Integrated Clinical Systems, Inc.

Integrated Clinical Systems, Inc. releases JReview 12.0.1 – with Report Reviewer Note extensions, volcano plots, histogram distribution plots, composite Hy's Law plot, Dashboard Views performance improvements and lots of other enhancements.
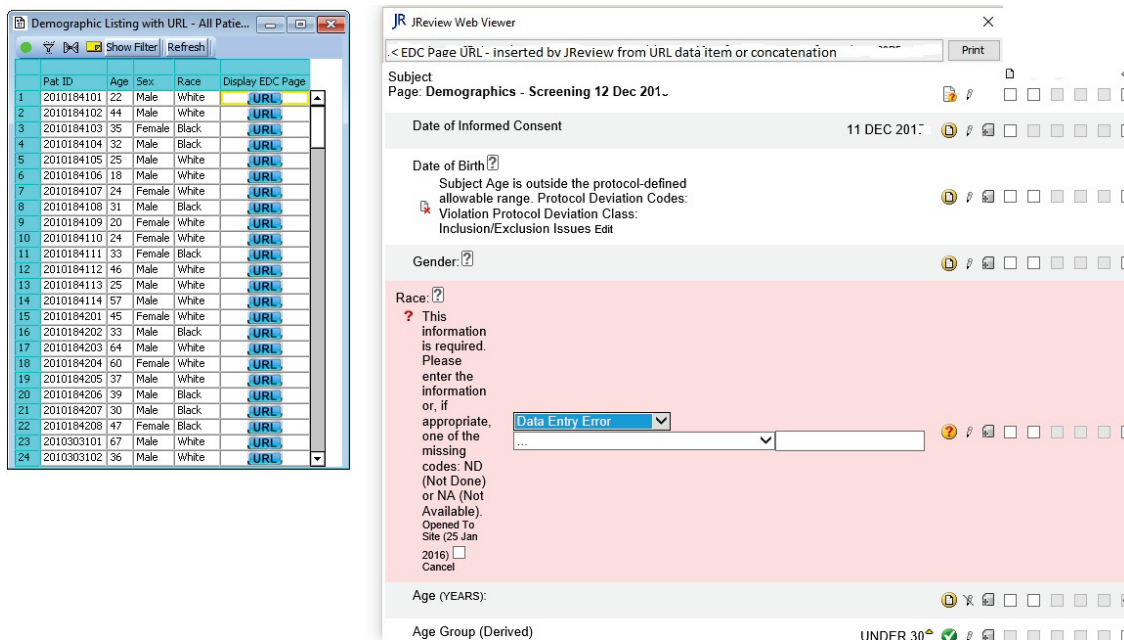
Frenchtown, NJ – January 6, 2017

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 the release of JReview version 12.0.1.

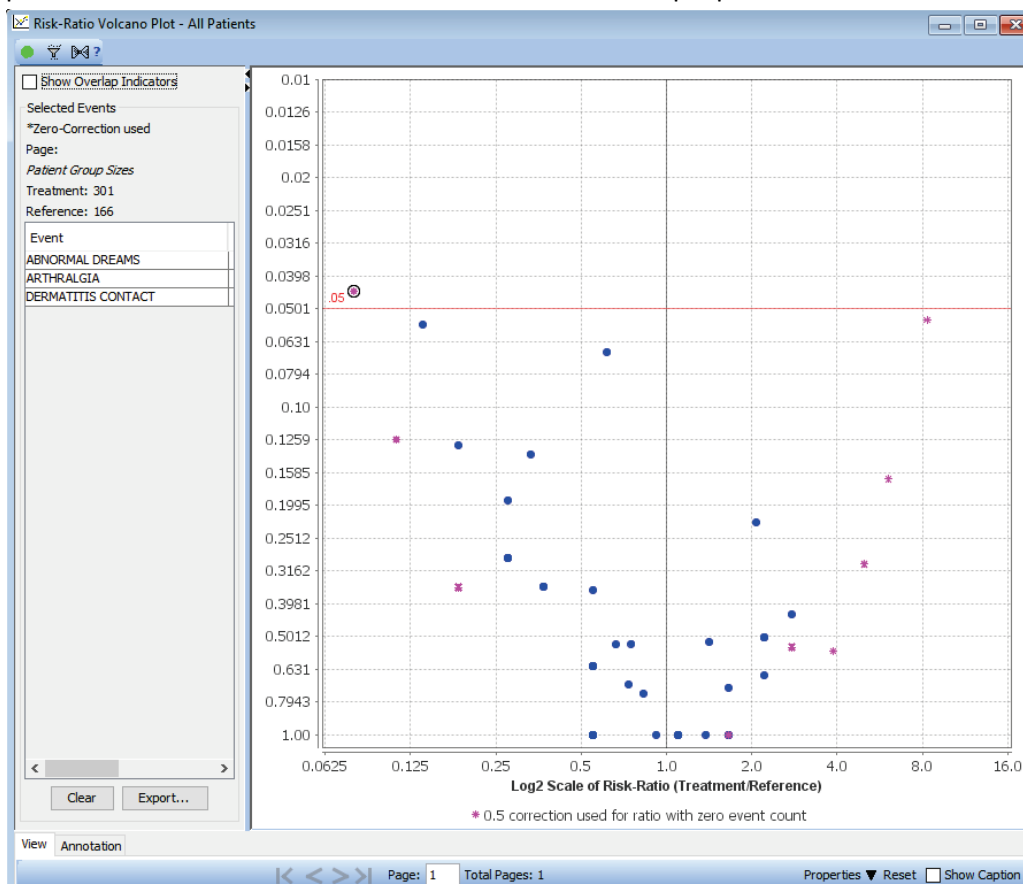Here are some of the major highlights of this new JReview release:

- **Dashboard Performance and threading improvements**
  Significant updates in appoach used when retrieving multiple reporting objects in a dashboard view (threading), gathering prompting parameters, and performance improvements.

- **Patient Narrative Enhancements**
  New capability to map each PSC referenced to retrieve a selected group of patients – to a 'reason for narrative' default setting.   This is especially useful when generating patient narratives in batch.

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

- **Detail Reports - Data Highlighting – modified Data Highlighting approach**
  Improved data highlighting – performance enhancements – also sorting supported.

- **Mapping text terms** provides user definition - through a remapping definition window - to allow the users to select a text item (for example AE Preferred Term), then defining a 'mapped' term – and selecting which of the available existing terms (AE Preferred Term, for example) – should belong to that remapped term.   An example would be defining a mapped term of 'Hypersensitivity reaction', then selecting each of the preferred term values in the data that you'd like to remap to that general term. Then – in reports, graphs, crosstabs, etc., the remapped term can be included in addition to or instead of the original term. If original term is not on the mapped list – the original term is displayed in the report – so referencing the mapped term – yields either the new mapped categories or the original terms. Also, the named 'mapped terms' definition can be referenced/associated with other terms, i.e., if AE Preferred Terms have been mapped to a new mapped category definition, that mapped category definition can also be reused for Medical History preferred terms.

- **Detailed Reports –** locked columns, specified column width, or auto size, etc.
  Added capability to specify number of locked/frozen columns in definition – so that in the generated report – those number of columns on the left will be locked or frozen, when the remainder of the report is horizontally scrolled.   Also – column width can be specified by sizing the definition column or leaving the autosize checkbox checked (default), and whether to word wrap column contents, etc.

- **Detailed Reports** – added ability to launch a URL in a JReview managed, embedded Web Browser – when a 'URL' type field is clicked in a detailed report.   The 'URL' type field can be either a NewItem definition – which combines a specified URL lead in string followed by a specific 'page ID' from the data – to launch and display a referenced EDC page data contents, for example.   Many other uses are possible – such as displaying scanned images of reference documents, medical images, etc.
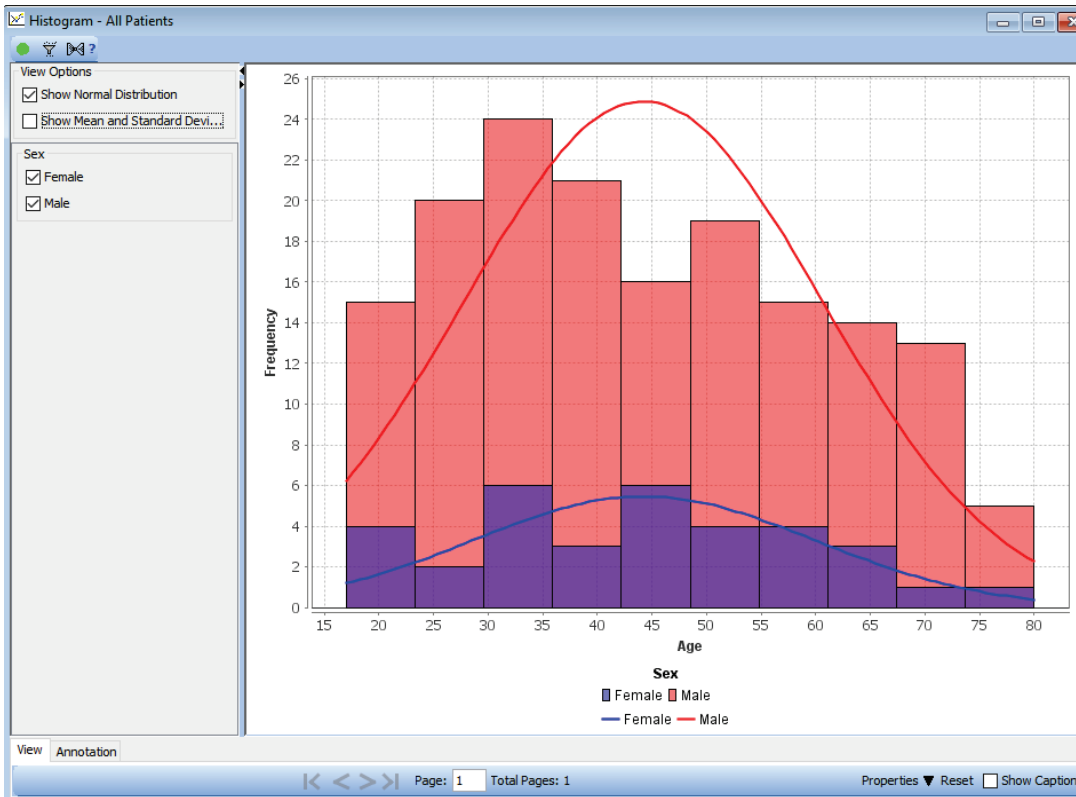

- **Report Reviewer Notes – added 'PREFILLNOTES=Open;' config.options option –** if present, report reviewer notes are prefilled with 'Open' state, rather than the default, post note record as you go.   That way, number of Open, Closed, etc. issues can be tallied.   The '=Open;' tells the system the initial value of the REVIEWSTATUS field for the 'prefilled notes entries'.   This can be whatever initial status is chosen.

- **Report Review Notes –** another variation 'PREFILLNOTESCOPYDATA=Open;' – if present, this option works as the 'PREFILLNOTES' case above, but when the user makes a change to any of the editable note fields, a full copy of the data from that line is also copied to the report notes table – for later comparison.   Then – the next time that same report is executed, with new or updated data, any rows that had note or status changes – have the previous notes and status copied to the current state, but then the data in that line is compared – with the previous data state – and if any items were changed – the status and comments are reset to initial state (Open, etc.).   But – as a reference, the user can also see the previous status and comments – that had been made in the previous context. The '=Open;' tells the system the initial value of the REVIEWSTATUS field for the 'prefilled notes entries'.   This can be whatever initial status is chosen.
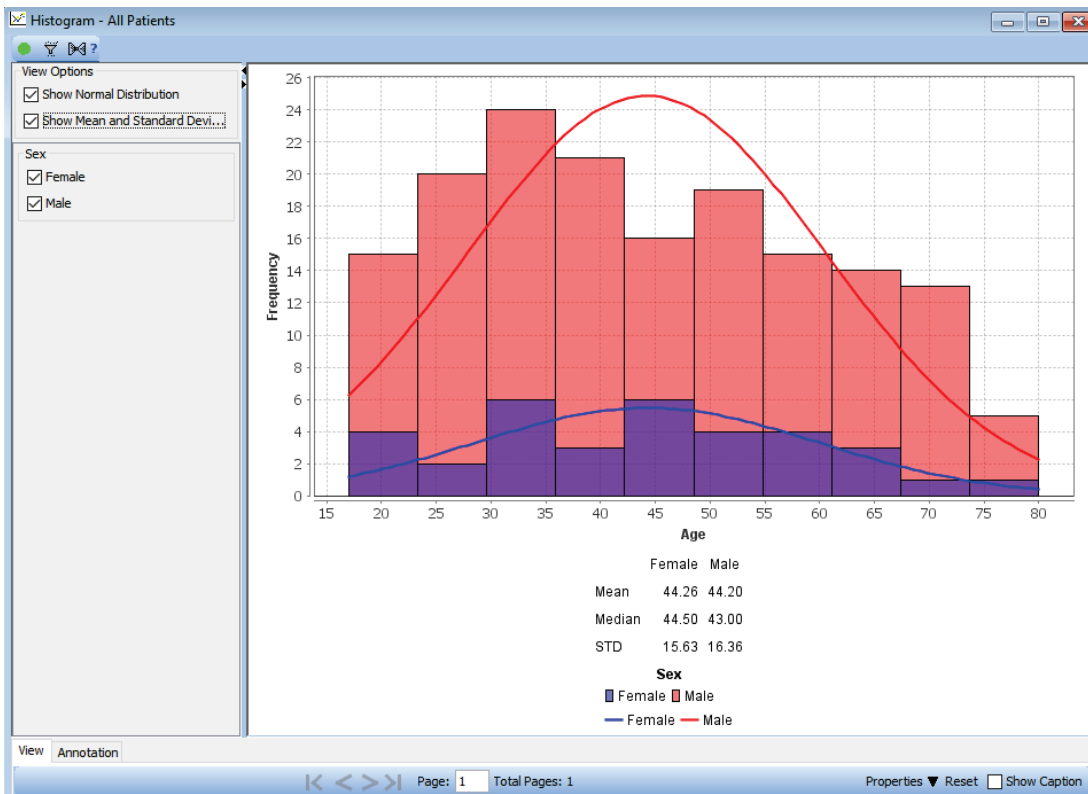
- **ErrorList – support for importing SAS dataset based 'error reports' –** bringing them into a single 'neutral' table for each study, but adding a 'virtual' reference to each original dataset – with SAS labels, etc. – so all 'error lists' can be reviewed separately (editable status/comment columns), but common table can be summarized with number Open, Closed, etc.

- **SAS Program scheduling – repetitive scheduling now supported.**

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

- **Study Management – Define Baseline, Endpoint and Post-Baseline within JReview.** In addition to defining baseline and endpoint definition, also define postbaseline flag/definition (if present) or visit/day/date field to be retrieved related to baseline/postbaseline state. The postbaseline definition or flag is needed in the new composite Hy's Law graph.

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

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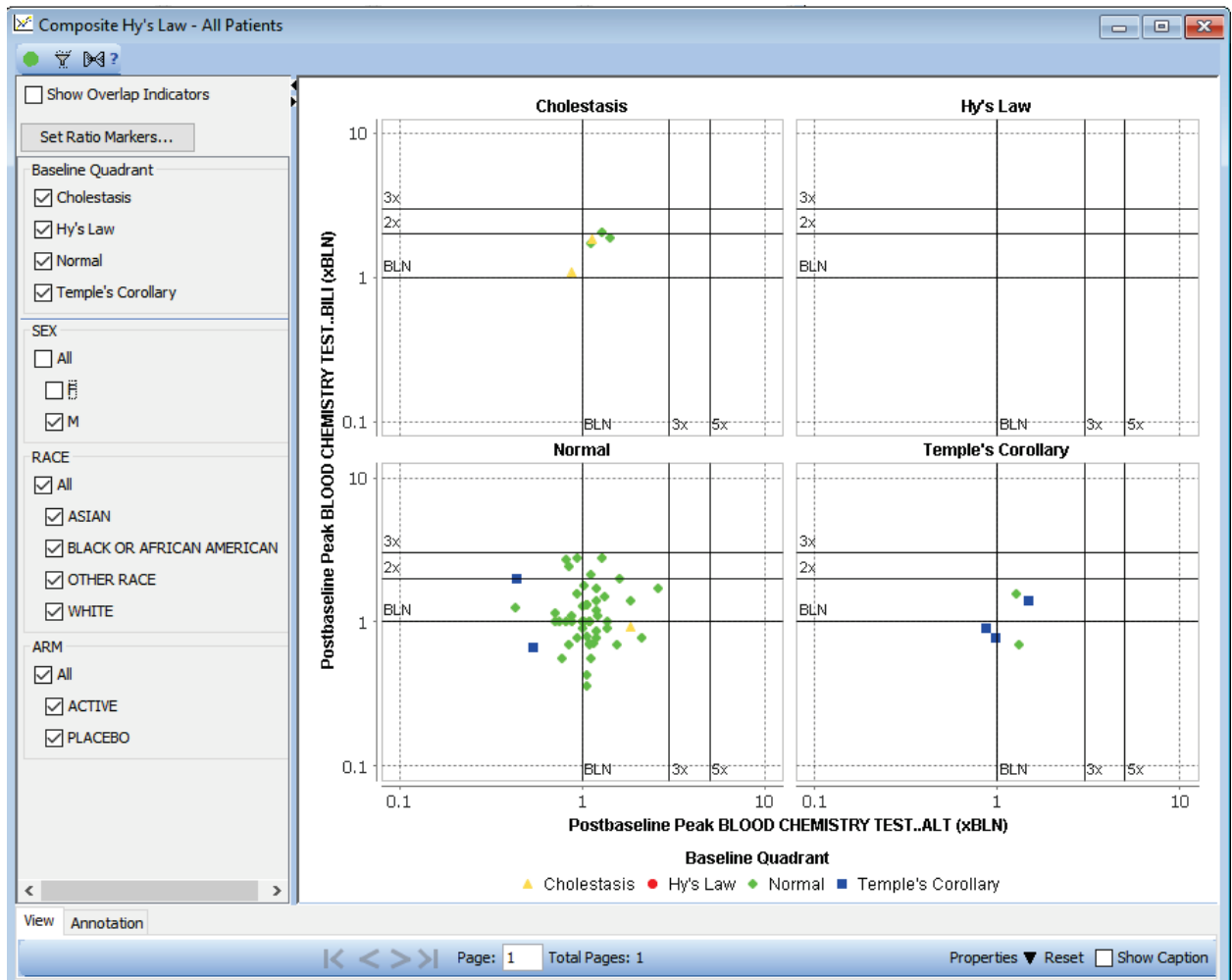
and with 'Show Mean and Standard Deviation' checked:

	Female	Male
Mean	44.26	44.20
Median	44.50	43.00
STD	15.63	16.36

Composite Visualization of Liver Tests for assessing patients for Drug Induced Liver Injury

Based on very recent discussions with the US FDA, we've added a new graph type – in addition to the 'classical Hy's Law plot', which was already included in JReview, we've added a new graph type which includes initial categorization of each patient at baseline regarding their position in a Hy's Law chart, then plots each patient's peak values as the ratio of the peak value to the patient's baseline value on a composite graph for each of the 4 possible liver injury states – Normal, Cholestasis, Hy's Law or Temple's Corollary, with color coding based on the legend as to their baseline condition.

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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