Tuberculosis Trials Consortium (TBTC): History

Early TB Clinical Trials

Since the 1940s, the U.S. Public Health Service (USPHS), and the U.S. Department of Veterans Affairs have conducted studies of anti-TB drugs; many of the agents studied are still in use today.

In the 1960s, the USPHS TB control and clinical research programs were transferred to CDC from the National Institutes of Health in Maryland. At this time, CDC began a series of clinical trials of rifampin that, in follow-up to key trials conducted by the British Medical Research Council, the British Thoracic Association, and others, helped to establish the efficacy and safety of rifampin-based, 6-month, short-course outpatient therapy for TB. By comparison, before rifampin became available, TB patients in the late 1950s and early 1960s were treated for 18-24 months, part of it in-hospital, to achieve high rates of cure.

TB Resurgence Leads to Increased Support for TB Programs

In the 1980s, when declining rates of TB in the United States led to declining TB funding, and when shorter course treatments were being increasingly adopted, federal support for TB control efforts diminished. Such was the lack of support for CDC's clinical trials program that a key CDC trial (USPHS Study 21, which confirmed for U.S. TB programs the efficacy of 6-month short-course therapy) was nearly terminated for lack of adequate funding.

As a result of the resurgence of TB in the United States in the late 1980s and early 1990s, and of the outbreaks of multiple-drug-resistant TB in hospitals and correctional facilities, federal support for TB control was greatly increased in 1992.

Creation of TBTC

In 1993-94, CDC announced a competitive solicitation to fund a group of TB researchers and sites capable of conducting TB clinical trials; successful applicants were funded for a period of 5 years (1993–1998). CDC selected sites that:

- provided access to significant numbers of TB patients,
- had experience with clinical trials,
- demonstrated qualifications of the trial team, and
- submitted robust plans for recruitment, management, and follow-up of patients.

Planning together, the researchers and CDC decided to conduct first a randomized, clinical trial comparing a once-weekly, rifapentine-based, continuation-phase regimen to the then-standard, twice-weekly, rifampin-based "Denver" regimen, both given for the last 4 months of the 6-month treatment for TB. This trial, called USPHS Study 22, began in 1995, enrolled 1,075 TB patients from the United States and Canada, and reported final results in 2002.

In 1997-98, CDC and the Study 22 investigators reorganized their collaboration as a structured consortium, creating the TBTC with the adoption of formal by-laws in 1998. The bylaws were updated in 2012 and again in 2021.

TBTC 1999-2009

In 1999, the TBTC underwent its second competitive process to select the clinical trial sites that would comprise the TBTC during 1999–2009. The selection of sites at that time resulted in a consortium of 23 centers located in the United States and Canada. In 2003, the consortium gained an international presence by adding sites in Brazil, Spain, and Sub-Saharan Africa.

TBTC: 2010-2020

In 2009, the TBTC underwent its third re-competition. During 2010–2020, TBTC's international presence expanded from a few clinical study sites located outside of North America, to sites in Peru, Spain, South Africa (two sites), Uganda, Kenya, Vietnam, and China (Hong Kong). The TBTC 2010–2020 also included U.S. sites in New York, Washington DC, Texas (four sites), Colorado, and Tennessee.

TBTC: 2021-2030 and Beyond

In March 2021, CDC announced the sites for the research cycle through December 2030.

TBTC clinical trials have enrolled more than 16,000 patients and volunteers over the past 20 years. The consortium's annual operating budget is approximately $11,000,000.00. Confronting the many challenges to the successful development of new TB drugs and treatment regimens, the TBTC looks forward with optimism.

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