Project title: Accelerating Innovation and Access to Medicines for Tuberculosis through Open Collaboration: A Push, Pull, Pool Approach (“the 3P Project”)

Project summary:*  

In 2011, there were 12 million people who needed TB treatment worldwide; 95% of whom live in low- and middle-income countries (L&MICs). Because the TB mycobacterium mutates quickly and requires prolonged therapy under the best of circumstances, it needs to be treated using drugs in combination. Multiple Drug Resistant TB (MDR-TB) infected over 310,000 people in 2011, and there are reports of Extensively Drug Resistant TB (XDRTB) and even Totally Drug Resistant TB (TDR-TB).

However, current TB medicines are over 50 years old. The first new TB medicine in 50 years was recently approved by the United States Food and Drug Administration (bedaquiline); however, it has mainly been tested with older medicines, and as yet no novel ‘pan-TB’ regimens (effective against drug-sensitive and drug-resistant TB) have been fully developed. In essence, while TB treatment and TB drug research and development has recently taken positive steps forward, the current R&D system has failed to deliver the giant leap forward that is needed – that is, a more effective, shorter and safe combination of multiple new TB drugs, active against both drug sensitive and drug resistant TB. Furthermore, a healthy pipeline is needed due to the expected emergence of drug resistance. However, there are not enough candidate drugs in the pipeline, and many of those that exist are stalled or moving forward too slowly. TB is not a high priority in commercial drug development, as it predominately affects patients in L&MICs and often vulnerable populations, such as the homeless, prisoners, migrants and those co-infected with HIV.

The ultimate goal in TB treatment is a combination of medicines that effectively, safely and quickly treats all forms of TB in as few pills as possible (i.e., a fixed-dose combination). There is an urgent need to improve MDR-TB treatment especially: the current treatment for DS-TB takes 6 months and MDR-TB treatment takes 2 years, including daily injections for at least 8 months. MDR-TB treatment is particularly difficult, because many medicines are toxic with side effects, such as deafness, psychosis and severe nausea. Thus, MDR-TB patients have difficulty in completing their treatment, making them less likely to be cured of TB, exacerbating their drug resistance and left with very limited future treatment options.

Today, existing incentives drive commercial drug developers to develop individual compounds in isolation. However, what is required is the simultaneous development of multiple compounds tested in combination with each other.

We propose to transform R&D for new TB treatments through the “3P Project” – incorporating novel approaches to financing R&D (Push, Pull) and managing intellectual property (Pool) in order to accelerate innovation and achieve more equitable access to better medicines. In this open, collaborative framework, researchers and clinicians will be incentivized to share scientific data and clinical trial results, and to conduct medically appropriate research on multiple compounds. A Technical/Scientific Advisory Committee, which could be hosted by organizations such as the WHO or the Critical Path to TB Drug Regimens (CPTR), will set technical priorities and define Target Regimen Profiles for TB treatment, including an improved treatment for MDR-TB. This system offers four benefits over the current system: 1) reducing the duplication of research efforts thereby saving time and money, 2) “de-risking” potential combinations as early and as affordably as possible, 3) accelerating drug combination development, and 4) reducing the risk of resistance to new compounds.

In addition, the project will have key milestone prizes for combination regimens of TB medicines that progress through major hurdles in the R&D process; these could include entry into clinical development (Phase I), proof of concept that a novel compound has TB activity in humans, and commitment to start
Phase III, alongside a prize for entering the open collaborative framework. Discretionary grant funding would also be a major component of the initiative as the present availability of grant funding (the Push component) is woefully insufficient to support even the present activities in new TB drug R&D. Where such Pull and Push incentives are not sufficient, royalty-bearing licenses could be negotiated between the patent pool and the IP holder(s).

The project would seek to leverage as much as possible the existing capacity and expertise in TB in novel ways to foster greater collaboration. Through this open collaborative approach to R&D, it is expected that new combinations of TB medicines to be delivered faster and made more accessible to millions of people in need.

The 3P Project responds to WHA Resolution 66.22 and the recommendations of the CEWG. It applies four CEWG-recommended mechanisms (prizes, grants, open-sharing of knowledge and patent pooling) to address a high-burden disease that disproportionately affects developing countries, where there are clear failures of the existing R&D system. It would ensure that innovators are fairly rewarded. And it would de-link the financing of R&D from medicines prices in an area where existing market incentives have proven to be inadequate, and thereby take a major step forward for affordability and access.

*As taken from original proposal template, question 5.*