

Integrated Clinical Systems, Inc. announces JReview 13.1 – with new AE Incidence Table (nested descending sort AE Table) Report Template, additional Graph Types, and a major new area – Data Quality Analysis for centralized statistical monitoring, and many other features.

Frenchtown, NJ – July 25, 2018

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 JReview version 13.1

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

Template Reports – major addition to template report area.

Initially introduced in version 13.0 – with the Demographic Summary Table ‘template’, version 13.1 adds the very commonly used ‘AE Incidence Table’ to the set. As with the ‘demographic summary table’ – it’s an easy to use drag and drop interface – adding the AE coded term levels to the definition – typically SOC and PT, as well as a ‘column’ variable – either Study, some other categorical item, etc. and some ‘general overview’ statistics – to display number of patients with AEs as well as different subsets, for example, number of patients with Serious AEs, etc. The default presentation is in descending order of most frequent SOC reports with PTs nested below, also in descending order of most frequent PT reports. The other very commonly requested feature is to be able to specify a cutoff % - for example – 2, which means that detail levels (PT) entries are only included if at least one of the entries for the PT are at least 2% of the population. And the SOCs are included only if at least one of their PTs meet the cutoff. Interestingly, the cutoff % or cutoff count is also interactive – so users can experiment with different cutoff % - to see the resulting content. If multiple columns, such as treatment group, are included, the user can choose which to use for descending sort, or <totals>. Here’s a screenshot of the ‘preview’ display of the Incidence table – showing the cutoff % selection of 2%:

Template Reports

Type ▼

Panels

- Randomization
- Medical History
- Previous Medication
- Concomitant Medication
- Dosage
- Demography
- Final
- Lab Chemistry
- Lab Hematology
- Lab Urinalysis
- Adverse Events
- Efficacy Evaluation
- Mycological Results
- Vitals & Physical Exam
- FBR: KA201.AE_DATA
- FBR: Lab Chem (trt days)
- FBR: LabDays
- FBR: Lab Vertical (days)

Items

- _Define New Item_
- _Define New Range_
- _Define New Term Map_
- Last Change Date
- Pat ID
- Visit No.
- Visit Date
- Visit Label
- Protocol
- Investigator
- Pat. No.
- Date of Randomization
- Treatment
- NI: Current Rand Date
- NI: StudyID

Designer Output

	Active	Placebo	Totals
Subject Count	97	99	196
Patients with AEs	28	27	55
	12	7	19
Skin and subcutaneous tissue disorders			
Skin burning sensation	9 (9.3%)	9 (9.1%)	18 (9.2%)
Pruritus	2 (2.1%)	0 (0.0%)	2 (1.0%)
Respiratory, thoracic and mediastinal disorders			
Upper respiratory tract infection	3 (3.1%)	1 (1.0%)	4 (2.0%)
Cough	1 (1.0%)	2 (2.0%)	3 (1.5%)
Sinusitis	2 (2.1%)	1 (1.0%)	3 (1.5%)
Nervous system disorders			
Headache	4 (4.1%)	4 (4.0%)	8 (4.1%)
Surgical and medical procedures			
Surgery	3 (3.1%)	5 (5.1%)	8 (4.1%)
Musculoskeletal and connective tissue disorders			
Back pain	2 (2.1%)	1 (1.0%)	3 (1.5%)
Gastrointestinal disorders			
Tooth disorder	1 (1.0%)	1 (1.0%)	2 (1.0%)
Renal and urinary disorders			
Urinary tract infection	3 (3.1%)	0 (0.0%)	3 (1.5%)

General

Name	Value
Count type	Subject Count
Cutoff number	2
Cutoff type	Cutoff is count
Decimal places (%)	1
Descend Sort By	<Totals>
Group row counts	<input type="checkbox"/>
Heading	Incidence Report
Include Subject Count	<input checked="" type="checkbox"/>
Include Total Column	<input checked="" type="checkbox"/>
Nested item sort	Descending

Item

Name	Value
Function	decoded value
Group Function	none
Item	Treatment
Panel	Randomization

Refresh Create Report

When the user either saves and executes the saved definition from the Object Explorer, or clicks the 'Create Report' button – a window displaying the results is displayed. Please note that the results are also clickable – just like a crosstab – so if the user clicks on any of the cells in the table – they'll see which patients are contained within the count (highlighting those patients in any reports, graphs, patient profiles displayed).

Incidence Report - All Patients

	Active	Placebo	Totals
Subject Count	97	99	196
Patients with AEs	28	27	55
	12	7	19
Skin and subcutaneous tissue disorders			
Skin burning sensation	9 (9.3%)	9 (9.1%)	18 (9.2%)
Pruritus	2 (2.1%)	0 (0.0%)	2 (1.0%)
Respiratory, thoracic and mediastinal disorders			
Upper respiratory tract infection	3 (3.1%)	1 (1.0%)	4 (2.0%)
Cough	1 (1.0%)	2 (2.0%)	3 (1.5%)
Sinusitis	2 (2.1%)	1 (1.0%)	3 (1.5%)
Nervous system disorders			
Headache	4 (4.1%)	4 (4.0%)	8 (4.1%)
Surgical and medical procedures			
Surgery	3 (3.1%)	5 (5.1%)	8 (4.1%)
Musculoskeletal and connective tissue disorders			
Back pain	2 (2.1%)	1 (1.0%)	3 (1.5%)
Gastrointestinal disorders			
Tooth disorder	1 (1.0%)	1 (1.0%)	2 (1.0%)
Renal and urinary disorders			
Urinary tract infection	3 (3.1%)	0 (0.0%)	3 (1.5%)

Scheduling

The 'print server/scheduling server' has been updated – supporting multiple 'threads' (configurable max number of threads), to multiple jobs at the same time. Scheduling of patient profiles and patient narratives continues to be supported as an optional module.

Graph Browser

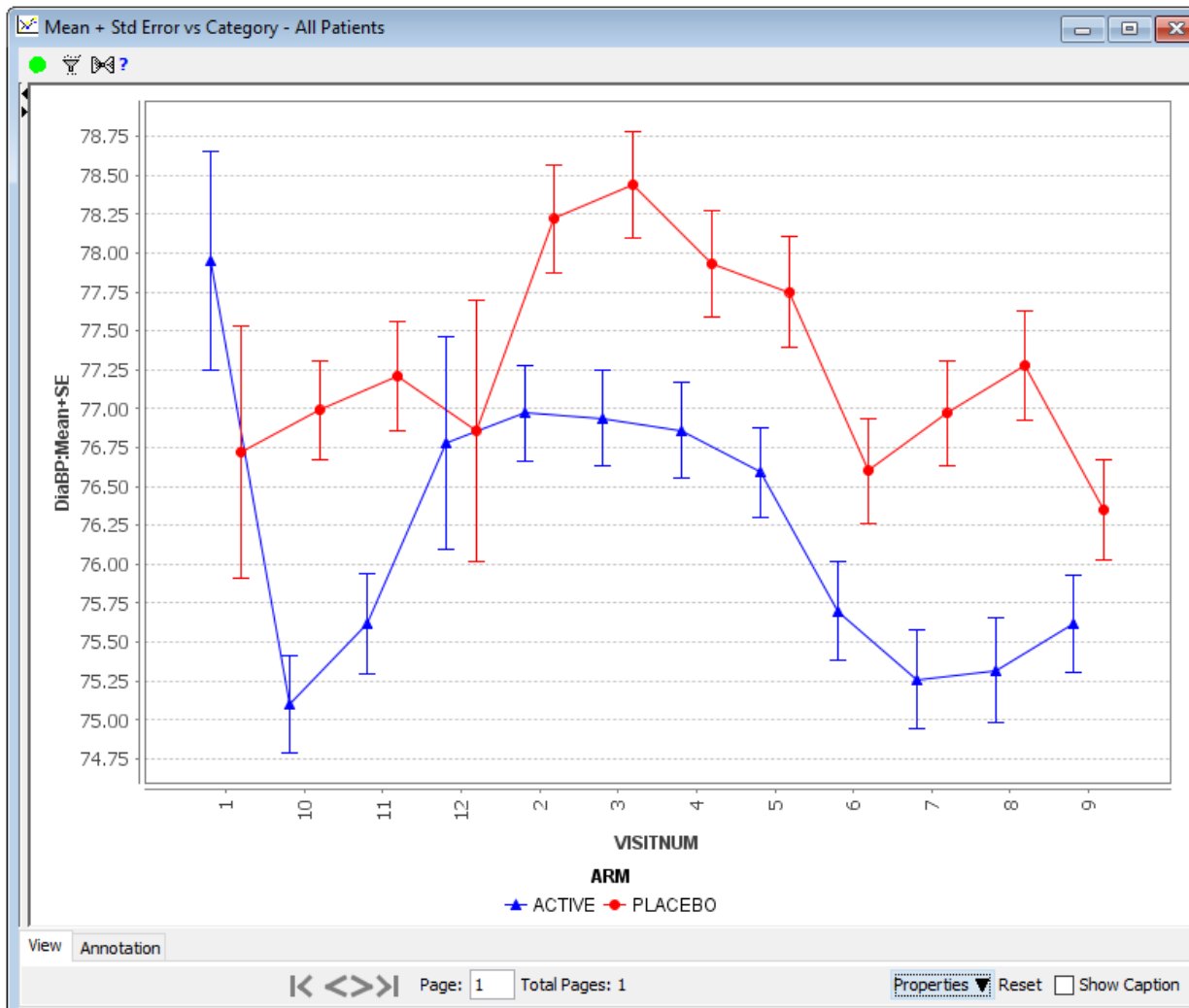
More control over graph properties – more colors – including more subdued colors as default, line thickness, symbol size, etc.

Continuing the addition of several graph patterns/types popular in oncology – version 13.1 adds two new graph types - a mean plus/minus standard error line chart and spider plot.

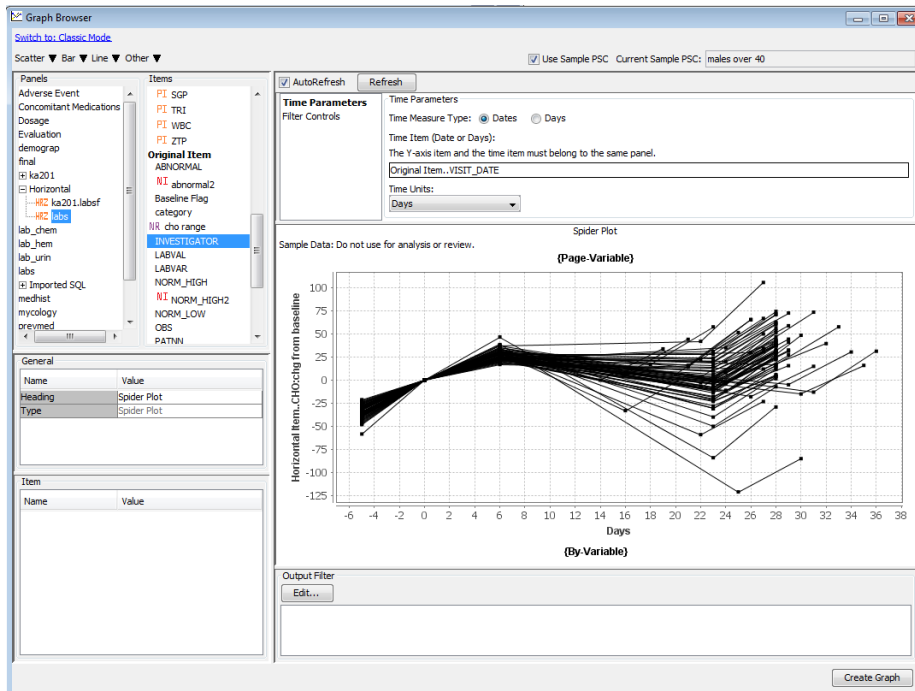
Line Chart – Mean +/- SE (Standard Error)

The error bars included in this line chart are Standard Error bars. Previously, only Std Dev was available.

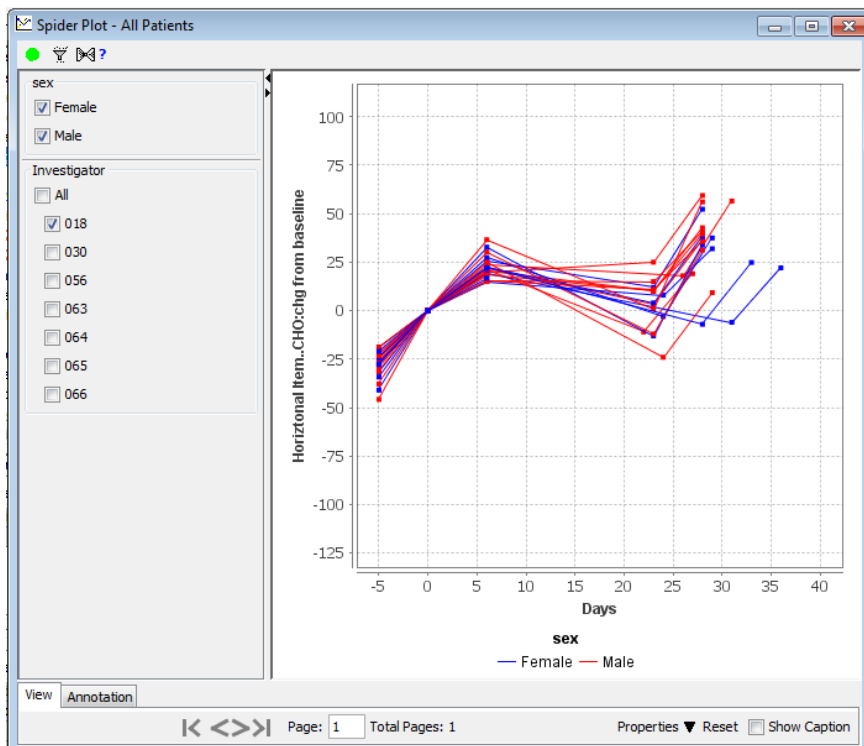
Here's an example screenshot:



The **spider plot** is used to display data over time (calculating days since a reference date on the fly), and by default plotting change from baseline values of the item on the y-axis. Here's the definition window, and a preview.



Here's a generated spider plot, with filter controls, to include/exclude specific groups, sites, etc.

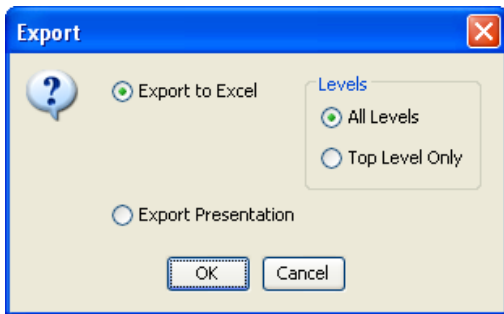


General – HRZ panels throughout

Previously, the HRZ panels (Vertical to Horizontal Panel definitions) were only available in the New UI in Graphs and Reports. Now – HRZ panels appear throughout JReview- including their use in Patient Selection Criteria, Output Filter, and any of the browser definition areas.

AE Risk Assessment

Added ability to export Risk Assessment information at multiple levels. After executing an AE Risk Assessment – the user can select ‘File ... Export’ – which displays the following dialog – where they can select if they want to export the details of the AE Risk Assessment – with All Levels of MEDDRA terms, or just the top level. Also – another option is to export the presentation (graphics).



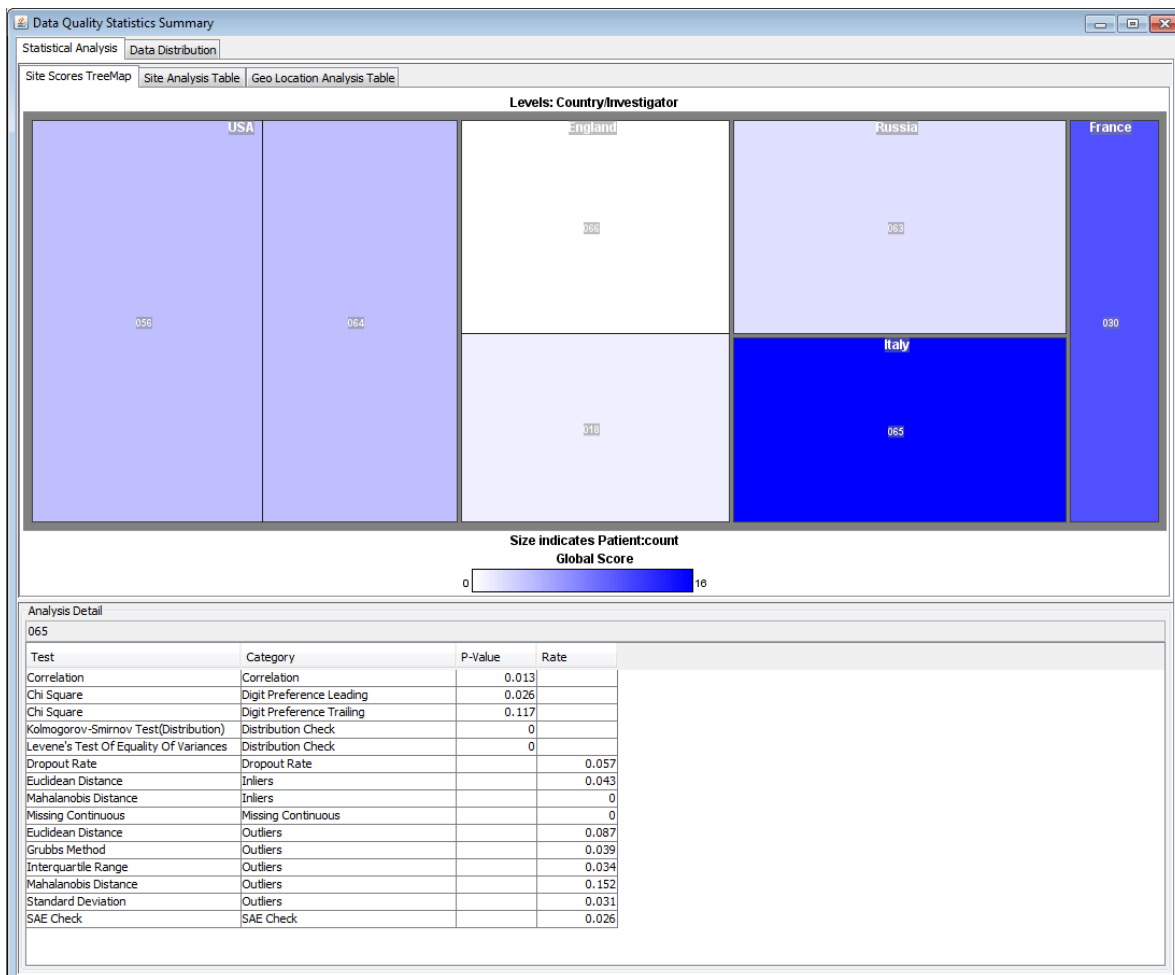
If the user selects ‘Export to Excel ... All Levels’ – here’s an example screenshot of the display – which includes a column for each of the MEDDRA levels that were included in the AE Risk Assessment – in this case SOC and PT, with the SOC repeated on each row for each PT:

Metric: Relative Risk Ratio (zero events corrected to 0.5)							
Treatment Group: Active							
Reference Group: Placebo							
Patient Subgroup: All Patient Subgroups (N=196)							
MedDRA Level: SOC							
Excluded Range:							
Date: March 15, 2018 12:13:34 PM EDT							
Treatment Groups	Size						
Active	97						
Placebo	99						
SOC	PT	Relative Risk Ratio	Lower CI Limit	Upper CI Limit	Occurrences in Treat	Ratio in Treatment	Occurrences in Refer
							Ratio in Reference
Renal and urinary disorders		7.144	0.371	137.514	3	0.031	0
Renal and urinary disorders	Urinary tract infection	7.144	0.371	137.514	3	0.031	0
Blood and lymphatic system disorders		3.062	0.125	74.848	1	0.010	0
Blood and lymphatic system disorders	Echymosis	3.062	0.125	74.848	1	0.010	0
Immune system disorders		3.062	0.125	74.848	1	0.010	0
Immune system disorders	Hypersensitivity	3.062	0.125	74.848	1	0.010	0
Psychiatric disorders		3.062	0.125	74.848	1	0.010	0
Psychiatric disorders	Somnolence	3.062	0.125	74.848	1	0.010	0
Reproductive system and breast disorders		3.062	0.125	74.848	1	0.010	0
Reproductive system and breast disorders	Vaginal infection	3.062	0.125	74.848	1	0.010	0
Vascular disorders		3.062	0.125	74.848	1	0.010	0
Vascular disorders	Echymosis	3.062	0.125	74.848	1	0.010	0
Infections and infestations		2.722	0.744	9.957	8	0.082	3
Infections and infestations	Urinary tract infection	7.144	0.371	137.514	3	0.031	0
Infections and infestations	Upper respiratory tract infec	3.062	0.324	28.929	3	0.031	1
Infections and infestations	Vaginal infection	3.062	0.125	74.848	1	0.010	0
Infections and infestations	Sinusitis	2.041	0.188	22.146	2	0.021	1
Infections and infestations	Tooth abscess	0.340	0.014	8.317	0	0.000	1
Musculoskeletal and connective tissue disorders		1.531	0.262	8.963	3	0.031	2
Musculoskeletal and connective tissue disorders	Arthritis	3.062	0.125	74.848	1	0.010	0
Musculoskeletal and connective tissue disorders	Back pain	2.041	0.188	22.146	2	0.021	1
Musculoskeletal and connective tissue disorders	Myalgia	0.340	0.014	8.317	0	0.000	1
Respiratory, thoracic and mediastinal disorders		1.225	0.387	3.881	6	0.062	5
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract infec	3.062	0.324	28.929	3	0.031	1
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	3.062	0.125	74.848	1	0.010	0
Respiratory, thoracic and mediastinal disorders	Sinusitis	2.041	0.188	22.146	2	0.021	1
Respiratory, thoracic and mediastinal disorders	Cough	0.510	0.047	5.537	1	0.010	2
Respiratory, thoracic and mediastinal disorders	Pharyngolaryngeal pain	0.340	0.014	8.317	0	0.000	1
Nervous system disorders		1.099	0.545	2.216	14	0.144	13
Nervous system disorders	Dizziness	3.062	0.125	74.848	1	0.010	0
Nervous system disorders	Dysgeusia	3.062	0.125	74.848	1	0.010	0
Musculoskeletal and connective tissue disorders		3.062	0.125	74.848	1	0.010	0

Data Quality Analysis – major new area

A major new capability has been added to JReview version 13.1 – which provides an ‘unsupervised’ centralized statistical review of data in a trial – on an ongoing basis – directly against the data accessed by JReview. This area runs a battery of tests against the data – including duplicate patient detection, and a wide range of statistical tests, then generates a ‘global score’ for each geographic area (country, for example), and each site within the region. The data to be included in the evaluation, as well as which tests should be included (default is all the tests that are included), plus weighting factors for generating the global score from the contributing tests – can all be selected/modified by the user setting up the definitions. Here’s a walk-through of the results – once an analysis has been conducted, followed by an overview of the definition area.

1. An overview display under the ‘Statistical Analysis’ tab, and ‘Site Score Treemap’ – shows the coloration of ‘global score’ – sites within country (optional level). When click on one of the sites, the darker color, the higher the ‘global score’ – the table below displays the ‘analysis details’ behind the global score.



When you click on the ‘Site Analysis Table’ or ‘Geo Location Analysis Table’ – (Geo Location in this screenshot) – you see the countries, and their respective ‘global score’, and the results of each of the specific analyses – a check mark means that country was ‘flagged’ for that analysis ... and each of the flagged analyses contribute to the ‘global score’ based on weighting factors that are defined in the definition screen – described below. If one of the analyses is blank (no checkbox) – that means the analysis wasn’t run – due to either not enough information, or the user had asked that the analysis not be included. Clicking on any of the country lines – updates the ‘Analysis Details’ table on the bottom of the window.

The screenshot shows a software window titled "Data Quality Statistics Summary" with two main sections. The top section is the "Geo Location Analysis Table" and the bottom section is the "Analysis Detail" table.

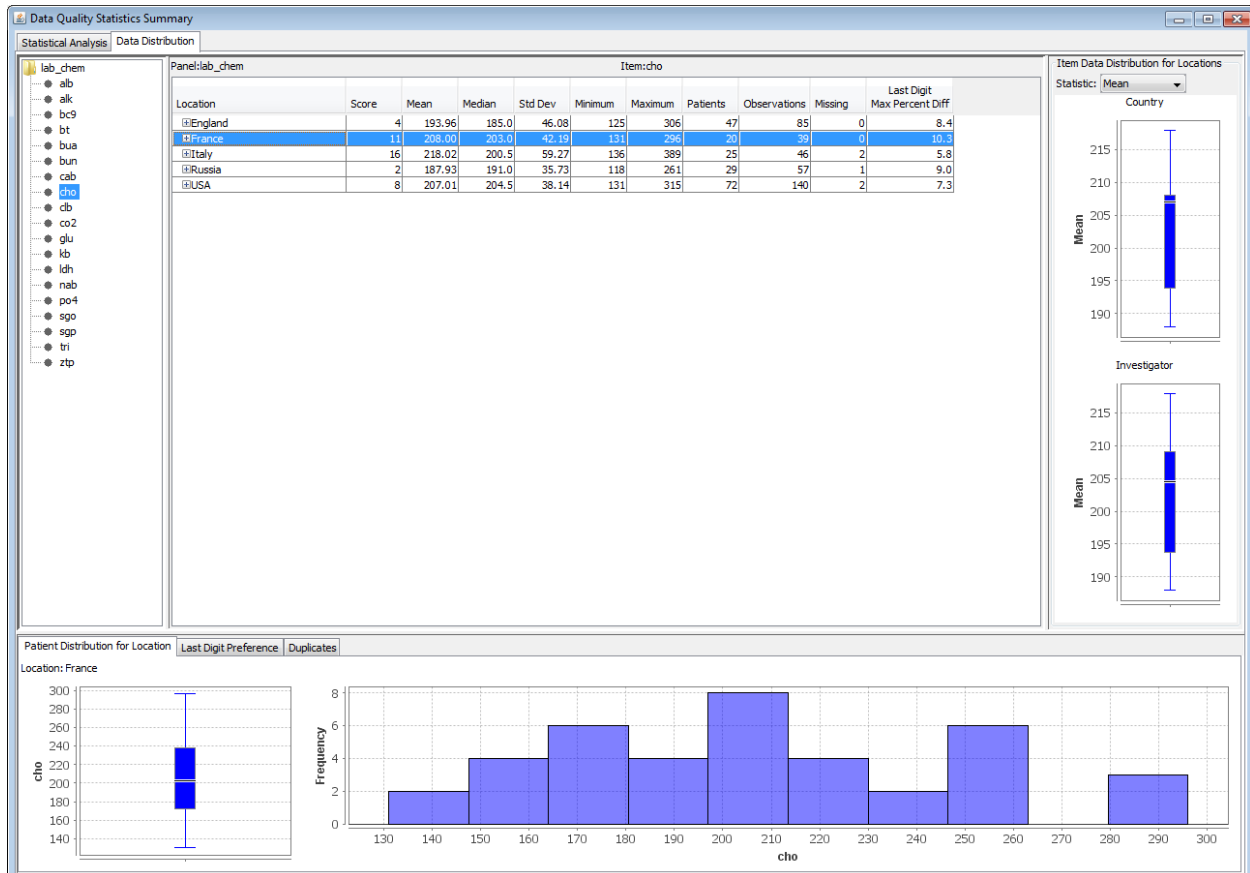
Geo Location Analysis Table

Location	Score	Category Check	Correlation	Digit Preference Leading	Digit Preference Trailing	Distribution Check	Dropout Rate	Duplicate Patients	Duplicate Records	Inliers	Integer Check	Missing Category	Missing Continuous	Outliers	SAE Check
Italy	16	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
France	11	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
USA	8	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
England	4	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Russia	2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

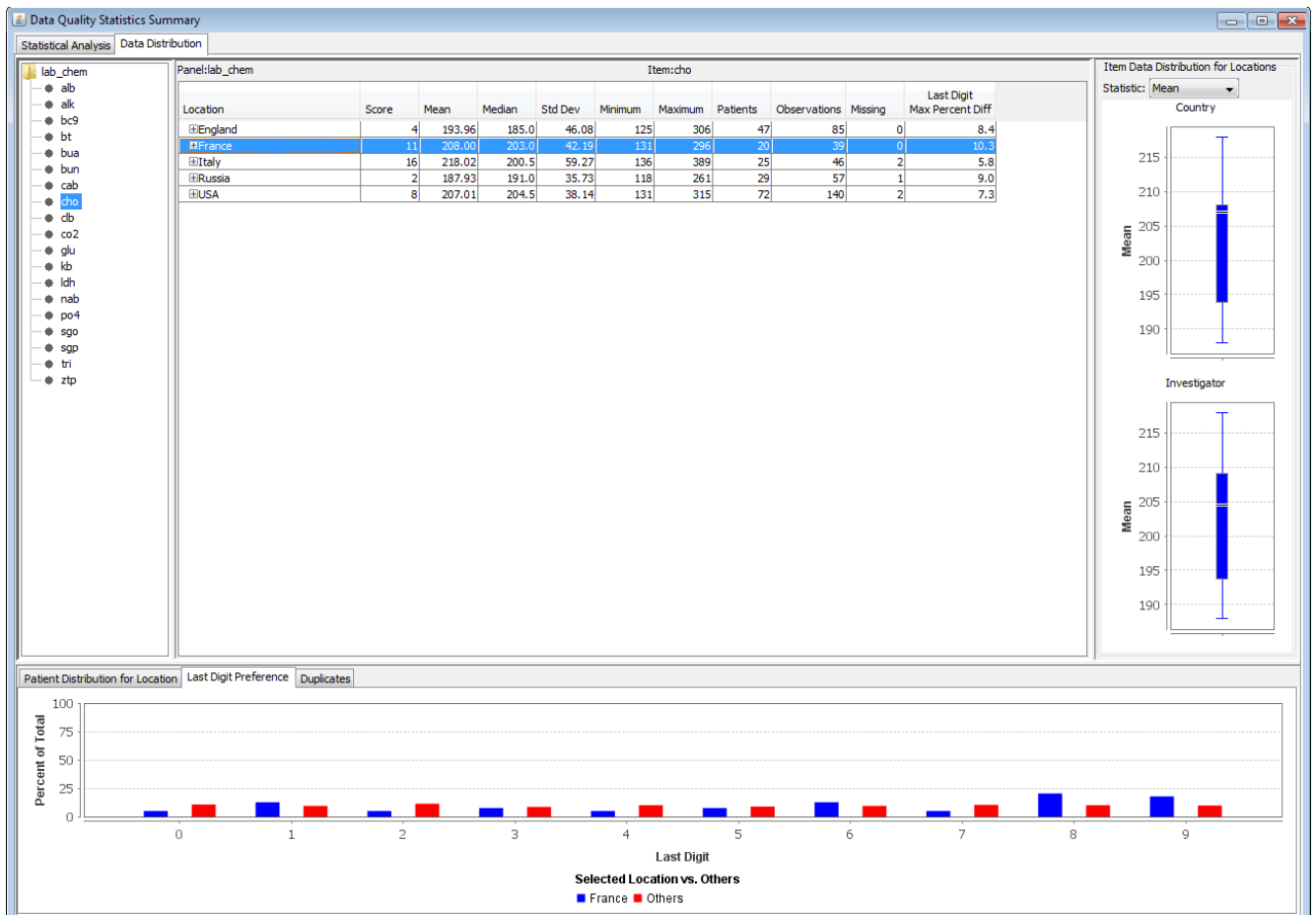
Analysis Detail

Test	Category	P-value	Rate
Correlation	Correlation	0.016	
Chi Square	Digit Preference Leading	0.026	
Chi Square	Digit Preference Trailing	0.117	
Kolmogorov-Smirnov Test(Distribution)	Distribution Check	0	
Levene's Test Of Equality Of Variances	Distribution Check	0	
Dropout Rate	Dropout Rate		0.057
Euclidean Distance	Inliers		0.043
Mahalanobis Distance	Inliers		0
Missing Continuous	Missing Continuous		0
Euclidean Distance	Outliers		0.087
Grubbs Method	Outliers		0.039
Interquartile Range	Outliers		0.034
Mahalanobis Distance	Outliers		0.152
Standard Deviation	Outliers		0.031
SAE Check	SAE Check		0.026

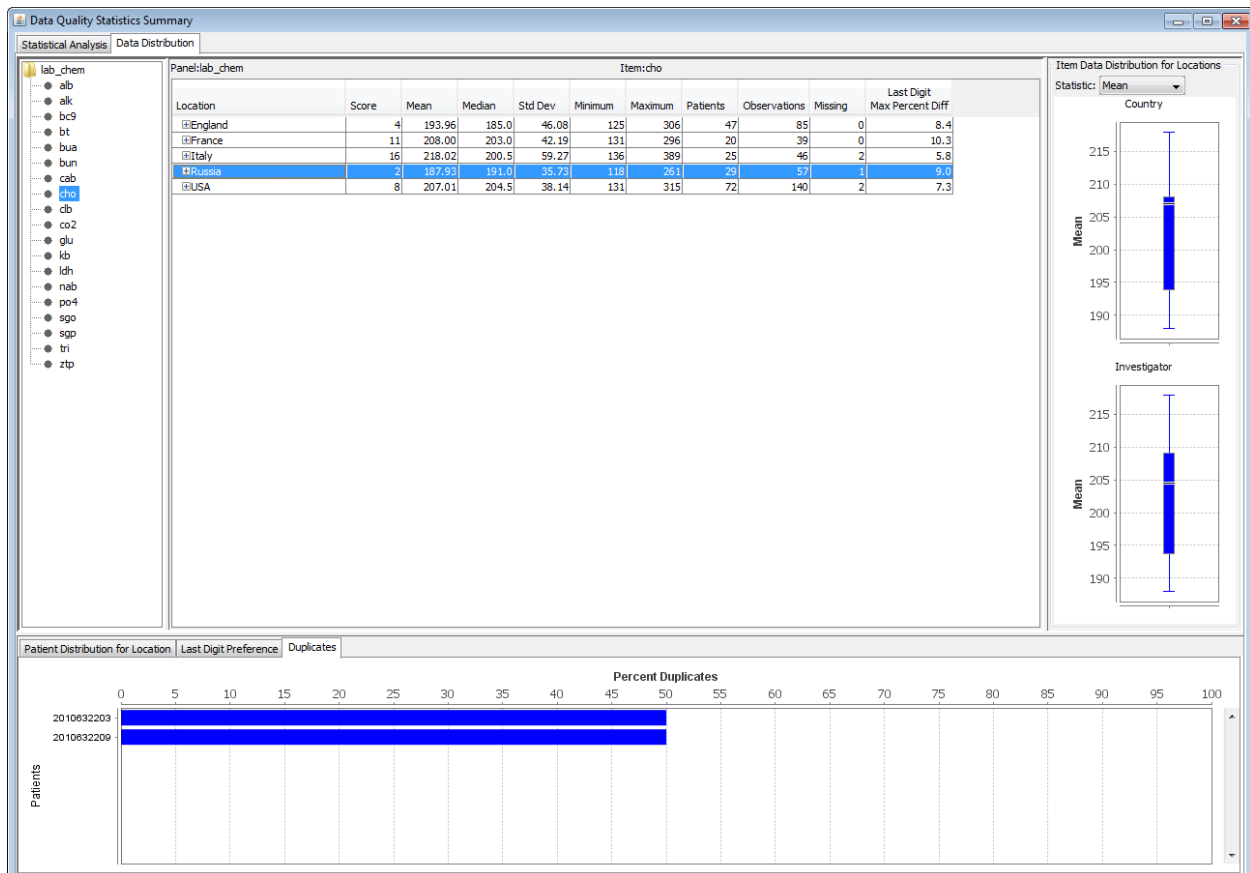
- Clicking on the 'Data Distribution' tab – displays a list of tables/datasets in the data, and items/columns within each. Clicking on any of the tables -> Items, then displays the details of a variety of statistics for that item – displayed by country, then clicking on '+' opens the country to display the included sites in the country. The Score (global score) column is included for information, but isn't specific to the item selected – the other statistics are ... but the score is present for information, and sorting purposes. Clicking on any of the countries or sites – then updates the other graphics on the page – data distribution for the item, histogram of distribution, etc.



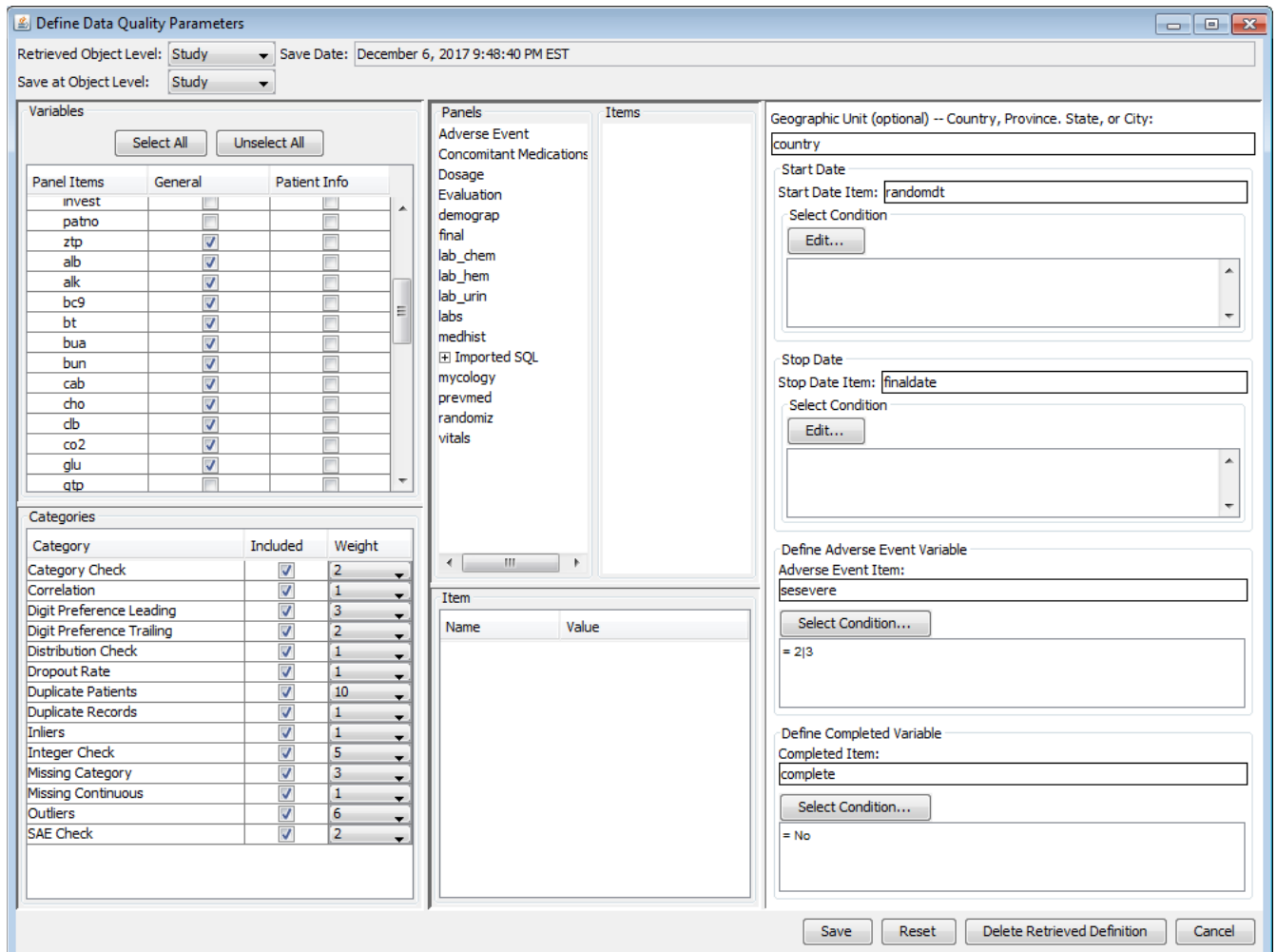
- Clicking on the 'Last Digit Preference' tab toward the bottom of the window – displays the digit preference for the country or site – compared to all others:



- Clicking on the Duplicates tab toward the bottom – displays the possible duplicate patients and ‘percent duplicates’. This info is driven by information provided during the definition step – described below:



- Definition step – done prior to scheduling analysis – selects which variables should be included (checked in the ‘general’ column, which items should be considered for ‘duplicate patient’ determination – checking items in the ‘Patient Info’ column. Next area is ‘Categories’ – those are the types of analyses that will be conducted – all are included by default. The weight column lets the user change the relative importance of each of the analyses. The definition areas to the right – are for options ‘GeoLocation’ definition (Country – typically), as well as information for Start and Stop dates (used during some of the analyses), location of an Adverse Event variable (with filtering possible), and Patient Completion information. All of these are considered during some of the analyses.



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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