Newcastle REDCap Validation Process

NJRO-INF-SOP-005

Contents

1. Background/Introduction

REDCap is a browser-based Electronic Case Report Form (eCRF) system, designed to capture research data from both research staff in medical settings and directly from patients via online tools for non-industry and industry research trials. The MHRA advise that computer systems used to support clinical trials should have first undergone Computer Systems Validation (CSV) to demonstrate GCP-compliance, and to document the suitability of the system to fulfil clinical trial requirements **(7.1)**. GCP guidance **(7.2)** suggests three key features which define computer system validation:

- Appropriate controls of the system are in place throughout the system's lifetime.
- Documentation is available to support the application of the controls.
- The system is fit for purpose and performs reliably and consistently as intended.

2. Purpose

This SOP describes the process which must be followed to consider the Newcastle REDCap system as validated and the situations which may trigger the requirement for revalidation.

3. Scope of Document

This SOP should be followed every time a validation or revalidation of the Newcastle REDCap system is required. Validation activity is carried out by the Newcastle Research Informatics Team and sign off includes input from the Newcastle Research Quality Assurance Team. The processes included in this SOP are followed to consider REDCap itself as validated, however researchers should ensure they perform adequate user acceptance testing on a project-specific level to ensure the suitability for their clinical research trial.

4. Definitions

eCRF – Electronic Case Report Form
IQ – Installation Qualification
LTS – Long Term Support
Q-Pulse – Quality Management System managed by Newcastle Research Informatics Team
UAT – User Acceptance Testing

5. Roles & Responsibilities

The typical roles and responsibilities of those involved in the validation process are described below. Roles may be deputised due to certain circumstances (e.g. staff availability).

Team	Role	Validation Responsibilities
ARO	Cloud Services Provider	Provides IQ
Newcastle Research Quality Assurance	Quality Assurance Manager	Signs off test script templates Signs off overall validation results
Newcastle Research Informatics	Information Manager or deputy	Signs off overall validation results
Newcastle Research Informatics	Senior Information Analyst	System build Signs off IQ Maintains Core Functionality Assessment Creates and modifies test script templates Signs off executed test scripts
Newcastle Research Informatics	Information Officer	Weekly assessment of REDCap update Executes test scripts

6. Procedures

The REDCap validation process is triggered by one of six conditions:

- Initial system validation required **(full validation required)**;
- A REDCap update (weekly release) is deemed essential;
- REDCap LTS branch update (six-monthly release) is available;
- A new Installation Qualification (IQ) is provided by ARO due to significant server upgrades **(full validation required)**;
- A new REDCap build is requested for a clinical trial, or significant change to an existing REDCap clinical trial;
- 24 months have passed since the previous full REDCap validation **(full validation required)**.

If any of the above conditions are met, the validation process is carried out in Q-Pulse as follows:

1. **Plan:** A new validation workflow is created in Q-Pulse estimating timescales based on current workload and responsibilities for validation activity.
    - If this validation was triggered by a critical update, validation is carried out within 14 days.
2. **User Requirements Specifications:** Log the reason for this validation being performed and how it meets user requirements (i.e. which of the above criteria has triggered the validation).
    - If this validation was triggered by an update, details of the update are logged.
    - If this validation was triggered by a new IQ from ARO, the latest IQ document is reviewed and signed off.
3. **Impact/Risk:** The Newcastle REDCap Core Functionality Assessment is reviewed to:
    - Assign risk levels and core/ancillary status to new functionality. New test scripts are created for new functions which have been assessed as core.
    - Reassess existing functionality to determine any changes to risk level or core/ancillary status. New test scripts are created for existing functions which have moved from ancillary to core.
    - Determine if a proposed update would affect existing core functionality. Existing scripts are modified if the core functionality they cover is deemed to be affected.
    - All changes to test script templates are signed off before use.
4. **Build (test system):** Details of the proposed build are logged.
    - If this validation was triggered by an update, the Research Informatics Team requests the update to be applied to the test instance of REDCap via ARO. Active REDCap users are informed of associated downtime and the new update is installed.
5. **Testing (test system):** Test scripts are executed and reviewed for new or affected core functionality, or all core functionality if full validation is required.
    - If test scripts fail:
        - If the functionality configuration can be altered in an acceptable way to alleviate the issue, this is enacted, and the script is amended (if necessary) and executed again.
        - If the function(s) configuration cannot be altered to alleviate the issue, the function(s) must be disabled or remain unused.
6. **Build (live system):** Details of the proposed build are logged.
    - If this validation was triggered by an update, the Research Informatics Team requests the update to be applied to the live instance of REDCap via

ARO. Active REDCap users are informed of associated downtime and the new update is installed.

7. **Testing (live system):** Test scripts are executed and reviewed for new or affected core functionality, or all core functionality if full validation is required.
    - If test scripts fail:
        - If the function(s) configuration can be altered in an acceptable way to alleviate the issue, this is enacted, and the script is amended (if necessary) and executed again.
        - If the function(s) configuration cannot be altered to alleviate the issue, the function(s) must be disabled or remain unused.
8. **Sign off:** This validation workflow is signed off by the Information Manager/deputy and QA Manager.
9. **Validation certificate:** A validation certificate is created to summarise the validated status of REDCap including version number and signatories.

All documents mentioned in the above steps are uploaded to the attachment area for the associated Q-Pulse validation workflow.

7. References

7.1 Computer System Validation – GCP, MHRA Inspectorate

7.2 ICH E6 (R2) Good clinical practice, European Medicines Agency