Visualization for Safety Surveillance

04 June 2015

Disclaimer

The views and opinions are those of the presenter and in no way represent official Biogen positions

All data presented in the materials is test data, and in no way represent Biogen product or development data, or subject data

Abstract

Over the past few years Biogen has undertaken an effort to implement data visualization as a means of enhancing the safety surveillance functionality. This effort utilizes clinical data standards and standard reports to improve clinical development efforts, identifying trends earlier, influencing future study design and ongoing safety monitoring.

Project history and lessons learned are presented along with high level tips gleaned from the implementation, as context to the included sample data visualizations.

The initial response to this effort has been positive, leading to the identification of additional opportunities both within the Safety and Benefit Risk function and across Development Sciences.

Acknowledgement

These workshop materials reflect the implementation of a visualization platform, and would not have been possible without the efforts of the full Biogen project team.

Agenda

- Project Background
- Notes on Data Visualization / Tips & Tricks
- Review of Sample Visualizations

Project Background

"Getting There"

Opportunity

Thousands of rows of data, outliers/ patterns not obvious

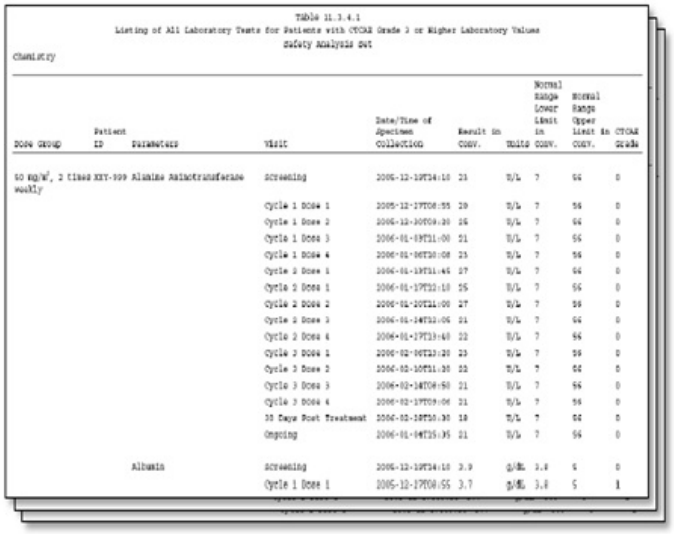
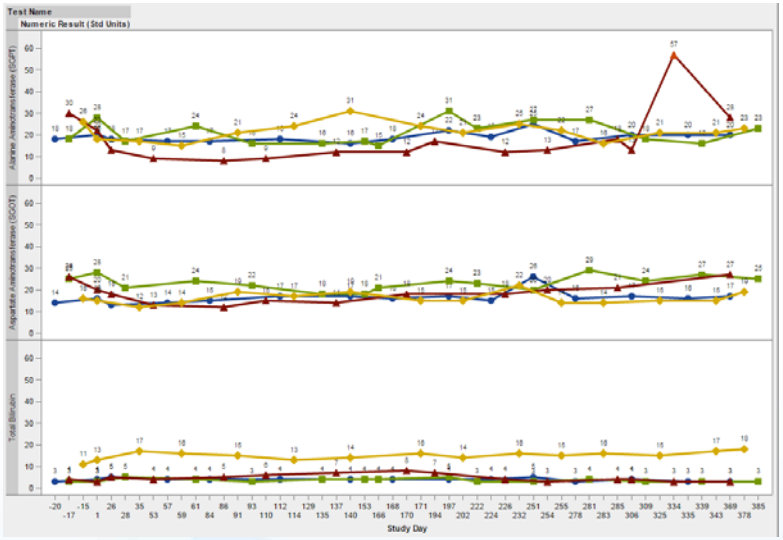


Table 11.3.4.1
Listing of All Laboratory Tests for Patients with CTCAE Grade 3 or Higher Laboratory Values
Safety Analysis Set

Chemistry

Dose Group	Patient ID	Parameter	Visit	Date/Time of Specimen Collection	Result in Conv.	Units	Normal Range Lower Limit in Conv.	Normal Range Upper Limit in Conv.	CTCAE Grade
60 mg/m², 2 times XXY-999 weekly		Alanine Aminotransferase	Screening	2005-12-19T14:10	21	U/L	7	56	0
			Cycle 1 Dose 1	2005-12-27T08:55	20	U/L	7	56	0
			Cycle 1 Dose 2	2006-12-30T09:20	16	U/L	7	56	0
			Cycle 1 Dose 3	2006-01-03T11:00	21	U/L	7	56	0
			Cycle 1 Dose 4	2006-01-06T10:08	25	U/L	7	56	0
			Cycle 2 Dose 1	2006-01-13T11:45	27	U/L	7	56	0
			Cycle 2 Dose 1	2006-01-17T12:10	55	U/L	7	56	0
			Cycle 2 Dose 2	2006-01-20T21:00	27	U/L	7	56	0
			Cycle 2 Dose 3	2006-01-24T12:06	21	U/L	7	56	0
			Cycle 2 Dose 4	2006-01-27T13:40	22	U/L	7	56	0
			Cycle 3 Dose 1	2006-02-06T13:20	23	U/L	7	56	0
			Cycle 3 Dose 2	2006-02-10T11:35	22	U/L	7	56	0
			Cycle 3 Dose 3	2006-02-14T09:50	21	U/L	7	56	0
			Cycle 3 Dose 4	2006-02-17T09:06	21	U/L	7	56	0
			30 Days Post Treatment	2006-02-28T10:30	18	U/L	7	56	0
			Ongoing	2006-01-04T15:35	21	U/L	7	56	0
		Albumin	Screening	2005-12-19T14:10	3.9	g/dL	3.4	5	0
			Cycle 1 Dose 1	2005-12-27T08:55	3.7	g/dL	3.4	5	1

Clean, visual representation with very obvious outliers/ patterns



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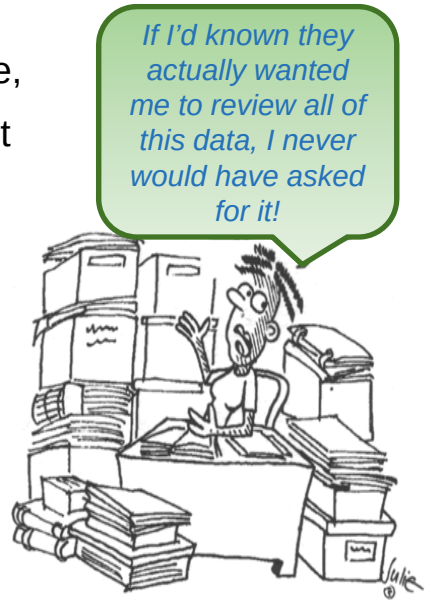
Project Team

A cross functional team was assembled within Development Sciences to evaluate, select and implement a data visualization tool in support of the Safety and Benefit Risk (SABR) Safety Surveillance practice.

The team included representation from SABR MDs, Clinical MDs, Clinical Data Sciences (CDS), Biostatistics, SABR Database Strategy & Administration (DSA), and R&D IT.

The project was sponsored by SABR and CDS.



Safety Surveillance Reports

Reports are built by the SABR DSA team, in close partnership with the MDs and the CDS Programmers, utilizing an agile development methodology

CDS Programmers work with the drug program teams to acquire the 6 input datasets; 9 integrated datasets are created, with some variable derivation, as part of the pre-processing for the reports; Programming independently verifies report values when new reports are developed

Release 1 Reports

- **Visualize Demographics, Adverse Event, Lab, Vital, Concomitant Medicine data**
- **Utilize CDISC SDTM compliant datasets**

Reports are for data review and hypothesis generation only and are not intended to support publications, or formal decision making processes

Trends that warrant further review are analyzed with Biostatistics using validated development processes

Returns

The reports provide a more efficient, interactive, standard tool for the Safety Surveillance practice and have helped standardize across MDs/ Drug Programs/ Therapeutic Areas

The use of CDISC SDTM compliant datasets and standardized reports allows for rapid deployment across programs and TAs

The reports provide the ability to drill down to longitudinal patient-specific views and roll up to aggregated views across a drug program

The integrated presentation of subject data allows for identification of trends more rapidly

Early identification of safety trends can lend to future study design

Data Visualization Tips & Tricks

"What We Learned"

Refined Problem Statement

A successful implementation required a refined problem statement

As with reports, the problem statement (“what we’re trying to show”) was developed iteratively in an agile manner:

- Start with basic visualizations per draft problem statement
- Iterated through further visualizations
- Let the data and the visual drive the solution

As experience with the reports and potential of the tool was developed, external references (publications, conference presentations) were used to further refine the reports

Following the Path

Visualization is *f*(x) of the data, a initial problem statement is required or users will generate own interpretation

As data is visualized, expect to continue to derive new visuals with more discrete functions or focus

Ability aggregate, drill down (study, up to program, down to subject) is an important consideration; different visualizations highlight different relations within the data

Need to have a well understood hierarchy in data, as it relates to the business use case (enrollment might be linked to investigator, site, geography)

Start Small * Plan Big * Go Fast

Biogen

Agile Development for Standardization

An agile approach was employed in both the tool selection and report development

The report development used an agile development methodology to drive towards standardization

The use of standard report templates, standard input data structure and independent verification of numerical values establish trust and enable rapid deployment

Standard reports, with limited data exploration by design, build capability within the report *f*(x) as opposed to at business user level

Technical Considerations

Report development should consider

- The source data (structure, format, content) and what is to be presented
- How the data is loaded into and managed by the platform
- Where to do any pre-processing of data
- How to put controls in for access to the underlying data
- The ability to export data

The User Experience

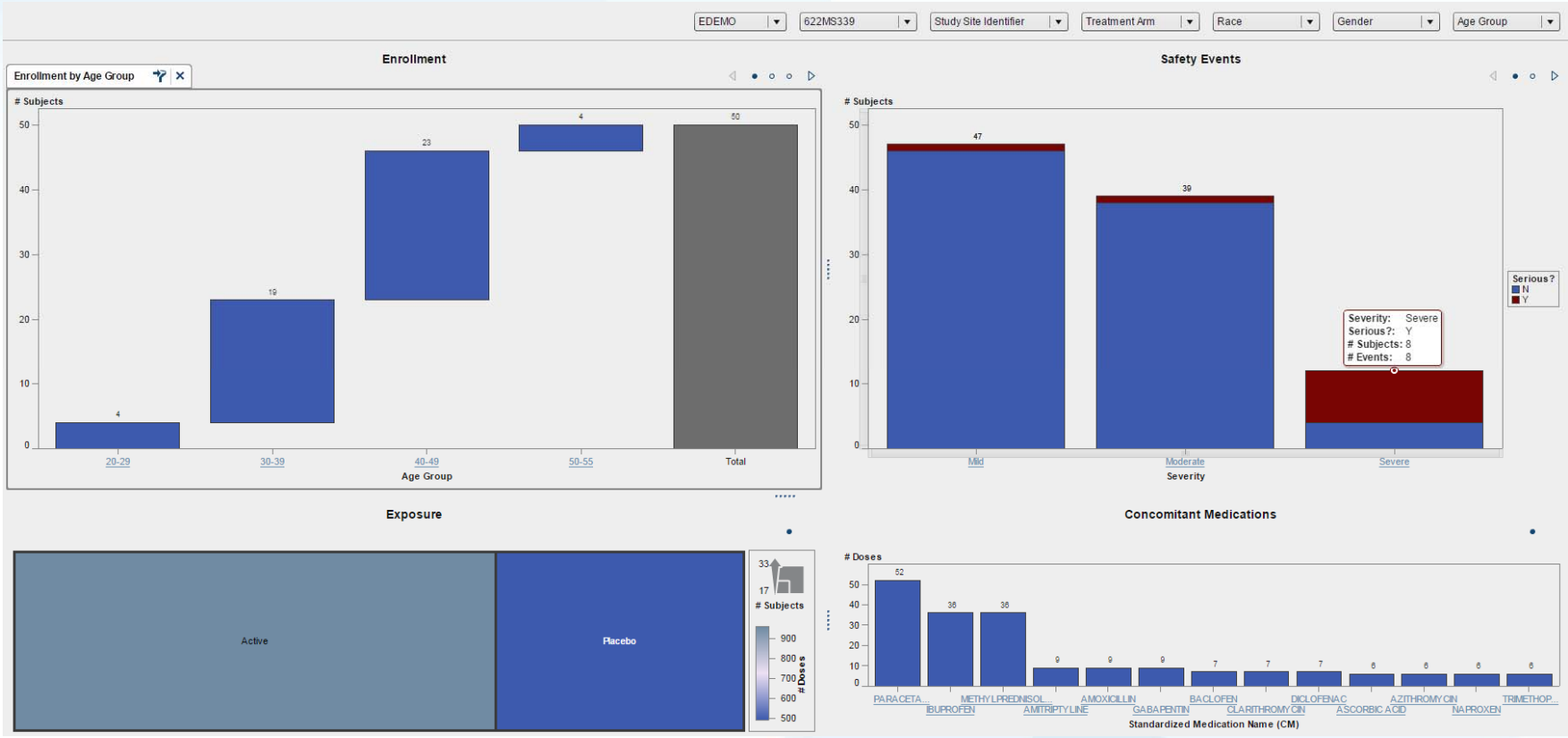
The User Experience should be considered during development, including

- Use of different visuals, colors, effects to call attention to anticipated trends
- Potential data flows across the different panels
- Presenting a consistent experience with similar look/ feel/ object placement
- Providing a similar experience across a range of hardware, designing for the lowest common denominator (screen space, memory use)

Data Visualizations

"The Good Stuff"

Study Overview



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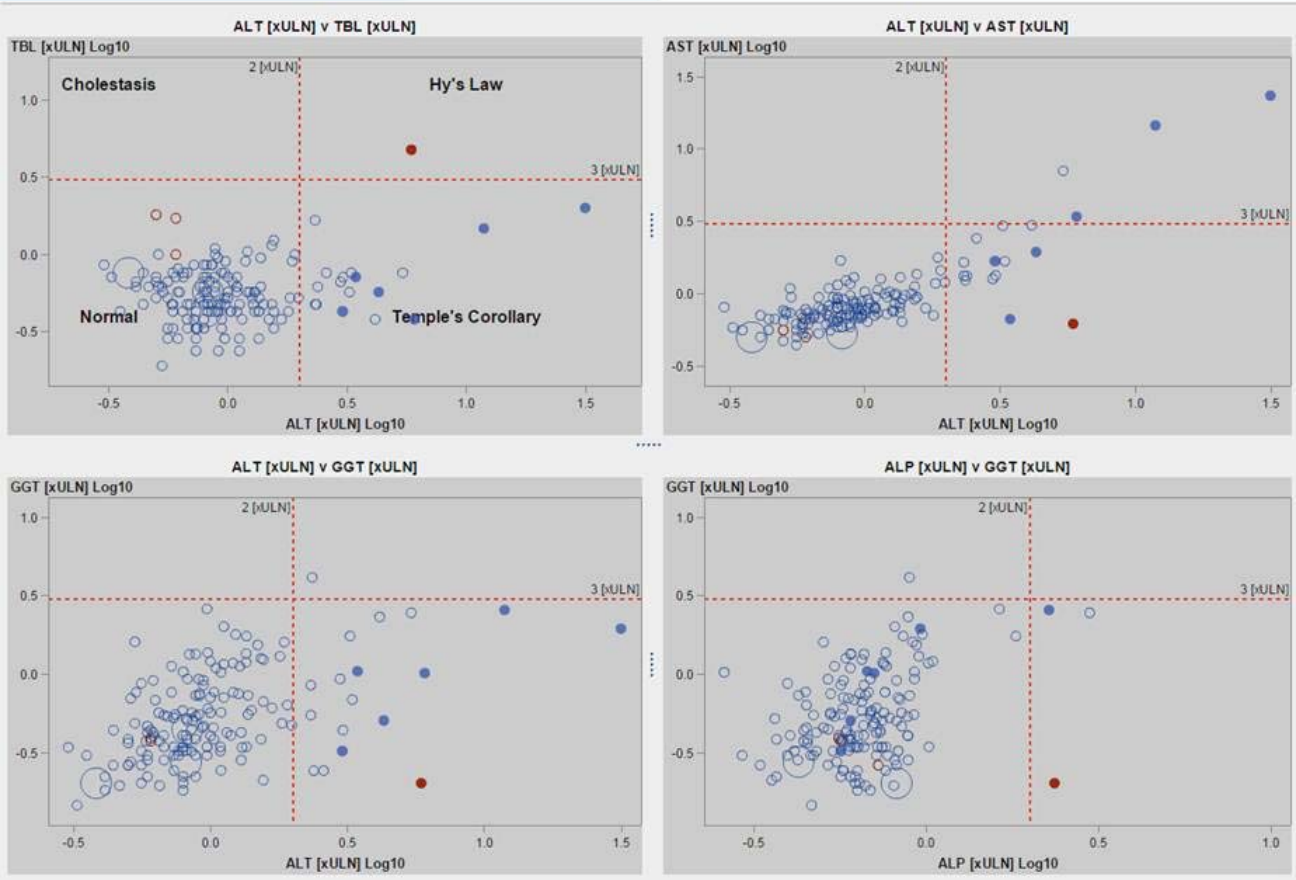
Evaluation of Drug-Induced Serious Hepatotoxicity (eDISH)



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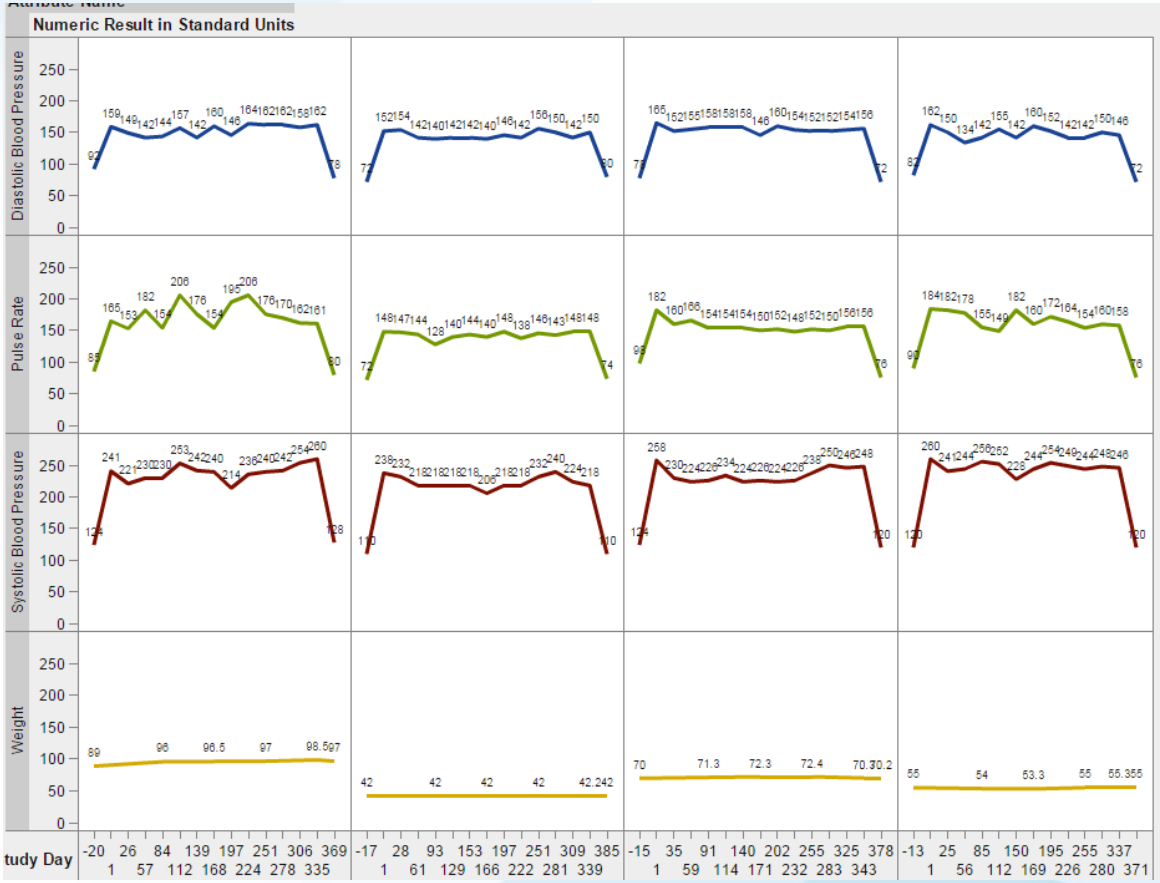
Vitals – Panels



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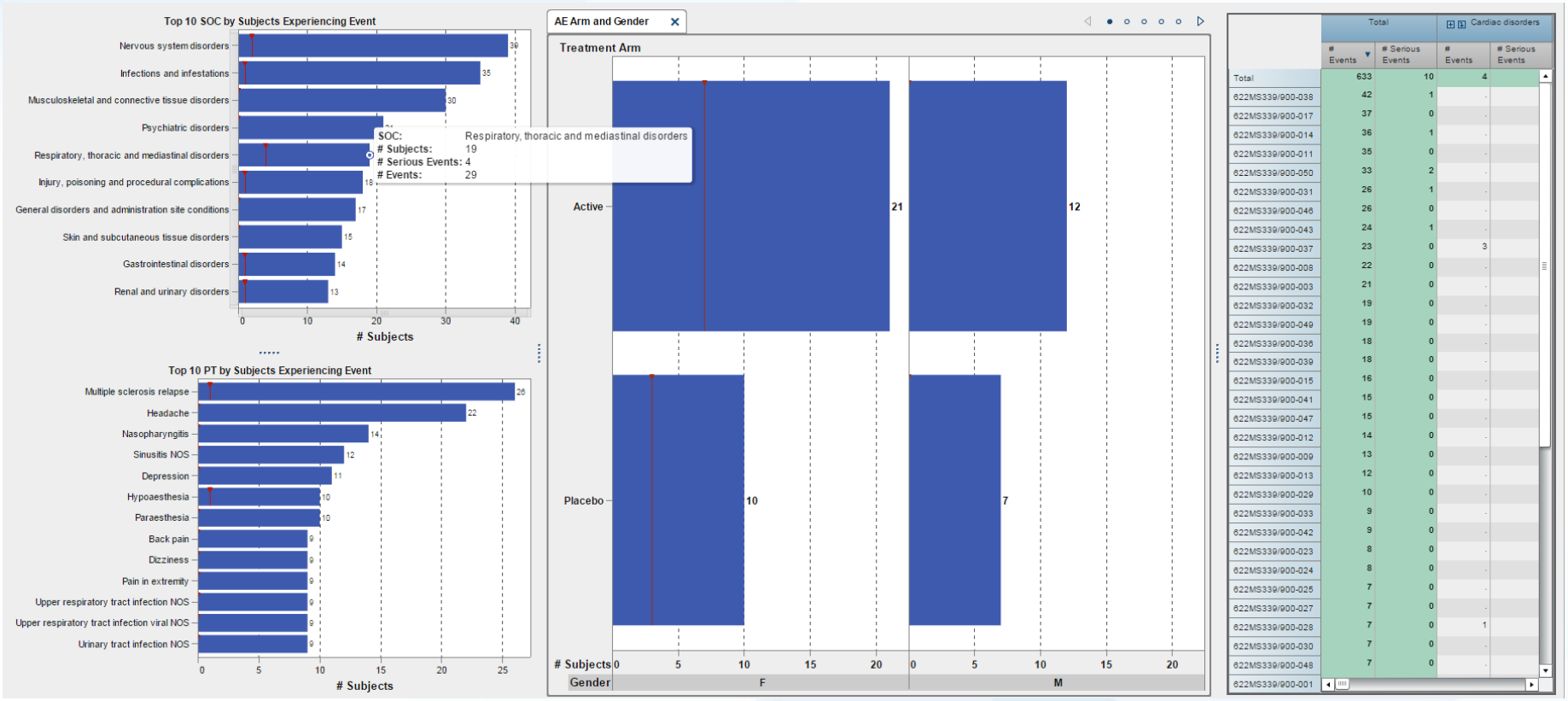
Adverse Events



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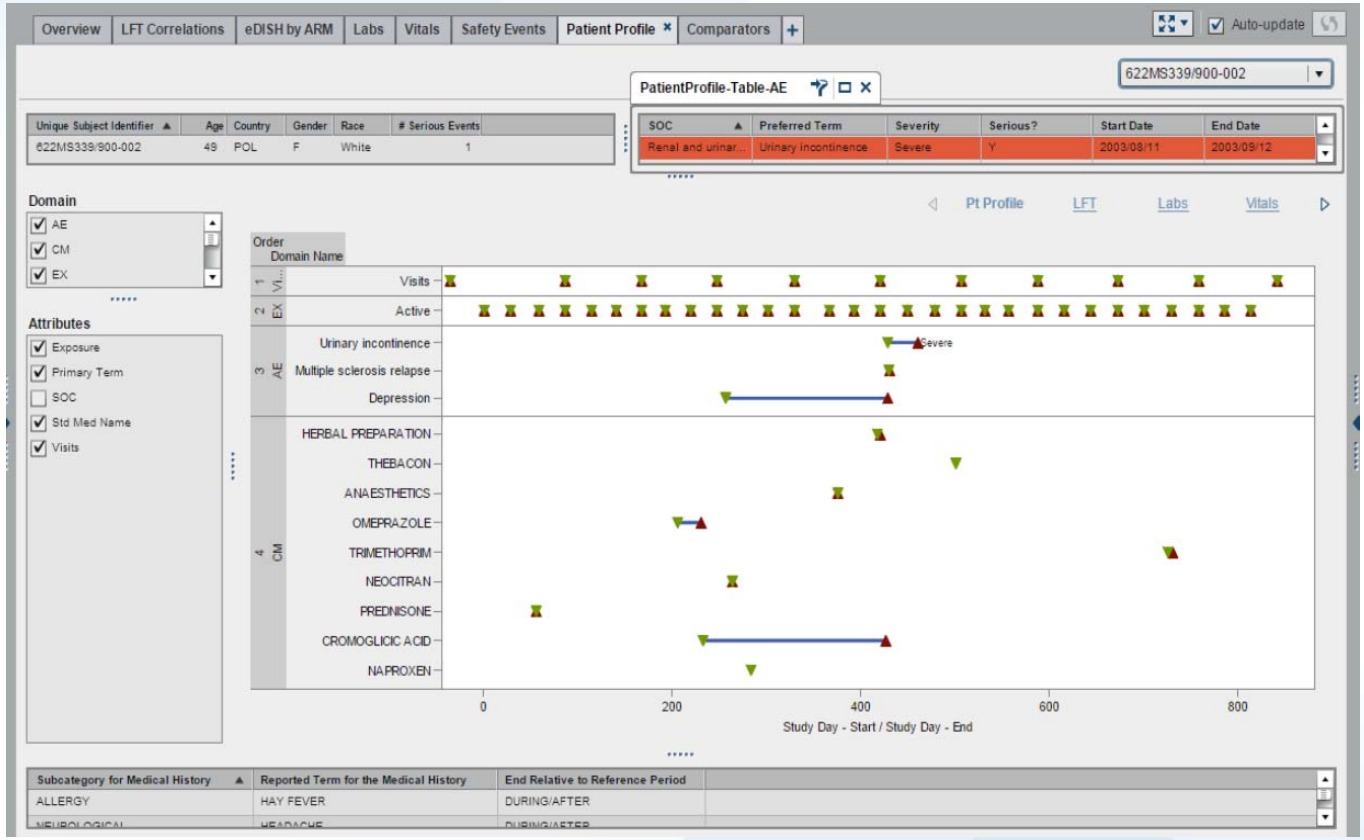
Patient Profile



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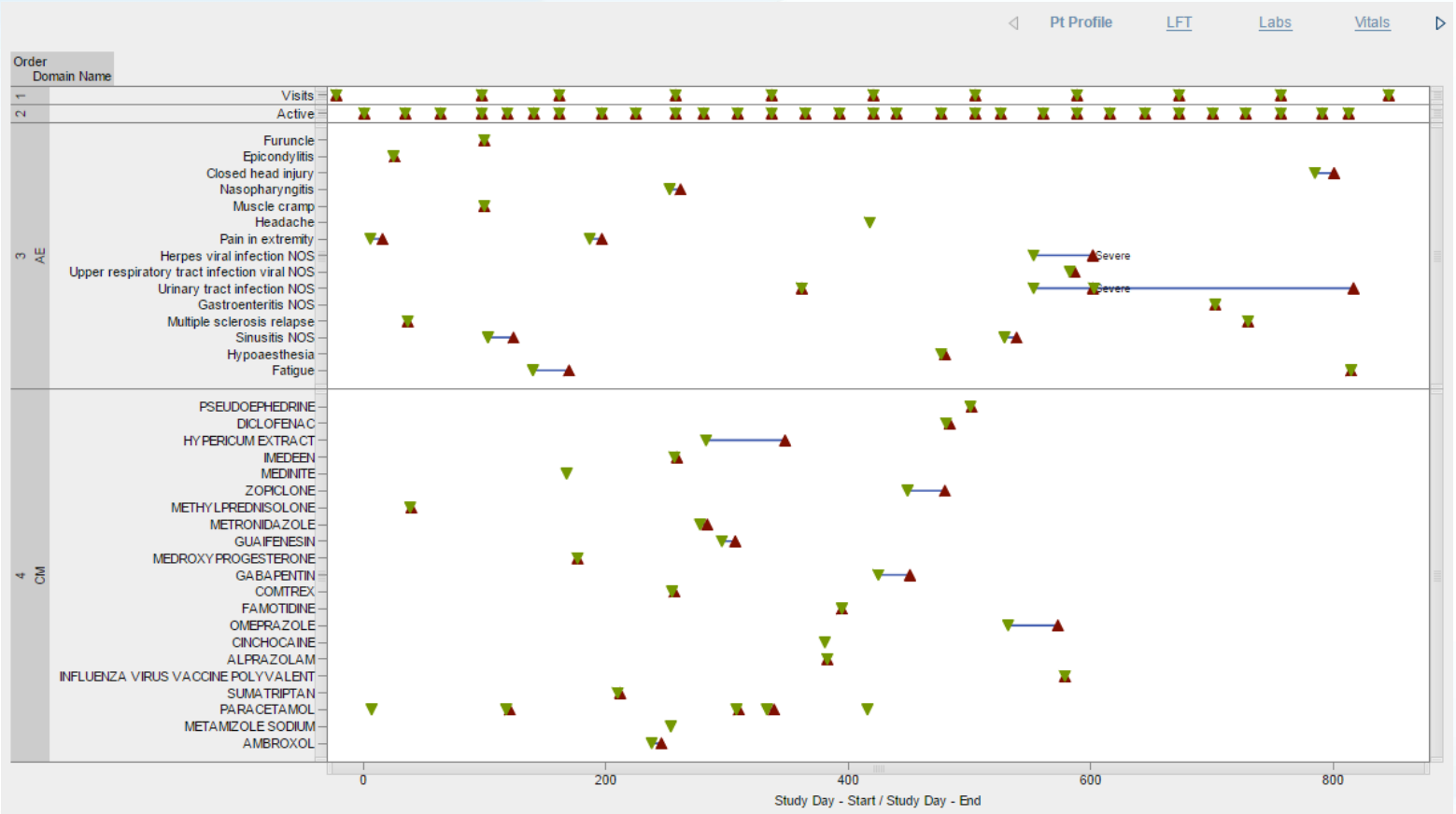

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