Interactive Data Visualizations for Clinical Trials and Pharmacovigilance

Shiva Katepalli[1], Sam Tomioka[1]
1 Data Science - Sunovion Pharmaceuticals

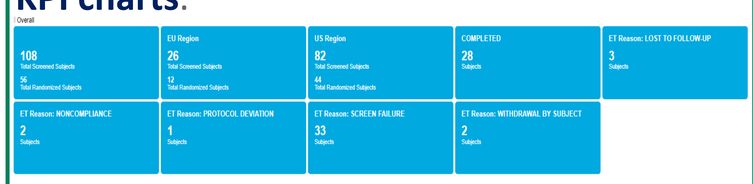
Summary

Objectives of the data review meeting are to identify safety signals and site performance by observing data trends, data anomalies during study conduct. Sunovion data analysts have used SAS as the main tool to generate visualizations to support clinicians and pharmacovigilance. Over the past few years Sunovion experimented successfully with **TIBCO Spotfire, R** and other open source tools to generate more interactive and informative visualizations.

TIBCO Spotfire, TERR, DataTables, SAS

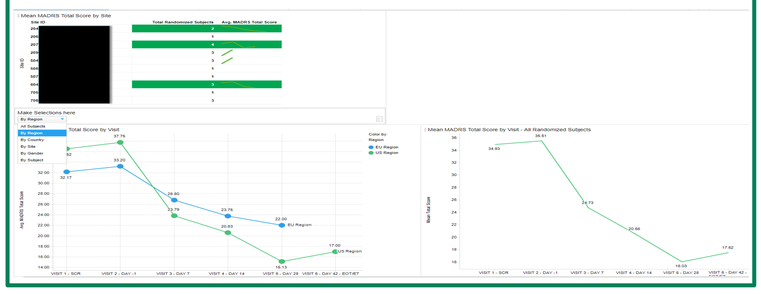
Study Dashboard

1 Study dashboard provides very essential details on screening, randomization and completion/termination numbers with flexible and scalable design using **Spotfire KPI charts**.

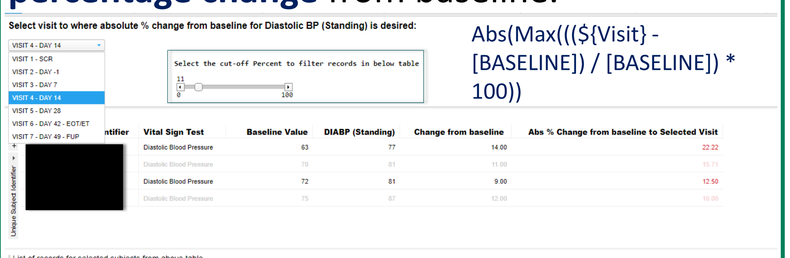


2 Patient demographics, disposition are presented with capability to **drill down** by **geographic region and country**.

3 Efficacy parameter was presented with options to select sites for data filtering and options to **categorize line plot by region/country/site/gender and subject** using **Spotfire property controls** feature.



4 Spotfire property controls and **basic scripting** enabled interactive visualizations with more control to end user to review in detail. This design helps user to **filter with custom percentage change** from baseline.

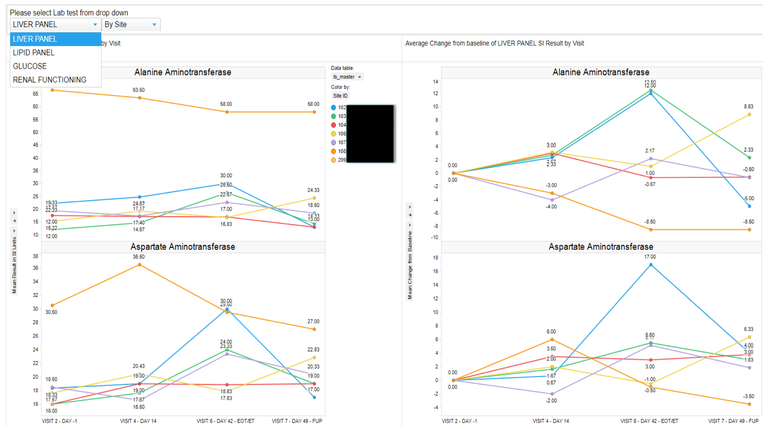


Abs(Max((${Visit} - [BASELINE]) / [BASELINE]) * 100))

List of records for selected subjects from above table

Unique Subject Identifier	Vital Signs Test Name	Site ID	VISIT 1 - SCR	VISIT 2 - DAY -1	VISIT 3 - DAY 7	VISIT 4 - DAY 14	VISIT 5 - DAY 28	VISIT 6 - DAY 42 - EOT/ET	VISIT 7 - DAY 49 - FUP
[redacted]	Diastolic Blood Pressure	103	72.00	63.00	72.00	77.00	82.00	67.00	76.00
	Diastolic Blood Pressure	106	78.00	72.00	73.00	81.00	77.00	91.00	87.00

Property controls are used to present lab data trends group by lab panels which helps with more logical review.



Advanced scripting can help analyst to develop controls to provide user with a choice to select different kinds of visualization on the same data.

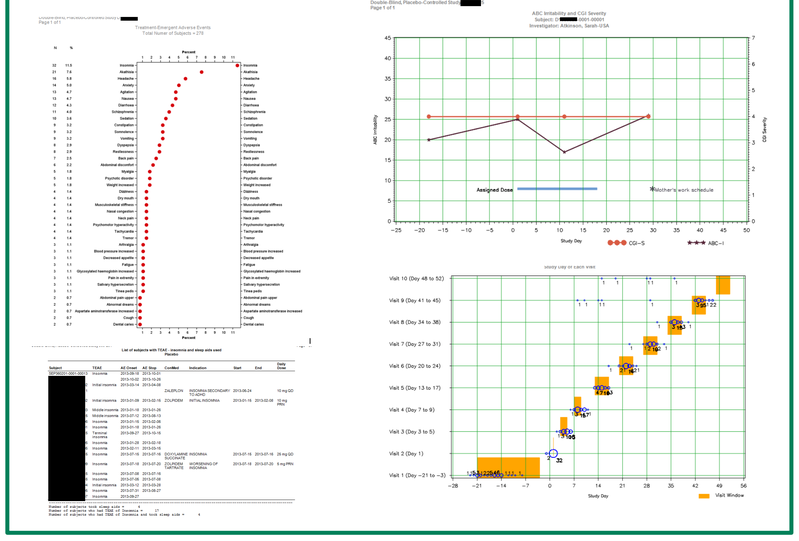
```
from Spotfire.Dxp.Application.Visuals import *
from Spotfire.Dxp.Application.Visuals import ScaleAxis


page=Document.ActivePageReference
vizExists=False
visual=page.Visuals.AddNew(VisualTypeIdentifiers.LineChart)
visualB=visual.As[LineChart]()
visualB.Title="Mean MADRS Total Score by Visit - All Randomized Subjects"
#a script parameter table referring to the Data Table required
visualB.Data.DataTableReference=table
visualB.XAxis.Expression="[Visit Name]"
visualB.YAxis.Expression="Avg([Numeric Finding in Standard Units])"
visualB.Data.WhereClauseExpression="[Question Short Name] = 'MADRS11' and [Subject_Count_by Visit] is not NULL and Find('UNSCH',[Visit Name]) = 0"
visualB.ShowMarkerLabels="True"
```

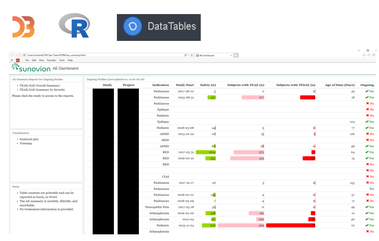
Safety Dashboard

1 Historically, **SAS** has been used to generate static outputs (PDF/RTF) for efficacy and safety as per requests. In general, programmers had been requested to produce more listings to answer questions identified during the review of the static outputs.

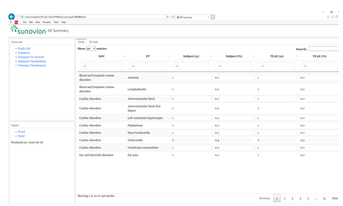
SAS



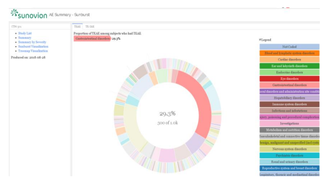
2 We have employed combinations of **R, Data-Driven Documents,** and **DataTables** libraries to generate interactive visualizations and enabled users to generate tables with no programming knowledge. This approach was a server-less approach so all data are written in html. This limits us from displaying integrated safety data since the amount of data to be written is huge for each html.



Dashboard home page with navigations to each study. Built with DataTables library



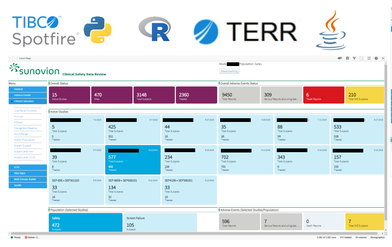
AE table built with DataTables library. This allows data export, sorting, dynamic color coding and much more.



Sunburst visualization of AE distribution built with Data Driven Document

Interactive Visualizations, Self-Service dashboard

3 Current approach uses **TIBCO Spotfire** as a base platform, and we employed **Python, R, TERR, and Java script** to enhance the functionality and usability.



Users can now **integrate studies** with just a mouse click

User can now **choose a safety reporting period** and **export generated tables**

User can now **adjust the thresholds** for safety signals

Instant Data Integration, Quick Navigation, Actionable Insights

Conclusion

The use of new tools by analysts will allow study team to gain more insights into the clinical data with minimal programming support. Analysts can develop the templates which can be re-used effectively.

More info **Question?**

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