RESEARCH PROGRESS REPORT

National Health Research and Training Institute

Contact details:

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www.nhrti.org.zm

Zambia Medicines Regulatory Authority

Contact details:

Head Office, Plot No 2350/M, Off Kenneth Kaunda International Airport Road

P.O. Box 31890, Lusaka, ZAMBIA

Tel: +260 211 220429,

E-mail: clinicaltrials@zamra.co.zm or pharmacy@zamra.co.zm;

Website: www.zamra.co.zm

Version 2

This progress report shall be submitted for all Health research to HRECs and NHRTI biannually. A progress report shall be submitted to ZAMRA (and NBA, where applicable), biannually, for Clinical trials involving investigational medicines and allied substances

SECTION A: ADMINISTRATIVE INFORMATION

Reference, Certificate or Permit Number and Date of Approval (a) NHRTI Reference Number: ……. (b) HREC Reference Number: …… (c) ZAMRA Clinical Trial Certificate Number: ……. (d) NBA Permit Number: ……	Planned Start and end Date of Study: **……/……/……**	Actual Date(s) of Commencement (at the Study Centre(s): ……/……/…….	Protocol Versio Number and Date …… ……	
Study Title:				
Study Site(s):	Place: Town: District: Province:			
Date of approval	**HRECs:**	**NHRA:**	**ZAMRA:**	**NBA:**

Reporting Period	From……to……
Principal Investigator:	Name: Phone: Address: Mobile: E-mail:
Co – Investigator(s):	Name: Phone: Address: Mobile: E-mail:

SECTION B: STUDY SUMMARY	
Please briefly: Describe the Research purpose or objective:	

SECTION C : STUDY STATUS (Tick, Delete as appropriate and explain relevant category)

☐ Enrolment has not begun
☐ Actively enrolling human participants/ animal subjects
☐ Enrolment closed on: (insert date): human participants/ animal subjects are receiving treatment/intervention
☐ Enrolment closed on: (insert date): human participants/ animal subjects are in follow up only

☐Both Enrolment and follow up of human participants/ animal subjects are completed(insert Las participant last visit Date):

☐ Analysing data
☐ Data analysis completed
☐ Report writing completed

Details of Study Status

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Version 2

SECTION D : INFORMATION OF PARTICIPANTS & STUDY ACTIVITIES

a. Number of participants consented…… screened……
b. Total number of participants consented and screened who are eligible for the study……
c. Number of participants who are enrolled ……
d. Number of participants to which the investigational product(s) has been administered ……
d. Number of participants left to be enrolled in the coming months (years)……

e. Number of human participants/ animal subjects who have discontinued the study:
- By Investigator: ……
- Voluntarily: ……
- Lost to follow up: …….
- 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 reporting period)	
h. Have these SAEs been reported to : ☐ZAMRA , ☐NHRTI, ☐NBA or ☐HRECs	
i. Explain if not submitted …… ……	Yes ☐ ☐ No
j. Have there been any Protocol Violations?	
k. Total number of Protocol Violations: ……	
l. Have these Protocol Violations been reported to : ☐ZAMRA, ☐NHRTI, ☐NBA or ☐HRECs	
m. Explain if not reported …… ……	Yes ☐ ☐ No
n. Have there been any Protocol Deviations?	Yes ☐ ☐ No
o. Total number of Protocol Deviations: ……	
p. Have these Protocol Deviations been reported to: ☐ ZAMRA, ☐ NHRTI, ☐NBA or ☐RECs	
q.	
r.]Explain if not reported …… ……	Yes ☐ ☐ No
	Yes ☐ ☐ No
s. Have there been any changes to the protocol since ZAMRA, NHRTI, NBA or RECs approved?	
t. Was this amendment submitted to: ☐ ZAMRA, ☐NHRTI, ☐NBA or ☐HRECs	
u. Explain if not submitted …… …… ……	

v. Report on any problems that have inhibited the progress of your study. Explain what impact the problems have had on study progress and how you plan to address these issues
……
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w. For MTAs, how much of the quantity stipulated in the protocol have been transferred. (*attach fraction form*)……

x. Attachments
   i. AEs Line listing
   ii. Protocol Deviation (s) log
   iii. Protocol violation (s) log
   iv. Protocol amendment(s) log
   v. Biological sample shipment log (International shipment)

n.

SECTION E : COMMENTS (if any)

SECTION F : SIGNATURE

_____	_____	_____
Name of Principal Investigator	Signature	Date

Return this form, Cover letter and supporting documentation to:

1. The Director General
Zambia Medicines Regulatory Authority
P. O. Box 31890, Lusaka Zambia
Submit to **zamra.co.zm/e-services-portal/**

2.The Director and CEO
National Health Research and Training Institute
P.O Box 71769, Ndola, Zambia
Submit to **nhrti.org.zm**

3. The Registrar and CEO

Version 2

National Biosafety Authority
P.O Box 37617, Lusaka Zambia
Submit to