The Monitoring Visit

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Disclosure

The information herein is not intended to replace any in-depth personal review of the Code of Federal Regulations, ICH GCP Guidelines, or any other applicable IRB, federal, state, or local rules, laws, or guidelines applicable to the conduct of clinical research at this site.
Upon completion of this module you should be able to:

- Describe the objectives of the monitoring visit
- List the steps involved in preparing for the monitoring visit
- Describe the general format & content of a monitoring visit
Sponsor contacts

- Clinical Research Organization (CRO) Rep
- Clinical Liaison specialists
- Auditors
- CRAs = Clinical Research Associates aka Study Monitors
Regulatory Requirements for Study Monitors

- Appropriate training
- Clinical / scientific knowledge
- Documented qualifications
Purpose of Monitoring Visits

- Verify that rights & well-being of subjects are protected
- Data are accurate, complete & verifiable
- Ensure protocol, GCP, regulatory & sponsor SOP compliance
  
  [ICH 5.18.1]
Monitoring Responsibilities

- Act as main liaison between Sponsor & Site
- Verify Investigator & Site adequately qualified to conduct trial
- Verify disposition of investigational product
- Verify PI follows approved protocol & amendments
- Verify written Informed Consent obtained prior to subject participation
- Ensure IB, documents and study supplies received
- Ensure PI & Staff are informed about trial
- Verify that PI & Staff following protocol
- Verify eligibility of enrolled subjects
- Report subject recruitment rates
Monitoring Responsibilities

- Verify that trial records are accurate, complete and up-to-date
- Verify PI submits all required reports, notifications, applications & submissions (accurate, complete, timely, legible, dated and identify the trial)
- Check accuracy & completeness of CRF entries with source
- Any dose/therapy modifications well documented
- AEs reported
- Concomitant meds reported
- Intercurrent illnesses reported
Monitoring Responsibilities [ICH 5.18.4]

- Subject missed visits reported & explained
- Procedures/tests/exams not performed are reported & explained
- Subjects withdrawn/dropped-out reported & explained
- Inform PI of CRF errors, omissions & corrections needed
- PI maintaining Essential documents
- PI documenting & reporting protocol deviations & appropriate actions to prevent recurrence
Pre-Study Assessment

Study Monitor will visit the site to discuss:

- Suitability of Investigator, Staff & Site
- Regulatory requirements
- Sponsor’s expectations

This contact may occur before, during, or after the Investigator’s meeting.
Investigator Meetings

- Scientific discussion
- Logistical issues
- 1:1 sponsor / site meetings
Initiation Visit

- Review Protocol with Study Staff
- Review Administrative/Regulatory Binder
- Review Data Handling Guidelines
- Perform Investigational Product Inventory
Initiation Visit (cont’d)

- Review Adverse Event Reporting
- Discuss Good Clinical Practices
- Agree on Source Documentation
- Discuss Roles & Responsibilities
Initiation Visit (cont’d)

- Review Procedures for Electronic Data Capture or Completion of CRFs or study Workbooks
- Discuss Recruitment Strategies
- Review Monitoring Procedures
Preparing for a monitoring visit

Make sure to arrange for:

- Space
- Time
- Telephone
- Internet Connection
- Documents
Preparing for a monitoring visit

- Subject Recruitment Log
- SAE data
- Protocol deviations
- Waivers
- Investigational Product Shipment & Dispensing Records
Preparing for a monitoring visit

- Complete Data Entry (EDC/CRFs)
- Ensure availability of Source Documentation
- Resolve previous data entry Queries
- Update Regulatory/Administrative Binder
Monitoring activities

- Regulatory Compliance
- Source Data Verification
- Completion of Case Report Forms (CRFs)
- Adverse Event Reporting
- Discrepancy/Query Resolution
- Monitoring Report
Close-out visit

- EDC/CRFs
- Study files
- Investigational Product Return
- Regulatory/Administrative Binder
- Study logs
- Records Retention
- Essential Documents
Post-study Closeout visit

- Items pending at closeout visit
- Field Monitor will contact site to schedule
Study monitor is site advocate & liaison for sponsor’s operational processes

Ensure Subject Rights are protected

Conduct Source Data Verification

Ensure Protocol, GCP, Regulatory & Sponsor SOP compliance