TITLE: 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: Address:	Phone: Mobile: E-mail:	

SECTION B: TRIAL STATUS (Check one category only)

- ☐ 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.
- ☐ Analyzing data
- ☐ Data analysis completed

SECTION C: INFORMATION ON PARTICIPANTS & TRIAL ACTIVITIES

a. Number of persons consented.....

b. Number of persons screened.....

c. Number of persons consented and screened who are eligible for the trial.....

d. Number of participants to which the investigational product(s) has been administered.....

e. 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:

g. Have there been any Serious Adverse Events (SAEs)?	Yes ☐ No ☐
h. Total number of SAEs:_____ (attach line list of SAEs documented for the quarter)	
i. Have these SAEs been reported to the Food and Drugs Authority	Yes ☐ No ☐
j. If No, explain.....	
k. Have there been any changes to the protocol since the Food and Drugs Authority approved?	Yes ☐ No ☐
l. Is this amendment submitted to the Food and Drugs Authority?	Yes ☐ No ☐
m. If No, explain.....	

…….. n. Total number of protocol deviations:_____(attach list of Protocol Deviations for the quarter) o. Date for the end of the trial p. 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 clinicaltrials@fda.gov.gh