

TB Alliance Stakeholders Association Declaration of Membership

TB Alliance Stakeholders are dedicated to the discovery and development of better, faster-acting, and affordable tuberculosis (TB) drugs that are available to all who need them, to help address what is, globally, the leading infectious disease killer.

<u>Global Killer</u>

In 2015, WHO reported 10.4 million people became infected with TB, and 1.8 million people died of the disease.¹ Nearly all TB cases and deaths occur in the developing world and those affected are mostly the poorest and most vulnerable.

Urgent Response

There is an urgent need for the development of new, faster-acting and affordable TB treatments that are made available to people around the world who desperately need them. The Global Alliance for TB Drug Development (TB Alliance) is working towards fulfilling its mission to develop a faster-acting "universal" treatment that can cure all forms of TB.

Combination regimens, currently in development, that shorten and improve treatment of drug-sensitive and all forms of drug-resistant TB will dramatically impact today's global TB pandemic. TB Alliance's growing portfolio of novel drugs; and results from its clinical trials, hold the promise to markedly reshape and simplify the treatment landscape and offer a common therapy for virtually all people with drug-sensitive and drug-resistant TB, and a closely related treatment for those with extensively drugresistant TB. Importantly, the regimens can be deployed in the context of currently available diagnostics. TB Alliance would be unable to make this exciting progress without the support of its partners and Stakeholders.

The Stakeholders Association

The TB Alliance Stakeholders Association is dedicated to ending the TB epidemic and to supporting the efforts of TB Alliance to develop new TB drugs and make them available to all who need them. Stressing the importance of developing new drugs to improve the prevention and treatment of TB disease, we as Stakeholders will advise and support TB Alliance on its activities related to:

- Research & development of anti-tuberculosis medicine and regimens;
- Access and rapid uptake of new TB products, ensuring the Alliance's "AAA Mandate" – all new products are adopted, available and affordable;
- Dissemination and sharing of relevant information globally;
- Fundraising and advocacy

The Stakeholder Association President, elected by active members, also serves as a voting *ex officio* member of the TB Alliance Board, providing guidance and input to Alliance governance.

As Stakeholders, we will support and advise TB Alliance together with partners from academia, industry, major agencies, non-governmental organizations, and donors around the world. Acknowledging a variety of efforts and institutional missions, this partnership will provide leadership, raise funds, advocate, and coordinate efforts in various sectors and settings to improve health equity by developing and delivering a simple and affordable TB treatment in endemic countries within a decade.

TB Kills the Most Vulnerable

Women and children are uniquely impacted by the disease as TB is the third leading cause of death among women of reproductive age. As a disease, closely associated with poverty, TB poses a risk to women, killing almost half a million each year. Among pregnant women,

TB is one of the leading causes of maternal mortality and pregnancy related complications and kills more women than all other causes of maternal mortality combined.²

Each year, one million children get sick with TB and approximately 10 million children are orphaned by the disease.³

TB is also the leading cause of death among people living with HIV; 35% of all HIV deaths were due to TB. 3

Inadequate Treatments

Current TB treatment is wholly inadequate, with heavy pill burden and lengthy treatment partly contributing to high failure rates. Adverse side effects, experienced by at least 10% of patients, range from mild to severe and those battling TB, HIV, and diabetes comorbidities are at higher risk.

Challenges in current treatment have in part contributed to the proliferation of resistant strains of TB. There are an estimated 580,000 drug resistant cases annually. Current treatment for DR-TB is ineffective with only 50% of patients successfully cured, toxic, and prohibitively expensive; with extensively drug-resistant TB being a virtual death sentence.

Analysis undertaken for the UK Government's Antimicrobial Resistance (AMR) Review underscores TB as the "cornerstone of global [antimicrobial resistance] challenge" and the most significant threat in terms of lives lost and financial impact.⁴ Growing resistance to antibiotics means a shrinking arsenal of effective drugs against TB, thus treatment options becoming increasingly limited and expensive.

Globally, even with the extremely poor treatment outcomes, average MDR treatment costs are reported to be on average 20 times more expensive, and a single case of XDR-TB 100x more expensive than regular TB treatment, putting intense pressure on TB treatment budgets.

Losses to the Poorest

TB will cost the world's poorest communities US\$1-3 trillion over the next decade. Over the next 35 years, multidrug-resistant tuberculosis could kill 75 million people and cost the global economy a cumulative US\$16.7 trillion.⁴

Funding Shortfall

The WHO Assembly passed a resolution in May 2014, approving with full support the new post-2015 Global TB Strategy to end the global TB epidemic, with targets to reduce TB deaths by 95% and to cut new cases by 90% between 2015 and 2035. The strategy calls for intensified research and innovation, particularly the discovery, development and rapid uptake of new tools, interventions and strategies. In 2017, the G20 Leaders' Declaration included commitments for a worldwide response to TB and AMR, calling for action plans, access to medicines, and increased support for new R&D. There is a significant funding shortfall of over US\$1 billion annually, to meet this ambitious goal that requires us to intensify our efforts to ensure funding for TB R&D.

We hereby join TB Alliance Stakeholders in dedicating ourselves to supporting the common vision of discovery and development of better, faster-acting, and affordable tuberculosis drugs that are available to all who need them

McGill International TB Centre

¹ "Global Tuberculosis report" WHO. Geneva 2016.

² WHO Trade, foreign policy, diplomacy and health. TB Control. The burden of tuberculosis: Social burden.

³ WHO Factsheet. Tuberculosis. Geneva 2017.

⁴ Review of Antimicrobial Resistance 2016. Tackling Drug-Resistant Infections Globally: final report and recommendations.

Other References

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[•] Tuberculosis: The cruel scourge for children in Papua New Guinea ChildFund Australia. 2016.

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[•] R. Diel et al. Cost of multi-drug resistance tuberculosis in Germany. Respiratory Medicine 2014.