

JReview®

Version 12.0.1

Next Generation
JReview

The fastest, easiest way to review, graph, report and analyze your clinical data.

Web enabled software written specifically for pharmaceuticals, biotech and regulatory agencies. Provides many vital tools needed to perform clinical data review, ad hoc reporting, data visualization, analysis, risk assessment of clinical data and generate patient narratives.

New in version 12.0.1 - Composite Hy's Law Chart, Extended Reviewer Notes, Remap Terms

Select Study(s) for review
- also across projects

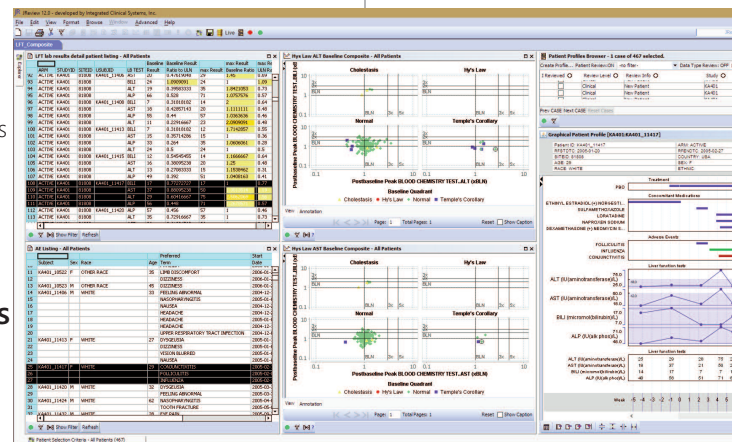
Open Dashboard Views
or traditional JReview User Interface

Dashboard Views

- Each 'favorite' tab displays reports, graphs, crosstabs, etc selected for inclusion, including **new composite Hy's Law chart**, reviewer notes
- Optionally a graphic or tabular patient profile is displayed in the rightmost frame.
- Click on graph points, report rows to highlight that patient in other displayed objects & profile.

Graphic and Tabular Patient Profiles

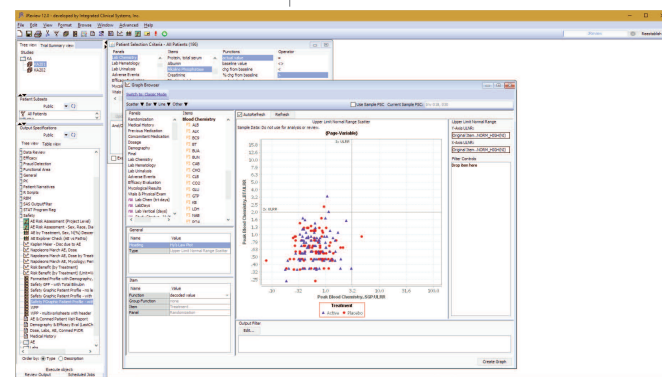
- Time oriented graphical display (days on drug): duration bars, trend plots with normal range.
- Tabular patient profiles (PDF) for high quality case summary or case report tabulations.



Select stored objects to explore the patient subset populations

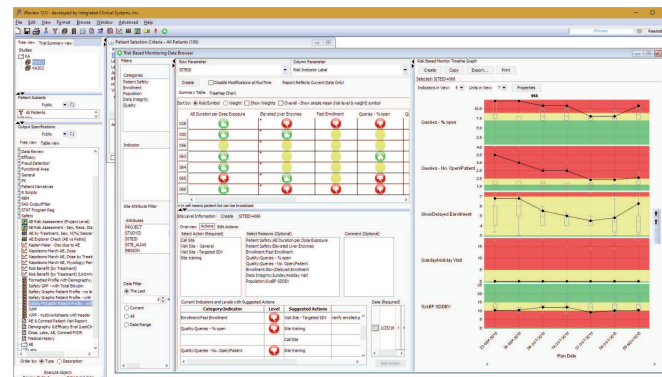
Drag & Drop Definition with Preview

- Interactive drag and drop definition interface for graphs, reports and crosstabs
- Interactive preview mode - see the graph, report, crosstab sample displayed as you add definitions - previewing the results on a data sample (quick)
- Vertical->Horizontal panel definition tells the system about vertically shaped data (labs, vitals, etc.) - so users can work with the lab tests, etc. without concern of the underlying data shape.



Risk Based Monitoring

- Centralized monitoring teams can define key risk categories and indicators from any clinical and operational data, set thresholds and specify suggested actions - with scheduled periodic analyses.
- The JReview RBM Data Browser - a Risk Indicator Results Visualization area - subset by risk categories, site attributes and interactively sort any column for site ranking. Suggested Actions can be reviewed, and actions taken entered.
- The RBM Data Browser also displays site distribution (box whiskers) over time, with selected site noted as line chart.



JReview integrates with commercial systems Oracle® Clinical, Oracle® LSH, Oracle® Clintrial, Oracle® AERS, ARGUS® and ARISg™. Using JReview's Data Dictionary (IRDD) it integrates directly with any Oracle, SQLServer or PostgreSQL based clinical data warehouse or EDC database such as Medidata Rave™, OmniComm TrialMaster®. Also integrates with SAS DD and SAS Datasets.

Patient Review Tracking

with formatted & spreadsheet profiles, reports

- After reviewing a patients data - click 'I-Reviewed' check-box - to mark event.
- Patients with new data since last review are highlighted,
- New data rows since last review date are also highlighted.

Report Browser

- Drag & Drop definition of Spreadsheet Reports. Formatted PDF Reports for high quality, easy to create reports. Patient Visit Data Report (Date merge reports)
- **New-Term ReMap** - remap terms to new groups/terms - useful for targetted AE groups, etc.
- **New-Extended Reviewer Notes** to report lines when enabled - to track review, status changes, comments. Green cells are 'editable' - and stored in separate note tables.

AE Risk Assessment

- Risk Ratio/Risk Differences - in interactive forest plot - displayed by MedDRA levels with hierarchy. TreeMap also displayed.
- Patient Subgroup - interactive display of selected patient characteristics - to detect patient distributions for selected AE SOC's, etc. or overlay subgroups on forest plot.

SAS® and R Program Browser

- Generates SAS code for selected SAS proc on selected items.
- Re-Execute SAS® or R Program you have registered to JReview.
- SAS® or R Programs are executed against the original SAS® datasets subsetted for the patient population meeting the current selection criteria defined - as well as parameterized row filters.

CrossTab Browser

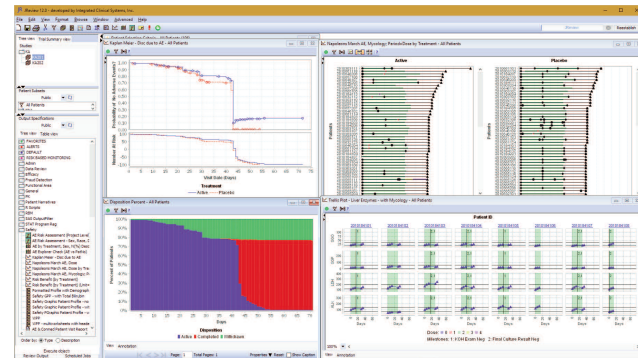
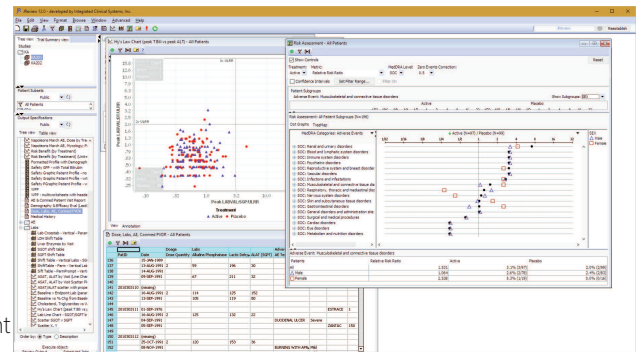
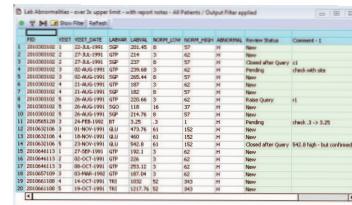
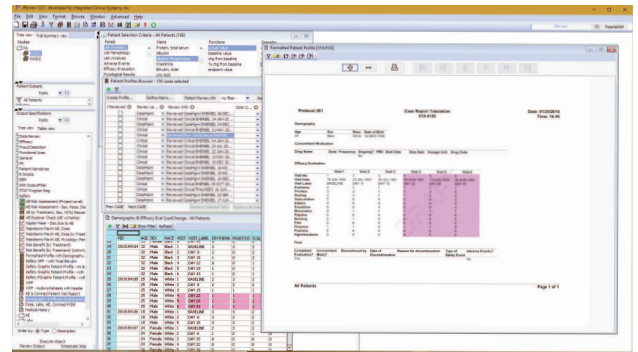
- Drag & Drop define of Crosstabs also allows users to identify patients underlying patient counts within each cell. Nested & Side by Side CrossTab
- Extensive col.sorting, N% & denominator control.

Graph Browser

- Drag & Drop definition with interactive preview mode.
- Multiple graphs per page - based on PageBy variable.
- **New Composite Hy's Law Chart** - baseline Hy's Law quadrant vs. peak Hy's Law location for each patient.
- Easy to create Graphs with drag and drop user interface
- Identify patients underlying graphical displays

Modest Set-up and Ongoing Support Requirements

- No Need for a dedicated Systems Administrator.
- 1/2 day of training typically needed for end users, 2 days for reporting authors.
- No custom programming.
- No reformatting of data required.
- Data dictionary driven configuration - study set-up is completed within minutes.



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