|  |  |  |
| --- | --- | --- |
| **ADMINISTRATIVE INFORMATION** | | |
| Reporting Period | **From: DD/MM/YYYY to: DD/MM/YYYY** | |
| 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 |  | |
| **CURRENT TRIAL STATUS** | | |
| *Tick as appropriate*  Enrolment has not begun  Actively enrolling participants  Enrolment closed on: (insert date): participants are receiving treatment/intervention  Enrolment closed on: (insert date): participants are in follow-up only.  Analysing data  Data analysis completed | | |
| **INFORMATION ON PARTICIPANTS & INITIATED TRIAL ACTIVITIES** | | |
| Number of persons consented....................................................  Number of persons screened......................................................  Number of persons consented and screened who are eligible for the trial......................  Quantity of imported investigational products and Placebos………………………….  Quantity of used investigational products and Placebos………………………….  Quantity of destroyed investigational products and Placebos ………………………….  Number of participants to which the investigational product(s) has been so administered the first dose.........................................................................................................................  Number of participants left to be enrolled into the trial.......................................................  Number of participants who have discontinued the trial:  by Investigator:  voluntarily:  due to SAE:  lost-to-follow-up:  Death  Have there been any Serious Adverse Events (SAEs)? **Yes  No**  Total number of SAEs: ………. [*attach line list of SAEs documented for the quarter*]  Have these SAEs been reported to the Authority? **Yes  No**  If No, explain....................................................................................................................  I there been any amendment to the protocol since the Authority approved? **Yes  No**  If **YES**, is the amendment submitted to the Authority? **Yes  No**  If No, explain......................................................................................................  Are there any other developments in the trial that you wish to report to the Authority? **Yes  No**  If YES, provide details......................................................................................................  Are there any ethical or regulatory issues on which further advice is required? **Yes  No**  If **YES**, provide details: m  Date for the end of the trial  Date for the final trial report  Other information not listed: | | |
| **SUMMARY OF TRIAL PROGRESS STATUS TO DATE** | | |
|  | | |
| **ADDITIONAL COMMENT FROM THE INVESTIGATOR** | | |
|  | | |
| **REEPORT APPROVAL** | | |
| ***Names of Investigator*** | ***Date*** | ***Signature*** |
|  |  |  |
|  |  |  |
|  |  |  |