PHASE 2A

# Lassa virus vaccine development program

Translating **science** into **global** health impact

**IAVI's promising Lassa virus (LASV) vaccine candidate is currently in a Phase 2a clinical trial in West Africa to evaluate the candidate's safety and immunogenicity – the most-advanced study of a LASV vaccine to take place anywhere in the world.**

The candidate uses recombinant vesicular stomatitis virus (rVSV), the same technology behind Merck's Ebola Zaire vaccine, ERVEBO®, which is licensed in more than a dozen countries.

## About LASV

- In the *Arenaviridae* family of highly pathogenic viruses.
- Causes Lassa fever, a severe and potentially fatal viral hemorrhagic illness.
- No licensed vaccine or specific treatment is available; prevention relies on promoting hygiene and infection control.
- Zoonotic; transmission by wildlife to humans can result in onward transmission between humans.
- Endemic to West Africa with significant annual outbreaks of disease.
- LASV's geographic footprint is expanding due to climate change, with increasingly severe outbreaks reported.[1]
- Included in the World Health Organization (WHO) Pathogen Prioritization framework as a priority pathogen for which a vaccine is urgently needed, and a prototype pathogen for the Arenavirus family.
- Up to 500,000 cases and at least 5,000 related deaths each year, although this is severely underestimated. One recent study estimated that there are 2.7 million infections a year – more than half in Nigeria – and almost 4,000 deaths.[2]
- Recent studies indicate that a vaccine could avert up to $128 million in societal costs over 10 years.[1]

## Impact

All partners involved are united in their commitment to global equitable access, with IAVI's LASV vaccine candidate to be accessible to all populations that need it should it be found safe and effective in clinical testing.

In 2025, ministers of health from 11 West African countries endorsed a communiqué to support late-stage development of IAVI's LASV vaccine candidate through a joint resource mobilization approach.

## LASV by the numbers

**0**
LASV vaccines available

**Annual**
Seasonal outbreaks each year

**<500,000**
Estimated cases each year

**5,000**
Deaths each year[3]

**20%**
Cases resulting in severe disease[4]

**15%**
Case fatality among hospitalized cases[3]

**80%**
Combined mortality rate for both mother and child during infection in third trimester of pregnancy[4]

## Results

### Phase 1 (IAVI C102)

- Conducted first-in-human Phase 1 clinical trial in the U.S. and Liberia (NCT04794218).
- Interim results found the candidate to be safe and immunogenic.
- Preclinical challenge studies show that 100% of vaccinated animals were protected from infection.
- Combined results provide strong rationale for further clinical development.

### Phase 2a (IAVI C105)

- IAVI is sponsoring the world's first-ever Phase 2a LASV vaccine clinical trial (NCT05868733), funded by Coalition for Epidemic Preparedness Innovations (CEPI).
- Involving diverse populations, including people living with HIV, adolescents, and children two years of age and older, at clinical research partner sites in Nigeria, Liberia and Ghana.
- Approximately 612 participants will receive one dose and be followed for six months to monitor safety and immune responses.
- A subset will be followed for an additional two years for extended monitoring.

### Epidemiology

- IAVI also led the Wellcome-funded X100 epidemiology study in Sierra Leone, the largest-ever study of LASV incidence in the country to support site selection for an upcoming efficacy

Visit IAVI's emerging infectious diseases page for more information.

## Partnerships

- IAVI's LASV R&D program is funded by CEPI and the European & Developing Countries Clinical Trials Partnership (EDCTP), including through the multidisciplinary Lassa Fever Vaccine Efficacy and Prevention for West Africa (LEAP4WA) collaboration.
- We are pursuing fast, flexible manufacturing solutions. For example, in partnership with the Institut Pasteur de Dakar (IPD) in Senegal, we're prioritizing the manufacturing and commercialization of and access to IAVI's LASV vaccine candidate, with the potential to advance additional emerging infectious disease (EID) vaccine candidates, including multivalent vaccines.
- We collaborate closely with the Viral Hemorrhagic Fever Consortium, a group of experts in affected countries.
- The Public Health Agency of Canada (PHAC) provided IAVI with a nonexclusive license to the rVSV vaccine candidates. The vector was developed by scientists at PHAC's National Microbiology Laboratory.

> **"As a Kenyan scientist, I'm gratified that the search for a Lassa fever vaccine is being led by prominent scientists and community leaders on the continent."**
>
> *– Gaudensia Mutua, medical director, IAVI*

[1] https://www.nature.com/articles/s41591-024-03232-y
[2] https://journals.plos.org/ploscompbiol/article?id=10.1371/journal.pcbi.1008811
[3] https://africacdc.org/disease/lassa-fever/
[4] https://www.who.int/news-room/fact-sheets/detail/lassa-fever


## IAVI gratefully acknowledges the generous support provided by the following major funders:

Biomedical Advanced Research and Development Authority (BARDA) | Foundation for the National Institutes of Health | National Institute of Allergy and Infectious Diseases | amfAR, The Foundation for AIDS Research | Broadway Cares/Equity Fights AIDS | The City of New York, Economic Development Corporation | Congressionally Directed Medical Research Program (DoD) | GSK | The Hearst Foundations | Keith Haring Foundation | Merck & Co., Inc., Kenilworth, NJ, USA (known as MSD outside the USA and Canada)

And many other generous individuals and partners around the world

As of January 2025