Exploratory Analysis vs Regulatory Reporting

The Revolution: A journey to exploratory
Mijanur Rahman
Roche Products Limited

REGULATORY REPORTING

Regulatory Reporting is any report of raw or summary data needed to evaluate the safe and sound condition and operations of a product. For example, Clinical Study Report (CSR), in the past programmers mainly worked more as a service provider with SAS being the main software being used. Regulatory reporting is still the main aspect of our job, however moving forward programmers will most likely not only be producing tables, figures and listings (TFLs).

The Revolution

As programmers we cannot stand still, we need to broaden our skill set, to show that we can add value to any type of work. There is an increase in standardisation which allows programmers to invest more time in different work. With new and exciting technology, software and data emerging, programmers are now moving towards exploratory or analyst type of work.

EXPLORATORY ANALYSIS

Exploratory analysis is an approach to analysing datasets to summarise their main characteristics, often with visual methods. Statistical models can be used or not, but primarily exploratory analysis is for seeing what the data can tell us beyond the formal standard statistics, modelling or hypotheses testing task. This seems to be the future for programmers.

Data

There is a vast amount of data to explore when it comes to exploratory analysis. Regulatory (clinical trial) data mainly comprises safety and efficacy data, but this can also be used for exploratory purposes. Exploratory data can be anything, from biomarkers to electronic medical records (EMRs) and hospital drug database and social media data. This is usually referred to as big data, but what exactly does this mean?

As programmers, we have the necessary skills and tools to analyse such data. Data is a major part of the work we do and we are at the forefront of this major change. The industry and data is constantly changing; we are seeing new and innovative endpoints, treatments and medicines which require us to explore different types of data.

Challenges

There are always challenges in any type of reporting. In regulatory you may find data issues, strict timelines etc. Exploratory is a whole new world and has many different challenges. From conducting an interview in our department, here are the main challenges faced with exploratory analysis:

- No Standards
- Unknown Science
- Data not designed for medical research
- Understanding the data
- Bigger data (more process power required)
- Having the right tools to manage and analyse data

Roles/Skills

New roles are appearing and our job descriptions are changing due to more exploratory or analyst type of work. We hear a lot about becoming more of a data scientist. This new role is needed for exploratory work. There are many skills needed in order to be proficient in exploratory work. From conducting an interview in our department, here are the main skills required when conducting exploratory analysis:

- Able to interpret the data
- Able to explain the data
- Take time to step back if you face an unknown challenge and succeed by broadening your skill
- Have business and science knowledge
- Become technically efficient in a variety of software packages, as different challenges require different tools

Summary

A programmer’s responsibility should not only be to produce TFLs from a set of specifications, but have the ability to understand different types of data; use different software packages, have business and science knowledge. This enables a programmer to move away from standard regulatory reporting and become more active in exploratory work. The industry is changing; exploratory analysis is becoming a major part of our job and programmers are at the forefront of producing the analysis and exploring the data. With regulatory reporting becoming more standard, this enables programmers to invest more time in exploratory.