

Integrated Review™

Version 7.0

A clinical data review, reporting, multi-dimensional analysis, graphical and statistical modeling tool designed to integrate with your existing clinical trial and regulatory data management systems. New Graphical Patient Profiles - Easy to use, easy to set-up - accesses your clinical data directly.

Integrates with your clinical/regulatory data

- No custom programming required
- Immediate access to your clinical and regulatory data
- Access registered SAS® datasets via SAS/Share™ server

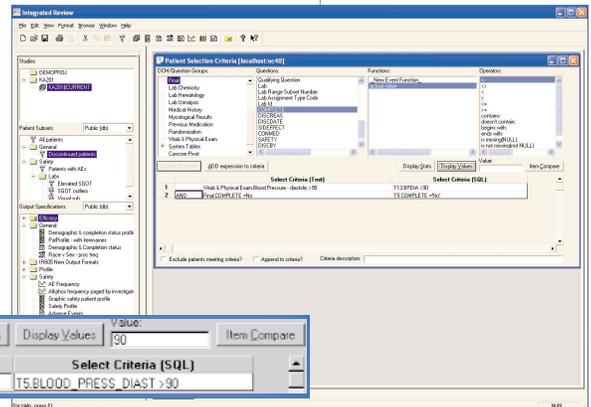
Client / Server Architecture

- Microsoft Windows client
- Server process accesses Oracle and SAS®
- Optimized networking using TCP/IP sockets.

Select Study(s) for review

Define Patient Subset for review

- Specify patient population subset criteria
- Click on Question Groups and Questions
- Specify the criteria value(s) from a list of values or type in a value
- Continue to add more criteria as needed and update browsers
- Or simply select from saved patient subset objects displayed in the Object Explorer.



Select browsers to explore the patient subset populations

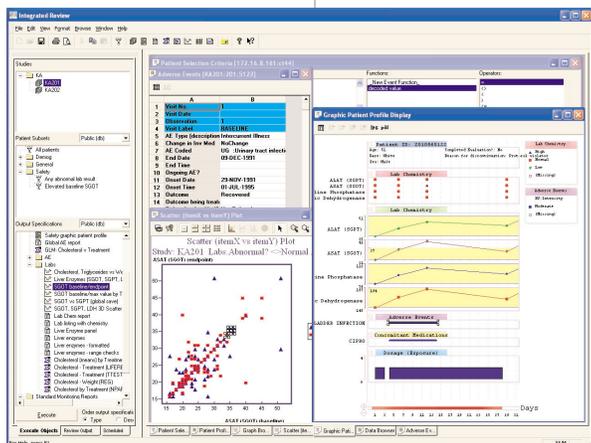
Patient Profiles Browser

Graphical Profiles

- Time oriented graphical display (days on drug):
 - duration bars for AEs, Concom meds, etc.
 - trend plots with normal range color region
 - high/low normal symbols for labs, vitals, etc
- Easy to setup - no programming, no data extraction or data manipulation required.
- Generate PDFs directly - for all patients selected

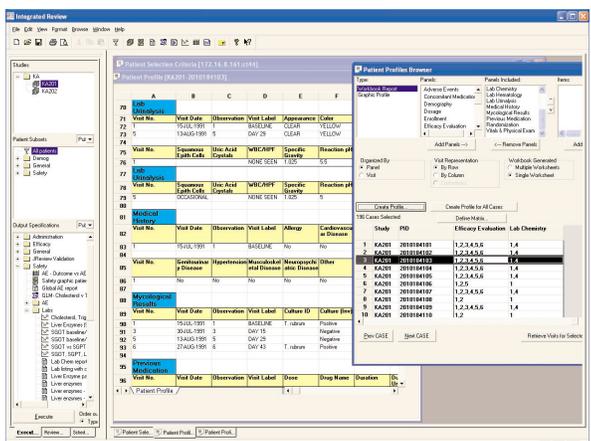
Tabular Profiles

- Displays selected patients and matrix of available data - Question Group or by Visit
- Optionally, request only a subset of question groups or items for each patient.
- Export to html, Excel spreadsheet, and more...



Data Browser

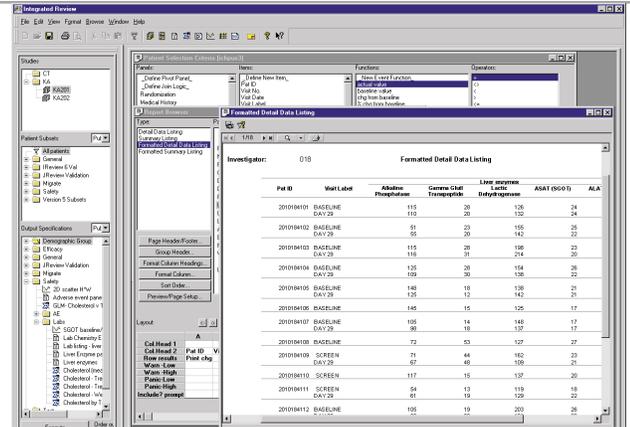
- View detail patient data DCM/Question views
- View Trend Graphs of patient data
- Browse patient data audit trails
- View data discrepancies (response history report)
- View source eCRF/CRF for selected data
- View Tags/Flags/Notes



Integrated Review integrates with commercial systems Oracle Clinical™, PhaseForward Clintrial™ 3.x, 4.x and Clintrace™, eResearch Technology eDataManagement and eSafetyNet, Clinarium ARISg™. Using Integrated Review's Data Dictionary (IRDD), Integrated Review integrates with any Oracle, Sybase or Microsoft SQLServer based clin.data mgmt system.

Report Browser

- New Formatted Reports for high quality, easy to create reports. Directly save to PDF.
- Specify Question and Reporting Clinically Relevant Function values: Actual values, Means, Baseline, Endpoint, Change from baseline, Patient Counts by Item Value, Change from prev
- Patient identification of graph points supported in Report Browser (spreadsheet reports)
- Save Report Specifications, Output (Results),
- Export to html, Excel spreadsheet, PDF, etc



SAS® Proc Browser

- Select from 11 default SAS® Procs to execute
- Create SAS® Datasets, SAS Transport files, and SAS® Views for the current patient subset population.
- Specify DCM Questions to be analyzed by clicking on the DCM Question and the appropriate function values

- Generate formats, attach formats, specify sort keys, specify index items, and composite index option...
- Schedule run-time (batch jobs) of your specified SAS® Proc for the defined patient subset population.
- Save results as PDF files directly
- electronic submission support - transport files & PDF documentation generated.

SAS® Program Browser (SAS® Library)

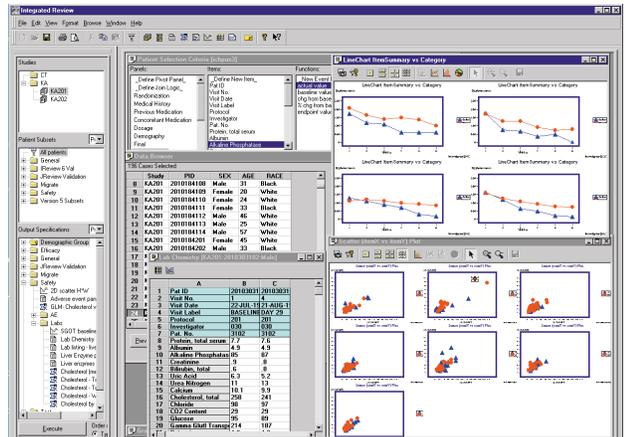
- Re-Execute SAS® Program you have registered to Integrated Review.
- SAS ODS output supported (PDF, RTF, CSV, etc).
- SAS® Programs are executed against the original SAS® datasets subsetted for the patient population meeting

the current selection criteria defined by the client using Integrated Review.

- Register SAS® Program Groups (Listed as a single batch job).
- Schedule the run-time of your SAS® Programs.
- Review SAS® Program output results (list,log,source).

CrossTab Browser

- Multi-dimensional clinical data analysis capabilities allow the user to identify patients underlying patient counts within each cell.



Graph Browser

- New Multiple graphs per page - based on PageBy variable.
- 21 different clinically relevant graphs templates
- Easy to create Graphs with simple point and click user interface
- Identify patients underlying graphical displays
- Graphically define patient subset populations, and much more...

Modest Set-up and Ongoing Support Requirements

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

Integrated Review is a trademark and JReview is a registered trademark of Integrated Clinical Systems, Inc.

Clintrial and Clintrace are trademarks of Phase Forward Corporation.

Oracle Clinical is a trademark of Oracle®.

SAS® is a registered trademark of SAS Institute

All other trademarks are held by their respective companies.

©2002 Integrated Clinical Systems, Inc.

Integrated Review™
The medical data review tool which supports ongoing collaboration with all members of the development team

38 Milltown Road, Stockton, NJ 08559 USA • (877) 996-4600
<http://www.i-review.com>

Integrated Clinical Systems, Inc.