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

V 2.0 Dated 10 June 2024
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DOCUMENT HISTORY

Version	Issue Date	Description	Prepared By
1.3	March 23	ATLS vs Standard Care Trial Study Data Management Plan	Martin Gerdin Wärnberg, KI
1.4	May 24	ATLS vs Standard Care Trial Study Data Management Plan	Manoj Soni, TGI

APPROVALS

Review and Approve	**Name:**	Martin Gerdin Wärnberg		
	Title:	Principle Investigator		
	Signature:		**Date:**	31 March 2025
Review and Approve	**Name:**	Abhinav Bassi		
	Title:	Co-Principal Investigator		
	Signature:	Abhinav Bassi Digitally signed by Abhinav Bassi Date: 2025.03.20 18:50:11 +05'30'	**Date:**	10 June 24
Review and Approve	**Name:**	Samriddhi Ranjan		
	Title:	Project Manager		
	Signature:	Samriddhi Ranjan Digitally signed by Samriddhi Ranjan Date: 2025.03.06 11:21:43 +05'30'	**Date:**	5 June 24
Review and Approve	**Name:**	Bijini Bahuleyan		
	Title:	Data Manager		
	Signature:	Bijini Bahuleyan Digitally signed by Bijini Bahuleyan Date: 2025.03.06 22:03:09 +05'30'	**Date:**	5 June 24

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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

1. 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.

2. Contact List

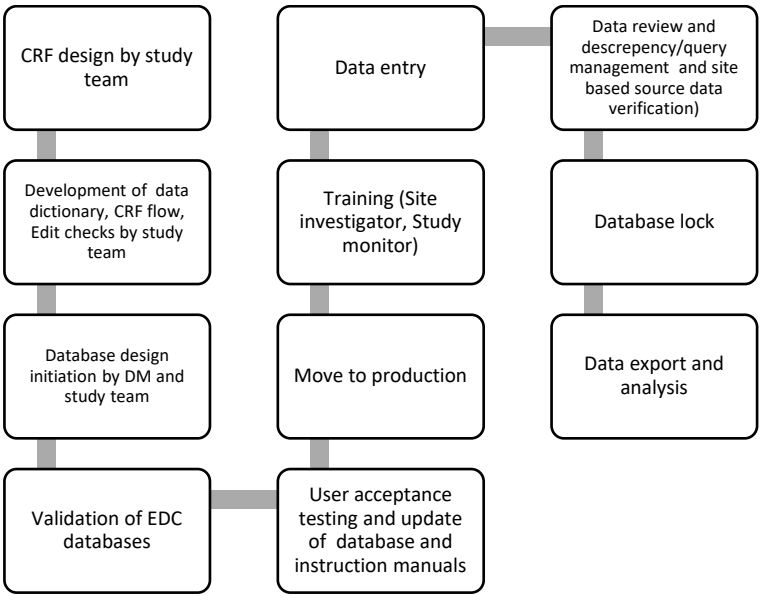
Task	Contact Person	Organisation	Email
Investigator-Trial conduct (Administration)	Nobhojit Roy	TGI, New Delhi	nroy@georgeinstitute.org.in
P. Investigator-Trial conduct (Administration)	Vivekanand Jha	TGI, New Delhi	vjha@georgeinstitute.org.in
P. Investigator-Trial conduct	Martin Gerdin Wärnberg	Karolinska Institutet	martin.gerdin@ki.se
Project Lead	Abhinav Bassi	TGI, New Delhi	abassi@georgeinstitute.org.in
Lead Investigator-Indian	Monty Khajanchi		
Data management	Bijini Bahuleyan Mr. Manoj Kumar Soni	TGI, Hyderabad TGI, New Delhi	bbahuleyan@georgeinstitute.org.in Msoni@georgeinstitute.org.in
Database development	Martin Gerdin Wärnberg		martin.gerdin@ki.se
Project management	Samriddhi Ranjan	TGI, New Delhi	SRanjan@georgeinstitute.org.in

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

Role	Responsibility
	-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



3. 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

Data Management Factor	Applicable?	If Yes,
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

4. 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	*ATLS vs Standard Care Trial protocol_V1.1.0_2024-05-09_FINAL*	*TGI ATLS KI Study TMF*
Final CRF (PDF)	*CRF_01.04.24_v1.0_ ATLS vs Standard Care Trial*	*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.

5. Privacy, Identifiers and Linkage

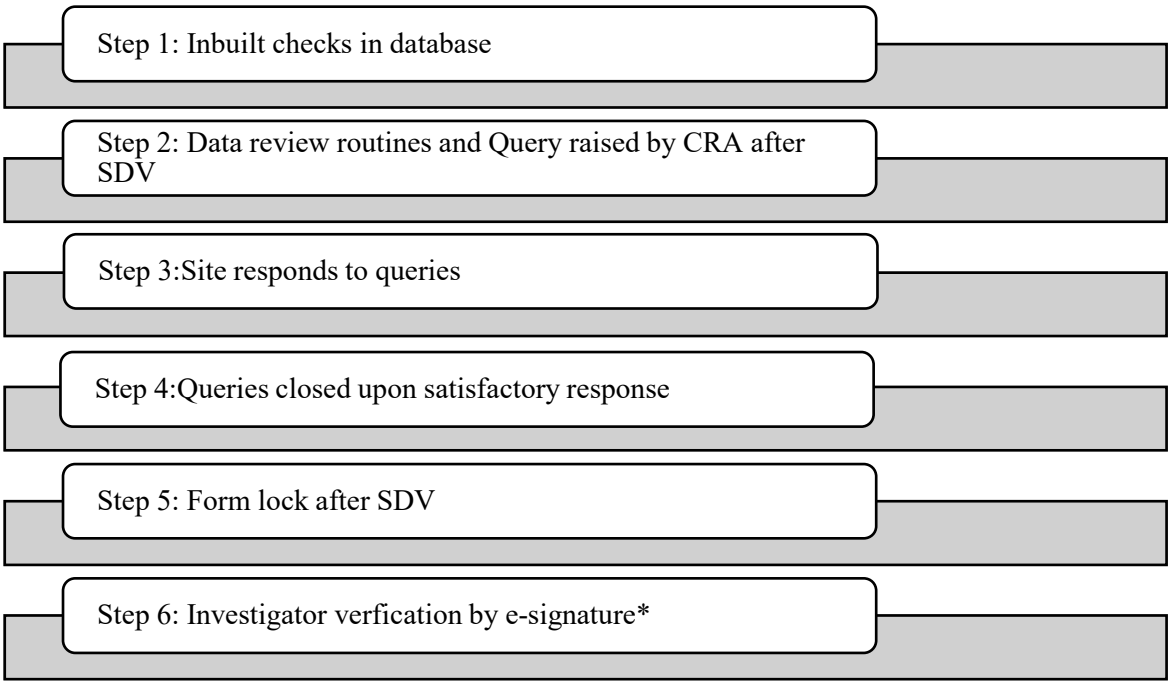
5.1 Personal Identifying Information and Sensitive Data Handling

No personal identifying information is collected for this study.

6. 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.

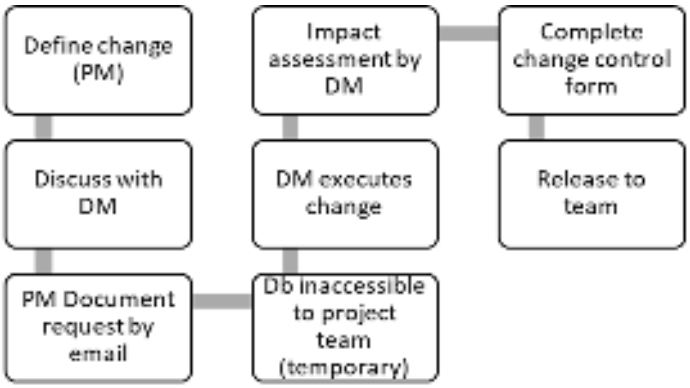


*E-signature is currently set for the all the forms.

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.



7. 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

8. 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. At KI, the data will be stored on project servers, accessible exclusively via a Virtual Private Network (VPN) with two-factor authentication, with regular backups.