

Veeva EDC: Data Entry and Electronic Signatures

Table of Contents

1.	<i>Purpose</i>	<i>2</i>
2.	<i>Scope</i>	<i>2</i>
3.	<i>Responsibility.....</i>	<i>2</i>
4.	<i>Compliance Statement</i>	<i>2</i>
5.	<i>Procedures</i>	<i>2</i>
5.1.	<i>Managing Casebooks</i>	<i>2</i>
5.2.	<i>Data Entry.....</i>	<i>3</i>
5.3.	<i>Resetting Data.....</i>	<i>3</i>
5.4.	<i>Answering Queries.....</i>	<i>3</i>
5.5.	<i>Providing Electronic Signatures</i>	<i>4</i>
5.6.	<i>Reviewing Closeout PDFs</i>	<i>5</i>
6.	<i>References</i>	<i>5</i>
7.	<i>Contact</i>	<i>5</i>
8.	<i>Document History.....</i>	<i>6</i>

1. Purpose

To define standard processes and procedures for components of data entry and for use of 21 CFR part 11 compliant electronic signatures in the Veeva EDC.

2. Scope

Applies to all Veeva EDC site users entering data and applying electronic signatures.

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. Compliance Statement

VCU uses Veeva EDC for their electronic data capture system for FDA regulated studies. Veeva EDC supports compliance with 21 CFR Part 11 requirements. Documentation of Veeva Vault's compliance with Validation of Computerized systems can be accessed at the Office of the Vice President for Research and Innovation. The system is validated for each change.

5. Procedures

5.1. Managing Casebooks

Creating a casebook automatically creates a new subject with events, forms, and items related to the study.

Each casebook displays events and forms chronologically in the casebook schedule in a tree view and displays only records you have permission to view.

Depending on the study design, casebooks can allow for cycles or repeating *Event Groups*.

When viewing the casebook schedule, several actions can be performed:

- Enter and change an *Actual Start Date* for an *Event*
- Enter and change the *Visit Method* for an *Event*

- Add an *Unscheduled Event* to the casebook
- View the Event History (audit trail)
- Provide an eSignature

From the casebook schedule it is easy to navigate to *Event* and *Form* records associated with the casebook.

- Clicking on an *Event* opens the first incomplete *Form* in that *Event*
- Clicking a *Form* opens that *Form*. Once a *Form* is submitted, you are returned to the parent casebook

5.2. Data Entry

Veeva EDC provides an interface that prioritizes pending tasks and auto-saves data.

When needed, a form can be edited with the ability to provide a reason for change. Visual indicators are provided to highlight out-of-range values for review.

Veeva EDC has the ability to auto-populate reference ranges and units based on lab selection and will highlight out of range values when entering lab results when Local Labs has been programmed.

Forms and individual items have the option of *Intentionally Left Blank* to indicate data was not collected and why.

Forms can be marked as restricted (blinded) where only specific users are given permission to view and enter data on the forms.

5.3. Resetting Data

Data can be removed by resetting Events and Forms.

- Item groups, forms and events can be reset and includes all system-generated queries and any closed manual queries on items and events are deleted.
- An item group can be reset if incorrect data was entered, a form can be reset if incorrect subject data was entered, and an event can be reset if incorrect visit data was entered. The information that was reset will still be captured in the audit trails.

5.4. Answering Queries

There are two types of queries that can be answered: system and manual.

- System queries are edit checks based on configured data validation rules in the study (i.e., out of range value).
- Manual queries are created by a CRA or data manager.

Users can view a list of open queries at the study, site, or casebook level using the task bar.

When the EDC creates a system query due to a data entry error, users can correct the data and save which may automatically close the query without having to 'answer it.'

- Veeva EDC does not automatically close queries in Answered status, even when the queried data has been corrected to within range.

When a CRA or data manager creates a query, users can update data (if applicable) and reply to the query. A CRA or data manager can close the query after reviewing site replies.

Quick queries allow users to select from pre-generated responses to answer queries and is available when Query Teams is enabled. When using query teams, a Lead Data Manager can close all queries when needed.

5.5. Providing Electronic Signatures

Specific to appropriate users (i.e., PI) that can sign forms, events, or casebooks.

Users can sign and date in the EDC using eSignature that meets the requirements of 21 CFR part 11.

Some actions can break a signature after it is applied, editing the EDC invalidates the signature and requiring a new signature:

- Editing a form which involves changes to item data.
- Resetting a form or event.
- Editing an event date or visit method.

A form or event can be signed when:

- Forms are submitted.
- A form, event and casebook are unlocked.
- There are no open queries.

When there is an open query on an event:

- Signatures cannot be done on event dates or visit methods on the event.
- Signatures can be done on forms within that event.
- Signatures can be done at the casebook level, but signatures are only applied to event dates and forms with no open queries.

When there is an open query on an item, but no open query on an event date:

- Signatures cannot be done on a form with an open query.
- Signatures can be done at the event level, but signatures are only applied to form with no open queries.

5.6. Reviewing Closeout PDFs

Lead data managers are responsible for sending the site a PDF version of all forms collected at the site for users to review and either accept or reject.

- PDFs will remain accessible and notifications as programmed will continue to be sent until users accept or reject them.
- Sites should download and retain these PDFs per regulatory requirements.
- For sites that include restricted data only appropriate users with access to restricted data can download, accept or review the closeout PDFs.

Closeout PDFs contain the following information:

- Event schedule
- Data
- Casebook, form, item and event audit trail

6. References

- [Managing Casebooks](#)
- [Entering Data](#)
- [Resetting Data](#)
- [Deleting a Subject](#)
- [Answering Queries](#)
- [Providing Signatures](#)
- [Reviewing Closeout PDFs](#)

7. Contact

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8. Document History

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