Partnership for Research on Vaccines and Infectious Diseases in Liberia (PREVAIL)

VISION
Improved global health through research

MISSION
To conduct collaborative biomedical and public health research in accordance with best practices, to advance science, strengthen health policy and practice, and improve the health of Liberians and people worldwide.

VALUES
Respect: Respect of staff, partners, and study participants. Respect encompasses tolerance of diverse people, cultures and ideas and subscribes to the principles of Good Participatory Practices.

Integrity: We protect our reputation by fulfilling our commitments, practicing fiscal responsibility, and adhering to the highest ethical standards of clinical research.

Innovation: We are flexible and encourage new solutions when challenged.

Teamwork: We accomplish more when we work together.
**PREVAIL GOVERNANCE STRUCTURE**

The Liberian Ministry of Health (MOH) and U.S. Department of Health and Human Services established the PREVAIL agreement. Both Liberian and US representatives are involved in PREVAIL governance.

### GOVERNING BOARD

- Minister of Health
- US Ambassador to Liberia

### EXECUTIVE COMMITTEE

- Ministry of Health
- National Public Health Institute of Liberia
- University of Liberia
- JFK Memorial Medical Center
- National Institutes of Health (NIH) National Institute of Allergy & Infectious Diseases (NIAID)
- Centers for Disease Control and Prevention
- World Health Organization

### HEADQUARTERS

- PREVAIL Director
- Operations Management Team (Assistant Directors, Deputy Directors, NIH NIAID, Leidos Biomedical Research, FHI Clinical)

### PREVAIL SCIENCE & STRATEGIC PARTNERSHIP COMMITTEE

### SCIENTIFIC REVIEW COMMITTEE

On the US team, the National Institute of Allergy & Infectious Diseases (NIAID) is responsible for the overall project objectives and technical input/guidance, while operations subcontractors assume responsibility for in-country logistics:

1. Sourcing, procuring and shipping of materials and supplies
2. Hiring of administrative and facilities staff
3. Managing facilities
4. Managing renovations projects

In addition, support for the following activities is provided:

- Planning and preparation for the conduct of clinical laboratory operations
- Data management, biostatistics and Data Safety Monitoring Board (DSMB)
- Social mobilization and community engagement, social analytics and participant biometrics for study enrollment, working closely with local staff
During the 2014-2015 Ebola outbreak in Liberia, collaborations between the Liberian government and international partners were essential to ending the epidemic. In 2014, the Liberia-U.S. Partnership for Research on Ebola Virus in Liberia (PREVAIL) was formed to conduct clinical research on Ebola therapeutics and vaccines. To avoid another public health disaster, the Liberian MOH aimed to create a sustainable research infrastructure, including shifting the focus of PREVAIL from emergency response to a long-term research network and expanding the scope to include other diseases of public health importance in Liberia.
COMPLETED AND CURRENT STUDIES

The focus of PREVAIL has expanded beyond Ebola to include other diseases of public health importance in Liberia.

<table>
<thead>
<tr>
<th>STUDY NAME</th>
<th>DESCRIPTION</th>
<th>CLINICALTRIALS.GOV IDENTIFIER</th>
</tr>
</thead>
<tbody>
<tr>
<td>PREVAIL *</td>
<td>Double-blind, placebo-controlled RCT of an Ebola vaccine</td>
<td>NCT02344407</td>
</tr>
<tr>
<td>PREVAIL II*</td>
<td>RCT of the experimental treatment ZMapp</td>
<td>NCT02363322</td>
</tr>
<tr>
<td>PREVAIL III*</td>
<td>Observational natural history study of Ebola survivors and their close contacts</td>
<td>NCT02431923</td>
</tr>
<tr>
<td>PREVAIL III Substudy: Birth cohort</td>
<td>Evaluation of children born to Ebola virus disease (EVD)-survivor participants of the Ebola natural history study</td>
<td>—</td>
</tr>
<tr>
<td>PREVAIL III Substudy: CYTOF</td>
<td>Detailed immunological analysis in select survivors and close contacts</td>
<td>—</td>
</tr>
<tr>
<td>PREVAIL III Substudy: Neurology</td>
<td>Longitudinal follow-up study of neuropsychological sequelae of EVD in a subset of survivors and close contacts</td>
<td>—</td>
</tr>
<tr>
<td>PREVAIL III Substudy: Ophthalmology</td>
<td>Longitudinal ophthalmologic follow-up study of a subset of survivors and close contacts</td>
<td>—</td>
</tr>
<tr>
<td>PREVAIL III Substudy: Viral persistence in semen</td>
<td>Assessment of the persistence of Ebola virus in the semen of adult male participants after resolution of the acute illness</td>
<td>—</td>
</tr>
<tr>
<td>PREVAIL III Substudy: Viral persistence in the CNS</td>
<td>Assessment of the persistence of Ebola virus in the central nervous system (CNS) of adult participants after resolution of the acute illness</td>
<td>—</td>
</tr>
<tr>
<td>PREVAIL IV</td>
<td>Double-blind, two-phase, two-arm trial RCT of GS-5734 among male Ebola survivors with persistent Ebola virus RNA in their semen</td>
<td>NCT02418582</td>
</tr>
<tr>
<td>PREVAIL V (PREVAC)</td>
<td>Quadruple blind, placebo-controlled RCT of two Ebola vaccines</td>
<td>NCT02876328</td>
</tr>
<tr>
<td>PREVAIL VI</td>
<td>Observational study of the genetic factors underlying Ebola risk and response</td>
<td>NCT03098862</td>
</tr>
<tr>
<td>PREVAIL VII</td>
<td>Clinical trial to evaluate the persistence of Ebola viral RNA in the eyes and assess the response to cataract surgery of Ebola survivors</td>
<td>NCT03309020</td>
</tr>
<tr>
<td>PREVAIL VIII (HONOR)</td>
<td>Observational cohort study to understand the impact of HIV infection on people in Liberia</td>
<td>NCT03733093</td>
</tr>
<tr>
<td>PREVAIL IX (PROPEL)</td>
<td>Prevalence of malaria in Liberia</td>
<td>NCT03733093</td>
</tr>
<tr>
<td>PREVAIL XI: The PREVAIL COVID-19 Observational Study (PCOS)</td>
<td>An observational cohort study of individuals who test positive for SARS-CoV-2 and of exposed individuals who test negative to describe characteristics and course of infection</td>
<td>—</td>
</tr>
</tbody>
</table>

*Initiated during the Ebola epidemic

RESEARCH COLLABORATORS

PREVAIL is committed to conducting relevant collaborative research with institutions that can sponsor their own studies, while benefiting from and contributing to this research capacity.

Examples of collaborating organizations include:

- ELWA Hospital in Liberia
- Emory University
- JFK Memorial Medical Center
- Liberian Ministry of Health programs (e.g., National Malaria Control Program, National AIDS Control Program, CH Rennie Hospital, Duport Road Health Center, Redemption Hospital)
- London School of Hygiene and Tropical Medicine
- NIAID Division of Intramural Research
- NIH National Eye Institute
- National Public Health Institute of Liberia (NPHIL)
- Stanford University
- University of Liberia
- University of Minnesota
- US Centers for Disease Control and Prevention
- West African Consortium for Re-emerging Pathogens (WACREP)
- World Health Organization (WHO)
INFRASTRUCTURE – THE “WARM BASE”

The “warm base,” funded by PREVAIL, consists of the essential core clinical research resources for sustainable research capacity and outbreak readiness across the existing clinical sites:

- Core complement of research staff trained in clinical research practices (i.e., ICH GCP)
- Facilities for initial and follow-up research participant visits
- Clinical laboratories (hematology, chemistry, serology) and biospecimen storage areas
- Specialized ophthalmology and neurology clinics
- Pharmacy operations
- Administrative and research operations offices

Additional facilities include the NPHIL’s Liberia Institute for Biomedical Research (LIBR); an imaging center providing access to CT scanning, x-rays and ultrasound at JFK Medical Center; and a research lab and biorepository.

For each of these research locations, the warm base includes stable operational infrastructure:

- **Clinical research site operations**
  - Internet service
  - Email and cell phone connectivity
  - Videoconferencing
  - Uninterrupted and safe electrical power with regularly maintained backup generators
  - Water availability
  - Functional waste management (including hazardous waste) and cleaning services
  - Equipment calibration and maintenance
  - Rental cars
  - Furniture
  - Office supplies
  - Facility renovation and maintenance

- **Clinical lab capacity**
  - Chemistry (ACE Alera & ACE Axcel)
  - Hematology (Abbott CELL-DYN Ruby)
  - Coagulation (Stago STA Compact Max)
  - Urinalysis (Siemens CLINITEK Status+ Analyzer)
  - Automated ELISA (Bio-Rad EVOLIS)
  - HIV confirmation (Bio-Rad Geenius HIV 1/2 Supplemental Assay)
  - CD4 counter (BD FACSPresto)
  - RT-PCR (Cepheid GeneXpert)
  - Nexcelom cell viability counter

- **Ophthalmology clinic capacity**

- **Imaging capacity**
  - CT scanner

- **Human resources management**

- **Staff training**

- **Travel support for site staff**

- **Accounting and financial management of sites**

- **Information technology management**

- **Supply chain, including cold chain, logistics**
PREVAIL STAFF

PREVAIL staff represent a diverse set of specialties to support clinical research and include a leadership team to assist with oversight. The list below provides an example of the positions within the staff.

<table>
<thead>
<tr>
<th>STAFF</th>
<th>EACH CLINICAL RESEARCH SITE</th>
<th>LIBR</th>
<th>CENTRALIZED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director (MD or MD/PhD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deputy and Assistant Directors (Admin, Clin Ops, DM, Collaborations and Partnerships)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site physicians</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study nurses</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychosocial staff</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacists</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study coordinators</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Community outreach staff</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Participant trackers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data management staff</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Regulatory affairs staff</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Laboratory technicians</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Biostatistics/Data analysis staff</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IT staff</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical site managers</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical facility managers</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Administrative staff</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Security personnel</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

PREVAIL RESEARCH SITES:

1. John F. Kennedy Medical Center (JFKMC) (Monrovia)
2. Redemption Hospital (New Kru Town)
3. CH Rennie Hospital (Kakata)
4. Duport Road Health Center (Paynesville)
5. Liberia Institute of Biomedical Research (LIBR) (Charlesville)

For more information, please contact the PREVAIL team at info@prevailcr.org.