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 Study Centre(s): ……/……./…….	Protocol Number: …… …… ……
Study Title:			
Study Site(s)			
Reporting Period	From……to……		
Principal Investigator:	Name:		
	Address:	Phone: Mobile: E-mail:	
Co-Investigators:	Name(s):	Phone: Mobile: E-mail:	
Other Study Contact (if applicable):	Name: Address:	Phone: Mobile: E-mail:	

SECTION B: STUDY STATUS (Check one category only)
☐ Enrolment has not begun
☐ Actively enrolling subjects
☐ Enrolment closed on: (insert date): subjects are receiving treatment/intervention
☐ Enrolment closed on: (insert date): subjects are in follow-up only.
☐ Analyzing data
☐ Data analysis completed

SECTION C: INFORMATION ON SUBJECTS & STUDY ACTIVITIES	
a. Number of subjects consented and screened.....	
b. Total number of subjects consented and screened who are eligible for the study.....	
c. Number of subjects to which the investigational product(s) has been administered.....	
d. Number of subjects left to be enrolled in the coming months (years).....	
e. Number of participants who have discontinued the study: • by Investigator: • voluntarily: • due to SAE:	
f. Have there been any Serious Adverse Events (SAEs)?	Yes ☐ No ☐
g. Total number of SAEs:_____ (attach line list of SAEs documented for the quarter)	
h. Have these SAEs been reported to the Food and Drugs Authority	Yes ☐ No ☐
i. If No, explain..... …….....	
j. Have there been any changes to the protocol since the Food and Drugs Authority approved?	Yes ☐ No ☐
k. Is this amendment submitted to the Food and Drugs Authority?	Yes ☐ No ☐
l. If No, explain..... …….....	
m. Date for the end of the study	
n. Date for the final study 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