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A Dynamic Graphical approach for Visualizing Clinical Trial Data

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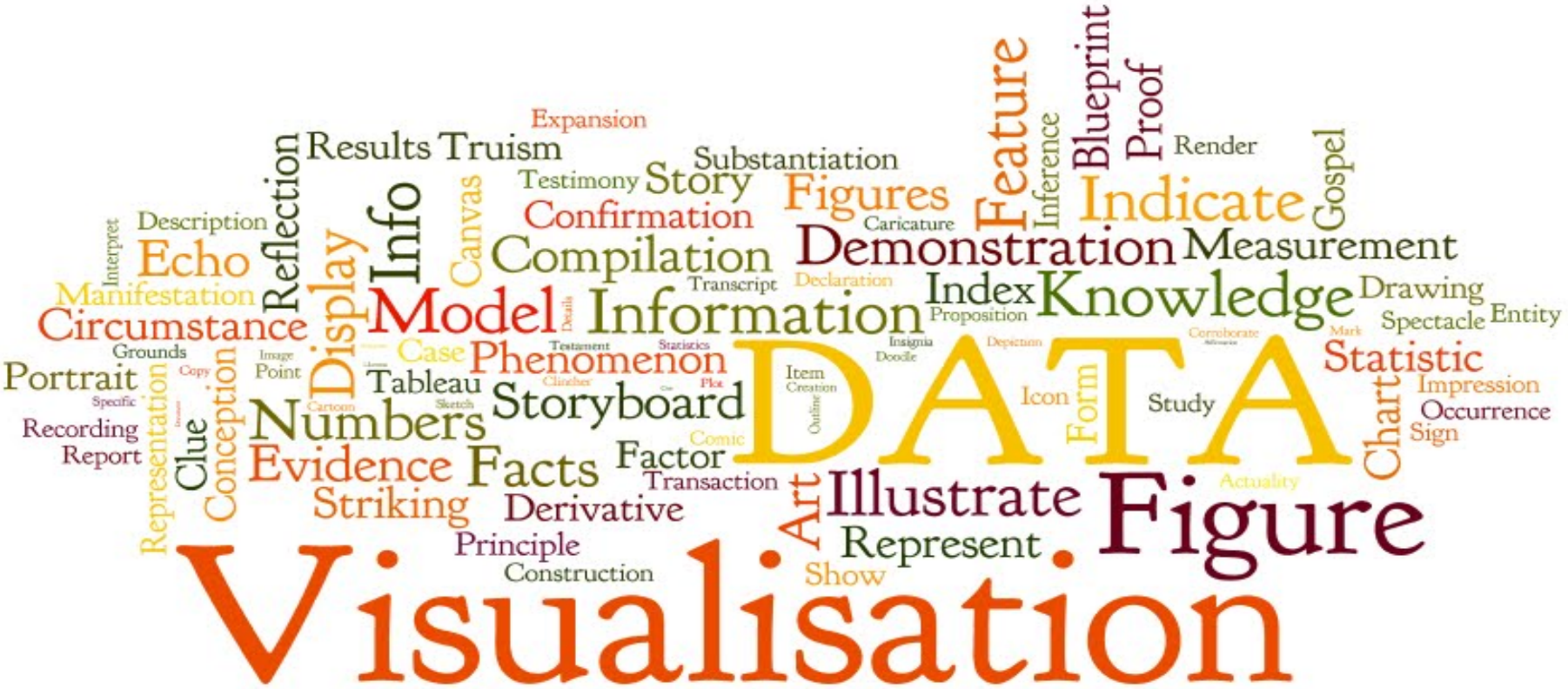


Agenda

- What is Data Visualization
- Need of Visualization in Pharma Domain
- Traditional Approach
- Infographics
- Dynamic Graphs
- Tools / Applications
- References

What is Data Visualization ?

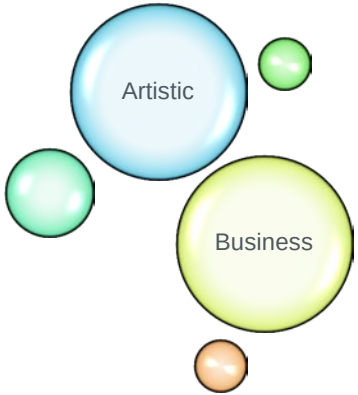
- A picture is worth a million rows.
- It is both an art and a science.
- Presentation of data in a pictorial or graphical format.
- It enables decision makers to see data presented visually, so they can grasp difficult concepts or identify new patterns with a interactive visualization software.
- Increased amounts of data created by Internet activity and an expanding number of sensors in the environment are referred to as "big data" or Internet of things.
- Processing, analysing and communicating this data present ethical and analytical challenges.

Data visualization can also:

- Identify areas that need attention or improvement.
- Clarify which factors influence customer behaviour.
- Help you understand which products to place where.
- Predict sales volumes.

What is Info Graphs ?

- Representations of information in a graphic format.
- Designed to make the data easily understandable, at a glance, without a deep knowledge of the data and without programming skills.
- Creates the combination of art and science: not unlike a dashboard.
- The amount of data available today is vast, and more infographics are being created.
- The world is at a point where the attention span of a consumer is only about eight seconds.
- Data visualization is a more effective way of getting a reaction from the audience.
- We need to combine infographics with big data to take advantage of the opportunity that presents.



Types

Info Graphs & Types

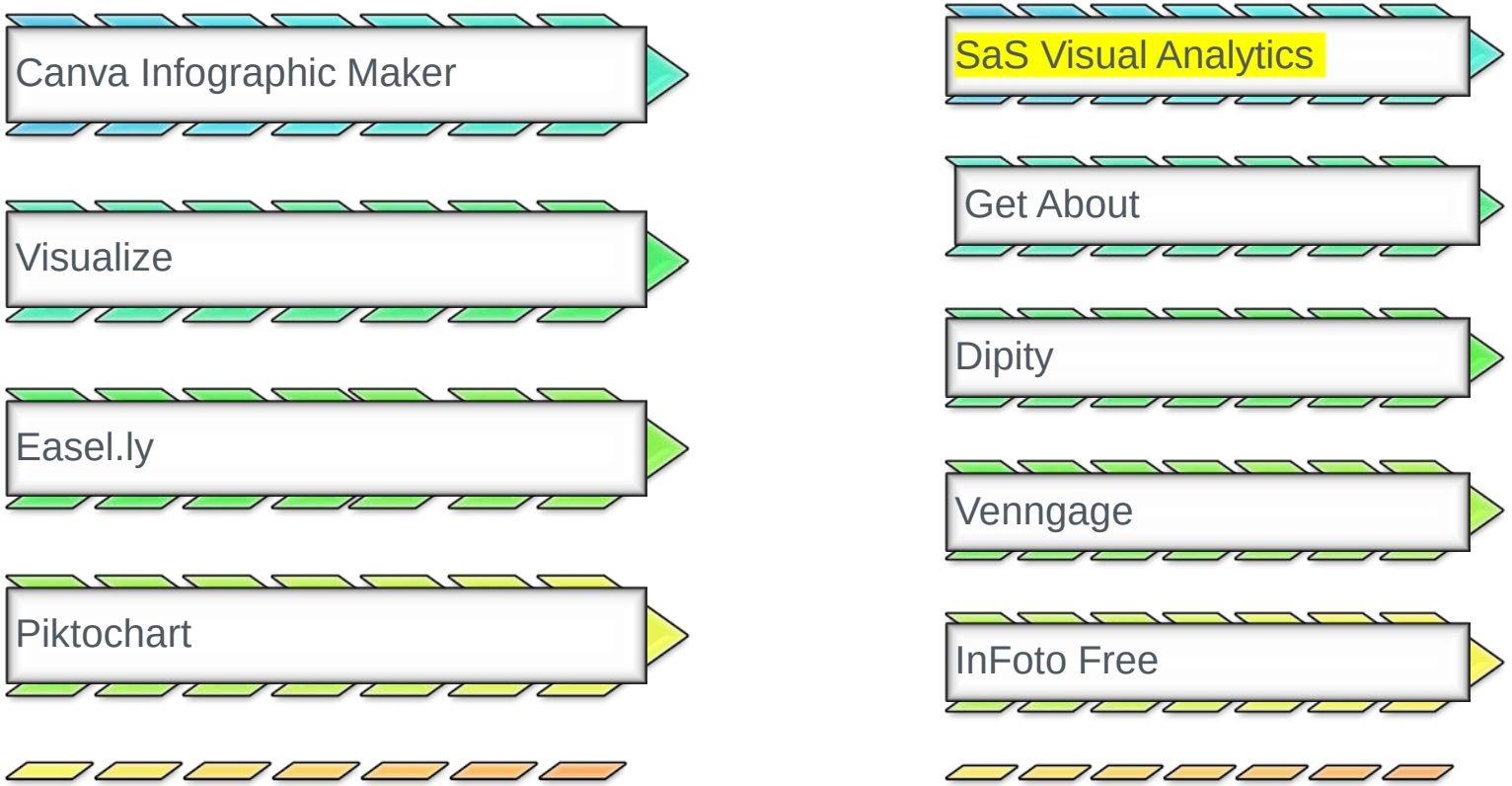
Artistic

The artistic infographic is one in which graphic designers take information from authors and create a very artistic visual. This visual could be hung on the wall as a poster or put on the front page to support a headline.

Business

This is a very structured visual and an extension of the dashboard concept. A dashboard can be an infographic as well. However, generally they are more about data than about being subjective, which often makes them a one-stop shop for self-service business intelligence.

Info Graphs & Tools



INFOGRAPHS IN PHARMA DOMAIN

Traditional Table

Final 1.0
28 March 2017

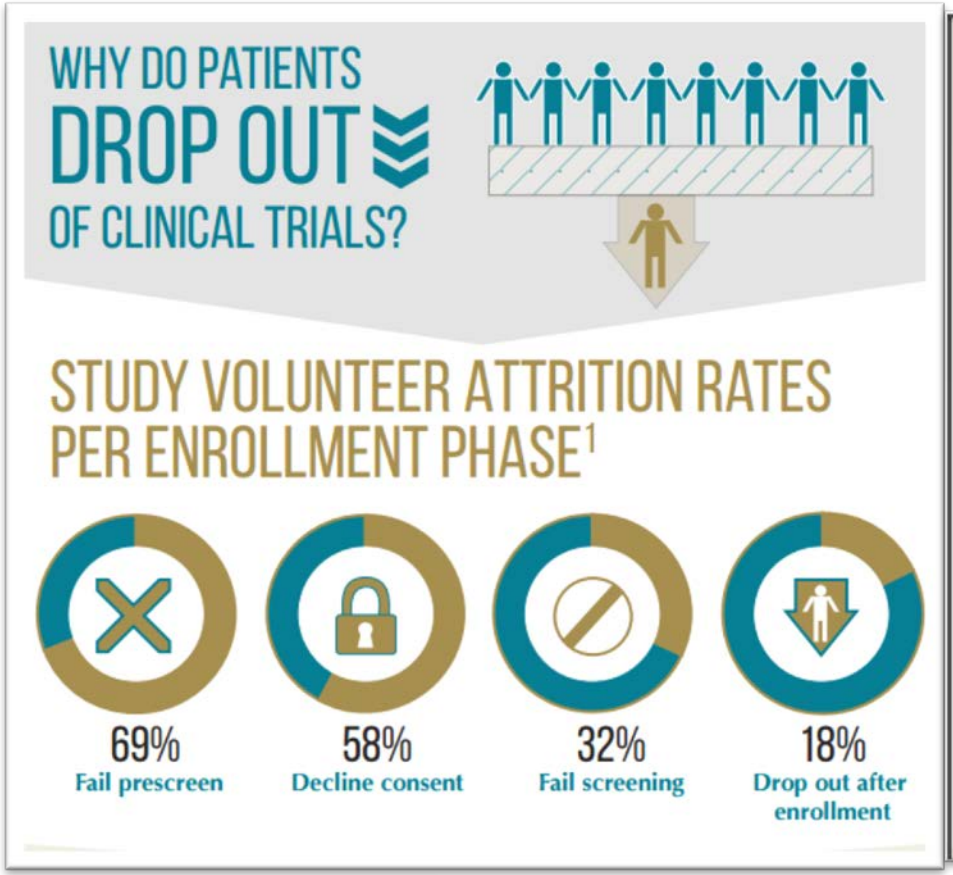
Section 14.1 Demographic Data Summary Figures and Tables

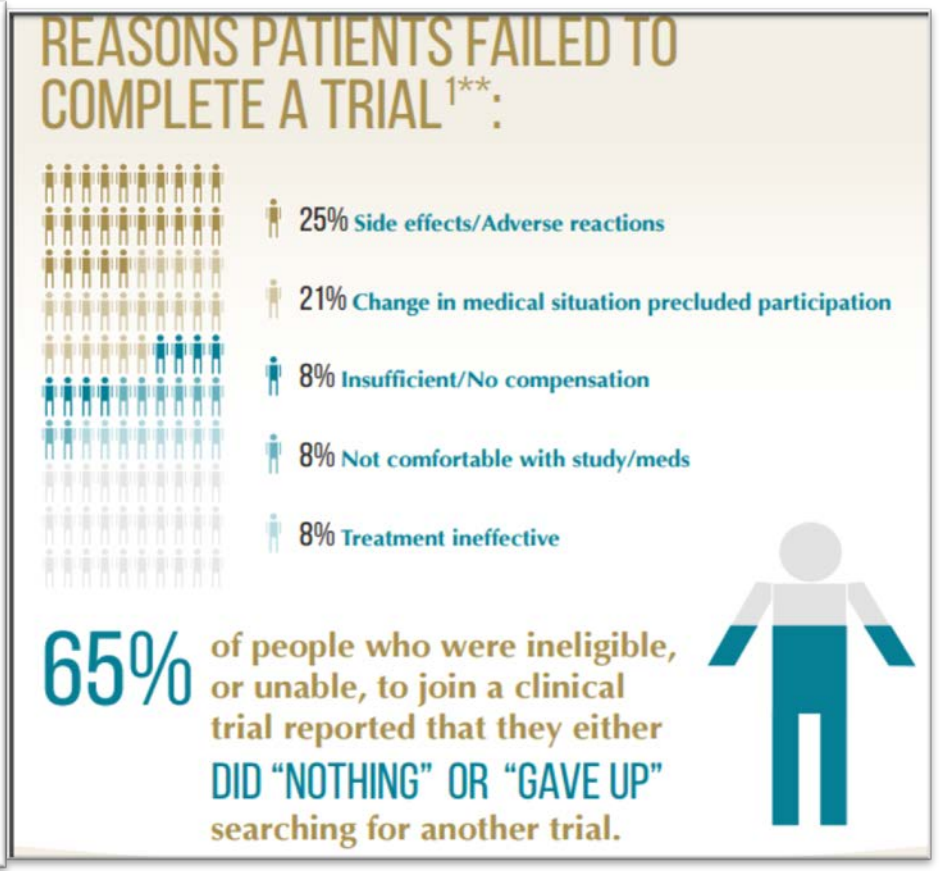
Table 14.1.1
Subject Disposition and Reasons for Discontinuation from the Study
(Safety Population)

Population	Cohort 1, single dose (N = xx) n (%)	Cohort 2, single dose (N = xx) n (%)	Cohort 3, single dose (N = xx) n (%)	Cohort 4, multiple dose (N = xx) n (%)
Subjects Dosed	xx (100)	xx (100)	xx (100)	xx (100)
Subjects Completed	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects Withdrawn	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawal by Subject	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol Violation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Physician Decision	0	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to Follow-up	xx (xx.x)	0	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

N: number of subjects in the safety population; n: number of subjects in the category; %: calculated using the N as the denominator.

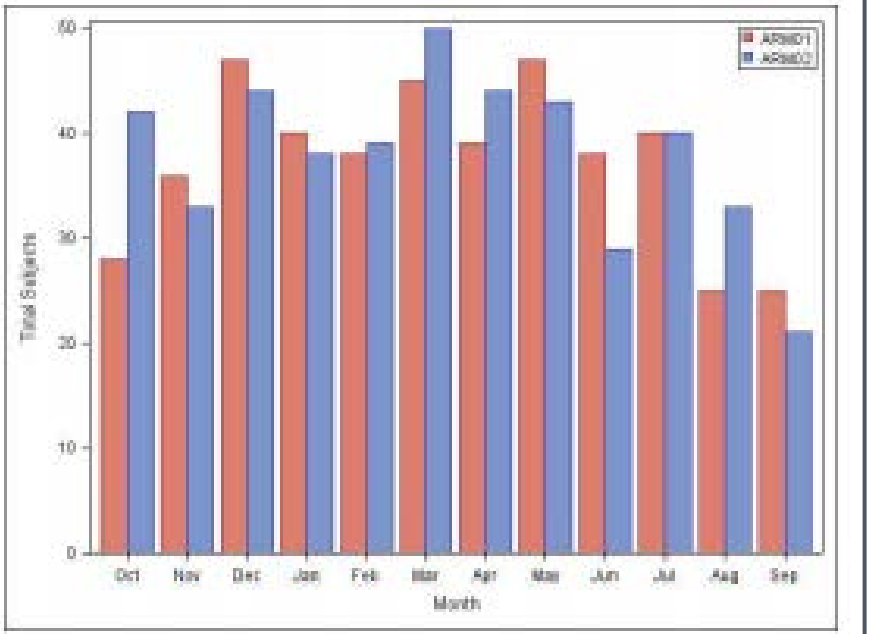
Info Graph Disposition Table

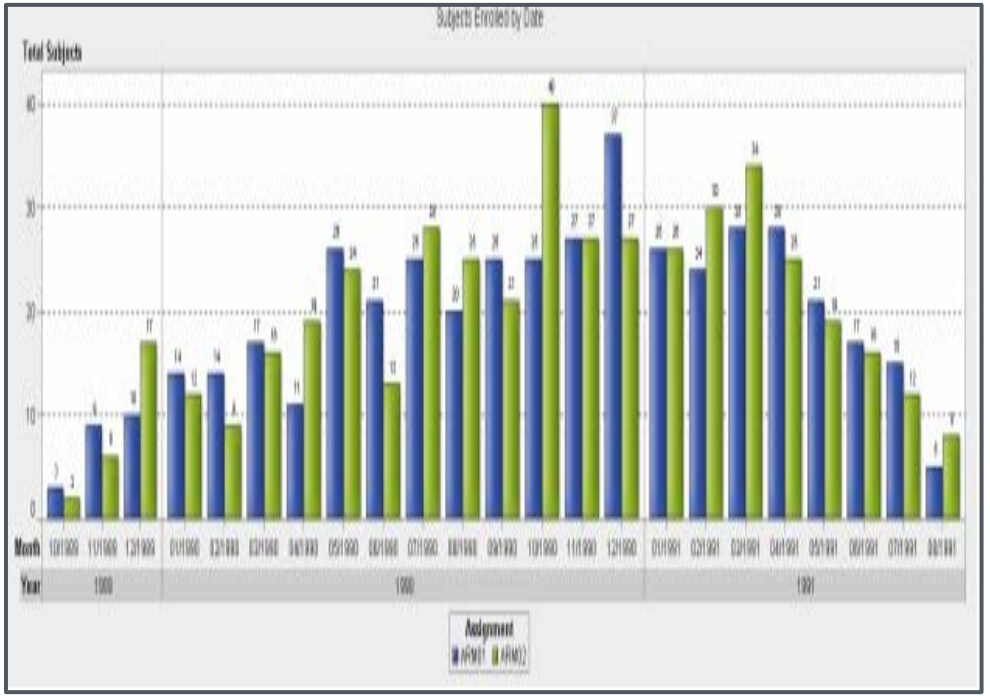




DYNAMIC GRAPHS IN PHARMA DOMAIN

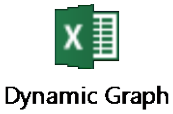
Traditional & Dynamic Graph





SaS Visual Analytics & Dynamic Graph

- It is a server-based software that users can access through ID and password. User privileges can be controlled by the System Administrator.
- But the true value of SAS Visual Analytics is the interactivity between these controls and graphs.



- In traditional scientific reporting, a graph is a fixed-format, static representation of a relationship. The X variable is on the horizontal axis and the Y variable is on the vertical axis.
- This graph was built using standard print-ready proportions. On paper, this graph would probably appear with a table of the actual values.
- This basic graph, surfaced as html on a web page, could have additional functionality, enabling users to scroll over bars to see the actual counts.
- The same interactivity exists for line graphs, pie charts, tree maps, and a wide variety of other objects.
- There are many different ways to represent the data and create opportunities for interaction, which is why the role of the data scientist remains so critical to the development of these types of reports.
- With so many reporting options available, it is always important to ensure that interactivity reflects the nature of the underlying data.

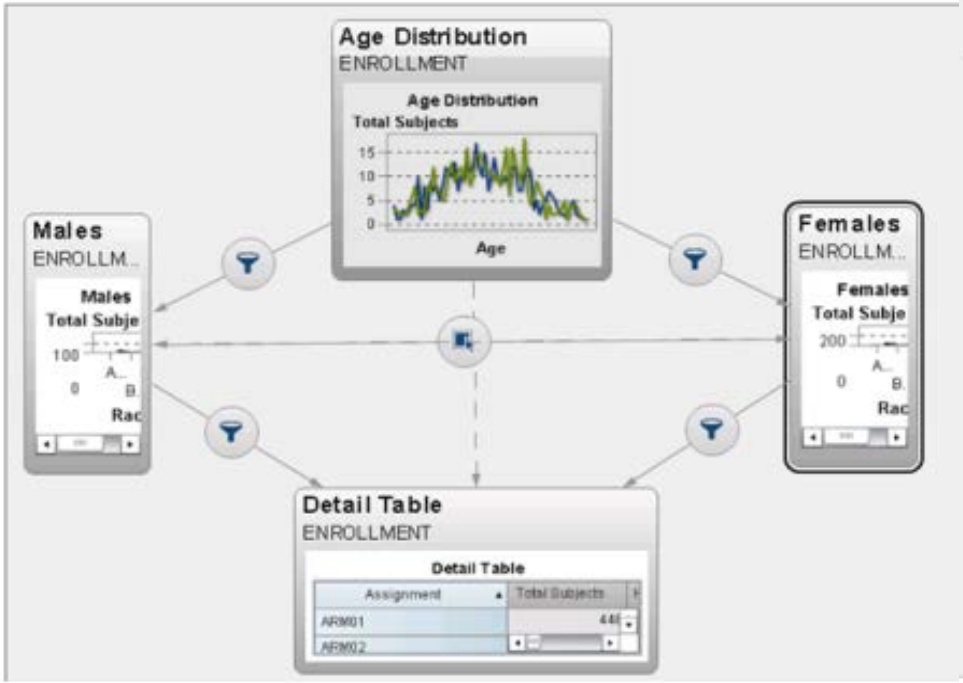
Dynamic Graph Template

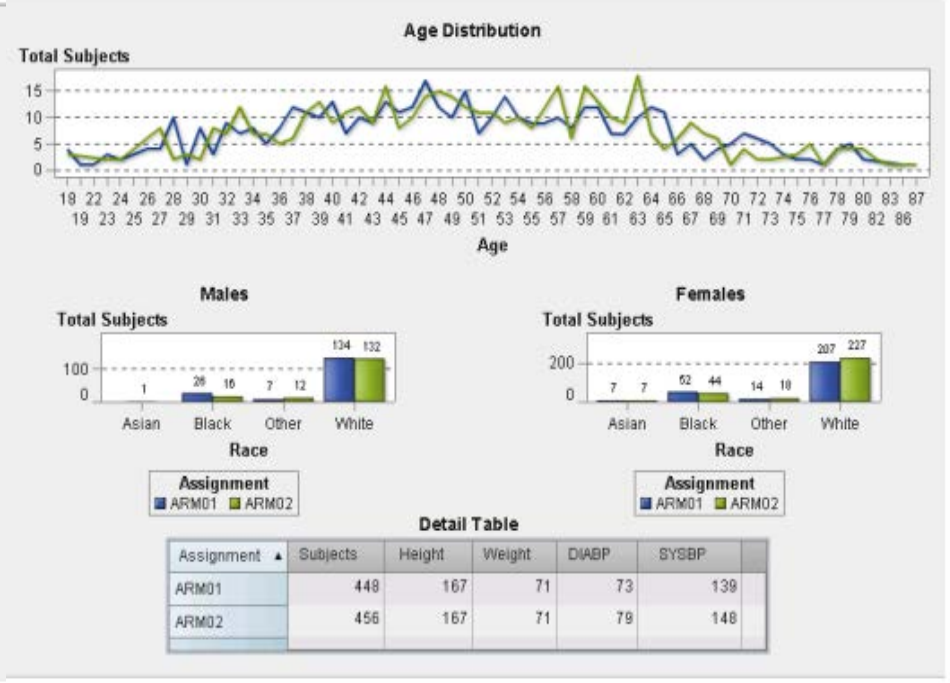
- Trial Assignment Analysis
- Enrolment History
- Lab Test Comparison
- Patient Lab Record
- Adverse Event Duration
- Adverse Events over Time

Trial Assignment Analysis

Specification	Description
Source Data	Demographic data file with the experimental assignment and the first measurement of height, weight, and blood pressure from associated data files. Data is at the one-patient-per-row level. This is a main data structure used in later reports.
Data Preparation	Most data elements are available in the format necessary for use in this report, but one modification was required. The line graph representing the Age Distribution at the top of the report required the transformation of the Age variable from a numeric to a character string. The line graph requires a character variable on the X axis. This simple format transformation was done to the SAS data set before the data was loaded into the SAS LASR Analytic Server. The Total Subjects count in the Detail Table was not in the original data loaded into the SAS LASR Analytic Server. The Frequency variable is automatically generated by SAS Visual Analytics for any data set.
Visual Analytics Objects	Line Plot (Age Distribution) Bar Chart (Males, Females) Crosstab (Detail Table)
Interactivity	This report begins top-down with selections made in the Age Distribution graph, driving changes in the Males and Females bar charts and Detail Table. Note as well that selections of race within the Males and Females graphs operate sideways, with bar chart selections on the right or left affecting the bar chart on the opposite side and the Detail Table.

Trial Assignment Analysis

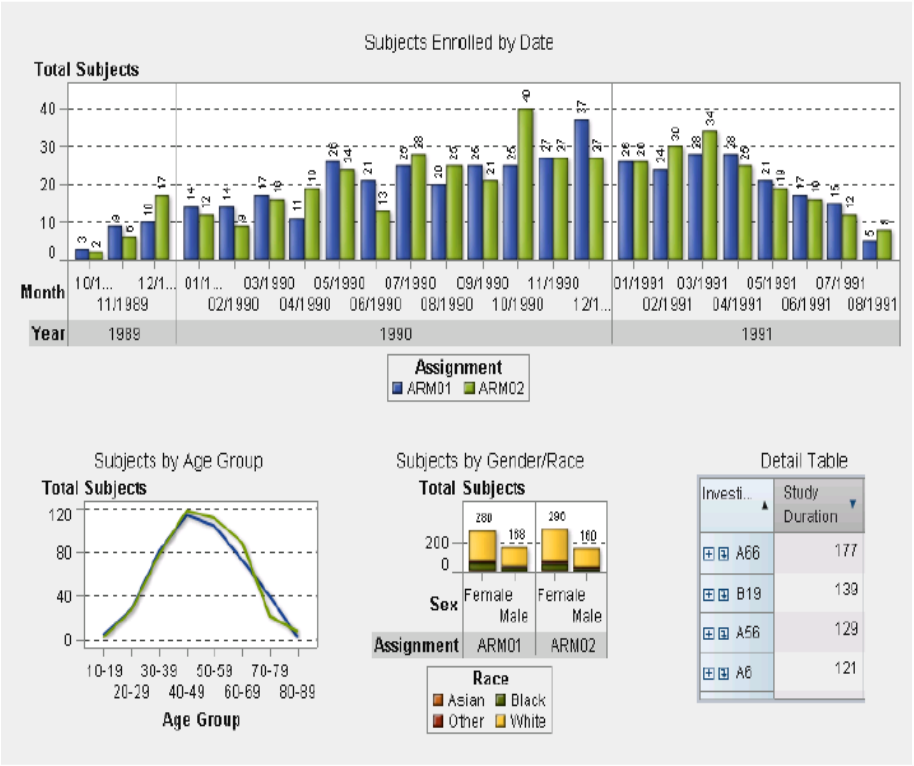


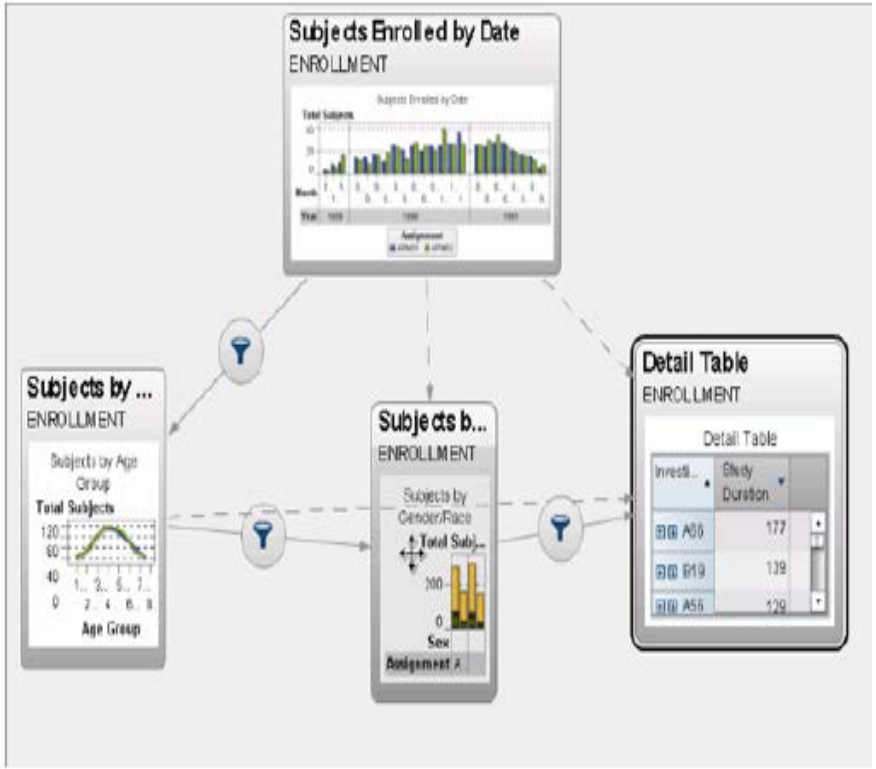


ENROLLMENT HISTORY

Specification	Description
Source Data	Same data as Trial Assignment Analysis, but this report uses other variables, such as the Investigator, culled from the same data. Data is at the one-patient-per-row level.
Data Preparation	For this report, two variables were converted into character strings, and one was calculated as follows: Created Month_Year (character variable for bar chart) Created Age Groups (character variable “10-19,” “20-29”) Calculated Study Duration (for Detail Table) using Last-First day over all events for each patient
Visual Analytics Objects	Bar Chart (Subjects Enrolled by Date) Bar Chart with stacked option (Subjects by Gender and Race) Line Plot (Subjects by Age Group) Crosstab (Details Table)
Interactivity	This report begins top-down, with the enrolment graph serving as a control to allow for selection of one or more groups (arm01/arm02, a range of months, and/or individual bars). That selection drives the graph, which can then be used left-to-right interactively. The Detail Table on the far right shows more data than is shown in Figure 6 and can be sorted and explored, reflecting all previous selections.

Enrolment History

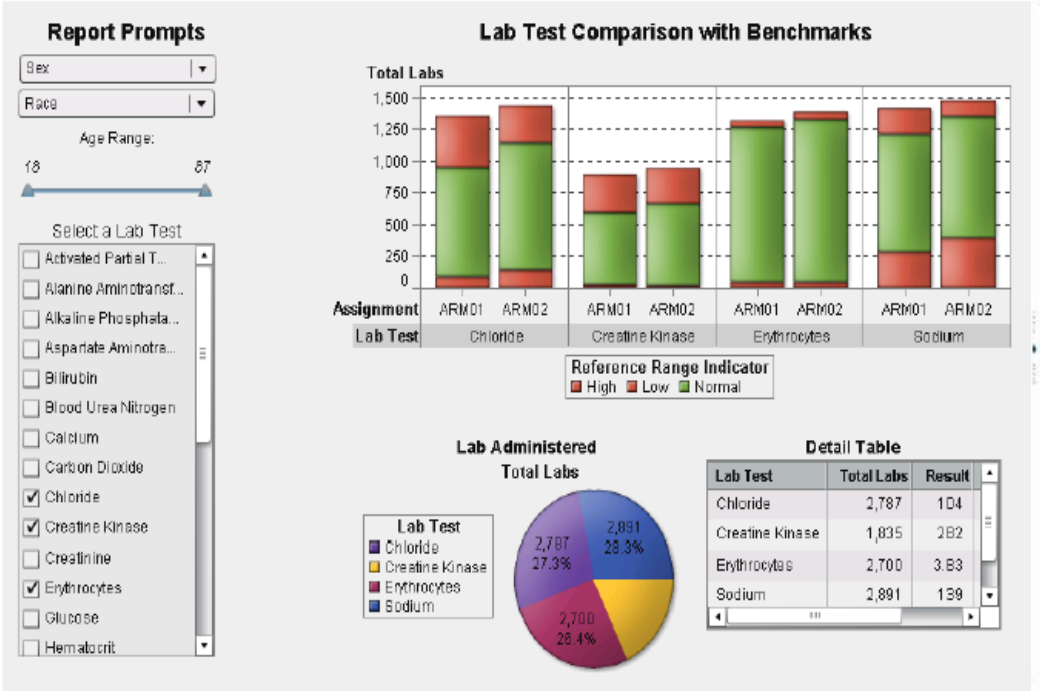


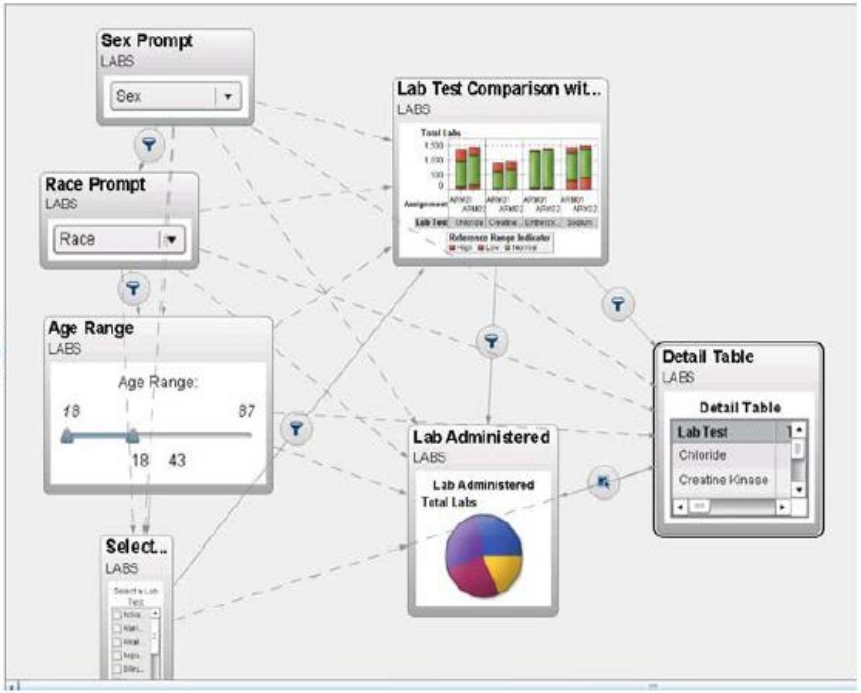


Lab Test Comparison Analysis

Specification	Description
Source Data	This data includes the same data structure used for the Enrollment History report with data from labs added to the data structure, resulting in a data set at the one-lab-per-row level, with patients and labs repeated to reflect all labs administered to all patients
Data Preparation	The stacked RED/GREEN/RED bars were achieved by using a Display Rule and assigning red to both Low and High, and green to Normal. Note that the Y axis is total labs administered for that lab for that experimental condition. This graph could not have been implemented using the actual value of the lab result as the labs being compared are expressed in units on very different scales. The Result in the Detail Table is the mean value for those labs. This value could be replaced with the median or another measure.
Visual Analytics Objects	Pulldown Control (Sex and Race) , Slider Control (Age) List (Select a Lab Test) , Bar Chart with stacked option and lattice column Pie Chart (Total Labs) ,List Table (Detail Table)
Interactivity	This report takes a more traditional reporting approach, allowing users to select pull-down choices for sex and race. A slider allows for selecting a range of ages. A lab test list allows the selection of one or more labs. One of the unique aspects of this interactivity is that the prompts cascade, meaning that the first selection filters the next and the next. All choices are then reflected in the bar chart, which can also be used to control the data used in the pie chart and Detail Table. The full scope of all interactivity is best shown in Figure 9, which details all of the interconnected links.

Lab Test Comparison Analysis





PATIENT LAB RECORD

Specification	Description
Source Data	Data for this report is the same as for the Lab Test Comparison report. Data is at the one-lab-per-row level with patients and labs repeated to reflect all labs administered to all patients.
Data Preparation	No additional data preparation required.
Visual Analytics Objects	Text Input Field (under Search for a Patient) List Table (Subject Details) Bar Chart data in clustered format (Lab Administration Timeline) List Table with display rules applied (Lab Results Details)
Interactivity	This report is very much a top-down, traditional report. By typing a patient ID into the text input field, a patient is selected. All data reflect that request. The bar chart with lab data is interactive in that it allows the selection of labs at a particular time or selection of labs with a particular result (low, high, normal), which are reflected in the Detail Table.

PATIENT LAB RECORD

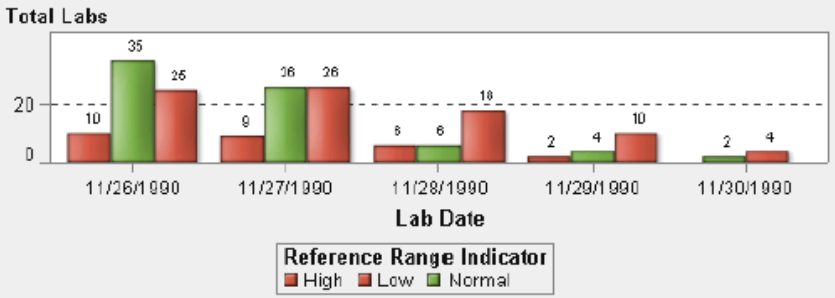
Search for a Subject

STUDY01-461007

Subject Details

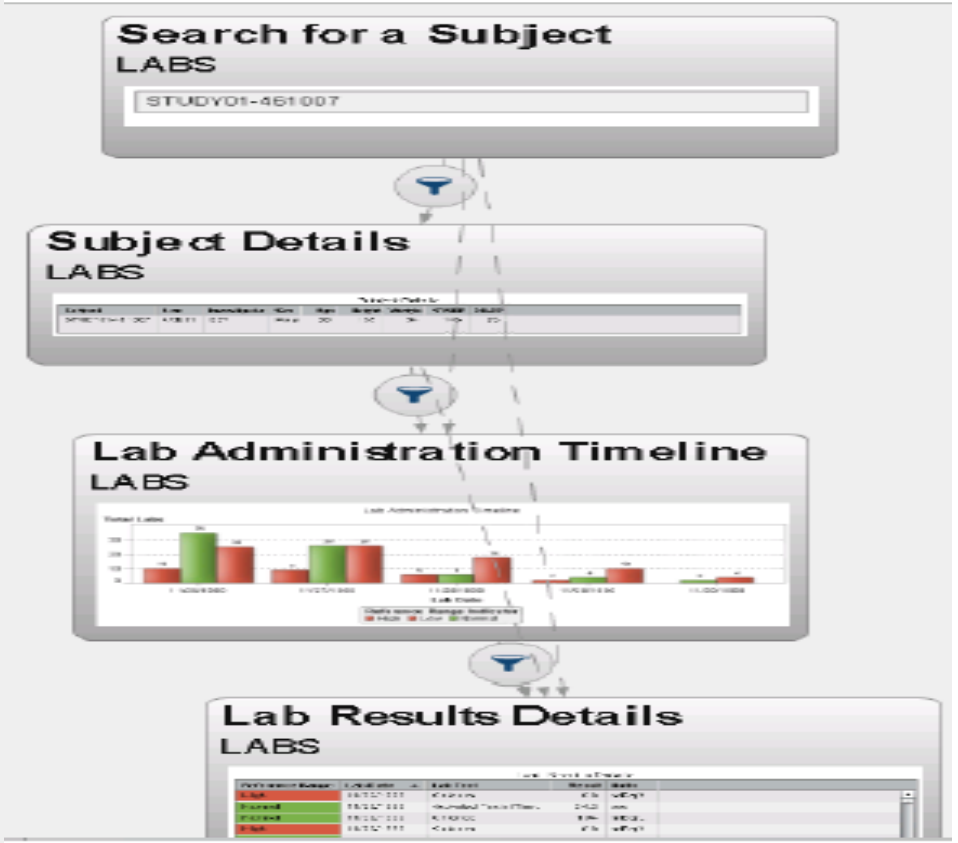
Subject	Arm	Investigator	Sex	Age	Height	Weight	SYSBP	DIABP
STUDY01-461007	ARM01	B27	Male	38	165	54	146	76

Lab Administration Timeline



Lab Results Details

Reference Range	Lab Date	Lab Test	Result	Units
High	11/26/1990	Calcium	9.9	mEq/dL
Normal	11/26/1990	Activated Partial Thr...	24.2	sec
Normal	11/26/1990	Chloride	104	mEq/L
High	11/26/1990	Calcium	8.9	mEq/dL



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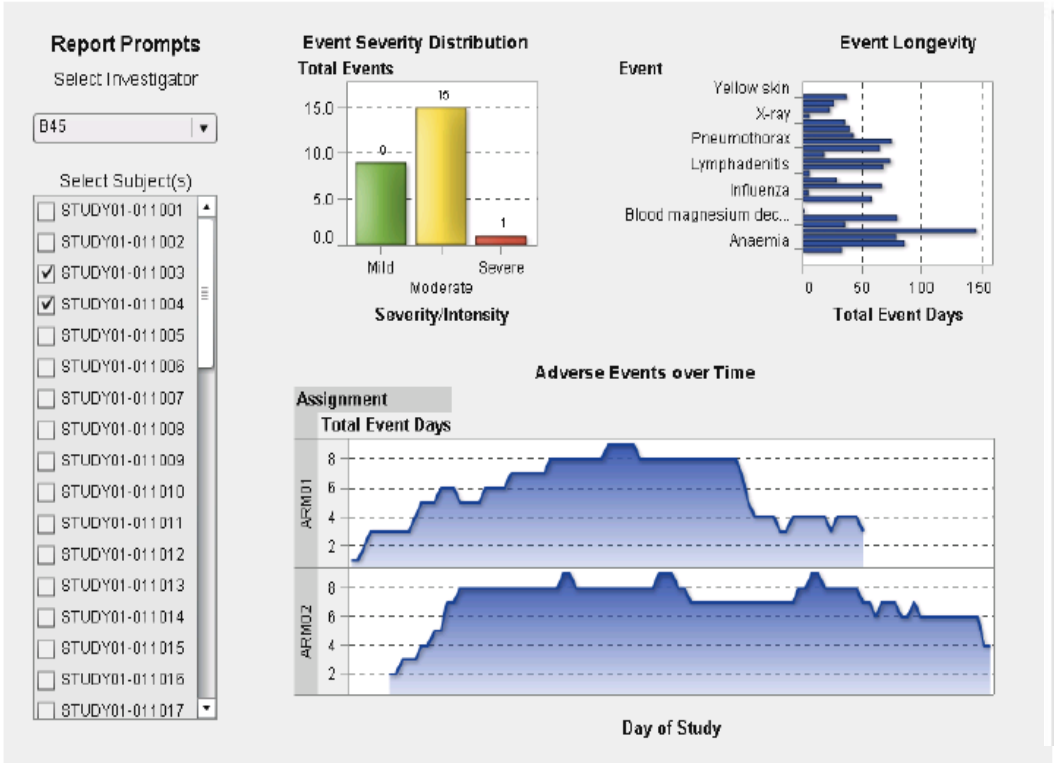
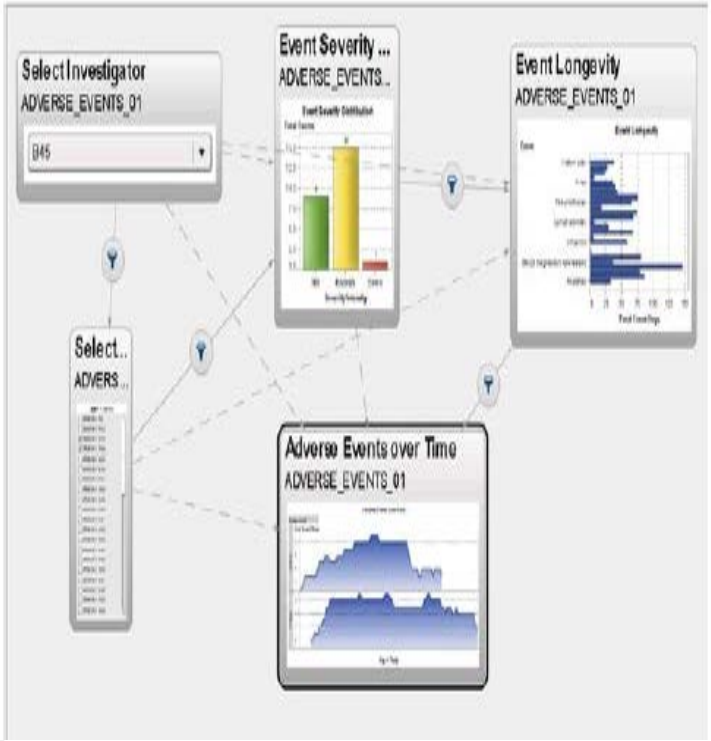
ADVERSE EVENTS OVER TIME

Specification	Description
Source Data	This is the same data as in the Adverse Event Duration report, with data at the one-event-per-row level. Patients and events are repeated to reflect all events experienced by all patients. Unlike the previous report, the data structure here is not stacked
Data Preparation	Day of study is represented in two ways in this report. The bottom graphic showing Day of Study uses the day of the event relative to the first day of the study. But the Event Longevity graph at the top right uses adverse event data normalized so that start of the event is set to 0. This is important as the intention here is to compare the relative length of the events, not the specific day of study that the event occurred.
Visual Analytics Objects	Pull Down Control (Select Investigator) List Box Control (Subject) Vertical Bar Chart (Event Severity Duration) Horizontal Bar Chart (Event Longevity) Line Plot with Vertical Lattice using the Overlay Filled property
Interactivity	From the left, the selection of an investigator cascades down to the subjects, meaning that only those patients associated with the selected investigator are shown in the list box. Those selections are reflected in the graphs, and each graph then modifies the next, moving left-right and top-down. The longest duration events can be captured by selecting only the right tip of the bars under Event Longevity, which will then modify the graph at the bottom to reflect only the longest duration events and to allow users to see when those started for the two experimental conditions.

ADVERSE EVENTS OVER TIME





Conclusion

- In an experiment, we define measurements, develop methods for collecting those measurements, gather data, and analyse that data, typically attempting to isolate the effects of one particular variable. To do so, we might implement experimental or statistical methods to control for the effects of other variables, factors that are not our primary concern.
- That is the approach of science and no reasonable person would question the value of that approach. On the other hand, we do not live in a controlled environment in which one isolated variable has an effect. We live in a multivariate world in which a tremendous number of variables are constantly interacting with effects changing over time.
- The real world is a complex, dynamic place. While there have been significant improvements in the statistical models used to explain that complexity, our methods for reporting the results of such models have lagged behind.
- Static reporting will always have a place in science. But newer technologies using interactive visualization of data have the potential to transform our ability to report on very complex data. To fully understand the relationship between all of the subject-state, time-dependent, and covariate relationships in data that we gather, we need a new way of reporting. SAS Visual Analytics provides data scientists with the technology to reflect these relationships.

References

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- **SAS Paper :** Visualizing Clinical Trial Data: Small Data, Big Insights --Michael Drutar and Elliot Inman

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