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UNITAID

Mid-Term Review "Expand-TB"

Narrowing the gap - Expanding and accelerating access to diagnostics for patients at risk of multi-drug resistant tuberculosis (MDR-TB)

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Abbreviations

DRC	Democratic Republic of the Congo
DST	Drug susceptibility test
FIND	Foundation for Innovative New Diagnostics
GDF	Global Drug Facility
GF	Global Fund to Fight AIDS, Tuberculosis and Malaria
GIZ	German International Cooperation
GLC	Green Light Committee
GLI	Global Laboratory Initiative
HIV	Human immunodeficiency virus
ISO	International Organization for Standardization
LIC	Low income country
LMIC	Lower middle income country
LPA	Line probe assay
MDR-TB	Multi-drug resistant tuberculosis
MGIT	Mycobacterium growth indicator tube
MoU	Memorandum of understanding
MSH	Management Sciences for Health
M&E	Monitoring and Evaluation
NRL	National Reference Laboratory
OECD	Organisation for Economic Cooperation and Development
PMM	Project management meeting
RDT	Rapid Diagnostic test for Malaria
RFP	Request for Proposal
SNRL	Supranational Reference Laboratory
SOP	Standard operating procedure
SWOT	Strengths, Weaknesses, Opportunities, Threats
UN	United Nations
USD	United States dollar (US$)
TB	Tuberculosis
UMIC	Upper middle income country
WHO	World Health Organization
XDR-TB	Extensively drug-resistant tuberculosis

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Executive Summary

The advent of powerful antibiotics revolutionized tuberculosis (TB) treatment, but also resulted in the selection and spread of drug-resistant strains. TB strains resistant to the two most important TB drugs, isoniazid and rifampicin, are called multi-drug-resistant (MDR-TB). It is estimated that globally, only 11% of the 50 million MDR-TB cases were detected in 2009.

In 2008, UNITAID launched the project *Narrowing the gap - Expanding and accelerating access to diagnostics for patients at risk of multi-drug resistant tuberculosis*. The project is coordinated by the Global Laboratory Initiative (GLI) of the World Health Organisation (WHO) in collaboration with the Global Drug Facility (GDF) and the Foundation for Innovative New Diagnostics (FIND), and is also known under the project identity *EXPAND-TB*. The project has three objectives: to expand and accelerate access to quality-assured new diagnostic technologies in project countries, to impact MDR-TB diagnostics market dynamics, and to improve case detection by ensuring that TB diagnostic tools are properly used by National TB Control Programmes. The project has a budget of USD 87,562,000 and operates in 27 countries. A total of roughly 120,000 cases of MDR-TB are expected to be diagnosed in the frame of the project.

Methodology

This is a consolidated external independent mid-term evaluation, including recommendations based on the findings of the evaluation. The evaluation had three components: firstly, the common evaluation areas relevance, effectiveness, efficiency and impact; secondly, project specific questions; and thirdly, quality of reporting. The project memorandum of understanding (MoU) and progress reports were used as primary sources of information. Data was extracted to form a project outline, and analyzed based on the questions specified in an evaluation matrix. Each evaluation area was assigned a rating and the quality of the underlying data was graded. Complementary information was obtained during direct exchanges with UNITAID and project partners. Recommendations were issued by consensus of the team of evaluators involved in all projects, based on the findings of the evaluation. Recommendations prioritised what was understood as being the critical issues in each evaluation area and across all areas. Several options to address the critical issues were listed and assessed against two main criteria: (a) the available evidence that the recommendations would effectively address the critical issue identified; and (b) the feasibility of implementing the recommendation.

Project Key Information

The main activities currently implemented in the 27 project countries are capacity and needs assessments followed by arrangements to upgrade infrastructure (mostly laboratories), train staff and transfer technology - which also includes arranging and managing third-party support - and supply of new diagnostic products. Laboratories in six countries have implemented new TB diagnostics and are ready to deliver services, or have already progressed to routine diagnosis. A total of 4,166 MDR-TB cases have already been diagnosed and reported by these six countries. Two countries are suggested for replacement by other countries.

Key Findings (31 December 2010)

- All 13 activities are consistent with the project plan and its three objectives, and in line with UNITAID's overall goal, objectives and strategy.
- Flexible project with scope for adjustment.
- Active participation of donor (UNITAID) in project management is unusual but beneficial.
- Technical capacity and partner consultation appear to have been limited during the design and planning phase of the project.
- The initial project schedule was overly optimistic and implementation of diagnostic services is behind schedule. Problems to secure political commitment and infrastructure/security challenges were underestimated.
- MoU signature proved a major obstacle to launching project activities in several countries (tax-free import of goods was a key issue of contention).
- The procurement model with a procurement agent managed by GDF is implemented as planned.
- 3.5% of the planned total number of MDR-TB cases has been diagnosed.
- Rapid scale-up of diagnostic services is observed once laboratory preparedness has been achieved.
- The initial disbursement schedule and planned expenditure were not aligned. 61% of the planned disbursements for the period have been made (USD 37,553,128 out of USD 61,690,848). Actual expenditure (USD 9,267,469) was lower than planned, representing 31% of the planned budget for the period (USD 29,989,755).
- Price reductions of key diagnostic items have been partially achieved (minus 11.4% for liquid culture tubes, minus 2% for LPA).
- There is no evidence for an expansion of the MDR-TB diagnostics market or price reductions conclusively attributable to the project.
- Limited purchase volume per item and small number of suppliers for key diagnostic items restrict impact on diagnostics market dynamics.
- A detailed reporting template exists for both programmatic and financial reporting.
- There is no independent verification of reported numbers and no consolidation process to detect inconsistencies between different sections of the project activity report.
- Reported performance and expenditure is not verified and disbursements are not linked to performance.

Key Recommendations

- Partners should develop a catch-up plan in which suggested activities to increase the speed of project implementation are outlined, and annual targets are provided for every country and area of activity. This plan and its budget implications should then be discussed with UNITAID, revised accordingly, and become a binding framework for activities and reporting.

- Critically analyse the MoU to identify discrepancies, determine conflicts of interest when assigning activities to partners and other issues, and revise the MoU in light of the findings.
- Coordinate with donors, Green Light Committee (GLC) and project countries to ensure the sufficient supply of MDR-TB drugs and the availability of the required human resources (specialized doctors, nurses, etc.) and infrastructure to administer and manage treatment, and its side effects.
- Develop a final version of the programmatic and financial reporting template based on the log-frame approach, which includes systematic risk identification and mitigation. Reporting should be actionable and as short and concise as possible with simple, meaningful and systemic indicators developed in collaboration with the partners. Each report should provide a snapshot of the project at the moment of reporting and include graphical trends/projections of future developments as well as an update of the risk assessment. It should also contain a summary, linking programmatic and financial reporting.
- Elaborate clear reporting guidelines, including an explanation of indicators and their calculation, rules for the non-reporting of certain items (e.g., in case insufficient data exist to calculate an indicator), consolidation processes for reported data and the report approval and revision process. A final revised version of the report should be published and shared with all partners whenever factual corrections/additions to a report are made.
- Develop and implement a representative and weighted rating system between contractual programmatic, procurement related and financial criteria in order to assess performance throughout the projects and to authorize disbursements of funds for projects. This tool could also be used to support cost extension/no cost extension decisions.
- Conduct periodic on-site data verifications/data quality audits in project countries covering the key indicators, including the number of diagnosed MDR-TB cases and stocks of diagnostic materials.

1 Project Description

1.1 Background

The tuberculosis bacillus *Mycobacterium tuberculosis* currently infects one third of the global human population, and 5-10% of them are estimated to experience morbidity at one point during their lifetime. The bacteria are usually contained by the human immune system and remain dormant, but particularly in people with depressed immune functions, or upon weakening of the immune system, the bacteria reactivate and a former carrier may become a sick TB patient. Most commonly, the bacteria reside in the lungs. An infected person expels the bacteria from his/her lungs into the air, infecting others who inhale the contaminated droplets. Thus, crowded and unhygienic conditions greatly favour the spread of TB.

The advent of powerful antibiotics revolutionized TB treatment, but unfortunately also resulted in the selection and spread of drug-resistant strains. TB strains resistant to the two most important TB drugs isoniazid and rifampicin are called multi-drug-resistant (MDR-TB). To treat such infections, prolonged treatment with costly second-line drugs is necessary. Adverse drug reactions elicited by these drugs are also much more severe. The advent of extensively drug-resistant TB (XDR-TB) brought a new level of complexity to TB prevention and treatment.

It is estimated that globally, only 5% of the 50 million MDR-TB cases were detected in 2007 and 11% in 2009, greatly hampering efforts for the management and control of the condition. The under-diagnosis has been ascribed to a lack of adequate diagnostic facilities, cumbersome diagnostic procedures and barriers to access services. According to the Stop TB Partnership, to meet the goal of universal access by 2015 at the level of the projected demand, a diagnostic gap of at least 50 million cultures and 4.5 million drug susceptibility tests (DSTs) per annum needs to be closed.

Newly developed diagnostic tools, such as liquid culture and line probe assay (LPA) which allow diagnosis of MDR-TB within three weeks (liquid culture and DST) or two days (LPA) instead of months, have recently been endorsed by the WHO for use in developing countries where the need for scale-up of diagnostic capacity is greatest. Comprehensive approaches for TB diagnosis in resource constrained settings adaptable to local conditions and needs have also been developed and approved by the WHO. The expansion of high quality diagnosis to additional populations is aided by agreements with manufacturers which ensure availability of these tools at the lowest possible costs, with further room for price reductions following volume expansion.

1.2 Project EXPAND-TB

Against this background and in coordination with other initiatives focusing on TB diagnosis and treatment, in 2008, UNITAID launched the project, "*Narrowing the gap - Expanding and accelerating access to diagnostics for patients at risk of multi-drug resistant tuberculosis (MDR-TB)*. The project is coordinated by the WHO's GLI in collaboration with the GDF and FIND, and is also known under the project identity *EXPAND-TB*. The scope of this project is broad, ranging from building and equipping laboratories to diagnose MDR-TB, to attempts to impact MDR-TB diagnostics market dynamics.

The project has three main objectives:

- Expand and accelerate access to quality-assured new diagnostic technologies.
- Impact market dynamics to leverage price reductions for diagnostic tools, instruments, reagents, and supplies, and stimulate a greater number of suppliers of modern TB diagnostics.
- Improve case detection and management of TB and MDR-TB by deploying all reasonable efforts to ensure the TB diagnostic tools supplied are taken up and properly used by National TB Control Programmes.

The project was initially designed to cover activities in 16 Low income countries (LICs) and lower middle income countries (LMICs) with a budget of **USD 26,129,897**. In 2010, the budget was increased to **USD 87,562,000** to allow for an expansion of the project to 27 countries, stratified into three categories according to their level of preparedness to implement MDR-TB diagnosis. A total of roughly **120,000 cases of MDR-TB are expected to be diagnosed in the frame of the project**. In 2010, UNITAID support was withdrawn from two countries (Democratic Republic of the Congo (DRC) and Zambia), as no consensus on the necessary agreement could be reached between the national health authorities of DRC,and FIND, and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF) and other partners suspended their support to Zambia. Mozambique and Rwanda have been proposed to replace them:. It has further been suggested that liberated funds be re-deployed - as the budget for the suggested replacement countries is smaller than that of the cancelled countries - towards the promotion of the GeneXpert® system. This is a novel tool which promises to revolutionise the diagnosis of MDR-TB by giving an answer to two crucial questions within 100 minutes: (i) is it *M. tuberculosis*, and (ii) is there resistance to rifampicin?

Political commitment is important for TB control. An important aspect of political commitment is the removal of administrative barriers to project implementation, e.g., a waiver of import duties and taxes. As of 31 December 2010, agreements between national health authorities and FIND on behalf of the WHO's Stop TB partnership have been signed in 18 countries, with an additional three agreements under review. Following initial visits, laboratory needs assessments and partner mapping were completed in 21 countries (plus one which was subsequently cancelled), and activities had been initiated in five category I and nine category II countries as of the end of 2010. The main activities currently implemented in the countries are capacity and needs assessments followed by arrangements to upgrade infrastructure (mostly laboratories), train staff and transfer technology - which also includes arranging and managing third-party support - and supply of new diagnostic products. Laboratories in six countries have implemented new TB diagnostics and are ready to deliver services, or have already progressed to routine diagnosis. Out of the 62,428 MDR-TB cases expected to be diagnosed in these countries through the project by the end of 2013, a total of **4,166 MDR-TB cases have already been diagnosed** and reported by these six countries (as of 31 December 2010).

Item	Description
Name	Narrowing the gap - Expanding and accelerating access to diagnostics for patients at risk of multi-drug resistant tuberculosis (MDR-TB)
Project summary	The overall objective of this project is to contribute to the improvement of the detection and management of TB and MDR-TB through the UNITAID-funded and managed establishment of well equipped laboratories in high burden countries and the supply of diagnostics.
Partners	GDF, GLI and FIND
Number of countries	27
Period	2008 - 2013
Budget	USD 87'562'000

2 Approach and Methods

This is a comprehensive external independent mid-term evaluation with an analysis of strengths, weaknesses, opportunities and threats (SWOT), including recommendations based on the findings of the evaluation.

The evaluation was conducted by a lead evaluator supported by a support evaluator responsible for preparing the project outline, compiling the data in the evaluation matrix and contributing to the other tasks in the evaluation process. The evaluators were supported by a financial expert, a procurement and supply management expert, the project leader and the project manager.

2.1 Evaluation Components

The evaluation had three components: (1) four common evaluation areas, (2) project-specific questions and (3) an assessment of the quality of reporting.

1. Common evaluation areas

The common evaluation areas have been provided in the RFP. They are compliant with the Organisation for Economic Cooperation and Development (OECD) evaluation criteria[i] and are defined as follows:

- **Relevance**: consistency between the activities of the project with the project plan and with UNITAID's objectives and strategy.
- **Effectiveness**: degree of achievement of the objectives of the project.
- **Efficiency**: relation between the efforts invested in carrying out the activities of the project and the results of the projects, mainly in procurement.
- **Impact**: effects of the project beyond the achievement of the short term objectives of the project.

For each evaluation area, 'questions', 'indicators', 'sources of information' and 'analytical methods' had been defined beforehand. 'Questions' were designed to unfold evaluation areas into items that could be described by quantitative or qualitative 'indicators'. For each indicator, sources of information where identified and the analytical methods to estimate each indicator were defined (see in Annex 2: Evaluation Matrix, Table 10 for the evaluation matrix for the common questions). All common questions were addressed consistently across all projects to minimise the risk of bias attributable to differences in the approaches by different evaluators.

2. Project-specific questions

UNITAID, in the RFP, proposed a series of project-specific questions. These questions were further adapted in discussions between the evaluators team, implementing partners and UNITAID secretariat. A full list of the project-specific questions is found in Annex 2: Evaluation Matrix, Table 11.

3. Quality of reporting

The evaluation team was alerted by UNITAID to the fact that programmatic and financial reports of projects sent to UNITAID might pose challenges in terms of their completeness,

consistency across projects and with the memorandum of understanding between UNITAID and the projects, and internal formal consistency (e.g., between the items formulated as objectives and as activities). Given that the evaluation of the project progress was mainly based on the information contained in semi-annual and annual programmatic and financial reports, reporting problems could affect the findings of the evaluation.

A guiding checklist was prepared to have a consistent assessment of the quality of reporting across evaluators and projects evaluated (Annex 2: Evaluation Matrix, Table 9).

2.2 Methods

1. Sources of information

The sources of information to conduct the evaluation were:

- MoU between UNITAID and the project implementing partners and other legal documents where appropriate, particularly the amended and restated MoU of May 2010 with annex and exhibits.
- Annual project progress report 2010 (1 January 2010 to 31 December 2010) submitted to UNITAID on 15 March 2011.
- Annual project financial report 2010 (1 January 2010 to 31 December 2010) submitted to UNITAID on 15 March 2011 as part of the annual project progress report 2010.
- Previous annual and interim progress reports.

2. Project outline

A preliminary reading of project documents suggested that not all projects were consistent in terms of what was considered to be an 'objective' and an 'activity', and in the links between them. The first step, therefore, consisted of creating a 'project outline' using a common log-frame[ii] to identify the objectives and the activities linked to them. An objective was defined as a statement which described what should be achieved at certain points in time and/or at the end of the project; an activity was defined as a description of the events that should occur in certain times and places, and involving certain people. Where possible, activities were linked to objectives, either based on the information contained in the reports or on the judgment of the evaluators. Any other information retrieved for the evaluation was references to the project outline. The project outline was adapted to reflect changes in the scope and objectives of the projects that took place in the course of implementation, ideally reflected in amendments to the MoU. The project outline included, among others:

- objectives and targets
- action plan (including dates and milestones)
- procurement plan
- budget and disbursement plan

3. Data extraction

Based on the log-frame, documents included in the evaluation were scrutinised to extract the relevant data for the evaluation. A set of templates were used to record the data and where necessary, tables were also copied into additional sheets. Data extraction followed the indicators attached to each evaluation question in the four evaluation areas and specific questions.

The publicly available WHO list of pre-qualified suppliers and the Management Sciences for Health (MSH) drug price indicator do not contain price information for MDR-TB

diagnostics. Instead, an effort was made to contact selected suppliers of such products to obtain market information and discuss the influence which the project had, and is likely to have, on the market. The contacted companies were **BD Europe** and **Hain Lifescience GmbH**.

The UNITAID TB portfolio manager, other UNITAID staff (Monitoring & Evaluation (M&E), financial) and representatives of the implementing partners GDF, GLI and FIND, have been contacted to discuss the project and clarify issues related to the availability, reporting and quality of data.

4. Analysis

The evaluation in each area was a composite of the evaluation of each question based on the indicators, as defined in the evaluation matrix. In the analysis, quantitative indicators were calculated and qualitative indicators formulated. When information to estimate an indicator was missing, this was made explicit to avoid confounding missing indicators with poor performance.

The evaluation of each area was accompanied by an assessment of the quality of the underlying data. Data was considered of poor quality when it was partial (e.g., describing what happened in one country but not in another one), when sources were not indicated, or when there were obvious inconsistencies not attributable to project performance (e.g., different figures for the same event in different reports).

When data is missing or of poor quality in a given evaluation area not much confidence can be placed on the truthfulness of the evaluation in reflecting the real situation of the project. On the contrary, when quality issues are minimal, the results of the evaluation can be reasonably trusted. The quality of the underlying data is explicitly described alongside the evaluation findings.

Efforts have been made to provide explanations to the findings, based on the available data - reasons for success and failure. Where it has been deemed that data was insufficient to provide reliable explanations, no attempt was made to extrapolate from other projects or to speculate based on anecdotal evidence.

A meeting was held between all evaluators and the project leaders to review the findings of the evaluations. The review process included the project outline, the indicators and the data analysis. Where necessary, findings were fine tuned to reflect the status of the project limiting those aspects that could be seen as subjective.

A rating was attached to each common evaluation area. The rating was qualitative and based on a consensus within the evaluators team, which included the evaluators of other projects. The rating had two parts - the proper rating of the evaluation area and an assessment of the quality of the underlying data to weight the confidence that can be put in the rating itself. For a guide to the rating scale and an interpretation of the different categories see Table 1.

Table 1. Rating of evaluation areas and quality of data.

	Definition	Interpretation
Rating scale		
Good performance	All indicators showed acceptable or positive results, according to the targets set	The project works as expected
Some concerns	Most of the indicators showed acceptable or positive results, but there were isolated cases where indicators suggested poor performance	The project needs minor adjustments to improve its performance or a further evaluation focusing on certain areas may be needed
Serious concerns	Most of the indicators showed poor performance.	The project needs crucial adjustments to improve its performance
Quality of data		
Good quality	Data to estimate all indicators was available without obvious inconsistencies	The rating reasonably reflects the true performance of the project
Moderate quality	Some data was missing or inconsistent, but most of the indicators could be estimated	It is possible that additional data might change the rating of the project
Poor quality	Most of the data was missing or inconsistent and only one or two indicators could be estimated	There is major uncertainty about the extent to which the rating reflects the true performance of the project

5. Validation exchanges with key stakeholders

Important question were shared and discussed with the UNITAID secretariat and the implementation partners. The aim of this exchange was to establish a common understanding of the project status, progress and key issues and to clarify open questions. An interview questionnaire was specifically developed for each meeting in order to focus on stakeholder relevant questions.

6. Analysis of project SWOT

The analysis of project SWOT was performed based on the analysis done along the evaluation matrix, differentiating internal factors that favour/hinder the implementation of the project (strengths/weaknesses) and external factors (opportunities/threats). It is a **summary** of the key factors influencing the achievement of the project's objectives.

Rather than being a formal fully-fledged SWOT analysis, the items identified in the frame of this mid-term evaluation are considered in a formal SWOT analysis of the project, in case such an analysis is undertaken.

7. Issuing of recommendations

Recommendations were issued by consensus of the team of evaluators involved in all projects, based on the findings of the evaluation. Recommendations prioritised what was understood as being the critical issues in each evaluation area and across all areas. Several options to address the critical issues were listed and assessed against two main criteria: (a) the available evidence that the recommendations would effectively address the critical issue identified; and (b) the feasibility of implementing the recommendation. Evidence was drawn from research, best practices or colloquial evidence. Recommendations were addressed to specific actors: projects implementation entities or UNITAID.

2.3 Project Specific

The process of drafting this mid-term review of the Expand-TB project closely followed the general outline presented above. In early 2011, background documents (MoU, progress reports) were obtained and reviewed, and a project outline was elaborated. The evaluation matrix was then completed based on the second interim programmatic and financial report finalized in October 2010. To obtain a current picture of project progress and base findings and recommendations on the latest information, it was imperative to stall the review process until the second annual programmatic and financial report became available. The evaluation matrix was updated based on this document, and meetings were arranged with representatives of all project partners, namely UNITAID, GDF, GLI and FIND, (see Annex 3: Stakeholders and People Interviewed) to clarify specific questions from the evaluators side, gain a deeper understanding of the project and discuss the perceptions of the partners of the project and its progress. These interviews were held in person during visits to Geneva (at least one visit/institution), by phone and by e-mail. The main obstacle during this evaluation was the delay until the annual report 2010 became available. The evaluators were impressed by, and acknowledged the commitment of all partners to the project, their efforts to provide information, answer questions and make themselves available for meetings and discussions.

3 Findings

This section is based on the findings recorded in the evaluation matrix template (Annex 2: Evaluation Matrix, Table 10). A summary of key findings is provided for each area in the boxes at the beginning of each section.

3.1 Relevance

The objective of this section is to assess whether activities implemented by the project are consistent with the initial project plan and in line with UNITAID objectives and strategy.

Rating	**Level of Confidence**
☐ Optimal	☐ Optimal
☒ Minor concerns	☒ Minor concerns
☐ Major concerns	☐ Major concerns

Key Findings

- All 13 activities (11 operational, 2 non-operational) are consistent with the project plan and its three objectives, and in line with UNITAID's overall goal, objectives and strategy.
- A detailed programmatic and financial reporting template with dedicated M&E and financial reporting sections has been developed and implemented. Reporting requirements are subject to change.
- A set of indicators measuring decisive project progress was developed and implemented. The number and definition of indicators varies between the project plan and different progress reports.
- Technical capacity and partner consultation appear to have been limited during the design and planning phase of the project.
- The initial project schedule was overly optimistic and implementation of diagnostic services is behind schedule. Problems to secure political commitment and infrastructure/security challenges were underestimated.
- The initial disbursement schedule and planned expenditure were not aligned. Until the end of 2010, 61% of the planned disbursements for the period were made (USD 37,553,128 out of USD 61,690,848). Actual expenditure (USD 9,267,469) was lower than planned, representing 31% of the planned budget for the period (USD 29,989,755). Thus, the disbursement schedule was not aligned with the budget and actual expenditure was also behind schedule.
- Project activities resulted in 4,166 MDR-TB cases diagnosed out of 62,428 in six project countries as of 31 December 2010 (total target for the six countries by project completion, end of 2013).
- Testing and reagent usage data reported by the countries are incomplete.

1. Are the activities and expected outputs of the project consistent with the objectives and expected outcomes as described in the project plan?

Project plan

The activities and expected outputs of the project are consistent with the objectives and expected outcomes as described in the project plan, with the exception of the proportion of funds allocated to LIC, LMIC and upper middle income countries (UMIC; see below). The MoU

and project plan are clearly structured and focus on a complex, but well-defined subject, namely, improving access to TB and MDR-TB diagnosis in low- and middle-income countries. The three objectives of the project stated in the MoU are supported by a total of 11 operational activities, all of which can be linked to one of the objectives (Table 2). An additional two non-operational activities related to M&E activities and reporting were defined and are implemented. There is no indication that certain activities are favoured over others, albeit the focus in this early phase of the project is clearly on fundamental activities, i.e., on providing the settings (laboratories) to deliver MDR-TB diagnostic services.

Table 2. Objectives and activities of the project *Expand-TB.*

	Objectives		Activities
1	Expand and accelerate access to quality assured new diagnostic technologies.	5.1	Beneficiary country selection process and definition of TB diagnostic services targets.
		5.2	Technical review by steering committee of the project.
		5.3	Agreements signed with the relevant authority of beneficiary programmes.
		5.4	Laboratory preparedness and implementation of new TB diagnostics.
		5.5	Procurement strategy and process for TB diagnostic instruments and reagents.
		5.6	Official purchase orders.
2	Impact market dynamics to leverage price reductions for diagnostic tools, instruments, reagents and supplies, and stimulate a greater number of suppliers of modern TB diagnostics.	5.7	Quality assurance of the diagnostics under this project, including potential future collaboration with the WHO Pre-qualification Programme.
		5.8	Engage and negotiate with industry to stimulate an increase in the availability of relevant diagnostics of assured quality and stimulate price reductions through economies of scale, tendering and long term agreements with suppliers of diagnostics.
		5.9	Stimulate an increase in number of quality assured diagnostics.
		5.10	Price reductions through economies of scale, tendering and long term agreements with suppliers of diagnostics.
3	Improve case detection and management of TB and MDR-TB by deploying all reasonable efforts to ensure the TB diagnostic tools supplied are taken up and properly used by National TB Control Programmes.	5.11	Laboratory preparedness, including involvement of Global Laboratory Initiative in-country and international partners.

The allocation of funds to LIC (37.5%), LMIC (59.7%) and UMIC (2.8%) is consistent with the global pattern of MDR-TB burden and health system capacities to treat identified MDR-TB cases. However, it markedly differs from the respective proportions generally targeted by UNITAID (LIC: >85%; LMIC: <10%; UMIC <5%).

The indicators defined in the project plan are aligned with the objectives of the project and allow measuring the project progress made over time. However, the precise formulation of several planned activities, and the number, formulation and definition of indicators to measure progress, have evolved, and continue to evolve in the process of developing and revising the M&E template which forms the basis for reporting by the partners (GDF, GLI, FIND). For four activities specified in the project plan, no indicators are proposed in the latest version of the M&E template (activities number 6, 7, 9 and 11; see Table 3).

Table 3. Activities and indicators of the project *Expand-TB*.

	Activities	Indicator 1*	Indicator 2*	Indicator 3*
5.1	Beneficiary Country Selection Process and definition of TB Diagnostic Services targets.	Per cent of budget allocated to LIC, LMIC, UMIC as per cent of the total budget.	Quantity of diagnostic instruments, consumables and supplies approved for supply to countries.	
5.2	Technical Review by Steering Committee of the Project.	Beneficiary countries approved for supply of new, quality assured TB diagnostic equipment, consumables and other essential supplies.		
5.3	Agreements signed with the relevant authority of beneficiary programmes.	Beneficiary countries with a signed agreement between FIND on behalf of WHO Stop TB and national health authorities.		
5.4	Laboratory preparedness and implementation of new TB diagnostics.	Laboratories assessed by FIND/GLI and identified as ready to introduce new diagnostic technologies.	Laboratory preparedness and implementation of new TB diagnostics. AND (separately) Per cent achievement of test performed in final consumption plan: 1. TB cultures performed; 2. No. of 1st and 2nd line DSTs 3. No. of LPAs	Per cent increase in the number of MDR TB cases detected.
5.5	Procurement strategy and process for TB diagnostic instruments and reagents.	New diagnostic technology supplied to eligible beneficiary countries with the timeframe set out by the PSC.	Average per cent of time that TB diagnostic equipment, reagents and consumables are in stock in countries.	
5.6	Official purchase orders.			
5.7	Quality Assurance of the diagnostics under this project including potential future collaboration with the WHO Prequalification Programme.			

5.8	Engage and negotiate with industry to stimulate an increase in the availability of relevant diagnostics of assured quality and stimulate price reductions through economies of scale, tendering and long term agreements with suppliers of diagnostics.	Existing manufacturers who have been briefed about the types of products and the projected market volumes to be funded by this project.
5.9	Stimulation of an increase in number of quality assured diagnostics.	
5.10	Price reductions through economies of scale, tendering and long term agreements with suppliers of diagnostics.	Per cent decrease in cost per patient diagnosis attributable to project (if possible, reflect pre- and post-negotiation prices).
5.11	Laboratory preparedness, including involvement of Global Laboratory Initiative in-country and international partners:	

* According to the 2nd annual programmatic and financial report, 01 January – 31 December 2010.

The constant evolution of the reporting template and requirements point to a deeper problem in the initial planning and design of the project, namely the absence of sufficient technical capacity and partner consultation when the MoU and reporting requirements were formulated. This point is also illustrated by the establishment of dedicated financial and M&E teams in UNITAID only after the project had been launched and activities assigned to partners which might pose a conflict of interest for them. (For the latter, see section 3.5 Project Specific Questions, point 2).

Project implementation

The implementation of activities in the project countries follows the project plan with regard to sequence and content, but is behind schedule in a number of countries. A detailed overview of the status of the project in the 27 project countries is provided in Annex 1: Project Progress per Country as of 31 December 2010, Figure 1. Provision of diagnostic services has begun in four of the six category I countries, namely Ethiopia, Lesotho, Myanmar and Uzbekistan. For the other two category I countries (Côte d'Ivoire and DRC), initiation of such services were planned for Q2, 2009 - as for the other countries in that group (in other words, delays of more than 1 ½ years have occurred). In DRC, political commitment represented by the signing of the MoU between national health authorities and FIND, providing for the waiver of import and customs duties and a prerequisite for project activities in any country, could not be secured. In Côte d'Ivoire, the precarious security situation following political instability forced prolonged suspensions of operational activities after the signature of the MoU.

Only two of the 18 category II countries, for which implementation of new diagnostic services was planned by Q2, 2011, have begun offering such services (India, Uganda). Signing of the required MoU between FIND and the national health authorities – a pre-requisite for all country activities with the exception of the needs assessment – was achieved in 13 category II countries. Negotiations for MoU signing are on-going in the three category III countries for which a deadline for MoU signing by Q4, 2011 has been set. Delays in MoU signing were most often attributable to disagreements about the tax-free import of goods (e.g., Kazakhstan, Belarus). Poor infrastructure, security problems and natural disasters have also delayed project implementation in a number of countries after the MoU had been signed (e.g., Haiti, Kyrgyzstan).

All activities in DRC (category I) and Zambia (category II) were cancelled in 2010, before an MoU was signed. Instead, two additional countries which requested inclusion in the project were proposed as replacements, namely Mozambique and Rwanda.

Mobilization of the required third party support to laboratory upgrading, training etc., was generally forthcoming as needed, and soliciting such support did not cause delays.

Project financing

The release of funds from UNITAID to the implementing partners was according to the original schedule until summer 2010 when further disbursements were halted to account for the major imbalance between disbursements and project expenditures. Accordingly, only 61% of the planned disbursements were made by the end of 2010 (USD 37,553,128 out of USD 61,690,848). The disbursement schedule was only loosely linked to the planned overall budget or approved yearly budgets. Indeed, disbursements at the reduced rate of USD 37,553,128 were still higher than both the originally planned budget until the end of 2010 (USD 29,989,755), and the approved budget until the end of 2010 (USD 32,023,376). The actual expenditures (USD 9,267,469) were much lower than anticipated, representing 31% of the planned budget, or 29% of the approved budget.

2. Is it possible to show how the project has contributed to UNITAID's overall goal of using innovative, global-market based approaches to improve public health by increasing access to quality products for treatment, diagnosis and prevention of HIV/AIDS, tuberculosis and malaria?

The project contributes to UNITAID's goal of using market-based approaches to improve public health by increasing access to quality products for diagnosis of TB, and especially MDR-TB, in resource-constrained countries. In the frame of the project, a total of 4,166 MDR-TB cases have already been diagnosed in six countries (Ethiopia, India, Lesotho, Myanmar, Uganda and Uzbekistan). Important to note, is that these were additional diagnoses directly attributable to project activities. To achieve this, the project established one or more state-of-the-art laboratories per country, thus establishing permanent infrastructure, and through the provision of training and mentoring, equipment and consumables, laying the foundation for the permanent availability of diagnostic services.

The reported number of diagnosed MDR-TB cases per country is based on data obtained from the diagnostic laboratories. Along with the numbers of diagnoses, laboratories also report on test performance and reagent usage while the number of supplies delivered to the country was available from the procurement agent. Reported numbers (tests performed, reagents used, diagnoses) are not verified by on-site data verification missions or physical inventory. The reported begin of MDR-TB diagnosis is not consistent with reported test performance and reagent use - data which the countries need to provide.

Among the 10 countries for which data on delivery, and sometimes use of diagnostic tools, was reported (Côte d'Ivoire, Djibouti, Ethiopia, Georgia, Haiti, India Kyrgyzstan, Lesotho, Myanmar, Uzbekistan), five have also reported diagnosed MDR-TB cases. The sixth country reporting diagnoses is Uganda. According to procurement data, liquid culture tubes have already been delivered to Uganda. Among the five countries where cases had been diagnosed and delivery data supplied, India did not provide information on the number of tests performed, reagents used or available stocks of diagnostics. Delivery of reagents to India was in December 2010, raising concerns whether the reported 740 MDR-TB cases can really be attributed to project activities. Ethiopia, Lesotho and Uzbekistan had reported the number of tests performed but other data (reagent use, stock) are based on theoretical calculations, i.e., the assumed amount of reagent used to perform the reported number of tests, and the delivered tests minus the assumed consumption to calculate the stock at the end of 2010.

Myanmar reported reagent use and the stock available at the end of 2010. Theoretical calculations based on the amount of diagnostics delivered, the reported number of tests performed and the assumed reagent use resulted in negative stocks in two countries: liquid culture tubes in Lesotho and line probe assay (LPA) in Uzbekistan. Negative values were explained by the use of available stock received before project initiation.

Georgia reported detection of MDR-TB cases, but did not provide numbers and did not report diagnostic test performance or reagent use.

3.2 Effectiveness

The aim of this section is to assess whether objectives of the project were achieved, and what the factors for achievement or non-achievement of those objectives are.

Rating	Level of confidence
☐ Optimal	☐ Optimal
☐ Minor concerns	☒ Minor concerns
☒ Major concerns	☐ Major concerns

Key findings

- Implementation of MDR-TB diagnosis is behind schedule in most project countries.
- 3.5% of the planned total number of MDR-TB cases to be detected through EXPAND-TB by the end of the project have been diagnosed. Since no annual diagnostic targets have been set, no benchmark exists to measure project progress against.
- Rapid scale-up of diagnostic services is observed once laboratory preparedness has been achieved.
- In project countries, no connection is apparent between the pace of progress at early stage of the project and pace of progress at late stage of the project.
- Price reductions of key diagnostic items have been partially achieved (minus 11.4% for liquid culture tubes, minus 2% for LPA).
- Limited purchase volume per item and small number of suppliers for key diagnostic items restrict impact on diagnostics market dynamics.
- Flexible project with scope for adjustment.
- Active participation of donor (UNITAID) in project management is unusual but beneficial.

3. To what extent were the objectives of the project achieved?

Diagnosis of MDR-TB cases I

The objectives of the project were to diagnose approximately 120,000 MDR-TB cases, achieve price reductions for diagnostic tools and increase the number of suppliers of relevant diagnostic tools.

By the end of 2010, a total of 4,166 MDR-TB cases had been diagnosed in the frame of the project in six countries out of the target number of 62,428 over the entire duration of the project (Table 4). Among these six countries were four category I countries for which implementation of diagnostic services were planned for Q2 2009 (See above for the reasons for delays in the other category I countries, namely Côte d'Ivoire and DRC.) The target date for category II countries is Q2, 2011 (current status: two countries implementing diagnostic

services) and for category III countries, Q3 2012 (current status: no countries implementing diagnostic services).

The 4,166 identified MDR-TB cases represent 3.5% of the 119,667 cases planned to be diagnosed through the project by its conclusion. Note that the MoU contains two estimates of the number of MDR-TB cases to be diagnosed in the frame of the project, specifically, 119,669 as the sum of the per-country estimates, and a global number of “approximately 129,000”.

In countries which implemented the provision of diagnostic services, the fraction of diagnosed cases versus planned diagnoses is 6.7%.

Table 4. Planned number of MDR-TB cases to be diagnosed over the entire duration of the project and number of MDR-TB cases diagnosed by the end of 2010, per country.

Country	Planned number of MDR-TB diagnoses (entire project)	Achieved number of MDR-TB diagnoses (since start of the project until end-2010)
Category 1		
Lesotho	176	274
Ethiopia	4,660	443
Côte d'Ivoire	1,922	
Myanmar	3,401	90
Congo Dem. Rep.	5,635	*Cancelled*
Uzbekistan	7,863	2509
Category 2		
India	45,684	740
Azerbaijan	1,918	
Georgia	522	
Kazakhstan	5,286	
Kyrgyz Republic	1,094	
Rep. of Moldova	1,628	
Tajikistan	2,563	
Belarus	877	
Peru	2,616	
UR Tanzania	1,664	
Haiti	476	
Djibouti	329	
Uganda	644	110
Cameroon	495	
Zambia	750	*Cancelled*
Senegal	1,000	
Kenya	1,766	
Swaziland	181	
Category 3		
Bangladesh	11,666	
Indonesia	9,714	
Vietnam	5,137	
Total (all countries)	**119,667**	**4,166** **Percentage of planned: 3.5**
Total (countries where MDR-TB diagnosis has started)	**62,428**	**4,166** **Percentage of planned: 6.7**

MDR-TB diagnostics market I

As shown in Table 5, the baseline price of the liquid culture tubes (BBL MGIT™ (myconacterium growth indicator tubes) for Bactec™ MGIT™ 960) procured by the project was USD 220/100 tubes. In 2010, liquid culture tubes for a total value of USD 319,215 were procured at a fixed price of USD 195/100 tubes, i.e., 11.4% lower than the initial price.

The reduced price was negotiated by FIND before the first procurement order was placed and no further price changes were recorded over the duration of the project. The price of the LPA (Hain DST MTBDR) at project initiation was EUR 316.80/96 tests, or approximately USD 480/96 tests. The total value of tests procured for the project was USD 160,692, and tests were bought at a median price of USD 470.40/96 tests (minimum price: USD 436.80; maximum price USD 527.52; weighted average USD 467.13/96 tests). This represents a reduction in USD terms of 2.0% from the initial price when considering the median price paid. At the same time, the price in EUR increased by 6.1% to EUR 336.00/96 tests. No information is available on the MPT64 rapid speciation for TB culture test, as no respective orders have were by the end of 2010.

Table 5. Procurement and price changes of key diagnostic products.

Product	Initial unit price	Median unit price	Decline	Amount procured
BBL MGIT™ tubes	USD 220/100 tubes	USD 195/100 tubes	11.4%	USD 319,215
Hain DST MTBDR	EURO 316.80/96 tests (USD 480)	USD 470.40/96 tests	2.0%	USD 160,692

There is no evidence of new products being developed or having been launched in response to the project. It is planned to launch a competitive bidding process for LPA in 2011 and two additional manufacturers of LPAs have been informed of the project and the upcoming competitive tender. Also, two additional manufacturers of rapid speciation assays have been identified. No additional manufacturers of liquid culture tubes are known to the project.

4. Based on the results at mid-term, to what extent are the objectives of the project likely to be achieved?

Diagnosis of MDR-TB cases II

Any predictions of the likelihood of achieving the objectives are very uncertain, as in most of the project countries the project is still in the phase of creating the conditions to deliver diagnostic services. While rapid progress has been achieved in certain project countries, the pace is very slow in others, and important changes have been proposed for deliberation at the upcoming board meeting in 2011, i.e., the replacement of the two project countries DRC and Zambia with Mozambique and Rwanda, and the trial introduction of the GeneXpert® in a number of countries.

No direct connection is apparent between political commitment (rapid MoU signing) and otherwise supportive conditions (e.g., local infrastructure, human capacity, security situation) and hence, it is not possible to predict the progress of the project in any given country based on the speed with which the initial agreement had been signed. Examples for countries with a complex political situation but rapid project implementation are Myanmar and Uzbekistan. A similar scenario is anticipated in other countries where MoU signing is currently pending, e.g., in Belarus. In some countries, political support has easily been obtained but weak local management, human resources and infrastructure massively delay project implementation. Recent developments suggest project implementation might accelerate in a number of countries, including Côte d'Ivoire (category I) and Kyrgyzstan (category II) where the security situation has improved, and Belarus where political commitment has become more apparent. The potential progress in Rwanda and Mozambique, the two countries replacing DRC and Zambia, might also be expected to be quick given that the countries specifically requested inclusion in the project.

The available data from countries which have achieved the stage of laboratory preparedness and implementation of new MDR-TB diagnostics, point to generally rapid scale up and expansion of diagnostic service provision, even from a very low base. Overall, only 3.5% of the total number of MDR-TB cases to be diagnosed in the frame of the project has already been diagnosed. Because as of 31 December 2010, only six countries reported diagnosed MDR-TB cases, the available data for projecting needed progress to achieve the end of 2013 targets is limited.

Table 6 provides an overview of the number of MDR-TB cases detected in the six project countries in the periods of January-June 2010 and July-December 2010, and offers a linear projection of the number of MDR-TB cases to be diagnosed by the end of 2013 assuming the pace of detection achieved in the second half of 2010 is maintained. In general, it is clear that there is a need for massive acceleration of diagnostic activities to achieve the planned number by 2013, with India's degree of progress being crucial.

Based on the six countries with reported cases, the following can be stated:

- Lesotho has already surpassed the projected number of MDR-TB cases to be diagnosed in the frame of the project and anticipates diagnosing almost the same number of MDR-TB cases in 2011, as in 2010. Based on the number of achieved and planned diagnoses, a similar scenario (i.e., surpassing the country target) is likely in Uzbekistan and Uganda. Uzbekistan and Uganda also aim at doubling the number of diagnoses from 2010 to 2011.
- Ethiopia, Myanmar and India need to rapidly accelerate detection of MDR-TB cases. According to the progress report 2010, Myanmar expects to diagnose 50 times more MDR-TB cases in 2011 compared to 2010 - a number above the target for the duration of the entire project. No explanation has been offered how such a high number of MDR-TB diagnoses could be achieved. Ethiopia and India also plan a massive increase of diagnostic activities in 2011 compared to 2010 (Ethiopia: five times more; India: 11 times more). Reaching the testing targets thus, appears ambitious. India is planning to diagnose about 8,000 cases in 2011, bringing the total number of diagnosed cases to less than 20% of the expected total number of cases in 2013. Ethiopia aims at having a bit less than 30% of the planned total for the project diagnosed by the end of 2011.

Coming anywhere close to the planned number is unlikely in a number of other project countries where project activities have been and continue to be delayed. It is also possible that further countries need to be cancelled from the list of project countries if political support is not soon forthcoming (e.g., Kazakhstan). Considering the absolute number of planned diagnoses and the relative share of different countries therein, the final result will be largely driven by the progress made in India (a category II country) and Bangladesh (a category III country). These two countries account for nearly half (48%) of all planned MDR-TB cases to be diagnosed.

Table 6. Number of MDR-TB cases detected per country and linear projection of diagnosed MDR-TB cases to end-2013 for countries already reporting MDR-TB diagnosis.

Country	Cases Detected by 31 Dec 2010	Cases detected Jan-June 2010	Cases detected July-Dec 2010	Cases detected by end 2013 if July-Dec 2010 detection rate is unchanged*	Target for end 2013	Conclusion
Lesotho	274	0	158	**1,222**	176	Target exceeded
Ethiopia	443	89	172	1,032	4,660	Acceleration needed
Uzbekistan	2,509	462	1,086	**9,025**	7,863	Target likely to be exceeded
India	740	0	740	5,180	45,684	Acceleration needed
Uganda	110	0	110	**770**	644	Target likely to be exceeded
Myanmar	90	0	90	630	3401	Acceleration needed

* Formula: "Cases detected by 31 Dec 2010" + ("cases detected July – Dec 2010" x 6)

MDR-TB diagnostics market II

The impact of the project on the MDR-TB diagnostics market is unclear and projections are very uncertain. By the end of 2010, relatively minor amounts of diagnostics were procured, as the bulk of the purchasing expenses were directed to funding equipment, general laboratory supplies and training, which are all required to create the basic conditions to implement diagnostic services. A substantial price reduction of 11.4% was acquired for liquid culture tubes during negotiation of the conditions for the first purchasing order. With regard to the LPA, the price paid remained basically stable while it increased by 6.1% on the open market. A major LPA price issue is the unfavourable exchange rate development, which made LPA - which is priced in EURO - relatively more expensive in USD.

In a phone interview, a representative of BD Europe responsible for TB diagnostics appeared well aware of the project Expand-TB and confirmed that an increase in purchase quantity will result in a decline in prices per unit. However, since Expand-TB is not the only initiative funding the purchase of MDR-TB diagnostics, it is difficult to determine the contribution of Expand-TB to price reductions. BD Europe is the only producer of liquid culture tubes (MGIT™) and thus, competition in the market is indirect: less liquid culture tubes will used once LPA and GeneXpert® are routinely used. However, once GeneXpert® shows rifampicin-resistance, liquid culture will still be needed to check for resistance against the other drugs. Similarly, once LPA shows rifampicin-resistance and/or isoniazid-resistance, liquid culture is then needed to check for resistance against the other drugs.

A phone interview with David Hain from HAIN Lifescience GmbH resulted in the following observations:

1. The company sees its TB engagement as part of its corporate social responsibility.
2. Currently, the EXPAND-TB project has no influence on the companies' production capacity or planning. Indeed, the number of LPA tests ordered so far is lower than anticipated.
3. When told that with project progress, there may well be an expansion of the number of tests to be ordered, Mr. Hain mentioned that once the numbers reach the millions it becomes interesting for the company and a price reduction might be possible,

although the current prices are already very low. The company reportedly has no margin on equipment while that of reagents is small.

4. The company has information that, while currently being the only manufacturer of LPA, some companies try to "copy" their products. However, the company is confident that its more than 10 years of experience with LPA afford it a major advantage in terms of quality and reliability of its products.
5. The contracts with EXPAND-TB relate to goods, but do not cover services to be provided by Hain. The company would be willing to provide on-site problem solving assistance.
6. The company suggests that technical collaboration with FIND be strengthened, as its people know its products and how to address challenges best. Such assistance need not be profit driven.
7. The company has good distribution agents in many countries and suggests that they take over certain tasks from FIND, as they generally have good technical and local knowledge.
8. The company recently released a version 2 of the LPA which is easier to use. It recently sent a draft agreement to FIND for the updated version.

A number of other issues also need to be considered:

- The amount of funds earmarked per item is relatively small, as a range of diagnostic tools and a multitude of general supplies and infrastructure/equipment has to be purchased, limiting leverage over pricing for individual items.
- The number of producers of the core diagnostic products is small, limiting the scope for competition between suppliers. Indeed, no competitive tenders have yet been launched (the first is planned for the purchase of LPA in 2011). In the case of liquid culture tubes, only one producer has been identified (BD Europe). For LPA and rapid speciation tests, alternative suppliers exist.
- The selection of a particular testing platform (e.g., BD BACTEC™ MGIT™ 960 System) limits the choice between consumables and supplies to those which are compliant with the selected platform.
- TB diagnostics is a relatively marginal field in the portfolio of the producers, limiting their incentive to compromise on price to remain in the market. However, according to a representative of BD Europe, suppliers reportedly consider price reductions out of philanthropic, corporate responsibility, image or public relations considerations and figure that philanthropy and the resulting good image also create business opportunities.

5. What are the main factors influencing the achievement or non-achievement of the objectives?

Diagnosis of MDR-TB cases III

The available evidence suggests that the following items are decisive factors for the **successful implementation** of the project in a country:

- Political commitment, as expressed in the form of rapid signing of the MoU between FIND and the relevant national authorities.
- A minimum quantity and quality of existing infrastructure in the country (institutions hosting MDR-TB testing laboratories, laboratory space, general infrastructure including technical capacity for laboratory upgrading works) and human capacity (technical, managerial, know-how for laboratory upgrading works).

- The availability of third-party funding and the ability and commitment to rapidly build up the needed infrastructure in a country.

Delays in project implementation were caused by opposing factors, namely:

- Delays in MoU signing, which were most often due to disagreements between the project and national health authorities on one side, and finance or customs authorities on the other, about the tax-free import of goods.
- Poor physical infrastructure and lack of human capacity (technical, managerial), and lack of technical know-how and capacity for laboratory upgrading works.
- Security problems (revolutions, unrest, etc.).
- Natural disasters (e.g., earthquakes).

MDR-TB diagnostics market III

No statement regarding the main factors positively influencing the **achievement** of market impact targets can yet be made.

The following factors have been identified as **potential threats** to the achievement of the market impact targets:

- The procurement volume per item is limited, as a high number of different items are procured, often in relatively low quantity.
- Many items are general laboratory supplies for which the volume procured by the project is minute compared to the overall market of that item.
- MDR-TB diagnostics generally do not represent core products for producers, limiting the leverage of the project in price negotiations.
- Some core diagnostic products are produced by a single supplier, while for others only a small number of suppliers exist, limiting competition. Of note is that the most significant price reduction achieved so far was for an item for which only a single producer exists.
- Unfavourable exchange rate fluctuations can mask even substantial price reductions if no measures to hedge prices are taken.

Project as a whole

The ultimate achievement of the objectives of the project is rendered more likely by the flexible structure and approach of the project, which is generally guided by the principle of "learning by doing" and "continuous learning". The active involvement of the donor (UNITAID) in regular project management meetings (PMM) has been identified by the implementing partners as unusual but highly supportive for the project. Lastly, reliance on dedicated implementing partners who are responsible for only those activities corresponding to their core competence assures the availability of the necessary expertise and skills to successfully implement the project.

The Inception report 2008 (dated 15 March 2009) contained a detailed table on assumptions and risks, outlining perceived risks for the project, their likelihood, impacts and mitigation measures. The use of this table was discontinued in subsequent reports, and consequently, no updated version of a risk management plan currently exists. Formal risk management and documentation thereof is expected to resume with the introduction of a revised reporting template, structured according to the log-frame approach.

3.3 Efficiency

The objective here is to assess if the partners are using UNITAID funding in the most efficient manner to achieve the objectives of the project. This covers aspects surrounding the procurement model, coordination with national authorities and other aspects of implementation arrangements depending on the project.

Rating	Level of Confidence
☐ Optimal	☐ Optimal
☒ Minor concerns	☒ Minor concerns
☐ Major concerns	☐ Major concerns

Key Findings

- MoU signing proved a major obstacle to launching project activities in several countries (tax-free import of goods was a key issue of contention).
- A procurement Standard Operational Procedure (SOP) has been developed and is updated based on gained experience.
- The procurement model with a procurement agent managed by GDF is implemented as planned. GDF questions whether the current arrangement is the most efficient.
- Exchange rate fluctuations markedly influenced paid prices for LPA (invoiced in EUR) while liquid culture tube prices were within budget.
- Average procurement lead times were at the upper limit or exceeded self-set targets for core diagnostic products. Large differences between countries exist.
- No core diagnostics stock-outs have been reported by project countries.

6. Are the project partners working closely with the relevant national authorities in the projects' beneficiary countries? (where applicable to the project)

The project is designed to working closely with the relevant national authorities in the project countries. A MoU between the national health authorities and FIND forms the basis for all project activities in the respective country, and National Reference Laboratories (NRL) for TB are the location of choice for the establishment of MDR-TB diagnostic services. In certain countries, additional laboratories are selected for support by the project. Such secondary institutions may be either public or non-governmental.

MoU's have been signed in five out of six category I countries (target date for signature: Q2, 2009; Annex 1: Project Progress per Country as of 31 December 2010, Figure 1). A MoU has not been signed with DRC, which has now been cancelled from the list of project countries. The number of category II countries which have signed the MoU is 13 out of 18 (target: Q3, 2011). Zambia, one of the category II countries without a signed MoU, has also been cancelled. MoU signature in category II countries is still pending in Kazakhstan, Belarus, Peru and UR Tanzania. None of the three category III countries (Bangladesh, Indonesia, Vietnam; target: Q4, 2011) has signed a MoU.

7. Is the project's procurement model well defined and designed to identify and solve procurement-related problems as they arise?

Procurement

A procurement SOP was developed following the launching of the project. The first version of the procurement SOP was approved in 2009 and formally presented in the 2010 annual report. This SOP is constantly updated and refined based on experience.

The Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ or German International Cooperation) business area, GIZ International Services, acts as the procurement agent of GDF. After re-tendering in 2010, the contract was re-awarded to the same institution on 1 May 2010. GIZ International Services provides delivery services to the project countries through the freight forwarding agent Geis/SDV GmbH. GDF expressed concern whether the current arrangement is efficient and whether there might be cost savings (e.g., procurement agent fee) and/or efficiency gains (e.g., shorter ordering lead times) if the arrangement were to change, e.g., GDF acting as procurement agent. The procurement model and performance of the procurement agent were not specifically analyzed in the frame of the current mid-term review. However, during the general review no data or information was encountered that suggested flaws in the current model, or unsatisfactory performance of GIZ International Services. Considering this and the administrative challenges associated with GDF, as part of the UN system, acting as procurement agent, it was concluded that the functioning procurement model should not be changed in order to not jeopardize project implementation.

Price of MDR-TB diagnostics

The median price of the core diagnostic products procured in the frame of the project is in line with the budget. Liquid culture tubes have been procured by the project for USD 195/100 tubes, i.e., 11.4% below the price negotiated by FIND at project initiation. The median price of LPA was USD 470.40/96 tests, 2% below the price negotiated by FIND before the launching of the project (USD 480). The costs for this product in EUR, the currency in which it is sold, increased from EUR 316.80 at project initiation, to the current level of EUR 336.00.

Lead time

The recorded lead times in 2010 for the delay from placing a purchase order, to the receipt of the health products in-country, was near the upper margin of the target lead time which was set at 37-82 days. The mean lead time was 80 days for liquid culture tubes and 88 days for LPA. Freight lead times were only seldom longer than the planned 3-12 days, but both ordering and supplier lead times were frequently exceeded. Time overruns occurred in most countries for both products at one point or another. The most notable problems were encountered in deliveries to Djibouti, Ethiopia, Georgia and India, for which both the ordering and the supplier lead times had been exceeded for at least one product.

Despite these delays in the procurement process, no stock-outs had been reported by the six countries which already diagnose MDR-TB cases.

Regarding lead times and overruns thereof, GDF emphasized that it must also be considered that long lead times can not always be equated with a weak supply chain. For example, a long ordering or supplier lead time might indicate long-term planning and pro-active action, (i.e., good planning and forecasting capacity) as future needs are identified and communicated well in advance of the urgent need for the product in question (resulting in long ordering lead time), and corresponding orders are placed for those goods to be delivered well in the future (resulting in long supplier lead time). In this regard, emergency and urgent orders, (which indicate weak planning and forecasting capacity of the order placing entity) and delays from the agreed delivery time (which indicate weaknesses at the level of procurement agent, producer or freight forwarder) are more significant, as they always entail the risk of stock-outs.

3.4 Impact

The objective is to assess to what extent it is possible to demonstrate the impact of UNITAID funding in the target countries

Rating	Level of Confidence
☐ Optimal	☐ Optimal
☒ Minor concerns	☐ Minor concerns
☐ Major concerns	☒ Major concerns

Key Findings

- Significant information (diagnostics purchased, number of cases diagnosed) is available on a per-country basis.
- According to GLI, the reported numbers pertain to project activities only (e.g., number of MDR-TB cases diagnosed).
- Reported numbers for specific items (e.g., amount of diagnostics procured) mentioned in different parts of the annual report do not match.
- There is no independent verification of reported numbers.

8. Can the partner organization attribute UNITAID funding to medicines and diagnostics purchased and patients treated by beneficiary country in a timely manner?

Indicators are either reported for the project or, if feasible, also stratified by individual project country (e.g., number of diagnosed MDR-TB cases, number of diagnostics procured and delivered). It has been pointed out that all numbers pertain to project activities only (e.g., number of MDR-TB diagnoses supported by the project versus national number of MDR-TB diagnoses).

Information on procurement (quantities ordered, quantities delivered) is directly available but all in-country information (e.g., reagents used, stock, no. diagnosed) is provided by the testing laboratories and not subject to on-site verification.

Relevant progress data of the project as of 31 December 2010 is listed in Table 7. Note that all information presented here is discussed in detail in the preceding sections 3.1 - 3.3.

Table 7. Relevant progress data of the project as of 31 December 2010.

Item	Achievement by end 2010
Initial assessment visit of country	22 out of 27 countries
MoU between national health authorities and FIND signed	18 out of 27 countries
New TB diagnostic services implemented in ≥1 laboratory	6 out of 27 countries
Number of MDR-TB cases diagnosed	4,166 out of 119,669 MDR-TB cases (3.5%)
Disbursement rate	61% (USD 37,553,128 out of 61,690,848)
Expenditure rate	29% (USD 9,267,469 out of 32,023,376)

3.5 Project Specific Questions

1. Can you demonstrate that the MDR-TB in-vitro diagnostics market has expanded?

It is currently not possible to demonstrate that the MDR-TB in-vitro diagnostics market has expanded in response to the project. The project began procurement of diagnostic tests in 2009 on a small scale and expanded procurements in 2010 when liquid culture tubes for a total sum of USD 319,215 were acquired and LPA for USD 160,692. Possible reasons for the failure to trigger an expansion of the MDR-TB in-vitro diagnostics market are listed in section 3.2., MDR-TB diagnostics market II and III.

No competitive tendering has yet been conducted for all the products due to be procured in the frame of the project. For liquid culture tubes, a single supplier is known to the project. For LPA and rapid speciation tests, two additional suppliers have been identified for each product. The launching of competitive tenders is planned for 2011.

In the annual progress report 2010, project partners suggest the introduction of the GeneXpert® MTB/RIF assay in six countries (45 systems; 20 for India and five for each Uzbekistan, Ethiopia, Lesotho, Uganda and Azerbaijan) with matching support provided by GDF (Stop TB budget). This would promote a promising new diagnostic technique, and support by a high-profile project such as Expand-TB could prove to be a decisive factor for the acceptance and spread of this new tool, leveraging the proposed bulk procurement to bring down prices in the future.

2. How has the pool of quality manufacturers been enlarged?

The WHO Prequalification Program currently does not cover MDR-TB diagnostics and relevant discussions for their inclusion are not documented in the Progress report. Instead, WHO endorses specific diagnostic techniques, e.g., LPA or the GeneXpert®. FIND has negotiated preferential terms for the purchase of diagnostic items with three manufacturers (BD Europe, Hain Lifescience GmbH).

There is currently no evidence for the emergence of new manufacturers of MDR-TB diagnostics in response to the project. Two additional manufacturers have been identified for each LPA and rapid speciation tests, but as of yet, neither procurement orders from alternative suppliers (LPA) nor relevant orders at all (rapid speciation tests) have been placed. For liquid culture tubes, no alternative to the single manufacturer identified so far is known to the project.

Of significance is the arrangement described in the MoU according to which GDF and FIND identify and contact potential manufacturers to promote the project and competition in market places where a potential conflict of interest could arise, as GDF also manages the procurement agent of the project. Additionally, GDF does not have the necessary technical expertise in diagnostics but FIND does.

3. How is the project facilitating the creation of new markets for diagnostic tools through the establishment of new quality assured laboratories in project countries?

The project aims at establishing in every project country, one or multiple high-quality MDR-TB diagnosis laboratories and train the required staff. While some project countries already implemented MDR-TB diagnosis before Expand-TB was launched, in other settings no such facilities existed before, or they had fallen into disrepair, or were limited in service provision by a lack of consumables, capital investment or both.

Through its activities of providing training, equipment and consumables to beneficiary countries the project directly and immediately contributes to the creation and enlargement of the market for MDR-TB diagnostic tools, as this immediate additional demand for MDR-TB diagnostics has to be satisfied. However, overall the direct impact of the project on the market is expected to be limited in the short term (see section 3.2, MDR-TB diagnostics market II and III). In the longer term, this project is expected to stimulate the market by expanding the number of laboratories which, even after project termination, continue purchasing diagnostic tools and consumables through national funds - unless the lifetime of the Expand-TB project is extended or another funding source takes over its current activities. Finally, the project sets quality and quantity benchmarks for other countries by establishing at least one quality assured MDR-TB diagnosis laboratory per country. It also contributes to local cost savings, as currently, samples are often sent to other countries for diagnosis at high cost, thus limiting the number of diagnoses that can be done. However, the sustainability of the project is not assured - substantial funds will be needed to secure the functioning of the laboratories established by the project, in addition to the expansion of services. It is questionable whether all project countries will be in a position to fund operations of their laboratories after project termination, albeit some certainly could, provided that political commitment is high and sustained, and operation of MDR-TB diagnostic laboratories is included in the national TB control plan. It is also unclear whether follow-up funding could be secured from international donors other than UNITAID.

4. Can the project show that it has been successful in negotiating 5-10% price reduction of TB diagnostics in resource limited settings, based on the forecasted uptake volume of new diagnostics?

The impact of the project on the MDR-TB diagnostics market is unclear and projections are very uncertain. (See chapter 3.2 Effectiveness and particularly Table 5 for full details.) The baseline price of the liquid culture tubes (BBL MGIT™ tubes for Bactec™ MGIT™ 960) procured by the project was USD 220/100 tubes. In 2010, the median price paid by the project was 11.4% lower than the initial price, i.e., USD 195/100 tubes. The reduced price was negotiated by FIND before the first procurement order was placed and no further price changes were recorded over the duration of the project. The price of the LPA (Hain DST MDR-TB) at project initiation was EUR 316.80/96 tests or approximately USD 480/96 tests. Tests were bought at a median price of USD 470.40/96 tests. This represents a reduction in USD terms of 2.0% from the initial price. At the same time, the price in EUR increased by 6.1% to EUR 336.00/96 tests. No information is available on the MPT64 rapid speciation for TB culture test, since no respective orders were placed by the end of 2010. In conclusion, no direct market impact of the project can be demonstrated at the time of the review.

5. Additional considerations

An area of concern is the proper treatment of all diagnosed MDR-TB cases required for ethical reasons and to achieve the ultimate goal of the project, namely a reduction of MDR-TB transmission. MDR-TB treatment, including treatment of side-effects, is costly and requires specialized medical capacity. According to its mission and objectives, UNITAID is unable to fund programmatic work. However, it provides a limited amount of drugs to treat MDR-TB through its project, "MDR-TB Scale-up and Acceleration of Access" which plans to fund treatment for 15,606 MDR-TB cases in 17 countries between 2008 and 2012 with roughly half of the treatments in India. This represents 13% of the number of MDR-TB cases expected to be diagnosed in the frame of the project Expand-TB.

National Reference Laboratories have teamed up with a Supranational Reference Laboratory (SNRL) which commits to providing external quality assurance and training. An SNRL often also assumes additional technical support functions. As the project boosts the number of MDR-TB laboratories, the demand for supervision, training and support through SNRLs will also increase. However, a very limited number of the designated SNRLs dispose of the means to fulfil their roles, not to mention assume additional responsibilities. A limited, but insufficient amount of funds has been made available by the WHO and other donors to support SNRLs. Additional funding is urgently needed.

3.6 Comments on Reporting Arrangements

Rating	Level of Confidence
☐ Optimal	☐ Optimal
☒ Minor concerns	☐ Minor concerns
☐ Major concerns	☒ Major concerns

Key Findings

- A detailed reporting template exists for both programmatic and financial reporting.
- Repeated revisions have introduced additional indicators, changes to indicator definitions, and targets which do not follow the logic and stipulated sequence of project activities.
- Programmatic and budget projections are not required.
- There is no consolidation process to detect inconsistencies between different sections of the report.
- Reported performance and expenditure is not verified and disbursements are not linked to performance.

General

A detailed reporting template consisting of a structured narrative section in MS Word, a numerical section in MS Excel for financial reporting and a numerical/graphical section in MS Excel for programmatic reporting were developed by UNITAID and completed by GDF, GLI and FIND as appropriate.

The template has repeatedly been revised and updated to comply with perceived data and information needs of UNITAID. The report templates ask for a considerable level of detail in reporting, but not all indicators are meaningful or carefully formulated (e.g., in procurement and financial reporting), and certain target dates are in illogical sequence considering the stipulated sequence of project activities (e.g., MoU Reference 5.3 deadline for country MoU signing is later than the MoU Reference 5.4.2.1 deadline for laboratory preparedness and implementation of new TB diagnostics), possibly a result of repeated revisions. Also, an

evolution of the number of indicators and their exact definition is noted between the MoU and different progress reports with a tendency towards increasingly comprehensive and complex reporting. No projection of programmatic and financial performance in the following period and by project conclusion is requested.

Reports also serve as a conduit for official requests for programmatic change by the partners, e.g., the cancellation of project countries or the introduction of additional diagnostic tools such as the GeneXpert®, for consideration by the board.

Reports are submitted before, or on fixed report submission dates, and satisfactory submission is a pre-requisite for further funds disbursements. Submitted reports are reviewed by UNITAID (TB portfolio manager, M&E and finance teams), including an assessment of internal consistency and data quality, and clarifications are requested from partners as needed. However, the answers to such requests for clarification are not formally documented e.g., in the form of a revised report.

Programmatic reporting

The programmatic reporting is detailed and structured both by country and by area of activity, in part, following the structure of the MoU and providing updates on planned activities and responsibilities. The programmatic report also provides information on project activities, procurement and achievements in the respective project countries. However, the absence of a consolidation process has allowed the reporting of different values pertaining to the same indicator in different sections of the report (e.g., number of tests procured overall and per country), limiting the level of trust to be placed in numbers and their further use for secondary analyses.

Table 8 provides an overview of key project performance indicators, namely the number of MDR-TB diagnoses per country, and the number of liquid culture tubes and LPA delivered per country. Note that not all numbers in the different sections of the report agree.

Table 8. Key project performance indicators as reported in different sections of the annual report 2010.

Country	MDR-TB diagnoses (since start of project)	Liquid culture tubes delivered (since start of project; packs of 100)		LPA delivered (since start of project; packs of 96)	
Year	2009-2010	2009-2010 [1]	2010 [2]	2009-1010 [1]	2010 [2]
Côte d'Ivoire	0	34	0	4	0
Ethiopia	443	96	45 [2] / 40 [1]	19	9
Lesotho	274	125	40	25	15
Myanmar	90	174	174	10	25 [2] / 10 [1]
Uzbekistan	2509	100	100	5	5
India	740	308	308	111	204 [2] / 111 [1]
Georgia	-	140	140	10	10
Kyrgyzstan	0	0	0	10	10
Haiti	0	25	55 [2] / 25 [1]	3	8 [2] / 3 [1]
Djibouti	0	40	40	4	4
Uganda	110	-	64	-	-
Total	**4166**	**1042**	**966** [3]	**201**	**290** [3]

[1]Annual Report 2010; 5.4.2 Diagnostics performed

[2]Annual Report 2010; Procurement M&E Country (data for 2010)

[3] Annual Report 2010; Procurement M&E Reagents Price (data for 2010): 1341 liquid culture tube packs delivered; 338 LPA packs delivered

Financial reporting

The financial reporting is detailed, showing both planned/approved and actual expenditures, and common budget items can be readily identified. However, disbursements were not according to actual project progress until the first half of 2010, when further disbursements were halted to account for the build-up of uncommitted funds with partners attributable to slower than expected project implementation. There is also no indication that disbursements were adjusted to account for budget revisions.

GDF, as part of the WHO, is subject to UN accounting rules. FIND generally follows these rules, although it is not a member of the UN system. Interest earned on bank accounts is not consistently declared and deducted from disbursement requests (FIND: yes; GDF/GLI: no). Interests earned can be used to cover general expenses and as buffer funds, e.g., to balance exchange rate losses. To declare interest, partners need to apportion their interest income according to the fraction of project funds relative to the total funds in their accounts, because no project specific bank accounts exist. Consequently, also no bank statements are submitted to support the reported account balances.

3.7 Projects Strengths, Weaknesses, Opportunities and Threats (SWOT)

Listed below are essential items identified in the frame of this mid-term evaluation of the project Expand-TB which could be considered in a formal SWOT analysis of the project. Strengths and weaknesses refer to internal factors while opportunities and threats represent external factors.

Strengths	Weaknesses
- Addresses neglected field of public health relevance - Flexible project - Dedicated partners - Open communication and collaboration with donors - Establishment of permanent structures - Integrated approach - Stimulates efforts to ensure MDR-TB treatment	- Lack of technical capacity and partner consultation during project planning - Over-optimistic project schedule - Limited leverage over market - Complex administrative arrangements - No verification of data reported by countries
Opportunities	**Threats**
- Availability of complementary funding - Development and commercialization of GeneXpert® - Complementary UNITAID project promoting MDR-TB treatment	- Complex project dependant on political support, minimum infrastructure and public security - Lack of funding after project conclusion threatens sustainability - Change of procurement agent or model - Over-burdening of project countries by MDR-TB patient treatment requirements - Neglect of regular TB control - Over-burdening of supra-national reference laboratories

Strengths

- Targeting a neglected field of considerable public health relevance.
- Flexible project with the scope for adjustments as need arises (project countries, diagnostic methods).
- Dedicated partners who work in their area of specialization.
- Open communication between partners in the form of regular project management meetings also attended by donor (UNITAID).
- Building up of permanent structures and capacity, strengthening of not only MDR-TB diagnostics, but TB control in general, fostering country ownership.
- Integration of laboratory strengthening (infrastructure, personnel) and supply of consumables.
- Awareness of the need to treat diagnosed cases as evident from continuous communication with GLC and launch of complementary UNITAID-funded project to provide MDR-TB drugs, ensuring treatment of diagnosed cases.

Weaknesses

- Lack of technical capacity and partner consultation during project planning and MoU writing, resulting in untenable (potential for conflicts of interest regarding

assigned activities and responsibilities (in the case of GDF: supervision of procurement agent and direct contacts with potential suppliers to stimulate market expansion/price reductions) and evolving (reporting, indicators) requirements.

- Over-optimistic project schedule (time for project set-up underestimated).
- Limited leverage over market due to multitude of items purchased, small number of suppliers and lack of competition.
- Complex administrative arrangements reduce efficiency (placement of GDF staff into FIND).
- No on-site data verification, creating doubts about the accuracy of the reported figures.

Opportunities

- Availability of required external complementary funding for laboratory rehabilitation, etc.
- Development of GeneXpert®, allowing introduction of a new diagnostic technique into routine use in a number of countries, thus supporting the evaluation and, if successful, eventual establishment of this technique.
- Complementary UNITAID project promoting the treatment of MDR-TB cases (MDR-TB Scale-up and Acceleration of Access).

Threats

- The complexity and long-term nature of the project makes it dependant on sufficient political support, infrastructure and public security in project countries.
- Lack of funding after project conclusion will threaten the sustainability of the project, as it will impact on the level and quality of services, procurement of consumables, maintenance, capital investments and continuous education.
- Project countries might become overburdened by treatment requirements of diagnosed MDR-TB patients; comprehensive capacity building in the 27 countries to adequately treat the diagnosed MDR-TB cases is a major endeavour.
- Change of procurement agent or procurement model might interrupt established supply channels and require re-negotiation of preferential prices, causing additional delays in program implementation.
- There is the potential for neglect of regular TB control as a result of focusing on MDR-TB diagnosis and treatment. The need to emphasize the importance of the control of regular TB is not stated in the documents reviewed by the evaluators.
- Overburdening of SNRLs which provide quality control and technical assistance for national reference laboratories, but are not strengthened in the frame of the current project.

4 Conclusions and Recommendations

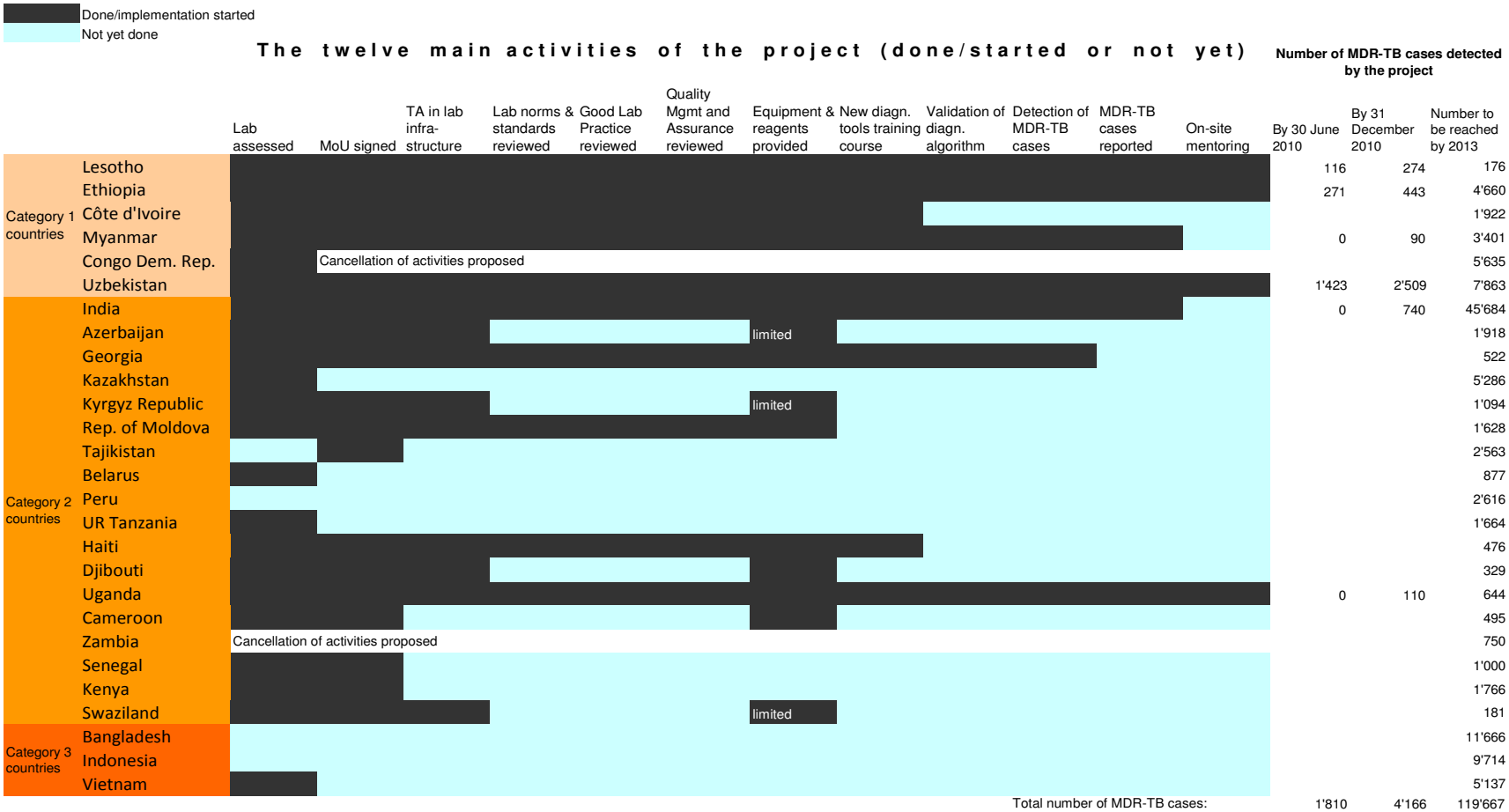
The project is likely to have a pronounced impact on the infrastructure and capacity for MDR-TB diagnosis in most project countries, generate demand for supplies to use and maintain this infrastructure, and increase the number of MDR-TB cases diagnosed in project countries. However, achievement of the target number of MDR-TB diagnoses within the scheduled project duration is questionable due to the challenges associated with creating the conditions to deliver diagnostic services. The impact on MDR-TB diagnostic capacity and case detection is likely more pronounced than on the market for key diagnostic products where traditional market forces play a limited role.

	Conclusions	Recommendations	Responsibility
1	Achievement of targets is questionable considering the current project implementation rate.	Partners should develop a catch-up plan incorporating activities to increase the speed of project implementation, and annual targets per country and area of activity. This plan and its budget implications should then be discussed with UNITAID, revised accordingly, and become a binding framework for activities and reporting.	GLI, FIND and GDF, in consultation with UNITAID
2	The MoU of the project Expand-TB contains inconsistencies (e.g., number of MDR-TB cases to be diagnosed) and some assigned activities could put partners in a conflict of interest situation (e.g., GDF contacting potential producers to stimulate competition while acting as procurement agent supervisor).	Critically analyse the MoU to identify discrepancies, determine conflicts of interest when assigning activities to partners, etc., and revise the MoU in light of the findings.	UNITAID
3	The project represents a major effort to develop the infrastructure for MDR-TB diagnosis and diagnose a high number of MDR-TB cases. While early diagnosis is important for the successful treatment of MDR-TB, the current capacity of many countries to adequately treat the diagnosed cases is questionable. UNITAID generally does not provide programmatic support and the UNITAID project "MDR-TB Scale-up and Acceleration of Access" provides only a fraction of the required drugs (15,606 treatments to 18 countries).	Coordinate with traditional donors and GLC to enable project countries to ensure the sufficient supply of MDR-TB drugs, availability of the required human resources (specialized doctors, nurses, etc.) and infrastructure to administer and manage treatment and its side effects.	UNITAID

	Conclusions	Recommendations	Responsibility
4	The constant evolution of reporting requirements and indicators creates confusion and frustration among partners. The existing programmatic and financial reporting template still needs to be revised, as it also contains unessential indicators.	Develop a final version of the programmatic and financial reporting template based on the log-frame approach, which includes systematic risk identification and mitigation. Reporting should be actionable and as short and concise as possible with simple, meaningful and systemic indicators developed in collaboration with the partners and based on the log-frame exercise. Each report should provide a snapshot of the project at the moment of reporting and include graphic illustrations of trends/projections for future developments, as well as an update of the risk assessment. It should also contain a summary, linking programmatic and financial reporting.	UNITAID, in consultation with GLI, FIND and GDF
5	Reports contain information of questionable accuracy (numbers pertaining to the same indicator vary between citations, e.g., number of diagnostics procured). Corrections, clarifications and additions are not summarized in a final revised version of the report.	Elaborate clear reporting guidelines including an explanation of indicators and their calculation, means of verification, rules for exclusion of certain items (e.g., in case of insufficient data to calculate an indicator), consolidation processes for reported data, and the report approval and revision process. A final revised version of the report should be published and shared with all partners whenever factual corrections/additions to a report are made.	UNITAID
6	Project implementation does not follow performance based funding principles, as disbursements are not related to progress, but rather made on the basis of a pre-defined scale as detailed in the MoU.	Disbursements should be tied to planned procurements and activities as specified in the log-frame. Develop and implement a representative and weighted rating system between contractual programmatic, procurement related and financial criteria to assess performance throughout projects, and to authorize disbursements of funds for projects. This tool could also be used to support cost extension/no cost extension decisions.	UNITAID
7	Data reported by project countries is incomplete and reported data are not verified.	Conduct periodic on-site data verifications/data quality audits in project countries covering the key indicators, including the number of diagnosed MDR-TB cases and stocks of diagnostic materials.	UNITAID, external audit agency

Annex 1: Project Progress per Country as of 31 December 2010

Figure 1. Overview per country of project status as of 31 December 2010.



		Number of MDR-TB cases detected by the project		
		By 30 June 2010	By 31 December 2010	Number to be reached by 2013
Category 1 countries	Lesotho	116	274	176
	Ethiopia	271	443	4'660
	Côte d'Ivoire			1'922
	Myanmar	0	90	3'401
	Congo Dem. Rep.			5'635
	Uzbekistan	1'423	2'509	7'863
Category 2 countries	India	0	740	45'684
	Azerbaijan			1'918
	Georgia			522
	Kazakhstan			5'286
	Kyrgyz Republic			1'094
	Rep. of Moldova			1'628
	Tajikistan			2'563
	Belarus			877
	Peru			2'616
	UR Tanzania			1'664
	Haiti			476
	Djibouti			329
	Uganda	0	110	644
	Cameroon			495
	Zambia			750
	Senegal			1'000
	Kenya			1'766
	Swaziland			181
Category 3 countries	Bangladesh			11'666
	Indonesia			9'714
	Vietnam			5'137
	Total number of MDR-TB cases:	1'810	4'166	119'667

Annex 2: Evaluation Matrix

Table 9. Reporting checklist.

Reporting received from implementing partners
1.1 Are project reports (interim report, annual reports) submitted on time?
1.2 Are there many clarifications required by UNITAID following the transmission of reports?
1.3 Does the content of the reports meet the requirements in the project plan?
1.4 Is the content of the report useful for decision making?
1.5 What is the internal UNITAID process for validating a progress report? How could it be improved?
Financial reporting
2.1 Are the reporting requirements clear in the project plan and MoU?
2.2 Does the financial reporting format allow easy identification of common budget items, e.g., salaries, travel, major acquisitions, and drugs/diagnostics?
2.3 Does the financial reporting give a clear picture of activities implemented and expenditures of the period compared to budget and work plan?
2.4 Does the project implementation follow performance based funding principles? Are the disbursements based on progress made?
2.5 Is interest received on bank accounts or others income reported, and are they reimbursed to the program/deduced on disbursement requests?
2.6 Does the financial reporting include a cash reconciliation supported by financial and bank statements?
Programmatic reporting
3.1 Are indicators defined both at the process level and outcome/impact level?
3.2 Does the programmatic/procurement reporting follow UNITAID content requirements?
3.3 Does the programmatic reporting provide a clear and actionable picture of programme implementation?
3.4 Does the programmatic reporting provide a clear picture of procurement activities (order list, etc.)?

Table 10. Evaluation matrix of common evaluation areas.

Relevance			
Evaluation area and questions	**Indicators**	**Sources**	**Methods**
1- Are the activities and expected outputs of the project consistent with the objectives and expected outcomes as described in the project plan?			
1.1 Are the activities from the project plan consistent with the objectives?	Consistency Rates: Number of objectives with activities/total (%) Number of activities related to objectives/total (%)	In the project outline, match the activities with the objectives	Match activities planned to reach each objective Also indicate if some of the activities are not linked to any of the objectives, and question their relevance
1.2 Do indicators, as defined in the project plan, allow measuring progress on each of the objectives?	% of objectives measured at least with one relevant indicator	In the project outline, match the objectives with indicators	Comment on the development of a log-frame for the project
1.3 Are all activities implemented as scheduled for the period?	Activity completion rate: Number of activities implemented/total	Planned activities from project plan Implemented activities from the last available progress report	Follow up on the completion of activities and milestones as described in the project plan. Give reasons for delays.
1.4. Are disbursements according to current budget forecasts and expenditures on the progress report?	Budget execution rate % (Disbursements vs. Budget) Budget absorption rate % (Expenditures vs. Budget)	Budget from project plan Disbursements and Expenditures from financial reports	Calculate total expenditures/disbursements for the budget period Verify that expenditures are in line with activities initially planned/implemented Explain relevant deviations
2- Is it possible to show how the project has contributed to UNITAID's overall goal of using innovative, global market-based approaches to improve public health by increasing access to quality products for treatment, diagnosis and prevention of HIV/AIDS, tuberculosis and malaria?			
2.1 Has the project already demonstrated the contribution of UNITAID to increased access to quality products to treat/diagnose HIV, TB, and Malaria?	Yes / No	Progress reports: estimated number of patients treated or diagnosed per country	

2.2 Are the numbers reported by the implementing partner reliable?	Yes / Mostly / No	Description of methods to estimate patients treated (if available) Interview UNITAID/partner	How did the partner estimate the number of estimated patients treated (or diagnosed)? Are the methods reliable? Does the partner have programmatic support in countries ensuring that treatments procured are effectively dispensed? Can the numbers be cross-checked with number of treatments procured?
Effectiveness			
Evaluation area and questions	**Indicators**	**Sources**	**Methods**
3- To what extent were the objectives of the project achieved?			
3.1 Were the targets of the project achieved in terms of health outcome (estimated number of patients treated or diagnosed)?	% achievement rates on patient outcome indicators	Project outline: targets in terms of health outcomes Results from the most recent progress report	Comment on the achievements in terms of patient outcome(number patients treated/diagnosed) against the targets Comment on reliability of information
3.2 Were the targets of the project achieved in terms of market outcome?	Include quantitative result/% achievement rate (or qualitative if % not applicable)	Project outline: targets in terms of market outcome Results from the most recent progress report Verify with market information (WHO pre-qualified product/supplier list, MSH drug price indicators)	Comment on the achievements in terms of market outcome (price, quality, availability, access)
4- To what extent are they the objectives likely to be achieved?			
4.1 What is the likelihood of achieving health outcomes objectives?	High / Medium / Low	Progress reports / interviews	No data collection should be included here. This should be answered in the evaluation based on what has been achieved and what is known on the project
4.2 What is the likelihood of achieving market objectives?	High / Medium / Low	Interviews / market knowledge	No data collection should be included here: This should be answered in the evaluation based on what has been achieved and what is known on the market for the drug or diagnosis
5- What are the main factors influencing the achievement of orfailure to achieve the objectives?			

5.1. What were the reasons for patient outcome targets not being met?	List of factors	Progress reports / interviews	For the main patient outcome indicator, analyze the chain of events: - Were the project plan activities implemented? - If yes, what were the factors causing targets not to be achieved? - Differentiate between internal factors (related to partner's organization and project implementation) and external factors (country context, market, complementary funding)
5.2. What were the reasons for market impact targets not met?	List of factors	Progress reports / interviews	Were the project plan activities implemented? If yes, what were the factors causing targets not to be achieved?
5.3. Was there an effective risk management plan in place during the project	Yes / Limited / No	Progress reports / interviews	Did the partner make an initial risk assessment? Were the issues that arose during implementation foreseen in the risk assessment? Did the partner take mitigation measures to limit the impact of negative events?

Efficiency

Evaluation area and questions	Indicators	Sources	Methods
6- Are the project partners working closely with the relevant national authorities?			
6.1 Has the MoU been signed by all beneficiary countries?	Number of MoU signed/total planned	Latest progress report Update by interviews	Number of MoU signed compared to number planned Analyze reasons for MoU not being signed
7- Is the project's procurement model well defined and designed to identify and solve procurement related problems as they arise?			
7.1 Has a procurement agent been selected and is he/she operational in the project?	Yes (name) In progress Process not started	Progress update Latest procurement review	
7.2 Is the product median price procured in line with the budget?	Median unit cost/planned unit cost (%) for key selected products	Procurement orders Targets and budget from initial project plan	Select a few items driving the overall procurement budget Comment on the reliability of information
7.3 What is the average lead time between purchase order and reception of health products in country?	Average lead time for all operational countries	Project plan Progress reports Copy of order sent by the country, reception certificate	Target time: effective time (in months) Number of months delay/lead compared to project plan Calculate average lead time for all the countries (if there ia a minority of extreme values do not include them in the calculation, but mention then in the comment) Is it in line with initial plan?

7.4 How many stock-outs of more than seven days were observed since the beginning of the project?	Number of stock-outs	Progress reports if information is reported Otherwise ask the implementing partner	Identify likely reasons for stock-outs / attribute stock-outs responsibility: Number of stock-outs with responsibility Number of stock-out without responsibility
7.5 Is the procurement model functioning as designed in the project plan?	Yes / No	Compare procurement model to project plan to reality	If deviations from the project plan are identified, try to obtain information on the reason of the change.

Impact

Evaluation area and questions	Indicators	Sources	Methods
8- Can the partner organization attribute UNITAID funding to medicines and diagnostics purchased, and patients treated by beneficiary countries in a timely manner?			
8.1 Did the project report on treatments/diagnostics procured per country in UNITAID Funding?	No information on treatments/diagnostics procured per country	Latest progress report	
8.2 Did the project report on patients treated/diagnosed per country in the UNITAID scheme?	No information on patients treated/diagnosed with UNITAID funding per country	Latest progress report	

Table 11. Project specific questions.

GLI/FIND/GDF - Project support for expanding access to diagnostics for patients at risk of multi-drug resistant TB (for Q1 2011)
1- Demonstrate that the MDR-TB in-vitro diagnostics market has expanded.
1. Number of new MDR-TB in-vitro diagnostics available
2- How has the pool of quality manufacturers been enlarged?
2.1. Number of new manufacturers of MDR-TB in-vitro diagnostics available
2.2 Number of (and increase since the beginning of the program in the number of) manufacturers proposing ISO/WHO standards compliant products
3- Is the project facilitating the creation of new markets for diagnostic tools through the establishment of new quality assured laboratories in project countries?
3.1 Number of in-country laboratories ISO certified or accredited
3.2 Quantity/value of quality diagnostics tools bought by in-country quality assured laboratory
4- Can the project show that it has been successful in negotiating 5-10% price reduction of TB diagnostics in resource limited settings based on the forecasted uptake volume of new diagnostics?
4.1. Comparison of median price for TB diagnosis on the international market/median price for TB diagnosis bought by the program
4.2 Variation in diagnostics price since the project began

Annex 3: Stakeholders and People Interviewed

Listed below are those in UNITAID, GDF, GLI and FIND who were extensively interviewed for the purposes of this mid-term evaluation of the project Expand-TB, either during a visit to project offices in Geneva or by phone and e-mail. All interviews took place between April and June 2011.

Stakeholder	Name of person interviewed	Role in the project
UNITAID	Lisa Cathy-Ann Regis	TB Portfolio Manager
	Kvetoslava Dzackova	Finance Specialist
	Kathleen Louise Strong	M&E Specialist
GDF	Caroline Bogren	GDF Manager
	Thomas Verges (placed in FIND)	Logistics Officer
	John Loeber	Procurement Team Manager
	Thierry Cordier-Lassalle	GDF Principal Officer
GLI	Fuad Mirzayev	TB Diagnostics and Laboratory Strengthening Unit
FIND	Giorgio Roscigno	Chief Executive Officer
	Eric Adam	Senior Implementation Officer
	C.N. Paramasivan	Head of TB Laboratory Support

Annex 4: List of Documents Reviewed

Document Title	Source	Year
Executive board resolutions and MoU		
Resolution no. 4. Action name: TB/MDR-TB project, Organization(s): Global Drug Facility (GDF), Global Laboratory Initiative (GLI) and Foundation for Innovative New Diagnostics (FIND). Executive Board, Meeting no. 7, 2-3 April 2008, Brasilia, Brazil	UNITAID	2008
Memorandum of Understanding, Annex 1 plus Exhibits 1-6 and Annex 2 for the "Narrowing the Gap" project: Expanding and Accelerating Access to Diagnostics for Patients at Risk of Multi-Drug Resistant Tuberculosis 2008-2011. December 2008	UNITAID	2008
Resolution no. 8. Action name: Proposal for Extension of the Project Narrowing the Gap - Expanding and Accelerating Access to Diagnostics for Patients at Risk of MDR-TB. Organization(s): The Global Drug Facility (GDF), The Global Laboratory Initiative (GLI) and the Foundation for Innovative New Diagnostics (FIND). Executive Board, Session no. 8, 12-13 May 2009, Geneva, Switzerland	UNITAID	2009
Memorandum of Understanding, Amended and Re-stated, Annex 1, Annex 1bis plus Exhibits 1-6 for the "Narrowing the Gap" project: Expanding and Accelerating Access to Diagnostics for Patients at Risk of Multi-Drug Resistant Tuberculosis 2008-2013. May 2010	UNITAID	2010
Progress reports		
Inception report for "Narrowing the Gap: Expanding and accelerating access to diagnostics for patients at risk of multi-drug resistant tuberculosis (MDR-TB)". 15 March 2009	UNITAID	2009
Interim progress report and disbursement request for the project: Narrowing the gap: expanding access to new diagnostics for patients at risk of multi-drug resistant tuberculosis (MDR-TB). Period: 01 January – 30 June 2009. October 2009	UNITAID	2009
Annual programmatic and financial report for the project: Narrowing the gap: expanding access to new diagnostics for patients at risk of multi-drug resistant tuberculosis (MDR-TB). Period: 01 January – 31 December 2009. March 2010	UNITAID	2010
2nd interim programmatic and financial report including section C (financial) and M&E section for the project: Narrowing the gap: expanding access to new diagnostics for patients at risk of multi-drug resistant tuberculosis (MDR-TB). Period: 01 January – 30 June 2010. October 2010	UNITAID	2010
2nd annual programmatic and financial report including section C (financial) and M&E section for the project: Narrowing the gap: expanding access to new diagnostics for patients at risk of multi-drug resistant tuberculosis (MDR-TB). Period: 01 January – 31 December 2010. March 2011	UNITAID	2011

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