

ISSUE 9: September 2019

44th Semi-Annual TBTC Meeting in Atlanta

October 15-17, 2019

Register Now! ([Link](#))

To secure your hotel reservations, go to the "Event Information" section on the main event page and click on the booking link at the end of "Book your group rate for CDCTBTC October 2019". [Hotel reservations must be made by September 25th to guarantee the group rate.](#)

DCC Staffing Update: Farewell to Barbara DeCausey

TBTC is sad to say farewell to Barbara DeCausey, who has accepted a new position at Virginia Tech as the Director of Human Research Protection Program (HRPP). We applaud Barbara for her service to the TBTC and wish her the best in her new position!

In Barbara's absence, please use the TBTC Admin e-mail for regulatory matters: tbtcresearchadmin@cdc.gov



CONSORTIUM NEWS

STUDY 37 BEGINS!

Congratulations to all study team members on the **first enrollments into Study 37!** Study 37 ASTERoiD (Assessment of the Safety, Tolerability, and Effectiveness of Rifapentine given Daily for LTBI) opened for enrollment July 26, 2019. The study will evaluate a new regimen for treatment of latent TB infection: six weeks of daily rifapentine. It will be compared against a 12-16 week rifamycin-based treatment of latent TB infection, chosen by the enrolling site. This trial will assess the regimen for safety, tolerability and effectiveness. CDC and site investigators and staff have worked tirelessly to fulfill the regulatory requirements and finalize protocols in order to begin this trial and we applaud your efforts with these first enrollments!

As of September 26, 2019, **5 sites are open** for enrollment and are actively screening/recruiting (San Antonio, Austin, Nashville, Denver, and Columbia) and **17 participants have been enrolled** from 4 sites (San Antonio, Nashville, Denver, and Columbia).

U.S. Congressional Visit to CRWU in Kampala, Uganda

The Global Health Technologies Coalition (GHTC) and International AIDS Vaccine Initiative (IAVI) organized a trip for U.S. Congressional representatives to Uganda to learn about the impact of U.S. funding for global health research. **The trip included a visit to the Mulago Case Western Research Collaboration site which was intended to inform members of Congress on the importance of research on tuberculosis.**

Dorothy Namutamba (CRAG and AER member) gave a presentation on her TB advocacy and community engagement work, stating, "We applaud the Tuberculosis Trials Consortium as a research network that recognized the importance of community engagement in research and established the Community Research Advisors Group for the benefit of TB affected communities."

The CAB, through a drama group, then presented a 5 minutes skit that depicted the importance and the benefit of community participation in TBTC research. It was crowned by a moving testimony of a young woman who had participated in TBTC research. She shared her experience that when she was first referred from the community to the TB research site and was confirmed to have TB, she was very scared. But because of the excellent care she got at the site, she overcame the fear. She described the benefits from participating in the research and was very grateful to the TB research team, as well as funders of TB research.

– by Dorothy Namutamba



Members of the CAB at Mulago Case Western Research Collaboration with the U.S. Congressional representative visitors.

Study 35 Update

Preparation for Study 35, a dose finding and safety study of rifapentine and isoniazid for LTBI treatment in children, will begin soon. Sites are working to complete start up activities. The CRADA with Sanofi has been finalized and the study drug is now in South Africa. Database development is nearly complete. The study plans to open in Oct 2019 at two sites in South Africa.

Current U.S. Legislation relevant to Tuberculosis, by Mike Frick

End TB Now Act (Global), S.2438

Sen. Menendez (NJ), Sen. Young (IN)
Introduced: August 1, 2019

- Sets goals for TB incidence reduction, program coordination, and surveillance/reporting at USAID
- Emphasizes the need for the inclusion of LTBI and comprehensive approach throughout elimination activities
- Outlines the crucial role of US programs in TB prevention, diagnosis, treatment, and research
- Calls for aggressive TB research coordination between several agencies, including CDC

Comprehensive TB Elimination Act (Domestic), H.R.3080 and S.834

Sen. Brown (OH); Rep. Engel (NY), Rep. Young (AK)

Introduced: March 14, 2019 (Senate) and June 4, 2019 (House)

- Reauthorizes five years of increasing domestic funding for TB programs and research at CDC
- Ensures coordination between health departments and community health centers on TB elimination
- Promotes domestic TB elimination activities as vital to achieving the goals of the *National Action Plan for Combating MDR-TB*
- Involves BARDA in TB R&D and highlights need for pediatric, pregnancy, and HIV coinfection research

COMMITTEE UPDATES

EXECUTIVE AFFAIRS GROUP (EAG)

- **SAVE THE DATE:** The **44th Semi-Annual TBTC Meeting will be held October 15-17, 2019**. See registration link and hotel information on Page 1. EAG is currently finalizing the meeting agenda.

CORE SCIENCE GROUP (CSG)

- Reviewed and discussed overall approach, timing of concept sheets, and plans for outputs from **Study 31**, led by Katya Kurbatova.
- Reviewed and discussed the **TB and Pregnancy Working Group's** work and research priorities, led by Jyothi Mathad and Lisa Cranmer, the new TBPWG chairs.
- Reviewed and approved **protocol team member changes for CRUSH-TB**.
- At the October meeting, CSG will review a new concept from **Neil Martinson** on **digital chest x-rays for use in machine learning of diagnosis and response to treatment**.

ADVOCACY AND EXTERNAL RELATIONS (AER)

Since the last meeting, AER and many others in the consortium have engaged in activities to promote TB research and control and to represent our work to others.

- The AER is working to ensure that **TBTC investigators participate on important policy and clinical guidelines committees that translate the results of research into clinical practice**. An inventory of key committees has been performed, and the TBTC is already well-represented among the members of many such groups, such as World Health Organization (WHO), US Public Health Service, CDC/ATS/IDSA, and other guidelines groups. Efforts to promote membership on other committees, and to broaden the diversity of representation from the TBTC, is continuing.
- **TB/HIV 2019 Conference:** As part of the International AIDS Conference in Mexico City in July, a full-day TB/HIV symposium was held to address the global response to TB/HIV co-infection. The TBTC was represented by Jyothi Mathad (Cornell Weill School of Medicine), co-chair of the TB and Pregnancy Working Group, and Richard Chaisson (Johns Hopkins University), AER Chair. Mathad spoke about TB prevention in pregnant women and children, and Chaisson spoke on current options for treatment of TB infection.
- **WHO Technical Meeting on Target Regimen Profiles for Latent TB Infection:** A workshop sponsored by the WHO was held in Montreal on September 16-17 to create target regimen profiles for the development of drugs to treat latent TB. Andrew Vernon (CDC) presented an overview of research from the TBTC and other studies and provided a synthesis of the current state of the art. Payam Nahid (University of California, San Francisco), chair of CSG, chaired the discussion of target profiles, and Richard Chaisson moderated a discussion session.
- **Inter-TB:** The annual Inter-TB meeting was held at St. George's Medical School in London in September, with a number of TBTC investigators making scientific presentations. Payam Nahid and Rada Savic (UCSF) presented the CURE TB study, and Kelly Dooley (JHU) presented CRUSH TB. Patrick Phillips (UCSF) discussed design issues. Andrew Vernon discussed paths to simplify TB treatment.
- **UN General Assembly:** As part of the UN General Assembly meeting in New York in September, follow up to last year's special session on TB is underway. Eric Goosby, UN Special Ambassador for TB, held forums with leaders from several

pharmaceutical companies to encourage investment in TB drugs. Richard Chaisson represented the TBTC at a meeting with GlaxoSmithKline.

- **Members of the CRUSH TB protocol team have been pursuing collaborations with industry and other partners as the study design is developed.** Kelly Dooley (JHU), Jason Stout (Duke) and others have held discussions with the Bill and Melinda Gates Foundation and Otsuka in recent months to get input and seek collaboration on the trial.
- **The New York Times** ran an article on the importance of TB preventive therapy and the potential for short-course regimens to transform global practices. Richard Chaisson (JHU) and Mike Frick (TAG) were quoted. Article link: <https://www.nytimes.com/2019/09/23/health/tuberculosis-prevention.html>

COMMUNITY ADVISORY GROUP (CRAG)

- CRAG focused its work this period on procedural updates of TBTC committees, planning upcoming workshops, and are currently engaged in an internal exercise to document the impact of its work and influence on the TBTC.

IMPLEMENTATION AND QUALITY COMMITTEE (IQC)

- Member update: Derusha Franks (Site 34 Soweto) departed, Helen Marin Samanez (Site 38 Peru) joined as our CRAG representative.
- IQC Reviewed:
 - Study 37 protocol amendment
 - Study 37 MOOP 'final' draft
 - Various new and updated Study 35 and Study 37 CRFs
 - Study 31 and Study 37 Memos
 - PI Interview Guides for the S31.A5349 Adolescent Evaluation project
- Ongoing IQC projects:
 - Planning the last Sandman-Tapy award to be given to representatives of the current TBTC at the end of the May 2020 meeting, Mascha Elskamp is leading this.
 - Continuing work on the Study Coordinator Manual revision.
 - Investigating and gathering information locally pertaining to dissemination of study results to study participants to determine a 'best methods' approach to present to TBTC.
- **The Training Resource Advisory Committee (TRAC)** planned and facilitated the May 2019 "Not Just for Study Coordinators" forum and is currently planning the October 2019 forum.
- **Quality Assurance (QA) WG** reviewed, modified, and added the new Study 37 performance measures; setting up and posting of QA tables on the TBTC2 portal are pending. Kia Bryant introduced the proposed Risk Based Monitoring measures for Study 37.

See you in October!

LTBI Treatment Guidelines

Tim Sterling is leading the process of the CDC/NTCA revision of the U.S. LTBI treatment guidelines, last published in 2000. A number of TBTC members are participating in the revision process. Tim provided presentations on the draft guidelines for comment to the Advisory Council for the Elimination of TB in December 2018 and the National TB Controllers Association in April 2019. The guidelines have been cleared by NTCA and CDC, and submitted for publication.

IMPAACT₄TB – Increasing Market and Public health outcomes through scaling up Affordable Access models of short Course preventive therapy for TB, by Dick Chaisson

IMPAACT₄TB is a four-year project funded by Unitaid that aims to introduce, promote, and catalyze the use of rifapentine and isoniazid (3HP) to prevent tuberculosis. Led by the Aurum Institute in South Africa, IMPAACT₄TB includes partners from KNCV, Johns Hopkins University, the Clinton Health Access Initiative, the Global Drug Facility, WHO, and the Treatment Action Group (TAG). The project will prioritize short-course TB preventive therapy with 3HP for people living with HIV and children under five, and subsequently all those in close contact with TB patients in 12 high-burden countries—who represent 50 percent of the global TB burden. The initiative includes promoting uptake of 3HP, encouraging generic competition and new formulations, and implementation and other research. IMPAACT₄TB is supporting TBTC Study 35, the PK of 3HP in children, by funding the participation of Site 34 in Soweto in the study.



CONTACT

If you have questions or concerns, please contact tbtcresearchadmin@cdc.gov

Or contact the Advocacy and External Relations Chair, [Richard Chaisson](#), or Vice-Chair, [Alicia Wright](#)

If you have contributions to the newsletter, please contact [Hilary Vansell](#)