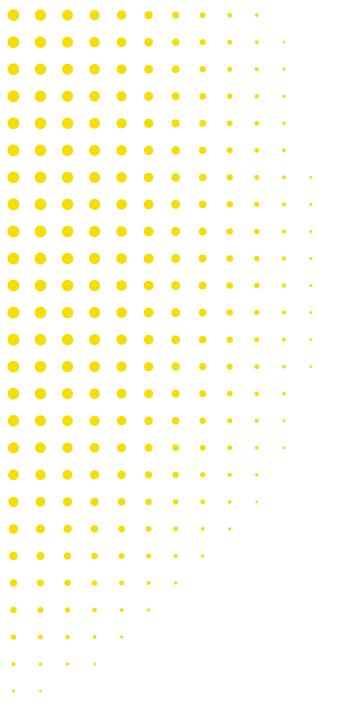
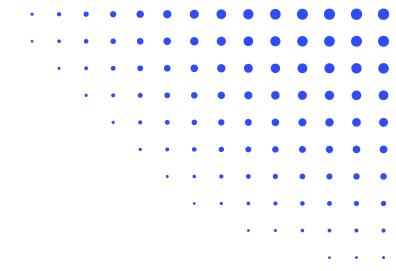


# The TB Quarterly Update Innovations

JULY 2025







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### About the TB Quarterly Update

The TB Quarterly Update is produced by the TB team at the Global Fund to share best practices, lessons learned and information from countries supported by the Global Fund, partners and other stakeholders, as well as updates on new innovations and tools coming onto market. If you have any information you would like to share, please reach out to TBQuarterly.Update@theglobalfund.org.



Cover photo: The Global Fund/Vincent Becker

# 1. What's New

## New lowest price for key tuberculosis drugs

In April 2025, the Stop TB Partnership's (STP) Global Drug Facility (GDF) announced a 25% price reduction for pretomanid produced by Lupin. The drug is now available at USD\$169 per treatment course, down from an October 2024 price of USD\$224. The price of the six-month bedaquiline, pretomanid, linezolid and moxifloxacin (BPaLM) regimen, which is used to treat drug-resistant tuberculosis (DR-TB), has also reached a new low of US\$310. These price reductions reflect ongoing efforts to improve TB drug affordability. More information is available at the <u>Stop TB website</u>.

### Regional Workshop on WHO guidelines for drug resistant tuberculosis management and uptake of innovations

Every year around half a million people develop rifampicin resistant/multidrug resistant tuberculosis (RR/MDR-TB). According to the Global TB Report (WHO, 2024), an estimated 165,400 people in the WHO South-East Asia region and 74,400 in the WHO Western Pacific region have developed RR/MDR-TB. Currently, the standard implemented treatment regimens are long, ranging between nine to 18 months. The latest WHO guidance calls for shorter, safer, all-oral and more effective drugresistant tuberculosis (DR-TB) treatment.

From April 1 to 4, 2025, the Global Fund—together with the WHO South East Asia and Western Pacific regions (WHO SEAR/WPR), the National TB Programme in Viet Nam, the Unitaid-funded Adherence Support Coalition to End TB (ASCENT) project, and KNCV TB Plus—held a four-day workshop in Hanoi, Viet Nam to facilitate rapid and effective implementation of the latest WHO guidelines on the management of DR-TB. The workshop brought together more than 80 representatives from different sectors, including national TB program managers, laboratory workers, focal points for TB in children and adolescents, civil society members, technical partners and donors. It aimed to strengthen TB prevention, diagnosis and treatment across the region. Participants shared implementation experiences in the two regions, including how to overcome barriers to introduction. The knowledge and tools gained during the workshop have the potential to drive tangible progress in the respective regions.

Session topics included: (1) WHO policy updates; (2) diagnostic methods, such as AI-CAD, next generation



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sequencing; (3) TB preventive treatment (TPT); (4) management of DR-TB in children and adolescents; (5) nutrition and market access; (6) new treatment regimens (BDLLfxC) for DR-TB; and (7) monitoring and managing adverse events, among other areas.

Parallel sessions were attended by TB advocates, civil society and partner organizations working directly with and for the communities affected by TB from eight countries, where the discussions highlighted stigma reduction strategies to shape public perceptions of TB.

## Key takeaways from stakeholder insights on near point-of-care and swab testing

The workshop focused on advancing discussion on new TB diagnostics, particularly near point-of-care (NPOC) molecular tests, which could revolutionize access to TB services and enable decentralized screening and detection. While WHO has not yet reviewed NPOC tests, understanding them and their potential use in the TB response have the potential to inform global efforts in advancing the use of new TB diagnostics.

NPOC diagnostics help expand access to TB services and diagnose more people in the communities where they are used. This is a priority for TB programs in the WHO South-East Asia region. Three potential use cases were explored during the workshop:

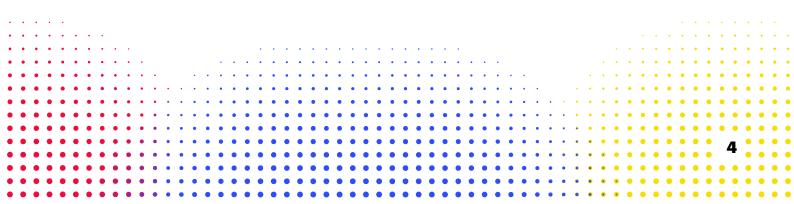
- 1. Containing costs by co-locating NPOC platforms with existing low complexity nucleic acid amplification tests (NAATs).
- 2. Replacing diagnostic microscopy.
- 3. Decentralizing diagnostics to primary healthcare (PHC) facilities.

The preferred approaches focused on replacing diagnostic microscopy and expanding access to lower health care levels, including health facilities in prisons, border posts serving migrant populations and

rural areas lacking molecular TB diagnostics. NPOCs were also considered for use in community screening activities. These discussions highlighted the urgent need to reach currently missed populations (e.g., children, migrants, hard-to-reach areas) and develop effective communication strategies to introduce and integrate this new class of diagnostics.

Key factors driving demand for new NPOC diagnostics include their lower cost, ability to decentralize testing and the use of tongue swabs for sample collection. However, one limitation is the lack of drug sensitivity testing. To ensure effective adoption, the cost benefits and decentralization capacity should be weighed against necessary changes in management, implementation logistics, and resource allocation, including human resource capacity, workload impact, space constraints in laboratories, healthcare facilities and battery requirements. These discussions underscored the importance of generating regional evidence, not only on accuracy, but also on the operational aspects for each proposed use case. Additionally, strong communication with stakeholders-including laboratory directorates, national TB programs, funding bodies, healthcare workers, civil society and other relevant groups-was emphasized as crucial for successful implementation, ensuring alignment with country-specific contexts and needs. By addressing these challenges through careful planning, stakeholder engagement and continuous quality evaluation, NPOC and swab testing implementation can greatly enhance TB diagnostic capabilities and improve patient outcomes in resource-limited settings.

The workshop concluded by emphasizing efforts to accelerate adoption of evidence-based practices and enhance programmatic approaches to DR-TB response. Resources and tools from the workshop can be found here.



# 2. Knowledge Sharing and Learning Resources

## Lessons learned: Optimizing investments to advance TB response

#### Background

Global Fund investments have driven innovation, market shaping and the adoption of advanced technologies in the fight against TB. This includes expanding access to sensitive screening tools (e.g., digital X-rays with CAD/ Al, rapid molecular diagnostic tools) and shorter, more effective treatment regimens (e.g., six-month BPaL/M for DR-TB and 3HP for TPT). These advancements have improved TB coverage and outcomes and increased the overall efficiency of TB response. However, despite an increase in the Global Fund allocation for TB in Grant Cycle 7 (GC7), funding for TB fell significantly short of the US\$22 billion target set at the United Nations Highlevel Meeting (UNHLM) on the Fight Against TB, reaching only a quarter of the required amount. Critical funding gaps and limited access to affordable health products threaten to undermine progress and underscore the need to strategically optimize interventions and use resources more efficiently. In light of these challenges, the Global Fund TB team reviewed evidence and experience in TB interventions to identify best practices and lessons learned to improve efficiencies in the global TB response. Findings from the assessment can be used to optimize financial, programmatic, and technical resources and ensure sustainability and greater impact of TB interventions, depending on the context.

#### Methodology

The study team conducted a desk review of existing literature, including published articles, policy briefs, case studies, and reports from the Global Fund and the World Health Organization, along with key informant interviews (KIIs), which provided a well-rounded understanding of current challenges and innovative strategies in TB response. The aim was to capture comprehensive insights on cost-effective, cost-efficient, scalable TB interventions and strategies, focusing on optimizing financial, human, and technical resources to improve efficiency, enhance program outcomes, and ensure



scalability and sustainability, particularly in resourcelimited settings. Additionally, lessons learned and best practices were identified, addressing challenges such as funding gaps, service delivery inefficiencies, and disparities in access to care. KIIs with representatives from international TB-focused organizations, academic and research institutions, national health ministries/ NTPs, and non-governmental organizations, offering diverse expertise across various aspects of TB response allowed for deeper insights and practical experiences related to TB funding, diagnostics, case finding, and access to care. The study team triangulated findings from the literature review and KIIs to produce key recommendations depending on country contexts, TB epidemiology and availability of resources.

#### Results

Key results emphasized integrating all TB services within existing TB programs, leveraging shared infrastructure for multi-disease integration, and optimizing the use of cost-effective and efficient screening, diagnostic, treatment tools, algorithms and strategies. Examples of cost-effective interventions identified in the study are included below:

#### Integration within TB programs

In **South Africa**, routine TB screening with contact tracing and TPT reduced costs (US\$9,050/DALY

averted). A mathematical model was used to evaluate age-based routine screening (up to five years of age) with and without contact tracing and preventive treatment in South Africa. Screening included symptom history, tuberculin skin testing, chest X-rays, and GeneXpert Ultra for confirmation. The model projected TB cases, deaths, disability-adjusted life years (DALYs), and costs. Routine screening with contact tracing and TPT for children starting at age two has averted 11,900 TB cases, 1,360 deaths and 40,000 DALYs. The combined strategy yielded an incremental cost-effectiveness ratio of US\$9,050 per DALY-demonstrating that routine TB screening for young children, combined with contact tracing and TPT, would significantly reduce pediatric TB deaths in high-incidence areas like South Africa and is costeffective.

In the Philippines, an innovative active case finding (ACF) strategy using mobile units significantly increased TB case detection and achieved high treatment success rates. The screening efforts targeted prisons, indigenous populations, and underserved urban and rural communities and enhanced case identification by combining the use of chest X-ray (CXR) and Xpert MTB/RIF. While CXR can be costly for initial screening, digital X-ray with CAD/ Al reduce expenses and streamline logistics, making them a feasible, cost-effective option for large-scale ACF in resource-limited settings. The country also implemented integrated services for people with drug-susceptible (DS-TB) and DR-TB through "iDOTs," which contributed to quick decentralization of DR-TB services, improved access and treatment outcomes, and saved patient and service costs.

In **Zambia**, a "One-stop TB services" integrated X-ray, CAD, and Xpert, improving multi-disease imaging and increasing access to affordable TB services. The "one-stop TB-service" concept facilitated access to TB diagnostics in key populations, such as those in prisons or mines, with a daily throughput capacity of over 300 individuals. Mobile diagnostic units bridged gaps in TB care by delivering services directly to highrisk and underserved populations, addressing barriers to accessibility and improving early case detection. They also provided economic efficiency through low-cost per test, ensuring affordability for patients and supporting diagnosis of multiple diseases (e.g., imaging for extra-pulmonary TB, trauma).

In **Pakistan**, private sector engagement models implemented by Mercy Corps and the national and provincial programs contributed to 45% of the national TB notification. Public-private mix models enhanced early diagnosis, improved treatment adherence, optimized resources, reduced diagnostic delays and improved patient outcomes.

## Integration of TB services with other programs and sectors

In **Zimbabwe**, an integrated specimen transportation model for TB, HIV and early infant diagnosis (EID) reduced diagnosis turnaround time dramatically: from months to just 72 hours, achieving an eight-day turnaround time for CD4 and TB sputum testing. The model covers 63 districts with a network of over 2,000 health facilities and is supported by 280 riders. The annual sample volume increased from 400,000 in 2021 to over 1 million in 2025. This has contributed to a 44% cost reduction per sample and 35% per facility. The model has also helped to improve health outcomes, such as strengthening care for infants born with or exposed to HIV, TB patients, improving sample tracking and reducing specimen rejection rates, and ensuring higher-quality results.

#### Lessons learned and next steps

While national TB programs and key TB stakeholders should advocate for more resources, including innovative and blended financing from domestic and external



sources, countries should also explore opportunities to gain efficiency and address urgent gaps in TB funding. Integration (within TB and beyond) and optimization of existing and new tools, approaches and algorithms along the cascade of care have proven effective. Evidencebased options highlighted below could be adopted, streamlined and further optimized to align with country need, context, capacity and resource availability. The following list of options provides additional details on how to gain efficiency and sustain TB responses:

Enhancing efficiency in TB programs	Integrating TB services with other programs and sectors	
Combine contact screening and TB screening in other high- risk groups with TB diagnosis, treatment and provision of TPT.	Integrate disease screening (e.g., TB, HIV, diabetes, maternal health and nutrition) across health programs for comprehensive care.	
Decentralize and integrate DR-TB and DS-TB activities.	Strengthen and empower community health workers (CHWs) for disease detection, treatment adherence and delivery of integrated health services across multiple conditions.	
Promote cost-effective, shorter treatment regimens for DR-TB and TPT and children with DS-TB.	Expand integrate sample transport networks on national/local platforms and systems for TB and other diseases.	
Optimize resources by combining screening using digital CXR with AI, sputum sample pooling and WHO-recommended rapid diagnostic tests (WRDs).	Promote multi-disease screening/testing platforms, which could contribute to resilient and sustainable systems for health (RSSH) and pandemic preparedness and response.	
Digitalize TB recording and reporting, enhance interoperability and strengthen surveillance system.	Use digital and online platforms for training and community engagement.	
Invest in new low-cost and more sensitive and specific tools for screening/diagnosis when available and recommended.	Leverage digital solutions for integrated health surveillance and reporting.	
Scale up innovative and the most efficient private provider engagement models in TB.		

For more information, find the report on "Programmatic Efficiency and Optimizing TB Response" here.

### Case study: Using the programme quality efficiency approach to integrate systematic screening for TB in the DRC

### Context

The Democratic Republic of the Congo (DRC) is among the top 30 countries with a high burden of TB, HIV/TB and DR-TB. In 2023, the TB incidence rate was 316/100,000 (WHO). The expected number of people with TB was 334,000. The incidence reported by the national TB program (NTP) in 2023 was 258,069 cases, representing a TB treatment coverage of 77%. The DR-TB gap remains significant, with more than 5,000 missing people with DR-TB in 2023. In 2022, the NTP, with the support of the Global Fund, initiated the program quality efficiency (PQE) approach, aiming to integrate systematic screening for TB within outpatient departments (OPDs) in health facilities to improve TB case detection and treatment.

#### Methodology

To start, the NTP conducted a situational analysis at health facility level to identify obstacles to DS-TB and DR-TB diagnosis and treatment, engaging entry point health staff (e.g., outpatient general consultation, antenatal care, nutrition, HIV, internal medicine, pediatrics). Roles and responsibilities were clarified to improve the quality of TB diagnosis and care, while strengthening the link between entry points, laboratory and TB focal points. The approach included monthly TB meetings, quality assurance reporting, regular mentoring and supervision and quarterly validation of data by involved provinces. The total cost to initiate the PQE approach per health facility was US\$4,675, including working tools, training and initial mentorship. The monthly running cost per PQE health facility is US\$271. This includes monthly meetings, mentorship and monitoring activities.

#### Results

Thirty health facilities piloted the PQE approach in Kinshasa in 2022. During this phase, TB notification increased from 4,957 TB patients notified in 2021 (before the intervention) to 7,841 (+58%) in 2022 (during the intervention). In 2023, 70 new health facilities were

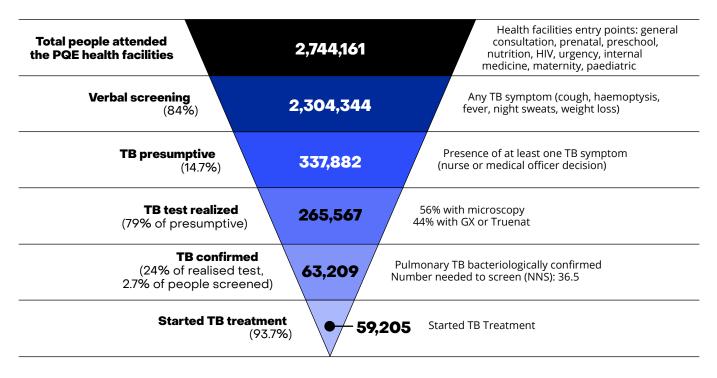
included in Kinshasa and 60 were included in Kwilu and Kwango. In 2024, the NTP extended the approach to four new provinces and 120 health facilities, covering a total of seven provinces and 280 health facilities.

From 2023 to 2024, the 280 PQE health facilities registered 2,744,161 patients (see Figure 1). Of these, 2,304,344 were screened for TB (84%), 337,382 were TB presumptive (15%), and 265,567 were tested for TB (79%). Of those tested (56% using microscopy and 44% using WHO-recommended rapid diagnostic tests), 63,209 were bacteriologically confirmed cases (24%), among whom 59,205 were put on treatment (94%).

#### Figure 1: ATB cascade results in the PQE health facilities in DRC

Source: The National TB Program

Data reported for 30 health facilities in 2022, 160 in 2023 and 280 in 2024



In 2024, the number needed to screen (NNS) in the PQE health facilities was 43 (see Table 1). This was lower than the NNS found in a 2022 review published by the International Journal of Tuberculosis and Lung Disease.<sup>1</sup> This study found that when using a positive symptom screen, the weighted mean NNS in adult

outpatients in medium/high TB incidence settings was only 463 (range 28–1,628). The cumulative number of additional people with TB identified through the PQE approach during 2023 and 2024 in the seven provinces was estimated by the NTP at 12,884.

<sup>&</sup>lt;sup>1</sup> https://pubmed.ncbi.nlm.nih.gov/35650693/

**Table 1:** TB data collected in the PQE health facilities from 2022 (pilot phase) to 2024 (scaling-up phase)

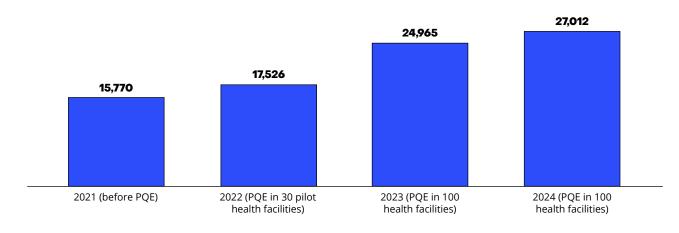
 **Source:** The National TB Program

	January to December	January to December	January to December
	2022 (pilot phase)	2023	2024
PQE health facilities	30	160 (included the 30 of the pilot phase)	280 (included the 160 of 2023)
Number of people screened/	383,730/465,413	742,981/914,001	1,561,363/1,830,160
registered in health centers	(82%)	(81%)	(85%)
Number of people with	32,062	121,880	215, 502
presumptive TB identified	(8%)	(16%)	(14%)
Number of people tested	23,427	92,987	172,580
for TB	(73%)	(76%)	(80%)
% of people tested with molecular tests	Data not available during	32,913	83,412
	the pilot phase	(35%)	(48%)
Total number of people	7,841	26,437	36,638
with TB (all forms)	(33% of people tested)	(28% of people tested)	(21% of people tested)
Number of people with TB started on TB treatment	7,568	25,419	33,786
	(97%)	(96%)	(92%)
Number needed to screen (NNS)	49	28	43

Figure 2 shows the number of bacteriologically confirmed TB patients notified in 100 health facilities in Kinshasa before the intervention in 2021 (n=15,770), during the intervention in 2022 (n=17,526), and in 2023 and 2024 (n=24,965 and n=27,012, respectively). Notably, the total number of health facilities in Kinshasa with a laboratory

and able to offer TB diagnosis in 2024 was 158, 63% of which were covered by the PQE. The variation in notification between 2023 and 2024 for Kinshasa (province) was +5% globally: 8% in the PQE health facilities and -0.1% in the non-PQE health facilities.

**Figure 2:** Number of bacteriologically confirmed TB patients notified in 2021 (before intervention) and during intervention in 100 health facilities of Kinshasa **Source:** The National TB Program



**Figure 3:** Number of bacteriologically confirmed TB patients notified before intervention and during intervention in 180 health facilities in 6 provinces in 2024



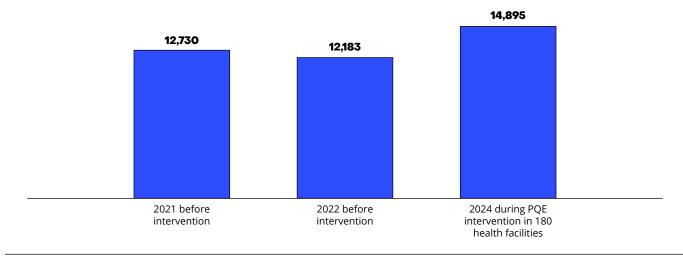
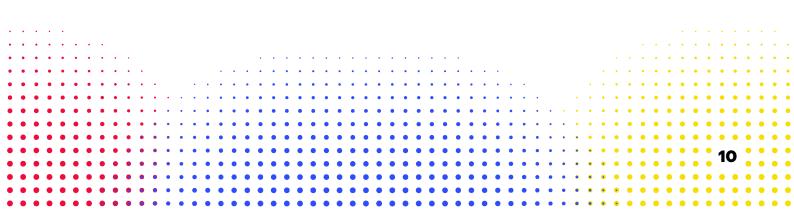


Figure 3 shows the number of bacteriologically confirmed TB patients in 2021 and 2022 (before intervention) and in 2023 (during intervention) in the 180 health facilities in Kwilu, Kwango, Sud Kivu, Mongala, Kasai Oriental and Kasai Central. The variation in notification for Kwilu and Kwango between 2023 and 2024 was +30% globally: 73.5% in the PQE health facilities and 8.5% in the non-PQE health facilities.

#### Lessons learned and next steps

By integrating TB screening in the other departments/ entry points in health facilities, DRC has improved detection of bacteriologically confirmed TB throughout the country. Moreover, monthly data analysis and performance meetings with entry point managers have provided a pathway to adopt the PQE approach. Staff reported that monthly TB reporting templates were useful tools to analyze performance during supervision and mentoring visits. Strengthening supervision of PQE health facilities has also stimulated providers to take ownership of the approach. Regular monitoring and supervision by the district and provincial team motivated staff at the health facilities to consistently screen for TB in the OPD. While the NNS appears to be aligned to similar approaches in high burden countries, there is not enough available data to develop a recommendation regarding cost-efficiency.

The NTP planned to extend the approach in four new provinces in 2025. Given expected funding cuts, the team will conduct an analysis to find efficiencies and reduce implementation costs. Reducing the frequency of monthly meetings and mentorship costs in current PQE health facilities is under discussion.



## **3. Voices**

Integrating TB control into health services remains a challenge for all NTPs. Indeed, many healthcare workers perceive TB as a dirty and highly contagious disease. This perception fosters fear, contributing to the discrimination of patients and the healthcare workers responsible for their care. It is within this context that service integration must occur to enhance efficiency. Ivory Coast's NTP has made significant efforts in this direction, including establishing container laboratories in primary healthcare facilities, using GeneXpert for TB diagnosis, viral load testing and detection of human papillomavirus (HPV), and integrating the sample transportation system with other health programs. In light of all this, integrating TB control into health services is feasible, but it must take into account key requirements such as proper completion of management tools, quality of care and daily patient monitoring. Furthermore, combating discrimination and fear are barriers that must be overcome through awareness-raising and strict implementation of infection control measures.

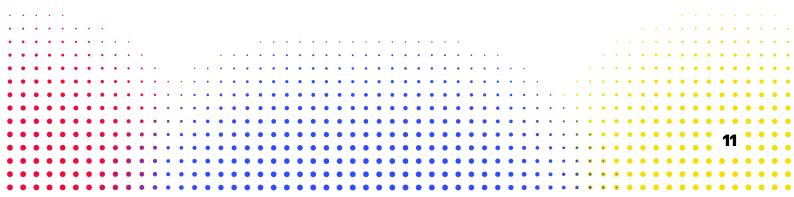
As countries face a reduced fiscal space, an integrated approach to implementation will result in efficiency gains and enable us to do much more with fewer resources. Further, multisectoral collaboration will provide opportunities to leverage resources in other sectors beyond health.



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#### About the NextGen Market Shaping Strategic Initiative

The NextGen Market Shaping Strategic Initiative, financed by the Global Fund, supports the implementation of innovative approaches and mechanisms for the introduction and scale up of new tuberculosis tools in Global Fund-supported countries. This initiative is part of the <u>Global Fund NextGen Market Shaping approach</u>, which outlines a holistic set of interventions to shape innovation and accelerate new product introductions at scale, promote capacity building for regional manufacturing and drive environmentally sustainable procurement and supply chains.