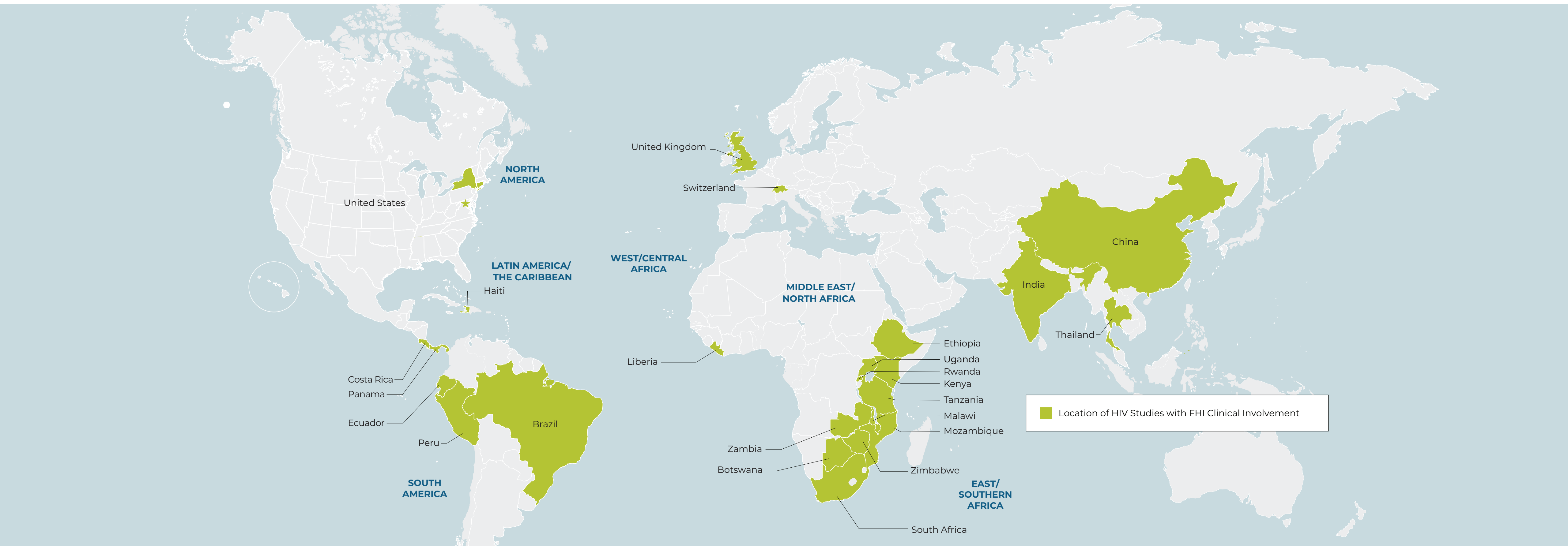




# OUR EXPERIENCE WITH HIV

The FHI Clinical project team has partnered with companies to conduct clinical trials as well as behavioral and observational studies for HIV in 24 countries worldwide.



# IMPACT OF HIV

**More than 40 million deaths worldwide**, including 650,000 deaths in 2021, resulted from HIV-related causes. Globally, 1.5 million people were newly infected with HIV in 2021, contributing to the total estimate of 38.4 million people living with HIV. The World Health Organization (WHO) African Region is affected the most, accounting for more than 2/3 (25.6 million) of the HIV infections globally.

## HIV STUDIES WITH FHI CLINICAL INVOLVEMENT

GO TO CURRENT STUDIES	<b>03</b>
GO TO COMPLETED STUDIES	<b>09</b>

# CHALLENGES FOR HIV RESEARCH

- **Hard-to-reach populations geographically and due to disease-related stigmatization**
- **Locations with limited research capacity**
- **Poor surveillance systems**
- **Migrant populations**
- **Only an estimated 79% of people with HIV are aware of their HIV status**

Source: <https://www.who.int/data/gho/data/themes/hiv-aids>



# **CURRENT**

**HIV STUDIES WITH FHI CLINICAL INVOLVEMENT**



# CURRENT HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

A phase I dose-escalation study of the safety, tolerability and pharmacokinetics of a human monoclonal antibody, CAP256V2LS (VRC-HIVMAB0102-00-AB) administered intravenously to HIV-negative and HIV-positive women or subcutaneously alone and in combination with VRC07- 523LS and /or PGT121 to HIV-negative women in South Africa

### Phase(s):

1

### Sponsor Type:

Non-governmental organization

### Duration:

2020–ongoing

### Population:

Pediatric and adult

### PACTR Identifier:

PACTR202003767867253

## FHI CLINICAL ROLE(S)

- Clinical monitoring
- Project management

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# CURRENT HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



LIBERIA

## STUDY TITLE

PREVAIL VIII: a cohort clinical, viral, and immunologic monitoring study of people living with retroviral infection in Liberia (HONOR)

### Study Type:

Observational

### Sponsor Type:

Public-private partnership

### Duration:

2020–ongoing

### Population:

Pediatric and adult

### ClinicalTrials.gov Identifier:

NCT03733093

## FHI CLINICAL ROLE(S)

- Technical assistance
- Training

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# CURRENT HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

STUDY TITLE		FHI CLINICAL ROLE(S)
Phase 2 placebo-controlled randomized trial of LACTIN-V (lactobacillus crispatus CTV-05) among women at high risk of HIV acquisition in Durban, South Africa	<b>Phase(s):</b> 2	<ul style="list-style-type: none"><li>• Clinical monitoring</li><li>• Project managmentt</li></ul>
	<b>Sponsor Type:</b> Pharmaceutical company	
	<b>Duration:</b> 2020–ongoing	
	<b>Population:</b> Adult	
	<b>ClinicalTrials.gov Identifier:</b> NCT05022212	

# CURRENT HIV 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:

Governmental organization

### Duration:

2020–ongoing

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT03435146

## FHI CLINICAL ROLE(S)

- Clinical monitoring
- Project management

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# CURRENT HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

STUDY TITLE		FHI CLINICAL ROLE(S)
Phase I, proof of concept, open-label, randomized clinical trial to evaluate the safety and effects of using prime-boost HIVIS DNA and MVA-CMDR vaccine regimens with or without toll-like receptor 4 agonist on HIV reservoirs in perinatally HIV infected children and youth		<ul style="list-style-type: none"><li>• Regulatory services</li><li>• Site management</li></ul>
<b>Phase(s):</b> 1		
<b>Sponsor Type:</b> Governmental organization		
<b>Duration:</b> 2020–ongoing		
<b>Population:</b> Adult and pediatric		
<b>ClinicalTrials.gov Identifier:</b> NCT04301154		



**COMPLETED**

**HIV STUDIES WITH FHI CLINICAL INVOLVEMENT**

# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

Regulatory and safety support for various CRSS studies

**Sponsor Type:**  
Governmental organization

**Duration:**  
2021–2022

## FHI CLINICAL ROLE(S)

- Pharmacovigilance
- Regulatory support

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

STUDY TITLE		FHI CLINICAL ROLE(S)
Phase 1 proof of concept open label randomized clinical trial to evaluate the safety and effects of using prime boost HIVIS DNA and MVA CMDR vaccine regimens with or without toll like receptor 4 agonist on HIV reservoirs in perinatally HIV infected children and youth	<p><b>Phase(s):</b> 1</p> <p><b>Sponsor Type:</b> Governmental organization</p> <p><b>Duration:</b> 2021–2022</p> <p><b>Population:</b> Pediatric</p> <p><b>SANCTR Identifier:</b> DOH-27-0720-6367</p>	<ul style="list-style-type: none"><li>• Pharmacovigilance</li><li>• Regulatory support</li></ul>

# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT

 KENYA UGANDA	STUDY TITLE		FHI CLINICAL ROLE(S)
	Audits of an HIV trial in Kenya and Uganda	<b>Sponsor Type:</b> Governmental organization  <b>Duration:</b> 2020	• Quality audits
 KENYA	STUDY TITLE		FHI CLINICAL ROLE(S)
	Audit of an HIV trial in Kenya	<b>Sponsor Type:</b> Public-private partnership  <b>Duration:</b> 2020	• Quality audits

# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

A phase I/II trial to assess the safety, acceptability, tolerability and pharmacokinetics of a sustained-release tenofovir alafenamide sub-dermal implant for HIV prevention in women

### Phase(s):

1/2

### Sponsor Type:

Public-private partnership

### Duration:

2019–2022

### Population:

Pediatric and adult

### PACTR Identifier:

PACTR201809520959443

## FHI CLINICAL ROLE(S)

- Clinical monitoring
- Project management

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA




STUDY TITLE		FHI CLINICAL ROLE(S)
Study of MDR TB cases and their household contacts: operational feasibility to inform PHOENix trial design		• Regulatory support
<b>Study Type:</b> Feasibility		
<b>Sponsor Type:</b> Governmental organization		
<b>Duration:</b> 2019–2020		
<b>Population:</b> Pediatric		
<b>SANCTR Identifier:</b> DOH-27-0116-5144		

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT

 SOUTH AFRICA	STUDY TITLE		FHI CLINICAL ROLE(S)
	Audit of an HIV trial in South Africa	<b>Sponsor Type:</b> Governmental organization  <b>Duration:</b> 2019–2020	<ul style="list-style-type: none"><li>• Quality assurance oversight</li></ul>
 SOUTH AFRICA	STUDY TITLE		FHI CLINICAL ROLE(S)
	Development of materials for training workshops to conduct HIV vaccine trials	<b>Sponsor Type:</b> Governmental organization  <b>Duration:</b> 2019	<ul style="list-style-type: none"><li>• Development of training materials</li></ul>
 UNITED STATES	STUDY TITLE		FHI CLINICAL ROLE(S)
	Audit of an HIV trial in the United States	<b>Sponsor Type:</b> Public-private partnership  <b>Duration:</b> 2018	<ul style="list-style-type: none"><li>• Quality audits</li></ul>

# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



MALAWI  
SOUTH AFRICA  
UGANDA  
ZAMBIA

## STUDY TITLE

A phase 3B open-label follow-on trial to assess the continued safety of and adherence to a vaginal ring containing dapivirine in women

### Phase(s):

3

### Sponsor Type:

Governmental organization

### Duration:

2018

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT02858037

## FHI CLINICAL ROLE(S)

- Supplementary review of ICFs

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

A long-term observational cohort study of HIV infection in participants who seroconvert after enrolment in dapivirine vaginal ring trials

### Study Type:

Observational

### Sponsor Type:

Public-private partnership

### Duration:

2018

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT01618058

## FHI CLINICAL ROLE(S)

- Project management of study close-out activities

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

STUDY TITLE		FHI CLINICAL ROLE(S)
A study to assess the efficacy of a heterologous prime/boost vaccine regimen of Ad26.Mos4.HIV and aluminum phosphate-adjuvanted clade C gp140 in preventing human immunodeficiency virus (HIV)-1 infection in women in sub-Saharan Africa		• Laboratory support
<b>Phase(s):</b> 2		
<b>Sponsor Type:</b> Non-governmental organization		
<b>Duration:</b> 2017–2021		
<b>Population:</b> Adult		
<b>ClinicalTrials.gov Identifier:</b> NCT03060629		

# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



KENYA  
UGANDA  
UNITED STATES  
ZAMBIA

## STUDY TITLE

Audit of an HIV trial in Kenya, Uganda, the United States and Zambia

### Phase(s):

1

### Sponsor Type:

Public-private partnership

### Duration:

2017

### Population:

Adult

## FHI CLINICAL ROLE(S)

- Quality audits



PERU  
SOUTH AFRICA  
UGANDA

## STUDY TITLE

Audit of an HIV trial in Peru, South Africa and Uganda

### Phase(s):

2/3

### Sponsor Type:

Governmental organization

### Duration:

2017

## FHI CLINICAL ROLE(S)

- Quality audits

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

STUDY TITLE		FHI CLINICAL ROLE(S)
Support of multiple HIV trials in South Africa		<ul style="list-style-type: none"><li>• Biostatistics</li><li>• IRB/EC support</li><li>• Regulatory support</li><li>• Safety monitoring</li></ul>
<p><b>Phase(s):</b> 2/3</p> <p><b>Sponsor Type:</b> Governmental organization</p> <p><b>Duration:</b> 2017</p>		

# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



ETHIOPIA

## STUDY TITLE

Observational study of the outcomes of HIV and tuberculosis co-infection

### Study Type:

Observational

### Sponsor Type:

Governmental organization

### Duration:

2016–2017

## FHI CLINICAL ROLE(S)

- Quality assurance

CURRENT STUDIES ▶

COMPLETED STUDIES ▶




# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



UNITED STATES

STUDY TITLE		FHI CLINICAL ROLE(S)
A phase 1 clinical trial of the safety and immunogenicity of an oral, replicating adenovirus 26 vector vaccine for HIV-1 (rcAd26.MOS1.HIV-Env) in healthy HIV-1-uninfected adults		• Quality audits
<b>Phase(s):</b> 1		
<b>Sponsor Type:</b> Public-private partnership		
<b>Duration:</b> 2016		
<b>Population:</b> Adult		
<b>ClinicalTrials.gov Identifier:</b> NCT02366013		

# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT

 KENYA UNITED KINGDOM	STUDY TITLE		FHI CLINICAL ROLE(S)
	Audit of an HIV vaccine trial in Kenya and the United Kingdom	<b>Phase(s):</b> 1 <b>Sponsor Type:</b> Public-private partnership <b>Duration:</b> 2016	• Quality audits
 UGANDA	STUDY TITLE		FHI CLINICAL ROLE(S)
	Audit of an HIV trial in Uganda	<b>Study Type:</b> Observational <b>Sponsor Type:</b> Public-private partnership <b>Duration:</b> 2016	• Quality audits

# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



- MALAWI
- MOZAMBIQUE
- SOUTH AFRICA
- ZAMBIA
- ZIMBABWE

STUDY TITLE		FHI CLINICAL ROLE(S)
A multicenter, randomized, double-blind, placebo-controlled phase 2b efficacy study of a heterologous prime/boost vaccine regimen of Ad26.Mos4.HIV and aluminum phosphate-adjuvanted clade C gp140 in preventing HIV-1 infection in adult women in sub-Saharan Africa		<ul style="list-style-type: none"><li>• IRB/EC support</li><li>• Regulatory support</li></ul>
<b>Phase(s):</b> 2		
<b>Sponsor Type:</b> Pharmaceutical company		
<b>Duration:</b> 2016		
<b>Population:</b> Adult		
<b>ClinicalTrials.gov Identifier:</b> NCT03060629		

# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

WRHI 060 (ADVANCE): a randomised, phase 3 non-inferiority study of DTG + TAF + FTC compared with DTG + TDF + FTC and EFV + TDF + FTC in patients infected with HIV-1 starting first-line antiretroviral therapy - extension to 192 weeks

### Phase(s):

3

### Sponsor Type:

Academic institution

### Duration:

2016

### Population:

Pediatric and adult

### ClinicalTrials.gov Identifier:

NCT03122262

## FHI CLINICAL ROLE(S)

- Biostatistics
- Clinical monitoring
- Data management
- Medical writing
- Pharmacovigilance

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



ZAMBIA

## STUDY TITLE

ART readiness in HIV-infected pregnant women: from formative qualitative research to individual randomized trial

### Study Type:

Observational

### Sponsor Type:

Governmental organization

### Duration:

2015–2018

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT02459678

## FHI CLINICAL ROLE(S)

- Project management
- Quality assurance
- Site monitoring

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



KENYA

## STUDY TITLE

Support of an HIV preventive treatment trial in Kenya

### Phase(s):

2

### Sponsor Type:

Governmental organization

### Duration:

2015–2016

## FHI CLINICAL ROLE(S)

- Clinical monitoring

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

CHAMPS: Choices For Adolescent Prevention Methods For South Africa. Pilot study B: 'PlusPills' a demonstration open label study to assess the acceptability and use of Truvada pre-exposure prophylaxis in healthy, HIV-uninfected adolescents, 15-19 years of age

### Phase(s):

2

### Sponsor Type:

Governmental organization

### Duration:

2015–2016

### Population:

Pediatric and adult

### ClinicalTrials.gov Identifier:

NCT02213328

## FHI CLINICAL ROLE(S)

- Clinical monitoring
- Project management

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

A phase IIa study to evaluate the safety, tolerability and pharmacokinetics of the investigational injectable HIV integrase inhibitor, GSK1265744, in HIV-uninfected men and women

### Phase(s):

2

### Sponsor Type:

Governmental organization

### Duration:

2015–2016

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT02178800

## FHI CLINICAL ROLE(S)

- Regulatory support

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



KENYA  
RWANDA  
UGANDA

## STUDY TITLE

Audit of an HIV vaccine trial in Kenya, Rwanda and Uganda

### Phase(s):

1

### Sponsor Type:

Public-private partnership

### Duration:

2015

## FHI CLINICAL ROLE(S)

- Quality audits



SOUTH AFRICA  
UNITED STATES

## STUDY TITLE

Audit of an HIV vaccine trial in South Africa and the United States

### Sponsor Type:

Public-private partnership

### Duration:

2015

## FHI CLINICAL ROLE(S)

- Quality audits

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

STUDY TITLE		FHI CLINICAL ROLE(S)
Observational ARV treatment in neonates		• Clinical monitoring
<p><b>Phase(s):</b> 4</p> <p><b>Sponsor Type:</b> Academic institution</p> <p><b>Duration:</b> 2015</p> <p><b>Population:</b> Pediatric</p>		

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

Phase II trial to assess the safety and acceptability of the long-acting injectable HIV integrase inhibitor, cabotegravir (GSK1265744), in HIV uninfected women in KwaZulu-Natal, South Africa

**Phase(s):**

2

**Sponsor Type:**

Non-governmental organization

**Duration:**

2015

**Population:**

Adult

**ClinicalTrials.gov Identifier:**

NCT02462772

## FHI CLINICAL ROLE(S)

- Regulatory support

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



COSTA RICA  
PANAMA  
PERU  
SOUTH AFRICA  
UGANDA

## STUDY TITLE

Audit of an HIV vaccine trial in Costa Rica, Panama, Peru, South Africa and Uganda

**Sponsor Type:**  
Governmental organization

**Duration:**  
2014–2017

## FHI CLINICAL ROLE(S)

- Quality audits



## STUDY TITLE

Statistical support for an HIV gel study

**Duration:**  
2014

## FHI CLINICAL ROLE(S)

- Biostatistics
- DSMB

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



ZAMBIA

## STUDY TITLE

Audit of an epidemiological study of HIV in Zambia

### Study Type:

Epidemiological

### Sponsor Type:

Public-private partnership

### Duration:

2014

## FHI CLINICAL ROLE(S)

- Quality audits

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



UNITED KINGDOM

## STUDY TITLE

Safety and immunogenicity study of rAAV1-PG9DP recombinant AAV vector coding for PG9 antibody in healthy male adults

### Phase(s):

1

### Sponsor Type:

Public-private partnership

### Duration:

2014

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT01937455

## FHI CLINICAL ROLE(S)

- Quality audits

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



KENYA  
RWANDA  
UGANDA  
UNITED KINGDOM

## STUDY TITLE

A phase I double-blind, randomized, placebo-controlled, dose-escalation trial to evaluate the safety and immunogenicity of a Sendai HIV vaccine SeV-G(NP) given intranasally and Ad35-GRIN administered intramuscularly in prime-boost regimens in HIV-uninfected, healthy adult volunteers

### Phase(s):

1

### Sponsor Type:

Public-private partnership

### Duration:

2013-2014

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT01705990

## FHI CLINICAL ROLE(S)

- Quality audits

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

A phase 1/2a trial to evaluate the safety/tolerability and immunogenicity of homologous Ad26 mosaic vector regimens or Ad26 mosaic and MVA mosaic heterologous vector regimens, with high-dose, low-dose or no clade C gp140 protein plus adjuvant for HIV prevention

### Study Type:

Adult

### Phase(s):

1/2

### Sponsor Type:

Biopharmaceutical company

### Duration:

2013–2014

### Population:

Adult and pediatric

### ClinicalTrials.gov Identifier:

NCT02315703

## FHI CLINICAL ROLE(S)

- Biosafety application

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

STUDY TITLE		FHI CLINICAL ROLE(S)
Support of multiple HIV vaccine studies		<ul style="list-style-type: none"><li>• Biosafety application</li><li>• IRB/EC support</li><li>• Regulatory support</li><li>• Safety monitoring</li></ul>

**Sponsor Type:**  
Governmental organization

**Duration:**  
2012–2017

# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

A phase III, multi-centre, randomized controlled trial to assess the safety and effectiveness of the vaginal microbicide 1% tenofovir gel in the prevention of human immunodeficiency virus type 1 infection in women, and to examine effects of the microbicide on the incidence of herpes simplex virus type 2 infection

### Phase(s):

3

### Sponsor Type:

Non-governmental organization

### Duration:

2012–2015

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT01386294

## FHI CLINICAL ROLE(S)

- Clinical monitoring
- Site assessments
- Quality audits

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

Observational study of HIV and tuberculosis co-infection

### Study Type:

Observational

### Sponsor Type:

Governmental organization

### Duration:

2012–2014

## FHI CLINICAL ROLE(S)

- Site monitoring

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



- BOTSWANA
- BRAZIL
- CHINA
- ECUADOR
- HAITI
- INDIA
- KENYA
- MALAWI
- MOZAMBIQUE
- PERU
- SOUTH AFRICA
- SWITZERLAND
- TANZANIA
- THAILAND
- UGANDA
- UNITED STATES
- ZAMBIA
- ZIMBABWE

STUDY TITLE		FHI CLINICAL ROLE(S)
HIV CRSS site support	<p><b>Sponsor Type:</b> Governmental organization</p> <p><b>Duration:</b> 2011–2017</p>	<ul style="list-style-type: none"><li>• Site management</li></ul>

# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



KENYA  
UGANDA

## STUDY TITLE

A phase I double-blinded, placebo-controlled, randomized trial in HIV-uninfected, healthy adult volunteers to evaluate the safety and immunogenicity of an adjuvanted GSK HIV vaccine administered with Ad35-GRIN investigational vaccine

### Phase(s):

1

### Sponsor Type:

Public-private partnership

### Study Duration:

2011

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT01264445

## FHI CLINICAL ROLE(S)

- Quality audits

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

A phase II, randomized, double-blind, placebo-controlled trial to evaluate the immunogenicity and safety of a therapeutic, recombinant, biologically active HIV-1 tat protein vaccine in HIV-infected, anti-tat negative, ARV-treated adult volunteers

**Phase(s):**

2

**Sponsor Type:**

Academic institution

**Duration:**

2010–2014

**Population:**

Adult

**ClinicalTrials.gov Identifier:**

NCT01513135

## FHI CLINICAL ROLE(S)

- |                         |                      |
|-------------------------|----------------------|
| • Biosafety application | • Medical writing    |
| • Biostatistics         | • Pharmacovigilance  |
| • Clinical monitoring   | • Project management |
| • Data management       | • Protocol writing   |
| • IRB/EC support        | • Quality audits     |
| • Medical monitoring    | • Regulatory support |

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



KENYA  
SOUTH AFRICA  
UGANDA

## STUDY TITLE

A phase 1 placebo-controlled, double-blind, randomized trial to evaluate the safety and immunogenicity of Ad26-ENVA and Ad35-ENV HIV vaccines in healthy HIV-uninfected adult volunteers

### Phase(s):

1

### Sponsor Type:

Public-private partnership

### Duration:

2010–2017

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT01215149

## FHI CLINICAL ROLE(S)

- Biosafety application
- Quality audits
- Regulatory support

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



- BOTSWANA
- CHINA
- KENYA
- MALAWI
- SOUTH AFRICA
- THAILAND
- UGANDA
- ZIMBABWE

STUDY TITLE		FHI CLINICAL ROLE(S)
Site audits for an HIV trial		• Site audits
<div><div>Sponsor Type:</div><div>Contract research organization</div><div>Duration:</div><div>2010–2012</div></div>		

# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

Phase IIb trial to assess the safety and effectiveness of the vaginal microbicide 1% tenofovir gel for the prevention of HIV infection in women in South Africa

### Phase(s):

2

### Sponsor Type:

Governmental organization

### Duration:

2009–2016

### Population:

Adult

### ClinicalTrials.gov Identifier

NCT00441298

## FHI CLINICAL ROLE(S)

- Data management
- Protocol development
- Site monitoring
- Training

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

A multicentre, observational, cross-sectional study to assess the seroprevalence of anti-tat antibodies in HIV-infected patients in selected areas of Gauteng and Eastern Cape

### Study Type:

Epidemiological

### Sponsor Type:

Academic institution

### Duration:

2009–2013

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT01359800

## FHI CLINICAL ROLE(S)

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

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



THAILAND

## STUDY TITLE

Study of the safety and efficacy of daily tenofovir to prevent HIV infection among injection drug users in Bangkok, Thailand

### Phase(s):

2/3

### Sponsor Type:

Governmental organization

### Duration:

2009–2012

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT00119106

## FHI CLINICAL ROLE(S)

- Site monitoring

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

STUDY TITLE		FHI CLINICAL ROLE(S)
Phase 1 study of the GTU-MultiHIV vaccine		<ul style="list-style-type: none"><li>• IRB/EC support</li><li>• Project management</li><li>• Regulatory support</li><li>• Site monitoring</li></ul>
<p><b>Phase(s):</b> 1</p> <p><b>Sponsor Type:</b> Biotechnology company</p> <p><b>Duration:</b> 2007–2009</p> <p><b>Population:</b> Adult</p>		

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

A phase I/IIa, double-blind, randomised, placebo-controlled, parallel group study to determine the safety, tolerability and immunogenicity of an HIV-1 immunotherapeutic vaccine expressing clade B antigens Gag and Pol (VIR201) in HIV-1-positive participants

### Phase(s):

2

### Sponsor Type:

Biotechnology company

### Duration:

2007–2008

### Population:

Adult

### SANCTR Identifier:

DOH-27-0908-2599

## FHI CLINICAL ROLE(S)

- Biosafety application

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



KENYA  
RWANDA  
TANZANIA  
UGANDA  
ZAMBIA

STUDY TITLE		FHI CLINICAL ROLE(S)
A phase II, randomized, placebo-controlled, double-blind trial to evaluate the safety and immunogenicity of a multiclade HIV-1 DNA plasmid vaccine followed by recombinant, multiclade HIV-1 adenoviral vector vaccine in healthy adult volunteers at risk for HIV infection		<ul style="list-style-type: none"><li>• Clinical monitoring</li><li>• Project management</li></ul>
<b>Phase(s):</b> 2		
<b>Sponsor Type:</b> Public-private partnership		
<b>Duration:</b> 2007–2008		
<b>Population:</b> Adult		
<b>ClinicalTrials.gov Identifier:</b> NCT00415649		

# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

A study to assess the pharmacokinetics of dapivirine (TMC120) vaginal microbicide gel in healthy HIV-negative women

### Phase(s):

1

### Sponsor Type:

Public-private partnership

### Duration:

2006–2007

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT00304642

## FHI CLINICAL ROLE(S)

- Project management
- Regulatory support
- Site monitoring

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



KENYA  
RWANDA

## STUDY TITLE

A phase I, randomized, placebo-controlled, double-blind trial to evaluate the safety and immunogenicity of a multiclade HIV-1 DNA plasmid vaccine followed by recombinant, multiclade HIV-1 adenoviral vector vaccine or the multiclade HIV-1 adenoviral vector vaccine alone in healthy adult volunteers not infected with HIV

### Phase(s):

1

### Sponsor Type:

Public-private partnership

### Duration:

2006–2007

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT00124007

## FHI CLINICAL ROLE(S)

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

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

Bioequivalence study of lamivudine and zidovudine for HIV prevention

### Study Type:

Bioequivalence

### Sponsor Type:

Pharmaceutical company

### Duration:

2006

## FHI CLINICAL ROLE(S)

- Regulatory support

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

HVTN Protocol 204 - a phase II clinical trial to evaluate the safety and immunogenicity of a multiclade HIV-1 DNA plasmid vaccine, VRC-HIVDNA016-00-VP, followed by a multiclade recombinant adenoviral vector HIV-1 vaccine boost, VRCHIVADV014-00-VP, in HIV-1 uninfected adult participants

### Phase(s):

2

### Sponsor Type:

Governmental organization

### Duration:

2005–2007

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT00125970

## FHI CLINICAL ROLE(S)

- Biosafety application

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

## STUDY TITLE

A double-blind, randomized, placebo-controlled phase I/II study to evaluate the safety and acceptability of dapivirine gel 4789, 0.05%, 2.5g, a vaginal microbicide, conducted using daily monitored adherence in healthy, HIV-negative women

### Phase(s):

1/2

### Sponsor Type:

Public-private partnership

### Duration:

2005–2006

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT00917904

## FHI CLINICAL ROLE(S)

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

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



RWANDA  
SOUTH AFRICA  
TANZANIA

## STUDY TITLE

A phase I/II double-blind, randomized study of the safety, tolerability and systemic absorption of TMC120 vaginal microbicide gel and matching placebo in healthy HIV-negative women

### Phase(s):

2

### Sponsor Type:

Public-private partnership

### Duration:

2005–2006

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT00303576

## FHI CLINICAL ROLE(S)

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

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

STUDY TITLE		FHI CLINICAL ROLE(S)
<p>A single dose, laboratory-blind, randomised two-part cross-over study to determine bioequivalence of a generic lamivudine and zidovudine (150mg/300mg) fixed-dose combination tablet with respect to Combivir 150mg/300mg tablets in fasted healthy male volunteers (Phase I study)</p>		<ul style="list-style-type: none"><li>• Site audits</li></ul>

**Phase(s):**

1

**Sponsor Type:**

Pharmaceutical company

**Duration:**

2005–2006

**Population:**

Adult

**SANCTR Identifier:**

DOH-27-0608-1222

# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



KENYA  
UGANDA

## STUDY TITLE

Epidemiological study of HIV in Kenya and Uganda

### Study Type:

Epidemiology

### Sponsor Type:

Public-private partnership

### Duration:

2005

## FHI CLINICAL ROLE(S)

- Site audits

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA  
UGANDA  
ZAMBIA

## STUDY TITLE

Phase II, placebo-controlled, double-blind, dose-escalation/dose-optimization trial to evaluate safety and immunogenicity of tgAAC09, an HIV vaccine containing clade C Gag-PR-ΔRT DNA in an adeno-associated virus (AAV) capsid

### Phase(s):

2

### Sponsor Type:

Public-private partnership

### Duration:

2004–2006

### Population:

Adult

### ClinicalTrials.gov Identifier:

NCT00888446

## FHI CLINICAL ROLE(S)

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

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

STUDY TITLE		FHI CLINICAL ROLE(S)
Site audits during a trial of the HVX-01 device		• Site audits
<b>Phase(s):</b> 1		
<b>Sponsor Type:</b> Biotechnology company		
<b>Duration:</b> 2004		
<b>Population:</b> Adult		

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



SOUTH AFRICA

STUDY TITLE		FHI CLINICAL ROLE(S)
Phase 1 study of the MVA.HIVA vaccine in South Africa	<p><b>Phase(s):</b> 1</p> <p><b>Sponsor Type:</b> Public-private partnership</p> <p><b>Duration:</b> 2003–2005</p> <p><b>Population:</b> Adult</p>	<ul style="list-style-type: none"><li>• Biosafety application</li><li>• Clinical monitoring</li><li>• IRB/EC support</li><li>• Project management</li><li>• Protocol writing</li><li>• Regulatory support</li><li>• Site audits</li></ul>

CURRENT STUDIES ▶

COMPLETED STUDIES ▶



# COMPLETED HIV STUDIES WITH FHI CLINICAL INVOLVEMENT



UGANDA

## STUDY TITLE

A phase I double-blind, randomized, placebo-controlled study to test the safety and immunogenicity of a clade A HIV-DNA/MVA prime-boost combination, in HIV-uninfected healthy volunteers at low risk for HIV infection

### Phase(s):

1

### Sponsor Type:

Public-private partnership

### Duration:

2002–2004

### Population:

Adult

## FHI CLINICAL ROLE(S)

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



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CURRENT STUDIES ▶

COMPLETED STUDIES ▶

