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Strategy Development: Landscape Analysis - TB

VERSION: 29 MAY 2020



SDGs and TB

Goal 3. Ensure healthy lives and promote well-being for all at all ages



Target 3.3: By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases

Indicator 3.3.2: Tuberculosis incidence per 1,000 population

End TB targets

By 2025

75%

Reduction in deaths

50%

Reduction in incidence

ZERO

Families facing catastrophic costs

By 2030

90%

Reductions in deaths

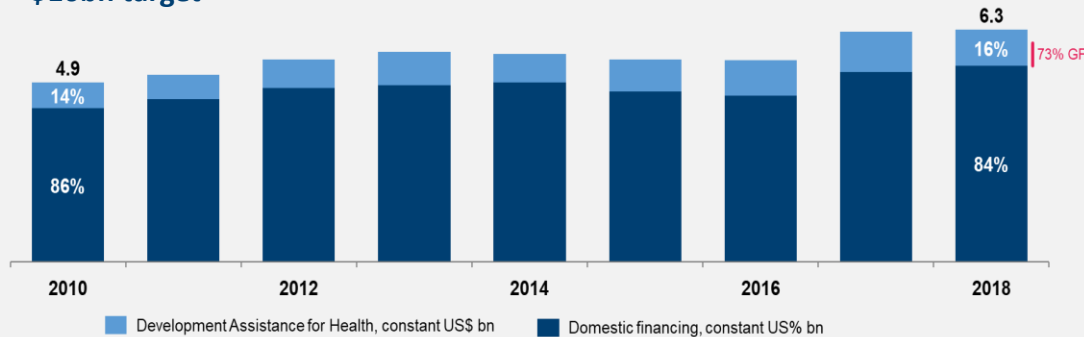
80%

Reduction in incidence

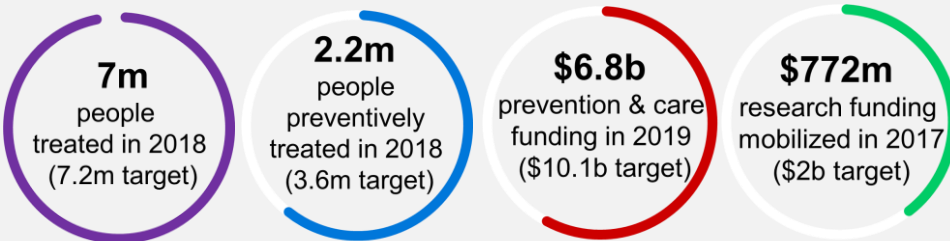
ZERO

Families facing catastrophic costs

TB funding: steady increase yet shortfall of \$6.3bn (2018) vs. \$10bn target



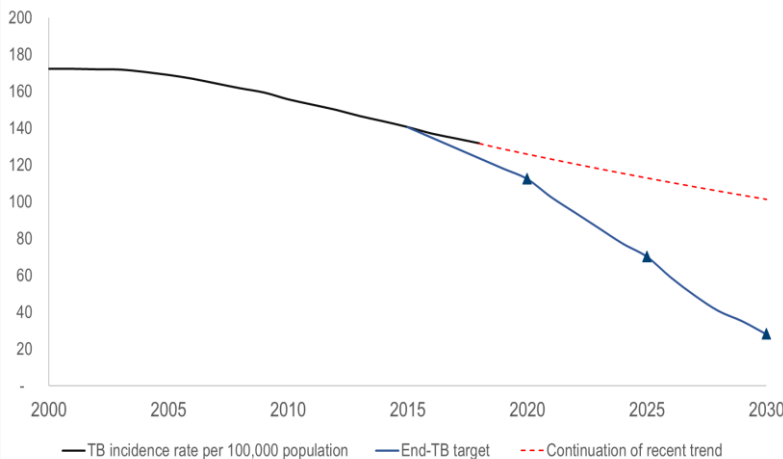
Progress towards United Nations High Level Meeting (UN HLM) targets



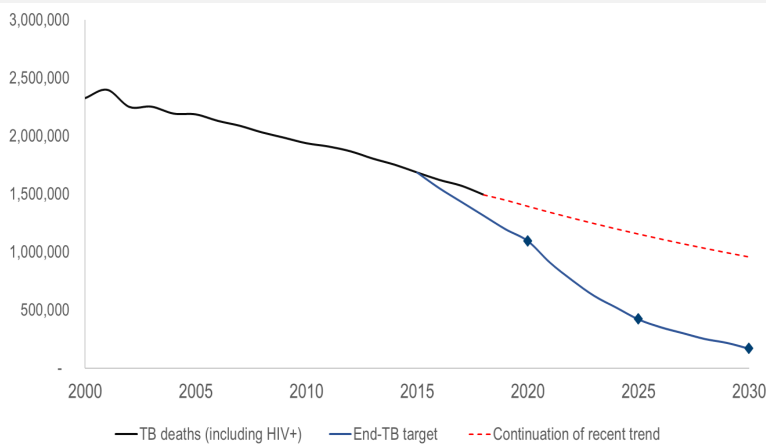
Key Messages

- Off track to meet END TB targets on TB incidence and mortality
- Insufficient investment to address human rights and gender-related barriers to accessing TB services
- Positive trends to achieve UN HLM targets on people treated for TB and Global Plan targets on treatment outcomes
- Gaps still exist in MDR-TB detection and treatment outcomes; progress on shorter, oral MDR-TB regimens
- Progress on the implementation of TB/HV activities, but gap in TB screening and TPT among PLHIV;
- Suboptimal scale-up of TB prevention measures for key and vulnerable populations in many countries
- Promising pipeline for new tools including drugs, diagnostics and vaccines
- Steady increase in TB funding, yet significant gaps to achieve targets (international and domestic)
- Focus effort on finding missing people with TB and DR-TB, especially in high risk and vulnerable groups, through engagement with the private sector and communities
- Opportunity to address AMR, global health security and new threats through investments in TB, including in resilient and sustainable systems for health

TB incidence per 100,000 population



of TB deaths (m)



Where we want to be: Global Targets

End TB targets (compared to 2015 baseline)		Milestones			Targets
		2020	2025	2030	2035
1	Percentage reduction in deaths due to tuberculosis	35%	75%	90%	95%
2	Percentage reduction in tuberculosis incidence rate	20%	50%	80%	90%
3	Percentage of affected families facing catastrophic costs due to tuberculosis	Zero	Zero	Zero	Zero

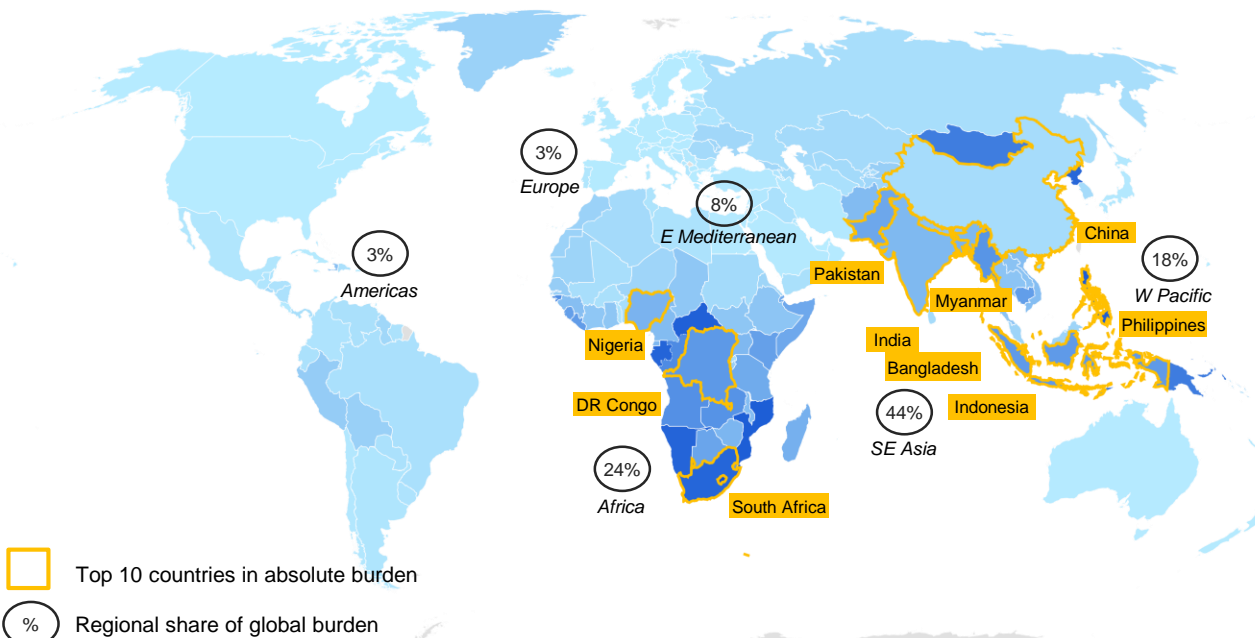
+ Global targets set at the UN high-level meeting on TB	A	At least 40 m people treated for TB 2018-22	+ 90-(90)-90 Stop TB Global Plan targets (by 2020)	90	>90% of all people with TB should be reached and placed on appropriate therapy
	B	At least 3.5 m children treated for TB 2018-22		(90)	>90% of the most vulnerable, underserved and at-risk populations, should be reached
	C	At least 1.5 m drug-resistant TB cases treated 2018-22		90	>90% treatment success for all people diagnosed with all forms of TB
	D	At least 30 m people receiving preventive treatment for TB 2018-22			
	E	\$13bn annual funding for prevention and care by 2022			
	F	\$2.2bn annual funding for TB research 2018-2022			

TB Incidence: Geographic distribution of Drug-Susceptible (DS-TB) and Drug-Resistant TB (DR-TB)

DS-TB incidence (2018)

Estimated TB incidence per 100 000 population

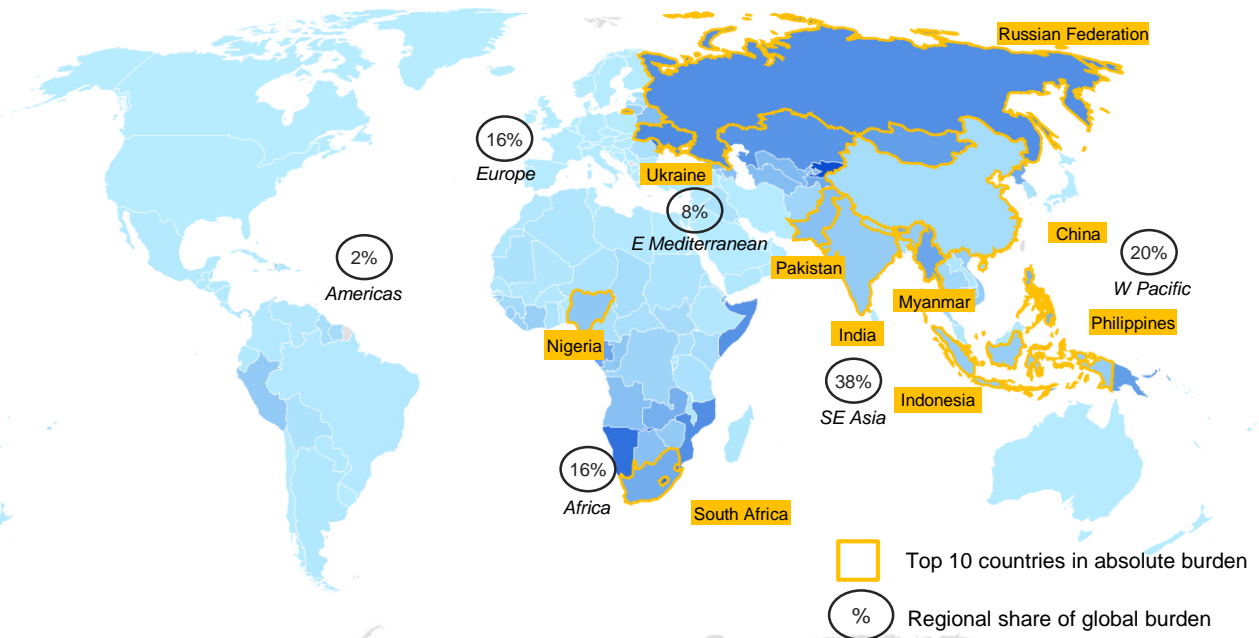
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MDR/RR-TB incidence (2018)

Estimated MDR/RR-TB incidence per 100 000 population

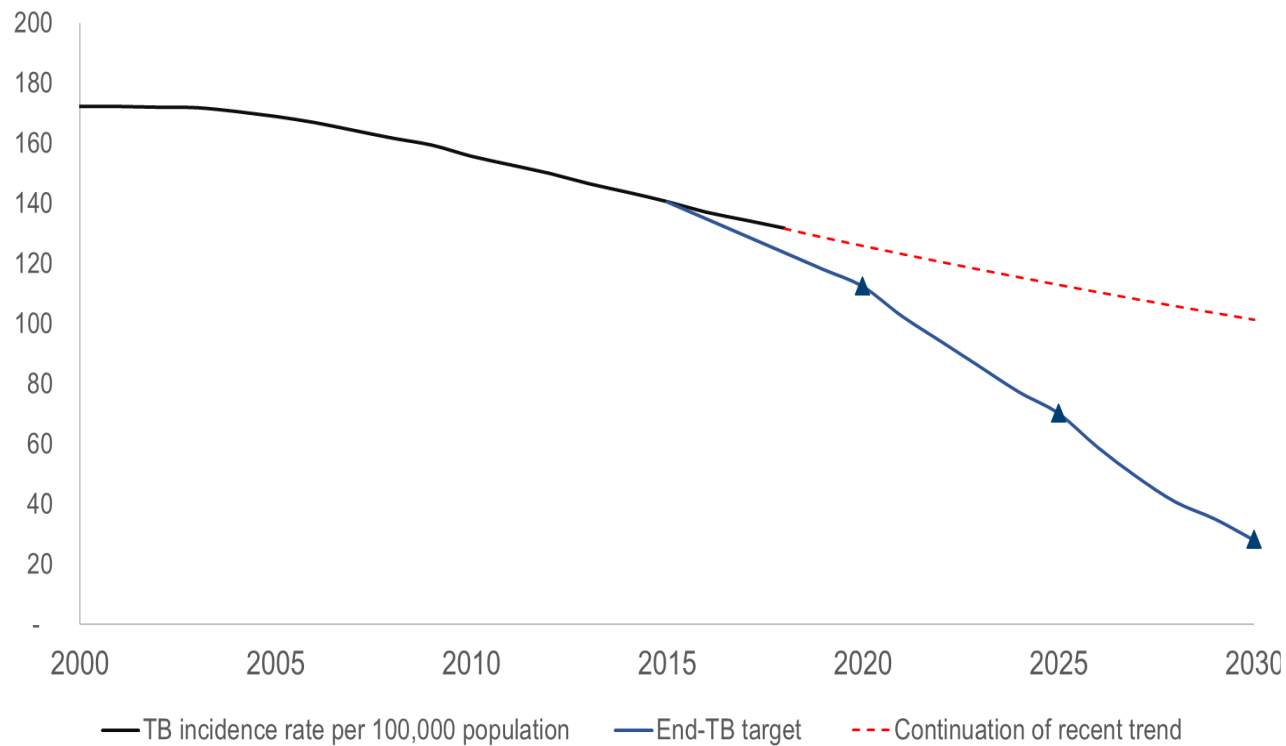
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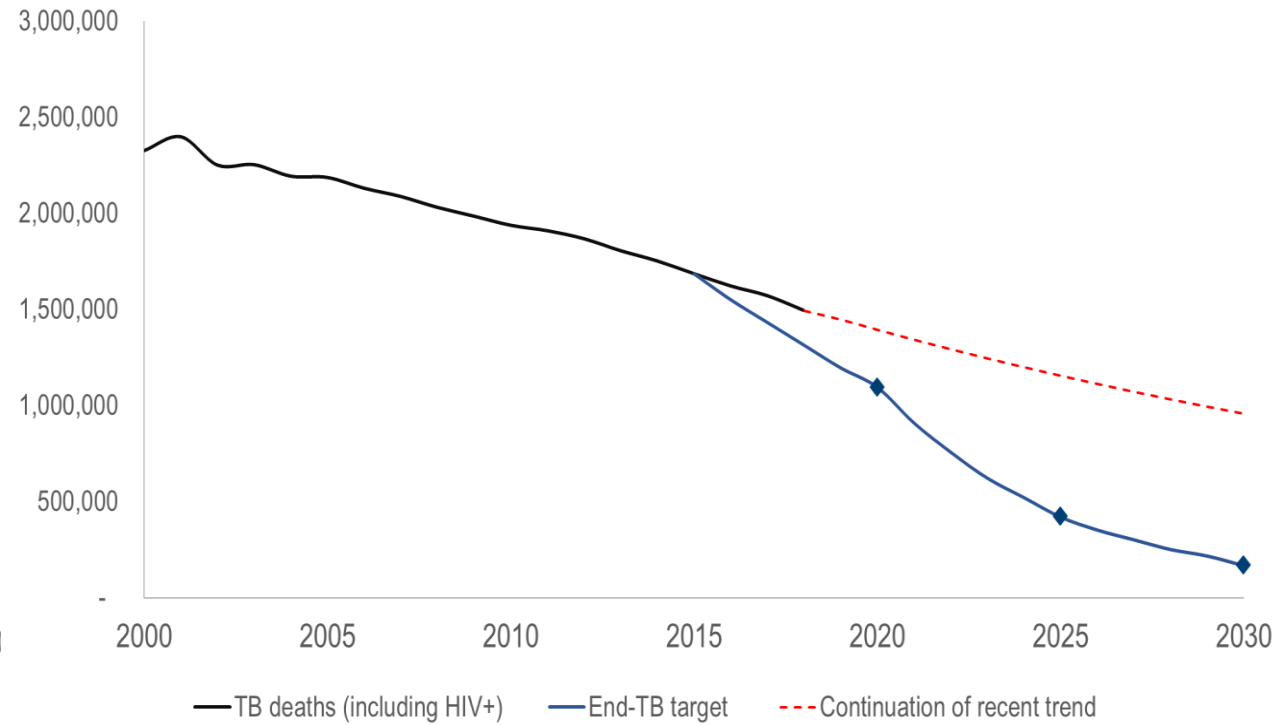
Greatest incidence of DS-TB in Asia and Africa, while DR-TB concentrated in EECA and parts of Asia and Africa

Incidence and mortality targets: acceleration needed to meet global targets

TB incidence (all countries)



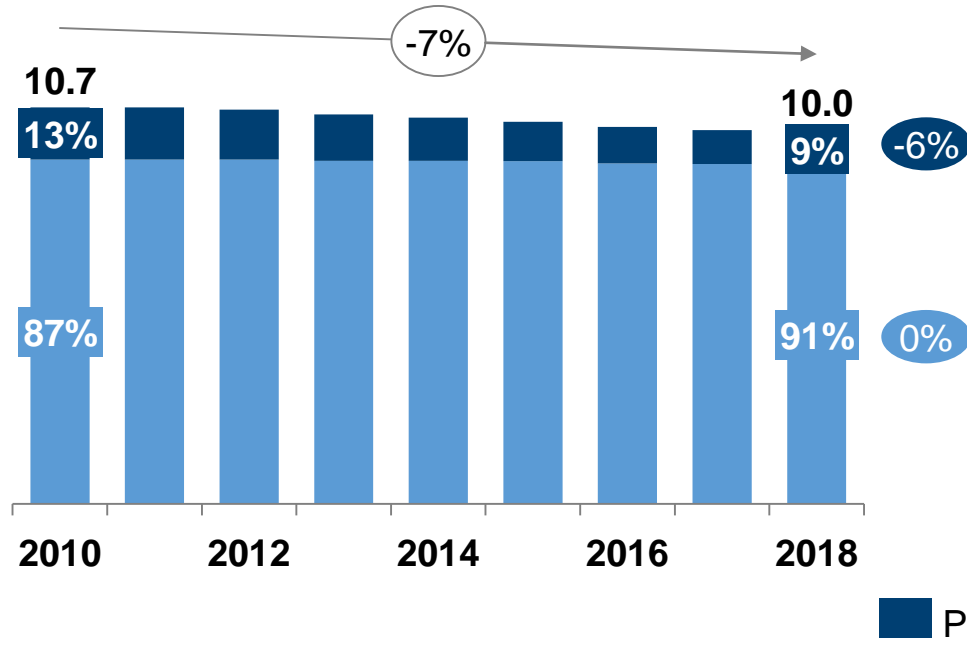
TB deaths (all countries)



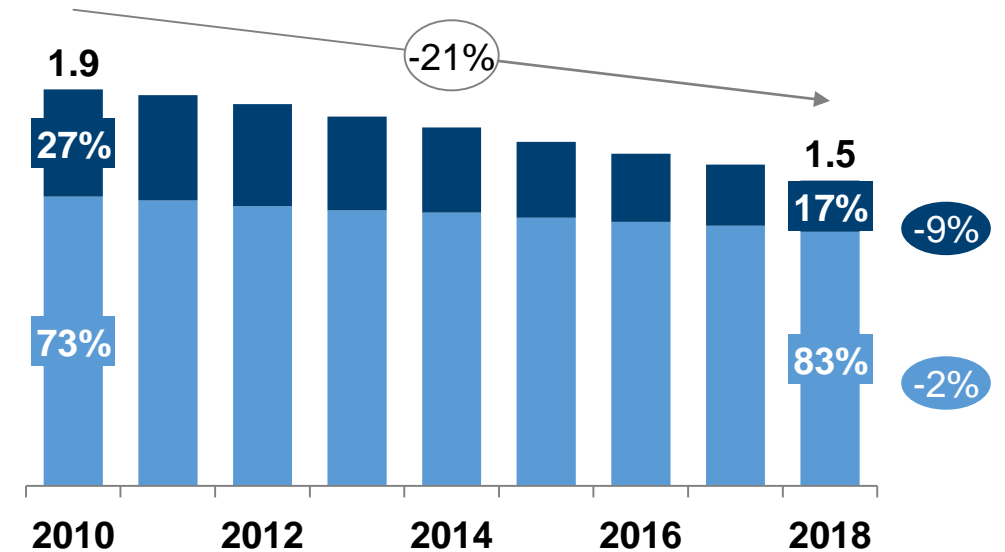
Drastic reductions in TB cases and deaths needed to reach 2030 targets

Cases and deaths: mortality has declined more than incidence

TB # of incident cases (m) (all countries)



TB # of deaths (m) (all countries)



Overall decline in mortality faster than in incidence, progress has been higher for PLHIV largely due to increased ARV coverage

High-risk groups disproportionately affected by TB, and more challenging to diagnose and treat



People living with HIV and other clinical conditions that make them more likely to have active TB*

Diagnosis and case finding, as well as achieving treatment success, is more challenging in these groups, compounded by drug-drug interactions, overlapping toxicity and reinforced stigma, discrimination and other socio-economic factors.



Refugees and other mobile populations due to precarious living conditions, stigma, discrimination, and lack of protective laws and policies, resulting in limited access to health services.



People living in poverty due to limited access to basic health services, poor nutrition and inadequate living conditions.



Children, especially younger children, due to weaker immune systems and higher risk of active TB disease after exposure and infection. Diagnostic tools are less sensitive and it is harder to collect specimens for testing.



Prisoners (incidence 100x civilian population) due to poor living conditions in prisons (overcrowding, poor ventilation), delayed TB detection, and inadequate and often interrupted treatment. Most prisoners come from socio-economically disadvantaged populations where the burden of disease may already be high and access to medical care is limited.



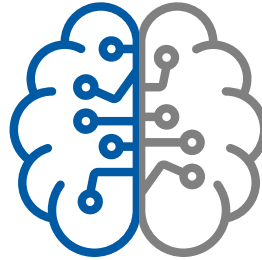
Miners and mining communities due to increased risk of developing active TB disease due to exposure to silica, compounded by often poor living condition for miners and their families.

Importance of programs responding to drivers of TB among high-risk groups; ensure treatment programs adequately address their specific needs and vulnerabilities which are compounded by gender and age

Challenges and opportunities in addressing barriers to scale-up of prevention interventions

Challenges

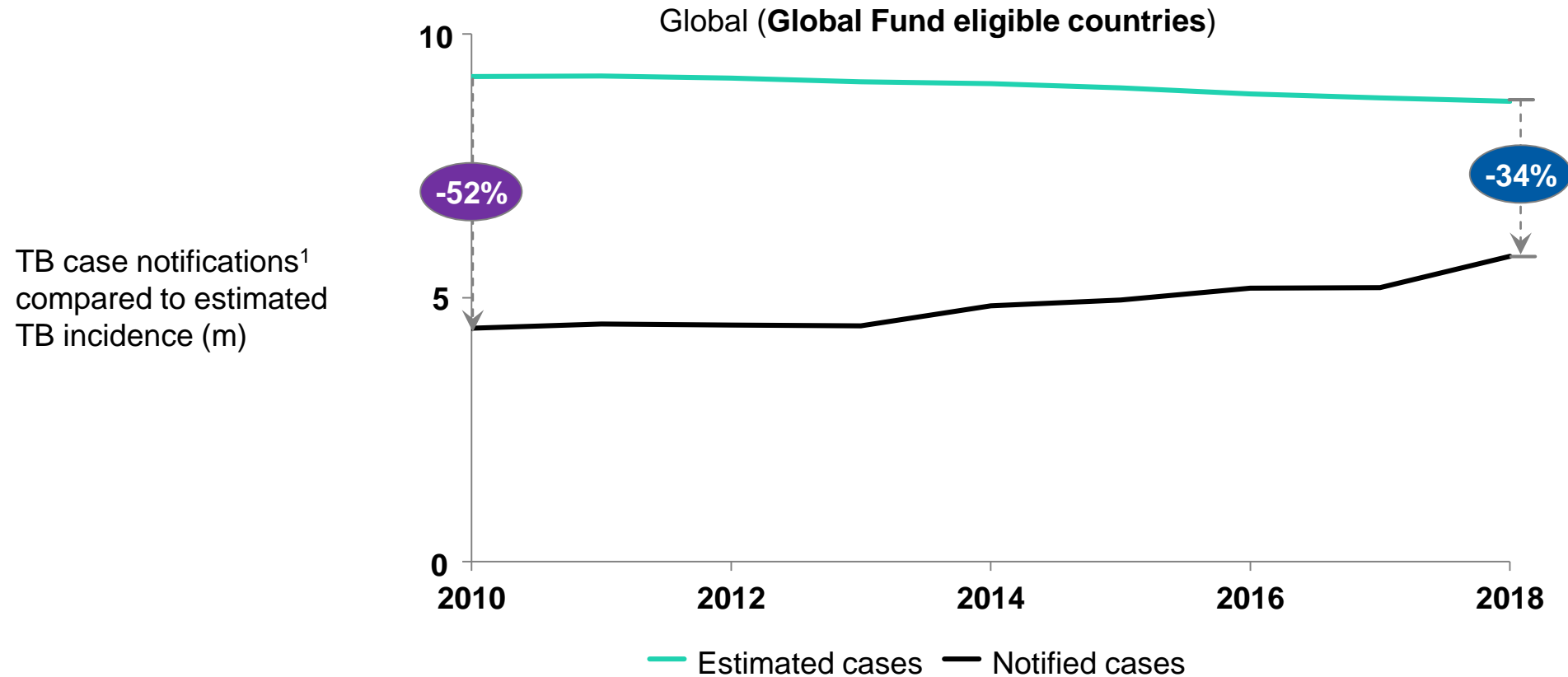
- Clinical reluctance to use TPT for PLHIV, despite evidence showing efficacy, and many countries do not include TPT in differentiated HIV services delivery
- Drug-drug interactions between TB drugs and ARVs and other medicines used to treat comorbidities
- High cost, limited availability and implementation challenges of tools to diagnose latent TB infection
- High cost and limited availability of some drugs for new TPT regimens
- Suboptimal implementation of large-scale contact tracing and investigation strategies in most countries
- Limited evidence of efficacy of preventive therapy in contacts of RR/MDR-TB patients
- Limited implementation of infection control policies, including in health facilities, and shortage of dedicated public health professionals for such tasks
- Measures that address social determinants, risk factors for TB and human rights and gender-related barriers to accessing TB services are not fully considered



Opportunities

- Scaling-up use of new, shorter regimens for TPT
- New expanded guidelines for TPT and TB prevention and infection control
- Additional funding for TPT confirmed through several mechanisms
- Catalyze existing initiatives to reduce TB incidence and mortality amongst PLHIV by scaling up TPT
- Addressing structural and policy barriers to providing and implementing TPT programs
- Community-based interventions to scale-up contact tracing and preventive treatment activities, including integrated HIV/TB health literacy programs for PLHIV
- Latent TB tests that are less expensive, more reliable and able to be used as point-of-care
- Engage with other sectors (e.g. ministries of finance, social welfare, labor, education, justice, transport) to address social determinants and risks
- New tools and guidance, including Stop TB CRG Assessments, TB Stigma Assessment and OnImpact tool, are available to better identify access barriers

Great increase in TB case notifications; yet still an estimated ~3m missing people with TB in Global Fund-eligible countries



More work to be done to close the gap of "missing people with TB"; the last mile will be the most intensive

Missing people with TB

Key challenges

- Every untreated person with TB can transmit to 10-15 people, so missing people with TB are a bottleneck in the effort to reduce incidence
- Universal access to the most effective TB diagnostics as first-line is still challenging, due in part to financing shortfalls
- Despite an improvement in access to rapid tests for TB, significant gaps remain
- Limited sensitivity of diagnostic tools in some populations, such as children, PLHIV and people with extrapulmonary TB
- Stigma, discrimination, legal, policy, gender and other human rights-related, socio-economic barriers
- Notifications have increased by almost 1 million but bacteriologically confirmed cases by less than 300,000 since 2014
- Increased notification (through finding new cases initiatives) not always matched by quality of care measures and improvements
- Sub-optimal recording and reporting systems

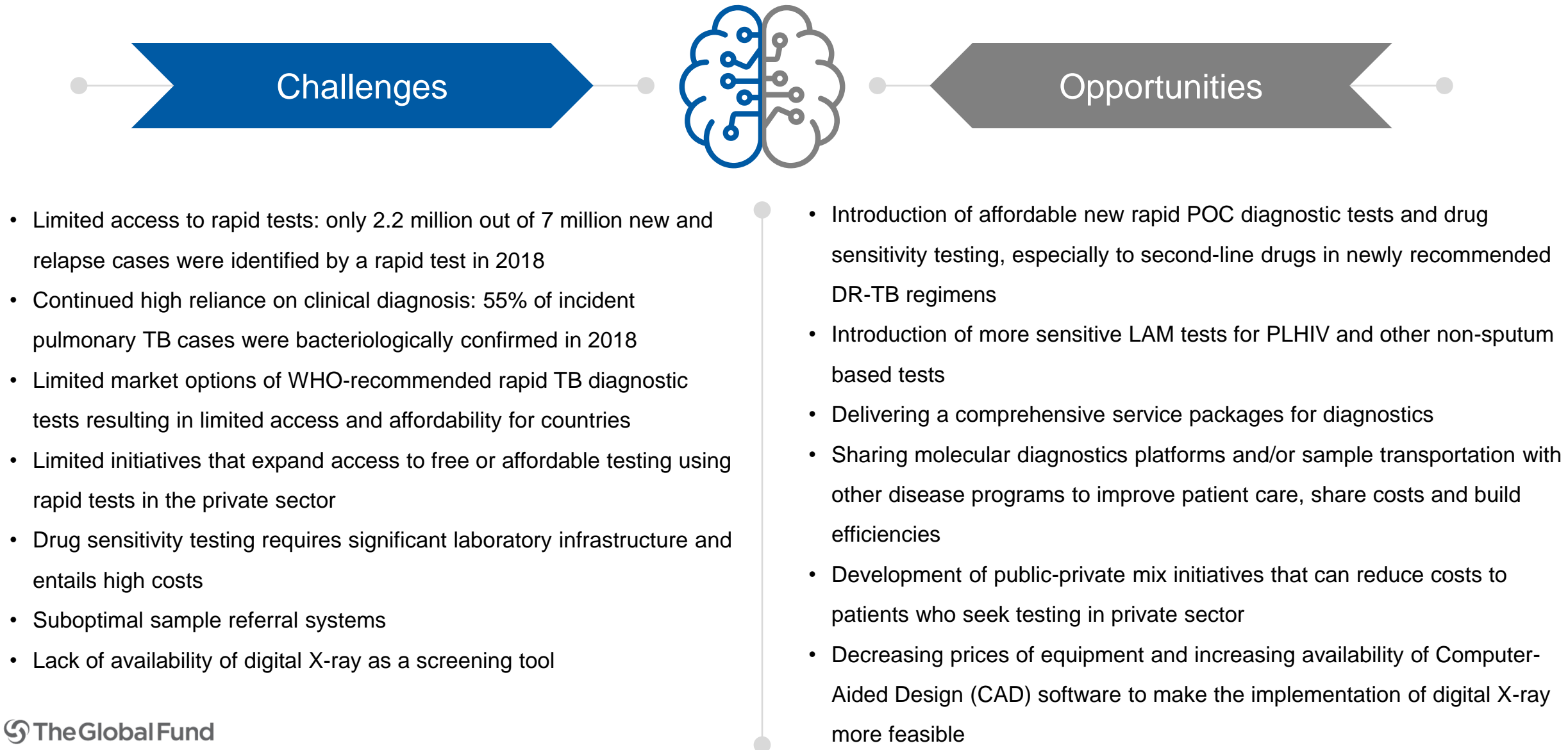
Lessons learnt

- Scaling-up innovative public-private models has been effective at finding missing people with TB, especially in Asia
- Scaling-up quality programs to address human rights and gender-related access barriers is necessary
- Innovative community engagement approaches improved TB case finding and uptake of health services among key and vulnerable populations
- Quality of TB care needs to be implemented along the entire cascade
- Need to leverage data to guide TB interventions, including sex- and age- disaggregation
- Interventions focusing on key and vulnerable populations should be tailored to specific needs

Opportunities

- Rational sharing of molecular diagnostics platforms and/or sample transportation
- Improving access to TB diagnosis, including through the development of affordable point-of-care diagnostics
- Innovations/new technologies, including more sensitive tests and non-sputum based tests
- Further scale-up successful public-private and community engagement models, including in monitoring service availability, accessibility, acceptability, affordability and quality (e.g. through community-based monitoring models)

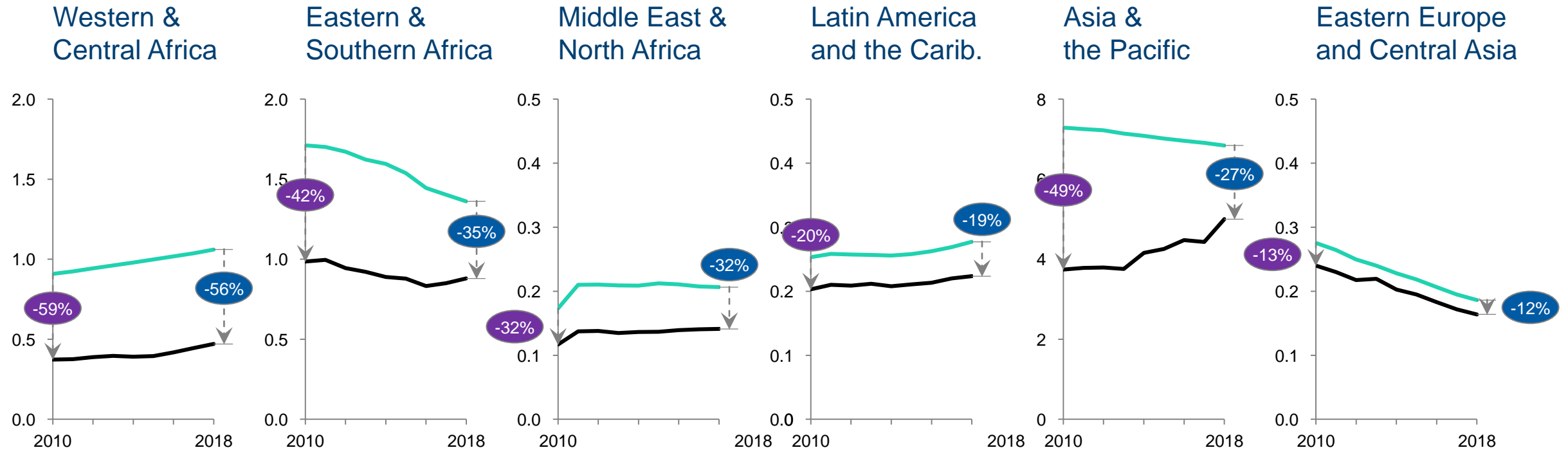
Challenges and opportunities in TB and DR-TB diagnosis



Missing people with TB: progress by region

Notifications of TB cases¹ compared with estimated TB incidences (m)

— Estimated cases — Notified cases



Reduction in number of missing people with TB largely driven by Asia & the Pacific, and India in particular

Drug-resistant TB (MDR/RR/XDR-TB) remains a global concern

MDR/RR-TB remains a problem...



~500k est. new cases in 2018
(~5% of TB cases). Only 156,000
(31%) were enrolled in treatment in 2018



56% successful treatment of
MDR/RR TB (vs. 85% for all new and
relapse cases)



Large case **detection gap** for
MDR-TB



Need for preventative efforts
that address **risk factors and
social determinants**

...with specific challenges...



DR-TB constitutes **one third of
deaths** from anti-microbial resistance
(AMR)



DR-TB treatment remains **complex**
and **costly** (>\$1000 average for
MDR-TB, vs. \$40 for DS-TB), and the
drugs cause **side effects**



Limited access to DR-TB diagnosis
due to the cost of diagnostics and the
need for significant laboratory
infrastructure



Prevention efforts for DR-TB must address
risk factors and social determinants

...calling for innovative solutions



Need for better **diagnostic tools**, shorter
and better tolerated **regimens** and
cheaper and more effective drugs.
-step up quality patient care and social
support
-full adoption of decentralized care
-strengthen human resources



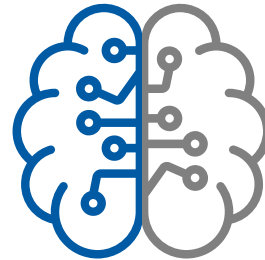
Need to **scale up the new regimens**,
especially shorter, oral regimens



Improve treatment coverage and quality
through **digital solutions**, including
through addressing socio-economic
barriers to adherence and providing
financial protection to the most vulnerable
populations

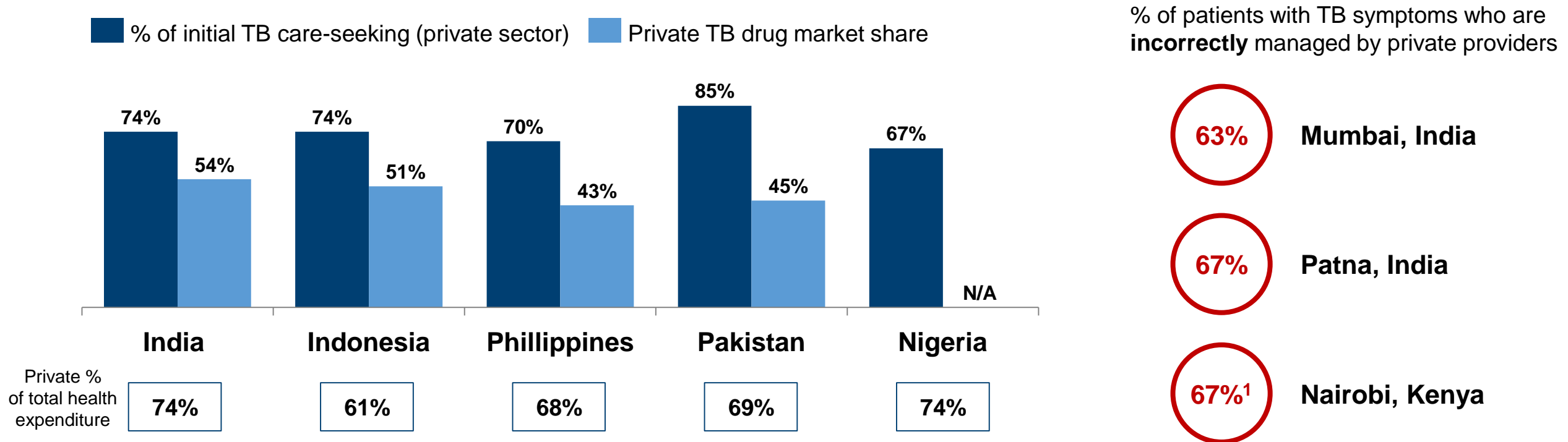
The response to DR-TB requires concerted effort, additional resources and innovative approaches to improve the coverage and quality of diagnosis, treatment and prevention services

Challenges and opportunities in supporting TB and DR-TB treatment completion



- Long duration of TB treatment (at least 6 months) and longer in the case of MDR-TB (9-12 for short regimens, up to 20 for long regimens), which are even more challenging in mobile populations. MDR-TB treatment incompleteness often exacerbated by non-patient-centered care models and insufficient patient support
- Access to DST preventing use of most effective TB treatment regimens
- DR-TB program managed as a separate or specialized entity
- Toxicity of some drugs, especially second-line drugs for MDR/XDR-TB
- Drug-drug interactions with ARVs and oral contraceptive pill
- TB and HIV services are still provided separately in some countries, despite efforts to integrate
- TB programs are highly dependent on overall health system capacity (laboratory networks, supply chains, management, data systems, human resources) and this is often very low
- Stigma and discrimination, lack of protection of human rights and social protection for key and vulnerable populations
- Implementation of people-centered health services
- Community support to follow-up and support patients on TB treatment (as well as on RR/MDR-TB care)
- New digital technologies such as Video Observed Therapy to help patients complete the treatment
- Shorter and potentially better tolerated RR/MDR/XDR-TB regimens that can improve patients' adherence to care
- Fully integrated services for TB/HIV co-infected patients to increase access to diagnosis and treatments and to improve adherence to TB and HIV care
- Ongoing efforts to strengthen health systems to ultimately build stronger and more sustainable disease programs, including through capacity building for governments and civil society and strengthening of community systems
- Treatment literacy interventions and peer-led counselling to improve treatment adherence and completion

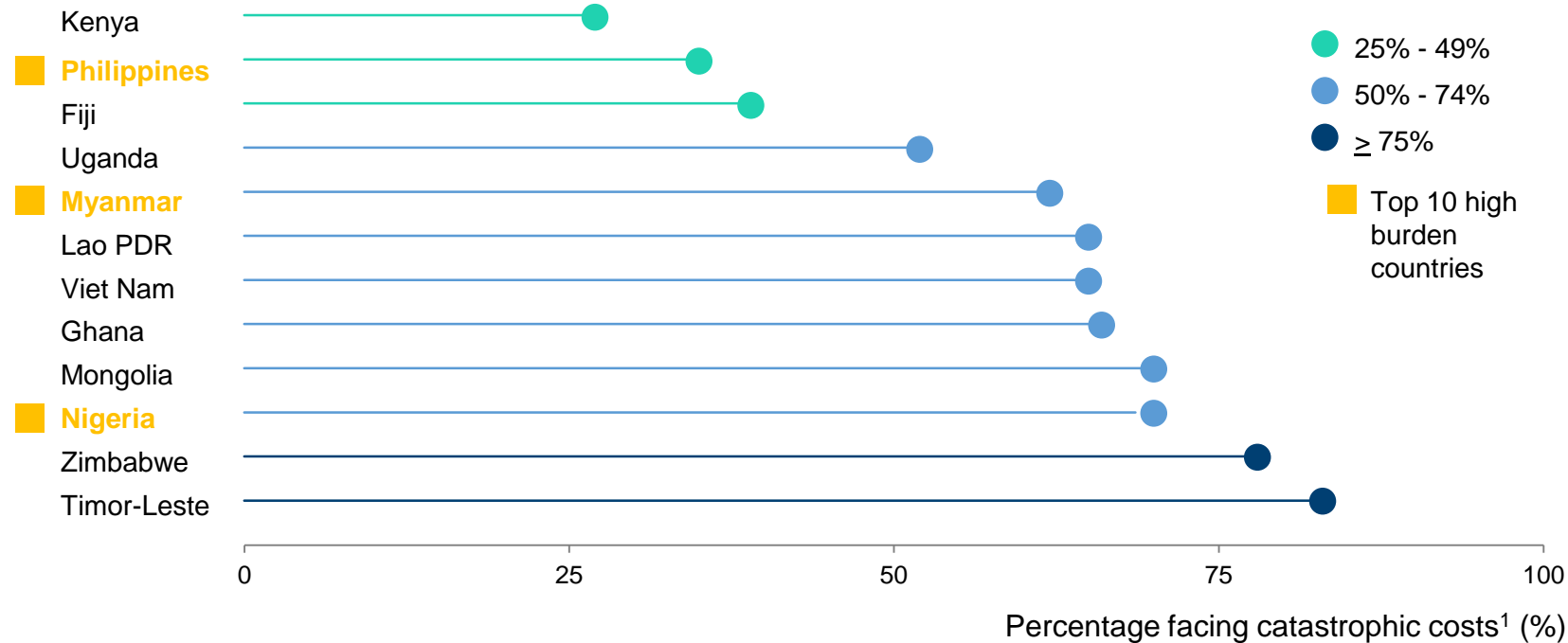
Private sector is the first point of contact in many countries, although treatment provision is sub-optimal



Urgent need to scale-up innovative private sector engagement models, especially in Asia, and make the public-private model more attractive to incentivize private providers

End TB target: TB-affected families still facing catastrophic costs

Estimate of the percentage of TB patients and their households facing catastrophic costs due to TB disease in 12 national surveys 2016-2019



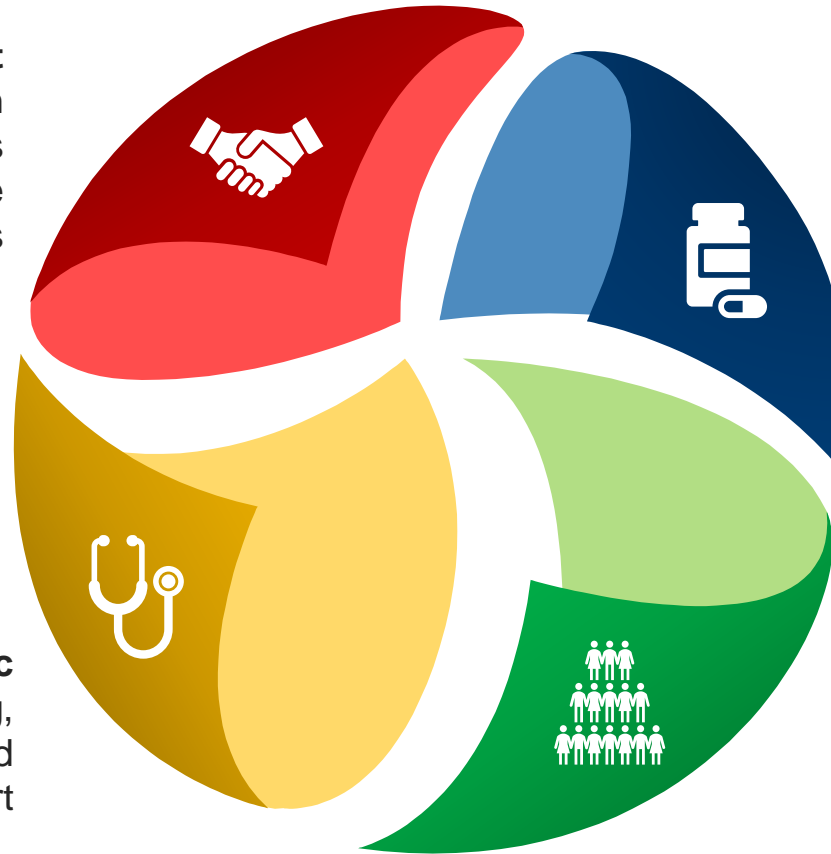
To meet End TB target, no patients and their households should face total TB costs that are catastrophic

Broader focus on UHC required to meet End TB targets; domestic resources should increasingly ensure no individuals face catastrophic costs

Stronger focus on health and community systems needed to meet global goals

Treatment adherence support through peer support, education and individual follow-up, as well as availability of high-quality palliative care services

Facilitating access to diagnostic services, e.g. initial screening, referral, specimen collection and transport

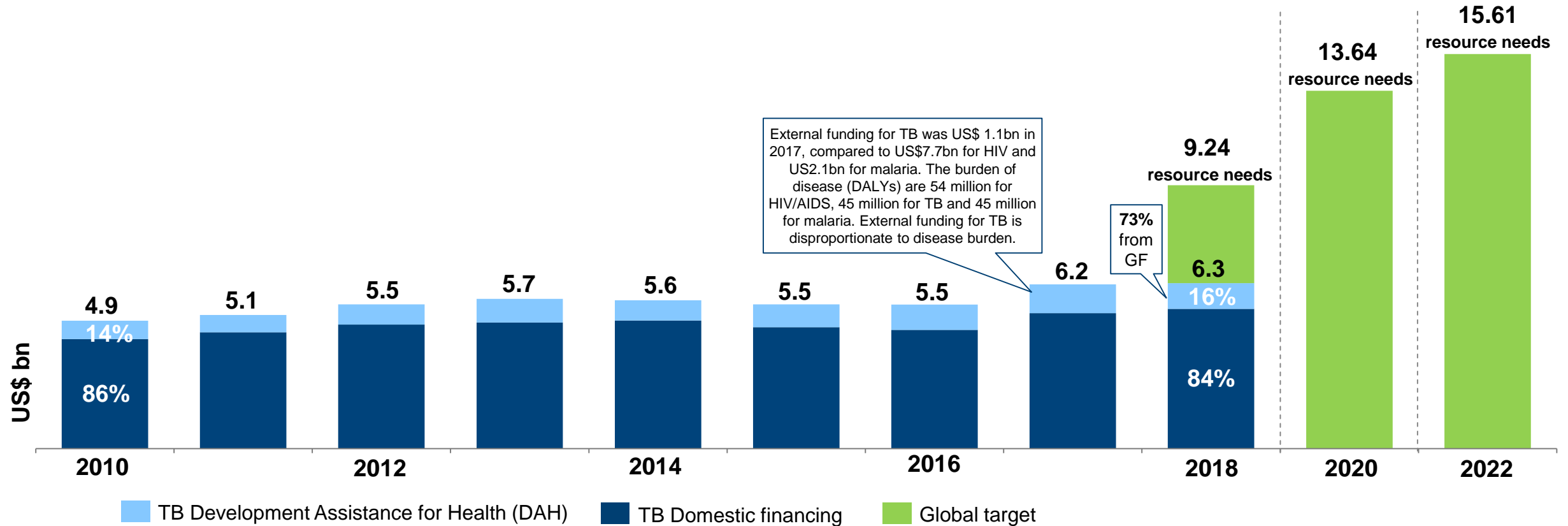


Initiation and provision of **TB prevention measures**, e.g. infection control, contact tracing and evaluation, TB Preventive Therapy (TPT)

Addressing access barriers: Financial protection, social support and rights protection, e.g. livelihood support, food supplementation, mobilization and advocacy

Community engagement in the design, delivery, monitoring and evaluation of TB interventions can help address multiple aspects of prevention and care. Integration, coordination and scale-up remain challenges

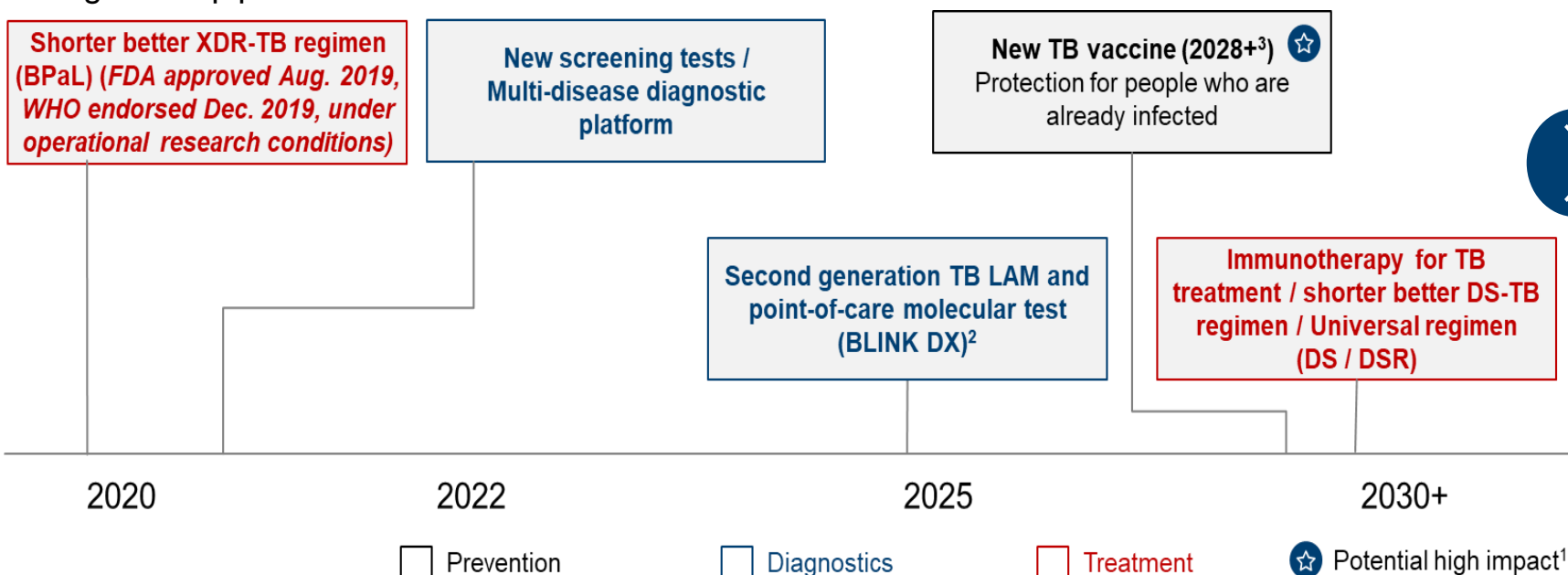
Funding gap remains large despite overall funding growth since 2010



As largest external funder, but small compared to domestic funding for TB, Global Fund should play an increasingly catalytic role that supports domestic investments

Multiple treatment and prevention tools in the pipeline; new TB vaccine in late 2020s could be promising

High-level pipeline



At country level: Rolling out new innovations at scale will require investments in delivery and information systems and capacity, including at community level

At partnership level: Ensuring coordination to prepare for efficient and effective roll-out of new technologies and products; early identification of 'game-changers'; use innovative health financing and market shaping mechanisms to enable affordable pricing of new products; support introduction and scale-up of new products; invest in demand creation; address human rights-related barriers to accessing new products

The Global Fund could play critical role in facilitating rapid scale-up of new tools

New TB vaccine could be promising



New vaccine with **50% protection¹** against active pulmonary TB could reach populations in need **from 2028 at the earliest**



If rigorous clinical trials indicate efficacy, a TB vaccine could be a **game-changer** in the fight against TB



Positive outlook, but still needs to be tested in additional populations (e.g., PLHIV) and with bigger trials before it can be licensed



Would require **long preparation phase (~5 years)** for the Global Fund to prepare for roll out, community sensitization and mobilization and evolve its approach to working with the vaccine community

Close monitoring of vaccine pipeline required to prepare for roll out if effective vaccine becomes available

COVID-19 and TB

- **COVID-19 threatens to substantially undermine progress** on TB.
- A recent modelling analysis by Stop TB et al¹ estimated that globally, a 3-month lockdown and a protracted 10-month restoration could lead to an **additional 6.3 million cases of TB between 2020 and 2025, and an additional 1.4 million TB deaths** during this time, implying a setback of at least 5 to 8 years.
- **Prevention and rapid containment of COVID-19 is a priority to minimize impact on TB programs** – need to consider responses to COVID-19 and TB together, not one at the expense of the other. Household quarantines can increase the risk of onward TB transmission to household members.
- **Maintaining essential commodities** - critical to ensure appropriate planning and monitoring to ensure procurement & supply of TB medicines and diagnostics – as well as personal protective equipment (PPE) – not interrupted.
- **Treatment** - ensuring sufficient TB drugs to cover a longer period of treatment, noting that inadequate treatment can also increase the risk of drug resistance. People with active or latent TB disease are at higher risk of COVID-19 infection and severe disease.
- **Stigma and discrimination** - stigma around respiratory symptoms could prevent people with TB from seeking healthcare due to fear of discrimination.
- **Diagnostics** - GeneXpert machines can also be used to diagnose COVID-19, which might decrease diagnostic capacity for TB and other infectious diseases. Further, symptom overlap between TB and COVID-19 may also increase demand for TB diagnosis.
- **Supply Chain** - TB specimen transport networks could be leveraged for COVID-19 diagnosis and surveillance, but may become overwhelmed.
- **Health workers** – there is a risk of health worker shortages, due to illness or task shifting away from TB to COVID-19.

1. Stop TB et al. 2020. The potential Impact of the COVID-19 Response on Tuberculosis in High-burden Countries: a Modelling Analysis.