



Meta Clinical Technology

Apply New Technology to Improve Data Quality

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Meta Clinical Technology®
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Agenda

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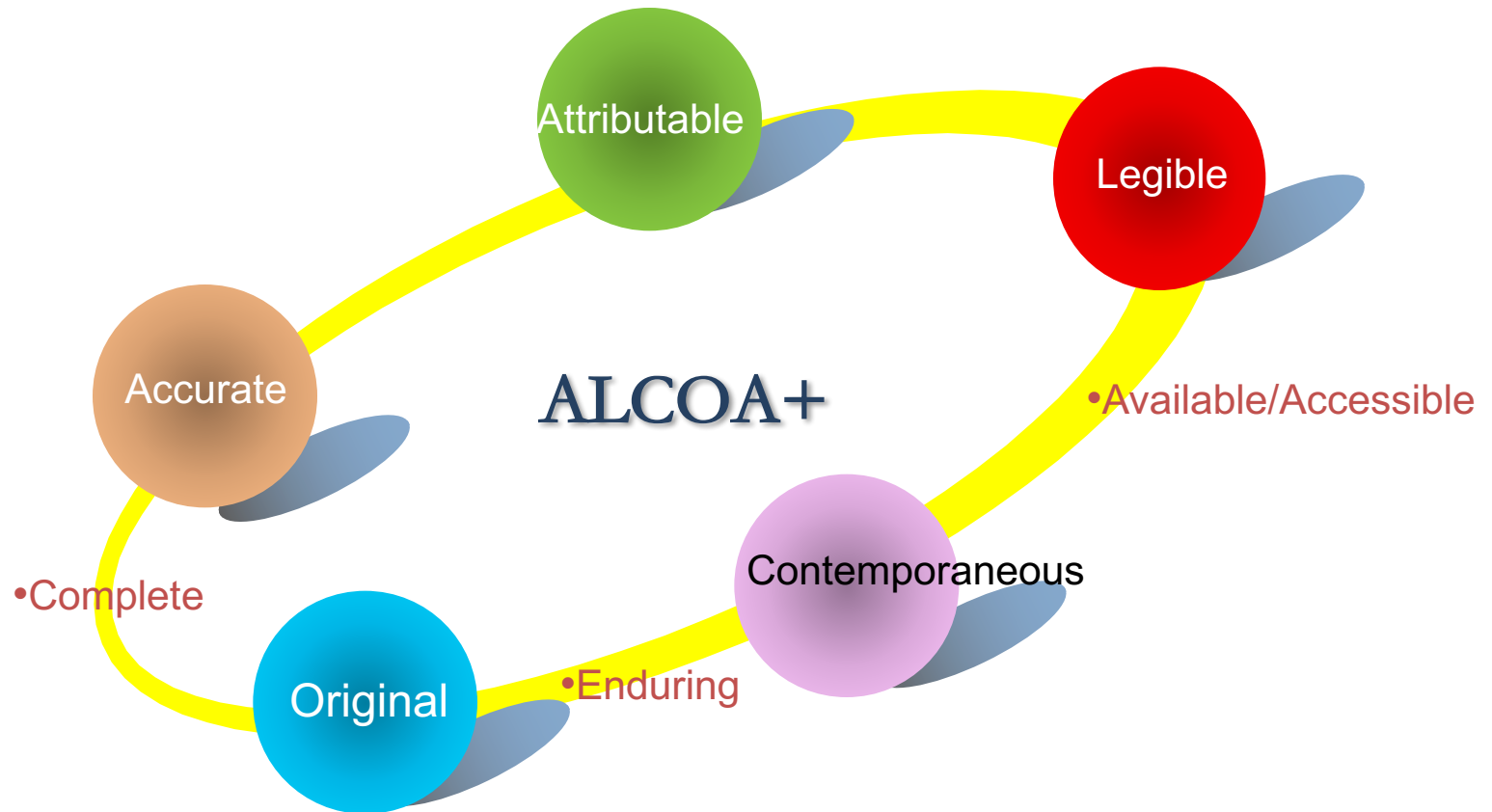
- Data Review –Traditional Perspective
- Benefit of New Technology
- Data Visualization and Analysis

Data Quality Elements- ALCOA+



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Data Review –Traditional Perspective



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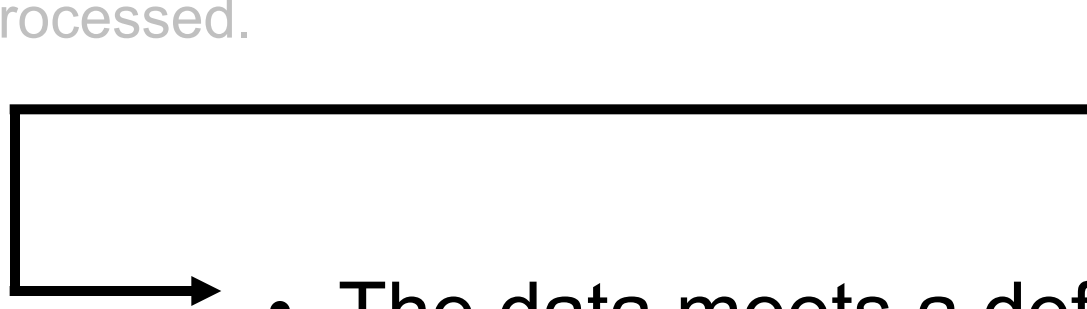
- ▲ CRAs perform SDV
- ▲ Data Cleaning and validation
 - System Checks
 - Automated Checks
 - Manual Checks
- ▲ Data Review –focus on individual data point
- ▲ Treats ‘all data as equal importance’



Data Validation Overview

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Data Validation ensures that the data is sensible before it is processed.



- The data meets a defined set of rules – As per protocol standards.
- Complete
- Correct
- Consistent



Manual Checks

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- ▲ Review 100% Offline listing and CRF
 - SAS Programming for Offline listing
 - Too much data or working too longer
 - Exhausting, error prone



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Data Review –Traditional Perspective



Challenges in Clinical Trials



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- ▲ Decrease costs
- ▲ Speed up the research and development process.
- ▲ Improve the data quality

Benefit of New Technology



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- ▲ Not only focus on individual data points, but also observe the data trend
- ▲ Easy to find outlier or non-compliance data
- ▲ Find inconsistent data between different countries or sites
- ▲ Productively
- ▲ Decrease human error



Risk Based ...

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- ▲ Current trend in many areas –Risk Based
- ▲ Risk based approach to Systems ...Risk Analysis ...
- ▲ Risk based monitoring
- ▲ Risk based site selection for audits (FDA)



Risk Based ...

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- ▲ Current trend in many areas –Risk Based
- ▲ Risk Based = Focus on highest risk issues
- ▲ Don't get 'bogged down in the weeds'



Clinical Data Review

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- ▲ Review clinical data –from an aggregate view –to the details.
- ▲ Review summarized views of the data - for an overview of the data in your trial – lets you look into the items of interest based on the aggregate view of the data, rather than doing a patient by patient review of a detail line listing directly



Data Visualization Tools

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- ▲ JReview
- ▲ JMP
- ▲ Tableau
- ▲ Others

Patient Profiles

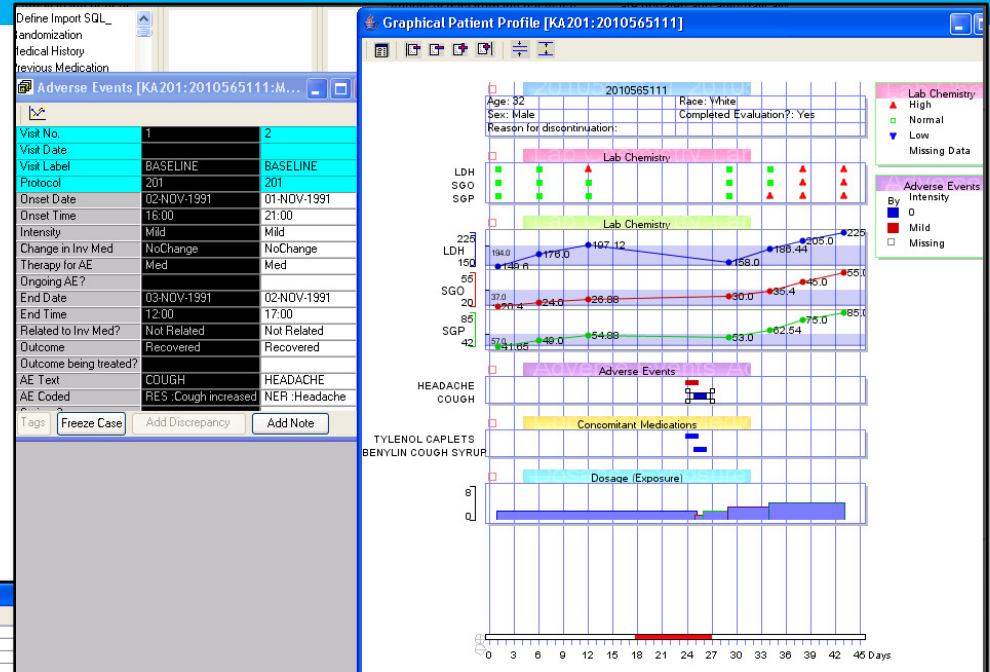


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- Time-oriented (days on drug) graph display of user selected parameters
- Dynamically choose categories and items to include
- Drilldown to selected data of interest
- Graphical or tabular (formatted) output
- Export to Excel, HTML, PDF
- Optional batch report option

</



Formatted Profile KA201:2010104101									
Demography									
Age	Sex	Race	Birth Date	Birth Time	Birth Place	Birth Country	Birth State	Birth City	Birth Zip
27	Male	White	1968-08-08						
Concomitant Medication									
Drug Name	Route	Frequency	Ongoing?	PK%	Start Date	Stop Date	Message	Unit	Group Code
Efficacy Evaluation									
Visit No.	Visit Date	Visit Label	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7
1	15-JUL-1991	BASELINE	0	0	0	0	0	0	0
2	20-JUL-1991	DAY 5	0	0	0	0	0	0	0
3	13-AUG-1991	DAY 29	0	0	0	0	0	0	0
4	27-AUG-1991	DAY 43	0	0	0	0	0	0	0
5	06-SEP-1991	DAY 50	0	0	0	0	0	0	0
6	13-SEP-1991	DAY 57	0	0	0	0	0	0	0
7	20-SEP-1991	DAY 64	0	0	0	0	0	0	0
8	27-SEP-1991	DAY 71	0	0	0	0	0	0	0
9	04-OCT-1991	DAY 78	0	0	0	0	0	0	0
10	11-OCT-1991	DAY 85	0	0	0	0	0	0	0
11	18-OCT-1991	DAY 92	0	0	0	0	0	0	0
12	25-OCT-1991	DAY 99	0	0	0	0	0	0	0
13	01-NOV-1991	DAY 106	0	0	0	0	0	0	0
14	08-NOV-1991	DAY 113	0	0	0	0	0	0	0
15	15-NOV-1991	DAY 120	0	0	0	0	0	0	0
16	22-NOV-1991	DAY 127	0	0	0	0	0	0	0
17	29-NOV-1991	DAY 134	0	0	0	0	0	0	0
18	06-DEC-1991	DAY 141	0	0	0	0	0	0	0
19	13-DEC-1991	DAY 148	0	0	0	0	0	0	0
20	20-DEC-1991	DAY 155	0	0	0	0	0	0	0
21	27-DEC-1991	DAY 162	0	0	0	0	0	0	0
22	03-JAN-1992	DAY 169	0	0	0	0	0	0	0
23	10-JAN-1992	DAY 176	0	0	0	0	0	0	0
24	17-JAN-1992	DAY 183	0	0	0	0	0	0	0
25	24-JAN-1992	DAY 190	0	0	0	0	0	0	0
26	31-JAN-1992	DAY 197	0	0	0	0	0	0	0
27	07-FEB-1992	DAY 204	0	0	0	0	0	0	0
28	14-FEB-1992	DAY 211	0	0	0	0	0	0	0
29	21-FEB-1992	DAY 218	0	0	0	0	0	0	0
30	28-FEB-1992	DAY 225	0	0	0	0	0	0	0
31	06-MAR-1992	DAY 232	0	0	0	0	0	0	0
32	13-MAR-1992	DAY 239	0	0	0	0	0	0	0
33	20-MAR-1992	DAY 246	0	0	0	0	0	0	0
34	27-MAR-1992	DAY 253	0	0	0	0	0	0	0
35	03-APR-1992	DAY 260	0	0	0	0	0	0	0
36	10-APR-1992	DAY 267	0	0	0	0	0	0	0
37	17-APR-1992	DAY 274	0	0	0	0	0	0	0
38	24-APR-1992	DAY 281	0	0	0	0	0	0	0
39	01-MAY-1992	DAY 288	0	0	0	0	0	0	0
40	08-MAY-1992	DAY 295	0	0	0	0	0	0	0
41	15-MAY-1992	DAY 302	0	0	0	0	0	0	0
42	22-MAY-1992	DAY 309	0	0	0	0	0	0	0
43	29-MAY-1992	DAY 316	0	0	0	0	0	0	0
44	05-JUN-1992	DAY 323	0	0	0	0	0	0	0
45	12-JUN-1992	DAY 330	0	0	0	0	0	0	0
46	19-JUN-1992	DAY 337	0	0	0	0	0	0	0
47	26-JUN-1992	DAY 344	0	0	0	0	0	0	0
48	03-JUL-1992	DAY 351	0	0	0	0	0	0	0
49	10-JUL-1992	DAY 358	0	0	0	0	0	0	0
50	17-JUL-1992	DAY 365	0	0	0	0	0	0	0
51	24-JUL-1992	DAY 372	0	0	0	0	0	0	0
52	31-JUL-1992	DAY 379	0	0	0	0	0	0	0
53	07-AUG-1992	DAY 386	0	0	0	0	0	0	0
54	14-AUG-1992	DAY 393	0	0	0	0	0	0	0
55	21-AUG-1992	DAY 400	0	0	0	0	0	0	0
56	28-AUG-1992	DAY 407	0	0	0	0	0	0	0
57	04-SEP-1992	DAY 414	0	0	0	0	0	0	0
58	11-SEP-1992	DAY 421	0	0	0	0	0	0	0
59	18-SEP-1992	DAY 428	0	0	0	0	0	0	0
60	25-SEP-1992	DAY 435	0	0	0	0	0	0	0
61	02-OCT-1992	DAY 442	0	0	0	0	0	0	0
62	09-OCT-1992	DAY 449	0	0	0	0	0	0	0
63	16-OCT-1992	DAY 456	0	0	0	0	0	0	0
64	23-OCT-1992	DAY 463	0	0	0	0	0	0	0
65	30-OCT-1992	DAY 470	0	0	0	0	0	0	0
66	06-NOV-1992	DAY 477	0	0	0	0	0	0	0
67	13-NOV-1992	DAY 484	0	0	0	0	0	0	0
68	20-NOV-1992	DAY 491	0	0	0	0	0	0	0
69	27-NOV-1992	DAY 498	0	0	0	0	0	0	0
70	04-DEC-1992	DAY 505	0	0	0	0	0	0	0
71	11-DEC-1992	DAY 512	0	0	0	0	0	0	0
72	18-DEC-1992	DAY 519	0	0	0	0	0	0	0
73	25-DEC-1992	DAY 526	0	0	0	0	0	0	0
74	01-JAN-1993	DAY 533	0	0	0	0	0	0	0
75	08-JAN-1993	DAY 540	0	0	0	0	0	0	0
76	15-JAN-1993	DAY 547	0	0	0	0	0	0	0
77	22-JAN-1993	DAY 554	0	0	0	0	0	0	0
78	29-JAN-1993	DAY 561	0	0	0	0	0	0	0
79	05-FEB-1993	DAY 568	0	0	0	0	0	0	0
80	12-FEB-1993	DAY 575	0	0	0	0	0	0	0
81	19-FEB-1993	DAY 582	0	0	0	0	0	0	0
82	26-FEB-1993	DAY 589	0	0	0	0	0	0	0
83	05-MAR-1993	DAY 596	0	0	0	0	0	0	0
84	12-MAR-1993	DAY 603	0	0	0	0	0	0	0
85	19-MAR-1993	DAY 610	0	0	0	0	0	0	0
86	26-MAR-1993	DAY 617	0	0	0	0	0	0	0
87	02-APR-1993	DAY 624	0	0	0	0	0	0	0
88	09-APR-1993	DAY 631	0	0	0	0	0	0	0
89	16-APR-1993	DAY 638	0	0	0	0	0	0	0
90	23-APR-1993	DAY 645	0	0	0	0	0	0	0
91	30-APR-1993	DAY 652	0	0	0	0	0	0	0
92	07-MAY-1993	DAY 659	0	0	0	0	0	0	0
93	14-MAY-1993	DAY 666	0	0	0	0	0	0	0
94	21-MAY-1993	DAY 673	0	0	0	0	0	0	0
95	28-MAY-1993	DAY 680	0	0	0	0	0	0	0
96	04-JUN-1993	DAY 687	0	0	0	0	0	0	0
97	11-JUN-1993	DAY 694	0	0	0	0	0	0	0
98	18-JUN-1993	DAY 701	0	0	0	0	0	0	0
99	25-JUN-1993	DAY 708	0	0	0	0	0	0	0
100	02-JUL-1993	DAY 715	0	0	0	0	0	0	0

Patient Review Tracking



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- System keeps track of patients reviewed
- Patients with new data are highlighted
- Review state for all patients can be displayed, as well as highlighted rows in patient profile – with new data since last review
- Data Type review tracking – to track data review by domain, i.e., AE, CM, LB, etc.
- Data listings optionally display 'New Data' highlighting – associated with Patient Review Tracking feature

The screenshot displays the 'Patient Profiles Browser' window with 196 cases selected. The 'Patient Review: ON' checkbox is highlighted with a red circle. Below it, a table lists patient data with columns for Review, Review Info, Color, Study, PID, and Not Defined. The 'I Reviewed' checkbox is also highlighted with a red circle. A red arrow points from the 'I Reviewed' checkbox to the 'Formatted Patient Profile' window.

The 'Formatted Patient Profile' window shows the profile for patient KA201-2010184103. It includes a table for 'Demography' and 'Efficacy Evaluation'.

Visit No.	Visit Date	Visit Label	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
1	15-JUL-1991	BASELINE	2	22-JUL-1991	30-JUL-1991	06-AUG-1991	13-AUG-1991	27-AUG-1991
2	22-JUL-1991	DAY 8	1	1	1	1	1	1
3	30-JUL-1991	DAY 15	1	1	1	1	1	1
4	06-AUG-1991	DAY 22	1	1	1	1	1	1
5	13-AUG-1991	DAY 29	1	1	1	1	1	1
6	27-AUG-1991	DAY 43	1	1	1	1	1	1

The 'Efficacy Evaluation' table shows various clinical parameters (Erythema, Pruritus, Scaling, Vesicles, Exudation, Maceration, Papules, Burning, Pain, Fissures, Pustules) and their values across the visits.

Patient Visit Data Report



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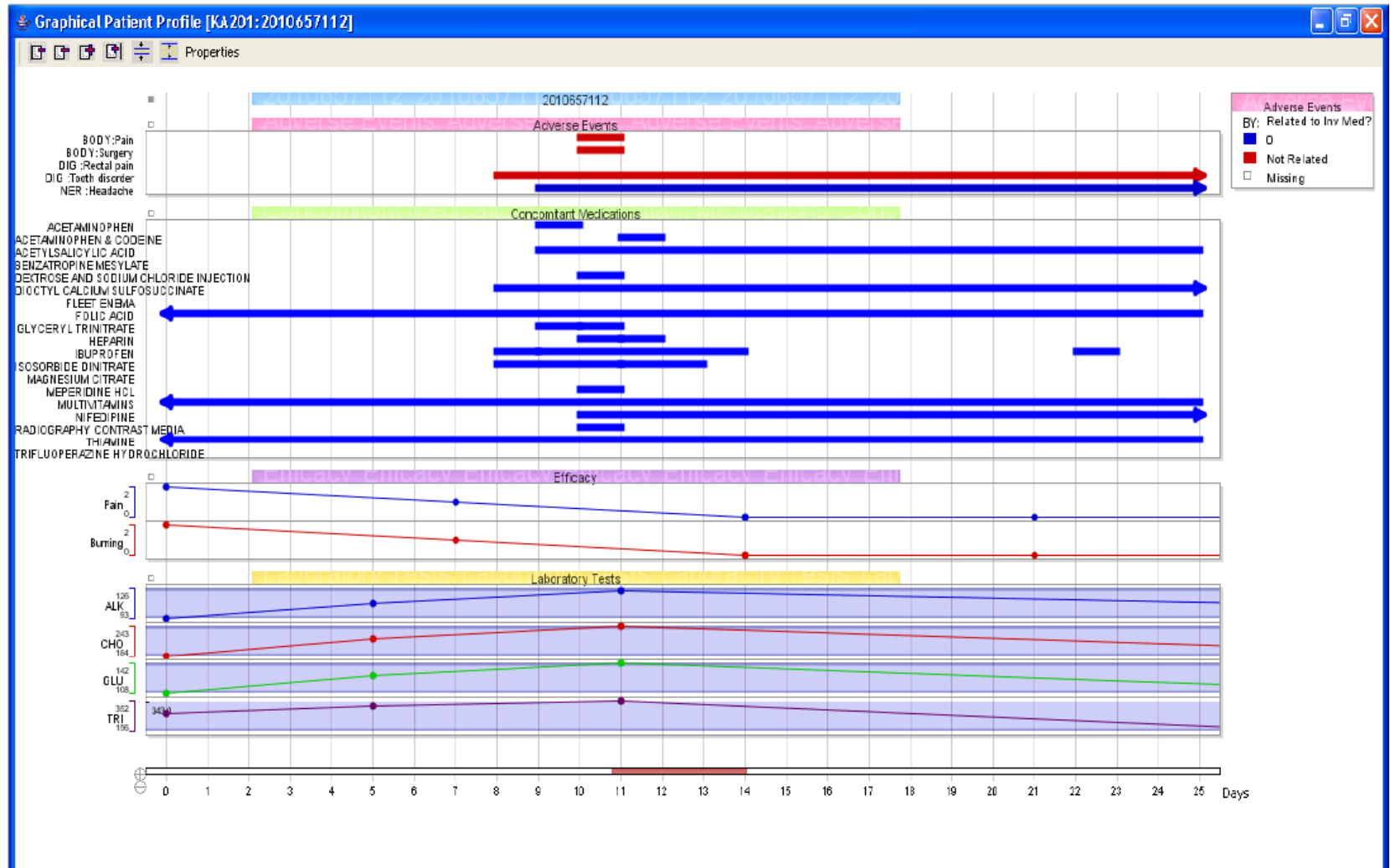
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- Special multi-pass – date merge report – developed with the NCI
- Very useful for AE-ConMed display, or any other data which is aligned more naturally by observed date (start date, onset date, etc) rather than typical visit joins

PatID	Date	Doage Dose Quantity	Labs Alkaline Phosphatase	Lactic Dehydrogenase	ALAT (SGPT)	Adverse Events AE Text	Intensity	ConMed Drug Name
2010184208	01-01-1974							PREMARIN 2.5MG
	01-01-1990							ISOPTIN
								TAGAMENT
	10-07-1991	2	74	141	16	INCREASED BURNING ON FEET	Moderate	
						INCREASED BURNING ON FEET	Moderate	
						INCREASED ITCHING ON FEET	Moderate	
	11-05-1991		85	141	18			
2010303111	09-01-1976							ESTRACE
	08-16-1991	2	125	132	22			
	09-04-1991					DUODENAL ULCER	Severe	
	09-05-1991							ZANTAC
2010303112	(missing)							
	10-25-1991	2	120	153	36			
	11-08-1991					BURNING WITH APPLICATION OF DRUG	Mild	
						BURNING WITH APPLICATION OF DRUG	Mild	
	11-22-1991		121	132	38			
2010303205	01-01-1981							DILTIAZEM ORAL
								METOPROLOL TARTRATE
								CIMETIDINE
	09-09-1991	2	100	156	23			
	09-16-1991					HEAT REACTION UPON APPLICATION OF MED	Mild	
						HEAT REACTION UPON APPLICATION OF MED	Mild	
	10-08-1991		111	172	23			
2010303206	(missing)							
	09-10-1991	2	93	151	33			



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Aggregate Table

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(Req'd PSC) Abnormal Labs per Arm - Subset of patie...

LBTEST	ACTIVE	PLACEBO	Subjects
ALANINE AMINOTRANSFERASE	3 (0.64%)	10 (2.14%)	13 (2.78%)
ALBUMIN	2 (0.43%)	10 (2.14%)	12 (2.57%)
ALKALINE PHOSPHATASE	1 (0.21%)	4 (0.86%)	5 (1.07%)
ASPARTATE AMINOTRANSFERASE	2 (0.43%)	3 (0.64%)	5 (1.07%)
BILIRUBIN	4 (0.86%)	3 (0.64%)	7 (1.50%)
CHLORIDE	28 (6.00%)	15 (3.21%)	43 (9.21%)
CREATININE	6 (1.28%)	5 (1.07%)	11 (2.36%)
GLUCOSE	15 (3.21%)	15 (3.21%)	30 (6.42%)
HEMATOCRIT	1 (0.21%)	0 (0.00%)	1 (0.21%)
HEMOGLOBIN	17 (3.64%)	13 (2.78%)	30 (6.42%)
LEUKOCYTES	9 (1.93%)	5 (1.07%)	14 (3.00%)
LYMPHOCYTES	1 (0.21%)	2 (0.43%)	3 (0.64%)
NEUTROPHILS	9 (1.93%)	4 (0.86%)	13 (2.78%)
PLATELET	5 (1.07%)	1 (0.21%)	6 (1.28%)
POTASSIUM	5 (1.07%)	4 (0.86%)	9 (1.93%)
SODIUM	3 (0.64%)	1 (0.21%)	4 (0.86%)
UREA NITROGEN	6 (1.28%)	2 (0.43%)	8 (1.71%)

AE Intensity by Treatment - All Patients

Intensity	Active	Placebo	Subjects
(missing)	3 (1.53%)	5 (2.55%)	8 (4.08%)
Mild	20 (10.20%)	18 (9.18%)	38 (19.39%)
Moderate	10 (5.10%)	7 (3.57%)	17 (8.67%)
Severe	1 (0.51%)	0 (0.00%)	1 (0.51%)
Subjects	97 (49.49%)	99 (50.51%)	196 (100.00%)
			(All patients)



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The screenshot displays the JReview 9.2 software interface, which is used for clinical trial data review. The main window is titled "Patient Selection Criteria - All Patients (467)". It features a "Panels" section on the left with a tree view containing "Adverse Events", "Concomitant Medic", "Demographics", "Disposition", "Exposure", "Laboratory Tests", and "Medical History". The "Items" section in the center lists various lab tests and events, and the "Functions" section on the right is empty. The "Operator" section is also empty. Below these sections are buttons for "Update Browsers", "ADD expression", "Display Stats", "Display Values", and "Item Compare".

On the left side of the interface, there is a "Studies" panel showing a tree view of study components, including "Demo", "KA_CDISC", "KA401", and "SEND". Below this is a "Patient Subsets" panel with a "Public" dropdown and a "Refresh" button. The "Output Specifications" panel at the bottom left shows a tree view of output specifications, including "CDISC Standards", "Demographics", "Disposition", "Labs", "Safety", and "Laboratory Tests Patient Listing <Lab Test Name>".

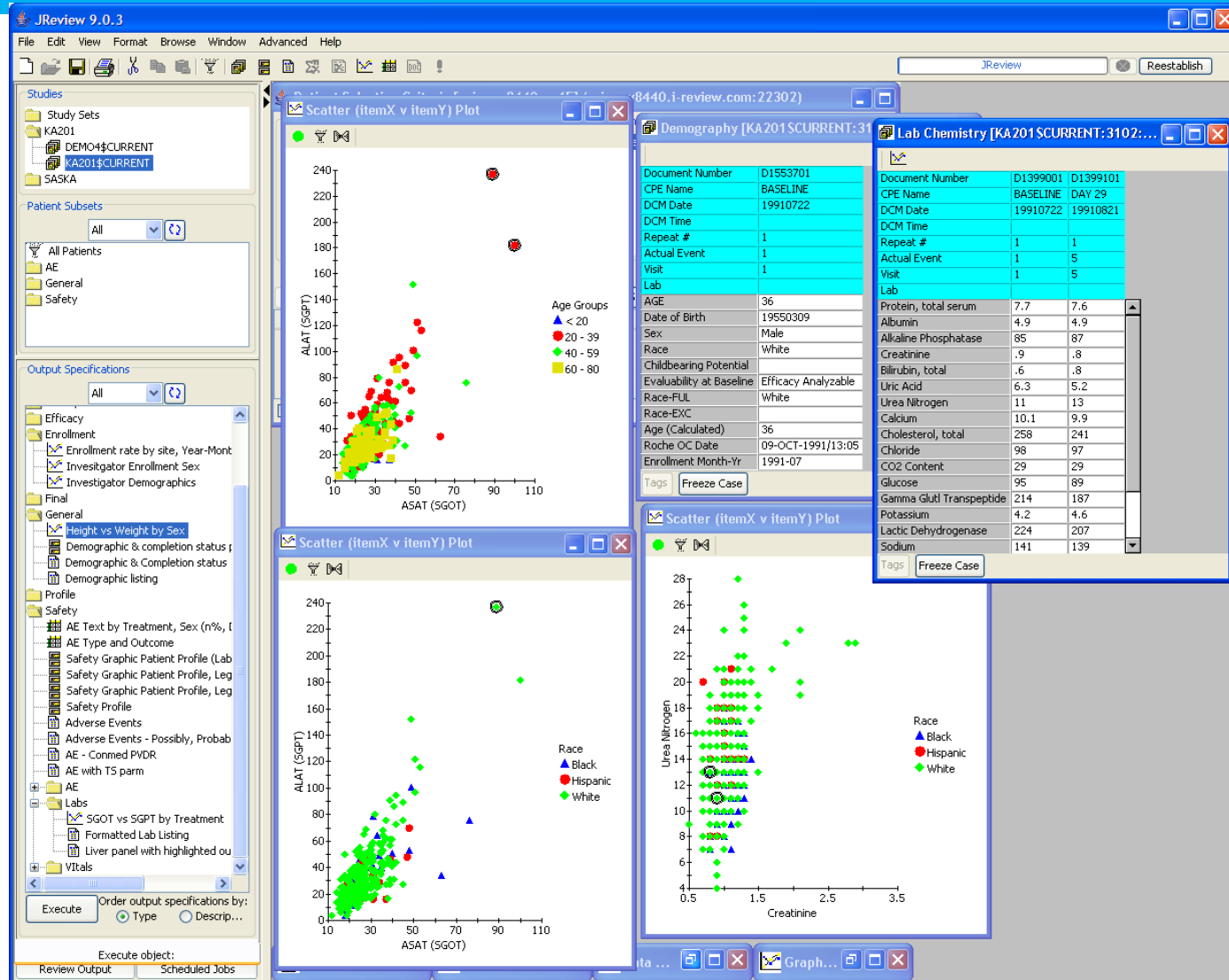
The "Laboratory Tests Patient Listing <Lab Test Name> - All Patients / Output Filter applied" window is open, displaying a table of laboratory test results. The table has columns for "Study Identifier", "Unique Subject ID", "Description of Planned Arm", "Visit Number", "Visit Name", "Baseline Flag", "Lab Test", "Result Std Units", "chg from prev in Std Units", "Reference Range Indicator", "ULN -Std Units", and "LLN -Std Units". The table shows data for two subjects: KA401_11417 and KA401_1405, with results for various lab tests like ALB, ALT, AST, BIL, and CRP.

The "Abnormal Liver Tests per Arm - All Patients / Output Filter applied" window is also open, displaying a table of abnormal liver test results. The table has columns for "LBTEST", "ACTIVE", "PLACEBO", and "Subjects". The table shows data for two subjects: KA401_11417 and KA401_1405, with results for various lab tests like ALB, ALT, AST, BIL, and CRP.



Data Visualization and Analysis

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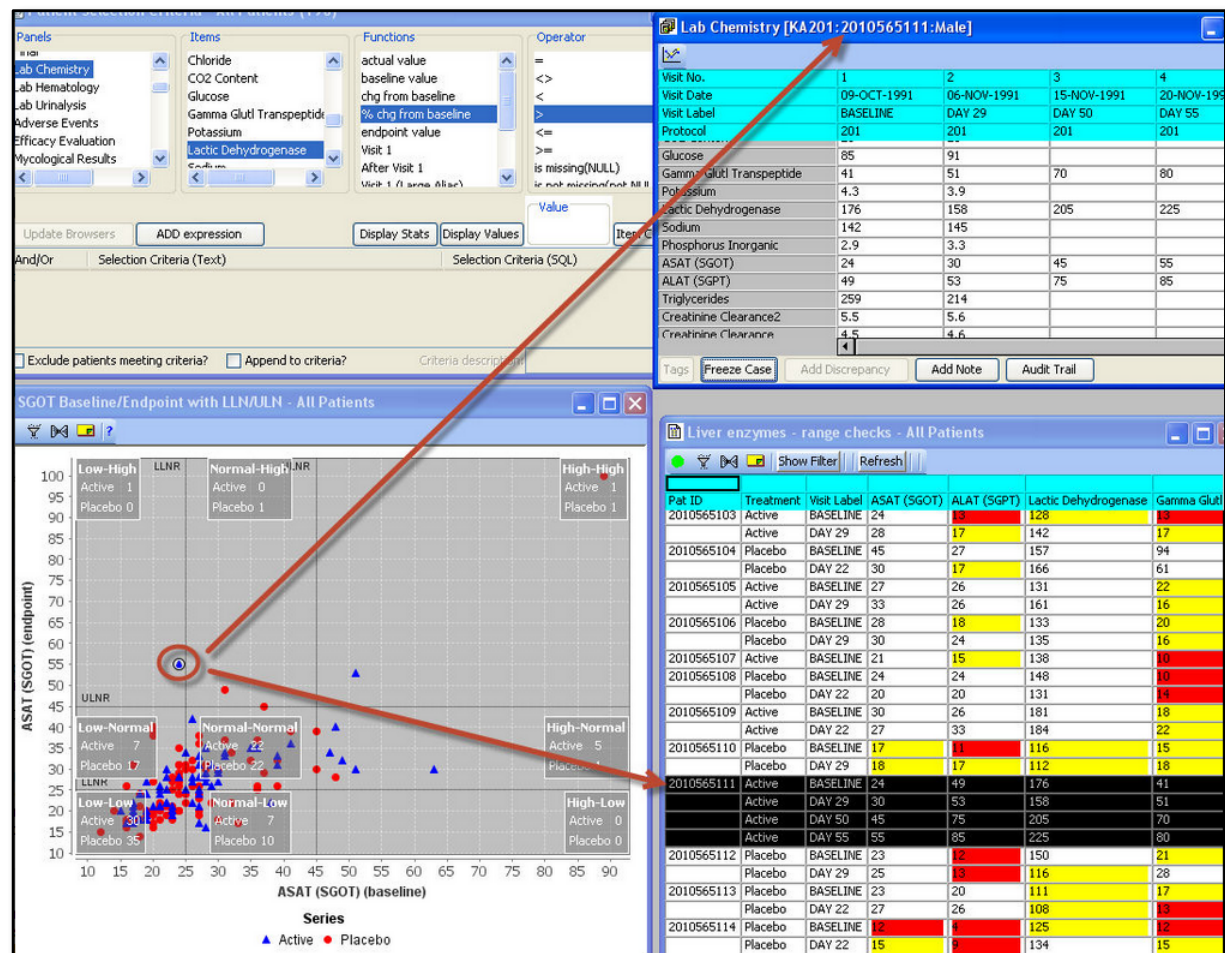
Data Visualization and Analysis



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- dynamically linked - allowing users to interactively track patients across multiple graphical and tabular outputs

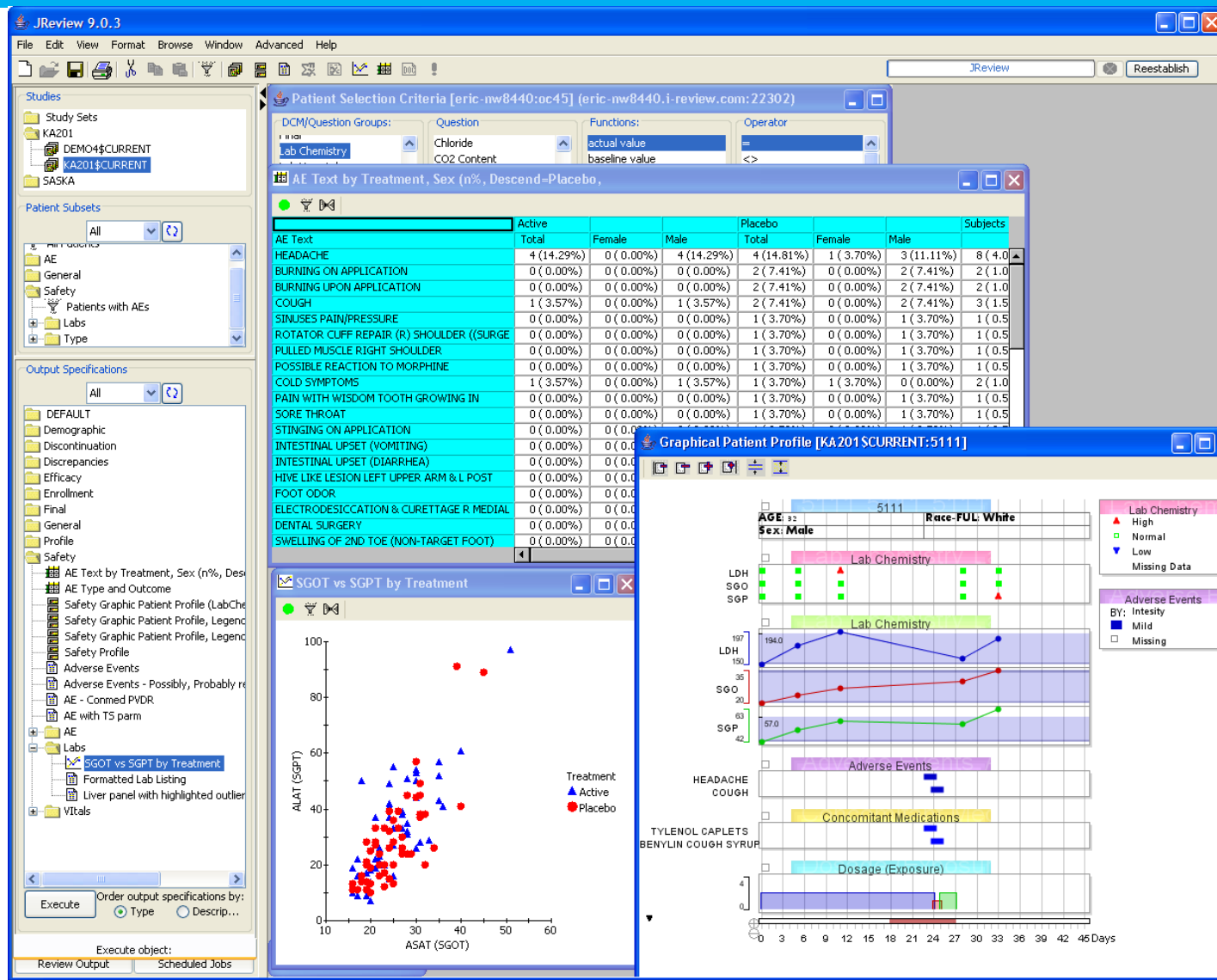


Data Visualization and Analysis



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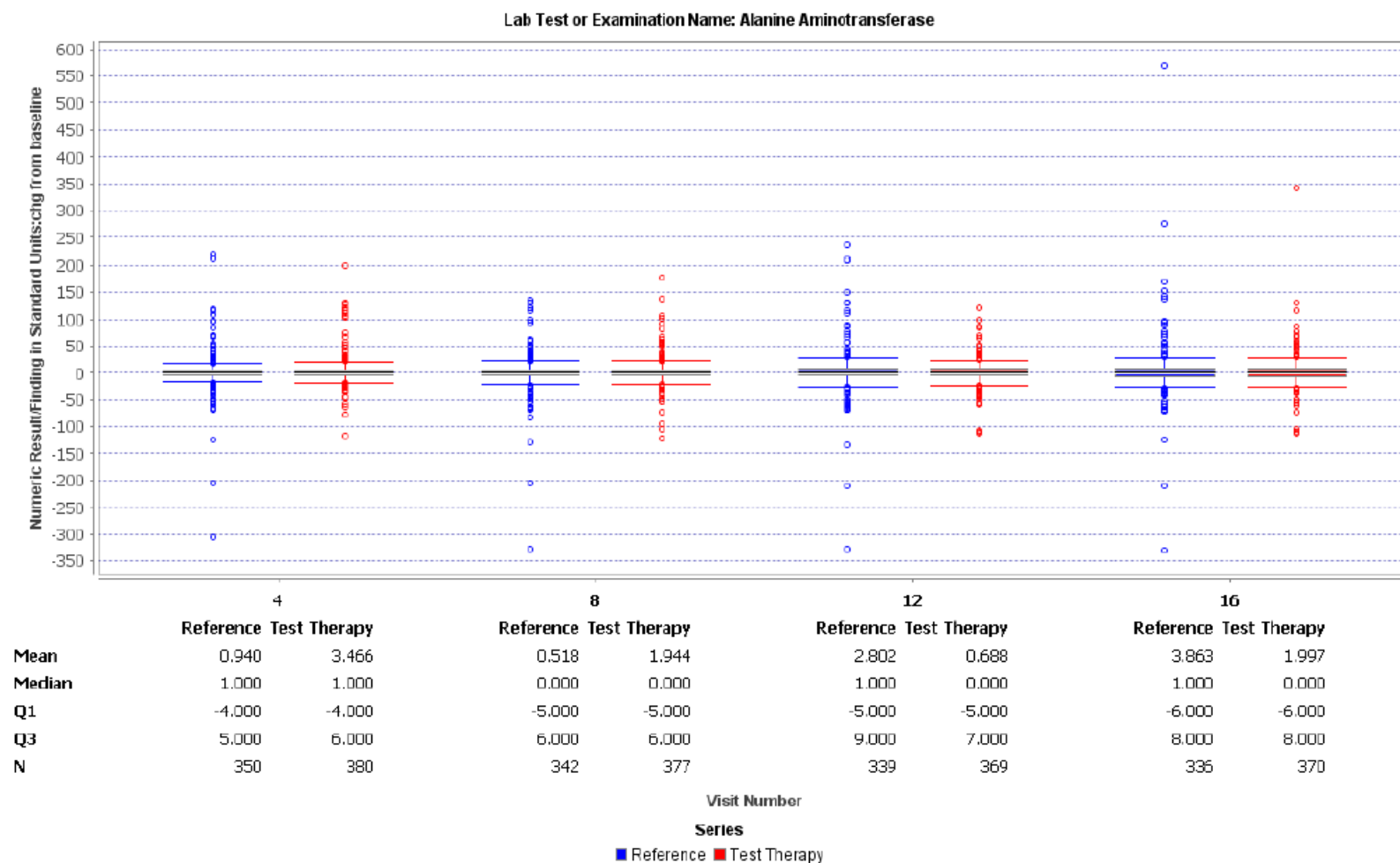
Data Visualization and Analysis

-Change from Baseline Box Whiskers



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Data Visualization and Analysis

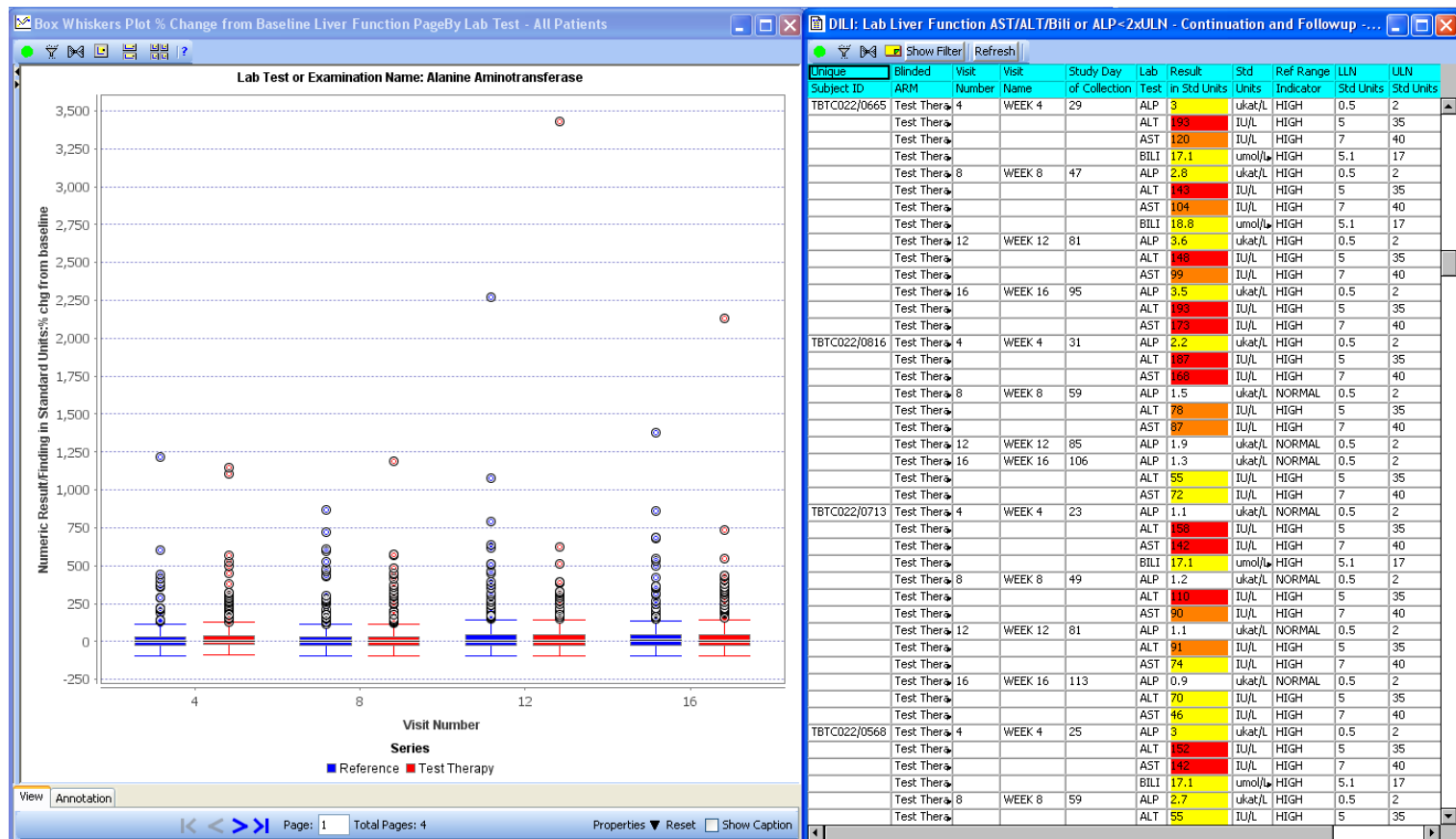
-Change from Baseline Box Whiskers



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- Identifying the outliers and reviewing their data



Data Visualization and Analysis

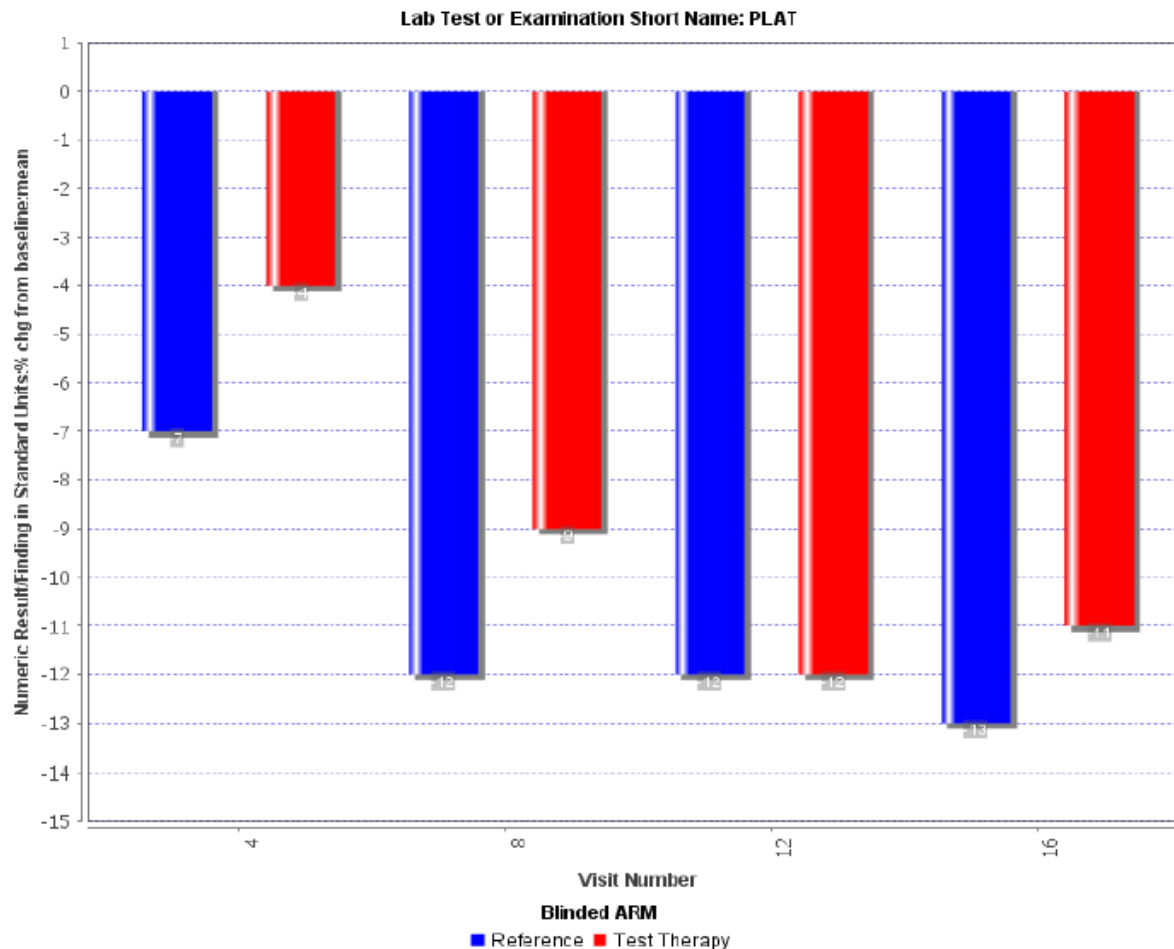
-Change from Baseline Bar Charts



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- Hematology: Platelets lab test % Change from Base line



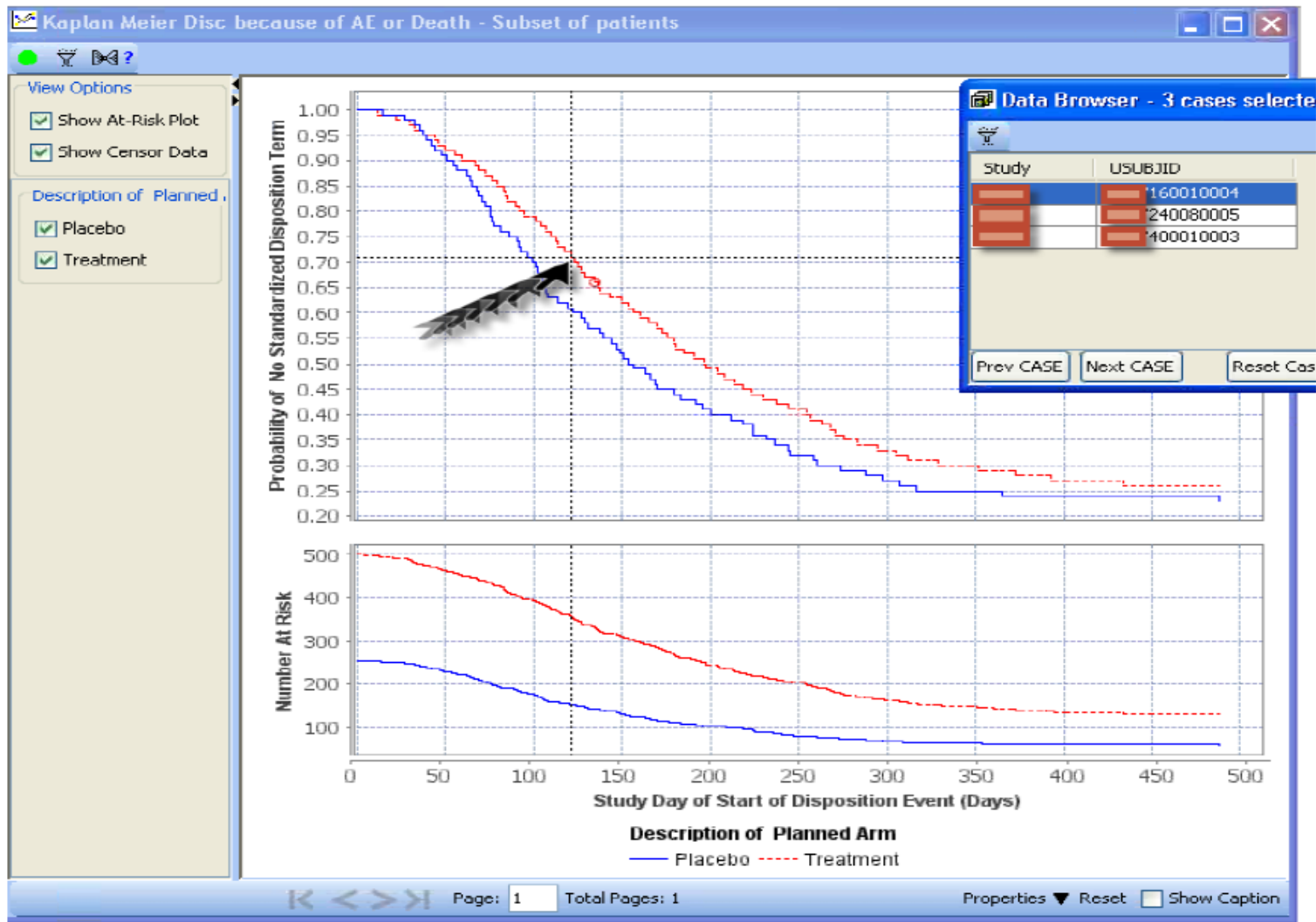
Data Visualization and Analysis

-Efficacy-Overall Survival



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THANK YOU !



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