

Empowering People in Data Review through Interactive Visualizations

PhUSE SDE: Transforming Data Visualization –
A Peek into the Future of Clinical Data Analysis
Rebeka Revis
Eli Lilly & Company

Disclaimer for Spotfire safety review package

- There is currently no guidance on interactive displays from regulatory or the PhUSE Analysis and Display Whitepaper (ADW) Project Team
- We don't recommend to create these displays instead of the recommended ones by ADW or in sponsor's standards library
- Updates/modifications will be needed when the package is adopted for a study



**Computational Science
Working Groups**



Why interactive visuals?



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Interactive Visualizations at Lilly

- Data Review and Exploration
- Generating Static Reports included for study reports, submission documents, regulatory response documents.
- Advisory board meeting
- Data mining and publication efforts
- Other



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What is Spotfire?

- A tool that allows users to create interactive visuals
- Interact across visuals, datasets, and pages
- Can integrate other scripts from programs such as R and Python
- Two types of accounts
 - Professional: Creates the visuals
 - Webplayer: Can view and interact with visuals through a web browser
 - A company needs to set-up a server



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Where to find the Spotfire file?

- Uploaded to GitHub as a DXP file
 - <https://github.com/phuse-org/phuse-scripts/tree/master/contributed/Spotfire>
 - DXP file contains:
 - Embedded de-identified ADaM data
 - Original data files: <https://github.com/phuse-org/phuse-scripts/tree/master/data/adam/cdisc>
 - Multiple pages with interactive visualizations for safety analyses



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Cautions when using interactive visuals?

- How to validate?
 - Procedures to validate interactive visuals
 - Design challenges
 - Use good graphic principles
 - Just because you can do it doesn't mean you should
 - Principles still applied with interactive visuals
 - Use of interactive features
 - Designing interactive visuals should put the customer experience first
 - How does interacting with one visual affect the rest of the package?
 - Working model shift
 - Team collaboration greatly increases with interactive visuals
-



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Spotfire Demo

**The premier community for people
working in the biometric area**



 **phuse.eu**

 **@PhUSETwitta**

 **/PhUSE**

 **phusewiki.org**

Back-up slides (static version of interactive demo)

**The premier community for people
working in the biometric area**



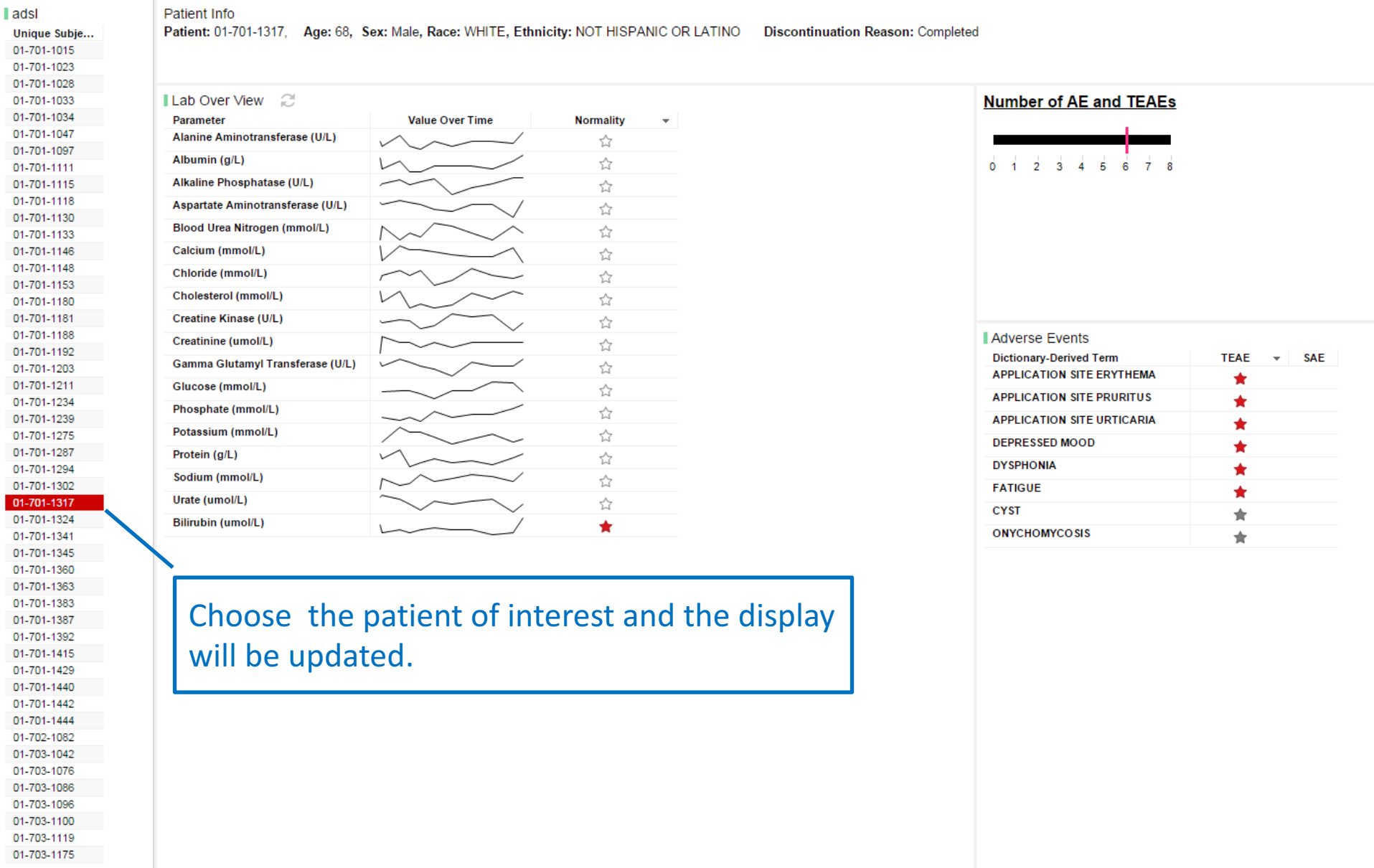
 **phuse.eu**

 **@PhUSETwitta**

 **/PhUSE**

 **phusewiki.org**

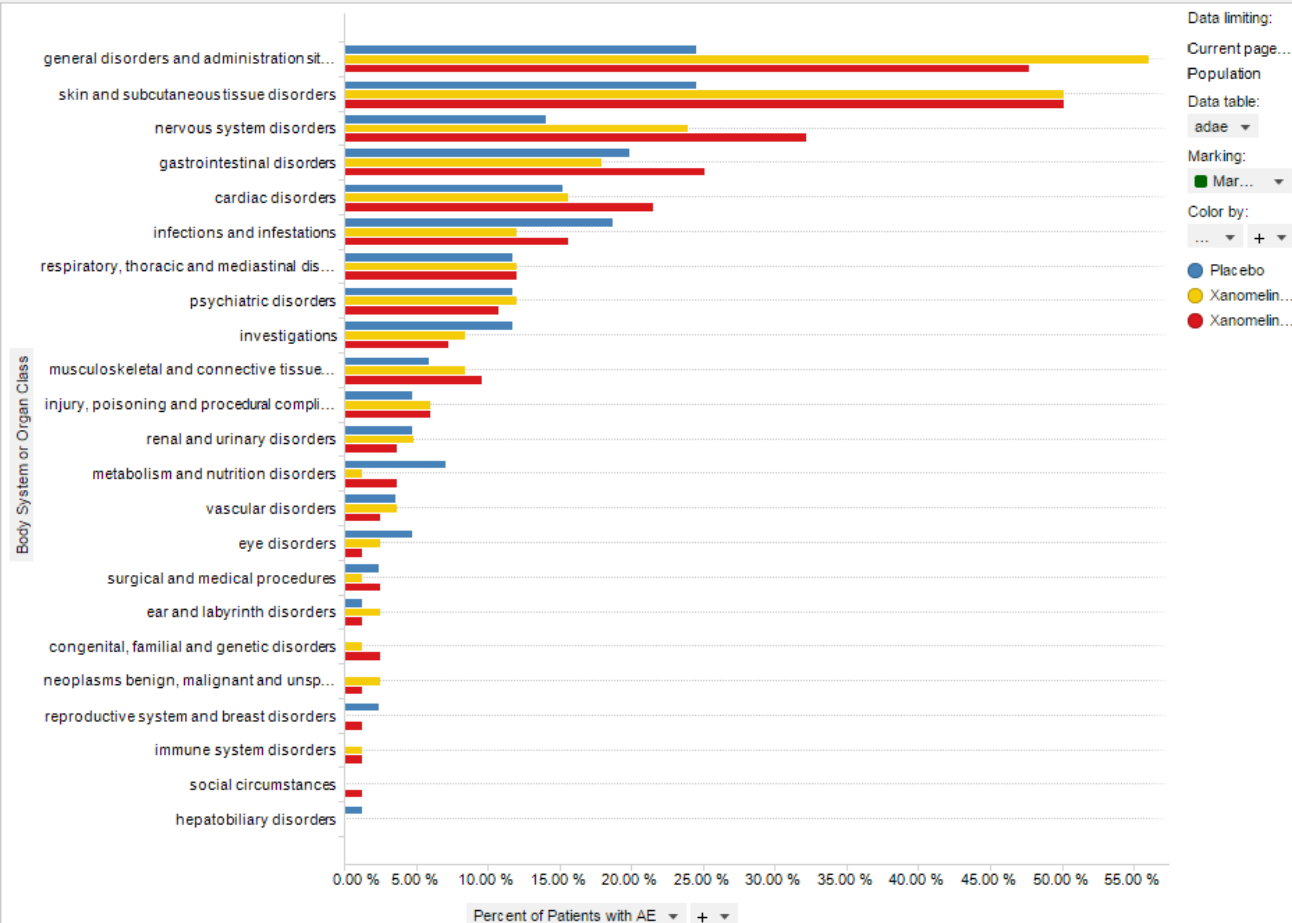
Overview of Patient Level Safety Data



Adverse Event Data in Connection of Lab Data Review

Percent of Patients with AEs by Body System or Organ Class - Sorted by decreasing frequency

[ZoomSlider On/Off](#)



Lab Over Time for Patients with Selected AEs

Analysis Value

+

+

No data to display. All data may have been filtered out or the data table is empty.

Analysis Relative Day

Percent of Patients with AEs by

Dictionary-Derived Term ▾

Lowest Level Term

Dictionary-Derived Term

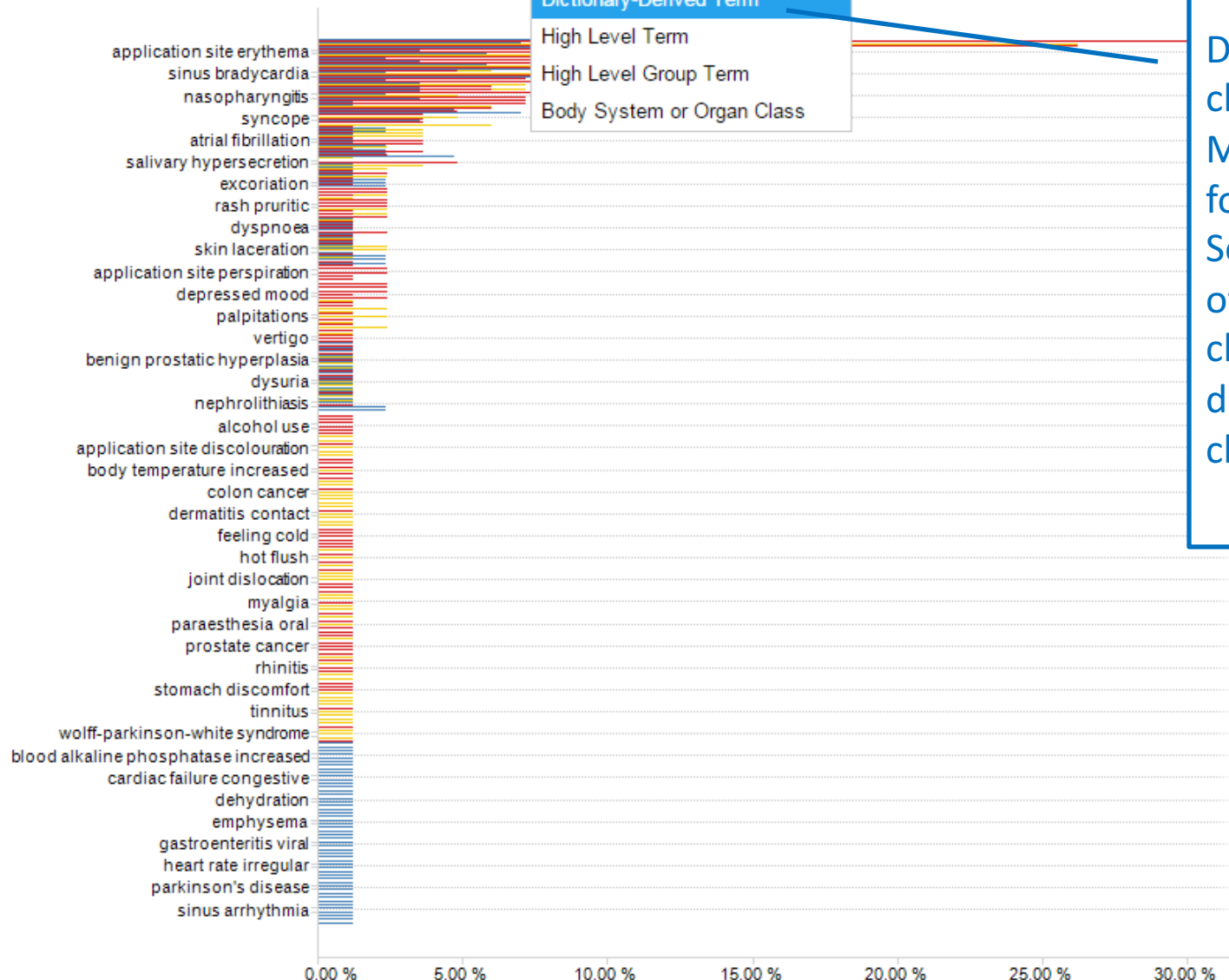
High Level Term

High Level Group Term

Body System or Organ Class

- Sorted by decreasing frequency

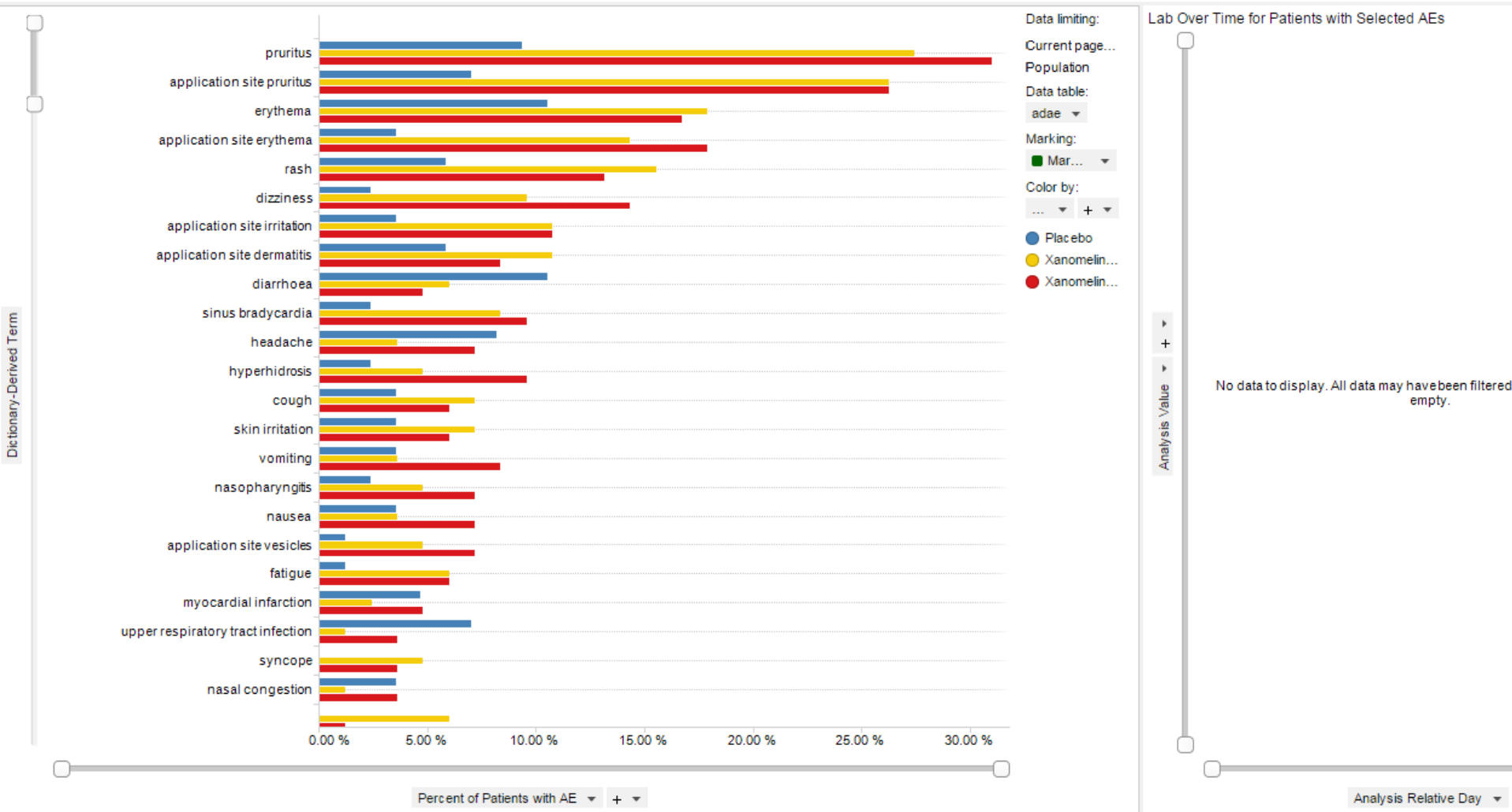
Drop down to choose the MedDRA Hierarchy for the AE terms. See how the y axis of the bar chart changes as the drop down selection changes.



Zoom slider can be turned on to get a zoomed in look at the plot.

Percent of Patients with AEs by Dictionary-Derived Term - Sorted by decreasing frequency

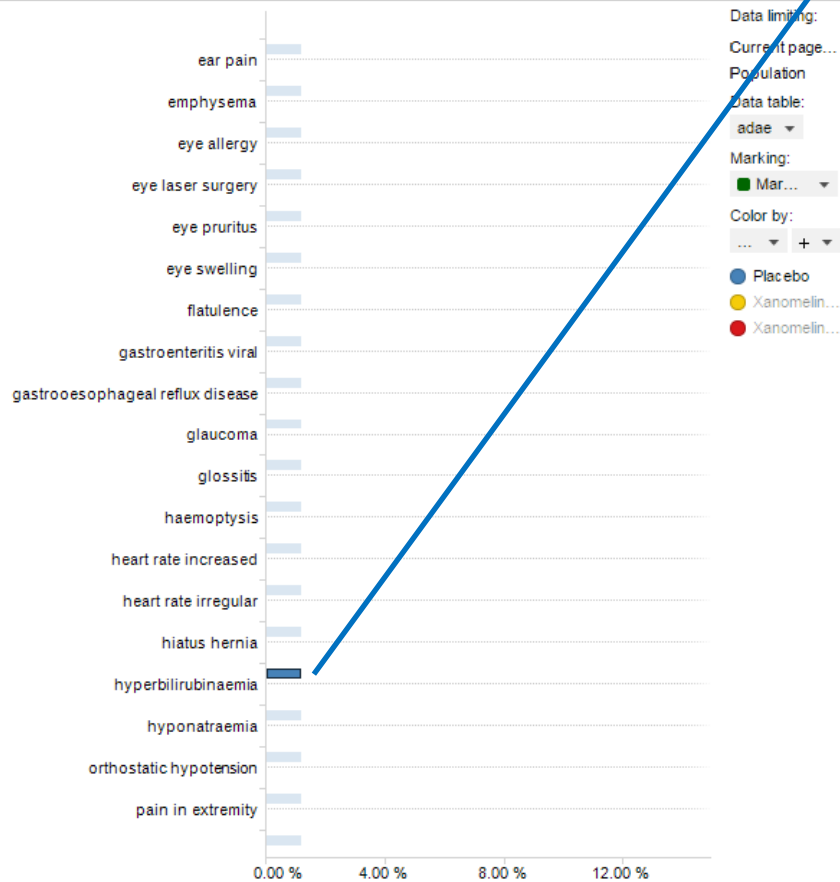
ZoomSlider On/Off



Choose an AE of interest and have all the lab information for those patients reporting that AE show up. Users can choose which labs they would like to show. Note: in this case, only one patient reported 'Hyperbilirubineamia'.

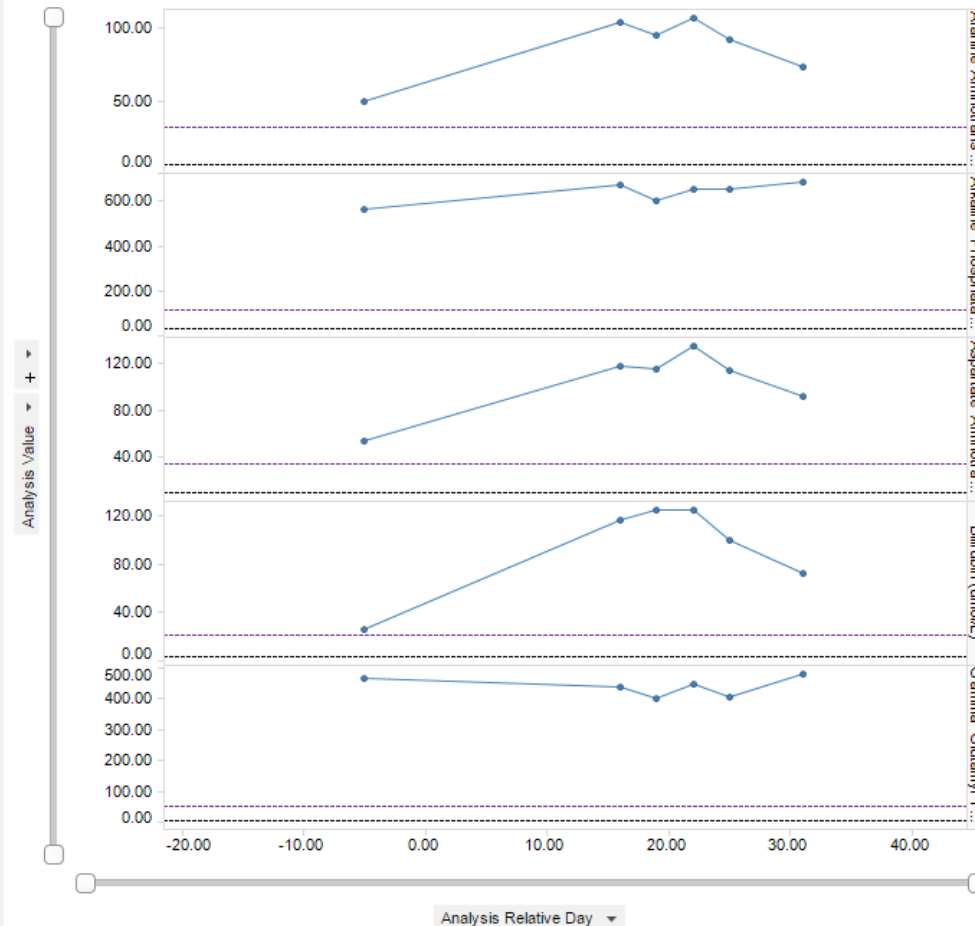
Percent of Patients with AEs by Dictionary-Derived Term - Sorted by decreasing frequency

ZoomSlider On/Off

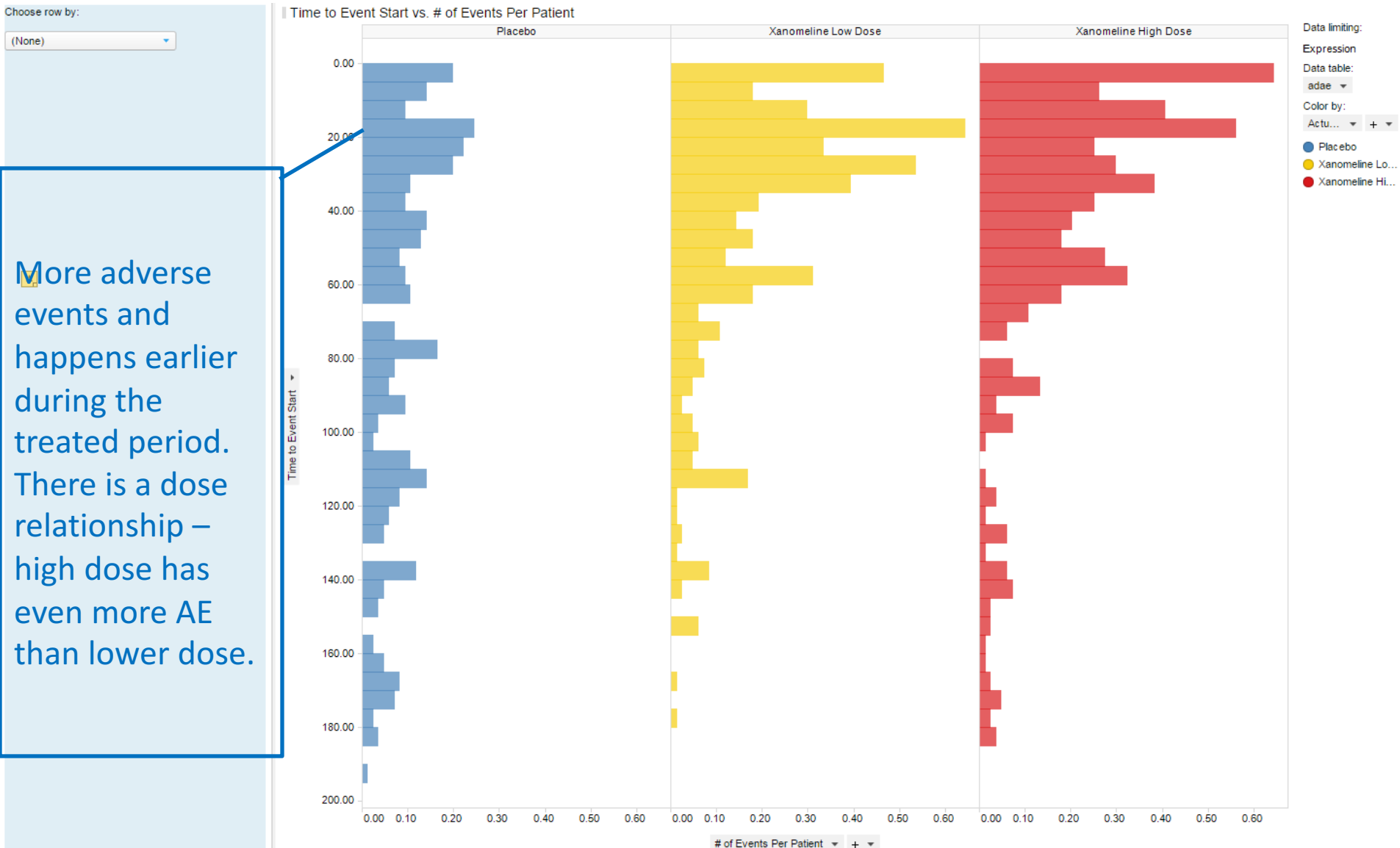


Data limiting:
 Current page...
 Population
 Data table:
 adae
 Marking:
 Mar...
 Color by:
 ... +
 Placebo
 Xanomelin...
 Xanomelin...

Lab Over Time for Patients with Selected AEs



Event Density and Onset



Drop down list for subgroup analysis

Choose row by:

Sex

Time to Event Start vs. # of Events Per Patient



Data limiting:

Expression

Data table:

adae

Color by:

Actu... +

Placebo

Xanomeline Lo...

Xanomeline Hi...

AE Summary Based on SMQs

Summary of Patients with Adverse Events - For Selected SMQs

Dictionary-Derived Term	Placebo		Xanomeline Low Dose		Xanomeline High Dose		Grand total of Count	Grand total of Percent
	Count	Percent	Count	Percent	Count	Percent		
CARDIAC FAILURE CONGESTIVE	1	1.16 %	---	---	---	---	1	0.39 %
OEDEMA PERIPHERAL	2	2.33 %	1	1.19 %	2	2.38 %	5	1.97 %
OEDEMA	---	---	2	2.38 %	---	---	2	0.79 %
Grand total	3	3.49 %	3	3.57 %	2	2.38 %	8	3.15 %

Choose SMQs

- Cardiac arrhythmia terms, nons...
- Cardiac failure (SMQ)
- Cardiomyopathy (SMQ)
- Cholestasis and jaundice of hep...
- Chronic kidney disease (SMQ)
- Conduction defects (SMQ)
- Congenital, familial and genetic ...

☒ Broad
☒ Narrow
Scope ☒ SMQ

Choose SMQ(s)

Summary of Patients with Adverse Events - For Selected SMQs

Dictionary-Derived Term	Placebo		Grand total of Count	Grand total of Percent
	Count	Percent		
CARDIAC FAILURE CONGESTIVE	1	1.16 %	1	0.39 %
Grand total	1	1.16 %	1	0.39 %

Choose SMQs

- Convulsions (SMQ)
- Depression (excl suicide and s...
- Disorders of sinus node functio...
- Dyslipidaemia (SMQ)
- Embolic and thrombotic events,...
- Eosinophilic pneumonia (SMQ)
- Gastrointestinal haemorrhage (...)

☐ Broad
☒ Narrow
Scope ☒ SMQ

Define scope

Safety for Patients Met a Lab Threshold

Define Threshold

Choose a Threshold:

100.00 1860.00

☒ Include empty values

ZoomSlider On/Off

Reset All Markings

of Patients Ever Met Threshold (Step1)

Planned Treatment	# of Patients
Xanomeline Hig...	1
Placebo	2
Grand total	3

of Patients with the Counts of Obs Over Threshold (Step2)

Counts of Obs Met Threshold	# of Patients
1	2
2	1
Grand t...	3

List of Patients With Obs Met Threshold (Step3)

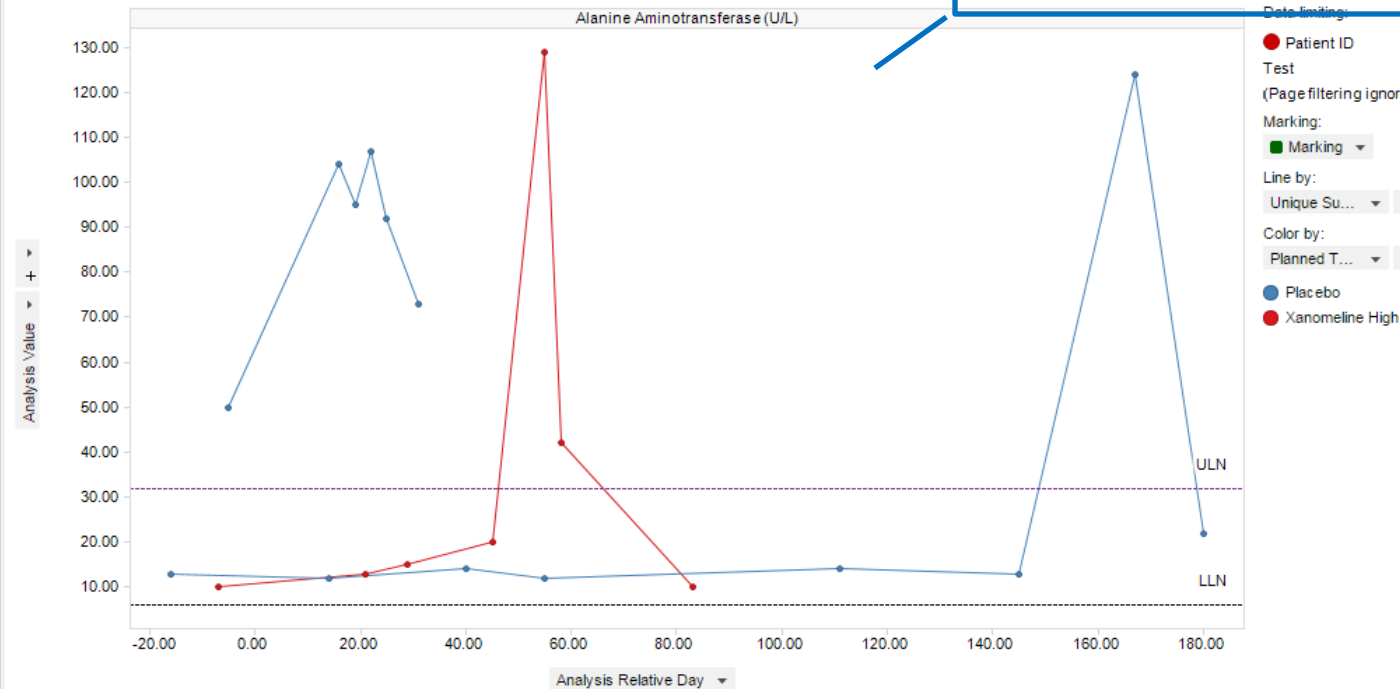
Unique Subject I...
01-705-1186
01-705-1310
01-708-1286

Over time measures for patients ever met the threshold

AEs for the Selected Patients

Dictionary-Derived Term	Placebo	Xanom... High Dose
ABDOMINAL PAIN	1	---
APPLICATION SITE PRURI...	1	---
CONSTIPATION	1	---
HYPERBILIRUBINAEMIA	1	---
MYOCARDIAL INFARCTION	1	---
RASH PRURITIC	---	1
WOUND HAEMORRHAGE	---	1

Lab Measures Over Time for Selected Patients (Defined in Step3)

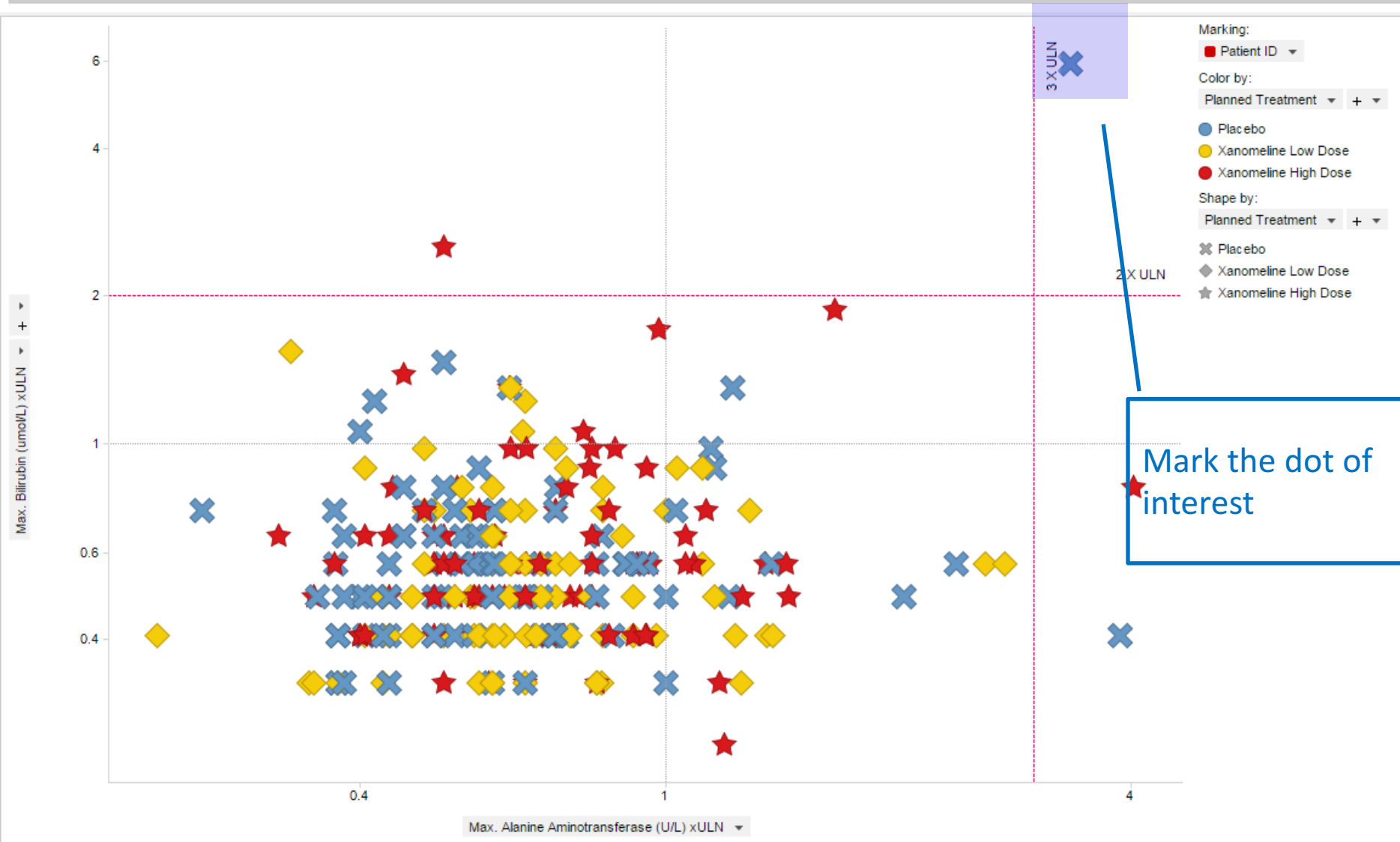


Adverse Events for those whose lab measures met the threshold.

Max. Bili vs Max. ALT

Max.Bilirubin (umol/L) xULN vs. Max.Alanine Aminotransferase (U/L) xULN

Zoom Slider On/Off



'Patient Profile Page' is synchronized to the patient selected in the previous page.

Patient Profile for Subject: 01-705-1186, Age: 84, Sex: Female, Race: WHITE, Ethnicity: NOT HISPANIC OR LATINO

Discontinuation Reason: Physician Decision

