**SHORT STUDY TITLE**

Long Study Title

STUDY DATABASE:

Requirements and Specifications

|  |  |
| --- | --- |
| Chief Investigator: | Insert |
| Sponsor: | Insert |
| Sponsor Reference: | Insert |
| IRAS Reference: | Insert |

|  |  |  |  |
| --- | --- | --- | --- |
| Role | Name | Signature | Date |
| Author |  |  |  |
| Chief Investigator |  |  |  |
| Statistician |  |  |  |
| GCP manager |  |  |  |

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**ABBREVIATIONS**

|  |  |
| --- | --- |
| Barts Health | Barts Health NHS Trust |
| CI | Chief Investigator |
| CRF | Case Report Form |
| EU | European Union |
| IRAS | Integrated Research Application System |
| JRMO | Joint Research Management Office |
| MedRA | Medical Dictionary for Regulatory Activities |
| PI | Principal Investigator |
| QC | Quality Control |
| Queen Mary | Queen Mary University of London  |
| SOP | Standard Operating Procedure |
| TMF | Trial Master File |
| UAT | User Acceptance Testing |
| UK | United Kingdom |

**BACKGROUND**

The SHORT STUDY TITLE requires a study specific database for the collection, storage and reporting of all study data.

In SHORT STUDY TITLE X patients will be enrolled to receive insert details of intervention. Approximately, X patients will be screened to recruit X. The following data is being collected:

The database will be locked at these time-points during the study:

* Insert details of interim analysis
* Prior to DMEC meetings ( if applicable)
* At end of study within X days of receipt of last Case Report Form (CRF) page for last study patient

*As a guidance note consider if a soft lock or hard lock will be required at various point in the study.*

At these time-points the database will be transferred to an appropriate statistical software package for analysis following the Study Statistical Analysis Plan.

No identifiable patient information is being collected as part of this study.

*Or,*

The following patient information is being collected as part of this study:

* Insert details i.e., hospital number, full name, address etc

This information will/will not be stored in the study database. This has been documented in the protocol & Integrated Research Application System (IRAS) form the agreed by the sponsors demonstrated by the protocol and sponsor approval.

This database will be designed and maintained in compliance with Joint Research Management Office (JRMO) Standard Operating Procedure (SOP) 38b Trial Data Management Systems.

< insert here if any additional local SOP will be followed : Statistical or database build SOPs for example>

This database will be built using < insert name and version of the database you will be using > and hosted < insert >. The < insert > team will be responsible for the database build, testing and maintenance**.**

1. **PURPOSE**

This document describes the requirements from which the SHORT STUDY TITLE database was designed and maintained.

1. **DATABASE REQUIREMENTS**

The following are requirements for the SHORT STUDY TITLE database:

|  |
| --- |
| 2.1Data* The database will be configured to capture the data defined in the SHORT STUDY TITLE CRF Specification (version, date) / section 4 of this specification.
* Participants will be identified via a unique identification number and duplicate entries cannot be made.
* The database will distinguish between missing/ incomplete data and unknown data.
* The database will allow for formatting of data fields, including conditional formatting where required.
* The database will consist of mandatory and non-mandatory fields.
* Data entry will be restricted to appropriately delegated training staff .
* Completed pages will be lockable.
* It will be possible for the Chief Investigator (CI) and Principal Investigator (PI) user roles to electronically sign completed pages.
* Comments can be added to data fields.
* Access is available to all metadata.
* Data will be encrypted at rest.
* Medical Dictionary for Regulatory Activities terminology will be used to log all adverse events.
* Blinding will be protected ( remove if an unblinded study)

*As a guidance note, these are minimum requirements and must be included in the database capabilities. If you are unsure if the database can perform them, please speak to the allocated GCP manager immediately as your software may not be suitable.* |
|  |
| 2.2QueriesThe database will be configured to raise automatic queries as defined in the SHORT STUDY TITLE CRF Specification (version, date):* It will be possible for the monitor user role to manually raise and close queries in the database
* It will be possible for some user roles to respond to open queries.
* The database will flag empty fields.
* There will be no/ There will be self-evident corrections permitted by the CI s data management . Please see <study specific data management plan> for full details.
 |
|  |
| 2.3Reports |
| * The database will be able to run reports as appropriate. All reports will be Quality Controlled (QC’d) as part of the set-up process or if a bespoke report is run on completion, ( please see <Study specific SOP XX>).
 |
| 2.4Export for Analysis |
| * No analysis needs to be performed within the database. However, the database will be able to transfer data to an appropriate statistical software for analysis at required time points throughout the study.
* Data will be exported without alteration.
 |
| 2.5Maintenance and periodic review  |
| * An appropriately trained individual must be identified to maintain the database for the duration of the study. This includes:
* Rectifying problems
* Updating the database as appropriate (i.e.: with CRF amendments etc)
* Providing training to new users of the database, and ongoing support to existing users.
* Ensuring that the database is backed up regularly and that the backups are stored in a separate secure location.
* Ensure the Sponsor is sent details of any changes made to the data base
* Reviewing the database every xxx months
* The database will be version controlled.
 |
| 2.6Storage and Security |
| * The database must be hosted on a secure server with access restricted to authorised personnel. The server will be located within Barts Health NHS Trust (Barts Health) / Safe haven for Queen Mary University of London (Queen Mary) / XXXXX within the United Kingdom / XXXXXX within the European Union
* The server will have an emergency power supply and have appropriate protection against fire, flood and vermin.
* Firewall and antivirus systems will be in place, with regular patching and a penetration testing schedule.
* The database will feature role-based access with individual user accounts.
* User accounts will be password protected or use a similar method of authentication.
* All linked components will be protected to the same standard.
* Storge and security arrangements will be detailed in, Study specific SOP XXXX>
 |
|  |
|  |
| 2.7Audit* The database will have a full audit trail to identify:
	+ Who has entered, amended or deleted data.
	+ When the data was entered, amended or deleted.
	+ What the original data was prior to the change.
* The database will provide the option for users to provide an explanation for changes that they have made to the data.
* The database audit trail will be built to enable audit trails to be viewed per filed, per participant, per site or per user.
* The audit trail will be reviewed periodically by XXXXXX < insert details of when and how> , for full details please see < study specific SOP XXXXXX>
 |
| 2.8Archive |
| * The database and its outputs must be archived at the end of the study as an electronic file in a format that can be accessed for a minimum of 25 years as per Sponsor policy.
* **The < insert precise location, host and system to be used> will be used for archiving.**
 |

**3.DATABASE CONSTRUCTION**

3.1 Program

Insert Program and version to be used

*Guidance note: This section should include as much detail as possible regarding the software or contractor*

3.2 Design

Database design and specification have been agreed with the CI and Study Statistician, based on version X, date of the protocol and version X date of the CRF specification / as defined below.

The following study specific pages will be utilised:

*Guidance note: This can be a separate document (Including an excel document)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Access Form Name | Field Name | Field Type (drop down, free text, number, date, radio-button. Include formatting requirements) | Options (i.e., list of drop downs or title or radio-button etc) | Mandatory or Not Mandatory? | Conditional formatting / auto query conditions |
| i.e., Baseline |  |  |  |  |  |
|  |  |  |  |  |
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|  |  |  |  |  |  |
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|  |  |  |  |  |

If data is missing, and will never be obtained, XX (insert agreed format for example 01/01/1900 for a date or 9999 for a figure etc) will be used to identify this, this will be made clear in the <Study specific CRF or data base manual>

3.3 Building

Building the database is primarily the responsibility of the insert role but may be assisted or backed up by the <Insert Role> as delegated by the CI.

The Insert role of person building database has been appropriately trained to build the database, by attending course name or description. Record of attendance on this course can be found in the Insert role of person building databases training file.

3.4 System testing

 The XXXXXX (insert role) will review the database once built to conduct system tests and confirm that the database has been built to specifications. This will occur prior to User acceptance testing. This will be fully documented in the test plan and report.

*Guidance note: The testing role should ideally be a separate person to the person responsible for the database build.*

3.5 User Acceptance Testing

A test plan will be created and signed off by CI and statistician prior to commencement of any testing .

Persons:

User Acceptance Testing (UAT) will be performed by the Research team, who are suitably experienced and trained and be delegated responsibility on the study delegation log. One tester will not hold authorisation access (unauthorised user).

*Guidance note: UAT should be performed by at least 2 separate people. One of whom should not have been involved in the specifications or build and one of who should be a user ( e.g., site staff)*

Process:

Testing scripts will be devised to perform UAT. These will be devised after the database has been built and System testing occurred. Copies of these will be available in the Trial Master File (TMF).

Scripts will also be created for report templates that have been created within the system.

Documentation:

The process of UAT will be fully documented on the testing scripts.

The individuals involved in UAT will collate their results to produce one report summarising the outcomes of UAT on the database.

A UAT report or summary should be written once all testing has been completed.

3.5 Approval

Results and evidence of UAT will be provided to the CI or designate team member who will evaluate if all requirements have been successfully met. CI and Statistician will sign of the <study specific database approval form> prior to forwarding it to the allocated GCP manager for approval and final signoff. The go live for the study will be the confirmation of Sponsorship by the sponsor.

Approval will only be given if all requirements have been met, or rationale provided if any requirement is not met.

Approval will be documented using the approval form. All documentation will be filed in the TMF