Global Fund
RDT Consultation Meeting

December 11, 2023

Cape Town, South Africa

Disclaimer

The Global Fund Procurement Strategy on **Rapid Diagnostics Tests** (RDTs) is currently under development and will be finalized after the meeting.

This document presents 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.

Meet the Team

THE GLOBAL FUND

Supply Operations

Hui Yang
Head, Supply Operations

Direct Sourcing

Lin (Roger) Li
Senior Manager
Direct Sourcing

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Manager
Global Sourcing
Health Technologies

Mustafa al Samaraee
Lead Diagnostic, Direct Sourcing

Fabrice Abalain
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Tender Process & Contract Management

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Strategy, Procedure, Innovation

Ellie Marsh
Senior Manager
Strategy, Procedure and Innovation

Clarisse Morris
Manager, Market Shaping and Partnership

Quality Assassurance

René Becker-Burgos
Specialist, Diagnostic Products Quality Assurance, HPM·

Technical Advice & Partnership (TAP)

Roopal Patel
Senior Disease Advisor Malaria

David Maman
Senior Disease Advisor HIV

Legal and Governance

Kiraz Bulut
Legal Counsel (Institutional Matters)

Ethics Office

Artem Lazurenko
Specialist, Integrity Due Diligence (IDD)

Opening remarks

Hui Yang
Head, Supply Operations
Global Fund

Objectives of RDT Consultation

11 and 12 December 2023, Cape Town

1. **Bring together suppliers and partners** to share progress updates in HIV, Malaria and other Rapid Diagnostic Test (RDT) markets
2. Create a platform to share perspectives to **inform** ongoing and future **RDT procurement strategies**
3. Provide an **opportunity for face-to-face** meetings with individual suppliers and partners
4. Present the Global Fund's Rapid Diagnostic Tests Procurement Strategy for 2024-2026 and obtain feedback from partners and suppliers
5. Engage with Regional manufacturers and provide visibly of Global Fund procurement activities in line with NextGen Market Shaping ambitions

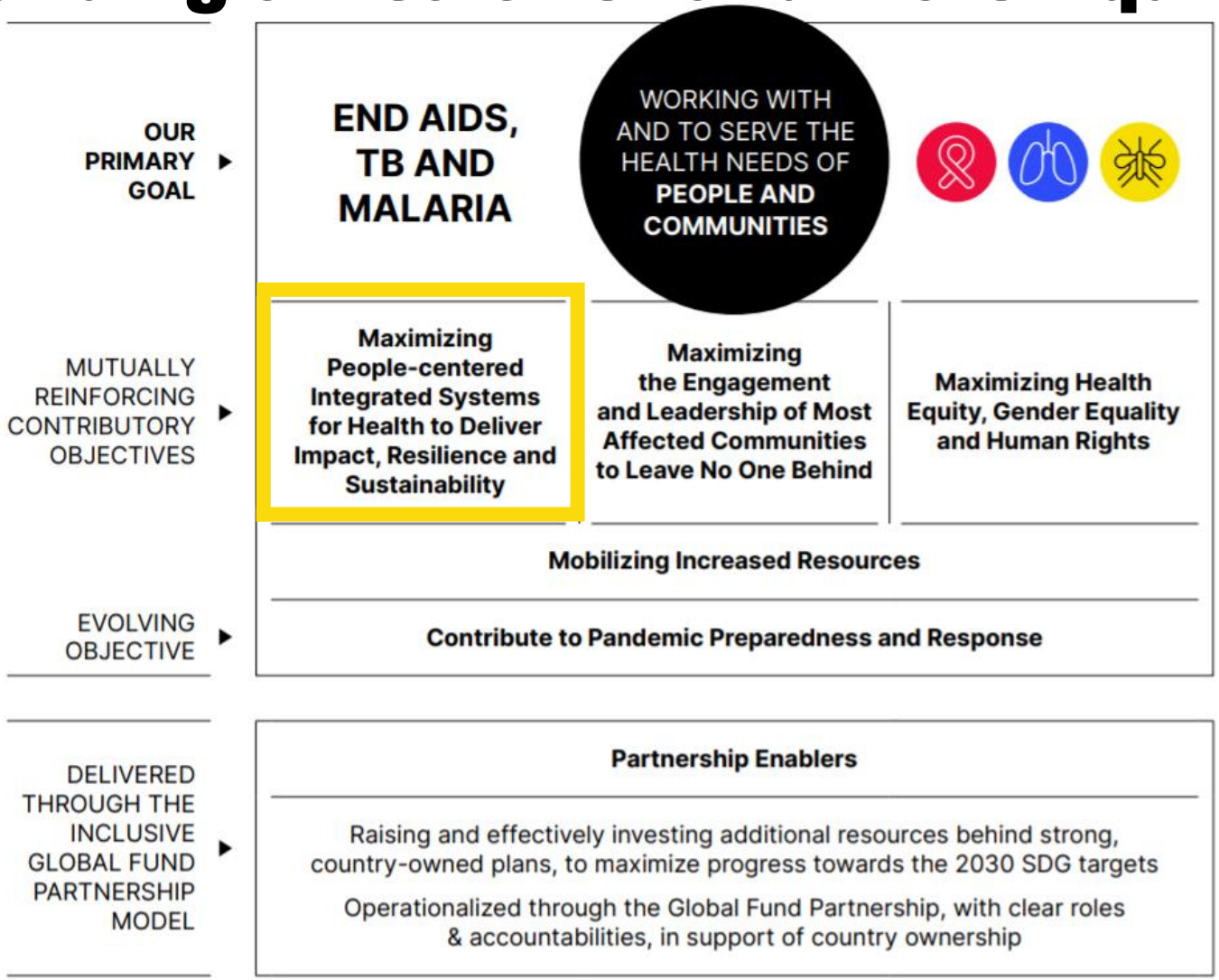
Agenda – 11 Dec 2023

8.30 – 9.00	*Registration & Welcome coffee*		
9.00 – 10.00	**Welcome & Global Fund updates**		
	1. Opening remarks	15m	Hui Yang / Head, Supply Operations – Global Fund
	2. NextGen Market Shaping	25m	Ellie Marsh / Senior Manager, Strategy Procedure and Innovation – Global Fund
	3. Pooled Procurement Mechanism (PPM)	20m	Lin (Roger) Li / Senior Manager, Direct Sourcing – Global Fund
10.00 – 10.15	*Coffee break*		
10.15 – 12.00	**Disease and technical updates**		
	4. Malaria Update	15m	Roopal Patel / Senior Disease Advisor, Technical Advice and Partnerships (TAP) - Malaria – Global Fund
	5. HIV Update	25m	Celine Lastrucci / WHO HIV David Maman / Senior Disease Advisor, TAP – HIV – Global Fund
	6. TB Update	10m	Grania Brigden / Senior Disease Advisor, TAP –TB – Global Fund
	7. WHO Prequalification	20m	Irena Prat / WHO PQ program
	8. Global Fund QA and ERPD	20m	René Becker-Burgos / Specialist, Diagnostic Products Quality Assurance, HPM – Global Fund
	Q&A / Discussion 1	20m	All
12:00 – 13:00	*Lunch break*		
13.00 – 14.30	**Innovation & Partners RDT Strategies**		
	9. Innovation pipeline	20m	Jeremie Piton / FIND
	10. PMI sourcing strategy	20m	Christine Hershey / PMI
	11. PEPFAR sourcing strategy	20m	Matthew Wattleworth / PEPFAR
	12. UNICEF 2023-2028 Procurement Strategy	20m	Wandani Sebonego / UNICEF
	Q&A / Discussion 2	10m	All
14.30 – 15.00	*Coffee break*		
15:00 – 17:00	**Global Fund RDT Procurement Strategy & tender timeline**		
	13. RDT Sourcing Strategy 2024-2026	60m	Azizkhon Jafarov, Mustafa al Samaraee / Global Health Technologies Team – Global Fund
	14. Request for Proposals (RFP) Approach & Timeline	30m	Fabrice Abalain / Global Health Technologies Team – Global Fund Kiraz Bulut / Legal Counsel (Institutional Matters), Legal Department – Global Fund Artem Lazurenko / Specialist, Integrity Due Diligence (IDD), Ethics Office – Global Fund
	Q&A / Discussion 3	30m	All

2. Global Fund Strategy (2023-2028) NextGen Market Shaping

Ellie Marsh
Senior Manager, Strategy Procedure and Innovation
Global Fund

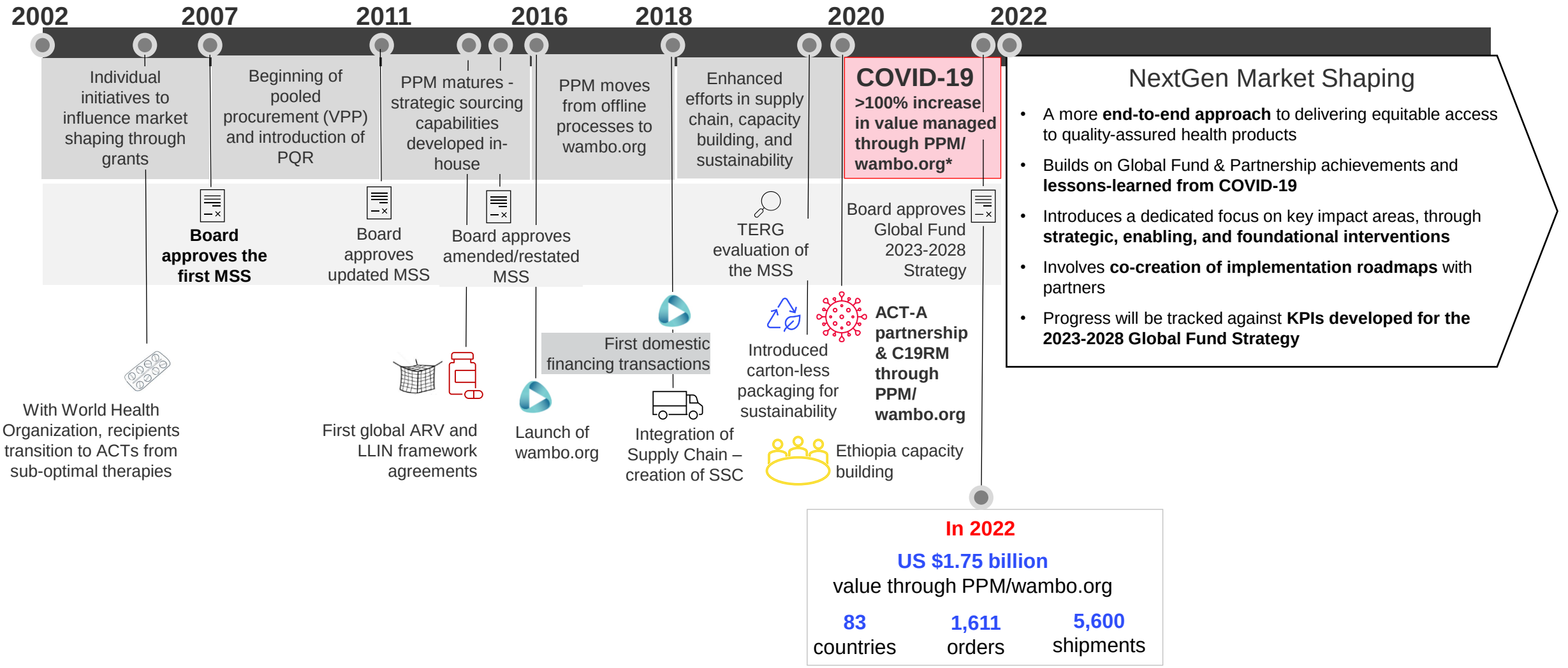
2023 - 2028 Global Fund Strategy: Fighting Pandemics and Building a Healthier and More Equitable World



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



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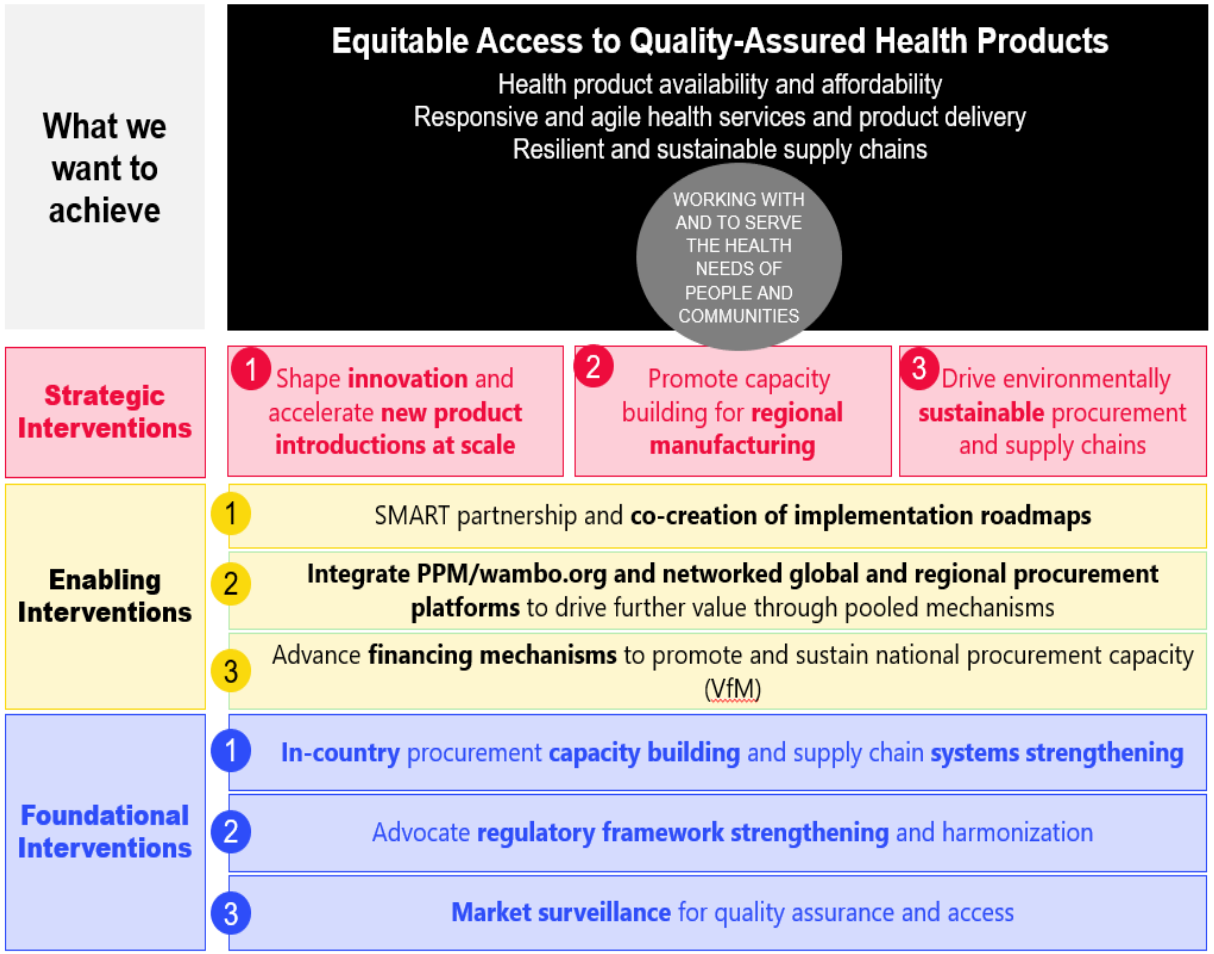
ARVs = Antiretrovirals
LLINs = Long-lasting Insecticidal Nets
ACTs = Artemisinin combination therapies
MSS = Market Shaping Strategy
*US$ 958M in 2019 versus US$ 2.2 billion in 2021
PPM = Pooled Procurement Mechanism
PQR = Price and Quality Reporting
SSC = Sourcing and Supply Chain
VPP = Voluntary Pooled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

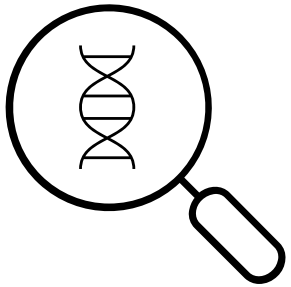
National

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

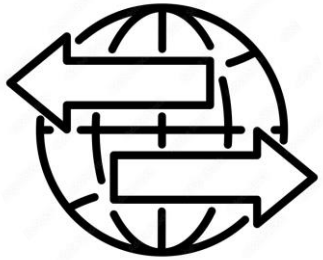
The NextGen Market Shaping approach is reflected in GF's sourcing strategies

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

Responsive to Global Fund tenders



Continue to invest in innovation targeted at the countries and communities the Global Fund serves



Adopt sustainable, inclusive and equitable go-to-market approaches

3. Global Fund Pooled Procurement Mechanism (PPM)

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

How we work

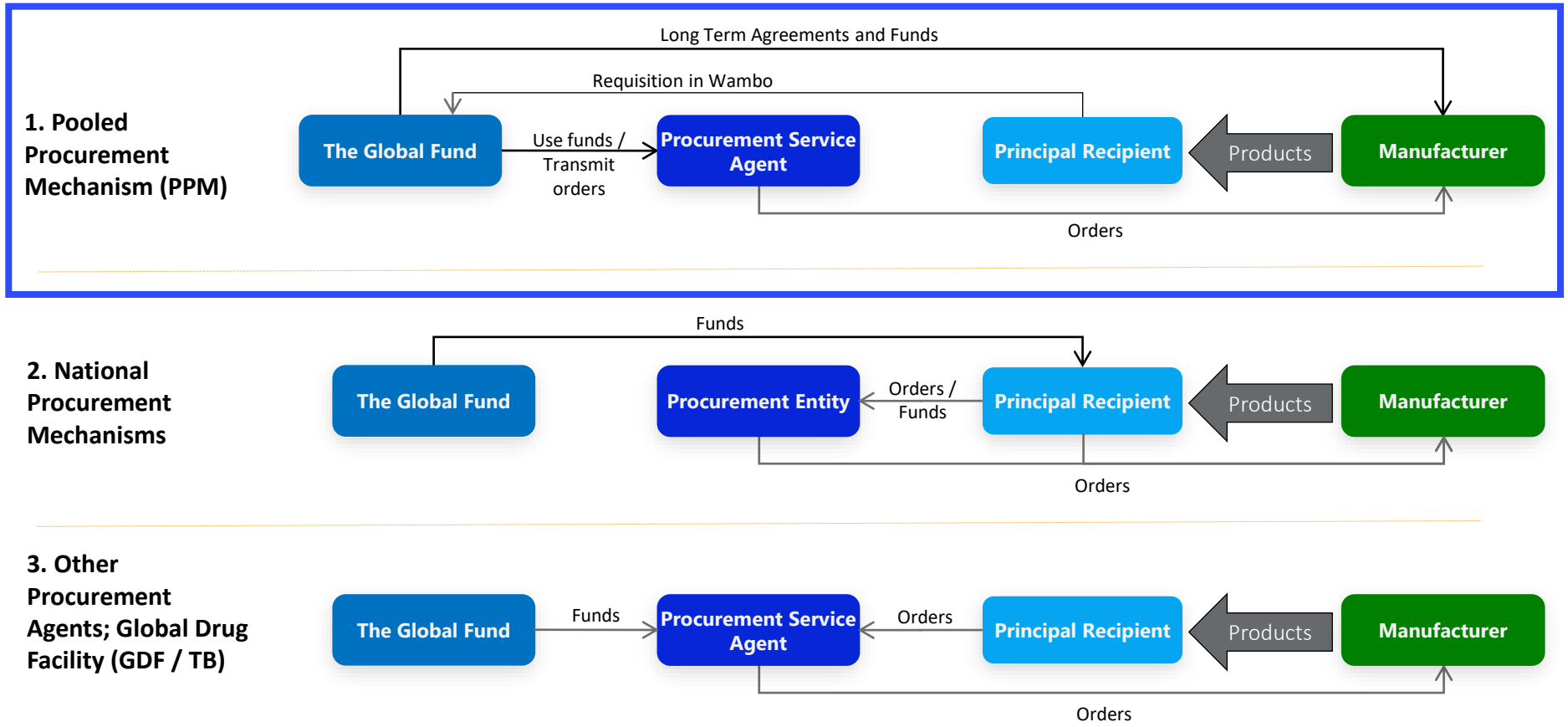
We raise funds and support programs

Oversight in Action

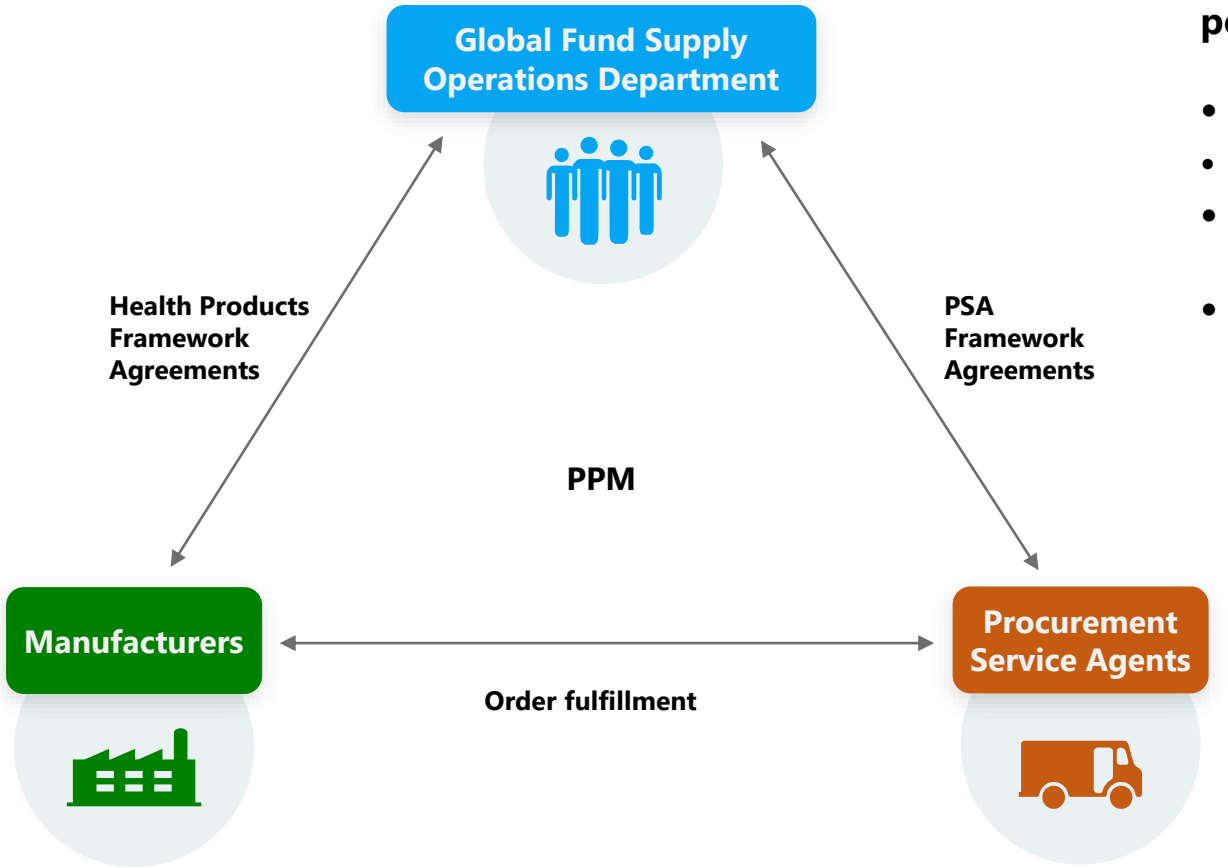
- Local Fund Agents in each country monitor the implementation of grants.
- The Global Fund's Office of the Inspector General conducts audits and investigations.
- The Secretariat reports information to the Global Fund Board and the wider public.

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



The GF Pooled Procurement Mechanism holds Framework Agreements (long term agreements with manufacturers for key product categories: ARVs, ACTs, LLINs and RDTs



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:

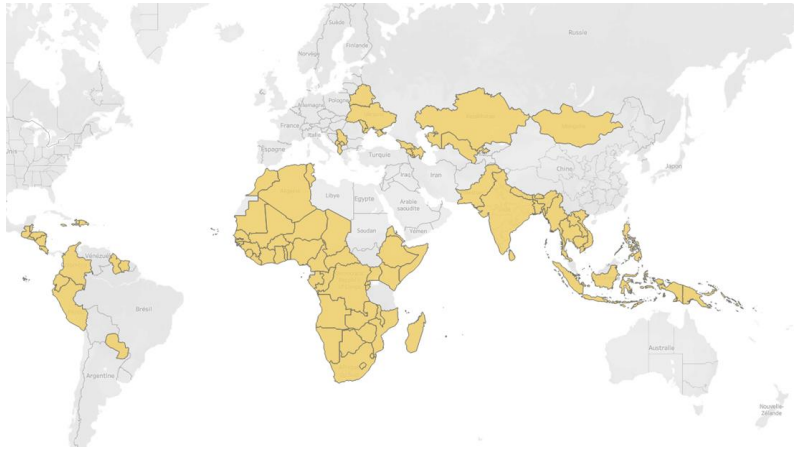
- Liaise with framework agreement manufacturer
- Manage procurement for other categories and non-catalogue items where needed
- Provide logistics estimates and ensure delivery to country per the the agreed incoterm

Overview PPM: More than 80 countries served in 2022 through PPM/Wambo

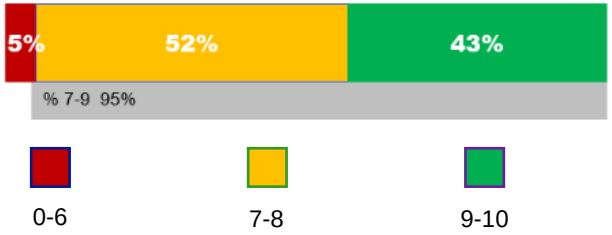
There are a number of More than 6,000 shipments of needed health products delivered despite global supply chain disruptions in 2022

Since its creation, PPM/wambo.org has connected **531 PR users** from **107 organizations** in **83 countries**

(including **40 organizations** from **27 countries for non-grant funded transactions**)



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



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

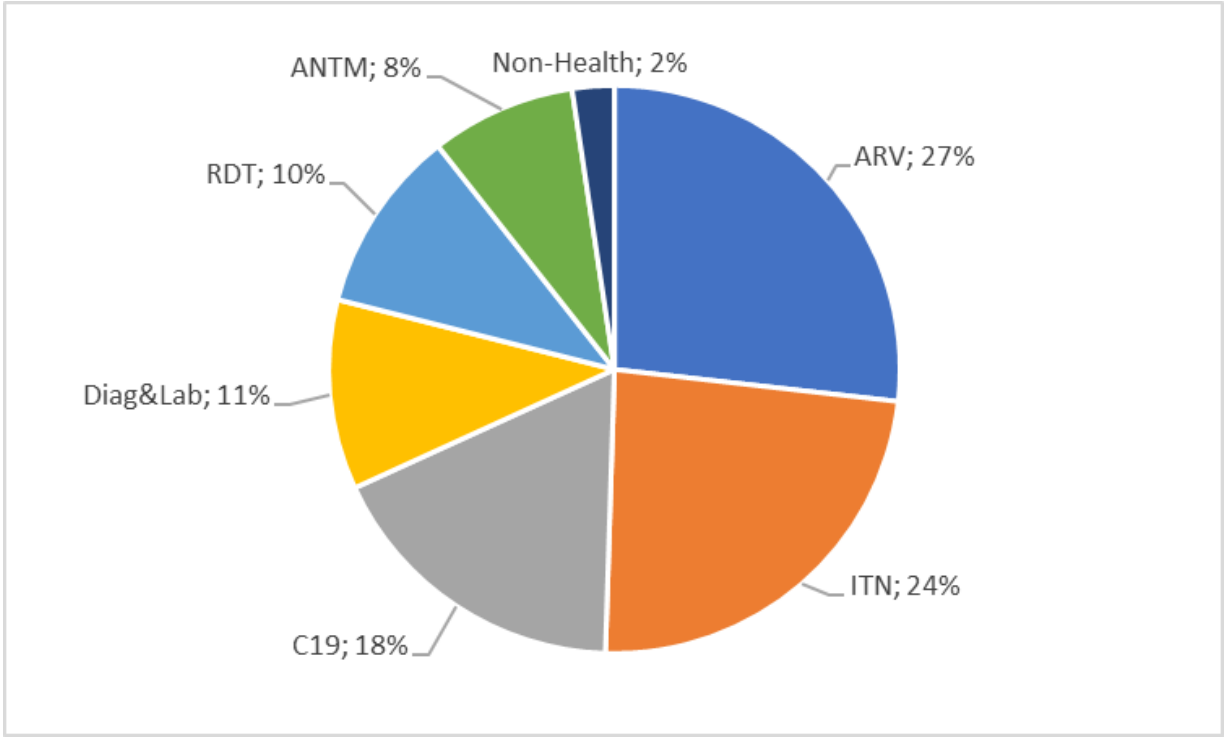
Tracked more than 6,000 shipments
from shipping to delivery

count	**2,498 by sea**	**3,116 by air**	**452 by road and rail**
volume	79%	18%	3%
value (USD)	1.107 Bn	266 Mn	49 Mn

Overview PPM: USD 1.75 bn orders placed in 2022 through PPM/Wambo

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

- **In 2022**, PPM processed 1,611 Purchase Orders **$1.75 bn** to more than 80 countries in all continents
- Largest category **ARVs** – enough to treat **7,3 million people on 1st line ART**
- **ITNs** – in 2022, PPM procured **119 million bed-nets** including new generation innovative nets)
- **Diagnostics** including **RDTs** are a significant spend (including HIV rapid tests)



Volume split per Product Category

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. For example, an estimated plastic waste reduction of 1,110 metric tons was achieved in 2020 via the elimination of the use of individual bags for ITNs.

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.*

Disease and technical updates

4. Malaria Update
5. HIV Update
6. TB Update
7. WHO Prequalification
8. GF QA and ERPD

Q&A / Discussion 1

4.

Diseases update Malaria

Roopal Patel
Senior Disease Advisor, Technical Advice and Partnerships (TAP) - Malaria Global Fund

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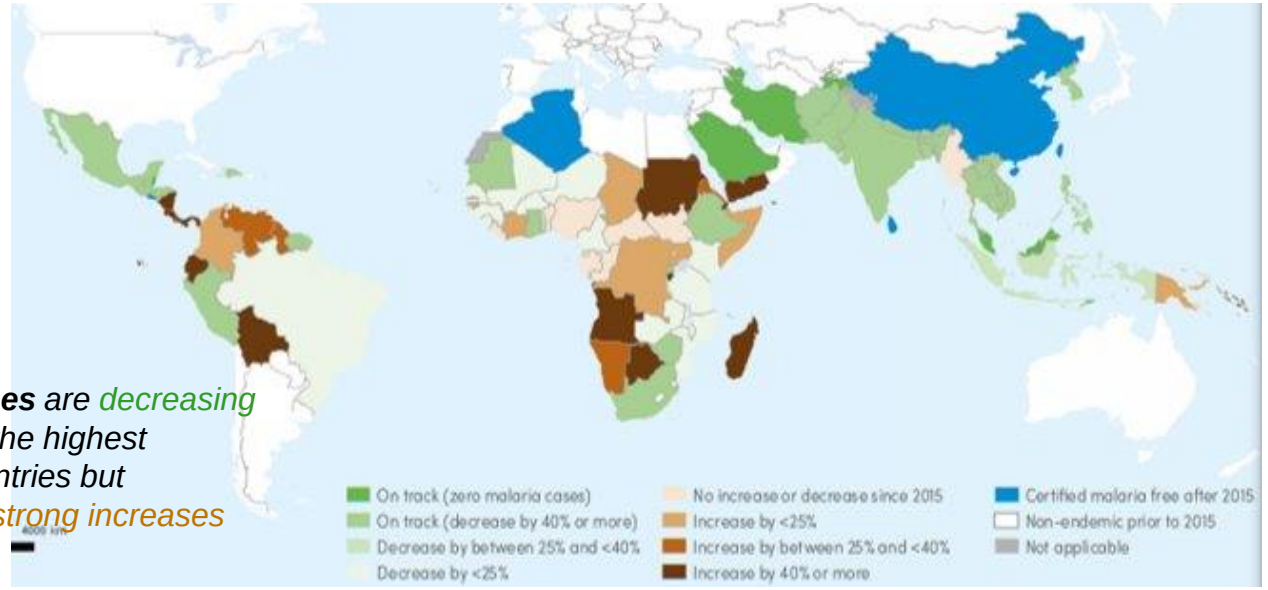
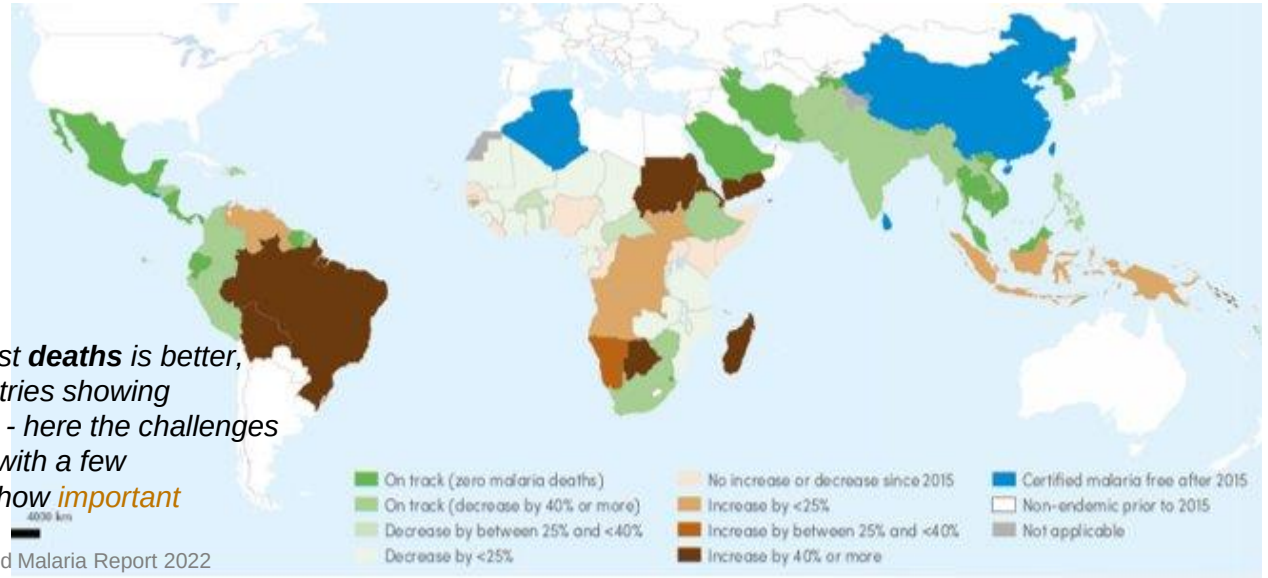
GF Malaria strategy objectives 2023-2028

1. Ensure optimal effective vector control coverage
2. Expand equitable access to quality early diagnosis and treatment of malaria, through health facilities, at the community level and in the private sector, with accurate reporting
3. Implement malaria interventions, tailored to sub-national level, using granular data, and capacitating decision-making and action
4. Drive towards elimination and facilitate prevention of reestablishment of malaria
5. Accelerate reductions in malaria in high burden areas and achieve sub-regional elimination in (a) select area(s) of sub-Saharan Africa to demonstrate the path to eradication

*Malaria **cases** are decreasing in some of the highest burden countries but most have strong increases*



*Progress against **deaths** is better, with more countries showing strong declines - here the challenges are more focal with a few key countries show important reversals*



Source WHO estimates. Reference World Malaria Report 2022

Priorities for Malaria Case Management in GC7

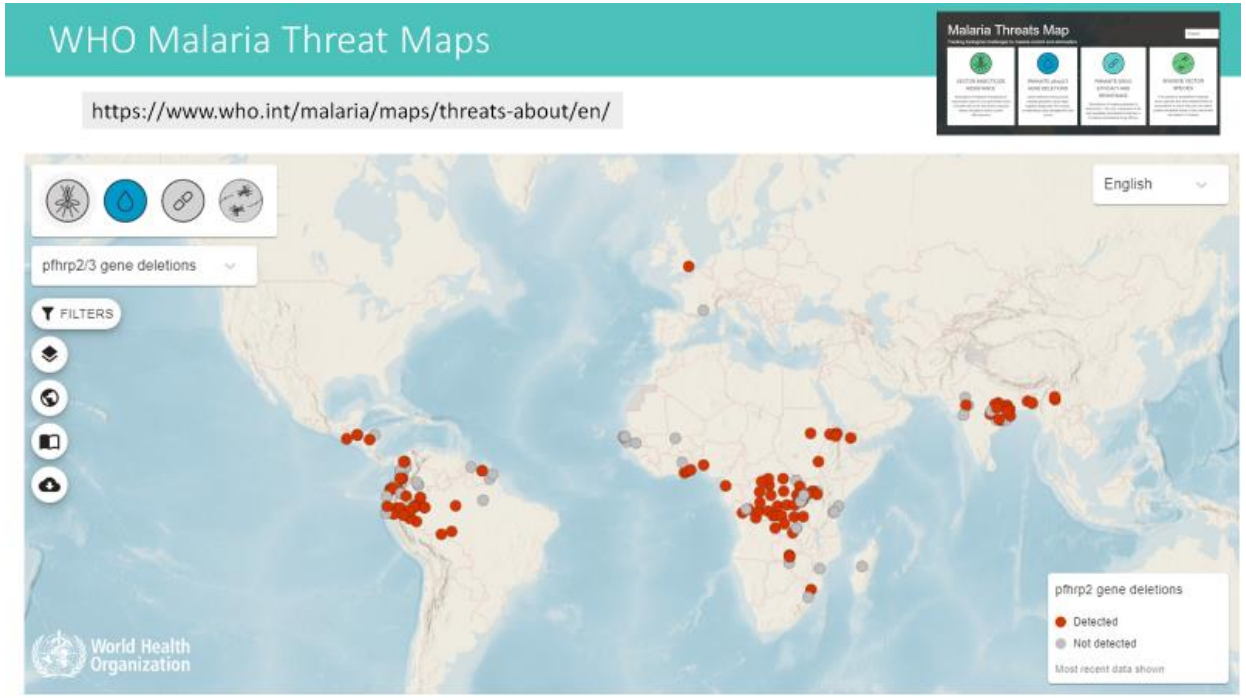
Malaria case management

- Improving access and quality of diagnosis and treatment across all sectors.
  - Engage private sector providers to drive parasitological testing before treatment
  - Expand community platforms where access is low.
- For diagnostics, continued focus on availability, capacity for testing, ease of use, adherence to test results and accurate reporting and recording.
  - Deployment of both microscopy and RDTs should be supported by a
  - quality assurance programme
- Addressing *P. vivax* including G6PD testing for radical cure.
- Severe malaria and the continuum of care.

Addressing biologic threats

- Improved surveillance and mapping of drug resistance and Pfhrp2/3 gene deletions
- Prevention and mitigation of resistance – strategies to reduce selection pressure of current ACTs including diversifying 1st line treatments
- Availability and adoption of appropriate diagnostics based on surveillance and normative guidance

Biological Threats in Case Management: Diagnostics



Deletion of *Pfhrp2* and related *hrp2* genes allow the parasite to escape from RDTs based on HRP2 antigens – major threat to early diagnosis and effective, prompt treatment as >80% of RDTs use in Africa are hrp2-only

- Limited surveillance to detect scale and scope of *Pfhrp2/3* gene deletions to inform diagnostic selection.
- Malaria threat maps typically show percentage of *pfhrp2* deleted samples amongst those tested and NOT all P. falciparum cases, ⟶ national surveys of symptomatic, confirmed cases needed to determine prevalence of clinically significant deletions.
- Eritrea, Djibouti and Ethiopia have confirmed with national surveys, > 5% of false negatives due to *pfhrp2/3* deletions
  - *All three countries have switched/about to switch to non-HRP2 based RDTs*
- Healthy market of Pfhrp2 based RDTs, appropriate for most settings but limited options for PLDH based RDTs with sensitivity to detect Pf with gene deletions.
- Normative guidance limited on reactive versus proactive response to risk of hrp2/3 gene deletions

Mitigating Diagnostic Biologic Threats

Global Fund:

- GC7: Increased support for surveys and surveillance for hrp2/3 gene deletions in coordination with PMI, BMGF and other partners
- Promote data sharing, to inform appropriate introduction of health products
- Promoting diverse and stable RDT market including addressing emerging needs

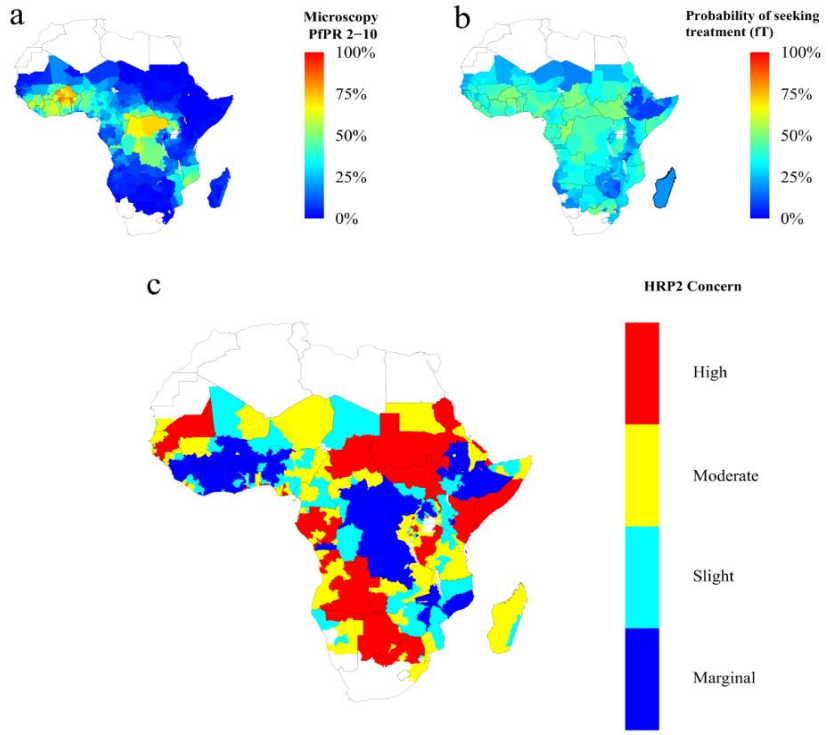
WHO:

- Review of guidance in response to emerging hrp2/3 gene deletions, potential risk-based transition to non-exclusive HRP2 RDTs
- Identify factors that put countries in Africa at increased risk of
  - pfhrp2 deletions emerging
  - pfhrp2 deletions having clinical impact
  - pfhrp2 deletions spreading
- Supporting countries and aligning across partners for strong data sharing, to inform appropriate introduction of health products

Other partners, e.g. UNITAID, PATH, FIND, BMGF

- Promotion with suppliers of expanded availability and access of products that respond to biologic threats

Predicted concern impact of *pfhrp2*-deleted mutants.



*Source: Watson et al eLife **6**:e25008*

Malaria Portfolio: Key Messages on GC7

Based on *preliminary analysis* of new grants to date, themes emerge throughout, particularly funding gaps

- Unprecedented fiscal pressure faced by countries and donors– in particular, low-income countries in Africa where malaria is concentrated
- Biologic threats, climate change and population growth all leading to increased costs of commodities and service delivery
- W1 saw gaps in essential services in Y3
- Led to TRP recommendation to fully fund ‘essential’ case management across GC7 including ACTs and RDTs
    - Vector control and seasonal malaria chemoprevention remain underfunded – struggle to maintain coverage means inability to innovate around delivery models or expanded deployment.

Insufficient program scope owing to funding challenges, prioritization decisions and/or bio-threats

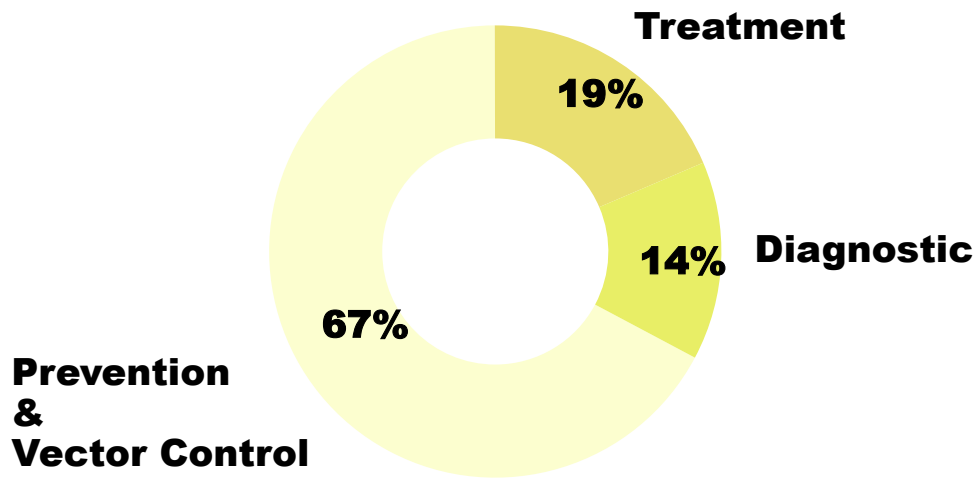
The estimated malaria **funding gap for Windows 1 and 2 is approximately US$1 billion** to *sustain* essential services

Malaria Portfolio: Key Messages

Category focus expected to continue toward case management with diagnostics, specifically malaria RDTs, continuing to play a key role

- **Effective, quality case management is a major focus of the malaria strategy, beyond commodities including training, service delivery, supervision and health systems strengthening.**
- **Treatment and Diagnostics** represent ~ 33% of the overall Malaria PPM Portfolio spend.
    - **Diagnostic portfolio represented over 14% of the GF 2022 PPM spend** of $1.75 billion
- **The product portfolio is more mature driven by a less dynamic market however** ensuring continued access to all required products and aligning with disease dynamics remains essential

PPM Malaria Portfolio Overview 2022 (Spend $)



5. Diseases update HIV

Celine Lastrucci

WHO, Global HIV, Hepatitis and STI Programmes

Updated WHO testing recommendations and RDTs needs

New 2023 consolidate HIV Testing services guideline

Hepatitis and STIs testing WHO guidance

Céline LASTRUCCI, technical officer, HIV Testing Services (HTS)

WHO, Global HIV, Hepatitis and STI Programmes

GF RDTs stakeholders consultation - 11 dec 2023

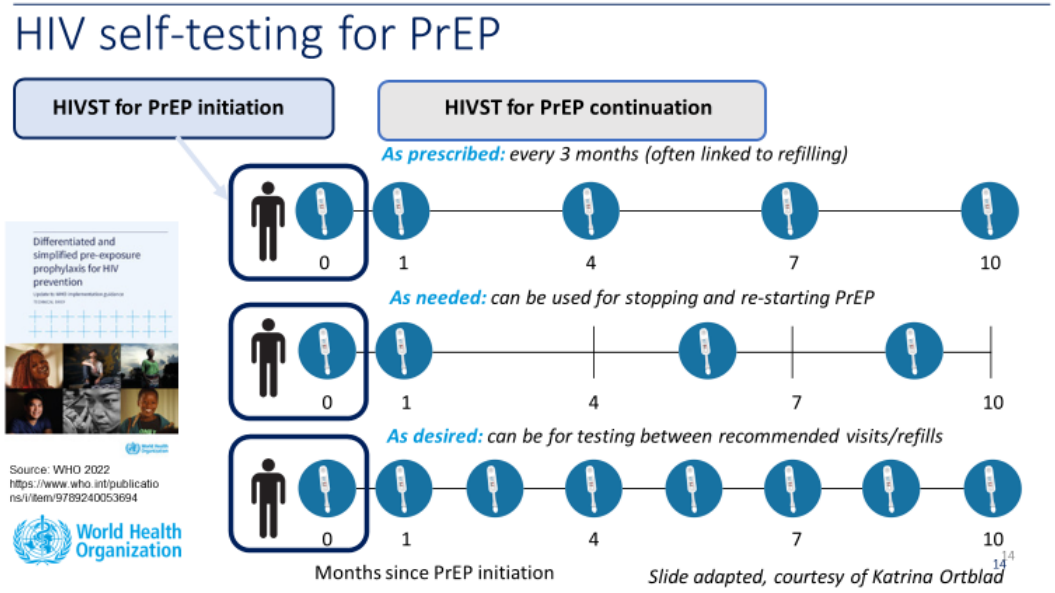
WHO new 2023 recommendations on HIV self-testing

New use Cases for HIVST

NEW: HIV self-testing may be used to deliver pre-exposure prophylaxis, including for initiation, re-initiation and continuation *(conditional recommendation, low-certainty evidence)*

Remarks

- HIVST-supported PrEP delivery may be an important tool to reach underserved populations.
- HIVST is an option to support PrEP delivery; its use should be driven by client needs and preferences.
- There is a range of PrEP options available for which HIVST use could be considered, including oral PrEP (daily or on-demand) and the dapivirine vaginal ring (DVR). HIVST can also be considered as part of post-exposure prophylaxis (PEP) implementation. Further research on the role of HIVST in implementing long-acting injectable prevention options, such as cabotegravir (CAB-LA), is needed.



NEW: HIV self-testing may be offered as an additional option for testing at facilities *(conditional recommendation, low-certainty evidence)*.

Remarks

- HIVST does not replace provider administered testing. Individuals with a reactive self-test result should receive further testing from a trained provider using the full national testing algorithm.
- HIVST can replace risk screening tools* to optimize testing among those presenting at health facilities.

NEW: Caregiver-assisted testing using HIVST: There is insufficient evidence to support caregiver-assisted testing using HIVST kits currently.

Therefore, prior to further implementation, challenges, concerns, and research gaps need to be addressed

WHO does urge already recommended approaches to reach children

- EID
- index/family testing
- Indicator testing (eg testing in malnutrition clinics)
- Screening tools to **screen in** for testing clinical settings

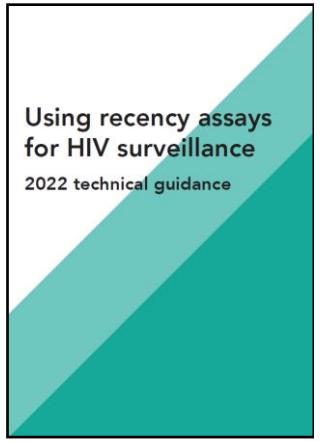
WHO does NOT recommend using recency assays in HIV testing services

World Health Organization

Recency testing for surveillance

WHO recommends use of recency assays in surveillance

- Utility of recency testing has been demonstrated in population-based surveys to measure HIV incidence
- Use of recency testing in programmatic settings should only be considered when existing HIV testing coverage of the population being studied is high, when a combination of assays including viral load can be delivered to reduce false recent results and analysis plans make appropriate statistical adjustments and infer population-specific trends in recent infection



- **There are no WHO prequalified recency assays**
  - No WHO prequalified recency tests in the pipeline or planned to be in the pipeline for WHO prequalification at this time.
  - No current pathway for recency testing to receive WHO prequalification as process reserved for recommended HTS interventions & diagnostic tests.

NO benefits of recency testing in routine HTS,

2023 HTS consolidated guideline

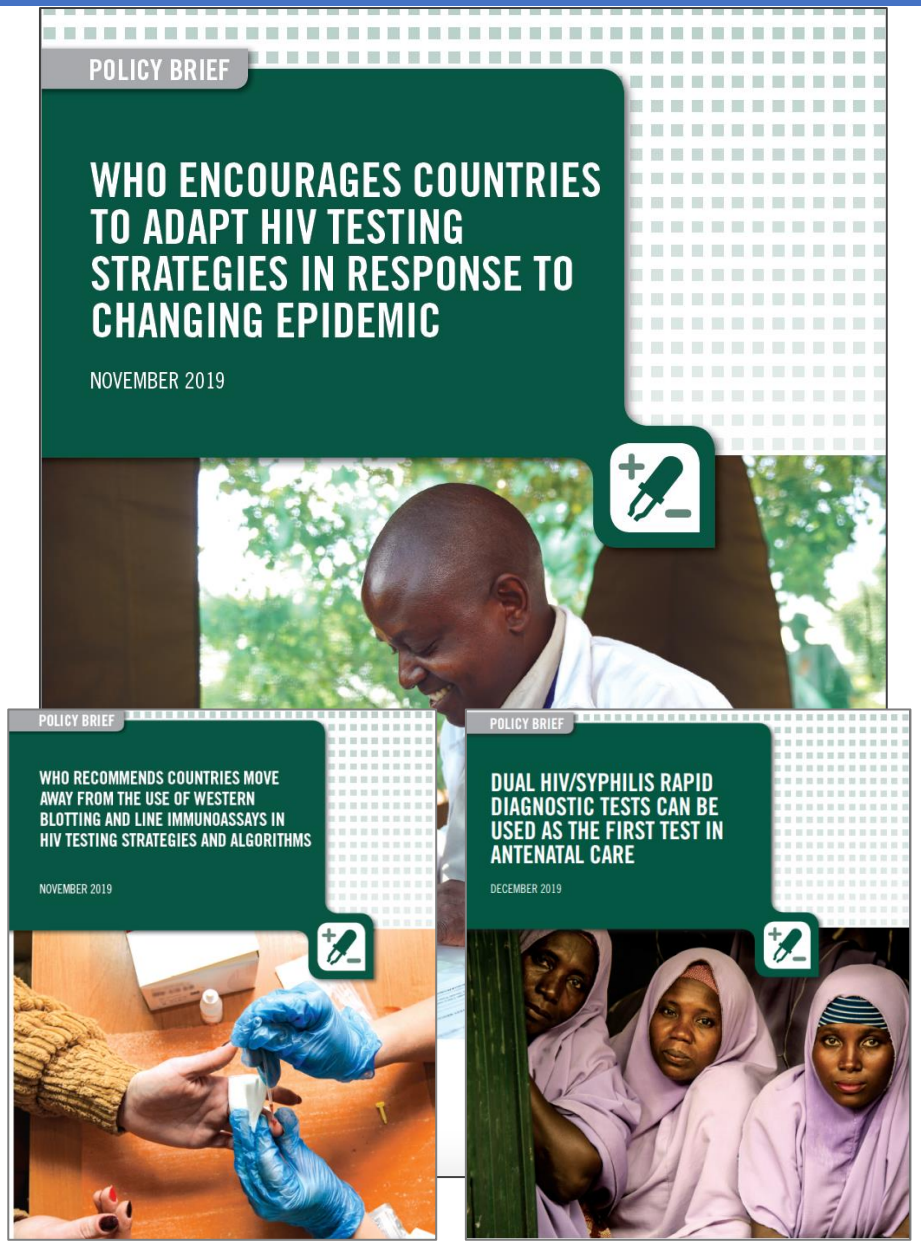
New WHO recommendation

HIV recency testing is not recommended as part of routine HIV testing services (conditional recommendation, low-certainty evidence)

Remarks

- This recommendation calls for excluding recency testing from routine HIV testing services. HIV testing services are defined as a package of services including brief pre-test information and post-test counselling; linkage to appropriate HIV prevention, care and treatment services and other clinical and support services; and coordination with laboratory services to support quality assurance.
- Recency assays can, however, be used for surveillance of HIV incidence. WHO has published guidance on this in Using recency assays for HIV surveillance: 2022 technical guidance (https://apps.who.int/iris/rest/bitstreams/1486096/retrieve

Adapting national HIV testing strategies



WHO recommends all countries currently using two consecutive reactive tests for an HIV-positive diagnosis to move torward using three consecutive reactive tests for an HIV-positive diagnosis. This is increasingly important as treatment-adjusted HIV prevalence and national HTS positivity continue to decline over time.

- **Ensure that the testing strategy has a positive predictive value ≥99% (PPV)**
  - Meaning of the persons classified as HIV+, ≥99% will truly be living with HIV
  - PPV depends on positivity rate among testing population

- **Quality assured assays, such as WHO prequalified, should be used:**
  - **≥99% sensitivity:** fewer than 1 *'false negative'* for 100 truly positive
  - **≥98% specificity:** fewer than 2 *'false positive'* for 100 truly negative
  - Either rapid diagnostic tests (RDTs) or immunoassay (EIA, CLIA, ECL)

Principles for the selection of HIV Testing Algorithms

World Health Organization

WHO recommends to use only quality-assured products: HIV assays that have undergone stringent regulatory assessments (product & manufacturing)

Performance characteristics	
Highest sensitivity (to rule in all positives [true + false])	**A1**
Highest specificity (>A1) (to rule out all false positives)	**A2** and **A3**

Correctness of the final HIV status is dependent on:

- Specificity of the individual products used (for A1, A2, A3), and
- Probability that any specimen that is falsely-reactive on the first assay (A1) is not also falsely-reactive on the second assay (A2) and third assay (A3) – **this can vary by region**

It is suggested to conduct a **verification study of the new testing algorithms** in order to:

1. Identify the **combination of products which have minimum possible common cross-reactivity** to reduce the risk of false HIV-positive diagnosis. (Note: *Products from the same manufacturer should not be used as part of the testing algorithm to minimize common cross-reactivity*)
2. Identify **flexible algorithms**: replacement tests in case of a "problem" with one of the selected tests, e.g. stock out, lot recall, etc. One for A1 and one for A2/A3
3. **Not intended to reevaluate sensitivity and specificity of individual products**!

First verification studies results

World Health Organization

Study outcomes in 3 countries (non exhaustive list):

	CHAD (100 samples)	Cameroon (100 samples)	Mali (200 smples)
SUPPORT RECEIVED			
Global fund	comodies+ runing costs + HR	comodies+ runing costs + HR	comodies+ runing costs + HR
WHO	HR (consultant)+ remote technical support	HR (consultant)+ remote technical support	HR (consultant)+ remote technical support
PREPARATION PHASE			
procurement time (months)	16	7	15 *
tests selection, protocol and other tools developement , ERB (months)	3	4	6
SAMPLES COLLECTION PHASE			
sample collection duration (days)	5	7	10
sample carracterisation duration (days)	2	2	4
Nb sample collected	171	172	250
true positives	14 (8%)	15 (9%)	TBC
trues negatives	154 (90%)	147 (85%)	247
non conclusive	3 (2%)	10 (6%)	TBC
VERIFICATION PHASE			
tests included in the study	6	8	12
total nb of tests performed	2400	3200	4800
Verification phase duration (days)	8	8	10
inter reader variability	0	0	TBC
invalid rate	0	0	0.5-2.5%
false reactivity	1 test (1%)	4 tests (1 to 4%)	12 (0.25-1%)
share false reactivity	0	1 sample (3 tests)	4 samples (2 to 5 tests)
TOTAL TIME operational phase (days)	15	17	24

* 2 steps order because of additional tests included 6 months after initial order

How did the countries use the results (non exhaustive list):

	share false reactivity identified	Does country changed A1	does the country changed A2	does country change A3	HIV/syphilis dual test choice
CHAD	NO	NO (training)	YES	YES	TBC
Cameroon	YES	YES	YES	NO (decided to keep same test used as tie breaker before)	standard Q
Lesotho	NO	NO (training)	NO (training)	YES (decided to NOT keep same test used as tie breaker before)	1st response
Kenya	NO	YES	YES	YES (decided to NOT keep same test used as tie breaker before)	standard Q
DRC	YES	NO (training)	NO (training)	YES (discontinued)	Bioline
Zambia	NO	YES	NO (training)	YES (no 3rd test before)	1st response
Mali	YES	YES	No (training)	YES (no 3rd test before)	1st response
Philipine	YES	not applicable (not using RDTs before verification study)			
South Soudan	NO	decision making process on going			

Key testing messages from new HIV WHO testing guidelines

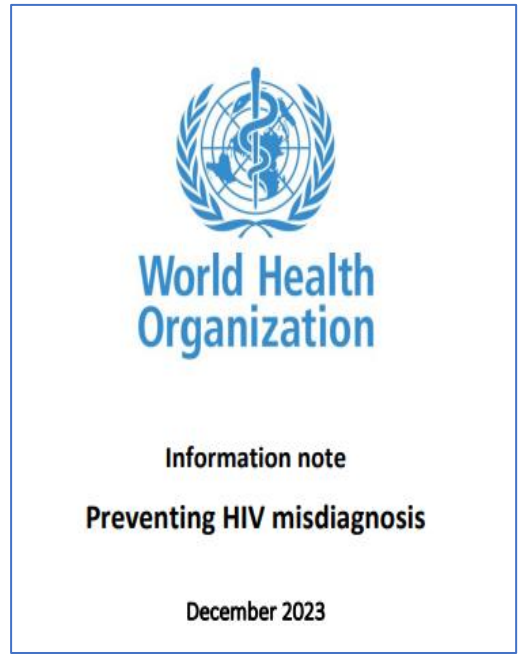
1. Select a strategic mix of **differentiated testing approaches** to fill the testing gaps

2. **Community based testing**, by **trained providers** will increase access and coverage, including for key populations

3. **HIV self-testing** should be expanded widely to allow greater access for people not testing in facilities and to increase ease of using oral PrEP, DVR and PEP

4. **Testing quality is critical**. **Avoiding misdiagnoses is critical**
    - Misdiagnoses have serious implications for people, programmes and public health
        - Misdiagnoses can be avoided by:
            - Using **Quality assured** product
            - Using the **serial 3 test strategy**
            - **Re-testing** prior to ART initiation
            - Conducting **verification studies**: the right tests in the right order
            - Instituting strong **quality management systems**

5. **Voluntary partner services**, including **Social Network Testing** may be used to increase HIV diagnoses and identify additional people with HIV
6. Use **Dual HIV/syphilis tests** in ANC and for KP
7. Think about **STI** and **viral hepatitis testing** alongside HIV testing
8. **Recency testing** adds complexity and costs in HTS and is **not recommended by WHO**



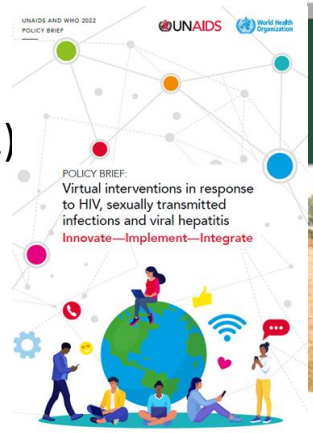
hiv-testing-information-note.1.12.2023.pdf (who.int)

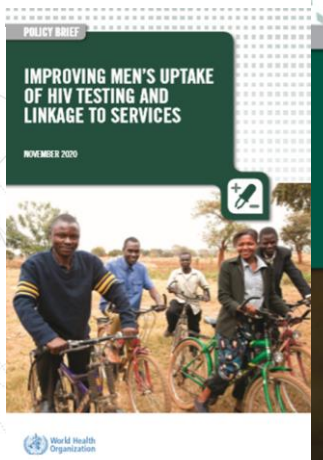
WHO guidelines on Testing Services

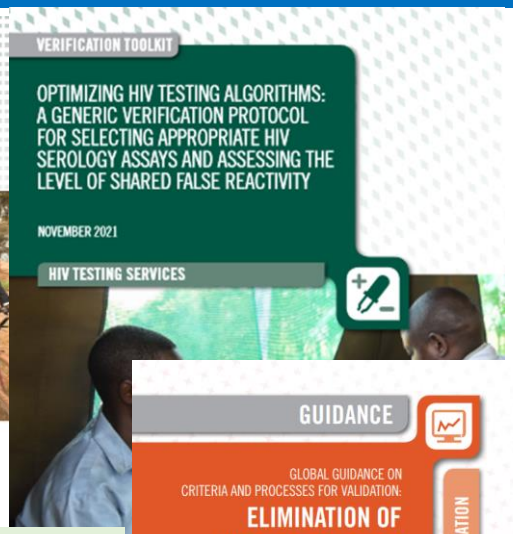
World Health Organization

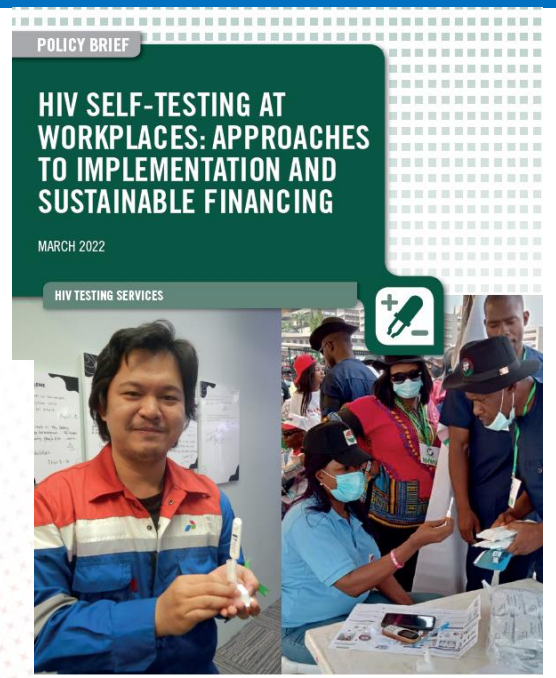
Other testing updates

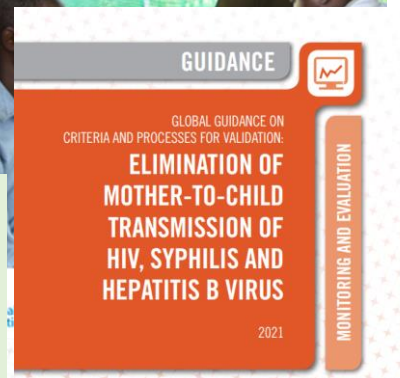
- HIV algorithm **verification toolkit** (2021)
- **Virtual intervention** (policy brief 2022)
- **Key populations** (KP guideline 2022)
  - Optimal retesting frequency
  - Dual HIV/syphilis RDT

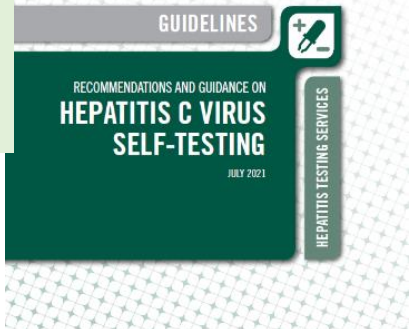


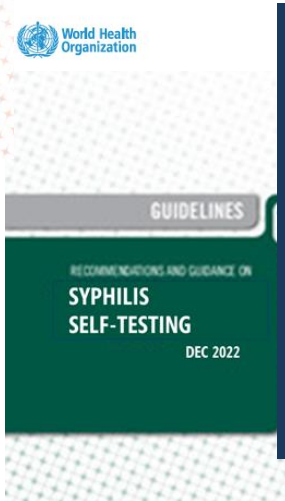












- **Triple EMTCT** : HIV, Syphilis, Hepatitis B
- Use of **self-testing extended to Hepatitis C and Syphilis**
- **Trep/Non trep RDTs** to improve **active syphilis** diagnosis
- **Partners services extended to STIs and Hep-C**
- **Improving men uptake**: Reaching men by testing in the **workplace (including HIVST)**
- **Risk screening tools** to optimize testing should be considered for **<u>screening "IN"</u> those with symptoms & risks** that might otherwise be missed (not screening "out").

Self-testing and self-care becoming standard of care across many different areas

- HIVST
- HCVST
- C19ST
- Syphilis ST
- ST for pregnancy,

Key takeaways: STIs

World Health Organization

SCALE UP

- **Dual test is being taken up fast, market opportunity remains large**
  - Greater uptake stimulating **growing needs in syphilis testing**, including **non-treponemal RDT**s or **dual T/NT**, and RPR/VDRL
  - Pooled procurement and increased volumes in ANC can increase affordability
- **Self-collection of samples for STIs; pooled samples**

URGENTLY NEEDED affordable & WHO PQ products

- **New WHO recommendations coming for**
  - **syphilis self-testing** (none in the market)
  - **dual T/NT RDT** ($$ and not PQ)
  - **Evidence-based STI partner services:** may increase volume
- **Multiplex/dual/multipanel RDTs**
  - e.g. combined HIV, HBV, Syp (T/NT) to support ETMCT
- **RDTs for Ng/Ct**
- **Target product profiles for STIs POC tests:** Point-of-care tests for sexually transmitted infections: target product profiles (who.int)

Key take aways: Viral hepatitis

World Health Organization

Product pipeline needs support

- One new HCV WHO-PQ in November 2023
- No product with stringent regulatory approval yet for **HbeAg or HCVcAg**
- Strong interest to mobilize around **HBV rapid testing** through **multiplex assays & self-testing** (no PQe product available yet)
- Formal recommendations for testing of HDV (who to test and what assay to use) done in framework of HBV guidance update: **Need for an RDT for HDV-serology+++; better options for EIA and NAT needed**
- **Liver function Tests** remain important**: POC would be interesting**

Strategic planning for viral hepatitis testing

- **For further scale up:** Countries need support in developing cost-effective and adapted national testing strategies for HCV and HBV in different epidemiological contexts
  - WHO will develop further implementation guidance in 2023 for strategic country planning; this will include best practices from different countries and using different approaches
- Leverage the work under **Global Fund**, which has extended support to include HCV and HBV testing and treatment (independent of HIV status) in framework of HIV prevention programs in key populations and in triple elimination

Contributors

WHO: Rachel Baggaley, Cheryl Johnson, Alaleh Abadpour, Maggie Barr-DiChiara, Busisiwe Msimanga, Anne Bekelynck, Purvi Shah, Carlota Baptista Da Silva, Anna Elizabeth Monroe-Wise, Niklas Luhman, Funmi Lesi, Teodora Wi, Maeve B. Mello, Belen Dinku, Anita Sands, Michel Beusenberg, Heather Marie Schmidt, Michelle Rodolph

UNAIDS: Victoria Benaud and colleagues supporting GAM

Special thanks to all participating Ministries of Health, Academic Partners, Community Groups, UN agencies, and members of related WHO Guideline Development Groups

Funders: WHO receives grants supporting on testing services from Unitaid, the Bill and Melinda Gates Foundation, Global Fund and USAID

For more information on HIV testing services

WHO HIV Testing Services Dashboard	WHO HIV Testing Services Info App	WHO HTS GL

5.

Diseases update HIV

David Maman

Senior Disease Advisor, Technical Advice and Partnerships (TAP) - HIV 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

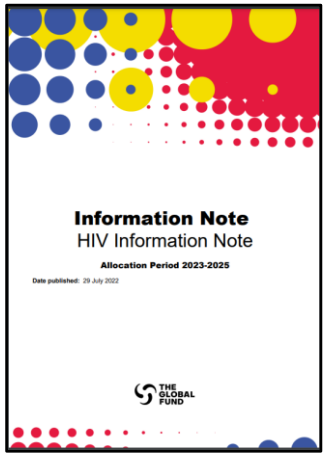
Epidemiological Update & Consequences for HIV Testing

The proportion of people living with HIV who know their status was **86% in 2022*** (92% in Eastern and Southern Africa).

- **HIV testing positivity is decreasing**
  - All countries to adopt a **3-test algorithm** to keep a positive predictive value above 99% (**HIV Program Essential**)
  - The need for confirmatory A2 and A3 tests is decreasing **-> Countries need smaller packs if not individual packs for A2 & 3 or the possibility to buy buffer separately**
- **New strategies are needed for hard to reach, still undiagnosed populations:** HIV testing services include **HIV self-testing**, safe ethical index testing and social network-based testing (**HIV Program essential**)
- The **relative weight of Antenatal Testing & testing for Key Populations** in the total HIV testing mix will continue to increase
  - **Testing at ANC** responds to a logic of **elimination of Vertical Transmission**
  - **Key populations** are increasingly driving the HIV Epidemic

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

- **HIV Testing:**
  - 3 test Algorithm
  - Self-Testing in the mix of HIV Testing Services

- **Advanced HIV Disease: CD4, CrAg and TB LAM**

Investment Priorities:

- From PMTCT to Integrated Approach towards **Triple Elimination of HIV, Syphilis and Hepatitis B**
  - More usage for Multi disease tests

- **Dual HIV/Syphilis tests also for Key Populations**

- With Hepatitis B comes the need of HBe Ag and with Syphilis TP, the need of non-TP testing

Looking Ahead:

- Triple RDT HIV/Syph/HBs Ag
- Tenofovir Urine test

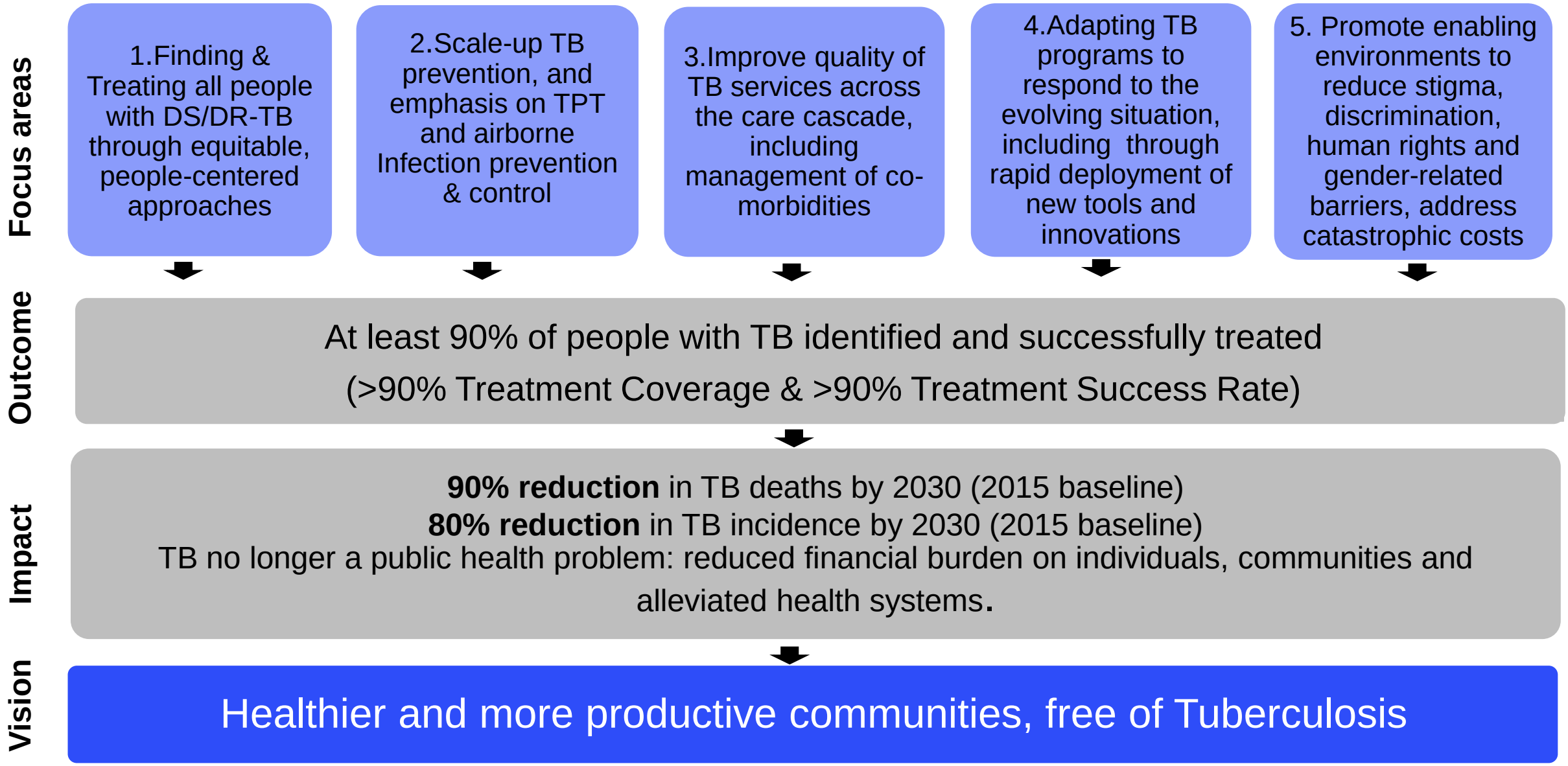
6.

Disease update TB

Grania Brigden

Senior Disease Advisor, Technical Advice and Partnerships (TAP) – TB Global Fund

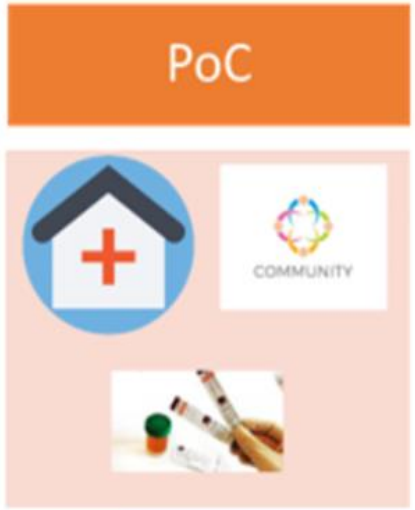
TB priority areas of focus and expected results

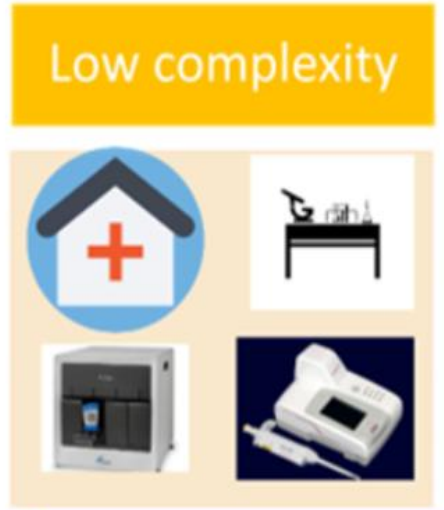


TB and Diagnostics

- **Current TB diagnostic tests are not true point of care tests**
- **The current TB diagnostic network has issues with:**
  - Monopoly market until recently (Cepheid GeneXpert)
  - 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.

RDT for TB should ideally match POC requirements below.





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)

7.
WHO Prequalification

Irena Prat

WHO PQ program

World Health Organization

Update on Prequalification of in vitro diagnostics

11 December 2023

Irena Prat | Group Lead –Diagnostics Assessment | PQ Team

Update on Prequalification of in vitro diagnostics

Presentation outline

01 Introduction to the prequalification assessment of IVDs

02 PQ Technical specifications

03 Collaborative registration procedure for IVDs

04 Specific information for RDTs

Update on Prequalification of in vitro diagnostics

World Health Organization

Introduction to the prequalification assessment of IVDs

PQ of IVDs: aim & scope

Prequalification of IVDs began in 2010

- 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 113 IVDs are prequalified

PQ List available at:

Prequalified In Vitro Diagnostics | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

HIV

Malaria

Hepatitis C

Hepatitis B

HPV

G6PD

Cholera

Syphilis

Tuberculosis NAT

SARS-CoV-2 Ag RDTs and NAT

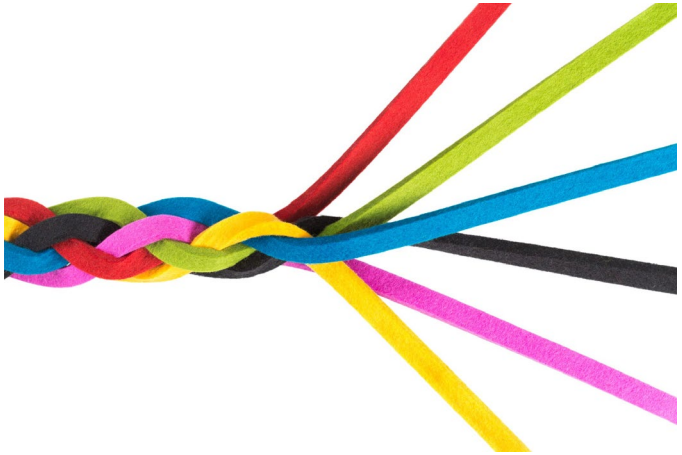
Glucose meters & test strips*

HbA1c PoC*

PQ of IVDs: design

The PQDx programme is aligned with best international practice for IVDs

- ISO (and EN) standards
- GHTF/IMDRF guidance
- CLSI guidance
- Requirements of national regulatory authorities including: FDA, EU, TGA, HC, Japanese Ministry of Health, Labour and Welfare



What PQ does differently

Requirements are based on the same standards as GHTF/IMDRF

- PQ is aligned with internationally accepted practice

BUT assesses regulatory versions intended for the **global market**:

- Where a stringently reviewed versions exist, they are often not supplied to the global market
- RoW versions can differ from stringently assessed version
  - *site of manufacture, QC, labelling, key suppliers, composition, intended use…*

Reviews aspects of particular relevance for **resource-limited settings**

- Risk assessment, stability, flex studies, labelling, customer training & support
- Considers environmental & operational factors

PQ assessment components

A comprehensive assessment of individual IVDs through a standardized procedure aimed at determining if the product meets WHO prequalification requirements

The prequalification assessment process includes three components:

Review of a product dossier

Performance evaluation

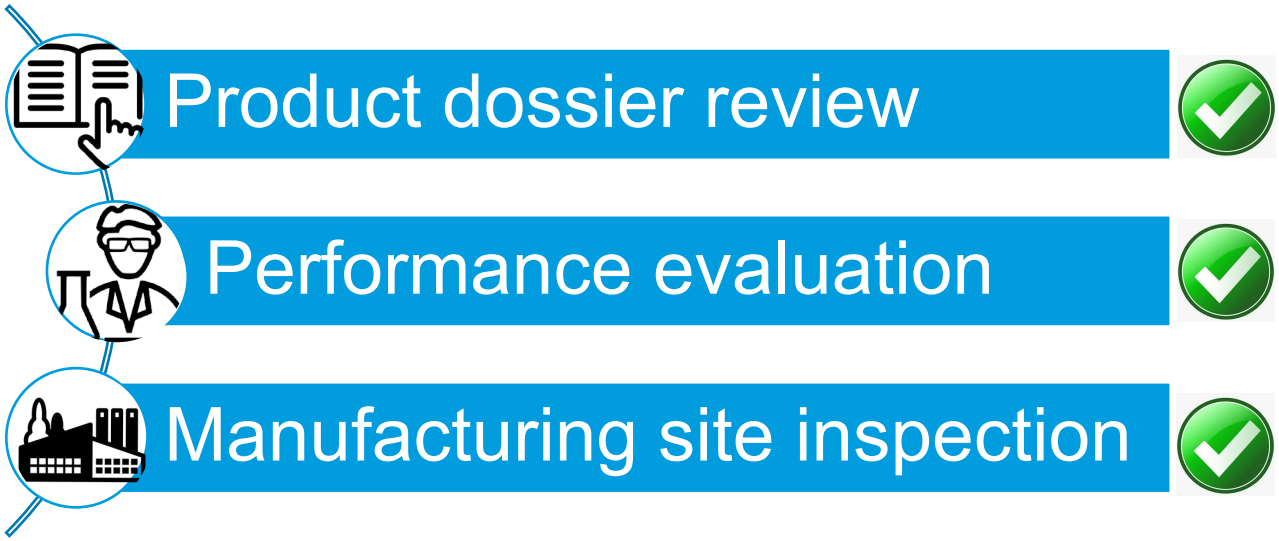
Manufacturing site inspection

Labelling review

Full assessment or Abridged assessment

Prequalification decision

Final prequalification outcome depends on:



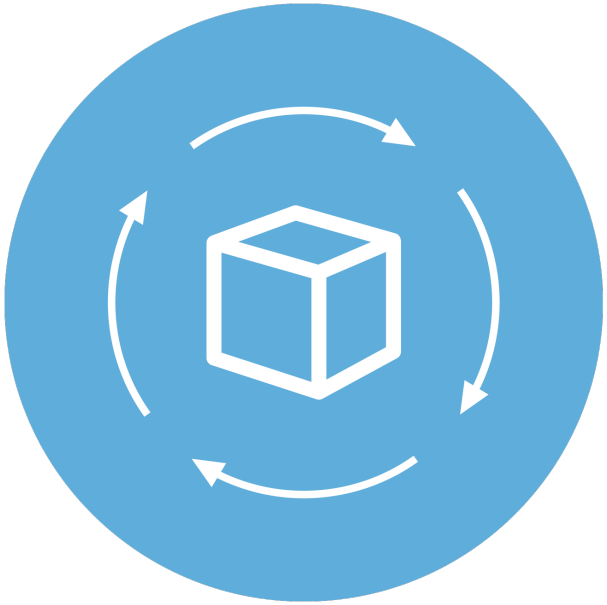
- Final labelling review is conducted & the public report prepared
- The product is added to the list of WHO prequalified IVDs
  - IVD is eligible for WHO and UN procurement **& CRP**

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
- Change reporting
- Post market surveillance obligations
- Ongoing compliance with TSS
- Routine site inspections



Update on Prequalification of in vitro diagnostics

World Health Organization

PQ Technical specifications

PQ-IVD Technical specifications published in 2023

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

***TSS-18**

HbA1c point of care analysers for professional use

TSS-19

IVD medical devices for monitoring of blood glucose in capillary blood

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

TSS 20 and TSS 21: SARS-CoV-2

World Health Organization

- Published as part of transition from EUL to PQ
- Emergency Use Listing (EUL) is an extraordinary process intended to provide guidance to interested UN procurement agencies and NRAs of WHO Member States on IVD **quality, safety and performance**
- End of the PHEIC (May 5, 2023) triggered:
  - No new EUL submissions accepted
  - Cancellation of ongoing assessments (unless close to completion)
  - Start of transition phase (EUL → PQ)
- Q&A document available:
- https://extranet.who.int/pqweb/sites/default/files/documents/IVD_Tran

TSS under development

World Health Organization

TSS-22 Haemoglobin point of care analysers

- Expansion of PQ: non-communicable diseases (NCD), risk class B
- Technical consultation including 18 experts
- Public comment period: planned Q1 2024

TSS-23: RDTs to detect mycobacterial lipoarabinomannan (LAM) antigen

- Technical consultation (Jan 2024): approx. 15 experts
- Public comment period: planned Q1 2024

TSS under revision

TSS-3: Malaria rapid diagnostic tests, 2nd edition

- Technical consultation: June 2023
- Public comment period: planned Q1 2024

Scope of the revision:

- Format changes → align with IMDRF ToC chapter numbering
- Availability of WHO International Standard for Pf & Pv (analytical studies)
- Clinical evidence to support claim for the detection of parasites with HRP2/3 deletions (applicable to all IVDs that detect Pf non-HRP antigens, e.g. LDH)

Planned new TSS and TSS revisions

World Health Organization

- TSS-4: In vitro diagnostic medical devices used for the detection of high-risk human papillomavirus (HPV) types in cervical cancer screening (mRNA, self-collection)
- TSS-6: Syphilis rapid diagnostic tests (self-testing)
- Open platform molecular tests (bridging studies)
- Sexually transmitted infections
    - TSS: Neisseria gonorrhoeae POC
    - TSS: Chlamydia trachomatis POC
- Tuberculosis
    - TSS: TB next-generation sequencing technologies for the detection of mutations associated with drug resistance in Mycobacterium tuberculosis complex

Update on Prequalification of in vitro diagnostics

World Health Organization

Collaborative registration procedure for IVDs

Collaborative Registration Procedure (CRP)

Collaboration between NRA, Manufacturer and WHO

Aims to accelerate country registration of prequalified IVDs through information sharing between WHO PQ and National Regulatory Authorities

PRINCIPLES

- Voluntary for Mx of prequalified IVDs
- Product sameness must be guaranteed
- Confidentiality of data shared
- Target timeline: 90 days for NRA decision

WHO PQ REPORTS SHARED

- Dossier review & Change requests
- Site Inspection
- Performance Evaluation

CRP Roles and Responsibilities

World Health Organization

The Manufacturer

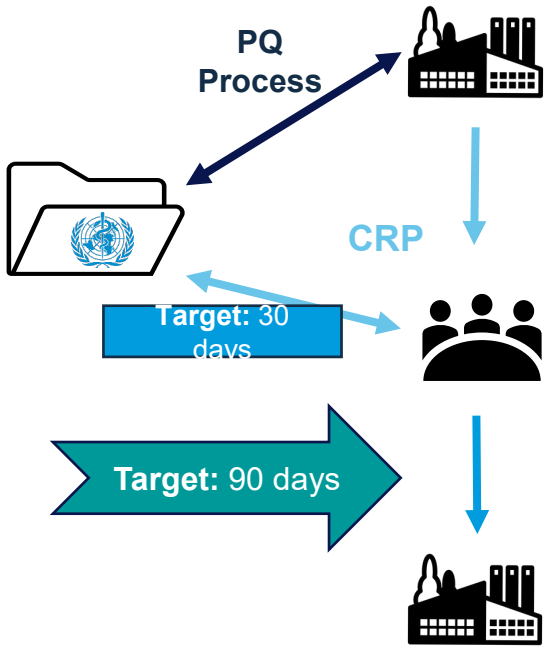
- Submit an expression of interest to the NRA
- Provide consent for WHO to share PQ reports
- Submit product dossier to NRA

WHO

- Make reports available to NRA via secure transfer
- Provide advocacy and support to regulatory authorities

The NRA

- Treat WHO PQ reports as confidential
- Issue a national regulatory decision within 90 days



NRAs participating in CRP for IVDs

Rwanda
Nigeria
Mauritania
Uganda
South Africa
Ethiopia
Tanzania
Kenya
Bhutan
Namibia
Malawi

Eritrea
Burundi
Gabon
Togo
DR Congo
Senegal
Zanzibar
Mozambique
Ivory Coast
Cameroon
Ghana

Thailand
Yemen
Cabo Verde
Togo
Angola
Zimbabwe
Botswana
Comoros

As of October 2023

Update on Prequalification of in vitro diagnostics

World Health Organization

Specific information for RDTs

Specific information for RDTs

- TSS updates: ensuring compliance
- Upcoming new TSS / PQDx expansion plan

Performance evaluations:

- New panel for HIV serology assays under development
- Development of protocol for HIV urine tests and parallel revision of protocol for HIV oral fluid tests
- Revision of other HIV serology protocols (serum/plasma and capillary blood)
  - New panel for « main » protocol for HIV tests on serum and plasma and HIV-syphilis dual tests
  - Align analytical panels with above
  - Protocol revision planned for Q1 2024, once panel fully characterized

Specific information for RDTs cont'd

World Health Organization

Malaria:

Collection of new specimens with *P. falciparum* hrp2/3 deletion in Africa planned for 2024

Revision of protocol in parallel with revision of TSS requirements scheduled for 2024

- Hrp2/3 deletion panels
- Addition of P. vivax international standard

Performance evaluation laboratories – list

- 15 listed laboratories

  https://extranet.who.int/prequal/vitro-diagnostics/prequalified/performance-evaluation-laboratories

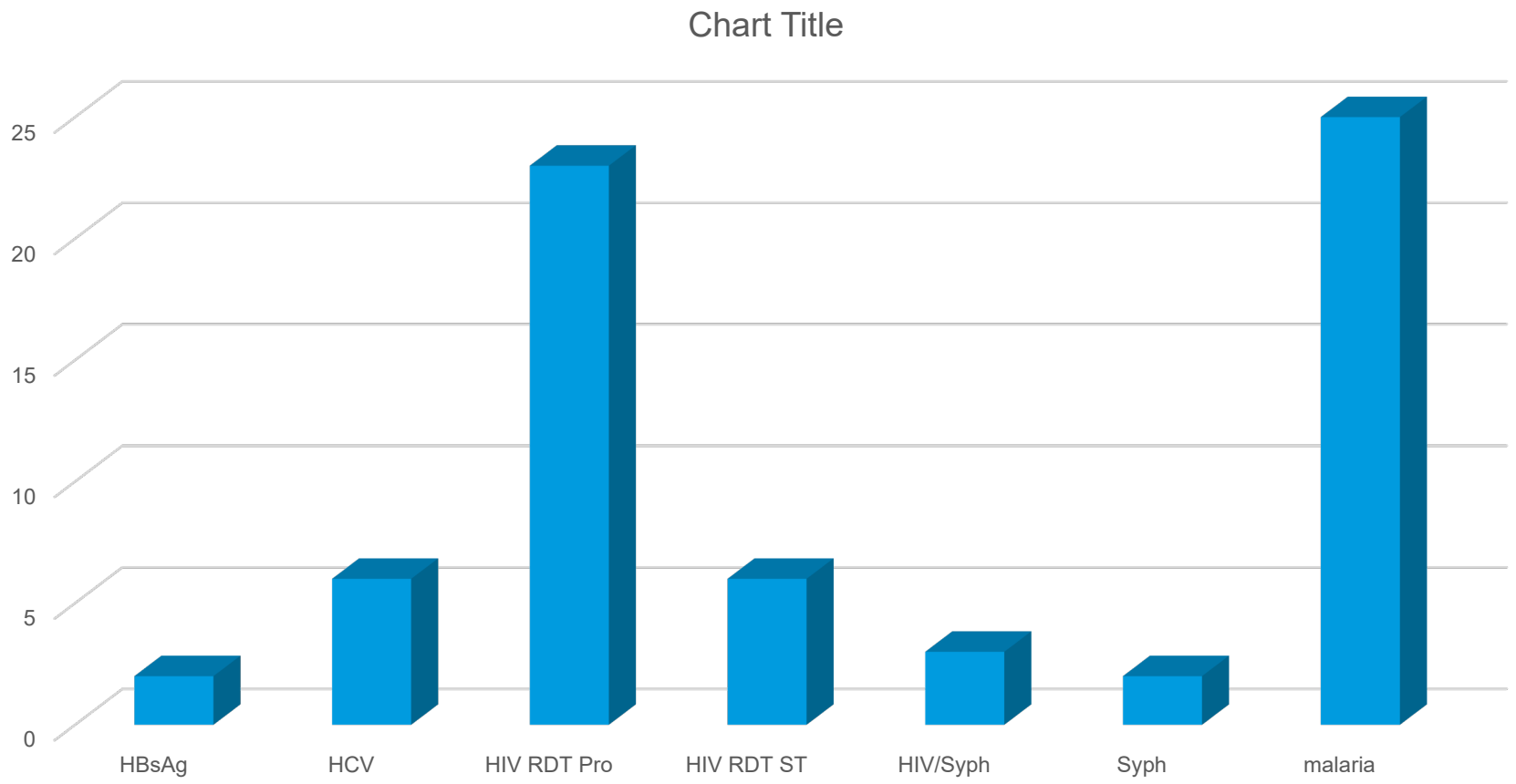
Performance Evaluation Laboratories

Analyte | Laboratory | Apply

Download list as CSV file

Laboratory	Country	Date of Listing	Laboratory Option List	Analyte (s)
Biotechnology and Genetica Laboratory,Instituto Nacional de Saude (INS)	Mozambique	9 Jun, 2022	Option 1	HIV NAT (quantitative) HIV NAT (qualitative - EID)
CDC Division of Global HIV/TB International Laboratory Branch Viral Load and Early Infant Diagnosis Team	United States	10 Sep, 2018	Option 1 Option 2	HIV NAT (quantitative) HIV NAT (qualitative - EID)
Central Public Health Laboratories Kampala	Uganda	8 Apr	Option 1	HIV NAT

Prequalified RDTs



ACCESS TO QUALITY ASSURED IVDS: PUTTING THE PIECES TOGETHER

THURSDAY 14 DECEMBER 2023 - 7.00 TO 9.00AM

Updates on initiatives that support access to quality assured IVDs, with a focus on the African region. Followed by interactive panel discussion.

Laboratory professionals, IVD regulators and product manufacturers are welcome.

ASLM 2023 Satellite Session

Workshop Agenda

- Welcome & Opening Remarks (WHO)
- Stakeholder updates (PEPFAR/USAID, UNITAID, The Global Fund)
- Expert Review Panel for Diagnostics (The Global Fund)
- PQ Assessment of IVDs (WHO)
- The Collaborative Registration Procedure (NRA)
- HIV Testing Algorithms (WHO)
- Post-market Surveillance (WHO)
- Panel discussion with audience Q&A

Questions and answers

World Health Organization

WHO

20, Avenue Appia
1211 Geneva

Switzerland

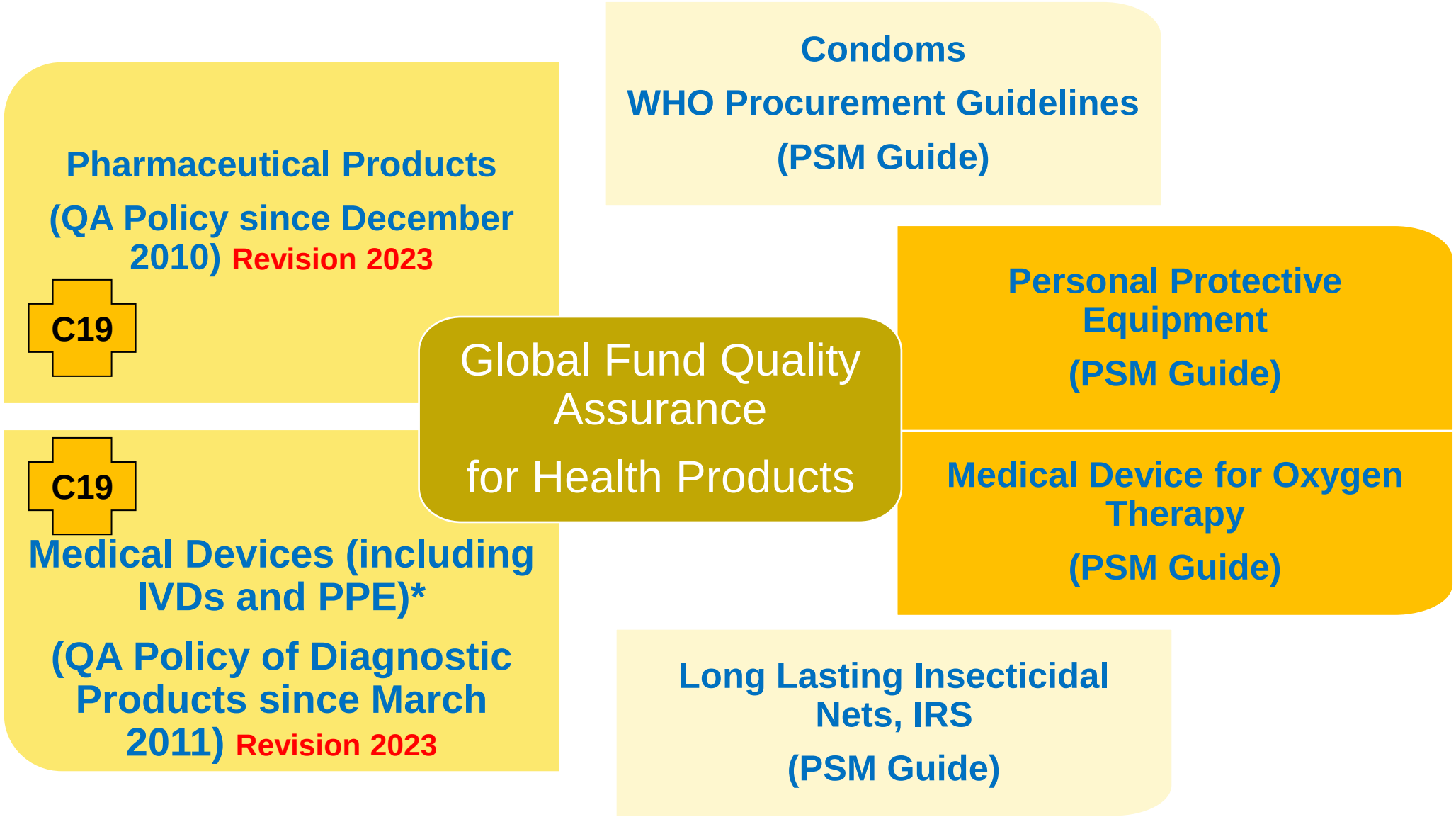
diagnostics@who.int

https://www.who.int/diagnostics_laboratory/evaluations/en/

8. Global Fund Quality Assurance and Expert Review Panel

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

Overview of TGF QA Requirements



QA policies update

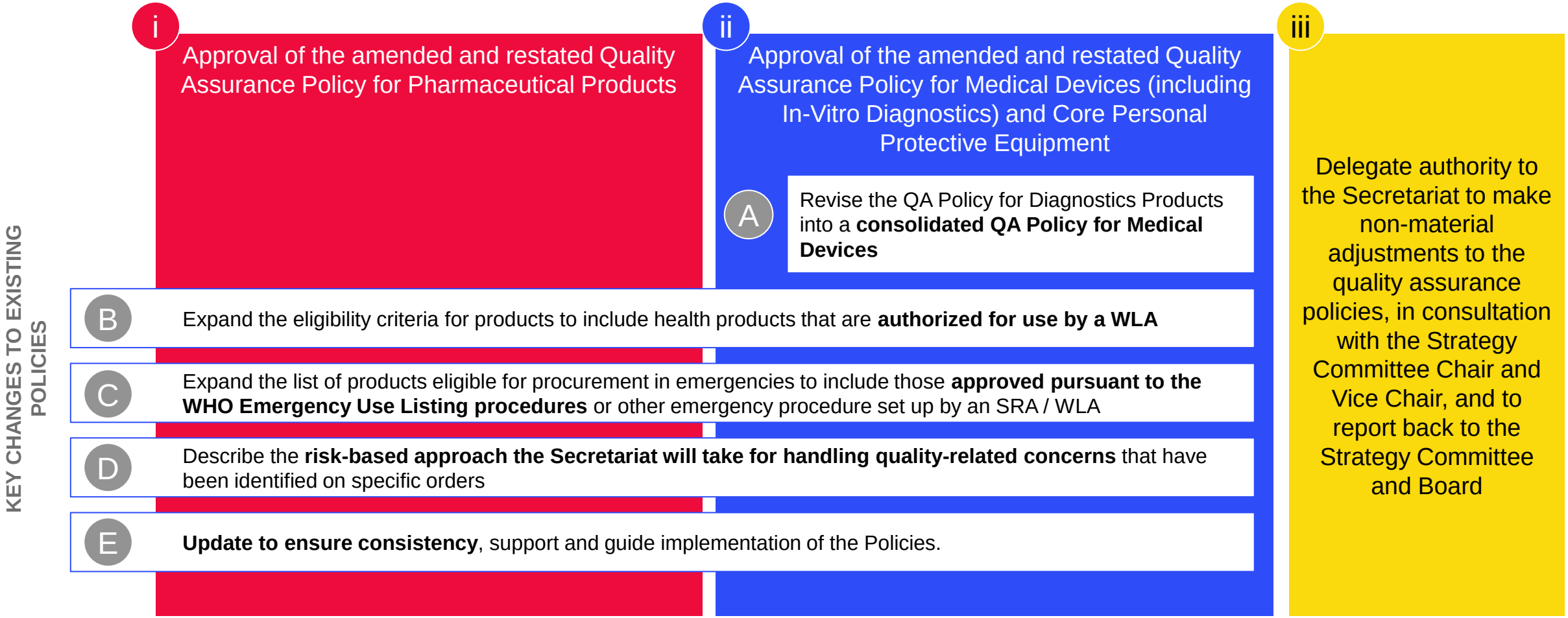
Updates to the QA Policies approved by The Global Fund Board on 15th of November 2023

Decision point: GF/B50/DP06:

Amended and Restated Global Fund Quality Assurance Policy for Pharmaceutical Products

and Amended and Restated Global Fund Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment

What are the key changes ?

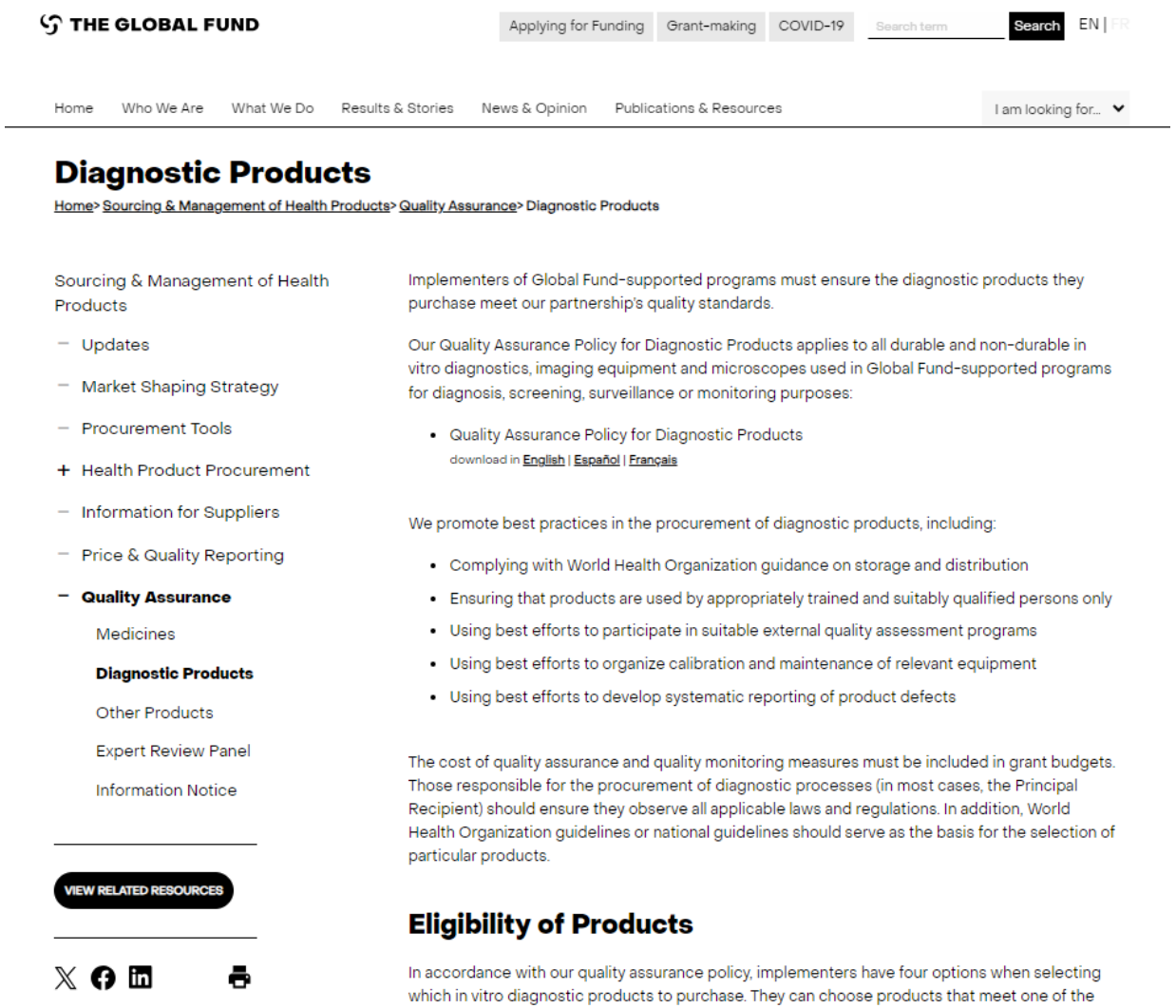


What are the key changes for IVDs?

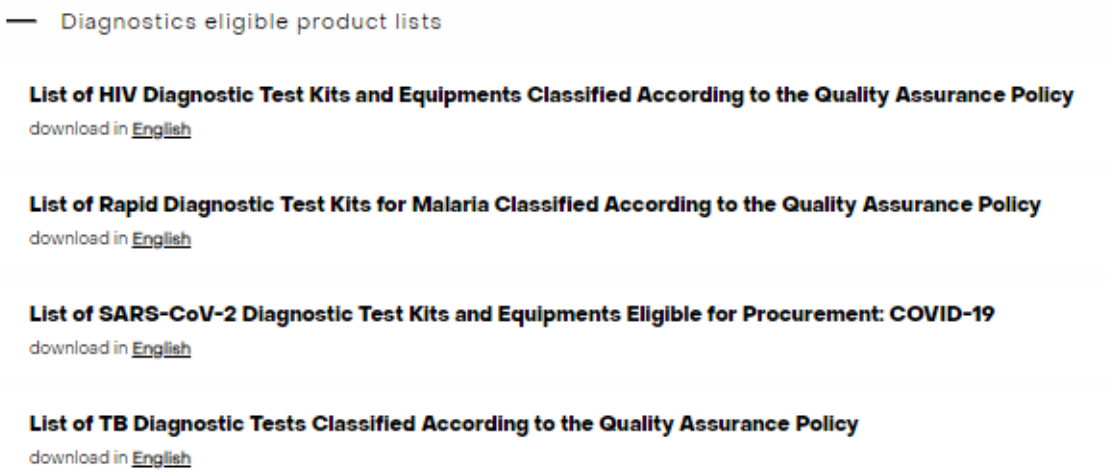
	Former QA POLICY Framework
Reference	***QA Diagnostic Products Policy (2017)***
Product applicability	For all Diagnostic Products (IVDs plus others)
General quality standards (section 7)	Quality Management System requirements (ISO 13485 or equivalent)
Additional Quality Requirements (section 8)	IVDs 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 WHO Listed Authority (WLA)** Or After assessment by Expert Review Panel **In case of Public Health Emergencies of International Concern (PHEIC)** **Approved under the WHO Emergency Use Listing (EUL)** **Or** **Under SRA/WLA Emergency procedures**

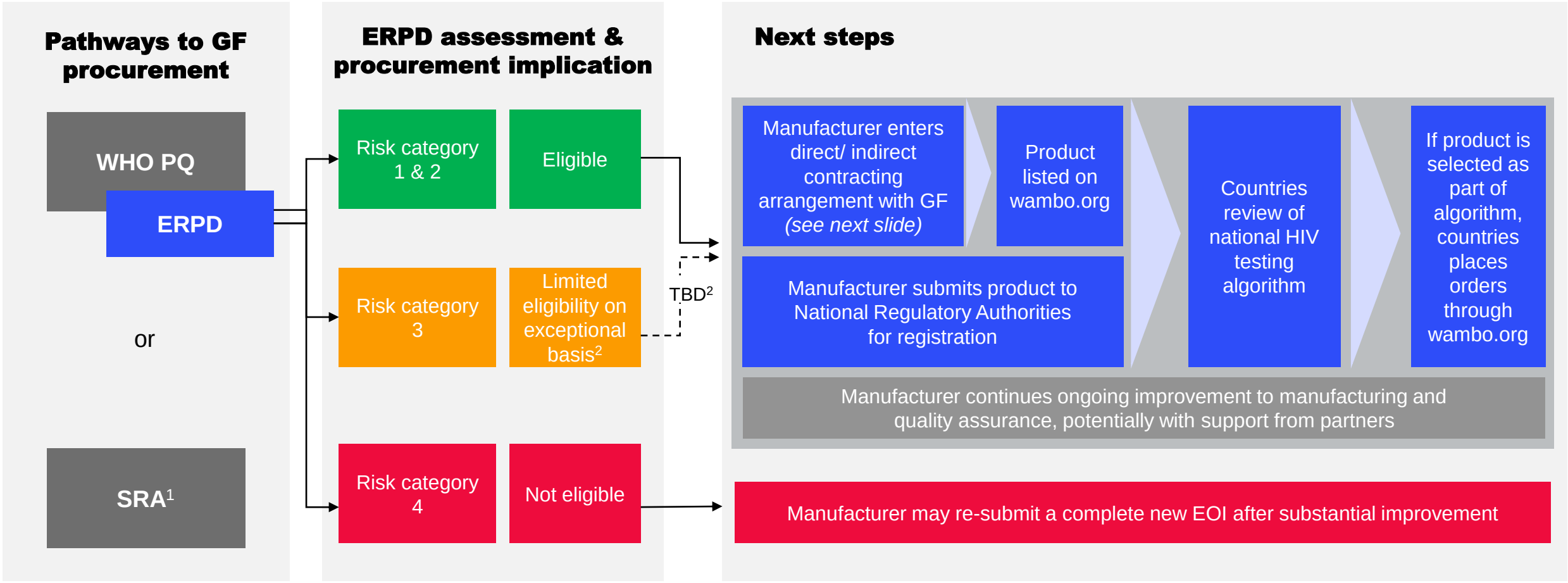
More available on Global Fund website



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



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



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

ERPD is hosted by WHO, initiated by the Global Fund

Global Fund's role includes:

- prepares and circulates the invitations for EoI in close collaboration with UNITAID and partners,
- manages the receipt of product questionnaires as sent by manufacturers,
- forwards complete questionnaires and associated documents to WHO for review,
- notifies manufacturers of the outcome of the ERPD's review of their respective submissions,
- maintains on the website an up-to-date list of diagnostics submitted and/or eligible for procurement as per QA policy, based on ERPD advice

WHO role's role includes:

- arranges the timely review of the product questionnaires,
- assess data provided in the submissions, draft the corresponding quality risk assessment reports, and allocate each product questionnaire to the appropriate risk category; the data for each product will be reviewed at least by two assessors,
- reports the conclusion on the acceptability or non-acceptability for procurement of each product,
- provides advice on measures to mitigate identified risks

Global Fund, Unitaid and PEPFAR, supported by WHO, are piloting the use of the Expert Review Panel to accelerate approval of HIV rapid tests manufactured in Africa

What do we hope to achieve?

1. To **accelerate equitable access to quality assured HIV rapid diagnostic tests** (RDTs) **manufactured in Africa**

2. To incentivize manufacturers to conduct sustainable, **end-to-end manufacturing of HIV RDTs in Africa within the next 10 years**, as a step in the pathway to securing an uninterrupted supply of RDTs in Africa

What is the Expert Review Panel for Diagnostics (ERPD)?

1. **Group of independent experts, convened by WHO**, that reviews the potential risks and benefits associated with the use of diagnostic products that may have a high public health impact but have not yet undergone a stringent regulatory assessment

2. Favorable ERPD risk rating **can result in time-limited addition to the list of eligible products for procurement** by countries using grant funds

3. ERPD assessment **does not replace WHO PQ / Stringent Regulatory Assessment (SRA)** but provides an interim solution for a time-limited period in anticipation of the completion of a stringent review process

Manufacturers must meet the following criteria and submit the following documents in order to be eligible for ERPD review

Criteria

1. **Regulatory status**: Product is under review by WHO PQ or SRA, or manufacturer submits a Letter of Commitment to apply to WHO PQ or SRA
2. **Quality Management System (QMS) status:** Product is manufactured at a site compliant with Iso 13485:2016 or equivalent management system
3. **Intent to expand manufacturing steps:** Manufacturer provides a signed Letter of Intent indicating its intent to expand the manufacturing steps for the product in African sites to end-to-end manufacturing within the next 10 years.
4. **Manufacturing in the African Union:** Product is at least partially manufactured in one of the 55 Member States of the African Union (AU)

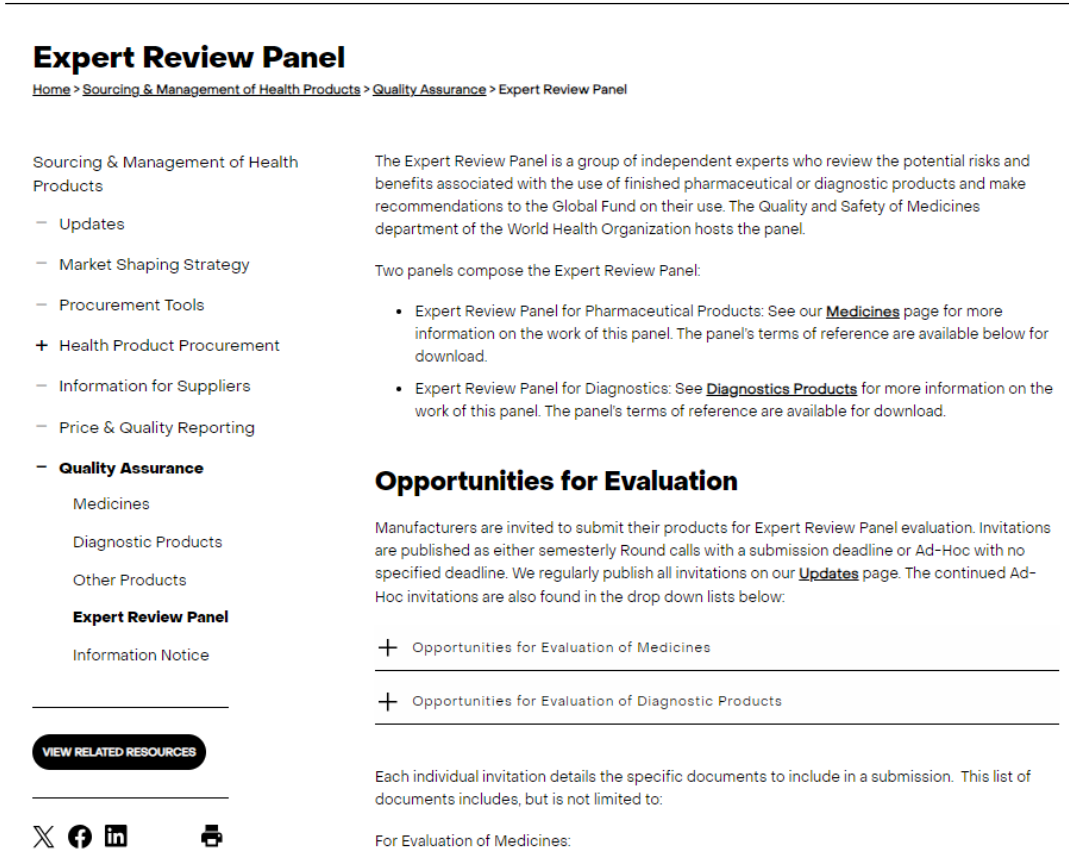
Unique to this GF/ERPD/ Adhoc 24/08-2023 ERPD call

Documentation

1. **Cover letter**
2. **Letter for regulatory status**, either from WHO Prequalification of In-Vitro Diagnostics Program, or a SRA or – in the absence of such a confirmation letter – a Letter of Commitment from the manufacturer
3. **Quality Management System (QMS) status** documents
4. **"Letter of Intent"** to expand manufacturing steps conducted in Africa
5. Completed **product questionnaire**, which can be found on the Global Fund website: https://www.theglobalfund.org/en/sourcing-management/quality-assurance/expert-review-panel/

See call for EOI for details

More available on ERP on Global Fund website



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:

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

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

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

Innovation & Partners RDT Strategies

9. FIND Innovation pipeline
10. PMI sourcing strategy
11. PEPFAR sourcing strategy
12. UNICEF 2023-2028 Procurement Strategy

Q&A / Discussion 2

FIND

DIAGNOSTIC INNOVATION PIPELINE AT POC

Jérémie Piton, PhD

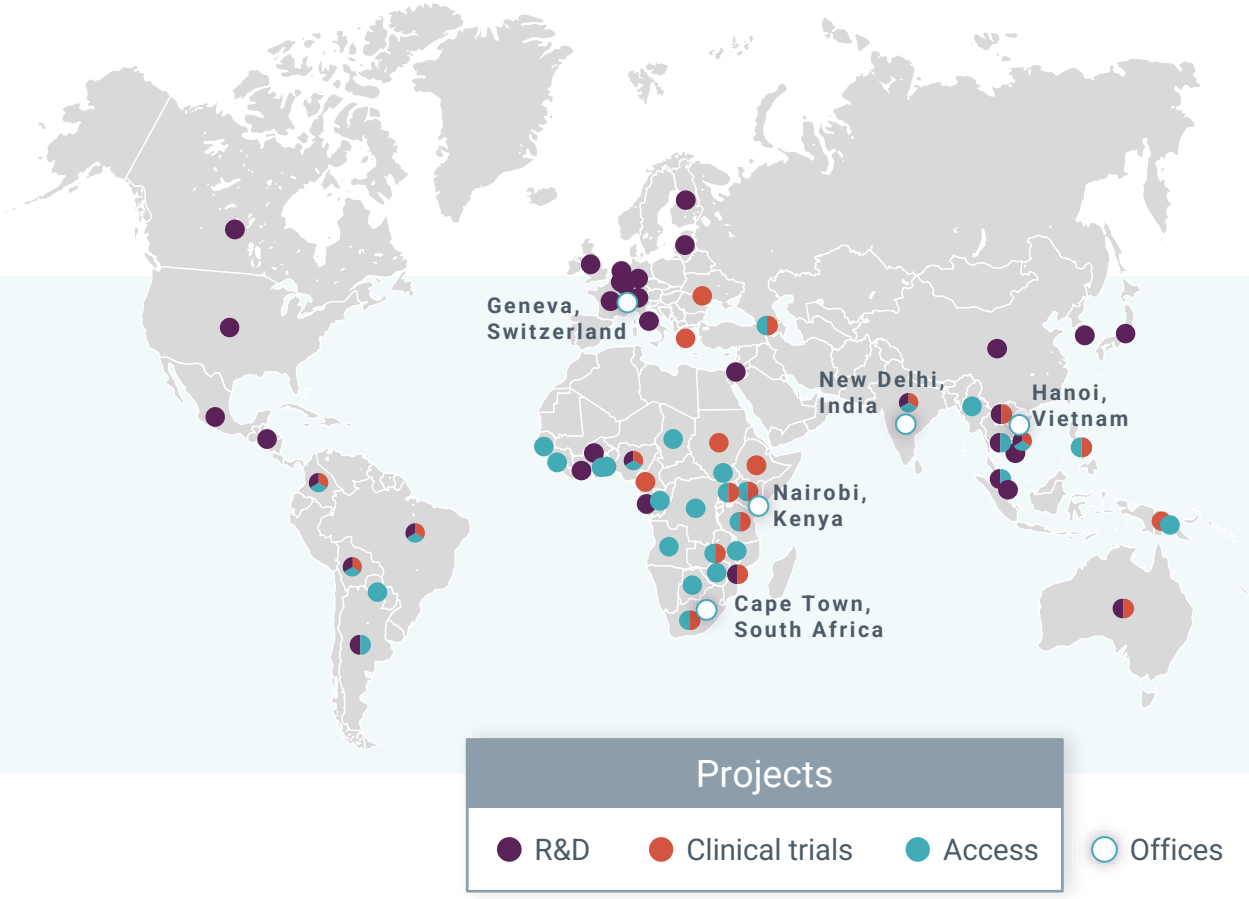
11 December 2023, Cape Town

FIND ACCELERATES

EQUITABLE ACCESS TO RELIABLE DIAGNOSIS AROUND THE WORLD

In partnership with WHO, other global health agencies and the G20/G7, we are driving progress towards universal health coverage and global health security

- Established in 2003 as a product development & delivery partnership
- Co-convener of the Access to COVID-19 Tools (ACT) Accelerator Diagnostic Pillar
- WHO Collaborating Centre for Laboratory Strengthening & Diagnostic Technology Evaluation
- WHO SAGE-IVD member



FIND STRATEGIC PRIORITIES TO

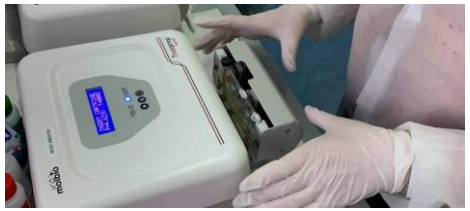
TO STRENGTHEN HEALTH SYSTEMS AND MAXIMIZE IMPACT

Responding to countries' priorities

- Support packages tailored to country / regional needs for sustainable uptake and impact
- Strong partnership with MoH to influence policy on critical regional global health priorities

Collaboration with: Brazil, Indonesia, India, Kenya and South Africa

Multiplex point-of-care molecular test launch



Identifying multiple pathogens from a single test enables health systems to be structured around patients, not diseases

Primary care and patient-centered diagnostics

Accessible diagnosis and health management where patients seek care is critical to Universal Health Coverage

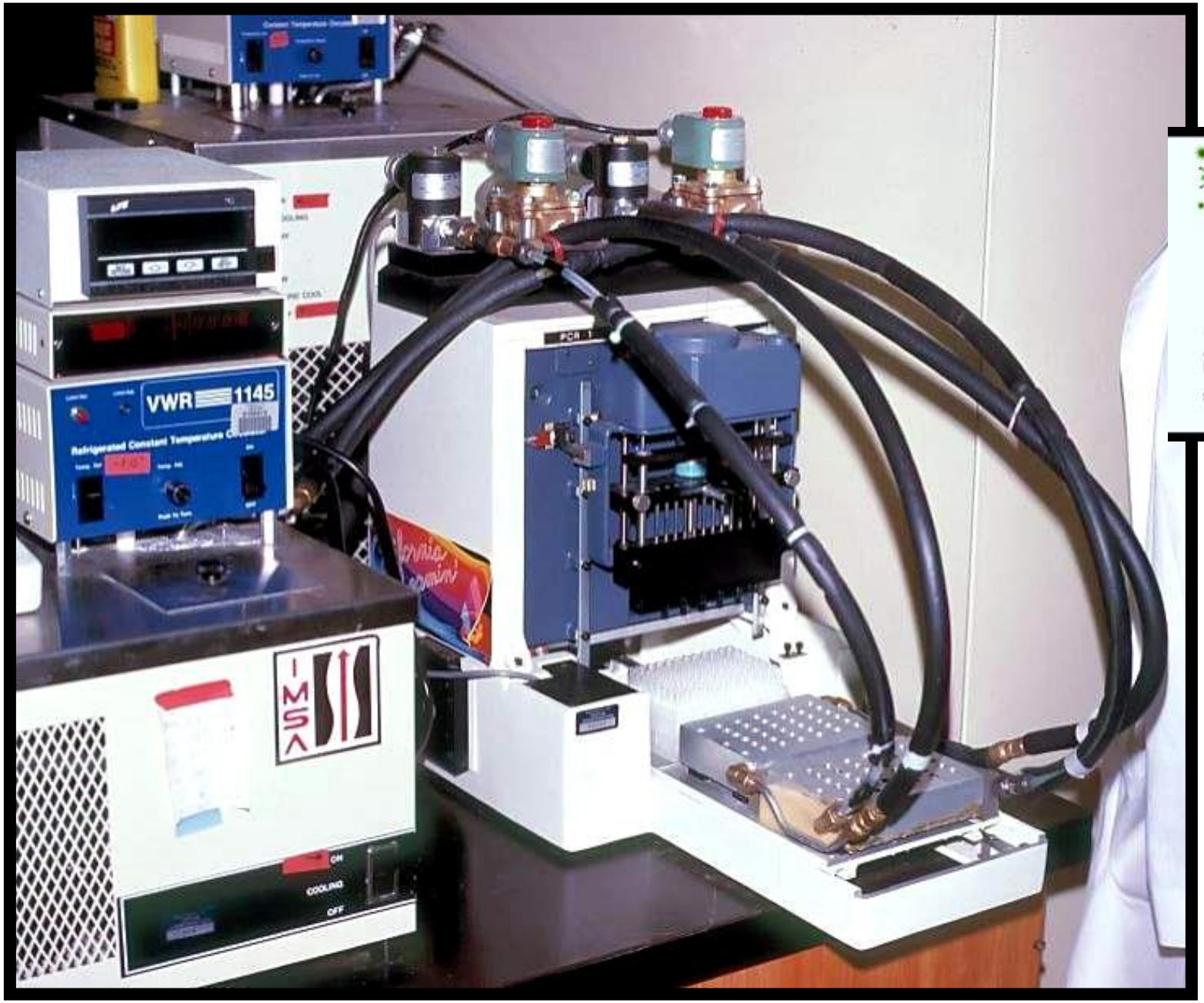
Regional diagnostic manufacturing

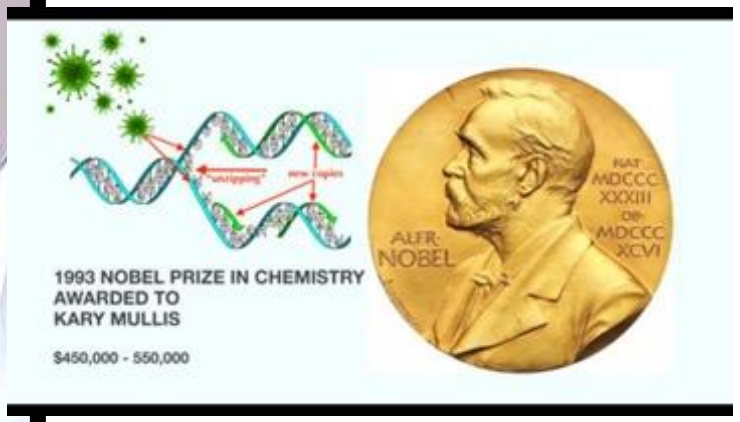
Manufacturing RDTs closer to those who need them ensures sustained, secure and affordable supply

Disease surveillance

Reliable, connected and optimized networks provide essential early warning systems and track disease elimination

Equitable access to reliable diagnosis around the world





Kary Mullis' first thermocycler

Disclaimer: The product depicted in this slide (Cobas system by Roche Diagnostics) was selected to represent a product class. The selection does not represent endorsement or recommendations on any particular product by FIND.

TB Lab tech in Kenya, photo from 2016

Ebola Xpert training in DRC, photo from 2015

Malaria LAMP testing in Peru, photo from 2015

TB lab tech in India, photo from 2017

HAT LAMP testing, photo from 2012

Disclaimer: The products depicted in this slide (Gene Xpert by Cepheid and HAT LAMP by Eiken) were selected to represent a product class. The selection does not represent endorsement or recommendations on any particular product by FIND.

DISRUPTING THE TRADITIONAL TRADE-OFF

BETWEEN PERFORMANCE AND ACCESSIBILITY

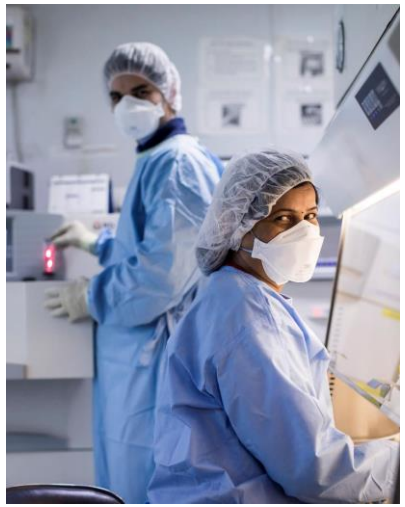
Community

Primary care

Hospital/laboratory

Improved access

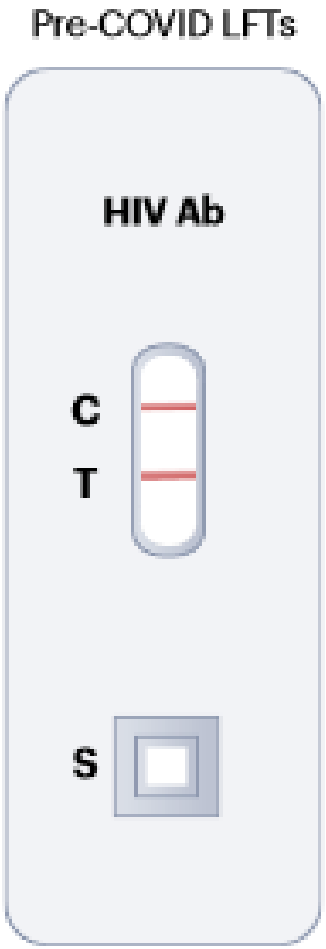
Improved performance



Today, new innovations mean high-quality testing is getting closer and closer to the point-of-care where people can most readily access it

KEY REQUIREMENTS FOR NEW LFA

TO MAKE A TRANSFORMATIONAL IMPACT



Use cases : clinical diagnostic, self-testing

Data Capture : Visual reading and manual reporting

Targets : Antigens, Antibodies,

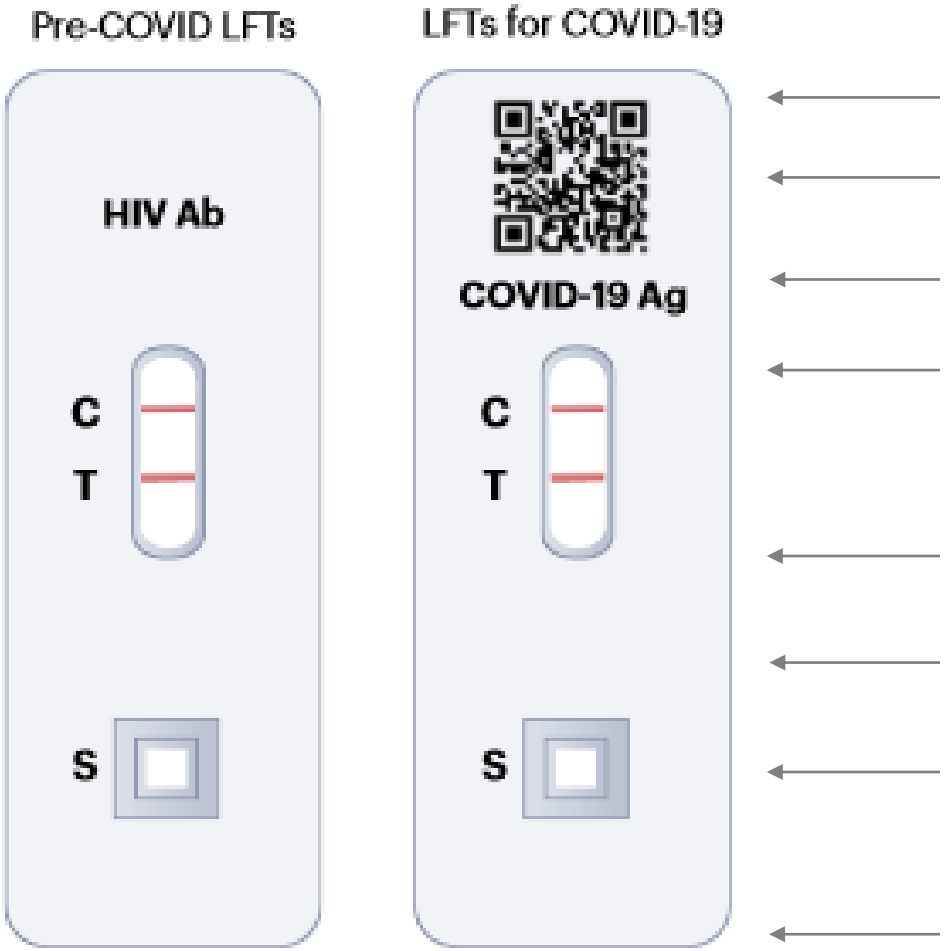
Materials: Gold particle, Latex nanobeads,

Sample type Blood, swab, urine

Price: Low price

KEY REQUIREMENTS FOR NEW LFA

TO MAKE A TRANSFORMATIONAL IMPACT



Lateral flow test engineering and lessons learned from COVID-19. Budd *et al.*, **2023** *Nature reviews Bioengineering*

Use cases : clinical diagnostic + self testing**, mass testing,**

Data Capture : **manual and Digital**,

Disease : COVID-19

Targets : Antigens, Antibodies

Increased Performance : Gold particles, Latex nanobeads, **Quantum dots,**

Manufacturing: **Regional manufacturing**,

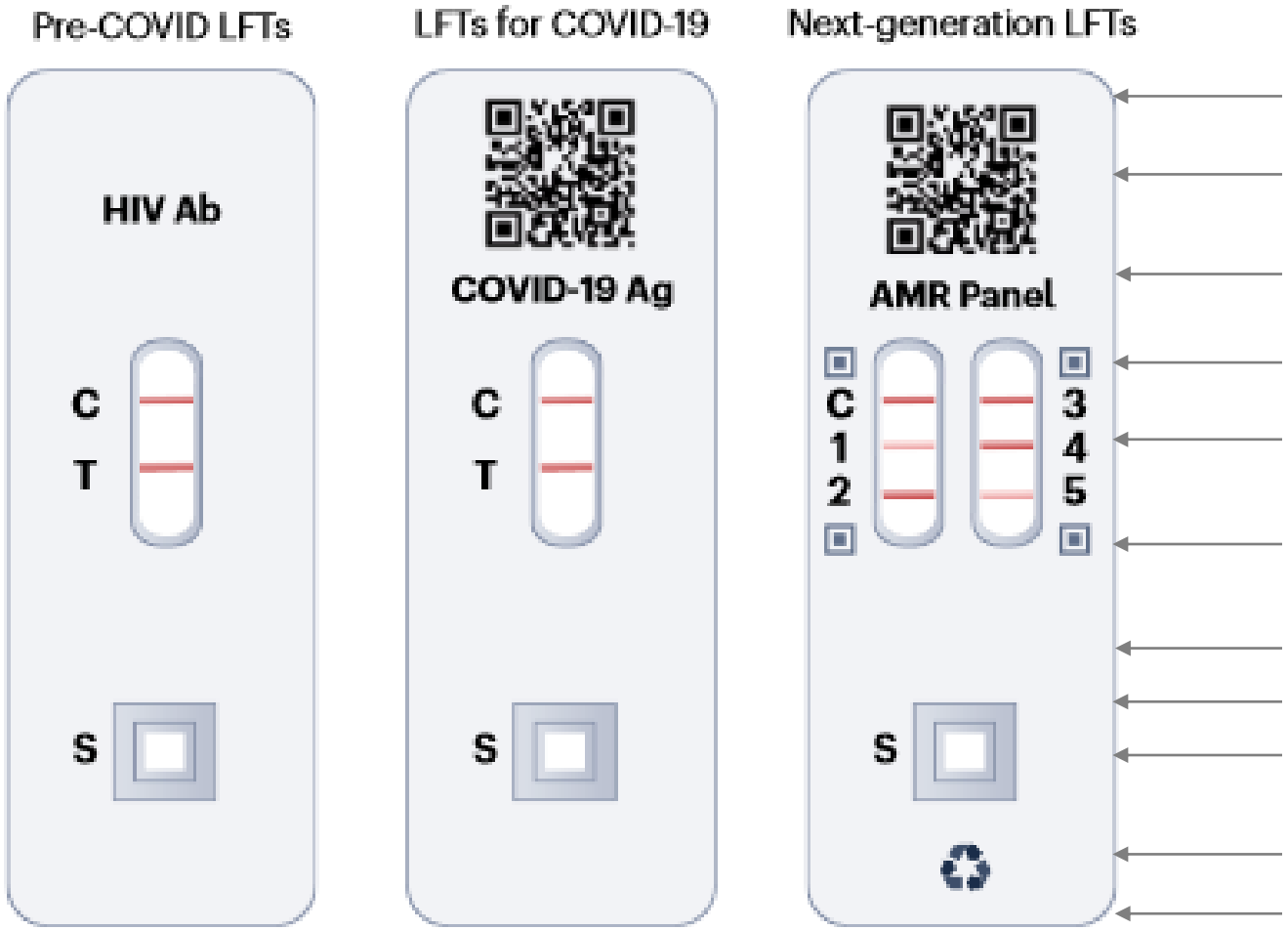
Sampling methods: **Non invasive, self sampling**

Price: Lower price

Readers: branded readers

KEY REQUIREMENTS FOR NEW LFA

TO MAKE A TRANSFORMATIONAL IMPACT



Lateral flow test engineering and lessons learned from COVID-19. Budd *et al.*, **2023** *Nature reviews Bioengineering*

Use cases : self testing, clinical diagnostic, **surveillance**

Data Capture : **Digital, automatic connection to healthcare systems, Post market Surveillance**

Challenging Disease : TB, NG/CT, Schistosomiasis, AMR, Vaccine preventable disease (YF, Mening, Cholera, Measles)

Targets : Antigens, Antibodies, **Molecular**

Multiplex : **Multi-pathogen, Multi-markers, Resistance, Pan-virus, disease X**

Increased Performance : Gold particle, Latex nanobeads, Quantum dots, **Fluorescence**, **Nanodiamonds, enzymatic nanoparticles**

Manufacturing: Innovation, Regional manufacturing,

Stability : Increase stability at higher temperature

Sampling methods: Non invasive, self sampling

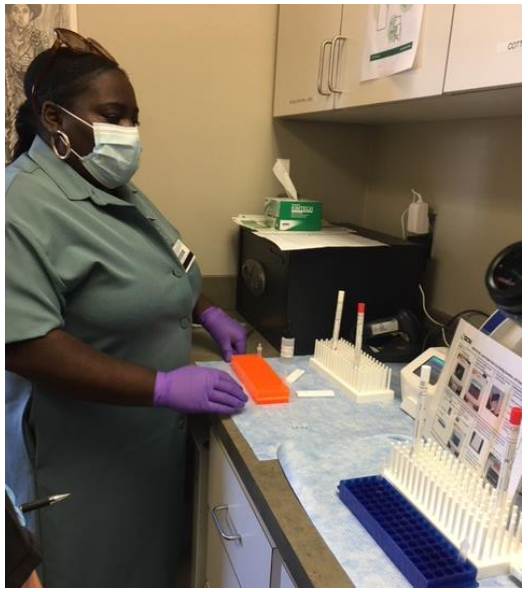
Eco-friendliness: **Packaging, less plastic**

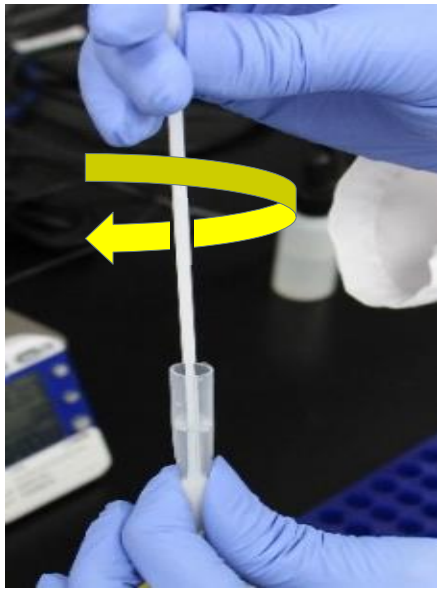
Price: Lower price

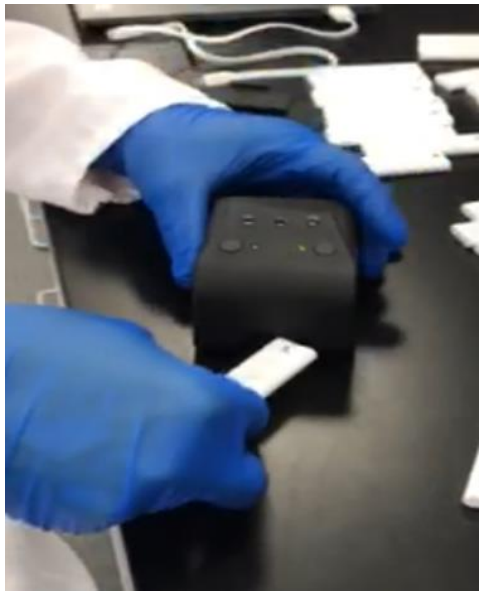
Readers: **Universal** readers,

Sample prep: **Sample prep, urine concentrator**

FLUORESCENT NG ASSAY DEVELOPED BY FIND AND DCN AND EVALUATE IN SOUTH AFRICA CLINICS







TPP	Minimal requirement	Optimal requirement
Sensitivity	>80%	>90%
Specificity	>95%	>98%

Symptomatic men

Performance

Sensitivity	96% (91% – 98%)
Specificity	97% (90% – 99%)

Symptomatic women

Performance

Sensitivity	92% (78% – 97%)
Specificity	96% (92% – 98%)

CT/NG

MOLECULAR TEST ON LFA FORMAT

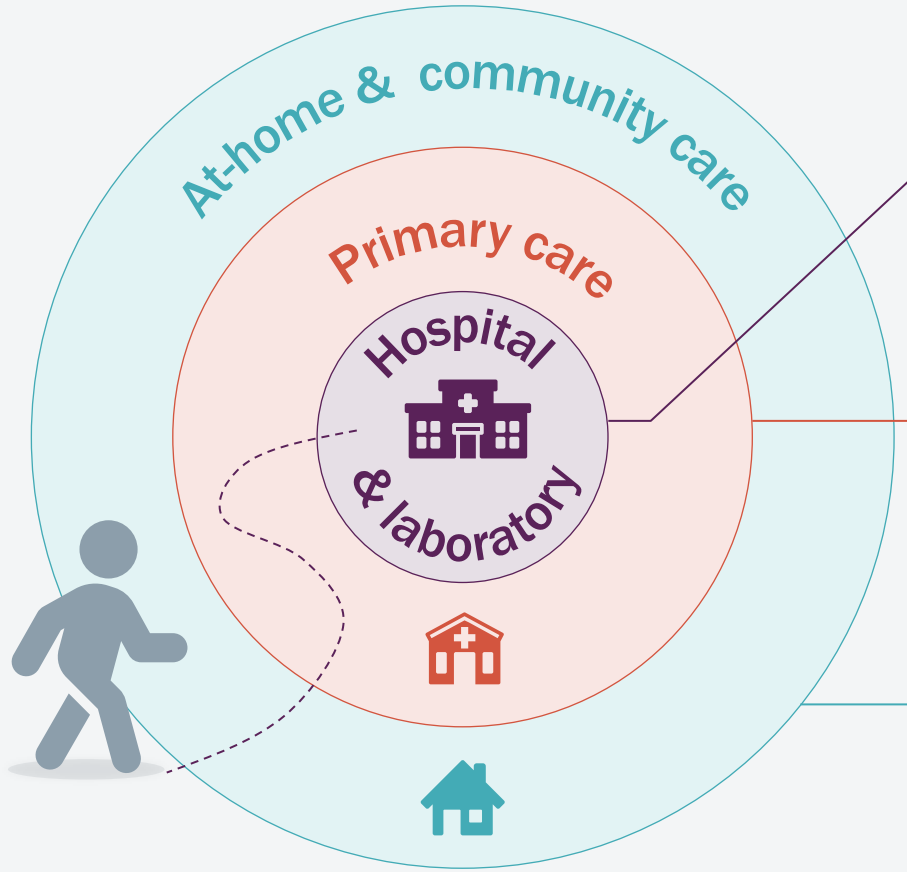
U.S. FOOD & DRUG ADMINISTRATION

https://www.accessdata.fda.gov/cdrh_docs/reviews/K200748.pdf

Disclaimer: The products depicted in this slide were selected to represent a variety of product classes. The selection is not comprehensive and does not represent endorsement or recommendations on any particular product by FIND.

MOLECULAR DIAGNOSTICS AT THE POINT OF CARE COULD

FILL CRITICAL GAPS ACROSS DIFFERENT HEALTHCARE SETTINGS



Technologies suitable to testing infrastructures

Near POC

- Basic lab equipment requirements
- Benchtop/desktop units, mains power
- Semi-automated testing processes

True POC

- No laboratory equipment requirements
- Portable, battery-operated devices
- Kits including disposable sample materials
- Fully automated testing process

Instrument free POC

- No instrument or power requirements
- Kits including disposable sample materials
- Fully automated testing processes

Increasing accessibility

PRE-PANDEMIC

LIMITED TOOLS, MAINLY IN HOSPITALS

Disclaimer: The products depicted in this slide were selected to represent a variety of product classes. The selection is not comprehensive and does not represent endorsement or recommendations on any particular product by FIND.

THE DELUGE

THE COMING EXPLOSION IN NEW POC DIAGNOSTIC TECHNOLOGIES

Connected diagnostics and interoperable systems for data management, data aggregation and data sharing for surveillance

Disclaimer: The products depicted in this slide were selected to represent a variety of product classes. The selection is not comprehensive and does not represent endorsement or recommendations on any particular product by FIND.

THE POC MOLECULAR DX DEVELOPMENT PIPELINE HAS THE POTENTIAL

TO TRANSFORM HEALTHCARE DELIVERY IN LMICS

160
Total Platforms in the Landscape

Near POC pipeline:

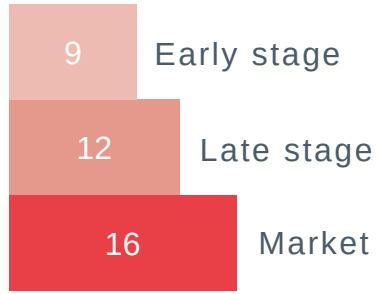
- 80 novel platforms
- Competitive characteristics compared to Cepheid
- Strong multi-pathogen, potential for syndromic testing

Hospitals / laboratories (L2)

True POC pipeline:

- >30 platforms
- Mostly based on isothermal amplification; costs now below US$5
- Growing market penetration

Primary care facilities (L1)

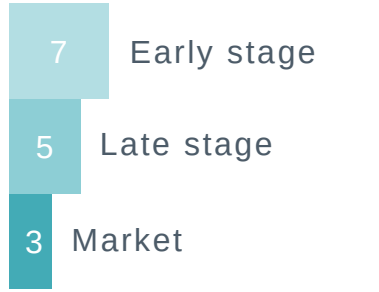


45%
Platforms based on isothermal amplification

Instrument free POC pipeline:

- >10 platforms in development; 3 on the market
- Test costs still still high
- Commercialization mostly limited to the US

At home/ communities (L0)



Disclaimer: Landscape and development stage assessment conducted based on the COVID-19 test offering for each platform. Data last updated on Q4-2022

THE POC MOLECULAR DX DEVELOPMENT PIPELINE HAS THE POTENTIAL

TO TRANSFORM HEALTHCARE DELIVERY IN LMICS

Near POC pipeline:

- 80 novel platforms
- Competitive characteristics compared to existing tests
- Strong multi-pathogen, potential for syndromic testing

SDB M10

BIONEER IRON Q PCR

CEPHEID GENE XPERT

MOLBIO TRUENAT

True POC pipeline:

- >30 platforms
- Mostly based on isothermal amplification; costs now below US$5
- Growing market penetration

PLUSLIFE DOCK

THERMO FISHER ACCULA

LUMIRA DX

CUE HEALTH

Instrument free POC pipeline:

- >10 platforms in development; 3 on the market
- Test costs still high
- Commercialization mostly limited to the US

VISBY COVID19

SENSE VEROS (Sherlock Bio)

LUCIRA COVID19

SELF-DIAGNOSTICS

Disclaimer: Data last updated on Q4-2022. The products depicted in this slide were selected to represent a variety of product classes. The selection is not comprehensive and does not represent endorsement or recommendations on any particular product by FIND.

OPEN-SOURCE PLATFORMS CAN FACILITATE THE DEVELOPMENT OF TESTS

TAILORED TO LOCAL HEALTH PRIORITIES

Traditional model:

‘PROPRIETARY’ PLATFORMS

- Proprietary assays developed by platform manufacturer only
- Addition of new tests subject to market opportunities (limited interest for niche markets)
- High reliance on one provider increases risk of product shortage

MOLECULAR PLATFORMS

one platform – multiple assays

Innovative model:

OPEN PLATFORMS

- Development of specific panels/kits possible by ‘local’ developers
- Addition of new tests facilitated to address local health priorities
- Development of validation & biobanking protocols and reference & QA/QC panels
- Requires partnerships & innovative financing

CONCLUSION : KEY REQUIREMENTS FOR NEW DIAGNOSTIC TOOLS

TO CLOSE THE GAP AT POC (MOLPOC AND LFA)

Improved performance

POINT-OF-CARE (POC)

Usable where people live and seek care
(incl. communities and primary care settings)

MULTI-PATHOGEN

Able to identify multiple diseases in one sample (incl. outbreak-prone pathogens)

AFFORDABLE

Pricing structures adapted to LMICs

ACCURATE

Robust and highly sensitive results

Improved access

FIND

Thank you !

TOGETHER,
we can ensure that
everyone who needs
a test can get one

Invitation

Regionalizing Diagnostics Value Chains: The path to expanded, equitable access

Official Satellite at the ASLM conference co-hosted by Unitaid, FIND, ASLM, and partners, followed by a cocktail. Please RSVP here to attend.

Date 12 December 2023

Time 17:30 – 19:00

Venue Cape Town International Convention Centre (CTICC), South Africa

AFRICA CDC Centre for Disease Control and Prevention

ASLM

FIND

PEPFAR 20 YEARS OF IMPACT

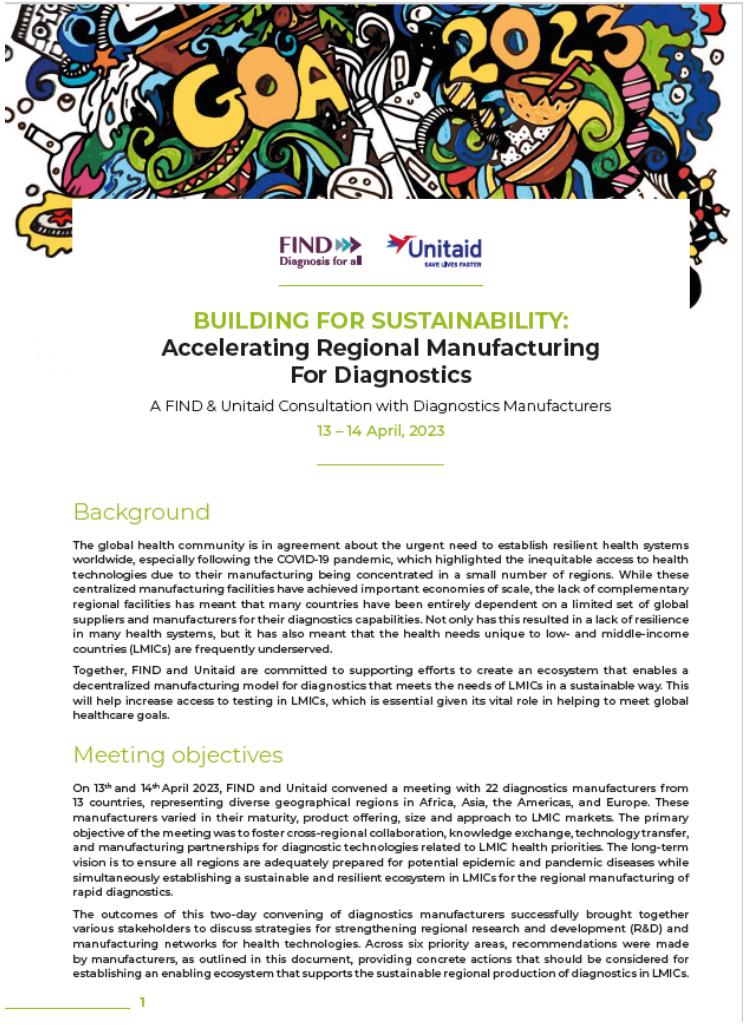
THE GLOBAL FUND

Unitaid SAVE LIVES FASTER

USAID FROM THE AMERICAN PEOPLE

World Health Organization

MEETING REPORT AVAILABLE



https://www.finddx.org/wp-content/uploads/2023/11/20231103_evt_G20_acc_reg_man_FV_EN.pdf

https://www.finddx.org/wp-content/uploads/2023/11/20231103_rep_G20_acc_reg_man_FV_EN.pdf

FIND & Unitaid will open a call to accelerate & strengthen regional IVD supply in LMICS

- Register to be notified when EOI is open for submissions

SCAN ME

Potential future funding and matchmaking opportunities for

Regional supply strengthening projects to meet unaddressed regional priority public health IVD needs

Matchmaking/partnership requests to strengthen the regional IVD supply base

Professional services covering specialized expertise and services that may be essential to regional IVD supplier(s)

THROUGHOUT 2023 THERE WERE 14 NON-IVD PIPELINE PRODUCTS

Health Programme`	Disease Target	Product Development Phase					Non- IVD Products
		Phase 0 Concept	Phase 1 Feasibility	Phase 2 Development	Phase 3 Verification & Validation	Phase 4 Regulatory Authorization	
Antimicrobial Resistance	Gonorrhea			●	●		
	Chlamydia		●				
	AMR				● ●		● ●
Diagnostic Network Optimization	Multi-Disease						● ●
Fever and Malaria	Multi-Disease						●
	Malaria		●		●		●
	Fever			● ●			
Hepatitis & HIV	Hepatitis C			●	● ●		
Neglected Tropical Diseases	Visceral Leishmaniasis		●	●			
	Schistosomiasis			● ●			
	Chagas			●			
	Buruli Ulcer			●			
Non-communicable Diseases	Liver disease		● ●	● ●			
Pandemic Threats	Yellow Fever			●	●		
	Multi-Disease						● ●
	Covid-19 / TB multiplex						●
	Covid-19		●		● ● ● ● ● ● ●	● ● ● ●	● ● ●
Tuberculosis	Tuberculosis	●	●		●		● ●
	Multi-Disease				●		

● Rapid Diagnostic Test ● Molecular POC ● Instrument ● Reagents ● Hematology Test ● Clinical Chemistry Test ● Accessory ● Digital Tool ● Other

U.S. President's Malaria Initiative
Malaria RDT Procurements

Lisa Hare & Christie Hershey
Malaria Supply Chain Branch
USAID/U.S. President's Malaria Initiative
December 2023

Global Fund RDT Stakeholder Consultation Meeting

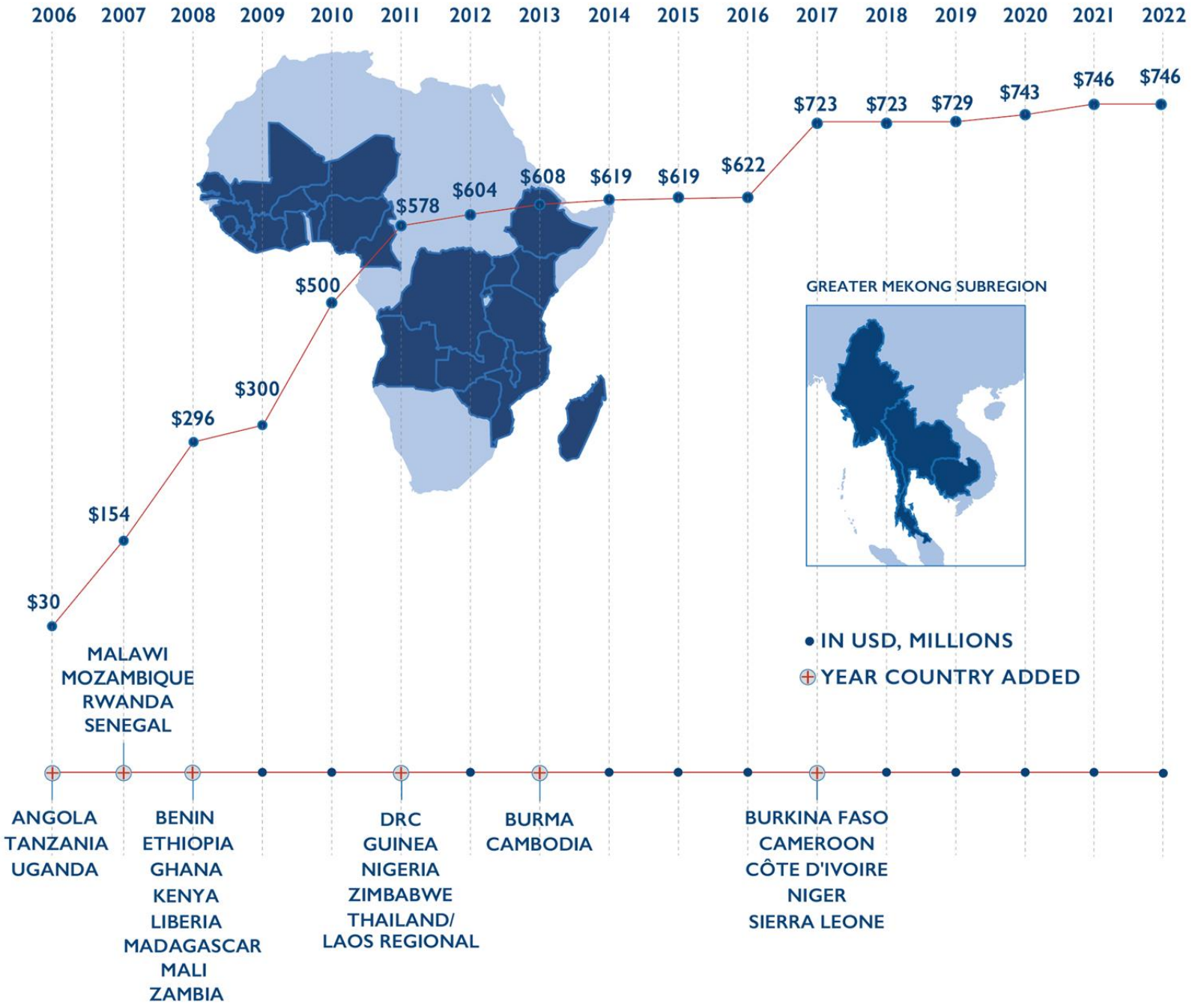
PMI | U.S. PRESIDENT'S MALARIA INITIATIVE
LED BY
USAID FROM THE AMERICAN PEOPLE
CDC

OUTLINE

1. U.S. President’s Malaria Initiative
2. Historical Malaria RDT Procurements
3. Malaria RDT Sourcing Process
4. HRP2 Deletions
5. Contacts

PMI COUNTRIES & FUNDING

PMI HAS INVESTED APPROXIMATELY **$9 BILLION** IN HELPING PARTNER COUNTRIES FIGHT MALARIA AND STRENGTHEN HEALTH SYSTEMS



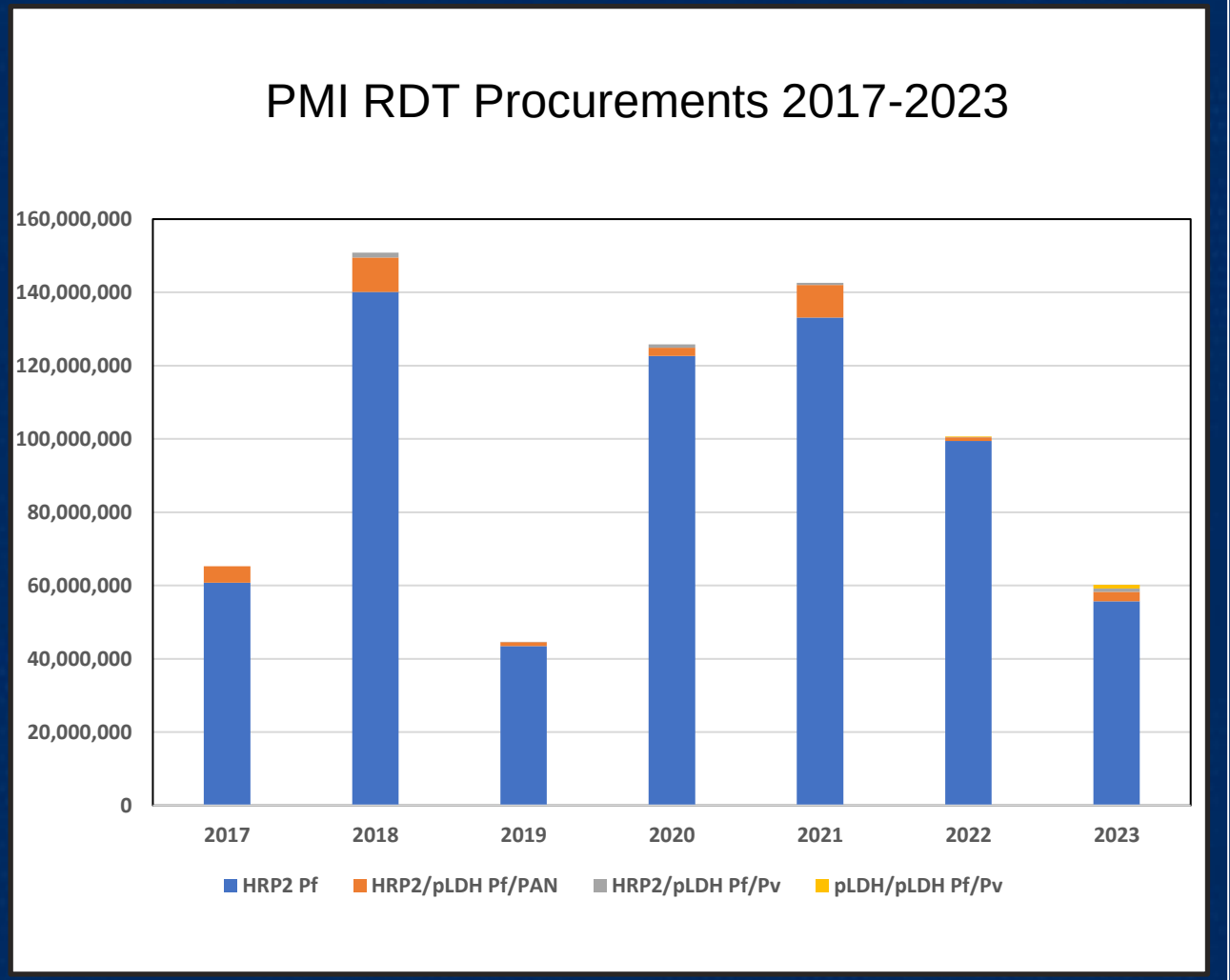
PMI'S HISTORICAL MALARIA RDT PROCUREMENTS

Procure ~ 99 million malaria RDTs per year

1. 95% HRP2 Pf
2. 1% HRP2/pLDH Pf/Pv
3. 4% HRP2/pLDH Pf/Pan (no longer procuring)

First pLDH/pLDH Pf/Pv tests procured in 2022/2023

Mostly 25 packs, but a recent increase in 10 packs for HRP2 Pf and HRP2/pLDH Pf/Pv



PMI's Malaria RDT Sourcing Process

- PMI's malaria RDT sourcing events are conducted by our procurement service agent, currently the Global Health Supply Chain-Procurement and Supply Management (GHSC-PSM) project led by Chemonics
- Best Value Criteria in Allocations for FY2024:
  - Total Landed Cost
  - Supplier Performance
  - Innovation (non-HRP2 based tests)
  - African/Regional manufacturing
  - Registration Coverage

PMI'S PERSPECTIVE ON HRP2 GENE DELETIONS

- Targeted support for surveillance, testing through therapeutic efficacy studies
- Support partner countries to review data and update policies
- Procurement of pLDH RDTs in areas with >5% prevalence of deletions in those patients presenting with symptomatic malaria
- Consider non-HRP2 based tests to be a nessessary tool for malaria control

RDT TASK FORCE

- Review evidence and work on alignment across procurers
- Concerns about increase in *hrp2* gene deletions but limited data to guide decisions
- Potential development of a risk based approach to prioritize surveillance and guide procurement of pLDH tests
- Potential shift to proactively diversify RDTs by procuring pLDH tests before demonstrating the 5 percent threshold
    - Promote innovation and investment in non-HRP2 tests
    - Increase demand and potentially lower cost
    - Requires approaches to limit impact on individual country malaria budgets
    - Given combined HRP2/pLDH tests there may no longer be the need to tradeoff detection due to sensitivity issues vs. deletions

CONTACTS FOR PMI RDT PROCUREMENTS

Lisa Hare, Chief Malaria Supply Chain Branch
lhare@usaid.gov

Christie Hershey, RDT Procurement Lead
chershey@usaid.gov

PMI | U.S. PRESIDENT'S MALARIA INITIATIVE
LED BY
USAID FROM THE AMERICAN PEOPLE
CDC


THANK YOU

PEPFAR/USAID RTK Procurement Overview

December 11, 2023

Jason Williams, Technical Branch Chief
USAID Washington, SCH

December 11, 2023

PEPFAR
20 YEARS OF IMPACT

Overview

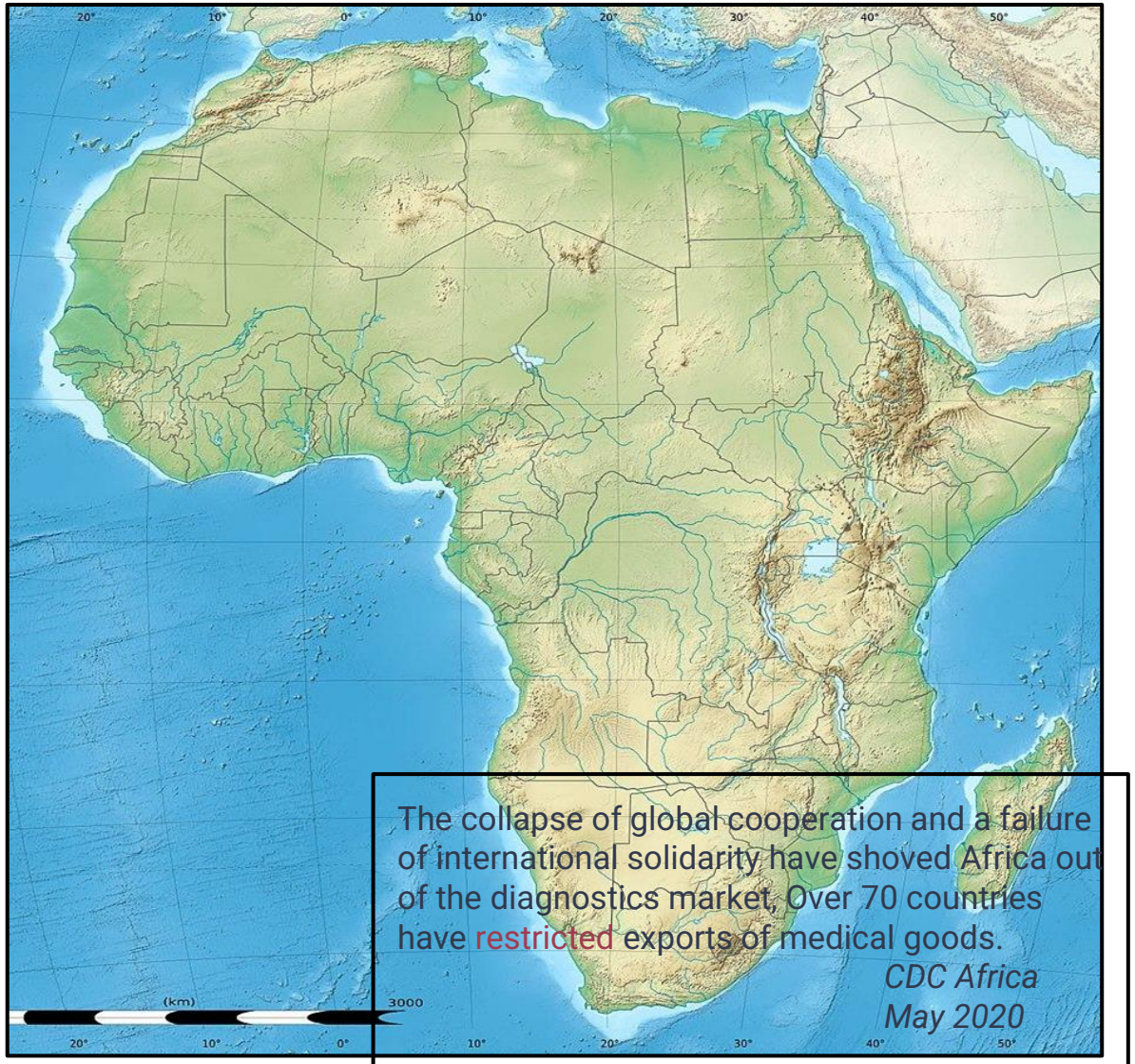
- Diversifying RTKs market (African manufacturing)
- Procurement history of RTKs
- PEPFAR funding dynamics
- Order processing and flow
- Key takeaways

Why is African Based Manufacturing Important?

During the COVID surge in 2020, African countries had very limited access to RTKs, drugs, and medical supplies, as countries limited exportation and products were hoarded by manufacturing countries

Supporting African Based Manufacturing of RTKs:

- Aligns with USAID's broader strategy to support economic development
- Improves the continent's self-reliance and expands economic opportunity
- Enhances platform for pandemic preparedness and response
- Supports supply chain diversification
- Supports strengthening and development of regional regulatory bodies
- Increases resiliency and growth throughout the region



The collapse of global cooperation and a failure of international solidarity have shoved Africa out of the diagnostics market, Over 70 countries have restricted exports of medical goods.

CDC Africa
May 2020

https://www.thenewhumanitarian.org/news/2020/05/18/Africa-coronavirus-test-kits

PEPFAR has announced procurement targets to support African Based Manufacturing of RTKs

- PEPFAR aims to procure 15 million HIV tests produced by African manufacturers in 2025 at an estimated cost of $20 million
- PEPFAR will make key adjustments to its procurement policies to better support emerging African manufacturers to scale-up over time
- PEPFAR will explore additional regulatory pathways to ensure proper approvals for quality-assured HIV products for purchasing, and over time, will contribute to strengthening of regional regulatory mechanisms on the continent

★ ★ ★

PEPFAR sets bold manufacturing targets for Africa

PEPFAR RELEASE

DECEMBER 13, 2022

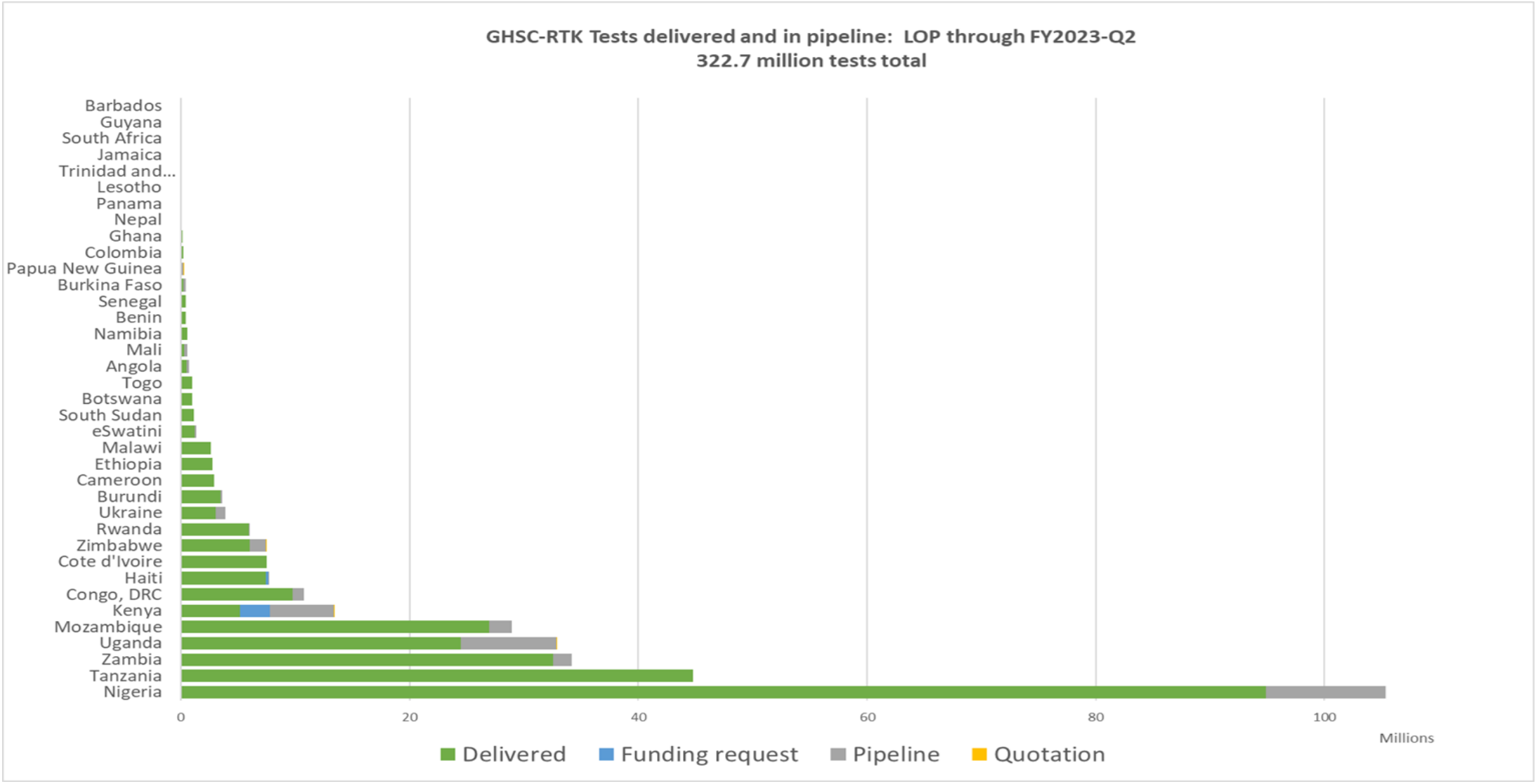
At the U.S.-African Leaders Summit on December 13, Ambassador Dr. John Nkengasong announced the start of a new United States President's Emergency Plan for AIDS Relief effort to accelerate regional manufacturing of critical health commodities on the continent. Building on existing capabilities and an analysis of future expansion potential, PEPFAR aims to procure 15 million HIV tests produced by African manufacturers in 2025 at an estimated cost of $20 million, alongside those purchased by other donors and partners. For antiretroviral treatments, by 2030, PEPFAR aims to work alongside other partners and buyers to shift at least two million clients on first-line ARV treatments to use African-made products.

The United States government purchases more than $1 billion of health commodities (diagnostics, therapeutics, vaccines, equipment) per year, the majority of which are consumed by people in Africa, but only a small fraction of which are produced in Africa. The PEFPAR program alone, currently spends roughly $750 million on HIV-related commodities such as HIV tests and anti-retroviral treatment every year but procures less than 1 percent of the value of these commodities from Africa due to the limited number of high-volume HIV product manufacturers on the continent today. Today, PEPFAR is seizing an opportunity to shape a more sustainable, resilient, and equitable future market for these products.

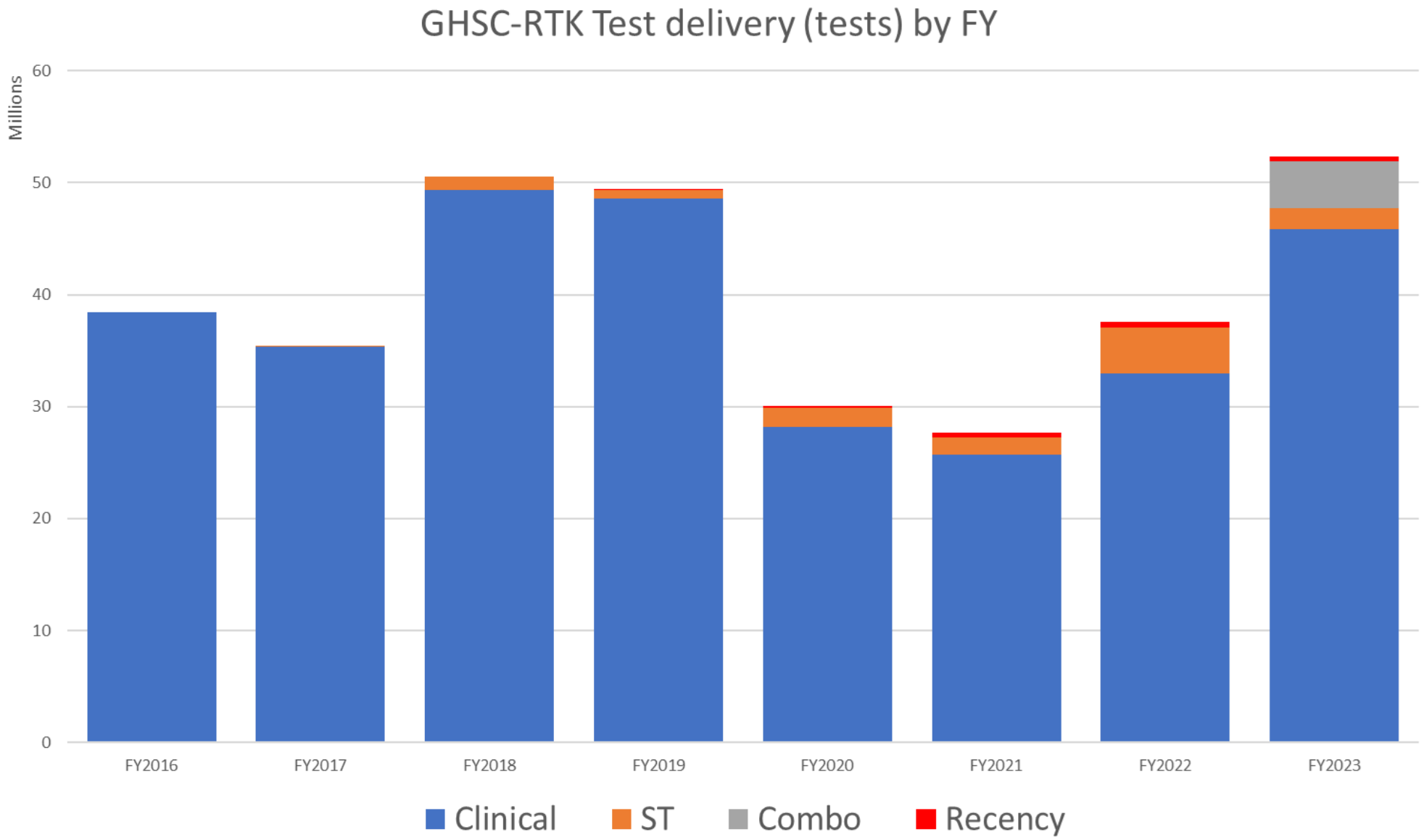
PEPFAR's five-year strategy highlights regional HIV commodity production as a critical priority for sustaining the HIV/AIDS response. A strong regional manufacturing capability on the continent of Africa will have tremendous health, economic development and national security benefits. It will lead to a more diversified, resilient, and efficient supply chain that is more responsive to local needs. It can create

https://www.state.gov/pepfar-sets-bold-manufacturing-targets-for-africa/

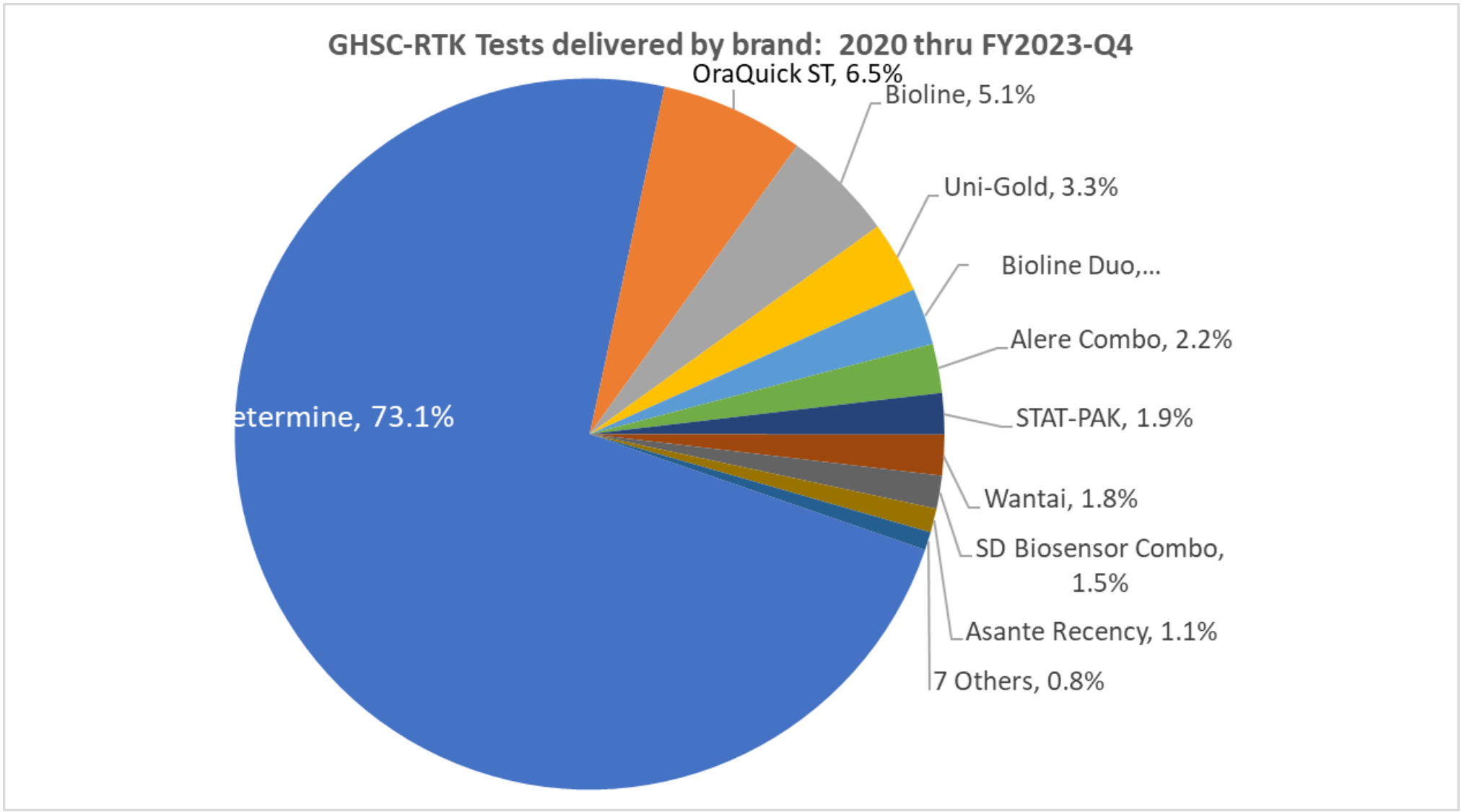
PEPFAR GHSC-RTK has delivered over 320 million RTKs since 2016 with Nigeria, Tanzania, Zambia, Uganda and Mozambique as largest recipients



PEPFAR GHSC-RTK has procured and delivered over 50 million total tests in FY23



PEPFAR GHSC-RTK Brands (2022-2023)



PEPFAR GHSC-RTK Procured Country of Manufacture (2022-2023)

Country of Manufacture Four quarters		Amount	%
Japan	$	28,021,088	63.7%
United States	$	6,655,524	15.1%
Thailand	$	5,388,668	12.2%
Ireland	$	1,772,992	4.0%
Korea	$	1,527,499	3.5%
China	$	410,105	0.9%
India	$	171,534	0.4%
Canada	$	46,670	0.1%

PEPFAR funding dynamics - 101

- PEPFAR strategic priorities determined
- Funding levels determined at the country level (COP process)
- Treatment targets established - associated testing requirements/needs, all while balancing programmatic implementation
- Volumes and timing of deliveries established (SPT)
    - Brands established by national testing algorithms
    - Donor and local funding levels established and validated
- Overall COP budgets approved (FAST - FY Oct-Sept)
- Congressional approvals and funding released
- RTK budgets allocated to RMI (PEPFAR PSA for RTKs)
- Procurements initiated at established intervals within SPT

PEPFAR funding dynamics - 101

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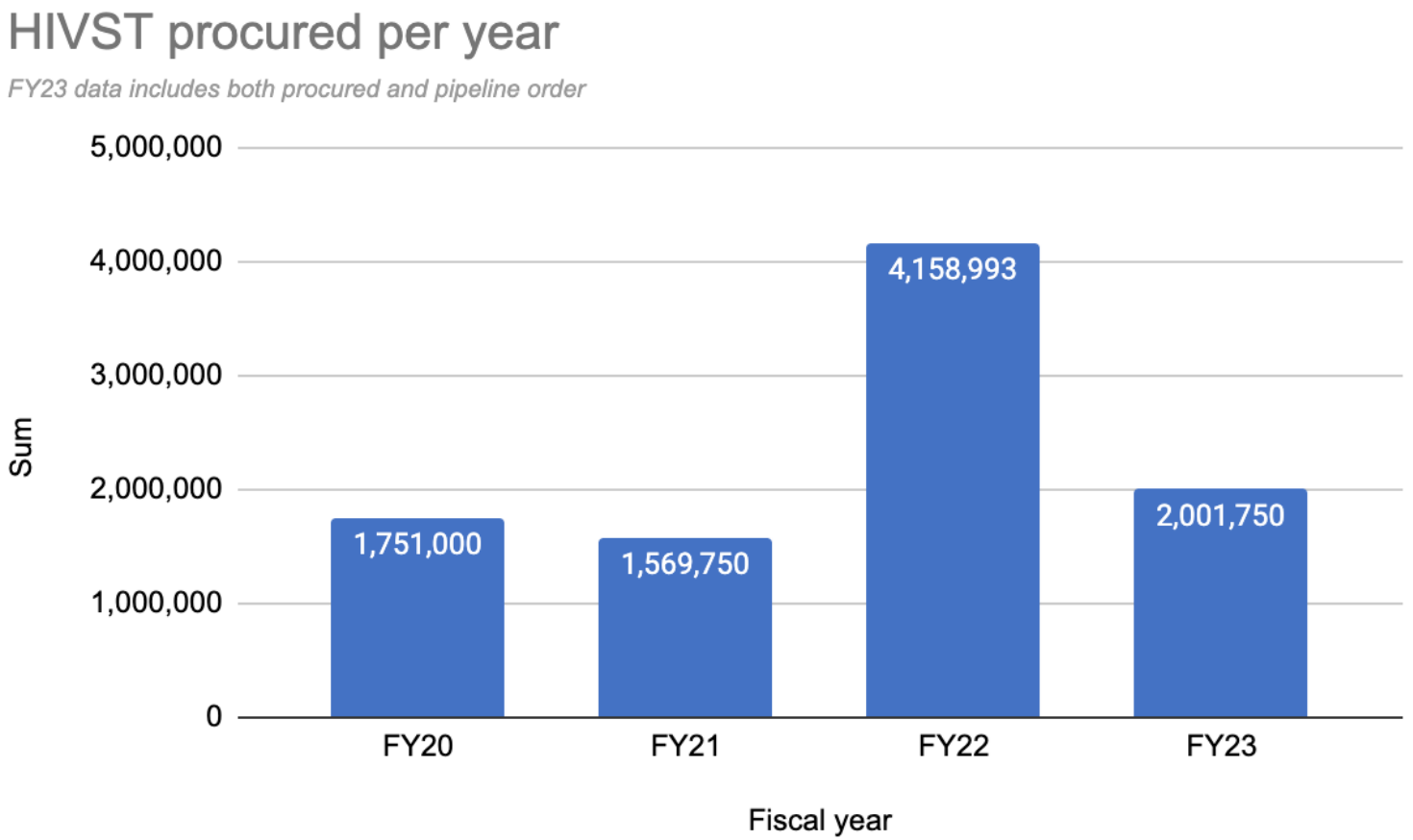
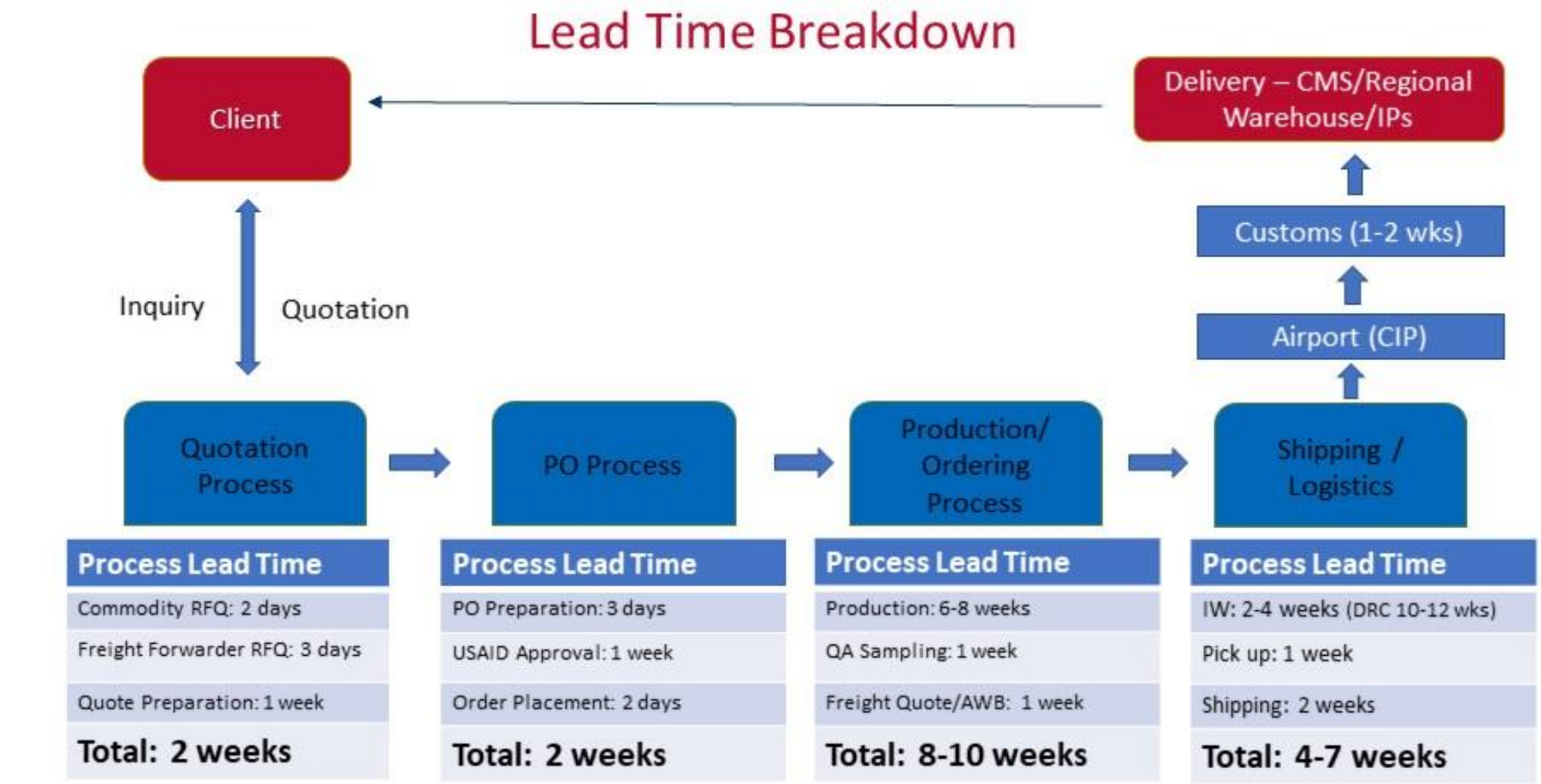
HIV self test kit procurement surged during COVID

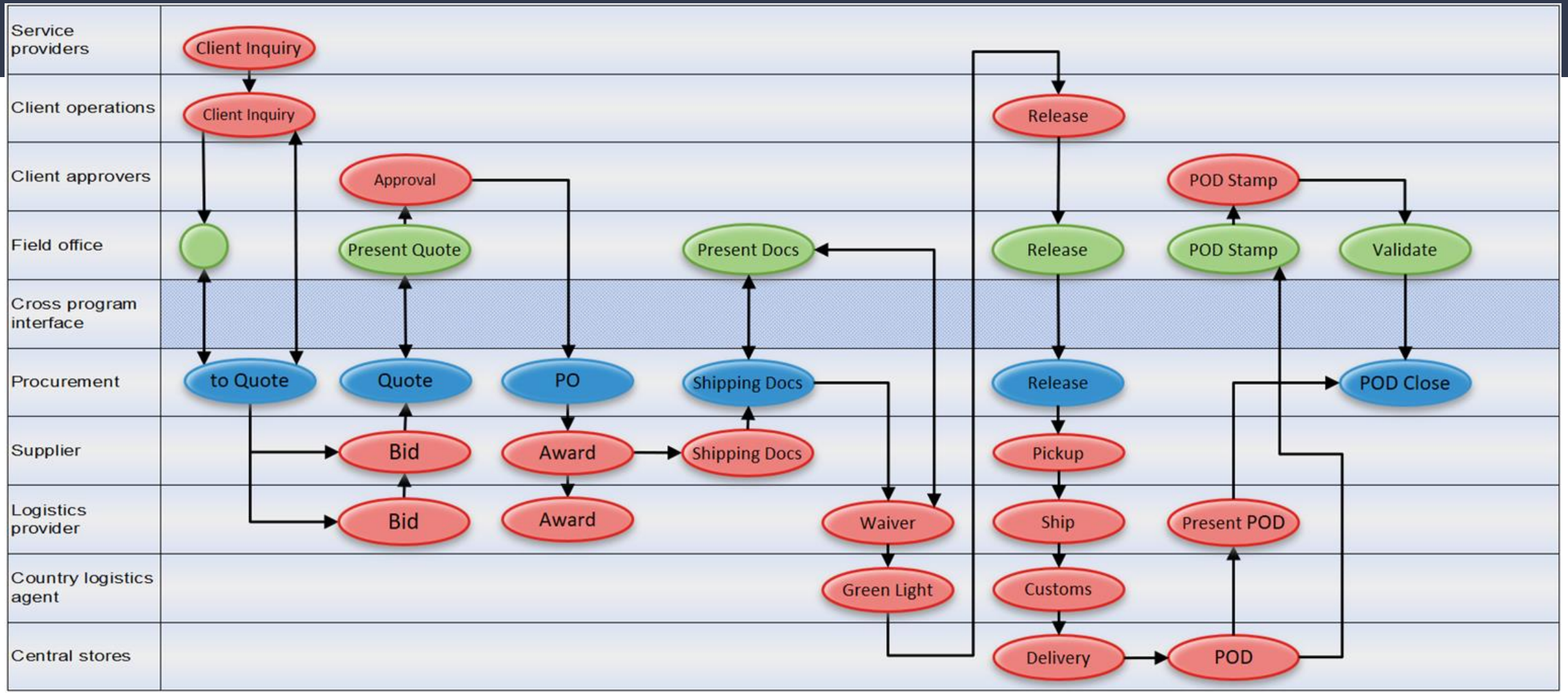
- Smaller market segment in comparison to clinical use products (donor procured)
- Private sector market segment could be considerable
- Private sector strategies required



RMI - Order processing and flow



RMI - Order processing and flow



Key takeaways

- PEPFAR has established targets for local/regional manufacturing
- Budget allocations are established annually at each country level
- RMI is PEPFAR's centralized procurement mechanism
- Brands of products are determined by national algorithms
- Self test market is limited in the donor space - significant opportunity in the private sector space

Questions?

11 Dec 2023

UNICEF 2023 – 2028 PROCUREMENT STRATEGY FOR RAPID DIAGNOSTICS FOR HIGH - RISK DISEASES

Wandani Sebonego

UNICEF Supply Division

unicef | for every child

UNICEF 2023 – 2028 PROCUREMENT STRATEGY FOR RAPID DIAGNOSTICS FOR HIGH-RISK DISEASES

- Goal
  - Every child including adolescents survives and thrives with access to quality health care
  - Every child including adolescents lives in a safe, sustainable climate and environment
    - ✓ Clean air
    - ✓ Safe water
    - ✓ Healthy food

- Strategy Specific Objectives
  - Secure access to quality assured rapid diagnostics for high-risk diseases (malaria, HIV, Syphilis, viral hepatitis and cholera)
  - Reduce negative environmental impacts of RDTs procured and delivered by UNICEF
  - Secure sustainable and equitable prices
  - Secure access to new and innovative RDTs
  - Shape a diverse and resilient supplier base for supply security

UNICEF 2023 – 2028 PROCUREMENT STRATEGY FOR RAPID DIAGNOSTICS FOR HIGH- RISK DISEASES

- Approach

  - Collaborate with partners, governments, civil societies, regulators and manufactures to ensure
    - ✓ quality primary health care
    - ✓ Sustainability agenda

  - Sustainable procurement
    - ✓ Technical
    - ✓ Commercial

Securing access to quality assured rapid diagnostics for high-risk diseases

- Quality and Regulatory requirements

  - Test Devices
    - ✓ QMS requirement: ISO 13485 certified
    - ✓ Regulatory compliance: WHO pre-qualified

  - Kits accessories (alcohol swabs, lancets and specimen transfer devices)
    - ✓ QMS requirement: ISO 13485
    - ✓ Regulatory Compliance: GHTF founding members

Procurement Strategy Pillars

- Reduce negative environmental impacts of RDTs procured and delivered by UNICEF
  - Local production and procurement agenda
  - Product packaging considerations
  - Freight considerations: Air vs Road vs Sea

- Shape a diverse and resilient supplier base for supply security
  - New products and suppliers
  - Local manufacturing (Africa)

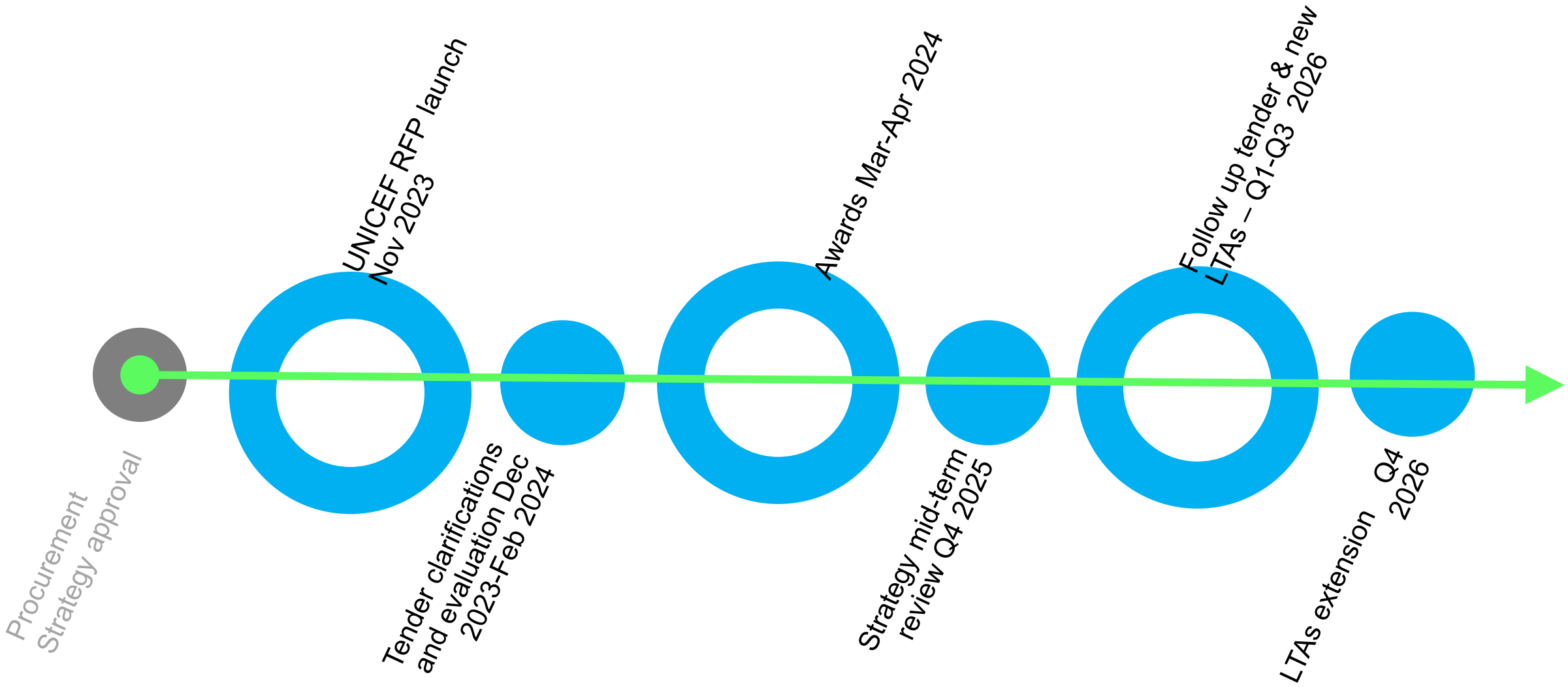
Technical and Commercial Evaluation Criteria

- Technical Evaluation Criteria (documentary evidence)
  - WHO PQ public report
  - Valid ISO 13485 (test device and accessories)
  - Valid regulatory documents
  - Certificate of sterility, COA
  - Labelling and packaging requirements
  - Shelf life

- All submitted documents will be verified through relevant authorities

- Commercial weighted evaluation criteria
  - Price and volume 65 %
  - Sustainability criteria 35%

UNICEF RDT tender timeline

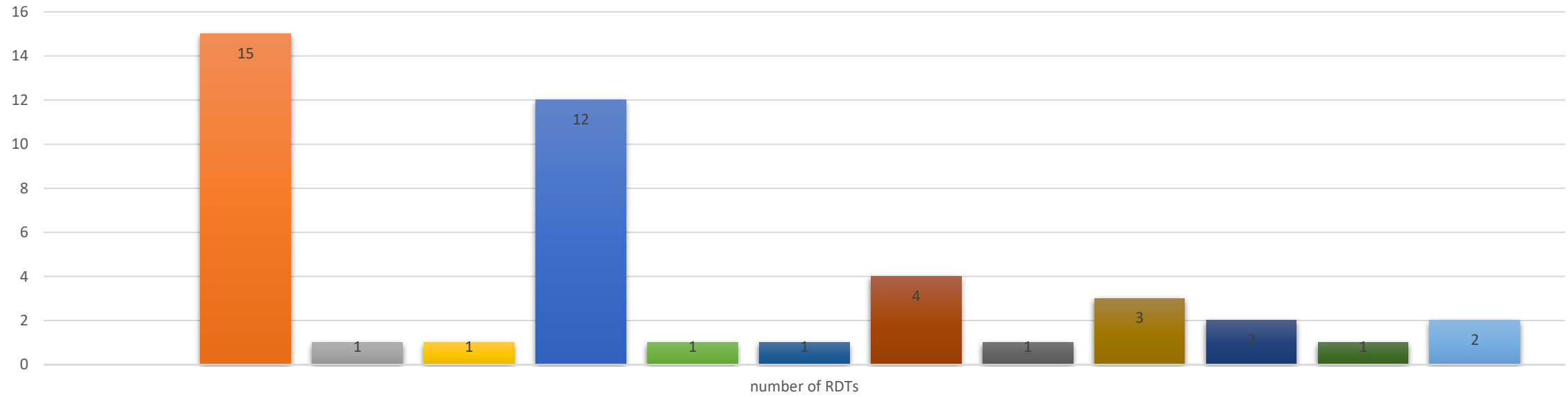


CLIMATE CHANGE GLOBAL WARMING & PRODUCT ADAPTATION

Temperature tolerance of existing RDTs

> 40 C degree environments

RDTs temperature tolerances ≤ 30 vs ≤ 40



HIV HIV ≤30° C HIV ≤40° C Malaria ≤30° C Malaria ≤40° C HBV ≤30° C HBV ≤40° C HCV ≤30° C HCV ≤40° C Syphilis ≤30° C HIV/Syphilis ≤30° C HIV/Syphilis ≤40° C Cholera ≤30° C


Q & A
unicef | for every child
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Global Fund RDT Procurement Strategy 2024-2026 & tender timeline

13. GF RDT Sourcing Strategy 2024-2026
14. Request for Proposals (Approach and timeline)

Q&A / Discussion 3

RDT PPM Procurement

Highlights 2020-2023

Mustafa al Samaraee
Lead Diagnostic, Direct Sourcing
Global Fund

All-RDT/ Global Fund RDT scope

The Rapid Diagnostics Test portfolio covers several product segment and type of tests used in the fight against AIDS, Tuberculosis and Malaria

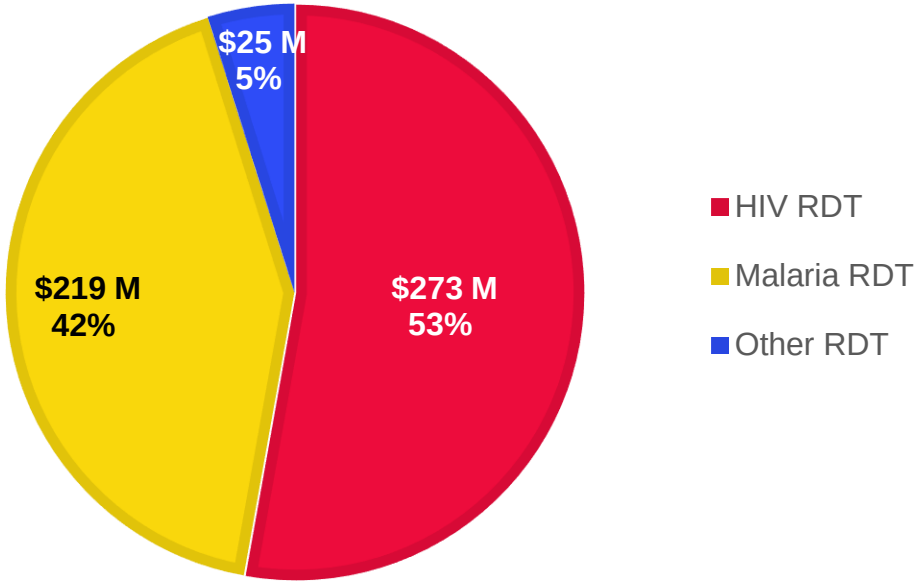
Malaria RDT (MRDT)	HIV RDT (HRDT)	Other RDT (ORDT)
❖ Plasmodium falciparum (P.f) ❖ P.f and Plasmodium vivax (P.f / P.v) ❖ P.f and all Plasmodium species (P.f / Pan) ❖ G6PD	❖ HIV RDT Professional ❖ HIV RDT Self-Test ❖ HIV/Syphilis Combo ❖ CD4 RDT	❖ Hepatitis B and C ❖ Syphilis ❖ Cryptococcus ❖ TB LAM ❖ Other: Gonorrhea, Chlamydia, Cryptosporidiosis, Pregnancy (hCG)

All-RDT/ 1.1 Bn tests procured since 2020

Big gap in price between the different RDT types

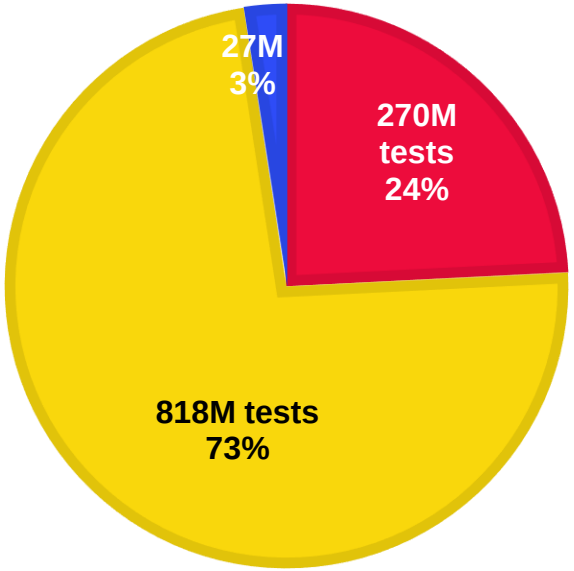
VALUE

US$518M worth of RDTs procured…



VOLUME

…for 1.1Bn tests



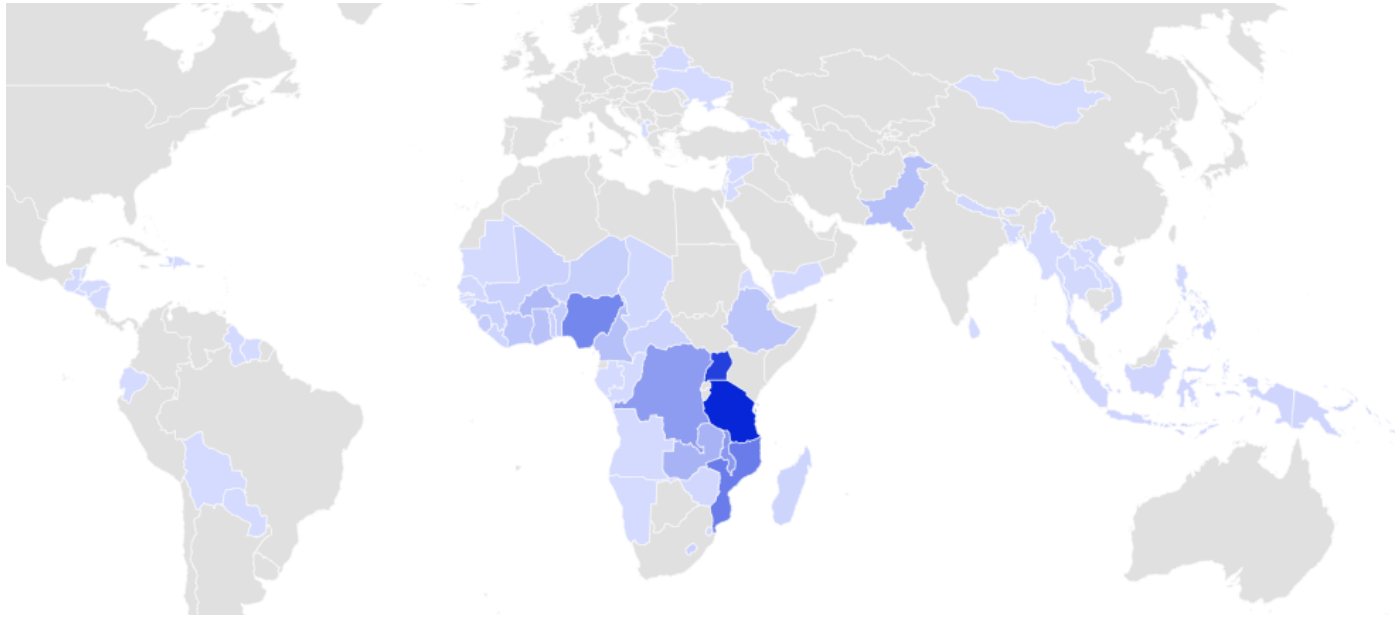
- From 2020 to Sep 2023 Global Fund procured **818 million Malaria RDT**, worth **US$ 219M**
- **270 million HIV RDT** worth **US$ 273M** procured during same period
- Despite high **HIV RDT** volumes, spend remains high comparing to Malaria RDT

Data Source: Global Fund Procurement Service Agent

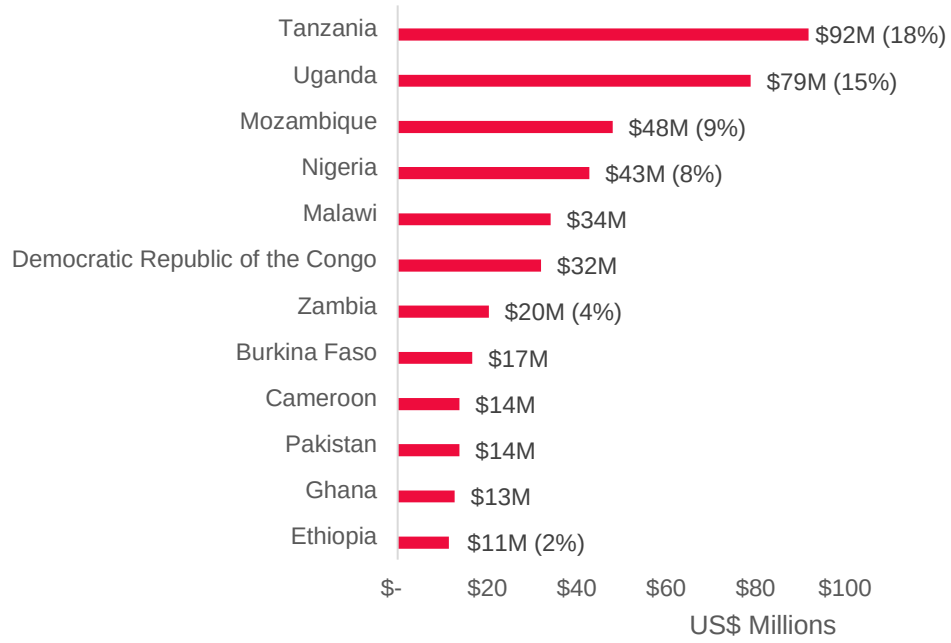
All-RDT/ $518M procured since 2020

Demand across 78 countries with lion's share in few countries

PPM supplied RDTs to 78 countries* across all continents from 2020 to Sep 2023, …



… and 12 countries accounted for 80%



* Albania, Angola, Armenia, Azerbaijan, Bangladesh, Belarus, Belize, Benin, Bhutan, Bolivia, Burkina Faso, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Dominican Republic, East Timor, Ecuador, El Salvador, Eritrea, Eswatini, Ethiopia, Gabon, Georgia, Ghana, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, Indonesia, Ivory Coast, Jordan, Kosovo, Laos, Lebanon, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mongolia, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Papua New Guinea, Paraguay, Philippines, Republic of the Congo, São Tomé and Príncipe, Senegal, Sierra Leone, Solomon Islands, Sri Lanka, Suriname, Syria, Tanzania, Thailand, The Gambia, Togo, Uganda, Ukraine, Vietnam, Yemen, Zambia, Zimbabwe

Data Source: Global Fund Procurement Service Agent

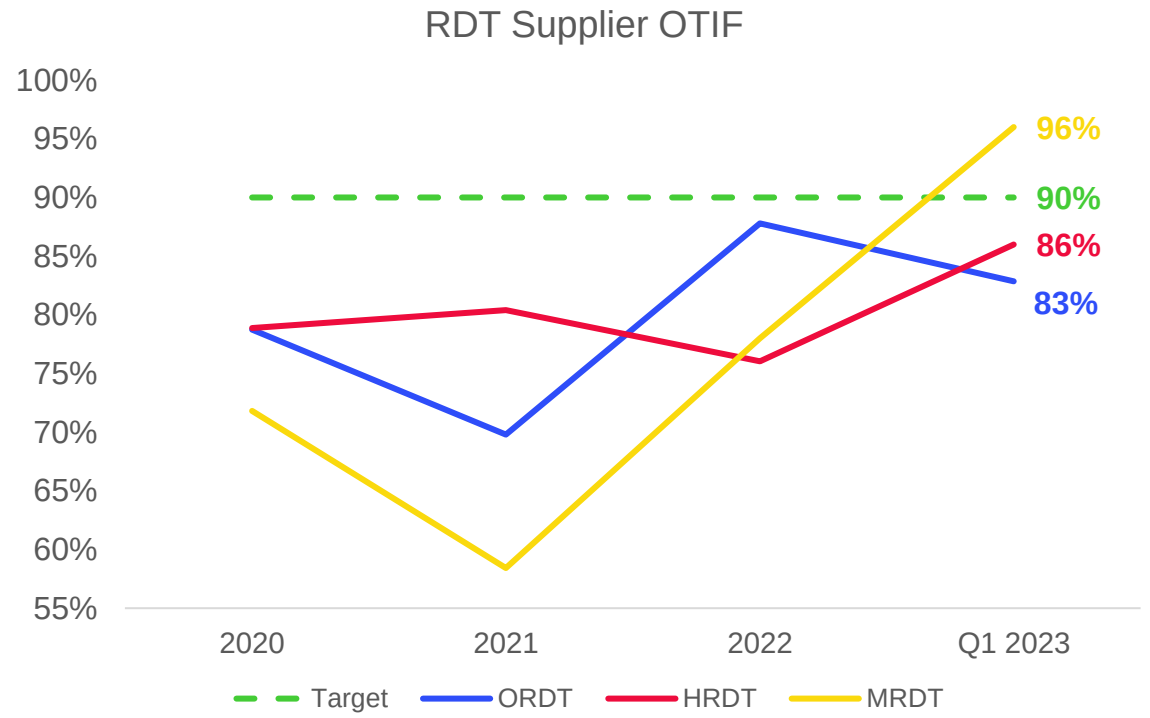
All-RDT/ Strengthening supplier performance

While supplier OTIF* performance was adversely affected by the COVID-19 pandemic, our efforts and commitment to improve performance has yielded significant results

- **COVID-19** had a **significant negative impact** on the availability of all RDTs, especially the Malaria RDTs due to supply chain challenges and **deprioritization** in favor of more **profitable tests**.

- **Supplier Performance** has significantly increased for the **Malaria RDT**, above the target since Q3 2022, due to several measures taken by the Global Fund including:
  - Intensified communications with suppliers
  - Supply base diversification
  - More frequent updates regarding forecasts
  - Performance improvement plans for low performance

- **Improved performance** for **HIV** and **Other RDT** categories remain **below target**, mainly due to limited supplier diversification



** Supplier OTIF is a key performance indicator (KPI) comparing supplier purchase orders delivered "On Time in Full" (OTIF) against total number of Supplier Purchase Orders. The KPI measures when Supplier has fulfilled their obligations to the PSA regarding the Committed Delivery Date.*

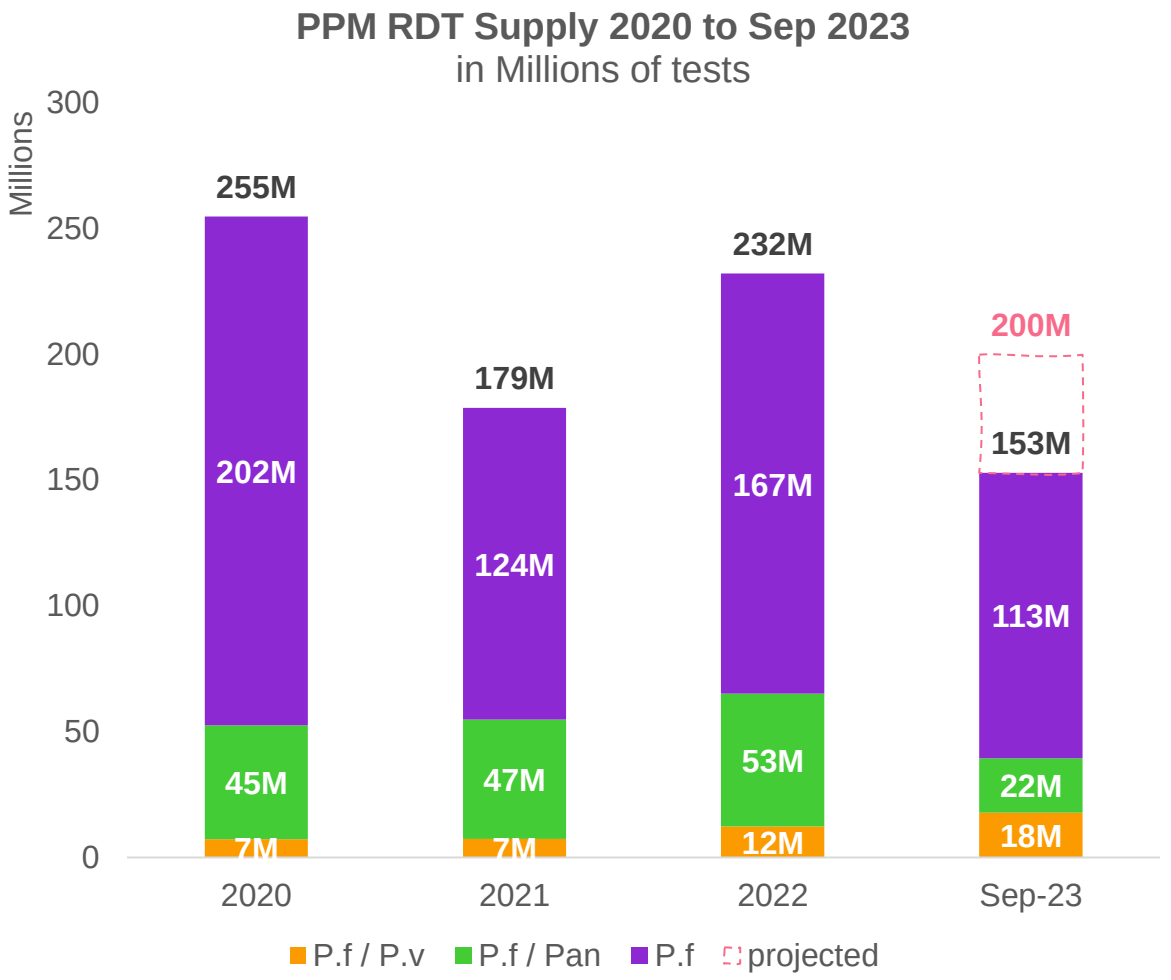
Data Source: Global Fund Procurement Service Agent

Malaria RDT/ Demand remains high

Covid-19 impacted Malaria programs, as evidenced by the demand dip in 2021

1. Global Fund **demand is cyclical** by nature of the funding Grant Cycles, yet
   - Higher demand in **2020** was a mitigation measure against future **anticipated supply constraints**
   - Lower volumes in **2021** owing to the **pandemic**
   - Steady **demand recovery** in **2022**
   - **2023 total** volume is expected to be around **200M tests**

2. PPM volume procured indicates
   - The share of **P.f only** tests is **reducing** from almost **80%** in 2020 to **74%** of in 2023
   - **P.f/P.v** demand **grew** from 7.2M tests in 2020 to **17.8M** as of Sep 2023
   - **P.f/Pan** decreased in 2023
   - Demand for **pLDH** based tests remains low

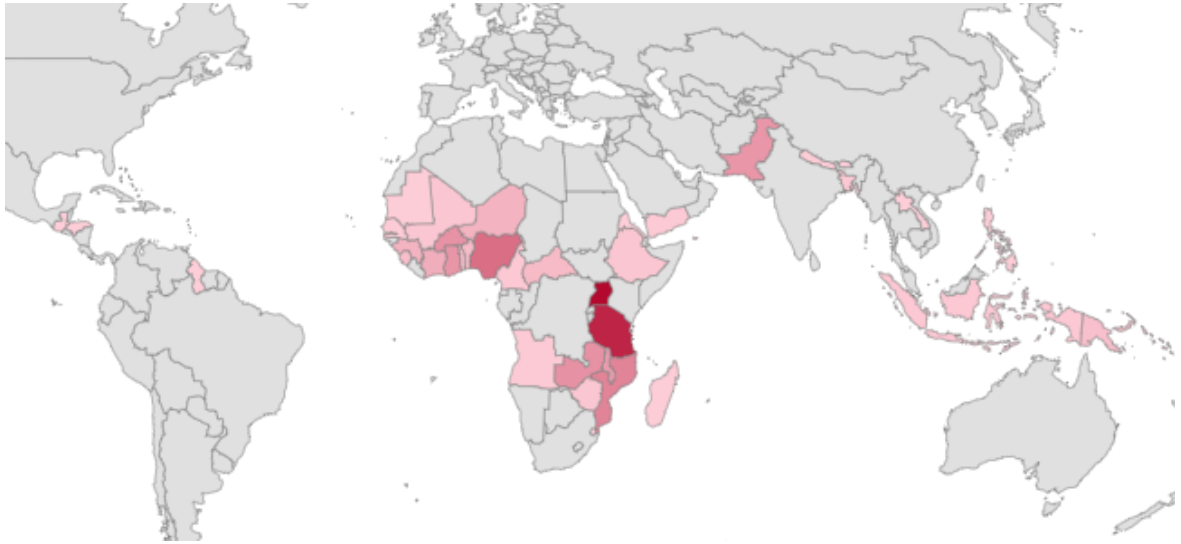


Data Source: Global Fund Procurement Service Agent

Malaria RDT/ Tests procured in 45 countries

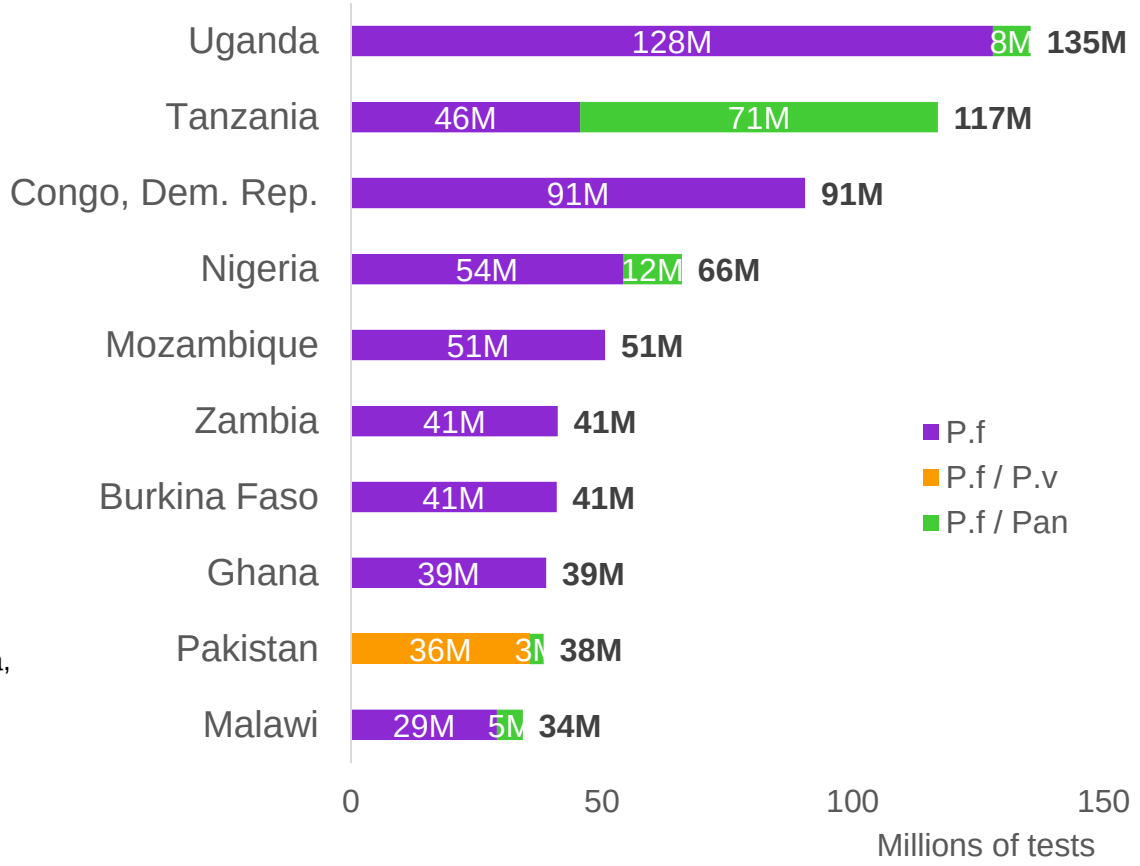
Nigeria, DR Congo, Uganda, Mozambique and Tanzania, who gather over half of malaria cases worldwide, also represented over 50% of global MRDT demand

PPM served 818M tests to 45 countries*,…



* 45 countries (from 2020 to Sep 2023): Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Cameroon, Cape Verde, Central African Republic, Comoros, Democratic Republic of the Congo, East Timor, Eritrea, Eswatini, Ethiopia, Ghana, Guatemala, Guinea, Guyana, Honduras, Indonesia, Ivory Coast, Laos, Madagascar, Malawi, Mali, Mauritania, Mozambique, Nepal, Niger, Nigeria, Pakistan, Papua New Guinea, Philippines, Republic of the Congo, São Tomé and Príncipe, Senegal, Sierra Leone, Solomon Islands, Tanzania, The Gambia, Togo, Uganda, Yemen, Zambia, Zimbabwe

… and **10 countries accounted for 80%** of the volumes



Data Source: Global Fund Procurement Service Agent

Malaria RDT/ Market dynamics

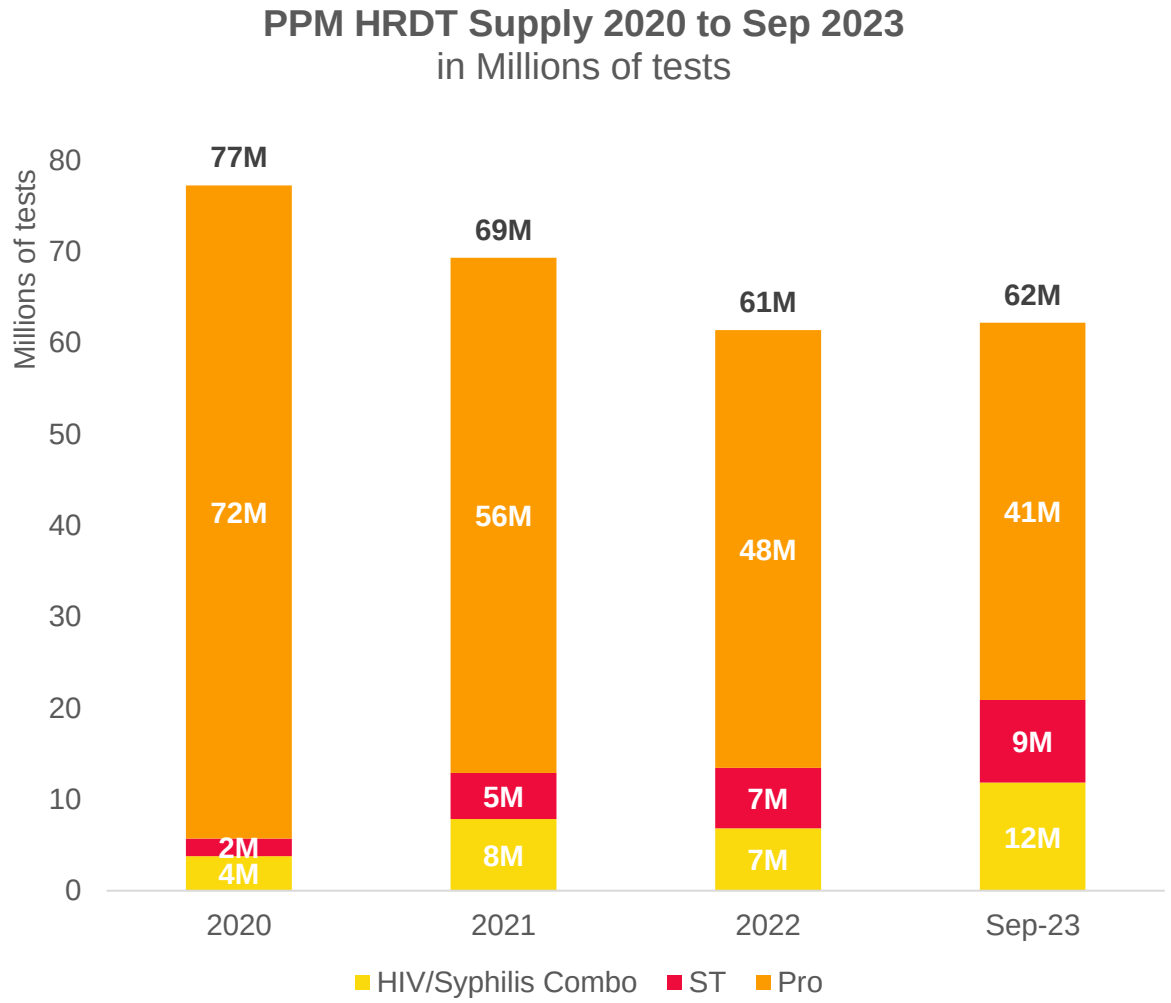
Supplier base for malaria tests have notably increased

- Malaria rapid tests remain the **main malaria diagnostic tool**. Other technologies will likely address specific use cases with unique value.
- The Malaria rapid tests market consistently shows **high demand**. Demand continues to concentrate on the HRP II type of tests.
- Over the last 3 years, the pool of **WHO approved malaria rapid tests suppliers has expanded** contributing to healthy market and supply security. However, the pool of suppliers with pLDH based tests is limited.
- There is an emerging risk of increasing **HRPII gene deletion**. However, certainty of gene deletion scale and location is yet to be determined. This may lead to increased demand for the pLDH tests in the coming years.
- The production capacity of WHO-prequalified malaria RDT suppliers has increased exponentially during the pandemic. However, larger **suppliers tend to priortise manufacturing of other types of tests** over malaria rapid tests**.**
- Malaria rapid test **prices have increased** but remain **stable** for the last couple years.

HIV RDT/ 270M tests procured since 2020

Combo and Self-Test share increased steadily to one third of total demand by Sep 2023

- **270 Million HRDT tests**, worth **US$ 273M** in total, was procured through PPM from 2020 to Sep 2023
- Demand share of **HRDT Professional** tests remains **predominant** but steadily **reducing** from over 90% in 2020 to about two thirds by Sep 2023
- **HIV Syphilis combo** test demand **grew** 313% from 3.8M tests in 2020 **to 11.8M** as of Sep 2023
- **Self-Test** demand **grew** 473% from 1.9M tests in 2020 **to 9.0M** as of Sep 2023

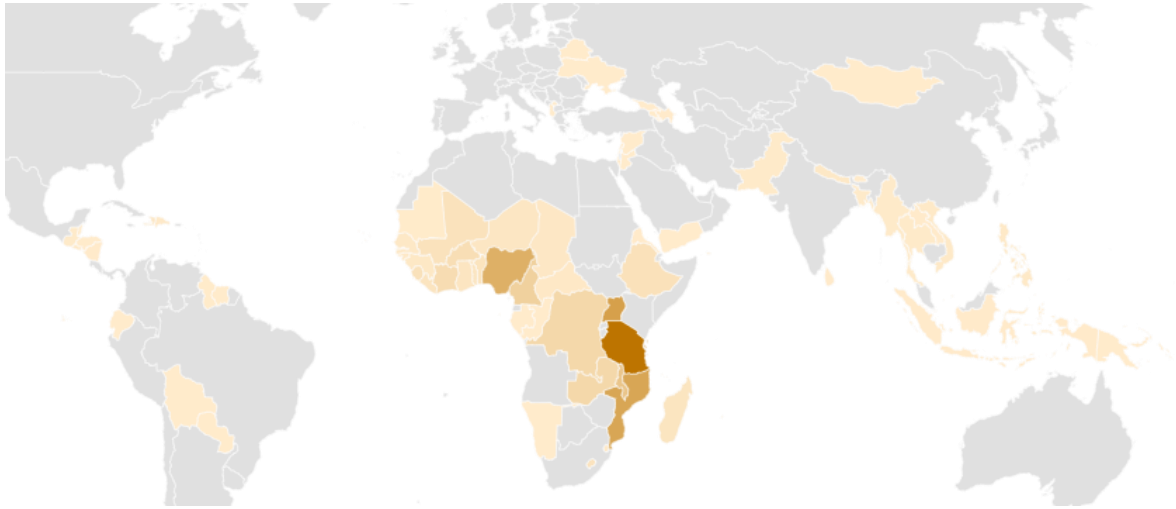


Data Source: Global Fund Procurement Service Agent

HIV RDT/ Tests procured in 75 countries

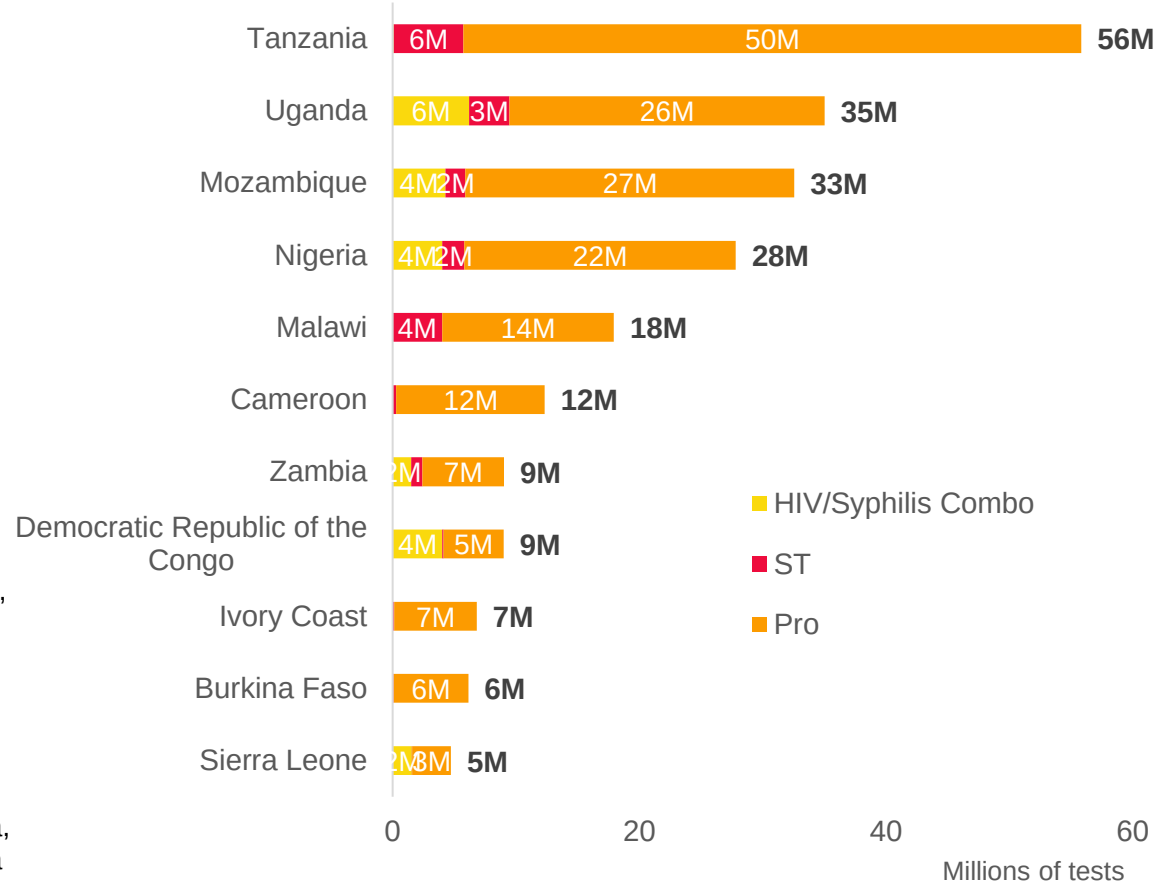
Tanzania, Uganda, Mozambique, and Nigeria each had over 20M+ tests procured and together represented over half of PPM worldwide demand

PPM served 270M tests to 75 countries*,…



* 75 countries (from 2020 to Sep 2023): Albania, Armenia, Azerbaijan, Bangladesh, Belarus, Belize, Benin, Bhutan, Bolivia, Burkina Faso, Cape Verde, Cameroon, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Republic of the Congo, Ivory Coast, Dominican Republic, Ecuador, El Salvador, Eritrea, Eswatini, Ethiopia, Gabon, The Gambia, Georgia, Ghana, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, Indonesia, Jordan, Kosovo, Laos, Lebanon, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mongolia, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Papua New Guinea, Paraguay, Philippines, São Tomé and Príncipe, Senegal, Sierra Leone, Solomon Islands, Sri Lanka, Suriname, Syria, Tanzania, Thailand, East Timor, Togo, Uganda, Ukraine, Vietnam, Yemen, Zambia

… and **11 countries accounted for 80%** of volumes



Data Source: Global Fund Procurement Service Agent

HIV RDT/ Market dynamics – HIV Professional

Cost remains high compared to similar tests

- **Demand** for HIV tests have **diversified** as combo tests and self-tests integrated into the HIV programs. Overall, demand for HIV professional tests **remain high (above 60% of all HIV RDT)**.
- HIV professional rapid tests **cost** remains **high** compared to other similar tests, despite high volumes due to **concentrated demand** around a preferred set of products related to **product selection practices**.
- As a result, HIV professional market limited ability to ensure **supply security** and healthy **competition**.
- **Combo tests demand is growing.** Over 40 countries are in process of adopting the dual test.
- **Increase in dual test** share is also **related to decreasing prices.**
- Expected demand from countries for a **triple combination tests** HIV, HBs Ag, Syphilis.

HIV RDT/ Market dynamics – HIV Self-Test

More options available but demand remain concentrated

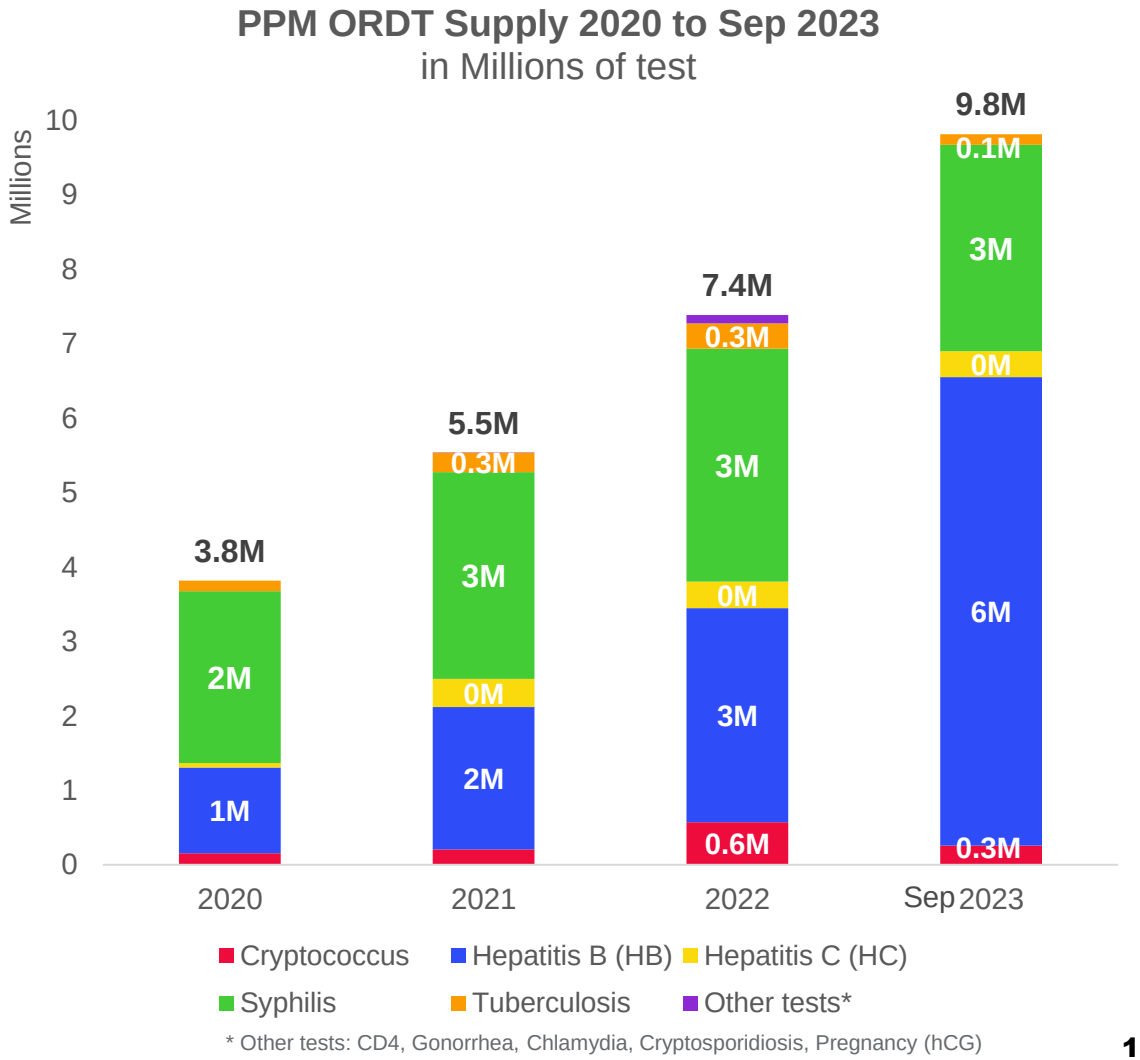
- **Demand** for HIV self-tests **significantly increased** and more countries planning to order self-tests. However, forecast volumes are largely **stalling** due to high cost and lack of diversity between oral and blood-based test.
- Increased number of **WHO PQ-ed** ST with **lower-cost**. Yet, weighted average **price** for HIVST remains **substantially higher** than professional test and more affordable tests are needed to reach ST full potential.
- Despite increased interest and procurement in **blood-based** test **supply security** is still at risk in short term due to **concentrated demand on oral-based.**
- Currently **one WHO PQ** HIV ST manufacturer **in Africa.**

Other RDT/ US$ 25M procured since 2020

Syphilis and Hepatitis B (HB) together represent about 90% of total demand of tests

ORDT volume procured through PPM from 2020 to Sep 2023 offer following observations

- **Sustained strong demand growth** from 1M test in 2020 to 6M in Sep 2023 of **Hepatitis B (HB)** tests with total 12 Million tests worth US$ 11M
- **Stable demand** of ~3M **Syphilis** test per year with total 11 Million tests worth US$ 7M, and of ~300k **Hepatitis C (HC)** tests with total 1.1 Million tests worth US$ 1.1M
- **Tuberculosis** cyclical demand over the period with total 882k tests worth US$ 3.2M
- Over **100K CD4 tests** procured in 2022 and 2023
- **Six countries** (Malawi, Ethiopia, Mozambique, Uganda, Burkina Faso and Haiti) represent **80% of total 27M ORDT** tests procured



Data Source: Global Fund Procurement Service Agent

RDT Procurement Strategy 2024 – 2026

Scope & Forecast

Aziz Jafarov
Manager, Direct Sourcing, Global Sourcing Health Technologies
Global Fund

All-RDT/ Global Fund RDT scope

The Rapid Diagnostics Test portfolio covers several product segment and type of tests used in the fight against AIDS, Tuberculosis and Malaria

Malaria RDT (MRDT)	HIV RDT (HRDT)	Other RDT (ORDT)
❖ Plasmodium falciparum (P.f) ❖ P.f and Plasmodium vivax (P.f / P.v) ❖ P.f and all Plasmodium species (P.f / Pan) ❖ G6PD	❖ HIV RDT Professional ❖ HIV RDT Self-Test ❖ HIV/Syphilis Combo ❖ CD4 RDT	❖ Hepatitis B and C ❖ Syphilis ❖ Cryptococcus ❖ TB LAM ❖ Other: Gonorrhea, Chlamydia, Cryptosporidiosis, Pregnancy (hCG)

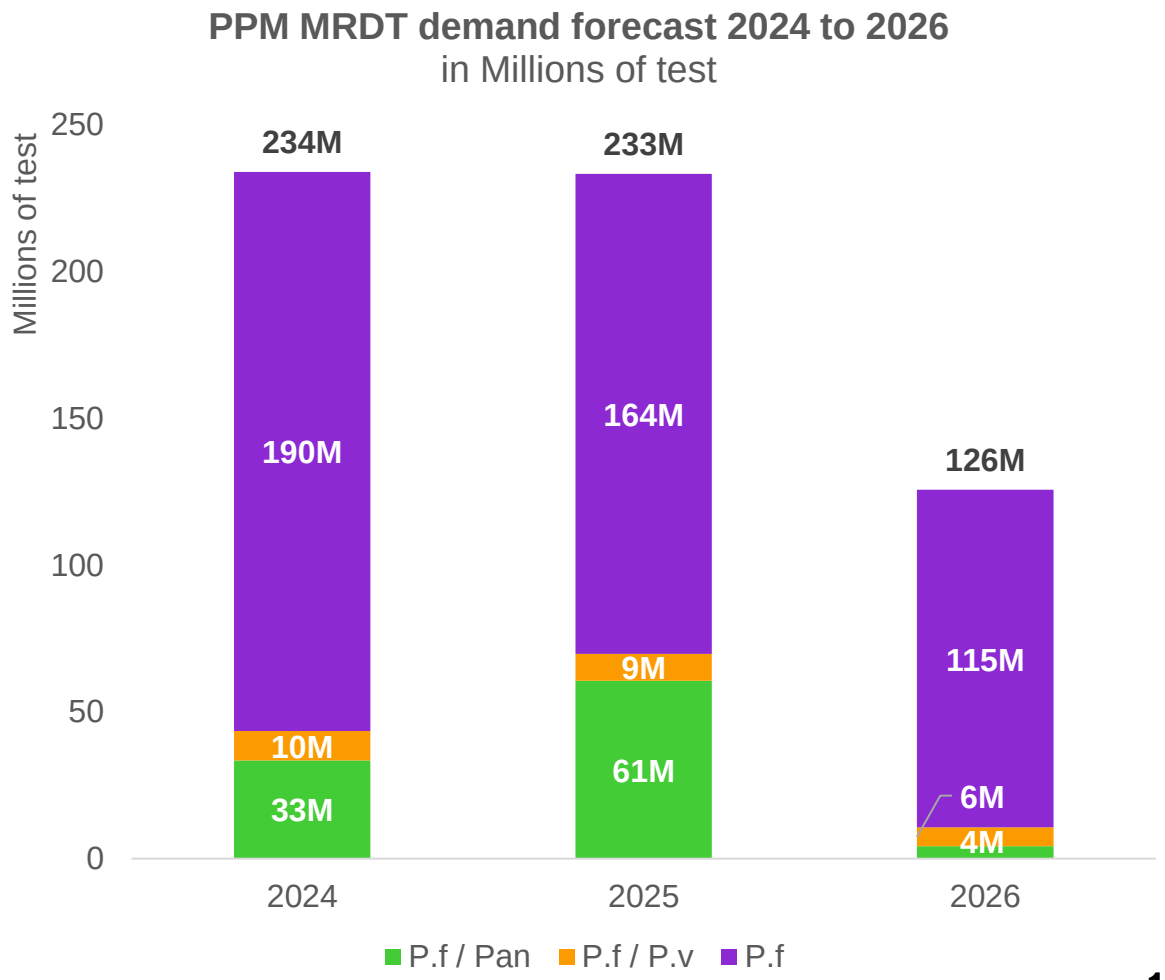
Malaria RDT/ GC7 Volume Forecast

Volume forecast for Pooled Procurement Mechanism (PPM) for 2024 – 2026 period

CONTEXT

- **Preliminary forecast** based on Health Product Management Tools submitted as part of the **GC7 Funding Request**
- **3-year forecast** totals close to **600 millions** of Malaria RDT tests.
- Overall forecast of GC7 **similar to GC6** volumes
- Volumes **driven by** demand for MRDT **P.f only**
- **2026** demand **likely to increase** due to potential savings at the end of the cycle

PRELIMINARY FORECAST



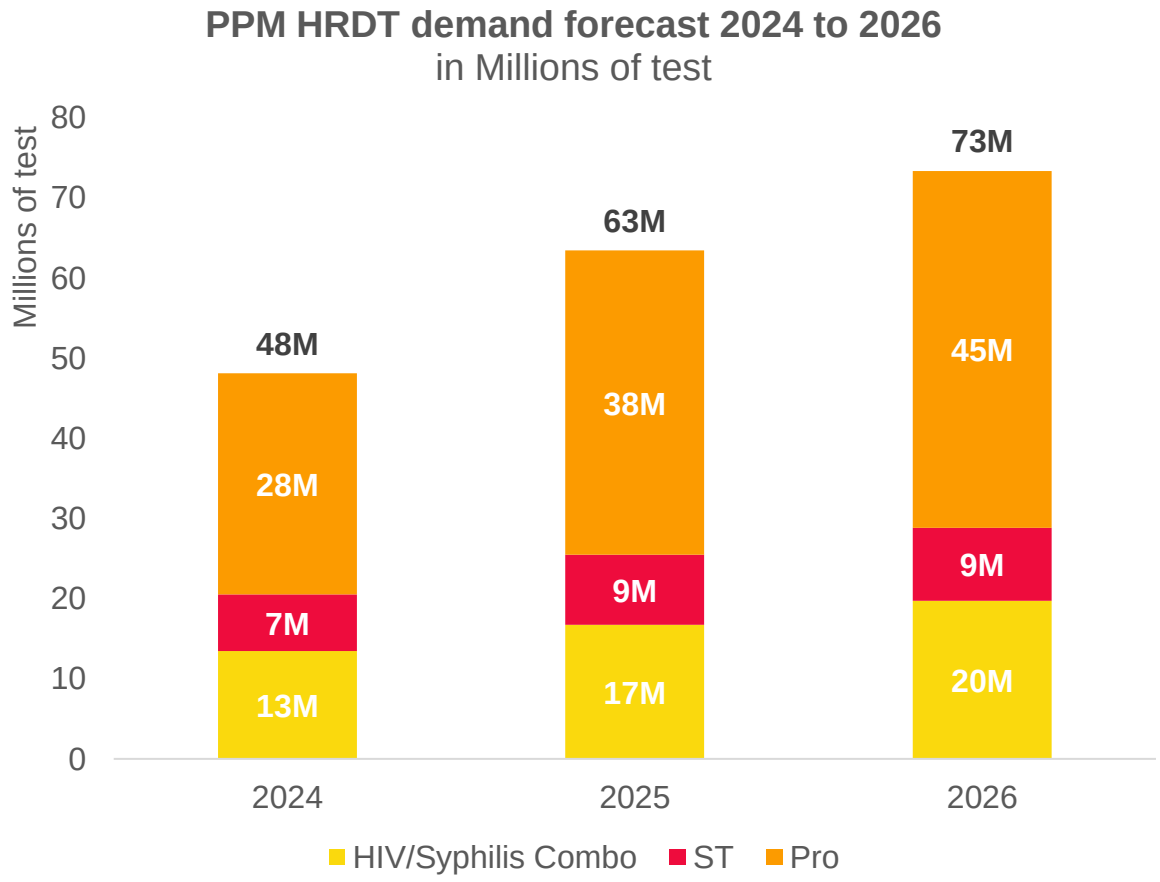
HIV RDT/ GC7 Volume Forecast

Volume forecast for Pooled Procurement Mechanism (PPM) for 2024 – 2026 period

CONTEXT

- **Preliminary forecast** numbers are based on Health Product Management Tools submitted as part of the GC7 Funding Request
- The overall number of planned RDTs is relatively stable for GC7 (as a comparison to GC6)
- Total 3 years forecast amounts 184 millions of test
- Volumes are driven by demand for Professional test
- Stable demand of Self-Test across the years

PRELIMINARY FORECAST



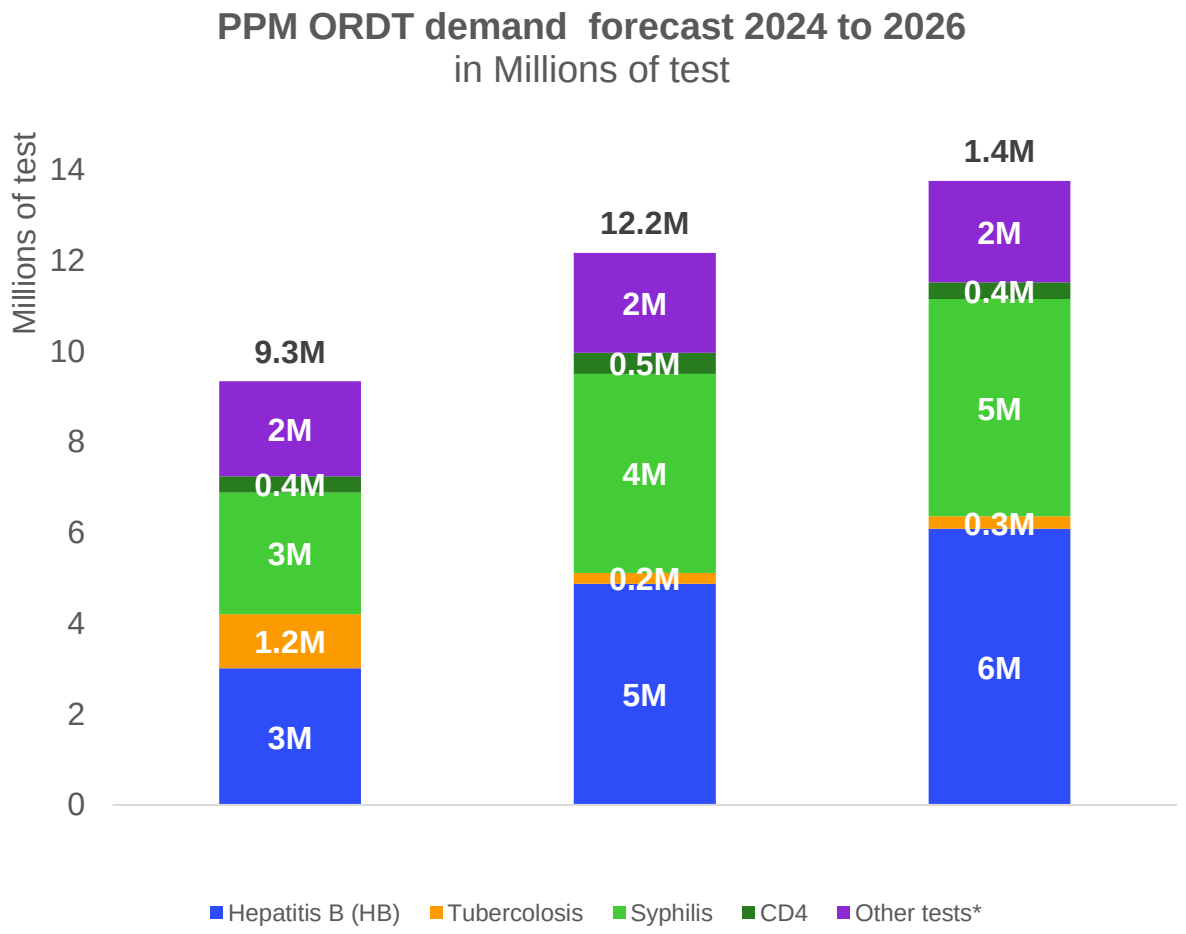
Other RDT Volume Forecast

Volume forecast for Pooled Procurement Mechanism (PPM) for 2024 – 2026 period

CONTEXT

- **Preliminary forecast** numbers are based on Health Product Management Tools submitted as part of the GC7 Funding Request
- Total 3 years forecast amounts **35 millions of tests**
- Increase in **Syphilis demand** from 3M test in 2024 to 5M in 2026
- Increased demand of CD4 tests compared with previous cycle: addition of 'new' countries ordering large volumes
- *Cryptococcus* tests accounts for: 250k tests year 1; 300k tests year 2 and 200k tests year 3 (*included in "Other tests" category*)

PRELIMINARY FORECAST



* Other tests: Cryptococcus, Hepatitis C (HC), Gonorrhea, Chlamydia, Cryptosporidiosis, Pregnancy (hCG)

RDT Procurement Strategy 2024 – 2026

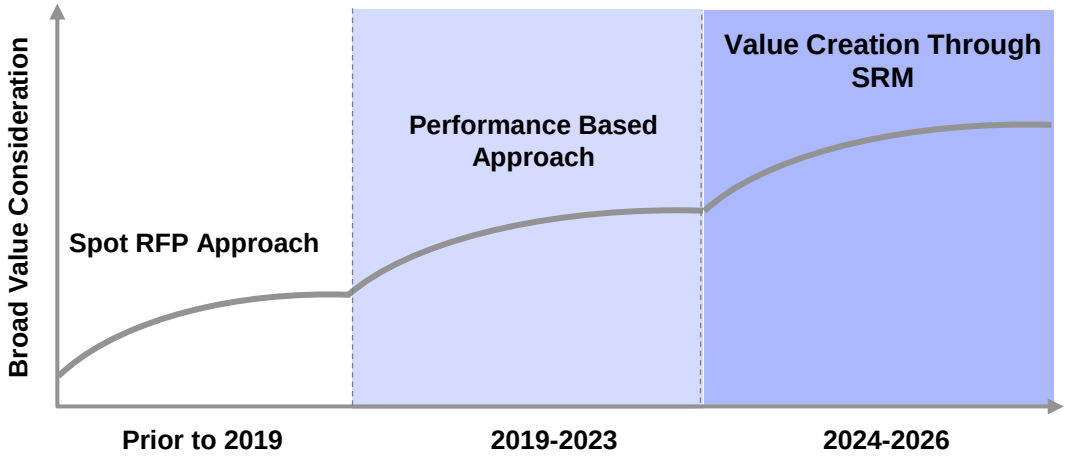
Strategy & Objectives

Aziz Jafarov
Manager, Direct Sourcing, Global Sourcing Health Technologies
Global Fund

RDT Strategy Evolution

The RDT Procurement Strategy has evolved in cycles, building on learnings as well as disease specific dynamics

RDT Procurement Strategy cycles



Spot RFP Approach (Prior to 2019)

- **Purchase Order agreement** implemented
- Spot tenders pricing approach
- Performance management matrix set up

Performance Based Approach (2019 - 2023)

- **Long-Term Framework Agreement** implemented
- **Rigorous supplier performance** implemented
- **Market Shaping** intervention including **MRDT interchangeability**
- **Strengthened QA** policy with **WHO PQ requirements**

Value Creation through SRM (2024 - 2026)

- **Key principles of supplier relationship management** (SRM) applied
- **Performance management matrix enhanced** to enable decision-making
- More direct engagement with **suppliers**

The 5 Strategic Objectives for 2024 - 2026

1. Ensure Equitable Access to RDTs: Affordability and Availability	Maintain competitive & sustainable pricing through diversified supply base and value delivery
2. Secure RDTs supply chain including by incentivising Regional Manufacturing	Improve supply chain for responsive and agile RDTs delivery
3. Supply Quality-Assured RDTs	Ensure access to quality-assured health products through strict Quality Assurance (QA)
4. Encourage environmentally sustainable RDTs	Drive sustainable procurement and supply chains in line with NextGen Market Shaping ambitions
5. Accelerate the introduction of the innovative RDTs at scale	Enable product introduction and innovation to ensure optimal care for people we serve, cost reduction and reduced environmental impact

Objective 1 Ensure Equitable Access to RDTs: Affordability and Availability

Maintain competitive & sustainable pricing through a diversified supply base

Affordability: Competitive and Sustainable pricing

- GF will **continue to support and maintain competitive and sustainable markets**
- **Cost will remain a key element** of the sourcing strategy to ensure an optimal use of resources
- Continue to broaden the **definition of "Value" beyond pricing** and looking for opportunities to add value beyond product costs
- **Increasing supplier accountability** including Most Favoured Nations implementation

Availability: Diversified Supply Based

- **Continue with multi-year agreements** aligned with strategic objectives
- Ensure the inclusion of **new market entrants** supplying **existing** and **innovative** RDTs.

Objective 2 Secure RDTs supply chain including by incentivising Regional Manufacturing

Promote regional manufacturing and improve supply chain for responsive and agile RDTs delivery

A. Incorporate previous tender cycles & Covid-19 pandemic **learnings,** and with a stronger focus on supplier accountability & supply chain robustness

- Strategy will **continue to ensure the reliable supply** of all required RDTs through **resilient and diversified supply base**
- **Deepen partnership with suppliers** to proactively understand and mitigate supply challenges, including challenges related to upstream supply security, to maintain high delivery performance
- **Improving overall lead times** through robust forecast periodically communicated with suppliers

B. Promote **local** and **regional manufacturing**

- Encourage **regional RDT manufacturing closer to end users** to improve access and diversify the supply base
- Continue to **promote geographic diversification & promote local manufacturing and capability building**
- **Consider regional manufacturing as evaluation criteria in RDT tender**

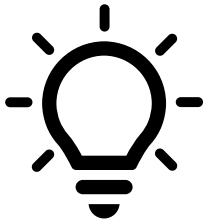
Objective 3 Supply Quality-Assured RDTs

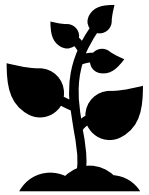
Ensure equitable access to Quality-Assured health products through strict Quality Assurance (QA)

- **Product Quality is essential** to ensure that quality assured RDTs are sourced and delivered to the people we serve
- Global Fund Quality Assurance **(QA) eligibility requirements** will continue to ensure that health products are available **at internationally recognized quality standards**
- **Framework Agreement** proposed under RDT Procurement cycle 2024 – 2026 will continue to include a strong **QA section at its core**
- **Quality Assurance** will also continue to be an **integral part of our supplier review process** and focus on quality updates and topics impacting supply

Objective 4 Encourage environmentally sustainable RDTs

Drive sustainable procurement and supply chains in line with NextGen Market Shaping ambitions

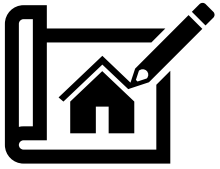




- Supply Operations is piloting a **Responsible Procurement Framework** which **embeds sustainability principles** and practices into our sourcing activities
- This Framework was developed in response to the challenges of **Climate Change** and supports the implementation of the Global Fund Supplier **Code Of Conduct**
- Through the RDT Procurement cycle 2024-2026, **suppliers will be encourage** to
  - **Continuously strengthen** sustainability credentials and practices throughout their manufacturing and supply chains, and **share** baseline information to **measure our impact**
  - Minimize **environmental impact of distribution, delivery, and at end-user level** through enhanced planning, adapting transport routes, reduce packaging etc.
  - Implement projects to address **environmental impact of manufacturing RDTs**
  - Leverage innovations to further **reduce packaging and shipping costs**

Objective 5 Accelerate the introduction of the innovative RDTs at scale

Enable equitable access to innovations to ensure optimal care for people we serve, cost reduction and reduced environmental impact



- **Continue to stimulate innovation** through agreed supplier-driven projects
- Leverage procurement process to **support a robust pipeline of new products** intended to improve efficacy, reduce cost, & better meet the needs of end users in line with disease guidelines, latest WHO recommendations
- **Align with partners** regarding new innovative tests needed in the market **and harness their support** to facilitate new product introduction at scale
- Leverage innovations to **improve packaging, shipping costs, and product design and reduce plastic waste.**

Request for Proposals (RFP)

Approach & Timeline

Fabrice Abalain
Associate Specialist, Direct Sourcing Health Technologies Diagnostic
Global Fund

Kiraz Bulut
Legal Counsel (Institutional Matters)
Global Fund

RFP process and timelines *(indicative)*

Phase I:
Supplier and Partner Engagement
(Q3 - Dec 2023)

- Consultations with suppliers and partners
- **RDT Procurement Strategy Presentation Partners & Suppliers 11 Dec 2023**
- Invite feedback from suppliers and partners

Phase II:
RFP launch and bid submissions
(Dec 2023 - Feb 2024)

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

Phase III:
Evaluations
(Feb – Mar 2024)

- Evaluations
- Internal Approvals
- Award

Phase IV:
Contracting
(Q2 2024)

- Contract finalization & signature

Tender evaluation structure

RDT RFP

Commercial criteria (55%)

1. Unit Price & Total Landed Cost
2. Volume Discounted Price* & Total Landed Cost

Compliance requirements:
- **Financial Due Diligence**
- **Integrity Due Diligence**

Technical criteria (45%)

1. Product & Country Registration Coverage
2. Innovation & Sustainability
3. OTIF delivery performance (incl. capacity & lead time)
4. Regional manufacturing in sub-Saharan Africa

- **The full scope of evaluation criteria** will be **reapplied at annual performance reviews** for subsequent allocation periods
- There will be **a process** to consider **new entrants and/or new products** that become **eligible** for procurement **after tender closure (subject to review)**

** Volume Discounted Price to apply depending on product category*

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

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

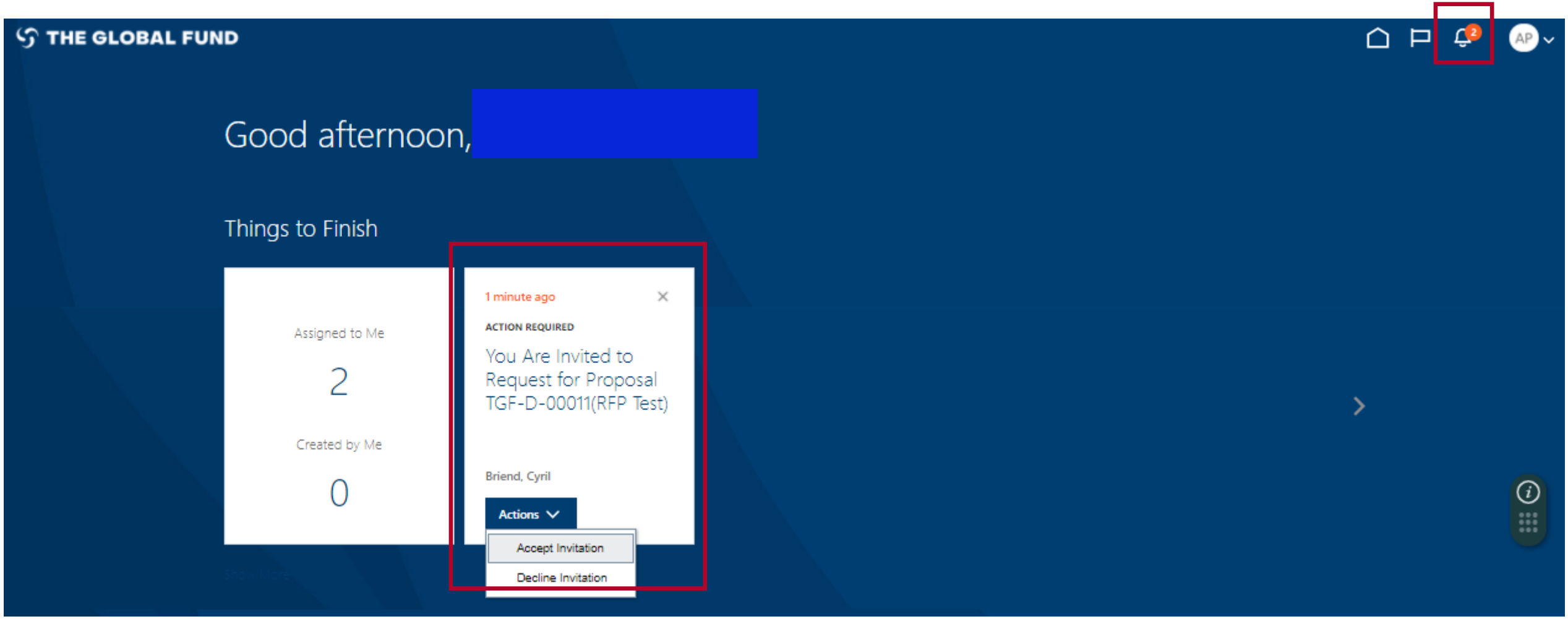
- Prohibits both direct and indirect:
  - Corruption
  - Fraud
  - Coercion
  - Collusion
  - Anti-competitive practices
- Full and open disclosures of CoI, including potential and perceived
- Safeguarding (with obligatory reporting):
  - Protection from Sexual Exploitation, Abuse and Sexual Harassment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

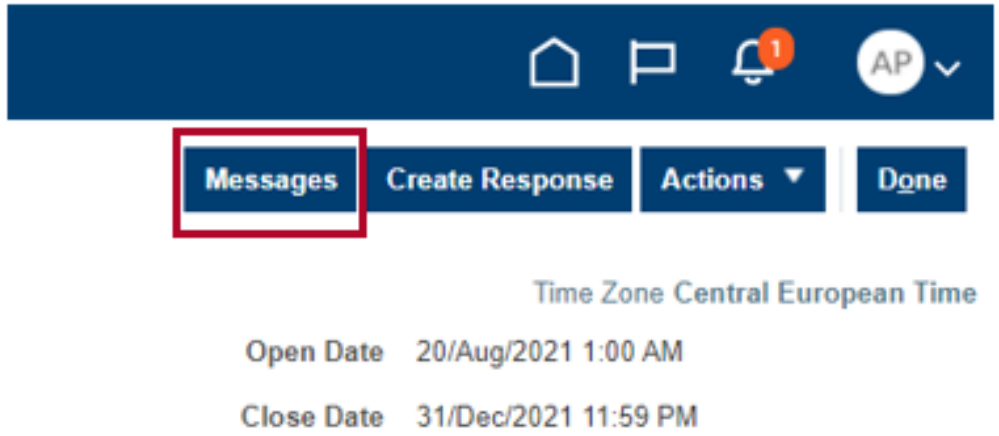
Sourcing Platform used for all RFP communications

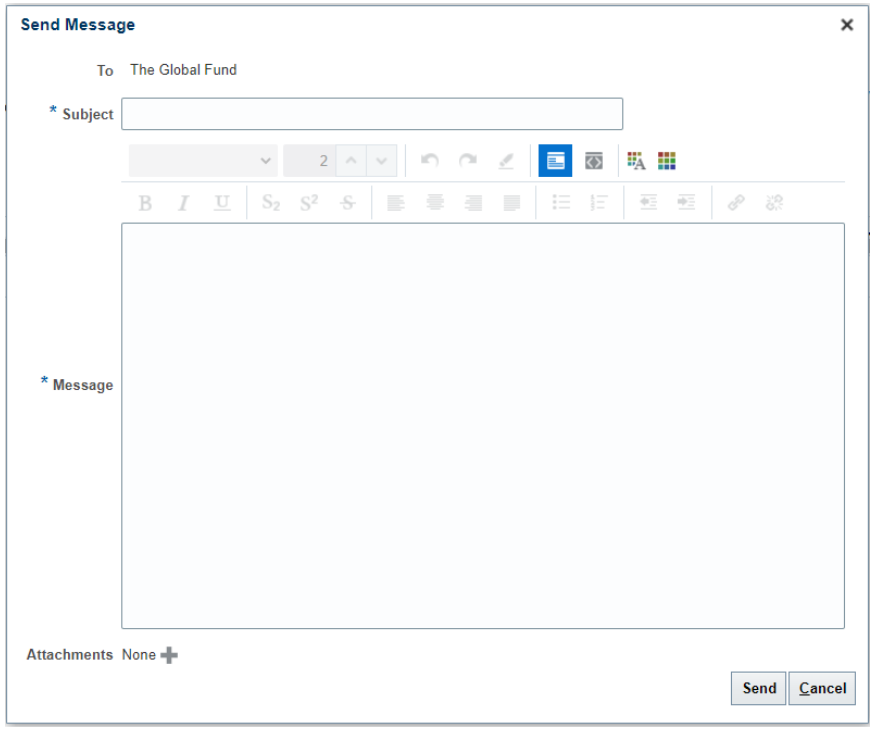
Welcome page & notifications



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.





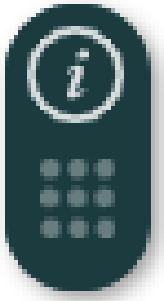
Sourcing Platform: Other Matters

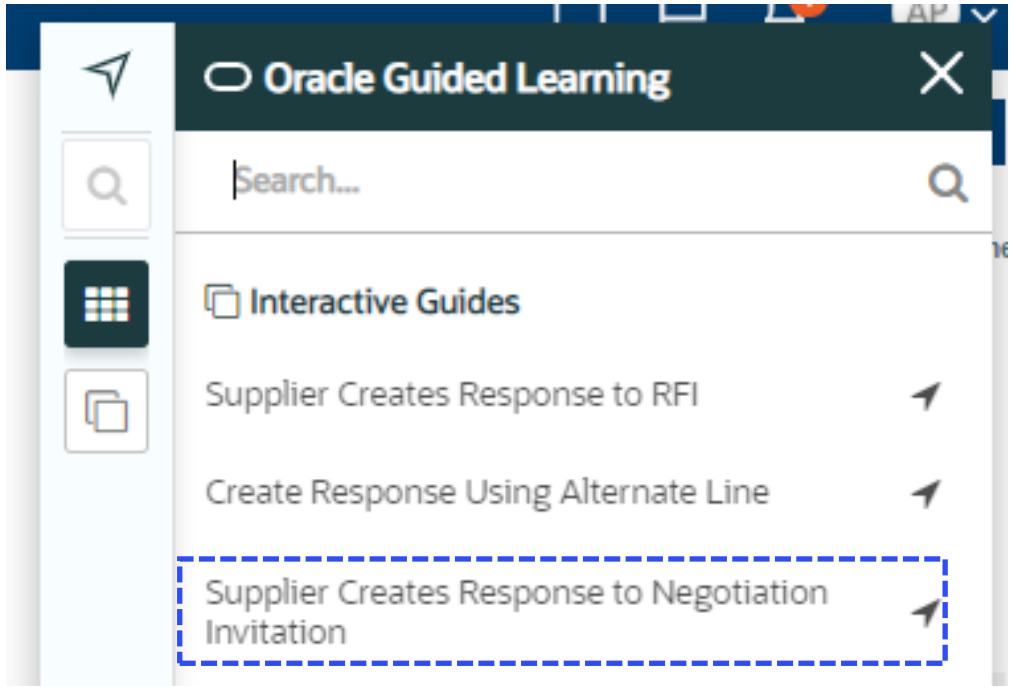
Oracle Guided Learning (OGL)

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

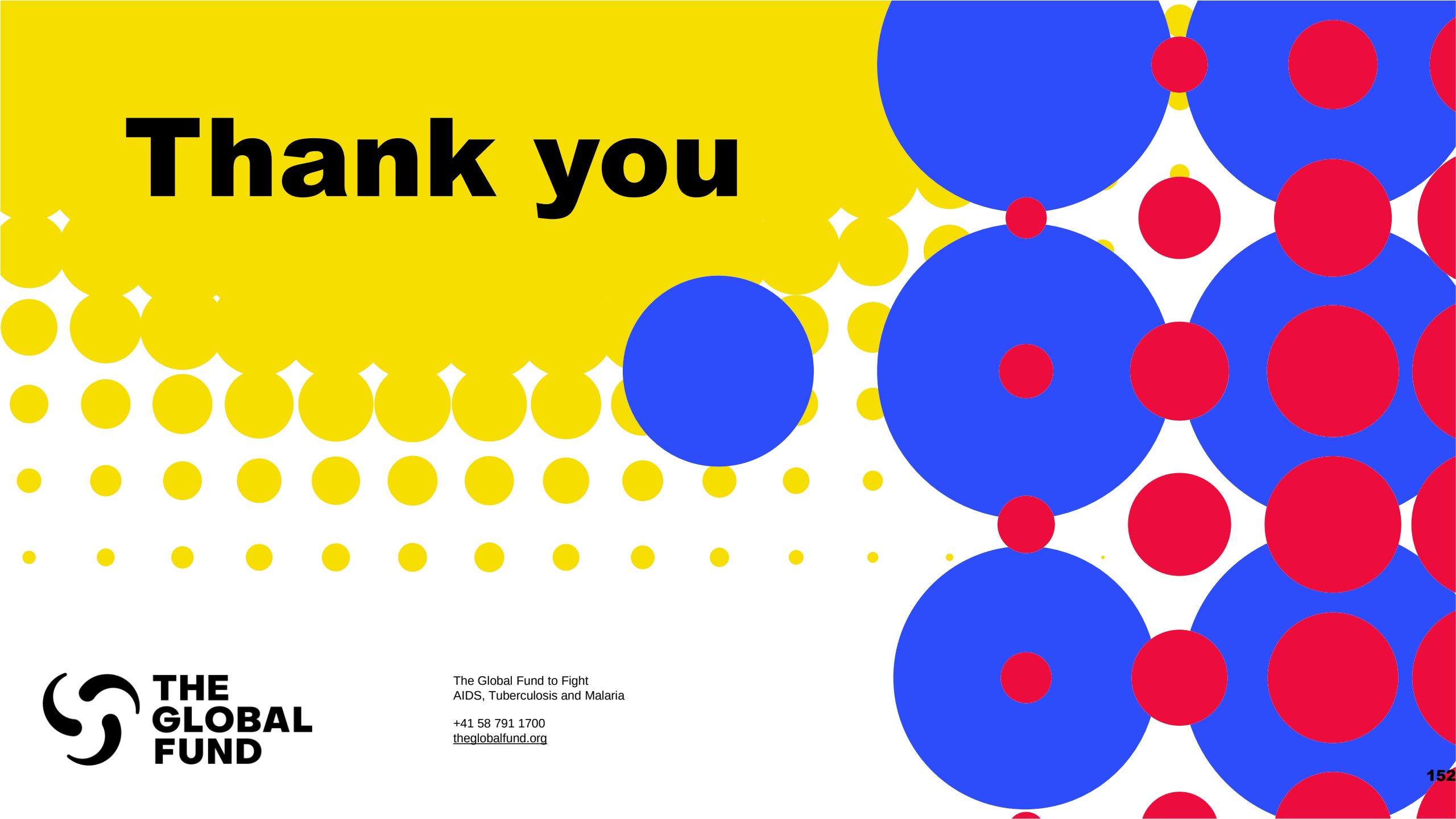
- Please open the following link in your browser to see the step guide (Supplier Creates Response to Negotiation Invitation):
  https://guidedlearning.oracle.com/player/latest/api/scenario/export/v1/WpUIM+OJRoSJYo3jQu37UA/k7hjkrg1/lang/--/?draft=undefined

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





Thank you



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AIDS, Tuberculosis and Malaria

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