Chapter 1
Overview of Clinical Trial and Pharmacovigilance Process and Areas of Application of Computer System

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ABSTRACT

The overall process of getting a drug to the market is a long one and takes 10-15 years and costing close to a billion dollar. The success rate as the compound travels from the initial discovery phase to clinical and then through to the market is about 1 in 10,000. The two key phases which together contribute the most to the cost and timeline are clinical development and pharmacovigilance. These two phases together also account for the maximum number of failures. In this chapter, we will look in detail at these two phases with a focus on the business process and process areas which have application of computer systems. The chapter will focus on looking at the various phases of clinical development and their endpoints. Clinical development is the process of testing a drug for safety and efficacy in human subjects. Clinical trial is conducted in 3 phases with the 4th phase which is ongoing post approval which forms an important part of the pharmacovigilance process. These phases will be elaborated in detail.

INTRODUCTION AND BACKGROUND

The overall process of getting a drug to the market is a long one and takes 10-15 years and costing close to a billion dollar. The success rate as the compound travels from the initial discovery phase to clinical and then through to the market is about 1 in 10,000. The two key phases which together contribute the most to the cost and timeline are clinical development and pharmacovigilance. These two phases together also account for the maximum number of failures. In this chapter, we will look in detail at these two phases with a focus on the business process and process areas which have application of computer systems.

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Figure 1 illustrates the value chain of bringing a drug to the market starting from understanding of disease to commercialization of the drug for the disease. (R&D Pipeline Management, University of Wisconsin, n.d)

The entire process of drug discovery and development starts *in silico* (in the computer), moves to *in vitro* (in the laboratories) and then finally *in vivo* (inside living beings like animals and humans). This is keeping with the spirit of ensuring safety to all living beings. As the molecule progresses to becoming a drug it graduates from computer to laboratory to living beings.

The initial phase of drug discovery is focused on understanding the disease better and potential drug targets that are relevant for the disease which is largely driven by biology. This part primarily focuses on:

- Understanding the mechanism of diseases;
- Identifying potential targets for therapeutic intervention;
- Evaluating potential drug candidates.

Once the disease is better understood and potential targets identified, the next phase focuses on various aspects of the molecule that can become potential drugs and is largely driven by chemistry. This part addresses the following needs:

- Inventing or identifying safe & effective chemical entities that will become potential drug candidates.
- These drug candidates will act as leads to act on the target disease

These two initial phases of biology and chemistry are largely *in silico* and *in vitro*.

One of the key qualifying parameter for a molecule to become a drug is its medicinal properties. This science is called medicinal chemistry and this characterizes the molecule before it is used in any living being.

Medicinal chemistry is a scientific discipline involved with designing, synthesizing and developing pharmaceutical drugs.

Medicinal chemistry involves the identification, synthesis and development of new chemical entities suitable for therapeutic use. It also includes the study of existing drugs, their biological properties, and

Figure 1.