UNITAID Executive Board Meeting
3 - 4 June 2015
Fiocruz Headquarters
Rio de Janeiro, Brazil

Agenda item 9

Update on ongoing projects

Report on Project Development, Implementation and New Investment Opportunities

For Information ☒ **For Review & Advice** ☐ **For Endorsement** ☐

Table of Contents

I. Introduction

This Report, prepared by the Operations Division in collaboration with the rest of the Secretariat (particularly the Divisions of Strategy & Results and Finance & Administration), provides in the *narrative sections* (I – VII):

- An overview (graphically) of the evolution of UNITAID funded Grants and Grantees (current and projected number of projects and Grantees; % distribution of funds per portfolio for active projects/Board-approved projects under development (Grant Agreement Development – GAD - phase); and
- A high level overview, broken down by portfolio (HIV, TB, Malaria and Transversal), of: the strategic "fit"* of all active/approved projects funded by UNITAID as a part of the global response to HIV, TB and Malaria; project performance (key achievements, challenges and a summary of performance ratings per project); a spotlight on potential new investment opportunities** that the Secretariat is considering/could consider; strategic partner engagement to inform new investment opportunities and optimize implementation of active projects.

  *In relation to "strategic fit" a high level *investment mapping* has been done per portfolio, showing that UNITAID has developed a targeted portfolio, focused on global objectives in each disease area. Its current investments contribute to the global response, are aligned to globally recognized health goals, and the key criteria for identifying interventions emphasize impact, innovation and articulation.

  **Regarding *new investment opportunities* per portfolio, this specifically refers to: (i) proposals under development that were selected by the Secretariat from past invitations for Letters of Intent (last two rounds in 2014) and (ii) concept proposals under development based on investment opportunities identified through ongoing partner engagement and UNITAID landscaping: these concept proposals comprise potential projects that would directly complement existing projects through an extension and/or expansion of scope. The former category would only be eligible for a funding based on a decision of the Executive Board (EB) at EB22 on 2-3 June and the latter would be eligible for funding based on an EB decision made under the New Operating Model, once it is launched based on the outcomes of the Special EB retreat, 23 April.

Annex (1) provides a graphical overview of the evolution of UNITAID's Grants and Grantees (for active projects and board-approved projects under development).

Annex (2) provides an update for each project presenting cumulative results as of December 2014 as well as status, challenges and next steps/ corrective actions.

Annex (3) to the narrative report provides a consolidated assessment of Grant Performance for all active projects in the four portfolios.

Annex (4) provides a detailed overview, *per portfolio*, of the US$ value, duration and % of UNITAID investments for: active projects; board-approved projects under development; proposals and concept proposals under development; and potential new areas of intervention based on landscape analyses and partner engagement.

In providing the above information, the objective of this report is to provide the PSC with sufficient rather than exhaustive insight into the overall performance and strategic fit of UNITAID's grant operations. The report is more concise and focused than previous reports and provides *highlights and snapshots* on: portfolio performance and direction; project progress and challenges; and strategic/operational partner engagement, rather than extensive details, in order to facilitate a less time consuming and more focused review process for the PSC (and EB at large). Detailed reports (semi-annual and annual) prepared by Grantees are of course available upon request (though normally post-EB sessions), should individual PSC members or Board constituencies want to make a deeper dive into specific project performance details.

II. HIV Portfolio overview

Strategic investment mapping

Disease	Global Target	Challenges	Opportunities	UNITAID Projects
HIV	*Prevention*: 75% reduction in new infections, zero new infections among infants by 2030 *Diagnosis and Treatment*: 90-90-90 by 2020 - UNAIDS	Only 50% know status, 42% for children Only 38% on treatment, 24% for children Only 25% have access to VL 2.1M new infections in 2013	New tools and approaches (e.g. self-testing, Point of Care (POC) infant diagnostics, near-POC, optimizing laboratory capacity) Better ARV formulations; voluntary licenses and TRIPS flexibilities to reduce patent barriers Overwhelming evidence of highly effective pre-exposure prophylaxis with tenofovir/emtricitabine in key populations *For HCV*: new, highly effective directly acting antivirals.	Supporting a demonstration project in multiple countries to identify best delivery models for self-testing and to improve market characteristics of current test to enable scale-up of the strategy. The project is implemented by a consortium of partners led by PSI. Large-scale procurement projects with EGPAF and CHAI/UNICEF to introduce and scale innovative POC diagnostics; demonstration projects to promote greater access to and optimization of EID/VL tests (MSF, CHAI, FEI); streamlining diagnostic regulatory pathways and promoting market entry of new POC tools (LSHTM; grants to POC developers). Support to product formulation for child-friendly ARVs (DNDi, industry); Market coordination and support to improve demand and supply dynamics for paediatric ARVs (CHAI). Projects addressing IP barriers to ARV access, implemented by MPP, Tides/ITPC, and Lawyers collective. *For HCV*: Improved, affordable treatment for HCV (MSF; Coalition Plus).

Project Overview

UNITAID's diverse HIV Portfolio is aligned with both UNITAID's strategy and the 90-90-90 treatment targets launched by UNAIDS in 2014. The Portfolio comprises a balance of medicines and diagnostics projects with diverse partners, aiming to enable sustainable access to quality-assured and affordable HIV treatment and diagnosis.

During its first 5 years, UNITAID's HIV portfolio largely consisted of investments in ARV 2nd line and paediatric ARV medicines and in prevention of mother to child transmission of HIV. These major procurement projects (>US$ 500M) helped to improve the affordability of new commodities and dramatically stimulate scale-up, by leveraging UNITAID's purchasing power to negotiate the timely supply of quality-assured health products at lower prices.

From 2012, the portfolio became more diverse and now covers a much wider spectrum of the value chain (Intellectual Property, Operational Research, Market Entry, Affordability, Quality and Delivery, among others). Through its current HIV grants (~35%[1] of all investments; projected to grow to 42%

[1] US$ value of Executive Board approved amounts for projects (excludes CHAI Paediatric ARV project which closes in 2015 and is only supporting 3 countries this year out of the original 41)

by 2017 – see Annex 4), UNITAID is supporting the development of new, better-adapted paediatric formulations, removal of regulatory and patent barriers, introduction of innovative diagnostics for infant and adult testing, and tools for monitoring the HIV infection in people who receive treatment. Additionally, in 2014, the Executive Board approved the first HIV co-infection projects, aimed at increasing access to treatment of HCV (Médecins Sans Frontières (MSF) and Coalition Plus).

A high-level overview of all active projects in the portfolio and their latest performance update (where applicable) is provided below.

To maximize UNITAID's HIV investments, the Secretariat continues to build on its partnership engagement with key global health stakeholders such as the Global Fund, The U.S. President's Emergency Plan for AIDS Relief (PEPFAR), The World Health Organization (WHO), UNAIDS, the Bill and Melinda Gates Foundation (BMGF), and the Children's Investment Fund Foundation (CIFF). Regular meetings have taken place with these partners and ongoing dialogue is planned for improved alignment and information sharing on active and potential HIV grants (see Section VII for more details).

HIV Diagnostics

Progress
UNITAID's focus on diagnostic tools is a key element of the response to the HIV epidemic and has generated a wave of diverse HIV grants. New Point-of-Care (POC) diagnostic tools are becoming available (viral load (VL), CD4 and Early Infant Diagnosis (EID)), and the support to their market entry, in-country introduction and scale up is needed in order to achieve higher impact more rapidly. The HIV diagnostic grants also support policy harmonization and the regulation of diagnostic products while aiming to secure demand and reduce prices.

Current commodity grants, i.e. **The Clinton Health Access Initiative (CHAI)/UNICEF and MSF** suffered from significant delays due to late market entry of CD4, VL and EID POC diagnostics. Nevertheless:

- CHAI/UNICEF supported countries to develop POC policy and implementation guidelines; to prepare for in-country POC scale-up through facility mapping and market segmentation, product selection, training, clinical workflow improvements, connectivity solutions piloting and data management; and through setting up systems for quality assurance. It is expected that key polices and processes will be in place for all project countries when more POC devices reach the market in late 2015/early 2016.

- UNITAID's grant to MSF remains an essential driver for VL implementation in project countries. For example, in 2014 the UNITAID funded MSF grant supported the Zimbabwe National Medical Research Laboratory in processing an average of ~ 3000 VL samples per month (~ 34,000 in the year). No other funding source for VL testing was available in the country. The results and costing estimates of the intervention to date are being used to determine national scale up plans and budgets. The catalytic effect of the grant very importantly lies with its evidence generation – for example, MSF's viral load toolkit produced within the grant has been widely recognized by several partners and countries.

In line with its strategy, two grants to support CD4 POC products for market entry (with **Daktari, Burnett Institute**) were approved in 2012, as well as a market entry grant that focuses on VL and EID, namely **Diagnostics for the Real World (DRW).** The DRW project has exceeded all year one milestones. Three new market entry proposals, having received approval, in principle, from the EB in December 2014 (EB21), are currently undergoing due diligence reviews.

Complementary grants, including those to the London School of Hygiene and Tropical Medicine (LSHTM) and to the WHO Prequalification Programme, work to improve and accelerate regulatory processes for diagnostic products. In 2014, LSHTM supported the selection of trial sites across Africa where new tools can be evaluated, using the generic protocol specifically produced for that purpose.

This could potentially lead to recognition of the evaluation results for regulatory purposes between countries and support the generation of data for WHO prequalification submissions.

In addition, UNITAID and the Global Fund have created the Expert Review Panel for Diagnostics (ERPD), a panel of experts who provide their opinion on the risks and benefits of using highly-needed tools that are yet to receive prequalification or another stringent regulatory authority certification. Two ERPD rounds in 2014 reviewed and determined the readiness for procurement of a variety of improved diagnostic tests.

OPPERA Phase 1 ended in December 2014, with over 10,000 viral load (VL) tests conducted in 4 project countries, as procurement delays related to the quality certification of amplification reagents (a key element of the open platform) were eventually resolved. Testing was initiated only in July 2014 (no-cost extension of 6 months), with revised targets that were met by the project in all but one of three target countries. Major work on defining the scope and priorities of the cost extension (18 months) is currently ongoing, with an emphasis on a sustainable and quality VL solution through the open platform concept.

Key Challenges

- One market entry grant was terminated in 2014 (Zyomyx) for failing to meet critical performance milestones;
- The two remaining active CD4 grants are struggling to find additional funding for commercialization, particularly given the WHO guideline change in 2013 which recommended VL (in place of CD4) for treatment monitoring; the Secretariat is closely monitoring their progress against stringent performance milestones.

With the arrival of new tools in the market in 2015, especially for infant diagnosis, UNITAID's HIV Diagnostics portfolio will be focused on demonstrating the impact, cost effectiveness, and utility of new tools and optimized sample transport for conventional tools, and on developing the evidence needed to inform health policy and normative guidance. Questions on where and how to introduce the new tools, seeking complementarity to conventional platforms, still need answers in order to maximize the impact. UNITAID's support to a diagnostics adviser position at WHO in 2015, will help consolidate the wealth of evidence generated through UNITAID grants and thus inform implementation globally.

HIV Treatment

Progress

The HIV treatment portfolio has diversified in response to gaps identified through market landscape analyses. Currently, the portfolio is addressing these challenges in three ways: 1. Funding grants that address intellectual property barriers to generic products entering the market to increase product adaptability and affordability, including the projects implemented by **Medicines Patent Pool (MPP), Lawyers Collective and the International Treatment Preparedness Coalition (ITPC)**; 2. Development of new child-friendly ARV formulations such as the project being implemented by the **Drugs for Neglected Diseases initiative** (DNDi); 3. Technical assistance to countries and support to industry and partners, to improve market coordination (demand and supply dynamics), through the CHAI implemented **Innovation in Paediatric Medicines Access (IPMA)** project.

In addition to the Paediatric HIV Treatment Initiative (PHTI), which was launched in 2014 during the 67th World Health Assembly by UNITAID, MPP, CHAI and DNDi, UNITAID is involved in two other complementary initiatives (launched in 2014) aimed at accelerating achievement of paediatric ARV treatment goals:

- *Accelerating Children's HIV/AIDS Treatment (ACT) Initiative*, established by PEPFAR in partnership with the CIFF which aims to double to 300,000 the number of children on ARV treatment by end 2016.

- *Global Paediatric ARV Commitment-to-Action (Commitment-to-Action):* PEPFAR, the PHTI, and the Global Fund bring together, via this initiative, all leading organizations as well as industry to accelerate the development of missing high-priority paediatric ARV co-formulations for first-and second-line treatment by 2017.

Key Challenges

- DNDi' s partnership with Cipla to develop infant-friendly formulations for a priority WHO-recommended first-line regimen (including LPV/r), has hit a stumbling block. Last year studies in dog models of the new formulations were unfavourable, delaying progression to human clinical studies and the overall project timeline. However, the latest outcomes of new dog studies have been finalized, resulting in two candidate formulations that can progress to human trials in 2015 (Phase I). If the trials are successful, these formulations, and those developed independently by another Indian generic manufacturer (Mylan), will be used in multi-country (in Sub-Saharan Africa) implementation studies assessing feasibility and acceptability.

HCV

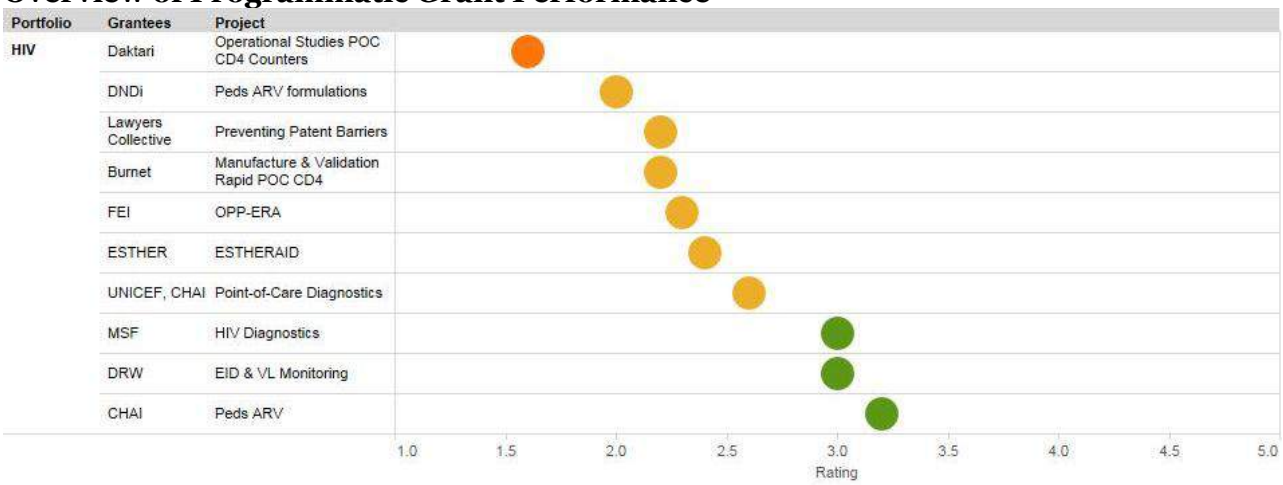
Progress

In May 2014, the Executive Board approved two proposals that focus on availability of the game-changing new drugs to cure the hepatitis C virus (HCV). The **HCV grant with MSF** was signed in January 2015, after collaborative work on the project to ensure appropriate measurement of performance and results. This grant is expected to produce key evidence on use of Directly Acting Anti-virals (DAAs) and simplified diagnostic algorithms for HCV in low- and middle-income countries (LMICs); as the pioneer of the HCV response in project countries, the grant will facilitate introduction of new treatment. It will also work on ensuring affordable prices through direct negotiations with manufacturers, as well as targeted actions against patent barriers.

Key Challenges

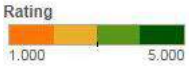
- HCV grant development work with **Coalition Plus** has been delayed due to grantee capacity constraints. However, through tactical and catalytic pre-Grant funding progress is being made on the development of an implementable project plan, taking into consideration organizational capacity and, in particular, the availability of key staff to carry the core project activities. A Grant signature is expected by end Q2.

Overview of Programmatic Grant Performance



Note: Covers the period from 1 January 2014 to 31 December 2014. The following grants i) Innovation in ARV Paediatric market access (IPMA), CHAI; ii) Novel, disposable POC CD4 test, Zyomix, iii) Access to treatment for PLHIV in MIC, Tides ITPC; and iv) Ensuring access to HCV treatment revolution, MSF; are not presented in the above graph as there are no basis for assessment.

Red = below average; yellow = average; light green = above average; dark green = excellent



Opportunities for investment

1. UNITAID is exploring potential studies to avoid delays on introduction of game-changing ARVs, including DTG and Tenofovir alafenamide fumarate (TAF). In addition, CHAI submitted a LOI in a previous call, which is now being developed as a proposal, to accelerate market entry of affordable and more convenient ARV formulations for priority WHO products in first- and second-line ART, so as guidance is issued, products might be readily available in the market avoiding unnecessary delays from innovator approval to availability in LMICs. Likewise, and in complementarity to BMGF funds, UNITAID supports WHO on optimization of ARVs to enable the timely policy and normative work needed to introduce these game-changing ARVs into countries.

2. UNITAID is exploring a concept with the Government of Brazil, on a multi-country collaboration project in Latin America for prevention of HIV transmission, where UNITAID would support early adopter countries to make PrEP commodities (TDF/FTC) affordable and available, and to address implementation questions on the optimal delivery model for target groups at most risk. The project will build on evidence from studies in the region, including research on the use of PrEP. Also, programmatic collaboration would involve other global health partners, specifically UNAIDS and civil society organizations in Brazil and other Latin American countries.

3. FIND is developing a concept proposal to build HCV testing capacity in early adopter countries through a two pronged approach to; drive use of existing/emerging tests in simplified algorithms, and introduce a transformational core antigen test (1-step diagnosis). The project is anticipated to define the diagnostics market for HCV treatment by demonstrating a clear pathway for procurement and suitable HCV diagnostic algorithms for a large-scale roll-out within public sector co-infection programs.

4. UNITAID is discussing a strategic partnership with WHO's HIV department and its Hepatitis team. The partnership will focus on a set of concentrated efforts to accelerate the uptake of HCV diagnosis and treatment in national programmes. This will be done through intense global normative work, and concentrated effort in selected pilot countries, where WHO will support regulatory processes, intellectual property (IP)-barrier removal, development of models of care for efficient delivery of service, and other work across the main pillars of the response to the disease.

5. CHAI is considering submission of a concept proposal an intervention aimed to catalyse the public sector HCV market over the next 3 years. To achieve that, CHAI and UNITAID would work with 3-7 highly motivated early adopter countries to initiate public sector treatment programs for HCV co-infected patients. UNITAID's commitment to a co-financing commodity program (either thorough CHAI and/or in collaboration with the Global Fund, based on its new Framework for Financing Co-infections and Co-Morbidities) would enable CHAI to negotiate with suppliers. CHAI would work with target countries to ensure that innovator products receive rapid and/or waived registration to start treating patients within the first 6 months and to allow generic products to register quickly once available. Lastly, CHAI would also support WHO on optimization of HCV treatment to enable the timely policy and normative work needed to introduce game-changing DAAs and other HCV therapies.

III. Tuberculosis Portfolio overview

Strategic investment mapping

Disease	Global Targets	Challenges	Opportunities	UNITAID Projects
TB	Controlling the TB epidemic to achieve by 2035: Reduction in # of TB deaths by 95%; and reduction in # of new cases by 90%	Underdiagnosis, in part due to lack of inexpensive TB diagnostics for use at the point of care (POC) Poor access to drug susceptibility testing; evolving testing needs with advent of new TB medicines and regimens Current diagnostics and medicines not adapted for specific patient groups (e.g., children) Long, complex, expensive MDR-TB regimens with severe side-effects Fragmented, small medicines markets, especially for MDR TB: quality-assured drugs a fraction of the global market; common use of inappropriate tests and medicines, especially in the private sector; poor visibility on demand	More competitive market for POC (or near-POC) tests to improve diagnostic speed and access Improved access to drug susceptibility testing, with new diagnostics reflecting shifts in medicines market (new regimens) Better diagnostics and appropriate medicines for children to identify use and inform appropriate treatment Inform use of new TB medicines and better, shorter, less toxic, novel regimens to increase access, improve outcomes – and ultimately focus the market Ensure stability and sustainability of TB medicines markets with targeted interventions (e.g., API)	EXPAND TB (WHO Global TB program/FIND/Stop TB Partnership/GDF): Expanded access to QA TB Dx– three new technologies scaled up, over 106,000 MDR-TB cases detected TBXpert: Reduced price and scaled up Xpert MTB/RIF, with over 1.4 million cartridges used in 21 recipient countries Paediatric TB drugs (GDF): Improved uptake of paediatric TB medicines in 58 countries STEP TB (TB Alliance/WHO): Develop fixed-dose paediatric medicines MDR-TB Strategic Rotating Stockpile (GDF): Stabilize supply of MDRTB medicines – including reduced stock-outs and lead times END-TB (PIH, MSF, IRD): Accelerate access to new TB drugs and develop better, shorter, less toxic, novel treatment regimens

Project Overview

The TB portfolio comprises 31%[2] of UNITAID's investments (projected to be 27% by 2017 – see Annex 4). During UNITAID's earlier lifecycle the portfolio was dominated by treatment and diagnostics projects (MDR-TB and paediatric TB) implemented by the Stop TB Partnership (STB)/Global Drug Facility (GDF) and WHO Stop TB Program (now Global TB Programme - GTB). However, from 2013 new projects broadened the scope of the portfolio covering paediatric product development, novel, near POC diagnostics (Xpert MTB/RIF) and accelerated access to new TB drugs in better, shorter, less toxic, treatment regimens.

TB Diagnostics

Progress

The **TBXpert Project** represents a game-changing approach to TB diagnostic testing through the scale-up of Xpert MTB/RIF. Implemented by WHO/GTB and STB/GDF the project has realized significant achievements including:

- ~10 million cartridges ordered in over 100 price discount eligible countries since the Buy-down agreement with Cepheid in August 2012 (funded by UNITAID, BMGF, PEPFAR, USAID). The Buy-down triggered a price reduction of 40% (US$17 to 9.98, resulting in significant savings (US$ millions –analysis ongoing) for public and private sector buyers (governments, donors, public-private partnerships);
- Steady scale-up of use of cartridges in project countries. Under the project, tests performed increased by 6 times, to 340,000 in 2014. The cartridges procured in 2014 increased 60% over procurement figures in 2013.
- The number of incident TB cases detected in 2014 was 56,000 and the number of Rifampicin resistant cases detected was 15,000, which are in line with project targets.
- A mid-term Evaluation of the project was successfully conducted and is being concluded presently.

The **EXPAND-TB Project** (~$90M, 2009 – 2015) also has notable achievements:

- Up till the end of 2014, more than 106,000 MDR-TB cases were detected by the project (cumulatively) since onset in 2009, which represents 72% of the overall project target. The total number of MDR-TB cases detected in 2014 was 35,000.
- 13 of 27 project countries transitioned out successfully to other projects at the end of 2014. The remaining 14 countries are now engaged with discussions on transition to other donors, mainly the Global Fund.
- 101 of expected 103 laboratories under this project are now routinely diagnosing and reporting MDR-TB cases.
- Over 3000 staff were trained on lab technologies in over 340 training sessions for the project sites and for country national programs.

Key Challenges

- The Xpert project will end in 2015. To ensure sustainable scale-up of Xpert while project countries transition to other funders, UNITAID is working closely with Global Fund and PEPFAR to include Xpert in their funding plans (New Funding Model and Country Operational Plans, respectively).
- The pricing of Cepheid's service and maintenance package for Xpert is far from optimal. UNITAID is planning to revive and lead efforts by key partners (Global Fund, PEPFAR, WHO, FIND) in Q3 to negotiate improved pricing terms.
- Under the EXPAND-TB project, lack of equipment maintenance for major pieces of equipment is a challenge.

[2] US$ value of Executive Board approved amounts for projects

TB Treatment

Progress

The **Speeding Treatments to End Paediatric Tuberculosis (STEP-TB) project** implemented since July 2013, is making significant inroads to increasing optimal access to paediatric TB medicines that are correctly dosed, properly formulated, affordable and of high quality. New, prequalified fixed-dose combinations (FDC)s are expected to be available in 2015.

Implemented by the Global Alliance for TB drug development, WHO GTB, and WHO Essential Medicines Program the project has so far achieved the following:

- Memorandum of understanding (MOU) signed with four pharmaceutical companies for paediatric drug formulation development.
- A new collaboration agreement was signed by TB Alliance with UNICEF to promote uptake of paediatric TB drugs and wider visibility for Paediatric TB in MCH services and at specialised (tertiary) MCH health care facilities of high burden countries.
- Almost all market estimation studies are on track or have been completed.
- Interim analysis for the pharmacokinetic study of first-line TB drugs in newborns and infants under 5kg has been completed in partnership with Stellenbosch University and the University of Cape Town in South Africa.
- Mid-term Evaluation of the project was conducted in February 2014 and noted good progress on all outputs.

Key Challenges

- The first FDC to market is expected to have a premium entry price (+20% over baseline by TB Alliance's estimation).
- Demand creation beyond displacing those children on current drugs will require further work.

The **MDR-TB Strategic Rotating Stockpile Project (SRS)** is increasing access to quality MDR-TB medicines by smoothing demand fluctuations and facilitating faster delivery – thus reducing the risk of stock-outs, long lead times, and treatment interruptions. The US$ 29M SRS, implemented by STB/GDF, consists of 12,500 intensive phase medications for MDR-TB and is located physically in Amsterdam. During 2014, 67 programs received medicines through the SRS. In total 118 orders were delivered using the SRS during 2014 with a median lead-time of 42 days.

Key Challenges

- About US$ 1.8 million worth of the drug PASER expired (demand plummeted after a WHO recommendation for use of an alternative drug was issued) and had to be written off the stock.
- Grant performance in 2014 was below average with delayed reporting and sub-optimal collaboration with UNTIAID.
- The Project is due to end in June 2015 but GDF will submit for UNITAID's consideration in June (EB22), a project plan, metrics for performance assessment and a risk management plan for a new credit facility on a reimbursable loan basis (same value, but operating costs covered by USAID). UNITAID has already discussed the planned submission with USAID and Global Fund, particularly with a view to improving on GDF's implementation performance and on ensuring coordinated partner oversight.

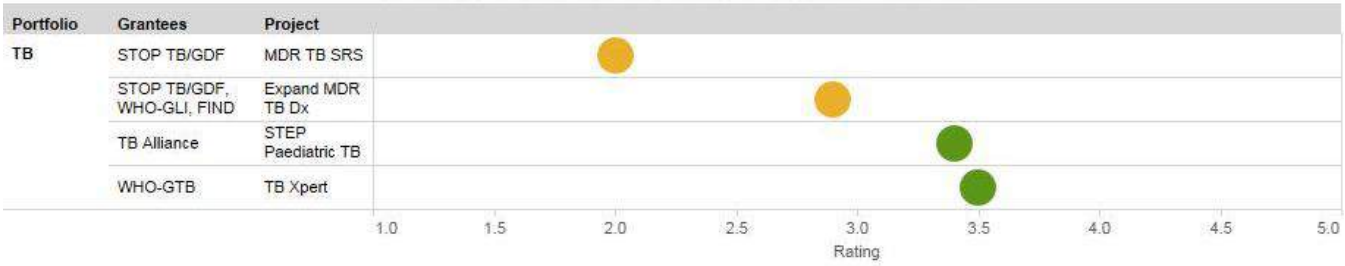
Lastly, the US$ 60.4M **END-TB project** was launched in March 2015 on World TB Day. This project aims to accelerate access to new TB medicines, while ensuring appropriate use and gathering evidence to inform the place of new medicines in shorter, more effective, novel regimens.

Implementers are Partners in Health, MSF and Interactive Research and Development (with WHO/GTB technical input and support).

Key Challenges

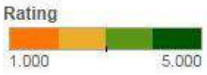
- Extensive due diligence, post Board approval, on the design of the cohort studies and clinical trials meant a protracted Grant Development period of 9 months.
- UNITAID will need to work closely with the project to assure availability of key drugs (plans are in place to leverage the Janssen-USAID bedaquiline donation; discussions with Otsuka are planned for delamanid).

Overview of Programmatic Grant Performance



Note: Covers the period from 1 January 2014 to 31 December 2014. The following grants i) Innovation in ARV Paediatric market access (IPMA), CHAI; ii) Novel, disposable POC CD4 test, Zyomix, iii) Access to treatment for PLHIV in MIC, Tides ITPC; and iv) Ensuring access to HCV treatment revolution, MSF; are not presented in the above graph as there are no basis for assessment.

Red = below average; yellow = average; light green = above average; dark green = excellent



Opportunities for investment

1. FIND is developing a concept proposal to foster introduction of second generation molecular TB diagnostic solutions. The project would complement UNITAID's END-TB project by anticipating diagnostic needs to enable accelerated market entry and broader access to new drug regimens. The two-phase approach would 1) generate evidence leading to the endorsement of new diagnostics packages and 2) establish policy and implementation support to take these to scale. Specifically, the FIND project would aim to:
    a. reinforce a more competitive diagnostics market – ensuring availability of multiple endorsed companion diagnostics matched to emerging drug regimens, as well as rapid molecular diagnostics suitable for use closer to patients;
    b. ensure capabilities for full drug susceptibility testing after rapid testing, as needed; and
    c. demonstrate feasibility of connectivity-enabled products.

2. With the advent of new paediatric TB medicines from UNITAID's STEP-TB project, UNITAID and partners are exploring needs to scale up appropriate medicines for children. The immediate opportunity is to displace current, inappropriate medicines (e.g., crushed or split adult tablets) with the new paediatric, FDCs. However, additional work is needed to reach the significant number of currently untreated children – up to 70% of children with TB do not have access to TB medicines.[3] Opportunities for investment may include demand creation to grow the paediatric market, improved TB diagnostics to address problems of under- and misdiagnosis in children, facilitated market entry of paediatric versions of new TB medicines, and strengthened contact tracing and delivery.

3. UNITAID's END-TB project will accelerate access to new TB medicines, while ensuring appropriate use and gathering evidence to inform the place of new medicines in shorter, more

[3] UNITAID Market Dynamics dashboard, April 2015.

effective, novel regimens. UNITAID is engaging with partners (USAID, others) and manufacturers (Janssen, Otsuka) to ensure availability of new TB medicines for END-TB and to explore longer-term opportunities for sustainable access.

4. Additional potential opportunities currently under consideration include: interventions to address current or potential future supply constraints in active pharmaceutical ingredients for TB medicines; rationalization of the more mature second-line drugs catalogue to simplify treatment and focus the market, pending more significant shifts toward new regimens; work to establish or support reliable, transparent demand forecasting for TB medicines – a key factor in stabilizing markets for both finished product and active pharmaceutical ingredients.

IV. Malaria Portfolio overview

Strategic investment mapping

Disease	Global Target	Challenges	Opportunities	UNITAID Projects
Malaria	≥75% reduction in malaria mortality ≥75% reduction in malaria case incidence Eliminate malaria from 20 countries Prevent re-establishment of malaria in all malaria-free areas	Low access to prevention, diagnosis and treatment services in the most affected endemic countries Inadequate health systems performance; unregulated private health sector in endemic countries Emergence of parasite and vector resistance to medicines and insecticides Lack of advanced tools to diagnose and treat P. vivax and asymptomatic infections Slow validation and uptake of new and advanced tools	Closing the gap Globally: 8 countries have eliminated malaria and many others have reduced transmission to low levels Lessons and experience gained inform options and opportunities for scale up There are promising new developments in vaccines, vector control, diagnostics and medicines	Accelerated uptake of injectable artesunate for the treatment of severe malaria Development of artesunate suppository for pre-referral treatment of severe malaria Expansion of SMC targeting 7.5m children in seven countries in the Sahel Improved quality control systems for malaria RDTs Introduction of malaria RDTs in private sector markets

Project Overview

UNITAID's diverse malaria portfolio (~21%[4] of UNITAID's investments; projected to grow to 23% by 2017 – see Annex 4) is aligned with UNITAID's strategy, the WHO Global Malaria Programme (GMP) draft *Global Technical Strategy for Malaria 2016-2030* and the Roll Back Malaria draft *Global Malaria Action Plan 2*. In addition, the UNITAID Malaria Portfolio has grown and developed over the past nine years in close consultation and collaboration with key stakeholders including WHO/GMP, the Global Fund, the US President's Malaria Initiative (PMI) and the BMGF. The Malaria Portfolio today comprises a balanced mix of projects that address the most important

[4] US$ value of Executive Board approved amounts for projects

investment opportunities where UNITAID can play a key role in improving and accelerating access to the best products for the prevention, diagnosis and treatment of malaria for the people who need them most around the world.

Malaria Prevention

Progress
UNITAID's most recent investment in malaria prevention is aimed to improve market conditions and demonstrate the feasibility and affordability of scaling-up malaria seasonal malaria chemoprevention (SMC) in the Sahel subregion of Africa.

Achieving Catalytic Expansion of Seasonal Malaria Chemoprevention Project (ACCESS-SMC) (~$67M, 2014-2016) is being implemented by the Malaria Consortium with an aim of: reducing the cost of SMC administration, promoting its wider adoption, generating evidence of the safety and efficacy of SMC, increasing the global supply of quality assured SMC, and mobilizing additional resources so that more children can sustainably benefit from this important intervention both now and into the future. To date the project has had significant achievements including:

- The Malaria Consortium has secured an order for 14.76M treatments of SPAQ, enabling approximately 3.3M children to be reached with SMC in 2015.
- Country teams are engaged with national malaria control programmes to develop detailed implementation plans for SMC for 2015.
- MSH has conducted supply chain situational analyses and developed supply chain models as the basis for implementation plans in each country.
- Country teams have developed high-level SPAQ pharmacovigilance (PV) situation analyses and PV implementation plans.

Key Challenges

- Delays experienced in contracting for PV, drug resistance monitoring and SMC impact assessment have now been resolved.
- A global shortage of SMC drugs has led to a 50% reduction in SMC coverage targets for 2015.

Malaria Diagnostics

Progress
UNITAID's investments in malaria diagnostics focus on innovative approaches to improve the availability, affordability and access to quality point-of-care tests, including a special focus on the private sector.

The **Global & National Quality Control for Malaria RDTs Project** (~$9.2M, 2013-2017) implemented by FIND and supported by WHO is designed to support national malaria control programmes by assuring the quality of rapid diagnostic tests (RDTs) for malaria. This project has had notable achievements:

- A total of 900 RDT lots were tested representing 210M RDTs distributed in 2014, of which, 99% were in compliance with WHO recommended standards.
- Round 5 product testing results and recommendations have been concluded and published.
- There has been a positive response from RDT manufactures to the Round 6 call for expression of interest and to the introduction of user fees.
- Recombinant antigen selection and refinement to replace live parasite tests as a basis for RDT quality control is progressing.

Key Challenges

- Following the end of support from BMGF in June 2014, there have been financial challenges to complete the recombinant antigen-based test development.
- There have been technical challenges hindering the development of high-quality recombinant antigen-based products and lot testing capacity (comparable to parasite-derived antigens).

- There are significant staff and budget demands required to meet the needs of the product and lot testing programmes – these will be partially addressed through the introduction of the recombinant antigen-based tests.

The **Creating a Private Sector Market for Quality-Assured RDTs in Malaria Endemic Countries Project** (~$34M, 2013-2016) is being implemented by PSI as a catalytic market intervention to develop methods, learn lessons and disseminate experience around accelerating the introduction and scale up of malaria RDTs in the private sector. To date, the project has had significant achievements including:

- Regulatory approval to deploy RDTs in private pharmacies and drug shops provided by national authorities in Kenya, Madagascar, Nigeria and Uganda.
- A total of 3.91M quality assured RDTs were procured and 2.14M RDTs delivered to wholesalers and retail outlets in the 5 project countries.
- ~800 private sector health providers from private outlets were trained on the safe and effective use of malaria RDTs, in addition to managing clients with fever.
- The Malaria Consortium has developed and is using mobile technology (smart phones) to record and report RDT results use in Nigeria and Uganda.

Key Challenges

- Delays in timely recruitment of project staff in addition to high staff turnover, have hindered overall project implementation and oversight.
- Delays in RDTs being delivered to Uganda and Nigeria due to various procurement-related issues that are now resolved.
- To ensure supply in private sector outlets, project revisions were required for the procurement ACT treatments for Madagascar and Kenya.

Malaria Treatment

Progress

UNITAID's current investments in malaria treatment focus on improving the availability, affordability and access to the best available treatment for severe malaria at the home and community (intrarectal artesunate) and at health facilities (injectable artesunate).

The **Improving Severe Malaria Outcomes Project** (~$34M, 2013-2016) implemented by MMV, is working to reduce severe malaria deaths through improved access to and use of injectable artesunate. By the end of 2014, 4.8M vials of injectable artesunate were procured through the combined efforts of MMV, UNITAID and the Global fund, resulting in not only lives saved, but also shaping the market for this medicine for the future. This project has had significant achievements including:

- MMV, the Global Fund and UNITAID carried out joint price and volume negotiations with Guilin Pharma, the sole manufacturer of injectable artesunate.
- Artesunate suppository product development has been progressing since an agreement was signed between MMV and two manufactures, Strides and Cipla, in February 2014.
- All country implementation agreements have been signed, treatment guidelines have been updated and 1 175 health workers have been trained in 5 out of 6 project countries.
- An emergency order of 324 000 vials of injectable artesunate was delivered to Kenya, Nigeria and Ethiopia.
- A total of 2.7M vials of injectable artesunate were ordered in 2014 for the 6 beneficiary countries.
- In August 2014, a product development agreement for a second manufacturer of injectable artesunate was signed with Ipca.

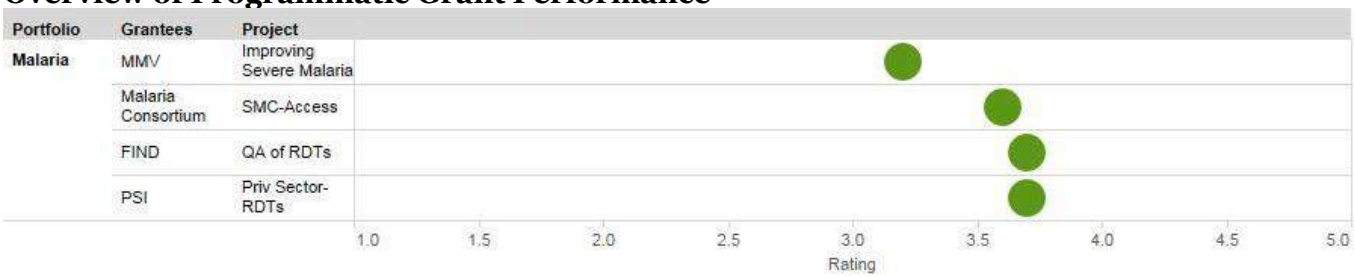
Key Challenges

- Access to up-to-date information on the status of procurement and delivery of injectable

artesunate to project countries in a timely manner.

- Delays in concluding country project implementation agreements as well as delays in the procurement and delivery of injectable artesunate to beneficiary countries.
- Delay in the submission of the injectable artesunate product dossier to the WHO Prequalification Programme for assessment.

Overview of Programmatic Grant Performance



Note: Covers the period from 1 January 2014 to 31 December 2014. The following grants i) Innovation in ARV Paediatric market access (IPMA), CHAI; ii) Novel, disposable POC CD4 test, Zyomix, iii) Access to treatment for PLHIV in MIC, Tides ITPC; and iv) Ensuring access to HCV treatment revolution, MSF; are not presented in the above graph as there are no basis for assessment.

Red = below average; yellow = average; light green = above average; dark green = excellent

Opportunities for investment

Opportunities for future investment in malaria span from concrete intervention ideas that are already under development, to new ideas that require further exploration and investigation:

- Vector control, one of the primary tools used for preventing malaria, is currently threatened by the rapid development and spread of resistance to insecticides. IVCC has submitted a revised proposal that will be presented to EB22, which aims to create a sustainable, growing and competitive market place for effective next-generation insecticides at affordable prices. By accelerating and expanding uptake of existing products, as well as increasing the number of suppliers and variety of products, the project will enable the implementation of insecticide resistance management strategies, particularly insecticide rotations in indoor residual spraying. Looking forward, opportunities are also likely to exist to support new vector control tools, particularly in relation to incentivizing new products to market, supporting policy recommendations related to product deployment, and supporting a more streamlined and efficient regulatory process.

- As part of UNITAID's "Improving Severe Malaria Outcomes" project, the MMV is currently working with two manufacturers to develop a rectal artesunate product for submission to the WHO Prequalification Programme. In anticipation of the availability of a prequalified product in the near future, MMV is developing a concept proposal to optimise the introduction and use of rectal artesunate in high burden/low resource settings. The project would focus on the pilot introduction of rectal artesunate in a selection of countries, with particular emphasis on integrated community case management (ICCM) delivery channels.

- FIND and partners are developing a concept proposal to support the introduction of positive control wells (PCWs), small plastic wells coated with dried recombinant proteins that can be diluted with water to test malaria RDT performance at the point-of-care. PCWs have the potential to increase confidence in RDT quality after transport to remote areas or prolonged storage, thereby supporting greater adherence to test results. To support the introduction of this new tool, implementation would be pilot tested in a selection of countries alongside efforts to facilitate registration and determine optimal procurement, distribution and

packaging. The proposed project would be an extension of UNITAID's "Sustainable Global and National Quality Control Malaria Rapid Diagnostic Tests", whose objectives include the creation of a market for malaria RDT quality control materials based on recombinant antigens.

- Looking ahead, it is likely that additional efforts will be needed to improve access to appropriate malaria case management in the private sector through interventions that target both ACTs and RDTs. Additional opportunities may also exist in relation to improving access to intermittent preventive treatment of malaria in pregnancy (IPTp) as well as supporting improved case management of P. vivax malaria. The latter would include the deployment of POC diagnostics tests for glucose-6-phosphate deficiency, a condition that can cause an adverse reaction to the drugs used to cure P. vivax, thereby limiting use. UNITAID will continue to work with partners such as WHO, the PMI, the Global Fund, and others to further explore and refine these opportunities.

V. Transversal Portfolio overview (including MPP)

Strategic investment-mapping (Quality assurance of medicines, diagnostics and preventives)[5]

Disease	Global Target	Challenges	Opportunities	UNITAID Projects
HIV, TB, Malaria	Availability of quality-assured priority medicines, diagnostics and devices for HIV, TB, malaria	Desire of manufacturers to avail themselves of WHO Prequalification (PQ) Ability of manufacturers to meet prequalification requirements Absence of a single, harmonized laboratory evaluation mechanism Lack of harmonized procurement standards (particularly among national buyers) Lack of harmonized registration	Building manufacturers` capacity to meet requirements More collaboration with Stringent Regulatory Authorities Harmonization of procurement requirements New, cheaper and better public health products for LMICs, especially for children Facilitating fast-track registration and harmonized review	WHO PQ programme enables access to quality-assured, effective and affordable treatments, diagnostics and preventives for HIV, including co-infections such as HCV, TB, malaria

UNITAID's transversal portfolio (14%[6] of UNITAID's investments; projected to be 8% by 2017 – see Annex 4) consists of three projects; the WHO Prequalification (PQ) Programme for Medicines (~$104M, 2006 – 2016); the WHO PQ Programme for Diagnostics (~$23M, 2009 – 2016); and the Medicines Patent Pool (~$31M, 2011 – 2015).

The PQ projects provide guidance on the quality, safety, and efficacy of drugs, vaccines, and diagnostics used in public health to a range of stakeholders, including donors, countries and procurement agencies. These projects are also important providers of technical assistance and normative guidance on quality assurance to countries with insufficient or underdeveloped regulatory capabilities. The MPP project aims to bring down prices of HIV medicines (including priority

[5] MPP covered under HIV strategic investment mapping on page 4
[6] US$ value of Executive Board approved amounts for projects

paediatric medicines) and facilitate the development of better adapted HIV medicines (e.g. FDCs for adults and children) by creating a pool of relevant patents for licensing to generic manufacturers and product development partnerships.

Quality Assurance of Medicines, Diagnostics and Preventives

Progress
The bulk of the funding for these very important initiatives comes from UNITAID (with the remainder largely provided by BMGF). The latest notable achievements of the **WHO PQ Medicines and Diagnostics Programme** are:

- In 2014 the WHO PQ revised processes and procedures for prequalifying in vitro diagnostics (IVDs) resulting in the launch of a streamlined prequalification process with improved transparency, efficiency and partnership with key organizations. The first IVD to be prequalified under the new procedure took place on 18 September 2014 and since that date eight other IVDs have also been prequalified.
- Collaboration has been initiated with the United States Government (USG) to establish a single quality assurance (QA) mechanism for IVDs, to be used both by UN agencies and PEPFAR.
- The WHO PQ Team secured additional funding from BMGF, to supplement UNITAID funding for IVD prequalification. UNITAID and BMGF have formalized close collaboration on their joint funding of the WHO PQ (joint review of funding proposals, performance reports; regular coordination meetings).
- During 2014, 28 priority medicines (Finished Pharmaceutical Products), 17 APIs, and seven Quality Control laboratories were prequalified.
- With respect to the long-term financing of WHO PQ, development of a financing model by McKinsey & Company was undertaken from June to August 2014 (funded by BMGF). The terms of reference specified the development of a model that aims to generate sufficient income to cover 50% of the operating costs of prequalification and related regulatory activities.
- The WHO PQ participated in the piloting of the Medical Device Single Audit Program of the International Medical Device Regulatory Forum (IMDRF).
- Eight additional countries agreed to participate in the medicines collaborative registration procedure to accelerate the rate at which prequalified medicines are registered and made available to patients.
- The Expert Review Panel for Diagnostics, similar to the Expert Review Panel for medicines, was piloted and implemented successfully.

Key Challenges
- Absence of a single, harmonized laboratory evaluation mechanism.
- Lack of harmonized procurement standards for Malaria medicines, especially for the procurement derivatives of natural resources, to support local manufacturers continues to be a major risk to medicines prequalification.
- The bulk of purchases with donor funds are concentrated on a few large-scale suppliers, which is detrimental to local producers who have invested in improving the quality of their production. The latter now need to see some returns on their investment if they are to be encouraged to adopt and maintain quality assurance standards.
- It is expected that several diagnostics manufacturers that failed to meet prequalification requirements in the past, but whose dossiers were retained in the pipeline, will not be able to comply with prequalification requirements. Their dossiers will therefore be removed from the assessment process, resulting in a pipeline that contains only active applications.
- The feasibility of the options being proposed by McKinsey for a more sustainable long term financing solution for WHO PQ need to assessed by UNITAID and BMGF and messaging around the selected option(s) carefully managed.

Removing Intellectual Property Barriers to Medicines Access

Progress:

The **Medicine Patent Pool Foundation (MPPF)** project could potentially include HCV and TB medicines in its scope, should the UNITAID Executive Board approve the inclusion of licenses for TB and HCV medicine patents. This would enable MPPF to support improved market access by generic manufacturers to HIV, HCV and TB medicines. In this regard, MPPF has completed the Feasibility studies on diversification of funding and expansion into tuberculosis and hepatitis C studies and they are currently being reviewed by the MPPF's governance bodies. The studies are still a work in progress with more time for further analysis for the MPPF to continue developing the studies. They will serve as a starting point for the MPPF's own proposals to be provided to UNITAID later in the coming months after appropriate consideration and consultation. The MPPF will share the findings of these works with stakeholder groups as part of the consultation process that the MPPF will undertake including with civil society and patient groups active in these treatment areas. The latest notable achievements of the project include:

- In February 2015, the MPPF signed a Licensing Agreement with MSD for Paediatric Formulations of Raltegravir covering 92 countries, allowing generic manufacturers to reformulate the formulations for use and distribution in resource-limited settings.
- MPPF has secured licence agreements on 50% (8/16) of the priority products identified in the ARV priorities document.
- Sub-licensees for the development of the Quad, a FDC of TDF, FTC, EVG and COBI have planned the bioequivalence studies and developed prototype pills.
- The MPPF has completed its milestone of the expansion of its Patent Status Database covering 25 ARVs in 85 countries.
- PricewaterhouseCoopers will conduct an audit of the MPPF's financial statements for 2014 in Q2 2015.

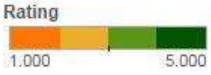
Key Challenges:

- More focus is required on strengthening engagement with various stakeholders, and on advocacy and communication to raise visibility of MPPF
- MPPF needs to strengthen its M&E framework including measurement of downstream results.
- There are major challenges in achieving MPPF's goals of generic competition and price reduction. The paediatric formulations goal is especially difficult, given the multiple barriers – in addition to patents - to product development and access.

Overview of Programmatic Grant Performance

Note: Covers the period from 1 January 2014 to 31 December 2014. The following grants i) Innovation in ARV Paediatric market access (IPMA), CHAI; ii) Novel, disposable POC CD4 test, Zyomix, iii) Access to treatment for PLHIV in MIC, Tides ITPC; and iv) Ensuring access to HCV treatment revolution, MSF; are not presented in the above graph as there are no basis for assessment.

Red = below average; yellow = average; light green = above average; dark green = excellent



Opportunities for investment

1. To enable sustainability in grants funded by UNITAID, leverage the WHO PQ Programme to provide more Technical Assistance to National Drug Regulatory Authorities and support local manufacturers to build strategic manufacturing capacity
2. If the MPPF starts negotiating licenses for TB and HCV medicines, market access by generic manufacturers is expected to increase the opportunity for cheaper formulations. This in turn may bring about an opportunity for investments both on the part of UNITAID and manufacturers.

VI. Partner Engagement

UNITAID's New Operating Model - partner engagement to secure strategic alignment and impact

UNITAID's new operating model, which will presented at EB22, has a strong emphasis on *strengthening and leveraging partnerships* with a focus on results. Acknowledgment of the importance of partnerships in support of UNITAID's role in global health is rooted in 2 main objectives: 1) alignment on strategy and areas for intervention, and 2) ensuring articulation of projects in the real-world, with a view to securing scale-up and sustainable impact, through complementarity (non-duplication) and efficient coordination of investments. With this approach, UNITAID aims to engage partners throughout the life-cycle of a project (from inception to transition/close) thus, enabling partners to do more with less, ultimately providing the populations in need with quality, affordable and effective commodities for HIV, TB and malaria and making them available faster.

How have we been engaging partners to align on strategies?

UNITAID has been actively engaging key global health partners in dialogue on potential areas for strategic alignment and overall collaboration. In addition to validating UNITAID's vision and evolving role in global health, partners agreed upon the need for increased communication, information sharing and coordination. The following are examples of strategy alignment:

Key Partners Engaged	Example: agreed co-investment areas
Global Fund	▪ *Near-term:* artesunate pricing, market entry of rectal artesunate, new insecticides; transition of MDR-TB grants (Xpert and EXPAND-TB); scale-up of new paediatric TB medicines (introduced via TB Alliance STEP-TB project); coordination on inclusion of POC Dx in country concept notes. ▪ *Medium-long term:* facilitating uptake of vector control innovations and HIV POC Dx; HCV Tx and Dx co-financing; potential scale-up of HIV ST.
PMI	▪ *Near-term:* new insecticides, rectal artesunate, positive control wells. ▪ Areas for future exploration e.g. vivax Tx/G6PD tests.
PEPFAR	▪ *Near-term*: Optimization of laboratory-based platforms for VL, EID and development of new paediatric ARVs. ▪ *Medium/long-term*: Coordinated scale-up of multiplex Dx (HIV, TB, HCV); potential scale-up of HIV ST
CIFF	▪ *Near-term*: Agreement on priority countries and approaches for scale-up of POC EID, linked to CHAI/UNICEF and EGPAF projects and coordinated with PEPFAR and Global Fund laboratory-based/treatment efforts
USAID	▪ Continued commitment to support SRS: USAID will cover operational costs and UNITAID the capital investment loan.

How have we been engaging partners to secure impact?

UNITAID Operations and Strategy/Results staff, working in cross-divisional project teams, have already begun implementing the approach laid out in the New Operating Model on more effective strategic alignment new concept proposals with other key partners. The table below provides examples of this work for two proposals (For EB22 Decision: Institut Bouisson Bertrand [from last LOI call] and IVCC proposal resubmission to EB21) and three new concept proposals that are being explored for ultimate submission under the New Operating Model procedures (subject to EBSS approval). These engagements have so far taken place during Q1/April through regular meetings and teleconferences.

Proposals/ Concept Proposals	Partners engaged	Example outputs
CONCEPT PROPOSAL *New TB diagnostics* to complement END-TB project Tx goal (FIND)	PIH, BMGF, WHO, USAID, MSF	• Alignment on strategy with co-funders (BMGF) • Alignment on real-world linkages between Dx and Tx (PIH, MSF) • Alignment on coordination of policy and product endorsement (WHO)
PROPOSAL[7] *New insecticides* for Malaria vector control (IVCC)	PMI, BMGF, GF, WHO	• Agreement on need to incentivize new insecticides and other innovations to manage resistance • Endorsement of detailed project approach (IVCC)
CONCEPT PROPOSAL *New diagnostics, WHO technical support, IP barrier removal, and Tx optimization* to complement *the already approved MSF and Coalition Plus HCV Tx projects* (CHAI, FIND, ITPC, WHO)	MSF, Coalition Plus, WHO	• Alignment on strategy • Identification of gaps and possible complementary interventions (Dx, Tx, IP, Demand Creation, evidence gathering for policy making)
CONCEPT PROPOSAL *ARV treatment Optimization* (CHAI)	WHO, PEPFAR, Global Fund	• Agreement on need to pursue the market entry of improved, simplified first and second-line ART • Accelerating availability of new, affordable and more convenient ARV formulations for priority WHO products in first- and second-line ART.
PROPOSAL[8] *Evidence on new ARV Tx regimens in LMICs* (Institut Bouisson Bertrand)	WHO, CHAI	• Enabling improvement of first-line ART regimens by gathering evidence in affected populations in LMICs for priority WHO products, including DTG and EFV low dose.

Global Fund Engagement Plan

In Q1/April 2015, UNITAID and the Global Fund have been actively mapping out areas to further strengthen collaborative efforts. There have been three tiers of discussion around which specific areas of support/leverage have been identified.

Executive Office: Both executive offices have been working to align on a high level strategy for collaboration based on the current MoU. A "Principals meeting" of the heads of UNITAID, Global Fund and PEPFAR was convened by UNITAID on 02 April to validate key areas of strategic alignment. This successful meeting resulted in agreement on areas for collaboration on the HIV, TB and malaria response (update to be provided during PSC13 and EB Retreat on 23 April 2015).

[7] EB21 resubmission
[8] From last LOI Call

Operations Team Leads and Fund Portfolio Department Heads/Managers: in 2014, more proactive, frequent and focused engagements with some Fund Portfolio Managers (FPMs) were already initiated in relation to ongoing projects (e.g. MMV Severe Malaria: coordinated price negotiations for Inj. Artesunate; transition planning for EXPAND-TB and Xpert projects) and on new UNITAID projects (e.g. CHAI/UNICEF POC). Building on this collaboration, Operations Division Team Leads have been actively engaging Global fund Department heads and FPMs to agree on the most effective way to coordinate on co-investment opportunities for existing projects and on transition plans, by disease and country. These meetings have confirmed that multiple entry points are required/needed at Global Fund Secretariat for different purposes:

- *FPMs* (In relation to linking UNITAID investments to Global Fund concept note development/grant making for mapping co-funding; coordinated country engagement);
- *Disease Advisors* (On strategic alignment and policy);
- *Procurement and Sourcing Team* (on coordinated tendering, forecasting, price negotiations, quality assurance);
- *Health Product Management Specialists* (on rational product selection; coordinated budgeting and quantification in concept notes/grants);
- *Innovation Team* (on new, out of the box investment areas, approaches)

UNITAID has taken the following approach to the above collaboration:

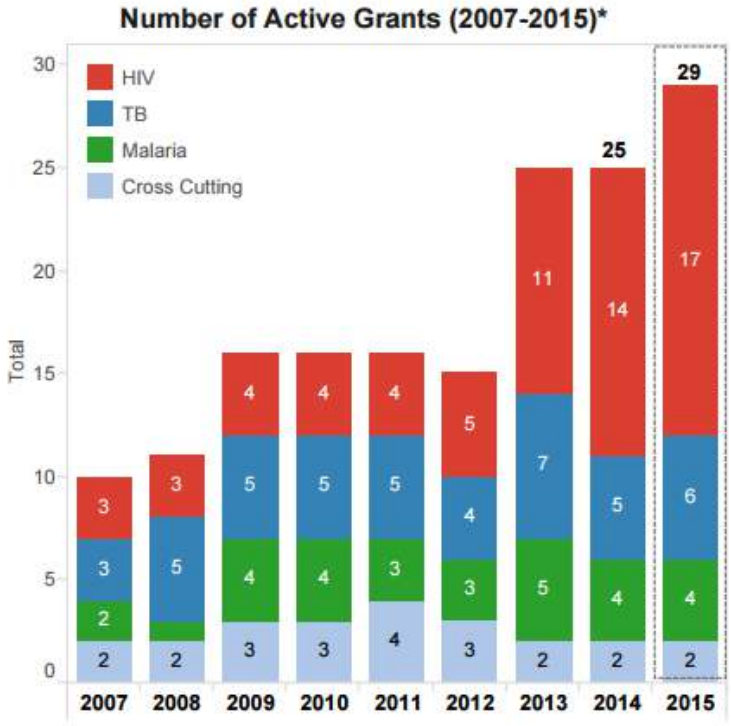
- Continuing the frequent engagement of the PSM team initiated in 2014 (via quarterly meetings and more frequent bi-lateral discussion on focused project issues). The next meeting is scheduled on 01 May.
- Working initially with the head of the largest Grant Management Division (Africa and the Middle East) and her team to prioritise linkages between UNITAID's projects and Global Fund grants. So far a focal point for UNITAID has been appointed for this division and several meetings have been held with country specific FPMs and HPMs. Once a smooth modus operandi is established the same approach will be taken with the other two divisions (High Impact Africa I and II).
- Agreement on periodic meetings in 2015 with the HPM team (every quarter)
- Continued close collaboration on the implementation of the co-funded Expert Review Panel on Diagnostics (Technical engagement led by Market Dynamics TO)
- One-on-one meetings with FPMs of a more informal nature to facilitate relationship building.

Project teams: Cross-divisional project teams (Programme Managers/Project Officers (PM/Os) from Operations and Technical Officers (TOs) from Strategy and Results: Market Dynamics) have been engaging the Global Fund on:

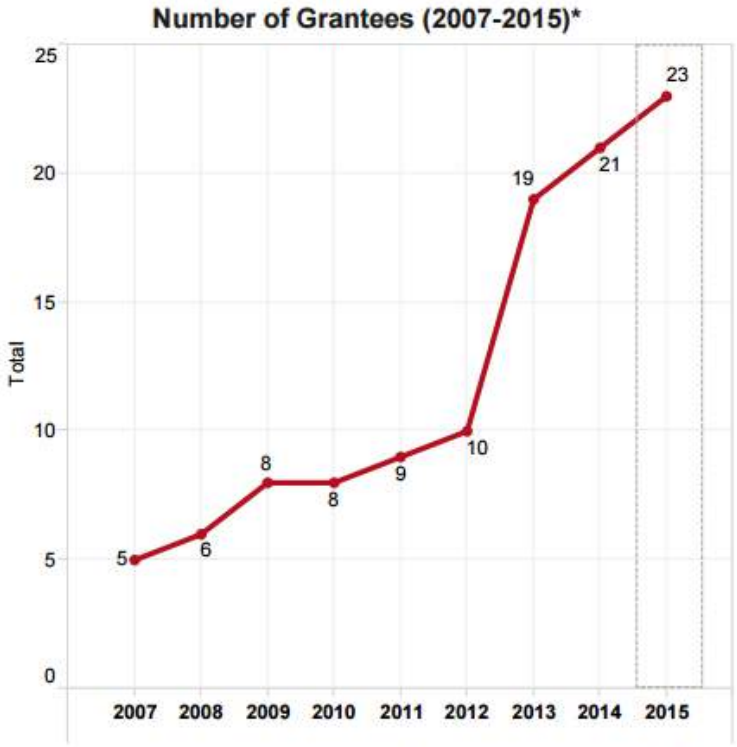
- Strategic alignment and validation of potential opportunities (e.g. concepts detailed above) (Market Dynamics TOs are focal-points in the teams for this work).

- A mapping process to identity all countries supported by UNITAID HIV, TB and Malaria projects and at which stage they are in the Global Fund funding cycle (pre-concept note, concept note development post-concept note approval/grant development, post grant-approval). This will help UNITAID and Global Fund to develop a prioritised plan of action in Q2 to ensure that UNITAID investments, where relevant, are reflected in Global Fund Concept Notes and/or Grants (Operations PM/Os are focal points in the teams for this work.

Annex 1. Evolution of Grants and Grantees



2015 is a projection: includes active grants as of 31 March 2015 and GAD. *PMTCT I , PMTCT II and PMTCT III with UNICEF, is counted as one. Includes Cepheid. Excludes Secretariat Initiatives. POC I, II (CHAI, UNICEF) counted as two grants.



2015 is a projection: includes active grants as of 31 March 2015 and GAD. *Includes lead grantees and not consortiums/sub-recipients; excludes Secretariat Initiatives. WHO Departments (EMP, GTB, GLI) counted as one. Includes Cepheid.

Annex 2. Project updates

Annex 3. Combined programmatic and financial project performance assessment

Annex 4. Portfolio of Investments: Active to Potential Grants

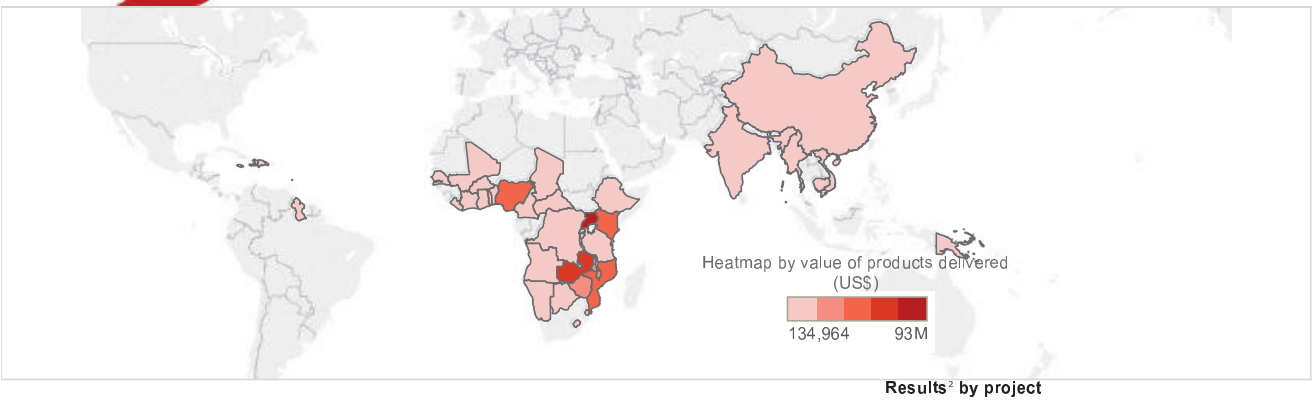
(See next pages)

Annex 2: Project Updates

For Information ☒ For Review & Advice ☐ For Endorsement ☐

Provisional update as of 15 May 2015.

HIV/AIDS Portfolio Profile



Results[2] by project (Includes all project countries, 2006-2014*)

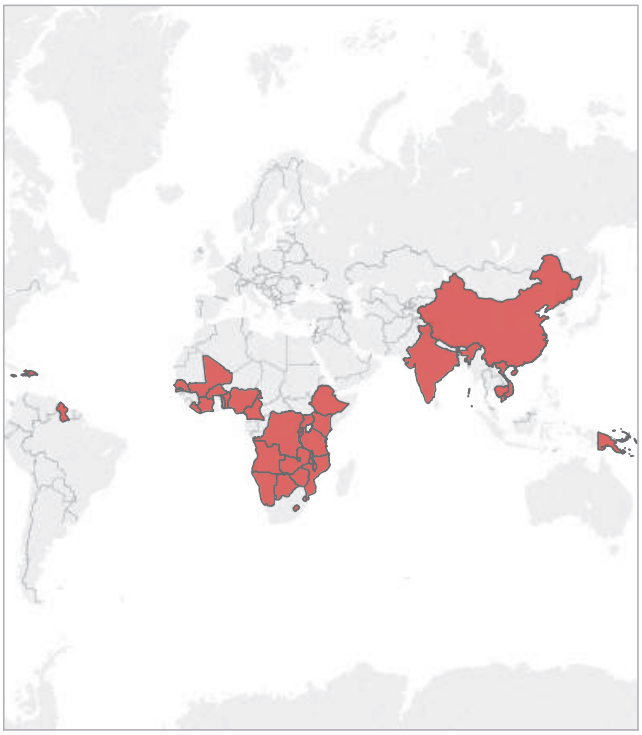
Project	Duration	Description	Results
Paediatric ARV (CHAI)	01/11/2006 - 31/12/2014	# of HIV tests delivered for early infant diagnosis	2,220,574
		# of new children on HIV treatments	498,572
HIV CD4 and VL Diagnostics (MSF)	25/12/2012 - 31/12/2015	# of PoC CD4 tests done	47,982
		# of viral load (VL) tests done	149,243
		# of EID tests done	168
ESTHERAID (ESTHER)	03/07/2009 - 31/12/2014	# of sites with patient monitoring tool since 2009	55
		# of sites with stock management tool since 2009	57
OPP-ERA Phase 1 (FEI)	12/02/2013 - 30/06/2016	# of VLT tests performed by target countries	11,921
		# of VLT procured and delivered	20,536
Point-of-Care HIV Diagnostics Phase I, II (CHAI, UNICEF)	30/11/2012 - 28/02/2016	Volume of Pima products procured (Pima devices)	115
		Volume of Pima products procured (Pima tests)	124,700
Ped ARV formulations (DNDi)	31/05/2013 - 31/05/2016	Devt of better adapted FDC ARVs for children	
Preventing Patent Barriers (Lawyers Collective)	01/08/2013 - 30/07/2016	Filing of Patent Oppositions	
		Patent landscape produced	

The Market Entry projects are not mentionned in the above table but project updates are presented and available in this section.

Grantees

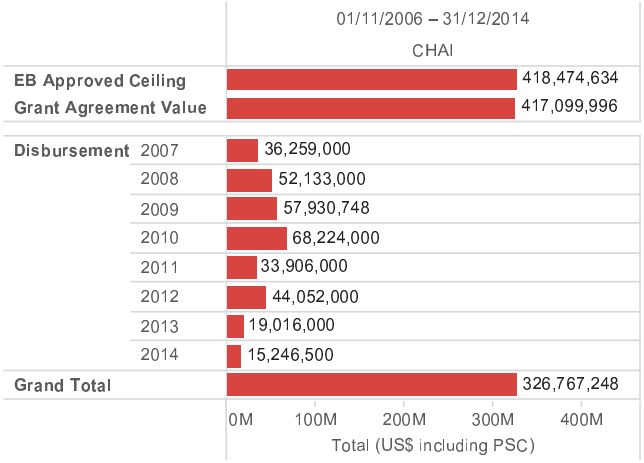
Provisional figures as of 31 December 2014.
Visit http://www.unitaid.eu/en/what/hiv
[1]Value (US$) of products provided to countries.
[2]Estimates of patients treated (new and existing) based on data provided by the MoH/grantees or on volumes ordered where data are missing. [3]Includes Tenofovir ordered as first line treatments for Namibia (2008), Uganda and Zambia (2008-2010).

Paediatric ARV Program (2007-2014)



Strategic Objective 2: Affordable, adapted paediatric medicines

The goal of the Project is to maintain on-going access to paediatric ARVs, diagnostic bundles and related components. It also aims to increase the sustainability of the paediatric marketplace through the use of supplier selection techniques that increase the number of quality assured paediatric products and reduce their prices. The project is also working to identify long-term funding sources for paediatric ARVs and related commodities and support countries in securing these funds.



Financial data as of 31 December 2014

All

Project Activities	2008	2007	2011	2009	2012	2010	2013	2014	Total
# of new children on HIV treatments	55,995	134,677	65,916	60,014	32,727	73,578	44,412	31,254	498,573
# of HIV tests delivered for early infant diagnosis	168,123	75,115	422,096	302,578	401,959	372,810	257,883	220,010	2,220,574
US$ value of HIV diagnostics purchased	2,773,175	1,823,495	17,541,535	13,411,220	10,511,671	14,289,285	4,804,296	4,002,029	69,156,705
US$ value of opportunistic infections medicines purchased	8,538,277	8,158,958	2,811,884	2,218,649	1,672,068	795,154			24,194,990
US$ value of paediatric ARVs delivered	25,889,010	20,178,640	26,484,204	16,370,168	12,429,353	17,940,882	12,986,918	7,115,166	139,394,341
US$ value of ready-to-use therapeutic foods purchased	6,316,407	3,887,897	2,019,825	6,364,263	3,741,147	5,544,320			27,873,858
Off-cycle emergency orders for all beneficiary countries								2,041,023	2,041,023

Update on Peds ARV

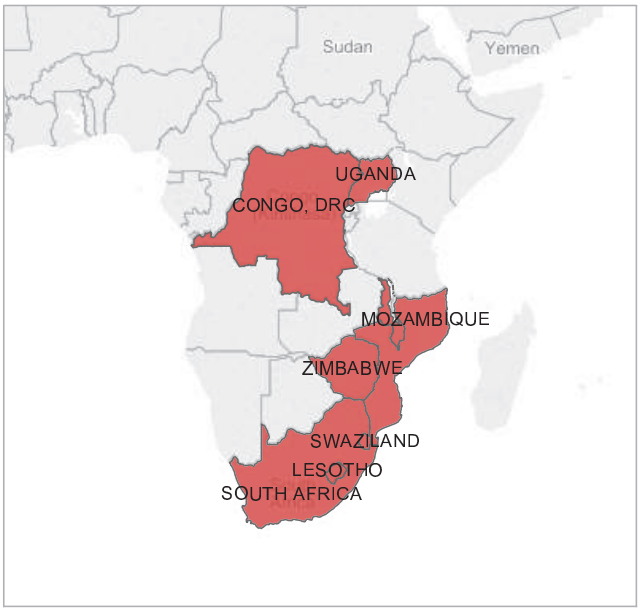
Status	• Final orders placed in Dec 2014. Deliveries out of such orders will be made in 3 countries from January-June 2015.
Challenges	• After 2 cost extensions the project is on track for full transition of the last 3 countries to Global Fund support. • UNITAID/current funder, the Global Fund/new funder and CHAI are in close collaboration including joint communication to the countries.
Next Steps/ Corrective Action	• End of project evaluation and final audit to be conducted in Q3 2015.

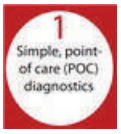
Update as of May 2015.

For more information, visit www.unitaid.org/impact

EB22/2015 PROJECT UPDATE

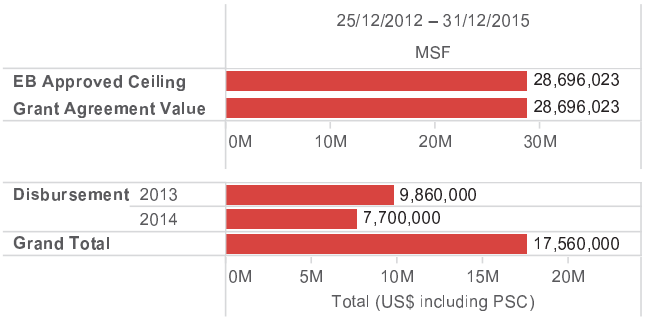
Implementation of CD4 and VL testing in decentralized, resource-limited settings (2012-2015)





Strategic Objective 1: Simple, point-of-care (POC) diagnostics

The project engages in operational research on introduction of PoC and adapted laboratory-based monitoring to understand how, where and when PoC fits in the mix of laboratory services available in the health services. Eleven different MSF-supported HIV/AIDS programs in the seven project countries engage in complementary work to compare different strategies and identify the most feasible and affordable options for optimal deployment and use of diagnostic tests in given types of resource-constrained settings.



Financial data as of 31 December 2014

Project Activities	2013	2014
# of EID tests done	0	168
# of PoC CD4 tests done	18,063	29,919
# of Viral Load tests done	54,305	94,938
# of stable ART patients tested by routine district/regional lab-based viral load follow-up	32,063	61,154
# of stable ART patients tested by routine peripheral facility viral load follow-up	2,414	9,571

Provisional results figures as of 31 December 2014. Estimates of patients treated (new and existing) are based on data provided by the Ministry of Health/Implementing partners or on volumes ordered where data are missing. Country data disaggregated by year.

Update on HIV Diagnostics

Status

• Project maintains its dynamic nature by introducing operational changes based on new evidence and opportunities in countries, while taking stock of product pipeline delays.

• A one year no-cost extension has been granted for majority of the project sites, with the validation of the revised operational plan and budget taking place in May 2015.

• Additional country (Kenya) was added in 2015 with research on optimal placement of POC EID devices beyond PMTCT sites.

• The increased number of viral load tests implemented and a steep rise in the request of external sites - from both MoH and other partners - for viral load testing are testimonies of the steady uptake of viral load activities at country level.

Challenges

• Delayed availability of devices slowed down the uptake of viral load activities; introduction of UNITAID's QA policy for procurement further delayed the selection of some platforms in countries.

• Sustainable funding: most countries are facing a funding gap; MSF has been very active in liaising with partners, notably the Global Fund; more work is required both nationally and globally to ensure that funding for viral load monitoring is maintained, and does not divert funds from other health priorities.

Next Steps/ Corrective Action

• Preparing sustainability plans in the bigger frame of scaling down support at country level.

• Setting up and implementing hand-over and advocacy strategies to ensure quality of care and sustainable scale up of viral load activities at country level.

• More advocacy activities will be implemented with a specific focus on raising the profile of viral load activities at patient level (civil society mobilization) and health facilities.

• Consolidation and expansion of viral load activities (South Africa, Zimbabwe, Mozambique, Uganda) and focusing on better integration with the MoHs' laboratories (Uganda, Swaziland, Malawi and Mozambique).

Update as of May 2015.

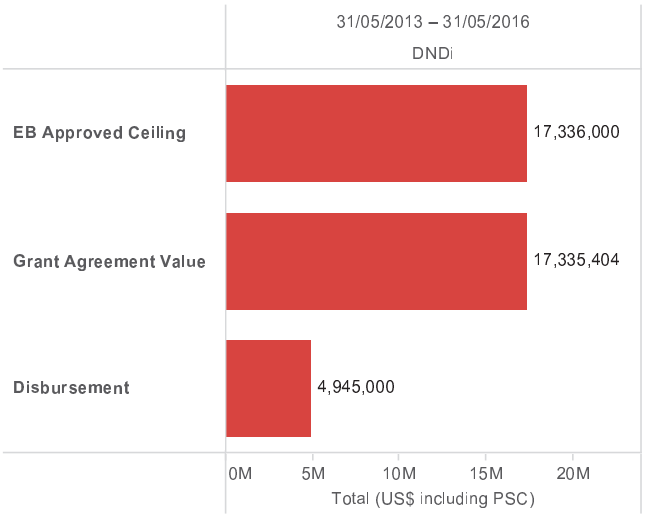
For more information, visit www.unitaid.org/impact

EB22/2015 PROJECT UPDATE

Market entry of an improved solid protease inhibitor-based first-line ARV combination therapy for infants and young children with HIV/AIDS (2013-2016)

Strategic Objective 2: Affordable, adapted paediatric medicines

The Project will be implemented with a view to increasing access to optimal ART for children under three years and will involve the development of three products through the DN-Di's partnership with Cipla.



Financial data as of 31 December 2014

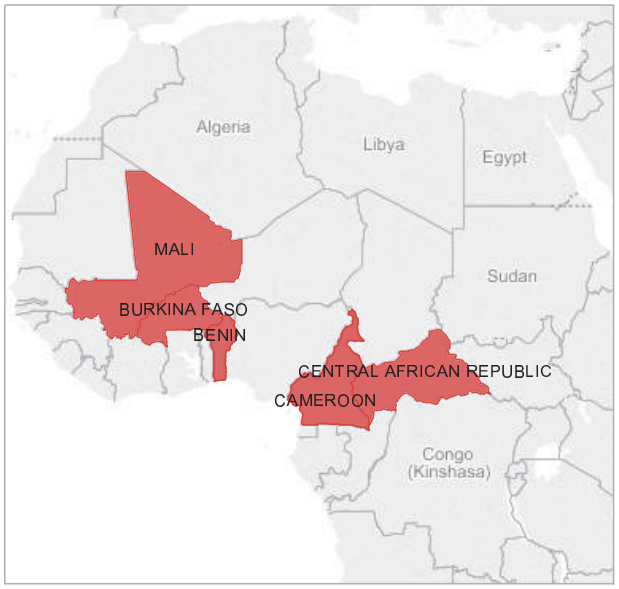
Update on Peds Formulations

Status	• Delays in implementation of project activities.
Challenges	• The project is facing delays in developing a suitable paediatric formulation to progress to phase I human studies.
Next Steps/ Corrective Action	• Cipla and DNDi teams reassessed the formulation(s) development plan in consultation with experts from pharmaceutical companies, manufacturers and scientists. • A series of 20 plus variants were tested in dogs between Jan-Dec 2014. • Several formulations are promising and demonstrate that a new taste masking approach by coating the formulation may be most effective. • Operational review/financial audit planned for late Q2 2015 (helping DNDi/UNITAID plan for the next steps of this project).

Update as of May 2015.

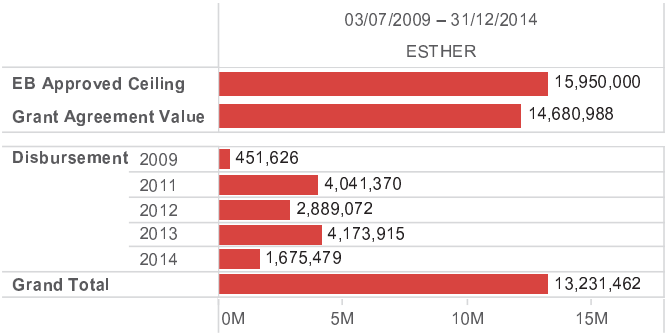
For more information, visit www.unitaid.org/impact

Easing and safeguarding the availability of ARV treatment (2009-2014)



Strategic Objective 3: Treatment of HIV/AIDS and co-infections

This project contributes to improving supply chain management from national central medical stores to treatment centres in 5 West African countries by improving logistic information systems and patient monitoring systems. The project also supports the efforts of treatment centres to improve treatment choices by making sure that UNITAID supplied tests and treatments are received and used.



Financial data as of 31 December 2014

Project Activities	2012	2013	2014
# of people trained on HIV patient care*	1,388	1,215	1,750
# of people trained on procurement & supply management*	87	345	823
# of people trained on data mgt system*	206	283	819
# of sites with patient monitoring tool since 2009*			55
# of sites with stock management tool since 2009*			57

Provisional data as of 31 December 2014. 2012 figures on training is cumulative covering the period from January 2011 to December 2012. Patients treatment and test numbers are a breakdown by year. Number of sites is a cumulative figure since 2009.

Update on Estheraid

Status	• In Jan 2015, six main French technical assistance operators (including ESTHER) merged and formed a new agency, Expertise France. • Letter of Agreement (LOA) signed (UNITAID Executive Director/France Expertise Director) confirming new agency assumes obligations agreed to by ESTHER under original Grant Agreement (ESTHERAID-Project).
Challenges	• Not all milestones will be met: political conflicts in Mali and Central African Republic required adaptation with suspension of hospital partners' missions and international technical assistance.
Next Steps/ Corrective Action	• End of project evaluation and final audit to be conducted in Q3 2015.

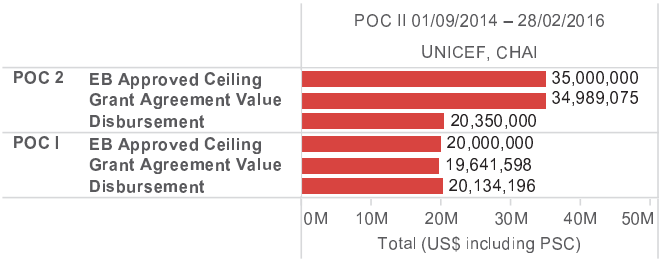
Update as of May 2015.

For more information, visit www.unitaid.org/impact

Accelerating access to Innovative POC HIV diagnostics (Phase II) (2014-2016)

Strategic Objective 1: Simple, point-of-care (POC) diagnostics

The project prepares the market for accelerated scale-up of POC HIV Dx: CD4, VL and EID by working with 7 high-volume early adopter countries to prepare for rapid scale-up of POC Dx, while helping new suppliers through the regulatory and policy approval processes.



Financial data as of 31 December 2014. POC Phase 1 from November 2012-August 2014

Project Activities	2014
The number of patients registered at sites receiving UNITAID-funded POC devices and device-free POC tests	80,066
Volume of orders for devices placed and delivered	110
Volume of orders for test placed and delivered	770,100
US$ of orders for devices placed and delivered	674,882
US$ orders for tests placed and delivered	4,582,095

Provisional data as of 31 December 2014.

Update on POC II

Status

• 110 POC devices and 770,100 POC tests totaling approximately $5.3 million delivered across the seven project countries.

• Extensive programmatic work to implement and optimize wide-scale POC CD4 testing, and to prepare the countries for wide-scale implementation of POC EID and viral load (VL) testing.

• Special project meeting took place in April to discuss reprogramming in order to strengthen overall lab networks (in particular EID and viral load), as a basis for successful POC introduction.

• CHAI is currently going through a research capacity assessment in order to strengthen the setup for planned research within the grant.

Challenges

• Further product pipeline delays or failed product evaluations may slow down the product selection process and subsequent scale-up of new POC products.

• Given the introduction of PMTCT Option B+ and the transition of ART monitoring from CD4 to VL, the project countries may decide not to introduce a new POC CD4 product.

• Lack or delay of complementary funding from other partners, particularly the GF NFM, may diminish the public health and market impact the Project can have on accelerating the introduction of new POC products.

Next Steps/ Corrective Action

• In light of the lessons learned from 2.5 years of project implementation, CHAI and UNICEF will work on preparing the Phase 2b project documentation for Board's approval in 2015.

• A comprehensive set of in-country evaluations will be implemented in S1 of 2015. This will facilitate further uptake in countries, as well as evidence generation on critical performance criteria.

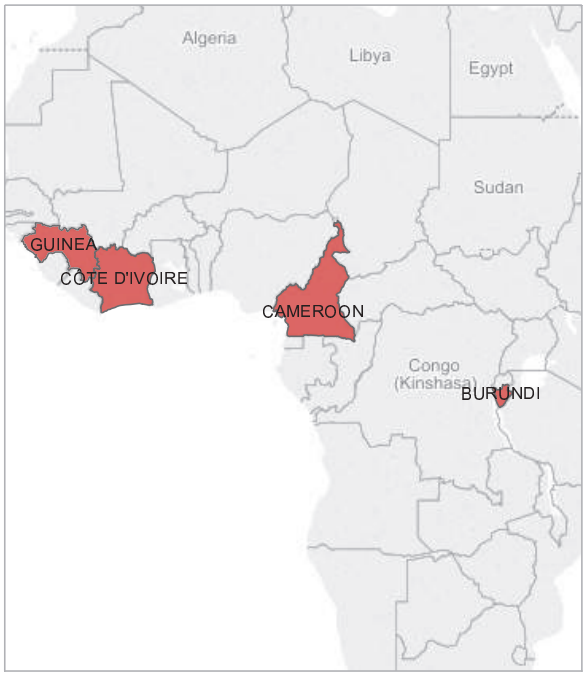
• The EID work will focus on evaluating new products, completing the market segmentation in each country, determining the optimal service delivery strategy including new entry points and deployment models such as testing at birth.

• The VL work will continue to emphasize policy work to ensure that all seven countries introduce routine VL testing into their HIV care and treatment programs, as well as evaluating new products and determining the appropriate balance between POC and conventional lab-based VL testing.

• Key alignment meetings with PEPFAR and EGPAF are ongoing for POC EID element of the project, in light of PEPFAR's Accelerated Children's HIV Treatment (ACT) Initiative and EGPAF's new grant with UNITAID on POC EID.

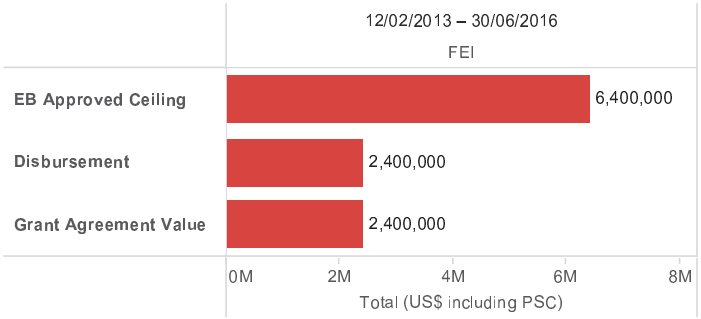
Update as of May 2015.
For more information, visit www.unitaid.org/impact

Open polyvalent platforms (OPP) for sustainable and quality access to VL in resource limited settings (OPP-ERA) (2013-2014)



Strategic Objective 1: Simple, point-of-care (POC) diagnostics

The Project improves access to viral load testing (VLT) and early infant diagnosis (EID) for adults and children living with HIV through the introduction of innovative Open Polyvalent Platforms (OPPs). During Phase I of the Project, the lead project implementer, France Expertise International (FEI) has been working with other partners to develop a full Business Plan for scaled-up commercialization of VLT/OPP, prepare a proposal for the second phase of the Project, develop a procurement strategy and plan for the 4 project target countries and commence deployment of OPPs in these countries.



Financial data as of 31 December 2014

Project Activities	2014
Number of operational platforms established in target countries	7
Number of VLT procured and delivered	20,536
Number of staff trained on use of OPP for virological monitoring of HIV infected patients	244

Provisional data as of 31 December 2014.

Update on OPP-ERA

Status	• Procurement delays related to the quality certification of the key element of open platform resolved through an interim quality policy. • Major work on defining the scope and priorities of the project cost extension (18 months, 4 million value), as approved by the UNITAID Board in December 2014. • Testing was initiated only in July 2014 (no-cost extension of 6 months); all 7 platforms in 4 project countries performed 11,921 viral load tests by December 2014.
Challenges	• The pool of eligible suppliers for VL amplification reagents, who respond to the technical criteria, remains extremely limited.
Next Steps/ Corrective Action	• Finalization of the cost extension workplan, focusing on 5 major workstreams: addressing certification issues, enhancing QA plans, facilitating country buy-in, including lab-clinic integration, increased communication on OPPs. • Independent evaluation of OPPERA platforms by the Centers for Disease Control and Prevention (CDC); Expert Review Panel for Diagnostics (ERPD) expanded to look into OPPs.

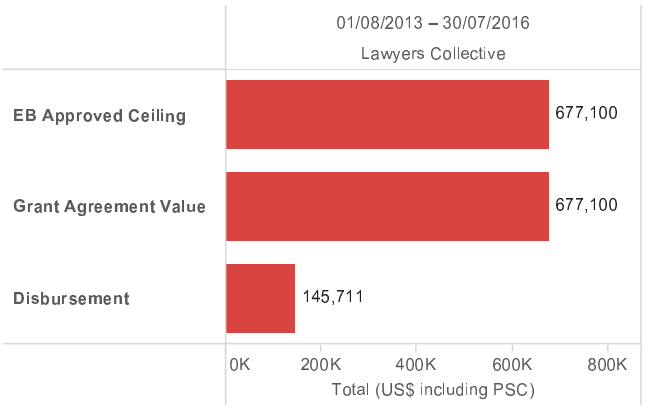
Update as of May 2015.

For more information, visit www.unitaid.org/impact

Opposition: Preventing Patent Barriers (2013-2016)

Strategic Objective 3: Treatment of HIV/AIDS and co-infections

This project aims to prevent the creation of patent-based market entry barriers, or, where such barriers already exist, remove them, for medicines for HIV, TB and hepatitis C, as well as other HIV co-infections agreed to by UNITAID (approved and under development).



Financial data as of 31 December 2014

Update on Lawyers Collective

Status	• Delays in implementation of project activities.
Challenges	• Difficult collaboration with generic companies to receive their inputs on priority medicines : i) identification of key blocking patent applications for filing oppositions and ii) their intention to produce generic version of newer medicines.
Next Steps/ Corrective Action	• Lawyers Collective (LC) continues to explore options of engaging with interested, independent generic companies. • LC working with government for policy changes enabling sustenance of generic industry (making submissions on vital issues on IP rights). • A mid-term review will be conducted in Q3 2015. • Towards the end of 2014 progress has been made on the establishment of an online patent database for priority HIV products.

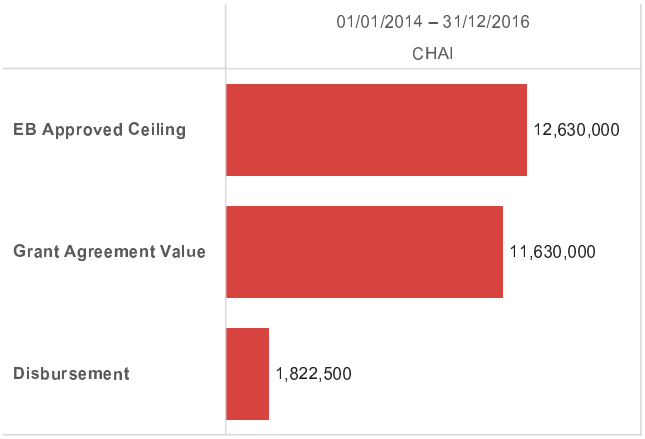
Update as of May 2015.

For more information, visit www.unitaid.org/impact

Innovation in paediatric market access (IPMA) (2014-2016)

Strategic Objective 2: Affordable, adapted paediatric medicines

IPMA builds on the UNITAID Paediatric Project by providing greater market stability without requiring a commodity donation. The project aims to ensure 630,000 patients currently on treatment as well as HIV-exposed infants have continued access to critical, life-saving ARVs and that further scale-up efforts to reach the remaining 2 million children in need of immediate treatment are supported with the stable supply and pricing of optimal paediatric HIV commodities.



Financial data as of 31 December 2014

Update on IPMA

Status	• During the reporting period, CHAI/UNITAID developed the project plan, logframe, budget, market intelligence deliverables (other annexes for the Grant Agreement). • Grant covering January 2014 - December 2016. Grant Agreement signed Oct 2014, following Board resolution, agreement is retroactive - January 2014. • With advanced funds received, CHAI carried out crucial project related activities to a limited extent (including Paediatric ARV Procurement Working Group).
Challenges	• None identified at this stage.
Next Steps/ Corrective Action	• 2015 semi-annual report will be submitted in Q3.

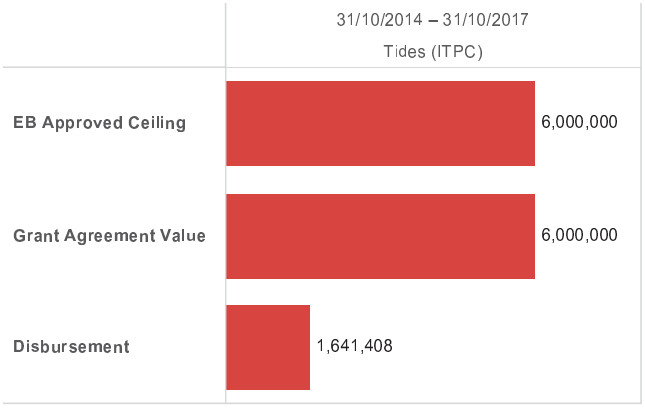
Update as of May 2015.

For more information, visit www.unitaid.org/impact

Access to Treatment for People Living with HIV in Middle Income Countries (2014-2017)

Strategic Objective 3: Treatment of HIV/AIDS and co-infections

The project aims to use TRIPS flexibilities to remove barriers to generic competition for 2nd and 3rd line ARVs. This will result in lower prices in four intervention countries (Argentina, Brazil, Thailand, Ukraine) and expand the overall market for newer ARVs. In addition, the proponents will work toward reform of intellectual property (IP) laws or regulations in order to facilitate continued/future use of such flexibilities.



Financial data as of 31 December 2014

Update on ITPC

Status	• No basis for assessment, the grant was signed in October 2014.
Challenges	• None identified at this stage.
Next Steps/ Corrective Action	• 2015 semi-annual report will be submitted in Q3.

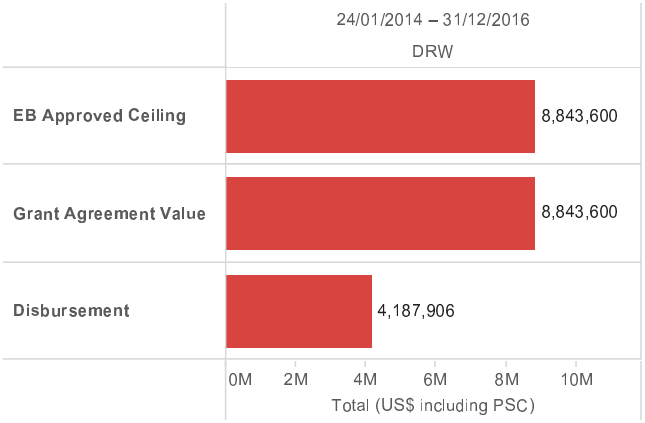
Update as of May 2015.

For more information, visit www.unitaid.org/impact

EID & Viral Load Monitoring (2014-2016)

Strategic Objective 1: Simple, point-of-care (POC) diagnostics

The project aims to implement SAMBA for EID and VL in seven countries. Phase 1 will involve independent evaluation in reference laboratories before feasibility studies at lower-level health care settings. The final phase of the project will be to implement SAMBA in 10-20 sites in each of the project countries.



Financial data as of 31 December 2014

Update on EID & VL Monitoring

Status	• Budget reconciliation, spend and fair access. • DRW will require additional capital investment of $8-10MM for the associated automation and scale-up costs. • On track in regards to technical verification of performance claims against TPP; and project progression.
Challenges	• Delay with in-country validation in Nigeria due to mandatory stoppage of external projects of MoH to focus on Ebola outbreak. • Differences in the support to SAMBA I and SAMBA II. • Clear identification of the project phases.
Next Steps/ Corrective Action	• Mapping of SAMBA I and II differences. • Review of project plan. • Budget revision.

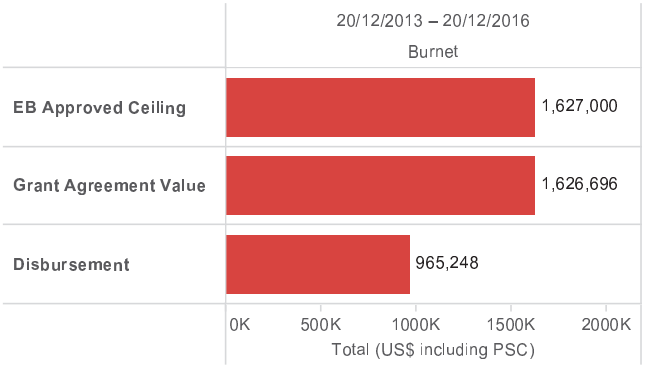
Update as of May 2015.

For more information, visit www.unitaid.org/impact

Manufacture & Validation of Rapid POC CD4 Testing (2013-2016)

Strategic Objective 1: Simple, point-of-care (POC) diagnostics

The purpose of the project is to catalyse global market access to CD4 testing in developing countries burdened with HIV, through the use of an appropriate low cost, instrument free, point of care CD4 test. It is expected that this will increase the rate of ART initiation and retention of patients in health care. The project focuses on interventions to achieve successful field evaluations of the test, together with regulatory approvals, the scale-up of manufacturing capacity, distribution and availability of the test in low and middle income countr..



Financial data as of 31 December 2014

Description	2014
Number of patients tested using POC CD4	na
Number of sites conducting field evaluation of POC CD4 testing	na
Number of sites providing quality assured POC CD4 testing with quality assured training for POC CD4 testing	na

Update on Manufacture & Validation of Rapid POC CD4 Testing

Status	• Budget-reconciliation, spend and fair access as planned. • Off track with delays in the technical verification of performance claims against Target Product Profile (TPP) and overall project progression.
Challenges	• Manufacture up-scale and automation process issues. • Hand laminated devices used were not fully automated. • Buffer bottles delivered different volumes compared to those used in test development resulting in inconsistencies (thus results deemed unreliable).
Next Steps/ Corrective Action	• Further troubleshooting efforts to be carried out with alpha and beta testing studies before lock down of a final test device. • Follow up technical review planned including a visit to OMEGA (early 2015). • New buffer bottle delivering correct volume has been sourced by Omega and included in test kits. • Next critical step is design lock. • VISITECT CD4 tests for future studies will be laminated/assembled (automated process) with preparation of raw materials scaled-down (transitioning to new manufacturing-site).

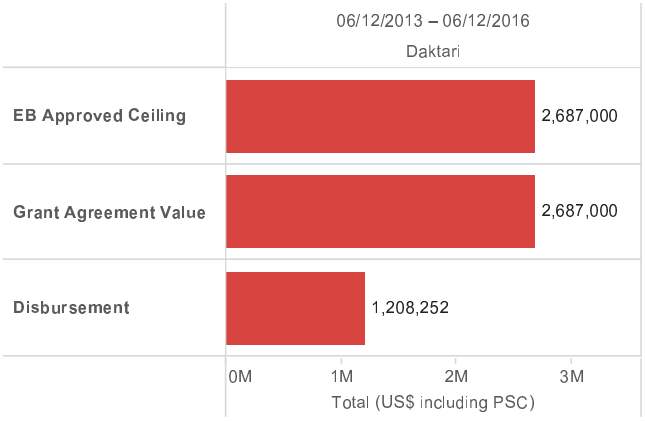
Update as of May 2015.

For more information, visit www.unitaid.org/impact

Operational Studies POC CD4 Counters (2013-2016)

Strategic Objective 1: Simple, point-of-care (POC) diagnostics

The support aims to support the introduction of a novel point-of-care CD4 diagnostic to the market in sub-Saharan Africa, Latin America, and South-east Asia at affordable prices. This will be done through clinical validation of the Daktari CD4 system; enhancing manufacturing capacity development; and conducting operational studies for regulatory approval.



Financial data as of 31 December 2014

Description	2014
# of CD4 tests produced by Daktari per year	298,000
# of eligible patients initiating ART	3,772,498
# of HIV patients retained in care at 24 months	308,860
# of patients enrolled in studies (by country)	60

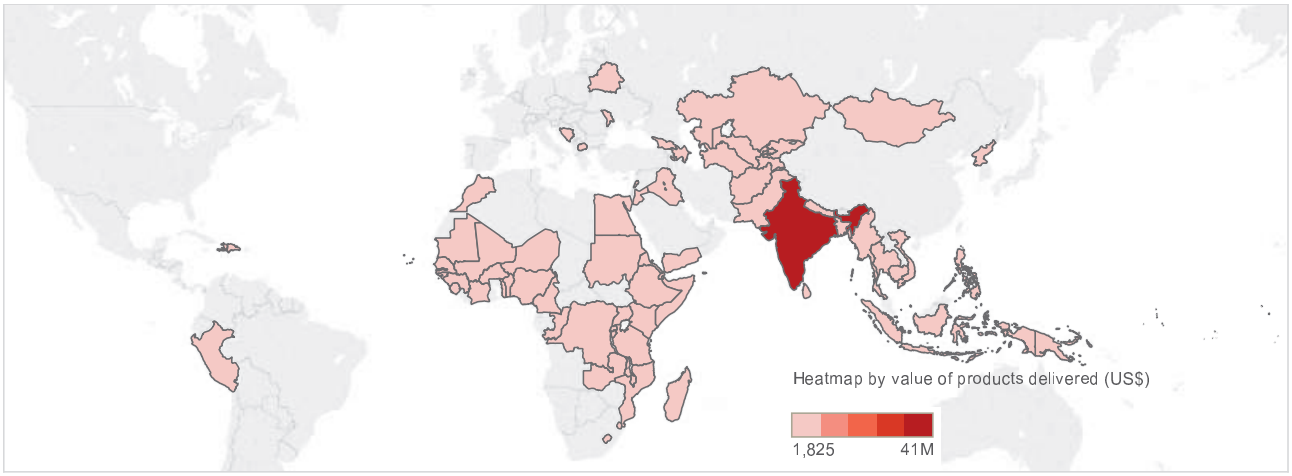
Update on Operational Studies POC CD4 Counters

Status	• Budget reconciliation and spend on track. • Off track with delays around technical verification of performance claims against Target Product Profile (TPP), project progression and fair access.
Challenges	• 2014 - market for POC CD4 testing changed quickly, in response to the WHO call for viral load testing. • A critical CD4 Cartridge instability issue identified with two of the validation lots resulting in recalling use of tests. • 2015 - Board reorganization and lack of support for CD4 has resulted in downsizing of the team and re-prioritization to other activities. • No additional strategic partner/funding source for CD4 can be confirmed.
Next Steps/ Corrective Action	• April 2015 additional technical verification site visit was conducted - Daktari provided an update confirming no additional funding sources identified. • UNITAID worked closely with Daktari to fully understand the situation and organisational changes (change of Board members and CEO). • A clear pathway has been put in place for Daktari to follow. • UNITAID continues to closely monitor this grant having given Daktari an additional three months to identify the required funding.

Update as of May 2015.

For more information, visit www.unitaid.org/impact

Tuberculosis Portfolio Profile



Results[2] by project
(Includes all project countries, 2008-2014*)

Project	Duration	Description	Results
Expand MDR TB Diagnostics (GDF, WHO-GLI, FIND)	10/12/2008 - 31/12/2015	# of MDR-TB cases detected	106,983
MDR TB Strategic Rotating Stockpile (STOP-TB/GDF)	20/11/2008 - 30/06/2015	Number of programmes ordering emergency MDR-TB drugs from the stockpile	3
		Number of programmes ordering non-emergency MDR-TB drugs from the stockpile	114
STEP Paediatric TB (TB Alliance)	22/07/2013 - 22/07/2016	# of signed agreements/MOUs for formulation devt with manufacturers	3
		# of market studies conducted	9
TB Xpert (WHO-GTB)	28/01/2013 - 31/12/2015	# of incident TB patients detected	63,251
		# of incident HIV-positive TB patients detected	7,342
		# of incident rifampicin-resistant TB patients detected	17,017
		# of Xpert MTB/RIF tests performed	394,290
		# of GeneXpert instrument modules procured	898
		# of Xpert MTB/RIF cartridges procured/delivered	621,240

Grantees

Provisional Figures as of 31 December 2014.
For more information visit http://www.unitaid.eu/en/what/tb

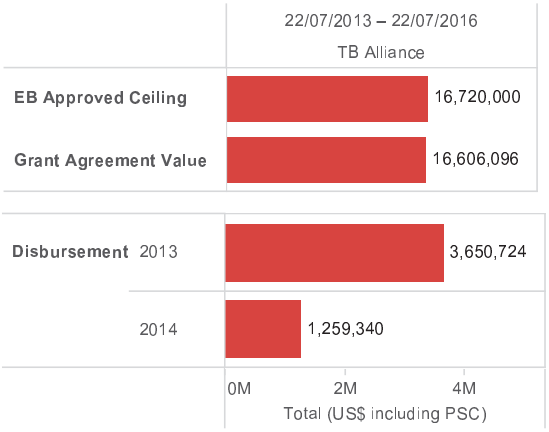
[1]Value (US$) of products provided to countries.

[2]Each treatment provided represents treatment for an 18 to 24 month period. Variations in patient treatment costs across countries are due to the different treatment regimens adopted by each country.

STEP Paediatric TB (2013-2016)

Strategic Objective 2: Affordable, adapted paediatric medicines

The project aims to increase and accelerate the availability of properly formulated, appropriately dosed international-standard quality paediatric tuberculosis (TB) medicines.The project's focus is on lowering market barriers that currently serve as a key impediment to supplying purchasers, providers, and ultimately patients with appropriate, high-quality TB medicines for children. The project will act as a market catalyst and creator by facilitating adoption and uptake of improved paediatric TB medicines, and by making it appealing to manufacturers to produce medicines that address a major public health issue.



Financial data as of 31 December 2014

Project Activities	Results
# of market studies conducted	9
# of signed agreements/MOUs for formulation development with manufacturers	4

Provisional results data as of 31 December 2014.

Update on STEP TB

Status	• A number of collaborations and partnerships have been initiated to develop interest on better diagnosis and treatment for paediatric TB.
	• Mid-term Evaluation of Project has been completed.
	• All outputs of the project have progressed steadily and most milestones have been met.
	• The products under development will be brought to market by 2015.
Challenges	• The project is engaging other donors to help large scale uptake of new products.
	• Internal staffing efficiencies and utilization of consultants, fine-tuning of strategy and specific activities resulted in low utilisation of staff/consultancy amounts.
Next Steps/ Corrective Action	• New formulations are expected to be market-ready in the second half of 2014.
	• Budget reallocation from TB Alliance to WHO has been proposed to improve activity implementation. Review and approval are pending.

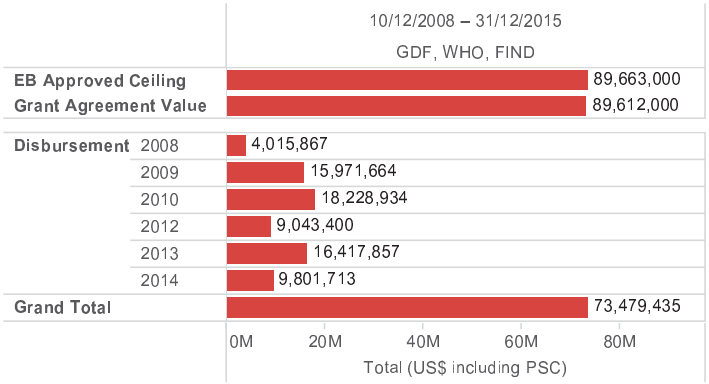
Update as of May 2015.

For more information, visit www.unitaid.org/impact

EXPAND MDR-TB Diagnostics (2007-2014)

Strategic Objective 5: Treatment of second-line TB

The project accelerates access to MDR TB diagnosis by introducing new and rapid technologies and laboratory service together with the necessary know-how for technology transfer. The intention is to identify an estimated 115,000 MDR TB patients in 27 countries to enable appropriate treatment of these patients.



Financial data as of 31 December 2014

Project Activities	2009	2010	2011	2012	2013	2014	Grand Total
# of MDR-TB cases detected	1,810	2,386	6,878	24,869	35,736	35,304	106,983
US$ MDR TB diagnostics product costs**			7,435,266	6,354,740	9,191,655	11,146,343	34,128,004

Provisional results data as of 31 December 2014.**Values reflect orders paid that comprise essential equipment, consumables and reagents and exclude freight and insurance and pre-shipment inspection expenses. Country data disaggregated by year, and estimates are revised with more accurate data available from countries.

Update on Expand TB

Status

- More than 600,000 tests were done during 2014 under project support in 27 countries.
- Cumulatively, 106,983 MDR-TB cases have been detected since project start.
- 101 culture drug susceptibility testing (DST) and LPA labs and 47 Xpert sites were established.
- Transition underway: 13 countries transitioned out in 2014, 14 countries will transition at the end of the project in end-2015.

Challenges

- Change of hosting arrangement for the Stop TB Partnership's GDF
- Resignation of GDF procurement agent for diagnostics
- Utilisation rate of Liquid culture and Line Probe Assay (LPA) decreased after more widespread availability of Xpert MTB/Rif (an easier test).

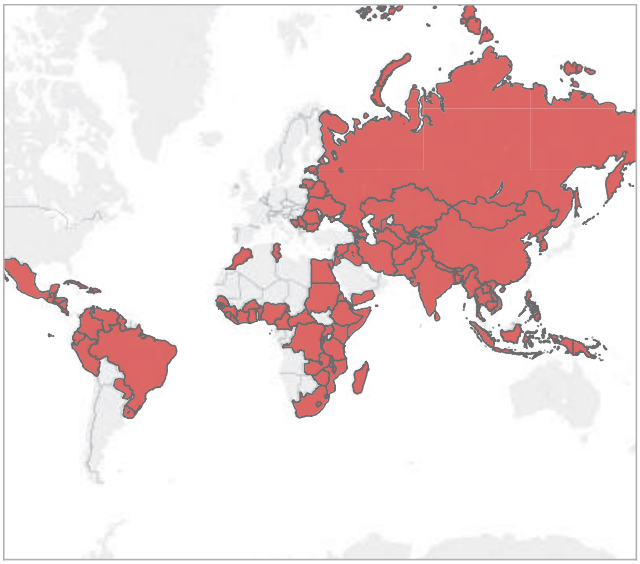
Next Steps/ Corrective Action

- The project is in the process of transition and will close by the end of the year.
- Appropriate provisions to countries to continue Liquid culture testing and Line Probe Assay are being ensured.

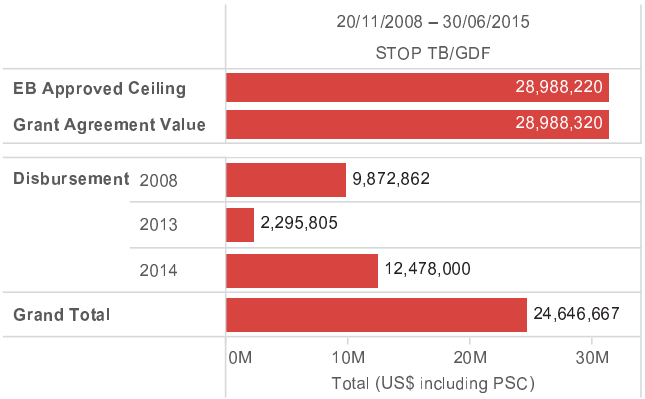
Update as of May 2015.

For more information, visit www.unitaid.org/impact

MDR-Strategic Rotating Stockpile (SRS) (2007-2015)



Strategic Objective 5: Treatment of second-line TB
The project intends to prevent treatment disruptions in 2nd line TB treatments through a strategic rotating stockpile available to countries.



Financial data as of 31 December 2014

Project Activities	2013	2014
# of countries ordering MDR-TB drugs from the stockpile	67	67
# of programmes ordering emergency MDR-TB drugs from the stockpile		3
# of programmes ordering non-emergency MDR-TB drugs from the stockpile		114
Value of products delivered (US$)		9,625,793

Provisional results data as of 31 December 2014.

Update on MDR-SRS

Status	• The project has expanded the drug stock from 5800 to 12500 MDR-TB patient regimens during 2014. • USAID is supporting some Cat 5 drugs in the stockpile and will support operational costs of the project till 2017. • Annual report of GDF reported reductions in the prices of drugs.
Challenges	• The GDF and Stop TB Partnership has changed hosting arrangements and moved to UNOPS. • About US$ 1.8 million worth of the drug PASER expired (demand plummeted after a WHO recommendation for use of an alternative drug was issued) and had to be written off the stock.
Next Steps/ Corrective Action	• No-cost extension request under review by Secretariat. • A credit facility to support SRS is proposed to be implemented with monitoring by multi-stakeholder committee.

Update as of May 2015.

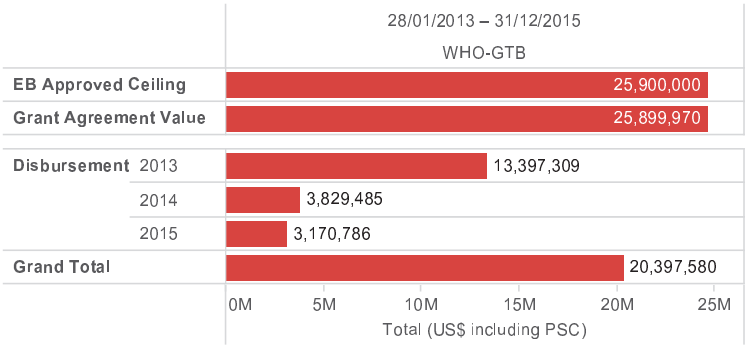
For more information, visit www.unitaid.org/impact

EB22/2015 PROJECT UPDATE

Scaling up access to contemporary TB diagnostics (GeneXpert) (2013-2015)

Strategic Objective 1: Simple, point of care (POC) diagnostics

The project will scale up TB diagnostic testing using state-of-the-art Xpert MTB/RIF, providing approximately 1.4 million test cartridges and over 200 GeneXpert instruments for the rapid detection of TB and rifampicin resistance in 21 recipient countries. To ensure country absorptive capacity and effective use of the technology, the project links a broad network of partners and existing initiatives for TB laboratory strengthening to expand access to vulnerable populations in the public and private sector.



Financial data as of 31 December 2014

Project Activities	2013	2014	Grand Total
# of incident TB patients detected using TBXpert project commodities	7,647	55,604	63,251
# of incident rifampicin-resistant TB patients detected using TBXpert project commodities	1,791	15,226	17,017
# of incident HIV-positive TB patients detected using TBXpert project commodities	992	6,350	7,342
# of GeneXpert instrument modules procured within framework of TBXpert project	844	54	898
# of Xpert MTB/RIF cartridges procured within framework of TBXpert project*	248,760	372,480	621,240
US$ value of GeneXpert instruments procured within framework of TB Xpert project	3,716,160	239,340	3,955,500
US$ value of Xpert MTB/RIF cartridges procured within framework of TB Xpert Project*	2,382,825	3,677,430	6,060,255

Provisional results data as of 31 December 2014.Country data disaggregated by year. All cartridges procured at US$ 9.98, the agreed price with CEPHEID.
*A shipment of 4,000 cartridges was sent in early 2014 but paid for in 2013. The value that corresponds to this indicator is USD 84,830 for 8,500 cartridges

Update on Xpert

Status

- 237 machines including 898 modules were procured in the 21 countries.
- In 2014, project made significant progress on many performance indicators (previously lagging due to supply disruption by manufacturer -early 2013).
- 607,240 cartridges have been procured during 2013-14, versus a target of 912,990 cartridges.

Challenges

- Electronic connectivity of the machines is under progress; not fully provisioned under the grant.
- Social Business models have not been able to reach sustainability
- Warranty and Service support costs are only covered minimally under the project and discussions are underway with the manufacturer. UNITAID is planning to revive and lead efforts by key partners (Global Fund, PEPFAR, WHO, FIND) in Q3 to negotiate improved pricing terms.

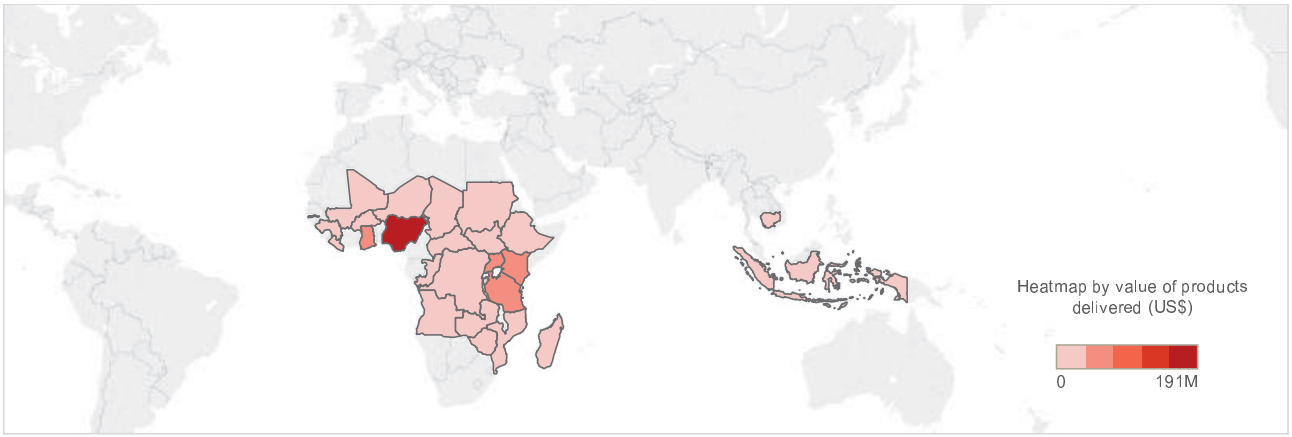
Next Steps/ Corrective Action

- Corrections of Social Business Model indicators is proposed to be undertaken.
- The project is working on making a submission for a cost extension of one year to continue patient result monitoring. UNITAID is working closely with Global Fund and PEPFAR to include Xpert in their funding plans.

Update as of May 2015.

For more information, visit www.unitaid.org/impact

Malaria Portfolio Profile



Results by project
(Includes all project countries, 2007-2014*)

Project	Duration	Description	Results
Improving Severe Malaria (MMV)	05/06/2013 - 05/06/2016	# of secondary and tertiary health facilities with at least one health worker trained in Inj AS	2,091
Private Sector Market for RDTs (PSI)	23/04/2013 - 29/02/2016	# of children under 5 seeking fever treatment through private sector outlets received an RDT	2,250
		# of children over 5 and adults seeking fever treatment through private sector outlets received an RDT	4,824
		# of children under 5 years clients testing positive for malaria at registered private sector outlets that receive an effective antimalarial treatment	221
		# of children (5 years and over) and adults testing positive for malaria at registered private sector outlets that receive an effective antimalarial treatment	530
		# of RDTs procured in line with CO-specific procurement plan timeline	2,410,125
Quality Assurance of Rapid Diagnostic Test (FIND)	01/01/2013 - 31/12/2017	# of lots evaluated	2,010
		# of endemic target countries procuring RDTs on the basis of product testing results/WHO procurement criteria results	12
Access to SMC Services (MC)	01/09/2014 - 31/08/2017	# of treatments administered to eligible children by country	0
			na
		Volume of quality assured SP+AQ delivered to countries	0
			na

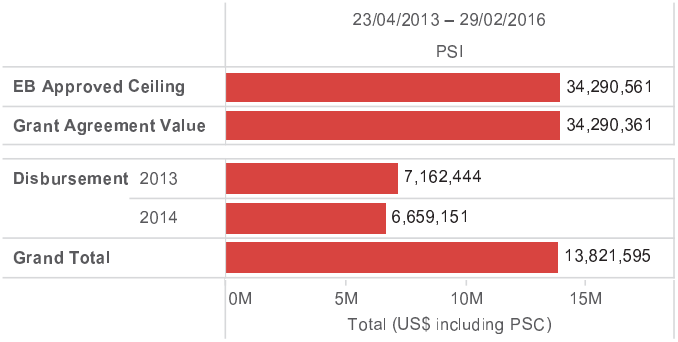
Grantees

Provisional Figures as of 31 December 2014.
[1]Value (US$) of products provided to countries;
For more information visit http://www.unitaid.eu/en/wh

Creating a Private Sector Market for Quality Assured RDTs in Malaria-Endemic Countries (2013-2016)

Strategic Objective 1: Simple, Point-of-Care Diagnostics

PSI and the collaborating implementers, Malaria Consortium (MC), FIND, and WHO/Global Malaria Programme (GMP), will stimulate the creation of a private sector market for malaria RDTs. The partnership will operate in five target countries where the UNITAID-supported AMFm has been implemented. The project is designed as a catalytic market intervention to develop methods and to learn and to disseminate experience and project lessons learned to accelerate the introduction and scale up of malaria RDTs in the private sector.



Financial data as of 31 December 2014

Project Activities	2013	2014
# of RDTs procured in line with country-specific procurement plan timeline	510,000	1,900,125
# of private sector outlets with quality assured RDT brands in stock	44	668
# of children under 5 years clients testing positive for malaria at registered private sector outlets that receive an effective antimalarial treatment		221
# of children over 5 and adults seeking fever treatment through private sector outlets received an RDT		4,824
# of children under 5 seeking fever treatment through private sector outlets received an RDT		2,250
Value (US$) of RDTs procured	220,325	2,685,000

Provisional results data as of 31 December 2014.

Update on Private Sector Market for RDTs

Status	• Regulatory approval to use malaria RDTs in private sector outlets in the project area granted in Kenya, Tanzania, Nigeria, Uganda. • 801 private sector health providers (682 private outlets) trained on safe, quality use of malaria RDTs and management of clients with fever. • A total of 3.91 million quality assured RDTs were procured (as of March 2015) and 2.14 million RDTs delivered to wholesalers/retail outlets in 5 project countries. • Regulatory approval to use malaria Rapid Diagnostic Tests (RDT) in private sector outlets nation-wide granted in Madagascar.
Challenges	• Lengthy procurement of the RDTs bundled with training, supervision, supply services etc. led to late delivery of RDTs to Uganda and Nigeria. • Project revisions were required for procurement of 123,578 ACT treatments (Madagascar) and 30,000 (Kenya) ensuring supply in private sector outlets. • Low utilization/sale of RDTs in private sector facilities.
Next Steps/ Corrective Action	• Expedite procurement and delivery of RDTs. • Monitor RDTs utilization/sale in private sector outlets.

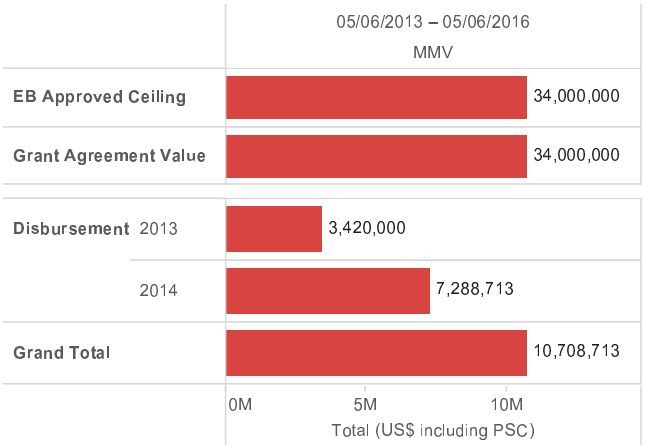
Update as of May 2015.

For more information, visit www.unitaid.org/impact

Improving Severe Malaria Outcomes (2013-2016)

Strategic Objective 2: Affordable, adapted paediatric medicines

The goal of the project is to contribute to the reduction in mortality from severe malaria through the accelerated global adoption of Injectable Artesunate and availability of Artesunate suppository.



Financial data as of 31 December 2014

Project Activities	2013	2014
# of secondary and tertiary health facilities with at least one health worker trained	434	1,657
# of targeted countries which have case management training materials aligned with latest WHO guidelines on administration of Inj AS	5	6

Provisional results data as of 31 December 2014.

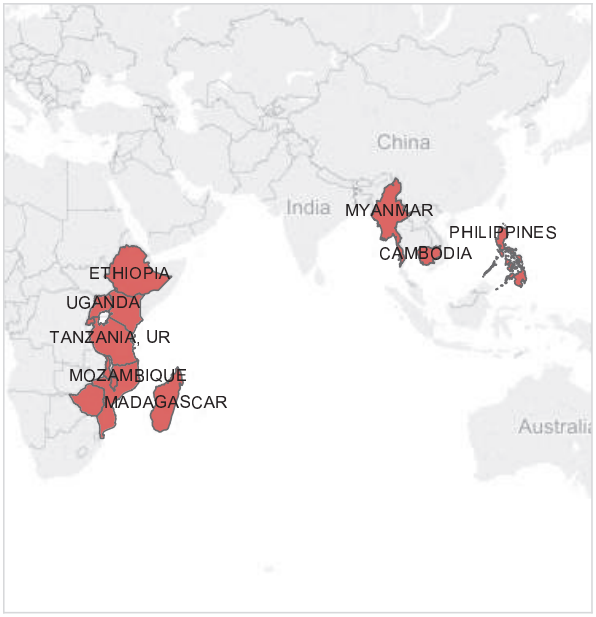
Update on Improving Severe Malaria Outcomes

Status	• UNITAID, GFATM & MMV joint price negotiations concluded with Guilin Pharma, for Inj AS. • Procurement of 2.7 million vials completed, of which 2.14 million vials (80%) delivered in 2014 to five project countries. • Injectable artesunate and artesunate suppository product development agreement signed between MMV & three pharmaceutical companies.
Challenges	• Procurement delays due to lengthy price negotiations with manufacturer and project implementation agreements with countries. • Delays in the submission of the Injectable artesunate and artesunate suppository product dossiers to WHO due to technical problems.
Next Steps/ Corrective Action	• Accelerate Injectable Artesunate (AS) & intrarectal AS product dossier submissions to WHO for assessment. • Improve Inj AS procurement and delivery efficiency to countries.

Update as of May 2015.

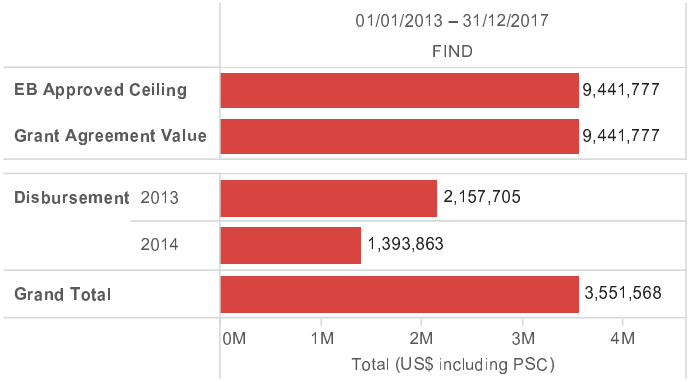
For more information, visit www.unitaid.org/impact

Sustainable Global and National Quality Control for Malaria Rapid Diagnostics Tests (2013-2016)



Strategic Objective 1: Simple, Point-of-Care Diagnostics

The goal of this project is to establish sustainable standards to ensure that quality malaria RDTs are increasingly used to support rationale treatment of malaria in endemic countries. FIND will coordinate implementation of the RDT product and lot testing services in collaboration with WHO/GMP. FIND and partners will establish and employ RDT quality control procedures and will develop and pilot the introduction of recombinant antigen-based evaluation panels.



Financial data as of 31 December 2014

Project Activities	2013	2014
# of lots evaluated	1,083	927
# of country malaria programmes and procurement agencies submitting lots for testing.	6	6
# of country malaria programmes submitting lots for testing.	43	49
# of endemic target countries procuring RDTs on the basis of product testing results/WHO procurement criteria results	12	12
# of malaria endemic countries conducting their own lot testing according to quality standards/practices	2	2

Provisional results data as of 31 December 2014.

Update on RDT Quality Control System

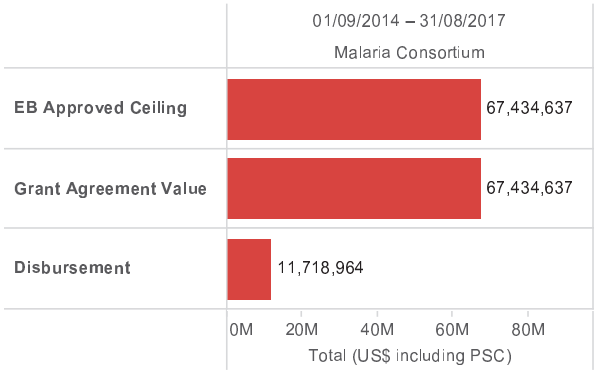
Status	• Round 5 RDTs product testing results published. Round 6 RDTs testing launched.
	• User fee for RDTs product testing introduced to support program sustainability.
	• 900 RDT lots tested representing 210 million RDTs globally distributed.
	• Recombinant antigens for RDT quality control (QC) testing identified.
Challenges	• Significant additional staff time and budget requirements.
	• Technical challenges related to recombinant antigen development.
Next Steps/ Corrective Action	• Coordinate with FIND to secure funding sources for recombinant protein technology development to replace BMGF funding that ended in June 2014.

Update as of May 2015.

Achieving Catalytic Expansion of SMC Services in the Sahel to Save Lives (ACCESS-SMC) (2014-2017)

Strategic Objective 6: Preventatives for HIV/AIDS, TB and Malaria

The project aims to expand seasonal malaria chemo-prevention (SMC) in 7 countries (Burkina Faso, Chad, Guinea, Mali, Niger, Nigeria, The Gambia), in order to accelerate impact and build markets for SMC products.



Financial data as of 31 December 2014

Update on Access-SMC

Status	• Procurement of 14 m treatments (SPAQ for 2015 malaria season) , thereby enabling 3.3 million children access to SMC in 2015.
	• Country teams are engaged with National Malaria Control Programmes (NMCPs) to develop detailed implementation plans for SMC for 2015.
	• MSH developed supply chain models for seasonal malaria chemoprevention (SMC) drugs as the basis for implementation plans in each country.
Challenges	• Global shortage of SMC drugs has led to a 50% reduction in SMC coverage targets for 2015.
	• Project implementation delays due to lengthy sub-contact negotiations for pharmacovigilance, drug resistance monitoring, SMC impact assessment studies.
Next Steps/ Corrective Action	• Monitor SMC drug delivery and country level preparations to implement for the 2015 season (June – September 2015).
	• Coordinate with MC and MMV to ensure July 2015 submission of sulfadoxine API dossier to WHO by Guilin Pharma.

Update as of May 2015.

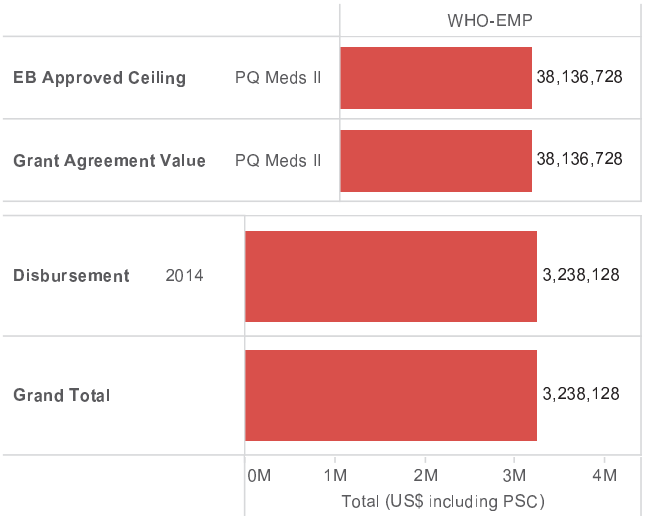
For more information, visit www.unitaid.org/impact

EB22/2015 PROJECT UPDATE

Prequalification of Medicines II (2014-2016)

Strategic Objective 3,4 and 5: Treatment of HIV/AIDS and co-infections; treatment of malaria and second-line TB

The WHO prequalification programme addresses shortcomings that exist across multiple diseases or product types. It serves as a single entry point to donor funding for generic manufacturers willing to offer quality medicines. To pass this entry point, these products must meet WHO-specified global standards for quality, safety and efficacy. WHO PQ programme has prequalified over 300 priority medicines for in-need and at-risk patient populations, including UNITAID priority products since 2009.



Financial data as of 31 December 2014

Prequalified Medicines

Description	2009	2010	2011	2012	2013	2014	Total
Priority medicines prequalified (HIV)	11	9	11	6	8	15	60
Priority medicines prequalified (Malaria)	3	1	1	10	7	6	28
Priority medicines prequalified (TB)	6	5	7	18	17	7	60
Grand Total	20	15	19	34	32	28	148

Update on Prequalification of Medicines

Status	• Modification has been made to some activities (Quality Control Laboratories training workshop).
	• Some delays on the part of technical staff in using Customer Relationship Management (CRM) system including for uploading of their data and reports.
Challenges	• Absence of a single, harmonized laboratory evaluation mechanism.
	• No harmonized procurement standards for medicines, i.e. procurement derivatives of natural resources to support local manufacturers (risk to medicines prequalification).
	• International procurers procuring from a few large-scale suppliers - detrimental to local producers (invested in improving quality of production).
	• The New financing model being considered by PQ to reduce dependency on UNITAID and the Gates Foundation funding requires further consultation with industry and other stakeholders before being approved by WHO and implemented in 2016.
Next Steps/ Corrective Action	• Synergy/collaboration with other partners for harmonized laboratory evaluation mechanism, procurement standards for medicines for faster, simpler, more predictable prequalification process.
	• Further development of the financing model based on wider consultation.

Update as of May 2015.

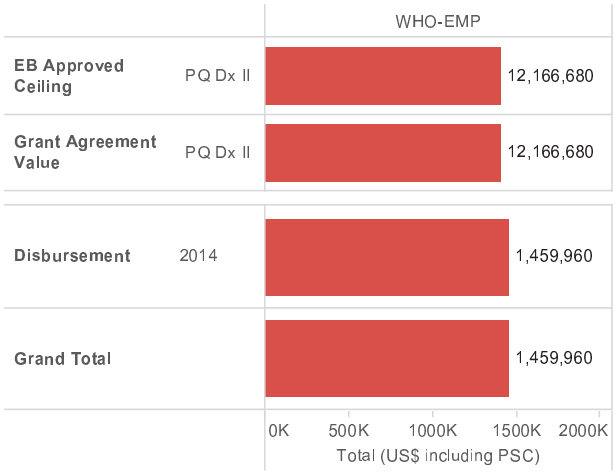
For more information, visit http://www.unitaid.eu/en/what/cross-cutting/prequalification

EB22/2015 PROJECT UPDATE

Prequalification of Diagnostics II (2014-2016)

Strategic Objective 1 and 6: Simple, POC diagnostics; preventatives for HIV/AIDS, TB and malaria

The WHO prequalification programme addresses shortcomings that exist across multiple diseases or product types. It serves as a single entry point to donor funding for generic manufacturers willing to offer quality diagnostic products. To pass this entry point, these products must meet WHO-specified global standards for quality, safety and efficacy. WHO PQ programme has prequalified over 25 diagnostics and one male circumcision device for in-need and at-risk patient populations, including UNITAID priority products since 2009.



Financial data as of 31 December 2014

Prequalification of UNITAID Priority Dx

Description	2010	2011	2012	2013	2014	Total
Number of prequalified diagnostics/medical devices (HBV)					1	1
Number of prequalified diagnostics/medical devices (HCV)					0	0
Number of prequalified diagnostics/medical devices (HIV)	0	9	9	7	6	31
Number of prequalified diagnostics/medical devices (Malaria)	1	1	0	1	2	5
Number of prequalified diagnostics/medical devices (TB)	0	0	0	0	0	0
Grand Total	1	10	9	8	9	37

Update on Prequalification of Diagnostics

Status	• Some project outputs delayed due to the streamlining diagnostics prequalification processes and procedures during the first half of the year. • Some activities on track (i.e. abbreviated assessment, manufacturing sites inspections), some had to be postponed (the development of additional guidance).
Challenges	• Several diagnostics manufacturers that failed prequalification requirements previously, with dossiers still in pipeline, will not meet prequel requirements. • Their dossiers will therefore be removed from the assessment process, resulting in a pipeline that contains only active applications. • The New financing model being considered by PQ to reduce dependency on UNITAID and the Gates Foundation funding requires further consultation with industry and other stakeholders before being approved by WHO and implemented in 2016.
Next Steps/ Corrective Action	• Synergy/collaboration with other partners for harmonized laboratory evaluation mechanism, procurement standards for medicines for faster, simpler, more predictable prequalification process. • Further development of the financing model based on wider consultation.

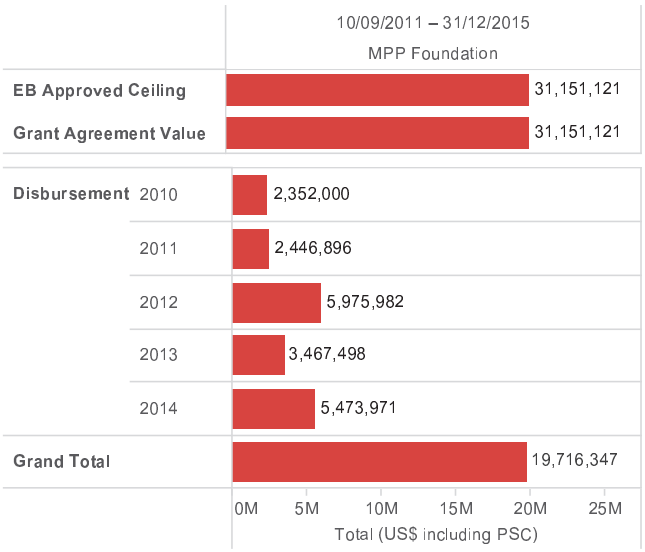
Update as of May 2015.

For more information, visit http://www.unitaid.eu/en/what/cross-cutting/prequalification

Medicines Patent Pool (2011-2015)

Strategic Objective 3: Treatment of HIV/AIDS and co-infections

This project aims to bring down the prices of HIV medicines and facilitate development of better-adapted HIV medicines, such as fixed-dose combinations (FDCs) and special formulations for children, by creating a pool of relevant patents for licensing to generic manufacturers and product development partnerships.



Financial data as of 31 December 2014

Update on MPP

Status	• Grant covering from 1 January 2011 - 31 December 2015.
	• New multi-funding year for Medicines Patent Pool Foundation (MPPF) will cover from 1 January 2016 - 31 December 2020.
	• Disbursement request for January - June 2015 on hold with on-going discussions around staff budgeting (UNITAID requested MPPF for clarification).
Challenges	• Engagement with various stakeholders, advocacy and communication to raise visibility of MPPF.
	• M&E framework for measuring downstream results.
Next Steps/ Corrective Action	• Collaboration/strengthening relationships with other partners on paediatrics as well as to support licence recruitment and management, and better forecasting.

Update as of May 2015.
For more information, visit www.unitaid.org/impact

Annex 3:

Combined programmatic and financial project performance assessment

Grant Performance

The performance rating covers the period from 1 January to 31 December 2014. The grant assessment criteria are:

Grant Assessment Criteria

1) Grant targets have been met on schedule
2) Grant milestones have been met on schedule
3) Proactive risk assessment and management during the grant implementation
4) Collaboration (responsiveness to questions raised by the Secretariat and to findings of assessments conducted during reporting period)
5) Reporting (submitted in timely manner, quality of overall report and data provided)

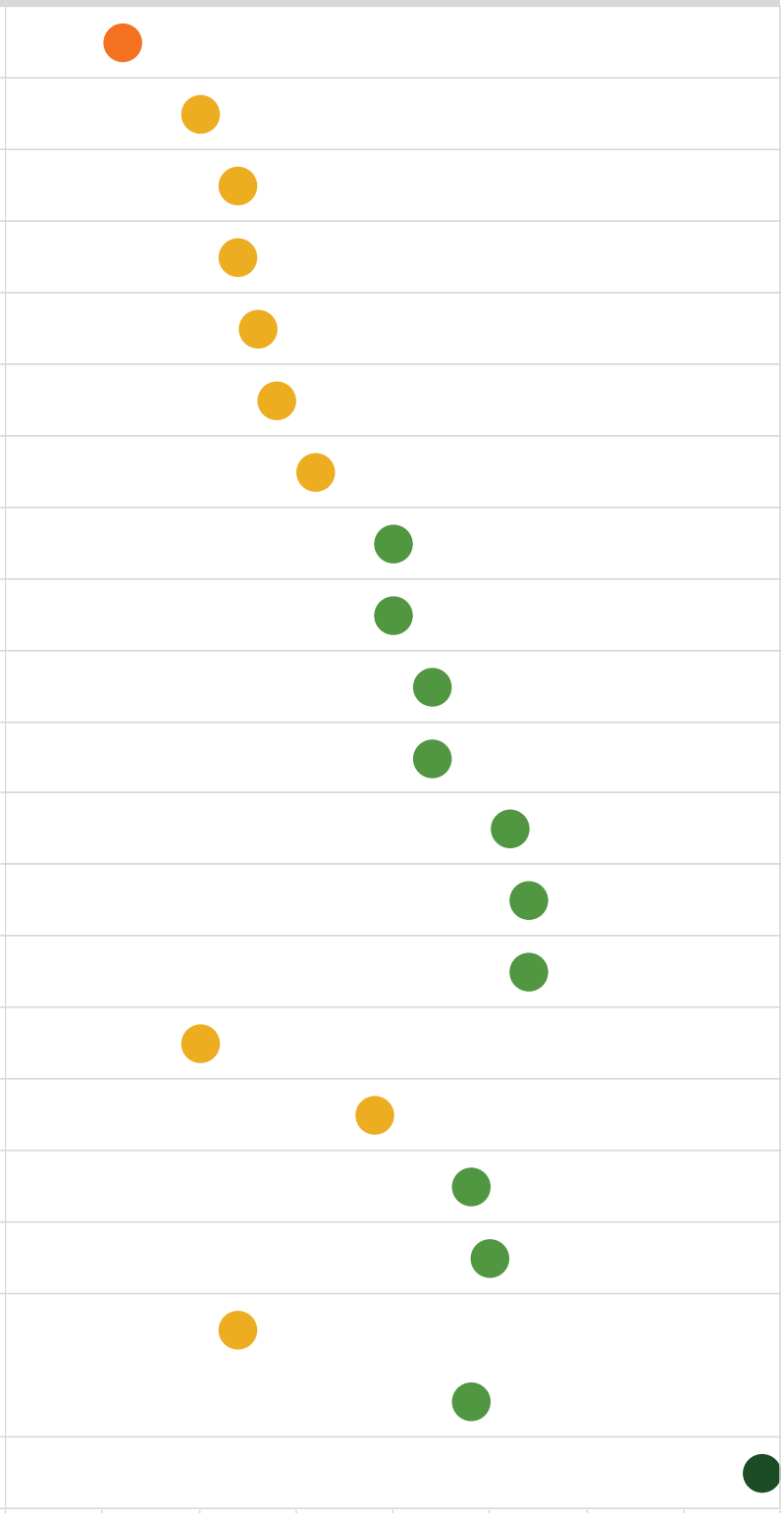
The Grant Assessment criteria are ranked by Programme managers on a five-point, Likert-type response option that indicates the extent to which each criterion is met by the Grantee. The scores are then peer reviewed and finally validated by the Monitoring and Evaluation Unit to ensure an unbiased and consistent scoring exercise across all portfolios and projects. This Likert-type scale resulted in 4 categories for assessment as follows:

Icon Descriptions

Description	Score	Criteria description	
Excellent	≤ 4	Sophisticated, innovative and exceeds minimum requirements : on track	
Above average	≤ 3	Exceeds minimum requirements/ expectations : on track	
Average	≤ 2	Meets the minimum requirements/ expectations : at risk of falling off track	
Below average	≤ 1	Does not meet minimum requirements : off track	
No basis for assessment	0	No basis for assessment	

Overview of programmatic grant performance in 2014

Portfolio	Grantees	Project
HIV	Daktari	Operational Studies POC CD4 Counters
	DNDi	Peds ARV formulations
	Lawyers Collective	Preventing Patent Barriers
	Burnet	Manufacture & Validation Rapid POC CD4
	FEI	OPP-ERA
	ESTHER	ESTHERAID
	UNICEF, CHAI	Point-of-Care Diagnostics
	MSF	HIV Diagnostics
	DRW	EID & VL Monitoring
	CHAI	Peds ARV
Malaria	MMV	Improving Severe Malaria
	Malaria Consortium	SMC-Access
	FIND	QA of RDTs
	PSI	Priv Sector- RDTs
TB	STOP TB/GDF	MDR TB SRS
	STOP TB/GDF, WHO-GLI, FIND	Expand MDR TB Dx
	TB Alliance	STEP Paediatric TB
	WHO-GTB	TB Xpert
Transversal	WHO-EMP	PQ Dx
		PQ Meds
	MPP Foundation	MPP



Rating
1.000 5.000

Note: Covers the period from 1 January 2014 to 31 December 2014. The following grants i) Innovation in ARV Paediatric market access (IPMA), CHAI; ii) Novel, disposable POC CD4 test, Zyomix, iii) Access to treatment for PLHIV in MIC, Tides ITPC; and iv) Ensuring access to HCV treatment revolution, MSF; are not presented in the above graph as there are no basis for assessment.

Red = below average; yellow = average; light green = above average; dark green = excellent

Overview of programmatic and financial grant performance

Programmatic data as of 31st December 2014 and financial data as of 31 March 2015

In millions of US$

Project Name	Grantee	Project Lifespan	Project Lifespan % elapsed	Original value of GA	Estimated value of GA*	Actual disbursements	Estimated disbursable balance	% of actual disbursements vs estimated value of GA	PROGRAMMATIC PERFORMANCE Rating		PROGRAMMATIC PERFORMANCE Narrative	FINANCIAL PERFORMANCE Rating	FINANCIAL PERFORMANCE Trend	FINANCIAL PERFORMANCE Narrative
HIV GRANTS														
Paediatric ARV Program	**CHAI**	2006-15	92%	417.1	330.6	326.8	3.9	99%		**3.2**	The goal of the Project was to maintain on-going access to paediatric ARVs, diagnostics bundles and related commodities. The project also increased the sustainability of the paediatric marketplace through the use of supplier selection techniques that increase the number of quality assured paediatric products and reduce their prices. 40 countries participated in the project; by end 2013, 37 transitioned to other donors and in 2014 three countries included in the project - Malawi, Mozambique and Uganda.	**3**	⇧	Good level of collaboration generally maintained; improved coordination and information sharing since the last review; better coordination of annual audits.
Estheraid	**ESTHER**	2009-14	100%	14.7	13.2	13.2	0.0	100%		**2.4**	This project contributed to improving supply chain management from national central medical stores to treatment centres in five West African countries — Benin, Burkina Faso, Cameroon, Central African Republic and Mali — by improving logistic information systems and patient monitoring systems.	**2**	⇨	Collaboration has been satisfactory overall; budget management and cash planning were areas of concern. Grant is now closed. Final audit and settlement of accounts to be arranged.
Access to innovative POC Diagnostics	**CHAI/UNICEF**	2013-16	71%	55.0	55.0	40.5	14.5	74%		**2.6**	The project continues implementing a comprehensive set of activities in country in preparation for POC device arrival to the market; major delay remains product market entry; special project meeting took place in April to discuss reprogramming in order to strengthen overall laboratory network. Project remains the main vehicle for in-country evaluations of POC devices.	**2**	⇨	Collaboration is satisfactory overall; some issues with the timeliness of cash requests. Constant attention to the project is needed.
Innovation in ARV Paediatric market access (IPMA)	**CHAI**	2014-16	41%	11.6	11.6	1.8	9.8	16%			No basis for full assessment. The Grant Agreement was signed in October 2014, but with a 01 Jan. retroactive start date. An Inception Report was submitted by CHAI in March; a 2015 semi-annual report will be submitted in Q3. This project will play a coordinating role across the Paediatric ARV Procurement Working Group (PAPWG), global procurement agents, suppliers, and countries to aggregate demand forecasts and orders, generate insight into global demand, key trends, and opportunities for further optimization of paediatric treatment and ascertain potential supply risks especially for low-volume products. The amount disbursed to CHAI so far has allowed the organization to start crucial activities, especially CHAI's important role in the PAPWG.	**3**	n/a	The project reviewed for the first time; the review of the performance mostly based on routine collaboration, which so far has been good; no major issues identified so far.
Implementation of CD4 and VL testing	**MSF**	2013-15	78%	28.7	28.7	17.6	11.1	61%		**3.0**	The project maintains its dynamic nature by introducing operational changes based on new evidence, market delays and opportunities in countries. Initial major delays (project setup, including MOUs in countries, market delays) will be mitigated through a no cost extension into 2016. Additional country (Kenya) added in 2015 with research on optimal placement of POC EID devices beyond PMTCT sites.	**3**	⇨	Good level of collaboration generally maintained; some budgetary issues being resolved; otherwise, no major challenges.

OPP-ERA	**FEI**	2013-14	100%	2.4	2.4	2.4	0.0	100%	**2.3**	Procurement delays related to the quality certification of the key element of open platform were resolved through an interim quality policy; testing was initiated only in July 2014 (no-cost extension of 6 months), with revised targets that were met by the project in all countries but Cameroun. Major work on defining the scope and priorities of the cost extension (18 months) is ongoing.	**2**		Collaboration is satisfactory overall; issues with understanding of UNITAID requirements for grant budget planning and cost allocation.
Paediatric ARV Formulations	**DNDi**	2013-16	53%	17.3	17.3	4.9	12.4	29%	**2.0**	The project aims to increase access to optimal ART for children under three years and will involve the development of three products through the DNDi's partnership with Cipla: two 4-in-1 FDC of LPV/r based ARVs regimens; and a complementary granule formulation of ritonavir that can be added to the 4-in-1 LPV/r-based FDC during simultaneous treatment of HIV and TB. DNDi signed a MOU with the South African National Department of Health to improve access to paediatric HIV treatment in the country. The MOU aims to ensure clinical studies commence rapidly in order to prepare for the transition from the current alcohol-based liquid formulation to the new formulation. The project also showed progress in the facilitation of the adoption of LPV/r based first-line ART and RTV granules; the study protocol 'Prospective study of lopinavir based ART for HIV Infected children globally (LIVING study)' was developed and shared with clinical investigators in potential partner countries.	**3**		Good level of collaboration generally maintained; internal control policies have been strengthened; information sharing and coordination with UNITAID has improved since the last review, including coordination of annual audits.
Manufacturing rapid POC CD4 testing in India	**The Burnet Institute**	2013-16	44%	1.6	1.6	1.0	0.7	59%	**2.2**	Technical Performance against TPP criteria for the CD4 POC device continues to remain only partially complete. CD4 POC device design and manufacturing processes remain unlocked and invalidated. Key milestones have been missed and others will be missed (including CE marking and product registration with delays of approximately six months plus). The grant can get back on track for expected milestones to be met in 2016 if design lock is achieved in 2015. Progress is being monitored closely.	**3**		Good level of collaboration generally maintained; budgets revised to reflect the delays in the implementation.
Validate and accelerate update of POC CD4 counters	**Daktari Diagnostics**	2013-16	44%	2.7	2.7	1.2	1.5	45%	**1.6**	Early manufacturing delays (4 months plus) mean that the Daktari CD4 System is not yet commercially available. A significant milestone was the release of Daktari InSight, Daktari's proprietary connectivity solution. In February 2015 it was reported that Daktari may wind down the CD4 programme. This grant is at high risk of termination in 2015.	**3**		Good level of collaboration generally maintained; information sharing and reporting has been good.
Access to EID and VL monitoring by SAMBA	**Diagnostics for the Real World**	2013-16	41%	8.8	8.8	4.2	4.7	47%	**3.0**	SAMBA I meets the majority of TPP requirements for both EID, qualitative and VL, semi-quantitative. SAMBA I design and manufacturing processes for the instrument and EID, VL cartridges have been locked and validated. Technical Performance of the SAMBA II is still in development but nearing completion. The system design and manufacturing has reached "production phase" but requires additional validation. Definition of the validation process for the 2 systems is still required. DRW is looking for capital investment for automation and scale up.	**3**		Good level of collaboration generally maintained; information sharing and reporting has been good; some budgetary issues pending resolution.
Preventing Patent Barriers	**Lawyers Collective**	2013-16	57%	0.7	0.7	0.2	0.5	30%	**2.2**	The Project aims at ensuring healthy ARV market conditions by eliminating low quality patent barriers which would facilitate early entry of generic versions of ARVs and drugs to treat opportunistic infections to the market. This will be done through identifying patent applications for essential ARVs and opportunistic infection drugs and filing oppositions against these applications in India.	**3**		Good level of collaboration generally maintained; 2014 annual report slightly delayed.

Tides-ITPC Access to treatment for PLHIV in MIC	**Tides Center (ITPC)**	2014-17	13%	6.0	6.0	1.6	4.4	27%			No basis for Assessment. The Grant Agreement was signed in October 2014.The intervention is based on the adoption and use of the Trade-related Aspects of Intellectual Property Rights (TRIPS) flexibilities. The primary aim is to allow generic competition in the ARV markets in the four countries included in the project — Argentina, Brazil, Thailand, and Ukraine —by removing unmerited patents and/or influencing originator pricing through such actions. The impact will be price reductions and significant cost-savings for the countries, enabling treatment scale-up for tens of thousands of additional patients.	**3**	n/a	This project is reviewed for the first time; good level of cooperation maintained; no major issues so far.
Ensuring access to HCV treatment revolution	**MSF**	2015-17	8%	15.0	13.4	0	13.4	0%			No basis for assessment, project initiated in Jan 2015.	**3**	n/a	New project; good level of collaboration maintained; no major issues so far.
TUBERCULOSIS GRANTS														
MDR TB SRS	**GDF**	2008-15	97%	29.0	29.0	24.6	4.3	85%		**2.0**	The project is due to close in June 2015 and a dialogue is underway with GDF for a no-cost extension of the project. Reporting has been delayed. Collaboration has scope for improvement, especially with respect to risk management.	**3**		Good level of collaboration generally maintained; some coordination challenges as a result of move of Stop TB Partnership to UNOPS earlier in the year, which are now resolved.
MDR TB Diagnostics (EXPAND-TB)	**GDF**	2009-14	100%	89.6	86.8	76.5	10.4	88%		**2.9**	This project is in the process of clausing and transitioning . The most relevant target of case detection of MDR-TB is likely to be reached at the end of the project in 2015. 13 countries have transitioned out and 14 countries will transition at the end of the project. Reporting is timely and of good quality. Project closing activities are on schedule.	**3**		Good level of collaboration generally maintained; some cash planning and coordination challenges as a result of move of Stop TB Partnership to UNOPS earlier in the year, which are now resolved.
Scale up access to contemporary diagnostics (GeneXpert)	**WHO / Stop TB**	2013-15	77%	25.9	25.9	20.4	5.5	79%		**3.5**	The project has met all milestones. Targets related to the Social Business model could not be met. Mid-term evaluation has been conducted with a generally positiveassessment of project performance. Quality of monitoring and reporting is excellent.	**3**		Good level of collaboration generally maintained; information sharing and reporting has been good; some delays in cash disbursement as a result of move of Stop TB Partnership to UNOPS.
Paediatric TB Centre for Excellence	**TB Alliance**	2013-16	60%	16.6	16.6	4.9	11.7	30%		**3.4**	All outputs of the project have progressed steadily and most milestones have been met in a timely manner. Market entry of the products under development is expected in 2015. A number of collaborations and partnerships have been initiated to develop interest on better diagnosis and treatment for paediatric TB.	**3**		Good level of collaboration generally maintained; good budgetary control; very responsive grantee; information sharing and reporting has been good.
MALARIA GRANTS														
QA for RDTs	**FIND/WHO**	2013-17	46%	9.4	9.4	3.6	5.9	38%		**3.7**	The project aims to create sustainable global and national RDTs Quality Control system in 12 countries. The overall project programmatic implementation and financial performance in 2014 is on track to meet the project targets.	**3**		Good level of collaboration generally maintained; very responsive grantee; 2013 audit was somewhat delayed but the outcome is positive.
Private Sector RTDs	**PSI/WHO**	2013-16	67%	34.3	34.3	13.8	20.5	40%		**3.7**	The project aims to create a private sector market for quality assured malaria RDTs. The overall project programmatic implementation and financial performance in 2014 is on track to meet the project targets.	**3**		Good level of collaboration generally maintained; budgetary issues due the shift in the procurement timelines resolved.

Improving Severe Malaria Outcomes	**MMV**	2013-16	61%	34.0	34.0	10.7	23.3	31%	**3.2**	The project aims to accelerate policy adoption, uptake and global supply of injectable artesunate and artesunate suppository treatments for severe malaria. The overall project programmatic implementation and financial performance in 2014 is on track to meet the project targets. The main challenges are with procurement of Inj AS and initiation to work with new manufacturers.	**3**	Good level of collaboration generally maintained; procurement budget implementation has been slow due to delays in price negotiations and procurement process; the situation is now improving.
ACCESS - SMC	**Malaria Consortium**	2014-17	20%	67.4	67.4	11.7	55.7	17%	**3.6**	The project aims to expand access to Seasonal Malaria Chemoprevention (SMC). Implementation of planned project activities is on track however, programmatic and financial performance cannot be fully assessed due to the short implementation period in 2014.	**3**	Good level of collaboration generally maintained; provisional budget being finalized.
TRANSVERSAL GRANTS												
PQ Medicines	**WHO**	2014-16	43%	38.1	38.1	7.9	30.2	21%	**3.4**	The expected target and activities for all Outputs are on track. More improvement can be made in relation to the prequalification process (simpler, faster and more transparent procedures) in order to attract the manufacturers to apply for prequalification. Though a major achievement has been made in the medicines collaborative registration procedure to accelerate the rate of available registered and prequalified medicines with 8 additional countries participating in the procedure, more collaboration/synergy can also be done to harmonize evaluation and regulatory processes with other UTD partners. Under the new financing model (ongoing development), an annual financial contribution from manufacturers of health technologies to the PQ programme will be introduced with no major changes to the fees currently charged for initial assessment and major variations. Additional public consultation on the new model ended on 3 May 2015 (via questionnaire) with Contractual provisions enabling implementation of the new financing model to be put in place progressively in May 2015, and entry into force planned for January 2016.	**3**	Good level of collaboration generally maintained; improved cash planning and reporting.
PQ Diagnostics	**WHO**	2014-16	43%	12.2	12.2	2.8	9.3	23%	**2.2**	More improvement can be made in relation to prequalification process (simpler, faster and more transparent procedures). Though, significant achievements have been made in streamlining procedures for IVD prequalification, a pilot and implementation of Expert Review Panel for Diagnostics (ERPD) and Partnership activities with the United States Government (USG) to establish a single quality assurance (QA) mechanism for IVDs, more collaboration/synergy can also be done to harmonize evaluation and regulatory processes with other UTD partners. Under the new financing model (ongoing development), an annual financial contribution from manufacturers of health technologies to the PQ programme will be introduced with no major changes to the fees currently charged for initial assessment and major variations. Additional public consultation on the new model ended on 3 May 2015 (via questionnaire) with Contractual provisions enabling implementation of the new financing model to be put in place progressively in May 2015, with the entry into force planned for January 2016.	**3**	Good level of collaboration generally maintained; improved cash planning and reporting.
SPECIAL PROJECTS												

Medicines Patent Pool Foundation	**MPP**	2010-15	83%	31.2	31.2	19.7	11.4	63%	**4.9**	Overall the MPPF`s performance meets or exceeds all the agreed targets/milestones laid out in the 2014 annual work plan, and well performing to achieve the target Milestones by the end of 2015. Significant achievement in concluding a Licensing Agreement with MSD for Paediatric Formulations of Raltegravir covering 92 countries, allowing generic manufacturers to reformulate the formulations for use and for distribution in resource-limited settings as well as a license agreement with Abbvie for paediatric formulations of lopinavir/ritonavir, the first ever HIV voluntary licence for developing countries. Sub-licensees for the development of the Quad, a FDC of TDF, FTC, EVG and COBI have planned the bioequivalence studies and developed prototype pills. All Reports on the Feasibility studies on diversification of funding and expansion into tuberculosis and hepatitis C were duly submitted on 30 April 2015 for the UNITAID Secretariat`s feedback and suggested next steps.	**3**	n/a	Overall good level of cooperation maintained; quality reporting and coordination of budgetary and audit issues.

Programmatic and Financial Performance

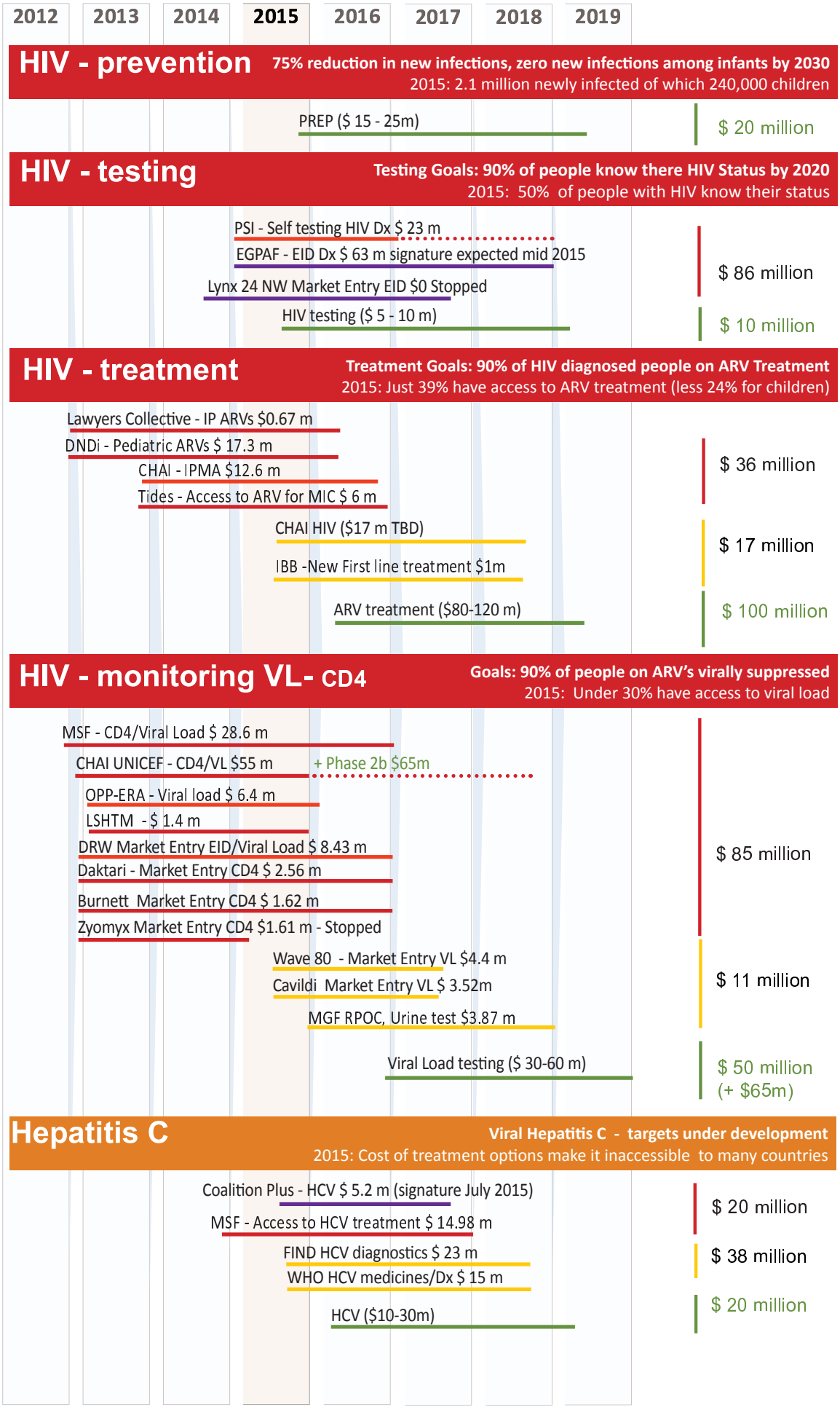
≤ 4	*Excellent; exceeds all expectations*	*All financial performance standards are fully met*
≤ 3	*Above average; exceeds minimum requirements/expectations*	*Most critical financial performance standards are fully met*
≤ 2	*Average; meets the minimum requirements/expectations*	*Most of the UNITAID's critical financial management standards are met*
≤ 1	*Below average; does not meet all requirements*	*Gaps in meeting the critical standards*
0	*No basis for assessment*	*No basis for assessment*

Annex 4:

Portfolio of investments
Active to potential projects

Portfolio of investments
Active to potential projects

14 April 2015



Legend:

- Active projects
- Planned
- Board approved new project - pending MOU signature
- Pending Board June 2015
- Possible areas of intervention

HIV/HCV Portfolio:

$248 million active projects

- Diagnostics: $192 m
- Treatment: $37 m
- HCV: $20 million

Represent **35 %** of active portfolio

- $82 million for EB22 approval
- If approved represents 36 % of portfolio

Investments by 2017

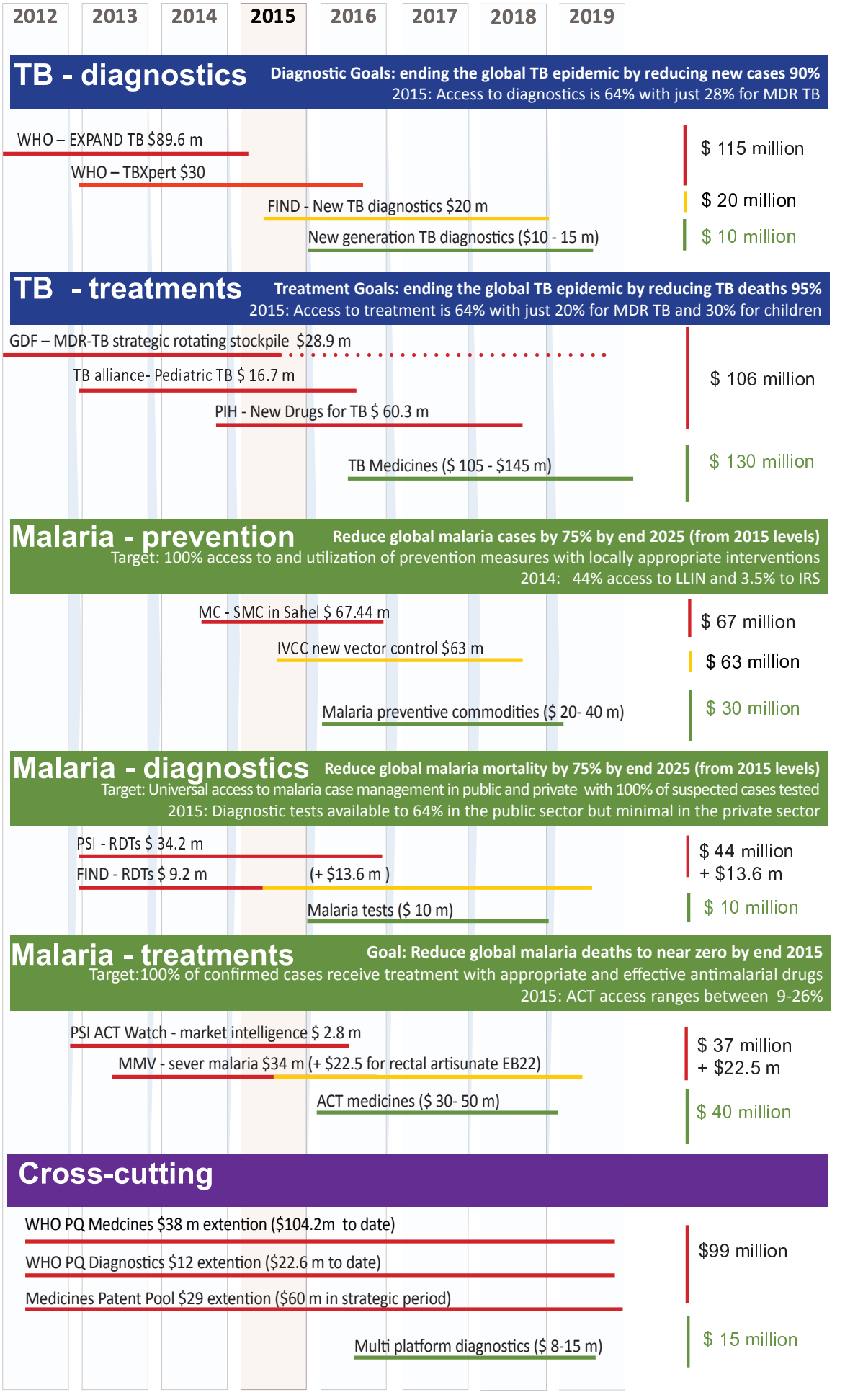
Projected:

42 %

of UNITAID portfolio

Portfolio of investments
Active to potential projects

14 April 2015



Legend:

- Active projects
- Planned
- Board approved new project - pending MOU signature
- Pending Board June 2015
- Possible areas of intervention

TB Portfolio:

$222 million active projects

- Diagnostics: $116 m
- Treatment peds: $17 m
- Treatment MDR: $89 m

Represents 31 % of portfolio

$20 million for EB22 approval

Investments by 2017 Projected:

27 %

of UNITAID portfolio

Malaria Portfolio:

$148 million active projects

- Diagnostics: $44 million
- Treatment: $37 m
- Prevention $67 m

Represents 21% of portfolio

$67 million for EB approval

Investments by 2017 Projected:

23 %

of UNITAID portfolio

Crosscutting

$99 million active projects

Currently **14%** of portfolio

Investments by 2017 Projected:

8 %

of UNITAID portfolio