INSTITUT PASTEUR de Dakar

CEPI

World Health Organization
African Region

Phenuiviridae CORC

Scientific Consultation

A CORE Protocol for RVF Vaccines Clinical trials evaluation in the context of outbreaks

AGENDA

31 October 2025
12:00 – 15:30 Central European Time CET

Format: Virtual (Zoom)
https://who.zoom.us/j/91691440795

UK Health Security Agency

R&DBlueprint
Powering research to prevent epidemics

Proposed objectives:

1. To discuss detailed design issues for consideration to move forward the evaluation of RVF using CORE protocols

Expected outputs:

1. Outline of suitable primary, secondary and exploratory endpoints.
2. Outline on trial designs that can be used (including alternative designs with
3. immunological endpoints)
4. Revise key research gaps to inform efficacy evaluation.

This consultation focuses primarily on study design consideration and will not include other important elements related to the implementation of clinical trials, including but not limited to logistics, operations, community engagement, funding, and training

DRAFT Agenda

Chairperson: Phil Krause

Time	Topic	Speaker
12:00-12:05	Welcome remarks	Yper Hall (UKHSA), CORC Lead
12:05-12:10	Objectives of the consultation	Ana Maria Henao Restrepo (WHO)
Session 1. What are the current research priorities?		
12:10-12:20	Overview of the outcomes of the recent consultation and proposed roadmap: emphasis on vaccines research	Cristina Cassetti
12:20-12:30	Target Product Profile for RVF vaccines	Ximena Riveros (WHO)

Session 2. Trial design options and innovative approaches to consider in the context of outbreaks		
12:30-12:40	Seroprevalence data from previous surveys	Gamou Fall (IPD)
12:40-12:55	Strawman: what about these design options?	Phil Krause (WHO)& Ira Longini (Univ. Florida, US)
12:55-1:20	**Panel discussion** o What are the characteristics of the setting selected for the trial? o What is the ideal trial design? o What groups should be compared? o Which unit of randomization; individual, clusters around cases, other? o Evaluation of co-vaccination of animals? o Other design options, e.g. pragmatic or non-randomized, immunobridging, animal rule?	Moderator: Peter Hart (CEPI) Abdourahmane Sow (IPD Senegal) Gideon Akintunde (CEPI) Ira Longini (Univ. Florida, US) Christophe Fraser (Univ. of Oxford) Betz Halloran (Univ. Of Washington, US) Christl Donnelly (Oxford Univ. UK)

Session 3. Clinical considerations and possible endpoints: defining primary and secondary objectives		
1:20-1:30	Strawman: what about these design definitions and possible objectives/endpoints?	Janet Diaz (WHO)
1:30-1:50	**Panel discussion** • Which endpoint(s) and what is needed to refine their definitions and achieve consensus? • Which target population(s)? • Disease severity versus infection? • Which immunological endpoints?	Moderator: Pontiano Kaleebu (UVRI) Catherine Cêtre-Sossah (INRAe, France) Julius Lutwama, (UVRI Uganda) Moussa Seydi (Centre Hospitalier National Universitaire de Fann, Senegal) Ndéye Méry Dia (Centre Hospitalier Régional de Saint-Louis, Senegal) Emmanuel Agogo (FIND) Zacchaeus Anywaine (MRC Uganda) **TBC** Inès Vigan-Womas (IPD, Senegal) Tom Monath (Quigley Bio)* Alan Barrett (Univ. Texas, US) Lorenzo Subissi (WHO) Haritha Adhikarla (CEPI) Nischay Mishra (Columbia Univ., US) Janet Diaz (WHO) Peter Gilbert (Fred Hutch) **TBC**

Session 4: Which candidate vaccines can/should be evaluated?		
1:50-2:10	Developers corner	Moderator: Phil Krause (WHO) Larissa; Paul Wichgers Schreur DDVax; Brian Bird ChAdoX RVF; Daniel Wright Sabin – MP-12; Amy Finan Mab; James Crowe
2:10-2:20	TAG on Vaccine prioritization committee recommendations	Mike Levine (University of Maryland, US)
2:20-2:30	Overview of safety considerations for candidates undergoing clinical evaluation	Eileen Farnon (Brighton Collaboration)
2:30-2:50	**Panel discussion**	Moderator: Liz Miller (LSTMH)

	• Given the TPP, which candidate vaccines should be included in the trial? • How can we assess the impact of co-vaccination in the context of the trial?	Ally Olotu (Ifakara Health Inst, Tanzania) Mike Levine (Univ. Maryland, US) Laura Merson (IPD, Senegal) Eileen Farnon (Brighton Collaboration) Claudio Struchiner (Oswaldo Cruz Foundation, Brazil) Esam Ibraheem Azhar (Egypt) **TBC**

Session 5: Regulatory expectations and key considerations.		
2:50-3:00	Overview of potential regulatory pathways	Marco Cavaleri (EMA)
3:00-3:20	Panel discussion • Are there scientific gaps that should be addressed in order to support the evaluation of these candidates? • What regulatory pathways can be considered?	Marco Cavaleri (EMA) Jeremie Lacroix (Canada) Rania Ibrahim (Egypt) Beno Yakubu (Nigeria) Yoro Tine (Senegal) Florence Wanyenze (Uganda) **TBC** Goodluck Gotora (Tanzania) **TBC** Kwasi Nyarko (WHO) UK Rep **TBC**

Session 6: Summary and next steps.		
3:20-3:30	Summary of key design attributes and next steps	Phil Krause (WHO)
3:30	Adjourn	

Background documents

Efficacy trials of Rift Valley Fever vaccines and therapeutics: Guidance on clinical trial design
Rift Valley Fever Research and Development (R&D) Roadmap
Rift Valley Fever WHO Webpage
Rift Valley Fever WHO Fact Sheets