

C19RM Monthly Update to the Board

Report for September - October 2021

Publication Date: 29 October 2021

Geneva, Switzerland

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) Health Products Overview



Focus on Genomic Surveillance

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Progressive Development of C19RM Reporting.

The <u>previous board report</u> focused on 2020 health product delivery and distribution data, investments in community systems, insights on surveillance systems strengthening and ongoing operationalization of the Monitoring and Oversight framework. This report will include the regular updates on awards, health products and non-oxygen therapeutics and will focus on genomic surveillance as a thematic area, given the detailed update on diagnostics in the previous report.

Update on COVID-19 Epidemiological Situation and Disruption to HIV, TB and Malaria

Services. In most low- and middle-income countries, the crisis is far from over, with infections and deaths from COVID-19 continuing to increase, and the knock-on impact on HIV, TB and malaria continuing to escalate.

HIV, TB and Malaria Program Disruption. The overall trend of individuals newly starting on ART is decreasing in 2021 compared to 2019 and 2020. With the drop in case management for malaria, we face a risk of a spike in mortality. While some countries in Asia are recovering gradually, much of the progress we've made to close the gap on finding missing people with TB has also been reversed.

<u>C19RM 2020 Updates (Absorption).</u> C19RM 2020 in-country execution and funds utilization is estimated at 63%-70% after an average implementation period of 6-8 months as of 30 June 2021. This analysis is based on High Impact and Core Countries representing 90% of investments.

C19RM 2021 Funding Request and Awards. As of 20 October 2021, C19RM has awarded or recommended for Board approval US\$3,084 million to over 116 applicants, for a portfolio average of 24% of the 2020-2022 allocation.

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Update on COVID-19 Epidemiological Situation and Disruption to HIV, TB and Malaria Services

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C19RM 2021 Funding Requests and Awards Overview

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Health Products Overview.

- Of the total US\$3,084 million awarded by 20 October, US\$477 million was for <u>oxygen</u> and clinical care-related products representing 15.5% of overall health product spend. We have also awarded US\$2 million for a special project on pressure swing adsorption (PSA) plants (Project "Build Oxygen for the COVID-19 Emergency Response", aka Project BOXER).
- Out of the US\$171 million invested in <u>non-oxygen therapeutics</u>; over US\$ 34 million has been invested in evidencebased pharmaco-therapies that have demonstrated benefits in reducing COVID-19 mortality. This includes one country, Honduras, with approved financing for the newly recommended IL6 Blocker, tocizilumab.
- Over US\$512 million is now invested in personal protective equipment (PPE) across all three C19RM Board priority areas. The Secretariat has continued to identify specific areas of investment for PPE and for malaria. For example, we are taking on new approaches for PPE prioritization for malaria such as working with national programs and partners to identify PPE gaps.
- **Diagnostics** remain a priority, representing around US\$690 million 22.4% of awarded C19RM 2021 funds and should enable the supply of more than 120 million tests. Having covered diagnostics in detail in the previous report, in this report we have provided more information on genomic surveillance and will share further updates on diagnostics in future reports.

6 Focus on Genomic Surveillance.

The ongoing response to COVID-19 has demonstrated the need to leverage existing investments in core grants to strengthen surveillance capacity as part of a robust COVID-19 surveillance system. Continued genomic surveillance enables health authorities, governments, and researchers to monitor the evolution of COVID-19 and adjust response accordingly. While since 2014 the Global Fund has budgeted a total of US\$13.2 million for genomic surveillance in core HIV, TB and malaria programs, and there is a significant increase of US\$37 million for COVID-19 genomic surveillance from C19RM funding, this is still low.

<u>C19RM Country Case Studies.</u>

- <u>Peru:</u> The C19RM award of US\$14,937,883 allowed the country to invest in genomic surveillance and strongly engage with communities in awareness-raising campaigns on gender-based violence and human rights; as well as support mental health of affected communities.
- <u>Malawi:</u> The C19RM award of US\$102,555,602, has enabled the country significant investments in COVID19 national response, HTM mitigation and urgent health systems support. Malawi has faced some challenges across the three areas. For mitigation for example, Malawi saw declines in facility attendance for mitigation, but also exhibits some commendable practices such as expansion of mobile integrated clinics for treatment services

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C19RM 2020 Absorption



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Health Products Overview



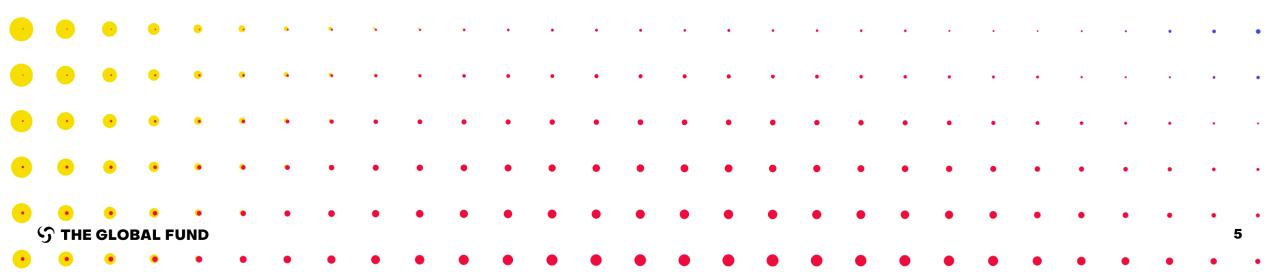
Focus on Genomic Surveillance





Progressive Development of C19RM Reporting

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REPORT FOCUS

Progressive development of C19RM Monthly Reporting

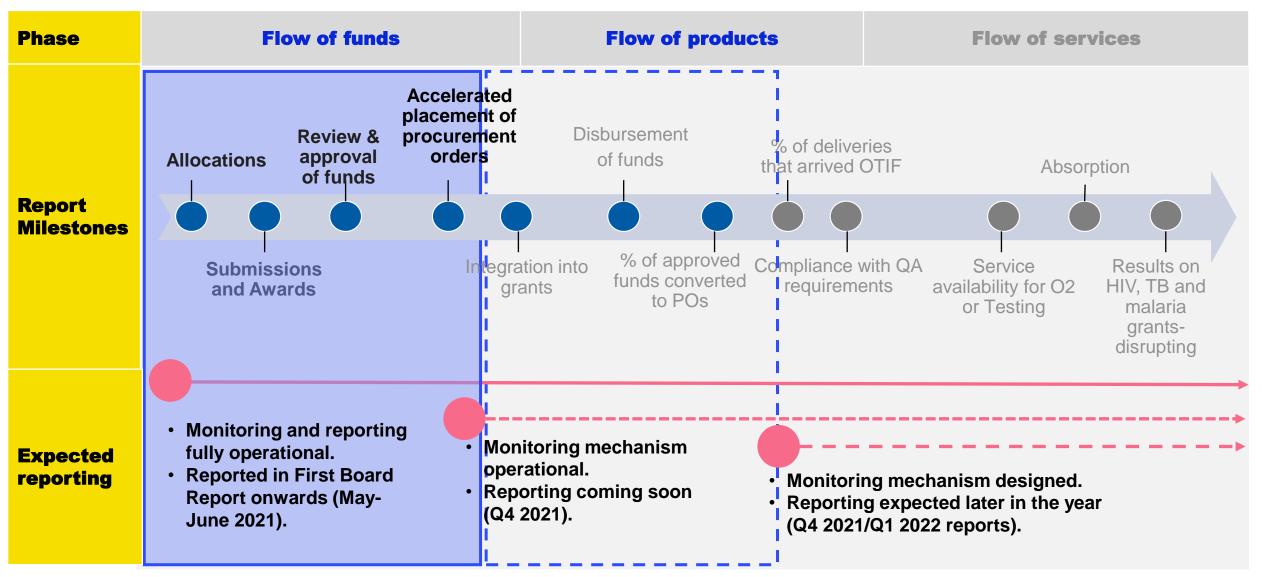
In last month's report, we covered COVID-19 program disruption, award and pipeline updates, lessons learned and case studies. We will continue to update these sections on subsequent reports and provide additional analysis on emerging themes. Greater details on these core sections will be included as relevant data becomes available.

Last Report	This Report	Subsequent Reports		
 Last Report C19RM 2020 update including 2020 distribution and delivery of health products and available estimated absorption data. COVID-19 and HIV, TB and malaria disruption update with Q2 estimates. C19RM 2021 Awards and Pipeline update. Health Products Overview, including detailed update on diagnostics, PPE and oxygen. Focus on Surveillance pillar as key resilient and sustainable systems for health (RSSH) component. Assurance Monitoring and Oversight framework and update. Case Studies on resilient systems strengthening. 	<section-header><list-item><list-item><list-item><list-item><list-item></list-item></list-item></list-item></list-item></list-item></section-header>	 Future reports will cover topics as relevant data becomes available. C19RM 2020 update including 2020 distribution & delivery of health products and absorption data as available. C19RM 2021 Programmatic data including financial data as it becomes available. COVID-19 and HIV, TB and malaria disruption update. C19RM 2021 Awards and Pipeline. Health Products Overview including order placement and delivery. Overview of thematic areas: topics based on issues highlighted in reviews, GAC/CTAG meetings and Board calls, bidirectional testing. Assurance Monitoring and Oversight framework and update. Case Studies: on emerging lessons/ 		

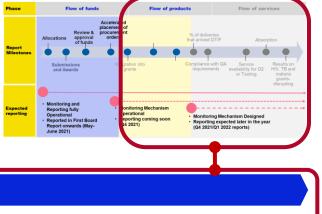
successes relevant to thematic areas.

REPORT FOCUS

Progressive Development of C19RM Monthly Reporting



The Monitoring and Oversight (M&O) framework has been largely operationalized, with data expected from new reporting tools from Q4.



	Award	Implementation					
Phase / Focus		Financial	Health products	Services	Programmatic		
Indicators	 Funding Request pipeline Funds approved and committed Investment in Board categories, interventions and pillars Unfunded demand 	 Disbursement forecast Actual disbursement Expenditure 	 Order placement In-country central delivery Delivery at facility / testing site level On-shelf availability 	 Service availability: testing and oxygen therapy Service disruption at health facility and community sites Implementation progress (PR evaluation) 	 Tracer indicators for HIV, TB and malaria Programmatic performance at country and portfolio level 		

	Pulse Checks	LAUNCHED	Pulse Checks were launched on 4 October. The closing date for PR submissions is 5 November. Data being reported through Pulse Checks includes aggregated data on expenditure and forecasts, PR assessment of implementation progress and programmatic results.
Ĭ	Supply Chain & Health Services Spot Checks	LAUNCHED	Contracts signed with service providers for Supply Chain and Health Services Spot Checks. Suppliers are being onboarded, including country level introductions. Data collection has started in a subset of countries with scale-up planned throughout November.
	Strengthened processes for monitoring and oversight	LAUNCHED	Strengthened internal processes for monitoring and oversight have been implemented. Performance of upstream processes are frequently and regularly reviewed through a dedicated cross-cutting forum, and quarterly reviews will leverage data being collected through Pulse Checks and Spot Checks.

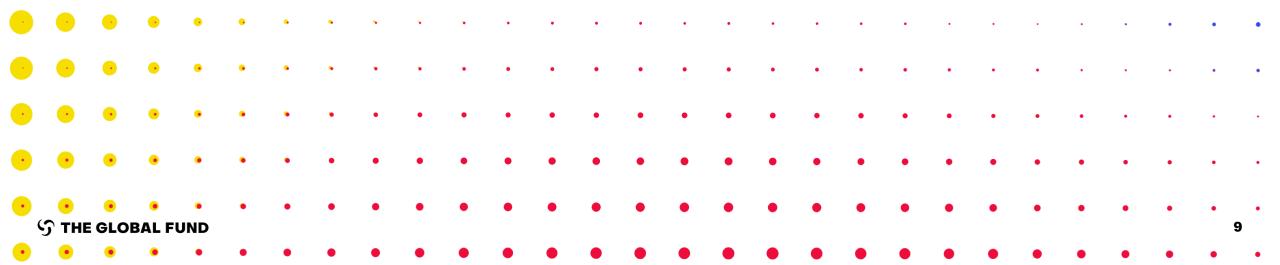
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Update on COVID-19 Epidemiological Situation and Disruption to HIV, TB and Malaria Services.

HIV, TB and Malaria Disruption

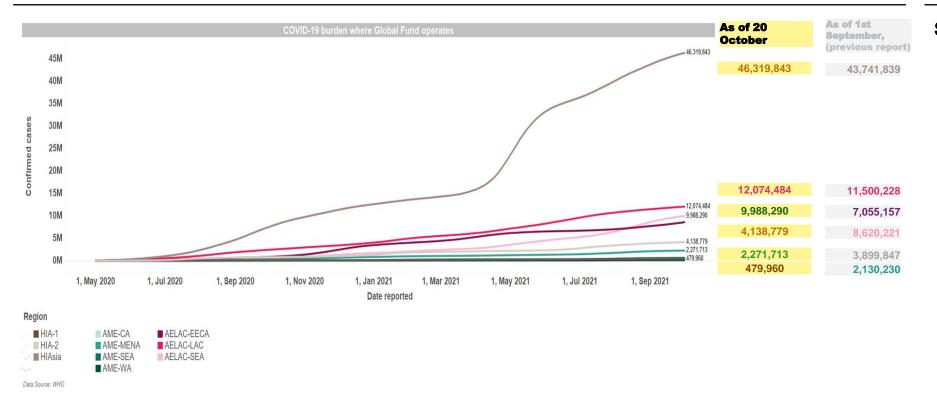


COVID-19 EPIDEMIOLOGICAL SITUATION

COVID-19 burden in the regions we support

High Impact Asia remains the region with the highest confirmed cases.

Low testing and the spread of the Delta variant suggest infections far outnumber confirmed cases.



Note that true infections far outnumber confirmed cases in many countries. See <u>https://ourworldindata.org/covid-models</u>

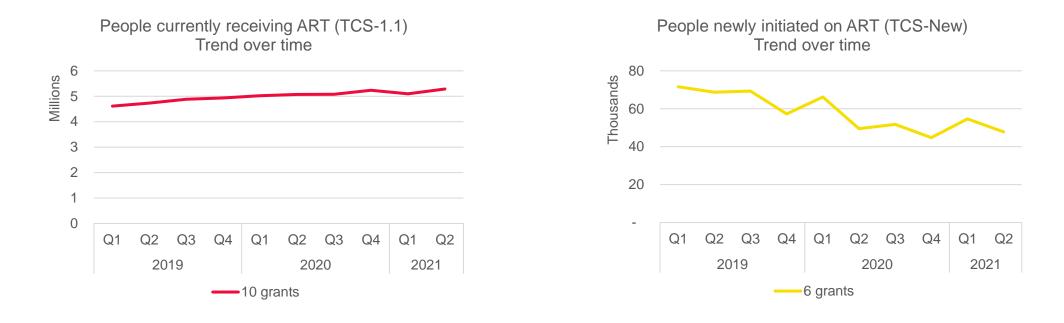
<u>*High Impact Africa 1:</u> Burkina Faso, Congo (DRC), Côte d'Ivoire, Ghana, Mali, Nigeria
<u>**High Impact Africa 2:</u> Ethiopia, Kenya, Mozambique, South Africa, Tanzania, Uganda, Zambia, Zanzibar, Zimbabwe,

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SUMMARY

- Globally, as of 20 October 2021, there have been 241,411,380 confirmed cases of COVID-19, including 4,912,112 deaths reported to WHO. The surge in COVID-19 cases may be attributed to the rapid spread of the more infectious Delta variant.
- As of 20 October 2021, High Impact Asia has 46,319,843 confirmed cases, a raise of more than 2.5 million in less than two months. Cases in Southeast Asia also show a rise in number at over 9 million.
- Confirmed cases in Latin America and Caribbean are at over 12 million while those in High Impact Africa 2* and High Impact Africa 1* continue to rise to over 4 million and 479'000, respectively.
- Over ten Global Fund implementing countries are also among the top 25 countries in the world with the highest cumulative cases. These include India, Russia, Iran, Indonesia, South Africa, Philippines, Malaysia, Peru, Iraq, and Thailand.

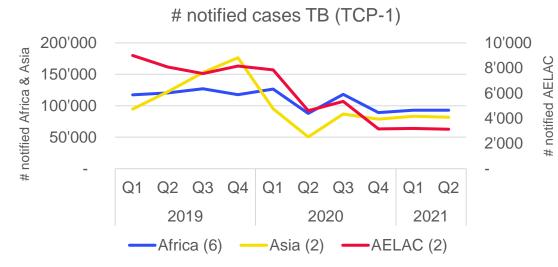
Although there is an increase in the number of people on antiretroviral therapy (ART), the country samples indicate that the number of people newly initiated on ART is declining.



- Of countries with complete data, there continues to be increases in the number of people on ART.
- The overall trend of individuals newly starting on ART is decreasing in 2021 compared to 2019 and 2020. Note this trend is based on a small sample.

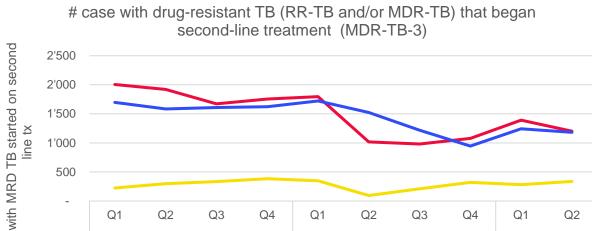
CONTEXT: PROGRAMMATIC DISRUPTION – TB

Delivery of TB services is stabilizing in the first half of 2021 Still showing lower progress relative to first semester of 2019.



Target Candidate Profile-1 (case notification):

Results semester 1 (S1) relative to S1 2019



Africa (6)

MDR TB-3:

Q1

Results semester 1 (S1) relative to S1 2019

AELAC (2)

2019

Region (# countries)	2020	2021	Trend	Region (# countries)	2020	2021	Trend
AELAC (2)	73%	51%	-	AELAC (2)	72%	92%	
Africa (6)	90%	87%	+	Africa (6)	99%	75%	+
Asia (2)	67%	113%		Asia (1)	85%	139%	\uparrow

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Ongoing Actions

- Support course correction for TB case notification.
- Monitor and support course correction for MDR (Multi Drug Resistant) TB in Africa & AELAC.
- Engage PRs to increase data reporting rates.

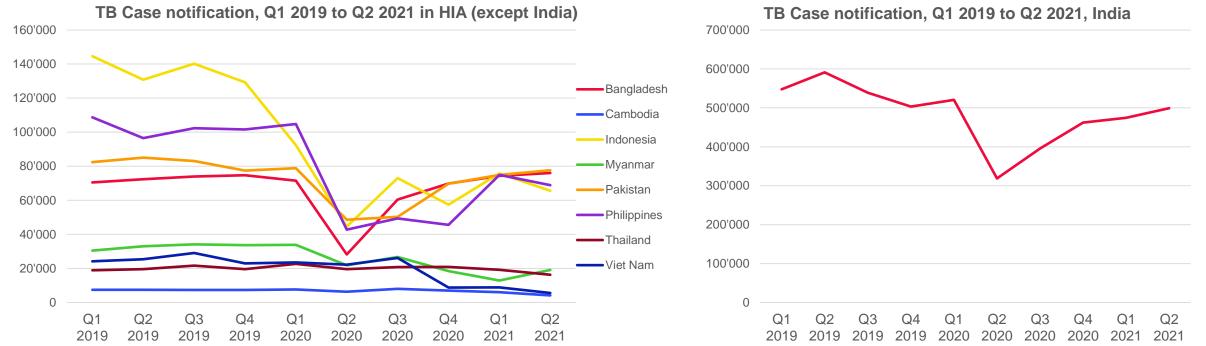
2020

Asia (1)

Q1

2021

Focus on High Impact Asia: TB case notification is recovering but not to pre-COVID-19 levels.



Insights

India & Pakistan: recovering gradually, on the way to pre-COVID-19 level Bangladesh: Recovered and exceeded pre-COVID-19, need to sustain and scale-up Cambodia and Thailand:

low level of disruptions

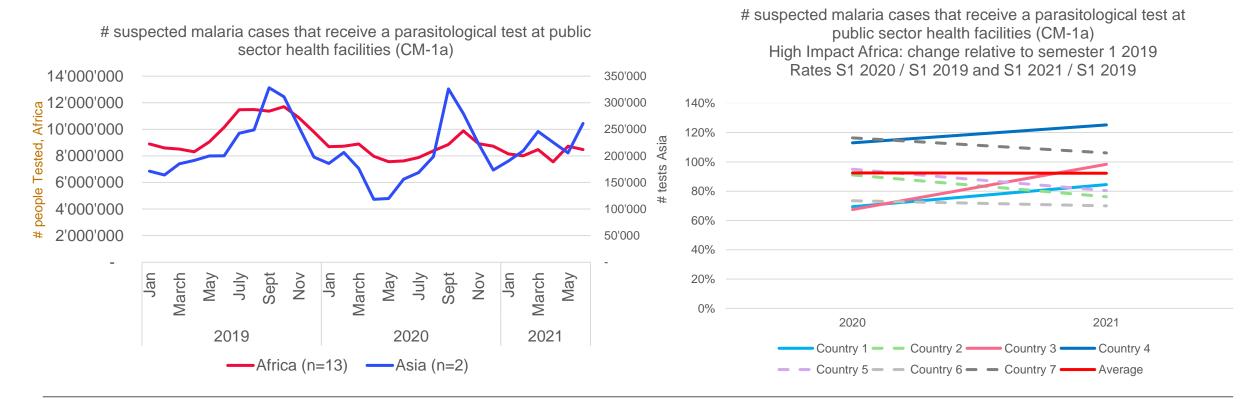
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Viet Nam:

Disruptions experienced since Q4 2020 and worsening

Indonesia and Philippines: recovering but very fragile **CONTEXT: PROGRAMMATIC DISRUPTION – MALARIA**

Suspected Malaria Cases Trends in 2019, 2020 and 2021 Semester 1 data in 2020 and 2021 on suspected malaria cases tested illustrate the same trend documented in semester 1 of 2019.



Semester 1 (S1) of 2020 and 2021 showed the same decline relative to 2019 based on the data of 15 countries in Africa and Asia. However, this data does not illustrate country differences: with **five countries showing improvements** (three High Impact and two Core countries), while **seven other countries** (three High Impact and four Core countries) showed S1 2021 levels decline further relative to 2019. The other **two countries** remain stable.

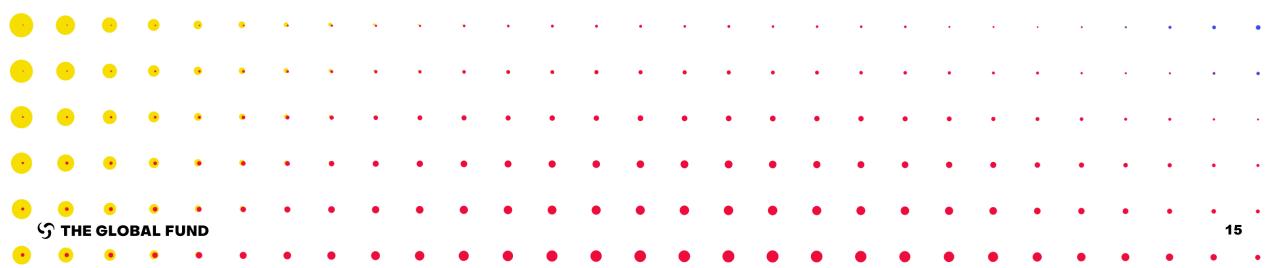
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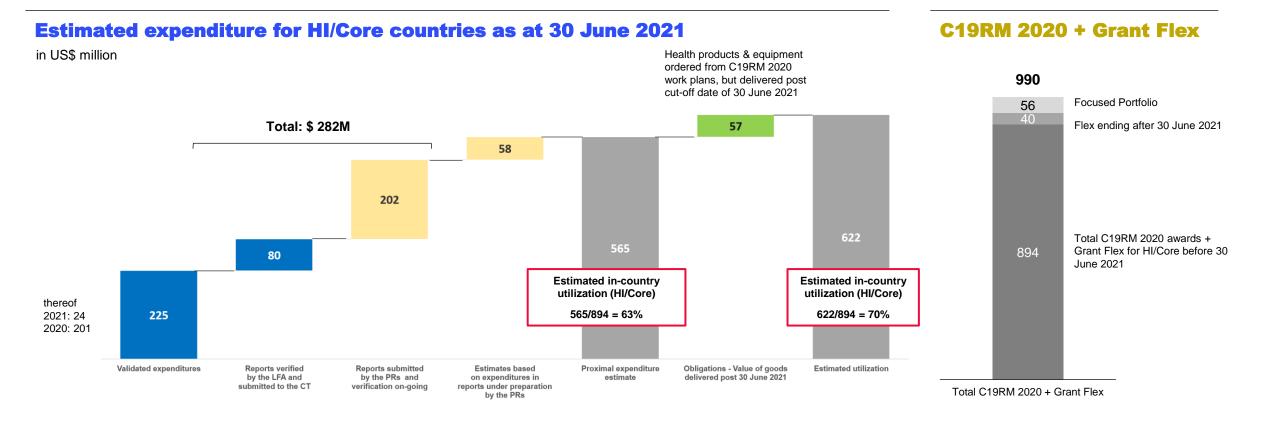
Update on COVID-19: C19RM 2020

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Absorption and Product Delivery



C19RM 2020 in-country execution and utilization is estimated at 63%-70% after an average implementation period of 6-8 months.



- Analysis focus on 54 High Impact and Core Countries, representing 90% of total C19RM 2020 investments.
- Taking into account the further technical analysis of financial reports in the pipeline, the Secretariat estimates that C19RM 2020 final utilization as of 30 June 2021 will be within 63%-70% against total awards and grant flexibilities, taking into account the slippage on health product procurement.

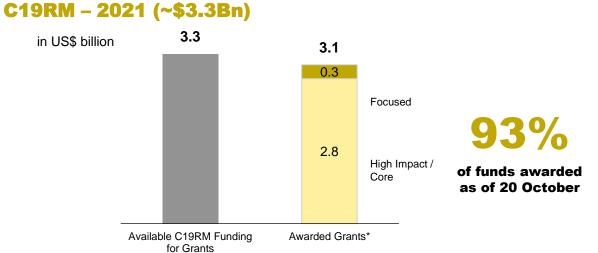
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Integrating lessons from C19RM 2020, strong acceleration for C19RM 2021 related processes



2020: After 8 months 80% of awards granted. Impact of COVID-19 on implementer's ability to rapidly execute and provide timely reporting in the current context.

- The analysis is based on High Impact and Core Countries representing 90% of investments.
- **Updated in-country utilization estimates** of \$565M for HI/Core countries utilization at 63% as of 30 June 2021.
- **90% of expenditure estimates** (\$ 507M) based on validated reports or still being verified by LFA.
- 63% 70% utilization for an average of 6-8 months of in-country execution of a new initiative is above historical Secretariat trend for HIV, TB and malaria grants and strategic initiative (SI).
- Challenges in the supply chain pipeline impacted timely delivery of products delays encountered for products valued at \$57M with expected June delivery date.



2021: After 6 months 93% of awards granted. Illustrates accelerated deployment enabled by dedicated Secretariat resources.

- Disbursement forecast for 2021 of \$1.2Bn 95 % of available funds are forecasted to be disbursed by December 2023 (incl. transfer of unused C19RM 2020 funds to C19RM 2021).
- Lessons from C19RM 2020 award and execution processes are being mitigated through the monitoring and oversight framework. Strategic actions implemented also include
 - o Accelerated Award Approval facilitated by Investment Committee & GAC/CTAG Review.
 - $\circ~$ Enabled advanced procurement order and follow-up.
 - Finalized the pulse check portal for data collection launch from implementors (Q4/2021).
 - Specific country deep-dives as part of the Investment Committee to manage bottlenecks.

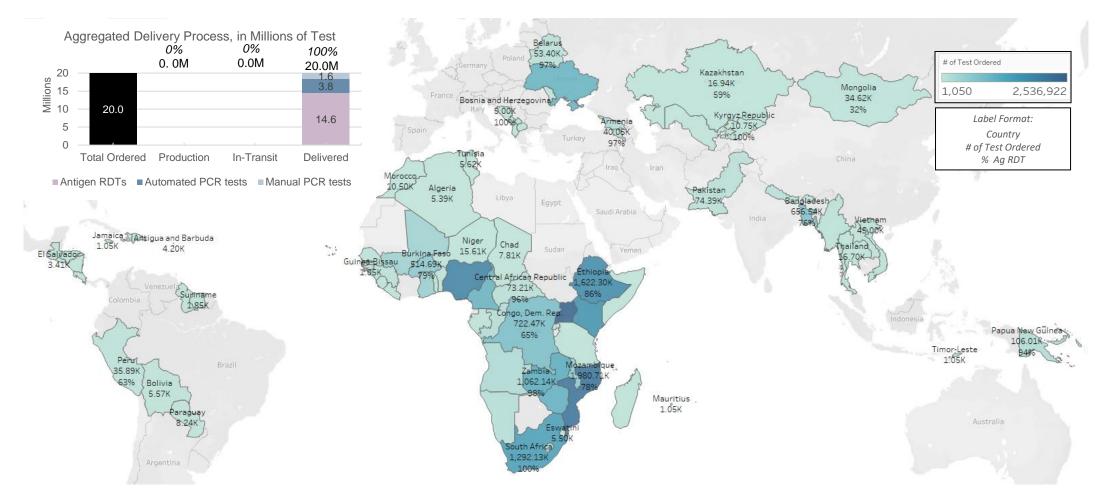
*Total may not sum up due to rounding

** Health products & equipment ordered from C19RM 2020 work plans but delivered post cut-off date of 30 June 2021.

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Principal Recipients from 79 countries invested C19RM 2020 funds to receive 20.0 million diagnostic tests through pooled procurement mechanism (PPM)/wambo.org*

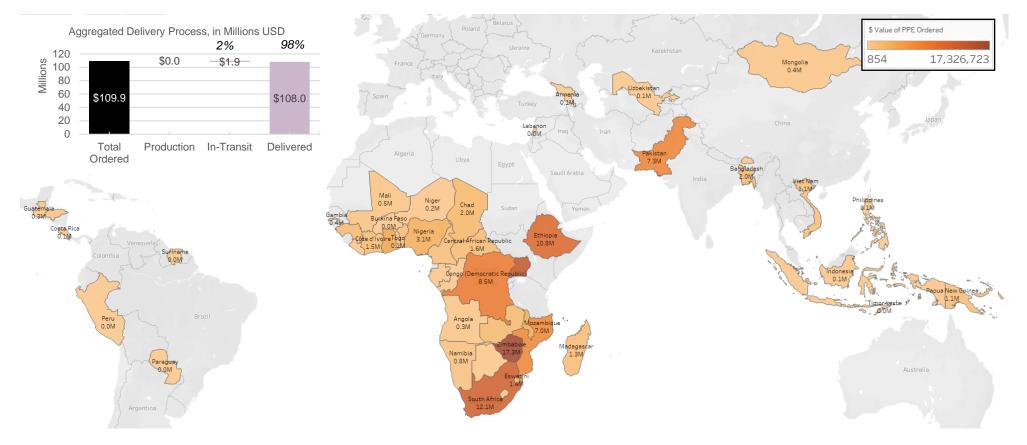
The ordered amount corresponds to 82% of total approved diagnostics funding in 2020 (US\$150/US\$182 million).



Principal Recipients from 52 countries invested C19RM 2020 funds to place orders of US\$110 million worth of PPE through PPM/wambo; 98% have been delivered*.

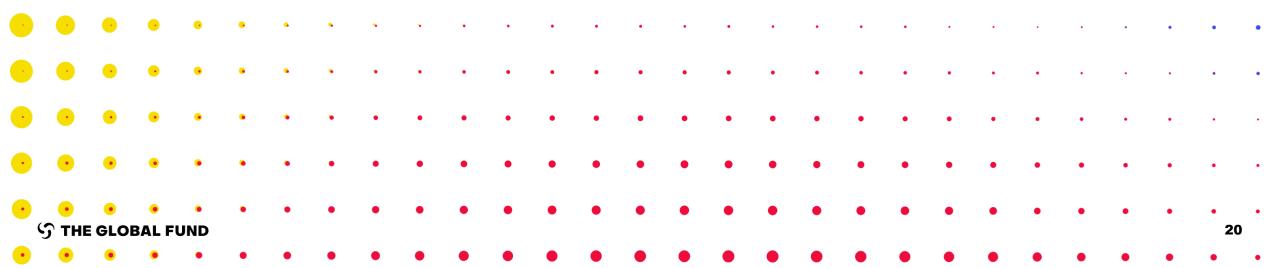
The ordered amount corresponds to 42% of total approved PPE funding in 2020 (US\$113/US\$267 million).

Note: Sourcing through PPM/wambo.org began in September 2020 - first through an engagement with UNICEF, and in a second phase from December through existing PPM-Procurement Service Agents (countries were encouraged to source locally until September 2020).









C19RM 2021 Awards: Highlights

C19RM 2021 Fast-track Requests Awarded

- The Global Fund has awarded US\$591 million to 36 applicants via Fast-track. Applicants to Fast-track have requested an average of 7% of their 2020-2022 allocation.
- Notification Letters with confirmation of awards are sent to applicants in an average of 7.3 business days.

C19RM 2021 Full Funding Requests Awarded

- US\$2,493 million awarded to 114 applicants, including funding recommended for Board approval, for a portfolio average of 20% of 2020-2022 allocation (excluding previously approved Fast-track applications).
- An Unfunded Demand of US\$1,025 million in demand pipeline registered by 70 countries.

C19RM 2021 Awarded by Priority Area, WHO pillar and ACT Accelerator pillar

- **C19RM Board Priority Areas:** US\$3,084 million have been awarded or recommended for Board approval with the following breakdown: 75% to reinforce national COVID-19 responses, 14% for urgent improvement to health and community systems, and 11% for HIV mitigation.
- WHO Pillars: C19RM awards are primarily directed towards Pillar 5: National laboratories (26%), Pillar 6: Infection prevention and control (24%) and Pillar 7: Case management (25%). The remaining investments are mostly awarded into Pillar 9: Maintaining essential health services and systems (11%).
- ACT-A Pillars: 85% of the US\$3,084 million C19RM awards is directed towards ACT-A Gap Filling Activities.

C19RM 2021 Status of Awards Submissions and Pipeline

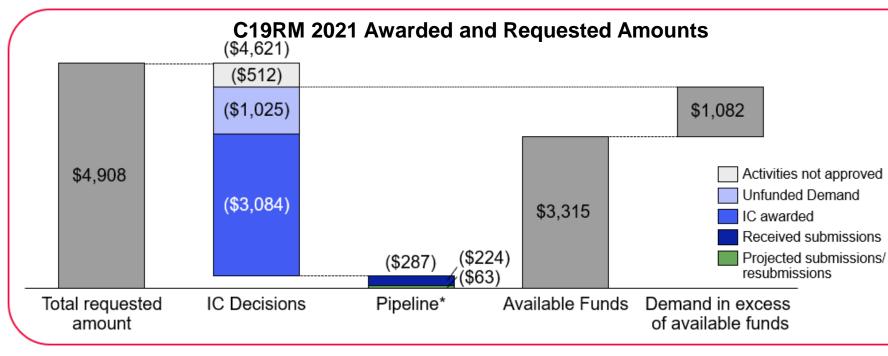


US\$3,084 million (93%) of C19RM 2021 funding is awarded or recommended for Board Approval to 116 applicants (either Fast-track or Full Funding request) for a portfolio average of 24% of HIV, TB and malaria allocation.

Full Funding requests: US\$2,493 million was awarded or recommended for Board approval to 114 applicants. **Fast-track requests:** US\$591 million was awarded to 36 applicants.

Including Unfunded Demand of US\$1,025 million for 70 applicants, the total of Investment Committee (IC) Decisions is up to US\$4,621 million. This includes US\$512 million of activities not approved.

Demand pipeline: 7% or US\$224 million has been submitted or under review for potential C19RM 2021 funding. US\$63 million is projected for submission or resubmission.



- Since the last monthly report 23 Full and three Supplementary Funding requests were awarded for an amount of US\$461 million.
- As of 20 October 2021, Full Funding Requests from four applicants were pending Board approval: Zimbabwe, Russian Federation, Cameroon and Congo (Democratic Republic).

All values are in US\$ million and rounded.

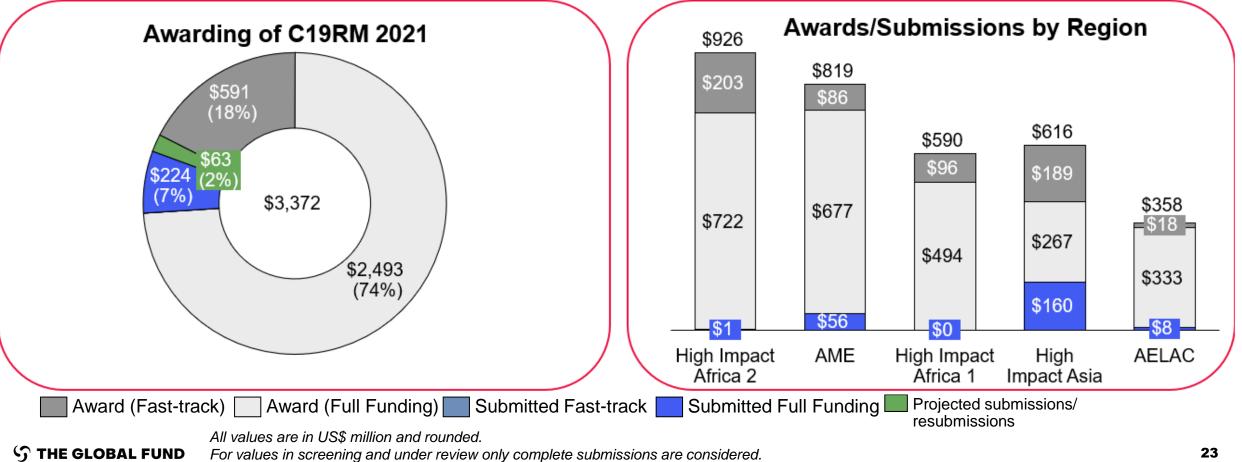
For values in screening and under review even incomplete submissions are reported.

*Pipeline includes submissions under review, in screening, projected resubmissions and remaining eligible applicants.

OVERVIEW: AWARDS AND SUBMISSIONS (as of Oct 20) C19RM 2021 Overall Award: Submission Drill Down

US\$3,084 million (93%) of C19RM 2021 funding is awarded or recommended for Board approval. Demand pipeline is robust in funding requests received/in process showing demand exceeds supply of available funds:

- Country demand is high with the majority of applications requesting 30% or more of their HIV, TB and malaria allocation.
- Unfunded demand of US\$1,025 million is registered from 70 applicants.

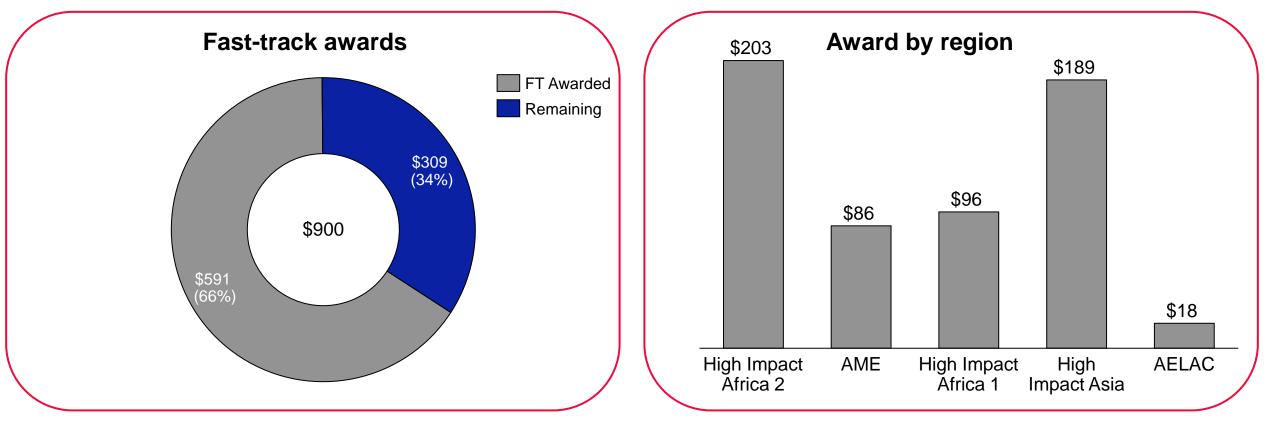


Values under Full Funding request awards also include values recommended for board approval.

OVERVIEW: AWARDS AND SUBMISSIONS

C19RM 2021 Fast-track Drill Down

- **US\$591 million is awarded** to 36 applicants via Fast-track (with an average of 7.2% of applicants' HIV, TB and malaria allocation). This represents 66% of the total Fast-track mechanism.
- In total 40 Fast-track requests were received, including four to be resubmitted due to incomplete documentation or withdrawn.



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For values in screening and under review only complete submissions are considered.

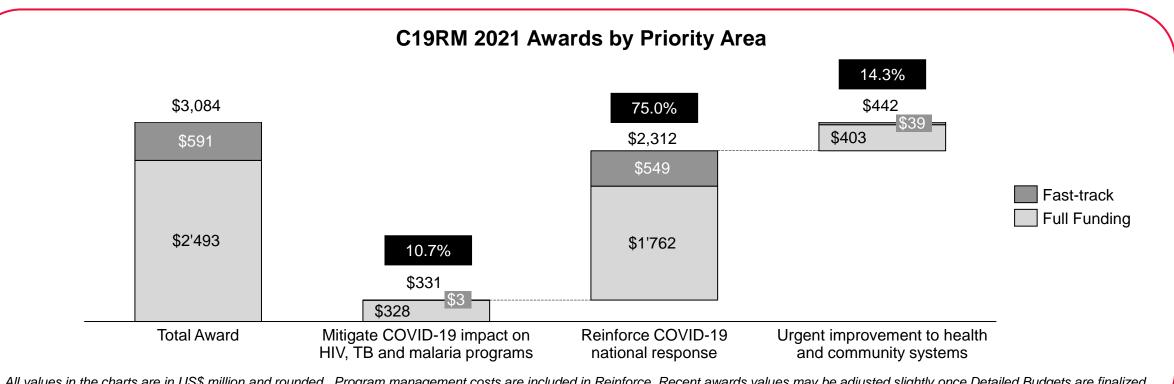
(as of Oct 20)

C19RM 2021 Award by Priority Area



Award by priority area: investments are mainly directed towards reinforcing COVID-19 national response.

Out of the Full Funding requests **awarded or recommended for Board approval**, we continue to see prioritization of reinforcing the COVID-19 national response likely due to the rapid increase in cases across a number of countries.

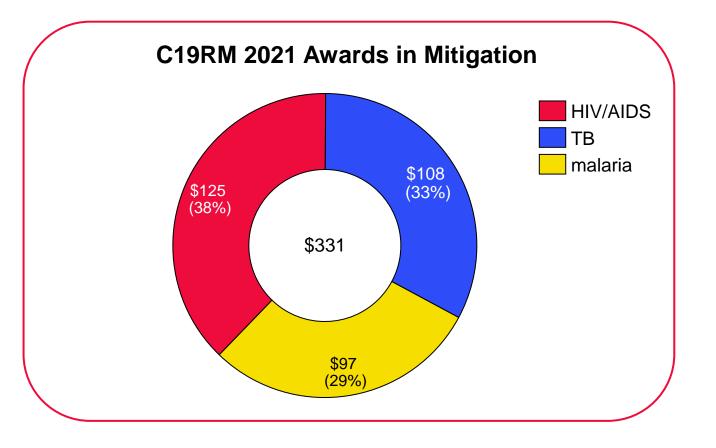


All values in the charts are in US\$ million and rounded. Program management costs are included in Reinforce. Recent awards values may be adjusted slightly once Detailed Budgets are finalized. Values above include Fast-track awards and Full Funding requests awarded and/ or recommended for Board approval.

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C19RM 2021 Investments in Mitigation

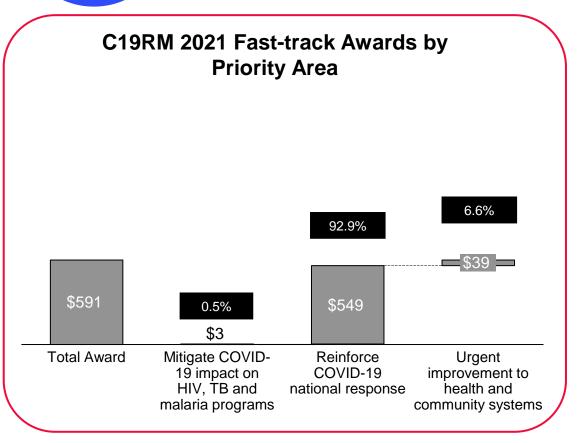
- Of the US\$3,084 million awarded (including recommendations for Board approval), US\$331 million (11%) is invested in mitigating the impact of COVID-19 on HIV, TB and malaria programs.
 - Investments in mitigating the impact of COVID-19 are primarily covered within the core HIV, TB, malaria grants (2020-2022 allocation); Malaria grants (2020-2022 allocation) incorporated a significant amount of PPE needs for mass campaigns and community activities.

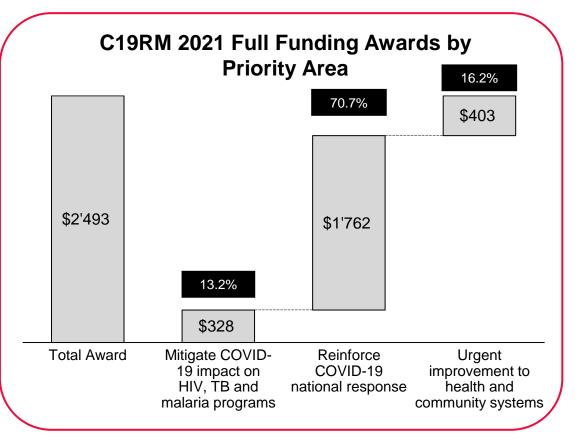


FUNDING REQUESTS AND AWARDS OVERVIEW

C19RM 2021 Award by Priority Area

Award by priority area: Fast-track investments are mainly directed towards reinforcing COVID-19 national response. Full Funding investments show a more balanced picture across the three priority areas.





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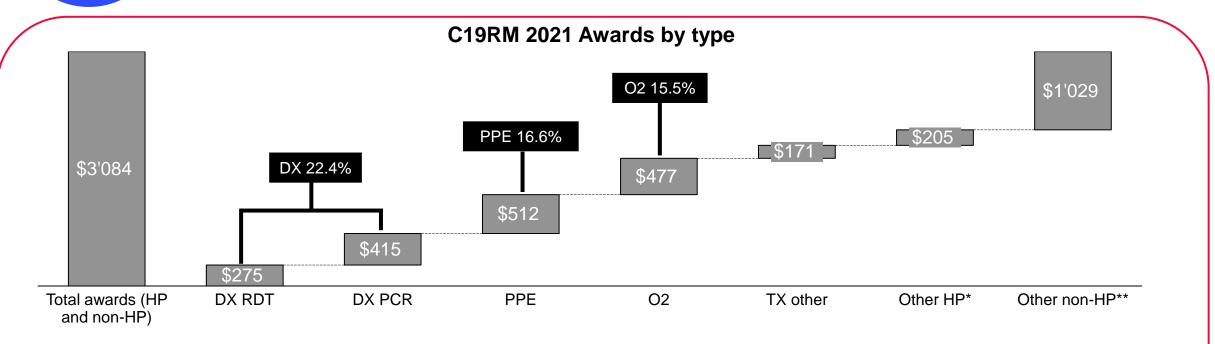
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FUNDING REQUESTS AND AWARDS OVERVIEW

C19RM 2021 Award by Health Products

Health product investments are more balanced across key Health Products.

Approximately 65% of awards to date are expected to use wambo as the procurement channel.



All values in the charts are in US\$ million and rounded. Recent awards values may be adjusted slightly once HPMTs are finalized. Note that these exclude C19RM 2020 carryover amounts. Values above include Fast-track awards, Full Funding requests awarded and/ or recommended for board approval.

Differences in values between Global Fund defined health products are accounted for by a more limited set of products that are included under these categories.

*Other Health Products include: non-PPE disinfectants, waste management and genomic surveillance, among others.

**Other non-Health Product investments include: most activities within "Mitigating COVID-19 impact on HIV, TB and malaria" and "Urgent improvements to health and community systems" as well as non-health product awards within "Reinforce COVID-19 national response".

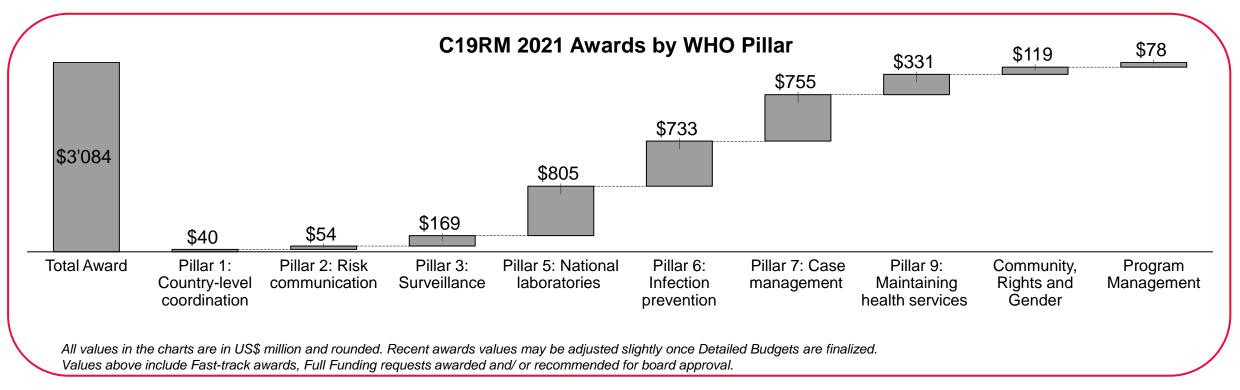
(as of Oct 20)

C19RM 2021 Award by WHO Pillars



C19RM investments are primarily directed towards Pillar 5: National laboratories (26%), Pillar 6: Infection prevention and control (24%) and Pillar 7: Case management (25%)

The remaining investments are mostly invested into Pillar 9: Maintaining essential health services and systems (11%).

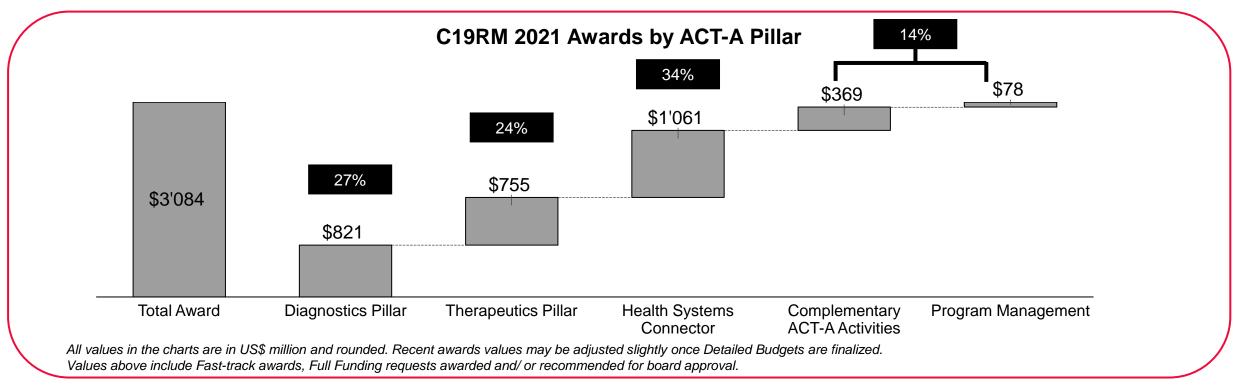


C19RM 2021 Award by ACT-A Pillars



85% of US\$3,084 million of C19RM 2021 investments are directed towards ACT-A Gap Filling Activities, given most awards to date are via Fast-track and Full Funding request prioritize reinforcing the COVID-19 response. These investments are split across the Diagnostics Pillar (US\$821 million or 27%), the Therapeutics Pillar (US\$755 million or 24%), and Health Systems Connector (US\$1,061 million or 34%).

The share of complementary activities has increased with Full Funding requests forming the majority of awards.



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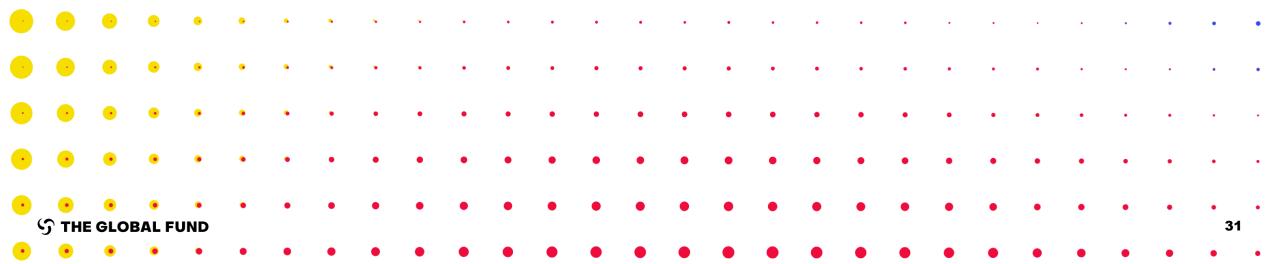
(as of Oct 20)





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Overview | Oxygen | Clinical Therapeutics (non-O2) | PPE



HEALTH PRODUCTS OVERVIEW

Despite improving Supply in diagnostics, IPC, and case management, there is additional effort required to support Health Product delivery

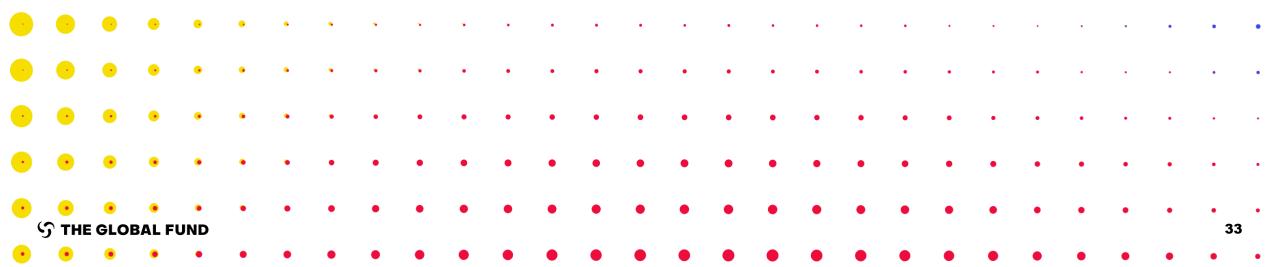
	Health Product Demand	Health Product Sourcing and Supply				
General	 Approximately 67% of awards is being allocated for health products. The Secretariat is working with Principal Recipients to ensure timely conversion of approved funding to approved orders, which is slower than anticipated. As of 18 October, 37% of total C19RM 2021 procurement planned through PPM confirmed as PO or in process of approval (\$432M / \$1,180). 	 Sufficient supply with inventory available to meet current demand of key diagnostics and PPE; constraints in the supply of oxygen interventions lessening. Monitoring and mitigating current global supply chain constraints impacting ocean and air freight - scarcity, port congestion and COVID-19 control measures at origin and/or destination. These constraints are expected to last through most of 2022 and will likely increase cost and extend lead-times. Closely following-up on national importation clearance bottlenecks to be able to ship products as soon as possible when ready. 				
Diagnostics	 Diagnostics: around 22.4% of awarded C19RM 2021 funds should enable the supply of more than 120 million tests. Analyses continue to show the increased proportion of 4:1 for Ag RDTs to PCR tests is maintained vs. the earlier months of C19RM 2021 	 Increasing supplier base of QA-approved Ag RDTs and manual PCR tests to support countries to implement their testing strategies that should also bring about greater competition. The weighted average ex-factory prices remains at around US\$10.50 for PCR tests (manual and automated) and just under US\$3.00 for Ag-RDTs. Surveillance technologies are now fully listed on Wambo. 				
Infection Prevention and Control	 <u>PPE:</u> Represents close to 16.6% total awarded C19RM 2021 funds. 	 Supply improves as demand decreases in some high-income countries. Further price reductions for PPE category of around 30% in Q4 after similar price reductions earlier in 2021. 				
Case Management	 <u>Oxygen</u>: 15.5% of awarded C19RM 2021 funds being allocated for oxygen interventions. <u>Non O2 therapeutics</u>: Demand for dexamethasone and anticoagulants (heparin & enoxaparin) continues. 	 Supply of oxygen interventions remains constrained and challenging: Availability increasing for concentrators and non-invasive ventilation. Operationalizing oxygen supply solution initially for PSA-plants with countries needing support. Monitoring COVID-19 Tx pipeline with a focus on molnupiravir following clinical data published by Merck. Timing for WHO review on recommendation for use not yet confirmed. Encouraging engagement with originator and generic manufacturers including for anti-coagulants, IL-6, molnupiravir and others as they emerge. 				



Health Products Overview

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Overview | Oxygen | Clinical Therapeutics (non-O2) | PPE



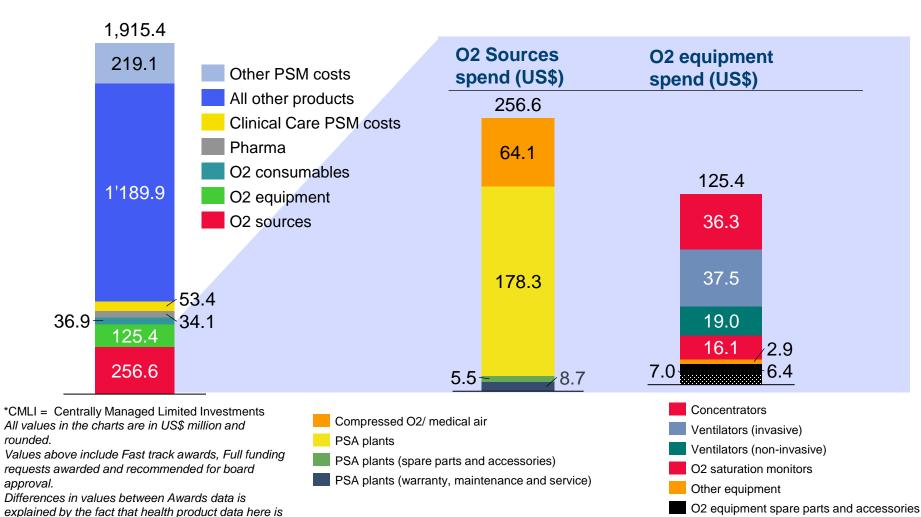
HEALTH PRODUCTS: OXYGEN

based on finalized HPMTs only, whereas awards is

based on Notification Letter.

US\$477 million has been awarded for Oxygen related products and we are supporting implementation of these awards through CMLI*.

Total planned Health Product Procurement per aggregate HPMTs as of 18 October 2021



- Of the total US\$3,084 million awarded by 20 October, we have recorded US\$477 million in awards for O2- and clinical care-related products representing ~23% of overall health product spend.
- With US\$178.3 million already awarded for on new Pressure Swing Absorption (PSA) plants, the Global Fund is continuing to strengthen support for already made investments.
- Through Centrally managed Limited Investments (CMLI) we have awarded an additional US\$ 2 million to a technical assistance partner to support implementation.

O2 equipment warranty, maintenance and service

HEALTH PRODUCTS: OXYGEN

We have invested CMLI funds to maximize effectiveness of Global Fund's Oxygen Investments.

Problem Statement

We need to strengthen available technical knowledge, field expertise, and implementation know-how to support countries to effectively implement C19RM oxygen interventions, improve our assurance capacity, and maximize the impact of our investments.

Solution Proposed

Introducing Project "Build Oxygen for the COVID-19 Emergency Response", aka Project BOXER: to use CMLI* funds for a technical assistance partner who can support substantial C19RM investments in oxygen clinical care and related products, especially PSA Plants.

*CMLI = Centrally Managed Limited Investments

39 countries with O2 PSA Plant investments.

25 countries (64%) >US\$1 million.

Country	Amount (in US\$)	# PSA plants	Country	Amount (in US\$)	# PSA plants
India	66,958,659	396	Chad	1,176,593	4
Pakistan	35,055,864	36	Cambodia	1,176,000	6
Tanzania (United	9,906,066	74	Niger	1,102,901	2
Republic)	-,,		Papua New Guinea	1,000,000	2
Bangladesh	7,283,289	29	Liberia	885,462	4
South Africa	6,047,276	30	Sierra Leone	846,090	3
Zambia	5,223,438	3		,	
Uganda	4,710,000	8	Togo	722,139	11
Kenya	3,952,876	20	Gambia	645,600	2
Madagascar	3,665,000	2	Sri Lanka	499,127	2
Sudan	3,200,000	10	Tunisia	449,599	2
Rwanda	3,182,340	2*	Moldova	425,719	4
Namibia	2,553,920	2			
Ethiopia	2,500,000	5	Lao (Peoples	ſ	
Nigeria	2,400,000	12	Democratic	400,000	1
Côte d'Ivoire	2,363,876	8	Republic)		
South-Eastern Asia	2,304,000	9	Zanzibar	350,985	6
Burkina Faso	2,029,921	1	Afghanistan	300,000	3
Lesotho	1,740,556	4	Georgia	270,000	1
Somalia	1,625,000	5	Western Asia	250,000	1
Mali	1,548,480	15	Djibouti	200,000	1
Indonesia	1,473,899	2	Mauritania	160,000	4
Eswatini	1,374,026	1	L		35

HEALTH PRODUCTS: OXYGEN

We have supplemented C19RM Oxygen interventions with Broader Implementation support and partnership engagement. Some of this work will occur through Project BOXER (Build Oxygen for the COVID-19

Emergency Response).

Differentiated support and robust management approach

Country demand-driven technical assistance (TA) based on identified country/region risk differences, based on:

• Available in-country technical expertise:

- Technical capacity of Principal Recipient (PR), Local Fund Agent (LFA).
- \circ Technical capacity of in-country partners.
- Past experience with pressure swing absorption (PSA) plants.

• Technical complexity:

- Number and location of plants, size of investment.
- Environmental risk (general and site specific).
- Quality of installation, including size / capacity:
 - Type of housing.
 - Operational complexity.
 - Duration of confirmed service and maintenance & warranty.
 - Dedicated technical staff at site.
- Advise on possible re-channeling, where appropriate.

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Monitoring and Evaluation

Services/payments will be based on demand and per country (and/or number of sites).

NOTIONAL Indicators:

- # of countries supported with specific O2 PSA plant installation, commissioning, engineering and maintenance guideline development.
- # of PRs trained through organized trainings and clinics in 2021/2022 on engineering aspects of PSA Plants and/or supported via virtual consultations.
- # of LFA Teams trained on Global Fund O2 technical implementation assurance tool (developed by Build Health Initiative (BHI)) and/or supported via virtual consultations for in-country assurance.
- # of countries supported with demand-driven incountry site assessments and/or PSA plant commission and system acceptance checks.
- # of new PSA plants fully operational <u>as planned</u> within +/- 2 months, with BHI support, where requested.

Partnerships Engagement

To maximize impact of oxygen interventions, which will include activities such as installation, operations and monitoring and oversight.

- Project oversight committee including multiple Global Fund units, teams and the Oxygen working group with TAP, SO, GMD:
 - Contract Terms of Reference (TORs), including performance framework.
 - o Routine bi-weekly calls.
 - Monthly reports based on key performance indicators.

Complementing work with other partners such as:

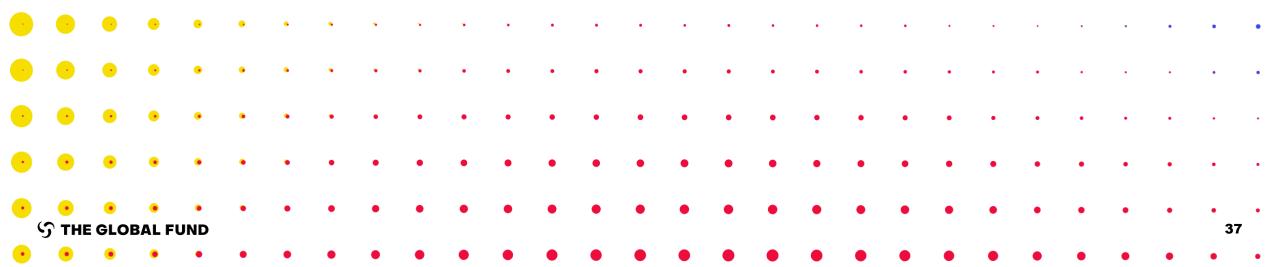
WHO, CHAI, PATH, USAID, UNICEF, Assist International, Oxygen Hub, ACT-A Oxygen Task Force, WHE Biomedical Consortium, CTAG partners, USG (including secondees to TAP), Local Fund Agents and I-Plus Solutions.



Health Products Overview

5

Overview | Oxygen | Clinical Therapeutics (non-O2) | PPE



Non-O2 Clinical Therapeutics

Several novel therapeutics for COVID-19 continue to progress within and emerge from the R&D pipeline.

IL6 Blockers

- 7 July 2021 WHO announcement of a new recommendation on IL6 blockers for severe/critical COVID-19.
- 7 September 2021: IL6 blockers were confirmed by IC as "in scope" of C19RM.
- Honduras Funding Request for ~5,000 doses of tocizilimab was Investment Committee (IC)-approved; drug approved by the National Regulatory Authority, recommended in national COVID-19 clinical guidelines, and considered available on local market (under the local procurement channel).
- Demand currently limited by supply, high price, and formulations.

Regeneron Ab Cocktail

- 24 September 2021 WHO announcement of a new recommendation on Regeneron Ab "cocktail" of casirivimab and imdevimab.
- Effective in patients with non-severe COVID-19 who are at highest risk of hospitalization and those with severe or critical COVID-19 who are seronegative (meaning they have not mounted their own antibody response to COVID-19).
- Under review by C19RM.
- Demand anticipated to be limited for similar reasons to the IL6B's.

Molnupiravir

- Broad spectrum antiviral.
- Oral administration.
- Clinical trial ended early on 1 October 2021, based on interim analysis submitted by Merck to FDA for EUA.
- Primary data shared with WHO Health Emergencies Programme (WHE), technical review pending.
- BMGF has pledged US\$120 million to accelerate generics scaling up for lower middle-income countries (LMICs).
- Pre-purchase for LMICs under discussion by ACT-A partners.
- MSD and Generics pricing not confirmed for LMICs, ACT-A Tx tender underway.
- Voluntary licensing agreements signed with eight Indian generic drug makers, including a recent agreement with Medicines Patent Pool (MPP) to expand greater access.

C19RM Funding Requests with Highest Investments in non-O2 Clinical Therapeutics

Total Baseline Spent in 2021: US\$ 34 million

Drugs include dexamethasone and other steroids, various heparins, and other respiratory care and critical care medications. With more therapeutics being made available, we expect C19RM investments in therapeutics to increase.

Zambia	4,860,472	Central African Republic	348,599
Ethiopia	4,023,507	Mongolia	347,058
Côte d'Ivoire	3,322,276	Mauritania	265,841
Honduras	2,864,919	Nigeria	250,759
Philippines	2,296,201	South Sudan	189,680
Malawi	1,491,700	Sierra Leone	174,402
Venezuela	1,491,550	Eswatini	163,865
Liberia	1,242,280	Zanzibar	163,003
Madagascar	1,214,549	Sudan	147,293
Haiti	1,064,322	Somalia	132,126
South-Eastern Asia	903,948	Niger	117,010
Mali	843,537	Namibia	108,615
Senegal	781,399	Djibouti	89,284
Angola	711,020	Gambia	45,000
Guinea	707,551	Chad	36,790
Congo	648,009	Lesotho	33,927
Cuba	629,763	Nepal	15,925
Tunisia	550,150	Тодо	15,233
Cambodia	493,873	Multicountry EECA APH	8,000
Burkina Faso	462,881	Guinea-Bissau	7,425
Afghanistan	420,436	Panama	7,223
Tanzania (United Republic)	359,003		

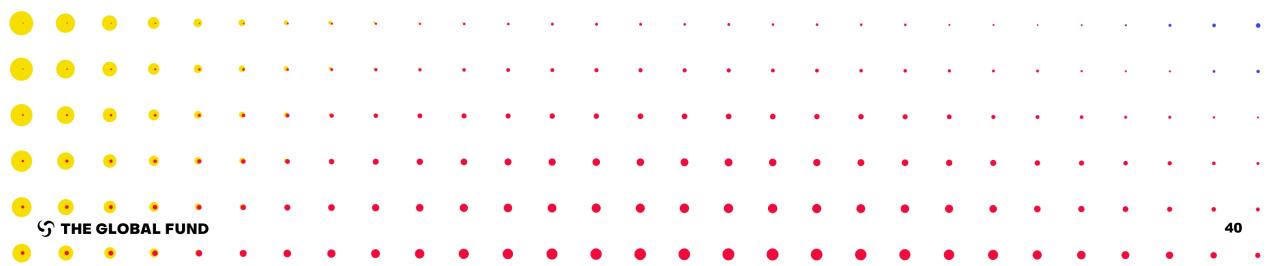
S THE GLOBAL FUND





Health Products Overview

Overview | Oxygen | Clinical Therapeutics (non-O2) | PPE



We continue to support personal protective equipment (PPE) investments by financing mitigation of COVID-19 impact on Malaria.

108 out of 116 applicants that have received an award have invested in PPE for an average of 17%.

Strategic areas of investment of PPE in malaria include:

- PPE combined with operational adaptations to allow campaigns, .e.g., for ITN campaign staff to proceed in the COVID-19 context through to 2023.
- PPE needs to maintain primary health services both at facility & community level, including Community Health Workers.
- Use of medical masks for community outreach activities (non-medical/fabric masks are not considered PPE & are reviewed case-by-case basis).
- Associated PPE waste management encouraged to be factored into requests.

Approaches taken for PPE prioritization for malaria:

- The Secretariat has worked with national programs and partners to identify PPE gaps with a focus on 2022 campaigns and health workers. The work to refine the gap analyses for both PPE and adaptations, particularly for 2023 campaigns, continues.
- The Secretariat encouraged applicants to:
 - Include PPE within the Base Allocations (BA) for 2022 for frontline health workers, including community health workers, and for any campaigns in that order of priority (if the budget allowed).
 - Include PPE for these two categories as a top priority in the Above BA for 2023 if they could not be met within the BA for 2023.

Bolivia:

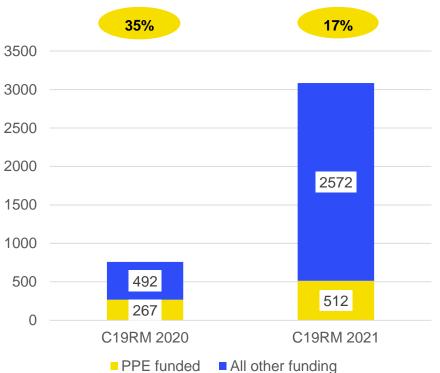
PPE for malaria brigades/volunteers that have doubled-up as COVID-19 response teams

ら THE GLOBAL FUND

Madagascar:

Masks being used for seasonal malaria chemoprevention and cIPT pilots.





*including PSM costs. Amounts are rounded. Source: approved HPMTs Recent awards values may be adjusted slightly once HPMTs and Detailed Budgets are finalized.

Amount reduction from last months reporting explained by price reduction All values in the charts are in US\$ million and rounded. Recent awards values may be adjusted slightly once Health Product Management Templates (HPMT) are finalized. Values above include Fast-track awards, Full Funding requests awarded and/or recommended for Board approval.

Differences in values between Global Fund defined health products are accounted for 41 by a more limited set of products that are included under these categories.

HEALTH PRODUCTS: PPE

C19RM applicants with current malaria grants have been provided guidance to include and prioritize HIV, TB and malaria mitigation activities in their C19RM Funding Requests.

Malaria is an example of how we have been very structured in supporting mitigation action activities.

The table below is an example of what applicants can include in their funding request form or as a supporting document, to outline the source of funding used for campaigns.

Interventions	Global Fund 2020-2022 grants	Global Fund C19RM	Other funding sources (domestic, PMI, etc.)
PPE for health workers – including community health workers for delivery of routine malaria services			
PPE for SMC campaigns for 10 GF districts (2021, 2022, 2023)			
PPE for SMC campaigns for 7 PMI districts (2021, 2022, 2023)			
PPE for 2022 mass ITN campaign and other routine activities for the entire country			
Additional operational costs related to the C19RM project interventions for the 2022 ITN campaign and routine activities for 20 districts in the GF zone			
Additional operational costs related to the C19RM project interventions for the 2022 ITN campaign and routine			
activities for 18 PMI zone districts			s should olumns that

apply.

The following activities must be prioritized within the C19RM base allocation, or clearly documented if covered by other resources:



PPE for health workers, including Community Health Workers.



PPE for campaigns for each year through 2023: seasonal malaria chemoprevention (SMC), insecticide treated nets (ITN) and indoor residual spray (IRS). This excludes PPE for IRS spray personnel that is routinely needed and should already be funded in current malaria grants.



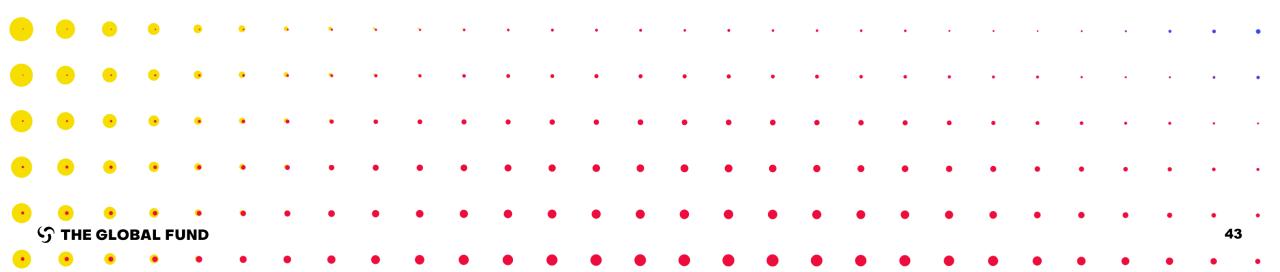
Costs for adaptations, particularly for campaigns, including any increases in transport costs, that are due to the COVID-19 context.

Note: These activities apply to all settings.



Focus on Genomic Surveillance

6



Why Genomic Surveillance?

Widespread transmission and replication of SARS-CoV-2 increases the likelihood of novel variants emerging.

 The ongoing response to COVID-19 has demonstrated the need to strengthen surveillance capacity as a part of robust COVID-19 surveillance for variants of concern. Routine genomic surveillance may enable health authorities, governments, and researchers to monitor the evolution of COVID-19 and adjust public health responses accordingly.



https://www.nature.com/collections/aijdgieecb/ https://www.who.int/publications/i/item/WHO-WHE-2021.02

- The Global Fund has budgeted a total of US\$13.2 million for genomic surveillance in core HIV, TB and malaria grants (across three funding cycles from 2014-2016, 2017-2019, and 2020-2022).
- While the response to the pandemic has largely pivoted towards distribution of vaccines in high-income countries, global investment in surveillance will be important in understanding vaccine effectiveness and informing policy. As a critical step in identifying mutations and informing clinical and vaccination protocols, it is vital to **build laboratory** capacity globally to ensure surveillance capacity that is sustainable and can better guide public health measures.

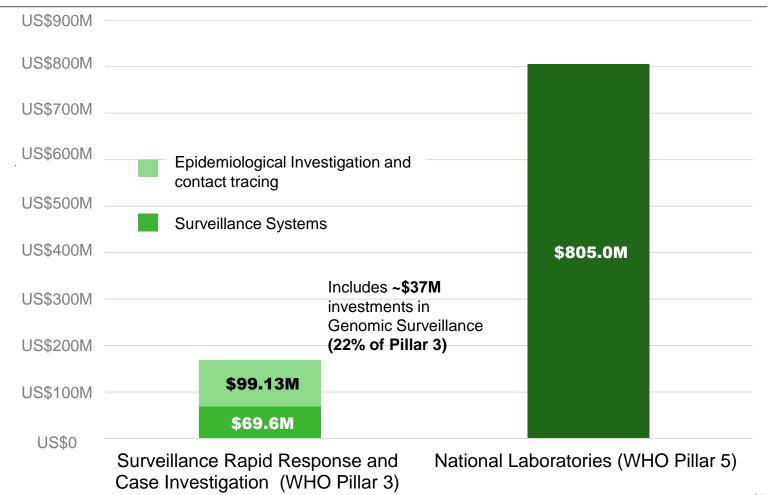
HEALTH PRODUCTS: FOCUS ON GENOMIC SURVEILLANCE

(as of 20 October)

C19RM 2021 Budgeted Investments in Genomic Surveillance

C19RM 2021 awards of US\$169 million for the Surveillance Pillar budgeted across 2 intervention areas

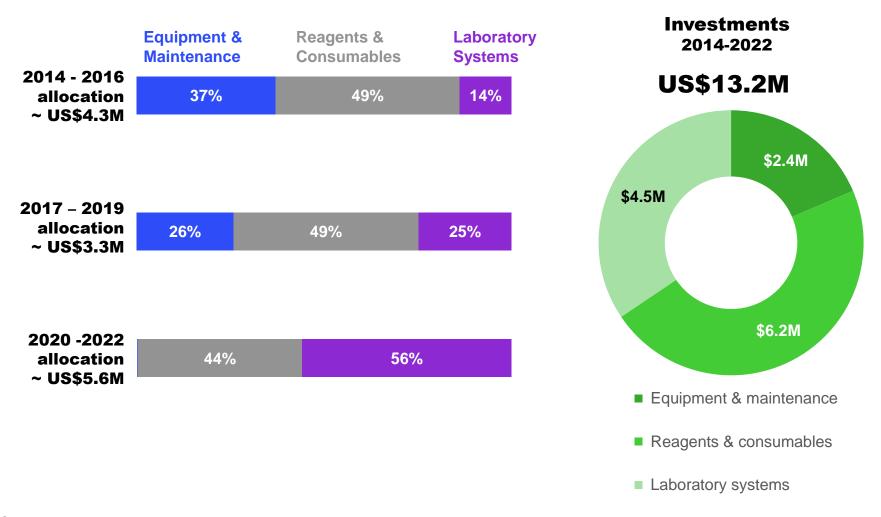
- Investments in genomic surveillance, including equipment, infrastructure and human resources capacity, account for 22% of total awarded funds in WHO Pillar 3 (Surveillance).
- Low investments in genomic surveillance (US\$37 million) within Pillar 3 compared to the significant investments in diagnostics (within Pillar 5), indicates that countries are prioritizing testing to meet high demand and are leveraging on existing regional/partner support for genomic surveillance.
- Need for robust testing to better inform public health countermeasures i.e., vaccines, treatment, diagnostics and others.



Source: C19RM Awarded Budgets. Total US\$3.084B in scope. Data provided 20 October 2021

Global Fund Investments Genomic Surveillance:

Allocations from 2014 – 2022 Funding Cycles



- Genomic surveillance for pathogens of pandemic potential is strengthened and scaled for quality, timely and appropriate public health actions within local to global surveillance systems.
- Total of US\$13.2 million is budgeted for genomic surveillance in core grants (HIV, TB and malaria) (2014-2016; 2017-2019 and 2020 – 2022).
- Equipment, reagents and consumables allocations jointly account for ~63% of budgeted investments for genomic surveillance. Laboratory systems allocation accounts for ~34% of total investments.

Sthe GLOBAL FUND Source: Detailed budgets 2014 – 2022 (data as at 13 September 2021). 50 countries in scope.

Review of C19RM Funding Requests: Observations

Best Practices

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Leveraging on regional initiatives to support surveillance.

Genomic surveillance data is informing public health responses.

Leasing arrangements being discussed in select countries to improve cost dynamics.

South-South collaboration via fee for service arrangements to support genomic surveillance i.e., testing, training, technology transfer.

Challenges



Absence of National Genomic Surveillance strategy and sampling plan.

Sampling lacks representativeness

- Low testing rates.
- Antigen rapid diagnostic test (Ag RDT) results are not captured into disease surveillance systems.
 - Focus on positive cases at point of entry (POE).

No global guidance/standards on:

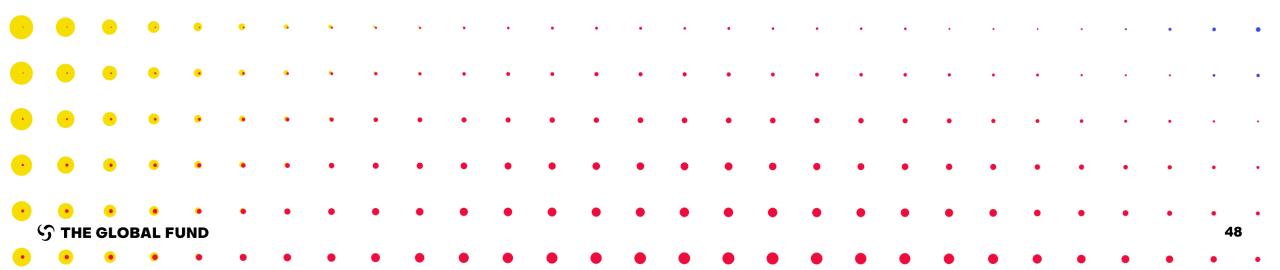
- How much surveillance is enough.
- Resampling for Ag RDT positives.
- Pricing or quantification tools for sequencing.



Limited investment in equipment service and maintenance.







C19RM COUNTRY CASE STUDY Peru ranked highest in the world in terms of excess mortality per million people.

Global Fund supports implementation of National Response to the COVID-19 crisis and genomic surveillance.

Context

Since the start of the epidemic in March 2020, COVID-19 has had a devastating impact on Peru's health system and economy. Confirmed COVID-19 cases peaked at 10,143 in a single day in August 2020. Following a downward trend in the second half of 2020, cases started to increase again since December 2020, with a peak of 13,326 cases in a single day by mid-April 2021. Cases have now reduced to less than 1,000 per day on average, although a third wave is expected. The COVID-19 epidemic has caused severe disruptions in service delivery, in particular at the primary health care level, including for HIV and TB.

COVID-19:

- Peru ranked highest in the world in terms of excess mortality per million people 34% reduction in HIV screening. • Insufficient ICU beds were available to support the flow of COVID-19 and other • 40% reduction in PLHIVs initiating ART. patients in critical condition during the peak of the pandemic and the Ministry of • Twofold increase in PLHIVs lost to follow up. Health reported a shortage of medical oxygen of 70 tons per day.
- Impact on HIV response: 2020 data compared to 2019 data

- Impact on TB response: 2020 data compared to 2019 data
- 62% reduction in examination of patients for respiratory symptoms
- 45% reduction in screening of contacts of TB patients.
- 26% reduction in TB case notification.

Roll out of COVID-19 vaccinations has had a slow start, although vaccination rates increase significantly in recent week. Currently, 50.9% of the population received one dose, and 38.6% received both doses.

C19RM Response	The Investment Com	<u>imittee awai</u>	rded US\$ 14	4,937,883
Considering the country context, the Global Fund recommended US\$ 14,937,883 for immediate		\$	% 2020-2022 allocation	
award to address identified strategic priorities. With the support of the Global Fund, the following interventions are currently being rolled out in Peru:	CCM requested	US\$ 14,948,052	75%	
 Support for COVID-19 management units with equipment, staffing and community support; Oxygen support in prisons; 	Fast-track award	US\$ 0		
 Funding for PPE and waste management; 	Carry over	US\$ 328,835	2%	
 Rapid COVID-19 Ag tests; Equipment for COVID-19 molecular tests; 	Secretariat recommended Immediate award	US\$ 14,937,883	75%	
 Interventions to bring back PLHIVs lost to follow up; Assisted partner notification and support for ART centers; 	Total 2021 new award	US\$ 15,266,718	77%	
 Training and support for a mobile application to link PLHIVs to HIV care; TB active case finding through mobile units and campaigns. 	Total 2021 new award excluding carry over	US\$ 14,937,883	75%	
 Mobile adherence support for MDR-TB; 	Unfunded demand	US\$ 0	0%	© UNICEF/García/AFP-Services
 Institutional capacity building and community engagement in the various interventions proposed; Platforms to reduce stigma and discrimination and support for community-based monitoring; 	Not recommended*	US\$ 10,169	0%	
 Community involvement in awareness-raising campaigns on gender-based violence and human rights; 				sulin and syringes for in-patient treatment of I line with the Global Fund guidelines.

Support for mental health of affected communities.

Looking Ahead

• While implementation of the C19RM 2021 interventions has only recently started, the funding awarded to Peru is expected to help the country to be better prepared for a possible third wave of COVID-19 infections. Moreover, funding for mitigating the impact of COVID-19 on the HIV and TB response is expected to contribute to bringing key programmatic indicators back on track.

Malawi is an example of progress in the AME region, which form part of lessons learned.

Global Fund supports countries in African and the Middle East and has awarded US\$894 million to this region alone

Context

AME region investments have increased fivefold from US\$155 million 2020 to US\$763 million in 2021. In 2021, for AME, the largest area of focus remains reinforcing the region national covid19 responses with mitigation of impact on HTM programs and urgent improvements in health and community systems following close behind. Malawi follows the same prioritization as shown below

Malawi as a Case Example in AME

<u>1. C19RM 2020 Investment (MM, US\$)</u>		Challenges	Operations	Commended Practice
Total 30.8 MM US\$ 32.2%	COVID 19 Response	 Low testing rates due to limited lab capacity (partially addressed). Inadequate bidirectional testing PPE shortages due to lack of supply and lengthy government procurement processes (partially addressed). HRH gap due to overstretched health system and health worker C19 burden (partially addressed). 	 Governance Covid 19 and other Health priorities Products Management Coordination Coordination: HIV and Covid antibiotics need. Waivers, PMRA and PPM Delivery delays and freight protocols. Health workforce 	 PPE provision and IPC training in the most vulnerable populations to support testing (including TB screening services). Functional product logistics committee
2. C19RM 2021 Investment (MM, US\$) Total 102.6 MM US\$	Mitigation	 Declines in facility attendance Decline in HIV relate testing (partially addressed). Community intervention suspension (addressed). Reductions in TB screening(partially addressed). 	 Guidelines to protocols 16 done, 2 in pipeline Interim shared protocols – TB IPC Updating protocols – HIV client care, Xpert use, Bidirectional testing, sample transportation. Lab screening protocol Reestablishing access Increased coverage of mobile units and deployment of health staff Maintaining routine reporting 	 Expansion of mobile integrated clinics for treatment services. Geospatial analysis to optimize care & treatment service expansion. Step up surveillance activities Strengthen district's capacity to assess the impact on services and implement mitigation measures in real time. Use of online supportive supervision and mentorship.
 Mitigating COVID-19 impact on HIV, TB, Malaria programs Reinforcing national COVID-19 response Urgent improvements in health and community systems 	Health System	 Limited health infrastructure (partially addressed). 	 Infrastructure – Isolation wards, lab renovations, 2 infectious disease wards, O2 plant etc. Rapid increase of interlocutors – coordination capacity Public Procurement & Disposal Agency 	Multiple technical capabilities 50