8 Questions CRAs Should Ask the CRC

AT THE START OF A MONITORING VISIT

Clinical Research Associates (CRAs) typically have eight hours on-site to complete an Interim Monitoring Visit (IMV).

The goal of the CRA and Clinical Research Coordinator (CRC) is to have a productive monitoring visit and leave with a resolution for critical items, including re-training where needed and clear action items to complete before the next visit.

To ensure a successful visit and avoid the frustration of not completing all of their priorities, a CRA should request to meet with the CRC at the start of the monitoring visit and ask eight specific questions to help structure their day.

The 8 Best Questions

A CRA Can Ask the CRC to Get the Information Needed to Prioritize the Day and Conduct a Successful Monitoring Visit:

Hint: Bring a printed or electronic copy to each monitoring visit to use as a checklist!

- ☐ **Have any new Serious Adverse Events (SAEs) occurred since the last visit?** SAEs are always the top priority of every monitoring visit. Knowing about any SAEs enables the CRA to review the patient(s) with SAEs first, understand what happened, and report to the study team if needed.
- ☐ **Have there been any new staffing changes?** CRAs have different tasks to complete for staff members who are no longer employed at the site, as well as for new staff.
- ☐ **Have there been any issues with the Investigational Product (IP)?** Dealing with temperature excursions or low drug supply is another priority action item for a monitoring visit.
- ☐ **Are you having any issues with lab reports?** Lab report issues are a patient safety concern, so this would become a top priority.
- ☐ **What are the monitoring hours?** Monitoring hours differ from site to site; knowing the stop time is vital for planning.
- ☐ **Are there any issues with the study equipment?** If there are issues with the study equipment, it can be assumed that the site cannot accurately capture the data required by the study protocol.
- ☐ **When is the Investigator available to meet?** End-of-day is the ideal time for the CRA to meet with the Investigator. If this is not possible, the CRA will want to know the meeting time to plan accordingly.
- ☐ **Do you have any questions?** This allows the CRC to receive answers to their questions, tell the CRA about something they are struggling with, or request additional training.

5 Pro Tips!

ClinEssentials
CRA Audit Notes

SHOP 3X3 AUDIT NOTES

1 Many CRAs and site teams use CRA Audit Notes from ClinEssentials to help communicate more effectively and increase efficiency by up to 30% at monitoring visits. Among the 16 color-coded adhesive CRA Audit Notes options are Serious Adverse Event, Adverse Event, and Adverse Event of Special Interest, which help flag immediate actions to address. Shop for CRA Audit Notes!

2 If IP is low, ask the CRC when the next patient visit is scheduled where the study drug must be dispensed. The study team needs to know this information, so it's good to be proactive and request this information up front.

SHOP 1.5X3 AUDIT NOTES

3 Meetings with the Investigator are often brief, so the CRA needs to use the time efficiently and effectively. CRA Audit Notes are helpful tools for summarizing visit findings because they make it easy to see the most essential items to discuss and questions to ask.

4 The CRA needs to check the expiration dates on the lab kits, as expired kits are a patient safety issue.

5 Other important tasks for CRAs to accomplish during a monitoring visit include an Informed Consent Form (ICF) review, Source Data Verification (SDV), Source Data Review (SDR), Investigational Product (IP) Accountability, Investigator Site File (ISF) review, or staff training.

Having goals in mind for a visit helps CRAs stay on track, organized, and efficient - and develop a streamlined monitoring visit game plan.