
Benefits of a Rapidly Growing Library of Clinically Relevant Visualization Templates/Patterns

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JReview[®]



by Integrated Clinical Systems, Inc.

Topics

- Trends toward data standardization
- Typical ongoing study – clinical data review
- Continually evolving ways of visualizing clinical data
- Importance of quick use patterns/templates
- Rapid addition of clinically relevant visualization patterns/templates

Data Standardization

- Trends toward data standardization (CDISC)

FDA: Studies started after Dec 17, 2016 must use standards in the data catalog (SDTM, ADaM, SEND, define.xml)

That means – when submitting data – for those studies – data must be in standards based format.

<https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>

Study Data Collection

- Significant adoption of EDC/eSource

Many sponsors have standardized on use of EDC or eSource

Medidata Rave

Oracle Inform

Omnicom Trialmaster

Medrio

IBM/Merge

Clinical Ink

... more vendors emerging every day

Study Data Collection & Export

- EDC/eSource data structures

Typically not SDTM or standards based

-> 'EDC Raw Data Format'

- Data export format ('SAS on demand', etc.)

Typically not SDTM or standards based

-> 'EDC Raw Data Format'

Study Data Export

- Option to transform to SDTM on export

Many EDC vendors offer that – but most charge \$\$\$

- So – we're seeing:

- sponsors converting to standard format in-house

or

- reviewing ongoing studies in 'EDC raw data format'
then converting to SDTM later in the process

Data Visualization of ongoing study data

- Challenge of use a 'standard approach' to reviewing data on ongoing studies
- Standard Safety Review Library
based on FDA Safety Review Guidance

2 options:

1. spend time/resources developing data transformation to SDTM upfront for each study

- or -

2. spend time defining/developing data visualizations for each study

Ways of Visualizing Study Data

- Working with many FDA medical reviewers and sponsors customers

we see continually evolving ways of
visualizing clinical data

- How do we accommodate this?

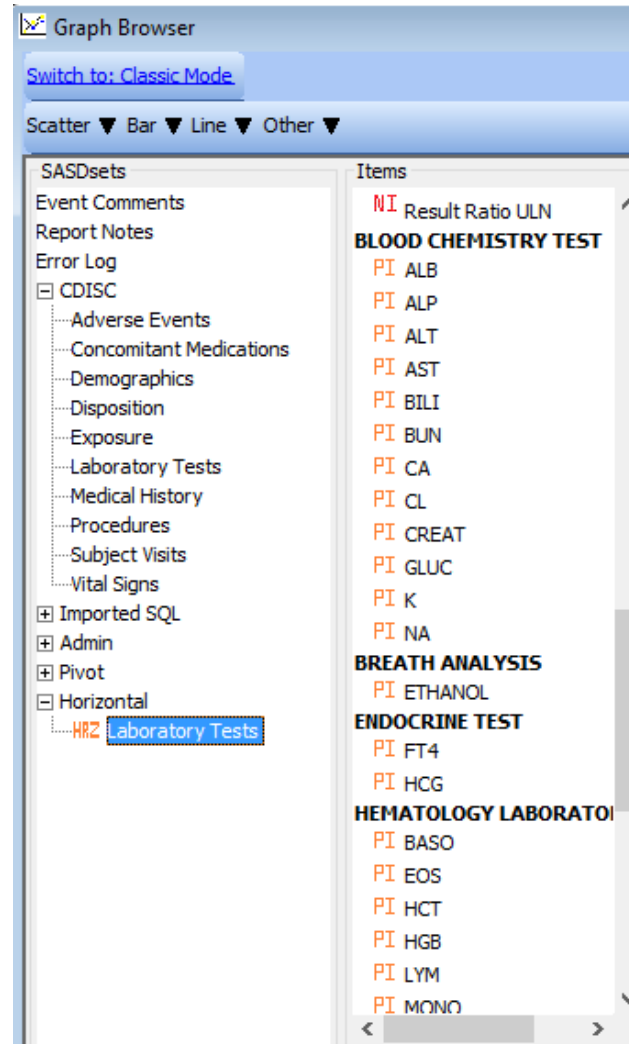
Quick use patterns/templates

- Design a system that presents a wide selection of clinically relevant visualization templates/patterns
- Build in intelligence – processes and complex algorithms in the templates
- Keep the user interface quick, easy, simple to use.
- Facilitate reusability by storing definitions at higher 'scope'/'level' (project or 'StudyGroup')

Facilitate use of common data shapes

- Many types of data/domains are vertical
Labs, ECGs, Vitals, etc.
- Very flexible for adding content
-> but really tough for reporting and graphing
- Define 'Vertical to Horizontal' transformation
once – per vertical dataset/domain & scope
- Use as 'virtual horizontal' structure thereafter

Vertical to Horizontal 'Virtual Panel'



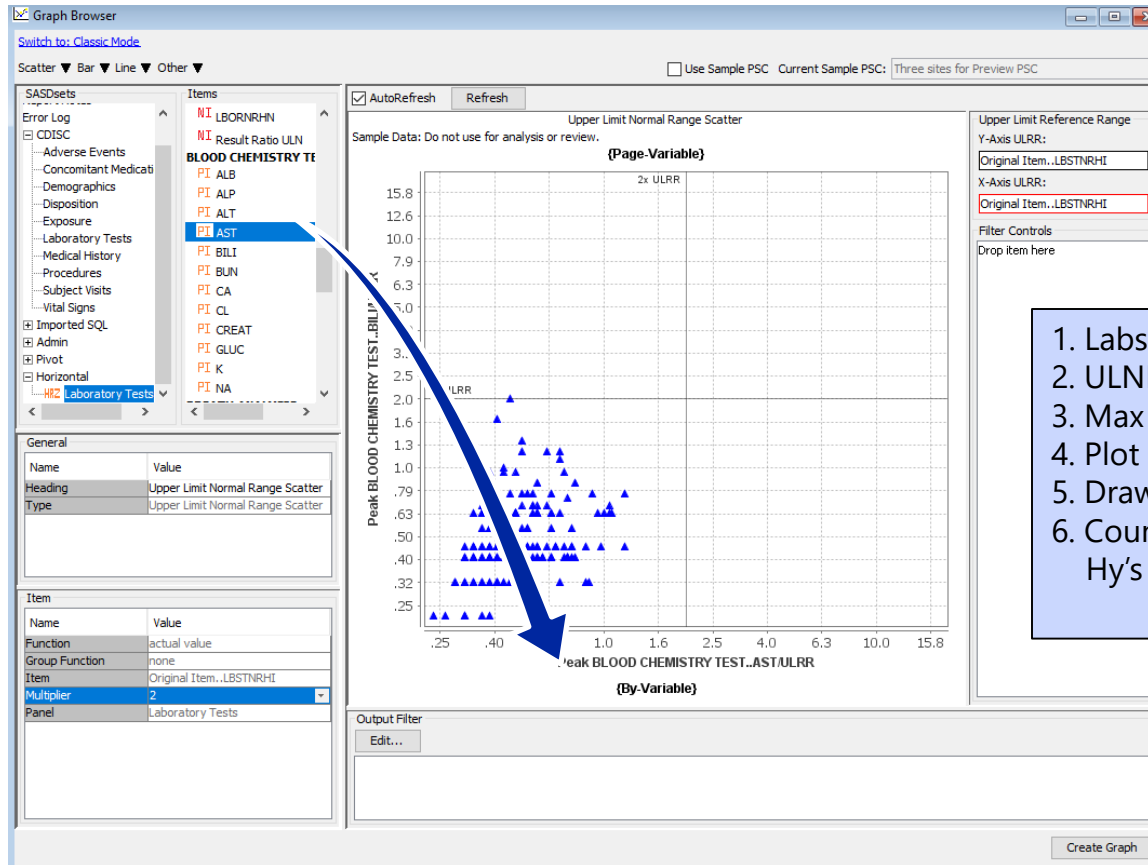
Rapid addition to clinically relevant templates

- Continually evolving ways of visualizing clinical data to pick up trends, outliers, signals
- Recent examples
 - FDA – 'composite Hy's Law chart'
 - Sponsor customers - Waterfall Plot, Swimmer Plot, Sunburst Plot
 - AE Incidence table & Demographic Summary Table
- Previous year-FDA Cardio-Renal div – histogram for data distribution, cumulative count by time, exposure by dose, disposition percent
- Earlier – Napoleon's March, Benefit/Risk, Volcano Plot, AE Risk Assessment, Spaghetti Plot, Tree map/Heat map
- Original set – baseline vs min/max or endpoint, box whiskers, bar chart freq, pareto plot, line chart over time, bubble chart, Kaplan Meier, Timeline Trellis.

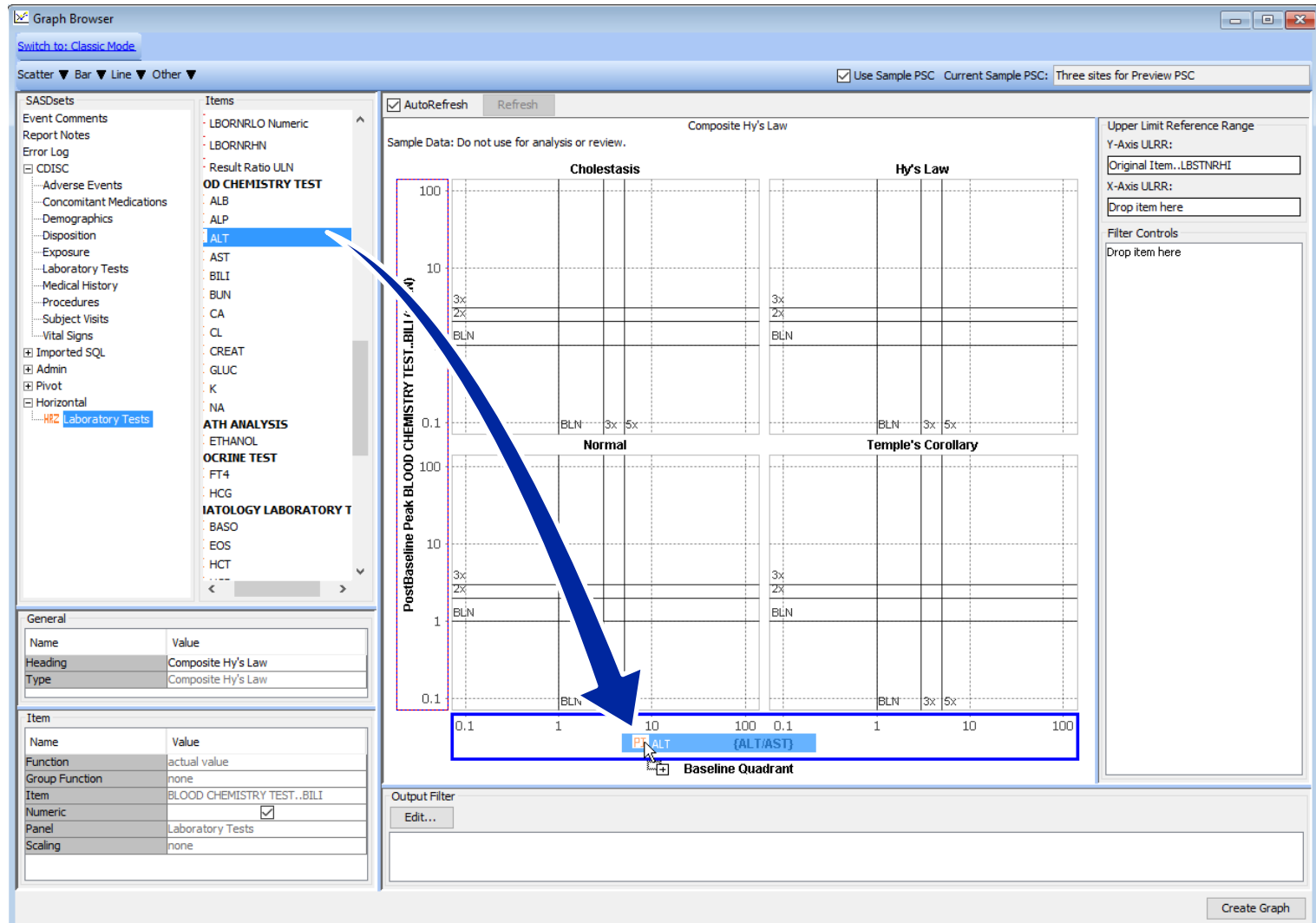
Characteristics of clinically relevant templates

- Not just – scatter plot, bar chart, line chart, etc.
- Graph type defined, but then clinically relevant definitions, processes, algorithms embedded in the template, i.e., baseline or endpoint or ratio of peak value to ULNR, etc.
- Automatically handle data shape transformations – to be able to easily work with vertically shaped data.
- Easy to use user interface – drag and drop – to select which variables to use in the template.
- Build in the complexities necessary for the visualization – but keep it simple for the user!

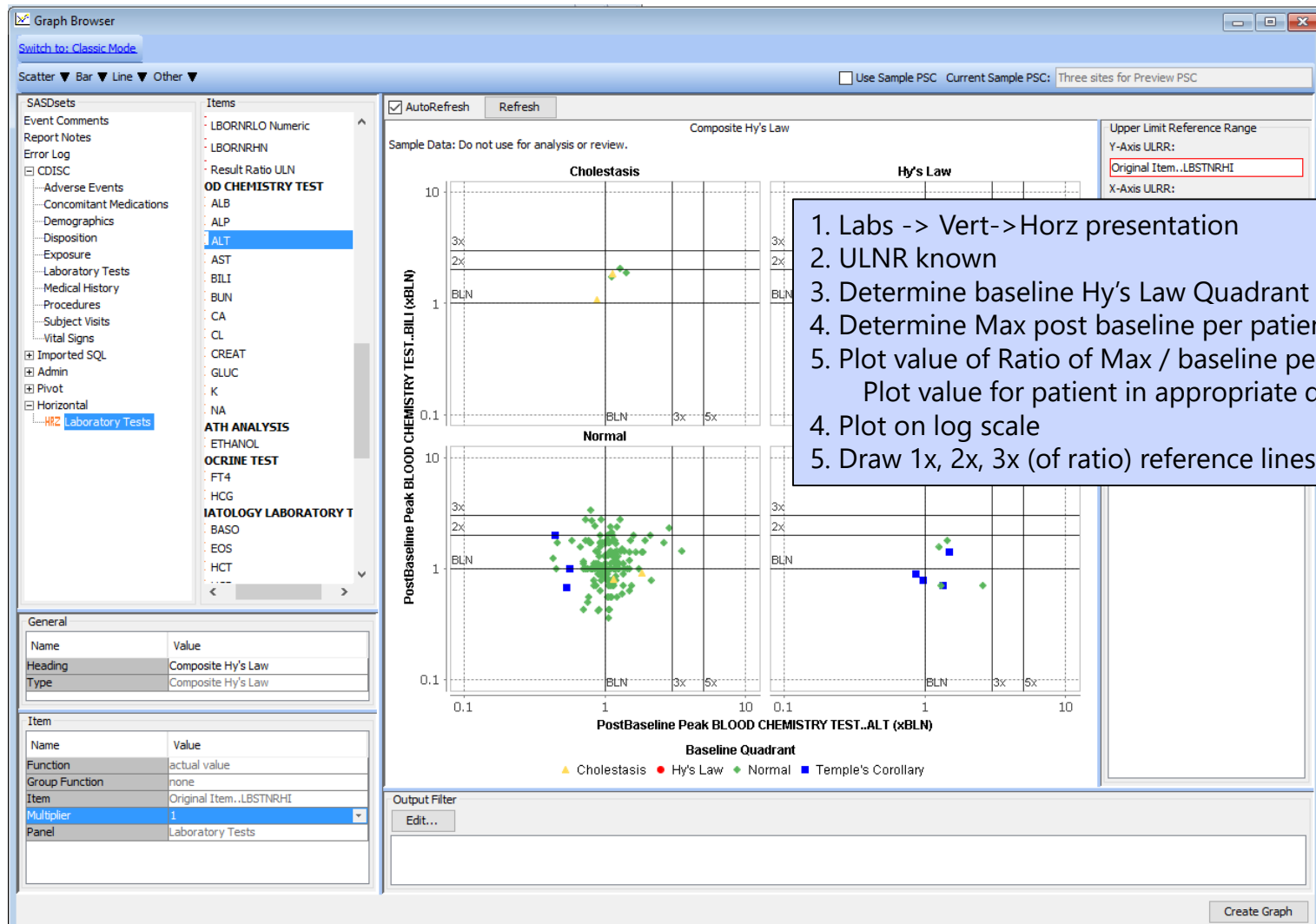
Hy's Law Chart – drag & drop UI



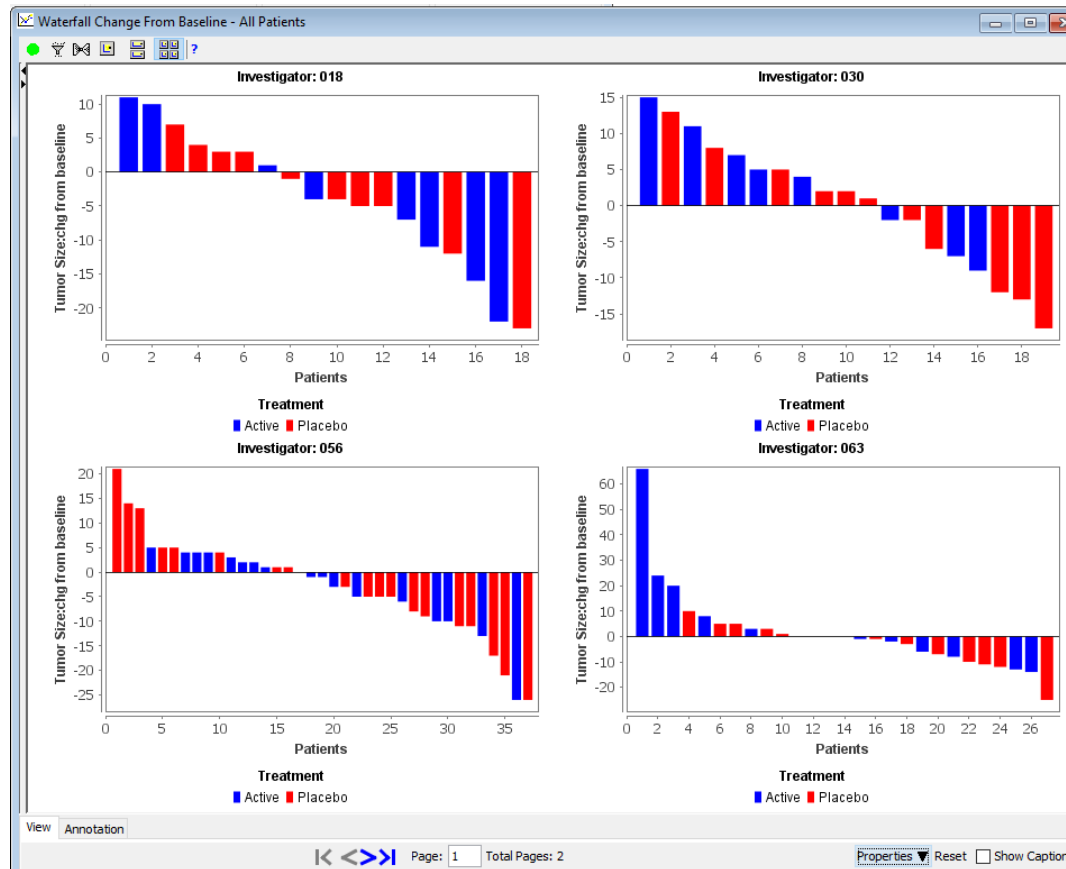
Composite Hy's Law Chart – drag & drop UI



Composite Hy's Law Chart



Waterfall Plot



Swimmer Lane Plot



Demographic Summary Table

Template Reports [Object:5182]

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
- PK: KA201.AE_DATA
- PK: Lab Chem (trt days)
- PK: LabDays
- PK: 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.
- Race
- Sex
- Date of birth
- Age
- Childbearing Potential
- Evaluability at Baseline
- NI Merge DataTime

General

Name Value

Decimal places (%) 1

Descend Sort By <Totals>

Heading Demographic Summary Report

Include Subject Count ☒

Include Total Column ☒

Item

Name Value

Demographic Summary Report

Designer Output

Columns

Treatment

Filter

Report Rows - To Group/UnGroup select rows then right click

Group Desc	Item Desc	Function	Group Func	Sort	Filter
Age	mean and std. dev.	mean and std. dev.	range	NONE	Filter
Sex - count subjects and %	decoded value	count s		NONE	Filter
Race - count subjects and %	decoded value	count s			
Evaluability at Baseline - count subjects and %	decoded value	count s			
Completed Evaluation? - count subjects and %	decoded value	count s			
Reason for discontinuation - count subjects and %	decoded value	count s			
AE Intensity - count subjects and %	decoded value	count s			
Related to Inv Med? - count subjects and %	decoded value	count s			

Demographic Summary Report

Designer Output

Subject Count	Active	Placebo	Totals
Age			
mean and std. dev.	44.43 [16.26]	44.01 [16.21]	44.22 [16.19]
range	17-80	18-80	17-80
Sex - count subjects and %			
Male	78 (80.4%)	83 (83.8%)	161 (82.1%)
Female	19 (19.6%)	16 (16.2%)	35 (17.9%)
Race - count subjects and %			
White	77 (79.4%)	82 (82.8%)	159 (81.1%)
Black	16 (16.5%)	9 (9.1%)	25 (12.8%)
Hispanic	4 (4.1%)	8 (8.1%)	12 (6.1%)
Evaluability at Baseline - count subjects and %			
Efficacy Analyzable	79 (81.4%)	85 (85.9%)	164 (83.7%)
Safety Analyzable	17 (17.5%)	14 (14.1%)	31 (15.8%)
Not Evaluable	1 (1.0%)	0 (0.0%)	1 (0.5%)
Completed Evaluation? - count subjects and %			
Yes	76 (78.4%)	74 (74.7%)	150 (76.5%)
No	21 (21.6%)	25 (25.3%)	46 (23.5%)
Reason for discontinuation - count subjects and %			
Lack of Efficacy	2 (2.1%)	17 (17.2%)	19 (9.7%)
Protocol violator	12 (12.4%)	5 (5.1%)	17 (8.7%)
Moved or LTF	1 (1.0%)	2 (2.0%)	3 (1.5%)
Subject unreliable	3 (3.1%)	0 (0.0%)	3 (1.5%)
Subject Requested DC	2 (2.1%)	0 (0.0%)	2 (1.0%)
Other	0 (0.0%)	1 (1.0%)	1 (0.5%)
Safety	1 (1.0%)	0 (0.0%)	1 (0.5%)
AE Intensity - count subjects and %			
Mild	20 (20.6%)	18 (18.2%)	38 (19.4%)
Moderate	11 (11.3%)	7 (7.1%)	18 (9.2%)
(missing)	3 (3.1%)	5 (5.1%)	8 (4.1%)
Severe	1 (1.0%)	0 (0.0%)	1 (0.5%)
Related to Inv Med? - count subjects and %			

AE Incidence Table

Template Reports [Object:5552]

Type ▼

Panels

- Randomization
- Medical History
- Previous Medication
- Concomitant Medication
- Dosage
- Demography**
- Final
- Lab Chemistry
- Lab Hematology
- Lab Urinalysis
- Adverse Events
- Efficacy Evaluation
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- Race
- Sex
- Date of Birth
- Age
- Childbearing Potential
- Evaluability at Baseline
- NI Merge DateTime

Incidence Report

Designer Output

Columns

Treatment

Filter

Top Summary Rows - To Group/UnGroup select rows then right click

Group Desc	Item Desc	Group Func	Filter
	AE Text - count subjects with data	count subjects with data	Filtered
	Intensity - Moderate/Severe	count subjects with data	Filtered
	Ongoing AE? - count subjects with data	count subjects with data	Filtered

Nested Row Items

count subjects and % SOC
count subjects and % PT

Filter

Incidence Report

Designer Output

	Active	Placebo	Totals
Subject Count	97	99	196
AE Text - count subjects with data	28	27	55
Intensity - Moderate/Severe	12	7	19
Ongoing AE? - count subjects with data	3	1	4
Skin and subcutaneous tissue disorders	10 (10.3%)	11 (11.1%)	21 (10.7%)
Skin burning sensation	9 (9.3%)	9 (9.1%)	18 (9.2%)
Pruritus	2 (2.1%)	0 (0.0%)	2 (1.0%)
Skin disorder	0 (0.0%)	1 (1.0%)	1 (0.5%)
Skin odour abnormal	0 (0.0%)	1 (1.0%)	1 (0.5%)
Respiratory, thoracic and mediastinal disorders	6 (6.2%)	5 (5.1%)	11 (5.6%)
Upper respiratory tract infection	3 (3.1%)	1 (1.0%)	4 (2.0%)
Sinusitis	2 (2.1%)	1 (1.0%)	3 (1.5%)
Cough	1 (1.0%)	2 (2.0%)	3 (1.5%)
Respiratory disorder	1 (1.0%)	0 (0.0%)	1 (0.5%)
Pharyngolaryngeal pain	0 (0.0%)	1 (1.0%)	1 (0.5%)
Nervous system disorders	5 (5.2%)	4 (4.0%)	9 (4.6%)
Headache	4 (4.1%)	4 (4.0%)	8 (4.1%)
Dizziness	1 (1.0%)	0 (0.0%)	1 (0.5%)
Dysgeusia	1 (1.0%)	0 (0.0%)	1 (0.5%)
Surgical and medical procedures	3 (3.1%)	5 (5.1%)	8 (4.1%)
Surgery	3 (3.1%)	5 (5.1%)	8 (4.1%)
Renal and urinary disorders	3 (3.1%)	0 (0.0%)	3 (1.5%)
Urinary tract infection	3 (3.1%)	0 (0.0%)	3 (1.5%)
Musculoskeletal and connective tissue disorders	3 (3.1%)	2 (2.0%)	5 (2.6%)
Back pain	2 (2.1%)	1 (1.0%)	3 (1.5%)
Arthritis	1 (1.0%)	0 (0.0%)	1 (0.5%)
Myalgia	0 (0.0%)	1 (1.0%)	1 (0.5%)
Gastrointestinal disorders	2 (2.1%)	2 (2.0%)	4 (2.0%)
Proctalgia	1 (1.0%)	0 (0.0%)	1 (0.5%)
Tooth disorder	1 (1.0%)	1 (1.0%)	2 (1.0%)
Duodenal ulcer	1 (1.0%)	0 (0.0%)	1 (0.5%)

General

Name Value

Count type Subject Count

Cutoff number 1

Cutoff type Cutoff is count

Decimal places (%) 1

Descend Sort By Active

Group row counts

Heading Incidence Report

Include Subject Count

Include Total Column

Nested item sort Descending

Item

Name Value

AE Incidence Table

Cutoff 2% or greater

Template Reports [Object:5552]

Type ▼

Panels

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- Concomitant Medication
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- Race
- Sex
- Date of Birth
- Age
- Childbearing Potential
- Evaluability at Baseline
- NI Merge DateTime

General

Name	Value
Count type	Subject Count
Cutoff number	2
Cutoff type	Cutoff is count
Decimal places (%)	1
Descend Sort By	Active
Group row counts	☐
Heading	Incidence Report
Include Subject Count	☒
Include Total Column	☒
Nested item sort	Descending

Item

Name	Value

Incidence Report

Designer Output

	Active	Placebo	Totals
Subject Count	97	99	196
AE Text - count subjects with data	28	27	55
Intensity - Moderate/Severe	12	7	19
Ongoing AE? - count subjects with data	3	1	4
Skin and subcutaneous tissue disorders			
Skin burning sensation	9 (9.3%)	9 (9.1%)	18 (9.2%)
Puritus	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%)
Sinusitis	2 (2.1%)	1 (1.0%)	3 (1.5%)
Cough	1 (1.0%)	2 (2.0%)	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%)
Renal and urinary disorders			
Urinary tract infection	3 (3.1%)	0 (0.0%)	3 (1.5%)
Musculoskeletal and connective tissue disorders			
Back pain	2 (2.1%)	1 (1.0%)	3 (1.5%)
Tooth disorder	1 (1.0%)	1 (1.0%)	2 (1.0%)

Refresh Create Report

Other Important Considerations

- Integrate with many clinical data sources
- Dynamic multi-study pooling
- Built-in 'patient identification/drill down'
- Patient review tracking & report review notes
- Many clinically relevant graphics, tabulations, patient profiles, risk assessments, etc. including defining critical data
- Graph Patient Profiles – directly access study data (no need for external data setup) – run-time day calculations
- Built in codelist/sas format awareness
- SAS/R program integration
- Patient Narratives

Dashboard Views in JReview

JReview 12.0 - developed by Integrated Clinical Systems, Inc.

File Edit View Format Browse Window Advanced Help

Live

Review Reestablish

LFT_Composite

LFT lab results detail patient listing - All Patients

ARM	STUDYID	SITEID	USUBJID	LAB TEST	Baseline Result	max Result	Baseline Ratio	max Ratio
92	ACTIVE	KA401	81808	AST	20	0.47619048	29	1.45
93	ACTIVE	KA401	81808	ALT	24	1.0909091	24	1
94	ACTIVE	KA401	81808	ALT	19	0.39583333	35	1.8421053
95	ACTIVE	KA401	81808	ALT	66	0.528	71	1.0757576
96	ACTIVE	KA401	81808	ALT	7	0.31818182	14	2
97	ACTIVE	KA401	81808	AST	18	0.42857143	20	1.1111111
98	ACTIVE	KA401	81808	ALT	55	0.44	57	1.0363636
99	ACTIVE	KA401	81808	ALT	11	0.22916667	23	2.0909091
100	ACTIVE	KA401	81808	ALT	7	0.31818182	12	1.7142857
101	ACTIVE	KA401	81808	AST	15	0.35714286	15	1
102	ACTIVE	KA401	81808	ALT	33	0.264	35	1.0606061
103	ACTIVE	KA401	81808	ALT	24	0.5	24	1
104	ACTIVE	KA401	81808	ALT	12	0.54545455	14	1.1666667
105	ACTIVE	KA401	81808	ALT	16	0.38095238	20	1.25
106	ACTIVE	KA401	81808	ALT	13	0.27083333	15	1.1538462
107	ACTIVE	KA401	81808	ALT	49	0.392	51	1.0408163
108	ACTIVE	KA401	81808	ALT	17	0.77272727	17	1
109	ACTIVE	KA401	81808	ALT	37	0.88095238	50	1.3513514
110	ACTIVE	KA401	81808	ALT	29	0.60416667	75	2.5520833
111	ACTIVE	KA401	81808	ALT	56	0.443	71	1.5799551
112	ACTIVE	KA401	81808	ALT	57	0.456	57	1
113	ACTIVE	KA401	81808	ALT	35	0.72916667	35	1

AE Listing - All Patients

Subject	Sex	Race	Age	Preferred Term	Start Date	
11	KA401_10522	F	OTHER RACE	35	UPPER RESPIRATORY TRACT INFECTION	2006-01-12
12	KA401_10523	M	OTHER RACE	45	DIZZINESS	2006-01-12
13	KA401_11406	M	WHITE	33	FEELING ABNORMAL	2004-12-15
14				33	FEELING ABNORMAL	2004-12-15
15				33	FEELING ABNORMAL	2004-12-15
16				33	FEELING ABNORMAL	2004-12-15
17				33	FEELING ABNORMAL	2004-12-15
18				33	FEELING ABNORMAL	2004-12-15
19				33	FEELING ABNORMAL	2004-12-15
20				33	FEELING ABNORMAL	2004-12-15
21	KA401_11413	F	WHITE	27	DYSGEUSIA	2005-01-22
22				27	DYSGEUSIA	2005-01-22
23				27	DYSGEUSIA	2005-01-22
24				27	DYSGEUSIA	2005-01-22
25	KA401_11417	F	WHITE	29	CONJUNCTIVITIS	2005-02-26
26				29	CONJUNCTIVITIS	2005-02-26
27				29	CONJUNCTIVITIS	2005-02-26
28	KA401_11420	M	WHITE	32	DYSGEUSIA	2005-03-29
29				32	DYSGEUSIA	2005-03-29
30	KA401_11424	M	WHITE	62	NASOPHARYNGITIS	2005-04-30
31				62	NASOPHARYNGITIS	2005-04-30
32	KA401_11432	M	WHITE	28	EYE PAIN	2005-05-09

Hys Law ALT Baseline Composite - All Patients

Postbaseline Peak BLOOD CHEMISTRY TEST...ALT (xBLN)

Baseline Quadrant

Cholestasis • Hy's Law • Normal • Temple's Corollary

Hys Law AST Baseline Composite - All Patients

Postbaseline Peak BLOOD CHEMISTRY TEST...AST (xBLN)

Baseline Quadrant

Cholestasis • Hy's Law • Normal • Temple's Corollary

Patient Profiles Browser - 1 case of 467 selected.

Create Profile... Patient Review: ON - no filter - Data Type Review: OFF (no Data Type filter)

I Reviewed Review Level Review Info Study USUBJID

Prev CASE Next CASE Reset Cases

Graphical Patient Profile [KA401:KA401_11417]

Patient ID: KA401_11417 ARM: ACTIVE
RFSTOTC: 2005-01-20 RFEINDTC: 2005-02-27
SITEID: 81808 COUNTRY: USA
AGE: 29 SEX: F
RACE: WHITE ETHNIC:

Treatment

Concomitant Medications

Adverse Events

Liver function tests

ALT (U(aminotransferase)/L)

AST (U(aminotransferase)/L)

BLI (micromol(bilirubin)/L)

ALP (U(alk phos)/L)

Week -5 -4 -3 -2 -1 0 1 2 3 4 5 6 7 8 9 10 11 12

Dashboard Views in JReview

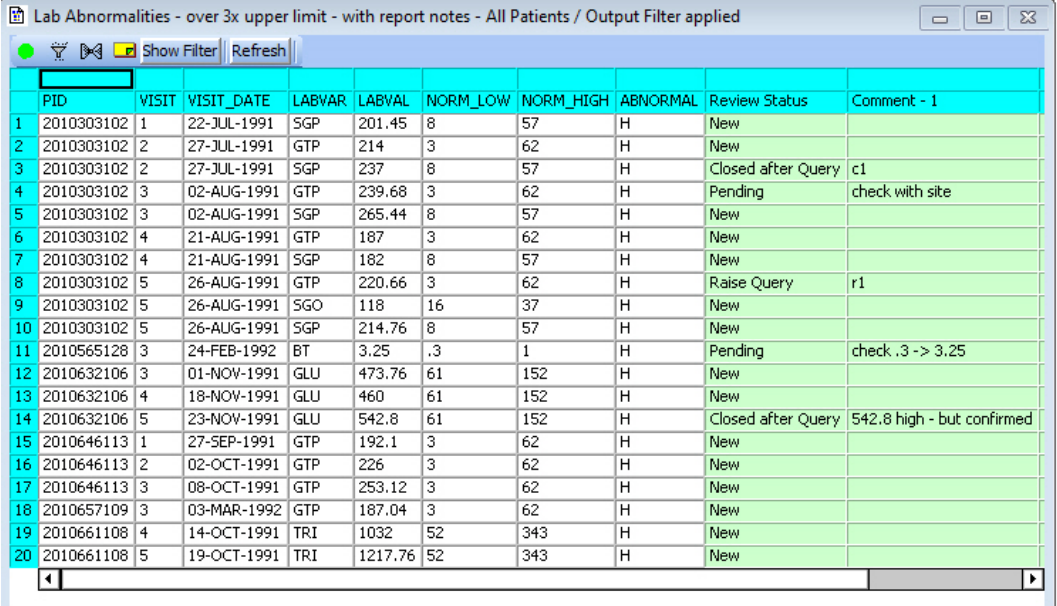
The screenshot displays the JReview 12.0 software interface, developed by Integrated Clinical Systems, Inc. The interface is divided into several panes:

- Left Pane:** Contains a 'Tree view' showing the study structure (KA, KA201, KA202) and 'Patient Subsets' (All Patients). It also includes 'Output Specifications' and a list of data review items such as 'Data Review', 'Efficacy', 'Fraud Detection', 'Functional Area', 'General', 'Patient Narratives', 'R Scripts', 'RBM', 'SAS OutputFilter', 'STAT Program Reg', and 'Safety'.
- Top Center Pane:** 'Patient Selection Criteria - All Patients (196)'. It shows a list of items (Protein, total serum Albumin, Bilirubin, total, Uric Acid) and functions (actual value, baseline value, % chg from baseline, % chg from baseline endpoint value).
- Bottom Center Pane:** 'Patient Profiles Browser - 196 cases selected'. It displays a table with columns for PID, AGE, SEX, RACE, VISIT, VISIT LABEL, ERYTHEMA, PRURITUS, and SCALING. The table lists patients and their corresponding visit data.
- Right Pane:** 'Formatted Patient Profile [018:4105]'. It shows a 'Case Report Tabulation 018-4105' for Protocol:201. It includes demographic information (Age, Sex, Race, Date of Birth) and a table for 'Efficacy Evaluation' showing visit dates and labels. A large 'DRAFT' watermark is visible over this pane.

The 'Efficacy Evaluation' table shows data for visits 1 through 6, with columns for Visit No., Visit Date, Visit Label, and various efficacy parameters (Erythema, Pruritus, Scaling, Vesication, Edema, Exudation, Maceration, Papules, Burning, Pain, Fissures, Pustules, Hyperkeratosis).

Report Reviewer Notes

- Report Notes – review exception listings – editable review status, action, comments – stored separately
- When data updates (typically nightly) – notes are retained – unless have option to reset status when any data changes on the report line.



	PID	VISIT	VISIT_DATE	LABVAR	LABVAL	NORM_LOW	NORM_HIGH	ABNORMAL	Review Status	Comment - 1
1	2010303102	1	22-JUL-1991	SGP	201.45	8	57	H	New	
2	2010303102	2	27-JUL-1991	GTP	214	3	62	H	New	
3	2010303102	2	27-JUL-1991	SGP	237	8	57	H	Closed after Query	c1
4	2010303102	3	02-AUG-1991	GTP	239.68	3	62	H	Pending	check with site
5	2010303102	3	02-AUG-1991	SGP	265.44	8	57	H	New	
6	2010303102	4	21-AUG-1991	GTP	187	3	62	H	New	
7	2010303102	4	21-AUG-1991	SGP	182	8	57	H	New	
8	2010303102	5	26-AUG-1991	GTP	220.66	3	62	H	Raise Query	r1
9	2010303102	5	26-AUG-1991	SGO	118	16	37	H	New	
10	2010303102	5	26-AUG-1991	SGP	214.76	8	57	H	New	
11	2010565128	3	24-FEB-1992	BT	3.25	.3	1	H	Pending	check ,3 -> 3.25
12	2010632106	3	01-NOV-1991	GLU	473.76	61	152	H	New	
13	2010632106	4	18-NOV-1991	GLU	460	61	152	H	New	
14	2010632106	5	23-NOV-1991	GLU	542.8	61	152	H	Closed after Query	542.8 high - but confirmed
15	2010646113	1	27-SEP-1991	GTP	192.1	3	62	H	New	
16	2010646113	2	02-OCT-1991	GTP	226	3	62	H	New	
17	2010646113	3	08-OCT-1991	GTP	253.12	3	62	H	New	
18	2010657109	3	03-MAR-1992	GTP	187.04	3	62	H	New	
19	2010661108	4	14-OCT-1991	TRI	1032	52	343	H	New	
20	2010661108	5	19-OCT-1991	TRI	1217.76	52	343	H	New	

Standard Library of Definitions

- Use of these clinically relevant templates – with specified graph type, variables, filters
 - > saved definition
 - > library (at study, project or studyGroup)
- As quick as it is to use a quick use template – selecting variables of interest & filters
 - > it's quicker to re-execute a saved definition!
 - > and published to a dashboard view.

Typical Process

- Either access data directly in clinical data source
 - or –Register SAS Datasets (with SAS Share)
 - or –Load SAS datasets or ODM-XML -> database
 - > register or load new study – loading study meta data automatically
 - > about 10 minutes
- If totally new study/data structures
 - > define new set of standard library objects
 - > about 2-3 hours for about 100 object definitions
- If a new study, but based on previous non-standard definitions – inherit from project or studygroup

Thank You!

Any questions or comments?

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