FHI CLINICAL
Mission-driven clinical research

Phase II/IIb Trial of a Zika Vaccine Spanning Nine Countries

Study conducted at 17 sites spanning nine countries in a Zika endemic region:

Brazil
Belo Horizonte, Minas Gerais
São Paulo, São Paulo

Colombia
Barranquilla, Atlantico
Bucaramanga, Santander

Costa Rica
San José, Los Yoses

Ecuador
Guayaquil, Guayas

Mexico
Guadalajara, Jalisco

Panama
Panamá, San Miguelito Province

Peru
Iquitos, Maynas/Loreto
Lima

Puerto Rico
Ponce
San Juan (3)

United States
Miami, Florida
Edinburg, Texas
Houston, Texas

BACKGROUND

Study Duration: 2016–2020

Therapeutic Area: Infectious Disease

Indication: Zika

Intervention: Vaccine

Phase(s): II/IIb

Originally discovered in 1947 in Uganda, Zika virus infected relatively few people in Africa and Southeast Asia until 2006, when it started to spread. It is currently found in over 80 countries and territories worldwide. Primarily transmitted to humans via infected *Aedes aegypti* mosquitoes, Zika virus infection is asymptomatic for most people and generally eliminated from the body after a few weeks. However, infected pregnant women can transmit the virus to their babies during pregnancy, increasing the risk of serious birth defects, including microcephaly.

During a randomized, controlled Phase II/IIb trial of a Zika virus investigational DNA vaccine, safety and efficacy data were collected by enrolling approximately 2,500 healthy adults and adolescents in areas of confirmed or potentially active mosquito-transmitted Zika infection. Participants were followed for up to two years.

CHALLENGE

The study responsibilities were contracted across multiple companies in the pharmaceutical industry. In this funding model, exercising flexibility throughout the study is critical to address issues and keep all stakeholders informed as well as to manage the expectations of multiple prime contractors and subcontractors.

Lead clinical research associates (CRAs) (one per site) and additional CRAs to serve as co-monitors were needed, and some sites required bilingualism (Spanish/English or Portuguese/English).

Laboratory management was the responsibility of another prime contractor, who required assistance with laboratory assessment, training and monitoring.

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To ensure the success of the study, we engaged in the following responsibilities:

- Site initiation
- Site monitoring
- Laboratory assessment
- Laboratory support
- GCLP training
- Interpretation
- Translation

Throughout the study, we helped prepare sites and laboratories for an FDA inspection.

SOLUTION

FHI Clinical was engaged as a sub-contractor for two separate contracts—one to monitor all 17 sites, including blinded and unblinded interim site visits, and the other for laboratory management.

Staffing of bilingual CRAs was challenged by country-specific considerations. For example, Costa Rica recently updated its research and healthcare policies to require in-country registration of monitoring staff; therefore, we subcontracted with a contract research organization (CRO) in Costa Rica to hire a qualified local CRA. For the remainder, we internally sourced CRAs from the US, hired independent contractors or hired from a third-party agency.

Before deployment to the sites, all CRAs completed Collaborative Institutional Training Initiative (CITI) Human Subject Protection (HSP) and Good Clinical Practice (GCP) training. Protocol training was provided by the sponsor and the prime contractor at the site initiation visits, which we attended.

Because reports were to be written in English (by CRAs with English as a second language), we implemented an internal quality review strategy before submitting the reports to the prime contractor.

For laboratory management, FHI Clinical was initially engaged to assist with one- to two-day assessments of 18 potential site laboratories. We were also mobilized to provide two-day Good Clinical Laboratory Practice (GCLP) training sessions at five sites, in English and/or Spanish. Throughout the study, we continued to review validation details, such as linearity and reference range, that were not completed prior to site activation.

During our post-activation site visits, we assessed compliance with the protocol, Manual of Operations and GCLPs; observed real-time study activities; and reviewed laboratory study data. On-the-spot training was provided when needed.

RESULTS

We quickly mobilized the site monitoring resources and were able to adapt to the needs of each specific contract and country. We prepared and shipped binders to each GCLP training session participant, in English and Spanish where needed, that included the agenda, 400+ PowerPoint slides and participant activities.

The study is now closed to follow-up, which is earlier than the original timeline due to the absence of Zika cases. Closeout visits began in October 2019, and we will continue to support the study through the completion of our contract.

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**.

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