



7TH GLOBAL FORUM ON TB VACCINES

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Rio de Janeiro, Brazil

Driving innovation from discovery to access



Challenges in recruiting neonates for a phase III TB vaccine trial and mitigations taken: Lessons learned for community engagement in Mbeya, Tanzania

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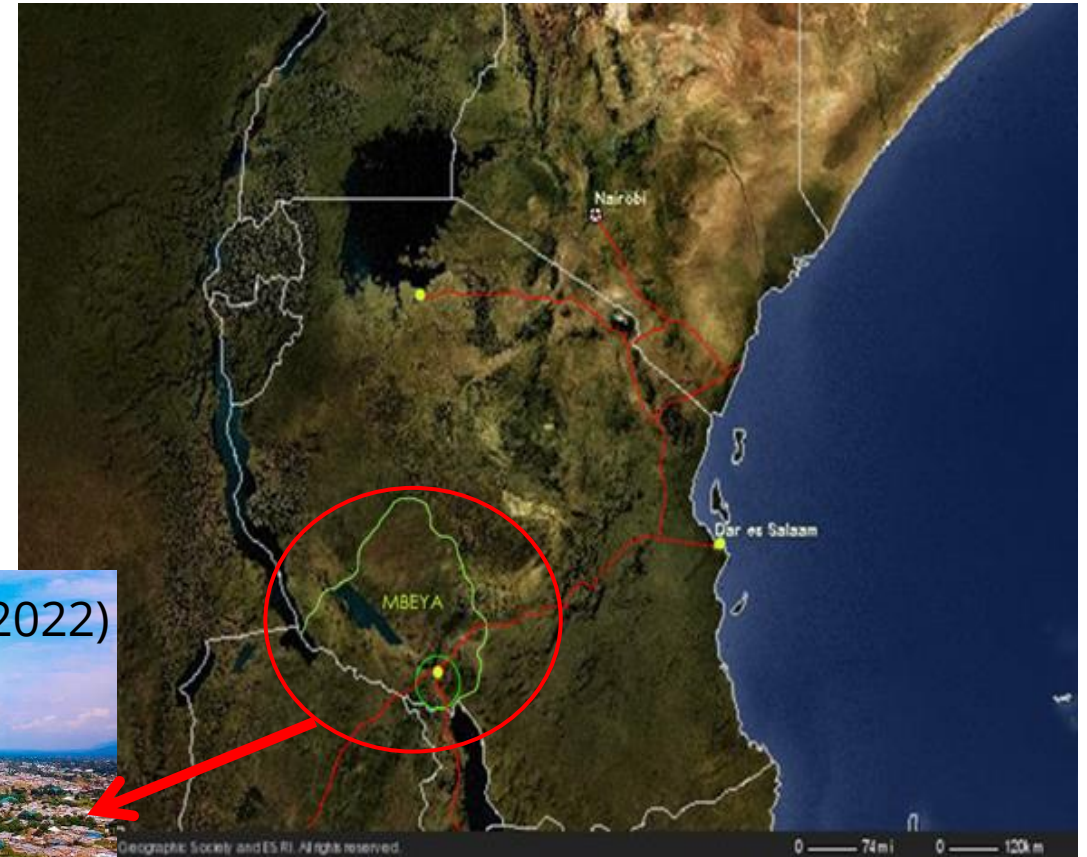
9th October 2024



Background



- Development of new TB vaccines requires retained participation in trials
- priMe TB trial is a phase III clinical trial evaluating the safety and efficacy of a novel TB vaccine candidate (VPM 1002) among neonates
 - Kenya, Tanzania, Gabon, Uganda and South Africa
 - Two sites in Tanzania (IHI and NIMR)



Background con't

- First neonatal TB vaccine trial in Mbeya region
- Initial recruitment strategies:
 - referral maternity hospital
 - community advisory board members
- challenges were encountered during recruitment
- Recruitment: 6940 across all countries
 - Initial target in Mbeya: 700
 - 547 neonates recruited (Aug.2021-Jun.2022)





Objective

To describe challenges experienced in recruiting neonates and mitigations adopted to attain recruitment and retention targets set within the priMe TB trial

We held semi-structured in-depth interviews with the study team in May 2024

- 3 medical doctors, 2 nurses and 1 community engagement officer



Recruitment challenges

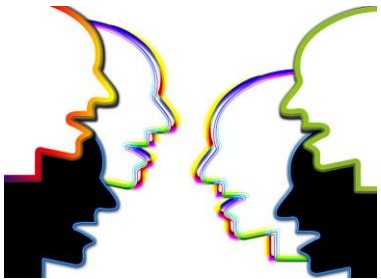


attributing COVID-19 vaccination to the candidate TB vaccine



lack of community awareness about neonatal TB vaccine research

misconceptions about TB vaccine research



family disputes arising from prevailing patriarchal values and religious beliefs impeding participation



Mitigations for recruitment challenges



regular sensitization meetings with communities

frequent engagement of community leaders

- meetings with community advisory board members
- meetings with heads of families





Designated community engagement staff



Engaging healthcare providers in routine facilities



participant retention meetings



Take Home Message!



Early and sustained engagement of community stakeholders is crucial

Community sensitization on TB vaccine research prior and during implementation of trials is necessary

Regular engagement with health providers in non-research facilities is salient particularly in less experienced research sites

Trial partners and recruitment sites



SERUM INSTITUTE OF INDIA PVT. LTD.
Cyrus Poonawalla Group

Serum Life Science Europe GmbH

Max-Planck-Institut für Infektionsbiologie

satvi
SOUTH AFRICAN TUBERCULOSIS VACCINE INITIATIVE

European Investment Bank

FANCRU

VPD Vaccine Preventable Diseases RMPRU
Respiratory & Meningeal Pathogens Research Unit

DiagnoSearch

EDCTP

ih! IFAKARA HEALTH INSTITUTE
research | training | services

TBVI
TuBerculosis Vaccine Initiative

UNIVERSITÄTSKLINIKUM TÜBINGEN

SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY

Mecru Clinical Research Unit
A member of The Commonwealth Council of Health Care Education

KENYA MEDICAL RESEARCH INSTITUTE (KEMRI)

EUROPEAN UNION

MRC/UVRI and LSHTM Uganda Research Unit

MRC Medical Research Council

Uganda Virus Research Institute

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