PUBLIC HEALTH FOUNDATION OF INDIA

Guideline for Good Data Management Practice (DMP)

PUBLIC HEALTH FOUNDATION OF INDIA

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Approved By:	Dr. D. Prabhakaran	V.P. Research and Policy	

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Revision History:

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1.0 Policy

It is PHFI policy to document the complete process of Data Management, in accordance with Good Clinical Data Management Practices (GCDMP). This SOP describes a documented practice/ process for good data management stating objectives, process of obtaining the relevant project/ study information, team definition, roles and responsibilities between Sponsor/Funder and PHFI with appropriate timelines.

2.0 Scope

This SOP is applicable to all the research studies conducted by PHFI, (e.g.- Observational Studies, Epidemiological Studies), study planning and setup, study conduct and study close-out for data management activities of such projects that are undertaken by PHFI. This SOP may not be applicable if sponsor/ third party SOP(s) are used. However, annexure documents may be used during the implementation process, which should be identified and documented before the trial activity commences.

3.0 Abbreviations

AD	:	Annexure Document
BS	:	Biostatistics
DM	:	Data Management
DMS	:	Data Management System
DMP	:	Data Management Plan
DMTMF	:	Data Management Trial Master File
GCDMP	:	Good Clinical Data Management Practice
DM	:	Data Manager
DC	:	Data Coordinator
DBP	:	Database Programmer
PM	:	Project Manager

QA	:	Quality Assurance
SOW	:	Scope of Work
TRL	:	Trial Responsibility Log
DCF	:	Data Clarification Form
SDCF	:	Site Data Clarification Form

4.0 Responsibilities

Principal Investigator (PI): It is the PI's duty to ensure that all members of the study team with access to the research data adhere to good research data management practice. Shall be responsible for assigning project to the Project Manager (PM) and in consultation with the PM, shall allocate Data Management (DM) team to project / study. PI shall also be responsible for compliance of this SOP.

Project Manager (PM): Shall be responsible for ensuring availability of Confidentiality Agreement/ equivalent document and contractual agreement/ equivalent document, reviewing and approving of DMP and Project Milestones, allocating study team in consultation with PI to the project / study, completing project specific Trial Responsibility Log (TRL) , reviewing the Data Management Trial Master File (DMTMF) and returning files to sponsor or for internal archival.

Data Manager (DM): Shall be responsible for developing project/ study specific Data Management Plan (DMP)(in discussion with the Project Incharge and or Project Manager), completing Project Milestones and monitoring the process of the project/ study on an ongoing basis, providing periodical updates of Data Management status reports as defined in DMP, ensuring that all change(s) in the DMP during the life cycle of the project/ study are documented and released as revisions, and also filing each approved version of the DMP along with the Document Approval Form in the DMTMF.

Database Programmer (DBP)/designee: Shall be responsible for providing inputs for preparation of DMP and review of draft DMP in discussion with Data Manager/Project manager.

5.0 Procedure

- Once a project/ study is undertaken by PHFI, the PI shall assign a Project Manager (PM)/ designee to the project/ study.
- PM/ designee shall ensure that a Confidentiality Agreement/ equivalent document and Contractual agreement/ equivalent document are in place so that PHFI can undertake the role of the "Sponsor's Legal Representative".
- Before initiating study activities, PM/Designee shall seek from the sponsor/ investigator details regarding the regulatory/ country specific requirements to be complied with while performing study activities. These training requirements shall be documented in the Data Management Plan. All study staff involved should be trained on these additional requirements before performing any study specific tasks. Serious deviations, if any should be assessed per applicable requirements and be documented.
- PM/ designee, in consultation with PI, shall allocate study team for project/ study tasks and assignments and complete the Trial Responsibility Log specific for the study.
- Once protocol is received and the study team is finalized, DM/Designee shall conduct protocol training and file the training certificates in the DMTMF.
- DM, in consultation with PM, shall be responsible for developing project/ study specific Data Management Plan (DMP)
- For the development of such project/ study specific DMP, a study team discussion meeting shall be arranged to clearly understand the details of the project/ study.
- The outcome of the meetings shall be documented in the Minutes of Meeting (Refer: DM-SOP-XX-AD-X) by a designated study team member.

5.1 Project / Study Planning and Set-up

All aspects of data management processes are described below and should be documented as relevant to the project/ study as per Scope of Work (SOW). The DM/ Designee shall develop the Data Management Plan (DMP) in consultation with study team members. The DMP shall be comprised of the following DM processes, but not limited to;

- Data Management Team Structure
- Annotation of Case Report Form and Development of Metadata Document as per Designing of Project Database.
- Database development and testing as per Designing of Project Database, Study Set-up for Data Management System.
- Access permissions to the project team members as per Creation of Data Management System User and Study Permissions.
- Medical Coding dictionaries description and Validation (If applicable).
- Edit Check Programming and Testing as per Designing of Project Database.
- Receiving of CRF/ any project/ study document and process of tracking and filing as per Study Data Document Receiving and Tracking log.
- Preparation of Data Entry Guidelines as per Study Protocol and CRF.
- Data Cleaning activity/ discrepancy or query management as per Data Validation Process.
- Preparation of data coding guidelines
- Preparation of Serious Adverse Event (SAE) Reconciliation Guidelines, If Applicable
- Preparation of Quality Control plan
- Data Extraction plan
- Preparation of Data Transfer Guidelines as per Data Transfer Process of PHFI
- Data Management status reports that describe the format, timelines, transfer method (e.g., email or fax copies) and recipients of study related reports from the Sponsor designee. These are customizable reports generated if required by sponsor as per Sponsor specifications.
- Minutes of Data Management discussion meetings
- Final database lock
- Filing project/ study related documents and reports in project/ study specific Data Management Trial Master File as per Data Management Trial Master File.
- Document control and archiving of the project/ study data and documents as per Data sharing policy of PHFI and Data Security policy for Central Research Data Repository.
- Scanning of CRFs/ DCFs/ SDCFs as per Document Scan Process of PHFI
- Handling of Non-CRF data as per the project guidelines

The scope of the development of these documents depends on the tasks assigned to PHFI as per the scope of work. The responsibilities for development of each document shall be clearly identified in the DMP.

DM/ Designee shall decide the scope and information required to be completed in the DMP based on the complexity of the project/ study. DM/ designee would seek input from the following personnel:

- Project Incharge/Project Manager
- PM/ Designee
- Any other study team members
- Sponsor (If Required)

If the draft DMP is prepared, the DM/ Designee shall forward the same to DBP and PM for review. After review, the DMP is forwarded to PI and to the Sponsor's designee for review and final approval, respectively, using Document Approval Form. The approved DMP along with approval form shall be placed in the relevant section of the DMTMF.

The approved copy of the DMP shall be filed in the DMTMF and distributed electronically to the designated project/study team members by the DM/ Designee.

5.2 Project / Study Management

- All project/ study specific information will be detailed in the respective project/ study DMP. Type of data capture (EDC or Paper), type of CDMS used etc. will be specified in the DMP.
- DM/ Designee will monitor the progress of the project/ study on an ongoing basis and periodically update the PM/ designee, PI and the Sponsor by providing Data Management status reports as defined in the DMP.
- DM/ Designee will list Project/ Study milestones as per approved DMP on annexure document Project Milestones (Refer: DM-SOP-DMP-PM-01).
- Monthly project/ study status updates shall be forwarded to the study team, PIand Sponsor (If applicable) by completing annexure document Minutes of Meeting form where applicable.
- Changes in the study team structure and the responsibilities shall be effective after the updating of annexure document Trial Responsibilities Log (Refer: DM-SOP-XX-AD-X).

5.3 Amendments to the Data Management Plan

- DM/ designee shall ensure that all change(s) in the DMP during the life cycle of the project/ study are documented and released as revisions. DM/designee should also inform the PI, study team members and the Sponsor (if applicable) about these changes.
- Revision of the DMP is considered necessary if the CDM processes or Sponsor contact details or revision of protocol will have an impact on DM plan activities etc., but revision is not limited to mentioned changes.
- Version and change control of DMP shall be done as per Preparation and Control of Standard Operating Procedure and Annexure Documents (AM-SOP-XX).
- The DM/ designee shall file each approved version of the DMP, along with the Document Approval Form in the DMTMF

5.4 Project/ Study Close-out

- The Close-out processes cover the close down of all activities of the project/ study, once the project/ study has reached its required milestone or the PI and or Sponsor has requested that the project/ study is terminated.
- PM/ designee shall ensure final signing off of annexure document Trial Responsibilities Log for all study team members at the time of close out.
- PM/ designee shall ensure the final review of Data Management Trial Master File (DMTMF) and shall return the files to PI and or sponsor (if applicable) or forwards the files for internal archival (depending upon the scope of work).
- A final Project Summary Report shall be prepared in accordance with the DMP, and send to PI. This can also be shared with the sponsor (if required).
- If applicable, any unresolved issues present throughout the Project/ Study, shall be documented in annexure document 'Unresolved Issues Summary Report' at the end of project/ study.

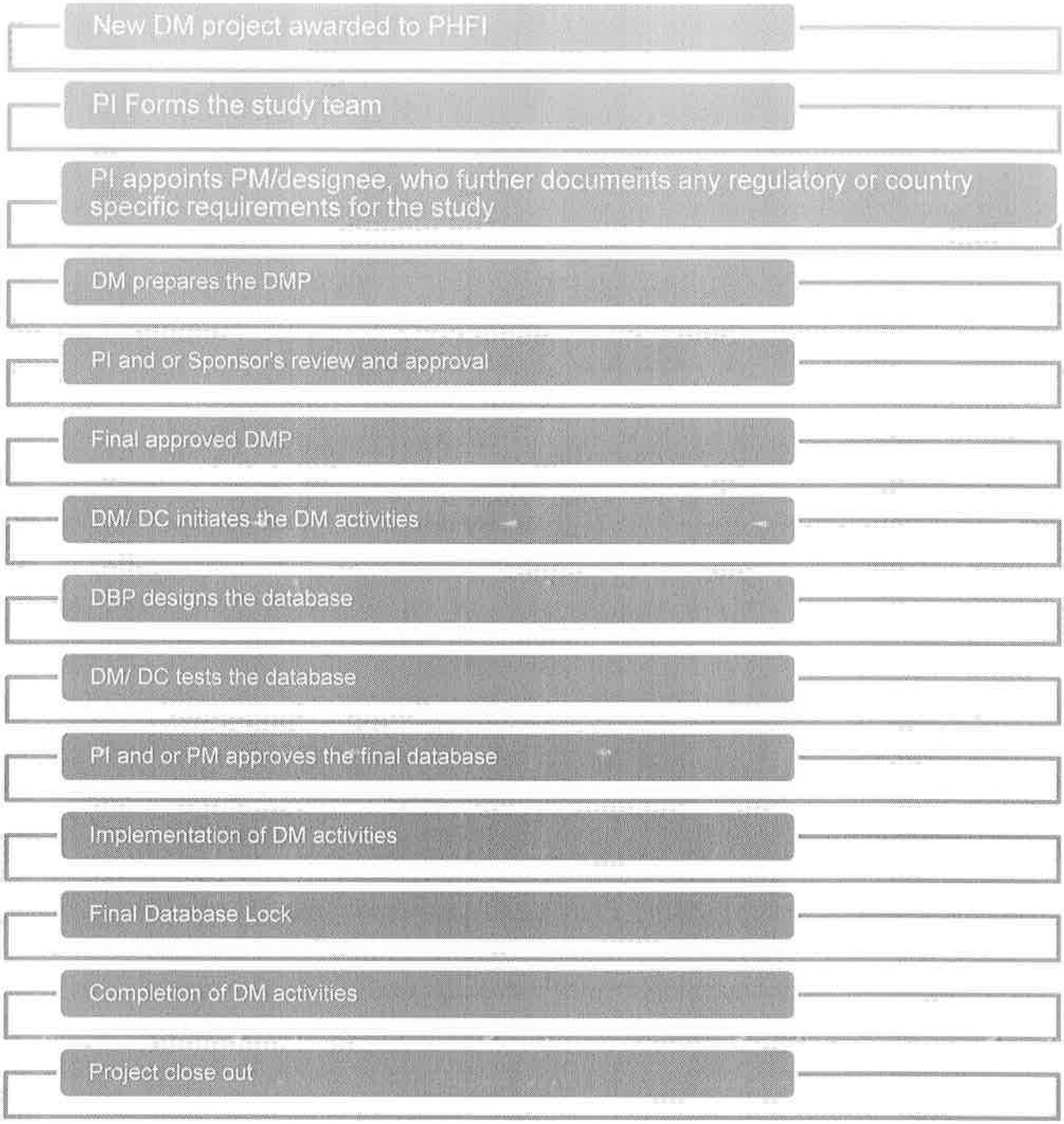
DMTMF cover page should be prepared for each DMTMF. The number of a particular file can be more than one and the files of each type should be numbered as 1 of 2, 2 of 2, and so on. In the Annexure Document 'DMTMF Cover Page' the space provided in parenthesis in 'Study Code' 'Study Title' and 'Sponsor' should be completed as

per project requirement. All the scanned documents will be saved in the DMS section of the CRDR platform for future reference by the PI/Collaborator and the team members.

6.0 List of Annexure Documents

- Trial Responsibility Log (DMP-SOP-AD-1)
- Data Management Plan Template (DMP-SOP-AD-2)
- Project Milestones (DMP-SOP-AD-3)
- Minutes of Meeting (DMP-SOP-AD-4)
- Unresolved issues Summary Report (DMP-SOP-AD-5)

7.0 Flowchart



8.0 References

- International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline (May 1997).
- Good Clinical Data Management Practices, Version, April 2011.
- E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) – March 2018

TRIAL RESPONSIBILITY LOG

Study Code:			**Study Title:**				
Sponsor:			**PM/ Designee:**				
Name **Email ID**	**Initials**	**Study Role**	**Trial Involvement**				**Remarks**
			Start Date	**Signature & Date**	**End Date**	**Signature & Date**	

Trial Responsibility Log	Doc: DMP-SOP
	Version: 1.0

Study Start	**Name of the Project Manager:**	
	Signature & Date:	
End of Study	**Name of the Project Manager:**	
	Signature & Date:	

Data Management Plan Template

Version 1.0

Date of Issue: ☐☐ ☐☐☐ ☐☐☐☐

D D M M M Y Y Y Y

<<Protocol Title>>

Study Code: << >>

Contact: <<Name of PM/ Designee>>

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Revision History:

Version #	Author (s)	Date of Issue	Brief Description of Change
<<Insert previous version no's>>	<<Author(s)>>	<<Date of Issue>>	<<Revisions made to the previous versions>>

Abbreviations:

AE	:	Adverse Event
BLH	:	Business Line Head
CD	:	Compact Disk
CDMS	:	Clinical Data Management System
CRF	:	Case Report Form
SA	:	System Administrator
DBP	:	Database Programmer
DC	:	Data Coordinator
DM	:	Data Manager
DMP	:	Data Management Plan
DMTMF:	Data Management Trial Master File	
DVD	:	Digital Video Disc
ECD	:	Edit Check Document
FTP	:	File Transfer Protocol
PM	:	Project Manager
PSDVG	:	Project Specific Data Validation Guidelines
QA	:	Quality Assurance
QC	:	Quality Control
SAE	:	Serious Adverse Event
SDVG	:	Standard Data Validation Guidelines
SOP(s)	:	Standard Operating Procedure(s)
DCF	:	Data Clarification Form
SCDF	:	Site Data Clarification Form
TBD	:	To be Discussed

Table of Contents

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the process for creating, approving, and amending Data Management Plans (DMP) for the projects conducted using Clinical Research Data Repository (CRDR) platform at PHFI.

2. Scope

This procedure applies to all DM projects managed by PHFI using CRDR. This procedure identifies the documents needed to produce a DM Plan.

3. Introduction

The following Data Management Plan is on support of the study <<Study Code>>:

<<Study Title>>

Following are the list of Data Management activities:

- Unique page list
- Annotated source document template
- Metadata Document
- Edit Check Document documenting manual and automatic checks to ensure data accuracy
- Database Designing and Testing
- CRF completion Guidelines
- Data Entry
- Data Entry Guidelines
- Data Transfer Guidelines
- Data Sharing Guidelines
- Data Archiving guidelines
- Self-evident correction Guidelines
- Standard Data Validation Guidelines

- Data Entry Tracking
- Query Management
- SAE Reconciliation , If applicable
- Quality Control Plan
- Database Lock
- Errata List (If any)
- Data Management Report
- Data Transfer in agreed upon format-interim and final

The following responsibilities are assigned to the designated team members as defined by their roles in a project/ study; the responsibilities include, but not limited to:

- The Clinical Data Management Project Manager (CDM-PM) or Designee is responsible for the management and oversight of all the processes.
- The Data Manager (DM) is responsible for ensuring that all the processes are carried out as per Scope of Work. Any additional activities required to be done, are to be treated as 'out of scope' and a change request form with approval should be filed for carrying out the activity.
- The Data Coordinator/designee (DC) is responsible for carrying out data management activities (data entry tracking by site, query management, report generation, QC, etc.) as per applicable SOP(s).
- The System Administrator (Sys Admin) is responsible for setting up / troubleshooting the Project database, providing access permissions, and database locking activities.
- The Database Programmer/designee is responsible for designing and maintaining / troubleshooting the Project / Study database as per applicable regulatory guidelines and SOP(s).

The Sponsor\Principle Investigator\Investigator is responsible for:

- Providing final source document template
- Approving of Data Management Plan
- Approving of Edit Check Document
- Approving of other applicable documents/activities

3.1 Project Description

Sponsor Name and Address	
Principal Investigator Name	
Project ID	
Project Title	
Study Type	
For Clinical Study Phase/Epidemiological Study(Cross-sectional/Case control/Cohort)	
Mode of Study	
Indication	
Study Objectives	**Primary Objectives**
	Secondary Objectives
	Exploratory Objectives

Primary Variables	
Secondary Variables	
Total Sample Size	
Number of Study Center's / Sites	
Number of Evaluable Subjects	
Number of Treatments	
Treatment Period	
Follow-up Period	
Expected Total Study Duration	
Number of Study Centers Planned	
Planned Recruitment Rate	
Number of Subjects Expected per Study Center	
Estimated Serious Adverse Events (SAEs)	
Expected Duration of the Study (Clinical Data Management)	
Protocol	
Source Document Template	
Total Number of Pages in Source Document Template	
Number of Study Visits	
Instructions on CRF Modules	
Ancillary Data Requirements	
Standard Dictionary Coding (MedDRA/WHODD), if applicable	
Standard Existing Dictionary for AE	

Standard Existing Dictionary for Concomitant Medications	
Data Entry	
Data Entry Type	
Data Validation	
Data Management Plan	
Electronic Laboratory Uploads	
SAE Entry and Reporting	
SAE Reconciliation to be Performed	
Sponsor Timelines (Final Data Transfer statistical data listings)	
Interim Analysis	
Final Analysis	

3.2 Reference Material

S. No.	Name of the Document	Version No. and Date	Mode of Receipt*	Date Received
1	Protocol		E-mail	
2			E-mail	
			E-mail	
			E-mail	
			E-mail	
			E-mail	

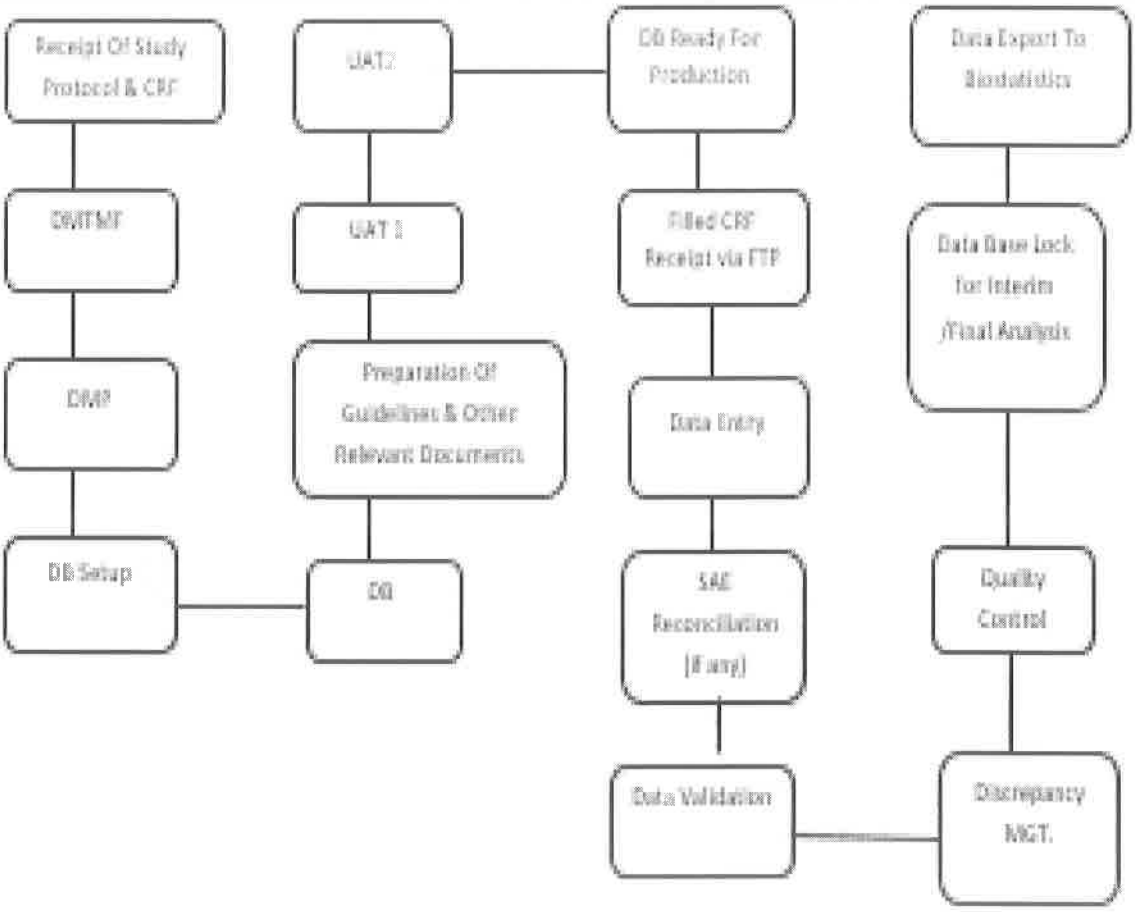
** Mode of receipt: Courier, e-mail, ordinary mail, by hand, fax*

3.3 SOP(s) to be used for the study

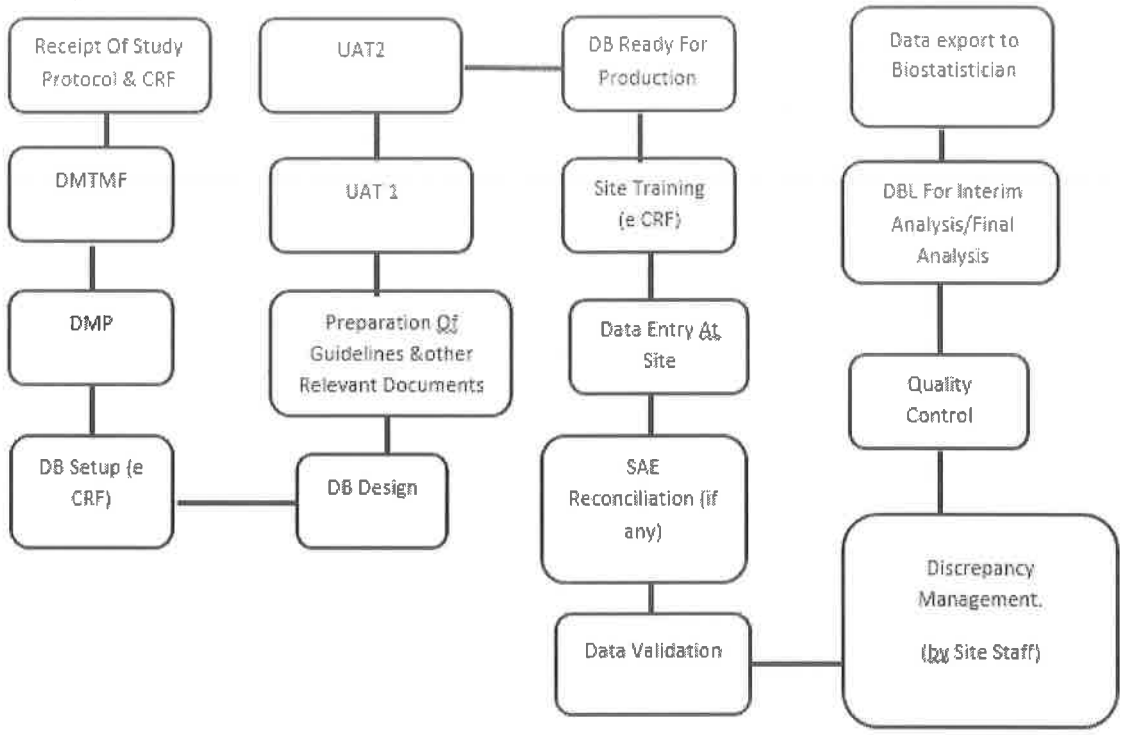
All the applicable PHFI and / or Sponsor SOPs would be used during the course of the study.

3.4 Flow of Data Management Activities

Paper based studies



Electronic Data Capture (EDC) studies

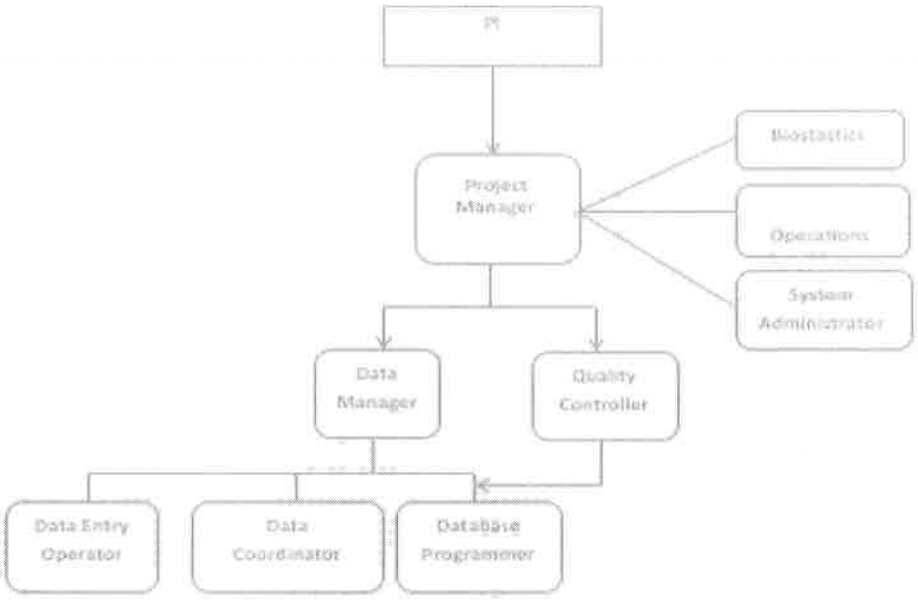


Abbreviations: DMTMF-Data management trail master file; DMP - Data management plan; DB-Data base; UAT- User acceptance testing ; e CRF- Electronic case report form; SAE-Serious adverse event; DBL-Data base lock

4 Data Management Process

4.1 Project Start-Up

4.1.1 Project Organisation – Data Management



PI: Principal Investigator

PI: Principal Investigator

Note: The responsibilities of the study team as per roles are not limited to those mentioned in the SOP, the DM can act as a designee for the PM, the DC can act as a designee for the DM.

4.1.2 Project team contact List

Principal Investigator	Address		Tel/Fax No./e-mail
Sponsor	Address		Tel/Fax No./e-mail
Operations	Address		Tel/Fax No./e-mail
Data Management and Biostatistics	Address		Tel/Fax No. /e-mail
Site/Field Investigators	Site No.	Site Name	Site Address

4.1.3 Data Management Discussion Meeting

After the initial briefing meeting with PI, the PM shall conduct Data Management Project Start-up Meeting with the Project Team members on discussing Project timelines and the Data Management Plan. The Project Manager shall conduct Data Management Project Team Members meetings on a regular basis to track the timelines of deliverables along with the progress of the project. A document containing meeting minutes shall be distributed to all the participants and other appropriate personnel after the meeting.

5 Project Management

5.1 Database Security and User Accounts

All Data Management personnel working on <<Study Code>> study will be granted access by the System Admin. Each user will be granted access to study database based on assigned role i.e. Project Manager, Data Coordinator, Data Manager, Database Programmer, and Data Entry Operator.

The Data Manager shall complete the "Clinical Data Management System Study Access\ Revoke Form" clearly documenting the "User Name" and "Role Assigned" for all study personnel. The PI and/or Project Manager will review and approve the "Clinical Data Management System Study Access Revoke Form".- All users will be granted access to the study database by the System Administrator based on "Role Assigned" as specified in the "Clinical Data Management System Study Access Revoke Form." Only personnel assigned to <<Study Code>> will have access to the project database. The "Clinical Data Management System Study Access Revoke Form" will be maintained in Data Management Trial Master File.

5.2 Sponsor Requested Security Measures

To follow sponsor specified guidelines, if any.

5.3 Database Design

The Database programmer/Designee will prepare a Document Declaring Unique Pages of CRF and get it reviewed and approved by DM/ , PM/ PI respectively. The Database programmer will then prepare an Annotated CRF and get it reviewed and approved by DM/ PM/ PI and Sponsor (if applicable) . Immediately after the approval of the Annotated CRF, the DBP/ designee will prepare the Metadata Document and get it reviewed from DM and then get it approved by PM / PI.

The Database programmer will create the draft project database in development environment, ensuring compliance with regulatory guidelines. The draft project database will then be declared ready for User Acceptance Testing. Before declaring the draft database ready for testing, the DM will route a request through PM to SA – System Administrator to grant access to the study database to required project team members. The DM/ designee will perform two rounds of User Acceptance Testing of the project database. (Using 3 Dummy CRF and 2 clean CRF data) The DBP and DM will also test the programmed edit checks. Once the testing of draft project database is completed, the DM/ designee will use Database Testing Form to approve/ request for modification of the project database. If for any reason the draft database requires modification, the modification will be completed by the DBP and the retesting of the database is performed.

Once the project database is approved by the PI the PM/ designee will request the System Administrator (Sys Admin) to move the approved project database from development environment to production environment. An e-mail to this effect would be sent out by PM/ designee to the study team declaring the database as Live.

The Sys Admin will move the database to production mode after the database is declared ready to be moved to production environment. Once the Database is moved into production, the DM will route a request through PI and or PM to Sys Admin to grant project team members access to the project database. DM will request the Sys Admin\ Designee to declare patients\ subjects in the production database for live data entry.

5.3.1 Database Specifications

<Preferably As per CDISC standard to be followed for all clinical domain>

5.3.2 Database Design Documents

Database design documents are:

- Source Document template
- Unique Page(s) of CRF
- Annotated source document template
- Metadata Document
- Edit Check Document
- Sponsor-requested database specifications (if applicable)

5.3.3 Changes to the Production Database

All changes made to the database design after moving the database to production mode will be documented in a paper audit trail (If applicable), which will include updates to the annotated CRF and metadata document. All production database change documents will be filed with the Data Management project documentation.

6 Document Management System – (DMS)

All PHFI projects will be for routing / exchange of project documents and data to Site\Sponsor using DMS section of CRDR platform.

Study team members from PHFI and Sponsor will be provided access by the PI. Project documents and final data will be uploaded to this DMS. An e-mail will be sent to relevant study team members and Sponsor informing about uploaded documents or data.

7 CRF / SDCF/ DCF Transmission and Logging

7.1 Standard Procedure for CRF Receipt and Logging

Study filled CRF will be received by Data Management though FTP server\Courier for all paper-based studies. CRF transmittal form to be acknowledged by both parties i.e, party uploading CRF and Data Management staff receiving the CRFs. Data Manager\ Designee will maintain CRF tracker and will be responsible for maintaining the same with each download. Data Manager\ Designee will also be maintaining DCF transmittal form along with DCF tracker. For EDC all the queries will be tracked electronically and the summary report shall be generated from the application on an ongoing basis as per the project requirement.

7.2 Site Data Clarification Forms (SDCFs)

Site Data Clarification Forms are to be filled by the site staff if there is a need of data correction or data change. SCDFs are to be shared via FTP server along with DCF transmittal form, and to be acknowledged by the Data Management staff receiving the SDCFs. All SCDFs will be given a unique code and will be prefixed with "SXX", where "XX" is the sequential number of the site data clarification form.

7.3 Standard Procedure for DCF Transmission and Logging

Upon Successful completion of batch validation session, Queries from the system\ CDMS will be transcribed into Data Clarification Forms or provided be the CDMS. Manual queries, when necessary, will be transcribed into DCF(s) and will be shared with the site staff via FTP along with DCF transmittal form.

Site staff\ Designee will download the DCFs and the respective DCF transmittal form from FTP. The person downloading the DCF(s) will be acknowledging the DCF transmittal form, If the transfer has any issues\Queries, the same will be documented in the transmittal form for clarification.

Data Manager will maintain a DCF tracking sheet, and share the same within the study team on periodic intervals or soon after the download or upload.

8 Data Entry

8.1 Standard Data Entry Guidelines

Paper Based Study: Data Entry Guideline will be prepared by the Data Coordinator (DC)/ designee before the database is moved to production environment. DC/ designee will forward the Data Entry Completion Guideline to the DM designee and Sponsor for review and approval.

OR

EDC Study: eCRF filling guidelines will be prepared by the Data Coordinator (DC)/ Designee before the database is moved into production. DC/ designee will forward the same to DM/ designee and Sponsor for review and approval. Post approval, Data Manager/ designee will train the site staff as per the finalized mode of training.

8.2 Mode of Data Entry

In-House Study: Study data will be entered by the designated Data Entry Operator(s)/Designee. Double Data Entry to be followed and will depend upon the project requirement.

EDC Study: Study data will be entered at site by the site staff assigned for the study. Single entry to be followed post completion of eCRF filling training. Re- Training will be imparted where the high volume of queries are generated for the site.

9 Non CRF Data Management

9.1 Standard Procedures for Processing Non-CRF Data (<<External data - Central Laboratory Data/central ECG etc>>)

External Data <<Central Laboratory Data Management (electronic), includes the following processes: formal definition of the data that is being transferred from the central laboratories, standard format for data and testing procedures for the external data, maintenance of external data normal ranges and units and loading and validation of the external data.

Central laboratory data transfers will contain only new data and data corrections unless otherwise specified in the Non-CRF Data Handling Convention. A final cumulative transfer is required to be loaded into the database at the end of the study.

The following Non-CRF Data Management documents will be prepared for this process:

- Laboratory Normal Ranges
- Non-CRF Data Guideline

Or

<<As per study requirements>>

9.2 Querying for Non-CRF Data

Non CRF data will be checked for discrepancies using standard/ study specific edit checks as appropriate. Inconsistencies between the External data and the CRF data will be resolved with the investigator site and/or the laboratory as necessary>>

OR

As per the study requirements

9.3 Contact Persons in this study

<<Laboratory Contact Person: (Fill in contact details below)

Data Management Contact Person: (Fill in the Data Management contact details below)

OR

<<As per the study requirements>>

10 Data Validation

Data Validation is a process which ensures that all the data captured during the course of Study are accurate and consistent with applicable regulatory requirements and the protocol. It also ensures that the data are produced in a format to support accurate and consistent analysis by the biostatisticians.

The Data Validation Process would require the generation of following documents:

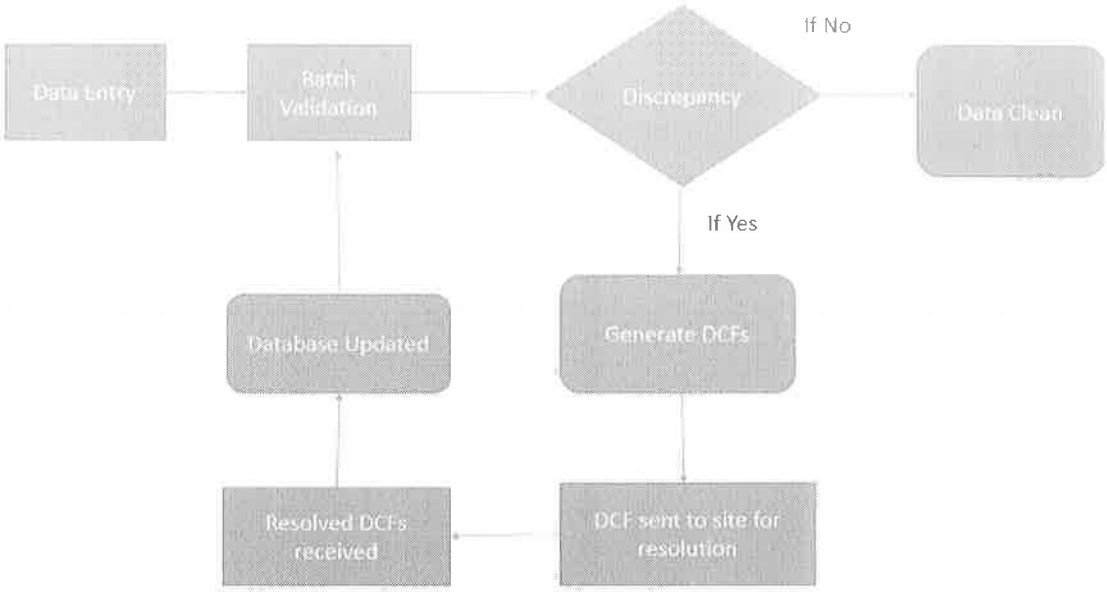
- Standard Data Validation Guidelines (SDVG)
- Project Specific Data Validation Guidelines (PSDVG)

These documents will include a list of automated edit checks (according to field) programmed into the database, as well as manual checks that are completed (see discrepancy management section for additional information). This list, as well as the SDVG and PSDVG, will be reviewed and approved by PM/Designee/ Principal Investigator/ Sponsor prior to finalization.

10.1 Discrepancy Management

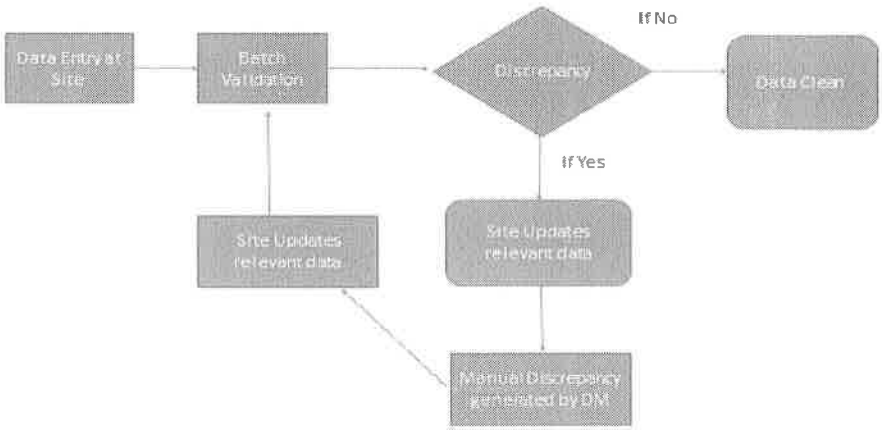
Discrepancy Management is the process of identifying and resolving data discrepancies. Discrepancies are identified electronically and manually. Electronic discrepancies are identified when programmed edit checks produce online / offline (Batch Validation). Manual discrepancies are identified based on manual checkpoints specified in the PSDVG. The DM should raise manual discrepancies identified as such post data entry process and a successful Batch Validation session.

The following process is followed for data validation (Paper Based Study):



OR

The following process is followed for data validation (EDC Study):



10.2 Discrepancy Tracking

Each discrepancy will be uniquely identified for tracking purposes. Customized tracking reports will be generated as needed to summarize the number of discrepancies per module, their current statuses reports will also be generated regarding outstanding queries. Trend analysis of Discrepancies will be shared with the project team to take the preventive action.

11 Dictionary Coding

11.1 Dictionary Coded Items and Coding Dictionaries

The following items are coded for safety purposes in this study:

Dictionary (Version) (MedDRA 21.1)	**Module Name**	**Variable Name**

The coding dictionary will not be changed/ updated once the coding process is initiated. Same version of Dictionary will be followed for the entire duration of the study and before Database lock, the latest available version will be mapped for coding.

12 Adverse Event Data Management

12.1 Standard Practices

Records of Adverse Events are checked against relevant data reported in the CRF e.g. if Hemoglobin level is specified as "Clinically Significant", this should also be recorded as an adverse event. If for an adverse event, <<Action Taken>> is selected as <<Concomitant

Medication Taken>>, medication recorded in Concomitant Medication Log for indication and corresponding dates are confirmed.

12.2 Reconciliation of Serious Adverse Events (If applicable)

The data in the Clinical Data Management Database will be reconciled with Serious Adverse Events recorded in the SAE Report Forms/ Safety Database. Reconciliation is performed to assure that serious events are accurately captured, interpreted, and consistently reported to regulatory authorities.

SAE reconciliation (if applicable) between Data Management Database and Safety Forms/ Database will be performed as per project specific SAE Reconciliation Guidelines after completion of DM activities/ QC activities and prior to Soft Lock.

12.3 Sponsor-Requested AE Practices (If applicable)

<<Not Applicable>> or <<As per the study requirements>>

13 Quality Control of Data

13.1 Quality Control Process

A Quality Control Plan will be prepared to document measures taken to ensure quality of data. A QC report will be generated to document error rate.

The error rate is calculated as follows:

$$\text{Percentage Error Rate (\%)} = \frac{\text{Number of Error's Identified}}{\text{Total Number of Fields Checked}} \times 100$$

The acceptable error rate for Critical Data is <<0.01%>> and for Non-Critical Data is <<0.05>>.

13.2 Quality Assurance Audit

An independent person will be assigned the responsibility to performing an audit of database and associated documentation post soft lock. The audit is conducted to document the compliance of

relevant guidelines and practices followed. Post closure of audit, report is shared with the DM team and after closure of any observations identified in the audit report, database will be hard locked and data would be transferred to the Biostatistician /Investigator/ Sponsor.

14 Database Lock/ Unlock

The Database will be declared ready for soft lock when the study database is considered as "Clean" and prior to the start of the Quality Assurance Audit.

14.1 When is a study database considered as "Clean"?

The study database will be considered as "Clean" when all the following tasks have been completed:

- All CRFs /Survey forms are in-house.
- All data are entered.
- No second pass is pending for entry.
- All discrepancies are resolved.
- All data are reviewed and validated. There are no queries pending for resolution.
- Final dictionary coding is completed, reviewed and approved (If applicable).
- SAE reconciliation is complete, (If applicable).
- Final data QC is complete and all queries resulting from this process are resolved.
- Corrective and Preventive Action (CAPA) report is approved by PI/Sponsor, if applicable
- Final batch validation is run and no new errors / discrepancies are generated and resolved by PI and updated in Database.

14.2 Database Lock/ Freeze Process

Post closure of QA audit and after closure of any observations identified during the audit, the database will be locked based on the following procedure.

- The DM will prepare the Database Lock/ Freeze Approval Form and forward it to the PM for approval/signature.
- After the Database Lock/ Freeze Approval Form is approved/ signed by the PM, the DM will then forward the request to the Sponsor/ PI for approval/signature of study database lock.
- Once the approval/ signature is received from the Sponsor/ PI, the DM will request the Sys Admin to lock the study database.

15 Study Documentation

DM designee will compile following study documents:

Document	Details
Master Service Agreement or Any other agreement related to the Study	• Scope of Work to be performed by data management
Protocol	• Protocol and Protocol amendment(s) (if any) • All previous versions of Protocol and Protocol amendments(s) (if any)
Case Report Form (CRF)/Survey forms	• CRF/Survey form and approval document (if applicable), CRF/Survey form addendum(s) (if any) • All previous versions of CRF/Survey form along with approvals (if any)
Data Management Plan (DMP)	• DMP with Annexure Documents and approval document • All previous versions of DMP with Annexure Documents and approval document
Training	• Project Specific Training Records
Database Documents	• Checklist for receipt of documents for Database Designing • All versions of Annotated CRF and approval document • Metadata Document and approval document • List of CRF Unique Pages • Study Set-up Request Form • Data Management System Study Access/ Revoke Form • Database Design Request Form • Dictionary Approval Form (if applicable) • Database Testing Form • Database Lock/Unlock Request Documents I. Database Lock Approval Form II. Database Lock Change Request Form (if any) • Data Extraction Checklist Form • Batch Data Load Guideline (if applicable)

Document	Details
Data Validation Documents	• Edit Checks Document and approval document • Test script / filled CRFs as applicable • Data Validation Guidelines (PSDVG and SDVG) and approval document • Data Coding Guidelines and approval document • SAE Reconciliation Guidelines and approval document (If applicable) • Data Entry Guidelines and approval document • Lab Ranges document, If applicable • Batch Data Load document (if applicable) • Corrective And Preventive Action plan
Data Transfer Document	• Data Transfer Guidelines and approval document • Data Transfer Setup Approval Form /Electronic Data Transfer Form (as applicable)
Quality Control Documents	• Quality Control Plan • Quality Control Report
Document Receipt Log	• Document Receipt Log
Audit	• Verification and Close-out Report.
Communication	• Documents of communication with sponsor/ site/ operations
Minutes of meeting	• Minutes of telecon and internal project team meetings
Other documents as required by applicable Standard Operating Procedures	

16 Data Transfer

A Project specific Data Transfer Guideline will be prepared for the study and reviewed and approved by the Sponsor/ PI. Data transfer will be done as and when required, as per the request from PM/ DM/ DC/ Biostatistics team/ PI or Sponsor. Upon receipt of any such request the Data Manager or Designee/ System Administrator will extract the datasets and provide the same to the requester.

16.1 Periodic Data Transfer during Study

<<NA>> or <<As per the study requirements>>

16.2 Final Data Transfer at End of Study

PHFI will use DMS section of CRDR to transfer data between Data Management team and the Biostatistics team/PI/sponsor; else the same can be performed by password protected e-mail attachments/ secure e-mails or access to extract the data will be granted to the team member. The formats which would be used are: CSV, XLS Datasets. A different format request if received will be analyzed and data will be provided in the said format if deemed feasible by the System Administrator/ database programmer.

The transfer of datasets to the sponsor will be done through password protected e-mail attachments, DVD, CD, USB flash drive, FTP server or on a sponsor requested media.

17 Project Close-out

PI and or PM/ designee will ensure that all study closeout activities are done, sign off the Trial Responsibilities Log, and ensure all outstanding tasks are complete. PHFI will establish and maintain files for study documents in a secure place with access limited to only the PHFI staff assigned to the project and the collaborators of the project. (PHFI) will archive the database of the study on the necessary media at the end of the study and the data will be available for 7 years in the CRDR application for the team or as per the funding agency guidelines.

PROJECT MILESTONES

Study Code/Project Title:

Protocol No./ Code:		**Project / Study Title:**		
Sponsor:		**PM/ Designee:**		
Activity	Responsible Person	Planned Date	Completion Date	Default Time (In Days) May vary as per project timelines
Project Start-up meeting				1
Submission of Draft Data Management Plan to Sponsor/ Designee (If Applicable)				3
Submission of Draft Annotated CRF to Sponsor/ Designee (If Applicable)				5
Designing of Database				30
Testing of database				20
Database Migration to Production				20
First CRF Expected Date				1

Project Milestones	Doc: DMP-SOP-AD-03
	Version: 1

Data Entry Start Date				TBD
Last Query Generated				TBD
Modification in Database, due to protocol amendment				TBD
Database Lock				30 – 40 Days (LPLV)
Archiving of Study Documents				TBD

Data Manager Name:	
Signature & Date:	
Project Manager Name:	
Signature & Date:	

MINUTES OF MEETING TEMPLATE

Date of Meeting		Time (24 Hr)		Venue	
Purpose of Meeting					
Minutes Issued By			Date of Issue		

Participants:

Sponsor / Investigator / Site Personnel(s)	PHFI Study Personal

Copy Distribution: *Each Copy (Soft Copy) of Minutes of Meeting to be shared with all the participants and copy to be saved in CRDR platform under Minute minute's folder of the project*

S.No	A /D / I	Topic	Action	Responsible Person (s)	Status O-Open, I-In Progress, C-Closed, H-On Hold	Due Date

Prepared by:

Name: _____

Signature: _____ **Date:** ____/____/_____

UNRESOLVED ISSUES SUMMARY REPORT

Protocol No./ Code:				Project / Study Title:		
Sponsor:				PM/ Designee:		
S.No.	Issue Title	Issue Description	Impact on Project	Date Communicated to Sponsor	Signature of DM/ Designee	Date

Project Manager Name:		Sponsor Representative Name:	
Signature & Date		Signature & Date	