Chapter 1
Evolution of Digital Technologies and Use of Virtual Assistants in Drug Development

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ABSTRACT

The drug development phase is one of the most time-consuming and expensive stages in the lifecycle of a drug. Marred by patent expirations, price regulations, complexities in disease conditions, life sciences companies are facing a daunting task to bring new molecular entities into the market. Digital health technologies are playing a critical role in addressing some of the challenges faced during drug development. In this chapter, the author talks about the challenges and key trends in the world of drug development, use of new digital health technologies, and the future of drug development. As an example, the author dives into a specific case study on the use of virtual assistants in clinical trials and the benefits of its usage on patients, healthcare professionals, and life sciences companies.

INTRODUCTION

It is a common knowledge in the Life Sciences Industry that conduct of clinical trials and their approvals by regulatory authorities as part of the drug development journey takes a major share of the time and cost spent by pharmaceutical companies in their attempt to bring a new drug into the market. While there have been big advances in improving the operational and process efficiencies in drug development, there are still ample avenues to further automate and reduce the cost and schedule burden on the pharma companies. Information technology have been on the forefront in this journey and have been enabling companies to move away from traditional business models to more patient centric models in drug development.

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The chapter begins with an understanding of the current state of drug research and development, various challenges faced and key trends. It then goes through the evolution and use of various technologies that have shaped drug development. It introduces new technologies like artificial intelligence, machine learning, automated / virtual reality, blockchain and how they can be adopted to change the way various functions in the research and development operate today. The chapter provides an overview of the ongoing developments taken up by regulatory authorities favouring the adoption of new technologies by industry players. As an example of use of AI technology, the chapter deep dives into a conceptual model and few use cases of how virtual assistants or chatbots can benefit the main stakeholders in clinical trials – the subject, the investigator and the sponsor. The chapter concludes by providing the reader with a view into the future of clinical development – a digital convergence.

DRUG RESEARCH AND DEVELOPMENT OVERVIEW

It takes 10-15 years for a single drug to reach the market. The overall cost for this process increases every few years and currently stands at around $1.4 billion. It is not just the time and cost involved but also the success rate of the compound that makes development of a drug one of the most complex and risky process in the whole pharma value chain. If one starts to screen 10,000 compounds during the initial discovery phase, there is a chance of just 1 compound to get a market approval from a regulatory authority. Hence, both from a social and economic perspective, it is quite natural that drug research and development phase is a key focus area to implement process and operational efficiencies, automation and risk reduction techniques.

Drug research and development comprises of four major stages namely, discovery, pre-clinical, clinical development and pharmacovigilance. As the drug passes through these phases in the development life cycle, there are important regulatory milestones that defines the progress of the compounds till market approval. Figure 1 depicts the various R&D phases and regulatory milestones.

During the drug discovery phase, the scientists get involved in understanding the mechanisms of the disease, identifying the disease targets, screening the potential compounds that can bind with the target and selecting the most promising compounds that exhibit good potency with minimal toxicity. Most of the work is done in the laboratory through in silico (using computer simulation and modelling) and in-vivo (in test tubes) methods.

The high potential compounds enter the pre-clinical phase where they are tested on animals whose animal models are analogous to humans and appropriate for the tests being conducted. The main objectives of the pre-clinical testing are to arrive at the right dosages of the compound that are safe for human

Figure 1. Drug research and development process