

"Chasing Medical Miracles: The Promise and Perils of Clinical Trials"

Alex O'Meara, 2009, 263 pages, Walker & Company, \$25.00

Review by Norman M. Goldfarb

"Chasing Medical Miracles: The Promise and Perils of Clinical Trials" was inspired by the author's personal experience in a clinical trial. The book's narrative of his experience offers an interested perspective on investigator-initiated studies. The chapter on Uganda describes clinical research in a low-resource country with some excellent research institutions facing lots of challenges. The rest of the book is a rehash of the usual issues facing clinical research. It is hard for anyone outside clinical research to make sense of such a complex enterprise. As a result, the book is littered with factual errors and unsupported opinions, such as the following:

- "When a doctor receives \$8,000 from a large medical company for recruiting a patient into a trial, the level of patient care a doctor is providing could be compromised." Investigators do not receive \$8,000 for recruiting a subject; they receive \$8,000 for all the work associated with the subject, which is often less profitable than their regular clinical practice.
- "There can even be several investigators for each study, one for each site where a trial is being conducted." There are, of course, often dozens or hundreds of investigators in a study.
- "The one hundred people remaining [after a phone screen] are invited to come to the CRO office for an exam." Potential subjects, of course, do not come to CRO offices.
- "Therapeutic misconception means that researchers who recruit and conduct clinical trials will subtly, and sometimes overtly, lead subjects to believe they are receiving medical treatment when they sign up for a clinical trial, even though treatment is *never* the reason for a clinical trial." Therapeutic misconception is a serious problem in clinical research, but it is incorrect to attribute all of it to unethical researchers. Wishful thinking by study subjects is certainly a major contributor.
- "CROs conduct 77% of all clinical trials carried out in the world." CROs can provide many different services for a clinical trial, from project management to printing. The source of the 77% number is unclear, but it far overstates the percentage of trials "conducted," i.e., managed, by CROs, even if only industry-sponsored studies are considered.
- "All institutions that conduct clinical trials then report their test results to the FDA, the Office for Human Research Protection (OHRP) at the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), and a host of other local, state, and federal agencies..." In fact, investigators normally report results from industry-sponsored studies to the sponsor or, if it is investigator-initiated, to the FDA and/or NIH.
- "Only 20 percent of drugs submitted for FDA approval are ever sold across the counter." In fact, very few drugs are sold across the counter; most are sold through pharmacies. About 45% of New Drug Applications (NDAs) submitted to the FDA are approved in the first review cycle.

The book consists of 10 chapters:

- Introduction
- Entering the Risky World of Clinical Trials
- The Right and Wrong of Clinical Trials
- Money Makes the Trial Go 'Round
- Legal Trials
- There's a Subject Born Every Minute
- Going Global
- The Perfect Laboratory for Clinical Trials
- The Stories Behind the Subjects
- Transplanted

The book is available in bookstores.

Reviewer

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