

A prospective, multi-site, cohort study to estimate incidence of infection and disease due to Lassa fever virus in West African countries (the *Enable* Lassa research programme)

Study protocol overview and co-ordination perspectives



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Study status

At the time of presentation, The *Enable* Lassa research programme is nearing completion of data collection from **23,193 participants**, an interim analysis is ongoing, and plans are being developed for further research and setup of clinical trials. The involvement of the programme headquarters, with P95 as the coordinating partner, continues.

Background

Lassa fever (LF), is a zoonotic disease caused by the Lassa fever virus (LASV). The most common mammal reservoir is the rodent, *Mastomys natalensis*. LASV is transmitted to humans via direct contact with or ingestion of items contaminated with infected rodent excreta. Person-to-person transmission also occurs through contact with infected blood or body secretions in healthcare settings. LASV infections most commonly occur in resource-poor, rural areas.

LF is endemic in West Africa and causes 5000 fatalities annually, although its true prevalence and incidence rates are unknown. This is because, although considered a haemorrhagic illness, the symptoms of LF are varied, non-specific, and often difficult to distinguish from other febrile illnesses. Also, often LF infections are asymptomatic and surveillance systems are not robust.

Aim

The *Enable* Lassa research programme aims to estimate the incidences of LASV infection and LF disease in five West African countries.

Funding and Acknowledgements

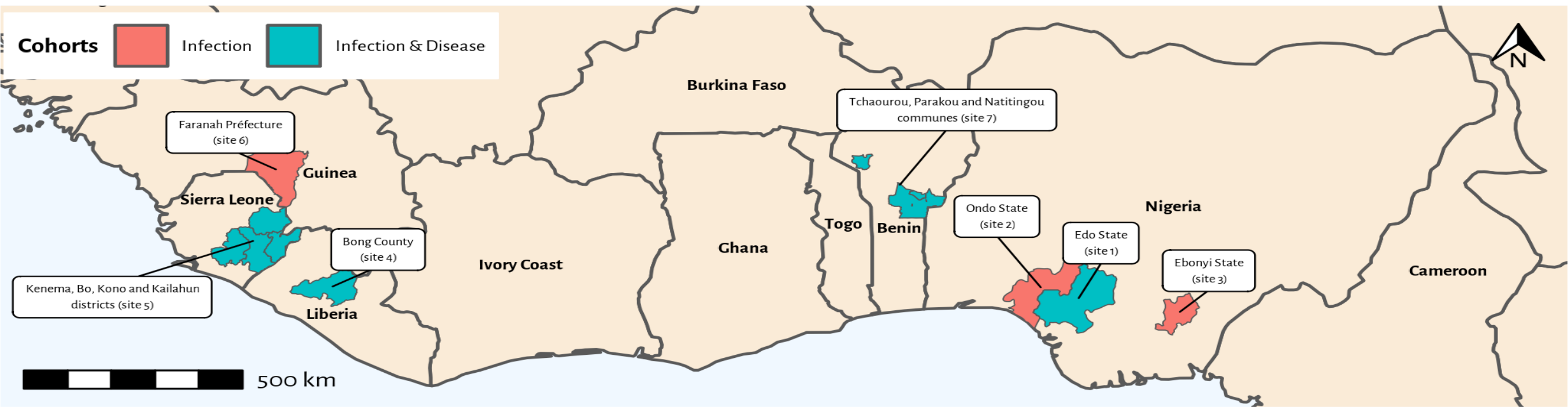
The Coalition for Epidemic Preparedness Innovations (CEPI), an innovative global partnership between public, private, philanthropic, and civil society organisations to develop vaccines to stop future epidemics (<https://cepi.net/>), funds the *Enable* Lassa research programme.

The authors acknowledge Ana Goios (P95) for medical writing and visualisation support.

Methods

1. Study design

The *Enable* study is a **prospective cohort study** in Benin, Guinea, Liberia, Nigeria (three sites), and Sierra Leone, from 2020 to 2023, with 24 months of follow-up planned.



2. Study flow

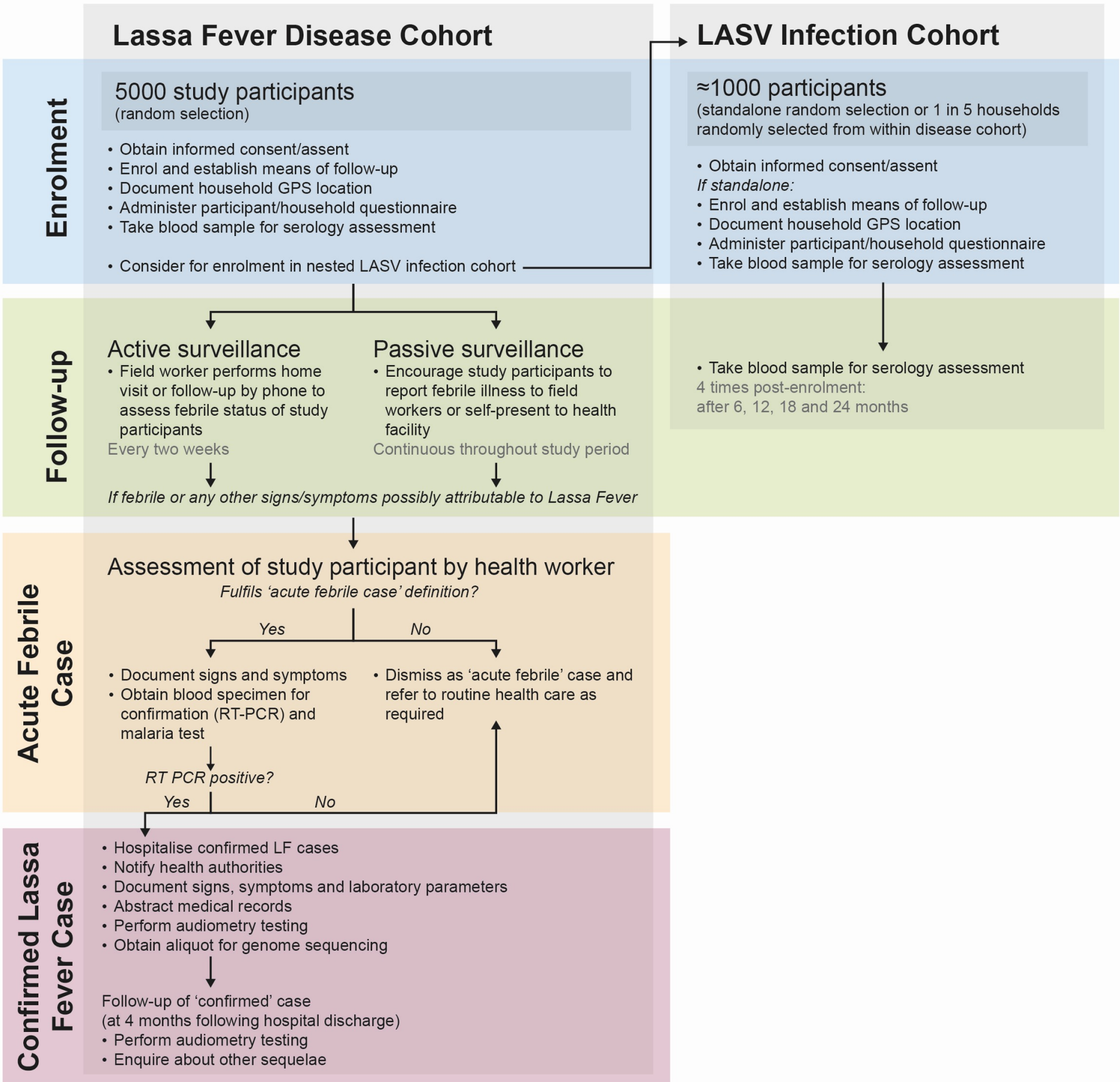
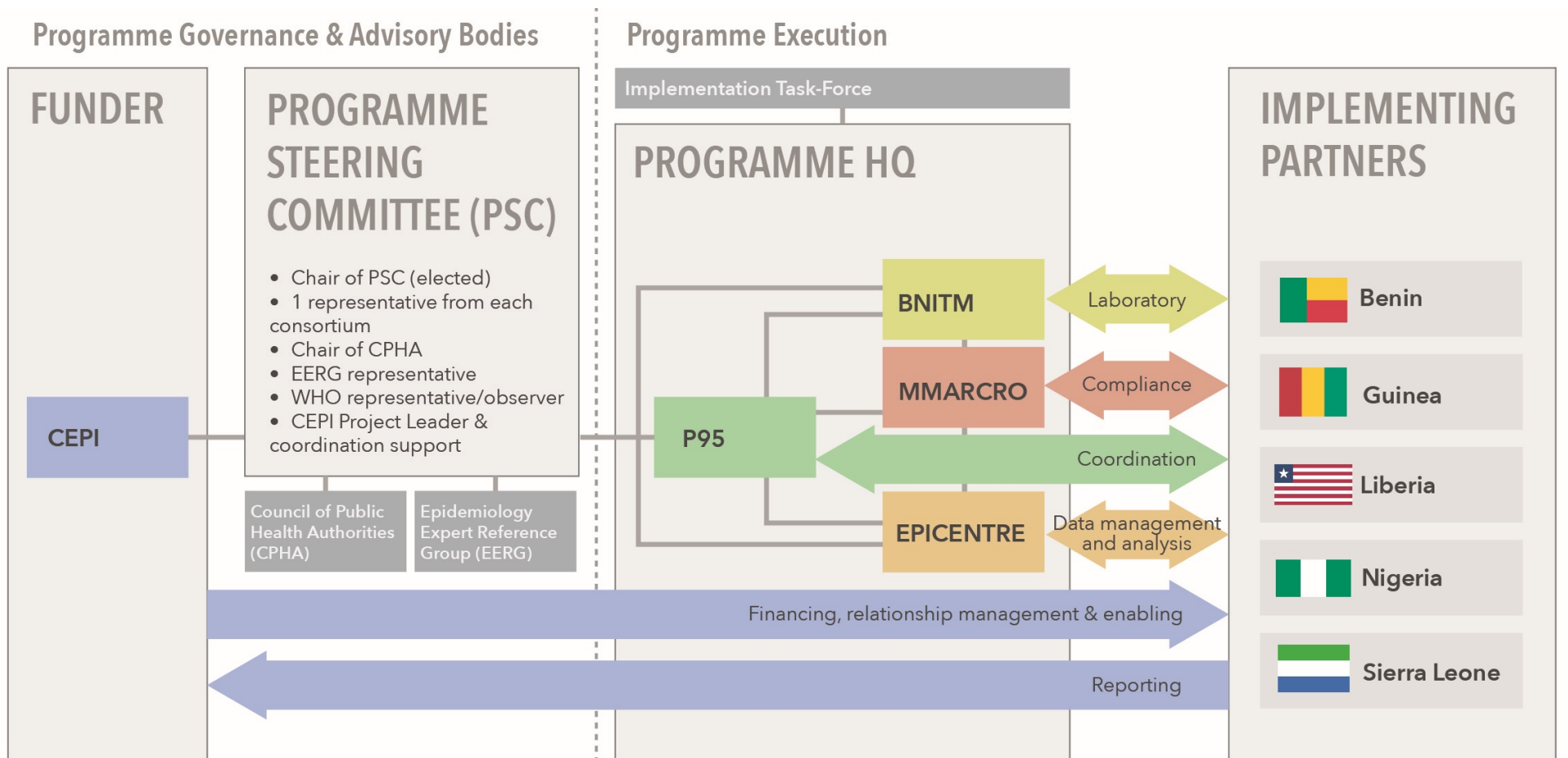
Each site assesses the incidence of LASV infection, LF disease, or both. When both incidences are assessed, the LASV cohort (nmin=1000 per site) is drawn from the LF cohort (nmin=5000 per site). During recruitment, participants complete questionnaires on household composition, socioeconomic status, demographic characteristics, and LF history. Blood samples are collected to determine IgG LASV serostatus.

LF disease cohort participants are contacted biweekly to identify acute febrile cases, from whom blood samples are drawn to test for active LASV infection using RT-PCR. Symptom and treatment data are abstracted from medical records of LF cases. LF survivors are followed up after four months to assess sequelae, specifically sensorineural hearing loss.

LASV infection cohort participants are asked for a blood sample every six months to assess LASV serostatus (IgG and IgM).

3. Study governance

The implementation of this multi-country study is led by a team in each country, overseen by a headquarters of technical partners and a steering committee. Within the headquarters, P95 leads the coordination and epidemiological design of the programme by hosting scheduled and ad hoc meetings between partners, developing study documentation, following up on action points, and facilitating problem-solving.



Discussion

P95 is the *Enable* coordinating partner with project management and epidemiological expertise. Situated within the programme headquarters we provide a single point of contact for the numerous study partners spread across different geographical regions. In this role, we facilitate communication, facilitate the implementation of the study elements required to be consistent across sites, and strengthen epidemiological and project management of the programme.

P95 has been grappling with a multitude of operational challenges within *Enable*. The Covid-19 pandemic wrought significant disruptions to the procurement process, affected the availability, pricing, and logistics of essential supplies, and imposed travel obstacles for programme headquarters and implementing partners to study sites. Study sites in post-Ebola areas face their own hurdles. Overcoming community hesitancy to engage with the health system or staff proves to be a significant challenge. Access to sites has been further complicated by safety and security concerns, e.g. during elections. Weather-related issues, such as flooding, combined with subpar road conditions compounded these difficulties. Lastly, the temporary relocation of participants due to seasonal employment, such as mining or harvesting, adds another layer of complexity to the operational landscape.

Enable data on LASV infection and LF disease incidence in West Africa will determine the feasibility of future Phase IIb or III clinical trials for LF vaccine candidates.

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https://cepi.net/news_cepi/largest-ever-lassa-fever-research-programme-launches-in-west-africa/?swcfpc=1

https://cepi.net/news_cepi/as-cepi-ramps-up-vaccine-research-a-new-study-warns-lassa-fever-is-set-to-expand-its-reach-across-africa/

Reference

Penfold S, Adegnika AA, Asogun D, Ayodeji O, Azuogu BN, Fischer WA, II, et al. (2023) A prospective, multi-site, cohort study to estimate incidence of infection and disease due to Lassa fever virus in West African countries (the *Enable* Lassa research programme)–Study protocol. PLoS ONE 18(3): e0283643.