Template of Project Management Plan

Sponsor:

Protocol Number:

Study Title:

	Prepared By	**Review by**	**Review & Approved by Sponsors**
Name			
Designation			
Signature			
Date			

Distribution List:

1.0 PURPOSE

To provide the guidelines for the project management for following protocol.

2.0 PROJECT MANAGEMENT TEAM

3.0 RESPONSIBILITIES:

3.1 Director, Clinical Trials: Authorizes the project management plan. In his absence the activities specified in the PM plan would be conducted / supervised by the representative authorized for the purpose by the Director, Clinical Operations.

3.2 Manager- Clinical Trials: Ensures that the project management activities are conducted as per the plan and the Standard Operating Procedures (SOPs) of ...

The Manager- Clinical Trials will be responsible for finalizing study related documents with the relevant study team members

- Conduct Site feasibilities and Site Qualification visit of the sites selected by the IR in consultation with Sponsor and coordinate with Investigator
- Finalization of study budget, contracts and Clinical trial agreements.
- Training study team members : ICH GCP & Project Specific
- Supervising activities of the CRAs
- Ensure study timelines are met with quality data
- Overseeing document management and preparation of site specific binders.
- Manager- Clinical Trials will be responsible for facilitation of EC submission, coordination with, preparing pre study documentation, Site Initiation Visits (SIV), Interim Monitoring Visits (IMV), coordination for safety reporting from site through Medical Monitor, Clinical Trial Material accountability (CTM), tracking of completed case report forms (CRFs), Compliance with protocol and Good Clinical Practices, maintenance and archival of Trial Master File (TMF) through IR CRAs will be responsible for facilitation of EC submission, coordination with, preparing pre study documentation, Site Initiation Visits (SIV), Interim Monitoring Visits (IMV), coordination for safety reporting from site through Medical Monitor, Clinical Trial Material accountability (CTM), tracking of completed case report forms (CRFs), Compliance with protocol and Good Clinical Practices, maintenance and archival of Trial Master File (TMF) through IR CRAs

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- In the absence of Manager- Clinical Trials, these activities would be conducted by the designee under the supervision of the Head, Clinical Trials

3.3 Assistant Manager- Clinical Trials / CRA-II:

- Locates and selects clinical investigators appropriate to the therapeutic area and phase of the study.

- Assesses potential study sites to ensure the facility, staff and patient population are sufficient for study conduct.
- Negotiates the study budget (grant) and any other contract agreements required by the Sponsor/CRO, if required.
- Plans or assists in conducting study start-up meetings
- Meets with Clinical Investigators and their staff prior to study initiation to ensure all aspects of the study are understood by the investigator and staff, confirm the appropriateness of the IRB and ensure that all documentation required to initiate the study is complete.
- Monitors study progress to assure compliance with protocol requirements, FDA regulations and Good Clinical Practice by conducting site visits as directed by the Sponsor/CRO.
- Monitors and tracks patient enrollment and study progress.
- Performs site audits to include source document review.
- Ensures the track patient enrollment and study progress.
- Identifies, addresses, and resolves issues and problems as they might occur.
- Coordinates with vendors as applicable for the study.
- Coordinates with the PIs for site contracts.
- Ensures Clinical Trial Material compliance if applicable.
- One point of contact for the sponsors.
- Providing timely updates to the sponsor.
- To strategize for timely enrollment.
- Ensuring the study is completed within budgeted timelines and resources.
- Tracking the enrollment and retention of subjects at each site.
- Supervising a team of CRAs.
- Ensures collection of all data and remaining study supplies for return to the Sponsor/CRO at study completion.
- Ensures that appropriate study documents are completed and properly filed at study completion.
- Prepares the site for possible FDA inspection at study completion.
- Assists the Sponsor/CRO in problem solving and provide consultation on monitoring and study related activities at study completion.

3.4 CRA's Responsibility

3.4.1 Clinical Research Associate

- Ensuring compliance to Project Management Plan
- Conduct Site initiation, Monitoring & Close out visits
- Site management and monitoring at sites as a monitor.
- CTM management.
- Coordination with all sites for data transcription and Query resolution
- Organization and maintenance of TMF at the sites
- Timely completion of Reports as per IR monitoring plan
- CRF retrieval from the sites
- Timely requisitions of IP from the Sponsor Pharmacy after verifying accountability at the site
- Safe storage of IP to maintain their potency and shelf life as per Sponsors guidelines
- To check proper IP accountability record maintenance at site.
- Coordinate to send back IP to Sponsor Pharmacy from the study sites at the end of the study. Coordinate to send IP to sponsor Pharmacy after the study end from the study sites as per instruction given by Sponsor
- Reconciliation of IP supplies at the site
- Primary point of contact with Site & CRO for all study related issues.

3.5 Medical Monitor (MM)

Medical Monitor is responsible for safety management of the study.

MM is responsible for processing and reporting of adverse events and serious adverse events as per SOPs of IR in compliance with the study protocol and principles of ICH GCP.

The responsibilities will include but not limited to:

- Study Protocol compliance & waiver for project team and sites in consultation with the Sponsor
- Provide medical oversight regarding protocol deviation, protocol eligibility issues, concomitant medications & general study related issues.
- Conduct training for the project team concerning the disease, study design & medical related safety issues.
- Provide medical review of coding of adverse events, concomitant medications, disease & medical histories.

- Medical review of laboratory data on serious adverse events.
- Regulatory submission of SAE on a monthly basis.

  In the absence of the MM, the Manager- Clinical Trials will be responsible for safety management.

4.0 PROJECT MANAGEMENT PLAN

4.1 Team Contact Detail

S.No	Name	Role	Address	Email ID	Contact Numbers

4.1.1 Communication Plan with Sponsor Clinical Project Team

Responsibility	Timeframe	Trial Role Responsible

4.1.2 Information forwarded to the Site

Information/Document	Timeframe	Trial Role Responsible

5.0 PRE-TRIAL MONITORING ACTIVITIES

A site pre trial assessment or Site Qualification visit report is required for all the sites/ Principal investigators.

Visits would be conducted by IR Team (Manager- Clinical Trials /CRA-II/ CRA) & follow up letters would be sent to the site as per IR SOP following the approval from Sponsors (*to be completed after the SQV at all sites are done)*

Dates of Site Qualification Visit	**Site Name**

5.1 Investigator's Meeting

Date(s) of Meeting	NA
Location	NA

5.2 Site Initiation Related Activities

Site Initiation Visits are required for each site prior to screening subject.

Visits will be conducted according to ICH GCP Guidelines, .. SOP

The table below lists the key pre-trial responsibilities, the timeline/milestones or other requirement associated with the activity, and the clinical project team member responsible for the activity.

Responsibility	**Requirement/Timeframe**	**Trial Role Responsible**

5.3 Interim Monitoring Visits

These visits will be conducted according to .. SOP.
The table below lists the key monitoring responsibilities, the timeline/milestones or other requirement associated with the activity, and the clinical project team member responsible for performing the activity.

Responsibility	**Requirement/Timeframe**	**Trial Role Responsible**

5.3.1 Monitoring Plan – An overview

Document	Submit To	Timeframe for Submission	Trial Role Responsible

5.3.2 Recruiting and Enrollment Targets

Enrollment Target	Protocol-Specific Target

5.3.3 Source Document Verification (SDV)

Source documents verification will be conducted according to IR SOP -100% source data verification will be done for this trial.

5.3.4 Serious Adverse Events Reporting (SAE) & Medical Safety Management

Responsibility	Requirement/Timeframe	Trial Role Responsible

Safety Monitoring – SAE Processing and Management at all sites

Role of CRA in IP Management

IP Reconciliation:

6.0 SITE DRUG ACTION PLAN:

6.1 Equipments and Instruments used in …central Pharmacy:

6.2 Log Books Maintained at VMRC Central Pharmacy:

6.3 Responsibilities:

6.4 Process of Clinical Trial Supplies from Sponsor to Site Pharmacy

6.5 Process Flow of Clinical Trial Supplies from Central Pharmacy the study sites

6.6 Essential Forms used at Site Pharmacy:

6.7 Process to Request for Clinical Trial Supplies

6.8 Clinical Trial Supplies Received at the Site

6.9 Process of Return of Clinical Trial Supplies from the Central Pharmacy to the Sponsor at the end of the clinical Trial:

6.10 Responsibilities

6.10.1 Site Study Coordinator:

6.10.2 Site - CRA:

7.0 SITE CLOSE - OUT

Responsibility	Requirement/Timeframe	Trial Role Responsible

8.0 PROJECT UPDATES

9.0 Attachment (if any)

Annexure-I: List of Amendment

Annexure-I

Amendment In Project Management Plan

	Prepared By	Review by	Review & Approved by Sponsors
Name			
Designation			
Signature			
Date			

2.0 PROJECT MANAGEMENT TEAM

4.0 PROJECT MANAGEMENT PLAN

4.1 Team Contact Detail

S.No	Name	Role	Address	Email ID	Contact Numbers

5.0 PRE-TRIAL MONITORING ACTIVITIES

Addition of site and pre-trial activities at the addition site

Dates of Site Qualification Visit	Site Name

5.3.2 Recruiting and Enrollment Targets

Enrollment Target	**Protocol-Specific Target**
Total number of expected enrolled subjects	
Number of Study Sites	
The enrollment period	
Total Duration	
Site Initiation Visits	
Total Number of Days for SIV	