|  |
| --- |
| **ADMINISTRATIVE INFORMATION** |
| *Title of Protocol* |  |
| *Protocol Reference Number* |  |
| *Protocol Version Number (where applicable)* |  |
| *Date and Reference Number of the Trial Approval*  |  |
| *Expected Date of Starting (as indicated on the certificate):* | *dd/mm/yyyy* |
| *Actual Date(s) of Start (at the Trial Centre(s):* | *dd/mm/yyyy* |
| *Names and contact of Principal Investigator*  |  |
| *Names and contact of Co-Investigator* |  |
| *Names of Sponsor (If applicable)* |  |
| *Name and address of the Contract research Organization (s) (CRO)where the clinical studies proving efficacy and safety of the product were conducted if applicable* |  |
| *Phase of Trial (if applicable)* |  |
| *Number of Clinical Trial Site.* |  |
| *List of Clinical Trial Sites* |  |
| *Duration of Clinical Trial* |  |
| *Name of Investigational Product (IP) strength, and dosage form.* |  |
| *IP Therapeutic indications* |  |
| *IP Route of Administration* |  |
| *IP Storage Information* |  |
| **TRIAL SITE INFORMATION** |
| Name and address of Clinical Site |  |
| Date of last recruitment |  |
| Reason for closure |  |
| Site Personnel involved in trial: |  |
| ***Names*** | ***Title*** | ***Contact*** |
|  | Site coordinator |  |
|  | Site Monitor |  |
|  | Pharmacist |  |
|  | Data Manager |  |
| *Are there changes to trial staff since the last* |  |
| *Is the delegation log up to date?* |  |
| *Are all training records up to date?* |  |
| *Have all CAPA’s been completed?* |  |
| *Are progress report submitted according to the timelines?* |  |
| **OBJECTIVES** | **COMMENTS** |
| *All regulatory and other essential documents are up-to-date and enclosed in Trial Master of File (TMF)* | *Provide list of documents on file at the site* |
| *Notification of all relevant oversight bodies of**closure of study such FDA, IEC/IRB* |  |
| *Signed, informed consent is in TMF for each**trial participant* | *Provide list of participants (use codes/ study IDs)* |
| *Documentation of all protocol violations/deviations and/ or appropriate note- to- files in the relevant essential document* | *Provide list* |
| *Appropriate follow- up and reporting of all SAEs**to the Authority* | *Provide number of SAEs reported and Summary**of outcome for SAEs listed is relevant* |
| *Completion of all Case Report forms for each**participant* |  |
| *All AEs and SAEs have been captured, followed, and resolved per protocol, and reported to the**appropriate parties (Sponsor, IRB, and regulatory**authorities, if applicable) according to protocol reporting requirements* |  |
| *Source documents for the following Participant ID numbers were reviewed at this visit (add rows as needed): or NA* |  |
| *Entry/ submission of all relevant data into database / to sponsor/ coordination center. If NOT complete, indicate the timeline for accomplishing this and document in the comments section* |  |
| *Tentative date for submission of full Clinical Study Report*  |  |
| ***Investigational and Placebo accountability****:* |  |
| *Quantity of IPs received* |  |
| *Quantity of IPs utilized in the study* |  |
| *Quantity of IPs destroyed* *(Attach copy of destruction certificate (s)* |  |
| *Quantity of IPs onsite/ returned to sponsor* |  |
| *Status/ shipment/ analyses of all participant specimen according to protocol requirements (including plans for future shipments or period of time they will be stored on- site)* |  |
| *If blinded study drug was used, confirm that the tear- off labels were not opened. For any that were opened, documentation should be obtained noting the reason for unblinding* |  |
| *All unused trial supplies properly disposed (on site) / returned to sponsor or manufacturer per instructions from sponsor*  |  |
| ***Collected Laboratory Specimens (Samples)*** |
| *Confirm that all specimens have either been analyzed or stored for future use* |  |
| *Ensure that specimens collected for future use have been adequately processed, labeled/de-identified, and stored* |  |
| *Confirm site process for identification and disposition of future use specimens connected to subjects who withdraw consent or do not consent for their specimens to be saved* |  |
| *Confirm destruction, per institutional policies, of specimens not identified for future analysis* |  |
| *Confirm final disposition of study supplies and any equipment provided for the study: <insert study-specific items>* |  |
| *Specimens collected for future use to be shipped elsewhere (if yes, specify if sponsor or Investigator arranges shipment, file shipping documentation in the Investigator* |  |
| **CURRENT TRIAL STATUS**  |
| Number Screened: ………………….. Number enrolled: …………………..Number of loss of follow-up: ………………….. Number of Follow-up required: ………………….. Number of SAE reported: …………………..Number of protocol amendments: ………………….Number of death recorded |
| **ESSENTIAL DOCUMENTS RECONCILIATION**  |
|  | **YES** | **NO** | **NA** | **COMMENTS** |
| *Anonymized Subject Screening & Enrolment**Log* |  |  |  |  |
| *Delegation Log* |  |  |  |  |
| *Visit Log* |  |  |  |  |
| *Training log* |  |  |  |  |
| *Protocol Deviation Log* |  |  |  |  |
| *IP Accountability/Inventory Log* |  |  |  |  |
| *IP Approval for Transfer (if applicable)*  |  |  |  |  |
| *IP Return documentation* |  |  |  |  |
| *IP Destruction Form* |  |  |  |  |
| *IP Storage Temperature Log* |  |  |  |  |
|  *Maintenance Log (Device)* |  |  |  |  |
| *Sample Inventory Log* |  |  |  |  |
| *Sample Storage Temperature Log* |  |  |  |  |
| *Temperature monitoring Device (LogTag) if applicable* |  |  |  |  |
| **STATUS OF PAST OBSERVATIONS/ RECOMMENDATIONS MADE DURING MONITORING/ GCP INSPECTIONS** |
| *Have corrective measures been implemented for all observations and recommendations?), Provide summary of measures implemented for each point* |
| **OUTSTANDING ISSUES OR ACTIVITIES TO BE IMPLEMENTED** |
| *Include problems identified, if any, and recommendations/ action items for corrections* |
| **REPORT APPROVAL** |
| ***Names of Investigator*** | ***Date***  | ***Signature*** |
|  |  |  |