**Food and Drugs Authority Clinical Trials Quarterly Progress Report Form**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **SECTION A: ADMINISTRATIVE INFORMATION** | | | | | |
| FOOD AND DRUGS  AUTHORITY Clinical  Trial Certificate Number:    ……………………… | | | Expected Date of Commencement (as indicated on the certificate):    ……./………./………. | Actual Date(s) of  Commencement (at the Trial Centre(s):      ……./………./………. | Protocol Number:  …………………………  …………………………  ………………………… |
| Trial Title: | | |  | | |
| Trial Site(s) | | |  | | |
| Reporting Period | | | From………………………………………….to………………………………… | | |
| Principal Investigator: | | | Name: | | |
| Address: Phone:    Mobile:    E-mail: | | |
| Co-Investigators: | | | Name(s): Phone:    Mobile:    E-mail: | | |
| Other Trial Contact (if applicable): | | | Name: Phone:    Address: Mobile:    E-mail: | | |
| **SECTION B: TRIAL STATUS (Check one category only)** | | | | | |
|  |  | Enrolment has not begun    Actively enrolling participants | | | |

# SEPTEMBER 2019 SMT/CTD/FOR-05/3.0

|  |  |  |
| --- | --- | --- |
|  |  | Enrolment closed on: (insert date): participants are receiving treatment/intervention    Enrolment closed on: (insert date): participants are in follow-up only.    Analyzing data    Data analysis completed |
|  |

**SECTION C: INFORMATION ON PARTICIPANTS & TRIAL ACTIVITIES**

# SEPTEMBER 2019 SMT/CTD/FOR-05/3.0

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. Number of persons consented............................. 2. Number of persons screened............................... 3. Number of persons consented and screened who are eligible for the trial........................... 4. Number of participants to which the investigational product(s) has been administered......................... 5. Number of participants left to be enrolled into the trial............................... | | | | | |
| f. Number of participants who have discontinued the trial:   * by Investigator:      * voluntarily:      * due to SAE:      * lost-to-follow-up: | | | | | |
| 1. Have there been any Serious Adverse Events (SAEs)?      1. Total number of SAEs: (attach line list of SAEs documented for the quarter)      1. Have these SAEs been reported to the Food and Drugs Authority      1. If No, explain.................................................................................................................      1. Have there been any changes to the protocol since the Food and Drugs Authority approved?      1. Is this amendment submitted to the Food and Drugs Authority?      1. If No, explain.................................................................................................................   .…………………………………………………………………………......................     1. Date for the end of the trial | Yes |  | No |  |  |
|  |
|  |
| Yes |  | |  | | --- | |  |   No | | |
|  |
| Yes |  | No |  |  |
|  |  |
| Yes  No | | | | |

# SEPTEMBER 2019 SMT/CTD/FOR-05/3.0

|  |  |
| --- | --- |
| o. Date for the final trial report |  |

**SECTION D: COMMENTS (if any)**

**SECTION E: SIGNATURE**

. .

Signature of Principal Investigator

Date

Return this form and all supporting documentation

to:

THE CHIEF EXECUTIVE

FOOD AND DRUGS AUTHORITY P. O. BOX

CT 2783, CANTONMENTS, ACCRA or submit via e-mail to drug.safety@fdaghana.gov.gh

SEPTEMBER 2019 SMT/CTD/FOR-05/3.0