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"Re-Engineering Clinical Trials: Best Practices for Streamlining the Development Process"

Peter Schueler and Brendan M. Buckley, 2015, 360 pages, Academic Press, $99.95

Review by Norman M. Goldfarb

"Re-Engineering Clinical Trials: Best Practices for Streamlining the Development Process" covers a broad range of areas in which best practices could be adopted more broadly in the industry. The book is a good resource for clinical research organizations undecided about where to innovate or ready to innovate and unsure about how to proceed.

The following excerpt from the chapter on investigator site files illustrates the nature of the best practices discussed in the book:

> Differing from the sponsor TMF, the investigator will usually not have specialist staff for filing and will maintain the ISF in avocation. Therefore, there are some essential requirements for the ISF solution:
>
> - Clear integration with eTMF
> - Temporary permission to be able to see document or download for a short term
> - Sponsor sees metadata to know what is in the file
> - Principal investigators need to see and access files in ISF all the time
> - Should be a repository
> - Hide tasks that are not pertinent or timely
> - Table of contents to know where things are
> - Improved user experience
>
> Artifacts may be pushed into the TMF from different originating feeding systems. Because systems used in clinical trials are validated, the respective interfaces also need to be validated. Systems without a validated interface are classified as "nonqualified feeding systems."
>
> A qualified feeding system will push data into the TMF, and document metadata from the feeding system are persistent throughout the feeding process: This includes eSignature status, revision and version history, and document ownership.
>
> Nonqualified feeding systems will not be able to push data directly into the TMF, but they will feed documents into the inbox of the TMF. They trigger the review process and act as the originator of a new artifact. Depending on the risk assessment, the default filing process might be shortened for nonqualified feeding systems.
>
> The eTMF defines the documentation status of a clinical trial. At different time points, different requirements for the status of documents apply. Study phases such as preparation, start-up, conduct, close-out and reporting, define a different volume and amount of artifacts stored in the TMF. The TMF-responsible person should at any time be informed on the quality and completeness of the TMF.
>
> The TMF receives external information to measure the completeness of a TMF at a given time point. Usually, this information is kept in a clinical trial management system of the sponsor. However, this information is not standardized. The eTMF should not take over trial management functionality but can provide an interface to receive the required information either manually or as an automatic upload.

Focusing on the entire business process and then applying technology offers the most complete and efficient solution for the TMF. Implementing a solution that focuses solely on sponsor-TMF interaction is incomplete and does little to improve sponsor relationships with sites.

The book consists of 31 chapters:

- Why Is the Pharmaceutical and Biotechnology Industry Struggling?
- What Are Current Main Obstacles to Reach Drug Approval?
- Japan: An Opportunity to Learn?
- The "Clinical Trial App"
- Re-Engineering Clinical Trials: Best Practices for Streamlining the Development Process
- How Can the Innovative Medicines Initiative Help to Make Medicines Development More Efficient?
- 2E: Experiences with Lean and Shop Floor Management in R&D in Other Non-Pharmaceutical Branches
- Failure Mode and Effects Analysis (FMEA): Well-Known Methodologies, But Not in Our World
- No Patients—No Data: Patient Recruitment in the Twenty-first Century
- The Impact of Bad Protocols
- Data Mining for Better Protocols
- It's All in the Literature
- What Makes a Good Protocol Better?
- The Clinical Trial Site
- Do We Need New Endpoints in Clinical Trials: Surrogate and Biomarkers
- On the Measurement of the Disease Status in Clinical Trials: Lessons from Multiple Sclerosis
- Generating Evidence from Historical Data Using Robust Prognostic Matching: Experience from Multiple Sclerosis
- Studies with Fewer Patients Involved — The Adaptive Trial
- Connected Health in Clinical Trials: The Patient as Sub-Investigator
- Studies Without Sites: The Virtual Trial
- Re-Engineering Clinical Research with Data Standards
- Data Management 2.0
- What Do the Sites Want? The Trial Master File
- From Data to Information and Decision: ICONIK
- Knowledge Management
- Taking Control of Ever-Increasing Volumes of Unstructured Data
- Share the Knowledge Based on Quality Data
- You Need Processes, Systems and People — It's All about the People (and Their Competences)
- Managing the Change — You Need Processes, Systems and People
- How Quality Performance Metrics Enable Successful Change
- Conclusion

The book is available in bookstores.

Reviewer

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