

# Unitaid Strategy Review 2017–21

**Final Report**

**Vol. 1: Main report**

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## Abbreviations and Acronyms

ACT-A	Access to COVID-19 Tools Accelerator
Afi	Area for Intervention
AIDS	Acquired Immunodeficiency Syndrome
AIRE	Improving the Identification of Respiratory Distress in Children
ALIMA	Alliance for International Medical Action
ARV	Antiretroviral
BMGF	Bill & Melinda Gates Foundation
BSC	Board Steering Committee
CHAI	Clinton Health Access Initiative
CIFA	COVID-19 Innovation For All
CSO	Civil Society Organisation
DALY	Disability-Adjusted Life Year
DFID	Department for International Development
DHSC	Department of Health and Social Care
DNDi	Drugs for Neglected Diseases Initiative
DRC	Democratic Republic of the Congo
EB	Unitaid Executive Board
EBC	Every Breath Counts
FCDO	Foreign, Commonwealth & Development Office
FGD	Focus Group Discussion
FIND	The Global Alliance for Diagnostics
GAD	Grant Agreement Development
GF	Global Fund to Fight AIDS, Tuberculosis and Malaria
GFF	Global Financing Facility
GH	Global Health
GHIT	Global Health Innovative Technology
GHS	Global Health Security
HCV	Hepatitis C Virus
HIC	High-Income Country
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Testing
HPV	Human Papillomavirus
HTA	Health Technology Assessment
HW	Health Worker

IMCI	Integrated Management of Childhood Illness
IP	Intellectual Property
IPT	Intermittent Preventive Treatment
IPTi	Intermittent Preventive Treatment in Infants
IPTp	Intermittent Preventive Treatment in Pregnancy
KI	Key Informant
KII	Key Informant Interview
KPI	Key Performance Indicator
LIC	Low-Income Country
LMIC	Low- and Middle-Income Country
M&E	Monitoring & Evaluation
MCH	Maternal and Child Health
MDG	Millennium Development Goal
MDR	Multi-Drug Resistant
MIC	Middle-Income Country
MNCH	Maternal, Newborn and Child Health
MNRH	Maternal, Newborn and Reproductive Health
MOH	Ministry of Health
MPP	Medicines Patent Pool
MTR	Midterm Review
NgenIRS	Next Generation Indoor Residual Spraying
NGO	Non-Governmental Organisation
NICE	National Institute for Health and Care Excellence
NNP	New Nets Project
NTD	Neglected Tropical Disease
OECD DAC	Organisation for Economic Co-operation and Development's Development Assistance Committee
OKPI	Operational Key Performance Indicator
OPP-ERA	Open Polyvalent Platforms [OPP] for Sustainable and Quality Access to VL [Viral Load] in Resource-Limited Settings
PATH	Program for Appropriate Technology in Health
PEPFAR	US President's Emergency Plan For AIDS Relief
PHC	Primary Healthcare
PMI	President's Malaria Initiative
POC EID	Point-of-Care Early Infant Diagnosis
PPE	Personal Protective Equipment

PPH	Post-Partum Haemorrhage
PQ	Pre-Qualification
PRC	Proposal Review Committee
PrEP	Pre-Exposure Prophylaxis
PSC	Policy and Strategy Committee
PTRS	Probability of Technical and Regulatory Success
R&D	Research & Development
RAG	Red-Amber-Green
RDT	Rapid Diagnostic Test
RM	Resource Mobilisation
RMNCH	Reproductive, Maternal, Newborn and Child Health
RQ	Review Question
SDG	Sustainable Development Goal
SKPI	Strategic KPI
SMC	Seasonal Malaria Chemoprevention
SMT	Senior Management Team
SO	Strategic Objective
STAR	Self-Testing Africa
STI	Sexually Transmitted Infection
TB	Tuberculosis
TIMCI	Tools for Integrated Management of Childhood Illness
TIPTOP	TIPTOP Transforming IPT for Optimal Pregnancy
ToC	Theory of Change
ToR	Terms of Reference
TWN	Third World Network
UHC	Universal Health Coverage
UNICEF	United Nations Children’s Fund
UK	United Kingdom
UMIC	Upper Middle-Income Country
USA	United States of America
USAID	United States Agency for International Development
VfM	Value for Money
WHO	World Health Organization
WS	Workstream

# Executive Summary

## Overview of Unitaid

Unitaid is an international organisation that invests in innovations to prevent, diagnose and treat human immunodeficiency virus (HIV), tuberculosis and malaria more quickly, affordably and effectively. It also works to improve access to diagnostics and treatment for HIV co-infections such as hepatitis C and human papillomavirus (HPV), and joined the Access to COVID-19 Tools Accelerator (ACT-A) partnership in 2020 in response to COVID-19. As of 2020, Unitaid managed a portfolio of over 45 grants worth around US \$1.3 billion. Unitaid's 2017–21 strategy was developed at a key moment in the transition from the Millennium Development Goals (MDGs) to the Sustainable Development Goals (SDGs) and places innovation at its core, as a key driver of impact in the global health response. With the current strategy period coming to an end, Unitaid is in the process of identifying opportunities and priorities for the next strategic period and defining its strategy for 2022–26.

## Focus and evidence base for this report

Itad was appointed by Unitaid's Executive Board to conduct an independent external review of Unitaid's 2017–21 Strategy. The review had two overarching objectives: 1) **to review progress in delivering the 2017–21 Strategy** – specifically to assess the Relevance, Coherence, Efficiency and Effectiveness of Unitaid's interventions during this period; 2) **to identify opportunities and priorities for the 2022–26 Strategy** – a 'forward looking' exercise focused on generating strategic lessons and formative recommendations to feed into the design and implementation of Unitaid's next strategy, with a view to maximising the organisation's value-add in an evolving global health (GH) landscape.

This report presents the methods, findings, conclusions and recommendations from this independent review. These are based on a review of over 200 existing secondary documents, triangulated through 100 key informant interviews (KIIs) with a range of stakeholder categories. We also conducted four thematic case studies, a high-level comparative landscape study, and a survey of Unitaid's grantees, to generate more in-depth information to inform our analysis. Preliminary findings and conclusions were presented to the Unitaid Board Policy and Strategy Committee (PSC) and Unitaid Secretariat in July 2021.

Our review was designed to generate strategic lessons and areas for Unitaid's new strategy to focus on, timed to fit with the development of Unitaid's 2022–26 strategy. As such it was necessarily limited in scope, bounded by an agreed set of research questions.<sup>1</sup> It explicitly does not form a comprehensive evaluation of Unitaid's performance against its 2017–21 strategic objectives (SOs), and as such may not capture all progress made towards these.

## Summary of findings

We present below a summary of high-level findings from the report, organised by the three workstreams that frame the review: Right things, Right ways, and Right results. We present a comprehensive set of findings with more detail, nuance and supporting evidence in the main body of the report.

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<sup>1</sup> See Annex 1 of Vol.2 for Strategy Review ToR

## Right things

Under the Right things workstream we looked at the relevance of Unitaid's investments, asking whether Unitaid's Strategy focuses on the right topics, including specifically looking at the relevance of Unitaid's areas for intervention, its prioritisation processes, and the broader value of Unitaid's outputs.

We found that Unitaid's commitment to HIV, tuberculosis (TB) and malaria and a limited expansion to other disease areas is appropriate. Unitaid makes considerable effort to consult with a wide range of stakeholders, and has broadly been responsive to beneficiaries' needs in line with the focus areas of this Strategy period. Unitaid has also demonstrated flexibility and an ability to course-correct in the dynamic contexts in which it operates, including shifting resources in and out of disease areas. Unitaid has generated influential evidence for policy and practice, and its landscape/horizon-scanning work is considered useful and high-quality. However, there is scope for Unitaid to strengthen the relevance of its investments, including through stronger, more systematic engagement with beneficiaries, clearer articulation of Unitaid's strategic investment priorities, and clearer assessment and documentation of trade-offs in investment decisions.

## Right ways

Under the Right ways workstream we looked at the coherence of Unitaid's interventions in terms of Unitaid's comparative advantage, the external and internal coherence of Unitaid's investments and the extent to which Unitaid's achievements are recognised. We also looked at efficiency in terms of how Unitaid's Strategy is being operationalised, its operating model, and approach to risk- and grant-management.

On coherence, there is broad consensus that Unitaid's core comparative advantage relates to the space 'between innovation and scale', its ability to 'flexibly identify access barriers to address' and its model of 'catalytic investments to open up markets'. Unitaid proactively collaborates within the GH space, and much emphasis is placed on detailed explorations of the landscape and players as part of the area for intervention (Afl) development process, which is central to identifying Unitaid's niche within specific technical areas. The portfolio as a whole is broad and deliberately spread across the elements of the value chain, and there is relatively good coherence within Afls/disease areas. We did find a lack of formal partnership engagement strategy or macro-level targets to guide strategic decision making on priority foci above the disease-level investment, and the need for clearer articulation and explanation in terms of Unitaid's role in market shaping, innovation and scalability. There is also scope for more joined-up planning, implementation and evaluative efforts across projects and Afls, and more effective cross-grantee working.

On efficiency, Unitaid has made important improvements to its operating model to promote efficiency, including through the introduction of UnitaidExplore, which demonstrates the potential for future adaptations to the model to improve agility; Unitaid's response to COVID-19 also provides evidence that Unitaid can be flexible, in particular during the design of its interventions. We also found that Unitaid has in place both strong systems for risk management and clear incentives to promote scalability of its investments. Some concerns remain that the operating model is too slow and bureaucratic, although we note that these challenges are not unique to Unitaid. We also note both the potential link between oversight (in terms of existing governance mechanisms) and the pace and agility of Unitaid's decision making, as well as potential benefits and drawbacks on whether changes to these structures should be made. We also found that Unitaid's risk appetite is generally considered to be too low, and that scalability appears to be under-considered in planning and implementation, with potential improvements that could be made to strengthen guidance and emphasise earlier engagement with key scale partners.

## Right results

Under the Right results workstream we looked at Unitaid's effectiveness, asking the extent to which Unitaid's Strategy is achieving the right results, specifically in terms of value for money and target setting. We also looked at equity as a key cross-cutting priority in Unitaid's 2017–21 strategy.

We found that Unitaid’s value for money (VfM) framework compares well to those of many GH organisations and has significantly improved over the Strategy period. SOs are consistently applied across the grant portfolio, while operational key performance indicators (OKPIs) seek to promote VfM within Unitaid organisationally. The objectives are appropriate for the driving of substantive change within what is an increasing range of diseases. Importantly, a closer look at two grants that depended on close interaction between Unitaid and the Global Fund suggests that this can sometimes work very well, with impressive catalytic results, although the relationship could be strengthened further by development of additional institutional links rather than reliance on good personal connections. We also found that target setting generally works well with grants, although targets are not used as a tool to influence disease areas, where they could be a part of AfIs. Unitaid’s SOs offer a good set of target indicators, except for equity. Equity is a key declared component of the Unitaid 2017–21 Strategy, and its interventions target vulnerable people by design. Unitaid’s focus on access barriers filters down to the award selection criteria. While the 2017–21 Strategy manifests commitment to addressing inequities, there is a lack of meaningful equity-related KPIs, which makes it difficult to assess whether Unitaid as a whole has delivered on equity.

## Conclusions

There have been many achievements during this Strategy period, including in terms of innovation, access and scalability, and ‘good practice’ in process and management. We recognise some of them here – and in more detail in the main text. These highlights provide a very strong foundation to build on with new strategy. But the focus of our review is to provide insights for an *improved strategy* moving forward, and we have necessarily focused on challenges and areas to improve. This should not diminish the fact that there is much to commend in Unitaid’s performance over the 2017–21 strategic period.

We have flagged below nine areas that Unitaid can focus on in the new strategy. Some of these are on Unitaid’s radar and some require trade-offs with other priorities. Given differing views about where to strike the balance on these trade-offs, Unitaid should reflect with its partners and be clear about the process and the positions taken so that others know and understand Unitaid’s point of view.

1. **It is clear that this Strategy period has included important work universally recognised as having improved access to innovations for vulnerable groups in low- and middle-income countries (LMICs).** This focus should be a central part of the new strategy. Although the review did not examine specific projects beyond the case studies, examples include the development of lower-cost paediatric dolutegravir formulations (otherwise left to inaccurate and distasteful dosing), HIV self-tests to reach men (otherwise missing from HIV testing and, ultimately, treatment and prevention) and efforts to increase access to pre-exposure prophylaxis (PrEP), which has the potential to empower adolescent girls and young women to reduce their very high levels of risk of being infected with HIV.
2. **Unitaid’s unique niche and comparative advantage are widely recognised – the ‘missing middle’ between research and development (R&D) and scale on the one hand and market shaping on the other. However, Unitaid lacks an overarching strategic plan/strategy, and instead relies on a set of tactics or actions they executed during the ‘Strategy’ period.** As Alvin Toffler observed, ‘*If you don’t have a strategy, you’re part of someone else’s strategy*’. In this case, Unitaid’s Strategy is essentially a blend of manufacturers’ strategy (innovation to access) and its delivery partners’ strategy (access to scale). Specifically, what appears to be lacking is a higher-level effort to look across its technical strategies and development of targets. This could drive investment decisions in the medium/long term and more sensitive measurement approaches which could help review progress and outcomes. Coupled with a stronger impact vision, Unitaid’s Strategy could more clearly illustrate its unique role and add value as the missing middle.
3. **It is hard to assess the extent to which Unitaid has focused on the ‘right things’. This is primarily due to the fact that Unitaid does not explicitly consider trade-offs within and across portfolios.** Unitaid’s VfM framework is strong, particularly at the award and pre-award stages; and the prioritisation process underpinning the development of disease narratives and AfIs includes

important criteria. But, crucially, Unitaid does not explicitly consider trade-offs between risk (in terms of technical success and scale), impact and cost-effectiveness of its investment options. This requires adopting a portfolio analysis approach, which is standard practice in the biopharmaceutical industry and has been adapted and adopted by some similar organisations, most notably the Bill & Melinda Gates Foundation (BMGF).

4. **It is unclear whether Unitaid is focused on the ‘right risks’, and identified risks need to be explicitly balanced with the speed/agility<sup>2</sup> of Unitaid’s decision making.** While we have found that Unitaid has established a robust risk management framework that represents close to or actual best practice, our assessment is that Unitaid is often risk-averse in its investment choices, more risk-averse in management, and less risk-averse when it comes to scalability.<sup>3</sup> Success for Unitaid is the adoption and scale-up of innovations they supported among their targeted beneficiaries. Yet it seems that many of its grants are scored as high-risk on scalability – i.e. that they may fail to scale up. It is unclear whether this risk is underestimated before grants are made, whether Unitaid is too bullish in terms of its ability to mitigate this risk over time, or whether it does too little to assure scale-up. There is also a visible bias towards risk assurance at the expense of agility. Obstacles to greater agility appear to relate to governance structures, including the role of the Board in approving project-level funding, as well as the consensus-style decision making. Where adaptations to the model have been made to increase agility and speed up decision making (in the form of UnitaidExplore), concerns have emerged about the impact on accountability and oversight in terms of consultation and inclusion. Further thought is needed on what drives the need for greater agility, including how and in what scenarios this is instrumental in maximising Unitaid’s effectiveness.
5. **In spite of the importance of scalability to Unitaid’s impact, there are potential improvements that could be made to strengthen guidance and emphasise earlier engagement with key scale partners.** While Unitaid’s focus on scalability has increased during the current Strategy period, and Unitaid is providing leadership in the field through the central importance it attaches to scale-up, there is a clear need and demand to continue to strengthen the approach through further guidance and clarity on the roles and expectations of key stakeholders in achieving scale-up. This is important given that Unitaid’s success is defined in terms of impact that rests on effective work to support scale-up.
6. **The extent to which governments and affected communities in LMICs are aware of Unitaid is unclear, which could pose a risk to sustainability and ongoing partnership at country levels. This is partly a symptom of limited dissemination of Unitaid knowledge products and limited engagement with country stakeholders: governments, civil society organisations (CSOs) and communities.** It is clear that Unitaid is aware of the need to strengthen its approach in this critical area, and it does have existing mechanisms to enable engagement of key constituencies, including through representation of non-governmental organisations (NGOs), communities and countries on the Unitaid Board. We recognise that this is a work in progress, but it should be prioritised during the next strategy. Related to this is the dissemination of Unitaid’s knowledge products (e.g. analysis of market demand and horizon scanning), which are high-quality and of value to the wider GH community but subject to limited Unitaid investment (time/resources) in sharing this work. Prioritising this could raise the profile of Unitaid’s work and strengthen awareness of both its role in the GH architecture and its specific value-add.
7. **While Unitaid does a good job in demonstrating efficiency, its effectiveness in the 2–5 years after grants have ended is insufficiently demonstrated.** Although its grant closure evaluations

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<sup>2</sup> It is also important to recognise that risk vs agility is just one trade-off at play in determining risk; others include risk and innovation, and risk and the source of funds. These issues are currently under discussion in the context of investment decisions (at various levels).

<sup>3</sup> The view that Unitaid is risk-averse was also expressed across a range of informants, including DPs, grantees, NGOs and Unitaid. Some respondents across these categories reported that risk appetite is appropriate.

meet with the Organisation for Economic Co-operation and Development’s Development Assistance Committee (OECD DAC) criteria, and all Unitaid grants undergo a systematic evaluation, Unitaid does not track effectiveness beyond a maximum of a year after grant closure, producing only a forecast for results beyond this point. In the context of catalytic grants, this means that grant outputs are well captured but the outcomes that these lead to are not.<sup>4</sup> Additionally, targets are not used as a tool to influence disease areas; a strategy without specific targets is a challenging one to completely review. There is recognition that Unitaid is taking a less disease-specific/product-focused (or ‘vertical’) approach than in the past. However, Unitaid would benefit from a clearer articulation of how its work contributes to the SDGs, including the Universal Health Coverage (UHC) agenda. Insufficient evidence of effectiveness may affect recognition and resource mobilisation – an area of significant concern.

8. **While Unitaid’s OKPIs generally work to increase efficiency and effectiveness, some issues remain.** Overall, the OKPIs have strengthened management discipline during the current Strategy period. But OKPI A’s limit on staff spending will increasingly limit the organisation’s ability to develop its capability in key areas – designing/managing more complex grants; engaging in-country and with health systems issues; managing post-grant monitoring and evaluation (M&E); and developing and applying disease-level strategic planning. OKPI B, relating to resource mobilisation, is also not currently a clear approach.
9. **Unitaid’s current approach to equity is too narrow, and the existing targets could be made more helpful.** Unitaid does not sufficiently consider who benefits from its work – such an enquiry is, of course, hindered by the fact that Unitaid does not do scale-up directly. But equity is a critical element of how Unitaid describes its effectiveness. And, as the previous bullet above states, Unitaid does not track effectiveness after grant closure. There are broader concepts of equity that Unitaid could look at too, such as who does the work (where are the grantees based?), who decides Unitaid’s priorities, and who decides who does the work. Unitaid might go further in terms of soliciting inputs from country voices, be they national governments, civil society or the targeted beneficiaries, leveraging its unique role in GH and partnerships with these stakeholders.

### Areas for the new strategy to focus on

The following recommendations were informed by a co-creation workshop held on 16 July with Itad, the Secretariat and members of the PSC.

1. **Unitaid’s next strategy should define its goals with greater specificity.** While the strategy should continue to outline Unitaid’s broad mission and global targets, it should also define Unitaid’s goals (with defined targets) at portfolio level, such as for disease areas of focus.
2. **The Unitaid Strategy should improve its framework for investment by incorporating clear decision criteria** that make explicit trade-offs within existing AfIs and a clearly defined process to adopt new AfIs and review whether an AfI is on or off strategy pre-AfI development.
3. **Unitaid should keep under review the existing articulation of its risk appetite and the implications of this for its ways of working.** It should consider whether it has the right mechanisms in place to strike the right balance between a range of (sometimes competing) agendas, including risk, innovation, agility, inclusion and consultation, accountability, and impact, and agree with the Board where to strike the balance wherever trade-offs are identified. This could include reflecting on risk appetite for each of the aspects of the risk taxonomy and recognising that risk appetite may be different for each.

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<sup>4</sup> It should be stressed that we are not aware of others, who operate in the middle of the value chain, conducting *ex post* independent evaluations of effectiveness. More generally, this remains the exception and not the rule even among delivery partners. But we have concluded that the inability to clearly articulate ultimate effectiveness in the years beyond a grant has implications, and for us this emerges as an area that Unitaid could choose to lean into and in which it could lead the field.

4. **The Secretariat should review, revise and strengthen its approach on scalability** to include: 1) more emphasis on grantee proposals to assess their plans for achieving scalability, to provide a basis to forecast prospects for achieving scalability; 2) detailed guidance on how to achieve scalability, differentiated for specific contexts (e.g. where no scaling partners, product type, disease burden); 3) stronger Secretariat engagement on scalability and clear division of labour with grantees; 4) early and explicitly defined/structured engagement with scale partners, and potential representation on the Unitaid Board; and 5) emphasis on communicating results, learning and opportunities for scale-up through grantees and country government partners, while prioritising a lot of space for discussion, wider learning and planning.
5. **Unitaid should review and revise its engagement strategies, including for country government and civil society engagement and knowledge dissemination.** Perhaps most importantly, governments and civil society need to be engaged prior to the AfIs being selected for development, to ensure that there is sufficient country commitment and community engagement. This is not necessarily straightforward to achieve, given the stage in solution development that Unitaid engages and the profile that it has at country level; there are also often congested partner landscapes at country level. We also recognise that there are potential resource implications for Unitaid to consider. Unitaid should also develop a strategy to inform how they can transfer more of the knowledge generated from their investments into policy and practice. In particular, the strategy should clearly define their priority audiences, e.g. donors, grantees, civil society, country governments, and normative agencies such as the World Health Organization (WHO). There should be clear indicators and targets that help track the success of this strategy.
6. **Unitaid should invest in independent *ex post* evaluations** (i.e. beyond a year after grant closure), where these might be achievable at reasonable cost. *Ex post* evaluation is both a relatively new area for development partners and a challenging one for those partners involved catalytically and at earlier stages of the value chain. However, the prospect of developing expertise and generating learning in this area should be viewed as major potential future assets for Unitaid. The evaluations would be useful in building a credible analysis of contribution, even if attribution was impossible to define. An ‘outcomes harvesting’ approach might be helpful in arriving at a specification, especially of those outcomes that are unexpected.
7. **Unitaid should revise selected organisational key performance indicators (KPIs).** OKPI A’s limit to staff spending should be relaxed to allow for strengthened capabilities in key areas – such as in-country engagement; health system skills; disease-level analysis; and post-grant (*ex post*) evaluation – as identified as priorities for the new Strategy. OKPI B’s approach to resource mobilisation targeting also needs revision. Revised targeting should achieve better clarity on annual/cumulative objectives, rather than merely stating a goal for the final year of the organisation’s five-year Strategy. If disease-level strategies with goals are also developed (Recommendation 1), then with some donors there may be opportunities for resource mobilisation to be tied to achievement of these objectives.
8. **Unitaid should consider the equity dimensions of its work beyond the removal of access barriers.** In particular, Unitaid should expand its definition and application of equity principles to include the way it develops and implements interventions. The equity and inclusion lens needs to be broadened to consider who does the work (grantees) and who decides the what and who (governance and epistemic community). Nevertheless, given Unitaid’s commitment to equity and delivery through partners in LMICs, there is an opportunity for Unitaid to demonstrate leadership in this area. Unitaid should develop more specific equity indicators that enable greater portfolio-level disaggregation of data on equity-related categories to improve targeting and monitoring.

Unitaid is well positioned to define and elaborate an exciting new strategy that builds on the work it has done to date and will position the organisation at the heart of the response to some of the most challenging GH issues that are facing the world at this time. We hope this review is a useful input in to the process of articulating this new strategy.

## 1 Introduction and Context

Unitaid's 2017–21 Strategy was developed at a key moment in the transition from the Millennium Development Goals (MDGs) to the Sustainable Development Goals (SDGs). The SDGs, particularly SDG3 (Ensure healthy lives and promote well-being for all at all ages), set a holistic and transformational agenda for health and called for novel approaches. It is with this framework in mind that Unitaid developed its 2017–21 Strategy, which crystallised Unitaid's unique mission to maximise the effectiveness of the global health (GH) response by catalysing equitable access to better health products. The Strategy places innovation at its core, as a key driver of impact in the GH response, and adopts an integrated approach to health to create synergies and efficiencies for health systems and patients in low- and middle-income countries (LMICs). Halfway through its implementation in 2019, Unitaid undertook a review. This Midterm Review (MTR) assessed how Unitaid is delivering on its Strategy and how Unitaid's impact can be amplified in the future.

With the current Strategy period coming to an end, Unitaid is in the process of identifying opportunities and priorities for the next strategic period and defining its Strategy for 2022–26, drawing on lessons learned from implementation of the current Strategy, the MTR and the organisation's contribution to the COVID-19 response. The Unitaid Strategy for 2022–26 will be developed during 2021 and the first half of 2022, and presented to the Unitaid Executive Board by June 2022.

The Executive Board commissioned an external review of Unitaid's current Strategy to provide key inputs for the ongoing development of the organisation's next Strategy. The Board formally requested the Unitaid Secretariat to commission an external review to be conducted by consultants and overseen by the Board leadership, acting as a Board Steering Committee (BSC).<sup>5</sup> Following an open call for proposals (see Annex 1: Strategic Review ToR), Unitaid selected Itad to conduct the 2017–21 Strategy Review. As per the terms of reference (ToR), this review is 'expected to focus on specific aspects of Unitaid's model and strategy that are particularly relevant to consider for the next strategy. It is expected to develop recommendations to address potential areas for improvements over the next strategy cycle and will complement analyses being conducted by the Unitaid Secretariat'.

This final report provides an overview of the methods, findings, conclusions and recommendations. Recommendations follow a co-creation workshop held on 16 July with the review team from Itad, the Secretariat and members of the Policy and Strategy Committee (PSC).

- This Final Report includes the incorporation of feedback from the Unitaid Secretariat and the BSC on the previous iteration of the report; the report is still based on the data collection and analysis work carried out between April and May 2021.

The rest of this report is structured as follows:

- **Section 2** presents the purpose, objective and scope of the evaluation.
- **Section 3** presents a summary of the evaluation design and methodology, including: the evaluation framework; review questions (RQs); data collection, analysis and synthesis methods; and limitations.
- **Section 4** presents findings by workstream.
- **Section 5** sets out our conclusions.
- **Section 6** presents our recommendations.

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<sup>5</sup> The BSC was chaired by Marisol Touraine, and included Maria Luisa Escorel de Moraes (Brazil), Stephanie Seydoux (France), James Droop (UK) and Jamie Morris (BMGF/Foundations) as members.

This is supported by the following Annexes:

- **Annex 1:** Strategy Review ToR
- **Annex 2:** Strategy Review Framework
- **Annex 3:** List of People Interviewed (by Global, Case Studies and Comparative Landscape Analysis)
- **Annex 4:** List of Documents Reviewed (general and case studies)
- **Annexes 5-8:** Case studies (TB Prevention, Malaria Chemoprevention, HIV Self-test, Fever Management)
- **Annex 9:** Analysis of Unitaids Grant-Making and Management against VfM Good Practice
- **Annex 10:** Resource Mobilisation
- **Annex 11:** Organisational Profiles (Gavi, the Global Fund, USAID, Foreign, Commonwealth and Development Office, Bill & Melinda Gates Foundation, Children’s Investment Fund Foundation, the Wellcome Trust, and the Global Financing Facility)
- **Annex 12:** Evidence Table
- **Annex 13:** Draft Portfolio-Level Theory of Change
- **Annex 14:** Cross-Case Analysis Table
- **Annex 15:** Unitaids GF Market Shaping Successes
- **Annex 16:** Two Grants as Case Studies for Unitaids Relationship with the Global Fund

## 2 The Review’s Objectives and Approach

### 2.1 Review objectives

The review has two overarching objectives:

1. **Review progress in delivering 2017–21 Strategy:** a ‘looking back’ exercise focused on how well Unitaid has performed against its 2017–21 Strategy. Specifically, as per the ToR, this looks at Relevance, Coherence, Efficiency and Effectiveness of interventions chosen and implemented during this period.
2. **Identify opportunities and priorities for 2022–26 Strategy:** a ‘looking forward’ exercise focused on generating strategic lessons and formative recommendations to feed into the design and implementation of Unitaid’s next Strategy, with a view to maximising the organisation’s value-add in an evolving GH landscape. In addition to the main formative approach – looking backward to look forward – our overall approach was guided by three additional ‘principles’.

First, the use of a portfolio-level Theory of Change (ToC) to provide an analytical framework for understanding and testing the theory which links Unitaid’s interventions and grants to their aims and achievements as outlined in the Strategy. While Unitaid uses ToC as a tool in its grant management approach, a portfolio-level ToC has not been articulated, which represents a gap in Unitaid’s strategic planning. Setting out a clear intervention logic that explains why (on what basis) Unitaid believes its approach will generate the results it has committed to achieve will, in turn, help strengthen Unitaid’s overall approach, and can be used in communicating intended impact with partners. Much of the thinking needed to fill this gap exists, and Itad facilitated a preliminary discussion with the Unitaid Secretariat on 23 April 2021 to postulate a draft ToC (Annex 13) as the working basis for aspects of analysis in this review. However, due to the compressed timeline of this review, we have not been able to finalise this together with the Secretariat, and the ToC did not significantly inform the analysis presented in this report.

Second, in line with the principle of utilisation-focused evaluation, we proposed that recommendations should be co-created in a virtual participatory workshop with members of Unitaid’s senior management team (SMT) and the Policy & Strategy Review committee. This workshop took place on 16 July 2021. The focus was on getting stakeholders to engage with the draft main findings and conclusions from this report and to discuss and co-create options for moving forward. Ahead of the workshop, we shared a short note to introduce participants to the objectives, methodology, format and spirit of the workshop.

Third, reflecting Unitaid’s mission to catalyse equitable access to better health products, and as equity is one of the four Unitaid’s investment commitments, we have built in equity as a cross-cutting principle of enquiry (see Section 4.4.1 below).

### 2.2 Overall approach

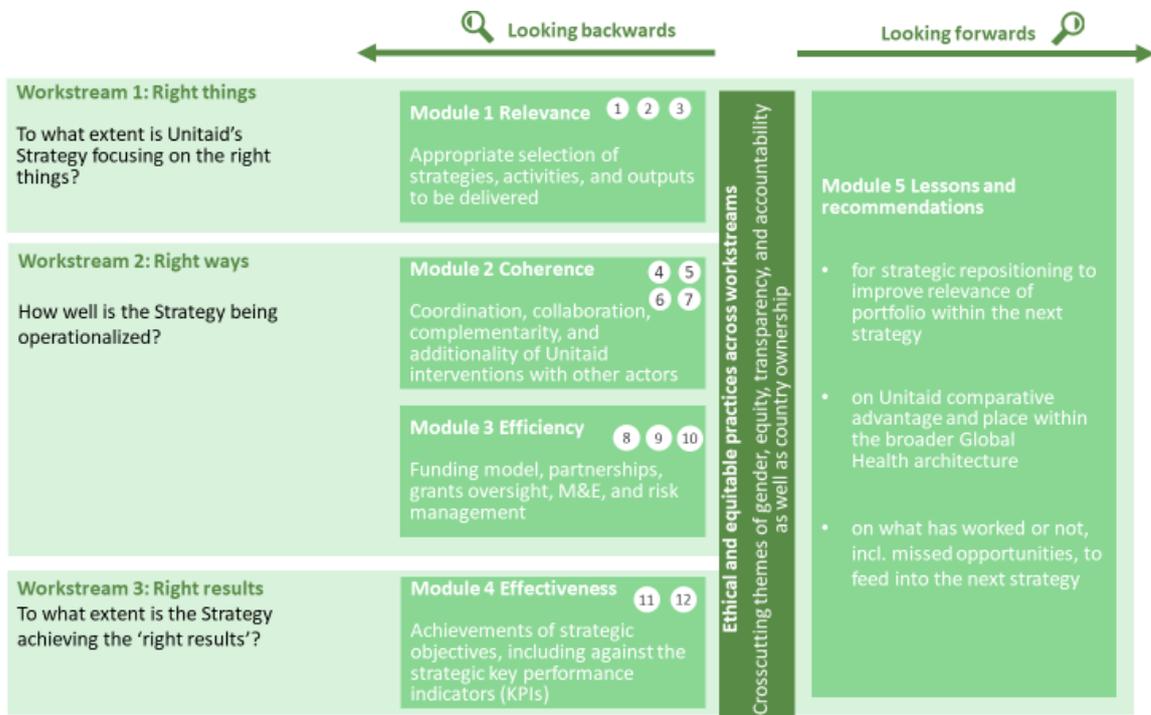
We organised our approach around three interrelated ‘workstreams’ which cover and cluster what we view as the three high-level strategic questions that were addressed in this review. They can be summarised as:

1. **To what extent is Unitaid’s Strategy focusing on the right things?** Workstream 1 on ‘Right topics’ explores the relevance of Unitaid’s interventions to contribute to the desired results as articulated in its results framework and in the Strategy.
2. **How well is the Strategy being operationalised?** Workstream 2 on ‘Right ways’ explores this overarching question, with a focus on the coherence of the Unitaid interventions within the GH architecture as well as on how well Unitaid resources are being used (Efficiency).
3. **To what extent is the Strategy achieving the right results?** Workstream 3 on ‘Right results’ assesses the effectiveness of Unitaid in meeting the objectives outlined in its Strategy, including against the strategic key performance indicators (KPIs).

Within each of the three workstreams (right topics/right ways/right results) we identified modules which cluster specific groups of RQs and priority issues covered in the ToR in a way that provides a framework for structuring our work and, in turn, for conducting a focused and specialised analysis.

For modules 1–4, our work focused around interrogating a cluster of RQs (see Figure 1 and text below, where the RQs are repeated) through a set of bespoke data collection and analytical methods. Module 5 does not rely on specific data collection or analysis methods; rather, it builds on findings and insights gathered through ‘looking backwards’ to generate lessons and recommendations for the next Strategy.

Figure 1: The main formative approach – looking backward to look forward



### 3 Review Design and Methodology

#### 3.1 Review questions

On reflection, we felt that the RQs posed in the ToR allowed us to meet the review objectives. As such, the questions were retained, with only some refinement as clarified with Unitaïd during the Inception Phase.

The RQs and sub-questions are presented in the review framework in Annex 2, including the approaches used for data collection and analysis for each RQ and sub-question. The review framework also specifies the criteria (or modules) that are pertinent to each RQ (i.e. Relevance, Coherence, Efficiency and Effectiveness, as per the ToR), as well as criteria against which judgements have been made. The review framework thus illustrates how data collection and analysis methods have allowed for systematic extraction and synthesis of evidence to generate findings and, ultimately, recommendations. Structuring it in this way will ultimately allow users of the Final Report to trace back from recommendations to the data upon which they are based. Table 1 provides a summary of the RQs by workstream (WS).

Table 1: Summary of review questions by workstream

WS	Modules and overarching questions	Review questions
WS 1 Right Things	Module 1: Relevance  Have Unitaïd’s interventions been focusing on the right topics/issues – particularly in a dynamic context?	<b>RQ1 Relevance of areas for intervention (Afls)</b>  To what extent has Unitaïd responded to the needs of targeted beneficiaries/addressed global goals? To what extent has Unitaïd selected the right priorities? Were any topical areas or potential innovations missed?
		<b>RQ2 Prioritisation process</b>  To what extent is the process underpinning the development of disease narratives and Afl well suited for prioritising focus areas? To what extent have priorities been adapted/course corrected to respond to significant changes, where these have occurred?
		<b>RQ3 Global public goods</b>  To what extent are or could the outputs of the process be useful to inform other organisations’ priority setting and investments?
WS 2 Right Ways	Module 2: Coherence  What is Unitaïd’s Unique Selling Proposition in the global health (GH) space?	<b>RQ4 Complementarity</b>  To what extent does Unitaïd’s work complement that of other actors?
		<b>RQ5 Comparative advantage</b>  To what extent has Unitaïd consistently focused on Afls aligned with its Strategy, mandate, and operating model and where it is well positioned to deliver results?
		<b>RQ6 Internal coherence</b>  To what extent do the projects in Unitaïd’s portfolio add up to a coherent whole with the potential to drive transformative change?
		<b>RQ7 Visibility and recognition</b>  To what extent are Unitaïd’s positioning, work and achievements recognised relative to those of other relevant actors? To what extent is Unitaïd recognised as a key player and as bringing value to its investment areas?
Module 3: Efficiency  How well are Unitaïd resources being used?	<b>RQ8 Operating model</b>  To what extent is Unitaïd’s model fit for purpose, fast and agile enough to seize key opportunities and deliver in a timely manner?	
	<b>RQ9 Risk management</b>	

		To what extent are the trade-offs between rigour and assurance vs speed and agility appropriate given Unitaid’s mandate, priorities and risk appetite?
		<p><b>RQ10 Grant management model</b></p> <p>To what extent does the grant management model make efficient use of resources (both at Unitaid and implementing organisations)? What opportunities are there to enhance the model to enable the optimal balance between empowering implementers with the flexibility they need to innovate in delivery and ensuring accountability for delivery?</p>
<b>WS 3 Right Results</b>	<b>Module 4: Effectiveness</b>	<p><b>RQ11 Value for money (VfM)</b></p> <p>To what extent is Unitaid’s organisation and portfolio delivering against its objectives and providing VfM? Are the results consistent across areas? To what extent are the objectives and associated targets sufficient to drive expected transformations at grant and portfolio levels?</p>
		<p><b>RQ12 Target setting</b></p> <p>To what extent are objectives and targets well defined upfront and subsequently at grant level? At Afl level? At organisation level?</p>

## 3.2 Data collection methods

To answer the RQs presented above, the review team applied five different data collection methods: 1) extensive review of existing secondary data; 2) key informant interviews (KIIs) of different stakeholder groups at different levels; 3) a grantee survey; 4) a structured case study approach; and 5) a comparative landscape analysis.

### 3.2.1 Review of existing secondary data

We have completed a comprehensive and structured review of documentation shared by the Unitaid Secretariat and other external secondary data sources identified by the review team to i) systematically extract evidence against the RQs and to ensure a comprehensive understanding of Unitaid’s approach, and ii) develop a draft overarching ToC. See Annex 4 for a full list of documents consulted. In total we reviewed 221 documents and captured excerpts using MAXQDA, as described in Section 3.3 below, with additional documents reviewed by workstream leads and thematic case study leads which were incorporated in their analyses.

### 3.2.2 Key informant interviews

Secondary data was enhanced and complemented by KIIs designed to enable the review to listen to a diverse group of stakeholders and collect new opinions, insights and ideas related to the RQs and/or independent corroboration of existing analyses on strengths, weaknesses and opportunities relating to Unitaid’s approach. KIIs were carried out using a semi-structured interview protocol. The identification of key informants (KIs) drew on a two-stage sampling strategy. First, with the help of the Secretariat we identified key individuals to interview. We then employed a snowball approach, asking respondents for connections with other potential KIs that they deemed relevant for us to interview. We therefore worked with the Secretariat to identify those KIs who were best placed to respond to the RQs, with the final selection made by the review team. We conducted a total of 101 interviews (compared with 80 that we had planned to conduct in our proposal), with more than 150 different stakeholders from 68 different organisations, of which just under 18% were identified by the review team. See Annex 3 for a full list of people interviewed.

### 3.2.3 Grantee survey

We were requested by the Secretariat to independently administer the grantee survey, in order to address concerns that previous surveys (which had been managed by the Secretariat) may not fully reflect

concerns that grantees had about Unitaid’s approach or performance. The survey was made up primarily of questions defined by the Secretariat, with a small number added by the review team. This survey was conducted online, using SurveyMonkey, between 18 May and 4 June 2021. All 49 grantees with active grants in January 2021 were invited, of which 35 (71%) responded (down from 86% in 2020). The survey covered 59 questions, including 12 open-ended questions.

### 3.2.4 Thematic case studies

We conducted four thematic case studies (see Annexes 5–8), the purpose of which was to take a horizontal look across the RQs and modules to provide a discrete, comprehensive analysis to add depth and illustrative examples to the broader analysis for each specific module. Case studies were also the main mechanism through which country perspectives were gathered, and so they provide an important complementary lens for the review. The choice of cases was informed by the following criteria: 1) prioritising the diseases that represent the largest investment by Unitaid; 2) different intervention types – i.e. prevention, diagnostics and treatment – and access barriers – affordability, demand, adoption, innovation, availability, quality, supply and delivery. Options for case studies were discussed with the Secretariat and Board, and the following four were chosen:

- Tuberculosis (TB) prevention (Annex 5)
- Malaria chemoprevention (Annex 6)
- Human immunodeficiency virus (HIV) self-test (Annex 7)
- Fever management (Annex 8)

Case studies were carried out remotely through a mix of KIIs and document review. Full details of who we spoke to and which documents we consulted are available in the Annexes.

### 3.2.5 Comparative landscape study

We conducted a comparative landscape analysis to see what we could learn from other organisations who face similar strategic and operational challenges to Unitaid. In response to Unitaid’s request to consider comparators other than in addition to Gavi and the Global Fund, which the Secretariat know well, we focused on eight organisations that met the following criteria: funding organisations active in health product markets through support to innovation, enabling equity in access and/or building scalability; focus of support includes health commodities for use in the control of HIV/AIDS, TB or malaria; core focus is on low- and/or middle-income countries; active at the global and/or regional/multi-country level; qualitative considerations in agreement with Unitaid, such as organisations not previously studied by Unitaid. Organisations included in the study were: the Bill & Melinda Gates Foundation (BMGF), the Children’s Investment Fund Foundation, Gavi, the Global Financing Facility, the Global Fund to fight AIDS, TB and Malaria, the United States Agency for International Development (USAID), the United Kingdom’s (UK’s) Foreign, Commonwealth & Development Office (FCDO) and the Wellcome Trust. The analysis was based on document reviews and several remote KIIs.

## 3.3 Analysis and synthesis

Data from all sources were thematically coded using a coding tree based on our review framework, using software called MAXQDA. This helped shed light on common patterns across global and country levels, the portfolios – innovation, access and scalability – and the four investment commitments. Coding was done using an a priori coding structure applied by a group of four Research Analysts, with support from the Deputy Team Leader and Project Manager, to ensure consistency in application of the codes. The analyses from the desk-based reviews of the Unitaid Strategy, as well as programme and country reports, including the quantitative financial and other analyses, were triangulated and synthesised.

Triangulation in our analysis took place at four levels:

- Different data collection methods;
- Different stakeholder groups;<sup>6</sup>
- Different team members (e.g. we conducted four internal analysis workshops to cross-check and triangulate findings among the team); and
- Different analytical methods (e.g. VfM analysis vs qualitative analysis of interviews).

Where possible, triangulation was used to ensure that findings were based on a credible and robust evidence base. For example, if KIs expressed certain perspectives, we examined whether this was corroborated by documentary evidence or by other stakeholder groups, or indeed by broader experience as documented in published literature or held by the review team.

From the 101 KIIs and 221 documents reviewed, we coded 4,239 excerpts of data. Table 2 shows how these excerpts were distributed across a selection of key codes<sup>7</sup> and underlines that for the majority of key areas of enquiry there was a good balance of documentary and KI evidence to support triangulation. In some cases slightly more pieces of ‘information’ were coded from the KIIs compared to the documents, although this may be best explained by the fact that documents cannot be asked questions. The first column shows the codes we used, mapping to the RQs and the four case studies (HIV self-test, TB prevention, malaria chemoprevention and fever management). The second and third columns show the numbers of excerpts of data that were extracted against these codes, from the document review and KIIs<sup>8</sup> respectively. The final column shows the total across both sources. The colour scale is Green to Yellow to Red, with high values getting the green colour and low values getting the red colour.

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<sup>6</sup> The following stakeholder categories were used to simplify presentation of our analysis; sub-categories within each group were captured to enable further disaggregation if useful: **Development Partners** (including donors, Foundations, UN agencies), **Unitaid** (including Secretariat, Board and PSC), **Grantees** (recipients of Unitaid funding), **NGOs/CSOs** (non-grantee civil society representatives), **Country Governments**, and **Private sector organisations**.

<sup>7</sup> Additional excerpts were coded on strategic objectives (innovation, access and scalability), investment commitments (VfM, partnerships, and health system), and COVID-19 (both adaptation and response).

<sup>8</sup> This includes global KIIs, as well as KIIs conducted for the case studies and the comparative landscape analysis.

Table 2: Heat map of data excerpts by code and source

	Documents	Interviews	
RQ1 Relevance of AfIs	160	216	376
RQ2 Prioritisation process	57	100	157
RQ3 Transferability	27	94	121
RQ4 Complementarity	222	165	387
RQ5 Comparative advantage	60	162	222
RQ6 Internal coherence	50	72	122
RQ7 Visibility and recognition	47	163	210
RQ8 Operating model	154	203	357
RQ9 Risk management	78	46	124
RQ10 Grant management model	144	104	248
RQ11 VfM	109	131	240
RQ12 Target setting	38	63	101
Equity	90	97	187
Access to HIV self-testing in LMICs	236	180	416
Fever management	15	11	26
Malaria chemoprevention in pregnant women and children	82	214	296
Prevention of TB	67	12	79

Table 3 disaggregates the 1,519 excerpts of data that we coded from the 100 KIIs, using both the 12 RQs and six stakeholder categories. It demonstrates how the review team have integrated internal perspectives from the Secretariat and Board with external perspectives from donors, private sector, non-governmental organisations (NGOs) and host country governments in our analyses. The lower number of excerpts coded from stakeholders from LMIC governments is a function of a lower absolute numbers of KIIs (n=17 out of 100), compounded by the fact that many of the RQs were not relevant to them.

Table 3: Heat map of data excerpts from the KILs by RQ and stakeholder group

RQ	Development partners	Unitaid	Grantees	NGOs/civil society organisations (CSOs)	Private sector	LMIC govts	
1	60	66	57	19	13	1	216
2	28	37	14	12	9	0	100
3	27	34	18	9	3	3	94
4	61	49	25	14	13	3	165
5	53	46	32	20	9	2	162
6	23	35	6	7	1	0	72
7	42	73	25	15	3	5	163
8	35	68	47	27	25	1	203
9	8	16	12	9	0	1	46
10	15	15	54	5	9	6	104
11	38	53	25	5	8	2	131
12	14	31	12	3	3	0	63
	404	523	327	145	96	24	1519

We also mapped out Unitaid’s approach to efficiency and effectiveness within grant-making and management, and benchmarked it against best practice principles that we have consolidated as part of a recent literature review on ‘Elements of Good Practice in the Delivery of Value for Money (VfM) in Development Grant Programmes’.<sup>9</sup> These principles encompass eight dimensions in total pre-award/award/post-award/closure stages i) across the grant portfolio and ii) within individual grants, as shown in Annex 9. We then compared Unitaid’s approach vis-à-vis good practice using a Red-Amber-Green (RAG) rating approach. The purpose of doing this was to have a transparent framework for making judgements about the efficiency of the grant-making model and to support identification of ways in which this could be strengthened.

In our presentations of preliminary findings, which were based on incomplete data, we included an approach to rank the strength of evidence. Although data collection is now complete, and despite our best efforts, in some areas we have not managed to collect sufficient good-quality data to consider the evidence base against all RQs as very strong. As such, we have used the same approach to assessing the strength of evidence in a systematic way, to convey to readers what sort of evidence has been used to generate the findings and how robust these are.

Table 4 presents our approach to ranking the strength of evidence. This ranking is used throughout this report.

<sup>9</sup> This literature review was conducted by Itad in the framework of The Fleming Fund Evaluation. The Fleming Fund is a £265 million UK government investment managed by the UK Department of Health and Social Care (DHSC). It is administered through a portfolio of country and regional grants, global projects and fellowship schemes which aim at strengthening antimicrobial resistance surveillance systems in 24 countries across Africa and Asia to tackle antimicrobial resistance.

Table 4: Strength of evidence framework

Rank	Justification
1	<b>HIGH</b> Evidence comprises multiple data sources, both internal – e.g. Unitaid Secretariat and Board – and external (good triangulation = at least two different sources, e.g. document review AND KIIs or multiple KIIs of different stakeholder categories), which are generally of good quality.
2	<b>MEDIUM</b> Evidence comprises multiple data sources (good triangulation) of lesser quality, or the finding is supported by fewer data sources (limited triangulation, e.g. only documents or KIIs of one stakeholder category) of decent quality.
3	<b>LOW</b> Evidence comprises few data sources across limited stakeholder groups (limited triangulation) and is perception-based, or generally based on data sources that are viewed as being of lesser quality.
4	<b>VERY LOW</b> Evidence comprises very limited evidence (single source) or incomplete or unreliable evidence. Additional evidence should be sought.

### 3.4 Limitations

**The number of interviews conducted had to be balanced with resources available as well as stakeholder availability.** Good practice when using a snowball approach would be to continue identifying new KIIs until the point where no new data, categories or relationships seem to be emerging. Unfortunately, time<sup>10</sup> and resources have meant that we have not been able to reach this point and it must be acknowledged as a limitation – although, as noted above, we did conduct more interviews that anticipated in our proposal.

Moreover, the team has been unable to interview a number of stakeholders, owing to scheduling difficulties. More resources or greater stakeholder availability would have meant, again, a wider evidence base to support findings and recommendations. **In particular, there was limited participation from government stakeholders based in LMICs**, as highlighted in the heat maps above. However, we did prioritise southern-based grantees when we decided which of the 43 grantees to interview, and this will have mitigated the limited responses from host country government stakeholders. It is also important to note that there was a high proportion of non-responses from LMIC stakeholders (i.e. we tried to include more but may have struggled due to competing priorities for Ministry of Health staff, in particular relating to COVID-19).

**The comparator analysis is not as prominent as we would have hoped.** In part this is a timing issue, in that the comparator analysis ran in parallel with a bit of a lag. In an ideal world, we would have done a targeted comparator analysis focused on the areas for improvement surfaced by our review. However, and furthermore, to generate insightful, useful findings, multiple KIIs within organisations would also have been conducted to explore and cross-validate various aspects, which would have stretched the methodology and timeframe. There is also the question as to whether various informants within other organisations would have been open about internal processes and challenges to enable effective

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<sup>10</sup> This review began in April. The data collection period was for six weeks (26 April–4 June). It is worth noting that the MTR timeline was December 2018–June 2019.

comparisons in line with our findings. In the end we have sought to highlight (in the Recommendations section) examples of organisations we believe have something to offer Unitaid on specific issues.

**The review was conducted over a compressed three-month time period**, with a preliminary briefing by the Secretariat taking place in early April, discussion of our approach with the BSC in mid-April, data collection essentially throughout May and submission of a draft report in early July. Given timing constraints, the Itad team had limited flexibility to accommodate challenges in data collection – even after welcome revisions to initial timeframes that the Board agreed – or to refine the analysis presented in this final report.

The team is, however, confident that the evidence collected and analysed is sufficient to formulate sound conclusions and actionable recommendations.

## 4 Findings

The findings presented in the sections below are based on a range of data sources and the data collection and analytical approaches described above and in the review framework. Our rating of the strength of evidence is presented next to the high-level finding in response to each review question.

### 4.1 Workstream 1: Right things

This workstream is concerned with whether Unitaid’s interventions are focusing on the right things. It covers Module 1 on Relevance.

#### 4.1.1 Detailed findings by sub-issue

RQ1	Relevance of AfIs: To what extent has Unitaid responded to the needs of targeted beneficiaries/addressed global goals? To what extent has Unitaid selected the right priorities? Were any topical areas or potential innovations missed?	Strength of evidence
High-level findings	<p><b>Unitaid has broadly been responsive to beneficiaries’ needs in line with the topical focus areas of this Strategy period.</b></p> <p>Unitaid would benefit from more engagement with beneficiaries and a clearer articulation of how its work contributes to the SDGs.</p> <p>There are mixed views about its work beyond the ‘core business’ of HIV, TB and malaria.</p> <p>Some potential missed opportunities were identified but no assessment of trade-offs documented, without which it is unclear whether they should have been pursued instead of other things Unitaid funded. This speaks to a concern that Unitaid selects its AfIs based on opportunities as they arise, and this is not always linked to planned strategic prioritisation.<sup>11</sup></p>	<p>Evidence for Findings #1.1–1.3 is stronger than for Findings #1.4–1.6. There is strong triangulation across KIs, documents, and review team experience for Findings #1.1–1.3. While there are multiple sources of evidence for Finding #1.5, the picture with regard to trade-offs is nuanced, and strength of evidence is medium.</p>

In the 2017–21 Strategy, Unitaid describes its priorities as a continuation of its commitment to HIV/AIDS (including co-infections such as hepatitis C), TB and malaria – commonly referred to as its ‘core business’. Furthermore, the Strategy states that Unitaid will also support a more integrated approach to health, to increase both access to health products and effectiveness of care; and that it will evolve to encompass more projects supporting integration, specifically in reproductive, maternal, newborn and child health (RMNCH). These priorities were to be informed by public health needs and the goals agreed to by the GH community, such as the SDGs.

Given the Strategy’s stated priorities, this first RQ looks at whether Unitaid has focused on the ‘right things’ in terms of topical areas (problems), beneficiaries, and innovations (solutions). RQ2 examines in more detail the process for selecting specific AfIs within these broad topical areas.

**Finding # 1.1: The continued commitment to HIV, TB and malaria and a limited expansion to other disease areas is considered appropriate, though could be more clearly defined.**

Overall, 90% of respondents to the grantee survey believe that Unitaid is investing in the right areas, and this belief was echoed by many stakeholders interviewed. However, as acknowledged in Unitaid’s Strategy review workshop, the global response to the ‘core business’ is maturing and becoming increasingly sophisticated, and this has led to divergent views on how much remains to be done in relation to HIV, TB and malaria. While a few people maintain that Unitaid should focus only on HIV, TB and malaria,

<sup>11</sup> Innovations are both opportunistic and relevant. *Opportunistic* characterises the process of how they were identified (see 2.1 and 2.2), whereas *relevant* explains how useful they are to beneficiaries (detailed in 1.1).

respondents in all sectors thought that some expansion of scope was beneficial, but that expansion had to be limited and not extended to all World Health Organization (WHO) priorities. Some highlight a reduction in market shaping opportunities in HIV treatment and malaria but a potential increase in opportunities for HIV prevention, TB treatment, prevention and diagnostics, and malaria elimination. The adjacent (e.g. hepatitis, fever) and new AfIs (e.g. RMNCH, chagas) provoked considerable discussion from all groups of stakeholders, and there is no consistent language to describe Unitaid's investments beyond the three priority diseases.

**Finding # 1.2: Unitaid is recognised by the international community as being responsive to the needs of the targeted beneficiaries, but more can be done to consult directly with LMIC governments, civil society and affected communities to ensure alignment and eventual demand.**

Unitaid's Strategy focuses on reaching underserved people, and country income is the primary proxy for need (e.g. people in low-income and lower-middle-income countries), with burden of disease and other geographic differences also taken into consideration on a project-by-project basis. Unitaid closely aligns its AfIs with global disease-specific agendas; for instance, the TB prevention project is very responsive to the goals of the WHO's End TB Strategy. Although a full-scale portfolio review was not conducted, several projects can be highlighted as examples of reaching people in need, including: development of lower-cost paediatric dolutegravir formulations (otherwise left to inaccurate and distasteful dosing), multi-country introduction of HIV self-tests to reach men (otherwise missing from HIV testing and, ultimately, treatment and prevention) and increased access to pre-exposure prophylaxis (PrEP) among adolescent girls and young women (with very high levels of risk of being infected with HIV). However, Unitaid does not conduct systematic beneficiary analysis, so it is hard to know the extent to which innovations reach and improve the lives of the targeted beneficiaries – something we address in more detail in RQ12 (on target setting). Consultations with international stakeholders raised the point that Unitaid could put more emphasis on understanding beneficiary needs, with stronger connections to and partnership with national governments, civil society and affected communities in beneficiary countries (see RQ 4 below on complementarity, and Section 4.4.1 on Equity).

**Finding # 1.3: There is recognition that Unitaid is taking a less disease-specific/product-focused (or 'vertical') approach than in the past, while some KIs think that Unitaid has not gone far enough in terms of pursuing more integrated/platform (or 'horizontal') innovations.**

The Strategy recognises that the agenda for GH has expanded 'beyond HIV/AIDS and co-infections, tuberculosis and malaria towards universal health access as enshrined in the Sustainable Development Goals'. It also states that through the interventions it supports 'Unitaid aims to contribute to the strengthening of overall health systems in resource-limited settings'.

While our review has not assessed the extent to which Unitaid's focus on improving access to innovative products has strengthened – or is likely to strengthen – health systems, KIs we spoke to noted that Unitaid's product-focused and relatively short-term engagement was not likely to significantly strengthen health systems, though the interventions could have an impact. KIs did not uncover a strong call for greater engagement on Health Systems Strengthening (HSS), giving the impression that Unitaid's indirect impact is sufficient. As highlighted in the malaria case study, malaria chemoprophylaxis requires strong horizontal health system delivery platforms to be successful, and Unitaid did not have a comparative advantage in this area. Whether Unitaid *should* have been more engaged on strengthening health systems reflected the broader and long-standing debate between those who advocate a more vertical approach to GH priorities and those who believe that a more horizontal perspective leads to more sustainable progress without distorting country priorities.<sup>12</sup> Integration across disease areas is expanding, such as the addition

<sup>12</sup> See for example, Mills A. Vertical vs horizontal health programmes in Africa: idealism, pragmatism, resources and efficiency. *Soc Sci Med* 1983;17(24):1971-81; Sepúlveda J, et al. Improvement of child survival in Mexico: the diagonal approach. *Lancet*. 2006;368(9551):2017-27; Storeng KT. The GAVI Alliance and the 'Gates approach' to health system strengthening. *Glob Public Health*. 2014;9(8):865-79.

of RMNCH to the portfolio. Unitaid’s more recent disease narratives reflect integration at disease level through consideration of needs across treatment, prevention and diagnostics. Several KIs, however, suggested that Unitaid has not gone far enough in terms of pursuing more integrated (or ‘platform’) innovations. For instance, the fever case study noted calls for more integrated thinking on the linkages between fever and the three diseases or between fever and an overall Maternal, Newborn and Child Health (MNCH) approach. A few KIs mentioned the need to further consider the internal coherence of Unitaid’s entire portfolio to ensure organisation-wide impact. As noted in the midterm Strategic Review, Unitaid is broadly contributing to SDG3 and also, according to some, to SDG1. Additionally, several disease narratives explicitly link Unitaid’s work to the SDG goals, such as the RMNCH in the Thematic Narrative, New Tools for Maternal Mortality Afl and nascent post-partum haemorrhage (PPH) projects; the projects will track impact on lives saved and model this on the maternal mortality SDG target. This review was unable to identify an analysis that details Unitaid’s total contributions to the SDGs. Building on the RMNCH example, detail of the contributions resulting from Unitaid’s entire grant portfolio would help to quantify and increase recognition of Unitaid’s contribution to the SDGs, and could contribute to resource mobilisation efforts.

**Finding # 1.4: Intellectual property, medicines and diagnostics were widely considered relevant and important tools, but some respondents perceived an inherent tension between the Strategy’s pillars of innovation and access.**

While largely confirming the 2019 MTR finding that Unitaid has a strong capability to identify relevant innovations,<sup>13</sup> this end-of-Strategy review calls out particular Afls for their relevance (i.e. how useful they are to beneficiaries): Unitaid’s ongoing commitment to the Medicines Patent Pool (MPP) and Unitaid’s understanding of the role of intellectual property (IP) in access and innovation<sup>14</sup> are unique and highly valued resources. Grantees noted that Unitaid need not ‘shy away’ from its IP investments and could expand IP work within HIV, TB, malaria and outside the core disease areas. Respondents in all categories also considered Unitaid’s focus on medicines and diagnostics highly appropriate. While some informants highlighted the focus on innovation,<sup>15</sup> others questioned whether Unitaid paid sufficient attention to opportunities to repurpose old tools. Some respondents expressed concern that innovation and more upstream investments had, in recent years, taken precedence over a focus on more downstream access strategies, which they viewed as Unitaid’s core comparative strategic advantage. However, in 2021 around a third of Unitaid’s projects were in upstream innovation and late-stage product development; while all Unitaid grants include overcoming access barriers as a component at project level, some expressed a concern that access requirements in upstream projects were not sufficiently transparent and demanding. Such a tension is not unique to Unitaid and reflects ongoing challenges with public–private collaboration in product development.

**Finding # 1.5: With the benefit of hindsight, Unitaid missed some opportunities to 1) build technology and disease area platforms, 2) support cross-cutting tools and systems and 3) challenge IP. But without a portfolio analysis approach to systematically weigh one opportunity against another, it remains unclear whether these ‘missed opportunities’ might have been better investments; this is covered in RQ2.**

Unitaid has committed to integration across disease areas,<sup>16</sup> and Unitaid’s disease area narratives outline broad areas for expansion within the disease areas.<sup>17</sup> Despite a focus on disease-specific narratives,

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<sup>13</sup> UNITAID\_EB32\_2019\_10\_Report of the Midterm Strategy Review.

<sup>14</sup> Detailed in 2016\_Dec\_Update on IP approach and potential opportunities and 2021.02 - Appendix 1 - Terms of Reference (ToR).

<sup>15</sup> UNITAID\_EB32\_2019\_10\_Report of the Midterm Strategy Review highlighted that Unitaid was ‘investing in the most relevant innovations’.

<sup>16</sup> UNITAID\_2019\_October\_Joint\_FACPSC\_2\_Investment plan 2019-2021.

<sup>17</sup> E.g. HIV Disease Narrative, TB Disease Narrative, Malaria Disease Narrative.

Unitaid developed cross-cutting<sup>18</sup> product-focused AfIs, including for long-acting technologies during this review period. Unitaid’s TB disease area narrative included digital chest X-rays but, applying Unitaid’s prioritisation process (Unitaid expertise, health impact, feasibility and use of resources), it was not prioritised within TB; however, respondents noted it could be a more compelling investment if framed as a multi-modal product with potential for impact across multiple disease areas, including TB, pneumonia, COVID-19 and opportunistic infections.<sup>19</sup> Respondents observed that Unitaid had not applied its expertise in HIV self-testing to build out a platform of self-care diagnostics. Both areas – TB and HIV – remain potential opportunities for cross-cutting investment, particularly in connection with COVID-19.

At delivery level, Unitaid opted out of an opportunity to leverage Unitaid’s private sector experience with malaria rapid diagnostic tests (RDTs) and the AMFm initiative,<sup>20</sup> when it chose not to invest in malaria chemoprophylaxis and HIV self-test.<sup>21</sup> These decisions were based on decisions by the Board and PSC in the previous strategy period<sup>22</sup> and insufficient community support,<sup>23</sup> and could be reconsidered as need and opportunity arise.

At systems level, Unitaid developed an Afi to further its work in IP. Some respondents thought Unitaid missed logical additions to Unitaid’s IP work, including support to regulatory systems (given that regulatory reviews consider protection of intellectual property) and a challenge to the IP of TB drugs bedaquiline and delamanid, though this perceived gap in TB may be under discussion in closed-door deliberations, given IP sensitivities.

**Finding # 1.6: Unitaid took steps to examine the strategic rationale behind the selection of AfIs, although this is not consistently documented.**

To prioritise challenges identified in AfIs, Unitaid ‘applies strategic, programmatic and pragmatic criteria’.<sup>24</sup> Our fever and malaria case studies found that the programmes had a very clear programmatic rationale, but the longer-term strategic framing and prioritisation of fever within the MNCH context, and of intermittent preventive treatment in infants (IPTi) within a portfolio of malaria interventions, was not evident. In the latter part of this strategy period Unitaid has increasingly incorporated strategic prioritisation in discussions such as the annual retreat of the Strategy team, though this work is not fully documented. With Unitaid’s growth into new areas, some development partners cautioned that expansion should not just be a series of projects that do not overlap, but should be grounded in a strategic prioritisation. The prioritisation is discussed further in RQ2.

This limited strategic prioritisation, as suggested by some stakeholder groups, created an opportunity for flexibility to build on synergistic areas and flex where an opportunity arises. However, the lack of an overarching strategy enhances the need for extensive Board review and approval, potentially limiting this flexibility.

<b>RQ2</b>	<b>Prioritisation process: To what extent is the process underpinning the development of disease narratives and AfIs well suited for prioritising focus areas? To what extent have</b>	<b>Strength of evidence</b>
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<sup>18</sup> Note that Unitaid uses ‘cross-cutting’ in two ways: to refer to ‘challenges that may affect the disease response as a whole’ (HIV Disease Narrative) and ‘cross-cutting investments underpin Unitaid’s efforts to support equitable access to better health products *across disease areas*’ (2020 Portfolio Performance Report – FINAL).

<sup>19</sup> Unitaid TB Disease Narrative.

<sup>20</sup> Malaria Disease Narrative and 2015\_Nov\_Strategic narrative for Malaria and Areas for Intervention.

<sup>21</sup> HIV Self-Test Case Study and Malaria Case Study.

<sup>22</sup> PSC16 pre-read ‘Methodology for addressing access through non-state actors’.

<sup>23</sup> Malaria Case Study.

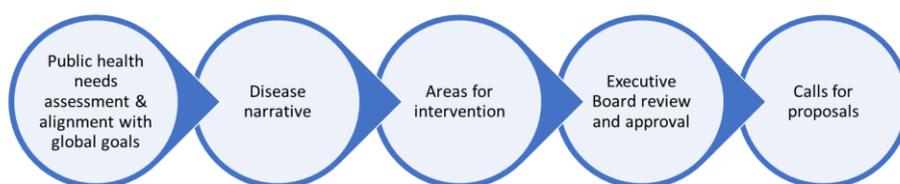
<sup>24</sup> Grant Management Guidelines\_final 17Oct2018. These include: fit with the Unitaid strategy (e.g. challenges related to health product access), public health impact, availability of technology, and added value of Unitaid in addressing a gap in the response.

	priorities been adapted/course corrected to respond to significant changes where these have occurred?	
High-level findings	<p><b>Despite Unitaid’s considerable effort to consult with a wide range of stakeholders, the development of Afls is still perceived to be heavily reliant on key relationships among the Secretariat, the Board and key global partners.</b></p> <p><b>The absence of a portfolio analysis approach makes it difficult to evaluate whether the interventions are the right ones.</b></p> <p><b>Unitaid has demonstrated flexibility and an ability to course-correct, including shifting resources in and out of disease areas.</b></p>	<p><b>Strength of evidence for Findings #2.1–2.3 varies. The strength is high for 2.1, and this is primarily based on the review team’s analysis/experience. While the perception is high among KIIs for 2.2, we were unable to fully triangulate with other sources, hence the score is low. Finding 2.3 is medium, because of the limited set of examples we identified.</b></p>

The Strategy states that ‘Unitaid has developed tools to help understand the risk exposure of its investments and manage it throughout implementation: the VfM framework enables Unitaid to measure the return on investment of a project (up until grant closure), based on its cost and its estimated public health impact; and the risk framework enables risks associated with each project to be considered in a systematic manner’. It further states that Unitaid follows a structured and transparent investment framework.

Figure 2 below captures the main five steps in the process, and strategic, programmatic and pragmatic criteria to define Afls.<sup>25</sup> We have identified some areas that could be improved (see Table 5), and where possible we have highlighted practices from other organisations that could potentially be adapted and adopted by Unitaid.

Figure 2: Process for developing disease narratives and Afls



The Strategy review identified a lack of an analysis of trade-offs at portfolio level (e.g. across all Unitaid investments). While there are several examples of consideration of investments at the broad disease level (e.g. fever in the context of malaria, and MNCH and PPH within the RMNCH portfolio),<sup>26</sup> the *process* for consideration of the portfolio-level trade-offs (e.g. why RMNCH and not non-communicable diseases) is not clearly established, though there is documentation of some of the decisions. In addition to the criteria currently applied at Afl level (fit with the Unitaid Strategy, public health impact, availability of technology, and added value of Unitaid in addressing a gap in the response), there is a need to include analysis of cost-

<sup>25</sup> Fit with the Unitaid strategy, public health impact, availability of technology, and added value of Unitaid in addressing a gap in the response.

<sup>26</sup> Afls: Better tools for integrated management of childhood fever: diagnostics and New Tools for Reducing Maternal Mortality.

effectiveness, as some of the more recent disease-specific analyses have done (e.g. cost-effectiveness of IPTi vs other malaria interventions).<sup>27</sup>

The beginning of the process could benefit from an expansion of the view of the horizon, which could be done through convenings with GH donors and beneficiary governments (outside of those already represented on Unitaid’s Board) who may have a better – or different – line of sight in some areas. Unitaid has started this sort of consultation with public discussions on fever and long-acting tools, but donor and beneficiary country engagement could be strengthened. During the development of the disease narrative, gathering of information and ideas from the beneficiaries via human-centred design or focus group research could enhance long-term viability. Overall, opportunities to shorten the entire cycle, such as delegation of Board review and approval to a smaller more operational subcommittee of the Board and keeping disease narratives up to date, would help ensure that the planned investments did not fall out of date mid-process.

**Table 5: A selection of challenges and potential solutions in the prioritisation process**

Challenges identified	Models and solutions
The length of the process, which can create a challenge to Relevance	Delegation of Board review and approval to a Board subcommittee <sup>28</sup> with a more hands on role than the entire Board (often called an ‘Executive Board’) and keeping disease narratives consistently up to date
Absence of an explicit approach to consider trade-offs	Portfolio analysis, traditionally used by biopharmaceutical industry and, more widely, by health technology assessment agencies, such as the National Institute for Health and Care Excellence (NICE) in the UK
Lack of a horizon-scanning unit	Convene donors to exchange information and commitments
Not enough beneficiary engagement and knowledge	Human-centred design or focus group research at Afl stage

**Finding # 2.1: Absence of an approach to consider the inherent values and risks of a given intervention or portfolio makes it difficult to evaluate whether the interventions funded are the right ones.**

Our first finding is specific to the criteria that are used to define Afls. Unitaid uses four criteria:

1. Unitaid’s expertise: focus on challenges in access to health products and/or access to innovation.
2. Potential public health impact: focus on challenges for which there is high potential public health impact.
3. Feasibility: focus on challenges for which the necessary technology can be available in the relevant time frame.
4. Optimised use of resources: focus on challenges for which critical gaps exist in the global response and where scale-up is possible.

Our analysis highlights that other criteria would help inform the trade-offs Unitaid needs to make; currently trade-offs appear to be made implicitly rather than explicitly. In some cases the criteria are assessed, but not brought together in a way that facilitates trade-off discussions.

While the disease area narratives extensively detail the options for investment within the disease scope, the process for selection of the Afls across disease areas is less clear and transparent. As an example, the

<sup>27</sup> Malaria Chemoprophylaxis Afl.

<sup>28</sup> The subcommittee proposed would be granted by the full Board the authority to review and approve grants, following the strategy and any additional policies of the Board and the Policy and Strategy Committee.

p. vivax Afl did not compare p. vivax opportunities to other malaria opportunities or to opportunities being considered under separate Afls, even within a single disease area.<sup>29</sup> More recent Afls have taken into account trade-offs within disease areas. For instance, Unitaid commissioned an external disease-level evaluation of the hepatitis portfolio and others like it are under way. However, the review team envisions this analysis not only at disease level but also portfolio level across all of Unitaid's grants. Having a strategic process in place would enable Unitaid to identify and focus on priority areas outlined in the strategy rather than realigning the strategy to assess the opportunities as they arise.

BMGF raised this issue to Unitaid in 2019, noting a need for a system to 'prioritise across different area (e.g. trade-offs, implications of funding more in a particular area, especially if suggested by one constituency's comments in e-vote)'.<sup>30</sup> The follow-up in 2021 indicated that a start had been made, with potential trade-offs between opportunities, and an Impact, Cost and Risk analysis included in the RMNCH and TB diagnostic Afls,<sup>31</sup> but these were still focused within the disease area.<sup>32</sup>

The Box below provides a brief overview on an approach that has been developed by BMGF. This approach borrows from portfolio analysis used widely in the biopharmaceutical industry<sup>33</sup> and is an example of early-stage health technology assessment (HTA). The use of HTA to help inform pricing and reimbursement decisions has become mainstream in many high-income countries, perhaps best exemplified by NICE<sup>34</sup> in the UK. Since its establishment in 1999, many countries throughout the world – including more and more in LMICs – have established HTA processes and mechanisms to guide healthcare spending decisions. There may be opportunities to engage with some of these agencies to learn more about their best practices and see what can be adapted and adopted to suit the unique space Unitaid works in. Equally, these agencies will increasingly have a greater say in country adoption decisions for new health technologies; it would be wise to begin to engage with them to understand their evidence needs.

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<sup>29</sup> 2018\_Dec\_Afl P. vivax.

<sup>30</sup> Unitaid agreement BMGF Milestone Table - January 2019 – FINAL.

<sup>31</sup> Unitaid agreement BMGF Milestone Table - 2021 reporting FINAL.

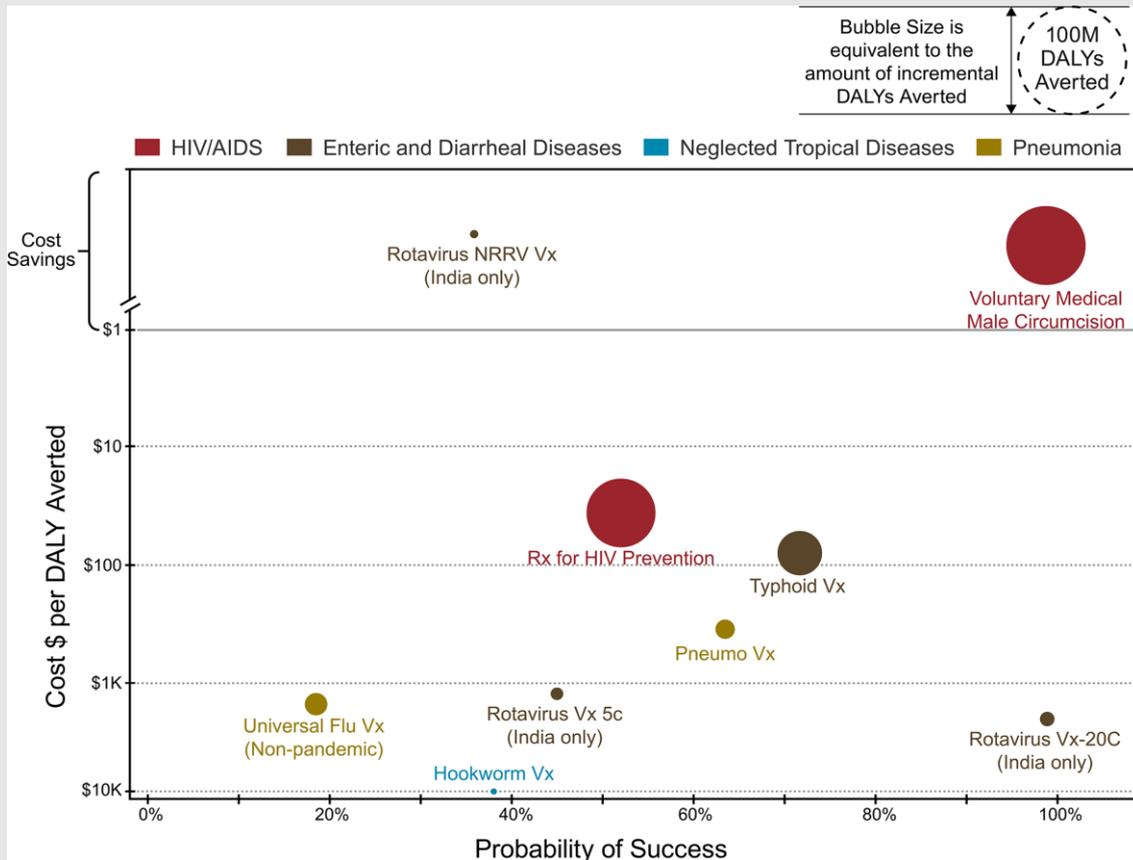
<sup>32</sup> UNITAID 2020 April Joint FACPSC Update on 20-22 Investment Plan.

<sup>33</sup> Evans R, Hinds S and Hammock D (2009) Portfolio analysis and R&D decision making. *Nature Reviews Drug Discovery*, **8**: 189–190.

<sup>34</sup> <https://www.nice.org.uk/>

### Box 1: Portfolio analysis for global health impact

BMGF uses an integrated portfolio management approach to help inform the investments it makes in global health. In this approach, cost per disability-adjusted life year (DALY) averted is the incremental cost to avoid DALYs compared to the standard of care. The probability of success is the estimate of probability of technical and regulatory success (PTRS) informed by industry benchmarks and expert opinion. Both the cost and the probability of success are dynamic values and subject to change with information that is constantly evolving. This approach provides BMGF with a consistent and comparable framework to more systematically consider the inherent values and risks of a given intervention or portfolio. The process itself is also critically important as it forces BMGF to state their assumptions explicitly for debate and reconciliation. But it should be noted that the approach fails to capture probability of scale-up, which is distinct from the PTRS.



**Finding # 2.2: Despite Unitaid’s considerable effort to consult with a wide range of stakeholders, the development of Afls is still perceived to be heavily reliant on key relationships among the Secretariat, the Board and key global partners.**

Our second finding refers to the whole process. Unitaid has clearly articulated a process for Afl development,<sup>35</sup> and the Secretariat makes efforts to engage partners, including WHO, in the consultative process in both group settings (organised by Unitaid and others) and one-to-one. However, respondents in all stakeholder groups did not regard the process as sufficiently inclusive. Some respondents perceived that long-time grantees have an outsized influence on Afl development; as long as this is a perception, it can lead to mistrust of the integrity of the process. Some respondents questioned why their own input was not sought, and this ranged across stakeholder groups. However, respondents report a more structured Afl process with input and ideas from more recent grantees, including those of the global South.

Civil society and country governments are well represented on Unitaid’s Board. Efforts are made to solicit input from a broader collection of civil society representatives,<sup>36</sup> such as focus groups, but the usefulness of the output is uneven, underscoring the challenge of incorporating the voices of civil society at portfolio level. However, the TB prevention project has incorporated civil society into its project in a structured way, which could serve as a model for others.<sup>37</sup> Likewise, country governments face a challenge to ensure that all viewpoints in such a wide range of disease areas and countries are heard. As noted in the malaria and fever management case studies (Annexes 6 and 8) and by KIs across stakeholder groups, dialogue with communities – directly or through a human-centred design process early in the development of some Afls – could have strengthened beneficiary and country government involvement, particularly in the absence of a Unitaid in-country presence.<sup>38</sup> The Secretariat validated its Afls with key partners to prioritise potential focus areas for Unitaid.<sup>39</sup> By bringing together stakeholders and a broad range of GH donors, Unitaid could potentially use its power as a convener to broaden engagement on Afls while also influencing global agendas. The success of this approach during the development of the long-acting technologies Afl was highlighted. A fever management workshop took a similar approach, with extensive interviews done in preparation as well as an IP consultation with a broad range of participants. Likewise, regular one-to-one meetings with fellow donors (beyond personal relationships and Unitaid Board members) to do horizon scanning, while also sharing updates on results and aligning on future plans, were suggested as ways to establish Unitaid as a key driver/shaper of global plans. Unitaid has initiated regular meetings with the Australian Department of Foreign Affairs and Trade and the Indo-Pacific Centre for Health Security on malaria, and more could be done with potential and existing donor partners (e.g. USAID and Global Fund in specific disease areas).

**Finding # 2.3: Unitaid has demonstrated flexibility and an ability to course-correct, including shifting resources in and out of disease areas.**

KIs across across stakeholder groups provided numerous examples of Unitaid’s flexibility at strategic level down to granular changes in projects. Unitaid’s rapid scale-up of involvement with COVID-19 was noted as an example of Unitaid’s agility in responding to significant changes in context, both in terms of its ability to engage and participate at global level and to deliver essential products, such as personal protective equipment (PPE).

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<sup>35</sup> Methodology-for-developing-strategic-narratives.

<sup>36</sup> e.g. Civil Society Focus Groups, May/June 2021.

<sup>37</sup> TB Prevention Case Study.

<sup>38</sup> Unitaid, Malaria case study; a notable exception is the 2018\_Dec\_Afl Long-acting technologies, which engaged communities, national governments and many others in an open dialogue during development of the Afl.

<sup>39</sup> Detailed in, for example, TB Disease Narrative, and also New Tools for Maternal Mortality Afl.

UnitaidExplore displayed Unitaid’s capacity to adapt at structural level, with decision making power granted to the Secretariat, and the Proposal Review Committee (PRC) shifting its review process to engage directly with prospective grantees.

Other examples of flexibility were the TB portfolio (both in terms of reprogramming mid-project for prevention and the ability to course-correct by closing down a sizeable investment in the Multi-Drug Resistant (MDR) TB programme),<sup>40</sup> the withdrawal from hepatitis C direct programming to more broad-base support<sup>41</sup> and the shift in use of pulse oximeters for fever to COVID.<sup>42</sup> At project level, grantees reported having flexibility to accommodate unexpected events.<sup>43</sup>

<b>RQ3</b>	<b>Transferability/Global Public Goods: To what extent are the outputs of the process useful (or to what extent could they be useful) to inform other organisations’ priority setting and investments?</b>	<b>Strength of evidence</b>
High-level findings	<b>Unitaid has generated influential evidence for policy and practice. Similarly, Unitaid’s landscape/horizon-scanning work is considered useful and high-quality. But efforts to translate and disseminate outputs could be more deliberate. A thorough assessment of Unitaid’s knowledge, translation and exchange approach is warranted, leading to a clear communications strategy.</b>	<b>Evidence for Finding 3.1 is stronger than for Finding 3.2. There is strong triangulation across KIs, documents, and review team experience for Finding 3.1. While there are multiple sources of evidence for Finding 3.2, some aspects were not fully triangulated, and strength of evidence is therefore medium.</b>

Unitaid directly and indirectly (via its grantees) produces a lot of knowledge and evidence. This question sought to answer the extent to which others use and find useful what Unitaid produces.

**Finding # 3.1: Unitaid has generated influential evidence for policy and practice.**

Several projects – including TB prevention, Next Generation Nets, Hepatitis C Virus (HCV) and HIV self-tests – contributed data to support WHO’s normative guidance and product pre-qualification.<sup>44</sup> These projects were designed to catalyse scale-up while also generating policy data.<sup>45</sup> In some cases, the WHO enabler grants created awareness of the timing and information emerging from the grant, and this probably facilitated the guideline development.<sup>46</sup> Data also supported scale-up at country level, as is clear from the Global Fund investments; for instance, when the recipient countries under the Access Seasonal Malaria Chemoprevention (SMC) grant (2014–18) completed the project, all of them secured funding from the Global Fund and the President’s Malaria Initiative (PMI), with adoption of SMC in National Strategic Plans and national ability and capacity to implement.

At national policy level, for HIV self-testing, project data influenced both policies and practice; for instance, after five years of investment in HIV self-test, 88 countries had policies in place and were investing in HIV self-testing.

<sup>40</sup> TB Case Study.

<sup>41</sup> E.g. <https://unitaid.org/assets/Ensuring-access-to-the-Hepatitis-C-HCV-treatment-revolution-for-HCV-HIV-co-infected-patients-in-LMICs.pdf> and <https://unitaid.org/assets/Impact-story-paving-the-way-to-hepatitis-c-elimination.pdf>

<sup>42</sup> Fever Case Study, Development Partner.

<sup>43</sup> Grantee Survey, 2021.

<sup>44</sup> TB Case Study, HIV Self-Test Case Study, Disease Narrative for Hepatitis C, 2017\_UNITAID\_EB27\_4\_Grant portfolio update.

<sup>45</sup> [https://path.azureedge.net/media/documents/NNPproject\\_brief\\_final.pdf](https://path.azureedge.net/media/documents/NNPproject_brief_final.pdf) and mentioned in UK annual review Unitaid - Nov 2017 19976237.

<sup>46</sup> TB Case Study.

**Finding # 3.2: Unitaid’s landscape/horizon-scanning work is considered useful and high-quality, but efforts to translate and disseminate them together with results from projects could be more deliberate.**

The disease narratives and landscaping documents, which compile an inventory of challenges that threaten the achievement of global goals in the disease area,<sup>47</sup> are widely regarded by a wide array of stakeholders as valuable. Respondents have mixed opinions about Unitaid’s influence via Afl dissemination: some said donors are going to do what they are going to do without Unitaid, while others believed that dissemination of Afls, together with convenings to allow discussion, might truly influence the disease areas.

Several respondents noted that the frequency and public availability of the Afl write-ups had declined. Given that BMGF and others are not publishing and disseminating Afls, this might represent an opportunity for Unitaid. Another opportunity highlighted was the scoping of new technologies, such as was done for long-acting technologies; dissemination of such information can help to engage development partners, and, critically, countries and civil society in Unitaid’s work. Although Unitaid’s project plans include dissemination of outcomes, several respondents thought more could be done to share summaries of both positive and negative project outcomes and lessons about how market shaping tools work. This finding is confirmed by the lack of information about the HCV treatment projects on Unitaid’s website.<sup>48</sup> For dissemination, a key constituency still to be reached was the countries, though some thought WHO was better positioned for country engagement.

**4.2 Workstream 2: Right ways**

This workstream is concerned with how well Unitaid interventions fit in the GH space, and also how well resources are being used. Module 2 on Coherence is covered in RQs 4–7, and Module 3 on Efficiency is covered in RQs 8–10.

As with workstream 1, the findings presented in the section below are based on a range of data sources and the data collection and analytical approaches described above and in the evaluation framework. Our rating of the strength of evidence is once again presented next to the high-level finding in response to each evaluation question.

**4.2.1 Detailed findings by sub-issue**

<b>RQ4</b>	<b>Complementarity: To what extent does Unitaid’s work complement that of other actors?</b>	<b>Strength of evidence</b>
High-level finding	<p><b>Unitaid proactively collaborates within the GH space, and much emphasis is placed on detailed explorations of the landscape and players as part of the Afl development process, which is central to identifying Unitaid’s niche within specific technical areas.</b></p> <p><b>However, the lack of a formal partnership engagement strategy or specific criteria or macro-level targets to guide strategic decision making on priority foci above the disease-level investment may inhibit opportunity to explore more comprehensive complementarity with other donors and actors.</b></p> <p><b>Investment planning, delivery and scale-up may benefit from more formalised engagement and collaboration processes.</b></p>	<p><b>Evidence for these findings is high. There is strong triangulation across KIs, documents, and review team experience, and the grantee survey, case studies and comparative analysis also contribute to the strength of these findings.</b></p>

<sup>47</sup> Process detailed in Grant Management Guidelines\_final 17Oct2018; TB Disease Narrative; Malaria Disease Narrative.

<sup>48</sup> Review of [www.unitaid.org](http://www.unitaid.org)

‘Partner’ and its variations (partners, partnering, partnership(s)) appears more times (n=67) than any other word in the Strategy. It is clear that partners and partnerships matter to Unitaid. The Unitaid website reports reliance on 40 partner organisations, including technical partners to implement new techniques and bring innovations to the field, companies in the private sector to use market forces to make medical innovations more accessible, funding partners to help lower the cost of medicines and diagnostics with systems such as co-payments, IPs working to bring health innovations to those who need them most, and CSOs helping to raise awareness about medical issues.<sup>49</sup> As stated in the Strategy, ‘There is one GH response and Unitaid is one of the many players in the response. Unitaid is connected to its partners and works to ensure coordination between partners around its projects.’<sup>50</sup> Here we look at the extent to which Unitaid’s work complements that of its partners, as well as that of other actors operating in the market shaping space.

**Finding # 4.1: Unitaid proactively collaborates within the GH space, though the lack of a formal partnership engagement strategy or specific criteria or macro-level targets to guide strategic decision making on priority foci above disease level may inhibit opportunity to explore more comprehensive complementarity with other actors in this space.**

As indicated through documentation and interviews with a range of GH partners and internal stakeholders, Unitaid has made important efforts to continue to expand and enhance its partnerships in line with the growing depth and breadth of its portfolio, particularly over the past three years. These include: the signing of new collaboration frameworks, such as with the Global Health Innovative Technology<sup>51</sup> (GHIT) Fund, that aims to increase awareness of and access to innovation and expertise in key areas such as malaria, TB and Neglected Tropical Diseases (NTDs); joining existing partnership networks, such as Every Breath Counts<sup>52</sup> (EBC), a key public–private coalition to support national governments to end preventable child pneumonia deaths by 2030; and the formulation of new partnership groups, such as the Pacific Friends of Global Health,<sup>53</sup> a network (and collaboration with the Global Fund) based in Australia which is intended to improve outreach to GH actors and government funders in the region.<sup>54</sup> These efforts are echoed in responses to the recent grantee survey, with just 6% of respondents suggesting that Unitaid needs to better define its role in partnerships and collaborate better with others.<sup>55</sup>

However, the challenges in coordinating complementary investments in crowded, evolving technical spaces, as well as effectively linking downstream with upstream interventions, were raised by numerous GH partners and donors. Complementarity can be facilitated by partnership engagement and collaboration as well as clarity and transparency around strategic priorities and scope of activity across partners. Comparative landscape analysis highlighted that partnership engagement strategies are not common across GH partners, including Unitaid – perhaps owing to the breadth, complexities and fast-evolving nature of various partnership activity. However, some partnership engagement plans exist that are focused on specific stakeholder groups. Unitaid has a Civil Society Engagement Plan,<sup>56</sup> which articulates well the principles for engagement between Unitaid and civil society, though the extent to which this has been applied and has been useful has not been explored. Specific engagement frameworks

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<sup>49</sup> Unitaid website, accessed 30 June 2021.

<sup>50</sup> Unitaid Strategy, 2017-2021.

<sup>51</sup> <https://www.ghitfund.org>

<sup>52</sup> <https://stopppneumonia.org/about-us/>

<sup>53</sup> <http://glham.org/pfgh/>

<sup>54</sup> DFID review of Unitaid, 2020.

<sup>55</sup> Grantee survey findings, 2021.

<sup>56</sup> Civil Society Engagement Plan, 2016.

or strategies with the private sector are also more common, for example the Global Fund’s Framework on Private Sector Engagement,<sup>57</sup> which has the specific purpose of outlining engagement opportunities for the purpose of resource mobilisation.

With regard to clarity and transparency around strategic priorities, Unitaid’s Strategy describes clearly the ‘investment framework’ for guiding investment decisions.<sup>58</sup> As outlined in the Strategy and disease narratives, as well as being described by a range of KIs from the Board and Secretariat, emphasis is placed on analysis of the context for each disease, focused on: the disease characteristics (including burden, key health products, access to these); challenges that threaten the achievement of the global goals; and, finally, Unitaid’s potential role in addressing specific challenges – all as part of a coordinated global response.

From these ‘disease narratives’ AfIs are developed, informed by four criteria: 1) Unitaid’s expertise: focus on challenges in access to health products and/or access to innovation; 2) potential public health impact: focus on challenges for which there is high potential public health impact; 3) feasibility: focus on challenges for which the necessary technology can be available in the relevant time frame; and 4) optimised use of resources: focus on challenges for which critical gaps exist in the global response and where scale-up is possible.<sup>59</sup>

While this selection process is clear, no specific criteria exist to guide strategic decision making on priority foci above disease level, which hampers prioritisation across disease and other complementary areas, and also inhibits consideration of the integration or complementarity of different disease areas within the portfolio.

Similarly, nine strategic KPIs are presented in the Strategy which are used to review the macro benefits of investment decisions (see RQs 11 and 12 for further discussion of the strategic key performance indicators (SKPIs)). What is not included in the Strategy are macro-level targets which also guide investment decision making around key priorities. Many donors and GH partners also discussed the need for Unitaid to more transparently ‘carve out’ specific investment spaces, through medium/long-term investment ‘frameworks’ with overriding aims and targets clarified, as well as cross-benefits of multiple investments.

This lack of specificity in strategies of GH organisations is not uncommon. Our comparative landscape analysis found that investment areas continue to be quite siloed across organisations, despite the integration agenda having been prominent for some time and reinforced through the SDGs and Universal Health Coverage (UHC) principles, as well as growing awareness of the cross-benefits of investing more multi-sectorally. Other organisations do not make public their strategy or criteria for guiding investment decision making (e.g. Gates Medical Research Institute), or frequent ‘updates’ of strategies can inhibit efforts to ensure complementarity with other organisations (e.g. BMGF), and some strategies are based on ‘principles’ and interest areas’ without specifying specific criteria to guide macro investment decision making (e.g. Wellcome Trust). As such, Unitaid is not ‘behind’ others in terms of the extent to which its Strategy transparently guides macro-level prioritisation, but there is room for further articulation, which would also probably boost complementarity with other actors in this space.

Another related point which emerged from interviews across donors is that, while it appears that an additional intention from Unitaid may be to offer the AfIs as a ‘public good’ to guide further investments, activity and collaboration in that specific space (based on the detailed scanning of investment foci across the landscape and review of alignment of stakeholders), donors operating in similar landscapes tended to view the purpose of AfIs as solely to inform the Unitaid Strategy. Some suggestions were made to broaden

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<sup>57</sup> The Global Fund Framework on Private Sector Engagement, 2015 (updated 2019).

<sup>58</sup> Unitaid Strategy, 2017-2022.

<sup>59</sup> Unitaid Strategy, 2017-2022.

the scope, gaze and collaborative input of the AfIs, which could open up the possibility of their usage to guide some co-creation/planning efforts across partners. A report by BMGF also emphasised that there were more opportunities for knowledge management and sharing on market dynamics to guide collaborative efforts, though these were not specifically articulated.<sup>60</sup>

**Finding # 4.2: Ongoing collaboration across partnership groups relies to some extent on personal networks rather than more formalised engagement processes, and there are opportunities for deeper and broader collaborations across groups.**

As indicated above, engagement with strategic partners is a cornerstone of Unitaid’s Strategy and is featured as the third improvement area identified in the 2017 Operating Model Review.<sup>61, 62</sup> There are some good examples of effective collaboration across projects and within AfIs, such as the fever management case study, and the Access to COVID-19 Tools Accelerator (ACT-A) was also commonly mentioned as a positive example. However, a range of KIs across stakeholder groups discussed how engagement often continued to be based on personal networks rather than through more formalised engagement processes, and commented on the potential benefits from deeper and broader engagement with many partnership groups. A summary of key points from KIs as well as the documentation review is presented in Table 6 below, alongside what the Strategy says in terms of each partnership.

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<sup>60</sup> Minutes of Unitaid-BMGF meeting on milestones, 2019 reporting.

<sup>61</sup> Operating model review, 2017.

<sup>62</sup> Report of the Midterm Strategy Review, 2019.

Table 6: Unitaid’s coordination with specific organisations and stakeholder groups – a high-level summary of findings

Organisation/ stakeholder group	What the Strategy says	Summary of our findings
Countries	<p><i>‘Countries are at the centre of the response. For Unitaid, understanding countries’ concrete needs is crucial to address the most critical challenges, and support the most relevant and impactful projects. Countries also have a critical role in ensuring the scale-up of interventions supported by Unitaid. Where relevant, Unitaid will also strive to work with regional organisations to facilitate country engagement.’</i></p>	<ul style="list-style-type: none"> <li>• Unitaid’s engagement with countries is critical to understanding needs and ensuring support for the introduction of innovations and implementation of grants. However, engagement is reported to be challenging given that it is grantee-dependent, and, as such, <b>effective engagement with the Ministry of Health and other in-country technical/operational partners, as well as scale-up partners, can vary enormously</b> – and later impact on acceptability and scale-up potential.</li> <li>• Given its catalytic timeframe (three to four years), <b>Unitaid appears to prioritise known ‘early-adopter’ countries or ‘regional influencers’</b>, which may have the potential to shape markets to drive affordability for further adoption in the region.<sup>63</sup> How this links to the overall equity KPIs, though, remains unclear (see RQ12).</li> <li>• Country representation at Board level could be more formalised – or alternative <b>ways need to be found to bring in country views more</b>, e.g. technical advisors.</li> <li>• Various GH partners discussed that the <b>delivery side is often crowded at the country end and, as such, effective in-country engagement is critical.</b></li> </ul>
Technical partners, e.g. WHO	<p><i>‘Technical partners define global health priorities and strategies. Working with technical partners enables Unitaid to better understand global health opportunities and challenges.’</i></p>	<ul style="list-style-type: none"> <li>• <b>WHO’s hosting</b> of Unitaid has boosted resource mobilisation and created some system efficiencies (see RQ11 for more details), <b>though the relationship can cause confusion among partners, and there were suggestions that there is scope for more strategic collaboration and alignment.</b></li> <li>• Unitaid and WHO’s technical partnership has been operationalised and supported through the WHO Enablers and further reinforced by cooperation on COVID-19.<sup>64</sup> However, for some workstreams, <b>Unitaid does not have full visibility on complementary funding in similar areas, which inhibits effective collaboration.</b><sup>65</sup></li> <li>• Some Secretariat staff discussed how there is still a need for WHO to revisit workstream alignment in view of its reorganisation in 2019, which affects its collaboration with Unitaid.</li> <li>• The WHO Enablers Review identified <b>a need to better align on roles at country level</b>, and also to avoid WHO reporting on the same efforts as Unitaid at HQ level.<sup>66</sup></li> </ul>

<sup>63</sup> Report of the Midterm Strategy Review, 2019.

<sup>64</sup> DFID review of Unitaid, 2020.

<sup>65</sup> Unitaid WHO Enablers Review, 2020.

<sup>66</sup> Unitaid WHO Enablers Review, 2020.

<p>Donors at large, e.g. Global Fund</p>	<p><i>‘The Global Fund is a key strategic partner in the scale-up of Unitaid’s interventions. Through its catalytic effect on access to health products, Unitaid maximises the effectiveness of the investments performed by the Global Fund by providing more cost-effective products and services which the Global Fund can bring to scale. Unitaid actively collaborates with the Global Fund at the strategic and operational levels to ensure coordination at all stages from identification of areas for intervention all the way through to scale-up and transition of Unitaid investments.’</i></p>	<ul style="list-style-type: none"> <li>• In 2019 the <b>two organisations signed a Strategic Framework for Collaboration</b>, which aligns efforts to drive innovations at scale and catalyse impact in the global response.<sup>67</sup></li> <li>• Reviews report that the collaboration between the Global Fund and Unitaid has continued to solidify and move from ad hoc collaborations to regular and structured engagements on both strategic and operational areas and across units/teams/ departments.<sup>68</sup> However, there are suggestions from KIs that this could go further, and this was echoed in the TB prevention case study (see Annex 5). Informants across stakeholder groups still commonly discussed a <b>lack of formal mechanisms that would enable more strategic dialogues, particularly in terms of the ‘end point(s)’ of Unitaid’s investment</b> and when it hands off to the Global Fund.</li> </ul>
<p>Private sector</p>	<p><i>‘The private sector is a key partner in the global health response as most innovative health products are developed by private sector organisations. Collaboration with the private sector is essential for Unitaid to be able to identify and support high potential innovative health products in late-stage development.’</i></p>	<ul style="list-style-type: none"> <li>• There are <b>numerous examples of productive and more varied engagements with the private sector</b> across the market dimensions of affordability, innovation, availability and quality.<sup>69</sup></li> <li>• However, there were some suggestions that <b>collaborations with the private sector – with the aim of optimising investments relating to both upstream and in-country private sector, including manufacturers and distributors – continue to be under-explored</b>. It is noted though that partnerships should always be made under a prism of promoting equity and access to technologies developed with Unitaid’s resources.</li> <li>• However, the TB case study raised <b>concerns about whether investments in the private sector will have lasting impact</b> (see Annex 5).</li> <li>• There were also <b>calls from the private sector for more focused engagement and collaborations around product volumes and targets</b>.</li> </ul>
<p>Implementing partners</p>	<p><i>‘Implementing partners conduct projects in countries. Partnering with implementing partners is critical to ensure the success of a project’s implementation, transition and scale-up.’</i></p>	<ul style="list-style-type: none"> <li>• Various stakeholders raised that there were <b>some technical areas where complementarity and coordination could be improved, though noting that this is beyond the sole efforts of Unitaid</b>. For example, HIV self-testing (see case study, Annex 7) was reported to be particularly crowded and there has become an increasing tendency for donors to protect their space. Stakeholders also discussed the TB space, with suggestions that there was ineffective proactive exploration to explore specific overlays or any duplications (see case study, Annex 5).</li> <li>• There are also <b>notable positive examples of good collaboration and alignment within AfIs</b>. For example, according to GH partners, there are many players working in intermittent preventive treatment in pregnancy (IPTp) from both the malaria and</li> </ul>

<sup>67</sup> Report of the Midterm Strategy Review, 2019.

<sup>68</sup> DFID review of Unitaid, 2020; Report of the Midterm Strategy Review, 2019.

<sup>69</sup> For example, Unitaid and CHAI reached an important agreement with Omega Diagnostics to help deliver same-day CD4 testing technology for people living with HIV at just USD \$3.98 per test – the lowest price for such a test in the world. In October 2019 Unitaid, in conjunction with the Global Fund, also secured a landmark agreement with Sanofi, who agreed to significantly lower the price of rifapentine, a critically important drug used to prevent TB, by nearly 70% in the public sectors of 100 LMICs. These examples were reported in the DFID review of Unitaid, 2020.

		<p>reproductive health space, and there are reports of a strong collaborative community – Unitaid is a key player here. Also, in the context of constrained resources, the malaria community is increasingly adopting an approach to supporting the scale-up of SMC, based on geographically tailored and demarcated intervention combinations (see case study, Annex 6).</p> <ul style="list-style-type: none"> <li>• However, there are suggestions across some GH partners <b>that Unitaid’s ‘one project at a time’ approach to grant-making,<sup>70</sup> even if some are complementary to each other, makes it challenging to support decision making on allocation of resources across a growing number of effective interventions, including across implementing partners.</b> This is discussed in more detail in the malaria chemoprevention case study (Annex 6).</li> <li>• The <b>ACT-Accelerator was commonly mentioned as a positive example of collaboration across partners</b>, with Unitaid playing a central role in driving the effectiveness of this.</li> </ul>
<p>Civil society</p>	<p><i>‘Civil society has a crucial role to play to facilitate the demand-creation and adoption of new health products in countries. Partnering with civil society is key to ensure the successful scale-up of Unitaid’s interventions.’</i></p>	<ul style="list-style-type: none"> <li>• The <b>Civil Society Engagement Plan with Unitaid was developed in 2016</b> on the acknowledgement that, in order to achieve ambitious SDGs and GH targets, it was ‘essential to maximise the potential of Unitaid’s partnerships with civil society’.<sup>71</sup></li> <li>• Unitaid has made several efforts to strengthen its partnership with civil society during the new strategic period.<sup>72</sup> <b>However, delivering on the Plan remains challenging. Engagement levels vary across grantees and almost all civil society lead grantees are based in high-income countries (HICs), which also raises equity questions.</b><sup>73</sup></li> <li>• As suggested in the Midterm Review and emphasised by KIs, it will be <b>important for Unitaid to emphasise a systematised approach to planning for in-country CSO engagement with grantees in the future.</b><sup>74</sup></li> <li>• <b>Civil society participation/contributions are, according to KIs, not always given similar ‘weight’ as other contributors on Board</b>, referring to various power imbalances and the ability of the constituency to influence decisions/choices. There was suggestion from some that ‘money talks’.</li> </ul>

**Finding # 4.3: The scalability framework is useful, but more could be done in terms of collaborating with others to enable complementarity when setting the stage for scale-up. There also appears to a lack of clarity, both internally and externally, over what is meant and required for ‘scalability’.**

<sup>70</sup> It should be noted that Unitaid often selects and introduces multiple grants at a time to tackle the most prominent barriers to access in a given area and where Unitaid considers it can make a difference. The proposals for ‘go ahead’ are selected and sent to the Board at the same time. Hence, the perception some have that Unitaid adopts a ‘one project at a time’ could be a function of deviations in the timeframe it takes to develop, finalise and sign each grant, which depends on multiple factors, including the extent of Board comments to be addressed from go-ahead, grantee capacity, complexity of each grant, etc.

<sup>71</sup> Civil Society Engagement Plan, 2016.

<sup>72</sup> For example, Unitaid supported the establishment of community advisory boards for HIV and TB clinical trials, and increased its engagement of civil society organisations as lead implementers of Unitaid grants, as reported in the Report of the Midterm Strategy Review, 2019.

<sup>73</sup> This is discussed further in the Efficiency section (4.2) as well as the section on Equity (4.4.1).

<sup>74</sup> Report of the Midterm Strategy Review, 2019.

Scalability has been given increasing attention within Unitaid, and related guidance and practices have seen significant evolution over the last two to three years. For example, scalability, usually based on discussion with key potential scale-up partners (the Global Fund, USAID, the World Bank, the Department for International Development (DFID), etc.) is now considered from the outset (Afl and disease narratives), and reportedly there has been a growth in concerted efforts to track how funding is leveraged around transition processes and scale-up within countries and related to other donors. The scalability framework and guidance for applicants and grant implementers has also been developed, emphasising the various factors which feed into scalability – considering three aspects (global conditions, country readiness and transition), spanning access conditions, alignment with partners, political and financial support, programmatic and operational readiness, and community-driven demand (effectiveness of the scalability framework is discussed further under RQ10).<sup>75</sup>

For all these factors to feed into scalability, and to enable effective linkage into the Global Fund or other scale-up investments, as well as to inform global or local policy and service delivery priorities, there is a need for demonstration of evidence of transferability and scalability of piloted innovations, considering both private and public sectors. Unitaid is clear that it does ‘scalability rather than scale-up’, but the question is raised as to whether there is enough clarity, both within and outside Unitaid, of what scalability entails/covers to drive effective engagement and collaboration, with the aim of boosting scale-up once Unitaid’s investment ends.

A number of stakeholders suggested that preparation for scale-up is not seen enough as Unitaid’s responsibility, but rather is largely ‘outsourced’ to grantees. This is clearly evident in some investment areas; for example, in the malaria chemoprevention case study (Annex 6), there was strong evidence for the need for the Secretariat to take direct ownership in this process, with suggestions that work in community IPTp and IPTi posed a ‘failure to scale’ risk without additional efforts to strengthen the delivery platforms they rely upon as well as increased coordination with the Maternal and Child Health (MCH) community to avoid a ‘funding cliff’ when Unitaid grants come to an end.

Nevertheless, there is variability among projects, Afls and disease areas, due to variances according to partners and context and, in some cases, inherent differences among diseases. For example, in the case of hepatitis C, an informed decision was made to invest even though the pathway to scaling up was/is unclear (and as such, the need for project findings to be transferred into WHO guidelines to inform country specific practice was emphasised from the start).<sup>76, 77</sup> Other positive examples also exist from which important learning can be drawn. For example, the New Nets Project (NNP), which is co-funded by the Global Fund, reportedly built a strong focus on scalability from the outset, and Unitaid’s decision to pursue co-funding was driven by the desire to ensure a strong pathway to scale-up of the products. According to KIIs, collaborative work with the Global Fund to explore scale-up potential as a first step was also initiated in relation to long-acting buprenorphine, likely to be the key scale-up partner, given that it is the main funder of harm reduction.

To guide complementarity at implementation/country levels, both Secretariat and grantee stakeholders also talked of the need for results to be shared and discussed in a more coordinated way, as well as the need for engagement with potential scale-up partners from the start. There was also a broad suggestion that there can be less emphasis than there should be on advocacy and communications around the processes of implementation and results of projects, which also provide a basis for scalability discussions. Where in-country communications and collaboration efforts were emphasised, there are examples where this clearly pays off. For example, Unitaid staff shared the experience of ACCESS-SMC, whereby

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<sup>75</sup> Unitaid Scalability Framework: Guidance for Applicants and Grant Implementers, 2021.

<sup>76</sup> WHO (2018); Guidelines for the case and treatment of persons diagnosed with chronic Hepatitis C virus infection.

<sup>77</sup> WHO (2021): Recommendations and guidance on hepatitis C virus self-testing.

dissemination and engagement activities led to RBM Country Support Partner Committees forecasting need for drug availability and human resources needs in a scale-up environment, and by the end of the project SMC had been adopted by the Global Fund, the World Bank, DFID, PMI and the GiveWell Foundation.<sup>78</sup>

RQ5	Comparative advantage: To what extent has Unitaid consistently focused on AfIs aligned with its Strategy, mandate, and operating model and where it is well positioned to deliver results?	Strength of evidence
High-level finding	<p><b>There is broad consensus across stakeholders of Unitaid’s core comparative advantages, relating to the space ‘between innovation and scale’, its ability to ‘flexibly identify access barriers to address’ and its model of ‘catalytic investments to open up markets’.</b></p> <p><b>At the same time, Unitaid’s focus has become more blurred over time, with, overall, less clarity on the technical priorities and parameters of its work, and with some possible loss of identity. Further articulation and explanation relating to market shaping, innovation and scalability may be particularly helpful.</b></p>	<p><b>Evidence for Finding 5.1 is stronger than for Finding 5.2. There is strong triangulation across KIs, and the grantee survey for 5.1. While many KIs agreed on 5.2, this is certainly a more perception-based finding.</b></p>

Here we examine further what Unitaid is known for and compare that to what it has undertaken this Strategy. For those reasons, it is worth repeating that the Strategy states that it is ‘firmly grounded in its Constitution’ which states that Unitaid aims to ‘contribute to scale up access to treatment for HIV/AIDS, malaria and tuberculosis for the people in developing countries *by leveraging price reductions of quality drugs and diagnostics*, which currently are unaffordable for most developing countries, and to *accelerate the pace at which they are made available*’ (emphasis added).<sup>79</sup>

**Finding # 5.1: There is broad consensus across stakeholders of Unitaid’s core comparative advantages, variously described as the ‘missing middle’, between research and development (R&D) and delivery at scale.**

According to the current Strategy, Unitaid looks to maximise effectiveness of the GH response by catalysing equitable access to better health products, with projects aiming to fill the gap between late-stage development of health products and their widespread adoption.<sup>80</sup> When stakeholders across groups were asked about Unitaid’s core comparative advantage(s), there was broad consensus in their responses, with little divergence in opinion across groups. In large part, stakeholders discussed Unitaid’s focus on the space ‘between innovation and scale’, its ability to ‘flexibly identify access barriers to address’ and its model of ‘catalytic investments to open up markets’. Unitaid is also regarded as an ‘accelerator’ (not just in the context of the ACT-Accelerator) that helps get products to market faster, i.e. ‘with Unitaid’s involvement, you can do things X% faster – accelerates the pace and helps you get to market sooner.’

According to the recent grantee survey, the achievements Unitaid is most known for among grantees include (in no particular order) market shaping/being a ‘market catalyst’, introducing innovative products, reducing drug prices, creation of the MPP and intervention scale-up/scalability<sup>81</sup> – which broadly aligns with Unitaid’s strategic focus areas. In contrast, 45% of respondents thought that Unitaid needed to

<sup>78</sup> ACCESS SMC Final Report, 2017.

<sup>79</sup> Unitaid Strategy, 2017-2021.

<sup>80</sup> Unitaid Strategy, 2017-2021.

<sup>81</sup> Grantee survey findings, 2021.

better define its niche area of focus to some degree, compared to 32% who said they did not need to – the remaining 23% said they did not know.<sup>82</sup>

**Finding # 5.2: At the same time, Unitaid’s focus has become more blurred over time, with some possible loss of identity.**

Despite broad consensus on the ‘niche’ held by Unitaid relating to the way it aims to operate, there was, overall, less clarity on the technical priorities and parameters of its work. There were some concerns among global-level stakeholders both internal and external to Unitaid that its mandate and focus over time had blurred. This is, seemingly, owing to Unitaid’s expansion in scope beyond the three diseases and the lack of a clear medium/long-term strategic vision and targets across AfIs articulated in a complementary and integrated way (see RQ 1, Finding 5 and RQ 4, Finding 1 above). It was recognised that a broadening in scope may reflect some flexing to evolving complementary needs of mutual benefit to existing and new areas of investment, though there were also claims of Unitaid being opportunistic in funding, resulting in some loss of identity.

Overall, based on discussions across stakeholder groups, three areas emerged where further articulation and explanation on Unitaid’s specific focus would be considered useful. With the most commonly questions raised, these are:

1. *Market shaping* – while Unitaid is focused on addressing access barriers, to what extent are they also looking to amplify demand, and how does this link with sustainability of its market shaping agenda? How much is market shaping the key imperative which drives investments, given that some investments appear not to be driven by a market shaping aim? Can Unitaid play a more communicative and/or advocacy role in the context of market shaping?
2. *Innovation* – can ‘innovation’ be better defined in relation to Unitaid’s Strategy and comparative advantage? Is it imperative that all Unitaid funds be considered ‘innovation investments’ from some perspective? How can Unitaid provide evidence for scale-up partners to assess cost-effectiveness of comparable investment options (also see RQs 2, 11, 12)?
3. *Scalability* – what do Unitaid see as the parameters for ‘scalability’ and how can a sustainable approach to scalability be taken through a narrow entry point? When is Unitaid looking to stop involvement and on what basis will success in terms of scalability be assessed (see RQ11)? How is/can the extent to which a specific investment is catalytic be explored?

Two other points are important to mention here. Firstly, several KIs among GH partners highlighted the need for more senior market shaping expertise with Unitaid, given that the role of market shaping director remains unfilled<sup>83</sup> – it was suggested that this directly affects the extent of Unitaid’s comparative advantage in this area.<sup>84</sup> Secondly, to exercise its comparative advantage to optimal effect requires risk-taking, and there are concerns that Unitaid is increasingly politically safe, in part due to Board approval processes which encourage a conservative approach. This is discussed further in the Efficiency section.

RQ6	Internal coherence: To what extent do the projects in Unitaid’s portfolio add up to a coherent whole with the potential to drive transformative change?	Strength of evidence
High-level finding	<b>The portfolio as a whole is broad and deliberately spread across the elements of the value chain, though arguably focused on ‘closing critical gaps in access’ rather than a strategically coherent investment at macro level.</b>	Evidence for these findings is medium, primarily because of the reliance of

<sup>82</sup> Grantee survey findings, 2021.

<sup>83</sup> Unitaid Organigramme revised, March 2021.

<sup>84</sup> It is understood that the senior market shaping lead in Unitaid left but has not been replaced.

	<p><b>There is relatively good coherence within AfIs/disease areas, with some variability, though there are calls for coherence to be boosted by more joined-up planning, implementation and evaluative efforts across projects and AfIs, as well as more effective cross-grantee working.</b></p>	<p><b>KIIs, although it should be noted that the case studies triangulated with the global KIIs perceptions on this matter.</b></p>
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In this section we look at internal coherence both across the portfolio and within disease areas and AfIs.

**Finding # 6.1: The portfolio as a whole is broad and deliberately spread across the elements of the market shaping value chain, though arguably focused on ‘closing critical gaps in access’ rather than a strategically coherent investment at macro level.**

As has already been discussed under RQ1, numerous global-level stakeholders argued that investment decisions were focused on ‘good gap-filling’ or ‘closing critical gaps in access’ rather than strategically coherent investments which emphasised, for example, complementarity of investments across disease areas, spearheading integrative approaches and/or enabling focus on core solutions that could take promising innovations to scale. Again, as discussed under RQ4, this may reflect a lack of overarching strategic investment framework, where the common threads are highlighted, as well as the need for more effective coordination across projects both within and across AfIs.

The fever management case study (Annex 8) is illustrative of this point, in that internal coherence and coordination could have been improved through consideration of the malaria portfolio as a whole during planning and design phases, which may have further clarified the overall strategic direction of fever management investment. Close linkage to malaria is understandable and logical given the entry point of fever management (and an approach to addressing childhood mortality which aims to ensure that every child who presents with a fever is managed holistically, rather than through vertically focused programmes, is strategic), but clarity on the overall vision and direction of the fever management investment may be useful to guide planning and engagement with partners in this space.

Within AfIs there are some solid examples. For example, Unitaids work on paediatric HIV over the years has followed a more strategic narrative, that has evolved since the first grants in paediatric HIV were announced in 2006. These grants initially focused on the delivery of paediatric medicines and were followed up with grants in paediatric HIV diagnostics to compliment the need for case finding and linkage to care between diagnostics and treatment. These grants evolved to include innovative diagnostics at the point of care, innovative medicines (pellets) to ensure less turnaround time between diagnosis and treatment, and subsequent linkage to care. Most recently, Unitaids Explore has put out a call for innovative paediatric drug formulations. The next steps are considering not only the technical and strategic linkages within AfIs but also across them, considering cross or multiplicative benefits or additionalities, for example.

Similarly to the above point, it was also suggested by Secretariat stakeholders that coherence and coordination across projects would be boosted through the development of ToCs at portfolio level, and that fever management could feature in the malaria-specific version but potentially also others, e.g. relating to MNCH.

Respondents were also concerned about the risk of dilution of impact if Unitaids engaged across too many AfIs, unsure whether the AfIs came together as a strategic whole and wary that ‘Unitaid works with too wide an agenda/scope and anything can fit in there’. The availability of resources over the past five years, combined with a push to expand, has led to some caution that expansion should not just be ‘a load of things which don’t overlap’ but be grounded in a strategic prioritisation.

**Finding # 6.2: There is relatively good coherence within AfIs/disease areas, with some variability, though there are calls for coherence to be boosted by more joined-up planning, implementation and evaluative efforts across projects and AfIs, as well as more effective cross-grantee working.**

The development of AfIs requires solid landscape and gap analyses which can inform prioritisation by disease area with the aim of achieving internal coherence within AfIs/disease areas. Relatively good coherence was discussed and reported within AfIs/disease areas, though with some variability. For example, many stakeholders suggested that HIV/AIDS potentially has the most internal coherence compared with other investment areas (see the case study in Annex 7, and also as discussed in the finding above). Within the TB space, there are mixed opinions over the extent of clarity in the overall mission and strategy, though there is a suggestion of broader and more holistic approaches over time (see case study in Annex 5). The malaria case study (Annex 6) suggests that the internal coherence of the malaria chemoprevention portfolio could benefit from a portfolio management approach that accounts for intervention combinations and prioritisation across the full package of interventions in Unitaids' malaria portfolio. In the context of constrained resources, the malaria community is increasingly adopting an approach based on geographically tailored intervention combinations. As such, stakeholders commented that Unitaids' 'one project at a time' approach to grant-making makes it challenging to a) generate evidence of impact across packages of intervention, and b) support decision making on allocation of resources across a growing number of effective prevention interventions. Further, stakeholders reported that internal fragmentation across various Secretariat teams sometimes makes it difficult to understand how malaria investments add up to a coherent whole. Internal prioritisation of interventions in both chemoprevention and the malaria portfolio at large, and a more streamlined plan for donor outreach (including more communication on how Unitaids prioritises interventions internally), would help reduce stakeholder transaction and would align Secretariat advocacy efforts with the highest priorities.

There were also mixed opinions on the COVID-19 response investments,<sup>85</sup> 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 Unitaids' ongoing work'.

While the Afl development processes have been credited across stakeholder groups for their use in guiding internal decision making, there is awareness internally of the need to give more detailed consideration of the linkages and potentially multiplicative benefits (or otherwise) of more coordinated planning, implementation and evaluation across both projects and AfIs. Over the last few years there have been attempts to develop ToCs at Afl level, with some initial estimates in terms of impact but without indicators and targets as yet.<sup>86</sup>

Following the detailed upfront landscape review effort, it was also suggested by other donors that it may be helpful to understand what drives any changes to investment decisions.<sup>87</sup> There were also reports, across development partners in particular, of insufficient/ineffective cross-collaboration of grantees, with a probable effect on the internal coherence of Unitaids investments, with claims that grantees focused on similar spaces 'may either be unaware of each other, not knowledgeable of each other's work and even at times in competition with each other'. It is noted that Unitaids does organise coordination meetings with its implementing partner grantees (pre-COVID these were full-day physical meetings, though recently they have shifted online), at which participants present their ongoing and planned work, sometimes oriented around specific themes. While these are intended to guide general collaboration, some grantees discussed how specific project collaborations needed another step. There have been some reports of successful grantee collaborations guided by Unitaids, although, for example since 2017, Unitaids has played an active role in coordinating among its HCV grantees through coordination meetings, which have reportedly been

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<sup>85</sup> A combination of ACT-Accelerator coordination & investment and discrete support to COVID-19 national-level responses integrated or attached into existing grant infrastructure.

<sup>86</sup> AfIs.

<sup>87</sup> Minutes on BMGF-Unitaid meeting on milestones, 2019.

led increasingly by grantees over time. Since October 2017, Unitaid has also been convening the Integrated Diagnostics Consortium – initially formed as a way to coordinate Unitaid grantees, but expanding to include a broad range of stakeholders, including researchers, implementers, buyers and technical agencies, who are concerned with the well-being of the diagnostics market in low-resource settings. Other collaborations within AfIs, such as grantee collaboration between the Alliance for International Medical Action (ALIMA) and the Program for Appropriate Technology in Health (PATH) to facilitate coordination across the fever management projects, is reportedly relatively good but ad hoc and informal, and led largely by the grantees themselves.<sup>88</sup> There is potential for grantee collaborations to be more formally strengthened and guided to more fully benefit from cross-learning opportunities.

RQ7	Visibility and recognition: To what extent are Unitaid’s positioning, work and achievements recognised relative to those of other relevant actors? To what extent is Unitaid recognised as a key player and as bringing value to its investment areas?	Strength of evidence
High-level finding	<p><b>There have been notable efforts to raise Unitaid’s profile in recent years, with the primary aim of expanding resource mobilisation opportunities.</b></p> <p>Visibility and recognition continue to vary by technical space, and Unitaid’s ‘added value’ can also be hard to distil. Unitaid’s niche, distinct ways of working and various impacts can be hard to communicate.</p> <p>The extent to which governments and affected communities in LMICs are aware of Unitaid is also unclear.</p>	<p><b>Evidence for these findings was medium. This is because visibility and recognition is largely a matter of perception and hence the findings are mostly informed by the KIIs and, to a lesser degree, the grantee survey.</b></p>

In this section we discuss visibility and recognition of Unitaid and the range of perspectives on the outcomes of efforts to boost these. Evaluation of specific resource mobilisation opportunities or successes are beyond the scope of this review; similarly, we were not able to explore missed opportunities for raising Unitaid’s profile or boosting resource mobilisation.

**Finding # 7.1: There have been notable efforts to raise Unitaid’s profile in recent years, with the primary aim of expanding resource mobilisation opportunities.**

Given Unitaid’s scope and scale as per its total portfolio value and the number of countries it works in, its profile could be considered to be quite large in relative terms. In the recent grantee survey, 45% of respondents thought that Unitaid’s achievements were ‘quite visible’ or ‘very visible’, with no respondents suggesting they were ‘not at all visible’.<sup>89</sup> Similarly, in response to the questions as to whether Unitaid needs to raise visibility of this work, 55% replied ‘yes’ or ‘partially’.<sup>90</sup>

According to Secretariat and other GH partner informants, there have been notable efforts to raise Unitaid’s overall profile and the scope of its achievements in recent years, such as through the Hummingbird newsletter and through impact stories via the website. Internal and external stakeholders at global level who commented on this generally agreed that the primary aim of the profile efforts was resource mobilisation and linked, potentially, support to scalability activities. It was suggested by some GH partners that, to boost its profile, Unitaid needs to better align its vision, mission and scope of work with other organisations, particularly in relation to linkage for scale-up – though it was noted that this relies on the willingness of organisations to credit Unitaid where there may not be the incentives to do so.

In its review, the FCDO echoes feedback from some internal stakeholders in recommending that Unitaid invest further time into a strategic, focused and prioritised resource mobilisation strategy, both to raise funds for the existing strategic period and COVID-19 work and ahead of the upcoming Strategy period –

<sup>88</sup> Fever management case study.

<sup>89</sup> Grantee survey findings, 2021.

<sup>90</sup> Grantee survey findings, 2021.

and that this should incorporate a clear communications strategy.<sup>91</sup> There was also broad agreement that Unitaid’s COVID-19 response work has contributed to raising Unitaid’s profile, despite related investment diversifying from the core business. There is also hope that this visibility boost may contribute to resource generation and enhanced recognition across the broader portfolio of work.

**Finding # 7.2: However, visibility and recognition continue to vary by disease area, and Unitaid’s ‘added value’ can also be hard to distil. The extent to which governments and affected communities in LMICs are aware of Unitaid is also unclear.**

Visibility and recognition of Unitaid’s work varies by disease area/technical strategies and relative to similar and complementary activity in that space. Unitaid is perhaps best known for work in HIV but is also very prominent in the TB space, owing in part to the dearth of other investors, for example.

Numerous stakeholders recognised the challenges of communicating Unitaid’s ‘added value’, which in the current era must relate to both the SDGs and UHC agendas, which themselves are all-encompassing. Unitaid’s niche and distinct ways of working are also not easily communicated, given the need to ‘simplify key terms used, such as “catalytic effect” and “equitable access”’. The impact of Unitaid’s investments is also hard to distil, given their catalytic nature and the challenges in tracking and measuring this. There have been recent efforts to communicate achievements in relation to impact on lives saved based on modelling work (see RQ12), though these can appear rather indirect for both evaluative and communication purposes. Various internal stakeholders discussed how descriptions of their work are still very much technical and operational in terms of their style and content focus, and generally related to specific products.

As mentioned previously, Unitaid’s visibility at country level is also dependent on chosen promotion efforts of their partners, with few specific requirements from Unitaid with regard to communication and branding (though it is recognised that Unitaid does undertake activities through its grantees to help country implementers understand the role of Unitaid).<sup>92</sup> There were variable examples here, though – for example, the Transforming IPT for Optimal Pregnancy (TIPTOP) IPTp project hosts Regional Learning Meetings to gather relevant stakeholders (including funders, implementers, scale-up donors and country implementers from project and non-project countries) to share experience and plot pathways for scalability beyond the project, which also raises the profile of Unitaid. There were some suggestions to place more emphasis on leveraging partner communications efforts, though questions were also raised around how much attribution of investment to Unitaid at country level is important. Various case studies did highlight, however, that suboptimal awareness of Unitaid’s scope of work and approach, as well as market shaping objectives, may pose risks to sustainability and partnership at country level. As explained in the malaria case study (Annex 6), country-level informants from Senegal, the Democratic Republic of the Congo (DRC) and Nigeria all perceived Unitaid grantees as primarily *implementers* and there was limited understanding of the time-limited or catalytic role of Unitaid funding, including the need to transition to other funding sources at the end of the grant. KIs suggested that increased communications and public relations with country stakeholders to communicate the short-term role of Unitaid and ‘prime’ countries to make follow-on funding requests could enhance Unitaid’s effectiveness (this may be just about messaging rather than any step up in communications efforts – it is fully recognised that Unitaid has a small secretariat and limited spare capacity in this regard). NGO, LMIC and development partners all mentioned that additional country visits and efforts to understand country context by the Secretariat would be highly valued and would also help to raise Unitaid’s profile.

## RQ8

**Operating model: To what extent is Unitaid’s model fit for purpose, fast and agile enough to seize key opportunities and deliver in a timely manner?**

**Strength of evidence**

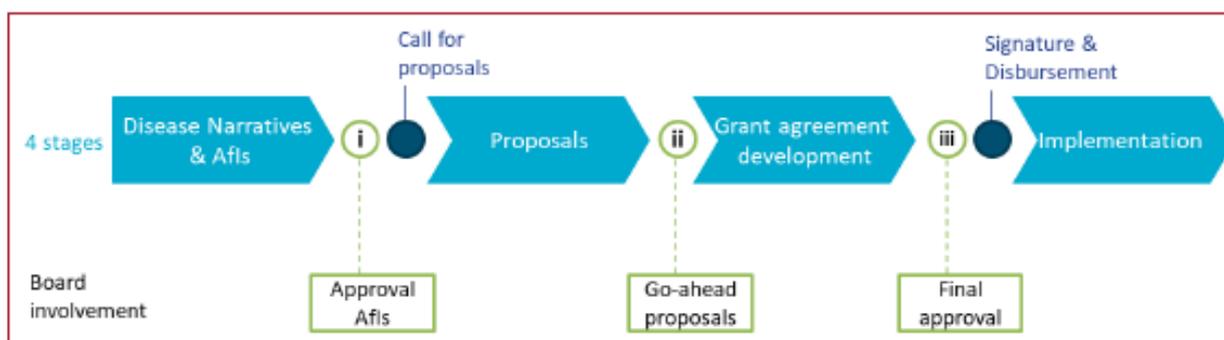
<sup>91</sup> DFID review of Unitaid, 2020.

<sup>92</sup> It should be noted, however, that a limited number of consultations were conducted at country level, despite attempts to arrange more.

<p>High-level findings</p>	<p><b>Multiple stakeholders expressed ongoing concerns, as highlighted in the MTR, that the operating model is too slow and bureaucratic – although it is important to note some improvements over time and that these challenges are not unique to Unitaid.</b></p> <p><b>The introduction of UnitaidExplore and Unitaid’s response to COVID-19 demonstrate that there is potential for future adaptations to the model to improve agility.</b></p> <p><b>Existing governance mechanisms have an important bearing on the pace and agility of Unitaid’s decision making, although there are mixed views, including potential benefits and drawbacks, on whether changes to these structures should be made.</b></p>	<p><b>While there is nuance and some divergent views from KIs, these are broadly expressed across multiple stakeholder categories. Findings are triangulated across KIs, document review and case studies for all three findings, and additionally through the grantee survey and review team experience for Findings #1 and #3.</b></p>
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The 2017–21 Strategy describes key elements of Unitaid’s operating model (also shown in Figure 3:<sup>93</sup>), including: surveying and identifying areas of need in the global response; inviting and selecting potential ideas to help close gaps; developing grants; and disbursing funds and implementing grants, including transitioning to other sources of funding. The Strategy also notes that a core aspect of Unitaid’s operating model is to make investments that trigger and accelerate changes for better health, complementing the role of organisations which fund or provide health services and products. Its impact is achieved through partners who build on the work that Unitaid funds. In this light, a key measure of Unitaid’s success is the scale-up — by countries and partners — of the products it supports. Many of these elements are covered in other parts of this report.<sup>94</sup> Here we focus on whether these elements add up to an overarching approach that supports responsive and timely delivery.

Figure 3: Unitaid’s operating model



**Finding # 8.1: The model has evolved to become more complex, and now has some inbuilt inefficiencies. While these appear to have improved over time, there remain concerns about the agility of the model – in particular in terms of the time it takes to get grants up and running. At the same time there are divergent views on whether it is important to speed up the decision making in order to increase agility, with the risk that this comes at a cost of less consultation, inclusion and rigour.**

Based on a review of Unitaid’s operating model, changes were made, including incorporating the PRC process, risk management policy, and scalability framework.<sup>95</sup> While the Grant Agreement Development (GAD) process has been shortened and streamlined over time, respondents from different stakeholder

<sup>93</sup> MTR.

<sup>94</sup> For example, surveying areas of need is discussed under RQ2; the balance of flexibility and agility is discussed under RQ9; and the process of grant management (developing and disbursing funds, implementation) is covered under RQ10.

<sup>95</sup> MTR, p. 22.

categories reported that it remains long (typically around six months,<sup>96</sup> i.e. at the upper end of the target range of three to six months<sup>97</sup>) which reduces the chance to flex to emerging opportunities as the time lag can coincide with changes in context; this view was expressed across stakeholder categories and is consistent with findings from the document review.<sup>98</sup>

However, the picture is somewhat nuanced. While grantees noted delays due to alignment of expectations at the start of the grant and at the ‘notification of proposal selection to Board approval of the grant’ stage of the grant-making process,<sup>99</sup> the initial stages of grant-making (i.e. the time to submit proposals and for initial proposal selection) were considered ‘fast’ or ‘just right’.<sup>100</sup> The grantee survey also noted that responsiveness of Unitaid processes is broadly equivalent to that of other donors.<sup>101</sup> Similarly, respondents from across a range of stakeholder categories reported that current timelines are acceptable – indeed, necessary – in order to support rigour and ensure appropriate, inclusive consultation. Furthermore, there is evidence that disbursement performance is not a major concern, and has improved over time.<sup>102</sup> While our review has not systematically looked for evidence on speed of decision making at equivalent organisations, there is evidence that other grant-making bodies (specifically the Global Fund and UK’s Fleming Fund) are also faced with the challenge of how to introduce efficiencies and speed up grant-making processes.<sup>103, 104</sup> As discussed in the next section, striking the right balance remains a priority for Unitaid<sup>105</sup> given that ‘working in innovation implies dealing with uncertainties and being able to respond in a fast and agile manner to new evidence or emerging opportunities’.<sup>106</sup>

Inefficiencies, as discussed elsewhere in this section and under RQ10 below, were noted by many grantees in terms of: Unitaid reporting and engagement processes, which can detract from actual implementation; additional encumbrances due to Unitaid’s WHO status (e.g. ethical review rules); and implications of limited agility for responding to emerging opportunities.

**Finding # 8.2: The response to COVID-19 helped demonstrate that Unitaid can be more agile, through existing grant infrastructure, and the limited scope for agility within the existing model was further addressed through UnitaidExplore.**

There are many of examples of where Unitaid has made fast approval of adaptations to project activities and complementary funding to support COVID-19 response activities, largely through existing grant infrastructure but also through Unitaid’s engagement in the ACT-A pillar. There are examples from a range of grants, supported by responses from multiple stakeholder groups, of this flexibility, including in the Third World Network (TWN), Solthis MTV, Aurum and Expertise France grants; and 42% of respondents to

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<sup>96</sup> MTR, FCDO annual review, Nov 2020.

<sup>97</sup> High-level review of the operating model (2017); UNITAID/PSC17/2017/3.

<sup>98</sup> MTR: ‘the overall timeline needed to perform all stages ranges between 9 months and 1.5 years’.

<sup>99</sup> Grantee survey, Q16.

<sup>100</sup> Grantee survey, Q16.

<sup>101</sup> Grantee survey, Q17, which specifically mentioned other major donors as ‘DFID, the Gates Foundation, the Global Fund, PEPFAR, PMI, USAID, the World Bank’.

<sup>102</sup> The average time needed to execute a disbursement was 5.2 weeks, substantially better than the target of 8 weeks. All disbursements (100%) were executed within 12 weeks (against 90% in 2017). UK annual review Unitaid - Nov 2020.

<sup>103</sup> Global Fund MOPAN institutional assessment (2015-16), p. 81. [http://www.mopanonline.org/assessments/globalfund2015-16/Mopan%20Global%20Fund%20report%20\[interactive\]%20\[final\].pdf](http://www.mopanonline.org/assessments/globalfund2015-16/Mopan%20Global%20Fund%20report%20[interactive]%20[final].pdf)

<sup>104</sup> Fleming Fund implementation Annual Review (2018), pp. 5-8. <https://aidstream.org/files/documents/Fleming-Fund-Annual-Review-2018-20190627100641.pdf>

<sup>105</sup> UNITAID/PSC17/2017/3.

<sup>106</sup> MTR.

the grantee survey<sup>107</sup> reported that changes to Unitaid tools, processes and guidance had streamlined work or increased flexibility. In one grant in Côte d'Ivoire, an idea to develop a digital series for COVID-19 was proposed and funded within two weeks. The fever management case study highlights how COVID-19 response has required activities that are likely to generate enhanced benefits to project in the long run, such as in raising awareness of the role that pulse oximeters can play, and in strengthening engagement with ministries of health (MOHs) and other national stakeholders. Overall, lessons from the COVID-19 pandemic reinforce the need for maximum agility and flexibility in grant management to reinforce Unitaid's comparative advantage (and yet, as discussed below, the grant agreement process is still largely considered heavy and cumbersome).

Unitaid also strengthened its agility through the UnitaidExplore pilot (see Box 2). This initiative was developed to enable actual flexibility to engage with innovators. While this has been introduced with a low financial risk, there are mixed views about whether it is a move in the right direction for Unitaid. On one hand, it is an important alternative to horizon scanning and backing a limited number of innovations with substantial investments that characterises the core business model – one respondent described it as a mechanism to 'let a thousand flowers bloom' and another recognised the need to have a larger number (albeit smaller and targeted) of active investments; on the other hand, some respondents highlighted concerns about the potential for faster decision making to reduce consultation with a broad range of stakeholders.

At this stage it seems important to recognise UnitaidExplore as a pilot, set up to achieve specific objectives and to report back to the Board with lessons learned.<sup>108, 109</sup> While there is less Board involvement in UnitaidExplore funding decisions and more delegated authority to the Secretariat,<sup>110</sup> this is consistent with the following finding – that the Board is too involved in operational decisions. It will, though, be important that future strategy and implications for the operating model associated with UnitaidExplore continue to be discussed and agreed by the Board.

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<sup>107</sup> Grantee survey, Q39.

<sup>108</sup> UNITAID/EB33/2019/4.

<sup>109</sup> UNITAID/PSC24/2020/6.

<sup>110</sup> UNITAID/EB33/2019/4.

## Box 2: UnitaidExplore

Following a number of discussions during 2019, the Executive Board recognised the opportunity for Unitaid to support innovation in new ways by piloting a mechanism that would allow Unitaid to move fast, be flexible and engage more effectively with innovators and funders/scale-up partners.

The Executive Board agreed to allocate a suitable portion of the pipeline to explore working in new ways, specifically to allow Unitaid to achieve the following target outcomes:

- Support untapped innovations with transformative potential
- Strengthen Unitaid’s position as a leader for innovation and scalability in global health
- Learn and inform Unitaid’s next strategy.

Unitaid will pilot an agility mechanism, through which USD \$20 million in funds would be allocated to two to three projects in 2020. The mechanism differs from the current operating model in two ways. 1) The administration of the agility mechanism is delegated to the Unitaid Executive Director, with the Secretariat determining what projects to source and select and taking responsibility for supporting projects and assessing progress. 2) The Secretariat reports annually on any projects supported by the agility mechanism to the Board, in place of the three Board endorsements required by the core operating model – except on projects over USD \$5 million, for which the Secretariat will seek Board endorsement.

The agility mechanism respects six key principles: 1) focus on innovation with transformative potential; 2) address global health needs in LMICs; 3) ensure transparency and fairness; 4) adopt a proportionate response; 5) ensure complementarity with other global health initiatives and the rest of Unitaid’s portfolio; 6) inform future strategic direction.

### **Finding # 8.3. Limited agility appears to be linked to governance structures, but there are divergent views about if and how these should be reformed.**

Respondents identified a range of governance-related factors that have a bearing on the speed and agility of Unitaid’s operating model. We have not undertaken a full governance review, but simply report here some concerns (which may not be comprehensive) as raised by a broad range of KIs which, in our view, are of strategic importance for consideration in the next Strategy. These relate to the role of the Board in project-level approval, the composition of the Board and the hosting by WHO of the Unitaid Secretariat. Each is briefly considered below.

- **Board approval of project-level investments:** The Board is currently involved in approving AfIs, and later in approving specific grants.<sup>111</sup> There is, however, broad agreement across a range of stakeholder groups that the Board should not be involved in approving project-level investments; nor, indeed, is this common practice in equivalent multilateral organisations.<sup>112</sup> Stakeholders questioned whether it is the best use of the Board’s time, whether the Board has the right technical skills to make decisions at this level,<sup>113</sup> and, indeed, if the Board receives the right information to enable it play this role.<sup>114</sup> That the Board operates on a consensus basis<sup>115</sup> appears to compound the challenge associated with its project-level involvement, as it

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<sup>111</sup> UNITAID/PSC17/2017/3.

<sup>112</sup> Based on review team experience.

<sup>113</sup> UK annual review 2017.

<sup>114</sup> Also discussed under RQ2 on trade-offs.

<sup>115</sup> Board Operating Procedures Unitaid/EB33/2019/8; ‘Introduction to Unitaid’ briefing from the Secretariat.

may encourage conservatism, and limits risk-taking. Because all funding decisions (with the exception of those under the UnitaidExplore pilot) are made by the Board, there is a risk of politicising decisions rather than making decisions on the basis of a clear strategic framework. Any changes to the delegated authority given to the Secretariat could be informed by the experience with UnitaidExplore pilot,<sup>116</sup> based on clear parameters set by the Board.

- **Board composition:** There have been recent reviews and changes to Unitaid’s governance structure.<sup>117</sup> Multiple stakeholder groups raised questions about whether the Board represents the right mix of skills and stakeholder groups,<sup>118</sup> and around whether to further adjust the Board composition to strengthen representation of countries, communities and beneficiaries. There is some support for this move, but concerns exist over the potential for this to further slow decision making, given the issues highlighted above. The Executive Board consists of 13 members,<sup>119</sup> of whom two are non-voting. Setting demands for changes to Board composition in the context of other similar organisations is instructive: our comparative analysis found that most Boards include around 20 voting seats, with varying representation in terms of stakeholder groups; so the Unitaid Board is comparatively small. The Global Fund is, perhaps, leading the way in terms of country and civil society representation, and Unitaid may identify appropriate governance changes through reviewing the Global Fund’s experience more closely. Our comparative analysis also notes that all organisations appear to struggle with the achieving the right ‘balance’ between active representation and enabling effective agility.
- **WHO hosting:** Some concerns were raised about the effects of having Unitaid hosted by WHO and drawing on WHO’s administrative processes. For example, WHO has to be assured that each grant and expenditure has the proper authorisation and political cover,<sup>120</sup> which adds time to the process.<sup>121</sup> There are divergent views on this issue. A range of stakeholders consider the influence of WHO hosting to be to drive down Unitaid’s risk appetite and introduce bureaucratic processes that are obstacles to agility. Different respondents from the same stakeholder groups also underline the importance of WHO as a key normative partner to Unitaid. Given the importance of WHO’s normative role, and the influence and reach that can contribute to scalability of Unitaid’s investments, this is clearly an area that would benefit from further consideration (discussed further under RQ11).

<b>RQ9</b>	<b>To what extent are the trade-offs between rigour and assurance vs speed and agility appropriate given Unitaid’s mandate, priorities and risk appetite?</b>	<b>Strength of evidence</b>

<sup>116</sup> As per UNITAID/PSC24/2020/6.

<sup>117</sup> UNITAID/PSC17/2017/3.

<sup>118</sup> UK annual review, 2017.

<sup>119</sup> One representative nominated from each of the five founding countries (Brazil, Chile, France, Norway and the United Kingdom), Spain and the Republic of Korea; one representative of African countries, designated by the African Union; two representatives of relevant civil society networks (nongovernmental organisations and communities living with HIV/AIDS, malaria or tuberculosis); one representative of foundations; one representative of temporary shared non-voting seat (Japan); one representative of the World Health Organization (non-voting). <https://unitaid.org/about-us/governance/#en>

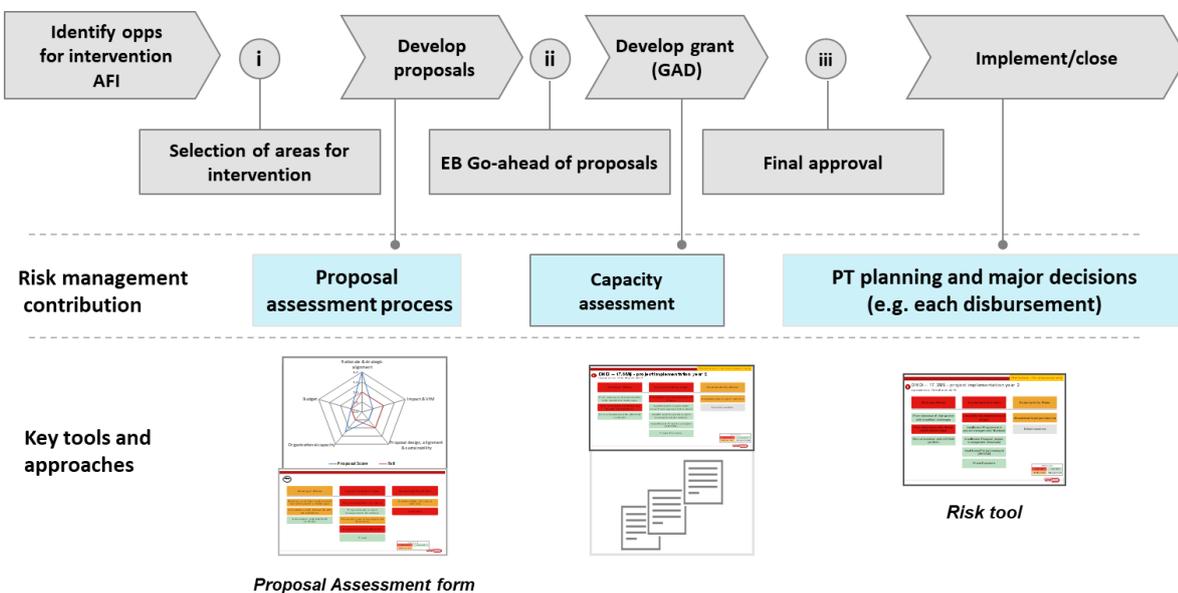
<sup>120</sup> One respondent noted that ‘WHO need a certain assurance that when expenditure is taking place under the Secretariat, it’s either doing so under the WHO or it’s a programmatic grant [...] we need to make sure that when Unitaid instructs us to process a grant payment we have the necessary political cover that this has been approved. Otherwise we could process grants and payments without the proper authorisation. The flexibility needs to come with defined and clear parameters from the Board’. (EB)

<sup>121</sup> One respondent estimated this to be two to three weeks extra.

<p>High-level findings</p>	<p><b>Unitaid has developed a robust risk management framework that represents close to or actual best practice.</b></p> <p><b>However, Unitaid’s risk appetite is generally considered to be too low.</b></p> <p><b>There is evidence that Unitaid can be flexible, in particular during the design of its interventions, but this is reduced during implementation.</b></p>	<p>Evidence for Findings #1 and #3 is stronger than for Finding #2. There is strong triangulation across KIs, documents, grantee survey and review team experience for Findings #1 and #3. While there are multiple sources of evidence on Finding #2, the picture on risk appetite is nuanced and strength of evidence is medium/high.</p>
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Unitaid’s approach to risk management is summarised in Figure 4:, and described in a number of Unitaid and external documents.<sup>122</sup> The high-level review of the operating model<sup>123</sup> notes that risk management is embedded at all steps of the model: at proposal stage, a preliminary risk analysis identifies key risks and potential corresponding mitigation plans and is provided to the Executive Board; at GAD stage, full risk assessment and capacity assessment are performed prior to Board approval, using the relevant tools; during implementation, risk is monitored and risk assessments are updated at least twice a year.

Figure 4: Summary of Unitaid’s approach to risk management



**Finding # 9.1: Unitaid has developed, and is implementing, a robust risk management framework that represents close to or actual best practice for grant-making organisations.**

Unitaid’s risk management framework has undergone significant refinement,<sup>124</sup> especially over the last two years, and now utilises robust grant risk management tools which are applied and updated throughout the grant, reviewing risks to strategy, implementation and scalability. These are matched with organisational risk tools, including a risk management policy, risk register, heat map, risk library and the use of an Impact, Cost and Risk portfolio tool, supported by a robust audit and sound financial systems.

<sup>122</sup> UNITAID/EB30/2018/4c; UNITAID/PSC17/2017/3; FCDO annual review, 2019.

<sup>123</sup> High-level review of the operating model (2017). UNITAID/PSC17/2017/3.

<sup>124</sup> FCDO annual review, 2019.

The majority of grantees reported that Unitaid’s risk management approach helps to identify and manage risks in their project,<sup>125</sup> which represents an improvement over time.<sup>126</sup> Based on the experience of the review team, having reviewed multiple organisations’ VfM and risk management systems, our view is that Unitaid’s approach represents close to or actual best practice<sup>127</sup> for a grant-making organisation; and positive assessments have also been made of the implementation of this framework, including by external partners.<sup>128, 129</sup>

**Finding # 9.2: However, Unitaid’s risk appetite is considered to be too low by most stakeholders, given its focus on innovation, with potential implications for returns on investments and equitable impact.**

While Unitaid clearly describes its risk appetite in its 2018 risk management policy, there are diverging opinions among stakeholder groups about whether Unitaid’s current risk appetite is appropriate. While there are examples of where Unitaid has embraced risk, e.g. the Self-Testing Africa (STAR) project (see HIV case study, Annex 7), and some reports from the stakeholders that Unitaid is less risk-averse than other donors,<sup>130</sup> there is broad consensus among most stakeholder groups that Unitaid’s risk appetite is too low. Respondents reported that Unitaid does not take many risks – i.e. that there are few (if any) examples of failure. Multiple stakeholder groups observed that an organisation focusing on innovation should embrace and learn from failure. Currently, the probability of success needs to be high, with the potential consequence that only ‘good bets’ get approved/funded. This may limit investment in riskier, more innovative solutions and could potentially crowd out investments by other, more traditional funders, e.g. governments.

Aversion to risk seems to also translate into Unitaid’s partnerships, with a limited number of organisations receiving grants, with KIs highlighting the need to increase the number of recipients in the global South; although we note that this is something that Unitaid has recognised itself, as noted in the MTR. Some grantees report that Unitaid has not traditionally engaged extensively with civil society, particularly from LMICs, but may need to explore approaches in doing so, with the aim of enabling equity in its approach. Documents underline how this continues to improve over time,<sup>131, 132</sup> and our comparator analysis identifies this as a challenge for other similar organisations;<sup>133</sup> however, there is recognition that more can be done, including through work to develop a community engagement framework.<sup>134</sup> It was raised by some grantees that NGOs can potentially be relatively nimbler, which can be aligned with an innovative approach. There may also be missed opportunities<sup>135</sup> from not engaging more with the private sector at country level, which will also boost scalability and sustainability efforts.

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<sup>125</sup> Grantee survey, Q32.

<sup>126</sup> High-level review of the operating model (2017) UNITAID/PSC17/2017/3. In November 2016, fewer than half of grantees thought that the Risk framework and the Value for Money framework were useful for them to manage risks and articulate impact of their project.

<sup>127</sup> Some elements of best practice on risk management can be observed in the MOPAN framework (indicator 5.4): [http://www.mopanonline.org/ourwork/themopanapproach/MOPAN\\_3.1\\_Methodology\\_4downloading.pdf](http://www.mopanonline.org/ourwork/themopanapproach/MOPAN_3.1_Methodology_4downloading.pdf). This assessment is also based on experience of the review team in assessing other international organisations risk and VfM approaches.

<sup>128</sup> FCDO annual review, Nov 2020.

<sup>129</sup> Strategic and Operational Key Performance Indicators 2020; UNITAID/EB38/2021/7.

<sup>130</sup> NGO stakeholder group.

<sup>131</sup> High-level review of the operating model (2017); UNITAID/PSC17/2017/3.

<sup>132</sup> MTR.

<sup>133</sup> Unitaid Grantee network analysis (Feb 2021).

<sup>134</sup> Community and civil society engagement briefing to the review team, April 2021.

<sup>135</sup> Including not having a private sector strategy.

**Finding # 9.3: There is some evidence of flexibility, but this tends to be during finalisation of design – in the window between grant approval and implementation – outside of which flexibility is limited.**

Development partners recognise the importance of Unitaid being flexible and agile, and the need for agility is a recurring theme in Unitaid and external documentation.<sup>136</sup> Multiple stakeholder groups reported that Unitaid’s current performance is acceptable – especially in the context of COVID-19. At the same time, different respondents from the same stakeholder groups expressed concerns that Unitaid is not flexible or agile enough, in particular for projects focused on advocacy. A limited number of respondents also highlighted risks associated with too much flexibility and agility, in terms of the effects on clarity of contribution relative to others in the GH architecture.

While there is strong evidence that Unitaid can be flexible, it appears that this flexibility exists more during grant design than during grant implementation. 16% of respondents to the grantee survey reported that GAD processes can be streamlined and that the model to take technical decisions can be more flexible.<sup>137</sup> The business model prioritises achievement of positive results within short time frames, which may reduce the flexibility for grants to adapt and for genuine learning to take place from innovative approaches; this was a finding of the fever management case study (see Annex 8).

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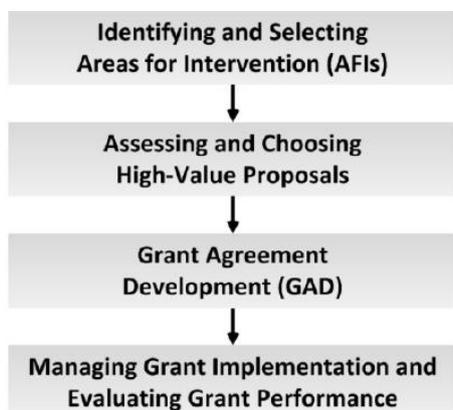
<sup>136</sup> MTR; FCDO annual reviews; also highlighted as a priority in the review of operating model. High-level review of the operating model (2017) UNITAID/PSC17/2017/3.

<sup>137</sup> Grantee survey, Q26.

<b>RQ10</b>	Grant management model: To what extent does the grant management model make efficient use of resources (both at Unitaid and implementing organisations)? What opportunities are there to enhance the model to enable the optimal balance between empowering implementers with the flexibility they need to innovate in delivery while ensuring accountability for delivery?	Strength of evidence
High-level findings	<p><b>High transaction costs (time spent by the Secretariat and grantees) of the model, and the implications this has for the diversity of the grantee portfolio and the pressure placed on Secretariat staff, raise questions about how efficient the grant model is.</b></p> <p>Efficiency may also be adversely affected by reporting arrangements, as the lack of standardised data prevents comparisons across place, time and grants.</p> <p>Furthermore, scalability appears to be under-considered in planning and implementation, in spite of its importance to Unitaid’s impact; however, there are potential improvements that could be made to strengthen guidance and emphasise earlier engagement with key scale partners.</p>	<p>All findings are triangulated across multiple sources and analyses, with Findings #1 and #3 supported through KIs, document review, grantee survey and case studies. Finding #2 also has high strength of evidence given the range of key informants, the nature of documentation, evidence from two case studies and experience from the review team. Findings #4 and #5 have weaker evidence (medium), mainly because either the breadth of stakeholder categories is smaller and/or there is limited analysis in documentary evidence.</p>

As described in the grant management guidelines,<sup>138</sup> each Unitaid grant is developed through an approach with four key stages (see overview in Figure 5): 1) understanding the public health landscape and identifying AfIs; 2) calls for and selection of proposals that respond to the AfI; 3) development of grants through the GAD; and 4) management and monitoring through implementation. A description of the specific process steps that go into each of these four stages is described in detail in the grant management guidelines.

Figure 5: Overview of the grant-making process



<sup>138</sup> Unitaid Grant Management Guidelines, 2017.

**Finding # 10.1: The Secretariat has become more involved with the implementation of grants over time, and it can take a long time for Unitaid and grantees to reach ‘alignment’ in terms of vision and approach.**

Many grantees, as well as other stakeholder groups, have raised the fact that engagement with the Secretariat can be demanding. There are diverging views on the effects of close Secretariat engagement in grant management: on one hand, a number of stakeholder groups noted the high transaction costs,<sup>139</sup> micromanagement and the diversion from implementation that this requires – which the Secretariat is aware of and keen to address; on the other, grantees and other stakeholders also welcomed collegiality, partnership and added value that comes from close engagement with the Secretariat. Similarly, there remain different opinions on how stringent grant management processes are, once approved – some say overly so, which places a high burden on grantees, whereas others suggest that Unitaid is less stringent in programmatic and financial reporting and auditing/financial accountability requirements than others (e.g. USAID). Respondents to the grantee survey report some improvement in grant management processes but say that there is scope for more: 50% of respondents agree or strongly agree that Unitaid’s grant management improved in recent years;<sup>140</sup> however, 42%/65% feel that Unitaid’s programmatic/financial reporting requirements are more complex/challenging compared to those of other major donors.<sup>141</sup>

**Finding # 10.2: There is demand and scope for Unitaid to partner with a wider range of grantees, and Unitaid has ongoing plans to strengthen in this regard.**

Several stakeholders noted that having heavy grant management processes can translate into reluctance by smaller organisations applying for Unitaid funding. The prior work up front and the high management capacity required impact on equity and capacity building opportunities<sup>142</sup>. And yet there is recognition of the need to diversify the portfolio of grantees;<sup>143</sup> there are demands for Unitaid to do that from the outset and as primary recipients (not subcontractors), and there is evidence that Unitaid has made some progress in this respect.<sup>144</sup> For example, IMPAACT4TB is a model for engagement of civil society for Unitaid grants,<sup>145</sup> and the HIV self-test case study notes that Unitaid has demonstrated improvement in promoting implementation through national partners (but still has some way to go).<sup>146</sup> Unitaid’s latest thinking also suggests that the importance of civil society and communities as partners is well understood (see Figure 6:)<sup>147</sup> but there is work to do to systematically put this into practice through the grant portfolio, and there is potential to learn from experience of comparable organisations, such as the US President’s Emergency Plan For AIDS Relief (PEPFAR), the Global Fund and Gavi.<sup>148</sup>

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<sup>139</sup> Malaria case study.

<sup>140</sup> Grantee survey, Q31.

<sup>141</sup> Grantee survey, Q36: major donors listed as DFID, the Gates Foundation, the Global Fund, PEPFAR, PMI, USAID, the World Bank.

<sup>142</sup> While the barrier to smaller organisations applying for funding was reported by grantees, Unitaid also noted that its PPF mechanism is designed to fund a significant proportion of the costs incurred by applicants during the GAD process.

<sup>143</sup> UNITAID/PSC17/2017/3.

<sup>144</sup> MTR, Grantee network analysis.

<sup>145</sup> See TB case study for more detail.

<sup>146</sup> See HIVST case study for more detail.

<sup>147</sup> Community and civil society engagement briefing to review team, April 2021.

<sup>148</sup> Comparator analysis.

Figure 6: Importance of community and civil society engagement

## Importance of community and civil society engagement



**Finding # 10.3: Pressure has increasingly been placed on the Secretariat staff as a result of the operating model requirements, the growth in both portfolio scope and number of grantees, and the surge capacity needed for Unitaid’s COVID-19 response.**

With a comparatively small number of people relative to the task of managing a portfolio of USD \$1.3 billion (covering 18 AfIs and more than 50 grants, which are implemented by 40+ grantees in just under 100 countries), concerns were raised by both internal and external stakeholders that the Secretariat staff are spread too thinly. Pressure has increasingly been placed on the Secretariat staff as a result of changes to the operating model requirements: for example, UnitaidExplore was more resource-intensive than expected, but came with no additional administrative resources.<sup>149</sup> Similarly, the growth in both portfolio scope and number of grantees, and the surge capacity and remote working that has been needed for Unitaid’s COVID-19 response, have increased demands on the Secretariat. Staff morale is being monitored regularly (through team meetings and ‘pulse’ surveys).

In spite of this, 87% of respondents in the grantee survey agreed that there was strong support from Unitaid project teams to manage their projects,<sup>150</sup> for example in terms of bringing knowledge, insight and expertise of the market landscape which can be tapped, and providing a buffer between project implementation and discussions at Board level. However, some questions were raised by a limited number of stakeholders (in the grantee and Unitaid categories) about whether the Secretariat has the right skills and capacity, in particular in terms of upstream expertise and sufficient understanding of field realities; and a key question for consideration is whether Unitaid should add these in-house or whether it can access them through its partnerships.

**Finding # 10.4: Output and results data across grants cannot easily be aggregated or compared, and there is a bias to quantitative data at the expense of qualitative data which may contribute nuanced insight.**

While guidance at the level of individual grants is comprehensive and clear, and two thirds of grantees reported that this helped them fulfil their reporting requirements,<sup>151</sup> emphasis is on grant-level results.

<sup>149</sup> UNITAID/EB33/2019/4.

<sup>150</sup> Grantee survey, Q29.

<sup>151</sup> Grantee survey, Q37.

Grantees have to develop their own indicators<sup>152</sup> – which, while flexible, leads to a lack of standardised data. Impact analysis is also primarily at project/grant level, rather than across disease investment areas, AfIs or broader. Together this makes an overview of cumulative benefits (or otherwise) challenging and hinders comparisons across place, time and grants, integration feasibility and general learning (see RQ11 for more detail). Planning and impact assessment also appear to be largely quantitative and overly theoretical, with some feedback from grantees that it is hard to capture qualitative aspects of grants in planning and assessments – especially for advocacy and sustainability-focused interventions as set out in the scalability framework.<sup>153</sup> the processes and intermediate outcomes that lead to creating the conditions for scalability – such as securing political support or establishing supportive policies – do not easily translate into quantitative measures.<sup>154</sup>

**Finding # 10.5: While critical to the success of grants, scalability and sustainability may be under-considered in project planning and implementation, potentially limiting the effectiveness of the groundwork required for both, and hampering the opportunity for lessons to be learned.**

The focus on scalability has increased over the past couple of years, including through the development of the scalability framework,<sup>155</sup> and a new role has been created to promote engagement around scale-up. There are examples of Unitaid’s effectiveness in supporting scale-up of its interventions, although with some different perspectives: SMC,<sup>156</sup> HIV self-testing, dolutegravir, point-of-care early infant diagnosis (POC EID) and Next Generation Indoor Residual Spraying (NgenIRS) were all noted as areas in which Unitaid investments have been scaled up, although the extent of scale and of Unitaid involvement appears to have differed.<sup>157</sup> However, while on paper scalability is integrated throughout the grant cycle,<sup>158</sup> a range of stakeholder categories reported that more formal processes or detailed guidance could be put in place to guide and strengthen implementation related to scalability,<sup>159</sup> for example on how to scale (e.g. who to engage with, with what evidence and when – having a clear strategy and intervention logic); as noted in the malaria case study, ‘Unitaid’s work in community IPTp and IPTi poses a “failure to scale” risk without additional efforts to strengthen the delivery platforms they rely upon’.<sup>160</sup> Linked to this, questions were also raised by respondents in the development partner and Unitaid stakeholder categories around the extent to which enabling sustainability of interventions is considered comprehensively from the outset. Furthermore, some grantees noted that efforts to plan for scalability towards the end of the project tend to be oriented around communication of results by partners, and that the Secretariat could play a more active role in engaging potential scale partners. Broader support for exploring scale-up options could be boosted through an enhanced focus on advocacy and communications at both country and global levels. This may help address the sense – expressed by in-country stakeholders – that projects ‘won’t ever end’ (as has been observed in the case of IPTi and TIPTOP). Beyond funding for scalability of a product, other aspects may also be important for Unitaid to consider, such as enhancing local research and evaluation capacity, collaborations with the local manufacturing sector, and integration

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<sup>152</sup> Results framework guidance, 2021.

<sup>153</sup> Scalability framework guidance, 2021.

<sup>154</sup> Based on review team experience.

<sup>155</sup> Scalability framework guidance, 2021.

<sup>156</sup> MTR.

<sup>157</sup> MTR.

<sup>158</sup> UNITAID/PSC17/2017/3.

<sup>159</sup> MTR.

<sup>160</sup> Malaria case study.

with government plans and services; there may also be value in increasing the length of Unitaid grants, to strengthen the prospects for scale and sustainability.

### 4.3 Workstream 3: Right results

This final workstream focuses on whether Unitaid is achieving the right objectives.

As with workstreams 1 and 2, the findings presented in this section are based on a range of data sources and use the data collection and analytical approaches described above and in the evaluation framework. Our rating of the strength of evidence is presented next to the high-level finding in response to each RQ.

#### 4.3.1 Detailed findings by sub-issue

RQ11	Value for Money (including Economy) To what extent is Unitaid’s organisation and portfolio delivering against its objectives and providing VfM? Are the results consistent across areas? To what extent are the objectives and associated targets sufficient to drive expected transformations at grant and portfolio levels (e.g. is price reduction sufficient to drive substantive or only incremental change?)	Strength of evidence
High-level findings	<p><b>Unitaid’s VfM framework compares well to those of many GH organisations and has significantly improved over the Strategy period, but it could be further strengthened. Strategic Objectives (SOs) are consistently applied across the grant portfolio, while Operational key performance indicators (OKPIs) seek to promote VfM within Unitaid organisationally.</b></p> <p>According to the benchmarking analysis we conducted against VfM good practice, Unitaid’s grant-making and management rated in line with good practice at award stage. Unitaid’s pre-and post-award stages were rated amber (i.e. there is room for improvement). Finally, Unitaid close-out stage was rated ‘red’ (i.e. some concerns). <b>Economy is not explicitly addressed within the framework, but this review found no evidence of problems in this area.</b></p> <p><b>Unitaid’s WHO hosting produces both positive and negative influences on VfM.</b></p> <p><b>The current framework monitors grant efficiency and effectiveness during and at the closure of each project (including forward projections). Results vary over this time period but have remained largely positive. Unitaid’s VfM framework retains two significant weaknesses. Firstly, it only measures results to a maximum of a year after grant closure. Since these are relatively brief catalytic grants, this means efficiency is more visible than effectiveness (Outcomes). Secondly, analysis remains at grant level, without extending to disease narratives/AfIs, limiting overall effectiveness analysis, strategy development and potential resource mobilisation (see also RQ12).</b></p>	<p>There is generally a high level of agreement in the evidence from KIIs on RQ11 findings. This was supported by analysis of Unitaid financial statements for Findings 3 and 4 and of project and portfolio analysis for Finding 4. However, the lack of data collection post-grant and above grant level by Unitaid precludes comprehensive analysis of effectiveness, keeping evidence strength below High. All stakeholder groups had some contribution to evidence for this RQ.</p>

One of Unitaid’s four investment commitments is that VfM will be maximised. Two of the other commitments relate closely to this: that the investments selected will be those that have ‘the most benefit’; and that Unitaid will ‘strive for equity’. All three of these require application of a very robust VfM framework. The VfM framework was introduced in 2015/16. Its portfolio section rests on nine SOs, which were reorganised in 2019 with an added ‘scalability framework’, aimed at boosting effectiveness by more comprehensively creating the conditions for scale-up by partners and countries. Project evaluation criteria were revised at the same time. In parallel there are ten OKPIs, which aim to drive VfM within the organisation.

Table 7: Strategic objectives (post-2019)

SO 1&2 Innovation and access	SO 4 Mission-level indicators
1 Catalyse innovation	4.1 Increase public health impact
2 Overcome market barriers	4.2 Generate efficiencies and savings
SO 3 Scalability	4.3 Deliver positive returns
3.1 Securing funding	SO 5 Equity
3.2 Scaling up coverage	5.1 Investing for the poorest
	5.2 Investing for the underserved

This section covers the extent to which Unitaid and its portfolio are delivering against objectives and providing VfM.

**Finding # 11.1: Unitaid’s VfM framework compares well to those of many GH organisations and has significantly improved over the Strategy period but it could be further strengthened, especially at close-out stage.**

Unitaid’s SO framework is more comprehensive than those of many GH organisations, with its five headings covering all key aspects of effectiveness. It meets the Organisation for Economic Co-operation and Development’s Development Assistance Committee (OECD DAC) evaluation criteria,<sup>161</sup> and is well aligned with that of the Global Fund.<sup>162</sup> With SOs having been revised in 2019 and the OKPIs also being revised, it is clear that Unitaid takes this framework seriously, and it appears well ‘mainstreamed’ within the organisation.

Externally, however, some stakeholders are not aware of the framework. Others see it as better suited to procurement than for harder-to-measure benefits such as IP, or for advocacy work, which requires more flexibility in the face of evolving contexts. Despite its revision, concern was also expressed that it will need to be further strengthened given the current economic climate.

According to the benchmarking analysis we conducted against VfM good practice (see Annex 9), Unitaid’s grant-making and management rated in line with good practice at award stage, especially in view of the thorough technical review process (including an external review panel) and results and budgets being agreed upfront. Unitaid’s pre-and post-award stages were rated amber (i.e. there is room for improvement) in view of some issues already covered under previous RQs, such as Unitaid’s risk appetite and grant agreement process still largely being considered heavy and cumbersome. Finally, Unitaid close-out stage was rated ‘red’ (i.e. some concerns) in light of the following considerations:

- there are currently no *ex post* impact evaluations, e.g. 2–5 years after end of grant (discussed below).
- not enough evaluations are commissioned at an aggregated level (Afl/country) (discussed below).
- reporting and synthesis across/access to data from grant reporting is currently not suited to estimate and report results at country level.
- Unitaid does not have an impact model, with specific targets per disease/cross-cutting theme (see RQ12).

<sup>161</sup> <https://www.oecd.org/dac/evaluation/daccriteriaforevaluatingdevelopmentassistance.htm>

<sup>162</sup> [https://www.theglobalfund.org/media/8596/core\\_valueformoney\\_technicalbrief\\_en.pdf](https://www.theglobalfund.org/media/8596/core_valueformoney_technicalbrief_en.pdf)

**Finding # 11.2: Economy is not explicitly addressed within the framework, but this review found no evidence of problems in this area.**

One notable feature is that the framework omits Economy, whereas some other organisations focus on this significantly for VfM analysis.<sup>163</sup> This means that there is no explicit framework element to drive improvement in the quality and price of Unitaid’s Inputs. Unitaid’s framework effectively counts grant disbursement as the sole input cost for its VfM analysis.<sup>164</sup> In this respect, stakeholders believe Unitaid focuses well on input costs (e.g. grantee salaries and commodity price negotiations), and the analysis of GAD in RQ 10 supports this. In 2020 the average disbursement per grant was USD \$4,475,000. But Unitaid also spent an average of another USD \$632,000 organisationally and to administer the grant,<sup>165</sup> which, arguably, should be included in any calculation of grant cost-effectiveness.

Table 8: Unitaid cost drivers (share of total operating expenditure), 2016–20<sup>166</sup>

	2016	2017	2018	2019	2020
Staff costs	9%	7%	8%	7%	10%
Other costs	6%	5%	5%	4%	3%
Disbursements	85%	88%	87%	89%	87%

In looking at these other costs (cost driver analysis), as Table 8 shows, it is clear that staff costs are the main component. The stability of these shares<sup>167</sup> is due to the effect of OKPI A, which limits administrative spending (see RQ12, Finding 3) and salary levels, which are set by WHO. However, as Unitaid projects become more complex, the ratio of work required to disbursement is likely to rise. Staff are considered generally to be of high quality;<sup>168</sup> are given responsibility (e.g. every risk on the register is assigned to a staffer); are invested in (OKPI I);<sup>169</sup> but exhibit declining satisfaction (OKPI J). Overall, it seems reasonable to conclude that Unitaid addresses Economy implicitly, outside of its VfM framework.

**Finding # 11.3: Operational KPIs (OKPIs) generally drive efficiency within the organisation but some issues still remain.**

The 10 OKPIs support continuous focus on many aspects of efficiency and, to a lesser extent, effectiveness (G–J):

Table 9: Unitaid’s OKPIs

Area	OKPI	Target
Finance	A – Secretariat efficiency	2%
	B – Resource mobilisation	+ USD \$100 million by 2021/22
GAD	C – Speed of grant development	6 months

<sup>163</sup> Examples are Global Fund and UK FCDO.

<sup>164</sup> E.g. its Return on Investment analysis.

<sup>165</sup> Review analysis of financial statements.

<sup>166</sup> Review analysis of financial statements.

<sup>167</sup> Note that the apparent jump in staff costs is related less to headcount and salary levels than to a one-off contribution to the staff insurance and pension fund, which accounted for approximately USD \$7 million out of a total of USD \$25 million.

<sup>168</sup> E.g. Grantee – TB; CS – Aurum.

<sup>169</sup> Although note that UK FCDO’s Annual Review of Unitaid called for greater staff empowerment – Annual Review (November 2020), p. 3.

Grant Implementation	D – Grantee reporting timelines	80%
	E – Disbursement efficiency	8 weeks
	F – Grantee responsiveness	80%
	G – Audit status	100%
	H – Risk management	100%
Human Resources	I – People development	100%
	J – Secretariat satisfaction	75%

Each has a target, and these are effectively pursued and closely monitored on an annual basis.

While the OKPIs have been revised during the Strategy period, some issues still remain, relating to trade-offs and interactions between objectives:

- The limit on Secretariat expenditure (OKPI A) keeps Unitaid a ‘lean’ organisation, but the staffing restrictions this may mandate may constrain Unitaid’s ability to improve its efficiency and effectiveness in some ways (see RQ12, Finding 3).
- The risk management focus (OKPI H) and the Risk Tool developed to pursue it have important benefits, but also act to reduce grant management efficiency, through mandating processes that some KIs see as restricting flexibility (see, for example, Findings 9.2 and 9.3 as well as the administrative burden associated with the Tool). The effect could also create headwinds for OKPIs C, D, E and F, since it may mean that there is reduced flexibility in pursuing each of these. Contrastingly, the issue of inefficiencies flowing from a risk management focus has been well recognised (UnitaidExplore).
- The challenge of resource mobilisation (RM) (OKPI B)<sup>170</sup> may require more than the current proposed mitigations (‘operationalise new RM strategy with new agreements’ and ‘demonstrate agility and value, e.g. ACT-A’), though these are sensible steps. Addressing the shortcomings seen by donors and funding partners (under Finding 5 below), and supporting this with adequate human resources as needed, might be a much more effective way of reviving contributions, in which case it would pay for itself.

Another internal issue, not explicitly measured, is use of funds. Before the current Strategy period, only around half of Unitaid’s approximately USD \$800 million assets were committed to projects. Now virtually all are. This can be seen as increased efficiency, and helped elicit some further contributions. However, what is effectively a declining rate of RM relative to use of funds for grants means that a buffer of available investment resource has been exhausted, again increasing pressure for further contributions or for reduced activity.

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<sup>170</sup> See Annex 10.

**Finding # 11.4: Unitaid’s WHO hosting produces both positive and negative influences on VfM.**

Table 10 summarises some of the advantages and disadvantages of the WHO hosting arrangement as far as VfM is concerned. It should, however, be noted that Unitaid has full autonomy in setting its budget and running its Board. Furthermore, grant disbursements are also generally free of WHO strictures.

Table 10: List of advantages and disadvantages of the WHO hosting arrangement

Advantages	Disadvantages
Reassurance for donors; Attractive staff terms and conditions; Location: access to technical expertise; Low cost of hosting; <sup>171</sup> Use of WHO systems (for HR, some finance).	Human resources <sup>-172</sup> and procurement <sup>-173</sup> related considerations; Location: high cost; away from innovators and countries; Ethics review restrictions, reported as causing severe delays to projects by some grantees.

**Finding # 11.5: Results vary over this time period but have remained largely positive. In 2019, over a third of projects fully met or exceeded expectations.**

Applying the SO/OKPI framework to projects<sup>174</sup> suggests a varied but reasonably good performance during grant life. The approach is consistent, even though some grants (IP-related, possibly pre-qualification (PQ)) might benefit from more flexible independently-advised evaluation frameworks. While results vary, an innovative organisation would expect some projects to fall short of expectations, as they do; otherwise (i.e. if no projects ever failed) this could be seen as evidence of excessive organisational risk aversion. Table 11 shows how Unitaid’s core grants (i.e. those other than ACT-A) have performed during the Strategy period.

Table 11: Project performance under 2016–18 and 2019 onwards classifications (core portfolio)

	Definition	2019	2020
A: Exceeds expectations/Strong	>100%	4 (11%)	1 (2%)
B: Fully meets expectations/Good	80–100%	9 (24%)	16 (4%)
C: Some improvements needed/Average	60–79%	21 (55%)	19 (44%)
D: Several improvements needed/Weak	30–59%	3 (8%)	6 (14%)
E: Significant improvements needed/Unsatisfactory	<30%	1 (3%)	1 (2%)
Total		38	43

	Definition	2016	2017	2018
Strong	>80%	10 (31%)	6 (26%)	16 (47%)

<sup>171</sup> In 2020, 0.7% of Unitaid’s budget, whereas WHO can often charge organisations or programmes 13%.

<sup>172</sup> E.g. six months advertise–hire versus two months average in private sector; also Secretariat – HIV CS.

<sup>173</sup> If over USD \$200,000.

<sup>174</sup> Using annual Project Portfolio and accompanying One-page Performance Assessments.

Good	60–79%	12 (32%)	14 (61%)	12 (35%)
Weak	30–59%	10 (31%)	2 (9%)	6 (18%)
Critical	<30%	0	1 (4%)	0
Total		32	23	34

Based on One-page Performance Assessments (Annexes to Portfolio Report) and Review team calculations; % scored in 'Definition' column relates to % of overall objectives met.

The apparent decline in ratings between 2019 (35% of grants meeting/exceeding expectations) and 2020 (6%) is probably not significant, given the small sample and unusual conditions of the pandemic. Looking across disease areas, if the classifications A–E are given a weighting of 1–5 then 2020 performance is as follows:

Table 12: 2020 grant performance by disease area (core portfolio)<sup>175</sup>

	Grants	Average score (out of 5)
Cross-cutting	8	2.5
HIV	17	2.6
Malaria	10	2.9
TB	8	3.3

TB grants appear to be performing best (although the one 'unsatisfactory' Unitaid grant in 2020 was End TB), but again the sample size and unusual context mean it is not clear whether this is meaningful.

Some 13 grants fall within the ACT-A COVID response and are treated separately from the Core Portfolio (and they will be assessed by an upcoming evaluation). These are, so far, performing well given the extremely rapid setup and implementation. Seven are rated 'good' or 'strong' and only two as 'weak'; the average under the above system would be 2.5. Initial data suggests that targeted R&D for LMICs may be a more challenging area, with country support and access going particularly well. The scalability risk is estimated as medium to low on almost all ACT-A grants.

<sup>175</sup> Project Portfolio, 2021.

Table 13: 2020 grant performance (ACT-A)<sup>176</sup>

		Implementer	Grant	Overall performance
Therapeutics	Targeted R&D for LMICs	DNDi	ANTICOV – evidence generation	Average
		Liverpool	AGILE – evaluate treatments	Average
		Ezintsha	COVER CHW – Health worker prophylaxis	Weak
		(multiple)	COHIV – People living with HIV outcomes evidence	Average
		UNICEF	Dexamethasone for LMICs	Weak
	Country support and access	ALIMA	Health worker and patient protection/case management	Good
		PATH	Respiratory support systems	Good
		MTV Shuga	Public health awareness	Good
		Wemos	Access to COVID tools (CIFA)	Strong
Diagnostics	R&D and availability	FIND	Access to diagnostics, resource-limited settings	Strong
		(multiple)	Unitaid/FIND: Access to antigen RDTs	Average
	Supply and demand	CHAI	Diagnostic supply chains	Good
		CHAI	Antigen RDTs – prepare markets	Good

**Finding # 11.6: Some concerns exist, however, around likelihood and frequency of scale-up.**

Interestingly, the main annual Project Portfolio document refers to grant overall assessment, performance and risk outlook, without specific reference to scalability (which is covered by an individual grant in Annex 3 to this document, but not reviewed across the whole portfolio). Looking more deeply, the grant data does suggest that likelihood of scale-up is a weak point. For example, in 2017 57% of projects were registered as showing strong performance, but only 9% as showing strong scalability and transition. In the same year, 22% of projects showed weakened overall performance compared to 2016, but as much as 57% showed weakened performance with scalability and transition. It should be noted that projects launched before the current Strategy – the scalability framework and UnitaidExplore – would not have enjoyed the same focus on transition. The first scalability framework grants will only complete in 2021, the first UnitaidExplore grants in 2023.

Scale-up is often indeed much lower than expected, with grantees sometimes feeling inadequately supported at this stage and products not reaching their full potential. Unitaid’s Midterm Review noted that ‘scale-up remains highly variable across countries and projects [...] Scalability is complex – and getting it right [...] will require further efforts’.<sup>177</sup> A key continuing bottleneck, and hence where much VfM could be achieved, is in translation of innovations into WHO and country guidelines, which are essential for sustainability (see RQ3). Some interviewees felt that Unitaid did not target scale-up funds and stakeholders (including at country level) enough given its importance as a challenge, or that Unitaid lacks health systems operational expertise.

<sup>176</sup> Project Portfolio, 2021.

<sup>177</sup> Midterm Review (2019), pp. 15–16.

Unitaid collaboration with the Global Fund remains significant; it remains the dominant scale-up partner. A joint estimate to aid the last Global Fund Replenishment suggested that between 2015 and 2028 Unitaid-backed innovations could save 1.2 million lives and USD \$3.4 billion.<sup>178, 179</sup>

Table 14<sup>180</sup> reproduces a list of Unitaid grants for which the Global Fund is the key funding partner and which Unitaid sees as having been clear successes (eight cases, drawing in part on reference to these as examples of collaborative market shaping in an independent Global Fund review)<sup>181</sup> or potential successes though further work by the Global Fund is still required (two cases, cited as behind schedule in the same review).

Table 14: Unitaid grants contributing to Global Fund market shaping work<sup>182</sup>

Global Fund product	Unitaid grants	Grant funding <sup>183</sup> (USD \$ million)	Key access barriers
EID	EGPAF POC; UCPOC Ph2B	137.3	Availability; demand/adoption; affordability; supply/delivery
Ped ARV	DNDi peds; Optimal; SPAAN	91.3	Innovation/availability; affordability; demand/adoption; supply/delivery; quality
TLD (tenofovir/lamivudine/dolutegravir)	Optimal; ADVANCE; NAMSAL; DolPHIN-2	104.5	Innovation/availability; affordability; demand/adoption
Flucytosine (5FC) for AHD	Optimal	70.8	Affordability; demand/adoption; supply/delivery
SMC	ACCESS-SMC	67.4	Demand/adoption; supply/delivery
HIV self-testing	STAR; ATLAS; MTV-SAF Shuga; Challenge Fund	96.0	Demand/adoption; supply/delivery; affordability
PRO nets	New Nets Project	66.0	Innovation/availability; demand/adoption; affordability
RTSS	MVIP/RTS,S	9.6	Supply/delivery
TPT	IMPAACT4TB	58.9	Innovation/availability; demand/adoption; affordability
IPTp	TIPTOP; MMV Supply Side	53.1	Demand/adoption; supply/delivery; quality

<sup>178</sup> Midterm Review (2019), p. 17.

<sup>179</sup> It is assumed that this exercise used GF disease transmission modelling, a somewhat contested methodology drawing on changes in disease burden. One alternative would be to use health technology assessment to measure the actual effects of innovations – see for example [www.ncbi.nlm.nih.gov/pmc/articles/PMC5582439/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC5582439/)

<sup>180</sup> See a more extensive version of this table in Annex 15, which contains additional detail on implementers and components of results.

<sup>181</sup> Global Fund 'Strategic Review 2020', Volume 2.

<sup>182</sup> Unitaid grants which the GF sees as contributing to GF successful product innovations are highlighted in green. Grants which the GF sees as warranting additional GF work are highlighted in orange.

<sup>183</sup> Grant funding is total across all relevant grants, though some (e.g. Optimal) may be used for multiple Global Fund products.

The evaluators were not able to extensively review supporting documentation and carry out targeted KIIs to assess all of these grants. However, Annex 16 reviews the results generated by two of them in some detail: HIV self-testing (also the subject of a wider case study within this report); and New Nets. In both examples, significant direct and catalytic results were generated through successful collaboration between Unitaid and the Global Fund, demonstrating that at times this relationship works well. Among the lessons that could be learned from this is the need to institutionalise additional links between the two (and other partner) organisations, rather than depending on good existing personal connections.

Note also that, although return on investment (an SKPI) is calculated for some grants, there is no systematic analysis across all grants weighted by cost, when such a weighting could give a better evaluation of how the portfolio was performing as a whole. So, looking at two grants that completed in 2019, for example, NgenIRS (malaria) performed well, with a forecast return on investment (SO 4.3) of 12:1, while the Open Polyvalent Platforms (OPP) for sustainable and quality access to VL in resource-limited settings (OPP-ERA) project (HIV) performed poorly, with a limited return. Yet NgenIRS involved an investment that was more than four times as large (USD \$65 million) as OPP-ERA (USD \$15 million), even though they are treated equally in Unitaid's reporting. If we assume that OPP-ERA only recouped its costs, an equal weighting suggests that Unitaid might make a return across the two projects of 6:1 (still good) whereas, cost-weighted, the return would be nearer to 10:1.<sup>184</sup> Several other development partners (e.g. GF, Gavi) aggregate results across their portfolios of activity (which effectively acts to weight activities, allowing overall cost:benefit analysis) rather than treating each activity/grant equally.

**Finding # 11.7: Contribution to desired outcomes and impact-level changes is insufficiently demonstrated to some donors/funding partners (given the absence of *ex post* evaluations) which may impact on resource mobilisation.**<sup>185</sup>

Naturally, there are challenges to a catalytic organisation influencing scale-up by others, and it should be noted that post-grant results visible now tend to be from prior to Unitaid's increased focus on scalability (e.g. SO 3). Nevertheless, concern about scalability was ubiquitous among both internal and external KIs, even though some efforts have been successful. Despite the regular interactions, Unitaid's relationship with the Global Fund regarding scale-up does not always appear as strong as it could be (though Annex 16 analyses two of the significant successes achieved by the two organisations). The fact that Unitaid does not measure post-grant results (see RQ12, Finding 12.4) means that, despite Unitaid's stated aims, catalytic achievement and sustainability cannot be systematically shown. This may contribute to declining contributions from donors in a context of competing funding requests.<sup>186</sup>

KII evidence also suggested that the lack of analysis by Unitaid at higher levels than grants – Afl, disease or portfolio – also acts to concern donors, who scrutinise results and who see it as underlining an emphasis on opportunism rather than concerted strategy (see workstreams 1 and 2). Such analysis could then feed back into a linked package of interventions across a disease area rather than a single intervention, and sometimes multisectoral approaches would be need to achieve scale-up.

If Unitaid itself does not systematically obtain information on what happens in the years after its grants close, and also does not systematically analyse and act above grant level, then it is hard to see how it can achieve its transformative potential or its four investment commitments, including that of maximising VfM. Note that Unitaid's risk management, for example, has both grant and organisational elements (see

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<sup>184</sup> All figures ignore Unitaid organisational cost – see Finding 1 above.

<sup>185</sup> This report interprets effectiveness as the achievement of Outcomes through programme/grant Outputs. See <https://icai.independent.gov.uk/wp-content/uploads/Inception-report-ICAIs-Approach-to-Effectiveness-and-VfM.pdf>

<sup>186</sup> See Annex 10 – France and UK (the two dominant donors), Norway, Brazil and Chile have all reduced contributions during the current strategy period.

above), but in contrast VfM remains assessed only at grant level. Several members of Unitaid’s Board recognise that the lack of analysis on overall impact against specific diseases is a major problem.

More intensive monitoring of results might uncover significant additional benefits from Unitaid grants, sometimes in unexpected areas – some probably connected to key rising parts of the global health agenda, such as UHC and Global Health Security (GHS), the health system strengthening that both of these require, and the SDGs.<sup>187</sup> While the costs of extended monitoring and evaluation (M&E) naturally would need comparison with expected benefits, many donors now state that they would like to see progress in this area. Unitaid does contribute to health outcomes at country and regional levels, but currently cannot clearly demonstrate it, which might have a negative impact on resource mobilisation efforts going forward.

It should be noted that ACT-A represents a greater level of magnitude than other grants in terms of scale, speed and global concern. Since only 2019 grant data was available to the Review team, there are no documented results for this so far, but key informants had a positive opinion of this work.

RQ12	Target setting: To what extent are objectives and targets well defined upfront and subsequently at grant level? At Afl level? At organisation level?	Strength of evidence
High-level findings	<p><b>Target setting generally works well with grants.</b></p> <p><b>Strategic Objectives offer a good set of target indicators, except for equity.</b> Targets used for the organisational KPIs relating to Secretariat expenditure and for resource mobilisation could also be improved.</p> <p><b>Targets are not used as a tool to influence disease areas, where they could be a part of Afls, although Unitaid may have significant influence over some of these at times.</b></p>	<p>There is generally consistent evidence from KIIs on RQ12 findings. Finding 3 drew to a greater extent on Review team experience of working with many GH organisations, while the other findings drew more on KII evidence. The findings throughout were supported by analysis of a range of documents related to SOs and OKPIs. The absence of targets during the post-grant period and for disease/strategy level prevented the evidence base being extensive enough to warrant a full High rating.</p>

This section examines how Unitaid sets and uses targets at different levels of the organisation.

**Finding # 12.1: Extensive target setting is used as a successful incentivising technique for grantees with their logframes, and with the organisation as a whole. Target setting as a process could, however, be strengthened.**

Target setting is introduced very early with consideration of any new proposal. Grantees generally approve of Unitaid’s process in setting initial project targets, though grantee capacity for setting targets varies, and some grants lend themselves more easily to target setting than others, e.g. price and volume changes are amenable, but technical support – such as to WHO PQ and IP-related work – is more challenging (and has not been sufficiently addressed). No undue pressure to make targets either more or less demanding was reported, although the Secretariat stated that they will often reduce proposed pilot coverage sizes in an effort to increase cost-effectiveness.

<sup>187</sup> Over half of grants are estimated to address AMR concerns – Midterm Review (2019), p. 36; UK FCDO Annual Review.

There was positive support for the ambition/realism of initial target levels from both grantees and some development partners. On occasions, there was complaint about tight timelines. Some other development partners found the focus on targets excessive and at the expense of analysis of underlying issues, as well as being over-ambitious. Other grantees felt that targets were too cautious, and lacked the 'right to fail'.

Some development partners and Board members were unhappy at not being more included in the target setting process, while some grantees saw target setting negotiations with product manufacturers as opaque. Some in the Secretariat saw targets as sometimes uneven and inconsistent. Others thought that price points were over-emphasised because they are so easily measurable. Targets have flexibility in that they may include variables that other UN agencies would not use, such as price levels.

It is not clear that there is sufficient use of counterfactuals and scenarios when using targets. Some Board members reported that only one, 'best guess' view of the future is presented rather than trying to model and prepare for multiple possible scenarios, making it hard to consider trade-offs. But the Secretariat reported increasing use of scenarios with Afl and grants (see RQ2 on prioritisation).

Project targets are revised in response to evolving project developments. This is generally useful and appropriate (if slow) given the relatively long duration and innovative contexts of Unitaid projects, tends to be collaborative and is done in conjunction with active use of logframes. The ability to flexibly revise targets is an agility that other UN agencies sometimes lack, e.g. involving some grant-related procurement. ACT-A seemed to some to demonstrate increased flexibility from Unitaid regarding targets.

These targets, and the quantified results that they represent, are generally appreciated by donors as an approach.

Finally, grant results are systematically checked against targets soon after grant closure, with independent evaluation, which grantees appreciated.<sup>188</sup> There is some feedback at a general level, visible in an increased focus on scalability targets (e.g. extension to further countries) in the light of disappointing scalability results.

**Finding # 12.2: Strategic Objectives offer a good set of target indicators. The SKPI for equity, and targets used for the organisational KPIs relating to Secretariat expenditure and for resource mobilisation, could also be improved.**

Evidence suggests that the SOs are taken seriously by Unitaid and that they have served as a helpful framework for targeting. The SO definitions were revised in 2019. The Return on Investment target was de-emphasised as a criterion for project approval, but is still usually measured at grant closure.

The SO targets are incorporated into grant logframes, which the Secretariat finds work well to link finance to impact, though grantees may only see the financial items. While the market shaping targets are reported as broadly appropriate, simplification is alleged sometimes to miss some important aspects, such as quality-related ones, which may be very influential on future take-up. Other stakeholders pointed out that transition is only loosely defined and that Unitaid is not as rigorously focused on challenges as the private sector and so is less able to mitigate them. In addition, the SOs may contribute to Unitaid focusing on products but neglecting services and health system challenges.

However, while the SOs generally work well, SOs 5.1 and 5.2, which relate to equity, seem weaker as indicators/targets. These indicators are:

- 5.1: Total number (or USD \$) of active grants designed to benefit people living in low-income countries (LICs) and LMICs/total number of active grants (or USD \$); and

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<sup>188</sup> NGenIRS Final Evaluation Report – by CEPA.

- 5.2: Total number (or USD \$) of active grants designed to benefit the underserved/total number of active grants (or USD \$).

SO 5.1 (Investing for the poorest) restricts itself to national analysis, and would approve e.g. a grant providing items to Vietnam or Ukraine (both LMICs) as automatically ‘equitable’ due to country status alone. SO 5.2 (Investing for the underserved) uses disease-specific categories of population groups – so if, for example, a TB grant is expected to benefit anyone in a prison population, it would qualify as ‘equitable’. Looking at geographical and population group dimensions is a reasonable start, but neither indicator looks at who the actual measured beneficiaries turn out to be, something required elsewhere by many donors – which acts as a counterfactual.<sup>189</sup> Unitaid grants are classified as equitable using these two SOs at their start, and it is left at that. Equity is a key component of VfM, since reaching more disadvantaged people can create higher value than reaching those with more resources/options, other things being equal – something recognised by some development partners. Conversely, pursuing equity can also sometimes generate trade-offs with other objectives,<sup>190</sup> although these can be managed effectively only if full equity effects are monitored and understood.

Some grantees and development partners specifically want, or attempt to target, key disadvantaged population groups, something they feel is not captured by Unitaid’s aggregate numbers. Other grantees said that with the current system they target easier-to-reach populations but that ‘looking at hard-to-reach populations would be very useful’, although it is also likely that Secretariat staff and grantees often tend to focus pilots on key populations in need, even without reference to the SOs. Some interviewees did not believe that Unitaid referred to equity currently in grant design. However, Unitaid’s Midterm Review (2019) calls for equity to be a key criterion for pursuit of new opportunities – again, possible to judge only if it is effectively measured.<sup>191</sup>

This lack of precision prevents Unitaid telling what may be a strong story on equity – even as compromise indicators may be the understandable result of differences of perspective at Board level. Development partners recognise that making new products affordable is highly likely to have positive equity implications, and Unitaid does focus on products that will benefit patients, including key underserved populations. It should also be noted that some grants are also transformative for South-based grantees. The lack of focus on measuring end users may mean that volume of products is prioritised without being sure how well these are being used.

**Finding # 12.3: OKPI A’s 2% target restricts spending on staff to an extent that may reduce effectiveness and, possibly, efficiency.** Firstly, the 2% level is treated as a limit rather than a target, with a policy that allows spending below that target but, so far, a commitment not to exceed that. There is no evidence of a basis for the decision of 2% as the target level, although it is thought that this number may reassure donors who are worried about unnecessary administrative cost. It relates an annual numerator (Secretariat spend) to a denominator (grant portfolio) of grants agreed in past years, irrespective of their staffing requirement. It ignores changes in grant complexity<sup>192</sup> and in levels of M&E associated with grants, as well as non-grant activity such as strategic and disease-level work, or convening or liaising with stakeholders, both directly and via health policy forums.

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<sup>189</sup> For example, this UK FCDO (ex-DFID) programme identifies the proportion of its beneficiaries who are (a) below 18 years of age; (b) below the USD \$1.90 poverty line or equivalent: <https://devtracker.fcdo.gov.uk/projects/GB-1-205241/documents>

<sup>190</sup> Unitaid Midterm Review (2019, p. 19) speaks of grants that ‘are expected to have a more modest return but will deliver on Unitaid’s equity commitments’.

<sup>191</sup> p. 35.

<sup>192</sup> Available data did not allow an allocation of staff costs to different categories of grants, although this possibility was explored. However, it is clear that, for example, more intensive upstream and downstream (health systems) involvement increases the demands on Unitaid staff.

If staff are spread too thinly for their required tasks, this may reduce motivation (note declining job satisfaction in staff surveys under OKPI J) and may also contribute to disappointing scale-up achievement, which at present is reported to depend mainly on grantee efforts alone. KIIs suggested that scalability would be helped by more advocacy and communications staff who worked at country level as well as with global funders, so that, before grants concluded, demand for continuation was already built up.

Greater country-level knowledge and insight, and health systems skills, among staff would also help as regards understanding implementation. The Global Fund’s own most recent market shaping review noted that scale-up of Unitaid commodities was a country decision over which it has limited influence.<sup>193</sup> Persuading national authorities rather than donors is preferable in terms of sustainability. Unitaid’s Midterm Review proposes ‘leveraging [...] WHO Representatives and Country Offices’<sup>194</sup> (although these are variable in capacity) rather than trusted and influential local institutions and experts. Note that other comparable organisations also struggle with transition to national funding (Global Fund, Gavi, FCDO, World Bank). Grantees did seem happy with Unitaid staff capabilities in grant management, so this seems less of a problem area.

**Finding # 12.4: A second problematic area is resource mobilisationM (OKPI B), where the target seems likely to be missed.** This target seems unclear/imprecise. It states that the annual contribution in 2021 must be USD \$100 million higher than the figure for 2016<sup>195</sup> (which was USD \$187 million on an adjusted basis<sup>196</sup>), without stating how the USD \$100 million figure was arrived at or, notably, what targets there were for the years in between. So Unitaid could raise USD \$2 billion during 2017–20 and USD \$250 million in 2021 (USD \$2,250 million in total) and have failed to reach its target, or just USD \$200 million during 2017–20 and USD \$300 million in 2021 (USD \$500 million in total) and have met its target. More helpfully, two additional targets were added to OKPI B in 2019, aimed at bringing in new donors and increasing the share of contributions, which took the form of multi-year agreements.<sup>197</sup>

Within any future ToC, RM could arguably be viewed as an organisational output, in that persuading donors to allocate funding to Unitaid is one of the organisation’s key activities, without which no others can take place. Failure to raise sufficient resources is identified by Unitaid as the most serious risk facing the organisation (see RQ9). While this is indeed a priority area, given the significant uncertainty of when donors will choose to invest, annual targets may not be as appropriate as Strategy ones or, for example, rolling three-year averages.

**Finding # 12.5: Post facto grant targets are a significant absence.**

Unitaid grants close with a review of whether targets to date have been met and a forecast of what may happen going forward, typically for five years. While forecasting has become more sophisticated, it still cannot substitute for out-turn measurement at an appropriate period (say, 2–5 years) after the grant as a method of understanding grant sustainability (often seen as a key dimension of VfM) and of Unitaid’s overall contribution to desired outcomes and impact-level changes.<sup>198</sup> To the extent that sustainability is not analysed, it is not possible to conclude that current objectives and targets fully drive the transformations that are potentially possible.

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<sup>193</sup> Global Fund. Market Shaping Strategy – Midterm Review (2019) – page XI.

<sup>194</sup> p. 37.

<sup>195</sup> Note this is, in fact, only one part of the target; another states that two new core donors will be found.

<sup>196</sup> See Annex 10.

<sup>197</sup> Percentage of Unitaid contributions covered by multi-year agreements (by value of contribution) at the end of the strategic period to rise to 70%; two additional donors added during 2019–21.

<sup>198</sup> See e.g. <https://icai.independent.gov.uk/html-version/dfids-approach-to-value-for-money-in-programme-and-portfolio-management/>

Several development partners and Board representatives stated that they would prefer to verify post-grant results rather than just rely on Unitaid’s modelled approach, with important useful information being missed through this. Some grants’ effects will be well beyond the project cycle. Moreover, the assumptions on scalability applied to a grant may not be realistic. Reliable post-grant data provides better potential for feedback to other grants and the *ex ante* assumptions they will rest upon.

The current forecasts offer a simple basis for conversion to targets, although their monitoring would require increased resources and, possibly, skills – e.g. additional health systems expertise – as some development partners felt this is not currently a Unitaid strength. One informant noted that using post-grant targets may help ensure that, in the future, system operational costs (and quality) are considered as much as acquisitional costs already are now (i.e. that Unitaid and partners would be able to focus more on the scaled-up continuous use of new products by health systems, in addition to what is needed to initially introduce them).

Unitaid, grantees and donors could all benefit substantially from systematic, independent *ex post* analysis of grants.<sup>199</sup> It is quite possible that post-grant targets and monitoring would demonstrate significant and currently under-appreciated health, economic and equity benefits due to Unitaid activities. This new evidence base could greatly support resource mobilisation efforts.

**Finding # 12.6: Targets are also missing and needed with disease narratives/Afls/in the Strategy.**

Of parallel concern to the lack of targets post-grant is the lack of targets above grant level, especially at disease and Afl level and within Unitaid’s strategy linked to both global policy and national strategic plans. This means that it is hard for donors and development partners to discern with precision overall long-term objectives of Unitaid’s activity, and contribute to the impression that Unitaid acts ‘opportunistically’ rather than to a strategy which draws on explicit prioritisation (see RQ2). Targets are seen as a useful tool in driving strategy, when worked in conjunction with a culture of trust and appetite for risk (which some stakeholders feel is also lacking – see RQ9).

As a comparator, specific strategic targets have been key drivers with, for example, the SDGs,<sup>200</sup> UK FCDO(ex-DFID)<sup>201</sup> and the G7 member states’ GH policy.<sup>202</sup>

Several interviewees within the Secretariat also commented that targets within Afls and across the portfolio would be useful.<sup>203</sup> At present there is not yet a cycle: disease narrative > Afl > grants, with linked targets at each stage, and systematic feedback from grant results (including post facto) back to disease narrative/Afl revision. As a result, Afls serve currently as a project identification document, rather than being a ‘living document’ with shared ownership and continuous revision in the face of new evidence (similar to a ToC). One notable exception that did seem to be approaching an Afl rather than product target was the Optimal antiretroviral (ARV) platform, which applied relative agnosticism regarding which commodity would best function.

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<sup>199</sup> As an example, the Next Generation IRS project ‘estimated 240m people will be protected by 3GIRS over the project life and up to five years beyond (2016-24)’ and that 50,000 lives would be saved with a return on investment of 12:1, based on 2019 modelling. But that modelling had a wide range of scenarios. What happened since?

<sup>200</sup> <https://unstats.un.org/sdgs/report/2020/Overview/>

<sup>201</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/360906/DFID-external-results-Sep\\_2014.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/360906/DFID-external-results-Sep_2014.pdf)

<sup>202</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/990319/G7\\_Carbis\\_Bay\\_Report.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/990319/G7_Carbis_Bay_Report.pdf)

<sup>203</sup> ‘Looking ahead, there is potential value to monitor progress at the level of areas for intervention’ – p. 19.

## 4.4 Cross-cutting perspectives

### 4.4.1 Equity

Equity	No specific RQ on Equity: it is one of several cross-cutting themes that cuts across our RQs and for which we have coded our data.	Strength of evidence
High-level findings	<p><b>Equity is a key declared component of the Unitaid 2017–21 Strategy, and its interventions target vulnerable people by design. Unitaid’s focus on access barriers filters down to the award selection criteria.</b></p> <p><b>By addressing access barriers, Unitaid investments tackle inequities.</b></p> <p><b>While the 2017–21 Strategy manifests commitment to addressing inequities, the lack of meaningful equity-related KPIs as well as <i>ex post</i> evaluations makes it difficult to assess whether Unitaid as a whole has delivered one of its core commitments.</b></p> <p><b>While there is recognition of Unitaid’s increased intention to work through local partners, engagement with them, particularly in LMICs, could be stronger in order to enhance equity in decision making processes.</b></p>	<p>The strength of the findings in this section is mixed; for E 1–3 it is high, for E 4–6 it is medium. The wording of the equity-related KPIs, as well as a lack of <i>ex post</i> evaluations, limits the evidence available to measure the extent to which Unitaid has contributed to equitable outcomes.</p>

Reflecting Unitaid’s mission to catalyse equitable access to better health products, and equity being one of the four Unitaid’s investment commitments, we have also looked at equity as a cross-cutting principle of enquiry.

**Finding # E1. Equity is a key declared component of the Unitaid 2017–21 Strategy, and its interventions target vulnerable people by design.**

Unitaid’s 2017–21 Strategy mission makes explicit reference to promoting equity and catalysing equitable access to better health products.<sup>204</sup> Equitable access is also one of the three core SOs and one of the four investment commitments, and two out of the nine KPIs are dedicated to measuring equity (although, as we have seen under RQ 12 (Finding # 12.2) above, these could be strengthened).

Through its focus on malaria, HIV and TB, Unitaid interventions have targeted some of the most at-risk populations globally. Informants broadly agreed that this is at the heart of Unitaid’s work. There has also been recognition among informants of increasing focus through new interventions, in particular on Maternal, Neonatal and Reproductive Health (MNRH), on some of the most vulnerable.

**Finding # E2. Unitaid’s focus on access barriers filters down to the award selection criteria.**

Access barriers have been defined in conjunction with the GF and include: innovation and availability; quality; affordability; supply and delivery; and demand and adoption.

There was consensus among informants that targeting these access barriers is aligned with Unitaid’s mandate, and that Unitaid is well placed to address them. More than half of the Unitaid grants tackle more than one access barrier, with ‘demand & adoption’ being the most widely addressed barrier across all grants.

Unitaid’s focus on equitable access filters down to the award selection criteria. The grantee selection process requires applicants to design interventions that are sensitive to equity of beneficiaries. The application requirements encourage grantees to think carefully about equity considerations in terms of country selection, as well as clearly defining vulnerable populations and impact on those populations at

<sup>204</sup> Unitaid Strategy, 2017-2021.

country level. At grant level, indicators are adapted to intervention and local contexts. Informants from the PRC and grantees confirmed that, compared to other GH organisations, particularly the GF, equity features more prominently in the process of designing proposals.

Moreover, at pre-award stage, the Secretariat adopts a systematic approach for assessing potential impact on populations, which includes indicators on access for target populations<sup>205</sup> as well as more specific equity-oriented criteria – i.e. more qualitative benefits of ensuring that investment will target underserved populations and reduce inequities in health access (e.g. addressing women and children, or other particularly vulnerable populations).

**Finding # E3. By addressing access barriers, Unitaid investments tackle inequities.**

There are many examples of how interventions have had a major impact on reducing inequities by reducing access barriers on innovation & availability of health products, as well as on quality, affordability, supply & delivery, and demand & adoption.

Looking at the current portfolio, more than half of the grants address more than one access barrier. For example, the HIV self-testing (HIVST) investment has increased reach of testing to some of the most underserved groups, and has helped make these self-testing kits more affordable. Indeed, affordability is a clear element of breaking access barriers, and Unitaid has an increasingly important role in procurement and pricing negotiations across the different diseases it intervenes in. The HIVST case study provides a clear example of Unitaid's leadership in driving down prices for health products.

Another aspect of equity which Unitaid has been targeting includes children and pregnant women receiving appropriate health services. In 2016–18 the number of grants with investments in paediatric HIV, TB and malaria has been steadily increasing, with grants on paediatric tuberculosis and latent tuberculosis, PrEP, malaria vector control, malaria prevention (SMC and RTS,S) and others. In the case of pregnant women, Unitaid has for example worked to increase access for pregnant women to preventive treatment against malaria.

**Finding # E4. While the 2017–21 Strategy manifests commitment to addressing inequities, the lack of meaningful equity-related KPIs as well as *ex post* evaluations makes it difficult to assess whether Unitaid as a whole has delivered one of its core commitments.**

Although impact results on equity are, to some extent, captured at grant level, Unitaid's overarching equity-related KPIs are not helpful for capturing impact. As we have seen under Finding 12.2, equity is tracked through two strategic KPIs: the first indicator, Investing for the poorest (KPI 5.1), aims to ensure that 100% of Unitaid's investments are designed to benefit people living in low- and lower-middle-income countries; and the second indicator, Investing for the underserved (KPI 5.2), aims to ensure that 100% of Unitaid's investments are designed to benefit underserved groups across HIV (including co-infections and comorbidities), TB and malaria. In both cases, it is difficult to see how Unitaid would not achieve 100% for both indicators, given its core mandate and Afls. As such, they are not helpful for understanding how, at an aggregate level, Unitaid Afls have contributed to reducing equity and how contribution to equitable outcomes could be strengthened.

As articulated under Finding #E4, Unitaid investments tackle inequities by addressing access barriers. However, the lack of meaningful portfolio-wide KPIs and monitoring of equity risk undermining Unitaid's overarching ambition to implement an 'equity-oriented approach'. The Strategy Review team understands the challenges associated with establishing an agreement across the Unitaid Board of what equity means

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<sup>205</sup> Disease burden/target patient population that interventions would target – i.e. an understanding of the magnitude of the gap to be addressed (e.g. number of people that could benefit from an intervention). Degree of change – i.e. what difference could be expected from a technology or approach supported by Unitaid's investment (e.g. x% increase in treatment efficacy, y% coverage increase due to price decrease effected by Unitaid intervention).

in practice and how it should be measured, particularly across a diverse portfolio of interventions where inequities are context-specific. Nevertheless, as articulated in the Recommendations section, the Strategy Review team believes that the lack of clear systematic targeting of the poorest and underserved across all areas of intervention is a missed opportunity to drive and demonstrate Unitaid's impact on equity.

Moreover, although impact on equity tends to be measured at the end of specific grants, the lack of follow-up evaluations to measure impact 2–5 years after programme closure means opportunities are being missed to understand the long-term equity impact of Unitaid investments. Based on our interviews, we believe that in many cases *ex post* evaluations would show a success story. For example, the investment in HIVST is widely attributed to have catalysed innovation of HIVST kits, resulted in affordable kits, produced evidence of effectiveness of HIVST that has justified further investments, and ultimately delivered millions of test kits to underserved populations. Assessing and documenting long-term impact on equity could provide valuable evidence for improving the achievement of equitable outcomes, as well as visibility and recognition of Unitaid's work.

**Finding # E5. While there is recognition of Unitaid's increased intention to work through local partners, engagement with them, particularly in LMICs, could be stronger.**

Unitaid have clearly manifested intention and will to increase engagement through local partners, as evidenced through interviews with the Secretariat, grantees and civil society, and as set out in the Civil Society Engagement Plan. Nevertheless, several grantees from civil society and the grantees claimed that, while Unitaid is increasingly receptive, they still sometimes struggle to persuade Unitaid to invest the time and resources needed to work with local partners. Informants from the Secretariat also expressed their desire to further increase delivery through partners in LMICs. Unitaid's understanding of equity is mainly framed as concerning access and programme beneficiaries, but not the way in which Unitaid programmes are delivered. Expanding the definition of equity to include the way in which Unitaid investments are delivered may provide further organisational impetus to increase delivery through more disadvantaged partners. As highlighted in the fever management case study, for instance, there is a need for more flexibility within the operating model to enable adaptation to more varied operational contexts and a wider range of partner capacities (including from the CSO/communities sector).

The majority of grants are awarded to grantees from HICs, and informants (from the HIVST and Fever Management case studies among others) expressed that this may be a missed opportunity to reduce inequities by increasing capacity of organisations in LMICs through the process of grant-making. Unitaid investments are supposed to be catalytic, and increased participation of civil society and communities can help achieve this objective. As pointed out by stakeholders at the Secretariat and among grantees, delivering programmes through partners in LMICs increases local capacity and knowledge transfer, as well as increasing national ownership of interventions (and hence chances of sustainability). Nevertheless, there is a lack of evidence of systematic efforts to increase inclusion of partners in LMICs across the Unitaid portfolio.

With the right support, informants from the Secretariat, civil society and grantees felt local partners could do more to help Unitaid achieve its objectives. Increasing support to local CSOs and communities could help Unitaid achieve its mandate, in particular scale-up: increasing capacity of local organisations improves the sustainability of the programmes and can help ensure continuity after the investment has ended.

**Finding # E6. The presence on the Board of community and NGO representation is recognised as an important driver of equity in the process of defining AfIs. However, this representation could be strengthened in order to enhance equity in decision making processes.**

Informants across all categories generally recognised the important role of community/NGO representation on the Board in defining equitable priorities for interventions. The presence of ongoing community and civil society engagement strategies is also recognised. Some informants (from grantees and civil society in particular), however, raised the point that, given Unitaid's mandate to serve

communities and populations at risk, community representation could be stronger, as well as representation of LICs, including during development of AfIs and grant development and in all of Unitaid's committees in order to enhance equity in decision making processes. This was also in line with what found under our VfM benchmarking analysis (see Annex 9).

## 5 Overall Conclusions

There have been many achievements during this Strategy period, including in terms of innovation, access and scalability, and ‘good practice’ in process and management. We recognise some of them here – and in more detail in the main text. These highlights provide a very strong foundation to build on with new strategy. But the focus of our review is to provide insights for an *improved strategy* moving forward, and we have necessarily focused on challenges and areas to improve. This should not diminish the fact that there is much to commend in Unitaid’s performance over the 2017–21 strategic period.

We have flagged below nine areas that Unitaid can focus on in the new strategy. Some of these are on Unitaid’s radar, and some require trade-offs with other priorities. Given differing views about where to strike the balance on these trade-offs, Unitaid should reflect with its partners and be clear about the process and the positions taken so that others know and understand Unitaid’s point of view.

1. **It is clear that this Strategy period has included important work universally recognised as having improved access to innovations for vulnerable groups in LMICs.** Although the review did not examine specific projects beyond the case studies, examples include the development of lower-cost paediatric dolutegravir formulations (otherwise left to inaccurate and distasteful dosing), HIV self-tests to reach men (otherwise missing from HIV testing and, ultimately, treatment and prevention) and efforts to increase access to PrEP, which has the potential to empower adolescent girls and young women to reduce their very high levels of risk of being infected with HIV.
2. **Unitaid’s unique niche and comparative advantage are widely recognised – the ‘missing middle’ between R&D and scale on the one hand and market shaping on the other. However, Unitaid lacks an overarching strategic plan/strategy, and instead relies on a set of tactics or actions they executed during the ‘Strategy’ period.** As Alvin Toffler observed, *‘If you don’t have a strategy, you’re part of someone else’s strategy’*. In this case, Unitaid’s Strategy is essentially a blend of manufacturers’ strategy (innovation to access) and their delivery partners’ strategy (access to scale). Specifically, what appears to be lacking is a higher-level effort to look across their technical strategies and development of targets. This could drive investment decisions in the medium/long term and more sensitive measurement approaches which could help review progress and outcomes. Coupled with a stronger impact vision, Unitaid’s Strategy could more clearly illustrate its unique role and could value-add as the missing middle.
3. **However, it is hard to know whether Unitaid has focused on the ‘right things’ because Unitaid does not explicitly consider trade-offs within and across portfolios.** Unitaid’s VfM framework is strong, particularly at the award and pre-award stages; and the prioritisation process underpinning the development of disease narratives and Afls includes important criteria. But, crucially, Unitaid does not explicitly consider trade-offs between risk (in terms of technical success and scale), impact and cost-effectiveness of its investment options. This requires adopting a portfolio analysis approach, which is standard practice in the biopharmaceutical industry and has been adapted and adopted by some similar organisations, most notably the BMGF.
4. **It is unclear whether Unitaid is focused on the ‘right risks’, and identified risks need to be explicitly balanced with the speed/agility<sup>206</sup> of Unitaid’s decision making.** While we have found that Unitaid has established a robust risk management framework that represents close to or actual best practice, our assessment is that Unitaid is often risk-averse in its investment choices, more risk-averse in management, and less risk-averse when it comes to scalability.<sup>207</sup> Success for

<sup>206</sup> It is also important to recognise that risk vs agility is just one trade-off at play in determining risk; others include risk and innovation, and risk and the source of funds. These issues are currently under discussion in the context of investment decisions (at various levels).

<sup>207</sup> The view that Unitaid is risk-averse was also expressed across a range of informants, including DPs, grantees, NGOs and Unitaid. Some respondents across these categories reported that risk appetite is appropriate.

Unitaid is the adoption and scale-up of innovations they supported among their targeted beneficiaries. Yet it seems that many of their grants are scored as high-risk on scalability – i.e. that they may fail to scale up. It is unclear whether this risk is underestimated before grants are made, whether Unitaid is too bullish in terms of its ability to mitigate this risk over time, or whether it does too little to assure scale-up. There is also a visible bias towards risk assurance at the expense of agility. Obstacles to greater agility appear to relate to governance structures, including the role of the Board in approving project-level funding, as well as the consensus-style decision making. Where adaptations to the model have been made to increase agility and speed up decision making (in the form of UnitaidExplore), concerns have emerged about the impact on accountability and oversight in terms of consultation and inclusion. Further thought is needed on what drives the need for greater agility, including how and in what scenarios this is instrumental in maximising Unitaid’s effectiveness.

5. **In spite of the importance of scalability to Unitaid’s impact, there are potential improvements that could be made to strengthen guidance and emphasise earlier engagement with key scale partners.** While Unitaid’s focus on scalability has increased during the current Strategy period, and Unitaid is providing leadership in the field through the central importance it attaches to scale-up, there is a clear need and demand to continue to strengthen the approach through further guidance and clarity on the roles and expectations of key stakeholders in achieving scale-up. This is important given that Unitaid’s success is defined in terms of impact that rests on effective work to support scale-up.
6. **The extent to which governments and affected communities in LMICs are aware of Unitaid is unclear, which could pose a risk to sustainability and ongoing partnership at country levels. This is partly a symptom of limited dissemination of Unitaid knowledge products and limited engagement with country stakeholders: governments, CSOs and communities.** It is clear that Unitaid is aware of the need to strengthen its approach in this critical area, and it does have existing mechanisms to enable engagement of key constituencies (including through representation of NGOs, communities and countries on the Unitaid Board). We recognise that this is a work in progress, but it should be prioritised during the next strategy. Related to this is the dissemination of Unitaid’s knowledge products (e.g. analysis of market demand and horizon scanning), which are high-quality and of value to the wider GH community but subject to limited Unitaid investment (time/resources) in sharing this work. Prioritising this could raise the profile of Unitaid’s work and strengthen awareness of both its role in the GH architecture and its specific value-add.
7. **While Unitaid does a good job in demonstrating efficiency, its effectiveness in the 2–5 years after grants have ended is insufficiently demonstrated.** Although its grant closure evaluations meet with OECD DAC criteria, and all Unitaid grants undergo a systematic evaluation, Unitaid does not track effectiveness beyond a maximum of a year after grant closure, producing only a forecast for results beyond this point. In the context of catalytic grants, this means that grant outputs are well captured but the outcomes that these lead to are not.<sup>208</sup> Additionally, targets are not used as a tool to influence disease areas; a strategy without specific targets is a challenging one to completely review. There is recognition that Unitaid is taking a less disease-specific/product-focused (or ‘vertical’) approach than in the past. However, Unitaid would benefit from a clearer articulation of how its work contributes to the SDGs, including the UHC agenda. Insufficient evidence of effectiveness may affect recognition and resource mobilisation – an area of significant concern.

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<sup>208</sup> It should be stressed that we are not aware of others, who operate in the middle of the value chain, conducting *ex post* independent evaluations of effectiveness. More generally, this remains the exception and not the rule even among delivery partners. But we have concluded that the inability to clearly articulate ultimate effectiveness in the years beyond a grant has implications, and for us this emerges as an area that Unitaid could choose to lean into and in which it could lead the field.

8. **While Unitaid’s OKPIs generally work to increase efficiency and effectiveness, some issues remain.** Overall, the OKPIs have strengthened management discipline during the current Strategy period. But OKPI A’s limit on staff spending will increasingly limit the organisation’s ability to develop its capability in key areas – designing/managing more complex grants; engaging in-country and with health systems issues; managing post-grant M&E; developing and applying disease-level strategic planning. OKPI B, relating to resource mobilisation, is also not currently a clear approach.
9. **Unitaid’s current approach to equity is too narrow, and the existing targets could be made more helpful.** Unitaid does not sufficiently consider who benefits from its work – such an enquiry is, of course, hindered by the fact that Unitaid does not do scale-up directly. But equity is a critical element of how Unitaid describes its effectiveness. And, as the previous bullet above states, Unitaid does not track effectiveness after grant closure. There are broader concepts of equity that Unitaid could look at too, such as who does the work (where are the grantees based?), who decides Unitaid’s priorities, and who decides who does the work. Unitaid might go further in terms of soliciting inputs from country voices, be they national governments, civil society or the targeted beneficiaries, leveraging its unique role in GH and partnerships with these stakeholders.

## 6 Recommendations

The following recommendations were informed by a co-creation workshop held on 16 July with Itad, the Secretariat and members of the Policy and Strategy Committee. Each of the headline conclusions above is repeated here so the ‘source’ of the recommendation is clear.<sup>209</sup> We provide examples from our comparative landscape analysis of other organisations who, we believe, have something to offer in terms of how to address our recommendations. For example, there may be certain approaches or practices that Unitaid could adopt and adapt for their own purposes.

**Conclusion: While Unitaid’s unique niche and comparative advantage are widely recognised – the ‘missing middle’ between R&D and scale on the one hand and market shaping on the other – Unitaid lacks an overarching strategic plan/strategy, and instead relies on a set of tactics or actions it executed during the ‘strategy’ period.**

**1. Recommendation: Unitaid’s next strategy should define its goals with greater specificity.**

Although challenging and not without risk, such specificity can help with communication of Unitaid’s more direct contribution and impact, and help to define Unitaid’s operating space, so as to also protect Unitaid’s strategy from potential donor demands to work outside agreed strategic priorities.<sup>210</sup> While the strategy should continue to outline Unitaid’s broad mission and global targets, it should also define Unitaid’s goals (with defined targets) at portfolio level, such as for disease areas of focus. For example:

- How far will Unitaid’s efforts move toward malaria elimination?
- With Unitaid’s support, what will happen to HIV new infection trends in the next five years?
- Unitaid will help to ensure that X% of ‘missing’ TB cases are identified.

(It is possible that cross-cutting themes would also be appropriate, e.g. long-acting products and/patents, e.g. ‘Unitaid’s commitment to intellectual property will increase the availability of off-patent products by X%’ or ‘X% of patients will move to a long-acting formulation supported by Unitaid’.)

Importantly, this approach will require a more deliberate emphasis on the collation of outcome and impact data at disease level, through aggregation of data from across projects (at the close of projects) as well as any available country data on disease control (and related health systems strengthening) progress to span the scale-up periods post-project close up. Countries are generally routinely tracking this data from DHIS2 and large-scale surveys conducted at intervals (MIS, AIS, TB prevalence surveys, MICS, etc.) and attempts should be made to connect the Unitaid inputs to population-level outcomes, through an enhanced understanding of scalability pathways. This could be based on a (relatively simple) retrospective modelling effort, to also complement the prospective modelling effort conducted at the onset of grants, alongside insightful narrative which explores the scalability pathway in-country during the specific Unitaid strategic period, based on more qualitative assessment. This would require inputs from country governments, (former) grantees and donor/development partners, which would also extend and focus ongoing collaborations at country level. This approach would also facilitate planning and review at portfolio level, and also enable more specific consideration of cross-benefits and additionalities

<sup>209</sup> With one exception: the conclusion that ‘It is clear that this Strategy period has included important work universally recognised as having improved access to innovations for vulnerable groups in LMICs’.

<sup>210</sup> The alternative is to be explicit that Unitaid’s strategy is to focus on strategic gap filling, as a means to manage expectations.

across disease investment areas (all important if Unitaid is to also position its work within the more cross-cutting UHC space). It is noted that the same data (quantity and quality) will not be available for all diseases/investment areas which will need to be discussed in accompanying narratives. There may also be a need to highlight more qualitative than quantitative sources in some underfunded areas.

Additional goals, with accompanying targets, could focus on partnerships. For example:

- Unitaid will secure financial support/collaboration with X number of partners and/or \$X additional revenues.

Other goals (some of which are currently monitored by Unitaid) to consider systematically tracking at portfolio level could focus on tools and innovation, e.g.:

- Number of new tools moved from Phase 3 to market introduction;
- Number of new tools identified;
- Number of tools repurposed; or
- More broadly, Unitaid aims to introduce step-change innovation in each of its priority areas.

Cross-cutting goals could focus on prevention, self-test/diagnostics and treatment above and beyond disease-specific targets. These potential goals (and their counterfactual) would have to be costed and considered as part of the development of the follow-on strategy.

**Conclusion: Unitaid currently lacks the appropriate metrics and frameworks to enable explicit consideration of trade-offs within and across portfolios.**

- 2. Recommendation: The Unitaid Strategy should improve its framework for investment by incorporating clear decision criteria that make explicit trade-offs within existing AfIs and a clearly defined process to adopt new AfIs and review whether an AfI is on or off strategy pre-AfI development.** Currently the AfIs help to define the opportunity for Unitaid investment, but prior to AfI development Unitaid would benefit from clear agreement about who decides (and how) what disease areas and approaches might move to development of an AfI. Current frameworks and practices do not enable full consideration of trade-offs. Clear criteria are needed at this pre-AfI development stage, and we have suggested some indicative criteria below, many of which Unitaid already applies at various stages of review. Most importantly, this process needs to weigh one opportunity against another (within AfIs and for comparing new AfIs) and make early trade-offs more explicit, rather than consider them individually.

Criteria that Unitaid might consider to help inform trade-offs include:

*Quantitatively:*

- General % allocation to various components within an AfI
- % likelihood of success
- Proportional/comparative alignment among technical partners
- Risks
- Number lives improved/saved
- % likelihood of sustainability (i.e. Y/N existing pathway for scale)
- % of key target groups who would benefit.

*Qualitatively:*

- Importance of knowledge contribution (success or failure)
- Contribution to addressing inequities.

We recognise that this process would require considerable effort, as does its counterfactual, so we would suggest limiting a review of this nature to once or (as a maximum) twice a year. We acknowledge that it is both inherently challenging to compare opportunities of different natures and levels of maturity and that making comparisons calls for a holistic view across a broad portfolio at a given point in time, which may or may not align with the timing when opportunities materialise. However, we also recognise the challenges presented by not having a mechanism in place to evaluate portfolio-level trade-offs. We have, under Finding 2.1, highlighted the portfolio approach that is used by BMGF; while this approach is not a perfect fit for Unitaid (most notably falling short in on estimating scalability), it does give an indication of the kind of approach that Unitaid could look to develop for the new strategy period.

**Conclusion: It is unclear whether Unitaid is focused on the ‘right risks’, and identified risks need to be explicitly balanced with the speed/agility of Unitaid’s decision making.**

3. **Recommendation: Unitaid should keep under review the existing articulation of its risk appetite and the implications of this for its ways of working.** It should consider whether it has the right mechanisms in place to strike the right balance between a range of (sometimes competing) agendas, including risk, innovation, agility, inclusion and consultation, accountability, and impact, and agree with the Board where to strike the balance wherever trade-offs are identified. This could include reflecting on risk appetite for each of the aspects of the risk taxonomy and recognising that risk appetite may be different for each. Given differing views about where to strike this balance, it is somewhat difficult to make a clear evidence-based recommendation on which direction Unitaid’s risk appetite should move for each of these categories; however, from the perspective of the review team we would recommend:
- a. On **investment choices** – a learning approach to risk at the level of AfIs with a combination of higher-risk, smaller-scale investments and lower-risk bigger investments. The ‘risk’ could, for example, relate to technical foci of investment and/or operational/political context in which the investment will be made, which could also lead to funding a grantee that could be seen as more ‘risky’, though the trade-offs in terms of the potential benefit of the investment could be seen as worth it.
  - b. On **implementation** – a higher risk appetite, giving more delegated authority and accountability to grantees, including space to fail, with appropriate monitoring and learning support from the Secretariat.
  - c. On **scalability** – a lower risk appetite, with clearer analysis of what will be achieved and specific strategies to work with scale partners to maximise the potential for impact through scale-up.

We also recognise that there are trade-offs between risk appetite and the speed of decision making, and that an appetite for higher risk could come with slower decision making in order to ensure appropriate oversight and mitigating actions are in place. We also recognise that there will probably be differing views within Unitaid’s governance structures and stakeholder groups around where to strike the balance between risk and agility. Our recommendation is, therefore, for Unitaid to agree a set of policies/targets to make the balance between risk and agility explicit and provide a basis for future learning and adaptation. This will probably require consultation with the Board and grantees (in the first instance), as well as with funders and partners to clarify expectations and priorities. These could include:

- Define clear targets or parameters for the proportion of Unitaid’s investments that are high, medium and low risk.

- Differentiate governance/oversight mechanisms that are required for each level of risk. This might also take into consideration the size of investment, potentially combining a risk score and investment value to arrive at an overall score that determines level of oversight/sets expectations around speed of decision making and future iteration.
- Be explicit about how key stakeholder groups will be involved in decision making and oversight for design and implementation of all investments.

Key strategic questions to answer as part of this process could include:

- Is agility the most important priority, and in all circumstances? Or are there some theatres of engagement where the context is more stable and slower decision making is acceptable?
- Are there some innovations that require more careful consideration and consultation in order to maximise long-term benefits and sustainability?
- What capacities or governance arrangements (delegated authorities, etc.) enable the Board to have sufficient oversight and reassurance without unduly slowing decision making; and what mechanisms are needed for managing exceptions?

Unitaid could also consider USAID's approach,<sup>211</sup> which defines risk appetite in terms of the following risk categories: programmatic, fiduciary, reputational, legal, security, human capital and information technology.

**Conclusion: In spite of the importance of scalability to Unitaid's impact, there are potential improvements that could be made to strengthen guidance and emphasise earlier engagement with key scale partners.**

4. **Recommendation: The Secretariat should review, revise and strengthen its approach on scalability.** Recognising that the approach to scalability has strengthened over the current strategy period, but noting that there is scope to strengthen further, the co-creation workshop generated ideas on how this could be done, which we have reflected on and capture below:
  - More emphasis on grantee proposals for achieving/further exploring scalability, which can provide basis to forecast prospects for achieving scalability (note that this emphasis may be better placed after selection to ensure the bar for successful proposals does not deter potential grantees, particularly those from the global South);
  - Detailed guidance on how to achieve/work towards (given existing evidence base) scalability, differentiated for specific contexts (e.g. where no scaling partners, product type, disease burden);
  - Stronger Secretariat engagement on scalability and clearer division of labour with grantees and other partners;
  - Early and explicitly defined engagement with scale partners, and potential representation on the Unitaid Board;
  - Emphasis on communicating results, learning and opportunities for scale-up through grantees and country government partners, while prioritising a lot of space for discussion, wider learning and planning.

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<sup>211</sup> U.S. Agency For International Development Risk Appetite Statement – June 2018.  
[https://www.usaid.gov/sites/default/files/documents/1868/USAID\\_Risk-Appetite-Statement\\_Jun2018.pdf](https://www.usaid.gov/sites/default/files/documents/1868/USAID_Risk-Appetite-Statement_Jun2018.pdf)

**Conclusion: The extent to which governments and affected communities in LMICs are aware of Unitaid is unclear, which could pose a risk to sustainability and ongoing partnership at country levels. This is partly a symptom of limited engagement with country stakeholders: governments, CSOs and communities.**

- 5. Recommendation: Unitaid should review and revise its engagement strategies, including for country government and civil society engagement and knowledge dissemination.** While we recognise that Unitaid does have existing mechanisms to enable engagement of key constituencies (including through representation of NGOs, communities and countries on the Unitaid Board), Unitaid should review and revise its approach to country government and civil society engagement to ensure these voices are appropriately included in investment decision making. Perhaps most importantly, governments and civil society need to be engaged *prior* to the AfIs being selected for development, to ensure that there is sufficient country commitment and community engagement. This is not necessarily straightforward to achieve, given the stage in solution development that Unitaid engages and the profile that it has at country level; there are also often congested partner landscapes at country level. We also recognise that there are potential resource implications for Unitaid to consider. A key question for Unitaid to reflect on is whether (and what) additional measures are needed to engage these constituencies, and the extent to which there is scope to build on existing structures.

Unitaid is encouraged to develop new processes, or better utilise existing ones, to introduce the ideas to country governments and solicit not only their feedback but also their input within a constellation of options and in the context of existing country plans. Similarly, new approaches to engage community representatives, via appropriate CSOs or networks, are recommended to bolster the current focus group approach. Some other GH partners have tended to limit in-country engagement with civil society, so as to avoid broad raising of expectations or giving rise to inconclusive dialogue around national or subnational priorities. However, where this has been tackled directly, such as through the GF engagement mechanisms when planning for grant applications, there is a broad view that this has positively shaped the overall investments, giving priority focus to addressing inequities from the start and, overall, more effective prioritisation of investments.

Unitaid should also develop a strategy to inform how they can transfer more of the knowledge generated from their investments into policy and practice. In particular, the strategy should clearly define their priority audiences, e.g. donors, grantees, civil society, country governments, and normative agencies such as WHO. While there is good evidence that Unitaid-supported work has informed WHO guidelines, more could be done to disseminate Unitaid's products such as disease area narratives and technology landscapes, as well as lessons from projects and in disease areas to inform and drive policy and practice across countries and development partners. Document dissemination should be complemented with convening of GH actors to facilitate knowledge sharing, gain new insights and influence policies and practices. While this is not an insignificant undertaking, such an effort would dovetail with building information exchange with development partners and expanding engagement with country governments. There should be clear indicators and targets that help track the success of this strategy.

**Conclusion: While Unitaid does a good job in demonstrating efficiency, its effectiveness in the 2–5 years after grants have ended is insufficiently demonstrated.**

- 6. Recommendation: Unitaid should invest in independent *ex post* evaluations** (i.e. beyond a year after grant closure), where these might be achievable at reasonable cost. *Ex post* evaluation is both a relatively new area for development partners and a challenging one for those partners

involved catalytically and at earlier stages of the value chain. However, the prospects of developing expertise and generating learning in this area should be viewed as major potential future assets for Unitaid. One useful precedent is Millennium Challenge Corporation’s requirement to conduct *ex ante*, *ex post* and independent ‘evaluation-based economic return on investments’.<sup>212</sup> Another is the less systematic, but nevertheless increasing, focus of the UK FCDO in *ex post* evaluation. Attribution is a major potential challenge. But if delivery and funding partners (such as the GF, Gavi, PEPFAR and PMI, as well as countries) could be persuaded to jointly fund such evaluations then this problem could be addressed as ‘jointly achieved results’. The evaluations would be useful in building a credible analysis of contribution, even if attribution was impossible to define. An ‘outcomes harvesting’ approach might be helpful in arriving at a specification especially of those outcomes that are unexpected. Note that in some cases it will be appropriate to conduct evaluations (not only *ex post* but also *ex ante* and on grant closure) in relation to full disease areas in addition to single grants. This will make sense where there are various grants which contribute to a joint objective (e.g. reducing HIV infections or malaria mortality), especially if there are interdependencies between the grants. Such wider evaluations would naturally be linked to revised disease-level strategies (Recommendation 1). No matter if it is imperfect, *ex post* evaluation capability will allow Unitaid to far more robustly demonstrate the effectiveness of funding invested through the organisation – something that is likely, but until now has not been provable. Naturally, the costs of such evaluations are relevant as well as their benefits, and for this – and for learning purposes – it may be prudent to begin by conducting only some pilot *ex post* evaluations for selected key grants.

**Conclusion: While Unitaid’s organisational KPIs generally work to increase efficiency and effectiveness, some issues remain.**

7. **Recommendation: Unitaid should revise selected organisational KPIs.** OKPI A’s limit to Secretariat spending (especially on the key cost driver, staff) should be relaxed to allow for more easily strengthened capabilities in key areas – such as: in-country engagement; health system skills; disease-level analysis; and post-grant (*ex post*) evaluation – as are identified as priorities for the new Strategy. It may be that a new target level, such as 2.5% or 3%, is appropriate going forward, though this would depend on a careful assessment of human resource needs, costs and likely benefits per role. If the possibility of joint development of disease-specific strategies with other partner organisations (Recommendation 1) is taken up, then it may be possible to jointly fund one or more positions in disease-level analysis and post-grant evaluation. OKPI B’s approach to RM targeting also needs revision. Revised targeting should achieve better clarity on annual/cumulative objectives, rather than merely stating a goal for any single year or the final year of the organisation’s five-year strategy. This may include multi-year rolling average or full Strategy targets. If disease-level strategies with goals are also developed (Recommendation 1), then there may be opportunities with some donors for RM to be tied to achievement of these objectives. These two revisions (together with continuing review of all KPI definitions and targets) will help ensure and demonstrate Unitaid’s commitment to maximising internal efficiency and effectiveness to the same extent as its focus on external objectives.

**Conclusion: Unitaid’s current approach to equity is too narrow, and the existing targets could be made more helpful.**

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<sup>212</sup> <https://www.mcc.gov/our-impact/err>

8. **Unitaid should consider the equity dimensions of its work beyond the removal of access barriers.** In particular, Unitaid should expand its definition and application of equity principles to include the way it develops and implements interventions in a more equitable manner. The equity and inclusion lens needs to be broadened to consider who does the work (grantees), and who decides the what and who (governance and epistemic community). Given Unitaid’s commitment to equity and delivery through partners in LMICs, there is an opportunity for Unitaid to demonstrate leadership in this area by:

- Developing and applying a broader definition of equity to processes and practices, with increased focus on the actual beneficiaries of grants and, potentially, scale-up.<sup>213</sup>
- Developing concrete plans to increase delivery through partners in LMICs, to increase capacity of organisations in LMICs, which could include:
  - encourage applications from grantees in LMICs, reducing access barriers for organisations in LMICs to act as lead grantees where possible, or requiring consortiums to include LMIC partners<sup>214</sup>
  - set expectations of grantees to build capacity of local partners
  - issue smaller grants to increase likelihood that these can be led by a national organisation from a LMIC
  - encourage and support more specific engagement across grantees in comparable country settings or working in similar technical spaces with common aims
  - set and monitor targets/KPIs to show extent of delivery through LMIC partners.
- Strengthening engagement of key stakeholder groups, particularly from LMIC governments, civil society and affected communities:
  - in the development of AfIs
  - to promote scalability and sustainability of the programmes, and to help ensure continuity after the investment has ended.
- Conducting evaluations that draw lessons and show impact of CSOs/NGOs in scale-up.

Unitaid should also develop more specific equity indicators that enable greater portfolio-level disaggregation of data on equity-related categories to improve targeting and monitoring. Given the centrality of equity in its mission, Unitaid should strengthen its approach to equity through the following adaptations to provide accountability and show results at an aggregate level:

- Develop equity indicators to show how disadvantaged people’s needs have been addressed, which would help with monitoring progress, measuring VfM, supporting RM, and understanding what the trade-offs are in pursuing equity compared to other objectives.<sup>215</sup> Key dimensions that should be monitored systematically are gender, age, and poverty. Indicators could be divided into two types:
  - 1) a limited number of overarching dimensions measured across all of the Unitaid portfolio. These could include: a) the number of people who are in poverty who have benefited from Unitaid grants, both directly and through subsequent scale-

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<sup>213</sup> We believe that in terms of Unitaid’s work in expanding access, equity is best expressed as ensuring Unitaid grants benefit disadvantaged groups, whether such disadvantage relates to additional disease burden or barriers to care. We also recommend Unitaid expand its definition of equity to include inclusiveness in its programme delivery, in particular to encourage working with a diverse range of individuals and organisations from LMICs.

<sup>214</sup> Note that in broadening the base of grantees and partners, Unitaid must be mindful of likely trade-offs between inclusiveness and efficiency and effectiveness (which has implications in turn for equity in population benefits).

<sup>215</sup> E.g. in West Africa disease burden might not be as high, but more fragile contexts, weak health systems and less donor funding may mean there is a strong case to invest there on the basis of equity. At the same time, there are vulnerable populations in bigger MICs which are in theory excluded from Unitaid grants, which could also be targeted on the grounds of equity. Unitaid could also consider more targeted approaches to products that are available but not widely accessible for marginalised groups.

up. There are well-developed methodologies for identifying this population group, such as the World Bank definition and approach. This would show Unitaid's commitment to addressing SDG1 on ending poverty; b) gender distribution of benefit, which is also relatively easy to measure and speaks to SDG5 on gender equality.

- 2) target populations by disease area and geography.<sup>216</sup> Articulating how grants help mitigate these situations requires some investment in maintaining current data, some in incorporating these issues into routine evaluations, and a willingness to differentiate M&E according to geographical context.
- Devise specific targets that show how vulnerable/marginalised populations' needs have been addressed. The lack of clear systematic targeting of marginalised groups across all AfIs puts into question whether Unitaid's approach is in fact equity-based. Grantee reporting for key population groups is not captured by Unitaid's aggregate numbers.
- Review progress through various mechanisms. These could include conducting an equity audit, involving both overarching and grant-specific types of equity indicator, as part of each midterm and full strategy review, as well as including equity in each end-of-grant evaluation (which Unitaid already does).
- Unitaid should measure the impact on equity through *ex post* evaluations 2-5 years after grant closure (see also Recommendation 7). While we recognise that this will be a substantial endeavour, the above suggestions are intended to help in this regard.
- Greater definition and disaggregation of equity approaches could also be made part of grant proposals and agreements. Measurement should be proportionate so that, for example, grants with smaller budgets might only measure for poverty and gender. There is a cost to equity M&E, not only directly in the resources needed to do it effectively but in potential trade-offs against efficiency and effectiveness. The Board will have to decide on strategic questions, such as whether to focus more on countries with most health need or more on countries best able to facilitate and scale up pilots; and how to consider pockets of poverty in higher income countries (UMICs).

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<sup>216</sup> E.g. in some countries women and girls carry a heavier HIV disease burden than men and are not served accordingly. In some countries men who have sex with men or the trans population are similarly disadvantaged with HIV. In some countries the male prison population or male migrant workers are more affected by TB or malaria. Irrespective of disease, rural, ethnic or religious groups could be most disadvantaged.