**Data Management Plan**

**ATLS Study**

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

V1.5 23.05.2024

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**DOCUMENT HISTORY**

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| --- | --- | --- | --- |
| **Version** | **Issue Date** | **Description** | **Prepared By** |
| 1.3 | March 23 | TERN Study Data Management Plan | KI |
| 1.5 | May 24 | TERN Study Data Management Plan | TGI |
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# Abbreviations

ATLS Advanced Trauma Life support

CDMS Clinical Data Management System

CRF Case Report Form

DMP Data Management Plan

eCRF Electronic Case Report Form

EDC Electronic Data Capture

TMG Trial Management Group

GDS Data management system used by George Clinical

GUI Graphical User Interface

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 (TGI) 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/ Principal Investigator and to the project team members.

# Contact List

|  |  |  |  |
| --- | --- | --- | --- |
| **Task** | **Contact Person** | **Organisation** | **Email** |
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## 2.2 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/ Manager** | Designing the database in REDCap  -Integration of databases  -Database validation  -Support for any database related issues through the trial  -Impact analysis for change control  -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 (CRA)** | - Site initiation and training  -Onsite monitoring  - Source data verification  - Raise queries |

## 2.3 Flow of data management activities across teams

# Project milestones

## 3.1 Project and Data Milestones

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

| **Milestone/Task** | **Description** | **Actual Date** |
| --- | --- | --- |
| Final CRF | PDF of the eCRF that is generated by REDCap | 22 March 24 |
| User access document | Name, email, and role of those who have access to the production version of study database | TBD |
| Database moved to production | Validation checklist and approval for moving Database to production | TBD |
| Data collection start | Date of First Patient first visit | Oct 2024 |
| Interim analysis | Safety data summary | TBD |
| Data collection end | Date of Last Patient last visit | 2029 |
| Final QC | Reconciliation, Query resolution, | 2029 |
| Soft Lock | Batchwise form lock | Progressively as batch data collection is completed |
| Database lock | Approval to database lock. Remove access to sites | 2029 |
| Final data | Data shared with statistician with final data quality report | 2029 |
| Project closure (Data management) | After site closure procedures and reports are complete. DMP completed and filed. | 2029 |
| Archive | Archival of study data | Batch wise (data) |

## 3.2 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 | Collect on the paper and transfer to REDCap |
| PII/ sensitive data collection and processing | No | NA |
| End point adjudication | No | NA |
| Data linkage | No | NA |
| Data storage & security | Yes | Data is stored on REDCap server, India office.  Data is downloaded by data manager or the study team as per requirement. Extracted data files will be kept in project’s folder in TGI Network drive. |
| Big data storage/ data processing requirement | No | NA |
| Data destruction | No | NA |

# Database system details and file location

## 4.1 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  V13.1.29 | Vanderbilt University (TGI License) | Develop, deploy and configure eCRF and deploying the database. All data collection is done using this database. | No | India |  |
| Power BI | Microsoft | Preparing dashboard | No |  |  |

|  |  |  |
| --- | --- | --- |
| **Document** | **File name** | **Location** |
| TGI DM Service Request | *DM Request Form v1.0\_ATLS study* | *TGI ATLS KI Study TMF* |
| Trial protocol | *TERN protocol\_V1.0.0\_2024-03-28\_FINAL* | *TGI ATLS KI Study TMF* |
| Final CRF (PDF) | *CRF\_01.04.24\_v1.0\_TERN* | *TGI ATLS KI Study TMF* |
| Database validation plan and report |  |  |
| User Access document |  |  |
| Post-Production changes Documentation (PDF) |  |  |
| Routine data cleaning codes |  |  |
| Final quality report |  |  |
| Database lock |  |  |
| Project Closure report |  |  |

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.

# Privacy, Identifiers and Linkage

## Personal Identifying Information and Sensitive Data Handling

No personal identifying information is collected for this study.

# Data Quality and Change Management

## 6.1 Data Quality and Review

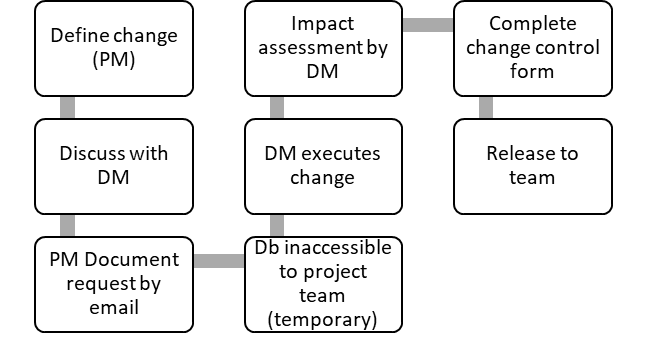
The study monitoring team and data management team will work in coordination to ensure data quality. The below flow describes the steps to be taken for data quality.

\*E-signature is currently set for the all the forms.

Manual queries will be raised by the CRA during SDV or during data review routines. These queries are answered by the investigator or site coordinator which will be closed by the Project Manager or CRA, upon a satisfactory/acceptable response. The CRA can lock the forms or record as and when the data is completed and reviewed.

## 6.2 Database Change Management

Any requests for post-production changes to the database content (including addition and/or removal of new forms, addition and/or removal of questions) will be reviewed and approved by the Project Manager. The Data Manager will execute the changes in change control environment. The EDC will be suspended briefly for mid-study updates and impact assessment to the data entered so far and existing CRF manual. Only after satisfactory validation the EDC can be resumed. Change request, documentation of change and impact assessment will be documented using a change request form (Post-Release changes document) and filed.



# Database Locks and Archiving

## 7.1 Database Locks

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

| **Lock** | **Required** | **Description** |
| --- | --- | --- |
| Soft lock | Yes | Frequency: As advised by Principal Investigator  Who: CRA  What is locked: CRFs event wise |
| Hard lock | Yes | Frequency: Once.  Who: Data Manager  What is locked: All the forms for all the records.  All data entered and SDV completed with all queries resolved. All access to database revoked. Study closure checklist/report required for all sites. |

The following task should be completed before database lock.

|  |  |
| --- | --- |
| **Task** | **Who does it?** |
| All forms completed by sites | Sites |
| SDV/QC done as per study requirements | CRA |
| PI signature (eSignatures) done | Site PI |
| SAE documentation complete | Project manager and CRA |
| All queries resolved or closed | Clinical research coodinator |
| Site permissions set to read only | Data manager |
| Approval for lock obtained | Project manager and Data manager |
| All records marked as locked | Data manager |
| Final quality report | Project manager |

## 7.2 Paper Storage and Archiving

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

Data manager will be responsible for the archiving of data management related documents. The data archival period is 15years from the time of database lock.

|  |  |  |
| --- | --- | --- |
| **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 |

# Data Sharing

TGI will share data with KI following the Joint Controller Agreement. All data sharing will be followed as per the TGI External data sharing policy.