FHI CLINICAL
Mission-driven clinical research

OUR EXPERIENCE WITH TUBERCULOSIS

The FHI Clinical project team has partnered with companies to conduct more than 65 clinical trials as well as epidemiological and observational studies for tuberculosis in 30 countries worldwide.

IMPACT OF TUBERCULOSIS

More than 1.6 million deaths worldwide, including 187,000 people with HIV, resulted from tuberculosis in 2021. Globally, 10.6 million people fell ill with tuberculosis in 2021, including 1.2 million children. The World Health Organization (WHO) South-East Asian Region is affected the most, followed by the WHO African Region and WHO Western Pacific Region, and eight countries accounted for more than two-thirds of new TB cases globally in 2020: India, Indonesia, China, the Philippines, Pakistan, Nigeria, Bangladesh and the Democratic Republic of the Congo.

TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT	
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CHALLENGES FOR TUBERCULOSIS RESEARCH

- **Emergence of multidrug resistant tuberculosis**
- **Hard-to-reach populations geographically and due to disease-related stigmatization**
- **Locations with limited research capacity and access to healthcare**
- **Poor surveillance systems**
- **Migrant populations**

World Health Organization, https://www.who.int/news-room/fact-sheets/detail/tuberculosis

CURRENT

TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

CURRENT TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

LIBERIA

STUDY TITLE

PREVAIL VIIIa: evaluation of latent tuberculosis infection screening methods in people living with retroviral infection in Liberia

Sponsor Type:
Public-private partnership

Duration:
2021–ongoing

Study Type:
Prospective cohort

Population:
Adult

ClinicalTrials.gov Identifier:
NCT04926922

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

CURRENT TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

MADAGASCAR

SENEGAL

SOUTH AFRICA

STUDY TITLE

Randomised, double-blind, controlled phase 3 trial to evaluate the efficacy, safety and immunogenicity of MTBVAC administered in healthy HIV unexposed and HIV exposed uninfected newborns in tuberculosis-endemic regions of sub-Saharan Africa

Phase(s):
3

Sponsor Type:
Biotechnology company

Study Duration:
2021–ongoing

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT04975178

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Laboratory support
- Medical writing
- Pharmacovigilance
- Project management
- Regulatory services
- Study start-up

CURRENT TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

METHOD Trial - a prospective, randomized open-label phase II study of the safety and tolerability of metformin in combination with standard antimicrobial treatment of pulmonary tuberculosis in people co-infected with HIV

Phase(s):
1/2

Sponsor Type:
Non-governmental organization

Study Duration:
2021–ongoing

Population:
Adult

SANCTR Identifier:
DOH-27-082021-5331

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Project management

CURRENT TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

TANZANIA

STUDY TITLE

A phase IIb, open label, randomized controlled dose ranging multi-center trial to evaluate the safety, tolerability, pharmacokinetics and exposure-response relationship of different doses of delpazolid in combination with bedaquiline delamanid moxifloxacin in adult subjects with newly diagnosed, uncomplicated, smear-positive, drug-sensitive pulmonary tuberculosis

Phase(s):

2

Sponsor Type:

Biotechnology company

Study Duration:

2020–ongoing

Population:

Adult

ClinicalTrials.gov Identifier:

NCT04550832

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Project management

CURRENT TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

MOZAMBIQUE

SOUTH AFRICA

STUDY TITLE

AUR1-1-313 DRTB-HDT - A randomized controlled trial of two adjunctive host-directed therapies in rifampin-resistant tuberculosis (DRTB-HDT)

Phase(s):
2

Sponsor Type:
Non-governmental organization

Study Duration:
2020–ongoing

Population:
Pediatric and adult

SANCTR Identifier:
DOH-27-042021-8345

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Project management
- Regulatory affairs

CURRENT TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

GABON

MALAWI

MOZAMBIQUE

SOUTH AFRICA

TANZANIA

UGANDA

STUDY TITLE

Phase 2 study of an investigational tuberculosis treatment

Phase(s):

2

Sponsor Type:

Academic institution

Study Duration:

2020–ongoing

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Data management
- Project management

CURRENT TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

TANZANIA

STUDY TITLE

A phase IIB, open-label, randomized controlled dose ranging multi-center trial to evaluate the safety, tolerability, pharmacokinetics and exposure-response relationship of different doses of sutezolid in combination with bedaquiline, delamanid and moxifloxacin in adult subjects with newly diagnosed, uncomplicated, smear-positive, drug-sensitive pulmonary tuberculosis

Phase(s):
2

Sponsor Type:
Academic institution

Study Duration:
2019–ongoing

Population:
Adult

ClinicalTrials.gov Identifier:
NCT03959566

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Data management
- Project oversight
- Regulatory support
- Vendor management

CURRENT TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A prospective phase Ib/IIa, active-controlled, randomized, open-label study to evaluate the safety, tolerability, extended early bactericidal activity and pharmacokinetics of multiple oral doses of BTZ-043 tablets in subjects with newly diagnosed, uncomplicated, smear-positive, drug-susceptible pulmonary tuberculosis

Phase(s):
1/2

Sponsor Type:
Academic institution

Study Duration:
2019–ongoing

Population:
Adult

ClinicalTrials.gov Identifier:
NCT04044001

FHI CLINICAL ROLE(S)

- Medical writing
- Project management

CURRENT TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase 2a dose-defining safety and immunogenicity study of MTBVAC in South African neonates living in a high-burden tuberculosis-endemic region

Phase(s):
2

Sponsor Type:
Biotechnology company

Study Duration:
2018–ongoing

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT03536117

FHI CLINICAL ROLE(S)

- Biostatistics
- Clinical monitoring
- Data management
- Medical writing
- Pharmacovigilance
- Project management
- Regulatory support
- Study start-up

CURRENT TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Safety, tolerability, and drug-drug interactions of short-course treatment of latent tuberculosis infection with high-dose rifapentine and isoniazid or standard isoniazid preventative therapy among HIV-infected patients taking dolutegravir-based antiretroviral treatment

Phase(s):
1/2

Sponsor Type:
Non-governmental organization

Duration:
2017–ongoing

Population:
Adult

ClinicalTrials.gov Identifier:
NCT03435146

FHI CLINICAL ROLE(S)

- Clinical monitoring
- IRB/EC support
- Project management
- Regulatory support

COMPLETED

MALARIA STUDIES WITH FHI CLINICAL INVOLVEMENT

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

BANGLADESH
BRAZIL
BURKINA FASO
CENTRAL AFRICAN REPUBLIC
CÔTE D'IVOIRE
DEMOCRATIC REPUBLIC OF THE CONGO
ETHIOPIA
GABON
GHANA
INDIA
KENYA
LIBERIA
MALAWI
NIGERIA
PAKISTAN
PERU
PHILIPPINES
SOUTH AFRICA
SRI LANKA
UGANDA
VIETNAM

STUDY TITLE

Feasibility assessments for the continued development of the M72/AS01E tuberculosis vaccine candidate

Study Type:
Feasibility assessment

Sponsor Type:
Non-governmental organization

Duration:
2021

FHI CLINICAL ROLE(S)

- Project management
- Site feasibility assessments

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

CHINA

STUDY TITLE

Evaluation of bedaquiline as part of combination therapy for multi-drug resistant, pulmonary tuberculosis through a New Drug

Sponsor Type:
Pharmaceutical company

Study Duration:
2017–2019

Population:
Adult

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

ETHIOPIA

STUDY TITLE

Observational study of adults co-infected with HIV, tuberculosis and syphilis

Study Type:
Observational

Sponsor Type:
Governmental organization

Duration:
2016–2017

Population:
Adult

FHI CLINICAL ROLE(S)

- Quality assurance

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Using biomarkers to predict TB treatment duration

Phase(s):
2

Sponsor Type:
Governmental organization

Study Duration:
2016

Population:
Adult

ClinicalTrials.gov Identifier:
NCT02821832

FHI CLINICAL ROLE(S)

- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase 3 clinical trial of isoniazid and rifapentine for tuberculosis treatment

Phase(s):
3

Sponsor Type:
Academic institution

Study Duration:
2016

Population:
Adult

ClinicalTrials.gov Identifier:

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Data management
- Lab monitoring
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A ph2 randomized trial to evaluate the safety preliminary efficacy and biomarker response of host directed therapies added to rifabutin-modified standard therapy in adults with drug-sensitive smear-positive pulmonary TB

Phase(s):
2

Sponsor Type:
Non-governmental organization

Study Duration:
2016

Population:
Adult

ClinicalTrials.gov Identifier:
NCT02968927

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Lab monitoring
- Project management

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Observational study of tuberculosis

Phase(s):
3

Sponsor Type:
Academic institution

Study Duration:
2016

Study Type:
Observational

FHI CLINICAL ROLE(S)

- Clinical monitoring
- IRB/EC support
- Lab monitoring
- Project management

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

VIETNAM

STUDY TITLE

STREAM: the evaluation of a standard treatment regimen of anti-tuberculosis drugs for patients with MDR-TB

Phase(s):
3

Sponsor Type:
Non-governmental organization

Study Duration:
2015–2018

Population:
Pediatric and adult

ClinicalTrials.gov Identifier:
NCT02409290

FHI CLINICAL ROLE(S)

- Site management

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

CHINA

STUDY TITLE

STREAM 2 - The evaluation of a standard treatment regimen of anti-tuberculosis drugs for patients with multi-drug-resistant tuberculosis

Phase(s):
3

Sponsor Type:
Non-governmental organization

Study Duration:
2015–2018

Population:
Adult

ClinicalTrials.gov Identifier:
ISRCTN18148631

FHI CLINICAL ROLE(S)

- Project management
- Site assessments

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase II double-blind, randomized, controlled study to evaluate safety and immunogenicity of VPM1002 compared with BCG in HIV-exposed and HIV-unexposed, BCG-naive newborn infants

Phase(s):
2

Sponsor Type:
Biopharmaceutical company

Study Duration:
2015–2018

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT02391415

FHI CLINICAL ROLE(S)

- Biosafety application
- Biostatistics
- Clinical monitoring
- Data management
- Medical monitoring
- Medical writing
- Pharmacovigilance
- Project management
- Protocol writing
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

STUDY TITLE		FHI CLINICAL ROLE(S)
Regulatory oversight for a tuberculosis study	**Study Duration:** 2015	• Regulatory oversight

VIETNAM

STUDY TITLE		FHI CLINICAL ROLE(S)
Site support for a study of a tuberculosis treatment	**Sponsor Type:** Public-private partnership **Study Duration:** 2015	• Site support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

TANZANIA

STUDY TITLE

A Phase 2, randomized, placebo-controlled, double-blind, study of the prevention of infection with *Mycobacterium tuberculosis* among adolescents who have previously received BCG

Phase(s):
2

Sponsor Type:
Academic institution

Study Duration:
2015

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT02712424

FHI CLINICAL ROLE(S)

- Clinical monitoring

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A randomized, placebo-controlled, partially blinded phase 1b clinical trial to evaluate the safety and immunogenicity of BCG revaccination, H4:IC31, and H56:IC31 in healthy, HIV-1-uninfected adolescent participants

Phase(s):
1

Sponsor Type:
Biotechnology company

Study Duration:
2014–2018

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT02378207

FHI CLINICAL ROLE(S)

- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase 2 dose-ranging trial to evaluate the bactericidal activity, safety, tolerability and pharmacokinetics of linezolid in adult subjects with newly diagnosed drug-sensitive, smear-positive pulmonary tuberculosis

Phase(s):
2

Sponsor Type:
Public-private partnership

Study Duration:
2014–2017

Population:
Adult

ClinicalTrials.gov Identifier:
NCT02279875

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Data management
- IRB/EC support
- Medical writing
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase 2A, randomized, double-blind, placebo-controlled, clinical trial to evaluate the safety and immunogenicity of the ID93 + GLA-SE vaccine in HIV uninfected adult TB patients after treatment completion

Phase(s):
2

Sponsor Type:
Public-private partnership

Study Duration:
2014–2017

Population:
Adult

ClinicalTrials.gov Identifier:
NCT02465216

FHI CLINICAL ROLE(S)

- Clinical monitoring
- IRB/EC support
- Pharmacovigilance
- Project management
- Protocol writing
- Quality audit
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase 2 trial of bedaquiline, PA-824 and linezolid to treat tuberculosis

Phase(s):
2

Sponsor Type:
Public-private partnership

Study Duration:
2014–2016

Population:
Adult

FHI CLINICAL ROLE(S)

- IRB/EC support
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

KENYA

MOZAMBIQUE

SOUTH AFRICA

TANZANIA

UGANDA

ZAMBIA

STUDY TITLE

A phase 3 open-label partially randomized trial to evaluate the efficacy, safety and tolerability of the combination of moxifloxacin plus PA-824 plus pyrazinamide after 4 and 6 months of treatment in adult subjects with drug-sensitive smear-positive pulmonary tuberculosis and after 6 months of treatment in adult subjects with multi-drug resistant, smear-positive pulmonary tuberculosis

Phase(s):
3

Sponsor Type:
Public-private sponsorship

Study Duration:
2014–2016

Population:
Adult

ClinicalTrials.gov Identifier:
NCT02342886

FHI CLINICAL ROLE(S)

- Clinical monitoring
- IRB/EC support
- Lab consulting
- Lab monitoring
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase I, double-blind, randomized, placebo-controlled, study to evaluate the safety and immunogenicity of AERAS-456 in HIV negative adults successfully treated for drug-susceptible pulmonary tuberculosis

Phase(s):
1

Sponsor Type:
Biotechnology company

Study Duration:
2014–2016

Population:
Adult

ClinicalTrials.gov Identifier:
NCT02375698

FHI CLINICAL ROLE(S)

- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A randomized, placebo controlled, double-blind phase II study to evaluate safety, immunogenicity, and prevention of infection with *Mycobacterium tuberculosis* (Mtb) of H56:IC31 in healthy adolescents

Phase(s):
2

Sponsor Type:
Biotechnology company

Study Duration:
2014

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT03265977

FHI CLINICAL ROLE(S)

- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase II, double -blind, randomized, placebo-controlled, dose-escalation study to evaluate the safety, immunogenicity and efficacy of AERAS-456 in reducing the rate of TB disease recurrence in HIV negative adults successfully treated for drug-susceptible pulmonary tuberculosis

Phase(s):
2

Sponsor Type:
Biotechnology company

Study Duration:
2014

Population:
Adult

FHI CLINICAL ROLE(S)

- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

STUDY TITLE		FHI CLINICAL ROLE(S)
Project management of a tuberculosis treatment study	**Sponsor Type:** Public-private partnership **Study Duration:** 2014	• Project management

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase 1 study of the MTBVAC tuberculosis vaccine

Phase(s):
1

Sponsor Type:
Biotechnology company

Study Duration:
2014

Population:
Pediatric and adult

FHI CLINICAL ROLE(S)

- Biosafety application
- Biostatistics
- Clinical monitoring
- Data management
- IRB/EC support
- Medical monitoring
- Medical writing
- Pharmacovigilance
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A randomized, placebo controlled, partially blinded phase II study to evaluate safety, immunogenicity, and prevention of infection with *Mycobacterium tuberculosis* of AERAS-404 and BCG revaccination in healthy adolescents

Phase(s):
2

Sponsor Type:
Biotechnology company

Study Duration:
2013–2018

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT02075203

FHI CLINICAL ROLE(S)

- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase 1b, randomized, double-blind, placebo-controlled, dose-escalation study to evaluate the safety and immunogenicity of the ID93 + GLA-SE vaccine in BCG-vaccinated healthy adults

Phase(s):
1

Sponsor Type:
Public-private partnership

Study Duration:
2013–2016

Population:
Adult

ClinicalTrials.gov Identifier:
NCT01927159

FHI CLINICAL ROLE(S)

- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase 1/II, safety and immunogenicity study of a recombinant protein tuberculosis vaccine (AERAS-404) in BCG-primed infants

Phase(s):
1

Sponsor Type:
Biotechnology company

Study Duration:
2012–2018

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT01861730

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Epidemiological study of NTP biobanking

Study Type:
Epidemiological

Sponsor Type:
Public-private partnership

Study Duration:
2012–2016

FHI CLINICAL ROLE(S)

- Clinical monitoring
- IRB/EC support
- Lab monitoring
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

TANZANIA

STUDY TITLE

A multiple arm, multiple stage, phase 2, OL, randomized, controlled trial to evaluate 4 treatment regimens of SQ109, increased doses of rifampicin, and moxifloxacin in adults with newly diagnosed, smear-positive pulmonary tuberculosis

Phase(s):
2

Sponsor Type:
Academic institution

Study Duration:
2012–2015

Population:
Adult

ClinicalTrials.gov Identifier:
NCT01785186

FHI CLINICAL ROLE(S)

- Biostatistics
- Clinical monitoring
- Data management
- IRB/EC support
- Medical writing
- Pharmacovigilance
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase I/IIa double-blind, randomized, placebo-controlled dose-finding study to evaluate the safety and immunogenicity of AERAS-456 in HIV-negative adults with and without latent tuberculosis infection

Phase(s):
2

Sponsor Type:
Biotechnology company

Study Duration:
2012–2015

Population:
Adult

ClinicalTrials.gov Identifier:
NCT01865487

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Monitoring of sites during an observational study of tuberculosis

Study Type:
Observational

Sponsor Type:
Governmental organization

Study Duration:
2012–2014

FHI CLINICAL ROLE(S)

- Site monitoring

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase II, randomized, observer-blinded, single centre trial evaluating the immunogenicity and safety of 2 doses of an adjuvated TB subunit vaccine (Ag85B-ESAT-6 + IC31®) using 2 different vaccination schedules in healthy adolescents

Phase(s):
2

Sponsor Type:
Biotechnology sponsor

Study Duration:
2012–2014

Population:
Pediatric

SANCTR Identifier:
DOH-27-0612-3947

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Project management

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

STUDY TITLE		FHI CLINICAL ROLE(S)
Site training for a tuberculosis treatment study	**Study Duration:** 2012–2013**:**	• Training

STUDY TITLE		FHI CLINICAL ROLE(S)
Project management of a phase 3 tuberculosis study	**Phase(s):** 3 **Sponsor Type:** Public-private partnership **Study Duration:** 2012	• Project management

KENYA
SOUTH AFRICA
TANZANIA
ZAMBIA

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase II randomised controlled trial to evaluate safety and immunogenicity of MVA85A and selective, delayed bacille Calmette-Guerin (BCG) vaccination in infants of HIV infected mother

Phase(s):
2

Sponsor Type:
Academic institution

Study Duration:
2011–2015

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT01650389

FHI CLINICAL ROLE(S)

- Biosafety application
- Clinical monitoring
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase II open label, randomized, controlled study to evaluate safety and immunogenicity of VPM1002 in comparison with BCG in HIV-unexposed, BCG naive newborn infants in South Africa

Phase(s):
2

Sponsor Type:
Biotechnology company

Study Duration:
2011–2013

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT01479972

FHI CLINICAL ROLE(S)

- Biosafety application
- Biostatistics
- Clinical monitoring
- Data management
- Medical monitoring
- Medical writing
- Pharmacovigilance
- Project management
- Protocol writing
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase I open label dose-escalation study to evaluate the safety and immunogenicity of H56:IC31 (AERAS-456) in HIV-negative adults with and without latent tuberculosis infection

Phase(s):
1

Sponsor Type:
Biotechnology company

Study Duration:
2011–2013

Population:
Adult

ClinicalTrials.gov Identifier:
NCT01967134

FHI CLINICAL ROLE(S)

- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase 2 study of a tuberculosis vaccine in adolescents

Phase(s):
2

Sponsor Type:
Biotechnology company

Study Duration:
2011–2012

Population:
Pediatric

FHI CLINICAL ROLE(S)

- Biosafety application
- Clinical monitoring
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

STREAM: the evaluation of a standard treatment regimen of anti-tuberculosis drugs for patients with MDR-TB

Phase(s):
3

Sponsor Type:
Academic institution

Study Duration:
2010–2016

Population:
Pediatric and adult

ClinicalTrials.gov Identifier:
NCT02409290

FHI CLINICAL ROLE(S)

- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

KENYA

MOZAMBIQUE

SOUTH AFRICA

UGANDA

STUDY TITLE

A phase II, double-blind, randomized, placebo-controlled, multicenter study to evaluate the safety and immunogenicity of AERAS-402 in BCG-vaccinated, HIV-uninfected infants without evidence of tuberculosis

Phase(s):
2

Sponsor Type:
Biotechnology company

Study Duration:
2010–2011

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT01198366

FHI CLINICAL ROLE(S)

- Biosafety application
- Regulatory support
- Site assessments

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase 1 study of a tuberculosis vaccine in infants

Phase(s):
1

Sponsor Type:
Biotechnology company

Study Duration:
2010

Population:
Pediatric

FHI CLINICAL ROLE(S)

- Quality audit

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SENEGAL

SOUTH AFRICA

STUDY TITLE

A phase II, proof of concept, randomized, double-blind, placebo-controlled study to evaluate the protective efficacy against TB disease, safety, and immunogenicity of MVA85A/AERAS-485 in healthy, HIV-infected adults

Phase(s):
2

Sponsor Type:
Biotechnology company

Study Duration:
2009–2014

Population:
Adult

ClinicalTrials.gov Identifier:
NCT01151189

FHI CLINICAL ROLE(S)

- Biosafety application
- Clinical monitoring
- IRB/EC support
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SENEGAL

SOUTH AFRICA

STUDY TITLE

Phase II double-blind, randomized, placebo-controlled study to evaluate the safety and immunogenicity of AERAS-402 in HIV-infected, BCG-vaccinated adults with CD4+ lymphocyte counts greater than 350 cells/mm^3

Phase(s):
2

Sponsor Type:
Biotechnology company

Study Duration:
2009–2013

Population:
Adult

ClinicalTrials.gov Identifier:
NCT01017536

FHI CLINICAL ROLE(S)

- Biosafety application
- Clinical monitoring
- IRB/EC support
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase II double-blinded randomized controlled evaluation of MVA85A/AERAS-485 for safety, immunogenicity and prevention of tuberculosis in BCG-vaccinated, HIV-negative infants

Phase(s):
2

Sponsor Type:
Biotechnology company

Study Duration:
2009–2013

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT00953927

FHI CLINICAL ROLE(S)

- Clinical monitoring
- IRB/EC support
- Project management
- Protocol writing
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase Ib open label, randomized, controlled, dose-escalation study to evaluate safety and immunogenicity of VPM1002 in comparison with BCG in healthy volunteers in South Africa

Phase(s):
1

Sponsor Type:
Biotechnology company

Study Duration:
2009–2011

Population:
Adult

ClinicalTrials.gov Identifier:
NCT01113281

FHI CLINICAL ROLE(S)

- Biosafety application
- Biostatistics
- Clinical monitoring
- Data management
- Medical monitoring
- Medical writing
- Pharmacovigilance
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase I double-blind randomized controlled dose escalation study to evaluate safety and immunogenicity of AERAS-402 in BCG vaccinated, HIV-negative infants at least 6 months of age without evidence of tuberculosis

Phase(s):
2

Sponsor Type:
Biotechnology company

Study Duration:
2008–2011

Population:
Pediatric

SANCTR Identifier:
DOH-27-0209-2655

FHI CLINICAL ROLE(S)

- Biosafety application
- Clinical monitoring
- IRB/EC support
- Project management
- Protocol writing
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase II double-blind, randomized, placebo-controlled, dose escalation study to evaluate the safety of AERAS-402 in adults recently treated for pulmonary tuberculosis

Phase(s):
2

Sponsor Type:
Biotechnology company

Study Duration:
2008–2011

Population:
Adult

ClinicalTrials.gov Identifier:
NCT02414828

FHI CLINICAL ROLE(S)

- Biosafety application
- Clinical monitoring
- IRB/EC support
- Project management
- Protocol writing
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase II study evaluating the safety and immunogenicity of a new TB vaccine, MVA85A, in healthy children and infants after BCG vaccination at birth

Phase(s):
1

Sponsor Type:
Academic institution

Study Duration:
2008–2010

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT00679159

FHI CLINICAL ROLE(S)

- Biosafety application
- Clinical monitoring
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase I randomized placebo-controlled, double-blind study to evaluate safety and immunogenicity of AERAS 404 when administered as a single adjuvant amount with different antigen amounts in HIV-negative BCG-vaccinated adults without evidence of tuberculosis infection

Phase(s):
1

Sponsor Type:
Biotechnology company

Study Duration:
2008–2010

Population:
Adult

ClinicalTrials.gov Identifier:
NCT02109874

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Project management
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

KENYA

STUDY TITLE

A phase I randomized placebo-controlled double-blind study to evaluate safety and immunogenicity of AERAS-402 administered in HIV-negative, BCG-vaccinated, QuantiFERON®-TB Gold (+) and QuantiFERON®-TB Gold (-) adults without evidence of tuberculosis

Phase(s):
1

Sponsor Type:
Biotechnology company

Study Duration:
2008–2009

Population:
Adult

ClinicalTrials.gov Identifier:
NCT02430506

FHI CLINICAL ROLE(S)

- Clinical monitoring

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

KENYA

SOUTH AFRICA

STUDY TITLE

Epidemiological study of tuberculosis in infants

Study Type:
Epidemiological

Sponsor Type:
Biotechnology company

Study Duration:
2008

Population:
Pediatric

FHI CLINICAL ROLE(S)

- Site audits

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

KENYA

SOUTH AFRICA

TANZANIA

ZAMBIA

STUDY TITLE

A randomised placebo - controlled double blind trial comparing 1) a two month intensive phase of ethambutol, moxifloxacin, rifampicin, pyrazinamide versus the standard regimen (ethambutol, isoniazid, rifampicin, pyrazinamide) and 2) a treatment shortening regimen comparing two months moxifloxacin, isoniazid, rifampicin, pyrazinamide followed by two months moxifloxacin, isoniazid, rifampicin versus the standard regimen (two months ethambutol, isoniazid, rifampicin, pyrazinamide followed by four months isoniazid and rifampicin) for the treatment of adults with pulmonary tuberculosis

Phase(s):

3

Sponsor Type:

Public-private partnership

Study Duration:

2007–2014

Population:

Adult

ClinicalTrials.gov Identifier:

NCT00864383

FHI CLINICAL ROLE(S)

- IRB/EC support
- Lab monitoring
- Project management
- Regulatory support
- Site audits
- Site monitoring

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase I study evaluating the safety and immunogenicity of a new TB vaccine, MVA85A, in asymptomatic volunteers who are infected with either *Mycobacterium tuberculosis* (M.tb.), human immunodeficiency virus (HIV) or both

Phase(s):
1

Sponsor Type:
Academic institution

Study Duration:
2007–2011

Population:
Adult

ClinicalTrials.gov Identifier:
NCT00480558

FHI CLINICAL ROLE(S)

- Biosafety application
- Project management

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

BOTSWANA
CAMEROON
KENYA
LESOTHO
MALAWI
NIGERIA
SOUTH AFRICA
TANZANIA

STUDY TITLE

Site assessments for a drug for multi-drug resistant (MDR) tuberculosis

Sponsor Type:
Public-private partnership

Study Duration:
2007–2008

FHI CLINICAL ROLE(S)

- Site assessments

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Study of AERAS-402 in healthy *Mycobacterium tuberculosis*–uninfected BCG-vaccinated adults from a tuberculosis-endemic region of South Africa

Phase(s):
2

Sponsor Type:
Biotechnology company

Study Duration:
2007–2008

Population:
Adult

FHI CLINICAL ROLE(S)

- Biosafety application
- Clinical monitoring
- Project managementt
- Protocol writing
- Regulatory support
- Site audits

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase I study evaluating the safety and immunogenicity of a new TB vaccine MVA85A, in healthy volunteers with no evidence of infection with *Mycobacterium tuberculosis*, in Cape Town

Phase(s):
1

Sponsor Type:
Academic institution

Study Duration:
2005–2008

Population:
Pediatric and adult

ClinicalTrials.gov Identifier:
NCT00460590

FHI CLINICAL ROLE(S)

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

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase 1 study of the rBCG30 tuberculosis vaccine in children

Phase(s):
1

Sponsor Type:
Biotechnology company

Study Duration:
2004–2005

Population:
Pediatric

FHI CLINICAL ROLE(S)

- Biosafety application
- Regulatory support

COMPLETED TUBERCULOSIS STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Randomized, controlled trial comparing efficacy of percutaneous and intradermal vaccination with Japanese (Tokyo) 172 BCG in the prevention of tuberculosis in infants vaccinated at birth

Phase(s):
4

Sponsor Type:
Public-private partnership

Study Duration:
2001–2003

Population:
Pediatric

ClinicalTrials.gov Identifier:
NCT00242047

FHI CLINICAL ROLE(S)

- Site audits

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