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Treatment Action Group

Stop TB Partnership
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THE VITAL ROLE OF
RESEARCH FOR TB ELIMINATION

What you need to know about tuberculosis (TB) research and development and its centrality to universal health coverage in preparation for the United Nations High-Level Meeting on TB.

The United Nations High-Level Meeting on Tuberculosis comes at a critical juncture in the fight against TB and the implementation of the Sustainable Development Goals (SDGs) and targets within Agenda 2030. TB kills more people each year than any other single infectious agent, and drug-resistant forms of TB are the leading cause of death due to antimicrobial resistance (AMR). The deadly persistence of the global TB epidemic in large part reflects decades of underfunding research, as well as the lack of a needs-driven approach to research and development (R&D), which has left patients and health systems reliant on outdated or nonexistent technologies to prevent, diagnose, and treat TB.

The development of new health technologies to address TB will be necessary to end the TB epidemic by 2030, a commitment made by UN member states in SDG 3.3. To reach this goal, the world urgently needs to develop and introduce easier to use, rapid tests for diagnosing all forms of TB; shorter, safer, and more effective drug regimens for treating TB in all its forms; and more effective TB vaccines; and to ensure that these tools are affordable and available to all those who need them. Devising new public health strategies and models of care that ensure the benefits of these health technologies extend to all people with and at risk of TB will also be essential.

ELEANOR ROOSEVELT was the chief architect of the Universal Declaration of Human Rights, which established the right of everyone to share in scientific advancement. She died from TB that was drug resistant. Today, many people with TB suffer from a lack of innovation in new health technologies and struggle to access life-saving medical advances. The human rights system established by Roosevelt and others is clear: **all people with and at risk of TB have the right to enjoy the benefits of scientific progress.**

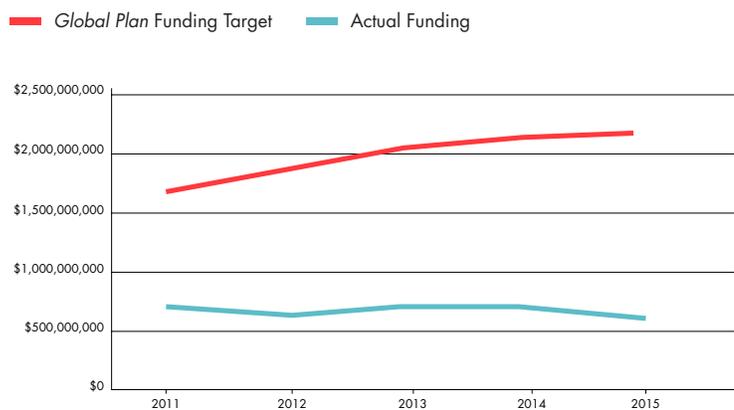## TB R&D AND UNIVERSAL HEALTH COVERAGE

Research is essential to securing the health of all people. SDG 3.8 calls for universal health coverage (UHC), including "access to safe, effective, quality, and affordable essential medicines and vaccines for all." For diseases like TB, where inadequate or nonexistent tools hinder an effective public health response, providing access to health technologies will require governments to invest in R&D. Accordingly, in SDG 3.B states committed to supporting R&D of new medicines and vaccines.

Research is also central to the World Health Organization (WHO) End TB Strategy. Modeling underpinning the End TB Strategy shows that existing interventions—even if implemented in the context of UHC—cannot reduce TB incidence and mortality to subepidemic levels.[1] To end TB by 2030, new tools must be developed and introduced by 2025, a milestone that will only be reached if states significantly increase investments in R&D, starting today.

FINANCING AND INCENTIVIZING NEEDS-DRIVEN TB R&D

The Global Plan to End TB calls for $9 billion in funding for TB R&D between 2016 and 2020.[2] TB research only receives one-third of this target on an annual basis, leaving a funding gap of $1.3 billion each year.[3] TB receives less research funding per fatal case and year of healthy life lost than other global epidemics such as HIV and malaria.[4] Despite scant financing, TB researchers have made significant progress in recent years, and they are poised to unlock even greater advances if fully resourced.

2011–2015
***GLOBAL PLAN* TB R&D FUNDING TARGET VERSUS ACTUAL FUNDING**

The funding required is just a fraction of the costs of inaction. One study estimated that, if left unchecked, TB-related mortality will cause the global economy to incur losses worth $984 billion between 2015 and 2030. Closing the R&D funding gap could have a transformative impact on ending the epidemic and would cost less than one percent of the total costs of inaction.[5] In this context, research is not a luxury, but a necessity that no country committed to ending TB and achieving UHC can afford to ignore.

The complexities of TB, and its distinction as a key element of the AMR response, present a unique set of challenges and opportunities. To address these, governments need to introduce innovative financing and appropriate incentive mechanisms that delink the costs of R&D from prices and volumes of sales (delinkage). R&D strategies to address TB must be needs driven, evidence based, and guided by the core principles of affordability, effectiveness, efficiency, and equity and the objective of delinkage. Governments have already agreed to these R&D safeguards and principles in commitments made at the World Health Assembly and in the UNGA political declaration on AMR.[6,7,8] These prior resolutions and declarations affirm that health research and development should be considered a shared, global responsibility.

For TB R&D, the principle of collaboration is also important, since TB is a complex disease. TB must be treated using multi-drug regimens, and new vaccines may require accompanying new diagnostics.

Developing these new tools will require funders and developers to work together and share data, pool intellectual property, and leverage resources across sectors. Several concrete proposals have been put forward in recent years that would offer states the opportunity to work together and in partnership with stakeholders, including the private sector, to deliver the transformative science required to eliminate TB. In 2017, the G20 called for establishing an AMR R&D Collaboration Hub; it is vitally important that TB research have a prominent place within this endeavor.[9] At the Moscow Ministerial Conference on TB, the BRICS countries announced the formation of a BRICS TB research network.[10] These proposed initiatives could galvanize progress in TB research if designed around the core R&D principles agreed on by member states and articulated above. These principles are already at the heart of the Life Prize, an innovative proposal for financing and incentivizing the development of new drug regimens for TB in a way that promotes sharing of ideas, expertise, and data to ensure that the products developed are acceptable, affordable, and accessible to all.

PRIORITY ACTIONS: DEVOTE THE RESOURCES, DEVELOP THE TOOLS, AND DESIGNATE THE OUTCOMES AS GLOBAL PUBLIC GOODS

By taking the following priority actions, heads of state and government can support the research required to end TB in line with the SDGs and the End TB Strategy:

DEVOTE THE RESOURCES

- **Increase funding for TB research, including basic science research, to close the annual funding gap.** At least $2 billion for TB R&D is needed annually. For example, if each country spent up to or beyond just 0.1% of its annual gross domestic expenditure on research and development (GERD) on TB research, the world would close the annual funding gap of $1.3 billion.[11]

DEVELOP THE TOOLS

- **Accelerate the development and use of new tools to prevent, diagnose, and treat TB in all its forms.** This will require supporting the full spectrum of TB R&D, from basic science to product development through implementation research.

- **Develop and fund national plans for TB research**, or integrate TB into national health research agendas. The goal is to create research-enabling environments by encouraging capacity building, coordination, partnership, and national regulatory and policy environments that support research and the rapid uptake of new interventions.

DESIGNATE THE OUTCOMES AS GLOBAL PUBLIC GOODS

- **Ensure that all R&D efforts are needs driven, evidence based, and guided by the core principles of affordability, efficiency, equity, and collaboration and the objective of delinkage.** The 2018 UN High-Level Meeting on TB is a key opportunity to reiterate these norms for TB R&D to ensure a fair return on public investments in science.

QUESTIONS AND CONTACT:

To be put in contact with global and country-level experts on TB research, or for UN mission briefings, please contact Mike Frick (mike.frick@treatmentactiongroup.org).

END NOTES

1. World Health Organization. End TB Strategy: global strategy and targets for tuberculosis prevention, care, and control after 2015. Geneva: World Health Organization; 2014. http://www.who.int/tb/post2015_strategy/en/

2. Stop TB Partnership. Global plan to end TB, 2016–2020: the paradigm shift. Geneva: UNOPS; 2015. http://www.stoptb.org/global/plan/plan2/.

3. Treatment Action Group. The ascent begins: tuberculosis research funding trends, 2005–2016. New York: Treatment Action Group; 2017. http://treatmentactiongroup.org/tbrd2017

4. World Health Organization. Global investments in tuberculosis research and development: past, present, future. Geneva: World Health Organization; 2017. http://www.who.int/tb/publications/2017/Global_Investments_in_Tuberculosis_Research_Investment/en/

5. Global economic impact of tuberculosis. London: KPMG; 2017. https://www.globaltbcaucus.org/en-research

6. World Health Assembly. Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination [WHA69.23]. Geneva: World Health Organization; 2016.

7. World Health Assembly. Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination [WHA66.22]. Geneva: World Health Organization; 2013.

8. United Nations. Political declaration of the high-level meeting of the General Assembly on antimicrobial resistance [A/RES/71/3]. New York: United Nations General Assembly; 2016. https://digitallibrary.un.org/record/845917?ln=enSB0806 [Internet]. Nashville: Tennessee General Assembly; (cited 2017 July 26). http://wapp.capitol.tn.gov/apps/BillInfo/Default.aspx?BillNumber=SB0806.

9. G20 leaders declaration: shaping an interconnected world. Hamburg: G20 Summit; 2017. http://www.g20.utoronto.ca/2017/2017-G20-leaders-declaration.html

10. BRICS leaders Xiamen declaration. Xiamen: BRICS Summit; 2017. http://mea.gov.in/Uploads/PublicationDocs/28912_XiamenDeclaratoin.pdf

11. Treatment Action Group. Investing in R&D to end TB: a global priority. New York: Treatment Action Group; 2017. http://treatmentactiongroup.org/sites/default/files/Funding%20target%20brief_final_31Oct.pdf

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