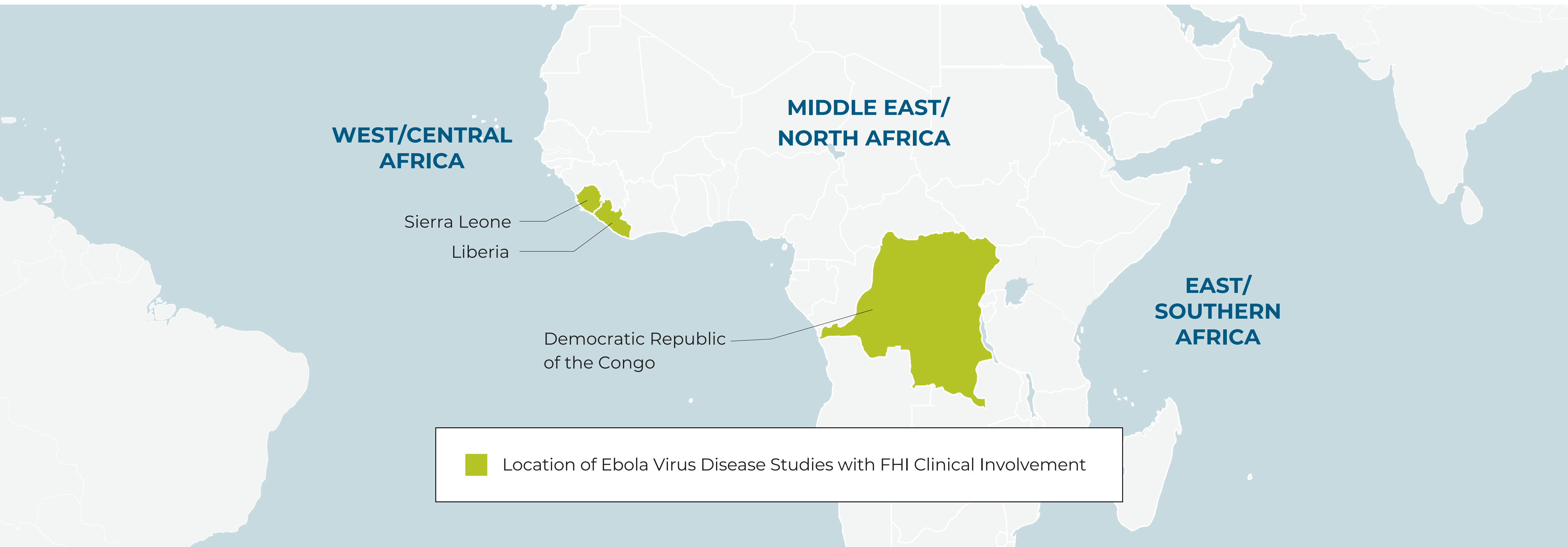




OUR EXPERIENCE WITH EBOLA VIRUS DISEASE (EVD)

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 ten 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

EVD STUDIES WITH FHI CLINICAL INVOLVEMENT

GO TO CURRENT STUDIES	03
GO TO COMPLETED STUDIES	07

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



CURRENT

EVD STUDIES WITH FHI CLINICAL INVOLVEMENT

CURRENT EVD STUDIES WITH FHI CLINICAL INVOLVEMENT



LIBERIA

STUDY TITLE		FHI CLINICAL ROLE(S)
PREVAIL VI: Identification of Host Genetic Factors Underlying Ebola Virus Disease Risk, Mortality, Long-term Sequelae, Viral RNA Persistence, Humoral Immunity, and Ebola Vaccine Response	<p>Study Type: Observational</p> <p>Sponsor Type: Public-private sponsorship</p> <p>Study Duration: 2017–ongoing</p> <p>ClinicalTrials.gov Identifier: NCT03098862</p>	<p>Operational management of the Partnership for Research on Vaccines and Infectious Diseases in Liberia (PREVAIL) network</p> <ul style="list-style-type: none">• Sourcing, procuring and shipping• All staff hiring• Staff training• Facility management• Renovation project management• Planning and preparation for conducting research laboratory operations• Data management, biostatistics and Data Safety Monitoring Board (DSMB)• Social mobilization and community engagement, social analytics and participant biometrics for study enrollment
PREVAIL VII: Persistence of Ebola Virus in Aqueous Humor and Outcomes of Cataract Surgery in Survivors of Ebola Virus Disease	<p>Phase(s): 1/2</p> <p>Sponsor Type: Public-private sponsorship</p> <p>Study Duration: 2017–ongoing</p> <p>ClinicalTrials.gov Identifier: NCT03309020</p>	

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



CURRENT EVD STUDIES WITH FHI CLINICAL INVOLVEMENT



LIBERIA (CONTINUED)

STUDY TITLE		FHI CLINICAL ROLE(S)
PREVAIL IV: Double-Blind, Randomized, Two-Phase, Placebo-Controlled, Phase II Trial of GS-5734 to Assess the Antiviral Activity, Longer-Term Clearance of Ebola Virus, and Safety in Male Ebola Survivors With Evidence of Ebola Virus Persistence in Semen	<p>Phase(s): 2</p> <p>Sponsor Type: Public-private sponsorship</p> <p>Study Duration: 2016–ongoing</p> <p>ClinicalTrials.gov Identifier: NCT02818582</p>	<p>Operational management of the Partnership for Research on Vaccines and Infectious Diseases in Liberia (PREVAIL) network</p> <ul style="list-style-type: none">• Sourcing, procuring and shipping• All staff hiring• Staff training• Facility management• Renovation project management• Planning and preparation for conducting research laboratory operations• Data management, biostatistics and Data Safety Monitoring Board (DSMB)• Social mobilization and community engagement, social analytics and participant biometrics for study enrollment
Partnership for Research on Ebola VACcinations (PREVAC)	<p>Phase(s): 2</p> <p>Sponsor Type: Public-private sponsorship</p> <p>Study Duration: 2016–ongoing</p> <p>ClinicalTrials.gov Identifier: NCT02876328</p>	

CURRENT EVD STUDIES WITH FHI CLINICAL INVOLVEMENT



LIBERIA (CONTINUED)

STUDY TITLE		FHI CLINICAL ROLE(S)
Partnership for Research on Ebola Vaccines in Liberia (PREVAIL)	<p>Phase(s): 2</p> <p>Sponsor Type: Public-private sponsorship</p> <p>Study Duration: 2015–ongoing</p> <p>ClinicalTrials.gov Identifier: NCT02344407</p>	<p>Operational management of the Partnership for Research on Vaccines and Infectious Diseases in Liberia (PREVAIL) network</p> <ul style="list-style-type: none">• Sourcing, procuring and shipping• All staff hiring• Staff training• Facility management• Renovation project management• Planning and preparation for conducting research laboratory operations• Data management, biostatistics and Data Safety Monitoring Board (DSMB)• Social mobilization and community engagement, social analytics and participant biometrics for study enrollment
Partnership for Research on Ebola Virus (PREVAIL) Prevail III: Ebola Natural History Study	<p>Study Type: Observational</p> <p>Sponsor Type: Public-private sponsorship</p> <p>Study Duration: 2015–ongoing</p> <p>ClinicalTrials.gov Identifier: NCT02431923</p>	



Read the brochure at FHIclinical.com

CURRENT STUDIES ▶

COMPLETED STUDIES ▶





COMPLETED

EVD STUDIES WITH FHI CLINICAL INVOLVEMENT

COMPLETED EVD STUDIES WITH FHI CLINICAL INVOLVEMENT



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STUDY TITLE		FHI CLINICAL ROLE(S)
Multicenter, multi-outbreak, randomized, controlled safety and efficacy study of investigational therapeutics for the treatment of patients with EVD		• Site monitoring
Phase(s): 2/3		
Sponsor Type: Government sponsor		
Study Duration: 2018–2020		
ClinicalTrials.gov Identifier: NCT03719586		

COMPLETED EVD STUDIES WITH FHI CLINICAL INVOLVEMENT



SIERRA LEONE

STUDY TITLE

[rVSVΔG-ZEBOV] Ebola prevention vaccine evaluation in Sierra Leone



Read the case study at [FHIClinical.com](https://fhiclinical.com)

Phase(s):
2/3

Sponsor Type:
Government

Study Duration:
2015–2016

ClinicalTrials.gov Identifier:
NCT02378753

FHI CLINICAL ROLE(S)

- 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**.

CURRENT STUDIES ▶

COMPLETED STUDIES ▶

