FHI CLINICAL
Mission-driven clinical research

Site Monitoring & Management in a Clinical Trial of a Spatial Repellent for Vector-Borne Disease Control

Sumba Island, Indonesia

Major outcomes of the interim monitoring visits included:

- Verification of consistent compliance with the protocol, GCP guidelines and relevant regulatory requirements
- Early detection of potential challenges and the opportunity to correct issues and deliver appropriate refresher training
- Development of collaborative and cross-functional teamwork with the site management, site staff and Notre Dame investigators

"The FHI Clinical CRAs always demonstrated respect to our site partners, all the while informing, training and conducting oversight on best practices."

—Nicole L. Achee, PhD
Research Professor
Department of Biological Sciences
Eck Institute for Global Health
University of Notre Dame

1 Syafruddin D, Asih PBS, Rozi IE, et al. Efficacy of a Spatial Repellent for Control of Malaria in Indonesia: A Cluster-Randomized Controlled Trial [published online ahead of print, 2020 May 18]. Am J Trop Med Hyg. 2020;10.4269/ajtmh.19-0554.

BACKGROUND

Years: 2016-2018

Sponsor: University of Notre Dame

The Eijkman Institute for Molecular Biology, Jakarta, Indonesia conducted a double-blinded, randomized-cluster, placebo-controlled clinical trial to generate evidence for the World Health Organization (WHO) to assess the public health value of a spatial repellent to inform a potential global health policy for control of vector-borne disease.[1] Village clusters were randomized to the intervention (spatial repellent) or control (placebo) arm. Outcomes included newly diagnosed malaria infections, abundance of biting mosquitoes and number of infected mosquitoes.

SERVICES PROVIDED

The FHI Clinical project team was contracted to support site monitoring, site management and project management to assist the University of Notre Dame investigators achieve a level of rigor not typically required for a non-medical product. Responsibilities were later expanded to include quality assurance/regulatory oversight and trial master file (TMF) management. The original team consisted of a project manager and two regionally based clinical research associates (CRAs); after a change in project scope, the team was downsized to the project manager and one CRA.

Site readiness support visits were conducted, and the site initiation visit included two-day Good Clinical Practice (GCP) training for site staff. At each of the five interim monitoring visits, the CRA verified the site's continuing fidelity to the protocol, refreshed the staff's GCP understanding and implementation, reviewed study procedures and verified essential study documents in the TMF. Concerns/queries from ongoing remote monitoring for protocol deviations and safety events were discussed with the site until closure. During the site close-out visit in April 2018, the CRA ensured that all outstanding issues and data queries, particularly safety event reporting and follow-up, were resolved. The CRA conducted a full, final review of the essential documents and informed consent forms and reminded site staff of the record retention requirements for study documentation. Accountability of the remaining investigational product and other study supplies was documented, and instructions for disposition were provided.

The trial's success resulted in funding for an additional study in Kenya and Mali, currently in the start-up phase. FHI Clinical will also provide site monitoring, site management and project management services for the upcoming trial.