AX1-V6.1/SOP15/V6.1
Study Monitoring Visit Report

Instructions for completing the monitoring report:

TITLE PAGE:

- This box must appear on the title page of the final document.
- Monitoring reports may also feature the monitoring report title and preparers' name and contact information more on the title page.

MONITORING REPORT:

- Instructions for completing the monitoring report can be found under the section headings in this template.
- Applicable study details (Title page, Section 1-4) can be entered before the commencement of the monitoring visit for effective time management at the site during monitoring.
- Sections which are not applicable may be left blank but should NOT be deleted from the final document.

All instructions, including this introductory text, should be deleted from the final document.

Project Title & Short title	
Project ID *(TMC IRB Project No.)*	
Monitoring Date(s) *DD-Month-YYYY*	
Monitored By	
Contact *Telephone, email*	

1. SUMMARY OF FINDINGS

Study File related
ICF related
Inclusion/Exclusion Criteria
Source Document related
Study Drugs related
Others **(IRB, Compensation, Administration related)**

2.Introductory Information	
2.1 Date/Time of monitoring visit ***DD-Month-YYYY***	
2.2 Purpose of monitoring ***Site Qualification Visit*** ***Site Initiation Visit*** ***Routine Monitoring Visit*** ***Site Close-Out Visit***	
2.3 Date of Last monitoring visit ***DD-Month-YYYY***	
2.4 Enumerate the open queries from the last monitoring visit if any	**1.** **2.** **3.** **4.** **5.**
2.5 Mention the study file numbers (subject IDs) which were reviewed at this visit	

3.Project Details	
3.1 Study Title	
3.2 Project Type*(Investigator initiated/sponsored)*	
3.3 Any changes in the study team since last monitoring visit	
3.4 If Yes mention the details	
3.5 Have the changes been notified to the IRB	
3.6 Project start date ***DD-Month-YYYY***	

4.Project Status	
4.1 Current protocol version and date	
4.2 Current status ***a. Ongoing*** ***b. Completed*** ***c. Accrual Completed*** ***d. Follow-up*** ***e. Suspended*** ***f. Terminated*** ***g. Closed*** ***h. Closed Prematurely***	
4.3 If the response to the above question is option e, f or h, kindly provide relevant explanation	
4.4.1 Total patients to be randomized	
4.4.2 Total Subjects screened	
4.4.3 Total subjects randomized **(a) Total number of patients registered form general category** **(b) Total number of patients randomized form the private category** *(Please specify the total and category specific randomization figures)*	
4.4.4 Recruitment status on schedule*(Yes/No)* ***Comments(if any)***	
4.4.5 Total subjects who withdrew consent	
2.4.6 Total Subjects who discontinued ***Comments/Reasons***	
2.4.7 Total Subjects who completed the study ***Comments/Reasons***	
2.4.8 Total Subjects who are active in the study	

5.Informed Consent						
Enumerate subject IDs of the monitored subjects' ICDs	***Subject ID***	***Any Findings (Yes/No)***	***Details***	***Reported to IRB (Yes/No)***	***Issues Closed/ Open***	***Corrective Action/Suggestions/Comments***
a. Has appropriate consent been obtained before beginning any study procedure						
b. Correct version of the ICF						
c. Source record documentation						
d. Signature/date of PI administration of ICP						
e. Has the subject been given a copy of the consent form						
f. Others please specify in details section						

Kindly add separate word pages to this sheet if needed

6. Protocol specific deviations/violations						
	Subject IDs	***Any Findings (Yes/No)***	***Details***	***Reported to IRB (Yes/No)***	***Issues Closed/Open***	***Corrective Action/Suggestions/Comments***
a. Inclusion/Exclusion criteria related **b. Efficacy parameters related** **c. Visit windows related** **d. Labs related** **e. Others please specify in details section e.g. PK sampling related**						

Kindly add separate word pages to this sheet if needed

7.SAEs						
Subject ID	***Any SAE (Yes/No)***	***SAE type***	***Source Documentation***	***Reported to IRB (Yes/No)***	***Issues Closed/Open***	***Corrective Action/Suggestions/ Comments***

8.Study Drug Management - delete section if non CTIMP (Not applicable)				
	Yes	No	NA	Comments (if applicable include a comment and describe any corrective actions that were initiated)
8.1- Is there sufficient IMP on site/held in the pharmacy?				
8.2- Are the drug accountability records correct and up-to-date?				
8.3- Are IMP returns being destroyed appropriately & destruction certificates available?				
8.4- Is IMP being stored in a secure location & under the correct storage conditions?				
8.5- Is there an automated or min/max temperature monitoring procedure in place?				
8.6- Has the temperature stayed within the correct range throughout the duration of the study?				
8.7- If not, has this been reported and resolved?				
8.8- Are the code-breaks intact / has the blind been maintained?				

9. Site Personnel, Facilities & Equipment / Study Supplies				
	Yes	No	NA	Comments (if applicable include a comment and describe any corrective actions that were initiated)
9.1- Has there been a repeated breach of GCP or protocol?				
9.2- If yes, has this been reported appropriately?				
9.4- Have there been any changes in facilities or equipment?				
9.5- Do the facilities & equipment remain adequate for the conduct of the study?				
9.6- Are there adequate study supplies (CRFs, lab kits etc) available on site?				
9.7- If yes, are lab ranges documented and updated?				
9.8-Does the study involve reimbursement of: **(a) Study specific investigations** **(b) Medical Management of SAEs** **(c) Travel**				
9.9- Have the proof of reimbursement been maintained in form of voucher/ledger/any other? Please specify in the comments section				

10. Ethics Committee Related				
10.1. General Information				
	Yes/No	**If Yes please provide details**	***Issues Closed/Open***	***Corrective Action/Suggestions/Comments***
10.1.1. Change in IEC membership		-	-	-
10.1.2. Change in IEC SOP		-	-	-
10.1.3. Change in IEC registration		-	-	-
10.2. Study Related Documents				
10.2.1. Latest version of study related documents submitted and approved?				

10.3. Details of Study Documents				
Documents	**Version Number**	**Version Date**	**Approval/ Notification**	**IEC approval/notification acceptance date**
10.3.1. Protocol				
10.3.2. IB (if applicable)				
10.3.3. IB updates (if applicable)				
10.3.4. ICD				
10.3.5. ICD Back Translation				
10.3.6. CRF				

11. Source Data Verification				
	Yes	No	NA	Comments (if applicable include a comment and describe any corrective actions that were initiated)
11.1.Is the Source Data Verification done?				
11.2. Have the data queries been resolved?				

12.Investigators Site File				
	Yes	No	NA	Comments (if applicable include a comment and describe any corrective actions that were initiated)
12.1. Was the ISF reviewed for accuracy and completeness?				
12.2. Have the required documents being filed in the relevant section of the ISF?				
12.3. Was the ROMV visit recorded on the Site Visit Log?				

13.General Comments

(any information relevant to the study, other than Summary or specific sections e.g. deficiency identified in protocol, CRF vs Protocol etc.)

Name/Designation /Signature & Date of PI/study team member

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