

Problem

Address the challenge of an estimated 100,000 patients worldwide with multi-drug resistant TB (MDR-TB) and additional fluoroquinolone (FQ) resistance. Treatments are long in duration and have potentially toxic side-effects.

Proposed Solution

Identify an effective, shorter, less toxic and all-oral regimen. Conduct clinical trials to assess if the efficacy of an experimental 6- or 9-month regimen (26 or 39 weeks) is non-inferior to the efficacy of the control regimen at 73 weeks. Assess early treatment response, the efficacy of the experimental regimen at 39 and 104 weeks, and the toxicity (death rates and grade 3 or higher adverse events at 73 weeks).



Potential Impact

- Targets **drug-resistant TB** that affects the most vulnerable populations
- Potentially reduces the prevalence, incidence, morbidity, and mortality of resistance to new drugs

Viability

- Strong project team and partnerships with Partners In Health (PIH) and the Institute of Tropical Medicine (pharma support, lab tests)

Risk Mitigation

- Includes trial oversight for participant safety
- Regulatory approval for endTB-Q has been obtained in all countries

Scalability

- Generates high-quality evidence on an effective, simpler and shorter regimen that could result in a dramatic scale-up globally

Area/Type: Medical R&D; Large-Scale

Sponsor/Support: OCP sponsor / OCB and OCA support

Length/Project Status: 4 years; **ONGOING**