Briefing Note
Integrated Laboratory Systems Strengthening Catalytic Initiative

Allocation Period 2023-2025

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THE GLOBAL FUND

Contents

Executive Summary

Integrated Laboratory Systems Strengthening (ILSS) Catalytic Initiative

The ILSS Catalytic Initiative is delivered through three workstreams during the 2023-2025 allocation period or Grant Cycle 7 (GC7), with:

1. Ten countries supported through the Strategic Initiative.

2. Nine countries supported through Matching Funds.

3. Two regional bodies supported through multicountry grants.

The objective of the ILSS Catalytic Initiative is to support advancement in lab systems readiness capabilities to detect and respond to health threats of pandemic potential. This objective aligns with the [Global Fund's 2023-2028 Strategy](#)

New in Grant Cycle 7

The following process and administrative changes have been implemented following feedback from Secretariat stakeholders, partners and TA providers:

- Countries have been notified of eligibility for catalytic investments in their 2023-2025 allocation letters, enabling better coordination with grant-supported activities. Countries eligible for technical assistance (TA) may now define the scope of TA simultaneous to preparing their funding request.

- Planning for TA, including defining a TA provider is expected to be completed prior to the start date of their GC7 grant, which enables Country Teams and Principal Recipients (PRs) to contract TA providers by the first day of grant implementation.

- To ensure synchronization of TA with grant-supported activities and align with the agreed TA workplan, the Country Team and PRs are requested to support the coordinated planning of required disbursements and procurement.

- The catalytic investment will be evaluated, focusing on whether the expected direct and indirect impact of investments has been achieved. Practical insights will also be shared to guide investment priorities.

1. Purpose

This document provides guidance to Country Teams and in-country partners (namely Country Coordinating Mechanisms and Principal Recipients) of portfolios that are eligible for support through the Integrated Laboratory Systems Strengthening (ILSS) Catalytic Initiative planned for implementation in Grant Cycle 7.

This document seeks to:

- Outline the investment principles and rationale for the targeted laboratory systems investments.

- Provide operational details to Country Teams on the process of accessing the available funds.

- Provide high-level operational information on implementation arrangements expected in Grant Cycle 7 for catalytic investments.

2. Background

Efficient and reliable health laboratory systems are an essential component of any resilient health system and are central to achieving the core mission of the Global Fund. Investments in systems to deliver diagnostic services underpin the ability to decentralize patient-centered service delivery, and are vital to achieving impact against HIV, tuberculosis (TB), malaria and other priority diseases.

The ILSS Catalytic Initiative builds on Global Fund's investments in diagnostic services and laboratory systems strengthening. Laboratory investments have accounted for approximately 11% in Grant Cycle 4, 15% in Grant Cycle 5 and 18% in Grant Cycle 6 of the total Global Fund funding budget. Investment in laboratory systems and diagnostic services are expected to continue increasing in Grant Cycle 7.

The ILSS Catalytic Initiative will contribute to strengthening and expanding laboratory systems across sub-Saharan Africa, Southeast Asia, and Latin America at regional, national, and local levels. Improved laboratory systems will not only enhance national responses to HIV, TB and malaria, but may establish the core capabilities required to sustainably detect and respond to outbreaks before they become epidemics.

The ILSS Catalytic Initiative aims to achieve important steps to strengthen disease surveillance capabilities by working toward accelerating four levers:

1. **People:** Contribute to strengthening and expanding workforce development initiatives to fill skill gaps and empower future laboratory leaders in countries.

2. **Data:** Establish/augment, scale, and integrate critical data systems to improve access to and timeliness of laboratory system data points.

3. **Regional collaboration:** Support regional coordination structures to foster regional collaboration, improve quality assurance mechanisms, and spur sub-regional resource mobilization for cross-country disease detection and response.

4. **Process**: Advance the establishment and use of laboratory governance processes to improve the effective, sustainable, and efficient management of laboratory system resources.

The ILSS Catalytic Initiative Theory of Change is found in Annex 5.

3. Structure of the ILSS Catalytic Initiative

The ILSS Catalytic Initiative will be delivered through three distinct workstreams:

1. Strategic Initiative.

2. Matching Funds.

3. Regionally-managed multicountry grants.*

Countries have been notified of their eligibility to access support delivered through the Strategic Initiative and Matching Fund modalities of the ILSS Catalytic Initiative in their 2023-2025 allocation letters, delivered in December 2022.

A separate guidance document will be made available for multicountry grants.

4. Investment principles

4.1 Empowering laboratory directorates and country ownership

Siloed disease programming has resulted in the absence of strong governance structures to oversee the entirety of clinical testing service delivery, including both laboratory-based and community-based testing. Strong national laboratory leadership is critical to provide coordination and drive better integration. Country ownership is a core principle of Global Fund's investment model. As such, entities within ministries of health (MoHs) that are responsible for the entirety of clinical testing (i.e., National Laboratory Directorates) are empowered to mobilize the financial resources and to oversee and implement the activities outlined in National Laboratory Strategic Plans (NLSPs) or National Action Plans for Health security (NAPHS). These critical planning documents, as well as available laboratory assessment outputs, should inform the investment plan for laboratory systems strengthening. Excessive reliance on donor and partner funding creates inadequate country-level ownership and will lead to unsustainable laboratory services for both routine clinical work and epidemic response.

Active leadership of the National Laboratory Directorate and involvement of the Technical Working Group for Laboratory Services from the planning stage is vital to ensuring investments are cross-cutting, horizontally relevant and serve patients beyond verticalized diseased programs. Laboratory Directorates should be positioned as coordinators of investments, providing systems-level support to disease response.

4.2 Integrated service delivery

Integration of diagnostics services refers to the consolidation/coordination of existing resources[1] and supportive processes[2] for multiple disease programs of public health importance. Integrated approaches are essential to scaling up quality-assured clinical laboratory services which bolster a country's ability to diagnose infections, perform drug susceptibility testing, support patient management of comorbidities, and contribute to broader programs of syndromic surveillance.

Although vertical approaches have improved disease-specific responses, in some cases they have also resulted in the fragmentation of laboratory services and duplication of efforts. In addition, they have often left important gaps in the capacity of individual countries to perform crucial clinical and disease surveillance functions in a coordinated manner. Therefore, it is imperative to secure the establishment of integrated national laboratory services, networks and systems. An integrated approach allows both programs and

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[1] Examples of existing resources include facilities, multi-disease testing analyzers/equipment and personnel.
[2] Examples of supportive processes include specimen referral, test reporting, inventory management, quality management, post-market surveillance.

clinicians to use more comprehensive information that can lead to more informed clinical decision-making and more effective patient care.

Investments made through this Catalytic Initiative must directly contribute to adoption or scaling of integrated laboratory services.

4.3 Knowledge transfer and capacity building

To sustain investments in national integrated laboratory systems , countries rely on continuous investment in human resources for continued management and improvement. Insufficient investments in capacity building and the lack of continued workforce development inhibits productivity, capacity and efforts to advance service delivery. Excessive focus on the products, commodities and materials to diagnose disease has drawn attention away from the training and resourcing of staff to ensure the functioning of such resources. This can yield poor results in efficiency, under- or unutilized equipment, fragmented availability of services, overwhelmed laboratory technicians and generating sub-optimal results.

Capacity building should be incorporated into funding requests to secure utility of the systems-level investments, and the capability of key stakeholders to independently manage the functioning of the system. Delivery of technical assistance through the Laboratory Strategic Initiative is expected to encourage adopting best practices and innovative approaches, advancing knowledge transfer, and maximizing opportunities for human resources at the Laboratory Directorate to learn directly from contracted technical experts.

4.4 Coordination of investments

Laboratory system improvements should be built on a common vision, which has been articulated in a National Laboratory Strategic Plan (NLSP) and guided by a National Laboratory Policy. The engagement of the Laboratory Directorate in funding request development ensures coordination of investments from the country level, aligning activities to be supported to the NLSP and ensuring continuity of key initiatives.

Parallel to national coordination efforts, the Global Fund Resilient and Sustainable Systems for Health (RSSH) Laboratory Systems Team coordinates activities with multilateral donors and partners to ensure alignment of milestones and objectives to avoid overlapping investments. Activities funded through catalytic investments are reported to key partners[3] through the ILSS Catalytic Initiative Technical Working Group.

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[3] Key partners include WHO, Rockefeller Foundation, USG, Bill and Melinda Gates Foundation (BMGF), Stop TB, UK Government, Agence Française de Développement (AFD).

5. Strategic Initiative

This section provides information and guidance to countries eligible for **Strategic Initiative** support through the Integrated Laboratory Systems Strengthening Catalytic Initiative. For information on Matching Funds, see section 6.

5.1 ILSS Strategic Initiative – Planning

Countries have been notified of their eligibility to access support delivered through the ILSS Strategic Initiative in their allocation letters, delivered in December 2022. Country eligibility is listed in Annex 1 of this document.

(a) Investment principles

The Strategic Initiative finances activities that support the procurement of technical assistance (TA) to enable the successful adoption of best practices in establishing or scaling integrated laboratory services. Technical assistance is demonstrated to be a low-cost, highly impactful mechanism to support countries in implementing complex interventions, enabling direct knowledge transfer, capacity building and encouraging ownership over results. Investment in the relevant laboratory resources, services and commodities in national grants for technical assistance providers to support is a prerequisite to securing TA.

Critical approaches to invest in laboratory systems strengthening are included in the RSSH Information Note:

1. Funding requests should be based on updated National Laboratory Strategic Plans and adopt a transparent and reliable tracking system to monitor implementation progress, including metrics on timeliness, coverage, and access of diagnostic testing services.

2. Successful participation in External Quality Assurance Schemes for all diagnostics. This may include activities such as proficiency testing (PT) panels, inter lab comparisons, site supervision and mentoring, and virtual/online PT panels .

3. Establishing all-inclusive pricing modalities that include service and maintenance and training for laboratory equipment and point of care instruments.

4. Implementation of ISO 15189 standards to attain accreditation in all clinical public and private laboratories.

5. Routinely conduct integrated diagnostic network optimization/assessment exercises to increase efficiency and effectiveness of laboratory networks and systems and inform investments in diagnostics and lab systems.

6. Planning and implementation of integrated specimen referral networks for priority disease surveillance (zoonoses and food safety) and outbreak response. Outsourcing of transport services to the private sector is encouraged.

Technical assistance is procured and managed centrally at the Global Fund Secretariat, with national stakeholders involved in selection of the TA provider. Strategic Initiative funds cannot be disbursed to the Principal Recipient, be used to procure commodities, or diverted to support any other activity.

(b) Investment rationale

Laboratory systems are an integral component of delivering reliable and timely diagnostic services to inform both clinical and public health decision-making. Gaps in laboratory systems and inadequate diagnostic capacities present some of the most intractable and complex barriers to achieving disease-specific targets for HIV, TB and malaria. Inefficiencies in laboratory operations and systems are multi-factorial, arising from weaknesses at all levels of governance/leadership, management, infrastructure, and operations, with siloed, disease-specific infrastructure that exacerbate incapacity to sustainably scale service delivery.

Low- and middle-income countries (LMICs) have demonstrated difficulty in adopting and scaling complex interventions to advance laboratory systems. Insufficient local expertise and competing funding priorities also limit the adoption of best practices. Technical assistance is required to support adoption of robust, well-coordinated interventions, while simultaneously improving key capacities in country to independently advance scaling of services.

(c) Eligible activities

Activities supported through the Strategic Initiative should reinforce or strengthen the core capabilities of the laboratory system, towards developing or scaling integrated laboratory services in line with the investment principles outlined in Section 4 of this document.

All interventions listed in the RSSH/PP Laboratory Systems Module of the Modular Framework are eligible for TA support. The following are examples of grant-funded activities are eligible for Technical Assistance through the Strategic Initiative:

- Reinforcing governance and leadership of the laboratory network.

- Human resources, training, skills development and capacity building for laboratory systems.

- Infrastructure, equipment management systems and laboratory supply chains.

- Laboratory information systems, interoperability and use of digital solutions.

- Quality management systems for all levels of the tiered testing network.

- Specimen transport systems and diagnostic network optimization (DNO).

- Laboratory-based surveillance, genomics, next-generation sequencing, environmental surveillance, integrated human and animal disease surveillance, surveillance under the One Health approach, including antimicrobial resistance (AMR).

(d) Planning process

The overall planning process indicated below is dependent on the timelines for development and submission of the GC7 Funding Request.

	Activity	Timeline	Stakeholders involved
1	Develop draft GC7 funding request	Q1-Q2 2023 (dependent on FR submission window)	**Responsible**: Country Team, CCM **Involved**: National Stakeholders **Consulted**: Lab Advisor, RSSH Focal Point
2	Define eligible grant-funded activities in need of TA	Q2-Q3 2023	**Responsible**: Country Team **Involved**: National Stakeholders **Consulted**: Lab Advisor, RSSH Focal Point
3	Establish Terms of Reference (TORs) for TA	Q3 2023	**Responsible**: Country Team, Lab Directorate/ Technical Working Group **Involved**: Lab Advisor, ILSS Catalytic Initiative Project Manager **Consulted**: RSSH Focal Point, Global Fund Partners
4	Solicit TA Providers to commit to undertake TA activities	Q3-Q4 2023	**Responsible**: ILSS Catalytic Initiative Project Manager **Involved**: Lab Advisor, Country Team, National Stakeholders
	GC7 Grant Start Date		
5	Open formal RFP to contract TA provider	GC7 Grant Start Date (estimated January 2024)	**Responsible**: Project Manager **Involved**: Lab Advisor, Country Team
6	Establish a detailed workplan with implementation timelines	Q1 2024	**Responsible**: Country Team **Involved**: National Stakeholders, Lab Advisor, ILSS Catalytic Initiative Project Manager **Consulted**: RSSH Focal Point, Global Fund Partners
7	Establish a schedule for release of grant funds synchronized to TA workplan	Q1 2024	**Responsible**: Country Team **Involved**: Principal Recipient, TA Provider, Lab Advisor, ILSS Catalytic Initiative Project Manager

5.2   ILSS Strategic Initiative – Implementation

Implementation of the ILSS Strategic Initiative begins in January 2024, with launch of Grant Cycle 7. Activities under the Strategic Initiative cannot start prior to the beginning of GC7.

(a)   Contracting a TA provider

Support through the Strategic Initiative is managed at the Global Fund Secretariat level, by contracting the Technical Assistance (TA) provider to support implementation managed through the Global Fund's Request for Proposal (RFP) process. Eligible TA providers submit bids to implement Strategic Initiative activities and are pre-qualified under the Integrated Laboratory Systems Strengthening Technical Assistance Pool (Lab TA Pool). Technical assistance providers are listed in Annex 3.

The engaged TA providers have demonstrated their technical capabilities to undertake the defined work, ability to deploy experts to the country, and align with value for money principles. Technical assistance should maximize opportunities for knowledge transfer and encourage capacity building, facilitated by continuous presence of the provider in the country. Remote TA, or 'fly-in fly-out' TA is actively discouraged and will be accepted only where alternatives cannot be sourced.

(b)   Catalyzing grant funds

Technical assistance is made available to catalyze the implementation of interventions and activities funding through core country grants, thereby maximizing potential impacts and accelerating adoption of best practices and innovative solutions. To achieve this objective, Principal Recipients are strongly encouraged to understand the linkage between the budgeted activities/interventions, any related procurement of commodities, and the anticipated TA support to facilitate implementation. Timely release and disbursement of funds from the PR to the implementing agencies is essential and must be well coordinated with the scheduling of in-country TA support. the Global Fund Country Team and Principal Recipients are requested to support the coordinated planning of required disbursements and procurement and to synchronize with the agreed TA workplan.

(c)   Duration of technical assistance

Duration of TA will vary based on the complexity of tasks and expected deliverables, as well as the cost quoted by TA providers to complete the expected deliverables. The expected length of TA is 12-24 months, beginning in Q1 2024 at the earliest.

(d)   Progress monitoring and deliverables

Implementation progress is monitored by the ILSS Catalytic Initiative Project Manager, with support of the Lab Advisor assigned to the country and focal point assigned from the Country Team. The TA implementer reports on progress of activities against the agreed workplan to

the Catalytic Initiative Project Manager and Lab Advisor in monthly meetings, organized by the Catalytic Initiative Project Manager.

Other progress monitoring mechanisms include:

- Quarterly narrative and financial reports submitted by the TA provider.

- Invitation of the Country Team to quarterly meetings.

- Participation of the TA provider in other regular working groups and communication forums (e.g. monthly update calls between CTs and PRs).

Deliverables agreed upon in the contracting stage are submitted to the Global Fund for review, based on the contract disbursement schedule. The TA provider is paid only upon satisfactory completion of deliverables. All deliverables must be reviewed by the Lab Advisor, and a member of the Country Team or the Catalytic Initiative Project Manager, with feedback recorded in the Milestones Report.

(e) Measuring impact

The contracted TA provider may be required to support development of a Performance Framework (PF) to monitor inputs, activities and outputs. Performance Framework support is dependent on the complexity of planned activities, availability of alternative information sources, and need for programmatic oversight to mitigate implementation risk.

An external evaluator will be contracted to assess whether TA providers have achieved their deliverables, and the extent to which their work contributed to programmatic outputs and outcomes. The evaluator will also provide insight over the quantitative and qualitative measures of success of implemented activities. External evaluation is expected to define how implementation of interventions can be further improved. Potential improvements could be to maximize scalable (if applicable) and sustainable outputs and outcomes of similar TA projects in the future. Countries selected to be included in this evaluation will be notified by the Catalytic Initiative Project Manager. The respective Country Teams will then request support to secure participation of key stakeholders in country to permit the evaluator to operate in the country, and permit collection of primary data.

6. Matching Funds

This section provides information and guidance to countries eligible for **Matching Funds** under the Integrated Laboratory Systems Strengthening Catalytic Initiative.

6.1 Matching Funds - Planning

Countries have been notified of their eligibility to access support delivered through the ILSS Catalytic Initiative in their 2023-2025 allocation letters, delivered in December 2022. Allocation letters detail the programmatic and access conditions required to be met to access the funds.

(a)   Investment principle

Matching Funds aim to complement country allocations in delivering the Global Fund Strategy. Where catalytic change is key to accelerating responses through the country allocations, these limited, additive resources can incentivize increased resources, innovation and prioritization, leveraging the core investments defined in HIV, TB, malaria and RSSH grants.

Matching Funds under the ILSS Catalytic Initiative are intended to incentivize direct investment in cross-cutting, integrated laboratory systems where such investments would otherwise not be prioritized, or where disease-specific solutions would be adopted. The primary objective of investing in this manner is to encourage the uptake of best practices and innovative solutions in integrated lab systems strengthening, to create an environment for long-term, sustained investment from both domestic and donor funds.

Applicants for Matching Funds are required to include relevant, appropriate interventions funded by both the country allocation and Matching Funds in their funding request to the Global Fund. See the Global Fund OPN in the [Resources](#) section of this document for more information.

(b) Eligible activities

The investment focus of Integrated Laboratory Systems Strengthening Matching Funds is within three overall focus areas, described below. Activities are not required to be selected from a single category; multiple categories of activities and interventions may be prioritized.

i.   Scaling of network coverage and rapid response

Scaling of network coverage and rapid response includes activities contributing to expansion of services to further decentralize laboratory service delivery, reducing barriers to access, improving timeliness of diagnostic services, driving resource efficiency, and improving patient outcomes.

Interventions in the Modular Framework eligible for support include:

- RSSH/PP: National laboratory governance and management structures.
- RSSH/PP: Specimen referral and transport system.
- RSSH/PP: Network optimization and geospatial analysis.
- RSSH/PP: Laboratory supply chain systems.
- RSSH/PP: Laboratory based surveillance.

The following are examples of activities enabling improved network coverage and rapid response:

- Organization of the tiered laboratory network, including governance, coordination and management of the integrated system, establishment of an Essential Diagnostics List (EDL).
- Establishment and scaling of a tier-specific basic testing package; improvement of accessibility of laboratory services to cover a minimum 80% of the population at a rate of 1 facility/100,000 population in all districts.
- Mapping of the laboratory network, including geospatial analysis, diagnostic network optimization (DNO), implementation of optimized scenario of DNO.
- Scaling the specimen referral network to all districts; establishment of tracking mechanisms for samples from collection to the laboratory and results return.
- Private sector contracting to undertake specimen transport
- Procurement of sequence analyzers and accessory laboratory equipment for core sequencing facilities to support sequencing for multiple pathogens.
- Establishment of genomic surveillance strategic plans, including integration of genomic surveillance sample collection into the existing national and/or regional sample referral systems.

ii. Systems intelligence, data science and system monitoring

Enhancing data-driven and evidence-based decision-making in the management, scaling and operation of the laboratory system is driven by investment in systems intelligence, data science and system monitoring.

Interventions in the Modular Framework eligible for support include:

- RSSH/PP: Laboratory Information Systems.

The following are examples of activities contributing to improved system oversight:

- Training, human resource capacity building to enable statistical data to be reported, analyzed and used for decision-making purposes and shared.
- Establishment of integrated laboratory information system (LIS), deployment to laboratories and training for laboratory staff on use of LIS and other tools.

- Development, deployment and maintenance of data interoperability tools to support connectivity of LIS to LMIS, health management information system (HMIS), centralized data repositories and other critical digital infrastructure.

- Establishment, scaling and maintenance of critical data systems, repositories, warehouses, connectivity and related infrastructure.

- Development of digital tools to track samples, return results through innovative solutions (i.e. SMS results return); patient information portals, digital health registers and other digital tools.

- Deployment of electronic systems for reporting of notifiable diseases.

- Development of systems to monitor and forecast supply requirements and procurement of diagnostic commodities.

iii.   Improvement of laboratory infrastructure

Improvement of laboratory infrastructure involves investment in resources and activities that enhance the laboratory facilities and supportive services that enable continuous functioning.

Interventions in the Modular Framework eligible for support include:

- RSSH/PP: Quality management systems and accreditation.

- RSSH/PP: Laboratory supply chain systems.

- RSSH/PP: Biosafety and biosecurity, infrastructure and equipment.

The following are examples of activities contributing to improved laboratory infrastructure:

- Key infrastructure upgrades for existing or new laboratories, including water, electricity, internet; facility enhancement.

- Establishing connectivity for diagnostic analyzers and connectivity to a national database.

- Aligning deployed equipment with the national standardized list of laboratory equipment.

- Establishment, scale-up and management of a maintenance plan for all equipment at all tiers.

- Private sector contracting for in-sourcing of diagnostic capacity.

- Development and scaling of national waste management capabilities.

- Improvement of quality infrastructure, Quality Management Systems, systems for inspecting and licensing laboratories, establishment of national accreditation schemes and accreditation of laboratories.

- Development of site-specific biosafety and biosecurity standard operating procedures (SOPs); pathogen control measures, development of an incident reporting system, upgrading infrastructure including refurbishing facilities to meet biosafety and biosecurity standards.

> **Important**
> Support to scaling infrastructure must be demonstrated to contribute directly to integrated service delivery. Disease-specific infrastructure is out of scope of investment.

(c) Planning process

Matching Funds are incorporated into Global Fund HIV, TB, malaria and RSSH grants. As such the funds are administered by the respective Country Team, using the same planning, grant management and implementation oversight mechanisms outlined in the Operational Policy Note.

In order to operationalize the catalytic Matching Funds for integrated laboratory systems strengthening catalytic priority component, eligible countries can receive technical support through the Integrated Laboratory Systems Strengthening Strategic Initiative. Technical assistance is available to support Matching Funds to secure the impact of the funded activities and interventions.

When developing the GC7 funding request and delineating Matching Funds, the Country Team should:

1. Identify the activity/activities that are the most technically complex to implement or carry the greatest implementation risk.
2. Submit a request to the Lab Catalytic Initiative Project Manager for TA to support the prioritized activities.

Technical assistance procurement follows the procedures outlined in Section 5.1 of this document, with contracting managed at the Secretariat as outlined in Section 5.2.

6.2 Matching Funds – implementation

(a) Implementation arrangements – progress monitoring

Matching Funds are implemented by the recipient country, with the Global Fund Secretariat overseeing implementation through the routine grant implementation and monitoring mechanisms.

Additional progress monitoring mechanisms may be agreed upon with the Country Team to collect information and review progress of implementation. Data requested is limited to

programmatic reporting. Reporting on financial progress is not required unless required by the relevant Operational Policy Note.

(b) Measuring impact

As Matching Funds are incorporated in the grant allocation for the country in scope, implementation and impact should be monitored using the Performance Framework and/or Workplan Tracking Measures relevant to the interventions and activities selected.

In addition to routine grant monitoring, Matching Funds supported through TA may be monitored through a separate Performance Framework, managed by the technical assistance provider. More details on Matching Fund monitoring will be provided at a later date.

7. Resources

Resource	How to use this resource
Global Fund Modular Framework Handbook Pages 38-41	To define the interventions in scope for support in line with the eligible interventions listed in the allocation letter.
RSSH Information Note Section 4.7	To define strategic laboratory systems investment guiding principles, best practices and critical approaches.
Global Repository of Laboratory eTools	To assess available digital laboratory tools that may be procured by the MOH/Laboratory Directorate.
Global Fund Operational Policy Manual OPN on Design and Review of Funding Requests	To access operational guidance on development of funding requests including Matching Funds.
Global Fund Operational Policy Manual OPN on Overseeing Implementation and Monitoring Performance	To review operational guidance and responsibilities of Country Teams in management of Matching Funds.

Annexes

Annex 1: Countries in scope and support

	Scope	Area of Support	Geographies in Scope
Multicountry Grants	Regional	Support to laboratory capacity building and system development	Southern & Eastern Africa
			South-East Asia
Strategic Initiative	National	Technical assistance to support strengthening core laboratory system capabilities	Nigeria
			El Salvador
			Sierra Leone
			DRC
			Guinea-Bissau
			Burundi
			Zambia
			Tanzania
			Cambodia
			Guyana
Matching Funds	National	Scaling of network coverage and rapid response **OR** Systems intelligence, data science and system monitoring **OR** Improvement of laboratory infrastructure	Uganda
			Ghana
			Ethiopia
			Nepal
			Laos
			Zimbabwe
			South Sudan
			Liberia
			Sierra Leone

Annex 2: Matching Fund access and programmatic conditions

Access Conditions	• 1:1 match is required from allocation funds. Domestic resources are not in scope.
	• A maximum of US$2 million may be matched in the RSSH lab systems strengthening module of the Modular Framework.
	• The country must identify the Matching Fund eligible activities that carry the greatest implementation risk to be supported by dedicated TA through the Strategic Initiative component of the GC7 Lab Catalytic Initiative.*
Programmatic Conditions	• Alignment with the integrated Laboratory Systems principles in the RSSH Information Note.
	• 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.
	• Activities must be identified in the National Laboratory Strategic Plan (NLSP) and/or the National Action Plan for Health Security (NAPHS).
	• 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.

Annex 3: Integrated Lab Systems Strengthening Technical Assistance Pool

Agency	Country Headquarters	Number of contracts awarded in GC6
Fondation Mérieux	France	5
Association of Public Health Laboratories (APHL)	USA	4
Chemonics International, Inc	USA	0
WITS Health Consortium (PTY) LTG	South Africa	1
LTS Health Africa (PTY), Ltd	South Africa	0
RARS (Réseau Africain de Recherche sur le SIDA)/ IRESSEF (Institut de Recherche en Santé, de Surveillance, Epidémiologie, et de Formation)	Senegal	3
Foundation for Innovative New Diagnostics (FIND)	Switzerland	2
Integrated Quality Laboratory Services (IQLS)	France	1
African Society for Laboratory Medicine (ASLM)	Ethiopia	3
Medical Access Uganda, Ltd (MAU)	Uganda	0
Global Agency for Health Logistics and Consultancies (GAHLC)	Uganda	2
Clinton Health Access Initiative (CHAI)	USA	2
Datos BV / KIT Royal Tropical Institute	Netherlands	1
US Pharmacopeia (USP)	USA	0
A Global Healthcare Public Foundation (AGHPF)	Uganda	0
Clinical and Laboratory Standards Institute (CLSI)	USA	0
PATH	USA	0

Annex 4: Programmatic indicators

RSSH/PP: Laboratory Systems (including national and peripheral)		
Coverage	RSSH/PP LAB-1	Percentage of laboratories accredited according to ISO15189 standard or achieving at least four stars towards accreditation or two-star incremental improvement.
Coverage	RSSH/PP LAB-2	Percentage of molecular diagnostic analyzers achieving at least 85% functionality (ability to test samples) during the reporting period.
Coverage	RSSH/PP LAB-3	Percentage of laboratories successfully participating in external quality assurance (EQA) or proficiency testing (PT) schemes.
Coverage	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.
Coverage	RSSH/PP LAB-5	Percentage of health facilities that have an appropriate set of diagnostics for their healthcare facility level, based on the WHO's model list of essential in vitro diagnostics (EDL 3).

Integrated Laboratory Systems Strengthening in LMICs

Context

Effective and proactive disease surveillance requires a **functional, decentralized laboratory system** to detect pathogens in a timely and accurate manner

Without addressing laboratory system shortfalls, health systems remain vulnerable and ill-equipped to **safeguard local and global health security**

Barriers

Gaps assessed at country/regional-level

- **Shortage in skilled workforce** to conduct testing, analyse data, or drive scale up
- **Siloed investments** in disease-specific lab systems threaten system functionality, efficiency, and service delivery
- **Lab information systems** are often not integrated and lack the coverage necessary to generate representative insights
- **Data literacy and data science capabilities** at the national level are inadequate to drive cooperation, integration, system advancement and service delivery
- **Strengthened global and regional mechanisms** are required to improve coordination and governance

Acceleration Levers

People

Strengthen workforce development to fill skill gaps and empower future lab leaders in countries

Capacity building, mentorship opportunities, peer-to-peer learning

Regional Collaboration

Enhance regional capacities and foster multi-national resource mobilization

Regional quality assurance, accreditation, workforce communities of practice and information sharing programs

Innovative approaches catalysed

Connected and strengthened ecosystem

Data

Establish, scale and integrate critical data systems in countries

Lab Information Systems (LIS), data warehouses, monitoring dashboards, interoperability to HMIS, geospatial mapping and network optimization

Process

Support advancement of laboratory governance and processes in countries

Laboratory system governance, centralized system-level decision-making, enhancing procurement of diagnostic technologies, engaging non-state sector and adopting proven innovative technologies

Target Outcomes

Leveraging $35–48m in additional funding, 20-25 countries in Africa, Asia and Latin America advance in lab systems readiness and capability ratings to detect and respond to health threats of pandemic potential

Through data-informed approaches, increased quality, timeliness, and linkage of laboratory systems in LMICs

Goals

For communities: lives saved and livelihoods protected due to accessible and timely diagnostics

For countries: improved resilience of health services delivery as able to address both pandemic and endemic diseases

For the economy: cost savings as ability to detect and respond to existing and new health threats swiftly and effectively

For global health: advancements in essential health services delivery protected while addressing emerging infections

Delivery Mechanisms

Multicountry Grants

Grants administered by regional partners to address regional/cross-cutting issues and enhance national capacities

Matching Funds

Matching national funding to incentivize laboratory systems investments

Strategic Initiative

Country-demand driven technical assistance to support grant-funded activities and accelerate impact