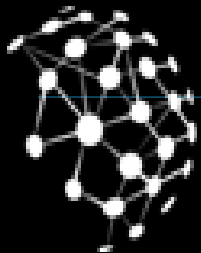


Phenuiviridae CORC

Scientific Consultation

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

OBJECTIVES



R&DBlueprint

Powering research
to prevent epidemics



Outbreaks provide a unique opportunity to evaluate candidate vaccines by assessing their clinical efficacy, safety among populations at risk...

...while also potentially generating data to inform development of correlates of protection and field effectiveness given certain delivery strategies



Proposed objectives

To discuss design options to advance the evaluation of RVF vaccines, using CORE protocols (in the context of an outbreak)

..... there are additional research that developers will conduct to evaluate and generate evidence on immunogenicity, clinical efficacy and safety of their candidates

Expected outputs

1. Outline on **trial designs** that can be used
(including alternative designs using immunological endpoints)
2. Outline of suitable **primary, secondary and exploratory endpoints**.
3. Discuss key **research gaps** to inform candidate vaccines evaluation.

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