

End of Project Evaluation for Unitaids Investment in Enabling TB Preventive Treatment in High-Risk Populations

Unitaid

24 July 2026



EXECUTIVE SUMMARY

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ACRONYMS

Acronym	Definition
1HP	One-month daily isoniazid and rifapentine regimen for TB preventive treatment
3HP	Three-month once-weekly isoniazid and rifapentine regimen for TB preventive treatment
3HR	Three-month daily isoniazid and rifampicin regimen for TB preventive treatment
API	Active pharmaceutical ingredient
CBO	Community-based organisation
CCSE	Civil society and community engagement
CHAI	Clinton Health Access Initiative
CHIP-TB	Child household contact investigation and TPT delivery study under I4TB
CLHIV	Children living with HIV
COP	Country Operational Plan
CSO	Civil society organisation
DOLPHIN	DOLPHIN studies on dolutegravir and rifapentine-based TB preventive treatment
DR-TB	Drug-resistant tuberculosis
DTG	Dolutegravir
EMAV	Early Market Access Vehicle
FDC	Fixed-dose combination
GDF	Global Drug Facility
HHC	Household contact
I4TB	IMPAACT4TB
IPT	Isoniazid preventive therapy
KNCV	KNCV Tuberculosis Foundation
LONGEVITY	Unitaid-funded project on long-acting formulations for TB preventive therapy
MDR-TB	Multidrug-resistant tuberculosis
MPP	Medicines Patent Pool
NTP	National Tuberculosis Programme
PEPFAR	United States President's Emergency Plan for AIDS Relief
PLHIV	People living with HIV
RPT	Rifapentine
TAG	Treatment Action Group
TB-CHAMP	TB Child and Adolescent Multidrug-Resistant Preventive Therapy trial
TPT	Tuberculosis preventive treatment
WHO	World Health Organization

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Introduction

Tuberculosis (TB) remains the world's leading infectious killer. Worldwide, one in four are infected with TB bacteria, however only 5-10% will go on to develop active TB disease. Preventing this progression is a cornerstone of the World Health Organization (WHO) Global End TB Strategy (2015-2035) and WHO recommends TB Preventive Treatment (TPT) for those most at risk: People living with HIV/AIDS (PLHIV), household contacts of people with active TB disease, and other high-risk groups, supported by effective screening, early diagnosis, and prompt treatment.

For decades, TPT uptake remained limited because existing regimens were long (6–36 months), making them impractical to deliver in resource-constrained settings where TB burden is highest. A major advance came in 2018 when WHO recommended shorter rifapentine-based regimens (3HP and 1HP¹). However, country and donor adoption lagged due to unresolved questions about use with dolutegravir among PLHIV, the high cost of rifapentine (US\$72) from a single supplier (Sanofi) with insufficient production capacity in relation to global need, and uncertainty about implementing the new regimens within weaker health systems. The absence of a fixed-dose combination (FDC) for 3HP and 1HP also meant an increased pill burden, raising concerns about acceptability and treatment completion. For children, the lack of a child-friendly 3HP formulation and dosing guidance for the youngest age groups further constrained access.

The IMPAACT4TB project

To address these challenges, Unitaid launched the 'Increasing Market and Public Health Outcomes through Scaling Up Affordable Access Models of Short Course Preventive Therapy for TB (IMPAACT4TB) (I4TB) project in 2017, led by the Aurum Institute (Table 1). Following the original project, additional resources were added in 2022 to address priority TPT access barriers for children and pregnant women.

The flagship I4TB project formed part of Unitaid's broader TB prevention portfolio, which comprised multiple complementary investments targeting different population groups and both drug-sensitive (DS) and drug-resistant (DR) TB. The portfolio also included several cross-cutting enabling investments, such as support to the WHO Global TB Programme and WHO Prequalification, aimed at accelerating the adoption of new TB drugs and formulations and strengthening normative guidance.

Table 1: Unitaid IMPAACT4TB overview

Goal: To reduce TB incidence and deaths among PLHIV and child contacts through sustainable implementation of affordable, quality-assured 3HP			
Outcomes: Increase the number of PLHIV (15-49) and child contacts <5 years starting treatment with affordable, quality-assured 3HP; and contribute to revising WHO preventive therapy guidelines based on evidence generated.			
Grantees: Aurum Institute (lead), Implemented with CHAI, KNCV, Johns Hopkins University (JHU), Treatment Action Group (TAG)			
Duration	Budget	Key objectives	Focus countries
Original grant 2017-2022	US\$ 58.9m	To catalyse access to short-course TPT for PLHIV and child contacts by removing critical market and access barriers and creating the conditions for sustainable scale-up	12 high burden countries: Brazil, Cambodia, Ethiopia, Ghana, India, Indonesia, Kenya, Malawi, Mozambique, South Africa, Tanzania, and Zimbabwe
Extension 2022-2025	US\$ 19.1m	To increase the number of child and adult household contacts (HHCs) and PLHIV started on TPT and contribute to the revision of WHO guidance for children and pregnant women	
Total project period: 8 years, 4 months (Total value of US\$ 78.0m)			

¹ 3HP and 1HP combine rifapentine and isoniazid, taken once weekly for 3 months (3HP) or daily for one month (1HP) to kill latent TB infection. Source: IMPAACT4TB Clinical Guidelines.

Evaluation objectives, framework and methodology

This end-of-project evaluation assesses the extent I4TB and Unitaids's complementary TB prevention investments accelerated access to quality-assured, affordable rifampentine-based TPT for high-risk groups, with a focus on effectiveness, scalability, impact, and sustainability. It also examines the contribution of Unitaids through its roles as a pathfinder, investor, and influencer. As a learning-focused evaluation, it explores key lessons on community and civil society engagement (CCSE) and market shaping. While centred on I4TB, the evaluation also considers other Unitaids TB prevention investments to assess coherence and contributions to portfolio-level results. Figure 1 summarises the evaluation methods and data sources. A key limitation was the considerable time elapsed since the original I4TB grant in terms of stakeholder recall and availability, with further detail and mitigations in the full report.

Figure 1: Evaluation methods and data sources

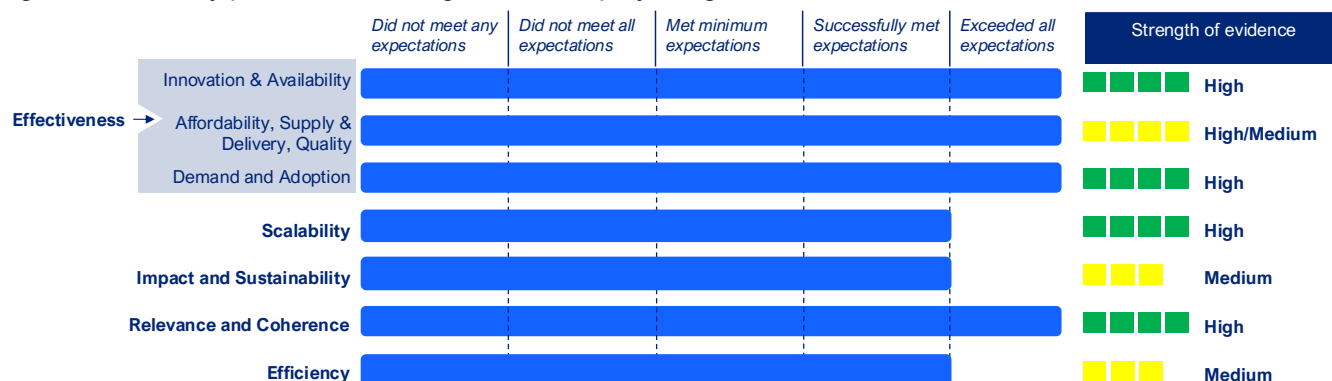


Summary of project performance and Unitaids's contribution

Figure 2 provides an overall summary of project performance across the Organisation for Economic Co-operation and Development - Development Assistance Committee (OECD DAC) evaluation criteria, and strength of evidence.

I4TB was a highly successful Unitaids investment. The project exceeded expectations in addressing priority access barriers to rifampentine-based TPT and in its relevance and coherence, while meeting expectations across the remaining evaluation criteria. It made a substantial contribution to global adoption of short-course TPT, with more than 100 countries procuring rifampentine-based TPT by 2025, and shorter regimens accounting for almost half of all TPT initiations globally. While TPT scale continues beyond the close of I4TB country activities in 2022, countries are not on track to reach the ambitious global target of 90% coverage by 2027 among high-risk populations. In 2024, TPT coverage reached 58% among PLHIV and 25% among household contacts—well below the target but representing substantial progress from baseline levels of less than 40% and less than 5%, respectively.

Figure 2: Summary performance rating of the I4TB project against OECD DAC evaluation criteria



The evaluation finds that alongside its investor role, Unitaid played a particularly strong pathfinder and influencer role in I4TB. Key contributions included shaping the project to address critical evidence gaps important for global 3HP demand, supporting studies on 3HP use among pregnant women and young children, championing a 3HP fixed-dose combination (FDC) and child-friendly formulations, and engaging with PEPFAR, manufacturers, and other stakeholders to accelerate policy adoption and market development. Examples of Unitaid's *direct contribution* to key I4TB achievements are summarised in Figure 3.

Figure 3: Unitaid contribution assessment

Role	I4TB key achievement	Assessment of Unitaid contribution			Strength of evidence
		Low	Medium	High	
 Pathfinder	- Foundational DOLPHIN studies demonstrating safety of 3HP for PLHIV on dolutegravir, supporting market confidence in 3HP demand - Closed evidence gaps for groups often neglected in clinical and operational research (children and pregnant women). - Stimulation of generic 3HP and 1HP, including FDC	[Full bar]			High
		[Full bar]			High
		[Full bar]			High
 Investor	- Absorbed early market shaping risks for Sanofi and generic rifapentine formulations - EMAV for paediatric-friendly rifapentine, securing same price as adult formulation, and cheaper vs. alternatives - Global public goods: clinical and operational evidence in different epidemic and health systems contexts - Scale of 3HP for PLHIV and child and household contacts	[Full bar]			High
		[Full bar]			High
		[Full bar]			High
		[Full bar]			High
 Influencer	- Key brokering role with PEPFAR and partners to agree to US\$15 for Sanofi rifapentine product - Global TPP for adult 3HP FDC - PADO engagement to agree on a paediatric dispersible 150mg rifapentine in place of an FDC - Coordination with WHO, PEPFAR, the Global Fund, manufacturers, civil society and country stakeholders, helping shape discussions around TPT access, evidence priorities, pricing and implementation approaches.	[Full bar]			Medium
		[Full bar]			Medium
		[Full bar]			Medium
		[Full bar]			High

Evaluation key findings

The main evaluation report contains 15 findings, along with two learning briefs: on CCSE and market shaping, analysis of what worked well and less well across the project components and their implications for future Unitaid investment. The evaluation findings and insights are summarised into the 5 key finding areas below.

Key finding area 1: I4TB catalysed a 70% reduction in the price of 3HP, market entry of quality-assured FDC products and a child-friendly formulation, and strengthened supply resilience through market diversification. This was the combined result of direct Unitaid engagement, I4TB consortium efforts, and a well-coordinated effort amongst key partners.

Unitaid market shaping achieved the first agreement with Sanofi to lower the price of 3HP from US\$72 to US\$15 per adult course. Unitaid's added value was described as its ability to convene and coordinate actors including Sanofi, PEPFAR, the Global Fund, iPlus solutions, CHAI, MedAccess and PAHO early on, and flexibility to apply the most appropriate market shaping instruments at different timepoints and for different products. Clarity from PEPFAR on a target price was a key breakthrough, with Unitaid taking on early market risks through its adjustable purchase order with Sanofi and targeted market shaping support to generics entering the market. This was later complemented by a Volume Guarantee (VG) by MedAccess to support multi-year market stability. The price of 3HP has since further declined to under US\$10 through the VG and subsequent market shaping efforts. Later in 2024, Unitaid and I4TB also implemented an Early Market Access Vehicle (EMAV) to encourage demand for a paediatric-friendly rifapentine. This 150mg dispersible formulation developed by Lupin and WHO Prequalified in 2024 is considered a "game-

changer” for children at risk of TB disease, and the EMAV a valuable ‘demand-driven’ market shaping tool for new product introduction.

“From the \$72 per patient cost down to \$15 was one of the reasons that the government eventually came to agree that we can move to shorter regimens.” (Tanzania stakeholder)

Early on, 3HP demand significantly outstripped available supply, which was also challenged by impurity concerns, leading to rationing. Use of the ‘ARV procurement working group’ to coordinate 3HP procurement became a best practice model for procurement coordination, offering good insights on managing the demand and supply interface in a multi-donor, multi-stakeholder context.

Key Finding Area 2: Evidence generation was fundamental to policy change and scale-up, most significantly for introducing 3HP within HIV services, which was a key scale platform.

Evidence generated through I4TB was highly influential in shaping global and national policy. In total approximately nine WHO policies and guidelines were significantly, or in-part, informed by work under I4TB to date, including the foundational WHO TPT 2018 and 2020 guideline expansion for 3HP on PLHIV taking dolutegravir, as well as the WHO TPT 2024 guidelines on pediatric dosing, and the 2025 HIV treatment guidelines. Together with negotiations with PEPFAR on 3HP affordability, the DOLPHIN study evidence which informed the 2018 TPT guidelines was a key enabler of market confidence. All 12 I4TB countries updated their TPT policies during the project period and as of 2025, more than 100 countries are procuring 3HP.

“These studies were the key ones informing policies...and government decisions. And the WHO endorsement was key.” (Global stakeholder) *“The Aurum-led consortium has been the go-to group for accessing evidence on TPT.”* (Global stakeholder)

Unitaid’s WHO enabler grant was highly complementary to I4TB, with WHO playing a central role in advancing rifapentine-based TPT. In particular, WHO played an important role in ensuring I4TB research questions and design aligned to key policy priorities. The WHO guidelines for TPT were updated multiple times over 2018 to 2024, utilizing the results of Unitaid-supported research, with WHO coordinating regularly with National TB Programs to accelerate their adoption. WHO enabler support included the development and publication of ‘Guidance on evidence generation for new regimens for TPT’², which consolidated lessons learned from the research supported by I4TB and other TPT trials.

The 2022 project extension had a significant focus on closing evidence gaps for pregnant women and children living with HIV (DOLPHIN-Moms and DOLPHIN-Kids). These studies, together with the EMAV for a dispersible rifapentine, reinforced Unitaid’s leadership in ensuring these groups are not left behind. The project also generated practical implementation evidence to guide decision-making on optimal delivery models and choice of 3HP vs 1HP regimens in different contexts.

Key Finding Area 3: Community engagement was essential to successful product introduction, particularly where communities and health providers were ‘starting from a deficit’.

A distinctive feature of I4TB was the strong integration of CCSE. Civil society organisations played a critical role in building treatment literacy, addressing misconceptions about TPT, supporting demand generation, and maintaining confidence during supply disruptions and product quality concerns. Stakeholders consistently reported that TPT introduction required rebuilding confidence among providers and communities following decades of experience with longer regimens where acceptance for 3HP was ‘starting from a deficit’

“The impacts of [I4TB] cannot be underestimated. It has shaped and made possible the very rapid uptake of 3HP. And nowadays, if you come to [these] countries, people talk about 3HP as if it’s just normal. As

² WHO (2025). Guidance on evidence generation on new regimens for tuberculosis preventive treatment. Available at: <https://tbksp.who.int/en/node/3187>

if it's nothing special, which is, of course, good but then you forget it's only been a few years." (I4TB implementing partner)

Despite the overall effectiveness of CCSE, the scale and duration of funding allocated underestimated the level of effort required to sustain community engagement and policy influence. The small grants programme represented less than 1% of the total I4TB budget. While widely regarded as catalytic, the one-year funding cycle limited sustainability, continuity of advocacy efforts, and long-term relationship building with policymakers and communities offering important lessons for future CCSE. Since the close of I4TB, TB civil society partners have also been significantly affected by the dismantling of USAID in 2025 which had been the largest bilateral TB funder, further undermining sustained community engagement in TB.

Key Finding Area 4: I4TB catalysed uptake of 3HP for PLHIV and child contacts. It was less successful in adoption of TPT for adult household contacts due to lower prioritisation at the policy level. The project made a significant contribution to the country and global scale-up of rifapentine-based TPT.

By the end of 2022, more than 504,000 PLHIV and nearly 45,000 household contacts had initiated TPT through I4TB-supported and catalytic scale-up driven by governments and other partners across the 12 project countries. Uptake was supported by strong CCSE and I4TB's deliberate integration of 3HP into existing structures and systems, including data systems, which strengthened country ownership and implementation.

I4TB also contributed to substantial global scale-up. WHO reports the share of TPT initiations using shorter regimens (including 1HP and 3HP) increased from less than 1% in 2018 to 44% in 2024. This represents a growth from 0.19 million people in 52 countries in 2021, to 2.1 million people in 88 countries in 2024.

The evaluation examined trends in 3HP coverage after I4TB country activities ended in 2022. Coverage among PLHIV has levelled off since its 2020 peak, reaching 58% in 2024, suggesting that earlier intensive enrolment efforts were not sustained. Initiations among household contacts are increasing, reaching 25% in 2024, but the gap remains substantial. Overall, global TPT coverage has progressed, but not at the pace needed to reach the 2023 UN High-Level Meeting target of 90% coverage among high-risk populations.

"The need might be there, but the demand is not there...because programs aren't doing contact tracing." (Global Stakeholder)

Many of the barriers that constrained early TPT scale-up have now been addressed at global and country level. The principal constraints to future growth increasingly relate to service delivery, particularly household contact investigation which is under-funded (USAID was previously a key funder), screening, diagnosis, provider confidence, and linkage to care, along with financing.

Key Finding Area 5: Unitaïd demonstrated agility in seizing opportunities to advance the 3HP agenda and employed a flexible approach to respond to emerging evidence and implementation experience. Together with Aurum's strong leadership and consortium partners, this contributed to the project's overall effectiveness.

Throughout I4TB, Unitaïd adapted its approach in response to evolving market conditions, implementation challenges, and emerging evidence. Examples included incorporating the DOLPHIN studies during grant development to address a critical evidence gap for PLHIV on dolutegravir, which were implemented relatively swiftly in existing Aurum research sites; strategically expanding the US TBTC Study 35 to include additional African-based sites to address an important evidence gap on 3HP dosing for children under 2 years; tailoring market-shaping approaches and instruments as the rifapentine market evolved; reallocating resources to address supply disruptions and nitrosamine-related challenges; supporting procurement and scale-up in additional countries beyond the original project scope; and extending the project to address priority access barriers for children and pregnant women (DOLPHIN-Moms and DOLPHIN-Kids studies). Stakeholders consistently viewed this flexibility as a key strength, enabling Unitaïd and its partners to maximise opportunities for impact, rapidly address emerging barriers, and maintain momentum towards global adoption of rifapentine-based TPT. Aurum, based in South Africa, was a strong lead partner and stakeholders consider the full consortium was well designed and leveraged its expertise and networks.

Recommendations for Unitaid

Recommendations are provided on: (i) Unitaid's investments in TPT; and (ii) broader recommendations for Unitaid's grant-making approach across its portfolio, in support of its roles as a pathfinder, investor and influencer within the global health architecture. They integrate feedback from Unitaid, the I4TB consortium, and other key stakeholders consulted as part of the evaluation. Expanded recommendations are included in the full evaluation report.

Part 1. Recommendations for Unitaid's investments in TPT

These recommendations consider key trends relevant to TB services, notably the significant shift in the TB funding and implementation context, emerging technologies that bring TB diagnosis closer to communities, including near-point-of-care (NPOC) and tongue swabs which are recommended in the latest Global Fund guidance for Grant Cycle 8, and Unitaid's strong credibility within the TB community through I4TB and its wider TB portfolio and engagement.

Recommendation 1: Consolidate remaining I4TB gains by (i) accelerating policy uptake relevant to priority populations, and (ii) supporting regional API manufacturing

- Unitaid should collaborate with WHO to rapidly translate the forthcoming DOLPHIN-Moms and DOLPHIN-Kids evidence into updated global guidance and support timely country dissemination, in collaboration with TAG and other partners.
- Unitaid should collaborate with the Global Fund, WHO and civil society to support countries to incorporate forthcoming WHO guidance into Global Fund Grant Cycle 8 planning and national policies, using existing TB investments and partnerships to provide technical assistance, where needed. This approach is already being applied through Unitaid's Advanced HIV Disease grant to Aurum and other Aurum-led TB activities.
- Unitaid should assess the early results of investment with CPT Pharma and identify opportunities for continued support if promising. This could be linked with Unitaid's other regional manufacturing efforts.

Recommendation 2: Integrate TPT with new TB screening, diagnostics and community-based delivery to close the gap in TPT uptake - supporting more integrated, people-centred approaches for priority populations

- Unitaid should promote integration of TPT into community-based TB screening and diagnostic pathways, using portable digital X-ray/CAD in the near term, and emerging near-POC diagnostics and simplified specimen collection approaches as they become available.
- Unitaid should support implementation models that strengthen contact investigation and active case finding, recognising these are now among the principal constraints to expanding TPT.
- Unitaid should continue prioritising integrated, people-centred approaches that bring TB services closer to vulnerable populations.

Recommendation 3: Sustain Unitaid's leadership in developing TB prevention and treatment options for underserved populations, including children and pregnant women

- Unitaid should explore strategies to accelerate country availability of child-friendly formulations. This could include engaging civil society for national advocacy and country support to address bottlenecks in product registration.
- Unitaid should build on I4TB lessons from paediatric market shaping. Where achieving price parity with adult formulations is not feasible, explore mechanisms to incentivize inclusion of child-friendly products in domestic financing strategies, and in Global Fund and other financing mechanisms.

Recommendation 4: Leverage Unitaïd's influencer role to ensure TPT and complementary activities are covered as high burden countries plan for the transition to domestic financing

- Unitaïd should bring the lessons learned from I4TB and other TB prevention projects, and its credibility in demand forecasting to inform national and subnational planning and budgeting processes. In some cases, it may be strategic for Unitaïd and/or its partners to participate directly in domestic financing discussions.

Recommendation 5: Continue to position Unitaïd for the next generation of TB prevention innovations

- Build on Unitaïd's leadership in TB prevention by convening partners around future TPT innovations and preparing for TB vaccine introduction. Use Unitaïd's convening role to help clarify delivery models, financing approaches and country readiness for future TB prevention technologies.

Part II. General recommendations for Unitaïd across investment areas

The following cross-cutting recommendations draw from the market shaping and CCSE learning themes and other evaluation insights, and reflect the current health financing context.

Recommendation 6. Continue investing in integrated access strategies where relevant

- I4TB's effectiveness stemmed from addressing multiple barriers to rifapentine access simultaneously, including supply constraints, limited clinical evidence, lack of child-friendly formulations, weak demand, and policy hesitancy. Future Unitaïd investments should consider this comprehensive approach, acknowledging I4TB's comparatively large value within Unitaïd's portfolio.
- Future investments should strengthen alignment between supply and country demand activities, informed by robust review of production capacity and risks. This is particularly critical where there is a single supplier. The EMAY is a good example of aligning country readiness (e.g. policy) with supply.

Recommendation 7: Evolve Unitaïd grant-making to improve speed and agility, whilst retaining Unitaïd's flexibility within project delivery

- Unitaïd should test more co-creation and flexible approaches to project development with implementing partners. This could include (i) targeted expressions of interest based on partner landscape analysis and early engagement; (ii) small number of strategic portfolio partnerships that provide a flexible 'call-down' mechanism, improving agility and reinforcing Unitaïd's catalytic role. To inform such options, Unitaïd could scope the grant-making approaches of other organisations having a similar catalytic role. This could also inform early analysis for Unitaïd's future strategy.
- Unitaïd should continue enabling projects to adapt as evidence and implementation experience evolve, which was considered a strong value-add within I4TB.
- Unitaïd should continue to encourage consortia with leadership based in the global South and maintain a strategy-level KPI to monitor progress.

Recommendation 8: Address bottlenecks to shorten the pathway from evidence generation to policy impact

- Unitaïd should review the value for money of its evidence generation approach to identify the mix of research approaches that delivers the greatest policy influence and country uptake.
- Unitaïd should explore where appropriate, a greater emphasis on evidence generation approaches such as operational and implementation research that can more rapidly inform country policy and programme decisions. Such research should leverage and strengthen national data systems, using routine and real-time data to support adaptive implementation and accelerate learning.
- Unitaïd should also work with the WHO Ethics Review Committee (ERC) to identify and address the main constraints within review processes without compromising scientific rigour.

Recommendation 9: Strengthen integrated, people-centred investment portfolios and the use of gender-based approaches

- New investments should consider opportunities beyond disease ‘silos’, drawing on resources such as Unitaids’ recent landscape analysis of care pathways for populations at higher risk of tuberculosis. Unitaids is also supporting this through forthcoming integrated diagnostics investments.
- Strengthen gender and equity analysis during investment design and implementation, including routine use of sex-disaggregated data to identify gaps across the service cascade.

Recommendation 10: Continue to embed CCSE in Unitaids’ work, with implementation timelines and financing that reflect the contribution to project outcomes

- CCSE contribution to project outcomes should be strengthened within results frameworks. Future investments should also explore more sustainable funding models than one-off grant cycles, strengthening organisational capacity where needed, and promoting longer-term financing mechanisms such as social contracting where appropriate.



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