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5 Guidelines for Writing a Useful Clinical Monitoring Report

By Brandy Chittester, IMARC Research, Inc.

A well-written monitoring report is an essential part of documenting clinical trial oversight. In addition to being required by ISO and ICH guidelines, it also tells the story of the clinical trial to the FDA, demonstrating site performance and sponsor oversight during an FDA inspection.

Unfortunately, this important task often doesn't get the attention it deserves. Between scheduling visits, traveling and conducting the visits, it can fall down on a monitor's priority list.

Whether you're a monitor out in the trenches or a sponsor overseeing a study at a high level, here are a few important guidelines you and your staff should follow to ensure your clinical monitoring reports are accurate and complete.

1. Do Your Homework Before the Site Visit

To ensure all the information will be available to write the report, monitors should be thoroughly prepared for the site visit. Before they arrive on site, they should be able to answer the following questions:

- What data should be source-verified?
- How many queries are outstanding?
- Will the regulatory documents should be reviewed and what updates are needed?
- What data and action items still are outstanding?

A monitor's time on site is often limited. Taking the time to look into these issues ahead of time will help them prioritize tasks and make the most of the time they have.

In addition to site-specific preparation, monitors must also be sure they understand the visit report template and the purpose of each question, since these templates can vary from one sponsor to the next. Likewise, monitors should always consult the monitoring plan for the study to be sure to complete activities during the visit as required by the sponsor.

2. Take Good Notes During the Visit

To make sure they don't miss an important step, monitors should keep the monitoring report template open throughout the visit, making note of activities as they are completed.

We can't overstate the importance of taking good notes. So many things that happen during a monitoring visit seem obvious at the time (like a follow-up item to correct a source worksheet or to re-review select data points), but in many cases, those items are forgotten soon after the monitor leaves a site.

Each monitor will find his or her own way of taking notes, but filling in the report during the visit is a good way to keep important issues top of mind.

Some suggested methods for keeping notes might be for monitors to mark off sections of the report as tasks are completed or use highlighting or another font color to show what requires assistance from the site. Although monitors always want to cross off every item on the list during a site visit, there almost always will be items that require follow-up later. No matter how they choose to do this, monitors need make note of what items require their attention after the visit to ensure nothing slips through the cracks.

3. Write the Report as Soon as Possible

The report should be written as soon as possible after the visit. The best-case scenario is to write the report before preparing for and going on the next visit, but this is not always possible or practical. The next best practice would be to write one report before writing the next. When a report sits incomplete for a few weeks and other visits have taken place in the meantime, the likelihood that the report will be accurate and complete is low, even with the most thorough notes.

This article is related to the Product Data Sheet: MasterControl Clinical Quality Management System (CQMS)™
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4. Check Reports Carefully

A great monitoring report should be clear, concise and grammatically correct. Sloppy oversights, such as grammar mistakes and carrying over information from a previous report, can diminish confidence in the monitor's work. Copying and pasting information from a previous report may seem like a shortcut, but it leaves too much room for error. Monitors should start fresh and check their work carefully when they're finished.

5. Be Sure the Report Only Includes Essential Information

A good clinical monitoring report should be a summary of items the monitor reviewed during the visit—no more, no less.

Too much narrative or detailed descriptions of what was in compliance can make finding what was out of compliance more difficult. Monitors also should avoid documenting details that are already on record elsewhere. For example, if an adverse event has been submitted to the sponsor, there is no reason to include detailed information about the event again in the monitoring report.

Bonus: Take the Report from Good to GREAT

In general, monitors do an acceptable job documenting in their reports the issues noted during site visits. However, a monitor's job doesn't end with simply documenting issues; he or she also needs to *document the efforts made to bring the site into compliance.* Additionally, a monitor should document any discussions or actions taking place to *prevent issues from reoccurring.* Adding such details to monitoring reports illustrates the ongoing efforts by the sponsor and site to work together to address issues in real time and ensure the study stays compliant.

Writing effective monitoring reports requires an in-depth knowledge of the job, the study protocol, the site, their practices, the sponsor's procedures, the monitoring plan, the report template and, of course, the regulations.

As a leading medical device CRO, IMARC Research has extensive experience in writing monitoring reports. IMARC's latest resource is designed to provide guidance to monitors writing reports as well as those who review them.

Before you write your next monitoring report, download this resource for more tips and a checklist you can follow to ensure your clinical monitoring reports are as complete, accurate and useful as possible.

About the Author

Brandy Chittester *is the chief of clinical operations for IMARC Research, Inc. IMARC is a medical device CRO, specializing in monitoring, auditing, training and consulting services. Along with leading clinical monitoring teams, Brandy has been a trainer in Good Clinical Practices and FDA Regulations for many sponsors and sites.*

Brandy has published articles with the Journal of Clinical Research Best Practices, GxP Lifeline™, and Med Device Online, in addition to contributing whitepapers to IMARC's library of resources. She has also spoken at local and national conferences, including the Association for Clinical Research Professionals (ACRP) Global Conference, MAGI Clinical Research Conference, and the Medical Device Clinical Trials Conference. Her articles and presentations focus on the difference in device and drug studies and how to raise the bar in medical device clinical research. Contact her at bchittester@imarcresearch.com.

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