



QA Perspective of the Electronic Field Trial Notebook (eFTN)

Considerations for Field Facilities

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What is Being Covered in this Session

Field Facility Records

- SOPs
- Logbooks
- Archives
- Personnel Records

Auditing eFTN Field Studies

- Validation
- Critical Phases
- eFTN (electronic field trial notebook)

Field Facility Records: SOPs

Data Storage, Transfer & Archiving

Backups

Disaster/Recovery

Computer System Maintenance

Software Version Control

Security

Validation

Data Storage, Transfer & Archiving

- Where is data kept?
- How is it transferred to the Sponsor?
- What is the data retention policy?

Backups

- Storage media used?
- How often ?
- Where will it be stored?

Disaster/Recovery

- Make an assessment of what could be lost and what is retrievable.
- Resolution/Recovery Plan
- Notification of Study Director and Sponsor

Computer System Maintenance

- What routine maintenance is done?
- Who is Responsible for the systems?
- Documentation of routine/non-routine maintenance in the logbook.

Software Version Control

- Where is the current version of the software documented?
 - Suggest a logbook for this.
- Who has authority to load/download new versions/releases/updates of software onto system?
- Treat the computer like a piece of equipment.
 - Suggest assigning a Person In Charge (PIC).

Security

- Physical Security
 - How are laptops, desktops, etc. in the facility protected?
- System Security
 - Is the computer password protected?
 - Is the software password protected?
- Who is allowed access to computer & software systems? (May want to list by job position rather than by name or have approved personnel list.)

Validation

- Keep copies of the testing records.
- Have the validation certificate readily available.
- Keep the documentation as part of the equipment logbook.
- How often does it have to be done?
 - Any time a new software version is installed, new computer, or new operating system.

Auditing Facility Documentation

Logbooks

- System Description
- Maintenance Records
- Software Version
- Backups
- Validation Documentation

Auditing Facility Documentation

Archives

Personnel Records

- Training Records
 - GLP training, training by SOP review, or specialized eFTN training.

Auditing eFTN Field Studies

Before you start – take time to go through the notebook validation process.

Auditing the eFTN

Critical Phases

- Procedures should be the same.
- Know the forms and how they impact each other.
- Communicate with the trialist and encourage them to record information in the electronic Notes Section.
- Make sure the information requested in the protocol is recorded in the eFTN.
- Confirm supporting documentation.

Auditing the eFTN

eFTN/Raw Data

- Audit from the computer screen or printouts
- If auditing the electronic version, suggest printing some forms before beginning:
 - Chemical Log
 - Notes Section
 - Sample Log
 - Plot Map
 - DRR (Data Revision Record) – Audit Trail

