FHI CLINICAL
Mission-driven clinical research

Providing Site Monitoring and Management Expertise in Malaria Vaccine Trials in Equatorial Guinea

The Equatorial Guinea Malaria Initiative (EGMVI) and Sanaria are partnering to eliminate malaria transmission on Bioko Island through a series of clinical trials to evaluate Sanaria's PfSPZ Vaccine.

First, they gathered data to evaluate alternative delivery strategies and inform planning for an island-wide vaccination program.

Second, they had to establish research capacity to prepare for the first-ever clinical trial in the country:

- Establish a National Ethics Committee (NEC)
- Engage regulatory authorities to review and approve the import of the vaccine for research purposes
- Train a team of Equatoguinean nationals to conduct clinical trials

We addressed several challenges:

- Data monitoring behind schedule
- Need for a bilingual CRA
- Site's limited experience with clinical trials

BACKGROUND

Study Duration: 2018-2019

Sponsor: Sanaria Inc.

Therapeutic Area: Infectious Diseases

Indication: *Plasmodium falciparum* malaria

Intervention: Vaccine

Phase(s): 2

According to the World Health Organization (WHO), over 400,000 deaths and 200 million clinical cases annually worldwide result from *Plasmodium falciparum* malaria. The number of malaria-related deaths is highest in sub-Saharan Africa, where malaria is the leading cause of death in children younger than 5 years. Multidrug resistant *P. falciparum* malaria and insecticide-resistant mosquitoes are present in much of the region, posing huge challenges to established treatment efforts.

Sanaria Inc., a biotechnology company, is developing vaccines that have been shown to be highly protective against *P. falciparum* infection in humans. Their innovative approach uses *P. falciparum* (Pf) sporozoites (SPZ) as the platform technology. To date, there have been no related serious adverse events in the 1,600 research subjects who have received the vaccine. Subjects ranging in age from infants to the elderly have been administered PfSPZ in 19 different clinical trials in the US, Europe and 6 African countries. Excellent safety and tolerability have been documented in 11 randomized, double-blind, placebo-controlled trials where the rate of adverse events following vaccination was no different than with normal saline placebo.

This phase 2 trial, funded through the Equatorial Guinea Malaria Vaccine Initiative (EGMVI) and conducted at a single site, aims to evaluate the safety and efficacy of PfSPZ Vaccine in 104 healthy adults in Equatorial Guinea.

CHALLENGE

The Sanaria team requested assistance conducting timely and consistent site monitoring, data monitoring and site oversight. As of December 2018, only one site visit had been performed by an external site monitor, and about 10% of data monitoring had occurred. Database lock was scheduled to occur by May 2019.

To ensure the success of the study, we provided the following solutions:

- On-site and remote monitoring
- Data monitoring
- Strategies to share source documents with the remote monitoring team
- Site management
- Training
- Assistance meeting IRB submission requirements

5 months

Time to process the backlog of data monitoring to enable timely database lock

The primary language in Equatorial Guinea is Spanish, requiring a bilingual (English/Spanish) clinical research associate (CRA) to perform the on-site monitoring. Also, due to the limited number of clinical studies conducted in Equatorial Guinea to date, a CRA with experience working in resource-limited areas was strongly preferred.

SOLUTION

Sanaria contracted FHI Clinical to help with on-site and data monitoring, and we joined the project in late December 2018. We selected a qualified bilingual CRA from our network who immediately commenced on-site monitoring.

The CRA quickly realized that additional support would be needed to complete the data monitoring by the intended database lock date. Therefore, we proposed remote monitoring, which was added to our contract.

In this study, data were entered directly into the database, leaving very few available source documents to review. For those that were available, we proposed strategies to share them with the remote monitoring team (e.g., scanning, sending via certified mail).

At the same time, the CRA identified that the site would benefit from additional oversight. Moving some of the data monitoring tasks to the remote monitoring team freed up the CRA to assume more of a site management role. The CRA provided additional training as well as retraining (e.g., Good Clinical Practice [GCP], documentation practices), guidance for patient consent processes and assistance with meeting IRB submission requirements.

RESULTS

The combination of on-site and remote data monitoring resulted in successful completion for 104 participants and database lock by early June 2019. Study closeout occurred in August 2019.

Sanaria greatly appreciated our ability to quickly identify and resolve issues, and our partnership will continue in future studies including a follow-on double-blind, placebo-controlled phase 3 study in Equatorial Guinea with a broader population.

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