Unitaid's Impact 2017

Results and Key Performance Indicators

Abbreviations

ACCESS SMC	Achieving Catalytic Expansion of Seasonal Malaria Chemoprevention in the Sahel
ACT	Artemisinin-Based Combination Therapy
AIDS	Acquired Immunodeficiency Syndrome
APIs	Active Pharmaceutical Ingredients
ART	Antiretroviral Therapy
ARVs	Antiretrovirals
CAB	Community Advisory Board
CE Marking	European Conformity Marking
CHAI	Clinton Health Access Initiative
DBS	Dried Blood Spot
DNDI	Drugs For Neglected Diseases Initiative
DRW	Diagnostics For The Real World
DTG	Dolutegravir
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
EID	Early Infant Diagnosis
FDA	Food and Drug Administration
FDC	Fixed Dose Combination
FIND	Foundation For Innovative New Diagnostics
FIND QARDT	Quality Control Of Malaria Rapid Diagnostic Tests Project
FIOTEC	Foundation For Scientific And Technological Development In Health
FPPs	Finished Pharmaceutical Products
GAD	Grant Agreement Development
GDF	Global Drug Facility
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Testing
IPMA	Innovation In Paediatric Market Project
IRS	Indoor Residual Spraying
IVCC	Innovative Vector Control Consortium
IVD	In- Vitro Diagnostics

Jhpiego	Johns Hopkins Program For International Education In Gynecology And Obstetrics
KPI	Key Performance Indicator
LiCs	Lower-Income Countries
LMICs	Lower-Middle Income Countries
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières
MSF Dx	Implementation Of CD4 And Viral Load Testing In Resource-Limited Settings Project
PEPFAR	President's Emergency Plan For AIDS Relief
PMDS	Performance Management and Development System
POC	Point-Of-Care
PrEP	Pre-Exposure Prophylaxis
PSI	Population Services International
QC	Quality Control
RDTs	Rapid Diagnostic Tests
SAMBA	Simple AMplification Based Assay Platform
SDGs	Sustainable Development Goals
SMC	Seasonal Malaria Chemoprevention
STAR	Self-Testing Africa Initiative
STEP-TB	Speeding Treatments To End Paediatric Tuberculosis Project
TB	Tuberculosis
UNICEF	The United Nations Children's Fund
WHO-EMP	World Health Organization, Essential Medicines and Health Products
WHO	World Health Organization
WHO PQ	World Health Organization Prequalification Programme
Wits RHI	Wits Reproductive Health and HIV Institute

Introduction

Reaching the Sustainable Development Goal (SDG) to "Ensure healthy lives and promote wellbeing for all" by 2030 is going to take a strong dose of boldness and ingenuity.

Remarkable progress has been made in global health over the past two decades, yet pressing needs remain. It took 15 years to put just over half of all people living with HIV onto antiretroviral (ARV) therapy. To get the other near 50 per cent of people on treatment, we will have to work harder and faster. Many critical gaps also persist in other diseases such as tuberculosis or malaria: health products are often not adapted to the needs of vulnerable people, such as children or pregnant women; many have unacceptable side effects; others are losing their effectiveness because of antimicrobial resistance; and sophisticated tools such as testing devices are simply too complex and expensive for use in remote locations.

We need practical solutions that test the frontiers of medical science if we are to succeed in delivering on our goals. This is what Unitaid aspires to do.

Unitaid works at the interface between cutting-edge innovation and the realities of fighting killer diseases on the ground. We analyse potential roadblocks that stand in the way of innovations being adopted and used at scale in low- and lower-middle income countries, and we then start removing them, one by one. If a product is not adapted to patients' needs, we develop a better version, drug combination, or formulation. If decision-makers are unsure about when and how to use an innovative product, we put it to the test in real-life settings and demonstrate its added value. If prices are too high, we accelerate entry of new suppliers to increase competition. Additionally, we put in place mechanisms that support demand, increase market size and help manufacturers to lower their production costs.

Since its establishment in 2006, Unitaid has received approximately US$ 2.8 billion in contributions from donors, with our main donors being France, the United Kingdom, Norway, the Bill & Melinda Gates Foundation, Brazil, Spain, the Republic of Korea, and Chile. These funds are invested in grants that aim to accelerate the introduction of innovative health products that can help prevent, diagnose and treat major diseases such as HIV/AIDS, tuberculosis, malaria or hepatitis C for the poorest and the underserved. Unitaid's current portfolio represents approximately 40 grants, worth US$ 1 billion in total. More than 50 per cent of the portfolio addresses issues related to resistance management and antimicrobial resistance.

A growing number of grants span more than one disease, and aim to create efficiencies and maximize impact for health systems.

At Unitaid, we are often the first to introduce innovations in countries. But we do so at a limited scale, for a finite period of time. In order to succeed, we have to persuade others to adopt these innovations, and to use them at large scale. For this reason, we invest considerable time in working with national disease programmes and their funders to make sure new products are integrated in their operational plans, and that financial resources are secured to support scale-up. Only then can we claim success, in the knowledge that much-needed innovations will reach those who most need them, and can deliver greater impact for the global health response.

This approach is reflected in our Strategy for 2017-2021, and is anchored on three strategic objectives: innovation, access, and scalability. The implementation of the Strategy is monitored through a set of key performance indicators (KPIs), which are divided into a set of strategic and operational KPIs. A summary KPI framework is outlined in figure 1, below.

Figure 1. **Summary of Unitaid's Key Performance Indicator framework and related targets**

Strategic KPIs		
1-	**Catalyzing innovation**	80% of products available
2 -	**Overcoming market barriers**	80% of barriers overcome
3.1 -	**Securing funding**	80% of project countries have secured funding
3.2 -	**Scaling-up coverage**	Projection
4.1 -	**Increasing public health impact**	Projection
4.2 -	**Generating efficiencies & savings**	Projection
4.3 -	**Delivering positive returns**	Projection
5.1 -	**Investing for the poorest**	100% of projects
5.2 -	**Investing for the underserved**	100% of projects

Operational KPIs		
A -	**Secretariat efficiency**	2% operational expenditure
B -	**Resource Mobilization**	$40 M in 2018 $100 M in 2021
C -	**Speed of grant development**	6 months in 2017
D -	**Grantee reporting timeliness**	100%
E -	**Disbursement efficiency**	Year-on-year improvement - 100% from 2019
F -	**Grantee responsiveness**	Year-on-year improvement - 100% from 2019
G -	**Audit status**	100%
H -	**Risk management**	100%
I -	**People development**	100%
J -	**Secretariat satisfaction**	No decrease vs. 2017 baseline

Strategic KPIs measure our progress in delivering impact from our investments, which is described in figure 2, below. They focus on the key moments that lead towards impact: from the point of closure of our grants, where innovation and access barriers are expected to be overcome (KPI 1 and KPI 2), to the scale-up of a new product (KPI 3) and its ultimate impact on lives and health systems (KPI 4). In addition, the portfolio's alignment with equity is measured (KPI 5). While KPIs apply to the whole portfolio of Unitaid, they are formally measured at the point of grant life when catalytic changes are meant to occur, and when adequate evidence is available: typically grant closure (for KPIs 1-4). This implies that each year's Strategic KPI reporting focuses on a subset of Unitaid's portfolio.

In effect, many of Unitaid's investments span the full value chain from late-stage product development to ensuring quality, affordability, demand generation and the ultimate supply and delivery of better health care. Following this logic, Figure 3 provides an application of this framework in respect to a project which closed in 2017 – STEP-TB. This is a good example of how Unitaid's investments connect upstream product development to downstream realities. This investment was focused on securing the availability of child-friendly tuberculosis medicines that meet World Health Organization (WHO) guidelines. As a further step, the project undertook some work to secure the demand and adoption of the new medicines. Working with a range of partners, including the STOP TB Global Drug Facility (GDF), the new child-friendly treatment has been rapidly adopted with almost 80 countries procuring the new treatment by March 2018. This investment is part of a continuum focused on meeting global goals for childhood TB. Building upon the success of STEP-TB, in 2017 Unitaid invested further into childhood TB. The objective of the new investments is to identify, as quickly as possible, the estimated 600,000 children with undiagnosed TB, using innovative approaches for diagnosis and integrated approaches for active case management.

Strategic KPIs are complemented by operational KPIs, which measure the performance of Unitaid as an organization in key categories such as finance, the development of new grants, grant implementation and human resources.

The new KPIs came into effect in 2017, at the start of our new strategic period, and this is the first time that Unitaid reports against them. Significant progress was achieved across the portfolio in delivering against the three strategic objectives of innovation, access, and scalability. Highlights from across our entire portfolio are provided in the 'Key highlights 2017' section of this document, with examples of grants where major progress was made. Following this, the 'Strategic KPIs 2017' section provides details on the subset of grants that fell under the scope of Strategic KPI reporting this year. Finally, the 'Operational KPIs 2017' section provides an overview of performance against operational KPIs.

Figure 2. **Summary of Unitaid's impact framework & Strategic KPIs**

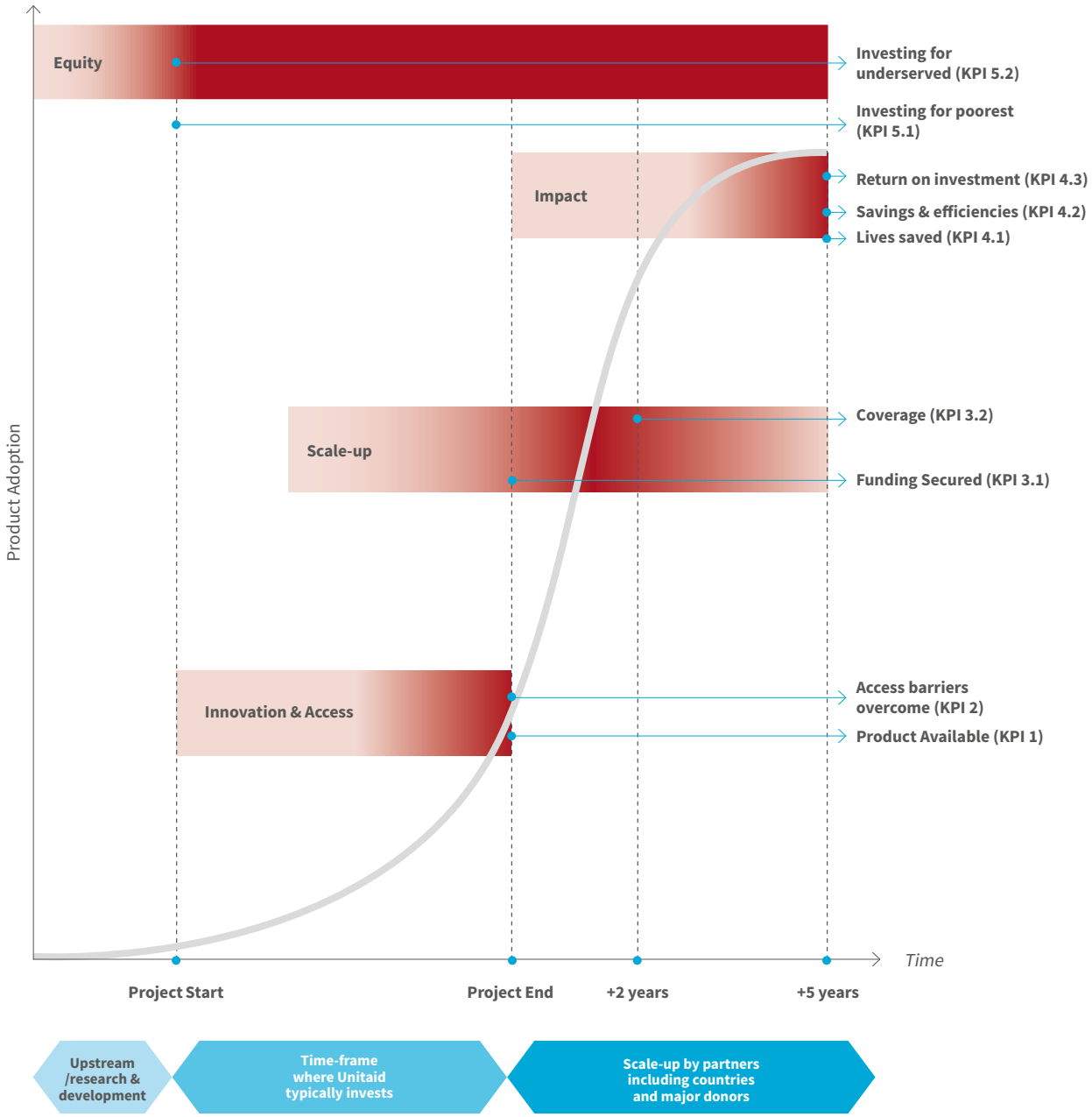


Figure 3. **Application of Unitaid's impact framework to the STEP-TB project**

2013

No properly dosed pediatric TB medicine

1 TB is a major cause of child mortality: 1 million children are infected and 250,000 children die from TB each year.

2 Prior to the beginning of the project there was a lack of properly dosed child-friendly TB medicines. Caregivers relied on varying and imprecise treatment practices such as splitting or crushing multiple, bitter-tasting pills to try and provide treatment to children with TB.

3 Unitaid invested US $15.2 million into the STEP-TB project implemented by the TB Alliance and WHO.

2016

INNOVATION
Development of new pediatric formulations

4 The TB Alliance collaborated with the pharmaceutical industry to accelerate product development and entry on the market of two new paediatric TB medicines that meet WHO guidelines.

2016-2017

ACCESS
WHO prequalification & affordable price - New estimates of childhood TB burden

5 The WHO prequalification programme, also supported by Unitaid, approved two child friendly TB medicines in late 2017, ensuring the quality.

6 The new products were introduced at an average price of US$15 for a treatment course of 6 months - affordable for donors and countries.

7 The project developed a method for more precisely estimating the annual number of childhood TB cases, which led to a doubling of the previous estimate, to 1 million cases. The revised estimates shed a new light on the problem of childhood TB and enabled manufacturers to form a clear picture of the market size. The project also worked with countries to update their treatment polices and promote demand for the child-friendly medicines.

2018-2019

SCALABILITY
Scale-up in 79 countries to date

8 With assistance by partners including the STOP TB Partnership's Global Drug Facility (with US Government funding), the Global Fund and Global Affairs Canada, by March 2018, 79 countries, including 23 high burden TB countries, had ordered 590,000 treatment courses of the child-friendly medicine.

9 Over a two year period after project closure, it is estimated than an additional 170,000 to 340,000 children with TB will benefit from the new child-friendly TB medicines.

2021-2022

IMPACT
Public health impact

10 The STEP-TB project has paved the way for better childhood TB care. Increased public health impact at scale will only be possible once there is significant progress in identifying more childhood TB cases and ensuring they are put on treatment. Unitaid's current investments in childhood TB include making available faster, better TB diagnostics and integrated approaches to active case finding.

Key highlights 2017

Innova

Unitaid's investments are highly effective at delivering innovative health solutions of high quality that ultimately benefit millions of people. Unitaid has a strong track record of kick-starting innovation and making the global health response faster, more affordable and more effective.

ation

Although low-income countries share many of the health challenges that high-income countries face, several factors including high burden of disease and small or unpredictable demand create uncertainty and limit investment into serving low-income markets. While many new health products are developed and commercialized each year, most are not adapted for use in low-income settings. Specific features are sometimes also required for a product to be usable in resource-limited settings: adaptation to certain populations, ability to store at higher temperature, simple packaging adapted to weak supply and distribution channels, and ease of use, even in the absence of a health care professional.

Unitaid's investments aim to catalyse the introduction of innovative health products that address these problems. When these products don't exist, Unitaid engages with manufacturers and other upstream partners to develop them. Once products become available, Unitaid funds projects to bring the most promising solutions to those who need them in low- and lower-middle income countries.

In 2017, Unitaid's portfolio of projects were working on a range of solutions, including new TB regimens that are specially adapted to children's needs, innovations in paediatric HIV treatment, and optimal HIV treatments for adults.

This is how our innovation objective is addressed. Success is measured by the number of these products that are successfully made available.

Unitaid measures innovation through KPI 1 – Catalysing innovation.

Innovation: progress made in 2017

2017 saw the culmination of two investments that sought to accelerate access to a child-friendly TB treatment and a diagnostics platform that can be used at the point-of-care in resource-constrained settings.

STEP-TB: ACCELERATING ACCESS TO CHILD-FRIENDLY TB MEDICINES

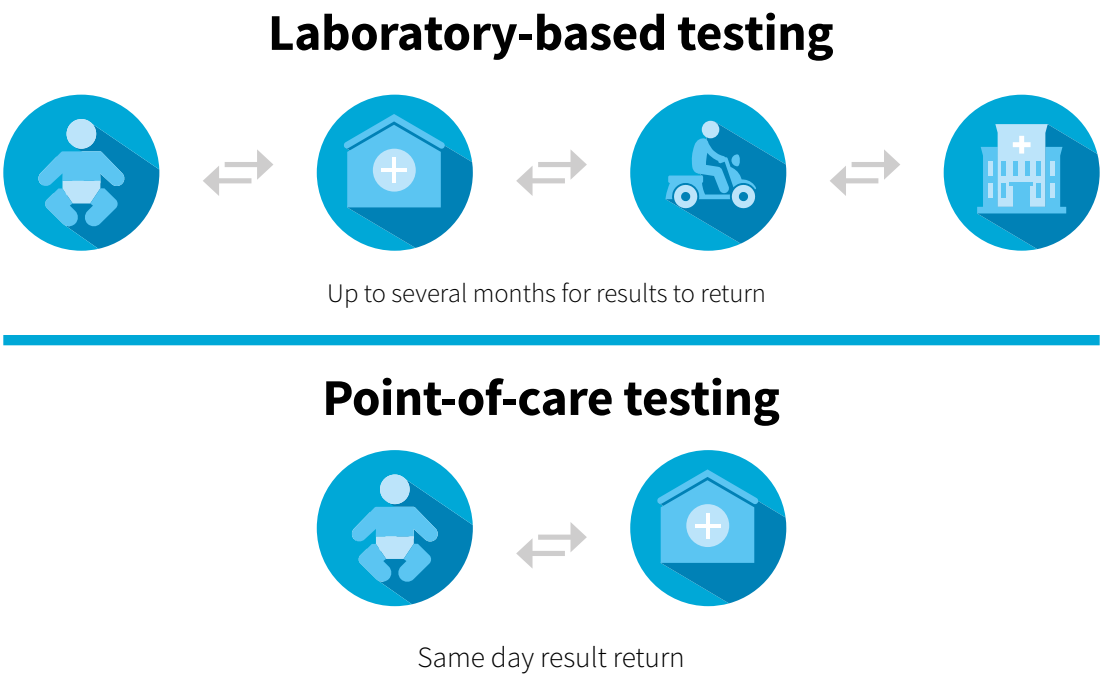
Before child-friendly TB medicines were made available through the **STEP-TB project**, country programs, clinicians, and caregivers relied on varying and imprecise treatment practices such as splitting or crushing multiple, bitter-tasting pills to try and provide correctly dosed treatment to children. The TB Alliance collaborated with the pharmaceutical industry to accelerate product development and entry of two new paediatric TB medicines that met WHO guidelines, as well as the needs of children and care givers (cf. also figure 3 and section 3).

PROVIDING ACCESS TO VIRAL-LOAD MONITORING AND EARLY-INFANT DIAGNOSIS BY SAMBA

Unitaid is making a significant investment to accelerate access to point-of-care diagnostics that can be used to diagnose and monitor a number of diseases, including HIV in adults and infants. One investment, into the **SAMBA (Simple AMplification Based Assay) platform**, developed by Diagnostics for the Real World, sought to improve testing for HIV in places where reliable diagnosis and monitoring is often unavailable. SAMBA offers a simple, heat-stable, accurate and robust point-of-care diagnostic technology specifically designed for resource-constrained settings. A key feature is its ability to test at the point of patient care. This is particularly important in settings where conventional laboratory systems are weak. In many low and lower-middle income countries HIV test turnaround times can average a few months; as a result, those who test positive for HIV are not always followed up with treatment and care. This is a major issue for infants living with HIV. Without access to diagnosis and treatment, one in three infants living with HIV will die by the age of one. With testing at or near the point of care, delays in the return of test results can be averted, enabling clinicians to initiate treatment quickly for children, and to identify and address adherence challenges and treatment failure sooner; ultimately generating a more efficient testing system.

Unitaid's investment in SAMBA supported the CE marking and in-country registration of the SAMBA I and II platforms, for viral load and EID assays on both systems.

Figure 4 - **Point-of-care testing provides faster test results linking more infants to treatment.**



Progress on our innovation objective was also made in 2017 through active projects in Unitaid's portfolio. For example, Unitaid is investing in the **Drugs for Neglected Diseases initiative (DNDi)** to support the availability of three new paediatric HIV antiretroviral (ARV) medicines. Globally 2.1 million children are living with HIV, yet less than half have access to life-saving ARV treatment. One of the major obstacles in treating paediatric HIV is the limited availability of paediatric ARV formulations. Existing HIV treatments for children can be complicated, some are difficult to swallow and can taste unpleasant. The treatment of children less than three years of age is a further challenge, because of high levels of the HIV virus in the blood and limited treatment options.

The DNDi project is working to increase access to optimal ARVs for young children that are properly dosed, more palatable, easy to store, and better adapted to children's needs. In February 2017, a bioequivalence study[1] of the paediatric HIV drug (protease inhibitor - Lopinavir/Ritonavir) granules against the currently available harsh-tasting syrup returned positive results. This was an important milestone towards the goal of developing an optimal 4-in-1 paediatric fixed-dose combination by the end of 2018. In the long term, optimal paediatric HIV medicines are expected to improve treatment coverage and adherence, and eventually to reduce child mortality. In addition, Unitaid is investing in four clinical trials to generate evidence to support the scale-up of optimal HIV treatments for adult populations including pregnant women, and those with HIV-associated TB.

[1] A product found to be **bioequivalent** means that it would be expected to have the same therapeutic effect, i.e. the same safety and efficacy as the reference drug (e.g. see FDA website).

Acces

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Access to health products for underserved populations depends on many often interlinked factors. Products must be commercially available and ready for rapid introduction in relevant settings, quality assured, and affordable for those who need them. Demand for innovative health products, and evidence to guide their adoption, are essential for optimizing their impact. Finally, a healthy, sustainable supply chain and effective delivery mechanisms are needed to ensure that critical health products reach those who will benefit from them at scale.

In reality, these conditions are rarely all met in low- and lower-middle income countries, and the underlying reasons are complex. A frequent issue is low market demand for innovative new tools that fails to incentivize manufacturers to supply products at scale. This in turn results in either high prices, which further curb demand, or no supply at all. A well-targeted intervention, addressing such underlying causes, can help to catalyse access to innovation.

Unitaid makes investments across the value chain to overcome the key barriers to access, whether they relate to quality, affordability, demand & adoption, or supply & delivery.

Unitaid measures access through KPI 2 - Overcoming access barriers.

Access is secured when there is...

Quality

The medicine or technology is quality-assured, and there is reliable information on the quality of the product.

Affordability

The medicine or technology is offered at the lowest sustainable price, is cost-effective and is affordable; it does not impose an unreasonable financial burden on governments, donors, individuals, or other payers, with a view to increasing access for the underserved.

Demand & Adoption

Countries, programmes, providers (e.g. healthcare providers, retailers), and end users rapidly introduce and adopt the most cost-effective products within their local context.

Supply & Delivery

Supply-chain systems function effectively to ensure that products reach end users in a reliable and timely way. Effective and efficient delivery models are adapted for the local context.

Access: progress made in 2017

Quality

Ensuring the quality of health products is critical to the long-term success of the global health response. In 2017 good progress was made by the **WHO Prequalification (PQ) programme**. WHO PQ is a flagship investment by Unitaid to ensure access to safe, effective, quality and affordable medicines and diagnostics. Unitaid's support to the PQ programme is intended to catalyse the introduction of urgently needed medicines and diagnostic products in low- and lower-middle income countries that have limited regulatory capacity. In 2017, the programme exceeded its target for prequalifying diagnostics and medicines, including many directly related to the wider Unitaid portfolio. The pre-qualified products in 2017 included the:

- **First HIV self-test (HIVST) kit**, which supports the investments being made by Unitaid in this space, including the STAR initiative led by Population Services International (PSI) that aims to develop the HIVST market;

- **First generic dolutegravir (DTG)** for treatment of HIV, which is the focus of five Unitaid investments (one market-shaping project and four clinical trials) that aim to generate evidence and accelerate access to DTG-based regimens and other optimal treatments;

- **First generic sofosbuvir** for treatment of hepatitis C (HCV) , which Unitaid is also supporting through three investments that aim to accelerate access to new HCV diagnostics and treatments available in low- and middle-income countries;

- 2-drug and 3-drug fixed dose combinations (FDCs) for **1st line TB treatment for children**, which Unitaid has also supported through the STEP-TB project.

Affordability

In 2017, a number of Unitaid projects made substantial progress in improving the affordability of innovative medicines and diagnostics through product price reductions and the demonstration of cost-effectiveness and budgetary affordability.

The **ACCESS SMC** project, led by Malaria Consortium in partnership with Catholic Relief Services, proved that large-scale administration of **seasonal malaria chemoprevention to children is feasible, cost-effective, and affordable to scale up**, with a strong public health impact. The cost of delivering seasonal malaria chemoprevention has fallen by more than 20 per cent since the start of the project. Today it stands at $3.40 on average for a full treatment course, per child, for a season. This fares well when compared to the cost of other malaria prevention tools.

Unitaid is also focused on **making next-generation insecticide more affordable.** Otherwise, the market for indoor residual spraying (IRS) will remain stagnant. Unitaid's investment through the Innovative Vector Control Consortium (IVCC) aims to improve the affordability of next-generation insecticide, and to create stable market conditions with affordable prices. In 2017, access to a next-generation insecticide, Actellic, was secured for 12 African countries and led to the protection of 50 million people from malaria. Negotiations with Syngenta (Actellic's manufacturer) led to an 18 per cent price reduction of the insecticide for 2017 campaigns in 12 countries. A second next-generation product, SumiShield, was prequalified by WHO in November 2017, and two additional new insecticides are also in the WHO review process. The prequalification of additional novel products will allow for rotation of insecticides to prevent resistance. It will also generate increased competition that could result in further price reductions and increased supply stability for next-generation indoor residual sprays.

Accelerating access to better and less expensive HIV treatment: Almost half of all people living with HIV do not have access to treatment. Without antiretroviral therapy (ART), people living with HIV risk rapid progression to death. A significant proportion of people living with HIV who have no access to treatment live in resource-limited settings. New antiretrovirals (ARVs), including dolutegravir (DTG) based regimens, are the standard of care in high-income countries.

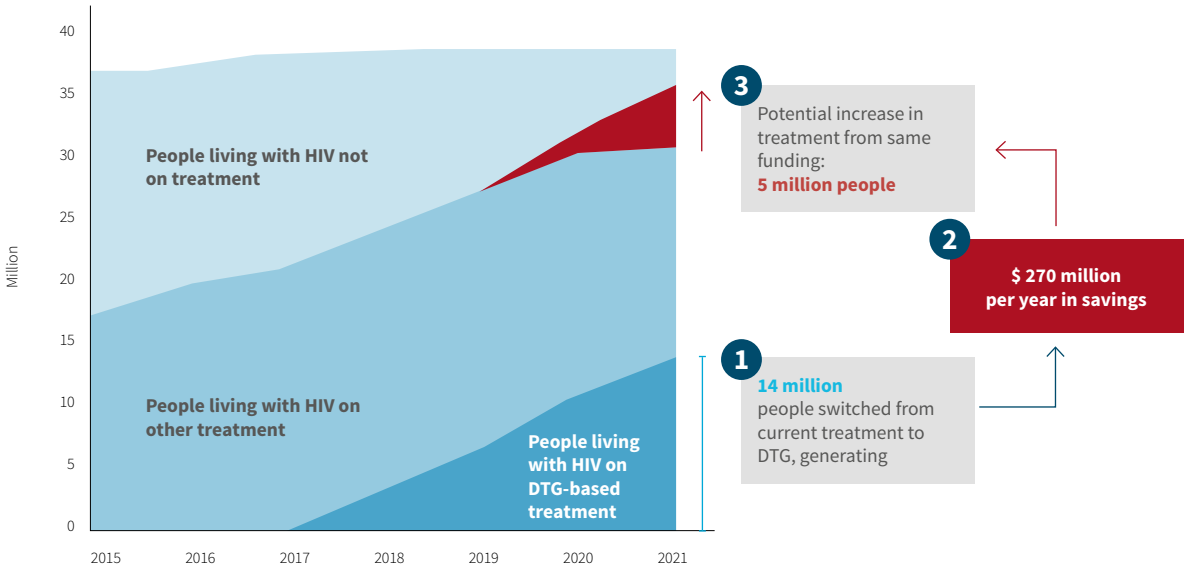
However, it can take up to 10 years for new ARVs to reach resource-limited settings[2], because their initial price is too high to be affordable in low- and lower-middle income countries.

Unitaid has made a range of investments that have led to faster access to better ARVs, at lower prices. Resulting from voluntary licenses secured by the Medicines Patent Pool, and a related investment through the Clinton Health Access Initiative (CHAI) to shape the market for optimal regimens, dolutegravir was introduced into Africa only three years after US regulatory approval.

As a result of Unitaid's investments and the actions of partners such as CHAI and the Bill and Melinda Gates Foundation, in 2017, the once-a-day generic fixed-dose combination of tenofovir disoproxil fumarate, lamivudine, and dolutegravir (TLD), became available for public sector purchase in low- and lower-middle income countries, for only US $75 per person, per year. This global low price will unlock access to improved treatment for millions of people living with HIV, and has the potential to fall even further over time. **More people living with HIV could access treatment due to savings from DTG.** Based on current estimates, by 2021, 14 million people living with HIV could be on a dolutegravir-based regimen. Additional price reductions are anticipated; if achieved, this could lead to savings of around US $270 million per annum, which would secure treatment access for an additional 5 million people from the same funding.

[2] http://www.unsgaccessmeds.org/inbox/2016/2/26/unitaidb

Figure 5- **Additional people living with HIV accessing treatment due to the savings possible from optimal regimens**



Demand & Adoption

Demand-generation and support for global and in-country guideline change are key objectives of Unitaid projects. The **STEP-TB grant** helped shed new light on the problem of childhood TB and worked with countries to update their treatment policies and practices to reflect the WHO 2010 recommendations on management of tuberculosis in children, helping to promote demand for the child-friendly medicines (cf. more details are available in figure 3 and section 3).

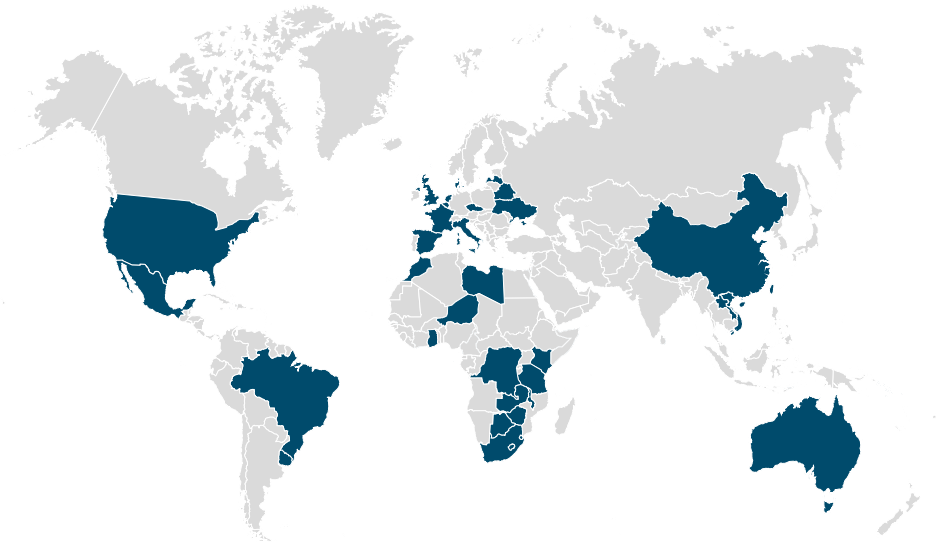
The Médecins Sans Frontières **(MSF) project on the implementation of CD4 and viral load testing in resource-limited settings** project contributed to the 2016 WHO guidelines for ART treatment and monitoring through provision of clinical data and examples of best practice on laboratory work and programmatic considerations. At country level, the project supported national policy development and HIV treatment guidelines and worked with civil society organizations, health workers and beneficiaries to facilitate demand-creation and adoption of routine viral load monitoring.

Civil society has a crucial role to play to facilitate demand-creation and adoption of new health products in countries to ensure the successful scale-up of Unitaid's interventions. In 2017, Unitaid's **CHAI optimal antiretrovirals (ARVs)** project, which aims to make the best HIV medicines available in low- and lower-middle income countries, supported project countries to adopt new ARVs including DTG into treatment guidelines and established the Optimal ARV Community Advisory Board (CAB) with the goal of fostering engagement with civil society partners to co-develop product adoption strategies and improve knowledge of, and demand for, new ARVs among people living with HIV. In 2017, thanks to these efforts, DTG was successfully integrated into the national procurement systems in Uganda, Nigeria and Kenya.

Unitaid projects aim for increased awareness and

Figure 6 - **Adoption of HIVST policies worldwide**

More than 40 countries have implemented an HIV Self-Testing policy in just over one year



demand of new medicines and diagnostics not only in project countries but also globally. For example, one of the key strengths of Unitaid's pathfinding investment in **HIV self-testing (HIVST), the STAR project**, led by Population Services International (PSI), has been raising awareness of HIVST at the global level. One of the key deliverables of the STAR project has been a strong body of evidence to support the development of the first WHO guidelines for HIVST. The release of the WHO guidelines has been accompanied by a rapid increase in policy uptake of HIVST globally. As of October 2017, more than 40 countries had national HIVST policies, more than half of which were low- and lower-middle income countries (LMICs), as per figure 6 above.

Similarly, because of the demand-generation activities implemented through the **Innovative Vector Control Consortium (IVCC)** next generation Indoor Residual Spraying (IRS) grant (described above) more countries and funders are supporting the procurement of next- generation IRS products beyond the volumes procured by the project.

Supply & Delivery

Effective supply and delivery systems are needed to ensure that critical health products reach those who will benefit from them. Unitaid investments address both supply side issues by, for example, improving the sustainability of product supply, and delivery issues by piloting innovative delivery models, to determine which models are well suited for resource-limited contexts.

The **ACCESS SMC** project has tackled supply side problems which restricted access to preventive treatment for seasonal malaria. There was insufficient funding for seasonal malaria chemoprevention (SMC)

implementation, and limited demand from countries, which discouraged manufacturers from supplying the market with easy-to-administer, quality-assured child-friendly formulations. The project contributed to the improvement of the supply chain by encouraging introduction of a palatable formulation as well as support for additional manufacturers to supply quality-assured SMC. The project also worked to ensure an effective delivery channel for quality-assured SMC through community health workers.

From the delivery perspective, the **MSF project** on implementation of CD4 and viral load testing in resource-limited settings, which closed in 2017, pilot-tested conventional laboratory-based and point-of-care (POC) approaches to viral load monitoring and early infant diagnosis, with delivery through differentiated models of care. A key aspect of the MSF work was the management of the dried blood spot (DBS) approach for viral load monitoring, which demonstrated its effectiveness as the most feasible approach for broader scale-up by governments. The MSF project also included studies looking at the feasibility of conducting early infant diagnosis of HIV in decentralized rural clinics using POC devices.

This work has been taken forward by the **EGPAF early infant diagnosis and CHAI/UNICEF point-of-care grants**. These projects are pilot-testing hub and spoke models (one decentralized instrument and several sample collection points) of delivery for point-of-care early infant diagnosis. Preliminary results indicate that the model is delivering test results significantly faster, with a faster treatment initiation, for a greater proportion of infants tested than conventional laboratory EID testing.

Figure 7 - **Comparison of conventional and point-of-care testing for early infant diagnosis**

Point-of-care testing brings early infant diagnosis closer to those most in need

	FASTER RESULTS	MORE INFANTS DIAGNOSED	MORE INFANTS TREATED	MORE COST-EFFECTIVE
LABORATORY-BASED TESTING	Median test turnaround time of **122 days**	**12%** of infant patients received results within 60 days	**13%** of newly identified HIV positive children started on antiretroviral therapy within 60 days	While the cost of point-of-care tests is higher than conventional laboratory testing ($21 versus $15), point-of-care may be more cost-effective as it shortens the time it takes to diagnose infants and start them on HIV treatment, and leads to a greater proportion of results returned
POINT-OF-CARE TESTING	Median test turnaround time of **0 days**	**99.5%** of infant patients received results within 60 days	**87%** of newly identified HIV positive children started on antiretroviral therapy within 60 days	

Source: Ilesh Jani et al. Effects of point-of-care testing on antiretroviral therapy initiation rates in infants. Conference on Retroviruses and Opportunistic Infections, 2017 / S.C. Frank et al. The clinical impact and cost-effectiveness of incorporating POC assays into early infant HIV diagnosis programs at 6 weeks of age in Zimbabwe: a model-based analysis. International AIDS Society Conference 2017

Scala

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bility

Unitaid invests in innovative products or approaches for a limited time period. In order to realize the full benefit of these innovations and deliver maximum impact, Unitaid relies on countries and key partners. For this reason, Unitaid places strong emphasis on the transition and scale-up process in the projects it supports; all the way through from the moment that challenges and opportunities are identified to project implementation and closure. In practical terms, Unitaid works to create conditions for broader adoption by others – through country and partner engagement – in all stages from the development of the 'Disease Narratives', the identification of the 'Areas for Intervention', to the design, implementation and transition of projects.

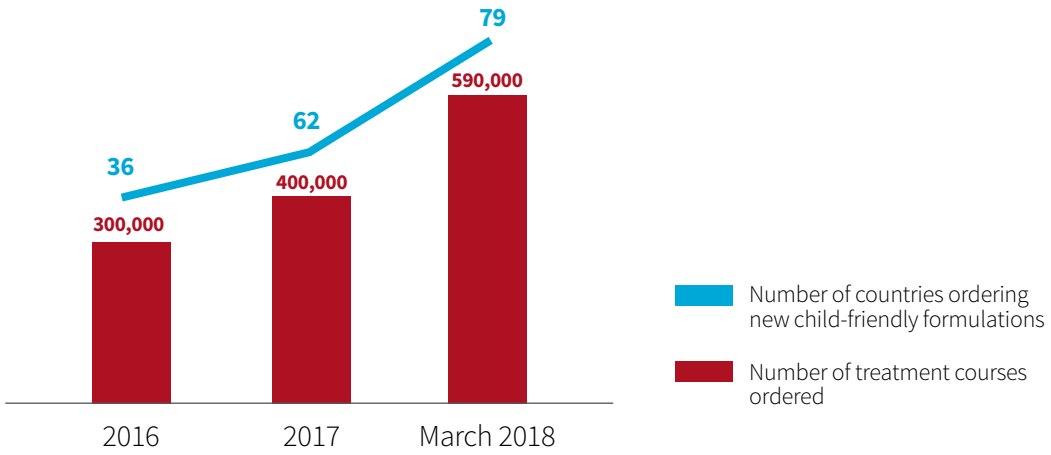
Unitaid measures scalability through KPI 3.1 & 3.2 – Securing Funding & Scaling up coverage

Scalability: progress made in 2017

All Unitaid projects designed under the new strategy (2017 – 2021) aim to create the right conditions for scale-up. Although scalability of project interventions is monitored through the project life cycle, transition to scale is the end-point for Unitaid projects. Therefore, project performance on transition and scale-up is most evident at or near the end of projects.

As noted above, the **STEP-TB** project, which closed in 2017, reshaped the market of paediatric TB drugs by reducing barriers to entry for the development of child-friendly medicines, and through the mobilization of demand for the new regimens. By ensuring affordable pricing and sustainable supply of the medicines, the project has created a favourable environment for scale-up. Since the end of the project, thanks to additional support from partners including Stop TB Partnership's Global Drug Facility (GDF) and the Global Fund, 79 countries had ordered more than 590,000 treatment courses of new paediatric medicines by March 2018 (cf. also figure 3, figure 8, and section 3).

Figure 8 - **Uptake of new child-friendly regimen since launch**



Source: Stop TB Partnership, Global Drug Facility

The **ACCESS SMC** project led by Malaria Consortium, was drawing to a close in early 2018 with the transition of Unitaid support to other donors. The Global Fund, the President's Malaria Initiative, the World Bank and philanthropic funding had been secured to continue access to seasonal malaria chemoprevention in all seven project countries. In addition, Cameroon, Ghana, Guinea-Bissau, Senegal and Togo have also started seasonal malaria chemoprevention programmes.

Despite more than two years remaining in the **Innovative Vector Control Consortium (IVCC) next generation Indoor Residual Spraying (IRS)** project, good progress is already being made on transition and scale-up. More countries and funders are supporting the procurement of the new insecticides, beyond the volumes procured by the project. The success of project scalability going forward will depend on a number of factors, including reliable demand forecasting, adequate market competition, and rational rotation of insecticides, linked to product prices.

Finally the **Innovation in Paediatric Market (IPMA)** project implemented by Clinton Health Access Initiative (CHAI), which closed at the very end of 2016, has demonstrated effective scale-up of paediatric treatment for HIV, benefiting hundreds of thousands of children living with HIV. Building on an earlier investment by Unitaid (through CHAI) to build a market for paediatric HIV treatment, IPMA strengthened the paediatric antiretroviral market further along the full value chain. The result being access to paediatric antiretroviral formulations, healthy competition among suppliers, expanded eligibility criteria for children to receive treatment, and sound market intelligence to inform forecasting global demand, key trends, and the product landscape for paediatric HIV treatment.

Market improvements and increased access to treatments has resulted in an estimated **540,000 additional children being initiated on treatment across both projects**. As part of transition arrangements, CHAI played an important role in supporting countries to incorporate paediatric commodities into their Global Fund applications, and also worked with funders and procurement agents at the global level to ensure supply was not interrupted. The funding of paediatric medicines has been taken up by PEPFAR and the Global Fund, and includes PEPFAR's Accelerating Children's HIV/AIDS Treatment (ACT) Initiative, which as of 2016 was supporting 560,000 children (aged 19 or under) with access to high-quality treatment across 10 sub-Saharan countries – Cameroon, Côte d'Ivoire, Democratic Republic of Congo, Kenya, Lesotho, Malawi, Mozambique, Tanzania, Zambia, and Zimbabwe.[3] These efforts are complemented by PEPFAR, Global Fund, and Unitaid investments to improve the diagnosis of children living with HIV/AIDS through the optimization of conventional laboratory-based diagnostics and scale-up of new point-of-care diagnostic technologies.

[3] PEPFAR (2017) Accelerating Children's HIV/AIDS treatment.

Looking forward

Unitaid's active portfolio comprises investments addressing innovations across the spectrum of testing, prevention, treatment and monitoring for HIV/AIDS, tuberculosis, malaria and beyond. In addition to the projects described above, Unitaid's current portfolio investments are expected to result in: [4]

- **Innovative childhood TB diagnostic** approaches, detection tests, and innovative ways of integrating paediatric TB control into maternal and child health services *(EGPAF and University of Bordeaux);*

- Shorter, safer, simple to administer, highly **effective and affordable new MDR-TB regimens** *(Partners in Health);*

[4] These are examples and not an exhaustive list of innovative products Unitaid aims to deliver.

- **Quality-assured** optimal first-line antiretroviral treatment for children (DNDi);
- **A shorter, more affordable** preventive TB treatment *(Aurum Institute);*
- **Affordable** HCV diagnosis and treatment in lower-middle income countries due to reductions in drug pricing and cost-effective screening, testing and treatment delivery models (Coalition PLUS, FIND, and MSF);
- **Demand and adoption** of pre-exposure prophylaxis (PrEP) services for adolescent girls, men who have sex with men, and transgender women through catalyzing action and generating evidence on the delivery of PrEP to underserved groups (Fiotec, and Wits RHI);
- Integrated diagnostic **delivery models**, using the same point-of-care platform to diagnose TB and HIV (CHAI/UNICEF);
- Community-based **delivery** models for malaria prophylaxis in pregnant women (Jhpiego).

Strategic KPIs

2017

Strategic Key Performance Indicators 2017

For purposes of annual reporting on its Strategic Key Performance Indicators 1-4 Unitaid evaluates all grants that have closed in the previous calendar year. KPI 5 (equity) is assessed against the grants signed in the previous calendar year. This section provides an overview of the strategic KPI results (table 1) as well as details on each project in scope of KPI 1-4 reporting.

Table 1 - **Overview of strategic KPI results**

Indicator	Projects in scope	Target	Result 2017
Innovation			
KPI 1 – Catalysing Innovation *Evidence-supported, adapted quality products are rapidly introduced in markets. A product is considered to have been successfully developed when it has achieved a relevant stringent regulatory approval.*	**Projects with a grant agreement end date in 2017.**	**80% of innovative products successfully developed.**	**100% (2 out of 2) products have been successfully developed.** **STEP-TB** Successful development of a child-friendly TB medicine that meets WHO guidelines. **DRW SAMBA** CE-marking (IVD) and in-country registration of SAMBA I and II platforms secured.

<table>
<tr><th>Indicator</th><th>Projects in scope</th><th>Target</th><th>Result 2017</th></tr>
<tr><td colspan="4">Access</td></tr>
<tr><td>KPI 2 – Overcoming market barriers
Total numbers of critical barriers overcome during the strategic period. Critical access barriers cover the following effective market dimensions – Quality, Affordability, Demand & Adoption and Supply & Delivery.

NB - For some projects, a broader set of access-related issues have been addressed to support the critical access barriers identified. These are highlighted using grey ticks in the summary table.</td><td>Projects with a grant agreement end date in 2017 plus WHO PQ.</td><td>80% of critical access barriers overcome.</td><td>71% (5 out of 7) critical access barriers overcome.
<table>
<tr><th>Grant</th><th>Quality</th><th>Affordability</th><th>Demand & Adoption</th><th>Supply & Delivery</th></tr>
<tr><td>STEP-TB (TB Alliance)</td><td>✓</td><td>✓</td><td>✓</td><td></td></tr>
<tr><td>HIV Dx (MSF)</td><td></td><td></td><td>✓</td><td>✓</td></tr>
<tr><td>SAMBA (DRW)</td><td>✓</td><td>x</td><td></td><td></td></tr>
<tr><td>QARDT (FIND)</td><td>✓</td><td></td><td></td><td>x</td></tr>
<tr><td>Patents (Lawyers Collective)</td><td></td><td>TBC</td><td></td><td></td></tr>
<tr><td>PQ (WHO)</td><td>✓</td><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td colspan="4">Scalability</td></tr>
<tr><td>KPI 3.1 – Securing Funding
Proportion of project countries where future funding has been secured at grant closure through partners and countries.

KPI 3.2 – Scaling-up Coverage
Additional people who benefit from a better health product or approach.</td><td>Projects with a grant agreement end date in 2017.</td><td>3.1) 80% of project countries have scale-up funding in place

3.2) Projection 2 years after end of grant</td><td>STEP-TB: As of March 2018, 79 countries, including 23 high burden TB countries had ordered 590,000 treatment courses of the child friendly medicine. An estimated 170,000 -340,000 children will benefit from new formulations 2 years after grant end. Scalability of other projects that closed in 2017 was either not achieved (FIND QARDT), not relevant (Lawyers Collective, WHO PQ), or could not be assessed because it may be achieved through complementary active Unitaid grants (MSF HIV Dx, DRW SAMBA)</td></tr>
</table>

Indicator	Projects in scope	Target	Result 2017
Mission Indicators: *adding value to the global response*			
KPI 4.1 – Increasing Public Health Impact *Additional number of lives saved and/or number of infections averted.* **KPI 4.2 – Generating efficiencies and savings** *Financial savings ($) and health system efficiencies ($).* **KPI 4.3 – Delivering Positive Returns** *Return on Investment = $ Benefits / $ Costs.*	**Projects with a grant agreement end date in 2017.**	**Projection 5 years after grant closure.**	**While all projects that closed in 2017 delivered significant achievements, none of them were designed to deliver long term impact on their own. Several projects resulted in complementary investments that are still being implemented. Mission level indicators for these projects will therefore be reported at a later point.**
Mission Indicators: *reducing inequities in access*			
KPI 5.1 – Investing for the poorest *Total number of active grants designed to benefit people living in developing countries (LICs, LMICs).* **KPI 5.2 – Investing for the underserved** *Total number of active grants designed to benefit the underserved.*	New projects started in 2017.	**100% for both KPIs.**	**100% of the projects started in 2017 were designed to benefit the poorest and the underserved.**

STEP-TB: Speeding Treatments to End Paediatric Tuberculosis

Tuberculosis (TB) is a major cause of child mortality worldwide. Each year about a quarter of a million children die from TB, including 52,000 children with HIV-associated TB. Almost all the children who die from TB receive no treatment.[5] In 2010, the World Health Organization (WHO) revised recommendations for the treatment of TB in children, which would require drug manufacturers to develop new appropriately dosed child-friendly medicines. However, initial interest was low. Country programs, clinicians, and caregivers thus relied on varying and imprecise treatment practices such as splitting pills to get the correct doses for children.

Unitaid invested US$ 15.2 million in the STEP-TB project, which was implemented by the TB Alliance and WHO. The project made available and accelerated access to paediatric TB medicines that meet WHO guidelines. The dissolvable pills taste good, come in the proper doses, and simplify administration of treatment for children and those who care for them. The project also helped to generate more robust estimates of the global burden of childhood TB; a new estimate indicates that 1 million children each year are affected by TB.

Grant Summary

Grantee: TB Alliance and WHO

Duration: July 2013 – January 2017

Total budget: US$ 15.2 million

Disease area: TB

Innovation

KPI 1 – Catalyzing innovation

Project supported the development and rapid introduction of the new paediatric TB medication in high-burden TB countries.

Access

KPI 2 – Overcoming market barriers

Demand & Adoption

STEP-TB helped project countries, which included 23 high-burden TB countries, transition to the new paediatric formulations.

Scalability

KPI 3.1 – Securing Funding

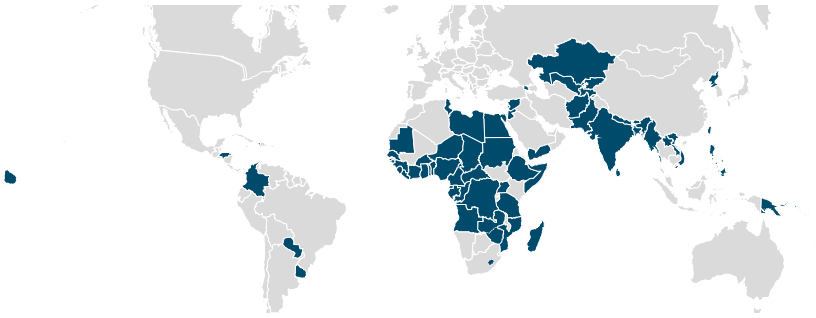
79 countries have received 590,000 treatment courses of the child-friendly medicine.

KPI 3.2 – Scaling up Coverage

Additional 170,000 to 340,000 children with TB will benefit from the new pediatric formulation.

Figure 9 - **Rapid global adoption of the new paediatric TB medicine**

As of March 2018, 79 countries have ordered 590,000 treatment courses of the child-friendly TB medicine.



[5] Dodd P.J., et al. Global burden of drug-resistant tuberculosis in children: a mathematical modelling study. Lancet 2016

MSF Dx: Implementation of CD4 and Viral Load Testing in Resource-Limited Settings

Proper use of antiretroviral therapy (ART) includes monitoring of a person's response to treatment. Monitoring the number of viral particles in a person's body (viral load) is important for detecting non-adherence to treatment, and/or the emergence of HIV drug resistance. To date, the rapid rollout of ART has not been matched by a comparable increase in viral load testing. Less than half of people living with HIV on treatment globally receive periodic viral load tests, and up until just a few years ago, viral load testing was rarely available in low- and lower-middle income countries. Limited access to virological monitoring in these settings has led to a reliance on immunological and clinical criteria which have been shown to perform relatively poorly as predictors of ART treatment failure and the need for second-line treatment. In this context, from 2012-2017 the Unitaid-funded MSF grant on Implementation of CD4 And Viral Load Testing in Resource-Limited Settings supported the programmatic and laboratory scale-up of viral load testing in seven countries in Africa. This led to almost 540,000 viral load tests being performed. The project also contributed to global normative guidance and national policies for viral load testing. The project offered a good platform to support a wider set of investments by Unitaid which aim to increase access to viral load testing.

Grant Summary

Grantee: Médecins Sans Frontières (MSF)

Duration: December 2012 – April 2017

Total budget: US$ 28.7 million

Disease area: HIV

Access

KPI 2 – Overcoming market barriers

Demand & Adoption ✓

The project has contributed to increasing demand & adoption of viral load monitoring by supporting global normative guidance.

Supply & Delivery ✓

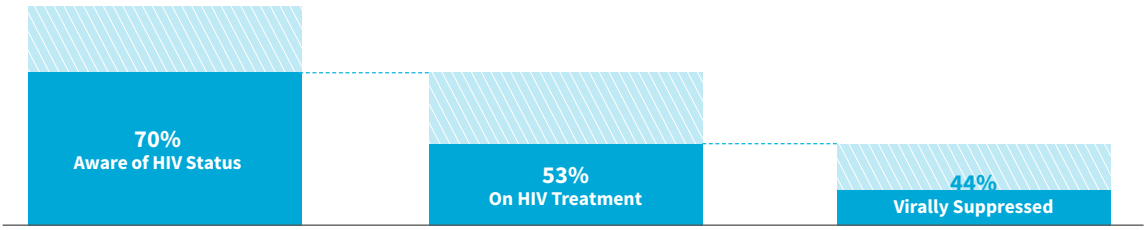
The project demonstrated the feasibility of lab-based and point-of-care and routine viral load testing at the district level in low-resource settings.

Scalability

KPI 3.1 – Securing Funding
KPI 3.2 – Scaling up Coverage ✗

The full path to scale-up requires further work, although noting that the MSF contribution through this project has set the stage for scale-up

Figure 10. **HIV Treatment Cascade**



Source: UNAIDS 2017

DRW SAMBA: HIV point-of-care diagnostic platform

Viral load monitoring is the standard for measuring the therapeutic effect of HIV treatment in high-income settings. In resource-limited settings, however, laboratory diagnostics are often available only at centralized laboratories in urban centres far from where many people requiring a test live. Both the samples taken and the test results have to travel long distances and can be lost along the way. Test turnaround times can average a few months, with consequent losses to follow-up. With point-of-care testing, delays in the return of test results can be averted, enabling clinicians to identify and address adherence challenges and treatment failure sooner, and in case of early infant diagnosis, infants can be tested, receive their result, and potentially start treatment on the same day.

Diagnostics for the Real World (DRW) developed the SAMBA HIV point-of-care diagnostic platform for viral load monitoring, acute infection testing and early infant diagnosis. SAMBA offers a simple, heat stable, accurate and robust point-of-care technology specifically designed for resource-constrained settings. The SAMBA (Simple AMplification Based Assay) system is a rapid test particularly suitable for HIV diagnostics. A key feature is its ability to provide a "test and treat" facility at point-of-care and, critically, to do so in resource-limited areas where reliable diagnosis and monitoring would otherwise be unavailable. Unitaid provided US$ 8.8 million in funding to DRW to evaluate the product in six countries, obtain WHO prequalification, and to secure stringent regulatory and in-country approvals. In 2016 DRW obtained stringent regulatory approval (CE-IVD) for SAMBA I and II early infant diagnosis and viral load.

Grant Summary

Grantee: Diagnostics for the Real World (DRW)

Duration: January 2014 – January 2017

Total budget: US$ 8.8 million

Innovation

KPI 1 – Catalysing innovation ✓

Project supported the regulatory approval and in-country registration of the SAMBA I and II platforms.

Access

KPI 2 – Overcoming market barriers ✗

Affordability

Although some reductions in the cost of SAMBA were achieved during the project, the targets for price per test cartridge and the price per device for SAMBA I and SAMBA II were not fully met. DRW is currently exploring opportunities to further improve its market competitiveness.

Scalability

KPI 3.1 – Securing Funding
KPI 3.2 – Scaling up Coverage ✗

At the time of publication of this report Zimbabwe is the only country which has adopted the SAMBA II platform at scale. The scale-up of point-of-care viral load testing and early infant diagnosis is an ongoing objective of Unitaid investments.

CE Mark for SAMBA I & II machine

FIND QARDT: Quality Control of Malaria Rapid Diagnostic Tests

Prompt diagnosis and effective treatment are the cornerstones of malaria case management; patients recover rapidly if diagnosed and treated early. Presumptive treatment of malaria (i.e. based on symptoms alone) no longer represents an optimal approach to malaria case management; it increases the risk of inappropriate use of antimalarial drugs such as artemisinin-based combination therapy (ACT) that can lead to antimalarial drug resistance.

Rapid diagnostic tests (RDTs) are a key tool for routine diagnosis of malaria. These portable and disposable tests can provide quick, reliable and inexpensive malaria diagnosis at the community level where other diagnostics such as microscopy may be unreliable or unavailable. At the start of the project there were more than 60 manufacturers of malaria RDTs and more than 200 different products available on the market. Regulation of RDTs, which is normally an important incentive for manufacturers to produce good quality tests, was not in place and not enforceable in most malaria-endemic countries due to lack of resources and tools to monitor product performance and quality. As a result, it was difficult for national malaria control programmes to determine which tests to purchase for their context. Decisions to purchase were often driven by the lowest price. As a result products varied in performance when they reached the end user.

This project aimed to address quality control of RDTs at two different points in the supply chain: before products are procured (global level product testing) and through in-country evaluations of lots of RDTs at national referral labs (lot testing). The grant also aimed to make a quality-control system for RDTs sustainable by speeding up the transition to the use of recombinant panels instead of using more costly and complex frozen blood samples.

Grant Summary

Grantee: Foundation for Innovative New Diagnostics (FIND) and World Health Organization (WHO)

Duration: January 2013 – December 2017

Project budget: US$ 9.4 million

Access

KPI 2 – Overcoming market barriers

Quality ✓

90 per cent of globally sold RDTs complied with WHO quality recommendations, and the product testing programme was transitioned to WHO PQ.

Supply & Delivery ✗

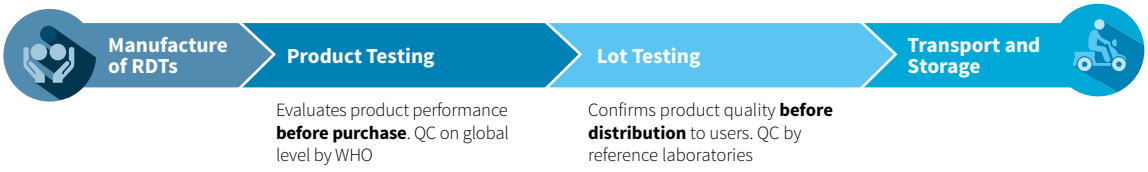
Decentralization of lot testing to 12 countries in Africa and Asia using recombinant protein panel testing, while in progress, is not yet established.

Scalability

KPI 3.1 – Securing Funding
KPI 3.2 – Scaling up Coverage ✗

The project has successfully transitioned the product testing programme to WHO PQ and the funding for it has been secured through user fees paid by RDT manufacturers. The future financing of the lot testing programme, however, remains uncertain.

Figure 11. **Quality control process for malaria RDTs**



PROJECT SUMMARY (5/6)

Lawyers Collective: Preventing Patent Barriers

Historically India has played a vital role in providing affordable generic HIV medicines to low- and lower-middle income countries, including high-burden HIV countries in Africa. Indian generic companies account for more than 80 per cent of the global antiretroviral (ARV) supply. The introduction of product patents in India in 2005 had the potential to hold back the production of generic versions of newer HIV medicines. The new laws could prevent Indian manufacturers from producing affordable generic versions of second and third-generation HIV/AIDS drugs patented after 2005. Those who require these medicines would be forced to pay much higher prices as there would be no generic versions. Furthermore the new patent laws also threaten production of new generic medicines for treatment of co-infections such as tuberculosis and hepatitis C. Using patent oppositions to prevent low-quality patents from being granted, the project aimed to ensure that production of affordable generic versions of new medicines for HIV, TB and HCV in India could continue.

Grant Summary

Grantee: Lawyers Collective
Duration: August 2013 - July 2017
Total budget: US$ 677,000

Access

KPI 2 – Overcoming market barriers

Affordability TBC

It is not possible to assess if the affordability barrier has been overcome. However, if the oppositions filed by Lawyers Collective are successful in preventing patents, the grant will have facilitated entry of affordable generic versions of newer HIV medicines and hepatitis C drugs.

Scalability

KPI 3.1 – Securing Funding
KPI 3.2 – Scaling up Coverage N/A

Not Applicable – The nature of the intervention means that limited transition is required under this project. Once a final decision on a patent opposition case has been made, no further work pertaining to the same application is necessary. However, the mechanism of patent opposition itself would require sustained funding.

PROJECT SUMMARY (6/6)

WHO PQ: Prequalification of Diagnostics and Medicines

The WHO Prequalification (PQ) programme is a key mechanism for enabling Unitaid to meet its objective on access to safe, effective, quality and affordable medicines. Unitaid supports the expansion of access to quality-assured products (for both existing products and newly available products) through an investment in the WHO PQ programme for medicines and diagnostics. Unitaid's support is intended to catalyse the introduction of urgently needed medicines and diagnostic products in low- and lower-middle income countries that have limited regulatory capacity.

In 2017 the Prequalification programme exceeded its targets for prequalifying diagnostics and medicines. Numerous products were important due to their complementarity with other Unitaid investments, to contribute to the global health response on HIV, TB and hepatitis C (HCV). The prequalified products in 2017 included:

- The first **HIV self-test (HIVST) kit**, which Unitaid is also investing in through the STAR initiative that aims to develop the HIVST market;
- The first **generic dolutegravir (DTG)** for treatment of HIV, which is also the focus of five Unitaid grants (one market entry grant and four clinical trials) that aim to generate evidence and accelerate access to DTG and other optimal ARVs;
- The first **generic sofosbuvir** for treatment of HCV, which Unitaid is also supporting through three investments that aim to make new HCV diagnostics and treatments available in low- and middle-income countries;
- 2-drug and 3-drug Fixed Dose Combinations (FDCs) for **1st line TB treatment for children**, which Unitaid is also supporting through the STEP-TB project.

Grant Summary

Grantee: World Health Organization, Essential Medicines and Health Products (WHO - EMP)
Duration: July 2017 – December 2018

Access

KPI 2 – Overcoming market barriers

Quality

29 finished pharmaceutical products (FPPs), 9 active pharmaceutical Ingredients (APIs) and 4 in-vitro diagnostics (IVDs) corresponding to Unitaid's areas of focus were prequalified and available for procurement by international procurers and funders.

Operational KPIs

2017

Operational KPIs: purpose and guiding principles

The purpose of the operational KPIs is to help the Unitaid Secretariat make sure that it works in an effective way, to successfully achieve the goals of the 2017-2021 strategy while using resources in an efficient manner, and to enable continuous improvement of organizational performance.

Operational KPIs: what they measure

Unitaid's ten operational KPIs are linked to key organizational objectives across (i) finance, (ii) grant agreement development, (iii) grant implementation, and (iv) human resources.

Most of the operational KPIs have annual targets. The exceptions to this are: the KPI on resource mobilization, which has two different targets at two points in time (in 2018 and 2021); two of the operational KPIs that are expected to deliver year-on-year improvements to reach their target by 2019 (specifically KPI E disbursement efficiency and KPI F grantee responsiveness); and finally, the operational KPI on staff satisfaction which has a target of no decrease in satisfaction vs. the 2017 baseline.

Operational KPIs: headlines from 2017

In terms of 2017 performance, six of the ten operational KPIs had specific targets in 2017. Of these, Unitaid met three targets, specifically for the Secretariat efficiency (KPI A), audit status (KPI G), and the risk review (KPI H) KPIs. For the three other KPIs with 2017 targets Unitaid almost met the target for people development (KPI I) and average time taken for grant agreement development (KPI C), but did not meet the targets related to some newer operational processes, specifically grantee reporting timeliness (KPI D).

This performance reflects in part the move to fully implement the revised operating model and introduction of a new set of systems and standard operating procedures. KPI C - speed of grant development - was 6.5 months on average, against a target of an average of 6 months. Unitaid implemented a new grant agreement development (GAD) process in 2016 and the grants signed in 2017 reflect projects given a go-ahead in 2016 and 2017. The Unitaid Secretariat is now embedding a number of streamlining processes, to support meeting the target of 6 months in the next operational KPI report. Similarly, for KPI D (grantee reporting timeliness), new processes and guidelines are intended to markedly improve the 2017 performance of 60 per cent of semi-annual or annual reports submitted on time towards meeting the target of 100 per cent. The remaining four operational KPIs did not have explicit targets for 2017. A summary of 2017 performance is presented in table 2 below.

Table 2. ***Summary of 2017 Operational KPI performance***

OPERATIONAL KPI	DEFINITION	TARGET	2017 PERFORMANCE
KPI A – Secretariat efficiency	Unitaid Secretariat operational costs (including staff costs, rent and other business running costs) relative to the total size of the Unitaid portfolio of grants	2.0% Secretariat operational expenditure relative to grant portfolio	**1.95%** Secretariat operational expenditure relative to grant portfolio
KPI B – Resource mobilization	Increase in annual donor commitments from baseline set in 2016	US$ 40m increase in annual commitments by 2018 US$ 100m increase in annual commitments by 2021	**No target for 2017** **Progress:** implementing resource mobilization strategy to meet 2018 target
KPI C – Speed of grant development	Average time it takes to complete the Grant Agreement Development Process (GAD) measured from the moment of GAD kick-off to submission of the grant package to the Executive Board	Average 6 months in 2017	**Average 6.5 months in 2017**
KPI D – Grantee reporting timeliness	Timely submission of annual and semi-annual reports by Unitaid grantees	100% of annual and semi-annual reports submitted on time	**60%** of reports submitted on-time
KPI E – Disbursement Efficiency	Disbursement requests executed by the Unitaid Secretariat within 8 weeks of completed disbursement request being received from grantee	Year-on-year improvement to reach 100% by 2019	**No target for 2017** **Progress: 72%** of disbursements executed in 8 weeks or less
KPI F – Grantee responsiveness	Proportion of grants that have implemented the critical recommendations identified in semi-annual / annual reviews in a timely manner	Year-on-year improvement to reach 100% by 2019	**No target for 2017** **Progress: 93%** of grants have implemented critical recommendations
KPI G – Audit status	Proportion of Unitaid grants with an up-to-date financial audit	100% of grants have an up-to-date financial audit	**100%** of grants in 2017 had an up-to-date financial audit
KPI H – Risk review	Proportion of Unitaid grants with an up-to-date risk review	100% of grants have an up-to-date risk review	**100%** of grants in 2017 had an up-to-date risk review
KPI I – People development	Delivery of timely performance reviews (PMDS) to facilitate Unitaid staff in their professional development	100% PMDS reviews completed on time	**96%** of PMDS completed on time
KPI J – Staff satisfaction	Level of Unitaid Secretariat staff satisfaction reported in the biennial staff survey	No decrease in staff satisfaction versus the 2017 baseline	**No target for 2017** **Progress: high staff satisfaction** with overall average **83%** positive and very positive responses

Unitaid Secretariat

T +41 22 791 12 00

unitaid@who.int

www.unitaid.org

Unitaid is a hosted partnership of the World Health Organization

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