Preface

The increasing cost of medicine and healthcare is subject of significant concern throughout the world. Even though significant improvement for medicinal sciences over last one and half centuries, the debate around universal provisioning of healthcare and its quality, spiraling cost of medicines and safety issues associated with them gained momentum in last two decades. Inability to control development of chronic conditions and manage them well, inability to build patient centric model and manage costs though building coalition of the private, public, academic corporate and governmental stakeholders are primary set of challenges for this sector. Existing model of drug discovery and development accentuates these challenges. Life sciences industry, associated with drug discovery and development, is challenged with patent cliff, the significantly smaller pipeline and concerns over compliances & safety. In response to these challenges, healthcare & life sciences industry has started reflecting on the internal inefficiencies of the sector and external change agents, such as change in disease patterns & life style, changing context of urbanization & standard of living, lack of public private partnership, slower adoption of new age technology. Various organizational, institutional and technological initiatives & interventions are seen in different countries. One of these initiatives is considerable adoption of information technology and software application to improve functioning of healthcare & life sciences core process.

Adoption of information technology & software application in healthcare & life sciences is still an emerging phenomenon. There is a need to formalize this to an academic discipline. Few initiatives are taken towards launch discipline like Pharmacoinformatics, Biostatistics etc. However, there is need of significant initiative to consolidate them by theorizing, conceptualizing and defining structures and foundation of a discipline. Emphasize needs to be laid on potential in improving effectiveness & efficiency of the core process along with patient centric services & outcomes as well as improving decision making at the operational, strategic and scientific levels. Focus needs to be given on structured training & learning of this emerging discipline.

This publication aims to create a foundation of a comprehensive guide of software engineering for the purpose of drug discovery, clinical trial, genomics, life science and drug safety. It includes various areas of application of computer; their architecture & design patterns, information models, building search techniques, guidance of implementation of various regulations in software code including US FDA 21 CFR Part 11, security & data privacy, computer system validation.

This publication aims to address the above considerations in three sections. The first section describes the business processes of clinical trial & drug safety, area of improvement through software innovation. It describes the information framework required to build effective software system to streamline the workflow in the business process and to better analytics for decision making. This section has six chapters Sowmyanarayan describes overview of clinical trial & drug safety process & application of
computer system in the first chapter. In the second chapter Kanishka discusses data warehouse & data virtualization techniques, which can be adopted to create information store, required as foundation to form decision insight. In the third chapter, Chandrakant talks about metadata repository and master data management in clinical trial and drug safety. Semantic technologies have gained prominence over the last several years. Semantic technologies & semantic integration are explored in detail in the fourth chapter. Ramin et al describes safety signal detection in drug development process in the fifth chapter. Cloud, analytics, mobile and social media have gained prominence in this decade and show a lot of potential in improving the efficiency of clinical trial & drug safety process area. The section ends with discussion from Manu on application of Social, Media, Analytics& Cloud.

The second section includes topics on software innovation in drug discovery process. This section has four chapters. DNA sequencing is the process to identification of nucleotides order in genome which developed from very broad history. Udaya raja describes personal diagnostics using DNA sequencing in the seventh chapter. In the next chapter, he explains topic of pharmacogenomics; genome wise association with clinical studies. Pharmacogenomics is widely use in drug discovery where drug response is measured with genomic level. Amit explains role of epigenetic in cancer genomics which is very popular modern technique in cancer research. The main aim of this technique is to identify novel drug targets in cancer. Anu et al describes impact of human exome sequencing on clinical research and how it leads to personalize medicine & therapy. Exome sequencing is very popular technique use in drug resistance gene identification which helps in drug discovery process.

The third section reflects computer system validation and agile methodology of software development and how to remain compliant. Subbu, Avik and Arindam describes details of the methodology of computer system validation in the life sciences industry and implication of FDA 21 CFR part 11. This section describes case study on how to remain compliant while adopting agile methodology in software development in the area of clinical research.

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