

FDA/HPT/SMC/CTD/CTA/22/0011

12th January 2022

Dr. John H. Amuasi
The Principal Investigator
Kumasi Center for Collaborative Research in Tropical Medicine
Southend Asuogya Road
KNUST
Kumasi

Tel: +233 206300405

Email: amuasi@kccr.de

Dear Dr. Amuasi,

APPROVAL OF CLINICAL TRIAL APPLICATION – RECOVERY TRIAL

This is to acknowledge receipt of your letter dated 22nd December 2021 and the documents submitted (list attached) for the study titled ***“Randomized Evaluation of Covid-19 Therapy (RECOVERY)”***.

The FDA has completed the review of your responses and has issued a Clinical Trial Certificate with number **FDA/CT/222a** (attached) for the conduct of the study at the **Ghana Infectious Disease Center** site.

You are however reminded to:

1. Take note of the conditions specified in the Certificate issued and to inform the FDA on the **exact date of commencement** of the study.
2. Provide **monthly updates** on the study (format attached).
3. Submit the final ethics approval from the Komfo Anokye Teaching Hospital Institutional Review Board (KATH-IRB) for the conduct of the study.
4. Submit CoA for Empagliflozin once available or prior to importation.

Yours sincerely,



DELESE A. A. DARKO (MRS.)
CHIEF EXECUTIVE OFFICER

LIST OF DOCUMENTS SUBMITTED

1. Proof of submission for registration with the Pan African Clinical Trials Registry (PACTR).
2. Data Monitoring Committee Charter version 1.1 dated 21st December 2021.
3. Ghana Health Service Ethics Review Committee (GHS-ERC) Approval letter dated 17th December 2021.
4. Certificate of Conformance for Jardiance 10MG FTAB30 SSA.
5. Evidence of advice by the Pan African Clinical Trials Registry to the Recovery Trial Sponsor not to proceed with registration of the trial with the PACTR.



12th January 2022

CLINICAL TRIAL CERTIFICATE – No. FDA/CT/222a

In pursuance of the Public Health Act, 2012, Act 851, Part 8, Sections 150-166, the Food and Drugs Authority hereby grants approval for the conduct of Clinical Trials as per information herein provided.

**NAME/MANUFACTURER OF INVESTIGATIONAL PRODUCTS:
TREATMENT/CONTROL**

1. Dexamethasone (MANUFACTURER: Consilient Health Ltd)
2. Empagliflozin (MANUFACTURER: Boehringer Ingelheim Limited)
3. Standard of care for COVID-19 as per the COVID-19 standard treatment guidelines.

APPROVED PROTOCOL:

Version 16.0 dated 7th July 2021

APPROVED INFORMED CONSENT FORM:

Informed Consent Form and Participant Information Sheet (English), Version 14.0 dated 30th June 2021

INVESTIGATOR'S BROCHURE:

Summary of Product Characteristics for:

1. Dexamethasone
2. Empagliflozin

STUDY TITLE:

Randomized Evaluation of Covid-19 Therapy (RECOVERY)

NAME AND ADDRESS OF SPONSOR:

University of Oxford Clinical Trials and Research Governance.
University of Oxford Clinical Trials and Research Governance, Boundary Brook House,
Churchill Drive. Headington, Oxford, OX3
Tel: +44(0)8001385451
E-mail: recovery_trial@admin.ox.ac.uk

NAME AND ADDRESS OF PRINCIPAL INVESTIGATOR(S):

- | | |
|--|---|
| 1. Dr. John H. Amuasi
National Principal Investigator
Kumasi Center for
Collaborative Research in
Tropical Medicine (KCCR)
Southend Asuogya Road
KNUST
Tel: +233 20 6300405
E-mail: amuasi@kccr.de | 2. Dr. Christian Owoo
Site Principal Investigator
P.O.Box 77 Korle Bu
Accra
Telephone Number: 0244668871
E-mail: cowoo@ug.edu.gh /
chris_owoo@yahoo.com |
|--|---|

NAME AND ADDRESS OF STUDY CENTRE(S):

Ghana Infectious Disease Centre,
Ga-East Municipal Hospital, Kwabenya, Accra

TARGET POPULATION:

Adult patients 18 years and above who are hospitalized with SARS-CoV 2 infection-associated disease.

EXPECTED DATE FOR COMMENCEMENT: 18th January 2022

DURATION OF STUDY: 24 months

EXPECTED DATE OF END OF STUDY: 18th January 2024

This Clinical Trial Certificate remains valid only under the following condition:

1. Any amendment to the protocol mentioned herein, date for commencement and duration of the trial shall be communicated to and authorized by the Food and Drugs Authority (FDA) and an amended Clinical Trial Certificate issued.
2. If the trial does not begin or is delayed as per the expected date of commencement on the Clinical Trial Certificate issued, the FDA shall be informed of the actual date of commencement within ninety (90) days of issuance of the Clinical Trial Certificate. Failure of notification within the stipulated time would invalidate the Clinical Trial Certificate issued. A new certificate would attract administrative fees.
3. All Serious Adverse Events (SAEs) observed during the study and the actions taken shall be reported to the FDA within forty-eight (48) hours.
4. Monthly updates on the progress of the trial shall be submitted to the FDA within stipulated timelines upon commencement of the trial.
5. The conduct of this trial is restricted only to the study site mentioned herein; Ghana Infectious Disease Centre, Accra.
6. All investigational products and comparators as well as quantities received for the study shall be communicated to the FDA within 48 hours of receipt at the site.

Yours sincerely,



DELESE A. A. DARKO (MRS.)
CHIEF EXECUTIVE OFFICER

**FOOD AND DRUGS AUTHORITY****DOC. TYPE: FORM****DOC NO.: FDA/CTD/FOR – 05b****Page 1 of 3****Ver. No.: 00****Effective Date: 09/08/2021****TITLE: FOOD AND DRUGS AUTHORITY CLINICAL TRIALS MONTHLY 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
- ☐ 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



FOOD AND DRUGS AUTHORITY

DOC. TYPE: FORM

DOC NO.: FDA/CTD/FOR – 05b

Page 2 of 3

Ver. No.: 00

Effective Date: 09/08/2021

TITLE: FOOD AND DRUGS AUTHORITY CLINICAL TRIALS MONTHLY PROGRESS REPORT FORM

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. Date for the end of the trial

o. Date for the final trial report



FOOD AND DRUGS AUTHORITY

DOC. TYPE: FORM

DOC NO.: FDA/CTD/FOR – 05b

Page 3 of 3

Ver. No.: 00

Effective Date: 09/08/2021

TITLE: FOOD AND DRUGS AUTHORITY CLINICAL TRIALS MONTHLY PROGRESS REPORT FORM

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