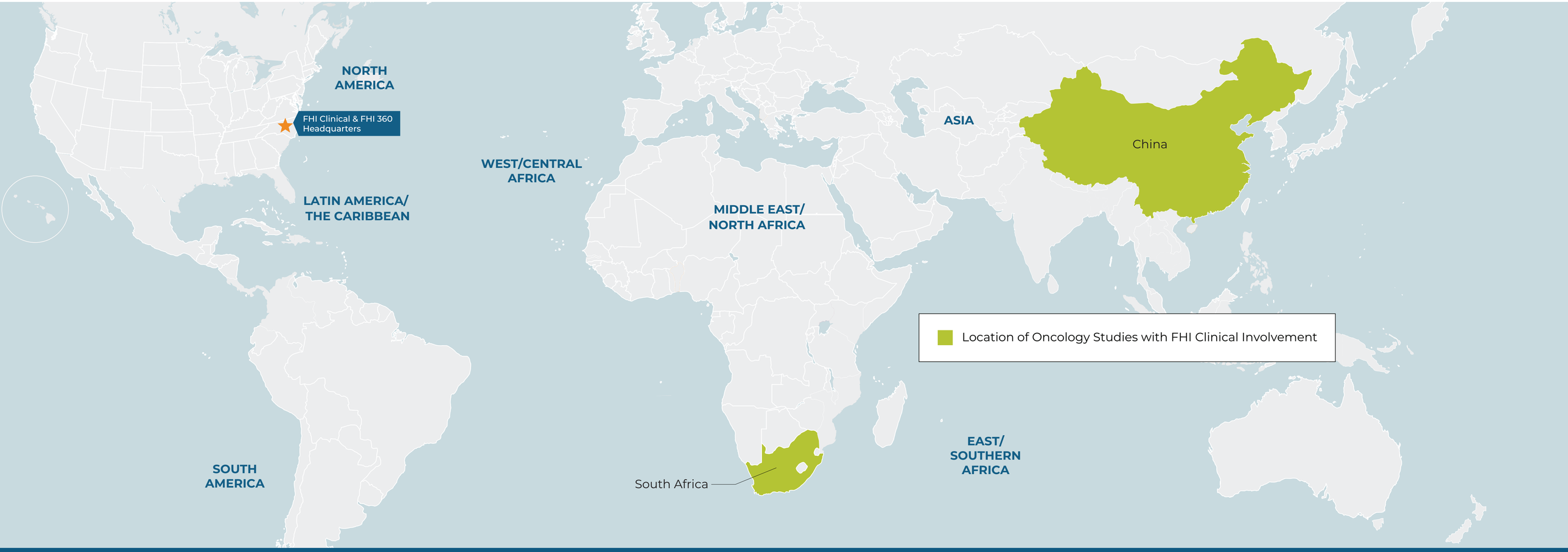
FHI CLINICAL
Mission-driven clinical research

OUR EXPERIENCE WITH ONCOLOGY

For nearly 20 years, the FHI Clinical project team has partnered with organizations developing and deploying vaccines, treatments and diagnostic tests for multiple oncology indications.



IMPACT OF ONCOLOGY

Cancer accounts for nearly one in six deaths globally, making it a leading cause of mortality. Breast, lung, colon and prostate cancers are the most common cancers, the majority of which are attributable to lifestyle-related causes such as tobacco use, high BMI, alcohol consumption, inadequate nutrient intake and lack of physical activity. However, in some areas, infections such as human papillomavirus (HPV) and hepatitis contribute to the cancer burden.

ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT	
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CHALLENGES FOR ONCOLOGY RESEARCH

- **Early detection**
- **Multifactorial etiologies**
- **Identification of biomarkers to facilitate treatment success**
- **Sufficient sample sizes given increasing stratification for precision medicine**
- **Increasing use of adaptive protocols**

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

CURRENT

ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

CURRENT ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Efficacy of personalised irradiation with rhenium-skin cancer therapy (SCT) for the treatment of non-melanoma skin cancer: a phase IV, multi-centre, international, open-label, single arm study

Phase(s):
4

Sponsor Type:
Medtech company

Study Duration:
2022–ongoing

Population:
Adult

Cancer type:
Non-melanoma skin cancer

ClinicalTrials.gov Identifier:
NCT05135052

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Clinical site management
- Project management
- Regulatory services
- Site training
- Study start-up

CURRENT ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

AcTION: a phase I study of [225Ac]Ac-PSMA-617 in men with PSMA-positive prostate cancer with or without prior [177Lu]Lu-PSMA-617 radioligand therapy

Phase(s):
1

Sponsor Type:
Pharmaceutical company

Study Duration:
2018–ongoing

Population:
Adult

Cancer type:
Prostate cancer

ClinicalTrials.gov Identifier:
NCT04597411

FHI CLINICAL ROLE(S)

- IRB support
- Lab audits
- Project management
- Regulatory support
- Site monitoring
- Vendor management

CURRENT ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

An open-label observational proof-of-concept study of microdose 195mPt-cisplatin as a means of predicting safety and tumour response outcomes in ovarian cancer patients exposed to cisplatin chemotherapy

Phase(s):
1/2

Sponsor Type:
Governmental organization

Study Duration:
2016–ongoing

Population:
Adult

Cancer type:
Ovarian cancer

FHI CLINICAL ROLE(S)

- Audits
- Biostatistics
- Clinical monitoring
- Data management
- IRB support
- Medical monitoring
- Medical writing
- Pharmacovigilance
- Project management

CURRENT ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

CHINA

STUDY TITLE

Aspirin for Dukes C and high risk Dukes B colorectal cancers (ASCOLT)

Read the case study at FHIClinical.com

Phase(s):
3

Sponsor Type:
Non-governmental organization

Study Duration:
2013–ongoing

Population:
Adult

Cancer type:
Colorectal cancer

ClinicalTrials.gov Identifier:
NCT00565708

FHI CLINICAL ROLE(S)

- Full-service CRO

COMPLETED

ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

COMPLETED ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A multicenter phase 3, open-label study of bosutinib versus imatinib in adult patients with newly diagnosed chronic phase chronic myelogenous leukemia

Phase(s):
3

Sponsor Type:
Pharmaceutical company

Study Duration:
2014

Population:
Adult

Cancer Type:
Chronic myeloid leukemia (CML)

ClinicalTrials.gov Identifier:
NCT02130557

FHI CLINICAL ROLE(S)

- Clinical monitoring
- IRB support
- Site assessments

COMPLETED ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Multicentre, randomised, controlled, open-label study comparing the efficacy and safety of doxorubicin Transdrug™ to best standard of care in patients with advanced hepatocellular carcinoma. ReLive study

Phase(s):
3

Sponsor Type:
Pharmaceutical company

Study Duration:
2014

Population:
Adult

Cancer Type:
Hepatocellular carcinoma

ClinicalTrials.gov Identifier:
NCT01655693

FHI CLINICAL ROLE(S)

- Site assessments

COMPLETED ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A randomized, multicenter, double-blind phase 3 study of PD-0332991 (oral CDK 4/6 inhibitor) plus letrozole versus placebo plus letrozole for the treatment of postmenopausal women with ER (+), HER2 (-) breast cancer who have not received any prior systemic anti cancer treatment for advanced disease

Phase(s):
3

Sponsor Type:
Pharmaceutical company

Study Duration:
2013

Population:
Adult

Cancer Type:
Breast cancer

ClinicalTrials.gov Identifier:
NCT01740427

FHI CLINICAL ROLE(S)

- Site assessments

COMPLETED ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A randomized phase 3 clinical trial to evaluate the efficacy and safety of treatment with OncoVEX^GM-CSF compared to subcutaneously administered GM-CSF in melanoma patients with unresectable stage IIIb, IIIc and IV disease

Phase(s):
3

Sponsor Type:
Biotechnology company

Study Duration:
2010–2014

Population:
Adult

Cancer Type:
Melanoma

ClinicalTrials.gov Identifier:
NCT00769704

FHI CLINICAL ROLE(S)

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

COMPLETED ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Phase 1 clinical trial of midostaurin in adult patients with AML or ASM and hepatic impairment

Phase(s):
1

Sponsor Type:
Pharmaceutical company

Study Duration:
2010–2012

Population:
Adult

Cancer Type:
Acute myeloid leukemia (AML), aggressive systemic mastocytosis (ASM)

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Project management

COMPLETED ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase I, multicenter, single-dose, randomized, open label, two-sequence, two-treatment, four-period, replicate crossover, comparative bioavailability study of capecitabine tablets 500 mg [Teva Pharma] and Xeloda® Tablets 500 mg [Roche Registration Limited], in colon cancer and/or metastatic colorectal cancer and/or locally advanced breast cancer and/or metastatic breast cancer patients receiving capecitabine as monotherapy or in combination with docetaxel under fed conditions

Phase(s):
1

Sponsor Type:
Pharmaceutical company

Study Duration:
2010–2011

Population:
Adult

Cancer Type:
Colorectal and/or breast cancer

FHI CLINICAL ROLE(S)

- Clinical monitoring
- Project management

COMPLETED ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A single center, single dose, open-label, randomized, two-period crossover study to assess the bioequivalence of an oral mercaptopurine suspension 100 mg / 5 mL versus an oral mercaptopurine tablet 50 mg (Purinethol®) in at least 62 healthy male subjects under fasting conditions

Study Type:
Bioequivalence

Sponsor Type:
Pharmaceutical company

Study Duration:
2009

Population:
Adult

Cancer Type:
Acute lymphocytic leukemia (ALL)

ClinicalTrials.gov Identifier:
NCT01697020

FHI CLINICAL ROLE(S)

- Clinical monitoring
- IRB support
- Project management
- Quality audit
- Regulatory support

COMPLETED ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Study comparing bevacizumab + temsirolimus vs. bevacizumab + interferon-alfa In advanced renal cell carcinoma subjects (INTORACT)

Phase(s):
3

Sponsor Type:
Pharmaceutical company

Study Duration:
2008–2012

Population:
Adult

Cancer Type:
Renal cell carcinoma

ClinicalTrials.gov Identifier:
NCT00631371

FHI CLINICAL ROLE(S)

- Clinical monitoring
- IRB support
- Regulatory support

COMPLETED ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Compare bosutinib to imatinib In subjects with newly diagnosed chronic phase Philadelphia chromosome positive CML

Phase(s):
3

Sponsor Type:
Pharmaceutical company

Study Duration:
2008–2011

Population:
Adult

Cancer Type:
CML

ClinicalTrials.gov Identifier:
NCT00574873

FHI CLINICAL ROLE(S)

- Clinical monitoring
- IRB support
- Regulatory support

COMPLETED ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

A phase 1/2 study of bosutinib (SKI-606) in Philadelphia chromosome positive leukemias

Phase(s):
2

Sponsor Type:
Pharmaceutical company

Study Duration:
2008–2011

Population:
Adult

Cancer Type:
Philadelphia chromosome-positive leukemias

ClinicalTrials.gov Identifier:
NCT00261846

FHI CLINICAL ROLE(S)

- Clinical monitoring
- IRB support
- Regulatory support

COMPLETED ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

An open-label, multi-centre, extension study evaluating the long-term safety and tolerability of degarelix one-month depots in patients with prostate cancer

Phase(s):
2/3

Sponsor Type:
Pharmaceutical company

Study Duration:
2005–2009

Population:
Adult

Cancer type:
Prostate cancer

ClinicalTrials.gov Identifier:
NCT00215683

FHI CLINICAL ROLE(S)

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

OUTCOMES

- Supported five sites, from site initiation visits to close-out visits

COMPLETED ONCOLOGY STUDIES WITH FHI CLINICAL INVOLVEMENT

SOUTH AFRICA

STUDY TITLE

Bioequivalence study of bicalutamide to treat prostate cancer

Study Type:
Bioequivalence

Sponsor Type:
Pharmaceutical company

Study Duration:
2005

Population:
Adult

Cancer type:
Prostate cancer

FHI CLINICAL ROLE(S)

- Regulatory support
- Site assessment

Global expertise, responsive approaches and proven solutions to manage complex clinical research in resource-limited settings around the world. To learn more, visit **fhiclinical.com** or email **info@fhiclinical.com**.