

Integrated Clinical Systems, Inc. releases JReview 11.0.1 – introducing enhancements in the Risk Based Monitoring & AE Risk Assessment areas and much more.

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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 11.0.1

For this new JReview release, we have continued to expand the intuitive drag-and-drop user interface first introduced in JReview 11 which provides immediate preview of results while building objects like graphs, reports and crosstabs. This release also incorporates enhancements in the Risk Based Monitoring and AE Risk Assessment areas. Here are some of the highlights:

- Horizontal→Vertical panels – now supported in Output Filters in Graphs & Reports so a 'PI' (Pivoted Item) can be referenced in an output filter, for example, cholesterol > 250.
- Brought back 'Copy To' – right mouse click from Output Explorer.
- AE Risk Assessment – quite a few great enhancements requested recently. Some aspects include superimposing patient subgroup member symbols on the main AE Risk Assessment graph so the user can see the distribution of a selected patient subgroup type across all the SOCs, etc. Also added other ways of exporting these results to resemble what is seen in many journal articles.
- Output Explorer – new 'Table' view option. You can not only display the contents of the Output Explorer in the familiar tree style, but also in a table format which is sortable (like reports) up to 3 levels deep. Also checkboxes allow you to include/not include certain values from the Object Catalog. We also added 'Status' to the list of available objects and a Find/Search capability that dynamically filters displayed content as soon as any filter condition letters are entered.
- Multi-study Union Warning – This optional setting (not enabled by default) will warn if the user is doing a multi-study union. If the warn option is requested by the site, a configuration setting can be added so JReview will display this warning message. One caveat, we've added a checkbox for the user to let them select if they don't want to see the warning again which is stored at the user level.
- Graphing – The new drag-and-drop user interface has been expanded to include Trellis Plots and Napoleans March graph types.
- Spaghetti Plots – New graph type added which displays patients as separate lines. If a By Variable is defined, the line color corresponds to the By Variable values in the legend. Patient identification, patient drill down and patient ID tooltips are also supported in this graph type. If a user clicks on any of the lines in the spaghetti plot, that patient's data is highlighted/selected in any other patient level object that is also open at the time.

Risk Based Monitoring – New Suggested Actions & Actions Taken Overview

JReview 11.0.1 introduces the ability to check suggested actions that have been generated by JReview based on risk indicator/suggested action definitions. You can then define and post actions taken from within the JReview Risk Based Monitoring Data Browser. After opening the RBM Data Browser, you start by selecting a SITEID as the Row Parameter, then either Risk Category or Risk Indicator as a Column Parameter, and then click Create. You can then click on a site of interest, especially if you as a CRA or site monitor are responsible for monitoring that site, then click ‘Create’ again in a new area toward the bottom of the window in the ‘Site Level Information’ area. A historical view of the selected site’s indicator results are then displayed in the ‘Overview’ tab.

To see a list of ‘Suggested Actions’ which have been generated as a result of the Risk Based Monitoring indicators and triggered suggested actions for various indicators and levels, click on the ‘Actions’ tab. This will display the list of current indicators, levels and suggested actions, along with additional comments from the RBM definition designer.

Once you have taken an action regarding the site, select that Action from the first listbox of available actions that have been defined in your environment, then select as many of the ‘Reasons’, i.e., Indicator descriptions, that apply to the action. Optionally enter a comment, select the ‘Date’, then click ‘Add Action’.

If you click on the ‘Edit Actions’ tab, you’ll see all actions that you or anyone else has added for the currently selected site.

Trial Summary – New Study Characteristic Browsing Table & Study Selector Overview

JReview has provided multi-study analysis since the initial version was introduced in 1999. This has been expanded to cross project (drug project) multi-study analysis since version 10.0 in January 2014. This built-in feature, along with a new feature now being introduced in JReview version 11.0.1 which displays a table view of your studies with all available Trial Summary information, will form the basis of many new use cases since your study selection can now be dynamically filtered.

In addition to the traditional ‘tree’ display of studies by drug project (or configured as a multi-level hierarchy which includes drug class, sponsor, drug name, then study, etc.), version 11.0.1 new Trial Summary table ‘tab’ displays the first few items from a table that we maintain containing the relevant trial summary information for all studies in your environment. The first 4 columns from that table are displayed by default, then the user can select checkboxes on any of the other Trial Summary items to browse through those available studies.

Then the user can right-mouse click on any of the Trial Summary column elements to dynamically filter the contents of the other columns so only those studies which meet all filtering conditions are shown. This new feature will be very useful since it allows you to select studies by drug class, or any other trial summary characteristic, with multiple filtering conditions.

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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