

"IND Submissions: A Primer"

Meredith Brown-Tuttle, 2009, 628 pages, Barnett International, \$295

Review by Norman M. Goldfarb

"IND Submissions: A Primer," in a perfect world, would be the first in a 50-volume series that lays out the nuts and bolts of clinical research. The book is a primer in the sense that it covers the basics of each topic in a clear, practical manner that inexperienced readers can understand. However, it is not a primer in the sense that it sticks to basic aspects of the subject. Instead, its 62 chapters cover the entire life-cycle process in detail from "Submission Planning" to "Responding to Clinical Holds" to "Change in Company Name, Address, Contact Person, Medical Monitor or Ownership."

This book has been selected for
[The First Clinical Research Bookshelf](#)
Essential reading for clinical research professionals

Here is an excerpt from the book:

What can result from poor or confounding communication?

- FDA misunderstands the submission's purpose or content and therefore cannot complete its review or give the sponsor a timely answer.
- Submission content does not support its intention.
- FDA questions the submission's content because it raises more issues than it answers.
- FDA refuses to review because it is so poorly written.
- Due to poor formatting, reviewers cannot find information and spend more time searching for relevant sections and information than reviewing.
- Sloppy submissions might lead reviewer to think that the data or information included is not up to regulatory standards.
- Text that is too dense or written in the passive voice is difficult for a reviewer to read, comprehend and ultimately assess.
- Inconsistent information between or within sections can raise so many questions it prevents a decision.

How do you combat this?

- Determine the audience for each section and write for it (internal/external to company, technical knowledge, background, vocabulary usage, level of detail, etc.). Remember that the reviewer is not as familiar with the information as you are.
- Determine the submission's goal or desired result (approval of an IND, protocol or marketing application) and write to support this goal.
- Simplify sentence structure, using layman's terms and short, declarative sentences.
- Be concise, precise and avoid "flowery" language.
- Avoid ambiguity by providing an organized submission and writing structure.
- Create a table of contents and submission structure for contributors to follow.

- Repeat information throughout the submission to support key messages and to instill important information. Repeating the same information in different ways at least three times helps to create memory.
- If the submission structure is too dense or the author did not follow the suggested format, add headers to break text into “units” so it is easy to follow and links to other sections, building on previous information.
- Use consistent terms and simple vocabulary. Do not overuse technical or complex terminology that can confuse the reviewer or delay the review process.
- Utilize white space in the document layout to make the document easier to read.
- Include graphics to support textual information.
- Have a proofreader review the text for grammatical, typographical and spelling errors.
- Utilize an easily readable font (at least 11 points, 12 points is more common).
- The most readable layout format is “justified left,” with ragged right margins.

The book consists of 62 chapters, such as the following:

- Style guides
- Paper publishing
- Electronic publishing
- Managing references
- FDA meeting information package
- Meeting minutes
- The IND team and how to start the IND
- Nonclinical IND
- IND: Items 9, 10, 11 and potentially 12
- Transfer of obligations
- IND safety reports
- Fast track designation
- Clinical study reports
- Special protocol assessment – stability
- IND annual report
- Orphan drug designation
- Target product profile
- Trade or proprietary name development
- Drug and biologics master files

The book includes a CD-ROM with over 800 forms, templates, checklists, sample letters, naming conventions, sample press releases, and probably any other document that could conceivably turn out to be handy.

The book is available in bookstores.

Reviewer

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