STUDY CLOSE OUT

Topics Covered

- Study documentation
- Data Management
- IRB/RA
- Drug Accountability
- Sample storage

Definition

- This relates to the closure of a study at a participating site once all subjects have completed the study and all data queries have been resolved.

Notes

- Close out is not a one-off visit but is a process that may take weeks to months to complete
- Can have multiple close out visits
- It is essential that data and information are retrievable and stored in a safe and logical manner. This process must be conducted in accordance with GCP and regulatory requirements.

Key areas

Use the study close out SOP to provide guidance but the key areas are as follows:

- Study documentation
- Data Management
- IRB/RA
- Drug Accountability
- Sample storage

Study Documentation

- Study filing: Ensure filing of documentation has been maintained throughout the study and provides a clear audit trail
- Archiving: Meet archiving requirements and make corresponding arrangements

Data Management

- Data Validation: Completed data entry and all queries are resolved.
- Electronic Data: mainly sponsor responsibility
- Serious Adverse Event (SAE) Reconciliation

IRB/IEC

- Inform IRB/IEC and local institution.
- The reason for premature termination of a site if study stopped early.
- All relevant safety issues and safety updates at and after close-out
- The date of site closure

Drug Accountability

- Reconcile accountability, supply and inventory logs for the study product.
- Ensure proper documentation for return of product or drug destruction.
- Any deviations should be documented.

Sample storage

- Ensure long-term storage of clinical samples meets the requirements and is documented

  e.g. storage of baseline(screening) malaria slides or exportation of pk samples

Closing remarks

- The study should be closed out such that its ready for an audit or inspection at a later date, as late as 10 years from now!

References

- 21 CFR 312.66 Assurance of IRB Review;
- 21 CFR 312.68 Inspection of Investigator's Records and Reports.
- FDA Sheet: January 1988 Guidelines for Monitoring of Clinical Investigations;