

Exploratory Analysis vs Regulatory Reporting

The Revolution: A journey to exploratory

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ABSTRACT

The role of a programmer is constantly evolving. Most programmers today use SAS to produce tables, listings and graphs for health authority work (regulatory reporting) but will this picture remain true in the future, and what other opportunities might appear? New roles and activities for a programmer are starting to emerge that require a different set of skills and tools to produce innovative, dynamic and interactive analysis to enable better decision making. A key component of this will be exploratory analysis. This paper has captured a variety of opportunities for exploratory analysis and regulatory reporting whilst meeting the needs of the business. Based on the author's experience and surveys conducted, a comparison of the different skills and tools for these analyses are presented.

INTRODUCTION

The industry is changing and so is the role of a programmer. This paper will cover one of the main changes we are currently seeing in the industry; exploratory analysis. Throughout the years in the pharmaceutical industry, regulatory reporting has been the main trait of a programmer. Even though, regulatory reporting is still one of the main aspects of our job; programmers are now moving towards more exploratory type work. Throughout this paper we will be observing some of the main characteristics of exploratory analysis whilst also comparing this to regulatory reporting.

REGULATORY REPORTING

Regulatory reporting consists of 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). With standards coming in place for data collection, reporting etc. Regulatory reporting becomes streamlined so more time to do exploratory or analyst type of work.

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 hypothesis testing task. This seems to be the future for programmers. Some of the main aspects of exploratory analysis are discussed further below whilst also comparing some of these with regulatory.

DATA

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

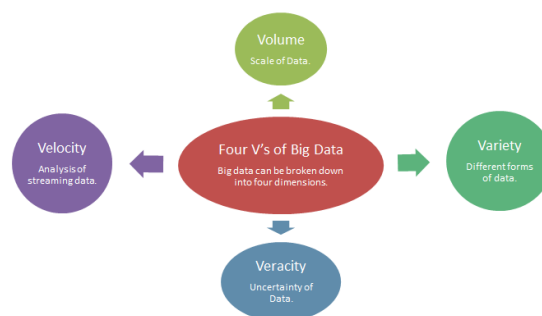


Figure 1

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To define big data, the four V's describes this very well.

- Volume – the amount of data is large, easily terabytes daily.
- Velocity – data comes at high speed; time-sensitivity analysis must be fast.
- Variety – data is heterogeneous.
- Veracity – sources and results of analysis must be trusted.

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.

RESOURCE/TIME

In the past we may have seen programmers working 100% on regulatory work. From surveys conducted within our department we can see programmers are spending some time on exploratory work each month (22%). This shows the programmer's role is changing and in time we may see programmers conducting more exploratory analysis when compared to regulatory.

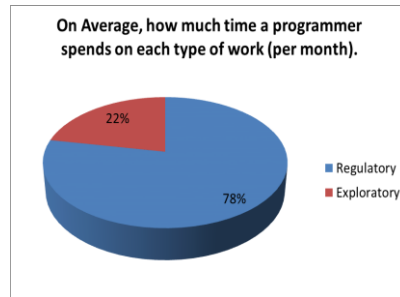


Table 1

TOOLS AND PROGRAMMING

With new tools and programming languages emerging, programmers are becoming more proficient in other software packages. Although SAS® is still the main software used; we can see other tools coming into existence in both regulatory reporting and exploratory analysis. From surveys conducted within our department, programmers are using more different types of tools for exploratory when compared with regulatory. With new software packages appearing and programmers getting opportunities to conduct exploratory work, will SAS® still be our main software in the future?

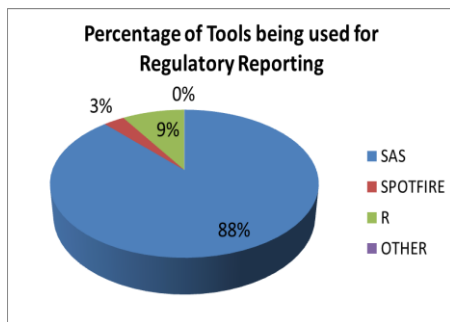


Table 2

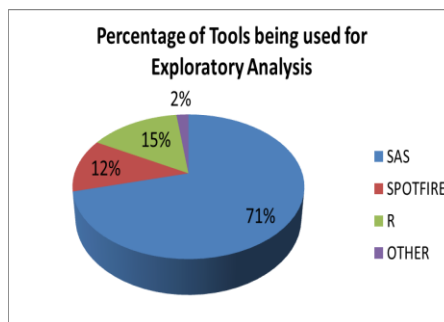


Table 3

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.

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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.

CONCLUSION

A programmer's responsibility should not only be to produce TLGs 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 standardized, this enables programmers to invest more time in exploratory reporting.

REFERENCES

Big data, four V's reference:

<http://www.ibmbigdatahub.com/infographic/four-vs-big-data>

ACKNOWLEDGMENTS

The author would like to thank Bhupendra Mistry, Vijay Reddi, Ryan De Costa, Ross Farrugia, Richard Houghton, Hiren Naygandhi and Michael Hall for feedback, review and support, especially for the poster.

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