Global Fund support for Lab Systems Strengthening :

Updates and perspectives for GC7

19 October 2023

Virtual LabCop meeting

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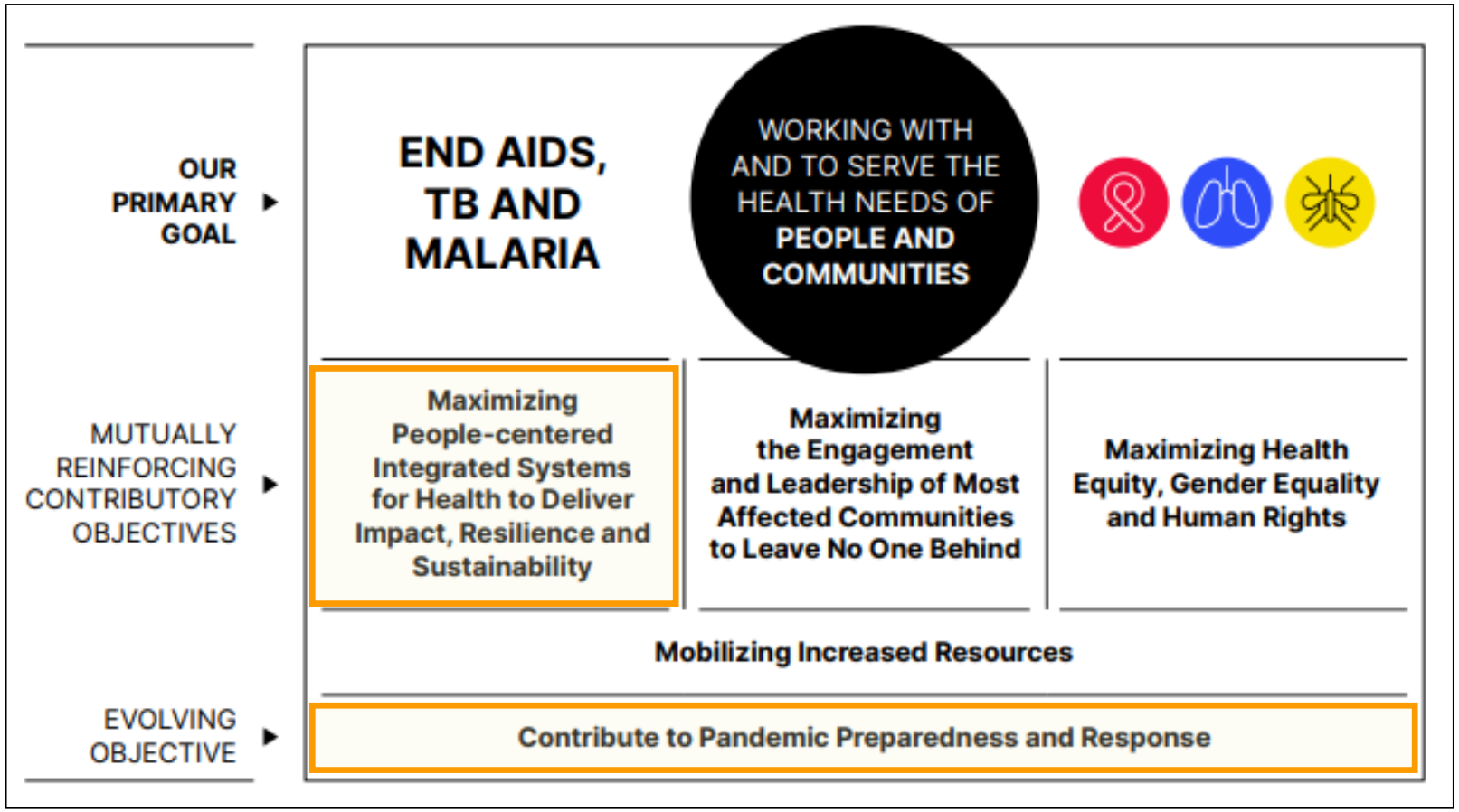
Outline

- **The shift towards new priorities: RSSH and laboratory systems**
- **Metrics of success: Lab Systems indicators for the next grant cycle**
- **Catalytic regional initiatives (“CMLIs” Centrally Managed Limited Investments)**

Global Fund Strategy 2023-2028

Fighting Pandemics and Building a Healthier and More Equitable World



2023-2028 Strategy

Changes in strategic focus

- Greater emphasis on **data-driven** decision-making, investing in systems and capabilities that enable rapid generation, analysis and use of high-quality data
- Greater focus on accelerating equitable deployment of - and access to - **innovations, addressing bottlenecks** to deploy resources to those in need

Global Fund's Model

1

We raise and invest more than US$4 billion a year to defeat HIV, TB and malaria, fight COVID-19 and strengthen health and community systems and increase pandemic preparedness in 100+ countries.

2

We leverage the unique expertise within each country. Country experts work together as a Country Coordinating Mechanism (CCM) to develop a funding request tailored to their country's needs that is based on national plans. The CCM is made up of representatives from affected communities, civil society, health care and government.

3

An independent group of experts evaluates the funding request. This group, known as the Technical Review Panel (TRP), may also provide feedback to further ensure the development of high-performing grants.

4

Funding requests that are considered implementation-ready are then recommended for approval to the Global Fund's Board by the Grant Approvals Committee (GAC).

5

The Global Fund Board approves grants based on TRP and GAC recommendations. The first disbursements of grant funds can be made following Board approval.

6

Following the disbursement of grant funds, a Principal Recipient, selected by the CCM, implements programs with Global Fund financing. Principal Recipients are the organizations that implement the programs we support through our grants. In most cases, Principal Recipients then disburse funds to other smaller organizations who serve as sub-recipients or even sub-sub-recipients, allowing financing to effectively cascade down.

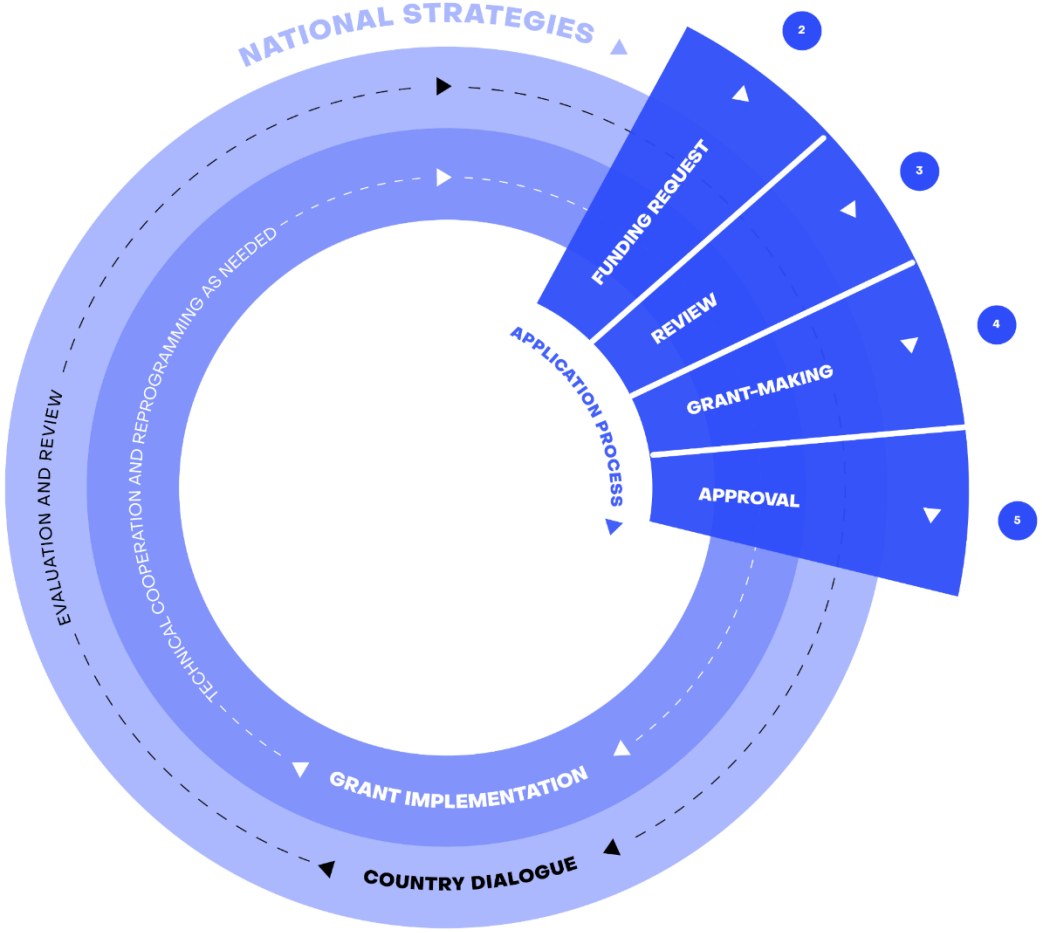
7

We monitor and evaluate grant performance throughout the grant cycle to ensure program impact and integrity.

- Each grant requires a **performance framework** that outlines the indicators and targets to achieve along with a monitoring and evaluation plan outlining how to collect, collate and analyze the data from programs in order to check the program is meeting its goals.
- Independent organizations in each country serve as **Local Fund Agents** that work closely with the Global Fund to evaluate and monitor activities before, during and after the implementation of a grant.
- Oversight and auditing functions are also provided by the Global Fund's **Office of the Inspector General (OIG)**. The OIG reports on all its activities in the interests of transparency and accountability.

8

The Global Fund regularly publishes impact reports.



APPLICATION PROCESS : 6-9 MONTHS

GRANT IMPLEMENTATION : 3 YEARS

Preparing Funding Requests

Funding requests are prepared by the Country Coordinating Mechanism with the support and input of key stakeholders through the Country Dialogue process

Develop and implement National Strategic Plans

December 2022
Countries notified of Global Fund Allocation

Funding Request

Country Dialogue

Technical Partners

Private Sector

Civil Society

Academia

Laboratory Directorate

Government

Key populations

Youth

Funding Request Development

Q1 – Q3 2023
Funding Requests are submitted to Global Fund

Window 1: 20 March 2023
Window 2: 30 May 2023
Window 3: 21 August 2023

Grant Making

Technical Review Panel reviews Funding Requests

Grant Negotiation

Arrangement of disease and RSSH modules in performance frameworks, budgets and other templates

HIV

- Prevention
- PMTCT
- Differentiated HIV Testing Services
- Treatment, care and support
- TB/HIV
- Reducing human rights-related barriers to HIV/TB services
- Program management

+ all RSSH modules

TB

- TB care and prevention
- TB/HIV
- MDR-TB
- Removing human rights and gender related barriers to TB services
- Program management

+ all RSSH modules

Malaria

- Vector control
- Case management
- Specific prevention interventions
- Program management

+ all RSSH modules

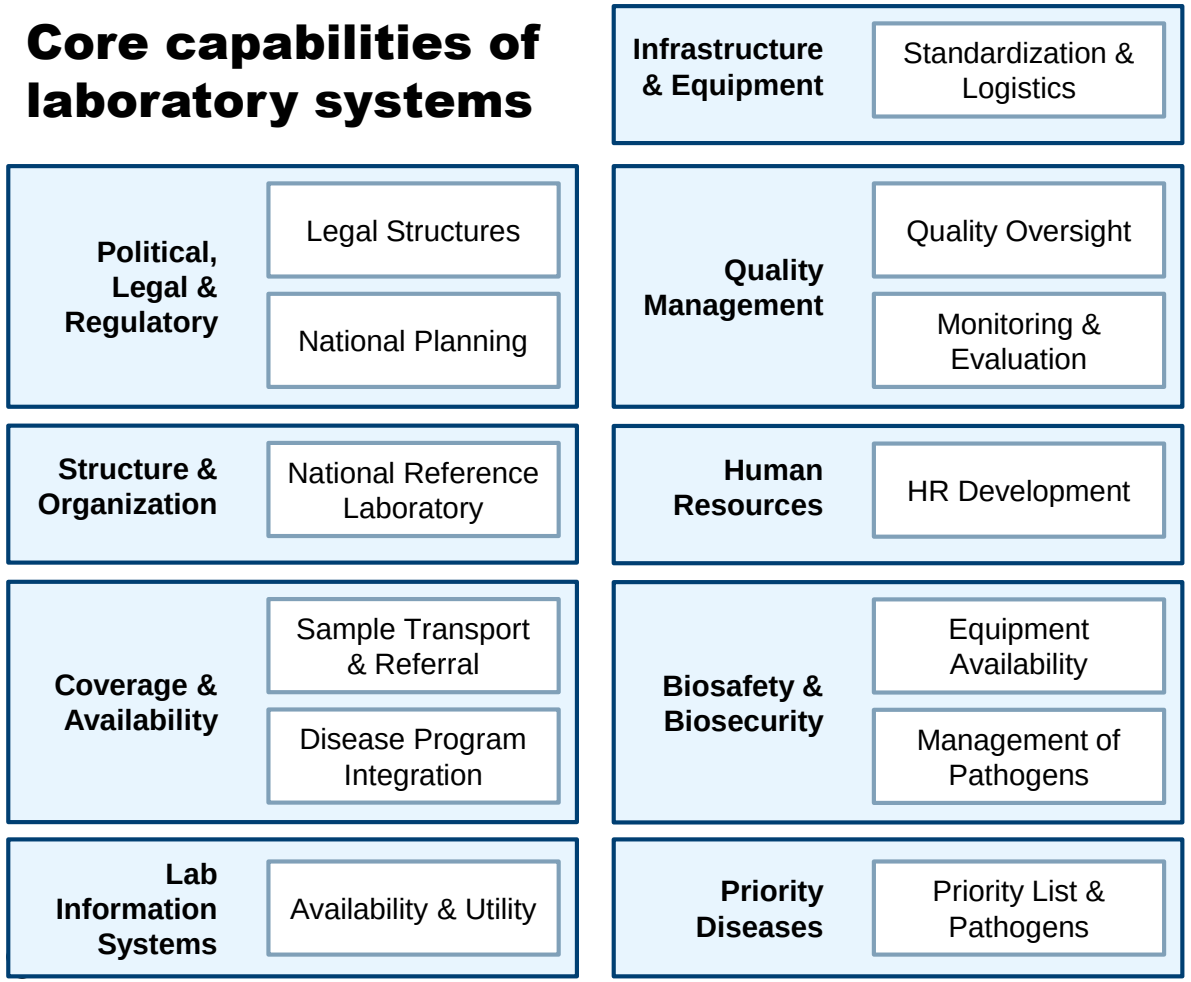
RSSH/PP

- Health Products Management Systems
- HMIS and M&E
- Human Resources for Health, including Community Health Workers
- Integrated service delivery and quality improvement
- Financial Management Systems
- Health sector governance and planning
- Community systems strengthening
- Laboratory systems
- Program management

Integrated Laboratory System Strengthening (ILSS)

Global Fund investments in grants and catalytic initiatives support core capabilities of laboratory systems

Core capabilities of laboratory systems



Investment principles

- Activities should be aligned with the NLSP, or National Action Plan for Health Security.
- Active involvement of the Laboratory Directorate is necessary to define strategic, cross-cutting systems priorities
- Activities must be directly related to, or contribute to advancing uptake of integrated service delivery; no siloed or disease-specific interventions are eligible to be considered
- Adequate resources must be allocated to capacity building / human resource development to sustain the outputs of activities and ensure continued ownership of systems-level investments
- Alignment with the integrated Laboratory Systems principles in the RSSH Information Note

Laboratory Systems Strengthening Core Capacities

8 interventions within RSSH-Lab module

- National laboratory governance and management structures
- Quality management systems and accreditation
- Laboratory Information systems
- Network optimization and geospatial analysis
- Laboratory based surveillance
- Laboratory supply chain systems
- Specimen referral and transport systems
- Biosafety and biosecurity, infrastructure and equipment management

Investment analysis is complicated by changing classification rules:

- Are diagnostic commodities/ reagents considered part of LSS budgets?
- How are Human Resources and training investments classified ?
- Are GeneXpert equipment investments considered part of RSSH/Lab, or are they part of TB grants?
- Should Chest Xrays be considered LSS investments?

- How to distinguish Lab vs Surveillance investments?

Integrated laboratory-based disease surveillance

Opportunities to expand testing capacities

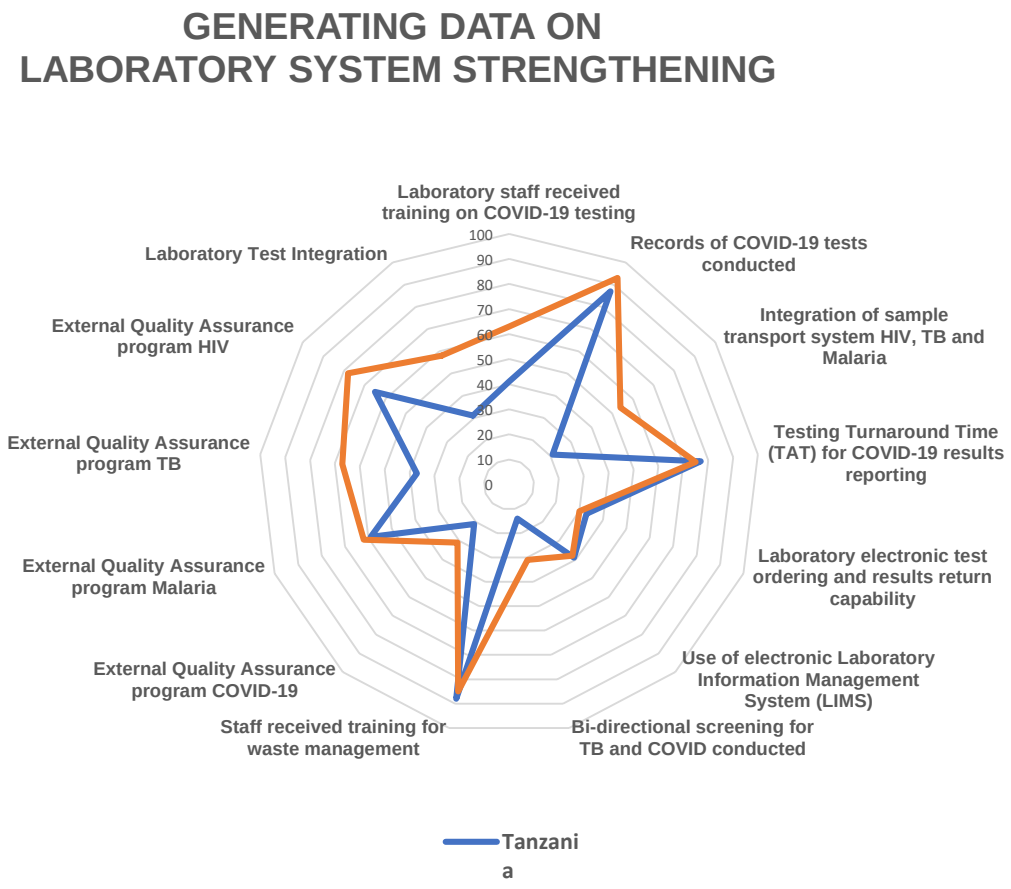
- **Sentinel syndromic surveillance for non-malaria fevers:** routine testing of representative suspect cases of respiratory, enteric and vector-borne illnesses → broader use of RDTs are peripheral levels → confirmatory testing at central level using multi-disease testing platforms

  Surveillance activities can be the engine to drive integration of Sample Transport

- **Genomics and Next Generation Sequencing**: build core sequencing facilities for detection of new pathogens and variants
- **Environmental surveillance**: Wastewater / sewage surveillance to monitor ongoing community-level transmission of priority diseases & new variants
- **Integrated multiplexed serosurveillance:** Establish population-representative, serosurvey platforms to test for pathogens using multiplex bead array technology to inform programmatic interventions
- **Biobanking:** Establish and strengthen quality-assured blood banks, and strategic use of these repositories for population-based immunology studies
- **Antimicrobial resistance stewardship & One Health Initiatives**

Measuring Lab System Readiness: C19RM Spot Checks

Conducted in **45 countries** to monitor C19RM interventions : identify gaps in core capabilities, measure progress over time, provide a regional view lab of system maturity



Lab System Readiness: Heat Map

Data from 3rd (and last) round of C19RM SpotChecks: identifying gaps in core capabilities

Output Indicators Input Indicators	Burkina Faso	Malawi	Mali	Mozambique	Chad	DRC	Madagascar	Niger	Sierra Leone	South Sudan	Cameroon	Zimbabwe	Benin	Burundi	Guinea	Senegal	Togo	Bangladesh	Ghana	Indonesia	Kenya	Zambia
% of facilities with HIV Testing service	82%	97%	34%	72%	70%	72%	65%	78%	74%	71%	76%	56%	74%	100%	82%	86%	74%	45%	65%	96%	87%	90%
% of facilities with Viral Load Testing service	64%	87%	29%	58%	57%	62%	58%	53%	45%	71%	46%	51%	26%	82%	44%	76%	54%	94%	58%	100%	86%	85%
% of facilities with Drug Sensitive TB diagnosis service	95%	97%	45%	77%	86%	89%	78%	79%	97%	97%	77%	51%	67%	95%	82%	100%	77%	18%	71%	92%	87%	92%
% of facilities with Malaria Diagnosis service	51%	79%	32%	63%	22%	40%	58%	48%	34%	55%	63%	56%	38%	31%	31%	59%	67%	45%	44%	100%	58%	87%
% of facilities with eLMIS	44%	46%	33%	47%	16%	5%	10%	25%	13%	31%	28%	69%	54%	8%	56%	50%	41%	14%	40%	61%	35%	44%
% facilities with electronic test ordering & results return capability	25%	27%	15%	46%	8%	6%	20%	13%	8%	49%	12%	59%	26%	3%	23%	16%	22%	20%	38%	92%	32%	37%
% facilities conducting routine surveillance (like IDSR, reporting to higher admin)	42%	93%	61%	89%	32%	93%	87%	49%	88%	79%	77%	92%	50%	93%	49%	96%	61%	74%	93%	99%	69%	82%
On-shelf availability of HIV diagnostic products	76%	100%	96%	95%	85%	71%	69%	73%	83%	83%	97%	97%	87%	87%	92%	88%	84%	79%	88%	#DIV/0!	76%	95%
On-shelf availability of TB diagnostic products	64%	75%	97%	82%	45%	84%	39%	90%	80%	81%	80%	88%	100%	74%	92%	90%	100%	96%	73%	91%	69%	70%
On-shelf availability of Malaria diagnostic products	86%	100%	82%	100%	81%	94%	93%	85%	81%	84%	79%	100%	76%	100%	94%	97%	85%	86%	90%	74%	86%	100%
% facilities with Integration of sample transport system HIV, TB and Malaria	40%	44%	41%	62%	5%	20%	19%	27%	26%	41%	44%	85%	46%	15%	28%	42%	44%	3%	33%	73%	58%	64%
% facilities with testing for multiple different diseases	67%	74%	63%	41%	67%	56%	52%	67%	80%	64%	50%	91%	48%	50%	69%	25%	77%	28%	68%	86%	50%	69%
% facilities with External Quality Assurance program TB	49%	69%	32%	62%	43%	36%	27%	41%	54%	69%	33%	77%	36%	36%	51%	45%	49%	74%	38%	80%	75%	51%
% facilities with External Quality Assurance program Malaria	71%	62%	42%	63%	73%	41%	36%	33%	67%	79%	44%	82%	59%	56%	67%	47%	69%	19%	54%	75%	74%	51%
% facilities with External Quality Assurance program HIV	53%	77%	30%	64%	51%	31%	26%	32%	59%	69%	65%	85%	59%	56%	72%	37%	54%	19%	47%	76%	85%	67%
Lab staff availability	71%	77%	82%	73%	78%	81%	68%	100%	64%	85%	94%	79%	90%	87%	97%	79%	90%	93%	69%	100%	95%	49%
Facilities where staff trained on waste management (%)	81%	41%	86%	74%	81%	58%	77%	74%	82%	79%	82%	82%	85%	77%	95%	68%	92%	38%	83%	96%	82%	49%
Facilities with formal waste management system handling over 50% waste (%)	26%	15%	47%	14%	8%	15%	23%	29%	20%	26%	33%	15%	56%	26%	36%	24%	33%	20%	17%	17%	19%	28%
Facilities disposing medical/lab waste through open burning (%)	10%	54%	11%	40%	30%	0%	0%	7%	33%	64%	10%	44%	8%	5%	21%	37%	3%	66%	50%	56%	46%	59%

Performance Frameworks: current summary of country adoption of Lab-related indicators for C19RM (i)

	Cohort																									
	Malawi	Zambia	Nigeria	Burkina Faso	Tanzania	Mozambique	Benin	Ghana	Ethiopia	Congo (DRC)	Bangladesh	Guinea	Philippines	Burundi	Liberia	Mali	S Sudan	CAR	Namibia	Chad	Congo	Sierra Leone	Togo	Haiti	Côte d'Ivoire	Pakistan
Laboratory Systems Funding Request (US$m)	22	13	80	13	16	26	10	9	16	19	9	3	5	4	4	7	5	2	3	1	3	5	8	3	3	5
RSSH/PP IPC-4 Number of health facilities participating in HAI / AMR surveillance		■										■														
RSSH/PP LAB-2 Percentage of molecular diagnostic analyzers achieving at least 85% functionality (ability to test samples) during the reporting period	■				■	■		■	■	■	■				■	■	■	■	■	■	■	■				
RSSH/PP LAB-4 Percentage of laboratories that have electronic test ordering and results return capability via a remote test order module of the LIMS						■		■	■									■				■	■			
RSSH/PP LAB-6 Percentage of instruments covered by a service contract during the reporting period	■						■														■	■	■			
RSSH/PP LAB-7 Number of health facilities providing SARS-CoV-2 testing services (+ specify technology)					■				■					■								■				
RSSH/PP M&E-5 Percentage of laboratories capable of electronically returning patient laboratory results to the patient-level programmatic data system				■						■				■	■	■			■		■	■			■	
WPTM	N	N	2	1	N	3	2	5	N	N	N	N	3	1	N	N	N	1	N	1	6	1	N	1	N	N

■ Indicator proposed ■ Still in discussion

Performance Frameworks: current summary of country adoption of Lab-related indicators for C19RM (ii)

	Malawi	Guinea	Zambia	Nigeria	Philippines	Burundi	Liberia	Mali	Burkina Faso	S Sudan	Tanzania	Mozambique	CAR	Namibia	Benin	Chad	Ghana	Congo	Sierra Leone	Togo	Ethiopia	Haiti	Congo (DRC)	Côte d'Ivoire	Bangladesh	Pakistan
Surveillance Systems Funding Request (US$m)	16	1	10	26	7	1	2	4	11	3	7	24	7	2	1	1	8	3	5	2	5	4	3	4	0	9
M&E-4.1-Percentage of service delivery reports from community health units integrated/interoperable with the national HMIS.							■	■						■			■	■		■		■				
M&E-5.1- Percentage of reporting units which digitally enter and submit data at the reporting unit level using the electronic information system.	■	■	■	■	■					■	■		■				■	■	■	■			■			
RSSH/PP M&E-9 - Percentage of districts reporting events (per national guidelines).	■	■	■				■		■			■	■	■		■	■	■						■		
WPTM*	N	N	N	N	4	1	N	N	2	N	N	6	5	1	N	1	3	5	4	N	N	N	1	N	N	N

*#WPTM: does not indicate these have been thoroughly reviewed and are the most appropriate

■ Indicator proposed ■ Needs Follow Up ■ SONAR supported countries, others not yet to IC at the time this table was created include Madagascar, Cameroon,

Data-driven decision making: new strategies require new metrics

Lab System Strengthening indicators (some examples)

Lab-2 Equipment functionality

Lab-3 External Quality Assurance (EQA)

Lab-4 Laboratory Information Systems (LIS)

- Electronic results reporting to clinicians/patients
- Electronic reporting to DHIS2

Lab-5 Essential Diagnostic Lists

Customized workplan tracking measures (WPTMs) can be added to grants as needed

Lab Systems Strengthening Indicators

Equipment functionality

Indicator	Definition	Purpose of indicator
Lab-2 (equipment functionality)	**Percentage of molecular diagnostic analyzers achieving at least 85% functionality (ability to test samples) during the reporting period.**	**Increase visibility on current status of national fleets of molecular Dx platforms; informs understanding of utilization rates and Value for Money of lab equipment investments. Data source: Laboratory Directorates**

- Definition of “functionality”? → refers to machines/modules that are calibrated and operational at the time of reporting
- **Disaggregrated data** by platform type (POC vs conventional).
- For Genexperts and TrueNATs, use modules for both numerator and denominator.
- Report on all instruments, not just those procured via Global Fund.
- Consider designing custom WPTMs as needed to meet your needs and context.
- KPIs for equipment performance are critical for monitoring adherence to Maintenance & Servicing contracts.
- Advocate for a national database (register) of laboratory equipment.
- Prioritize having a designated focal person within the MoH/ Lab Directorate to manage equipment inventories.
- Lab information systems (LIS) with ‘middleware’ to connect to analyzers → automated reporting

Lab Systems Strengthening Indicators

External Quality Assurance

Indicator	Definition	Purpose of indicator
Lab-3 (EQA)	**Percentage of laboratories successfully participating in external quality assurance (EQA) or proficiency testing (PT) schemes.**	**Helps understand level of adherence to GF requirements for established laboratory quality assurance systems. Data source: Laboratory Directorates, Natl Public Health Institutes**

- **Please focus on the denominator !!**
- **Which EQA programs to include ???**
- **Disaggregated data** reporting by type of program
- **Numerator**: # of labs achieving satisfactory results in the selected PR scheme
- **Denominator**: total number of labs participating in selected EQA/PT scheme

- **TB**
  - Microscopy
  - Mol Dx (GxP; TB Lamp)
- **HIV**
  - Serology
  - Mol Dx (VL; EID)
- **Malaria**
  - Microscopy
- **AMR**
  - GLASS pathogens & Drug Susceptibility
- **Vaccine Preventable Diseases**
- **Parasitology, Mycology**
- **Viral Hemorrhagic Fevers**
- **Hematology/ Biochemistry**

Lab Systems Strengthening Indicators

Laboratory Information Management Systems

Indicator	Definition	Purpose of indicator
Lab-4 (LIMS)	**Percentage of laboratories that have electronic test ordering and results return capability via a remote test order module of the LIMS.**	**Monitors laboratory data management linked to improvements in the patient care cascade. Data source: PEPFAR, Laboratory Directorates.**
M&E - 5 (LIMS)	**Percentage of laboratories capable to send by electronic means the lab test results to central level. .**	**Monitors the adoption of LIS capable of automated reporting to DHIS2 (and other HMIS).**

- For both indicators, the goal is to measure laboratory capacity for **paperless** automated results reporting
  - Lab - 4 measures reporting to clinicians/patients
  - M&E – 5 measures reporting to DHIS2/ HMIS
- For both indicators, the **denominator** is # of laboratories registered and licensed to operate in the country.

Lab Systems Strengthening Indicators

Essential Diagnostics List (EDL)

Indicator	Definition	Purpose of indicator
Lab-5 (Essential Dx List)	**Percentage of health facilities that have an appropriate set of diagnostics for their healthcare facility level, based on national Essential Diagnostic Lists.**	**Informs understanding of access to diagnostics for key pathogens of public health importance, and progress towards integrated people-centered care. Data source: Health Facility Assessments, Laboratory Directorates.**

- Requires measurement via **targeted Health Facility Assessments (tHFA)**
- Survey instruments must be customized based on each country's priority disease & diagnostic lists
- **Illustrative example:**
  - Country X has guidelines requiring that small health posts can test for malaria and COVID-19 with RDTs (i.e. 2 test types), and that medium-sized health centers can test for malaria, COVID-19, syphilis, HIV, blood sugar, proteinuria, and pregnancy (i.e.7 test types). If the HFA finds that a particular health post has only malaria tests, then the score would be 1/2, or 50%. If the HFA finds that a health center has malaria, COVID-19, syphilis, HIV, and pregnancy tests, then the score would be 5/7, or 71%.
  - Note that if a country guideline does not require any diagnostic testing for a specific facility type (e.g., a very small health hut), then the facility score for that type of facility would be set to missing.
  - To calculate the indicator at the country level, all non-missing facility-specific scores are averaged together.

Catalytic Regional Initiatives 2024-2026 (GC7)

Build regional institutional capacity, enhance collaborative networks, drive innovation at level of national reference laboratories

Eastern Central Southern Africa

21 countries; continuation of previous ECSA grant

Western Africa

15 member states of ECOWAS/ WAHO

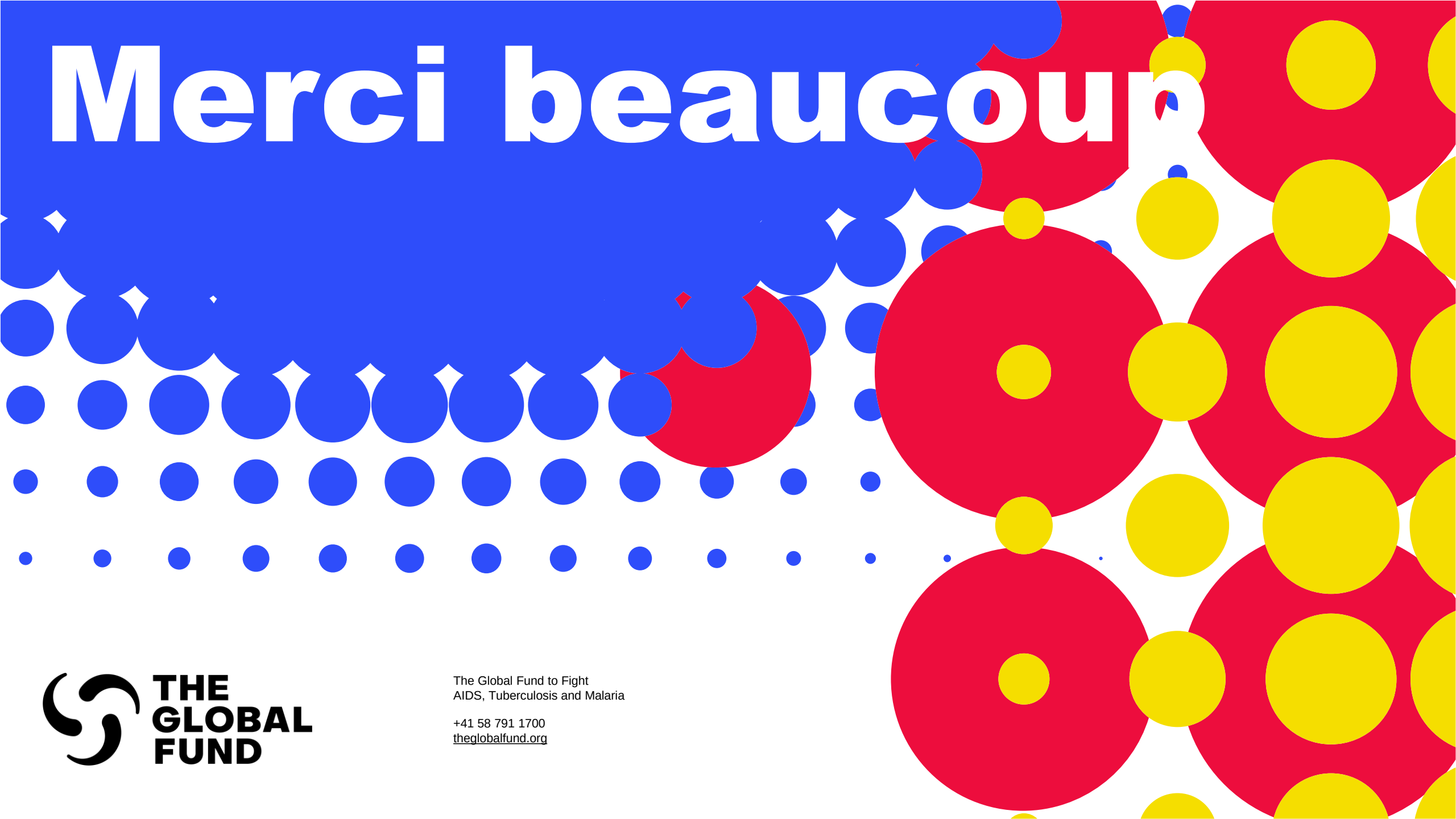
Proposed activities currently under review

- Address regulatory barriers for introduction of in-vitro diagnostics; regional frameworks for regulatory reliance
- Promote autonomous capacity to produce EQA proficiency testing panels for HTM and epidemic threat pathogens in NRLs and SRLs
- Expand enrollment in EQA programs → provide training on EQA program management & reporting systems
- **AMR**: Define minimum capacity for antimicrobial laboratory services package, supply and equipment requirements, strengthen surveillance for GLASS pathogens, quality for AMR laboratory and data reporting
- Enhance **Sentinel Syndromic Surveillance** via AuCDC RISLNET; adoption of harmonized/ standardized case definition, protocols, reporting mechanisms, data warehouses

Key messages

- The paradigm shift towards investing in ***integrated systems*** is ongoing → *Global Fund priorities & processes continue to evolve*
- The push for data-driven decision making means more emphasis on Performance Frameworks and 'Value for Money'
  - ➢ Countries are encouraged to customize their indicators & WPTMs, invest in targeted HFAs, and conduct surveys/ assessments
- Need stronger regional bodies and regional collaborations to drive integration and innovation → *stay tuned to learn more in December in CapeTown!*
- Absorption rates still considered the most important gauge of implementation success
  - ➢ Improved relations between PRs and Lab Directorates are key, as well as lab sector governance and coordination

Merci beaucoup



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