FHI CLINICAL
Mission-driven clinical research

Rapid Site Assessment and Recommendations for Clinical Trials of a New Malaria Treatment

Countries of interest included:

- Bangladesh
- Benin
- Burkina Faso
- Côte d'Ivoire
- Democratic Republic of the Congo
- Gabon
- The Gambia
- Ghana
- Indonesia
- Kenya
- Malawi
- Mozambique
- Nigeria
- Philippines
- Senegal
- Tanzania
- Vietnam
- Zimbabwe

2.5-day SEV assessments included:

- Capability to conduct human subjects research
- Understanding of trial conduct per ICH-GCP guidelines, local and national regulations, and sponsor requirements
- Physical facilities and SOPs
- Site personnel qualifications
- Number of site personnel
- Data entry capacity
- Site infrastructure
- Ability to recruit and retain participants

38 → 

site feasibility assessments conducted within a two-month period

BACKGROUND

Year: 2014

Sponsor: Novartis

In its ongoing effort to develop and market therapeutic options for malaria, Novartis is developing the KAE609 compound, a synthetic antimalarial spiroindolone analogue active against *Plasmodium falciparum*. Targeted geographic areas included malaria-endemic regions in Africa and Asia, and Novartis requested assistance identifying and assessing potential clinical sites for their planned clinical trial.

SERVICES PROVIDED

The FHI Clinical project team was contracted to identify sites, recommend sites for site evaluation visits (SEVs), conduct SEVs and provide detailed SEV reports to the sponsor. SEV recommendations were based on site responses to questionnaires used to gauge their interest and research capacity. In Africa, Novartis distributed and collected the questionnaires. In Asia, FHI Clinical distributed and collected the questionnaires.

All FHI Clinical clinical research associates (CRAs) complete an individually tailored, rigorous training program that includes demonstration of comprehensive good clinical practice (GCP) knowledge and three supervised monitoring visits before they independently monitor or assess sites. This training, along with their cultural competence and ongoing relationships with clinical sites, helps ensure comprehensive site assessment and monitoring.

During October and November 2014, FHI Clinical CRAs conducted 38 rapid, in-depth, 2.5-day site feasibility assessments in the 18 countries. Six CRAs, including a core team of four Kenya-based CRAs and two CRAs from other regions in Africa, evaluated 27 sites in Africa. For Asia, regional experts based in the country offices of FHI 360, FHI Clinical's parent company, led the process of identifying potential sites, and four regionally based CRAs in Asia were deployed to conduct SEVs at the 11 identified sites.

During the SEVs, the CRAs used a detailed evaluation checklist of study-specific selection criteria to assess the sites. They also gathered supporting site documentation, including CVs, laboratory standard operating procedures (SOPs), ethics committee and institutional review board (IRB) SOPs, IRB membership and training records. The team used the SEV reports to systematically score and rank the sites. Based on these results, the team recommended 25 (19 in Africa, 6 in Asia) of the 38 sites.