FDA Inspections and Sponsor Audits

Presenter:
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Objectives

• Learn the proper planning for a successful audit/inspection
• Understand the steps to take prior to an FDA inspection
• Understand the scope of an audit/inspection
• Discuss the potential outcome of an inspection
• Identify common audit/inspection findings
BE AUDIT READY AT ALL TIMES
Why prepare for an audit?

- To facilitate a more efficient audit
- To ensure all required documents are available
- To avoid unexpected surprises
Scheduling a Date for a Sponsor Audit

- Are the necessary people available?
- Can the pharmacy accommodate visitors?
- Is a suitable room available?

- Auditor will send a confirmation letter
  - Lists what will be reviewed on site
  - Lists what to send prior to the audit
  - May receive a separate patient case list
FDA Inspection Notification

- FDA Inspection may be unannounced
- In an announced inspection, they will call to schedule the inspection
  - When the inspector calls, write down:
    - Their name & contact info
    - Will there be additional inspectors
    - Name of PI
    - What studies are involved
    - What specific info they want available
FDA Inspection Notification

- Who do you need to notify?
  - Study PI
  - Sub-Is
  - The Study Sponsor
  - Legal
  - Compliance
  - Quality Assurance
  - IRB
  - Pharmacy
  - Leadership
  - Etc.
FDA Inspection Plan

- Develop a preparation plan
- Schedule a PI/Study Team prep meeting
- Schedule a room for the inspector
- Who will greet the inspector & where?
- Will the PI be available to receive the FDA form 482?
- Who will be with the inspector at all times?
- Where or how will you make copies for the inspector?
- How will you recap each day of the inspection & to who?
- Educate office staff on how to interact with the inspector and how to answer their questions
How will the Inspector Conduct the Inspection?

- They’ll follow the BIORESEARCH MONITORING for CLINICAL INVESTIGATORS AND SPONSOR-INVESTIGATORS Guidance for FDA Staff
Scope of Inspection

- Protocol & Amendments
- IRB Documentation
  - Initial review
  - Continuing review
  - Amendment approvals
  - Local Serious Adverse Events submissions
  - Safety Report submissions
- Financial Disclosures
- 1572s
- Delegation Logs & Staff Training
- Informed Consents
Scope of Inspection (Cont.)

- Case Histories
  - Doctor notes
  - Treatment records
  - Labs
  - Radiographic evaluations
- Case Report Forms
- Drug/Device Accountability Records
  - Drug logs (DARFs)
  - Drug Receipts
  - Record of Drug Returns, Transfers or Destructions
- Temperature Logs
- Pharmacy Policies
- Sponsor Correspondence
Exit Interview

- The inspector will hold an interview to discuss findings
  - Study staff should take notes
- Any formal deficiencies will be given to the PI on a Form FDA-483
  - A verbal response can be given, but should be followed up with a written response within 15 days
    - May include new SOPS or other CAPAs
After the Inspection

- FDA reviews your response to the 483 (if issued)
- Issues an Establishment Inspection Report (EIR) with inspection outcome:
  - NAI - No Action Indicated
  - VAI - Voluntary Action Indicated
  - OAI - Official Action Indicated
    - This is when a Warning Letter may be issued
    - [https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm](https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm)
- Site should have an inspection recap meeting
Potential Effects from an Inspection

- Site suspension by sponsor
- Study suspended from FDA or sponsor
- Re-inspection or audit
- Rejection of study data
- Disqualification of investigator
- Fine for the study site
Common Audit/Inspection Findings

• Failure to Follow the Protocol
• Inadequate recordkeeping
• Informed Consent Issues
• Inadequate investigational product accountability
• Failure to report AEs
Resources

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