

Reviews

The Ultimate Step-by-Step Guide to Conducting Pharmaceutical Clinical Trials in the USA for Investigators and Clinical Research Coordinators

Ruth Ann Nysten, PhD, RPh (The RAN Institute, Inc., Land O Lakes, FL, 2000), 146 pages, \$149.

The clinical research industry is indebted to Ruth Ann Nysten for developing a comprehensive, step-by-step instruction manual for *beginning* investigators and clinical research coordinators. As promised in the “scope of this guide” section, the manual omits requirements specific to devices and focuses on drugs.

Nysten’s credentials are most appropriate for undertaking this professional guide. She acknowledges the contributions of her professional colleagues and workshop participants to the body of shared knowledge and experiences that made the guide possible.

The content framework of the guide is logical, consistent, and easy to follow. The information is divided into six sections: Introduction, Activities Before Subject Enrollment, Activities During Subject Enrollment, Activities After Subject Enrollment, Sample Documents, and Glossary. Procedures described in the three activity sections—the heart of the manual—are laid out in four columns: What Should Be Done, The Regulatory Basis, Relevant Documentation, and Hints (see photo).

One activity is shown per page. For example, in Activities Before Subject Enrollment, activity 1.12

describes what to do to document IRB compliance. A Hint points out that “It is the investigator’s responsibility to ensure that the IRB that reviews his/her research is in compliance with relevant IRB and informed consent regulations (See FDA Form 1572, Commitments (Box 9)).” The Regulatory Basis column cites relevant parts of 21 CFR 56, 21 CFR 312, and 45 CFR 46 along with FDA Form 1572 and the records section of the ICH guideline on GCP.

The guide has no index, but its table of contents accurately lists each page’s content. Finding what you need is very easy. To further unify the content and increase the clarity of the topic, each page in the activity sections has a single

goal, stated from the user’s perspective with an action verb. You know exactly what you are going to learn from the page. The goal of activity 1.1, for example, is to identify potential sponsors.

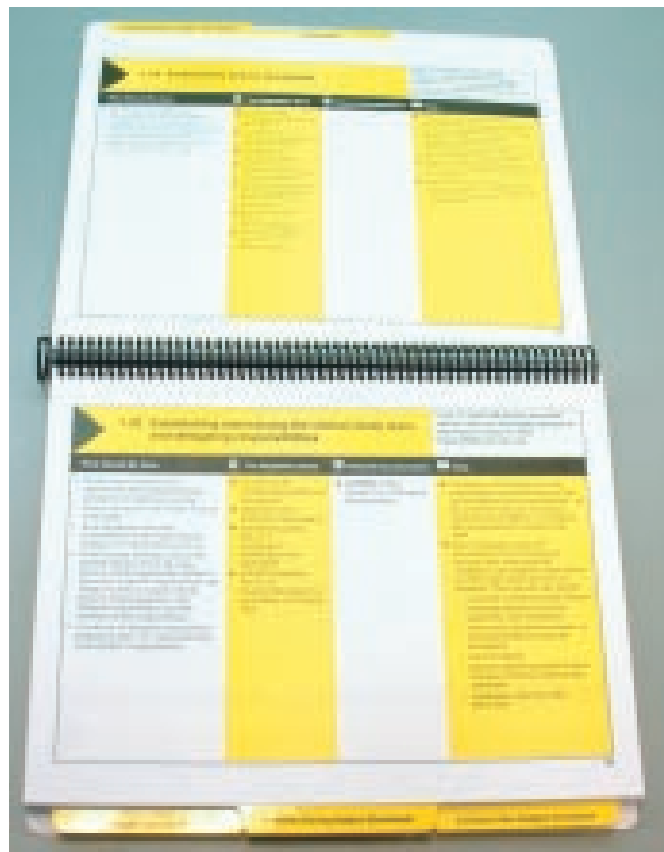
The presentation of the guide deserves special mention. It is printed in a landscape (horizontal) presentation with a ½-inch black plastic spiral spine. The flip chart–like presentation makes it very easy to use. Black and bright yellow on white are used effectively to increase readability. The format is consistent throughout the three activity sections. The paper that the guide is printed on is heavier than expected and is coated for a plasticlike feel. This makes for a sturdy guide that encourages

frequent usage. The font is large and easy to read. Overall, the presentation adds significantly to the value of the guide.

The content is most appropriate for the intended users and purpose. Nysten carefully dissects the processes of participating in a clinical trial, isolating each step and giving clear, specific directions on what should be done. The verbs in What Should Be Done columns are specific and directional—*review, evaluate, contact, discuss*. Material under The Regulatory Basis for activities comes from the Code of Federal Regulations and includes references to the ICH Guideline for Good Clinical Practice and specific FDA forms. If you need more clarification, look it up. The references are precise. The sample documents are meant to be models—so you can follow or use them. Nysten’s advice is solid. She knows and understands what’s involved in being an investigator or clinical research coordinator. Heed her guidance.

Usage of the guide should and will go beyond the stated intended audience and purpose. It can be used as a reference for clinical research professionals in other roles. It has immense value as a textbook for university- or college-based programs. I encourage Nysten to write a supplemental text with case studies and problem-solving exercises. Self-paced and self-corrected test items would be a valuable addition.

My overall evaluation of the guide is extremely high. The author accomplished her stated goals. The information is vital for the beginning investigator and



This material would be useful to those who seek additional resources to supplement SOPs and training.

clinical research coordinator. It is also an excellent review for the seasoned clinical research professional. The consistency in the format and terminology is beneficial for understanding the material. There is no weakness in the guide. Solid information that is easy to use is an unbeatable combination. Again, the clinical research industry owes a debt of gratitude to Ruth Ann Nysten.

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Clinical Research Bookshelf

Some recent publications of interest:

Avoiding Fraud and Misconduct in Clinical Trials, by Kris Terzotis (Theta Reports, 2000).

Assuring Data Quality and Validity in Clinical Trials for Regulatory Decision Making: Workshop Report, Jonathan R. Davis, Vivian P. Nolan, Janet Woodcock, and Ronald W. Estabrook, Eds. (Roundtable on Research and Development of Drugs, Biologics, and Medical Devices, Institute of Medicine, 1999). Available online at <http://www.nap.edu/books/0309065941/html/>.

Cancer Clinical Trials: Experimental Treatments and How They Can Help You, by Robert Finn (O'Reilly & Associates, 1999).

Clinical Data Management, 2nd ed., Richard K. Rondel, Sheila A. Varley, and Colin F. Webb, Eds. (John Wiley & Sons, 2000).

Clinical Trials in Neurologic Practice, by Jose Biller and Julien Bogousslavsky (Butterworth-Heinemann, 2000).

Do I Want to Enrol in a Clinical Trial? by Peter Charlish (Brookwood Medical Publications, 2001).

New Drug Development: A Regulatory Overview, 5th ed., Mark Mathieu, Ed. (PAREXEL, 2000).

The Clinical Audit in Pharmaceutical Development, Michael R. Hamrell, Ed. (Marcel Dekker, 2000).