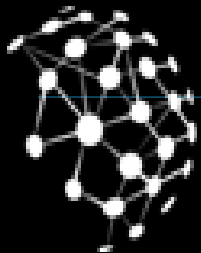


Phenuiviridae CORC

Scientific Consultation

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

END POINTS



R&DBlueprint

Powering research
to prevent epidemics



PRIMARY OUTCOME

Vaccine efficacy in humans for preventing
laboratory-confirmed RFV disease
(using a combination of RT-PCR testing and IgM testing
for case confirmation)

SECONDARY OUTCOMES

Vaccine efficacy in preventing severe disease

Stratified analysis by disease severity

Severe disease can be defined as requiring hospitalization, progression to organ failure/complications, or death.

For hospitalized patients, the CFR can be high in some places so would need to see what proportion of cases are being hospitalized, depends on surveillance and access to diagnostics.

Viral clearance kinetics in a subgroup could help provide more information to plan for therapeutic trial

SECONDARY OUTCOMES

Vaccine safety

Evaluate the safety and tolerability of the RVF vaccine candidate in healthy adult volunteers, including assessment of solicited local and systemic adverse events

SECONDARY OUTCOMES

Immunogenicity data

Immunological Endpoints

Duration of Immunity