Sponsor Visits and Monitoring

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By the end of this presentation you will:

• Learn about the different types of monitoring visits
• Understand the objective of each type of monitoring visit
• Know the expectations of the site by the monitor
Monitoring

- Monitoring is a very important aspect of a trial.
- Monitoring is the act of overseeing the progress of a clinical trial and ensuring that it is conducted in accordance with the protocol, SOPs, GCP, and any other regulatory requirements.
- The monitor or Clinical Research Associate (CRA) acts as a liaison between the site and the sponsor.
Types of Monitoring Visits

The most common types of site visits for industry-sponsored studies are:

- Site Evaluation (Pre-Study) Visit
- Site Initiation Visit
- Interim Monitoring Visit
- Close Out Site Visit
Site Evaluation Visit

- This visit is conducted to evaluate a site’s and investigator’s resources and capabilities to conduct a study in terms of site infrastructure, adequacy and availability of the site facilities for study conduct.
What are they looking for at Site Evaluation Visit?

- Investigator Qualifications
  - Up to date CV
  - Principal Investigators expertise in the Specialty
  - Previous experience in conducting a trial

- Adequate resources
  - Sufficient time
  - Adequate staffing
  - Population
What are they looking for at Site Evaluation Visit?

- Adequate Facilities
  - Exam Rooms
  - Pharmacy/Study Drug Storage area
  - Laboratory or specimen processing area
  - Special testing areas (x-rays, MRIs, CT scans, etc.)
  - Record keeping facilities - regulatory binders, CRFs, Off site storage
What are they looking for at Site Evaluation Visit?

• Protocol review and discussion
  • Study objectives
  • Inclusion/exclusion criteria
  • Study procedures/tests
  • Schedule of assessments
  • Competing trials
How can you make this visit go smoothly?

- Make sure everyone who needs to attend this visit is given ample time to make room in their schedules.
- Have updated (signed and dated) CVs and current licenses for all key players.
- Usually the monitors only need 1 hour with the PI so you can work this visit around the PI’s schedule.
- If you need to visit another department (i.e., radiology or Investigational Pharmacy) please be sure they are aware of the visit.
any questions?
Site Initiation Visit

- The Site Initiation Visit is planned to provide study-specific information to investigators and staff prior to study start-up and to reassess resources and capabilities of the site to conduct the research study.

- The monitor will also discuss with the staff about research obligations as per the GCP. The monitor provides necessary guidance to the site to help the site be successful.
What happens at the Site Initiation Visit?

- Review of Investigator responsibilities
- Protocol Overview
- Discussion of General Study Procedures
- Safety: Definitions, Collection, and Reporting of AE/SAE
- Data Collection/Source Documentation
- Investigational Product
What happens at the Site Initiation Visit?

• Specimen Processing
• Clinical Monitoring Plan
• Regulatory Documents Review
• Tour of Facility
• Review of any action items
• This could also count as training for others who did not attend an Investigator Meeting
QUESTIONS?
Interim Monitoring Visit

• Routine or Interim Monitoring visits are basically any visit that occurs after the site is initiated and up until the site is closed out

• The objective of these visits is to assess the progress of the trial in terms of accuracy, completeness and verification of reported trial data
What information is reviewed during the visit?

- Informed Consent Documents
- Study subjects research records
- Source documentation
- Regulatory binders
- Occurrence and reporting of adverse events and protocol deviations
- Action items from previous monitoring visit
Other Comments about monitor visits

• Monitors usually come out an average of every three months for a one day visit. This may vary depending on the study and enrollment
• It is expected that your monitor will come out within 2 weeks of you enrolling your first patient
• You must provide for your monitor a desk or other ample space in a fairly quiet area with access to a telephone and an internet connection
• They also will want to meet with the PI for a few minutes to discuss the study and any other issues or concerns
What Can You Do To Make These Visits Stress Free?

- Complete all notes and enter all visit data in a timely manner
- As soon as you get your Monitoring Visit Follow-Up letter from the previous monitoring visit review and complete all action items as soon as possible
- Answer all queries promptly
- Review patient medical records on a regular basis to capture any adverse events
- Think like a monitor
QUESTIONS?
Close Out Site Visit

• The close out visit occurs after study completion or site withdrawal

• In general, three activities are required to “officially” close out a site
  • The monitor conducts a close-out visit and signs the monitoring log
  • The Principal investigator submits a final report to the IRB stating that the site is closed
  • The sponsor sends a letter stating that the site is closed
What happens at a Close out visit?

• The monitor conducts a final data review/collection of all outstanding data
• Study drug is returned or destroyed on site
• A final review of the regulatory binder is done
• And, if applicable, verification that all blood/biological samples have been submitted
• Return or destruction of all unused forms/CRFs
• Review and collection of Delegation of Authority forms and other “original” logs
• Collection of IRB closure report/letter
What Steps Can You Take To Have a Stress Free Close Out Visit?

- Insure that all logs are up to date and accurate
- Make sure all logs that need the PI signature are signed prior to the monitor visit
- Have copies of any temperature logs ready to give to the monitor
- Review the Regulatory Files and Patient binders with a monitor’s “eye” to make sure everything is in order
QUESTIONS?