Site Inspection Preparedness

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Where do we start? From Notification to Audit

- Reviewed participant documentation:
  - Prescriptions, chain of custody documents, packing lists
- Reviewed pharmacy records:
  - Temperature logs, calibration certificates, routine maintenance reports for equipment (freezers, refrigerators), sponsor reports (i.e. IRF, TERF)
- Collected all binders containing SOPs, pharmacy establishment plan, organized and completed
  - Ensure appropriate version control of pharmacy documents
  - Collate different version of SOPs, PEPs, and other documents

Audit Day

- Prior to arrival, print accountability logs
- Auditor arrived, presented credentials and requested my identification
- Pharmacy tour
  - All study product bins labeled with IRB#, drug name, and investigator name
  - Inventory check
- Requested study records:
  - Drug accountability records
  - Temperature storage logs
  - Documentation of destruction and returns

Auditor questions

- Study product return
- General process from notification of participant to administration
- Current version of Vestigo® (electronic inventory tracking program)
- Temperature excursions
- Detail of POR responsibilities
- Delegation of Duties log
- Training
- Randomization procedure

Takeaways and Best practices

- Maintain communication with study team and PAB
- Ensure all records are organized, complete and available
- Ensure all procedures are outlined in SOPs
- Answer only the question that is asked
- If auditor flags a potential discrepancy, review records and timelines to provide explanation to the best of your knowledge
- Be calm