VCU Office of the Vice President for Research and Innovation

Veeva EDC: Study Build Best Practices

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1. Purpose

This procedure defines the standardized process and best practices for building clinical studies using Veeva Electronic Data Capture (EDC) to ensure high-quality, efficient and compliant study builds.

2. Scope

This procedure applies to all clinical data management and study build personnel involved in the design, configuration, testing, and deployment of studies using Veeva EDC.

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

Study Builders: Design and configure study components in Veeva Studio.

Clinical Data Managers: Review and validate study design and data collection forms.

Study Environments: represent your *Study* as it exists in different stages of development. There are multiple environments that may be used throughout the study design.

**Note: environments may be spread across multiple vaults.*

Development Environment: where the study is built. Each study can have 2 development environments.

Test Environment: where a study can go through user acceptance testing. Each study can have up to 5 test environments.

Training Environment: This optional environment where appropriate staff is trained on specific roles where they can learn to use the system without having real data to input. Each study can have up to 2 training environments.

Validation Environment: checks for any issues in the study design that may cause errors during casebook creation or data collection

Production Environment: where the study goes live. This environment is where data from a study is inputted. Each study can have 1 production environment.

Post Production Test: able to test or preview any post-production changes (amendments) without affecting the production environment. Each study can have 2 post-production testing environments.

5. Procedure

5.1. Study creation in EDC

Prior to building a study, the study shell needs to be created by OVPRI and can be done by completing the RedCap form.

5.2. Study Design Planning

Conduct a kickoff meeting with all applicable stakeholders to define study requirements and review any outstanding protocol questions. Use Veeva Vault EDC Studio specification tools to outline study schedule, CRFs, edit checks, and workflows.

5.3. Components Hierarchy

There are five (5) main object types:

- Event groups is an object that holds a group of events (e.g., eg_TREATMENT could contain all treatment events).
- Events are most analogous to a visit during a study. Each event has a date and a group of forms to be completed for that event.
- Forms contain a collection of data points and is analogous to paper CRFs.
- Item Groups contain all items and represent a section on a form; multiple item groups can be added to a form. All items must be grouped under an item group.
- Items represent a question or field on a form as a single data point.

5.4. CRF Development

- Build CRFs using Veeva Studio with drag-and-drop tools or copy identical forms from other studies or the library.
- Follow naming conventions and version control standards.
- Include edit checks and dynamic rules to ensure data quality.

5.5. Edit Checks and Rules

- Use standard libraries where possible to reduce custom programming.
- Validate logic with clinical and data management teams.
- Document all edit checks in study specification.

5.6. Testing and Validation

- Perform internal testing of all forms, rules, and workflows. Whenever possible, use difference reports to identify what doesn't need to be tested with prior validation.
- Conduct a formal UAT with documented test scripts and results.
- Address all findings before moving to production.

5.7. Deployment

Use Veeva's deployment tools to move the study from test to production.

Ensure all applicable stakeholders sign off on a go-live checklist.

- Checklist Items for Deployment to Production
  1. Set up learning management system
     a. This allows users to complete the appropriate study training before accessing the study.
     b. Enable Veeva Training Integration.
     c. Add learning system to the study and add all available curriculum from Veeva training.
     d. Assign curriculum to study roles.
  2. Add Countries and Sites.
  3. Set up labs and coding dictionary.
  4. Enable Bulk Signature & Sign of open queries.
  5. Add applicable users.
  6. Assign review plans (SDV/DMR).
  7. Email Group Assignments.

5.8. Post-Go Live Amendments

- Use Veeva's amendment tools to make mid-study changes.
- Follow change control procedures and revalidate affected components.

6. References

- Veeva EDC: Study Designers
- Managing Casebook Versions & Amendments
- Comparing Casebook Versions in EDC Tools
- Managing Change with an In Progress Study Design
- Deploying a Study

7. Contact

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8. Document History

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