TB Diagnostics Webinar: Where do we go from here? Unitaid investments in TB Diagnostics and diagnostics in the new strategy
A 1.5b$ portfolio covering a range of diseases and areas

83 projects

USD 1.5 billion
Unitaid 2023-27 strategic framework

**Vision**

EQUITABLE ACCESS TO HEALTH INNOVATIONS TO ENSURE HEALTHY LIVES AND PROMOTE WELL-BEING FOR ALL

We expand the reach of the best health products for those who need them most

We design and invest in innovative approaches to make quality health products available and affordable in low- and middle-income countries. We inspire and promote collective efforts with partners, countries, and communities, unlocking access to the tools, services and care that can deliver the best results, improve health and address global health priorities.

**Mission**

We invest in health products, that...

- Improve health outcomes, in particular at primary care level and for HIV, co-infections, TB and malaria
- Support people and communities in engaging with their own health
- Contribute to making health systems more efficient and resilient, including for future challenges
- Contribute to making health care greener and more conducive to sustainable development

**Strategic principles**

We ensure equitable, intersectional and people-centered approaches across our model

**Strategic Objectives**

1. Accelerate the introduction and adoption of key health products
   - Boost the development of fit-for-purpose health products
   - Use market shaping approaches to enable suitable, affordable, quality supply
   - Support product adoption and scale up in countries, as part of simple, effective and evidence-based models of care

2. Create systemic conditions for sustainable, equitable access
   - Establish an enabling environment for access, including IP and regulation
   - Support innovative supply models & approaches, including local manufacturing and technology transfer
   - Disseminate knowledge and evidence on access

3. Foster inclusive and demand-driven partnerships for innovation
   - Maximize the engagement of affected communities and responsiveness to their needs
   - Maximize alignment and synergies with governments, in-country stakeholders, affected communities and civil society organizations
   - Further develop global alliances for product scale up

**Programmatic Priorities**

- HIV & co-infections
- TB
- Malaria
- Women & children’s health
- Respond to global health emergencies

Cross cutting technologies and topics
Programmatic priorities

HIV & co-infections
- Sustain effectiveness of prevention & treatment
- Optimize and enable scale of AHD packages of care
- Drive HCV elimination through testing and prevention
- Increase access to screen & treat for cervical cancer and STIs

TB
- Enable TB prevention tools for high-risk groups
- Accelerate adoption of new drugs and regimens

Malaria
- Introduce and optimize prevention tools
- Improve access to quality case management

Women & children’s health
- Improve access to better tools for safe pregnancy and birth for women and newborns

Respond to global health emergencies
- Improve quality of clinical care packages for COVID-19

Decentralize testing and treatment for COVID-19

Accelerate access to self-testing & integrated diagnostics

Long acting & new technologies

Intellectual Property, regulatory and innovative supply models
TB in Unitaid’s Portfolio
Unitaid TB investments: 29 countries across 5 WHO regions

**Region of the Americas**
- Brazil (3), Peru (1)

**Africa**
- Cameroon (2), Cote d’Ivoire (2), DR Congo* (1), Ethiopia* (2),
  Ghana (1), Kenya* (2), Lesotho (2), Malawi (2), Mozambique* (2),
  Nigeria (1). Sierra Leone (1), South Africa* (5), Tanzania (3),
  Uganda (2), Zambia (1), Zimbabwe (2)

**SE Asia**
- Bangladesh (1), India* (5), Indonesia* (1),
  Pakistan* (1)

**Western Pacific**
- Cambodia (2), China* (1), Philippines* (2),
  Vietnam (2)

**European Region**
- Georgia (1), Ukraine* (1),
  Kazakhstan* (1)
Call For Action

(...) Accelerate the development of, and access to, essential new tools to end TB. **By ceasing**, before World TB Day (24 March) 2021, the use of all outdated and harmful TB diagnostics, drugs and models of care (including injectable-based regimens and **smear microscopy**), for all in accordance with the WHO Guidelines.

(...) Instead, **scaling-up access to** newer, safer and quicker options, and fast-tracking the development of priority, innovative new tools, including: an accessible vaccine; a rapid, user-friendly and point-of-care test; and shorter and less side-effect prone treatments for all forms of TB. Also, **funding the operational and implementation research necessary to improve TB treatment outcomes for all**.

Source: First Global TB civil society and affected communities accountability report on UNHLM TB progress
Reminder: Main challenge identified in Disease Narrative update

Existing Tools

Limitations

- Lack of simple tool
- Lack of performance in a single tool (specificity and sensitivity)
- Lack of reliable power sources
- Use primarily at centralized labs and higher level clinics
- Too expensive for triage testing
- High technical knowledge required

Low or No TB case detection at primary and community levels
Overview of Unitaid’s TB portfolio

Accelerating tools to drive TB Diagnosis

Better use of existing tools

Development & introduction of new tools

Enable preventive TB treatment in high-risk groups

Long-acting formulations

Scale-up of better TB treatment for children

Better, shorter treatment for MDR-TB

Long-acting formulations

Prevent

Test

Treat

Adherence

CROSS-CUTTING

Intellectual property, quality, WHO enabler
## Unitaid Direct TB investments - $290M invested

<table>
<thead>
<tr>
<th>Project name &amp; Lead Implementer</th>
<th>Budget (US $)</th>
<th>Timeline</th>
<th>Description</th>
<th>Focus areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascent</td>
<td>14.0m</td>
<td>Jul 19-Dec 23*</td>
<td>Scalable, affordable, patient-centred treatment support package informed by DAT</td>
<td>✓</td>
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<tr>
<td>endTB</td>
<td>81.4m</td>
<td>Apr 15-Dec 23</td>
<td>Shorter, safer, simpler to administer, more effective and affordable MDR-TB regimens</td>
<td>✓</td>
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<tr>
<td>BENEFIT</td>
<td>20.6m</td>
<td>Oct 19-Dec 24</td>
<td>Improved child-friendly prevention and treatment solutions for MDR-TB</td>
<td>✓ ✓</td>
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<tr>
<td>Seq&amp;Trt</td>
<td>14.5m</td>
<td>Oct 19-Sep 23</td>
<td>Catalyse the use tNGS for rapid and comprehensive TB drug resistance testing</td>
<td>✓</td>
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<tr>
<td>CaP TB</td>
<td>36.4m</td>
<td>Oct 17-Sep 22</td>
<td>Facilitate demand, adoption, and availability of treatments for scale-up of paediatric TB care</td>
<td>✓ ✓ ✓</td>
</tr>
<tr>
<td>TB Speed</td>
<td>14.7m</td>
<td>Sep 17-Aug 22</td>
<td>Available, feasible, cost-effective, and decentralized childhood TB diagnostic approach</td>
<td>✓ ✓</td>
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<tr>
<td>IMPAACT-4TB</td>
<td>78.1m</td>
<td>Sep 17-Dec 24</td>
<td>Increased access to more affordable TPT with a focus on 3HP in PLHIV and child contacts</td>
<td>✓</td>
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<tr>
<td>DriveDx4TB</td>
<td>15.9m</td>
<td>Aug 22 - July 26</td>
<td>Introduction of 3 new technology classes (3rd Generation LAM; POC MDx and near POC MDx)</td>
<td>✓</td>
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<tr>
<td>Start 4-All</td>
<td>14.8m</td>
<td>Aug 22 - July 26</td>
<td>Optimized TB diagnostic combinations at primary care level</td>
<td>✓</td>
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* - NCE under development
Seq&Treat: Next Generation Sequencing for Drug Resistant TB Testing

- Dossier of trial data, costing analysis and modelling to support WHO guidance on sequencing based diagnosis of DR TB
- Knowledge base to enable standardized analysis and interpretation of sequence data
- Proof of principle of sustainable and scalable delivery models
- Access pricing
Start-4-All: Combine diagnostics and tailor to context for improved performance at primary care

**Problem:**
No single test suitable for all screening/diagnosis use cases

**Combining diagnostics in algorithms**
- Use in sequence/parallel
- Selected by 3Us: Use, Usability, Users
- Rule-in vs. rule-out
- Optimise accuracy

**IMPROVED TB DETECTION**

**Prioritise by population & setting**
- Integrated reporting and linkage to treatment

**Time to results**
- Costs of individual and total tests
- Yield and accuracy
- Alignment to current algorithms

**Countries:**
- Bangladesh
- Brazil
- Cameroon
- Malawi
- Nigeria
- Kenya
- Vietnam
Drive4DXTB: Supporting the introduction of 3 new classes of TB DX products

India
Kenya
South Africa
Vietnam
IMPACT Potential : TB Dx (FIND and LSTM)

Central Scenario

Additional ~500K diagnosed in 2031 (representing 15% of the global missing population)

➢ Assumptions: 3% additional people diagnosed per year (.5%–1% increase in India)

➢ Population groups:
  • Primary health attenders
  • District/Secondary hospitals
  • Key marginalised populations
  • Children

People Correctly Diagnosed (in millions)

<table>
<thead>
<tr>
<th>Year</th>
<th>Project countries</th>
<th>Scale-up countries</th>
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<tbody>
<tr>
<td>2022</td>
<td></td>
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<td>2023</td>
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<td>2030</td>
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<tr>
<td>2031</td>
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India

Current trend (counterfactual)
Thank you!

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