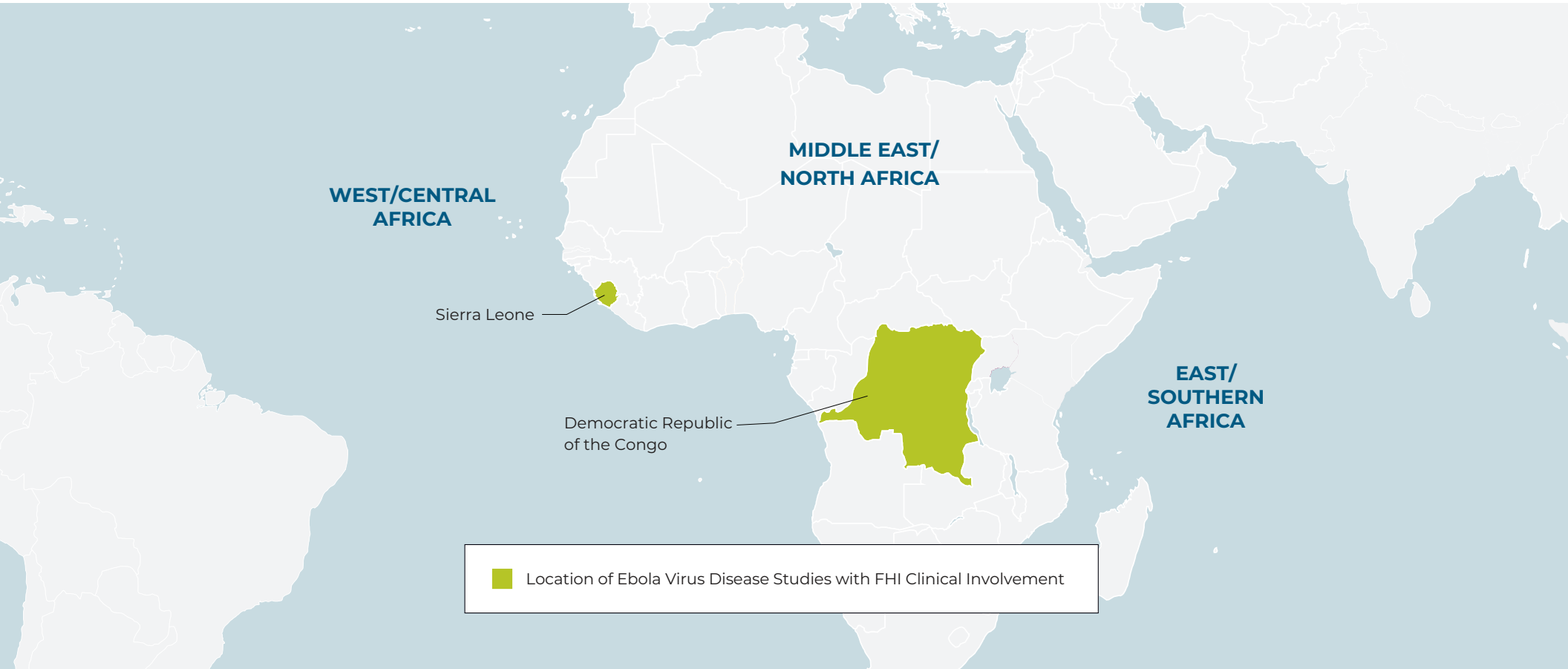




OUR EXPERIENCE WITH EBOLA VIRUS DISEASE (EVD)

In response to Ebola virus disease (EVD) outbreaks, the FHI Clinical project team has partnered with both government and non-government agencies to rapidly deploy clinical trials in critically affected areas.



IMPACT OF EVD

Since 1976, EVD outbreaks have primarily occurred in eleven countries: Democratic Republic of the Congo, Gabon, Guinea, Liberia, Mali, Nigeria, Republic of Congo, Sierra Leone, Sudan and Uganda. Although it is generally rare, it is often fatal, with death rates ranging from 25 to 90% in past outbreaks (average case fatality rate, 50%). No treatment or vaccine is currently approved, but there are several promising vaccines and treatments under development.

CHALLENGES WITH EVD RESEARCH

- Locations with limited research capacity including regulatory processes
- Rapid response required in outbreaks
- Remote and inaccessible geographical outbreak areas
- Local mistrust of foreign researchers
- Poor surveillance systems
- Migrant populations
- Difficult to clinically distinguish EVD from other infectious diseases
- Ensuring sufficient study product availability
- Potentially insufficient data collected during outbreak windows for meaningful analysis of product effectiveness

World Health Organization, <https://www.who.int/health-topics/ebola/>

CURRENT EVD STUDIES WITH FHI CLINICAL INVOLVEMENT

DEMOCRATIC
REPUBLIC OF
THE CONGO

GOVERNMENT SPONSOR

Study Duration: 2018–ongoing

Phases: II/III

Study Title: Multicenter, multi-outbreak, randomized, controlled safety and efficacy study of investigational therapeutics for the treatment of patients with EVD

ClinicalTrials.gov Identifier: [NCT03719586](https://clinicaltrials.gov/ct2/show/study/NCT03719586)

FHI Clinical's Role:

- Site monitoring

COMPLETED EVD STUDIES WITH FHI CLINICAL INVOLVEMENT

SIERRA LEONE



Read case study at
FHIClinical.com

GOVERNMENT SPONSOR

Study Duration: 2015–2016

Phases: II/III

Study Title: [rVSVΔG-ZEBOV]

Ebola prevention vaccine
evaluation in Sierra Leone

ClinicalTrials.gov Identifier:

NCT02378753

FHI Clinical's Roles:

- Project management
- Hiring and managing data entry staff
- Site initiation
- Site monitoring
- Site closeout
- Clinical supply management
- Training
- Cold chain technical assistance

Outcomes:

The study team enrolled 8,651 participants, and the FHI Clinical team:

- Enabled first patient first visit (FP/FV) within six weeks after arrival in Sierra Leone
- Continued training for the 300-member staff, as needed, throughout the trial
- Maintained real-time visibility to study costs
- Achieved 99.998% accuracy of the planned-to-execute budget using a robust financial platform



Global expertise, responsive approaches and proven solutions to manage complex clinical research in resource-limited settings around the world. To learn more, visit fhiclinical.com or email info@fhiclinical.com.