Integrated Molecular PCR Technologies Procurement

Engagement Session

27 June 2024

Disclaimer

The Global Fund Procurement Strategy on **Molecular PCR Technologies** is currently under development and will be finalized after the meeting.

This presentation covers the Global Fund's current intention, which is subject to change.

The data and information herein are provided for illustrative purposes and derive from a limited and preliminary analysis by The Global Fund.

The present document shall not be considered as The Global Fund's representation or commitment of any kind.

Agenda, June 27

13:00 – 13:45	**Welcome & Global Fund updates**		
	1. Opening remarks	15m	Hui Yang / Head, Supply Operations – The Global Fund
	2. NextGen Market Shaping	15m	Ellie Marsh / Senior Manager, Strategy, Procedure and Innovation – The Global Fund
	3. Pooled Procurement Mechanism (PPM)	15m	Lin (Roger) Li / Senior Manager, Direct Sourcing – The Global Fund
13:45 – 15:00	**Disease and technical updates**		
	4. HIV Update	20m	David Maman / Senior Disease Advisor, TAP – HIV – The Global Fund
	5. TB Update	20m	Grania Brigden / Senior Disease Advisor, TAP –TB – The Global Fund
	6. WHO Prequalification	20m	Anne-Laure Page & Susie Braniff / WHO PQ program
	7. Global Fund QA and ERPD	15m	René Becker-Burgos / Specialist, Diagnostic Products Quality Assurance – The Global Fund
15:00 – 15:10	*Break*		
15:10 – 15:30	**Partner's Molecular PCR Strategies**		
	8. PEPFAR Sourcing Strategy	20m	Matthew Wattleworth & Konrad Bradley / Senior Laboratory Systems Advisors, USAID
15:30 – 16:30	**Global Fund Molecular Technologies Procurement Strategy & Tender Timeline**		
	9. Molecular PCR Technologies Sourcing Strategy 2024-2026	30m	Aziz Jafarov, Mustafa al Samaraee, / Health Technologies Team – The Global Fund Thomas Schuster / Health Technologies Team – The Global Fund
	10. Request for Proposals (RFP) Approach, Timeline & Due Diligence	15m	Artem Lazurenko / Specialist, Integrity Due Diligence (IDD), Ethics Office – The Global Fund
	11. Q&A / Discussion	15m	All

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Opening Remarks

Hui Yang
Head, Supply Operations Department
The Global Fund

Executive Summary

The Global Fund Diagnostics Procurement

The Global Fund's overall **two-phase Diagnostics Procurement approach** was launched in December 2023. The two-phase approach was adopted to **appreciate the different nature and specific market dynamic patterns** between Rapid Tests and Molecular PCR Tests.

Phase 1 covered Rapid Diagnostics Tests (RDTs) for HIV, Malaria and Co-Infections. This phase is at the final stage.

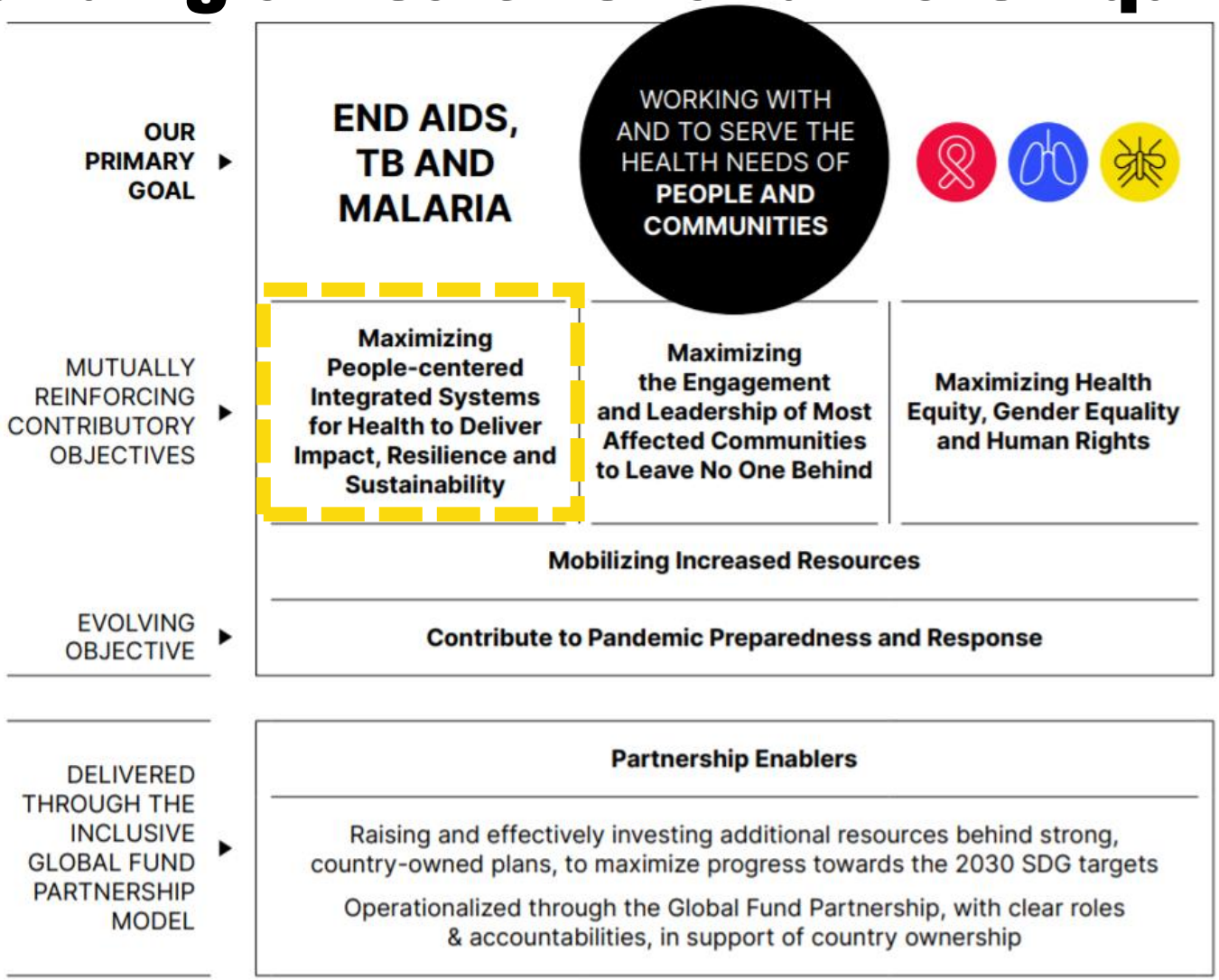
Phase 2 now covers Molecular Technologies, with latest updates on **procurement strategy, reflecting on key objectives, opportunities, challenges and timeline.**

- The expected goal is to **promote equitable access** to molecular HIV, TB and Co-Infections tests and to promote the **implementation of innovative procurement modalities.**
- It will effectively support the creation of a **platform for integrated use of multiplexing technologies** across the targeted diseases.

Next Generation Market Shaping (2023-2028)

Ellie Marsh
Senior Manager, Strategy, Procedure and Innovation
The Global Fund

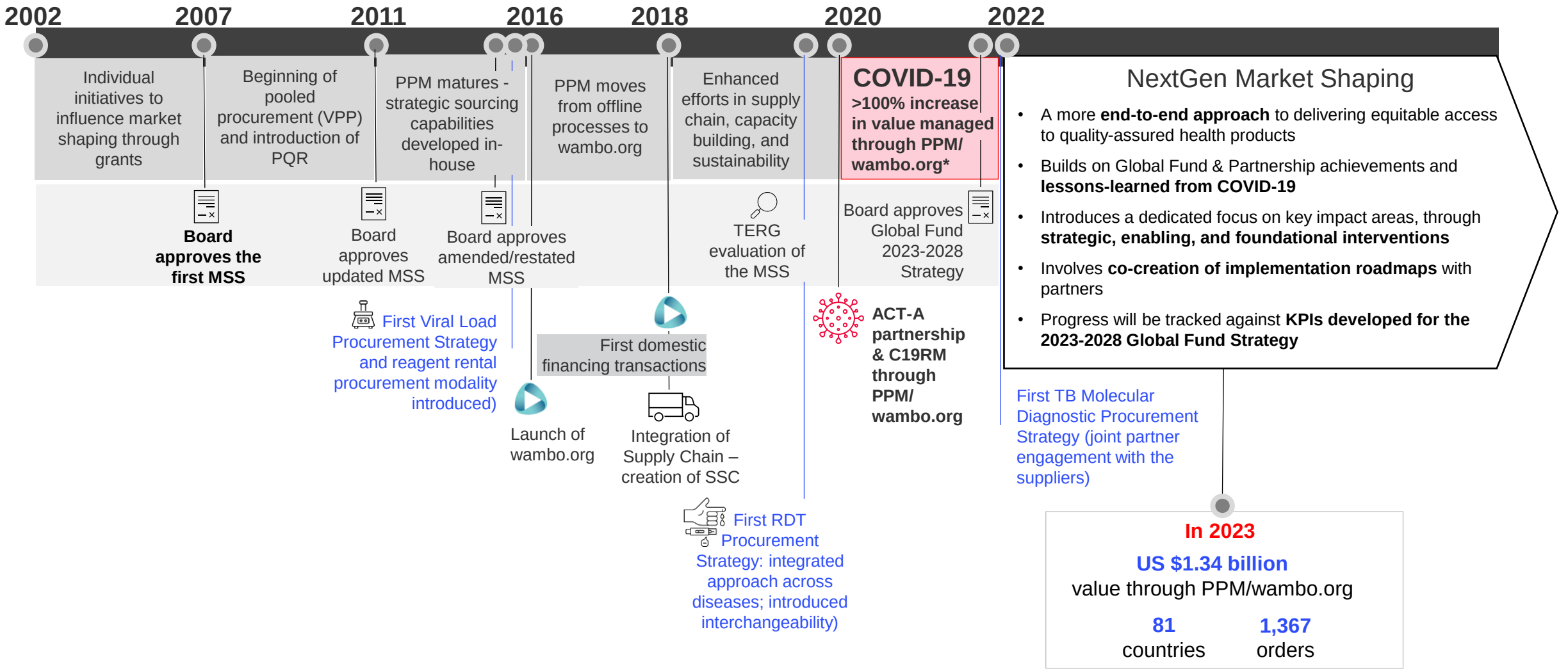
2023 - 2028 Global Fund Strategy: Fighting Pandemics and Building a Healthier and More Equitable World



Equitable access to quality assured health products and innovations is **critical** to deliver on more resilient and people-centered integrated systems for health.

Health products remain the **number one tool** to address HIV, TB and malaria, and for ending the three diseases.

Evolution of the Global Fund's Market Shaping partnership efforts, including for diagnostics



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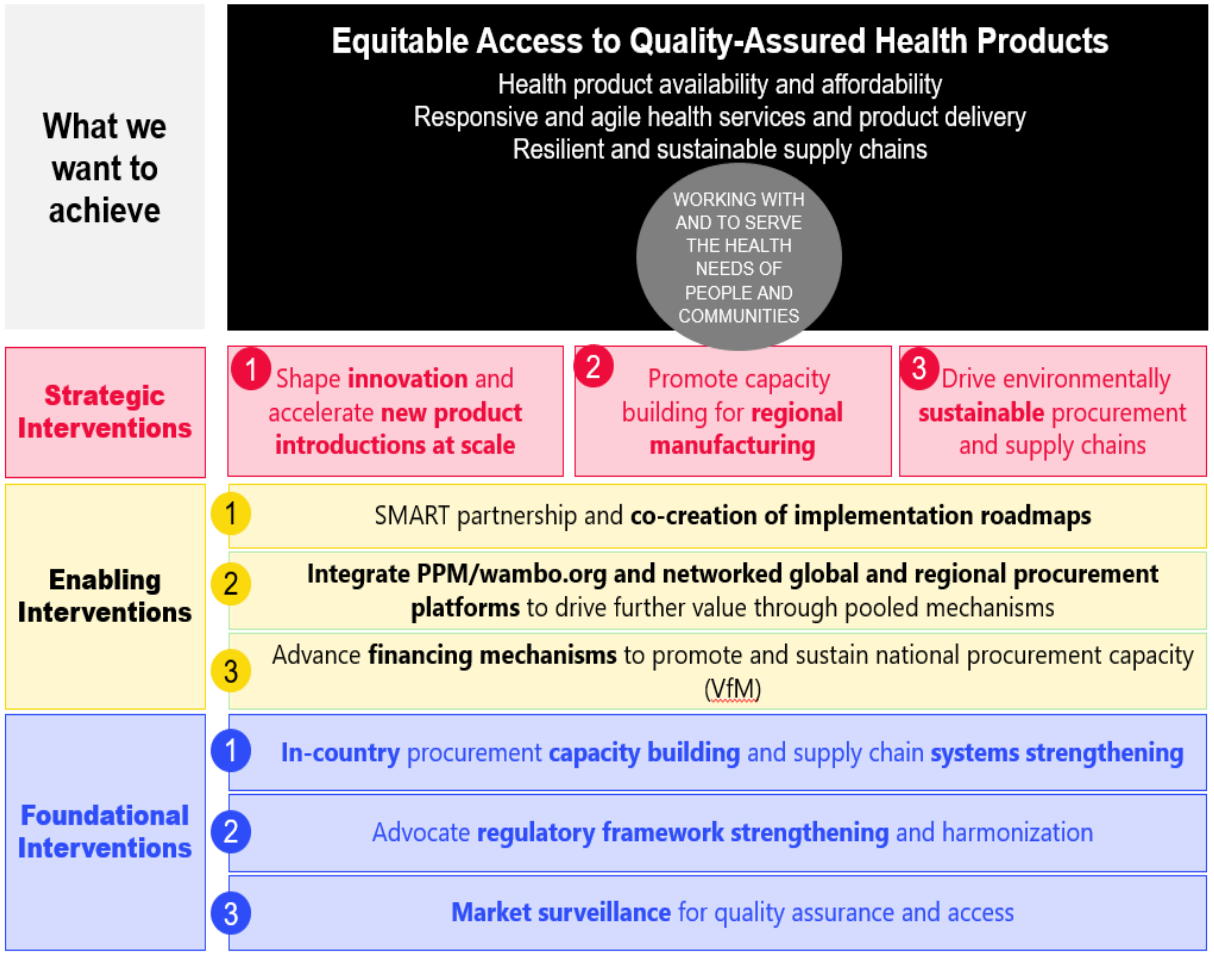
ARVs = Antiretrovirals
LLINs = Long-lasting Insecticidal Nets
ACTs = Artemisinin combination therapies
MSS = Market Shaping Strategy
PPM = Pooled Procurement Mechanism
SSC = Sourcing and Supply Chain
*US$ 958M in 2019 versus US$ 2.2 billion in 2021
PQR = Price and Quality Reporting
VPP = Voluntary Pooled Procurement

Global Fund's NextGen Market Shaping approach to drive equitable access to quality health products



Global

1. Work with industry and partners to **drive innovation that is accessible** to LMICs
2. Secure supply that is **affordable, available, quality and responsiveness**
3. Foster **South-to-South collaboration**

Regional

1. Leverage PPM / wambo.org procurement mechanism to collaborate with partners to build regional procurement capacities
2. Stimulate and sustain regional manufacturing capacity building

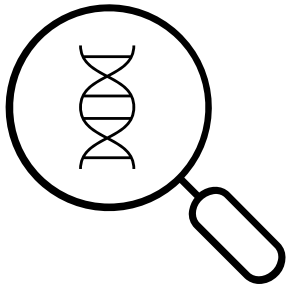
National

1. Use grant investments and country partners to strengthen in-country supply chain systems
2. Ensure quality assured health products will be distributed effectively and efficiently to communities and people we serve

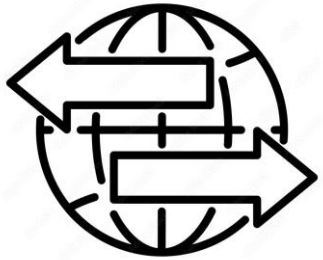
The NextGen Market Shaping approach is reflected in GF's sourcing strategies

The success of the NextGen Market Shaping approach is **dependent on the contribution of, and partnership with, industry**. This will require industry to:

Be responsive to Global Fund tenders



Continue to invest in Point of Care innovation to expand access to testing

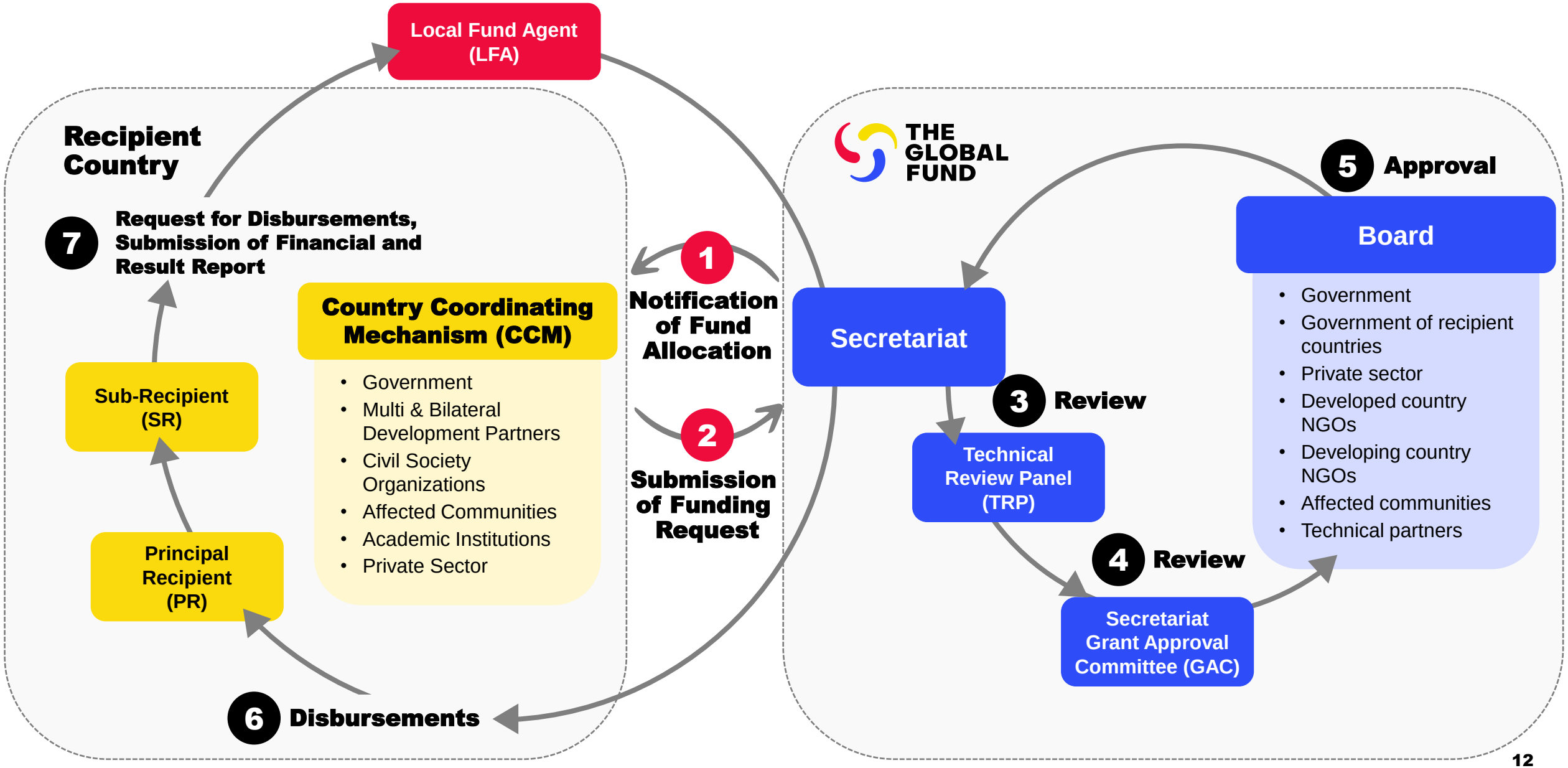


Adopt sustainable, all-inclusive pricing approaches that deliver value for money and increased transparency

Pooled Procurement Mechanism (PPM)

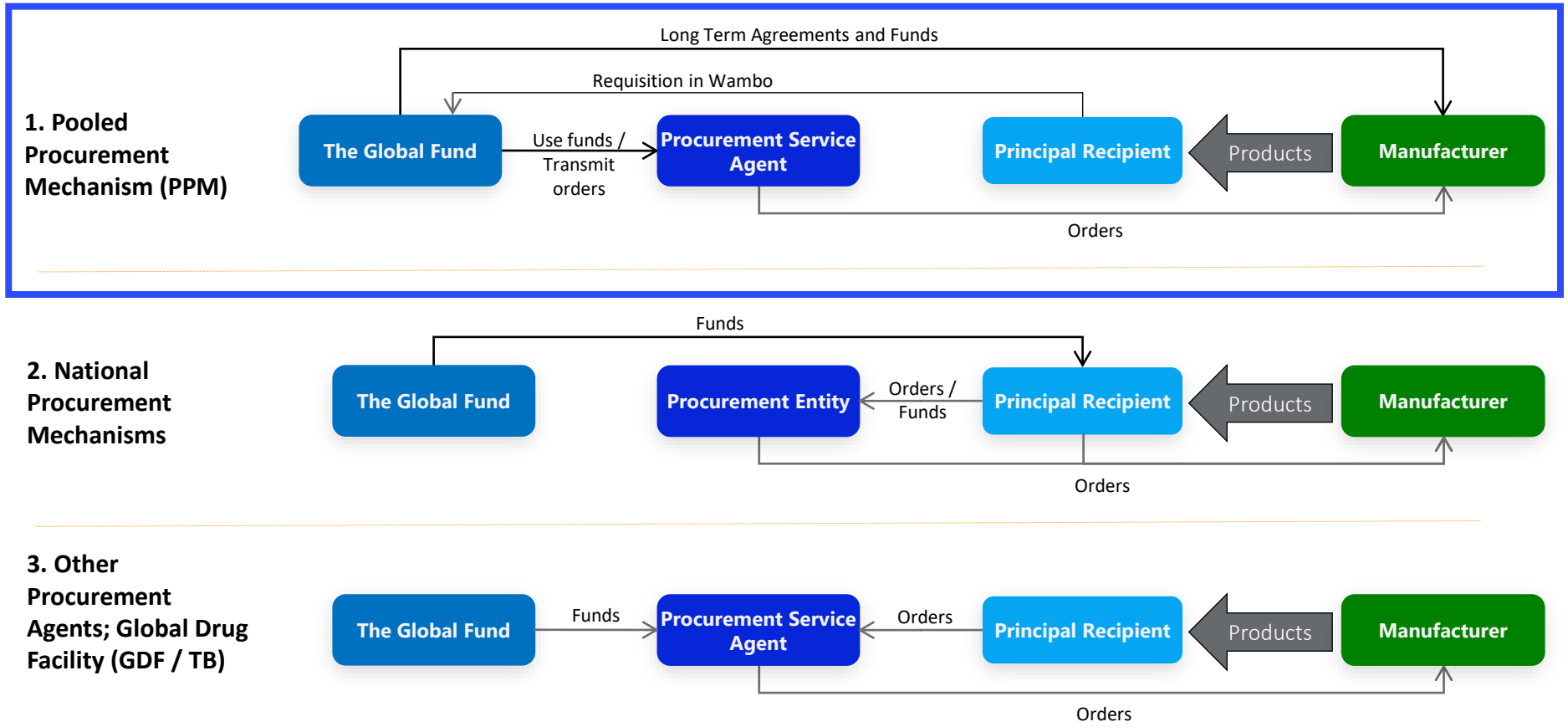
Lin (Roger) Li
Senior Manager, Direct Sourcing
The Global Fund

How the Global Fund operates

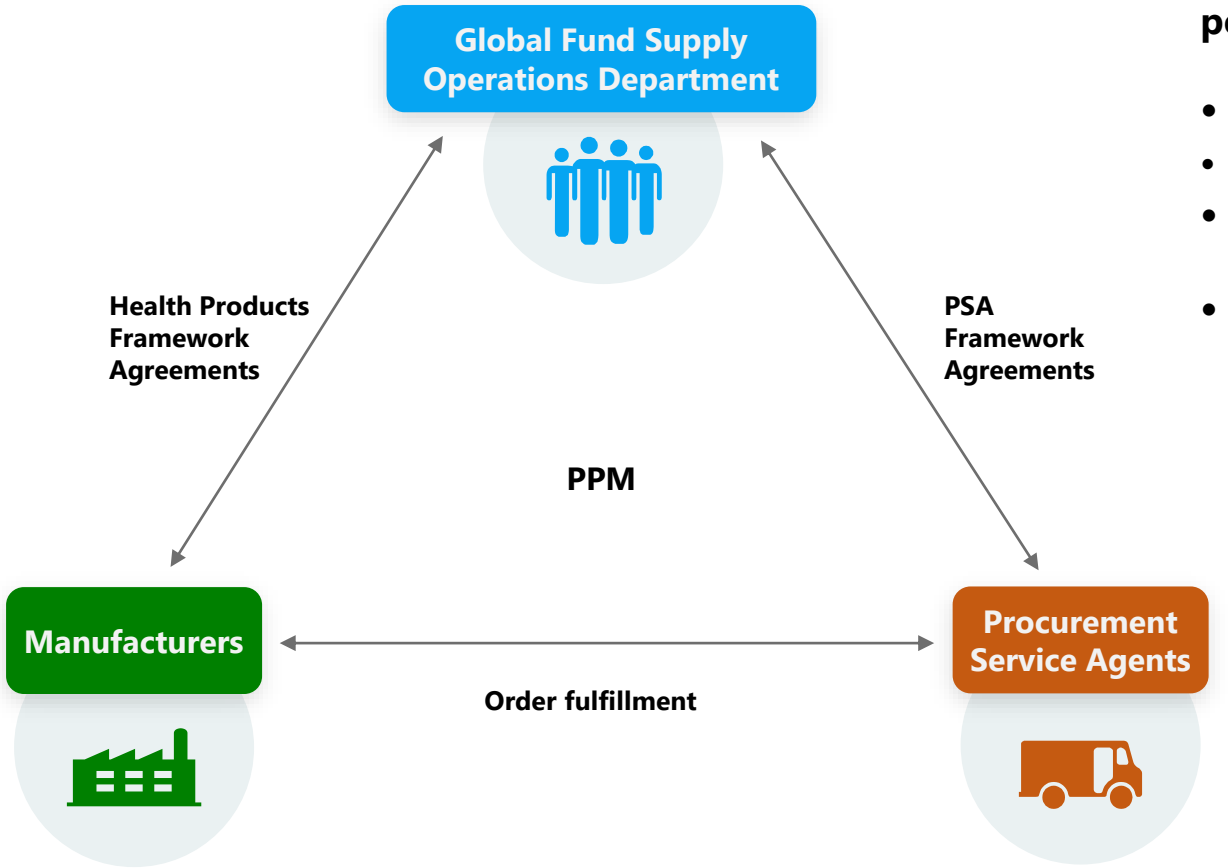


Procurement Channels and Routes to Market

There are a number of procurement channels - with the Pooled Procurement Mechanism (PPM) representing around 60% total Global Fund health product spend



PPM holds long-term Framework Agreements with suppliers for key categories: ARV, ACT, ITN & RDT



The Global Fund aggregates order volumes to leverage our spending power and achieve value-for-money:

- Competitive tenders to select manufacturers
- https://www.theglobalfund.org/en/sourcing-management/health-products/
- Require adherence to GF quality assurance policies https://www.theglobalfund.org/en/sourcing-management/quality-assurance/
- Stringent performance management through contract implementation

Procurement Service Agents:

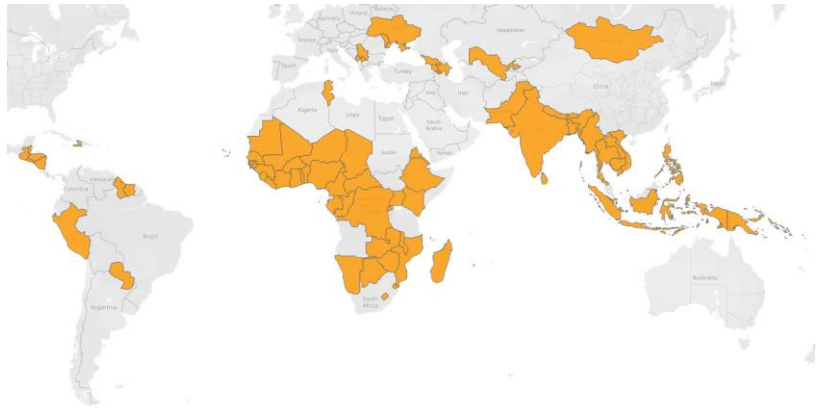
- Liaise with framework agreement manufacturer
- Manage procurement for other categories and non-catalogue items where needed
- Provide logistics estimates and ensure delivery to country per the the agreed incoterm

Overview PPM: More than 81 countries served in 2023 through PPM/Wambo

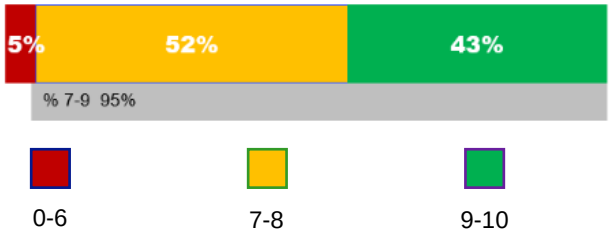
There are a number of nearly 5,000 shipments of needed health products delivered despite global supply chain disruptions in 2023

Since its creation, PPM/wambo.org has connected **452 PR users** from **108 organizations** in **81 countries**

(including **organizations** from **28 countries for non-grant funded transactions**)



Overall **user satisfaction** with the Wambo platform: **95%**



Scale: 0 = Not satisfied at all to 10 = Fully satisfied

Tracked nearly 5000 shipments
from shipping to delivery

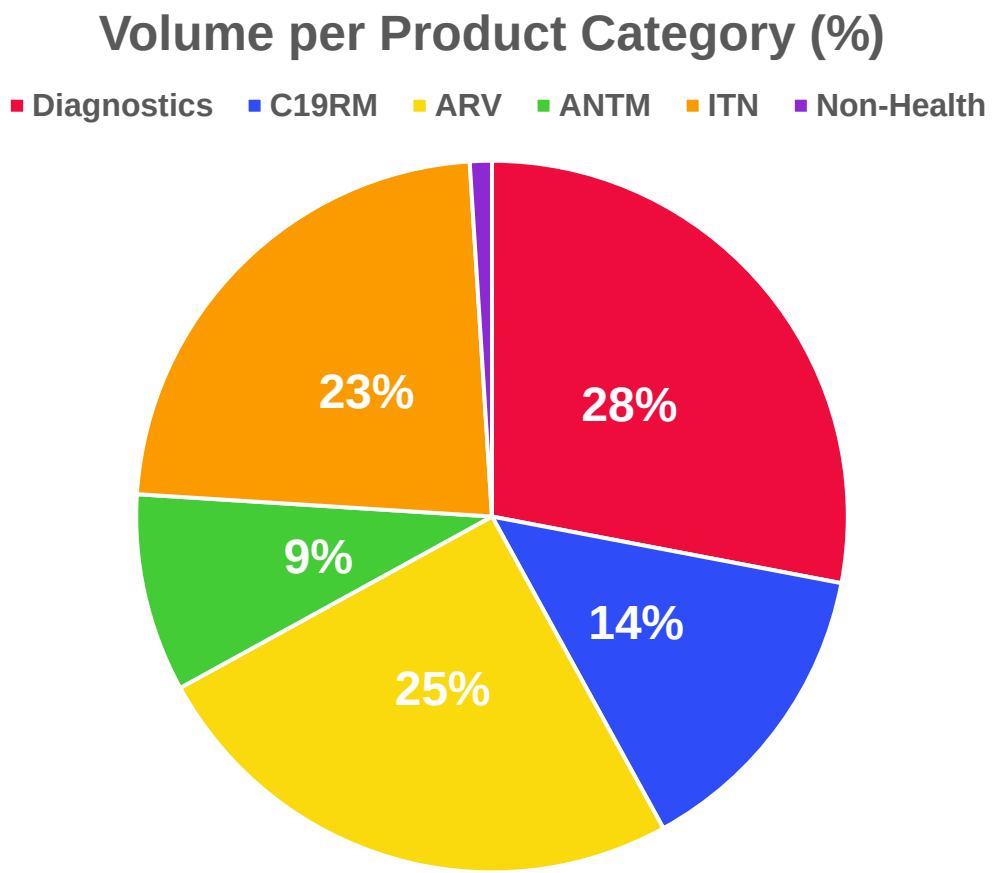
Tracked 4,954 shipments
from shipping to delivery

count	**1,979 by sea**	**2,656 by air**	**319 by road and rail**
volume m3	85%	4%	11%
value (USD)	982 Mn	228 Mn	94 Mn

Overview PPM: USD 1.34bn orders placed in 2023 through PPM/Wambo

PPM operates at a significant scale – largest LMIC buyer in many categories

- **In 2023**, PPM processed 1,367 Purchase Orders **$1.34 bn** to more than 80 countries in all continents
- **Diagnostics** (**RDTs** and machine-based technologies) are a significant spend
- **ARVs** category – enough to treat **8.3 million people on 1st line ART**
- **ITNs** – in 2023, PPM procured **115 million bed-nets** including new generation innovative nets)



The Responsible Procurement Framework - realising our ambitions and achieving our goals.

To date, the Global Fund's Supply Operations Department has put many of these principles into action through the adoption of a responsible procurement approach, yielding significant results:

- **Artemisinin EHS Compliance:** The Global Fund mitigated EHS risks and incentivized best practices by leveraging 3 year volume allocations
- **Adoption of Standards:** Global Fund LTAs require suppliers to comply with international environment, health & safety standards. The number of insecticide-treated net manufacturers whose systems meet ISO standards for environmental management (14001:2015) and occupational health & safety (ISO 45001:2018) has increased by 19% since 2020.
- **Packaging Waste:** The Global Fund strives to reduce packaging waste across categories.

Nevertheless, **a systematic approach** was needed to realize the Global Fund's sustainability ambitions.

The Global Fund is building on our successes to date through the implementation of our "Responsible Procurement Framework" (RPF).

The RPF is -

- Based on the Triple-Bottom-Line framework.
- Developed in consultation with the UN informal Interagency Task Team on Sustainable Procurement in the Health Sector (SPHS).
- Endorsed by the Global Fund Management Executive Committee.
- A Secretariat-level operational guide for Global Fund sourcing; allowing buyers to identify, monitor, mitigate sustainability risks.

Suppliers may be expected to -

- Provide baseline sustainability & metric information.
- Strive to minimize the environmental impact of your activities*.
- Align with internationally recognized standards (e.g. ISO) where required.
- Support the Global Fund's sustainability ambitions.

**For example, these can include (non exhaustive) reduction in GHG emissions, pollution during production, packaging waste.*

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Disease and Technical Updates

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HIV Updates

David Maman
Senior Disease Adviser, Technical Advice and Partnerships
The Global Fund

Global Fund Strategy 2023-2028: END AIDS sub-objectives

1. Accelerate access to and effective use of precision combination prevention, with behavioral, biomedical, and structural components tailored to the needs of populations at high risk of HIV infection, especially KVP
    - Close gaps in HIV prevention coverage
    - **Accelerate access to and use of new HIV prevention options**
    - Evolve and expand the range of platforms for access to and delivery of people-centered HIV prevention

2. Provide quality, people-centered diagnosis, treatment and care, to improve well-being for PLHIV, prevent premature mortality and eliminate HIV transmission
    - Optimize diagnostic pathways
    - Differentiate and scale up quality HIV treatment services
    - Integrate services to prevent, identify, and treat advanced HIV disease, comorbidities, and coinfections
    - Evolve care pathways to strengthen therapeutic alliances between the people in care and the health and community systems
    - **Accelerate the introduction of diagnostics, therapeutics, technologies, and service delivery innovations**

3. Advocate for and promote legislative, practice, program and policy changes to reduce HIV-related stigma, discrimination, criminalization, other barriers and inequities and uphold the rights of PLHIV and KVP

Epidemiological Update & Consequences for Molecular Diagnostic

- **29.8M (76%) people living with HIV were receiving ART** in 2022,including 17M in ESA
- Most of the **patients have been transitioned to DTG based regimen**.
  - Second line regimens are at least five times more expensive than TLD
  - Patients with 2 high viral load on DTG based regimens are less likely that patients on NNRTI to have resistance for the moment.

→ **Viral Load (Program Essentials)** is increasing with the number of patients

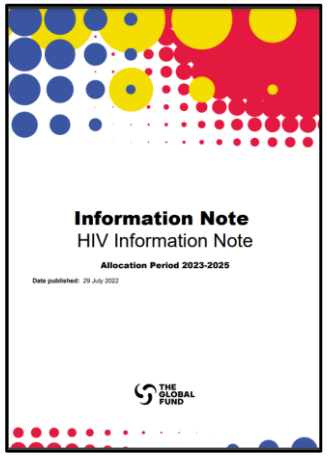
→ **Genotyping needs especially for DTG resistance for surveillance and clinical Mgt is also increasing**

- However, it was estimated that only **63% of children living with HIV** aged 0-14 were diagnosed in 2022 (**37% in WCA**). In the absence of treatment, it is estimated that 50% of the children who acquired HIV at birth will have died by the age of 2.

→ **Need for EID is also increasing.**

Key HIV Resources for Funding Requests

Updates for the 2023-2025 Allocation Period



HIV Information Note

The RSSH, TB and Malaria Information Notes are also available here.

Additional Resources

1. Technical Briefs

Technical Briefs will be published here. These resources will include additional detail on specific topics (HIV Service Delivery in COE, Health & Longevity, HIV, Human Rights and Gender Equality).

2. Global Guidelines

Links to all key technical guidance documents are in footnotes of the HIV Information Note.

Program Essentials

- **Critical interventions needed to achieve outcomes and impact**
- Program Essentials are **key evidence-based interventions and approaches** to address the ambitious goals set out in **the HIV, TB, and Malaria global strategies.**
- Elements **recommended by technical partners** (WHO, UNAIDS, Stop TB, RBM) and further described in their respective technical guidelines
- When part of national programs, **Program Essentials will support countries to achieve their national targets.** They can be funded by either The Global Fund or other sources.

HIV Investment priorities for GC7

Program Essentials

- CD4 and viral load testing, and diagnosis of common comorbidity and coinfections are available for management of HIV
- HIV testing, including early infant diagnosis (EID) is available for all HIV-exposed infants.

Eligible investments for GC7:

- From PMTCT to Integrated Approach towards Triple Elimination of HIV, Syphilis and Hepatitis B
  - HBV Viral Load for PMTCT eligibility is now eligible.
- HCV Viral Load for PLHIV and Key Populations, especially people who use drugs.
- Molecular diagnosis for HPV (for PLHIV), for STI Mgt (for PLHIV and Key Populations)

Investment Priorities

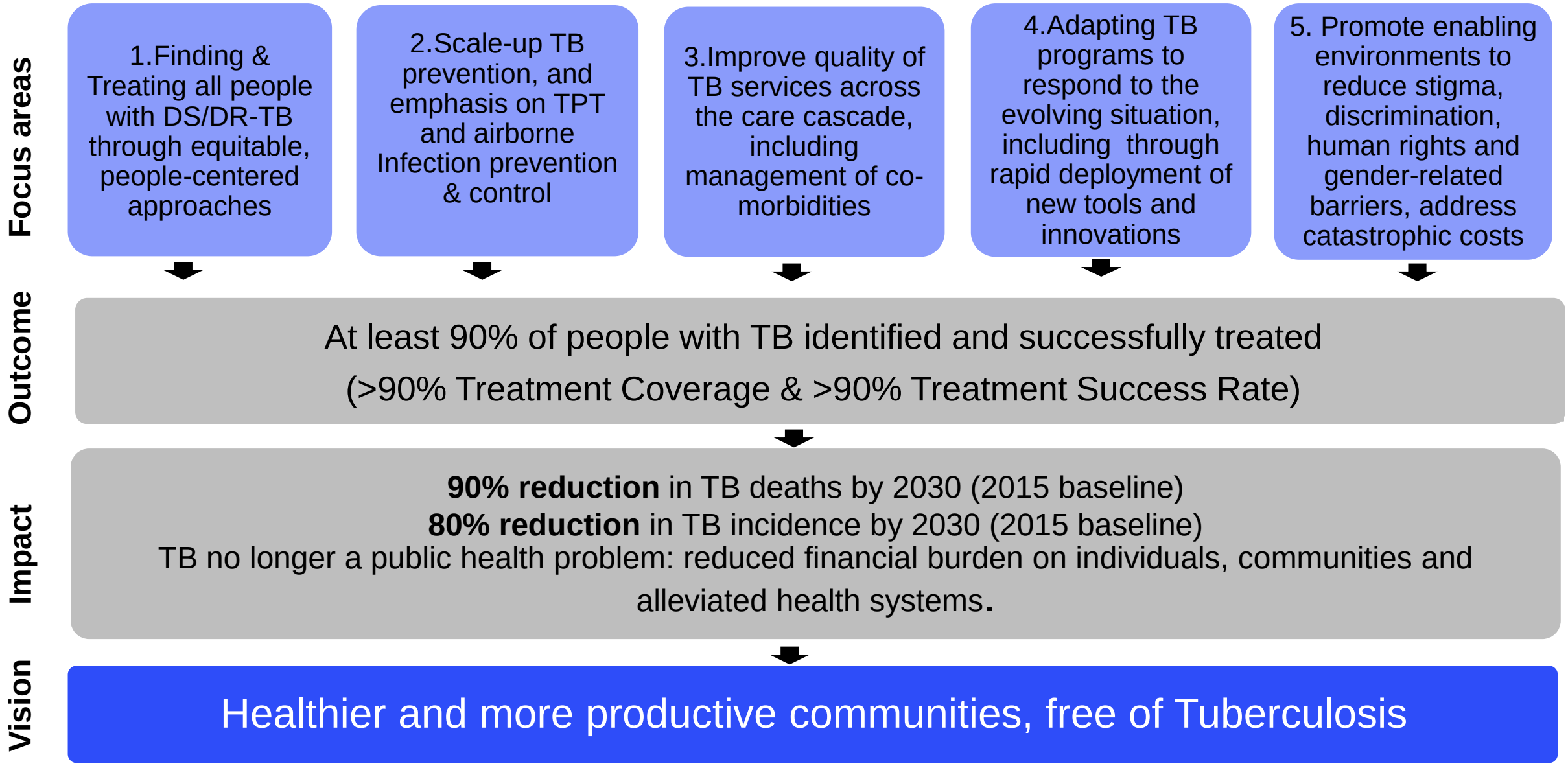
- **Integration:** We favor investment in multi disease platforms

- **Devices need to be able to handle DBS for both Viral Load and EID:**
  - HIV Viral Load monitoring is not usually not an emergency and most of the time doesn't require same day results.
  - Conservation and transportation for plasma requires cold chain.
- **Genotyping ?? Connectivity??**

Tuberculosis Update

Grania Bridgen
Senior Disease Advisor, Technical Advice and Partnerships
The Global Fund

Global Fund TB priority areas and expected results

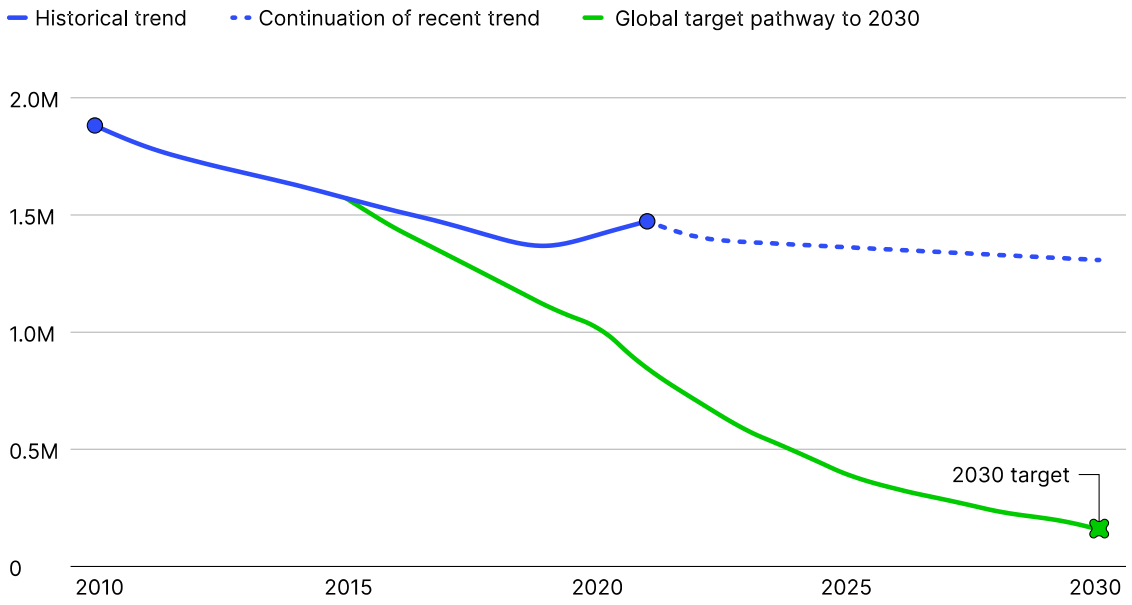


Tuberculosis: State of the Fight

Very slow progress towards global targets

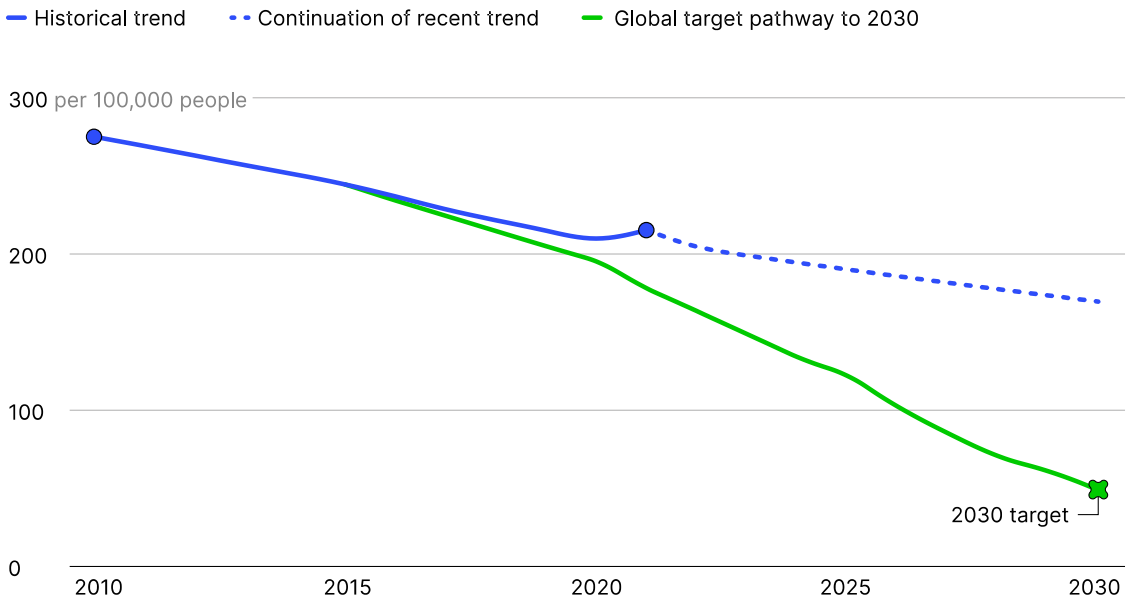
TB deaths: progress towards the WHO target*

In countries where the Global Fund invests



TB incidence rate: progress towards the WHO target

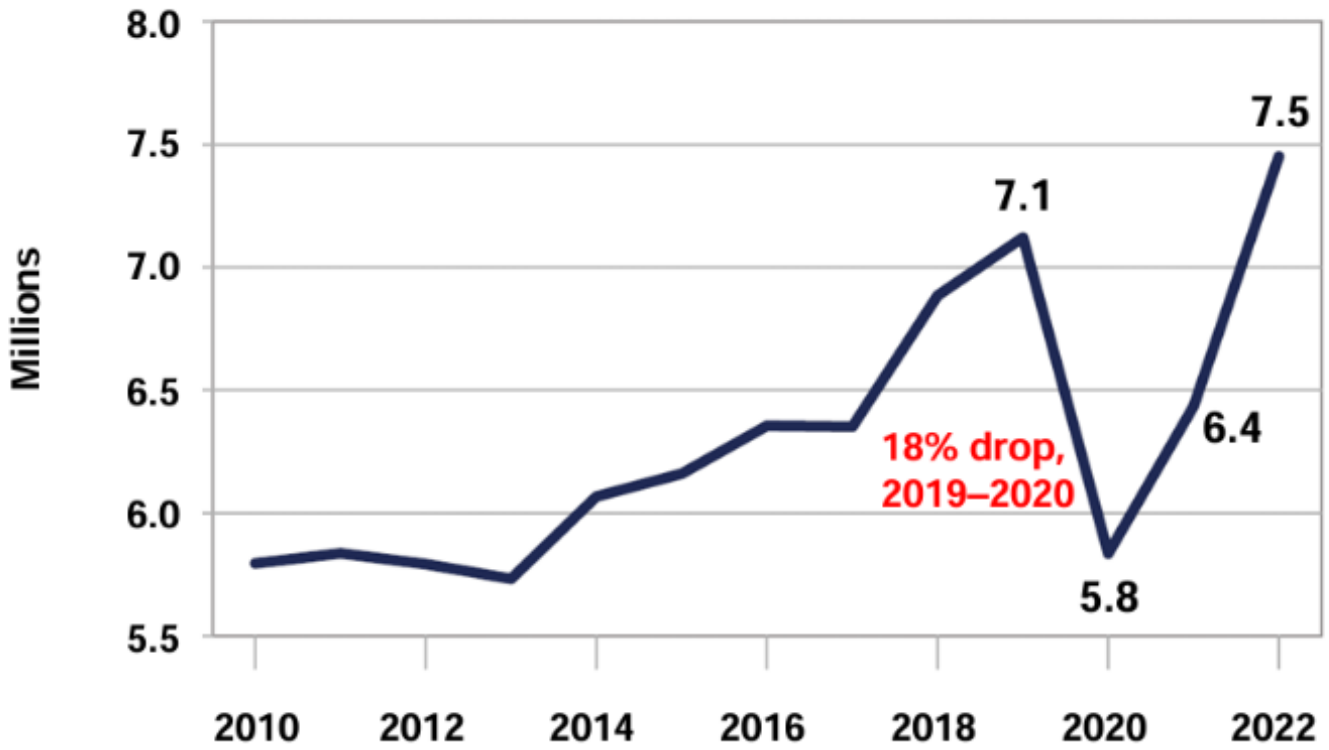
In countries where the Global Fund invests



*TB deaths include HIV-positive. “Continuation of recent trend” projection is based on reverting to pre-COVID-19 (2014-2019) trends. “Global target pathway to 2030” is based on targets from the WHO End TB Strategy. Countries eligible for Global Fund support in 2022.

Global recovery in reported number of people newly diagnosed with TB

7.5 million in 2022: highest number since WHO started global TB monitoring in mid-1990s



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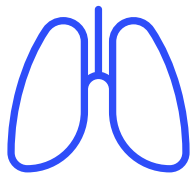
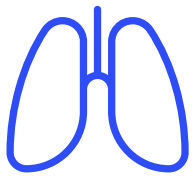
TB: Results

Key TB results in 2022 in countries where the Global Fund invests:



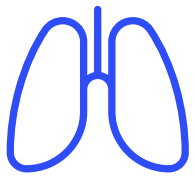
6.7M

People treated for TB.



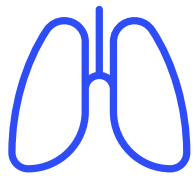
331K

HIV-positive TB patients on antiretroviral therapy.



118K

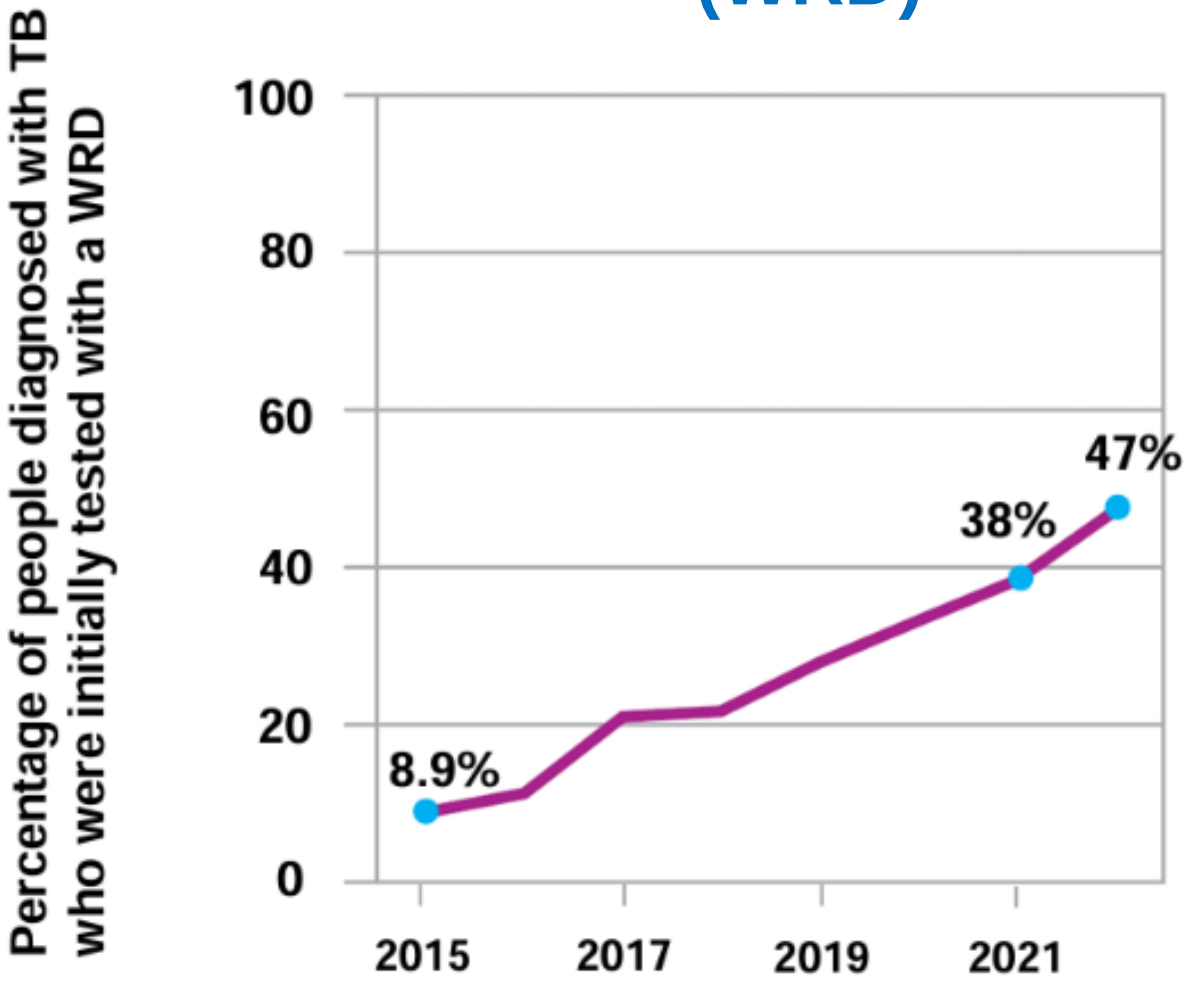
People on treatment for drug-resistant TB.



1.5M

People exposed to TB received TB preventive therapy.

Coverage of WHO recommended Rapid Molecular Diagnostics (WRD)



WRD: WHO-recommended rapid diagnostic test

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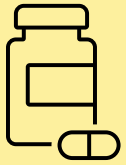
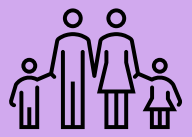
Implementation of GC 07: TB Program Essentials

Program Essentials were introduced in GC7 as a strategic lever to support the **equitable access** to highly **impactful interventions**

1.TB Screening & Diagnosis		• Systematic screening using CXR +/- CAD • Rapid molecular assays as first diagnostic test • Testing for at least rifampicin resistance in bacteriologically confirmed TB • Efficient TB diagnostic networks
2.TB Treatment & Care		• Child friendly formulations, 4-month regimen for non-severe DS-TB in children • Shorter all-oral regimens for DR-TB • People-centered support for treatment completion
3.TB Prevention		• TB Preventive Therapy available for all eligible people: PLHIV, children, eligible household contacts of people with bacteriologically confirmed TB. • Shorter TB Preventive Therapy regimens
4.TB/HIV Collaborative Activities		• All PLHIV with active TB started on ART early as per recommendations
5.Cross-cutting areas		• Real-time digital case-based TB surveillance • Private sector engagement • Decentralized, community & home-based people centered services • Human rights & gender-responsive programming

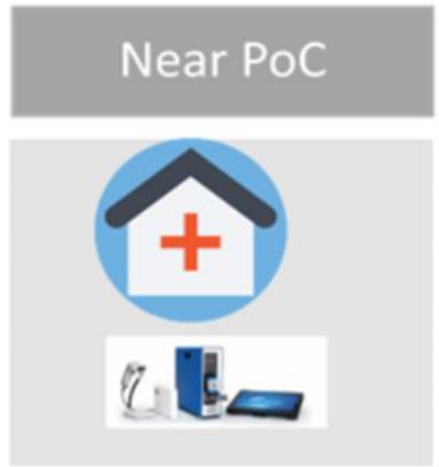
TB Diagnostics

Need a near Point of Care or true Point of Care test

Current TB diagnostic tests are not true point of care tests

The current TB diagnostic network has issues with:

- Majority of tests require lab infrastructure/electricity to run and/or recharge
- Require sample that is difficult to obtain (Sputum/stool – for children)
- Where is it POC (urinary LAM test) it is for a sub section of the at risk population.



Complexity	PoC	Near PoC	Low complexity
Equipment	None	Maybe, preferable battery operated	Yes
Infrastructure	None	None	Basic laboratory infrastructure needed (like electricity), but no special laboratory infrastructure
HR skill level	Unskilled	Basic Technical Skills (basic pipeting, precision not critical, etc)	Basic Technical Skills (basic pipeting, precision not critical, etc)

WHO Prequalification

Anne-Laure Page & Susie Braniff
WHO

27 June 2024

Update on Prequalification of In Vitro Diagnostics

World Health Organization

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PQ In Vitro Diagnostics Assessment Team

Outline

- Overview of the prequalification (PQ) assessment pathway
- PQ assessment updates
  - Technical Specifications
  - Product dossier assessment
  - Performance Evaluation
  - Specific information for molecular IVDs

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WHO prequalification (PQ) for IVDs

PQ of IVDs: Aim & Scope

- The aim of PQDx is to promote and facilitate **access** to safe, appropriate and affordable IVDs of good quality
- Focus is placed **on IVDs for priority diseases** and their suitability for use in **resource-limited settings**
- The **scope** of IVDs eligible for PQ continues to expand
- Currently 117 IVDs are prequalified

PQ List available at: https://extranet.who.int/prequal/vitro-diagnostics/prequalified-vitro-diagnostics

HIV

Malaria

Hepatitis C

Hepatitis B

HPV

G6PD

Cholera

Syphilis

Tuberculosis NAT

SARS-CoV-2

Blood Glucose meters and test strips

HbA1c POC analysers

Haemoglobin POC

TB LAM

C. trachomatis, N. gonorrhoeae, Trichomonas V

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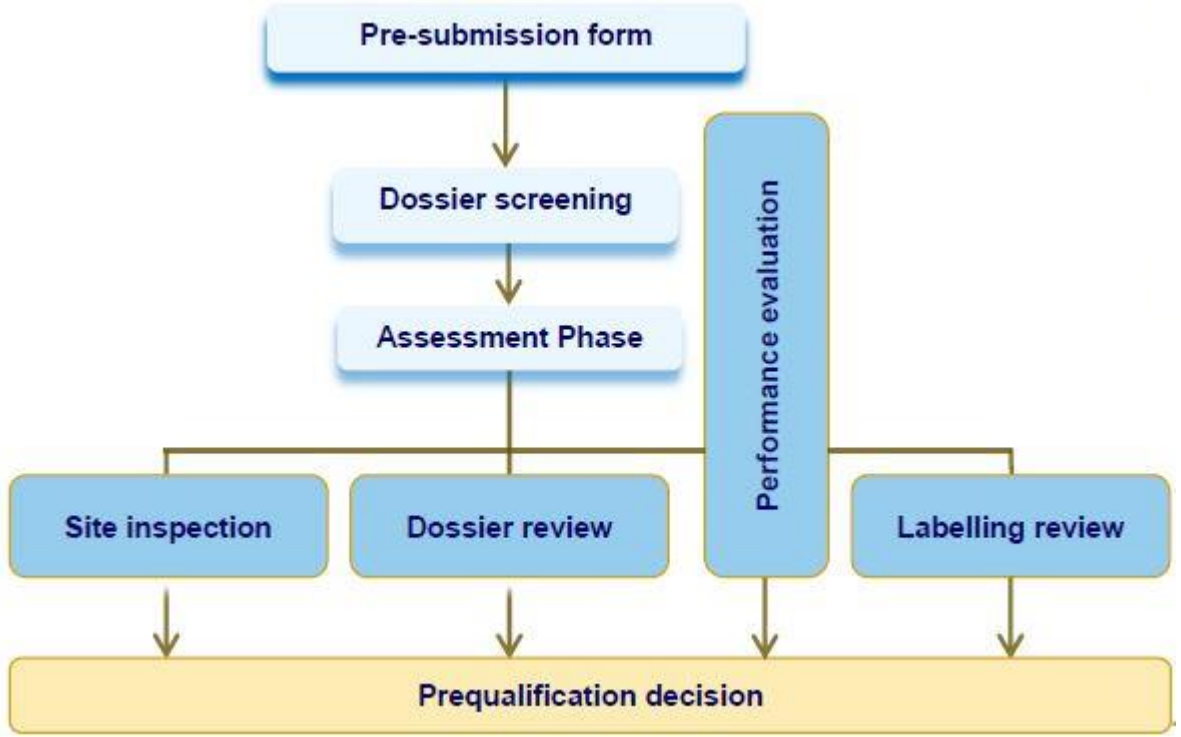
PQ Application Process

UPDATE: ePQS to launch in 2024



Pre-submission

- Manufacturer completes the pre-submission form
- WHO schedules a pre-submission meeting
- WHO screens the pre-submission form to determine if product is eligible & type of assessment (full or abridged)

PQ assessment

- Review of product dossier (full or abridged)
- Performance evaluation
- Site Inspection
- Labelling review

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Prequalification decision

For IVDs that meet PQ requirements

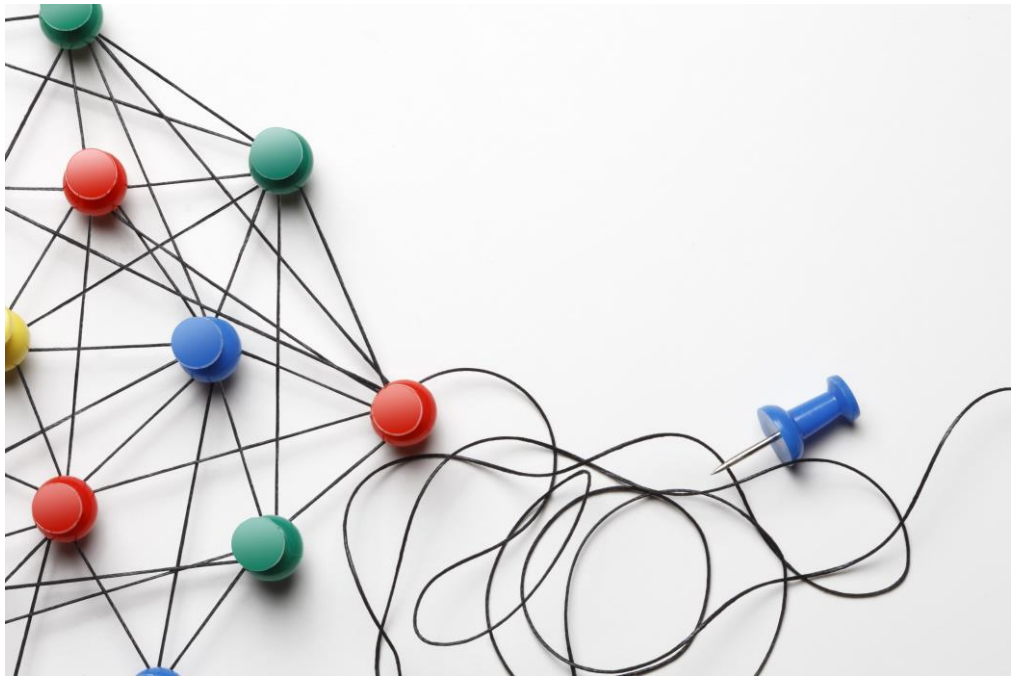
- The product is added to the list of WHO prequalified IVDs
- The public report is prepared & published

→ IVD is eligible for WHO and UN procurement & CRP

Post-PQ Activities - Ongoing requirements to maintain PQ listing

Manufacturer must comply with:

- Commitments to PQ
- Annual reporting
    - Sales data, complaints, Field Safety Correction Notices (FSCN)
- Change reporting
- Post market surveillance obligations
- Ongoing compliance with TSS
- Routine site inspections



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PQ IVD Assessment Updates

WHO PQ Technical Specifications Series (TSS)

- Each TSS document is tailored to a specific pathogen/type of assay
  - Requirements that address needs of Member States in LMIC
  - Requirements that relate to general performance characteristics
- Summarize minimum performance requirements for WHO prequalification, to establish:
  - Performance validation criteria
  - Appropriate reference methods and reference materials
- Clarify requirements:
  - Manufacturers
  - Assessors

TSS developed in alignment with relevant international and national standards, literature and best practise (e.g., CLSI, IMDRF, FDA, ISO ..)

- Deviations might be due to additional requirements to demonstrate
- Suitability of the IVD in resource limited settings
- Lessons learned
- Scientific evidence/experience/disease programme

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Technical specifications (TSS) Updates

Documents in development

- **TSS-22** Haemoglobin point of care analysers
- **TSS-23** RDTs to detect mycobacterial lipoarabinomannan (LAM) antigen
- **TSS-3** Malaria rapid diagnostic tests (update HRP2/3 deletion)

Technical Consultation August 2024

- IVDs for Neisseria gonorrhoeae, Chlamydia trachomatis and Trichomonas vaginalis NAT (TSS-24)
- Neisseria gonorrhoeae and Chlamydia trachomatis RDTs (TSS-25 / 26)
- Self testing requirements for syphilis RDTs (TSS-27)

Recently published TSS

TSS-18
HbA1c point of care analysers for professional use

TSS-19
IVD medical devices for monitoring of blood glucose in capillary blood

TSS-20
IVD medical devices used for the qualitative detection of SARS-CoV-2 nucleic acid

TSS-21
SARS-CoV-2 antigen rapid diagnostic tests for professional use and self-testing

https://extranet.who.int/pqweb/vitro-diagnostics/technical-specifications-series

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Product dossier assessment

- Technical review of manufacturer's evidence of quality, safety & performance
  - Performed by subject matter experts
- Analyzing the relevance of the data in the dossier
  - Reliable data that supports the manufacturers claims of quality, safety and performance
  - Appropriate & well-designed validation studies
- Review of completeness, accuracy and consistency of data over IVD life-cycle
  - From initial product design, through validation, manufacture, quality control and release onto the market

→ Are the specifications in the TSS met?

→ Has the manufacturer considered the use of the product in RLS

Dossier assessment Update

Subject matter experts work in teams to review product dossiers and corrective action plans

Assessment sessions were piloted by PQT-IVD in 2023

- Increase pool of technical experts
- Ensure standardization of technical reviews conducted
- Capacity building

Sessions held every second month

1. 26 Feb – 1 March	**4.** 26 – 30 August
2. 22 – 26 April	**5.** 7 – 11 October
3. 10 – 14 June	**6.** 9 – 13 December

- Materials for review received 15 days prior to an assessment session will be available for assessment
- Between session dossier & CAP review will also be arranged as needed

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Performance Evaluations

Verification of a subset of manufacturer's claim

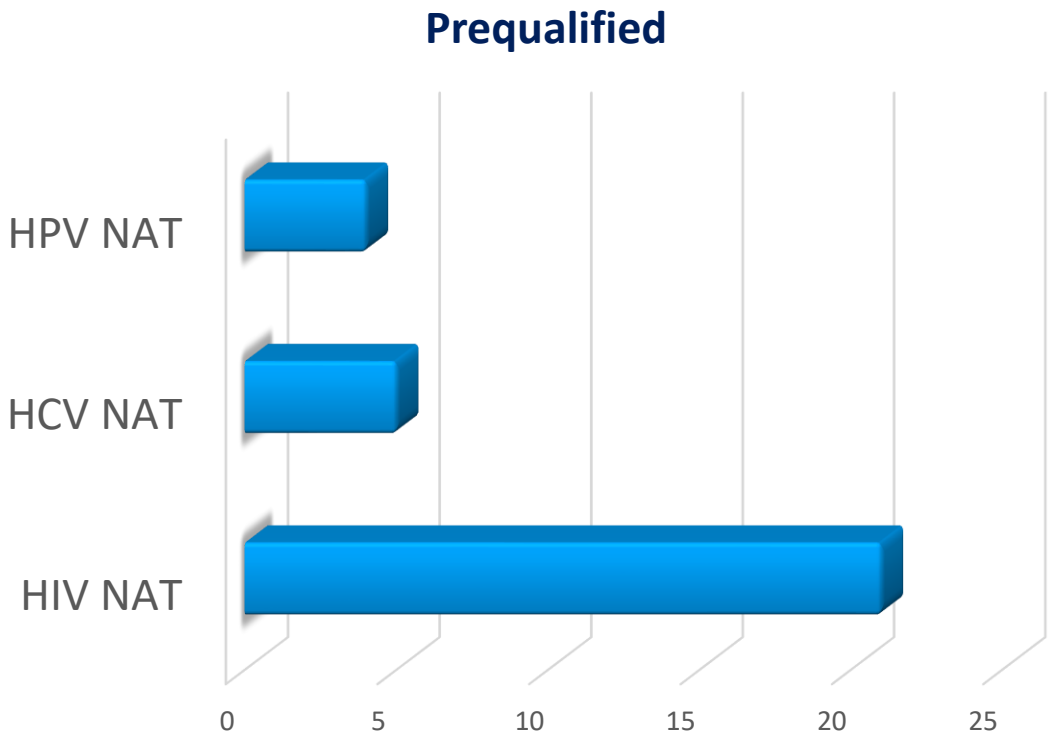
- Generally, for molecular tests
  - Analytical evaluation
    - Limit of detection
    - Precision
    - Linearity, if applicable
    - Subtype/genotype/resistance panels
    - Cross-contamination / carry-over
  - Clinical evaluation
    - Sensitivity/specificity
    - Correlation with comparator method for quantitative tests
- Performance evaluation required for different specimen types if not equivalent (even if introduced as change request)

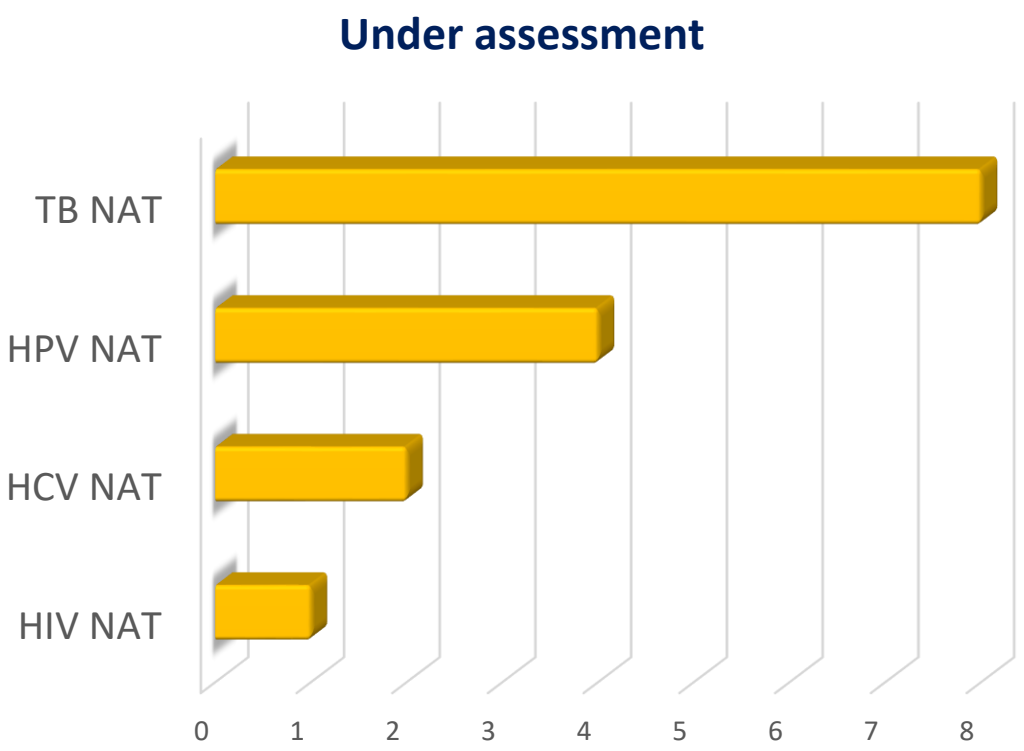
New protocols

- Evaluation of TB NAT with or without drug resistance
- Evaluation of TB NAT for drug resistance
- Evaluation of SARS-CoV-2 NAT (*in progress*)

Prequalification of molecular IVDs

PQ Pipeline now open for SARS-CoV-2 molecular tests





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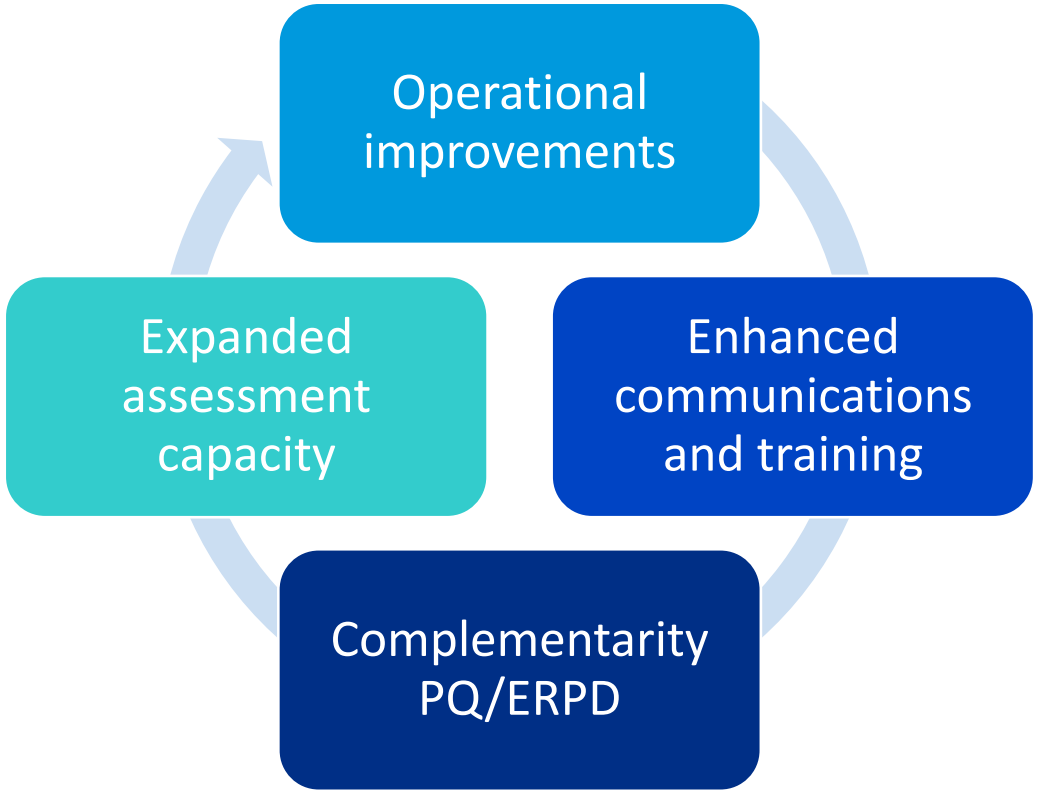
PQ IVD Process enhancements are ongoing

- Review of the change assessment procedure
- Further modelling on abridged PQ assessment
- Development of additional guidance
  - Open platform PCR
- Collaboration with mature NRAs enhanced
- Lab network expansion
- Exploring collaboration with CABs
- Expansion of ERPD scope
  - Transitioning products through QA with a progressive approach: no QA → ERPD → PQ



Updates are available on the PQ-IVD webpage

https://extranet.who.int/prequal/vitro-diagnostics

PQDx webinars

- Monthly webinars scheduled
- Focus on specific topics: technical, but not only
- Keeping you informed on ongoing work, upcoming changes etc.
- Webinars recorded and posted on the website for extended outreach

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Thank You

diagnostics@who.int

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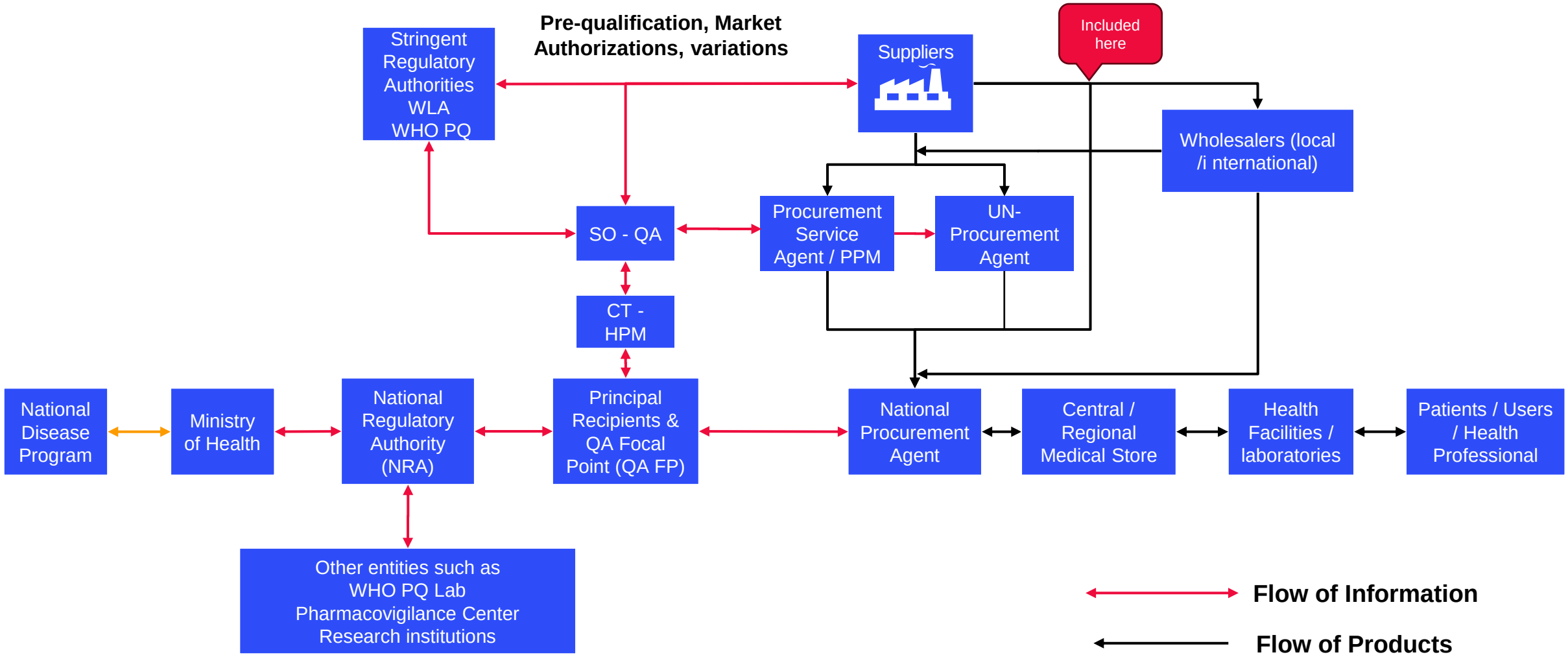
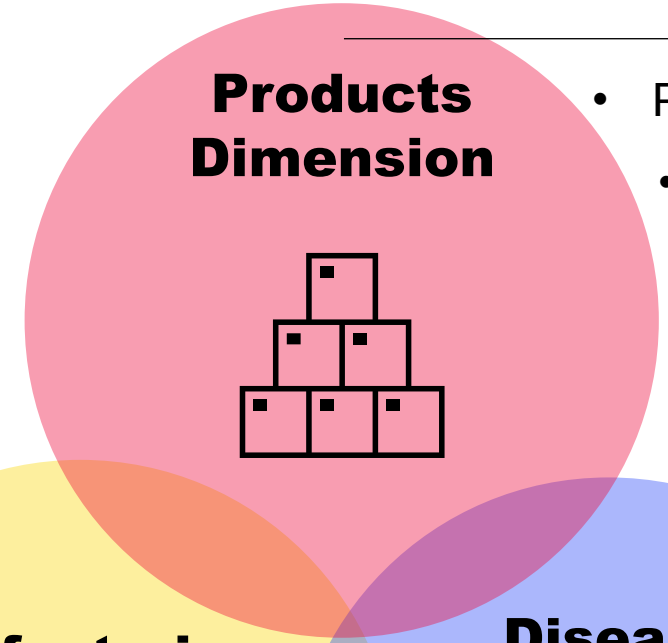
Global Fund Quality Assurance and ERPD

René Becker-Burgos, Specialist, Diagnostic Products Quality Assurance, HPM
The Global Fund

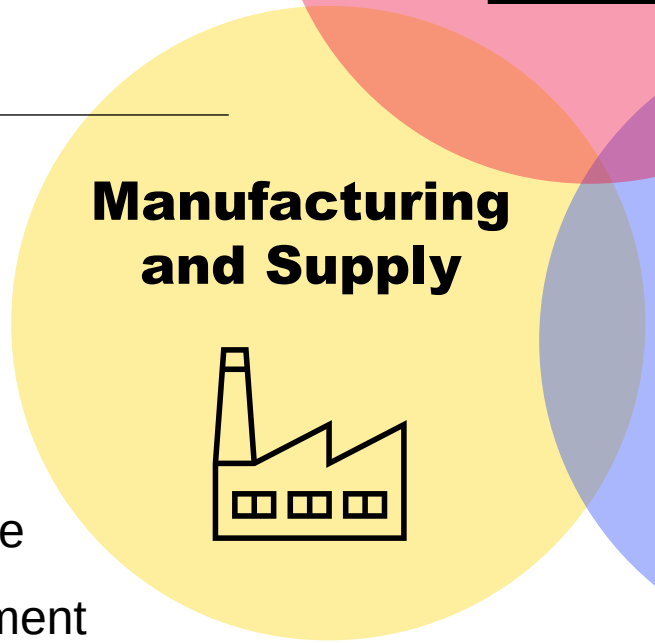
Quality Assurance Ecosystem



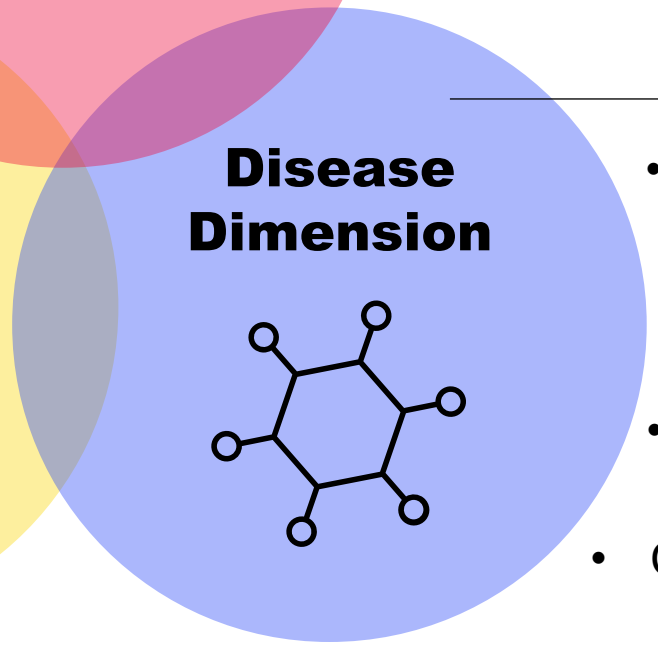
Scope of quality assurance requirements



- Pharmaceuticals
- Medical Devices
  - In-vitro Diagnostics
  - Personal Protective Equipment
- Vector Control Products

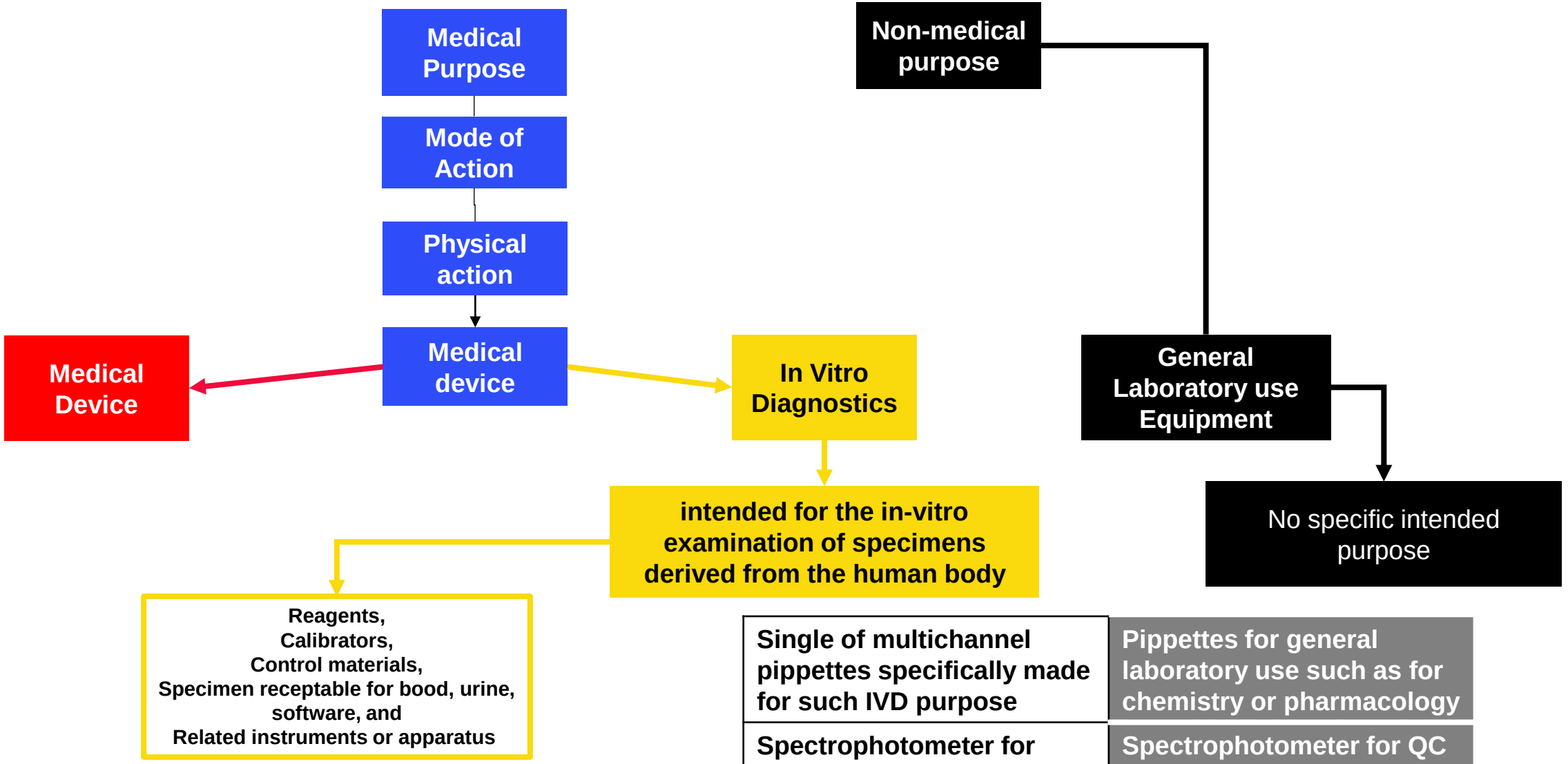


- Registration
- Procurement
- Storage & Distribution
- Vigilance
- Market Surveillance
- Waste Management



- HIV
- Tuberculosis
- Malaria
- Co-Infections and Co-Morbidities (COIM)
- COVID-19

The QA Policy Framework covers a broad range of Medical devices



Stringent Mechanisms for procurement of core Health Products

Reliance on stringent mechanism in addition to national mechanism

MA Mechanism	Description	Practices
Stringent Regulatory Authorities (SRA)	• Robust legal/regulatory environment • ICH Requirements • Experienced & Skilled Staff in Quality/Safety/Environment • Applicable in the procurement of core FPP	• Regular GMP inspection as per related regulation • Mutual Recognition Agreement • Prioritization based on risks
WHO PQ program	• Program managed by WHO • WHO requirements • Experienced & Skilled Staff • Applicable to core FPP, IVD, VCP	• Regular inspection as per WHO PQ Procedure • Consideration of stringent assessment decisions for FPP and IVDs • Dossier review
WHO TB program recommendation	• Program managed by WHO Global TB Program • Applicable exclusively to TB IVDs	• WHO GRADE process

Stringent mechanisms of core Health Products

Reliance on stringent mechanism in addition to national mechanism

MA Mechanism	Description	Practices
GHTF RA	• RA of founding members of GHTF i.e USA, Canada, Japan, Australia and EU including UK • Robust legal/regulatory environment • Applicable in procurement of MDs (including IVDs) and core PPE • Experienced & Skilled	• Regular GMP inspection as per related regulation • Prioritization based on risks
WHO Listed Authority (WLA)	• Performance evaluation process conducted by WHO to designate a RA or RRS as a WLA • RA or RRSs must have attained ML 3 to be eligible for consideration as a WLA • Applicable in procurement of core FPP and MDs	• Meets WHO standards and other internationally recognized standards • Listing includes scope of designation, products and / or regulatory function • Risk-based approach used to renew listing
Expert Review Panel (ERP/ERPD)	• Mechanism used upon Global Fund request • Panel of external technical experts • Used for introduction of innovative products • Supported by WHO • Applicable for core FPP, MDs (including IVDs), VCPs	• Assesses abbreviated product dossiers • Clear analysis of benefits and potential risks • Product categorization with specified risk mitigation measures

Procurement of Medical Devices (Including IVDs) and core PPE – 1/3

Medical Devices classification

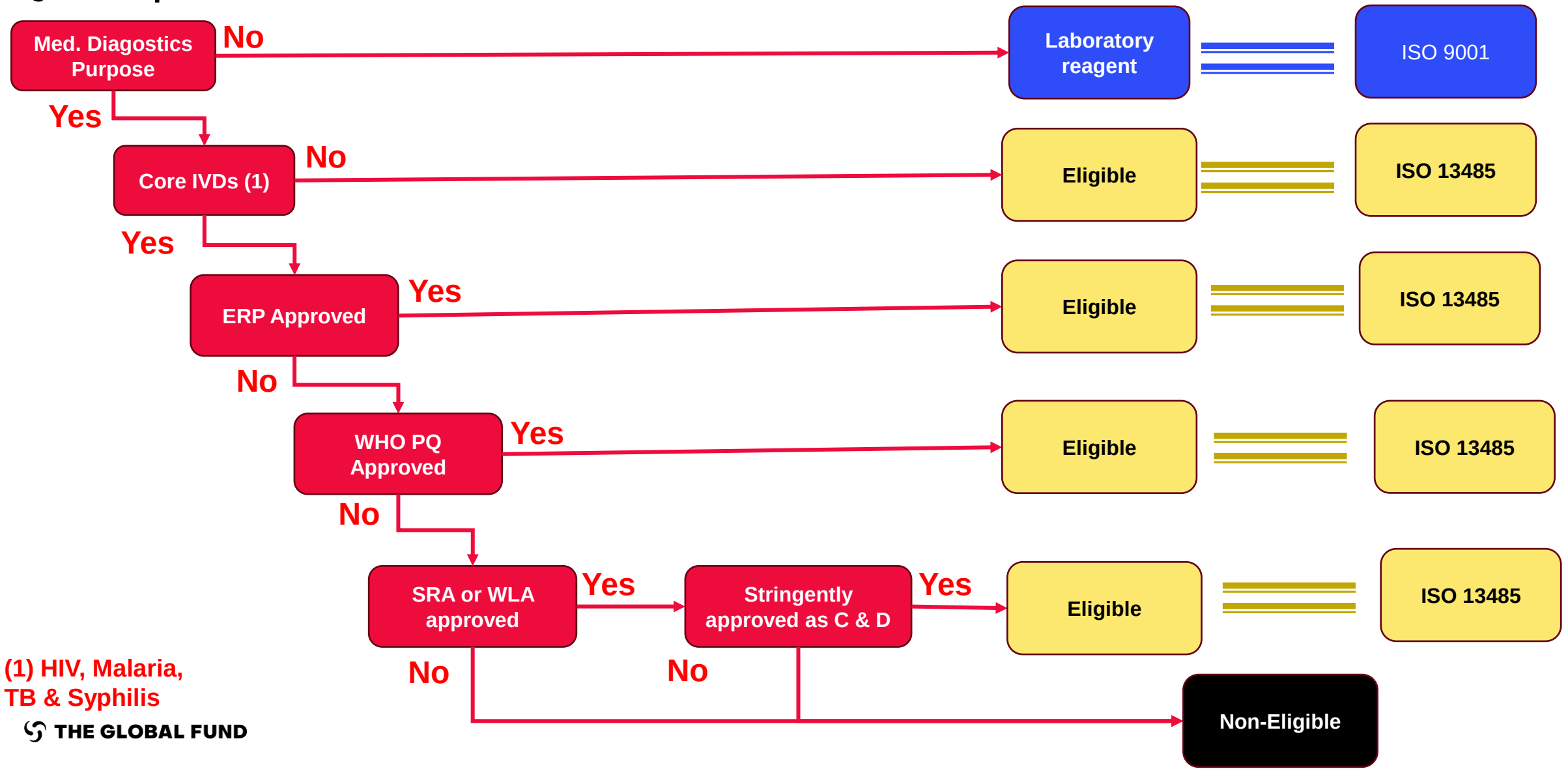
- Medical Devices are classified per the globally harmonized principles[1] of the Medical Devices classification consisting of 4 classes; A,B,C and D where A represents the lowest risk and D the highest
- Depending on the intended purpose, the risk classification can change
- When Class C or D, stringent requirements must be complied with

Class	Risk level	MDs examples
A	Low	Laryngoscope
		Oxygen mask
		Endotracheal tube
B	Low - moderate	Electrocardiogram
		Oxygen cylinder
		Patient monitor
C	Moderate - high	PSA oxygen plants
		X-rays
		Mechanical ventilator
D	High	Absorbable sutures

[1] https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf

Procurement of Medical Devices (Including IVDs) and core PPE – 2/3

QA requirements



(1) HIV, Malaria, TB & Syphilis

Procurement of Medical Devices (Including IVDs) and core PPE – 3/3

Key Changes - Quality Assurance Policy for Medical Devices (including IVDs) and Core PPE

Major changes

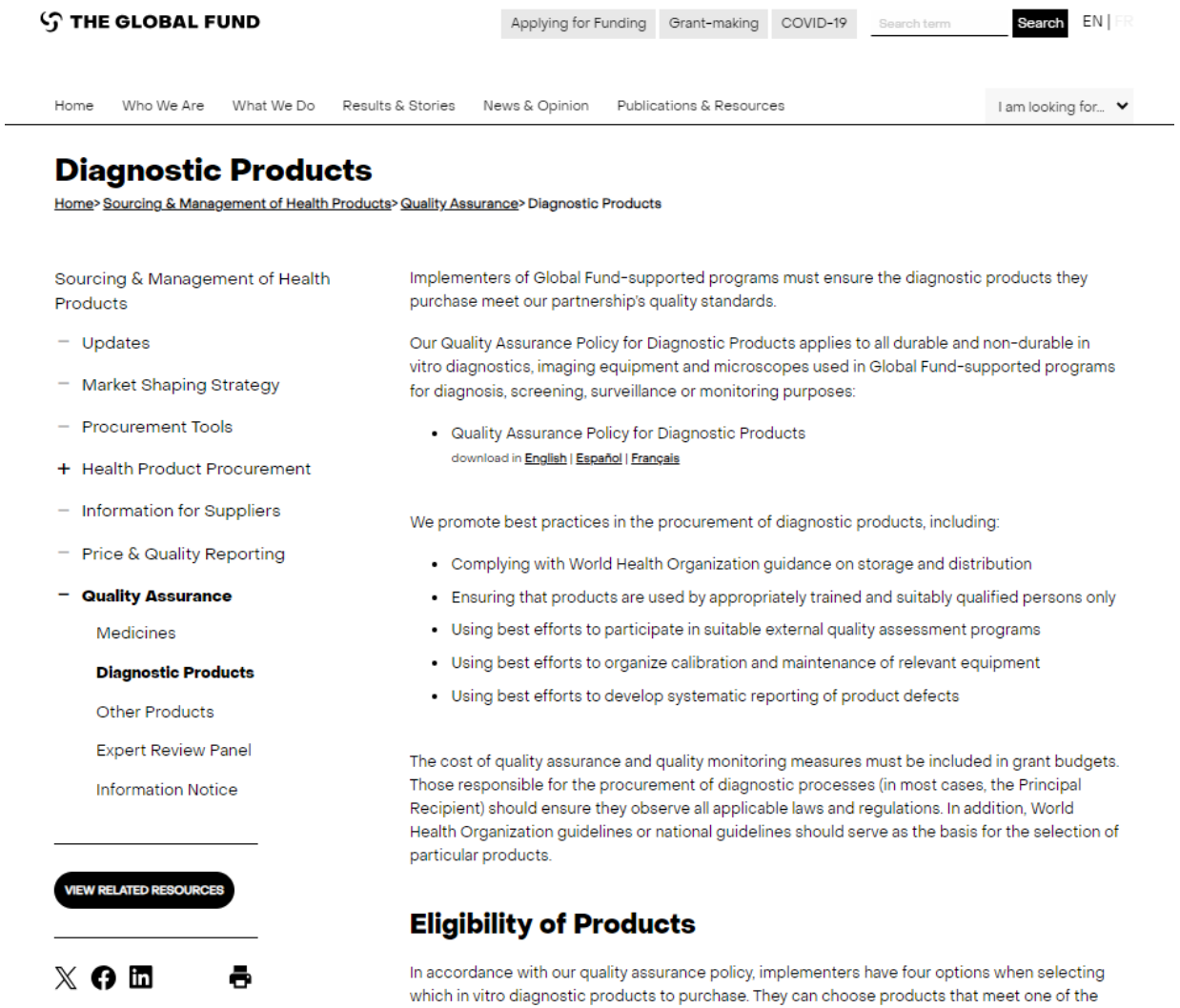
- QA Policy for Diagnostics expanded to become QA Policy for **ALL** Medical Devices including in-vitro diagnostics and core personal protective equipment.
- Eligibility includes products authorized for use by a WLA within their scope of listing
- Eligibility includes MDs (IVDs) and PPE authorized through emergency use procedures during a PHEIC
- Monitoring Policy Implementation Section:
  - *Guidance and training*
  - *Management of QA issues*
  - *Monitoring and Oversight*
- Section describing role of the Global Fund's Strategy Committee (SC) in overseeing Policy implementation
- Provision for WLA transitioning although this will be on a different timeline than for Pharmaceutical Products.

What are the key changes for IVDs?

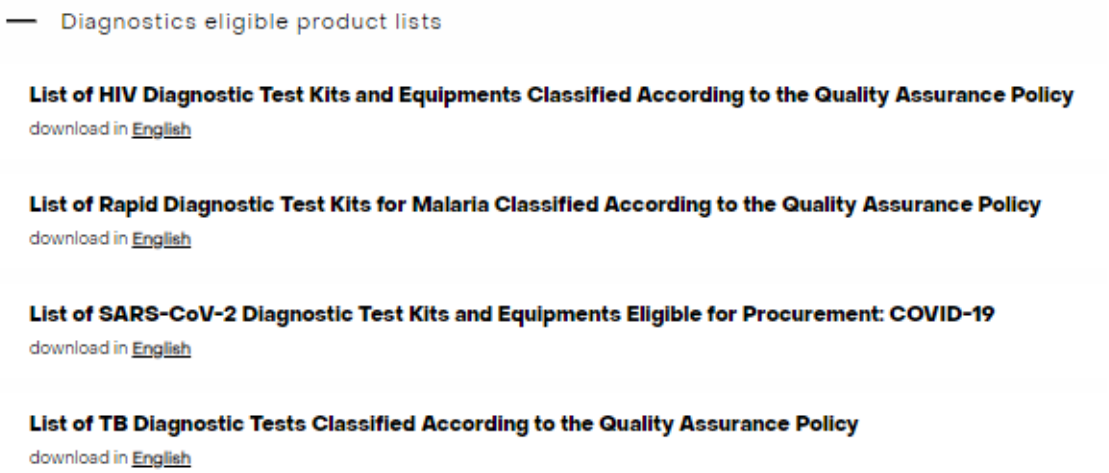
	Former QA POLICY Framework
Reference	***QA Diagnostic Products Policy (2017)***
Product applicability	For all Diagnostic Products (IVDs plus others)
General quality standards (section 7)	Quality Management System requirements (ISO 13485 or equivalent)
Additional Quality Requirements (section 8)	IVDs with respect to HIV, tuberculosis and malaria and to Hepatitis B, hepatitis C and syphilis co-infections, as well as IVDs providing information that is critical for patient management of these diseases Prequalified by the WHO Prequalification Programme Or WHO Global TB programme recommendation Or Authorized for use by Regulatory Authorities of the Founding Members of the GHTF when stringently assessed (as high risk) Or After assessment by Expert Review Panel

	NEW QA POLICY Framework
Reference	***QA Medical Device Policy (2023)***
Product applicability	For all Medical Devices (including In-Vitro Diagnostics)
General quality standards (section 7 & 8)	Quality Management System requirements (ISO 13485 or equivalent)
Additional Quality Requirements (section 10)	IVDs with respect to … Prequalified by the WHO Prequalification Programme Or WHO Global TB programme recommendation/Rapid Communications Or Authorized for use by Regulatory Authorities of the Founding Members of the GHTF when stringently assessed (Class C & D) Or **Authorized for use by WLA** Or After assessment by Expert Review Panel **In case of Public Health Emergencies of International Concern (PHEIC)** **Approved under the WHO EUL** **Or** **Under SRA/WLA Emergency procedures**

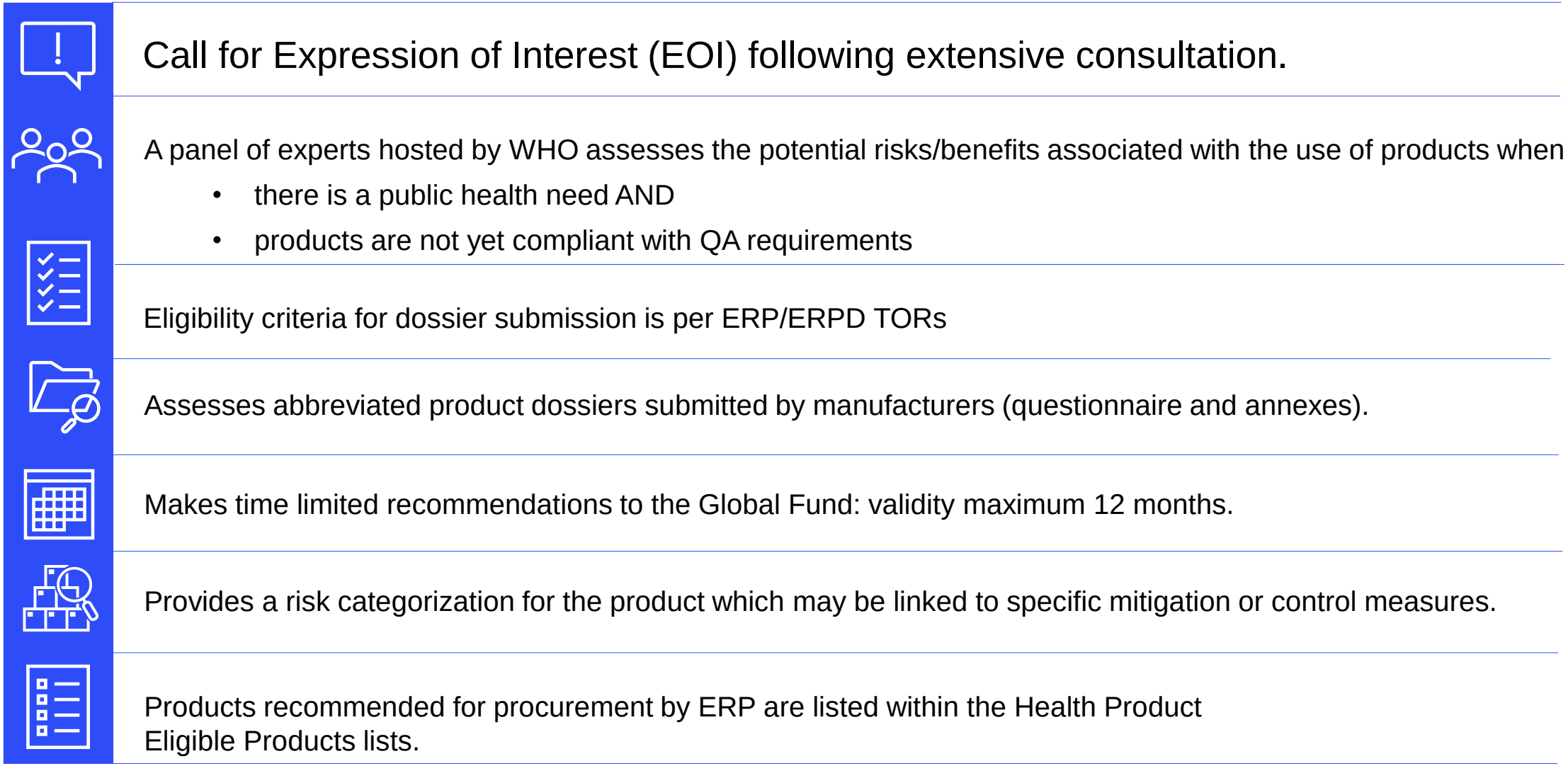
More available on Global Fund website



https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/



The Expert Review Panel (ERP) – 1/3



Call for Expression of Interest (EOI) following extensive consultation.

A panel of experts hosted by WHO assesses the potential risks/benefits associated with the use of products when

- there is a public health need AND
- products are not yet compliant with QA requirements

Eligibility criteria for dossier submission is per ERP/ERPD TORs

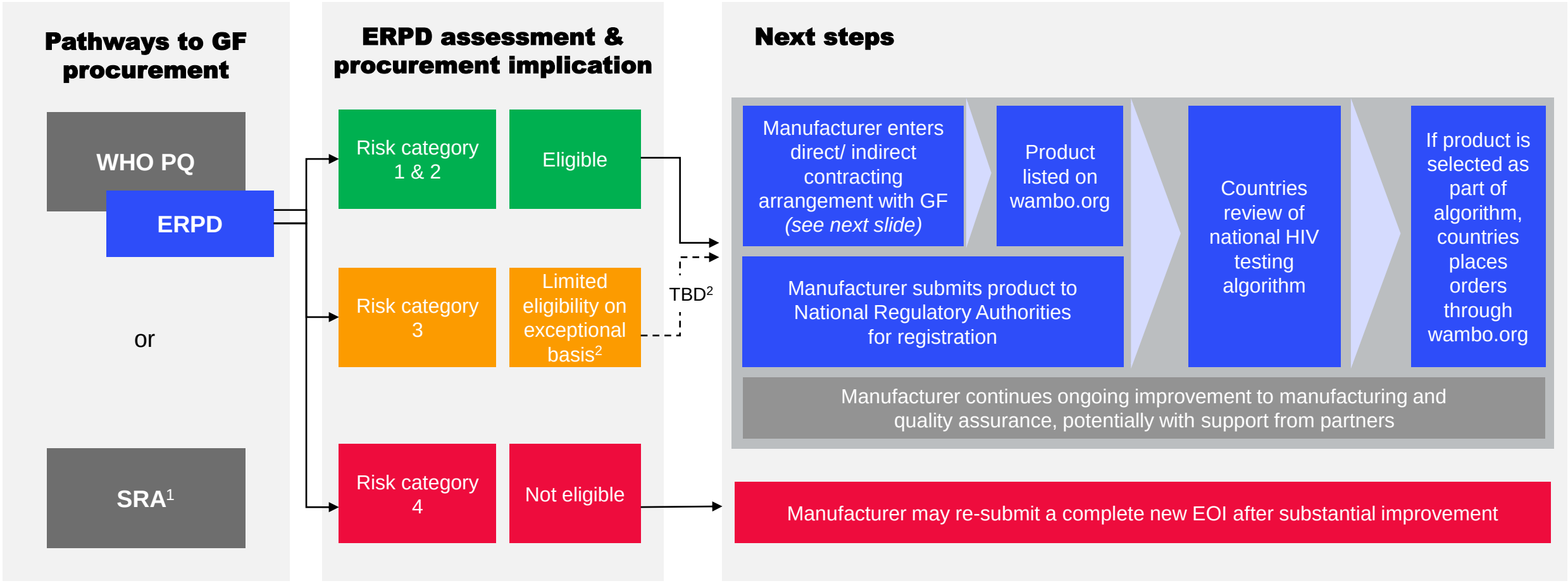
Assesses abbreviated product dossiers submitted by manufacturers (questionnaire and annexes).

Makes time limited recommendations to the Global Fund: validity maximum 12 months.

Provides a risk categorization for the product which may be linked to specific mitigation or control measures.

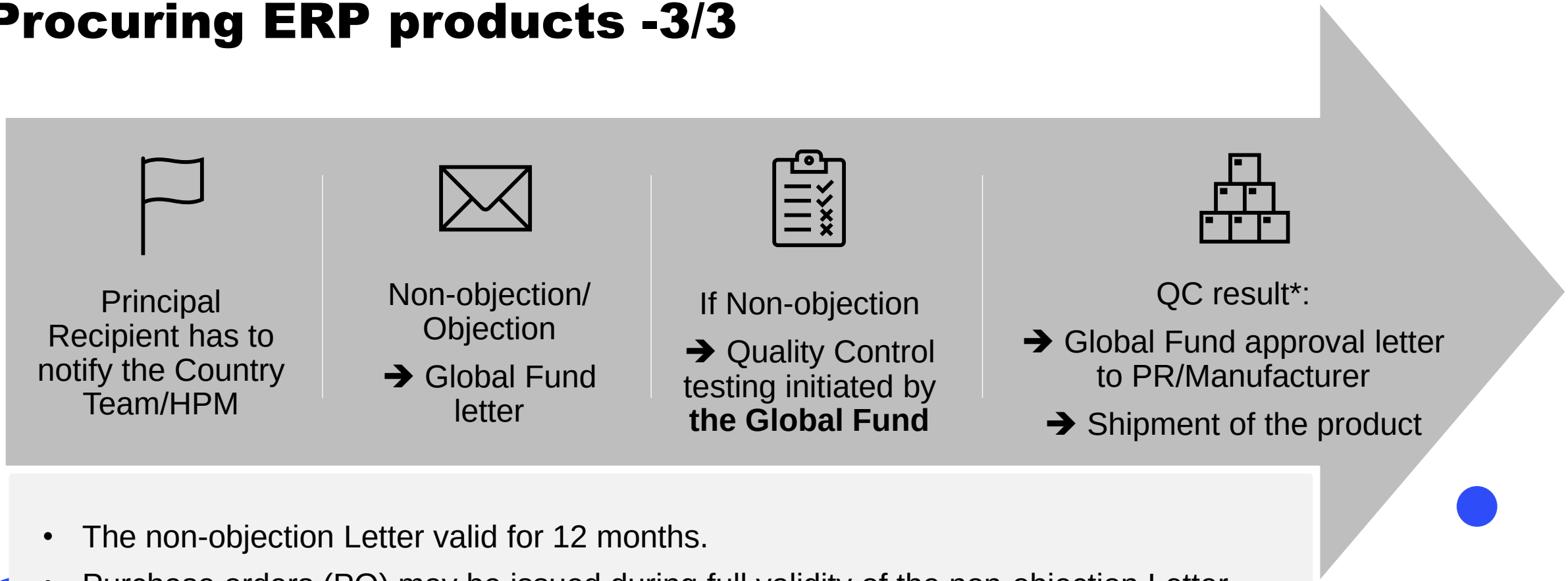
Products recommended for procurement by ERP are listed within the Health Product Eligible Products lists.

Indicative next steps before following ERPD, before a test can be procured using Global Fund funds -2/3



1 SRA is not possible for HIV RDTs for self testing (see QA Policy)
2 Procurement permitted if no alternatives that can meet programmatic and/or operational requirements

Procuring ERP products -3/3

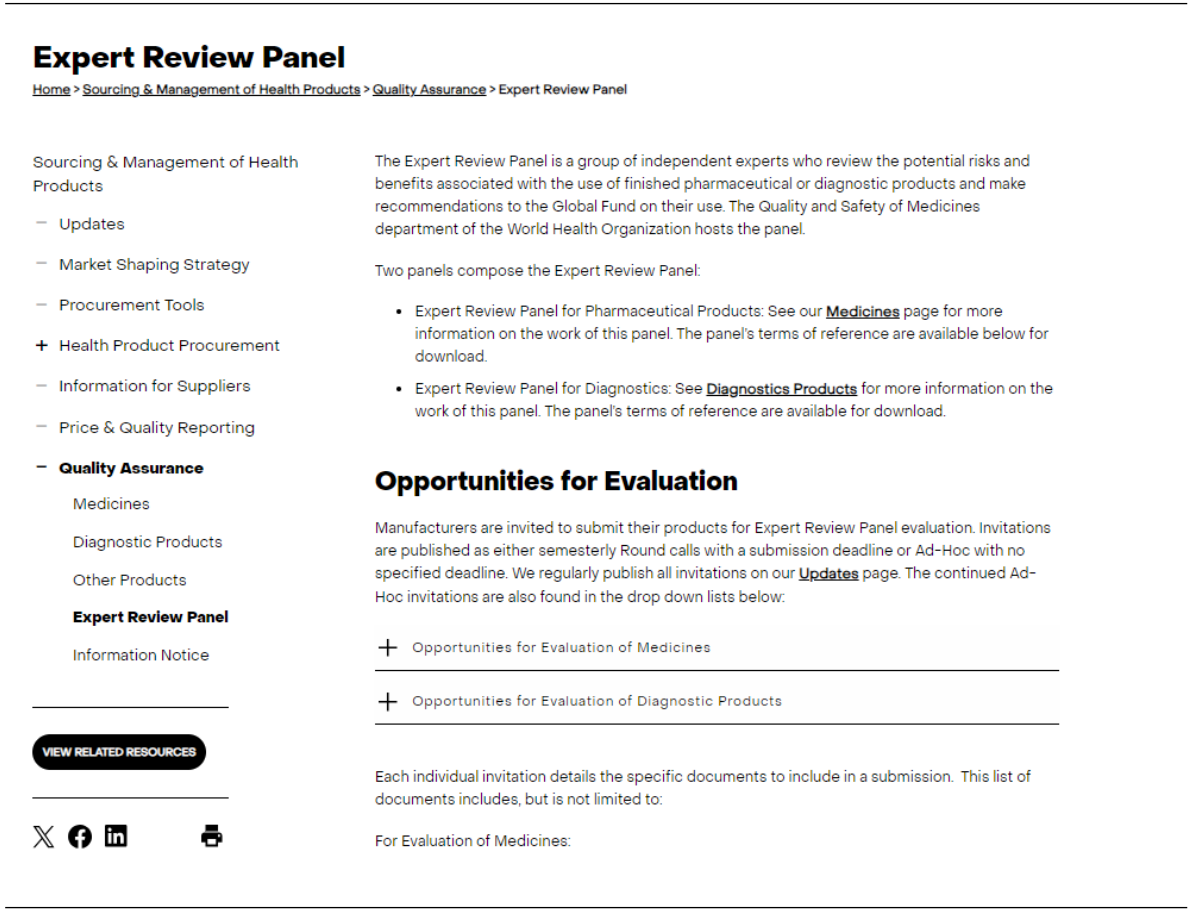


- The non-objection Letter valid for 12 months.
- Purchase orders (PO) may be issued during full validity of the non-objection Letter.
- There is a possibility to organize for a shipment under quarantine status to allow the transport and the testing of the goods to be done in parallel.

*QC testing is required for all Pharma ERP assessed products and only applicable to Diagnostic ERP assessed products depending on the associated risk mitigations.

More available on ERP on Global Fund website

https://www.theglobalfund.org/en/sourcing-management/quality-assurance/expert-review-panel/



Expert Review Panel

Home > Sourcing & Management of Health Products > Quality Assurance > Expert Review Panel

Sourcing & Management of Health Products

- Updates
- Market Shaping Strategy
- Procurement Tools
- Health Product Procurement
- Information for Suppliers
- Price & Quality Reporting
- **Quality Assurance**
  - Medicines
  - Diagnostic Products
  - Other Products
  - **Expert Review Panel**
  - Information Notice

VIEW RELATED RESOURCES

The Expert Review Panel is a group of independent experts who review the potential risks and benefits associated with the use of finished pharmaceutical or diagnostic products and make recommendations to the Global Fund on their use. The Quality and Safety of Medicines department of the World Health Organization hosts the panel.

Two panels compose the Expert Review Panel:

- Expert Review Panel for Pharmaceutical Products: See our Medicines page for more information on the work of this panel. The panel's terms of reference are available below for download.
- Expert Review Panel for Diagnostics: See Diagnostics Products for more information on the work of this panel. The panel's terms of reference are available for download.

Opportunities for Evaluation

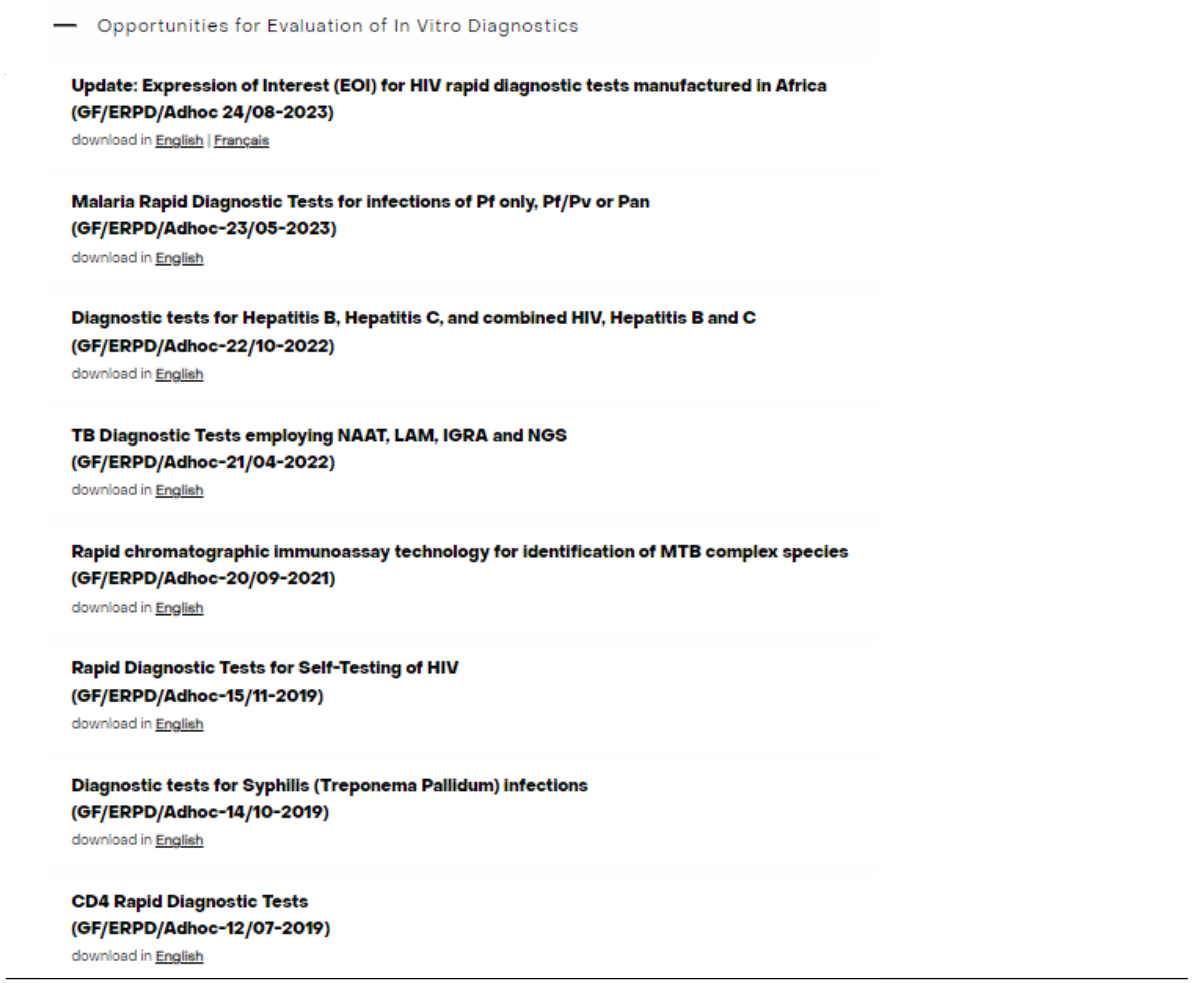
Manufacturers are invited to submit their products for Expert Review Panel evaluation. Invitations are published as either semesterly Round calls with a submission deadline or Ad-Hoc with no specified deadline. We regularly publish all invitations on our Updates page. The continued Ad-Hoc invitations are also found in the drop down lists below:

+ Opportunities for Evaluation of Medicines

+ Opportunities for Evaluation of Diagnostic Products

Each individual invitation details the specific documents to include in a submission. This list of documents includes, but is not limited to:

For Evaluation of Medicines:



— Opportunities for Evaluation of In Vitro Diagnostics

Update: Expression of Interest (EOI) for HIV rapid diagnostic tests manufactured in Africa (GF/ERPD/Adhoc 24/08-2023)
download in English | Français

Malaria Rapid Diagnostic Tests for infections of Pf only, Pf/Pv or Pan (GF/ERPD/Adhoc-23/05-2023)
download in English

Diagnostic tests for Hepatitis B, Hepatitis C, and combined HIV, Hepatitis B and C (GF/ERPD/Adhoc-22/10-2022)
download in English

TB Diagnostic Tests employing NAAT, LAM, IGRA and NGS (GF/ERPD/Adhoc-21/04-2022)
download in English

Rapid chromatographic immunoassay technology for identification of MTB complex species (GF/ERPD/Adhoc-20/09-2021)
download in English

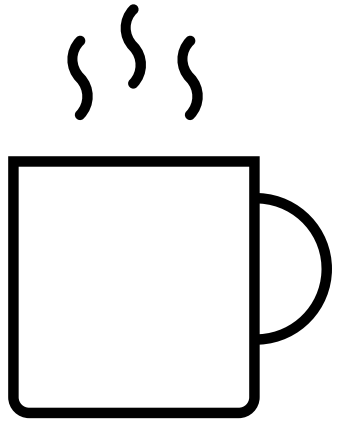
Rapid Diagnostic Tests for Self-Testing of HIV (GF/ERPD/Adhoc-15/11-2019)
download in English

Diagnostic tests for Syphilis (Treponema Pallidum) infections (GF/ERPD/Adhoc-14/10-2019)
download in English

CD4 Rapid Diagnostic Tests (GF/ERPD/Adhoc-12/07-2019)
download in English

THE GLOBAL FUND

Break Meeting will reconvene at 3:00PM GVA time



PEPFAR Sourcing Strategy

Matthew Wattleworth & Konrad Bradley
Senior Laboratory Advisors
USAID, PEPFAR

USAID Long Term Strategy - Integrated and Sustainable National Laboratory Networks

Office of HIV/AIDS
Matt Wattleworth and Konrad Bradley
Senior Laboratory Systems Advisors, SCH/OHA/GH

Topics of Discussion

Introduce PEPFAR's Global Laboratory Supply Chain Strategy

A move to Vendor Managed Solutions

Discuss other private sector opportunities that advance PEPFARs sustainability and USAID laboratory strategy

USAID Supply Chain transformation model is a four step phased approach to enable transition to host governments

Strategy is to lead efforts to advance value added services and enable contract transition

PHASE I
Traditional SC Activities

Support or provide direct traditional SC activities and diagnostic network optimizations that inform all inclusive procurement

PHASE II
All-Inclusive Services

Provide data driven approaches to advance negotiations under all inclusive contracts and to move countries from traditional SC activities to all-inclusive procurements

PHASE III
VMI Implementation

Work with host governments and existing SC partners to include VMI strategies within all-inclusive contracts

PHASE IV
Contract Transition

Development of contract management strategies and support for host governments to transition contracts

Past challenges – reasons to shift

There have historically been a range of challenges in the VL and EID testing markets

Lack of "all-inclusive" service packages in most countries, with inadequate budgeting for and procurement of some services (esp., maintenance)

No formal supplier service contracts or target service levels established in most countries, limiting countries' ability to hold suppliers to a high level of service performance

Limited donor transparency into instrument performance and usage, with only a small minority of countries publicly publishing national lab system data

High variations in pricing across countries (up to 2x for same exact product), driven by:

- **Fragmented procurement and planning activities** across global partners and countries, with negotiations often done on a country-by-country basis
- **Limited competition,** with only two major market players and some countries locked into sole-supplier situations
- **Low transparency into pricing and terms**

USAIDGlobalHealthSupplyChainP

PEPFAR used several strategies to address the challenges in viral load procurement, with a shift on prioritizing services

Challenges	Strategies used	RFP process
Lack of all-inclusive service packages	Developed standardized, **all-inclusive service package** for suppliers to bid on for all countries	PEPFAR enacted its strategies through a **Global RFP for VL and EID testing**
No formal supplier contracts and service levels	Established **standardized service agreements** and KPI tracking, with regular supplier performance dialogues Made **suppliers contractually accountable** for their distributors' performance	
Lack of data transparency	Required suppliers to **enable automated reporting** of operational data from all instruments	
High variations in pricing	**Aggregated PEPFAR spend** to maximize buying power **Leveraged new entrant** (Hologic) to promote competition **Restructured global pricing approach**: – Global price for reagents & consumables by supplier – Price transparency for individual country services – Volume-based discounts	

USAIDGlobalHealthSupplyChainP

The Global RFP has been structured in two waves to cover all PEPFAR-supported countries

2019

Wave 1 kickoff

Global RFP initiated with focus on reagents and consumables for all countries and all-inclusive services for 6 high-volume “Wave 1” countries

2020

Wave 1 implementation

New global reagents and consumables prices enacted

All-inclusive services pricing goes into effect for the 6 Wave 1 volume countries

Instrument operational data reporting begins in Wave 1 countries

2022

Wave 2 kickoff

Global RFP extended to cover services for an additional 42 “Wave 2” countries

2023

Wave 2 implementation

All-inclusive pricing goes into effect for 12 Wave 2 countries with regular PEPFAR-supported purchases

Engagement occurs with the main procurers (GFATM, MoHs) for the remaining 30 Wave 2 countries to make them aware of Wave 2 benefits (terms and pricing)

This effort builds on the Global Viral Load (VL) initiative from 2020 that implemented the new all-inclusive package in 6 large pilot countries

Pilot countries: Kenya, Mozambique, Nigeria, Tanzania, Uganda, Zambia

6	Largest PEPFAR-supported countries have all-inclusive pricing with stronger service levels
~$100M	Cumulative savings for PEPFAR since 2020 compared to pre-RFP savings
10	Standardized KPIs in the Global VL initiative to drive network performance through stronger, formal, service levels
1	Global VL Dashboard developed to capture a wealth of data for improved commodity security, testing results and network optimization
	More than 300 instruments providing live reporting of operational data to the dashboard
	3rd supplier ramping up in several countries to increase competition and supply security

USAIDGlobalHealthSupplyChainP

This past year, Wave 2 expanded the Global VL initiative to cover all PEPFAR-supported countries, including many countries in which Global Fund is the primary funder

Africa

- Cameroon
- Cote d'Ivoire
- DRC
- Eswatini
- Ethiopia
- Lesotho
- Rwanda
- Zimbabwe
- Angola
- Benin
- Burkina Faso
- Ghana
- Liberia
- Malawi
- Mali
- Sierra Leone
- Botswana
- Burundi
- Namibia
- Senegal
- South Sudan
- Togo

Latin America & Caribbean

- Haiti
- Bahamas
- Brazil
- El Salvador
- Honduras
- Jamaica
- Guatemala
- Guyana
- Nicaragua
- Panama

Asia & Europe

- Cambodia
- India
- Indonesia
- Kazakhstan
- Nepal
- Papua New Guinea
- Philippines
- Thailand
- Ukraine
- Vietnam

Volume (2022) of annual tests:

- 9M+ total
- 3M+ PEPFAR

In many of these countries, GF or its PR is the primary procurer

May 13-17, 2024 – First Wave 2 workshop, Addis Ababa, Ethiopia

First, some statistics

12 + Workshop and training sessions conducted

15+ Hours of tutorials have been conducted in 3 days

75+ Workshop participants from 10 countries

24+ Organizations represented

May 13-17, 2024 – First Wave 2 workshop, Addis Ababa, Ethiopia

If there is one thing you should remember from each training module, it should be…

1. **Change Management:**
   - Developing a **case for change** and **communicating it effectively** to your stakeholders is critical to **enabling sustainable and lasting change.**
2. **SLA**:
   - The SLA must be **included under a larger general framework agreement** such as BOA.
   - The **SLA template is flexible** to accommodate your needs and constraints.
3. **Supply Chain Management:**
   - Any incoterm change should be carefully **discussed and considered with all relevant stakeholders**.
   - Additional strategies should be considered if and when the country needs to evaluate products with lower remaining shelf-life
4. **Pricing**:
   - All Inclusive Price = R&C Price <which is global> + Services Price <which is country-specific>
   - **Further collaboration is encouraged to unlock best value**; however, W2 countries will almost always **continue to use CVI's**

May 13-17, 2024 – First Wave 2 workshop, Addis Ababa, Ethiopia

If there is one thing you should remember from each training module, it should be…

5. **VMI:**
   - All **key stakeholders must be present** from the start to implement VMI
   - **Proactively take the steps necessary** that would qualify you for VMI
6. **KPI:**
   - KPIs help create accountability and transparency between you and the supplier
   - Meeting with your supplier to discuss their KPI performance regularly is the only way to improve their performance and create corrective action plans for poor performing KPIs.
7. **VIPMA:**
   - **Data sharing capabilities are necessary for fully implementing KPI monitoring** and VMI
   - All machine monitoring is done in compliance with strict data privacy regulations
8. **Instrument Placements:**
   - Consider **network, laboratory/site preparedness, instrument, and products** when thinking about instrument placements

The all-inclusive package of services was designed in collaboration with Integrated Diagnostic Consortium partners, including Global Fund

Services category	What is included
Instrument lease, installation and removal	Equipment lease and installation costs, including placement, delivery of machines to site, inspection of machines, initial end user training and instrument removal at end of life or end of contract
Service and maintenance, insurance, and ongoing end user training	All aspects of servicing and maintaining instruments and providing ongoing end user training, including insurance, preventative maintenance, repairs and replacements, and necessary updates
Connectivity and data reporting	Automated reporting of operational data from instruments
Commodity supply chain management	Freight and logistics of reagents and consumables delivered to the central medical store or laboratory
Equipment upgrades	Planned enhancements and upgrades to instruments

Three suppliers have agreed to these service packages[1]

Abbott

Roche

HOLOGIC®
The Science of Sure

1. Not all suppliers bid on all countries, and a small number of service level exceptions exist

Core components necessary to move to VMI

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VIMPA Data availability and visibility

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Connec reporti ng	**Shift in INCOTERMS – EXW/FCA to DAP/DDP**
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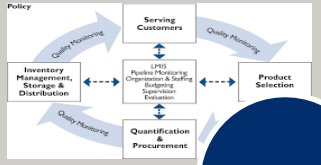
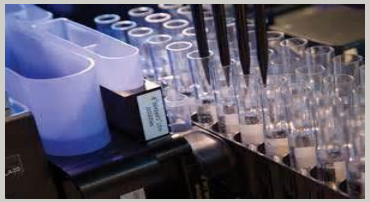
Supply Chain – Traditional approach





Quantification

Procurement

Manufacturer

Transport

Central medical stores

Incountry distribution

Laboratory

Multiple data systems & sources

PEPFAR
U.S. President's Emergency Plan for AIDS Relief

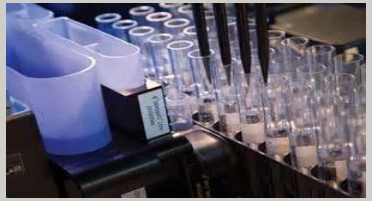
Supply Chain – Shift in INCOTERMS

Dashboards

Procurement

Centralized data

Laboratory



Transport

Manufacturer

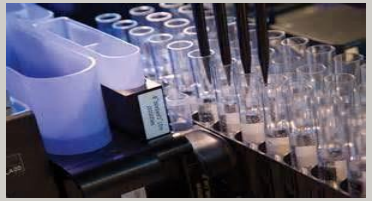
Shift in INCOTERMS – EXW/FCA to DAP/DDP

PEPFAR
U.S. President's Emergency Plan for AIDS Relief

Supply Chain – Move to VMI

Dashboards

VMI – a full vendor managed inventory approach



Laboratory

Centralized data

Manufacturer

Transport

PEPFAR
U.S. President's Emergency Plan for AIDS Relief

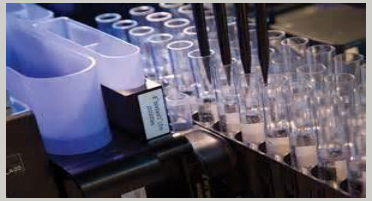
Supply Chain – Move to VMI

Current pilots:

Nigeria

Mozambique

VMI – a full vendor managed inventory approach



PEPFAR
U.S. President's Emergency Plan for AIDS Relief

Topics of Discussion

Introduce PEPFAR's Global Laboratory Supply Chain Strategy

A move to Vendor Managed Solutions

Discuss other private sector aspects that advance PEPFARs sustainability strategy

Advantages of moving to service driven contracts and private sector integration for national laboratory networks

- Contract driven – defined service level expectations
- Centrally managed
- Performance based
- Annual renegotiation of contracts and lower switching costs
- Standard KPI monitoring
- Ease of contract transition to host governments
- Transparency – cost and performance

- Flexibility
- Scaleable
- Known costs
- Service driven and payment for services only
- Drives competition and value for money
- Develops private sector capabilities
- Long term sustainability

Opportunities moving to service driven contracts and private sector integration for national laboratory networks

- Transitioning public sector laboratory supply chain into a service oriented model that includes all-inclusive pricing contracts (VMI solutions, instrument connectivity, data visibility and transparency) with overall management and oversight provided by MOHs
- Utilize DNO to map public and private sector laboratory coverage and define overall laboratory network, sample collection points, and inform development of approaches to improve service delivery coverage and potential surveillance structures.
- Fully integrate private sector laboratories to improve coverage and to move to a service oriented model that compliments existing public laboratory systems.
- Developing systems of data reporting that integrate public and private laboratories, leveraging national sample transport networks to serve as the backbone for a national surveillance network providing disease data and samples to national reference laboratories

USAID is working to better understand and pilot fee-for-service contracts within the private sector laboratory and sample transport marketplace

Strategy is to expand business intelligence within the private sector, pilot, monitor, and scale as appropriate

PHASE I
RFI and market intelligence

Research market based on testing needs, quality, accreditation status, price and regulatory oversight - **RFI**

Phase 1a- Utilize DNO to model and inform integration pilot

PHASE II
RFPs and Award Process

Engage the private laboratory market to award testing volumes through a competitive process - **RFP**

PHASE III
Develop and integrate Reporting Systems

Develop Systems for reporting and integrating private sector testing into national surveillance systems

PHASE IV
Monitor performance of key metrics

Monitor performance of private labs through to include quality, TAT, cost,

PHASE V
Utilize performance data to inform strategic sourcing and expansion of private laboratory services

Annual review and recompetition of contracts

USAIDGlobalHealthSupplyChainP

Comments/Questions

Acknowledgement – many of the slides in this presentation are the work of GHSC/PMS – All-inclusive and Wave 1 and 2 updates

THE GLOBAL FUND

Molecular Technologies Procurement Strategy

The Global Fund, Direct Sourcing Team

Context – Molecular Technologies

Integrated Molecular PCR Diagnostics is a complex category and essential for the successful implementation of HIV, TB and RSSH programs

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1. Integrated molecular technologies is a core diagnostic category that **includes HIV viral load, early infant diagnostics, multi-drug resistant tuberculosis and other co-infections**. GC6 spend including C19RM investment was $265M, representing ~2% of $5.1bn* global diagnostics market, consisting of **instruments, assays, consumables, service & maintenance and connectivity solutions**.
2. In the framework of Resilient and Sustainable Systems for Health (RSSH), molecular diagnostic technologies **strengthen the national laboratory systems, enhance country capabilities for emergency preparedness** and provides **access to life saving diagnostics for HIV, TB and Co-Infections**.
3. The Global Fund, PEPFAR, USAID TB and StopTB have been working together to **implement innovative procurement modalities including all-inclusive pricing** (reagent rental).
4. Implementation of effective procurement modalities require **collaboration and coordination at the national, regional and global levels**. **National programs** and **laboratory networks** need to have strong administrative capacity to manage the technologies, and closely engage with suppliers and global partners for technical support and funding.
5. In collaboration with key internal and external stakeholders, the Sourcing team will **implement a refreshed procurement strategy aiming to create a stronger system alignment and improved Value for Money through optimizing di**agnostic network and well-defined performance criteria.

* HIV Market: HIV Diagnostic Market, FMI Inc. (2022)
TB Market: Tuberculosis Diagnostic Market Definition and Segments (2024)

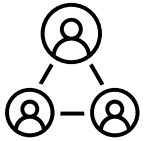
Integrated Molecular PCR Technologies Matrix

Effective category management requires an integrated and multi-dimensional approach

Cross-Disease

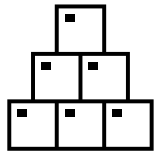
- HIV
- Tuberculosis
- Co-Infections: Hepatitis B, Hepatitis C, and Human Papilloma Virus (HPV)

Multilateral Stakeholder



- The Global Fund (TAP, Lab, GMD, SO)
- Large Partner Organizations (PEPFAR, USAID TB)
- Procurement Service Agent
- Manufacturers
- Distribution Networks
- National Disease Programs & Laboratories

System Solutions



- Instruments
- Tests
- Consumables
- Warranties and Services
- Data connectivity and Reporting

Multiple Procurement Modalities

- Direct Purchase
- All-Inclusive Pricing
  - For legacy (directly purchased) instruments
  - For new instruments

Requires tailored approach per country at implementation stage

Integrated Molecular PCR Technologies Scope

The portfolio covers multiple diseases, products and components

Disease Scope	
HIV	• **Viral Load (VL)** • **Early Infant Diagnosis (EID)**
TB	• **MTB Nucleid Acid Amplification** • **RIF** • **XDR**
Co-Infections	• **Hepatitis B** • **Hepatitis C** • **Human Papilloma Virus**

Components
Tests
Instruments – Platform, Analyzer, etc.
Consumables – Calibrators, Sample Preparations, etc.
Service and Maintenance – SLAs, Warranty, Training & Installation, Spare Parts
Connectivity – Software, Data Management & Reporting

Scope: QA eligible automated PCR Testing Technologies for VL/EID, Tuberculosis and Co-Infections

Multiple Procurement Modalities

Proposed procurement modalities range from direct purchase of individual components to all-inclusive price per test

Direct Purchase

- Components are purchased individually
- Responsibility divided between customer and supplier
- High Potential logistics risks for the recipient

Hybrid

- More inclusive than direct purchase
- Equipment lease with direct procurement of tests (no volume commitment)
- Some cost components may be included in the price per test
- Service and maintenance may be included

All-Inclusive

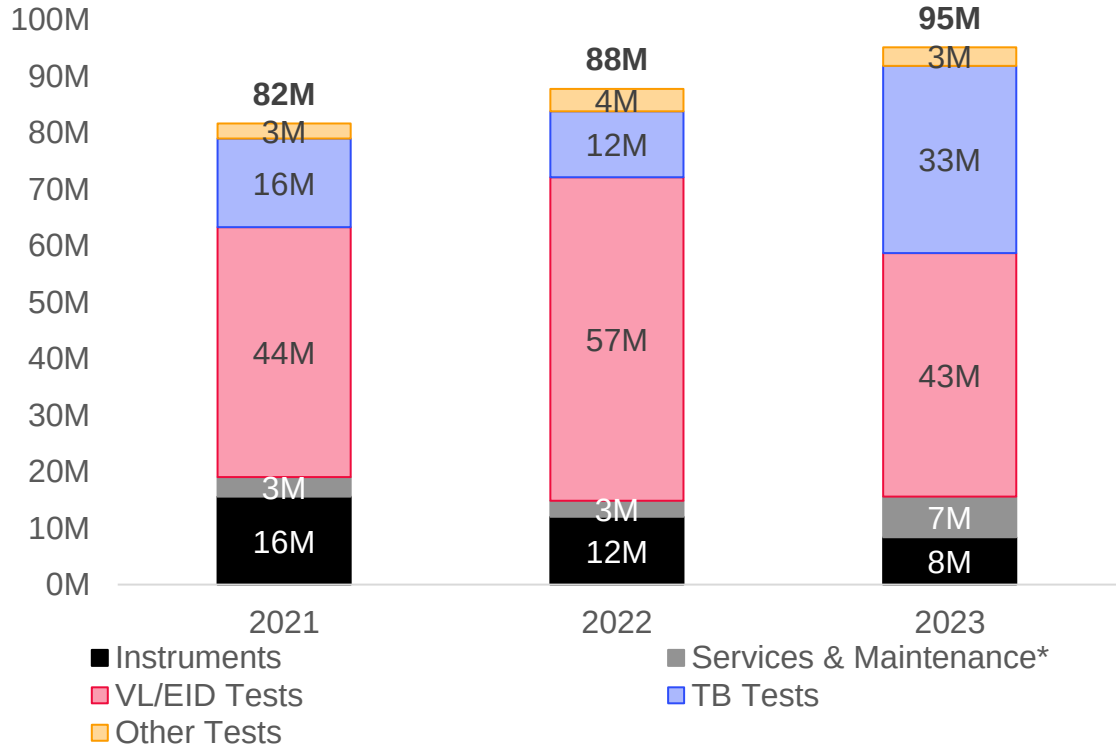
- Test price includes all components (platform, test, services, etc.)
- Supplier responsible to monitor and report against KPIs
- Required time-bound volume commitment

Molecular Procurement Overview 2021-2023

A range of PCR Technologies valued at $265M were procured through PPM across HIV, Tuberculosis and related Co-Infections

- **Total spend for tests** represent over **80%** and total of **$215M**
  - i. VL/EID[1] test spend was $145M, or two thirds of total spend on tests.
  - ii. Tuberculosis test spend was $61M, representing 28% of spend on tests; 20% of spend funded through C19RM investment
  - iii. Other tests (Co-Infections[3]) accounted for $10m
- Procurement of **equipment** (including instruments, services & maintenance) amounted **$49M** and represented about **20%** of spend, mainly driven by C19RM investment.
- Demand for GC7 (2024-2026) is expected to remain at a similar level – with a potential increase. Indicative demand information will be shared with the Request for Proposals (RFP) publication

Molecular US$ spend[2] for 2021 to 2023



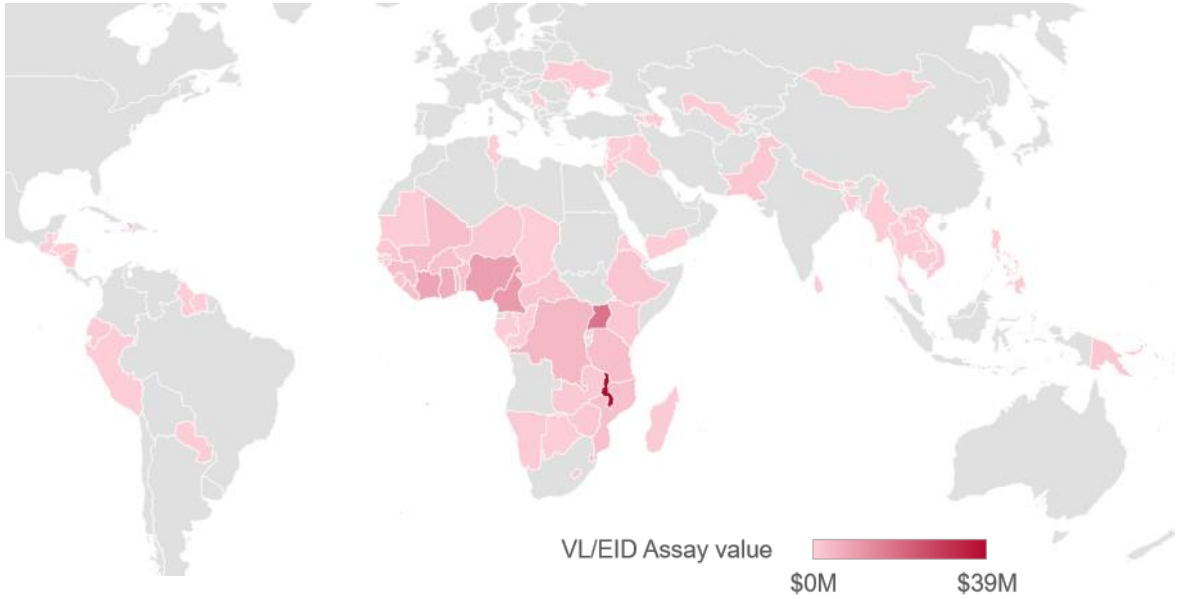
*incl. spare parts, components, warranty, services, and other equipment related costs

[1] VL/EID = HIV Viral Load and Early Infant Diagnosis
[2] Data Source: Global Fund Procurement Service Agent. PPM procurement data for 2021 to 2023
[3] Other tests includes Hepatitis B and C (HBV, HCV), Human Papillomavirus (HPV), and other Molecular reagent and consumables

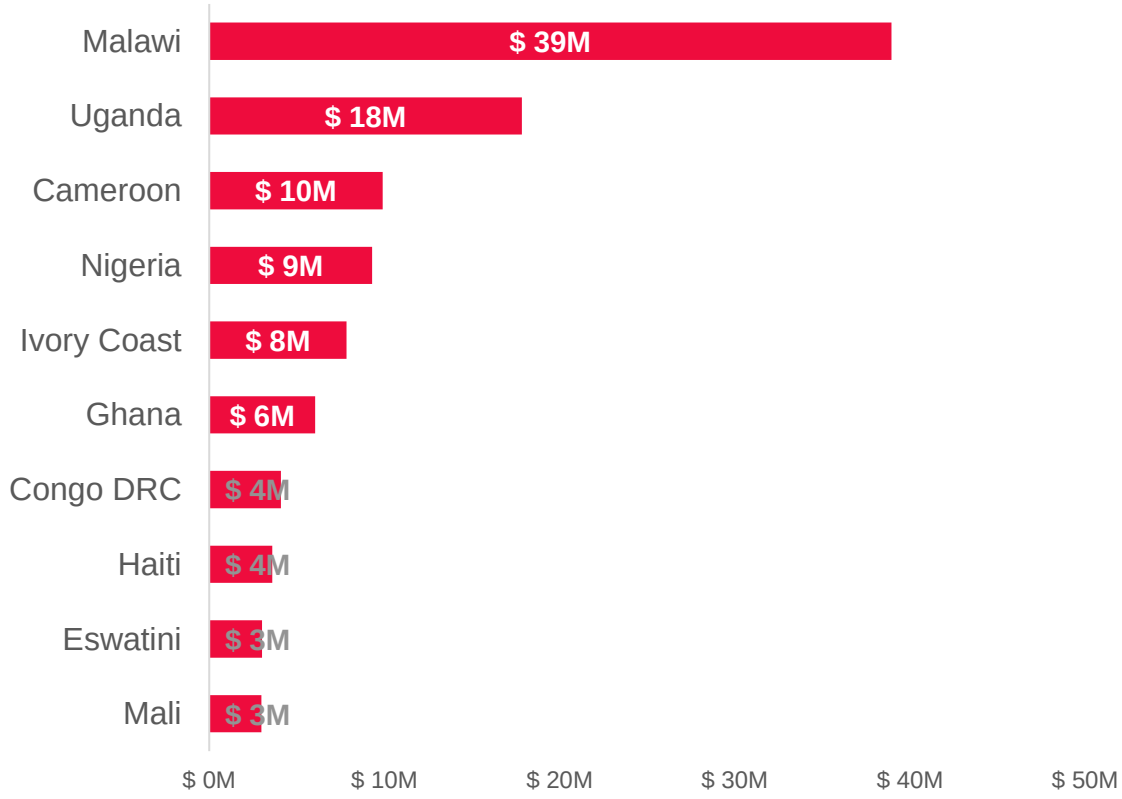
VL/EID tests supplied to 79 countries in 2021-2023

Top 5 countries account for 58% of spend. Bottom 40 countries account for ~2%

$145M VL/EID tests procured for 79 countries*,…



… and **10 countries accounted for 71%** of the volumes



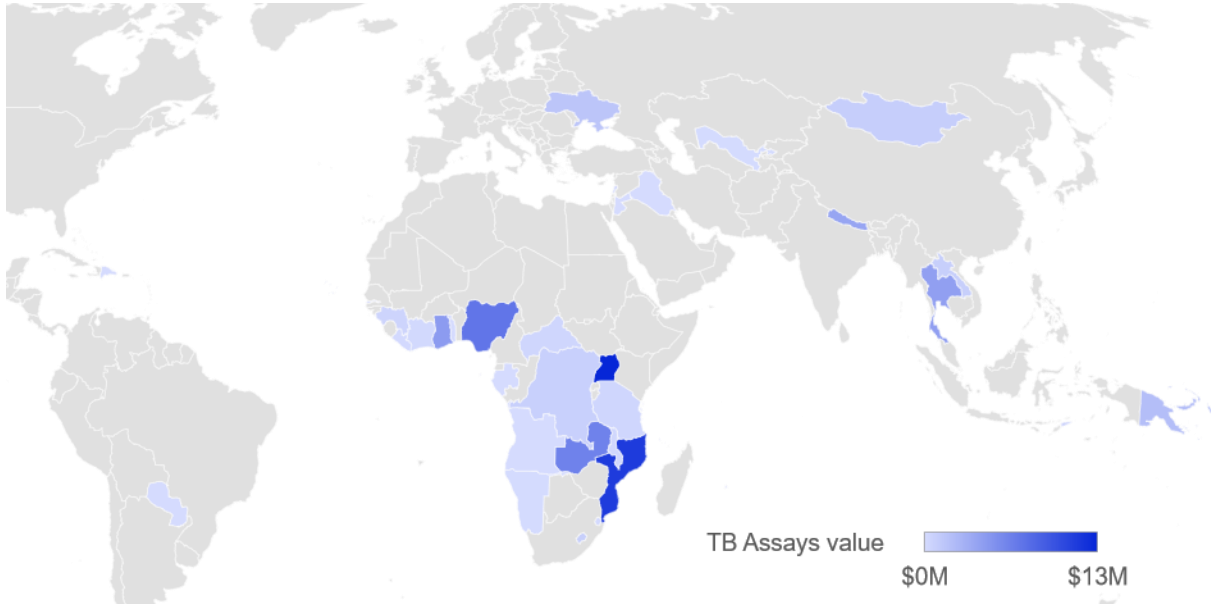
* 79 countries (from 2021 to 2023): Armenia, Azerbaijan, Bangladesh, Belize, Benin, Bhutan, Botswana, Burkina Faso, Cambodia, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, East Timor, Ecuador, El Salvador, Eritrea, Eswatini, Ethiopia, Gabon, Ghana, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, Iraq, Israel, Ivory Coast, Jordan, Kenya, Laos, Lebanon, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Moldova, Mongolia, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Papua New Guinea, Paraguay, Peru, Philippines, Republic of the Congo, Rwanda, São Tomé and Príncipe, Senegal, Serbia, Sierra Leone, Solomon Islands, Sri Lanka, Suriname, Syria, Tanzania, Thailand, The Gambia, Togo, Tunisia, Uganda, Ukraine, Uzbekistan, Vietnam, Yemen, Zambia, Zimbabwe

Data Source: Global Fund Procurement Service Agent. PPM procurement data for 2021 to 2023

TB tests supplied to 37 countries in 2021-2023

Uganda, Mozambique, Nigeria, and Zambia represented over 50% of demand in 2021-2023

$61M Tuberculosis tests procured for 37 countries*,…



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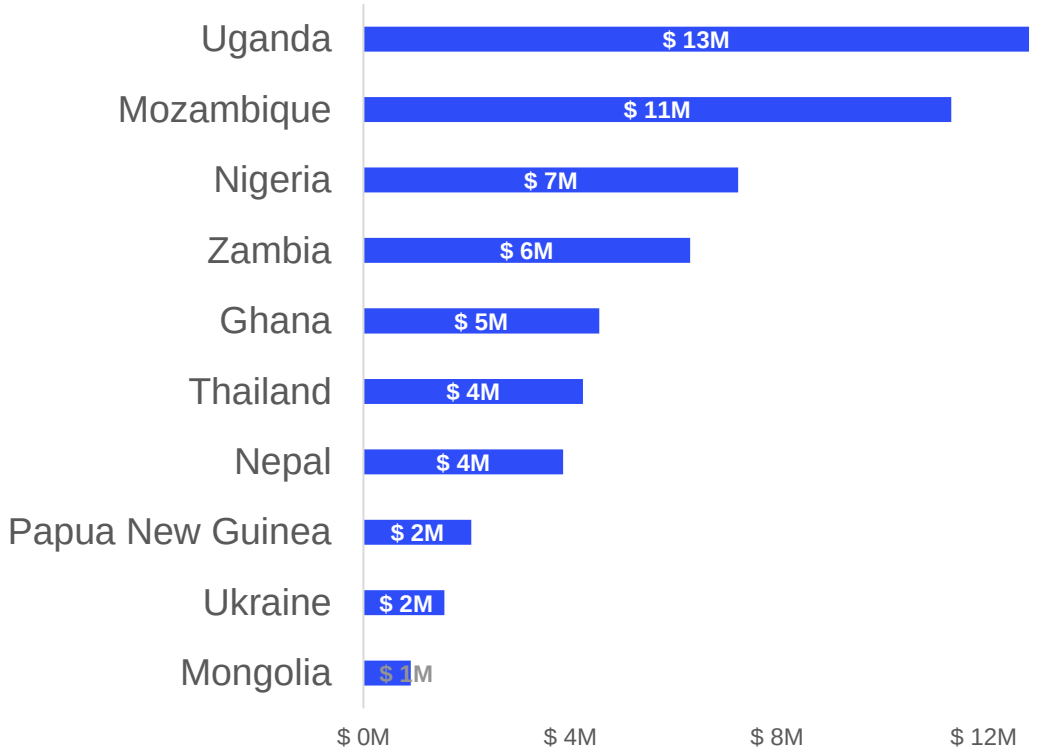

* 37 countries (from 2021 to 2023): Angola, Cape Verde, Central African Republic, Comoros, Democratic Republic of the Congo, Dominican Republic, East Timor, Eswatini, Gabon, Ghana, Guinea, Iraq, Ivory Coast, Jordan, Laos, Lebanon, Lesotho, Liberia, Malawi, Mauritius, Mongolia, Mozambique, Namibia, Nepal, Nigeria, Papua New Guinea, Paraguay, São Tomé and Príncipe, Solomon Islands, Tanzania, Thailand, The Gambia, Togo, Uganda, Ukraine, Uzbekistan, Zambia

Data Source: Global Fund Procurement Service Agent. PPM procurement data for 2021 to 2023

Market Dynamics

An integrated approach across diseases can unlock value opportunities

1. Molecular technologies and related components (tests, instruments, services) are often **funded by multiple sources** (such as Global Fund, PEPFAR, USAID TB, MOH) with limited visibility on ownership, use and plans.
2. **Multiple technologies are available for HIV molecular diagnostics while TB has limited options.** Therefore, introduction of new TB options is critical. There are few promising new technologies in the pipeline for TB.
3. **Limited molecular point of care level (community) options** are available, caused by high service and maintenance requirements and relatively low utilization rates.
4. Suppliers have and are developing **Co-Infection tests** (such as Hep B, Hep C, HPV) which can be used on the same platforms.
5. **Service and maintenance** is essential to maintain functionality and access, however this area remains a challenge as countries **do not always have service level agreements (SLAs)** with clear terms, conditions and accountabilities.
6. Molecular technologies are generally multiplex; however, they are often owned by individual disease programs and have focused use. This appears to be caused by differentiated programmatic needs and vertical management of the disease programs. **Not all countries have integrated multi-disease diagnostic strategies.**
7. Recent market developments offer opportunities for integration through **inclusive pricing modalities with improved total cost of ownership with unlocking value opportunities.**

Molecular Technologies SWOT Analysis

Addressing weaknesses and threats require multi-stakeholder alignment and coordination

Strengths

- Suppliers provide complex technologies for LMIC
- Strong footprint of certain technologies in countries
- Most of the technologies offer multi-disease solutions
- Clear WHO recommendations for use of these technologies for disease programs

Opportunities

- Integration of disease strategies to increase efficiencies and empower country ownership
- Inclusive pricing modalities to simplify procurement
- Creating coordination and collaboration platforms globally and locally

Weaknesses

- Forecasting: Country plans are unclear
- Countries may not have integrated multi-disease strategies
- Insufficient country capacity to manage technologies
- Limited purchase power by major public buyers
- Lack of clarity in service and maintenance terms and conditions

Threats

- Resistance of disease programs to integrate
- Strong inter-dependance among stakeholders threatening implementation success
- Technology underutilization leads to ineffective procurement due to unoptimized networks
- High service and maintenance requirements
- Price increases due to inflation in western economies

Strategic Objectives: Procurement of Molecular Technologies

1. Ensure Equitable Access to Quality-Assured Technologies: Affordability and Availability	Maintain competitive & sustainable pricing through diversified supply base, value for money considerations and value delivery
2. Provide multiple procurement modalities based on the total cost of ownership concept	Ensure countries have access to multiple procurement modalities to determine the optimal solution based on country specific parameters
3. Accelerate the introduction of innovative products and technologies	Enable product innovation to ensure optimal care and cost reduction through creating a platform for accelerated introduction to market
4. Encourage environmentally sustainable practices	Drive sustainable approaches in line with Global Fund's NextGen Market Shaping ambitions to reduce environmental impact
5. Improve supply chain response by applying best distribution practices	Improve supply chain for responsive and agile molecular technologies delivery through procurement and supply chain capacity building

Approach and Process

Success will rely on the implementation stage, where collaboration across all stakeholders is essential to improve access

- Internal and External Stakeholder Consultation
- Scoping of Multiplexing Technologies
- Identification of Value-Added Initiatives (Total Cost of Ownership, All-Inclusive Pricing)

Procurement Process (RFP)

- Inclusive Compliant Tender
- Capture pricing for multiple procurement modalities
- Qualification of Suppliers for Framework Agreements
- Sign framework agreements

Implementation

- Clearly defined Rules and Responsibilities of all Stakeholders involved
- Country-specific evaluation based on individual situation

Multi-stakeholder implementation approach

Success depends on the collaboration, coordination and alignment of internal and external stakeholders

The Global Fund	Other Donor Organizations	Technical Partners	Nat. Programs & Labs	Procurement Service Agent	Suppliers	Distribution Networks
Develop global procurement strategy		Programmatic guidance and technical advice	Develop demand landscape and integrated disease strategies	Provide operational support and logistics	Offer global access pricing and innovative procurement modalities	Optimize supply of all components in-country
Negotiate Global Access Prices Lead implementation and market shaping			Fund allocation		Management and connectivity of instrument fleet	Route optimization
GMD/CTs to ensure cross-disease collaboration and secure budgets	Close coordination with TGF and country programs	Regulatory Affairs	Capacity development and organization	Assists TGF in overall coordination and implementation	Provide regular KPI reporting on system servicing	Contingency planning
TAP, Disease and Lab Teams to lead programmatic guidance and DNO	Provide Technical Support					Support capacity building and promote sustainable practices

Requires tailored approach per country at implementation stage

Request for Proposals (RFP): Timeline and Approach

The Global Fund, Direct Sourcing Team

RFP process and timeline *(indicative)*

Stage I:
Supplier and Partner Engagement
(End Q2 2024)

- Consultations with suppliers and partners
- **Molecular PCR Technologies Procurement Engagement Session: Partners & Suppliers 27 June 2024**
- Invite feedback from suppliers and partners

Stage II:
RFP launch and bid submissions
(July 2024 - August 2024)

- RFP documents are uploaded on Sourcing Platform, including both technical and commercial sections
- Q&A on the RFP documents and process
- Bid submissions

Stage III:
Negotiations
(Sep – Oct 2024)

- Evaluations
- Supplier Negotiations
- Internal Approvals
- Award

Stage IV:
Contracting
(End Q4 2024 onwards)

- Contract finalization & signature

Tender evaluation structure

Molecular PCR Technologies RFP

Commercial criteria

- Unit Prices for all QA eligible components Assays, Machines, Consumables, Services
- Pricing structures for all offered procurement modalities (i.e. all-inclusive)
- Compliance requirements:
  - **Financial Due Diligence**
  - **Integrity Due Diligence**

Technical criteria

- Technical Description of all components
- Product & Country Registration Coverage
- Innovation & Sustainability
- QA Eligibility
- Manufacturing capacity & lead time

There will be **a process** to consider **new entrants and/or new products** that become **eligible** for procurement **after tender closure (subject to review)**

Legal Matters

The Global Fund, Direct Sourcing Team

Legal Matters: Certificate of Conformance

RFP Bidders will be required to submit a signed certificate by an authorized officer, to acknowledge and agree (among other things):

- Bidder will comply with Global Fund's Code of Conduct for Suppliers.
- Bidder's RFP submission implies Bidder's unconditional acceptance of the terms and conditions of the Strategic Partnership Agreement.
- Any reservations on the Partnership Agreement must be notified to the Global Fund as part of the RFP submission.
- Only limited, non-material amendments to the draft Strategic Partnership Agreement submitted as part of the Bidder's proposal may be considered by the Global Fund.
- The reservations or amendment requests will be considered in the overall evaluation of the Organization's proposal.
- Modifications to the following provisions of the Partnership Agreement will not be accepted:
  1. Record-Keeping and Audits,
  2. Governing Law and Dispute Resolution,
  3. No Waiver of Privileges and Immunities,
  4. Compliance with the Global Fund's Quality Assurance Policy, Code of Conducts and Sanctions Panel Procedures,
  5. Principles set forth in Most Favored Nation clause.

Integrity Due Diligence

Artem Lazurenko
Specialist, Integrity Due Diligence (IDD), Ethics Office
The Global Fund

Integrity Due Diligence

The Global Funds Ethics policies in relation to suppliers

RFP Schedules

- All suppliers must complete the IDD questionnaire to its full extent
- Information on ownership and control is required for sanctions checks
- Conflict of interest disclosures required to develop mitigations
- Policies and case histories required to assess the ability to fulfill obligations under the Code of Conduct and other policies
- Limited fulfilment of expectations will inform risk management decisions

Code of Conduct

- Prohibits both direct and indirect:
  - Corruption
  - Fraud
  - Coercion
  - Collusion
  - Anti-competitive practices
- Full and open disclosures of CoI, including potential and perceived
- Safeguarding (with obligatory reporting):
  - Protection from Sexual Exploitation, Abuse and Sexual Harassment
  - Child protection

Other documents

- Policy to Combat Fraud and Corruption
- Policy on Conflict of Interest
- Contractual terms with respect to ethical issues
- Sanctions Panel Procedures

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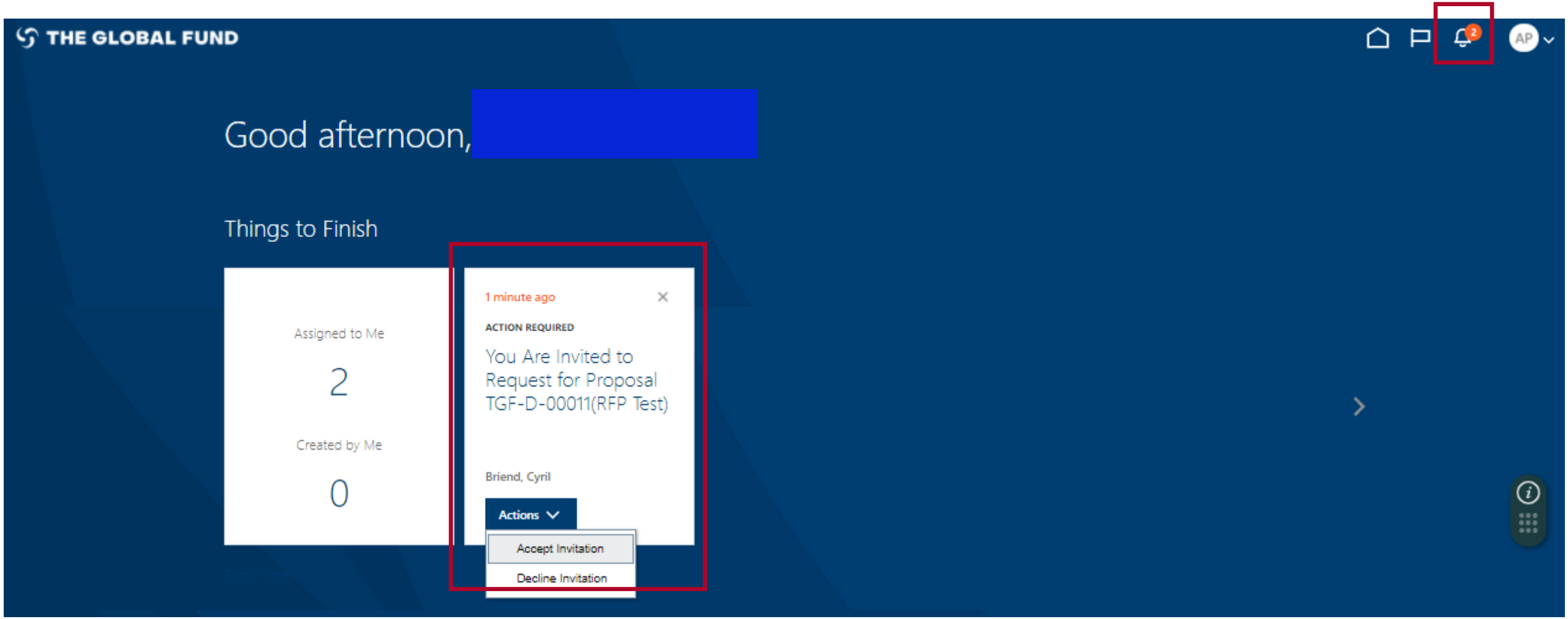
Tender Management

The Global Fund, Direct Sourcing Team

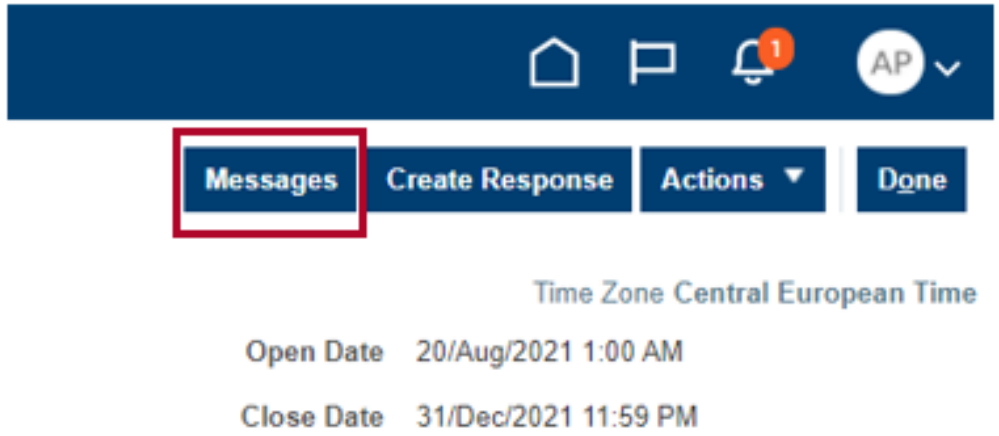
Sourcing Platform used for all RFP communications

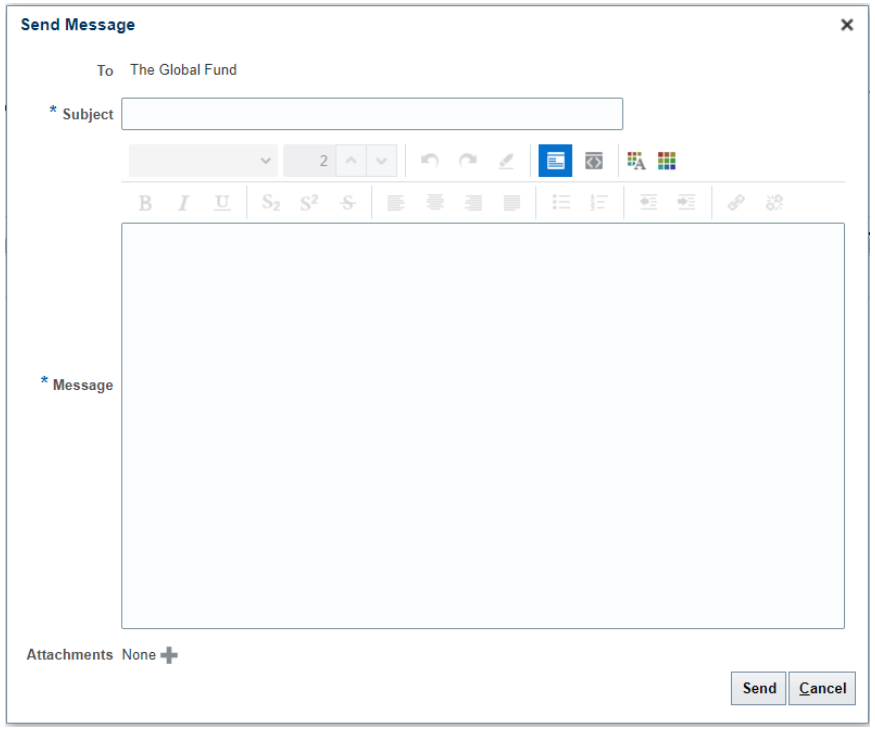
Welcome page & notifications



Communications & Support on Platform Access

- All communications with regards to this RFP, including clarification questions, shall be in writing and sent through the TGF Sourcing Platform using the online discussion (see below).
- Any communication from an RFP Participant to the Global Fund related to this RFP which is **not** through the designated channel (https://fa-enmo-saasfaprod1.fa.ocs.oraclecloud.com/), is not permitted and will not be answered.
- Should the Global Fund deem it necessary to revise the RFP as a result of a clarification, it shall do so as an amendment to the RFP available on the Global Fund's website.





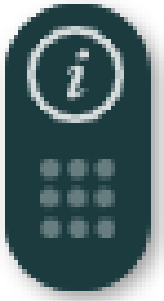
Sourcing Platform: Other Matters

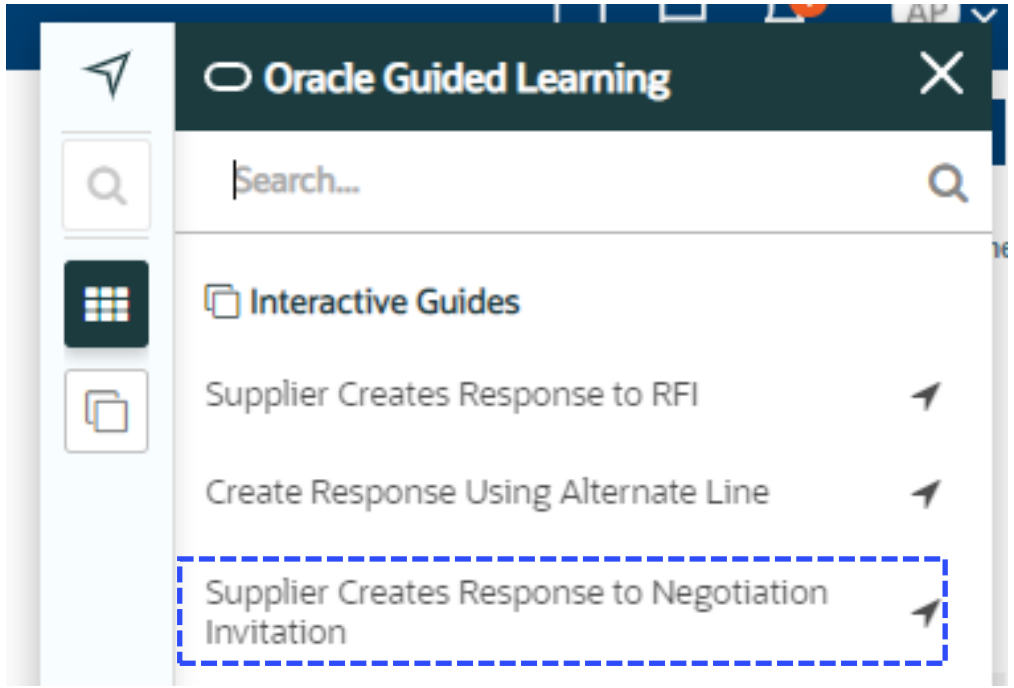
Oracle Guided Learning (OGL)

- Feature which provides step-by-step and personalized guides in the negotiation module.

- Please open the following link in your browser to see the step guide (Supplier Creates Response to Negotiation Invitation):
  https://guidedlearning.oracle.com/player/latest/api/scenario/export/v1/WpUIM+OJRoSJYo3jQu37UA/k7hjkrg1/lang/--/?draft=undefined

- Access to the OGL: Click on the “I” icon and select the appropriate Guide





Questions and Answers