**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** |