DOI: 10.4103/0971-5916.211685



Principles of translational science in medicine: From bench to bedside, 2<sup>nd</sup> edition, M. Wehling, editor (Academic Press, Elsevier Inc., USA) 2015. 364 pages. Price: Not mentioned

ISBN 978-0-12-800687-0

This multi-author book has been published in consonance with the growing interest in translational medicine (TM). It consists of 11 chapters. The first chapter introduces and explains the concept of TM. It takes us through the history of TM and analyses the obstacles, low output syndrome in terms of true medical innovations as well as its implications on big pharmaceutical companies. In short, it gives a snap shot of the present status of TM and the main challenges faced by it.

"Target Identification The second chapter, and Validation" has 10 subchapters. The first two subchapters describe various aspects of the "Omics" cascade in broad terms, the challenges, technologies, promises and benefits for molecular medicine. The obstacle in translation of proteomic research and the recommended steps for clinical proteomics are described concisely in tables. The six phases of the road map for translational research of biomarkers starting from discovery to clinical application are described. The Omics technologies namely sequencing by ligation or synthesis, arrays, quantitative reverse transcriptase PCR, low density arrays, nuclear magnetic resonance and mass spectrometry are described in brief. This chapter also covers the clinical applications of genomics and metabolomics/ metabonomics.

The new cellular therapy is making rapid inroads in the field of biological therapy. The third subchapter describes the potency analysis of cellular therapy. The use of assays, the complexities and challenges associated with potency testing of cellular therapies are well written. An updated information given using suitable tables and figures on potency testing of haematopoietic stem cells and dendritic cells and the use of miRNAs for potency assay adds value to this book.

The next subchapter is focused on translational pharmacogenetics. The status of translational pharmacogenetics in depression, cardiovascular diseases, statin therapy, proton pump inhibitors, pain treatment and anticancer drugs are explained with suitable examples. The author rightly mentioned about the lack of reliable clinical data hampering translational pharmacogenomics. It also provides an appropriate flow chart of pharmacogenetic studies illustrating the evidence needed to support pharmacogenetically driven prescribing practices. The next chapter is on the tissue bio-banking and deals briefly with the principles, types and research on vascular biobanking and their clinical relevance.

In translational research, it is difficult to find suitable animal models of human diseases. The book includes a chapter entitled "Animal Models: Value and Translational Potency" which outlines several strategies that may fill the translational gap that is common to all current pre-clinical modeling of human diseases.

The next few subchapters focus on the validation of new biomarkers using localization techniques and immunoassays. The key steps involved in validation namely validation of scientific hypothesis, development of technology and diagnostic tests or medical devices are briefly written. The roles of health authorities and biomarkers consortia in ensuring the safety of biomarkers are discussed. Reverse pharmacology and identification of new purposes for old drugs are written with examples.

It is relatively easy to identify a potential target for a drug action but the critical assessment, validation and druggability of the identified target for translation is a challenging job. The book provides a helpful translatability scoring system of an early project in a table format. A few case studies are also provided for assessment of translatability of drugs.

The third chapter is devoted to "Biomarkers". The first six subchapters discuss in detail about the definition, characteristics, classification and development of biomarkers. A case study using atherosclerosis imaging is included for easy understanding of validation process of biomarkers. In the next few subchapters, the translational aspects of hypertension, atherosclerosis and heart failure in drug development are written which includes a few animal models also. Separate subchapters for biomarkers in oncology, translational imaging research and challenges of imaging biomarkers in psychiatry are written.

BOOK REVIEWS 409

Chapter 4, "Early Clinical Trial Design" will be useful for clinical pharmacologists and other scientists involved in phase 0 and phase 1 clinical trials. Its coverage includes patient entry criteria, calculation of starting dose, dose escalation, stopping rules, measuring endpoints, proof-of-principle, proof-of-concept and decision making at the end of phase I study. The pros and cons of exploratory clinical trial (phase 0), accelerator mass spectrometry microdosing and positron emission tomography microdosing are also written with adequate details. The types of adaptive trial designs, combination of regulatory and exploratory trials and accelerating proof-of-concept by smart early clinical trials are other important areas covered in this chapter.

The chapter, "Pharmaceutical Toxicology" describes the basic principles and new approaches in regulatory toxicology. Several important websites are also provided. The next chapter is written on the statistical problems in translational science, biological modelling, statistical models and inference.

The last few chapters cover patents, intellectual property, innovation in translational medicine,

translational research in geriatrics and changing roles of big pharmaceutical industries. The author summarizes that the translational science in medicine requires input both at the conceptional and implementational levels. Four major tasks have been listed as cornerstone assets of this novel science. At the end, examples have been provided for successful and failed translational process in the cardiovascular field.

To summarize, this book is well written and has state-of-the-art knowledge in translational medicine. This book will benefit scientists involved in translational medicine, clinical pharmacologists, clinical researchers and scientists working in pharma industries. This is a useful book which should find a place in the libraries of institutions involved in medical research and drug development.

## C. Adithan

Professor of Pharmacology, Mahatma Gandhi Medical College & Research Institute, Puducherry 605 006, Tamil Nadu, India adithan50@gmail.com