**Data Management Plan**

**ATLS Study**

|  |
| --- |
| **Effects of Advanced Trauma Life Support®**  **Training Compared to Standard Care on Adult**  **Trauma Patient Outcomes: A Cluster**  **Randomised Trial** |

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**CTRI number:**

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**DOCUMENT HISTORY**

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| 1.0 | 13 March 24 | ATLS Study Data Management Plan | Mr. Manoj Soni |
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# Abbreviations

ATLS Advanced Trauma Life support

LMIC Low- and Middle-Income countries

PTC Primary Trauma Care

CDMS Clinical Data Management System

CRF Case Report Form

CTRI Clinical Trial Registry of India

NELS National Emergency Life support

PHTLS Pre-Hospital Trauma Life support

DMP Data Management Plan

eCRF Electronic Case Report Form

EDC Electronic Data Capture

ATCN Advanced Trauma Care for Nurses

GCP Good Clinical Practices

ISF Investigator Site File

TMG Trial Management Group

DMC Data Monitoring Committee

TSC Trial Steering Committee

GDPR General Data Protection Regulation (European Union)

GDS Data management system used by George Clinical

GUI Graphical User Interface

LPFV Last Participant First Visit

LPLV Last Participant Last Visit

MOP Manual of Operations

NA Not Applicable

PII Personal Identifying Information

QC Quality Control

SAE Serious Adverse Event

SDV Source Data Verification

TGI The George Institute

UAT User Acceptance Testing

URL Uniform Resource Locator

# Introduction

This Data Management Plan (DMP) specifies the tools and processes that will be used by The George Institute in the generation of the clinical database from project set-up through to database lock and then to data archival, data sharing or data destruction. This document may be revised during course of project to address changing needs of the project. Revisions to the DMP will be reviewed and approved before changes are implemented.

The original DMP and any revisions will be filed in this document and will be kept with data management team . A copy of the DMP and any revisions will be provided to the Sponsor/ Chief Investigator and to the project team members.

# Contact List

|  |  |  |  |
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| **Task** | **Contact Person** | **Organisation** | **Email** |
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| Funder and co-Sponsor |  | Swedish Research Council |  |

# Project summary

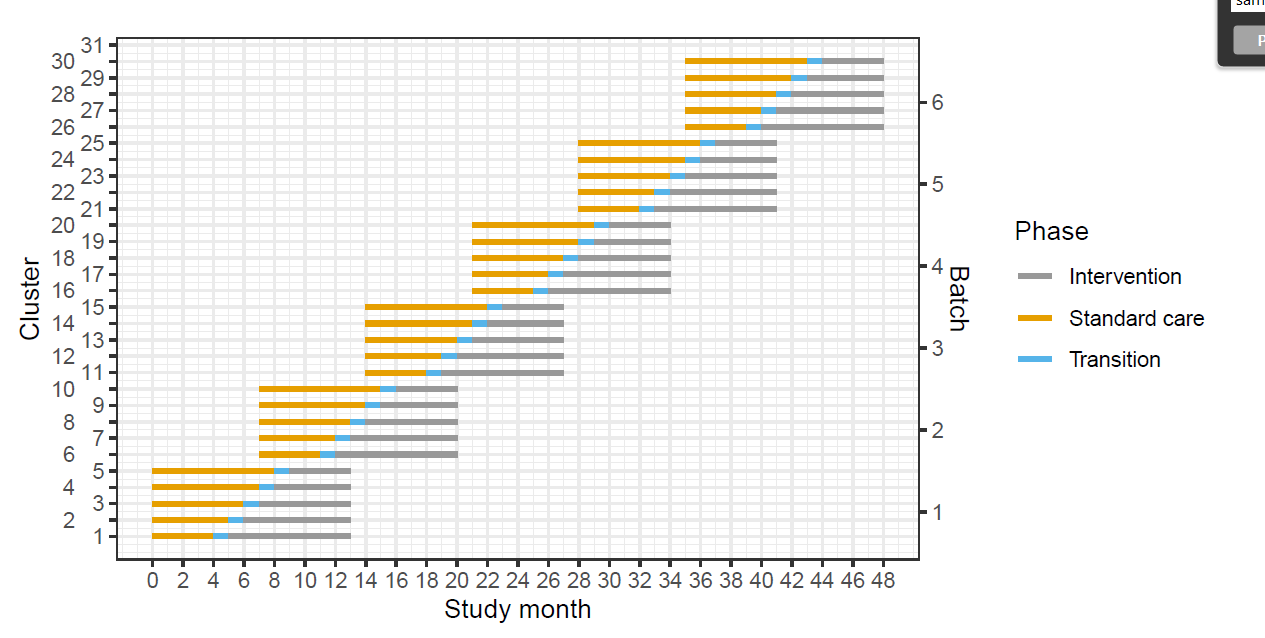
## 3.1 Protocol summary

|  |  |
| --- | --- |
| **Study title** | Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial |
| **Running title** | ATLS Study |
| **Version Number and Date:** | 0.6.1, 22 February, 2024 |
| **Funder:** | Swedish Research Council |
| **Study Principal Investigator:** | Dr Vivekanand Jha, New Delhi |
| **Sponsor** | karolinska institutet |
| **Data Coordinating Centre** | The George Institute for Global Health, New Delhi |
| **Primary Contact** | Dr Abhinav Bassi  Senior Research Fellow and Operations Lead - CORE India  Dr Samriddhi Ranjan  Project Manager |
| **Trial coordinating centre** | TGI, New Delhi |
| **Background** | Several trauma life support training programmes have been developed to improve the early management of patients in the hospital by providing a structured framework for assessment and treatment. The proprietary Advanced Trauma Life Support® (ATLS®) is the most established trauma life support training programme and more than one million physicians in over 80 countries have been trained in the programme since the first course in 1978. In the US and many other countries training in ATLS® is virtually mandatory for trauma care physicians. Uptake in low- and middle income countries (LMIC) has been slow, potentially due to high costs. |
| **Rationale** | Trauma is a massive global health issue. Many training programmes have been developed to help physicians in the initial management of trauma patients. Among these programmes, Advanced Trauma Life Support® (ATLS®) is the most popular, having trained over one million physicians worldwide. Despite its widespread use, there are no controlled trials showing that ATLS® improves patient outcomes.  **Aim:** To compare the effects of ATLS® training with standard care on outcomes in adult trauma patients.  **Primary Outcome:** All-cause mortality within 30 days of arrival at the emergency department. |
| **Population** | Adult trauma patients above 15 years of age presenting to the emergency department of a participating hospital. |
| **Intervention** | The intervention will be ATLS® training, a proprietary 2.5 day course teaching a standardised approach to trauma patient care using the concepts of a primary and secondary survey. Physicians will be trained in an accredited ATLS® training facility in India. |
| **Control** | Standard Care |
| **Drug distribution** | NA |
| **Outcomes** | Primary outcome: The primary outcome will be all-cause mortality within 30 days of arrival at the emergency department.  Secondary outcomes:   * All-cause mortality within 24 hours and three months of arrival at the emergency department. Data on this outcome will be collected in the same way as for the primary outcome. * In-hospital mortality within 30 days of arrival at the emergency department. Data on this outcome will be collected in the same way as for the primary outcome. * Quality of life within seven days of discharge, and at 30 days and three months of arrival at the emergency department, measured by the official and validated translations of the EQ5D3L. Data on this outcome will be collected in person if the patient is still in hospital, or by phone if the patient has been discharged. We will collect this data from a stratified random sample (site and period) of patient participants. The sampling will be designed so that is maximises statistical efficiency. * Disability within seven days of discharge, and at 30 days and three months of arrival at the emergency department, assessed using the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0). Data on this outcome will be collected in person if the patient is still in hospital, or by phone if the patient has been discharged. This data will also be collected from a stratified random sample of participants. * Return to work at 30 days and three months after arrival at the emergency department. Data on this outcome will be collected in person if the patient is still in hospital, or by phone if the patient has been discharged. * Length of emergency department stay. Data on this outcome will be collected from patient hospital records. * Length of hospital stay. Data on this outcome will be collected from patient hospital records. * Intensive care unit admission. Data on this outcome will be collected from patient hospital records. * Length of intensive care unit stay. Data on this outcome will be collected from patient hospital records. |
| **Expected SAE** | Any untoward medical occurrence in a trial participant that:  • leads to death  • is life-threatening  • requires inpatient hospitalization or prolongation of existing hospitalization  • results in persistent or significant disability or incapacity  • results in a congenital anomaly/malformation |
| **Randomization** | Cluster randomization within batches |
| **Follow-up time points** | Daily, 24 hours, 30 days, 90 days |
| **Follow-up activities** | Mortality data collection |
| **Sample size** | 4320 |
| **Sites** | 30 (In 6 batches) |
| **Data capture** | Electronic data capture (EDC) using REDCap |
| **Data monitoring** | REDCap and PowerBI/MS Excel |

## 3.2 Role and responsibilities

| **Role** | **Responsibility** |
| --- | --- |
| **Project Lead** | -Approve CRF  -Approve database design specification  -Approve validation of databases  -Approve user-roles  -Approve CRF manual  -Approve data review plan  -Approve database lock  -Approve Statistical analysis plan |
| **Database designer** | - Designing the database in REDCap  -Integration of databases  -Database validation  -Support for any database related issues through the trial  -Impact analysis for change control |
| **Data manager** | -Provide approved database design specifications  -Validate database  -Site, user and role management  -Execute data review  -Generate and share monthly reports  -Query management  -Final data export  -Subject lock/Study lock |
| **Database administrator (System admin)** | -New Study set up  -Trouble shooting in access  -Approval of new users  -System security  -Database lock  -Database backup/recovery |
| **Clinical monitor** | - Site initiation and training  - Source data verification  - Raise queries |
| **Project manager** | -Overall trial conduct |
| **Statistician** | -Development of Statistical analysis plan  -Prepare interim report  -Execution of analysis |

## 3.3 Design Justification



## 3.3 Flow of data management activities across teams

# Milestones, Considerations and Blinding

## 4.1 Project and Data Milestones

A summary of key project and data milestones are provided in the table below.

| **Milestone/Task** | **Responsibility** | **Planned Date** | **Actual Date** |
| --- | --- | --- | --- |
| **Project Milestones** | | | |
| Final protocol | Chief Investigator |  |  |
| Ethics committee approval | TGI |  |  |
| Data collection start (eg. FPFV) | Clinical Sites |  |  |
| Data collection end (eg. LPLV) | Clinical Sites |  |  |
| Database lock | Data Manager |  |  |
| Statistical report | Statistician |  |  |
| Project closure | Study PI |  |  |
| Publication | Study Team |  |  |
| Archive | Data Manager |  |  |
| Data sharing | Investigator |  |  |
| **Data Management Tasks** | | | |
| Randomisation database | Study team/DM Manager |  |  |
| Data collection form/ CRF design | Project Manager |  |  |
| Database design and build | Data Manager |  |  |
| Edit check programming | Data Manager |  |  |
| Database and edit check testing/ UAT | Data Manager |  |  |
| Database go-live | Data manager |  |  |
| Report design and build | Data Manager |  |  |
| Project report runs/ preparation | Data Manager |  |  |
| Data exports/ extracts | Data Manager |  |  |
| Safety/medical review | Chief Investigator and CDSA team. DSMB appointed for the study |  |  |
| Query generation, tracking and resolution | Clinical Sites and Project manager |  |  |
| Coding | Not applicable |  |  |
| Clinical and safety database reconciliation | Not applicable |  |  |
| Paper form/ document storage & archive | Clinical sites Team |  |  |
| Electronic archive | Data Manager |  |  |
| Data destruction |  |  |  |

## 4.2 Data Management Considerations

A summary of all the data management considerations that are likely to impact data collection, storage, use or sharing for this project are provided in the table below.

| **Data Management Factor** | **Applicable?** | **If Yes,** |
| --- | --- | --- |
| Consent | Yes | Consent is obtained on Paper form and kept in clinical sites. |
| Blinding | No | NA |
| Randomization | Yes | Randomization will be done for the hospital batches |
| Drug intervention | No | NA |
| Data or participants are from outside India | No | NA |
| Language other than English required | No | NA |
| Paper data collection forms | Yes |  |
| PII/ sensitive data collection and processing | Yes | Name of the patient is being collected. Database access will be with authorized personnel and this variable will be excluded before export of the data. |
| End point adjudication | No | NA |
| Data linkage | No | NA |
| Data storage & security | Yes | Data is stored in REDCap server, India office.  Data is downloaded by data manager and study team as per need. Data files to be kept in project’s folder in TGI Network drive. |
| Big data storage/ data processing requirement | No | NA |
| Data destruction | No | NA |
| Electronic data archive | Yes | Electronic data archive will be done by Data Manager. At first level all data files, meta data, pdf attachments (Source data),eCRFs, Logs will be downloaded and filed in TGI Network drive.  Another level of archive will be done in the REDCap  Consent forms and essential documents will be stored at the clinical sites. |
| Data sharing | No | The codebook will be made available in a data sharing repository (e.g., GitHub or Zenodo), connected to a unique DOI. Upon the publication of the primary research findings, an anonymized version of the dataset will be released under the same DOI as the metadata. The data will be shared under the Creative Commons Attribution 4.0 license. |

## 4.3 Blinding and Unblinding

The table below summarises the blinding and unblinding requirements for the study.

|  |  |
| --- | --- |
| Blinding requirements | NA |
| Unblinding requirements | NA |

# Project Data and Database Systems

## 5.1 Project Data Set

The table below lists the data sets and their sources that will be used for this project.

| **Data Description** | **Data Source** | **Country of Source** | **Method to Collect Data** | **Responsibility** | **Data Retention Period** | **Data Destruction Date** |
| --- | --- | --- | --- | --- | --- | --- |
| eCRF Data | Patient medical records ( MRI, USG, X-ray, MRI) | India | Web based EDC | Sites | Permanent | NA |
| Project documents | Prepared during project activities | India | Offline saved files | Study team | Permanent | NA |
| Participant Reported Outcomes | EQ-5D-5L & WHODAS & CRF data of Project participants | India | Paper form completion at site | Site staff | Permanent | NA |
| Serious Adverse Events data | SAE form | India | Paper form completion at site | Site staff | Permanent | NA |

## 

## 5.2 Data management systems

The following hardware and software systems will be utilised for the managing and processing data for this project.

| **Hardware/ software and version number** | **Vendor** | **Tasks** | **Contains PII/ Sensitive Data\*** | **Primary Data Centre** | **Secondary Data Centre** |
| --- | --- | --- | --- | --- | --- |
| REDCap  V 13.1.29 | Vanderbilt University (TGI License) | Develop, deploy and configure eCRF and deploying the database. All data collection is done using this database. | Yes | India |  |
| MS Office Applications (Word, Excel, and Power point) | Microsoft | Screening and follow up tracking and other project activities | Yes | India |  |
| Power BI | Microsoft | Preparing dashboard | No |  |  |
|  |  | Data analysis | No |  |  |

All clinical data management systems are password protected and access will be restricted to the project team members. All data files will be stored in a secure network directory and access will be restricted to the project team members.

\* see Personal Identifying Information and Sensitive Data Handling section for definitions of PII/ Sensitive Data

# Privacy, Identifiers and Linkage

## 6.1 Personal Identifying Information and Sensitive Data Handling

**Personal Identifying Information (PII)** is defined as any data item or combination of multiple data items that can be used to directly identify an individual project participant. The collection, processing, storage and destruction of PII must ensure protection of the confidentiality of project participants at all times and ensure that the PII data is only used for the purpose for which it was consented.

**Sensitive information** is a sub-set of PII that also requires higher levels of protection and handling. Examples include an individual's health, racial or ethnic origin, political opinions, membership of a political association, professional or trade association or trade union, religious beliefs or affiliations, philosophical beliefs, sexual orientation or practices, criminal record, biometric information that is to be used for certain purposes, and biometric templates.

The table below summaries the PII that will be collected for the project and the security measures that will be applied.

|  |  |
| --- | --- |
| **PII Collection** | |
| Data items collected |  |
| Purpose of PII |  |
| Collection method and tools | Paper/EDC system(REDCap). |
| Security measures to protect PII during collection | All data entered by sites in a web-based password protected EDC system with a role-based access and can only be accessed by Data Manager.  PII data will be excluded before sharing with statistician and study team. This PII will be linked using a unique identifier. |
| **PII Processing** | |
| Subject anonymisation | REDCap automatically generates record ID which is linked with PII. |
| Who will have access to identifiable PII data? | Clinical sites, study team |
| Security measures to protect PII during processing | Completed paper form and patient tracking sheet s will be securely stored at the Site with access restricted to authorised individuals. |
| Sharing of PII data | No information that contains PII will be shared. |
| **PII Storage at TGI** | |
| Storage locations of PII data | Not applicable and no data is stored at TGI servers |
| PII retention | It will be there in only project database developed in REDCap |
| Security measures to protect PII during storage | REDCap server will have access only to authorised personnel. REDCap server data is backed up on regular interval as per IT Policy. |

## 6,2 Unique subject identifier

Each subject enrolled in the project will have a single unique identifier record id assigned by REDCap. Depending on sites, this identifier can be customized based on site code used in the study.

## 6.3 Data Linkage

|  |  |
| --- | --- |
| **Mechanism of linkage** | NA |
| **Linkage restrictions** | NA |

# Data Quality and Change Management

## 7.1 Data Quality and Review

Data quality will be ensured at various levels. These are as follows:

1. UAT of database
2. Training of site staff
3. Electronic data capture
4. Source data verification
5. Data review checks/Dashboard

**a) UAT of database**

The database will be validated as per the validation plan before being moved for production. This validation plan includes the plan for testing, procedure for documentation of testing along with steps to ensure change control procedures are in place. This step is done after building of database (eCRF with edit checks) and integration with IWRS, and before moving the database to production. The validation team and responsibilities are listed below.

|  |  |
| --- | --- |
| **Role in CDMS** | **Responsibility** |
| Study PI/Project Lead, TGI | Approval of plan  Approval of database to move to production |
| Data manager, TGI | Develop, execute and document the validation process |
| Database designer, TGI | Update as per testing procedure  Ensure change control plan is in place |
| User acceptance testing, Study team | Give feedback on the eCRF and the associated CRF instruction manual |

The following steps will be followed for testing the EDC.

**Step 1:** Creation of dummy CRF with various scenarios mimicking real-life situation. Refer to associated documents, database design specification with the associated edit checks.

**Step 2:** Testing the following aspects in the staging version of the database

* Creation of site and users work-flow
* Assigning roles and sites to users
* Enrolling patients (unique screening ids)
* CRF flow
* Upload and download of documents if required
* Format of the eCRF (layout) and typo errors
* Tab order and skip patterns of questions within CRF
* Automated in-built checks for missing values and valid ranges. Display of error messages
* Functioning of cross-form checks, hard checks
* Auto query generation and resolution with audit trails
* Report generation as per entry in the Dashboard
* Format of data in excel
* Exporting data to excel and merge all forms to ensure data structure integrity. Also check for variable name against data description, data type, coding, date format and missing value format
* Importing data to Stata to ensure data structure integrity if required

**Step 3:** Document the testing results in the validation sheet and share with developers

Repeat, **Step 2** and **3** until all issues are resolved.

**Step 4:** Give access to study sites or use dummy sites (at least 2 sites (site investigators, site co-ordinators role) for user acceptance testing.

**Step 5:** Summarize the testing results as per Validation and UAT format and move to production only after approval. Any changes after moving to production will follow change control procedures.

**b) Training**

**Person/team responsible:** Manuals will be developed by study team and are responsible for the training.

For training purposes of the clinical site, trial monitor and data manager following manuals will be developed.

* eCRF guidelines
* Data Monitoring guidelines

All manuals will be placed in project’s Network drive.

**c) EDC**

**Person/Team responsible:** Database development Team and Data Management Team

EDC is developed with data type checks, range checks, skip patterns to ensures the validity of data items in the CRFs. When entering invalid inputs, appropriate messages come in and auto queries are generated. The list of these checks is saved within the REDCap dictionary.

**d) Source data verification**

**Person/Team responsible:**  Clinical site team

When a mismatch is found during source data verification, a manual query is raised in query management system by trial monitor. The clinical monitor will do SDV of critical data that may include various data points decided by study team. The critical fields that can undergo SDV via EDC are as follows.

**e) Data review checks/Dashboard**

**Person/Team responsible:** Project Manager and Data Manager

The scope of data review will be to identify discrepancies that may not be detectable by inbuilt automatic checks or by SDV and to facilitate data-assisted trial operations. Dashboard will also be developed in Power BI. The data manager at TGI will be responsible for running the data review routines and generating periodic reports. Reports will be either made in MS Excel or Power BI or both.

## 7.2 Database Change Management

Changing a database after the database is live is not ideal and no one wants this to happen. However, when if there is any change in the existing database is required, proper impact analysis needs to be done.

Any changes to the CRF content, structure and edit check post-production will have to approved by the Study PI/Project Lead before changes are made to the database. Post changes the database will be tested and the extent of test will depend on the impact of change.

The postproduction changes will be documented by the data management team as follows.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Change request number** | **Location of change** | **Reason for change** | **Impact of change** | **Date of change** | **Associated document** |
| *xx/date/CRFname* | *Associated item:*  *Nature of change:* |  | *Entry screen*  *Derived field*  *In the CRF completion manual*  *Data extraction tables*  *Validation of data*  *Data collected before change* |  | *Annotated CRF, Impact analysis document* |
|  |  |  |  |  |  |

# Coding, Database Reconciliation and Exports

## 8.1 Coding Dictionaries

NA

## 8.2 Clinical and Safety Databases Reconciliation

Any SAE will be documented in study specific event forms. SAE form is a paper form that is used for submission to institutional ethics committee. The scanned pdf of the form will be uploaded as a source data to the event form. No reconciliation will be required.

All safety events will be recorded in the Case Record Form (CRF) and reported to the trial

management team within 24 hours of its occurrence. The trial management team will then

assess if the event can be considered related to the trial or the intervention within 24 hours of

it being reported. Events that are considered probably related will be reported immediately

to the combined Trial Steering and Data Monitoring Committee.

## 8.3 Data Export

Data exports will be performed as needed. Once the project is live, a planned can be made available and written below.

| **Export Purpose** | **Format** | **Export Date** | **Responsibility** |
| --- | --- | --- | --- |
|  | MS Excel |  | Data Manager |
|  | MS Excel |  |  |
|  | MS Excel |  |  |

# Database Locks and Archiving

## 9.1 Database Locks

The table below details the database locking requirements for this project.

| **Lock** | **Required** | **Description** |
| --- | --- | --- |
| Soft lock | Yes | Frequency: As Advised by Study Investigator  Who: Data Manager  What is locked: All CRF’s editing  Soft lock can be applied with or without open query.  Will done before interim analysis and before hard lock for the final QC |
| Hard lock | Yes | Frequency: After all CRFs data entered and all queries closed.  Who: Data Manager  What is locked: All CRF’s editing  Hard lock cannot be applied with open query.  Will be done when final QC is done. All data captured, queries resolved, no diagnostic discrepancies outstanding, coded data reviewed and updated as required, signed Investigator declaration, write access to database revoked for all users except the system administrator. |
| User lock | Yes | Frequency: On site closure or on request.  Who: Data Manager  What is locked: Access to EDC by user.  Users can be unlocked at any point of time.  Will done when user leaves the trial team or at the the end of project |
| Site lock | Yes | Frequency: On Site closure or on request.  Who: Data Manager  What is locked: Access to site in EDC  Sites can be unlocked at any point of time.  Site closure |
| Study lock | Yes | Frequency: On Study closure  Who: Data Manager  What is locked: Access to study in EDC  Study can be unlocked at any point of time.  When final analysis is complete and approved for publication |

## 9.2 Paper Storage and Archiving

Data sharing considerations for this project’s data are summarized in the table below.

|  |  |  |
| --- | --- | --- |
| **Task** | **Responsibility** | **Location** |
| Paper CRF and document location during the active project phase | Site PI | Site |
| Paper CRF and documentation archive | Site PI | Site |
| Electronic archive | Data manager | TGI Network drives at the Excel export level |

# Data Sharing

Data sharing considerations for this project are summarized in the table below.

|  |  |
| --- | --- |
| **Data owners** |  |
| **Participant consent** |  |
| **Data sharing model** |  |
| **Data sharing content** |  |
| **Other content to share** |  |
| **Data sharing period** |  |
| **Permitted analysis** |  |
| **Sharing mechanism** |  |
| **Data sharing notifications** |  |

# Storage and Security Measures

The study database is built using REDCap. The study is built by the study team.

The database security procedure will follow the IT department’s server security guidelines.

Key features include.

* Restricted access to study database
* System admin permission to access from external IPs
* Audit log of uploaded or downloaded data or data change
* Activity log
* System admin permission for all new users
* Password strength, password changing and password renewal policy.
* Connection time out will be 30 minutes in case of inactivity

The access to the EDC application is restricted to clinical site PI and is password protected. All users will be approved by system administrator. The users, the role of users and the accessibility options as per agreed responsibility log will follow the procedures laid out in the data manager manual The sites will have only access to the eCRF. The data extraction option will only be available with the data manager/designer of the database. The log of the extraction of CRF, data or any reports are logged in the system that can be audited.

**Storage location:**

Physical location: TGI India, Hyderabad office.

Virtual location: <https://redcap.georgeinstitute.org.in/redcap_v13.1.29/index.php?pid=183>

**Access and permission**

User and password detailed are stored in the REDCap database system and in user access matrix document saved in DM folders and maintained by Data manger.

Users can be deactivated or unlocked upon receiving intimation from project manager about change of staff.

**Portable electronic devices**

Not data is stored in any portable devices

**Offline data collection**

None. All data are collected on the web-based platform only.

**Data anonymization**

* Personal information is stored in a secure EDC database and linking to the research data set using a unique identifier.

**Encryption**

Only File opening password-based encrypting may be used in some files. No other encryption is used.

**Backups**

Data extracted on a regular basis are kept in I drive which is backed up on as per TGI IT policy. All data related to the study is in the I drive.

**Data transfer**

* Data Transfer will be done after receiving a data request form. This will be a format decided towards study closure phase.
* Data files will be deidentified and may be encrypted using file opening password.

**Data destruction**

Not applicable

**Data archive**

Entire database can be archived by doing a study lock in the EDC database. This will be done after project closure. This is done by data manager.

Data file level archival will also take place by putting all data and meta data with a time stamp. This can be done either by using an external hard disk drive or on a network drive or both.

Archived data will be accessed to system admin.

# Additional Project information

## Dynamic reference list

This is a live document and will be updated through the period of the trial. The table summarises the list of live documents, the key contents, and the location in the designated Dropbox folder for this trial.

|  |  |  |
| --- | --- | --- |
| **Item** | **Content** | **Location** |
| **Data management plan by funding agency** | About the dataset summary and data sharing along with data properties such as data reusability, openly accessibility and data security. | // DMP\_ATLS\_Received from funding agency.docx |
| **Study sites** | Site contacting details and site credentials |  |
| **CRF** | All CRFs word document final version used in Database |  |
| **Database design specification/dictionary** | CRF wise variable details along with edit checks |  |
| **Validation report** | Validation details  Consolidated validation report |  |
| **CRF completion manual** | Manual for all study related data collection activities done by Site Investigator |  |
| **Data manager manual** | Manual for all data management activities of the study done by Data Manager |  |
| **Data monitoring manual** | Manual for data monitoring activities done by study monitor |  |
| **Data review plan** | Batch wise data cleaning plan until database lock |  |
| **Post-production changes to database** | List of changes with all relevant documents |  |