other active patient-level Scatter Plot graph, Detail Data Listing report, and Data Browser patient listing, when you click on a table value.



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.

Note: Use patient categorical counts for low, normal and high to highlight the same patients in graphs. Do not use total counts.



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.

Object storage: saving your work

(See *Chapter 6: Report Browser: Object storage: saving your work)*

Schedule output

Note: You cannot schedule a saved Shift Table specification, however, you can schedule a saved CrossTab specification. (See *Chapter 6: Report Browser: Schedule output)*

Closing CrossTab tables and 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.

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.*

Pivot panels

Pivot panels provide a powerful display of data, and provides a data structure that can be uniquely utilized by the CrossTab Browser in producing clinically pertinent presentations of data “on the fly”.

Note: Saved specifications using a pivot panel will only work with the pivot panel it was created with. If the same pivot panel is recreated with the same name, the objects using the original panel will not work because the system naming convention iterates with each created panel. (See *Chapter 12: Common Topics: Define Pivot Panel*.)

Join logic

The pseudo-panel ‘_Define Join Logic_’ provides an opportunity to investigate relations within the clinical data defined by medical investigators “on the fly.” Join logic defined for the Clintrial type 0 panel is required to utilize the items within Clintrial type 0 panels. (See *Chapter 12: Common Topics: Define Join Logic*.)

Clintrial tags

Clintrial tags are accessible format in CrossTab specifications. Clintrial tags are listed as a pseudo-panel, and definitions and categorizations of tags in the item list. (See *Chapter 12: Common Topics: Clintrial tags*.)

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* and *Chapter 12: Common Topics: Derived Function Values _New Event Function*.)

9 Generating Statistics

Patient selection criteria **443**

Selection set 443

Opening the SAS Proc Browser 443

Selecting a SAS Proc type **444**

Selecting a SAS Proc 444

Defining a SAS View and Dataset **445**

Create SAS View and Dataset 445

Select format library options 448

SAS Transport Files 449

V5 (FDA Guidelines) option 449

Edit panels 451

Defining a SAS Proc Specification **452**

Define SAS Proc specification 452

Adding items to be analyzed 452

Adding BY variables 454

Statistics options 454

Defining a SAS Proc title 455

Creating the SAS Proc output 456

Change a SAS Proc specification 456

Output filter 457

SAS Proc results display **457**

Toolbar 457

Find menu command 458

Displaying the SAS output, source, or log 458

Exporting and printing results **459**

Print Preview 459

Printing the SAS Proc results 459

Exporting the result 460

Other SAS Proc displays **461**

Multiple SAS Proc outputs **470**

Opening multiple SAS Proc results 470

Snapshot output **470**

Multiple population mode 470

Saving a SAS Proc specification **471**

Review output 471

Schedule SAS Proc jobs **471**

Close SAS Proc Browser and results **472**

Closing a SAS Proc output window 472

Closing the SAS Proc Browser 472

Exploring data **472**

Changing the patient selection criteria 472

SAS Proc output filter 472

Pivot panels 473

Join logic 473

Clintrial tags 473

Protocol comparison 474

New Event Function 474

Patient selection criteria

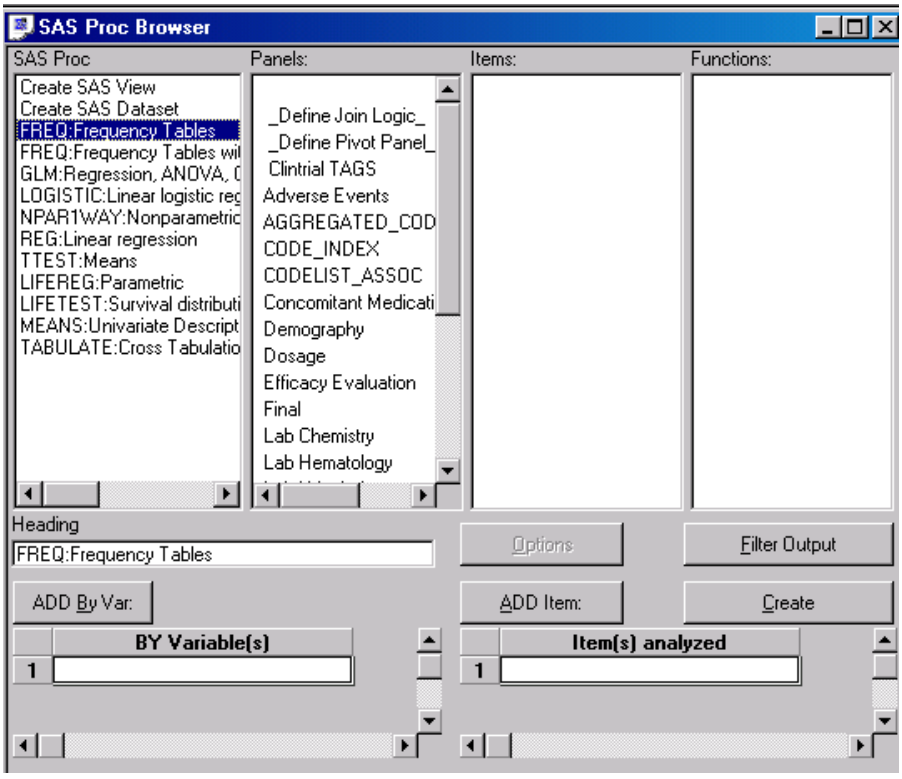
Selection set

You can explore statistical reports of selected items for the patients who meet the current patient selection criteria by using the Statistics Browser (SAS Proc Browser).

Note: 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.

Opening the SAS Proc Browser

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.



Selecting a SAS Proc type

Selecting a SAS Proc

Select one of the following types of **SAS Proc**:

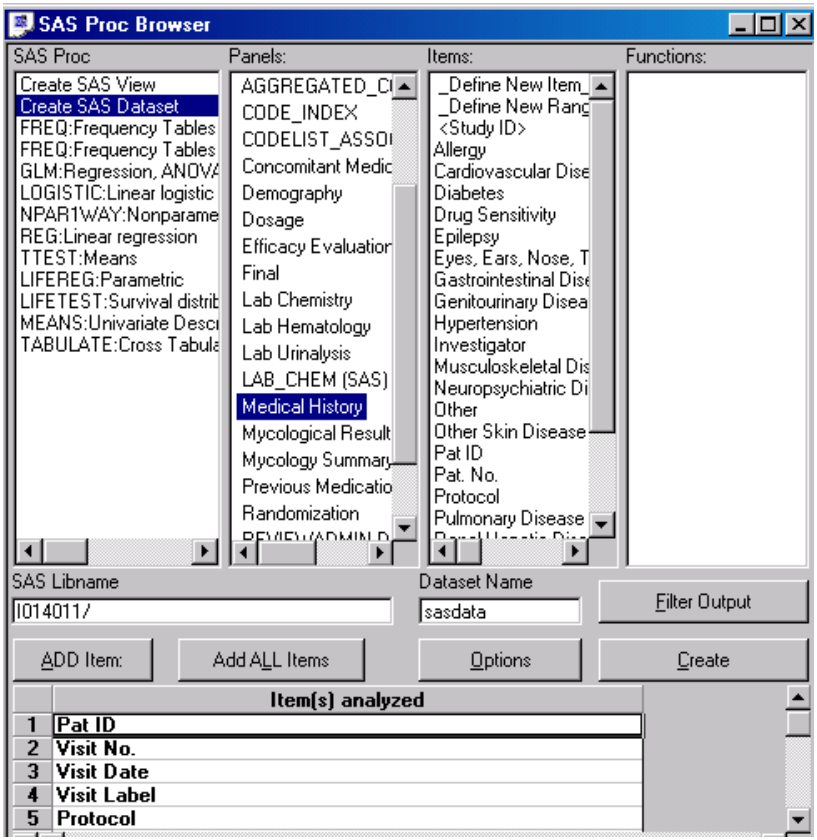
- Create SAS View - generates a SAS View of the items selected.
- Create SAS DataSet - generates a SAS Dataset of the items selected for the patient population currently selected.
- FREQ - generates a frequency distribution matrix of the items specified.
- FREQ with Statistics - generates a frequency 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 - The LIFEREG procedure estimates the parameters by maximum likelihood using a Newton-Raphson algorithm.
- LIFETEST - lifetime or survival data is the presence of right-censored observations due either to withdrawal of experimental units or to termination of the experiment.
- 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.

Defining a SAS View and Dataset

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.

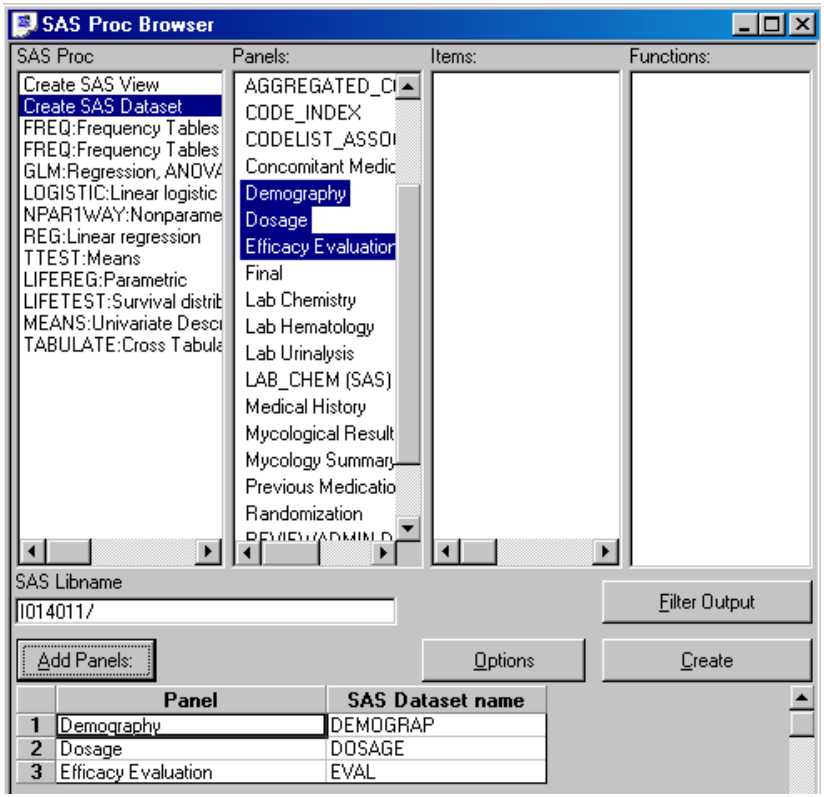


5. You can create multiple SAS Views or Datasets by selecting multiple panels in the following ways:

   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).



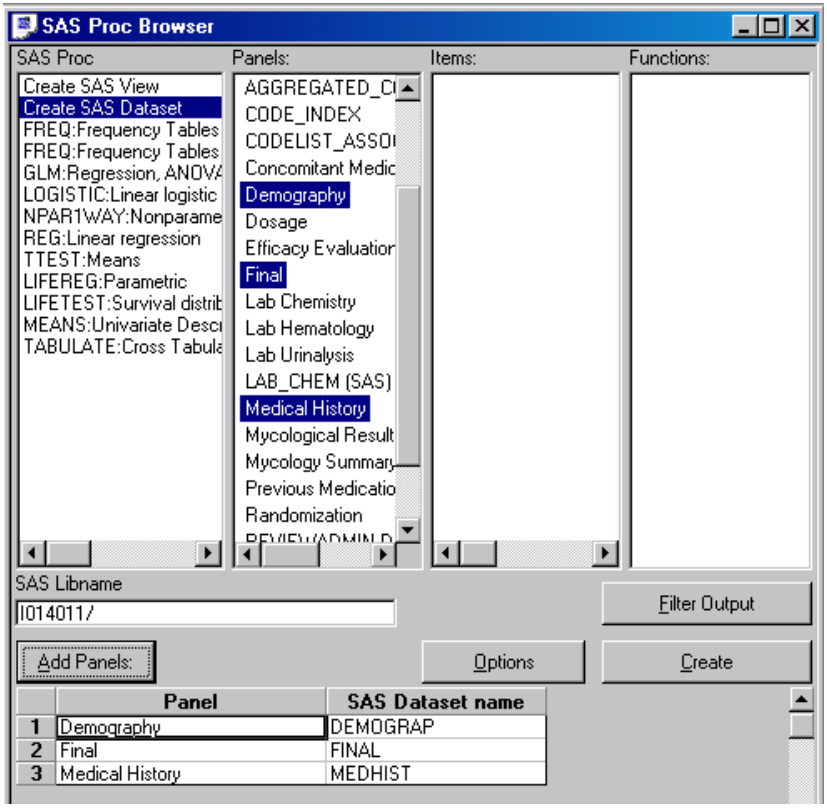
For non-contiguous panels (panels not listed next to each other):

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.

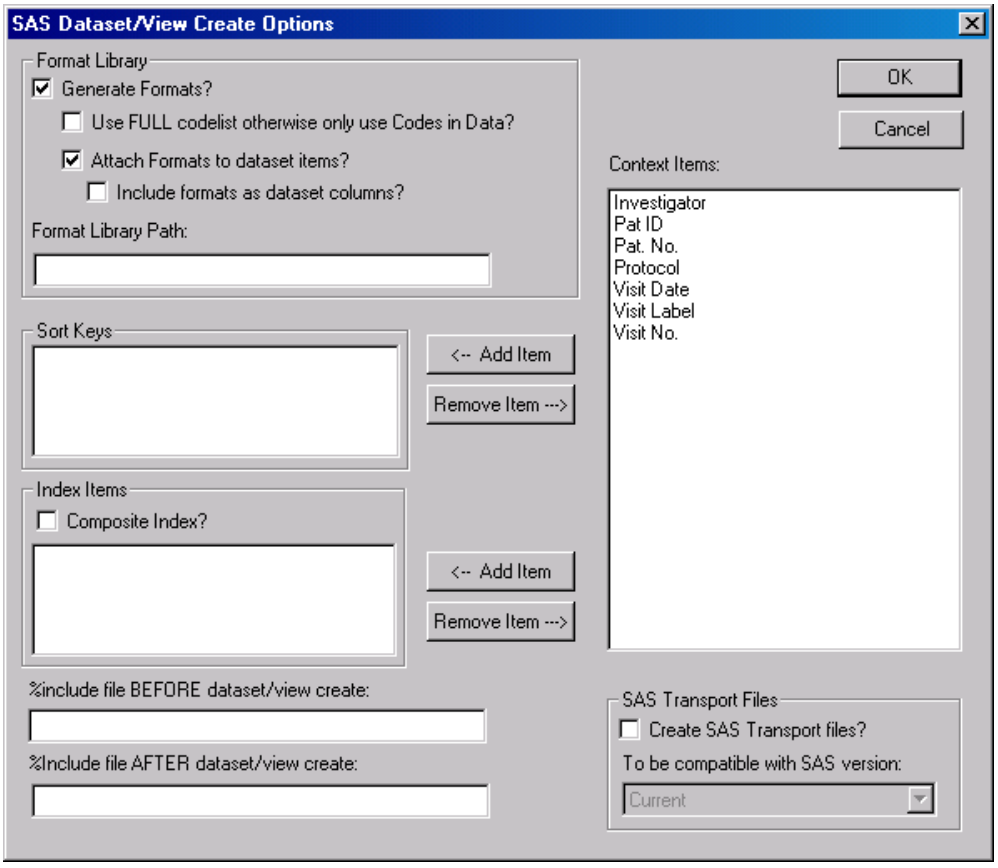


Select format library options

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.

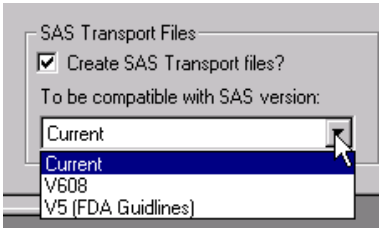
You must select 'Generate Formats?' in order to 'Use FULL codelist' or to 'Attach Formats'. Likewise, in order to 'Include formats as dataset columns', you must first select the 'Attach Formats' in order to create those columns.

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.



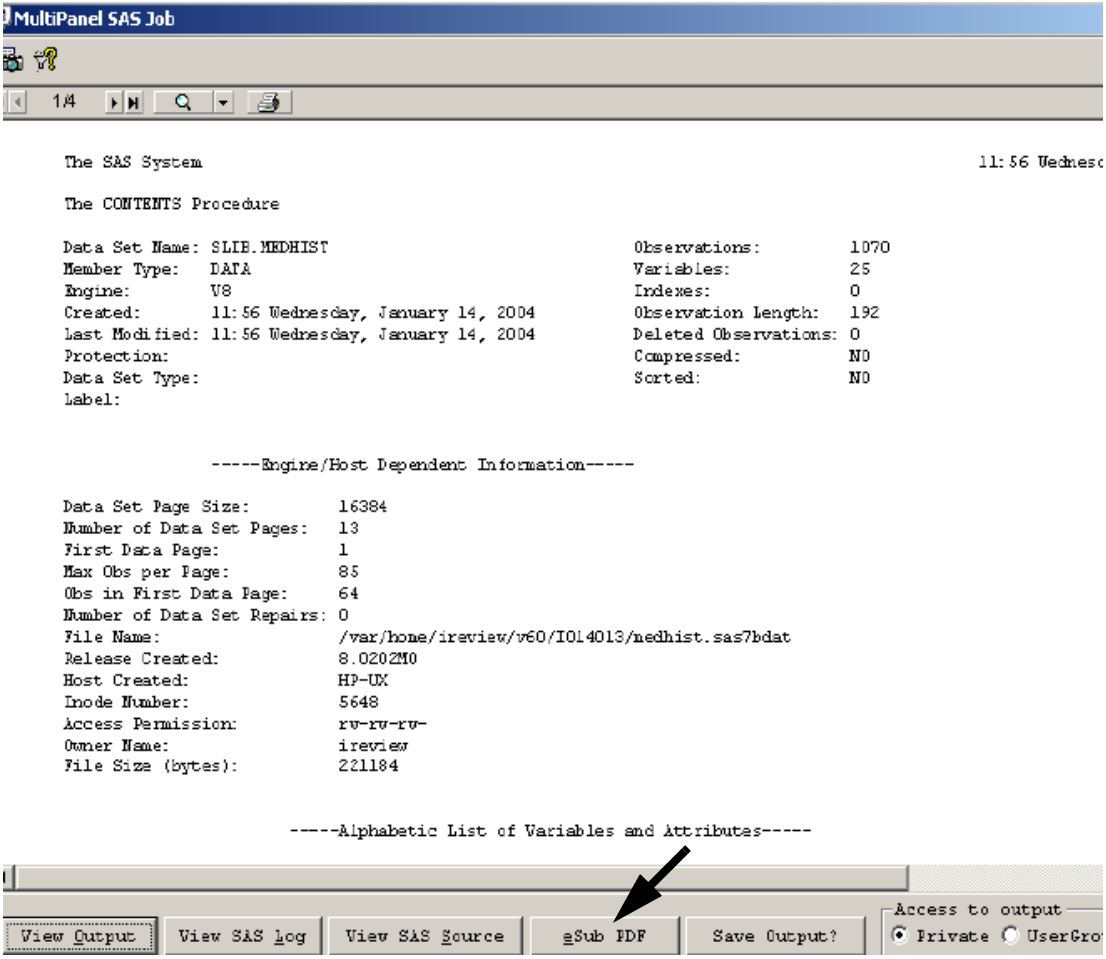
The SAS Views you create are dynamic, i.e., whenever accessed by SAS return the current Oracle data. The SAS Dataset created contains the selected items of the current patient population. This feature allows you to take snapshots of the data while the study is ongoing. Simply select panels and items 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'.

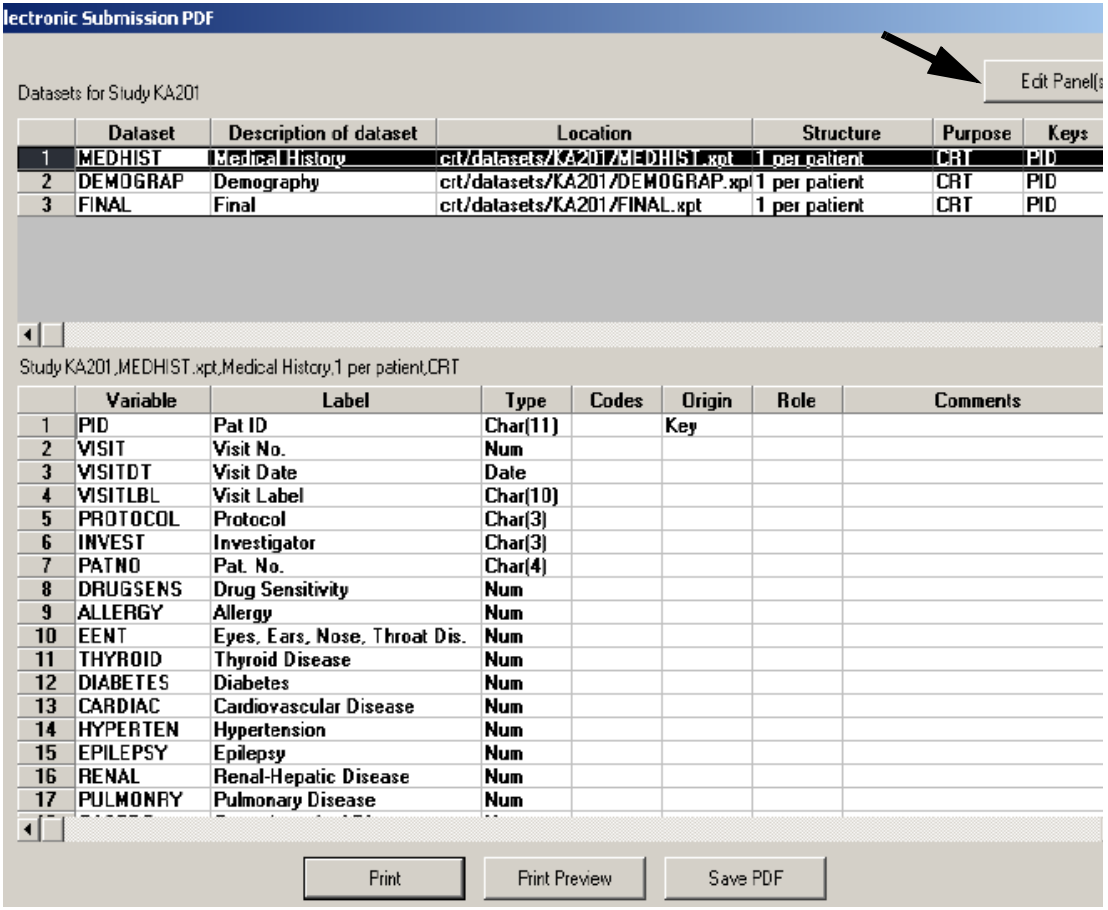
Note: When you click the V5 option the two required options are selected for you and you cannot change it.


MultiPanel SAS Job
1/4
The SAS System
11:56 Wednesd
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: 1070
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/ireview/v60/IO14013/medhist.sas7bdat
Release Created: 8.0202M0
Host Created: HP-UX
Inode Number: 5648
Access Permission: rw-rw-rw-
Owner Name: ireview
File Size (bytes): 221184
-----Alphabetic List of Variables and Attributes-----
View Output
View SAS Log
View SAS Source
eSub PDF
Save Output?
Access to output
Private
UserGro

Edit panels

When you select the V5 (FDA Guidelines) option and create the SAS Dataset / View, you can edit the panels by clicking the **eSub PDF** button. The Electronic Submission PDF window displays as a panels spreadsheet. The primary function of the panels spreadsheet is to display format details.

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



	Dataset	Description of dataset	Location	Structure	Purpose	Keys
1	MEDHIST	Medical History	crt/datasets/KA201/MEDHIST.xpt	1 per patient	CRT	PID
2	DEMOGRAP	Demography	crt/datasets/KA201/DEMOGRAP.xpt	1 per patient	CRT	PID
3	FINAL	Final	crt/datasets/KA201/FINAL.xpt	1 per patient	CRT	PID

	Variable	Label	Type	Codes	Origin	Role	Comments
1	PID	Pat ID	Char(11)		Key		
2	VISIT	Visit No.	Num				
3	VISITDT	Visit Date	Date				
4	VISITLBL	Visit Label	Char(10)				
5	PROTOCOL	Protocol	Char(3)				
6	INVEST	Investigator	Char(3)				
7	PATNO	Pat. No.	Char(4)				
8	DRUGSENS	Drug Sensitivity	Num				
9	ALLERGY	Allergy	Num				
10	EENT	Eyes, Ears, Nose, Throat Dis.	Num				
11	THYROID	Thyroid Disease	Num				
12	DIABETES	Diabetes	Num				
13	CARDIAC	Cardiovascular Disease	Num				
14	HYPERTEN	Hypertension	Num				
15	EPILEPSY	Epilepsy	Num				
16	RENAL	Renal-Hepatic Disease	Num				
17	PULMONRY	Pulmonary Disease	Num				

Defining a SAS Proc Specification

Define SAS Proc specification

Define the specifications of the SAS Proc run by applying the same method that you used to build the patient selection criteria:

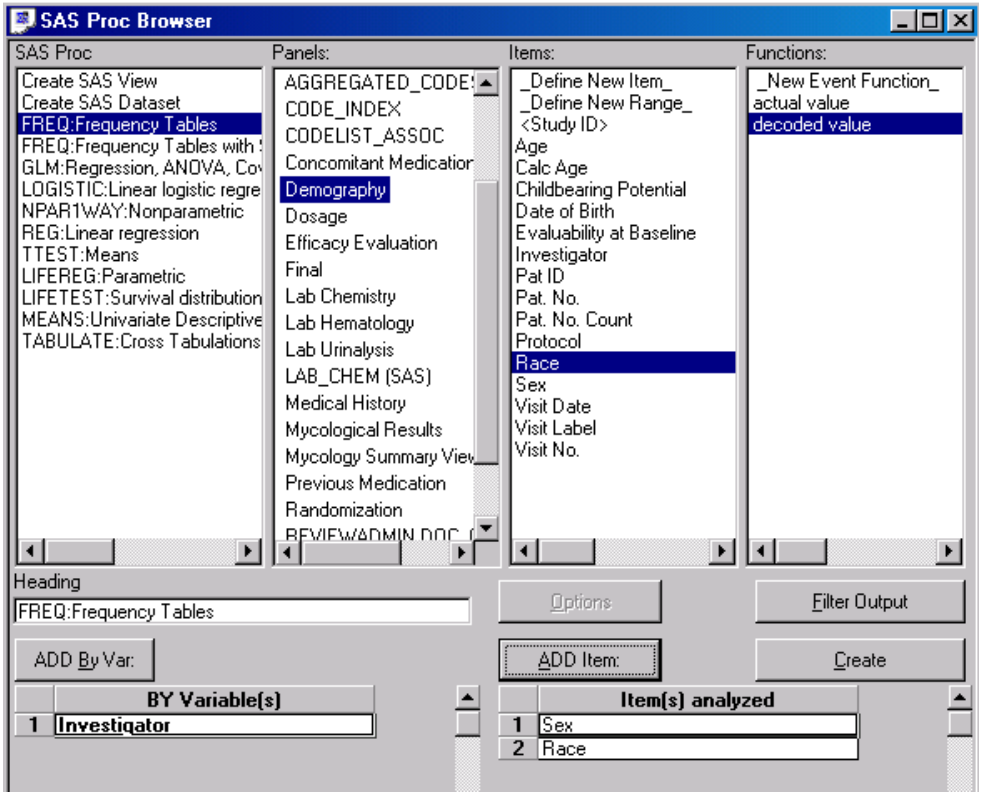
1. Select a SAS Proc.
2. Select a panel.
3. Select each item of interest and an appropriate function or use the default function.
4. Select a BY Variable(s) to categorize the data if applicable.
5. Click Create.

Adding items to be analyzed

The following SAS Procs share the same display window for the selections ADD By Var and ADD Item.

- FREQ
- MEANS
- TABULATE
- FREQ with Statistics

Select the individual item(s) to be analyzed and click **ADD Item** to add the item to the SAS Proc specification.



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.

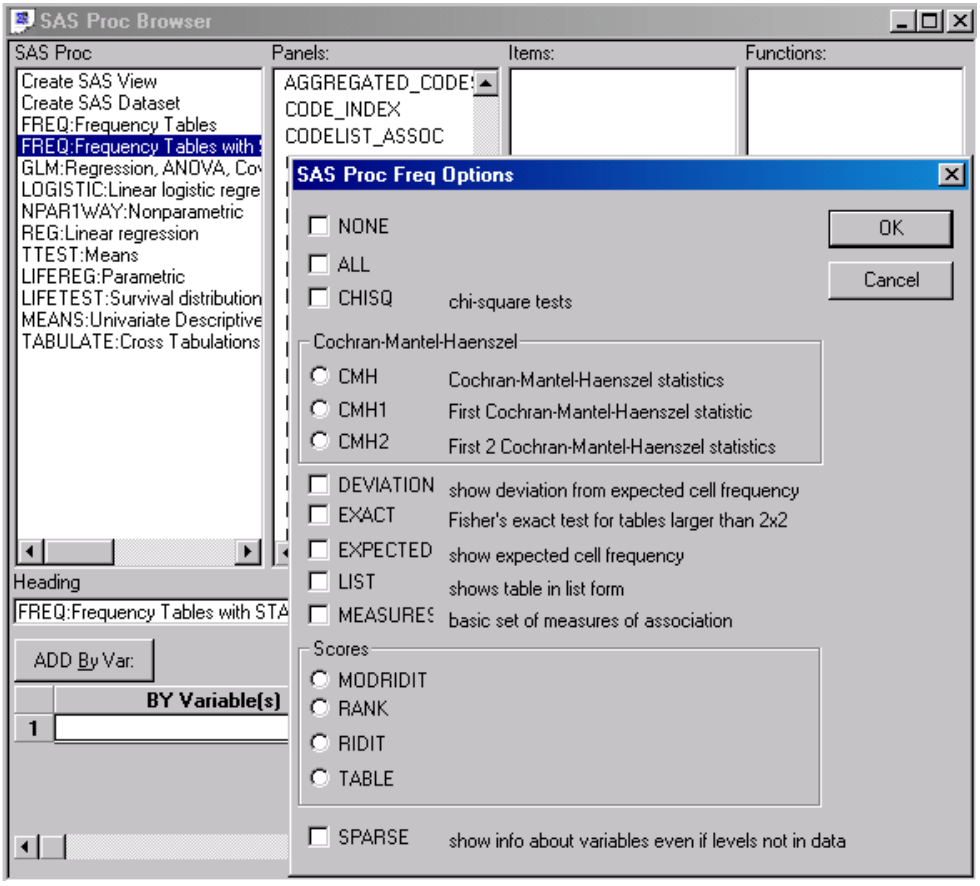
A BY variable is a variable by which the data sets are ordered according to the BY statement variable. Statistical observations on BY variables are carried out on ordered, grouped, or indexed values of one or more variables.

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**.

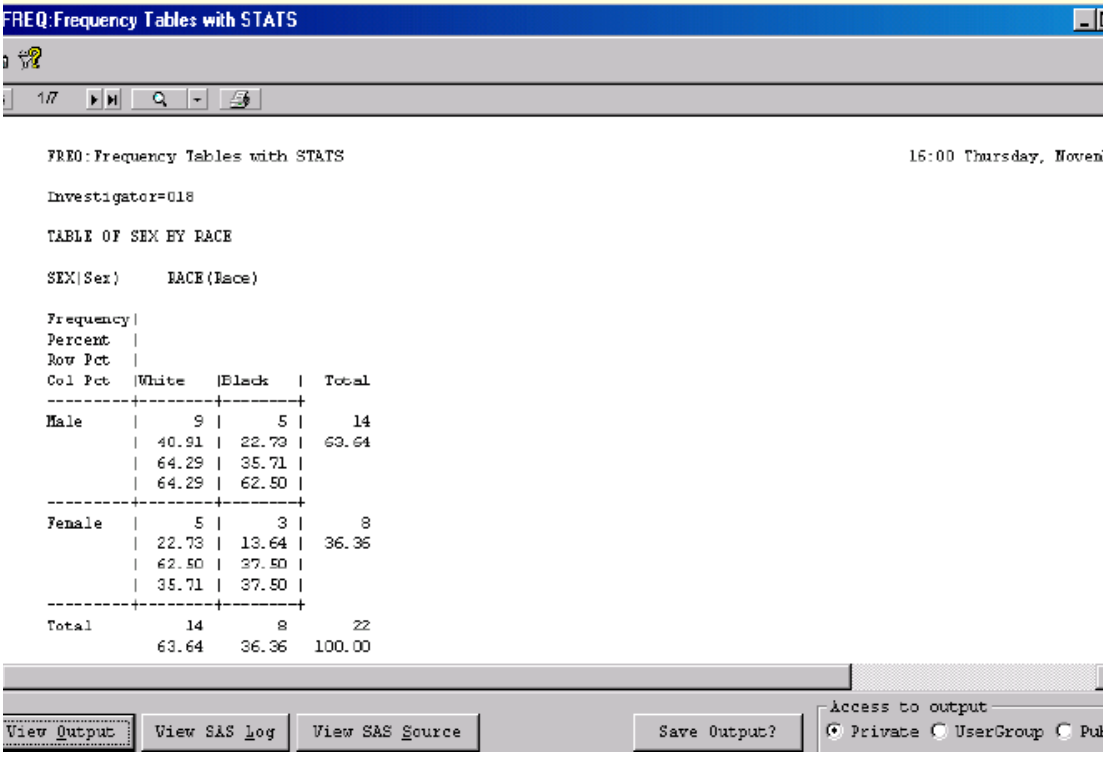


Defining a SAS Proc title

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 .

Output filter

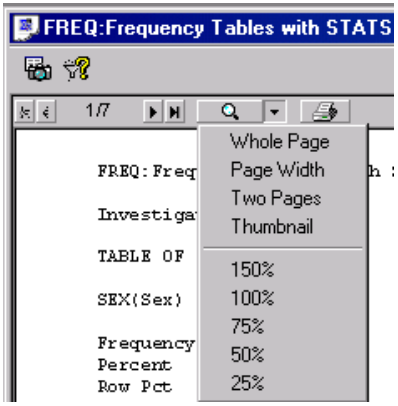
(See *Chapter 6 Report Browser: Output Filter.)*

SAS Proc results display

Toolbar

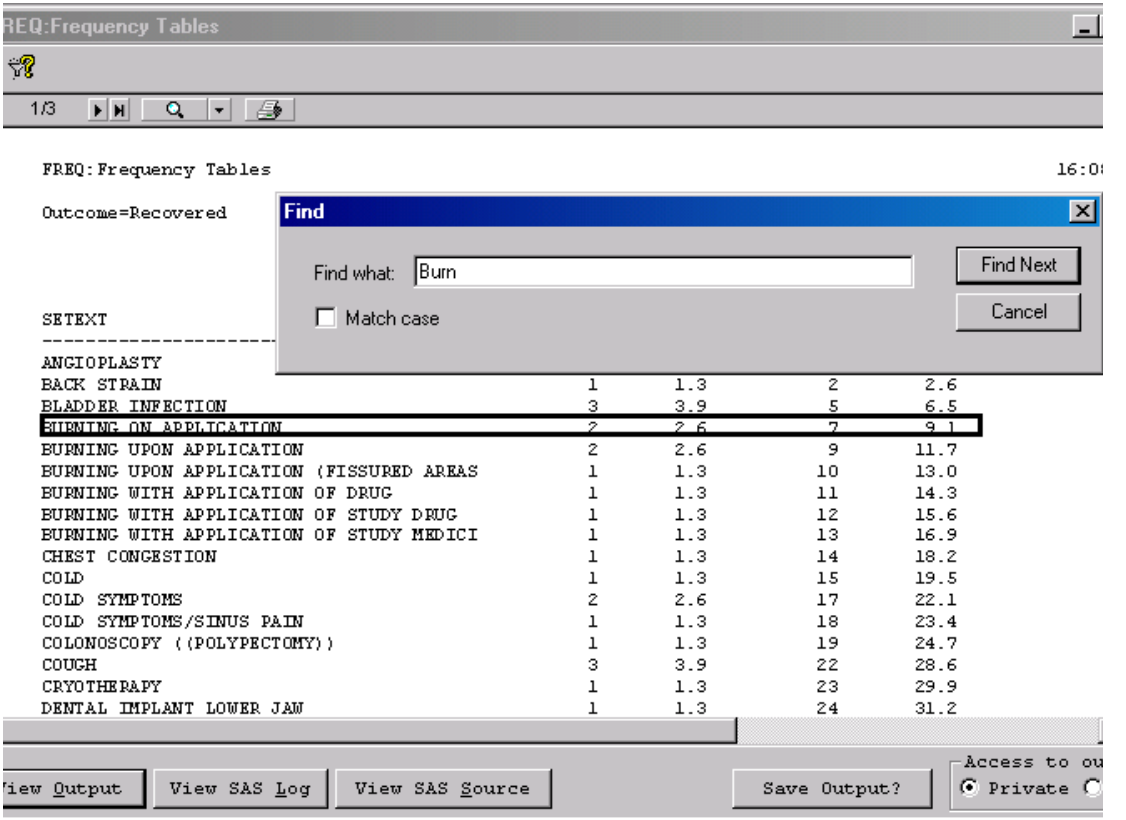
The toolbar at the top of the output display window allows you to page through the output. The paging feature is necessary to view listings where ADD BY Var is applied to create the output. For example, if investigator is the BY Var then a page break by investigator is applied to the output display.

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

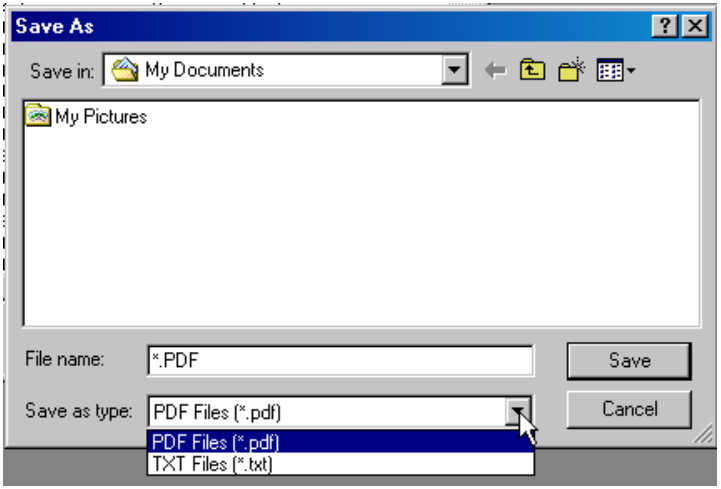
1. Click , or from **File** menu, select **Print**. Review displays the Print window dialog.
2. Enter printing selections and click Print**.**

   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.

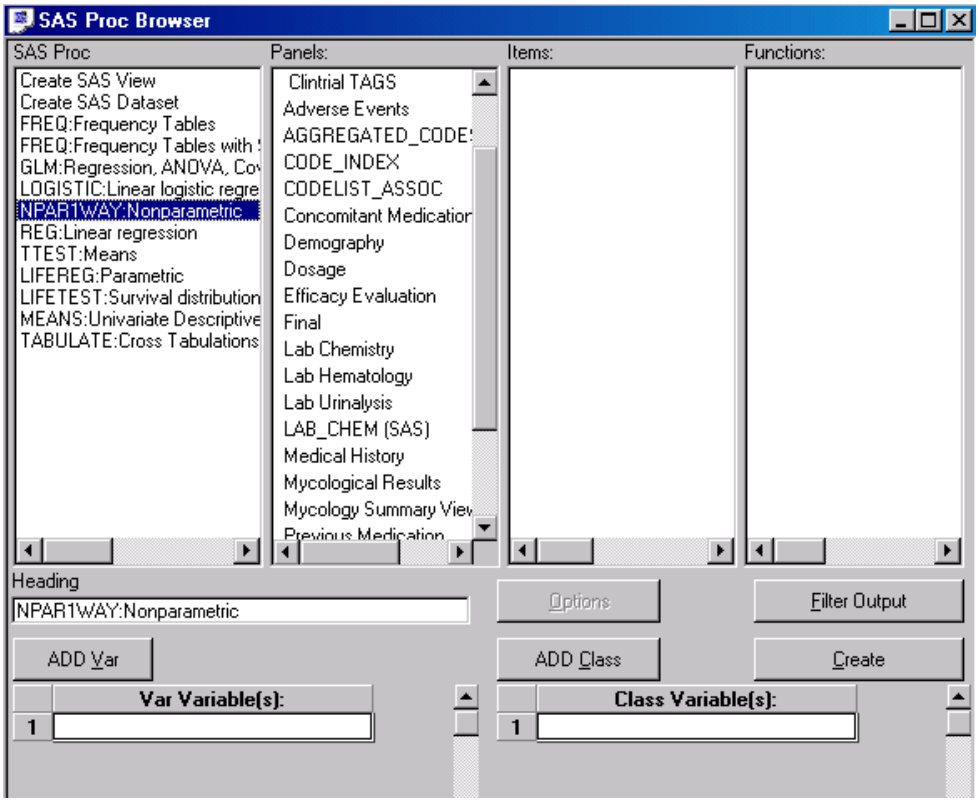


2. Enter the storage location.
3. Enter the storage type.
4. Click OK.

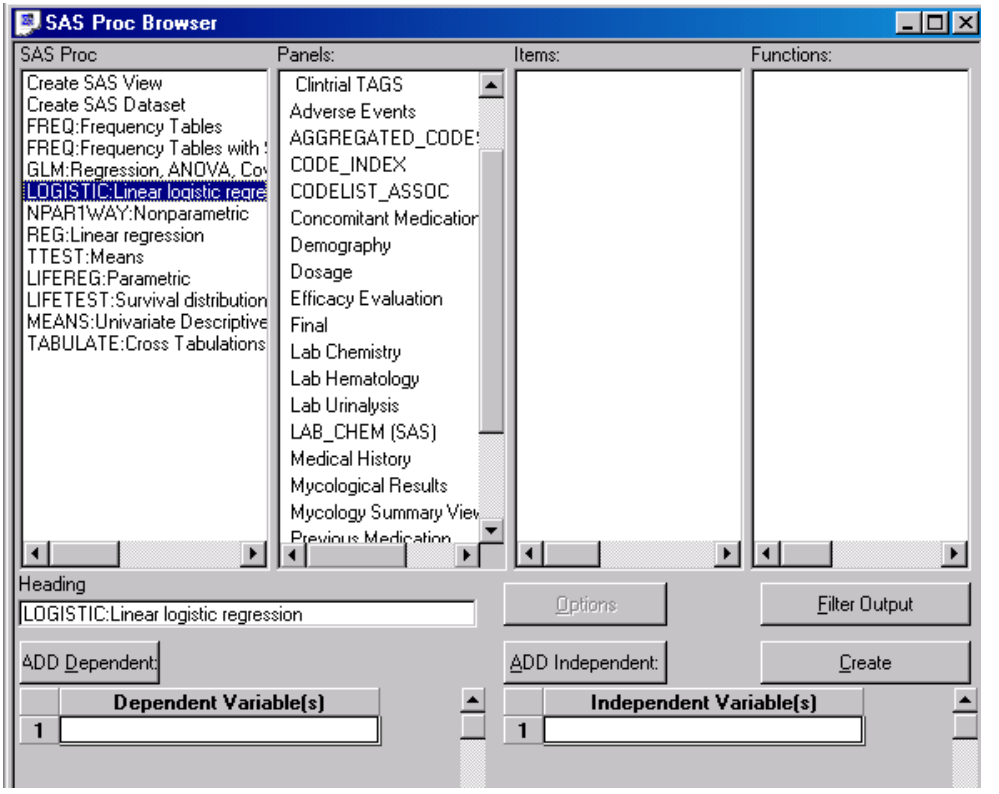
   The result is exported to the currently selected disk directory.

Other SAS Proc displays

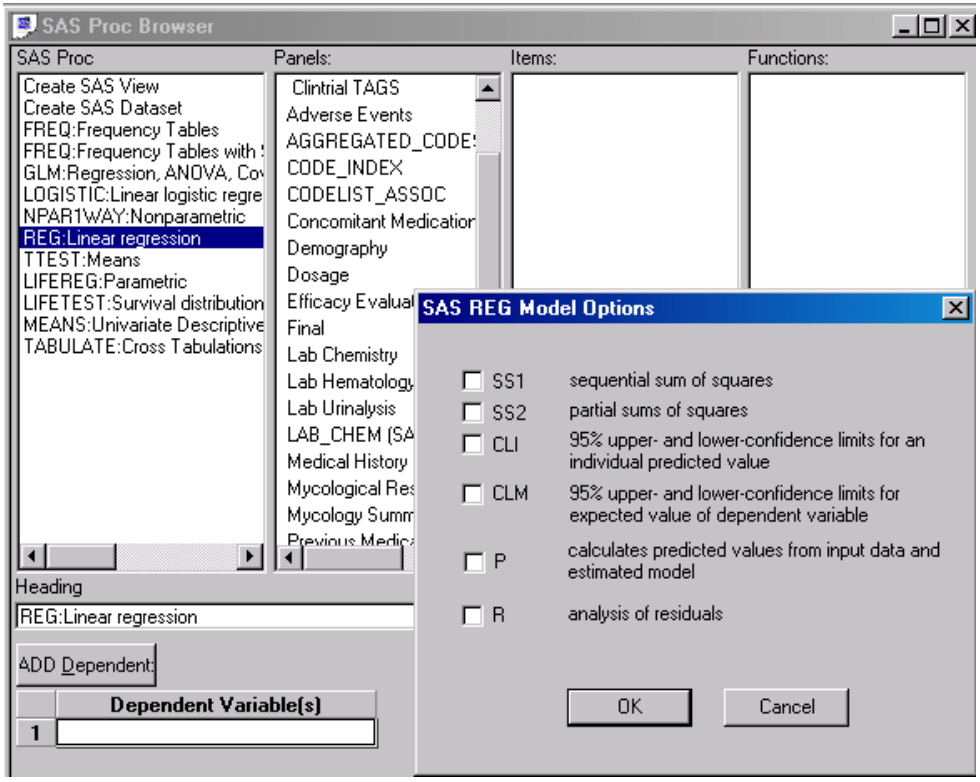
The following SAS Procs: NPAR1WAY and TTEST share the same display window for selections ADD Var and ADD Class. Select panel and item, then click **ADD Var** and **ADD Class** buttons for data items to be analyzed.



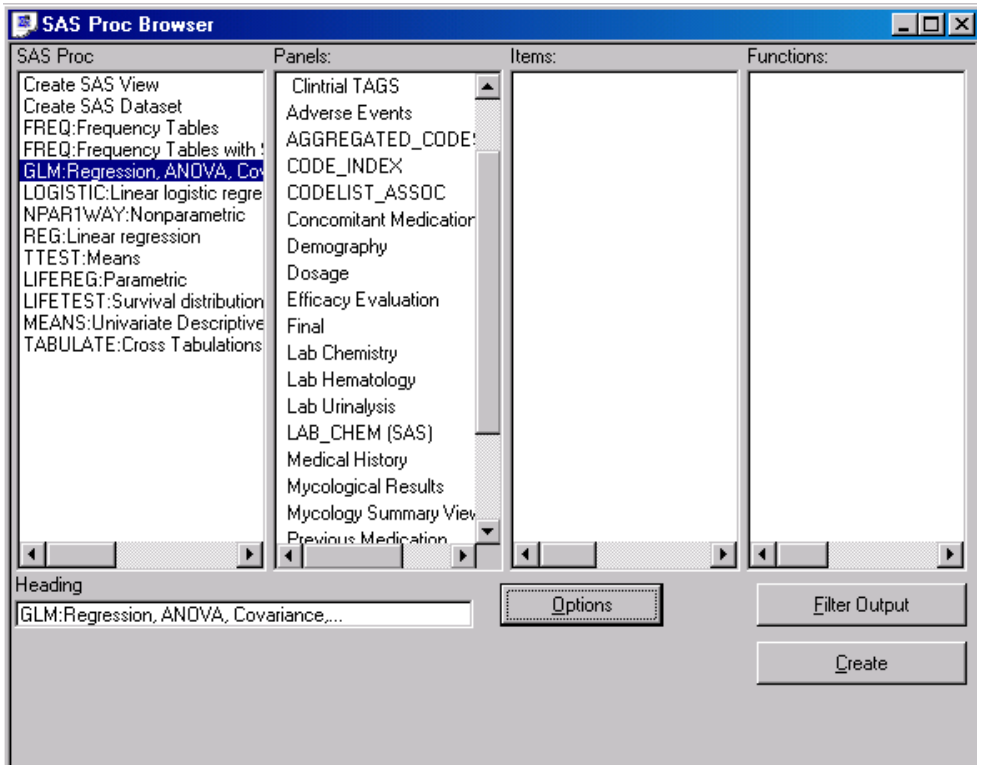
The following SAS Procs LOGISTIC and REG share the same display window for selections ADD Dependent and ADD Independent. Select panel and item, click **ADD Dependent** and **ADD Independent** buttons for data items to be analyzed.

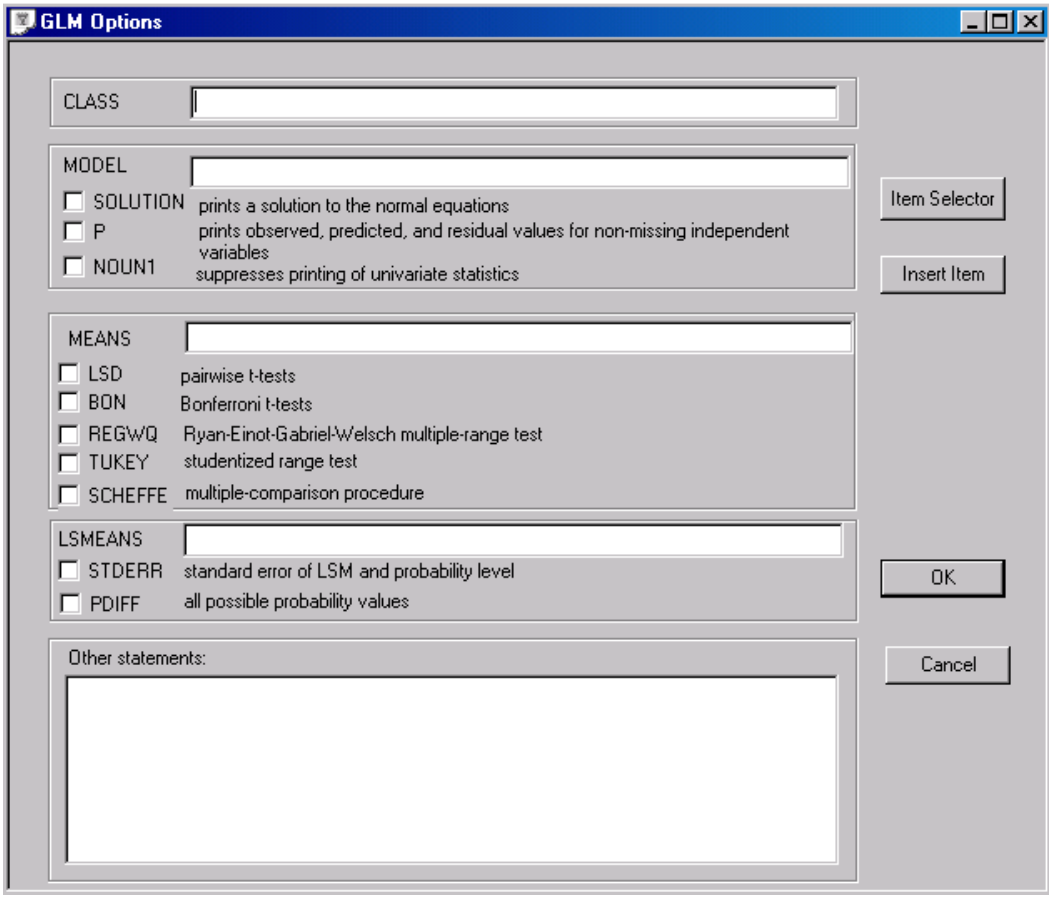


When you select SAS Proc REG, the 'Options' button is automatically enabled for selection of REG Model Options. Click selection boxes desired and click **OK**. The click **Create to generate SAS output**.

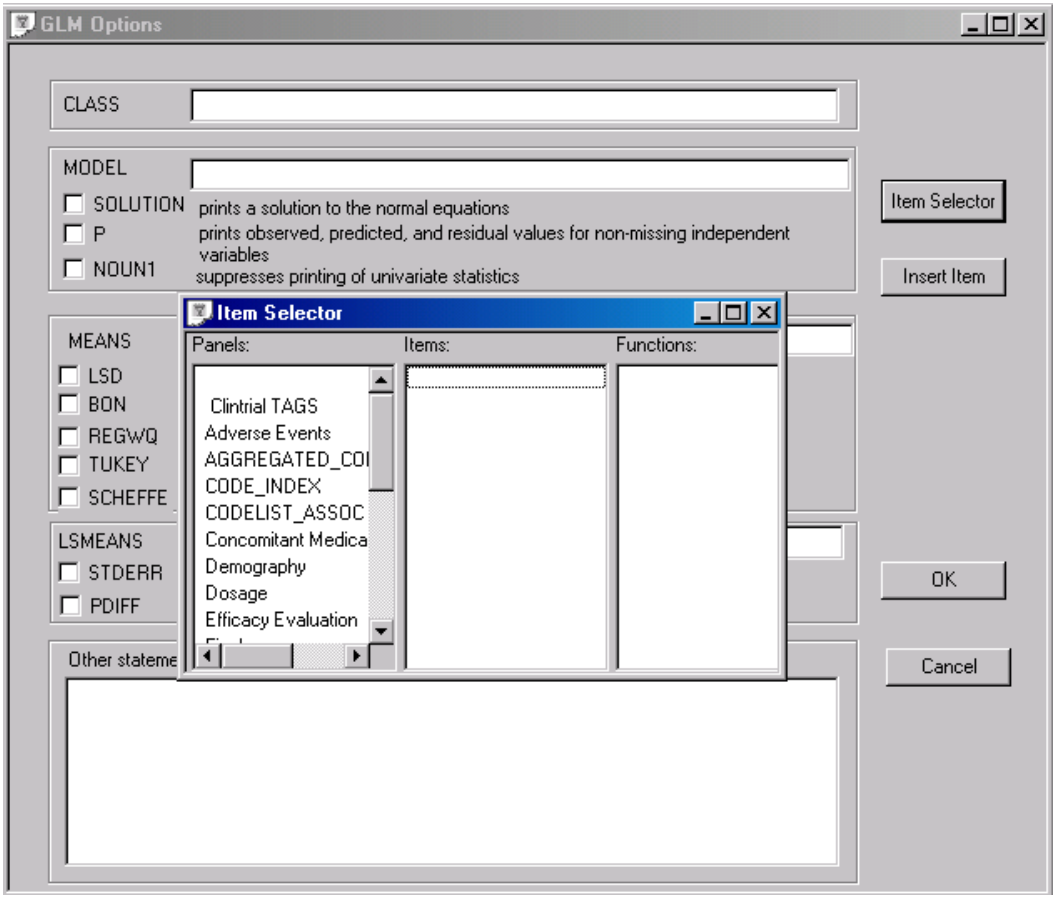


When you select the SAS Proc GLM, the browser window only displays the 'Options' button. Click **Options** to display the GLM Options and define your analysis definitions.

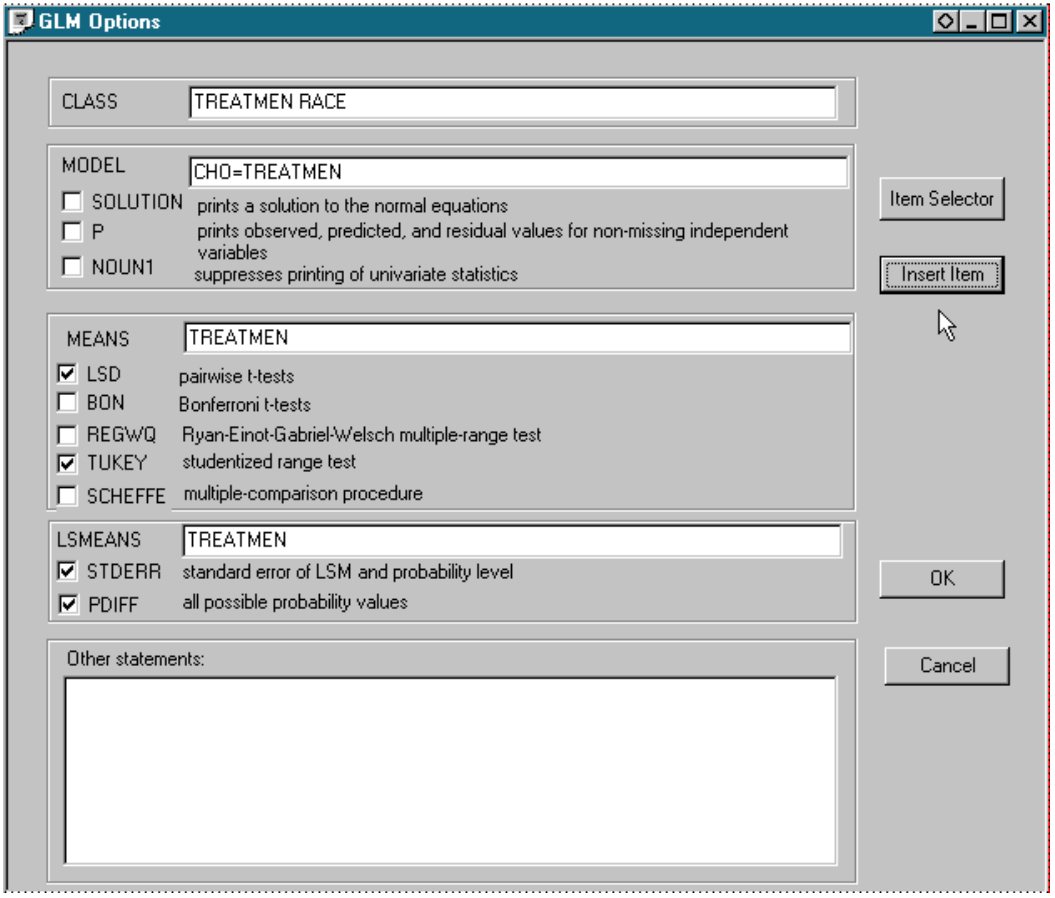



GLM Options
CLASS
MODEL
SOLUTION
prints a solution to the normal equations
P
prints observed, predicted, and residual values for non-missing independent variables
NOUN1
suppresses printing of univariate statistics
Item Selector
Insert Item
MEANS
LSD
pairwise t-tests
BON
Bonferroni t-tests
REGWQ
Ryan-Einot-Gabriel-Welsch 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.



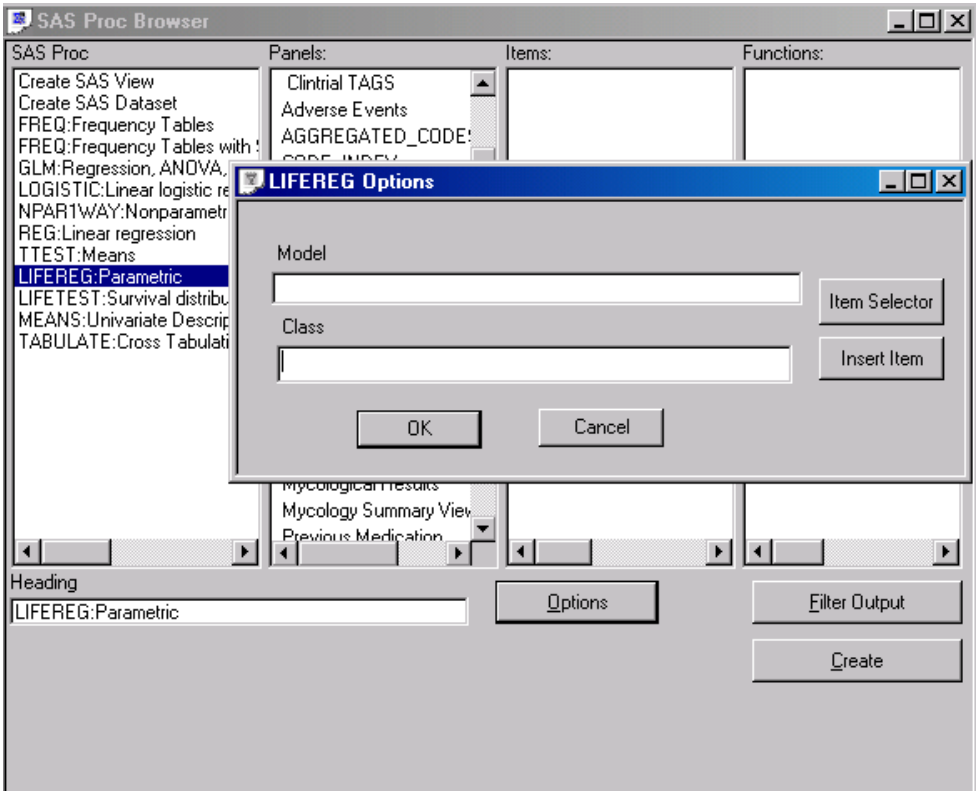
*Note: Do not type text items into the edit areas. You must select items by clicking **Item Selector** and make selections from the panels and items displayed in the Item Selector window. Insert a space between each item selected if you add multiple items within the same edit area.*



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

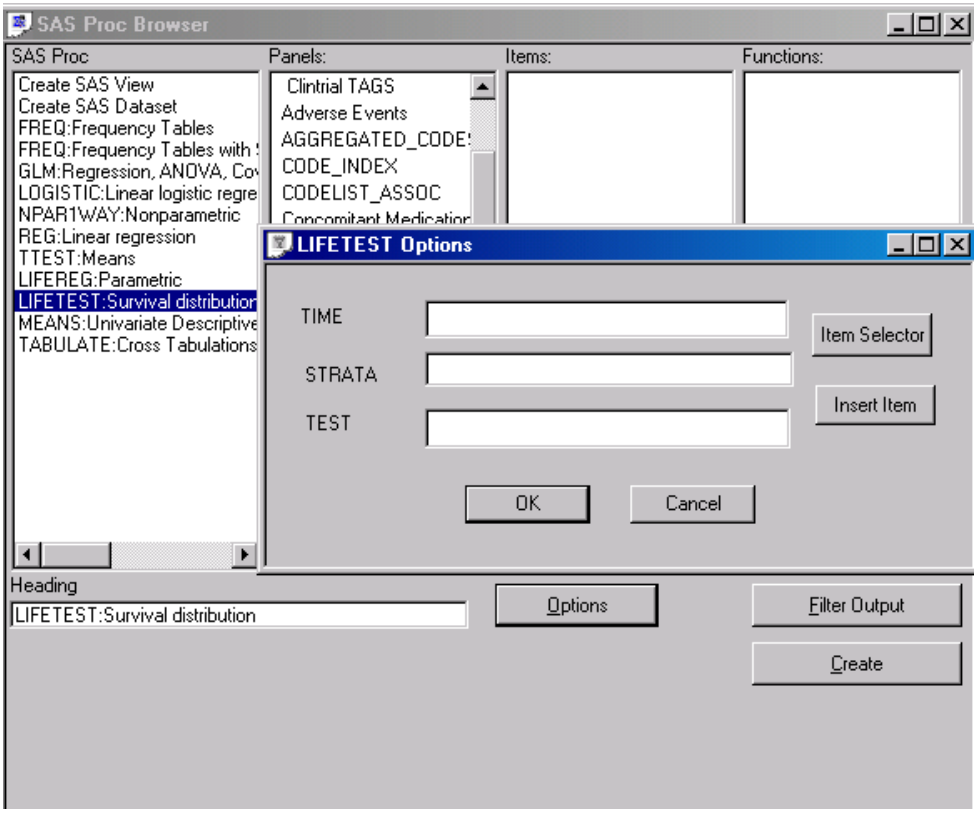
Click **OK** to submit the GLM Options. Click **Create.**

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.**

Multiple SAS Proc outputs

Opening multiple SAS Proc results

You can have multiple SAS Proc result windows active at the same time. 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.

Review 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).

Snapshot output

Multiple population mode

Review has an optional multiple-population mode available in the SAS Proc Browser. The Snapshot output allows you to change the patient selection criteria and view the different output within the SAS Proc browser at the same time. When the results are executed and displayed from the SAS Proc browser output window, two icons are displayed for “Snapshot Output” and “Who?”.

(See *Chapter 6: Report Browser: Snapshot Output and Chapter 12: Common Topics: Snapshot output)*

Saving a SAS Proc specification

Save the SAS Proc specification for later use or for validation of results. All saved SAS Procs with output filters on are saved with the filters. (See *Chapter 6: Reporting: Object Storage: saving your work.)*

All output specification functions for saving, retrieving, exporting, scheduling and removing are covered in the Report Browser. These functions are the same and apply for all Review output browsers.

Note: 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.

Schedule SAS Proc jobs

(See *Chapter 6: Reporting - Scheduling Output.)*

Review output

The Review Output folders are from the category folder definition for each of the objects that were run. You only see folders in the Review Output if an object has output saved.

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.

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 define the specifications of your report, and create it by clicking **Create**, you can use the output(s) that are currently displayed as data exploration views:

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 Registered SAS Programs

Selection criteria **476**

Selection set 476

SAS program browser **476**

Registered SAS programs 476

Opening the SAS Program Browser 476

Selecting a table 477

Schedule SAS Program jobs **478**

SAS program results and log files **478**

Multiple table outputs 479

Snapshot output **479**

Multiple population mode 479

Exporting and printing SAS program results **480**

Print Preview 480

Printing the table output 480

Exporting the result 481

Close SAS Program results window and SAS Program Browser **482**

Closing the table output window 482

Closing the SAS Program Browser 482

Exploring data **482**

Opened SAS production table results 482

Update patient selection criteria 482

Selection criteria

Selection set

You can use the SAS Program Browser to regenerate previously programmed SAS Production Tables, with the original complete patient population, or to regenerate the tables 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 *Chapter 6: Report Browser: Schedule Output)*

SAS program browser

Registered SAS programs

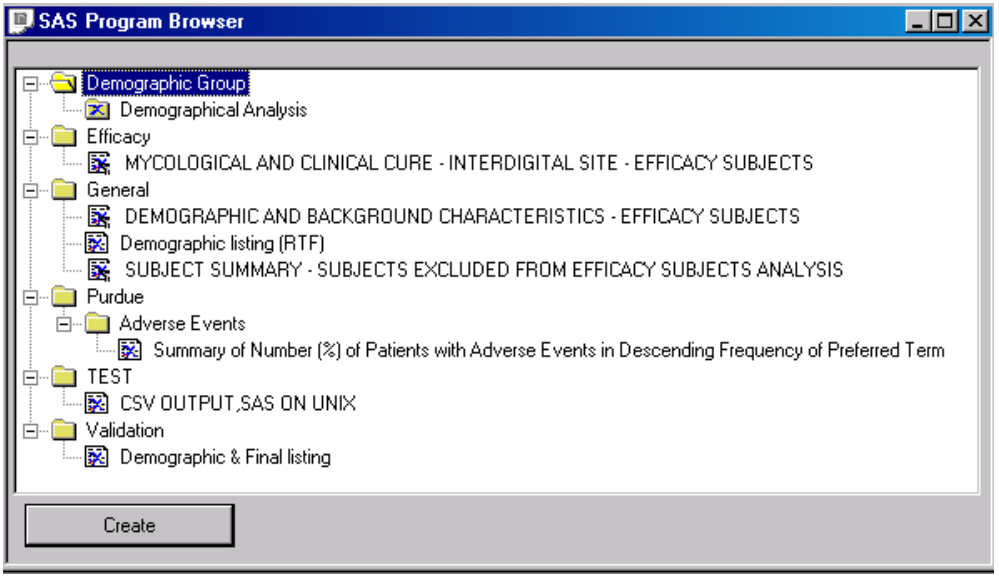
Your System Administrator can register SAS programs and SAS Data Sets used in the formal analysis of the protocol(s) of interest. They can be current Global and Study Specific SAS programs or Project global SAS programs. These programs and datasets can be made available and registered to Review, typically after the completion of the protocol and cleaning of the database. Thereafter, you can access these programs and datasets by using the SAS Program Browser.

Opening the SAS Program Browser

The SAS Program 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 SAS Program Browser window to display the categorical folders containing additional subfolders and all SAS Production Tables registered by your System Administrator for the current protocol. Groups of SAS programs can also be defined and executed.

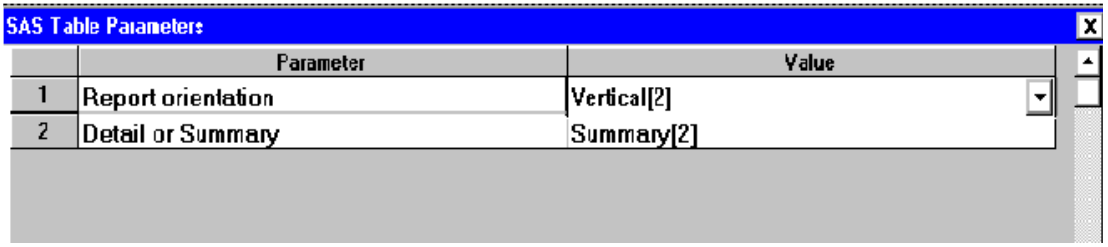
Selecting a table

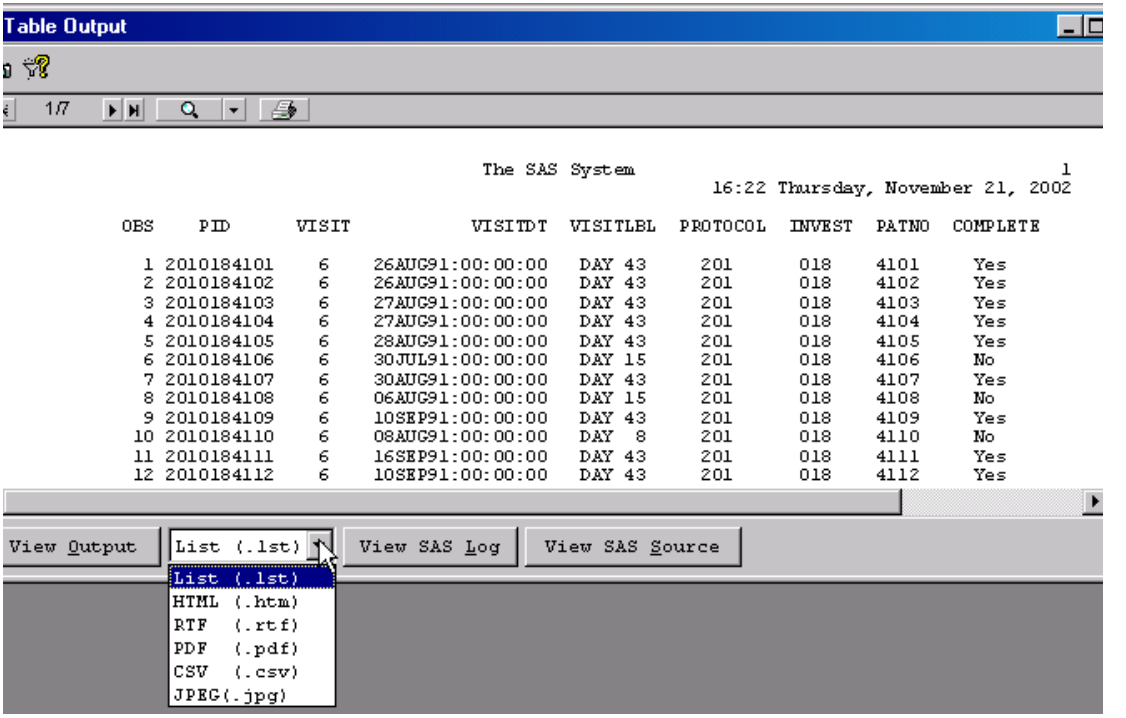
Select an entry from the list of available SAS programs to be executed.



A SAS Program that requires parameterization opens a SAS Table Parameters Window, which facilitates the selection of variable parameter values.

1. Each row value is a drop list box when clicked on. Select the parameter value you want to apply to the analysis.
2. Click on the value, and the drop list box with all possible values will be listed and made available for you use in the execution of the SAS program.
3. Once you have selected the applicable values, you are ready to create the SAS program output.
4. Click Create.





5. You can choose to change the file type for exporting.

Schedule SAS Program jobs

(See Chapter 6: Report Browser: Schedule Output)

SAS program results and log files

For information to View SAS Source, View SAS Log, View SAS Output and Toolbar. (*See Chapter 9: SAS Proc Browser: SAS Proc results display*)

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 by clicking **Create**.

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

Multiple population mode

Review has an optional multiple-population mode available in the SAS Program Browser. The Snapshot output allows you to change the patient selection criteria and view the different output within the SAS Program browser at the same time. When the results are executed and displayed from the SAS Program browser output window, two icons are displayed for “Snapshot Output” and “Who?”. (*See Chapter 6: Report Browser: Snapshot output* and *Chapter 12: Common Topics: Snapshot output)*

Exporting and printing SAS program 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.

   The Print Preview function is applicable to all browsers with output results.
3. Click either **Print** or **Close.**

Printing the table output

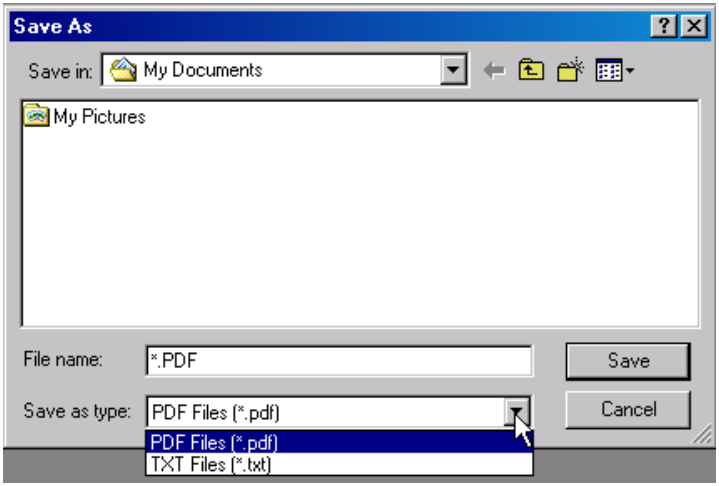
To get a printed copy of your SAS Proc output:

1. Click , or from the **File** menu, select **Print**.
2. Click **OK.** The SAS Proc output prints on the 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.

Close SAS Program results window and SAS Program Browser

Closing the table output window

If you are finished reviewing the output of a table, and do not want to use the output to review any other patient populations; double-click on the window's close box.

Closing the SAS Program Browser

If you are finished with all SAS Program Browser outputs, and do not want to define any other reports; double-click on the close box of the **SAS Program Browser** window.

Exploring data

Opened SAS production table results

After you have selected a SAS Production table to be executed, click **Create Output**, 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 Accessing Documents

Data source (protocol) **484**
Selecting a data source 484
Open the Document Browser 484
Displaying a document 485
Closing the Document Browser 485

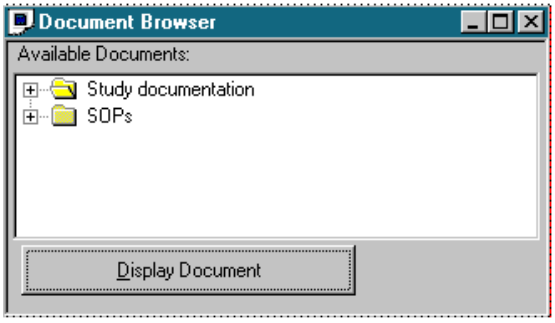
Data source (protocol)

Selecting a data source

After you select a data source (protocol) to review, you can access any documents that have been made accessible to Review.

Open the Document Browser

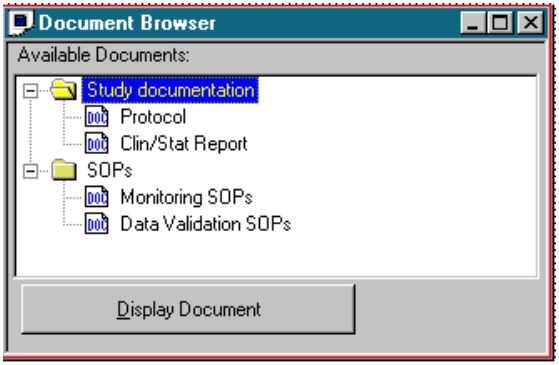
Click , or from the **Browse** menu, select **Documents**. Review displays a list of folders of the saved documents.



Displaying a document

To select one of the available documents:

1. Single click to to open a folder.



2. Click on the document and then click **Display Document**, or double click on the document.

   Review invokes the appropriate Windows program to display the document you have selected.

Closing the Document Browser

To close the Document Browser; double-click on the close box of the Document Browser window.

Note: Review does not automatically close the Windows program previously opened. When you are finished reviewing the document in the program, you must exit the program manually.

12 Common Topics

Shared object storage 490

Exploring interpretative consensus 490
Consensus of data interpretation 490
PC Based Object Storage 490
Private object storage 490
WorkGroup object storage 491
UserGroup object storage 491
Public object storage sites 491
SuperUser 492

Server-based global object storage 492

Global object storage 492
Sharing objects 492
Object level 492

Change User Password 493

Change password 493

Snapshot output 493

Multiple population mode 493
Snapshot output 494
Who is the patient population? 494

Pivot panels 495

Transposing normalized clinical data 495
Creating pivot panels 496

Defining logical joins 501

User-defined logical joins 501
Logical joins with Clintrial Type 0 501
Creating logical joins 502
Global object storage of join logic 503
Removing logical join 505

Import SQL **506**
Access Import SQL 506
Enter Import SQL SELECT statement 507
Using Clintrial tags **509**
Tags for selection and reporting 509
Access Clintrial tags items listing 509
Exploring clinical data with derived item values **510**
Derived data item values 510
Derived items across panels 510
"_Define New Item_" 512
Adding operators 515
Saving the new item 517
Saving a Global new item 520
Editing defined new items 521
Removing saved new item definitions 522
Exploring clinical data with range variables **523**
User-defined range variables 523
"_Define New Range_" 523
Defining range cut points 524
Saving the new range variable 525
Editing a defined range variable 525
Removing saved range variables 526
New event function **527**
User-defined time related milestones 527
"_Define New Event_" 527
Editing or deleting a new event function 528
Exploring clinical data in multi-protocol mode by StudyID **529**
Multi-protocol mode: protocol comparisons 529
Using the <StudyID> 529
Reviewing preferences **530**
Open preferences 530
Automatic Outer joins 531
Optional Outer joins in Results 531
Use full joins in Selection Criteria 531

Displaying panel names 531
Displaying item names 531
Sort panels alphabetically 532
Sort items alphabetically 532
Patient subset footer as text 532
Clintrial Data Source 532

Single patient mode 532

Identify Patients with interactive browsing design 532
Patient-level results interact 532

Multiple patient mode 533

Patient-level and summary displays interact 533
Browsers interact 533
Summary results and patient level results 534

Displaying spreadsheets 534

Exporting browser spreadsheets 534
Browsers export spreadsheets 535

Copy to Clipboard 535

View SQL details dialog 535
Copying and pasting browser results 536

Shared object storage

Exploring interpretative consensus

Exploring clinical data interpretative consensus by using selection criteria and result specifications defined by co-workers.

Consensus of data interpretation

The shared object storage feature facilitates quick communication of review specifications that may serve as powerful tools for fellow reviewers. The four-level Object storage also functions to allow for consensus of interpretation on the data derived from a shared reviewing tool and an assortment of shared review criteria and views of patient data.

PC Based Object Storage

You have four levels of object (browser specifications) storage using Review. The four levels, Private, WorkGroup, UserGroup and Public, offer varying degrees of sharing these objects with peers.

Private object storage

The Private object storage site is only available to you on your PC. The Private object storage site is defined in the Review.ini file. (See the *Review Configuration Guide*.)

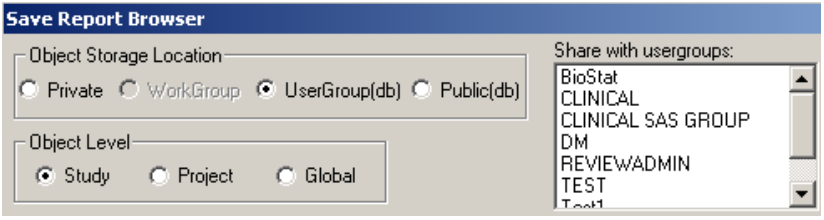
WorkGroup object storage

Note: The WorkGroup object storage is no longer used as it has been replaced by the preferred UserGroup method to achieve the same function of sharing between users and based on a database saved object. The WorkGroup function is still available for backward compatibility.

The WorkGroup object storage site is network designated PC based to be accessed by all within the WorkGroup. The WorkGroup object storage site is defined in the Review32.ini file. However, **Change WorkGroup Location** button in the Open save object window, facilitates the browsing of other defined workgroup object storage sites. (See the *Review Configuration Guide.*)

UserGroup object storage

The UserGroup object storage site is 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. Saving on database object storage sites, requires the author to have "Publishing Authorization" defined in the configuration tables. (See the *Review Configuration Guide.*)



Public object storage sites

The Public object storage site is database object storage for all users of Review who have shared drive access beyond the local WorkGroup. The Public object storage site is a database storage defined in the Review.inifile. Saving on database object storage sites, requires the author to have "Publishing Authorization" defined in the configuration tables. (See the *Review Configuration Guide.*)

SuperUser

Individual users can be granted special privileges as ‘SuperUsers’ to update and delete stored objects created and saved by other users. Typically only the author of a stored object can modify or delete it. However, the SuperUser has access to those stored objects when modification or deletion are needed for maintenance and cleanup.

Server-based global object storage

Global object storage

User-created objects such as, pivot panels, logical joins, and '_New Event Functions_' are saved in tables owned by the Review Admin ORACLE user. The site or user configuration can be enabled or disabled for user-created objects for pivot panels, logical joins, and user preferences selections. The panel listbox in the patient selection criteria window will look different if these functions are disabled by the site administrator.

The site default, usergroup or user level privileges can be set to control access to SAS to save objects at each level (Private, WorkGroup, UserGroup and Public). This also includes the ability to save patient notes.

Sharing objects

When the 'Share with other?' checkbox is checked as WorkGroup, UserGroup or Public; the stored object is accessible to those shared sites if the user has publishing privileges. If the checkbox is not checked, then the created object is only accessible by the author.

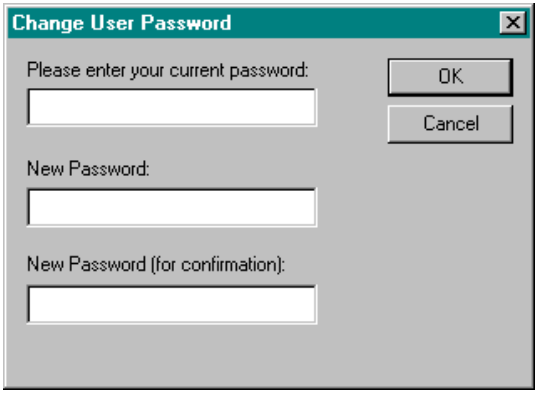
Object level

You can save output specifications (reports, graphs, SAS Proc, etc.) at Project or Global level when you select an Object Storage Location designated as ‘db’ for database. Therefore, when you select either UserGroup or Public for database object 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.

Change User Password

Change password

You can change your own password if you have the privilege set in ReviewAdmin. From the File menu, select ‘Change Password’.



Snapshot output

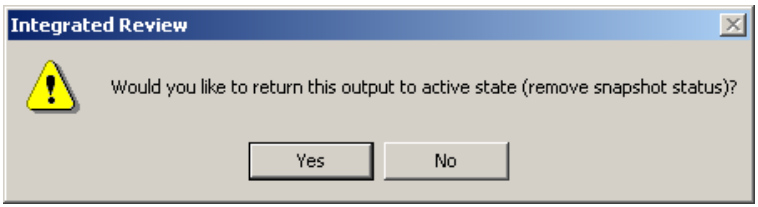
Multiple population mode

Review has an optional multiple population mode available for the following browsers: Report Browser, Graph Browser, SAS Proc Browser, SAS Program and CrossTab Browser. The Snapshot Output allows you to change the patient selection criteria and view the different output within a particular browser at the same time. When the results are displayed from an executed browser to the browser output window, two icons are displayed for “Snapshot Output” and “Who?”.

Snapshot output

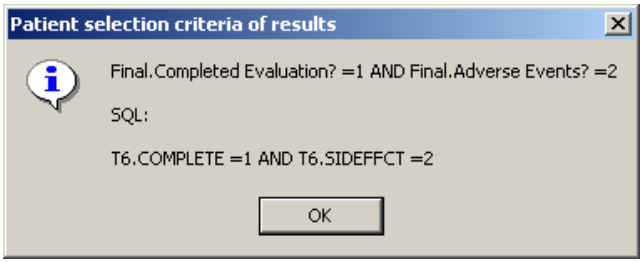
The first icon is “Snapshot Output” which allows you to keep a particular output as is for comparison purposes. Before you change the patient population, click the ‘Snapshot Output’ icon. The output window’s caption bar changes to include ‘[Snapshot]’ at the beginning - to let you know the output is a snapshot and will not be updated when you change the patient selection criteria and create output.

Click on the Snapshot Output icon again to return the output window to an active status for updating.



Who is the patient population?

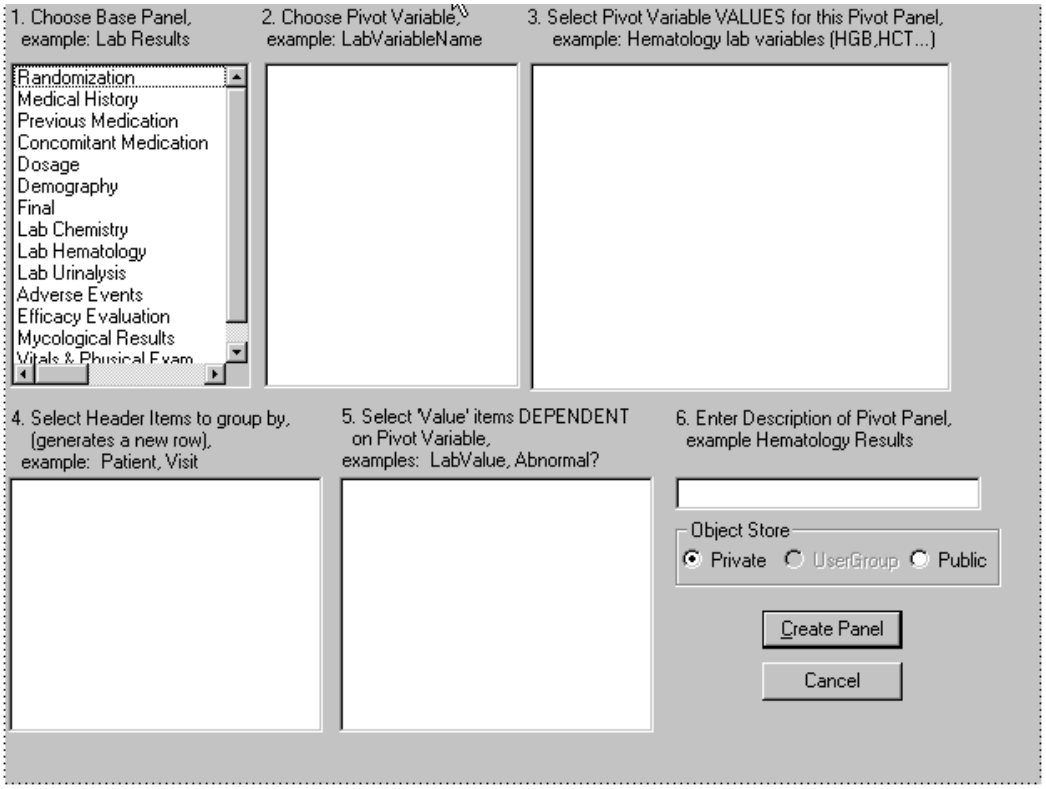
You can click on the second icon “Who?” to display a message box showing the current patient population for that output. The “Who?” message works with the ‘live’ output and the ‘snapshot’ output.



Pivot panels

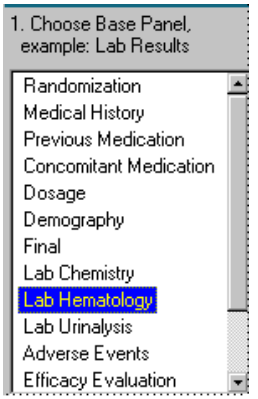
Transposing normalized clinical data

With pivot panels, you can transpose clinical data stored in a normalized manner into a more easily reportable horizontal data structure. Click on the pseudo-panel "_Define Pivot Panel_", and the Define Pivot Panel dialog box opens:

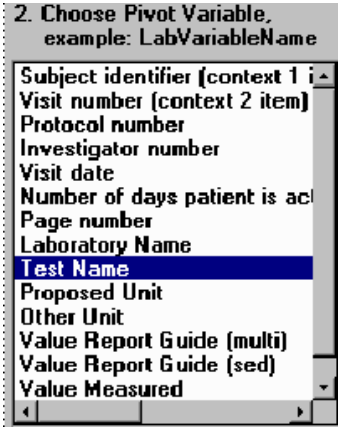


The creation of the pivot panel is a point and click operation. You construct the new data structure by selecting the appropriate items sequentially according to the number of the list box. Each list box is numbered and includes a brief description and instruction:

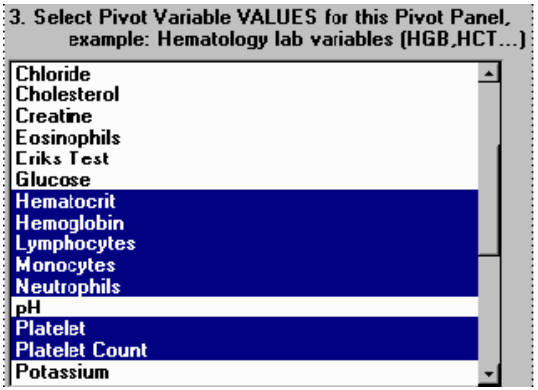
1. Choose a base panel:



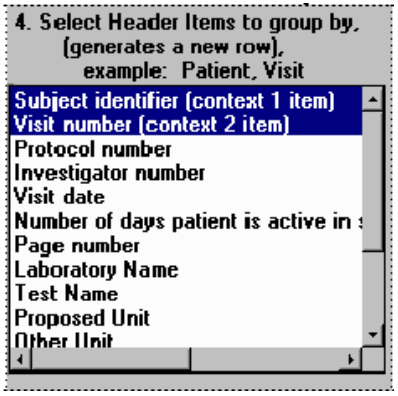
2. Choose a pivot variable.



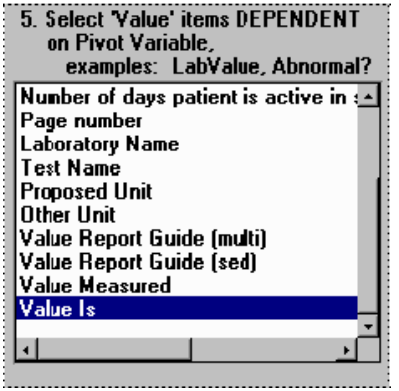
3. Select pivot variable Values. Hold down **Ctrl** and click to select multiple values.



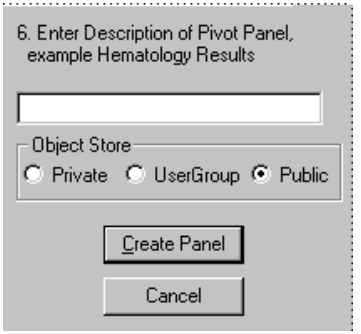
4. Select header items to group by, generating a new row in the new data structure for each change in the header items. By default, Patient ID is included as one of the header items. For example, if you include Patient ID and Visit Number, a new row will be created not only for a change in Patient ID, 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.

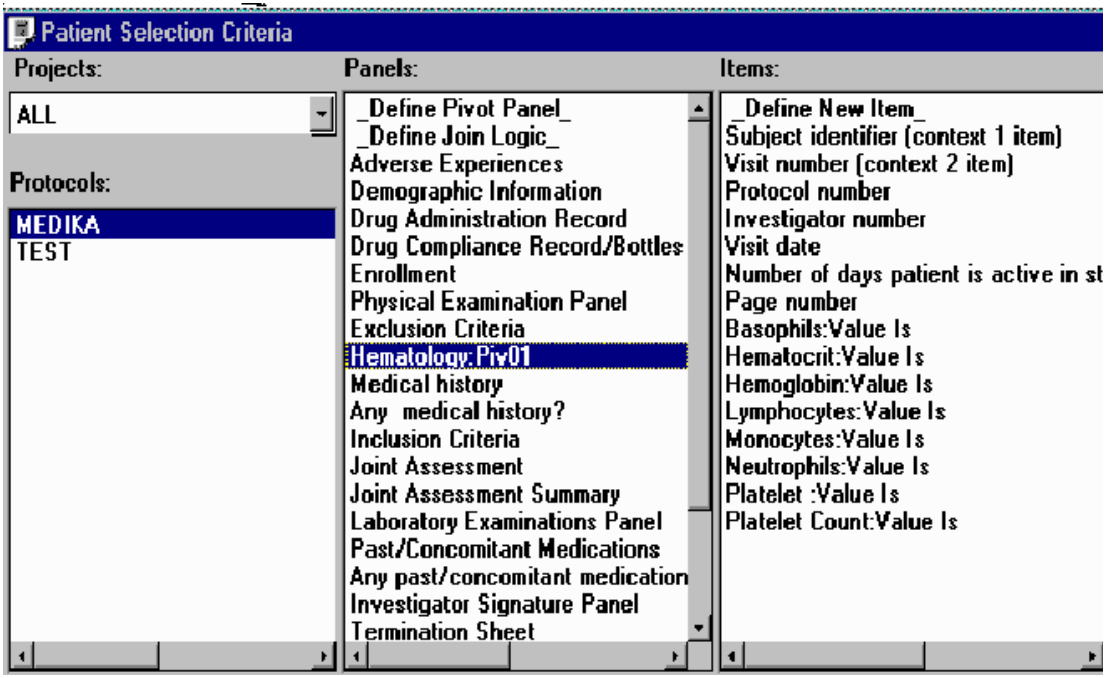


6. Enter a description of the pivot panel.
7. Select UserGroup or Public to make the new data structure accessible to others. (See *Common Topics: Sharing Objects*.



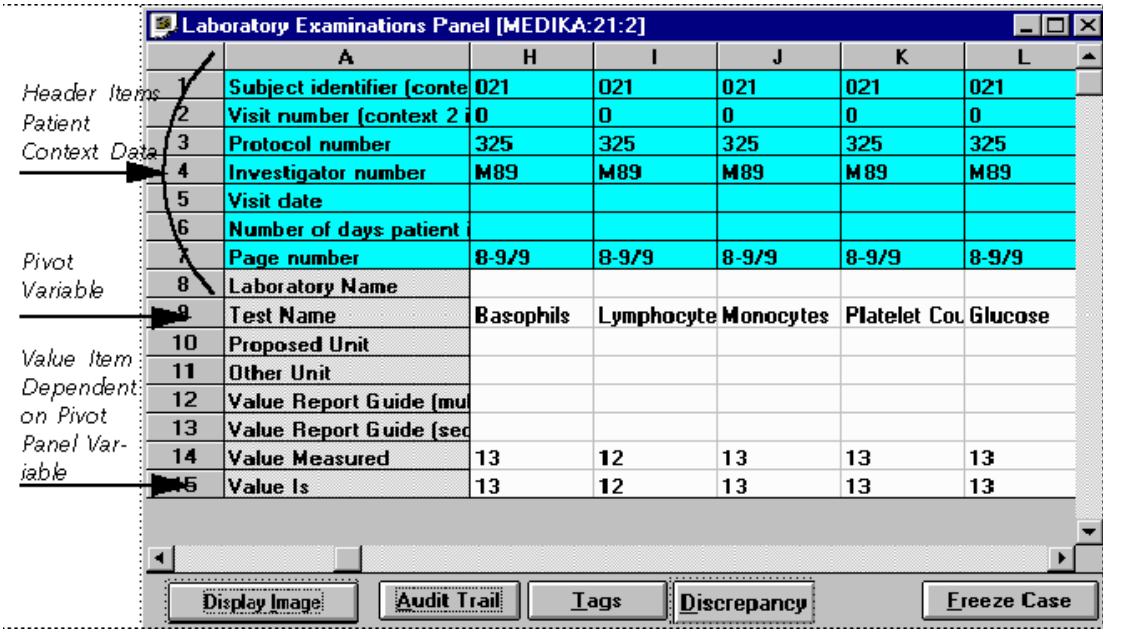
8. Click **Create Panel**. When the pivot panel is created, it is included in the panel listing with a dependent variables listing in the items list box.
9. To remove a pivot panel, click on the Edit menu and select remove pivot panel.

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.



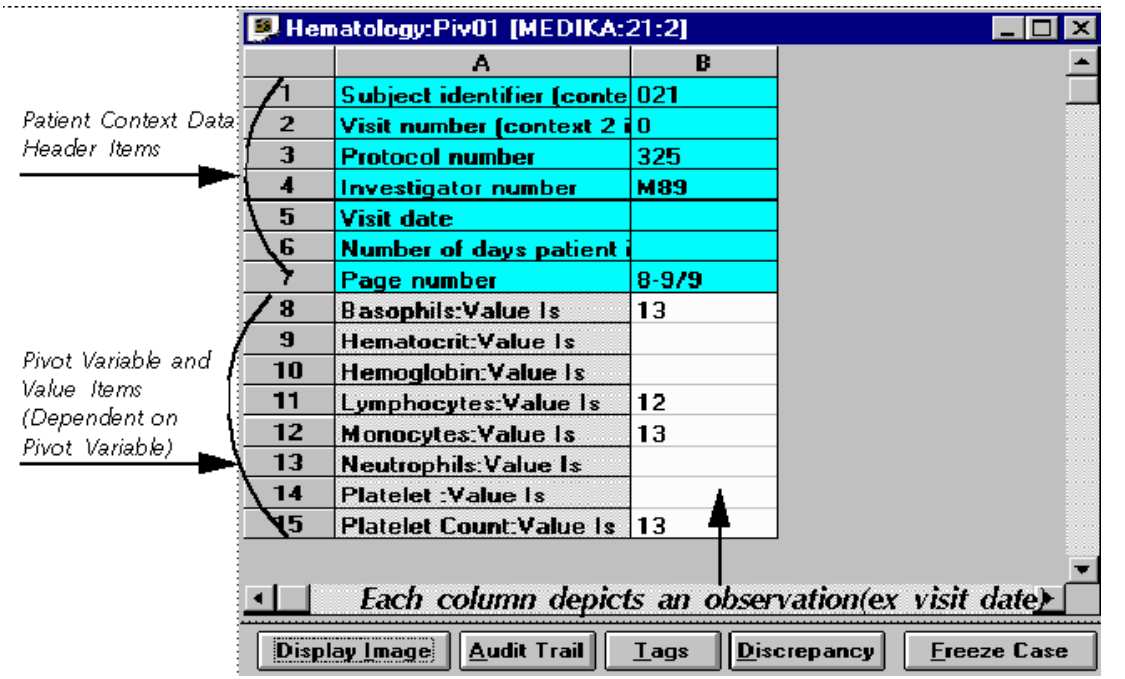
A comparison between the Laboratory Examination Panel and the defined Pivot Panel is best demonstrated by opening the panels with the Data Browser.

The Laboratory Examinations Panel previously stored in a normalized manner is pivoted into a horizontal data structure.



	A	H	I	J	K	L
1	Subject identifier (conte	021	021	021	021	021
2	Visit number (context 2 i	0	0	0	0	0
3	Protocol number	325	325	325	325	325
4	Investigator number	M89	M89	M89	M89	M89
5	Visit date					
6	Number of days patient i					
7	Page number	8-9/9	8-9/9	8-9/9	8-9/9	8-9/9
8	Laboratory Name					
9	Test Name	Basophils	Lymphocyte	Monocytes	Platelet Cou	Glucose
10	Proposed Unit					
11	Other Unit					
12	Value Report Guide (mul					
13	Value Report Guide (sec					
14	Value Measured	13	12	13	13	13
15	Value Is	13	12	13	13	13

The resulting Pivot Panel is defined as Hematology:Piv01.



	A	B
1	Subject identifier (conte	021
2	Visit number (context 2 i	0
3	Protocol number	325
4	Investigator number	M89
5	Visit date	
6	Number of days patient i	
7	Page number	8-9/9
8	Basophils:Value Is	13
9	Hematocrit:Value Is	
10	Hemoglobin:Value Is	
11	Lymphocytes:Value Is	12
12	Monocytes:Value Is	13
13	Neutrophils:Value Is	
14	Platelet :Value Is	
15	Platelet Count:Value Is	13

Defining logical joins

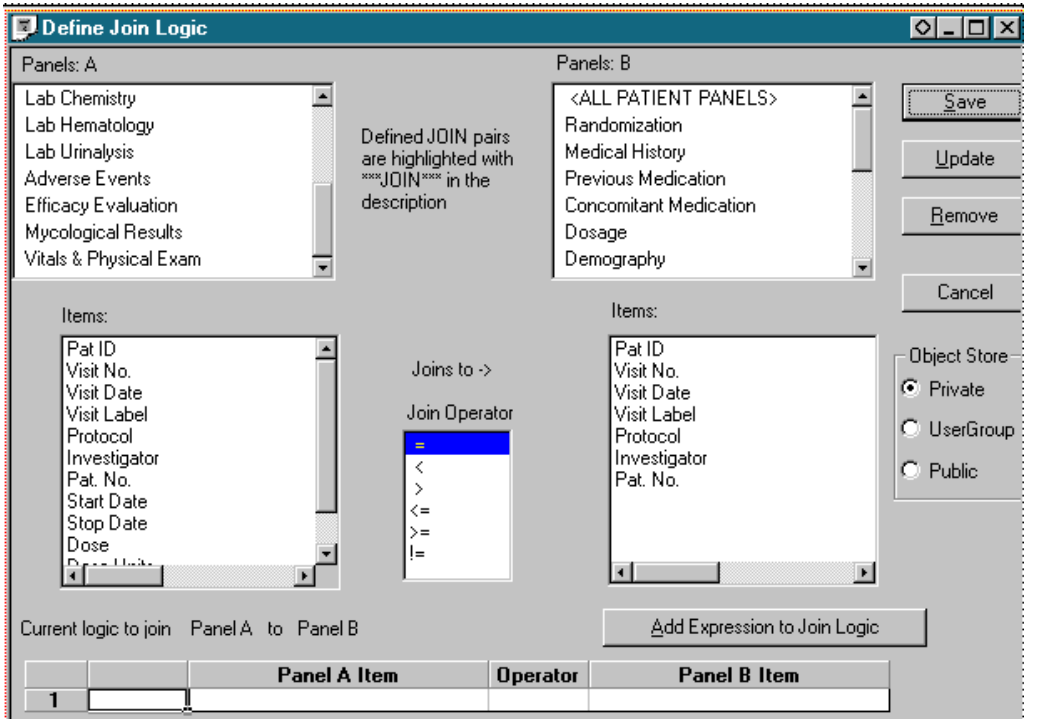
User-defined logical joins

If the default join logic used by Review is not appropriate for a pair of tables, you can specify the join logic Review will use between specified 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'.

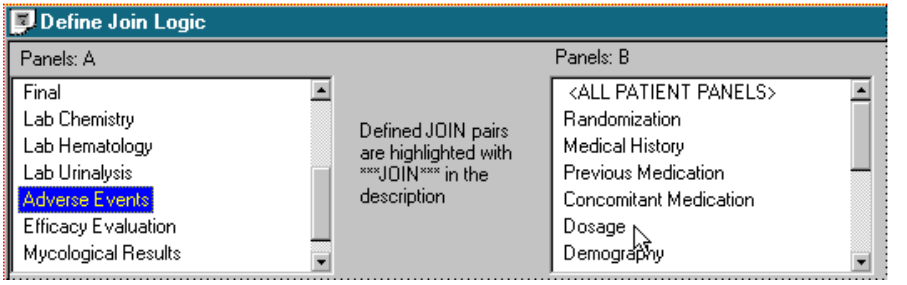
Logical joins with Clintrial Type 0

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.

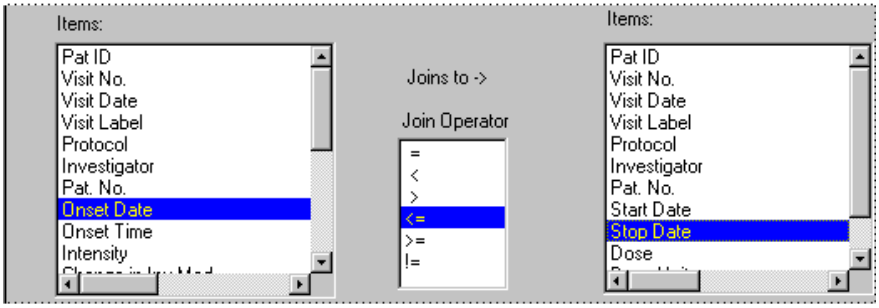
1. Click on the pseudo-panel '_Define Join Logic_' from any listing of available panels, and the following window opens:



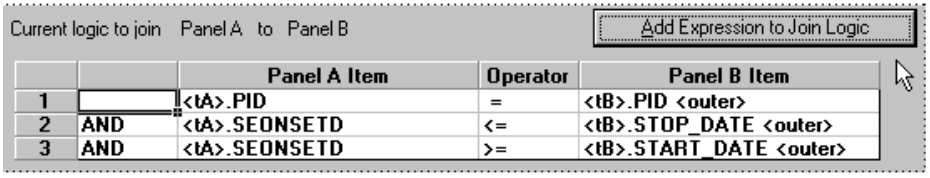
2. Point and click on the panels that you would like to join.



3. Point and click on items and join operators, defining relational joins.



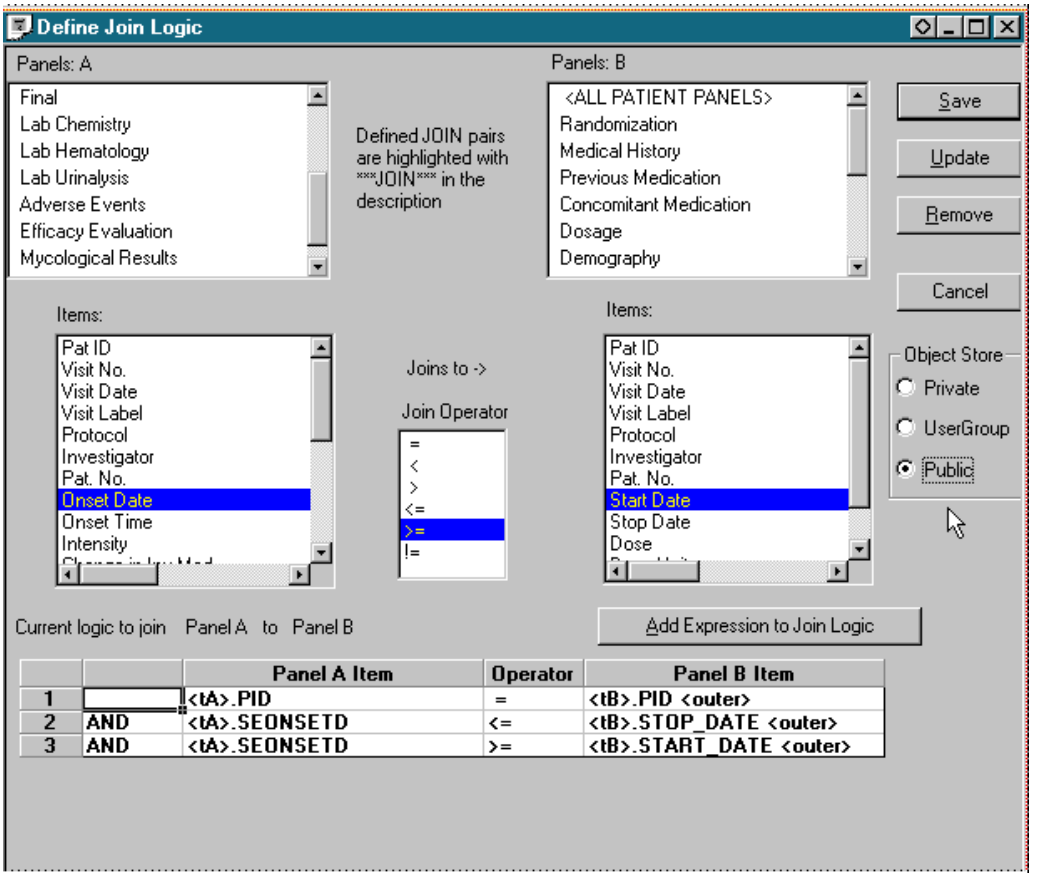
4. Then click **Add Expression to Join Logic** to build the logic for the join between the selected panels.



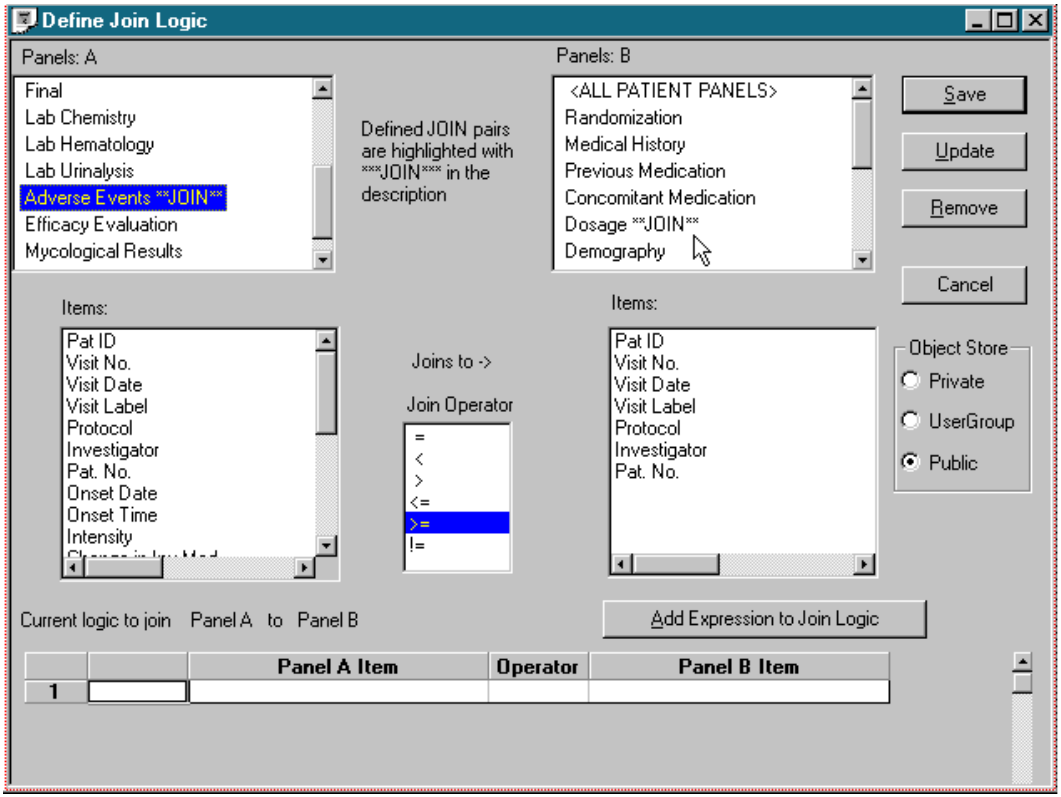
Global object storage of join logic

5. Define the **Object Store** as Public or UserGroup to share the defined Join Logic. The default is private and will allow access only its author.

6. Click **Save** for a new join definition, or **Update** to edit (update) an existing join definition.



Once the Define Join Logic has been saved, the defined JOIN pairs are highlighted in the description with '***JOIN***'. Click on the 'A' panel with '***JOIN***' description to list corresponding 'B' panel(s).



Removing logical join

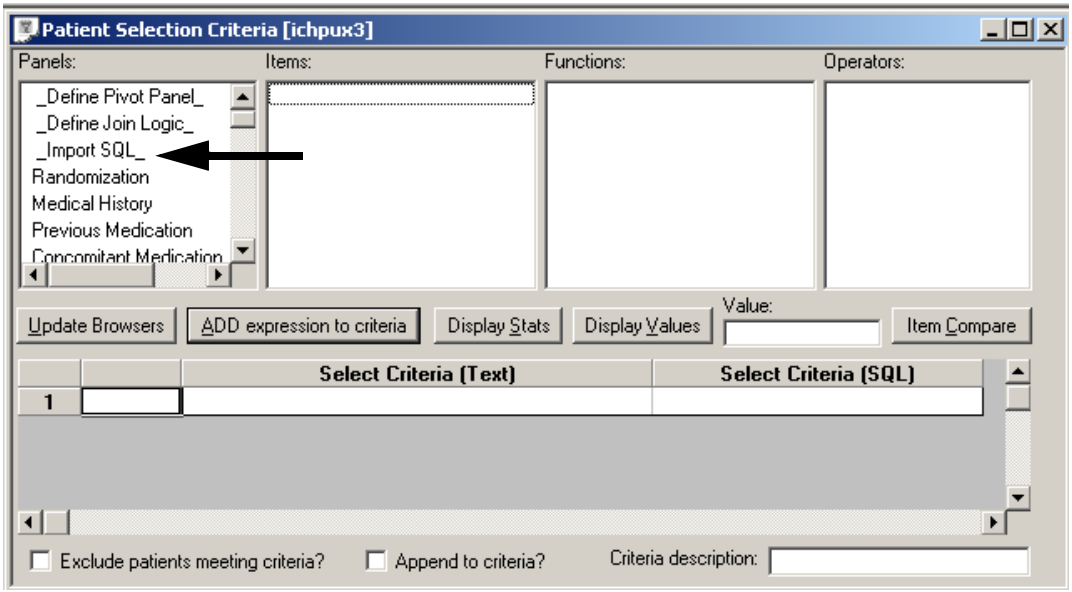
1. Click on the pseudo-panel '_Define Logical Join_'.
2. Select the joined panels.
3. Click **Remove** to delete a defined logical join.

Import SQL

Access Import SQL

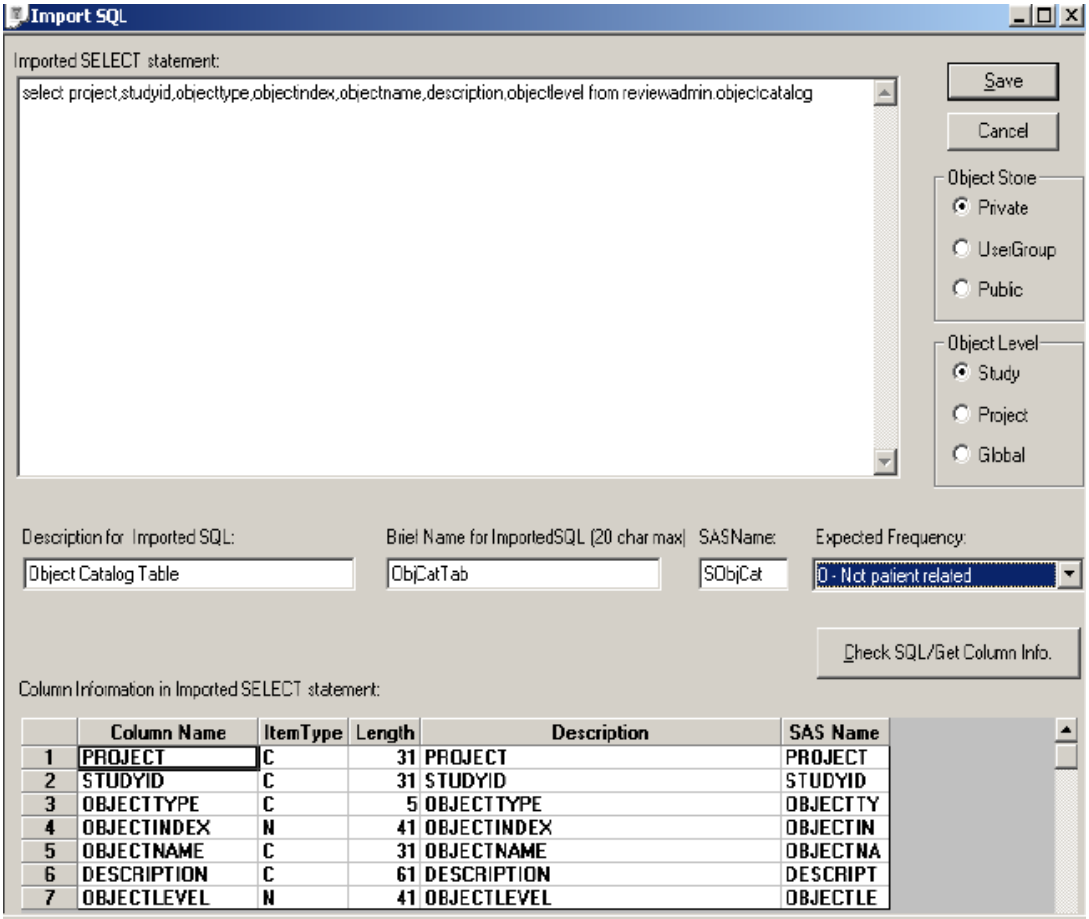
The Import SQL function is another way to create and access foreign panels for data review. *(See ReviewAdmin: Register Foreign Panels)*

After selecting a project and protocol, the 'pseudo panel' _Import SQL_ displays in the Panels list box:



Enter Import SQL SELECT statement

1. Click on _Import SQL_ to open the Import SQL dialog.
2. Either type in the desired SELECT Statement (don't end it with a semi-colon) or copy a SELECT statement to the clipboard and paste it into the 'Imported SELECT statement' edit control.

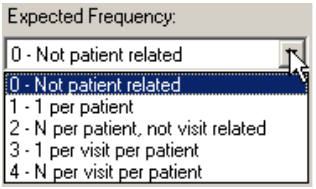


3. For an example of a select statement accessing our Object Catalog table in the ReviewAdmin oracle account:

   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.

4. Next provide a Description, 'Brief Name, i.e. PanelName', SASName (< 8 char).
5. Select the correct 'Expected Frequency' from the dropdown listbox. These are the same as Clintrial panel types. Non-patient data would be type 0, the default.



6. Select the appropriate 'Object Store' and 'Object Level' similar to Saved Objects terminology. The Private ObjectStore, however, is stored in the database. All of these definitions are stored in the new 'ImportSQL' table in the ReviewAdmin account.
7. Lastly, click on the 'Check SQL / Get Column Info' button which goes out to the database and checks the SQL syntax returning an Oracle error if there is one.

   If the SQL syntax is correct, you'll notice that the 'Column Information in Imported SELECT statement' spreadsheet is now filled with the column info from the select statement (col name, type, length, description, SASName).
8. Only the Description and SASName are able to be modified. Also, 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 IReview 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.

   Note: If it's not patient related, it's important that it not be subsetted using the Patient Selection Criteria.
10. To edit or remove after it's been defined use the same convention as Edit New Item. Just click on the description of the Imported SQL in the list of panels, then click the Edit menu for Edit 'Imported SQL' – where you can make changes, including changing the ObjectStore and ObjectLevel, or Remove.

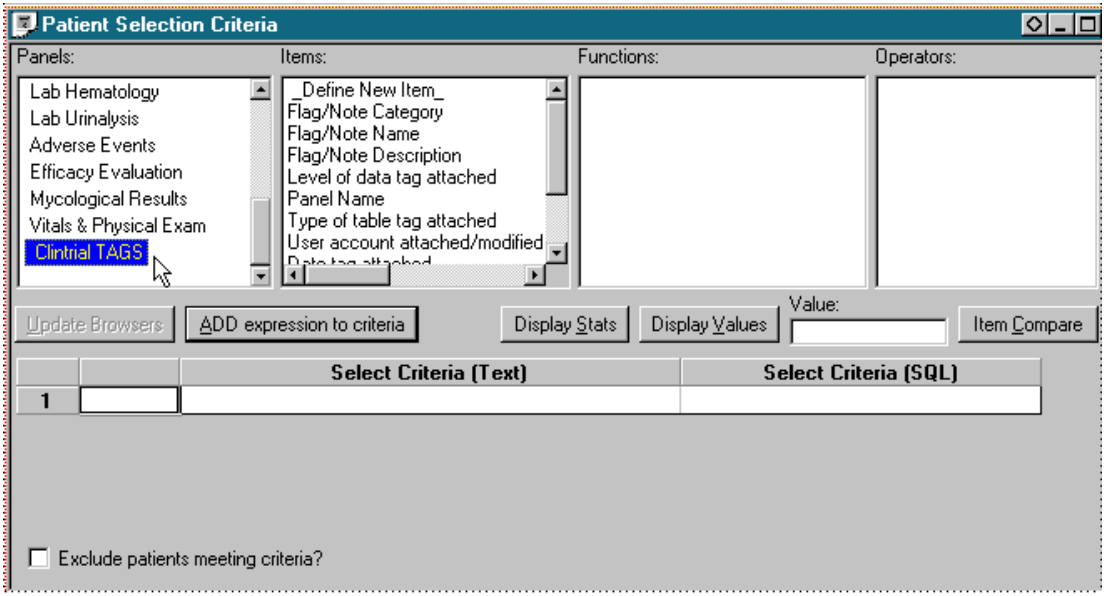
Using Clintrial tags

Tags for selection and reporting

'Clintrial TAGS' are listed and accessible through the entry 'Clintrial TAGS'.

Access Clintrial tags items listing

Click on the pseudo-panel "Clintrial TAGS" and a listing of all tags will be presented in the items list box.



You can use the listing of tags and tag descriptions as selection criteria and reporting elements.

Exploring clinical data with derived item values

Derived data item values

You may find it desirable to select and report a derivation of the original clinical data. For example, you may want to 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. You select the panels and the underlying items, using any mathematics operator to join Item expressions and save the derived items.

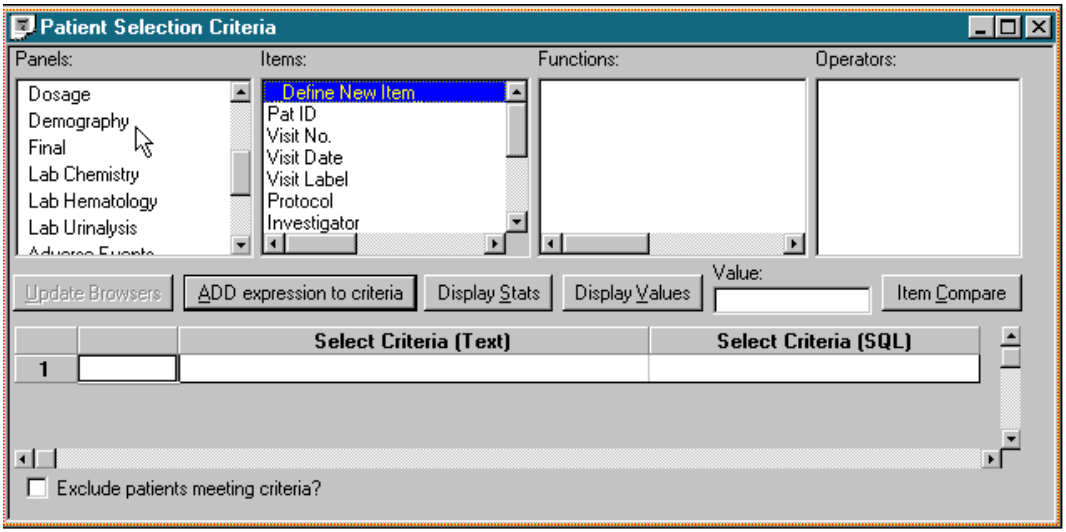
1. Select panel items.
2. Join item expression with mathematical operators.
3. Enter New Item Description.
4. Save New Item.

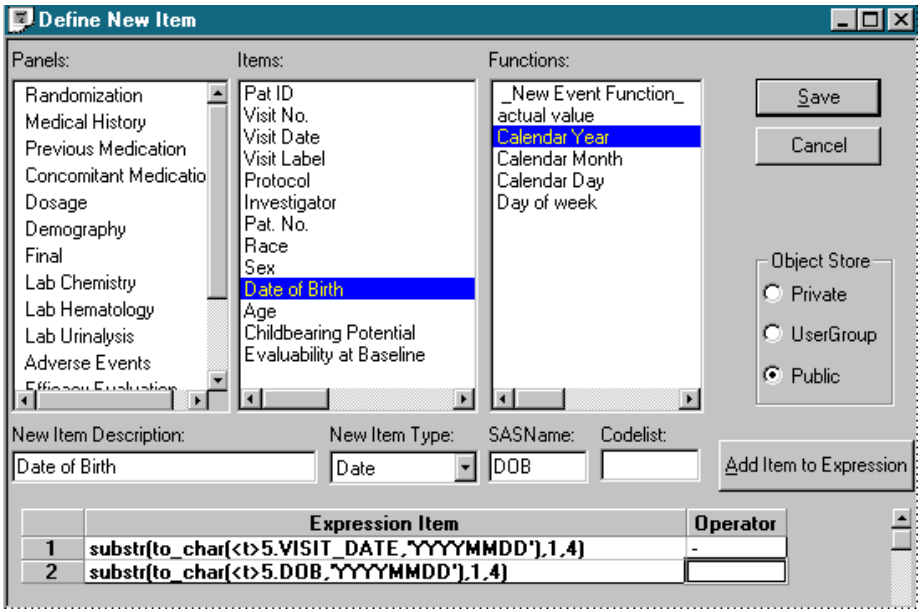
Derived items across panels

Deriving items across panels requires no programming. You just point and click to select the data items you want to include, and Review does all the rest.

Perhaps age was not collected, but you have collected Date of Birth. You could define a calculated age by doing date arithmetic on Date of Birth against the Date of the Visit. Such derived data items are supported throughout Review.

The newly defined item will be displayed and accessible from the active panel when you clicked on _Defined New Item_:

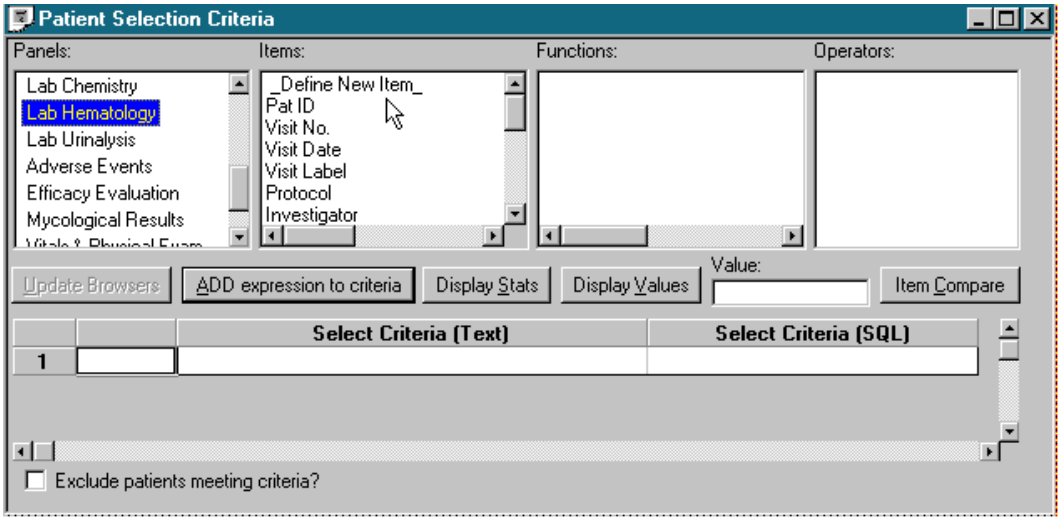




"_Define New Item_"

The first entry in the item list for every panel is the pseudo-item '_Define New Item_'.

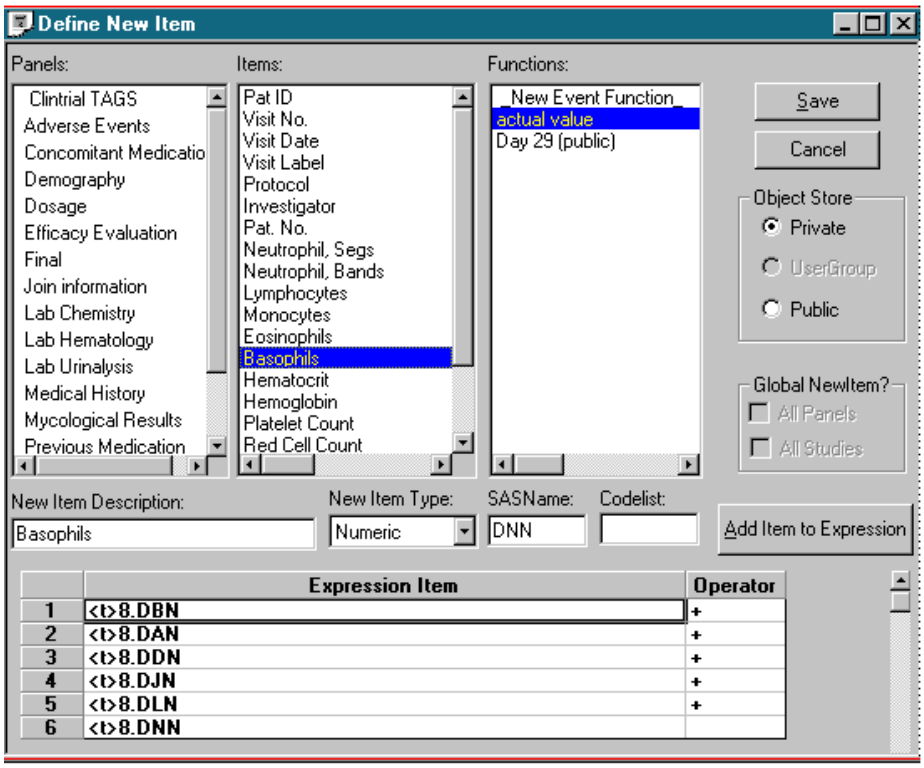
1. Click on this item. Review displays a dialog box where you can define the expression for the derived item.



2. Select the items. Click **ADD expression to criteria** to paste the item and function into the expression spreadsheet.

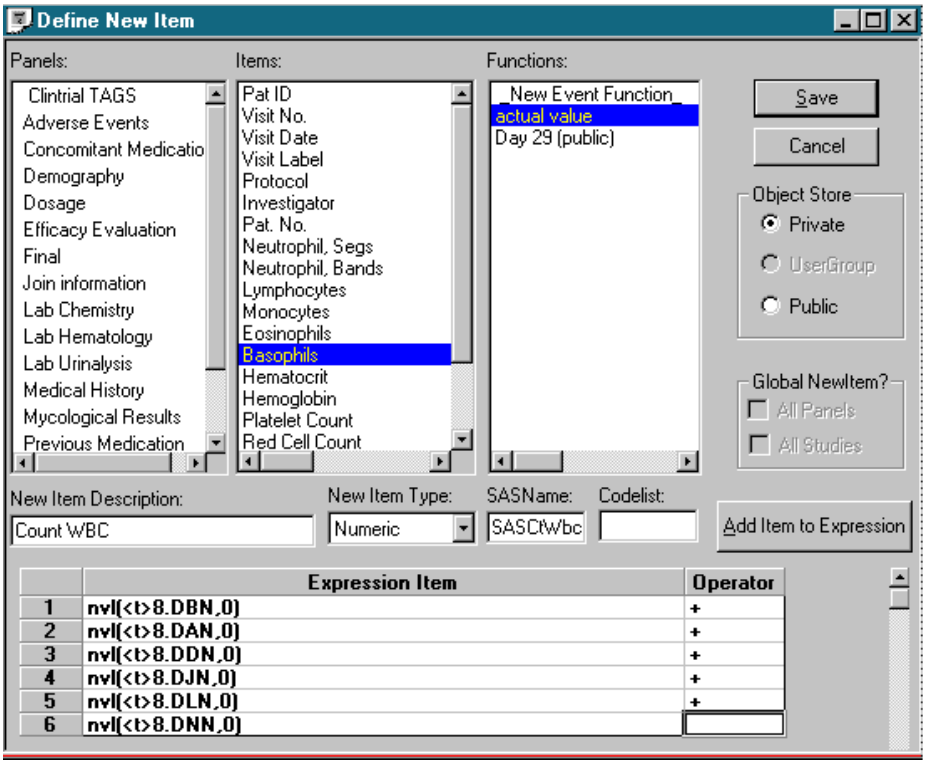
As each item is added, it's description and codelist reference is defaulted into the New Item Description text. This is handy if you want to copy an existing item(s) from one panel to another for convenience in display. The item(s) is than available for use throughout all the browsers.

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.



Note: If any items used in a mathematical calculation contain NULL data, the resulting derived item will be NULL per standard Oracle functionality.

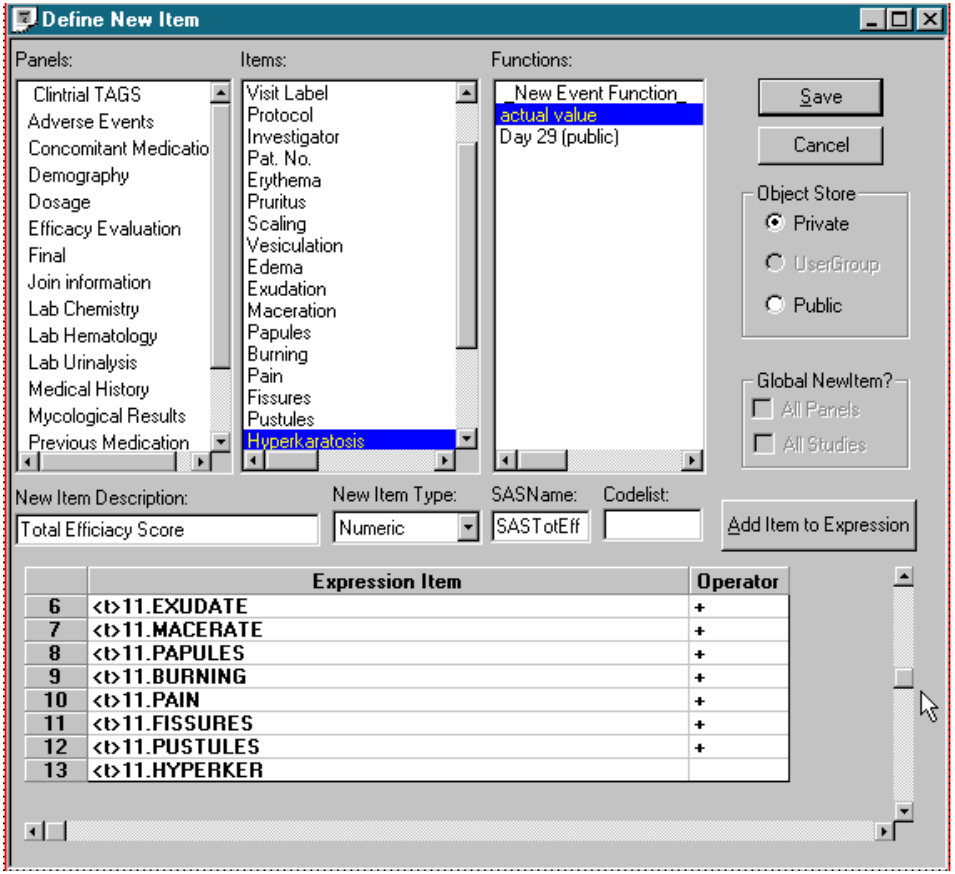
You can edit the SQL within the Expression Item editbox to adjust your derived item calculation, as shown in the next example.



Note: The overall length of the expression is currently limited to 256 characters. Review prevents you from exceeding this limit.

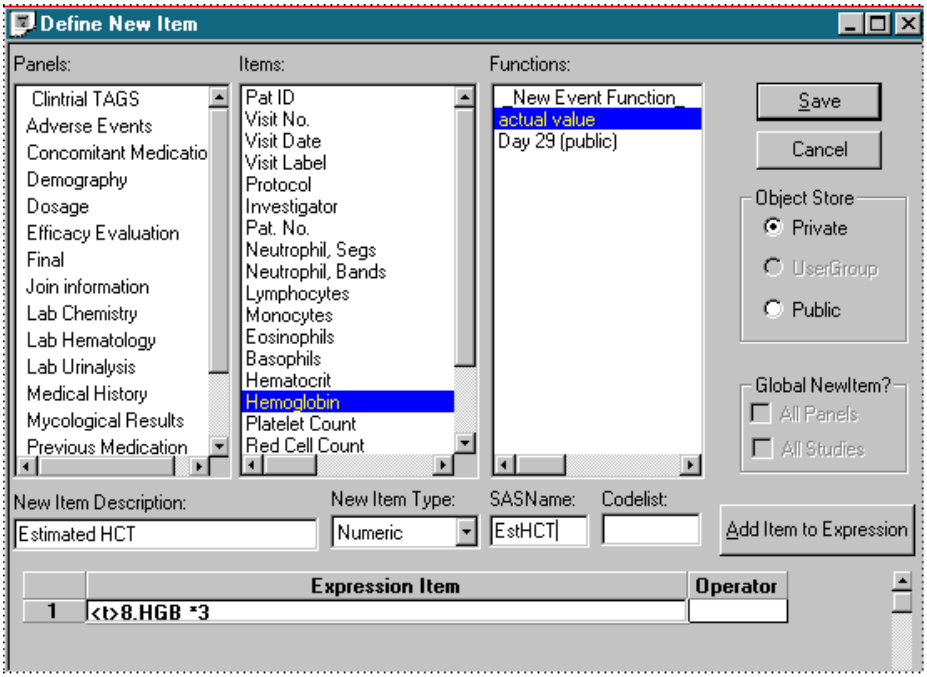
Adding operators

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 editbox. 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.



3. Enter a description.

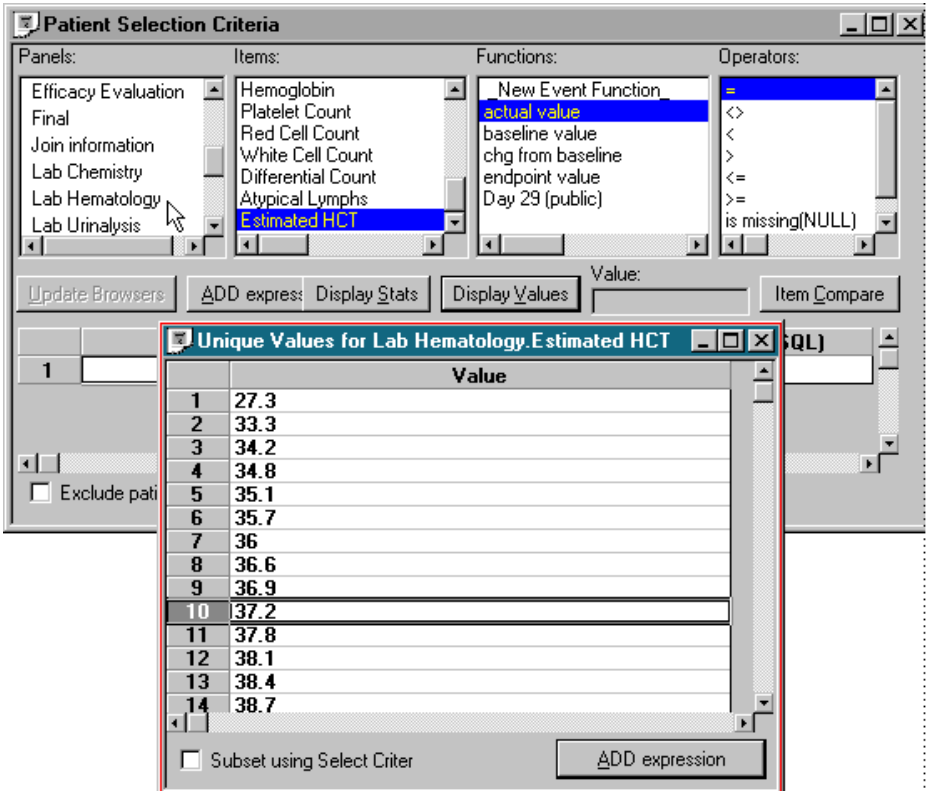
The "Description" field allows you to enter a description of your expression. This description will be in the item list when you select the panel to which you are adding the new data item.

If you need to change your item type from the default value:

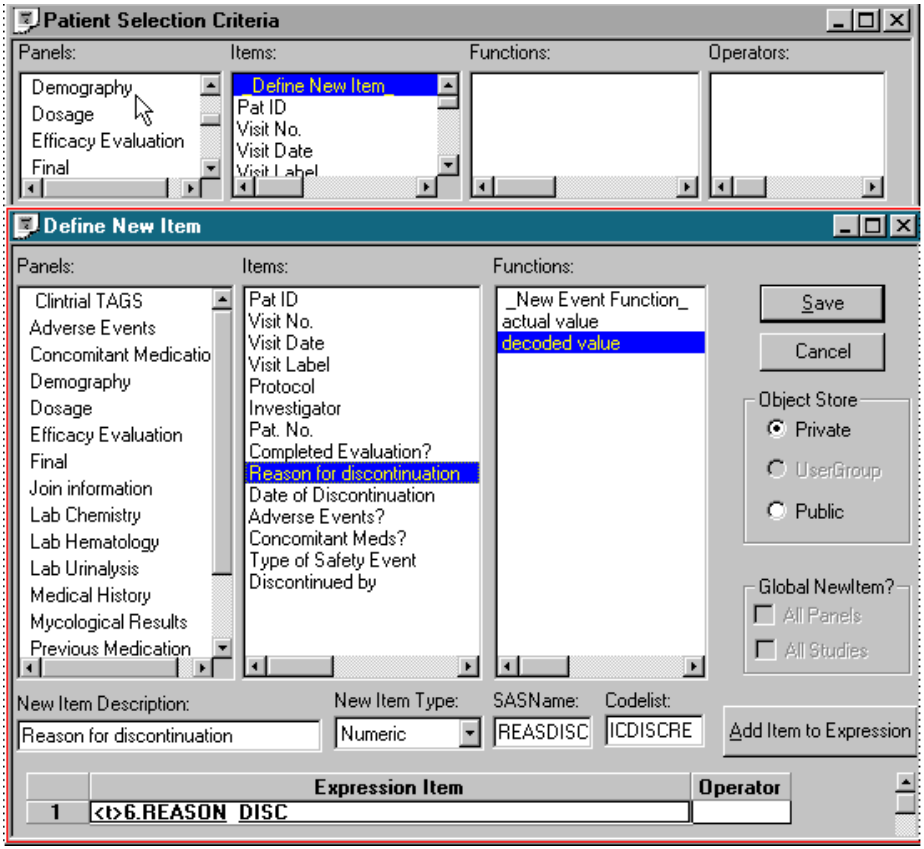
4. Click the New Item Type button to select from the droplist.

Saving the new item

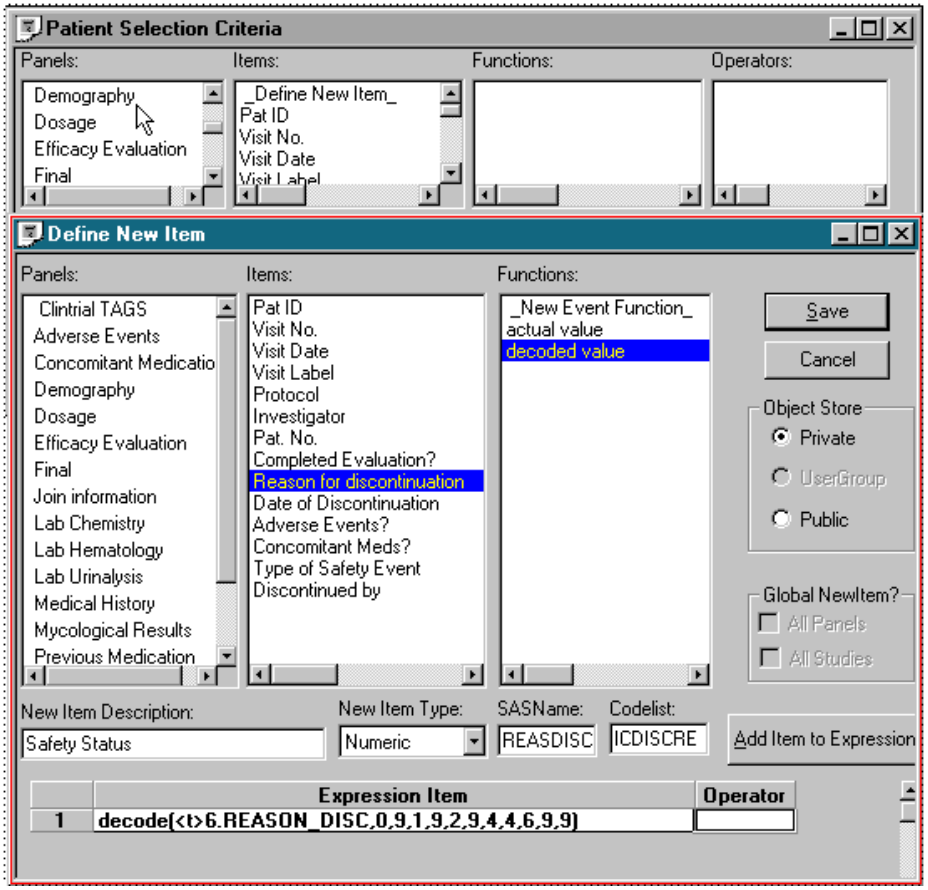
Click **Save**. Review saves the definition and the description and posts the New Item at the end of the list of items from the panel in which it was activated.

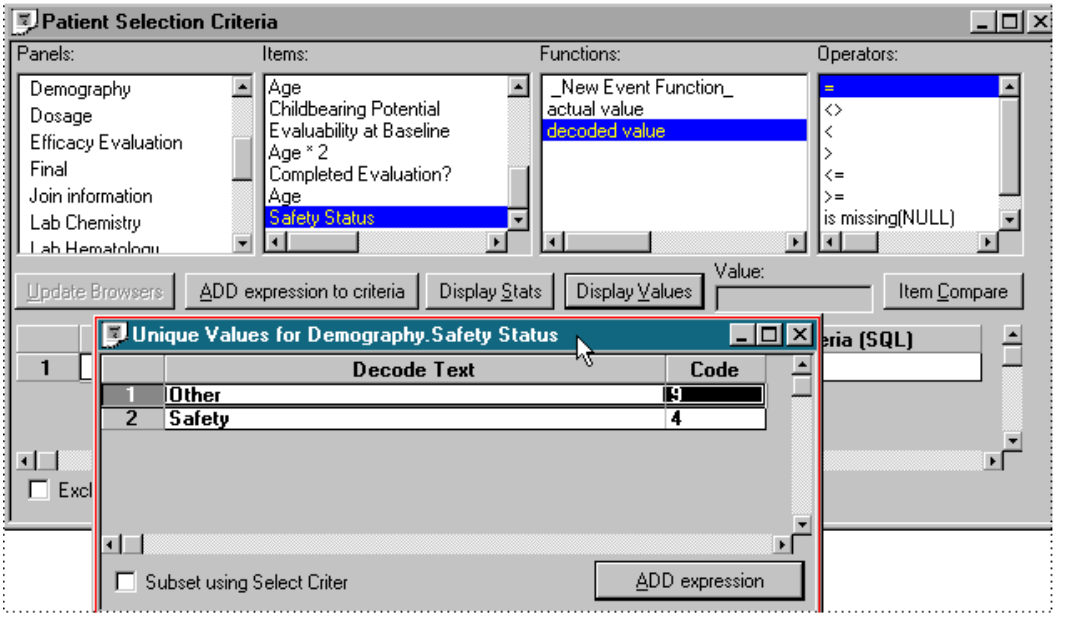


In the next example, you can define a new item to reference an existing decode in one panel and display the new item in a different panel:



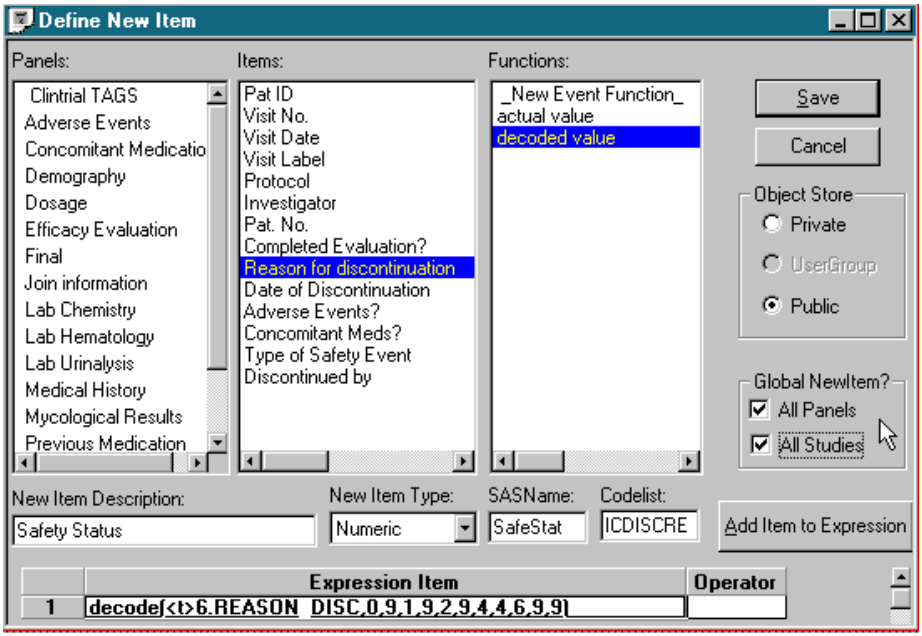
The Define New Item is added to the Demography panel, while decode information is taken from item Reason for discontinuation in the Final panel.





Saving a Global new item

If you are granted “SuperUser” capability through the ReviewAdmin’s Review Privileges, the “Global NewItem?” checkboxes are enabled when you select Object Store for the new item as either UserGroup or Public. This feature defines the new item further to automatically be saved in “All Panels” and / or “All Studies”.



Editing defined new items

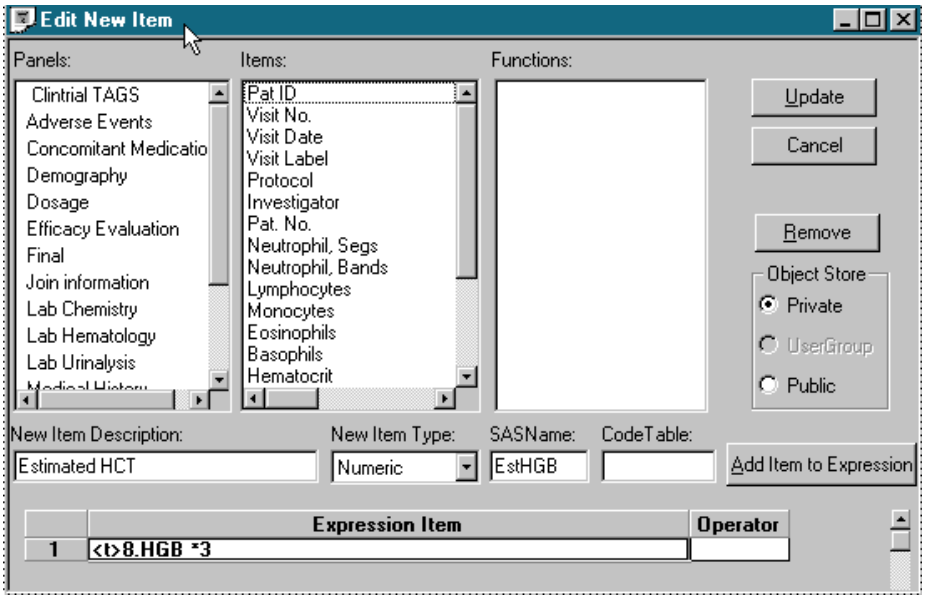
When you return to the define New Item dialog box, notice that the description of your newly defined item has been added to the end of the list of items.

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. From the **Edit** menu, select **Edit Defined Item**.

   Review displays the Edit New Item dialog box:



   You can click on, and change any portion of the New Item Expression with Add/edit items, functions and operators.

4. Click **Update** and Review saves the changes.

Removing saved new item definitions

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. From the **Edit** menu, select **Edit Defined Item**. Review brings up the dialog box displaying the new item expression and its description.
4. You can remove the item by clicking **Remove**. Review removes the new item.

Exploring clinical data with range variables

User-defined range variables

Reporting continuous numerical data as groups of values or categories based upon range variables is often a desirable task. Review supports user definition of range variables upon numeric data items throughout the Report, SAS Proc, and Graph Browsers.

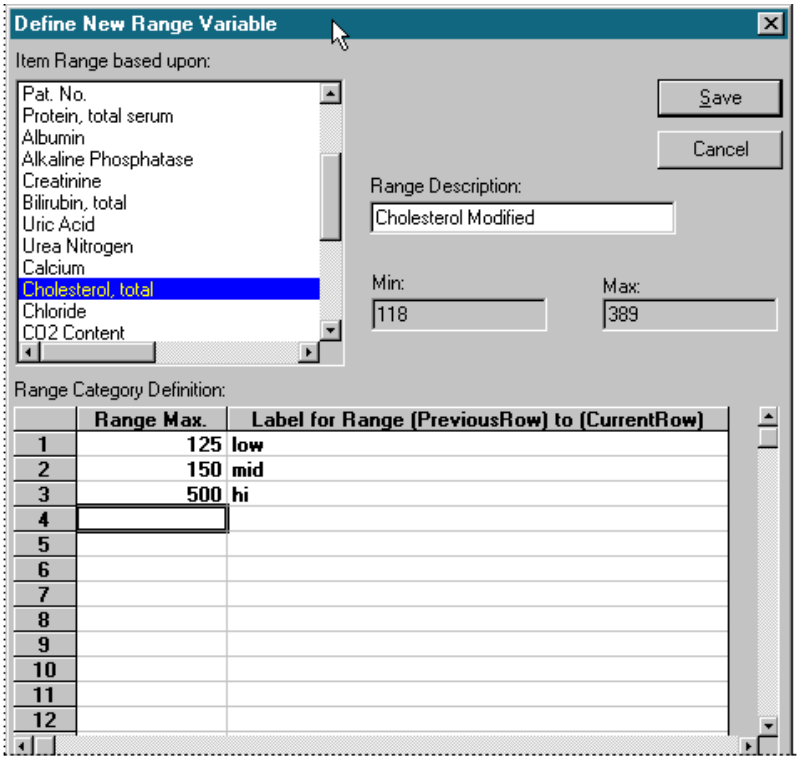
"_Define New Range_"

The second entry in the item list is the pseudo-item "_Define New Range_":

1. Click on this item. Review displays a dialog box where you can define the specifications of your new range variable.
2. Select the numeric item upon which to base your new range variable.

   Note: *Review automatically displays the current range of the numeric variable in the database.*

3. Enter a description for your range variable in the “Description field”. Your description will be listed in the item list whenever you select the panel in which you added the new range variable.



Defining range cut points

You enter the ‘cut points’ of your ranges in the Range Max column.

4. Enter a Label for Range to describe the relation of the previous row to the current row and to Range columns.

   Note: *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.

Saving the new range variable

5. Click **Save**. Review saves the descriptive information about the range in it's 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:

   ICRG_<nodeID>_<RangeNo>

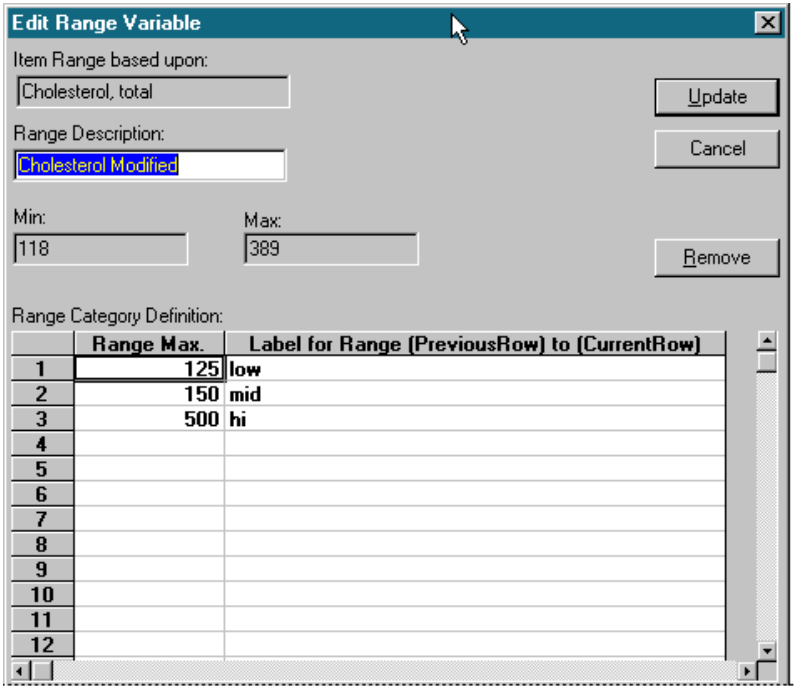
   where <nodeID> is the NodeName of your PC on the network, and <RangeNo> is a system generated unique sequence number assigned to the range. **Do not delete or modify this table in any way.**

   Note: *The description of your newly defined range has been added to the end of the list of items of the pertinent panel.*

Editing a defined range variable

To change the range values or description for the range variable that you have defined and saved:

1. Select the panel.
2. Select the range variable description in the items list.
3. From the **Edit** menu, select **Edit Range Variable**. Review displays the Edit Range Variable dialog box with the range variable definition and it's description.
4. You can click on and change the range description, or any of the range value definitions.



5. When your modifications are complete, click **Update** and Review saves the changes.

Removing saved range variables

To remove the range:

1. Select the panel.
2. Select the range variable description you want to remove.
3. From the **Edit** menu, select **Edit Range Variable**. Review displays the dialog box.
4. To remove the range variable, click **Remove**.

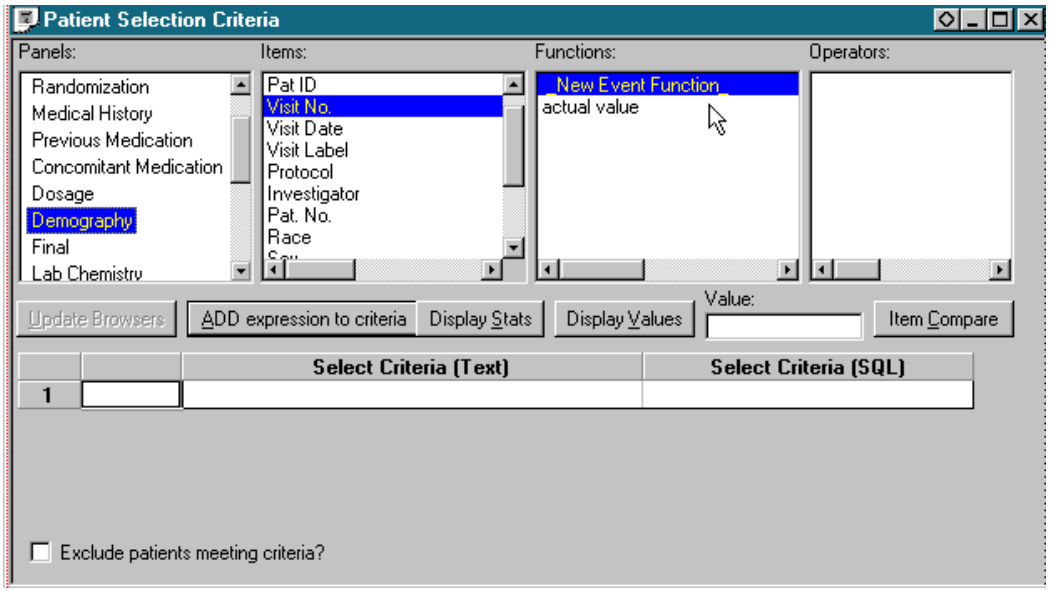
   Review removes the range variable from the panel's list of items, and removes the definition from your local PC and the remote database.

New event function

User-defined time related milestones

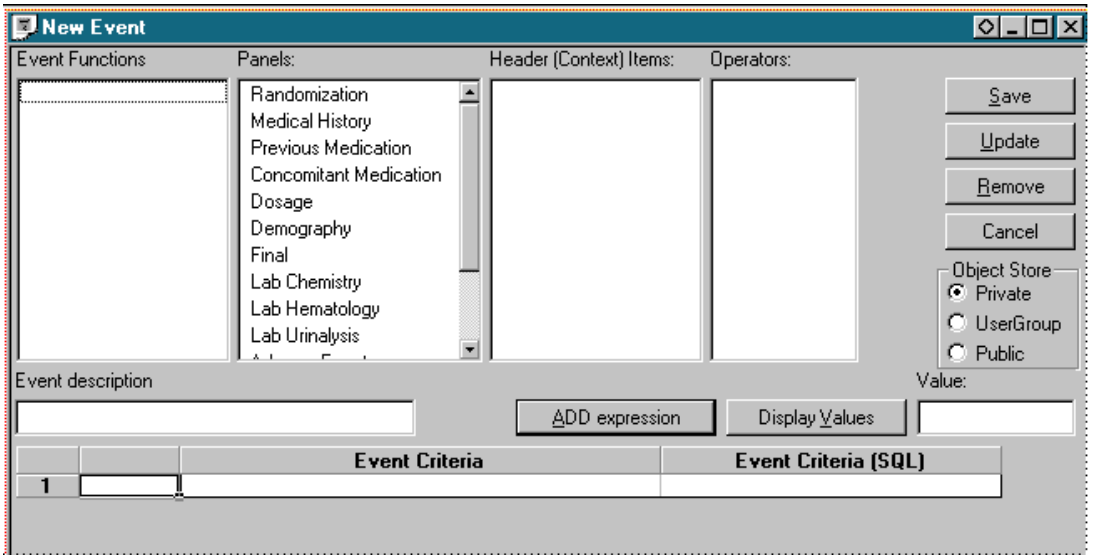
You can define time-related milestones, such as baseline, endpoint, or any description of your choice, for use throughout Review. From the pseudo-function "_New Event Function_" you can view a current listing of event derived-values and add new event criteria.

1. Click the pseudo-function '_New Event Function_' from the Functions list.

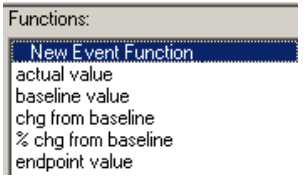


"_Define New Event_"

2. Select an existing event function, or start a new definition by clicking on a reference panel.



3. Select a header.
4. Select an operator.
5. Select a value from the **Display Values** listing, 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 build spreadsheet.
7. When you are finished building the event function value enter the event function description.
8. Click **SAVE** and the new event function will be listed with the function values.



Editing or deleting a new event function

If you select an existing function, the current values are added to the table, and you can click **Update** to edit the new event function or **Remove** to delete.

Exploring clinical data in multi-protocol mode by StudyID

Multi-protocol mode: protocol comparisons

When working in multi-protocol mode it is often desirable to identify the protocols, patient groups, or individual patients to which data points belong. Review supports the use of the StudyID pseudo-item throughout the report and graph browsers.

Using the <StudyID>

After opening a report or graph browser, the third entry in the item list for every panel is the pseudo-item entry <Study ID>.

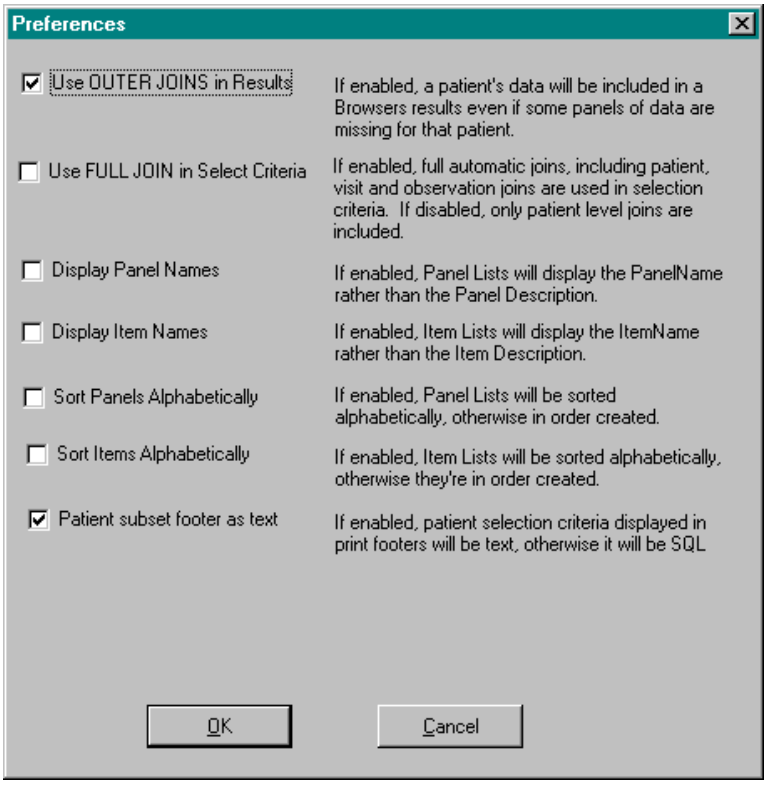
You can add the <StudyID> to the report, to one of the axes on a graph, or as an item or BY variable in a SAS Proc request.

Review processes your report or graph request and reports the StudyID description as it appears in the sources list in the Patient Selection Criteria window.

Reviewing preferences

Open preferences

When in the Patient Selection Criteria window, from the **Edit** menu, select **Preferences**. The following window opens:



When you enable or disable a preference and click **OK,** the change is immediately implemented.

Automatic Outer joins

By default, Review enables automatic Outer joins. With Outer joins enabled, all patients' data will be included in a browser's results, even if some panels of data are missing for that patient. The joins are based on the context items Patient ID, Visit ID, and Observation ID. Depending on the expect frequency of panel per patient, appropriate combinations of context items are used to execute joins between any and all included panels.

Optional Outer joins in Results

If enabled, a patient's data is included in a browsers results even if some panels of data are missing for that patient. With Outer joins disabled, patients will only be included in browser results if they have all panels of data.

Use full joins in Selection Criteria

By default, full joins are disabled. The disabled full joins allows the automatic outer joins to test selection criteria by row restricting criteria to visit and/or observation (depending on the type of panel).

An optional join preference is to enable the full automatic joins facilitating the selection criteria to be applied throughout all patient data rows. The criteria applied would test by Patient ID and not consider visit and/or observation, thus broadening the scope of the patients meeting the criteria.

Displaying panel names

If enabled, panel lists will display the panel name rather than the panel description.

Displaying item names

If enabled, item lists display the item rather than the item description.

Sort panels alphabetically

If enabled, panel lists will be sorted alphabetically; otherwise, panels are listed in order of creation.

Sort items alphabetically

If enabled, item lists are sorted alphabetically; otherwise, items are listed in order of creation.

Patient subset footer as text

If enabled, patient selection criteria definition when printed in footers will display as text; otherwise, definition displays in SQL.

Clintrial Data Source

Clintrial sites may select a storage preference in Clintrial Data Source which includes DATA, UPDATE or ALL. This allows the user to switch to the desired data source within Review. (Clintrial 4.x releases)

Single patient mode

Identify Patients with interactive browsing design

Review is designed to work with clinical data at the patient-level displays and summary displays. Throughout Review's data reviewing browsers, patient-level displays of data interact simultaneously to highlight and identify patient data.

Patient-level results interact

Review's patient-level displays of data interact simultaneously to highlight and identify patients underlying selected data points and values from any display of patient-level data. When you select a patient, or a data point in a patient level display, instantly all browsers receive a

broadcast message to highlight and identify the patients' data. Because review is built on patient-level data, all browsers communicate with each other at the patient-level.

Multiple patient mode

Patient-level and summary displays interact

Review's multi-patient mode refers to the reviewing of multiple patients throughout the various browsers by Subset or Highlight a selected group of patients.

Browsers interact

A subset of a selected group of patients may be viewed across multiple browsers by the way the browsers interact.

- Data Browser:
  - Patient Listing Subset to a selected group of patients from any Browser.
- Report Browser:
  - Detail Data Listing Subset to selected groups of patients from any Browser.
- Graph Browser:
  - Scatter Plot Graph Highlight all patients selected from any other Browser Specification.
  - Scatter Plot Graph: Mouse click and drag to lasso groups of patients within graphical regions, to broadcast and identify patients within such population regional subsets.
  - Bar Chart Graphs: Click on Bars within Bar Chart Graphs to broadcast and subset the patients underlying each Bar Value in all open patient level displays of data.
- CrossTab Browser:
  - CrossTab Table: Mouse click on a grid value (patient count), and all underlying patients will be highlighted and identified in all open patient level displays of data.
  - Shift Table: Mouse click on a grid value (patient count), and all underlying patients will be highlighted and identified in all open patient level displays of data.

Summary results and patient level results

All CrossTab and Shift tables, Bar Chart graphs and their summary values instantaneously highlight and subset the currently selected patient population when their summary values are clicked. For example, a value in a Shift table from the CrossTab browser, and all patient level displays of data will highlight, identify, and subset the underlying patients making up the count.

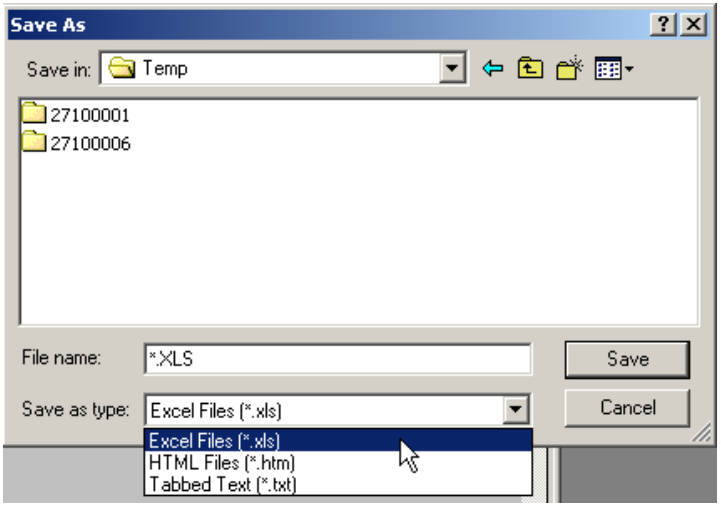
Displaying spreadsheets

Exporting browser spreadsheets

Review displays data by a spreadsheet control in many places throughout the product. You can export the results displayed in the spreadsheet controls to a Microsoft Excel or HTML formatted file.

First, display the data and then from the **File** menu, select **Export**. Review requires you to enter a filename for the Excel or HTML formatted file before you can save and store the data in the file you specified. The spreadsheets in review are supported by the spreadsheet control, by browser.

Non-formatted reports may be exported as Excel tab delimited files, HTML format or Tabbed Text. Formatted reports export as PDF files.



Browsers export spreadsheets

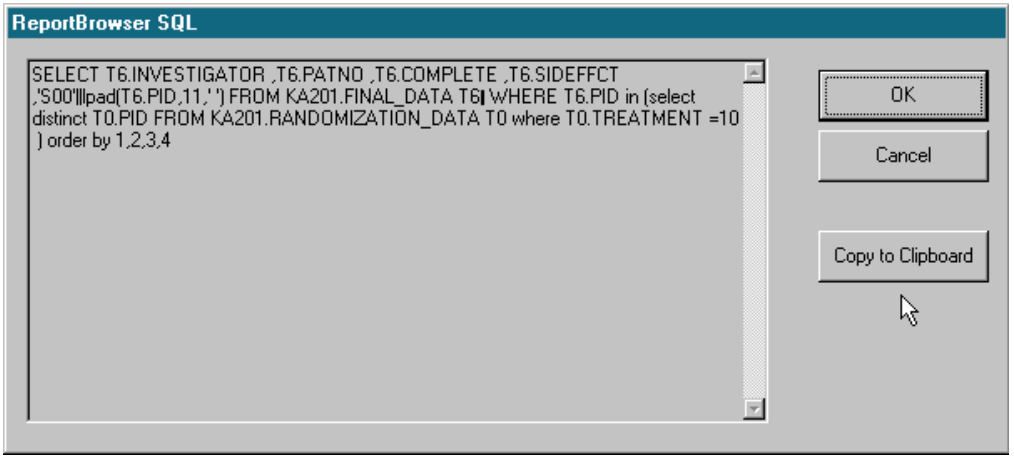
The areas of Review that support this functionality are:

- Selection Criteria: Display Values
- Data Browser: List of Patients
- DataView - any panel's display of data for a patient.
- Report Browser:Report Sheet - Detail Data or Summary Report.
- CrossTab Browser: Result Tables - CrossTab or Shift Table.

Copy to Clipboard

View SQL details dialog

You can view the SQL details dialog from the View menu, click **SQL details**. The various browsers will display the SQL details as you explore the data. Review allows you to copy the SQL to Clipboard.



Copying and pasting browser results

Review allows you to copy any portion or all of the resulting data displays in a spreadsheet control (for example, in a graph or SAS output window) to a clipboard for pasting functionality into other Microsoft Windows-based applications.

1. You select the portion of the results you want to copy by clicking and dragging until the area you are interested in is highlighted.
2. From the **Edit** menu, select **Copy.**

   Review copies your selection to the clipboard.
3. From the Windows-based application you want to paste the selection into, from the **Edit** menu, select **Paste**.

Browsers copy and paste

The areas of Review that support this functionality include:

- Selection Criteria: Display Values and Display Stats
- Data Browser: List of Patients
- DataView - any panel's display of data for a patient
- Report Browser: Report Sheet - either Detail Data or Summary Report.
- CrossTab Browser: Result Tables- either CrossTab or Shift Tables
- Graph Browser: Graph View
- SAS Proc Browser: SAS Output window
- SAS Program Browser: SAS Output window

Index

13850
  plabelrule
    Time Point Type category 205
21340
  plabelrule
    Category types 196
37751
  plabelrule
    Color settings 226

A

Access Import SQL 506
Access to SAS datasets 54, 155, 250, 341, 424
actual item 37
Actual value 72
ADD Class 461
ADD Dependent 462
ADD Expression 279
ADD Independent 462
ADD Var 461
Adding BY variables 454
Adding criteria expression 61
Adding expressions 279
Adding items 250
Adding items to be analyzed 452
Adding operators 515
AND 55
ANDSelect 55
Appearance options 224
Apply Page Header and Footer 296
audit table 35, 38
Audit trail 104
automatic join logic 78
Automatic Outer joins 531
Axis 411
Axis zoom 411

B

Bar Chart Frequency Distribution 375
Bar Chart Item Summary vs. Category 386
Bar Styles 342
BarChart Frequency Distribution graph 384
BarChart graph 407
BarChart Item Summary vs.Category 388
Baseline vs. Endpoint Scatter Plot 369
Boolean operators 62
Browse menu 245
Browsing saved selection criteria 88
Building a string expression 58
BY Item 213
By Var 454
BY variable 369, 400

C

Case Frozen 103, 114
categorical patient counts 407
Categories Included 211
Category settings 227
cell variable 425
Change graph specifications 346
Change graph style 349
Change Limit value 210
Change password 493
Change Schedule 328
change the report 252
Change Time Axis 209
Change WorkGroup Location 182, 236, 323
Changing a SAS Proc specification 456
Changing the patient selection criteria 139, 333, 414, 472
Changing the report specifications 252
Character (Text) type data 73
chg. from baseline 73
chg. from previous 73
Clintrial Data Source 532
Clintrial data storage 532
Clintrial objects 34

Clintrial tags 77, 334, 473, 509
Clintrial Type 0 panel 78, 141, 334, 501
Closing a graph window 413
Closing a panel view 139
Closing a report window 185, 239, 332
Closing a SAS Proc output window 472
Closing report browser and reports 332
Closing the Data Browser window 139
Closing the Document Browser 485
Closing the Graph Browser 413
Closing the Report Browser 185, 239, 332
Closing the SAS Proc Browser 472
Closing the Table Browser 482
Closing the table output window 482
color highlight 258
Color settings 226
Column Group Headings 300
common panels 51
Compare items 69
Comparing items 119
complex expression 516
complex join 78
configuration tables 79, 130, 177, 231, 315
CONTEXT 36
Context items 37
context panel 36
contiguous protocols 51
control operator precedence 516
count distinct 265
Count item value 266
Create Item 125
Create Options window 448
Create paramete 282
Create Profile 217
Create SAS DataSet 444
Create SAS View 444
Creating discrepancy records 106
Creating reports 277
Creating the SAS Proc output 456
CRF 35
CRF imaging system 104
Criteria expressions 55
CrossTab 420
CrossTab Browser 94
CrossTab table results 140
Custom panels 119

D

Data Browser and pivot panels 140
Data Browsers and join logic 141
Data Collection Modules 30
data dictionary tables 34
Data Extract Views 32
Data items 37
Data Review 99, 148
Data source 484
data table 35, 38
database tables 35
Date function 72
DCMs 30
Default and new events 250
default function 73
default join logic 501
Define Graphic Profile 209
Define Header 156
Define Join Logic 141, 334
Define New Event 527
Define New Range 523
Define Parameter 282
Define Pivot Panel 78
Defined New Item 511
Defining a CrossTab table 422
Defining a patient profile 155
Defining a report title 252
Defining a SAS Proc specification 445
Defining a SAS Proc title 455
Defining a Shift table 428
Defining logical joins 501
Defining range cut points 524
Defining Report Specifications 249
Defining row results 254
Delete saved output 472
Derived data item values 510

Derived function values 72
Derived items across panels 510
Detail Data Browser 93
Detail Data Graph 341
Detail Data Listing 246
Detail Data Listing reports 140
directional arrow buttons 251
Disable Filtering 282
Discrepancy Log panel 109
discrepancy message 108
Discrepancy records 106
Discrepancy reports 140
Display all studies 87, 182, 236, 324
Display excluded patients 70
Display item names 93
Display multiple pages 348
Display panel names 93
Display Stats 74, 121, 278
Display Time items 210
Display Values 121, 278
Displaying document 485
Displaying item names 531
Displaying item statistics 74
Displaying item values 58
Displaying panel names 531
Displaying subsets 75
Document Browser 94
Domains 30
Dosage Category Type 200
Duration Category Type 198, 199

E

Edit a saved SAS Proc specification 456
Edit column width 425
Edit graphic template 208
Edit menu 92
Edit panels 451
Edit reports sort order 251
Edited report column order 251
Editing a CrossTab specification 433
Editing a defined range variable 525
Editing defined new items 521
Editing or deleting a new event function 528
Editing Scatter Plot graphs 409
Enter Import SQL SELECT statement 507
Enter runtime parameter 285
exclude option 71
Exclude patient criteria 60, 70
Expanding spreadsheet columns 117, 163
Exporting a patient list or panel view 118, 165, 230
Exporting a patient profile 165, 230
Exporting the report 308
Exporting the result 460
Expression Items editbox 515

F

File menu 90
Filled Radar Chart Item Summary vs. Category 398
Filter is ON 281
Find menu command 112, 253
flags 105
Format Columns 171, 301
format library options 448
Formatted Detail Data Listing 246
Formatted Summary Listing 246
Freeze Case 103, 113
Freezing a case 113
FREQ 444
FULL JOIN 335
Functions 72

G

GLM 444, 464
Global object storage 492, 503
Graph Browser 94
Graph Browser output filter 347
Graph display results 347
Graph editing 409
Graph format display 102

Graph output filter 414
Graph settings 223, 409
graph specification 344
Graph Toolbar 347
Graph Type 341
graph zoom 354
Graphic Patient Profile 190
Graphic Patient Profile display 229
Graphic Patient Profile template 190
Graphic Profile Filter Output 221
Graphic Profile Template 190
Graphic regional patient selection 407
graphic user interface 218
Group Functions 343
group functions 386
Group Header 298

H

Header Items 195
Headers and footers 227
Highlight the graph 351
Highlighting data check ranges 258
Highlighting patients 311, 404
horizontal data structure 78

I

Identify Patients with interactive browsing design 532
Insert Item 466
instance ID 25
Interactive patient-level displays 436
invalid ORACLE user ID 26
item 37
Item Analyzed box 429
Item comparison selector 69
Item Mean and Standard Deviation vs. Category 402
Item Selector 466, 467
Items Included 212

J

Join logic 473
Join Order 272
Join order in multi-panel reports 272

L

LIFEREG 444
LIFEREG Options 468
LIFETEST 444
LIFETEST Options 469
Line Chart Item vs. Category 400
Logical expressions 55
Logical Operators 55
LOGISTIC 444, 462

M

main window 39
mathematical break point 257
mathematical row results 255
mathematics operator 510
Maximum value 524
Mean at change 255
Mean at Change and Mean 255
MEANS 444
Menu Bar 42
Metadata 34
Minimum value 524
Missing data 218
Modifiable items 124
Modify profile content 155
Modifying coded data 128
Modifying data 126
Move the chart 410
multi-dimensional analysis 419
MultiLine Chart Item Value vs. Category by Case 371
Multi-Line graph 409
multiple contiguous values 59, 204
Multiple CrossTabs 433
Multiple graphs 355

multiple non-contiguous values 59, 204
Multiple patient mode 407
Multiple population mode 270, 355, 493
Multiple protocols 414
Multiple SAS Proc outputs 470
Multiple table outputs 482
Multiple worksheet mode 152
Multiple-patient mode 113, 313, 407
multi-protocol mode 51, 75, 529
multi-visit 334, 414, 428

N

New Event 250
New Event Function 72, 73, 335, 474, 527
New Item dialog box 521
NodeName 525
non-contiguous protocols 51
Normal range multiplier 214
Note Browser 94
notes 105
NPAR1WAY 444, 461
Numeric Format 302
Numeric type data 73

O

Object 83, 177, 231, 315
Object Explorer quick execute 181, 235, 322
Object Explorer window 50, 83, 180, 234, 319
Object level 83, 181, 235, 316, 492
Object properties 89, 183, 237, 320
Object storage 70, 413, 438, 490
Object storage location 83, 130, 177, 231, 315
On-line help 27
Open preferences 530
Open save Data Browser settings 134
Open the Document Browser 484
Opened SAS production table results 482
Opening multiple SAS Proc results 470
Opening the SAS Proc Browser 443
Opening the Table Browser 476
operator field 515
Operators 60
Optional Outer joins in Results 531
Optional output filter 277, 425
OR 55
ORACLE account 34
Oracle Clinical keys 29
Oracle Clinical terms 29
ORACLE connect string 26
ORACLE database 26
ORACLE user ID 25, 124
Outer join in Results 92
Outer Joins 335
Output filter 277

P

Page Down 363
Page Setup 309
Page Up 363
panel 35
panel type 36
Panel type 0 36
Panel type 1 36
Panel type 2 36
Panel type 3 36
Panel type 4 36
Panel type 5 36
parallel modifiable items 124
parameterization 477
Pareto Chart Frequency Distribution 390
partial strings 60
password 25
patient counts 420, 437
Patient Info Items 289
Patient level notes 110
Patient Profiles Browser 93, 146, 189
Patient selection criteria 245
Patient subset by graph 407
Patient subset footer 532

Patient Visit Report 246
PC Based Object Storage 490
Pie Chart 392, 407
Pie Chart Item Summary vs. Category 392
Pivot panel presentations 333
Pivot panels 473, 495
Polar Chart Item Summary vs. Category 394
Preferences 92, 530
Print change 254
Print Preview 117, 164, 229, 309, 412, 434, 480
Print Setup 90, 185, 239, 321
Print / PDFs 225
Printing a panel view 118, 165, 230
Printing a patient listing 117, 164, 229
Printing a patient profile 229
Printing Graphs 412
Printing the CrossTab specifications 438
Printing the report 309
Printing the report specifications 185, 239, 321, 438
Printing the SAS Proc results 459
Printing the selection criteria 90
Printing the table output 480
priority value 109
Private object storage 490
Private storage 79, 130, 177, 231, 315
project 34
protocol 34
Protocol comparison 335, 474
Public object storage sites 491
Public storage 79, 130, 177, 231, 315
Publishing Authorization 79, 130, 177, 231, 315, 491

Q

Question Groups 30
Questions 30
Quick remove 136, 184, 238

R

range bars 402
Range values 430
record 38
REG 444, 462
regenerate the tables 476
register SAS programs 476
Registered production tables 476
Remove a stored object specification 331
Remove note 112
Remove Scheduled Jobs 327
Remove Visual Subset 359
Removing a saved report specification 184, 238, 331
Removing a saved selection criteria 136, 185, 239, 332
Removing logical join 505
Removing saved new item definitions 522
Removing saved range variables 526
Report Browser 94
Report Column Formatting 301
report heading 252
Report options 287
Report output filter 334
report specification 317
Report types 246
Reset scale and position 412
Result Filter Rows 281
Retrieve stored specification from file menu 323
Retrieving a saved report specifications 182, 236, 323
Retrieving a saved selection criteria 86
Review Admin ORACLE user 492
Review icon 25
Review.ini file 491
Reviewing preferences 92, 530
Reviewing tags 105
Reviewing with browsers 93
Rotate 3D BarChart 412
Row results 254
Runtime parameter 282

S

SAS datasets 54, 94, 120, 250, 341, 424
SAS log 458
SAS Name field 513
SAS output 458
SAS Proc FREQ with Statistics 444
SAS Proc output filter 457, 472
SAS Procs 443
SAS Production Tables 94, 476
SAS Program Browser 94
SAS source 458
SAS Table Parameters Window 477
SAS Transport Files 449
SAS user-level setting 443
Save Filter 280
Save template 208
Save the object specification 317
Save Visual Subset 357
Saving Data Browser specifications 119, 177, 231
Saving the new item 517
Saving the new range variable 525
Saving the report specification 317
Saving the selection criteria 81, 317
Scatter (Item X vs. Item Y) Plot 360
Scatter Plot 367
Scatter Plot graph 407
Scatter plot graph 140, 407
Scatter Plot with Regression Line 365
Schedule output 324
Schedule SAS Proc jobs 471
Schedule SAS Program jobs 478
Select defined template 209
Selecting a data source 484
Selecting a panel 55
Selecting a panel, item, and function 249, 422
Selecting a project 50
Selecting a SAS Proc type 444
Selecting a table 478
Selecting a value 59
Selecting an operator 60
Selection set 245, 340, 419, 443, 476
server names 25
Server-based global object storage 492
Shared object storage 490
Shared with Others 333
Sharing objects 492
Shift Table 420
Single patient mode 311, 532
Single worksheet mode 148
single-protocol mode 50
Snapshot output 270, 355, 412, 493
Sort by Code Value 424
Sort items alphabetically 93, 532
Sort Order 304
Sort panels alphabetically 93, 532
special privileges 492
SQL details 535
standard deviation 402
Statistics Browser 94
Statistics options 454
storage location 132, 180, 234, 318
Store a selection of panel views 131
string expression 60
study start date 192
StudyID 51
StudyID pseudo-item 529
Sub Panel 156
submenu Items 42
sub-populations 52
Subquery 67
Subset by graphic regional selection 356
subset graphic displays 369
Subset on observation and / or visit 277
subset patient populations 407
Subset patients 98
Subset using Select Criteria 75
Sum at change 255
Summary Data Graph 341
Summary Listing 246
Summary Listing features 263
summary statistic 388
SuperUser 492

Supplying a value 60
Suppress duplicate rows 260
System Administrator 476
System items 37

T

Table Browser 94
TABULATE 444
tags 105
Text Category Type 201
Text data type 60
text string operators 60
Time Axis scale 198
Time Point Type category 205
time-related milestones 527
Toolbar 457
Transposing normalized clinical Data 495
TTEST 444, 461

U

Unique Values 59
Update patient selection criteria 482
update table 35, 38
Updating Browsers 74
Use full joins in Selection Criteria 531
User-created objects 492
User-defined logical joins 501
User-defined range variables 523
UserGroup object storage 491
Usergroup storage 79, 130, 177, 231, 315
Using Clintrial tags 509

V

V5 (FDA Guidelines) option 449
View Scheduled Jobs 327

W

Who 494
Workbook Report types 147
WorkGroup object storage 491
WorkGroup storage 79, 130, 177, 231, 315
Wrong password 26

Z

Z elevation value 367
Zoom the graph 354, 411