Integrated Clinical Systems, Inc. releases JReview 12 – introducing Report Reviewer Notes, additional Graph Types and lots of other enhancements.

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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 12.

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

- **Report Reviewer Notes**
  Many pharmaceutical companies and CROs review data exception listings – based on a variety of criteria to select those exceptions.   Those same organizations have often managed the handling of those exception listings in Excel spreadsheets – making notes in the exported Excel spreadsheets.   But – when the data is updated in the database, it's not easy to reconcile the notes made in spreadsheets with updated exception listings.   JReview version 12 introduces an integrated way of doing this all within JReview – where JReview users can define the exception listsings directly in JReview and easily add 'comment' or 'status' columns to the same discrepancy listing – by adding those columns from the a standard 'report notes' table built into the system.   Then – when the user reviews the discrepancy report – they can make notes directly in those 'comment' or 'status' columns – which are maintained in separate tables by the system – but aligned with the original discrepancy table.   Then – when data is updated, the original notes appear along with the corresponding discrepancy records – for further comment or closing.   These 'report notes' can also be reported, anaylized, etc., in other areas of JReview.   And – of course – since the patient identification/patient drill down capability is native to any patient level review object (reports, graphs, patient profiles, etc.) – if the user has other reports, graphs or profiles displayed at the same time they're reviewing the discrepancy listing and making notes – the patient data that they're working on/clicking on/highlight at the time – is sent to all other patient level displays to highlight the current patient.   So it's really easy to see other potentially related data to the discrepant records.

- **Tabular Patient Profiles (Formatted and Workbook profiles) – added Item Function specification support**
  When adding items to a tabular patient profile, the user can select which data display function to use when including the item in the profile.   The current default item function for each item type is automatically selected, but the user can override that – especially interesting for some sites – to change the way date items are displayed, etc.

- **Enable Composites in SAS program registration** when accessing a database data source (Oracle, SQLServer, PostgreSQL). This feature has been supported for R scripts previously. Essentially this functions much like defining a 'report', i.e., specifying which items from which tables are of interest – to be combined into a single SAS view made available to the registered SAS program.

- **New Scheduling Support** – if Patient Profile Scheduling Server is licensed (optional license): Previously, Formatted Patient Profiles could be scheduled as a batch job – to generate the PDFs for each of the patients (either selected patients or all patients in a subset). The generated PDFs were accessible directly through the JReview 'Review Output' tab, but could also be directed to be saved to a study specific directory which could be externally accessible to users.

  JReview version 12 extends this to now include the same functionality for **Workbook Patient Profiles** – generating Excel spreadsheets for each patient – also accessible externally if desired.

  In addition, **Patient Narratives** can also be schedule – generating the RTF files for each patient in batch – saving the resulting RTF files for access from within JReview as well as in an externally accessible directory.

- **CrossTab browser – Incidence counts/ percent of some denominator, etc.**
  Crosstabs now support Incidence tabulations – by unchecking 'Count Subjects', then adding the row variable also as the Cell Variable then check 'Count' – the Crosstabs switch to 'incidence mode' – including % of some denominator which can be either row totals or col totals. Descending Sort is also supported.

- **New 'Document' feature in Manage/Migrate**
  We've added a new capability – accessed from the Manage/Migrate feature in JReview – to generate nicely formatted documentation for any JReview reporting object (graphs, crosstabs, reports, patient profiles, RBM definitions). The documentation is stored in an Excel spreadsheet – downloaded to the user's PC.

- **New Graph Types: Exposure by Dose, Disposition Percent, Cumulative Count by Time & TreeMap**

  Exposure by Dose
  On the fly days since some reference date calculation, displaying number of patients by By Variable (if defined) – on drug/receiving dose – by day – to provide a quick comparison of different patient groups dose exposure experience, off drug, etc.

  Disposition Percent
  On the fly days since some reference date calculation, displaying percent of patients either Active, Completed or Withdrawn over the course of the study.

Cumulative Count by Time
On the fly days of events being counted, then plotted as the cumulative number over time – with By-Variable and Paging Variable support.

Tree Map
A very flexible, easy to define implementation of Tree Maps – allowing definition of multiple 'levels' – category variables at each level, with size of included nodes based typically on counts of the lowest level object, with coloration based on any other information – for example a TreeMap of AE SOC, AE PT with size based on count(incidence) of AEs, with coloration based on mean age of patients within that 'leaf'.

Also – if the user double clicks on any of the major nodes (SOC in this case) – the system zoom in on that node – just displaying the details of the contained leaf nodes for the selected SOC – Nervous Disorders in this case.   Also – in both the original display and the zoomed in display – clicking on any of the nodes broadcasts those patients to any other reports, graphs, etc. – as usual convention in JReview.

Alternatively – if numeric data such as labs are being included as the coloration – the system automatically sets up color range scales – which can be adjusted – to be auto ranging or zero based range or specified range based.   In this example – we're displaying max AlkPhos (change from baseline) by the levels Investigator, Sex – to see if identify investigator/gender patients with the highest change from baseline (more intense red).

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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