REDCap Study Database Testing

Study Title / Protocol No:	
Principal Investigator:	
Protocol Version:	
Testing Start Date:	

This document is intended to lead a clinical trial project team through the process of testing a REDCap project. The team should review project setup and enter enough test data to verify that protocol requirements are met. At the end of this process the Principal Investigator (or Sponsor) will be in a position to approve the project database for live use. This document and copies of test data and logs should be retained for inspection purposes.

Study Test Plan

Our approach to REDCap project development uses a dynamic development approach in which study configurations are built based on the study protocol and draft data collection forms. The process involves multiple reviews and testing takes place iteratively throughout the development process. This document summarises the result of this process. Study logs and test data are retained for inspection purposes but there is no formal requirements definition for the project.

Risk Level

1. High Risk – feature is critical to data collection, data security or GCP compliance.

   These features must be thoroughly tested/reviewed before data entry commences.
2. Medium risk – feature may impact data quality.

   These features should be thoroughly tested prior to data entry, but they are not as critical as high-risk features.
3. Low risk – feature is cosmetic or not used in this study. This category may also include features that are validated centrally and which are minimally influenced by study configurations.

   These features should be reviewed but need not be subject to rigorous testing.

Study Configuration

Study sites and users

Risk Level 1

In REDCap, study sites are represented as Data Access Groups (DAGs). Review the data access group configurations to ensure that the DAGs match the sites as defined in the study protocol.
For ease of documentation, we recommend that user roles are configured for each type of user who will be accessing the study database. These roles should be documented and should reflect the terms used in the site delegation logs.

- Are the study sites (Data Access Groups) correctly configured? Yes [ ] No [ ] N/A [ ]
- Are appropriate user roles configured with the correct user rights for the role? Yes [ ] No [ ]
- Do the names of these user roles reflect the terminology used in the delegation logs? Yes [ ] No [ ]

Details / Comments:

Study events and data collection forms

Risk Level 1

In a longitudinal study, data collection forms are configured to be used at one or more time points (study events). If the study is not longitudinal there will be only a single study event.
The REDCap project must have the correct forms configured for the correct study events, as required by the protocol.

• Are the required study events (visits) correctly represented in the Record Status Dashboard?	Yes [ ]	No [ ]	N/A [ ]
• Are the study data collection forms present in the necessary study events?	Yes [ ]	No [ ]	
Details / Comments:			

Data Collection Forms / Data Entry

Enough test data should be entered to verify that all the required data is collected at the correct study events and that branching logic functions correctly.

Basic

- Field labels (questions) are correct
  Risk level 1
  Yes [ ] No [ ]
- Any identifiers present in the database have been flagged.
  Identifiers may be defined based on local regulations but may include participant names, email addresses, dates of birth, postal codes, etc.
  Risk Level 1
  Yes [ ] No [ ] N/A [ ]
- Record numbering is working (either through auto-numbering or custom numbering).
  Risk level 3
  Yes [ ] No [ ] N/A [ ]
- Answer options (radio buttons, checkboxes drop-down lists) are correct
  Risk level 1
  Yes [ ] No [ ]
- Any required questions are enforced
  Risk level 2
  Yes [ ] No [ ]
- Test records have been entered and saved
  Yes [ ] No [ ]

Branching Logic

Risk Level 1

• Branching Logic has been tested on the eCRFs	Yes [ ]	No [ ]	
• The correct fields are displayed and/or hidden when expected	Yes [ ]	No [ ]	
• No error messages are displayed in reference to branching errors	Yes [ ]	No [ ]	

Range Checks

Risk Level 3

Range checks are an aide to data entry and data quality but are considered low risk.

Are range checks used in this study?	Yes [ ]	No [ ]	
• Range checks have been tested on the eCRFs	Yes [ ]	No [ ]	N/A [ ]

Calculations Risk Level 1			
Do the data collection forms involve any calculations (such as age)?	Yes [ ]	No [ ]	
• If so, have all the calculations been tested and found to be accurate?	Yes [ ]	No [ ]	N/A [ ]
Repeating Instruments and Events *REDCap study configuration may allow for individual forms (such as adverse events) or entire study events (such as unscheduled/ad-hoc visits) to be repeated.* *Repeating forms and events may be labeled for convenience and to reflect key information such as the visit date or adverse event description.*			
Does this study use repeating forms or repeating events?	Yes [ ]	No [ ]	
• Do the required forms/events repeat as required? Risk Level 1	Yes [ ]	No [ ]	N/A [ ]
• Are repeating forms/events labeled appropriately? Risk Level 3	Yes [ ]	No [ ]	N/A [ ]
Details / Comments			

Randomization

Risk Level 1

If a study uses randomization, it may be performed electronically in the REDCap database, or it may be performed manually or externally from the study database. In either case, the study team must ensure that the randomization data is properly collected so that study data can be matched with the intervention data during analysis.

Does this study involve randomization? Yes [ ] No [ ]

- Is stratification information (if any) required for randomization collected in the study database prior to randomization? Yes [ ] No [ ] N/A [ ]
- Do the data collection forms correctly reflect the randomization process for this study? Yes [ ] No [ ] N/A [ ]
- Have you successfully randomized a number of test cases? Yes [ ] No [ ] N/A [ ]

Details / Comments:

Surveys (Diaries, patient-reported outcomes)

Risk Level 1

Automated electronic surveys can be critical to data collection in a clinical trial, but they can be difficult to test. The study team should perform enough testing to ensure a high degree of confidence in the delivery of the surveys. If it is not possible to test scheduled invitations over the entire participation of one or more patients then the study team may supplement traditional testing with other evidence such as exported survey invitation settings.

Does this study use REDCap surveys, either by email or SMS message?	Yes [ ]	No [ ]	
• Have you entered data to invoke and test the surveys?	Yes [ ]	No [ ]	N/A [ ]
• Have you entered enough data to test the scheduling logic?	Yes [ ]	No [ ]	N/A [ ]
• Are the correct instruments delivered to the study participants at the correct study time-points.	Yes [ ]	No [ ]	N/A [ ]
• Have you provided other evidence (e.g. database listings or reports) that indicate you have reviewed the survey configuration and found it to be acceptable?	Yes [ ]	No [ ]	N/A [ ]
• Do invitation emails (or SMS messages) contain the correct text?	Yes [ ]	No [ ]	N/A [ ]

Details / Comments:

Electronic Signatures

Risk Level 1

REDCap forms can be configured for electronic signing. Forms that you may choose to use this feature could include: enrolment, adverse events, protocol deviations, etc. It is also common practice to include an investigator sign-off form or have the investigator sign off on an end of study page.

Does this study use electronic signatures?	Yes [ ]	No [ ]	
• Are user roles properly configured to allow investigators to apply electronic signatures?	Yes [ ]	No [ ]	N/A [ ]
• Are electronic signatures configured and working on the correct forms?	Yes [ ]	No [ ]	N/A [ ]

Comments:

File Repository

Risk Level 1 / 2

Some studies may use the File Repository to store and share documents. Access to these documents may be restricted by DAG. For REDCap eConsent projects the File Repository may be critical to regulatory compliance.

Does this study use the File Repository?	Yes [ ]	No [ ]	
• Can files be uploaded to the File Repository?	Yes [ ]	No [ ]	N/A [ ]
• Are uploaded files accessible and/or downloadable by the correct study sites and/or individuals.	Yes [ ]	No [ ]	N/A [ ]
• Are PDF copies of survey responses stored correctly and accessible?	Yes [ ]	No [ ]	N/A [ ]
• Does this study use the eConsent Framework?	Yes [ ]	No [ ]	N/A [ ]
• If so, are copies of the completed eConsent documents saved in the File Repository?	Yes [ ]	No [ ]	N/A [ ]
Comments:			

Reporting and Data Export

Data export and reporting is critical to most studies. However, data export features and reporting features are validated at the system level with minimal study level configuration available.

Rick Level 3

Does the study use custom reports?	Yes [ ]	No [ ]	
• Have the reports been tested to make sure they return the correct results?	Yes [ ]	No [ ]	N/A [ ]
Has test data been exported and compared with the data displayed by the data collection instruments?	Yes [ ]	No [ ]	
Comments:			

Additional Components or Customizations

List any additional features, customizations, or external components that require testing below. Include information regarding the purpose of these components and how they have been tested.

Any additional information or comments relating to study database testing?

Does this study use any additional REDCap or non-REDCap features that require testing? If yes use this section as a template.	Yes [ ]	No [ ]	
•	Yes [ ]	No [ ]	N/A [ ]
Comments:			

Database Testing Performed by:

Name(s): Date:

Authorization

I have reviewed the REDCap database for the above-named study and agree that the database appropriately reflects the study's data collection needs as described in the study protocol.

Signature (PI or designee) Date: