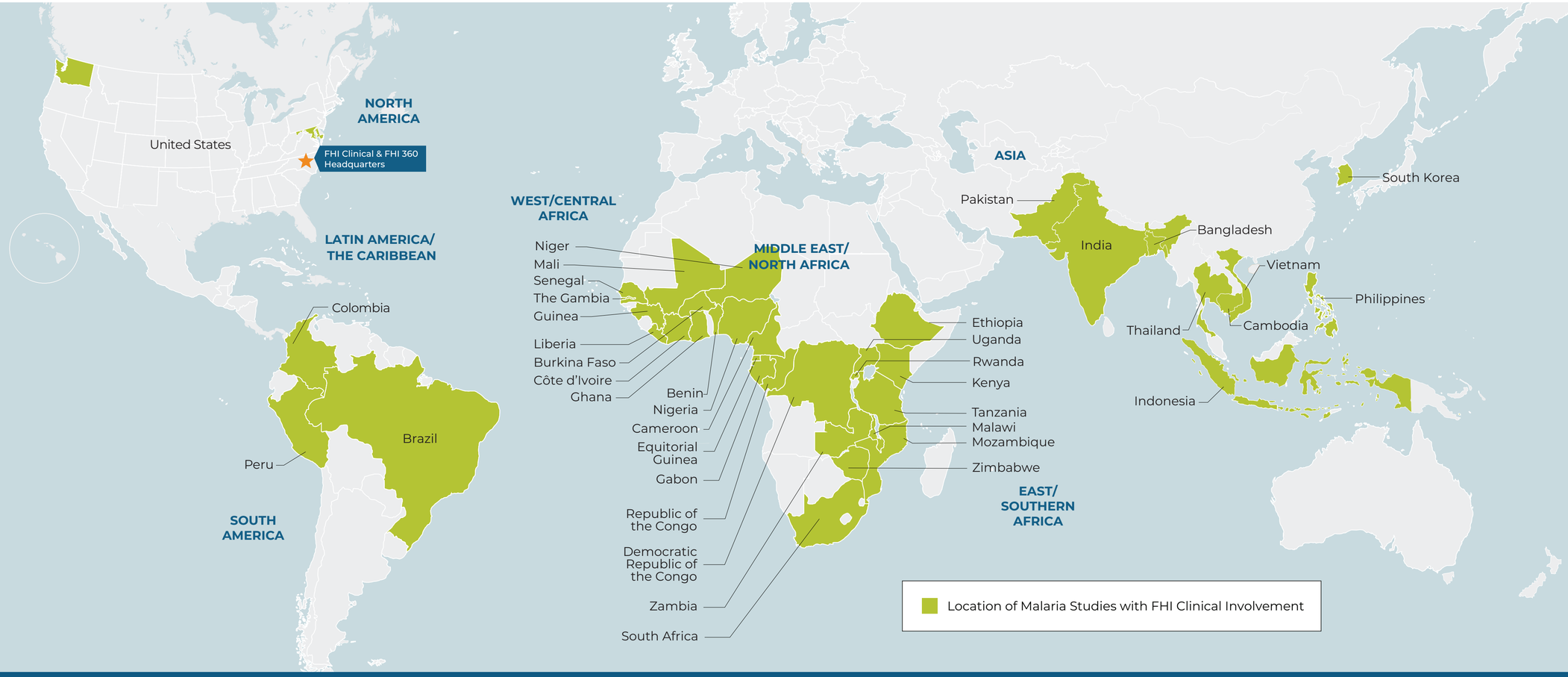
FHI CLINICAL
Mission-driven clinical research

OUR EXPERIENCE WITH MALARIA

For nearly 20 years, the FHI Clinical project team has partnered with companies developing and deploying vaccines, treatments and preventive devices for malaria in 38 countries worldwide.



IMPACT OF MALARIA

Nearly half a million deaths worldwide annually result from malaria caused by *Plasmodium falciparum*. Ongoing malaria transmission was present in 84 countries and areas in 2021. Four countries account for nearly half of all malaria cases worldwide (listed in descending order): Nigeria, the Democratic Republic of the Congo, Uganda and Mozambique.

MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT	
GO TO CURRENT STUDIES	**03**
GO TO COMPLETED STUDIES	**10**

CHALLENGES FOR MALARIA RESEARCH

- **Hard-to-reach populations**
- **Locations with limited research capacity**
- **Poor surveillance systems**
- **Migrant populations**

World Health Organization, https://www.who.int/malaria/en/

CURRENT

MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

CURRENT MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

UNITED STATES

STUDY TITLE

Phase 1 study of a monoclonal antibody against malaria

Phase(s):
1

Sponsor Type:
Public-private sponsorship

Study Duration:
2023–ongoing

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Pharmacovigilance
- Project management
- Study start-up

CURRENT MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

BURKINA FASO

GABON

MOZAMBIQUE

UGANDA

STUDY TITLE

Phase IIa proof of concept, multicentre, randomized, open-label, dose-escalation study to evaluate the safety, efficacy, and pharmacokinetics of the combination M5717 plus pyronaridine administered once daily for 1 or 2 days to adults and adolescents with acute uncomplicated *Plasmodium falciparum* malaria

Phase(s):

2

Sponsor Type:

Pharmaceutical sponsor

Study Duration:

2021–ongoing

Population:

Pediatric and adult

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Medical writing
- Project management
- Regulatory support

CURRENT MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

KENYA

STUDY TITLE

A phase 2b randomized, open-label, controlled, single center study in *Plasmodium falciparum*-infected and uninfected adults age 18-55 years old in Kenya to evaluate the efficacy of the delayed, fractional dose RTS,S/AS01E malaria vaccine in subjects treated with artemisinin combination therapy plus primaquine

Phase(s):
2

Sponsor Type:
Public-private partnership

Study Duration:
2020–ongoing

Population:
Adult

ClinicalTrials.gov Identifier:
NCT04661579

FHI CLINICAL ROLE(S)

- Biostatistics
- Clinical monitoring
- Data management
- Medical writing
- Pharmacovigilance
- Project management
- Quality assurance
- Site training
- Study start-up

CURRENT MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

LIBERIA

STUDY TITLE

PREVAIL IX/PROPEL malaria prevalence study

Read the brochure at FHIClinical.com

Study Type:
Epidemiological

Sponsor Type:
Public-private sponsorship

Study Duration:
2020–ongoing

Population:
Adult

FHI CLINICAL ROLE(S)

Operational management of the Partnership for Research on Vaccines and Infectious Diseases in Liberia (PREVAIL) network

- Sourcing, procuring and shipping
- All staff hiring
- Staff training
- Facility management
- Renovation project management
- Planning and preparation for conducting research laboratory operations
- Data management, biostatistics and Data Safety Monitoring Board (DSMB)
- Social mobilization and community engagement, social analytics and participant biometrics for study enrollment

CURRENT MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

UGANDA

STUDY TITLE

Randomized trial to evaluate Mirasol whole blood pathogen reduction technology system to reduce malaria and emerging transfusion transmitted infections

Phase(s):
3

Sponsor Type:
Academic institution

Study Duration:
2019–ongoing

Population:
Pediatric and adult

ClinicalTrials.gov Identifier:
NCT03737669

FHI CLINICAL ROLE(S)

- Project management
- Site assessment
- Site management
- Site monitoring

CURRENT MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

BURKINA FASO

DEMOCRATIC REPUBLIC OF THE CONGO

THE GAMBIA

GUINEA

NIGER

NIGERIA

RWANDA

TANZANIA

STUDY TITLE

A multi-centre randomised controlled non-inferiority trial to compare the efficacy, safety and tolerability of triple artemisinin-based combination therapies versus first-line ACTs + placebo for the treatment of uncomplicated *Plasmodium falciparum* malaria in Africa

Phase(s):
3

Sponsor Type:
Academic institution

Study Duration:
2019–ongoing

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT03923725

FHI CLINICAL ROLE(S)

- Site monitoring

COMPLETED

MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

UNITED STATES

STUDY TITLE

A clinical trial of a 3-dose, 28-day regimen of PfSPZ vaccine in healthy, malaria-naïve, adult subjects to determine safety, tolerability and efficacy against heterologous CHMI conducted 14, 42 or 70 days after immunization

Phase(s):
1

Sponsor Type:
Biotechnology sponsor

Study Duration:
2021–2022

Population:
Adult

ClinicalTrials.gov Identifier:
NCT04966871

FHI CLINICAL ROLE(S)

- Biostatistics
- Data management
- Project management
- Site monitoring

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

UNITED STATES

STUDY TITLE

A phase 2 clinical trial of PfSPZ vaccine

Phase(s):
2

Sponsor Type:
Biotechnology sponsor

Study Duration:
2021–2022

FHI CLINICAL ROLE(S)

- Biostatistics
- Data management
- Project management
- Site monitoring

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

INDONESIA

STUDY TITLE		FHI CLINICAL ROLE(S)
Biostatistics support for a malaria vaccine clinical trial	**Sponsor Type:** Biotechnology sponsor **Study Duration:** 2020	• Biostatistics

MALAWI

STUDY TITLE		FHI CLINICAL ROLE(S)
Assessment of sites for a malaria study	**Sponsor Type:** Academic institution **Study Duration:** 2020	• Site feasibility assessments

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

EQUATORIAL GUINEA

STUDY TITLE

A phase 3 clinical trial of PfSPZ vaccine

Phase(s):

3

Sponsor Type:

Biotechnology sponsor

Study Duration:

2019–2022

FHI CLINICAL ROLE(S)

- Biostatistics
- Data management
- Site monitoring

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

KENYA

STUDY TITLE

Cluster randomized trial of the efficacy of a spatial repellent (the Envelope) on *Plasmodium falciparum* malaria incidence as measured by time to first infection in western Kenya

Phase(s):
3

Sponsor Type:
Academic institution

Study Duration:
2019–2021

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT04766879

FHI CLINICAL ROLE(S)

- Data and Safety Monitoring Board (DSMB)
- Document management
- Quality assurance
- Regulatory oversight
- Site management
- Site monitoring

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

EQUATORIAL GUINEA

STUDY TITLE	FHI CLINICAL ROLE(S)
Support for the statistical analysis plan for a malaria study **Sponsor Type:** Biotechnology sponsor **Study Duration:** 2019–2020	• Statistical analysis plan

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

BANGLADESH

CÔTE D'IVOIRE

DEMOCRATIC REPUBLIC OF THE CONGO

GABON

KENYA

MALAWI

MOZAMBIQUE

NIGER

NIGERIA

PAKISTAN

TANZANIA

UGANDA

VIETNAM

ZIMBABWE

STUDY TITLE

An adaptive, randomized, active-controlled, open-label, sequential cohort, multicenter study to evaluate the efficacy, safety, tolerability and pharmacokinetics of intravenous cipargamin (KAE609) in adult and pediatric participants with severe *Plasmodium falciparum* malaria (KARISMA - KAE609's Role In Severe Malaria)

Phase:
2

Sponsor Type:
Pharmaceutical company

Study Duration:
2019–2020

Population:
Pediatric and adult

ClinicalTrials.gov Identifier:
NCT04675931

FHI CLINICAL ROLE(S)

- Project management
- Site assessment

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

THE GAMBIA

ZAMBIA

STUDY TITLE

Randomized, open-label exploratory study to determine the efficacy of different treatment regimens of Pyramax® (pyronaridine-artesunate) in asymptomatic carriers of *Plasmodium falciparum* monoinfections

Phase(s):
2

Sponsor Type:
Public-private sponsorship

Study Duration:
2018–2020

Population:
Pediatric and adult

ClinicalTrials.gov Identifier:
NCT03814616

FHI CLINICAL ROLE(S)

- Project management
- Site monitoring

OUTCOMES

- Assessed two sites (one in each country)
- Assisted both sites with RA/IRB submissions

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

INDONESIA

STUDY TITLE

Safety, tolerability, immunogenicity and protective efficacy against naturally-transmitted malaria in eastern Indonesia of two *Plasmodium falciparum* sporozoite vaccines, Sanaria® PfSPZ vaccine and Sanaria® PfSPZ-CVac: A randomized, double-blind, placebo-controlled phase 2 trial in healthy Indonesian adults

Phase(s):
2

Sponsor Type:
Biotechnology sponsor

Study Duration:
2018–2020

Population:
Adult

ClinicalTrials.gov Identifier:
NCT03503058

FHI CLINICAL ROLE(S)

- Biostatistics
- Data management
- Quality audits
- Site monitoring

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

EQUATORIAL GUINEA

STUDY TITLE

Randomized, double-blind, placebo-controlled, regimen optimization study of a radiation-attenuated *Plasmodium falciparum* sporozoite vaccine (PfSPZ vaccine) in adults

Read the case study at FHIClinical.com

Phase(s):
2

Sponsor Type:
Biotechnology sponsor

Study Duration:
2018–2019

Population:
Adult

ClinicalTrials.gov Identifier:
NCT03590340

FHI CLINICAL ROLE(S)

- On-site and remote monitoring
- Site training

OUTCOMES

- Achieved successful completion for 104 participants
- Completed database lock by June 2019

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

THE GAMBIA

ZAMBIA

STUDY TITLE

A randomized, open-label exploratory study to determine the efficacy of different treatment regimens of Pyramax® (pyronaridine-artesunate) in asymptomatic carriers of *Plasmodium falciparum* monoinfections

Phase(s):
2

Sponsor Type:
Public-private partnership

Study Duration:
2018

Population:
Pediatric and adult

ClinicalTrials.gov Identifier:
NCT03814616

FHI CLINICAL ROLE(S)

- Regulatory support
- Site assessments

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

TANZANIA

STUDY TITLE

Quality audit of a malaria trial in Tanzania

Sponsor Type:
Public-private partnership

Study Duration:
2017

FHI CLINICAL ROLE(S)

- Quality audit of a malaria trial

OUTCOMES

- Conducted one 3-day site audit
- Recommended significant changes to the site SOPs and processes
- Suggested retraining for all staff on ICH GCP and good documentation practices

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

INDONESIA

STUDY TITLE

Double-blind, double-dummy, randomized, parallel group, placebo-controlled superiority study to evaluate the efficacy and safety of tafenoquine co-administered with dihydroartemisinin-piperaquine (DHA-PQP) for the radical cure of *Plasmodium vivax* malaria

Phase(s):
3

Sponsor Type:
Pharmaceutical company

Study Duration:
2016–2020

Population:
Adult

ClinicalTrials.gov Identifier:
NCT02802501

FHI CLINICAL ROLE(S)

- Laboratory support

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

CAMEROON

CÔTE D'IVOIRE

DEMOCRATIC REPUBLIC OF THE CONGO

GABON

REPUBLIC OF CONGO

STUDY TITLE

Phase IIIb/IV cohort event monitoring study to evaluate, in a real life setting, the safety and tolerability in malaria patients of the fixed-dose artemisinin-based combination therapy Pyramax®

Phase(s):
3/4

Sponsor Type:
Public-private sponsorship

Study Duration:
2016–2020

Population:
Pediatric and adult

ClinicalTrials.gov Identifier:
NCT03201770

FHI CLINICAL ROLE(S)

- Site monitoring

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

BRAZIL

PERU

THAILAND

VIETNAM

STUDY TITLE

An open label, non-comparative, multicenter study to assess the pharmacokinetics, safety and efficacy of tafenoquine (SB-252263, WR238605) in the treatment of pediatric subjects with *Plasmodium vivax* malaria

Phase(s):
2

Sponsor Type:
Pharmaceutical company

Study Duration:
2016–2020

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT02563496

FHI CLINICAL ROLE(S)

- General and study-specific training for malaria microscopy and related procedures at the sites
- Quality assurance (QA) for malaria microscopy
- Quality control (QC) reporting
- Long-term temperature-controlled sample storage

OUTCOMES

- Trained 58 laboratory technicians/scientists at six study sites in the three countries
- Quality-checked ~1,200 samples
- Prepared and submitted 15 preliminary and 15 final reports to the sponsor

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

ETHIOPIA

STUDY TITLE

Open-label study to assess the efficacy, safety, tolerability and pharmacokinetics of a single dose of MMV390048 over a 35-day period in adult patients with acute, uncomplicated *Plasmodium vivax* or *P. falciparum* malaria monoinfection

Phase(s):
2

Sponsor Type:
Public-private partnership

Study Duration:
2016–2018

Population:
Adult

ClinicalTrials.gov Identifier:
NCT02880241

FHI CLINICAL ROLE(S)

- Project management
- Site monitoring
- Site management
- Regulatory oversight

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

STUDY TITLE		FHI CLINICAL ROLE(S)
Site evaluations for a study of a spatial repellent	**Study Type:** Interventional **Sponsor Type:** Chemical company **Study Duration:** 2016–2017	• Site assessments

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

CÔTE D'IVOIRE

STUDY TITLE		FHI CLINICAL ROLE(S)
Study start-up activities for a study of a malaria treatment	**Phase(s):** 3/4 **Sponsor Type:** Public-private partnership **Study Duration:** 2016	• Study start-up

THAILAND

VIETNAM

STUDY TITLE		FHI CLINICAL ROLE(S)
Training of sites involved in a study of a malaria treatment	**Sponsor Type:** Pharmaceutical company **Study Duration:** 2016	• Site training

SOUTH AFRICA

STUDY TITLE		FHI CLINICAL ROLE(S)
Audits of a malaria study in South Africa	**Sponsor Type:** Public-private partnership **Study Duration:** 2016	• Quality audits

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

INDONESIA

STUDY TITLE

Spatial repellent products for control of vector borne diseases — malaria — Indonesia

Read the case study at FHIClinical.com

Sponsor Type:
Academic institution

Study Duration:
2015–2019

Study Type:
Interventional

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT02294188

FHI CLINICAL ROLE(S)

- Site monitoring
- Project management

OUTCOMES

- Verification of consistent compliance with the protocol, GCP guidelines and relevant regulatory requirements
- Development of collaborative and cross-functional teamwork with site management, site staff and investigators
- Funding for an additional study in Kenya and Mali

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

BRAZIL
CAMBODIA
ETHIOPIA
PERU
PHILIPPINES
THAILAND

STUDY TITLE

Multi-center, double-blind, randomized, parallel-group, active-controlled study to evaluate the efficacy, safety and tolerability of tafenoquine (TQ) in participants with *Plasmodium vivax* malaria

Phase(s):
2/3

Sponsor Type:
Pharmaceutical company

Study Duration:
2015–2018

Population:
Pediatric and adult

ClinicalTrials.gov Identifier:
NCT01376167

FHI CLINICAL ROLE(S)

- Laboratory support, including:
  - Study-specific training for malaria microscopy at the sites
  - Quality assurance (QA) for malaria microscopy
  - Quality control (QC) reporting
  - Long-term temperature-controlled sample storage
- Recruitment and retention
- Hiring and training outreach coordinators at each site

BRAZIL
COLOMBIA
ETHIOPIA
PERU
THAILAND
VIETNAM

Randomized, double-blind, double-dummy, comparative, multicenter study to assess the incidence of hemolysis, safety and efficacy of tafenoquine (SB-252263, WR238605) versus primaquine in the treatment of *Plasmodium vivax* malaria

Phase(s):
2/3

Sponsor Type:
Pharmaceutical company

Study Duration:
2015–2018

Population:
Pediatric and adult

ClinicalTrials.gov Identifier:
NCT02216123

OUTCOMES

- Developed site-specific recruitment and retention plans at 14 sites across the 8 countries
- Achieved 97% retention at all sites
- Conducted microscopy training at all Bangkok sites

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

STUDY TITLE		FHI CLINICAL ROLE(S)
Site assessments for a study of a malaria treatment	**Study Duration:** 2015–2016	• Site assessment

VIETNAM

STUDY TITLE		FHI CLINICAL ROLE(S)
Support for sites in a study of a malaria treatment	**Sponsor Type:** Academic institution **Duration:** 2015	• Regulatory support • Site training

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

DEMOCRATIC REPUBLIC OF THE CONGO

STUDY TITLE

Randomised phase IIb study of efficacy, safety, tolerability & pharmacokinetics of a single dose regimen of artefenomel (OZ439) in loose combination with piperaquine in adults and children with uncomplicated *Plasmodium falciparum* malaria

Phase(s):
2

Sponsor Type:
Public-private partnership

Study Duration:
2014–2016

Population:
Pediatric and adult

ClinicalTrials.gov Identifier:
NCT02083380

FHI CLINICAL ROLE(S)

- Site monitoring

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

COUNTRIES IN
AFRICA AND ASIA

STUDY TITLE

Site assessments for study of a treatment for malaria in Africa and Asia

Phase(s):
2

Sponsor Type:
Pharmaceutical company

Study Duration:
2014–2015

Population:
Pediatric and adult

FHI CLINICAL ROLE(S)

- Site assessments

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A single centre, two-part, double-blind, randomized, placebo-controlled phase I study to investigate the safety, tolerability, and pharmacokinetic profile of ascending doses of MMV390048 in healthy adult volunteers

Phase(s):
1 (first-in-human)

Sponsor Type:
Public-private partnership

Study Duration:
2014–2015

Population:
Adult

ClinicalTrials.gov Identifier:
NCT02230579

FHI CLINICAL ROLE(S)

- Biostatistics
- Clinical monitoring
- Data management
- Medical monitoring
- Pharmacovigilance
- Project management
- Protocol writing
- Regulatory support
- Quality assurance

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

BANGLADESH
BENIN
BURKINA FASO
CÔTE D'IVOIRE
DRC
GABON
THE GAMBIA
GHANA
INDONESIA
KENYA
MALAWI
MOZAMBIQUE
NIGERIA
PHILIPPINES
SENEGAL
TANZANIA
VIETNAM
ZIMBABWE

STUDY TITLE

To support an anticipated study of KAE609 for malaria treatment

Sponsor Type:
Pharmaceutical sponsor

Study Duration:
2014

FHI CLINICAL ROLE(S)

- Site identification (Asia only)
- Reviewing site questionnaires and recommending sites for site evaluation visits (SEVs)
- SEVs and generating the corresponding reports
- Site selection recommendations

OUTCOMES

Within a 2-month period, FHI Clinical clinical research associates (CRAs):

- Conducted 38 in-depth, 2.5-day site feasibility assessments (27 in Africa, 11 in Asia) in the 18 countries
- Met with the local ethics committee, when possible, and gathered supporting documentation including CVs, laboratory standard operating procedures (SOPs), ethics committee and Institutional Review Board (IRB) SOPs, IRB membership and training records
- Recommended 25 of the 38 sites

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

THAILAND

VIETNAM

STUDY TITLE

A study to find the minimum inhibitory concentration of KAE609 in adult male patients with *P. falciparum* monoinfection

Phase(s):
2

Sponsor Type:
Pharmaceutical company

Study Duration:
2013–2015

Population:
Adult

ClinicalTrials.gov Identifier:
NCT01836458

FHI CLINICAL ROLE(S)

- Document management
- Laboratory support
- Site monitoring

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

THAILAND

VIETNAM

STUDY TITLE

An open label, single dose study to assess efficacy, safety, tolerability and pharmacokinetics of KAE609 in adult patients with acute, uncomplicated *Plasmodium falciparum* malaria mono-infection

Phase(s):
2

Sponsor Type:
Pharmaceutical company

Study Duration:
2013–2015

Population:
Adult

ClinicalTrials.gov Identifier:
NCT01860989

FHI CLINICAL ROLE(S)

- Site assessments
- Site monitoring
- Training

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

BURKINA FASO

GUINEA

MALI

STUDY TITLE

A Phase IIIb/IV comparative, randomised, multi-centre, open label, parallel 3-arm clinical study to assess the safety and efficacy of repeated administration of pyronaridine-artesunate, dihydroartemisinin-piperaquine, artemether-lumefantrine or artesunate-amodiaquine over a two-year period in children and adult patients with acute uncomplicated *Plasmodium sp.* malaria.

Phase(s):
3/4

Sponsor Type:
Public-private partnership

Study Duration:
2012–2016

Population:
Pediatric and adult

PACTR.org Trial ID:
PACTR201105000286876

FHI CLINICAL ROLE(S)

- Project management

OUTCOMES

The study team:

- Randomized and treated 4,750 patients in the three countries
- Treated more than 8,500 episodes of malaria, including up to 13 episodes for some children
- Demonstrated efficacy of all four studied ACTs for treating uncomplicated malaria

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

THAILAND

VIETNAM

STUDY TITLE

A proof-of-concept, open label study to assess efficacy, safety, tolerability and pharmacokinetics of KAF156 in adult patients with acute, uncomplicated *Plasmodium falciparum* or *vivax* malaria mono-infection

Phase(s):
2

Sponsor Type:
Pharmaceutical sponsor

Study Duration:
2012–2015

Population:
Adult

ClinicalTrials.gov Identifier:
NCT01753323

FHI CLINICAL ROLE(S)

- Document management
- Site monitoring
- Site evaluation/assessments
- Training

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase I healthy volunteer study investigating the safety, tolerability & pharmacokinetics of co-administered single doses of OZ439 and mefloquine

Phase(s):
1

Sponsor Type:
Public-private partnership

Study Duration:
2012–2013

Population:
Adult

ClinicalTrials.gov Identifier:
NCT01615822

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Project management
- Regulatory affairs

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

TANZANIA

STUDY TITLE

Quality audit of a malaria study in Tanzania

Study Type:
Epidemiological

Sponsor Type:
Public-private partnership

Study Duration:
2012

Population:
Pediatric

FHI CLINICAL ROLE(S)

- Quality audit

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

THAILAND

STUDY TITLE

A proof-of-concept, open label, 3-day repeated dose study to assess efficacy, safety, tolerability and pharmacokinetics of KAE609 in adult patients with acute, uncomplicated *Plasmodium falciparum* or *vivax* malaria mono-infection

Phase(s):
2

Sponsor Type:
Pharmaceutical company

Study Duration:
2011–2013

Population:
Adult

ClinicalTrials.gov Identifier:
NCT01524341

FHI CLINICAL ROLE(S)

- Document management
- Laboratory support
- Site monitoring

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

THAILAND

STUDY TITLE

Phase IIa exploratory, open label, single/multiple dose testing clinical study to assess the preliminary efficacy, tolerability and pharmacokinetics of OZ439 in adult patients with acute, uncomplicated *Plasmodium falciparum* or *vivax* malaria monoinfection

Phase(s):
2

Sponsor Type:
Public-private sponsorship

Study Duration:
2010–2012

Population:
Adult

ClinicalTrials.gov Identifier:
NCT01213966

FHI CLINICAL ROLE(S)

- Document management
- Site management
- Site monitoring

OUTCOMES

- The study team enrolled 82 participants, 33% higher than target.

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

DEMOCRATIC REPUBLIC OF THE CONGO

THE GAMBIA

GHANA

KENYA

MOZAMBIQUE

NIGERIA

RWANDA

TANZANIA

UGANDA

STUDY TITLE

The Africa quinine versus artesunate in severe malaria trial

Phase(s):
4

Sponsor Type:
Academic institution

Study Duration:
2008–2011

Population:
Pediatric

ISRCTN ID:
ISRCTN50258054

FHI CLINICAL ROLE(S)

- Site monitoring

COMPLETED MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

BURKINA FASO

CAMBODIA

CÔTE D'IVOIRE

DEMOCRATIC REPUBLIC OF THE CONGO

THE GAMBIA

GABON

INDIA

NDONESIA

KENYA

PHILIPPINES

SENEGAL

SOUTH KOREA

THAILAND

VIETNAM

STUDY TITLE

A phase III randomised, double-blind, double-dummy, comparative study to assess the safety and efficacy of pyronaridine artesunate (180:60 mg) versus chloroquine (155 mg) in children and adult patients in Korea with acute *P. vivax* malaria

Phase(s):
3

Sponsor Type:
Public-private sponsorship

Study Duration:
2006–2011

Population:
Pediatric and adult

ClinicalTrials.gov Identifier:
NCT04368910

FHI CLINICAL ROLE(S)

- Document management
- Site monitoring

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