Global Impact of TB

2015 Global TB Report Statistics

- World population: 7 billion
- TB infection: 2.3 billion
- TB disease: 9.6 million / year
- 1.5 million deaths per year

- Roughly 4000 people a day die from TB
- Not just a "developing nations" problem--found in every country in the world
- Leading cause of death from infectious disease (higher than HIV): 1.5 million people died of TB in 2014
- HIV and TB are a deadly combination
- TB is the leading killer of people with HIV/AIDS
- People with HIV are 20 times more likely to contract TB
- Current TB treatment involves taking 14,000 pills and 6 months of daily injections
- Treatment lasts from 6 months to over two years (30 mos.)
Accelerate the development of new, safe, and highly effective regimens for TB by enabling early testing of drug combinations.

Accelerate the development of a clinically useful, regulatory approvable, WHO-qualified in vitro diagnostic assay for rapid drug susceptibility testing of TB to facilitate drug development and rational use of new drug regimens.
CURRENT REGIMEN DEVELOPMENT PARADIGM:
Existing regimen consists of four drugs

Current regimen development paradigm: Inefficient approach for development of single agents unnecessarily delays innovation wasting valuable resources. The development timeline becomes unacceptably long for patients suffering from TB.
Emphasis on combination study approaches rather than development of single agents reduces time to develop a novel TB drug regimen by 75%

**How to Get There:** Acceleration of combination approaches enabled through Critical Path Roadmap of endorsed drug development and modeling and simulation tools

**A Major Challenge:** Increasingly “fragile” TB drug development pipeline with the continued divestment of companies in the Anti-infective space

Ensure an equivalent paradigm is applied to an accompanying drug susceptibility test(s) to ensure any new regimen can be deployed
The Evolving CPTR Partnership

- **Bill & Melinda Gates Foundation**
- **CRITICAL PATH INSTITUTE**
- **TB ALLIANCE**
- **PreDiCT-TB**
- **World Health Organization**
- **NIAID**
- **REAGAN-UDALL FOUNDATION for Food and Drug Administration**

New research and development partners
Providing Solutions via Data Collaboration

TB Clinical Trial Data
Pre-Clinical Research Data
C-Path / WHO Partnership
Whole Genome Sequence, Phenotypic, Patient Outcome Data

Validated Drug Development Tools
Validated Biomarkers
TB Clinical Trial Modeling and Simulation Tools

Rapid DST Assay Developers
Clinicians
Researchers

Our Work on Drug Regimens
Regulatory Science Consortium
CPTTR
Our Work on TB Diagnostics
Rapid Drug Susceptibility Test Consortium

SUPPORTIVE EVIDENCE BASE

TB Data Collaboration Platform (CDISC TB Data Standard Integration)
Accomplishments and Impact

**TB Data Standard**
- Developed and in-use

**Pre-clinical drug development tool (in vitro hollow fiber system-TB)**
- Qualified by European Medicines Agency
- Inserted by FDA into draft Guidance on Drug Development for Pulmonary TB
- New regulatory strategies and editorial publications by regulators in leading journals

**Drug priority list to inform global TB diagnostic Target Product Profile**
- Developed and in-use

**Globally standardized surveillance terminology for TB resistance**
- Defined via partnership which includes C-Path, World Health Organization, Centers for Disease Control
Impact in 2016

- Relational Sequencing TB Data Platform (ReSeqTB) globally accessible
  - 20,000 Isolate Data Contributions

- Clinical Trial Data Platform (TB-PACTS) globally accessible
  - Independent to CPTR
  - Partnership with C-Path World Health Organization

- Five of seven modeling and simulations tools developed
  - Training for drug developers and clinical trialists in progress
  - TB Alliance to implement as “best practice”

- TB Data Standard implementation in clinical trials mandated by:
  - Bill & Melinda Gates Foundation
  - World Health Organization (TB Treatment Guidelines)
  - National Institute of Health TB Clinical Trials Network