

Make Your Life Easy! How SpotFire and SAS together can help with better Data Review and Data Quality

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ABSTRACT

Data quality and data review to identify data issues are both very important to ensure quality, accuracy and integrity of the data analysis in clinical studies. Often, depending on size of company and tools available, clinical data review could be very cumbersome, time consuming and manual. It leads reviewer to miss critical issues which leads to poor quality of data hence less accurate results. Spotfire along with SAS, with all these features, ensures very efficient data and timely data review. Many different functions can also use Spotfire visualization for their own benefits. For ex- SAS programmers can easily identify data issues critical for analysis or do quick informal qc on data, Clinical Scientist/Data Monitors can easily and optimally conduct data review by drilling down data using Spotfire features, Safety Science/Pharmacovigilance can easily identify safety issues with subjects and Data Managers can get a quick summary of outstanding data issues.

This paper talks about an actual use case and how Spotfire was utilized to achieve the propose of quality and timely data review and how different functions including statistical programming can benefit using Spotfire for data visualization and data review. For data privacy reason, dummy data is used for visualization.

INTRODUCTION

Spotfire has gained substantial popularity in recent years because of its versatility and ease of use. Many different functions within an organization can benefit from its potential. In smaller companies where resources are very limited and deadlines are always tight, Spotfire can be utilized for data review, adhoc informal analysis and so much more.

This paper talks about a case study where sponsor, a smaller size biotech with limited resources, successfully utilized Spotfire for many different proposes including clinical data review and data analysis.

DATA FLOW FOR VISUALIZATION

As most of the studies were at initial stages and SDTM/ADaM datasets were not available, it was decided to use raw data extracted from EDC (Electronic Data Capture) system. Figure 1 below depicts the data flow leading up to the visualization.

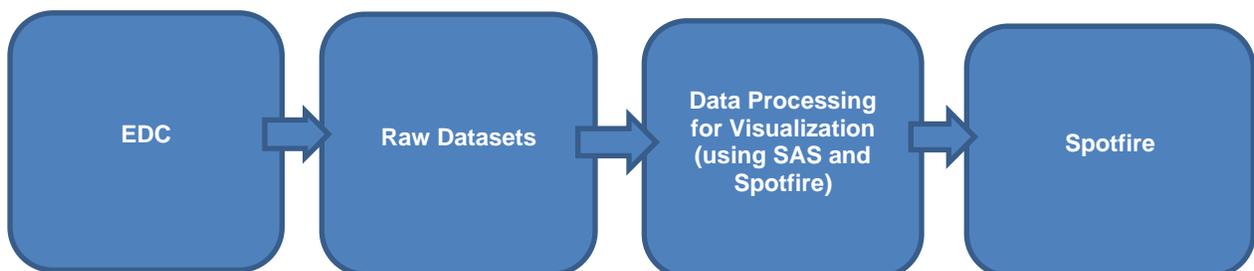


Figure 1. Data Flow for Spotfire Visualization

USER REQUIREMENTS FOR DASHBOARD

After the flow of data into Spotfire has been established, next came the stage to define what visualizations team wants to see for data review. A team consist of Clinician Scientists, Biostat and Statistical Programmer has been set-up to gather the dashboard requirements. This encompasses collecting user requirements, creating draft visualizations, sharing with the team, collecting feedback, and then finalizing the visualization.

Figure 2 below process flow for dashboard visualization



Figure 2. Example of process flow for dashboard visualization

SPOTFIRE DASHBOARD

Final dashboard included almost all the safety and efficacy data collected through EDC (Electronic Data Capture) system.

Figure 3 below shows visualization from enrollment data



Figure 3. Enrollment Data Visualization using Spotfire

SPOTFIRE FUNCTIONALITIES

What makes Spotfire desirable for data visualization and data review is built in functionalities within Spotfire. There are vast number of features within Spotfire, some key ones which users find useful for data review are listed below

Filters

Once data is read in Spotfire, it automatically creates different filters based on the data. These filters are very useful for data review as user can drill in and out of the data as needed.

Multiple Visualizations

Many different visualizations can be fit on same page. This helps reviewer to see different data on same page. Fig 4 below highlights these features.

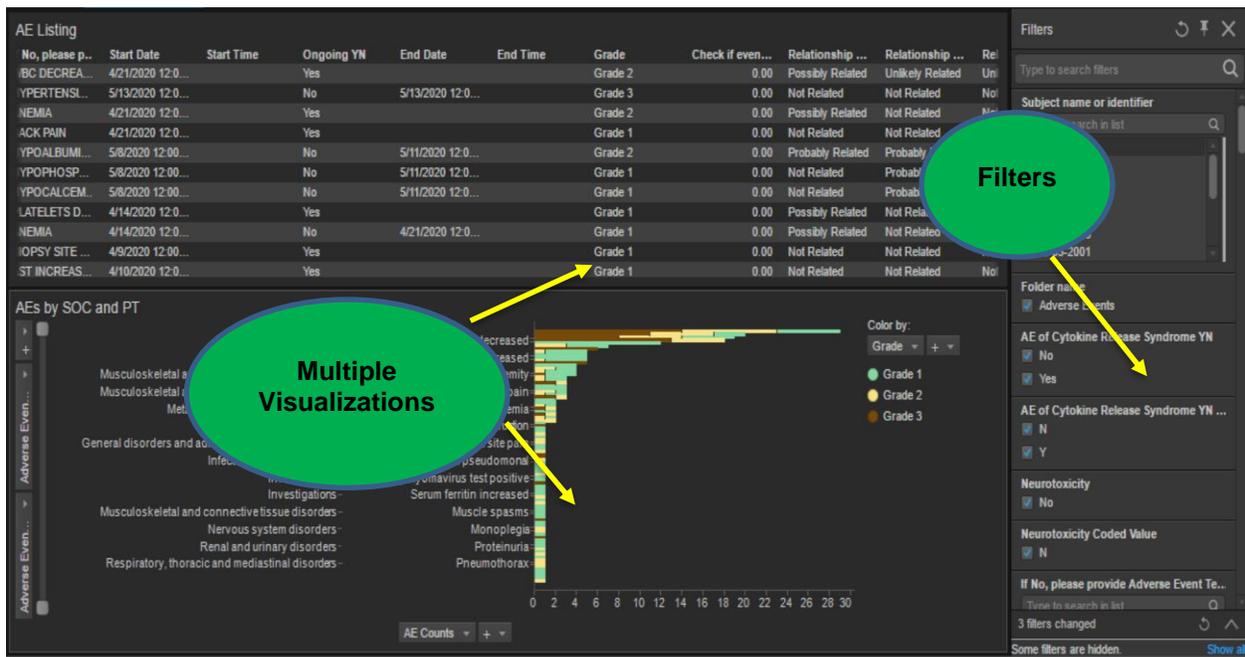


Figure 4. Filters and multiple visualizations

Exporting Visualizations

Spotfire visualization can be easily exported into different format, including underlying data used for visualization. This built in functionality within Spotfire can be used to easily import and share visualization with different team members.

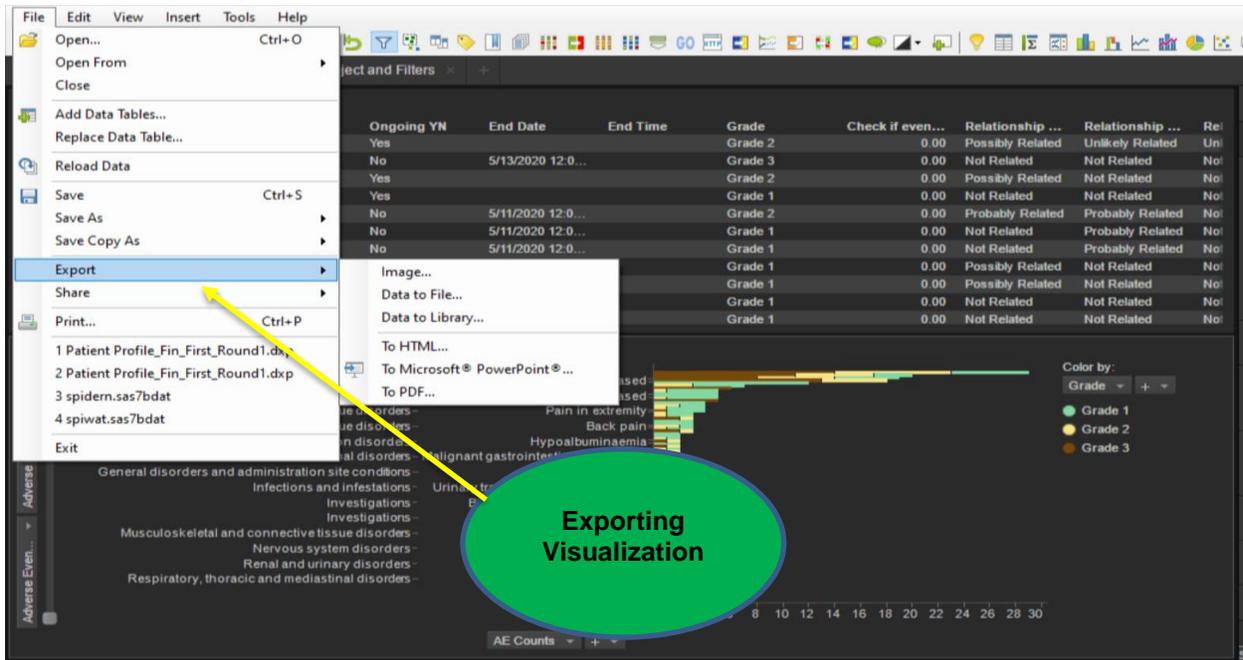


Figure 5. Exporting visualization

Switching Visualization

User can easily switch in between different visualizations. However, user will have to customize the display after doing such switch. For ex- switching from table layout to pie chart layout may not yield a display which user is looking for. User will need to customize the pie chart using correct variables. Fig 6. below display this functionality.

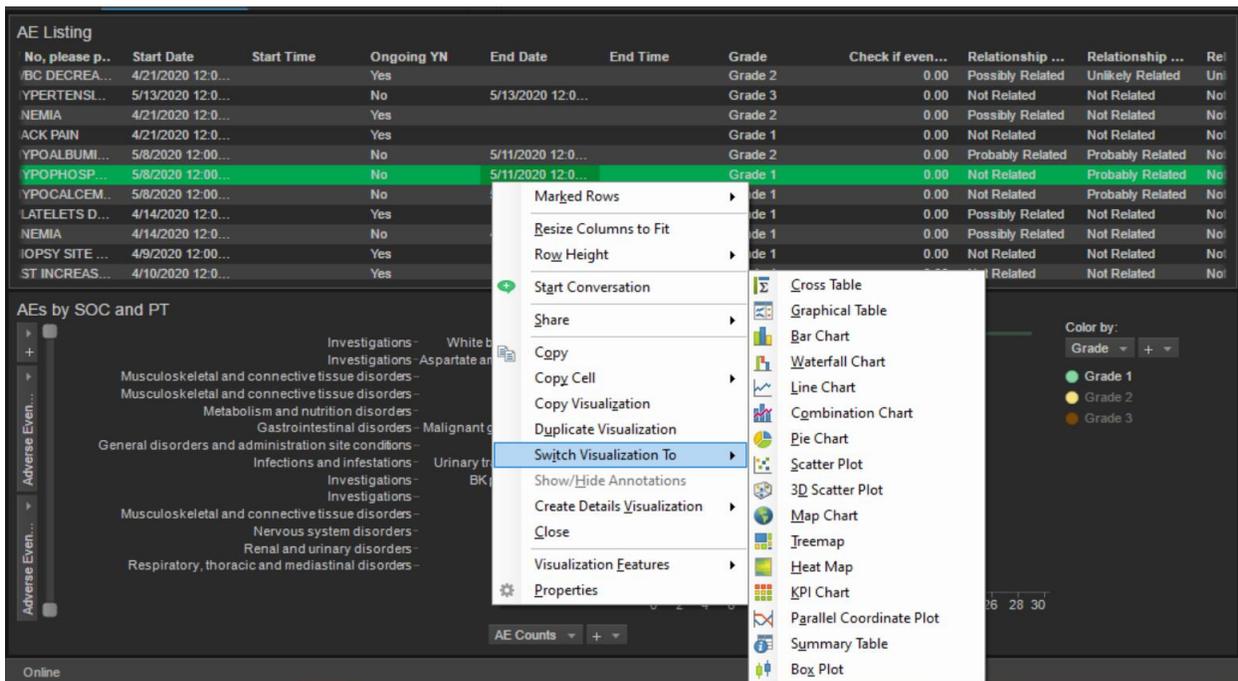


Figure 6. Switching in between visualizations

FINAL DASHBOARD

The final dashboard which came out of this initiative, with different displays/visualizations is shown below, because of space constraints, not all displays/visualizations are presented. However, user can add as per their needs.

Enrollment

Fig 7. below displays subject's enrollment data. Many different visualizations including bar charts, pie charts, etc. are used to display enrollment information. This is very helpful to get a bird's eye view on how many subjects are enrolled, status of subjects, disease type, number of subject enrolled by site, etc. Medical monitors and other functions found this display very useful; it also gives a quick familiarity to team members who are new or transitioning from other projects.



Figure 7. Study Enrollment Data

Demography

Demographics display provides like enrollment display, provides a summary of demographic information of the subjects enrolled in the study and it can be customized as per the need of the team. In the display below bar charts, box plots and pie chart are used to display various stats for different measurements.



Figure 8. Study Enrollment Data

Adverse Events

Adverse events are always of high importance for any company and its of vital importance to properly review and clean AE data. Fig below show the one of the display were three different visualizations are shown, a) A subject listing with all AE data b) A bar chart which shows number of subjects with AE by SOC, PT and max grade c) A table which displays number of subjects by PT and Grade. It also highlights a key point that a summary table can also be generated within Spotfire if needed.

Team can use built-in filtering capabilities within Spotfire to filter serious, related, etc AE data for review. Individual subject data can be filtered as well.

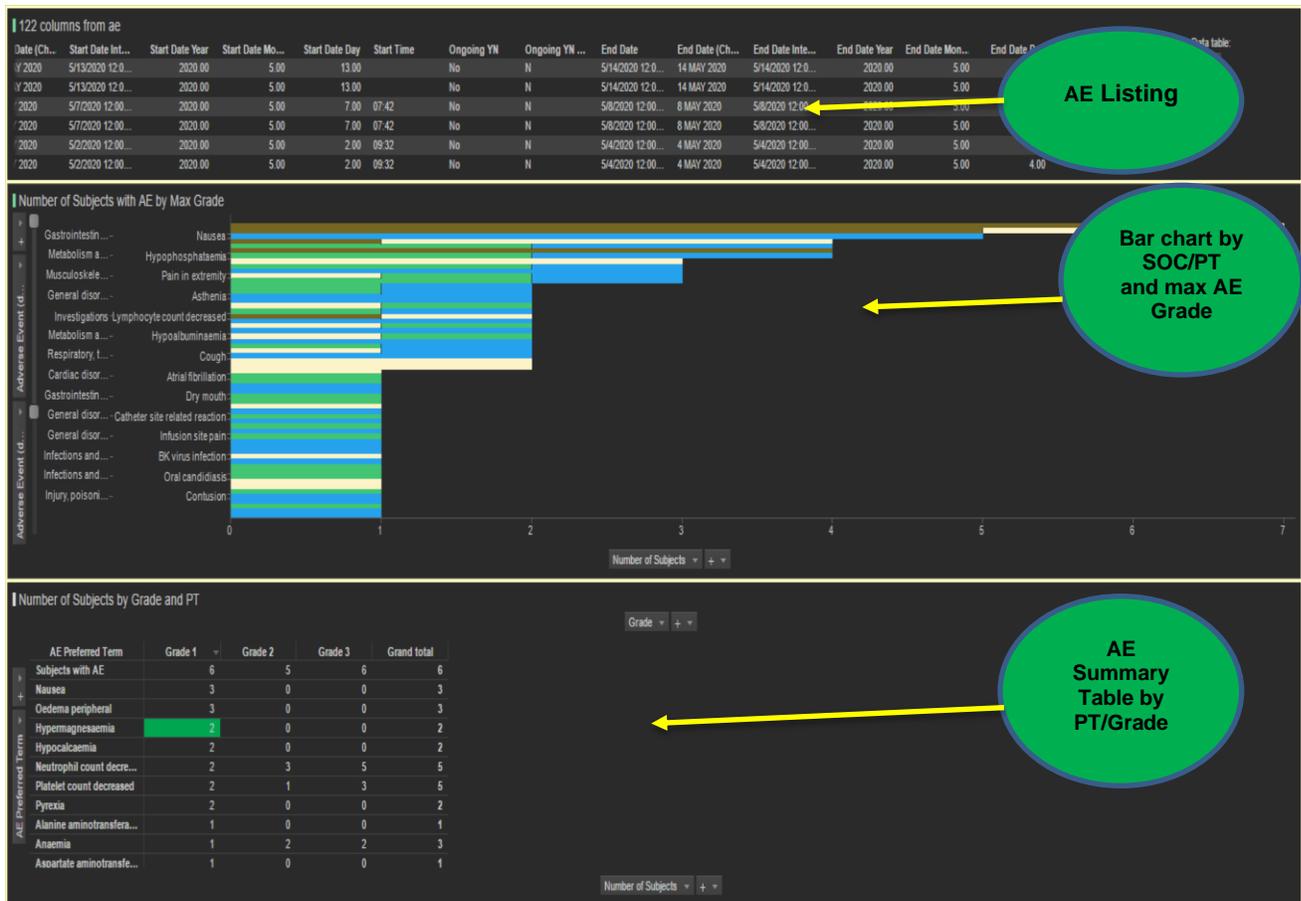


Figure 9. Adverse Events

Laboratory Results

Labs display was generated to display different lab tests. On top of the display, filter was provided to filter by subject and panel. Team can choose individual subject data using this filter or can select to all subject's data together. Reference ranges are also included to easily detect any high and low values.

Laboratory results can be displayed in many different forms, for this initiative team choose to keep it simple to easily detect values above/below ranges and capability to see any individual subject's data. Fig 10. below shows laboratory display.



Figure 10. Laboratory Results

Vitals

Vitals display showed box plot for height and weight distribution along with descriptive statistics below the plot. Various series plots displaying Systolic, Diastolic, Pulse Oximetry, Heart Rate etc. were displayed.



Figure 11. Laboratory Results

Disposition

A subject listing which shows disposition data on left and a bar chart color coded with different type of disposition event is shown on right.

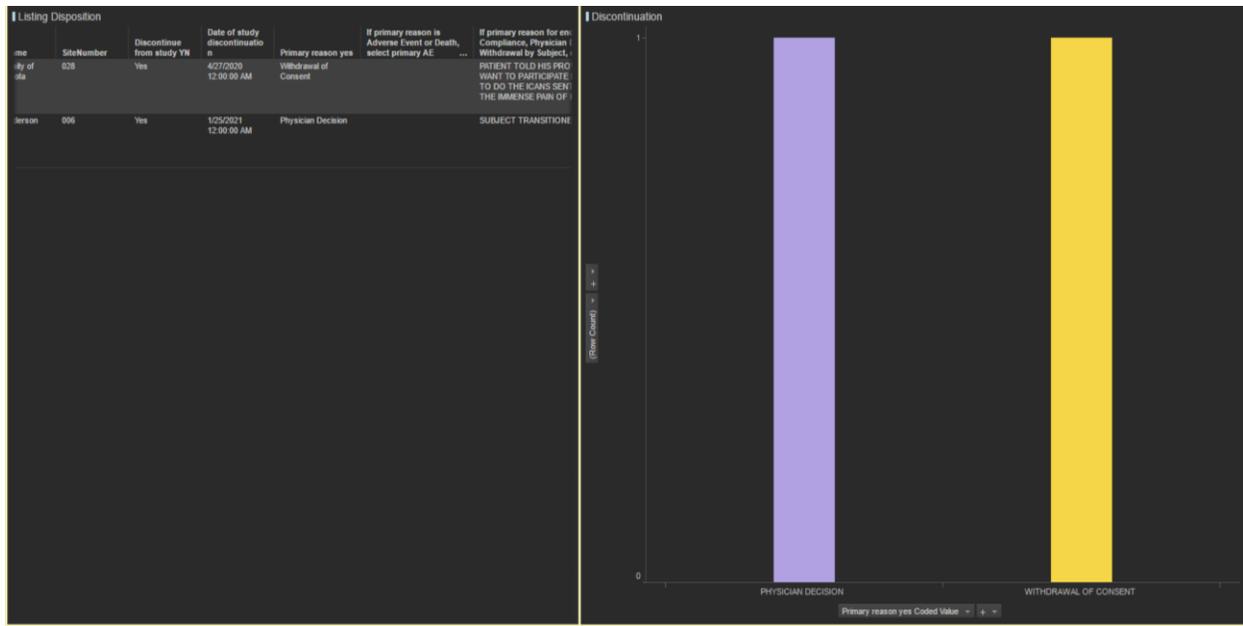


Figure 12. Subject Disposition

Timeline Display

A timeline of subject exposure, adverse event and concomitant medication taken during study was produced as shown below. This is very helpful to get an idea on when subject was exposed and when AEs happened and what concomitant medication were taken by subject during that time. y-axis displays different categories and events and x-axis displays study days. Star and circle shapes are used to display start and end of event, different colors are used to show the different categories as well as AE grades.

This display was very helpful for the team as it gives comprehensive view of various intervention and events.

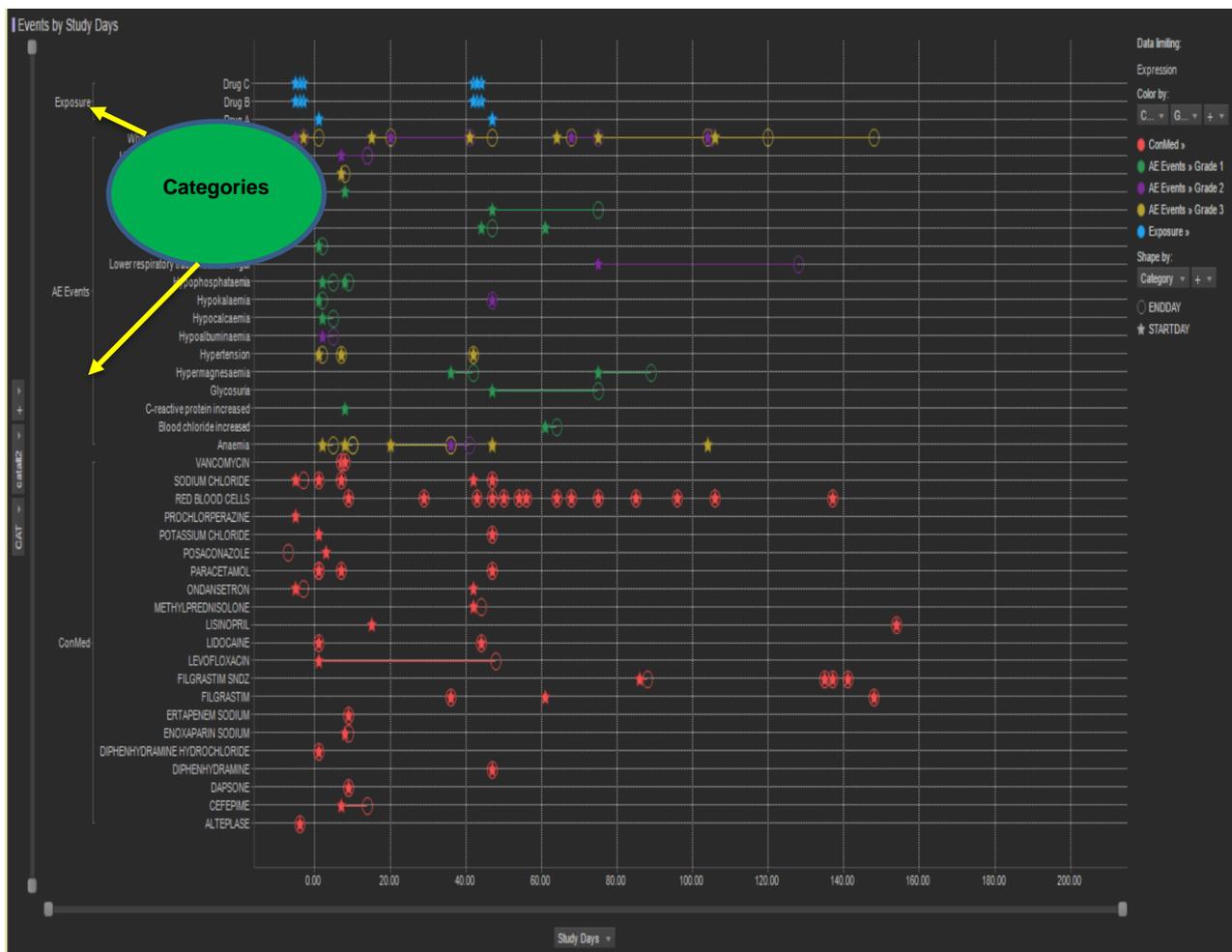


Figure 13. Subject Timeline

CONCLUSION

TIBCO Spotfire, with its built-in functionality, is very powerful to generate dynamic and interactive visualization. TIBCO Spotfire can tremendously help with efficient data review, which results in better data quality. Dynamic adhoc visualization which can help internal team to make decision can be quickly generated using Spotfire. Spotfire visualizations can customized and can used as per the need of different functions. All in all, Spotfire could be very useful tool.

REFERENCES

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<http://tibco.spotfire.com>

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