Activities of the Tuberculosis Trials Consortium (TBTC)

Working Group on New Drugs Annual Meeting

November 3rd, 2022

Wendy Carr, PhD
Branch Chief
Clinical Research Branch
Division of Tuberculosis Elimination

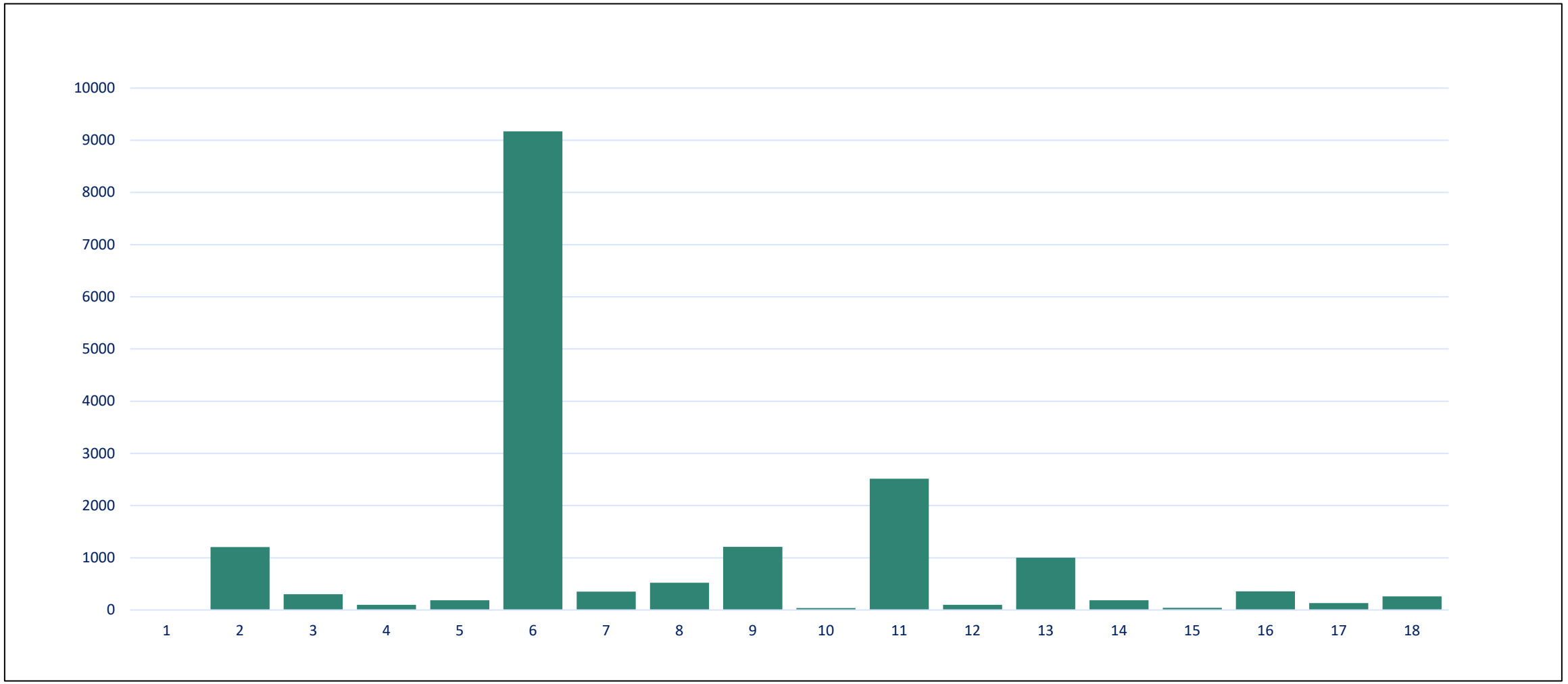
TBTC Tuberculosis Trials Consortium

Tuberculosis Trials Consortium (TBTC)

- "… is a collaboration of researchers from CDC, domestic and international public health programs, academic medical centers, and selected Veterans Administration medical centers, whose mission is to conduct **programmatically relevant** clinical, laboratory, and epidemiologic research concerning the diagnosis, clinical management, and prevention of tuberculosis infection and disease."

Health Reports, 01 Jan 2001, 116 Suppl 1:41-49

TBTC Trials Enrollment, 1995-2022



Total enrolled **17,688** participants*

TBTC established in 1993, first enrolment in 1995

*As of 12 July 2022

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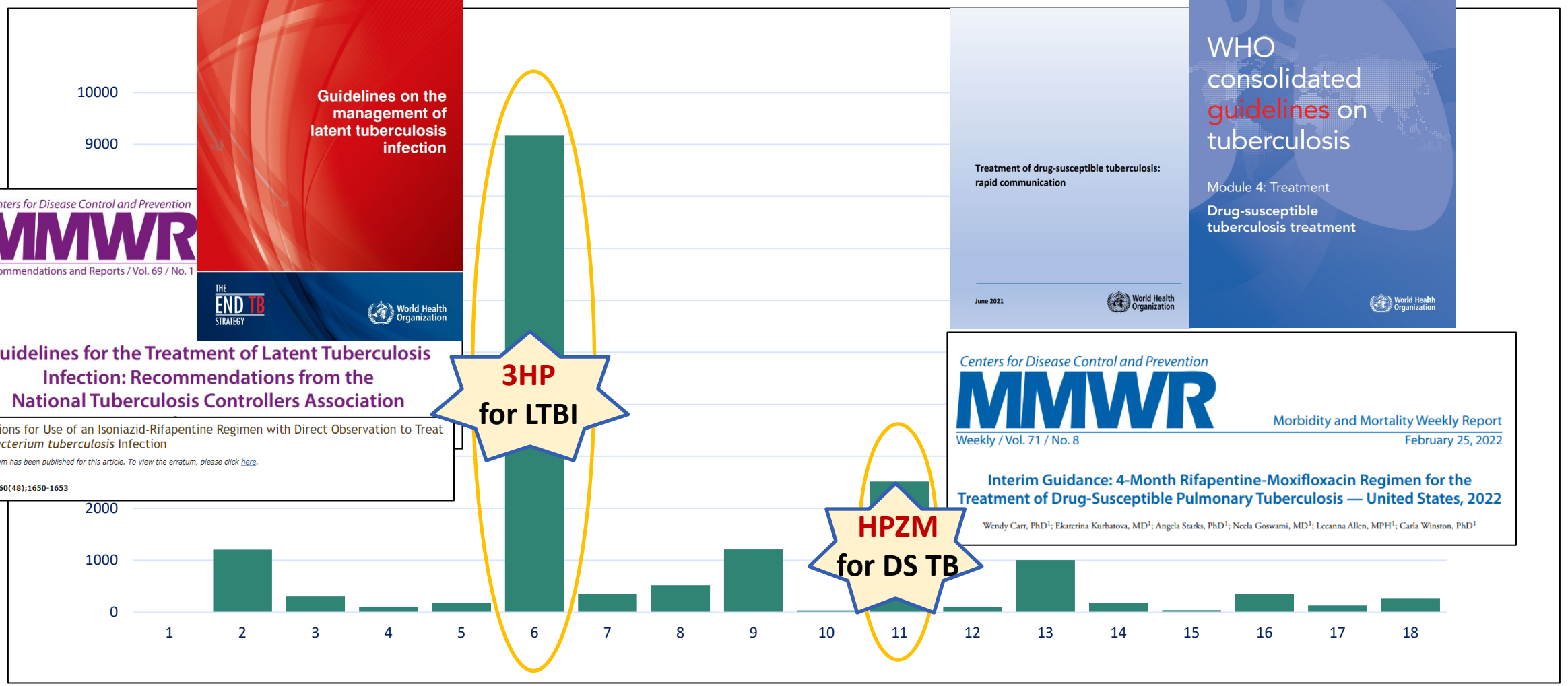

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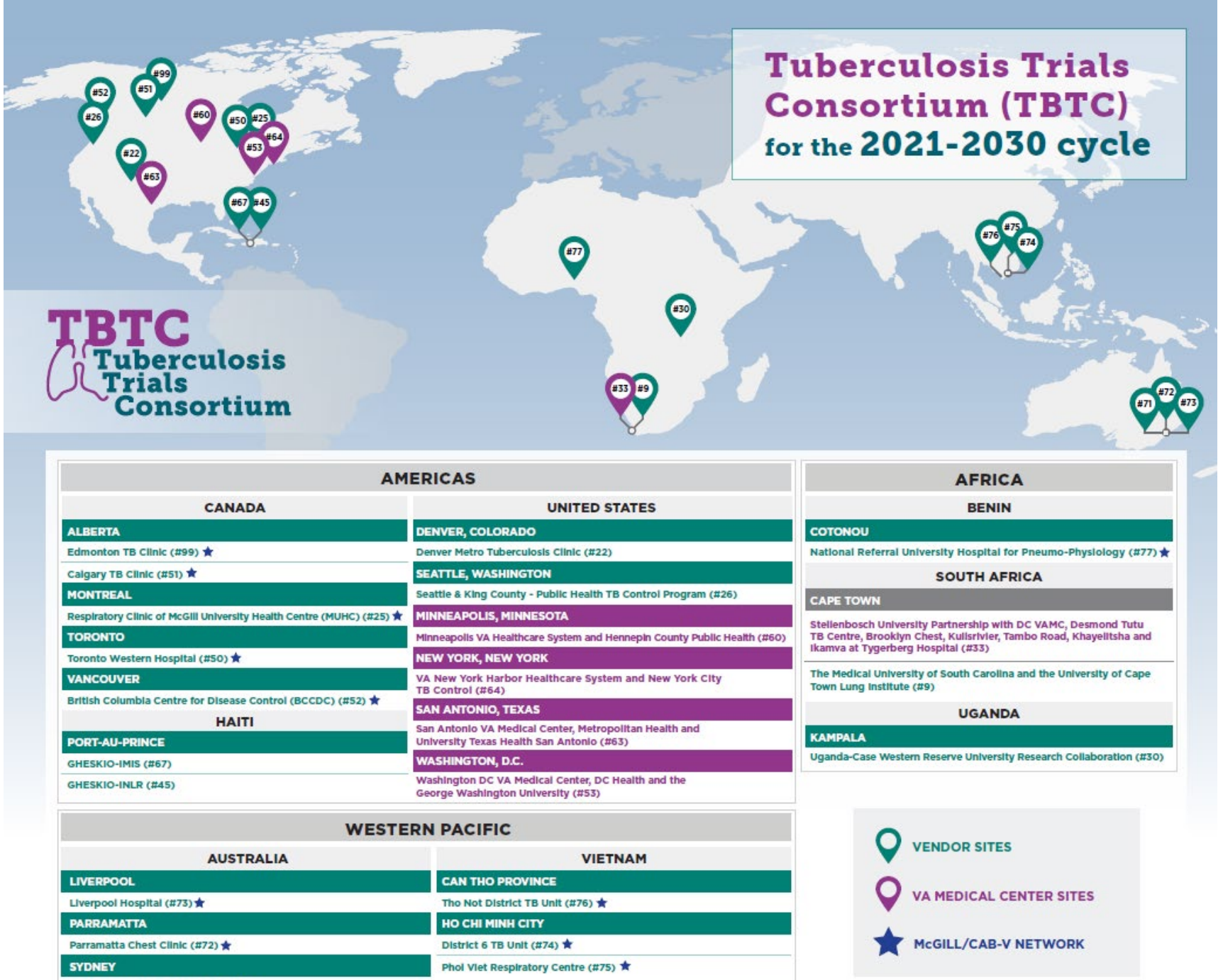


TBTC Sites

United States
Canada
Australia

Haiti
South Africa
Uganda
Vietnam
Benin

TBTC Studies: ongoing and in planning

Study	Phase	Topic	Status
S31/A5349	**3**	**4-month daily rifapentine (RPT) regimens for active DS TB**	**Completed** Secondary analyses ongoing
S31PK	Sub-study	Pharmacokinetics (PK)/pharmacodynamics (PD) TB drugs	Analysis
S31PG	Sub-study	Pharmacogenetics and PK, drug response, and safety	Analysis
S31A	Sub-study	MTB RNA transcriptomic expression profiling in sputum	Analysis
S31B	Sub-study	Novel biomarkers to shorten TB treatment	Analysis
S31 Adolescents	Sub-study	Adolescent recruitment, enrollment, and retention	Analysis
S35	**1/2**	**Novel pediatric formulation RPT PK/safety for LTBI**	**Enrolling**
S35A	Sub-study	Acceptability of pediatric formulation RPT	Analysis
S37/ASTERoiD	**3**	**6-weeks daily RPT for LTBI**	**Enrolling**
S38/CRUSH-TB	**2C**	**Novel short-course BMZ-based regimens for DS TB**	**Planning**
Radiant Kids	**1/2**	**Pediatric PK, safety, tolerability of RPT-MOX Study 31 regimen**	**Planning**

Study 35: Novel pediatric formulation RPT PK/safety for LTBI

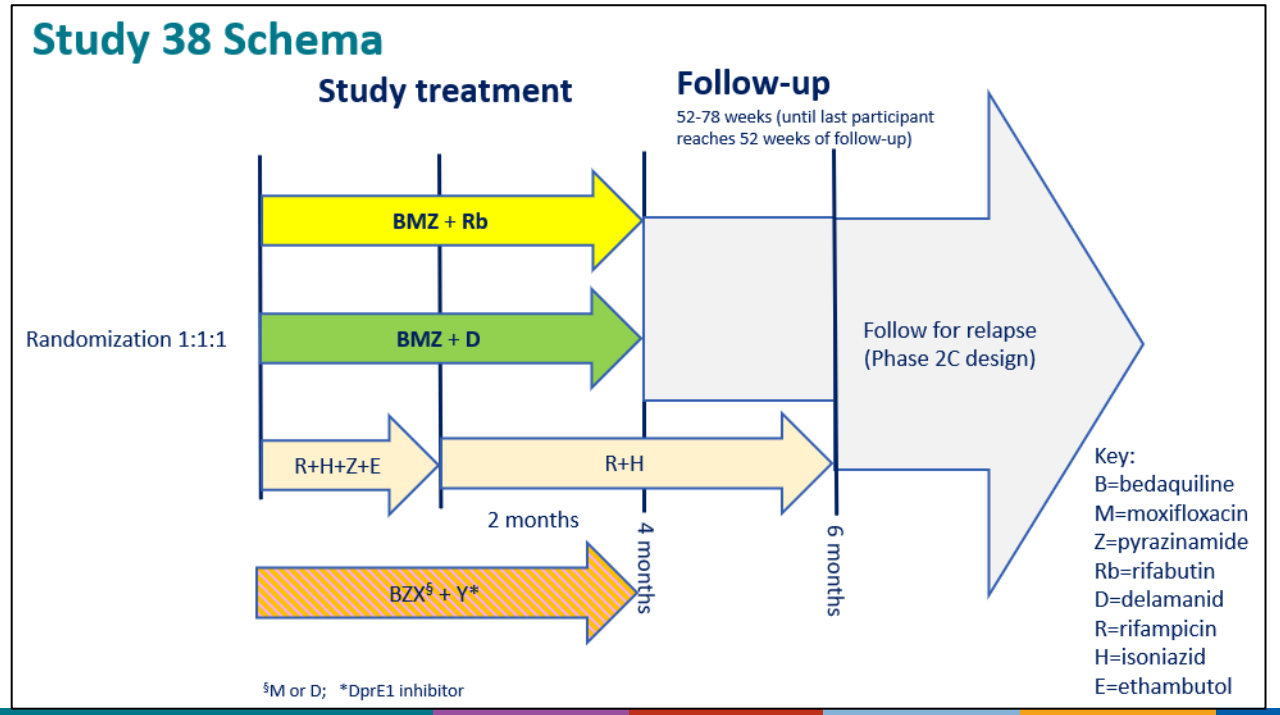
- **Design:** Phase 1/2, single arm, open-label, exposure-controlled dose finding study using an adaptive design
- **Objective:** Evaluate the PK, safety and tolerability of **rifapentine (RPT)** given in a new, water-dispersible fixed dose combination formulation with isoniazid once-weekly, for 12 weeks, in HIV-infected and HIV-uninfected children aged 0-12 years with LTBI
- **Sample size:** 72 participants (4 age cohorts)
- **Status:** Enrolling

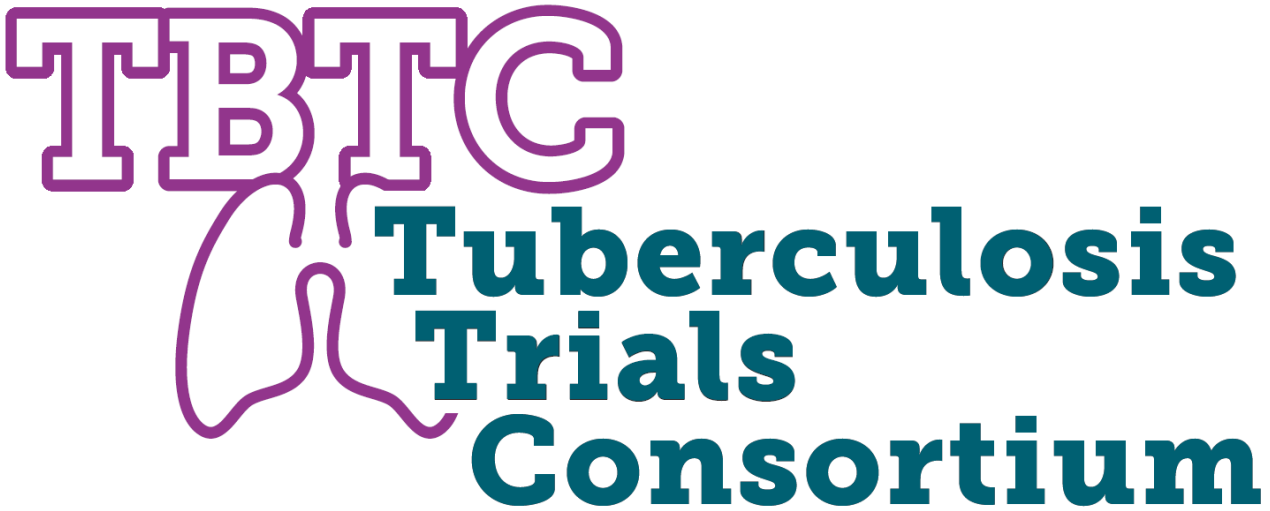
Study 37: 6 weeks daily RPT for LTBI (ASTERoiD)

- **Design:** Phase 3, randomized, controlled, open-label non-inferiority trial
- **Objective:** Compare the safety – and if safe, compare the effectiveness of daily **rifapentine** for 6 weeks (**6wP**) to a comparator arm for the prevention of TB in persons >12 years old with LTBI
- **Regimens:**
  - 6wP
  - Control (local standard 12-16 week rifamycin-based treatment 3HP, 3HR, or 4R)
- **Sample size:** 3,400 participants
- **Status:** Enrolling

Study 38: Novel short-course BMZ-based regimens for DS TB (CRUSH-TB)

- **Design:** Phase 2C randomized, open-label adaptive trial, 3+ arms
- **Objective:** Assess safety and efficacy of 4-month **bedaquiline**, **moxifloxacin**, **pyrazinamide** (**BMZ**)-based regimens compared to 6-month standard of care among adult and adolescent patients with drug-susceptible pulmonary TB
- **Regimens:**
  - 2BMZRb/2BMRb
  - 2BMZD/2BMD
  - Control (2HRZE/4HR)
- **Sample size:** 288 participants
- **Status:** Nearing Implementation





Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov