Workshop

Joint SEAR-WPR workshop to plan the accelerated implementation of new WHO TB policies

Global Fund Support for Tuberculosis Diagnostics



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Global Fund Investments in Diagnostics, including TB

- In Grant Cycle 7, the Global Fund is investing close to \$600M USD in TB screening, diagnostics and susceptibility testing over the 3-year cycle. This amounts to approx.
 25% of Global Fund's overall investment in TB (allocation \$2.4bn in GC7).
- Over 50% of this investment is towards health equipment, test and PSM costs to improve access to molecular diagnostics
- Investments also include diagnostic network assessments. Important as these can support visibility over future development of the national laboratory system in a country and support appropriate introduction new technologies





NextGen Market Shaping Strategic Initiative (SI): catalyzing impact across HIV, TB, and Malaria programs (2024-2026)

Global Fund 2023-2028 Vision and Strategy Implementation

NextGen Market Shaping SI

Drive equitable access to quality-assured HIV, TB and malaria products to meet the needs of the people and communities we serve

Accelerate Health Product Introductions at scale

Accelerate the introduction and scale-up of new, more effective health products to increase availability, affordability and uptake of the best health products on the market, working with suppliers and country teams

Promote capacity-building for regional manufacturing

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Promote health product manufacturing close to where products are consumed, building capacity among manufacturers, regional procurement platforms and regulatory processes to reduce impact from global supply chain disruptions

3

Drive in-country supply chain systems strengthening

Strengthen systems and in-country capacity for procurement and supply chain to improve availability of commodities through efficient supply chain design and operations

\$35M

The NextGen SI: Country Readiness Interventions for Tuberculosis (TB) aims to support improved access to quality diagnostics

	Component	Activities
1	Market size estimation to support and enable at-scale introduction of new TB Diagnostic tools	 Support baseline assessment of WHO Diagnostic standards Use existing DNO/DNAs to identify potential procurement needs for new low complexity NAATs, near POC platforms Landscaping/mapping of CXRs & CAD in country 20 TB priority countries + 5 WCA
2	Regional engagement to support demand for introduction of new diagnostic tools	 Facilitate regional platforms for knowledge sharing to support potential demand generation and implementation planning All interested countries in the region can participate
3	Technical assistance to translate normative guidance into national strategies and planning	 Provide technical support for guideline updates, trainings, etc. for new diagnostic tools. Open to all countries, likely towards end of GC7

Eligible Products

Urinary Point Of Care tests

- 3rd Generation LAM tests in trials
- Larger market if indication broadens to outside PLHIV
- GDG 2026 may give guidance



New sampling techniques with near Point of Care tests

- Tongue swabs
- Potentially very large market, depending on the indication
- Use in new near point of care platforms
- WHO GDG 2025/26 may give guidance



Low complexity diagnostics

- Multi-disease platforms
- Similar space as GeneXpert and TrueNat
- Additional competition to market with potential lower prices and better S&M
- GDG 2024 gave guidance on class with new products in late 2025- 2026



Notes (1)Component 1, 2 and 3 to be implemented with support from TB partners.

(2)Continuous engagement & alignment among TB partners in this space will be ensured to avoid duplication.

(3) Tools used for component 1 can be made available for countries to adopt and use to map procurement needs and or CXR mapping.

Preliminary use cases for NPOC - market estimation and implementation strategies

- **1. Cost Saving: low cost of change, considerable financial savings**
- For countries with relatively high WHO-recommended rapid diagnostic test (WRD) coverage to reduce cartridge costs
- Introduced as an initial diagnostic test, filtering off samples that require drug sensitivity testing.
- 2. Improving quality of diagnostics: Minimal cost of change, continued savings on less LC-aNAAT cartridges, Impact on WRD coverage and potentially notifications (*more sens. than smear*)
- Replacement of sputum microscopy sites (for diagnosis) with molecular diagnostics
- Already linked to existing infrastructure (HR, sample referral systems to DST, Rx initiation etc.)
- 3. Improved access to diagnostics: Considerable cost of change, positive impact on notifications and WRD coverage.
- Decentralization to PHC levels, increasing access to communities. Potentially further tiered in line with DNO/DNA information (TAT, distance to HCF)
- Infrastructural costs include decentralizing TB treatment, sample referral systems, etc.

Market Shaping: Bringing affordability forward.

To Shape the market, we need to know the size of the market



Market Demand: What are countries plans for new near POC tests? To discuss more today.

Serviceable Market (Budgeted): What

budget is available – domestic and others. Can demand and budget be matched with market shaping activities?



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Thank you



The Global Fund to Fight AIDS, Tuberculosis and Malaria

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Driving Access and Affordability: Integrated Procurement Strategy for Multi-Disease Diagnostics

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In line with the Next Gen Market Shaping Framework, we are currently implementing an **integrated molecular diagnostics procurement strategy** to create better conditions for cross-disease use of multiplex technologies (ie. diagnostics that can be used for several diseases). This would allow us to combine test quantities from HIV, TB and other diseases to improve our commercial leverage and stimulate lower prices for TB tests



Additionally, we encourage the development of more affordable TB tests both in molecular technology and simple rapid tests through **supplier engagement and procurement processes**. We are closely monitoring the progress of new multi-disease diagnostic platforms bringing additional competition in the space as well as the development of a completely new class of near-point-of-care molecular diagnostics for TB, which we are hoping will receive WHO guidance during GC7.