
Elizabeth Weeks-Rowe, CenterWatch, 2019, 542 pages, $97

Review by Norman M. Goldfarb

“This book has been selected for
The First Clinical Research Bookshelf
Essential reading for clinical research professionals


The following excerpt on matters to address at the end of a site monitoring visit illustrates the book’s clear writing, attention to detail, and practical approach:

Before concluding a monitoring visit, there are some miscellaneous items to attend to. It is important to check the last site visit report for any noted problems or unresolved issues. These items should be followed up on until they are resolved, and the site visit reports must show how they were followed up. This is something an auditor will look for if the site is inspected later, plus it is good monitoring practice.

The CRA will also want to see if more study supplies need to be ordered, including drug/product, case report forms, lab kits, and anything else that may be necessary for the study. If so, ordering should be done before the CRA leaves the site.

If the CRA is involved in grant requests, this should be discussed with the investigator and, if appropriate, a grant request should be submitted.

Before leaving, plan ahead for the next monitoring visit. Explain what materials should be ready for review. If there are scheduled enrollment updates planned, remind the coordinator. The CRA should always schedule the next visit before leaving the site, while both the CRA and the coordinator have their calendars available.

If possible, it is good to write the CRA visit report before leaving the site. If not, write it as soon as possible after leaving, while the details are still fresh in your mind. Before leaving, be sure you have everything you need to take with you and that it is organized. If you have collected CRFs, they should be inventoried, in order, and ready to mail. The investigator and the CRC should have been debriefed about monitoring findings and the status of the study. Before leaving, the CRA should thank everyone for his or her time and efforts during the visit.

If the CRA has told site personnel that he or she will find out any particular information for them, be sure this is done and reported back. It is also nice to follow the visit with a letter recapping any pertinent information, thanking the site personnel for the work they have done and verifying the date of the next monitoring visit.

The book includes 21 chapters:

- Introduction
- The History Behind the Regulations
- Regulations and GCPs
- Roles and Responsibilities in Clinical Trials
- The Research Process

Subscribe free at www.firstclinical.com © 2019 MAGI and the Author(s)
The book includes 32 pages of forms, checklists and logs, and 352 pages of CFR regulations and the ICH E6(R2) GCP guideline.

The book is available at https://store.centerwatch.com/.

Reviewer

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