**SHORT STUDY TITLE**

Long Study Title

STUDY DATABASE:

Test Plan

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| --- | --- |
| Chief Investigator: | Insert |
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| Sponsor Reference: | Insert |
| : | Insert |
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**ABBREVIATIONS**

|  |  |
| --- | --- |
| CRF | Case Report File |
| TMF | Trial Master File |

1. **Validation Risk Assessment**

The SHORT TITLE study database will be used to store research data generated from a clinical trial. Therefore, computer system validation is required.

High impact data (data generated from clinical trial participants) will be stored in the database.

The database will be built using category x software [insert the most appropriate from the three categories below]

*Category 3 – Commercially available software that has not been configured or modified for the database.(e.g., Excel spreadsheet with minimal formatting)*

*Category 4 – Commercially available software that has been configured for the database. (e.g., Excel spreadsheet or Access database programmed to meet study specification)*

*Category 5 – Bespoke software programmed specifically for the database.*

The database will store high impact data and will use category 4/5 software. Therefore, a full validation will be required.

OR

The database will store high impact data but will use category 3 software. Therefore, a reduced validation will be completed. XXX will not be tested.

1. **Test Environment**

A test version of the database has been generated. The test database will not contain any live data. The database will be accessed via the following URL: XXX.

X user accounts have been generated to test the database. These accounts have been assigned the following user roles: XXX. Additionally, one tester will not be given a user account in order to test security.

The following staff roles within the research team have been delegated responsibility for testing the database: XXX.

1. **Test Scripts**

Test scripts will be prepared to test the following functions of the database, and the following Case Report Forms (CRF) pages:

Features:

e.g.

* User roles
* Password authentication
* Randomisation
* Unblinding
* Query generation
* Query resolution
* Audit trail
* Investigator sign-off
* Encryption

CRF Pages:

List the CRF pages to be tested. In a software category 4/5 database, all fields should be tested. In a software category 3 database, some low-risk pages may be excluded from testing (e.g., CRF pages not relating to participant safety, eligibility or primary or secondary outcome measures.)

The following types of test scrips have been prepared [select all appropriate test types and remove any others]:

**Requirement of entering the value** – checking if the data needed to be entered is possible to be entered in a particular field

**Format of values -** checking if all variables are of expected format

**Range checks** – checking if all variables are of expected ranges by using tests for values, which are:

* within expected range (approximately central value between two extremes)
* within expected range, but close to the extreme values
* within expected range, equal to extreme values
* beyond expected range, but close to the expected extreme values
* far beyond expected range at both sides of extremes

**Negative value check** – to assess if any numeric data is not negative

**Future Date Checks** – to evaluate if the data fields forbid entering future dates

**Multiple data fields** – to check, if the fields that should be repeating during the study, work properly within different visits (i.e., Concomitant Medications, Adverse Events)

**Duplicated data** – to assess if any field was double - added incorrectly to the eCRF

**Auto-queries** – checking, if all queries set while designing auto-queries appear in the right position, under the proper circumstances

**Confirmation of logic between particular fields** – checking if all logic conditions are valid and work properly

**Regression testing** – checking, if changes in the structure of tested eCRF will not damage other parts of the system

**Comparing extracted data to the original** **data** – checking, if the data downloaded from the tested database, is the same as the original data, entered to the eCRF

**Personal data protection evaluation** – to check, if all data entered into the eCRF are prevented from possibility of patient identification

**Correction of lab values units and** ranges – checking, if the lab values units in eCRF are correctly counted into standard international units, and if their lower and upper range values are compatible with standards

**Patient ID Number check –** to evaluate if each patient has unique ID number, consistent with the numbering set up while designing the eCRF

**Unscheduled, Follow-up visits** **check** – to assess if designed database contains appropriate forms to manage with Unscheduled of Follow-Up visits, covered in the protocol.

Blank and completed test scripts will be located in [electronic file location] and filed in the Trial Master File (TMF).

1. **Testing Procedure**

The database developer will notify testers when the database is ready for testing. Testers will access the database via URL and log in using their test account.

Testers should check that all functions and CRF pages required by the database specifications are present, note any absent functions or CRF pages and notify the database developer.

Testers should complete the allocated test scripts noting who completed each test, the date that each test was completed and whether the test passed or failed. Testers may also add comments to the test scripts to advise the database developer.

Completed test scripts should be returned to the database developer who will review which tests passed and failed, and any comments. The database developer will update the test database to address any failed fields or functions and notify the testers when the update has been completed.

Testers will complete a second round of testing on the database. All failed tests must be rerun to confirm whether they now pass or fail. Testers should also consider whether any other tests need to be rerun – e.g., fields associated with fields that have failed testing. Retests will be documented as before, and the test scripts will be sent to the database developer for review.

Database testing and updating will continue until the database meets all pass criteria as defined below.

1. **Pass criteria**

State that testing will continue until as test scripts pass or justify lower pass criteria.

1. **Test Report**

Once testing is complete, a test report will be prepared to summarise the testing that has taken place. All completed test scripts and the test report will be filed in the TMF.