VCU Office of the Vice President for Research and Innovation

Veeva EDC: Data Management

Table of Contents

1. Purpose

This procedure defines the standardized process for managing clinical trial data using Veeva Vault EDC, ensuring data quality, regulatory compliance, and operational efficiency.

2. Scope

Applies to all clinical trials utilizing Veeva Vault EDC for electronic data capture and data management activities.

3. Responsibility

VCU personnel will be responsible for both performing and complying with this SOP and assuring the appropriate personnel are trained on this SOP.

4. Definitions

Data Manager: Oversees data collection, validation, query management, and data cleaning through DMR.

Study Builder: Builds and maintains study configuration in Vault EDC.

Clinical Research Associate/Monitor (CRA/M): Performs SDV and supports site query resolution.

Source Data Verification (SDV): A process by which data is reviewed against source.

Data Management Review (DMR): A process to ensure data collection follows study protocols.

Data Management Plan (DMP): Represents the targeted SDV or DMR plan created for the site or study. This may include details on query management.

5. Procedure

5.1. Study Setup

- Configure study design using Veeva Vault EDC Studio.
- Reuse standard components and templates to ensure consistency.

5.2. Data Collection

- Design CRFs with built-in edit checks and dynamic rules.
- Ensure forms are protocol-compliant and user-friendly.

5.3. Query Management

Query Lifecycle: Open → Answered (optional- a data change may auto-close a query without a comment necessary) → Closed. All queries must be resolved before database lock.

There are 3 types of queries that may appear throughout a study:

System Queries - automatically generated based on properties programming

- When a system query is manually closed, it will not re-fire when forms are resubmitted.
- Examples of system queries:
  - Required: if an item is left empty.
  - Range: if numeric value is out of range (based on study design).
  - Future Date: study design can disallow a future date.
  - Out of Window: study design can create a window of allowed dates.

Programmed Queries - queries can be configured as study rules including comparison rules by the study builder during initial study build to auto-fire under specific circumstances.

Manual Queries - created by data managers or CRAs during review.

Best Practices for Query Management:

- Use clear, concise language.
- Avoid redundant or unnecessary queries.
- Track query metrics for performance monitoring.

5.4. Freezing and Locking

Freezing

- Prevents further data entry or modification at the item, form or event level.
- Useful before or after data review activities.
- All actions on frozen data are included in the audit trail.

Locking

- Prevents any changes or actions at the form, event or subject level.
    - A study or site can also be locked (for interim analysis, safety issues, hold, or completed data collection).
    - If a study requires an amendment, locked data will not be updated to the latest version and will remain as is.
- Useful before or after data review activities.
- When locked item is in a read-only state.

5.5. Source Data Verification (SDV) and Data Management Review (DMR)

Depending on study design, there could be SDV, DMR or both.

- SDV - performed by a CRA
    - Used to confirm CRF data matches source documents.
    - SDV status is tracked in Vault EDC (e.g., Not started, In progress, Complete).
    - SDV strategy is defined in the Monitoring Plan (100%, risk-based, or targeted).

- DMR - performed by a data manager
    - Ensures data accuracy and completeness.
    - DMR status tracked in Vault EDC (e.g., Not started, In progress, Complete).

5.6. Data Lock and Archival

- Final review of all data, queries, SDV, and DMR prior to locking study in EDC.
- Archive data per regulatory and sponsor requirements.
- See Study Closeout and Archival policy.

6. References

- Managing Queries
- Performing SDV
- Freezing Data
- Monitoring Protocol Deviations
- Performing DMR
- Locking Data
- Snapshots (Bulk Lock & Freeze)
- Creating Sites
- Assigning Review plans to Sites
- Managing Study Countries

- Locking Studies & Sites
- Completing Source Data Verification (SDV)
- Completing Data Management Review (DMR)
- Creating Manual Protocol Deviations
- Reviewing Protocol Deviations
- Additive Review
- Creating rules
- Comparison rules

7. Contact

Please contact either of the following for questions regarding this document:

Lauren Wallace, MS
Director of Clinical Research Regulatory Affairs
kanigherl@vcu.edu

Liz Kissell, MPH
Clinical Research Monitor/FDA Program Admin
kisselle@vcu.edu

8. Document History

VERSION	EFFECTIVE DATE	BRIEF DESCRIPTION OF CHANGE
1.0	8/27/25	INITIAL VERSION