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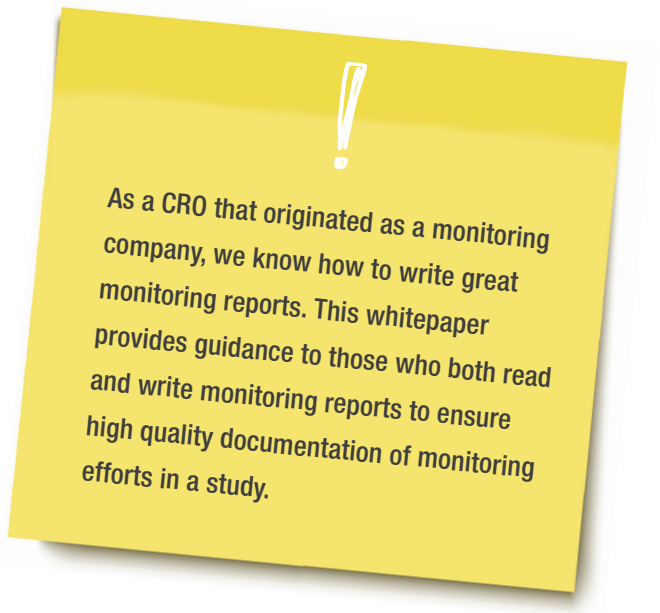
How to Write a GREAT Monitoring Report

Writing monitoring reports is an important task, but one that often doesn't get the attention it deserves. Between scheduling visits, traveling and conducting the visits, managing sites between visits, attending to study team needs and requests (and many other things!), the task of writing good monitoring visit reports can fall down the priority list. But it should not! Not only are reports required by the regulations (1,2), they are also an extremely useful way to demonstrate site performance and sponsor oversight should there be a regulatory inspection.

In the midst of a clinical study, communication is happening frequently. Monitors often join study team calls and provide updates from site visits. Major issues are escalated immediately and handled by the study team. As such, taking the time to document those same issues in monitoring reports can seem redundant. The monitor may feel it is not a good use of time to write a report for the Lead CRA and/or Project Manager to read, when they are often already aware of site issues. This thinking, however, is short sighted. When, not if, FDA (or any regulatory body) schedules an inspection, the monitoring reports will play a critical role for 'telling the story' of a study across sites. Great monitoring reports will also help facilitate any inspection, regulatory or otherwise.

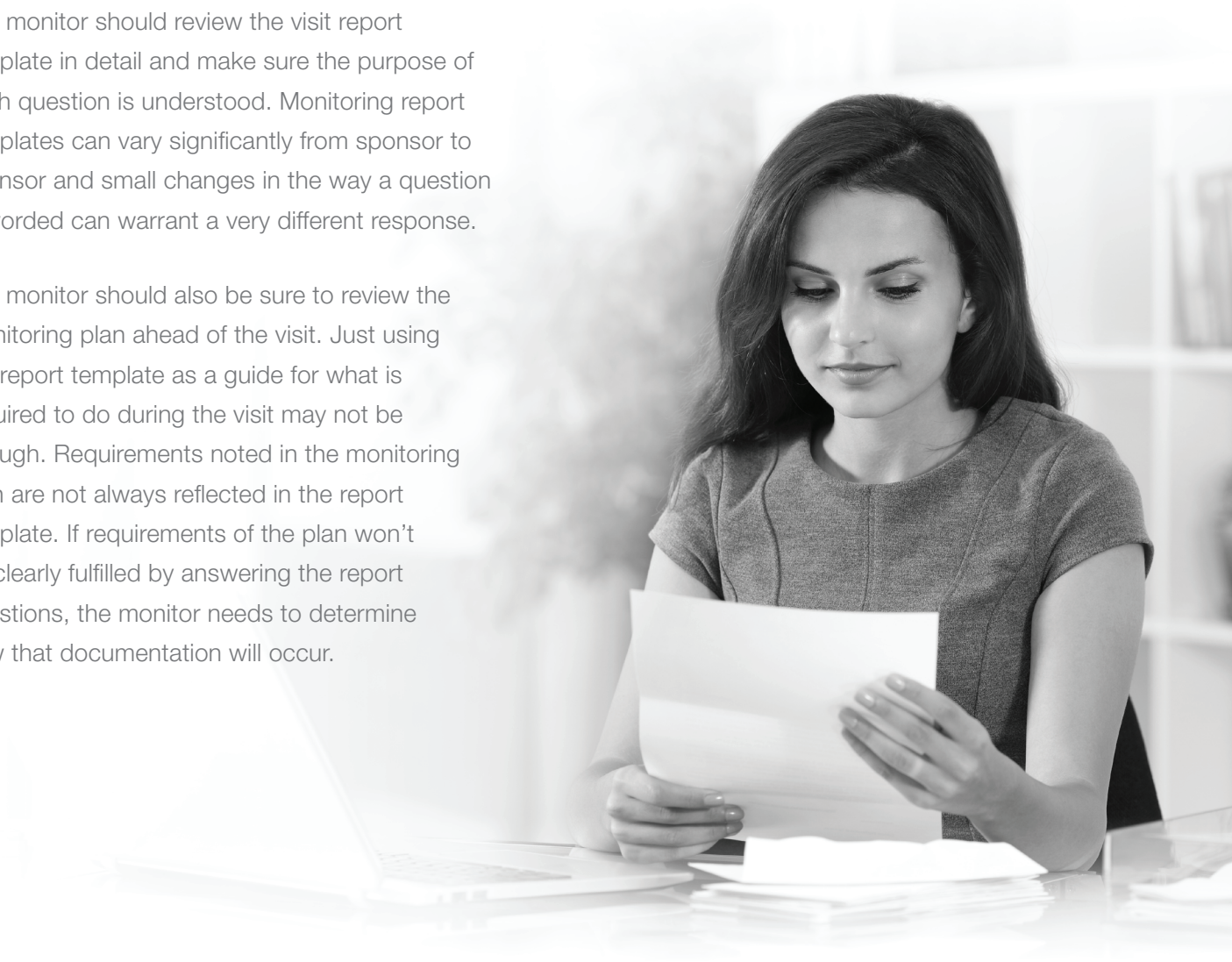


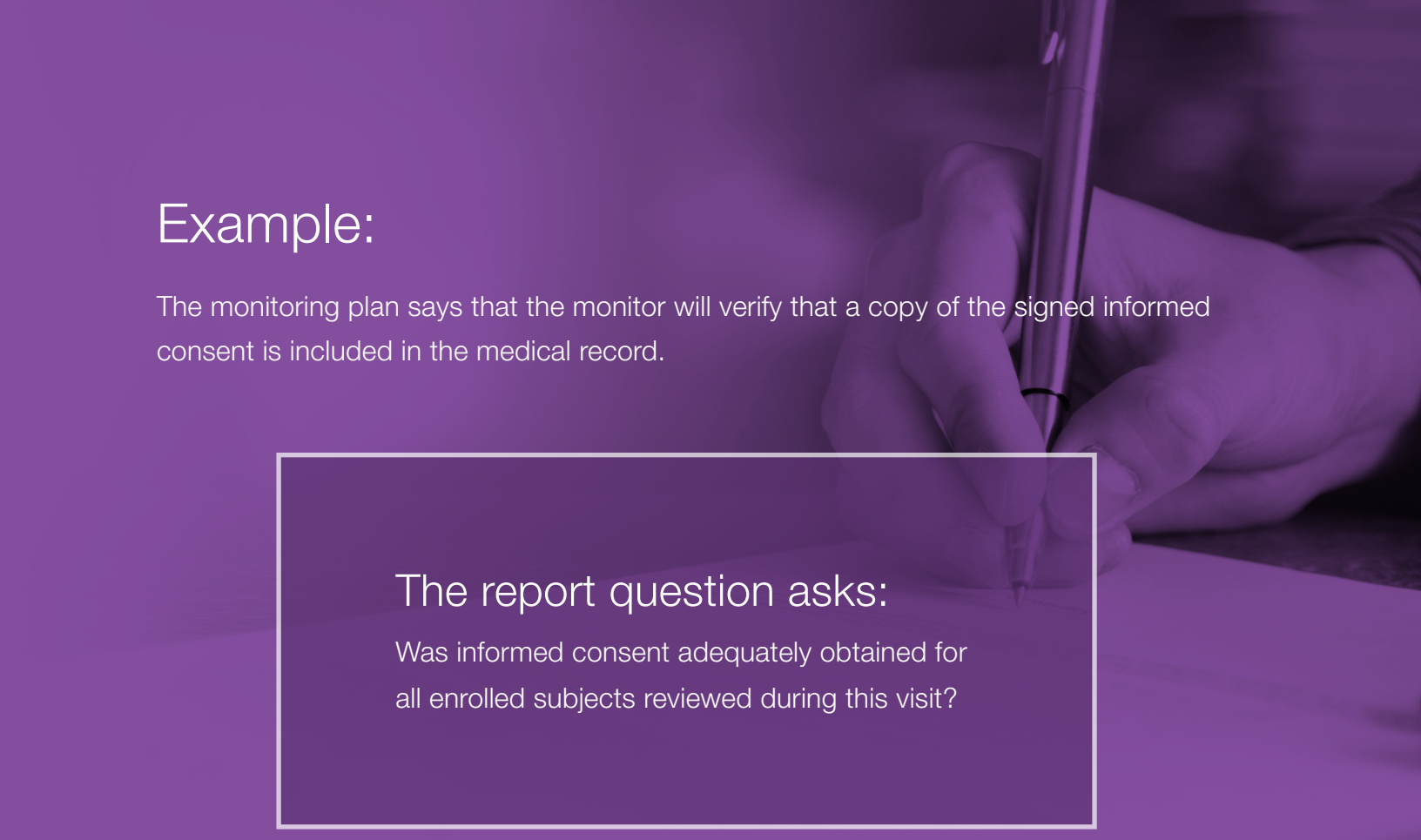
Writing a great report begins during visit preparation

The first step toward writing a great monitoring report has little to do with the actual act of writing the report. In order to ensure all the information will be available to write the report, the monitor must be thoroughly prepared for the site visit. This ensures everything will be reviewed and discussed during the visit to allow for the report to be completed. Thorough preparation includes knowing what data should be source verified, how many queries are open, whether the regulatory documents should be reviewed and what updates are needed, what data is outstanding, whether action items are unresolved, etc. The monitor should also know ahead of time how tasks will be prioritized if time is compromised.

The monitor should review the visit report template in detail and make sure the purpose of each question is understood. Monitoring report templates can vary significantly from sponsor to sponsor and small changes in the way a question is worded can warrant a very different response.

The monitor should also be sure to review the monitoring plan ahead of the visit. Just using the report template as a guide for what is required to do during the visit may not be enough. Requirements noted in the monitoring plan are not always reflected in the report template. If requirements of the plan won't be clearly fulfilled by answering the report questions, the monitor needs to determine how that documentation will occur.





Example:

The monitoring plan says that the monitor will verify that a copy of the signed informed consent is included in the medical record.

The report question asks:

Was informed consent adequately obtained for all enrolled subjects reviewed during this visit?

This is an opportunity for the monitor to ask questions ahead of the visit. If this question is answered with a “Yes” – what does that mean? Adequate consent would likely indicate, according to the regulations, that the correct version of the consent document was used, that a qualified individual obtained consent, that the subject signed and dated the consent themselves, and that the subject received a copy. However, to show compliance with regulations and the monitoring plan, the question may be answered “The monitor confirmed that consent was obtained in accordance with the regulations and that copies of the consents were added to the medical records.”

* The monitor should review the report template side-by-side with the monitoring plan to ensure all requirements of the plan are documented when writing the report. A helpful tip might be to add comments to the report template to be used to ensure documentation that the plan was followed.

Writing a great monitoring report continues during the visit

During the visit, the monitor should refer to the template as activities are completed to make sure nothing is missed. An easy way to do this would be to keep the report open throughout the visit. The monitor also needs to take good notes! So many things that happen on a 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, as soon as the monitor leaves a site, new issues come up and those items are long forgotten.

Each monitor will find their own way of taking notes, but often a great practice (when time and space allow) is to fill in the report during the visit. Perhaps the report sections are highlighted as tasks are completed to show what has been done. Or maybe another color font is used to show what requires assistance from the site. Monitors should try different techniques until they find what works.

However, as much as monitors want to go on a site visit and cross all of the 'to-do' items off the list, most of the time it is impossible to accomplish. This means that there will be items left for follow-up after the visit. It is critical that these are included in the monitoring report not only for documentation purposes, but to ensure nothing slips through the cracks.

Put it to practice – one way to do it

During a monitoring visit, the monitor fills out the report as tasks are completed and highlights areas that are skipped over to make sure they are revisited. As any activity is completed, the monitor will re-check the report template to make sure nothing was missed. When it comes time to write the final report, any item still left highlighted is easily identified as an action item that will need to be documented for follow-up.

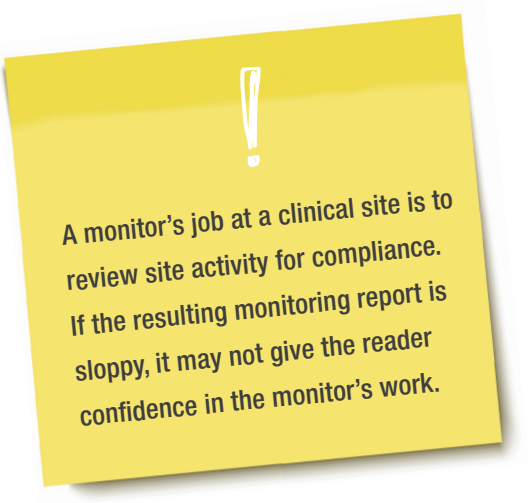
Having thorough preparation and using the report template as a guide during the visit will also help ensure the visit is completed during the visit, and not afterward as the monitor writes the report and finds that certain tasks were not completed. Research coordinators are often frustrated by monitors who email them after the visit to ask questions about items they should have reviewed while they were on site.

Writing a great monitoring report includes paying attention to details

A great monitoring report should be easy to read, in a grammatical sense. It should clearly summarize the visit activities and state the findings. Responses in the monitoring report should not be copied/pasted from a previous report, nor should the previous report be used as a starting point for the next. This allows too much room for error and makes it easier to submit a report that is not accurate if comments from prior visits are inadvertently carried over.

It is also important that the summary of what was reviewed during the visit is just that: a summary. Too much narrative or descriptions of what was in compliance can make finding what was out of compliance more difficult. Brevity makes it easier to determine what an issue is and what is not!

Brevity should extend to other areas of the report as well; the monitor does not need to document in the report details that are already 'known'. For example, if an adverse event has been submitted to the sponsor, there is no reason for a monitoring report to detail the adverse event, when it occurred, the course of the event, etc. That information is readily available in the Case Report Form. If there is an issue with the event, such as not being reported in a timely manner or being incorrectly reported, the report should state that as the issue and leave out the other 'known' details. In this way, the monitor describes what was reviewed (adverse events) and what the issues were without losing the reader with extraneous details.



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, no matter how good the notes were that were taken during the visit.

Taking the monitoring report from good to GREAT

In general, monitors do a good job at documenting the issues noted during site visits in their reports. In addition to documentation of issues, however, the efforts toward resolution need to be reported. This is one area where monitoring reports often fall short. It is so important to document efforts toward securing compliance. The old adage “if it’s not documented, it wasn’t done” is true in site source documentation, but also in monitoring reports. And more often than not, monitors are already working with sites to resolve noted issues, but they just don’t include those details in the report. Monitors need to take credit for these actions!

And to take it a step further, the monitor should also document discussions and/or actions taken to **prevent recurrence of the issue**. This will take monitoring and visit reports from GOOD to GREAT. As an outside eye to the site, and as someone with the opportunity to see how the study is carried out across multiple sites, the monitor has a great advantage and viewpoint to recommend solutions to sites.

Preventing recurrence involves determining whether the issue is a one-time or recurring issue, what the impact of the issue is or could be, and whether it might happen again. This process allows the monitor to determine where to focus efforts during site visits, and what to emphasize in reports.

To illustrate this practice, here is an example.

During a site visit, the monitor reviews an informed consent form and notices that the wrong version of the informed consent was used for the most recently enrolled subject.

How should this be written in a monitoring report?

The question asks: "Was informed consent adequately obtained for all enrolled subjects reviewed during this visit?"

The answer could be written as: "The monitor confirmed that consent was obtained in accordance with the regulations and that copies of the consents were added to the medical records for all reviewed subjects except subject 1234567."

While this answer is technically correct, it begs further questions. One wonders what was the issue with the consent for subject 1234567? What was done about it? Was it a major issue? Does the IRB need to know? Was the sponsor aware? Did the monitor inform the site during the visit?

A better answer is: The monitor confirmed that consent was obtained in accordance with the regulations and that copies of the consents were added to the medical records for all reviewed subjects except subject 1234567. Subject 1234567 signed version X of the consent when version Y was the approved consent at the time. The only difference between the two versions of consent is that the site had recently added a new Co-Investigator to the study. The monitor discussed the error with the site team and the research coordinator agreed to correct the issue by having the subject sign the current consent version at the next visit. The research coordinator agreed to submit this error to the IRB at continuing review, per their policy.

This answer includes the issue and resolution, but does not indicate how this happened or how recurrence could be prevented. To take this to a great answer, the monitor could add:

The monitor and the site team also discussed the consenting process. The team agreed that for future consents, the research coordinator would obtain and print the consent document directly from the IRB Portal to ensure the current, correct version is used.

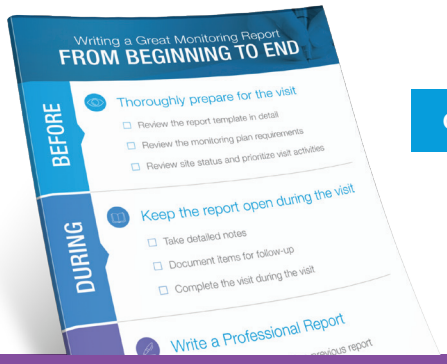
Writing a great monitoring report is not black and white

It is not practical to take every issue noted during a visit and turn it into a half-page narrative of what happened and how it will be prevented. The monitor must think through the issues noted and the potential impact of the issues and their potential recurrence to determine when such actions are warranted. In the example provided, the issue is with informed consent, which always carries the potential for high risk. What if using the wrong consent version meant the subject was not fully informed of all the risks of the study? What if having that information might have caused them to say no?

On the other hand, while every action the monitor takes during a visit may not be documented in a monitoring report, the monitor has to carefully think about how the "small stuff" is handled. Correcting a date issue on a source worksheet or obtaining a signature on a log might not warrant an explicit corrective and preventive action process, but sometimes the "small stuff" adds up! Depending on the site performance, documenting such issues may be advantageous if they continue and escalate into bigger issues. Monitors will need to work with their Lead CRA and/or Project Manager to determine the expected level of detail that should go into their monitoring reports.

In conclusion, writing great monitoring reports is not just about writing the report. It 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. Attention to visit preparation, clear notetaking during the visit, and prompt, clear report writing pays off in delivering a high-quality document. It is a difficult skill to master, but one that is rewarding, especially when faced with a regulatory inspection.

Take your Monitoring Report from Good to GREAT



Get the Checklist

Brandy Chittester Chief of Clinical Operations

At IMARC, Brandy has held many positions advancing in responsibility. While she has spent much of her time in the monitoring department, she has also assisted with GCP audits, performed many client and internal trainings, and assisted with high-level consulting projects. She is a critical thinker, adept at problem solving and able to think through situations to garner a solution.

Brandy has published articles with the Journal of Clinical Research Best Practices, GxP Lifeline™, and Med Device Online, in addition to contributing to IMARC's library of resources. She has 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. Brandy has earned her CCRA credentials through ACRP. She received her Master of Science in Biomedical Engineering from Case Western Reserve University and Bachelor of Science degree in Mechanical Engineering from the University of Cincinnati.

References:

1: ISO 14155:2011 Clinical Investigation of medical devices for human subjects – Good Clinical Practice. Section 8.2.4.7 Monitoring Reports.

2: ICH GCP E6(R2): International Conference on Harmonization Good Clinical Practice. Section 5.18.6 Monitoring Reports.