UNITAID Executive Board Meeting
21st Session
11 – 12 December 2014
WHO Headquarters, Salle B
Geneva, Switzerland

Agenda item 6

Operations Update

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

ACRONYMS AND ABBREVIATIONS

ACT	**ARTEMISININ-BASED COMBINATION THERAPY FOR MALARIA**
AIDS	**ACQUIRED IMMUNE DEFICIENCY SYNDROME**
API	**ACTIVE PHARMACEUTICAL INGREDIENT**
ARV	**ANTI-RETROVIRAL MEDICINE FOR HIV/AIDS**
ASLM	**AFRICAN SOCIETY FOR LABORATORY MEDICINE**
BMGF	**BILL AND MELINDA GATES FOUNDATION**
CD4	**IMMUNOLOGICAL INDICATOR OF TREATMENT FAILURE FOR HIV/AIDS**
CHAI	**CLINTON HEALTH ACCESS INITIATIVE CM**
DNDI	**DRUGS FOR NEGLECTED DISEASES INITIATIVE**
EID	**EARLY INFANT DIAGNOSIS**
ESTHER	**ENSEMBLE POUR UNE SOLIDARITÉ THÉRAPEUTIQUE HOSPITALIÈRE EN RÉSEAU**
FDC	**FIXED-DOSE COMBINATION**
FEI	**FRANCE EXPERTISE INTERNATIONALE**
FIND	**FOUNDATION FOR INNOVATIVE NEW DIAGNOSTICS**
GDF	**GLOBAL DRUG FACILITY OF THE STOP TB PARTNERSHIP**
GFATM	**THE GLOBAL FUND TO FIGHT AIDS, TB AND MALARIA**
GLI	**GLOBAL LABORATORY INITIATIVE (WHO)**
HIV	**HUMAN IMMUNODEFICIENCY VIRUS**
IATI	**INTERNATIONAL AID TRANSPARENCY INITIATIVE**
KPI	**KEY PERFORMANCE INDICATOR**
LOI	**LETTER OF INTENT**
MC	**MALARIA CONSORTIUM**
MDR-TB	**MULTI-DRUG RESISTANT TB**
MMV	**MEDICINES FOR MALARIA VENTURE**
MOU	**MEMORANDUM OF UNDERSTANDING**
MSF	**MÉDECINS SANS FRONTIÈRES**
NGOS	**NON-GOVERNMENTAL ORGANISATIONS**
OECD/DAC	**ORGANIZATION FOR ECONOMIC DEVELOPMENT AND COOPERATION/DEVELOPMENT ASSISTANCE COMMITTEE**
PEPFAR	**THE UNITED STATES PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF**
POC	**POINT OF CARE**
PQP	**PREQUALIFICATION OF MEDICINES AND DIAGNOSTICS PROGRAM (WHO)**
PSC	**PROGRAMME SUPPORT COST**
PRC	**PROPOSAL REVIEW COMMITTEE**
PSI	**POPULATION SERVICES INTERNATIONAL**
RDT	**RAPID DIAGNOSTIC TEST**
SO	**STRATEGIC OBJECTIVE**
SRS	**STRATEGIC ROTATING STOCKPILE FOR MDR-TB MEDICINES**
TB	**TUBERCULOSIS**
UNAIDS	**THE UNITED NATION'S AGENCY FOR HIV/AIDS**
UNICEF	**UNITED NATIONS CHILDREN'S FUND**
UNIPRO	**UNITAID PORTFOLIO MANAGEMENT SYSTEM**
UNITAID	**UNITED NATIONS INTERNATIONAL DRUG PURCHASE FACILITY**
WHO	**WORLD HEALTH ORGANIZATION**
WHO/GTB	**WORLD HEALTH ORGANIZATION GLOBAL TB PROGRAMME**

1. Background

This document summarizes UNITAID's grant implementation and grant management while providing an overview of active grants by portfolio[1] for the semi-annual reporting period January to June 2014. This report also describes actions taken across the following areas:

- Results and achievements;
- Monitoring the implementation of UNITAID's strategy;
- Value for money;
- Performance-based grant management ;
- Key challenges on grant development and management;
- Field programme oversight;
- Civil society and partners engagement;
- Country ownership;
- Implementation of the new evaluation framework; and
- An overview of the portfolios and grant results (Annex 1).

A comprehensive overview of active grants, including grant performance ratings, is available in Annex 1. Grant performance ratings are available but reflect the period from January to June 2014. A full reconciliation of grant achievements against targets for the period from January to December 2014 will be available at the first Executive Board meeting in 2015. These results will be analyzed to produce UNITAID's Key Performance Indicator report for 2014.

2. Results and Achievements

Twenty-seven grants[2] and two Secretariat initiatives[3] are currently active in 2014. Of the six new grants approved at the June 2014 Board meeting, two have been signed[4], two will be signed by December 2014, one, the HIV/HCV drug affordability project with Coalition plus, will be signed in January 2015 and the last one, the EndTB grant

[1] HIV, TB, malaria and cross-cutting
[2] Including the Medicines Patent Pool Foundation
[3] ACT Watch (Malaria) and London School of Health and Tropical Medicine (HIV).
[4] SMC-PSI and ITPC

with PIH will be signed by February 2015.

The EndTB grant needed additional due diligence and the resulting report was discussed with the PRC. An update is included in Annex 3 of this report.

One new grant, Stimulating and shaping the market for HIV self-testing in Africa, was approved in October 2014. It will be signed by February 2015. One market entry grant, Zyomyx, was closed in July 2014. A separate update on this grant is included as Annex 2.

The chart below shows the break down of grants according to where they are in the funding cycle:

	HIV	TB	Malaria	Cross cutting	All portfolios
Active Grants (2014)	16	5	4	2	**27**
Under negotiation (2014)	3	1	0	0	**4**
New proposals (2014)	6	0	1	0	**7**
Closing (2014)	6	0	0	0	**6**
Total (by 2015)	**19**	**6**	**5**	**2**	**32**

Note: Information as of 29/11/2014

In 2014, 11 grant agreements were signed. These results are presented in the table below:

New grants	Extensions	Phase 2
• Access to SMC services (Malaria Consortium) • EID and VL monitoring (DRW) • IPMA (CHAI) • PQ Medicines and Diagnostics (2 grants) • ITPC (Tides) • North Western Global Health Foundation (NWGHF)	• MDR-TB SRS (GDF) • Paediatric ARVS (CHAI) • EXPAND-TB (GTB/WHO)	• POC HIV diagnostics (CHAI/UNICEF)

Six grants are closing at the end of 2014. A further 7 proposals will be presented to the Board for approval in December 2014, foreshadowing that UNITAID will potentially be supporting 32 active grants by June 2015.

The results for 2014 show that UNITAID continues to:

1. align its portfolio of grants with the Strategy 2013-2016;
2. increase its investments so that they are now spread across all 6 strategic objectives;
3. work with new grantees - 22 grantees are currently engaged with grants; and
4. distributes investments across product types and the value chain to address opportunities identified by market landscape analyses and market fora.

Challenges in grant agreement development

We encountered challenges in negotiating grant agreements for complex projects because of lack of grantee capacity for providing project plans that met UNITAID standards for risk mitigation and/or grant management. For example, the End-TB grant, approved in the June 2014 Board meeting, required additional due diligence to cover the following areas of concern:

1. appropriateness of the clinical trial design and the cohort approach;
2. the need for pharmacovigilance systems to be in place in countries taking part in the trials; and
3. readiness of countries to participate in the trials; and
4. compliance with WHO guidelines for research and trials.

The outcome of the due diligence report was reviewed by PRC and its recommendations were shared with Partners in Health and MSF. The grant agreement is now expected to be signed in February 2015 because the grantee needs additional time to complete all necessary documentation to comply with PRC requirements. A separate update is in Annex 3 of this report.

Serious challenges of organizational capacity meant that the Coalition plus grant on HIV/HCV drug affordability was delayed in its start date. The grant needed considerable input to define management arrangements to make the project plan operational. The grant is now expected to be signed in January 2015.

Two grants, Innovation in Paediatric Market Access (IPMA) of CHAI and POC of CHAI/UNICEF, also faced considerable delays in grant signing in 2014. The reasons were:

1. protracted negotiation between UNITAID and grantees on legal agreements,

including market intelligence data collection requirements;

2. validation of the scope of proposed operational research, including grantee's capacity to carry it out; and
3. lack of internal human resources in the Operations team during the transition period in the UNITAID Secretariat.

Increasing transparency on grants

In August 2014, UNITAID became fully compliant with the International Aid Transparency Initiative's (IATI) standard for reporting financial information for all active grants from 2007 to 2013. UNITAID's information is published in the IATI format on the IATI website at http://iatiregistry.org/publisher/utd. UNITAID is officially recognized within the IATI community and will continue to update this information for grants in 2014 and beyond.

3. Monitoring Strategy Implementation

UNITAID is using the data held in its Portfolio Information Management tool, UNIPRO, to analyse grantee performance and monitor budget implementation rates. Trends and patterns are identified to provide support for future funding decisions of the Executive Board. For example, the distributions of UNITAID's grant agreement value by product type, value chain activity and Strategic Objective are shown in Figures 1 and 2.

Figure 1 shows that in 2014, UNITAID is increasing its support to the full range of product types from medicines, diagnostics to prevention and actions that support the uptake of the vital products in low resource settings. UNITAID is mainly supporting medicines and diagnostics but support for prevention and uptake of better adapted products has increased in 2014. The second part of Figure 1 demonstrates that UNITAID is addressing a wider range of opportunities across the market value chain than ever before. This shift is supported by the opportunities identified in the market landscape analyses and market fora produced by UNITAID's Market Dynamics team.

Figure 1: Cumulative grant agreement value (US$) by product type and value chain shows increasing diversification of UNITAID grants across product type and the full range of areas where UNITAID adds value to prevent, diagnose and treat HIV, TB

and malaria.

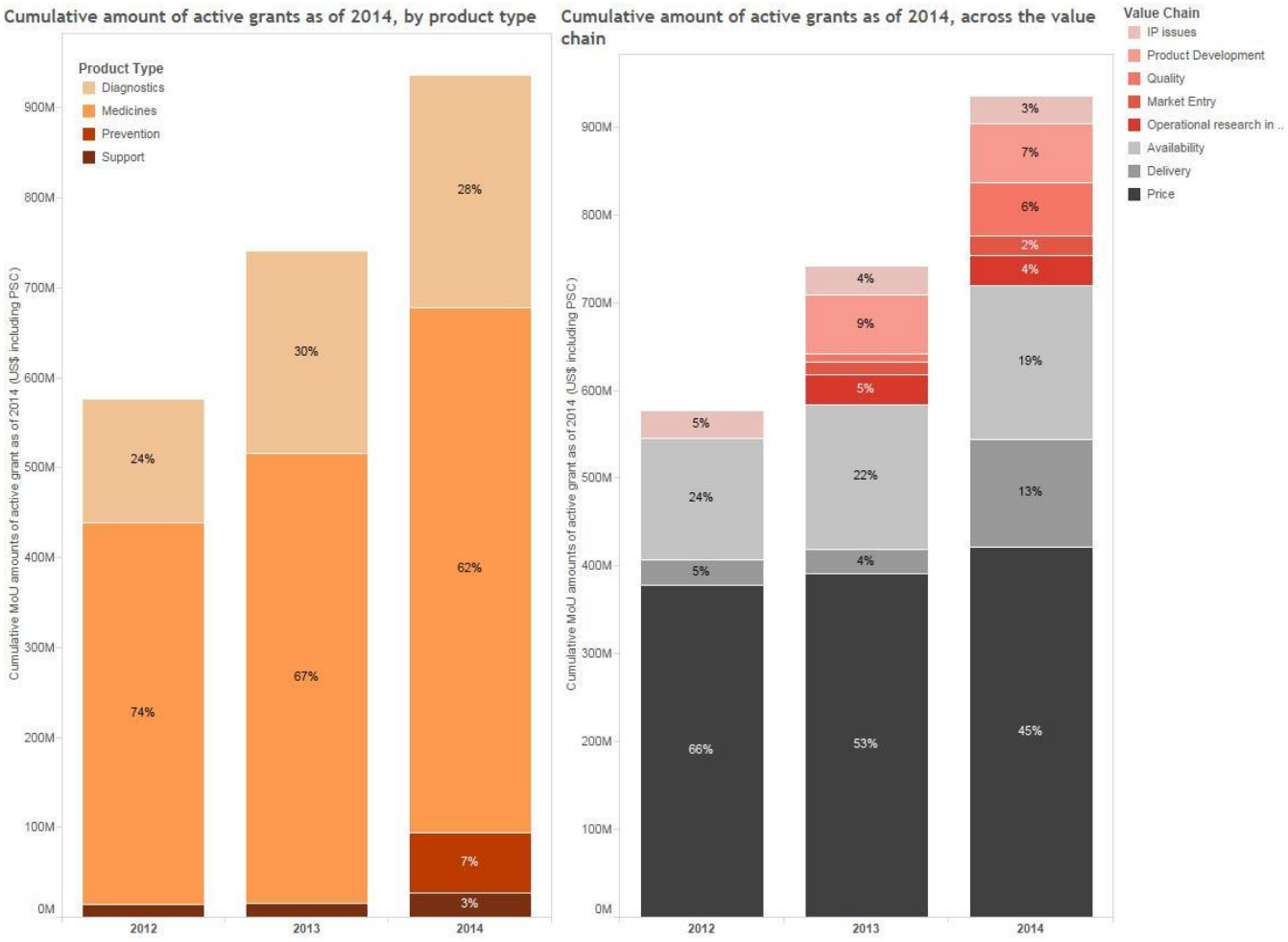


Figure 2 (below) shows that UNITAID continues to diversify its portfolio of grants to align with its Strategy 2013-2016. By 2014, investments are spread across all 6 strategic objectives. The shift from 2012 to 2014 demonstrates that UNITAID is implementing its Strategy 2013-2016 and responding to new opportunities that are being presented to it through the Letters of Intent (LOI) and proposal mechanisms. These figures, together with figure 3 (below), highlight the consistent nature of UNITAID's Board decisions across the three disease areas.

Along with the shift to addressing more opportunities across the value chain comes a decrease in UNITAID support to procurement of products for distribution in countries. This trend occurs across all of the disease portfolios but is a critical gap for the malaria and TB portfolios because there are no longer any UNITAID grants that deliver ACTs or MDR-TB medicines in countries. Although the GFATM has included private sector ACTs in its funding mechanism, this is not sufficient to meet the needs

for this medicine in high burden countries. MDR-TB medicines continue to be under-funded by the global public health donors. The current LOI which closes on 09 December 2014 is designed to generate new grants that may address these gaps.

Figure 2: UNITAID grant agreement value by Strategic objective shows that UNITAID is increasing supporting all 6 strategic objectives.

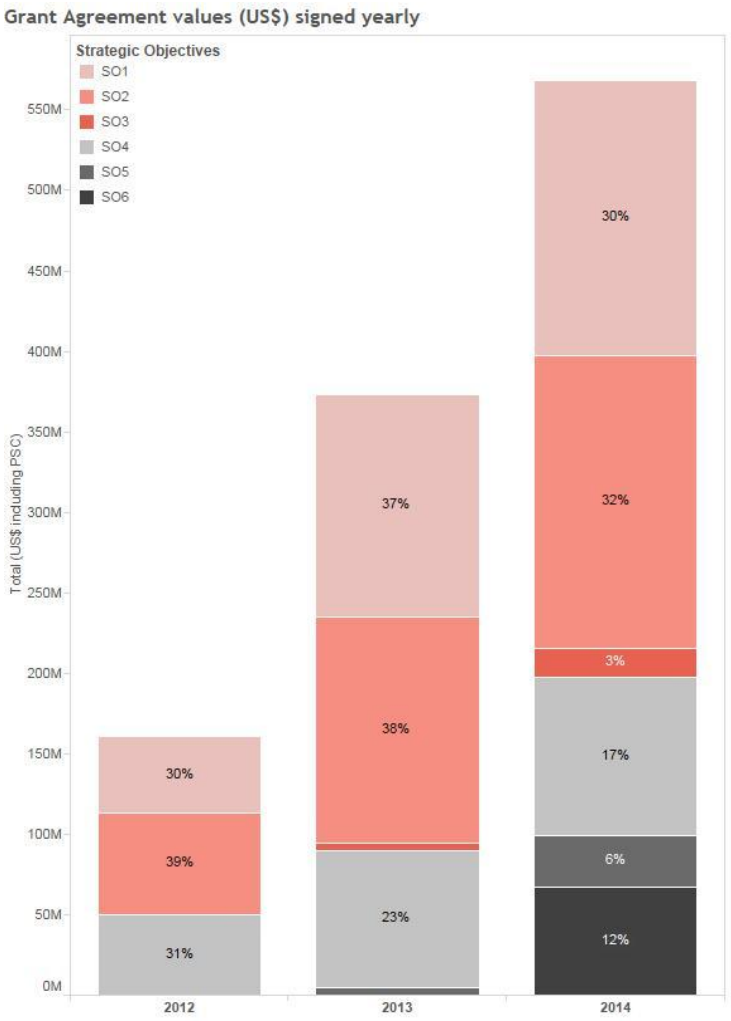
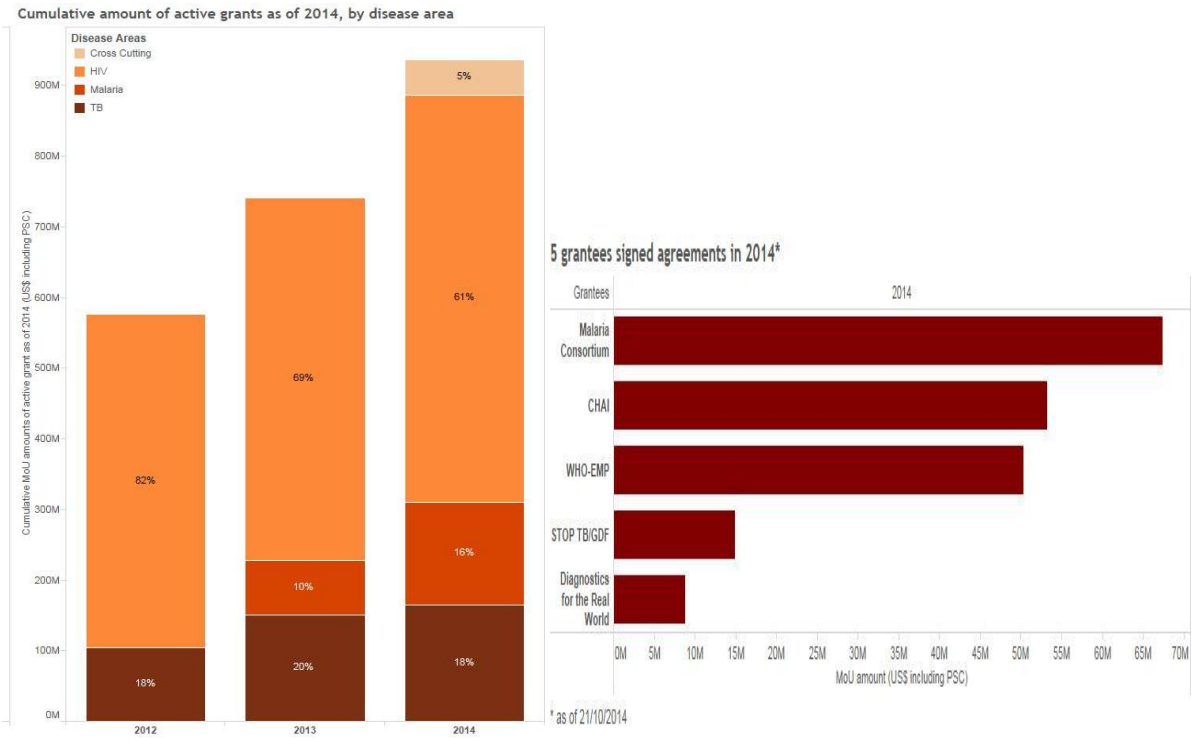


Figure 3. Investments are increasing across all disease areas and 5 grantees have signed agreements with UNITAID for the reporting period to 21 October 2014.

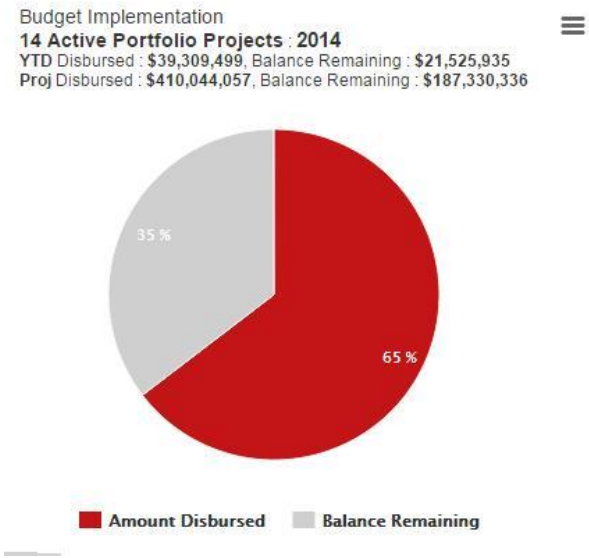


Monitoring grant performance is done by the Portfolio teams through regular communication with grantees, review of grantee reports, participation in grantee review meetings, and also through oversight visits to selected programs. Progress of the grants toward their targets of 2014 is presented in the performance management section of this report and summarized in Annex 1. The analysis of financial and programmatic information shows the performance within each of our 4 portfolios, HIV, TB, malaria and cross-cutting. The results are presented here according to portfolio type.

HIV

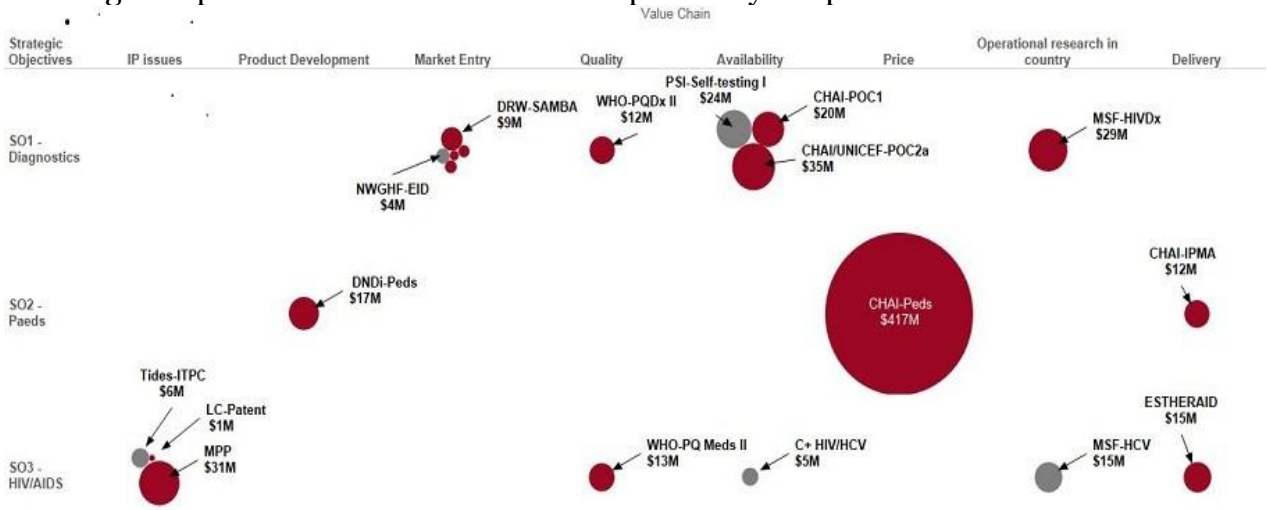
The HIV portfolio has 16 active grants, including the newly signed grants for ITPC-Tides and NWGHF. The figure below shows the overall budget implementation of the portfolio as of 31 October 2014. Sixty-five per cent of the 2014 budget for the portfolio has been disbursed for the grants up to end of October 2014.

Figure 4. HIV portfolio: budget implementation rate, 01 January to 31 October 2014.



The portfolio has diversified in response to gaps identified through market landscape analyses. For example, UNITAID made initial investments in ARV treatment projects for both 2nd line and paediatric medicines and also in prevention of mother to child transmission of HIV/AIDS. With more patients able to afford treatment, the market landscape reports predicted the need for rapid point of care tests to identify adults and children with HIV and to monitor that their treatment was still effective. In fact, POC testing is needed to increase universal access to testing and also appropriate treatment. The figure below shows the spread across the value chain for all active grants in 2014.

Figure 5. Distribution of active grants across the value chain as of 31 October 2014, showing the spread of value chain actions captured by the portfolio.



The figure shows that in 2014, the HIV portfolio has 9 grants related to strategic objective 1, rapid POC diagnostics for early infant diagnosis (EID), viral load (VL) and CD4 tests. Five of these grants are for market entry of new, innovative POC tests for HIV/AIDS, the remaining 4 are for making tests available in high burden countries and performing operational research to determine the optimal placement of new POC tests compared with laboratory based testing. If successful, the current investment in POC diagnostics may be sufficient to address market needs. In addition, the MPP work to promote the entry of generic manufacturers into the ARV market means that the next generation of second and third line ARVs will cost less, representing considerable value for money to the larger global funders like PEPFAR and GFATM.

Faster test results facilitate faster initiation onto appropriate treatment. This presents a challenge for the following reasons:

1. newer ARVs, including 2nd and 3rd line medicines may be unaffordable in low income countries;
2. there is still a need for better adapted and formulated medicines for children, especially infants detected using EID; and
3. the closure of the CHAI/UNITAID paediatric ARV grant in December 2014 will leave a gap in the portfolio addressing the availability and delivery of paediatric ARVs to low income countries.

UNITAID's portfolio is addressing these challenges in two ways;

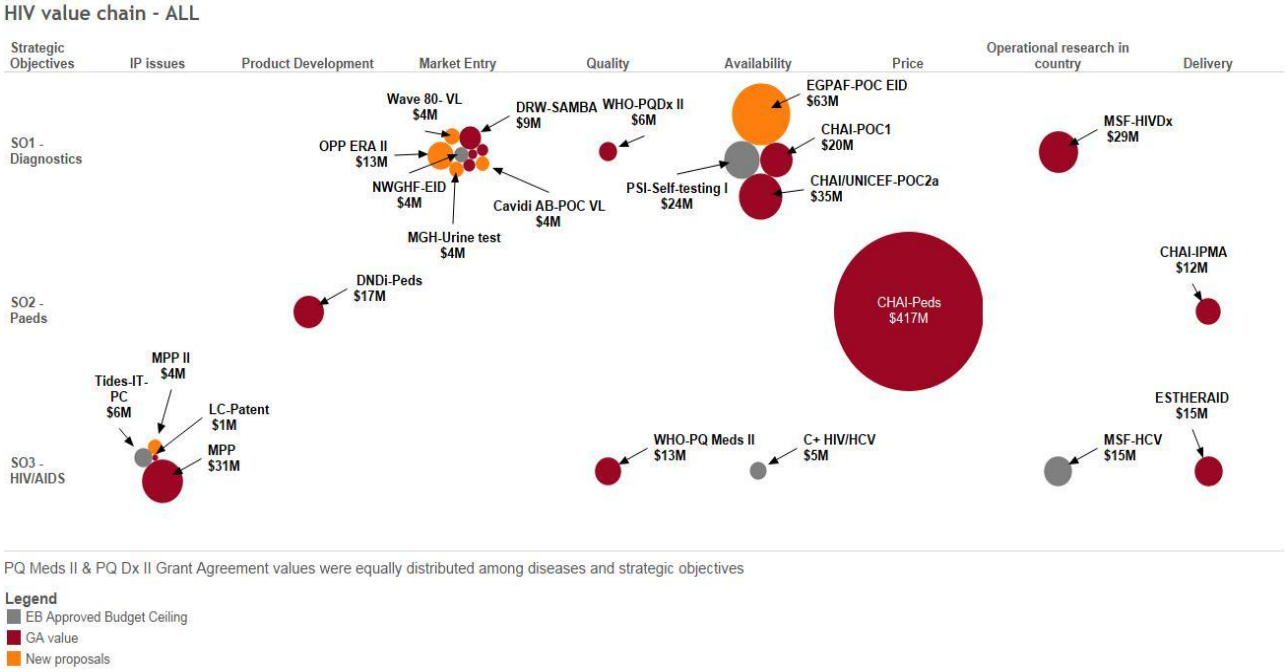
1. Funding grants that address intellectual property barriers to generic

manufacturers entering the market to make new and improved products at lower cost (ITPC, Lawyers collective); and

2. Development of new child adapted fixed dose combination ARV formulations.

The figure below shows the new proposals in the portfolio for approval at the December 2014 EB. The market dynamics dashboard[5] indicates that the market shortcomings are severe for the new Viral Load POC tests and early infant diagnostic (EID) tests that are being presented to the Board for approval. However, the figure below also shows that delivery of affordable ARVs in low and middle income countries for second line and paediatric patients will be a gap in the portfolio from the end of 2014 until new grants are funded in this area.

Figure 6. Distribution of active grants and new proposals for the HIV portfolio across the value chain.

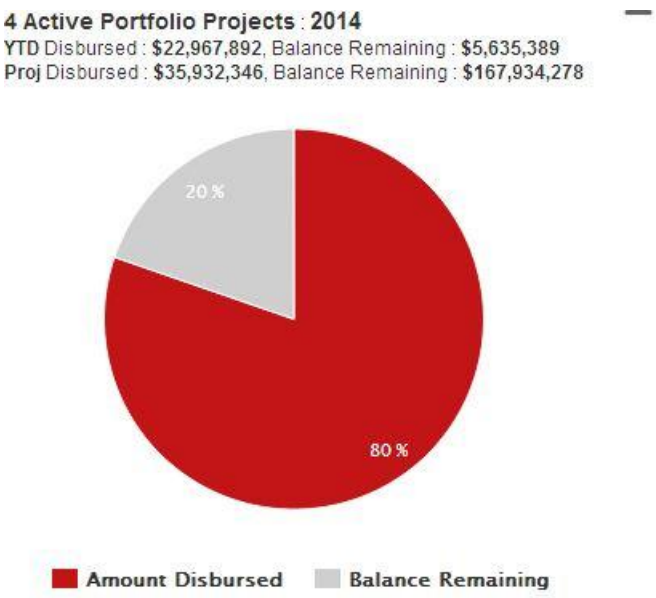


Malaria

The malaria portfolio has 4 active grants, one of which was newly signed in September (ACCESS-SMC with Malaria Consortium). The figure below shows the overall budget implementation of the portfolio as of 31 October 2014.

[5] Updated November 2014

Figure 7. Malaria Portfolio: budget implementation rate from 01 January to 31 October 2014.



Eighty per cent of the 2014 budget for the portfolio has been disbursed for the grants to the end of October 2014.

UNITAID's initial investment in malaria (AMFm) focused on increasing the uptake of artemisinin combination therapy (ACTs), the most effective treatment for malaria, over cheaper, non-effective medicines. The focus of the AMFm grant (with GFATM) was on outlets where patients and their families seek treatment in low income countries, namely private sector pharmacies. Now that the grant has been completed, the provision of ACTs to private sector facilities is being scaled up through the GFATM grant mechanism in high burden malaria countries.

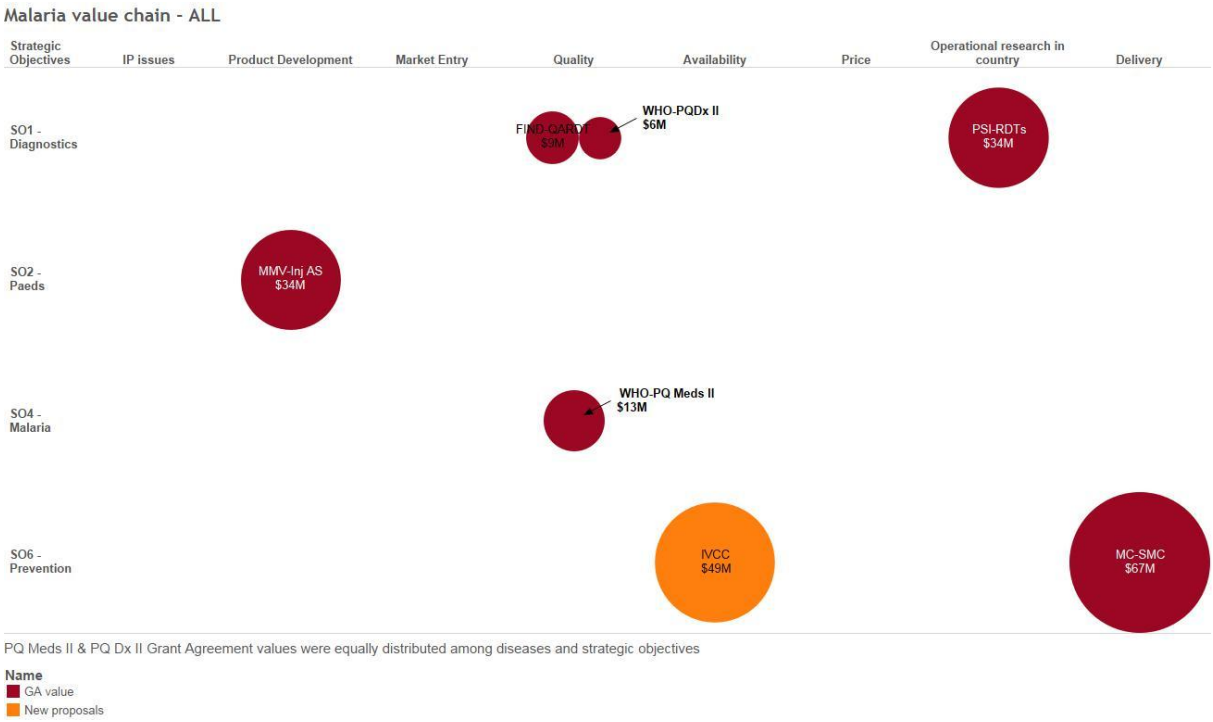
Over the course of the AMFm implementation, a need for effective, rapid diagnostic tests for malaria was identified as a means to ensure that ACTs were appropriately used for malaria treatment to reduce the development of resistance to ACTs in *Plasmodium falciparum*. In 2014, two of UNITAID's active malaria grants addressed the need for RDTs for malaria; one focuses on ensuring the quality of the tests on the market and the other works to facilitate use of quality RDTs in private sector outlets to promote testing for malaria before treatment with ACTs. This is essential because the majority of people seek treatment for malaria in private sector facilities so adding testing to these sites means that individuals can be detected quickly and provided with the most appropriate treatment, facilitating a cure and limiting the ability of the parasite to develop resistance to ACTs.

The other two grants in the portfolio address previously neglected challenges in malaria. The first is making better, effective treatments available for severe malaria by replacing the traditional hard to use treatment, quinine, with injectable Artesunate. The second is providing seasonal malaria chemoprophylaxsis (SMC) to children from 3 months to 5 years of age the Sahel region of West Africa. The aim of this grant is to improve market conditions for the standard recommended SMC drugs by providing generic manufacturers with incentives to invest in these products. Through this intervention, we intend to pave the way for widespread scale up of this high-impact intervention to prevent malaria and malaria deaths in children.

The figure below shows the value chain for the malaria portfolio. There is a gap in addressing the availability and delivery of treatments to high burden countries. This is well documented in the market dynamics dashboard[6] for ACTs to treat both adults and children. There is an additional gap in preventive products for the portfolio, especially those that focus on preventing the development of malaria through indoor residual spraying or provision of long-lasting insecticide treated nets to families in high burden countries. The new LOI closing on 09 December focuses on malaria and TB and may provide grants to address these gaps in 2015 and beyond.

[6] Updated November 2014

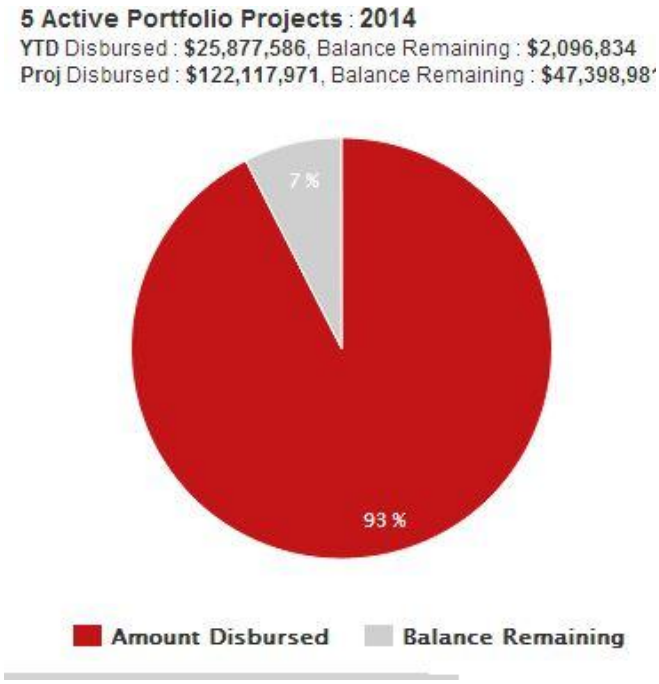
Figure 8. Active grants and new proposals in the malaria portfolio spread across the value chain.



TB

The TB portfolio has 5 active grants and one grant which will be signed in February 2015 (END-TB). The figure below shows the overall budget implementation of the portfolio as of 31 October 2014. Ninty-three per cent of the 2014 budget for the portfolio has been disbursed for the grants so far.

Figure 9: TB portfolio: budget implementation rate from 01 January to 31 October 2014.



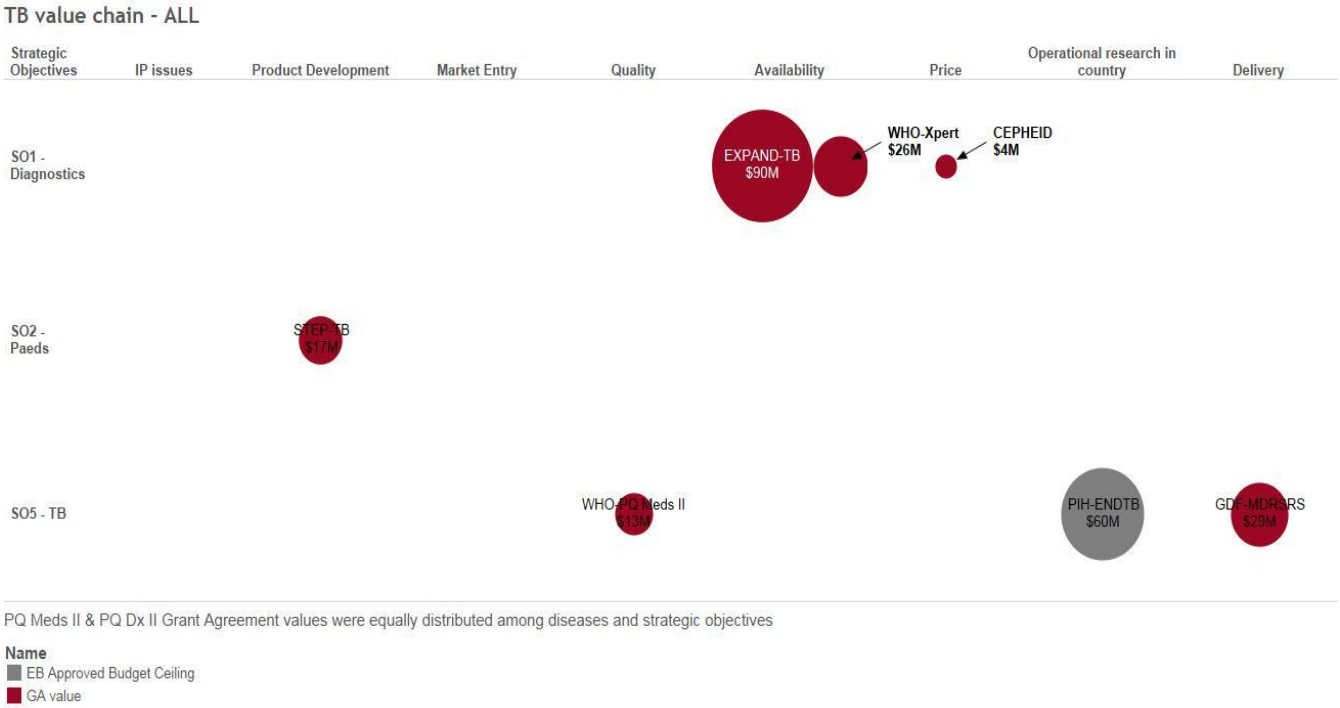
One grant, the Expand-TB diagnostics project with FIND and WHO, has been extended to support 14 countries who are transitioning to the GFATM and other funding sources in 2015. Two grants that support delivery of paediatric TB medicines and MDR-TB treatments to high burden countries ended in 2013. These are the subject of end of grant evaluations. There are no new proposals being presented to EB 21 in support of the TB portfolio.

The figure below shows that there is a gap in availability and delivery in country of medicines for children and MDR-TB patients because of the completion of grants related to delivery of these medicines. The strategic rotating stockpile for MDR-TB medicines remains but this is a mechanism to provide emergency treatments in stockout situations and is not designed to scale up treatment of newly detected cases. Appropriate paediatric formulations are still missing and the Step-TB grant with TB Alliance is designed to bring these products to the market so that they can be purchased in the future.

The market dynamics dashboard also highlights the severity of market shortcomings related to second-line and paediatric TB medicines. By way of contrast, TB and MDR-

TB diagnostics are well supported in this portfolio. The new call for LOIs on-going to 09 December 2014 is a chance for the gap in availability and delivery of anti-TB medicines to be filled in 2015 and beyond.

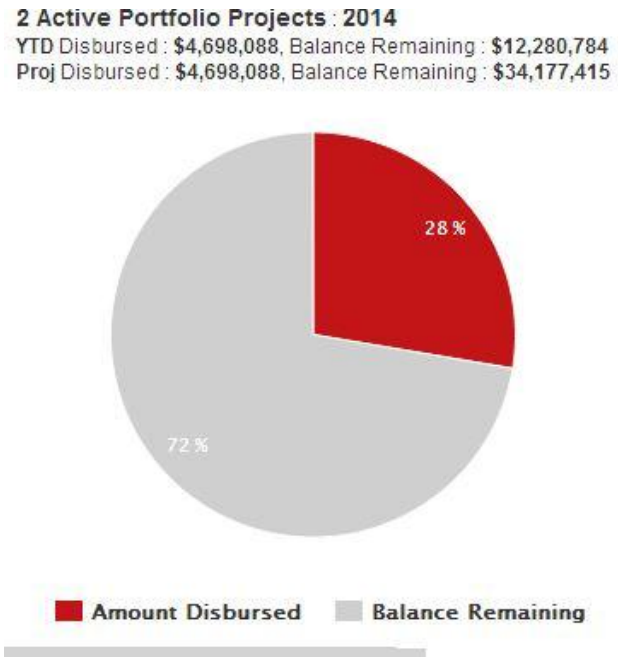
Figure 10. Active and pending grants in the TB portfolio across the value chain.



Cross-cutting

The cross-cutting portfolio has 2 active grants whose actions address all three diseases. This category is for support to the WHO/UN prequalification programme to quality assure medicines and diagnostic tests. The figure below shows the overall budget implementation of the portfolio as of 31 October 2014. Twenty-eight of the 2014 budget has been disbursed for the grants to the end of October 2014, reflecting the recent initiation of the two grants in this portfolio. Implementation of these two grants are coordinated with other investments being made by the Bill and Melinda Gates Foundation (BMGF).

Figure 11: Cross-cutting portfolio: budget implementation rate from 01 January to 31 October 2014.



UNITAID has supported these two programmes since its inception but the grants closed at the end of 2013 and new grant agreements were signed in the first (prequalification of medicines) and second (prequalification of diagnostics) quarters of 2014. The new grants reflect the lessons learnt from the previous grant implementations, including the need for enhanced support for staffing within the two WHO programmes. The Medicines Patent Pool (MPP) is investigating the addition of licenses for TB and Hepatitis C (HCV) medicine patents to the patent pool mechanism. This will make the MPP grant an addition to the cross-cutting portfolio, allowing it to support improved market access by generic manufacturers to both HIV, HCV and TB medicines.

4. Generating value for money

UNITAID's focus on value for money is demonstrated by its investment in products that will generate greater value for money for key partners such as the GFATM, PEPFAR, and national programs. Examples of products that are now available for use by our global partners include:

- 2 new HIV POC products[7] have been initiated with UNITAID support and are

[7] 1) SAMBA for EID and VL monitoring from Diagnostics for the Real World; 2) Daktari POC CD4 system for low resource settings.

being tested in countries now;

- Injectable Artesunate is being procured as the perferred treatment for severe malaria and countries are now starting to use it instead of injectable quinine. Price negotiations for injectable artesunate done jointly with the GFATM have resulted in more reasonable prices (US$ 1.45 per vial) for 2015. A second manufacturer is expected to reach the market in the next 12 months;
- Detection of MDR-TB using TB Expert devices and cartridges is now less expensive through UNITAID support; cartridge prices have decreased by 40% to US$9.98. This price reduction is available for 145 countries, and public sector purchasers[8] have saved US$ 50 million to date as a result of the price reduction; and
- Opening of the generic market for tenofovir (TDF) and TDF-based formulations by the Medicines Patent Pool (MPP) resulted in enhanced competition, price reductions and royalties saving leading to an estimated US$ 42 millions savings from January 2012 to June 2014.

A new POC diagnostic device, SAMBA II, which gives same-day results for the detection of HIV genetic material, was rolled out to 3 African countries in October 2014. SAMBA II is produced by our grantee Diagnostics for the Real World (DRW). Additional HIV diagnostics are expected to be launched in 2015, thus increasing access to testing and monitoring tools at affordable prices in low income countries. Once these tools are available, other UNITAID's diagnostic grants with commodity components (CHAI/UNICEF and MSF) will support countries to select appropriate products for their context and needs and assist their optimal introduction in healthcare settings.

UNITAID is supporting more grants of smaller value but addressing a wider range of actions and product types aimed at improving access to important products for the three diseases in low income countries. Having a diversified range of grants means we act at different points along the value chain, from addressing intellectual property challenges to delivering essential products to low income countries (Figure 1). The range of actions that we take and the types of products that we support help us to sustain market changes. For example, investing in HIV POC diagnostics for early

[8] including Brazil and South Africa

infant diagnosis helps to get more children on the correct treatment faster, sustaining the nascent paediatric ARV market. This, in turn, will help us when we bring innovative, new paediatric ARVs to market because we will be able to sustain these products at lower prices. The recently signed IPMA grant will provide 2014-2015 demand forecast to guide future ARV planning and disseminate information to government, procurement agents, implementers, and suppliers. With CHAI's analytical support, ARV procurement order planning has been streamlined among procurement consortium members.

UNITAID investments enable the large global donors to increase access to medicines and diagnostics for less money in high disease burden countries. For example, key second line and paediatric ARVs continue to decline in price[9] following UNITAID's intervention in these markets with grants to CHAI. Multiplying the effects of our initial investments so that national governments and larger global funders can have better access to products for the three diseases at lower prices is a core value at UNITAID. We continue to work on a methodology to demonstrate the impact of our investments for the global health community so that we can measure our impact across all grant types.

[9] Over 30% since 2007 for paediatric LPV/r and over 70% since 2007 for second line regimens TDF/FTC & LPV/R and TDF/3TC & LPV/R

5. Performance Management

UNITAID has a pre-launch grant agreement development phase that clearly defines what is required from grantees, grantee capacity to manage implementation, monitoring and evaluation, financial management systems, clear timelines for deliverables as well as reports which include collection of programmatic, procurement and market intelligence data. Grant Agreement Development (GAD) process map and guidelines indicate clearly various steps for grant agreement development. A new tool on risk assessment has been introduced which is now tested with new grants. The tool will be finalized by December 2014. A grantee capacity assessment tool has been developed to assess capacity of grantees to determine their operational readiness. This tool is being tested with three new grantees. Finance and Operations teams are working on defining guidelines on fraud detection, fraud prevention and risk management.

We continue to improve our grant development and management processes so that we can work efficiently and effectively with grantees. One of the new initiatives that is improving the way we work with grantees is the UNITAID on-line reporting tool. After developing the IT tool, pilot testing and grantee training were organized. Any new IT system requires extensive testing to promote useability. Our on-line reporting tool has benefited from extensive feedback from grantees who used the system for their semi-annual reports. This feedback is being used to ensure that problems are resolved and that annual reporting for 2014 goes smoothly. The advantage of our new reporting tool is that it facilitates the upload of grantee programmatic information directly into the UNITAID information system, allowing for:

- timely submission of reports;
- more efficient data verification;
- less use of paper; and
- a reduced need for manual data entry.

Once the system is fully functional, it will facilitate much quicker feedback to grantees, as well as internal sharing of project results and data analysis. In order to facilitate more efficient and focused reporting on grant performance and capture lessons learned, a template for reporting the narrative component of annual and semi-annual reports is being developed and will be rolled out in time for the annual

reports. This narrative template will become an integral part of the on-line reporting system in UNIPRO. The reporting system will be simpler, taking less time to review internally, thus allowing quicker feedback to grantees. This will improve the efficiency of the Operations team.

Other tools developed by the Operations team aim to make UNITAID operations more efficient. These have been completed or are nearing completion. These tools are listed in the table below.

tool	purpose	progress	release date
Risk assessment	to identify risks at the grant level and to facilitate the development of mitigation plans	testing phase	operational in 2015
Grantee capacity assessment	to identify capacity gaps, risks, and operational issues which may hinder grant implementation and address them during grant negotiation	testing phase	December 2014
Field program oversight framework	criteria and guidance to the portfolio teams on evidence-based selection and effective planning and execution of program oversight visits	under development	December 2014
Framework for grant transition or scale up	facilitate grantees and the portfolio management to identify early on whether and when they will need to transition grants or find additional funding to scale up successful market shaping interventions	under development	December 2014
Performance-based disbursement	guideline for grantees on disbursement request will be prepared by December 2014 so that grantee request align with results-based disbursement principle	Under development	December 2014

6. UNITAID's grantee forum

Building positive relationships with grantees is important to UNITAID's success. To facilitate a better understanding between the Secretariat and grantees and to focus on results-based management, UNITAID held its first Grantee Forum in 2 years. This was held on the 18th and 19th of November 2014 in Geneva and had three key objectives to:

1. improve our relationships with grantees and provide a forum for open discussion;
2. update grantees on some of our recent changes including grant management processes and guidelines, risk assessments, fraud prevention measures, our expectations, focus on results, Communication, Market Dynamics, timely reporting, and partnership for scaling up; and
3. introduce UNITAID Senior Management Team and the new Executive Director.

Highlights from the forum include presentations from all teams in UNITAID including Operations, Market Dynamics, Communications, External Relationships, and the Executive Office of UNITAID. The forum included a break-out session designed to receive feedback from grantees on their working relationship with UNITAID, especially what works well and what could be improved. Grantee feedback on grant implementation challenges and lessons learnt included the following important points:

- Grantees would appreciate full assessment of their proposals before they are sent to the Board for approval;
- There was a need for standardized templates and operating procedures but an equal need to keep processes as simple as possible;
- Grantees requested faster decision making from UNITAID;
- The role of civil society in generating demand for optimal and innovative products was critical and needs to be incorporated into project planning; and
- Grantees were happy to have the opportunity to network with colleagues at the forum and to see how their investments were contributing to the shared goals of improving the health of those living with HIV, TB and malaria.

UNITAID now has the opportunity to take this feedback forward as it works to refine some of its new agreement development tools. Comments collected at the end of the two days were unanimously positive and include requests for the Grantee forum to be a regular event in UNITAID's annual calendar. An independent grantee satisfaction survey will be conducted in December 2014.

7. Key challenges for Operations

Operations has experienced some challenges in the implementation of grants and also in signing grant agreements approved by the EB20. The innovative nature of UNITAID's work means that there may be some unforeseen delays, especially with new grant types and grantees. The reason for delays is that we are making grants for products that are upstream in the value chain and there is uncertainty around how these products will be commercialised for use in low resource settings. The five (5) major challenges for this reporting period are:

1. Barriers to starting clinical research grants;

2. Market entry grants that fail;
3. Reaching agreement with grantees on the provision of market intelligence information;
4. Lack of grantee capacity for implementation management of grants; and
5. Procurement from a quality assured monopoly producer.

The table below illustrates these challenges by challenge type with an example of a grant affected by the challenge, the issue that arose and the solution that is now being implemented by the Secretariat teams.

Challenge type	Grant involved	Challenge to grant	Solution	Lesson learnt
Barriers to starting clinical research grants	Expand new drug markets for TB (end-TB)	Expected outcomes of the cohort and clinical trial component of the grant not clearly presented to UNTAID or partners. Internal lack of capacity in clinical trial and clinical research	Market Dynamics team are leading a technical due diligence process to clarify clinical research goals for this project. A report is being produced by expert consultants and a new timeline for grant agreement development is being finalized. UNITAID hired clinical trial and clinical research consultants to provide overall guidance and support to UNITAID teams.	UNITAID needs specific operational guidelines and policies to fund clinical research as well as clinical trial capacity assessment of grantees. UNITAID has contracted clinical trial consultants to develop such guidelines which will allow Operations to manage these types of grants better.
Market entry grants –risk of failure (commercialization)	Market Entry Grants	Zyomyx was unable to raise additional funds to commercialize their product. UNITAID does not fund the commercialization of market entry products. Two other Market Entry	Market Entry grantees have been informed that UNITAID will not provide additional funding. UNITAID is in discussion with the grantees and Gates and CIFF about the funding situation.	UNITAID does not provide money for commercialization of a product so market entry failures are a major risk. For Market Entry grants such as this, additional due diligence is required at the proposal stage which is being done for the new market entry proposals for the December Board meeting; staff need

		grants are now experiencing funding deficits and may fail before getting to the commercialization stage. CD4 and EID products with a low resource setting focus are most at risk.		additional guidance for managing Market Entry grants. Halteres provide technical support and oversight for all active market entry grants. The Secretariat will increase capacity to manage Market Entry grants with additional guidance, information sessions with industry experts and knowledge building from conference and workshop attendance. The Secretariat plans to continue building strong partnerships in this area.
Reaching agreement on Market Intelligence data collection	IPMA; CHAI/UNICEF HIV POC diagnostics	Grantees were concerned that confidential and nationally and/or commercially sensitive data would be made available to partners outside UNITAID. Extensive and time consuming negotiations were needed, thus resulting in significant delays in grant signing;	Make grantees aware of how UNITAID uses market intelligence information	Ensure that grantees are aware of this requirement during proposal development; for existing grants, ensure timely communication and re-negotiation of grantee reporting; develop an information paper to educate grantees the usefulness of such information for UNITAID current and future investments as well as attracting larger donors for scaling up

Grantee capacity and ability to sign agreements	Coalition plus (phase 1)	PRC & Secretariat identified the need for the grantee to establish sufficient capacity to launch the grant; Lack of grantee capacity will lead to delayed grant signing;	Signing of the grant is being facilitated by the release of pre-Grant signing funds within the limits of UNITAID's policy. External consultants hired by Coalition plus to help grant documentation. A meeting with grantee senior management team and UNITAID portfolio team took place recently to agree on next steps and possible use of a consultancy firm to provide much needed support for the project setup and initial phases, while an intensive project staff recruitment takes place.	Grantee Capacity Assessment should be initiated during proposal development phase.

Procurement from a quality assured monopoly producer	MMV improving severe malaria outcomes	Protracted price and volume negotiations with the only WHO pre-qualified manufacturer of injectable Artesunate led to a delay in the availability of injectable Artesunate in project implementation countries	MMV has been working with the Global Fund and UNITAID to develop a combined strategy to enhance the negotiation position with the manufacturer.	Risk mitigation for single source products should start at the proposal stage. Appropriate planning is required to introduce a second supplier quickly.

8. Field Programme Oversight

Field Programme Oversight is an important part of supporting UNITAID's strategy 2013-2016 and helps to ensure the success of its grants. Whenever necessary UNITAID Portfolio Teams visit field sites of active grants in order to support grant implementation and address challenges faced by grantees in doing ground breaking work in low resource settings. During the reporting period, a number of field visits were made. Examples of field visits made to date are provided in Annex 4 of this report.

9. Civil Society and Partner engagement

Civil Society is a critical partner in raising community awareness about new and existing products for HIV, TB and malaria. Without strong Civil Society support, many grants would be limited in their scope and impact. Grant agreements signed with UNITAID require grantees to include Civil Society engagement in their project plans. Examples of grants with strong Civil Society engagement include:

- the MSF Project to implement CD4, Viral Load and Infant Testing in decentralized, resource limited settings which provides strong, accountable, community-based treatment literacy and adherence support along with strong social protection programs;
- the Coalition Plus Project plans to increase access to affordable Hepatitis C (HCV) treatment and will work with key Civil Society organizations in 10 target countries to move the national agenda on HCV treatment and Intellectual Property issues.

An update on these grants is available as part of Annex 1 of this report.

UNITAID works closely with other global health donors to ensure that it provides additional support to the work of the global public health community. During field oversight visits, the portfolio team meets Global Fund and PEPFAR partners and other stakeholders. Oversight visits include:

- meetings with all country stakeholders, including national programme representatives;
- finalizing strategic plans for the roll out of new technologies for high burden

countries; and

- generating work plans that actively involve other public health agencies that are dedicated to the fight against HIV, TB and malaria.

Specific examples of partner engagement for the reporting period are provided below.

- Manufacturers workshop to update manufacturers of paediatric ARVs on the GFATM and PEPFAR's planned tender approaches in 2014/2015 (Dubai, UAE June 2014);
- Participation in the GFATM Diagnostics manufacturers meeting to align UNITAID HIV POC diagnostic strategies with the GFATM;
- Participation in workshop in October in Tanzania on joint review of POC technologies evaluation data with regulators from 8 countries to align regulatory requirements for POC diagnostics in selected African countries, majority of which are participants in UNITAID funded diagnostic projects. The success of this effort will directly impact project scopes, especially that of CHAI/UNICEF and MSF, as well as the market entry grants.
- Participation in the sourcing and Market dynamics strategy review meeting of the GFATM to leverage important market-shaping actions for TB medicines from all stakeholder and create a roadmap for TB supply chain management to increase access to life-saving medicines.

We report additional information on our work with the GFATM during the Partnership session of EB 21.

10. Country Ownership

UNITAID grantees are expected to work with national governments of beneficiary countries and to inform them about the support that UNITAID grants are providing in their countries for the benefit of people living with the three diseases. At a minimum, UNITAID expects MoUs or letters of support to be signed with national authorities before a grant is implemented in a country. Country engagement from the beginning of a grant provides countries with the opportunity to make the funded interventions their own and use them to improve healthcare in their national settings. Country engagement also includes national level registration of products and interaction with the national regulatory authorities. During field program visits,

portfolio teams meet national programs managers as well as key stakeholders.

UNITAID actively participates with grantees and other global public health partners to support countries to plan the introduction of lifesaving new technologies. For example, country priorities are reflected in the choice of POC diagnostic tests introduced by UNITAID grants to CHAI/UNICEF and MSF and also in their placement in countries. These grants use existing national laboratory technical working groups to structure country operational plans and prioritize activities in each country. These grants also collaborate with national research institutes for product evaluation.

Another example arose in September 2014 when the HIV team participated in a meeting in Ethiopia to develop strategic plans for the introduction and roll out of viral load technology in high HIV burden countries. This was done in conjunction with national governments and other key global public health stakeholders, especially USG/PEPFAR, GFATM, ASLM, CHAI/UNICEF, and MSF. The strategic plans and linkages between global public health agencies will help high burden countries harmonize donor investments in HIV more effectively.

In the Expand TB grant with FIND, national authorities are taking active country engagement one step further. The governments of Rwanda, Myanmar, Peru are exploring the possibility of financing the MDR-TB detection laboratories at the end of the UNITAID grant. National TB Control programmes of other countries have already included the costs of running Expand TB supported laboratories in their concept notes to GFATM. These countries are taking ownership of their grant achievements. As a result, these achievements will be sustained over time, facilitating the detection of people suffering from MDR-TB so that they can start treatment faster.

11. Evaluation Framework

Grant evaluations allow UNITAID to be transparent about grant progress and to share this information with key stakeholders and the general public. UNITAID and its grantees both benefit from an independent, external evaluation of their joint work.

UNITAID currently commissions mid-term and end-of-grant evaluations. Evaluators are provided with a framework for performing UNITAID evaluations as part of the terms of reference for their assignments. This framework follows closely those specified by the OECD/DAC with the addition of grant specific topics designed to produce optimal recommendations to maximize grant performance.

In 2014, UNITAID revised the Evaluation framework to align more closely with the Strategy 2013-2016. Key changes include:

- a focus on country verification;
- increased country stakeholder consultations including with civil society;
- Corroboration of grant achievements by external partners (GFATM, PEPFAR, UNAIDS, PMI and others);
- Focus on value for money, impact and country ownership;
- Increased visibility of UNITAID's role in grant achievements at the country level; and
- Transparent communication with grantees and stakeholders.

To make use of the revised evaluation framework, UNITAID launched a request for proposals (RFP) for evaluation consultancies that were independent and external from its operational activities. Seven firms[10] were selected to hold long term agreements with UNITAID to facilitate evaluations aligned to the UNITAID evaluation framework. This process will be repeated annually to add qualifying evaluation firms, increasing the number and diversity of external independent evaluators. Firms will be removed if they fail to produce timely evaluations meeting UNITAID's quality standard as outlined in its Evaluation Framework 2014.

UNITAID has started 4 evaluations this year. Two of the on-going evaluations are end-of-grant evaluations and two are mid-term reviews of active grants. A list of evaluations is provided in the table below.

[10] Price Waterhous Coopers (PWC), ADD Project, Dalberg, Euro Health Group, Cambridge Economic Policy Associates (CEPA), ICF International, Swiss Tropical Institute of Public Health.

Grant evaluations started in 2014.

Name of grant	Evaluation type	Evaluation team selected
Open Polyvalent Systems for access to viral load (OPP-ERA) (FEI)	Final (End of Phase 1)	Euro Health Group
TB Xpert (WHO-STB)	Mid-term	CEPA
Paediatric TB (GDF, Stop TB)	Final	Dalberg
MDR-TB Scale up (GDF, Stop TB)	Final	Swiss Tropical Institute

Preliminary results of the final evaluations will be provided to EB 21 in the form of a presenation.

12. Introduction to Annex 1: overview of grant performance

This section presents an overview of the results of active grants for the semi annual period until 30 June 2014. A full report on the achievements and challenges of 2014 will be described in the Key Performance Indicator Report on 30 June 2015. Information describing our results across all years, grantees and countries will continue to be updated and displayed at www.unitatid.org/impact.

This year, we have made significant changes to the way we display information for analysis. New features include:

- Trends in active grants and grantees from 2007 to 2014;
- Value of Executive Board approved amounts (cumulative since 2006);
- Summary of value of US$ disbursed for active grants in 2013 by strategic objective;
- Overview of grant results against targets for 2013;
- A summary of grant performance ratings;
- A comprehensive update of grant performance; and
- A grant transition status overview.

UNITAID revised its scoring of grant performance in 2014 to provide clearer guidance to grantees and Portfolio teams on how to measure grant performance. This change has been made to standardize grant performance assessment to ensure that grants are fairly assessed within the boundaries of the contractual agreements that UNITAID has signed with grantees. The criteria, which are not new to grantees because they are part of the performance framework that UNITAID negotiates with grantees during the grant agreement phase of a project, are fully explained in the grant performance section of Annex 1.