

Integrated Clinical Systems, Inc. launches JReview 10.0 - introducing Analytics for Risk-based Monitoring

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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 launch of JReview version 10.0.

JReview version 10.0 introduces direct Analytics support for Risk Based Monitoring (RBM), enabling centralized monitoring teams to define key risk categories and indicators from clinical & operational source data available, set thresholds, and specify suggested actions in a newly introduced RBM module. The new RBM Data Browser provides an overview of the generated risk-based monitoring information – from the regularly scheduled batch jobs. Also, a newly developed native iPad app provides easy access to key RBM metrics and recommended actions for CRAs and monitors in the field.

“We are really excited to offer RBM capabilities to our customers with this release” says Eric S. Herbel, President of ICS. “RBM has become a critical industry trend since the US FDA & EMA have released their guidance on risk-based approaches to clinical monitoring recently. Also, many of our customers are members of the cross-industry consortium [Transcelerate Biopharma Inc.](#) that has developed a methodology¹ suggesting to shift monitoring processes from an excessive concentration on Source Data Verification to comprehensive risk-driven monitoring.” Risk indicators can involve any data accessible by JReview – including the actual study data, but also other important trial metrics, such as queries, entry rates, etc., which would typically be accessed from EDC systems or CTMS databases.

JReview 10.0 also introduces Trellis plots – ‘grid’ displays, such as the timeline trellis by patient, which is particularly useful when reviewing lab data. Direct import of MS Excel™ spreadsheets is now supported, including the option to store the spreadsheet contents in a common table in the database's ReviewAdmin account or separate SAS datasets. A new multi-level study hierarchy and multi-study mode across projects facilitates the selection and pooling of multiple studies.

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.

Integrated Review™ is trademarked and JReview® is a registered trademark of Integrated Clinical Systems, Inc. Copyright © 2014. All rights reserved.

¹ *Transcelerate Biopharma Inc.; [Position Paper: Risk-Based Monitoring Methodology](#)*

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