ANNUAL REPORT

Fiscal Years 2023 and 2024

(July 2022 - June 2024)

VANDERBILT UNIVERSITY
MEDICAL CENTER

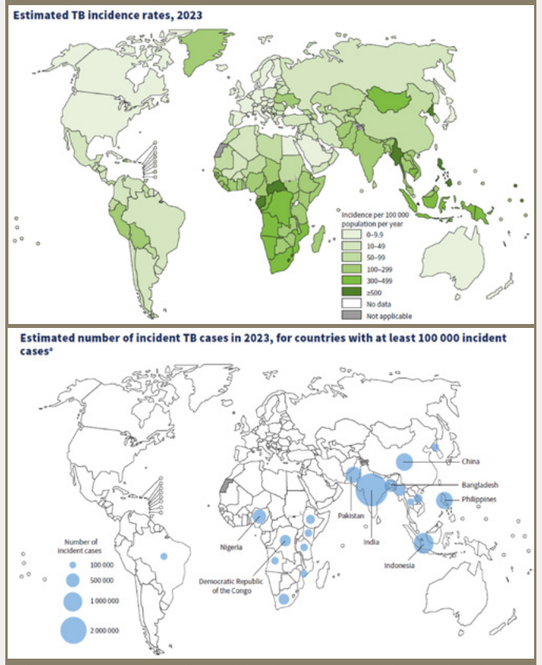
Tuberculosis Center

About the Vanderbilt Tuberculosis Center
The global burden of tuberculosis (TB) is enormous; approximately one-quarter of the world's population is infected with M. tuberculosis, and there are approximately 10 million new TB cases each year worldwide. Established in 2012, the Vanderbilt Tuberculosis Center (VTC) is a focal point for collaborative efforts in TB research that contribute to a reduction in the burden of TB and TB/HIV globally, including in Tennessee and Nashville. The VTC facilitates this in three ways:

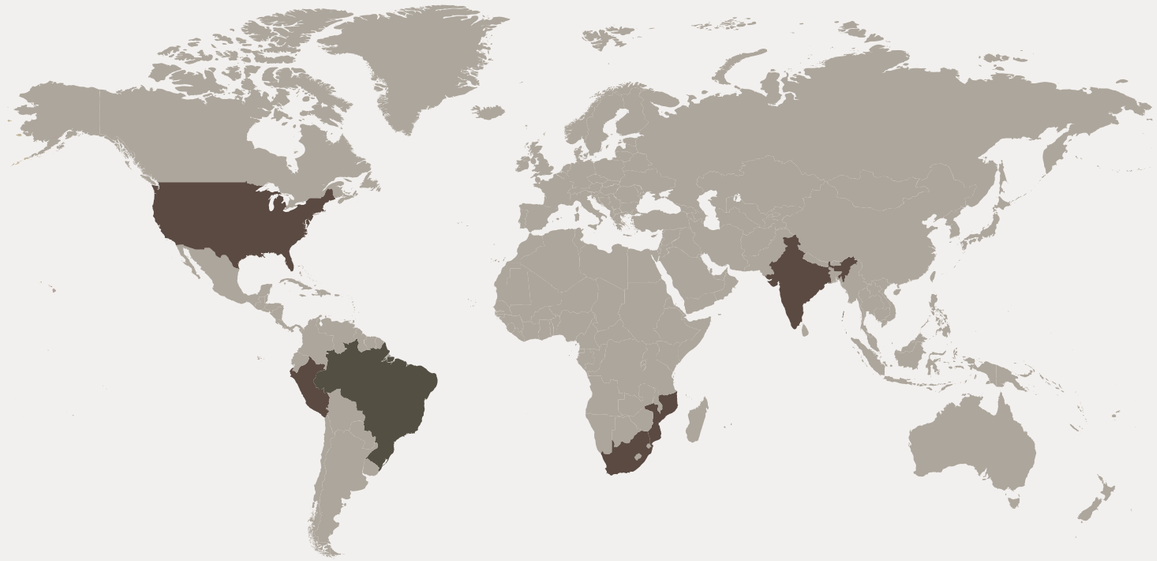
1. **Expand the Vanderbilt global research portfolio** in TB and TB/HIV, with a focus on epidemiology, clinical trials, and translational research.
2. **Develop and mentor junior faculty members, fellows, and students** from Vanderbilt, Meharry, and collaborating health departments and international institutions. Particular attention is paid to investigators who are under-represented minorities and/or women, given the disproportionate burden of TB and HIV in these groups.
3. **Provide technical assistance to the Vanderbilt-linked local and global service programs engaged in TB control:** the Metro Nashville Public Health Department, the Tennessee Department of Health, and PEPFAR/ Global Health Initiatives in the Americas, Africa, and Asia.

The VTC builds on the strengths of Vanderbilt University Medical Center and Vanderbilt University in clinical and translational research, and includes the full spectrum of discovery from bench to bedside to outcomes. With expertise in population data management, data quality, and study coordination, our research focuses particularly on epidemiology, host and pathogen factors that predispose to disease, clinical trials, and outcomes and implementation research. We do this in eight broad area of research: Treatment and Prevention, Drug Resistance, TB/HIV, Transmission and Pathogenesis, Tools and Diagnostics, TB Pharmacology and Therapeutics, and Nontuberculous Mycobacteria (NTM), as well as Training the Next Generation of TB Scientists.

The Tuberculosis Epidemic
Tuberculosis (TB) is the **leading cause of death from a single infectious agent (higher than HIV/ AIDS and COVID-19)**. In 2023 the World Health Organization (WHO) estimated that 10.8 million people developed TB disease, there were 1.25 million deaths (HIV-seronegative people and persons living with HIV). The figure below details incidence by country (WHO Global TB Report 2024). The Vanderbilt TB Center works in many of the countries that have high TB incidence rates (see map), and contributes to research to decrease the TB disease burden.



The severity of national TB epidemics, in terms of the number of incident TB cases per 100 000 population per year, varies widely among countries. In 2023, countries with the highest rates were mostly in the WHO African Region.



Vanderbilt Tuberculosis Center Collaborators
The VTC is a joint effort of the Division of Infectious Diseases within the Department of Medicine and the Vanderbilt Institute for Global Health. In addition to other partners at Vanderbilt, local and international collaborators include:

- Metro Nashville Public Health Department
- Tennessee Department of Health
- Meharry Medical College
- Boston University
- Emory University
- Harvard University
- University of Massachusetts
- University of Washington
- Johns Hopkins University
- Rutgers University
- University of California San Francisco
- Southeastern National TB Center
- Instituto Nacional de Infectologia at FIOCRUZ, Brazil
- Centro Municipal de Saude de Duque de Caxias, Brazil
- Universidade Federal do Rio de Janeiro, Brazil
- Fundação de Medicina Tropical, Brazil
- Instituto Brasileiro para Investigação da Tuberculose, Brazil
- Fundação Jose Silveira, Brazil
- Universidad Peruana Cayetano Heredia, Peru
- University of Cape Town, South Africa
- Stellenbosch University, South Africa
- University of Witwatersrand, South Africa
- Aurum Institute, South Africa
- African Health Research Institute, South Africa
- CAPRISA, South Africa
- Government of Mozambique, Zambézia Province, Mozambique

The Vanderbilt TB Center participates in the following research networks:

- Regional Prospective Observational Research in Tuberculosis (RePORT), **Brazil, South Africa**, India, China, Philippines, Indonesia, South Korea, Uganda
- The Tuberculosis Trials Consortium (TBTC) of the Centers for Disease Control and Prevention (CDC)
- International Epidemiologic Databases to Evaluate AIDS (IeDEA)—NIH
  - » The North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD) of IeDEA
  - » The Caribbean, Central and South America Network (CCASAnet) for HIV Epidemiology-IeDEA
  - » Tuberculosis Sentinal Research Network (TB-SRN)
- The Antiretroviral Therapy Cohort Collaboration
- Advancing Clinical Therapeutics Globally (ACTG)
- Preclinical Design and Clinical Translation of TB Regimens (PReDicTR) Consortium

Dr. Kelly Dooley, MD, PhD, MPH, was appointed the Addison B. Scoville Jr. Professor of Medicine and director of the Division of Infectious Diseases in September 2022. Dr. Dooley's research focuses on tuberculosis therapeutics, clinical pharmacology of anti-infectives, HIV-tuberculosis co-treatment, and evaluation of HIV and TB drugs in special populations, such as children and pregnant women. She has been a lead investigator for trials of treatments for drug-sensitive and drug-resistant TB, pediatric TB meningitis, HIV-associated TB, and TB prevention. Dr. Dooley is an invaluable addition to our Division and our TB Center!

In March 2024, **Kelly Dooley** (VUMC), **Rada Savic** (UCSF), and other colleagues were awarded **a five-year $30.8M, UM1 cooperative agreement award from NIAID/ NIH** to establish a consortium of tuberculosis preclinical and clinical experts to research the most effective treatment options for future clinical testing, called the **'Preclinical Design and Clinical Translation of TB Regimens (PReDicTR) Consortium'** (UM1AI179699). PReDicTR will establish a multidisciplinary consortium of scientific leaders, drug developers, and other stakeholders to comprehensively assess evolving preclinical research challenges and opportunities, with the goal of identifying novel regimens that have the greatest potential for clinical success in adults and children with TB.

The **Tuberculosis Trials Consortium (TBTC) launched the CRUSH-TB** trial in January 2024, which aims to identify new combinations of drugs to shorten treatment of active TB disease. Kelly Dooley is a Protocol Chair for this new study. These new regimens may improve drug tolerability and minimize drug interactions, giving healthcare providers more options to treat TB disease and completion of treatment. The trial compares the effectiveness and safety of 4-month bedaquiline, moxifloxacin, and pyrazinamide-based regimens to the standard of care 6-month regimen among patients with drug-susceptible pulmonary TB disease.

The Regional Prospective Observational Research for Tuberculosis (RePORT) – Brazil network was re-funded for another 5-years. The $5.0 million grant was awarded by the National Institutes of Health and began in January 2023. Drs. Timothy Sterling and Bruno Andrade serve as the co-PIs for the network. The new grant supports a team of more than 60 Brazil- and U.S.-based investigators who work to enroll people in Brazil with active and latent TB into the 2nd phase of the network. With funding from the NIH and Brazil's Ministry of Health, RePORT-Brazil was established in 2013 as a partnership

between five study sites in Brazil — three in Rio de Janeiro, one in Salvador, one in Manaus — with VUMC serving as the coordinating center. Brazil's Ministry of Health is also providing new funding for the project. In Phase 1 the program enrolled over 1,000 TB cases and approximately 2,000 of their close contacts. Data collected through RePORT-Brazil has provided the foundation for projects exploring drug resistance, TB/HIV, latent TB, transmission and pathogenesis, and treatment and prevention, resulting in some 40 publications to date. "In this next phase of our work with RePORT-Brazil," Sterling said, "we look forward to doubling our enrollment of TB patients and their close contacts, and to expanding our specimen and data repository and utilizing it for new insights into the diagnosis, treatment, and prevention of TB. This funding will also enhance collaboration with other researchers, and support and develop the next generation of TB scientists in Brazil." Excerpt from the VUMC News feature in February 2023. Phase 2 enrollment began in June 2022 and as of June 2024, 617 participants have been enrolled into Cohort A, and 449 into Cohort B. The team has also been busy analyzing the existing data and specimens collected during Phase I, and have published several important manuscripts in the past year (see publication list).

The RePORT International Coordinating Center (RICC) was renewed for its 3rd iteration in April 2023. The National Institutes of Health awarded a five-year, $19.5 million grant to Rutgers University in New Jersey, for support of Regional Prospective Observational Research in Tuberculosis International, or RePORT International. Many TB Center faculty are involved in RICC leadership, including **Drs. Timothy Sterling, Stephany Duda, and Yuri van der Heijden**. Dr. Sterling is a co-PI for the RICC, as well as the co-chair of the Scientific Review Committee. VTC faculty and staff traveled to **Cape Town, South Africa** in August 2022 and then to **Goa, India** in September 2023 to participate in the annual **RePORT International Meeting**. These meetings included all eight regions of RePORT: Brazil, China, South Africa, Uganda, South Korea, India, Indonesia, and the Philippines. They were both very successful meetings full of presentations and collaborative discussions, as well as presentations from young investigators.

We hosted a variety of **project meetings at Vanderbilt** over the last two years. In April 2023, we hosted researchers from Brazil, University of Massachusetts, and Harvard University for a meeting pertaining to our study, "**Predictors of Treatment Toxicity, Failure and Relapse in HIV-Related Tuberculosis**" (R01AI120790), and in March 2024, we hosted researchers from Brazil, South Africa, and University of Washington for a meeting pertaining to our study, "**Immunogenetic predictors of active and incipient TB in HIV-negative and -positive close TB contacts**" (R01AI147765). We are finishing analyses on both of these studies and will be submitting applications for competitive renewals in the coming year.

In August 2023, **Yuri van der Heijden** hosted visitors from the **Aurum Institute in South Africa** (Gavin Churchyard, Violet Chihota, and Arshad Hassim). Their visit strengthens the ongoing collaborative partnership between the two institutions, which is focused on research and global health. Included in the visit were a variety of strategic planning meetings, programmatic evaluations, and a presentation at ID Grand Rounds by Violet Chihota. **Yuri van der Heijden continues to work on his R01** study "Poor Treatment Response and Outcomes in Bedaquiline-Based Treatment Regimens for Drug-Resistant Tuberculosis in South Africa" (R01AI158605) in partnership with the Aurum Institute.

Rebecca (Ribka) Berhanu continues work on her K08 study "Transmission of drug-resistant tuberculosis in a South African city with a high prevalence of HIV infection" (K08AI150352), while splitting her time between Johannesburg and Nashville.

In September 2022, VUMC was awarded a **C06 grant "Developing the VUMC MICRO facility to advance innovative BSL3 research" from NIH for development of a new BSL3 research laboratory**. This new facility will markedly enhance our ability to perform laboratory-based TB research and we continue to work with the team on its development.

Vanderbilt TB Center in the VUMC News

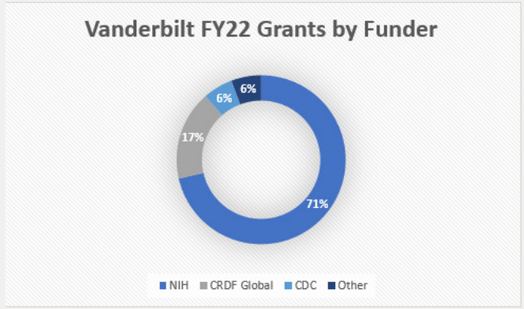
VUMC joins $31 million project to speed new TB therapies
Research into TB Expands Internationally
NIH grant boosts international TB research consortium
NIH grant supports TB research network in Brazil
Dooley honored by Treatment Action Group
Dooley to lead Division of Infectious Diseases
New Clinician Spotlight: Rebecca (Ribka) Berhanu

In the current FY 2024 (July 1, 2023 – June 30, 2024), there were 48 TB research projects with total grant funding of $16,525,342 ($12,221,200 direct costs, $4,304,142 indirect costs), funding has been stable over the last 3 years.

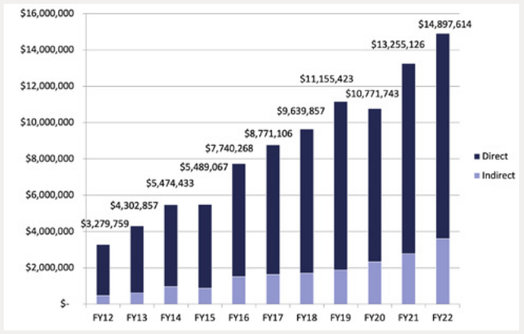
In FY 2022 (July 1, 2021 - June 30, 2022), there were **36 TB research projects** with total grant funding of **$16,062,381** ($12,177,071 direct costs, $3,885,310 indirect costs).

In FY 2023 (July 1, 2022 - June 30, 2023), there were **45 TB research projects** with total grant funding of **$16,539,437** ($12,287,725 direct costs, $4,251,711 indirect costs).

In the current FY 2024 (July 1, 2023 – June 30, 2024), there were **48 TB research projects** with total grant funding of **$16,525,342** ($12,221,200 direct costs, $4,304,142 indirect costs).



Total Grant Funding by Year for TB-related projects at Vanderbilt



Funding has been stable over the past 3 fiscal years, totaling around $16M per year, but the number of funded projects has increased. Since the center's inception in 2012, funding for TB research projects has increased five-fold, from $3.3M in 2012 to $16.5M in 2024, and the number of TB research projects has increased from 10 funded projects in 2012 to 48 funded projects in 2024.

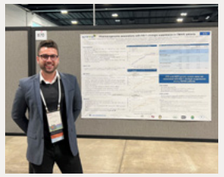
We acknowledge research funding from the U.S. National Institutes of Health, Centers for Disease Control and Prevention, Civilian Research and Development Foundation, Brazilian Ministry of Health, and South African Medical Research Council. We would like to acknowledge support from the Vanderbilt Institute for Global Health and the Division of Infectious Diseases in the Department of Medicine.

The **TB case conference**, held monthly in collaboration between the Metro Public Health Department, the Tennessee Department of Health, Meharry Medical College, and Vanderbilt, continued for its 21st year, led by Metro TB Medical Director, **Joanna Shaw-KaiKai**. With the assistance of **Jason Cummins** and **Ben Katz** at the Tennessee Department of Health and **Christina Fiske** at Vanderbilt, this has been expanded to a **state-wide online case conference** that includes clinicians and staff from TB clinics throughout Tennessee. TB cases from international settings are also presented occasionally. This has been a great platform to discuss complicated TB and LTBI cases, and get input from providers across the state of Tennessee. Additional consultation was provided by **Timothy Sterling and Ritu Banerjee** throughout the year. Vanderbilt infectious disease fellows continued to see patients with Drs. Shaw-KaiKai and Sterling on Friday mornings at the Metro Public Health Department TB Clinic.

Dr. Christina Fiske and **Dr. Kelly Dooley** have spearheaded an effort in conjunction with the Vanderbilt Lung Institute to establish a center dedicated to the care of patients with **nontuberculous mycobacteria and bronchiectasis**. This multidisciplinary clinic is staffed by Dr. Fiske, Jessica Rice NP, Dr. James Tolle and Dr. Stacy McIntyre. Patients referred to the NTM/bronchiectasis center have the opportunity to meet with respiratory therapy for education on airway clearance techniques, have joint appointments with ID and pulmonary and participate in clinical trials. Over the next 12 months, the center plans to extend telehealth capabilities into surrounding states such as Indiana, Illinois, Kentucky, and Alabama.

We began a new monthly '**Works in Progress' meeting series** in July 2023, focused on providing investigators a platform to present and receive feedback on research projects. It has been a great platform to practice conference presentations, receive scientific feedback on upcoming grants and ongoing analyses, and provide an update to the group on current research projects.

We had **multiple international trainees** appointed at Vanderbilt over the last two years. **Felipe Ridolfi**, MD, PhD from Instituto Nacional de Infectologia Evandro Chagas – FIOCRUZ, Brazil, completed his PhD sandwich program at VUMC, August 2022 – August 2023. He worked on a prediction model for treatment toxicity in the RePORT-Brazil cohort. **Maria Arriaga**, PhD, RN, MSc, was appointed as a postdoctoral fellow from September 2022 – April 2024, during which her work was focused on building a prediction model to assess the propensity of close contacts to progress to active TB disease. **Leonardo Barreto**, Public Health Technologist at Instituto Nacional de Infectologia Evandro Chagas – FIOCRUZ, spent February – August 2022 in the Sterling Lab evaluating subtle changes in drug resistance (Minimum Inhibitory Concentration - MIC) in M. tuberculosis isolates from study participants from the NIH-funded project "Predictors of treatment toxicity, failure, and relapse in HIV-related tuberculosis" (R01AI120790). Finally, **Jotam Pasipanodya**, MD, DrPH, is currently working as a research fellow in the Division of Infectious Diseases under Kelly Dooley. He focuses on treatment response biomarkers for nontuberculous mycobacteria (NTM) infection and disease in the hopes of integrating those biomarkers in pharmacokinetic (PK) and pharmacodynamic (PD) studies of currently used drugs with the aim to reduce adverse events by optimizing the drug doses, dose scheduling and drug combinations.



In September 2023, we launched the **RePORT-Brazil Advanced Career Training (ReACT) program**, funded through the RePORT-Brazil Phase 2 grant (NIH U01AI172064). The ReACT program focuses on the development of early-career Brazilian scientists and provides funding for pilot projects in TB research, mentorship, and access to data and specimens collected in Phase 1 of the project. Dr. Rodrigo Menezes, PhD in Human Pathology from the Federal University of Bahia/FIOCRUZ and Dr. Isabella Brige, MD, a physician scientist and PhD student at the Bahia School of Medicine and Public Health, were selected from among the pool of applicants to comprise Cohort 1 of the ReACT program.

The TB Center supported two scholars' participation in the Vanderbilt Institute for Research Development and Ethics (VIRDE) program in 2022 and 2023. VIRDE is an annual intensive research training program designed to facilitate trainee research productivity in low- and middle-income countries (LMICs). This month-long program is intended to bolster and further develop the skill sets necessary for conducting responsible human subjects' research and developing a grant proposal for submission. **Artur Queiroz**, Research Scientist with FIOCRUZ Bahia and MONSTER (Multinational Organization Network Sponsoring Translational and Epidemiological Research) joined the 2022 class and **Beatriz Barreto Duarte**, PhD candidate and researcher at MONSTER was part of the 2023 class. Both hail from Salvador, Brazil.

Drs. Sterling and Dooley continued to serve on the **U.S. Department of Health and Human Services Adult HIV Opportunistic Infection Guidelines Committee** for treatment of HIV-related TB.

The VTC website continues to highlight VTC research and offer resources related to TB treatment and grant funding. The website is frequently updated with grant opportunities, publications, documents for grants and upcoming conferences and workshops. Please see the Events section for upcoming meetings and events. To receive VTC newsletters, sign up here.

TB Center Project List

Projects are categorized by the VTC's key research areas.

Treatment and Prevention

Reducing the human reservoir of M. tuberculosis infection through early TB detection, treatment and prevention are vital to reducing the global burden of TB.

Active Projects:

- TBTC Study 37, ASTEROID (Assessment of the Safety, Tolerability, and Effectiveness of Rifapentine given Daily for LTBI); Nashville, TN; PI – Timothy Sterling; CDC
- Patient-centered intervention to prevent TB among children less than 5 years old; Peru; PI – Larissa Otero (Peru); NIH K43TW011137
- Immune-mediated adverse drug reactions to HIV and TB treatments in South Africa: predict, prevent and improve long-term outcomes (IMARI SA study); South Africa; PIs - Elizabeth Phillips, Graeme Meintjes (South Africa); NIH R01AI152183
- TB Treatment and Prevention at the Metro Nashville Public Health TB Clinic
- Innovative Modelling for predicting TB treatment outcomes in global cohorts; PIs Bruno Andrade (Brazil), Timothy Sterling; CRDF Global
- Multi-level and Intersectional Stigma and other Social determinant Effects on TB case Detection, care, and treatment outcomes: The MISSED TB Outcomes Study; PIs - Carolyn Audet; Desmond Tutu Foundation

Completed Projects:

- Tuberculosis Trials Consortium (TBTC); Peru; PIs – Timothy Sterling, April Pettit; CDC
- Tuberculosis Epidemiology Studies Consortium (TBESC); Nashville, TN; PIs – April Pettit, Timothy Sterling; CDC
- Characterizing the impact of HIV disease severity in prediction models for tuberculosis treatment outcomes; Nashville, TN; PI – Lauren Peetluk; NIH F31AI152614

Drug Resistance

Multidrug-resistant TB (MDR-TB), defined as resistance to at least isoniazid and rifampin, and extensively drug-resistant TB (XDR-TB), defined as MDR-TB strains that are also resistant to fluoroquinolones and second-line injectable agents, are a growing concern. Researchers at Vanderbilt, with collaborators in Tennessee as well as Cape Town and Durban, South Africa, study resistance to TB drugs, with a particular focus on the fluoroquinolones. These agents are widely used to treat other bacterial infections, which can increase the risk of drug resistance in TB, and also affect the diagnosis and treatment of TB.

Active Projects:

- Predictors of Resistance Emergence Evaluation in MDR-TB Patients on Treatment (PRE-EMPT); India and Brazil; PIs – Robert Horsburgh (BU), Timothy Sterling; NIH R01AI134430
- Poor Treatment Response and Outcomes in Bedaquiline-Based Treatment Regimens for Drug-Resistant Tuberculosis in South Africa; PI – Yuri van der Heijden; NIH R01AI158605
- Drug-resistant Tuberculosis in Gauteng Province, South Africa: Understanding Facilitators and Barriers to Successful Patient Treatment; PI – Yuri van der Heijden; VUMC ID Fund
- Mechanistic Studies of Gyrase/Topoisomerase IV-Targeted Antibacterials (R01); Nashville, TN; PI – Neil Osheroff; NIH R01AI170546
- Mechanistic Studies of Type II Topoisomerases and Topoisomerase-Targeted Agents (R01); Nashville, TN; PI – Neil Osheroff; NIH R01GM126363
- Fluoroquinolones and Efflux-Mediated Cross Resistance in HIV-related TB; Nashville, TN; PI – Timothy Sterling
- Transmission of drug-resistant tuberculosis in a South African city with a high prevalence of HIV infection (K08); South Africa; PI – Rebecca Berhanu; NIH K08AI150352

Completed Projects:

- Fluoroquinolone resistance in patients with multidrug-resistant tuberculosis; South Africa; PI – Yuri van der Heijden; NIH K08AI106420
- Mechanisms of Quinolone Resistance; Nashville, TN; PI – Neil Osheroff; VA Grant
- Mechanisms of antibiotic resistance development in bacterial pathogens; Nashville, TN; PI - Houra Merrikh; NIH R01AI127422

TB/HIV

TB is closely linked to HIV; HIV has been a key contributor to the TB epidemic. People with living with M. tuberculosis and HIV infection are significantly more likely to develop TB than persons who are HIV-negative. To control TB in high HIV-prevalence settings, it is imperative to coordinate efforts for TB and HIV control. Vanderbilt collaborates with international organizations and performs studies in population-based cohorts to identify ways to reduce the burden of TB among persons living with HIV.

Active Projects:

- International Epidemiologic Databases to Evaluate AIDS (IeDEA), NIH
- Caribbean, Central, and South America network for HIV Epidemiology (CCASAnet); Argentina, Brazil, Chile, Haiti, Honduras, Mexico, Peru; PIs – Jessica Castilho, Stephany Duda, Pedro Cahn (Argentina); NIH U01AI069923
- The North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD); Nashville, TN; PIs – Richard Moore (JHU), Keri Althoff (JHU), Timothy Sterling (VUMC Site PI); NIH U01AI069918
- Harmonist: A Scalable Toolkit for Standardizing and Coordinating Data Sharing Across International Research Networks (R24); PI - Stephany Duda; NIH R24AI124872
- Regional Prospective Observational Research for Tuberculosis (RePORT)- South Africa; PIs – Mark Hatherill (South Africa), Timothy Sterling; CRDF Global
- Associative BRICS Research in COVID-19 and Tuberculosis (ABRICOT); PIs - Valeria Rolla (Brazil), Timothy Sterling (VUMC); CRDF Global
- Avante: Towards Epidemic Control, improving TB/HIV diagnosis and care in Mozambique; PI – Bill Wester; CDC/PEPFAR
- AIDS Clinical Trials Group (ACTG) for Research on Therapeutics for HIV and Related Infections [TSG TB] (UM1); PIs- Judith Currier (UCLA) Kelly Dooley (VUMC); NIH UM1AI068636
- Statistical methods for correlated outcome and covariate errors in studies of HIV/AIDS; South America and East Africa; PI – Bryan Shepherd; NIH R01AI131771
- The Antiretroviral Therapy Cohort Collaboration (ART-CC); North America and Europe; PI – Jonathan Sterne, Timothy Sterling; NIH U01AA026209

Completed Projects:

- Immune activation and dysglycemia in tuberculosis patients with and without HIV; South Africa; PIs – Yuri van der Heijden, John Koethe, Al Leslie (South Africa); CRDF Global
- Predictors of treatment toxicity, failure, and relapse in HIV-related tuberculosis; Brazil; PIs – Timothy Sterling, Valeria Rolla (Brazil); NIH R01AI120790
- RePORT International Data Harmonization; PIs - Timothy Sterling, Stephany Duda; CRDF Global

Transmission and Pathogenesis

A better understanding of the pathogenesis of TB is key to developing novel approaches to combatting this disease. Researchers at Vanderbilt along with international collaborators have been working to improve our understanding of the mechanisms behind M. tuberculosis transmission and pathogenesis.

Active Projects:

- Regional Prospective Observational Research in Tuberculosis (RePORT)-Brazil; PIs – Timothy Sterling, Bruno Andrade (Brazil); NIH U01AI069923
- RePORT International Coordinating Center (RICC) 3.0; PIs – Jerrod Ellner (Rutgers), Timothy Sterling; CRDF Global

- Epidemiologic, immunologic, and genetic predictors and mechanisms of incipient, sub-clinical, and active TB in HIV-infected and -uninfected close TB contacts; Brazil; PIs – Timothy Sterling, Bruno Andrade (Brazil), Thomas Hawn (UW); NIH R01AI147765
- Characterization of Genomics and Metabolomics among Individuals Highly-Exposed, but resistant to Mtb Infection; PIs - Neel Gandhi (Emory); NIH R01AI139406
- Prevalence, Incidence, and Biomarkers of Subclinical Tuberculosis (TB) in Close Contacts in the RePORT International Consortium; Brazil; PI - Timothy Sterling; CRDF Global
- Regional Prospective Observational Research for Tuberculosis (RePORT)- Philippines; TB Pathogenomics Study - PI - Ribka Berhanu; CRDF Global
- Functionally distinct human CD4 T cell responses to novel evolutionarily selected M. tuberculosis antigens (R01); PIs - Joel Ernst (UCSF) Timothy Sterling; NIH R01AI173002

Completed Projects:

- Molecular analysis of the adaptive immune response to tuberculosis; Nashville, TN; PI – Spyros Kalams; NIH R21AI127129
- Towards a global TB biomarker: Comparison of small transcriptomic signatures to predict, diagnose and monitor TB disease; Brazil, South Africa; PIs – Bruno Andrade (Brazil), Timothy Sterling, Mbandi Kimbung; CRDF Global
- Prospective profiling of eicosanoid and inflammatory balance in TB-diabetes; Brazil; PIs – Timothy Sterling, Bruno Andrade (Brazil), John Koethe, Henrique Serezani; CRDF Global
- Macrophage immunogenetics and incipient tuberculosis in Brazil; Brazil; PIs – Thomas Hawn (UW), Timothy Sterling, Bruno Andrade (Brazil); CRDF Global

Tools and Diagnostics

Rapid and accurate diagnosis is critical for timely initiation of TB treatment, but many people with TB (or TB symptoms) do not have access to adequate initial diagnosis. New tools and diagnostics are needed that can accurately diagnosis TB disease and be utilized in settings across the globe.

Active Projects:

- A 100-fold more sensitive TB diagnostic based on magnetic concentration and “coffee ring” formation; PIs – David Wright and Rick Haselton; NIH R01AI135937
- Novel urine lipoarabinomannan (LAM) test; Brazil; PIs - David Wright, Micaella Jorge, Valeria Rolla, Adriano Gomes
- Sputum PCR-based test (Truenat) for the diagnosis of TB; Brazil; PIs – Afranio Kritski (Brazil)

Completed Projects:

- Urine TB diagnostic by amplicon reconstruction for PCR detection of DNA fragments; PI – Rick Haselton; NIH R21AI152497.

TB Pharmacology and Therapeutics

Improving existing treatment and therapy options by utilizing expertise in the pharmacology of anti-TB drugs; through the use of pharmacokinetic/pharmacodynamic (PK/PD) analysis to optimize treatment regimens; and the exploration of safety and PK in people living with HIV, children and pregnant women.

Active Projects:

- Second Generation InSTIs for the Treatment of HIV-1 in patients with TB co-infection on Rifampicin-based Treatment in KwaZulu Natal, South Africa; South Africa; PIs - Naidoo, Anushka, Kelly Dooley; NIH R01AI152142
- Preclinical Design and Clinical Translation of TB Regimens (PReDicTR) Consortium (UM1); PIs - Rada Savic (UCSF) Kelly Dooley (VUMC); NIH UM1AI179699
- Investigating Multiple PK and PD Relationships for TB-HIV (IMPPRove TB-HIV) (R56); PI - Kelly Dooley; NIH R56AI174911
- Baseline pRescription According to Direct from Sputum Sequencing and TArgeted drug Concentration Strategy (BRASS TACS) (R01); PI - Jeffery Tornheim (Johns Hopkins) Kelly Dooley (VUMC); NIH R01AI168371
- ACTG Study A5409, “A Phase 2A+ Randomized, Adaptive, Dose-Ranging, Open-Label Trial of Novel Regimens for the Treatment of Pulmonary Tuberculosis (RAD-TB)”

Completed Projects

- Innovative PK/PD approaches to optimize TBM treatment in children (TBM-KIDS trial); Baltimore, MD; PI - Kelly Dooley; NIH R01HD074944
- Phase 2 Study of PA-824 for Treatment of Pulmonary Tuberculosis IND 117472; Baltimore, MD; PI - Kelly Dooley; FDA R01FD004794
- Ph2a Study: Rifampin, Meropenem, Augmentin.

Nontuberculous Mycobacteria (NTM)

Improving existing treatment and therapy options for Nontuberculous Mycobacteria is of critical importance. The VTC is working to advance knowledge, diagnosis, and treatment of NTM.

Active Projects:

- A Phase 2/3, Randomized, Double-blind, Placebo-controlled, Multicenter, Prospective Study to Assess the Efficacy, Safety, and Pharmacokinetics of Orally Administered Epetraborole in Patients with Treatment-refractory Mycobacterium avium Complex Lung Disease (MACrO2); PI - Christina Fiske; Medpace Clinical Research LLC
- A Phase 2, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy, Safety, and Tolerability of Oral Omadacycline in Adult Subjects with Nontuberculous Mycobacterial (NTM) Pulmonary Disease Caused by Mycobacterium abscessus Complex (MABc); PI - Kelly Dooley; Paratek Phamaceuticals, Inc.

Training the Next Generation of TB Scientists

The VTC aims to train the next generation of TB scientists, enabling them to succeed in their research and academic goals, and provide opportunities for TB training.

Active Projects:

- HIV-Associated Tuberculosis Training Program (HATTP); South Africa; PIs – Graeme Meintjes (South Africa), David Haas; NIH D43TW010559
- RePORT Advanced Career Training Program (ReACT); Brazil; PIs - Timothy Sterling, Bruno Andrade (Brazil); NIH U01AI069923
- Mentoring Investigators in HIV and Tuberculosis Therapeutics Research; Nashville, TN; PI – Kelly Dooley; NIH K24AI150349
- Vanderbilt SCHolars in HIV and Heart, Lung, Blood, and Sleep ReSearch (V-SCHoLARS); Nashville, TN; PIs – Matthew Freiberg, John Koethe; NIH K12HL143956
- Vanderbilt Infection Pathogenesis and Epidemiology Research Training Program (VIPER); Nashville, TN; PIs – Spyros Kalams, Timothy Sterling, April Pettit, Peter Rebeiro; NIH T32AI007474
- Centers for AIDS Research (CFAR); Nashville, TN; PIs – Simon Mallal, David Haas; NIH P30AI110527

Next Steps and New Submissions

There are currently several NIH grants in development or under review. Program Managers Hilary Vansell Riley and Cody Staats will continue to seek out and announce TB funding opportunities as they are posted and offer support in developing the necessary components.

We also wish to add a laboratory-based investigator with strengths in latent *M. tuberculosis* infection, including methods to improve its detection, and factors associated with progression to tuberculosis disease. A background in host and/or pathogen genomics would be beneficial for both the VTC and the Division of Infectious Diseases. Such a scientist would provide synergy with the current strengths of the VTC, including expertise in population-based work, and access to large, well-characterized cohorts.

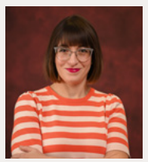
Speaker and Presentation Highlights

The VTC continued to host meetings to foster collaboration in TB research at Vanderbilt and collaborating partner sites. The below list highlights seminars and presentations given during FY2023-2024, including TB-focused presentations at Infectious Diseases Grand Rounds (IDGR) and Vanderbilt Institute for Global Health Grand Rounds (VIGH GR).


October 2022
Rada Savic (University of California San Francisco) and **Florian van Groote-Bidlingmaier** (Evotec), TB Center seminar, "Developing antimicrobial therapeutics for a public health purpose: academic and industry perspective"

March 2023
Timothy Sterling, Washington DC VA Medical Center, Fred Gordin Memorial World TB Day Grand Rounds, "Latent M. tuberculosis infection: update on pathogenesis and treatment"

April 2023
Eduardo Amaral (National Institute of Allergy and Infectious Diseases) VI4 Annual Symposium, "BACH1 regulates host resistance in M. tuberculosis infection by modulating glutathione metabolism"

May 2023
Robert Watson and **Kristin Patrick** (Texas A&M University) VI4 Special Seminars, "Balancing innate immune responses and inflammation during Mycobacterium tuberculosis infection" (Watson), and "Nuclear RNA processing pathways orchestrate the macrophage innate immune response" (Patrick)

June 2023
Timothy Sterling, U.S. National TB Conference, "Considerations on the usage of 1HP in the management of LTBI"

August 2023
Violet Chihota (Aurum Institute) Infectious Diseases Grand Grounds: "Case Finding and Prevention of Tuberculosis in People Living with HIV: Experiences from High TB and HIV Burden Settings"

November 2023
Anne Stone (Arizona State University), hosted by Vanderbilt University TB & Leprosy: Insights into the Evolutionary History of Past (and Present) Mycobacterial Pathogens Using Ancient DNA

January 2024
Leslie Enane (Indiana University) TB Center virtual seminar: "Bridging the Gaps: Global research in the adolescent HIV and TB care cascades"



March 2024
TB Center presentations at the Conference on Retroviruses and Opportunistic Infections (CROI) 2024:
Gustavo Amorim (VUMC), "Estimating Optimal Anti-TB Drug Concentrations in a Prospective, Observational Cohort in Brazil"
Felipe Ridolfi (VUMC, Brazil), "Pharmacogenetic Associations With HIV-1 Virologic Suppression Among Patients with TB/HIV in Brazil"
Maria Arriaga (VUMC), "Effect of Smoking on Longitudinal Interferon-Y Release Assay Results Among Tuberculosis Contacts"


March 2024
Thomas Hawn (University of Washington) and **Thomas Scriba** (University of Cape Town) Infectious Diseases Grand Rounds: "TB Immunopathogenesis and Clinical Applications"

April 2024
Timothy Sterling, American College of Physicians Annual Conference, "Tuberculosis management: RIPE for a change"

Selected Recent Publications (2023-2024)

1. Mendelsohn SC, Andrade BB, Mbandi SK, Andrade AMS, Muwanga VM, Figueiredo MC, Erasmus M, Rolla VC, Thami PK, Cordeiro-Santos M, Penn-Nicholson A, Kritski AL, Hatherill M, Sterling TR, Scriba TJ; RePORT-South Africa and RePORT-Brazil Consortia. Transcriptomic signatures of progression to TB disease among close contacts in Brazil. J Infect Dis. 2024 May 6:jiae237. doi: 10.1093/infdis/jiae237. Epub ahead of print. PMID: 38709708.
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3. Moro RN, Mehaffy C, De P, Phillips E, Borisov AS, Sterling TR, Dobos KM. Assessment for Antibodies to Rifapentine and Isoniazid in Persons Developing Flu-like Reactions During Treatment of Latent Tuberculosis Infection. J Infect Dis. 2024 Apr 19:jiae180. doi: 10.1093/infdis/jiae180. Epub ahead of print. PMID: 38640958.
4. Gausi K, Ignatius EH, De Jager V, Upton C, Kim S, McKhann A, Moran L, Wiesner L, von Groote-Bidlingmaier F, Marzinek P, Vanker N, Yvetot J, Pierre S, Rosenkranz SL, Swindells S, Diacon AH, Nuermberger EL, Denti P, Dooley KE; A5312 Study Team. High-Dose Isoniazid Lacks EARLY Bactericidal Activity Against Isoniazid-resistant Tuberculosis Mediated by katG Mutations: A Randomized, Phase 2 Clinical Trial. Am J Respir Crit Care Med. 2024 Apr 2. doi: 10.1164/rccm.202311-2004OC. Epub ahead of print. PMID: 38564365.
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Photo credit: VUMC News

Image from 1925 of the open-air porch and walkways in Medical Center North, designed for tuberculosis patients to sit in the sunshine and fresh air.

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