

# SETTING UP AN RCT TO EVALUATE CANDIDATE VACCINES IN THE CONTEXT OF AN OUTBREAK?

Bruce J Kirenga MBChB, MMed, PhD, FRCP

Principal Investigator



**R&D Blueprint**

Powering research  
to prevent epidemics

# Introduction

An EVD outbreak was declared on 20th Sept 2022

- The outbreak was caused by the Sudan ebolavirus (SUDV) species

Vaccines are an integral part of any disease outbreak response

However, there was none with proven efficacy & safety against the SUDV species at the time of the outbreak

- Only vaccines against EBV were available

There were SUDV candidate vaccines, but these needed to be evaluated in a trial

A ring vaccination trial (Solidarity against Ebola/) was thus initiated to evaluate the efficacy & safety of candidate SUDV species

- With support from WHO & Uganda Ministry of Health

# Introduction

The trial was given a local text through a local name: TOKOMEZA Ebola trial

Trial was to evaluate the 3 candidate vaccines

By week 11, the trial was ready to enrol, **at least 1 ring was defined\_** however this did not happen as the pandemic was controlled

Capacity was established & several lessons learned

We document experiences with Tokomeza Ebola trial set up & highlight factors that facilitated readiness for trial start

# Stewardship of the sponsors



Stewardship from WHO & MOH-Uganda

Within 1<sup>st</sup> week of outbreak, MOH-Uganda assigned Investigation team of scientists & implementing organisation (MLI)

WHO provided logistics & supplies

Regular meetings with the sponsors were held

# Institutional capacity



Inherent capacity to conduct trials during disease outbreaks

MLI had been involved in several COVID-19 studies

Through this capacity had been established

- Human resource (Investigation/scientists, project managers, trialists, trial physicians, QC, finance managers, grants managers etc)
- Existing facilities used (data management, CTU....)

The institute leveraged structures established during COVID-19 & other research studies to support TOKOMEZA trial processes

# Collaborations



North – South: provided scientific oversight

- WHO HQ
- CEPI etc

South – South collaboration

- Created by WHO that included experts from the West African zaire ebolavirus Ebola Virus Vaccine trial (Ebola ca suffit)
- Worked with country team to finalise the protocol & tools
- Worked with country team to train trial teams

In country collaborations

- Makerere University
- Ministry of Health
- Mulago Hospital
- National Medical stores



# Ethical & regulatory approvals



Leveraged the **Joint scientific** & ethical review mechanism for clinical trials

- Brings together all regulators (IRB, NDA, UNCST & Investigators) in one sitting
- This optimized TAT & ensured all ethics & regulatory approvals were obtained within 9 weeks of the outbreak



Involvement of NDA at an early stage helped expedite regulatory approvals for vaccine import & vaccines arrival



# Leadership & governance



Immense support at the national level from the sponsors (WHO country office & MoH)

Support from district leadership in outbreak districts (RDC, CAO, DHO....)

- Aailed space
- Supported community entry

Support from MoH response structures

- Ebola task forces in the outbreak districts
- Operating space at Mulago hospital (currently a vaccine house)

Makerere University

- Administrative & leadership support



# In conclusion.....

Narrowing the gap between the onset of an outbreak & the implementation of clinical trials is key

This is possible through stewardship, leveraging prior research experience & multiple stakeholder involvement

But.....

- The trial team was able to fast track trial preparations, trial didn't start by the end of the outbreak
- Missed opportunity of over 100 rings which would have been sufficient to provide at least preliminary efficacy candidate SUDV vaccines
- The current efforts of pre approved, pre assembled teams are probably the solutions to evaluation epidemic MCM

# In conclusion.....

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# Thanks