JReview®

The fastest, easiest way to review, graph, report and analyze your clinical data.
Web enabled software written specifically for pharmaceuticals, biotechs and regulatory agencies.
Provides many vital tools needed to perform clinical data review, ad hoc reporting, data visualization, analysis, risk assessment of clinical data, data quality analysis (CSM) and generate patient narratives.
New in version 13.1 - AE Incidence-Template Report, Data Quality Analysis (CSM), ...

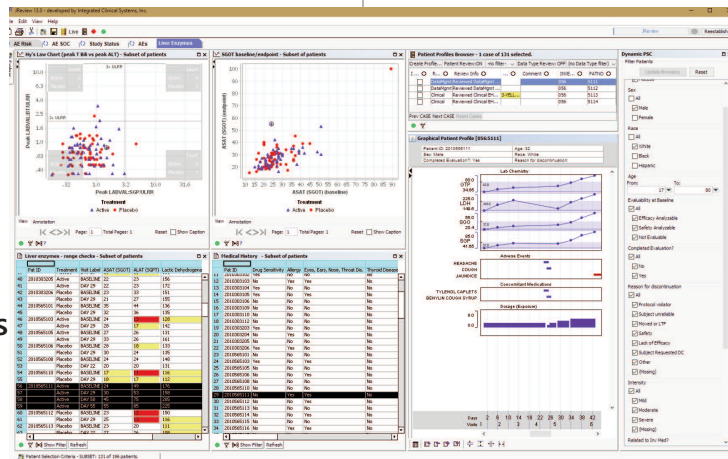**Select Study(s) for review - also across projects**

Open Dashboard Views or traditional JReview User Interface

Dashboard Views

- Each 'favorite' tab displays reports, graphs, crosstabs, etc selected for inclusion, including reviewer notes and new **Dynamic PSC** (patient selection criteria) for dynamic patient filtering.
- 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.

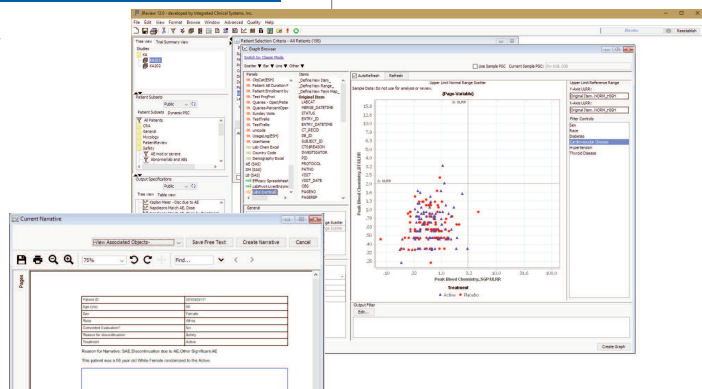## Graphic and Tabular Patient Profiles

- 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.)
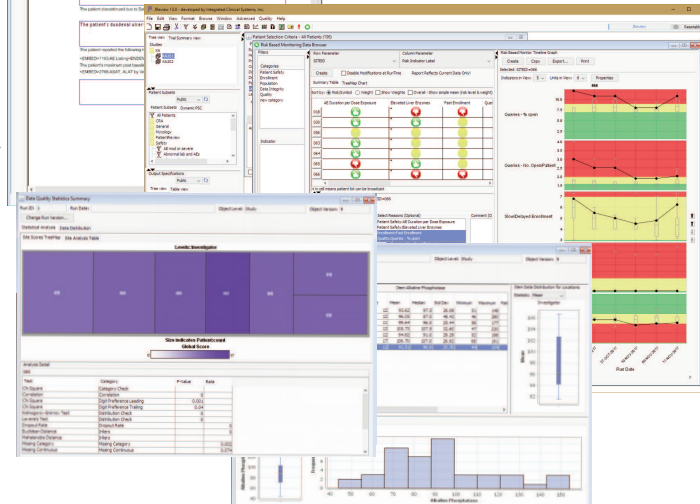
Automated Patient Narratives

- Define Patient Narrative templates-value substitution, conditional logic, embedded reports & graphs. Also enter additional free text interleaved with generated text.

Risk Based Monitoring and Data Quality Analysis (CSM) *new*

- Define RBM key risk indicators, thresholds, then review results in JReview RBM Data Browser - a Risk Indicator Results Visualization area - subset by risk categories, site attributes and interactively sort any column for site ranking - and over time.
- **New** Data Quality Analysis area executes a battery of statistical and other tests for 'unsupervised' overview of data by site - for data anomaly detection - presenting a global view by region & site - to detect sites needing a closer look.

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®, and SAS Datasets via SAS Share.

Patient Review Tracking
with formatted & spreadsheet profiles, reports
- After reviewing a patients data - click 'I-Reviewed' checkbox - 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)
- **Extended Reviewer Notes** - track review, status changes, comments. Green cells are 'editable' - data cells changed since last review are highlighted, status->'Updated'

Template Report Browser & AE Incidence Table
- Drag & Drop definition of Tempate based reports - quickly create reports similar to 'demographic summary reports', 'AE incident - nested sort table.
- Many 'packaged' group functions such as range, mean [sd]

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 - overlay subgroups on forest plot.

SAS® and R Program Browser
- Generates SAS code for selected SAS proc on selected
- 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.
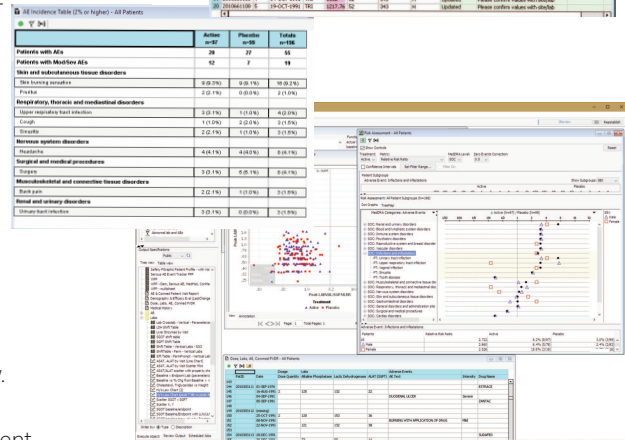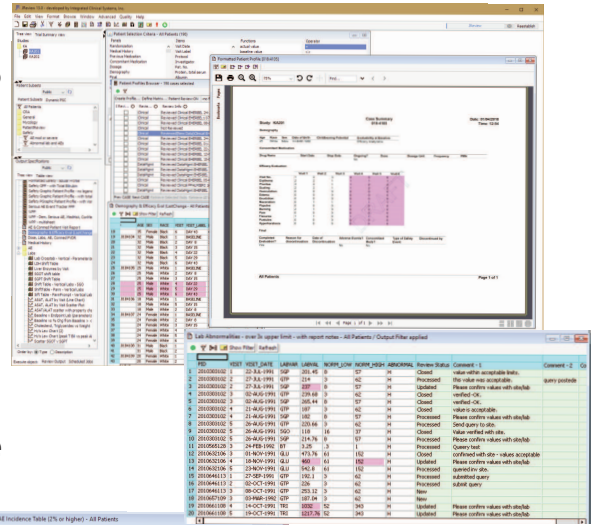
CrossTab Browser
- Drag & Drop define of Crosstabs also allows users to identify patients underlying patient counts within each cell. Nested & Side by Side CrossTab
- Extensive col.sorting, N% & denominator control.

Graph Browser
- Drag & Drop definition with interactive preview mode.
- Multiple graphs per page - based on PageBy variable.
- **New Swimmer, Waterfall & Sunburst plots**
  Composite Hy's Law - 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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