PULL • POOL • PUSH
Better TB treatment. Faster.

3P: PUSH. PULL. POOL. Better TB treatment. Faster.

Proposal to accelerate innovation and access to new treatment regimens for TB

WHY THE '3P PROJECT' FOR TUBERCULOSIS IS NEEDED

Tuberculosis (TB) mainly affects low- and middle- income countries with 95% of cases occurring there. 1.5 million people were killed by the disease in 2014 and there were 9.6 million new cases requiring treatment. In 2014 only one in four (26%) of the 480,000 people estimated to have developed multidrug-resistant TB (MDR-TB) were diagnosed. Of which only 111,000 started on treatment with less than half of them successfully completing treatment.

The ultimate goal in TB treatment is the development of new treatment combinations to effectively, safely, quickly, affordably and simply treat all forms of TB. In the immediate term there is an urgent need to improve the treatment for MDR-TB. In order for these new treatment combinations to be developed the status quo must be transformed to deliver:

- **a healthy TB drug pipeline** with a number of compounds in all phases of development. The pipeline for new TB drugs is weak; there are only 8 new chemical entities in clinical development.
- **an increase in investment;** the current spending of $674 million on all TB R&D (vaccines, diagnostics and treatment) is only 33% of the $2 billion annual funding target outlined in the 2011–2015 WHO Global Plan. Of particular concern is the continued decrease in private sector investments.
- **an open collaborative R&D approach** that reduces risks and costs associated with testing multiple drugs for combination treatments by incentivizing research organizations to share scientific data, clinical trial results as early as possible and to conduct medically appropriate research on combinations of compounds.

SUMMARY OF THE '3P PROJECT'

The **'3P Project'** aims to rapidly deliver affordable, effective new regimens for TB through an open collaborative approach to conducting drug development and through novel approaches to financing and coordinating R&D. The 3P Project implements three mechanisms to facilitate the necessary and appropriate R&D for TB regimens:

- **pull** funding to incentivise R&D activities through the promise of financial rewards on the achievement of certain R&D objectives (i.e. through milestone prizes)
- **pooling** of intellectual property (IP) and data to ensure open collaborative research and fair licensing for competitive production of the final products
- **push** funding to finance R&D activities upfront (i.e. through grants)

A JOINT POOLING & FUNDING MECHANISM TO PROMOTE INNOVATION AND ACCESS

The '3P Project' creates a new open collaborative framework for regimen development based on the sharing of data, the pooling of intellectual property and the creation of incentives for multiple actors to enter the R&D process in order to accelerate drug regimen development timelines.

Opening up the pipeline to promote collaboration for drug combinations and regimen development and offering incentives to facilitate progression will help ensure that preclinical compounds are brought forward to clinical trials. Drug-drug interaction and potential beneficial drug combinations can be discovered sooner if products are tested together at an early stage, which will accelerate the development of new regimens. The increased investment and structuring of funding through both push and pull mechanisms will dramatically increase the number of compounds in the clinical development pipeline.

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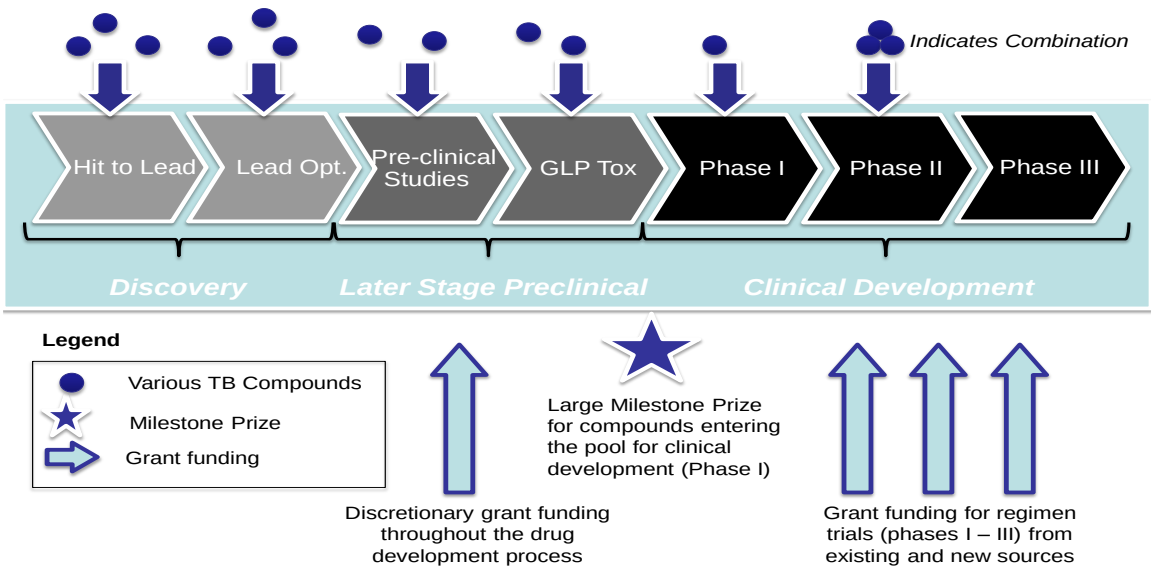
In order to ensure affordability of the final medicines, the 3P Project separates (or "de-links") the cost of R&D from the price of the resulting treatments. Once a regimen receives regulatory approval, the individual drugs or fixed-dose combinations could be licensed to multiple manufacturers with proven capacity to produce quality-assured drugs through the patent pool, allowing competition to lower prices to a sustainable level in developing countries. Regimen prices would be determined independent of the cost of R&D. In this way, international donors, developing country governments and patients will not be asked to cover the cost of medical R&D through the price they pay for the treatment.

CONCLUSION: The 3P Project offers benefits over the current TB R&D framework by:

- Reducing duplication of research efforts, thereby saving time and money
- Reducing the risks associated with developing potential combinations early in the R&D process
- Accelerating the development of all-new drug regimens
- Reducing the risk of resistance to new compounds by ensuring their use as part of regimens
- Coordinating disparate sources of funding and linking financial rewards to an obligation to share scientific and clinical data and IPR
- Separating ("de-linking") R&D costs from the final price of the new TB combination regimen

Schematic representation of the proposed mechanism including prizes, grants and patent pooling:



Organizational Chart