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GLOBAL INVESTMENTS IN TUBERCULOSIS RESEARCH AND DEVELOPMENT

PAST, PRESENT, AND FUTURE

A POLICY PAPER PREPARED FOR THE FIRST
WHO GLOBAL MINISTERIAL CONFERENCE
ON ENDING TUBERCULOSIS IN THE
SUSTAINABLE DEVELOPMENT ERA:
A MULTISECTORAL RESPONSE



World Health
Organization

Global investments in Tuberculosis research and development: past, present and future. A policy paper prepared for the first WHO global ministerial conference on ending tuberculosis in the sustainable development era: a multisectoral response

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A policy paper prepared for the First Global Ministerial Conference on
Ending TB in the Sustainable Development Era

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ABBREVIATIONS

ACTG	AIDS Clinical Trials Group	LTBI	latent TB infection
AIDS	acquired immunodeficiency syndrome	MDR-TB	multidrug-resistant TB
AMR	antimicrobial resistance	MTB	Mycobacterium tuberculosis
BCG	bacille Calmette–Guérin	NCE	new chemical entity
BRDPI	biomedical research and development price index	NIH	National Institutes of Health (United States)
BRICS	Brazil, Russian Federation, India, China and South Africa	NTP	national TB programme
CAGR	compound annual growth rate	OR/IR	operational and implementation research
CDC	Centers for Disease Control and Prevention (United States)	PEPFAR	US President's Emergency Plan for AIDS Relief
CEWG	WHO Consultative Expert Working Group on Research and Development: Financing and Coordination	POI	prevention of infection
CHIM	controlled human infection model	R&D	research and development
CMV	cytomegalovirus	RCT	randomized controlled trial
CPI	consumer price index	SAMRC	South African Medical Research Council
DALY	disability-adjusted life-year	SDG	Sustainable Development Goal
DNA	deoxyribonucleic acid	TAG	Treatment Action Group
DOD	Department of Defense (United States)	TB	tuberculosis
DR-TB	drug-resistant TB	TBTC	Tuberculosis Trials Consortium
DS-TB	drug-susceptible TB	The Union	International Union Against TB and Lung Disease
EDCTP	European and Developing Countries Clinical Trials Partnership	UN	United Nations
EU	European Union	UNESCO	United Nations Educational, Scientific and Cultural Organization
FDA	Food and Drug Administration (United States)	United Kingdom	United Kingdom of Great Britain and Northern Ireland
FDC	fixed-dose combination	US	United States
FIND	Foundation for Innovative New Diagnostics	USAID	United States Agency for International Development
Gates	Bill & Melinda Gates Foundation	USAMRIID	United States Army Military Research Institute of Infectious Diseases
GDP	gross domestic product	USPHS	US Public Health Service
GERD	gross domestic expenditure on research and development	WHO	World Health Organization
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria	XDR-TB	extensively drug-resistant TB
HIV	human immunodeficiency virus		
LPA	line probe assays		

FOREWORD

Research is the sine qua non to pursue substantial improvements in health outcomes: every diagnosis, intervention and treatment carried out in tuberculosis (TB) programmes has been conceived and developed through scientific research. Simply put, research translates into health benefits every day, with wider (and usually underestimated) positive benefits trickling down to create further social and economic well-being. In the WHO End TB Strategy, we make the case for TB research being central to improving patient health, and positively transforming health-care services with better interventions and products. In doing this, we need to consider three main issues. The first is that an estimated 10 million people contract TB disease every year, most of them in poor, underserved areas, and all of them need to have their safety and well-being protected. Second, only one third of investment needs for TB research and development are currently met – a situation that hampers the development of new and better tools for detecting, treating and preventing TB. Third, what sets 2017–2018 apart is our ability, through two forthcoming unprecedented high-level meetings, to secure commitment from Member States and the research community at large in addressing critical impediments to TB R&D. Hence, now it is a critical time to articulate what we need from TB R&D.

Together with our various partners, academics and civil society groups, we have developed a policy paper on TB R&D for use in the context of the “WHO’s First Global Ministerial Conference on Tuberculosis in the Sustainable Development Era – A Multisectoral Response” in Moscow. This document aims to articulate a coherent vision of the research needs to end TB and elaborates on the funding and structural requirements that are necessary to operationalize this vision. It describes how some of the research funded in the past has delivered benefits to patients and influenced policy- and decision-making, but also how little is being invested in TB R&D in comparison with other diseases, such as HIV and malaria, that also affect poor populations. The paper shows that, despite significant progress, previous investments were not sufficient to warrant success in tackling difficult challenges, such as multidrug-resistant TB (MDR-TB), expedited development of new and improved tools, and effective deployment of such tools. To tackle these challenges, the present policy paper recommends the development of a global strategy for TB Research to foster collaboration, improve efficiency and increase R&D financing. The strategy, will serve as a coherent

source of direction so the opportunities commencing from the forthcoming meetings are used optimally.

Further findings from this report are expected to inform the debate at both national and global levels on prioritizing the policy approaches that are urgently needed to advance TB R&D in the era of the SDGs.

Since it is our shared responsibility to foster TB R&D at all levels (national, regional and global) and lay the foundations for the speedy development of new tools and strategies, we need to take tangible steps to increase our TB R&D commitments. Such steps include increasing research funding & capacity, reducing regulatory impediments in health research, and encouraging greater public, private and civil society engagement to facilitate equitable and affordable access to new diagnostics, medicines and vaccines.

All relevant stakeholders – including governments, industry, nongovernmental organizations, academics and civil societies at large – should continue to explore ways to support innovations that address the unique set of scientific, economic and regulatory challenges presented by TB, while promoting access to affordable treatment and prevention.

The two forthcoming high-level meetings offer a unique and exciting opportunity for Member States, partners, stakeholders and the overall TB community at large to move forward and foster innovative R&D policies that can promote the rapid achievement of the WHO End TB Strategy targets as well as the relevant SDGs target of ending the TB epidemic.

Through our united efforts, we must echo the pledge of the SDGs to “Leave No One Behind”. This begins with reinvigorated research as the basis for innovation.

Dr Mario Raviglione

Director, Global TB Programme
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EXECUTIVE SUMMARY

Tuberculosis (TB) is the most lethal infectious disease in human history, and it remains the leading cause of death from a single infectious agent globally. Drug-resistant forms of TB are responsible for a quarter of annual deaths due to antimicrobial resistance (AMR) and, if left unchecked, by 2050 it will claim millions of lives and cause the global economy to incur losses worth billions of dollars. The present and future threat that TB poses to human health is mainly a consequence of the enormous neglect the TB research field has experienced over the past several decades. Reversing this neglect and ending the TB epidemic by 2030 – as called for by the United Nations Sustainable Development Goals (SDGs) and WHO End TB Strategy – will require a decisive commitment by all countries and stakeholders to increase their support for TB research and innovation.

A renewed, global commitment to TB research and development

The analyses of the past decade of TB research funding presented in this policy paper make clear that past and present expenditures on TB R&D are wholly inadequate when measured against these ambitions. TB accounts for nearly 2% of disability-adjusted life-years (DALYs) and 2% of deaths globally, but receives only 0.25% of the estimated US\$ 265 billion spent on medical research annually. TB research receives less support than other global health threats such as HIV and malaria, both in absolute terms and relative to its share of DALYs and premature mortality. Annual funding for TB R&D has not grown appreciably since 2009 and has even lost ground in the face of inflation. Moreover, funding is highly concentrated: 30 institutions from a handful of countries account for over 90% of TB R&D expenditures in any given year. Declining investments by industry over the past 5 years, coupled with flat expenditures from major public and philanthropic funders, mean that there

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