|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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*** | |
|  | |  | | | |  | |