UNITAID Executive Board Meeting
20th Session
12 - 13 June 2014
WHO Headquarters, Salle C
Geneva, Switzerland

Agenda item 12

Operations Update

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

1. Background

This document summarizes UNITAID's Operational activities for 2013. It provides the Executive Board with an overview of UNITAID's active grants by portfolio (HIV, TB, Malaria and cross-cutting). It also describes actions taken to implement new grants that were approved by the Board in December 2014.

UNITAID's annual results are presented in its Key Performance Indicator Report available on 30 June of each year for the preceding year. This cycle is aligned with UNITAID's project funding cycle where Grantees report to the Secretariat twice a year, in September/October and in March/April. This report provides a brief update on relevant actions since the EB 19. A comprehensive overview of active grants is available in the Annex. The Annex also includes a section on grant performance ratings and a summary of grants needing transition or scale-up with the help of other global donors.

2. Performance in 2013

Twenty-three grants, one Special project[1] and four Secretariat initiatives[2] were active in 2013. Four grants and one Secretariat initiative ended in December 2013. Of the four grants, three are the subject of end of project evaluations in 2014[3] and one is the subject of an external audit.

The results for 2013 show that UNITAID:

1. continues to diversify its portfolio of grants to align with the Strategy 2013-2016;
2. is increasing investments in point-of-care diagnostics (SO1) and by 2014 investments will be spread across all 6 strategic objectives;
3. is increasing investments in all disease areas and 16 lead grantees were active in 2013; and
4. is distributing investments across product types and the value chain to address opportunities identified by market landscape analyses and market fora.

[1] Medicines Patent Pool Foundation

[2] Coordinated procurement planning initiative (CPP) with PEPFAR/SCMS (HIV), ACT Watch (Malaria), London School of Health and Tropical Medicine (HIV) and William Davidson Institute (Cross cutting).

[3] MDR-TB Scale up, Paediatric TB, AMFm, and A2S2. Three of these projects are the subject of end of project evaluations in 2014. A2S2 is the subject of an external audit that has just started.

3. Monitoring Strategy Implementation

UNITAID is using the data that are held in its Portfolio Management tool, UNIPRO, to analyse grantee reported information. 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 pinpoints the shift that UNITAID has made into diagnostic products for detecting HIV, TB and malaria in low resource settings. UNITAID is still mainly supporting medicines but support for diagnostics has increased over time. 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 2 shows that the UNITAID ontinues to diversify its portfolio of grants to align with its Strategy 2013-2016. By 2014, investments will be spread across all 6 strategic objectives. These figures, together with figure 3, which highlights consistent nature of UNITAID's Board decisions across the disease areas, demonstrate that UNITAID is on its way to providing support to all of its 6 strategic objectives. It has also increased the number of grantees that it supports to improve the health of those living with HIV, TB and malaria in low resource countries.

4. Generating value for money

UNITAID's commitment to getting value for money from its investments in projects to prevent, diagnose and treat HIV, TB and malaria translates into even bigger value for money for the global public health community. For example, in 2013 UNITAID supported more grants of smaller value but addressing a wider range of actions aimed at improving access to important products for the three diseases in low income countries. Having a diversified range of grants means that we act at different points along the value chain, sustaining market changes and bringing quality, innovative products quickly to market at lower prices. UNITAID creates value for money across four strategic areas :

1. Bringing innovative, life-saving products to the market in a way that creates incentives for competition to drive prices down so that those most in need can benefit;

2. Focusing on populations who need better adapted medicines and tests, especially children and those responding only to second or third line treatments;
3. Helping health systems to function more efficiently because they have access to better health products for HIV, TB and malaria as well as better methods for forecasting and managing supply chains; and
4. Creating stable markets for quality products so that our partners, the GFATM and others, can do more for less money in countries with high disease burdens.

The four market entry grants for innovative point of care (POC) HIV diagnostics demonstrate how UNITAID adds value to the efforts of others. These grants will open up the market for quality diagnostic tests that can be performed quickly at the point of care so that those needing tests can receive immediate care without waiting weeks for a result. UNITAID is providing the resources to get these products to market faster than would have been possible without its support. National governments and global donors will soon have a wider choice of efficient diagnostic products, resulting in better health outcomes for patients.

Similarly, UNITAID support to the Medicines Patent Pool Foundation (MPPF) is an opportunity to address patent barriers to the creation of badly needed fixed dose combination ARVs, especially 4 in 1 formulations for children which promote adherence, preventing the need for frequent switching to more costly regimens. UNITAID made an initial investment of USD 13 million in the MPPF, resulting in a cost savings of USD 22 million for countries needing Tenofovir (TDF). Examples and analyses like these explain how an organization like UNITAID with a “market shaping” focus can add value to the actions of other global donors in the fight against the three diseases.

Figure 1: UNITAID grant agreement value by product type and value chain, 2012-2013.

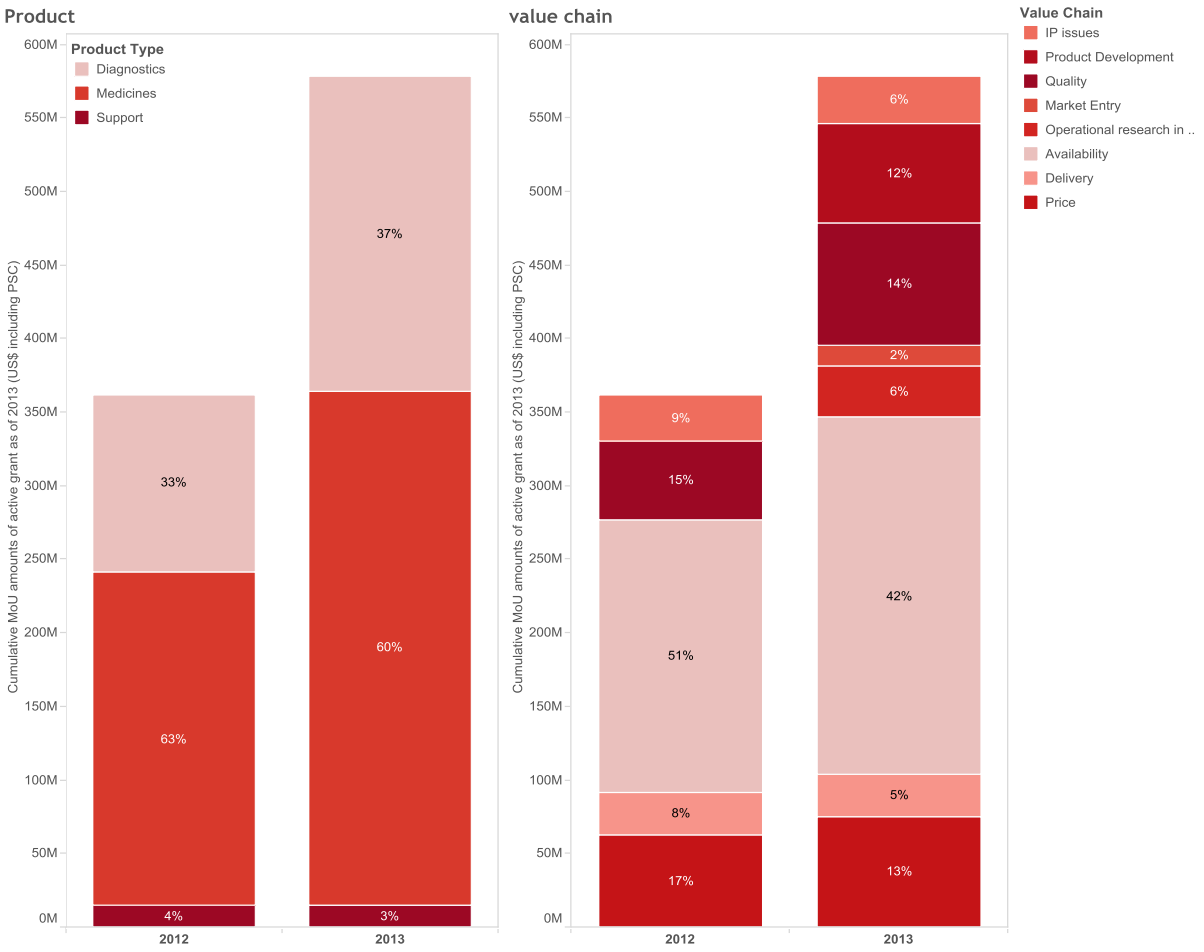


Figure 2: UNITAID grant agreement value by Strategic objective, 2012-2013.

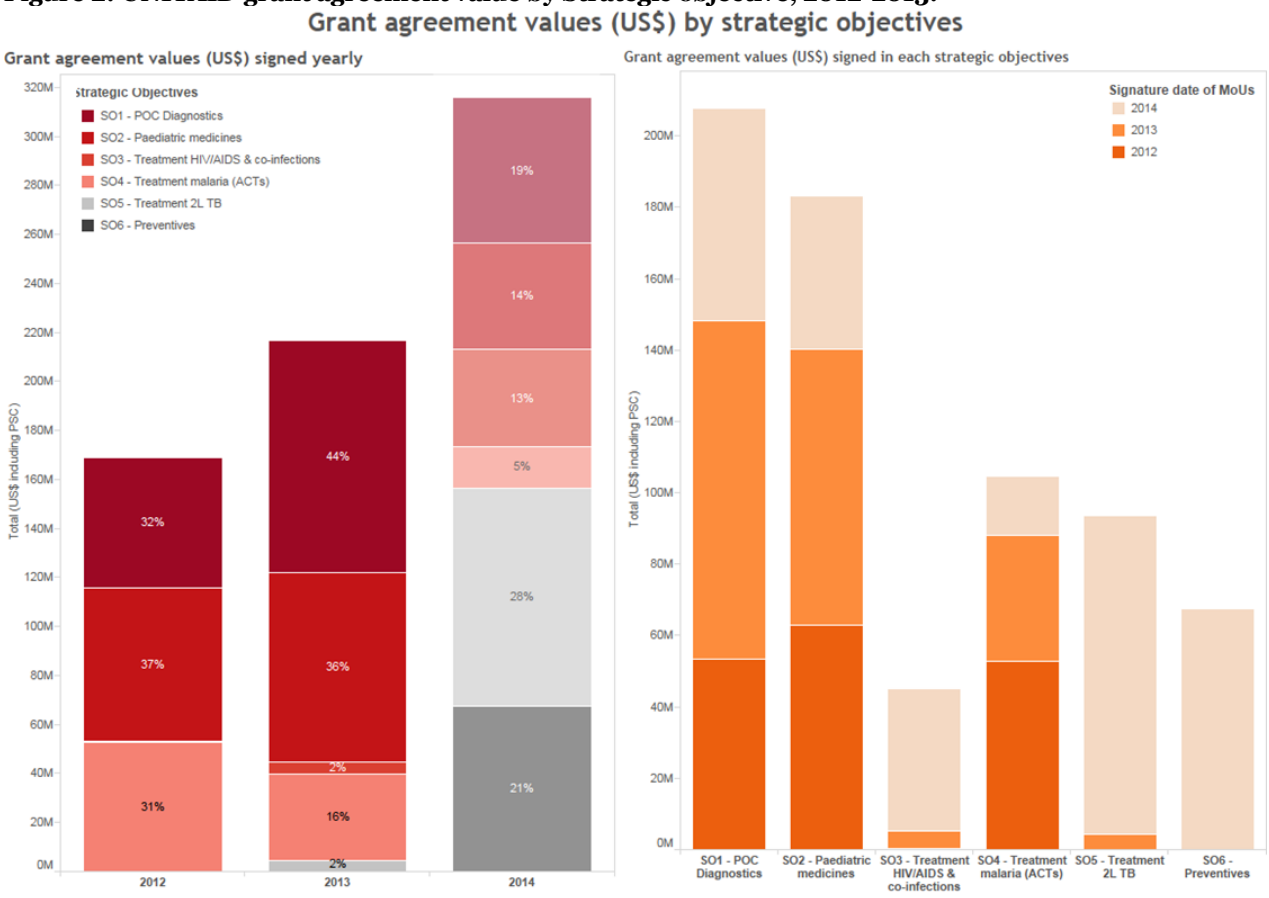
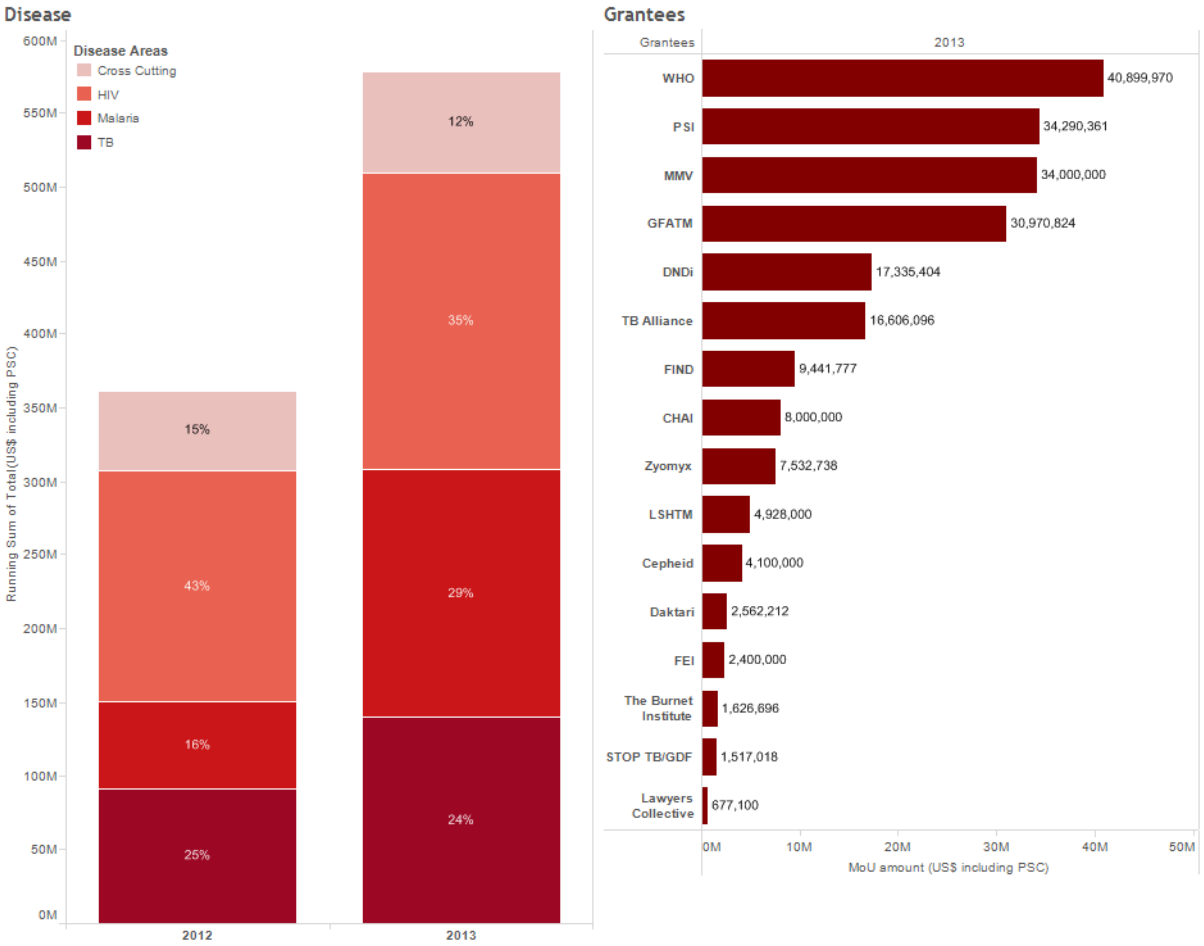


Figure 3. Investments are increasing across all disease areas and are spread across 16 lead grantees.



5. status of December executive board approved proposals

Five proposals for new or continuing funding were approved during EB 19. Of these, one grant, the CHAI paediatric ARV project, has been signed. The remaining grants and their expected timelines for signature are provided in Table 1 below.

Grant	Expected signature
Innovation in paediatric market access (CHAI)	30 May 2014
MDR-TB Strategic Rotating stockpile (StopTB/GDF)	agreement completed[4]
Prequalification of medicines and diagnostics (WHO)	agreement completed
Accelerating Access to POC HIV diagnostics (phase 2)	30 May 2014

[4] Amemdment to be added in June 2014.

6. Guidelines that are facilitating Grant Implementation

UNITAID is committed to managing grants to get optimal results. To support this commitment, the UNITAID has a rigorous pre-launch grant agreement development phase that clearly defines the project plan and timeline for implementation of this plan. This process provides UNITAID grants with a strong foundation for achieving objectives within a defined timeframe, appropriate risk management, and scale up planning as may be appropriate. Further strengthening of implementation oversight is critical to ensuring accountable use of funds, effective market interventions, and planned transition for scale up. Several guidelines are now available to portfolio teams to improve the way UNITAID works with its grantees. These guidelines are based on broader consultations, including with the PSC, on field experiences, and reviews of best practices from other organisatons. A list of guidelines and frameworks that are helping to improve our operational performance are listed below.

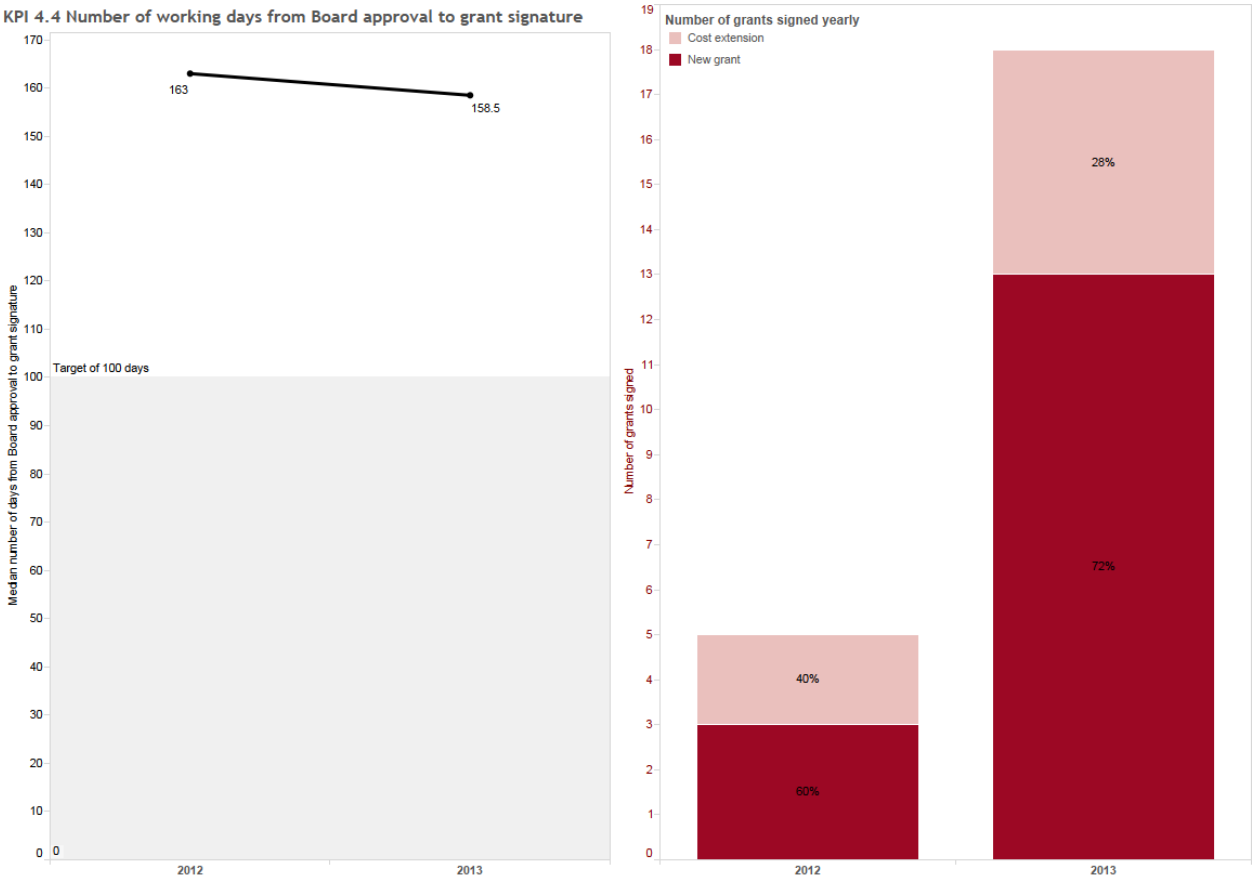
- Procurement guidelines for health products: As a financing organization, UNITAID has specific rules that grantees must follow to manage procurement under international best practices. This guideline makes those rules and regulations clear to grantees before they start their grant-related procurement processes.
- Quality assurance guidelines: UNITAID has specific rules that it must follow to provide products of known quality. This guideline specifies what UNITAID means by quality assurance so that grantees can adhere to these requirements. The policy is aligned with the current Global Fund Quality Assurance Policy for Pharmaceuticals and Diagnostics Products, which is itself the product of extensive stakeholder consultation and buy-in and founded on, *inter alia*, the quality assurance standards of the WHO Medicines and Diagnostics Prequalification Programmes and Stringent Regulatory Authorities.
- Grantee capacity assessment: This is a formal assessment of grantee capacity carried out by the Secretariat after Executive Board approval and before grant agreement finalization intended to improve grant implementation quality and timeliness. It covers key areas of program management, financial management, M&E, (green) procurement, value for money, communication etc. Previously, only fiduciary assessments were done. The assessment is also a risk mitigation step and capacity enhancement initiative to ensure that

grantees have appropriate capacity to implement UNITAID funded programs. This assessment will identify any weaknesses or risks to grantees' capacity to implement, manage or report on grant activities and support additional actions to effectively and efficiently manage grants.

- Program oversight framework for key interventions in priority countries: The framework provides priority criteria and guidance to the portfolio teams on evidence-based selection and effective planning and execution of program oversight visits. Periodic project monitoring of grant implementation by portfolio teams are focused on improving project implementation and achieving grant objectives through gathering lessons learned, ensuring accountable use of funds, enhancing timely execution of market interventions, and with appropriate communication with partners and key stakeholders, including civil society. The framework fosters the effective implementation and scale-up of its successful market interventions. Program oversight also contributes to visibility of UNITAID investments and contributes to effective transition and scale up of successful interventions.
- Framework for grant transition or scale up: Transition of successful market interventions to country and other sources of funding such as the GFATM will increase access to prevention, diagnosis and treatment, a key principle of UNITAID investment. This framework facilities 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. Using this framework, UNITAID interventions are shown to be a clear value for money proposition for countries and other funding organizations. This is also discussed under the section on Partnership with the Global Fund.

These processes and guidelines are already having a positive effect on the performance of the Operations team. Recent analysis of the lead times for signing of grant agreements shows that grant extensions are signed faster than ever before and that the time to signature of new grants has been decreasing over time (Figure 4). These changes can be attributed to a better understanding of UNITAID's policies and processes among both new and exisiting grantees.

Figure 4. Grant extensions are signed faster than new grant agreements but time to signing of both is decreasing.



7. Key challenges for Operations

Operations faces some key challenges in the coming months. In particular, the challenge of ensuring that grants are functioning well at the national level presents an opportunity for working more closely with in-country partners, especially national level civil society and representatives of UNITAID member countries. Major challenges include:

1. Engagement with the GFATM to transition or scale-up important results from grants made in paediatric ARVs, MDR-TB medicines and ACTs to treat malaria. In addition, a transparent arrangement of information sharing between the Global Fund and UNITAID needs to be agreed.
2. Management of market entry grants: The Secretariat is currently developing an IP and Access guidelines.
3. Monitoring optimal implementation as well as transition of our grants in the countries. This may require support from technical networks of Board

members through their country offices. Support from civil society and communities groups is also critical to the success of UNITAID grants in countries.

4. Ensuring complementarity between grants that are working in the same product type and countries, especially the grants supporting POC diagnostics for HIV. A synergy meeting addressed this challenge for the grants focusing on POC HIV diagnostics. The meeting was positive and UNITAID will use the process as an template for how to work contrstructively with grantees in similar areas of work.
5. Wider dissemination of UNITAID project information requires more efforts from all, especially at the country level. UNITAID is working to make its information sharing platforms, including its website easier for all to access and to understand. The benefit is that is will be easier to demonstrate that UNITAID investments are making a difference and what can be scaled up to benefit millions of people still needing tests and treatment. Information sharing about UNITAID funded grants is critical to ensuring maximum impact of these grants. Sustainability of successful market interventions facilitate greater access to quality assured products at affordable prices. Information about what we fund and where can be found in both French and English at www.unitaid.org/impact.
6. Sustainability of UNITAID investments beyond grant period. As required by newly approved KPIs, the Secretariat needs to monitor sustainability of successful products' availability and price reductions for a period of three years after grant ending date. This requires additional consultations and guidance from key stakeholders and Board members.

8. Grant Evaluation findings

UNITAID has revised is 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; and

- Transparent communication with grantees and stakeholders.

The complete Evaluation framework was endorsed by the PSC and is presented to the Board for information in Annex 2.

In 2013, UNITAID completed 2 mid-term and 4 end of project evaluations. These evaluations are fully available on the impact page at www.unitaid.eu/impact. The main findings have been that the grants have achieved key objectives, often under difficult circumstances. UNITAID needs to work more closely with other global partners to ensure that the market achievements of its grants are sustained into the future. A summary of follow up actions that have occurred within the Portfolio Management Teams as a result of these evaluations is in Table 2 below.

Table 2. Summary of evaluations and actions from 2013.

Name of grant	Evaluator	Type	Actions triggered
ESTHERAID (ESTHER)	DMI Associates	Mid-term	New grant indicators related are being used in the 2013 Annual report to UNITAID
Prequalification of diagnostics programme (WHO)	Euro Health Group	Mid-term	PQP has been reorganized and additional support identified from BMGF and CDC-USA
ACT Scale Up Initiative (UNICEF & GFATM)	Euro Health Group	Final	Grant has closed and unspent monies have been re-funded
Round 6, Phase 1 Initiative (GFATM)	Cambridge Economic Policy Associates	Final	Project logs are now kept in UNIPRO to improve tracking and accountability
A2S2-Assured Artemisinin Supply System Project (i+ Solutions, Triodos Bank, FSC, Artepal)	Dalberg	Final	Audit initiated for I+ solutions to reconcile loans
Second Line HIV/AIDS Project (CHAI)	Dalberg	Final	Planning for transition is being enhanced with options to co-fund grants or engage potential funding sources earlier

The evaluations planned for 2014 are shown in Table 3, below. To facilitate the quick turnaround of these evaluations an RfP to identify and quality assure evaluation teams was launched in April 2014 and the selection panel is now finalizing the results.

Table 3. Evaluations planned in 2014.

Name of grant	Evaluation type
HIV diagnostics (MSF)	Mid-term
Open Polyvalent Systems for access to viral load (OPP-ERA) (FEI)	Mid-term
Paediatric HIV (DNDi)	Mid-term
Paediatric TB (GDF, Stop TB)	Final
MDR-TB Scale up (GDF, Stop TB)	Final
MDR TB SRS /GDF, Stop TB)	Final
TB Xpert (WHO-STB)	Mid-term
STEP TB (TB Alliance)	Mid-term

9. Grant overviews 2013

This section presents an overview of the results of active grants in 2013. A full report on the achievements and challenges of 2013 will be described in the Key Performance Indicator Report on 30 June 2014. Information describing our results across all years, grantees and countries will be displayed at www.unitatid.eu/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; and
- A comprehensive update of grant performance

UNITAID has revised its scoring of grant performance to provide rigourous guidance for how grants are performing. This change has been made to standardize grant performance assessment and ensure that grants are assessed fairly and 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 the Annex.

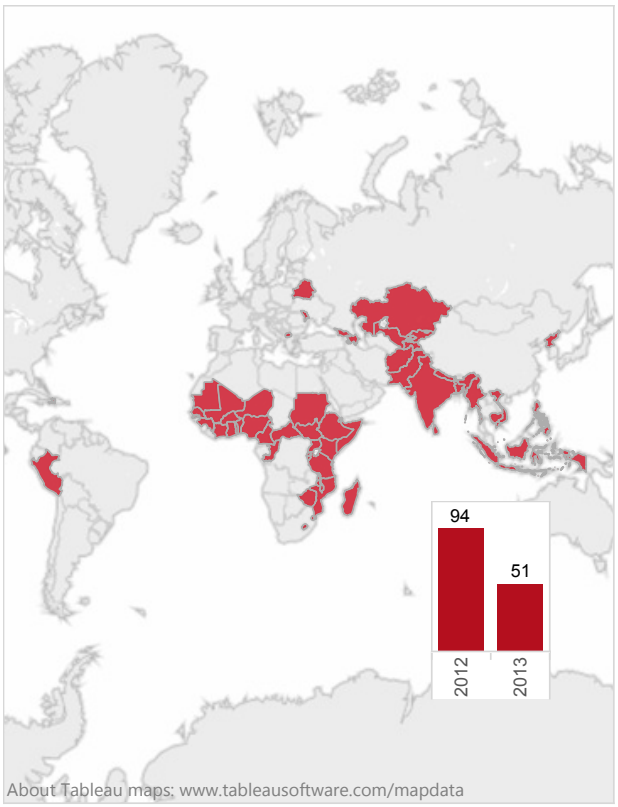
Annex 1: Operations Project Updates

For Information ☒ For Review & Advice ☐ For Endorsement ☐

EB20/2014 OPERATIONS PROJECT UPDATE

Grant Overview

Active Countries (2013)



Does not include countries for MDR-SRS or CPP.

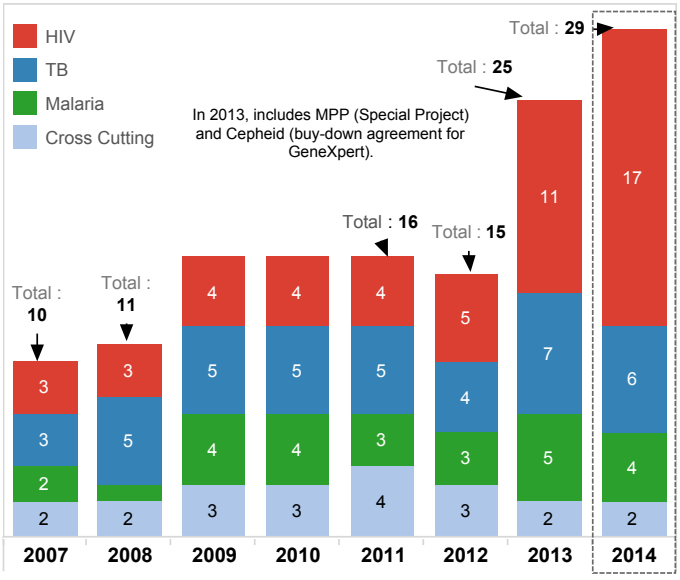
List of Active Projects (2013-2014)*

	SO	Project Duration	Project	Grantees
HIV	SO1	06/12/2013 – 06/12/2016	POC CD4 Counters	Daktari
		12/02/2013 – 30/06/2014	OPP-ERA	FEI
		20/12/2013 – 20/12/2016	Rapid POC CD4	Burnet
		23/12/2013 – 23/12/2016	Disposable POC CD4 Test	Zyomyx
		24/01/2014 – 31/12/2016	EID & VL Monitoring*	DRW
		25/12/2012 – 31/12/2015	HIV Diagnostics	MSF
		30/11/2012 – 30/06/2014	POC HIV Diagnostics	CHAI UNICEF
		EB19SS approved ('14)*	Lynx p 24 EID POC	NWGHF
	SO2	EB19 approved*	IPMA	CHAI
		01/11/2006 – 31/12/2014	Paediatric ARV	CHAI
		31/05/2013 – 31/05/2016	Peds ARV formulations	DNDi
	SO3	01/08/2013 – 30/07/2016	Prevent Patent Barriers	Lawyers Collective
		03/07/2009 – 31/12/2014	ESTHERAID	ESTHER
		05/05/2014 – 31/12/2016	HIV/HCV Drug Affordabili..	Coalition Plus
		05/05/2014 – 31/12/2017	HCV treatment revolution	MSF
		10/09/2011 – 31/12/2015	MPP (Special Project)	MPP Foundation
		EB19SS approved ('14)*	Treatment, PLHIV in MIC	Tides
Malaria	SO1	01/01/2013 – 31/12/2017	Quality Control of RDTs	FIND
		23/04/2013 – 29/02/2016	Priv Sec Market-RDTs	PSI
	SO2	05/06/2013 – 05/06/2016	Improving Severe Malaria	MMV
	SO4	02/11/2009 – 31/12/2013	AMFm	GFATM
		06/07/2009 – 31/12/2013	A2S2	i+solutions
	SO6	EB19SS approved ('14)*	Access to SMC Services	CRS
TB	SO1	10/12/2008 – 31/12/2014	Expand TB Dx	FIND STOP TB/GDF WHO-GLI
		28/01/2013 – 31/12/2015	TB Xpert	WHO-GTB
		28/12/2012 – 28/12/2020	Cepheid (Buy-down)	Cepheid
	SO2	12/01/2007 – 31/12/2013	Paediatric TB	STOP TB/GDF
		22/07/2013 – 22/07/2016	STEP Paediatric TB	TB Alliance
	SO5	20/11/2008 – 30/06/2015	MDR TB SRS	STOP TB/GDF
		25/07/2007 – 31/12/2013	MDR TB Scale Up	STOP TB/GDF
		EB19SS approved ('14)*	Expand Market for TB	PIH
CC	SO1	23/03/2009 – 31/12/2016	Prequal of Diagnostics	WHO-EMP
	SO3,4,5	14/12/2006 – 31/12/2016	Prequal of Medicines	WHO-EMP

Disease Areas

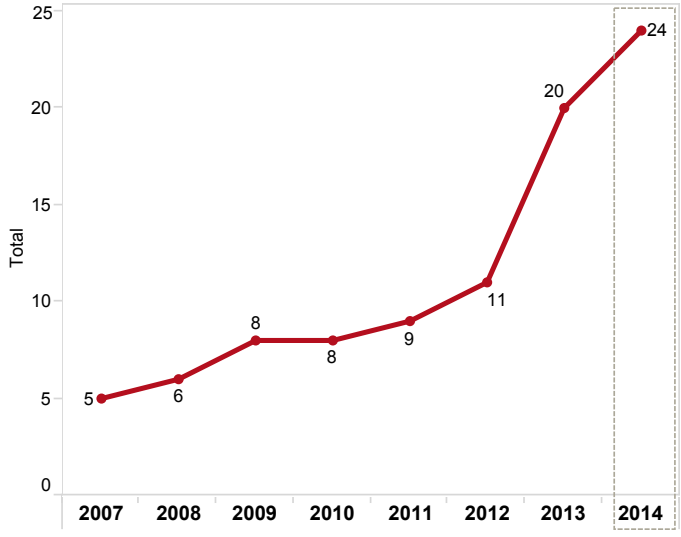
For more information on the Strategic Objectives refer to footnote. Excludes CPP, a secretariat initiative.

Active Projects (2007-2014)**



**PMTCT I (Acceleration), PMTCT II (Expansion) and PMTCT III (Nutrition) with UNICEF, is counted as one project from 2009-2011. Includes MPP, a Special Project from 2011-2013. Excludes CPP, a Secretariat Initiative from 2012-2013. Includes Cepheid. In 2014, includes EB19 Special Session (May 2014) approved six grants.

Active Grantees (2007-2014)***



***Includes only lead grantees and not consortiums/sub-recipients. There could be more than one lead grantee per project (e.g. tri-partite agreement.) Includes MPP Foundation for MPP, a Special Project; Excludes PSCM of the CPP project, a UNITAID Secretariat Initiative. WHO Departments (EMP, GTB, GLI) counted as one.In 2014, includes EB19 Special Session (May 2014) approved six grants. Includes Cepheid (buy-down agreement for GeneXpert).

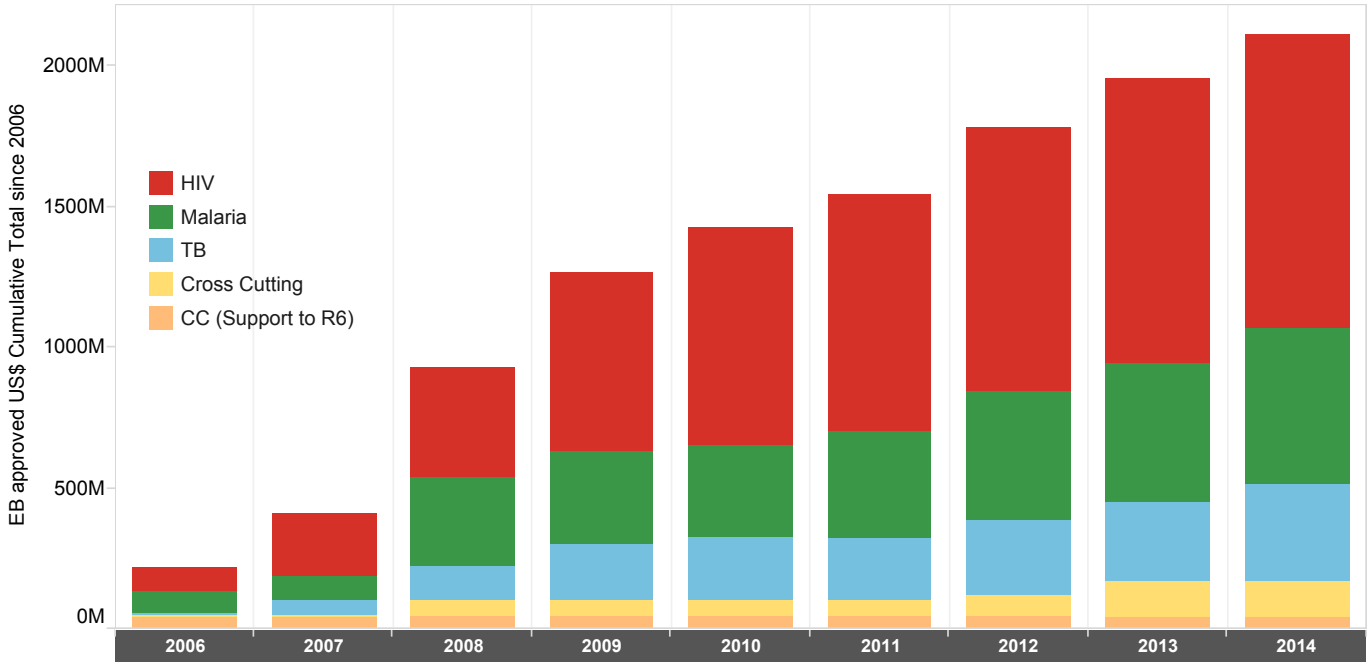
Data as of 31 December 2013. See below list of **Strategic Objectives.** (Updated 16 June 2014)

US$ value disbursed in 2013 (Active Grants in 2013)

Disease	Project Type	SO	Project	Grantees	Project Duration	2013
HIV	Standard Project	SO1	**HIV CD4 and VL Diagnostics**	MSF	25/12/2012 – 31/12/2015	9,860,000
			Point-of-Care Phase 1	CHAI	30/11/2012 – 30/06/2014	1,054,740
			OPP-ERA	FEI	12/02/2013 – 30/06/2014	1,040,000
		SO2	**Paediatric ARV**	CHAI	01/11/2006 – 31/12/2014	19,016,000
			Paediatric ARV formulations	DNDi	31/05/2013 – 31/05/2016	4,945,000
		SO3	**ESTHERAID**	ESTHER	03/07/2009 – 31/12/2014	4,173,915
			Preventing Patent Barriers	Lawyers Collective	01/08/2013 – 30/07/2016	83,711
	Special Project	SO3	**Medicines Patent Pool**	MPP Foundation	10/09/2011 – 31/12/2015	3,467,498
	Secretariat Initiative	SO3	**CPP**	PFSCM	01/08/2012 – 31/12/2013	63,144
Malaria	Standard Project	SO1	**Private Sector Market for RDTs**	PSI	23/04/2013 – 29/02/2016	7,162,444
			Quality Assurance of RDTs	FIND	01/01/2013 – 31/12/2017	2,157,705
		SO2	**Improving Severe Malaria Outcomes**	MMV	05/06/2013 – 05/06/2016	3,420,000
		SO4	**AMFm**	GFATM	02/11/2009 – 31/12/2013	30,970,824
			A2S2	i+solutions	06/07/2009 – 31/12/2013	-1,200,000
TB	Standard Project	SO1	**Expand MDR TB Diagnostics**	STOP TB/GDF, FIND, WHO-GLI	10/12/2008 – 31/12/2014	16,417,857
			TB Xpert	WHO-GTB	28/01/2013 – 31/12/2015	13,397,309
		SO2	**STEP Paediatric TB**	TB Alliance	22/07/2013 – 22/07/2016	3,650,724
			Paediatric TB	STOP TB/GDF	12/01/2007 – 31/12/2013	1,517,015
		SO5	**MDR TB Scale Up**	STOP TB/GDF	25/07/2007 – 31/12/2013	2,320,140
			MDR TB Strategic Rotating Stockpile	STOP TB/GDF	20/11/2008 – 30/06/2015	2,295,805
	-	SO1	**Cepheid (Buy-down)**	Cepheid	01/01/2013 – 31/12/2015	3,200,000
Cross Cutting	Standard Project	SO1	**Prequalification of Diagnostics**	WHO-EMP	23/03/2009 – 31/12/2016	2,363,140
		SO3, SO4, SO5	**Prequalification of Medicines**	WHO-EMP	14/12/2006 – 31/12/2016	14,398,610

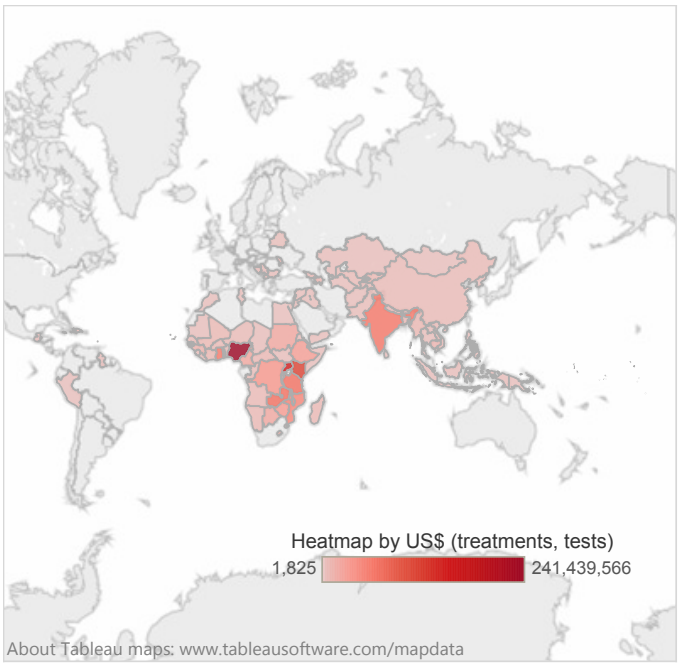
As of 31 December 2013. Prequalification of Medicines is SO3,4 and 5, and all values are listed under SO3 for this report. Includes CEPHEID (buy-down), MPP (Special Project) and CPP (Secretariat Initiative).

Cumulative value since 2006: US$ value of Executive Board approved amounts

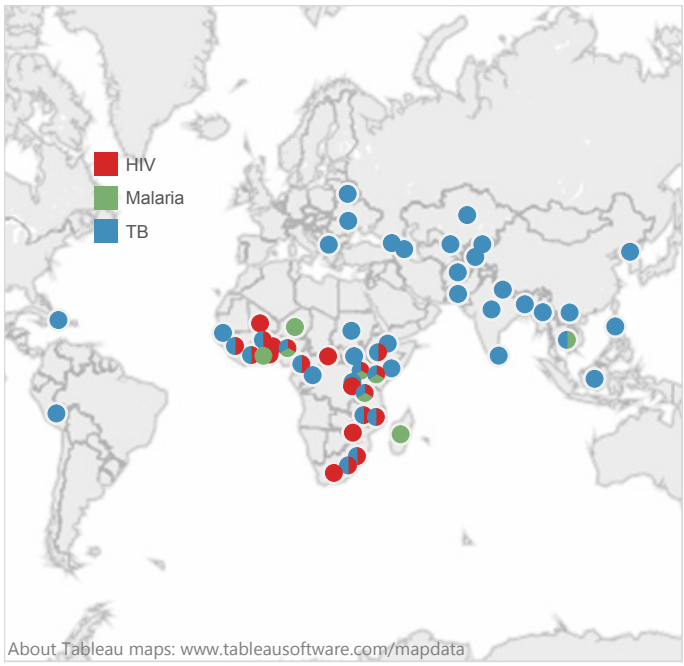


Overview of Countries supported

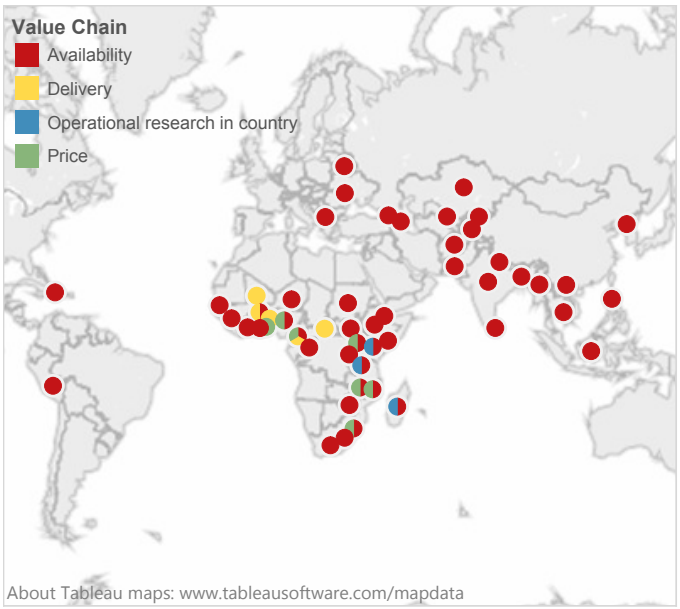
By US$ value of treatments/tests delivered (2006-2013)



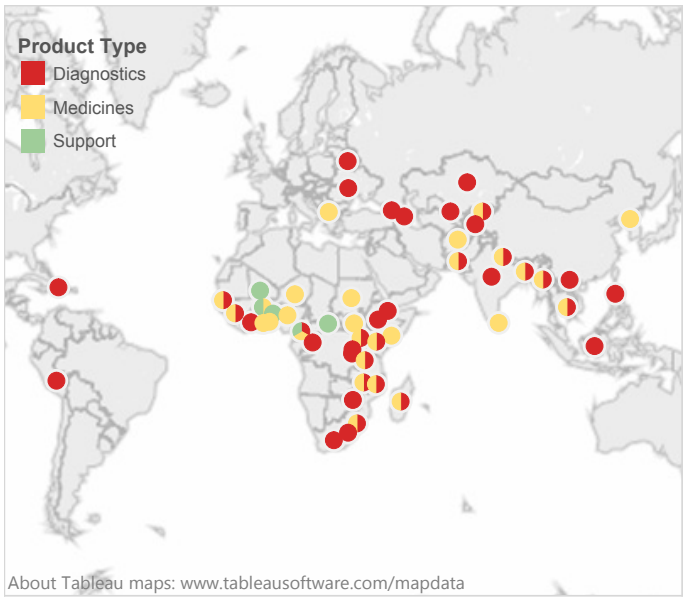
By disease (number of treatments, tests delivered in 2013)



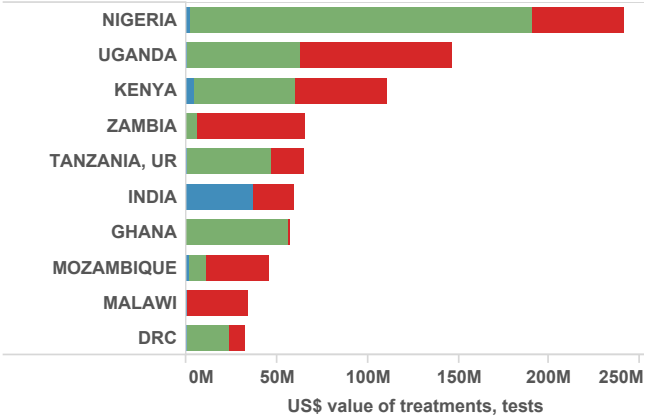
By value chain (number of treatments, tests delivered in 2013)



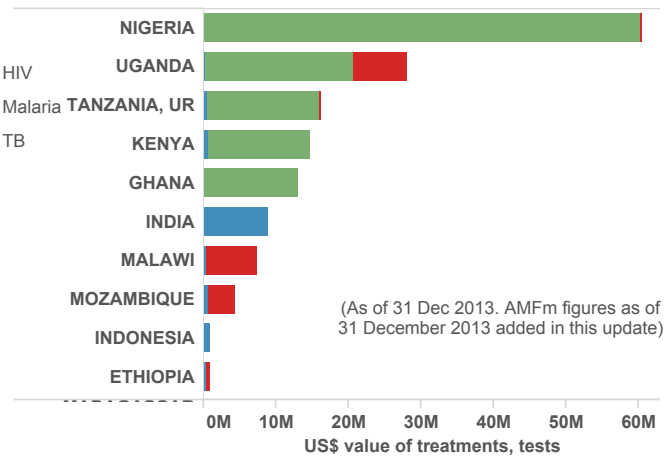
By product type (number of treatments, tests delivered in 2013)



2007-2013: Top 10 by cumulative US$ value of tests, treatments delivered



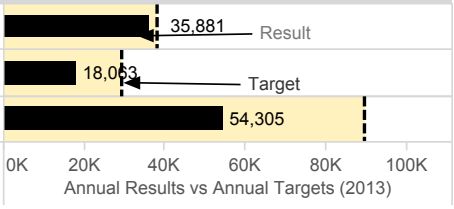
2013: Top 10 by US$ value of tests, treatments delivered



Overview of Key 2013 Annual Results versus Annual Targets

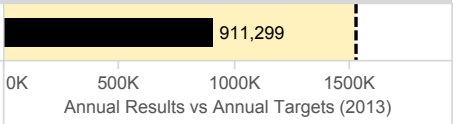
SO 1 - Project Indicators

SO	Project	Grantee	Duration	Description
SO1	**Expand TB Dx**	STOP TB/GDF	2008-2014	# of MDR-TB cases detected
	HIV CD4 and VL Diagnostics	MSF	2012-2015	# of PoC CD4 tests done
				# of Viral Load tests done



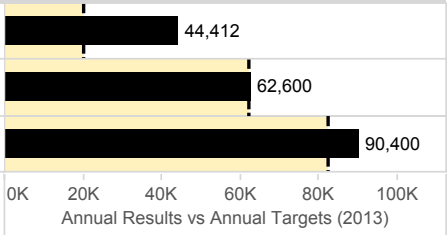
SO	Project	Grantee	Duration	Description
SO1	**TB Xpert**	WHO	2013-2015	# of incident TB patients detected
				# of Xpert MTB/RIF tests performed*

SO	Project	Grantee	Duration	Description
SO1	**Point-of-Care**	CHAI, UNICEF	2012-2014	# of tests performed on POC in focus countries



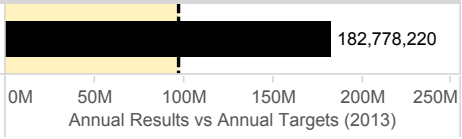
SO 2, 3 - Project Indicators

SO	Project	Grantee	Duration	Description
SO2	**Paediatric ARV**	CHAI	2006-2014	# of new children on HIV treatments
	Paediatric TB	STOP-TB/GDF	2007-2013	# of paediatric TB (curative) patient treatments delivered
				# of paediatric TB (prophylaxis) patient treatments delivered



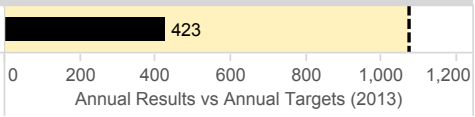
SO 4 Project Indicators

SO	Project	Grantee	Duration	Description
SO4	**AFMm**	GFATM	2009-2013	# of co-paid ACT treatments delivered



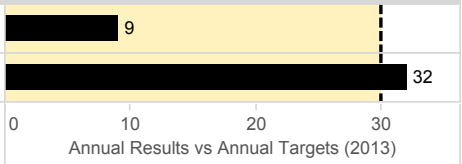
SO5 Project Indicators

SO	Project	Grantee	Duration	Description
SO5	**MDR TB Scale Up**	STOP-TB/GDF	2007-2013	# of MDR-TB patient treatments delivered**



Cross-Cutting: SO1, 3, 4, 5 - Project Indicators

SO	Project	Grantee	Duration	Description
SO1	**PQ Diagnostics**	WHO	2009-2016	# of priority products prequalified
SO3,4,5	**PQ Medicines**	WHO	2006-2016	# of finished pharmaceutical products (FPPs) prequalified***



Figures appearing on graphs are results. Figures as of 31 December 2013. Provisional analysis.

More detailed information on results and project status updates can be found in the indvidual project pages.
*For the Xpert project, below target for some indicators due to global shortage of cartridges that delayed the initial implementation in 2013.
**For the MDR-TB Scale Up project, the cumulative total delivered by 2013 was 16,309 against a cumulative target of 16,779, therefore, 98% target achieved.
***2013 target value for PQ Medicines are for FPPs prequalifed, not prioirty products prequalifed.

EB20/2014 OPERATIONS PROJECT UPDATE

Update: Grant Performance

UNITAID has revised its scoring of grant performance to provide rigorous guidance for how grants are performing. This change has been made to standardize grant performance assessment and ensure that grants are assessed fairly and within the boundaries of the contractual agreements that UNITAID has signed with grantees. Grant assessment criteria are:

Review Criteria

Criteria	Description
1	Submission of semi-annual and annual reports according to contractual agreements;
2	Quality of annual report submitted (i.e. full narrative explanation of indicators and changes made to the project for the reporting period);
3	Quality of data provided in semi-annual and annual reports (no gaps, inconsistencies with past data or errors in the reporting on standard indicators);
4	Responsiveness to questions raised by the Secretariat (i.e. Portfolio teams, M&E, procurement and Finance);
5	Grant targets and milestones met on schedule;
6	Proactive risk assessment and management during grant implementation; and
7	Responsiveness to the findings and recommendation of assessments done within the reporting period (i.e. fiduciary assessments, oversight, audits, external evaluations);
8	Financial performance (led by the Finance team).

These eight performance criteria are not new to grantees. They are part of the performance framework that UNITAID negotiates with grantees during the grant agreement signature phase of a project. Grants are rated on a five point scale according to the icon descriptions provided below. A separate financial performance score is provided by the Finance team according to their financial management criteria (previously described to the FAC). An average of the score across all criteria is calculated for each grant. Colour codes are assigned to each grant according to the final score for each grant. The results are shown across all grants with specific management actions taken and/or general remarks about the progress of each grant.

We will continue to track the performance of the grants under each portfolio throughout their implementation period. Per cent of grants maintaining or improving performance ratings will be a management KPI for UNITAID as we work to provide optimal results for each grant in the UNITAID portfolio.

Icon Descriptions

Description	
Excellent; sophisticated, innovative and exceeds minimum requirements	
Above average; exceeds minimum requirements/expectations	
Average; meets the minimum requirements/expectations	
Below average; does not meet all requirements	
Poor; fails to meet the minimum requirements/expectations	

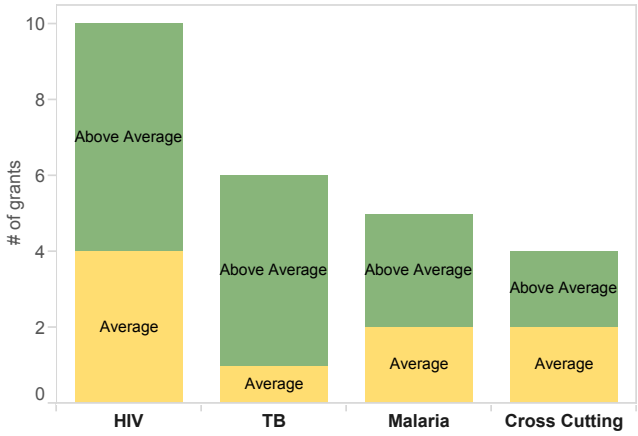
EB20/2014 OPERATIONS PROJECT UPDATE

Grant Performance (2013)

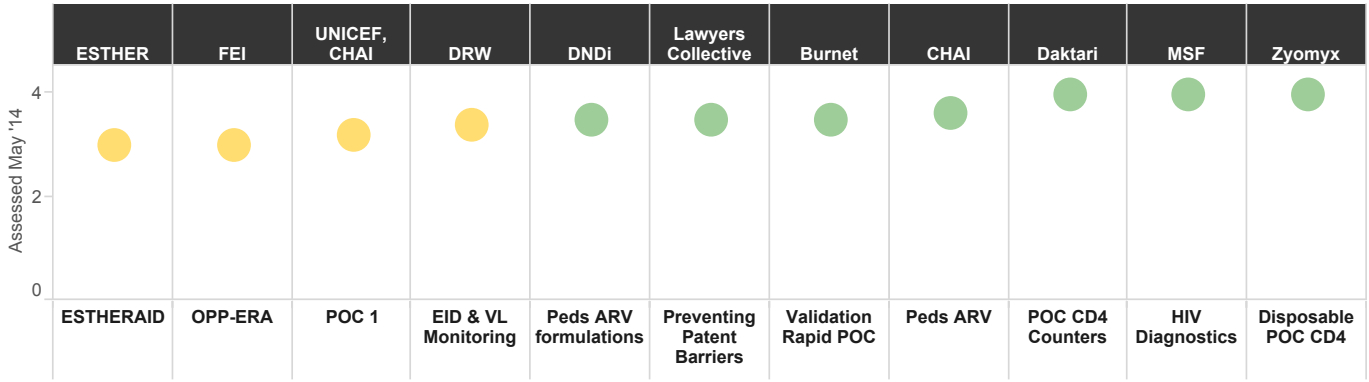
Disease	Project	Grantees	Management Action/General Remarks	Rating
HIV	**Peds ARV**	CHAI	Project in the final phase; project will meet all targets; overall good collaboration with the grantee.	
	Peds ARV formulations	DNDi	Grant Agreement signed in May 2013; potential delays related to drug development; overall good collaboration with the grantee.	
	ESTHERAID	ESTHER	Project in the final phase; not meeting all targets; good collaboration with the grantee.	
	HIV Diagnostics	MSF	Some delays in 2013 were due to delays in the signing of MoUs with countries; the implementations has since been on track.	
	OPP-ERA	FEI	Some delays in 2013 linked to limited number of eligible suppliers for all components of the open platforms; FEI did not have a robust mitigation strategy in place for this risk.	
	POC 1	UNICEF, CHAI	Some delays in 2013 were due to the late signing of MoUs with countries; the implementation has since been on track.	
	Disposable POC CD4	Zyomyx	Grantee is scheduled to report quarterly. The first quarterly report was submitted two weeks early; very well organized and complete. They are off to a good start.	
	POC CD4 Counters	Daktari	Grantee's first semi-annual report is due 30 July 2014.	
	Preventing Patent Barriers	Lawyers Collective	Grant agreement signed in May 2013; good collaboration with the grantee.	
	Validation Rapid POC	Burnet	Grantee's first semi-annual report is due 30 July 2014.	
	EID & VL Monitoring	DRW	Grantee's first semi-annual report is due 30 July 2014. The logframe is still outstanding as a first deliverable.	
Malaria	**A2S2**	i+solutions	The contribution that the A2S2 project made to the global artemisinin supply was limited. The project did achieve significant expansion and diversification of Artemisia cultivation and artemisinin extraction to Africa.	
	AMFm	GFATM	AMFm significantly increased the availability and affordability of quality assured ACTs in most of the AMFm phase I countries. Obtaining timely and reliable data was challenging in 2013.	
	Improving Severe Malaria	MMV	Composite score reflects the 2013 period. (In 2014, implementation is off track; timely resolution of price negotiations with Guilin Pharma for injectable artesunate (jointly with GFATM & MMV) is a high priority.	
	Priv Sector-RDTs	PSI	Project implementation is on track. Project related activities need to remain on track to avoid potential implementation delays and unanticipated costs.	
	QA of RDTs	FIND	Project implementation is on track. Project related activities need to remain on track to avoid potential implementation delays and unanticipated costs.	
TB	**Expand MDR TB Dx**	STOP TB/GDF, WHO-GLI, FIND	Project is on track and is expected to reach at least 90% of targets by end of project in 2014. Extension request received.	
	MDR TB Scale Up	STOP TB/GDF	Project was under transition in 2013 and only 5 of 16 countries reported in 2013. The project cumulatively placed over 16,000 cases of MDR-TB on treatment, and thereby achieving 98% of its project target.	
	MDR TB SRS	STOP TB/GDF	The UNITAID EB in December 2013 approved an expansion of the Stockpile from the current size of 5,800 patient treatments to 12,000 patient treatments.	
	Paediatric TB	STOP TB/GDF	Project was under transition in 2013, with only 12 of 58 countries reporting. Exceeded targets with delivery of curative and preventive treatments.	
	STEP Paediatric TB	TB Alliance	Project is making excellent progress on all outputs. Two manufacturers have been engaged to develop required Paediatric formulations.	
	TB Xpert	WHO-GTB	The Project was launched in all 21 countries. Certain supply chain issues led to delays in 2013 and have been resolved by end of 2013.	
Cross Cutting, Special Proj, Sec' Initiative	**PQ Meds**	WHO-EMP	Improvements in all aspects except timely reporting. Reforms to PQ management & performance oversight expected to lead to improvements in all areas under the new project (2014-2016).	
	PQ Dx	WHO-EMP	While the project has continued to improve, it did not meet all of its targets. 2013 reporting was considerably delayed. Reforms to PQ mgt & performance oversight expected to lead to improvements in all areas under the new project (2014-2016).	
	MPP	MPP Foundation	The project is on track and performing well with regards to its in-licensing targets, having secured license agreements for 40% of its priority ARVs (target = 50% for 2013).	
	CPP	PFSCM	Project closed in December 2013; met all targets; good collaboration with the grantee.	

Grant Performance Update by Portfolio

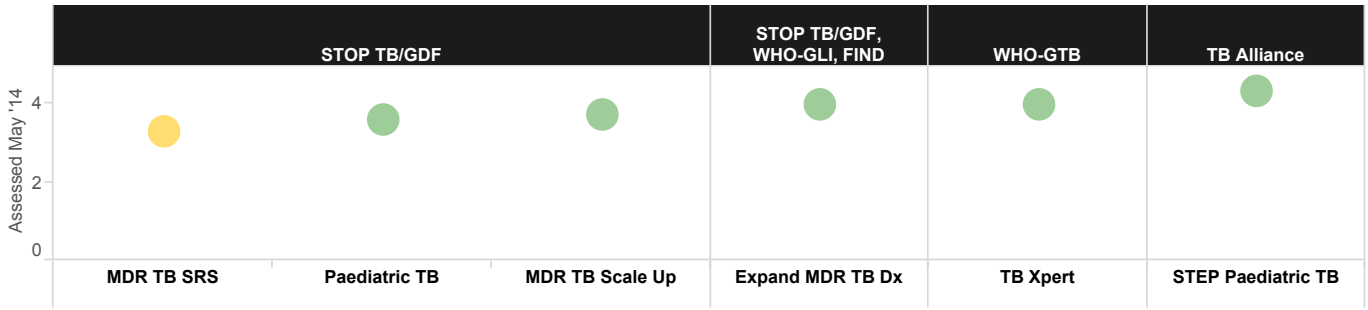
Description	
Excellent; sophisticated, innovative and exceeds minimum requirements	
Above average; exceeds minimum requirements/expectations	
Average; meets the minimum requirements/expectations	
Below average; does not meet all requirements	
Poor; fails to meet the minimum requirements/expectations	



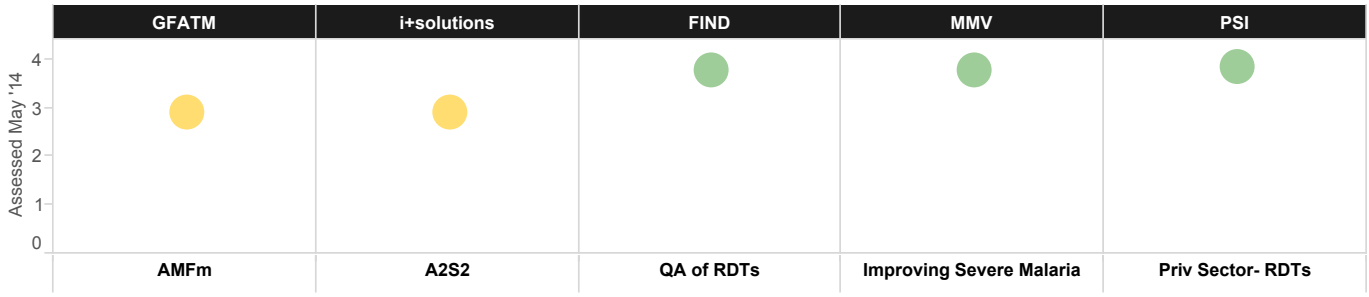
HIV Portfolio



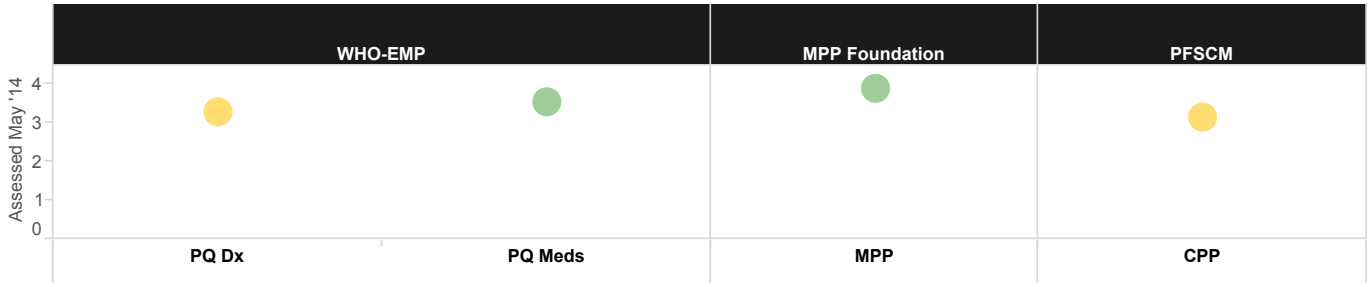
Tuberculosis Portfolio



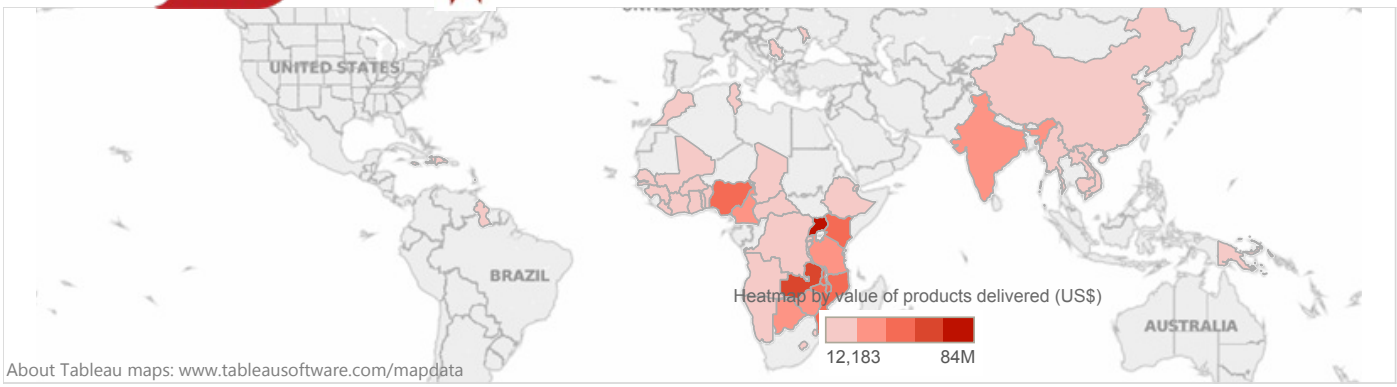
Malaria Portfolio



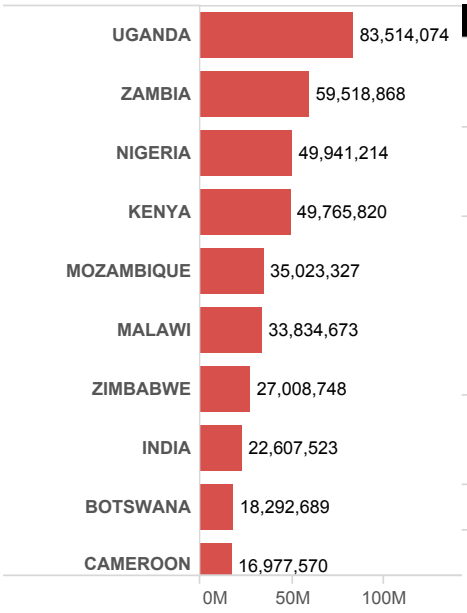
Cross-Cutting, Special Project & Secretariat Initiatives



HIV/AIDS Portfolio Profile



Top 10 countries by financial values[1] (US$) 2007-2013



Grantees

Results[2] by project (Includes all project countries, 2007-2013*)

Project	Duration	Description	Results
Paediatric ARV (CHAI)	01/11/2006 - 31/12/2014	# of HIV tests delivered for early infant diagnosis	2,000,564
		# of new children on HIV treatments	467,319
Second line ARV (CHAI)	08/03/2007 - 31/12/2012	# of patients on first-line ARV treatment	264,507
		# of patients on second-line ARV treatment	~10,000 patients per year
HIV CD4 and VL Diagnostics (MSF)	25/12/2012 - 31/12/2015	# of PoC CD4 tests done	18,063
		# of Viral Load tests done	54,305
		# of patients initiated on ART after 1 month PoC CD4 testing	618
		# of enrolled ART patients to a 2L regimen by VL testing	544
ESTHERAID (ESTHER)	03/07/2009 - 31/12/2014	# of sites with patient monitoring tool since 2009	37
		# of sites with stock management tool since 2009	44
Point-of-Care (CHAI, UNICEF)	30/11/2012 - 30/06/2014	# of tests performed on POC in focus countries	911,299
PMTCT (UNICEF)	31/07/2009 - 31/12/2011	# of cotrim provided to HIV positive women	197,090
		# of HIV tests delivered for early infant diagnosis	62,688
		# of ARV treatments delivered to prevent mother to child transmission	811,971
		# of CD4 tests delivered for HIV positive pregnant women	875,600
		# of HIV positive pregnant women on ART/HAART	64,877
		# of HIV tests delivered for pregnant women	8,011,678
		# of ready-to-use therapeutic food and cotrim delivered for children	201,991
Support to Global Fund Round 6 (GFATM)	21/12/2007 - 31/12/2011	# of new children on HIV treatments	32,810
		# of patients on second-line ARV treatment	8,615
Prequal Medicines (WHO)	14/12/2006 - 31/12/2016	# of UNITAID priority medicines prequalified (HIV)	53
Prequalification of Diagnostics (WHO)	23/03/2009 - 31/12/2016	# of UNITAID prioritydiagnostics prequalified (HIV)	23
CPP (PFSCM)	01/08/2012 - 31/12/2013	Monitored stock-outs of ARVs in country level	web tool in use
OPP-ERA (FEI)	12/02/2013 - 30/06/2014	# of VLT tests performed by target countries	na
Ped ARV formulations (DNDi)	31/05/2013 - 31/05/2016	Devt of better adapted FDC ARVs for children	na
Preventing Patent Barriers (Lawyers Collective)	01/08/2013 - 30/07/2016	Filing of patent oppositions	na
		Patent landscape produced	
POC CD4 Counters (Daktari)	06/12/2013 - 06/12/2016	Regulatory and operational studies	na
Manufacture Rapid POC CD4 (Burnet)	20/12/2013 - 20/12/2016	Field evaluations of VISITECT POC CD4 tests	na
Novel Disposable POC CD4 (Zyomyx)	23/12/2013 - 23/12/2016	Uptake of the novel, disposable POC CD4 Zyomyx tests	na
EID & VL Monitoring (DRW)	24/01/2014 - 31/12/2016	SAMBA in market implementation phase	na

Data as of 31 December 2013.
Visit http://www.unitaid.eu/en/what/hiv
[1]Value (US$) of products provided to countries.
[2]Estimates of patients treated (new and existing) are 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).
*Results data not yet available for some projects that started in 2013.

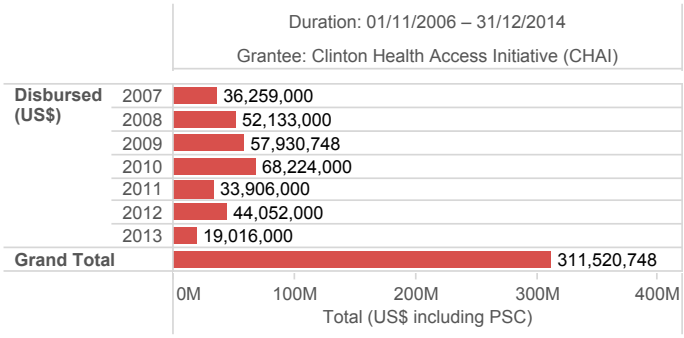
EB20/2014 OPERATIONS PROJECT UPDATE

Paediatric ARV Program (2007-2014)

2 Affordable, adapted paediatric medicines

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. The project is also increasing 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 of 31 December 2013.

Management Action/General Remarks	Rating Description	Rating
Project in the final phase; project will meet all targets; overall good collaboration with the grantee.	Above average; exceeds minimum requirements/expectations.	

Project Activities	2008	2007	2011	2009	2012	2010	2013	Total
Estimated number of new children on HIV treatments	55,995	134,677	65,916	60,014	32,727	73,578	44,412	467,319
Number of HIV tests delivered for early infant diagnosis	168,123	75,115	422,096	302,578	401,959	372,810	257,883	2,000,564
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	65,154,676
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	132,279,175
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

Breakdown by year.

Update on Peds ARVs

Status	•The extension of the project for one more year approved by UNITAID Board last December (EB19, Resolution 4) to transition countries in need of funding support.
Challenges	•Need to monitor funding transition so that it is achieved by end 2014. Countries are struggling to secure GFATM funds for paediatric ARVs.
Next Steps	• Continue the engagement with the Paediatric ARV Procurement Working Group. •As compared to ARVs which require larger funding, EID could be an area to support with limited budget but high visibility. •Maintain UNITAID's leadership role and visibility into the Pediatric HIV market despite not providing commodity funding. •Support development of newer more efficient products, investment in technology to reduce treatment costs. •Support the uptake of 2013 WHO HIV Treatment guidelines by low-income countries.

Provisional figures as of 31 December 2013. 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. Active countries in 2013 - Malawi, Mozambique, Swaziland, Uganda and Zimbabwe. For more information, visit www.unitaid.org/impact

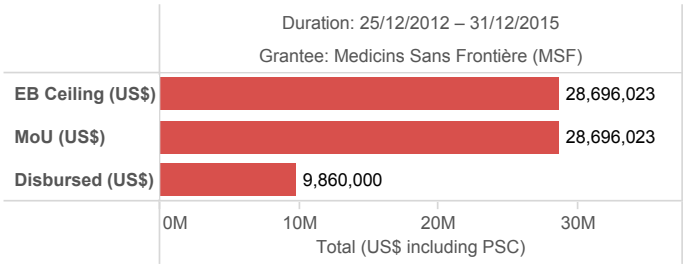
EB20/2014 OPERATIONS PROJECT UPDATE

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

1 Simple, point-of care (POC) diagnostics

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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Some delays in 2013 were due to delays in the signing of MoUs with countries; the implementations has since been on track.	Above average; exceeds minimum requirements/expectations.	

Project Activities	2013
Number of PoC CD4 tests done	18,063
Number of Viral Load tests done	54,305
Number of patients initiated on ART after one month PoC CD4 testing	618
Number of enrolled ART patients changed per protocol to a second line regimen by Viral Load testing	544

Update on HIV Diagnostics

Status	•Overall grant programmatic and financial performance on track.
Challenges	•Delays in clinical use of new devices might occur because lab and field evaluations depend on external partner activities.
Next Steps	•MSF's work with the civil society on advocacy was added to the scope of the project for 2014 and 2015; •Revised implementation plan for 2014 and 2015 includes new devices and new research questions that can help accelerate POC roll out in clinical settings. •An important focus will be working with MSF on transition planning in those project countries where MSF operations will be closing at the end of the project. •The inclusion of the new project country – The Democratic Republic of Congo – has the potential for expanding the project impact to the Francophone Africa and provide insight to the VL monitoring perspectives, in a very specific context.

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.

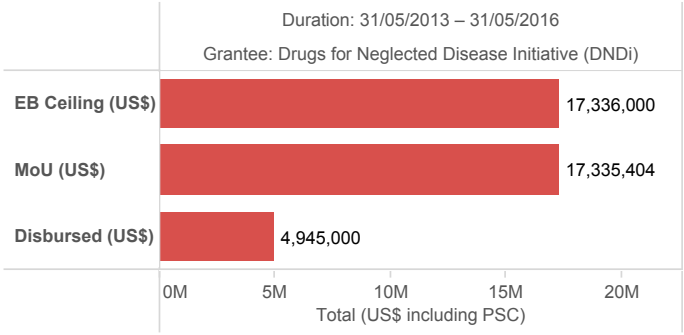
Provisional figures as of 31 December 2013. Country data disaggregated by year.
For more information, visit www.unitaid.org/impact

EB20/2014 OPERATIONS 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 DNDi's partnership with Cipla.



Financial data as of 31 December 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Grant Agreement signed in May 2013; potential delays related to drug development; overall good collaboration with the grantee.	Above average; exceeds minimum requirements/expectations.	

Project Activities	
Support to devt of better adapted FDC ARVs for children	Initial dosage form of lopinavir/ritonavir granules in capsule, to be used during clinical drug development, was developed by Cipla in June 2013. Phase I comparative bioavailability study in adults conducted.

Update on Peds Formulations

Status	•DNDi continues its activities with the goal to increase access to optimal first line therapy for children under three years old. •Project is delayed due to sub-optimal bio-availability studies of 4-in-1 LPV/r based FDCs.
Challenges	•Development of LPV/r granules plus NRTIs granules into 4-in-1 ARV continues to be a challenge. •The poor results of the clinical trial of an initial dosage form of lopinavir/ritonavir granules in capsule developed by Cipla.
Next Steps	•DNDi and Cipla team have evaluated new formulation options for the of LPV/r granules. These studies started in December 2013 and are ongoing. •DNDi continues to prepare for implementation studies which will provide early access to LPV/r heat stable pellets together with available dual NRTI dispersible tablet. This study is planned to start in several African countries in 2014.

As of 31 December 2013.
For more information, visit www.unitaid.org/impact

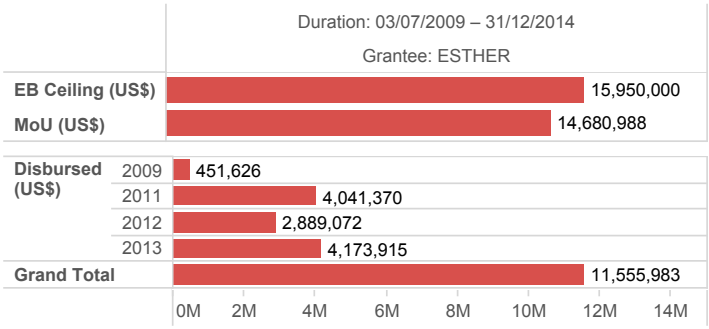
EB20/2014 OPERATIONS PROJECT UPDATE

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

3 Treatment of HIV/AIDS and co-infections

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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Grant Agreement signed in May 2013; potential delays related to drug development; overall good collaboration with the grantee.	Above average; exceeds minimum requirements/expectations.	

Project Activities	2011	2012	2013
Number of people trained on HIV patient care*		1,388	1,215
Number of people trained on procurement & supply management*		87	345
Number of people trained on data mgt system*		206	369
Number of sites with patient monitoring tool since 2009*			37
Number of sites with stock management tool since 2009*			44
Number of new and existing children receiving ARVs	3,418	4,339	4,612
Number of new and existing patients receiving 2nd line ARVs	4,820	5,143	5,333
Number of tests performed	48,475	57,672	71,856

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	•The Project was delayed and is entering its last phase. Activities will end in September 2014.
Challenges	•The stock-outs identified by the project were due to investigations or audits by GFATM. (i.e. Burkina Faso: change of PR and recruitment of a trust agency; Mali: suspension for two years and change of PR (UNDP); Cameroon: delay in disbursement for RD10). •Two of the five countries experienced political instability (coups d'état: Mali in 2012 and Central African Republic in 2013).
Next Steps	•75% of the project activities (and of the initial budget) will be implemented by end of 2014 . External End of Project Evaluation planned in 2014.

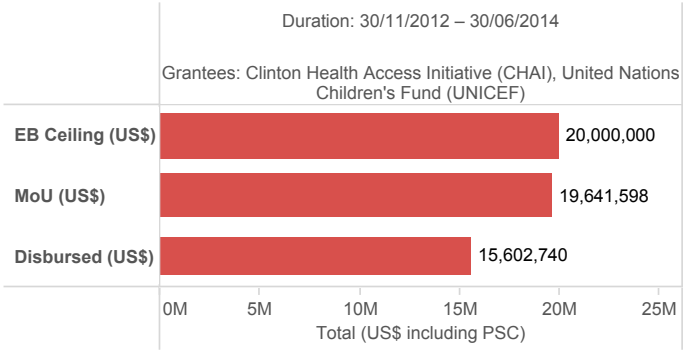
Provisional figures as of 31 December 2013.
For more information, visit www.unitaid.org/impact

EB20/2014 OPERATIONS PROJECT UPDATE

Accelerating access to Innovative POC HIV diagnostics (Phase 1) (2013-2016)

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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Some delays in 2013 were due to the late signing of MoUs with countries; the implementation has since been on track.	Average; meets the minimum requirements/expectations.	

Project Activities	2013
Volume of Pima products procured (Pima devices)	115
Volume of Pima products procured (Pima tests)	124,700
Number of tests performed on POC in focus countries	911,299
US$ value of Pima products procured (Pima Devices)	671,000
US$ value of Pima products procured (Pima Tests)	741,965

Update on POC 1

Status

- Overall grant programmatic and financial performance on track. Ready to proceed to Phase 2a.
- The project has finalized its procurement strategy and the quality assurance policy, with support of an independent procurement reference group.
- The project is under no-cost extension until 30 June 2014. The phase 2a is expected to be signed by June.

Challenges

- The VL pipeline remains uncertain as some products become delayed due to sensitivity issues.
- Potential delay in scale up of POC diagnostics in some countries due to limited budgets for HIV response.
- Regulatory environment and processes for IVDs and in particular for POC diagnostics remain unclear across majority of project countries.

Next Steps

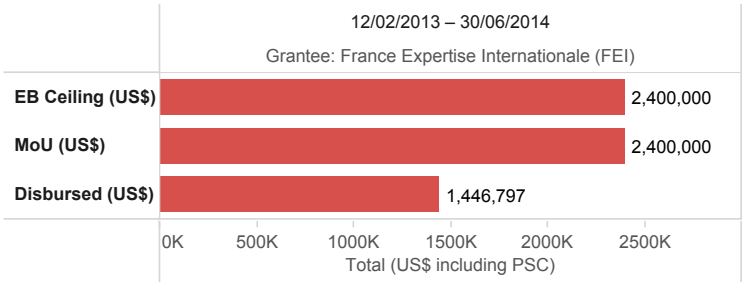
- Country Operational Plans for Phase 2a are being aligned with national Global Fund concept note development process.
- It will also provide essential information on the POC market, especially the pricing strategies of different manufacturers.
- Several grant development meetings between UNITAID and grantees result in a robust project plan (April 2014).
- The results of the first ever RFP for POC diagnostics routine use (due May) will inform the countries in their product selection efforts.
- The signature of the Phase 2a grant agreement in June 2014.

Provisional figures as of 31 December 2013.
For more information, visit www.unitaid.org/impact

EB20/2014 OPERATIONS PROJECT UPDATE

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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Some delays in 2013 linked to limited number of eligible suppliers for all components of the open platforms; FEI did not have a robust mitigation strategy in place for this risk.	Average; meets the minimum requirements/expectations.	

Project Activities	2013
Open Polyvalent Platforms for VL testing operational in 4 target countries	Project officially launched during a ceremony in Cote D'Ivoire (Sept 2013). Preparatory work carried out including 1) published call for tender (Sept 2013); 2) country project agreements signed (July-Sept 2013) with 4 target countries 3) market analysis finalized with an overview of eligible manufacturers for all components.

Update on OPP-ERA

Status	•Project delayed due to operational challenges in identifying quality assured reagents for viral load testing on polyvalent platforms (OPP) in project countries.
Challenges	•The project will not be able to generate sufficient implementation experience before the end of the currently approved Phase 1 (June 2014). •The pool of quality assured manufacturers for amplification reagents remains extremely limited.
Next Steps	•A no-cost extension is currently under negotiation to allow sufficient time for field testing in 2014 and allow for an evidenced-based phase 2 proposal submission for the December 2014 Board approval. •Based on the results of the final selection of OPPs, the project will start field testing as late as June 2014. •OPP-ERA project should use the extensive experience of MSF and CHAI/UNICEF projects to prepare countries for roll out of VL testing. •LSHTM work (funded by UNITAID) on regulatory environment across African countries to be used when preparing business case for OPPs. •OPP-ERA to consider encouraging manufacturers of different OPP components to submit dossiers to GFATM/UNITAID Expert Review Panel on Diagnostics. •A priority area for expanding the use of OPPs will be Hepatitis C.

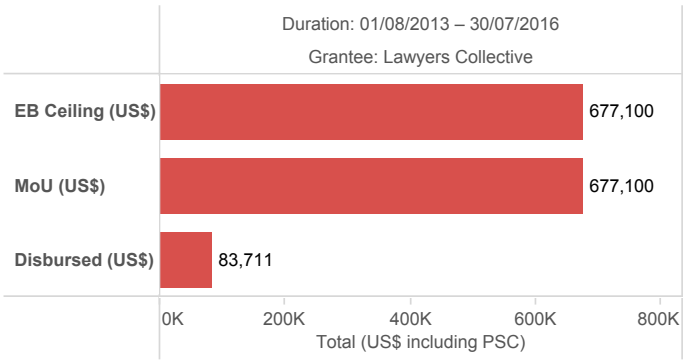
As of 31 December 2013.
For more information, visit www.unitaid.org/impact

EB20/2014 OPERATIONS PROJECT UPDATE

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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Grant agreement signed in May 2013; good collaboration with the grantee.	Above average; exceeds minimum requirements/expectations.	

Project Activities	
Filing of Patent Oppositions	12 priority medicines of public health relevance identified based on internal research,stakeholder feedback.
Patent landscape produced	Patent applications of the identified priority medicines are being monitored for potential patent oppposition applications.

Update on Lawyers Collective

Status	•The project is on track to challenge patents and encourage developing countries to curb evergreening through use of TRIPS flexibilities.
Challenges	•Lack of response from generic companies and government officials in the identification of the priority list of medicines.
Next Steps	•12 priority medicines have patents pending in India. Work is ongoing to identify the patent applications and what can be challenged. •Dissemination of an internal patent landscape; creation of a patent database.

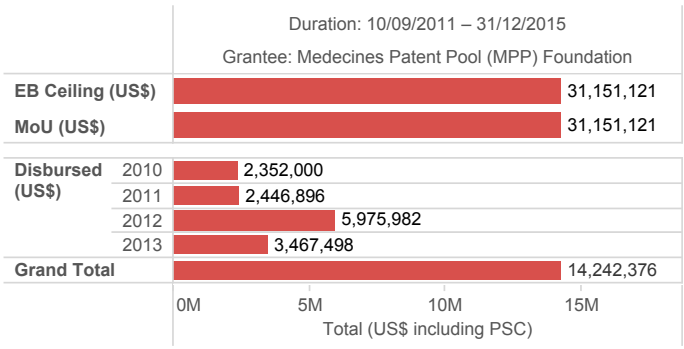
As of 31 December 2013.
For more information, visit www.unitaid.org/impact

EB20/2014 OPERATIONS PROJECT UPDATE

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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
The project is on track and performing well with regards to its in-licensing targets, having secured license agreements for 40% of its priority ARVs (target = 50% for 2013).	Above average; exceeds minimum requirements/expectations.	

Update on MPP

Status

- License agreements secured for 40% of its priority ARVs (the target is 50% for 2013).
- The external review indicates that MPP has achieved good performance. The review also indicates a well-managed organisation, with well performing systems and operating processes.
- The MPP and ViiV Healthcare signed two licensing agreement in April to increase access to dolutegravir (DTG), a promising new antiretroviral, for both adult and paediatric care.
- The MPP has also recently signed an agreement with BMS on atazanavir (ATV), bringing it closer to its target.

Challenges

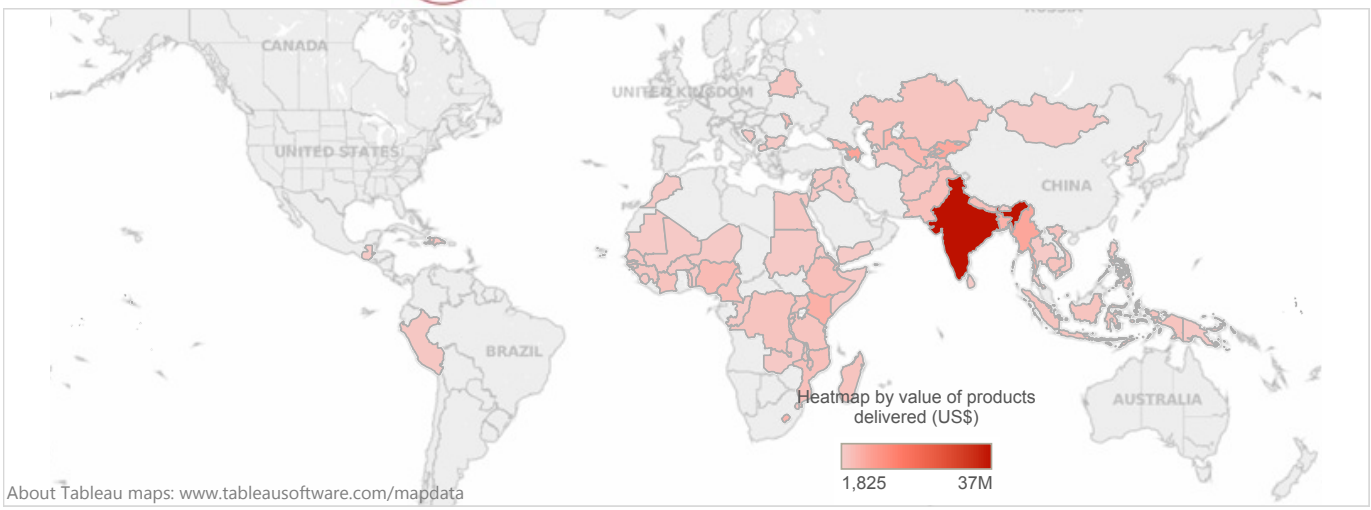
- More needs to be done on advocacy and communication as well as stakeholder engagement to raise visibility of MPP.
- MPP needs to strengthen its M&E framework including measurement of downstream results.
- There are major challenges in achieving its goals of generic competition and price reduction. The paediatric formulations goal is especially difficult, given the multiple barriers – in addition to patents - to product development and access.

Next Steps

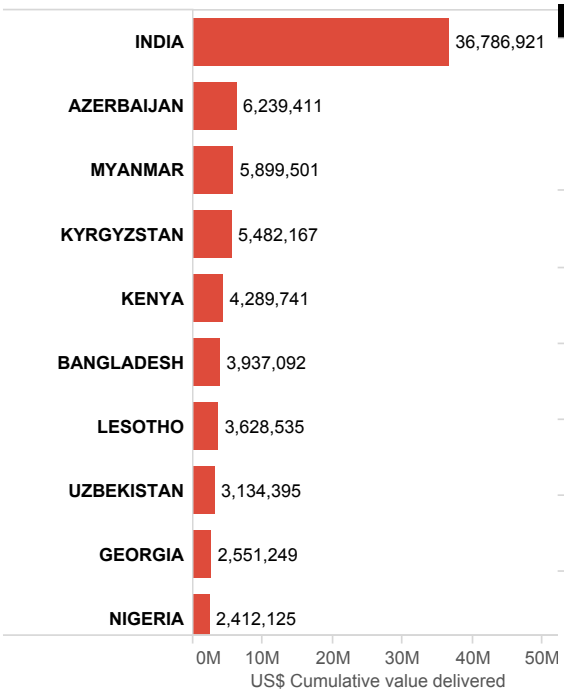
- Final Operational and Strategic Review report will be available by May 2014.
- Findings and recommendations of the report will be shared in the June Executive Board meeting.

As of 31 December 2013.
For more information, visit www.unitaid.org/impact

Tuberculosis Portfolio Profile



Top 10 countries by financial values[1] (US$) 2007-2013



Grantees

Stop TB Partnership GLOBAL DRUG FACILITY
FIND foundation for innovative new diagnostics
World Health Organization
The Global Fund To Fight AIDS, Tuberculosis and Malaria
TB ALLIANCE GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

Results[2] by project (Includes all project countries, 2007-2013*)

Project	Duration	Description	Results
Paediatric TB (STOP-TB/GDF)	12/01/2007 - 31/12/2013	# of paediatric TB (prophylaxis) patient treatments delivered	768,009
		# of paediatric TB (curative) patient treatments delivered	523,641
Expand MDR TB Diagnostics (STOP-TB, WHO, FIND)	10/12/2008 - 31/12/2014	# of MDR-TB cases detected	71,824
First Line TB (STOP-TB/GDF)	11/09/2007 - 31/12/2011	# of first-line TB treatments delivered	785,080
MDR TB Scale Up (STOP-TB/GDF)	25/07/2007 - 31/12/2013	# of MDR-TB patient treatments delivered[2]	16,309
MDR TB Strategic Rotating Stockpile (STOP-TB/GDF)	20/11/2008 - 30/06/2015	# of MDR-TB treatments available in the SRS	5,800
Support to Global Fund Round 6 (GFATM)	21/12/2007 - 31/12/2011	# of MDR-TB patient treatments delivered[2]	3,434
TB Xpert (WHO)	28/01/2013 - 31/12/2015	# of incident TB patients detected	7,647
		# of incident HIV-positive TB patients detected	992
		# of incident rifampicin-resistant TB patients detected	1,791
		# of Xpert MTB/RIF tests performed	57,018
		# of GeneXpert instrument modules procured	844
		# of Xpert MTB/RIF cartridges procured/delivered	234,760
STEP Paediatric TB (TB Alliance)	22/07/2013 - 22/07/2016	# of signed agreements/MOUs for formulation devt with manufacturers	2
		# of market studies conducted	6
Prequalification of Medicines (WHO)	14/12/2006 - 31/12/2016	Number of UNITAID priority medicines prequalified (TB)	58

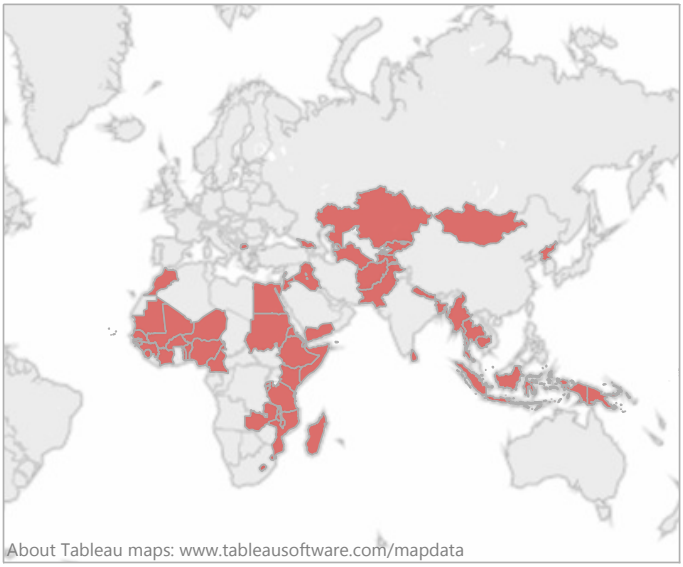
Data as of 31 December 2013.
Visit http://www.unitaid.eu/en/what/tb

[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.

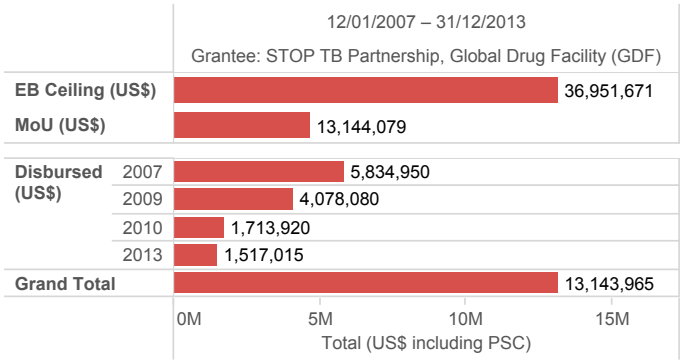
PSC/2014 - OPERATIONS PROJECT UPDATE

Paediatric TB Programme (2007-2013)



Strategic Objective 2: Affordable, adapted paediatric medicines

This project has provided 750,000 paediatric treatments to 57 countries and aims to foster the development of child-friendly formulations of TB treatments for children under-5 years of age.



Financial data as of 31 December 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Project was under transition in 2013, with only 12 of 58 countries reporting. Exceeded targets with delivery of curative and preventive treatments.	Above average; exceeds minimum requirements/expectations.	

Project Activities	2007	2008	2009	2010	2011	2012	2013	Grand Total
Paediatric TB (curative) patient treatments delivered	52,128	81,053	145,709	117,211	57,429	7,511	62,600	523,641
Paediatric TB (prophylaxis) patient treatments delivered	60,626	91,995	229,884	173,620	89,304	32,180	90,400	768,009
US$ value of TB paediatric treatments (curative, prophylactic) delivered. Cost Product Exworks.	244,980	1,048,546	2,290,403	1,501,681	1,117,228	335,809	445,169	6,983,816

Update on Paediatric TB

Status
- Project ended in December 2013 and has fully met its project objectives.

Challenges
- Due to change in WHO Guidelines, there are still no appropriately formulated products to treat children.

Next Steps
- The experiences and the lessons learned from the Paediatric TB project will be used during the phase of delivering these new products once available on the market after 2015.
- UNITAID is investing in the development of new paediatric first line TB formulations through its project with the TB Alliance from 2013 to 2015.

Pediatric TB treatment values are combined for Sudan and South Sudan. Active countries in 2013 are Tanzania, Macedonia, Nigeria, Somalia, Sudan, Sudan (South), Afghanistan, Bangladesh, Cambodia, DPR Korea, Pakistan, Sri Lanka.

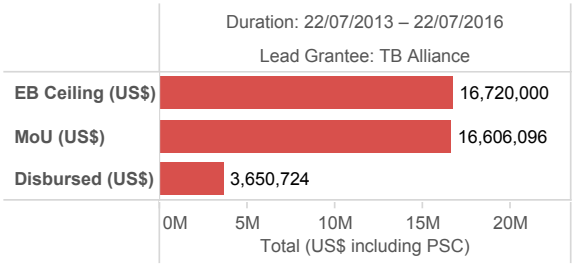
Provisional figures as of 31 December 2013. Country data disaggregated by year.

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

PSC/2014 - OPERATIONS PROJECT UPDATE

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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Project is making excellent progress on all outputs. Two manufacturers have been engaged to develop required Paediatric formulations.	Above average; exceeds minimum requirements/expectations.	

Project Activities	2013
# of market studies conducted	6
# of signed agreements/MOUs for formulation development with manufacturers	2

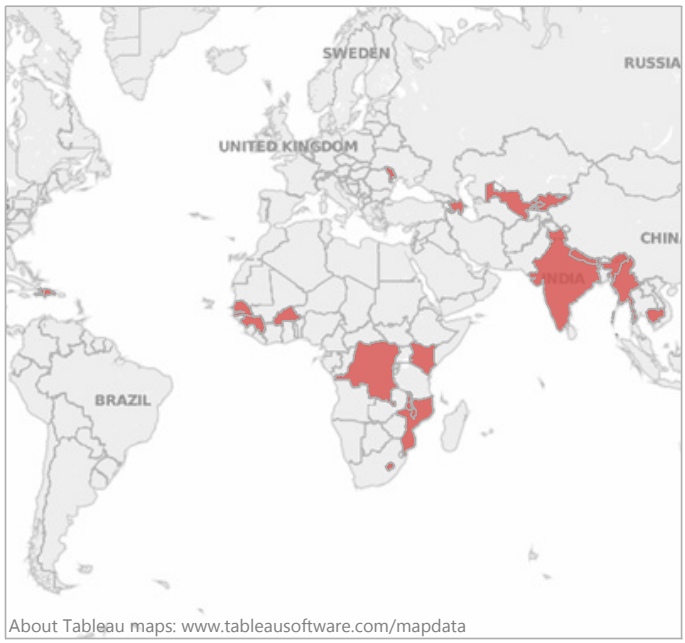
Update on STEP TB

Status	•The project is on track with agreements made with two manufacturers (Svizera, Macleods) in 2013. Svizera and Macleods will each develop two FDC pediatric formulations; •Macleods will also develop single tablet pediatric dosages of ethambutol and isoniazid.
Challenges	•Identified manufacturers will need quality assurance from Stringent National Regulatory Authorities (SNRA) or WHO Prequalification Programme, to ensure timely uptake of these products in countries. •Too many manufacturers on the market may fragment this very small market, deincentivizing manufacturers to develop pediatric products.
Next Steps	•Continue to work closely with the GDF, WHO PQ, and the Global Fund to coordinate and discuss procurement opportunities and timelines. •Discussions with additional one or two manufacturers in 2014 to ensure regional and country-specific coverage. •Provide technical guidance to countries planning to submit a Concept Note to the New Funding Model (NFM) of the Global Fund, to ensure childhood TB is included in the gap analyses.

Provisional figures as of 31 December 2013.
For more information, visit www.unitaid.org/impact

PSC/2014 - OPERATIONS PROJECT UPDATE

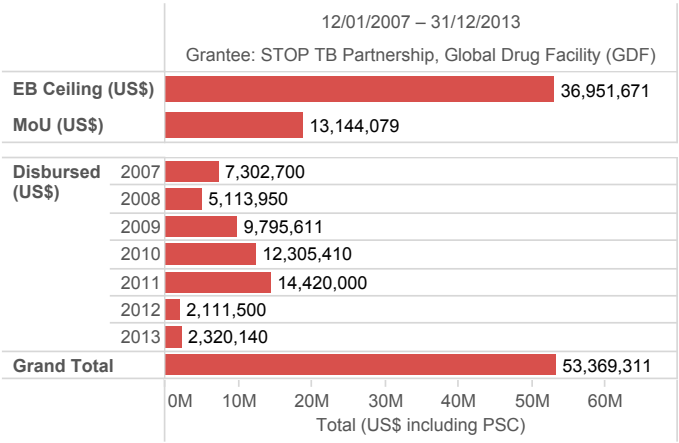
MDR-TB Scale-Up (2007-2013)



5 Treatment of second-line TB

Strategic Objective 5: Treatment of second-line TB

The aim of this joint Project (otherwise known as the MDR-TB Scale-up Initiative) is to scale-up access to quality assured anti-TB drugs to treat MDR-TB patients in eligible countries and positively impact the dynamics of the MDR-TB drug market.



Financial data as of 31 December 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Project was under transition in 2013 and only 5 of 16 countries reported in 2013. The project cumulatively placed over 16,000 cases of MDR-TB on treatment, and thereby achieving 98% of its project target.	Above average; exceeds minimum requirements/expectations.	

Project Activities	2008	2009	2010	2011	2012	2013	Grand Total
MDR-TB patient treatments delivered*	1,543	1,535	845	6,568	5,395	423	16,309
US$ value of MDR-TB treatments delivered			16,094,026	13,394,530	10,096,911	5,651,593	45,237,060

Update on MDR-Scale Up

Status	•The project ended in December 2013.
	•The project placed about 16,000 cases of MDR-TB on treatment, and thereby exceeded its target. Considerable price reductions were achieved on almost all MDR-TB medicines.
Challenges	•UNITAID currently has no projects delivering MDR-TB medicines to detected patients.
Next Steps	•UNITAID should look for new opportunities around projects that support the delivery and access of MDR-TB medicines, while working on market interventions for price reduction and increasing the number and quality of second-line TB medicines.
	•The Partners in Health (PIH) initiative, recently approved by the EB, will support the delivery and access of MDR-TB medicines in the future.

Each treatment provided represents treatment for an 18 to 24 month period. Variations in patient treatment costs accross countries are due to the different treatment regimens adopted by each country.
*In 2013, an additional 745 treatments were ordered but not yet delivered. Therefore, the 2013 value of treatments reflects orders for 1168 treatments.
**Country data disaggregated by year, except for 2010, where grantee reported cumulative value covering 2008 to 2010. In 2013, includes Burkina Faso, Dominican Republic, Guinea, India, Kenya, Kyrgyzstan, Malawi, Myanmar, Senegal.

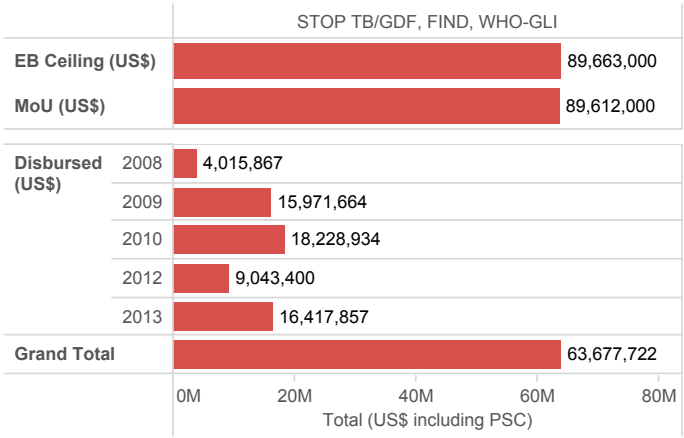
Provisional figures as of 31 December 2013. Country data disaggregated by year.

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

PSC/2014 - OPERATIONS PROJECT UPDATE

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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Project is on track and is expected to reach at least 90% of targets by end of project in 2014. Extension request received.	Above average; exceeds minimum requirements/expectations.	

Project Activities	2009	2010	2011	2012	2013	Grand Total
Number of MDR-TB cases detected	1,810	2,386	6,878	24,869	35,881	71,824
US$ MDR TB diagnostics product costs**			7,435,266	6,354,740	9,191,655	22,981,661

Update on Expand TB

Status	•The Project has expanded MDR-TB diagnostic capacity in laboratories supported, and cumulatively detected 71,824 MDR-TB cases. Case detection of MDR-TB tripled in the 27 countries as compared to the baseline in 2008. •The project is ending in December 2014. Project on track after significant delays.
Challenges	•There are now newer technologies such as the GeneXpert that supersede the Line Probe Assays (LPA). •Training of laboratory staff to acquire new laboratory skills and operate independently is still a challenge. •Under-estimation of the length of time needed to upgrade the sites to the required biosafety standards led to delays;
Next Steps	•Expand TB project is linked to the Xpert project because they both strengthen laboratory capacity. •Transitioning of the project activities is ongoing with alternative sources of funding having already been identified in 4 countries (Djibouti, Kyrgyzstan, Moldova and Tanzania). •UNITAID has been supporting the scale-up of GeneXperts in 21 countries through its TBXpert project with the WHO Global TB Programme (2013-2015);

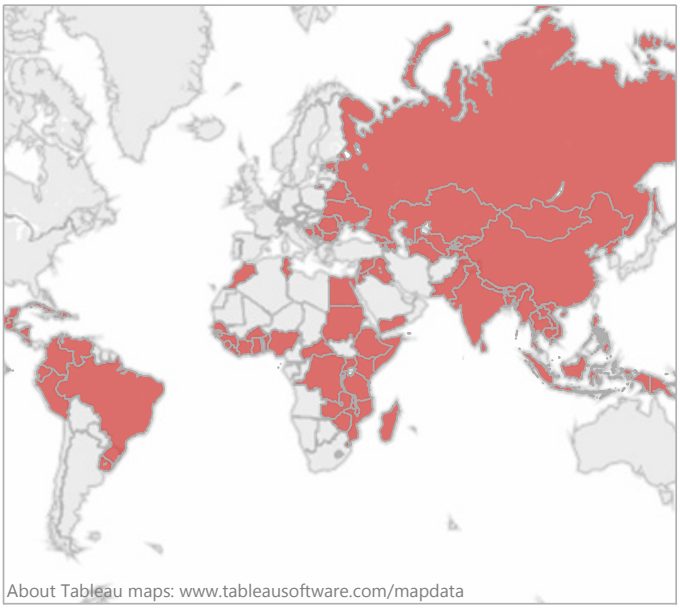
**Values reflect orders paid that comprise essential equipment, consumables and reagents and exclude freight and insurance and pre-shipment inspection expenses.

Provisional figures as of 31 December 2013. Country data disaggregated by year, and estimates are revised with more accurate data available from countries.

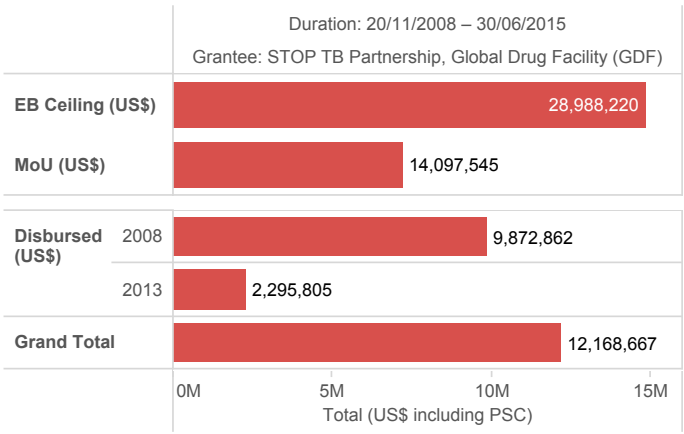
For more information, visit www.unitaid.org/impact

PSC/2014 - OPERATIONS PROJECT UPDATE

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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
The UNITAID EB in December 2013 approved an expansion of the Stockpile from the current size of 5,800 patient treatments to 12,000 patient treatments.	Average; meets the minimum requirements/expectations.	

Project Activities	2012	2013
Global average lead time for emergency orders from date order placed to first delivery in country	55	92
Number of countries ordering MDR-TB drugs from the stockpile	67	67

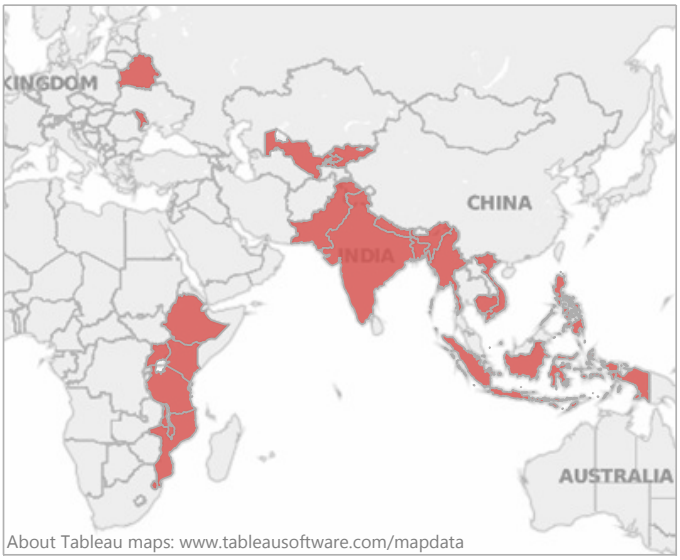
Update on MDR-SRS

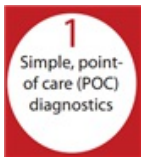
Status	•The Executive Board approved the cost-extension of the project for 18 months until 30 June 2015 that will allow an expansion of the SRS and transition to the Global Fund's Rapid Supply Mechanism (RSM). •Thus far, the SRS has been instrumental in responding to emergency situations, reducing lead times of selected medicines for MDR-TB treatments, preventing stock outs and enabling programs to rapidly start treatment of patients.
Challenges	•Despite the original intent as an emergency stockpile, several countries have been using the stockpile for non-emergency orders. •There is a need to continually monitor the stockpile and revise the composition of the SRS to reflect changes in the product prices, changes in the WHO Treatment Guidelines, country ordering patterns and quality assurance status of manufacturers. The need to have a smooth transition of the expanded SRS to the GFATM RSM was discussed during the grant negotiations with GFATM and GDF in 2013.
Next Steps	•Finalize the new SRS composition. •Finalize Project Plan, Log-frame, and budget for cost-extension. •The SRS program to be transitioned to the Global Funds Rapid Supply Mechanism (RSM) by June 2015.

Provisional figures as of 31 December 2013. Country data disaggregated by year.
For more information, visit www.unitaid.org/impact

PSC/2014 - OPERATIONS PROJECT UPDATE

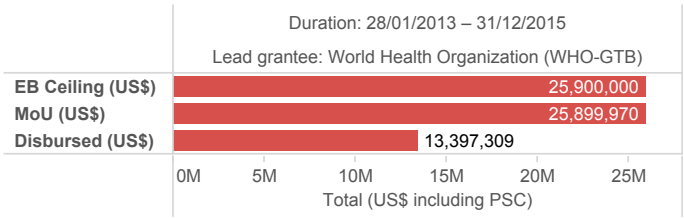
Scaling up access to contemporary TB diagnostics (GeneXpert) (2013-2015)





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

The TBXpert Project will scale up TB diagnostic testing using state-of-the-art Xpert MTB/RIF, providing approximately 1.4 million Xpert MTB/RIF 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 TBXpert 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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
The Project was launched in all 21 countries. Certain supply chain issues led to delays in 2013 and have been resolved by end of 2013.	Above average; exceeds minimum requirements/expectations.	

Project Activities	2013
Number of incident TB patients detected using TBXpert project commodities	7,647
Number of incident rifampicin-resistant TB patients detected using TBXpert project commodities	1,791
Number of incident HIV-positive TB patients detected using TBXpert project commodities	992
Number of GeneXpert instrument modules procured within framework of TBXpert project	844
Number of Xpert MTB/RIF cartridges procured within framework of TBXpert project	234,760
US$ value of GeneXpert instruments procured within framework of TB Xpert project	3,716,160
US$ value of Xpert MTB/RIF cartridges procured within framework of TB Xpert Project	2,482,624.8

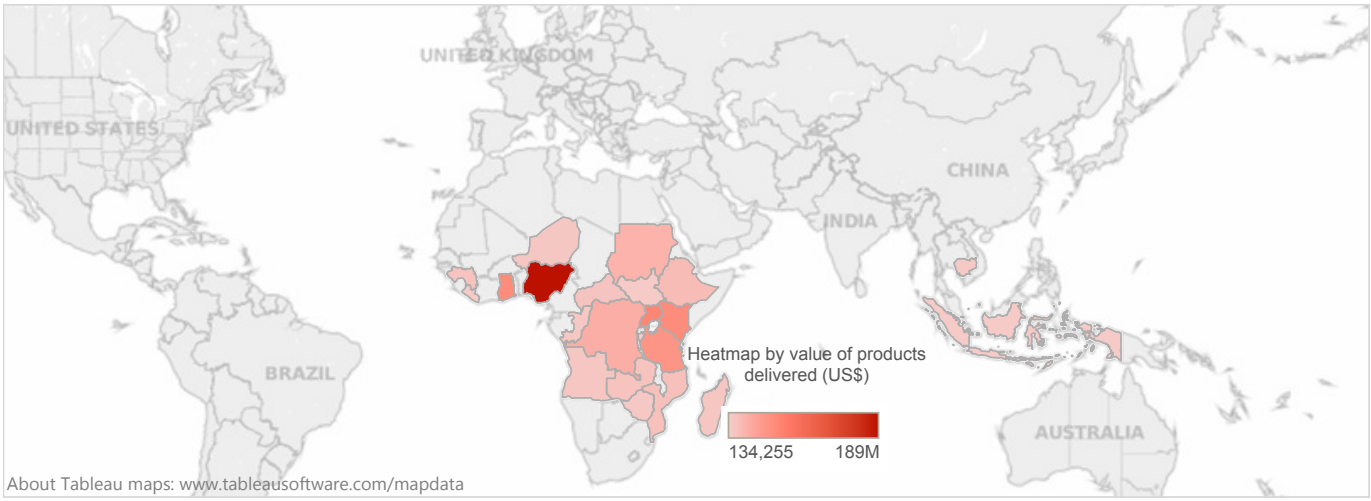
Update on Xpert

Status	•Project is on track to meet all its objectives in delivering GeneXpert instruments and cartridges to countries, with GeneXpert instruments procurement for all 36 recipient entities (15 NTPs, 21 partner NGOs) for 21 countries.
Challenges	•A global shortage in test cartridges in Q1-Q2 2013 due to a manufacturing problem of the supplier, CEPHEID resulted in initial delays with backlog of orders, which were cleared by Q2. •Independent research has reported high module failure rates for the GeneXpert. •The consumption rate of cartridges was also slower than expected at some sites due to reluctance to adopt diagnostic algorithms or restrictive national-level algorithms. •There were also delays in some recipient entities due to significant time required for site readiness, calculating order sizes and site allocations, procurements of GeneXperts from other funding sources that overburdened the National TB Programme;
Next Steps	•Follow-up with CEPHEID to investigate the challenges reported by countries in use of the GeneXpert modules. •Provision of country specific guidance to accelerate use of cartridges, including ensuring that national and site-specific diagnostic algorithms are in line with updated WHO recommendations. •Start discussion with countries, partners and donors to ensure smooth transitioning of the project at the end of 2015.

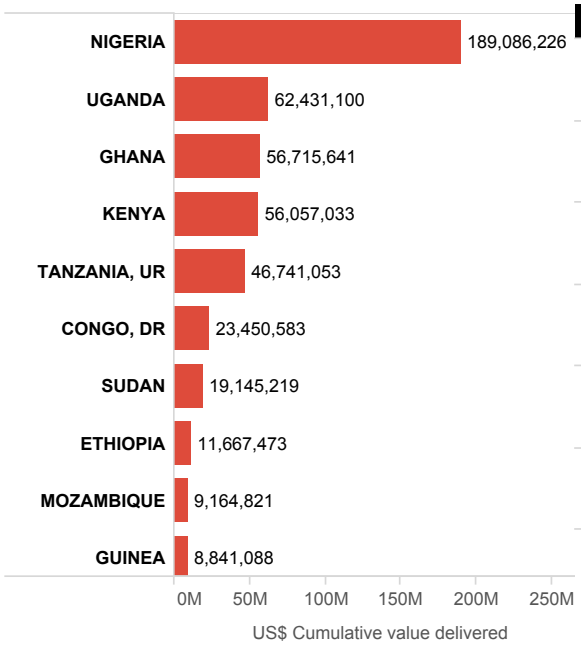
Provisional figures as of 31 December 2013. Country data disaggregated by year. All cartridges procured at US$ 9.98, the agreed price with CEPHEID.

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

Malaria Portfolio Profile



Top 10 countries by financial values[1] (US$) 2007-2013



Grantees

World Health Organization, The Global Fund To Fight AIDS, Tuberculosis and Malaria, unicef, MMV Medicines for Malaria Venture, psi, FIND, i+solutions

Results by project (Includes all project countries, 2007-2013*)

Project	Duration	Description	Results
Affordable Medicines for Malaria (GFATM)	02/11/2009 - 31/12/2013	# subsidized ACT treatments delivered	472,922,510
ACT Scale-up (GFATM, UNICEF)	04/12/2007 - 31/12/2012	# of ACT treatments delivered	37,709,795
ACT Liberia & Burundi (WHO)	28/03/2007 - 31/12/2007	# of ACT treatments delivered	1,401,228
Support to Global Fund Round 6 (GFATM)	21/12/2007 - 31/12/2011	# of ACT treatments delivered	4,554,962
Assured Artemisinin Supply System (i+solutions)	06/07/2009 - 31/12/2013	Volume (metric tons) delivered to manufacturers (CIPLA, Novartis, Strides)	9.4
Long Lasting Insecticide Treated Nets (UNICEF)	25/02/2009 - 31/12/2010	# of LLINs delivered	20,000,000
Improving Severe Malaria Outcomes (MMV)	05/06/2013 - 05/06/2016	# of secondary, tertiary health facilities with at least one health worker trained on Inj As	433
		# of countries with case mgt training materials aligned with WHO guidelines on Inj AS	5
Private Sector Market for RDTs (PSI)	23/04/2013 - 29/02/2016	# of registered private sector outlets quality assured RDT brands in stock	44
		# of RDTs procured in line with country-specific procurement plan	510,000
Quality Assurance of Rapid Diagnostic Test (FIND)	01/01/2013 - 31/12/2017	# of manufacturers participating in product testing	34
		# of products submitted to product testing	42
Prequalification of Medicines (WHO)	14/12/2006 - 31/12/2016	# of UNITAID priority medicines prequalified (Malaria)	29
Prequalification of Diagnostics (WHO)	23/03/2009 - 31/12/2016	# of UNITAID priority diagnostics prequalified (Malaria)	3

Data as of 31 December 2013.

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

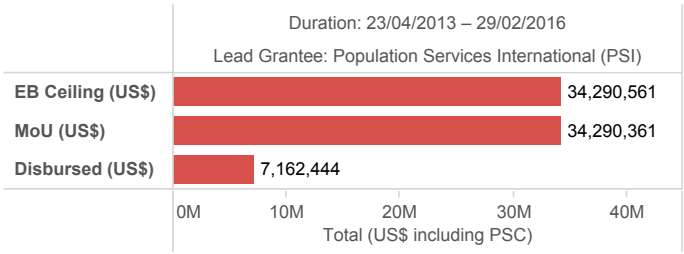
For more information visit http://www.unitaid.eu/en/what/malaria

EB20/2014 OPERATIONS PROJECT UPDATE

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

1 Simple, point-of care (POC) 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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Project implementation is on track. Project related activities need to remain on track to avoid potential implementation delays and unanticipated costs.	Above average; exceeds minimum requirements/expectations.	

Project Activities	2013
Number of RDTs procured in line with country-specific procurement plan timeline	510,000
Number of registered private sector outlets in project areas with quality assured RDT brands in stock	44
US$ value of RDTs procured	220,325

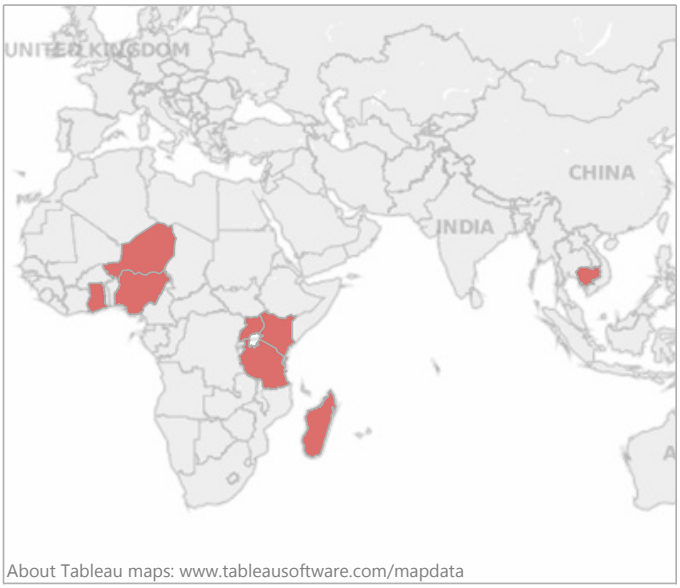
Update on Private Sector Market for RDTs

Status	• Delivery of RDTs to private sector outlets has begun in Kenya, Madagascar and Tanzania. The contracts with manufacturers for the procurement of bundled RDTs and related services has been finalized for Nigeria and Uganda. • Overall grant programmatic and financial performance on track.
Challenges	• Delays are expected in several project countries due to delays in finalising the working agreements with national governments.
Next Steps	• Ensure timely procurement and distribution of RDTs to participating private sector outlets.

Provisional figures as of 31 December 2013.
For more information, visit www.unitaid.org/impact

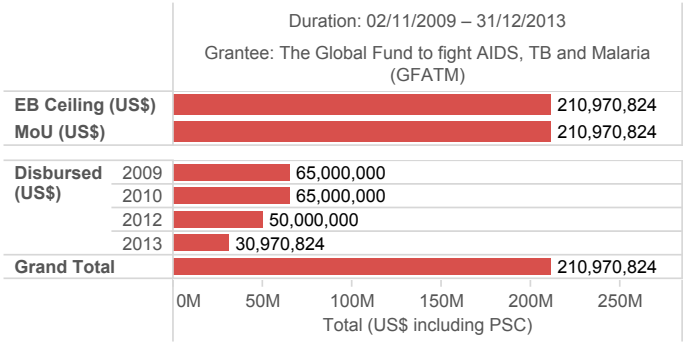
EB20/2014 OPERATIONS PROJECT UPDATE

Affordable Mecidines for Malaria Facility (2009-2013)



4
Treatment of malaria (ACT)

The AMFm objective is to significantly reduce the price for ACT treatments paid by end-users through a subsidy mechanism to the private sector. This is essential to increase access to effective malaria treatment and to delay the development of resistance to artemisinin. AMFm is currently implemented through nine programs in eight countries: Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania and Uganda.



Financial data as of 31 December 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
AMFm significantly increased the availability and affordability of quality assured ACTs in most of the AMFm phase I countries. Obtaining timely and reliable data was challenging in 2013.	Average; meets the minimum requirements/expectations.	

Project Activities	2010	2011	2012	2013	Grand Total
Number of co-paid ACT treatments delivered*	4,539,990	148,535,741	137,068,559	182,778,220	472,922,510
US$ value of ACT treatments delivered	4,662,673	136,801,399	119,937,703	123,591,186	384,992,960

Update on AMFm

Status	• Three AMFm Phase 1 countries have integrated their ACT co-payment needs for 2014 under their GF grants. The remaining five countries have partially covered their ACT co-payment needs for 2014 from other sources. •The GFATM Board decided to integrate the AMFm into core Global Fund grant mechanism in November 2012. This mechanism allows countries to allocate resources to the private sector for malaria diagnosis and treatments.
Challenges	• GFATM reporting on AMFm continues to be late and to lack consistency concerning the details of ACT orders and deliveries.
Next Steps	•The final programmatic and financial reports including reconciled data is expected by the end of June 2014.

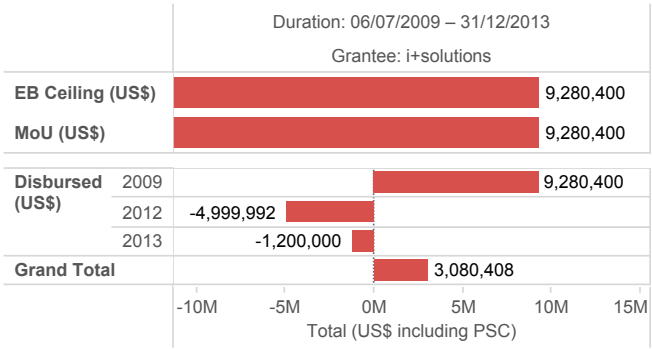
Data as of 31 December 2013.
For more information, visit www.unitaid.org/impact

EB20/2014 OPERATIONS PROJECT UPDATE

Assured Artemisin Supply Services (A2S2) (2009-2013)

4 Treatment of malaria (ACT)

The project supports the production of additional Artemisia (40 MT) to contribute to stabilizing the price of artemisinin, the key ingredient in artemisinin combination therapy (ACT). The project provides loans to artemisinin extractors through tri-partite agreements between an artemisinin extractor, a prequalified ACT manufacturer and i+solutions.



Financial data as of 31 December 2013.*

Grant Performance

Management Action/General Remarks	Rating Description	Rating
The contribution that the A2S2 project made to the global artemisinin supply was limited. The project did achieve significant expansion and diversification of Artemisia cultivation and artemisinin extraction to Africa.	Average; meets the minimum requirements/expectations.	

Project Activities	2013
Volume (metric tons) delivered to manufacturers (CIPLA, Novartis, Strides)*	9.4

Update on A2S2

Status	•Project operations ended in May 2013. As of March 2014, USD 7.7 million (92%) of the loan fund has been recovered and a cumulative volume of 9.4 metric tonnes (23%) of contracted artemisinin has been delivered. •The end-of-project evaluation was completed in September 2013. •The independent end-of-project evaluation found that the project had positive impact on the artemisinin market despite challenges that prevented artemisinin targets from being met within the original timeline.
Challenges	•Need for continued follow-up to ensure repayment of the outstanding loan fund of USD 297,164 and the delivery of 5.3 metric tonnes of artemisinin by Bionnexx/Innovexx in Madagascar.
Next Steps	• UNITAID will continue follow up to ensure repayment of outstanding loan and delivery of 5.3 metric ton of contracted artemisinin. •A project financial audit will be carried out in May and June 2014.

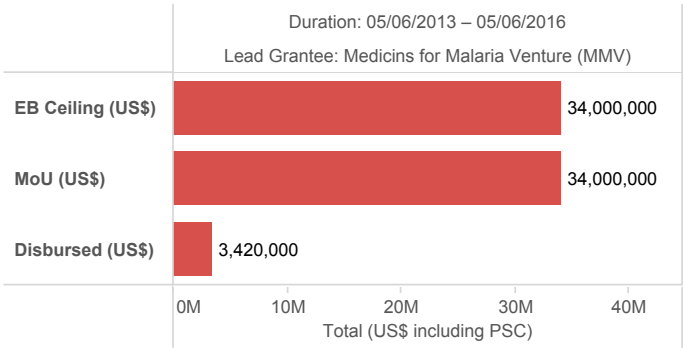
Figures as of **31 December 2013.**
***As of March 2014, additional loan of US$1,472,175 was recovered making the total recovered US$7,672,175 (92% of loans).**
For more information, visit www.unitaid.org/impact

EB20/2014 OPERATIONS PROJECT UPDATE

Improving Severe Malaria Outcomes (2013-2016)

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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Composite score reflects the 2013 period. (In 2014, implementation is off track; timely resolution of price negotiations with Guilin Pharma for injectable artesunate (jointly with GFATM & MMV) is a high priority.	Above average; exceeds minimum requirements/expectations.	

Project Activities	2013
Number of secondary and tertiary health facilities with at least one health worker trained in the administration of Injectable Artesunate in targeted countries	433
Number of targeted countries which have case management training materials aligned with latest WHO guidelines on administration of Injectable Artesunate	5

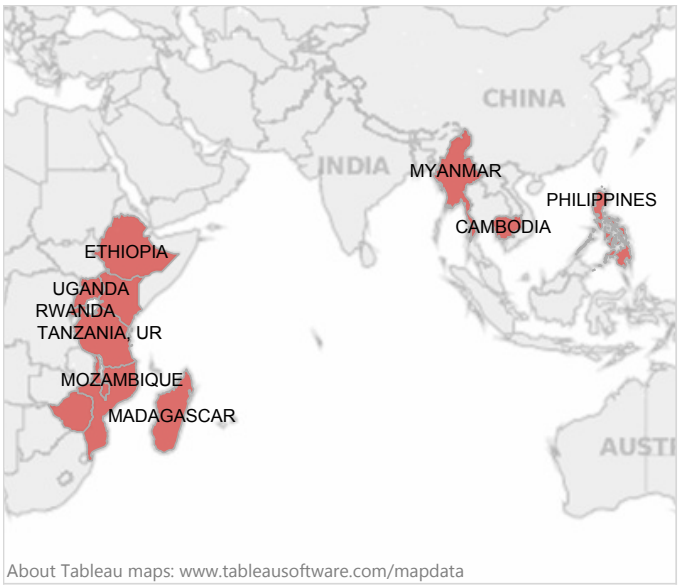
Update on Improving Severe Malaria Outcomes

Status	•Country project implementation agreements with MMV, CHAI and Malaria Consortium have been signed with all (five) countries except Malawi.
	•Overall grant programmatic and financial performance is off track due to lengthy price negotiations that has led to delays in the procurement and delivery of injectable artesunate to project countries.
Challenges	•Price increases demanded by the monopoly injectable artesunate manufacturer, Guilin Pharma, and ensuing price negotiations to reduce the price has slowed down the procurement and implementation of related activities.
	•Work with interested manufacturers to prepare generic artesunate suppositoty and artesunate injection product dossier for submission to WHO Medicine Prequalification Programme requires time.
Next Steps	•MMV and CHAI to complete project implementation agreement with the Ministry of Health of Malawi.
	•MMV is working to finalise the price negotiations with Guilin in consultation with UNITAID and the Global Fund. A reserve order for 300,000 vials of injectable artesunate for Kenya and Nigeria has been submitted to Guilin in parallel with the ongoing pri

Provisional figures as of 31 December 2013.
For more information, visit www.unitaid.org/impact

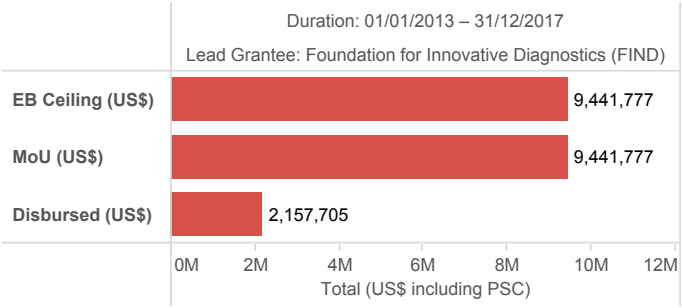
EB20/2014 OPERATIONS PROJECT UPDATE

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



1 Simple, point-of care (POC) 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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Project implementation is on track. Project related activities need to remain on track to avoid potential implementation delays and unanticipated costs.	Above average; exceeds minimum requirements/expectations.	

Project Activities	2013
Number of manufacturers participating in product testing	34
Number of products submitted to product testing	42

Update on RDT Quality Control System

Status

•Overall grant programmatic and financial performance is on track.

•(In 2014, delays in the development of recombinant antigen-based RDT quality testing panels may have programmatic and cost implications for 2014 and beyond.)

•RDT lot quality testing program is performing well and meeting the requests from countries and procurement agents in a timely fashion.

•Manufacturers have willingly accepted to pay fees imposed for the first time in order to submit products for evaluation under the RDT product testing program.

Challenges

•Development of recombinant antigen-based RDT quality testing panels has been delayed due to the failure of the contracted company to complete the development of those panels.

Next Steps

•Increased demand for RDT lot quality testing has challenged the limited capacity of the laboratories in supported through this project in the Philippines and Cambodia.

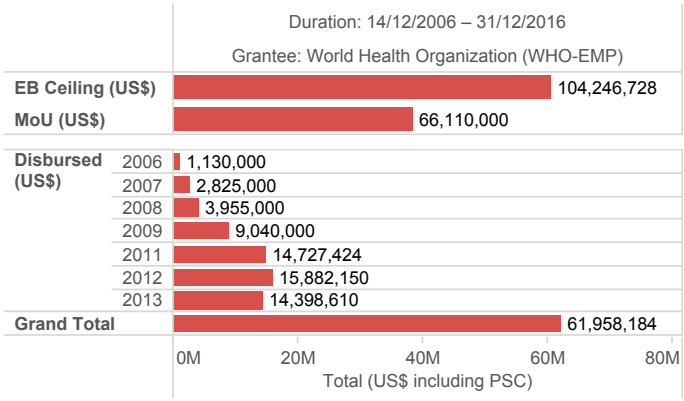
•FIND is negotiation with other companies to complete the development of the recombinant antigen-based RDT quality testing panels.

Provisional figures as of 31 December 2013.
For more information, visit www.unitaid.org/impact

EB20/2014 OPERATIONS PROJECT UPDATE

Prequalification of Medicines (2006-2016)

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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Improvements in all aspects except timely reporting. Reforms to PQ management & performance oversight expected to lead to improvements in all areas under the new project (2014-2016).	Above average; exceeds minimum requirements/ expectations.	

UNITAID Priority Products Prequalified

Description	2007	2008	2009	2010	2011	2012	2013	Total
Priority medicines prequalified (HIV)	2	6	11	9	11	6	8	53
Priority medicines prequalified (TB)	2	3	6	5	7	18	17	58
Priority medicines prequalified (Malaria)	1	6	3	1	1	10	7	29
Grand Total	5	15	20	15	19	34	32	140

Manufacturers (2013)

Mylan Laboratories Ltd
Macleods Pharmaceuticals Ltd
Lupin Ltd
Micro Labs Limited
Apotex Inc.
Guilin Pharmaceutical Co., Ltd.
Hetero Labs Limited
SC Antibiotice
Ranbaxy Laboratories Ltd
Strides Arcolab Limited
Ajanta Pharma Ltd
Laurus Labs Pvt Ltd
Sequent Scientific Ltd
Pen Tsao Chemicals Ltd
Pharmathen SA
Shanghai Desano Chemical Pharma
Biocom JSC
Kunming Pharmaceutical Corp
Shasun Pharmaceuticals Ltd
Shijiazhuang Lonzeal Pharmaceuticals Co., Ltd.

Update on Prequalification of Medicines

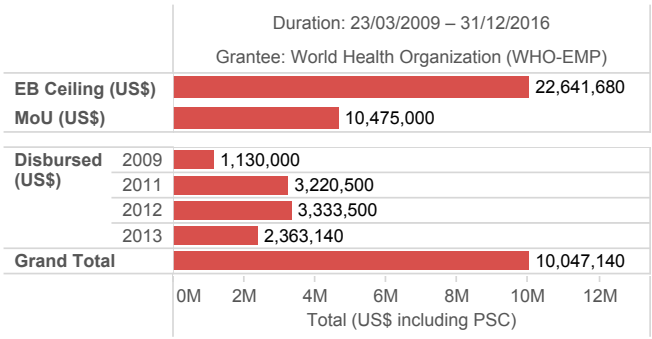
Status	•Grant covering the period from 2006 to 2013 ended in December 2013. Signature of the new grant supporting the joint PQ medicines and diagnostics programme (2014-2016) expected in June 2014.
Challenges	•Reconciliation of UNITAID funded activities and BMGF funded activities. •Identification of additional funding sources for PQ. •Improved regulatory harmonisation among national regulatory authorities.
Next Steps	•New grant to be signed in 2014, with stronger performance management components in place. •Ongoing discussions with BMGF for coordination and complementarity of activities.

Provisional figures as of 31 December 2013.
For more information, visit http://www.unitaid.eu/en/what/cross-cutting/prequalification

EB20/2014 OPERATIONS PROJECT UPDATE

Prequalification of Diagnostics (Dx) (2006-2016)

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 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
While the project has continued to improve, it did not meet all of its targets. 2013 reporting was considerably delayed. Reforms to PQ mgt & performance oversight expected to lead to improvements in all areas under the new project (2014-2016).	Average; meets the minimum requirements/expectations.	

UNITAID Priority Products Prequalified

Description	2010	2011	2012	2013	Total
# of UNITAID priority diagnostics prequalified (Malaria)	1	1		1	3
# of UNITAID prioritydiagnostics prequalified (HIV)		7	9	7	23
Grand Total	1	8	9	8	26

Manufacturers (2010-2013)

2010	Standard Diagnostics, Inc.
2011	Abbot Molecular Inc. Alere Medical Co. Ltd bioMérieux SA Biosynex Chembio Diagnostic Systems Inc.
2012	Alere Medical Co. Ltd Alere Technologies GmbH Becton Dickinson Chembio Diagnostic Systems Inc. Roche Molecular Systems Inc. Siemens Healthcare Diagnostics Trinity Biotec
2013	Abbot Molecular Inc. Biolytical Laboratories,Inc. bioMérieux SA Circ MedTech Limited Standard Diagnostics, Inc.

Update on Prequalification of Diagnostics

Status

•Grant covering the period from 2006 to 2013 ended in December 2013. Signature of the new grant supporting the joint PQ medicines and diagnostics programme (2014-2016) expected in June 2014.

Challenges

•Project delays due to the reorganization of the PQ Programme.

•Ongoing challenges due to the nature of the diagnostics market:

1)In general, the poor understanding of regulatory requirements by manufacturers remain a challenge in having UNITAID's priority products prequalified in a timely manner.

2)Manufacturers' dossier submissions are sub-standard quality as well as inspection findings show a lack of understanding of internationally accepted quality management standards.

3) Encouraging submissions of dossiers by developers/manufacturers of new and innovative point of care (POC) CD4, HIV VL/and EID tests due to lack of understanding of PQ process; product not in final stages, therefore, premature to submit applications.

Next Steps

•Ongoing discussions with the Bill and Melinda Gates (BMGF) for coordination and complementarity of activities.

•Joint GFATM/UNITAID Expert Review Panel for Diagnostics currently piloted for EID, POC devices. Other product types to be reviewed by end 2014.

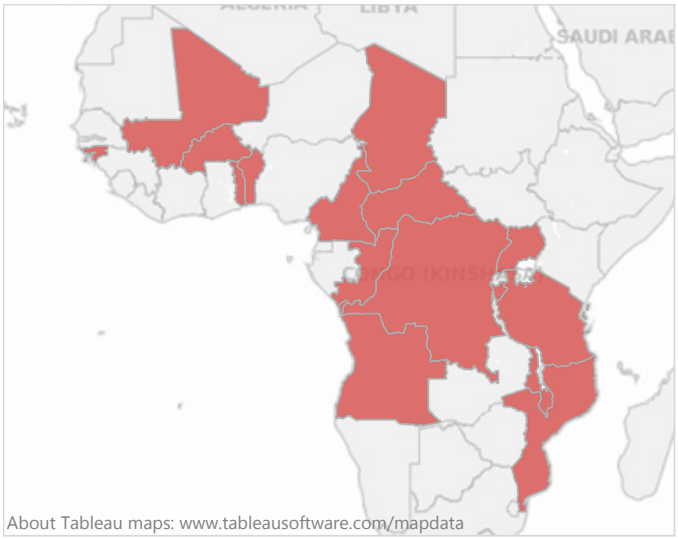
•Use reorganization of PQ Diagnostics Programme as an opportunity to improve performance.

•New grant to be signed in 2014, with stronger performance management components in place.

Provisional figures as of 31 December 2013.
For more information, visit http://www.unitaid.eu/en/what/cross-cutting/prequalification

EB20/2014 OPERATIONS PROJECT UPDATE

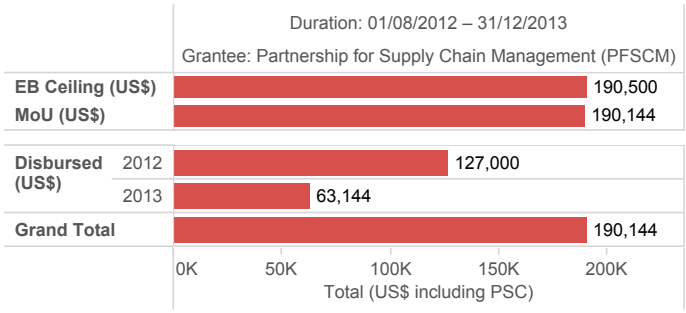
Coordinated Procurement Planning Initiative (2012-2013)



Countries on the map are indicative, as the Country At Risk Schedule of the PIE is a dynamic list depending on levels of risk.

3 Treatment of HIV/AIDS and co-infections

The Project aims to establish a common framework for understanding stock out risks, improving funding coordination and procurement and supply management of medicines for HIV/AIDS, TB and malaria. The financial contribution of UNITAID is to develop a publically accessible database and web-platform to improve information sharing between the CPP Members and to be more effective in preventing stock outs. Six countries are included in the initial phase of the project: Angola, Burkina Faso, Cameroon, Central African Republic, Mali, and Mozambique.



Financial data as of 31 December 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Project closed in December 2013; met all targets; good collaboration with the grantee.	Average; meets the minimum requirements/expectations.	

Project Activities	2013
Monitoring stock-outs of ARVs in country level	The Procurement Information Exchange (PIE) was launched (March 2013) and updated every two months to inform the bi-monthly CPP meetings.
ARV funding and stock situation for countries at risk of treatment disruption	The ARV Supply Risk Assessment resulted (Nov 2013) in data on ARV funding and stock situation for Benin, Cameroon, Chad, Congo, Guinea Bissau, Malawi, Mali and Togo.

Update on CPP

Status

•All project objectives were achieved including establishing a Procurement Information Exchange (PIE) web platform to provide CPP members information on ARV funding, stock availability, and procurement and supply management challenges for 25 countries.

•Project ended in December 2013. Final Report from grantee received in February 2014.

Challenges

•Regular updating and validation of the PIE data.

•Resolving stock-outs in at-risk countries identified from data collected for the PIE, especially given the insufficient involvement of national stakeholders (e.g. GFATM PRs, national programs, in country partners) during the short timeframe.

Next Steps

•Expand PIE to encompass a reliable early warning system to address lack of in-country planning and stimulate a forum for information exchange.

(e.g. capture commodity security issues by country, track donor and government finances and finance processes, funding needs on ARVs; enable direct communication of needs from donor to country)

•Convert the findings of the ARV Supply Risk Assessment in countries into a journal article to highlight issues faced and recommend possible donor interventions.

•Wider uptake of the web-based stock out reporting system funded by UNITAID.

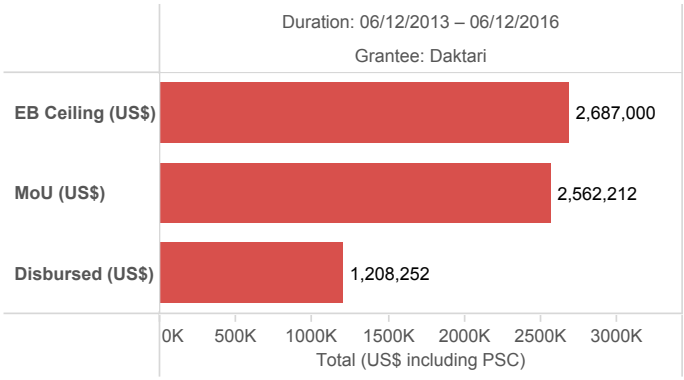
For more information, visit www.unitaid.org/impact
As of 31 December 2013.

EB20/2014 OPERATIONS PROJECT UPDATE

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 of 31 December 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Grantee's first semi-annual report is due 30 July 2014.	Above average; exceeds minimum requirements/expectations.	

Project Activities	
Regulatory and operational studies	Data to be available after first annual report received from grantee in Q1 2015.

Update on Operational Studies POC CD4 Counters

Status	•On track. Grant signed on 6 December 2013. First disbursement delivered.
Challenges	•No challenges reported yet during the start-up phase.
Next Steps	•First semi-annual report due 31 July 2014.

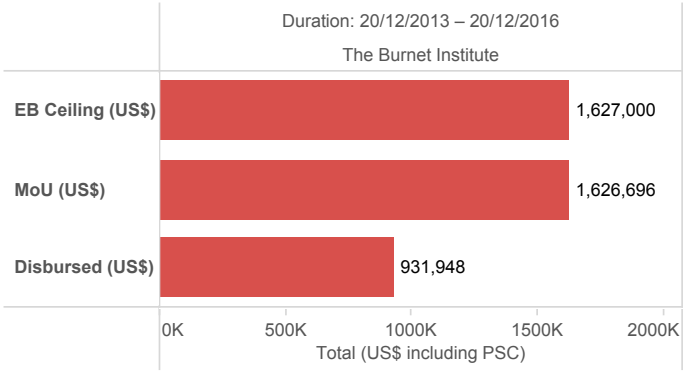
Information as of **31 December 2013.**
For more information, visit www.unitaid.org/impact

EB20/2014 OPERATIONS PROJECT UPDATE

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 countries.



Financial data of 31 December 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Grantee's first semi-annual report is due 30 July 2014.	Average; meets the minimum requirements/expectations.	

Project Activities	
Regulatory and operational studies	Data to be available after first annual report received from grantee in Q1 2015.

Update on Manufacture & Validation of Rapid POC CD4 Testing

Status	•On track. Grant signed on 20 December 2013. First disbursement delivered.
Challenges	•No challenges reported yet during the start-up phase.
Next Steps	•First semi-annual report due 31 July 2014.

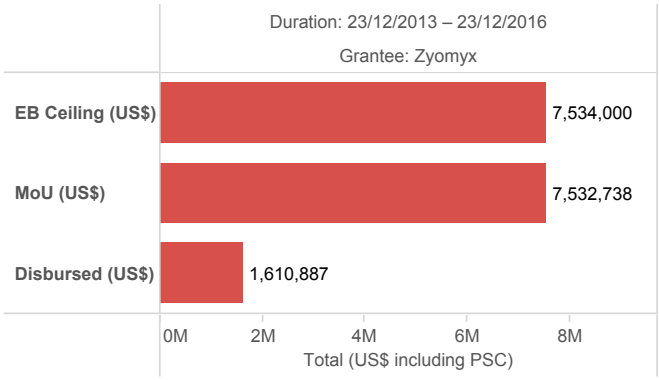
Information as of **31 December 2013.**
For more information, visit www.unitaid.org/impact

EB20/2014 OPERATIONS PROJECT UPDATE

Disposable POC CD4 (2013-2016)

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

The overall goal of this project is the uptake of the Zyomyx CD4 test in 12 low and middle income countries. The Grantee shall seek to achieve successful field evaluations of hte test, together with regulatory approvals, the scale up of manufacturing capacity and distribution of the test, in accordance with the commercialization and access.



Financial data of 31 December 2013.

Grant Performance

Grantee is scheduled to report quarterly. The first quarterly report was submitted two weeks early; very well organized and complete. They are off to a good start.	Above average; exceeds minimum requirements/expectations.

Project Activities	
Uptake of the novel, disposable POC CD4 Zyomyx tests	Data to be available after first annual report received from grantee in Q1 2015.

Update on Zyomyx

Status	•On track. Grant signed on 23 December 2013. First disbursement delivered.
Challenges	•No challenges reported yet during the start-up phase.
Next Steps	•First quarterly report was due 30 April 2014.

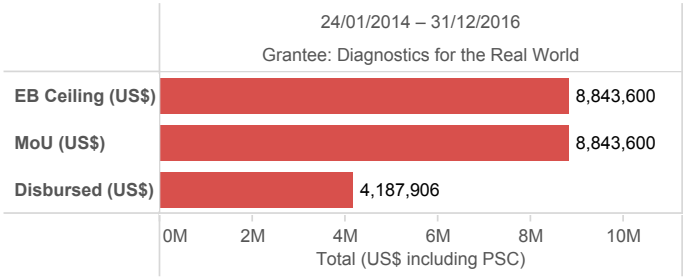
Information as of **31 December 2013.**
For more information, visit www.unitaid.org/impact

EB20/2014 OPERATIONS PROJECT UPDATE

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 of 31 December 2013.

Grant Performance

Management Action/General Remarks	Rating Description	Rating
Grantee's first semi-annual report is due 30 July 2014. The logframe is still outstanding as a first deliverable.	Average; meets the minimum requirements/expectations.	

Project Activities	
SAMBA in market implementation phase	Data to be available after first annual report received from grantee in Q1 2015.

Update on EID & VL Monitoring

Status	•Grant signed on 24 January 2014. First disbursement delivered.
Challenges	•Additional funding requested. •Challenge in scaling up production to projected demand of 1 to 2 million tests/annum.
Next Steps	•Close collaboration with grantee and Children's Investment Fund Foundation (CIFF) regarding additional funding request.

Grant Agreement was signed in January 2014.
For more information, visit www.unitaid.org/impact

EB20/2014 OPERATIONS PROJECT UPDATE

Status
- ○ Transition needed
- ◇ Transition on-going with GFATM
- △ Scaling up needed
- ✕ No transition needed

Transition Status Overview

Project name	Implementer	Next steps	Status
Expand TB	STOP TB/GDF, WHO-GLI, FIND	Transition required for 27 countries and implementers are currently negotiating transition at country level. For Djibouti, Moldova, Kyrgyzstan, Tanzania, transition ongoing with alternative sources of funding identified.	○
		Further follow-up will be made with WHO Global TB Programme.	○
OPP-ERA	FEI	Transition potential only if Phase 1 proof of concept is successful. FEI will apply for a NO cost extension for 2nd half 2014 only.	○
		More defined collaboration in Phase 2. No immediate action in 2014.	○
Paediatric ARVs	CHAI	Regular meetings with GFATM/ Country included in the New Funding Model/ GF has been informed that the final orders for the country will take place in Dec 2014	○
POC 1	CHAI - UNICEF	Ongoing collaboration and information sharing with the Global Fund. Briefing prior to and after country visits. Sharing of Ph2a project plan and country operational plans.	○
		Closer definition of necessary actions per country for transition. Critical discussions on co-investment for market shaping and public health impacts.	○
TB Expert	WHO-GTB	Project end date 31 Dec 2015	○
MDR-TB SRS	STOP TB/GDF	Monthly Rapid Supply Mechanism Joint working group working with GFATM and GDF for transition.	◇
AMFm	GFATM	Not applicable	△
Disposable CD4 POC	Zyomyx	Keep GFATM and other procurement orgs up-to-date on timing of market entry of these products. If the product is good, potential for scaling up.	△
Improving Severe Malaria	MMV	Not applicable	△
Peds formulation	DNDi	Scaling up: Global Fund to consider to include the new formulations in their procurement.	△
POC CD4 Counters	Daktari	Keep GFATM and other procurement orgs up-to-date on timing of market entry of these products. If the product is good, potential for scaling up.	△
POC CD4 in India	Burnet	Keep GFATM and other procurement orgs up-to-date on timing of market entry of these products. If the product is good, potential for scaling up.	△
Private Sector Malaria RDTs	PSI	Not applicable	△
SAMBA EID & Viral Load	Diagnostics for the Real World	UNITAID will keep GFATM and other procurement orgs up-to-date on timing of market entry of these products. If the product is good, potential for scaling up.	△
STEP TB	TB Alliance	A potential scaling up of the product is to plan depending on the output of the development of the product.	△
Asured Artemisin Supply	i+ solutions	Not applicable	✕
Coordinated Procurement	PFSCM	Not applicable	✕
ESTHERAID	Esther	Not applicable	✕
MDR-TB Scale Up	STOP TB/GDF	Project closed in December 2013. Lessons learnt will be shared with GFATM after the end-of-project evaluation planned in Q3 2014 and annual/ end of project report received in April 2014.	✕
MPP	MPP Foundation	Discussion needed on formal collaboration between UTD, MPP and GFATM PSM team on engagement with branded manufacturers to increase number of licences added to pool and pricing/access terms.	✕
MSF Dx	MSF	No immediate action in 2014	✕
Paediatric TB	STOP TB/GDF	Project closed in 2013. Lessons learnt will be shared with GFATM after the end-of-project evaluation planned in Q3 2014 and annual/ end of project report received in April 2014.	✕
Prequal Dx	WHO	Ongoing collaboration and co-funding of ERPD. Participation with other stakeholders in Global Dx Working Group. Ongoing harmonization of QA policies.	✕
Prequal Medicines	WHO	Ongoing collaboration and co-funding on ERP. Joint prioritization of products. Ongoing harmonization of QA policies.	✕
Preventing patent barriers	Lawyers Collective	Not applicable	✕
Quality Control Malaria RDTs	FIND	Not applicable	✕