TB is one of the top 10 causes of death worldwide¹

Illness from TB affected:

- **10M** people
- **1M** children

TB resulted in death for:

- **1.3M** people
- **230K** children

>95% of TB deaths were in low- and middle-income countries.²

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**BACKGROUND**

**Study Duration:** 2013–ongoing

**FHI Clinical Funding:** U.S. National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases (NIAID)

**Therapeutic Area:** Infectious Diseases

**Indication:** Tuberculosis

**Initiative:** China TB Clinical Trials Consortium (CTCTC)

**Initiative Funding:** US NIH, NIAID, Government of China

Tuberculosis (TB) remains one of the top 10 causes of death worldwide, surpassing both HIV/AIDS and malaria, and it is the leading cause of death from a single infectious agent.¹ Because it poses a greater risk for immunocompromised individuals, TB is a leading killer of HIV-positive people.¹ Further, multidrug-resistant TB (MDR-TB), caused by bacteria that do not respond to the two most effective first-line anti-TB drugs, is considered a serious public health issue.

Although TB occurs worldwide, eight countries accounted for two-thirds of the new TB cases in 2017 (in descending order): India, China, Indonesia, the Philippines, Pakistan, Nigeria, Bangladesh, and South Africa. Similarly, low- and middle-income countries account for more than 95% of TB deaths, primarily in seven countries (in descending order): India, Indonesia, China, Philippines, Pakistan, Nigeria, and South Africa. And, almost half of the global drug-resistant cases occurred in three countries (in descending order): India, China, and the Russian Federation.

TB is both preventable and curable—between 2000 and 2017, an estimated 54 million lives were saved through TB diagnosis and treatment.² Yet, the global TB incidence is decreasing only 2% annually.³
**SOLUTION**

With its large population, extensive hospital network, high TB burden, and low HIV rate, China provides a unique patient pool for TB clinical studies—one that has not yet been fully utilized. In September 2013, Beijing Chest Hospital (BCH), which also serves as the Clinical Center of TB (CCTB), China Center for Disease Control (CDC), initiated the China TB Clinical Trials Consortium (CTCTC). It is a multi-site, national consortium dedicated to building research infrastructure for multinational TB clinical trial research collaboration in China—to develop novel anti-TB agents, new pre-exposure vaccines, and diagnostics.

We provided technical support and guidance to implement strategies for clinical trial capacity building. In addition, we have partnered with other organizations to participate in the CTCTC, including the University of North Carolina Institute for Global Health & Infectious Diseases.

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RESULTS

The CTCTC hospital network currently consists of 24 TB clinical and research institutions (22 certified by the National Medical Products Administration), funded by the Government of China. Since the CTCTC’s inception, it has established monitoring procedures to assure internationally recognized levels of TB laboratory research capacity, site staff training, and relationships with the international TB scientific and pharmaceutical communities. For junior investigators, the program has provided training, mentoring, and small grants for TB-related research projects.

THE CTCTC HOSPITAL NETWORK CURRENTLY CONSISTS OF 24 TB CLINICAL AND RESEARCH INSTITUTIONS IN CHINA.

Standardized Treatment Regimen of Anti-tuberculosis Drugs for Patients with MDR-TB (STREAM)

The STREAM project presented an opportunity to leverage the CTCTC in China for TB research:

- Multi-national trial of bedaquiline treatment for MDR-TB patients
- FHI Clinical project team awarded the preparatory work for China: implementation and site support—training, mentoring, and import/export logistics
- Four CTCTC hospitals were selected and trained
FHI 360, FHI Clinical’s parent company, has also been involved in the following TB studies in China:

**International Maternal Pediatric Adolescent AIDS Clinical Trial (IMPAACT) Network**

- **P1108:** Phase I/II trial of bedaquiline treatment for HIV-infected and HIV-uninfected pediatric populations with MDR-TB in Haiti, India, and South Africa
- **P1078:** Phase IV trial to evaluate the safety of immediate vs deferred isoniazid preventive therapy for HIV-infected pregnant women and the infants born to the HIV-infected mothers in Botswana, Haiti, India, South Africa, Tanzania, Thailand, Uganda, and Zimbabwe
- **2001:** Phase I/II trial of once-weekly rifapentine and isoniazid for HIV-1-infected and HIV-1-uninfected pregnant and postpartum women with latent TB infection in Haiti, Kenya, Malawi, Thailand, and Zimbabwe
- **2005:** Phase I/II trial of delamanid in combination with an optimized background regimen (OBR) for HIV-infected and HIV-uninfected pediatric populations with MDR-TB in Botswana, India, South Africa, and Tanzania

Located at FHI 360, the IMPAACT Operations Center is responsible for supporting the development, implementation, and reporting of all IMPAACT scientific protocols and for providing a central point of coordination, communications, and support to the IMPAACT Leadership Group and all network committees, protocol teams, and working groups. The Operations Center is also responsible for arranging and supporting all network meetings and leadership travel; for the governance of the network and communications; and for providing logistical and administrative support for the IMPAACT leadership and other committees.

Staff from the Operations Center work closely with the IMPAACT leadership, protocol teams, staff from the Statistical and Data Management Center (SDMC), Laboratory Center (LC), CTUs, Division of AIDS (DAIDS), the network committees, and CTU community programs on all aspects of the IMPAACT research agenda.

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](http://fhiclinical.com) or email [info@fhiclinical.com](mailto:info@fhiclinical.com).