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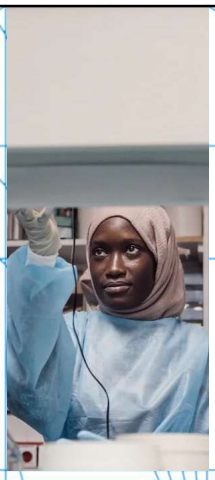
Accelerating Africa's health transformation



Rift Valley Fever Vaccine Clinical Trial CORE Protocol

Simple, large-scale, multi-country individually randomized placebo-controlled trial

Ibrahima Socé FALL
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CONTEXT: Rift Valley Fever Research Response, Senegal

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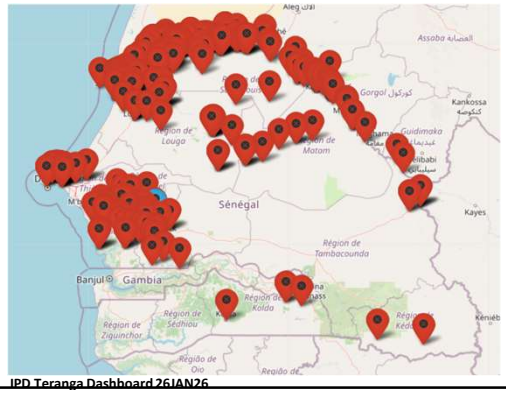
Senegal faces recurrent RVF outbreaks in humans and livestock, with significant health and economic impact.

SEPTEMBER - DECEMBER 2025

560 confirmed human cases; 51 severe cases including 31 deaths. Most severe outbreak recorded since 1988.



IPD Teranga Dashboard 26JAN26

IPD's RESEARCH RESPONSE ACTIVITIES

- Co-leadership of WHO Bunyavirales CORC with UKHSA
  Generation of RVF Research Roadmap & CORE Vaccine Trial Protocol
- Clinical characterisation study launched across the Saint-Louis region
  87 participants now followed for 6 months
- RVF assay development and harmonisation via CEPI's Centralised Laboratory Network
- Outbreak response stockpile capability
- Building clinical trials capability at IPD and the region
- Preparing RVF vaccine clinical trial (launch Q2 2026)

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CONTENT: Designed for scientific efficiency

OVERALL OBJECTIVE	To estimate the efficacy of an RVF vaccine in humans
OVERVIEW	A phase 2/3 study to evaluate the safety, tolerability, immunogenicity, and efficacy of vaccine candidates against RVF disease in healthy individuals at risk of RVF disease.
POPULATION	Humans at elevated risk of RVF infection. Livestock handlers, abattoir workers, herders, and others with frequent animal contact
INTERVENTION	One or more experimental vaccines
COMPARATOR	Placebo or active comparator
RANDOMIZATION	Individual randomization to vaccine or control Allocation ratio 1:1 Stratified by risk group (which may include location)

Single or double blind depending on feasibility

In Senegal, young people (ages 15–30), those working with animals, and males were most affected

Active comparator will increase community acceptance

Maximising statistical power to detect efficacy

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CONTENT: Objectives during inter-epidemic periods (Phase 2)

PRIMARY OBJECTIVE 1	To determine the reactogenicity and safety of candidate RVF vaccine(s) among healthy volunteers.
PRIMARY OUTCOME 1	Solicited local adverse events within 7 days, graded by severity Solicited systemic adverse events within 7 days, graded by severity Serious adverse events throughout study duration
PRIMARY OBJECTIVE 2	**To determine the immunogenicity of the candidate RVF vaccine(s)**
PRIMARY OUTCOME 2	Vaccine-specific antibody titers, neutralization activity, and cell-mediated immune responses at pre-defined follow-up visits.

As the Senegal outbreak has ended, our current RVF vaccine trial is in this phase.

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CONTENT: Objectives during outbreaks (Phase 2/3)

PRIMARY OBJECTIVE	**To estimate the efficacy of candidate RVF vaccine(s) in preventing laboratory-confirmed RVF disease during outbreak periods**
PRIMARY OUTCOME	New cases of RVF disease are ascertained through independent active surveillance visits and case detection reports through the national RVF disease surveillance system.
SECONDARY OBJECTIVE 1	**To quantify the protective effect of candidate RVF vaccine(s) specifically against severe and life-threatening manifestations of RVF disease during outbreak periods**
SECONDARY OUTCOME 1	This secondary efficacy endpoint will assess whether the vaccine offers differential protection for severe disease compared to mild to moderate illness.
SECONDARY OBJECTIVE 2	**To determine the reactogenicity and safety of candidate RVF vaccine(s) in outbreak conditions**
SECONDARY OUTCOME 2	Solicited and Unsolicited Adverse Events, Serious Adverse Events
SECONDARY OBJECTIVE 3	**To evaluate whether vaccine efficacy varies significantly across pre-defined population subgroups and geographic locations**

A DIVA-compliant vaccine is important to differentiate vaccine versus infection induced immunity – especially for a disese with a high proportion of asymptomatic cases.

It is important to address the challenges of standardising the definition of severe disease.

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CONCLUSION

By implementing the WHO CORE Protocol design in our trial in Senegal, the data we collect can be combined with the data from implementations of the same protocol in the future.

We encourage others to align with this work - enabling collaboration to accelerate the evidence needed to identify an effective and safe vaccine for RVF.

For those who do, we look forward to working with you.

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