



Interactive Dashboards for Early Data Access and Data Quality Control in a Clinical Trial



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PhUSE Single Day Event: Bringing Value to Patients: A Data-quality Perspective

Outline



- Data Quality Control
- Visualisation
- Demonstration
- Challenges
- Summary

Data Quality Control



- Ensure high-quality data
- Performance
 - Adherence to form completion instructions
 - Query handling
 - Time to respond to query
 - Time to query resolved
 - Query frequency
 - Visit window adherence
 - Trends within a subject
- Complete, valid and consistent data
 - Valid data checks
 - Automated edit checks
 - Comparison of eCRF against raw data
 - Manual checks
 - Outlier detection
 - Review data for strange patterns

Data Quality Control

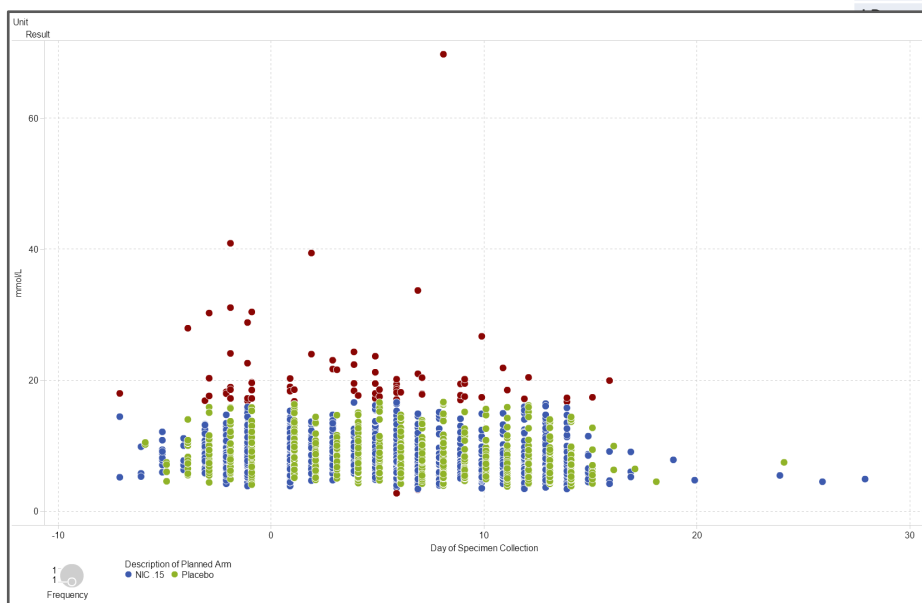


- Current process
 - Quality meetings at fixed time points
 - Tables, listings and figures give a fragmented view on data
 - No links between data
 - Difficult to find origin of data issue
 - Time-consuming

Visualisation



- Representation of data as a chart or other image



Domain	Subject ID	Test NameLaboratory	Laboratory Test Result	Laboratory Test Unit	Lower Reference Range Limit	Upper Reference Range Limit	Visit Number	Study Day of Specimen Collection	Reference Range Indicator
LB	101011	Glucose	6.327	mmol/L	3.33	16.65	1	1	Normal
LB	101012	Glucose	8.3805	mmol/L	3.33	16.65	1	1	Normal
LB	101013	Glucose	6.882	mmol/L	3.33	16.65	1	1	Normal
LB	101014	Glucose	7.77	mmol/L	3.33	16.65	1	1	Normal
	101017	Glucose	5.2725	mmol/L	3.33	16.65	1	1	Normal
	11001	Glucose	6.216	mmol/L	3.33	16.65	1	1	Normal
	11006	Glucose	9.324	mmol/L	3.33	16.65	1	1	Normal
	11010	Glucose	6.549	mmol/L	3.33	16.65	1	1	Normal
	11011	Glucose	8.214	mmol/L	3.33	16.65	1	1	Normal
	11013	Glucose	16.761	mmol/L	3.33	16.65	1	1	High
	11014	Glucose	6.882	mmol/L	3.33	16.65	1	1	Normal
	11015	Glucose	9.9345	mmol/L	3.33	16.65	1	1	Normal
	11018	Glucose	5.8275	mmol/L	3.33	16.65	1	1	Normal
	11020	Glucose	18.981	mmol/L	3.33	16.65	1	1	High
	11023	Glucose	6.771	mmol/L	3.33	16.65	1	1	Normal
	11024	Glucose	7.3815	mmol/L	3.33	16.65	1	1	Normal
	11026	Glucose	7.9365	mmol/L	3.33	16.65	1	1	Normal
	11027	Glucose	9.546	mmol/L	3.33	16.65	1	1	Normal

~ 2800 vs 20 data points

Visualisation Software



- Interactive data visualisation
 - Summaries and listings
 - Drill down to detailed insights
 - Filters/selections
- Automated updates of the data
- Alerts
 - Set rules for e-mail notification
- Sharing and exporting
 - In the visualisation tool
 - Export to PDF and Excel

Visualisation Software



- Tools to visualise data
 - SAS Visual Analytics, Spotfire, Qlik Sense, Jreview, Tableau
- Present data in dashboards
 - Domain-specific
 - Subject-specific

Demonstration



- Recruitment
- Queries
- Clinical Trial Data
 - Demographics
 - Adverse Events
 - Laboratory Data
 - Patient Profile

Challenges



- Data preparation
- Not all data are suitable for visualisation
- New tool
 - Other skills and mind-set
 - Different approach
 - Requires learning curve
- Validation

Summary



- Visualisation supports data quality control
 - Early identification of data issues
 - Improves performance
- Visualisation can improve data quality control and data quality

Thank you! Questions?



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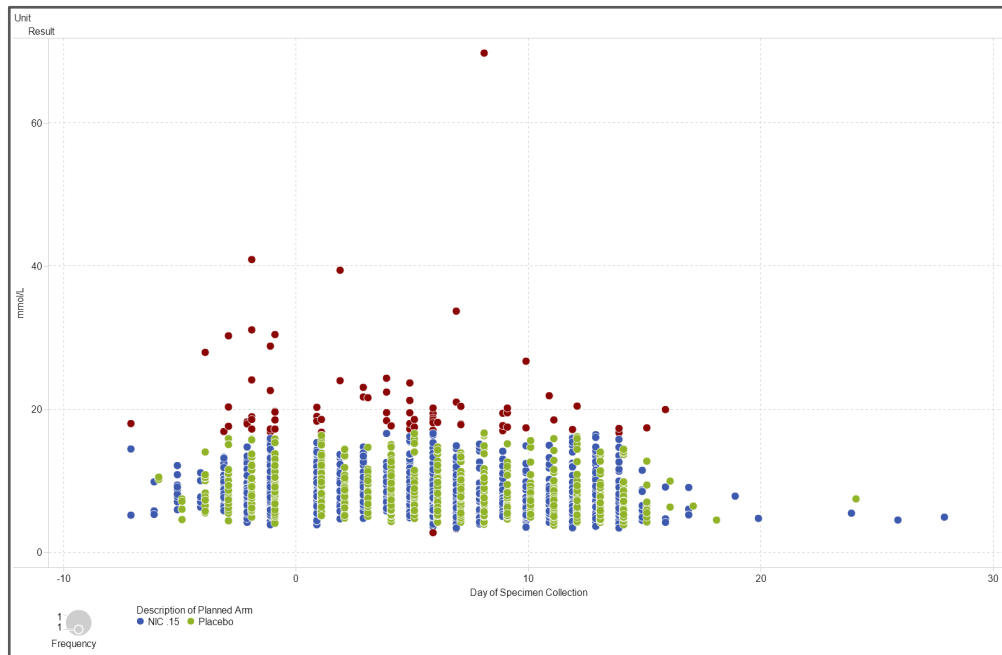
Lieke Gijsbers: lieke.gijsbers@ocs-consulting.com

Back-up slides

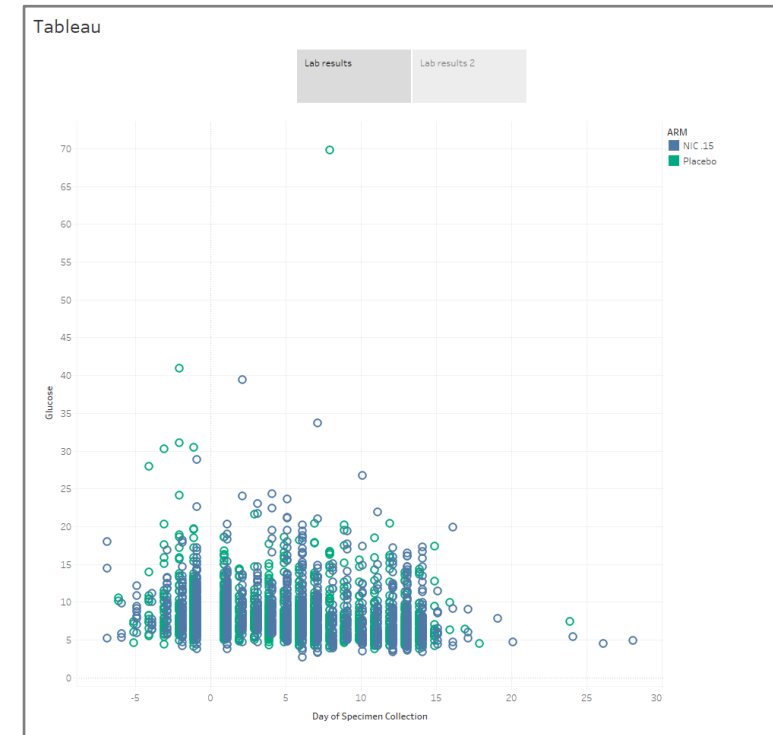


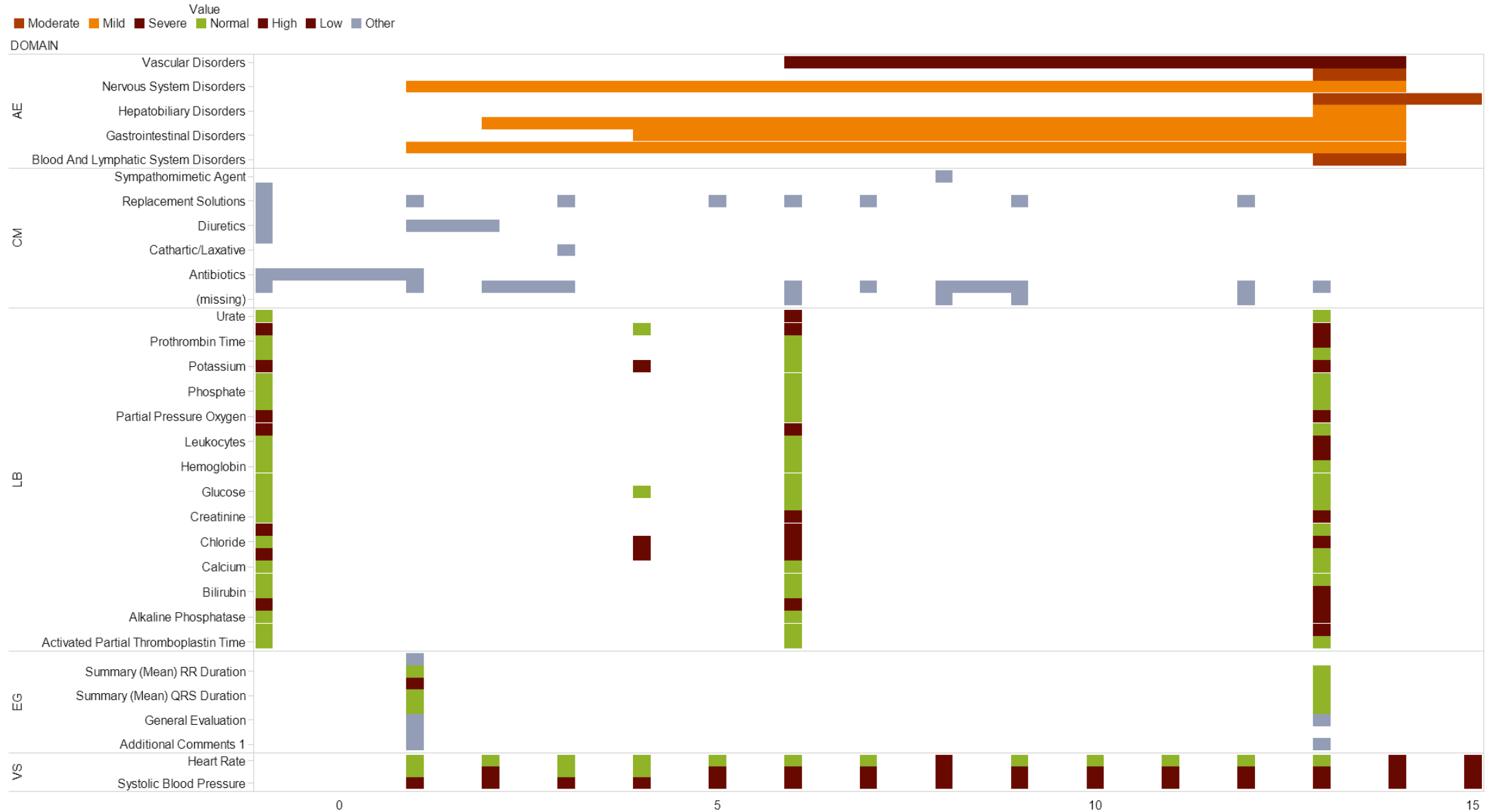


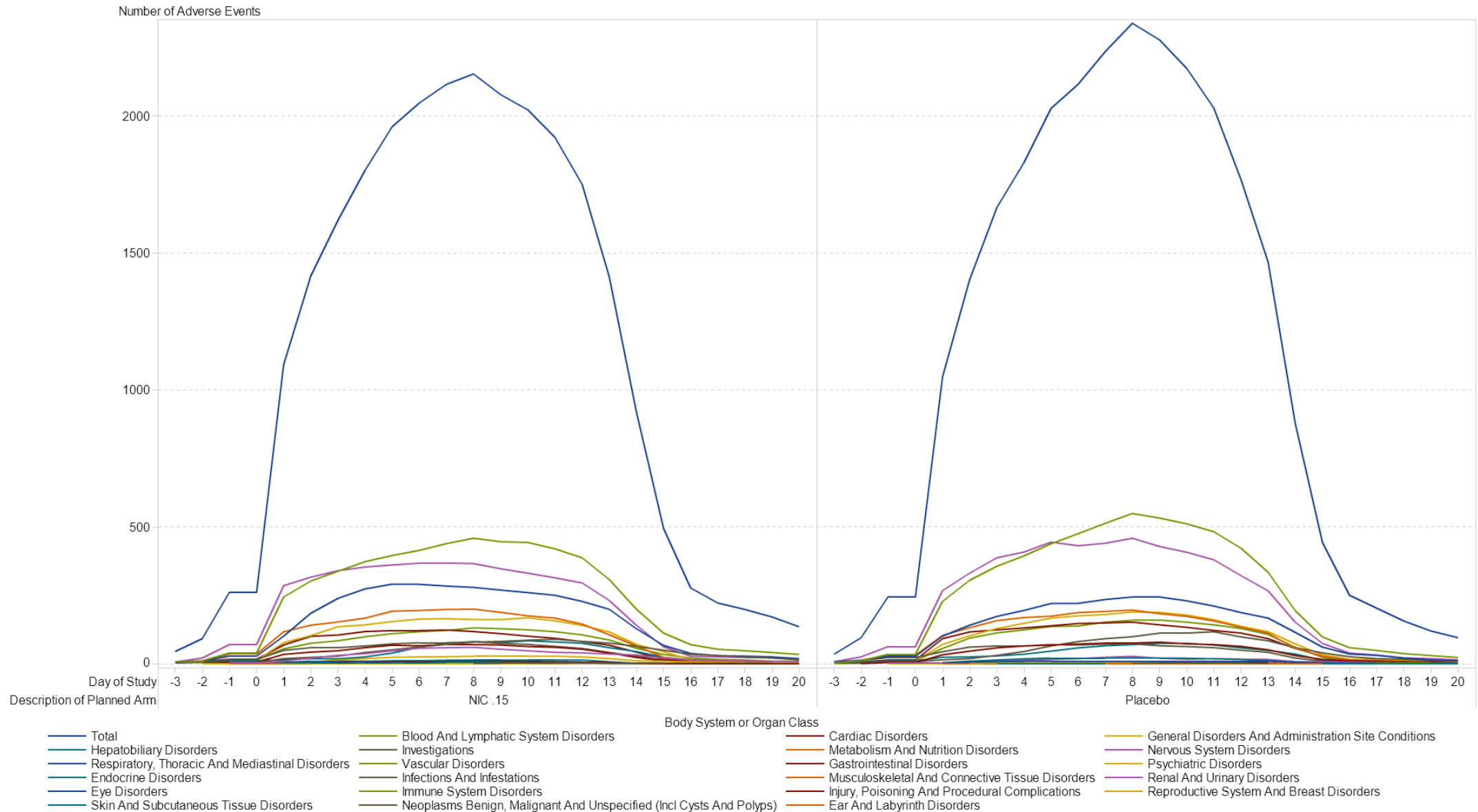
SAS Visual Analytics



Tableau









Data Quality Control

- Ensure complete, valid and consistent data
- CRF entry instructions: training
- Valid data checks (e.g. 30 February 2017)
- Automated edit checks (e.g. consistency among data: pregnant male)
- Monitor:
 - Compares eCRF against source data
 - Adherence to entry instructions
- Data manager:
 - Manual checks (not easily programmed as edit checks)
 - Adherence to visit window
 - Query handling

Data Quality Control



- Data quality meetings
 - Time to respond to queries
 - Time to query resolved
 - Visit window adherence
 - Data safety meetings
 - Review tables and listing at fixed time points
- Site performance
 - Monitor performance
 - Need for more monitor visits
 - CRF design/specific questions leading to more queries

Data Quality Control



- Data review meetings
 - Review of tables and listings for data issues at fixed timepoints
 - Outlier detection (for example for lab data)
 - Review data for strange patterns (for example if a certain group deviates from overall expected mean)
 - Trends within a subject
 - Safety

Data Quality Control



- Current process
 - At fixed time points
 - Fragmented view on data
 - No links between data
 - Difficult to find origin of issue
 - Time-consuming
- Visualisations
 - Ongoing monitoring and provides early insights which enables you react quickly
 - Navigate through the data, more detailed information

