“Intelligent Drug Development: Trials and Errors in Clinical Research”

Michael Tansey, 2014, 220 pages, Oxford University Press, $45.00

Review by Norman M. Goldfarb

“Intelligent Drug Development: Trials and Errors in Clinical Research” provides an industry veteran’s insights on drug development distilled from many years of management and consulting experience. One gets the sense that the author is amazed that he can make a good living giving clients advice on fundamental activities that should have been common practice decades ago. However, amazement is not in order — experienced clinical research professionals know that clinical research is not an industry that instantly grasps and implements best practices.

The core of the book is on developing target product profiles and study protocols, rather than conducting clinical trials. Anyone who has ever invested a good chunk of his or her life in an ill-conceived trial of a dicey product will appreciate the wisdom in this section of the book.

The following excerpt from a longer discussion promotes the sensible idea of identifying potential study participants before a study officially starts:

**A revelation**

This obvious fact was revealed to me (perhaps belatedly) in the late 1980s when discussing the PACK study (“Prevention of Atherotic Complications with Ketanserin Trial Group,” British Medical Journal, 1989) with a member of the study’s executive committee. I asked him how he went about recruiting the required 3,899 patients with intermittent claudication. His reply was to the effect that it was relatively simple in that the patients already existed and could therefore be identified before the start of the study. For the patients lined up in this way, enrollment was very rapid; the recruitment period extended many months only because not all patients had been identified in this way.

A look through the database ClinicalTrials.gov shows that (excluding oncology studies for reasons that are given below) over half of the trials involve patients with chronic diseases. This means that these patients exist right at this moment. Since they exist right at this moment, it is possible to identify them right at this moment, long before the start date for a study, and to have them ready and waiting for the day when the site is initiated and enrollment can start.

This is so obvious that it seems gratuitous to write about it. The reason why it is not gratuitous to write about it is because few companies make the most of this situation.

The process entails the investigator collecting the records of all patients with the relevant medical condition and going through them individually to see if they match the specific criteria of the study protocol. It is almost identical to part of the protocol feasibility process, except that all potential sites are involved.
The book includes 12 chapters:

- Introduction: Cutting the Gordian Knot
- Aiming for Excellence
- The Target Product Profile and Its Uses
- Planning the Individual Clinical Trial
- Distilling the Essence of the Protocol: The Protocol Synopsis
- Redistillation: Eliminating Impurities by Carrying Out Protocol Feasibility
- The Optimal Blend: The Approved Synopsis and the Final Protocol
- Of Chickens and Eggs: The Sponsor’s Dilemma
- Clinician or Clinical Trialist: The Physician’s Dilemma
- What About the Customer: The Patient’s Dilemma
- About Time: Making Meetings Matter
- The Brain-Scrambling, Fit-Inducing, Mind-Numbing Technicolor Laser Show

The book is available in bookstores.

Reviewer

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