

Integrated Clinical Systems, Inc.

Integrated Clinical Systems, Inc. announces JReview 13 – with newly introduced Dynamic Patient Select Criteria Panel, Report Templates and additional Graph Types, along with enhancements to Patient Narratives, Report Notes and many other features.

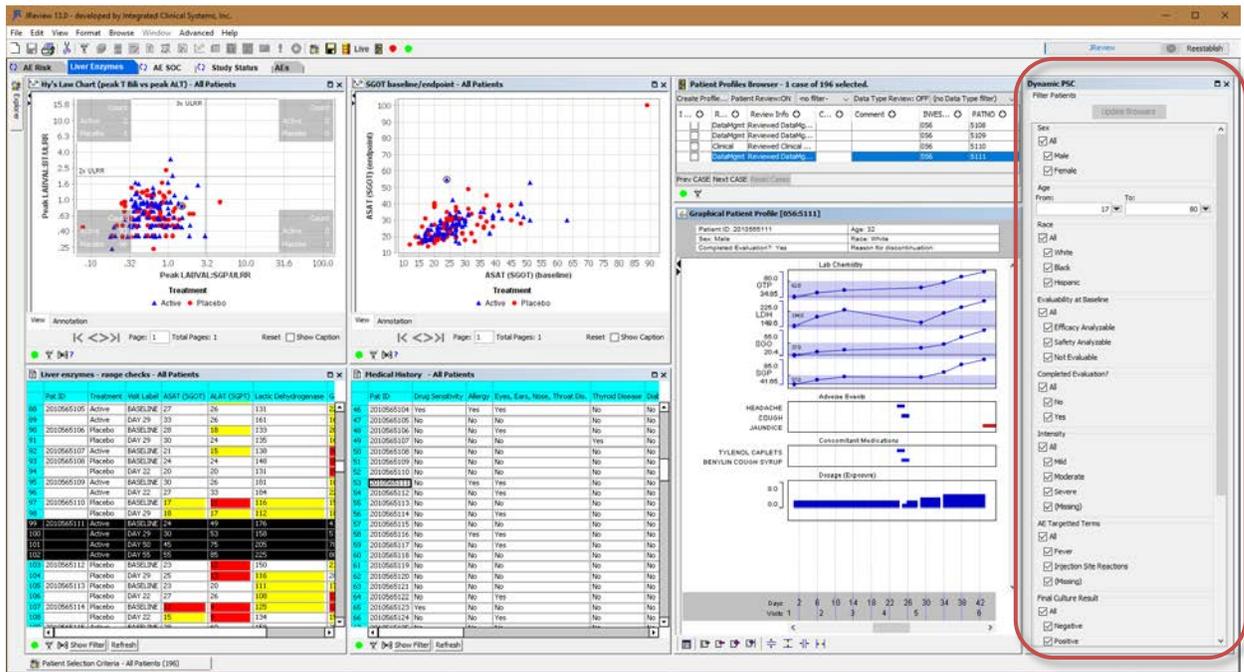
Frenchtown, NJ – January 8, 2018

Integrated Clinical Systems, Inc. (ICS) www.i-review.com, developers of Integrated Review™ & JReview®, the world's most comprehensive clinical review and analysis software tool, today announced JReview version 13.

Here are some of the major highlights of this new JReview version:

- **Dynamic Patient Select Criteria Panel (new)**

One can now add a patient data filter panel, similar to the graphics browser filter control panel, at the patient level to specify patient subset characteristics by selecting/unselecting various patient criteria values. This provides a more visual and intuitive method of selecting patients of interest. Patient selection filter panel contents are defined by an easy to use drag and drop interface, saving/sharing those with others, and having multiple filter panels to choose from. In Dashboard View mode the default Dynamic PSC is displayed automatically in the far right panel, but you can change to a different Dynamic PSC definition for a different set of selector questions:



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



- **Report Templates (new)**

Easy to use 'drag & drop' report templates for many reports commonly used in clinical studies like Subject demographics and baseline characteristics overview (but can be used for any data items). Use drag & drop ease for adding items and then select from extensive list of information/functions as well as 'group' rows as appropriate. In the example below, Type='Demographic Summary Report' – but that's really just a description of a very common table/pattern included for most studies:

The 'Template Reports' window is divided into several sections:

- Type:** A dropdown menu currently set to 'Randomization'.
- Panels:** A list of report categories including 'Randomization', 'Medical History', 'Previous Medication', 'Concomitant Medication', 'Dosage', 'Demography', 'Final', 'Lab Chemistry', 'Lab Hematology', 'Lab Urinalysis', 'Adverse Events', 'Efficacy Evaluation', 'Myoclogical Results', 'Vitals & Physical Exam', 'FBR: Lab Chem (trt days)', 'FBR: LabDays', 'FBR: Lab Vertical (days)', 'FBR: Study Startup - Multi', and 'FBR: Labs (vertical)'. 'Randomization' is selected.
- Items:** A list of data items for the selected report, including '_Define New Item_', '_Define New Range_', '_Define New Term Map_', 'Last Change Date', 'Pat ID', 'Visit No.', 'Visit Date', 'Visit Label', 'Protocol', 'Investigator', 'Pat. No.', 'Date of Randomization', 'Treatment', and 'NI Current Rand Date'. 'Treatment' is selected.
- Designer:** A table defining the structure of the report. The 'Columns' section shows 'Treatment' selected. The main table lists report items with their descriptions, functions, group functions, sort orders, and filters.
- Configuration:** Two sections for configuring the report:
 - General:** Name (Value), Heading (Demographic Summary Report), Include Subject Count (checked), and Include Total Column (checked).
 - Item:** Name (Value), Function (decoded value), Group Function (none), Item (Treatment), and Panel (Randomization).
- Buttons:** 'Create Report' button at the bottom right.

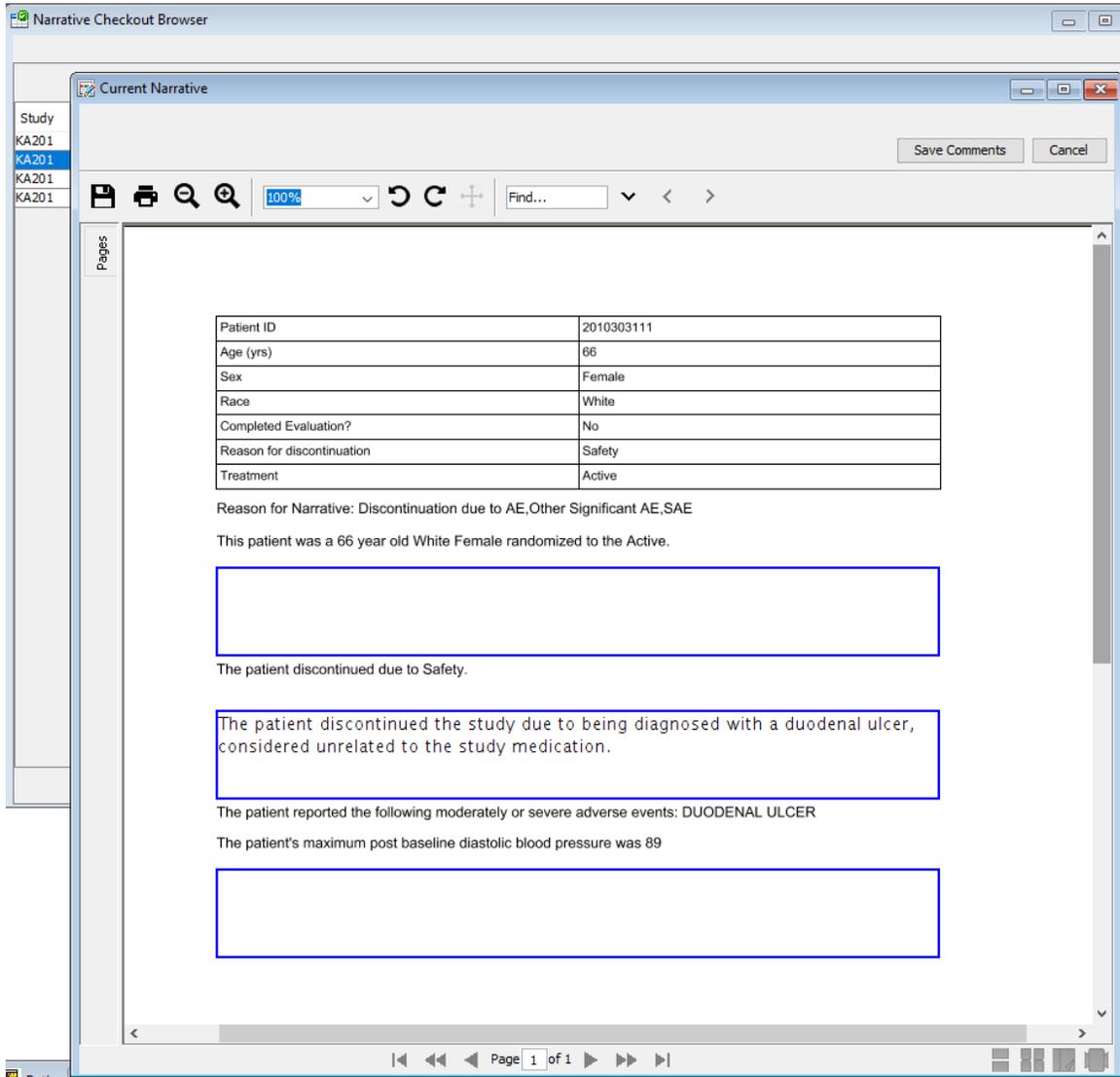
Group Desc	Item Desc	Function	Group Func	Sort	Filter
Age	mean and std.dev.	actual value	mean and std.dev.	NONE	Filter
	range	actual value	range	NONE	Filter
	Sex - count subjects a...	decoded value	count subjects and %	DESC	Filter
	Race - count subjects a...	decoded value	count subjects and %	DESC	Filter
	Evaluability at Baseline ...	decoded value	count subjects and %	DESC	Filter
	AE Intensity - count su...	decoded value	count subjects and %	DESC	Filter
	AE Causality - count su...	decoded value	count subjects and %	DESC	Filter
	Completed Evaluation? ...	decoded value	count subjects and %	DESC	Filter
	Reason for discontinuati...	decoded value	count subjects and %	DESC	Filter

Example of a finished Template Report output:

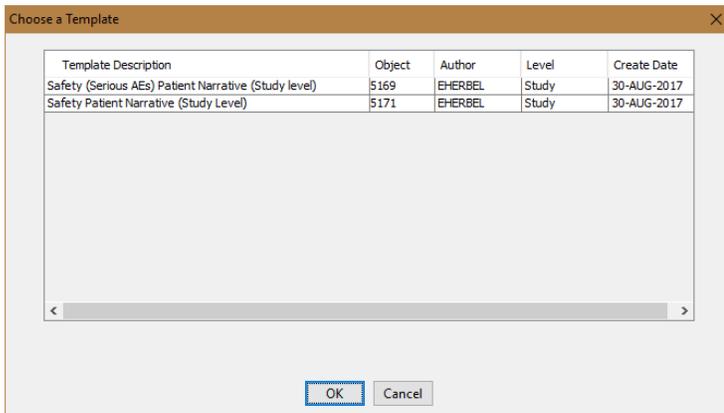
	Active	Placebo	Totals
Subject Count	97	99	196
Age			
. mean and std.dev.	44.43 [16.26]	44.01 [16.21]	44.22 [16.19]
. range	17-80	18-80	17-80
Sex - count subjects and %			
Male	78 (80.41)	83 (83.84)	161 (82.14)
Female	19 (19.59)	16 (16.16)	35 (17.86)
Race - count subjects and %			
White	77 (79.38)	82 (82.83)	159 (81.12)
Black	16 (16.49)	9 (9.09)	25 (12.76)
Hispanic	4 (4.12)	8 (8.08)	12 (6.12)
Evaluability at Baseline - count subjects and %			
Efficacy Analyzable	79 (81.44)	85 (85.86)	164 (83.67)
Safety Analyzable	17 (17.53)	14 (14.14)	31 (15.82)
Not Evaluable	1 (1.03)	0 (0.00)	1 (0.51)
AE Intensity - count subjects and %			
Mild	20 (20.62)	18 (18.18)	38 (19.39)
Moderate	11 (11.34)	7 (7.07)	18 (9.18)
(missing)	3 (3.09)	5 (5.05)	8 (4.08)
Severe	1 (1.03)	0 (0.00)	1 (0.51)
AE Causality - count subjects and %			
Not Related	19 (19.59)	18 (18.18)	37 (18.88)
Highly Probable	9 (9.28)	7 (7.07)	16 (8.16)
Possible	2 (2.06)	3 (3.03)	5 (2.55)
Probable	0 (0.00)	1 (1.01)	1 (0.51)
Completed Evaluation? - count subjects and %			
Yes	76 (78.35)	74 (74.75)	150 (76.53)
No	21 (21.65)	25 (25.25)	46 (23.47)
Reason for discontinuation - count subjects and %			
Protocol violator	12 (12.37)	5 (5.05)	17 (8.67)
Subject unreliable	3 (3.09)	0 (0.00)	3 (1.53)
Subject Requested DC	2 (2.06)	0 (0.00)	2 (1.02)
Lack of Efficacy	2 (2.06)	17 (17.17)	19 (9.69)
Moved or LTF	1 (1.03)	2 (2.02)	3 (1.53)
Safety	1 (1.03)	0 (0.00)	1 (0.51)
Other	0 (0.00)	1 (1.01)	1 (0.51)

- **Patient Narrative (major enhancements)**

Now allows interleaving of medical writer text entries between 'automated text' sections wherever the definer of the template had embedded 'comment' blocks. These comment blocks appear with a blue border, and are editable, in the displayed narrative during review. Any comments entered are saved to the database, then interleaved with the automated text. Only comment blocks with entered text take space in the resulting narrative (as an RTF or PDF):



Also added support for defining multiple 'target purpose' narrative templates per study for different purpose narratives (previously only supported one narrative template per study):



One can update the definition of an embedded object with 'standard text' at the definition stage.

- **Report Notes (enhanced)**

The ReportNotes option of PREFILLNOTESCOPYDATA=New; (or another initialization value) has been significantly enhanced. As before, when the user changes a ReviewStatus value or adds comments in editable fields (green fields), the current value of the rest of the report (typically the discrepancy report portion) – is copied to ‘neutral’ columns in the reportnotes table. With v13, when the same report is re-executed, the previous values of each report column entry is compared to the current value of the same column, and if any have been updated due to data updates, that cell is highlighted. Also, the ReviewStatus field is changed to ‘Updated’ for those records that contain any column updates for the row:

PID	VISIT	VISIT_DATE	LABVAR	LABVAL	NORM_LOW	NORM_HIGH	ABNORMAL	Review Status	Comment - 1	Comment - 2	Comment - 3
1	2010303102	1	22-JUL-1991	SGP	201.45	8	57	H	New		
2	2010303102	2	27-JUL-1991	GTP	214	3	62	H	New		
3	2010303102	2	27-JUL-1991	SGP	237	8	57	H	Updated	Please confirm values with site/lab	
4	2010303102	3	02-AUG-1991	GTP	239.68	3	62	H	New		
5	2010303102	3	02-AUG-1991	SGP	265.44	8	57	H	New		
6	2010303102	4	21-AUG-1991	GTP	187	3	62	H	New		
7	2010303102	4	21-AUG-1991	SGP	182	8	57	H	Processed	Please confirm values with site/lab	
8	2010303102	5	26-AUG-1991	GTP	220.66	3	62	H	New		
9	2010303102	5	26-AUG-1991	SGO	118	16	37	H	New		
10	2010303102	5	26-AUG-1991	SGP	214.76	8	57	H	Processed	Please confirm values with site/lab	
11	2010565128	3	24-FEB-1992	BT	3.25	.3	1	H	New		
12	2010632106	3	01-NOV-1991	GLU	473.76	61	152	H	New		
13	2010632106	4	18-NOV-1991	GLU	460	61	152	H	Updated	Please confirm values with site/lab	
14	2010632106	5	23-NOV-1991	GLU	542.8	61	152	H	New		
15	2010646113	1	27-SEP-1991	GTP	192.1	3	62	H	New		
16	2010646113	2	02-OCT-1991	GTP	226	3	62	H	New		
17	2010646113	3	08-OCT-1991	GTP	253.12	3	62	H	New		
18	2010657109	3	03-MAR-1992	GTP	187.04	3	62	H	New		
19	2010661108	4	14-OCT-1991	TRI	1032	52	343	H	Updated	Please confirm values with site/lab	
20	2010661108	5	19-OCT-1991	TRI	1217.76	52	343	H	Updated	Please confirm values with site/lab	

Report dynamic filtering can also be used to display only the ‘Updated’ rows for quick review:

PID	VISIT	VISIT_DATE	LABVAR	LABVAL	NORM_LOW	NORM_HIGH	ABNORMAL	Review Status	Comment - 1	Comment - 2	Comment - 3
2	2010303102	2	27-JUL-1991	SGP	237	8	57	H	Updated	Please confirm values with site/lab	
3	2010632106	4	18-NOV-1991	GLU	460	61	152	H	Updated	Please confirm values with site/lab	
4	2010661108	4	14-OCT-1991	TRI	1032	52	343	H	Updated	Please confirm values with site/lab	
5	2010661108	5	19-OCT-1991	TRI	1217.76	52	343	H	Updated	Please confirm values with site/lab	

- **Formatted Patient Profiles (enhanced)**

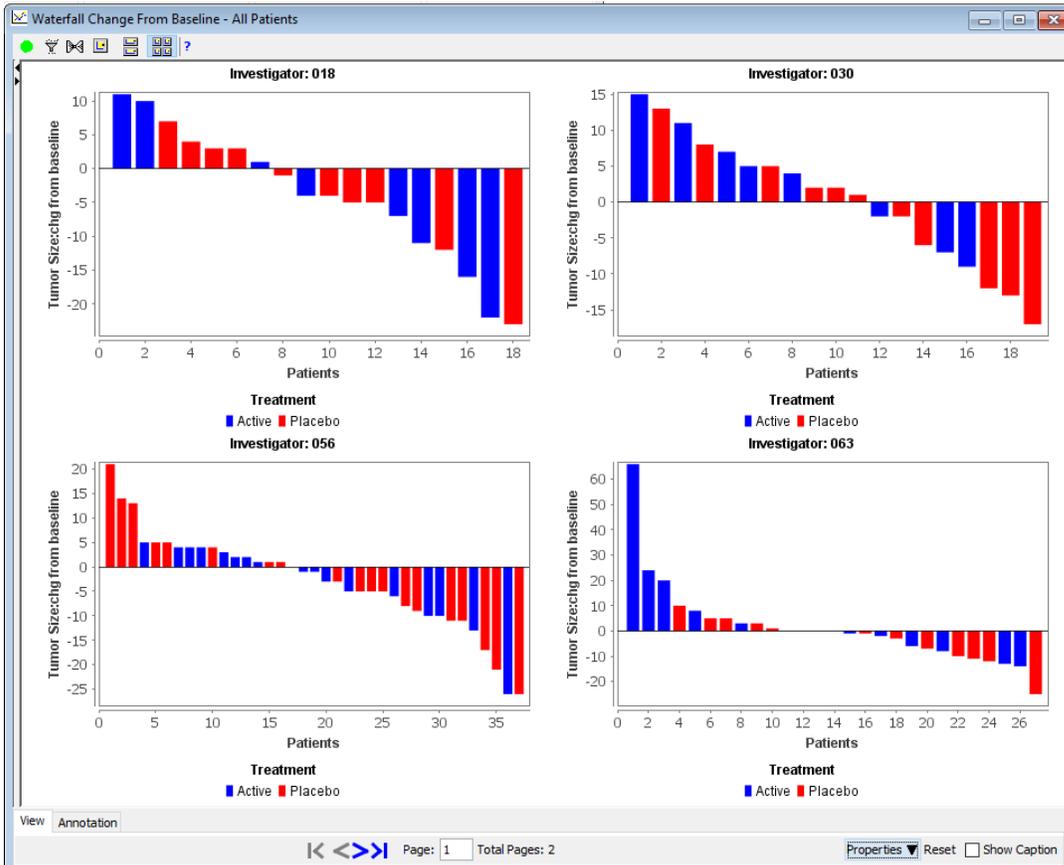
Enhanced PDF viewer capabilities – for multiple page viewing, smooth scrolling, book page turn, etc.

- **Workbook Patient Profile (enhanced)**

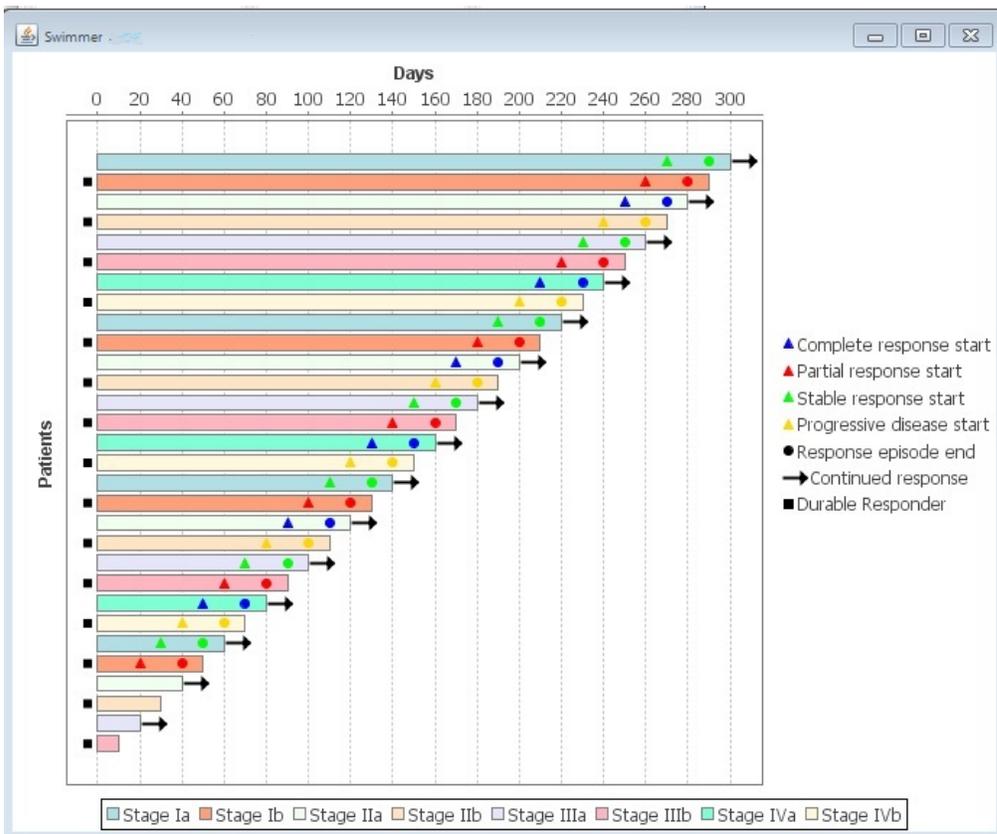
Support ‘no wrap’ option – to just write columns to the right, perhaps setting max col to 0 or unlimited.

- **Graphs (new types added):**

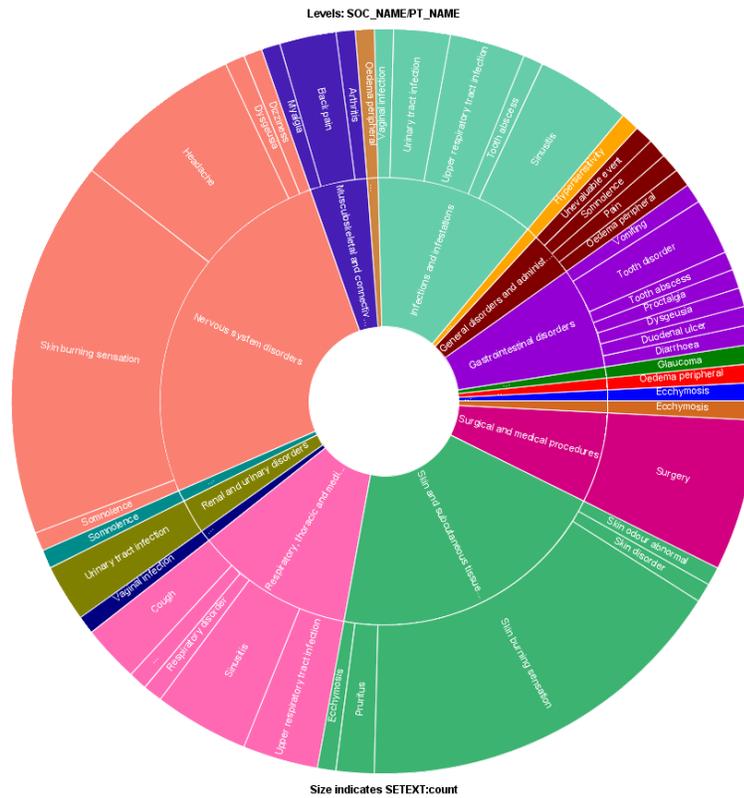
Waterfall Plot – Especially useful in Oncology trials. In this example, using the ‘Page’ variable of Investigator to see a chart for each investigator site:



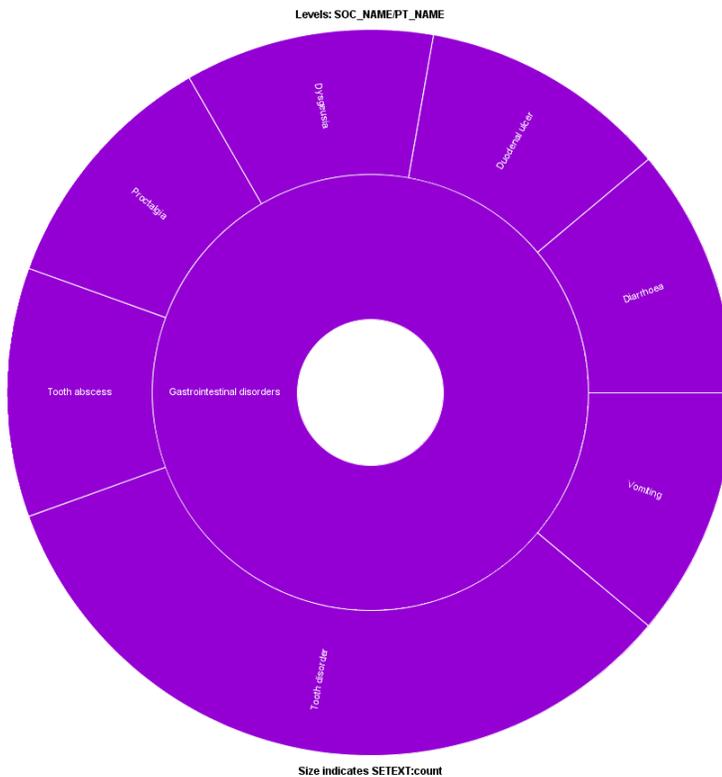
Swimmer Lane Plot – Also especially useful in Oncology trials.



SunBurst plot – Interactive SunBurst plot is useful at displaying sets of data by nested categories to see relative proportions of patients between groups. Interactive drill into (explode selected level/segment) to zoom to more details:



For example, to Zoom in on 'Gastrointestinal Disorders' one would double click it:



About JReview®

JReview® is the fastest, easiest way to review, graph, report, and analyze your clinical data. It is a web-enabled software application written specifically for pharmaceutical, biotech and medical device companies doing clinical research. It provides many vital tools needed to perform clinical data review, ad hoc reporting, data visualization, analysis, and risk assessment of clinical studies data. By interacting with various patient subsets and using any combination of browser modules or dashboards within the product, users can easily review and/or monitor their clinical trials for safety, efficacy, etc.

About Integrated Clinical Systems, Inc.

Integrated Clinical Systems, Inc. (ICS) <http://www.i-review.com>, headquartered in Frenchtown, NJ, is an industry-leading developer of software applications for pharmaceutical, biotech and medical device companies worldwide. Their original software application, Integrated Review™, provides ongoing, real-time review of clinical data and an easy-to-use, intuitive means of profiling patients, reporting, graphing, ad-hoc data mining and signal detection for clinical data stored in third-party or in-house data management software systems or data warehouses. This functionality has been ported to a web-enabled software application, JReview®, and has been expanded even more with new features. These products have been developed by professionals from the pharmaceutical industry, and they continue to be refined and enhanced by customer and FDA feedback. It is this specialization and industry focus that provides their clients with the reporting and analysis capabilities that allow them to bring products to the market safely, efficiently, speedily and cost effectively.

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