



# BREACH-TB Trial

# Bedaquiline Roll-out Evidence in Contacts and People Living with HIV to Prevent TB

## BACKGROUND

The U.S. government invests in and promotes American health innovation globally, with TB prevention research a vital component of these efforts. Tuberculosis (TB) is the leading global infectious killer, causing an estimated 1.23 million deaths in 2024 (Global TB Report 2025). While we lack a broadly effective vaccine, preventive therapy is crucial to prevent TB disease especially in those who are at higher risk and have complex considerations including children and people with HIV. Short-course regimens are more easily accepted and completed, meaning they can be more effective than longer treatments, have been available for several years for preventing drug-susceptible TB, but have not been tested in all these populations, and are not effective against the most common forms of drug-resistant TB. The powerful and safe anti-TB medicine bedaquiline offers potential for universal short-course TB preventive therapy and with it, could help millions around the world, including many in the U.S., who stand to benefit from preventive therapy.



### STUDY GOAL

To test a one-month (1BDQ) regimen of bedaquiline as preventive therapy for people at high risk for developing either rifampicin-resistant (RR-TB) or drug-susceptible TB (DS-TB).



### STUDY LEADERS

**Eric Nuermberger** and **Sonya Krishnan** at Johns Hopkins University, **Epifanio Sanchez Garavito** at Hospital Nacional Sergio E. Bernales and **Rosa Infante Castro** at Policlínico in Peru, **James Ngocho** at Kilimanjaro Clinical Research Institute in Tanzania, **Pauline Mary Amuge** at Joint Clinical Research Centre, **Bruce Kirenga** at Makerere University Lung Institute, and **Eric Wobudeya** at MU-JHU in Uganda



### STUDY POPULATION

600 participants including people who are high-risk and in close contact with RR-TB and DS-TB and people living with HIV who are in high incidence areas but are not in close contact with people living with TB.



### STUDY SITES

Peru  
Tanzania  
Uganda

## STUDY DESIGN [ClinicalTrials.gov, NCT06568484](https://ClinicalTrials.gov/ct2/show/study/NCT06568484)

BREACH-TB is a Phase 2/3, **open-label, multicenter, randomized controlled, non-inferiority trial**, enrolling approximately 600 people. The main objectives are:

To estimate the safety of 1BDQ and 3HP among adults, adolescents, and children who are in close contact with DS-TB index patients at high risk of developing TB, as well as adult and adolescent people living with HIV in high-TB-burden settings.

To estimate the safety of 1BDQ and 6 months of levofloxacin among adults, adolescents, and children who are in close contact with RR-TB index patients at high risk of developing TB.

To estimate on-time treatment completion of 1BDQ and 3HP among adults, adolescents, and children who are in close contact with DS-TB index patients at high risk of developing TB, as well as adults and adolescents living with HIV in high-TB-burden settings.

To estimate on-time treatment completion of 1BDQ and 6 months of levofloxacin among adult, adolescent, and children in close contact with RR-TB index patients at high risk of developing TB.

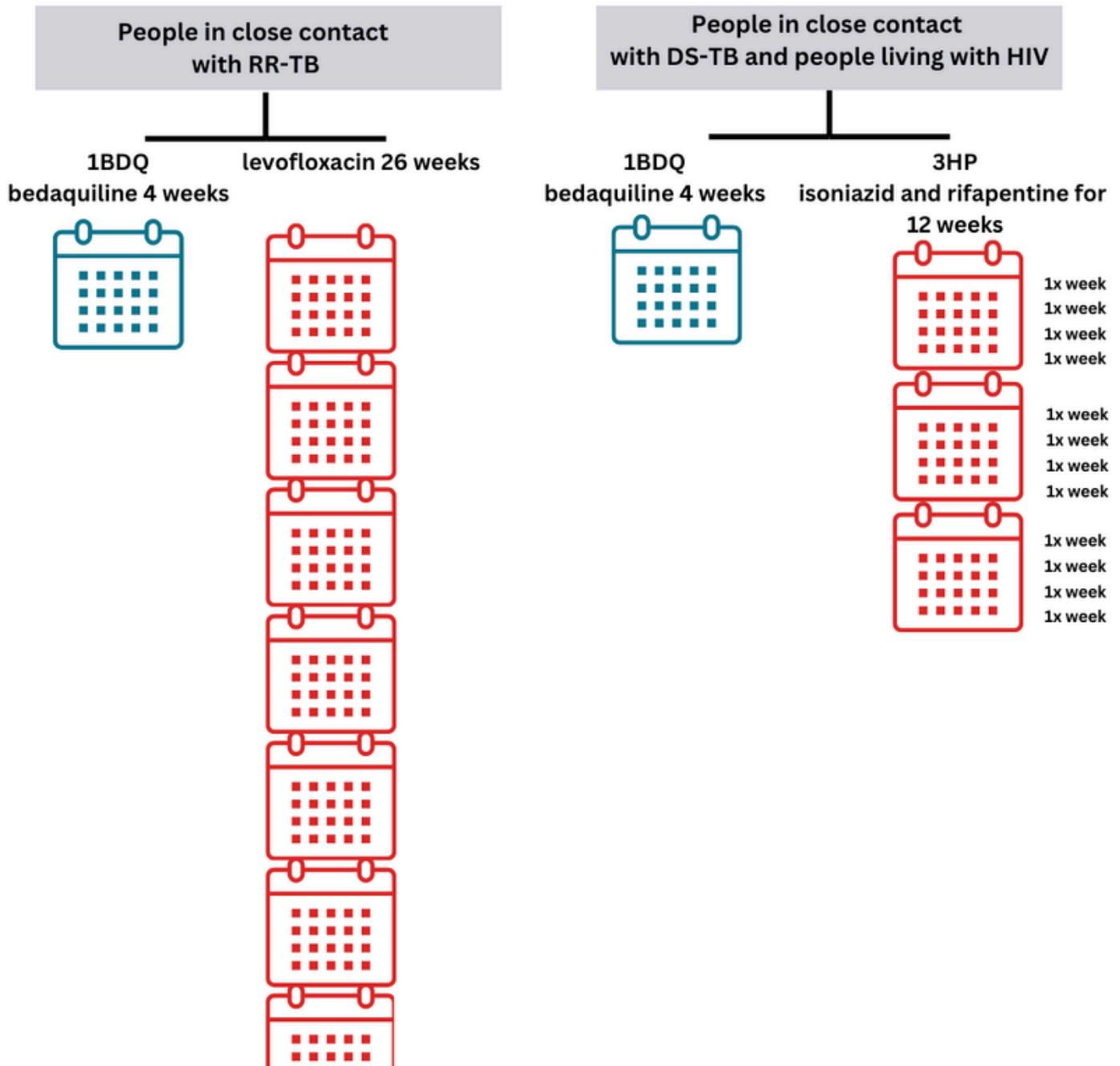
**Open-label** means the researcher and participant know the drug that is being used.

**Multicenter** means the trial is conducted at many sites, offering more diversity in participants, results relevant to more settings, and more efficiency in recruiting participants and sharing resources.

A **randomized controlled trial** assigns participants to the study intervention (in this case, the one-month bedaquiline regimen) or the control (the standard of care) at random, to balance participant characteristics with a goal of minimizing bias.

**Non-inferiority trials** test that the treatment being studied is not worse than standard treatment.

## STUDY DESIGN, CONTINUED



**If you have any questions, please contact [smart4tbcomms@jh.edu](mailto:smart4tbcomms@jh.edu)**

SMART4TB is made possible by the support of the U.S. Government through Cooperative Agreement 7200AA22CA00005. The contents are the sole responsibility of SMART4TB and do not necessarily reflect the views of the United States Government, consortium collaborators, or members.