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| **MONITORING CLOSE-OUT SITE VISIT CHECKLIST AND REPORT** |

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| **CLINICAL TRIAL DETAILS** | |
| Protocol Title |  |
| Clinical Trials Registry ID/number: |  |
| Site Name |  |
| Site Investigator Name |  |
| Monitor Name |  |

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| **VISIT SUMMARY** | | |
| Date of Close-Out Visit *(MM/DD/YYYY)* |  | |
| Study Personnel present during the visit | **Name** | **Title** |
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| **PATIENT RECRUITMENT STATUS** | |
| Total No. Subjects Planned |  |
| Total No. Subjects Completed |  |
| Total No. Subjects Screened |  |
| Total No. Subjects Withdrawn |  |
| No. Subjects Dropped treatment due to AEs |  |
| No. Subjects Dropped treatment due to other |  |
| No. Subjects completed treatment |  |
| No. Subjects entered follow-up |  |
| No. of withdrawals during first 8 weeks |  |
| No. Subjects dropped follow-up |  |
| Number of SAEs |  |

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| **FACILITIES / STAFF** | **Yes** | **No** | **N/A** | **Action items/issues comments** |
| Compliance with protocol, study procedures and SOPs |  |  |  |  |
| Was the staff properly trained for the study? |  |  |  |
| Has the investigator properly supervised the personnel? |  |  |  |
| Has the PI/study staff completed required study responsibilities? |  |  |  |
| Has the investigator completed his/her obligations to the sponsor/ IRB/ IEC/ regulatory authority? |  |  |  |
| Has the investigator been accessible during visits? |  |  |  |
| Has any staff or facility/work area change since last visit been properly recorded /updated? |  |  |  |
| Delegation log and training log complete and in accordance with qualifications and training? |  |  |  |
| Are facilities adequate? |  |  |  |

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| **PARTICIPANTS VERIFICATION** | **Yes** | **No** | **N/A** | **Action items/issues comments** |
| Compliance with protocol? |  |  |  |  |
| Compliance with study procedures and SOPs |  |  |  |
| Recruitment on schedule? |  |  |  |
| Screening and enrolment log completed and updated |  |  |  |
| Subject eligibility confirmed? |  |  |  |
| Medical record of enrolled participants references the study and indicates that the participants is receiving and IP? |  |  |  |
| All Participant Information Leaflet and Informed Consent Forms: | | | |  |
| * Current version used * Dated * Signed * Filed |  |  |  |
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| All HIV testing information leaflet and informed consent forms | | | |  |
| * Current version used * Dated * Signed * Filed |  |  |  |
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| All Informed Consent Forms for storage and use of your samples and data | | | |  |
| * Current version used * Dated * Signed * Filed |  |  |  |
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| All Informed consent forms for the use of blood samples for genetic testing | | | |  |
| * Current version used * Dated * Signed * Filed |  |  |  |
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| Has/Have there been any subject(s) lost to follow-up? |  |  |  |  |
| If withdrawals, are they during the first 8 weeks (while de IP are provided)? |  |  |  |
| If yes, are withdrawn subjects documented? |  |  |  |
| Has/Have there been any subject(s) discontinued from treatment or from the clinical trial? |  |  |  |

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| **CRF REVIEW** | **Yes** | **No** | **N/A** | **Action items/issues comments** |
| Have all CRFs been collected? |  |  |  |  |
| All CRF reviewed? |  |  |  |  |
| Are CRFs complete and on a timely basis?? |  |  |  |  |
| Is data accurate and backed up with source documents? |  |  |  |
| Are other worksheets legible, accurate and complete? |  |  |  |
| Were there any inconsistencies? |  |  |  |
| CRF adhere to the protocol for procedures and assessment related to:   * study endpoints * protocol-required safety assessment * evaluation, documentation and reporting of SAE, SUSAR, significant safety issues, participants deaths, and withdrawals related to AE |  |  |  |
| Documentation and reporting of serious breaches meet the principles of ALCOA, plus complete and traceable |  |  |  |
| If paper CRF used, is there a delay entering data on REDCAP? |  |  |  |  |
| If paper CRF used, is there any discrepancy between paper CRF and REDCAP CRF? |  |  |  |
| CRF problems discussed with staff and corrections made? |  |  |  |  |

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| **SAFETY VIGILANCE** | **Yes** | **No** | **N/A** | **Action items/issues comments** |
| Any SAEs since last visit? |  |  |  |  |
| Have all SAE been appropriately reported? |  |  |  |
| Has the blind been maintained? |  |  |  |
| Were any unreported SAEs/significant safety issues discovered? |  |  |  |
| Are there any participants deaths or withdrawals related to AE? |  |  |  |

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| **ISF REVIEW** | **Yes** | **No** | **N/A** | **Action items/issues comments** |
| Was the Investigator ISF reviewed during this visit? |  |  |  |  |
| Signed protocol, amendments and revisions and CRF |  |  |  |
| Investigators brochure |  |  |  |
| Package inserts |  |  |  |
| IRB/IEC approval and versions of:   * Protocol * Participant information leaflet and informed consent form * Informed consent form for storage and use of your samples and date * HIV testing informant leaflet and informed consent form * Informed consent form for the use of blood samples for genetic testing |  |  |  |
| Regulatory approval and versions of:   * Protocol * Participant information leaflet and informed consent form * Informed consent form for storage and use of your samples and date * HIV testing informant leaflet and informed consent form * Informed consent form for the use of blood samples for genetic testing |  |  |  |
| Financial aspects of the trial |  |  |  |
| Insurance statement |  |  |  |
| Signed agreement between involved parties |  |  |  |
| Curriculum vitae of investigator(s) and sub-investigator(s) |  |  |  |
| Safety reporting to the sponsor |  |  |  |
| Safety reporting to the IRB |  |  |  |
| SUSAR |  |  |  |
| Shipping records of investigational products and trial-related products |  |  |  |
| Instruction for handling of investigational product (IP) and trial-related materials |  |  |  |
| Normal value(s)/ranges for procedures included in the protocol |  |  |  |
| Medical/laboratory/technical procedures/tests |  |  |  |
| Certificates of analysis of IP shipped |  |  |  |
| Decoding procedures for blinded trials |  |  |  |
| Communication between team members |  |  |  |
| Agreements/contracts -executed |  |  |  |
| Source documents |  |  |  |
| Interim or annual reports to IRB/IEC and authority(ies) |  |  |  |
| Signed, dated informed consent forms |  |  |  |  |
| Source documents |  |  |  |  |
| Signed, dated and completed CRF |  |  |  |  |
| Documentation of CRF corrections |  |  |  |  |
| Notification by originating investigator to sponsor of serious adverse events and related reports |  |  |  |  |
| Notification by sponsor and/or investigator, where applicable, to regulatory authority(ies) and IRB(s)/IEC(s) of unexpected serious adverse drug reactions and of other safety information |  |  |  |  |
| Notification by sponsor to investigators of safety information |  |  |  |  |
| Interim or annual reports to IRB/IEC and authority(ies) |  |  |  |  |
| Subject screening and enrolment log |  |  |  |  |
| Current and completed Delegation Log |  |  |  |  |
| Completed Training log |  |  |  |  |
| Completed Investigational products accountability log |  |  |  |  |
| Record of retained body fluids/ tissue samples |  |  |  |  |
| Documentation of investigational product destruction |  |  |  |  |
| Final report by investigator to IRB/IEC where required, and where applicable, to the regulatory authority(ies) |  |  |  |  |
| Clinical study report |  |  |  |  |

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| **INVESTIGATIONAL PRODUCT** | **Yes** | **No** | **N/A** | **Action items/issues comments** |
| Was a pharmacy visit conducted? |  |  |  |  |
| Are all IPs correctly stored, dispensed and accounted? |  |  |  |
| Do the expiry dates of IP(s) have been compatible with the trial duration? |  |  |  |
| Is the IP accountability pharmacy log accurate and complete? |  |  |  |
| Disposition of unused IP at the trial sites complies with applicable regulatory requirement(s) |  |  |  |
| Receipt, use and return of IP at the trial site is controlled and documented |  |  |  |  |
| Participants are provided with necessary instruction on properly using, handling, storing, and returning the IP |  |  |  |
| Was the study blind broken for any patients during the study? |  |  |  |  |

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| **LABORATORY + DIAGNOSTIC SAMPLES** | **Yes** | **No** | **N/A** | **Action items/issues comments** |
| Have the labelling, storage and shipment of laboratory specimen/diagnostic material been adequate? |  |  |  |  |
| Is record of sample’s tracking updated? |  |  |  |

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| **SUMMARY OF FINDINGS IN CLOSE-OUT VISIT** | | | |
| **Finding:** |  | | |
| **Corrective measure to be completed prior to archiving** |  | | |
| **Name of person responsible for completing the task** |  | | |
| **Timeline for completion** |  | **Sign and date to confirm the tasks has been completed** |  |
| **Finding:** |  | | |
| **Corrective measure to be completed prior to archiving** |  | | |
| **Name of person responsible for completing the task** |  | | |
| **Timeline for completion** |  | **Sign and date to confirm the tasks has been completed** |  |
| **Finding:** |  | | |
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| **Timeline for completion** |  | **Sign and date to confirm the tasks has been completed** |  |
|  |
| **Finding:** |  | | |
| **Corrective measure to be completed prior to archiving** |  | | |
| **Name of person responsible for completing the task** |  | | |
| **Timeline for completion** |  | **Sign and date to confirm the tasks has been completed** |  |
|  |
| **Finding:** |  | | |
| **Corrective measure to be completed prior to archiving** |  | | |
| **Name of person responsible for completing the task** |  | | |
| **Timeline for completion** |  | **Sign and date to confirm the tasks has been completed** |  |
|  |
| **Finding:** |  | | |
| **Corrective measure to be completed prior to archiving** |  | | |
| **Name of person responsible for completing the task** |  | | |
| **Timeline for completion** |  | **Sign and date to confirm the tasks has been completed** |  |
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| **RECOMMENDATIONS OF MONITOR *(MARK)*** | |
|  | No action needed- study conduct is compliant with regulations, protocol and regulatory/IRB requirements. |
|  | No action required, but visit site again in \_\_\_\_\_\_\_\_ weeks to ensure corrections have been made. |
|  | Action required: investigator is noncompliant, schedule review meeting. |
|  | Action required: terminate study at site |

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| **SIGNATURE AND DATE** | |
| **MONITOR** | **PRINCIPAL INVESTIGATOR** |
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A copy of the signed template Close-Out Visit Checklist and report and any supporting information should be provided to the Investigator for inclusion in the TMF/ISF prior to archiving.