

Medical Data Review and Early Data Exploration using Data Visualization (PP10)



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1.BIG DATA AND PHARMA

There are huge costs involved in bringing a new drug to market and Pharma companies are under pressure to deliver innovative products quicker, with **reduced** budgets whilst **maintaining** regulatory **compliance**.

Driven by the increased use of electronic medical records, technological advances in genomic sequencing and monitoring devices, the challenge of handling “**Big Data**” is becoming more apparent in the Pharma industry.

Not only is the sheer volume of data growing, but the variance in complexity and the depth means that there is now an **opportunity** for clinical scientists to mine this data to gain insights and understandings that have never been possible previously.

This vast amount of data needs to be translated into **information** that is meaningful and impactful. It needs to be delivered in an easily-digestible format that allows the key stakeholders to make informed decisions swiftly and efficiently.

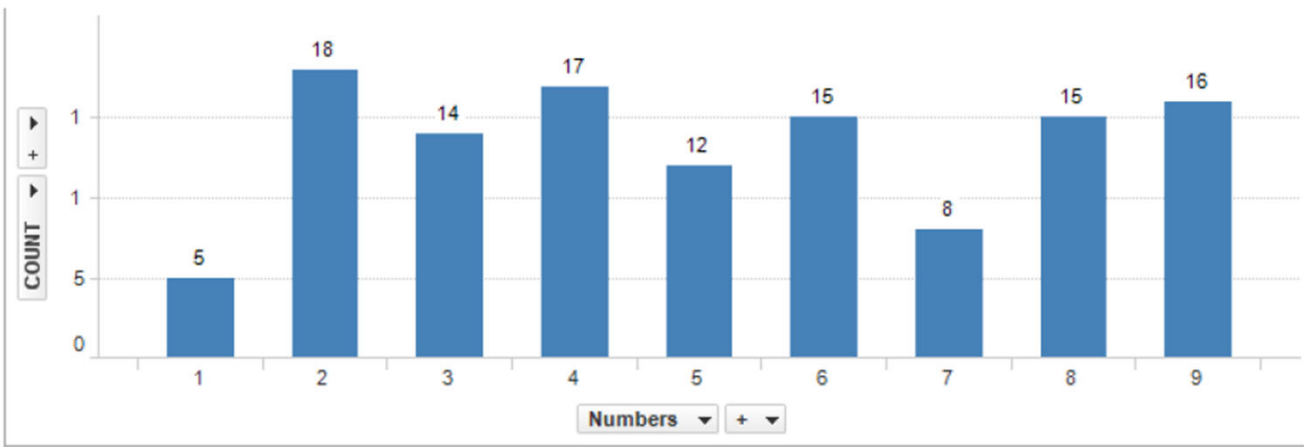


2.DATA VISUALIZATIONS

Data visualization represents the data in a way to engage the user as well as helping to **communicate** complex ideas quicker in a way to enable end users to discover **patterns** that might otherwise be hard to see in simple tables or listings.

Data visualizations offer ways to find **trends** and **dependencies** that can lead to important discoveries. Visualizations allow to understand and process enormous amount of information **quickly** because it is all represented in a single image or animation.

2	1	4	3	9	5	6	7	8	2	3	6	5	9	4	0	1
6	7	9	3	4	9	0	5	6	2	5	8	4	0	5	2	6
9	8	2	6	3	5	9	3	2	9	3	7	2	6	3	4	8
8	1	6	2	3	8	7	9	5	0	2	3	9	2	8	4	3
0	9	1	8	5	4	2	9	4	7	4	6	8	4	0	2	9
3	9	2	7	3	6	6	5	2	9	4	0	4	9	4	8	6
5	2	4	3	6	4	8	1	0	3	9	4	8	4	7	3	2
8	6	2	3	0	8	7	3	6	2	5	4	4	8	3	5	0



➔ **TRY IT** - A simple piece of data visualization, count the number of 7s in both listings above, the simple addition of color highlights the numbers of interest, or a simple bar chart provides much more information visually.

3.DATA PROVISION SPECIALISTS

The department of Pharma Research and Early Development (**pRED**) at Roche is encouraging project teams to increase their use of data visualization via various tools, including **Tibco Spotfire**, to improve both **efficiency** and **quality** of review/analysis activities.

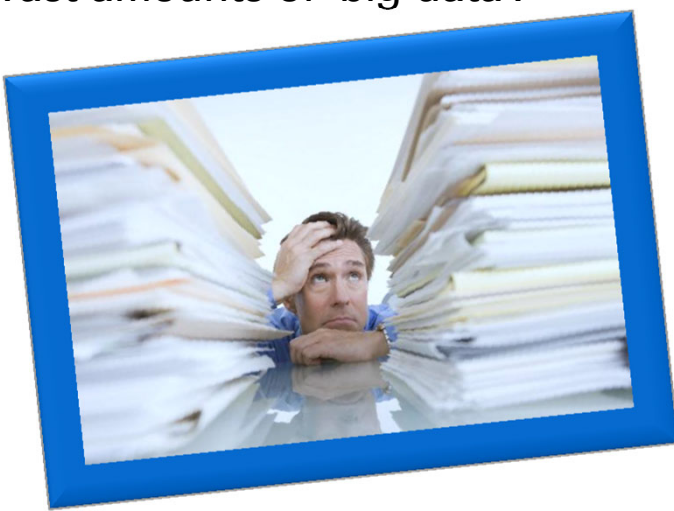
A new dedicated DPS (Data Provision Specialist) role has been created which allow scientist to **focus** on the review of safety data while the DPS is responsible for providing **dedicated**, desk-side and real-time **technical** support to colleagues in clinical science.



Having this technically minded **dedicated** resource allows the scientists to focus on the **trends** and the ‘information’ provided rather than having to mine through the vast amounts of ‘big data’.

The scientists will usually have a specific section of the data they will want to look at and often have **theories** that they would like to **confirm** or monitor for the safety of subjects in trials.

Viewing this large amount of information is becoming more and more difficult using the conventional method of tables and listings.

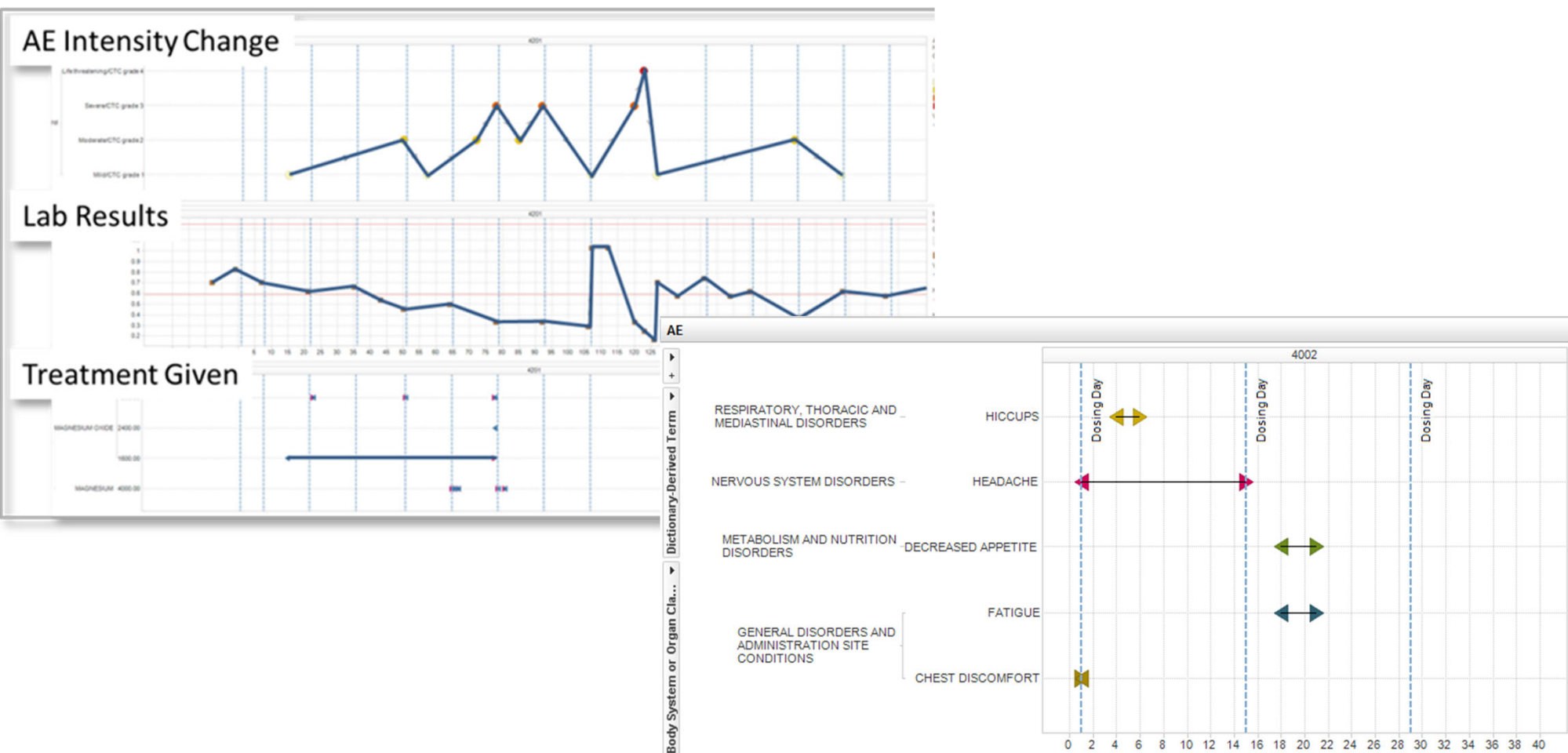


4.DATA VISUALIZATION IN ASSISTING MEDICAL DATA REVIEW

In a recent oncology trial at Roche, the following topic started to arise: large amounts of **complex** data with an increased variety were being generated.

Listings were created and even by **focusing** on one particular adverse event, 37 rows for AE intensity changes, 2,000+ lab results, and 8 AE treatments were created. Overall there are 2100 different AEs across 155 subjects in the study right now.

After a **collaboration** between the DPS and science teams, a total of 14 visualizations in one single **dashboard** were created initially to show all the different aspects of the AE data.



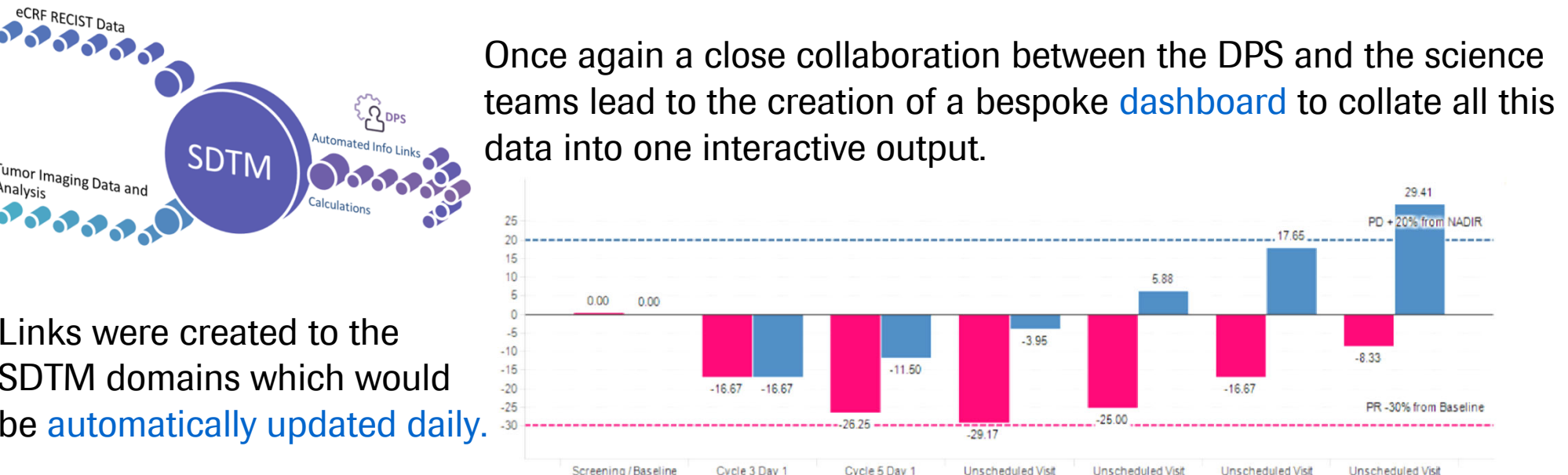
5.AUTOMATING DATA REVIEW CALCULATIONS

RECIST tumor data is collected on the eCRF in a very different way to how it is reported in the **SDTM** format - It is collected in 5 different eforms on the eCRF while the data is then split into 3 different datasets in SDTM.

The **technical aspects** of this data coupled with the need to **calculate** a large number of derived values (change from Nadir/ change from baseline) make using raw tumor data extremely **difficult**.

Previously this data was **manually transcribed** from the eCRF into Microsoft Excel and calculations done **manually** by the scientists.

This was proving to be a **time consuming** process and often meant reprocessing and rechecking the data as it was constantly cleaning and correcting the data.



Coupled with the data visualization capabilities and **calculation** functions within Spotfire and the knowledge of the DPS, meant the clinical scientists were able to see the **live** data with no overhead on recalculations and rechecking of the data.

6.EARLY DATA EXPLORATION

Medical data review is a planned and structured approach to looking at the data in a clinical trial, going through question and answer cycles while **interrogating** the data.

Early Data Exploration is an ad-hoc real time approach to **visually explore** the data on an on-going basis following the principle of question and answer cycles between the scientists and DPS.

Because of the fully interactive capabilities of the software, coupled with DPS **knowledge** of the study, therapeutic area and technical knowledge in the data structures, it is now possible for a scientist to have **access** and **support** for viewing the data in a matter of hours rather than days or weeks.

7.CONCLUSION

This **new way** of working, and the collaborations being formed between the DPS and the Science groups, is now flourishing at pRED Roche with almost **25%** of studies using these new tools and methods.

Science can concentrate on **looking** at their data and **applying** their clinical judgment.

The DPS can focus on the **technical aspects** to bring the data and the information closer to the science teams enabling them to make their **decisions** more **accurately** and on a timelier manner.

