2023-2025 Catalytic Investments Proposals

Supporting document to GF/B47/04: Catalytic Investments for the 2023-2025 Allocation Period

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2023-2025 Catalytic Investments Proposals

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Please note: Any budget breakdowns noted in the catalytic investment proposals are indicative and subject to change based on available funding.

HIV Incidence Reduction

HIV Incidence Reduction	
Strategy goal: End AIDS	**Recommended modalities:** Matching Funds (MF), Strategic Initiative (SI), Multi-Country approaches (MC)
Strategy's 10 changes: Incidence Reduction	

I.

Description

Progress on HIV incidence reduction has been hindered by several factors including, but not limited to, insufficient resources, poor prioritization, poor treatment access, low coverage and a wide variation in quality and outcomes of HIV prevention programs. Poor access to services, stigma and discrimination and human rights violations, as well as policy barriers affect the scale-up of targeted prevention and testing (and treatment) programs for key populations (KP), Adolescent Girls and Young Women (AGYW) and their respective sexual partners.

A range of new HIV prevention options such as long-acting PrEP, self-testing, virtual service delivery and new digital modalities offer possibilities to reach KPs, AGYW and their sexual partners with tailored HIV prevention approaches. Catalytic investments will be directed to program adaptations and greater differentiation of service delivery to improve access to services and reduce inequity.

This catalytic funding, comprised of MF, SI and MC, will accelerate the following Global Fund Strategy 2023-2028 sub-objectives: closing prevention gaps for people at high risk of HIV infection, accelerating access to and use of new HIV prevention options, and evolving and expanding the range of platforms for access to and delivery of people-centered HIV prevention:

HIV Incidence Reduction catalytic funding objectives:

- Catalyze progress in delivering primary HIV prevention outcomes (increased use of condoms, PrEP, harm reduction, VMMC, and related health communication to improve access to and use of HIV prevention options, as specified in the Global Fund Prevention Results Framework) in highly vulnerable populations (KP/AGYW/SP) to reduce unmet HIV prevention needs in specific geographies.
- Catalyze progress in delivering HIV prevention outcomes through new non-health facility and community delivery channels (including virtual) to highly vulnerable populations (KP/AGYW/SP) through integration, innovation, contracting and targeted demand creation.
- Ensure implementation of quality standards for HIV prevention services and/or implementation of policy changes support expanded access, coverage or quality of services for KP/AGYW/SP (e.g., lay providers, community service delivery, introducing harm reduction services for PWID, task shifting, over the counter availability of prevention options or other low threshold non-facility provision, HIV prevention services in SRH service platforms or other models for better prevention delivery).

Interventions will be delivered through three modalities:

How	*What*
MF	Catalyze HIV prevention outcomes for priority populations, interventions and locations (e.g., community-based/community-led service delivery platforms, sexual and reproductive health platforms, along with self-testing, self-care models and addressing lack of access to PrEP).
MC	Contribute to the sustainability and impact of evidence informed HIV programs for key populations. Focus on addressing bottlenecks and challenges impeding sustainable and high impact HIV responses for these communities via support for budget advocacy, data and evidence gathering and analysis, community systems strengthening, removing human rights related barriers in access to services, community-based monitoring, social accountability and strategic partnerships.
SI	Tailored implementation support to expand the objectives and impact of existing catalytic investments in KP, AGYW, DSD, HIVST and condom programming, and to expand the focus to address the need for improved PrEP access.

Rationale
In 2020, approximately 1.5 million people were newly infected with HIV. UNAIDS estimate that key populations, namely sex workers and their clients, gay men and other men who have sex with men, people who inject drugs, transgender people, people in prison and detention and the sexual partners of these populations accounted for 65% of these new HIV infections (93% of new HIV infections outside of sub-Saharan Africa, and 39% of new HIV infections in sub-Saharan Africa). In sub-Saharan Africa, women and girls are disproportionately vulnerable to HIV infection and accounted for 63% of all new HIV infections in 2020. Global Prevention Coalition (GPC) data and UNAIDS special analysis (2020) point to huge coverage gaps in HIV prevention programs for KPs/AGYW/SP in key countries. Global Fund investment in HIV prevention activities for KPs across portfolios is estimated at 7.2% - 8.5% of the overall HIV allocation for the 2020-2022 allocation period, below the Global Fund's 10% target (KPI5a[1]). The target for countries which monitor and report on coverage of a package of services for at least two KPs (KPI2b) was also not achieved due to lack of investment and prioritization and/or local capacity to produce quality and timely population size estimates. In the same period, there was a drop of 9% in performance against the target on coverage of KP services (KPI5c) exacerbated by COVID-19 and responses to COVID-19. The Global Fund Strategy 2023-2028 commits to closing these gaps in HIV prevention, improving access to new and existing prevention options, widening the range of service delivery platforms for HIV prevention, and addressing human rights, structural and policy barriers to HIV prevention. Remarkable gains have been made in the past five years in scaling up HIV testing and treatment services and in preventing AIDS-related deaths. Many countries have reached the 90–90–90 HIV testing and treatment targets. However, inequities continue to affect KP/AGYW/SP access to differentiated prevention, testing and treatment services. *What is the evidence of the effectiveness of such interventions?* Key Populations MF (2017-2019 and 2020-2022 allocation periods) contributed to an increase in investment in KP programs by approximately 20%. Investment increased from US$113 million in the 2017-2019 allocation period to US$190 million in the 2020-2022 allocation period, representing 7% of the HIV allocation in the 2017-2019 allocation period and 11% in the 2020-2022 allocation period for nine countries that received MF over two allocation periods. These countries have used the KP MF to pilot and scale up innovations such as self-testing, PrEP, OST (Opioid Substitution Therapy); to improve demand generation and delivery of services by supporting the strengthening of KP-led Civil Society Organizations and KP-led networks; and to catalyze national program scale-up. AGYW MF contributed to performance against targets for HIV prevention package coverage (most countries above 85%). Twelve out of thirteen priority countries now have national AGYW plans. Emerging data from Uganda shows increase in condom use attributable to Global Fund investments. The TERG determined the AGYW SI to be catalytic in a range of ways and that future implementation support should build on the lessons learned and needs identified from it. MC aim to contribute to the sustainability of HIV programs for KPs. They have been a catalytic investment priority for the 2017-2019 and 2020-2022 allocation periods. The regions of focus in both cycles include Eastern Europe and Central Asia, Latin America, the Caribbean, South-East Asia (non-high impact), and the Middle East and North Africa where availability of external financing, including via the Global Fund, is decreasing and domestic financing limited or non-existent for key population programs.

[1] KPI 5a: HIV grant investment in prevention for key populations

For the AGYW, DSD and Condom Programming SI, see “Progress to Date” section.

Funding

HIV prevention is not sufficiently prioritized in many countries and country allocations. HIV prevention investment is hampered by a range of characteristics that make investment choices more complex. These include:

- HIV prevention programs require the layering of multiple interventions and approaches. They also require tailoring to different sub-populations with age- and gender-related considerations, geographies, service delivery structures, policies and legal constraints addressed. In addition, new HIV prevention options are emerging that require programs to adapt and change.
- Human rights and structural barriers affect HIV prevention access. These barriers in turn create additional vulnerabilities.
- HIV prevention programs often operate outside of formal health facility-based systems. Prevention management receives inadequate attention and resources. This includes attention to systems factors, such as weak or dispersed community systems, inadequate strategic information, insufficient attention to last mile supply of prevention commodities and lack of sustainability of community-based/community-led delivery platforms and systems.
- Analysis of existing set aside technical support investments demonstrate low levels of investment in HIV prevention-related technical support, and limited ability for the Global Fund Secretariat to direct these investments. It is likely that most prevention-related technical assistance will be programmed into grants, however it is proposed here under SI funding to allow for agile and responsive support to accelerate the Global Fund’s HIV prevention and innovation ambitions.

To address the under-funding and adaptation needs of HIV prevention programs for priority populations, catalytic funding is proposed to:

- Reduce unmet need for HIV prevention in specific KP/AGYW/SP.
- Drive greater differentiation of service delivery platforms for prevention – taking services out of facilities and into communities as well as into sexual and reproductive health and private sector channels.
- Secure greater investment in HIV prevention programs - directed to priority populations.
- Support implementation, program adaptation, innovation, differentiation of prevention systems including improved last mile supply of key HIV prevention commodities – both new and existing.

The proposal considers an increase in number of countries eligible for KP MF from 13 to 20 with each receiving additional funding depending on the merits and strength of proposed plans for optimization of prevention for KPs and subject to verification and endorsement of intended beneficiaries that they have been engaged and involved in program design.

The proposed AGYW MF will ensure MF are available to the existing cohort of 13 countries.
Applying lessons learned from DSD, Condom Programming and AGYW and TPT SIs, tailored implementation support under the SI will be made available to all countries eligible for KP MF/AGYW MF. Technical partners (including WHO, UNAIDS, UNFPA and other specialist SRH and KP implementers) will be engaged to ensure evidence-based program design and precision in plans – and implementation support will be included with the MF and specified ahead of time. All MF will require a focus on improved HIV prevention-related outcomes. MC investments are critical to catalyze broader domestic commitment and that they also can include non-eligible countries. MC will also intensify focus on improved HIV prevention access for KPs.

- Indicative breakdown of major components:MF: to be integrated in country grants to incentivize improvement in prevention outcomes/prevention intervention delivery/attaining quality standards for prevention for KP/AGYW/SP.
- MC: to strengthen regionally focused prevention programs for KPs. (Geographical focus: MENA, LAC and EECA, and potentially for WCA -regional approaches to KP programming and addressing elimination of vertical transmission). SI: for tailored implementation support to improve the

management of scale, precision and quality of HIV prevention programs for KP/AGYW/SP for improved prevention-related outcomes.

II. Strategic Impact

Potential for increased impact

This priority will contribute to enhanced and underperforming areas, including the areas included under the current KPI 2 HIV Service Delivery, and KPI5a/b/c investment and coverage of services for key populations, which are underperforming or off target.

The priority will contribute to the following areas:

- **Improved access to primary HIV prevention options for key populations, adolescent girls and young women and male sexual partners**
- **Expansion of prevention options available and increased number of low threshold prevention delivery modalities** (focusing on out of facility, community, virtual and private sector delivery channels)
- **Pathways to scale or replication for innovations** proving to deliver prevention outcomes
- **Better measurement of prevention outcomes**

Levers

- Co-financing
- Enhanced Country Dialogue
- Enhanced TRP review
- Investment priorities addressed in the 2023-2025 allocation period guidance/instruments, including HIV Information Note and Allocation letters
- KPIs and targets
- Qualitative adjustment to drive investment
- Strengthened LFA assurance in implementation phase
- Aligned and clarified prevention related implementation support offer from partners for program design and implementation

Catalytic effect

☒ **More**: incentivize increased funding from allocations to close HIV prevention coverage gaps

☒ **New**: initiate novel approaches to HIV prevention challenges: demand creation, virtual service delivery, outcome monitoring

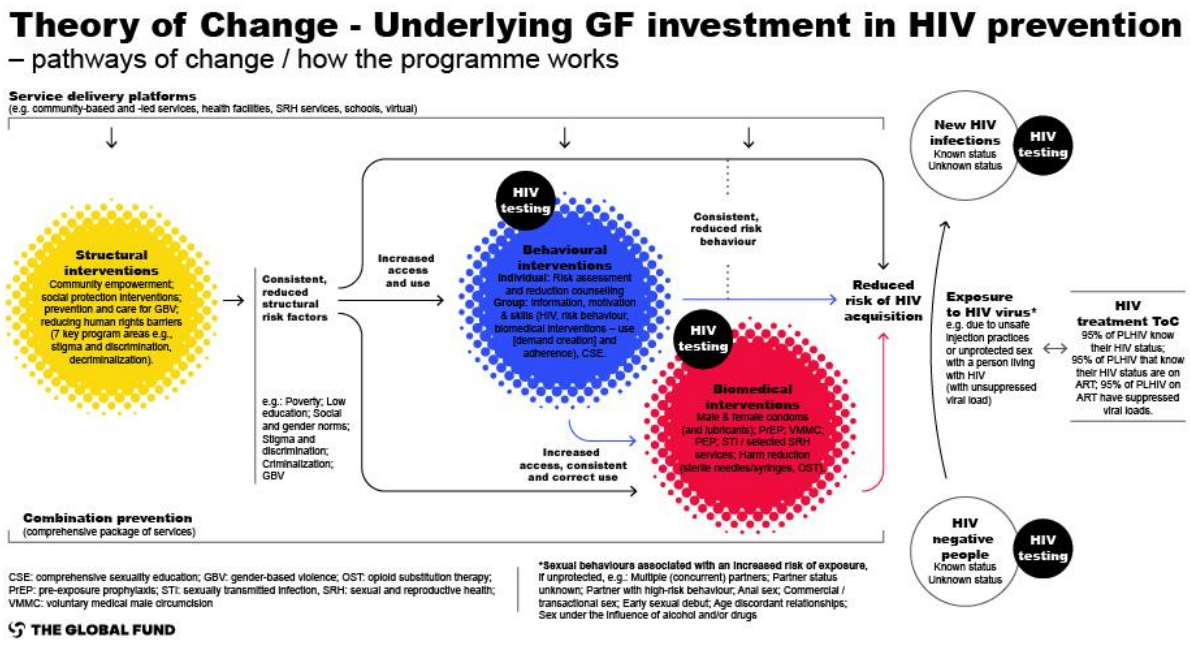
☒ **Improved**: improved investment in a wider range of service delivery platforms for HIV prevention and care, especially community based and SRH (Sexual and Reproductive Health) platforms; and improved investment in HIV ST (Self Testing) modalities, treatment literacy and differentiated treatment approaches

☒ **Faster**: accelerate new HIV prevention product access

Expected outcomes

- Innovation and differentiation of HIV prevention delivery in select countries
- Expanded access to and use of new prevention options by specific populations experiencing high incidence of HIV KPs/AGYW/SP in select countries
- Improved quality of prevention services delivery in select geographies

Theory of change



Risk if not funded
Prevention innovation and differentiation will not be funded for the specific target populations or to increase access to the new (and existing) prevention options in the face of continuing demand to maintain and expand diagnosis and treatment services and decreased fiscal space resulting from COVID-19 and other macro-economic forces and constraints. *What are the direct epidemiological risks if not funded?* Continued rises in new infections in select countries, and in others, insufficient reductions in numbers of new infections. Continued inequity in HIV prevention access and use for KPs/AGYW/SP. All these risks will undermine the Global Fund's HIV incidence reduction objective. *What are the programmatic risks if not funded?* Failure to catalyze investment to address access barriers and to support implementation challenges undermines the Global Fund Strategy 2023-2028 commitments to reduced HIV incidence. Reductions in MF to incentivize AGYW prevention investment risks diminishing existing investments and delaying AGYW implementation plans, along with loss of gains made in current and previous cycles. For KP HIV prevention, risks include lost opportunities to bring innovative approaches to scale, loss of gains achieved over past allocation periods, decrease in prevention coverage targets among KPs, sub-optimal access to HIV-related services among KPs and their sexual partners, lost opportunities to strengthen community systems for HIV prevention, and decrease in demand for HIV prevention, treatment and care services for KPs.

III. Previous Investments

2020-2022 Catalytic Investment	2020-2022 Budget Amount
HIV prevention: AGYW in high prevalence settings (MF/SI); Scaling up community-led key population programs (MF); Condom Programming (MF/SI), Differentiated HIV Service Delivery (SI)	US$201 million

Current implementers
KP MF: KP-led SRs and CBOs SRs working with key populations through Principal Recipient(s) AGYW SI: University of Cape Town; WHO; UNICEF ESARO Condom SI: UNAIDS DSD SI: Global specialist providers (10) national TA partners and technical experts MCG: Regional civil society networks

Current target populations
• KP MF countries: Belarus, Benin, Cameroon, Ghana, Honduras, Indonesia, Jamaica, Kenya, Myanmar, Pakistan, Philippines, Ukraine, Zimbabwe • AGYW MF countries: Botswana, Cameroon, Eswatini, Kenya, Lesotho, Malawi, Mozambique, Namibia, South Africa, Tanzania, Uganda, Zambia and Zimbabwe • MC regions: MENA, Latin America. The Caribbean, EECA (Eastern Europe & Central Asia), South-East Asia • Condom SI countries: Malawi, Mozambique, Uganda, Zambia • DSD SI: 10 countries
Progress to date
KP MF: There are eleven countries with MF integrated into country allocations and programs representing US$47.4 million (of US$50 million) for the 2020-2022 allocation period. Preliminary internal analysis highlights potential catalytic effects including geographical expansion of targeted HIV prevention programs for KPs, expansion of service package offering improved prevention choices for KPs, introduction of service packages for underserved KPs, scaling up differentiated treatment delivery, intensified support for CSS and community empowerment, better use of data for targeted delivery of HIV services for KPs and addressing/mitigating the impact of policy roadblocks to KP program scale-up. **AGYW MF:** Prior to AGYW MF, AGYW priority countries did not have national AGYW plans. Twelve out of thirteen priority countries now have national AGYW plans. AGYW MF contributed to performance against targets for HIV prevention package coverage (most countries above 85%). Emerging data from Uganda shows increase in condom use attributable to Global Fund investments. Additional country outcome data is forthcoming in Q2 2022. **AGYW SI**: This SI is in the first implementation year (2020-2022 allocation period) and as such, the outcomes cannot be reported yet. All three components have been contracted and are being implemented. The TERG Thematic Evaluation on SI determined the AGYW SI is likely to be catalytic in a range of ways. **Condom Programming MF:** US$10 million (2020-2022 allocation period) All four focus countries have invested MF into their condom programs ($2.5 million per country). In three of the four countries the investments have diversified from a focus only on commodities to more 'upstream' program investments, reflecting the objectives of the catalytic investment plans. These include program-related costs such as capacity building, investments in improved last mile supply and human resources. **Condom SI:** US$4.2 million (2020-2022 allocation period) for four countries for technical assistance managed by UNAIDS to four focus countries. Focus on demand creation, supply chain refinements and quality assurance to catalyze sustained increase in condom use amongst priority populations. Specific technical assistance needs have been identified and are currently being addressed. Too early in implementation to report outcomes. **DSD SI:** US$14.5 million (2020-2022 allocation period) for technical assistance, plus coordination by WHO. Ten high-burden countries with largest gaps to first and second 90 targets. TA focus: targeted HIV testing and close the treatment coverage gap among men, key populations, adolescents and children. Improve viral load suppression rates through: • Differentiated testing strategies applied and implemented for priority populations • Client-centered community and facility treatment service delivery models implemented at scale.
Expected evolution
HIV incidence reduction targets for AGYW in all thirteen priority countries are not being met and coverage gaps continue to be significant. However, countries have made gains that are worth protecting. Coverage gaps need to be closed, and new opportunities need to serve AGYW and their sexual partners. This underlines the need to catalyze new program approaches, platforms, and products. Implementation support for new prevention options such as long-acting PrEP and improved HIV prevention/SRH integration are critical priorities that require shifts and changes. Catalytic funding will be important to support these shifts.

The continuation and evolution of MF for KPs is a priority for catalytic funding. HIV incidence reduction targets for KPs are not being met in many countries. The Global Fund is not meeting its KPI5 KP investment and KP coverage targets, whilst KPs are prioritized in the new Strategy. The need to catalyze investment in KP programs continues.

The Global Fund has limited policy levers to incentivize investment in KPs in LMICs. Financial incentives will continue to drive strategic allocation of resources.

The Global Fund's technical partners have set out some important considerations for the next generation of MF:

- strategic selection of countries based on the Global Fund's comparative advantages and disease burden, in line with GPC priority countries
- introduction of strategic approach to incentivize countries to identify additional resources, for example by a matching condition for domestic financing and/or conditionality for national policy revision to support program scale up
- provision of conditionalities that promote increased amount of MFs in exchange for policy shifts and agreed ambitious service delivery targets
- continued prioritization of community-led, community-based implementers.

IV. Operational Considerations

Set-Aside Modality

☒ Can be integrated in country allocations but would need strong guidance

- Proactive planning: Design clear implementation support plans in priority countries for improved program design and implementation
- Timely coordinated support: Develop a menu of modalities and offers of prevention-related implementation support including those of existing bilateral and multilateral partners for timely quality-assured support
- Expand the pool of expertise and streamline procurement: Solicit and establish a pool of non-traditional providers aligning with CRG and MECA TA pools, to provide more direct options for implementation support. This can be funded from both catalytic funding and grants
- Improve quality: work with partners to develop training for program innovation priorities, create a catalog of quality TORs and quality products
- Enable communities and civil society dialogue, engagement and capacity towards this priority area
- Conduct in-country evaluations and reviews on progress in this priority area
- Track co-financing compliance towards this priority area

Global Fund Comparative advantage

☒ Global Fund is a leader in this priority area

☒ Global Fund has not contributed to this priority area before

The Global Fund is a lead donor in many aspects of HIV prevention investment. The Global Fund is the main donor for harm reduction interventions for PWID, and with PEPFAR is a main donor for other KP and AGYW investments.

The Global Fund's investment in SRH/HIV prevention service delivery is limited and needs to expand to improve the range of HIV prevention and sexual health services for AGYW and KPs.

Global Fund Competency

The Global Fund has demonstrated some significant ability to deliver results in large scale KP prevention programs – in some countries. In addition, the Global Fund has demonstrated significant results in terms of dramatically improved HIV treatment outcomes – for some people. These KP prevention and HIV treatment results need to extend to the countries and people where progress is stalled. The ability to deliver results for large scale AGYW prevention programs is still being tested.

Sustainability

- Integration of greater coverage ambitions and improved attention to high impact interventions are a feature of future grants
- Investment in improved coverage of high impact interventions for improved prevention outcomes leads to stronger value for money investments and greater impact
- Increased value for money from HIV prevention investments lead to improved sustainability of HIV prevention programs

End TB: Accelerate progress to End TB

End TB: Accelerate progress to End TB	
Strategy goal: End TB	**Recommended modalities:** Matching Funds (MF) and Strategic Initiative (SI)
Strategy's 10 changes: Incidence reduction	

I. Proposal

Description

Catalytic investments (CIs) will be used to accelerate progress to end TB by 2030. Demand-based, high quality technical assistance to countries will be supported through the SI, while MFs will be used to incentivize and catalyze country grant allocations towards prioritized and impactful interventions to decrease incidence and mortality. Multi-Country approaches (MC) will be discontinued and mainstreamed through country allocations.

The proposed focus areas and interventions are directly linked to the Global Fund Strategy 2023-2028 key changes, particularly incidence reduction, deployment of new tools and innovations, health equity, people-centered care, and community-based service delivery.

1.Find and successfully treat the missing people with DS-TB and DR-TB Matching Fund

- Equitable access to TB services with focus on key and vulnerable groups and hard-to reach populations
- Early and accurate diagnosis including through active case finding deploying new digital x-ray with computer aided detection (CAD)/artificial intelligence (AI) software for TB screening and other tools
- Universal use of rapid diagnostics and drug-susceptibility testing at the time of TB diagnosis, linked to appropriate oral treatment regimens
- Implement innovative private sector engagement models in countries with a large or emerging private sector, including insurance and contracting/outsourcing
- Decentralized, community-based, person-centered care through community engagement and service delivery and community outreach activities
- Support and advocate for country uptake of TB social protection policies to reduce the catastrophic costs associated with accessing and completing TB care.
- Adapt TB programming to respond to COVID-19 impacts, promote contingency planning for pandemic preparedness & response

2. Scale-up TB prevention - Matching Fund

- Increase TB preventive treatment (TPT) coverage among ALL household contacts, children and people living with HIV (PLHIV)
- Improve access to testing for TB infection among those who need it
- Integrate provision for TPT in active case finding and contact tracing activities, including "test and treat" approaches and early access to TPT
- Support innovations in airborne infection prevention and control (IPC)
- Support actions to mitigate TB risk factors, e.g., undernutrition and comorbidities
- Engage private sector, communities and other stakeholders in TPT and IPC activities

- Rapid deployment of vaccines, once they are approved

3. **Country readiness for innovation and quality TB programming - Matching Fund**

- Rapidly adopt and deploy at scale new tools (screening tools, diagnostics, drugs, vaccine) and other innovations including digital systems to support along TB care cascade and service delivery innovations, as they become available
- Capacity building for NTP stewardship and coordination, to support more rapid uptake and transition of latest evidence-based guidance (WHO guidance) to ensure quality TB services are offered to all, including by expanding TB partners/stakeholders.
- Support countries to incorporate quality of services in TB programming
- Conduct cascade analysis along pathway of care
- Manage comorbidities, adverse drug events, other risk factors for poor treatment outcomes as part of providing people-centered Integrated Systems for Health

Rationale

In 2020, case notification declined by 18% among DS-TB and by 22% among DR-TB patients, TB deaths increased for the first time in over a decade, and TB preventive treatment fell by 21%. Only about one-third of people estimated with DR-TB received treatment and the number of missing people with TB increased to 4 million (up from 3 million in the previous year). Renewed effort is needed to offset the disproportionate impact of COVID-19 on TB and get back on track to meet the 2030 targets.

Through catalytic investments (CIs), the Global Fund can influence country programs to be bold and ambitious to reduce incidence and mortality despite the recent setbacks due to COVID-19. Being the largest international funder of TB in low and middle-income countries, the CI support will turbocharge and catalyze key innovations in critical areas of TB care. The SI will provide TA on all the areas in the MFs.

CIs will support the linkage of case finding activities to TB prevention activities supporting early diagnosis and scale up of prevention in contacts to break the transmission cycle and reduce incidence and mortality. MFs can catalyze country investment in offering early access to quality diagnosis and treatment, country preparedness for rapid deployment, at-scale of new tools and innovation such as rapid diagnostics, LF-LAM, 10-colour GeneXpert module, CAD/AI software, ultraportable digital X-rays, and shorter oral treatment regimens for all forms of TB, including the use of new child-friendly formulations. As an example, the proportion of people tested with rapid diagnostics at the time of diagnosis in 2020 was 33%. The CI will prioritize early diagnosis, linkage to care and other interventions to treat TB patients successfully thereby addressing the issue of high TB mortality.

CIs offer a more agile and quicker mechanism than country allocations to bring new products for use and early adoption in countries, particularly those expected during the 2023-2025 allocation period. CIs will support countries to ensure that TB services delivered by Global Fund supported programs are people centered, equitable, safe, effective, affordable, align to the latest recommendations and available to the right time to all patients who need them.

The current catalytic investment on finding the missing people with TB has garnered global attention to the issue and contributed to the political declaration and targets of the UN high level meeting (UNHLM) on TB. Progress on finding the missing people with TB improved and the UNHLM target for case finding was achieved in 2018 and over 1 million additional people with TB were diagnosed and treated in 2019 compared to the baseline in 2015. This CI will build upon the current, successful CI to enhance and address the underperformance aggravated by COVID-19 and earmark funds for Global Fund priority areas - new tools & innovations, TB prevention, and quality services to reduce TB mortality and incidence. The current CI investment has demonstrated the ability to work in partnership to mobilize attention and actions to find the missing people with TB.

Funding

Globally, TB programs are under-funded. The Global Fund is the main donor accounting for 77% of international TB financing. USAID is the major bilateral donor financing TB projects implemented mainly by non-state actors in 23 USAID priority countries, and some countries have taken World Bank loans to fund TB

programs. Given the impact of COVID-19 on the economy of most high-TB burden countries, the fiscal space for domestic spending on TB and other health priorities will be even more constrained in the coming years.

While overall case finding activities are often prioritized by TB programming, adequate funding, and capacity to implement well-designed, targeted interventions to find the missing people, often among the most marginalized and vulnerable populations is lacking.

Unitaid and other R&D funders are supporting TB pipelines to develop and bring to market new diagnostic, treatment and service delivery innovations during the 2023-2025 allocation period. Funding from CIs will be used to prepare countries for, and support the timely scale up of, new innovations working in close coordination with Sourcing/NextGen to reverse the historically slow scale up and widespread implementation of new innovations in TB. (e.g., bedaquiline, a new TB drug introduced in 2012 has less than 20% of those eligible for the drug receiving it 8 years after it received WHO guidance.) With the new focus on quality services including offering the latest evidence-based care, CI funding will support countries to improve quality throughout the TB care cascade.

For the 2023-25 cycle, MC grants will be discontinued as they would have completed 6-9 years by 2022. Activities that need to be continued will be mainstreamed through country grants and coordinated through SI if needed. TA for DR-TB currently covered through contribution of earmarked funds in country grants will be integrated in the next TB SI to align and integrate all TA support.

II. Strategic Impact

Potential for increased impact

- Finding early and successfully treating the missing people with DS-TB and DR-TB is an area that needs **enhancemen**t to address the **underperformance** aggravated by COVID-19. The focus will not only be in finding missing people but finding them early and ensure prompt treatment especially among DR-TB.
- TB prevention is included as **a new priority are**a to align with the Global Fund Strategy 2023-2028 where it is one of the six sub-objectives for TB and plays a key role in reducing incidence. In the last cycle the focus was only on PLHIV but for the coming cycle this will also include children and all household contacts.
- Improve the quality of TB services across the TB care cascade including management of comorbidities is a **new priority area** and is linked to the need for rapid deployment of new tools and innovations, this will also help reduce high TB mortality.
- The SI will support specialized TA to countries in **prioritized and new areas** of the Global Fund Strategy 2023-2028, and support to shorten the learning curve on adoption of new tools and innovations, design, implement, and monitor interventions; facilitate experience sharing and cross-learnings among countries.
- MF will incentivize countries to **invest in the new and underperforming areas**: equitable access, addressing needs of KVPs and cross border issues, rapid uptake of new tools & innovations, integrated and quality services, and other priority areas in the Global Fund Strategy 2023-2028.

Levers

- **Leveraging the Global Fund's Partnership model**: WHO's role in reviewing evidence/data, publishing rapid communications and recommendations on new TB products; Stop TB's Global Drug Facility in making new diagnostics and drugs available for procurement. Other partners to promote and support implementation of Global Fund priority areas in countries.
- **Global Fund mechanisms:** Global Fund application materials including information notes and technical briefs will present priority areas for Global Fund investment and provide guidance for its inclusion in funding requests, PPM/wambo.org and the Expert Review Panel for Diagnostics (ERPD) to make new quality assured health products available promptly as they are approved.
- Best practices and lessons learned in deploying new tools and innovation will be shared by Global Fund (quarterly TB update) and through partners to promote uptake.
- USAID's Technical Assistance support will be leveraged and complement CI support.

Catalytic Effect

☒ **More**: incentivize increased funding from allocations to priority areas and/or additional funding outside of Global Fund *(through TB MF)*

☒ **New**: initiate new or innovative activities for more efficient and impactful programming *(through TB SI and MF)*

☒ **Improved**: enable more effective use of country allocations and coordinated responses for cross-border contexts *(through TB SI and MF)*

☒ **Faster**: accelerate implementation of specific priorities *(through TB SI and MF)*

CI will incentivize specific activities to find missing people with DS-TB/DR-TB and link with and create demand for the scale up of TB prevention. CI will enable adoption of new tools and innovations faster and at scale and ensure quality of services and improve performance of grants through quality assured TA. Outcomes from CI activities will inform more effective use of country allocations in NFM5 and accelerate progress to End TB. Please refer to section on potential for increased impact and levers.

Expected outcomes

- Improved TB treatment coverage
- Improved TB treatment success rate
- Improved TB preventive treatment coverage

Theory of change

Leveraging Global Fund influence to prioritize and focus on finding and treating the missing hard-to-reach, key and vulnerable people with TB including linking with TB prevention activities, coupled with rapid deployment of new tools & innovations- within a quality TB program will improve treatment coverage and success rate, decrease the number of people with TB infection developing active TB disease, resulting in reduction in TB incidence and mortality.

Risk if not funded

High risk of not finding missing people with TB especially after the COVID-19 pandemic; high risk for TB prevention, country preparedness for new tools and quality assessment.

What are the direct epidemiological risks if not funded (e.g., rising incidence, resurgence, drug resistance)? Needed decline in TB incidence will not be met due to ongoing transmission from undiagnosed DS/DR-TB patients, and from people with TB infection who develop active TB disease. Focus on quality services will contribute to decreasing mortality from TB

What are the programmatic risks if not funded (e.g. deteriorating service delivery, systems)? Low programmatic risk

III. Previous Investments

2020-2022 Catalytic Investment	2020-2022 Budget Amount
Finding the Missing People with TB, including DR-TB and DS-TB + TPT: MF, $150M Targeted TA for Innovative Approaches - Finding the Missing People with TB: SI, $40M	US$204 million

Current implementers

SI implementing partners: WHO and Stop TB Partnership; MF: See countries below

Current target populations

20 priority countries and 5 West and Central Africa (WCA) countries

Asia: Bangladesh, Cambodia, India, Indonesia, Myanmar, Pakistan, Philippines, VietNam.

Africa: Cameroon, Democratic Republic of Congo, Ghana, Ethiopia, Kenya, Mozambique, Nigeria, South Africa, Tanzania, Uganda, Zambia.

EECA: Ukraine

West and Central Africa (WCA): Burkina Faso, Mali, Chad, Congo and Niger

In the next cycle CI can be expanded to additional 10 countries (TBD)

Progress to date

Catalytic investments contributed to the unprecedented scale up of TB services since 2017 with the UNHLM target for case finding achieved in 2018. Over 1 million additional people with TB were diagnosed and treated in 2019 compared to the baseline in 2015. CI contributed to finding the additional million TB cases by 2019.

Progress to date with the current SI:

- 15 countries provided technical support in different technical areas to find and treat the missing people with TB

• Training and capacity building of pre-selected pool of TA providers to ensure quality of technical assistance, conducted in collaboration with implementing technical partners • 'TB quarterly update' developed and disseminated which includes sharing of best practices and innovations and other TB updates • Monitoring and follow up of TB case notifications and key indicators and impact of the COVID-19 pandemic on TB
Expected evolution
MC grants will be discontinued as they have fulfilled their objectives and can be mainstreamed into country grants. SI and MF for finding missing people needs to be continued and expanded to support and incentivize interventions in new priority areas (TB prevention, new tools, and quality of services approaches), or are underperforming/off-track to meet targets (finding the missing people with TB, TPT coverage). Finally, TA for DR-TB will be integrated in the next SI to align and integrate all TA support and reduce transaction costs through a separate mechanism.
IV. Operational Considerations
Set-Aside Modality
☒ Set-aside funds only, otherwise not feasible (TB SI) ☒ Can be integrated in country allocations but would need strong guidance (TB MF) Funding requests include limited or small-scale plans for TB prevention, none or limited requests for specialized international TA on Global Fund priority areas, limited ambition to rapidly adopt and deploy new tools or innovations at scale. *If integrated in country allocations, what policy levers would be needed to effectively implement this priority?* For TB MF, it needs to be conveyed in allocation letters and funding request application materials.
Global Fund Comparative advantage
☒ Global Fund is a leader in this priority area. As the main international financing source for TB, Global Fund is the lead funder of these TB priority areas.
Global Fund Competency
The Global Fund has demonstrated its ability to mobilize key partners and global attention to finding the missing people with TB. As the largest international funder for TB, Global Fund can catalyze the introduction of new tools and innovation which has been slow.
Sustainability
Increasing the demand for TB prevention services in the coming years will increase the likelihood that these interventions will be included in upcoming funding requests and funded through country allocations. Increased demand and political will to end TB, domestic funding and other donor support are other potential sources. In addition, sustainability and efficiency will be important considerations in designing the implementation arrangement for the next SI.

Addressing Biologic Threats in Malaria Case Management in Africa

Addressing Biologic Threats in Malaria Case management in Africa	
Strategy goal: End Malaria	**Recommended modality:** Strategic Initiative (SI)
Strategy's 10 changes: Incidence reduction	
I. Proposal	
Description	
In accordance with the Global Fund Strategy and to accelerate progress towards the 2030 malaria goals, this catalytic investment will support the Malaria sub-objective: **Promote the adoption and implementation of effective innovations to address biologic threats, including parasite drug resistance and diagnostic efficacy.** A multi-pronged approach will be used to address the emergence of	

critical biologic threats in case management with a focus on malaria endemic countries in Africa. The work will be achieved in collaboration with malaria partner initiatives, Global Fund catalytic investments in supply operations, and country grant allocations. Specifically, it is paramount to assess the scope and accelerate measures to address partial artemisinin and partner drug resistance and parasite gene deletions that evade diagnostic detection with commonly used, *hrp2/3* antigen-based RDTS in Africa. The primary areas of focus for this proposal include:

1. Enhance capacity for surveillance and mapping of drug resistance in malaria endemic countries in Africa in complement to malaria partner initiatives including but not limited to support for regional networks.
2. Implementation of strategies to reduce selection pressure of current ACTs:
    a. Landscaping of diversity of ACTs used across all sectors in targeted countries to help guide market interventions
    b. Establish country specific plans to address emerging drug resistance including introduction of diversity of antimalarials.
    c. Market interventions to expand base of affordable ACTs and accelerate the introduction of new products will be achieved through leveraging of the **SO SI, Next Generation Market Shaping.**
3. Intensify surveillance and mapping of *pfhrp2/3* gene deletions in malaria endemic countries in and outside of Africa including enhancing regional capacity for molecular testing and evaluation of surveillance methodologies
4. Accelerate country adoption and access to mRDTs that detect *P. falciparum* with *pfhrp2/3* gene deletions based on ongoing surveillance results.

Rationale

Drug resistance in *P. falciparum* has been and remains one of the greatest threats to malaria control and elimination. The emergence of artemisinin partial resistance in Africa requires a coordinated and proactive response. There are several factors behind the emergence and spread of resistance including selection pressure on one type of drug and lack of access to quality diagnosis and treatment leading to overuse or misuse of antimalarials. Another critical biologic threat is the emergence of *pfhrp2/3* gene deletions in countries in Latin America and the Horn of Africa that evade detection of the most commonly used mRDTs, leading to false negative results.

The approach to be used under this SI builds on experiences from the RAI. The emergence of artemisinin partial resistance in the countries of the Greater Mekong Subregion prompted a coordinated, well-funded response to tackle resistance and limit its spread by significantly lowering the malaria burden making malaria elimination a feasible target. Given the high malaria burden in most of SSA, it is not feasible to address drug resistance in SSA only by targeting elimination. Therefore, the proposed SI will catalyze efforts to identify strategies and accelerate interventions to mitigate the further spread of drug resistance in Africa using a multi-pronged approach to increase surveillance capacity and access to effective antimalarials and diagnostics. This SI's support for market entry of more expensive tools is also based on experience and lessons learned from previous Catalytic Investments for the New Net Project and Net Transition Initiative.

Funding

Although addressing biologic threats in case management is a priority across the malaria partnership, mechanisms to generate evidence and support new and more expensive antimalarials and diagnostics to mitigate resistance and gene deletions are limited. Country allocations are prioritized across core malaria interventions to reach at-risk populations, therefore prohibiting the use of more expensive tools when the full core package cannot be met. Thus, providing the cheapest, currently effective antimalarial is prioritized which has put selection pressure on the different individual drugs. In addition, standardized and systematic surveillance approaches to assess *pfhrp2/3* gene deletions have not been prioritized and there are limited mRDTs options to cost effectively address high prevalence of *pfhrp2/3* gene deletions in affected countries.

Budget estimates were based on current geographic signals of drug resistance and *pfhrp2/3* gene deletions, cost differential between ACTs, and experience from NNP/RAI. The total proposal contains the components as listed below:

1) Improved surveillance and mapping of drug resistance in SSA *(Capacity building, regional networks and technical assistance. Implementation of surveillance in country allocations).*
2) Implementation of strategies to reduce selection pressure on current ACTs*:*
   a. Landscaping of diversity of ACTs used across all sectors in targeted countries to help guide market interventions
   b. Establish and support country specific plans to address emerging drug resistance, including introduction of diversity of antimalarials. Evaluation of operational modalities.
3) Intensify surveillance and mapping of *pfhrp2/3* gene deletions in malaria endemic countries in and outside of Africa including enhancing regional capacity for molecular testing and evaluation of surveillance methodologies (*Capacity building, regional networks for molecular testing, evaluation of methodologies)*
4) Accelerate country adoption and access to mRDTs that detect *P. falciparum* with *pfhrp2/3* gene deletions based on ongoing surveillance results. (*Technical assistance for country specific plans and implementation)*
5) Secretariat costs: Management and oversight of this new SI, requiring cross secretariat/Global Fund and multiple stakeholder coordination. Personnel and travel-related costs for Global Fund Malaria SI staff

II. Strategic Impact

Potential for increased impact

This priority will contribute to the sub objective of *'End Malaria'* goal "Promote the adoption of effective innovations to address biologic threats, including parasite drug resistance and diagnostic efficacy." Preventing the spread of drug resistance through efforts to catalyze the upstream development of products, introducing effective diagnostics in the context of parasite gene deletions and adoption of innovative approaches in malaria case management programs will also accelerate reductions in malaria morbidity and mortality ("incidence reduction").

Levers

We will use the lever "Embed into funding request design" to target specific countries with signals of resistance and gene deletion to implement surveillance activities. The cost of newer ACTs is currently prohibitive within grant allocations to support wide scale implementation across service delivery sectors needed to address drug resistance.

Catalytic effect

☒ **More**: incentivize increased funding from allocations to priority areas and/or additional funding outside of Global Fund

☒ **New**: initiate new or innovative activities for more efficient and impactful programming

☒ **Improved**: enable more effective use of country allocations and coordinated responses for cross-border and regional contexts

☒ **Faster**: accelerate implementation of specific priorities

Health financing and innovative operational approaches will be initiated to accelerate the response to emerging drug resistance in SSA; outcomes will directly inform more effective use of country allocations in the 2023-2025 allocation period; progress to End Malaria will be accelerated by ensuring timely scale up of the most effective tools.

Expected outcomes

- Capacity for drug resistance surveillance and updated evidence via mapping established across SSA (implementation of surveillance through the grants).
- Targeted expansion of alternative ACTs based on country mapping and drug resistance profiles.
- Availability of alternative ACTs in select countries to reduce pressure on partner drugs.
- Market entry of newer antimalarials promoted through sound forecasting and potentially financial levers to support innovation of newer drugs and more suppliers in the market (in collaboration with SO- SI).

Theory of change

Progress against malaria in Africa is accelerated by comprehensively addressing biologic threats in case management including emergence and spread of drug-resistance and parasite gene deletions through enabling data-informed decision in rationale use, availability and affordability of ACTs, achieving access to quality-assured mRDTs appropriate to countries with high prevalence of *pfhrp2/3* gene deletions drugs and introduction of newer ACTs/antimalarials.

Risk if not funded
Given the need to cover essential services in the country allocation, the risk is high that this critical work, requiring additional resources, will not move forward without set aside funds. Preventing further spread of drug resistance and *pfhrp2/3* deletions in a pro-active approach is critical to avoid negative impact on malaria transmission and anticipated increased costs that would be required to address resurgences if drug resistance is not effectively addressed.
III. Operational Considerations
Set-Aside Modality
☒ Set-aside funds only, otherwise not feasible Recent experience includes examples of country programs that were unable to support shift to newer ACTs as a pre-emptive approach to drug resistance due to financial gaps. Implementation for ongoing surveillance can be integrated in country allocations, but evaluation of surveillance methodologies and strengthening regional capacity for molecular analysis requires coordinated approach beyond specific countries.
Global Fund Comparative advantage
☒ Global Fund is a leader in this priority area Drug resistance in SSA is an emerging area of concern and the Global Fund would be a leader in accelerating interventions. The Global Fund has already been leading similar efforts through the RAI, giving us a comparative advantage to implement in other regions and has demonstrated its leadership around insecticide resistance as well through the NTI/NNP. As part of the SI we expect to leverage technical capacity and financial complementarity from other organizations to maximize impact of the interventions.
Global Fund Competency
The rationale and approach follow similar models and builds on lessons learned from the RAI, the New Net Project and Net Transition Initiatives. Upstream support, demand/supply de-risking mechanisms or other advance market incentives and engagement with manufacturers will be under the purview of Supply Operations.
Sustainability
Development and support for the proposed mitigation approaches to emergence of drug resistance and *pfhrp2/3* gene deletions in SSA, will not only build in-country capacity to sustain surveillance but expanding the market for current ACTs will enable increased supplier capacity and resulting affordability of ACTs for mainstream procurement beyond this period.

E2030: Drive towards elimination and facilitate prevention of reestablishment

E2030: Drive towards elimination and facilitate prevention of reestablishment	
Strategy goal: End Malaria	**Recommended modality:** Strategic Initiative (SI)
Strategy's 10 changes: Incidence reduction	
I. Proposal	
Description	
The World Health Organization's (WHO) Global technical strategy for malaria 2016–2030 (GTS) has four goals, two related to reductions in the burden of malaria and two related to elimination and prevention of re-establishment. The elimination goal of the GTS is for 35 countries to eliminate malaria by 2030 with interim milestones set for 2020 (10 countries) and 2025 (another 10 countries). The purpose of the E-2030 SI is to contribute to the achievement of the GTS elimination targets. **Goal:** Reduce malaria transmission in E-2030 countries to contribute to the achievement of the global elimination target, certify eligible countries and prevent re-establishment in all countries that have been certified malaria-free **Objectives:** 1) Accelerate the elimination of malaria transmission in E-2030 countries. 2) Certify countries as malaria-free after three years of zero indigenous cases.	

3) Support all countries certified malaria-free to prevent re-establishment.

Interventions:

1. High-level engagement and networking to strengthen country motivation, knowledge, political will and fiscal commitment to elimination and prevention of re-establishment.
2. Reorientation of malaria programs to elimination through stratification, tailoring interventions at the subnational level, training, resolution of operational bottlenecks and monitoring of progress.
3. Certification of malaria-free status.
4. Prevention of re-establishment of malaria transmission through technical support for stratification, clearance of cross-border transmission foci and integration of malaria into rapid response teams.

Rationale

This SI will facilitate the certification of new countries as malaria-free; support countries that have interrupted transmission to maintain their malaria-free status and gain WHO certification, and support countries that have achieved certification prevent transmission re-establishment.

What is the evidence of the effectiveness of such interventions?

This SI is a continuation of the E2020 (and now E2025) SIs which are the only projects since the end of the Global Malaria Eradication Programme to assist a large group of countries in moving closer to elimination. The lessons learned from the initiative's participating countries has assisted the WHO in sharpening and clarifying its elimination guidance, as well as developing new tools to assist countries in assessing and strengthening their elimination programs and strategies to prevent re-establishment. Countries' certification has greatly helped in generating positive news coverage for malaria during a period when overall progress has stalled.

Funding

This priority cannot be funded through country allocations as it is supporting global and regional committees and processes in addition to the provision of technical assistance to countries. Additionally, part of this technical support is also provided to countries that are not eligible for malaria.

The proposed budget was estimated based on cost of implementation of similar activities under E2020 and E2025. The proposed increase in budget is linked to the bigger pool of countries during the next funding cycle (e.g., all Asia Pacific countries that have set elimination goals for 2030).

Indicative budget breakdown by major components (subject to change)

Summary by Deliverable	%
Accelerate the elimination in countries.	52%
Certify countries as malaria-free	15%
Prevent re-establishment.	18%
Management costs (secretariat resources to manage the SI and implementer's management costs)	15%

II. Strategic Impact

Potential for increased impact

This priority will contribute to underperforming area- reduced incidence- through contributing to 'End Malaria' goal, sub-objective: "Driving towards elimination and facilitate prevention of reestablishment"

Levers

No other levers could be used to implement this priority.

Catalytic effect

☒ **Improved**: enable more effective use of country allocations and coordinated responses for cross-border contexts

☒ **Faster**: accelerate implementation of specific priorities

The purpose of the SI is to achieve the 2030 GTS elimination milestone by providing: increased visibility to countries' efforts to eliminate malaria; specialized technical assistance to identify and resolve technical and operational bottlenecks; opportunities for the exchange of innovative approaches and lessons learned between countries from different regions; support to accelerate the certification process; and support to the development of robust programs to prevent re-establishment of transmission

Expected outcomes

- Technical assistance and program reorientation to enable countries to achieve and sustain malaria case reductions from 2015 baseline and 2022 status.
- Cross-border coordination platforms to prevent malaria reestablishment in countries that eliminated malaria.
- Support participating countries to achieve milestone reductions in the annual number of confirmed malaria cases and timely report progress.
- Facilitate the malaria-free certification of 7 additional 7 countries.
- Provide technical assistance to all certified countries to prevent the re-establishment of malaria transmission.

Theory of change

To achieve elimination and prevent re-establishment, there is a need for continued technical support from the Global Malaria Program to: accelerate progress towards elimination; certify countries as malaria free and support countries to prevent re-establishment. This SI provides funding from the Global Fund to the WHO Malaria Elimination Unit to help the last mile countries with certification of malaria elimination, prevention of reestablishment, highlight malaria successes and maintain the global momentum of malaria elimination.

Risk if not funded

If this SI is not funded as a set-aside, there is a high risk that this does not get funded at all. With direct epidemiological risk: increased risk and resurgence and programmatic risk: delayed certification process; lack of resources to support countries prepare for certification; lack of resources to support countries prevent re-establishment

III. Previous Investments

2020-2022 Catalytic Investment	2020-2022 Budget Amount
E2025	US$8 million

Current implementers

World Health Organization, Global Malaria Program, Elimination Unit

Current target populations

26 countries and territories: Belize, Costa Rica, Dominican Republic, Ecuador, French Guiana, Guatemala, Honduras, Mexico, Panama, Suriname (WHO Region of the Americas); Malaysia, Republic of Korea, Vanuatu (WHO Western Pacific Region); Iran (Islamic Republic of), Saudi Arabia (WHO Eastern Mediterranean Region); Botswana, Cabo Verde, Comoros, Eswatini, São Tome and Principe; South Africa (WHO African Region); and Bhutan; DPR Korea; Nepal; Thailand and Timor-Leste (WHO South-East Asia Region).

Progress to date

- Seven of the 10 countries met the GTS 2020 elimination milestone of reaching zero indigenous case were supported through the E2020: Algeria, Belize, Cabo Verde, China, El Salvador, Islamic Republic of Iran and Malaysia.
- Two Global Fora of 21 E-2020 countries held, to share their lessons learned and experiences related to elimination of malaria
- A 10-member Malaria Elimination Oversight Committee (MEOC) was established and supported to guide elimination strategies and program implementation
- Malaria Elimination Certification Panel established to provide robust and independent recommendations on malaria elimination certification
- China and EL Salvador certified malaria-free
- By June 2021, all 25 countries invited to participate in the E-2025 initiative had formally accepted
- Independent national elimination committees are up and running in 24 countries including 11 E-2025 countries: Belize, Bhutan, Costa Rica, Iran (Islamic Republic of), Malaysia, Nepal, Saudi Arabia, South Africa, Suriname, Thailand and Vanuatu.

Expected evolution

The SI objective, components and key interventions will remain the same.
Global, regional, national and sub-national strategies and coordinated efforts are essential to achieve elimination. The STOP-malaria programme provides dedicated technical assistance for malaria elimination and has improved surveillance in the countries where it has been implemented. Sharing experiences and best practices among countries nearing malaria elimination increases motivation, opens the door to new or

innovative approaches and expands guidance. Certification is a critical motivator for countries to allocate resources to intensify activities, ensure continued surveillance, and prevent re-establishment.
IV. Operational Considerations
Set-Aside Modality
☒ Set-aside funds only, otherwise not feasible This priority cannot be funded through country allocations as it is funding Global and regional committees and processes in addition to provision of technical assistance to countries. Additionally, part of this technical support is also provided to countries that are not eligible for malaria.
Global Fund Comparative advantage
☒ Global Fund is a leader in this priority area Global Fund is the main donor of this activity. During the 2020-2022 allocation period, complementary funding was obtained from the Gates Foundation. With established structures, processes, and relationships with the 25 countries joining the E2025, the Global Fund is able to provide efficient elimination support and build on lessons learned from previous SI implementation.
Global Fund Competency
Previous SIs (E2020, E2025) results and outcomes were achieved with wide acceptance of partners.
Sustainability
The SI focus areas are relevant until 2030, i.e., GTS end date. An increasing number of countries are progressing towards elimination of malaria. WHO certification of malaria elimination in a country requires proof that local transmission of all human malaria parasites has been interrupted and the country has capacity to prevent reestablishment of transmission. Funding through this SI helps identify the areas in each country that need improvement to achieve elimination and prevent the re-establishment of malaria including addressing sustainability and transition.

Malaria Elimination in Southern Africa

Malaria Elimination in Southern Africa	
Strategy goal: End Malaria	**Recommended modalities:** Multi-Country approaches (MC) and Matching Funds (MF)
Strategy's 10 changes: Incidence Reduction	
I. Proposal	
Description	
Accelerate Malaria Elimination in Southern Africa through enhancement and continuation of ongoing regional approaches to reduce cross border transmission, including the MOSASWA and Elimination 8 (E8) MC. Coordinated efforts to enable a regional environment for malaria elimination, including targeting interventions based on cross border dynamics, continued advocacy and resource mobilization including leveraging of private sector resources to accelerate elimination in low transmission countries while moving toward sub national elimination in bordering countries. The primary targeted countries through the two initiatives include Angola, Botswana, Eswatini, Mozambique, Namibia, South Africa, Zambia and Zimbabwe. Elimination 8: Building on lessons learned from previous catalytic investments in the region, the E8 initiative will continue to enable and accelerate towards zero local transmission in the eight countries, with elimination in four frontline countries by 2030. Broad objectives include: • Provide a joint platform for collaboration, strategic programming, pooling of technical resources and surveillance; • Promote country-led implementation of sub-national interventions in cross-border districts in line with the regional elimination agenda and to enhance efficiency and sustainability. MF will be used for Global Fund eligible countries to promote resource mobilization to sustain sub-national interventions; and	

- Facilitate phased introduction of malaria elimination concepts to SADC tier II countries (SADC Windhoek Declaration for E16) through advocacy and political engagement and sharing of tools and platforms.

MOSASWA: Building on lessons learned and progress seen through previous and current catalytic investments, the objectives of this grant are to accelerate the elimination of malaria in Eswatini and South Africa, through targeted and coordinated interventions in Southern Mozambique based on transmission dynamics in the sub-region.

- Implementation of district-led, innovative approaches to IRS delivery in Southern Mozambique.
- Case Management in the elimination context in Eswatini and South Africa in coordination with country strategic plans.
- Continued advocacy for and leveraging of private sector resources to target malaria interventions in southern Mozambique.

Rationale

Malaria transmission extends beyond national borders, and studies on transmission dynamics confirm that malaria is a regional problem in Southern Africa, rather than a national one. Strategic sub-regional interventions and multi-sectoral collaboration are needed to accelerate elimination in low transmission countries such as Botswana, Eswatini, Namibia and Republic of South Africa, which includes reducing the burden in areas that are contributing to ongoing transmission. It is critical at this stage to sustain the gains and build on the impact already achieved via the sub regional approaches supported by the Global Fund. The leveraging of private sector resources, targeting interventions based on sub-regional data analysis and innovative models for service delivery serve as a learning platform to catalyze replication in other regions.

Funding

Cross-border programming is feasible through country allocations, however the regional focus also includes non- eligible Global Fund countries. Additionally, the majority of the resources in the proposed project will be directed to lower burden areas of a high burden country. These areas are not prioritized in Global Fund grants (or with resources from US PMI), as the resources from allocations are most often prioritized first for the highest malaria burden areas.

The proposal includes:

- MOSASWA to maintain the previous levels of catalytic investments which have been successful in leveraging additional private sector and government contributions.
- E8 to support regional coordination, platforms and technical assistance, support for non-Global Fund eligible countries (Botswana, RSA) with a MF component for countries with malaria grants towards national implementation of activities with concurrent resource mobilization for sub-national elimination agenda.

II. Strategic Impact

Potential for increased impact

This priority will contribute to the sub objective of *'End Malaria'* goal to "Support eligible national and regional approaches to accelerate progress toward elimination". Building on established mechanisms used in the sub regional grant to date, the project will continue to expand joint financing efforts, foster effective cross-sector and cross-country collaboration; and promote equitable service delivery for at-risk populations, including communities living in border areas, refugees, and migrant populations.

Levers

Efforts will be made to embed into the funding request design of national grants through MF and to advocate to mobilize support, while recognizing that prioritization of essential services for high burden areas will still pose a challenge to the targeting of necessary resources to achieve the same coordinated approaches and leveraging of resources that can be achieved via the MC.

Catalytic effect

☒ **More**: incentivize increased funding from allocations to priority areas and/or additional funding outside of Global Fund

☒ **New**: initiate new or innovative activities for more efficient and impactful programming

☒ **Improved**: enable more effective use of country allocations and coordinated responses for cross-border contexts

These investments provide the ability to catalyze linkages and synergies between regional and country level resources across the region by leveraging additional funds both from Private Sector and domestic resources. In the current MOSASWA grant, the Bill and Melinda Gates Foundation contributed US$ 20 million, the South African Government committed approximately US$ 3 million towards a co-financing mechanism to support malaria interventions in neighboring southern Mozambique, and Good-Bye Malaria, as part of a public private sector collaboration continues to contribute US$ 4 million to the MOSASWA grant and this level of investment is expected to continue. The MF modality will prompt additional domestic resource mobilization.

The E8 grants devolution through 'pre-shaping' will continue to allocate operational funds as MF to be communicated as part of country allocations. The indicative amounts will be expected to be doubled through matching to increase the envelope and expand malaria elimination districts. The E8 regional component will continue to support the frontline and reservoir countries' regional platform while gradually expanding to self-invited, initially 'observer' countries from the pool of E16, in addition to supporting non eligible country needs.

Expected outcomes

1) Accelerate pre-elimination in higher burden countries via targeting vector control and case management interventions while building district capacity to manage and sustain these interventions.
2) Achieve elimination of malaria in Botswana, Eswatini, Namibia and South Africa through cross-national coordination, harmonization of interventions and sub-national capacity strengthening.
3) Leverage contributions from the private sector and governments to sustain interventions following this funding period.
4) Expand adoption of approaches and interventions to SADC countries more broadly.

Theory of change

Progressively expanding malaria elimination in the lower burden areas of higher burden countries is critical to achieving malaria elimination in the sub-region.

Risk if not funded

Without support to malaria elimination in the sub-region, there remains a risk of regional resurgence and a reversal of the gains to date.

III. Previous Investments

2020-2022 Catalytic Investment	2020-2022 Budget Amount
MOSASWA (MC) E8 (MC)	US$6 million (MOSASWA) US$14 million (E8)

Current implementers

MOSASWA: Lubombo Spatial Development Initiative 2 NPC
Stand-alone MC with Southern Africa Malaria Elimination 8 Initiative (E8) and MC funding also integrated into country grants for Namibia, Eswatini, Mozambique, Zambia and Zimbabwe

Current target populations

General population in low transmission areas, border communities, mobile and migrant populations in the eight countries.

Progress to date

The MOSASWA grant of US$ 27 million (including external/private sector resources) has supported extension of IRS to a total of 18 districts in Southern Mozambique. High coverage in the last two spray rounds was achieved despite the impact of the COVID-19 pandemic using innovative approaches such as mobile wall units for training.

An impact evaluation of the 2017-2019 allocation period grant found that the *"operational coverage for all districts exceeds 85% with high population coverages for all districts except for Matola, where a sub-targeting strategy was deployed. These high coverage values suggest the maximum impact of IRS; A decrease in yearly incidence was found in almost all districts where LSDI2/TTM was sprayed in the 2017-2019 allocation period. A detailed descriptive analysis showed that districts in Gaza and Inhambane had the highest difference between the incidence level when the intervention started and the incidence level 8 months after the intervention had been deployed. Further evaluation is needed to determine the regional impact by analyzing the connectivity and connected impact of the IRS program between countries, as well as within country"*.

E8: 2020-2022 allocation period investments focus on intensifying malaria elimination efforts through a mix of regional and country-focused approaches including investments across case management, vector control, program management and Social and Behavior Change Communication (SBCC) with a focus on migrant and

mobile populations and border communities, and sub-national elimination. The role of the E8 Secretariat has been well defined to capitalize on coordination and advocacy role while implementation shifts to the country and district level. Country-specific funding for frontline countries prioritizes activities with regional impact and strengthening essential interventions for elimination, while funding for second-line countries generally focuses on sub-national elimination efforts in border areas and minimizing cross-border movement of people with active malaria.
Expected evolution
The upcoming 2020-2022 allocation period grant for MOSASWA will explore and promote additional innovative financing mechanisms to mobilize domestic and external resources. For E8, efforts will continue to expand innovative approaches such as the Simon Kunene Awards for sub-national eliminations to reinforce continued attention to sub-national approaches. At the onset of the 2023-2025 allocation period planning, sustainability beyond catalytic funding will be a key objective for both mechanisms.
IV. Operational Considerations
Set-Aside Modality
☒ Set-aside funds only, otherwise not feasible Countries have prioritized coverage of interventions in higher burden areas, to maximize impact and target at risk populations in highest transmission areas. Supra-national collaboration and coordinated efforts has mobilized resources for the lower burden areas. Integration into the grants for sub-national interventions will be achieved through the MF modality. By evolving the singular allocations for E8 countries into MF, the countries will be incentivized to identify opportunities and raise additional funds for sub-national malaria elimination, and the Global Fund-eligible countries will be able to express full demand for malaria elimination activities through the PAAR.
Global Fund Comparative advantage
☒ Global Fund is one of many partners supporting this priority area As indicated above, Global Fund investments in regional elimination have catalyzed additional financial support from BMGF, Good-Bye Malaria, domestic contributions from the South African Government. .
Global Fund Competency
The Global Fund has successfully catalyzed regional elimination efforts through elimination initiatives including MC grants (E8, MOSASWA, RAI) and SIs (E2020, E2025).
Sustainability
Expected integration into country allocations, mobilization of domestic and external resources. At the onset of the 2023-2025 allocation period planning, sustainability beyond catalytic funding will be a key objective for both mechanisms.

Resistance to Artemisinin Initiative (RAI)

Resistance to Artemisinin Initiative (RAI)	
Strategy goal: End Malaria	**Recommended modality:** Multi-Country approaches (MC)
Strategy's 10 changes: Incidence reduction	
I. Proposal	
Description	
The Regional Artemisinin-Resistance Initiative (RAI) was launched in 2013 in response to the emergence of artemisinin-resistant malaria in the Greater Mekong Sub-region (GMS) with the **goal to eliminate all species of malaria from the region by 2030**. The response to eliminate artemisinin resistant parasites is key, as this threat goes beyond the GMS region. It is the largest Global Fund regional grant and the first with the defined goal of disease elimination. The past three RAI grants have operationalized a total of US$585 million and have proven ground-breaking in the fight against malaria in the region, enabling significant and sustainable investments in all dimensions	

of malaria control, aiding a remarkable **87% reduction in reported malaria cases and a 97% reduction in reported malaria deaths between 2010 and 2020**.

RAI funding has been used to purchase key malaria commodities, including vector control, diagnostics and quality-assured drugs; develop surveillance systems; support case management by community health workers and private sector providers; and build resilient and sustainable health and community systems. It has also supported research for innovations to develop and test new tools and interventions, applicable beyond the GMS, as well as a regional database to generate more real-time data, which is of particular use for border areas. **RAI has also incentivized an increase in domestic funding for malaria.**

The RAI4E grant will provide key malaria services to affected communities, while pivoting to an increased focus on the following priority areas with the objective of elimination and leveraging the networks that RAI has built for greater health impact:

- Priority 1: **Innovated accelerated interventions towards elimination**
- Priority 2: **Case-Based Surveillance and Prevention of Reestablishment**
- Priority 3: **Leveraging community malaria workers to enhance basic integrated health services**
- Priority 4: **Radical cure of *P vivax***
- Priority 5. **A data-driven Regional Approach**
- Priority 6. **Strengthening CSO contribution to the health system**
- Priority 7. **Strengthening Pandemic Preparedness and Response**

Rationale

Following the stable reduction in cases, malaria is increasingly concentrated in hard-to-reach areas, including densely forested regions and border and conflict-affected areas; mobile, migrant, ethnic minority and vulnerable populations are particularly affected. In order to continue the efforts for malaria elimination, it is critical to overcome challenges to ensure sufficient coverage of and engagement with these populations.

The situation around antimalarial drug resistance remains fragile, and the remaining parasites in the GMS are the most resistant. **This underscores the need to complete the task of malaria elimination.** Past experiences in other countries have shown that resurgence is possible from a promising near-elimination position. Pyrethroid-resistance has also been reported in all GMS countries; while there is limited evidence of operational significance at present, better insecticide resistance monitoring is needed to mitigate this risk.

COVID-19 has disrupted health services in all GMS countries; the utilization of essential services has dropped likely because of financial barriers, fear of infection and lack of trust in health providers. This underscores the importance of continuing to improve the quality of health care and community engagement and confidence to respond to emergencies. **In RAI4, the community systems will reinforce integrating malaria and non-malaria activities and setting the base workforce for pandemic preparedness and response.**

Political instability in Myanmar has resulted in significant operational challenges, including a volatile security situation, displacement, banking failures and supply chain disruptions, which have complicated the implementation of RAI3E and the COVID-19 Response Mechanism (C19RM), threatening the region's progress towards elimination. The largest share of RAI3E (43%) is allocated to Myanmar and a high level of continued support is critical. **The regional component of RAI has been critical in ensuring continued implementation of the grants in Myanmar.** The huge gains that have been made in fighting malaria in the GMS are fragile and face many challenges. Reducing support to malaria in the GMS at this point would be at significant cost. Multi-drug resistance, the COVID-19 pandemic and political turmoil threaten to reverse progress.

Numerous studies have estimated the economic benefits of malaria elimination at different geographical levels. Completing the job of eliminating malaria in the GMS would generate enormous value for money. **A 2017 study focusing on the GMS region specifically weighted the cost of malaria elimination against the epidemiological and economic costs of inaction.** It calculated the return for each additional dollar

invested in malaria elimination to be more than 5 to 1.[2] A 2019 study focusing specifically on Thailand, compared an elimination scenario with a resurgence scenario and found that every dollar (US$) spent on elimination would potentially result in a return on investment ranging from US$ 2 to US$ 15.[3]

Funding

This priority is insufficiently addressed by other sources of funding. The RAI grant is the main funder of malaria-related activities in the region. Malaria programs in the GMS have been funded through RAI including a catalytic funding (55%) and country allocations (45%) component. The way the grant is constructed allows for funding of regional components (including RAI Steering Committee, Operational Research, Independent Monitoring Panel, Regional Surveillance platform, a sole PR) as well as funding of each country's program. **The regional component has been instrumental to the success of the grant, and critical for continued implementation in Myanmar during the current conflict and will continue to be necessary to achieve the goals of RAI4**. The financial commitment of the Global Fund will continue to complement domestic investment, together with other donors, primarily the Bill and Melinda Gates Foundation (BMGF), the Australian Department of Foreign Affairs and Trade (DFAT) and the United States' President's Malaria Initiative (PMI), noting that BMGF funding has decreased, and PMI's support focuses on Cambodia, Thailand and Myanmar.

How was the proposed budget estimated? Estimates are based on an investment case developed by the RAI Steering Committee, which integrates academia, CSO representatives, and representatives of the malaria partnership. It is based on previous RAI budgets and current needs for interventions encompassing Case management, Vector control, Specific prevention interventions, RSSH, Covid 19 and Program Management.

II. Strategic Impact

Potential for increased impact

This priority will contribute to the sub objective of ***'End Malaria'*** goal by enabling the continued efforts to elimination and prevention of reintroduction in the Greater Mekong Subregion. Lessons learned in this region will contribute to the path to end malaria in other endemic regions.

Levers

Other levers would be using direct country allocations. While this could allow the individual country components to be separately implemented, it would be lacking the instrumental regional component which has been at the core of the success of this grant in previous funding cycles. Furthermore, with the current allocation formula, the funds will be insufficient to cover the current needs. Funding could also be provided through a Stage 1 qualitative adjustment approach which would impact other countries' allocations.

Catalytic effect

☒ **More**: incentivize increased funding from allocations to priority areas and/or additional funding outside of Global Fund

☒ **New**: initiate new or innovative activities for more efficient and impactful programming

☒ **Improved**: enable more effective use of country allocations and coordinated responses for cross-border contexts

☒ **Faster**: accelerate implementation of specific priorities

***Briefly explain*:** The priorities of the RAI4 grant are aligned with the new strategic priorities as detailed in the Description section. Continued work on elimination of P. falciparum and P. vivax and prevention of reintroduction in an area with artemisinin resistance will contribute to efforts made for over a decade. The lessons learned through the RAI on all priorities will serve as evidence for implementation activities in other malaria endemic regions.

Expected outcomes

- Improved implementation of innovative accelerated interventions for elimination, and future integration of these with broader people-centered integrated systems for health.

[2] Shretta R., Silal S., Avanceña A.L.V., Zelman B., Fox K., Baral R., White L. (2017). An investment case for eliminating malaria in the Greater Mekong Subregion. San Francisco: The Global Health Group, University of California, San Francisco.

[3] Sudathip P, Kongkasuriyachai D, Stelmach R, Bisanzio D, Sine J, Sawang S, Kitchakarn S, Sintasath D, Reithinger R. The Investment Case for Malaria Elimination in Thailand: A Cost-Benefit Analysis. Am J Trop Med Hyg. 2019 Jun;100(6):1445-1453. doi: 10.4269/ajtmh.18-0897. PMID: 30994098; PMCID: PMC6553898.

- Support to surveillance systems including monitoring of treatment failure and relapse and dedicated entomological surveillance systems.
- Increased number of integrated community malaria workers integrating services for a range of common conditions, tailored to the epidemiological context.
- Optimize the *P vivax* response and scale-up the provision of radical cure to accelerate elimination (Target 2030).
- Continue to ensure a data-driven regional approach to focus resources where they are most needed.
- Strengthened role of civil society organizations in the health system.
- Strengthen pandemic preparedness and response.

Theory of change

Malaria control and elimination in an area with artemisinin resistance is achieved using a coordinated regional approach. Elements of the approach taken in the GMS, including the robust regional coordination mechanism, could be hugely informative and transferrable to future efforts to eliminate malaria in other regions.

Risk if not funded

High risk. The individual country needs can be partially funded through malaria country allocations. The RSSH and regional component currently require set-aside funds.

What are the direct epidemiological risks if not funded? Lack of funding of the RAI (assuming that countries would receive individual allocations) would stall the progress to ensure P. falciparum elimination and would also hamper the path to P. vivax elimination. This would be a risk to the area due to increases in incidence and potential resurgence of new foci, as well as the spread of drug resistance within and beyond the region.

What are the programmatic risks if not funded? Without the RAI, regional coordination of activities would be hampered, contributing to a deterioration in surveillance and in operational efficiency. Cross-border activities, a main contributor to the current malaria burden would also be severely affected.

III. Previous Investments

2020-2022 Catalytic Investment	2020-2022 Budget Amount
RAI3E grant	US$226,5 million (including from country allocations)

Current implementers

PR: UNOPS

Current target populations

Populations in malaria endemic areas of the 5 GMS countries.

Progress to date

The RAI grants have proven ground-breaking in the fight against malaria in the region. They have enabled significant and sustainable investments in all dimensions of malaria control, aiding a remarkable 87% reduction in reported malaria cases and a 97% reduction in reported malaria deaths between 2010 and 2020, putting the countries on a stable path toward elimination.

In 2010, the GMS reported almost 600,000 cases of malaria and more than 1000 deaths. The RAI grant enabled a rapid scale-up of access to treatments, diagnostic tests, and preventive tools such as insecticide-treated mosquito nets. In 2020, the number of reported cases had fallen to 72,000, and deaths had been cut to 14.

Expected evolution

Continued funding is necessary to ensure prevention of reintroduction in countries reaching the 2023 P. falciparum elimination target as well as to continue the path to P. vivax elimination while using integration of malaria activities to strengthen the health systems.

IV. Operational Considerations

Set-Aside Modality

☒ Set-aside funds only, otherwise not feasible

While the individual country needs can be partially targeted through malaria country allocations, the RSSH and regional component currently require set-aside funds.

Global Fund Comparative advantage

☒ Global Fund is one of many partners supporting this priority area

The financial commitment of the Global Fund will continue to complement domestic investment, together with other donors, essentially the Bill and Melinda Gates Foundation (BMGF), the Australian Department of Foreign Affairs and Trade (DFAT) and the United States' President's Malaria Initiative (PMI).
Global Fund Competency
Under the previous RAI grants the Global Fund has designed and delivered on a financing and operational model that successfully implements malaria control activities nationally and regionally in the GMS.
Sustainability
The successes of the RAI4 grant will contribute to huge health and economic dividends, which can allow for an increase in domestic investment to tackle malaria in the future. Many of the tools developed through the RAI grant contribute not only to improving malaria control, but to overall health systems strengthening.

Regional Coordination and targeted Technical Assistance (RCTA)

Regional Coordination and targeted Technical Assistance (RCTA)	
Strategy goal: End Malaria	**Recommended modality:** Strategic Initiative (SI)
Strategy's 10 changes: Incidence reduction	
I. Proposal	
Description	
Technical assistance is needed to address bottlenecks in malaria-endemic Global Fund eligible countries, including high-burden countries, as well as facilitation of cross-border and sub-regional coordination and collaboration for malaria control and elimination. **Objective**: To increase the quality, coverage, and access of malaria programs through targeted, demand driven, responsive technical assistance and strategic cross-country and regional coordination. **Components:** 1. Strengthen program quality and address key implementation bottlenecks including support to the Alliance of Malaria Prevention (AMP) and support to countries to sustain their malaria control program activities during pandemics and emergencies. 2. Promote equitable responses to malaria through addressing human rights and gender-related barriers and promoting community responses.[4] 3. Coordinate and strengthen regional and cross-border efforts for malaria control and elimination. 4. Facilitate and support funding requests development and grant making activities.	
Rationale	
Addressing implementation bottlenecks to improve coverage and access and support to innovation in products and service delivery are needed to accelerate progress towards the Global Technical Strategy (GTS) targets. Ministries of Health and National Malaria Programs (NMCPs) face multiple challenges to scale up and sustain the progress achieved to end malaria. With limited resources available, it is critical to provide pooled, coordinated technical assistance (TA). This SI intends to address implementation bottlenecks; address human rights, gender and equity related barriers; mitigate the impact of pandemics and emergencies on programs; and improve regional and cross-country coordination. Support for the development of evidence-based funding requests in coordination with partners is required to meet GTS, National and Global Fund's goal to end Malaria.	
Funding	

[4] previously implemented by Human Rights Strategic Initiative – RBM Partnership component

Support for funding requests development sits outside of country allocations. TA to address implementation bottlenecks is not sufficiently funded in country allocations. Managing pooled resources for TA is an efficient, and cost-effective approach and facilitates south-south collaboration. TA is demand driven, with responsiveness, partners' satisfaction and impact being tracked as part of the SIs results framework.
Proposed budget was estimated based on experience of similar activities under the two SIs (RCTA SI and HR SI). The budget to support regional coordination was increased to extend support to Central Africa's Regional Economic Committee (REC)
Indicative budget breakdown by major components (subject to change)

Summary by Component	%
1. Addressing implementation bottlenecks	30
2. To promote equitable responses to malaria	12
3. Support regional and cross-country coordination for malaria control and elimination (four regions compared to three in the 2020-2022 allocation period)	25
4. Support to the development of Funding Request in 2023-2025 allocation period	22
5. Management costs (only implementer's management costs)	11

II. Strategic Impact

Potential for increased impact

This SI responds to the following areas: (1) **reduce malaria incidence:** This SI will help to improve malaria grants' performance by providing targeted technical assistance; and (2) **pandemic response:** by assisting countries to mitigate the impact of current and future pandemics and emergencies

Levers

Country dialogue, funding request development, grant making are critical levers in the integration of evidence informed interventions that act to respond to the implementation bottlenecks and capacity gaps including equity, human rights and gender related challenges specific to the malaria response. The SI is supporting innovation in service delivery models and use of tools such as the malaria matchbox. This SI is complementary to a number of proposed SIs including RSSH, New Nets Community Engagement, and strengthening community systems and responses.

Catalytic effect

☒ **More**: incentivize increased funding from allocations to priority areas and/or additional funding outside of Global Fund

☒ **New**: initiate new or innovative activities for more efficient and impactful programming

☒ **Improved**: enable more effective use of country allocations and coordinated responses for cross-border contexts

☒ **Faster**: accelerate implementation of specific priorities

Through this SI, targeted technical assistance for enhancing strategic planning, addressing implementation issues and removing human rights and gender-related barriers improve grants' performance; accelerate implementation; and enable evidence-based intervention prioritization will be provided. Support for cross-country and regional coordination improves the quality and efficiency of programs.

Expected outcomes

- Strengthened capacity to use available data, to tailor the national malaria responses to the local context.
- Design and implementation of evidence-informed interventions to address human rights, gender, and equity-related barriers to malaria response.
- Strengthened capacities of national malaria programs and TA providers on relevant human rights, gender, and equity barriers as they relate to the malaria context.
- Coordinated and strengthened regional and cross-border collaboration for malaria control and elimination.
- Strengthened funding requests quality and implementation

Theory of change

Activity	*Output*	*Outcome*	*Impact*
1-regional support *2-targeted TA* *3- support evidence informed intervention to address HR, gender and equity related barriers* *4-support to funding requests*	*1-stregthened regional and cross border coordination* *2-improved delivery, increased absorption, improved access and coverage.* *3-up to 80% of the countries targeted through the SI identify who is left behind in the malaria response and develop and implement plans to address these barriers.* *4- timely submission of high-quality, evidence-based prioritized funding requests*	*Improved program performance and quality* *Innovative, ambitious program* *Strengthened coordination*	*Accelerated progress towards ending Malaria* *Efficient use of country allocations* *Coordinated and sustainable cross-country and regional response*

Risk if not funded

Programmatic risk, negative impact on service delivery and grants' performance. The Global Fund, partners and country governments have invested significant resources to evolve global and regional TA mechanisms. These mechanisms address knowledge gaps, facilitate regional approaches, and support strategic decision-making at national levels. CRSPC support has been invaluable to national malaria control programs and covers both funding requests and implementation support.

III. Previous Investments

2020-2022 Catalytic Investment	2020-2022 Budget Amount
(1) Malaria Regional Coordination and targeted Technical Assistance for implementation and elimination (RCTA SI) (2) Human Rights SI Malaria component	US$10 million

Current implementers

RBM Partnership to End Malaria, Country/Regional Support Partner Committee (CRSPC)

Current target populations

Technical support to all Global Fund eligible malaria endemic countries, including high-burden countries and the facilitation of sub-regional coordination and collaboration around malaria control elimination.
The malaria component of the Human Rights SI assists at least 16 eligible countries in establishing partnerships, strengthening capacities, and catalyzing evidence and action on barriers to equitable malaria services and underserved populations.

Progress to date

- To date, the support provided has contributed to the successful implementation of the planned LLIN and IRS campaigns in more than 95% of the countries.
- Countries have managed to minimize the impact of COVID-19 on Malaria grants including support in addressing stock outs.
- In 2021, RBM's pool of technical assistance (TA) providers was expanded to include new CRG-focused consultants, providing short-term TA to support the design and implementation of evidence-informed interventions that address human rights and gender-related barriers to malaria services in up to 27 eligible countries.
- HR SI developed manual and course in 2021, aimed at building capacity to identify vulnerable and underserved populations and associated inequities, and designing programmatic approaches and interventions to address these inequities, including human rights and gender gaps in the context of malaria control and elimination.
- During NFM3 the CRSPC supported 43 eligible countries in their Global Fund malaria funding request development process.

Expected evolution

Improved program performance and quality. Innovative, ambitious program and strengthened coordination at regional and subnational level.
The SI scope has been expanded to include support to countries to address human rights, gender, and equity related barriers to access and coverage (HR SI). CRSPC, being the implementer of both SIs will work closely with the Malaria and CRG (Community Rights & Gender) teams in designing and implementing this SI. The SI intends to be more responsive and coordinated with GMD's needs and priorities.

IV. Operational Considerations
Set-Aside Modality
☒ Set-aside funds only, otherwise not feasible ☒ Can be integrated in country allocations but would need strong guidance The TA component could be integrated in the country allocation, but this will not allow for efficient use and proper prioritization of available resources pooling the TA resources proved to make this pool agile and responsive to programmatic needs
Global Fund Comparative advantage
☒ Global Fund is a leader in this priority area ☒ Global Fund is one of many partners supporting this priority area The Global Fund is the main donor for the targeted technical assistance support. CRSPC receives limited funds from the US (United States) government.
Global Fund Competency
Under this SI, the Global Fund has designed and delivered a model for responsive, high-quality technical assistance to address malaria grants' implementation bottlenecks.
Sustainability
In partnership with GMD (Grant Management Division), technical partners and national malaria programs this SI will co-create and implement a medium-term strategy for sustainable transition to country-led sourcing and financing of TA.

Addressing vector control threats and opportunities: supporting country readiness for an expanding toolbox

Addressing vector control threats and opportunities: supporting country readiness for an expanding toolbox	
Strategy goal: End malaria	**Recommended modality:** Strategic Initiative (SI)
Strategy's 10 changes: Accelerate equitable introduction & scale-up of new tools & innovation	
I. Proposal	
Description	
Accelerate impact against malaria by fast tracking deployment of effective new vector control tools for intensified prevention including in areas of *An. stephensi* distribution. The proposed SI will answer vital operational research questions required to inform adoption of new tools and understand their potential in specific contexts, including areas of *An. stephensi* distribution, and will support smooth market entry. It will be operationalized via a co-financing partnership with Unitaid (pending internal Unitaid approvals), to achieve the following outputs: **Output 1)** Operational and epidemiological evidence built to inform deployment of new vector control tools within the wider malaria control toolbox, focusing on cost-effectiveness, and operational deployment issues and with specific inclusion of areas of *An. stephensi* distribution. National capacity building for related surveillance and evaluations will be integrated into the operationalization approach. **Output 2)** Support smooth market entry by providing market shaping support in particular around demand forecasting.	
Rationale	

New challenges and opportunities in malaria vector control are emerging requiring set aside investment to achieve the catalytic impact that will ensure ramping up of malaria prevention progress. Challenges include, worsening insecticide resistance, residual transmission, invasive vector species, the need to better sustain vector control coverage over 3 year-cycles and on-going limited capacity for critical surveillance and evaluation work, are accompanied by the opportunities of a diversifying vector control tool box, including tools that may be recommended for use together rather than individually, and may have particular value in areas of the invasive *An. stephensi*. A number of innovative and unique tools are currently being evaluated for a possible WHO recommendation. These include spatial repellents and attractive targeted sugar baits (ATSB), ivermectin and eaves tubes, amongst others. WHO recommendation is possible for some of these tools mid-2025. These tools are entirely innovative in the vector control space and come with unique challenges for market entry but have the potential to be highly cost-effective and impactful additions to malaria vector control, there is particular hope that some of these tools will be more effective options than existing tools for control of malaria in urban and peri-urban areas including where *An. stephensi* is a vector.

Scale up of these tools will be slow unless three barriers are addressed: 1) the need for strong operational understanding of how best to integrate these very different new tools into the current malaria vector control portfolio; 2) the market entry challenges that will face suppliers, in particular around forecasting; 3) the need for financial support for countries interested in adopting these tools following WHO recommendation. This SI will focus on the first two barriers, priming to support financing decisions for the 2023-2025 allocation period (or potentially, via portfolio optimization/grant savings late in the 2020-2022 allocation period), to address the third barrier. **An urgent need to understand the most impactful and cost-effective ways to control malaria in *An. stephensi* settings, and the need to build capacity for such surveillance and evaluations,** will be addressed simultaneously, through output 1 activities and the implementation approach used.

This SI will use interventions known to be effective to achieve catalytic impact. The approach is modelled on the effective design of the Global Fund and Unitaid co-financed New Nets Project (NNP) and its successor, the Net Transition Initiative (NTI). These SIs have successfully smoothed market entry (strong forecasting, price reductions), developed impactful operational research that is already informing decision making, and supported early scale up of effective tools.

Funding

This priority is insufficiently addressed by other sources of funding. While funding is in place for the core epidemiological evidence needed for WHO to consider a recommendation around these tools; funding is not in place for vital operational research needed to underpin financing and programmatic decision-making, including in areas of *An. stephensi* distribution, nor to support market shaping. Country allocations cannot support overarching work, such as market shaping activities and a core set of generalizable pilot studies. 2020-2022 country allocations cannot fund scale up immediately post-WHO recommendation: budgets will not have included these new tools and the expectation that these tools will be deployed layered wither other vector control tools already planned, means reprogramming of grant funds will be unrealistic. This set aside will avoid a delay in scale up post -WHO recommendation whilst countries work to incorporate appropriate scale up in 2023-2025 allocation period funding requests.

How was the proposed budget estimated? Estimates are based on experience of similar activities under NNP and NTI.

What is the indicative breakdown by major components? Outputs (see 'Description') 1 and 2 are likely to be operationalized via a co-financing partnership with Unitaid, meaning the Global Fund's financial contribution will be matched, doubling the available funding for this component.

Output 1: H**alf funded from Global Fund**, half from Unitaid - predominantly *commodities, operational deployment costs and technical assistance/capacity building*.

Output 2: **Half funded from Global Fund**, half from Unitaid - predominantly *technical assistance costs and meetings*.

Secretariat costs: *Management and oversight of this SI, personnel and travel-related costs for Global Fund Malaria SIs*

II. Strategic Impact

Potential for increased impact

This priority will contribute to the sub-objective of *'End Malaria'* goal by enhancing malaria control progress through accelerating the adoption of newer more effective tools in appropriate settings.
Levers
Other levers in the Global Fund's core value chain (design and approval of, and implementation and management of, investments) have a role to play in ensuring scale up for impact in the 2023-2025 allocation period when these tools are mainstreamed. However, during the 2020-2022 allocation period, these levers are insufficient to address the initial barriers and achieve the catalytic effect that is possible with set-aside funding.
Catalytic effect
☒ **More**: incentivize increased funding from allocations to priority areas and/or additional funding outside of Global Fund ☒ **New**: initiate new or innovative activities for more efficient and impactful programming ☒ **Improved**: enable more effective use of country allocations and coordinated responses for cross-border contexts ☒ **Faster**: accelerate implementation of specific priorities Additional financing from Unitaid is expected to be incentivized (pending Unitaid internal approvals); Innovative tools and operational approaches will be initiated; outcomes will directly inform more effective use of country allocations during the 2023-2025 allocation period; progress to End Malaria will be accelerated by ensuring timely scale up of the most effective tools.
Expected outcomes
• Clear operational understanding of how to most impactfully incorporate innovative vector control interventions into malaria programming. • Better understanding on the most impactful and cost-effective approaches to controlling malaria in areas of *An. stephensi* distribution. • Market entry of innovative tools is smoothed through sound forecasting and potentially financial levers to support suppliers establish in the market.
Theory of change
Rapid introduction of new vector control tools, achieved through generating evidence for decision-making, market shaping, will lead to rapid scale up post WHO recommendation and accelerated progress against malaria.
Risk if not funded
High risk. Unitaid are committed to the value of a joint initiative (pending internal Unitaid approvals) and matching of financing, other partners do not have the competencies or unique financing and leverage position of the Global Fund; early adoption post recommendation would not happen unless a set aside is available. *What are the direct epidemiological risks if not funded?* Malaria control progress is stalling due to a number of challenges. New, more effective tools are urgently needed, failing to support accelerated deployment of the most effective tools risks further rises in incidence. *What are the programmatic risks if not funded?* Without the newer tools being introduced and should the limitations of current tools continue, failure of malaria vector control leading to reversal of global progress against malaria.
III. Operational Considerations
Set-Aside Modality
☒ Set-aside funds only, otherwise not feasible These tools cannot be included in the 2020-2022 allocation period grants given the lack of WHO recommendation. SI work will prime for appropriate inclusion of tools in 2023-2025 funding requests and subsequent grants, for wider scale up.
Global Fund Comparative advantage
☒ Global Fund is one of many partners supporting this priority area Unitaid, Gates Foundation, PMI and WHO GMP are all supporting work to expand vector control options. However, Unitaid and the Global Fund have specific areas of added value and competency at initial market entry and financing deployment.
Global Fund Competency

Under the NNP and NTI, the Global Fund has designed and delivered on a financing and operational model that successfully smooths and accelerates the market entry of vector control products.
Sustainability
It is anticipated that these tools will receive WHO recommendation by during 2025, following this, deployment can be mainstreamed into funding requests for 2023-2025 allocation periods.

Empowering regional reference laboratories and national diagnostic networks

Empowering regional reference laboratories and national diagnostic networks	
Strategy goal: Maximizing People-centered Integrated Systems for Health	**Recommended modalities:** Strategic Initiatives (SIs) and Multi-Country approaches (MC)
Strategy's 10 changes: People-centered integrated systems for health	
I. Proposal	
Description	
Laboratory diagnostic capacities of national health systems are central to global health security and to achieving objectives of the Global Fund Strategy 2023-2028. Limited competencies, expertise and leadership skills amongst laboratory professionals is recognized as one of the major limitations impeding epidemiological surveillance and outbreak response measures. New approaches are needed to address chronic deficiencies in the workforce for laboratory-based services, including investments in pre-service education for laboratorians, as well as innovative approaches for mid-career leadership training for senior level directors/managers within national laboratory networks. The Secretariat proposes to use Catalytic Investments (CI) to invest in lab systems strengthening by focusing on empowering regional entities (e.g. regional Supranational reference laboratories, centers of excellence, regional initiatives (e.g., AU CDC Pathogenic Surveillance initiatives, WHO /AFRO Flagship initiatives, PAHO regional integrated lab strengthening initiatives); enhancing laboratory governance structures at national level; and building the fundamental human resource capacities needed to modernize the laboratory sector of low and middle-income countries. With the explosion of novel nucleic acid point of care diagnostic tests, and rapid expansion of testing capacities to peripheral labs during the COVID-19 pandemic, there is an urgent need to leverage the expanded COVID-19 molecular diagnostics infrastructure for other key endemic and epidemic infectious diseases, i.e., to 'multi-pathogenize' laboratory networks as part of pandemic preparedness efforts. COVID-19 has yielded a pandemic with an unprecedented expansion of molecular diagnostic infrastructure with an estimated 6.9 million weekly tests across LMIC, approximately half in Africa. However, these intense and rapid investments in diagnostics infrastructure have not been matched by concurrent investments in systems components (specimen transport and result return, supply chain management, digitization and data management, quality management systems, biosafety and biosecurity, Human resources etc.). Diagnostic gaps in TB detection, HIV treatment monitoring, HIV early infant diagnosis, and malaria detection are potentially addressable with existing testing capacities, should they be utilized more effectively and efficiently. The cross-cutting opportunity to leverage the post-pandemic molecular infrastructure offers immediate value to disease control needs, yet will require strong leadership from national and regional bodies to drive integration of lab networks, and evidence-based optimization efforts.	

Three core areas of work to strengthen lab systems readiness in response to current and future epidemics are proposed:

1. ***Strengthen regional reference capacity to institutionalize laboratory quality management systems, laboratory certification, and drive innovation and operational research through technical assistance and educational programs in advanced laboratory sciences***. For 10-20 countries, expand enrollment of public and private medical laboratories in External Quality Assurance schemes (EQAs) for priority diseases; support operationalization of Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) or similar QMS initiatives under management of national laboratory directorates; assist development of national laboratory quality standards for licensing and registering diagnostic testing facilities; establish technical capacity to produce proficiency testing panels, and biological standards for reference testing and regulatory review. These objectives will be achieved through empowering regional entities to substantially increase and expand their breadth of activities, and fostering more strategic partnerships between the regional bodies, Global Fund, and other key actors in health systems. The regional entities will explore support for advanced post-graduate technical training programs (for example, in genomics/ bioinformatics and operational research on multi-disease detection programs), as well as potential avenues to promote domestic manufacturing of quality-assured diagnostic products and devices. This support will be coordinated through Laboratory Centers of excellence and Supra-national reference laboratories, using MC.
2. ***Strengthen national capacities for laboratory diagnostics and surveillance through workforce development***: In 10 – 15 countries, scale-up implementation of the flagship One Health program of WHO/OIE/FAO called the Global Laboratory Leadership Program (GLLP), that aims to foster and mentor current and emerging laboratory leaders from the human, animal and environmental health sectors. In addition, we will support learning platforms for advanced training in laboratory-based sciences, such as the Africa CDC Institute of Pathogen Genomics. Our approach will build upon existing regional initiatives (e.g., those led by the African Union, by PAHO, and other regional bodies based in Southeast Asia) that aim to institutionalize credentialled educational programs related to laboratory sciences. This component will be coordinated through partnerships with GSPN, WHO AFRO, PAHO, AU CDC and Supranational reference laboratories, using established SI mechanisms.
3. ***Targeted Technical Assistance:*** Country-specific Technical Assistance to 10 -15 countries will be provided using the Global Fund prequalified pool of lab TA providers, as well as the newly created pool of prequalified service providers for Diagnostic Network Optimization (DNO). Contracting for lab TA provides a flexible mechanism to support countries during implementation of core grants, and help drive adoption and scale up of specific innovations (e.g. private sector engagements; pooled procurement mechanisms for improved service delivery, all-inclusive pricing modalities for equipment; developing guidelines for health care waste management; estimating waste volumes; planning long term investments in lab information systems (LIS); linking LIS with supply chain & logistics systems; evaluating integration of molecular diagnostic platforms etc.). This component will be administered via established SI mechanisms.

Rationale

Intervention #1: ***Strengthen regional reference labs to autonomously administer quality assurance, accreditation, and proficiency testing schemes***; *leverage regional entities to promote innovation, adoption of new diagnostic tools & diverse approaches to multi-pathogen diagnostics and surveillance; and to coordinate advanced training programs.*

The primary focus on quality management systems (QMS) is driven by the recognition that more systematic and comprehensive participation in QA/QC programs is urgently needed across all levels of tiered lab networks. During the pandemic and the push to decentralize COVID-19 testing services, many new testing sites have been hastily set up, both in the private and public sector, and even small health posts may be producing large numbers of test results using low complexity testing devices. Testing processes along the diagnostic cascade require quality assurances to generate reliable data; to improve systematic and timely data capture; to foster trust between patients, clinicians, and laboratorians; and to help drive a shift in the culture of evidence-based clinical practice. The lack of organized QMS programs with sufficient capacity to

oversee site authorizations, registrations, and licensing of testing sites has proven to be a major obstacle in sustaining network efficiency and undermines the foundations of quality of care.

Intervention #2: *Workforce development.* A lack of technically skilled laboratory personnel at all levels of national lab networks is one of the most fundamental resource limitations that hinders countries from reaching HTM programmatic targets and scaling up testing services for pandemic threats. Modern laboratory workflows require personnel with basic competencies and understandings of microbiology, immunology, and molecular biology, as well as essential computer literacy for data management. In many countries, pre-service training in medical biology lacks rigorous standards, and graduates may be unprepared for diverse roles in facilities management. Lack of strong leadership at senior levels in national laboratory directorates also undermines RSSH grant implementation, and progress towards laboratory network integration. The SI will focus on pre-service education, as well as mid-career development programs such as GLLP; for GLLP will be expanded to additional countries, and further institutionalize the program in the 6 pilot countries (Mozambique, Tanzania, Sierra Leone, Mali, Guinea, Tchad), thereby building upon successes and ensuring sustainability. GLLP is conceived as a **One Health program** that strongly supports an integrated approach to lab workforce development to realize joint gains for the public health, animal health and environmental health sectors. Going forward, it is essential that countries fully embrace the integrated One Health mandate of GLLP, and/or secure the appropriate buy-in from partnerships, such that the full costs of all participants can be covered, including those coming from the animal and environment health sectors.
Through this SI innovative approaches to lab-based environmental surveillance (wastewater-based surveillance) and immunological monitoring (high throughput serosurveillance) will be promoted. Operational research on these topics via the GLLP, as a way to further 'multi-pathogenize' our support for lab systems strengthening, will be augmented.

Intervention #3: Targeted Technical Assistance. Many countries lack sufficient local expertise to help guide national implementation of technically complex lab systems interventions (e.g., workstreams on digitization of lab information systems (LIS), establishing genomics surveillance capacity, geospatial analysis to optimize diagnostic networks). In addition to highly technical consultations, external TA support can help drive policy reforms, facilitate in-country dialogue on lab sector governance, and support CCM evolution. TA often play an important role in preparation of funding requests, helping evaluate modified diagnostic screening & testing strategies, and facilitating innovations. The Secretariat has developed a pool of pre-qualified service providers and will be further expanding that pool during 2022, plus soliciting a specific cadre of providers with competencies in DNO.

What is the evidence on effectiveness of such interventions?

#1 **Laboratory systems strengthening using SLIPTA and Quality Assurance tools**: Progress to date with the SLIPTA initiative in the African region includes designation of SLIPTA focal persons in > 30 countries in the African region; training and certification of >200 SLIPTA auditors; completing audits of >400 labs; and successful accreditation of >30 labs. The Southeast Asia region (SEA) and Latin America and Caribbean regions (LAC) Multi country grants have been a cornerstone for implementation, with synergies to other ongoing initiatives (e.g., ORAS grant).

Our emphasis on establishing National and /or regional EQA schemes by SRLs and NRLs builds upon past highly successful regional TB multi country grants, that enabled National TB reference laboratories in Kenya, Mozambique, Uganda, Ethiopia, and Rwanda to achieve ISO 17043 accreditation, thereby facilitating the production and distribution of proficiency testing panels for COVID-19, TB, Malaria, and HIV quality assurance systems.

#2 **GLLP and Workforce development:** The GLLP model for workforce development differs significantly from Global Fund training support, which comprises mostly short-term (3-5 day long) in-service 'hotel-based' workshops. The poor efficacy and risks associated with short term in-service training have been well-documented. In contrast, the 2-year GLLP program introduced in the previous funding cycle (with pilot implementation in 6 countries) aims to promote senior level management & leadership skills among mid-

career lab professionals, through individual mentoring and project-based learning. The GLLP is modeled on the highly successful Field Epidemiology Training Program (FETP) which has been credited with helping transform capacities of national public health institutes over the past 30 years. GLLP is still in its infancy, with the first 'graduates' anticipated in 2023.

#3 **Targeted Technical Assistance**: Targeted TA for labs, has proven to be a critical support for countries that lack strong governance of their laboratory networks, and require sustained guidance and advocacy to drive the integration agenda. External TA has been instrumental for establishing functional Laboratory Technical Working Groups; the urgent need for more effective oversight and coordination mechanisms for lab investments has been clearly seen during the COVID-19 response. Targeted Technical Assistance remains particularly important so long as CCMs are dominated by leaders from national disease programs.

Funding

The need is significant and although other funders provide support for various types of laboratory testing, funding support to strengthen laboratory systems remains inadequate. Overall laboratory investments account for 11.3%, 15.3% and 18.7% of total budgets for NFM1, NFM2 and NFM3 respectively by Global Fund; however approximately 85% of budget allocations comprise diagnostic commodities (equipment, reagents, consumables) for HTM plus COVID-19. In contrast, key interventions to support sample transport, lab information systems, quality management systems, and equipment service and maintenance are often neglected or inadequate. Many National Laboratory Directorates (NDL) struggle to obtain adequate financing even for their own operating budgets; NDLs remain largely subordinate to the more powerful national disease programs, are not empowered with sufficient leadership and convening power to streamline external donor funding in a coherent way, and lack key fiduciary competencies that would enable them to assume roles as implementers of Global Fund grants. Therefore, many lab systems investments remain funded through vertical national disease programs. Weak governance of NLDs is undoubtedly one of the root causes of fragmented diagnostic services, and lack of functional and efficient lab networks. Funding support for labs must be significantly reformed if we are to achieve the strategic goals of network integration. Given these challenges, Catalytic Investments provide an important mechanism to galvanize fundamental change in governance structures, to raise awareness and advocate for lab systems through sustained engagement with NDLs, PRs, and CCMs, in order to influence the shape of future country funding requests.

The Global Fund has an opportunity to promote integrated lab systems, through helping countries prioritize investments, advocating for uptake of multi-disease molecular diagnostic platforms and innovative surveillance approaches (e.g., wastewater-based surveillance), and providing the resources and oversight for Change Management as countries transition to improved lab governance structures. Without sufficient focus on laboratory systems, there is a risk of very poor cost-efficiencies and lack of value for money for the many millions spent on equipment/commodities.

The indicative breakdown for the catalytic funding is estimated as follows:
Intervention #1: MC support to regional reference laboratories (MC)

- Four MCs, managed by regional bodies, within which:
    - Funds dedicated to establishing capacity/accreditation for proficiency testing panel production
    - Funds per regional body dedicated to training and certification of SLIPTA auditors; completion of audits in beneficiary countries; leveraging newly trained auditors to expand EQA programs
    - Funds to developing platforms for innovative surveillance activities, including multi-pathogen genomics; wastewater-based surveillance; serosurveillance

Intervention #2: GLLP and Workforce development (SI)

- Funds per country to implement a blended program of GLLP, mentoring, and additional degree-conferring training in biomedical sciences

Intervention #3:Targeted country-driven TA on LSS (SI)

- Funds per country per year of TA (most TA requiring 12-18 months)

II. Strategic Impact

Potential for increased impact

Underperforming: The gains made in SLIPTA and EQA for HTM were overridden by COVID-19. There is an opportunity to regain the lost performance.

New: Going beyond GLLP, intervention #2 will explore new approaches to financing pre-service training in medical laboratory sciences, and specialized technical training related to information technology, bioinformatics, genomic surveillance, and evaluation/ adopting of molecular based multi-disease testing platforms. In addition, this has the potential to build new partnerships with academia (public universities) and institutes of higher learning.

Enhanced: The proposed investments in laboratory accreditation, EQAs, workforce development, and governance are directly aligned with the evolving PPR objectives to build front-line capacity for detection and rapid response to epidemics; strengthen disease surveillance systems through use of real-time digital data and detection capacity; and the resilience of lab systems to respond to surges in service demand. The plans build upon the model of support to supranational labs success as the ECSA and ORAS grants, but the orientation and focus on SLIPTA and EQA will enable improved metrics and faster progress on reaching KPIs.

Levers

- This work will contribute to the 10 key changes of the Global Fund Strategy 2023-2028
- Advocacy and engagement across secretariat (ongoing)
- Collaborations with external partners AU CDC, WHO AFRO, USG, PAHO; SDI /SI TWG (ongoing)
- Multicounty grants for TB labs; Project Stellar; C19RM

Catalytic effect

☒ **More**: incentivize increased funding from allocations to priority areas and/or additional funding outside of Global Fund

☒ **New**: initiate new or innovative activities for more efficient and impactful programming

☒ **Improved**: enable more effective use of country allocations and coordinated responses for cross-border contexts

The components of the proposed work will increase awareness and enthusiasm for investments in lab systems, through accelerated progress in meeting specific disease testing targets, that will galvanize and incentivize increased funding from additional funders to further support lab networks.

The drive towards integrated multi-disease testing platforms and integrated network design will lead to economic efficiencies.

The TA provided to countries will contribute to positive feedback loops regarding performance metrics (achieving targets) and support preparation of robust funding requests.

Investments in national LIMS will help reduce testing turnaround times and demonstrate the transformative power of digitization and streamlined data management.

Development of autonomous nationalized EQA programs will contribute to transforming the culture of clinical practice, through increased confidence among both clinicians and patients in quality lab-based diagnostic results. Trust in quality diagnostics underpins the willingness of society to adhere to public health and social distancing measures (in the event of epidemics) and underpins successful deployment of immunization and other control measures.

Expected outcomes

1) Improved quality and effectiveness of national laboratory networks and systems for improved HTM program targets
2) Increased number of accredited public and private laboratories
3) Improved lab systems readiness level to respond to public health events, AMR and improved laboratory surveillance systems
4) Trained and empowered laboratory professionals

Theory of change

Strong integrated laboratory systems are critical for integrated and comprehensive people-centered service delivery and care services that are central to achieving global health priorities (UHC, AMR, PPR, impact

against HTM and disease surveillance). Integrated testing at the appropriate levels of care can maximize investment while increasing access.
SLIPTA and EQA programs are a framework for improvement of laboratory quality management systems (LQMS) in low- and middle-income countries (LMICs). This leads to more reliable laboratory results and statistics that can inform public health interventions and patient care.

Risk if not funded

If catalytic support for lab systems is not funded, and countries continue their current trajectories, the risk is that they will continue to spend heavily on diagnostic commodities/ equipment without reaping public health gains (poor cost efficiencies, poor value for money), delivery of laboratory services will remain highly donor-dependent, and countries will be even less prepared for the next destabilizing global pandemic. The investments proposed here will address fundamental root cause problems in the lab workforce, human resources, NLD leadership, and the institutional structures needed to produce future generations of medical laboratory scientists.

What are the direct epidemiological risks if not funded?
Stalled progress on meeting HTM targets for reducing incidence, case finding, providing access to key populations, increased AMR (particularly for MDR TB, HIVDR), delayed detection of outbreaks

What are the programmatic risks if not funded?
- Poor value for money of lab equipment & health commodity investments
- Continued delays in results reporting of lab diagnoses (and inability to rapidly aggregate lab data for use in public health decision making)
- Insufficiency in lab workforce, causing collapse of testing capacity during future surges

III. Previous Investments

2020-2022 Catalytic Investment	2020-2022 Budget Amount
Lab SI (component of the Service Delivery Innovations (SDI) SI)	US$9 million

Current implementers

Service providers for current LSS work: APHL; Fondation Mérieux; IRESSEF; Medical Agency of Uganda Laboratories; GAHLC; MAUL (Medical Access of Uganda, Ltg); CHAI; ASLM
[Other contracting with service providers for LabSI is ongoing).

Current target populations

West and Central African countries.

Progress to date

Multiple countries supported through the Global Fund to develop NLSPs, establish Lab Technical Working Groups, and to formulate specific plans on systems issues (e.g., Lab Data Management Systems, Waste Mngt). Diagnostic Optimization and geospatial mapping exercises are contributing to remodeling of networks. Various TA support is helping countries to develop quality control programs, scale up HIV VL and EID, TB diagnostics and address challenges in supply chain informatics and quantification.

Expected evolution

We will explore opportunities to streamline the TA support for countries, through working with external partners, for example WHO, AU CDC and ASLM, to help to administer the TA packages and liaise with national laboratory directorates in a similar manner to Project STELLAR (part of the Global Fund C19RM).

IV. Operational Considerations

Set-Aside Modality

☒ Set-aside funds only, otherwise not feasible
As evidenced by the 2021 Lab Systems Investments Review for the 2014-2016 to 2020-2022 allocation periods, Global Fund grant investments in commodities are higher than investments in human resources capabilities, developing lab leadership capacity and lab governance structures. Lab system investments, including human resources and training, accounted for 13% of total lab investment, in contrast to the 64% of lab investments budgeted on equipment and reagents, and 24% budgeted for health product management.
Without set-aside, dedicated funds, directing investments to driving critical human resources development in conjunction with the Lab Directorate and Ministries of Health may be limited; embedding these

investments in disease-specific grant available funds may also result in a larger proportion of funds being leveraged for commodity-driven, single disease responses.
Global Fund Comparative advantage
☒ Global Fund is one of many partners supporting this priority area In many settings the Global Fund has been the single most important source of revenue for investments in upgrading/expanding the install-base of molecular diagnostics equipment, and currently plays a key role in advocating for optimized and integrated network re-structuring. The Global Fund continues to support adoption of WHO recommended changes in testing strategies and algorithms and pushing for more **harmonized coordination of external partners to support the lab sector.** Other major funders include but are not limited to: GFF; World Bank; GAVI; PEPFAR/PMI/USAID; BMGF; AUCDC, GIZ, AFD, FCDO, JICA, AusAID
Global Fund Competency
The Global Fund is the largest funder of diagnostic commodities and equipment for HTM, and Global Fund procurement policies are often a major consideration for policy makers. National lab directorates need to be empowered to take a lead in remodeling the laboratory sector, and we can only have a voice in shaping the dialogue if we engage on multiple levels.
Sustainability
With empowered national laboratory leaders at the table to help make key decisions on budget allocations and programmatic priorities, investments in labs are much more likely to target cross-cutting interventions, leading to efficiencies, viable cost-recovery, and long-term sustainable gains. Improved quality in the laboratory services will attract further investments (both from other donors and co-financing from government), leading to new opportunities for fee for service models.

Data

Data	
Strategy goal: Maximizing People-centered Integrated Systems for Health	**Recommended modality:** Strategic Initiative (SI)
Strategy's 10 changes: Improve generation and use of data; Pandemic preparedness and response	
I. Proposal	
Description	
Building on the past Data SI, the focus of the next Data SI will be on two main work streams: i) **Enhancement and operationalization of global normative guidance and tools with continued focus on HTM/RSSH, including pandemic preparedness (~25% of SI budget):** Global guidance and tools will be developed or updated and operationalized in countries by national stakeholders with support from technical partners in response to evolving health systems and HTM program needs and risks. (The Global Fund is not developing additional guidance but steering/coordinating technical guidance development around HTM.) ii) **Capacity building for context driven data generation, analysis and use through regional hubs (~75% of SI budget):** Regional capacity building hubs, a center of collaborating regional partners, including academic institutions and communities, will be strengthened, and expanded. The objective is to institutionalize capacity building, promoting south-to-south learning and building local expertise and knowledge sharing. Countries will be able to access support directly, thereby reducing workload for Country Teams. During the 2023-2025 allocation period, the Secretariat will ask funding requests that include interventions supporting data system strengthening be based on a maturity model analysis (under development). As	

such, investment from country allocations and required complementary support via the Data SI will be tailored and respond to the maturity stage of a given country system.

Proposed core areas of focus and interventions by work stream addressing current gaps:

Core area of Focus	Interventions
i) Coordination of global normative guidance and tools for HTM and PP	
• Person-centered monitoring; • Real-time case-based surveillance; • Community-led surveillance; • Community, private sector, HIV and TB prevention, community led monitoring, data availability and use; • Equity/Human Rights and Gender monitoring; • Pandemic Preparedness	Adapt to evolving program needs and increasing sophistication of countries' digital data systems: • Development and implementation of guidance documents, digital tools, and training packages; • Support dissemination and coordinated use at country level
ii) Capacity building for context driven data generation, analysis and use for HTM and PPR	
Data **generation, analytics and use at all levels** of health pyramid tailored to context and disease burden	Solidify regional hubs responsible for: • Capacity building/technical support to institutionalize data analysis and use at all levels for in-country and performance and program reviews; • Enhancing localized knowledge exchange and e-learning platforms; • Capacity building in targeted areas for HTM program needs, e.g., key populations mapping and size estimation; population size estimation for AGYW, etc. • Capacity building for geospatial analytics, stratification, micro-planning for optimal service provision and resource deployment, (e.g., molecular diagnostic tools; severe malaria referral networks, etc.).
Digitalization and Innovation:	• Scale direct country HMIS reporting to the Global Fund; • Implement roadmaps for interoperability between HMIS, LMIS, Lab IS, HRHIS, GIS; • Support countries' Digital health/HIS strategy development and coordinated governance mechanisms; • Continued support to expand mass-campaign digitalization, AI and machine learning, etc.; • Global Fund Digital HMIS learning agenda/resources adapted and used through regional hubs.
Availability and use of community, HIV and TB prevention, and private health sector data	• Technical support/capacity building for data collection and exchange; • Master lists for Health Facilities and CHWs; • Technical support/capacity building on rapid and cost-effective outcome monitoring; • Capacity building in qualitative analysis.
Operational/ thematic reviews	Technical support/capacity building
TA pool of experts	Rapid deployment of quality technical support in the above areas and for emergency response surveillance (PP) if not funded elsewhere

Rationale

Despite high investment and progress made over the past two decades, **HMIS strengthening remains critical**. Most country data systems in Global Fund supported countries need further strengthening in response to evolving data needs, increasing complexity of disease programs, and emerging health threats. Country systems have reached **different levels of maturity** and require **tailored support**. Leadership and governance of health data and **lack of interoperability** across information systems remains a challenge.

Standards-based interoperable solutions are urgently needed to optimize data exchange. Improvements have been achieved in data quality, analysis and use at national levels, but recognized **universal gaps remain**, especially at **subnational levels**. **Building capacity** for **routine data analysis and use** at all levels is a **long-term process**. Work has just started in some of the regions and **needs to continue** in order not to waste past efforts and build on momentums initiated or gained. As data systems evolve, capacity building needs to evolve alongside.

Operational costs of data system strengthening are covered by country allocations. However, capacity building requires a centralized and coordinated approach which is not funded elsewhere**.** The goal of the **regional capacity building hubs** is that regions and countries will increasingly become **technically self-reliant,** with **sustainable**, **responsive**, and **integrated health information systems** that lead to longer-term efficiencies.

Some key achievements of the five workstreams of the past Data SI (referring to its five workstreams), results as of end of 2020:

Past/current workstream 1:

- **Fundamental shift in digitization of countries' data systems:** 98% of HI & Core countries have HTM aggregate program data digitized in their national data systems.
- **Significantly reduced number of "siloed" disease reporting systems:** HI & Core countries have integrated aggregate data reporting in the national HMIS: HIV: 78% (43), TB: 79% (42); Malaria: 90% (48). 3D: 77% (41); CHIS: 87% (partial or full integration).
- **Improved data reporting completeness and timeliness:** from 86% in 2018 to 91% in 2020, and from 68% in 2018 to 76% in 2020, respectively.
- **CHWs guidance** on strategic information and service delivery developed. As a result, the guidance is piloted and will be scaled-up further under the current Data SI.

Current workstream 2 (new in 2019-2022 cycle):

- **Digital tools:** dashboards for automated HTM analyses in around 30 countries; digital packages for HIV and TB real-time case surveillance systems and guidance and tools for malaria national data repositories developed.

Digital and HMIS results have informed the current Data SI as follows: Focus lies on district level automated digital outputs to inform analytics and decision taking; enhancement of aggregate level tools adding new components; enhancement and delivery of case-based surveillance for HTM; systematic approach to system digitalization; support roll-out of digital tools (mass-campaign, decentralization of digitalization to health facility level, patient-level monitoring tools, community data digitalization, etc.)

Past/current workstream 3:

- **Partnerships built between MOHs and academic institutions** to improve **analytical capacity** in Eastern/Southern Africa**.** As a result, this partnership model is being extended to six regions and 40 countries under the current Data SI.

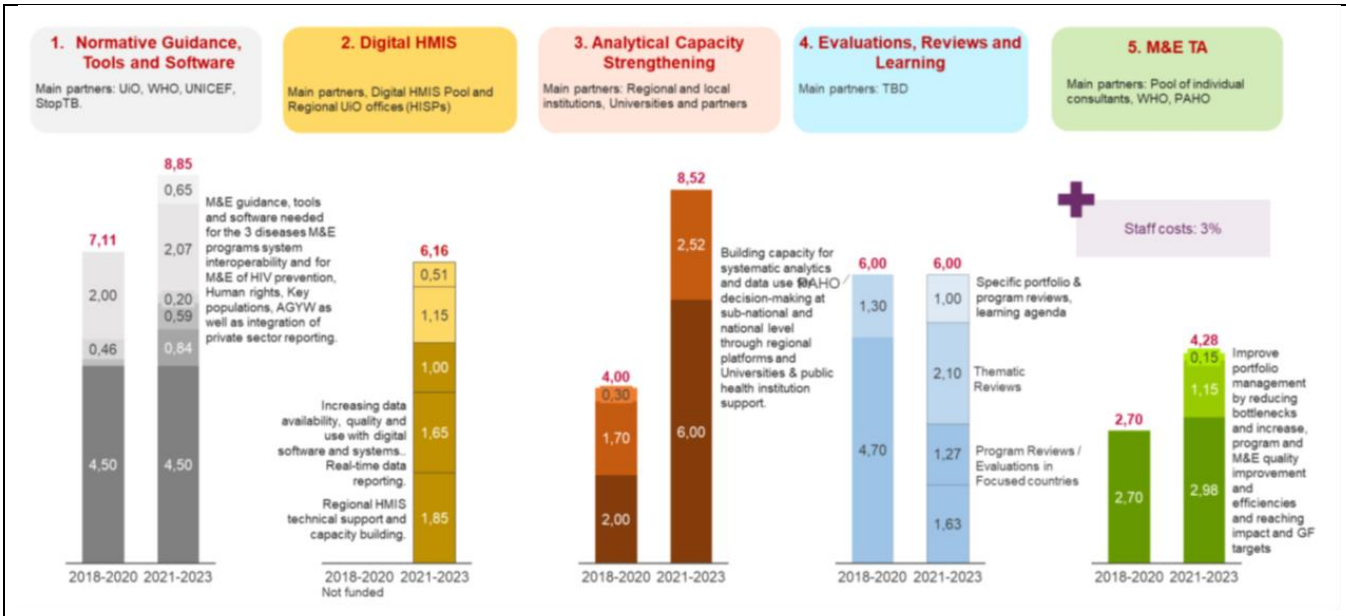
Past/current work stream 4:

- **10 Thematic reviews** implemented, informing program optimization, responding to TRP raised issues, leveraging partner funding, informing WHO technical guidance, etc.
- **74 evaluations** in focus portfolios informing reprogramming, NSPs and Funding Requests.

Past/current work stream 5:

- **Rapid deployment of quality M&E TA:** approximately 30 assignments/year; has led to quality M&E investment plans; cascade analysis and data quality reviews; epi reviews to inform program reviews and NSPs; informing reprogramming, funding requests, etc.

2017-2019 and 2019-2022 Data SI investments according to workstream:



Funding

There is **no other funding source** for this centrally led workstream. It **cannot be integrated in country allocations** due to its areas of focus. It involves a coordinated and centrally led approach to respond to evolving and more complex needs and to maximize strategic reuse of cross-cutting digital and HIS investments. This funding is leveraging the use and quality of HMIS and M&E investments in country allocations to strengthen data systems and institutional capacity.

II. Strategic Impact

Potential for increased impact

New: Part of the Data SI will provide guidance, tools and capacity building for HIV and TB prevention, community, and private sector data integration, pandemic preparedness and equity/gender responsive programming. Through a maturity model approach country allocations and technical support will be more focused. Countries will be able to access support through the regional hubs which will reduce workload to country teams.

Enhanced: It will strengthen the current regional approach by creating hubs to strengthen local capacities in response to evolving data system maturity model gaps, with an intensified focus on data governance and improved system interoperability. It will therefore contribute to long-term system resilience. Maturity model analysis will ensure a more focused data system investment and more efficient use of allocation. Monitoring of progress of maturity model will allow for clear outcome measurement.

Challenges (non-exhaustive) that will be targeted for scaled results:

- Inadequate availability of real-time quality data, analyzed and acted upon.
- Slow roll-out of patient-centered monitoring for improved service quality.
- Lack of country HIS architecture for interoperability and system integration.
- Deficient surveillance systems for rapid responses.
- Insufficient integration of community and private sector health information.

Levers

The future Data SI aims to put in place a **targeted system strengthening approach** whereby a HIS system maturity analysis is performed during funding requests to inform related country allocation funding and complementary support from Data SI. It links to the **Embed into funding request design** lever. It will help to **advocate and enhance** further the already **strong partnership** around Data Systems strengthening. It will also enhance the **implementation and capacity building** in this domain.

Catalytic effect

☒ **New**: Contribution to global guidance and tools in **emerging areas**, such as prevention and pandemic preparedness; setting up of regional hubs in **newly targeted** regions for **new beneficiary countries**.

☒ **Improved**: **Enhanced guidance and tools** in evolving fields such as patient-level monitoring; institutionalized data analytics and use; comprehensive approach to digital systems strengthening; etc.

☒ **Faster**: A central TA pool and regional hubs providing timely and quality technical support and capacity building to respond to countries maturity model, contributing to timely and quality implementation of grants' M&E module.

Expected outcomes

- **Enhanced global guidance and tools** responding to emerging HTM program needs and innovative approaches.
- **Strengthened data systems** based on **maturity model,** including real-time case-based surveillance.
- Strengthened, scaled, **integrated and interoperable HMIS/CHIS/LMIS/lab systems** to respond to emerging health threats and to optimize strategic program investments.
- Increased availability and use of **HIV** and TB **prevention, community-led monitoring, and private sector data**.
- Strengthened **analytical capacity at all levels** through regional hubs resulting in increased data-driven decision taking.
- Enhanced **strategic approach to health system digitalization** implemented with expertise brokered for country support using global standards, tools, and techniques.

Theory of change

Required inputs: central level funding (Data SI); global partner expertise; regional partner expertise; consultants with expertise in focus areas; country maturity model analysis

Focus Area	Activities	Outputs	Outcomes	Expected catalytic effect
Global Guidance & Tools enhancement and dissemination	Global guidance and tools developed/adapted to emerging HTM program needs and health threats	• Patient centered tools enhanced • PP guidance developed • Guidance and tools for digital enhancement	• Enhanced of global guidance and tools responding to emerging needs and innovative approaches. • Strengthened data systems based on maturity model. • Strengthened, scaled, integrated and interoperable HMIS/CHIS based on maturity model to respond to emerging health threats and strategic program investments. • Increased availability and use of HIV and TB prevention, community and private sector data.	• Contributing to delivery of GF strategy. • Increased data agility in countries: right data at the right time in the right place for decision taking. • Strengthened evidence-based decision taking. • Partner collaboration steered towards more targeted support in data system following a maturity model. • Mobilizing partners to co-finance regional expertise hubs for longer-term sustainability and local technical expertise. • PP guidance and capacity ready for further scale-up.
Capacity building for context driven data generation, analysis, and use	• Solidifying regional networks of expertise. • Capacity building in data analytics, key pops mapping/PSE, geospatial analysis, etc.	Capacities at regional and country level build in the priority focus areas	• Regional expertise hubs established • Data driven decision taking at all levels • Local and regional analytical capacity strengthened.	
Timely and quality technical support	Timely deployment of targeted expertise according to maturity model analysis	Quality implementation of country allocations M&E budget	Country data systems strengthened according to its maturity	

Risk if not funded

If not funded and no other central level funding will be available, Global Fund and partner investments of **past 20 years in data systems will be jeopardized**. More specifically:

- **Lost gains and slowdown in deployment**, digitization, scaling, for real-time HTM and COVID-19 data for lack of funding.
- **Lack of data driven programming** and limited institutional capacity resulting in sub-optimal impact and wasted resources.
- **Fragmented, uncoordinated, and poor** performing Health Information Systems.
- Technical Support: **late deployment**; **insufficient expertise/quality**; **fly-in/fly-out TA**.
- **Inefficient use of grant funds** for data system strengthening.
- Insufficient **innovative approaches** in data systems.

III. Previous Investments

2020-2022 Catalytic Investment	2020-2022 Budget Amount
Data SI	US$35 million

Current implementers

WHO, EURO, PAHO, UNAIDS, UNICEF; STOP TB, UiO, HISP – WCA/India/Uganda; Makarere University; AEDES, IQVIA, individual consultants.

Current target countries

HI and Core and impact countries (50).
TA pool: any country with expressed need.

Progress to date

- **Global Guidance**: Progress was achieved in versioning and improvement of aggregate and case-based DHIS2 packages for HTM; eLearning materials on HTM routine data analysis and use; release of malaria case-based surveillance and foci investigation module; updates to program and epi review; work on district level digital analytics outputs ongoing.
- **Data analytics**: Partnership extended from two to six regions: inception phase ongoing in WCA, MENA and ESA; Scoping phase for regional model in Asia concluded; EECA and LAC implementation ongoing.
- **Direct country reporting** to Global Fund through DHIS2 platform is piloted in 6 countries.
- **COVID-19 surveillance module** was added in 40 countries.
- Country rapid assessment on status/gaps in **real-time, case-based surveillance** conducted in 19 TB priority countries.

Expected evolution

Global guidance and tools for strong data systems continue to evolve. The next cycle will build on previous ones and focus on guidance and tools to meet emerging program data needs and gaps, as well as the increasing sophistication of countries' digital data systems. Building national capacity for data governance, analysis and use at all levels is a long-term process. Existing processes require adaptation, skills strengthening, and stakeholder behavior change. Through this SI, the Global Fund will build on and expand an already strong collaboration with key stakeholders. GFF and GAVI have expressed interest in co-funding the regional capacity building hubs.

IV. Operational Considerations

Set-Aside Modality

☒ Set-aside funds only, otherwise not feasible

Country allocations **only** include **country specific data system strengthening needs**. The Data SI focuses on supporting a **coordinated and centrally managed response** to continuously evolving and emerging elements in this field. It thus leverages and improves the quality of the investments made through country allocations.

Data SI targeted components require a coordinated response and **increasingly complex expertise** as data systems grow in maturity. Such expertise is **not readily available in countries, nor easily mobilized by countries**. Regional capacity building hubs offer an optimal approach to ensure high quality standards in the deployment of emerging or innovative data solutions to respond to the Global Fund's Strategic objectives.

Global Fund Comparative advantage

☒ Global Fund is a leader in this priority area

The Global Fund has been and is instrumental to **steer and catalyze** a **harmonized approach amongst funding partners** to align around a data governance mechanism and one national information system. The Global Fund has been instrumental to support enhancement and country up-take of global guidance and tools to meet Global Fund strategic objectives**.**

Some major partners are: GFF; WB; GAVI; PEPFAR/PMI/USAID; BMGF; DFID; etc.

Global Fund Competency

In many countries, Global Fund contributions, especially in data systems, remain unmatched. The Global Fund has immense convening power in this field and can steer discussions.

Sustainability

Global guidance and tool enhancement and dissemination will require funding as it is the result of emerging evidence in prevention, diagnosis and treatment approaches respective to health, or/and new threats. This is accompanied by a fast-growing digital environment. Other central funding options (flat rate per allocation cycle; percentage contribution based on allocation amount, etc.) may need to be envisaged should CI no longer be an option to fill this gap.

Once **regional capacity building hubs are autonomous,** they can **phase out** of the CI approach. This could potentially **start as of 2026** depending on the maturity of a regional hub. A percentage contribution from country allocations or co-financing budget could thereafter ensure their continuation.

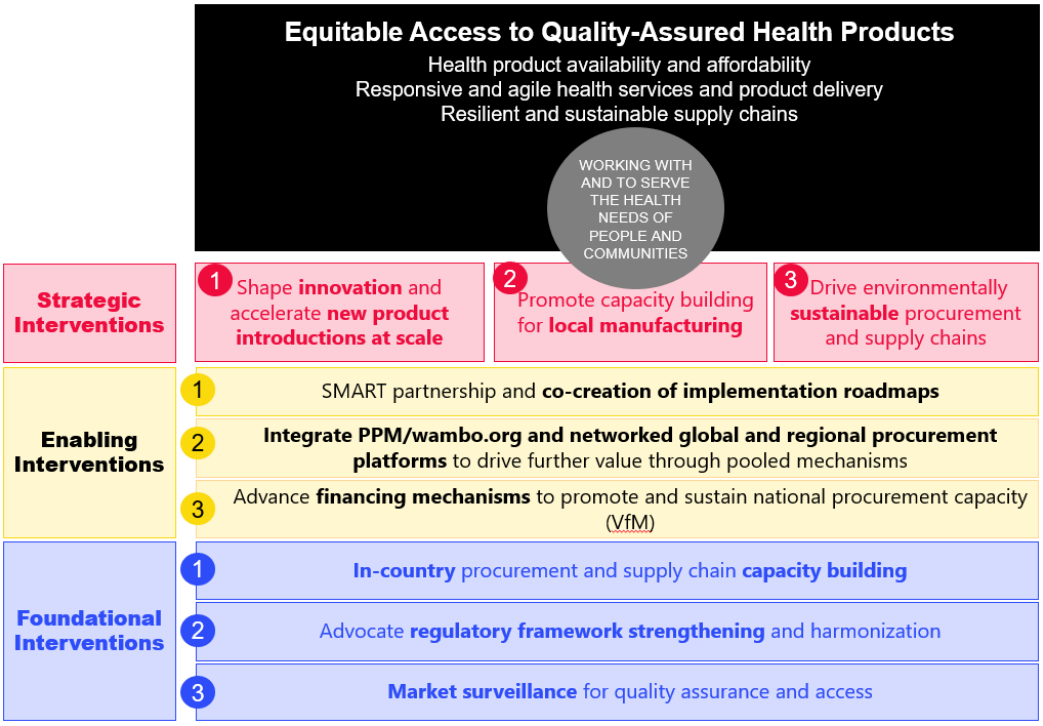
Equitable access to quality health products through innovation, partnership, and promoting sustainable sourcing and supply chains at global, national and community levels (NextGen Market Shaping)

Equitable access to quality health products through innovation, partnership, and promoting sustainable sourcing and supply chains at global, national and community levels (NextGen Market Shaping)	
Strategy goal: Maximizing People-centered Integrated Systems for Health	**Recommended modalities:** Strategic Initiatives (SIs) and Matching Funds (MF)
Strategy's 10 changes: Accelerate equitable introduction & scale-up of new tools & innovation	

I. Proposal

Description

NextGen Market Shaping is a key enabler to the Global Fund's Strategy (2023-2028) and aims to accelerate progress towards equitable access to quality-assured and innovative health products. It requires the integration of up-, mid- and down-stream interventions through partnerships at the global, national and community levels. The NextGen Market Shaping Framework includes a set of Strategic, Enabling, and Foundational Interventions, oriented around the people and communities the Global Fund serves.



Catalytic Investments are required for selected interventions due to their cross-cutting nature and to encourage co-financing or co-investment through grant and other funding mechanisms. The specific interventions requiring catalytic investment include:

1. Shape innovation and accelerate new product introductions at scale through two catalytic tools: a) **Access Fund;** and b) **Revolving Fund**
2. Promote capacity building for **local manufacturing**

3. Drive **environmentally sustainable procurement and supply chains**
4. **In-country capacity building** for procurement, quality assurance and supply chain

Rationale

Inequitable access and affordability to quality-assured health products continues to hinder progress in the fight against the three diseases and pandemic preparedness and response as exacerbated by COVID-19. Strategic interventions are needed to change the status quo and permit delivering on the ambition of the Global Fund Strategy 2023-2028. Investment in these areas can significantly improve HTM program outcomes and in-country capacity strengthening for sustained impact through catalytic investment on cross-cutting market shaping interventions, in complement to grant-specific investments.
Rationale for the components of the Catalytic Investment (which support the NextGen Market Shaping interventions) include the following:

Two funding mechanisms to accelerate introduction of new products at scale:

a) **Access Fund:** Access to new HTM products and tools for LMICs are often challenged and deprioritized due to the slower pace of scalable country off-take, limited visibility of country demand and procurement approach, and the often higher costs of introducing new, more effective interventions in resource-limited settings. To mitigate inequity and access delays, a set of up-, mid- and down-stream interventions are required in addition to the specific Market Shaping mechanisms that focuses on addressing barriers to the introduction and scale-up of new innovations.
b) **Revolving Fund:** There are often important time lags between an innovative product's recommendation for use and country-readiness to introduce it, translating to limited ability to secure timely supply. When supply can be secured in advance of country-specific demand, critical steps along the pathway from innovative product recommendation to product delivery in country can progress in parallel, instead of sequentially, to avoid historically significant time lags to successful and scalable product introduction.

Local manufacturing: When health products are produced far from where they are consumed, inefficiencies and global supply chain disruptions can disproportionally compromise timely supply of needed products.
Environmentally sustainable procurement and supply chain: The scale of health product production and supply for Global Fund-supported programs carry important implications for the environment and sustainability considerations.
In-country capacity building: Difficult trade-off decisions need to be made by CCMs for what to prioritize in Funding Requests, typically resulting in insufficient investment in PSM strengthening, despite large grant-funded health product investments. In-country procurement and supply management interventions are fundamental to disease program implementation and to sustain the outcome and impact of investments and result in more resilient health systems. The CI will help countries to build/adopt guidance/tools that incorporate cutting-edge knowledge to overcome some of the existing capacity constraints and trade-offs vis-à-vis ongoing grant implementation. Enabling the adoption of new innovative approaches, tools and capacity in procurement and quality assurance in country, while accelerating outcomes sustained through improved priorities set out in NFM4 grants.

What is the evidence on effectiveness of such interventions?
The Global Fund's mandate, procurement scale for influencing markets and ability to capitalize on multi-funding mechanisms place us in a unique position to lead and drive these critical cross-cutting interventions to make grant-specific investments go farther.
These investments will build on demonstrated successes in HIV/TB/malaria + C19RM, with a view to consolidate the outcome of previous and current PSM SIs, prior successes and harness lessons learned from the COVID-19 pandemic into a more cohesive and comprehensive market shaping approach.

Funding

These market shaping interventions are underfunded because they are cross-cutting and cannot be supported by grant-specific funding, and some are new, emerging areas that require catalytic funding to bring to life for the Global Fund and partners. These catalytic investments will permit grant funds to go further. MF for in-country capacity building would incentive grant and other partner investments.
How was the proposed budget estimated?
Based on ongoing consultations and past experience.
Indicative breakdown of major components

(1) Funding Mechanisms for accelerated new product introduction at scale:
a. **Access Fund** to enable supplier engagement/country transition planning (SI);
b**. Revolving Fund:** advance procurement to mitigate time to market (SI);
(2) **Local manufacturing** (SI); and
(3) **In-country capacity building** across procurement, supply chain and quality assurance, including integration of **environmentally sustainable procurement and supply chain** (MF).

II. Strategic Impact

Potential for increased impact

Does this priority contribute to a new, enhanced or underperforming area in the Strategy? How?
This priority directly aligns with sub-objective 5 on Next Gen Market Shaping, under the *Integrated, People-Centered Systems for Health* Objective. It also drives *Partnership-wide changes to accelerate the pace of impact,* where the priority of *Accelerate the Equitable Introduction and Uptake of Innovation* is explicitly noted. The proposal for catalytic investment directly contributes to this partnership-wide change. Local manufacturing and sustainable procurement are also mentioned explicitly in the new Strategy. There are also cross-cutting linkages with all 10 of the key changes in the strategy narrative.
Two funding mechanisms for accelerated new product introduction at scale:
a) Access Fund: This SI will promote early access to new products and tools through **strategic supplier engagement** and **country transition planning**. It may entail **demand/supply de-risking mechanism** or other advance market incentives. It will encourage co-investment and accelerated economies for more **affordable, compelling and sustainable entry pricing**. It will be complemented by **dedicated public/private sector funding**, which may include potential mechanisms to mitigate time to market. The new product portfolio/pipeline, including multiple first line ACTs, HIV prevention tools, and TB diagnostics, as well as the specific interventions for each product, is under continued development.
b) Revolving Fund: This SI will permit the ability to secure volumes in advance of country-specific demand, to enable delivery of products to be more closely aligned with country-readiness (in contrast to traditional delays of at least 6-9 months, per traditional approaches when sequential steps are followed and known country-specific demand is required for order placement).
Local manufacturing: This SI will promote **local manufacturing capacity building** as part of the interagency efforts with WHO, UNICEF, UNAIDS and others. The approach could include **specific TA support on product quantification, country demand forecasting, regulatory harmonization**, and others. Targeted investments in partnership will increase production hubs and supply for Global Fund-supported countries.
Environmentally sustainable procurement and supply chains: This SI will **operationalize the responsible procurement framework** to drive environmentally sustainable sourcing and supply chains. It will provide a catalytic opportunity for countries to adopt and scale sustainable procurement practices for their national procurement practices as well.
In-country capacity building for procurement, quality assurance and supply chain: MF are required to catalyze grant investment in strengthening procurement, quality assurance and supply chain capacity building. This SI builds on the Supply Chain strengthening experience and expands to procurement and systems for strengthening health product quality assurance.

Levers

The four levers specified under *Align Supply Operations* underpin this priority but must be complemented by the enhanced focus on the initiatives set out in this document. In addition, the levers around funding request guidance, country engagement, embedding priorities in grant making, and technical support and capacity building are important to complement and ultimately scale these catalytic investments.

Catalytic effect

☒ **More**: incentivize increased funding from grant allocations to priority areas and additional funding outside of Global Fund finances (partner investments), with increased resources translated to greater impact

☒ **New**: initiate new or innovative activities for more efficient and impactful programming. The Access Fund for accelerated introduction of new products at scale will be a new approach and key tool to permit strategic supply engagement and country transition planning. Efforts to support local manufacturing capacity building have not previously been implemented but hold promise for permitting the procurement of needed, quality-assured health products closer to where they are consumed for improved efficiencies. The MF for in-country capacity building will include elements not previously incentivized with MF: environmentally sustainable procurement and supply chain, procurement and quality assurance capacity building.

☒ **Improved**: enable more effective use of country allocations and coordinated responses for cross-border contexts, and supply chain capability building will build on prior investments to make further improvements in system enhancements that require greater than a 3-year cycle to be fully realized, with cross-disease benefits.

☒ **Faster**: accelerate implementation of specific priorities, including introduction of new products at scale

Expected outcomes

- Equitable and accelerated access to better, affordable and quality-assured products in countries where the Global Fund invests (e.g., multiple first line ACTs, HIV prevention tools, TB diagnostics)
- Improved responsiveness and agility through health product localization closer to the communities and people the Global Fund serves
- Positive climate and environmental impacts through Global Fund-supported initiatives, and enhanced in-country capability on sustainable sourcing and supply chain
- Improved HTM program outcomes linked to improved and more equitable access to quality-assured health products and in-country capacity for sustained cross-disease impact through strategic procurement and supply chain interventions, complementary to grant-specific investments (e.g., improved supply chain governance, people-centered supply chain design, information systems for data-driven decision making, private sector engagement).

Theory of change

Catalytic investment in NextGen Market Shaping:

- Better coordinated activity to introduce and scale new products across the Global Fund and partner ecosystem à better alignment of demand and supply management of new products à more cost-effective and timelier rollout and scale up at country-level.
- Develop tools for building local manufacturing capacity à reduce reliance on global manufacturing for more responsive and resilient health product supply chain à catalytic and sustainable impact on local economies, promoting the Global Fund's priorities on Communities and Equity, Human Rights, and Gender.
- Operationalize responsible procurement framework à Drive environmentally sustainable sourcing and supply chain with catalytic opportunity for countries to adopt and scale sustainable procurement practices
- Improved environmental impact linked to health products needed in the fight against HTM
- Investment in in-country cross-disease capability building for procurement, quality assurance and supply chain à better outcome of HTM program implementation à more sustainable public health security and responses.

Risk if not funded

If not funded as a set-aside, the ability to proactively de-risk demand/supply and encourage co-investment and accelerated economies for more affordable, compelling and sustainable entry pricing for new products will be compromised, with implications for planned scale-up of key disease tools (e.g., multiple first line ACTs, HIV prevention tools, TB diagnostics, etc.). Given difficult trade-off decisions to be made by CCMs for what to prioritize in Funding Requests, there is a high risk that little to no investment will be made for environmentally sustainable procurement and supply chain efforts and in-country capacity building for procurement, quality assurance and supply chain, as these have historically remained underfunded, despite having cross-cutting implications for disease programs. Without set-aside funds to incentive additional investment, it is likely that there would be limited update of innovative approaches (accelerated access to new product introduction at scale, local manufacturing, environmentally sustainable procurement and supply chain) and partnership engagement.

What are the direct epidemiological risks if not funded (e.g. rising incidence, resurgence, drug resistance)?

Failure to rapidly introduce a game-changing innovation could mean the difference between achieving the SDG targets on incidence reduction and failing on this target. The Global Fund must stay ahead of the curve with NextGen market shaping to accelerate progress towards global targets and support countries to achieve their corresponding epidemiological aims by ensuring that the right products and tools are available, and that countries can manage an optimal health product portfolio for their epidemiological context. There is also a strong link between promoting and scaling innovation to combat drug, insecticide resistance and other biological threats (e.g., such as gene deletions and malaria case management).

What are the programmatic risks if not funded (e.g. deteriorating service delivery, systems)?

Programmatic risks include backsliding and missed opportunities for equitable access at country-level, as well as a reduced ability to support countries for pandemic preparedness and responses. Countries might continue use of less expensive but less effective products and tools and miss opportunities for accelerating progress.

III. Previous Investments

2020-2022 Catalytic Investment	2020-2022 Budget Amount
SI PSM transformation (in-country supply chain) SI Accelerated uptake of innovations (Quality Assurance)	US$ 10 million US$ 20 million

Current implementers

WHO (for the Expert Review Panel and Pre-qualification function) Deloitte Consulting, Chemonics International, CAMEG, PICMA AFRICA, Palladium International, Freight In Time, KPMG CI, John Staff International Development, JPN Management Consulting, S4D Consulting, AEDES, IQVIA Solutions, Empower Swiss, MIT, JSI (for PSM transformation)

Current target populations

PSM Transformations: Bangladesh, Burkina Faso, Cameroon, Cote d'Ivoire, DRC, Ethiopia, Gambia, Ghana, Haiti, Liberia, Malawi, Mali, Multiple, Niger, Nigeria, Pakistan, PNG, South Africa, Sudan, Tanzania, Uganda, Zambia

Progress to date

Learnings from the 2017-2020 implementation of Catalytic Investments for **PSM-Transformations** that informed the 2021-2023 cycle include: (i) continued strengthening of **governance systems** for supply chains is critical for long-term sustainability of programs; (ii) to effectively identify supply chain inefficiencies and enhance optimization of disease responses, people-centered **supply chain design**, in partnership with the **private sector**, is important to improve equity of health product access; and (iii) enhanced alignment and integration of information systems is critical to support **data-driven supply chain decisions**, tailored to sub-national level, using granular data.

The US$12 million in SI Funding catalyzed US$51 million in grant funds and US$33 million in additional investments from various organizations, including BMGF, the World Bank (GFF), USAID and Global Fund NFM3 grants. Demand increased from 16 countries in the 2017-2020 cycle to 33 countries in the 2021-2023 cycle.

Implementation is underway for (i) strengthening of **HIV forecasting capacity** in across a number of countries to help achieve supply chain sustainability and resilience in countries to reduce dependencies on donor funds; (ii) improving equity, expanding access to treatment and diagnostics for **malaria products** by strengthening the capacity and performance of community health workers and **working with the private sector to support distribution**; and (iii) Working on improving the quality of **TB health product management by strengthening warehousing** in Bangladesh and Pakistan as a means of intensifying efforts to improve access to quality diagnostics and treatment products.

The Catalytic Investment for quality assurance (Accelerated Introduction of Innovations) contributed to the assessment of new health products for HIV and hepatitis, tuberculosis, malaria and syphilis by expert review panels (ERP) to expand the eligible supplier base for increasing access. In the current cycle, ERP rounds are planned for malaria diagnostics and pharmaceuticals, HIV and hepatitis diagnostics and pharmaceuticals, TB diagnostics and pharmaceuticals and COVID-19 diagnostics and therapeutic products. The CI has supported vector control inspections of 7 sites in 2021, and the development of norms and standards for insecticide-treated nets. Pharmacovigilance benchmarking is underway to identify areas of improvement, which will contribute to cross-disease benefits. The CI is supporting a study influencing scale-up of modified shorter treatment regimen through national TB programs for better treatment outcomes for MDR-TB patients, improving the collection and quality of clinical data collection in 11 EECA countries.

Expected evolution

The next cycle will bring ad-hoc initiatives together under one umbrella, with a holistic vision for Next Gen Market Shaping. It will also include an enhanced and complementary focus on three strategic interventions (access fund for **accelerated new product introductions at scale**, **local manufacturing** and **environmentally sustainable sourcing and supply chains**) and the foundational intervention of in-country capacity building for **supply chains**, but expanding it to include **procurement and quality assurance** as well,

in line with the Global Fund's new Strategy. This will provide the Global Fund with the opportunity to catalyze strategic priorities while creating a menu of tools and guidance to support programs at country level.

IV. Operational Considerations

Set-Aside Modality

☒ Set-aside funds only, otherwise not feasible

The interventions require more centrally led coordination and need to be managed through set aside funds. While some of the enabling and foundational elements of Next Gen Market Shaping can be integrated in country allocations, key interventions have a global dimension that rely on the scale of the Global Fund's combined market shaping power and unique position as a multilateral organization and procurer. However, the Global Fund's catalytic efforts must be complemented with readiness at country-level to scale and implement Next Gen Market Shaping priorities with investments in the right commodities and interventions through Global Fund grants.

Global Fund Comparative advantage

☒ Global Fund is a leader in this priority area

The Global Fund is the largest multilateral provider of HTM and COVID-19 support in low- and middle- income countries, and also has a successful history of health product procurement and pooled procurement successes under its current Market Shaping Strategy. For some product categories, the Global Fund is the largest buyer of commodities for low- and middle-income countries. The Global Fund has played a leading role on international procurement platforms, like the ACT-A Diagnostics and Therapeutics Pillar, and has a comparative advantage and expertise in the space of global health product procurement. Others, like UNITAID, the WHO, Stop-TB/GDF, UNFPA, UNICEF, UNOPS, the Bill and Melinda Gates Foundation, play important roles in health product procurement and market shaping; however, the Global Fund is unique in the scale that it brings and the market shaping power it holds.

Global Fund Competency

The Global Fund's mandate, procurement scale for influencing markets and ability to capitalize on multi-funding mechanisms place it in a unique position to lead and drive these critical cross-cutting interventions to make grant-specific investments go farther.

Sustainability

Promoting a healthy and sustainable product market will have positive long-term effects on product availability, affordability, and quality at country-level. Through an increased focus on new product introduction at scale, the Global Fund will support greater visibility for the pipeline of products post 2025, to support country planning for the next cycle of allocation and grants. Local manufacturing capacity building is similarly a long-term investment in country capabilities and sustainable health markets. Finally, by spearheading efforts on sustainable sourcing and supply chains the Global Fund will not only gain supply chain efficiencies but will reduce waste and will demonstrate the pathway to sustainable sourcing and supply practices at country-level. In-country capacity building, which can often require more than a three-year investment to fully reap returns, will be built in procurement, quality assurance and supply chain to permit sustaining of gains and prior investments made.

Incentivizing RSSH quality and Scale

Incentivizing RSSH quality and scale	
Strategy goal: Maximizing People-centered Integrated Systems for Health to Deliver Impact, Resilience and Sustainability	**Recommended modality:** Matching Funds (MF)
Strategy's 10 changes: People-centered integrated systems for health Pandemic preparedness and response	
V. Proposal	
Description	

What is the core area of focus?

The Global Fund Strategy 2023 – 2028 outlines a shift in its investment approach. It calls for action to rise above disease silos to build integrated people-centered systems for health that place people and communities, not diseases, at the center. The Investment Case 2022 estimates that approximately US$ 6 billion out of a replenishment of at least US$ 18 billion would be used to strengthen integrated people-centered health and community systems, and private sector approaches that deliver outcomes against HIV, TB, malaria (HTM), related areas of health, and build pandemic preparedness capabilities.

The proposed catalytic investment is one tool that aims to catalyze this shift by using MFs to incentivize and reward strong resilient and sustainable systems for health (RSSH) funding requests and National Health Strategic Plans (NHSP) that set out robust, equitable, efficient and sustainable approaches for building integrated people-centered systems and services. They will also be used to incentivize strengthening of metrics for RSSH measurement and use in decision making.

To incentivize strength of proposals and plans in these areas, the MF would be competitively accessed among a subset of higher-burden LICs and LMICs, with focus on countries with relatively lower maturity of integrated health systems and integrated services (including prioritized health system components key to program scale-up and sustainability). The MF will emphasize leverage of additional domestic and other external resources in support of these aims.

What are the interventions?

There will be flexibility around the types of interventions supported, as areas of need in building integrated, people-centered systems and services will differ greatly on a country-by-country basis. At their core they will catalyze delivery of outcomes against HTM, related areas of health and building the resilience of systems for health to future pandemic threats. They will be used in conjunction with other RSSH CIs (see more below) and would include but not be limited to:

1. Incentivizing investments in integrated people-centered systems and services that deliver multi-pathogen capabilities, aligned with RSSH investment quality standards[5], in the following areas: health information and surveillance systems, community systems strengthening, digital technologies, national laboratory systems, health workforce, systems for improving quality of care, private sector engagement, health financing.
2. Catalyzing the introduction and scale-up of people-centered, holistic services defined by national priorities and aligned with the aims of the Global Fund Strategy. This includes, but is not limited to, integrated management of childhood illness (IMCI), packages of community health services, sexual

[5] RSSH quality standards is a recent and evolving concept that refers to the few select critical enables (policy, design, organization) for RSSH components (such as lab strengthening, CHWs) that are consideration critical for RSSH investments to deliver outputs and boost broader health outcomes.

and reproductive health rights (SRHR), non-communicable diseases (NCDs), mental health, other coinfections and comorbidities of HTM, surveillance at health facilities and in communities, capabilities for early detection and response to novel outbreaks, and strengthening referral and counter-referral systems.

3. Advancing RSSH measurement and addressing the shortcomings identified by the TERG[6], by enabling country systems to collect and use data on RSSH investments for better tracking and improvement of implementation progress and quality, and to inform health strategies and policies. This includes measurement at health and community systems levels in relation to HTM outcomes, progress towards integrated service delivery, and in relation to specific RSSH components, including preparedness capacities.

How does this MF relate to other RSSH CIs?

As indicated above, these use of this MF must be synergistic with other RSSH CIs and will be fully coordinated through operationalization (e.g., next generation market shaping, supply chain, community systems and responses (CS&R), community engagement, human rights and gender-related barriers, data), to collectively incentivize robust plans and holistic improvements where they are most needed on a country-by-country basis. For example, in the same country, these MFs could be used to catalyze robust plans for delivering integrated, people-centered quality services and systems, while the community engagement CI would complement delivery of these aims by supporting meaningful engagement of communities throughout decision making and delivery of the plan. As a next step, further operational work is planned on how the RSSH CIs will work together and be awarded and delivered synergistically to catalyze achievement of the Strategy's aims.

Which countries would be eligible for the MF?

The countries eligible for this MF would indicatively include those that meet the following criteria:

- Higher burden LICs and LMICs, with focus on countries with relatively lower maturity of integrated health systems and integrated services.
- Enabling environment (including governance perspective) from country dialogue to implementation (and openness to capacity building).
- Ability to commit domestic co-financing, match in grant, and/or other donor funds. Use of domestic funds where possible is preferred, but use of grant or other donor funds could be accepted with clear political buy-in.
- Based upon quality RSSH plans and/or national strategies in place.
- Match from US$1 -US$ 10 million, aligned to size of each portfolio.
- A competitive process with only the most technically sound and impactful proposals accepted.

Rationale

6

While the historical scale, scope and quality of RSSH investments have varied greatly according to country context, there is consensus that RSSH investments in the 2023-2025 allocation period must be of higher quality and more coherently support the delivery and scale-up of integrated, people-centered health services, and strengthen the systems that underpin the resilience, readiness, quality, and sustainability of such services.

This is reflected in recent TRP, TERG and OIG findings that found that while the level of financing for RSSH has increased, the quality of these investments has been uneven and that increases in RSSH investments had mainly focused on short-term health systems support, with less focus on longer-term strengthening. RSSH funding has also tended to focus more narrowly on supporting disease programs rather than strengthening integrated service delivery, which can concurrently serve to deliver outcomes in related areas of health and resilience to future pandemic threats.

Past funding cycles suggest that there are insufficient incentives to catalyze high quality RSSH investments, and this combined with well-quantified gaps in critical HTM interventions has been a limiting factor to both quality and scale of RSSH investments. The revised guidance tools (e.g., information notes, technical briefs and the modular framework), while important, have not been fully adopted by countries nor sufficient to change this. Therefore, an additional push is needed to achieve the level and quality of RSSH investments envisaged to deliver the vision set out in the new Global Fund Strategy.

This catalytic investment will contribute to addressing some of these challenges, incentivizing countries to improve both quality and scale of investments in building integrated people-centered services and systems (recognizing it is total RSSH health financing that is important and not solely the Global Fund investment). Matching funds have been selected as they are the most appropriate tool to incentivize increased, quality investments in planning and programming at country level, to drive focused in-country dialogue and garner leadership in support of critical Strategy priorities.

Funding

Is the priority insufficiently addressed by other sources of funding? What are the key drivers of under-funding?

Previous approaches have been inadequate in catalyzing robust RSSH funding requests and plans that deliver equitable, efficient and sustainable approaches in building integrated people-centered systems and services, and in strengthening metrics for RSSH measurement and use in decision making. Previous approaches have also insufficiently maximized leverage of domestic and external partner financing (e.g., GAVI, grants and concessional loans from multilateral development banks) to build the sustainability of RSSH. This catalytic investment intends to incentivize development and prioritization of solutions to these longstanding challenges.

VI. Strategic Impact

Potential for increased impact

Does this priority contribute to a new, enhanced or underperforming area in the Strategy? How?

Enhanced: Aims to incentivize increased quality and scale of integrated, people-centered quality services and systems, and effective RSSH measurement, in contexts where there is greatest potential for improvement, while leveraging increased financing through domestic, other external and Global Fund grant sources. Integrated, people-centered quality systems and services lie on the critical pathway to achievement of the Strategy's primary goal to end AIDS, TB and malaria, to contribute to broader health outcomes as set out in SDG 3, and to strengthen preparedness and resilience to future pandemic threats.

Levers

What other levers could be used to implement this priority?

A combination of the following levers will be used in addition to the proposed MFs to improve the quantity and quality of the RSSH investments:

- More targeted technical guidance on priority sub-topics for RSSH through a revised information note, modular framework, allocation letter, and risk matrix.

- Revised approaches such as integrated funding requests, where appropriate.
- Strengthening RSSH representation, including representation of the health and care workforce (e.g., community health and peer workers), on Country Coordinating Mechanisms (CCMs) and embedding more CCM functions in health sector coordination bodies to strengthen scope, quality and scale of funding requests.
- Greater support for selection of most relevant Principal Recipients and Sub-recipients to deliver RSSH work (e.g., national public health institutes, lab directorates, ministry of health departments for community health, health workforce, including field epidemiology training programs, surveillance/HMIS, pandemic preparedness and emergency response management, etc.)More strategic and targeted RSSH technical assistance (TA) in response to country needs, and associated re-orientation of the secretariat's RSSH team and related teams to support countries and country teams through in country dialogue and the overall grant lifecycle.
- Strategic and operational partnership with our key partners to complement Global Fund investments with additional resources and TA (GAVI, bilaterals, MDBs, etc.).

Catalytic Effect

☒**More**: incentivize increased funding from allocations to priority areas and/or additional funding outside of Global Fund

☒ **New**: initiate new or innovative activities for more efficient and impactful programming

☒ **Improved**: enable more effective use of country allocations and coordinated responses for cross-border contexts

Expected outcomes

In countries with greatest potential for improvement:

- Significantly strengthened RSSH funding requests and plans that set out robust, equitable, efficient, and sustainable approaches for building integrated people-centered systems and services.
- Increased quality and scale of integrated, people-centered systems and services that significantly strengthen outcomes against HTM, related areas of health and build pandemic preparedness capabilities – including a focus on systems strengthening over support.
- Increased RSSH investments through domestic, other external and Global Fund grant sources.
- Strengthened metrics for RSSH measurement and use in decision making.

Theory of change

This MF will incentivize CCMs to invest more in integrated RSSH approaches and leverage additional matching funding for these areas. This will result in higher quality investments in these areas, leading to more integrated health system approaches, more integrated service delivery platforms, strengthened pandemic preparedness capabilities, and more resilient systems for health. These will facilitate better HTM and broader health outcomes and improve the preparedness and resilience of HTM services and systems for health to future pandemic threats. A competitively awarded MF will generate increased focus across all eligible countries while also ensuring funding of the highest quality RSSH proposals.

Risk if not funded

If not funded as a set-aside, how high is the risk that this does not get funded at all?

High risk that RSSH does not get funded at the quality or levels commensurate with the new Strategy. Countries find it difficult to prioritize investments in RSSH given urgent commodity needs for HTM priorities, and overall limited fiscal space. Countries also struggle to support integrated RSSH approaches due to lack of clear planning, prioritization and incentives.

What are the direct epidemiological risks if not funded (e.g. rising incidence, resurgence, drug resistance)?

Continued stagnation or reversed progress on HTM outcomes and increased vulnerability in the face of economic downturns and future pandemics. The literature shows that integrated approaches and systems strengthening interventions can lead to improved HTM outcomes and enhanced pandemic preparedness.

What are the programmatic risks if not funded (e.g. deteriorating service delivery, systems)?
Risks include not being able to effectively operationalize and sustain the vision for integrated, people-centered quality services in the new Strategy; missed opportunities to deliver value for money, efficiencies, and impact through current RSSH investments; missed opportunities for countries to realize the full benefit of prior investments in RSSH if funding is not continued and scaled up; HTM programs at greater risk of catastrophic knock-on effects of future pandemics due to inadequate system readiness and capabilities. From a pandemic preparedness perspective, this would be a missed opportunity to build pandemic preparedness capabilities on a marginal cost basis.

VII. Previous Investments

2020-2022 Catalytic Investment

Are there existing catalytic investment(s) related to this priority?
Yes, for the 2020-2022 allocation period there are SIs that focus on specific aspects of people-centered, integrated systems for health, however, through a more piecemeal approach. Going forward, RSSH catalytic investments will focus on areas where the Global Fund can be most catalytic to deliver the new Strategy's aims, while ensuring that operationalization leveraging linkages and synergies across these SIs.

Related 2020-2022 catalytic investments:
- Data SI (US$35 million)
- Sustainability, transition and efficiency (STE) SI (US$18 million)
- Service Delivery Innovation (SDI) SI (labs, private sector engagement, HRH, CLM, South-South learning) (US$47 million)
- PSM Transformation SI (US$20 million)
- PSM: Accelerated Introduction of Innovations SI (US$10 million)

Current implementers

Wide variety of technical and other partners

Current target populations

Mostly high impact and core countries

Progress to date

As described in the new SI proposals for the various components (laboratories, community systems & responses, data, health financing, equitable access to quality health products)

Expected evolution

As described above, past funding cycles suggest that additional incentives are needed for improved quality RSSH investments, and this has been limiting factor for scale-up. The effects of revised guidance tools (e.g. information notes, technical briefs and the modular framework) while important, have not been sufficient to change this. Therefore, a stronger push is needed to achieve the level and quality of RSSH investments envisaged in the new Global Fund Strategy to deliver outcomes against the three diseases, in related areas of health and to strengthen national pandemic preparedness capabilities.

VIII. Operational Considerations

Set-Aside Modality

☒ Set-aside funds only, otherwise not feasible
Many countries did not include funding for integrated RSSH approaches, which is why it is being highlighted in the new Strategy as an area to strengthen.

Global Fund Comparative advantage

☒ The Global Fund is one of many partners supporting this priority area.

Global Fund Competency

MFs have been demonstrated to result in real increases in the quality and quantity of investments in focus areas.

Sustainability

As countries tend to prioritize successful activities that they've already funded in the past cycle, the expectation is that countries will continue to fund most of these activities going forward once they are in

their grants. Also, as domestic funding will be leveraged to match the MF, this will help ensure sustainability.

Effective community systems & responses (CS&R) contributing to improved health outcomes, equitable access to integrated people-centered quality services, and pandemic preparedness and response

Effective community systems & responses (CS&R) contributing to improved health outcomes, equitable access to integrated people-centered quality services, and pandemic preparedness and response	
Strategy goal: Maximizing People-centered Integrated Systems for Health	**Recommended modalities:** Matching Funds (MF) and Strategic Initiatives (SIs)
Strategy's 10 changes: Service delivery by community based/led organizations	
I. Proposal	
Description	
Achieving the strategic objectives of the Global Fund Strategy 2023-2028 will require stepping up investments, bringing to scale community systems and responses in their diversity (community-led organizations (CLO), community-based organizations (CBO), and community health workers (CHW)) and investing in the key system components needed for strong and resilient community systems for health. This proposal focuses on three core areas of community systems and responses (CS&R): 1) **Catalyze CHW programming**: This proposal builds on the lessons of successful country experiences of CHW professionalization, institutionalization, and sustainability (e.g., for Ethiopia, Zambia, Liberia). For up to 10 countries committed to institutionalizing and sustaining a fairly paid, well-supported CHW workforce following WHO Guidelines (to be selected in coordination with donors, Roll Back Malaria and Situation Room partners), provide MF for catalyzing investment in: • System readiness for scale of the CHW workforce, • Scaling the CHW workforce, and • Institutionalization and sustainability of the CHW workforce, within government-led systems for delivering integrated, quality community health services, including for HIV, TB, malaria, pandemic preparedness (PP) and broader primary health care. MF will be used to incentivize investment in key systems components needed for system readiness to scale, attract new resources to scale (e.g., from private sector philanthropy and domestic financing (including through grants and loans from multilateral development banks)) and incentivize demonstrable progress on institutionalization and sustainable financing, including through domestic resources. MF will be coupled with SIs for targeted, high quality and timely technical support through leading-edge regional technical partners such as Africa Frontline First and AFENET to enable effective and efficient grant implementation, capacity building of national/local institutions, enhance coordination at country/regional/global levels (building on existing efforts such as the Community Health Roadmap) and alignment at country level behind country-led plans. This will be coordinated with other proposed Catalytic Funding (Health Financing, Data, Lab, TB, Malaria, HIV) for countries committed to institutionalization and sustainability of fairly paid, well-supported CHWs within government-led systems, leveraging funding from those proposals for the above CHW-focused	

purposes where possible and layering additional funding where needed to maximize catalytic effects.

2) **Accelerate community systems strengthening, particularly for community-led organizations (and networks of key and vulnerable communities):** Building on best practices and lessons learned in Kenya, Ghana and South Africa, the MF component will incentivize increased investments and prioritization of strengthening core competencies of CLOs to play active roles in designing, implementing and monitoring health services, policy and pandemic preparedness for HIV, TB and malaria as well as broader primary healthcare. A total of 10-12 countries will be prioritized for MF for six core domains: i.e., institutional strengthening and leadership development, community and social mobilization, program design, governance and monitoring and evaluation, coordinated with other proposed CIs (i.e. Data, Health Finance, TB, Differentiated Service Delivery). For maximum impact, and improved coordination, support will be complimentary to and leverage ongoing efforts from partners set asides and philanthropic investments i.e., Love Alliance (AidsFonds) and Robert Carr Fund, PEPFAR, L'Initiative, GiZ, USAID TB and the StopTB Challenge Facility for Civil Society (CFCS). The SI component will offer tailored and contextualized TA to support effective organization and delivery of quality health services through establishing minimum standards for community-led responses to HIV, TB, malaria and Primary Health Care that integrates human rights and gender, safety and security and stigma and discrimination reduction into service packages and delivery platforms. The SI will also set up a peer-to-peer learning mechanism to be coordinated through regional mentorship bugs to reinforce linkages between the community and public sectors.

3) **Embed Community-led monitoring (CLM) in health responses and catalyze the use of CLM feedback and data to inform programmatic and financial decision making.** For improved accountability and responsive quality programming, support scale up of CLM in 10-12 countries, coupled with high quality and targeted technical support for CLM data use for decision making, to generate evidence and learning for replication in other contexts and empower communities on health and legal literacy. This priority builds on the lessons learned from the CLM-SI implementation. Following significant investments in setting up CLM mechanisms, strengthening their data collection methods, validity, quality assurance and analysis, the next natural evolution is to focus on use of CLM data and feedback from services users/clients to improve services along four domains (acceptability, affordability, accessibility and quality). Investments in this area (both MF and SI) will prioritize setting up mechanisms where community-led groups and networks (linked to (2) above) can advocate for service improvements, adaptations through meaningful and evidence-based advocacy. Furthermore, this investment aims to strengthen use of CLM data with HMIS and DHIS M&E systems and frameworks to catalyze maximum effect.

Proposed Interventions

Area of focus	Interventions
Catalyze CHW programming	MF for catalyzing investment in: • System readiness for scale of the CHW workforce • Scaling the CHW workforce, and • Institutionalization and sustainability of the CHW workforce. SI for targeted, high quality and timely technical support through leading-edge regional technical partners such as Africa Frontline First and AFENET to enable effective and efficient grant implementation, capacity building of national/local institutions, enhance coordination at country/regional/global levels (building on existing efforts such as the Community Health Roadmap) and alignment at country level behind country-led plans. As noted above, this will be coordinated with other proposed Catalytic Funding (HF, Data, Lab, TB, Malaria, HIV) for countries committed to institutionalization and sustainability of fairly paid, well-supported CHWs within government-led systems to maximize catalytic effects.
Accelerate community systems	Strengthen large scale and more effective efforts to build operations, technical and governance capacities of community-led and -based

and responses strengthening particularly for key population-led organizations and networks	organizations (with a focus on key population-led) and associations/networks to reinforce linkage and mobilization of community health workforces, community-led responses (especially for prevention and care), rights-based and gender-transformative community systems. This will be achieved through differentiated capacity building on a maturity model delivered through a peer-to-peer and regional mentorship hubs that reinforces community-led organizations and accountability at greater scale (technical assistance through the SI) coupled with increased investments in community-led responses and systems components (MF).
Community-led monitoring	Building on lessons learned from the CLM-SI implementation, incentivize integration and scale up of CLM and community systems through more strategic use of CLM data (and systems) in evidence-based advocacy by establishing (or co-opting) mechanisms for greater, meaningful participation of service users/clients for more people-responsive and centered health services.

Rationale

Several reviews/evaluations including by the Technical Evaluation Reference Group (TERG), Technical Review Panel (TRP), Community, Rights and Gender (CRG)/MECA and the Office of the Inspector General (OIG) have concluded that there is scope for improvement in community engagement, community-led and -based responses and the importance of community health sector interaction and complementarity. In particular:

- **Current investment in CHW programming, CSS and CLM is not commensurate with the level of ambition of the Global Fund Strategy 2023-2028 and significant gaps exist which are not filled through other funding mechanisms.** Investment in these areas has been impeded by limited fiscal space in grants due to lack of prioritization, coupled with domestic and partner resource constraints. Global Fund investment in the 2020-2022 allocation period was US$127 million for CHW programming (all community cadres), US$96 million for CSS and US$36 million for CLM (collectively ~2% of the total 2020-2022 allocation). These amounts are inadequate relative to what is called for in the Global Fund Strategy 2023-2028 and consultations across the partnership. Significant increased investment in these areas is mission critical along with a technical support mechanism for tailored, high quality and contextualized support.
- **Current investment in CHW programming, CSS and CLM is not systems oriented, it is piecemeal and neglects game-changing systems strengthening interventions** across key domains (financing, health workforce, digital tools and systems, supply chain, leadership and governance, community systems strengthening and societal partnerships). Such systems strengthening interventions are a minimum requirement for effective and well-integrated CS&R – particularly for and by key and vulnerable populations (K&VP). The piecemeal approach has hindered effectiveness of CS&R investments and taking impactful approaches to scale i.e., in Ghana, South Africa and Liberia. The piecemeal approach is in part due to the overall inadequate level of funding but also to a lack of prioritization of important systems strengthening interventions (or prioritizing perceived cost savings at the expense of investing in what will deliver impact in the long term). Illustrative (non-exhaustive) examples of game-changing systems strengthening interventions that have been neglected include:
    - **Finance:** development of costed national community health strategic plans, including clear roles for CHWs and K&VP cadres (peers), community-based and community-led organizations in line with WHO guidelines and best practice (e.g. CHW AIM tool, SWIT, MSMIT, TGIT, etc.), inclusive of PP and long-term sustainable financing pathways (including optimized financing mix and transition toward increased domestic funding) and institutional capacity to develop and implement these; fair financial and non-financial remuneration for CHWs and K&VP cadres per WHO and ILO guidance and national statutes with guaranteed wage floor (minimum wage) and other benefits accorded to decent work; strengthened HR and payroll systems to enable payment to CHWs and K&VP cadres and broader health workforce on-time, in-full, every month.
    - **Workforce:** development of long-term 8-10 year plan for optimized CHW and KVP peers (all cadres) scale-up / right-sizing and targeting and institutionalize use of HRH optimization tools and approaches (CHW/HRH master lists, health labor market assessments, GIS modelling and robust

costing, implementation and costing guidelines) in national CHW, K&VP cadre, and broader HRH planning; strengthen institutional capacity to deliver pre-service training and ongoing professional development for CHWs, K&VP cadres and their supervisors and managers/leadership linked to accreditation (minimum standards) and career pathways, including neglected areas for PP (e.g. field epidemiology training program (FETP) curriculum adapted to community level), leveraging digital technology; institutionalization of a dedicated supervisor cadre for CHWs and K&VP based on best practice approaches to supportive supervision and quality improvement such as the 360 dedicated supervisor model; institutionalize facilitated referral and counter-referral from CHWs and K&VP cadres to / from health facilities. This will be coordinated with the HF CI proposal for countries committed to institutionalization and sustainability of paid, well-supported CHWs and K&VP cadres within government-led systems, leveraging funding from those proposals for the above CHW-focused purposes where possible and integrating additional funding where needed to maximize catalytic effects.

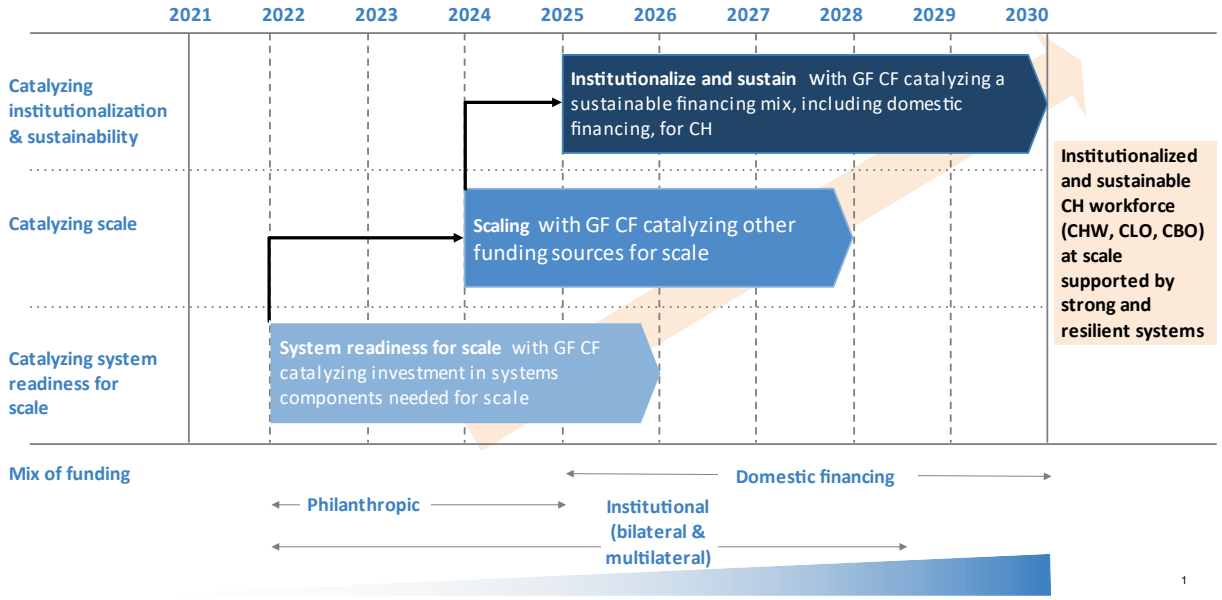
- **Digital tools and information systems:** strengthen and scale implementation of digital systems for community health data including interoperability with key systems. Integration of community level data-related interventions into FETP curricula and training activities, and build capacity of institutions (Ministries of Health, public health institutes) and frontline providers, including CHWs, K&VP cadres, and community-based and community-led organizations, on the FETP curriculum. This includes, but is not limited to: (1) integration of community event-based surveillance and rapid response into national Integrated Disease Surveillance and Response mechanisms at national scale; (2) risk communication and community engagement, and incident/response management; and (3) strengthening of institutional capacity to set up and manage mobile payments for CHWs and K&VP cadres, their supervisors and broader health workforce. This will be coordinated with the Data CI proposal and build on achievements of the current Rockefeller MF (where possible) for countries committed to institutionalization and sustainability of paid, well-supported CHWs within government-led systems.
- **Supply Chain:** integration of parallel procurement channels for CHWs and KP-led cadres at sub-national level, addressing barriers to CHW and K&VP cadre stock access, and progressing toward integration of community health supply chain policies and practices into national procurement systems.
- **Capacity strengthening and leadership development of community-led, particularly KP-led organizations has not taken into account maturity and operating contexts, or establishing formal partnerships with the health sector, as key to improve the health service continuum in and outside health facilities.** This is critical in contexts of criminalization where community and civil society operate in restrictive civic spaces. A differentiated approach to organizational capacity strengthening, leadership development and governance strengthening anchored in a south-south learning and regional mentorship hub approach, is needed to catalyze peer-to-peer learning and uptake of successful interventions. This will result in strengthening joint partnerships between community and public healthcare providers (MOH, CHW-led, community-based and key population-led organizations), including participation in mechanisms for coordination, multi-sectoral mobilization and coalition building. Tailoring support to reinforce these core domains remain major barriers to meaningful community engagement, peer-peer service delivery, community-led research evidence-based advocacy and accountability. Without this prioritization and approach, the enabling environments in which community-led and –based organizations need, CS&R investments will not yield the kind of health system dividend global partners are calling for, including UNAIDS and End TB Strategies. Contributions by communities will continue to be uneven and piecemeal and will not reach the scale we need for health system impact.
- **Investments in CLM have been small scale without clear pathways to embed social accountability within health responses and as a result, inadequate use of CLM data for evidence-based advocacy and decision making.** There is a proliferation of tools, guidance and established technical support mechanisms to strengthen the use and uptake of CLM mechanisms globally through PEPFAR, USAID, CDC, UNAIDS, STP and BMGF. At the local level, CLM data has been effectively used in adjusting programs to be more people-centered with clear recommendations to improve the quality, accessibility, affordability, and acceptability of services while at the same time documenting human rights and gender violations and redress. During

COVID-19, CLM data reinforced advocacy to leverage testing platforms for both COVID-19 and TB; in DRC, thanks to a treatment observatory mechanism, TB medicine stockouts were reduced from 95% to 5% over two years. This catalytic investment aims to 1) bring successful CLM models to scale, through integration where feasible, 2) advance CLM for prevention, particularly outside of the public health sector and in communities contributing to strengthened PHC and 3) strengthen the use of CLM data and feedback to inform decision making with the goal to embed social accountability in health response oversight functions and quality improvement strategies.

Funding

The proposed priorities are not addressed by other sources of funding (domestic, partners, OPEX) and large gaps remain due to limited fiscal space and lack of prioritization in grants. The proposal intends to catalyze grant investment in these neglected areas, leverage additional funding from private sector philanthropy and domestic financing (including through grants and concessional loans from multilateral development banks), and spur concrete progress on domestic financing in the medium/long-term for system readiness, scale and sustainability (see Figure 1 below). The Secretariat will reach out to HTM partners to identify priority countries and contexts for maximum catalytic effect.

Figure 1. Phased approach to drive sustainable financing and at-scale Community Health services



Strengthening CHW Programming - MFs and SI: Estimate based on 1) 3-year timeline 2024-2026, 2) robust estimates of average cost per intervention per year for up to 10 countries committed to institutionalizing and sustaining a fairly paid, well-supported CHW workforce following WHO Guidelines (and to be selected in coordination with donors, RBM, and Situation Room Partners) and 3) anticipated leverage of private sector contributions. The estimated breakdown is as follows:

- At least 80% of the total in MF for 5-10 countries along a maturity model
  - Up to 5 countries where targeted investment in the "foundations for scaling" will enable system readiness for scale, greater integration and enhance the prospects of sustainability; and
  - Up to 5 countries where targeted investment will accelerate movement from "good to great", focusing on optimization of systems for efficiency and effectiveness, scaling-opportunistically (e.g., where funding for sustaining can be assured) institutionalization, and sustainability
- Up to 20% of the total in SI funds for high quality and timely technical support to enable effective and efficient grant implementation, institutional capacity building, country/regional/global coordination, and learning

Private sector contributions are anticipated on top of the SI and MF. ~US$1-2 million of this private sector funding will be channeled through an existing/new SI in early 2023 to enable a start to implementation of

the CHW component of the proposal, avoiding problematic delays in implementation of previous SIs, as well as to help countries prepare for the 2023-2025 allocation period and set up the remaining funds to start in 2024, in line with the implementation period start dates of the 2023-2025 allocation period grants.

Community-led responses and CLM -MFs and SI: Prioritizing high burden, priority countries across the three diseases a mixed modality of MF and TA (SI) to complement philanthropic and bilateral and multilateral agencies focus and investments, including the Robert Carr Fund, AIDSFonds (Love Alliance), L'Initiative, SAID, RBM, StopTB, Civil Society Challenge Facility and PEPFAR through:

- MFs for community-led responses to key and vulnerable-led organizations along a maturity model across country contexts (COE, transition, high impact) and by key population i.e., PWID, sex workers, MSM, transgender, AGYW, PLHIV, TB Survivors, those most impacted by TB as well as malaria-affected communities.
- SI to deliver technical support through a regional and south-to-south learning model, establish a peer-led technical support mechanism including regional hubs to foster cross country collaboration and learning, leadership development and ownership.

II. Strategic Impact

Potential for increased impact

- **More**: Incentivizing increased financial resources and counterpart domestic financing for CS&R, with anticipated broader leverage in the medium term (e.g., additional private sector philanthropic funding, domestic financing (including grants and concessional loans from multilateral development banks) with a focus on KP-led and community-based systems strengthening components.
- **Enhanced**: Catalyzing investments are essential to ensure effective CHW programming, CSS, and CLM to accelerate systems readiness for scale, integration, efficiency and impact. Private sector contributions will enable a start to implementation in 2023, at least for the CHW component, avoiding delays in implementation of previous SIs.
- **New**: Focus on sustainable financing pathways, use of optimization tools to drive efficiency, and strengthening collaboration between the formal health sector and community health cadres (service packages, delivery modalities, supervision, facilitated referral, and PP – surveillance, FETP and community response) in support of high quality, integrated, peopled-centered services for prevention, care and treatment, particularly for key and vulnerable populations, as well as PP.

Levers

Several Strategy Delivery levers are relevant to this area, including:

- Leverage 10 Key Changes and organizational priorities identified as Impact Accelerators for Wave 1/programmatic and Wave 2/enablers (ongoing)
- KPI evolution process (ongoing)
- Advocacy and engagement across the Secretariat (ongoing)
- Advocacy and engagement with external partners (ongoing)
- Global Fund investment case for replenishment (ongoing)
- Programmatic updates in operational launch planning, including modular framework, technical guidance and information notes, country engagement, applicant briefings and CCM training, TRP guidance/briefing note budgeting guidance; allocation letters, engagement of countries, principal recipients and community and civil society etc.

However, collectively these will not adequately incentivize the critical changes necessary at country level, hence the need for the CI to complement the above and put the needed incentives in place.

Priorities align with priorities in relation to HIV (KP and AGYW precision prevention, improving testing update, retention on treatment), TB (awareness, contact investigation, case finding, treatment and prevention), malaria (improving access to quality case management and equitable access for underserved communities, and PP (strengthening preparedness, surveillance, and response at community level, building institutional and frontline capacity on FEPT). Furthermore, the CI leverages the multisectoral setup of the CRG Steering Committee and connects to other proposed CIs (Data SI, HF) – financing pathways for community-led responses (social contracting) and medium to long-term sustainability planning i.e., STC.

Catalytic effect

☒ **More**: Incentivizing increased financial resources and counter-part domestic financing for CS&R, with anticipated broader leverage in the medium term (e.g., additional private sector philanthropic funding, development banks)

☒ **Improved**: Catalyzing investments in essential but neglected systems strengthening interventions underpinning effective CHW programming, CSS, and CLM to accelerate systems readiness for scale, integration, efficiency and impact.

☒ **Faster**: Accelerate implementation of specific priorities: High quality and timely TA will strengthen institutional (national/local) capacity to accelerate implementation of prioritized interventions

Expected outcomes

- **Improved performance and quality** of community health services (CLO, CBO, CHW) for HIV, TB, malaria, pandemic preparedness and broader PHC
- **Increased absorption** of prioritized interventions for CHWs, CSS and CLM within grants
- **Increased system readiness to scale** community health services (CLO, CBO, CHW) and effective feedback loops
- **Improved capacity** of national and local institutions, enabling effective grant implementation and oversight for priorities across CHWs, CSS and CLM
- **Increased integration** of community health services (CLO, CBO, CHW) within national health systems as part of primary health care and pandemic preparedness
- **Improved coordination** of investment and technical assistance for community health services (CLO, CBO, CHW) at country, regional and global levels
- **Increased use of community-led monitoring data and feedback** on accessibility, quality, affordability and acceptability of services
- **Long-term sustainable financing pathways** developed for strong and resilient CH systems (CLO, CBO, CHW) including transitioning towards increased government investments

Theory of change

MF will be used to catalyze investment in

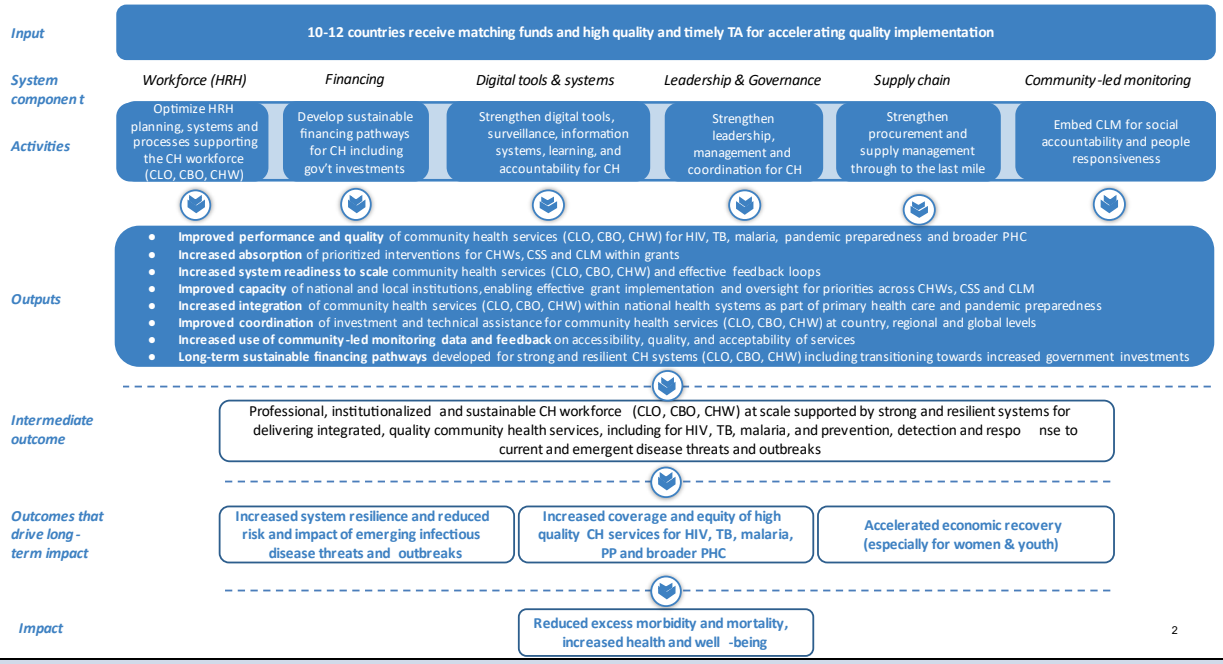
- System readiness for scale of the CHW workforce
- Scaling the CHW workforce
- Institutionalization and sustainability of the CHW workforce
- Differentiated capacity building of KP-led institutions along a maturity model.
- Scale-up of CLM mechanisms and development of national CLM frameworks, protocols, and data sharing agreements

SI funds for the CHW component of the proposal, will provide high quality and timely technical assistance through leading-edge regional technical partners such as Africa Frontline First and AFENET to enable effective and efficient grant implementation, capacity building of national/local institutions, enhance coordination at country/regional/global levels (building on existing efforts such as the Community Health Roadmap) and alignment at country level behind country-led plans. Private sector philanthropy seed funding will enable a start to implementation early in 2023, in order to avoid delays in implementation as experienced in previous SIs.

SI funds for the CLO/CBO and CLM components of the proposal will offer tailored and contextualized technical support for effective organization and delivery of quality health services through establishing minimum standards for community-led responses to HIV, TB, malaria, and PHC that integrates human rights and gender, safety and security and stigma and discrimination reduction into service packages and delivery platforms. The SI will set up a peer-to-peer learning mechanism to be coordinated through regional mentorship hubs to reinforce linkages between the community and public sectors. Lastly, the SI will support setting up mechanisms where community-led groups and networks can advocate for service improvements, adaptations through meaningful and evidence-based advocacy using CLM data with HMIS and DHIS M&E systems and frameworks to catalyze maximum effect.

See **Figure 2** for a visual summary of the theory of change. This, in combination with **Figure 1** above provides an overall view of *HOW* the proposal intends to achieve the expected catalytic effects.

Figure 2. Theory of Change



Risk if not funded

If not funded as a set-aside, there is a high risk that this does not get funded at levels commensurate with the level of ambition of the Global Fund's Strategy 2023-2028 and technical partner strategies i.e., End TB and UNAIDS.

- Analysis of the 2017-2019 and 2020-2022 allocation period investments in CS&R highlights that this remains an under-resourced, low priority for countries with piecemeal support.
- TERG, OIG, TRP and thematic reviews highlight the criticality of stepping up and reinforcing community systems and responses.
- Inadequate investment in and ineffective design of system strengthening interventions, particularly for capacity building of community-led organizations, supporting network building through increased civic space for dialogue, meaningful engagement and oversight functions undermine core principles which the Global Fund prioritizes as country-led, country-owned, evidence based and with communities at the center.

What are the direct epidemiological risks if not funded?

- Stalled or reversed progress on HIV incidence reduction, particularly among key and vulnerable populations.
- Stalled or reversed progress on TB case finding and TB mortality reduction as community approaches and systems are key for these.
- Exacerbated reversal of progress on global malaria targets for 2030, particularly for malaria mortality reduction, multiplying existing threats (COVID-19 disruptions, economic downturn)

What are the programmatic risks if not funded?

- Failing to adequately invest in the above noted essential but neglected systems strengthening interventions and peer and community-led approaches to quality integrated service delivery, addressing social and structural barriers and fragmentation between community and facility services, will continue to leave key and vulnerable populations behind, resulting in poorer programmatic and health outcomes for prevention, case finding, referral and linkage, treatment, and continuity of care, as well as weaker systems and greater vulnerability to future pandemics, shocks, and emergent threats.

III. Previous Investments	
2020-2022 Catalytic Investment	**2020-2022 Budget Amount**
Service Delivery Innovations (SDI) SI: ▪ Sub-component 1 - South-south Learning and Strategic Support to Countries (SSC). Operationalization of community health strategies. ▪ Sub-component 2 – Community-led monitoring	Sub-component 1: $5.1 million Sub-component 2: $3.0 million
Current implementers	
▪ South-South: Implementer TBC ▪ CLM: Eastern Africa National Network of AIDS Service Organizations (EANNASO), ITPC Global, Health Gap	
Current target populations	
▪ South-South: CHW programs in Central African Republic, Chad, Congo, Guinea Bissau and Mauritania. ▪ CLM – sex workers, PWID, transgender, TB affected communities, migrant and forest workers, MSM, prisoners, PLHIV. Priority countries: Bangladesh, Philippines, Ukraine, Cote d'Ivoire, Jamaica, Laos and Cambodia (RAI).	
Progress to date	
South-South: implementer being contracted. CLM-SI: • Eight landscape assessments completed in five priority portfolios and one MC. • Improved partner coordination, including among donors (PEPFAR) and technical partners on CLM support (UNAIDS and STP), minimum program requirements established, investment synergies at the global and regional levels. • 100% of grants reviewed to strengthen planned CLM interventions and support scale up through targeted technical support. • 10 technical resources under development to support better use of CLM data for decision making, budgeting, conflict of interest, indicator and tool development. • Initiated development of national CLM frameworks/strategies in three countries to provide guidance and direction to civil society on how to implement CLM, protocols and minimum standards, data use for decision making and conflict of interest.	
Expected evolution	
This proposal is not a continuation of the south-south learning CI but will build on lessons learned and leverage partners already engaged for continuation of support, and replication of successes. In addition, this CI will leverage private sector philanthropy to initiate early implementation where feasible to avoid any delays implementing this CI. *Based on lessons learnt, what will be done differently in the next cycle to improve impact?* A systems-oriented approach, underpinned through a shift (new and evolved) in how and what to prioritize in terms of effective CS&R across the three diseases and broader PHC, particularly for CHWs, K&VP-led organizations and networks. More intentional and strategic use of CLM data and feedback after years of investments in setting up CLM mechanisms will result in empowered communities and civil society to advocate for their health and legal rights from a service user/client perspective. Furthermore, this proposal will leverage philanthropic and private foundation investments, domestic finance (including grants and concessional loans from multilateral development banks), partner set-asides and launches from a functional coordination mechanism where partners are engaged, interested to support and welcoming innovations.	
IV. Operational Considerations	
Set-Aside Modality	
☒ Set-aside funds only, otherwise not feasible As noted above, investment in CHW Programming + CSS + CLM collectively amounts to <2% of total 2020-2022 allocation funding. Investments in key systems strengthening interventions across systems domains (noted above) are absent or inadequate. *If integrated in country allocations, what policy levers would be needed to effectively implement this priority?*	

• CSR SI: Set-aside only as funding requests include limited investments for driving forward effective community health models, including key systems components and the needed TA to accelerate regional and national capacity to scale effective models, promote south-south learning, innovate and enhance country, regional and global coordination. • CSR MF: Can be integrated in country allocations with strong guidance in allocation letters and funding request materials.
Global Fund Comparative advantage
☒ Global Fund is a leader in this priority area ☒Global Fund is one of many partners supporting this priority area The Global Fund is a leader in these priority areas (CHW Programming, CSS and CLM). Other major funders supporting these areas include USAID, PEPFAR, UNAIDS, UNICEF and in some instances development banks (e.g., the World Bank). However, other partners are not covering the above noted gaps and the Global Fund is best positioned to quickly catalyze these areas, leveraging additional funding from other major funders in the medium term in the context of sustainable financing pathways (proposed to be developed as part of this catalytic funding).
Global Fund Competency
Discrete country examples indicate Global Fund competency, despite limited funding in these areas, e.g., in Mali for CHWs and community systems strengthening, DRC, Cote d'Ivoire. Liberia and South Africa where CLM has resulted in significant improvements in stockouts of essential medicines, address quality issues in terms of accessibility of services and identified human rights and gender-related barriers, which improved health seeking behavior.
Sustainability
• The core of this catalytic investment is to incentivize increased domestic resource allocation and domestic financing (including grants and concessional loans from multilateral development banks), funding from other development partners and private sector philanthropy for community systems and responses. Support to the development and implementation of sustainable financing pathways is a game-changing intervention proposed here. • Catalytic investment will be monitored throughout implementation and evaluated, and South-South and cross portfolio learning will be fostered to encourage up take of best practice and refine approaches.

Community Engagement

Community Engagement	
Strategy goal: Maximizing Community Engagement and Leadership	**Recommended modality:** Strategic Initiative (SI)
Strategy's 10 changes: Voice for Communities	

I. Proposal

Description

The leadership of communities living with and affected by the three diseases has been central to the Global Fund since its foundation. The importance of community leadership and engagement is reflected across the Global Fund's model – with communities playing a central role in its governance at country and global levels, as implementors, in accountability, and as advocates for its mission.

The criticality of community leadership and engagement in achieving the Global Fund's goals and mission is reflected in the Global Fund Strategy 2023-2028 which emphasizes supporting and leveraging the unique and extensive knowledge and contribution communities bring.

The Global Fund is widely assessed as a global benchmark in its approach to meaningful engagement of communities and civil society. The success, effectiveness and importance of the current Community, Rights and Gender (CRG) SI has been noted by communities, partners and donors alike, and confirmed via independent evaluations.

Since the 2014-2016 allocation period, the CRG SI has focused on three inter-related components:

1. **Short-term technical assistance** delivered by and for community and civil society
2. **Long-term capacity strengthening** of key and vulnerable population networks and organizations
3. Regional **coordination and communication platforms** for community and civil society

Operationalization of the CRG SI has evolved since inception and in response to cyclical independent mid-term and end-term evaluations. For example, in the last cycle, the scope was broadened to enable TA across the grant cycle, capacity building of TB and malaria communities was included and specialized support for AGYW was provided. In the current cycle there is an increased focus on the use of TA outputs to inform decision-making and achieving country level outcomes.

Considering the elevation of community engagement and leadership in the next strategy cycle, in depth consultation with communities and technical and bilateral partners will occur to review and revise operational approaches and focus, augmented by findings of already planned external evaluations and priorities coming out of the Global Fund Strategy implementation planning.

Recognizing the need and importance of better tailoring the focus of any community engagement strategies as most relevant to communities impacted by TB and malaria – work to integrate express partner priorities within the operational approach and in funding allocations will commence immediately on Board approval of community engagement and leadership as a continuing priority under catalytic investments.

Should community engagement remain a priority under catalytic investments for the 2023-2025 allocation period, CRG anticipates the following stages in review:

- Mid-term evaluation in Q3 2022 will utilize a Value for Money lens to identify opportunities to evolve the CRG SI and further increase the economy, efficiency, effectiveness and equity of the CRG SI and its outcomes across HIV, TB and malaria communities
- Engagement with key HIV, TB and malaria community and civil society stakeholders and partners to inform and guide design as increasingly responsive to needs and to drive country level outcomes

- CRG SI Coordination Mechanism membership oversight and input into any review and redesign process to facilitate joint planning and strengthened alignment across the Secretariat and with bilateral and multilateral partners (see section VI for full secretariat and external membership of the CRG SI Coordination Mechanism)

Rationale

As the global responses and Global Fund double down on efforts to end the epidemics and to address issues of equity in access to critical services, particularly among those most marginalized, the need to maintain and scale up support for communities to effectively lead and engage at all levels of the responses is paramount.

Robust engagement of communities helps ensure that Global Fund investments are evidence and rights-based, gender and age responsive, equitable and sustainable. People and communities most vulnerable to and affected by HIV, TB and malaria make critical contributions to the design, implementation and oversight of investments maximizing impact, strengthening local accountability, and building stronger, more responsive systems for health.

Wider and more inclusive processes of country dialogue and in the determination of national priorities for funding on health make programs more effective and ensure that they evolve and remain responsive to the lived realities and needs of those most impacted.

As already noted, the CRG SI continues to evolve, integrating lessons and recommendations from periodic independent assessments. It is widely and consistently cited as best practice with respect to the focus and effectiveness of its approach - across the Global Fund partnership and in, for example, TERG evaluations. Partners such as GAVI and the GFF seek guidance from CRG to understand the model and adopt it in the development of their own approaches.

More broadly, there is ample and extensive evidence on the importance of community engagement in the health sector and beyond. These analyses consistently emphasize the connection between communities empowered to engage in decisions that impact on their lives, the criticality of building trust between communities and other actors in health responses, and the effectiveness of interventions, programs and systems responsive to actual need.

Funding

There are no viable external funding sources to support this cross-geographical work. Although donor set asides and other mechanisms provide critical and much needed support to communities, these are understandably aligned with their own bilateral and multilateral priorities areas and geographies. Given the unique diversity of the Global Fund portfolio across geography, diseases, and communities of focus – the Global Fund itself is best placed to effectively implement such interventions.

The investments and interventions proposed here are not feasible for funding via grants.

How was the proposed budget estimated?
Historical estimates and actual expenditure. The CRG SI is consistently assessed as high performing in budget execution and could incorporate increased funds.

The below budget is presented as estimates against provisionally proposed core operational areas. They are calculated using historical allocations and expenditure from past cycles. Within these high-level categories and to evolve as responsive to tailored support needs for communities across the HIV, TB and malaria spaces, final and approved amounts will be proposed as directly attributable by disease constituencies (e.g. minimum support for TB communities)

CRG SI – Indicative Breakdown by Component (subject to change depending on available funding)	%
Delivery of rapid support to strengthen engagement of HIV, TB and malaria community actors across the grant life cycle and in Global Fund related processes (e.g. NSP development)	38%

Strengthening long-term capabilities and capacities of regional and global HTM community networks to mobilize and support country constituencies	43%
Regional CS/Community communication, coordination, south to south knowledge sharing and generation	20%
TOTAL	100%

The current model is designed with agility in mind, as demonstrated by the speed and scale of support delivered for community engagement in relation to C19RM, as well as incorporation under its operations earmarked funds from philanthropic or private sector for focus on specific communities (e.g., Voix Essentielles – with a focus on women and girls in specific WCA countries). This agility will be intentionally maintained in the redesign for the next cycle.

II. Strategic Impact

Potential for increased impact

Learning from the lessons of the previous SI cycles, in the current cycle we have shifted the focus from implementing activities to achieving country-level advocacy outcomes and the approach in operationalization of any SI will continue to refine and further enhance this focus with an increased emphasis on influencing national decision-making and ensuring greater accountability.

There will be increased emphasis in a number of areas as aligned with the focus of the Global Fund Strategy 2023-2028 and as informed by community stakeholder priorities. These will include:

1. Tailored support strategies to strengthen bi-directional communication and accountability between communities and community representatives in CCM processes and oversight in a cohort of countries and in close collaboration with CCM hub and GF partners
2. Targeted assistance in the development and implementation of community engagement plans across the full grant life cycle – informing support strategies and actions including TA, partner coordination over grant life cycle
3. Continuing evolution and focus of support to communities and CS to engage in issues/responses/recommendations identified in funding request and other review processes (including TRP)
4. Community accessibility to Global Fund data and information at the country, regional and global levels

Levers

Support for community engagement could be embedded within Global Fund requirements and/or country grants however this would not be recommended as there are multiple political and implementation risks which could result in erosion of the Global Fund model, significantly less effective and community-owned investments, and higher burdens on CTs.

Catalytic effect

☒ **More**: incentivize increased funding from allocations to priority areas and/or additional funding outside of Global Fund

☒ **Improved**: enable more effective use of country allocations and coordinated responses for cross-border contexts

☒ **Faster**: accelerate implementation of specific priorities

Supporting the leadership and engagement of communities and civil society is central to ensuring people-centered investments and driving faster adoption and integration of global guidance, innovation and best practice. The central participation of most affected communities as experts in decision-making, service delivery and oversight will better ensure increased reach and quality of programs and accelerate the progress to ending the three diseases and to prevent, identify and respond to pandemics.

Expected outcomes

- Communities and CS at the country level have access to information, data and guidance necessary to effectively and meaningfully engage across the grant life cycle
- Communities and CS have access to high quality technical support necessary to improve engagement across the grant life cycle and which is focused on identified priorities and critical gaps
- Community representation on CCMs is assessed as increasingly effective

- Broader community and CS constituencies are effectively mobilized and engaged in processes related to national responses (eg: NSPs, mid-term reviews, TWGs) where there are critical interdependencies with GF grants
- Communities and civil society leadership. Capacity and capabilities to engage in Global Fund and related national processes are strengthened
- Increased integration of evidence and human rights -based, gender and age responsive, community-led and equitable and sustainable programming

Theory of change

Risk if not funded

The risk is extremely high. As already noted, integration into grants would not be feasible, effective or efficient and come with additional burden on CTs and countries. CRG SI resources have been used effectively to leverage additional contributions for specific sub-sets of communities and/or geographies. That leverage will be lost without a core contribution from the Global Fund itself.

Some funding for Global Fund staffing costs could be incorporated into OPEX to the extent that this is consistent with OPEX principles, should the AFC decide and provide for the same level of resourcing and MEC recommends.

What are the programmatic risks if not funded?

- Reduced accountability and oversight of Global Fund investments to those most vulnerable to and impacted by the three diseases.
- Gains made via investment in the previous cycles lost.
- If unfunded, there will be a disproportionate impact on contexts with concentrated epidemics, particularly in countries that marginalize, exclude or criminalize key and vulnerable populations.

- Significant reputational risks as the organization will be seen as deprioritizing an explicit objective in the strategy, and community engagement and leadership as a key principle, that communities are at the center of everything we do and discarding an area of significant comparative advantage of the Global Fund.

III. Previous Investments

2020-2022 Catalytic Investment	2020-2022 Budget Amount
CRG SI	US$16 million

Current implementers

The current CRG SI is implemented through 26 pre-approved civil society and community TA providers; 11 KVP networks across HIV (6) TB (4) and malaria; 6 regional communication and coordination platforms; and two engagement funds for women and girls which can be accessed through the Global Fund's community engagement webpage.

Current target populations

All countries eligible to receive a Global Fund allocation and those covered by MC are eligible to apply for CRG SI technical assistance.

The CRG SI supports communities and key populations groups in all countries eligible to receive a Global Fund allocation with a particular focus on those most vulnerable to and impacted by the three diseases. Should resources and capacity allow – there are significant opportunities to expand support to communities of women and girls, people living with disabilities, prisoners, migrants and refugees, the mental health community and other marginalized, excluded, and vulnerable populations and sub-populations.

Progress to date

With respect to the 2017-2019 allocation period, the number of eligible technical assistance (TA) requests increased by 185% (from 65 to 185), and the number of countries that received TA increased by 192% (from 24 to 70) as compared to the 2014-2016 allocation period. The CRG SI made new investments in the long-term capacity strengthening of TB communities, civil society organizations working on malaria elimination, and a small grants fund to support the engagement of adolescent girls and young women (AGYW). Key achievements included[7]:

- Information, communication and coordination support to 32,500 organizations, networks and individuals.
- 185 eligible technical assistance requests received with 125 technical assistance assignments delivered in 70 countries, including 18 challenging operating environments.
- Networks of key and vulnerable populations implemented long-term capacity strengthening activities in 66 countries for HIV, 19 countries for TB, and 8 countries for malaria.
- HER Voice Fund awarded 183 grants to support engagement of AGYW in 13 African countries.
- Malaria Equity Assessment Tool (Malaria Matchbox) developed and implemented.

At the outcome level, the external evaluation of the CRG SI during the 2017-2019 allocation period notes a range of examples where the CRG SI is identified as contributing to improved funding requests and grants – responsive to community priorities and need. The full assessment can be found at CRG SI 2017-2019 External Evaluation. As noted, the CRG SI conducts two external assessments each cycle during the mid-term and end-term.

In the 2020-2022 allocation period, to ensure more equitable access to resources, investment in long-term support to TB communities has nearly doubled, going from $647,000 in the previous cycle to $1,219,980. The CRG SI is investing in the organizational development of CS4ME, a nascent global malaria platform and, in addition to programmatic support, it is strengthening CS4ME's governance, M&E and member engagement. Additionally, the CRG SI is supporting:

- Information, communication and coordination support to 29,500 organizations, networks and individuals.

[7] Attribution to health outcomes as a direct consequence of community engagement is highly complex – methodologically and otherwise. Evolving the Global Fund's evaluation approach in this area is in discussion as part of the evolution of the corporate performance framework for the next strategy period.

- 44 eligible technical assistance requests received with 20 technical assistance assignments delivered and completed by December 2021.
- Networks of key and vulnerable populations implemented long-term capacity strengthening activities in 26 countries for HIV, 16 countries for TB, and 3 countries for malaria.
- HER Voice Fund awarded grants to support engagement of 94 AGYW grantees in 13 countries in SEA and over 1000 AGYW in the Global Fund strategy consultation process.
- Voix EssentiElles to support women and girls in 3 countries in WCA.

In relation to C19RM, the CRG SI was leveraged to respond agilely and rapidly to:

- Deliver 38 TA assignments (12 rapid assessments and 26 consultations) in 31 countries and one multicounty grant (LAC)
- Facilitate 128 consultation streams with civil society and communities to identify C19RM priorities in 64 countries
- Produce 11 new C19RM tools and translate 18 C19RM resources
- Provide line of sight to engagement bottlenecks in 20 countries that were successfully addressed in partnership with GMD CTs and CCM Hub

Expected evolution

As noted, the proposed CI on community engagement will evolve from the current CRG SI model in consultation with stakeholders and to determine where and the extent to which existing operational approaches can be better suited to align with the new Strategy and relevant technical and bilateral partner strategies and focus, and to achieve strengthened outcomes in the context of changing environments for community and CS at the country level. These will be informed by evaluation of the current cycle of the CRG SI and, as outlined, evaluation and ongoing consultation are planned throughout 2022 and into 2023.

IV. Operational Considerations

Set-Aside Modality

☒ Set-aside funds only, otherwise not feasible

- Community engagement has been a priority within CI in all allocation cycles
- Resourcing via grants is not feasible from an operational standpoint nor could it be recommended.
- Incorporating necessary resources into OPEX e.g., for Global Fund staffing costs, which are consistent with OPEX principles, is however an alternative with a strong rationale given the long-term core commitment and ongoing nature of investment required.
- At minimum this would require confirmed resources for a 3-year period at an amount equal to current CI investment, or increased to adequately respond to expanded scope as outlined in the 2023 strategy.

Global Fund Comparative advantage

☒ Global Fund is a leader in this priority area

The Global Fund champions community engagement both as a principle and as a core element of its unique implementation model. In order to create additionality and compliment the investments of the Global Fund's other SI and those of the wider Global Fund's partnership, the CRG SI Coordination Mechanism has been created and includes:

- The Community, Rights and Gender Department
- Grant Management Division
- Technical Advice and Partnership (TAP) Department
- The Country Coordinating Mechanism (CCM) Hub
- Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ), BACKUP Health
- Expertise France L'Initiative
- The World Health Organization
- The Joint United Nations Programme on HIV/AIDS (UNAIDS)
- The Stop TB Partnership
- The Roll Back Malaria (RBM) Partnership
- The Community-led Monitoring (CLM) SI
- The Human Rights SI

• The Sustainability, Transition and Efficiency (STE) SI In 2021, the CRG SI Coordination Mechanism began integrated tracking of all Global Fund-related technical assistance in order to streamline demand and reduce duplication of efforts. • Historically, the Global Fund's approach to the practical realization of community engagement in its processes and structures has been assessed as a 'global benchmark'. • The organization continues to present its capacity and commitment in this area as a comparative advantage within the broader Global Health architecture.
Global Fund Competency
During the 2017-2019 allocation period, the CRG SI achieved remarkable growth and maturation, expanding its remit across the grant cycle and solidly into malaria and TB, expanding geographic reach, and delivering increased volume of higher quality TA. The independent external evaluation concluded that "the CRG Strategic Initiative [is] ideally positioned to support meaningful engagement of key and vulnerable populations and networks in Global Fund-related processes as it moves into its next phase." The CRG SI continues to evolve, consistently delivering against effectiveness and efficiency targets and providing an essential platform that underpins communities' ability to rapidly respond to emerging issues and threats.
Sustainability
Strengthened capabilities, capacity, and systems in support of community engagement aim, in the long term, to integrate the core principle and practice of meaningful representation and engagement of communities most impacted by the three diseases into national strategy, policy and program decision making processes. As a leader in the practical realization of this right throughout its own processes, structures, and governance, Global Fund investment in this specific area acts to influence key stakeholders at the country level and provides for often marginalized and stigmatized communities platforms where they are seen as legitimate and equal partners.

Scaling up programs to remove human rights and gender related barriers

Scaling up programs to remove human rights and gender related barriers	
Strategy goal: Maximizing Health Equity, Gender Equality and Human Rights	**Recommended modalities:** Matching Funds and Strategic Initiative (SI)
Strategy's 10 changes: Maximizing Health Equity, Gender Equality and Human Rights	
I. Proposal	
Description	
This catalytic investment will make an essential contribution to objective C.1 of the Global Fund 2023-2028 Strategy *(Scale up comprehensive programs and approaches to remove human rights and gender-related barriers **across the portfolio)***. It builds upon lessons learned from the Human Rights (HR) MF and Human Rights SI in the 2017-2019 and 2020-2022 allocation periods. **Innovations include**: 1. During the 2023-2025 allocation period, **the HR MF will be made available** to **all 25 High-Impact portfolios.** This reflects the need to significantly scale up scope and quality of programming to reduce human rights- and gender-related barriers in the 15 High-Impact portfolios that have not benefited from MF in the 2017-2019 and 2020-2022 allocation periods (and have not been part of the Breaking Down Barriers (BDB) initiative). It is consistent with the commitment in objective C.1. of the Global Fund 2023-2028 Strategy to	

adopt a portfolio-wide, differentiated approach for incentivizing increased commitments to programs to remove barriers; as well as with a recommendation in the OIG Advisory on Human Rights.[8]

2.**Part of the MF will be made available for the highest priority TB countries,** for programming to reduce human rights-related barriers to TB services or integrated TB/HIV human rights programming, **with a particular focus on community-led and based programs**. Countries will be required to match the amount available to them from within their TB allocation. This responds to lessons learned in the 2017-2019 and 2020-2022 allocation periods where progress made in reducing barriers to TB services was more limited due to the lack of MF in this area. It also responds to the need to address the significant increase in barriers, particularly stigma and discrimination, as a result of COVID-19. This need is explicitly recognized in the Global Fund 2023-2028 Strategy.

3. The overall objective (aligned with and in support of the Strategy objective), remains to support scale up and sustainability of evidence-based **comprehensive programs** to remove human rights and gender-related barriers. However, within that objective, **there will be a greater focus on incentivizing** and/or requiring (through programmatic conditions) **stigma and discrimination programming, programming aimed at removing criminal laws and other harmful laws and programming to reduce gender inequalities**.

4. To **sustain gains made in all BDB countries** and to further increase results and impact, the HR MF will remain available to all BDB countries, **albeit at a lower amount and with more stringent financial and programmatic conditions**. Decreases will be less significant in best performing countries, using both quantitative criteria (the scorecard measuring progress in BDB mid-term assessments and the contribution countries made from within their own allocation) and qualitative criteria (such as the extent to which, based on a number of indicators, country ownership of human rights problems and solutions has increased).

Across the 35 eligible countries, the HR MF will provide greater opportunities for institutionalization of multi-stakeholder ownership and commitment to human rights- and gender-related responses at the country level; and enable to link such programs as integral to effective disease responses at the outcome and impact levels.

Rationale

There is ample evidence from the 2017-2019 and 2020-2022 allocation periods that the HR MF, supported by SI-funded critical activities, including timely TA to address implementation bottlenecks, make a very substantial difference. They have led to increased funding going to better quality programs to reduce barriers in countries with the HR MF compared to countries without the MF. They also led to increased country ownership, as evidenced by, among other things, development and implementation of costed, country-owned strategic plans to reduce barriers; and higher investments in programs from within allocation in the 2017-2019 allocation period compared to the 2020-2022 allocation period.

There is **also ample evidence of the results and impact of this HR MF**, as **documented in each of the 20 mid-term assessments (MTAs) of progress made** in the 20 countries that have had access to the HR MF and related support.[9]

Overall, what is proposed builds on extensive knowledge and innovations generated from implementation of the BDB initiative, as well as from efforts in countries where human rights investments and ownership were not sufficiently incentivized.

Funding

Human rights-programming continues to not be adequately prioritized in countries that do not have access to MF, despite some progress made in the 2017-2019 and 2020-2022 allocation periods. Overall, funding for such programs increased more than 10-fold in countries accessing the HR MF (from less than US$ 10 million to approximately US$ 130 million) compared to an overall four-fold increase across the entire portfolio.

Donor funding has also been insufficient and some key contributors have recently withdrawn their funding due to competing priorities.

Finally, **very few countries invest domestically** in these programs. Particularly in the current environment, it will take many years to change that, despite a very ambitious agenda to increase domestic investment in

[8] OIG Advisory Report on Human Rights: https://www.theglobalfund.org/media/9020/oig_gf-oig-19-023_report_en.pdf

[9] MTAs are available at https://www.theglobalfund.org/en/funding-model/throughout-the-cycle/community-rights-gender

human rights (and key population prevention) programs that CRG has embarked on, together with internal and external partners.
Therefore, the following is proposed: **For the 15 High Impact countries that will access the HR MF for the first time**, based on its experience to date, **the Secretariat will establish a minimum of US$ 0.5 to 1 million** for countries with the lowest allocations **and a maximum of US$ 2 to 3 million,** depending on the overall funding available.
For the 20 countries that have already accessed the HR MF, and where progress needs to be sustained, **the Secretariat proposes to apply a 35% to 40% cut** compared to the (already lower if compared to the 2017-2019 allocation period amount) 2020-2022 allocation period MF award, with the exception of highest performing countries where a less severe 15% cut would be done accompanied by access and programmatic conditions.
For the highest priority **TB countries** within the cohort in which incentivizing investment in TB human rights programming is most critical, **an amount to be determined,** would be allocated proportional to the size of the TB allocation.

For the HR SI, some innovations are also anticipated, with an increase in the budget for implementation support for countries that has proven to be critical (due to the larger number of countries) and for elements of the partnership with Thomson Reuters Foundation focusing on innovative efforts to reduce stigma and discrimination and remove criminal laws in Africa, offset in part by removing the in-depth country-by-country assessments that will be replaced by other elements of the Global Fund's monitoring and evaluation agenda moving forward. There will be an ongoing but renewed focus on addressing equity barriers to malaria services, with elements of the support currently provided being integrated into the broader malaria SI.

II. Strategic Impact

Potential for increased impact

Despite good progress made, in large part owing to the availability of the HR MF and other dedicated support in BDB countries, KPIs in this area of the current Strategy continue to **underperform**. **Human rights is enhanced in ambition across** the new Strategy with elevated and additional focus areas, particularly the elimination of stigma and discrimination, criminal laws, gender equality and equity. This proposal will contribute in progress towards the human rights related ambitions across the new Strategy.

Levers

The HR MF has proven to be an effective way of incentivizing not only far greater, much needed investments in programs, but also greater country ownership and capacity, as documented in the MTAs The HR MF should therefore be used for the subset of countries in which progress will have the biggest impact, in addition to other available levers. As the Global Fund Strategy 2023-2028 requires incentivizing across the portfolio, **other levers will also have to be used in core and focused portfolios, including by requiring minimum investment standards**.

Catalytic effect

☒ **More**: incentivize increased funding from allocations to priority areas and/or additional funding outside of the Global Fund
☒ **New**: initiate new or innovative activities for more efficient and impactful programming
☒ **Faster**: accelerate implementation of specific priorities
The catalytic effect has been demonstrated in all countries that have had access to the HR MF. They, together with supporting activities, **have led to vastly higher investments, incl from within the allocation** and growing over time, **much better and more integrated programming, greater country ownership and commitment**. Change in this area requires time, but initial signs of impact have been documented in independent MTAs.

Expected outcomes

Greater investment in critical programming, greater alignment of investments with key Strategy priorities (S&D, criminalization, gender inequality, equity, community led programming), greater country ownership and capacity and, ultimately, greater impact of grants through greater access to and retention in services of those left behind.

Theory of change

As in the 2017-2019 and 2020-2022 allocation periods, the HR MF will incentivize greater investments, including from within the HIV and TB allocations. Importantly, in the 2023-2025 allocation period, this will be

done in all High-Impact portfolios. Through new programmatic conditions, the Secretariat will enhance the focus of such investments on priorities such as stigma and discrimination and criminalization within the Strategy. To maximize the effectiveness of such investments, building upon lessons learned to date, technical support will be provided to meet key TA needs, mentorship will expand the currently limited pool of human rights and gender equality TA providers for more regional and country-specific expertise, and South to South learning among implementers will be fostered. Programmatic conditions will include, among others, functional coordination and oversight mechanisms and domestic funding, as this has been proven critical to fostering greater country ownership. The theory of change envisages that, given the inputs, capacity and supportive context, comprehensive responses to human rights-related barriers will continue to expand and be aligned with the Global Fund Strategy 2023-2028 priorities in the countries that previously had access to the HR MF, and that much needed expansion and alignment will happen for the first time also in the countries newly eligible for them, enhancing the impact of Global Fund grants, as outlined above.

Risk if not funded

- Decreased investment in and attention to comprehensive programs to remove human rights and gender related barriers in access to services, resulting in decreased impact of Global Fund grants.
- Decreased attention to criminalization, stigma and discrimination and community-led human rights programs.
- Lost opportunities to better integrate and align human rights programs with essential services, particularly for most marginalized communities.
- Loss of the momentum developed, thanks to the combination of the HR MF and supporting SI, over the current Strategy period.
- Risk that de-prioritization could be interpreted as decreased commitment to a core objective.

III. Previous Investments

2020-2022 Catalytic Investment	2020-2022 Budget Amount
MF: Programs to remove human rights-related barriers to health services (cross-cutting) Human Rights SI	MF: US$41 million SI: US$5 million

Current implementers

MF and SI components 1 (TA), 2 (MTAs and ETAs): all BDB countries (Benin, Botswana, Cameroon, Democratic Republic of Congo, Cote d'Ivoire, Ghana, Honduras, Indonesia, Jamaica, Kenya, Kyrgyzstan, Nepal, Mozambique, Philippines, Senegal, Sierra Leone, South Africa, Tunisia, Uganda and Ukraine)

SI Component 3 (partnership with Thomson Reuters Foundation): Botswana, Cameroon, CIV, DRC, Ghana, Kenya, Malawi, Mozambique, Nigeria, Senegal, Sierra Leone, South Africa, Tunisia, Uganda

SI Component 4 (malaria): – agreement with RBM covers 27 countries

Current target populations

Key and vulnerable populations, people living with HIV, people with and most affected by TB, people with and affected by malaria

Progress to date

- Continuous support under BDB and HR MF catalyzed much greater investment from within allocations, ultimately leading to a 10-fold increase in overall investment in human rights programs in BDB countries between the 2017-2019 and 2020-2022 allocation periods. Investments have continued to increase in NFM3. Importantly, country ownership and commitment have also increased (see KPI 9a and b reports for full details).
- Implementation capacity of Global Fund implementers has been strengthened through improved evidence base (baseline and mid-term assessments) and long-term TA based on an assessment and prioritization of needs (as will be detailed in Human Rights SI metrics).
- Improved technical guidance has been made available, and Implementers Guide developed in partnership with Frontline AIDS and GIZ Backup Health.[10]
- Capacity of implementers from 12 BDB countries to communicate about the results of their human rights programs in the context of HIV, TB and COVID-19 responses has improved, as detailed in the impact

[10] https://www.theglobalfund.org/media/9731/crg_programmeshumanrightsbarriershivservices_guide_en.pdf

report of trainings to date, and journalists from the same countries have been sensitized through trainings delivered in partnership with the Thomson Reuters Foundation.

- In close cooperation with RBM Partnership, capacity development on CRG solutions for malaria is underway for TA providers, the TA pool has been expanded to include human rights expertise, and TA is being deployed.

Expected evolution

The proposed approach to human rights catalytic funding builds upon the lessons learnt in the 2017-2019 and 2020-2022 allocation periods in the 20 countries that were eligible for the HR MF and support through the SI. In those countries, the catalytic nature of such set-aside funding has been proven. The HR MF will further evolve by: (1) Expanding to all High Impact countries, as informed by the OIG human rights advisory, aiming to incentivize greater and better quality investments where they are most needed and deliver more impactful grants; (2) continuing to make the HR MF available to the 10 non-High-Impact portfolios that have benefited from them in the 2017-2019 and 2020-2022 allocation periods, recognizing both the need to ensure sustainability and further scale up of efforts and the particular opportunities to affect change in those countries. However, in these countries, to improve impact, more stringent access and programmatic conditions will be used; (3) requiring a focus on "new" Strategy priorities (such as criminalization, stigma and discrimination and community-led programs); and (4) undertaking a dedicated effort to reduce barriers to TB services.

IV. Operational Considerations

Set-Aside Modality

☒ Can be integrated in country allocations

- Programs to remove human rights and gender related barriers must remain a priority for catalytic investments.
- Domestic commitment remains fragile requiring commitment to incentives and innovation in the longer term
- Ensuring adequate investment via grant core allocations alone would necessitate application of conditions and requirements and, in countries where grant funds are stretched, upward qualitative adjustment

Global Fund Comparative advantage

☒ Global Fund is a leader in this priority area

- The Global Fund model uniquely provides for multi-stakeholder engagement and partnership at the country and global levels.
- Global Fund capacity to convene key stakeholders at the country level including government, communities and partners.
- Evolved and increasingly sophisticated understanding resulting from the focus, lessons, and investment gained over the current strategy period.

Global Fund Competency

The mid-term assessments clearly demonstrate that the Global Fund has been able to achieve great results even in the most challenging environments.

Sustainability

Human rights is always going to be an area at risk, particularly if country allocations decrease. It includes programs and activities that sometimes challenge a country's own laws and deeply held beliefs and is work that requires time and sustained support. That being said, the increased ownership and commitment seen in BDB countries provides hope that countries will indeed increasingly fund at least some of these programs from within the allocation. Efforts to increase domestic financing will remain very challenging, but the Secretariat hopes to start making a difference in some countries, in some areas, and adapt to lessons learned.

Health Financing

Health Financing	
Strategy goal: Mobilizing Increased Resources	**Recommended modalities:** Strategic Initiatives (SIs)
Strategy's 10 changes: Health Financing	

I. Proposal

Description

Catalytic funding to support countries to deliver more money for health, and more health for the money: delivering programmatic and financial sustainability, strengthening Health Financing (HF) and Value for Money (VfM) systems, to ensure progress can withstand shocks, and that momentum is sustained in light of COVID-19's impact on global and national public resources for health.

Three SIs will be designed to accelerate progress towards the following shifts in the Global Fund Strategy 2023-2028 by enabling more effective use of country allocations, innovating, and leveraging additional funding outside the Global Fund.

- D2: catalyzing domestic resources for health
- D3: delivering value for money
- D4: leveraging blended finance and debt swaps into tangible health outcomes
- D5: supporting country health financing (HF) systems
- Plus, HF and sustainability, transition and co-financing (STC) aims nested in other high-level strategic objectives (strengthening sustainability, preparing for transition from Global Fund financing).

<u>SI 1: Domestic Resource Mobilization (DRM), Sustainability, Transition and VfM</u>

- Strengthening sustainability, and transition planning; scaled up effort to improve public financing of services by civil society and communities (social contracting), given prominence in the Global Fund Strategy 2023-2028; sustainable financing of priority interventions.
- Demand-driven technical assistance (TA) to build country capacity to deliver VfM, strengthen HF systems, and develop HF literacy. We would expect demand to be for support on costing; resource allocation; health technology assessment; strategic purchasing (including payment for results where appropriate in partnership with the World Bank, Gavi and others); HF aspects of public financial management; user fee reform; and program integration into health insurance schemes.
- Global, regional and national advocacy partnerships for domestic resource mobilization and efficient, equitable, sustainable investments in health.

<u>SI 2: HF Data; Resource Tracking</u>

- Enhancing generation, development, and use of HF data as a public good and in national decision-making. Strategic investments in National Health Accounts / Sub-national Health Accounts and innovative modalities of resource tracking, including country surveys. Alignment with USG / PEPFAR / PMI and other partners to enhance timely and granular visibility of domestic flows.
- Capacity building for HF data systems at country level to empower countries to spend domestic resources better and enhance efficiencies where possible in partnership with Finance, and in the context of the PFM strengthening agenda (including integrated financial management information and national health insurance systems / DHIS2 integration). Supporting roll out of diagnostic tools to improve the quality and availability of HF data within Africa for policy decision making in collaboration with WHO and other partners.
- Macro-level analyses with IMF and WB to identify and proactively mitigate HF risks at regional and country levels. C19RM and pandemic preparedness HF data visibility at partner and domestic levels.

<u>SI 3: Innovative Finance</u>

- Respond quickly to opportunities, and seed high-impact transactions: support pipeline identification, due diligence and seed funding to significantly increase resources for TB and other diseases by catalyzing innovative finance deals, especially leveraging new instruments ("buying" disbursement linked indicators, loan buy-downs).

- Inter-organization (Global Fund, MDBs) capacity building on IF to streamline joint-investment processes and ultimately increase the impact and volume of IF deals.
- TA / evaluations / research and market insights to support transactions in development, build pipeline on RSSH and HTM, build transaction implementation mechanisms, and evaluate past and current deals to apply lessons learned.
- Explore feasibility of reimbursing IF SI (if it is successful in seeding deals) with other sources of funding (e.g., grant savings or portfolio optimization funding).

Rationale

HF is prioritized and prominent in the Global Fund Strategy 2023-2028, cross-cutting across eight of the ten 'key changes' identified: it would be counter to the direction of the new Strategy, our institutional approach to risk and the Secretariat's investment in a dedicated HF Department if catalytic resources for HF were not to increase in the next allocation period.

COVID-19 has had significant impacts on international and national finance for health. Although most countries meet minimum co-financing requirements, we expect increased challenges to raise sustainable domestic resources to meet program targets in 2022 and beyond. There is an ongoing need to enhance sustainability of national responses and increase value for money of existing resources. Many HF interventions (e.g., health technology assessment) require scarce technical skills, and HF analysis is not common in national budgeting processes, so external financing is needed for TA.

Although significant HF support is provided through grants, SIs would be prioritized to activities where experience shows it is challenging to use grants, or where the Global Fund country-led model makes it difficult. Examples include:

- Contracting TA from providers / partners not easily contracted by PRs.
- Supporting pooled funds as part of global partnerships to support specific outcomes such as National Health Accounts, where funds cover multiple countries.
- Centralizing TA procurement where it means better VfM, greater standardization and quality assurance, similar to global pooled procurement of commodities.
- Transition planning in countries with small allocations / limited space within grants.

The Global Fund plays a critical role in fostering discussions around HF at the country level to ensure long term sustainability, transition to domestic financing and fundamentally the achievement of the Global Fund mission. The evidence for investing in core HF capabilities is demonstrated, for example, by the investments made by OECD countries in strong HF capabilities, valuing the effect that good HF policy has to maximize health impact from limited resources. In addition, if just 0.4% of the additional US$7 billion raised in domestic co-financing from the last allocation period was attributable to the work funded by the STE SI, then the SI paid for itself. Previous investments from HF SIs (VfM in 2014-2016, STE in 2017-2019) catalyzed significant progress in areas now identified as critical to achieve the Global Fund Strategy 2023-2028 including a significant expansion of transition planning, enhancements to our expenditure tracking work with partners, and development of a robust approach to resource optimization for enhanced efficiency, demonstrating the value-add of even small amounts of strategically targeted SI funding for key HF themes.

Funding

HF systems and broader efforts to strengthen VfM, sustainability and transition are routinely under-resourced in Global Fund grant-recipient countries, including by the international system. Catalytic funding allows us to make coordinated investments with key partners to ensure that their efforts are focused on Global Fund priorities. Grants that have prioritized HF activities have struggled to deliver them, meaning resources eventually become reallocated into other activities in the grant. Catalytic funding will help proactively link co-financing to programmatic priorities en route to the 2030 goals.

The combined value of current STE and IF SIs over the 2020-2022 allocation period is US$38 million. The 2023-2025 budget of this SI is driven by:

- An **enhanced** focus on HF in the new Strategy in light of the increased resource mobilization challenge due to COVID-19, and mainstreaming of HF across several other key shifts in the Global Fund Strategy 2023-2028; and

- Introduction of a **new** set of activities on HF data to support external systems on which the Global Fund relies (including for the effective realization of its co-financing approach). Funds would be split three ways: first, to support development of HF data systems to a level commensurate with our ambition to raise US$59bn through co-financing in the new Investment Case (data is critical to this aim). Second, to fund external expertise and projects on innovative ways to track resources and extract data from diverse sources. Finally, to build national capacity to generate and manage HF data – of benefit both to national programmes, for optimization choices, and to wider GF partners including the Secretariat, for DRM, resource allocation and portfolio optimization.

The estimated breakdown of major components is as follows (noting that 1 and 2 should be demand-driven):
1. DRM, Sustainability, Transition & VFM
2. Innovative Finance: potentially replenishable from PO
3. Data for Health Financing (**new**):
   a. To support HF data systems building in-country to support better reporting and sustainability of response
   b. To support catalytic HF data analysis, systems and research to inform prioritization decisions at global ad country levels e.g., optimizing product introduction, distribution of benefits and service delivery incl global public goods

II. Strategic Impact

Potential for increased impact

HF is an **enhanced** area in the new strategy. HF data is a **new** area for catalytic funding. We also expect rising risk of **underperformance** on domestic resource mobilization, due to the fiscal impacts of COVID-19 on global and domestic resources for health.

Levers

This proposal is designed to secure the effectiveness of three Global Fund levers (co-financing, innovative finance, technical assistance) for resource mobilization that ultimately supports all Global Fund strategic objectives, especially incidence reduction. With strong cross-Secretariat support, we can **enhance HF aspects of grant lifecycle policies and procedures**, leverage **allocation letters** and **grant commitments to strengthen efforts on co-financing,** and recommend **inclusion of HF in funding request application materials / applicant briefings / CCM training** to more proactively encourage countries to prioritize DRM, capacity building for health financing, sustainability / transition, and attention to VfM through grants. But these alone will not deliver objective D4 in the new Strategy narrative, nor regional and global aspects of D2 / D3; CF is needed. In addition to catalytic funding, working through GMD, the HF team will invest in ensuring GF staff advocate and build **partnerships on HF** with other donors, private sector, technical partners, communities and governments. Partnerships with technical partners will help ensure **high-quality funding requests** that incorporate HF aims. We will highlight the importance of HF during **community and civil society engagement**. Through a newly expanded team of country HF specialists, we will **broker in-country HF capacity building by technical partners.** We will prepare **technical guidance** on HF. We have helped revise the **TRP TORs** and will prepare **TRP guidance** and briefing notes to review HF in funding requests.

Catalytic effect

☒ **More**: DRM and innovative finance catalytic funding will leverage resources from other public and private sources, support civil society to advocate for more resources and better use of existing resources, and build capability within governments and other organizations to deliver more health for those resources.

☒ **New**: The Global Fund urgently needs to step up investment in HF data.

☒ **Improved**: A primary focus of proposed SIs is VfM for grants and wider resources.

☒ **Faster**: Catalytic finance will facilitate a faster shift to national ownership of program objectives through DRM.

Expected outcomes

- Greater domestic resource mobilization for health.
- Improved VfM in Global Fund grants and wider health system funding for economy, efficiency, effectiveness, equity, and sustainability.
- Leverage additional resources through blended finance and debt swaps for health.
- Greater capacity in country HF systems to improve sustainability, including reduced financial barriers to access, increased financing to remove structural barriers to outcomes in HTM, strengthened purchasing

efficiency especially for services provided by community-based organizations, and more evidence-informed procurement of commodities.
- Enhanced sustainability of national responses to HIV, TB, and malaria and improved preparations for transition from Global Fund financing.

Theory of change

For proposed SIs on HF and HF data:
- Better data and analysis improves decision-making across HF objectives set out above, including design and appraisal of co-financing commitments.
- TA and knowledge-sharing builds capacity in national governments and other national stakeholders to raise, allocate and spend limited resources for health to maximize impact and sustainability.
- Innovation and advocacy changes the incentives of national policymakers to raise, allocate and spend limited resources for health for efficiency, equity and sustainability.
- Availability of IF SI creates incentive to leverage major increases in resources from others.

Risk if not funded

High risk. See 'Rationale' above.

What are the direct epidemiological risks if not funded? Any failure to leverage wider resources for health and to maximize efficiency, equity and sustainability with which available resources for health are used will have a negative long-term effect on most of the epidemiological outcomes that the Global Fund is trying to achieve.

What are the programmatic risks if not funded? Reduced sustainability, efficiency and equity of programs; reduced likelihood that national governments and other service providers take responsibility for Global Fund-funded programming in the long term; reduced potential for mobilization of additional domestic resources for the three diseases; less attention at the national level on enhancing sustainability and preparing for transition from Global Fund financing.

III. Previous Investments

2020-2022 Catalytic Investment	2020-2022 Budget Amount
SI: Sustainability, Transition and Efficiency (STE) SI: Innovative Finance (IF)	STE: $18 million IF: $20 million

Current implementers

ABT Associates; AIDS Strategy Advocacy and Policy LTD (ASAP); APMG Health Inc; APMG Health Inc; Association Impact Sante Afrique (ISA); Avenir Health, INC.; Bankers Without Borders; CHAI; CHECOD Africa LTD; Curatio International Foundation; G:Enesis Analytics; ICF MACRO, INC.; IQVIA Solutions (PTY) LTD; INC.; Malaria No More; OECD; Oxford Policy Management LTD; Palladium International LLC; Pharos Global Health Advisors; Results Education; Swiss Centre for International Health, Swiss Tropical aAnd Public Health Institute; THINKWELL; The Macfarlane Burnet Institute for Medical Research & Public Health LTD; UCSF; UNICEF; Universite De Geneve, Faculte De Medicine CMU; WACI HEALTH NPC; WHO; WHO PAHO; and individual consultants.

Current target populations

All countries in the Global Fund portfolio included. Different components target different groups, e.g., transition preparedness countries.

Progress to date

The **2017-19 STE SI** supported implementation of health financing strategies and their components via collaboration with WHO, and strengthened MOF / MOH / Senior Budget Officials networks via collaboration with the OECD. 42 countries (64% LIC / LMIC) received expert support to track health & disease expenditure; 4 high-malaria-burden countries underwent malaria expenditure deep dive analysis. Policy briefs were developed to strengthen advocacy for domestic health financing in several countries. The STE SI financed a significant proportion of all transition readiness assessments. It provided expert advice to address specific transition bottlenecks across portfolios in EECA, LAC, MENA, and Southeast Asia, and strengthened efforts on public financing of CSO service provision, including collaborations with key partners (UNAIDS, UNDP, etc). It initiated new partnerships on procurement challenges in EECA (UNICEF) and capacity building around transition (with GAVI / WB). It supported resource allocation optimization analysis in approximately 50 countries to inform the development of NSPs and FRs, and launched collaboration with WHO on cross-programmatic efficiency analysis in 10 countries. The prospective TRP review of the **2020-22 STE-SI**

considered it to be strong overall, demonstrating "strong potential to strengthen value for money of Global Fund grants in the targeted countries", with no specific weaknesses identified during the review. It continues, expands and improves (responding to lessons learned) much of the work of the 2017-19 STE SI described above, including: the OECD senior budget officials network; a considerable scale up in health financing advocacy; support to preparation of national health accounts in forty countries with deep dives proposed in several of those countries to analyze NHA, identify policy recommendations and connect those recommendations to advocacy around health budgets; geospatial modelling to support resource optimization for health services; and continued technical support to transition planning and challenges.
Thus far, the **2020-22 IF SI** has been able to leverage additional external funding and crowd in additional resources for health in Gambia (US$10m). Work is in progress on leveraging IF SI funding to 'buy down' World Bank funding (an estimated US$200m) for TB in a high-impact, high-burden country.

Expected evolution

HF is increasingly prioritized and prominent in the Global Fund Strategy 2023-2028, cross-cutting across eight of the ten 'key changes' identified: it would be counter to the direction of the Strategy if catalytic resources for HF were to decline in the next allocation period. COVID-19 has had a significant impact on global public finance for health – international and national. Although most countries meet minimum co-financing requirements, we expect increased challenges in raising sustainable domestic resources to meet programmatic targets in 2022 and beyond. There is an ongoing need to strengthen focus on enhanced sustainability of national responses and increased value for money of existing resources. Many HF interventions (eg health resource tracking, health technology assessment) require technical skills not necessarily common in Global Fund grant-recipient countries, and HF analysis is not common in national budgeting processes, so external financing and contracting out are needed. Although most HF support is provided through grants, SIs have been prioritized to finance a group of activities where experience has shown it is challenging to use grants, or where the Global Fund country-led model makes it difficult. Examples include contracting TA from providers or partners who are not easily contracted from PRs; supporting pooled funds as part of global partnerships to support specific outcomes such as National Health Accounts, where pooled funds cover multiple countries and would require unrealistic levels of coordination if funded as single grants; centralizing procurement of particular skills where it is more cost-effective and provides greater standardization and quality assurance, similar to Global Fund global pooled procurement of commodities; and transition work in countries with limited space within grants.

Based on lessons learnt, what will be done differently in the next cycle to improve impact?
For regional and global analysis, research and advocacy, the Secretariat will consider a **challenge fund window** that prompts HF specialists outside the Secretariat to come with proposals for work to advance the objectives of the Global Fund Strategy 2023-2028.
Stronger alignment between SI funding and **country level priorities**. Increased clarity on a menu of services financed by SIs that address specific country challenges, with pre-qualified suppliers ready to deliver. This will speed up delivery.
Explore feasibility of reimbursing IF SI (if it is successful in seeding deals) with other sources of funding (e.g., grant savings or portfolio optimization funding)
A well-designed and tested **Operational Policy for Blended Finance transactions** (and possibly payment for results), making IF more attractive to deliver program objectives and easier to finalize transactions to more efficiently leverage catalytic funding.
For partnership annexes with important partners that will deliver multiple types of complex work, we will start discussions early and move to an overarching arrangement to speed up delivery, reduce transaction costs and contribute to the partnership.
We have reviewed the TERG evaluation recommendations on SIs and have clear actions on how we propose to respond in the design and implementation of the HF SIs.

IV. Operational Considerations

Set-Aside Modality

☒ Set-aside funds only, otherwise not feasible

☒ Can be integrated in country allocations but would need strong guidance

What is the evidence of lack of integration in country allocations?
Although we are aware that some health financing work is funded through grants, our Secretariat management information systems do not currently collect sufficiently detailed information to know exactly what is being

funded from country allocations, although this is being modified for the 2023-2025 cycle to enhance visibility on HF related investments. *If integrated in country allocations, what policy levers would be needed to effectively implement this priority?* Given incentives in this area, we would need hard requirements within country grants, with considerable time-cost implications for country teams. While the Secretariat is already working to enhance the focus on HF, STC, and VfM in access to funding processes and will continue, we would need strong requirements within country grants with considerable time-cost implications for country teams. This would require stronger ear-marking of grant funds for HF activities, stronger focus on HF in country dialogue, and stronger engagement on HF from partners focused on health financing. Health financing would need to be further prioritized across the range of allocation and grant agreement documentation. Without the ability to finance technical assistance directly, stronger coordination with other technical partners would be needed, and would limit the ability of the Global Fund to contribute to shared health finance objectives with key partners. None of these levers alone would realistically deliver outcomes on health financing data, innovative finance, or DRM / STC / VfM without additional catalytic funding.
Global Fund Comparative advantage
☒ Global Fund is one of many partners supporting this priority area The World Bank, regional development banks, WHO, bilateral development agencies, national governments and the Bill and Melinda Gates Foundation support this area, but it is not reliably and consistently supported in any one country and there are various activities – especially around DRM, health financing data, innovative finance, transition planning, cross-programmatic efficiency analysis and integration – that the Secretariat proposes to support through the SIs that are not supported by any of the above. In addition, catalytic funding allows the Global Fund to respond directly to country specific challenges and priorities, as well as contribute to shared objectives with other health finance partners.
Global Fund Competency
The 2017-2019 allocation period SI was successful in delivering outputs important for the wider theory of change around HF, STC and VFM outcomes, although attribution to outcomes is harder; this will be a key area of focus for HFD in the next cycle of SIs.
Sustainability
On DRM, sustainability, transition and VfM, the very aim of the funding is to build program and financial sustainability but arguably, catalytic funding will always be needed to facilitate and incentivize continuous improvement. For innovative finance, there is currently no mechanism to provide seed finance through grants. For HF data, the main push to achieve sustainability will need to be through work with technical partners to coordinate building systems for resource tracking at country level.

Emergency Fund

Emergency Fund	
Strategy goal: End AIDS, TB and Malaria	**Recommended modality:** Strategic Initiative (SI)
Strategy's 10 changes: n/a	
I. Proposal	
Description	
The Emergency Fund provides quick access to funds to prevent disruptions to the continuity of essential prevention and treatment services for the three diseases that cannot be funded through reprogramming, during certain emergency situations, including climate-related events. This includes, but it is not limited to: i) ensuring continuity of ART and tuberculosis treatment among the displaced and affected populations; ii) supporting preventive measures, such as indoor residual spraying and long-lasting insecticidal nets (LLINs) among the displaced, and those affected in malaria endemic/epidemic areas iii) supporting risk and situation assessments of the three diseases and related health systems functionality; iv) supporting costs of procurement and distribution of health products and limited operational costs of service delivery and staffing requirements during emergency situations, within reasonable ranges.	
Rationale	

Dynamics of conflicts are more complex, transnational and protracted, with increased global instability and fragility. Climate change is resulting in an increase of natural disasters impacting health services and infrastructures and is impacting both internal and external displacement of people. Increased forced displacement and the destabilization of essential healthcare services are having a devastating effect on key and vulnerable populations and impacting gains made in the fight against HIV, tuberculosis and malaria. The Emergency Fund continues to be an effective and rapid response mechanism to provide essential prevention and treatment services to affected populations during emergencies. While it is operationalized as a SI, funds are implemented directly through existing grants or through grants with pre-qualified implementers.

Funding

A centralized Emergency Fund allows for a rapid response, which is critical to maintaining the effectiveness of Global fund financing in emergency contexts. The Emergency Fund may be used to address needs of forcibly displaced population (refugees and migrants) that are not able to be effectively funded through country allocations. The amount of funding needed for emergency response in each country cannot be predicted but based on recent experience, the Secretariat anticipates an increased need by eligible countries to access additional resources from the Emergency Fund to respond to man-made and natural disasters.

The Secretariat proposes increasing the Emergency Fund allocation to US$40 million considering that the budget has always been fully utilized and the Secretariat has had to request an increase of funds both in the 2017-2019 and 2020-2022 allocation periods to be able to immediately address emergency needs. The proposed funding amount would provide the Secretariat with more flexibility to fully fund priority needs that cannot be addressed through grant reprogramming in emergency situations.

II. Strategic Impact

Potential for increased impact

It is critical to ensure continuation of prevention and treatment essential services during emergency while also preserving gains of the Global Fund investments.

Levers

Not applicable

Catalytic effect

☒ **More**: incentivize increased funding from allocations to priority areas and/or additional funding outside of Global Fund

☒ **New**: initiate new or innovative activities for more efficient and impactful programming

☒ **Improved**: enable more effective use of country allocations and coordinated responses for cross-border contexts

☒ **Faster**: accelerate implementation of specific priorities

The Emergency Fund can catalyze complementary funding from other donors and partners and explore innovative approaches during emergency situations. The revolving nature of the Emergency Fund allows for, where possible, reimbursement from country allocations once the emergency situation has subsided and, in the event where there is room to reprogram existing funding.

Expected outcomes

- Continuity of essential treatment and prevention services for eligible populations where there's a risk of disruption due to an emergency situation
- Rapid access to additional funds for countries in need to address emerging needs and respond to the situation
- Contribution to containment of disease outbreaks
- Innovations in service delivery during emergencies that can be replicated in other challenging operating environments

Theory of change

The catalytic nature of the Emergency Fund ultimately contributes to the fight against the three diseases by a simple, rapid and flexible mechanism to allow for the Global Fund to rapidly respond to emergencies and add additional resources to grants that cannot be quickly reprogrammed or do not have sufficient resources to respond to emergencies.

Risk if not funded

The Global Fund cannot accept a disruption of life-saving treatment and services even in emergency situations. Populations affected by emergencies, including refugees and other displaced populations, can contribute to increase risk of rising incidence and resurgence of the three diseases, if not adequately mitigated.

III. Previous Investments

2020-2022 Catalytic Investment	2020-2022 Budget Amount
The Emergency Fund continues to be an effective mechanism to provide essential prevention and treatment services to affected populations during emergencies. As of March 2022, three requests (US$31 million) have been approved (see below) with another four requests (estimated at US$17 million) currently in the pipeline. An additional US$30 million was exceptionally granted by the Global Fund Board in March 2022 (GF/B46/ER13) to ensure sufficient funds to address the pipeline of requests.	US$ 50 milion (US$20 million + US$30 million)

Current implementers

UNDP, UNICEF

Current target populations

Afghanistan, Haiti, Ukraine. Mozambique, Malawi, Ethiopia. Given the nature of emergencies, the target populations cannot be predicted.

Progress to date

- **Afghanistan:** Afghanistan was granted US$15 million to top-up an existing grant managed by UNDP to support the provision and continuity of essential prevention, diagnosis and treatment services, including those for the three diseases and COVID-19 in Afghanistan. Of this amount, US$ 5M was identified through reprogramming and reimbursed.
- **Haiti:** Haiti was granted US$ 1 million to top-up an existing grant to cover essential gaps in the malaria prevention and treatment campaign for the earthquake affected departments in Haiti. The target population are mainly displaced and hard to reach communities, vulnerable to the seasonal malaria surge occurring from October to December with risk of extending to nearby departments with increased population movement in the southern peninsula.
- **Ukraine:** US$ 15 million was approved for a new grant in Ukraine to maintain essential HIV and TB services in the regions affected by the Ukraine military conflict. The target populations are in government-controlled areas and in non-government-controlled areas, in both civilian and penitentiary sectors, and include internally displaced persons and hard to reach communities, who are vulnerable to treatment interruption**.**

Expected evolution

For the next allocation period, the Emergency Fund will continue to focus on the goals for which it was established: to be a flexible and rapid financing mechanism to support the short-term provision of essential prevention and treatment services related to the three diseases during emergency situations.

The Secretariat will undertake the following actions to further improve the efficiency and effectiveness of Emergency Fund implementation:

- more proactive and regular engagement with countries, humanitarian partners and coordination mechanisms to quickly identify areas for Global Fund support and ensure the complementarity of support
- update the Emergency Fund guidelines and procedures to incorporate lessons learned from the previous and current cycles, as well from implementation of C19RM.

IV. Operational Considerations

Set-Aside Modality

☒ Set-aside funds only, otherwise not feasible

Given the nature of the Emergency Fund where the thematic and geographic focus cannot be predicted in advance, this financing mechanism would still have to be a set-aside funding. Channeling Emergency Fund through separate, set-aside funding, enables the Global Fund Secretariat to adopt a more streamlined, flexible and rapid funding mechanism which is critical for responding to emergency situations.

Global Fund Comparative advantage

☒ Global Fund is a leader in this priority area The Global Fund is one of the main global health actors, providing grants to a broad network of humanitarian and development partners in more than 100 countries, including acute and protracted emergencies. At times of crisis, the Emergency Fund has offered an agile tool to ensure continuation of the HIV, TB and Malaria treatment services while contributing to humanitarian responses. The elaboration of the Emergency Fund proposal as well as its implementation is coordinated with existing humanitarian response mechanisms, including relevant humanitarian partners to ensure complementarity and integration of funded interventions in full alignment with the Humanitarian Development Peace Nexus. Responses to refugee crisis are led by UNHCR, while responses to internal displacements are coordinated by Humanitarian Clusters and the Health Cluster is leading the coordination of health responses. Other major donors supporting humanitarian responses include the European Office for Humanitarian Coordination (ECHO), USAID, DFID and JIICA.
Global Fund Competency
The Emergency Fund has proven to be an effective and efficient tool to prevent disruptions of Global Fund-supported programs in crisis contexts by complementing and integrating humanitarian responses. No one will be left behind, including in times of emergency. With the Emergency Fund and its continuous engagement during emergencies, the Global Fund has made significant contributions to the implementation of the Humanitarian Development Peace Nexus agenda.
Sustainability
The Emergency Fund remains an essential tool to respond to forced displacements and to contribute to the humanitarian development peace nexus. To ensure a sustainable and integrated use of the Emergency Funding, the Secretariat will further strengthen partner engagement and support to define affected population needs and more adaptive implementation modalities. It will also help provide transitioning support to refugees and internally displaced populations from the Emergency Fund to medium-term financing (such as country allocations*).*