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

October 2011

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Agenda

- THE ROLE
- DRUG DEVELOPMENT PROCESS
- INDUSTRY BACKGROUND
- GENERAL TECHNICAL TRAINING
- PHARMACEUTICAL COMPANIES
- CLINICAL RESEARCH ORGANISATION
- IMPROVEMENTS AND ALIGNMENT
- CONCLUSIONS



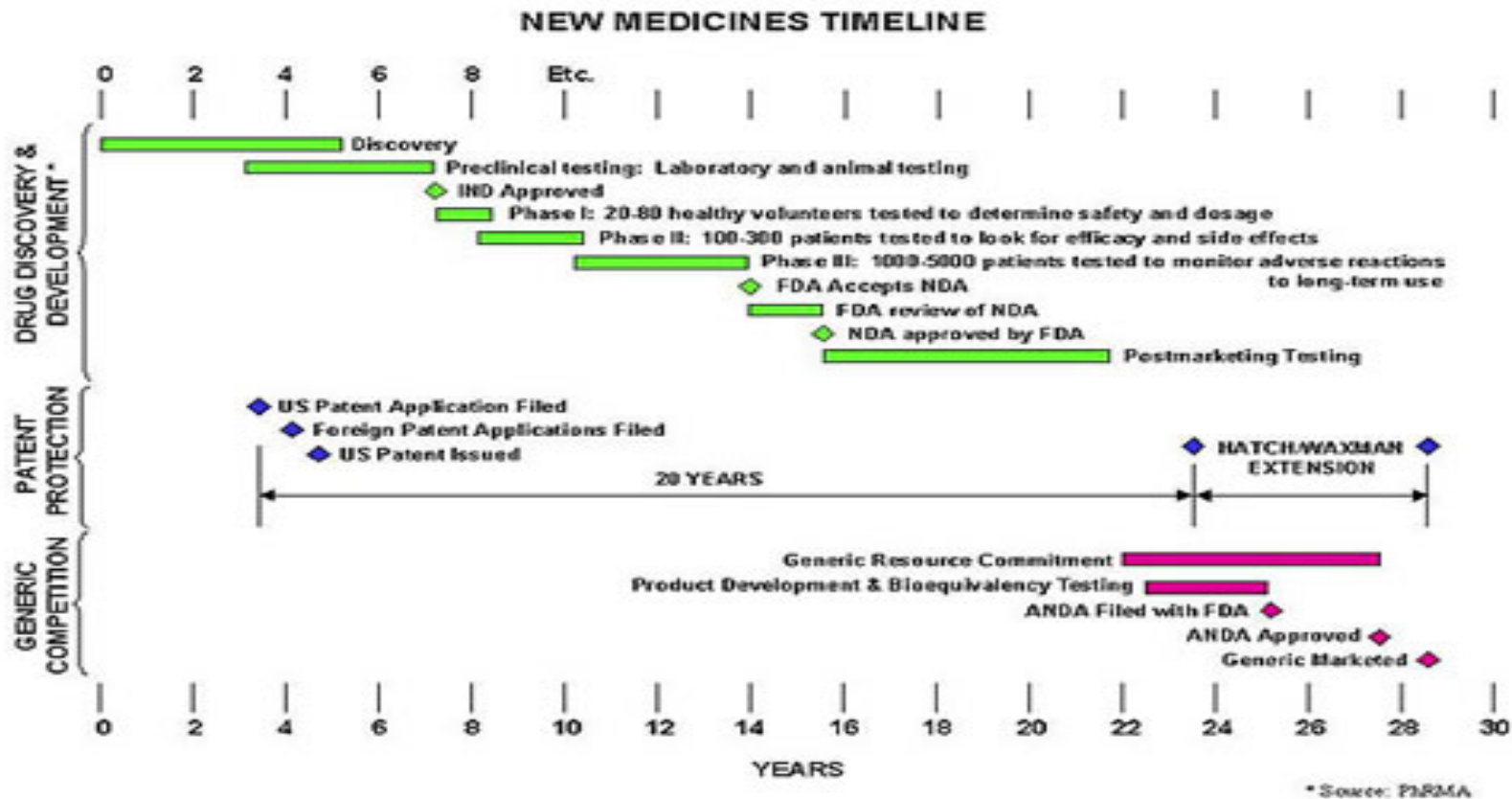
Job specification

The Role

The role of a SAS programmer mainly consists of reporting clinical trial data from Phase I-IV studies. The role typically involves understanding the requirements and writing programs to create statistical tables, listings and graphs from the data collected during a clinical trial.



Drug Development Process (Source PhRMA)



General Training Structure

- Generic Introduction : This covers the company' s overview
 - ✓E.g. Human Resources (Pensions) , IT awareness, company's values etc.
- Operation introduction
 - ✓This covers an overview of the pharmaceutical industry, drug development and specific training



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]



Industry Background...

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.

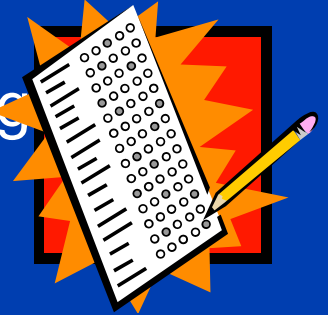
- A pharmaceutical company or drug company's main focus is to research, develop, market and/or distribute drugs
 - ✓ There is usually a drive to experience the overall drug development process and be involved in its results and patient impact
- Clinical Research organisations provide a service on specific tasks for Pharmaceutical companies.
 - ✓ There is usually a drive to meet timelines within agreed budget

General Technical Training Pharma/CRO

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✓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.

✓After training a mentor is assigned to guide them through real studies.



✓The new starter is usually 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.



General Technical Training...

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

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.

Pharma Advantages



- Working on a single therapeutic area and on one study means that they become familiar with the specific compounds under development, know the SOPs better and the people conducting the studies.
- 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. Similarly with the in-house reporting system.
- 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 team and will be able to influence the reporting outputs for the study

Pharma 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 research services (for both drugs and medical devices)[3].
Pharmaceutical /Biotech companies give CROs specific tasks to concentrate on allowing them to increase efficiency in the delivery of their product.

CRO Advantages

- 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. An in-house reporting system is a system for creating datasets and reports using the SAS system.
- There is a possibility of working on different studies at the same time.
 - ✓ This should develop and improve the New Starter's multitasking capabilities and communication skills within global teams.

CRO Disadvantages

- Working on studies for a short period of time.
 - ✓ This 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.
 - ✓ They will not gain in-depth experience of the study and the only information that they will be given will relate to the part of the study that they are working on.
- The new starter has to read a number of SOPs from different pharmaceutical 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 can take time to

Improvements and alignments



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.

IMPROVEMENTS AND ALIGNMENT

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

- Both Pharma companies and CROs should create a dummy study (within the live reporting system) for new starters to work on. New Starters can practice, gain confidence and get a good idea about what they will potentially face when they start working on a real study.
- 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.
- These alignments in the New Starter Models in Pharmaceutical and CRO environments will make it easier for new starters in both environments to smoothly transition into their careers and become efficient in undertaking work tasks more quickly.

CONCLUSION...

CRO or Pharma?

Depends on career plan

- ✓ Research on which environment best suits your career plan

What is important is that you will be helping to find a cure or improve the standard of living of patients!!

References

- [1] Wikipedia - http://en.wikipedia.org/wiki/Standard_operating_procedure
- [2] AskDefine - <http://pharmaceutical.askdefine.com/>
- [3] Wikipedia - http://en.wikipedia.org/wiki/Contract_research_organization

Questions





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