Electronic Report to the Board

Second Extension of C19RM and Operational Flexibilities

GF/B44/ER12 - Revision 2

Board Decision

Purpose of the paper: This paper seeks Board approval to further extend the timelines for the receipt, award, and use of funds for the Global Fund COVID-19 Response Mechanism (C19RM), and to extend the duration of the Secretariat's delegated authority to grant limited exceptions to the pre-shipment sampling and testing requirements under the Quality Assurance Policies.

Decision

Decision Point: GF/B44/EDP18: Second Extension of C19RM Timeline and Operational Flexibility for COVID-19:

The Board acknowledges its previous decision establishing the Global Fund COVID-19 Response Mechanism (C19RM) and agrees that the COVID-19 pandemic continues to have a devastating impact on global health systems, jeopardizing the fight against HIV, tuberculosis, and malaria and progress towards 2030 goals for the three diseases. Recognizing the acute needs at country-level, and the threat of diversion of resources towards COVID-19, the Board agrees that additional funding to support country responses to COVID-19 is necessary to safeguard the USD 14 billion raised through the 6th replenishment for HIV, tuberculosis, and malaria (HTM) programs. The Board further acknowledges that certain public donors wish to make significant additional pledges to the Global Fund to provide further support for country responses to COVID-19 and that this decision does not preclude further discussion and Board decisions within the Strategy development process on the future role and scope of Global Fund support for pandemic preparedness and response.

The Board agrees that C19RM should leverage existing Global Fund processes, controls, and frameworks, while acknowledging that modifications may be necessary to ensure the level of speed and agility necessary for an emergency response. The Board further agrees on the need for greater transparency on the operationalization and implementation of C19RM, to facilitate and ensure an appropriate degree of oversight from, and accountability to, the Board.

The Board therefore approves the following:

- 1. Timelines:
 - a. C19RM is a temporary, timebound mechanism established to address the current global emergency related to the COVID-19 pandemic;
 - b. The Secretariat will, through 31 December 2021, continue to mobilize additional funds from public donors and, pursuant to existing policies, private donors, which will be used to support C19RM;
 - c. C19RM funds may be awarded through 31 March 2022;
 - d. C19RM will continue to finance interventions across the 5th and 6th replenishment periods; and
 - e. While C19RM funding is expected to be used rapidly for emergency needs, the final deadline for use of C19RM funds will be 31 December 2023, to reduce the additional cost and burden associated with establishing and monitoring an independent deadline within core grants.

2. Use of funding:

- a. C19RM funding will finance interventions consistent with applicable World Health Organization (WHO) guidance, including on COVID-19;
- b. C19RM funding must be aligned with national Strategic Preparedness and Response Plans;
- c. C19RM funding may be used for the following types of interventions:

- *i.* COVID-19 control and containment interventions, including personal protective equipment, diagnostics, treatment, communications and other public measures as specified in WHO guidance;
- ii. COVID-19-related risk mitigation measures for programs to fight HTM (including, but not limited to, support for COVID-19 interventions needed to safely implement campaigns, community and health facilitylevel HTM programs, and additional delivery and procurement costs for HTM programs where related to addressing COVID-19 disruptions); and
- Expanded reinforcement of key aspects of health systems, such as laboratory networks, supply chains, and community-led response systems, to address advocacy, services, accountability, and humanrights based approaches;
- d. C19RM funds may be used to procure COVID-19 products approved under the WHO Emergency Use and Listing procedures or under other emergency procedures set up by any Stringent Regulatory Authorities as defined under the Quality Assurance Policy for Pharmaceutical Products and Quality Assurance Policy for Diagnostic Products; and
- e. The Secretariat will develop detailed technical guidance on eligible C19RM inteventions for countries, in consultation with relevant partners, as described in paragraphs 27.a and 44 of GF/B44/ER12 Revision 2.

3. Allocations:

- a. C19RM funding awards will use countries' 2020-2022 allocations as a starting basis; and
- b. C19RM funding awards will be qualitatively adjusted to better reflect countries' COVID-19 needs using the following factors: (i) COVID-19 burden; (ii) level of disruption to systems of health, including HTM services; (iii) availability of other sources of funding; and (iv) utilization of funds already awarded.

4. Funding requests:

- a. C19RM funding requests must be endorsed by Country Coordinating Mechanisms;
- b. C19RM funding requests must be developed through appropriate, multisectoral consultation, and fully-inclusive decision-making, which must engage communities and civil society, and ensure coordination with the national COVID-19 response coordinator;
- c. C19RM funding request development must include consideration of appropriate community, rights, and gender-related interventions, in alignment with the Global Fund's underlying principles of gender equity and human rights, and funding requests must articulate national HTM program adaptation needs and how these needs will be covered (e.g. through C19RM funding, grant funding, or other sources); and
- d. The Board calls on partners to support countries at the country, regional and global levels to develop robust, technically-sound C19RM funding requests.

5. <u>C19RM Funding Request Review and Approval:</u>

- a. <u>GAC</u>:
 - *i.* C19RM funding requests will be shared with partners on the Grant Approvals Committee (GAC) for review and input;
 - ii. C19RM funding requests will also be shared with a technical advisory group composed of relevant ACT-Accelerator partners with technical COVID-19 expertise (CTAG) for review and input;
 - *iii.* The Secretariat will consider input from GAC partners and CTAG in determining C19RM funding awards or recommendations; and
 - iv. The Secretariat will convene regular GAC review of C19RM to discuss awards made, emerging thematic issues relating to C19RM and Global Fund programs, and concerns and observations from partners. CTAG partners will be invited to participate in these reviews.
- b. <u>TRP</u>:
 - *i.* The TRP will be requested to input into upfront technical guidance relating to HTM adaptations/risk mitigation as referenced in paragraph 2.e above; and
 - *ii.* The TRP will also be requested to conduct an expedited review of HTM progam adaptation/risk mitigation elements of C19RM funding requests that entail material changes to existing Global Fund programs.
- c. <u>Fast-track investments</u>: The Secretariat may award countries up to USD 900 million of C19RM funding on an accelerated basis to support urgent needs for COVID-19 commodities (including personal protective equipment, diagnostics, and therapeutics) and costs relating to the effective deployment of such commodities.
- d. Board approval:
 - *i.* The Board must approve any C19RM awards exceeding USD 35 million, as measured in aggregate by country and not including any funding awarded pursuant to paragraph 5.c above or previously awarded C19RM funding;
 - *ii.* Commodity orders relating to paragraph 5.d.i above may be placed pending Board approval; and
 - iii. For C19RM awards approved by the Board, the Secretariat will have delegated authority to increase such awards by up to USD 10 million, in order to avoid the need for repeated Board approvals for increases to the same grants. This authority will be limited to increases that scale up interventions previously approved by the Board.

6. <u>Reporting, Monitoring and Evaluation:</u>

a. The Board emphasizes the need for comprehensive reporting, monitoring and evaluation of C19RM investments, while acknowledging the challenges of measuring results within an emergency response to a rapidly evolving pandemic. The Secretariat and TERG will further develop an evaluation approach for C19RM, as described in paragraphs 50 - 56 of GF/B44/ER12 – Revision 2. This approach will be presented to the Strategy Committee at its 16th meeting (July 2021) for review and input;

- b. The Board emphasizes the need for enhanced transparency on C19RM. The Secretariat will provide monthly detailed reporting to the Board on C19RM operationalization, as described in paragraph 21 of GF/B44/ER12 - Revision 2. This reporting will also be available on the Global Fund's external website to increase transparency of investments and support coordination of external support for COVID-19; and
- c. The Secretariat will continue to provide updates through regular Board and Committee engagements.

7. <u>Centrally Managed Investments</u>

- a. Up to 2.5% of C19RM funding may be used for centrally managed investments to address needs that are not well addressed through awards to individual countries, as described in paragraph 57 of GF/B44/ER12 Revision 2; and
- b. The Secretariat will develop any centrally managed investments under this provision in coordination with GAC and CTAG, and will report all such investments to the Board and its relevant Committees.

8. Management and Operating costs

- a. Up to 3% of C19RM funds may be used by the Secretariat to cover additional management and operating costs relating to C19RM. These costs may include (i) additional Secretariat resources and expertise, (ii) additional assurance costs, (iii) additional costs relating to enhanced reporting and monitoring and evaluation of C19RM investments, and (iv) additional costs to support CCMs;
- b. Management and operating costs under this provision are timebound, reflecting the temporary nature of C19RM, and will not form part of the Secretariat's annual budget for operating expenditures;
- *c.* The Audit and Finance Committee will review the Secretariat's plan for costs under this provision; and
- d. The Secretariat will provide regular reporting on any costs under this provision to the Audit and Finance Committee and the Board.

9. Additional changes:

- a. The Board will monitor C19RM on an ongoing basis to determine whether any changes are required as the pandemic continues to evolve; and
- b. The Secretariat will return to the Board, through its Committees, as relevant, for additional consideration and approval of any further modifications to C19RM.

10. Limited exceptions to Quality Assurance Policies:

a. The Secretariat may continue to grant limited exceptions to the Quality Assurance Policies to waive the requirement for pre-shipment sampling and testing (as originally approved under paragraph 3 of GF/B42/EDP10) through 31 March 2022.

Budgetary implications (included in, or additional to, OPEX budget): Incremental management and operating costs directly attributable to the proposed extension of C19RM

will be covered from any additional funds made available for C19RM, pursuant to paragraph 8.a above. Such costs will not exceed 3% of any C19RM funding.

A summary of relevant past decisions providing context to the proposed Electronic Decision Point can be found in Annex 5.

Executive Summary

As of 22 March 2021, COVID-19 has killed more than 2.7 million people. The pandemic continues to have a devastating impact on global health systems, including on efforts to fight HIV, TB, and malaria (HTM), and will further derail progress towards the Global Fund's ambitious targets for the 2020-2022 allocation grants. Modelling by UNAIDS suggests that COVID-19 could result in 123,000 to 293,000 additional new HIV infections and 69,000 to 148,000 additional AIDS-related deaths globally over the next five-years.¹ The 2020 Global Tuberculosis Report estimates that an additional 200,000 to 400,000 TB deaths occurred in 2020 as compared to the 2019 figure of 1.4 million. Malaria interventions have also been significantly impacted: for example, of the 222 million LLINs planned for distribution campaigns in 2020, only 105 million by November 2020 and 168 million to date have been distributed.

Countries are now confronting second and third waves of COVID-19 infections, fueled by the emergence of new, more transmissible variants, which also threaten to reduce treatment and vaccine efficacy. Given current death rates, COVID-19 will likely kill more people in 2021 than in 2020, and potentially more than HIV, TB, and malaria combined. These grim facts underscore the urgency of scaling up the global response and the imperative to ensure equitable distribution of vaccines, treatments and diagnostics. Since the pace of viral mutation is driven by global prevalence, it is essential to reduce transmission everywhere.

Meanwhile the knock-on consequences of COVID-19 continue to escalate. In many countries the response to COVID-19 is resulting in human and financial resources being diverted from HIV, TB, and malaria. Key and vulnerable populations are disproportionately impacted by the COVID-19 pandemic and the restrictions in place to curb the spread of the virus. These populations are amongst those most severely impacted by unemployment, homelessness, and food insecurity. Many face increased barriers to accessing health care and medicines, as well as increased human rights violations and gender-based violence. Having lost ground in the fight against HIV, TB, and malaria in 2020, the partnership faces the stark prospect of further reverses.

In response to this crisis, the Global Fund has taken swift action to reinforce countries' responses to COVID-19 and to support the global COVID-19 response. The Global Fund moved quickly to introduce Grant Flexibilities in early March 2020, followed closely by the establishment of the COVID-19 Response Mechanism (C19RM) in April 2020. As of 28 January 2021, the Global Fund has approved a total of USD 980 million to support countries' COVID-19 responses through these two mechanisms. Throughout 2020, the Global Fund played a critical role as one of the fastest and most flexible providers of support to countries for the purchase and deployment of COVID-19 diagnostics and treatments, for interventions to protect and reinforce health and community systems, including through the provision of Personal Protective Equipment (PPE), and for adaptations to HTM programs.

Yet country needs far exceed the support provided thus far by the international community. For example, an analysis of the latest available testing data suggests that low and lower middle-income countries are testing for COVID-19 at less than 15% of the average rate of high-income countries (HICs). Many countries face chronic shortages of quality PPE. Lack of oxygen facilities is exacerbating mortality. Adaptations to HTM programs need ongoing support to be sustained.

For the Global Fund to be able to sustain progress on HIV, TB, and malaria, ensuring that the USD 14 billion raised through the 6th replenishment can be safeguarded and deployed to drive reductions in infections and deaths from the three epidemics, it is vital that new funding is secured to step-up national COVID-19 responses (and not just for vaccine procurement and deployment), to bolster health and community systems and protect frontline health workers,

¹ <u>UNAIDS</u>, 14 December 2020.

and to sustain HTM program adaptations and risk mitigation measures. The Global Fund has a critical role to play in the next phase of the global response to COVID-19, given the partnership's unique experience and capabilities in fighting infectious diseases. Moreover, a more effective response to the pandemic is essential to protect and sustain progress against the 2030 goals for HIV, TB, and malaria. Acknowledging this context, some major public donors are poised to make significant additional pledges to the Global Fund to support countries' responses to COVID-19.

For these reasons, the Secretariat recommends that any additional public pledges made through 31 December 2021 be invested through C19RM. The Secretariat has worked with the Board and Committees to refine aspects of the original design of C19RM to reinforce technical guidance, the review and approval process for C19RM awards, assurance, oversight, transparency, reporting, and evaluation to be commensurate with the increased resources potentially available, while sustaining the speed and flexibility of the mechanism to deliver funding as quickly as possible to countries most in need.

The Board is requested to approve the following decision point:

• Decision Point: GF/B44/EDP18: Second Extension of C19RM Timeline and Operational Flexibility for COVID-19.

Input Received

- The Coordinating Group has been consulted in the development of this proposal, and on the approach to decision-making. Input was received from Board constituencies, the Strategy Committee (SC) and the Audit and Finance Committee (AFC), in line with their respective mandates. The decision-making approach enabled committee discussion and input, balancing inclusivity with the need for swift decision-making by the Board. Secretariat responses to the comments and questions received from the Board and Committees through 1 March 2021 are attached as Annex 4, or have been addressed through revisions to this paper.
- The Office of the Inspector General (OIG) has also provided preliminary inputs based on its ongoing assessment of C19RM. Although the report is still undergoing final checks in accordance with the OIG's standard Stakeholder Engagement Model, the Inspector General has exceptionally agreed to share the OIG's preliminary findings with the Board to support its decision making on this proposal. The full text of the OIG's inputs is reflected in Annex 1. The OIG has now shared its full draft report with the AFC.

What is the need or opportunity?

- 1. The COVID-19 pandemic continues to have a devastating impact on public health, societies, and economies around the world. As of 22 March 2021, there were 122 million infections and 2.7 million deaths attributed to COVID-19², comparable to the number of deaths from HIV (690,000), malaria (409,000), and TB (1.4 million deaths) in 2019.³ If the trend in current rates of infection continues, deaths from COVID-19 in 2022 could exceed 5 million, more than doubling the 1.8 million deaths over 2020. While the rollout of vaccines will reduce these totals, the emergence of new, more transmissible variants⁴ threatens to drive cases upwards while undermining the efficacy of both treatment and vaccines. Reducing transmission everywhere is essential to slowing viral mutation – reinforcing the global health adage that "no one is safe until everyone is safe". The pandemic continues to have grave economic and social impact, disrupting the global economy, jeopardizing livelihoods, and impairing access to basic services, exacerbating the plight of vulnerable populations. According to the World Bank, the COVID-19 pandemic is expected to result in a rise in extreme poverty for the first time in 20 years, with an estimated additional 88 million to 115 million being pushed into extreme poverty in 2020, potentially rising to 150 million in 2021.⁵ In short, while vaccines provide cause for longer term optimism, COVID-19 continues to pose an imminent threat to the populations served by the Global Fund, and immediate action remains necessary to prevent sweeping damage and the derailment of the Global Fund mission.
- 2. Early in the pandemic, modeling on the impact of COVID-19 on the three diseases indicated that COVID-19 would likely reverse decades of hard-won progress. Prior to the pandemic, the world was already off-track to meet the 2030 HIV, TB, and malaria targets. COVID-19 threatens to derail progress towards the ambitious targets set under 6th replenishment grants. While some of the early worst-case scenarios for treatment disruption were averted through prompt action, often funded through C19RM or Grant Flexibilities, there has been significant impact on prevention and case-identification, and the longer-term consequences of on-going or new disruptions are likely to be significant. As regions experience second and third waves of COVID-19 infections, many countries and regions are seeing an exponential increase in cases and the diversion of human and financial resources to respond to the pandemic as it continues to escalate. While some countries have reported an easing of containment measures that were leading to service disruptions, the new COVID-19 variants could see these measures quickly reintroduced.
- 3. The most recent survey of Global Fund programs in 106 countries indicates that approximately half to two-thirds of HTM programs reported service disruptions due to COVID-19.⁶ A Global Fund survey assessing COVID-19-related HTM disruptions in 38 countries indicated that while the provision of ART seems to be relatively stable, services for sex workers and people who inject drugs have been reduced by approximately 20%; and in some countries there is an urgent need for catch-up in community-based services for adolescent girls and young women (AGYW) (emerging

² WHO Coronavirus Dashboard, accessed 22 March 2021.

³ UNAIDS 2020 Data, WHO Global Tuberculosis Report 2020, World Malaria Report 2020.

⁴ Several new variants with an unusually large number of mutations have emerged since December. The three causing the most concern are the UK (B.1.1.7), South Africa (1.351) and Brazil (P.1) variants due to their increased transmissibility, which may lead to increased hospitalizations and put additional strain on already stressed health systems.

⁵ World Bank: COVID-19 to Add as Many as 150 Million Extreme Poor by 2021, 7 October 2020.

⁶ Approximately 12% (HIV), 12% (TB) and 14% (malaria) of Global Fund programs reported high to very high disruptions. 39% of the countries indicated that they were continuing to experience national restrictions and 19% reported local restrictions that impact Global Fund programs.

data and front line reports indicate that violence against women and girls, has intensified, increasing the risk of HIV acquisition and poor health outcomes). With respect to TB, the survey indicates that TB case notifications and MDR-TB enrollments fell significantly between Q1-Q3 of 2020 (as compared to the same period in 2019) with a 27% reduction in TB case notification (794,732 fewer TB notifications) and a 39% decline in second-line treatment enrollment (29,921 fewer people).⁷ For malaria, a 22% decrease in malaria testing was reported, as well as stock-outs of rapid diagnostic tests (RDTs), and delays in insecticide-treated net (ITN), indoor residual spraying (IRS), and seasonal malaria chemoprophylaxis (SMC) campaigns.⁸ These disruptions are anticipated to continue, and possibly grow worse this year. Section 3 of Annex 4 discusses the impact of COVID-19 on HTM in further detail.

4. Despite significant scientific and clinical achievements in the response to COVID-19. the countries and communities supported by the Global Fund will continue to be significantly impacted over 2021 and 2022. While global progress in developing technology to diagnose, treat, and protect people from COVID-19 has proceeded at record-breaking speed, countries served by the Global Fund face challenges in accessing these new tools. Although the deployment of effective vaccines is expected to reduce mortality and pressures on health systems, the inequities in global access to vaccines and the lack of sufficient supply has meant that very few low- and lower-middle income countries (L-MICs) have begun COVID-19 vaccination programs⁹, despite the significant financial resources made available through the COVAX Facility¹⁰ and the World Bank¹¹. By contrast, an acute lack of funding is the key constraint for COVID-19 diagnostics, therapeutics (including oxygen), and infection control (including PPE for front line health workers) in L-MICs. Testing rates in low and lower-middle income countries are currently less than 15% of the average of high income countries, and episodic and inadequate supplies and weaknesses in laboratory capacities compromise the implementation of coherent testing strategies.¹² The provision of oxygen also remains challenging in L-MICs, with COVID-19-related demand exacerbating already existing gaps. Countries are also facing critical gaps in PPE, such as gloves, masks, respirators, and gowns, which is critical to ensuring infection control and the protection of front-line health workers, including the community health workers which play such a vital role in delivering services to the poorest and most vulnerable.

 $^{^{7}}$ For TB notification data is from 13 countries and for MDR-TB enrollments data is from 18 countries. The period for comparison is Q1 – Q2 2020 to Q1 – Q2 2019. The main factors driving these reductions are restrictions which have impeded TB case finding and community-based activities, closure of health facilities (public and private), fear and stigma, supply chain disruptions, delays in transportation of specimens and re-assignment of TB program staff and health workers to the COVID-19 response.

⁸ Factors include inability to access the required PPE needed to protect and enable frontline health workers to go into communities and treat people safely and to do effective community malaria case management.

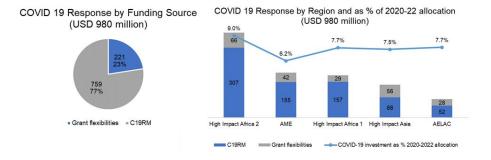
⁹As of 22 March 2021, 133 countries had begun vaccinations. Source: <u>Bloomberg COVID-19 Vaccine Tracker</u>, accessed 22 March 2021. On 28 January 2021 the <u>African Union (AU) announced</u> that it had secured an additional 400 million doses of coronavirus vaccines for the continent, with the roll-out of mass vaccinations expected to begin in March. As of 22 March 2021, 19 African countries had begun vaccination campaigns.

¹⁰ The COVAX Facility is the global pooled procurement mechanism for COVID-19 vaccines with the aim of ensuring fair and equitable access to vaccines for all 190 participating economies (Source: GAVI/COVAX). On 24 February 2021, the first international delivery of 600,000 vaccines were delivered to Ghana. Since then COVAX has delivered vaccines to 33 Global Fund supported countries, including Cote d'Ivoire, Nigeria, Sierra Leone, Angola, Cambodia, Democratic Republic of the Congo, Rwanda, the Gambia, Sudan, Kenya and the Philippines.

¹¹ In October 2020, the <u>World Bank approved USD 12 billion</u> to finance developing countries' acquisition and deployment of COVID-19 vaccines.

¹² From data as of 10 March 2021 for 112 countries available at https://ourworldindata.org/coronavirus-testing, the total tests per 1,000 people was on average 17 tests in low-income countries, 107 tests in lower-middle-income, 194 in upper-middle-income countries and 920 tests in high-income countries since the beginning of the pandemic.

In response to this crisis, the Global Fund has taken swift action to reinforce countries' responses to COVID-19 and to support the broader global response. As a founding partner of the ACT-Accelerator¹³, the Global Fund is playing an essential leadership role in the global response and is leveraging this position to enhance equitable access to diagnostics, PPE and therapeutics. Section 2 of Annex 4 provides additional detail on the Global Fund's role in the ACT-Accelerator. To support implementer countries, the Global Fund moved quickly to introduce Grant Flexibilities in early March 2020, followed closely by the establishment of C19RM in April 2020. To date the Global Fund has approved a total of USD 980 million to support COVID-19 responses (USD 759 million through C19RM and USD 221 million through Grant Flexibilities) across 106 countries and 14 multi-country programs. Of the USD 759 million that was awarded through C19RM, (i) USD 243 million (32%) was for mitigating impact on HTM responses, (ii) 442 million (58%) for reinforcing national COVID-19 responses, and (iii) USD 74 million (10%) for urgent improvements in health and community systems.¹⁴ A pipeline of USD 313 million of urgent demand remains from previously submitted requests. Annex 1 provides further details on awards made as well as illustrative examples of types of interventions funded.



6. Through C19RM, the Global Fund has played a critical role in supporting countries in their COVID-19 responses, serving as one of the key providers of support for the purchase and deployment of diagnostics, treatment, and PPE and for health systems strengthening. Yet additional and increased support will be necessary to enable countries to sustain HTM adaptations, protect progress, and respond effectively to the pandemic.¹⁵ Section 17 of Annex 4 provides more information on C19RM absorption and use. Continuing to support countries' responses to COVID-19 is essential to ensure health and community systems are not overwhelmed, treatment and prevention programs are not disrupted, and resources are not diverted away from Global Fund programs. Without additional resources, health and community systems will remain in a tenuous state and Global Fund programs are at critical risk of disruption. Accelerating the equitable deployment of all currently available tools to fight COVID-19 is critical to achieving the Global Fund's core mission. Ultimately these additional investments are necessary to safeguard the USD 14 billion raised through the 6th replenishment for the fight against HIV, tuberculosis and malaria.

¹³ The ACT-A Accelerator is a global collaboration of organizations and governments working to accelerate the development, production and equitable access to new COVID-19 tests, treatments and vaccines. For more information see: <u>https://www.who.int/initiatives/act-accelerator</u>

¹⁴ These amounts also include USD 182 million for COVID-19 diagnostics and USD 276 million for PPE.

¹⁵ By the end of December 2020, the Global Fund had signed 157 grants for a total of USD 8.54 billion to support HIV, TB, and malaria programs and strengthen health and community systems.

What do we propose to do and why?

What is the proposal?

Investment of additional pledges through C19RM:

- 7. In order to protect and sustain progress against the 2030 goals for HIV, TB and malaria, continuation of support for country responses to COVID-19 remains crucial to reduce transmission, deaths, and the knock-on impacts of the pandemic, through stepping up the provision of diagnostics, therapeutics, PPE, and ensuring the sustainable adaptation of HTM programming. Given its experience in supporting the fight against infectious diseases, the Global Fund is uniquely positioned to rapidly deploy additional resources to countries through its existing structures and partnerships, both at country and regional/global levels. Existing procurement capabilities and experience also position the Global Fund to provide valuable support to countries: for this reason, the Global Fund has been identified within the ACT-Accelerator partnership as one of the preferred procurement and deployment partner for diagnostics, treatment (including oxygen) and PPE. By leveraging existing implementation arrangements and Country Coordinating Mechanisms (CCMs), the Global Fund is also well positioned to support additional investments in health and community systems that will help mitigate the impact of the pandemic on existing programs.
- 8. In recognition of this potential to leverage the Global Fund's existing strengths to support countries in addressing the pandemic, more than one of the Global Fund's major public donors are considering significant new pledges for the Global Fund's support for country responses to COVID-19. While the timing and magnitude of such contributions are uncertain, the Secretariat believes that additional pledges are both likely and imminent, with an expected range between USD 3 4 billion. Because pledges of this magnitude would exceed the additional USD 500 million threshold for returning to the Board as set out in GF/B43/EDP12, the Secretariat is seeking Board approval for the next phase of C19RM, as clarity on the future approach to C19RM will be key to securing confirmation of any additional pledges. The Board must take swift action to ensure that it is in a position to immediately deploy any additional funding received.¹⁶
- 9. In 2021, the Global Fund's COVID-19 response must be adapted to reflect the current context and the start of the new 6th replenishment grant cycle. For countries beginning the new cycle, Grant Flexibilities will no longer be available as a distinct mechanism to support COVID-19 responses, as grant funds will remain focused on core HTM needs at the outset of the period. While Principal Recipients will be able to use established reprogramming flexibilities and any grant savings reinvested through portfolio optimization for HTM program adaptation and catch-up plans (including the provision of PPE), such resources will not be available for "pure" COVID-19 needs, such as COVID-19 diagnostics and therapeutics. Recognizing the significant unmet needs in countries' COVID-19 responses, the Secretariat recommends that any additional public pledges made through 31 December 2021 be invested through C19RM.¹⁷ Significant additional funding through C19RM will protect core programs by providing direct, additional

¹⁶ Section 2 of Annex 4 provides additional detail on the relationship between contributions to C19RM and ACT-Accelerator contributions.

¹⁷ Private donors will continue to be able to make restricted financial contributions in accordance with the <u>Amended and</u> <u>Restated Policy on Restricted Financial Contributions</u>. GF/B41/DP05

support for COVID-19 interventions, while also providing additional resources for HTM program adaptations and the reinforcement of health and community systems.

- 10. The Secretariat recommends that unutilized funds¹⁸ that become available from 5th or 6th replenishment funds continue to be invested through the existing portfolio optimization mechanism for HTM needs, including program adaptations, catch-up plans and other priorities captured in Unfunded Quality Demand (UQD). The Secretariat believes that taking this approach clearly separating new external funding for C19RM from core allocation funding, including reprogramming and the reinvestment of grant savings through portfolio optimization will ensure that the USD 14 billion raised through the 6th replenishment is protected from diversion, safeguarding this funding for the Global Fund's core HTM mission and ensuring that this funding is unambiguously utilized for HTM needs. Sections 3 and 4 of Annex 4 provide additional detail on the connection between C19RM and Global Fund core funding.
- 11. While raising questions about the Global Fund's potential role in pandemic response in the future, the continuation of C19RM as an urgent response to safeguard the fight against HTM remains rooted in the Global Fund's existing mandate. C19RM remains a temporary emergency response mechanism and is not intended to pre-empt broader discussions on the next Global Fund strategy. It remains for the Board to continue discussions and ultimately determine whether the Global Fund should take on an expanded role in pandemic response or global health security/solidarity going forward. In any event, continuing to leverage the Global Fund's unique strengths in fighting infectious diseases and relative advantages in reinforcing health and community systems to assist the global COVID-19 response will enhance the Global Fund's effectiveness in the continued fight against HIV, TB, and malaria, as lessons drawn from C19RM can be used to accelerate the global HTM response.

Proposed refinements to the current C19RM model:

- 12. The Board established C19RM as an urgent response mechanism with the priority of deploying funding as quickly as possible to address an emergency context. Recognizing the grave threat posed to millions of lives across Global Fund countries, this swift response allowed the Global Fund to quickly adapt to support countries in responding to this crisis. While the global response to the pandemic has evolved, the need to move with speed and agility remains critical. Yet given the scale of the expected increase in funding and the lessons learned from the first phase of C19RM, it makes sense to review and, where necessary, recalibrate the mechanism's key processes to ensure an optimal balance between speed, diligence, and assurance. Based on the magnitude of the expected additional pledges, the Secretariat recommends a number of specific refinements to the mechanism, in particular, to reinforce technical guidance, the review and approval process for C19RM awards, assurance, oversight, transparency, reporting, and evaluation, while maintaining C19RM's distinctive attributes of speed and flexibility.
- 13. In developing the proposal below, the Secretariat has sought to leverage existing Global Fund processes, controls, and frameworks as much as possible, while proposing modifications to maintain the speed and agility that countries value so highly in C19RM. The Board provided extensive input on the initial proposal, which the Secretariat and Board have carefully considered together, evaluating the benefits and trade-offs of various approaches in seeking a balance between additional layers of review and the speed of decision-making that is required to effectively support countries. The Secretariat and Board also agree that heightened transparency is necessary to ensure

¹⁸ This may include both actual and forecasted unutilized funds.

the Board is able to effectively carry out oversight over C19RM and its impact on core operations. The final recommendations described below reflect the feedback received, balancing the needs for rigor, oversight, and assurance, while not overly compromising the fundamental emergency nature of C19RM. Annex 3 provides a visual overview of the revised C19RM process from funding request development through award.

14. The recommended refinements are also based on learnings gathered from across the Secretariat and the OIG's preliminary informal findings from its ongoing assessment of C19RM, which is focused on the design and effectiveness of the C19RM application process (including governance and decision-making over C19RM resources), and the mechanisms in place to ensure that funding requests were processed promptly and that funds were made available at the country level in a timely manner.¹⁹ The OIG's statement on its preliminary informal findings is set out in Annex 1. Although implementation of C19RM interventions is ongoing, and detailed data on expenditures and results is as yet very limited, the Secretariat has regularly reflected on qualitative observations to inform course-correction and improvements. More detail on lessons learned to date is provided in Annex 2.

Scope of C19RM investments:

15. C19RM was designed to provide support across three categories of interventions: activities to mitigate the impact of the pandemic on HIV/AIDS, tuberculosis and malaria; support for "pure" COVID-19 interventions, such as COVID-19 testing and treatments, and the provision of PPE for front-line health workers; and urgent reinforcement of health and community systems, including strengthening laboratory systems and community mobilization.²⁰ The Secretariat recommends retaining these categories, as this definition of scope continues to be fit for purpose, allowing investment across a range of interventions to accommodate countries' evolving needs as the pandemic progresses. The Secretariat also recommends continuing to follow a country-led and country-owned approach to determine the precise distribution of funds across these different categories, and continue to require that requests are submitted and endorsed by CCMs. However in all cases, C19RM funding is expected to be additional to existing funding in-country and should not supplant existing funding, whether for HTM programming or COVID-19 responses. Based on known and expected country needs, it is anticipated that the greater portion of any additional funding will be directed towards addressing critical needs in countries' responses to COVID-19, including scaled-up procurement and distribution of diagnostics and PPE. Section 5 of Annex 4 provides additional detail on the anticipated focus of C19RM funding. Given the availability of other significant sources of funding (e.g. through GAVI's COVAX facility and the World Bank's USD 12 billion MPA facility), the Secretariat recommends that C19RM should not support the procurement of vaccines, nor be primarily focused on vaccine deployment. While the use of C19RM for the procurement of PPE and for some health systems interventions (such as strengthening community health workers) may contribute to the implementation of country vaccine deployment plans, GAVI and the World Bank are going to be the principal sources of external support to countries' vaccine deployment efforts. The Secretariat also recommends to avoid using C19RM funding to compensate for shortfalls in domestic procurement of HTM commodities, which should be covered by core grants and potentially portfolio optimization.

Allocation and award of funding:

¹⁹ The OIG draft report was shared with the AFC on 19 March 2021.

²⁰ GF/B42/EDP11.

- 16. **Allocation approach**: With the overarching objective of safeguarding Global Fund investments in programs to fight the three diseases, funding in the first phase of C19RM was awarded in proportion to countries' core allocations, with countries eligible to access an amount equivalent to up to 10% of their 2020-2022 allocations across C19RM funding and Grant Flexibilities, with some flexibility to adjust awards based on specific country circumstances. This approach worked well in the first phase and allowed for flexibility in a context in which the COVID-19 situation and country responses were both rapidly evolving, while remaining rooted in the ultimate objective of safeguarding existing Global Fund investments. While the allocation methodology based on HTM burden and economic capacity provided a sound foundation, in some cases adjustments were warranted to maximize the potential impact of C19RM funds; some C19RM awards were adjusted based on available information on the impact of COVID-19 on health systems, and the potential to fund activities through Grant Flexibilities or other sources.²¹
- 17. The Secretariat proposes to continue this flexible approach in the next phase of C19RM, using the proportion of countries' 2020-2022 allocations as a starting point²², but with flexibility to adjust awards to reflect COVID-19-related needs. Factors taken into consideration will include COVID-19 considerations, such as current incidence, mortality and potential vulnerability; the extent of disruption of services in Global Fundsupported programs; the amounts of C19RM funding already awarded and progress in implementing these funds; plus the availability of funding from other sources. Data inputs used to inform the adjustments will include data on COVID-19 infections and deaths (and the presence of epidemiologically significant variants), testing rates/positivity, demographics, available data on HTM service disruption (including LFA surveys, facility surveys, data from community-led monitoring (CLM), and national metrics), impact on HTM infections/deaths (where available), available data on utilization of C19RM funds already awarded, and information on domestic and other external sources of funding (including with respect to access to key COVID-19 commodities). These adjustment factors will be considered contextually and qualitatively, rather than formulaically, taking account of each country's latest situation and recognizing the limitations of COVID-19 burden data and the intrinsic difficulty of weighting the different factors. This approach will balance the C19RM's underlying objective of protecting core Global Fund allocations and objectives with the need to be responsive to the fact that countries' COVID-19-related needs may not always correlate to their HTM allocations, and to the rapidly changing nature of the pandemic.
- 18. Timing and operationalization: In terms of timing and operationalization, the Secretariat is currently working through the details of how best to make funding available to countries, drawing on the lessons from the first phase, and balancing the need for speed, quality, and flexibility. While speed remains a priority (not least because there is already a queue of urgent unfunded demand), feedback from countries indicates that some components of C19RM requests (such as those around community interventions, or requiring extensive coordination with partners) may need additional time to be developed. The process for awarding funding also needs to take into account changing country needs and the interaction with other planning and funding processes, including domestic budgeting and interaction with other funders, such as the World Bank. The goal is to give countries enough time and support to develop robust requests that fit within their overall COVID-19 responses, while also ensuring urgent needs are funded quickly; and to maintain sufficient flexibility to respond to changes in country priorities (for example, as new diagnostics and treatments become available), while also ensuring the funds do not remain unused. Another challenge experienced in the first

²¹ Awards to date are published under "Approved Funding" at <u>https://www.theglobalfund.org/en/covid-19/response-mechanism/</u> ²² This will include multi-country grants under both the 2017-2019 and 2020-2022 allocation periods. For multi-country grants with no fixed 2020-2002 allocation, funding will be awarded based on the relevant grants' 2017-2019 allocation.

phase related to the uncertainty about the timing and total amount of C19RM funding. This resulted in an ongoing process of distributing incremental amounts as additional pledges were made, which required countries to go back and update their requests, and then to revise grants several times – a time-consuming process that diverted energy and resources from implementation.

- 19. Building on the experience of phase 1 of C19RM, and once the initial funding capacity is known, the Secretariat will communicate to countries an initial allocation based on a standard base percentage of 2020-2022 HTM allocations that all Global Fund countries will receive (as long as they submit funding requests of an appropriate quality within a certain timeframe). Countries will be encouraged to submit a prioritized and ambitious expression of demand, going beyond the initial allocated amount, and will be told they may receive an incremental amount above their base allocation, depending on the qualitative adjustments relating to COVID-19 considerations, subject again to submission of funding requests of appropriate quality. The Secretariat will make clear that countries with low HTM allocations relative to COVID-19 need are likely to get higher incremental shares of C19RM funding and vice versa. This means all countries can be confident of receiving a defined base level of funding, and that countries that are particularly affected by COVID-19 may receive more funding than using HTM allocation alone would imply. This approach will also allow for the creation of the C19RM equivalent of unfunded demand, so that subsequent smaller donor contributions can be swiftly deployed.
- 20. Within these funding envelopes, countries will be invited to submit prioritized funding requests with defined time windows, rather than all in one go. As part of the initial base percentage, countries will be invited to submit a part of their C19RM application on an accelerated basis, which may request a portion of funds²³ to support urgent needs for COVID-19 commodities (including PPE, diagnostics, and therapeutics) and costs relating to the deployment of such commodities. This amount will be awarded on the basis of streamlined application materials focused on COVID-19 commodities, following an opportunity for inputs from the GAC and a COVID-19 Technical Advisory Group (CTAG), as discussed in further detail below in paragraph 33. Following submission of this accelerated component of their applications, countries can then take additional time to submit the balance of their funding requests, allowing for a longer timeframe to develop more complex interventions, including HTM mitigation measures, RSSH interventions, community- and civil society-led responses, and interventions to address human rights, gender, and equity considerations. Adopting a submission window approach will also allow the Secretariat to effectively utilize the adjustment factors as the pandemic evolves and new data becomes available. Another advantage of this approach is that it makes it easier for countries to align submissions to C19RM with domestic planning and budgeting processes, and to applications to other funding sources, such as the World Bank.
- 21. Monthly reporting to the Board and partners will include the amounts awarded to individual countries, the categories of investments, cumulative investments in COVID-19 commodities across the portfolio (diagnostics, PPE and therapeutics), plus visibility on the pipeline of pending submissions. The Secretariat will also include in the reporting the amount awarded as a cumulative percentage of each country's underlying HTM allocation and will provide an explanation for all significant deviations from the average. Reporting to the Board is described in further detail in paragraph 49.
- 22. This proposed approach strengthens the approach in phase 1 of C19RM by incorporating: (i) a more systematic approach to making adjustments from the

²³ Up to USD 900 million in aggregate across countries.

underlying HTM allocation, whereas in phase 1 this was on an exceptions basis; (ii) submission windows that provide predictability and visibility on the pipeline of demand pending submission, rather than waiting for CCMs to submit a single consolidated funding request, followed by ad hoc "top ups" as new donor contributions were received; and (iii) more regular and detailed reporting to the Board and partners, including explanations for adjustments based on qualitative factors.

- 23. Eligibility: At this stage, the Secretariat does not envisage extending the eligibility for C19RM beyond those countries already eligible for and receiving HTM grants (either directly or through multi-country grants). All low and lower-middle income countries have HTM grants and thus are eligible for C19RM. Multi-country grants, which remain eligible for C19RM funding, may also provide some funding for ineligible countries, where such funding is consistent with the relevant multi-country strategic priority. Previously eligible countries that have transitioned will continue to be able to purchase COVID-19 products through the wambo.org pilot for non-grant financed orders. Currently this option is available through 31 May 2021, pending SC and Board consideration of a recommendation to extend this timeline through 30 November 2022. Finally, ACT-Accelerator partners including WHO, World Bank, UNICEF, UNITAID and others are able to provide support to countries that remain outside of the Global Fund's eligibility policy.
- 24. The Secretariat proposes that the timeline for the award of C19RM funding be extended until 31 March 2022. Funding will continue to leverage existing implementation arrangements and assurance mechanisms.²⁴

Technical guidance and partner engagement:

- 25. The first phase of C19RM followed a streamlined process intended to deliver funding as quickly as possible to address urgent country needs in a rapidly changing context. In order to ensure the technical soundness of interventions, the Secretariat assessed requests to ensure they were in line with WHO technical guidance as well as national strategic preparedness and response plans and guidance from partners. Independent technical review by the TRP was not required, given time constraints, the need to focus TRP energies on reviewing the much larger quantum of HTM grants for the 6th replenishment cycle, and the fact that the majority of C19RM funding requests were for the COVID-19 response, including diagnostics, therapeutics, and protection of frontline health workers. The Secretariat leveraged internal technical expertise in the review of C19RM requests, drawing on HTM technical partners to produce technical guidance on risk mitigation activities for the three diseases, HSS and community, rights and genderrelated interventions, and on ACT-Accelerator partners for COVID-19 interventions. In the initial stages of the crisis, some countries faced challenges in determining what to prioritize in their C19RM applications, as national strategic preparedness and response plans were often in the process of development. Rapidly evolving technical guidance, the emergence of new tools, and the identification of best practice approaches also required countries to adjust to a constantly shifting landscape.
- 26. During the first phase of C19RM, partners engaged in-country during the preparation of funding requests, as well as on an ad hoc basis during funding request review. There has also been strong and regular engagement with partners at the global level through various forums such as the Situation Rooms and ACT-Accelerator. As the global COVID-19 response evolves, it has become even more important to strengthen partner engagement and coordination to ensure alignment on priorities, and complementarity

²⁴ New implementers may be considered in exceptional circumstances, subject to satisfactory assurance arrangements and ability to implement proposed interventions with speed.

with other funding sources, and to avoid duplication, while still maintaining the ability to move quickly given the emergency context. Based on experience during the first phase of C19RM and feedback from in-country stakeholders, partner engagement is most critical at the country level and must start early on to support the development of C19RM requests that reflect country-specific COVID-19, disease and health systems contexts.

- 27. For the second phase of C19RM, the Secretariat proposes to strengthen guidance, technical support, and partner engagement for C19RM request development, operational programming, and implementation through a number of measures:
 - a) Global coordination with partners: Global coordination with partners remains essential for delivering an aligned global response to COVID-19. Feedback from partners and CCMs indicates that there should be strong focus by the global partnership on developing clearer, upfront technical guidance to provide greater clarity on eligible C19RM activities; a stronger and more systematic approach to providing upfront technical and operational guidance to CCMs will be a key area of focus for the second phase of C19RM. The Secretariat will work with technical partners to define and illustrate a range of interventions that could be eligible for C19RM funding, including HTM adaptation packages (e.g. lab system strategies with combined testing for COVID-19 and tuberculosis), RSSH interventions, and COVID-19 interventions (e.g. a package of interventions aimed at COVID-19 control and containment in prisons). Leveraging the expertise of the global partnership to develop clear direction for countries on technically sound interventions eligible for C19RM funding will provide countries with greater focus and direction in developing their C19RM requests, expediting the request submission process and decreasing the time from request to implementation. Broader partner engagement at the global level will also continue across a range of forums:

• <u>Direct COVID-19 response</u>: For "pure" COVID-19 responses, strong engagement with partners will continue through the diagnostic and therapeutic ACT-Accelerator pillars. Key partners in this context include WHO, FIND, UNITAID, the World Bank, UNICEF, Wellcome, and BMGF, plus major bilateral partners, such as USAID. Drawing on the existing ACT-Accelerator workstreams, the Global Fund will convene a C19RM technical advisory group (CTAG) of relevant ACT-Accelerator partners to strengthen operational linkages between ACT-Accelerator and C19RM and coordinate partner support for C19RM, including on the development of technical guidance and providing technical assistance to countries to support funding request development, program design, and implementation.

• <u>HTM programming</u>: For core programs, the Secretariat will build on regular engagement and leverage existing capacity within the partnership through disease-specific Situation Rooms. Situation Rooms will be leveraged to monitor disruptions by disease, contribute to technical and operational guidance, and identify and disseminate best practice innovation, adaptation, and catch-up strategies. Key multilateral partners include UNAIDS, Stop TB, RBM, WHO, plus key bilateral partners. Technical guidance developed by partners should cover best practice approaches for HTM program adaptations, innovations, catch-up plans, and risk mitigation measures. The TRP will also be invited to provide input on guidance on HTM program adaptations and risk mitigation.

• <u>RSSH/CSS</u>: For reinforcements to health and community systems and responses, partners will be engaged through the ACT-Accelerator's Health

Systems Connector, with key multilateral partners including the World Bank (including GFF), WHO, GAVI, UNICEF, as well as other key multilateral and bilateral partners such as the Stop TB Partnership, USAID, FCDO, GIZ BACKUP Health, L'Initiative, and AFD. Technical guidance in this area will focus on the strengthening of health and community systems and responses to enable the response to COVID-19 and promote access to HTM services. Because investments in health systems can have benefits beyond the immediate crisis extending to future pandemic preparedness more broadly, technical guidance should be aligned with existing global preparedness and response frameworks, tools, and indicators.²⁵

- b) Ensuring partner engagement in-country during C19RM funding request development: Coordinated partner engagement with national and CCM leadership in C19RM request development remains essential to ensuring high quality, prioritized funding requests that form a key part of the national response, and are complementary to support from other partners. Partner engagement must also be coordinated to ensure access to any available data on disruption to HTM services, to ensure that funding requests account for the needs for HTM program adaptation to mitigate against further disruption. In order to enable countries to receive and deploy C19RM funding swiftly, it is critical that this engagement at the country level take place from the earliest stages. The Board is requested to call on partners to ensure engagement and support to countries in the coordinated development of their C19RM requests. The Secretariat will also coordinate with partners to ensure that appropriate technical assistance is provided to countries, whether for HTM program adaptation or COVID-19 responses.
- c) Enhancing internal Secretariat expertise and resources: The Secretariat will continue to leverage existing skills among partners, as well as strengthen its disease advisory teams for HTM, RSSH, and CRG to coordinate partner engagement, the development of technical guidance, and ongoing support to countries for HTM risk mitigation, program adaptations, health systems strengthening, and community responses. These resources will focus on ensuring coordination and alignment with technical partners to ensure effective engagement and integrated support to countries. The Secretariat also plans to build a limited degree of internal expertise on COVID-19 responses, including expertise on protection of frontline health workers, particularly relating to PPE, diagnostics, and COVID-19 therapeutics, including oxygen, primarily to ensure the ability to draw on external expertise as efficiently and effectively as possible.
- d) Improved application form and communications: The Secretariat will develop improved application materials and accompanying guidance to support countries in developing C19RM requests. The revised application form will be accompanied by clear guidance on how to complete various sections, with reference to relevant technical guidance from the Global Fund and partners. The application will solicit more country data to explain the requested activities and will solicit additional information on themes such as community engagement, partner coordination, other sources of funding, and national response plans, to provide additional context for the review of the proposed interventions. Detailed information on national COVID-19 response plans and other available sources of funding will be

²⁵ Examples of relevant tools include: the International Health Regulations (IHR), the Global Health Security Agenda Joint External Evaluation, the WHO Benchmarks for IHR Capacities (2019), and, where available, the National Action Plan for Health Security.

necessary to identify critical gaps and ensure that support through C19RM does not duplicate existing funding²⁶, and will also provide evidence of country commitments through domestic resourcing to inform plans for sustainability. The revised application materials will also solicit information on HTM service disruptions (requesting CCMs to consider all available sources of data on service disruption including facility surveys, CLM, and grant performance), and address how identified needs and gaps are being addressed (within the C19RM request or through other sources of funding including grant funds). A streamlined section of the application form will solicit urgent needs for COVID-19 commodities (and related costs for the effective deployment of such commodities) for a portion of each country's C19RM allocation; this component can be submitted on an accelerated timeframe as described in paragraph 20 above, and further detailed in paragraph 33 below. Experience from NFM3 and C19RM demonstrates that robust, prioritized, and evidence-based funding applications enable more efficient internal reviews, coordinated partner support, and faster implementation. Clearer application and communication materials from the Global Fund will assist countries in developing quality requests;

e) **Expedited TRP review of material reprogramming**: In addition to reviewing upfront guidance on HTM adaptations and health systems, the TRP will be requested to conduct expedited reviews of HTM adaptation/mitigation submissions that would result in material reprogramming²⁷ of the underlying grants. TRP leadership will need to be engaged to ensure this review can be delivered within an appropriately short timeframe. The Secretariat does not recommend TRP review of individual funding requests based on expected trade-offs on time for decision-making, significant additional workload on the Secretariat to produce briefing notes for the TRP, the TRP's expected workload over 2021 to review the remaining funding submissions for the 6th replenishment cycle, and the fact that the TRP has already reviewed the majority of the underlying HTM programs to which C19RM funding will be added.

Funding request review and decision-making process:

- 28. During 2020, with a primarily Secretariat-led approach, the Secretariat targeted (and very largely met) a 10-day turnaround time for C19RM decisions. Although there were gaps in both technical guidance and in-country support to CCMs at the time of the initial submissions, and many countries national response plans were still at an early stage of development, the vast majority of funding submissions were of good quality, with most requests being straightforward and consistent with technical guidance. In phase 1 of C19RM, the most difficult aspect of the decision-making process was the disconnect between available funds and the needs, rather than the robustness of the funding requests.
- 29. As the amount of C19RM funding becomes more significant, and given the lessons learned to date, the Secretariat agrees that it is appropriate to modify the earlier approach. Employing the full TRP, GAC and Board approval model used for core grants would take the current 10-day turnaround on decisions to closer to 16-18 weeks, far too long for an emergency funding mechanism, and would create a significant amount of extra work for countries, partners, the Secretariat, and the Board. The current proposal

²⁶ In providing this information, countries should refer where appropriate to any COVID-19 Intra-action Reviews and the WHO COVID-19 Partners Platform.

²⁷ Under Global Fund internal policy, a program revision is considered material when: a. It contradicts the TRP's original or modified review and recommendation on the funding request; or b. There is a lack of agreement in the normative guidance, significant gaps in evidence to support a Program Revision, unexplained lack of impact, or difficult trade-offs in decision making, which therefore requires an independent technical review of the Program Revision request.

is therefore designed to strengthen the approach used in phase 1 of C19RM, leveraging existing review, decision-making and oversight mechanisms where appropriate, without overly compromising the speed and flexibility that makes C19RM so valuable to countries, or creating excessive workload.

- 30. **GAC and CTAG engagement in funding request review**: The Secretariat agrees with the Board that alignment with partners is absolutely critical to ensuring success in the global COVID-19 response. C19RM requests will therefore be shared for review by GAC partners as well as CTAG for input in parallel to the Secretariat's review. Introducing this step in the process would allow for partners to check that upfront guidance has been followed and provide comments on alignment with other partner investments (reinforcing input that should also have been provided at the funding request development stage). In order to mitigate the potential additional delay entailed by this step, the period for input will need to be limited (e.g. 72 hours), and partners will be provided with criteria to tailor their reviews. To facilitate transparency and information exchange, GAC and CTAG review of funding requests will leverage existing discussion boards through which feedback is visible to all partners. The Secretariat will consider input provided by GAC and CTAG in determining funding awards or recommendations.
- 31. The Secretariat will also provide enhanced reporting to partners through monthly GAC reviews of C19RM to discuss submissions and awards made, synergies and emerging thematic issues potentially impacting HTM programs, and any concerns and observations from GAC partners. CTAG partners will be invited to join these GAC reviews. This monthly GAC engagement will create an ongoing feedback loop to inform revisions to guidance and future decision-making, while keeping GAC discussions focused on strategic issues impacting the global portfolio rather than the minutiae of individual requests. This will also allow GAC partners to provide input in shaping the strategic priorities proposed by the Secretariat providing additional technical validation on scope, expected outcomes and outputs and ensuring responsiveness of proposed strategic priorities and actions to cross-cutting problems observed at country and regional levels.
- 32. **Board approval**: Board approval of funding is a core aspect of the Global Fund model and reinforces collective ownership of funding decisions made. However, requiring Board approval of every C19RM request would likely add a minimum of an additional two weeks for decision-making, even with a sharply curtailed decision window (e.g. 4 days). This would take the overall decision-making process for C19RM to more than a month, which would significantly undermine the speed and flexibility that has characterized the process and may impede the rapid release of funding to address urgent needs (such as for diagnostics, PPE, and therapeutics, including oxygen). Seeking and obtaining Board approval of all individual C19RM investments would also entail significant additional workload for the Secretariat and all Board constituencies; packages of funding requests, review outcomes and recommended decisions would need to be sent to the Board for approval on a rolling weekly basis during peak periods - this would be in addition to regular funding approvals that will continue to go to the Board for core grants as well as the various decision items presented to the Board in the ordinary course of business. This would also likely entail several rounds of C19RM approvals for the same programs if multiple top-ups are required to deploy incremental funding as it becomes available.
- 33. Balancing these various considerations, and reflecting feedback received from the Board, the Secretariat proposes the following approach:
 - a) Fast-track investments for COVID-19 commodities: Countries have urgent needs for COVID-19 commodities, and orders for these commodities must be

placed immediately to ensure swift delivery; even with immediate order placement, current lead-times could mean months before commodities arrive incountry. To address the most immediate needs as quickly as possible, the Secretariat recommends to award countries up to USD 900 million of C19RM funding on an accelerated basis to support urgent needs for COVID-19 commodities (including PPE, diagnostics, and therapeutics/oxygen) and costs relating to the effective deployment of such commodities. Latest phasing estimates from the ACT-Accelerator for required external assistance for procurement and demand-generation/in-country delivery for Q1 and Q2 of 2021 for the relevant components of the ACT-Accelerator investment case are: (i) USD 1.15 billion in therapeutics (of which USD 1.06 billion is therapeutics/oxygen procurement); (ii) USD 1.72 billion in diagnostics (of which USD 1.64 is diagnostics procurement); and (iii) USD 3.1 billion for the Health Systems Connector (of which USD 2.9 billion is PPE procurement). This adds up to USD 5.97 billion and is calculated after assuming 45% of total need is met from local resources. Setting a ceiling of USD 900 million for fast-track approvals for these commodities would ensure coverage of up to 15% of these estimates, which the Secretariat views as the minimum commitment to make in order to rapidly and meaningfully support these needs.

Awards under this provision will be made on the basis of a streamlined component of the C19RM funding request focused on COVID-19 commodities, which must be consistent with WHO guidance and developed in consultation with the national COVID-19 response coordinator to ensure consistency with the national strategic preparedness and response plan.²⁸ The Secretariat will share these requests for input with GAC and CTAG on an expedited timeframe, in parallel to the Secretariat's review. Awards under this provision will not require additional Board approval. An initial round of fast-track investment targeting COVID-19 commodities will minimize the delay in deploying critical, basic elements to countries for their COVID-19 responses. All awards made through this fast-track channel will be notified to the Board.

b) Board approval of investments over USD 35 million: Taking account of the potential impact on timelines and the additional burden on Board time and resources, and drawing on feedback and requests from the Board, the Secretariat recommends that the Board approve any subsequent C19RM awards exceeding USD 35 million. This amount will be measured in aggregate by country and will not include any funding awarded for COVID-19 commodities through fast-track investments described above, or C19RM funding awarded in 2020. Introducing a threshold will balance the considerations on time and resources with the need for Board oversight and approval, by targeting the Board's review towards higher value and higher risk investments. Based on rough projections, the Secretariat estimates that with a USD 35 million threshold, the Board will review and approve approximately two-thirds of C19RM funds (not including amounts awarded for COVID-19 commodities through the fast-track approach described above) for approximately 20 to 25 countries (primarily high impact and core portfolios). Countries will be authorized to place related commodity orders pending Board approval.²⁹ Awards under USD 35 million will be made by the Secretariat and will be notified to the Board. Where the Secretariat's review of awards under USD 35 million suggests that the non-commodity components of an award are of a nature and scale to raise significant concerns about risk and complexity, the Secretariat

²⁸ Awards may also be based on existing demand meeting the criteria under paragraph 33.a, subject to confirmation with relevant CCMs to ensure that the previously expressed needs remain current. ²⁹ If the Board does not approve the related funding recommendation, the Secretariat will seek to reroute these orders to other

countries. In the unlikely event this is not possible, the order will be charged to the country's C19RM allocation.

may also submit such components to the Board for approval. While approval authorities will be differentiated, the Board will have full oversight of all C19RM awards made (whether approved by the Board or by the Secretariat under its delegated authority) through detailed monthly reporting to be provided by the Secretariat, which will include funding requests and the details of any awards made (including specific interventions and amounts).

- c) Delegated authority to increase Board-approved investments up to USD 10 million: Incremental contributions or distribution of remaining funds may entail the need for repeated top-ups to grants. To avoid returning to the Board for multiple increases, the Board is requested to delegate limited authority to the Secretariat to increase Board-approved C19RM awards by up to USD 10 million. This authority will be limited to increases that scale-up interventions previously approved by the Board. This approach will balance speed and workload considerations while ensuring Board approval for material increases. Any increases made under this delegated authority will be notified to the Board.
- 34. Based on discussions with the Board, implementers, and partners, the Secretariat views the above approach as an appropriate balance between speed and additional consultation and review. It appropriately leverages the benefits of existing Global Fund review, decision-making, and oversight mechanisms, with modifications to bring timelines and workload to a more manageable level. However, the Secretariat emphasizes that the above approach can only deliver funding to countries swiftly if those involved in the review and decision-making process the Secretariat, partners, and the Board can collectively commit to meeting ambitious timelines for review and remain aligned on the common objective of delivering funding to countries most in need.

CCM Engagement:

- 35. As in the first phase of C19RM, the Secretariat will continue to require that C19RM funding requests are submitted by CCMs, with appropriate consultation and inclusive decision-making. The quality of CCM engagement was critical to the funding request process; countries with strong CCM engagement produced more robust requests that were able to move more quickly from request to investment. However, some tensions were observed between the development of "pure COVID-19" aspects of C19RM requests and the primary focus of CCMs on HTM and RSSH, as national preparedness and response plans are generally multi-sectoral, spanning beyond the remit of the three diseases.
- 36. CCM development of C19RM requests is key to ensuring a country-led determination of the combination of C19RM interventions that will best address rapidly evolving country contexts. As multi-sectoral, partnership bodies, CCMs have mechanisms and resources already in place and are well positioned to lead consultation processes on health issues. CCMs have pre-established links within the health sector, including directly with Ministries of Health (with senior representatives of the Ministry often functioning as chairs or vice-chairs of CCMs), that can facilitate alignment with the national COVID-19 response. To further reinforce this area, funding requests will require details on the link between C19RM requests and the national COVID-19 response plan, and CCMs must ensure coordination with the entity coordinating the national COVID-19 response during funding request development. CCM dialogue may also engage additional technical experts as needed to facilitate epidemiological integration and alignment between C19RM funding requests and national priorities. In the second phase of C19RM, guidance on engagement with relevant national COVID-19 response coordinators during funding request development will be strengthened to ensure greater alignment, and national COVID-19 response coordinators will be

requested to endorse pure COVID-19 components of C19RM requests. Where health systems investments contribute to future pandemic preparedness, CCMs will be requested to ensure appropriate involvement of relevant actors (e.g. IHR focal points) and alignment with relevant plans where available (e.g. the National Action Plan for Healthy Security). This engagement will strengthen country-level accountability and ensure more rigorous alignment with other domestic and donor funding. As discussed in further detail below in the section "Community engagement and community-led interventions", having CCMs develop C19RM funding requests is also a powerful tool to include civil society and communities into national COVID-19 response schemes, where national programming entities and national COVID-19 response structures may not have always been inclusive.

- 37. In addition to host government and civil society, partners in-country are represented on CCMs through multi/bilateral seats, where their input is solicited from the initial funding request preparation stage through sign-off on the content and strategic approaches in the final funding request submission. Partner engagement and coordination at country level in the development of national response plans and strategies, as well as C19RM and other funding channels is an essential ingredient for success.
- 38. The Secretariat acknowledges that CCMs will require additional support to ensure inclusive dialogue in the development of C19RM requests, and will provide this support through available sources of funding (including existing CCM resources and additional C19RM management and operating costs described in paragraph 59 below) to address the needs for expanded engagement, not only with national COVID-19 response coordinators but also civil society and communities.³⁰ The fast-track approach for investments in COVID-19 commodities and related costs will also allow CCMs to address urgent, immediate needs for their countries, while taking a longer period to engage in the fully inclusive dialogue necessary to develop the balance of their requests.
- 39. Support for CCMs will also be strengthened through the development of upfront technical guidance by the Secretariat and partners, which will significantly strengthen CCMs' abilities to develop robust C19RM requests. As discussed above and below, the Secretariat is also developing revised application materials that will guide CCMs more clearly on relevant areas of consideration.
- 40. The requirement for full CCM endorsement of the final submission, including by representatives of civil society and highly impacted communities, will continue in the next phase of C19RM. National COVID-19 response coordinators will also be requested to endorse pure COVID-19 aspects of C19RM requests. The first phase of C19RM saw 100% endorsement of funding requests by all CCM representatives (or in some cases alternate members). While this is a key milestone, ensuring broader constituencies both have up to date information and can input through their representatives is a key opportunity for the next phase. Deliberate resources are dedicated to this in CCM Evolution under the Engagement pillar including ensuring bi-directional information sharing before and after key decisions with constituencies and can be augmented by additional C19RM management and operating funds described below.

Community engagement and community-led interventions:

41. Community, rights and gender-related interventions are critical for countries' responses to COVID-19 and the three diseases. During the first phase of C19RM, approximately

³⁰ The Secretariat is currently assessing available sources of funds to provide immediate additional support to CCMs for C19RM funding request development. Details on the additional funds to be made available through C19RM management and operating costs, including to provide additional support for CCMs, will be presented to the AFC, as described in paragraph 61.

6% of total C19RM funding was awarded for such interventions. Examples included: social protection, including nutritional support and other livelihood packages for key and vulnerable populations and people living with/affected by the diseases; mental health support to beneficiaries, including through online and virtual platforms; intimate partner violence (IPV) / gender-based violence (GBV) response services, including awareness raising tools, helplines for IPV/GBV reporting/referrals, psychosocial support/mental health, and trauma services; PPE directed to key populations, volunteers, peer workers, civil society, and community-based or community-led providers; and adaptation of existing harm reduction, human rights, and AGYW programs. The Secretariat has broadly consulted civil society and communities to develop a guidance note, "Examples of CRG-related investments during COVID-19: summary of COVID-19 Guidance Notes and recommendations from Civil Society and Communities", which should support the development of future C19RM funding requests.

- 42. The Secretariat agrees that community engagement should be strengthened at both the funding request and implementation stages for the next phase of C19RM. While some quality community, rights and gender interventions were successfully funded in the first phase of C19RM, there were challenges in ensuring the meaningful engagement of civil society and community representatives on CCMs during the process of developing funding requests, and in many countries' responses to the needs of key and vulnerable populations, the surge in GBV, and the increase in human rights violations, were not prioritized. The Secretariat requests the Board to underline to countries the importance of effective community engagement in C19RM requests and implementation and to call on partners for their support in making this happen. Effective community and civil society engagement remains crucial to ensuring appropriate mitigation of the risks to HTM programs posed by COVID-19, and is equally critical to developing robust responses to the pandemic itself - as these stakeholders can leverage their extensive experience in the fight against HTM to support the response to COVID-19 (both for purposes of C19RM and national responses more broadly), not only through contributing to funding request development, but also through implementation, oversight, and monitoring of C19RM investments.
- 43. CCMs may need to expand engagement of communities to include not only communities impacted by HTM, but also those communities most severely affected by COVID-19. The Secretariat will work closely with partners to identify and engage with such stakeholders, who may fall outside of existing civil society and community CCM representation and may leverage the additional C19RM management and operating funds to provide additional support to CCMs for effective engagement in this area. The Secretariat is also reflecting on implementation, monitoring and oversight arrangements and financing mechanisms that would facilitate access to funding for those best placed to implement relevant activities, in both HTM programs and the broader COVID-19 response.³¹
- 44. The Secretariat will reiterate guidance on the requirement for meaningful engagement in the launch of the next phase of C19RM. The Secretariat will also work with partners to encourage and support the inclusion of community-led interventions in C19RM funding requests, including both HTM adaptations and COVID-19 responses, consistent with national preparedness and response plans, and utilizing the above-noted guidance prepared in consultation with civil society and community partners. The Secretariat also recommends that updated technical guidance, to be developed with civil society and technical partners, must emphasize the importance of better-quality requests relating to communities/civil society, ensure alignment with disease and RSSH catch-up plans, and reiterate the critical role of communities and civil society in the response to COVID-

³¹ See section 10 of Annex 4 for more considerations on implementation arrangements.

19. Updated guidance should more effectively guide CRG regional platforms, CCMs and civil society and community constituencies in their consideration of CRG issues during funding request development, acknowledging that community engagement and inclusion of community-led interventions are critical to mitigating the impact of COVID-19 on the communities served by the Global Fund, and country responses to COVID-19 more broadly. This additional guidance will include, but will not be limited to, (i) evidence of the impact of COVID-19 on key and vulnerable populations for HTM as well as communities most impacted by COVID-19 (and on gender and human rights barriers and GBV) to help such communities to have a stronger voice during the prioritization of interventions discussions – focused on ensuring the inclusion of appropriate community-centric interventions and (ii) a list of concrete examples of CRG-related activities to respond to the impact of COVID-19 (informal CRG guidance already exists, but will be further developed and converted into clearer and more actionable guidance).

- 45. Modified C19RM application materials will also seek to facilitate CCM deliberations and civil society engagement, by soliciting additional information both on how COVID-19 is affecting and impacting key and vulnerable populations and programs (including on populations most severely impacted by COVID-19), and on the role civil society is playing in each country's overall COVID-19 response. To help CCMs during prioritization discussions, CCMs will be requested to assess HTM service disruptions, including disruptions to services for key and vulnerable populations, and elaborate on how identified gaps, challenges and needs are being addressed (within the C19RM request or through other sources of funding including grant funds). CCMs will also be asked to consider whether there are opportunities to reinforce the role and effectiveness of civil society organizations in the national COVID-19 response, including through supporting the most vulnerable communities, community tracing, supported isolation, and addressing vaccine hesitancy. In supporting community-led engagement in the broader COVID-19 response, the Global Fund will work closely with key partners, including Gavi, UNICEF and WHO.
- 46. To help address these challenges, the Secretariat will provide support through available resources and flexibilities to support (financially or otherwise) civil society and community engagement and constituency discussions. Support may be funded through CCM funding (including the CCM Evolution strategic initiative), additional C19RM management and operating funds where relating to CCMs, and a portion of the centrally managed C19RM funds for broader CRG areas, e.g. community-led monitoring. The Secretariat will continue to engage at country-level to reinforce these principles, including by leveraging existing initiatives (e.g. the CRG strategic initiative) to strengthen and support community engagement.

Timelines for use:

47. In the first phase of C19RM, funds were deployed flexibly across the 5th and 6th replenishment periods, but were required to be used by 30 June 2021. Establishing a separate cut-off date for fund utilization independent of the implementation period end dates of underlying grants has resulted in extra costs for financial reporting and reconciliation, while proving to have questionable added value, as the urgency of the needs in-country are naturally propelling countries to implement interventions as quickly as possible. The introduction of a separate deadline requires ringfencing of funding, segregated budgeting, additional verification and evaluation by both implementers and LFAs, and introduces complexity for both implementers (especially where a combination of both C19RM funding and grant funding is used for interventions) and the Secretariat, whose internal controls and systems are organized around core grants. The additional level of effort required to separately monitor and enforce an independent deadline is felt most acutely by in-country implementers, who are already under strain

with the demands of launching implementation under new grants in addition to incorporating C19RM interventions into their programs.

48. At the same time, as noted by the OIG, some countries face risks of completion delays due to the tight timeframe for implementation, leaving little room to manage uncontrollable circumstances; even where orders have been placed with expected delivery before 30 June 2021, volatility in the global supply chain due to COVID-19 may mean that some deliveries may arrive after this date. Strict adherence to the 30 June 2021 deadline is making some countries hesitant to launch critical interventions, for fear that unexpected delays may push out the completion date by as little as a few weeks. While C19RM funds are expected to be used quickly over the course of 2021 and 2022 for emergency diagnosis, treatment, PPE and HTM mitigation needs, the Secretariat recommends to set 31 December 2023 as the final deadline for use of all C19RM funds. including any funds received to date, to align with the implementation period end date of the 6th grant cycle for most of the HTM portfolio. This proposal is not intended to contradict the emergency nature of C19RM, nor encourage use of funding over this entire period, but instead reflects consideration of the significant cost and effort associated with monitoring and enforcing a funding use deadline that is separate from the framework governing core grants. This approach will reduce the costs associated with an independent cut-off, and will provide more flexibility for implementers to complete activities. This deadline will also more appropriately reflect the potentially significant amount of additional funding, possible longer-term investments in HSS and CSS, and the reality that the impact of COVID-19 will continue well into 2022.

Reporting and Impact:

- 49. The Secretariat remains fully committed to transparent and frequent reporting on C19RM investments and will continue to report regularly to the Board and on the Global Fund website on C19RM awards. The Secretariat will provide detailed monthly reporting to the Board on C19RM, which will set out cumulative awards (whether approved by the Board or by the Secretariat through delegated authority) categorized by country, regional, and global level, and will continue to be grouped by priority area - (i) reinforcement of national COVID-19 responses, (ii) risk mitigation activities for HIV, TB and malaria, and (iii) urgent improvement to health and community systems - but will provide disaggregated data on the types of investments e.g. investments in diagnostics (with disaggregation of Antigen RDTs), PPE, Oxygen support, therapeutics, communityled support; GBV/IPV; human rights, RSSH investments, as well as updates on funding requests pipeline, top-ups awarded, and details on unfunded demand. Reporting will also append award notifications issued to countries (which will detail approved interventions and related amounts) as well as the national plans and funding requests on which awards were based. Since Global Fund investments are fully aligned with the ACT-Accelerator priorities and the ten COVID-19 Strategic Preparedness and Response Plan pillars, the Secretariat will seek to align reporting to enable transparency and coordination across partners. The Secretariat will also highlight emerging themes and issues from C19RM to the Board, either through the detailed monthly reporting or through the informal Board calls on COVID-19. The Secretariat will also share detailed data on investments, award notifications, and funding requests on the Global Fund external website to further enhance transparency.
- 50. At the implementation stage, to assess the contribution of Global Fund investments through C19RM, the Secretariat will use a comprehensive monitoring, evaluation and results reporting approach including qualitative and quantitative measures covering a range of input (e.g. budgets allocated, expenditure on commodities and community-led support), process/output (e.g. number of people tested for COVID-19 and stock availability of tracer HTM and COVID-19 commodities) and outcome/impact data (e.g.

grant performance on programmatic results, performance on KPIs 1 and 2, COVID-19 cases averted, COVID-19 case fatality rate and COVID-19 deaths averted). This will enable reporting on, for example, the capacity of countries to test for COVID-19, to protect front line health and other essential workers with PPE, to provide treatment that can reduce deaths from COVID-19, and to mitigate the impact on HTM programs. The monitoring and evaluation approach for C19RM will focus on measuring the impact of COVID-19 on disruptions to HTM services and health systems and will ensure that the intended outcomes of C19RM funding are clear.

- 51. The primary impact measure of these investments will remain whether countries are able to achieve their grant targets for the 2020-2022 allocation period and for the overall 2017-2022 Strategy period, despite HTM service disruptions from COVID-19. This is measured through current grant targets that largely maintain pre-COVID-19 levels of ambition. This metric is readily available and provides a direct performance indicator on whether C19RM is able to operate effectively and at a scale sufficient to ameliorate the impact of the pandemic on the Global Fund mission.
- 52. Measuring the direct impact of C19RM on the COVID-19 pandemic through cases and deaths is also essential but presents different challenges from measuring the Global Fund's impact through KPIs. For HIV, TB and malaria KPIs, the Global Fund relies on costed and prioritized technical plans based on models that estimate the expected impact on incidence and mortality if specific interventions are implemented at scale with an estimated amount of available funds. None of these factors are currently present for the COVID-19 response. Furthermore, COVID-19 incidence and deaths to date are not only linked to public health interventions but to the political response of governments, the age structure of and co-morbidity within populations, and have proven highly variable over time. Potential vaccine scale-up, the further spread of more transmissible and lethal variants, and potential new treatments all complicate measurement of the impact of specific funding over time, as does the lack of widespread availability of diagnostic tests, which limits our understanding of even the most basic metric of the number of COVID-19 cases in a country. Therefore, transparent reporting on Global Fund-supported COVID-19 inputs such as the scale-up of diagnostics, PPE, and treatment (and other response pillars) and relevant outputs and outcomes measured at the country level are the most appropriate proxy measures for impact at this time.
- 53. The Secretariat will also consult and engage with the Technical Evaluation Reference Group (TERG) to develop an appropriately flexible and timely approach to evaluating the impact of C19RM investments in the longer-term. This approach will be presented to the SC at its 16th meeting (July 2021). The costs associated with enhanced reporting, monitoring, and evaluation, including TERG support, will be financed through the management, operational and assurance funds noted below.
- 54. In addition, the Secretariat is collecting substantial additional data to help understand the impact of COVID-19 and urgent C19RM needs. The Secretariat is undertaking frequent data collection on a small set of indicators to assess service disruption and undertaking quarterly spot checks to verify service availability at health facilities. Qualitative data on program disruption and adaptations/mitigation actions will also be considered. Data will be drawn from various available sources, including grant financial and programmatic reporting, LFA COVID-19 surveys, the Global Fund COVID-19 Indicator Survey, Global Fund spot checks, and WHO and other partner and country reports (e.g. early guidance from ACT-Accelerator and GAC partners). The Secretariat will leverage and support the strengthening of in-country data systems to enhance available data (for example, the Global Fund is also supporting updating HMIS for COVID-19 surveillance (e.g. DHIS2 or other COVID-19 modules) in many countries). CLM data, which already contributes to reporting and monitoring of performance under

core grants, will complement data from PR reporting and LFA surveys wherever CLM mechanisms are already in place. In addition, for countries which have included investments in CLM in their C19RM funding request, the Secretariat will support scalingup of CLM in coordination with civil society and technical partners such as Stop TB Partnership and UNAIDS.

- 55. C19RM investments are incorporated into regular grants and follow the semi-annual and annual reporting cycles of Global Fund grants. The financial performance of C19RM will be captured in the upcoming Progress Update and Disbursement Requests (PUDRs) due in April 2021 and in Q3 of 2021. The integration of C19RM investments into grants also facilitates semi-annual review of overall grant performance, which includes C19RM interventions. Upcoming PUDRs will also provide programmatic results against targets for HTM indicators in core grants.
- 56. The Secretariat will also seek to further align reporting with key partners and report on the contingent funding pipeline in order to provide visibility to the Board and to facilitate resource mobilization efforts. Reporting will continue to be updated regularly on the Global Fund COVID-19 website³². Specific reporting will also continue to be provided to the Board and its Committees through regular governance reporting mechanisms. As before, in-country expenditure reporting will be integrated into regular grant reporting and provided to the Board and AFC as part of the Financial Performance oversight.

Central management of limited investments:

- 57. The Secretariat anticipates that there may be some targeted needs relating to the global response to COVID-19 that cannot be addressed through country-submitted requests, but that are necessary to ensure the success of country-level C19RM investments. Some examples of such needs include: support to accelerate the introduction of new products (including through pre-gualification) and innovations; support for engagement of those most impacted by and vulnerable to COVID-19 in the development and implementation of C19RM interventions; support for global coordination on communityled monitoring (including for reporting on human rights violations and GBV and to address quantitative and qualitative data gaps on HTM service); support for community engagement; and support for global and regional platforms coordinating the COVID-19 response, where expertise is new and evolving, and where in-country capacity is limited. The Secretariat recommends that up to 2.5% of any C19RM funds be available for these targeted investments, which will be centrally managed by the Secretariat. This funding is separate and distinct from the catalytic funding under existing Strategic Initiatives, although the Secretariat will ensure that there is no duplication or misalignment with existing Strategic Initiatives. The Secretariat may consider using existing Strategic Initiative agreements or implementation platforms to deploy C19RM funding (for example, using the existing CRG SI platform to further support community engagement), but only where doing so would result in clear efficiencies and savings.
- 58. The Secretariat is still developing the design and decision-making process for these investments, but the process will be aligned with, and fully informed by, cross-cutting gaps in investments at country level, as ultimately these centrally managed investments will only be made where necessary to support needs and foundational areas necessary to ensure the success of country C19RM investments. In line with the approach to C19RM funding for countries, the Secretariat will consult GAC and CTAG on any centrally managed investments, which will provide additional technical validation on scope, expected outcomes and outputs and ensure responsiveness of proposed strategic priorities and actions to cross-cutting problems observed at country and

³² <u>https://www.theglobalfund.org/en/covid-19/</u>

regional levels. Any potential or actual conflicts of interest will be managed appropriately. The Secretariat will provide regular reporting on any investments made under this provision to the Board through its relevant Committees

Management and operational costs:

- 59. As the amount of C19RM funding increases significantly, additional costs will be required to ensure adequate support from the Secretariat, robust assurance, rigorous monitoring and evaluation, and reinforced reporting on C19RM investments. Given that C19RM is a temporary urgent response mechanism that will not be a permanent part of the Global Fund operating model, the Secretariat proposes to cover incremental management and operating costs through any additional funds made available for C19RM. These resources will be managed separately from the annual Secretariat OPEX budget and will be fully time-bound, reflecting the temporary nature of C19RM; no increase to OPEX recurring costs is therefore foreseen.
- 60. As an indication, the Secretariat expects that management and operational costs associated with additional C19RM funding will be up to 3% of any additional funding. Additional management and operational costs are envisaged for four main areas: (i) strengthening internal Secretariat resources and expertise; (ii) increased costs relating to the provision of assurance over C19RM funding; (iii) costs associated with enhanced monitoring, evaluation, and reporting on C19RM investments; and (iv) additional support for CCMs. For internal Secretariat resources, the Secretariat anticipates that additional resources will be required primarily to: strengthen internal technical expertise; enhance engagement and coordination with partners (both in the HTM space for scaleup in HTM mitigation responses and through ACT-Accelerator for the pure COVID-19 interventions covered under C19RM); strengthen monitoring, evaluation, and reporting; and support the increased workload associated with operationalizing C19RM (covering a range of elements such as supporting the submission and review of funding requests, tracking awards and overall resources, executing changes required to existing internal systems and controls, supporting increased sourcing activity. overseeing implementation and assurance, supporting additional monitoring and evaluation activities, and preparing enhanced reporting). An internal needs assessment is ongoing. Any additional staff will be contracted on defined duration contracts aligned to the temporary duration of C19RM funding. Additional external costs are also envisaged for assurance, including for LFA services, which need to be enhanced and expanded to cover C19RM funding in light of increased risk of fraud or misappropriation as the amount of funding increases. Section 11 of Annex 4 provides additional detail on strengthened assurance over implementation of C19RM funding, as well as for the development and execution of a monitoring and evaluation approach for C19RM, which may entail additional TERG costs. Finally, as described in previous sections, the Secretariat expects that additional funding for CCMs may be required to further support inclusive country dialogue and expanded engagement with additional stakeholders.
- 61. The Secretariat will seek AFC input on a framework for C19RM management and operational expenditures under this provision and will provide regular reporting on these expenditures to the AFC and the Board, which will enable the AFC and the Board to maintain oversight over these expenditures. The AFC will also provide the Board with regular updates on its review of C19RM management and operating expenditures to facilitate overall Board oversight. Reporting granularity will be aligned with regular OPEX (e.g. by nature and by function) and will be integrated into the regular Financial Performance Updates.

Further modifications:

62. The Board will monitor C19RM on an ongoing basis to determine whether any changes are required as the pandemic continues to evolve. Should further modifications of C19RM be required due to changes in global circumstances and as the pandemic continues to evolve, the Secretariat will seek further guidance and steer from the Board (and its committees, as relevant).

Extending the Limited Exceptions to Quality Assurance Policies:

- 63. Rapidly changing national responses to COVID-19, such as border closures on short notice and restricted access to work sites, continue to pose risks to timely implementation of pre-shipment inspection and sampling requirements for key products in line with Global Fund quality assurance policies. It is anticipated that disruptions related to COVID-19 may once again risk health product supplies as Global Fund-supported countries enter their second, in some cases more severe, waves of COVID-19 infections. Therefore, the Secretariat recommends to extend the flexibility to grant limited exceptions to Global Fund quality assurance policies pre-shipment and inspection requirements, where delays in shipments would result in negative program impact that cannot be mitigated through other means. Extending this flexibility through 31 March 2022 will help mitigate disruptions in the supply of life-saving health products in Global Fund-supported countries.³³
- 64. As noted in GF/B43/ER11, the Secretariat has established a cross-functional Health Product Risk Committee (HPRC) to review individual requests for exceptions and consider associated risks from diverse perspectives across the Secretariat. Requests to waive these requirements is possible for three categories of health products (i.e. Expert Review Panel-approved products, vector control products, and condoms) in specific circumstances. As before, waivers will only be considered where (i) sampling and quality control (QC) testing may not be physically possible due to the unavailability of sampling or QC testing services due to COVID-19 (e.g. closing of borders preventing timely access by inspectors), and (ii) where a delay would result in negative program impact that cannot be mitigated (e.g. missing an insecticidal net distribution campaign, or a prolonged stock-out of lifesaving drugs).
- 65. Inspection and testing services continue to adapt to COVID-related challenges, and the HPRC has not reviewed or recommended any additional waivers since September 2020.³⁴ It is possible that no additional waiver requests will be received. However, permitting the Secretariat to retain this flexibility to consider individual waiver requests (where strict compliance with the requirement could risk delaying the timely arrival of quality-assured life-saving health products), can permit a rapid, balanced response in specific instances to minimize supply disruptions (e.g. permitting the authorization of shipment in parallel to testing).

What are the risks and proposed mitigations?

66. Many of the C19RM-related risks described in detail in GF/B43/ER11 continue to exist. The most significant risk remains the lack of external funding needed by countries to deliver their COVID-19 responses. This also increases the risk that domestic resources are diverted away from other priorities, including HTM programming. Continued external support for countries through mechanisms like C19RM is vital to

³³ This flexibility was originally approved under GF/B42/EDP10 and subsequently extended through GF/B43/EDP12.

³⁴ To date the Global Fund has received 19 requests to waive QA policies' pre-shipment inspection and testing requirements; 12 waivers for 7 countries for ERP-approved medicines for tuberculosis and for vector control products (LLINs and IRS) have been granted, and 7 waivers were not granted. For the 12 waivers that were granted, all products were held upon arrival until the results of the pre-shipment sampling and testing were known; no non-compliance issues were detected in these cases. As noted in GF/B44/ER11, waivers were approved based on critical programmatic needs and limited out-of-specification concerns from historical testing results, and shipments were authorized ahead of receipt of test results.

mitigating this risk. This requires sustained resource mobilization, which in turn requires the Global Fund to continue demonstrating that C19RM represents a fast, effective and flexible deployment mechanism. At the same time, maintaining C19RM as a separate funding pool, as well as continuing to invest unspent core replenishment funds through portfolio optimization, represent important safeguards to the Global Fund's core mission.

- 67. As available funds increase, and given the urgency of the need for resources, the Global Fund must continue to be flexible and adapt to ensure there are no delays or long lead times in the deployment of C19RM resources. To mitigate this risk, existing flexibilities need to be maintained and additional ones need to be introduced to strengthen the end-to-end process and ensure rapid deployment of resources. Key improvements that need to be made include improved guidance for CCMs and PRs, split window submission for critical gaps while countries develop detailed funding submissions, maintaining speed and agility in funding request review and approval, and streamlining Secretarial internal processes for grant revisions.
- 68. Providing funding in a rapidly changing landscape with diverse players is inherently challenging. COVID-19 represents an emergency context where the underlying epidemiological situation and the resulting needs on the ground are often shifting from day to day. Though C19RM interventions will be aligned to national preparedness and response plans, these plans are likely to evolve rapidly. Strong coordination is needed to avoid duplication or misalignment between C19RM investments and other aspects of the national response (including other partner investments). To mitigate this risk the Global Fund needs to better capitalize on the presence of representatives from Ministries of Health and technical and bilateral partners on CCMs to ensure complementarity with national strategies. Strong and regular CCM and partner engagement and clearer upfront investment guidance will also contribute to managing this risk.
- 69. In most cases, the Global Fund will be using its existing implementers to implement C19RM investments. These implementers were originally selected in the context of HTM, which creates a risk that implementation arrangements are sub-optimal in the context of the national COVID response and program adaptations. This has been deemed acceptable because in an emergency context the benefits associated with using existing PRs outweigh the risk, including speed of execution, and better oversight. Existing PRs (governments and CSOs) are also well versed with Global Fund policies and reporting mechanisms and are covered by existing assurance mechanisms. In addition, the Global Fund also invests in areas that link to the COVID-19 response, including lab strengthening, supply operations, and work with communities. Existing PRs, therefore, have very relevant experience that can be leveraged.
- 70. The risk of fraud, in particular procurement-related fraud, and misuse of funds has increased substantially. This is due to changes in the operating environment attributable to the global crisis and is not limited to C19RM investments. This is being partially mitigated through applying the same assurance framework as standard Global Fund grants (leveraging existing controls and arrangements) and continued provision of detailed guidelines for COVID-19-related assurance activities for Country Teams and assurance providers (e.g. LFAs and fiscal agents). The Secretariat is also mitigating risk by continuing with proactive PPM-led procurements. Section 12 of Annex 4 provides additional detail on procurement arrangements and diversion of COVID-19 products, especially PPE and diagnostics. The Secretariat has strengthened assurance over downstream arrangements with the support of LFAs and detailed assurance reviews are underway in a set of prioritized countries. The Secretariat will continue to

enhance and tailor assurance arrangements based on proposed interventions, with continuous adaptations and adjustments over the course of implementation. Additional investment in assurance activities, including from the above noted management costs, is planned to further strengthen these arrangements and the Secretariat is currently detailing an enhanced end-to-end risk and assurance framework for C19RM, focusing in particular on in-country assurance. Furthermore, the mitigating actions described in detail in GF/B43/ER11 continue to be in place, including the requirement that implementers address mismanagement of waste through infection control, contracting and leveraging private sector capabilities and active assessment of the potential for tools to support commodity tracking.

- 71. Finally, there is a risk of under-absorption of either 6th replenishment or C19RM funds. Based on the successful 6th replenishment, the allocations for many countries have significantly increased, requiring ambitious scale-up plans. This raises the question of whether countries will be able to absorb additional funding on top of core grants during a time of severe disruption. However, the risk of under-absorption would be significantly higher without C19RM, which is essential to reducing COVID-19-related disruptions and service interruption. C19RM investments bolster the ability of Global Fund countries to adapt their programs, spend and deliver results under their 6th replenishment grants. In addition, C19RM awards will take account of ability to absorb additional funding. The Secretariat will continue to monitor in-country absorption, and will also provide CCMs with additional support to build their oversight capacity to ensure funds are used in a timely manner and for the purposes intended.
- 72. These risks in combination emphasize the need for maintaining flexibilities in allocation (to rapidly respond to the volatile environment), ensuring agile decision making and speed of deployment, and providing for flexibilities during the course of implementation to enable programs to continuously adapt to the evolving landscape.

Why is this the recommended option?

- 73. The Secretariat considered several options around the timing of this decision and the proposed refinements of C19RM in the next phase, as well as feedback from the Board, and believes the proposal described above will provide a balance between assurance, speed, and efficiency. The proposed refinements will further strengthen partner engagement at both the country and global levels, provide for enhanced Board oversight of C19RM, and allow for continued flexibility to respond rapidly to changing circumstances as the pandemic evolves.
- 74. Acknowledging the challenges inherent in discussing hypothetical funding scenarios, the Secretariat considered waiting for the confirmation of any additional pledges before seeking an extension of C19RM. However this was ultimately rejected for two reasons: first, the need to be in a position to immediately deploy funding to address the urgent gaps in Global Fund-supported countries at a time when the increased transmissibility of new variants, pace of vaccine deployment and gaps in essential supplies (e.g. PPE, diagnostics and oxygen) to address the pandemic could result in a significant upsurge in cases and deaths. Second, waiting could also hinder resource mobilization efforts as potential donors would have to consider making contributions to a lapsed mechanism, which would also translate into subsequent delays in implementation of any new funds at the country-level. By seeking approval now, before additional pledges are received, the Secretariat will be able to move quickly to address critical time-sensitive gaps as soon as pledges are confirmed as available.

75. The Secretariat also assessed several options in considering possible refinements to the existing C19RM model, including replicating the current process for core country allocations, but concluded that following the same process for C19RM would result in substantial delays in the award and implementation of funds at the country-level. The Secretariat considered various degrees in which partners – both technical and community-level – and the TRP could be leveraged in the design and review process and has reflected Board input into its revised proposal; the Secretariat's revised recommendation leverages the expertise and weight of the global partnership while maintaining the ability to fund countries as quickly as possible for an emergency response.

What do we need to do next to progress?

What is required to progress the proposal?

76. The Board is requested to approve the proposed decision point on page 2. Board approval is required to ensure that additional pledges/contributions received in 2021 will be effectively and efficiently invested through C19RM, with the ultimate objective of safeguarding the fight against the three diseases. This approval will facilitate the confirmation of potential additional pledges from donors who wish to provide additional support for country responses to COVID-19. Board approval is also required to extend the timeframe for the award of any additional C19RM funds through March 2022 and allow for countries to utilize any C19RM funds by 31 December 2023. By extending the limited QA policy exceptions through March 2022, the Global Fund will be able help mitigate potential program disruptions due to disruptions in the supply of health products due to COVID-19.

What will the Board/Committees have to do next?

- 77. The Committees and the Board will continue to receive periodic reports through regular governance check points and/or informal updates. The Secretariat will continue to publish bi-weekly COVID-19 Situation Reports. The Board will be made aware of any additional pledges made and the AFC will be requested to approve the availability of any additional funds for investment, in line with its mandate and relevant Board policy.³⁵
- 78. At its 15th Meeting (March 2021), the Strategy Committee will be requested to review and recommend to the Board an extension of the timeline for including COVID-19 products in the wambo.org pilot for non-grant financed orders, as the current timeline will expire on 1 June 2021.

What would be the impact of delaying or rejecting the decision to progress?

79. If the Board decides not to approve the decision point, the immediate investment of any new pledges³⁶ to support country responses to COVID-19 will not be possible, which could lead to a potential gap in support for countries and threaten HTM programs. Within the current global context, deploying funding as quickly as possible is crucial. Delaying or rejecting the decision may also be seen by donors and partners as the Global Fund withdrawing from its role in the global COVID-19 response, which may undermine confidence in the organization and impact how the Global Fund is positioned for the 7th replenishment. As many Global Fund-supported countries enter their second or third

³⁵ In accordance with the <u>Amended and Restated Comprehensive Funding Policy (GF/B36/DP04)</u>.

³⁶ Approved as available by the AFC.

wave of COVID-19 infections, it is anticipated that disruptions may go back to levels previously seen in Q2/Q3 of 2020, which could result in disruption to the availability of health products in-country. By not extending the current limited exceptions to the QA policies' pre-shipment inspection and testing requirements, health products may not arrive in a timely manner, which may negatively impact the health of people in Global Fund-supported countries.

Recommendation

The Secretariat recommends the Decision Point presented on page 2 to the Board for approval.

Annexes

The following items can be found in Annex:

- Annex 1: Office of the Inspector General (OIG) Statement
- Annex 2: Lessons Learned
- Annex 3: Overview of C19RM process from funding request development to award
- Annex 4: Secretariat Responses to Questions From the Board, AFC, and SC
- Annex 5: Relevant Past Decisions
- Annex 6: Links to Relevant Past Documents & Reference Materials

Annex 1 – Office of the Inspector General (OIG) Statement

The OIG has shared its initial findings with the Secretariat. While the report is still undergoing its final checks in line with its Stakeholder Engagement Model, the IG has exceptionally sanctioned that these initial findings can be shared with the Board to support its decision making on GF/B44/EDP18.

The OIG's review focused on two main areas: the design and effectiveness of application process including governance and decision-making over C19RM resources, and the mechanisms in place to ensure that funding requests were processed promptly and that funds were made available at the country level in a timely manner. The review did not cover grant flexibilities and or the implementation of C19RM activities in countries as this was not possible in the timeframe. Due to COVID-19 travel restrictions, all fieldwork was performed remotely.

The OIG's initial findings reveal that, in comparison with seven peer organizations and agencies (including the World Bank, GAVI and the development banks), the Global Fund's C19RM was one of the last funding mechanisms in the cohort to be approved and publicly announced, but it has one of the highest conversion rates in terms of approving funds.

In terms of process, the OIG found a robust, consultative and inclusive process was put in place very quickly to support countries by timely approval of funding requests. Clearly linked to the Global Fund's strategic objectives, this mechanism was rigorously developed and was designed to provide timely response to support countries in their fight against the pandemic. The OIG's analysis showed that overall, while funding request submissions registered some delays, the Secretariat reviewed and approved Funding Requests promptly. These requests were materially compliant with relevant policy requirements and funding was made available promptly after approval.

In terms of further improvements for any future version of the C19 Response Mechanism, the OIG found that the following enhancements would further increase the effectiveness of the C19RM:

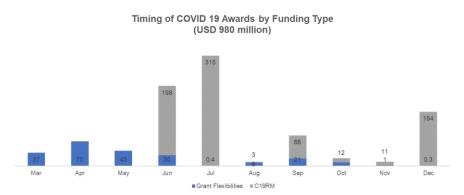
- Ongoing agility for evolving disease and data needed: The allocation methodology ensured a fast-tracked initial allocation of funds available, aligned with the organizational strategic objectives. However, the current model generated significant variations in the "per Covid case allocation" between different countries, which becomes more relevant if "pure" investments towards national Covid response increase. As this is a fast-evolving pandemic, disease trends, data availability and reliability, and fund utilization have evolved since the initial allocation, and it will be important to ensure that the model is responsive going forward.
- While activities have been initiated and are progressing in most countries, there are
 risks of completion delays, given the tight implementation period. There is a need to
 speed up the end to end procurement processes of health commodities (initial
 submission of order by PRs to final receipt of product in country) and the overall
 implementation, and to ensure sufficient visibility at the country level to proactively
 tackle operational challenges.
- Need for evolving the measurement of outcomes and impact of C19RM: While difficult to measure and attribute, there is a growing need to measure the results achieved by C19RM, especially if funding increases over time.

Annex 2 – Lessons Learned

Initial lessons learned from the first months of C19RM implementation were outlined in GF/B43/ER11³⁷. These lessons were related to: (i) the importance of having grant flexibilities and C19RM as two distinct mechanisms, which allowed countries to swiftly unlock smaller sums of money while developing their C19RM funding requests; (ii) a slower but effective conversion of C19RM funding requests into approval; (iii) challenges with ensuring meaningful engagement of civil society and communities in the development of C19RM funding requests; (iv) challenges regarding the focus on gender-based violence and human rights programs in C19RM funding requests due to the dynamic nature of the pandemic that affected countries' perception of their needs; and (v) opportunities for streamlining the Global Fund's operational processes to minimize transaction costs and to configure more optimal procurements channels.

Further lessons learned are described below and these have informed the proposed refinements to the C19RM model as outlined in this paper.

- 1. C19RM was able to rapidly deploy funds to countries, with demonstrated value in ensuring speed and agility of the approval process.
 - a. Access to immediate funds through the introduction of Grant Flexibilities (i.e. use of grant savings and/or reprogramming) in early March 2020, with an extremely rapid decision-making process, followed by the launch of C19RM, demonstrated a high degree of complementarity when responding to country needs. While the setup phase of C19RM was slower than anticipated, review and approval of C19RM funding requests was swift. During the current phase of C19RM, the slow uptake was mitigated by the immediate availability of grant flexibilities illustrating the need for refinements to continue the flexibility to award some portion of the new funding immediately, so as to be able to address urgent needs and immediate requirements for consumables, such as diagnostics and PPE.



C19RM was established by the Board in April 2020, and within two months of receiving the first request on 20 May 2020, USD 513 million of C19RM funding was approved, demonstrating effectiveness at rapidly deploying funding once CCM requests were submitted. Out of the 98 notification letters on approved C19RM funding, 77 were sent to countries within 10 business days from the date of receipt of the completed application (78% KPI achievement) and a total of 90 (92%) were sent within 11 business days.

³⁷ GF/B43/ER11 - Extension of C19RM Timeline and Operational Flexibility for COVID-19

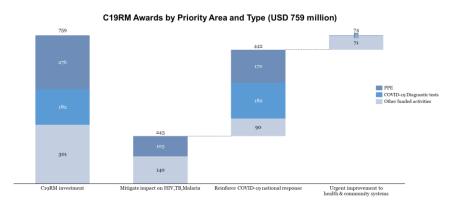
b. The allocation methodology used was fit for purpose but there is an opportunity for further refinement. The methodology enabled support to countries with the most strategic risks to the Global Fund mission - including countries with the highest HIV, tuberculosis and malaria disease burdens and the highest Global Fund allocations. However, with the rapidly evolving epidemiological context, new science and technologies coming on the market, dynamics in the COVID-19 investment landscape - experience quickly showed the need for adjustments to total awards to be systematically considered in order to account for factors such as, impact on vulnerable populations as compared to the country's disease allocation, upsurge in the COVID-19 epidemic, and risks posed by high COVID-19 burden in bordering countries with significant cross-border migration. For example, in Peru, an upward adjustment was exceptionally approved due to contextual considerations, noting that at the time of the award, Peru had the third highest number of COVID-19 cases in Latin America, and had recorded one of the highest COVID-19-related mortality rates in the world, and the overall situation was negatively impacting HIV and TB service delivery. With the Global Fund being the only major donor supporting the response to HIV and TB in Peru, there was an opportunity to invest in urgent needs to alleviate the pressure on the health system and mitigate the impact of COVID-19 on HIV and TB programs.

Lessons from the current phase also indicate that addressing the rapidly changing pandemic while maintaining the focus on the HTM strategic risks will require more systematic consideration of COVID-19 burden data and its implications for programmatic disruption at the award stage. For example, Bhutan was another country that received an upward adjustment to their allocation amount (C19RM and grant flexibilities combined) due to a strong programmatic rationale and technical merit. Assessment showed that COVID-19 related restrictions likely contributed to delays in conducting malaria case investigation and rapid response leading to the country experiencing the malaria outbreak during summer 2020 that hampered the goal to achieve zero indigenous cases by 2020. At the same time, the country was at a high-risk of cross-border epidemic transmission due to high rates of migration from India who was experiencing a spike in COVID-19 cases. With C19RM funding, there was an opportunity to mitigate the potential detrimental impact on the disruption of disease programs and sustain gains.

2. Funding request tools did not allow for the systematic collection of information for grant revisions and granular data for more robust reporting.

a. In an effort to move fast and keep requirements minimal, some design choices made in the C19RM funding request template later required additional tools to gather information on awards including on the split of investments across diagnostics, PPE, community, rights and gender-related interventions, etc. As a result, the process after award was more burdensome which translated into more time and effort needed to finalize grant documents for the grant revision. Also, reporting was challenging. Going forward, application forms need to gather essential information upfront and should be accompanied with clear guidance on how to complete each section with reference to relevant technical guidance from the Global Fund and partners. The application should capture more granular country data to support the rationale for the requested activities, as well as gather more information on themes such as community engagement, level of service disruption particularly for key and vulnerable populations, gender-based violence due to COVID-19 restrictions, human rights violations, partner coordination and national response plans which would enable a more informed review of the proposed interventions. More granular data collection will feed into a more detailed reporting. Experience from the 2020-2022 allocation period and C19RM funding request reviews, demonstrates that quality, robust, prioritized and evidence-based funding applications enable more efficient internal reviews, and facilitates coordinated partner support, more streamlined integration of funding into grants, and faster implementation.

- 3. A Secretariat review approach highlighted the benefits of leveraging internal expertise, technical guidance from partners, and effective coordination.
 - a. The review approach enabled assurance of quality of investments while maintaining speed and agility in the funding request review and approval processes. The review was conducted by teams across the Secretariat Technical Advice and Partnerships (TAP), Community, Rights and Gender (CRG), Supply Operations, Finance, Risk, and the Grant Management Division. Effectiveness of the review process relied on technical guidance from partners, CCM and in-country partner engagement and adhoc consultations during the funding request review to ensure development of quality funding requests, and systematic collaboration with partners at a global level through various forums such as the ACT-Accelerator partnership. As the funding landscape for the COVID-19 response becomes more diverse and complex with a larger number of stakeholders, continued engagement of technical partners at the country-level during the development of funding requests is essential to ensure quality and complementarity with other funding sources.
 - b. Broad stakeholder engagement during the development of the C19RM funding requests proved to be challenging. While C19RM requests were endorsed by CCMs, ensuring systematic broad and meaningful community engagement in the preparation of funding requests was not always possible. C19RM funding requests that were developed through a rigorous consultation process moved more quickly from award to implementation and looking ahead it is crucial that governments, partners, civil society and communities maintain active engagement in the process. This includes the bidirectional, constituency information-sharing expected of CCM members to ensure the greatest impact and non-duplication of existing, country-level investments. Recognizing that engagement may need to be virtual, the Global Fund continues to offer flexibilities for CCM funding to ensure virtual access for all members.
- 4. The scope of C19RM has been appropriate for responding to the emergency needs caused by the pandemic while maintaining a strategic focus on safeguarding the Global Fund's investments in HIV, tuberculosis and malaria.
 - a. A country-owned approach for determining the distribution of funds across three categories, enabled a response that was tailored to country needs, with due consideration of the local context and the evolution of the pandemic.



For example, in Burkina Faso, a network of 17,000 community health workers providing HIV services was quickly trained to support COVID-19 contact tracing to ensure that services could be provided in areas where formal care was less accessible. In Chad, malaria community health workers were trained to ensure activities could continue to be modified in line with COVID-19 restrictions and were provided with PPE to allow seasonal malaria chemoprophylaxis and LLIN campaigns to take place. With C19RM funding, 45 existing TB laboratories in Bangladesh integrated COVID-19 testing alongside TB testing on existing GeneXpert machines, to increase the country capacity for COVID-19 testing, while ensuring the continuation of TB diagnosis.

In addition, C19RM funding contributed to the adaptation of services and/or operations towards delivery of 137 million nets by end of February across 38 campaigns, against the Global Fund's planned distribution of 145 million LLINs in 2020.

b. Agility remains the cornerstone of C19RM. Due to the dynamic nature of the pandemic. each country's assessment of its needs has rapidly evolved. As countries' pandemic response matured and the impact of COVID-19 was better understood, and as newer technologies became available, the need for COVID-19 diagnostics and PPE steadily increased. Following approval of additional sources of funds, in November - December 2020, the C19RM Investment Committee awarded an additional USD 154 million to 14 countries through top-ups, out of which 48% was allocated to the procurement of PPE and 42% to the procurement of molecular SARSs-CoV-2 tests and Ag-RDTs. The topup process, while operationally challenging, was a demonstration of the agility of the mechanism to swiftly and dynamically respond to emerging needs and provide a channel for countries to rapidly access new technologies. In Uganda, the swift and significant support through C19RM contributed to the timely procurement of COVID-19 diagnostics and PPE and supported laboratory systems strengthening and crossborder surveillance and collaboration. These interventions complemented interventions being provided by the Civil Society Principal Recipient implementing community interventions, including community service provision of ART (differentiated service delivery) and support to key populations and other community members impacted by COVID-19.

The central role of agility is further illustrated by the investment decision made in response to Ukraine's top-up request, which received an award for the procurement of diagnostics and PPE to address the rapidly evolving epidemiological situation in the country. The award considered the country's high number of confirmed COVID-19 cases combined with a testing rate per capita that was significantly lower than other countries. An urgently approved top-up funding at a time when the country was seeing an exponential increase in cases was critical in reinforcing the COVID-19 response

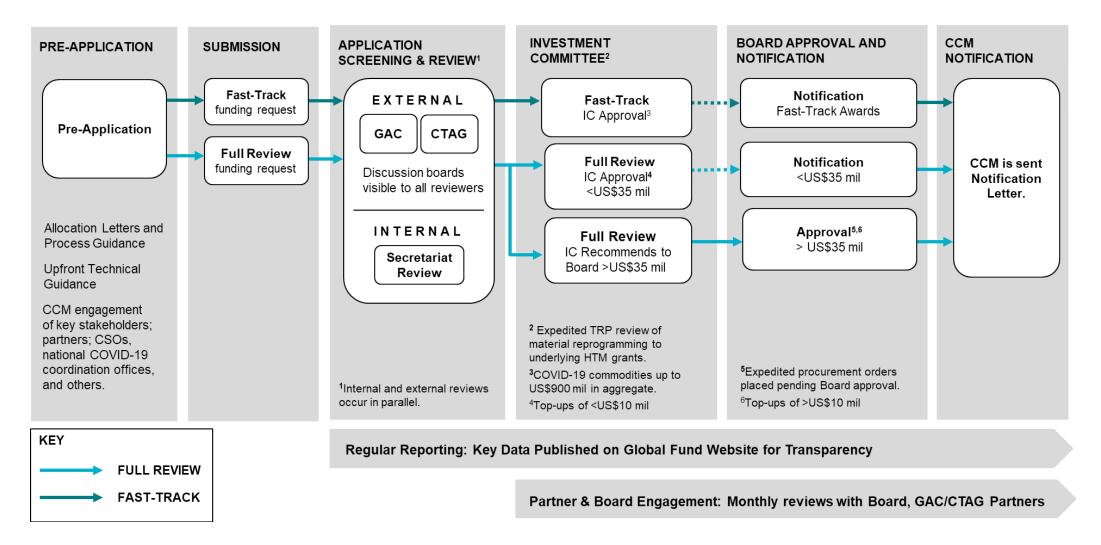
while also mitigating the risk of an adverse impact on the Global Fund supported HIV and TB programs in the country.

- c. Funding requested by countries for community-led interventions (including maintaining services for key and vulnerable populations and responding to the surge of genderbased violence and human rights violations) remained relatively low. Robust and impactful community-led interventions play an important role in mitigating COVID-19's impact on HIV, tuberculosis and malaria, however these interventions were not often prioritized by CCMs in C19RM funding requests. While some quality community interventions were funded, the Secretariat strongly recommends that countries should be supported by partners to ensure consideration of effective, at scale communitybased interventions in their C19RM applications. In South Africa, C19RM funding was used to adapt and strengthen community-based service delivery models (i.e. mobile, door-to-door, health posts, shelters, safe spaces and peer-based) to ensure uninterrupted provision of core interventions for key and vulnerable populations (AGYW, men who have sex with men (MSM), transgender persons (TG), sex workers (SW), people who inject drugs (PWID)) and for people with TB, including psycho-social support services; it was also used to engage civil society and community actors in responding to the COVID-19 pandemic. With greater emphasis on effective CCM engagement (including meaningful community engagement), strengthened guidance, and a modified funding request template that more clearly highlights community, rights and gender related interventions, there is an opportunity for more robust and impactful community-led interventions to be funded in the future.
- 5. Remaining responsive to evolving technologies on the market has helped countries access the products they need.
 - a. The global COVID-19 response has been a rapidly evolving field since the start of the pandemic, and new products have been made available on the market in record speed to help fight the pandemic. A key success factor for keeping C19RM relevant was to continue to evolve guidance and support on products that were eligible for C19RM funding. Similarly, the same was true for the publication of new normative guidance (WHO). C19RM Funding, in addition to guidance on key technologies and a means to order them through the Global Fund's online procurement platform, helped countries access the latest technologies and the most effective ways to fight the pandemic. In addition to new technologies, technical support to countries has also been helpful for reducing the time lag between new products being recommended and the updating of national policies and protocols to integrate their use, as was the case for national testing strategies to include Ag-RDTs

During 2020, to support access to tools for testing, C19RM has funded products such as automated PCR tests, providing a means for countries to access their allocations of the limited supply of these tests, in addition to Ag-RDTs that have become available more recently. Dexamethasone was also made eligible for funding to ensure access to tools for treatment. Countries that wished to order these products through the Global Fund's online procurement platform, wambo.org, could do so because of the Global Fund's sourcing capabilities, which optimized access to these scarcely available supplies by leveraging existing supplier and partner relationships. For example, in Malawi, an agility of the mechanism allowed the country to reallocate funding to swiftly respond to evolving technologies and secure volumes of Ag-RDTs once emergency use authorization was confirmed by WHO. In addition, an expedited review and approval of C19RM funding allowed the country to place urgent orders for molecular SARSs-CoV-2 tests to alleviate a near stock-out of test kits.

- 6. Lessons learned from implementation show that there is a room for improvement both by countries and the Secretariat.
 - a. Integration of C19RM funding into grants took longer than anticipated. In order to maintain speed and agility at the center of the C19RM business model and to reduce risk, C19RM was set up to award funding to existing implementers. This has been fundamental in maintaining the modus operandi of the emergency response. Existing Principal Recipients (PRs) are well versed with Global Fund policies and reporting, are covered within existing assurance mechanisms and are also best placed to initiate program adaptations. While operationally sensible, this approach had some challenges. When operationalizing C19RM funding, PRs were at the same time busy with grant making for their 6th replenishment grants. Workload constraints, both in countries as well as at the Secretariat level, was a major contributing factor to the delays in integrating C19RM funding into grants. Going forward, PRs will still need to balance competing priorities - managing core grants with increased allocations, carrying-out ambitious scale-up plans in 6th replenishment grants, which should also include prioritized service delivery adaptations (as defined by respective technical partners in collaboration with the Global Fund), managing the closure of the 5th replenishment grants - while at the same time implementing C19RM activities. It is critical to increase partner support by continuing to strengthen initiatives for joint platforms and systems, such as within lab systems strengthening and supply operations to further ensure the implementation arrangements are fit for purpose.
 - b. *Flexibility in managing C19RM funding during implementation is critical.* In the fastchanging context of the COVID-19 pandemic, it is critical to maintain the flexibility of the mechanism during implementation to ensure that the countries are able to rapidly respond to emerging needs on the ground and/or to reprioritize funding of interventions based on the realities on the ground. At the onset of the pandemic, Nigeria made efforts to prevent widespread community transmission and mitigate its impact. With C19RM funding, the country prioritized procurement of diagnostic tests and PPE, whereas oxygen support, not an urgent priority at that time, was approved as Contingent on Funding. The situation rapidly evolved. With an upsurge of COVID-19 cases the country was struggling with the oxygen production, with many states not having sufficient supply to support those infections that require oxygen treatment. Flexibility of the mechanism allowed the country to reallocate identified C19RM efficiencies to address urgent needs for the oxygen support.
 - a. At the Secretariat, there is an opportunity to streamline operational processes to reduce transaction costs by leveraging existing flexibilities, including using an expedited approach for placing procurement orders through wambo.org immediately after award, integrating funding into grants by the next reporting deadline, and consolidating grant revisions to avoid multiple transactions. There is also an opportunity to differentiate C19RM funding request review and approval and the grant revision processes based on the nature of funded activities (e.g., opportunities to accelerate integration of funds for diagnostics, PPE, and other commodities) and level of funding.

Annex 3 – Overview of C19RM Process



Annex 4 – Secretariat Responses to Questions From the Board, AFC, and SC

1. <u>Relationship of C19RM to the Global Fund strategy</u>

C19RM remains a temporary emergency response mechanism and is not intended to preempt broader discussions on the next Global Fund strategy. While clearly raising questions about the Global Fund's potential role in pandemic response in the future, the continuation of C19RM as an urgent response to safeguard the fight against HIV, TB, and malaria (HTM) remains firmly rooted in the Global Fund's existing mandate. Extending and expanding C19RM in the manner proposed is consistent with "Option 3+" discussed by the Board at its retreat, but does not lock the Board into any particular vision of the Global Fund's future role in this arena. It remains for the Board to continue discussions and ultimately determine whether the Global Fund should take on an expanded role in pandemic response or global health security/solidarity going forward.

Continuing to leverage the Global Fund's unique strengths in fighting infectious diseases and relative advantages in reinforcing health systems to assist the global COVID-19 response will enhance the Global Fund's effectiveness in the continued fight against HIV, TB, and malaria, as lessons drawn from C19RM can be used to accelerate the global HTM response. Moreover, C19RM can be used to demonstrate the power of country-owned and inclusive models for infectious disease response and preparedness leveraging governments, communities and the private sector.

2. The Global Fund's role in ACT-Accelerator

The Global Fund's contributions across Access to COVID Tools (ACT)-Accelerator pillars: The Global Fund is a founding partner of ACT-Accelerator and plays an essential leadership role in steering its progress. The Global Fund is recognized by ACT-Accelerator partners, G7/G20 stakeholders and implementing partners as key to the non-vaccine components of the global COVID-19 response, in particular for the procurement and deployment of non-vaccine tools for L/MICs. Within ACT-Accelerator, the Global Fund is seen by most partners as one of the preferred global partner to procure and deploy COVID-19 tests, treatments, and PPE to support L/MIC responses to the pandemics, as well as to mitigate the knock-on damage to AIDS, TB and malaria programs.

The Global Fund is a co-convenor of ACT-Accelerator's Diagnostics Pillar and the Health Systems Connector and leads the Supply Workstream in the Therapeutics Pillar. In the Diagnostics Pillar (known as ACT-Dx), the Global fund is primarily focused on the procurement of antigen RDTs (AgRDTs) and molecular PCR tests, the strengthening of laboratory infrastructure and capacities (including sequencing), and the significant requirements for training and technical assistance. In the Therapeutics Pillar the Global Fund is primarily focused on the procurement of repurposed treatments (e.g. dexamethasone), the procurement of novel antivirals and monoclonal antibodies (when and if these prove effective and become available), and the procurement of oxygen devices and supply, plus related capacity building. In the Health Systems Connector, the Global Fund is engaged in all seven workstreams38, but is particularly focused on the procurement of PPE (and broader support to infection prevention and control), the strengthening of supply chains, and supporting community-led responses.

³⁸ The seven workstreams are: health financing led by the World Bank and WHO; community-led responses led by the Global Fund and UNICEF; integrated data management led by WHO; protecting front-line health workers led by the Global Fund, UNICEF; private sector led by the World Bank; clinical care led by WHO, Global Fund; supply chain led by Gavi, UNICEF, and the Global Fund.

<u>C19RM and ACT-Accelerator</u>: C19RM is the mechanism through which the Global Fund fulfills its role in ACT-Accelerator, i.e. to deploy diagnostics, treatment, and PPE to countries and support urgent health and community systems improvements. Through 12 February 2021, the Global Fund has reported a total contribution of USD 458 million, of which USD 182 million is tracked against the Diagnostics Pillar (for the procurement of AgRDTs, PCR tests and related activities) and USD 276 million is tracked against the Health Systems Connector (for the procurement of PPE and related activities) of ACT-Accelerator.

In addition, the Global Fund also reports all donor commitments to ACT-Accelerator and C19RM as part of the ACT-Accelerator Commitment Tracker. For the purpose of calculating what contributes to reducing the ACT-Accelerator funding gap, the ACT-Accelerator records the amounts pledged to C19RM across the ACT-Accelerator pillars either based on expressed donor intent or proportionally according to need, contingent on the allocation of these funds through the C19RM process.

Discussions are ongoing with the ACT-Accelerator Hub to review and improve contribution reporting, including the introduction of the concept of "ACT-Accelerator complementary financing" which may enable better ACT-Accelerator recognition of those aspects of C19RM that are not currently included in the ACT-Accelerator investment case, such as HTM mitigation and some types of health systems investments. In line with the current trends, we can assume that a significant percentage of additional funds invested in C19RM will support ACT-Accelerator activities and contribute to reducing the ACT-Accelerator funding gap. The Secretariat reports regularly to ACT-Accelerator on these allocations.

3. Connection between C19RM and Global Fund core funding

Phase 2 of C19RM will be entirely funded through new external contributions, so will not draw on 6th Replenishment funding or on any potential carryover from earlier Replenishments. Replenishment funds will be solely for the fight against HTM and will not be available for pure COVID-19 responses, such as COVID-19 diagnostics and therapeutics. Grant savings will be available for reprogramming, including for adaptations and catch-up plans, through established procedures, which include CCM sign-off. Portfolio-level savings will be recycled through Portfolio Optimization (PO) to finance Unfunded Qualified Demand (UQD) through established procedures, which include GAC. Based on the experience of previous cycles, funding for PO is unlikely to become available until late 2021 at the earliest (the first PO awards in the 4th and 5th Replenishment cycles were made 18 and 12 months, respectively, after the start of the cycle). The Secretariat is in the process of reviewing PUDRs to assess absorption for 5th Replenishment grants that ended in December 2020. Once complete this analysis will be shared with the AFC for potential reinvestment into UQD through PO, in accordance with existing Board policy.

About two thirds of the dollar value of the 6th Replenishment cycle allocation is already signed into 6th Replenishment grants, with performance targets set without explicit consideration of COVID-19, since many program budgets were constructed before the full impact of COVID-19 and the development of guidance on program adaptation. Many countries have kept these ambitious targets despite the impact of COVID-19 and have developed catch-up/adaptation plans to keep pace. Some of these adaptations have been integrated into grants, and incountry reprogramming is likely to include further adaptation of programs to the COVID-19 context. Depending on the country context and the scale of the adaptation required, such changes may be fully funded through reprogramming, or with additional funding from C19RM. This will be for the CCM to determine. In many cases, reprogramming may make more sense than a separate C19RM application, where adaptation entails changes to the operating model rather than requiring incremental funding (e.g. moving to multi-month dispensing). Moreover, where the incremental funding for adaptation is small relative to the underlying grant, reprogramming may be a more cost-effective way for a country to proceed. The proposal envisages that all external contributions to the Global Fund through 31 December 2021 will be allocated to C19RM. This reflects the reality that donors are currently entirely focused on the COVID-19 response.

In ongoing resource mobilization efforts for C19RM, the Secretariat has particularly focused on new sources of funding – for e.g. stimulus/non-ODA public funds and private sector contributions, in an effort to ensure that funding for ongoing priorities is not diverted. The outreach for C19RM has proven very helpful in ensuring close relationships with donor representatives and an open ongoing dialogue with key stakeholders in donor governments which has supported timely pledge conversion.

It is important to note that the fundamentals of the Global Fund's resource mobilization strategy have not changed. Resource mobilization remains rooted in a formal replenishment process aimed at ODA funding. The Secretariat will continue to support countries on national health financing dialogues in collaboration with partners. Conversion of 6th Replenishment pledges into contributions is a key ongoing priority for the Global Fund, and throughout 2020 the Secretariat has implemented tighter controls and mitigations in this regard as part of its contingency plan.

In the Secretariat's view the extension of C19RM through to 31 December 2021 does not compete with core Global Fund HTM funding, but safeguards it for the fight against HTM. The Secretariat has been approached by both donor and implementer governments with suggestions that core HTM funding be repurposed for the fight against COVID-19. When the Secretariat can point to C19RM as the response to the pandemic, the Secretariat can deflect these suggestions. Without C19RM, the Secretariat anticipates these pressures will increase as needs in L/MICs become more acute.

4. Impact of COVID-19 on HTM:

While robust data on the impact of the COVID-19 crisis on the mortality and incidence of HTM remains as yet very limited, there is an increasing range of information available, including the Global Fund's LFA survey and, more recently, the Global Fund's facility survey, plus numerous surveys and data sources from technical partners, community organizations and countries, as well as extensive consultations with the Secretariat's Grant Management Division (including from internal regional teams). Based on these, the Secretariat offers the following high-level observations:

 On HIV, prompt action by the Global Fund and partners appears to have averted the worst-case scenarios put forward early on in the crisis about the scale of excess deaths amongst PLHIV from disruption of ART.³⁹ There was certainly significant disruption to ART services due to lockdowns and COVID-19 itself, but innovations like multi-month dispensing and courier delivery of ARVs, as well as a range of creative interventions by community-led organizations helped reduce the damage.

However, in many countries testing and enrollment on ART is down, testing and prevention services, including male circumcision, have been interrupted or disrupted for prolonged periods, human rights-related barriers to accessing health services have increased, and gender-based violence has surged. Men who have sex with men (MSM), transgender people, people who inject drugs (PWID) and young people have particularly struggled to access services. It therefore seems likely that, at least in some countries, significant ground on new infections will have been lost. With the reduction of incidence already off-track, there is an urgent imperative to scale-up targeted prevention interventions, as well as to ensure those who are infected are diagnosed and given treatment.

³⁹ https://www.who.int/publications/i/item/9789240004641

• **On TB**, the pattern appears similar. On the whole, treatment services appear to have been largely maintained despite considerable disruption, but in many countries, diagnosis and enrollment onto treatment has fallen sharply, both for drug-sensitive and drug-resistant TB. Countries in Asia have been particularly impacted. Much of the progress made in recent years on finding, testing and treating missing people with TB has been reversed.

The most urgent imperative on TB is to restore momentum on TB case finding and treatment. Some countries have recognized this need and have put in place catch-up plans. In other countries, TB has fallen off the radar screen, and leadership and resources have been diverted to fight COVID-19.

• On malaria, the picture is somewhat different. When the pandemic first hit, there was acute concern that lookdowns and the virus itself would severely disrupt vector control efforts and lead to a sharp upsurge in cases. Yet while some LLIN and IRS campaigns were delayed, the vast majority of those planned for 2020 have now been completed. This took rapid adaptation of campaign operations and intense collaboration amongst partners. However, there are indications that case management has been significantly disrupted in some countries, as primary healthcare has come under pressure, and community healthcare workers have fallen ill or been diverted to COVID-19 priorities. While reliable data on the scale of such impact is not yet available, delays in diagnosis and treatment would inevitably imply increases in mortality. It seems plausible that in some of the highest burden regions, such as the Sahel, incremental deaths from malaria as a knock-on impact of the pandemic, may well exceed deaths caused directly by the new virus. For malaria, therefore the imperative is to ensure vector control interventions remain on track, and to sustain case management.

Across all three diseases, the impact of COVID-19 may well escalate in 2021, both because of the direct impact of the pandemic on health workers and health systems, and because resources and leadership are diverted to fight the new virus. On a more positive note, the commencement of the 6th grant cycle means funding for all three diseases is increasing significantly, with country allocations up on average 23.4%.

5. Use of C19RM funding

The purpose of Phase 2 of C19RM, as with Phase 1, is to provide swift and flexible funding to countries to enable them to implement an effective response to the pandemic, minimizing both the direct impact of the crisis (e.g. COVID-19 deaths) and the knock-on impact (including incremental HTM infections and deaths). Since the optimal balance of interventions is very country-specific, and needs to take account of factors such as the differential burdens of disease, the state of the health system, and the availability of funding from other sources, the Secretariat does not recommend prescribing what the precise mix of interventions should be. This is for the CCM to decide, liaising with the appropriate entity overseeing the national response to the crisis.

Much of what is funded through C19RM serves multiple purposes. PPE, for example, is a core part of the COVID-19 response, is vital to protecting the viability of the health system (through protecting front line health workers and reducing nosocomial infection) and is a critical to adapting and sustaining HTM services to the COVID-19 context. Figure 2 in Annex 2 of the Board paper shows the composition of awards by type: of the USD 759 million total, USD 442 million (58%) was for reinforcing national COVID-19 responses, USD 243 million (32%) was for mitigating the impact on HTM, and USD 74 million (10%) was for urgent improvements in health and community systems. However, this split depends on how PPE is categorized. Secretariat reporting reflected how PPE was described in country funding submissions. By contrast, under ACT-Accelerator methodology, PPE is categorized as health system expenditure. Applying this approach to Phase 1 of C19RM would result in urgent

improvements in health and community systems being the largest component of Phase 1 C19RM awards, at 46%, followed by reinforcing national responses at 36% and mitigating the impact on HTM at 18%. This comparison illustrates the importance of clear and detailed reporting; in Phase 2 of C19RM the Secretariat is committed to providing more granular and detailed reporting to the Board and partners on a regular basis.

In Phase 2 of C19RM the Secretariat will remain responsive to country demand, while also being mindful of donor intent and aware of the particular role the Global Fund plays in the overall ACT-Accelerator response alongside other partners. Most donors to C19RM have been explicit in indicating that they would prefer their contributions to be used primarily, or wholly, for pure COVID-19 purposes, such as diagnostics or PPE. For some donors, it is important that the contributions count against the ACT-Accelerator investment case, which excludes HTM mitigation and only includes limited aspects of health systems strengthening (the latest version of the ACT-Accelerator introduces the concept of "ACT-Accelerator complementary financing" which covers both these items, but is not part of the core investment case). Within ACT-Accelerator, Gavi is playing the lead role on vaccine procurement for low and middle income countries through COVAX (and has attracted several billion dollars of funding for this purpose already) and the World Bank is taking the lead on supporting countries' preparations for vaccine deployment through the USD 12 billion MPA facility. This leaves the Global Fund, UNICEF to some extent, and WHO's Emergency Program as the major multilateral agencies supporting the other aspects of countries' COVID-19 responses. including diagnostics, treatments, and health systems reinforcements. This is why the Secretariat does not intend to use C19RM to fund vaccine procurement or deployment, as the World Banks's MPA is the primary source of support for vaccine deployment. However, the Secretariat is open to funding health systems enhancements that will bolster the immediate response to COVID-19 and HTM, as well as support vaccine deployment (e.g. increasing CHWs, or community-led interventions that reinforce tracing/isolation and tackle vaccine hesitancy).

The Secretariat anticipates that COVID-19 diagnostics and PPE will remain the two largest categories of expenditure through C19RM. To put this in context, the latest ACT-Accelerator investment case estimates a financing gap of USD 8 billion of external procurement of COVID-19 diagnostics to support testing in low- and middle-income countries' testing over the next 12 months. This figure excludes China and assumes: i) 45% of the total need is domestically financed; ii) low and middle income countries get to approximately 50% of the current rate of testing in high income countries by the end of 2021; and iii) an 80/20 RDT/PCR mix, and a significant reduction from current prices. The ACT-Accelerator investment case also includes a financing gap of USD 6.5 billion for PPE, based on relatively conservative modelling on required coverage of frontline health workers, current PPE prices, and an equivalent domestic resourcing assumption. For both diagnostics and PPE, the Global Fund is seen by countries and ACT-Accelerator partners as playing a lead role in meeting these gaps.

Demand for COVID-19 therapeutics, including oxygen, may well increase significantly, given ACT-Accelerator's greater emphasis on supporting countries with oxygen devices and supplies, and the potential emergence of new antivirals. The ACT-Accelerator investment case includes USD 2.8 billion for the procurement of therapeutics including oxygen. However, this number could change significantly depending on whether new therapeutic solutions emerge (or, as happened with monoclonal antibodies, are rendered less viable by COVID-19 variants). Here again, the Global Fund is expected to play a significant role, alongside the World Bank.

Health systems requirements for the COVID-19 response are largely excluded from the ACT-A investment case, bar the USD 6.4 billion for PPE and a further USD 900 million billion for catalytic spending across supply chain, infection prevention and control, data, community-led interventions, and private sector engagement. Much of the World Bank's USD 12 billion MPA facility will therefore not count against the ACT-Accelerator core investment case, but will count as ACT-Accelerator complementary financing. The same is true of a considerable part of the WHO's Emergency Programs support to countries through the SPRP. C19RM awards on health systems responses to COVID-19 will either count as part of the core investment case, or as ACT-Accelerator complementary financing depending on the precise nature of spend. C19RM spending on HTM mitigation will count as ACT-Accelerator complementary financing.

Looking beyond the costs of the (non-vaccine elements of the) COVID-19 response, such as diagnostics, therapeutics and PPE, there are significant costs relating to both the adaptation of HTM programs to ensure their continued effectiveness in a COVID-19 context, and to the implementation of catch-up plans to recover ground lost in 2020. While the Global Fund and its partners have devoted considerable efforts to designing and costing program adaptations, and to understanding the scale of the catch-up required, there is as yet no comprehensive estimate of the total funding requirement across the three diseases. This is partly because the impact of COVID-19 on HTM deaths and prevalence in 2020 is not yet known, and partly because the scale and nature of the knock-on impact is still unfolding as the crisis evolves. In the first few months of the pandemic, the impact was mainly due to the disruption to HTM services from lockdowns and other measures. More recently, some countries have seen the direct impact of the virus on populations also affected by HTM, shortages of health workers due to COVID-19 driven sickness and death, and diversion of HTM resources and leadership to fight COVID-19.

In May 2020, the Secretariat made a very crude top-down estimate that the incremental cost of adapting programs to mitigate the damage resulting from COVID-19 might amount to about USD 1 billion over a 12-month period, or a roughly 25% increase on the underlying spend. However, this figure only covered the adaptation of programs to minimize disruption and thus future downside; it did not include the costs of catch-up. During 2021, the Secretariat anticipates that technical partners will develop estimates of the cost of getting back on track toward the SDG3 goal of ending the epidemics by 2030. These figures are likely to be extremely large: for example, the draft UNAIDS strategy suggests that to meet the 2030 goal total annual financial expenditure to fight HIV in low- and middle-income countries must increase from USD 21.6 billion in 2019 to USD 30.4 billion in 2025, an increase of USD 8.8 billion.

The Secretariat envisages that awards for HTM mitigation through C19RM should focus primarily on adapting current programming, rather than on simply scaling up interventions to catch-up ground lost on 2020 (which the underlying increase in country allocations should help with, and can also be supported through future PO). The Secretariat will encourage CCMs to seek funding for interventions that simultaneously support HTM objectives and help contain COVID-19: TB examples would include "bi-directional" testing, increasing GeneXpert or X-ray capacity, and community-led initiatives on infection prevention and control.

What should be clear from this discussion is that the needs C19RM is designed to cover (non-vaccine COVID-19 response, HTM mitigation/adaptation, urgent health system fixes) are likely to exceed even the ambitious scenarios for C19RM resource mobilization by a considerable margin. Hence the need to be mindful of donor intent – to attract the maximum resources – and to allow countries to determine the priorities for C19RM spending, reflecting their specific context.

6. C19RM funding request submission and decision process

The proposal's recommendations on the funding request submission and decision process seek to balance the imperative for speed and flexibility with the need to have appropriate technical scrutiny and governance oversight. During 2020, with a primarily Secretariat-led approach, the Secretariat targeted (and very largely met) a 10-day turnaround time for C19RM decisions. Although there were gaps in both technical guidance and in-country support to CCMs at the time of the initial submissions, and many countries national response plans were still at an early stage of development, the vast majority of funding submissions were of good quality, with most requests being straightforward and consistent with technical guidance. In

Phase 1 of C19RM the most difficult aspect of the decision-making process was the disconnect between available funds and the needs, rather than the robustness of the funding requests.

Nonetheless, with the bigger sums now potentially envisaged, and given the lessons learned to date, the Secretariat agrees that it is appropriate to consider to what extent the earlier approach should be modified. It is clear that the Global Fund should not adopt the full TRP, GAC and Board approval model used for core grants; this would take the current 10-day turnaround on decisions to closer to 16-18 weeks, far too long for an emergency funding mechanism, and would create an enormous amount of extra work (not only for the Secretariat, but for countries, partners, and Board members as well). The current proposal is therefore designed to strengthen the approach used in Phase 1, leveraging existing review, decision-making and oversight mechanisms where appropriate, without overly compromising the speed and flexibility that makes C19RM so valuable to countries, or creating excessive workload.

The approach proposed in the Board paper currently envisages:

- A stronger and more systematic approach to providing upfront technical and operational guidance to CCMs, in line with WHO guidelines:
 - For HTM adaptations (and HTM-related health system enhancements), the guidance prepared for C19RM Phase 1 will be updated in collaboration with partners through the disease Situation Rooms, and with inputs from the TRP.
 - For COVID-19 interventions (including relevant health systems initiatives), the Secretariat will work with relevant ACT-Accelerator partners to ensure CCMs are provided with appropriate guidance on relevant topics, including diagnostics, therapeutics, PPE and infection prevention and control (IPC), and community engagement.
 - Additional technical guidance will also be developed with civil society and technical partners, and will include evidence of the impact of COVID-19 on key and vulnerable populations, including those communities most impacted by COVID-19 (and on gender and human rights barriers and GBV), highlight the importance of community engagement and inclusion of community-led interventions in COVID-19 responses, and provide concrete examples of community, rights, and gender (CRG)-related activities to respond to the impact of COVID-19.
 - Based on C19RM experience to date, technical guidance will focus on the more frequently requested investment areas, but will not be able to cover the entire spectrum of possible C19RM activities. Based on the specific country and health systems contexts, consideration will be given to other activities that may be requested by countries (while noting that interventions not covered by technical guidance are less likely to be impactful and therefore less likely to receive funding). Technical guidance will be updated regularly to reflect learning over time.
- A stronger and more coordinated approach to supporting countries in developing funding request submissions for C19RM. Country Teams will work with on-the-ground partners, with the support of the Situation Rooms and ACT-Accelerator partners represented within national COVID-19 response management structures, to reinforce support to CCMs in developing robust C19RM funding requests.
- Enhanced reporting to partners through updates to GAC and directly to the Board, with detailed regular reports laying out awards made by country and region, investments by category ("pure COVID-19" activities including Dx, PPE and Therapeutics/Oxygen; investments in community interventions and as well as alignment of Global Fund investments to the COVID-19 National Response Pillar Framework.
- Retaining the current decision-making process, with an Investment Committee composed of senior management from the Secretariat.

Responding to feedback received from Board members, the Secretariat proposes to modify this proposed approach in a number of ways and offers some further options for Board consideration. Key recommended modifications are:

- **TRP**: In addition to reviewing upfront guidance on HTM adaptations and health systems, the TRP can be requested to conduct expedited reviews of HTM adaptation/mitigation submissions that would result in material reprogramming of the underlying grants. TRP leadership will need to be engaged to work out how this can be done within an appropriately short timeframe (i.e. not more than a week). As laid out in the Board paper, the Secretariat does not recommend TRP review of individual funding requests based on expected trade-offs on time for decision-making, significant additional work load on the Secretariat to produce briefing notes for TRP, the TRP's expected workload over 2021 to review the remaining funding submissions for the 6th replenishment cycle, and that the TRP has already reviewed the majority of the underlying HTM programs to which C19RM funding will be added.
- **GAC**: in addition to working with partners to provide upfront guidance, and to support CCMs at a country level, the Secretariat proposes to hold a regular (e.g. monthly) GAC review of C19RM to discuss submissions and awards made, synergies and emerging thematic issues potentially impacting HTM programs, and any concerns and observations from GAC partners. This monthly GAC engagement will create an ongoing feedback loop to inform revisions to guidance and future decision-making, while keeping GAC discussions focused on strategic issues impacting the global portfolio rather than the minutiae of individual requests.
- **Board and Committees**: In addition to providing regular detailed reporting, one of the informal Board updates each month can be used to highlight key themes and issues from C19RM and to take questions. The Secretariat will also provide the AFC and SC with regular updates at committee meetings.

The Secretariat is also considering two additional modifications based on specific feedback received from the Board, which focus on increasing the involvement of the GAC and/or the Board in the review or approval of C19RM funding requests. While the Secretariat fully appreciates the considerations underlying the Board's feedback, each option entails significant trade-offs that will materially impact the timeframe for decision-making and the workload of all involved. The Secretariat therefore welcomes a discussion with the Board on how to collectively solve the challenge of balancing additional layers of review with the speed of decision-making that is required to effectively support countries, and requests the Board's steer on whether the trade-offs associated with either of these options are acceptable. These options are:

• Providing GAC partners with a timebound window to provide input on individual funding requests. Funding requests could be made available to GAC partners with a strict deadline (e.g. 48-72 hours) for providing input. Introducing this step in the process would allow for partners to check that upfront guidance has been followed and provide comments on alignment with other partner investments (although this input should also have been provided at the FR development stage). This approach has three main downsides: first, introducing this step will add time to the decision-making process. To limit the delay to timelines, the review window will need to be limited to 48-72 hours, putting a significant strain on partner resources. Even with this limit, this will add a minimum of 5 days to the expected timelines (allowing time for the Secretariat and countries to respond to partner feedback). Second, adding this step may introduce the risk of re-litigation of prioritization decisions already made in-country. To avoid reopening issues most appropriately resolved at the CCM level, the scope of partner input will need to be clearly defined upfront. For example, partner input on the technical quality of the propositions submitted by the CCMs will be considered, but input on the

relative prioritization of different categories (or on the absence of specific items) would be better directed at CCMs themselves to inform future submissions. Finally, establishing this review point may introduce the risk that partners may view the opportunity of the FR review as the key entry point for inputs, while early partner input and support at the country-level is essential; receiving comments too late in the process will create bottlenecks that in any event will need to be solved at country-level. The Board is requested to take account of these considerations against the value-add of this proposition – noting that for funding requests relating to COVID-19 items (which will likely represent the lion's share by value), this extra step will add limited value, since GAC partners are not, on the whole, the relevant providers of such technical input. Consideration of these costs should also bear in mind the likelihood of multiple rounds of C19RM top-ups to deploy incremental C19RM funds as they become available. If this route is taken, the Secretariat anticipates the need for flexibility to address comments received during implementation, so as not to create a bottleneck for entire requests.

Submitting all C19RM awards to the Board for approval. The Secretariat appreciates that some Board constituencies feel that given that the Board approves core grants, the same should be true of additional funding under C19RM, particularly given the potential sums involved. The Secretariat believes that Board review and approval is a valuable step that could reinforce collective ownership of funding decisions made. However, the main challenge here is that introducing this step would require a minimum of an additional two weeks for decision-making, even with a sharply curtailed decision window (e.g. 4 days). This would take the overall decision-making process for C19RM to more than a month, which would significantly undermine the speed and flexibility that has characterized the process and may impede the rapid release of funding to address urgent needs (such as for diagnostics, PPE and Oxygen therapeutics). Seeking and obtaining Board approval of all individual C19RM investments would also entail significant additional workload for the Secretariat and all Board constituencies; the Secretariat anticipates that packages of funding requests, review outcomes and recommended decisions will need to be sent to the Board for approval on a rolling weekly basis during peak periods - this will be in addition to regular funding approvals that will continue to go to the Board for core grants. This may also entail several rounds of C19RM approvals for the same programs if multiple top-ups are required to deploy incremental funding. Board constituencies will also need to mobilize additional resources to review all funding requests and make decisions within a shortened voting period. Board approval may also introduce some similar risks as GAC review of funding requests (i.e. in reopening prioritization decisions already taken at country-level or inadvertently encouraging late inputs). If this route is pursued, voting periods will need to be accelerated and multiple votes may be under Board consideration at the same time. The Secretariat would then also likely seek delegated authority to approve a limited round of initial fast-tracked investments to address urgent needs and will also request additional flexibilities from the Board to ensure that commodity orders and other limited urgent activities under Secretariatrecommended awards can be initiated pending Board approval.

The Secretariat would value the Board's feedback on the above two options. Whether to add one or the other is ultimately a decision for the Board to make, taking account of the trade-offs involved. While the Secretariat will be steered by the Board on this decision, the Secretariat strongly recommends that the Board consider adding only one of the above options, as adding both would have limited incremental value-add (and may in fact be duplicative) while adding a level of delay to decision-making that risks creating material challenges for countries as they wait on Global Fund decisions.

7. Allocation approach

The allocation methodology will take the 2020-2022 HTM allocations as a starting point. However, actual award levels to countries will also account for other factors, including: (i) COVID-19 considerations, such as current incidence and potential vulnerability; (ii) level of disruption to systems of health, including HTM services; (iii) availability of other sources of funding; and (iv) utilization of funds already awarded. These adjustments will be made on the basis of informed judgement, rather than mechanistically, given constraints of data availability/quality and the intrinsic difficulty of weighting the different factors.

Data inputs used to inform the such adjustments will include WHO data on COVID-19 infections and deaths (and the presence of epidemiologically significant variants), testing rates/positivity, demographics, LFA (and other) surveys of service disruption, impact on HTM infections/deaths (where available), and information on domestic and other external sources of funding (including with respect to access to key COVID-19 commodities).

The Secretariat is still refining the precise details of how to operationalize the allocation approach, but building on the experience of phase 1 of C19RM, and once the initial funding capacity is known, at this point the Secretariat envisages communicating to countries an initial allocation, based on a standard base percentage of 2020-2022 HTM allocations that all Global Fund countries will receive (as long as they submit funding requests of an appropriate quality within a certain timeframe). Countries will be encouraged to submit a prioritized and ambitious expression of demand, going beyond the initial allocated amount, and will be told they may receive an incremental amount above their base allocation, depending on the qualitative adjustments relating to COVID-19 considerations, subject again to submission of funding requests of appropriate quality. The Secretariat will make clear that countries with low HTM allocations relative to COVID-19 need are likely to get higher incremental shares of C19RM funding and vice versa. This means all countries can be confident of receiving a defined base level of funding, and that countries that are particularly affected by COVID-19 may receive more funding than using HTM allocation alone would imply. This approach will also allow for the creation of the C19RM equivalent of unfunded demand, so that subsequent smaller donor contributions can be swiftly deployed. If significant further donor contributions are secured, the Secretariat will reset the base amounts accordingly.

Within these funding envelopes, countries will be invited to submit prioritized funding requests with defined time windows, rather than all in one go. This will allow countries to submit requests for time-critical commodities quickly, while also allowing for time to develop more complex funding requests. Adopting a submission window approach will also allow the Secretariat to effectively utilize the adjustment factors as the pandemic evolves and new data becomes available. Another advantage of this approach is that it makes it easier for countries to align submissions to C19RM with domestic planning and budgeting processes, and to applications to other funding sources, such as the World Bank.

Monthly reporting to the Board and partners will include the amounts awarded to individual countries, and the categories of spend, visibility on the pipeline of pending submissions, plus the cumulative percentage of the underlying HTM allocation. We will provide an explanation for all significant deviations from the average.

This proposed approach strengthens the approach in phase 1 of C19RM by incorporating: (i) a more systematic approach to making adjustments from the underlying HTM allocation, whereas in phase 1 this was on an exceptions basis (for example, Peru's award was increased due to its high mortality rate and adverse impact on HIV and TB services, programs which rely significantly on Global Fund financing (see GF/B41/ER12 Annex 2)); (ii) submission windows that provide predictability and visibility on the pipeline of demand pending submission, rather than waiting for CCMs to submit a single consolidated funding request, followed by ad hoc "top ups" as new donor contributions were received; and (iii) more regular and detailed reporting to the Board and partners, including explanations for adjustments based on qualitative factors.

At this point the Secretariat does not envisage extending the eligibility for C19RM beyond those countries already eligible for and receiving HTM grants (either directly or through multicountry grants). All low and lower-middle income countries have HTM grants and thus are eligible for C19RM. Multicountry grants, which remain eligible for C19RM funding, may also provide some funding for ineligible countries, where such funding is consistent with the relevant multicountry strategic priority. Previously eligible countries that have transitioned will continue to be able to purchase COVID-19 products through the wambo.org pilot for non-grant financed orders. Currently this option is available through 31 May 2021, pending Strategy Committee and Board consideration of a recommendation to extend this timeline through 30 November 2022. Finally, ACT-Accelerator partners including WHO, World Bank, UNICEF, UNITAID and others are able to provide support to countries that remain outside of the Global Fund's eligibility policy.

8. <u>CCMs</u>

CCMs retain a core role in C19RM, and CCM development of C19RM requests is key to ensuring a country-led determination of the combination of C19RM interventions that will best address rapidly evolving country contexts. As multi-sectoral, partnership bodies, CCMs have mechanisms and resources already in place and are well positioned to lead consultation processes on health issues.

CCMs have pre-established links within the health sector, including directly with Ministries of Health (as senior representatives of the Ministry often function as chairs of CCMs), that contribute to CCMs by ensuring alignment with the national COVID-19 response. Detailing the link with the national COVID-19 response plan is an integral part of the Funding Request submission. In the second phase of C19RM, guidance on engagement with relevant national COVID-19 response heads during funding request development will be strengthened to ensure greater alignment. This engagement will strengthen country-level accountability and ensure more rigorous alignment with other domestic and donor funding.

Furthermore, having CCMs develop C19RM funding requests is a powerful tool to include civil society into national COVID-19 response schemes, where national programming entities and national COVID-19 response structures may not have always been inclusive. The Secretariat will continue to leverage available sources of funding (potentially including CCM resources, existing catalytic funding, or centrally managed C19RM funds) to financially support civil society and community engagement and constituency discussions (e.g. funding to facilitate discussions and technical assistance through the CRG platforms where applicable).

In addition to host government and civil society, partners in-country are represented on CCMs through multi/bilateral seats, where their input is solicited from the initial funding request preparation stage through sign-off on the content and strategic approaches in the final funding request submission. Partner engagement and coordination at country level in the development of national response plans and strategies, as well as C19RM and other funding channels is an essential ingredient for success.

Global Fund Country Teams will continue to engage with CCMs, Ministries of Health, partners and civil society stakeholders throughout the development of C19RM funding requests, similar to the level of engagement during the development of NFM3 funding requests and the first phase of C19RM, to ensure robust applications.

The development of upfront technical guidance by the Secretariat and partners will significantly strengthen CCMs' abilities to develop robust C19RM requests. The Secretariat is also developing revised application materials that will guide CCMs more clearly on relevant areas of consideration. Revised application materials will include a section in which CCMs must elaborate on what has been the impact of COVID-19 on KVP programs and how/which source of funding has been used to respond to the impact of COVID-19 on KVPs (GBV and human rights issues). The funding request guidance will also list explicitly which populations

are mostly and disproportionally impacted by COVID-19. The Secretariat is also reviewing options for additional support for the development of C19RM requests, although operationalizing such technical assistance modalities is challenging given tight timelines. Should additional technical experts be needed to facilitate epidemiological integration and alignment between C19RM funding request and national priorities, these can currently be integrated through CCM dialogue and broader engagement processes.

The requirement for full CCM endorsement of the final submission, including by representatives of civil society, communities, and people living with the diseases, will continue in the next phase of C19RM. This requirement also applies to any C19RM funds that are materially reprogrammed after award. The first phase of C19RM saw 100% endorsement of funding requests by all CCM representatives (or in some cases alternate members). While this is a key milestone, ensuring broader constituencies both have up to date information and can input through their representatives is a key opportunity for the next phase. Deliberate resources are dedicated to this in CCM Evolution under the Engagement pillar – including ensuring bi-directional information sharing before and after key decisions with constituencies. Certain CCMs have also indicated the need for more time to allow for consultation and review C19RM requests; allowing submission of requests through staggered submission windows will address this concern.

9. Community engagement and community-led interventions

The Secretariat agrees that community engagement, including with civil society stakeholders outside of CCMs, should be strengthened at both the funding request and implementation stages for the next phase of C19RM. Effective community and civil society engagement remains crucial to ensuring appropriate mitigation of the risks to HTM programs posed by COVID-19, and is equally critical to developing robust responses to the pandemic itself – as these stakeholders can leverage their extensive experience in the fight against HTM to support the response to COVID-19 (both for purposes of C19RM and national responses more broadly).

Engagement should however not be limited to traditional HTM communities. It should also include those most vulnerable to COVID-19. The Secretariat will work closely with partners to identify and engage with such stakeholders, who may fall outside of traditional civil society and community CCM representation and may leverage the centrally managed funds to enable support in this area. Coupled with this, the Secretariat is also reflecting on implementation arrangements and financing mechanisms that would facilitate access to funding for those best placed to implement relevant activities, however, this poses its own challenges (see section 10 – "Implementation arrangements").

In the first phase of C19RM, while a number of CRG interventions were successfully funded, there were challenges in ensuring the meaningful engagement of civil society and community representatives on CCMs during the development of funding requests, and requests did not systematically prioritize key and vulnerable populations or interventions to mitigate the increase in gender based violence (GBV) and human rights violations. To help address these challenges, the Secretariat will continue to leverage CCM resources and flexibilities to support (financially or otherwise) civil society and community engagement and constituency discussions. The Secretariat is also considering how to use the existing CRG Strategic Initiative to better support civil society CCM representatives to have stronger voices during funding request prioritization and finalization discussions.

As discussed above, additional technical guidance will also be developed with civil society and technical partners, which should more effectively guide CRG regional platforms, CCMs and civil society and community constituencies in their consideration of CRG issues during funding request development, as part of a holistic response, acknowledging that community engagement and inclusion of community-led interventions are critical to mitigating the impact of COVID-19 on the communities served by the Global Fund, and country responses to

COVID-19 more broadly. This additional guidance will include, but will not be limited to, (i) evidence of the impact of COVID-19 on key and vulnerable populations for HTM as well as communities most impacted by COVID-19 (and on gender and human rights barriers and GBV) to help such communities to have a stronger voice during the prioritization of interventions discussions – focused on ensuring the inclusion of appropriate community-centric interventions and (ii) a list of concrete examples of CRG-related activities to respond to the impact of COVID-19 (informal CRG guidance already exists, but will be further developed and converted into clearer and more actionable guidance).

Modified C19RM application materials will also seek to facilitate CCM deliberations and civil society engagement, by soliciting additional information both on how COVID-19 is affecting and impacting key and vulnerable populations and programs, and on the role civil society is playing in each country's overall COVID-19 response. To help CCMs during prioritization discussions, CCMs will be requested to assess HTM service disruptions, including disruptions to services for and vulnerable populations, and elaborate kev on how identified gaps, challenges and needs are being addressed (within the C19RM request or through other sources of funding). CCMs will also be asked to consider whether there are opportunities to reinforce the role and effectiveness of civil society organizations in the national COVID-19 response, including through supporting the most vulnerable communities, community tracing, supported isolation, and addressing vaccine hesitancy. In supporting community-led engagement in the broader COVID-19 response, the Global Fund will work closely with key partners, including Gavi, UNICEF and WHO.

10. Implementation arrangements

In 2020, awards for the COVID-19 response did not distinguish between implementer categories. The same PR (and its Sub-Recipients) may have implemented "pure COVID-19" and "program adaptation" at the same time. For practical reasons (e.g. familiarity with the Global Fund; assurance systems in place), only existing PRs were considered as implementers for C19RM awards, and implementation capacity as well as familiarity with the Global Fund and its systems was considered.

For the next phase, while expecting significantly increasing resources, the Global Fund is not anticipated to be the sole or main source of a national response, but rather a contributor. As such, the Secretariat does not, in general, anticipate that current implementers (or, in the case of Ministries of Health or Finance: their Global Fund Program Management Units, PMUs) would take on a role of the lead agency for a national scale response. The Secretariat would thus expect sufficient capacity for implementation even with significant additional resources, and where required, that additional funds could also buy increasing managerial capacity. The Secretariat, therefore, plans to continue to adhere to the general principle of using existing PRs for additional COVID-19 resources. However, where needed new SRs will be considered, including lead agencies for the national scale response.

In exceptional cases where new SRs could not deliver given unique circumstances in a country, the Secretariat may consider alternative implementation arrangements with a new PR, on a case-by-case basis in consultation with in-country stakeholders. However, as this would require a detailed capacity assessment and risks taking considerable time, preference would be given to implementers with proven and assessed capacity elsewhere, as would be the case with multilateral agencies or pre-qualified entities for emergency responses.

11. Oversight and assurance over implementation

C19RM funding will continue to be subject to existing assurance frameworks under core grants, leveraging existing controls and arrangements to the extent possible. In 2020, the Secretariat developed detailed guidelines for COVID-19-related assurance activities for Country Teams and various assurance providers (e.g. LFAs and fiscal agents) for C19RM.

Besides routine grant reporting (e.g. PUDRs), LFA spot checks and verifications and audits, the Secretariat also introduced regular LFA monitoring surveys and the monthly Indicator Reporting across 38 HI/priority countries to measure the direct impact on programs. This data will continue to inform the Secretariat's monitoring of both program disruptions and the impact of various program adaptation and mitigation initiatives. As the amount of funding increases, and the scale of pure COVID-19 interventions grows, the Secretariat anticipates the need to enhance and tailor assurance arrangements based on proposed interventions, with continuous adaptations and adjustments over the course of implementation. Expanding further on the lessons learned from the first phase of C19RM, the Secretariat is currently detailing an enhanced end-to-end risk and assurance framework for the next phase of C19RM, focusing in particular on in-country assurance. As highlighted in the Board paper (and further addressed below), a portion of future C19RM funding is proposed for strengthening in-country assurance activities, including by the LFA.

12. Procurement and wambo

Different products required in the fight against COVID-19 have different market dynamics, with some products being scarce on the global market and especially challenging for L/MICs and individual L/MICs to access. For such products, pooling of demand or coordination of order placement is needed to be able to secure volume that, if not timely ordered, is lost to non-L/MIC markets. Examples of this coordinated approach have included enhanced collaboration, including pooling of volume with other procurement and market entry platforms at the global and regional levels through ACT-Accelerator, as well as associated initiatives on diagnostics, PPE and therapeutics. This enhanced collaboration has included: (i) at the Global level: UNITAID, UNICEF, UNDP, WHO, World Bank, GDF, BMGF; and (ii) at the Regional level: PAHO and the African Medical Supplies Platform.

Automated PCR tests that were rationed through the WHO-led allocation was one example of a category of scarcely available diagnostic products that required a global-level coordination to secure access for L/MICs, and for Ag RDTs, access was secured through operationalizing the draw-down of the ACT-Accelerator volume guarantee. As product dynamics evolve over time, guidance will be updated periodically regarding which products should be preferably procured through the Global Fund's Pooled Procurement Mechanism (PPM)/wambo.org to be able to secure timely access due to the supply scarcity or partner volume guarantees as described above.

As is reported in the biweekly COVID-19 Situation Report, from April 2020 to date, requisitions for around half of the C19RM funding for PPE and 75% for SARS-CoV-2 diagnostics have been channeled through PPM/wambo. For SARS-CoV-2 diagnostic tests, cumulatively 18.6 million tests have been channeled through PPM/wambo.org, with Ag RDTs comprising 80% by volume and 50% by value (noting that Ag RDTs only became available at the end of September 2020). Regarding PPE, 87% of demand is for medical masks, N95 respirators, gloves, gowns, face shields and goggles. Requests for investing in oxygen therapy to date have been limited (USD 10 million); however, investment requests are expected to substantially increase with C19RM 2.0 as such investments will be actively encouraged.

In order to quickly access some HIV and malaria products (e.g., first line ARVs and HIV-self tests) that countries have struggled to source for various reasons, including due to the impact of COVID-19 control measures on supply chains, PPM/wambo.org has been utilized by a number of additional countries in 2020 that traditionally have managed their own procurements. Twenty-five additional countries utilized PPM/wambo for the first time in 2020, including 16 countries for COVID-19-products only, and 9 countries for other products as well. These countries have ranged from small countries across the different continents as well as some high impact countries in Africa.

Apart from one small request with national funding, all volumes procured through wambo.org for COVID-19 products to date have been procured with Global Fund funds (grant flexibilities and C19RM).

Updates on the commercial terms negotiated for SARS-CoV-2 diagnostics should be provided through the ACT-Accelerator/Diagnostics Consortium by the entity leading (or having a leading position) on a particular negotiation. Depending on the product, this could, for example, include FIND, UNITAID, CHAI or the Global Fund. Similarly, as developments advance on other product groups, such as therapeutics, updates would also be provided through the ACT-Accelerator therapeutics workstream.

Ensuring quality in procurement of health products: In addition to the ability to secure volumes of scarcely available products, procurement through PPM /wambo is a tool for country portfolios where there are concerns on quality assurance, fraud and corruption. In November 2020, the Guide to Global Fund Policies on Procurement and Supply Management of Health Products was updated to include a new section clarifying quality assurance requirements for core PPE (i.e., apron protection, gloves, face shields, masks, respirators, gowns and protective goggles). PPE ordered through wambo.org meet these requirements. For countries purchasing PPE outside of the wambo.org platform, the new quality assurance requirements for PPE become effective on 1 July 2021, to permit countries the time needed to be adequately informed of the new requirements and to implement them. PPM/wambo is providing access to oxygen equipment through UNICEF, which has been collaborating with WHO since 2017 to improve access to and utilization of oxygen therapy systems and has substantial technical experience in sourcing this product set.

13. M&E/Results and reporting

As noted in the proposal, the Secretariat is committed to transparent and frequent reporting on investments and has detailed a number of forthcoming improvements in C19RM reporting, including increased granularity and disaggregation of data.

At the funding allocation stage, the Secretariat will report on C19RM awards (aggregate and by country and region); investments in the three categories of C19RM investments; investments in diagnostics, PPE,= and Oxygen support; therapeutics; community-led support; GBV/IPV; human rights; and unfunded demand.

It is also particularly important to discuss how the Global Fund considers monitoring and evaluation and results in the context of potentially significant additional funds and a complex pandemic response with multiple contributors. At the implementation stage, to assess the contribution of Global Fund investments through C19RM, the Secretariat will use a comprehensive monitoring, evaluation and results reporting approach including qualitative and quantitative measures covering a range of input (e.g. budgets allocated, expenditure on commodities and community-led support), process/output (e.g. number of people tested for COVID-19 and stock availability of tracer HTM and COVID-19 commodities) and outcome/impact data (e.g. grant performance on programmatic results, performance on KPIs 1 and 2, COVID-19 cases averted, COVID-19 case fatality rate and COVID-19 deaths averted). C19RM investments are incorporated into regular grants and follow the semi-annual and annual reporting cycles of Global Fund grants. The financial performance of C19RM will be captured in the upcoming Progress Update and Disbursement Requests (PUDR) due in April 2021 and in Q3 of 2021. The integration of C19RM investments into grants also facilitates semi-annual review of overall grant performance, which includes C19RM interventions. An indirect measure of the impact of C19RM investments will also be reflected in the adaptations of HTM programs and on how quickly they make up for the loss in key prevention and service delivery indicators (captured in the results analysis). Measuring across inputs, outputs, outcomes, and results is the most appropriate way to monitor what the Global Fund is financing, how it is performing, and the linkage with impact on both the COVID-19 and HTM programs.

In addition, the Secretariat is collecting substantial additional data to help understand the impact of COVID-19 and urgent C19RM needs. The Secretariat is undertaking frequent data

collection on a small set of indicators to assess service disruption and undertaking quarterly spot checks to verify service availability at health facilities. Qualitative data on program disruption and adaptations/mitigation actions will also be considered. Data will be drawn from various available sources, including grant financial and programmatic reporting, LFA COVID-19 surveys, the Global Fund COVID-19 Indicator Survey, Global Fund spot checks, and WHO and other partner and country reports (e.g. early guidance from ACT-Accelerator and GAC partners). The Secretariat will leverage and support the strengthening of in-country data systems to enhance available data (for example, the Global Fund is also supporting updating HMIS for COVID-19 surveillance (e.g. DHIS2 or other COVID-19 modules) in many countries). The Secretariat is also expanding the investment tracking categories for C19RM, which will improve input data and facilitate enhanced reporting. These categories will be aligned as much as possible to the WHO response pillars for national strategic preparedness and response plans.

Finally, and as noted in the Board paper, the Secretariat will engage with the TERG to fund and develop an evaluation approach to C19RM investments. It is important to note however that any monitoring and evaluation of COVID-19-specific interventions, such as with respect to diagnostics and Oxygen therapeutics, should be approached in conjunction with ACTA-A and other relevant partners to allow for efficient and coordinated multi-stakeholder approaches.

14. 5% funding for centrally managed investments

The purpose of centrally managed limited investments (of up to 5%) is to enable support for cross-cutting areas of need that cannot be addressed through funding requests from individual countries, but that are necessary for the effective design, programming, coordination and implementation of C19RM investments. Strategic areas for investment are informed by lessons learned from phase 1 where cross-cutting gaps in effectiveness of C19RM investments at country level were observed and where refinements in the next phase are needed.

For example, lessons from phase 1 show that there was a lag in adoption of new tools and technologies e.g. PPE, Antigen RDTs and suboptimal requests for Oxygen products in part due to limited capacity, countries not understanding full scope of needs resulting in suboptimal demand, and delays in issuing technical guidance. Targeted investments to support demand generation and the acceleration of the introduction of new products (including through pre-qualification) and innovations could facilitate the introduction of new interventions incountry.

Additional strategic priority areas may include: centralized technical assistance for the development of C19RM requests and implementation of interventions, given the significant additional resources anticipated, need to embed partner support and technical rigor at country level, and need to ensure synergies with 6th replenishment grants; support for engagement of those most impacted by and vulnerable to COVID-19 in the development and implementation of C19RM interventions; support for coordination on community-led monitoring (including for reporting on human rights violations and GBV); and support for global and regional platforms coordinating the COVID-19 response where expertise is new and evolving, and where incountry capacity is limited.

This funding is separate and distinct from the catalytic funding under existing Strategic Initiatives, although the Secretariat will evaluate whether existing Strategic Initiative platforms (including existing agreements and plans) can be leveraged to deploy C19RM funds. The Secretariat is also evaluating how to ensure alignment with existing strategic priorities addressed through Strategic Initiatives, and where adaptations of existing Strategic Initiatives should be further enhanced to better address COVID-19 needs, within their original scope.

The Secretariat is still developing the design and decision-making process for these investments, but the process will be aligned with, and fully informed by, cross-cutting gaps in investments at country level, as ultimately these centrally managed investments will support needs and foundational areas necessary to ensure the success of country C19RM investments. In line with the approach to C19RM funding for countries, the Secretariat recognizes that there is value in considering upfront consultations with relevant partners in defining strategic priorities that cannot be addressed through country funding requests alone, to ensure alignment with the robust guidance provided to countries and facilitate coordination with other donors. Given lessons learned from Strategic Initiatives, GAC partners could provide input in shaping the strategic priorities proposed by the Secretariat through the C19RM GAC updates. This would provide additional technical validation on scope, expected outcomes and outputs and ensure responsiveness of proposed strategic priorities and actions to crosscutting problems observed at country and regional levels. Any potential or actual conflicts of interest will be managed as appropriate. As with country-level funding, the review and decision-making process will need to balance speed with ensuring technical review and oversight.

The details of any investments made under this provision (including amount, recipient, scope, and expected outcomes/outputs) will be reported to the Board through its relevant committees.

15. 3% management and operational costs

Up to 3% of C19RM funds will be used to ensure adequate support from the Secretariat, robust assurance, rigorous monitoring and evaluation, and reinforced reporting on C19RM investments. These resources will be managed separately from the annual Secretariat OPEX budget and will be fully time-bound, reflecting the temporary nature of C19RM; no increase to OPEX recurring costs is therefore foreseen.

Additional management and operational costs are envisaged for three main areas: (i) strengthening internal Secretariat resources and expertise, (ii) increased costs relating to the provision of assurance over C19RM funding, and (iii) costs associated with enhanced monitoring, evaluation, and reporting on C19RM investments.

For internal Secretariat resources, the Secretariat anticipates that additional resources will be required primarily to: strengthen internal technical expertise; enhance engagement and coordination with partners (both in the HTM space for scale-up in HTM mitigation responses and through ACT-Accelerator for the pure COVID-19 interventions covered under C19RM); strengthen monitoring, evaluation, and reporting; support the increased workload associated with operationalizing C19RM (covering a range of elements such as supporting the submission and review of funding requests, tracking awards and overall resources, executing changes required to existing internal systems and controls, supporting increased sourcing activity, overseeing implementation and assurance, supporting additional monitoring and evaluation activities, and preparing enhanced reporting). An internal needs assessment is ongoing. Any additional staff will be contracted on defined duration contracts aligned to the temporary duration of C19RM funding.

Additional external costs are also envisaged for assurance and monitoring and evaluation, including for LFA services, which need to be enhanced and expanded to cover C19RM funding, as well as costs associated to both developing and executing a monitoring and evaluation approach for C19Rm, which may entail additional TERG costs.

The Secretariat will provide regular reporting on these expenditures to the Board through its relevant committees. Reporting granularity will be aligned with OPEX (by nature and by function) and be integrated as part of the Financial performance update.

16. <u>Timelines for Use</u>

Given the scale and urgency of country needs for their COVID-19 responses. C19RM funds will be used quickly, regardless of whether an independent funding use deadline exists. The Secretariat's proposal to set a funding use deadline for the end of 2023 is not intended to contradict the emergency nature of C19RM, nor encourage use of funding over this entire period, but instead reflects consideration of the significant cost and effort associated with monitoring and enforcing a funding use deadline that is separate from the framework governing core grants. The introduction of a separate deadline requires ringfencing of funding, segregated budgeting, additional verification and evaluation by both implementers and LFAs, and introduces complexity for both implementers (especially where a combination of both C19RM funding and grant funding is used for interventions) and the Secretariat, whose internal controls and systems are organized around core grants. The additional level of effort required to separate monitor and enforce an independent deadline is felt most acutely by in-country implementers, who are already under strain with the demands of launching implementation under new grants in addition to incorporating C19RM interventions into their programs. This recommendation is informed by lessons learned during the first phase of C19RM, and country feedback in particular.

17. C19RM absorption and use

Investment breakdown: While of the USD 759 million that was awarded through C19RM, (i) USD 243 million (32%) was for mitigating impact on HTM responses, (ii) 442 million (58%) for reinforcing national COVID-19 responses, and (iii) USD 74 million (10%) for urgent improvements in health and community systems, such final breakdown was not predetermined by the Global Fund, rather, it was a result of prioritization decisions made by country applicants through consultative CCM dialogue (including with partners) and alignment with technical guidance and national strategic plans. Coordinated partner engagement with national and CCM leadership in C19RM request development remains essential to ensuring high quality, prioritized funding requests that form a key part of the national response, and are complementary to support from other partners. The Secretariat anticipates maintaining this country-driven approach to prioritization of need. It is difficult to determine what the breakdown of funding per C19RM category will be with additional funding, but the process for awarding funding will continue to take into account changing country needs, other country-specific contextual information and the interaction with other planning and funding processes, including domestic budgeting and interaction with other funders.

<u>Absorption</u>: C19RM awards were integrated into existing grants and are subject to the reporting of the underlying grant agreements. We do not monitor expenditure by subcategories separately. Since most of the C19RM funds were integrated into their grants during the second half of 2020, these grants are not yet due for full-year reporting. However, early indicators (USD 180 million in disbursements and USD 119 million in PPM, excluding procurement from UNICEF and UNDP) from the OIG audit, which solicited country feedback through two tailored surveys to CCMs, and the use of in country cash as soon as award notification is received (pending C19RM funding being integrated into the relevant grants) show that absorption is on track. By the time awards under C19RM 2.0 are made, absorption rates for the 2020 awards should be available.

18. Exceptions to pre-ship testing and sampling requirements under QA policies

To date, there were 3 requests to waive pre-shipment inspection and testing requirements for an ERP-approved product risk category 3. These were considered by the Health Product Risk Committee (HPRC) in May 2020. The HPRC considered the specific circumstances of each request, balancing quality, safety and efficacy/performance of health products with respect to impact on consumer health, programmatic impact, procurement and supply availability, the country disease situation and legal and institutional aspects. In two instances, the HPRC did not approve the waiver request as it was determined that there was insufficient evidence of an urgent programmatic need, due to adequate in-country stock levels. In one instance, there was an urgent program need, there was no history of out-of-specification test results for the product from earlier shipments and samples had already been taken and were with the Quality Control laboratory. The HPRC in this instance authorized shipment in parallel to testing; the country was informed that testing was still underway and that results would be communicated as soon as they became available. The country was subsequently informed that there were no out-of-specification results from the testing. It is possible that no additional waiver requests will be received. However, permitting the Secretariat to retain this flexibility to consider individual waiver requests (where strict compliance with the requirement could risk delaying the timely arrival of quality-assured life-saving health products), can permit a rapid, balanced response in specific instances to minimize supply disruptions.

Annex 5 – Relevant Past Decisions

Relevant past Decision Point	Summary and Impact
GF/AFC14/EDP04 ⁴⁰ : Approval of Available Sources of Funds for the C19RM Mechanism (December 2020)	The Audit and Finance Committee (i) approved an additional amount of USD 41 million as available sources of funds;
	(ii) acknowledged that the additional amount of USD 41 million would be applied to C19RM pursuant to Board decision points GF/B42/EDP11 and GF/B43/EDP12; and
	(ii) accepted that the total available sources of funds for C19RM would accordingly be USD 759 million.
GF/AFC14/EDP02 ⁴¹ : Approval of Available Sources of Funds for the C19RM Mechanism (November 2020)	The Audit and Finance Committee (i) approved an additional amount of USD 53 million as available sources of funds;
	(ii) acknowledged that the additional amount of USD 53 million would be applied to C19RM pursuant to Board decision points GF/B42/EDP11 and GF/B43/EDP12; and
	(iii) accepted that the total available sources of funds for C19RM would accordingly be USD 718 million.
GF/B43/EDP12 ⁴² : Extension of C19RM	The Board:
Timeline and Operational Flexibility for COVID-19 (September 2020)	(i) decided that the Secretariat may approve requests for C19RM funds through 15 April 2021;
	(ii) affirmed that all other previously approved principles under GF/B42/EDP11 would continue to apply to C19RM;
	(iii) requested the Secretariat to return to the Board, through its committees as relevant, for additional consideration and approval should further extensions of C19RM be required, or if total additional funding for C19RM exceeds USD 500 million; and
	(iv) approved that the operational flexibility under paragraph 3 of GF/B42/EDP10, delegating authority to the Secretariat to grant limited exceptions to the quality assurance policies to waive the requirement

 ⁴⁰ <u>GF/AFC14/EDP04</u>
 ⁴¹ <u>GF/AFC14/EDP02</u>
 ⁴² <u>https://www.theglobalfund.org/board-decisions/b43-edp12/</u>

Relevant past Decision Point	Summary and Impact
	for pre-shipment sampling and testing, would apply through 15 April 2021.
GF/AFC13/EDP01: Approval of Available Sources of Funds for the C19RM Mechanism (August 2020)	The Audit and Finance Committee (i) approved the additional amount of USD 165 million as available sources of funds;
	(ii) acknowledged that the additional amount of USD 165 million will be applied to C19RM pursuant to Board decision point GF/B42/EDP11; and
	(iii) accepted that the total available sources of funds for C19RM shall accordingly be USD 665 million.
GF/B43/EDP07 ⁴³ : Extending the wambo.org pilot to include COVID-19 products (July 2020)	The Board extended the scope of the pilot approved by GF/B42/DP05 to include COVID-19 products available in wambo.org for procurement by Global Fund Principal Recipients, subject to certain conditions and reporting.
GF/B42/EDP11 ⁴⁴ : Additional Support for Country Responses to COVID-19 (April 2020)	The Board has approved the creation and initial funding up to USD 500 million of a COVID-19 response mechanism to finance interventions consistent with WHO guidance on COVID-19 in the context of national Strategic Preparedness and Response Plans across the 5th and 6th replenishment periods.
GF/B36/DP04 ⁴⁵ : Approval of the Amended and Restated Comprehensive Funding Policy (November 2016)	Based on the recommendation of the Audit and Finance Committee, the Board approves the Amended and Restated Comprehensive Funding Policy, as set forth in Annex 1 to GF/B36/02 - Revision 1.

 ⁴³ <u>https://www.theglobalfund.org/board-decisions/b43-edp07/</u>
 ⁴⁴ <u>https://www.theglobalfund.org/board-decisions/b42-edp11/</u>
 ⁴⁵ <u>https://www.theglobalfund.org/board-decisions/b36-dp04/</u>

Annex 6 – Relevant Past Documents & Reference Materials

GF/B43/ER10:<u>Extension of C19RM Timeline and Operational Flexibility for COVID-19</u> GF/B42/ER09: <u>COVID-19 Response for Business Continuity and Country Support</u>