**AX1-V6/SOP15/V6**

**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.*

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

**1. SUMMARY OF FINDINGS**

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

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| **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** |

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| **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*** |  |

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| **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**1. ***Has appropriate consent been obtained before beginning any study procedure***
2. ***Correct version of the ICF***
3. ***Source record documentation***
4. ***Signature/date of PI administration of ICP***
5. ***Has the subject been given a copy of the consent form***
6. ***Others please specify in details section***
 | ***Subject ID*** | ***Any Findings******(Yes/No)*** | ***Details*** | ***Reported to IRB (Yes/No)*** | ***Issues Closed/******Open*** | ***Corrective Action/Suggestions/Comments*** |
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***\*Kindly add separate word pages to this sheet if needed***

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| **6. Protocol specific deviations/violations** |  |
|  | ***Subject IDs*** | ***Any Findings******(Yes/No)*** | ***Details*** | ***Reported to IRB (Yes/No)*** | ***Issues Closed/Open*** | ***Corrective Action/Suggestions/Comments*** |
| 1. **Inclusion/Exclusion criteria related**
2. **Efficacy parameters related**
3. **Visit windows related**
4. **Labs related**
5. **Others please specify in details section e.g. PK sampling related**
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***\*Kindly add separate word pages to this sheet if needed***

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

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| **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:**1. **Study specific investigations**
2. **Medical Management of SAEs**
3. **Travel**
 |  |  |  |  |
| **9.9- Have the proof of reimbursement been maintained in form of voucher/ledger/any other? Please specify in the comments section** |  |  |  |  |

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| **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** |  |  |  |  |

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|  **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?** |  |  |  |  |

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|  **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?** |  |  |  |  |

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| **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** **Name/Designation /Signature & Date of DSMU member/monitor**  |