

JReview® version 9.2.6 – New/Enhanced Features

Patient Profile Browser – Patient Review Tracking

In addition to supporting the current ‘patient level review tracking’, **version 9.2.6 introduces ‘Data Type (panel/table) level review tracking’ - ‘New Data Highlighting’**. If your database/environment is set up for ‘last change date’ processing, and some or all patients have been previously been marked as being reviewed (in the patient profile – patient review tracking area) – then that ‘last review date’ information is compared to the ‘last change date’ for each patient’s data rows.

If the user clicks on the ‘PatientReview:OFF’ button – to toggle Patient Review:ON, then the Patient Review Level filter combo listbox and a new ‘DataType Filter’ combo listbox are enabled. If the user clicks the DataType Review:OFF button – a dialog pops up – letting the user tell the system which types of data that they want to tell the system that they’re going to be declaring they’ve reviewed for each patient they check the ‘I-Review’d’ checkbox. Then – when new or updated data comes in for any of those types of data – the last change date is compared to the last review date for that data type rather than the patient level last review date – and the data is highlighted in green.

An example of a Formatted Patient Profile – with New Data highlighted – at the DataType level is:

Formatted Patient Profile [056:5111]

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

Formatted Patient Profile 056-5111

Adverse Events

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

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

Efficacy Evaluation

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

All Patients Page 1 of 1

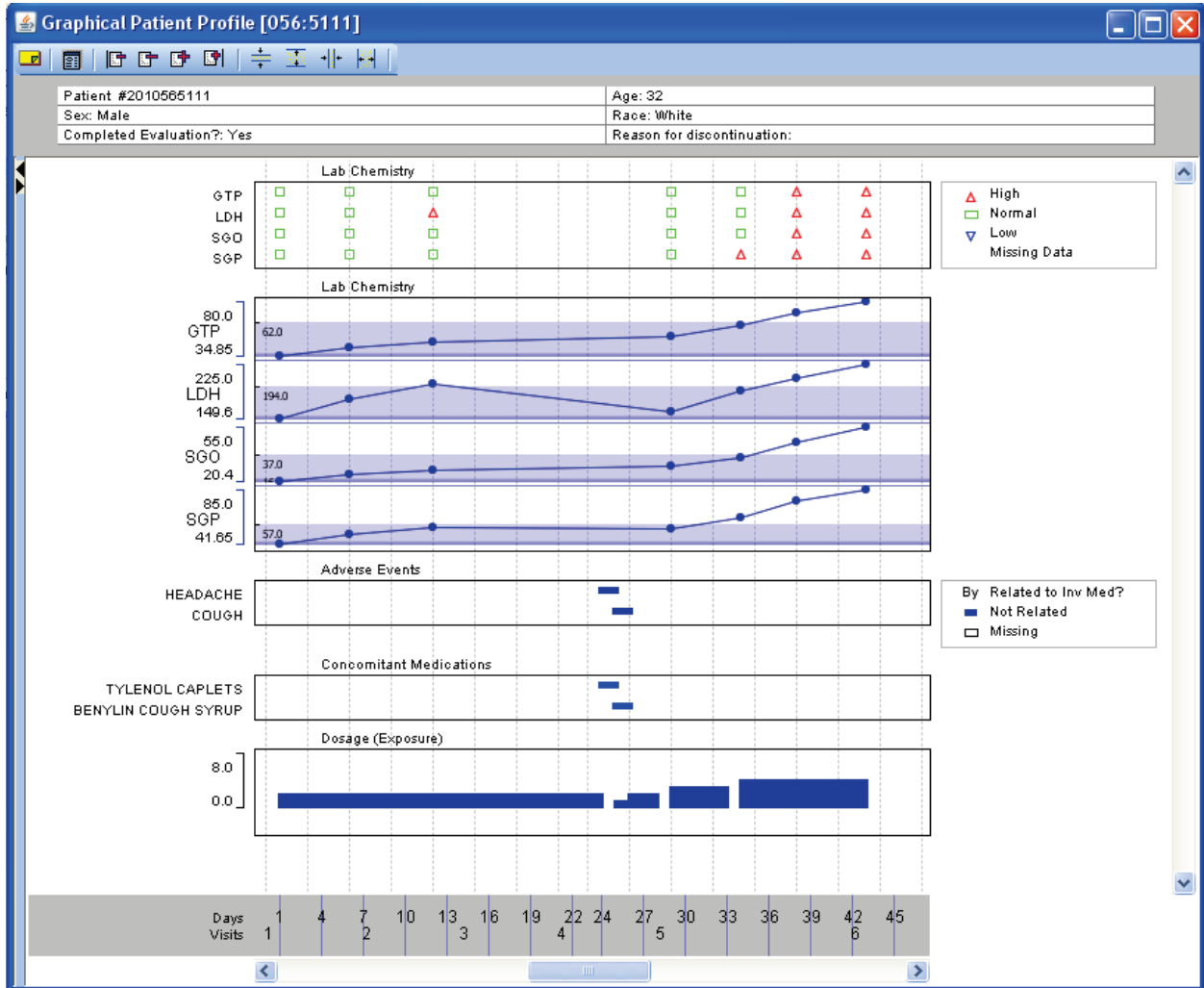
A Workbook Patient Profile – with ‘green’ DataType level highlighting example is:

The screenshot shows a window titled "Patient Profile [056:5111]" with a toolbar and a "Show New Data Only" checkbox. The main area contains a data table with several sections. The first section, "Adverse Events", has columns: Visit No., Visit Date, Visit Label, Protocol, Onset Date, Onset Time, Intensity, Change in Inv Med, and Therapy for AE. Rows 1 and 2 are highlighted in green. The second section has columns: Visit No., End Time, Related to Inv Med?, Outcome, Outcome being treated?, AE Text, AE Coded, Serious?, and AE Type (description). Rows 1 and 2 are highlighted in green. The third section, "Concomitant Medication", has columns: Visit No., Visit Date, Visit Label, Protocol, Start Date, Stop Date, Ongoing?, Drug Name, and Drug Code. Rows 1 and 2 are highlighted in green. The fourth section has columns: Visit No., Frequency, and PRN. Rows 1 and 2 are highlighted in green. The fifth section, "Efficacy Evaluation", has columns: Visit 1, Visit 2, Visit 3, Visit 4, Visit 5, and Visit 6. Rows 1 through 14 are highlighted in green. The status bar at the bottom shows "NEW Patient Profile".

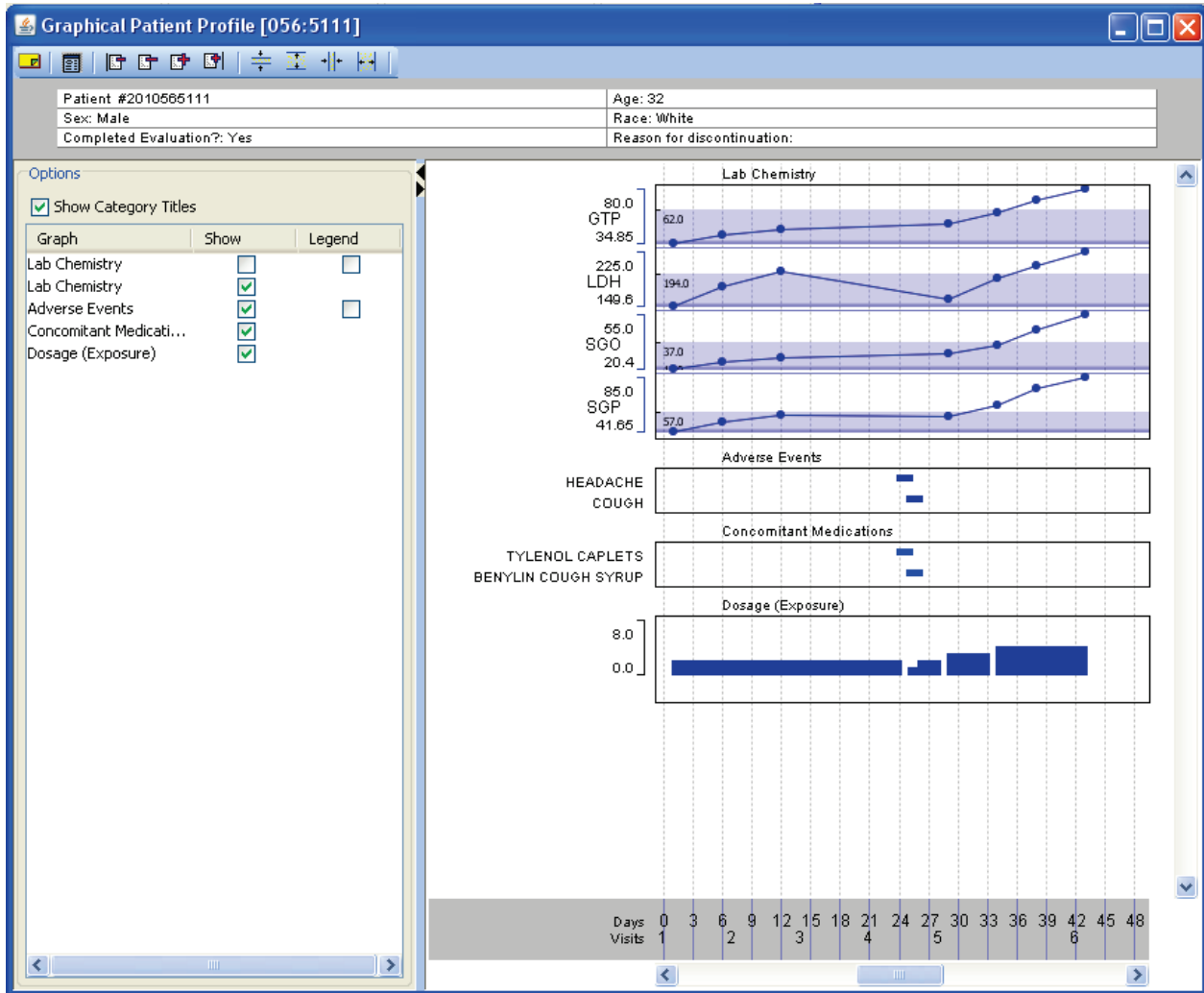
The user can use either or both of the filtering combo listboxes – the Review Level combo box (type of review that was declared) and/or the Data Type Filter combo listbox (DataTypes that have been reviewed). After selecting either or both of the filtering values, the list of patient’s review status reflects those filter choices. For example, if a user had previously selected ‘AE’ as the DataType under review – and checked a number of patients as being reviewed, then if the user selects ‘AE’ as the DataType Filter value – they’ll see the current state of review – for only the AE data type, i.e., any patients whose AE data has not been declared as reviewed will be listed as ‘Not Reviewed’. The ‘Reviewed (New Data) ...’ designation for any patient when this filter condition is enabled – tells us that the patient has new or updated AE data since the last AE data was reviewed.

Patient Profiles – Graph Patient Profile – Output Display Redesign

Graph Patient Profile output display has been redesigned – for improved readability, simplicity, and increased performance.

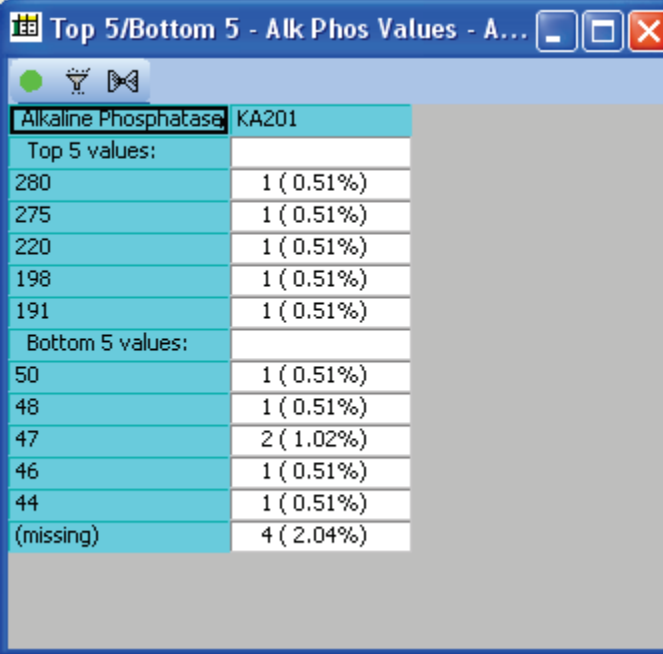


Also – we’ve added a run-time options panel – to let the end user toggle on/off display of individual categories and legend boxes. Click on the option ‘pop-out’ window’s right arrow/open window then uncheck any categories or legends you don’t want to see right now – and it immediately disappears.



CrossTab Browser – TopN/BottomN Crosstab

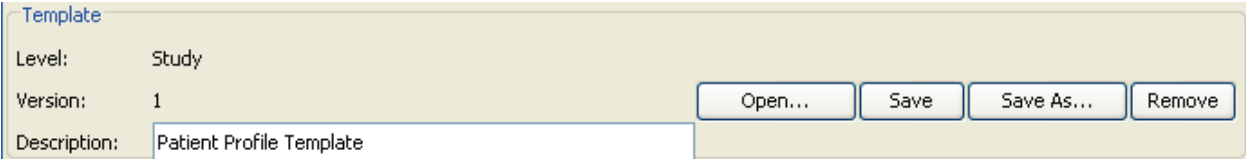
A new Crosstab type was added – to display the top N and bottom N values of a variable in a study – either for all patients or the current patient subset. After selecting which variable is to be analyzed, the user can also specify how many top and bottom values they'd like to see – default is 5. Once the Top N or Bottom N Crosstab is displayed, each cell is clickable, as with any Crosstab results – and highlights/selects the patients in the cell – in any other displayed output, such as lab listings, etc.



Alkaline Phosphatase KA201	
Top 5 values:	
280	1 (0.51%)
275	1 (0.51%)
220	1 (0.51%)
198	1 (0.51%)
191	1 (0.51%)
Bottom 5 values:	
50	1 (0.51%)
48	1 (0.51%)
47	2 (1.02%)
46	1 (0.51%)
44	1 (0.51%)
(missing)	4 (2.04%)

Patient Profiles – Graph Patient Profile – Template Definition

Graph Patient Profile – Template Definition – major enhancement adding ability to save multiple named templates at each object storage level, as well as retrieving previous versions of each. Also, when defining or updating a GPP definition, the user can choose to either continue to use the internally stored, referenced GPP template, or to update the definition to reference a different template definition. Rather than just saving a template at one of the available Object Storage Levels, now the user can use the familiar actions – similar to existing Save/Save As dialog options – at the bottom of the GPP Template window:

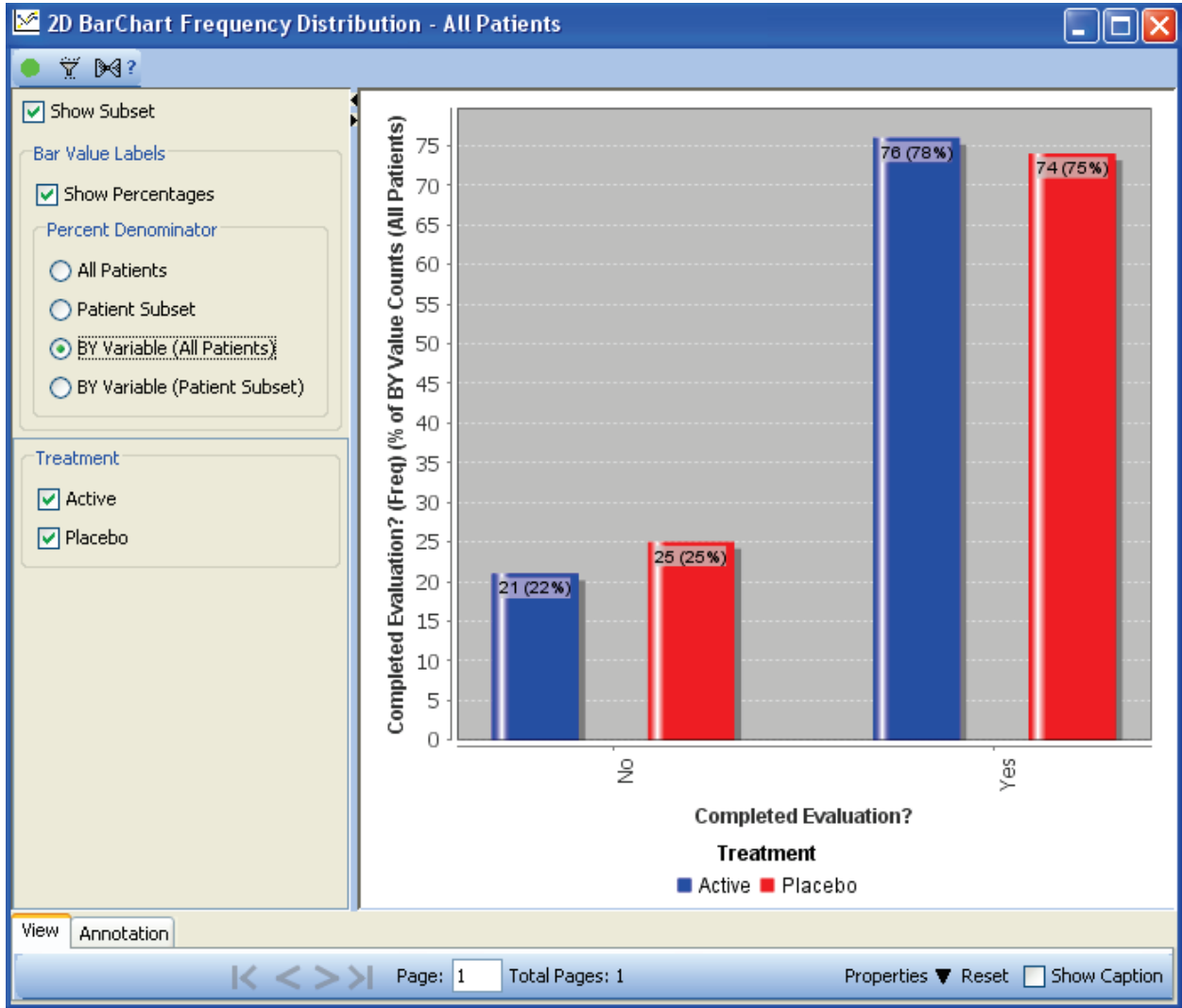


Template	
Level:	Study
Version:	1
Description:	Patient Profile Template
<input type="button" value="Open..."/> <input type="button" value="Save"/> <input type="button" value="Save As..."/> <input type="button" value="Remove"/>	

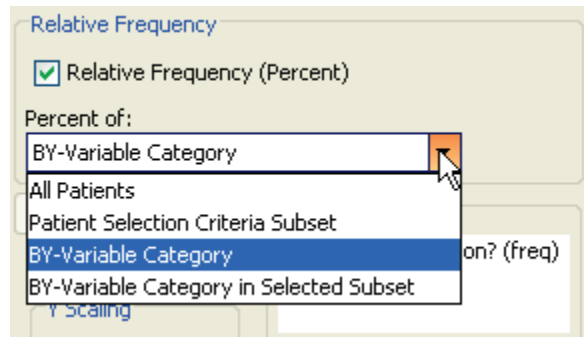
Graph Browser

2D Bar Chart Frequency Graph - added additional denominator choices – of ‘by var count’ – either for All Patients or current Patient subset.

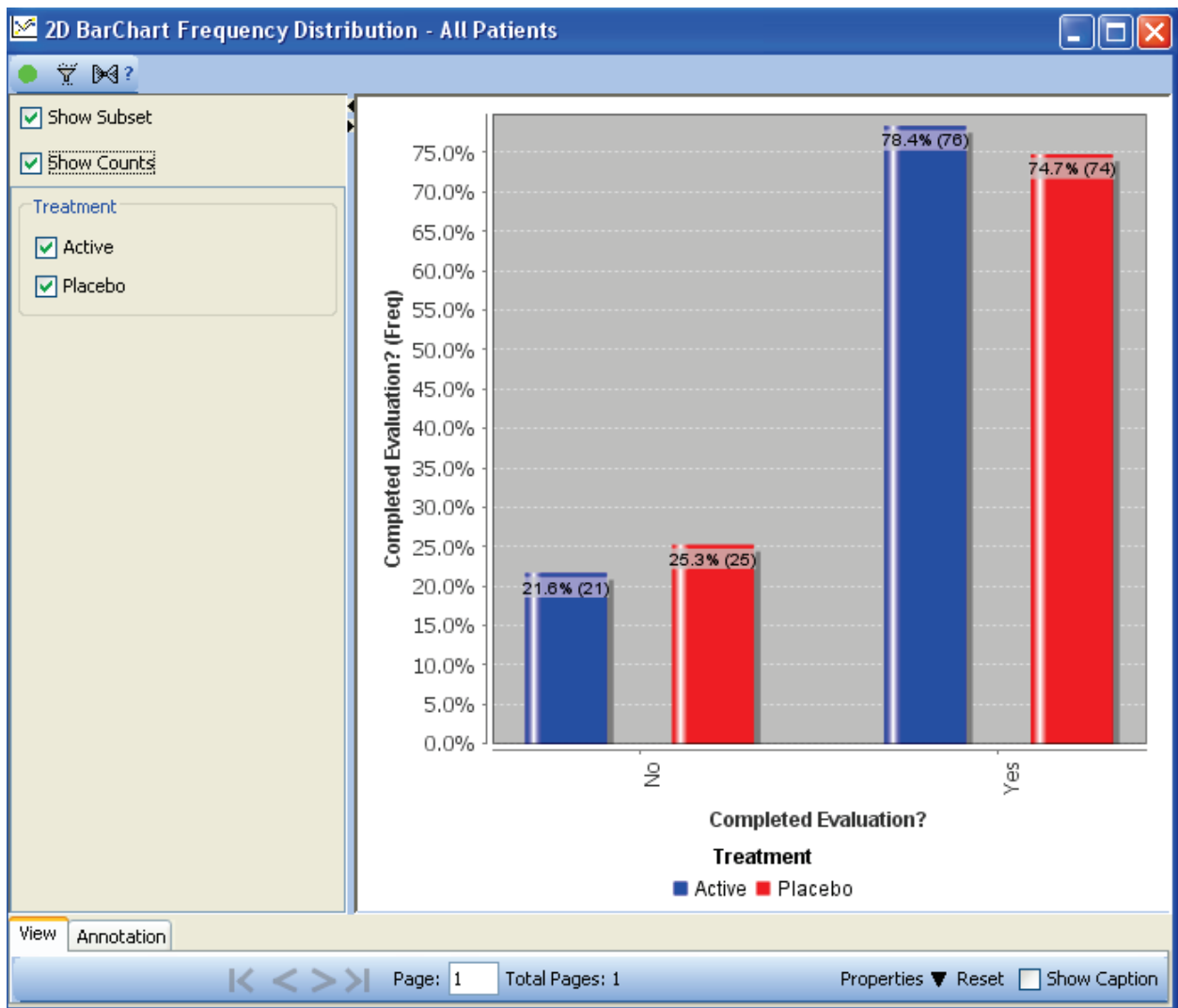
Also added ‘Relative Frequency’ plots for 2D bar chart frequency chart – allowing selection of Relative Frequency based on either: All Patients, Patient Subset, By-Var Category or By-Var-All Patients Category-PSC Subset. An example, which now includes the 4 denominator choices when ‘Show Percentage’ checkbox is checked is:



During the graph definition – the user can check the ‘Relative Frequency’ option, then choose from 4 different denominator options – by Variable options are only available if a By Variable has been defined:

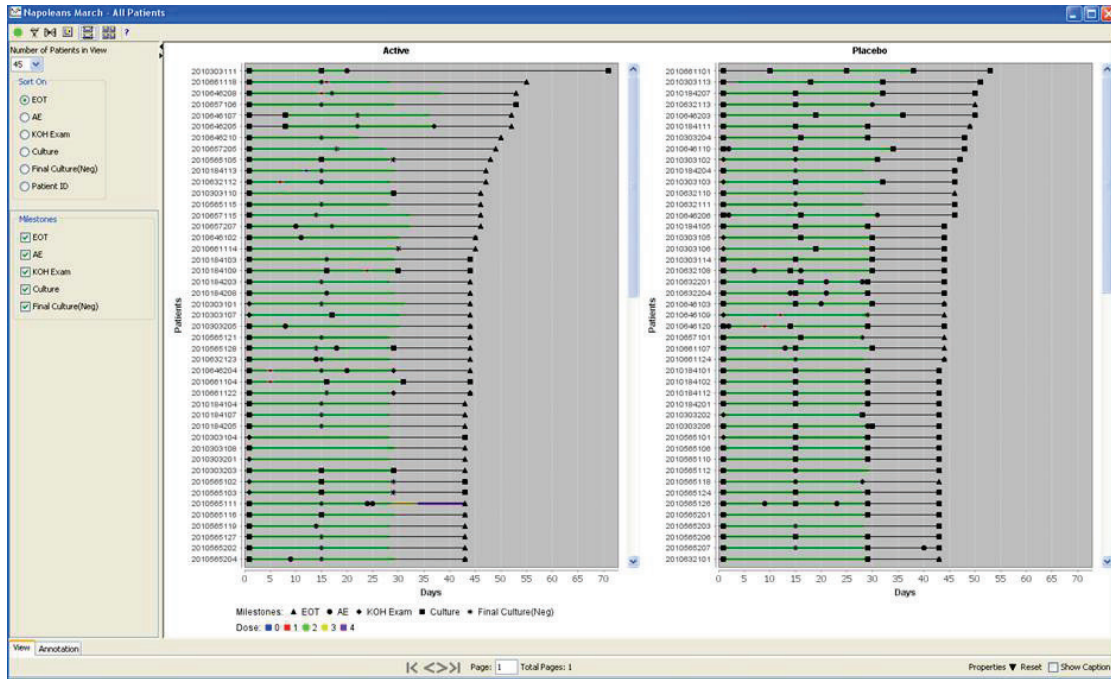


The resulting ‘Relative Frequency’ graph generated for this choice is:

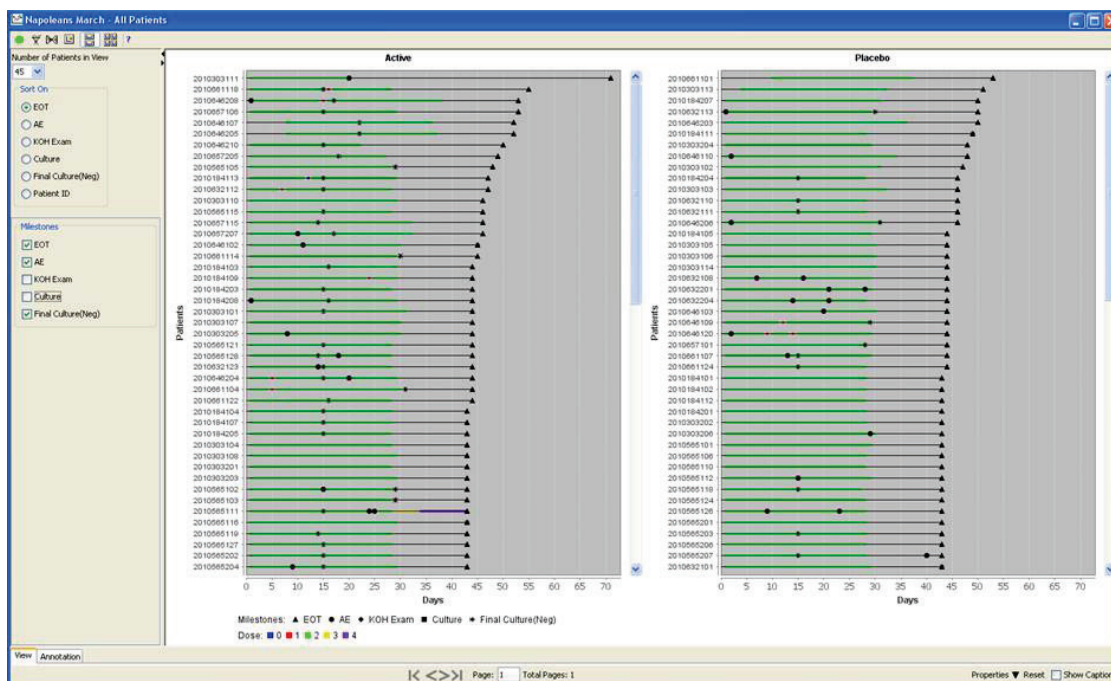


Napoleon's March plot.

A new graph type is included in JReview 9.2.6 – which lets the user see multiple patients together, with 'milestone events' noted on each patient's 'timeline', and ordered by either EOT (end of treatment) event, or any other of the milestones. Color coding of treatment periods is also provided to convey additional information on timing of milestones relative to treatment periods, phases, etc. This graphic visualization especially helps to see clustering of milestone events across patients.



The 'Milestone' checkboxes in the graph option panel on the left lets the user decide which milestone events should be displayed at that moment (after the graph is initially displayed), as well as changing the sort order item:



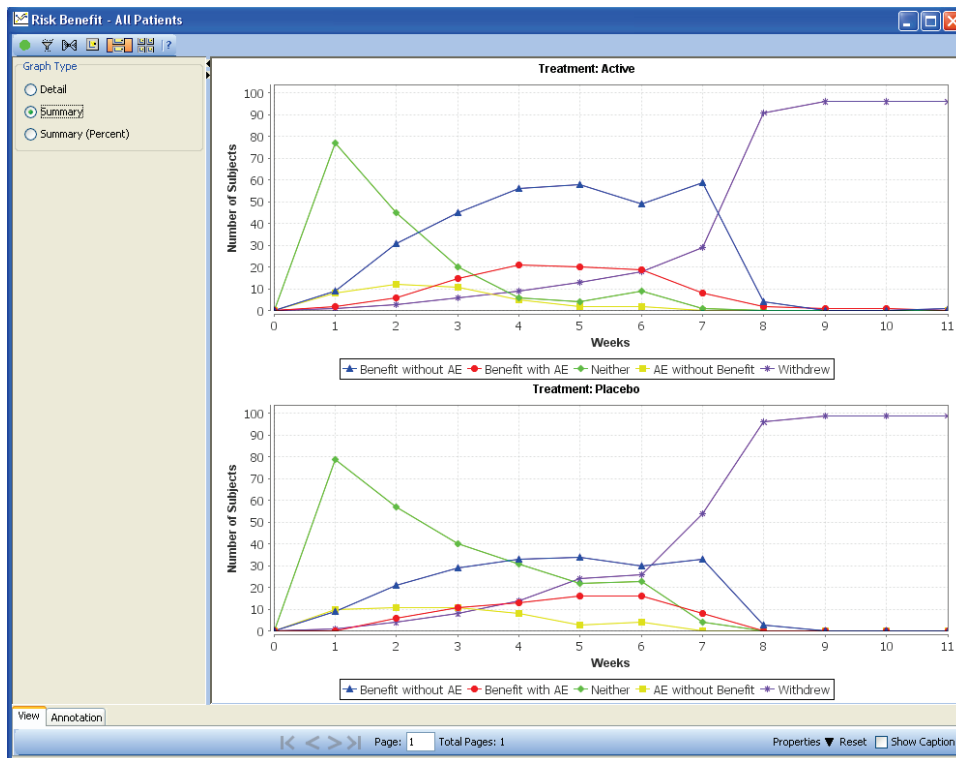
Benefit Risk Graph – Summary Chart – Summary Percent option added

The Benefit Risk Chart – now has three options for display:

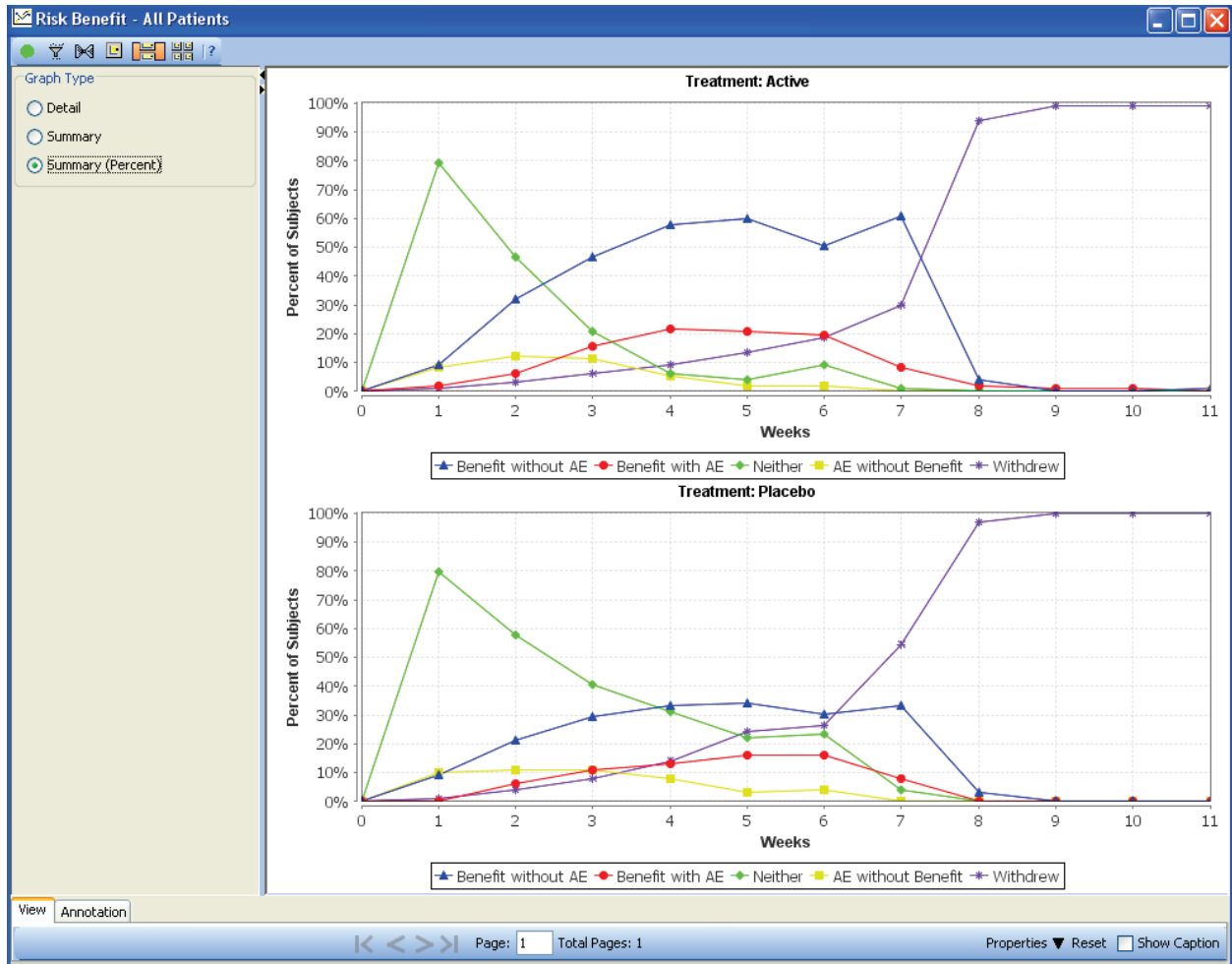
Detail – showing each patient as a color coded line – aggregated/sorted by benefit/risk category:



Summary – showing patient counts for each benefit/risk category at each time block:



Summary (Percent) – showing percent of patients for each benefit/risk category at each time block:



Notes Browser

Notes Browser – full auditing of patient notes – whenever updating or deleting patient notes – transaction is stored in a companion ‘Audit’ table for Patient Notes. If either a Patient Note text, or Patient Note Response text is being edited, a new ‘Reason’ field becomes active – where the user enters the ‘Reason for Change’:

The screenshot shows the 'Notes Browser' interface. At the top, there are fields for 'Patient ID' (2010104...), 'Panel' (Demography), 'Visit Date' (15-JUL-1991), and 'Item Name: REASON' (Evaluability at Ba...). Below these are two main text areas: 'Note' containing the text 'Dont think this patient should be efficacy analyzable' and 'Response' containing 'The issue was queried.'. At the bottom, there are buttons for 'Save ...', 'Cancel', 'Remove Note', 'Edit Response', and another 'Cancel'.