

Collaboration with Safety Scientists Using Interactive Data Displays

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Introduction

Recognizing the effectiveness of visual analytics in improving data review and data analysis for clinical data, we began our data visualization journey to explore various tools and conduct feasibility pilots. One such pilot supported safety data review and analysis using Spotfire. The success of this pilot and the increasing business need to become more agile through stakeholder partnerships, lead to a collaboration between safety scientists and statistical programming. The goal was to further assess and explore new data visualization methodology and technologies to improve information flows and analytics for safety data. The safety focused visualization suite in Spotfire is the outcome of our collaboration. The purpose of this poster is to share how interactive displays could be used as a self-service tool to empower our stakeholders to perform ongoing safety data review and analysis with latest clinical data in a more efficient and timely manner.

Spotfire for Safety Data Analysis

There are many visual analytics softwares on the market, and each has its own strength. We chose Spotfire as the collaboration tool not only because of its easy-of-use with interactive and dynamic features, but also because of our existing Spotfire infrastructure and stakeholders' familiarity with the tool.

What is Safety Focused Visualization Suite ?

The interactive safety reporting tool is a set of analysis-driven visualizations for safety data. It follows our standard analysis criteria for clinical study report and uses analysis datasets as the source data. Specifically, it accesses data routinely used by Safety Sciences such as demographics, adverse events, laboratory values, concomitant medications, study treatment and medical history. It provides interactive visualizations such as time to adverse event onset commonly used to assess the causal relationship between a drug and an adverse event. It can be further customized per molecule- or study-specific needs. Below is the table of contents for the visualization package with links:

Safety Data Domain	Summary Tables/Plots	Listings / By-Patient Plots
Demographics	Demographics 1 (Discrete) Demographics 2 (Continuous)	Listing: Demog
AE	AE Graph Time to AE Onset AE Table by PT AE Table by SOC and PT AE Table by Highest Grade	Listing: AE
Patient Profile	Patient Profile	
Lab	Lab Summary Lab Summary (Chg Fr BL)	Lab By-Patient Plot Listing: Lab Tests
Vital Sign	VS Summary VS Summary (Chg Fr BL)	VS By-patient Plot Listing: VS
Study Drug		Study Drug by-Patient Plot Listing: Dose Exposure
Concomitant Medication	Conmed Summary	Listing: Conmed
Medical History		Listing: Medical History

Highlights of Key Functionalities

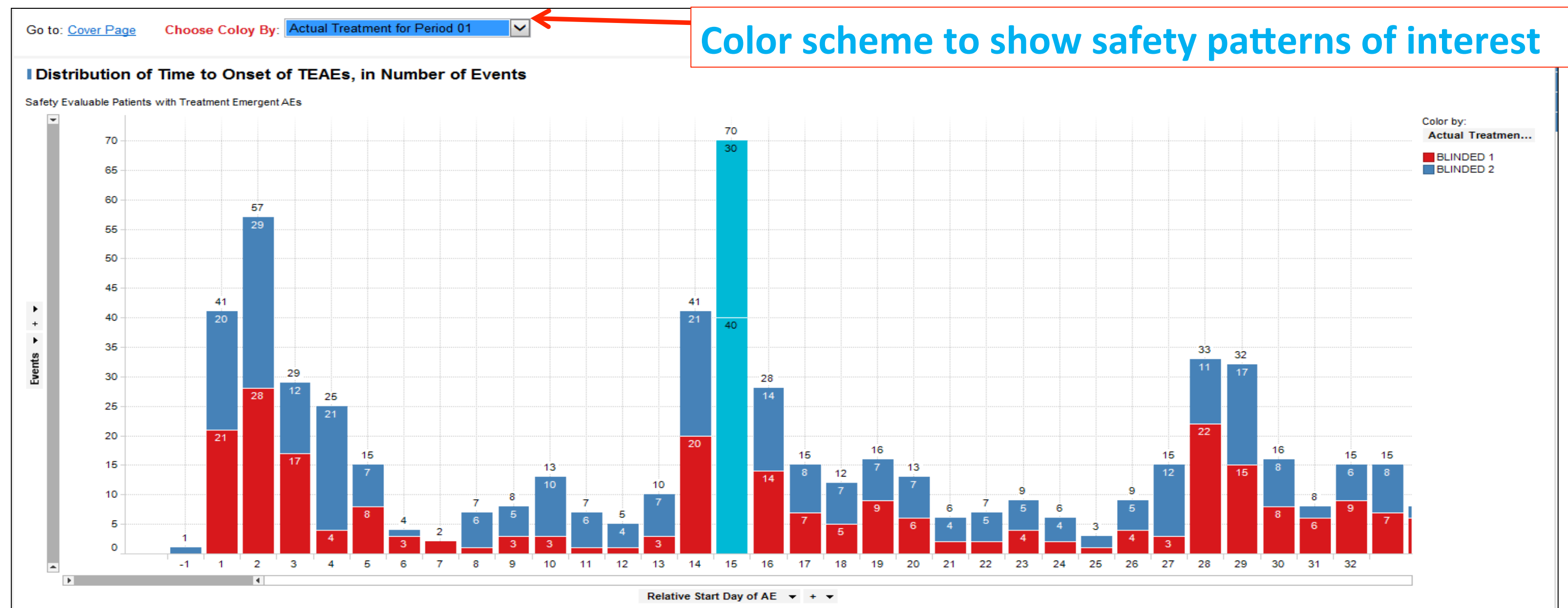
Throughout the collaboration, we worked closely with safety scientists to ensure the visualizations were designed to meet business needs for ongoing safety signal evaluation, exploratory analysis and reporting. Highlighted below are a few key functionalities of the tool:

- Use safety analysis datasets and follow analysis criteria to ensure quality and consistency with clinical study reporting;
- Enable subgroup analysis for population of interest across data domains;
- Allow flexibility for selection of denominator for % calculation;
- Put business process in place for interactive data displays to ensure compliance and results can be reproduced.

Example Interactive Data Displays to demonstrate the key functionalities as highlighted above.

Example 1: Distribution of Time to Onset of Adverse Events

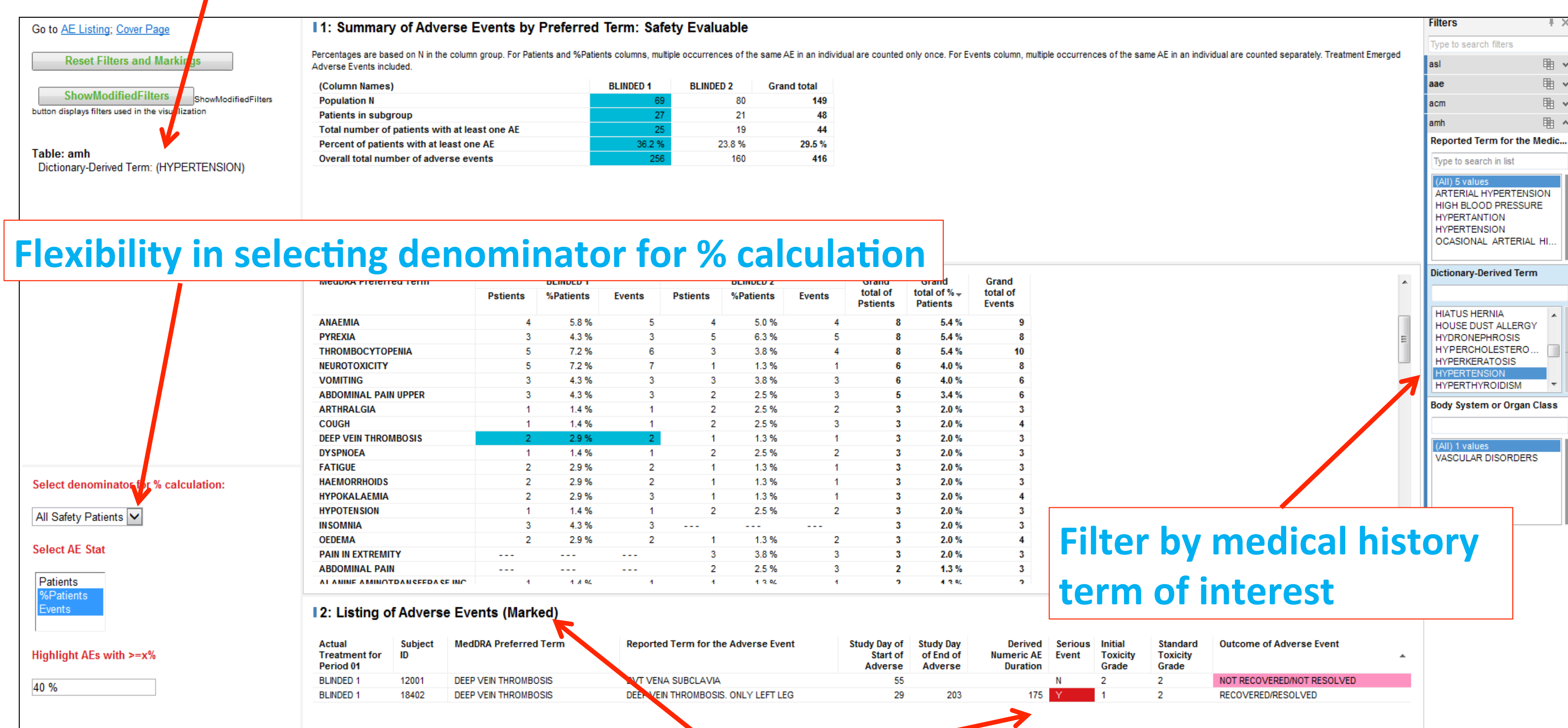
The bar chart displays number of treatment-emergent events by onset day. By using drop-down list via color scheme in Spotfire, it can be used to monitor safety pattern of interest such as difference between treatment groups, study drug relationship, serious events.



Example 2: Summary of Adverse Events by Preferred Term; Subset by Medical History Term of Interest

The interactive table below is a patient-level summary of adverse events, subset for patients with a medical history of hypertension. It can in fact offer flexibility to generate as many subgroup analysis as needed via filters and % calculation.

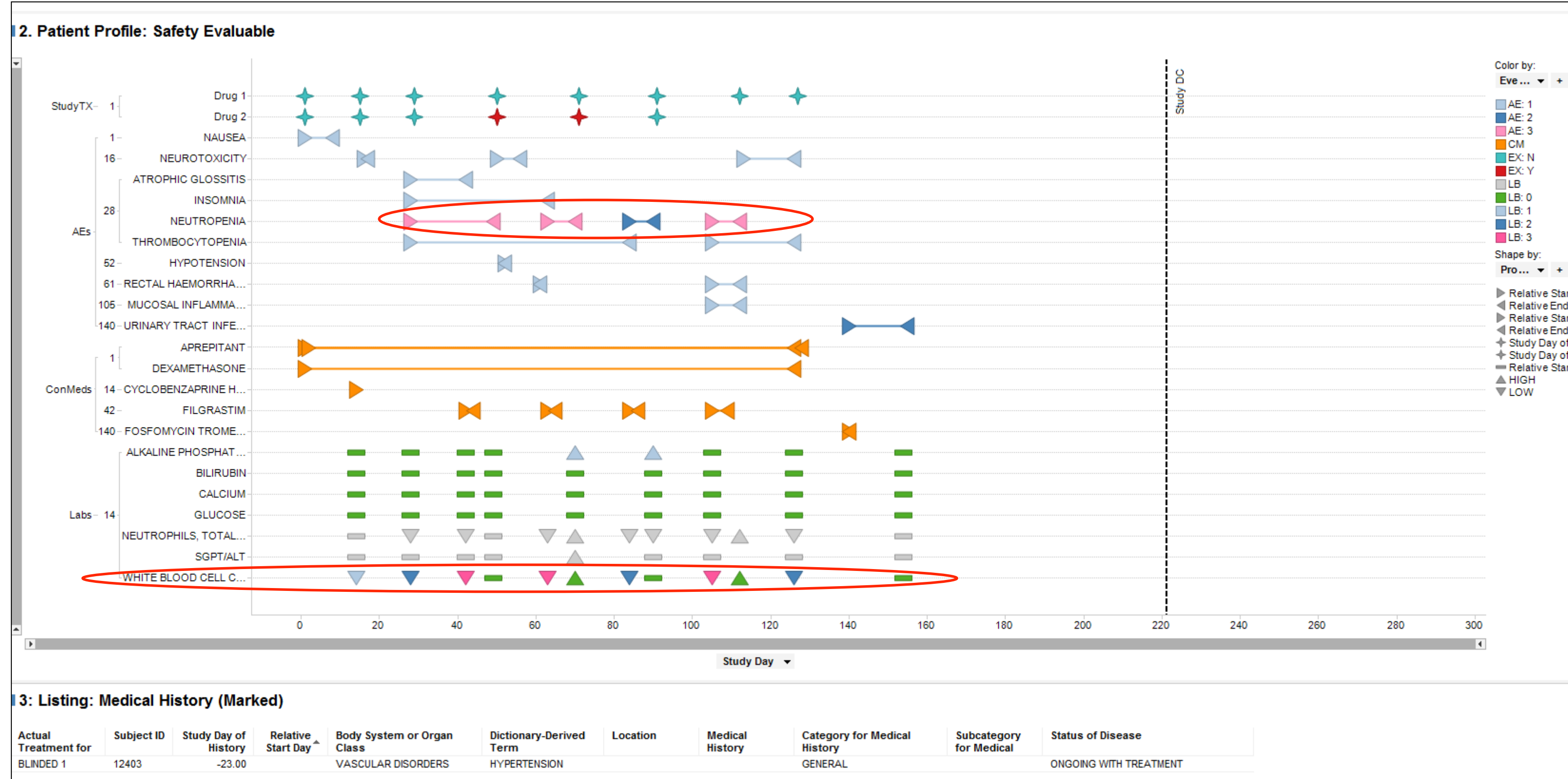
Reveal filters used for underlying data for accurate interpretation



Modernize review with interactivity to drill down patient-level data or highlight information of interest

Example 3: Patient Profile Shows Clinical Course with Neutropenia (Low White Blood Cell Count)

This visualization depicts the clinical course for one patient over time, displaying AE, study medications, concomitant medications, and labs.



Conclusion

With regular data refresh and the capability to slice and dice the data, the safety focused visualization suite is a useful self-service tool that enables stakeholders to gain greater insights of underlying data patterns and the ability to make better informed decisions using the last clinical data. This tool also allows us to streamline the process from exploratory analysis to formal deliverable by providing more targeted & refined analysis requests.

The interactive data displays signify a new platform for data review and data analysis. With more advanced technology and new learning and business use, we hope it will pave a new way for data analysis in the pharmaceutical industry.