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New Starter Models for Pharmaceutical Companies and Clinical Research Organisations (CROs)

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ABSTRACT

The paper compares and contrasts New Starter Models used by Pharmaceutical (Pharma) companies and Clinical Research Organisations (CROs). New starter refers to recent graduates, students on internship or someone who has changed careers and joined the pharmaceutical industry as a SAS®/statistical programmer from a different environment such as finance or marketing. The advantages and disadvantages of the models in both environments are discussed. Finally the paper ends by identifying improvements and alignment of the models in both environments.

INTRODUCTION

In the last four years as a SAS programmer in the pharmaceutical industry I have had the opportunity to work for a number of different companies, both Pharma companies and CROs. During that time I have been a new starter and have gone through different company induction models. The induction models have been similar in structure and can be divided into two categories:

1. Generic Introduction – this covers the company's overview
2. Operation introduction – covers an overview of the pharmaceutical industry, drug development and job specific training

The aim of this paper is to compare and contrast New Starter Models used by Pharma companies and CROs with reference to operation introduction-job specific training.

THE ROLE

The role of a SAS programmer mainly consists of reporting clinical trial data from Phase I-IV studies. The studies can be in different therapeutic areas such as Oncology, Psychiatry, Endocrinology, Cardiovascular disease and Infectious diseases to mention a few. The role typically involves creating datasets from the collected data, creating tables, listings and figures.

INDUSTRY BACKGROUND

The operation introduction training usually covers:

- The drug development process and the steps involved in clinical research
- The principles of clinical trials
- The importance of a trial protocol
- The different regulatory bodies of clinical trials
- Standard Operating Procedures (SOPs) which are detailed written instructions to achieve uniformity of the performance of a specific function [1]

The operation training differs depending on whether the new starter is working for a Pharma company or CRO. The objectives for Pharma companies and CROs are different which naturally leads to different New Starter Models. Pharma companies are involved in the whole drug development process whereas CROs provide a service on specific tasks for Pharma companies. CROs will target training to meet the specific tasks they will provide for Pharma companies. The Pharma Company training will be broader since there will be more interaction with other stakeholders in Science and Biostatistics and there is a possibility of leading studies which will be outsourced to CROs.

In this paper I focus on Pharma companies and CROs based on my experience.

GENERAL TECHNICAL TRAINING

The technical training for the new starter is generally the same for both Pharma and CROs. The new starter is enrolled in a SAS certification programme/recognised external SAS course or SAS training is provided in-house followed up by hands on experience - again in-house. An in-house reporting system is a system for creating datasets and reports using the SAS system. If the new starter is already a SAS programmer or after they have completed the

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SAS training they are provided with a mentor to guide them through real studies. Usually the mentor is also involved in reporting on other studies. This can cause a lot of strain on the mentor since they have to balance mentoring with working on their own studies. The new starter has to learn to be pro-active and to consult other sources of information before speaking to their mentor. This is helpful in that it increases their research skills and broadens their understanding of the concepts needed to do their work.

Being new and working on real studies has its challenges in both Pharma companies and CROs as follows:

- The time to report on the study can increase because the new starter has to become familiar with new concepts
- Resources can be lost from other studies as the mentor has to double check all the work done by the new starter

In addition for new starters in CROs, there are also these additional challenges:

- The new starter has to read a number of SOPs from different Pharma companies which also takes time to become familiar with
- They also have to be trained in the different in-house reporting systems for different clients which again can take time to become familiar with

The new starter is only granted access to the Pharma in-house reporting system after they have completed an initial training session. This training is not usually done in the real working environment and its detachment from the live reporting system means that they don't get any real experience of using the system until after access has been granted.

PHARMACEUTICAL COMPANIES

A pharmaceutical company or drug company is a commercial business whose focus is to research, develop, market and/or distribute drugs, mostly in the context of healthcare [2]. They can deal in generic and/or brand medications.

For example on average, about 8 years pass from the time a cancer drug enters clinical trials until it receives approval from regulatory agencies for sale to the public [3]. Some Pharma companies have two distinct departments for reporting of the different phases of clinical trials:

- Early Phase for Phases I and IIa studies which have shorter timelines of reporting
- Late Phase department for Phases IIb to IV which take a longer time to report.

If the new starter joins the Early Phase department they should expect to be responsible for multiple studies/projects which could cover many different therapeutic areas and different types of studies. If they join the Late Phase department they should expect to work in one therapeutic area and on one product for many years. Being in a Pharma they should also expect to provide input in the data collection, data handling and data analysis procedures for the study they're working on. They should also expect to use the company specific in-house reporting system. Here I focus on the Late Phase department since there are usually more new starters joining the Late Phase compared to Early Phase.

Being a new starter with a Pharma organisation has its advantages and disadvantages as follows:

ADVANTAGES

- Working on a single therapeutic area and on one study means that there is more time to learn one reporting system and it is possible to make suggestions for improvements to that system
- The new starter will only deal with the company's SOPs which means they are easier to become familiar with than if they are dealing with many different SOPs from different companies
- They will experience the overall drug development process and be involved in its results and patient impact
- They will be directly involved with the Science and Biostatistics team will be able to influence the data collection, data handling and data analysis procedures for the study

DISADVANTAGES

- There can be a lack of variety of studies to work on in different therapeutic areas
- Working on one in-house reporting system limits the new starter's experience as reporting systems vary and other systems used by other companies could have some features which are better than the system being used

CLINICAL RESEARCH ORGANISATIONS

A contract research organisation, also called a Clinical Research Organisation, (CRO) is a service organisation that provides support to the pharmaceutical and biotechnology industries in the form of outsourced pharmaceutical

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research services (for both drugs and medical devices)[4]. Pharmaceutical /Biotech companies give CROs specific tasks to concentrate on allowing them to increase efficiency in the delivery of their product.

CROs usually have a varied portfolio consisting of contracts from different Pharma or biotechnology companies. Since CROs provide a service to Pharma there is usually a drive to meet timelines within agreed budget. This may result in new starters working in different Pharma companies and therapeutic areas.

Being a new starter with a CRO organisation has its advantages and disadvantages as follows:

ADVANTAGES

Since CROs may provide services for different Pharma companies new starters could get to:

- Work on studies in different phases and therapeutic areas. This is an enriching experience since they have exposure to varied clients with different or similar in-house reporting systems.
- There is a possibility of working on different studies at the same time, which should improve multitasking capabilities and develop communication skills with global teams.

DISADVANTAGES

The varied portfolio has its pitfalls as follows:

- Working on studies for a short period of time does not allow new starters to develop a good grounding in the concepts of that therapeutic area
- They will not usually work on a whole study from beginning to end, so will not gain indepth experience of the study. The only information that they will be given will relate to the part of the study that they are working on.

With such a varied portfolio it is not surprising that the induction training received is geared towards the different systems that clients have. The client training facilities on the SOPs and in-house reporting systems will have to be accessed frequently and the training is usually restricted to the minimum information needed to carry out the work task and in-house experts will be relied upon to teach the new starter each client in-house reporting system.

IMPROVEMENTS AND ALIGNMENT

Pharma is responsible for the research, development and marketing for the drug whilst CROs offer services to Pharma. This difference leads to different New Starter Models. There is room to improve and align the common aspects of both environments. The following are suggestions of how this could be achieved:

Pharma

- The introduction of a dedicated training environment within the live reporting system. This will ensure that the concepts learnt during training can directly be applied to the working environment and that the initial training is beneficial.
- The introduction of a dummy study for new starters to work on with common reporting aspects across all therapeutic areas. This will provide insight into other therapeutic areas where the new starter might be required to report in the future and will give a general overview on the different types of reporting across different therapeutic areas.
- Access to be granted to the training area for new starters from CROs who will be working on the Pharma company studies. This will ensure that CRO new starters quickly become familiar with the tools required to successfully report on the studies.

CROs

- The introduction of a general dummy study which should preferably be independent of the client environment. This should cover common reporting aspects across all clients and not on one client system. This will have the benefit of giving new starters a general overview of the standards across different clients and therapeutic areas
- Access to be granted to the client job specific training environment and material (dummy study) prior to beginning to report on the real study. This will ensure that the new starter becomes familiar with their client's reporting system and how to use it as quickly as possible.

CONCLUSION

New starters have a great deal to learn when they begin working for either a Pharma company or a CRO. Because Pharma companies are responsible for the long term development of drugs and CROs undertake specific tasks for Pharma companies it follows that there will be differences in the New Starter Models. Even with these differences improvements can still be made to align the common areas.

- It would be beneficial for both to have a dummy study (within the live reporting system) to work on so that they can gain confidence and get a good idea about what they will potentially face when they start working on a real study. Although a dummy study will not cover all the possible scenarios they will meet when

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working on a real study, it will at least give them a good foundation to start from. The common practice of having a new starter working on a real study and shadowing a more experienced programmer may have the disadvantage of putting a strain on programming resources and potentially increasing the reporting time. Although the new starter may still need some mentoring time this can be greatly reduced if they get to work on a dummy study before being exposed to the real thing.

- Pharma companies allowing CROs to have access to their in-house dummy study in a controlled reporting environment will ensure that new starters from CROs are able to quickly become familiar with the reporting system so that they will be more effective when working on a real study with their client. This should also reduce the amount of mentor time needed to go through all the training with the new starter as well as resulting in them being more productive earlier on.

These alignments in the New Starter Models in Pharma and CRO environments will make it easier for new starters from both companies to smoothly transition into their careers and become efficient in undertaking work tasks more quickly.

For a new starter who is deciding whether to work for a Pharma or CRO they should be aware that the two sectors have different objectives which are reflected in the differences between the New Starter Models. Whichever path they choose should be based on their career plan. In both situations they will contribute to helping to find a cure or improve the standard of living of patients.

REFERENCES

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