

# Mid-term evaluation of Unitaid's COVID-19 portfolio of investments

Unitaid

8 April 2022

**Final Report**

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## ACRONYMS

Acronym	Full description
ACT-A	Access to COVID-19 Tools Accelerator
AFROX	African Oxygen Ltd.
Ag-RDT	Antigen rapid diagnostic test
AIRE	Améliorer l'Identification des Détresses Respiratoires chez l'Enfant
ALIMA	The Alliance for International Medical Action
API	Active Pharmaceutical Ingredient
ARV	Antiretrovirals
BMGF	Bill and Melinda Gates Foundation
BOHEMIA	Broad One Health Endectocide-based Malaria Intervention in Africa
C19RM	The Global Fund COVID-19 Response Mechanism
CHAI	Clinton Health Access Initiative
CIFA	COVID Innovations for All
COHIVE	Coronavirus (COVID-19) Outcomes in HIV Evaluation in Resource Limited Settings (clinical trial)
COVER	COVID-19 Emergency Response for Health Care Workers (clinical trial)
CSO	Civil Society Organisation
C-TAP	WHO COVID-19 Technology Access Pool
D2EFT	Dolutegravir and Darunavir Evaluation in Adults Failing Therapy
DCN	Diagnostic Consulting Network, Inc.
DNDi	Drugs for Neglected Diseases Initiative
EOI	Expression of Interest
EGPAF	Elizabeth Glaser Paediatric Aids Foundation
FIND	Foundation for Innovative New Diagnostics
FIOTEC	Foundation for Scientific and Technological Development in Health
IBB	Institut Bouisson Bertrand
ISGlobal	Barcelona Institute for Global Health
ISMT	Incident Management Support Teams
LMIC	Low and middle-income country
MoH	Ministry of Health
MNCH	Maternal, neonatal, child health
MPP	Medicines Patent Pool
MSD	Merck and Co
MTV SAF	MTV Staying Alive Foundation
NAAT	Nucleic Acid Amplification Tests
NAMSAL	New Antiretroviral and Monitoring Strategies in HIV-infected Adults in Low-income countries
NTZ	Nitazoxanide
PATH	Program for Appropriate Technology in Health
PIH	Partners in Health
PSI	Population Services International

<b>Acronym</b>	<b>Full description</b>
RfP	Request for Proposal
RT-PCR	Reverse transcription polymerase chain reaction
SOF	Sofosbuvir
TIMCI	Tools for Integrated Management of Childhood Illness
ToC	Theory of Change
TRIPs	Trade-Related Aspects of Intellectual Property Rights
UNDP	United Nations Development Programme
UNSW	The University of New South Wales
UOL	University of Liverpool
USAID	The United States Agency for International Development
WHE	WHO Health Emergency Programme
Wits RHI	The University of the Witwatersrand, Research Health Institute
WHO	World Health Organization

## EXECUTIVE SUMMARY

Cambridge Economic Policy Associates (CEPA) was appointed by Unitaid to conduct a portfolio-level mid-term evaluation of Unitaid's investments in COVID-19 over the period March 2020 to December 2021.

### Background/ context and evaluation objectives and scope

In March 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a global pandemic. Unitaid responded quickly to the public health crisis, with two initial waves of investments designed to enhance access to COVID-19 diagnostics, treatments and supporting tools, including oxygen. These two waves provided up to US\$ 65 million of Unitaid core funds, including: (i) Wave 1 of US\$ 30 million in March 2020; and (ii) Wave 2 of US\$ 35 million in bridge funding in June 2020. On 24th April 2020, Unitaid joined global health actors and other stakeholders to launch the Access to COVID-19 Tools (ACT) Accelerator and in 2021, Unitaid continued to focus on addressing market and country barriers in order to accelerate access to: (i) oxygen supply through a series of catalytic investments for oxygen support (US\$ 46 million); and (ii) to prepare for new innovations in diagnostics and therapeutics in the pipeline, through a series of new investments (through the "Test and Treat Request for Proposals" (RfP) for US\$ 47 million) to enhance access to COVID-19 "tests, isolate, care and treat". In addition, as co-leader of the ACT-A O<sub>2</sub> Emergency Taskforce, Unitaid has committed to further support for oxygen investments (through the "Access to Oxygen RfP") to accelerate access to medical oxygen during the COVID-19 pandemic (not within scope of the evaluation).

This mid-term evaluation covered Unitaid's direct investments in response to COVID-19 from March 2020 to December 2021, with the following objectives: (i) to assess the extent to which Unitaid's COVID-19 investments contributed to the COVID-19 response thus far, particularly in providing catalytic support, shaping market access and country preparedness for the adoption of COVID-19 diagnostics and treatment options; and (ii) to draw lessons learnt and recommendations for Unitaid to apply to its existing and future COVID-19 investments. A total of 27 investments in therapeutics, diagnostics, oxygen and cross-cutting for US\$155m were included in scope in the portfolio review. As a portfolio-level evaluation, the assessment draws on evidence and examples from the investments but does not consider every investment in depth. Further, as many investments have recently been signed, these are evaluated from a relevance and coherence perspective only. A review of role of Unitaid as a co-convenor within the ACT-A framework was not within scope.

The evaluation was based on an evaluation framework, structured around four dimensions: relevance and coherence; efficiency; effectiveness; and sustainability, scalability and impact. The evaluation used a mixed-methods approach: desk review of relevant documentation; consultations, including key informant interviews and focus group discussions; and quantitative analysis. Two workshops were conducted following the submission of the draft report: a workshop to co-create recommendations with the Unitaid Senior Management Team (SMT); and an external partners presentation to present the findings to grantees and key stakeholders.

We present the evaluation findings by OECD DAC criteria.

### Relevance

**Unitaid's COVID-19 investments have been of high strategic relevance, responding well to the priority needs of the pandemic.** Therapeutics investments commenced when there were no known preventative or curative treatments for COVID-19. Given the limited access to vaccines when they became available, Unitaid rightly anticipated the need for continuous investments in therapeutics. The diagnostic investments were also strategic and relevant, starting first with RT-PCR and then moving on to Ag RDT. The diagnostics and therapeutics pillars came together through the Test and Treat investments, which also support the introduction of new therapeutics and care models critical for access, as well as critical components of demand generation and community engagement. Both through its investments and advocacy in ACT-A, Unitaid has led efforts to ensure adequate global and country focus on medical oxygen. However, the strategic relevance of some of Unitaid's COVID-19 investments has been blunted by design issues, such as challenges in design and implementation of clinical trials in the midst of a pandemic, resulting in delays.

**There is a question as to whether the range of investments reflect Unitaid's comparative advantage.** On the one side, the partnership with FIND on diagnostics built on Unitaid's comparative advantages in terms of market shaping, access terms, etc., and Unitaid also leveraged its comparative advantage in market shaping and private sector engagement through the MoUs to improve availability and access to oxygen. Furthermore, the Test and Treat investments use Unitaid's comparative advantage in terms of piloting/ testing models of care and generating evidence, whilst also introducing innovative solutions. However, there is a question as to whether some of Unitaid's investments have been too focused on procurement and have played more of a "gap-filling", yet critical role, rather than its traditionally understood catalytic role in terms of "priming" for scale-up. For example, Unitaid's initial oxygen investments in 2020/21 were largely emergency commodity procurement, although they have evolved to become more strategic over time in terms of supporting longer term infrastructure development alongside technical assistance. Similarly, regarding the dexamethasone investment, although relevant and strategic at that time, stakeholders noted that Unitaid is not a procurement agency, and the investment was not complemented by needed demand generation interventions. Overall, however, we recognise Unitaid's speedy response, crucial in a rapidly developing pandemic, in comparison to other COVID-19 support mechanisms.

**There has been good adaptation of investments over time in response to the evolution of the pandemic.** For example, the diagnostics investments were sequenced from RT-PCR to Ag RDTs to address country testing needs. Unitaid and UNICEF responded quickly to positive emerging evidence to secure an inventory of dexamethasone. Unitaid's oxygen investments and efforts also took account of evolving oxygen needs. In 2021, the interconnectedness of testing, treatment, and care in case management of COVID-19 was addressed by issuing the Test and Treat RfP.

## **External and internal coherence**

**Unitaid's portfolio is fully aligned with ACT-A.** Although the first wave of Unitaid's COVID-19 investments preceded ACT-A, these and the later investments are aligned with ACT-A objectives and priorities. The investments have also been well coordinated and linked with the work of other partners, (for example with the Global Fund on oxygen) with significant examples of backward and forwards linkages. Within ACT-A, Unitaid is viewed as a valued partner, bringing unique benefits, including its niche role as an introducer and/ or fast-tracker of innovations and its expertise in market shaping.

**Leveraging existing investments and grantees has enabled Unitaid to act quickly.** A degree of built-in quality assurance with existing grants/ grantees helped reduce risks in an already risky pandemic environment. But, by building solely on its existing portfolio of investments, initially primarily in Sub-Saharan Africa and through its HIV, TB and malaria grants, Unitaid may have missed opportunities to contribute to the COVID-19 response in other high-burden countries.

**The investment portfolio has been coherent and complementary, with two main gaps:** (i) the linkages between testing and treatment have only been harnessed recently with the roll-out the Test and Treat RfP; and (ii) there have been limited demand generation interventions, with some grants primarily focusing on supply-side interventions including procurement of drugs (dexamethasone) and diagnostics, and to a lesser extent accompanied by the needed demand generation to support uptake of products, which have more recently been emphasized under the Test and Treat investments and a newly launched RfP to advocate and raise awareness on COVID-19 testing and treatment solutions.

## **Efficiency**

**Unitaid developed an ambitious COVID-19 investment portfolio at speed.** It reacted quickly to the pandemic by leveraging existing relationships, integrating the investments as grant amendments to simplify and expedite its response, and adapting its processes for grant approval and funding for faster decision-making. This approach was commended by grantees, global and national stakeholders alike.

**Processes for grant identification, approval and management evolved and adapted to the needs of the pandemic.** The grant approval process has been considerably streamlined and approval timelines shortened. However, the short timeframe for completing investments has been challenging at times and Unitaid's procurement processes have caused delays, although some flexibility has been introduced with regards to budget management.

**Stakeholders expressed appreciation for the dedication, expertise and leadership of the Secretariat.** However, the significantly increased Secretariat workload, both in project management and strategy work, may not be sustainable without adequate additional resources/ surge capacity over the longer term.

**Grant reporting requirements have been simplified but require improvement to monitor outcomes and impacts.** The grant reporting burden for grantees has been lightened from once a month to once a quarter, and reporting templates has been streamlined into flash reports, with grantees generally agreeing this had been a positive change. However, reporting is very much activity/output based, with limited to no emphasis on outcome and impact reporting. We consider this an area for improvement.

## **Effectiveness**

**There has been good progress to date across the portfolio in terms of completion of activities and delivering outputs,** with the exception of the therapeutics portfolio, where progress has been slower due to delays in implementation (clinical trials) and uptake (dexamethasone inventory). A deeper analysis of the effectiveness of these investments and their **significance** is as follows:

- For the **therapeutics portfolio**, the investments in clinical trials are still in progress and yet to deliver results, although the evidence they generate will add to the COVID-19 knowledge-base. For example, AGILE has identified one molecule - nitazoxanide (NTZ), which has moved to Phase 2 clinical trials in the United Kingdom and South Africa; observational studies from COHIVE will contribute to documenting COVID-19 HIV co-infections. An important contribution is also expected through the wider Unitaid work on COVID-19 in terms of its support for MPP, which has recently secured licenses for Molnupiravir and Paxlovid. Unitaid's involvement in equitable access is all the more important as it remains one of the few organisations funding and supporting access to medicine initiatives.
- **Diagnostics investments** in the more “upstream” ACT-A workstreams of product assessment, as well as market shaping and manufacturing through FIND, have been critical and with considerable potential for impact going forward. The more “downstream” investments on procurements and in-country work through CHAI have facilitated access to diagnostics and related know-how for countries, although lacking key elements for demand generation. In particular, Unitaid's partnering with FIND on an open call for proposal on Ag RDTs helped increase the availability of Ag RDTs in LMICs through increased manufacturing capacity and technology transfers, whilst the CHAI grants have been instrumental in expanding RT-PCR testing in certain countries, as well as supporting the introduction of Ag RDTs.
- The **oxygen portfolio** has included both the “softer” investments of TA and training of health care workers and biomedical engineers, which have contributed to improved strategic planning and capacity building; and “harder” investments for the procurement of emergency respiratory care equipment in selected countries. However, delays in procurement and delivery, together with a lack of metrics on use and deployment make it difficult to assess overall impact to date. The wider strategy-level work on oxygen, including engagement with oxygen manufacturers has been instrumental in kick-starting a global development effort towards market shaping for oxygen for public health, although the mechanics of the market and infrastructure imply that the potential of these agreements has been slow to unlock.
- The **cross-cutting grants** have been effective in generating awareness about unequal access to COVID-19 tools in LMICs and creating a supportive/ enabling environment for other grants to thrive e.g. (Wemos) as well as helping to address issues around misinformation of COVID-19 (MTV Shuga).

## **Sustainability, scalability, and impact**

**There is some evidence on the potential sustainability and scale-up of the investments.** For example, investments in diagnostics are likely to be sustained and scaled-up in the short-term through funding by the Global Fund and in the long-term through increases in the manufacturer's infrastructure and technical capacity. Some of the oxygen investments include sustainable components such as capacity building, development of national strategic plans, etc.



**However, assessment of the sustainability and scalability of Unitaid's COVID-19 investments is complex** given the type of emergency support provided and the particular context of the pandemic (where scale-up needs to be considered in a product agnostic way and needs/ requirements evolve over time) and the timing of the evaluation (mid-term, with only 2 of the 27 investments completed). The standard success factors included within Unitaid's scalability matrix may also not apply in this context. Also, much greater consideration to long-term financing is needed, as well as issues of integration with the broader health system.

**Unitaid designed its investments with equity considerations in mind, even as there is widespread inequitable access to COVID tools across LMICs.** We found that Unitaid's investments and wider work within ACT-A has had strategic benefits and positive externalities with regards to: (i) strengthening research capacity in LMICs for the future; (ii) increasing the focus on diagnostics as critical tools in disease response, including future diseases; and (iii) raising the profile of medical oxygen at the global and country levels.

## **Conclusions and lessons learnt**

The mid-term evaluation's overall conclusion is that Unitaid's COVID-19 investments have largely been strategically relevant and responsive to the priority needs of the pandemic in LMICs. Unitaid moved with speed and agility at the start of the pandemic to identify niches and gaps where it could meaningfully contribute to the global response. It made astute use of its network of partnerships and grantees to enable a fast and effective response. It adapted its grant selection, approval and management processes to efficiently support grantees, although there are some areas for improvement. Overall, in terms of effectiveness, there has been good progress across the portfolio to date, with the exception of therapeutics, where progress has been slower. There has also been some progress on sustainability and scalability of diagnostics and to some extent oxygen where there is a need to coordinate with longer term financing options. Unitaid's investments have been designed using equity principles and considerations, but widespread inequity in access to COVID-19 tools by LMICs continues to strongly persist.

Looking across the four evaluation dimensions, and in line with the overall evaluation objectives, this mid-term evaluation seeks to answer a number of cross-cutting questions described in Section 2, which form the basis for the overall conclusions, lessons learnt and the recommendations.

**Have Unitaid's COVID-19 investments, taken as a whole, made a significant contribution to the COVID response?** Our assessment is that Unitaid has made a solid contribution (with some gaps/ missed opportunities) in a rapidly evolving crisis, with the verdict on sustainability, scalability and impact largely still to come.

Taken individually, investments have been strategically relevant to country needs and to the evolving pandemic situation. Taken together as a portfolio, the investments span a significant range of interventions and geographies and exhibit good internal and external coherence (with some gaps). Unitaid has moved at speed and interventions are showing good progress in delivering outputs, although there is sparse information on outcomes.

Unitaid advocated for and jump-started oxygen investments, although the impact of these investments largely remains to be seen. Similarly, it is too early to determine the overall impact of Unitaid therapeutics investments, although, the evidence they generate will add to the knowledge-base on COVID-19 as well as more generally inform how to carry out clinical trials in a pandemic situation. Investments in diagnostics effectively leveraged Unitaid's existing footprint of diagnostics investments and have responded to critical testing needs. They are also likely to be sustained short-term through the Global Fund and in the long-term through increased manufacturer infrastructure and technical capacity.

**Has Unitaid been catalytic, and played to its comparative advantages?** Our assessment here is yes, to a large degree, but also somewhat inconclusive as Unitaid has in some respects played a very different role from its conventional one, but this has also been very impactful. We also note that as well as being an investor, Unitaid played an important convening role that has also been very catalytic. For example, in oxygen, both as an early investor, as joint lead with the Wellcome Trust, and as partner with the Global Fund.

We highlight first Unitaid's early entry into COVID-19, before many other donors and before ACT-A, and view this as an important factor catalysing the later interventions of large donors. Unitaid's overall agility through successive waves/ portfolios of funding has shown its ability to improvise, adapt and innovate in relation to the needs of the pandemic – and this feature in itself is reflective of a critical role wherein Unitaid has been able to “dive-in” to

opportunities as they present themselves. From a more conventional lens on Unitaids' role e.g. of shaping markets, small-scale introductions/ demonstrations to pave the way for scale-up by funders and governments etc., Unitaids' catalytic role is more doubtful. Some investments (e.g. FIND EOI, Test and Treat) are potentially more catalytic than others (e.g. some of the oxygen investments). However, it is debatable whether Unitaids should have initially prioritised a (conventional) catalytic role in its COVID-19 response, or whether, given the depth of the emergency, it should have responded as it did to achieve maximum short-term impact. Finally, Unitaids' catalytic role can also be viewed in its wider presence in the COVID-19 response, beyond its investments – e.g. kick-starting agreements with global oxygen suppliers, MPP licenses, etc.

This assessment presents important questions for Unitaids senior management and Board as it considers its role and comparative advantage in the pandemic going forward (as well as in any global health emergency/ future pandemics), particularly how to weigh being catalytic/leveraging comparative advantage versus urgent, high-impact gap filling that is doable but may not meet that test.

**Has Unitaids shaped market access? Has it helped advance country preparedness?** Our assessment is that at the time of the evaluation, and specifically through its portfolio of investments, Unitaids has contributed to a lesser extent on market shaping, but to a larger extent to support country preparedness.

Unitaid's footprint in market shaping for COVID-19 products does not appear yet to have been significant (see Figure 3.3 for example, that maps Unitaids' investments to the different ACT-A workstreams including market shaping). Unitaids' work with oxygen manufacturers has initiated potential market shaping work, although the impact to date is nascent. The same goes for MPP, where the licences for the newly recommended antivirals and their generic production can impact future market competition and affordability. The FIND EOI work, by creating greater manufacturing capacity, has the potential to shape Ag RDT markets once the new products are available and quality assured.

The work on country preparedness can however be considered to be more substantial, particularly through the ongoing Test and Treat investments. Earlier investments have also helped create systems in countries (e.g. CHAI's work on updating national guidelines and country procurement and supply systems, the different oxygen grantees' work on strategic planning, development of national O2 strategies/roadmaps and training). But, the Unitaids footprint has been restricted to the project/ funded countries, and to date there is little evidence on cross-over to non-project countries.

**Has Unitaids been learning and has it appropriately adapted (both its investments and operating model) over time?** Undoubtedly yes. The evidence points to a learning organisation able to modify investments, processes and procedures to adjust to the emerging pandemic.

Unitaid's structures and systems were not designed for emergency operations in a pandemic, but it did a good job at the outset, responding fast and in a reactive, pragmatic way to develop its response. Over time, it became more strategic and flexible – adapting both the kind of investments it made (more targeted, more top-down, more integrated) and its operating model (lighter, faster process, less arduous reporting), while taking into account the evolving nature of the pandemic, the evolving knowledge about effective interventions, and the actions of other partners. Unitaids has also worked in partnership with other organisations, in particular with FIND, which has brought in additional skills and expertise. Although there are still some areas which require improvement (for example, enabling greater flexibility in procurement and improving reporting to focus more on the outcomes/impact level), overall Unitaids has successfully adapted its response.

**What are the implications for Unitaids' continued support of COVID-19 and readiness for global health emergencies/ future pandemics?** The pandemic's future course is of course difficult to predict, but as the pandemic becomes endemic, Unitaids would need to further define its role and approach to the COVID-19 response. Further, given the likelihood of a future air-borne respiratory epidemic, Unitaids is well-positioned to learn from its experience with COVID-19 so that it can adapt its products and processes quickly to the next crisis. This evaluation suggests the following implications/ lessons learnt which form the basis for our recommendations:

- There is clear value for organisations like Unitaid that “break the mould” and reinvent themselves to respond to unprecedented circumstances. Unitaid has clearly demonstrated the value in being a fast, agile mover, adapting to the needs of the hour.
- With the experience of hindsight, there is a need to now better define its role and focus areas within the continuing pandemic and also in relation to any future health emergencies that may present themselves. As one of the few international organisations focusing on equitable access, there is an urgent need for action and progress, given the current circumstances of substantial inequity between HICs and LMICs access to COVID-19 tools.
- There is a need to re-think the design of interventions during pandemic times, for example to achieve the best balance between speed, delivery of results, accountability and developing coherent and integrated investments within the market access value chain that address both demand and supply side barriers. Equally, Unitaid has done well to support investments innovations through the RfP process where, within an overall portfolio, there is flexibility in the grant design to enable countries to respond to their respective needs and stages of the pandemic and through tailored approaches/ solutions.
- There is merit in leveraging existing partnerships/ networks to deliver less risky investments in an already risky pandemic environment. Working through existing grantees/ implementers of Unitaid grants is a worthwhile approach and can be expanded in relation to the evolution of the pandemic. Varied approaches to working – donor-grantee, partnership-based, co-funders, etc. – make for more effective delivery during the pandemic.
- The adaptation of Unitaid’s grant processes has worked well and offers a practical and feasible solution to more efficient working for COVID-19 (and global health emergencies/ future pandemics). It also offers options/ lessons for the adaptation of Unitaid’s standard operating model in the next strategic period.
- The Secretariat has delivered an unprecedented volume of work on COVID-19 and there is a need to better consider feasible delivery going forward, also to not detract from Unitaid’s core business in communicable diseases.
- There is a need for more focus on the measurement of outcomes and impacts of COVID-19 investments. There is an opportunity to better collect and disseminate country level data and information that Unitaid may have access to through its country-level work – invaluable at the time of the pandemic when there are so many gaps in information and asymmetries.
- There is a need for Unitaid and its partners to review the issues around sustainability and scale-up of COVID-19 investments given the very different nature of investments under a pandemic as well as the rapidly changing dynamics of the pandemic.

## Recommendations

This section presents recommendations based on the evaluation findings, conclusions and lessons learnt. These have been discussed and reviewed with the Unitaid Senior Management Team at a workshop held in March 2022.

Recommendations are framed in the following categories:

- **Strategic** – recommendations regarding Unitaid’s role and strategic approach with regards to COVID-19.
- **Operational** – recommendations regarding areas for improvement in key processes and delivery.
- **Global health emergencies/ future pandemics** – recommendations regarding Unitaid’s support for future pandemics.

## Strategic

**Recommendation 1: Critically review and confirm Unitaid's role and comparative advantage for COVID-19 going forward, in the context of its new Strategy 2023-27, the ACT-A framework and the evolution of the pandemic.**

We understand that Unitaid is currently developing its 2023-27 Strategy and this includes continuing work on COVID-19 as part of Unitaid's proposed programmatic priority of "responding to Global Health Emergencies".<sup>1</sup> As such, we recommend that Unitaid should:

- **Review its support strategy for the COVID-19 pandemic, in line with its comparative advantages, the new Strategy, and the ACT-A areas of contribution.** Importantly, given the range of needs under the COVID-19 pandemic and the types of investments delivered to date, Unitaid should consider the appropriate focusing and balancing of its role in terms of its conventional role in supporting introductions of innovations to initiate scale-up, versus emergency support and long-term infrastructure development. Unitaid should define and outline an organisational-wide understanding of its approach in terms of focus, timeframe and guiding principles.
- **Review the role of Unitaid as the world likely moves towards an endemic phase.** Linked to the above, Unitaid should define and characterise its approach in the eventual transition of the pandemic to an endemic phase - specifically, what types of technical support should Unitaid fund, as well as the relevant interventions to be supported in an endemic phase (e.g. surveillance, sequencing, access to products, etc). Unitaid should also consider its approach in the context of the culmination of ACT-A. More generally, Unitaid should review its approaches to ensure the sustainability of its investments in an endemic phase, focusing also on how they can be reprogrammed/ repurposed to support future global health emergency preparedness.
- **On a regular basis, review – through internal and light-touch processes – the Unitaid portfolio of COVID-19 investments in terms of their relevance, balance and impact potential** in light of the latest available information (e.g. evolution of the pandemic, knowledge of effective interventions, key affected populations and geographies, etc) and aim to target/ rebalance accordingly.
- **Consider Unitaid's role with regards to health systems support under COVID-19.** Unitaid's COVID-19 investments (especially in oxygen) have demonstrated that some engagement in health systems may be unavoidable, despite Unitaid lack of comparative advantage in this area. Unitaid should better define how it wants to work with other major funders, partners and countries and the interrelationships with their health systems strengthening work in COVID-19.

**Recommendation 2: Improve and refine the design of investments, drawing on emerging lessons from Unitaid's COVID-19 portfolio.**

This review has highlighted a number of key aspects including the need to:

- Continue to strengthen linkages between the diagnostics and therapeutics investments and supporting the continuum of test and treat (as exhibited through the Test and Treat investments, which have come at a particularly opportune time with the advancements in therapeutics).
- consider the market/ access barriers more comprehensively in terms of both demand and supply side challenges, and particularly the need to include specific activities to encourage demand generation amongst users (in addition to global level supply aspects and national level policy development), or ensure that complementary investments by others are addressing these barriers.

Further, learnings from the experiences of the different therapeutics clinical trials should be incorporated into the design of future clinical trial investments to ensure the best possible approaches to support timely results in an expedited emergency context. For example, Unitaid should engage with countries, WHO, the African Vaccine

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<sup>1</sup> Unitaid 2023-27 Strategy, Strategic framework and programmatic priorities, Executive Board meeting, 15 December 2021.

Regulatory Forum (AVREF) and others at an early stage to support timely regulatory approvals. The ANTICOV structure should in particular be reviewed further to improve its effectiveness going forward. Similarly, lessons should be drawn from the delays in market entry of manufacturers under the FIND EOI – whilst a standard challenge for commodity market entry in non-pandemic times, global health emergencies require renewed and innovative thinking. Unitaid should work with other relevant partners such as WHO and the Africa CDC on these aspects.

**Recommendation 3: Diversify and expand the range of partners and partnerships to support Unitaid's COVID-19 response. Continue to develop collaborative ways of working between Unitaid and grantees.**

Noting that the strong partner network of Unitaid has been one of the key success factors supporting its COVID-19 response, Unitaid should continue to invest in building and strengthening its partnerships. In particular by:

- **Diversifying its range of grantees/ partners.** While leveraging its existing network of grantees has enabled Unitaid to respond quickly and effectively, Unitaid should consider engaging new grantees/ partners to ensure it has the right organisations and people on the ground who can deliver impact, including, for example, emergency organisations.
- **Continuing to expand different partnerships, such as with FIND, that can complement Unitaid's strengths and comparative advantages.** Unitaid should continue to establish a variety of partnerships beyond the traditional donor-grantee arrangements, which complement Unitaid's comparative advantage and result in more effective investments. Varied approaches (e.g. donor-grantee, partnership-based, co-funders, etc.) have made for more effective delivery during the pandemic and should be explored for future global health emergencies.
- **Continuing to build strong approaches for collaborative working.** Work towards more seamless engagement with grantees in terms of ensuring a common understanding of overall objectives (primary and secondary for example) as well as future opportunities (e.g. where there is flexibility to extend timelines, or views that there may be some iterations or evolution in the approach).

**Recommendation 4: Review the issues around sustainability and scale-up of COVID-19 investments in the light of the very different nature of investments in a pandemic and the pandemic's rapidly changing dynamics.**

Key aspects to consider include:

- **The need for immediate/ near term scale-up in a pandemic situation** – for example, the usual five-year horizon that Unitaid applies in direct impact related to scale-up does not apply in a pandemic situation where the need for scale-up is immediate.
- **The very different attributes to scale-up** – for example, in terms of the global conditions included within Unitaid's scalability matrix, the evidence and normative guidance is continually evolving in a pandemic, pricing may not always be optimal (and affordability may not be the only priority criteria), etc.; in terms of country conditions included within Unitaid's scalability matrix, political buy-in and donor engagement is driven by the global discourse on the pandemic, etc. and new factors assume importance such as buying power of HICs, export restrictions by countries, etc.
- **Scalability needs to apply a longer-term view in terms of evolution of the needs of the pandemic** e.g. as we move from a pandemic to endemic state, certain issues such as post-COVID conditions, surveillance, sequencing, etc. assume more importance, and the initial efforts to ramp-up access to testing and treatments may become less relevant. As also noted under recommendation 1, there is a need to consider transition of investments and reprogramming, or repurposing of ongoing investments and infrastructure to support future preparedness for global health emergencies.

## Operational

**Recommendation 5: Optimise and institutionalise the successful adaptations and flexibilities to Unitaid's core processes that were introduced to support COVID-19 investments and continue to review and adapt these to ensure responsiveness to needs, whilst maintaining accountability and due diligence.**

The evaluation has highlighted a number of adaptations to the Unitaid model that have successfully served to promote agility and dexterity in its response to the pandemic, e.g. the RfP approach and the lighter application package. These should be optimised and institutionalised, not only for Unitaid's future response to COVID-19, but also for its core portfolio in HIV/AIDS, malaria and TB, where relevant models and delivery mechanisms should be considered as Unitaid finalises its next Strategy 2023-27. It is an important opportunity for Unitaid to draw lessons from COVID-19 for its core business delivery.

Further, Unitaid should address the remaining areas of improvement with regards to its grant processes for COVID-19 investments, and specifically with regards to the following:

- **Procurement channels:** Consider whether more flexibility can be given to grantees with regards to the selection and use of procurement channels – for example, by enabling grantees that have already gone through a strict due diligence process and with high procurement standards to use alternative procurement mechanisms to WHO/ UNICEF.
- **Procurement of goods/ products:** Consider accommodating waivers for products/ goods which do not have WHO PQ but have received regulatory approval from another stringent regulatory authority (SRA) such as the FDA, EMA, etc.
- **Budget management:** Ensure that approval processes for budget and other changes are as fast and streamlined as feasible, whilst ensuring due diligence.
- **Reporting:** Continue to streamline and harmonise reporting formats for grantees.
- **External communication and messaging on investments:** Unitaid should improve communication and messaging around synergies between investments to avoid misunderstanding amongst external stakeholders e.g. where Unitaid is supporting specific company product development alongside wider country introduction and access of the diagnostic/ therapeutic.

**Recommendation 6: Review Secretariat capacity and optimised delivery for future COVID-19 support.**

The mid-term evaluation has highlighted the significantly expanded workload amongst the Secretariat teams to respond to COVID-19 (although has not reviewed impacts on the core investments of HIV/AIDS, malaria and TB). Going forward, Unitaid should review Secretariat capacity and delivery for COVID-19 investments (and related ACT-A and other work). For example, should it continue as present with Secretariat staff supplementing their core portfolio work with COVID-19 work, or include a dedicated team for the COVID-19 portfolio? Other relevant questions for examination include whether the Secretariat should add full-time equivalents (FTEs) or as current, provide surge capacity through consultants. Planning needs to consider the future evolution of the COVID-19 pandemic, as well as preparing for new global health emergencies/ future pandemics (see below).

**Recommendation 7: With the maturity of investments and learning within Unitaid, expand M&E approaches to better define and measure outcomes and impacts from COVID-19 investments.**

The M&E approach to date has largely been activity and output-based for COVID-19 investments, expectedly so given the emergency response mode of Unitaid and the need to not impose additional financial and administrative burdens on grantees. With the consolidation of Unitaid's COVID-19 response and the progression of the pandemic however, there is a need to better define and measure downstream results in terms of outcomes and impacts from the COVID-19 investments and portfolio as a whole. This would entail:

- **Elaborating how outcomes and impacts will be defined and measured**, including which metrics will be used and at what level (portfolio vs. investment level), to better enable monitoring (going beyond input metrics in terms



of dollars spent, equipment procured, etc to outcome/ impact metrics which will enable the quantification of its contribution).<sup>2</sup> More generally, given the contribution of multiple ACT-A partners to results, Unitaid should work with partner organisations to define joint outcome and impact measures.

- **Assessing outcomes (and where possible impact) through specialised reviews and evaluations.** This should include a greater focus on country-level assessments and reviews through a case study approach. Where relevant, consider modelling of potential impacts e.g. in relation to the results to be achieved from the FIND EOI investments.
- **(Potentially) expanding the work of the Unitaid Secretariat** to elaborate a more comprehensive theory of change (that is not linear and takes account of the dynamism of the pandemic), the range of expected impact pathways as well as methodologies for measuring outcomes and impacts. Ultimately the Secretariat would work with grantees to secure more country-level information, including qualitative information that describes the value of the Unitaid investment, level of contribution and scalability.
- **For oxygen investments in particular, working with other global health organisations to develop relevant metrics and KPIs** (e.g. building on the ongoing multi partner effort led by WHO under the WHE 2 investment) as well as supporting countries with routine data collection on these aspects through HMIS. There may be useful lessons from Gavi's M&E approach for its Cold Chain Optimization Platform which also are infrastructure-based investments.<sup>3</sup>
- In addition to outcome and impact measurement, Unitaid should also **focus on measuring the sustainability of its investments**, especially as the pandemic evolves to an endemic state. There is also a need to ensure investments are repurposed to support future epidemic preparedness and response.

## Global health emergencies/ future pandemics

**Recommendation 8: Decide whether and under what conditions/ parameters, Unitaid is open, in principle, to support global health emergencies including future pandemics and position the organisation accordingly.**

With the benefit of experience of the COVID-19 pandemic, Unitaid should:

- **Formulate its position and strategy to combat future global health emergencies including pandemics.** As part of its Strategy 2023-27 and wider discussions around direction of travel for the organisation, Unitaid should discuss possible conditions and parameters that would necessitate its involvement in supporting any future pandemic or health emergencies. This should include areas of focus, types of support, overall approach and guiding principles, etc. Importantly, it should include more clarity on the nature of emergency support that falls within Unitaid's remit. It should also define some boundaries – e.g. when might Unitaid play a facilitator, rather than a core role, what might be areas where Unitaid does not get involved?
- **Depending on the chosen strategy, put in place the elements to rapidly enable support for future pandemic/ exceptional situations**, including decision-making/ governance procedures, flexibilities with regards to funds, staffing and processes, etc.
- **Continue to foster its commitment to equitable access**, for example by ensuring that R&D investments are based on confirmed access commitments.

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<sup>2</sup> For example, the Test and Treat portfolio includes metrics in relation to (i) evidence generation, (ii) supply chain and service delivery, (iii) policy and regulatory environment, (iv) demand creation and (v) transition and scale-up, however we would argue that a focus on (iii) and (v) would be most relevant to support an assessment of outcomes. For the balance areas, the focus is very much on measuring within-project results rather than multiplier effects of Unitaid investments to non-project countries (for example) in keeping with Unitaid's raison d'être.

<sup>3</sup> <https://www.gavi.org/sites/default/files/document/programming-guidance---supply-chainpdf.pdf>

**Better harness its vantage point for access to market and country level intelligence and data for global health emergencies/ future pandemics.** With Unitaids network of grantees across the globe, many of which are doing core work at the national and sub-national levels in countries, Unitaids should consider ways to better harness data and information that it has/ could have access to and channel for the global health response. This is an important learning through the experience of the COVID-19 pandemic, where data and information at the global-level has been limited/ patchy, also because of the continually evolving nature of the disease.



# 1. INTRODUCTION

Cambridge Economic Policy Associates (CEPA) was appointed by Unitaid to conduct a first portfolio-level mid-term evaluation of Unitaid’s investments in COVID-19 over the period 2020-21.

The introduction section sets out the evaluation objectives and scope (Section 1.1), evaluation framework and methodology, including a summary of the work completed to date and next steps (Section 1.2) and the structure of the report (Section 1.3).

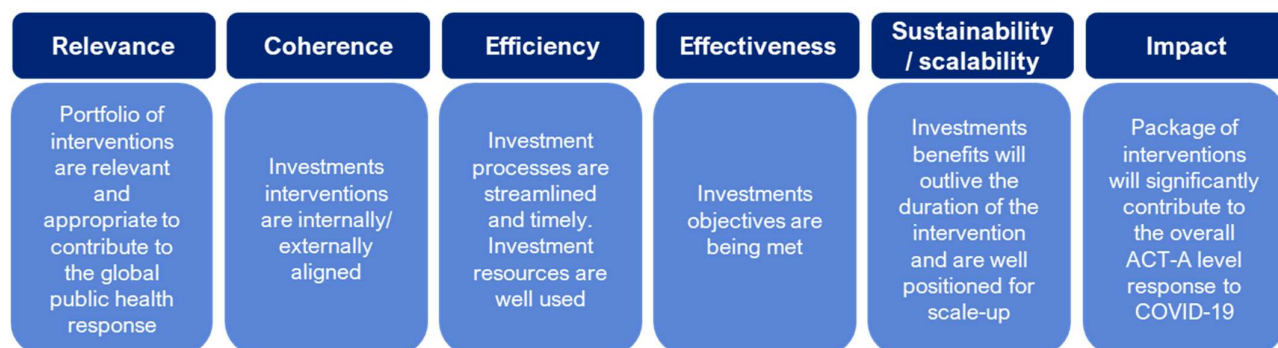
## 1.1. EVALUATION OBJECTIVES AND SCOPE

The mid-term evaluation covered Unitaid’s direct investments in response to COVID-19 from March 2020 to end 2021, with the following objectives:

- To assess the extent to which Unitaid’s COVID-19 investments contributed to the COVID-19 response, particularly in providing catalytic support, shaping market access and country preparedness for the adoption of COVID-19 diagnostics and treatment options.
- To draw lessons learnt and recommendations for Unitaid to apply to its existing and future COVID-19 investments.

The evaluation encompassed the Organisation for Economic Cooperation and Development (OECD) Development Assistance Committee (DAC) evaluation criteria to review the portfolio of investments, including: relevance, coherence, efficiency, effectiveness, impact and sustainability. Figure 1.1 describes the focus of the evaluation for each DAC criteria.

Figure 1.1. Focus of the evaluation by DAC criteria



A total of 27 investments for US\$155m were included in scope in the portfolio review (see Table 1.1. overpage).<sup>4</sup> The evaluation is a portfolio-level evaluation and draws on evidence and examples from the investments but does not consider every investment in depth. Also, as many investments have recently been signed, these are evaluated from a relevance and coherence perspective only.

The evaluation does not include the development of detailed country case studies, however feedback from consultations with grantees and country-level stakeholders is used to support the findings in the report and highlight evidence and examples from Unitaid’s country work.

Unitaid’s contribution to the COVID-19 response is broader than its portfolio of investments, and in particular is through its role within the ACT-A framework. This evaluation focused on the contribution of the investment portfolio alone and the role of Unitaid within ACT-A was not within scope. However, noting the significance of its wider strategic work on its investments per se, specific aspects of Unitaid’s engagement within ACT-A are considered whilst reviewing the effectiveness of the investment portfolio.

<sup>4</sup> Unitaid (2021) COVID-19 tracker and country mapping, MS Excel file shared with CEPA, October 7 2021.

Table 1.1. Summary of Unitaid's 27 COVID-19 investments in scope as of October 2021 (Area: D=diagnostics, T=therapeutics, O=oxygen, CC=cross cutting)

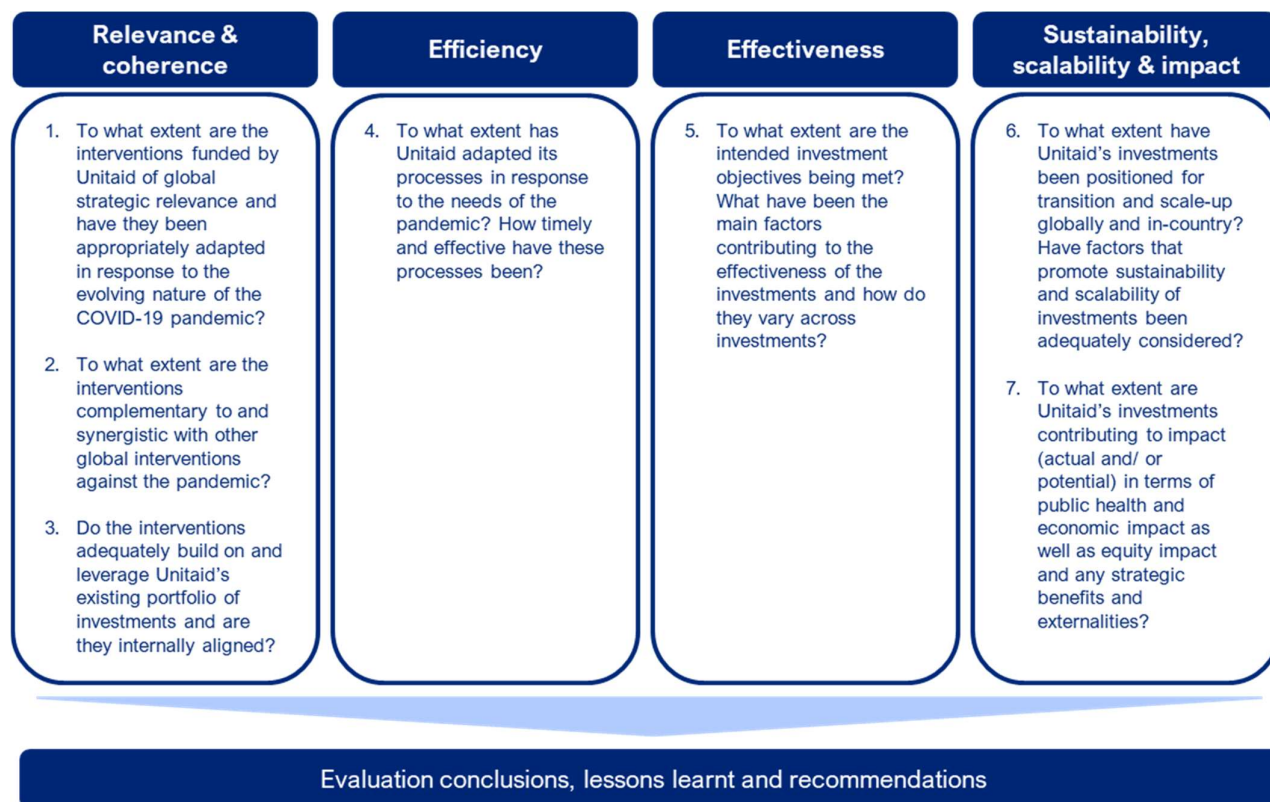
Funding (approval)	Implementer	Grant name	Area	Summary description	US \$	Status
Wave 1 (Mar – May 2020)	FIND	Output 5	D	To support access to COVID-19 diagnostics in resource limited settings, primarily through evaluations of diagnostic tests	4.5m	Ended
	CHAI	Output 5	D	To support strong COVID-19 diagnostics programmes and supply chain in 15 priority low and middle income countries	7.6m	Ended
	IBB, UNSW, UOL, Wits RHI	COHIVE	T	To support the COHIVE trials (Coronavirus Outcomes in HIV Evaluation in Resource Limited Settings)	0.8m	Active
	IS Global	ANTICOV	T	To generate evidence on safety and efficacy of therapies in mild/moderate cases of COVID-19 (ANTICOV Phase 1)	0.6m	Ended
	UOL	AGILE	T	To assess drugs for COVID-19 in early clinical phase expeditiously	2.8m	Active
	Wits RHI	COVER HCW	T	To support COVER HCW – COVID-19 Emergency Response for Health Care Workers: prevention and treatment of COVID-19 in South African healthcare workers	2.7m	Active
	ALIMA	Output 4	O	To support health worker and patient protection and systems for COVID-19 infection management in five African countries	4.5m	Active
	PATH	Output 6	O	To provide technical support to respiratory care systems to improve treatment of COVID-19 patients	1.7m	Active
	WEMOS	CIFA 1 and 2	CC	To enhance solidarity to ensure medical innovations for COVID-19 benefit all	1.7m	Active
	MTV SAF	Shuga	CC	To support public health awareness about COVID-19 through mass distribution of reliable information and messaging in Africa via popular media	0.3m	Ended
Wave 2 (Jun – Nov 2020)	FIND	FIND EOI	D	To drive equitable access to fit-for-purpose antigen rapid diagnostics tests for COVID-19 (Co-funded by FIND for a total of US\$40m)	10m	Active
	CHAI	Output 6	D	To prepare markets for accelerated implementation and uptake of antigen RDTs and transition to dual testing systems	9.7m	Active
	UNICEF	UNICEF	T	Dexamethasone procurement to secure quality assured supply for LMICs	4m	Active
	DNDi	ANTICOV	T	To generate evidence on safety and efficacy of therapies in mild/moderate cases of COVID-19 (ANTICOV Phase 2) (Co-funded with German Federal Ministry of Education and Research for a total of US\$30m)	14.7m	Active
O2 Catalytic Funding (Apr – Nov 2021)	PATH	Output 7	O	To facilitate the purchase of respiratory care equipment and procured services	5m	Active
	CHAI	Output 7	O	To support allocation of Unitaid funds for procurement of respiratory care medical devices and commodities	5m	Active
	CHAI	Output 8	O	To provide technical support to countries to facilitate strong respiratory care planning and implementation as part of the COVID-19 emergency response	5m	Active
	CHAI	Output 9	O	To accelerate access to medical oxygen through market and demand-side interventions	13m	Active
	WHO/WHE	WHO-WHE 1	O	To provide oxygen technical assistance and acute biomedical needs procurement	5m	Active
	WHO-WHE	WHO-WHE 2	O	To expand WHO's WHE oxygen procurement capabilities	10m	Active
Test and Treat (co-funded with FIND) (Aug - Nov 2021)	AURUM	Test and Treat RFP	D&T	To support (1) adoption and uptake of current and novel diagnostic tools, in particular, antigen-detected rapid diagnostics (Ag-RDTs) and self-tests, in the context of wider diagnostic strategies, (2) adequate delivery models and appropriate linkages and referral with other COVID-19 health interventions, (3) introduction of safe and effective therapeutics, current and new products (as they become available).	8.4m	Active
	IS Global		D&T		3.5m	Active
	EGPAF		D&T		7m	Active
	PIH		D&T		4m	Active
	CHAI		D&T		11.8m	Active
	FIOTEC		D&T		3.3m	Active
	PSI		D&T		8.8m	Active

## 1.2. EVALUATION FRAMEWORK AND METHODOLOGY

### 1.2.1. Evaluation framework

Based on the evaluation objectives and scope set out above, Figure 1.2 presents the evaluation framework, highlighting the key questions for reviews under the OECD DAC evaluation criteria, grouped in four dimensions as follows: (i) relevance and coherence; (ii) efficiency; (iii) effectiveness and (iv) sustainability/ scalability and impact.

Figure 1.2 Evaluation framework



### 1.2.2. Methodology

#### Theory-based approach

The evaluation methodology was theory-based, considering the overarching theory of change (TOC) developed by Unitaid for its COVID-19 portfolio (included as Appendix A). The theory-based approach has enabled a review of the “theory” of what Unitaid considered as it designed and implemented its investments, and provided a basis for comparison with actual practice and experiences. This has aided an understanding of the pathways to impact, including key assumptions and risks, and thereby facilitated the development of evaluation conclusions, lessons learnt and recommendations.

#### Description of methods, including limitations

The evaluation adopted a mixed-methods approach as follows:

- **Document review:** A comprehensive review of key documents, including from Unitaid, WHO and ACT-A, and other stakeholders as well as COVID-19 related literature. The bibliography is presented in Appendix B.
- **Consultations:** Key informant interviews and focus group discussions (FGD), with a total of 143 unique consultees over a total of 82 consultations and six FGDs including at the global level (Unitaid Secretariat, grantees, global stakeholders and ACT-A partners, community and civil society organisations, manufacturers) and at the country level (with grantees and country-level stakeholders in Cameroon, India, Kenya, and Senegal,

also expanded to other countries to solicit additional perspectives, included Ecuador, Ghana, Guatemala, Zambia and Zimbabwe<sup>5</sup>). However, the majority of country level interviews were planned for when the Omicron wave was taking place, as such consultations have been mainly conducted with grantees as opposed to national level stakeholders. The list of consultees is presented in Appendix C and the interview guides in Appendix D.





- **Data analysis:** Quantitative data analysis including review of global COVID-19 testing and procurement data as well as review of Unitaid accountability frameworks and M&E data from the investments. The bibliography in Appendix B also includes these sources.
- **Workshops:** including: (i) a Recommendations Co-Creation Workshop with the Unitaid Secretariat (senior management, strategy and programmes teams, etc.); (ii) an External Partners Presentation with key stakeholders (grantees, ACT-A partners, etc.) to discuss and review the main conclusions and recommendations; and (iii) a “brown-bag” session with Unitaid Secretariat to discuss and review the main conclusions and recommendations.

The detailed methodology, including limitations is presented in Appendix E.

## Robustness of findings

Findings have been assessed for robustness based on both the quality and quantity (e.g. triangulation) of evidence, as per the scale outlined in Table 1.2 below.

Table 1.2: Robustness rating for main findings/emerging themes

Rating	Strength of evidence
<b>Strong</b> 	<ul style="list-style-type: none"> <li>• The finding is supported by data and/or documentation which is categorised as being of good quality by the evaluators; <b>and</b></li> <li>• The finding is supported by majority of consultations across different stakeholder groups, whilst reflecting for any inherent consultee biases, as relevant.</li> </ul>
<b>Moderate</b> 	<ul style="list-style-type: none"> <li>• The finding is supported by majority of the data and /or documentation with a mix of good and poor quality; <b>and/or</b></li> <li>• The finding is supported by majority of the consultation responses.</li> </ul>
<b>Limited</b> 	<ul style="list-style-type: none"> <li>• The finding is supported by some data and/or documentation which is categorised as being of poor quality; <b>or</b></li> <li>• The finding is supported by some consultations as well as a few sources being used for comparison (i.e. documentation).</li> </ul>
<b>Poor (not included in the report)</b> 	<ul style="list-style-type: none"> <li>• The finding is supported by various data and/or documents of poor quality; <b>or</b></li> <li>• The finding is supported by some/few reports only and not by any of the data and/or documents being used for comparison; <b>or</b></li> <li>• The finding is supported only by a few consultations or contradictory consultations.</li> </ul>

### 1.3. STRUCTURE OF THE REPORT

The evaluation report is structured as follows:

- Section 2 presents the context/ background and a consideration of strategic issues.
- Section 3 presents key findings by the four dimensions of the evaluation framework (relevance and coherence (Section 3.1), efficiency (Section 3.2), effectiveness (Section 3.3) and sustainability, scalability and impact (Section 3.4).

<sup>5</sup> The Wave 1 and 2 diagnostics investments were only implemented in Sub Saharan Africa, so other review countries do not provide information in this regard.

- Section 4 presents overall conclusions and lessons learnt.
- Section 5 includes recommendations.

The main report is supported by the following appendices:

- Appendix A provides Unitaid's overarching Theory of Change for its COVID-19 investments.
- Appendix B presents a bibliography of key references.
- Appendix C provides the consultation list (global and country level stakeholders).
- Appendix D presents the interview guides for the consultations.
- Appendix E presents the evaluation methods and limitations in more detail.
- Appendix F presents a summary of the evolution of the ACT-A partnership objectives, 2020 - 2022.
- Appendix G presents the status (as of December 2021) of the Unitaid-FIND EOI investments in Ag-RDTs manufacturers, including successes and challenges.
- Appendix H presents the findings from four countries (Cameroon, Kenya, India and Senegal) on the Unitaid oxygen investments.

## 2. BACKGROUND AND STRATEGIC ISSUES

For scene setting, Section 2.1 provides a background to Unitaid’s work in COVID-19 and Section 2.2 a discussion of some of the key strategic issues facing the organisation in its response and how the mid-term evaluation seeks to bring these together to develop key conclusions, lessons learnt and recommendations.

### 2.1. CONTEXT/ BACKGROUND

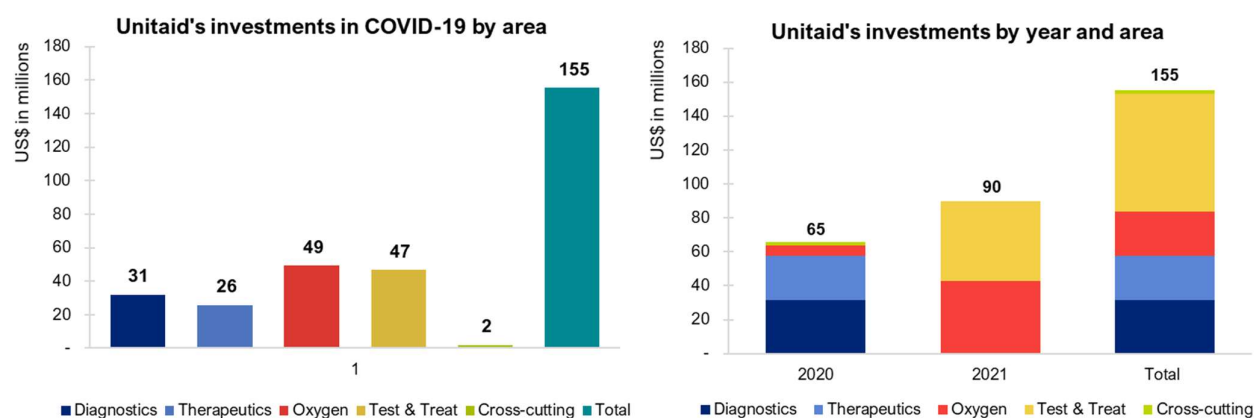
In March 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a global pandemic. Following this declaration, and with countries around the world being affected, a global response was initiated that required the engagement of national governments and coordination of partners. Unitaid responded to the public health crisis, with two initial waves of investments designed to enhance access to COVID-19 diagnostics, treatments and supporting tools, including oxygen. These two waves provided up to US\$ 65 million of Unitaid’s core funds, including: (i) Wave 1 of US\$ 30 million in March 2020; and (ii) Wave 2 of US\$ 35 million in bridge funding in June 2020. These funds were provided through expanding and adding additional investments and/ or funding of new grants to address some of the immediate challenges in countries for detecting and responding to COVID-19.

On 24th April 2020, Unitaid joined global health actors and other stakeholders to launch the Access to COVID-19 Tools (ACT) Accelerator. In partnership with ACT-A, Unitaid has focused its efforts on identifying and preparing the market for effective diagnostics and treatments against COVID-19. As co-lead of the Therapeutics Pillar of ACT-A (with Wellcome Trust) and as co-lead for the Market Readiness Working Group of the Diagnostics Pillar (with FIND), Unitaid has led on efforts to coordinate and respond to both therapeutics and diagnostics needs and barriers with a focus on equitable access. In addition, as a member of the Country Preparedness Working Groups within both the diagnostics and therapeutics pillars, Unitaid is supporting country introduction and uptake of COVID-19 interventions.

In 2021, Unitaid, with global ACT-A partners, continued to maintain its focus on addressing market and country barriers to accelerate access to: (i) oxygen supply through a series of catalytic investments for oxygen support (US\$ 46 million); and (ii) to prepare for new innovations in diagnostics and therapeutics in the pipeline through a series of new investments to enhance access to COVID-19 tests, isolate, care and treat (through the “Test and Treat Request for Proposals (RfP)” for US\$ 47 million). In addition, as co-leader (previously, and now sole lead) of the ACT-A O<sub>2</sub> Emergency Taskforce, Unitaid has committed to further support for oxygen investments (through the “Access to Oxygen RfP”) to accelerate access to medical oxygen during the COVID-19 pandemic (not within scope of the evaluation).

A summary of the Unitaid COVID-19 portfolio by year and area is provided in Figure 2.1.

Figure 2.1. Summary of Unitaid’s COVID-19 investments by area and year as of October 2021





## 2.2. STRATEGIC ISSUES

In the evaluation of Unitaid's portfolio of investments on COVID-19, a number of key aspects are noted:

- First, as noted above, Unitaid acted very quickly after the start of the pandemic, before most other international organisations developed their response, and before ACT-A was set up.
- Second, Unitaid's response to COVID-19 is broader than its portfolio of COVID-19 specific investments, and includes its work through ACT-A as well as other wider work such as on intellectual property barriers by the Medicines Patent Pool (MPP) and others, Unitaid's engagement with oxygen manufacturers as part of its market shaping efforts (discussed in more detail in Section 3), etc.
- Third, Unitaid used its core funds for its initial response to COVID-19 (for Waves 1 and 2), and thereafter has had access to new funding through ACT-A. While some investments are solely funded by Unitaid, many are also co-funded by ACT-A partners, implying a greater leveraging of Unitaid's funding and partnership-based approach.
- Fourth, while there has been additional monies for COVID-19 investments as noted above, Unitaid has largely worked within its existing staffing envelope, with some additional surge support.

Noting these aspects, there were a number of "degrees of freedom" that Unitaid had to navigate through and choose between – as reflected in the range of discussions amongst the Unitaid Board and Secretariat, which include:

- what types of technical interventions to fund (e.g., diagnostics or therapeutics or others, upstream or downstream, demand or supply side interventions, etc.) – while ultimately these discussions were under the ACT-A framework, Unitaid had important decisions to make in relation to what it could effectively deliver;
- linking with the above is the scope and design of its investments – which activities in support of which objectives, which geographies to fund, which partners to work with and how, etc.;
- ultimately, the above also reflects how Unitaid chose to position its operating model in its response to COVID-19 in terms of adaptation of key processes, working with grantees/ implementers, approach to risk, etc.;
- balancing across different objectives such as working in areas of Unitaid's comparative advantage, impact, speed, sustainability, potential for scale-up, value for money, appropriate risk management, etc.
- and, for all of the above, how Unitaid chose to adapt its approach with the evolving dynamics of the pandemic, the state of knowledge about effective interventions and the actions of other players.

These strategic issues closely link up with the questions included in the evaluation framework set out in Section 1.2 where, based on the OECD DAC criteria, we are looking to assess the following four evaluation dimensions:

- Relevance and coherence (Section 3.1) looks at whether Unitaid's COVID-19 investments made sense to the context at the time, both individually and as a portfolio. Key considerations include whether Unitaid investments targeted the needs of LMICs, focused on strategically astute interventions designed to deliver impact, built on Unitaid's comparative advantage, evolved adequately to take into account changes in the pandemic and the actions of other players, and were suitably synergised with the work of other partners and as a portfolio.
- Efficiency (Section 3.2) looks at the adaptations to Unitaid's operating model for COVID-19 investment delivery. Key areas of review include the speed of its response, the efficacy of its adapted grant processes for approvals, management and monitoring as well as delivery by the Secretariat.
- Effectiveness (Section 3.3) provides an assessment of the extent to which the Unitaid COVID-19 investments are meeting their objectives. Key considerations include the approach to measurement of results of the investments (which drives the scope of this analysis), an assessment of the progress to date, and importantly, what this progress amounts to in terms of making a difference to access to diagnostics and therapeutics for COVID-19.
- Sustainability, scalability and impact (Section 3.4) looks at the extent to which investments have been sustained and/ or scaled up (or have potential for scale-up) as well as delivered impact. Key considerations include an

understanding of the aspects driving sustainability and scalability, and what these mean for Unitaid investments in the context of the pandemic. For impact, while it is not possible to measure the public health and economic impact of Unitaid investments, we consider whether the investments have improved equity in access and wider strategic benefits.

Looking across the four individual evaluation dimensions, this evaluation seeks to answer a number of cross-cutting questions which are taken up in the conclusions, lessons learnt and recommendations sections, including:

- Does Unitaid's portfolio of COVID-19 investments taken as a whole make a significant contribution to the response?
- Has Unitaid been catalytic, and played to its comparative advantages?
- Has Unitaid shaped market access? Has it helped advance country preparedness?
- Has Unitaid been learning and has it appropriately adapted (both its investments and operating model) to respond to the evolving needs of the pandemic?
- What are implications and recommendations for Unitaid's continued support of COVID-19 as well as for future global health emergencies/ pandemics?



### 3. KEY FINDINGS

Section 3 of the report provides key findings across the evaluation dimensions – relevance and coherence (Section 3.1), efficiency (Section 3.2), effectiveness (Section 3.3) and sustainability, scalability and impact (Section 3.4). Each sub-section starts with a description of the approach, followed by key findings and the analysis and evidence-base.


#### 3.1. RELEVANCE AND COHERENCE

The first dimension of the evaluation framework covers the evaluation criteria of relevance and coherence. Relevance (Section 3.1.1) is assessed from the perspective of whether the investments/ portfolio has responded to the evolving needs and critical gaps in the pandemic response for LMICs in particular, whether the investments have been structured/ designed to deliver results, and whether the investments build on Unitaids’ comparative advantage. Coherence is assessed from the perspective of complementarity and synergy with the work of other partners (“external coherence” – Section 3.1.2) and synergies between the Unitaids investments (“internal coherence” – Section 3.1.3).

##### 3.1.1. Strategic relevance

**Q1. To what extent are the interventions funded by Unitaids of global strategic relevance and have they been appropriately adapted in response to the evolving nature of the COVID-19 pandemic?**

**1.1. Across the portfolio, investments have been strategically relevant to context, fully responding to the priority needs of the pandemic in LMICs.**

<i>Strength of evidence:</i>	<i>Strong</i> 
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Therapeutics and diagnostics investments, many of which came early in the pandemic, were found to be highly relevant to the context at the time, while the oxygen and test and treat investments represented an astute adaptation by Unitaids to the evolving pandemic and increased understanding of the most effective responses. More specifically:

- Unitaids’ **therapeutics** investments were initiated at the very start of the pandemic when there was no known preventative or curative treatment for COVID-19. Whilst the development of a vaccine generated most of the attention, Unitaids rightly anticipated the need for investments in therapeutics, with LMICs’ access to vaccines likely limited in the near term.<sup>6</sup> The relevance of the therapeutics portfolio is also highlighted by the following:
  - There was a need to facilitate research in LMICs with weak and fragile health systems, given most of the global research on therapeutics was focusing on high-income countries. Even almost two years into the pandemic, there are only 41 clinical trials that have at least one clinical study arm in a Sub-Saharan African country (excluding South Africa) which is 1.4% of all ongoing COVID-19 clinical trials.<sup>7</sup>
  - It was relevant to look at mild/moderate forms of COVID-19 for outpatient care through ANTICOV given the need to reduce hospitalisation and thereby contain the pressure on fragile LMIC health systems.
  - It was useful and catalytic to fund the AGILE clinical trial that provides a platform for the pre-clinical and Phase 1 and 2 evaluations of treatments, filling a gap between the more upstream work and the large-scale Phase 3 clinical trials, so that resources for the Phase 3 trials can be focused on the most promising treatments only.
  - Additionally, the clinical trials have focused on critical population needs including: (i) health care workers (COVER HCW) who have been critically exposed to the virus, often without adequate protective equipment; (ii) outpatients (ANTICOV), whose ability to access fully equipped health facilities is limited for many in LMICs,

<sup>6</sup> Less than 1% of the LIC population has been vaccinated as of January 2022, [www.one.org](http://www.one.org)

<sup>7</sup> CEPA analysis based on COVID-19 clinical data from <https://www.covid19-trials.com>

and even more challenging in pandemic times; and (iii) People Living with HIV (PLHIV) (COHIVE investment), for whom there was limited knowledge about the potential impact (including severity) of COVID-19 infection.

- It was appropriate to focus on generating evidence and data on the use of priority drugs which were affordable and available in LMICs. For example, the drugs selection under ANTICOV was guided by access issues including selecting drugs that are “*already marketed, repurposed, oral drugs, easy to administer, low cost, no cold storage required, etc*”.<sup>8</sup>
- It was useful that the clinical trials (ANTICOV and AGILE) were designed as adaptive platforms that could respond to the dynamism of the pandemic’s therapeutics landscape by shifting priorities and introducing/removing drugs.

Whilst the majority of the therapeutics portfolio rightly focused on research given the lack of treatment options (until recently), Unitaid also invested in an inventory for dexamethasone which aimed to ensure LMICs have guaranteed access to the first drug shown to be effective in reducing mortality amongst severe COVID-19 cases (although this investment faced some challenges in implementation which are discussed in Section 3.3 below).

- Unitaid’s **diagnostics** investments were also strategically relevant – in particular:
  - At the beginning of the pandemic, the global RT-PCR market was overwhelmed by an influx of tests by manufacturers across the globe with limited data on their technical performance. Countries, particularly LMICs, required data quickly to understand the performance of these tests and guide their procurement decisions. Unitaid, leveraging on its widespread investments in molecular diagnostics with CHAI quickly pivoted to support market access and implementation, collaborating with FIND to support comprehensive evaluation of existing tests to validate the quality and produce data on the accuracy of their performance (including sensitivity and specificity of tests).
  - Given the limitations of RT-PCR testing in some key LMICs settings, the use of Ag RDTs became highly relevant to scale-up the testing response in LMICs. However, few companies were manufacturing Ag RDT in sufficient quantities to meet global demand and HICs were competing for the few products available. In response, Unitaid, in partnership with FIND, made additional investments aimed to expand regional manufacturing capacity of Ag-RDTs. Supporting manufacturing strengthening and the technology transfer to local manufacturers in LMICs was an innovative investment aimed at bringing appropriate fit-for-purpose technologies to the target market of LMICs more efficiently and effectively. Alongside, CHAI supported product introduction, evidence generation and demand forecasting in select countries to facilitate increasing access to Ag RDTs.
- The diagnostics and therapeutics areas of Unitaid’s investments came together through the **Test and Treat** investments which are highly relevant as they frame the COVID-19 response from a holistic perspective – taking into account the full continuum of care and also focusing on piloting various models (e.g. integration with HIV, TB and MNCH services; introduction of self-testing). These investments are supporting country-level demand creation and adoption, as well as evidence generation about various test and treat models, thereby addressing a much-needed gap to encourage the scale-up of existing diagnostics and the introductions of treatments which are beginning to come through the pipeline. These investments have been sensibly set up as a package, being implemented in a wide range of geographies (22 countries) and by multiple partners (seven in total).
- **Medical oxygen** has historically been overlooked and underfunded by countries, particularly LMICs, notwithstanding the fact that it is included in WHO’s list of essential medicines. In the absence of suitable medicines to treat COVID-19, oxygen has been regarded as the main therapy for severe COVID-19 cases, and as such, access to medical oxygen is a priority in the COVID-19 response. For instance, with the COVID-19 pandemic, in 2021 it was estimated that approximately 15% of people with COVID-19 require access to medical

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<sup>8</sup> DNDi (2020) ANTICOV Project Plan, p. 32

oxygen<sup>9</sup> and that more than half a million COVID-19 patients in LMICs require oxygen treatment every day.<sup>10</sup> At the end of 2021, the Every Breath Counts Coalition estimated that 52 out of 68 LMICs on its Oxygen High Risk list continue to have high and rising oxygen demand.<sup>11</sup> Medical oxygen was originally included under the ACT-A Health Systems Connector but was moved to the Therapeutics Pillar in February 2021 due to the lack of traction by the global community. Unitaid's work in the area, both through its investments, leadership and advocacy at the ACT-A level (including through its role as co-Chair in 2021, now Chair, of the Oxygen Emergency Taskforce), has been highly relevant as it has led the much-needed global response on oxygen.<sup>12</sup>

Table 3.1 presents the **strategic relevance** of individual investments within the Unitaid COVID-19 portfolio.

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<sup>9</sup> PATH (2021), a year into COVID-19, medical oxygen scarcity still costing lives, available at [www.path.org/articles/year-covid-19-medical-oxygen-scarcity-still-costing-lives/](http://www.path.org/articles/year-covid-19-medical-oxygen-scarcity-still-costing-lives/) [Accessed 03 February 2022]

<sup>10</sup> WHO (2021), COVID-19 oxygen emergency impacting more than half a million people in low- and middle-income countries every day, as demand surges, available at <https://tinyurl.com/3eb3cb86> [Accessed 03 February 2022]

<sup>11</sup> Every Breadth Counts Coalition LMICs Oxygen Crisis Risk List, updated 9 Jan 2022, available at <https://docs.google.com/document/d/1EawG7nDVP1USdrPpJap0wA-3jpRdZZYduOsKI45tpM/edit> [Accessed 03 February 2022]

<sup>12</sup> On 5 March 2021, the Unitaid Board approved the investment of an initial US\$ 10 million for the COVID-19 Oxygen Emergency Response, as noted in Unitaid (2021) ACT-A COVID-19 Oxygen Emergency Response: proposal executive Summary – Report for Unitaid's Executive Board, p.2. A further US\$10m was invested August 2021.

Table 3.1: Strategic relevance of investments in the Unitaid COVID-19 portfolio

Area	Strategic relevance of investments	
<b>Therapeutics</b>	<ul style="list-style-type: none"> <li>● AGILE: relevance exemplified by the efficacy of a relatively small Unitaid investment in pre-clinical and early clinical Phase 1 and 2 trials to feed into larger investments in clinical trials; adaptive platform to enable flexibility and agility in the evaluation of therapeutics.</li> <li>● ANTICOV: focus on mild/moderate forms of COVID to reduce hospitalisations (as opposed to severe disease on which the majority of clinical trials were focusing); concept of platform useful to support research objectives and strengthen capacity; adaptive platform to enable flexibility and agility in the evaluation of therapeutics.</li> <li>● COHIVE: focus on the impact of COVID-19 on PLHIV as a vulnerable population group in the face of limited ongoing research on the co-infection of HIV and COVID-19, including risk factors and severity of outcomes.</li> <li>● COVER HCW: focus on the use of chemoprophylaxis for health care workers and urban workers who are high-risk groups with limited protection.</li> <li>● Dexamethasone: critically timed inventory of dexamethasone alongside emerging evidence on the first drug shown to be effective in reducing mortality amongst severe COVID-19 cases to ensure equitable access for LMICs.</li> </ul>	<ul style="list-style-type: none"> <li>● <b>Test and Treat:</b> much-needed investments seeking to provide end-to-end access to novel solutions for responding to the COVID-19 pandemic noting the gap in country introduction as well as evidence generation in support of normative guidelines development; covering multiple geographies and partners and being delivered as a portfolio.</li> </ul>
<b>Diagnostics</b>	<ul style="list-style-type: none"> <li>● FIND Output 5: much-needed work on generating independent performance data of newly available diagnostics, when LMICs had no transparent and independent evidence to guide their procurement decisions; online trainings on COVID-19 diagnostics given lack of in-persons trainings in countries; landscaping of sequencing capacity in LMICs even before new variants were identified; and early work on self-sampling of COVID-19 Ag RDTs.</li> <li>● CHAI Output 5: focus on the procurement and country introduction of RT-PCR test, which were not widely accessible to LMICs.</li> <li>● CHAI Output 6: focus on the procurement, country introduction and evidence generation of Ag RDTs to facilitate testing expansion and decentralisation.</li> <li>● FIND-Unitaid EOI: focus on gaps in the Ag RDT market including limited manufacturing capacity of Ag RDTs in LMICs and few products meeting performance, usability and affordability for LMICs.</li> </ul>	
<b>Oxygen</b>	<ul style="list-style-type: none"> <li>● ALIMA Output 4 and PATH Output 6 focus on responding to country immediate needs of COVID-19, including pulse oximeter donations which were one of the first method for triaging and referral of COVID-19 patients and repairing broken respiratory care equipment to enable rapid availability of existing oxygen equipment.</li> <li>● PATH Output 7 and CHAI Output 7 focus on immediate and urgent needs of nine countries with procurement of respiratory care equipment.</li> <li>● CHAI Output 8 and 9 focus on delivering TA for oxygen which was much needed in LMICs to support planning and capacity building to respond to the pandemic, as well as establishing flexible funding and collateral to allow for an agile, real-time needs-based response.</li> <li>● WHO WHE 1 and WHO WHE 2 focus on TA and critical gaps of human resources in WHO regional offices; focus on supporting WHO oxygen normative work when limited other funding available.</li> </ul>	
<b>Cross-cutting</b>	<ul style="list-style-type: none"> <li>● MTV SAF: focus on addressing misinformation in LMICs by providing a channel with trusted up-to-date health messaging.</li> <li>● WEMOS CIFA 1&amp;2: focus on HICs to mobilise support and political will for equitable access to effective COVID-19 technologies for LMICs.</li> </ul>	

## 1.2. The strategic relevance of some investments has been blunted by issues with design.

Strength of evidence:

Moderate 

In particular:

- The design of the **ANTICOV** platform through a large consortium with complex decision-making processes has lacked agility and been slow to respond to emerging evidence on drugs resulting in significant delays in the operationalisation of the trial in countries as well as evidence generation (exacerbated by challenges in obtaining country regulatory approvals). Box 3.2 in Section 3.3 on effectiveness provides a more detailed assessment of ANTICOV, including highlighting the need for a more detailed evaluation of the platform.
- The range of **clinical trial** investments have been fraught with delays and challenges in recruitment. Whilst these have been on account of a number of external reasons such as the evolving pandemic (e.g. varying incidence rate resulting from the waves, existing high prevalence of people having already developed antibodies without demonstrating symptoms in some African countries), policy/ access issues (e.g. lack of organised testing capacity for mild cases), and country ethics/ regulatory approvals, etc., there is a question as to whether more can be done at the design stage to circumvent or better plan for some of these challenges. While the clinical trials have undoubtedly been innovative and relevant, there is a need to better consider how these can deliver results within an emergency context to underscore their strategic relevance.
- The two CHAI **diagnostics investments** have focused on country-level introductions (procurement, forecasting, design of testing strategies, etc.) and have not included demand generation components viewed critical to facilitate uptake in LMICs. Specifically, the CHAI Output 5 investment focused on supply side engagements, country readiness and supply-chain related interventions and CHAI Output 6 on product introduction, evidence generation and demand forecasting. We understand however that demand generation aspects are now being picked up in the Test and Treat investments (as well as a new Unitaid-FIND RfP on “developing and deploying advocacy strategies to promote COVID-19 diagnostic testing and linkage to care and treatment in LMICs”).<sup>13</sup>

## 1.3. There is a question as to the fit of certain investments with what is understood to be Unitaid’s comparative advantage, raising the need to better define its role and added value in emergency contexts.

Strength of evidence:

Moderate 

A number of COVID-19 investments that have played to Unitaid’s strengths and comparative advantage – e.g. the Unitaid-FIND EOI partnership, where Unitaid has contributed by virtue of its experience in market-shaping, pricing, access-terms, and agreements with manufacturers; the Unitaid-CHAI diagnostics investments that reflect both organisations’ long term working to support catalytic introduction of commodities in countries; and the Test and Treat investments that are seen as fully leveraging Unitaid’s comparative advantage in terms of piloting/ testing models of care and generating evidence, whilst also introducing innovative solutions.

However, there is a question as to whether some of Unitaid’s investments have been too focused on procurement and have played more of a “gap-filling”, yet critical, rather than its traditionally understood catalytic role in terms of “priming” for scale-up. Although stakeholders recognised the value of supporting/ enabling rapid procurement during an emergency situation, it raises the question as to Unitaid’s comparative advantage in an emergency setting, which might be different from that in business as usual times – i.e. where speed and flexibility are prime, which may not be delivered by other agencies. Examples of these investments include:

<sup>13</sup> Unitaid/FIND, 2022, Request for Proposal, developing and deploying advocacy strategies to promote COVID-19 diagnostic testing and linkage to care and treatment in low- and middle income countries (LMICS) available at [https://www.finddx.org/wp-content/uploads/2022/01/20200111\\_rfp\\_advocacy\\_VF\\_EN.pdf](https://www.finddx.org/wp-content/uploads/2022/01/20200111_rfp_advocacy_VF_EN.pdf) [Accessed 03 February 2022]

- For the dexamethasone investment, some stakeholders noted that Unitaid is not a procurement agency, and the investment was not complemented by any demand side interventions to fully support the access objective.
- Majority of the procurement funding under the initial oxygen investments in 2020/21 was in response to critical needs in countries for oxygen supply, where Unitaid was particularly speedy and agile in the face of no/ limited support from other donors. <sup>14</sup> For example, the PATH Output 7 and CHAI Output 7 were solely focused on the procurement of urgent respiratory care equipment for nine selected countries for a total of US\$10 million. Whilst extremely responsive to country needs, these investments are not in line with Unitaid’s general procurement objectives namely to facilitate country introduction and support scale-up and to avoid funding of consumables. This was also in line with the findings of Unitaid’s Strategic Review, which noted that “*There were also mixed opinions on the COVID-19 response investments, with some stakeholders questioning these elements of ‘discrete support’ with ‘little potential for scale-up’, while others saw the investments as ‘reflective of agility to respond in countries where there is intense need and where they are already investing’ and where there are opportunities to ‘boost country engagement and visibility of Unitaid’s ongoing work’*”<sup>15</sup>. We understand however that later investments under the oxygen grants were more strategic in nature and supporting infrastructure developments that would facilitate greater uptake of oxygen by countries (e.g. supporting electrification, piping, etc).


1.4. There has been good adaptation of investments over time in response to the evolution of the pandemic.	
Strength of evidence:	Strong 

Figure 3.1 illustrates a timeline of key events with regards to the pandemic and the global response alongside the evolution of Unitaid’s response. From the start, Unitaid was quick to approve funding for COVID-19 just two weeks after WHO declared the global pandemic. We also note the following adaptations in response to changes in the COVID-19 landscape and key global events:

- Unitaid’s clinical trial investments have adapted their response to the evolution of the pandemic and related knowledge-base, thanks in part to having been designed with adaptive protocols. Actual adaptations included relocating trial sites (COVER HCW, ANTICOV), dropping unviable drug candidates (AGILE, ANTICOV), and adapting to COVID-19 wave-led recruitment (COVER HCW, ANTICOV, AGILE and COHIVE). Whilst treatment options have been limited until recently, Unitaid has been active in supporting treatments as they become available – starting with the dexamethasone inventory to the recent MPP licenses for Molnupiravir and Paxlovid.
- Starting in the autumn of 2020 as LMICs began to face increasing pressures on the centralized approaches through RT-PCR testing in the light of the beginning of second waves across countries, Unitaid approved a new diagnostic investment to CHAI to support the procurement and catalytic introduction of Ag RDT in African countries at the same time as these Ag RDT were still receiving WHO EUL approval.
- At the beginning of 2021, in light of increasing demand for oxygen, Unitaid was quick to respond to the need for medical oxygen in LMICs as countries started to face critical oxygen surges. As part of the response, Unitaid, together with Wellcome, allocated US\$20 million for catalytic oxygen support and focused significant efforts on advocacy and coordination amongst partners through its role as co-chair of the Oxygen Emergency Taskforce.<sup>16</sup>
- In early 2021, anticipating the arrival of new COVID-19 therapeutics which had previously not been available, Unitaid evolved its approach to the full test, isolate, treat and care by issuing the Test and Treat RfP and approving investments aimed to support end-to-end solutions across the continuum.

<sup>14</sup> The C19RM submission for country applications was 1 April 2021 for fast-track applications and end-May and end-June for regular applications, implying that if approved countries would not have received funding until after those deadlines. [https://www.theglobalfund.org/media/10698/covid19\\_2021-03-12-preparingfundingrequestsc19rm2021\\_letter\\_en.pdf](https://www.theglobalfund.org/media/10698/covid19_2021-03-12-preparingfundingrequestsc19rm2021_letter_en.pdf)

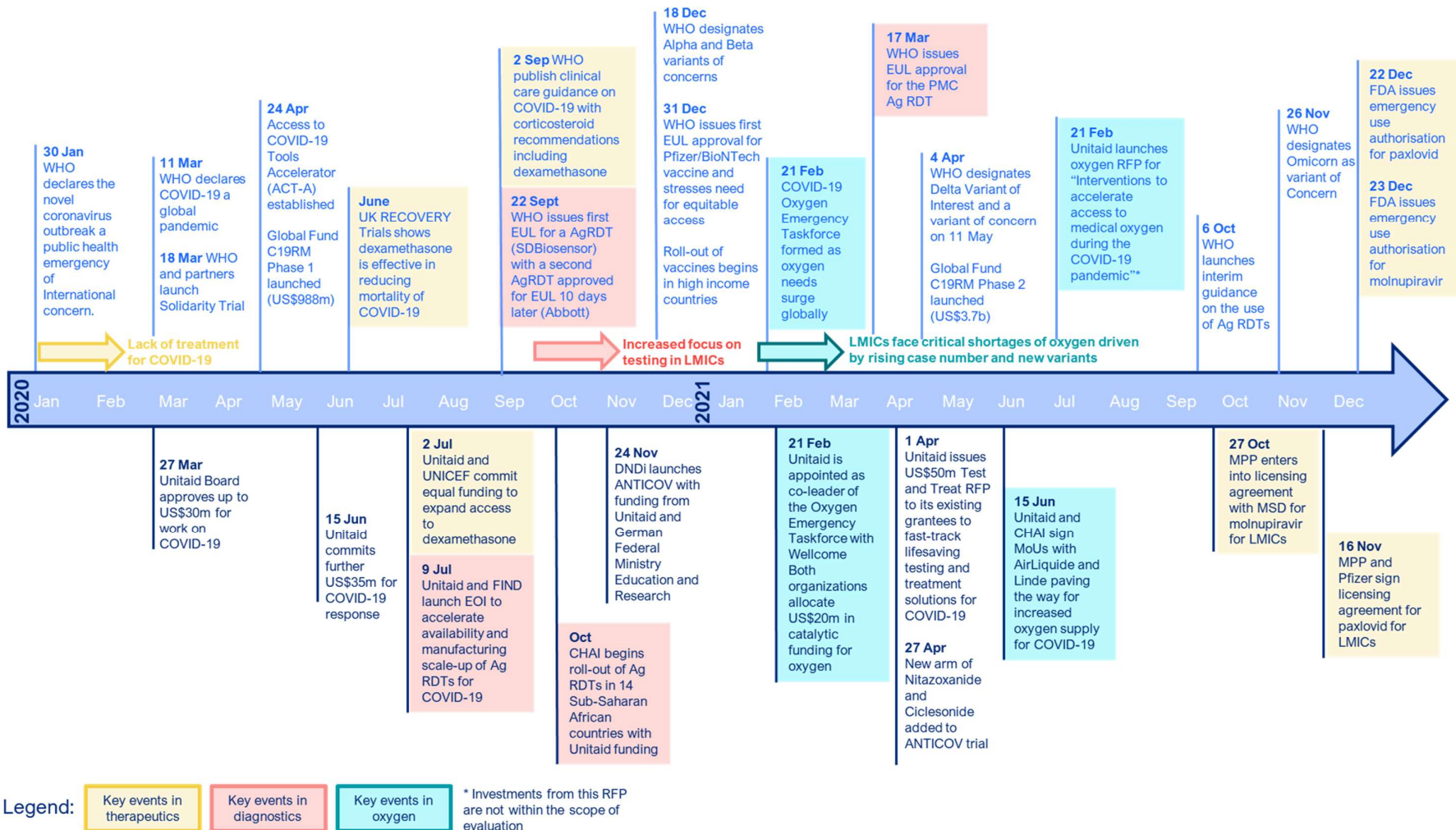
<sup>15</sup> Itad (2021) Unitaid’s Strategic Review 2017-2021, Final Report, p.48

<sup>16</sup> On 5 March 2021, the Unitaid Executive Board approved the investment of an initial US\$ 10 million for the COVID-19 Oxygen Emergency Response. A further US\$10m was invested August 2021.



Figure 3.1: Evolution of Unitaid's COVID-19 response

Key events in the pandemic and global response and UNITAID's COVID-19 response



### 3.1.2. External coherence

#### 2. To what extent are the interventions complementary to and synergistic with other global interventions against the pandemic?

##### 2.1. The Unitaid COVID-19 portfolio of investments is fully aligned with the ACT-A objectives and priorities.

Strength of evidence:

Strong



Unitaid's Wave 1 investments preceded the constitution of ACT-A, however all ACT-A partners consulted have indicated that these investments have been fully attuned with the ACT-A objectives and priorities (see Appendix F). Consultations also indicate that the objective and priority setting process within ACT-A has been very engaged and participatory and partners have together decided on priorities and the most relevant organisation to take these forward. In essence therefore, the Unitaid portfolio of investments has been fully aligned with the ACT-A objectives and priorities.

The ACT-A therapeutics strategy evolved from its first year in 2020, from a global aim to identify, procure and scale-up manufacturing to supporting countries in optimising clinical care in 2021.<sup>17</sup> Equally, the diagnostics pillar priorities in 2021 strengthened focus around equitable access. The Unitaid grants have evolved and continue to align closely with these priority developments. In respect of therapeutics, Unitaid investments in 2021 have focused on the introduction of oxygen as well the Test and Treat RfP supporting countries to integrate safe and effective therapeutics with appropriate linkages to diagnostics strategies.

##### 2.2. The Unitaid COVID-19 portfolio of investments has been well coordinated and synergised with other partners.

Strength of evidence:

Strong



Unitaid has historically worked closely in partnership with others and its experience if working through partnerships has allows it to coordinate it's COVID-19 with partners. Examples of coordination and synergies across investments are as follows:

- **Backward linkages (i.e. leveraging on the work of other partners):** For example:
  - The FIND diagnostics evaluations funded by Unitaid were based on some initial evaluations and validation work that FIND had been doing as a WHO Collaborating Centre to independently assess the performance of initial COVID-19 RT-PCR tests available on the market.
  - The oxygen investments of PATH Output 6 and 7 and CHAI Output 7 leveraged ongoing work and funding from the BMGF-funded Respiratory Care Response Coordination.
  - The MTV SAF Alone Together project was first piloted with 10-episodes supported by Every Woman Every Child.
- **Synergies and avoidance of duplication:** For example:
  - The PATH and CHAI Output 7 oxygen investments noted in the point above were focused on procurement and did not cover any other costs such as staff costs, negotiation of contracts, distribution and logistics, which were funded through the BMGF project.
  - Another example is AGILE, a collaborative platform with funding from multiple sources including Unitaid and Wellcome, where partners have been consulting each other to ensure funding is not duplicative.

<sup>17</sup> ACT-A hosted by WHO (May 2020), ACT Accelerator, COVID-19 Therapeutics Investment Case



- The FIND EOI partnership complemented the work of other partners such as the BMGF who have been focusing on innovative and accessible technologies that in more upstream stages that are fit-for-purpose and the NIH RADX programme supporting development of new diagnostics<sup>18</sup> (with the FIND work focusing specifically on the LMIC context). Box 3.1 presents the Unitaid-FIND partnership model which highlights how it has resulted in a successful partnership approach which has been able to leverage the synergies across the two partners.
- Unitaid has also been working in partnership with the Global Fund on the supply of oxygen resulting in the timely inclusion of respiratory care equipment in the last C19RM funding allocation. This was facilitated on account of Unitaid's previous oxygen experience (e.g. through its ongoing grants with PATH and ALIMA on testing the acceptability and feasibility of pulse oximeters for children used at primary healthcare) on the basis of which it actively participated in the weekly Biomedical Consortium and the Every Breath Counts Coalition COVID-19 Call throughout 2020, while the procurement of oxygen equipment was relatively new for the Global Fund.
- **Forward linkages (i.e. investments continuing or feeding into the work of other partners):** For example:
  - As a platform screening for preclinical molecules, the outcomes of AGILE have the potential for multiple forward linkages as they could feed into many ongoing clinical trials (such as SOLIDARITY, RECOVERY, PRINCIPLE, ANTICOV, etc.).
  - For other investments, forward linkages have been established to enable wider uptake of products such as the dexamethasone inventory amount being listed on the Global Fund's Wambo platform as an alternative procurement channel to the UNICEF procurement.
  - The MTV, Alone Together, has been commissioned for a further 10-episodes based in India through support from Johnson & Johnson.
  - The Unitaid diagnostics investments also supported the work of Africa CDC to rapidly assess the situation and the needs of their member states and respond quickly.<sup>19</sup>

**Box 3.1: Unitaid-FIND partnership model**

The evolving relationship between Unitaid and FIND on diagnostics, from grantee to partner and ACT-A workstream co-lead, has worked well and has been driven by their unique comparative advantages and synergistic processes. From the start of the pandemic, Unitaid and FIND have worked closely together and over time, Unitaid's model of engagement with FIND has changed, evolving from a grantee-donor relationship to a co-creation and partnership model. This has been a new approach for both organisations and has been facilitated through the ACT-A Diagnostics Pillar, which has provided a platform for the two organisations to work together. The evaluation highlights the following:

- **Partnership set-up/establishment:** the transition to partnership was not particularly challenging, as Unitaid and FIND had always worked closely and collaboratively, but reflects a strong commitment from both agencies in making this partnership a success. However, as is to be expected with any new partnership, the initial set-up of the partnership-model has been a learning process for both organisations: there were some administrative hurdles to overcome at the beginning, in particular with regard to commercial contracting of manufacturers as FIND is not a grant making organisation as well as to establish systems for joint investments (workplans, budgets, etc), but once they were addressed, the two partners have had a dynamic and productive working relationship resulting in three jointly developed requests for proposals.<sup>20</sup>
- **Factors of partnership success:** The success of the partnership has been attributed to the dedicated leadership at both organisations spearheading this strategic approach, along with dedicated staff and transparent working relations between the two entities on how to engage and represent the partnership externally. The success of the partnership has also been driven by the fact that the two organisations have different strengths to contribute: Unitaid brought experience in market-

<sup>18</sup> National Institutes of Health, Rapid Acceleration of Diagnostics, available at [www.nih.gov/research-training/medical-research-initiatives/radx](http://www.nih.gov/research-training/medical-research-initiatives/radx) [Accessed 03 February 2022]

<sup>19</sup> For example: CHAI staff on the ground assessed the situation and performed quantifications, helping Africa CDC prioritize support. FIND evaluations identified quality tests and Unitaid pivoted to Ag RDTs - this was needed for LMICs aligned with Africa CDC recommendations for member states.

<sup>20</sup> i) Manufacturing scale up RFP - drive equitable access to fit-for-purpose antigen rapid diagnostics tests for COVID-19 (Co-funded by FIND for a total of US\$40m); ii) FIND/Unitaid RFP on enhancing access to COVID -19 test, isolate, care & treat; iii) a developing and deploying advocacy strategies to promote COVID-19 diagnostic testing and linkage to care and treatment in low- and middle-income countries (LMICs)

shaping, pricing, access-terms, agreements with manufacturers, and having experience with country partners who could pave the way for introduction at the country level, whilst FIND has in-depth technical expertise to assess the interventions and evaluate different assays, as well as having a strong network of technical experts and relationships with manufacturers. As a result, this has made the partnerships' technical capabilities and the issuing, awarding and management of investments within the partnership highly synergistic.

The Unitaid investment with FIND provides a new investment model opportunity, bringing additional skills and expertise to the Unitaid portfolio. More partnerships like this could diversify Unitaid investments and bring in new grantees and partners.

**2.3. Unitaid has been considered as a highly valued partner within the ACT-A framework, bringing unique and value added benefits to ACT-A.**

<i>Strength of evidence:</i>	Strong 
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While a review of Unitaid’s engagement and contribution within the ACT-A framework is not within scope of this evaluation, many of our interviewees noted the added value and comparative advantage of Unitaid within the ACT-A framework, especially in relation to its portfolio of investments.

Our consultations have indicated that ACT-A partners value Unitaid’s niche role within the global aid architecture as an introducer and/ or fast-tracker of innovations as well as market shaping. Through its portfolio of investments, Unitaid is viewed as bringing considerable value in advancing the goals of ACT-A, and additionally, Secretariat knowledge and expertise has been viewed as an additional contribution, over and above Unitaid’s investments. Indeed, several partners commented on the Unitaid Secretariat being well aware of the landscape and making well-informed and expert-based decisions with regards to the work on COVID-19, as well as championing the access agenda. A clear example has been the role played by Unitaid as co-leader of the Oxygen Emergency Taskforce, where Unitaid brought both strategic leadership and technical know-how to elevate access to medical oxygen as a key priority for LMICs in their COVID-19 response.

The overall Unitaid model has also been viewed positively. Many commented on Unitaid’s dexterity and agility in making investments, as well as its network of partners to initiate and conduct country-facing work - vital in the current phase of COVID-19 when demand generation for available diagnostics and therapeutics is key. Importantly, many respondents emphasised the much-needed speed of Unitaid in comparison to UN and other partners during the pandemic. More is discussed below in Section 2.4 on the efficiency of the Unitaid model, including specific adaptations made for the COVID-19 portfolio.

**3.1.3. Internal coherence**

**3. Do the interventions adequately build on and leverage Unitaid’s existing portfolio of investments and are they internally aligned?**

**3.1. There has been good leveraging of existing Unitaid investments and grantees, although at times this has also restricted the reach and potential impact of the portfolio.**

<i>Strength of evidence:</i>	Strong 
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Unitaid’s overall approach to making investments in COVID-19 has been to leverage existing grants/ grantees – by expanding existing investments in the earlier waves of funding and by extending RfPs to a pre-selected list of existing and known grantees. This approach has enabled Unitaid to act fast without the need for detailed grantee capacity assessments or extensive scoping exercises, and with a degree of quality assurance helping to reduce risks in an already risky pandemic environment, as noted this has enabled the Secretariat to “*move quickly through leveraging*

existing relationships, capacity assessments and due diligence previously conducted, and where current legal terms can be used”.<sup>21</sup> Specifically:

- For **therapeutics**, Unitaid’s choice to prioritize projects nested in existing Unitaid-funded trials was highly appropriate as it allowed the organization to process grants with unprecedented speed, and to anchor its COVID-19 portfolio in a trusted collaboration between grantees and program managers.
- For **diagnostics**, Unitaid built on its extensive collaboration with CHAI and its diagnostic footprint in countries through previous projects such as the existing point-of-care molecular diagnostics platforms which CHAI had helped previously decentralise. Furthermore, the CHAI investments were also able to leverage CHAI’s significant in-country human resource capacity which was knowledgeable of existing systems and already connected to key national stakeholders. For example, CHAI has staff embedded within national laboratory directorates in a number of countries.
- For **oxygen**, working through the existing grantees allowed Unitaid to respond extremely quickly, approving its first two investments in oxygen supportive tools within weeks of the start of the pandemic. This was possible thanks to the in-country presence of its grantees - PATH and ALIMA – with knowledge of country needs and relationships to national stakeholders.
- For the **Test and Treat investments**, Unitaid issued the RFP and set up a new way of working, which resulted in an expeditious process, enabling Unitaid to move forward robustly without an open call for proposals. This approach was structured on the identification of a pre-selected group of grantees, based on an agreed set of criteria in line with the objectives of the RFP, who were invited to respond to the RFP.


However, relying solely on existing or previous grantees may have missed some opportunities:

- By not proactively inviting external applications, Unitaid may have missed some potentially relevant partners and proposals.
- Similarly, by building on its existing portfolio of investments which were primarily focused on Sub-Saharan Africa and not strategically selecting country sites based on the burden of COVID-19, Unitaid may have missed some opportunities for greater contribution to the COVID-19 response. This approach restricted Unitaid’s geographical reach and their ability to respond to high burden countries, where Unitaid did not have an extensive portfolio of active investments (such as South East Asia and Latin America). This issue was particularly highlighted in relation to the allocation of initial oxygen supplies, where the greatest need in 2021 was in India, Bangladesh, Brazil and Peru, whilst Unitaid’s investments were mainly focused on Sub-Saharan Africa. However, we do recognise that the geographical scope of Unitaid’s investments has expanded over the pandemic, particularly as part of the later oxygen investments and the Test and Treat investments which cover 22 geographies globally. Similarly, Unitaid’s COVID-19 diagnostic portfolio has focussed solely on sub-Saharan Africa. Equally, it is recognised that especially at the start of the pandemic, it was unpredictable how the virus would spread, reported case numbers were unreliable, and it was not predictable as to which countries would experience the highest case rates. As such it is also reasonable to argue that all countries needed support, and Unitaid were right to prioritise the speed of their response.
- Further, Unitaid’s work built on its existing investments in HIV, TB, and malaria, however the COVID-19 response for a lot of countries was managed by different departments such as respiratory illness, disaster management and others, and was not only focused on HIV, TB and malaria partners. This was highlighted by the work of some grantees in-countries who noted “*while [project] staff were well connected to MNCH branches of the MOH, new relationships needed to be established with the teams that were leading the COVID-19 response*”.

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<sup>21</sup> Unitaid (2020), 17 – 18 June 2020, Unitaid Executive Board Meeting 35<sup>th</sup> Session, Agenda Item 6, Unitaid/EB35/2020/6: Process for new COVID-19 investments

- Additionally, Unitaids grantees are not emergency response grantees (aside from ALIMA), so whilst Unitaids adapted to be more agile, the majority of its COVID-19 grantees have not been set-up to or have the scope to adapt to respond to an emergency.

<b>3.2. The portfolio has largely been coherent by area, but linkages between testing and treatment are only being harnessed recently and there have been limited demand-generation interventions.</b>	
<i>Strength of evidence:</i>	<i>Moderate</i> 

At the area level, Unitaids investments have been coherent and complementary to each other, and have built on synergies across investments. In particular:

- The **clinical trial investments** have all been coherent and complementary to each other without overlap as they have either targeted different populations (health care workers, PLHIV, outpatients) or have been designed to address different stages of clinical trials (pre-clinical for AGILE, Phase III mild/moderate for ANTICOV).
- The **diagnostics investments** have been sequenced in a coherent matter. The first CHAI investment was focused on the procurement and use of RT-PCR testing and was followed by a second investment supporting the introduction of Ag RDTs once they came on to the market. Similarly, the first FIND investment was focused on evaluations of existing tests, mainly automated RT-PCR platforms tests and some antibody tests which were available on the market, but also include Ag RDT as soon as they started to become available, and was followed shortly after by the joint FIND-Unitaid EOI focusing on addressing supply issues. Cross project collaboration is noted such as the case of the FIND evaluations that were prioritised based on CHAI country intelligence.
- The **cross-cutting investment to WEMOS** was also positioned in a complementary way to the ongoing work of Unitaids intellectual property and access work.<sup>22</sup> The CIFA 1 and CIFA 2 grants contributed to building awareness and political will in HICs on the importance of tech-transfer and patent-flexibilities to address critical access barriers in LMICs. The CIFA advocacy grant's strong advocacy for the sharing of intellectual property rights, data and know-how, and its considerable success in keeping the lack of access in LMICs in the spotlight contributed significantly to the enabling environment that is necessary for organizations and mechanisms such as the MPP and C-TAP to be successful in securing license agreements for COVID-19 health technologies.
- Furthermore, we also note how the portfolio of COVID-19 investments has become more coherent over time with the roll-out of a package of investments through the **Test and Treat investments** (and more recently the Access to Oxygen RfP)<sup>23</sup>. This Test and Treat RFP is based on the relative strengths of each grantee which is aligned to a common set of output and outcomes, thereby ensuring coherence across the package of interventions.

However, there have been some weaknesses in the coherence of the portfolio of investment, including:

- **The integration of testing and treatment investments** until recently. We note this has been in line with the global approach, which has focused on testing and isolating due to the absence of proven treatments, particularly for mild and moderate cases. However, some global stakeholders noted that the Test & Treat RfP, launched by Unitaids one year after the other therapeutic grants, came "*late in the game*". This issue has also been identified in the ACT-A Strategic Review, which noted: "*External stakeholders commented that the Diagnostics and Therapeutics Pillars have been slow to launch a collaboration on test and treat. Should promising antivirals be proven effective, test and treat strategies will be of great value to L/MICs given persistent vaccine inequity, and will require advanced planning to allow for a successful roll-out.*"<sup>24</sup> We also note though that the Test and Treat

<sup>22</sup> Although Unitaids has not provided additional funding to the MPP for COVID-19 work, it did expand the scope of work of the MPP-2 grant to include COVID-19.

<sup>23</sup> The Access to Oxygen RFP is not within the scope of the evaluation, but it's a good example of how Unitaids has continued the package of intervention approach.

<sup>24</sup> Dalberg (2021) ACT-A Strategic Review, 8 October 2021, p.18.

investments have been designed in a way that will enable faster linkages to treatment once these become available.

- The lack of demand generation interventions to complement the procurement/ supply-side work:** Grants across the portfolio have included the procurement of drugs (dexamethasone) and supply of diagnostics (RT-PCRs and Ag RDTs) but have often not been accompanied by the needed demand generation interventions required to support access. This issue has also been identified in the ACT-A Strategic Review: *“on-the-ground support has been insufficient. Interviewees acknowledged that the [diagnostics] pillar had significant room for improvement in terms of on-the-ground support to countries, building demand around testing, and supporting countries to develop testing and surveillance strategies”*.<sup>25</sup> However, we do note that community interventions for demand generation have been included in investments under the Test and Treat RfP, which is an important step to support uptake.

### 3.2. EFFICIENCY

The second dimension of the evaluation framework is on efficiency, which seeks to assess what worked well and less well in terms of the adaptation of the Unitaid operating model to deliver the portfolio of COVID-19 investments.

#### 4. To what extent has Unitaid adapted its processes in response to the needs of the pandemic? How timely and effective have these processes been?

The following aspects are reviewed below: (i) the speed of Unitaid’s response; (ii) the efficiency of Unitaid’s grant processes; (iii) the model of Secretariat delivery; and (iv) the use of Unitaid’s Theory of Change as a strategic and monitoring tool. Each of these aspects is considered in turn below.

#### Speed of response

4.1. Unitaid has developed an ambitious portfolio of investments on COVID-19 at speed.	
<i>Strength of evidence:</i>	Strong

Within a couple of weeks of WHO declaring COVID-19 as a global pandemic (11 March 2020), the Unitaid Board approved funding for the first wave of investments (27 March 2020). This was achieved at unprecedented speed, faster than the setting up of other global initiatives (e.g. the ACT-A initiative on 24<sup>th</sup> April 2020, whilst the Global Fund C19RM came about on 9<sup>th</sup> April 2020). Multiple stakeholders praised the agility and pro-activeness of Unitaid in commencing its response to COVID-19, facilitated by: (i) expanding existing grants and leveraging its extensive grantee/ partner network; and (ii) adapting its processes for grant approval and funding for faster decision-making. Each of these aspects is also discussed further below.

During the course of the pandemic to date, Unitaid has been credited with rapid investments and interventions at critical points – for example, the dexamethasone inventory was actioned based on emerging evidence even prior to WHO recommendation; Unitaid’s role on the Oxygen Taskforce and its oxygen focused actions and investments were initiated in advance of the Delta variant crisis in LMICs; amongst others.

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<sup>25</sup> One of the recommendations of the ACT-A Strategic Review was also to increase the downstream focus of *interventions*: *“Report Recommendation n.2: In addition to maintaining the urgency and focus on R&D and regulatory efforts, increase strategic emphasis on downstream work. This means supporting in-country product uptake and working to close the equity gap for currently available tools”*. Dalberg (2021) ACT-A Strategic Review, 8 October 2021

## Grant processes


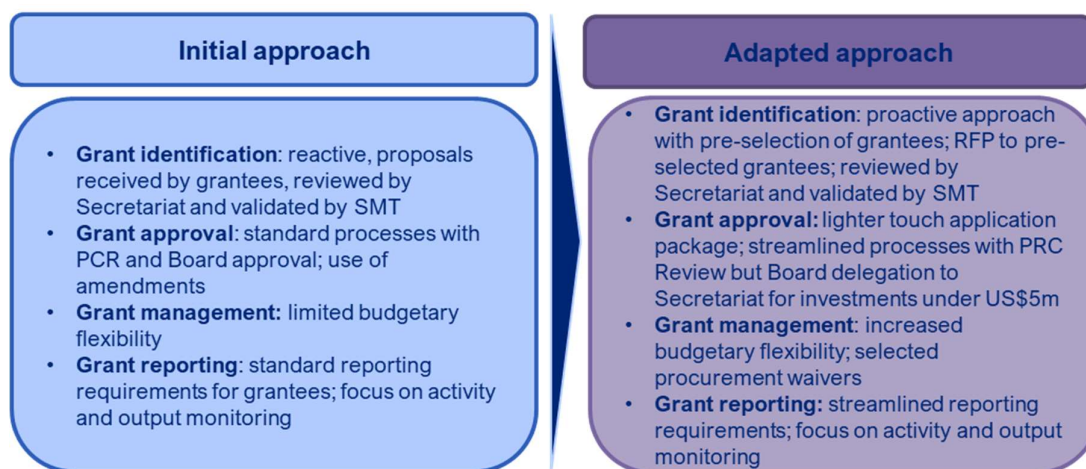
4.2. Grant identification, approval and management processes were well adapted to respond to the emergency and special circumstances of the pandemic. Grant reporting processes have been made lighter-touch but require improvement in terms of outcome/ impact based monitoring.	
Strength of evidence:	Moderate 

Figure 3.2 presents the evolution of key grant processes. Overall, the agility exhibited by Unitaid in amending its existing grant processes to meet the urgency of the pandemic has been praised by stakeholders and presents important lessons for Unitaid as it looks to streamline its operating model for its next strategic period 2023-27.

Figure 3.2: Summary of the evolution of key grant processes over time



### Grant identification

**The process of grant identification has evolved from being reactive, in terms of Unitaid accepting proposals from existing grantees, to proactive, in terms of Unitaid identifying strategic areas of work and pre-selecting grantees who are invited to submit proposals.** At the beginning of the pandemic, project selection was based on what “*came fastest and first that was relevant*”, as noted by staff at Unitaid. For example, through the therapeutics investments, Unitaid focused on what could be done immediately with the clinical trial infrastructure that they were already funding, with consideration for how ongoing trials could pivot and contribute to the global response. As mentioned in Section 3.1.3, working through existing grantees and leveraging Unitaid’s ongoing grants enabled Unitaid to respond quickly and effectively (see Section 3.1.3). However, although this approach was reactive to the immediate needs of the pandemic, we understand that selection was conducted by senior management with limited information flow for decision making amongst the Secretariat. With the evolution of the pandemic, and progression of Unitaid’s response, project identification has evolved to become more strategic, in line with the objectives of ACT-A pillars and workstreams and in relation to what Unitaid is best positioned to fund. In 2021, for the Test & Treat investments, Unitaid adopted a novel and proactive approach by issuing an RfP to preselected grantees.

Our assessment is that the evolution of these processes is efficient – enabling a rapid response at the start of the pandemic, and then being more strategic and measured as the pandemic evolved and the global as well as Unitaid response was consolidated.

### Grant approval

**The grant approval process has been considerably streamlined overtime expediting approval timelines.**

- At the start of the pandemic, when Wave 1 grants were being approved, Unitaid set these up as amendments to existing grants as opposed to setting up new grants. This simplified and expediated process considerably.



- In June 2020, the Unitaid Board endorsed an accelerated process to commit new investments, building on Unitaid's Agility Mechanism framework and in line with key strategic and operational principles.<sup>26</sup> This enabled the Secretariat to adapt the standard operating model for new investments requiring three Board endorsements<sup>27</sup> to a more streamlined light touch model in which the Secretariat takes more responsibility for what projects to source, select and progress. The Proposal Review Committee (PRC) is consulted on both shortlisted investments and proposed investments for selection, but Board approval is only required for projects over US\$ 5 million.<sup>28</sup> There have been different views on whether the approval process has struck an appropriate balance between speed and due diligence. A few consultees were of the view that given Unitaid was working through existing grantees the cut-off of US\$ 5 million for Board engagement could have been higher, but other consultees suggested that the limited engagement of the Board risked insufficient oversight on grants.
- For the Test and Treat RfP, applicants were requested to submit a much lighter-touch proposal package. For example, the process for submission of proposal under the RfP required applicants to submit slides according to a specified template.

The above has enabled investments to be approved much faster than standard Unitaid timelines for its Grant Agreement Development (GAD) approval processes. For example: the approval of selected grants in Wave 1 took no more than four weeks, approval of the Wave 2 grants took only a few weeks in respect of the dexamethasone inventory, and under four-months for the approval of CHAI Output 6, ANTICOV and Test & Treat RfP. The average number of months for the approval of COVID-19 grants in 2020 was 1.4 months compared to 5.8 months for Unitaid's core grants in 2019 through GAD.<sup>29</sup>

Our assessment is that these streamlined processes have been very impactful in facilitating agility and dexterity in the Unitaid COVID-19 response. A more detailed process review would be required that considers the different objectives in the grant approval process (e.g. speed, quality, risk, etc.) to define Unitaid's most appropriate approach going forward. There is also a good case to adapt processes to different circumstances/ investments/ grants, based on context.

#### *Grant management and implementation*

**Whilst working during the pandemic times has posed its own set of challenges and delays, the short timeframe for investments has been difficult at times and Unitaid's procurement and budget approval processes have caused delays (albeit with some adaptations over time).**

There have been delays in grant implementation due to the challenges of working in a pandemic environment. For example, procurement of oxygen equipment and diagnostics (e.g. GeneXpert) was impacted by their constrained availability on the international market as a result of huge demands and hoarding from HICs and international shipping delays. All the clinical trials faced delays ranging from challenges in procurement/import of API (AGILE), to slow regulatory approvals (both national and WHO Ethical Review Committee), to lower than anticipated enrolment of participants due to the different timing of COVID-19 waves across countries.

With regards to Unitaid processes:

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<sup>26</sup> Unitaid (2020), Unitaid Executive Board Meeting 35<sup>th</sup> Session, Agenda Item 6, Unitaid/EB35/2020/6: Process for new COVID-19 investments, 17 – 18 June 2020

<sup>27</sup> As of 2020, standard operating model included three Executive Board endorsements: i) Afl approval, ii) go-ahead for proposals recommended by the Joint Review Committee (JRC), and iii) approval of funding commitment and authorization for the Executive Director to sign the grant agreement.

<sup>28</sup> For example, with the "Test and Treat RfP", eight proposals were selected, (by Unitaid Secretariat, PRC process in conjunction with FIND); three of the selected proposal were budgeted below \$US5 million (Board approval not required); two of the remaining five proposals were combined, therefore requiring approval by the Board of four projects identified through the RfP with budgets over US\$ 5 million. Unitaid (2021), Decision report, Unitaid/EB/2021/TBC: Report including a request for Executive Board approval of four proposed investments aimed at enhancing access to COVID-19 test, isolate, care and treatment innovations and oxygen support, July 2021

<sup>29</sup> Unitaid (2021) Unitaid Executive Board Meeting, Portfolio Review, Agenda Item 13, PPT presentation

- **Implementation timelines have been challenging to deliver against:** The timelines for implementation of grants have varied by investment, but many grantees noted that the timelines had been too short and unrealistic given time taken for procurement, ethical board reviews, recruitment of patients etc. Equally, Unitaid has been quick to provide flexibility on project timelines, extending projects by up to a year where necessary. Furthermore, the one-year timeline for the Test and Treat investments is viewed as tight and unrealistic in relation to the investment objectives (and there was an observed misalignment between Unitaid and select grantees on the rigidity of the one-year timeframe). However, it is also recognised that the intention of the short timelines has been driven by the emergency needs of the pandemic, in terms of a supporting catalytic product introduction and the need for rapid evidence generation.
- **Limited flexibility of procurement processes:** Unitaid primarily relied on its usual procurement processes and was slow to adapt these to the urgent needs of the pandemic. As such, there have been significant delays with the procurement of commodities, in particular for oxygen: grantees raised the fact that they were required to procure oxygen commodities through WHO and UNICEF, which slowed the procurement process and resulted in delays for the procurement of commodities. For example, the PATH Output 7 grant was signed in April 2021, but equipment only started to arrive in country in September and as of the end of September 2021, only 44% of the overall procurement volume was in transit or had already arrived in country. Unitaid's procurement rules have been developed in a non-emergency environment to ensure accountability; however, whilst Unitaid is not an emergency organisation, the ability to procure rapidly in a pandemic is critical and there needs to be clarity with regards to the capacity of various procurement channels to respond with speed, as well as ensure competitive pricing for the equipment to be purchased. However, it was also noted, that for some products, Unitaid was able to provide waivers to enable grantees to buy commodities; for example, the same PATH Output 7 projects in Senegal and Zambia, was able to procure pulse oximeters directly from suppliers, and delivery was secured in under 2-months.
- **Unitaid has provided more flexibility to grantees in respect of budget management, which has been noted as an important improvement given the unpredictable needs of the pandemic.** Unitaid recognised the need to remain flexible and agile with regards to budgeting of the COVID-19 investments, which were being added as outputs through grant amendments to existing grants. As such, from the very first COVID-19 investment, Unitaid increased the flexibility for changes across expense groups from 10% to 25% of the budget; this has been viewed positively by many grantees as it has allowed them to more easily manage the uncertainties of the pandemic. However, discussion with grantees have indicate there is still room for further efficiencies with budget approval processes. For example, grantees in Zambia noted that any procurement change required approval, even if minor, and that the time taken to receive the approval slowed implementation timelines.

#### *Grant reporting*

**The routine monitoring and reporting of COVID-19 investments has adapted and been made lighter over time, although with further room for improvement.** The evolution of the reporting requirements for Unitaid's COVID-19 investments followed a positive trajectory with the reporting burden being lighter from once a month to once a quarter:


- At the start, the reporting requirements were seen as cumbersome, particularly given the emergency nature of the pandemic, and required consolidating and combining reporting on performance of COVID-19 work alongside the main Unitaid grant
- Starting in Wave 2, the COVID-19 investment reporting templates were streamlined into flash reports, requiring only a short narrative and a simplified template focused on progress and key issues. This agile and light touch approach has been highly appreciated by grantees. Grantees also mentioned that the increased flexibilities built up trust between Unitaid and grant implementers. In addition to reporting, Unitaid has also had regular touchpoints with grantees, monthly or quarterly (as required). In country, the increased flexibility in reporting has been noted and recognised as a real commitment from Unitaid to make the processes less complicated.

Nevertheless, a few grantees were of the view that Unitaid still had a very heavy M&E framework, which was reasonable for the larger grants, but continued to be overly burdensome for small, time-sensitive emergency response provision. Further, the Unitaid accountability frameworks and investment-specific progress reporting is



activity, and at times, output based, with limited to no emphasis on outcome and impact reporting, which is much needed, especially with the consolidation of Unitaid’s COVID-19 response and the progression of the pandemic.


## Secretariat delivery

<b>4.3. Unitaid Secretariat delivered a dedicated and effective response to the COVID-19 pandemic, but the approach is not regarded as sustainable.</b>	
<i>Strength of evidence:</i>	<i>Strong</i> 

There is no dedicated COVID-19 team at Unitaid and the Secretariat staff have been responsible for grant approval, management, and implementation, as well as providing inputs and contributing to the global level strategic work of ACT-A. As such, we note the following key issues:

- Although grantees unanimously praised Unitaid’s staff collaborative approach, responsiveness and dedication to the COVID-19 work during the pandemic, the current arrangements are not considered sustainable. Unitaid staff have had a significantly increased workload as a result of the COVID-19 portfolio of investments, and although surge capacity has been brought in to alleviate some of the workload, the lack of a COVID-19 specific team assigned to the COVID-19 investments has meant that Unitaid staff had to manage the additional COVID-19 investments on top of their existing workloads/grants.
- Unitaid staff have been involved in significant amounts of strategy work for the COVID-19 response at the ACT-A level, but without sufficient recognition or adequate additional resources to support such work. Stakeholders value Unitaid’s technical inputs at the ACT-A level and Unitaid’s expertise in respect to market-shaping, product introduction, and equitable access has been highly regarded over the course of the pandemic. However, adequate human resources need to be allocated for Unitaid staff to continue playing such a role.

## Use of Theory of Change

<b>4.4. The evolution of an overarching ToC for the portfolio has been sensible and appropriate, although it can be strengthened further.</b>	
<i>Strength of evidence:</i>	<i>Moderate</i> 

The evaluation reviewed Unitaid’s Theory of Change (ToC) for the COVID-19 investments and found the move from a pillar-based ToC approach to an overarching ToC sensible and strategic in terms of presenting the full scope of Unitaid’s COVID-19 portfolio across the entire results pathway.<sup>30</sup> However, as the ToC is a tool not only about reporting processes but has a wider strategic implication, we note the following key issues to maximise the strategic use of the ToC going forward:

- Given the dynamism of the pandemic, we do not view it useful to have a “static” TOC – rather, something that reflects the evolution of the pandemic, knowledge base and other partner work would be critical. This means enhancing the standard ToC structure (which for Unitaid includes the problem, pathway to impact, and key risks) to also include these additional aspects. The pathway to impact is not linear and needs to be reflective of failed investments and changing circumstances.
- A greater emphasis on assumptions and risks within the overarching TOC is needed. Assumptions, which are currently not included in the overarching TOC, would need to be considered in light of the challenges posed by the dynamism of the pandemic. Risks need to be re-thought – e.g. different from the standard scalability and

<sup>30</sup> Detailed review of the ToC in terms of the various components was not requested by Unitaid.

transition risks that Unitaid projects face, for COVID-19 it is about aspects such as linking in with longer term health systems financing for oxygen, or thinking through the requirements as the pandemic becomes endemic.<sup>31</sup>

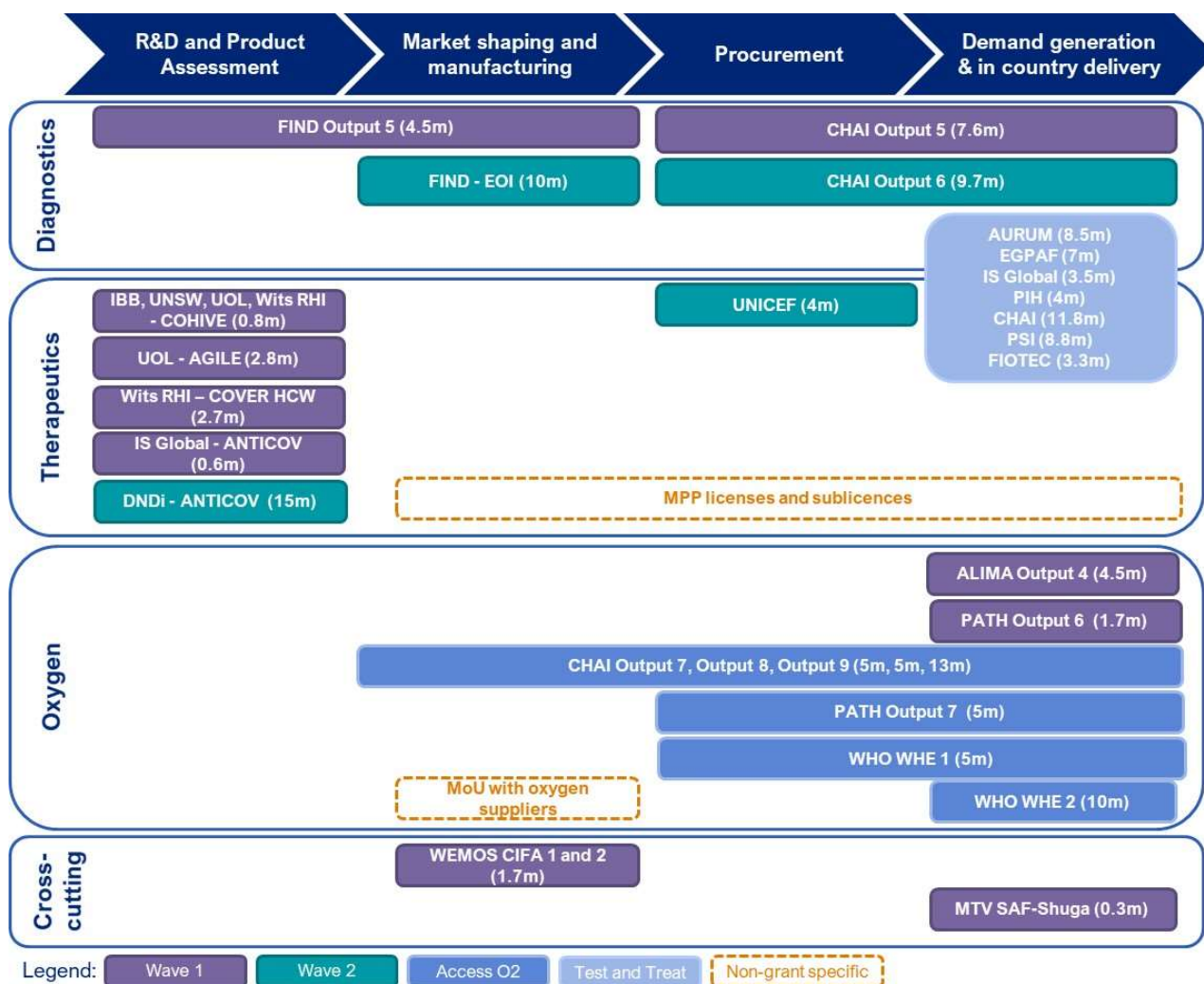
### 3.3. EFFECTIVENESS

#### 5. To what extent are the intended investment objectives being met? What have been the main factors contributing to the effectiveness of the investments and how do they vary across investments?

The effectiveness review considers the extent to which the intended investment objectives are being met – reviewing progress to date as a whole as well as the significance of the achievements.

Figure 3.3 presents a mapping of the Unitaid portfolio of COVID-19 investments by the four ACT-A workstreams of (i) R&D and product assessment; (ii) market shaping and manufacturing; (iii) procurement; and (iv) demand generation and in-country delivery. This mapping supports the effectiveness assessment presented below. Some additional Unitaid non-grant specific work is also mapped to contextualise achievements.

Figure 3.3: Mapping of Unitaid’s portfolio of COVID-19 investments by area and ACT-A workstream (by grantee/ grant name and includes US\$ Unitaid funding amount in brackets)



<sup>31</sup> We understand that Unitaid has a risk register for each individual investments and that the key investment level risks would be identified there.

The effectiveness assessment starts with a review of the project agreements and progress reports, and we find that, for the most part, investment objectives and related metrics have been defined fairly narrowly in terms of the activities and outputs, rather than outcomes and impacts<sup>32</sup> – with progress reporting also concomitantly following suit (as also noted in Section 3.2 above on grant reporting). As such, the effectiveness assessment has been limited by the fact that many investments are still ongoing (with only two of the 27 investments having ended at the time of the evaluation) as well as lack of clear documentation and data on the outcomes and ultimate results of the investments.

Noting this, we present the following key findings in terms of overall progress across investments/ the portfolio and key achievements and their significance by area (therapeutics, diagnostics and oxygen). The Test and Treat investments are not considered in this assessment given their recent commencement.

## Overall progress of investments


5.1. A review of the investment progress reports, supported by consultations, indicate good progress across the Unitaid COVID-19 portfolio, with the exception of the therapeutics portfolio, where progress has been slower due to delays in implementation (clinical trials) and uptake (dexamethasone inventory).	
Strength of evidence:	Moderate 

Table 3.2 summarises progress by presenting select key outputs across the portfolio to date. This is not comprehensive of the range of outputs under each investment – rather, focuses on the main and largest budget items. Subsequent findings below discuss this progress in context and in terms of their significance, reflecting stakeholder feedback. More details of the range of activities under the investments and their results/ potential results are also included in these sections.

Table 3.2: Summary of progress across portfolio

Area	Key aspects of progress
Therapeutics	<ul style="list-style-type: none"> <li>● <b>ANTICOV:</b> The platform has built a standardised protocol across sites to deliver a strong clinical trial. However, the trial has been significantly delayed<sup>33</sup>: patient recruitment has started in 15 sites across 10 countries with a total of 1,219 patients recruited (out of the anticipated 3,000).<sup>34</sup></li> <li>● <b>AGILE:</b> Eight candidates (each at different stages) had been identified through the AGILE project, five of which are being experimented upon, and one - nitazoxanide (NTZ) – has moved to clinical trials Phase 2, is which is being directly funded by Unitaid and tested in the United Kingdom and South Africa. The trial also suffered delays related to the importation of APIs.</li> <li>● <b>COHIVE:</b> Despite delays mainly linked to recruitment challenges, analysis from the COHIVE observational study will be produced in the first quarter of 2022 and will contribute to documenting COVID-19-HIV co-infections.</li> <li>● <b>COVER HCW:</b> The COVER HCW suffered significant delays due to recruitment challenges and operational issues but was able to adapt and the trial has recruited 867 out of 2,000 patients, with the results currently being analysed and expected for publication in the first quarter of 2022. Results from COVER HCW will document the safety and efficacy of ARV chemoprophylaxis against COVID-19.</li> </ul>

<sup>32</sup> As noted in CEPA's Inception Report, it was considered that impact-level results could not be done modelled robustly at this stage given that: (i) the majority of the investments are active and some are just starting or still under development; (ii) there is a lack of comprehensive and high-quality COVID-19 data in LMICs; (iii) the dynamic context of the pandemic makes it difficult to estimate indirect impact after investment closure; and (iv) there are very complex transmission dynamics which are highly dependent on country contexts and policies as well as virus variant.

<sup>33</sup> According to the ANTICOV Original Project Plan, total enrolment should have reached 3000 by June 2021 and all sites should have been closed by October 2021.

<sup>34</sup> ANTICOV, homepage, <https://anticov.org/> [Accessed 03 February 2022]


Area	Key aspects of progress
	<ul style="list-style-type: none"> <li>● <b>UNICEF:</b> By the end of November 2021, a total of 8.5 million dexamethasone injections and 4.6 million dexamethasone tablets have been delivered to 43 and 16 countries respectively (47% of available injection supply and 23% of tablet supply secured).<sup>35</sup></li> </ul>
Diagnostics	<ul style="list-style-type: none"> <li>● <b>FIND Output 5:</b> In total, 22 manual and 2 automated nucleic acid amplification tests (NAAT), 35 antibody-detection RDTs and 16 manual ELISAs, and 20 antigen-detection RDTs were evaluated<sup>36</sup>. Series of online training courses on COVID-19 diagnostics completed, framework for an integrated biobank network for COVID-19 developed, landscaping of COVID-19 sequencing technologies developed and self-sampling studies conducted.</li> <li>● <b>CHAI Output 5:</b> supported the introduction RT-PCR in 15 countries in sub-Saharan Africa countries through procurement, support for quantification, forecasting, and laboratory strengthening; directly procured 264,500 tests to 15 project countries.</li> <li>● <b>CHAI Output 6:</b> supported the introduction of Ag RDTs in 14 sub-Saharan African countries through procurement of more than 1.3 million Ag RDT (as of December 2021) and implementation support to 14 countries, including informing the revision of national guidelines to include Ag RDT, supporting mapping and quantification exercises to have better visibility of country needs for Ag RDT, informing procurement decisions, and developing trainings to support their roll-out and use</li> <li>● <b>UNITAID/FIND EOI:</b> 1. PMC – increased manufacturing capacity for production in India; EUL approval for an Ag RDT; price of Ag RDT at US\$2.50/test. 2. Wondfo and 3. Viatris: Increased capacity for both Wondfo and Viatris to support Ag RDT development and market access and regulatory activities. 4. DiaTropix: Technology transfer from BioNote completed and increased manufacturing capacity in Senegal; 5. DCN: Expanded of centre of excellence. 6. WAMA: Increased manufacturing capacity in Brazil (new equipment and increased facility space).</li> </ul>
Oxygen (Appendix H provides country specific examples)	<ul style="list-style-type: none"> <li>● <b>ALIMA Output 4:</b> Training of health care workers on hypoxemia; case management of COVID-19 patients at hospitals/ health care centres in 9 countries; procurement of pulse oximeters, oxygen concentrators and PPE; training of biomedical engineers at selected sites.</li> <li>● <b>PATH Output 6:</b> Oxygen gap assessment completed in three countries; rapid facility assessment of respiratory care equipment completed in 4 countries; donated pulse oximeters; supported the repairs of oxygen equipment in 3 countries; launched a catalogue of COVID-19 training resources for HCW and an online repository of respiratory care guidelines.</li> <li>● <b>PATH Output 7:</b> Procurement of emergency respiratory care equipment including concentrators, cylinders, flow meters, pulse oximeters etc. in 4 countries</li> <li>● <b>CHAI Output 7:</b> Procurement of emergency respiratory care equipment including concentrators, cylinders, flow meters, pulse oximeters etc. in 5 countries</li> <li>● <b>CHAI Output 8 and 9:</b> Providing technical assistance on the planning and delivery of oxygen services provided to 22 countries; training of HCW and biomedical engineers; procurement or emergency respiratory care equipment; collateral funding for dynamic O2 purchases and guarantees with gas companies</li> <li>● <b>WHO WHE 1:</b> Support provided by consultants to the 6 WHO regional offices; ongoing procurement of biomedical equipment based on country requests.</li> </ul>

<sup>35</sup> UNICEF, 2021, Report on the procurement of health products in support of the ‘access to COVID-19 tools accelerator -ACT-A) (August 2020-November 2021) <https://www.unicef.org/supply/media/8291/file/Dexamethasone-Inventory-August-2020-November-2021.pdf> [Accessed 03 February 2022]

<sup>36</sup> FIND (2021) Output 5: Unitaid FIND COVID Project, Semi-Annual Report, 31 August 2021 and FIND (2021) Output 5: Unitaid FIND COVID Project, Annual Report, 28 February 2021

Area	Key aspects of progress
Cross-cutting	<ul style="list-style-type: none"> <li>● <b>MTV SAF, Shuga, Alone Together:</b> The mini-series had a global reach across 5 continents, with a total 7.7 million views across MTV Shuga platforms. The series had almost 1 million views over 70 episodes and an average of 5,683 unique viewers per episode on YouTube.<sup>37</sup></li> <li>● <b>WEMOS, CIFA 1:</b> WEMOS advocacy contributed to the set-up of the WHO COVID-19 technology access pool (C-TAP), including building support for the establishment of C-TAP with European Union (EU) Member states.</li> <li>● <b>WEMOS, CIFA 2:</b> WEMOS advocacy widened their support to a broader range of technology transfer mechanisms including, but not limited to, the Medicine Patent Pool, TRIPS waiver<sup>38</sup>, and mRNA-hub in South Africa; providing a supportive enabling environment for three technology transfer deals, with C-TAP (Spanish National Research Council (CSIC) diagnostic ELISA tests) and MPP (MSD and Pfizer therapeutics). Spain and Belgium also provided funding towards C-TAP.</li> </ul>

## Therapeutics

<p>5.2. Unitaid investments in clinical trials are yet to deliver results and the evidence they generate will add to the knowledge-base on COVID-19 as well as inform how we do R&amp;D in a pandemic more generally. Whilst not funded directly for COVID-19 work by Unitaid in 2021, MPP's licensing for Molnupiravir and Paxlovid is expected to significantly impact access to treatments in LMICs, also contributed to by the advocacy work on equitable access in LMICs of the WEMOS grants.</p>	
<i>Strength of evidence:</i>	Strong 

There has been limited progress in finding suitable therapeutics for COVID-19 until the recent approval/recommendation of Molnupiravir and Paxlovid.<sup>39</sup> In this context we highlight the following key achievements of the Unitaid therapeutics portfolio:

- **Despite the delays in implementation, Unitaid's investments in clinical trials will add to the knowledge base on COVID-19 once their results become available.** As noted in Table 3.2 above, Unitaid's investments in clinical trials are supporting evidence generation and have the potential to enhance the knowledge-base around treatments for COVID-19 once their results are published. Specifically:
  - **ANTICOV** will generate evidence on the safety and efficacy of several marketed products including antiviral therapies that can prevent progression of COVID-19 to severe disease and potentially limit transmission. ANTICOV also has the potential to demonstrate new early treatment strategies for outpatients in low resources settings. Box 3.2 provides more insights into the ANTICOV investment.
  - **AGILE** is identifying candidates for the treatment of COVID-19 at the pre-clinical stage and generating early evidence on the safe dose for each treatment and its potential benefits.
  - The **COHIVE** study will provide evidence on the occurrence, the impact and the risks associated with COVID-19 in people living with HIV across a variety of clinical settings.
  - The **COVER HCW** trial will generate evidence on the safety and efficacy of Nitazoxanide (NTZ) and Sofosbuvir and Daclatasvir (SOF/DCV), in the prevention of COVID-19 in healthcare workers and inner-city inhabitants at high risk of exposure to COVID-19.

<sup>37</sup> Baker et al (2021), Young Adults' responses to an African and US-based COVID-19 edutainment miniseries: a real-time qualitative analysis of online social media engagement (Preprint)

<sup>38</sup> WEMOS consortium supported the proposal submitted by India and South Africa to the TRIPS Council for a temporary waiver.

<sup>39</sup> FDA authorized the emergency use of Molnupiravir and Paxlovid in Dec 2021. EMA advised on the use of Molnupiravir in Nov 2021 and of Paxlovid in Dec 2021.



More generally, the clinical trials have had positive externalities by supporting the capacity strengthening of researchers in LMICs countries, particularly in Africa, as discussed further in the impact section 3.4.2 below.

### **Box 3.2: Review of the effectiveness of the ANTICOV investment**

#### **The strategic relevance and potential value of the ANTICOV platform are widely recognised.**

The ANTICOV discussions were launched in May 2020, at a time when hospitals in HICs were being overwhelmed with COVID-19 cases and when the visibility of COVID-19 in Sub-Saharan African countries and their ability to prevent hospitalisations was limited. This prompted DNDi to look at out-patients and seek drugs that could be effective in addressing mild/moderate cases and limit hospitalisations. As of today, most knowledge about COVID-19 continues to be based on hospital cases. Less known and understood is the impact of the virus and how to mitigate it within communities, especially in Sub-Saharan Africa. For example, ANTICOV is the only trial that is taking place in Africa across 10 countries. In fact, there are only four COVID-19 trials, including ANTICOV, which had more than 50% of study arms taking place in more than five sub-Saharan African countries, with ANTICOV being the only one across more than six countries, therefore making it highly relevant in terms of generating evidence across multiple LMICs with varied characteristics.<sup>40</sup> Furthermore, with limited access to vaccines, the search for treatment remains crucial. All these elements contribute to making ANTICOV still pertinent today.

The idea of a platform of Randomised Clinical Trials (RCTs) built on a standardised protocol across sites (with core activities done centrally and platform trials and ancillary studies in selected relevant countries) is also valuable for strengthening knowledge about COVID-19 as well as contributing to building capacity and systems for future epidemics. This in fact is an important strategic element of the ANTICOV design as it sought to build an adaptive platform to conduct the clinical trial across many Sub-Saharan African countries, with the strategic intent of strengthening capacity and the knowledge base for COVID-19 research (although this objective was more strongly espoused by Unitaïd rather than the grantees and other external stakeholders). In addition, whilst Unitaïd is not investing at the same scale of pharma companies, ANTICOV can be leveraged as a platform to test the introduction and effectiveness of products in LMICs. For example, we understand that there are ongoing considerations about the inclusion of Paxlovid as an arm of the ANTICOV trial. This would have significant benefits as ANTICOV would enable the testing of Paxlovid to generate evidence on the effectiveness of Paxlovid: (i) in the general population in 10 LMICs across SSA; and (ii) potentially in combination with another drugs.

DNDi was able to rapidly build on its existing network and country linkages and engage a large consortium of research centres, most of which are part of the COVID-19 Clinical Research Coalition, which aims to fast-track research to provide evidence on COVID-19 prevention, diagnosis, and case management in LMICs.

#### **But its implementation raises questions**

At the time of this evaluation 1,219 patients have been recruited (out of the anticipated 3,000) at 15 sites across 10 countries, which is low compared to similar RCT platforms launched during the pandemic. Furthermore, one arm of the study has been interrupted due to lack of results. Like all other trials funded by Unitaïd, ANTICOV has faced delays in regulatory approvals and challenges with patients' recruitment. Focusing on priority drugs - which are already on the market, easy to administer (e.g. oral and with no cold chain requirements) and available at an affordable price - was a pragmatic and legitimate choice at the beginning of ANTICOV. However, during this evaluation, some questions have also been raised by global stakeholders regarding the governance and the coordination of the ANTICOV Consortium and the perceived opacity of decision-making (both with regards to product selection and broader decision-making processes) within the Consortium.

#### **A more thorough assessment of ANTICOV is required to assess its effectiveness**

There is more to learn from ANTICOV than what this evaluation is able to present. With its large and diverse deployment, the ANTICOV project is best placed among other Unitaïd-funded trials to help answer some of the questions that emerged in the therapeutic portfolio and inform future responses. Understanding better the delays and barriers in trial implementation, reflecting on multistakeholder approach to platform and trial design during a pandemic/epidemic, and looking at how these collaborations can contribute to greater locally rooted capacity would be of tremendous value for Unitaïd and its partners.

- **Unitaid's investment in dexamethasone has not seen the expected uptake by countries, particularly in 2020, which has diminished the effectiveness of the investment.** In July 2020, Unitaïd in partnership with UNICEF secured 2.9 million doses of dexamethasone as an inventory for LMICs to draw upon and ensure they have sufficient access to the first life-saving drug recommended for use in patients with severe COVID-19. However, LMICs have been slow in requesting dexamethasone through this inventory - by the end of November 2021, a total of 8.5 million injections and 4.6 million tablets have been delivered to 43 and 16 countries respectively (47% of available injection supply and 23% of tablet supply secured).<sup>41</sup> Stakeholders agreed that these requests have been much lower than anticipated (particularly in 2020, with demand slightly picking up in 2021). Multiple factors for the limited demand include: (i) lack of visibility of country's absorptive capacity, particularly as dexamethasone is used for severe cases of COVID-19; (ii) challenges with regards to country

<sup>40</sup> CEPA analysis based on COVID-19 clinical data from <https://www.covid19-trials.com>

<sup>41</sup> UNICEF (August 2020-November 2021) <https://www.unicef.org/supply/media/8291/file/Dexamethasone-Inventory-August-2020-November-2021.pdf> [Accessed 03 February 2022]

product introduction, including being recognised as a treatment specifically for COVID-19 in national guidelines<sup>42</sup>; (iii) limited financing options for countries to enable them to access the inventory; (iv) existing availability of dexamethasone in countries - as a well-known drug it was already part of countries supply chains through other channels. Overall, stakeholders agreed that more could have been done on the demand side of this investment to help generate demand for dexamethasone to benefit earlier for the inventory. We recognise that some mitigation measures have been put in place to increase demand, including: (i) an “informed dexamethasone push” based on a WHO survey on country preparedness for COVID-19 therapeutics which identified countries that have oxygen supply but limited/ no dexamethasone stock/ pipeline and which could be prioritised for engagement<sup>43</sup>; and (ii) linking the inventory to the Global Fund procurement system. Nevertheless, demand is still quite limited, and the investment has been less effective than anticipated.

- Unitaid’s support<sup>44</sup> of the Medicines Patent Pool to include COVID-19 within its scope of work has enabled the MPP to engage and negotiate with the manufactures of support for novel therapeutics and secure their licenses** – Molnupiravir, manufactured by MSD, and Paxlovid, manufactured by Pfizer. These licenses are significant as they will enable the acceleration and scale-up of generic production and thus have the potential to facilitate access to novel therapeutics for LMICs. MPP has also signed agreements with 27 generic manufacturing companies for the manufacturing of Molnupiravir and supply.<sup>45</sup> Some consultees have noted that there are limitations in these licenses: in particular, the geographical scope which currently only covers 105 and 95 countries respectively and excludes important upper-middle-income countries (UMICs) with robust manufacturing capacity, such as Brazil and China. Unitaid’s involvement in equitable access is all the more important as it remains one of the few organisations funding and supporting access to medicine initiatives. Contributions in this regard have also been made through the advocacy work on equitable access in LMICs under the WEMOS grants.

## Diagnostocs

5.3. Unitaid’s diagnostics investments in the more “upstream” ACT-A workstreams of product assessment as well as market shaping and manufacturing through FIND have been critical and with considerable potential for impact going forward for LMICs. The more “downstream” investments on procurements and in-country work through CHAI have facilitated access to diagnostics and related know-how for countries, although lacking key elements with regards to demand generation.

Strength of evidence:

Moderate



Key achievements and their significance across the four diagnostics focused investments are as follows:

### 1. The first investment to FIND (Output 5) supported performance evaluations of diagnostics, which were critical to inform global and country stakeholders on the performance of existing tests on the market.

As noted in Table 3.2, a number of evaluations of different diagnostics tests were carried out through the support of this investment, alongside other related activities. These evaluations ensured transparency of the performance results that were obtained independently using standardised protocols agreed with WHO and set performance benchmarks for manufacturers. The data produced by the evaluations was published on the FIND website, thereby increasing availability of these independent evaluations, and providing countries with evidence on the types of products available to be procured. Stakeholders’ views were unanimous in citing this as an “*impactful piece of work*” in establishing an

<sup>42</sup> Although dexamethasone was a well-known drug already registered in many countries, it was likely registered and used for different diseases.

<sup>43</sup> Unitaid/WHO (undated) Proposed Next Steps for Country Preparedness for COVID-19 therapeutics

<sup>44</sup> Unitaid funded MPP in 2020 to expand their scope to include COVID-19. In 2021, MPP has received funding from the Japanese Government to continue their COVID-19 work.

<sup>45</sup> Medicine Patent Pool (2022), signed agreements with 27 generic manufacturing companies, <https://medicinespatentpool.org/news-publications-post/27-generic-manufacturers-sign-agreements-with-mpp-to-produce-molnupiravir> [Accessed 03 February 2022]



overview of the diagnostics market for COVID-19 for countries at a critical time in the pandemic. As part of this initial investment to FIND, Unitaid supported three other critical global pieces of work, which have all been regarded as effective and areas of value add for strengthening the COVID-19 diagnostics space:

- A series of online diagnostic training, developed by FIND together with other partners, which were delivered online/ remotely at a critical time when health care workers and other medical practitioners required knowledge about COVID-19 testing. These trainings continue to being delivered online to support countries with scaling-up of testing globally.
  - The development of a framework for an integrated biobank network for COVID-19, with the aim of ensuring availability and access to available specimens for developers. Such a biobank is expected to add to the speed with which developers submit their products to SRA for regulatory clearance or WHO PQ.
  - A landscaping of COVID-19 sequencing technologies providing guidance on the strategies for sequencing in context of surveillance in COVID-19 in LMICs.
  - A self-sampling study in Malawi and Zimbabwe which is contributing to the global evidence base on self-sampling of COVID-19 in LMICs.
- 2. Unitaid and FIND investments under the joint EOI have increased manufacturing capacity and enabled technology transfers, but there are delays with bringing these new products to market.**

The investments funded by the joint FIND-Unitaid EOI, have increased manufacturing capacity and have supported/ are in the process of supporting the transfer of technologies to six manufacturers in LMICs. In particular, we note the following key achievements:

- **Manufacturers have increased their capacity** with new equipment, increased their infrastructure and human resources and are now able to increase production of Ag RDTs, while maintaining production of other products (e.g., HIV) and leveraging increased capacity for other new products (e.g., HIV self-tests). PMC has a new manufacturing facility with new equipment, Wondfo and DiaTropix increased their capacity to allow for production of their new improved Ag RDT, DCN procured new equipment and has expanded their centre of excellence for training (in-person and virtual) to LMIC manufacturers, which is particularly positive as they can link newer manufacturers to more experienced developers and have long-term effects. WAMA also increased their capacity, through which they have been able to bring their own test to the market in Brazil.
- **The technology transfers have supported improvements for production of high-quality tests and processes necessary for regulatory approvals and marketing.** For example, the BioNote technology transfer to DiaTropix enabled DiaTropix to benefit from partnering with a well-regarded and experienced manufacturer with audited manufacturing facilities, processes, and products. The relationship between an established manufacturer and local manufacturer helped DiaTropix to both identify and fill gaps and DiaTropix has used its investment to develop a more fit-for-purpose quality assay for the African continent and LMICs more broadly. Investments with Viatrix have also been designed to support increased market access capacity and regulatory support for the Wondfo product. However, some of the investments are still ongoing and have faced some challenges in implementation. The technology transfer for the WAMA investment has still not happened and it is unclear how successful this project will be in meeting the project objectives (technology transfer) as well as providing a marketable product (i.e. due to the high-cost of the product).

Overall, the investments in supporting manufacturing capacity and technology transfer have contributed to:

- increased availability of Ag RDTs on the market for LMICs (i.e., the PMC product has received EUL and is available to procure for LMICs; DiaTropix has received regulatory approval for their product which is being sold in Senegal; and WAMA has brought its own product to the market in Brazil);
- increased manufactures' development capacity, including capacity to support other diseases/outbreaks and technologies, and the regional diversification of diagnostic production to countries in LMICs.

Furthermore, the EOI was also designed to address the affordability barrier of Ag RDT for LMICs; in particular with the PMC investment, Unitaid and FIND were able to negotiate a price of US\$2.50 for the Ag RDT that would

be produced by PMC. Subsequently to the announcement of this investment in January 2021, Abbott and SDBiosensor who also had WHO EUL dropped their prices to US\$5.00 in October 2020 and US\$3.00 by April 2021.<sup>46</sup> However, there is a difference in perspectives as to whether the lowering costs of EUL diagnostics was due to investment PMC or was likely to happen through the inevitable evolution of market shaping, product competition, and the ongoing volume guarantees discussions with other global development partners.

- **Notwithstanding these achievements, consultations with manufacturers have highlighted a range of critical barriers which have been delaying market access of the products supported and therefore impacting the availability of key diagnostic products in the market.** Despite increased capacity for production and market access, at this time, most Ag RDTs supported through this investment are either pending technology transfer (e.g. DCN to WAMA), EUL approval (e.g. Wondfo, DiaTropix), or demand creation/procurement (e.g. PMC). Specifically:
  - Having a strong technical partner such as FIND is viewed as extremely valuable by manufacturers, but **WHO EUL and regulatory approvals remain as barriers to market entry**. Both PMC and Wondfo experienced long delays with EUL, including issues with completing the dossier. All companies also expressed concerns with the range of in-country approvals and lack of standardized processes, and some manufacturers will use their investments to support their local teams to go country-by-country to meet with regulatory agencies.
  - Despite Unitaid and FIND technically matching-up manufacturers and developers for technology transfers through the EOI, more **technical information-sharing and transparency on the requirements for a transfer** are needed to ensure a smoother and more successful technology transfer. Such transparency would help to better understand objectives and expected outcomes of the technology transfer, for example between DCN and WAMA.
  - **Lack of transparency in procurement decision-making and processes** is resulting in a surplus of tests which are not being procured. In the case of PMC, the investment resulted in the successful production of volumes of tests for the diagnostic market, however, procurement agencies such as Global Fund have not committed to fully procuring them. We understand that at one point PMC had 40m Ag RDT ready for procurement being stored in a warehouse with no orders for purchase or commitments to buy; this was subsequently partially resolved by GF and individual governments making commitments to purchase some of this stock. As such, more synergies are required between procurement agencies and manufacturers, with discussions and increased transparency starting earlier on in the investment process.
  - **Regulatory delays weakening potential synergies and creating misperceptions across Unitaid investments.** For example, despite strong coordination between CHAI and DiaTropix in Senegal (including CHAI staff seconded to DiaTropix), delays in obtaining WHO EUL approval for the DiaTropix AgRDT have meant that CHAI is only able to support implementation of other COVID-19 Ag RDTs in Senegal. To some stakeholders this appears as competition and lack of trust in the product; as such, there is a need for better messaging across investments to avoid misperceptions.
- 3. **The CHAI grants have been instrumental in expanding RT-PCR testing in select countries as well as supporting the introduction of Ag RDTs. Their supply side work has been very useful for countries, but more is needed with regards to demand generation to support testing uptake.**
- **The Unitaid investments in diagnostics leveraged CHAI and its existing network and footprint of diagnostics projects in Sub-Saharan Africa and supported the procurement and introduction of RT-PCR (CHAI Output 5) and Ag RDTs (CHAI Output 6).** At the very beginning of the pandemic, countries were facing real challenges in accessing RT-PCR tests on the global market and getting products into countries. CHAI, who was already working in countries supporting MOHs and partners, had good visibility on the country-level situations and needs, which helped to identify gaps and areas for support. The initial focus was on the

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<sup>46</sup> UNICEF, 2021, COVID-19 In Vitro Diagnostics Supply Assessment and Outlook Update, available at <https://www.unicef.org/supply/media/9776/file/COVID-19-In-Vitro-Diagnostics-Supply-Assessment-and-Outlook-Update-October-2021.pdf> [Accessed 03 February 2022]

quantification, forecasting, procurement and introduction of RT-PCR tests: starting May 2020, CHAI with Unitaaid funding directly procured 264,500 tests to 15 project countries and delivered to laboratories, which enabled the expansion of RT-PCR testing in a number of countries (see Box 3.3). This phase of the work also included critical support to Ministries of Health to operationalise the introduction and roll-out of RT-PCR tests, including enabling regulatory approval to be in place prior to the arrival of the RT-PCRs; developing testing strategies and strengthening laboratories/ ensuring site readiness. As noted by one grantee, Unitaaid's support "*leveraged the rich platform of existing resources that were in country and worked with the government to enable heightened testing in countries*".

Then once Ag RDTs started to become available on the market, CHAI with Unitaaid funding was one of the very first to expedite the introduction of these tests in countries. For example, Ag RDTs were introduced in Cameroon, Senegal and Zambia in November 2020. CHAI who was also part of the Africa CDC Laboratory Technical Working Group, supported mapping and quantification exercises to have better visibility of country needs for Ag RDT, inform procurement decisions, and develop trainings to support their roll-out and use (see below). The Ag RDT investment in particular was critical as they were not just about commodity procurement (with more than 14m Ag RDT procured by the investments), but also critical implementation support and technical assistance to countries, including providing evidence to Africa CDC and countries, which informed the revision of national guidelines to include Ag RDT in all 14 project countries (see Box 3.4).

**Box 3.3: Supporting the introduction of RT-PCR in Sub-Saharan Africa**

The CHAI Output 5 leveraged existing diagnostics networks in country to support the expansion and decentralisation of RT-PCR testing across 15 countries in Sub-Saharan Africa. This box provides some examples of the range of work that has been conducted in a sample of these countries to support the procurement and introduction of RT-PCRs, providing an indication of the value add and potential contribution to outcomes in terms of increasing testing as well as challenges faced.

- In **Cameroon**, at the beginning of the pandemic there was only one laboratory that could do RT-PCR testing and CHAI supported the country to: (i) rapidly expand testing capacity by leveraging the existing Abbott network of platforms; and (ii) decentralise RT-PCR testing through the use of GeneXpert. With regards to the rapid expansion of testing on Abbott platforms, CHAI very quickly procured 35,000 PCR tests, supported the importation process of these commodities, developed a distribution plan based on needs and effectively delivered the commodities to laboratories. This enabled the expansion from one laboratory in Yaoundé to 19 laboratories. In terms of decentralisation of testing, CHAI undertook a mapping of where existing GeneXpert platforms were located and how testing was organised in the country. This mapping indicated that the northern region of Cameroon had been neglected in terms of testing availability, and CHAI was able to procure 5,000 tests to activate the existing GeneXpert platforms in that area by enabling access to decentralised point-of-care testing.
- In **Kenya**, the very first molecular kits (1,000 tests) were procured by CHAI through the Unitaaid grant. CHAI was able to use these to support the initiation of testing utilising pre-existing infrastructure that had been put in place through previous Unitaaid investments over the past many years to support centralised HIV molecular testing. This was achieved through the provision of updated software, COVID-19 testing commodities and reagents, as well as the training of staff across central reference laboratories. This was also achieved through the newly established automated testing laboratory in Kenyatta University Teaching and Referral Hospital (KUTRRH) established at the start of the outbreak with support from CHAI, Abbot and the National Public Health Laboratory. The scope of activities was expanded to include the monitoring of COVID-19 commodities, to track consumption and stock levels and ensure appropriate allocation. The supported COVID-19 testing laboratories conducted 129,770 tests between August and October 2020, approximately 35% of the total tests conducted in Kenya for this period.
- In **Senegal** in March 2020 there was only one private laboratory that was doing RT-PCR testing in Dakar, with a second private laboratory accredited shortly after in Dakar. However, the challenge was with the sample transport system from Senegal's 14 regions, where the capacity to test was close to zero. As such, CHAI leveraged its experience with point-of-care testing for HIV to extend access to RT-PCR testing by supporting decentralisation both to (i) public laboratories in Dakar using existing Abbott platforms (7,500 Abbott tests procured); and (ii) public facilities in six regions by leveraging existing GeneXpert machines (13,500 GeneXpert tests procured). The support for decentralisation was critical, resulting in much quicker turnaround times and supporting contact tracing.
- In **Zambia**, CHAI supported the introduction of automated RT-PCR testing from manual testing (which was slow and resource-intensive). CHAI procured 15,000 RT-PCR automated tests for the existing Roche 800 platforms, which were deployed to diagnostics platforms in both Lusaka and the Copper Belt. However, following this initial introduction, Zambia faced significant challenges in accessing automatic tests due to unavailability and high prices in the international market, and as such also continued testing on manual platforms.
- In **Zimbabwe**, CHAI leveraged the previous diagnostic network optimisation work that had been supported under earlier Unitaaid-funded grants to identify which platforms had capacity for COVID-19 PCR testing. Based on this information CHAI supported the expansion and decentralisation of testing from three initial testing sites in March 2020 to 57 sites within three months.

**Box 3.4: Supporting the introduction of Ag RDT in Sub-Saharan Africa**

The CHAI Output 6 investment supported the procurement and in-country introduction of Ag RDTs thereby expanding access to diagnostics in the countries:

- **Cameroon** was an early implementer of Ag RDTs with the inclusion of antigen testing in the national algorithm as early as June 2020. Once Ag RDT received EUL, CHAI supported the catalytic procurement, introduction and strategic distribution of Abbott's Panbio Ag RDT in Cameroon. It also provided critical technical assistance on use cases for Ag RDTs and support for quantification and real-time procurement information management through the introduction of an openLMIS system. The system has enabled the country to have real-time visibility of its stock of COVID-19 diagnostics (and was also expanded to cover all COVID-19 commodities) and to inform quantification, forecasting and procurement decision-making accordingly.
  - **Ghana** was a late adopter of Ag RDTs and CHAI support was critical to ensure their adoption. CHAI provided evidence on various use cases for Ag RDTs, including evidence from other countries, and advocated for the inclusion of Ag RDTs in the national testing strategy, particularly given the limited availability of PCR testing. CHAI also worked closely with the MOH to define the algorithm for Ag RDTs which was adopted in May 2021. After that CHAI supported an initial catalytic procurement of 80,000 Ag RDTs as well as the training of health care workers in health centres across Ghana's 16 regions. Once they started being used, Ag RDTs were rapidly adopted across the country and Ghana has also been procuring a further 1million Ag RDTs through its GF C19RM allocation. As one stakeholder noted, Unitaids support "*set the ball rolling for increased testing in Ghana*".
  - In **Senegal**, CHAI supported the inclusion of Ag RDTs in the national testing algorithm through advocacy and evidence sharing; in fact, although Ag RDTs had been validated in the country as early as September 2020, the existing algorithm was not supportive of their use as it still required a RT-PCR to be taken in the case of both a positive and a negative Ag RDT result. CHAI strongly advocated for the inclusion of antigen testing and in July 2021, as Senegal started to face its third wave and RT-PCR services were becoming increasingly overwhelmed, the MOH approved the inclusion of antigen testing which then paved the way for a catalytic procurement by CHAI of approx. 154,000 Ag RDTs.
  - In **Zambia**, CHAI worked closely with the MOH to support the inclusion of Ag RDTs in the national testing strategy by providing evidence and sharing information on use cases for Ag RDTs, providing advice on WHO's interim guidance on the use of Ag RDTs, etc. Following the inclusion of Ag RDTs in the national algorithm in October 2020, in November 2020 CHAI supported the catalytic procurement of 100,000 Ag RDTs (60,000 Abbott Panbio and 40,000 SDBiosensor) and conducted technical assistance including training and mentorship of health care workers, which enabled the activation of 286 sites across the country to conduct antigen testing. CHAI supported the development of training material and training plans for master trainers and cascade trainers, which led to a total of 1,773 health care staff being trained.
- **CHAI, together with Africa CDC, has supported the development of regional training materials on RT-PCR and Ag RDT testing and has worked on policy guidance through Africa CDC to guide countries which were outside the scope of the project.** Through the Unitaids investment, CHAI has provided a unique perspective from country programmes based on its engagement with national programmes and the bottlenecks they were facing to support the development of guidance and trainings for countries. The training material developed by CHAI, in collaboration with the Africa CDC, has been key to guidance to health care workers for quality testing. The investments have also supported non-project countries, as a lot of the work done in the 15 project countries is applicable to others, particularly those in Africa. Furthermore, CHAI also participated in the development of WHO guidance documents on the use of COVID-19 diagnostics and is still undertaking operational research in project countries aimed to contribute to future guidance by WHO. This includes research on: (i) operational considerations for introducing antigen testing in LMICs; (ii) research on the feasibility and accessibility of antigen testing; and (iii) research on the impact of antigen testing on the epidemic.
  - **The CHAI supply side work has been very useful for countries, but more is needed with regards to demand generation to support testing uptake as mentioned in Section 3.1.3.** In fact, a core aspect not covered by CHAI grants was in terms of demand generation, which is critical to increase testing uptake. Consultees have emphasised that this is due to a number of bottlenecks, including: lack of a treatment, mild manifestation of symptoms, limited knowledge of the value add of testing, constraints linked to informal employment and quarantine requirements, reluctance of laboratory professionals to move from molecular to Ag RDTs, amongst many other context-specific challenges. As such consultees also noted that greater efforts are required on the demand side to support demand generation of testing particularly at the community level. In an effort to address this gap, demand-generation and community engagement interventions have been included as key components of the Test and Treat investments.

# Oxygen

<p>5.4. For the oxygen portfolio, the range of Unitaid funded support has been critical and much needed for project countries. The “softer” investments in terms of TA and trainings have contributed to improved strategic planning and capacity building. The “harder” equipment-based investments have improved the availability of respiratory care equipment in countries, but their contribution is more challenging to identify in the absence of metrics to measure use and deployment. The wider strategy-level work on oxygen, including engagement with oxygen manufacturers has been instrumental in kick-starting a global development effort towards market shaping for oxygen for public health, although the mechanics of the market and infrastructure imply that the potential of these agreements has been slow to unlock.</p>	
<p><i>Strength of evidence:</i></p>	<p>Moderate </p>

- **Unitaid investments have supported the procurement of emergency respiratory care equipment as well as longer term infrastructure improvements, contributing to an improvement in the availability of respiratory care equipment in countries, but delays in procurement and delivery of equipment, as well as lack of metrics with regards to use and deployment make it challenging to assess improvements in access in these countries.** The initial Wave 1 ALIMA (Output 4) and PATH (Output 6) grants procured pulse oximeters and provided training on their use at the facility level in nine countries. This was critical to support the roll-out of a tool that at the beginning of the pandemic was being used, in the absence of the availability of diagnostics, as a screening and referral tool for severe respiratory illnesses including COVID-19. The PATH Output 7 and CHAI Output 7 grants are also procuring a range of respiratory care equipment. Unitaid’s investments have also supported the strengthening of oxygen infrastructure, such as the installation of piping for the delivery of oxygen in at least six facilities in Rwanda, the updating of the whole electrical system of a hospital in Makary, Cameroon, and piping and wall outlets in selected hospitals in Ecuador and Guatemala, to enable the functioning of oxygen equipment and increase the hospitals’ capacity for the delivery of oxygen. However, the delays in procurement and delivery of equipment<sup>47</sup> (see also Section 3.2 on efficiency of Unitaid processes) as well as lack of metrics with regards to use and deployment of equipment has made it challenging to assess improvements in access. We understand that this is an issue not restricted to Unitaid but to all global health organisations working in the oxygen space, due to the lack of standardised metrics and KPIs for the measurement and reporting of the use of oxygen, and the complexity of measuring O2 access in real world settings (i.e. outside of modelling). Importantly, Unitaid through the WHO WHE 2 investment is funding WHO to develop KPIs for the tracking and monitoring of oxygen related data. However, a further challenge is the limited data collection through HMIS.
- **The range of trainings/ TA work across investments have supported strategic planning and capacity building for oxygen.**

  - **Unitaid’s oxygen investments through PATH, CHAI and WHO have expanded the provision of technical assistance to countries to increase capacity for oxygen care, management and delivery (see Box 3.5).** Through the CHAI grants (Output 8 and 9) technical assistance has been provided by CHAI to 22 countries to support them on a range of oxygen needs in line with national priorities (see Appendix H for country specific examples). Through the WHO WHE 1 grant, Unitaid provided funding to support regional Incident Management Support Teams (IMST), which had been significantly under-funded, but which are critical to provide technical assistance to governments on oxygen guidance.

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<sup>47</sup> Some of the selected procurement channels, for example through WHO’s WHE, have significantly slowed down the purchase time due to the need for MOUs to be in place to acquire quotations, thus delaying the delivery of equipment to countries. The PATH Output 7 project was approved in April 2021, but delivery of equipment only started in September 2021 due both to supply chain issues in the international market as well as the limited flexibility of Unitaid’s procurement processes.



**Box 3.5: Oxygen technical assistance**

Some country examples are provided below on the multi-faceted TA provided by CHAI to countries, highlighting the significance of this TA and strategic importance in supporting the countries' access to oxygen.

- In **Cameroon**, CHAI supported initial facility assessments and helped to set up a national oxygen task force to address the country's critical oxygen needs. Leveraging the findings from the facility assessments, CHAI supported the MOH in the development of a Strategic Plan for Oxygen which has been endorsed by the MOH and provides the country with the strategic direction for its future oxygen investments. Furthermore, CHAI is also currently supporting the government with the development of: (i) a norms and standards document to provide clear specifications on type of oxygen equipment country they country should purchase (and prevent suboptimal equipment being acquired); (ii) training modules for the training of biomedical engineers; and (iii) a maintenance plan for oxygen equipment in line with the endorsed Strategic Plan for Oxygen.
- In **Ghana**, CHAI supported the development of an emergency policy for oxygen delivery based on rapid facility assessments and manufacturers assessment to understand the oxygen market. These assessments enabled the government to understand the various types of oxygen sources at each facility and also the landscape of manufacturers. Through these assessments and the technical assistance, CHAI also dispelled concerned around the use of liquid oxygen and demonstrated that for Ghana it is a feasible alternative to the use of PSA plants.
- In **India**, CHAI provided technical assistance to both State and National government level taskforces, responsible for policy and the coordination of the country's response to the COVID-19 pandemic. As a part of these taskforces, CHAI supported the development of strategic plans for the oxygen response and forecasting exercises, using demand estimation assessments, to identify oxygen demand and future requirements. With regards to PSA plants which had been procured and installed by the government and other donors, CHAI took on a monitoring role, to ensure that the oxygen installations had been fitted correctly, and that there was the appropriate infrastructure in place to support their effective operation, including technical, operational, and monitoring and evaluation systems. To ensure the effective management of hypoxemia, CHAI is also supporting the MoHFW with the development of a comprehensive Standard Operating Procedure (SOP) for medical oxygen use.
- In **Zambia**, CHAI has provided technical assistance and coordination support to the MOH to optimise use of oxygen in country. CHAI supported the national oxygen response by: (i) playing a coordinating role by identify oxygen needs and challenges and how partners' resources could be used to respond – this role has now transitioned to the government who has appointed a National Oxygen Coordinator; (ii) supporting the development of training package for managing critical care patients that required oxygen support and the delivery of trainings; (iii) assisting the Zambia Medicines Regulatory Authority to develop guidelines for manufacturing of medical oxygen by all companies (which had been non-existent).

- **The technical assistance provided by Unitaids partners has supported countries on the development of funding proposals to global health partners.** Through the TA provided by CHAI and PATH, countries are assessing oxygen needs and including oxygen equipment in their funding requests to the Global Fund C19RM and World Bank application, thereby enabling countries to access funding for critical oxygen needs (see Section 3.4.1 for further details).
- **Unitaid's investments have also trained health care workers to increase their capacity for the detection and management of hypoxemia, and biomedical engineers to ensure the maintenance of oxygen equipment.** Unitaids investments have supported both the clinical training of health care workers to detect, manage oxygen needs of COVID-19 patients, as well as the training of biomedical engineers to ensure the equipment can be maintained and repaired over time. Furthermore, the ongoing investment in WHO/WHE includes a full output on supporting the maintenance, repairs and service agreements for oxygen generation systems and biomedical devices, including procurement of spare parts and service agreements.
- **Unitaid's investment through the PATH Output 6 grant enabled the repair of respiratory care equipment in country.** Leveraging existing respiratory care equipment in country was an excellent solution to enable a quick response to the surging oxygen needs of selected countries. The PATH Output 6 grant supported rapid facility assessment, including biomedical equipment inventory, in targeted facilities in Kenya, Myanmar, Senegal, and Tanzania, which identified non-functioning equipment and areas of focus for repairs. Following these assessments, PATH developed biomedical equipment repair plans in Kenya, Myanmar and

Tanzania<sup>48</sup> on the basis of which they were able to estimate costs for repair and contract out to local companies the repair of the equipment.

- **Unitaid has supported the market shaping agenda for oxygen by engaging with manufacturers of industrial oxygen to pave the way for increased access to medical oxygen in LMICs, although unlocking the potential of these agreements has been slow with some initial achievements at the end of 2021.** Beyond its investments in oxygen, Unitaid together with CHAI has signed Memoranda of Understanding (MoUs) with the two major suppliers of liquid oxygen – Linde Group and Air Liquide – with the objective of providing a pathway to increasing access to medical oxygen in LMICs.<sup>49</sup> This development has been viewed as positive by the majority of stakeholders given its potential to facilitate LMICs’ access to liquid oxygen and the fact that prior to the MOUs, the global health community had never had a global or regional arrangement with industrial gas companies. However, although “*these agreements represent an opportunity to open the industrial gas market to LMICs, so they have better oxygen supply options when dealing with case surges*”,<sup>50</sup> the potential of these MoUs has been slow to be unlocked. In particular:
  - Consultees noted that oxygen needs to be viewed as an entire ecosystem including production, storage, distribution and delivery at the bedside, with agreements often in place for multiple years which makes it difficult to react quickly to immediate surges in demand. It was noted that Unitaid recognised this ecosystem better than other actors. But with COVID-19 waves, countries have been experiencing oxygen surges often in an unpredictable manner and more work needs to be done to support the long-term planning of oxygen systems that will enable them to effectively react and respond to surges.
  - Stakeholders also emphasised that to ensure sustainable oxygen solutions, countries require sustainable financing based on the most appropriate context-specific oxygen solutions (whether liquid oxygen, PSA plants, or concentrators based on needs of hospitals/ facilities). This means moving away from a procurement-based approach to long-term financing mechanisms that can help manage emergency situations. To address this issue in the short-term, the CHAI Output 9 grant included a collateral fund to guarantee purchases of oxygen and enable countries to access medical oxygen whilst they seek longer-term sources of financing. This has been used successfully in Zambia where CHAI worked with Linde through AFROX to optimize the use of available medical oxygen and has stabilised oxygen supply in seven hospitals (see Box 3.6);<sup>51</sup> and in Ghana, where AirLiquide provided medical oxygen back-up to a hospital. We also understand that the Global Fund issued a liquid oxygen tender to both AirLiquide and Linde Group have responded to. Although these helpful approaches to facilitate access to medical oxygen during surges, thereby saving critical time to get oxygen to patients, much more needs to be done by all partners, including Unitaid, to think of oxygen as a critical part of health systems and to ensure its sustainably funded. Sustainable, long-term contracts are needed to ensure that there is sufficient local and regional capacity to supply and deliver medical oxygen where it is needed.

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<sup>48</sup> In Tanzania, PATH’s rapid assessment highlighted a shortage of oxygen supplied in almost all of the hospitals visited at all levels (national, regional, district and local facilities) and identified which equipment was in need of repair. Based on a detailed repair plan and leveraging local biomedical engineers for the repairs, around 500 respiratory devices across 26 facilities were repaired and recalibrated, with more than 98% of the malfunctioning and out-of-order equipment at the 26 facilities becoming functional for use. PATH (2021), broken equipment and surging demand for Oxygen left Tanzania hospitals in a bind, available at <https://www.path.org/articles/broken-equipment-and-surging-demand-oxygen-left-tanzania-hospitals-bind/> [Accessed 03 February 2022]

<sup>49</sup> Unitaid (2021), Unprecedented cooperation with global suppliers paves way to increase access for low- and middle-income countries to address COVID-19 crisis, available at <https://unitaid.org/news-blog/unprecedented-cooperation-global-oxygen-suppliers-june-2021/#en> [Accessed 03 February 2022]

<sup>50</sup> Unitaid (2021) Unitaid, July 2021, Decision report, Unitaid/EB/2021/TBC: Report including a request for Executive Board approval of four proposed investments aimed at enhancing access to COVID-19 test, isolate, care and treatment innovations and oxygen support, p35 of 42

<sup>51</sup> Clinton Health Access Initiative (2021), available at <https://www.clintonhealthaccess.org/actualizing-global-agreements-increasing-medical-oxygen-supply-to-hospitals-in-zambia/> [Accessed 03 February 2022]



### Box 3.6: Unlocking oxygen investments in Zambia

The global Unitaid-CHAI MoU signed with Linde and AirLiquide created the platform through which CHAI and AFROX – Linde’s subsidiary in Zambia – were able to engage and start in country discussion to increase the production of medical oxygen during Zambia’s third COVID-19 wave in mid-2021. Under the agreement, CHAI and AFROX negotiated the refilling of 10,000 oxygen cylinders (the procurement of which had been funded by the UK’s Foreign, Commonwealth and Development Office), which was extremely timely given the country’s surging oxygen needs. As part of the negotiations, AFROX was also able to convert one of their smaller plants in Lusaka to produce medical oxygen thus increasing the supply to address the needs of the country’s capital. As noted by one of the country level grantees, the global MoU was a “*gamechanger on our end, because have used that as basis for negotiations*”.

## Cross-cutting grants

5.3. Unitaid’s cross-cutting grants have been effective in generating awareness about unequal access to COVID-19 tools in LMICs and creating a supportive/ enabling environment for other grants, such as MPP, to thrive (Wemos) as well as helping to address issues around misinformation of COVID-19 (MTV Shuga).

Strength of evidence:

Moderate



Key achievements and their significance across the two cross-cutting grants are:

- **Wemos’s advocacy efforts have helped to generate awareness about unequal access to COVID-19 tools:** the advocacy led by Wemos supported the creation and launch of the C-TAP mechanism, which is designed to facilitate timely, equitable and affordable access of COVID-19 health products by improving their supply. Wemos’s advocacy also raised awareness about unequal access to COVID-19 tools, which contributed to building support for C-TAP amongst EU Member States, including some who went on to fund C-TAP such as the Spain and Belgium. Under C-TAP there has also been one technology transfer deal (Spanish National Research Council (CSIC) serology ELISA test)<sup>52</sup>: this technology transfer has the potential to facilitate production and supply of reliable ELISA antibody tests, which are particularly important to support countries in the COVID-19 surveillance efforts. Furthermore, the advocacy by Wemos around issues of IP rights and unequal access has also supported the enabling environment for a broader range of technology transfer mechanisms such as the mRNA hub in South Africa, TRIPS waiver proposal for COVID-related products<sup>53</sup>, and the WHO-sponsored mRNA-hub.
- **The MTV Shuga mini-series provided a reliable source of COVID-19 information and health messaging at the beginning of the pandemic, when there was a lot of misinformation being shared;** the mini-series specifically targeted adolescents, traditionally a neglected group, and evolved its messaging over time to keep pace with the changing guidelines on COVID-19 (from hand washing to the importance of vaccination). It also reinforced the importance of continued access to existing services, including reproductive and sexual I services, antenatal and maternal care, HIV, mental health services.

### 3.4. SUSTAINABILITY, SCALABILITY AND IMPACT

Sustainability, scalability and impact looks at the extent to which investments have been sustained and/ or scaled up (or have potential for scale-up) as well as delivered impact. Key considerations include an understanding of the aspects driving sustainability and scalability, and what these mean for Unitaid investments in the context of the pandemic. For impact, while it is not possible to measure the public health and economic impact of Unitaid investments, we consider whether the investments have improved equity in access and wider strategic benefits.

<sup>52</sup> <https://www.who.int/news/item/23-11-2021-who-and-mpp-announce-the-first-transparent-global-non-exclusive-licence-for-a-covid-19-technology>

<sup>53</sup> WEMOS consortium supported the proposal submitted by India and South Africa to the TRIPS Council for a temporary waiver.

### 3.4.1. Sustainability and scalability


#### 6. To what extent have Unitaid’s investments been positioned for transition and scale-up globally and in-country? Have factors that promote sustainability and scalability of investments been adequately considered?

Of the 27 investments within scope for this review, a number of investments are highly upstream in nature (e.g. the therapeutics clinical trials), at an early stage of implementation (e.g. the Test and Treat investments) or represent a one-time investment (e.g. the dexamethasone inventory), and hence are not within scope for the sustainability/ scalability assessment.<sup>54</sup> As such, the focus here is largely on the four diagnostics investments as well as the completed/ more progressed oxygen investments.

Given the very different nature of the investments, it is relevant to apply a different lens for these grants under assessment. In particular, the Wave 1 oxygen investments (completed) as well as the more recent CHAI and PATH oxygen investments have largely been in the nature of emergency response and hence an assessment of transition/ sustainability is relevant. For the diagnostics investments on the other hand, a wider view can be employed in terms of both whether they have/ will be sustained post project close as well as their potential for scale-up.

Considering the above, our main findings are as follows:

#### 6.1. Although the oxygen investments include several aspects that will ensure their sustainability, greater consideration needs to be given to the long-term financing of medical oxygen.

<i>Strength of evidence:</i>	<i>Strong</i> 
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For the **oxygen investments**, we understand that the very first investments during Wave 1 of Unitaid funding (PATH Output 6 and ALIMA Output 4) were delivered as an emergency response, and as noted by Unitaid and the grantees “*planning for transition and sustainability was a trade-off to ensuring an immediate response*”.<sup>55</sup> That said, there have been several aspects of these and later oxygen investments that can be viewed as sustainable investments and with longer-term impact, including provision of TA for the development of national strategic plans for oxygen, training of health workers resulting in capacity building and focus on repairs and maintenance of oxygen equipment (as discussed in Section 4 above). Further, TA provided through these investments have also facilitated development of proposals for funding from donors (Global Fund C19RM has allocated approx. US\$ 500m for oxygen and there is also funding from USAID and the World Bank), as well as inclusion of budget lines for oxygen within country government budgets. For example:


- In Cameroon, the development of the Strategic Plan for oxygen supported by CHAI was used as the key supporting document to the Global Fund C19RM application, which resulted in the approval of US\$22m for oxygen. Further, the Strategic Plan also led to the initiation of a discussion at MOH for the inclusion of an oxygen budget line to ensure there is budget allocated for the purchase of oxygen, equipment, maintenance, and capacity building. Although this has not yet been validated by the government, stakeholders noted that this was a step in the right direction.
- In Tanzania, the demand quantification and oxygen gap supported by PATH was included in an investment brief focused on oxygen used to inform Tanzania’s successful application for a World Bank grant.

However, both the Global Fund and USAID oxygen support are short-term funds, only available until the end of 2022, and more generally, medical oxygen is a health systems issue which requires long term financing to support

<sup>54</sup> In the Inception Report, the dexamethasone investment was to be considered under this evaluation criteria, however as a one-time inventory investment, we do not view it as relevant to this assessment.

<sup>55</sup> Consultations indicate that some of the early ALIMA work has been sustainable. For example, in Cameroon ALIMA supported full re-electrification of the district hospital in Makary which provides a strong basis for the implementation of activities at the hospital, including ensuring continuous oxygen flow. Further, the MOH hired one of the additional doctors and three of the additional nurses supported by ALIMA

infrastructure, maintenance and repair, transports and logistics, medical facility delivery infrastructure (e.g. pipes, ramps, shelter structures) and capacity building amongst other issues. For example, there has been some investment in oxygen in Kenya through the Global Fund and country budgets (e.g., piping and proper bed outlets, enabling a move from the use of cylinders to piped oxygen in around 300 health facilities, which will create efficiencies and some cost savings as it will be possible to convert from gas to liquid oxygen), and while this is a good start and represents government commitment, given the low baseline, more needs to be done. This means that countries require long-term financing including coordination and funding with development banks (such as the World Bank, African Development Bank and others), which are able to provide longer-term sustainable sources of financing to support the whole oxygen systems. There also appears to be limited discussion regarding ownership models (for example, leasing agreements between suppliers and MOH/hospitals) and stakeholders noted this is an area where Unitaid could bring value for LMICs by sharing evidence on potential models, which can best foster long-term sustainability of oxygen equipment.

<b>6.2. Investments in diagnostics are likely to be sustained and scaled-up in the near term through funding by the Global Fund and in the long-term through the increases in manufacturers' infrastructure and technical capacity.</b>	
<i>Strength of evidence:</i>	<i>Moderate</i> 

For the **diagnostics investments**, the following are specific points for each of the investments:

- The Wave 1 FIND grant for evaluations has provided a framework for continued evaluations of COVID-19 and other diseases diagnostics, with the results and reports being made available publicly and in real-time on FIND's website. We understand that while the Unitaid funding has been completed, the work is continuing and FIND is being funded through ACT-A.
- The Unitaid-FIND partnership EOI however has a more complex circumstance in terms of both sustainability and scalability given the more longer-term nature of the technology transfers. As discussed above on the assessment of the effectiveness of the investment (Section 3.3), there have been challenges with regards to timelines for the technology transfers, and going forward, the companies need commitments from procurement agencies to ensure sustainability and scale-up. That said, investments in technology transfer have helped build the technical and manufacturing capacity of manufacturers and to expand global manufacturing for diagnostics, and importantly in LMICs, which will have sustainability with COVID and beyond to include other diseases and epidemic preparedness.
- For the two CHAI grants, we note that:
  - **With regards to procurement volumes for Ag RDTs, CHAI project countries that received earlier support from Unitaid have been able to scale-up the procurement of Ag RDTs rapidly.** Data from CHAI indicates that the Unitaid procurement has been catalytic in supporting the procurement scale-up of Ag RDT in project countries: in November 2020 Unitaid-funded procurement of Ag RDT accounted for 31% of all procurement in 16 Sub-Saharan African countries, but by January 2021 this had decreased to 16% and to 4% by September 2021 indicating that countries were successfully procuring from other procurers such as Global Fund and UNICEF as well as their national procurement channels.<sup>56</sup> However, despite catalytic procurement of Ag RDT taking place, it is unclear how much this work has translated into actual country-level testing uptake, with testing rates in LMICs having not fundamentally changed over the course of the pandemic.
  - **Sustainability has been embedded through capacity building and linkages with the Global Fund C19RM.** In terms of capacity building, the training developed by CHAI, in collaboration with the Africa CDC, on the use of Ag RDTs have long-term implications in terms of supporting overall testing knowledge and capacity of health care workers including the use of Ag RDTs for other diseases/ future outbreaks. Countries have also applied to Global Fund C19RM for the continued procurement of COVID-19 diagnostics. For

<sup>56</sup> Data shared by CHAI during consultations.

example, in Senegal, the procurement of diagnostics is being sustained by the government who is procuring with Global Fund funding, as noted by one stakeholder “*Unitaid began the decentralisation of testing process which was then continued and strengthened thanks to funding from the Global Fund*”. In Cameroon, following the procurements of RT-PCR tests by CHAI, MOH took over procurement through GF and testing continues, particularly through the use of Abbott molecular platforms. In Zambia, CHAI advocated for the inclusion of Ag RDT test kits in the C19RM application, which has resulted in the procurement of 650.000 tests in 2021. In Kenya, there was limited clarity on transition financing for Kenya, although the country was able to secure 1.5 million USD from Global Fund for scale up this is insufficient to address the country’s needs.

- **The diagnostics work conducted by CHAI has potential spill-over effects to non-project countries.** As noted in Section 3.3 CHAI, together with Africa CDC, has supported the development of regional policy guidance and training material on COVID-19 testing, which is relevant and useful to countries outside the scope of the project.

<b>6.3. An assessment of the sustainability and scalability of Unitaid’s COVID-19 investments is more complex given the very different nature of support and the particular context of the pandemic.</b>	
<i>Strength of evidence:</i>	<i>Moderate</i> <span style="display: inline-block; width: 15px; height: 15px; background-color: #90d090; margin-right: 5px;"></span> <span style="display: inline-block; width: 15px; height: 15px; background-color: #90d090; margin-right: 5px;"></span> <span style="display: inline-block; width: 15px; height: 15px; background-color: #90d090;"></span>

Given the above experiences and assessments by investment, the following strategic issues come to the fore:

- **How Unitaid should consider the scalability of its COVID-19 investments – different from its “business as usual” approach applied for scale-up in relation to HIV, TB and malaria investments.** For example:
  - The need for immediate/ near term scale-up assumes particular importance in the context of the COVID-19, which may imply a need for focus on specific types of interventions (e.g. noting the challenges for the FIND EOI within the agreed timelines) and also different approaches to engagement with scale-up funders. (e.g. the need for long term health systems financing for oxygen).
  - The standard success factors included within Unitaid’s scalability matrix may also not apply in this context – e.g. in terms of the global conditions, the evidence and normative guidance is continually evolving, pricing may not always be optimal (and affordability may not be the only priority criteria), and supply base and delivery models adequate; and in terms of the country conditions, political buy-in and donor engagement is driven by the global discourse on the pandemic, and new factors assume importance such as buying power of HICs, export restrictions by countries, etc.
  - Scalability needs to apply a longer term view in terms of evolution of the needs of the pandemic e.g. as we move from a pandemic to endemic state, certain issues such as long-term COVID, surveillance, sequencing, etc. assume more importance.
- **Whether beyond the specific products of focus under the various investments, the Unitaid funded work has paved the way for the next generation of products to also be accessible.** This is particularly relevant in the pandemic context where there has been a rush to find the most suitable products, also with the expansion of knowledge (e.g. changing WHO/ other recommendations of the most relevant therapeutics and diagnostics) and the evolution of the pandemic (e.g. emergence of different variants). Our assessment is that the Unitaid COVID-19 portfolio has indeed supported a wider access approach which is largely product agnostic – also to be facilitated through the work under the Test and Treat investments. Further, by virtue of mobilising a myriad of researchers from various horizons on complex Randomised Control Trial platforms, Unitaid’s therapeutic portfolio contributes to increasing the know-how in countries and enhancing research capacity in limited resources settings.

### 3.4.2. Impact

#### 7. To what extent are Unitaid's investments contributing to impact (actual and/ or potential) in terms of public health and economic impact as well as equity impact and any strategic benefits and externalities? What difference did Unitaid's investments make in accelerating/ enabling equitable access?

It is not possible for the mid-term evaluation to assess the public health or economic impact of Unitaid's COVID-19 investments due to a number of issues including: (i) the majority of the investments are active and some are just starting or still under development; (ii) there is a lack of comprehensive and high-quality COVID-19 data in LMICs; (iii) the dynamic context of the pandemic makes it difficult to estimate indirect impact after investment closure; and (iv) there are very complex transmission dynamics which are highly dependent on country contexts and policies as well as virus variant. As such, our assessment of impact is qualitative and focuses on: (i) the equity impact, in terms of the contribution of Unitaid's investments on accelerating/ enabling equitable access to COVID-19 tools; and (ii) on strategic benefits and positive externalities of Unitaid's investments.

#### 7.1. Unitaid's investments have been designed based on equity principles/ consideration, but inequity in access to COVID-19 tools by LMICs persists.

Strength of evidence:	Strong 
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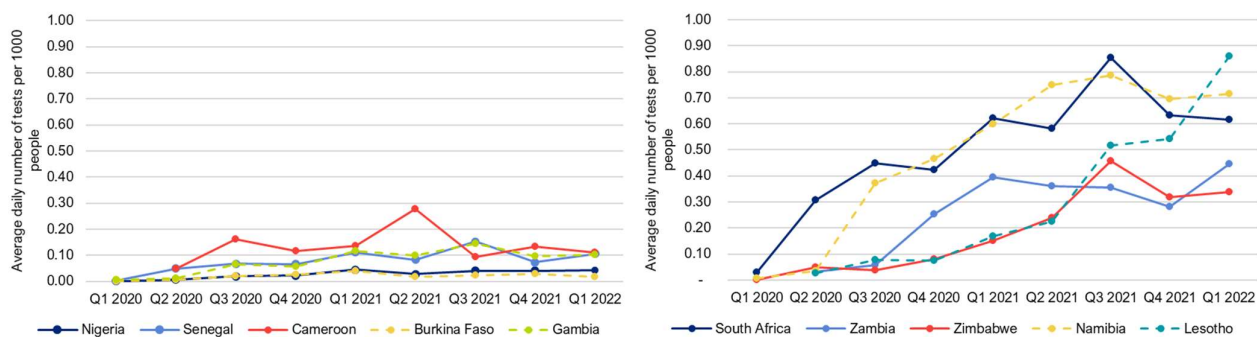
We highlight that Unitaid's investments were designed with equity considerations in mind – for example

- For the **therapeutics investments**, all drugs supported by Unitaid's clinical trials were selected with accessibility, affordability, and availability considerations in mind, which speaks to Unitaid's attention to equitable access. Chosen drugs were already approved by the countries involved and potentially available and affordable to them, which will enable faster access should any of the clinical trials demonstrate positive results. For example, should the results from the COVER HCW show some positive impact, the study could have a significant impact on access, as noted by one consultee: *"if the results show that there is an arm superior to others, it will be the first to show that chemoprophylaxis works. These drugs are very cheap so it would be a game-changer."* The dexamethasone investment was also designed with the purpose of ensuring equitable access to dexamethasone for LMICs.
- For the FIND Output 5 investment, **the diagnostics** to be evaluated were chosen based on equity considerations for LMICs, including their availability and accessibility: *"Automated molecular tests that could be used in lower-complexity laboratory settings were also prioritized; for automated molecular tests, it is important that the companies have an existing track record and presence in our target market of low- and middle-income countries already"*<sup>57</sup>. Furthermore, the CHAI Output 5 introduction of RT-PCR leveraged the use of existing GeneXpert machines which were already available and accessible in countries.

**However early data does not suggest a strong difference in trends between project and non-project countries, highlighting that there are a number of factors at play impacting increased access of and utilisation of COVID-19 tools.** Figure 3.4 illustrates the average daily number of tests per 1000 between selected CHAI-supported countries and other randomly-selected countries not supported by CHAI in each of West Central Africa and Southern Africa (left hand side and right hand side graphs respectively). While by no means comprehensive and there is a need for more analysis, a simple comparison of average daily number of tests per 1000 across project and non-project countries (selected at random) highlights no real difference in trend.

<sup>57</sup> FIND (2020) Output 5: Unitaid FIND COVID Project, Semi Annual Report, 31 August 2020

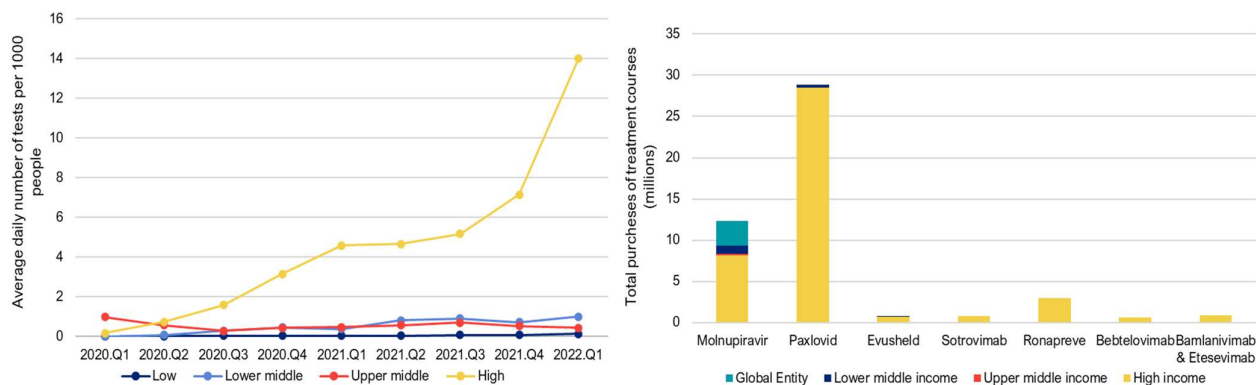
Figure 3.4: Average daily number of tests per 1000 people in select CHAI-supported and non-supported countries (lines indicate project countries and dashed lines indicate non project countries)



Source: FIND Test Tracker

**Further, inequities in access to COVID-19 tools between HICs and LMICs continue to persist.** For example, although Unitaid’s diagnostics investments have contributed to supporting access to COVID-19 diagnostics, in practice the global diagnostics response by development partners has not translated into significant shifts in the overall testing paradigms of countries, notwithstanding the challenging political economy of access of COVID-19 tools between HICs and LMICs. Figure 3.5 shows testing rates in LMICs in general have flatlined since the start of the pandemic and the “testing gap between high- and low-income countries grew wider across each quarter in the last 12 months, with high-income countries testing on average 79.4 times or more than low-income countries”<sup>58</sup>. With regards to therapeutics, there are concerns of huge inequalities in treatment access, as given their market prices, they are being mainly purchased by HICs. For example, for Pfizer’s new Paxlovid drug, HICs have already purchased the first 30 million courses expected to be available by July 2022, whilst it will take about a year for the generics to come onto the market through the MPP licences. Figure 3.5 also illustrates the existing inequalities for selected therapeutics. Both graphs are intended to highlight overall inequities rather than make any attribution to Unitaid’s work.

Figure 3.5: Average daily number of tests over time and purchases of COVID-19 treatments by income group




Source: FIND Testing Tracker and Launch and Scale Speedometer, COVID-19 Therapeutics

<sup>58</sup> FIND, COVID-19 Test Tracker, available at <https://www.finddx.org/covid-19/test-tracker/>, Accessed 03 February 2022



**7.2. Unitaid's investments and the broader non-investment work has had strategic benefits and positive externalities with regards to capacity building for research, integration for COVID-19 with other diseases, and raising the profile of key tools.**

Strength of evidence:	Strong 
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The evaluation found that there have been strategic benefits and positives externalities of Unitaid's investments in COVID-19 in particular with regards to:

- Strengthening research capacity for the future:** grantees and global stakeholders highlighted that the clinical trials have had positive externalities by supporting the capacity strengthening of researchers in LMICs countries, particularly in Africa. This capacity strengthening goes beyond the technical and scientific know-how of COVID-19 to increasing capacity of local research teams for doing research/ clinical trials in pandemic/ outbreak situations, with teams learning to work in non-traditional research conditions, designing and conducting research in a pandemic environment and acquiring knowledge, developing tools, setting-up procedures, which will be useful for research for other diseases as well as for future outbreak responses.
- Fostering the use of diagnostics/ increasing the focus on diagnostics as critical tools in disease response, including future diseases:** the COVID-19 pandemic has increased the spotlight on the use of diagnostics as a key tool in disease response, with positive externalities for the development and use of diagnostics for other diseases. Furthermore, the investments in technology transfer and capacity building have strategic externalities beyond COVID-19 as they can be leveraged for other diseases and for epidemic preparedness. In fact, the same technology (lateral flow assays) and platforms (RDTs) are relatively easy to develop using the same technology and could be developed quickly for new diseases and during outbreaks. Because they are cheap and easy to use, they can be distributed across countries and used for critical routine surveillance of diseases quick results could provide early alerts for outbreaks at more remote sentinel sites. Although more work needs to be done, the investments to manufacturers have bridged some gaps by bringing together developers, manufacturers, marketing and regulatory support.
- Raising the profile of medical oxygen at the global and country levels:** In oxygen, Unitaid's advocacy has helped to raise the profile of oxygen as a critical health systems issue and has helped to put oxygen on the global health agenda. Unitaid's efforts to advancing access to medical oxygen globally will also have an impact beyond COVID-19 and for strengthening health systems in countries so that they are better equipped to respond to other diseases, including adult and childhood pneumonia. A recent analysis from the BMJ found that "*strengthening oxygen systems could reduce hospital-based pneumonia deaths by nearly half and hospital-based pediatric deaths overall by a quarter*".<sup>59</sup> At a country level there is a clearer picture of needs and gaps, and oxygen systems will provide support to those with other respiratory conditions beyond COVID-19, as the infrastructure with the technical, operational, administrative, and M&E systems in place to support it.

<sup>59</sup> Lam F, Stegmuller A, Chou VB, et al (2021), Oxygen systems strengthening as an intervention to prevent childhood deaths due to pneumonia in low-resource settings: systematic review, meta-analysis and cost-effectiveness in BMJ Global Health; 6:e007468.



## 4. CONCLUSIONS AND LESSONS LEARNT

Our overall conclusion is that Unitaid's COVID-19 investments have largely been strategically relevant and responsive to the priority needs of the pandemic in LMICs. Unitaid moved with speed and agility at the start of the pandemic to identify niches and gaps where it could meaningfully contribute to the global response. It made astute use of its network of partnerships and grantees to enable a fast and effective response. It adapted its grant selection, approval and management processes to efficiently support grantees, although there are some areas for improvement. Overall, in terms of effectiveness, there has been good progress across the portfolio, with the exception of therapeutics, where progress has been slower. There has also been some progress on sustainability and scalability of diagnostics and to some extent oxygen where there is a need to coordinate with longer term financing options. Unitaid's investments have been designed using equity principles and considerations, but widespread inequity in access to COVID-19 tools by LMICs continues to strongly persist.

Looking across the four evaluation dimensions, and in line with the overall evaluation objectives, this mid-term evaluation seeks to answer a number of cross-cutting questions described in Section 2, which form the basis for the overall conclusions, lessons learnt and the recommendations.

**Have Unitaid's COVID-19 investments, taken as a whole, made a significant contribution to the COVID response?** Our assessment is that Unitaid has made a solid contribution (with some gaps/ missed opportunities) in a rapidly evolving crisis, with the verdict on sustainability, scalability and impact largely still to come.

Taken individually, investments have been strategically relevant to country needs and to the evolving pandemic situation. Taken together as a portfolio, the investments span a significant range of interventions and geographies and exhibit good internal and external coherence (with some gaps). Unitaid has moved at speed and interventions are showing good progress in delivering outputs, although there is sparse information on outcomes.

Unitaid advocated for and jump-started oxygen investments, although the impact of these investments largely remains to be seen. Similarly, it is too early to determine the overall impact of Unitaid therapeutics investments, although, the evidence they generate will add to the knowledge-base on COVID-19 as well as more generally inform how to carry out clinical trials in a pandemic situation. Investments in diagnostics effectively leveraged Unitaid's existing footprint of diagnostics investments and have responded to critical testing needs. They are also likely to be sustained short-term through the Global Fund and in the long-term through increased manufacturer infrastructure and technical capacity.

**Has Unitaid been catalytic, and played to its comparative advantages?** Our assessment here is yes, to a large degree, but also somewhat inconclusive as Unitaid has in some respects played a very different role from its conventional one, but this has also been very impactful. We also note that as well as being an investor, Unitaid played an important convening role that has also been very catalytic. For example, in oxygen, both as an early investor, as joint lead with the Wellcome Foundation, and as partner with the Global Fund.

We highlight first Unitaid's early entry into COVID-19, before many other donors and before ACT-A, and view this as an important factor catalysing the later interventions of large donors. Unitaid's overall agility through successive waves/ portfolios of funding has shown its ability to improvise, adapt and innovate in relation to the needs of the pandemic – and this feature in itself is reflective of a critical role wherein Unitaid has been able to “dive-in” to opportunities as they present themselves. From a more conventional lens on Unitaid's role e.g. of shaping markets, small-scale introductions/ demonstrations to pave the way for scale-up by funders and governments etc., Unitaid's catalytic role is more doubtful. Some investments (e.g. FIND EOI, Test and Treat) are potentially more catalytic than others (e.g. some of the oxygen investments). However, it is debatable whether Unitaid should have initially prioritised a (conventional) catalytic role in its COVID-19 response, or whether, given the depth of the emergency, it should have responded as it did to achieve maximum short-term impact. Finally, Unitaid's catalytic role can also be viewed in its wider presence in the COVID-19 response, beyond its investments – e.g. kick-starting agreements with global oxygen suppliers, MPP licenses, etc.

This assessment presents important questions for Unitaid senior management and Board as it considers its role and comparative advantage in the pandemic going forward (as well as in any global health emergency/ future pandemics),

particularly how to weigh being catalytic/leveraging comparative advantage versus urgent, high-impact gap filling that is doable but may not meet that test.

**Has Unitaid shaped market access? Has it helped advance country preparedness?** Our assessment is that at the time of the evaluation, and specifically through its portfolio of investments, Unitaid has contributed to a lesser extent on market shaping, but to a larger extent to support country preparedness.

Unitaid's footprint in market shaping for COVID-19 products does not appear yet to have been significant (see Figure 3.3 for example, that maps Unitaid's investments to the different ACT-A workstreams including market shaping). Unitaid's work with oxygen manufacturers has initiated potential market shaping work, although the impact to date is nascent. The same goes for MPP, where the licences for the newly recommended antivirals and their generic production can impact future market competition and affordability. The FIND EOI work, by creating greater manufacturing capacity, has the potential to shape Ag RDT markets once the new products are available and quality assured.

The work on country preparedness can however be considered to be more substantial, particularly through the ongoing Test and Treat investments. Earlier investments have also helped create systems in countries (e.g. CHAI's work on updating national guidelines and country procurement and supply systems, the different oxygen grantees' work on strategic planning, development of national O2 strategies/roadmaps and training). But, the Unitaid footprint has been restricted to the project/ funded countries, and to date there is little evidence on cross-over to non-project countries.

**Has Unitaid been learning and has it appropriately adapted (both its investments and operating model) over time?** Undoubtedly yes. The evidence points to a learning organisation able to modify investments, processes and procedures to adjust to the emerging pandemic.

Unitaid's structures and systems were not designed for emergency operations in a pandemic, but it did a good job at the outset, responding fast and in a reactive, pragmatic way to develop its response. Over time, it became more strategic and flexible – adapting both the kind of investments it made (more targeted, more top-down, more integrated) and its operating model (lighter, faster process, less arduous reporting), while taking into account the evolving nature of the pandemic, the evolving knowledge about effective interventions, and the actions of other partners. Unitaid has also worked in partnership with other organisations, in particular with FIND, which has brought in additional skills and expertise. Although there are still some areas which require improvement (for example, enabling greater flexibility in procurement and improving reporting to focus more on the outcomes/impact level), overall Unitaid has successfully adapted its response.

**What are the implications for Unitaid's continued support of COVID-19 and readiness for global health emergencies/ future pandemics?** The pandemic's future course is of course difficult to predict, but as the pandemic becomes endemic, Unitaid would need to further define its role and approach to the COVID-19 response. Further, given the likelihood of a future air-borne respiratory epidemic, Unitaid is well-positioned to learn from its experience with COVID-19 so that it can adapt its products and processes quickly to the next crisis. This evaluation suggests the following implications/ lessons learnt which form the basis for our recommendations:

- There is clear value for organisations like Unitaid that “break the mould” and reinvent themselves to respond to unprecedented circumstances. Unitaid has clearly demonstrated the value in being a fast, agile mover, adapting to the needs of the hour.
- With the experience of hindsight, there is a need to now better define its role and focus areas within the continuing pandemic and also in relation to any future health emergencies that may present themselves. As one of the few international organisations focusing on equitable access, there is an urgent need for action and progress, given the current circumstances of substantial inequity between HICs and LMICs access to COVID-19 tools.
- There is a need to re-think the design of interventions during pandemic times, for example to achieve the best balance between speed, delivery of results, accountability and developing coherent and integrated investments within the market access value chain that address both demand and supply side barriers. Equally, Unitaid has done well to support investments innovations through the RfP process where, within an overall portfolio, there is

flexibility in the grant design to enable countries to respond to their respective needs and stages of the pandemic and through tailored approaches/ solutions.

- There is merit in leveraging existing partnerships/ networks to deliver less risky investments in an already risky pandemic environment. Working through existing grantees/ implementers of Unitaid grants is a worthwhile approach and can be expanded in relation to the evolution of the pandemic. Varied approaches to working – donor-grantee, partnership-based, co-funders, etc. – make for more effective delivery during the pandemic.
- The adaptation of Unitaid’s grant processes has worked well and offers a practical and feasible solution to more efficient working for COVID-19 (and global health emergencies/ future pandemics). It also offers options/ lessons for the adaptation of Unitaid’s standard operating model in the next strategic period.
- The Secretariat has delivered an unprecedented volume of work on COVID-19 and there is a need to better consider feasible delivery going forward, also to not detract from Unitaid’s core business in communicable diseases.
- There is a need for more focus on the measurement of outcomes and impacts of COVID-19 investments. There is an opportunity to better collect and disseminate country level data and information that Unitaid may have access to through its country-level work – invaluable at the time of the pandemic when there are so many gaps in information and asymmetries.
- There is a need for Unitaid and its partners to review the issues around sustainability and scale-up of COVID-19 investments given the very different nature of investments under a pandemic as well as the rapidly changing dynamics of the pandemic.

## 5. RECOMMENDATIONS

This final section of the report presents recommendations based on the evaluation findings, conclusions and lessons learnt. These have been discussed and reviewed with the Unitaid Senior Management Team at a workshop held in March 2022.

Recommendations are framed in the following categories:

- **Strategic** – recommendations regarding Unitaid’s role and strategic approach with regards to COVID-19.
- **Operational** – recommendations regarding areas for improvement in key processes and delivery.
- **Global health emergencies/ future pandemics** – recommendations regarding Unitaid’s support for future pandemics.

### Strategic

**Recommendation 1: Critically review and confirm Unitaid’s role and comparative advantage for COVID-19 going forward, in the context of its new Strategy 2023-27, the ACT-A framework and the evolution of the pandemic.**

We understand that Unitaid is currently developing its 2023-27 Strategy and this includes continuing work on COVID-19 as part of Unitaid’s proposed programmatic priority of “responding to Global Health Emergencies”.<sup>60</sup> As such, we recommend that Unitaid should:

- **Review its support strategy for the COVID-19 pandemic, in line with its comparative advantages, the new Strategy, and the ACT-A areas of contribution.** Importantly, given the range of needs under the COVID-19 pandemic and the types of investments delivered to date, Unitaid should consider the appropriate focusing and balancing of its role in terms of its conventional role in supporting introductions of innovations to initiate scale-up, versus emergency support and long-term infrastructure development. Unitaid should define and outline an organisational-wide understanding of its approach in terms of focus, timeframe and guiding principles.
- **Review the role of Unitaid as the world likely moves towards an endemic phase.** Linked to the above, Unitaid should define and characterise its approach in the eventual transition of the pandemic to an endemic phase - specifically, what types of technical support should Unitaid fund, as well as the relevant interventions to be supported in an endemic phase (e.g. surveillance, sequencing, access to products, etc). Unitaid should also consider its approach in the context of the culmination of ACT-A. More generally, Unitaid should review its approaches to ensure the sustainability of its investments in an endemic phase, focusing also on how they can be reprogrammed/ repurposed to support future global health emergency preparedness.
- **On a regular basis, review – through internal and light-touch processes – the Unitaid portfolio of COVID-19 investments in terms of their relevance, balance and impact potential** in light of the latest available information (e.g. evolution of the pandemic, knowledge of effective interventions, key affected populations and geographies, etc) and aim to target/ rebalance accordingly.
- **Consider Unitaid’s role with regards to health systems support under COVID-19.** Unitaid’s COVID-19 investments (especially in oxygen) have demonstrated that some engagement in health systems may be unavoidable, despite Unitaid lack of comparative advantage in this area. Unitaid should better define how it wants to work with other major funders, partners and countries and the interrelationships with their health systems strengthening work in COVID-19.

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<sup>60</sup> Unitaid 2023-27 Strategy, Strategic framework and programmatic priorities, Executive Board meeting, 15 December 2021.

**Recommendation 2: Improve and refine the design of investments, drawing on emerging lessons from Unitaid's COVID-19 portfolio.**

This review has highlighted a number of key aspects including the need to:

- Continue to strengthen linkages between the diagnostics and therapeutics investments and supporting the continuum of test and treat (as exhibited through the Test and Treat investments, which have come at a particularly opportune time with the advancements in therapeutics).
- consider the market/ access barriers more comprehensively in terms of both demand and supply side challenges, and particularly the need to include specific activities to encourage demand generation amongst users (in addition to global level supply aspects and national level policy development), or ensure that complementary investments by others are addressing these barriers.

Further, learnings from the experiences of the different therapeutics clinical trials should be incorporated into the design of future clinical trial investments to ensure the best possible approaches to support timely results in an expedited emergency context. For example, Unitaid should engage with countries, WHO, the African Vaccine Regulatory Forum (AVREF) and others at an early stage to support timely regulatory approvals. The ANTICOV structure should in particular be reviewed further to improve its effectiveness going forward. Similarly, lessons should be drawn from the delays in market entry of manufacturers under the FIND EOI – whilst a standard challenge for commodity market entry in non-pandemic times, global health emergencies require renewed and innovative thinking. Unitaid should work with other relevant partners such as WHO and the Africa CDC on these aspects.

**Recommendation 3: Diversify and expand the range of partners and partnerships to support Unitaid's COVID-19 response. Continue to develop collaborative ways of working between Unitaid and grantees.**

Noting that the strong partner network of Unitaid has been one of the key success factors supporting its COVID-19 response, Unitaid should continue to invest in building and strengthening its partnerships. In particular by:

- **Diversifying its range of grantees/ partners.** While leveraging its existing network of grantees has enabled Unitaid to respond quickly and effectively, Unitaid should consider engaging new grantees/ partners to ensure it has the right organisations and people on the ground who can deliver impact, including, for example, emergency organisations.
- **Continuing to expand different partnerships, such as with FIND, that can complement Unitaid's strengths and comparative advantages.** Unitaid should continue to establish a variety of partnerships beyond the traditional donor-grantee arrangements, which complement Unitaid's comparative advantage and result in more effective investments. Varied approaches (e.g. donor-grantee, partnership-based, co-funders, etc.) have made for more effective delivery during the pandemic and should be explored for future global health emergencies.
- **Continuing to build strong approaches for collaborative working.** Work towards more seamless engagement with grantees in terms of ensuring a common understanding of overall objectives (primary and secondary for example) as well as future opportunities (e.g. where there is flexibility to extend timelines, or views that there may be some iterations or evolution in the approach).

**Recommendation 4: Review the issues around sustainability and scale-up of COVID-19 investments in the light of the very different nature of investments in a pandemic and the pandemic's rapidly changing dynamics.**

Key aspects to consider include:

- **The need for immediate/ near term scale-up in a pandemic situation** – for example, the usual five-year horizon that Unitaid applies in direct impact related to scale-up does not apply in a pandemic situation where the need for scale-up is immediate.
- **The very different attributes to scale-up** – for example, in terms of the global conditions included within Unitaid's scalability matrix, the evidence and normative guidance is continually evolving in a pandemic, pricing

may not always be optimal (and affordability may not be the only priority criteria), etc.; in terms of country conditions included within Unitaid's scalability matrix, political buy-in and donor engagement is driven by the global discourse on the pandemic, etc. and new factors assume importance such as buying power of HICs, export restrictions by countries, etc.

- **Scalability needs to apply a longer-term view** in terms of evolution of the needs of the pandemic e.g. as we move from a pandemic to endemic state, certain issues such as post-COVID conditions, surveillance, sequencing, etc. assume more importance, and the initial efforts to ramp-up access to testing and treatments may become less relevant. As also noted under recommendation 1, there is a need to consider transition of investments and reprogramming, or repurposing of ongoing investments and infrastructure to support future preparedness for global health emergencies.

## Operational

**Recommendation 5: Optimise and institutionalise the successful adaptations and flexibilities to Unitaid's core processes that were introduced to support COVID-19 investments and continue to review and adapt these to ensure responsiveness to needs, whilst maintaining accountability and due diligence.**

The evaluation has highlighted a number of adaptations to the Unitaid model that have successfully served to promote agility and dexterity in its response to the pandemic, e.g. the RfP approach and the lighter application package. These should be optimised and institutionalised, not only for Unitaid's future response to COVID-19, but also for its core portfolio in HIV/AIDS, malaria and TB, where relevant models and delivery mechanisms should be considered as Unitaid finalises its next Strategy 2023-27. It is an important opportunity for Unitaid to draw lessons from COVID-19 for its core business delivery.

Further, Unitaid should address the remaining areas of improvement with regards to its grant processes for COVID-19 investments, and specifically with regards to the following:

- **Procurement channels:** Consider whether more flexibility can be given to grantees with regards to the selection and use of procurement channels – for example, by enabling grantees that have already gone through a strict due diligence process and with high procurement standards to use alternative procurement mechanisms to WHO/ UNICEF.
- **Procurement of goods/ products:** Consider accommodating waivers for products/ goods which do not have WHO PQ but have received regulatory approval from another stringent regulatory authority (SRA) such as the FDA, EMA, etc.
- **Budget management:** Ensure that approval processes for budget and other changes are as fast and streamlined as feasible, whilst ensuring due diligence.
- **Reporting:** Continue to streamline and harmonise reporting formats for grantees.
- **External communication and messaging on investments:** Unitaid should improve communication and messaging around synergies between investments to avoid misunderstanding amongst external stakeholders e.g. where Unitaid is supporting specific company product development alongside wider country introduction and access of the diagnostic/ therapeutic.

**Recommendation 6: Review Secretariat capacity and optimised delivery for future COVID-19 support.**

The evaluation has highlighted the significantly expanded workload amongst the Secretariat teams to respond to COVID-19 (although has not reviewed impacts on the core investments of HIV/AIDS, malaria and TB). Going forward, Unitaid should review Secretariat capacity and delivery for COVID-19 investments (and related ACT-A and other work). For example, should it continue as present with Secretariat staff supplementing their core portfolio work with COVID-19 work, or include a dedicated team for the COVID-19 portfolio? Other relevant questions for examination include whether the Secretariat should add full-time equivalents (FTEs) or as current, provide surge capacity through consultants. Planning needs to consider the future evolution of the COVID-19 pandemic, as well as preparing for new global health emergencies/ future pandemics (see below).



**Recommendation 7: With the maturity of investments and learning within Unitaid, expand M&E approaches to better define and measure outcomes and impacts from COVID-19 investments.**

The M&E approach to date has largely been activity and output-based for COVID-19 investments, expectedly so given the emergency response mode of Unitaid and the need to not impose additional financial and administrative burdens on grantees. With the consolidation of Unitaid's COVID-19 response and the progression of the pandemic however, there is a need to better define and measure downstream results in terms of outcomes and impacts from the COVID-19 investments and portfolio as a whole. This would entail:

- **Elaborating how outcomes and impacts will be defined and measured**, including which metrics will be used and at what level (portfolio vs. investment level), to better enable monitoring (going beyond input metrics in terms of dollars spent, equipment procured, etc to outcome/ impact metrics which will enable the quantification of its contribution).<sup>61</sup> More generally, given the contribution of multiple ACT-A partners to results, Unitaid should work with partner organisations to define joint outcome and impact measures.
- **Assessing outcomes (and where possible impact) through specialised reviews and evaluations.** This should include a greater focus on country-level assessments and reviews through a case study approach. Where relevant, consider modelling of potential impacts e.g. in relation to the results to be achieved from the FIND EOI investments.
- **(Potentially) expanding the work of the Unitaid Secretariat** to elaborate a more comprehensive theory of change (that is not linear and takes account of the dynamism of the pandemic), the range of expected impact pathways as well as methodologies for measuring outcomes and impacts. Ultimately the Secretariat would work with grantees to secure more country-level information, including qualitative information that describes the value of the Unitaid investment, level of contribution and scalability.
- **For oxygen investments in particular, working with other global health organisations to develop relevant metrics and KPIs** (e.g. building on the ongoing multi partner effort led by WHO under the WHE 2 investment) as well as supporting countries with routine data collection on these aspects through HMIS. There may be useful lessons from Gavi's M&E approach for its Cold Chain Optimization Platform which also are infrastructure-based investments.<sup>62</sup>
- In addition to outcome and impact measurement, Unitaid should also **focus on measuring the sustainability of its investments**, especially as the pandemic evolves to an endemic state. There is also a need to ensure investments are repurposed to support future epidemic preparedness and response.

## **Global health emergencies/ future pandemics**

**Recommendation 8: Decide whether and under what conditions/ parameters, Unitaid is open, in principle, to support global health emergencies including future pandemics and position the organisation accordingly.**

With the benefit of experience of the COVID-19 pandemic, Unitaid should:

- **Formulate its position and strategy to combat future global health emergencies including pandemics.** As part of its Strategy 2023-27 and wider discussions around direction of travel for the organisation, Unitaid should discuss possible conditions and parameters that would necessitate its involvement in supporting any future pandemic or health emergencies. This should include areas of focus, types of support, overall approach and

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<sup>61</sup> For example, the Test and Treat portfolio includes metrics in relation to (i) evidence generation, (ii) supply chain and service delivery, (iii) policy and regulatory environment, (iv) demand creation and (v) transition and scale-up, however we would argue that a focus on (iii) and (v) would be most relevant to support an assessment of outcomes. For the balance areas, the focus is very much on measuring within-project results rather than multiplier effects of Unitaid investments to non project countries (for example) in keeping with Unitaid's raison d'être.

<sup>62</sup> <https://www.gavi.org/sites/default/files/document/programming-guidance---supply-chainpdf.pdf>



guiding principles, etc. Importantly, it should include more clarity on the nature of emergency support that falls within Unitaid's remit. It should also define some boundaries – e.g. when might Unitaid play a facilitator, rather than a core role, what might be areas where Unitaid does not get involved?

- **Depending on the chosen strategy, put in place the elements to rapidly enable support for future pandemic/ exceptional situations**, including decision-making/ governance procedures, flexibilities with regards to funds, staffing and processes, etc.
- **Continue to foster its commitment to equitable access**, for example by ensuring that R&D investments are based on confirmed access commitments.
- **Better harness its vantage point for access to market and country level intelligence and data for global health emergencies/ future pandemics**. With Unitaid's network of grantees across the globe, many of which are doing core work at the national and sub-national levels in countries, Unitaid should consider ways to better harness data and information that it has/ could have access to and channel for the global health response. This is an important learning through the experience of the COVID-19 pandemic, where data and information at the global-level has been limited/ patchy, also because of the continually evolving nature of the disease.



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