

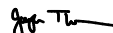



ECTU Central Office SOP ECTU_REDCap_03: Database Build Process

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Authorship and Approval			
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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	25-Nov-2015	<ul style="list-style-type: none"> Initial creation/New document
2.0	26-May-2016	<ul style="list-style-type: none"> Change to SOP name as separate naming convention allocated to REDCap SOP/WPDs
3.0	07 Aug 2024	<ul style="list-style-type: none"> Document moved to new template Change to SOP name All references to validation process removed as included in SOP ECTU_REDCap_04 Extensive changes throughout to better reflect build process

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1.0 PURPOSE

A study database consists of a series of data collection instruments designed in accordance with the study protocol and core functionality to support the management of the data collection

This SOP describes the process for building a new study database on the REDCap platform.

2.0 SCOPE

This SOP applies to staff in the following roles within the ECTU Data Management Team as REDCap study database developers:

- Data Manager
- Assistant Data Manager
- Data Management and Programming Architect

3.0 RESPONSIBILITIES

Staff in above roles who have completed and passed the training process outlined in ECTU Central Office SOP ECTU_REDCap_01 REDCap Database Build Training and Administrator Access may be allocated a study database to build by the Data Management Team Lead.

Once a study is allocated, the designated staff member will be responsible for building the study database in accordance with the specification provided as detailed in ECTU Central Office SOP ECTU_REDCap_02 REDCap Database Specification for Initial Release.

The ECTU Trial Manager or appropriate study designee is responsible for advising the database developer of the study timelines.

4.0 PROCEDURE

4.1 REDCap Build Process and Timelines

4.1.1 Depending on the specification and study requirements, a database build including preparation of all validation documentation will take a minimum of 3-6 months from receipt of initial specification documents/instructions. This timeframe is an estimate only and any significant changes to a specification throughout the build process are likely to impact the time taken to complete the build.

4.1.2 The Trial Manager or appropriate study designee is responsible for advising the database developer of the study timelines and informing them of any changes to this throughout the database build.

4.1.3 The database developer is responsible for advising the Trial Manager or appropriate designee of any delays or changes likely to impact the completion of the database build.

4.1.4 The database developer is responsible for liaising with the Senior Software Developer to implement any external functionality that may be required (for example Randomisation via API, Text Reminder system).

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4.1.4 Specific format, structure and function (for example, field types, branching logic) will be determined at the discretion of the database developer (unless otherwise requested) in accordance with the specification provided and Sponsor requirements.

4.1.5 The database will initially be built as a training version on the REDCap Development server. The database will be named using the following convention:

<<STUDY NAME/ACRONYM>> TRAINING – Do NOT enter live data onto this database

4.1.6 RC008 REDCap Database Development Guide describes the database build and release process in detail.

4.2 Database Review and Approval

4.2.1 At a minimum, the database must be reviewed and approved by the Trial Statistician or Unblinded Statistician or designee and the Trial Manager or appropriate study designee before it can be released. This is applicable to all studies.

4.2.2 Additional review and approval from the Sponsor (e.g. Trial Monitor) may be required for certain studies.

4.3 Database Validation and Release

4.3.1 The study database must be validated on the training version before it can be released to a live version. This is applicable to all studies. Further details are provided in ECTU Central Office SOP ECTU_SOP_REDCap_04 REDCap Study Database Validation.

4.3.3 Depending on the study, final review of all validation documents and release approval may be required from the study Sponsor before database release. The database developer and Trial Manager or appropriate study designee are responsible for ensuring the correct Sponsor approvals are obtained prior to database release.

4.3.4 The procedure for study database release is described in ECTU Central Office SOP ECTU_SOP_REDCap_05 REDCap Study Database Release

5.0 RELEVANT DOCUMENTS AND REFERENCES

[ECTU Website](#)

- ECTU_SOP_REDCap_01 REDCap Database Build Training and Administrator Access
- ECTU_SOP_REDCap_02 REDCap Database Specification for Initial Release
- ECTU_SOP_REDCap_04 REDCap Study Database Validation
- ECTU_SOP_REDCap_05 REDCap Study Database Release

[ACCORD Website](#)

- ACCORD SOP CR004 Recording and Reporting Study Data
- ACCORD SOP CR013 CRF Design and Implementation
- POL007 Computer System Validation

For studies with a different Sponsor, please refer to local guidance as required

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ECTU REDCAP_03, 04, 06 and W2

Final Audit Report

2024-07-17

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