EURO HEALTH GROUP

UNITAID – EVALUATION OF FEI GRANT: HIV PORTFOLIO – OPP-ERA PROJECT

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FINAL REPORT

Consultants: Jennifer Lissfelt and Julie Pasquier

Euro Health Group A/S
Tinghøjvej 77
DK-2860 Søborg
Tel: +45 3969 6888
Email: ehg@ehg.dk
Web: www.ehg.dk

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ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ANRS	Agence Nationale de Recherche sur le Sida
ART	Antiretroviral Therapy
CE IVD	Conformité Européenne/in vitro diagnostics
CEO	Chief Executive Officer
CHAI	Clinton Health Access Initiative
EHG	Euro Health Group
EID	Early Infant Diagnosis
Esther	Ensemble pour une Solidarité Thérapeutique Hospitalière en Réseau
FEI	France Expertise International
GF	Global Fund
GFATM	The Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	Human Immunodeficiency Virus
ISO	International Organization for Standardization
LMIC	Low and Medium Income Country
Logframe	Logical Framework
M&E	Monitoring and Evaluation
MOU	Memorandum of Understanding
NCE	No-Cost Extension
OPP	Open Polyvalent Platform
OPP-ERA	Open Polyvalent Platforms (OPP) for sustainable and quality access to VL in resource limited settings
PEPFAR	President's Emergency Plan for AIDS Relief
PMTCT	Prevention of Mother-to-Child Transmission
POC	Point-of-Care
PQDx	Prequalification of Diagnostics
PSM	Procurement and Supply Management
RUO	Research Use Only
Solthis	Solidarité Thérapeutique et Initiatives contre le SIDA
TOR	Terms of Reference
UNITAID	Innovative Financing to Shape Markets for HIV/AIDS, Malaria and Tuberculosis
VLT	Viral Load Test
WHO	World Health Organization

ACKNOWLEDGEMENTS

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1 EXECUTIVE SUMMARY

Overview

This report provides an evaluation of Phase 1 of the OPP-ERA Project financed by UNITAID for the period March 2013-Jan 2015. OPP-ERA (Open Polyvalent Platforms for sustainable and quality access to VL in resource limited settings) is a Project whose aim is to create a market for OPP technology for HIV viral load testing (VLT) and early infant diagnosis (EID). OPP, unlike existing integrated VLT systems, allows equipment and reagents made by different manufacturers to be used together, making the system more flexible, easy to use, and potentially more affordable in terms of total testing costs. OPP technology can also be used for diagnosing other diseases and is thought to be a good complement to integrated VLT systems, and suitable for decentralized or middle-throughput settings, such as district laboratories. Although OPPs had been used in research, these systems were not yet widely used for regular HIV viral load testing in clinical settings in most countries. Founding members of the consortium implementing this project (FEI, Esther, ANRS, Sidaction and Solthis), felt OPPs should be considered for wider, more routine use (given the lack of VLT in most countries, with only an estimated 10% of ART patients having access to VLT), and to enable better detection of various strains and sub-types of HIV (including non-B types prevalent in West Africa, which were being under-quantified on existing VLTs).

The evaluation was conducted in Oct-Dec 2014, and is intended to inform an upcoming decision by UNITAID's board on whether to fund Phase 2 of OPP-ERA. In addition to identifying lessons learned and examining progress toward objectives and key performance indicators set for phase 1 of the project, the evaluation team examined programmatic and financial risks for the proposed phase 2 and developed recommendations to enhance the project and mitigate those risks.

Evaluation Approach

This evaluation, conducted by a team of two under the Euro Health Group (EHG), entailed a thorough review of internal and external project documents; interviews with project stakeholders in Europe and by phone/Skype with pilot country representatives, partners, a supplier and other organizations; and a thorough analysis and drafting of findings and recommendations.

General findings of the evaluation team

Overall, the evaluators found that the project is valuable and relevant in providing an additional approach to supporting expansion of VLT to more patients. Notably, the OPP reagent is currently reportedly the only VL reagent to adequately detect non-B types of HIV (prevalent in West Africa). The project has also shown some benefit in playing a role to help disrupt the current VL market, dominated by a few large suppliers of integrated VL systems, with one of these major suppliers participating in the project's tender. With only one amplification reagent supplier (Biocentric) for now, which still does not have its prequalifications in place, the supply side for OPP is still not developed. Quality assurance (QA) for amplification reagents has been a major blockage/delay in the project. The project comes at a critical time, when the international community is focusing more on VLT and its importance to sound HIV treatment, and the VLT field is changing with this new attention, potential new suppliers and technologies, and new pricing. With new WHO guidelines (2013) recommending routine VLT for all patients on ART, demand from countries for access to VLT is set to

expand greatly. At least one of the major integrated platform suppliers has recently announced new global pricing for VLT, which may enhance access and reach of these tests.

The risk-averse nature of UNITAID and caution about the project investment has led to some micromanagement and difficult relations. All innovative pilot projects must incur risk. There are risks to this project, and some recommended risk mitigation actions, detailed below. OPP-ERA is a complex project and topic area, prone to significant misunderstandings, even within the project team. Management and reporting/communications challenges have exacerbated some misunderstandings. Cold chain and other infrastructure and PSM challenges remain a challenge in countries, and will require ongoing support to manage.

The project appears to have been very well received in the 4 pilot countries (where the project works with 7 laboratories), but with significant "hand holding", infrastructure development and capacity building required. The countries had at least some VLT equipment (integrated platforms) previously, but these were in many cases idle, and little or no VLT was happening in 2 of the 4 countries until the project started. The countries have all expressed satisfaction that, after many years, they are now able to conduct VLT. Their expressed interest was primarily to have much better access to more affordable and user-friendly VLT, which the project has helped deliver. It remains a question, discussed further in this report, whether these efforts will be sustainable and affordable once the project withdraws its support. There will be an ongoing need for support and donor funding (e.g. from Global Fund) to ensure capacity and testing infrastructure can be maintained.

Project Start-up and Launch

In Phase 1 of the project (March 2013-Dec 2014) the lead project implementer, France Expertise International (FEI) worked with the other project partners (ANRS, Esther, Solthis, Sidaction) in the consortium to test the OPP concept and to develop a full Business Plan for scaled-up commercialization of OPP viral load testing. Phase 2 should implement a procurement strategy and plan for the four pilot countries (Burundi, Cameroon, Cote d'Ivoire, and Guinea), plus another 3 countries (Burkina Faso, Sierra Leone, and Vietnam), with deployment of OPPs in these countries and beyond. Due to procurement delays in Phase 1, a no-cost extension was granted by UNITAID in July 2014, providing an additional 6 months to the project (to Jan 2015). During the initial year of the project, project team members visited countries, obtained agreements and signed MOUs with officials there, worked with them to quantify their needs, trained and worked with country counterparts, worked to refurbish laboratories in some countries, and prepared for procurement of testing equipment and reagents. After some delays procurements were conducted, and testing began in the countries in July-Aug 2014. All countries have met or exceeded their testing targets, and all country representatives contacted have provided very positive feedback on the project.

Project Structure, Implementation and Management:

The project is led by FEI (under the French Ministry of Foreign Affairs) for administration and management. FEI is the lead implementer under UNITAID, and manages the other partners as sub-grantees. Esther is a leading partner, providing project implementation in a number of countries, and working closely with FEI as a founding member of the project. ANRS provides the top scientific advice/support for the project. Sidaction and Solthis (well established French civil society organizations working in HIV and AIDS in numerous countries) round out the consortium, which

forms a network of experts with long experience and presence in the pilot countries. FEI signed a consortium agreement with the partners in mid-2013. The OPP-ERA Steering Committee meets once a month and is chaired by FEI, with representatives from each organisation attending. There are reportedly regular, ongoing communications as needed between the implementing partners, who appear to work well together and offer a good complementarity of skills and presence. The project has had some challenges in Phase 1 with human resources, reporting and communications, and procurement.

Technical Achievements and Results:
The evaluation measured the project's achievements by responding to a list of key research questions on relevance, effectiveness, efficiency, impact, and learning/risk mitigation (see section 4.4); and by examining project performance against its logframe indicators and targets. The evaluators attempted to discern major achievements, challenges, and impact to date. Overall, the project fared well in outcomes measured through the research questions and logframe, and had some notable achievements, while also facing numerous challenges (both internal and external).

Integration with UNITAID and Global Efforts:
This project falls under UNITAID's strategic objective #1 (Increase access to simple, POC diagnostics for HIV and AIDS, TB and malaria) introduced in April 2013 (after the project began), although the project is not currently focused on POC (point of care) technology as these are not yet available and feasible for VLT. However, the ambition behind POC, which is to significantly enhance access, especially outside of central labs, is largely offered by OPP systems. The objectives of the project are very much in line with the overall UNITAID objectives of impacting the market for HIV products and improving access and prices. The project fits well within the objective of enhancing access to important HIV diagnostics, to shaking up the market, to reducing costs, to increasing availability to simpler and more efficient systems, while still ensuring quality is assured. The project has not yet fulfilled all of these objectives in Phase 1, but evidence shows it has had an impact.

Lessons Learned:
Some main lessons regarding supply, demand and technology characteristics of the potential OPP market were identified during Phase 1 that required the project to make critical adjustments. The evaluators feel that the project team responded appropriately to the lessons learned in phase 1 and have proposed important efforts for phase 2 in response to these. Nonetheless, limited availability of quality-approved suppliers, potential incompatibility between supplies and equipment, and possible slow growth in demand for tests remain key risks to the project timeline and to the project's overarching goal of the development of a functioning market for OPP.

Value for Money (VFM):
Important steps have been taken to achieve cost efficiency and effectiveness. Phase 1 has been largely successful in testing proof of concept and developing systems so that value for money for UNITAID's investment is maximized. The project has demonstrated potential for lower per-test costs of OPP, has developed procurement procedures to ensure transparency and cost-efficiency, promotes the cost savings that are gained in ART treatment when proper VLT is done (reducing need to shift patients to costly 2nd line regimens, and reducing risk of building resistant virus), and provides UNITAID with additionality (co-funding) through cost-sharing by project partner organizations. However, there has only been one round of procurements to date. There may be a need to consider

re-allocating some funds in Phase 2 away from procurement and toward QA and other identified challenges to ensure OPP systems can run in country. Polyvalence and replicability and sustainability of the OPP concept have not yet been explored (although these would be important factors in measuring the project's VFM). A thorough assessment of VFM should be attempted in phase 2, when the project could be functioning more fully in all countries. At that point, the potential sustainability and longer-term value for money of the investments made by the project might also be analysed. It will also be important to update the baselines (and counterfactuals) used by the project to measure its effects and impact, as the VLT environment changes, with more suppliers, more competitive pricing, and more testing happening worldwide. These market changes will impact on the project's effectiveness and the viability of OPP as an option for VLT, given new potential market entrants and new pricing schemes. A detailed costing analysis, and full cost-benefit analysis across VLT platforms are recommended.

Market Impact and Niche:
The evaluation examined the market niche for OPP and the project, potential impact of the project on the VL market, outlook for the future of this market, and the project's strategies and Business Plan for Phase 2. Findings included the fact that there is a large untapped market for VLT at present, given that only an estimated 10% of patients needing VLT are being tested in Africa (according to project and CHAI experts consulted). The global market has been dominated by the integrated (closed) platforms made by large suppliers including Roche and Abbott, with the high total price per test (especially in the lower-prevalence countries where the project is working) being a major obstacle to wider access. Test (reagent) prices are coming down, at least in some high-volume markets, but remain high in the project's target countries, with total testing cost (including equipment, maintenance, infrastructure, etc) remaining high. There is potential for OPP as an additional alternative to integrated systems in high-throughput laboratories in lower-prevalence countries, in lower- and medium-throughput laboratories in high-or lower prevalence countries, in countries where non-B HIV sub-type is prevalent, in countries where affordability may become a larger issue as the Global Fund and other funding is reduced or ended, and elsewhere. There is a need for the project to develop a communications strategy to better inform countries and donors, and the international diagnostics community about OPP for VLT and to help build market potential, and to build credibility and understanding about the approach (which obtaining PQ will also assist in doing). The project might also consider broader geographic reach, not to remain in the niche of working only in Francophone countries. Future trends including price reductions (including some recently announced), new point-of-care technologies and increasing use of dry blood spot (DBS) analysis (which some respondents note is potentially an essential tool to expand VLT) must be studied and understood by the project as potential competitive risks.

Potential Risk and Risk Mitigation:
The evaluation conducted a review of potential risks identified by the project and outlined in their Business Plan, and their proposed risk mitigation efforts. These include risks of supply, demand, maintenance/support, competitive environment, patient access, and management and coordination in countries. Efforts to mitigate these risks are proposed, with additional suggestions made by the evaluation team. In addition to these identified risks, the evaluators detected a number of other potential risks to the project and proposed actions to mitigate these risks. These included programmatic, reputational, supply-side, and technical risks. Recommendations to mitigate these

risks include efforts to avoid any appearance of conflict of interest by the project, addressing supply risks by expanding to work with other suppliers, addressing operational risks by investing in market support and training activities, addressing compatibility concerns by investigating and clearly documenting the compatibility of components in the OPP system, and remaining attentive to potential market pressures from innovations in point-of-care technology, and use of DBS for sample handling.

Recommendations:
The evaluation concluded with a number of recommendations for UNITAID and the project implementers to 1) help UNITAID enhance project planning and efficiency using lessons learned from Phase 1; 2) enhance effectiveness and efficiency of implementation for Phase 2; and 3) mitigate risks in Phase 2. Recommendations were made on enhancing internal and external communications, analyzing and documenting cost comparisons with integrated VL systems, considering potential expansion to more countries and regions, addressing perceptions of any conflict of interest by the project, addressing the quality assurance obstacles faced in phase 1, addressing the PSM and other management challenges countries face on the ground (and considering more spending in addressing those, if required), addressing the supply-side risk of having only one supplier, clarifying the situation (and confusion) around compatibility of components and suppliers in OPP platforms, building better awareness and support in the international community, building demand and awareness in countries, addressing the need for sustainability, and meeting potential competitive risks in the market. These recommendations, and the related finding or issue to be addressed by each one are listed in the table below.

Recommended Actions	Issues to be addressed
PHASE 2 DECISION BY BOARD/UNITAID:	
The Board should make a rapid decision on Phase 2	Maintain continuity of staff
If Phase 2 is approved, UNITAID should urgently disburse a sufficient amount	Avoid interruption of VLT in existing target countries
If Phase 2 is not approved, UNITAID should consider bridge funding for reagents	Avoid interruption of VLT in existing target countries
COMMUNICATIONS AND REPORTING:	
UNITAID and OPP-ERA should communicate more through regular meetings than through document exchange.	Minimize misunderstandings
OPP-ERA's communications should be better aligned with the tools and concepts used by UNITAID.	Minimize misunderstandings
UNITAID and OPP-ERA should improve and streamline reporting and document management in phase 2.	Reduce document/ reporting burden (reduce number of ad hoc reporting requests, reduce feedback loop and report revisions required). Systemize and standardize archiving of documents for common understanding and easy access.
UNITAID should help promote communication and meetings between OPP-ERA and stakeholders in the diagnostic community (WHO PQDx, GF, PEPFAR, CHAI etc). Publicize the	Enhance awareness of OPP in the wider diagnostic community.

Recommended Actions	Issues to be addressed
results obtained in phase I to provide proof of concept (technical results as well as QA and QC of the tests). Publish the data officially.	
OPP-ERA should better communicate information about the project and adapt its communications to the target audience (public health or technical)	Enhance awareness of OPP outside of the project.
UNITAID should facilitate direct communication between the OPP-ERA and WHO PQDx projects	Establish relationship as OPP-ERA is highly dependent on WHO PQDx.
UNITAID should facilitate direct communication between OPP-ERA and MSF OPP project	Establish relationship for exchange of lessons learned.
OPP-ERA must develop and implement a communication strategy for strategic target audiences (technical and non technical)	Enhance awareness of OPP outside of the project to strengthen important alliances.
OPP-ERA should systematically participate in international conferences on diagnostics and present findings and experiences from phase 1.	Clarify confusion that OPP is not intended to replace the large, integrated VL systems in use, but to complement them, and offer an alternative to allow VL to be conducted more widely, in less central labs. OPP-ERA should contribute more to the global diagnostics discussion and decision making.
Enhance OPP-ERA Project web site	Improve visibility of project, understanding in international community
Include communication-related targets in Phase 2 logframe	Ensure improved communications for the project
REFINING OBJECTIVES:	
UNITAID should consider removing POC focus from Strategic Objective #1.	SO 1 narrowly focuses on POC diagnostics that while promising are still in development and only address one niche in the diagnostic market. OPP fills a niche that POC does not. (Note that SO 1 was only adopted after OPP-ERA had begun.)
UNITAID (and OPP-ERA) should clarify the value for money argument for VLT in general and OPP specifically.	Clarify misunderstandings about OPP, and importance of routine VLT, cost-benefit of doing testing
PHASE 2 EXPANSION PLANS:	
Scale up testing in existing countries, while addressing some expressed concerns, e.g. with staffing	Address issue raised in countries with question of remuneration of lab staff as workloads grow with increased testing
In phase 2, expand target countries to include non-Francophone Countries	Address concerns that the experience and lessons learned are applicable mainly to Francophone countries
Consider expanding target markets to include countries where VLT price is paramount to all other criteria, given reductions in donor support.	Help to meet the need in higher-income (lower priority) countries (e.g. Georgia) where GF and other funding is being reduced, and price per test will be critical in selection of VL procurement systems
Consider procurement of additional equipment pairings, broaden beyond the current single combination (Diasorin, Roche, Biocentric) – including use of reagents that may not be for	Demonstrate OPP's potential to run on different devices, to address different HIV sub-types. Show greater potential impact on the market.

Recommended Actions	Issues to be addressed
non-B type HIV	
PHASE 2 COORDINATION AND MANAGEMENT & PSM:	
Improve coordination with other projects in countries	Seek ways to cost share or leverage other groups that are working in the target labs
Consider increasing spending for support activities on the ground; ensure prerequisites are in place (infrastructure, training, regulatory, logistics, etc) for introduction and ongoing management of VLT; ensure longer-term support will be available to keep systems running	Address obstacles that have impacted VLT expansion worldwide and led to "equipment cemeteries" in many countries (e.g. PSM, maintenance, operations, staffing).
Liaise more with industry/manufacturers to get access to market data	Enable better visibility into market data and information
Keep some level of procurement at the local level	Support countries to establish local supply channels
Work on systematizing and standardizing the OPP VLT approach and producing a toolkit for the introduction and management of OPP in countries (modifying and using existing tools)	Minimize the risk that systems stall or become idle in labs.
Establish clear focus on PSM (procurement and supply management) issues.	Address concern that countries don't have the ability to manage the maintenance and supplies for OPP.
Ensure procurement from different manufacturers for each lot so that the project is not dependent on one manufacturer. Improve communications with various suppliers, keeping them informed of potential opportunities as well as international quality requirements.	Reduce dependence on single supplier.
Clarify responsibilities in maintenance contracts in countries, install thermocyclers in two's to build redundancy into the system.	Address concern over multiple suppliers with unclear responsibility if system breaks down or needs support (and for training, installation, other responsibilities). If one thermocycler needs repair, testing can still continue on the remaining machine.
Have external evaluators participate in product/supplier selection decisions, to avoid any conflicts of interest, or appearance of COI.	Avoid COI and ensure transparency in procurement decisions
PHASE 2 RESEARCH AND ANALYSIS & DOCUMENTATION:	
Consider running OPP system in parallel with an integrated platform, analyzing and documenting the differences in terms of cost, usage, maintenance, training, staff time, test quality, consumables needed, waste produced etc.	Expand awareness of OPP, understanding of cost parameters. Develop more complete set of price and costing data for easier comparison. Develop clearer cost-benefit analysis across platform options.
Document information about compatibilities between different equipment and different reagents.	Address concern over potential lack of compatibility between different suppliers of reagents and extracting machines.
Validate and communicate laboratory findings on the unequal abilities of reagents to quantify non-B HIV types by relating them to health outcomes: what is the risk of not using Biocentric reagents, e.g. what percentage of patients could get	Address lesson learned in phase 1, that common reagents used for VLT worldwide are inadequate for quantifying non-B HIV virus.

Recommended Actions	Issues to be addressed
wrongly diagnosed as a result. Broadly communicate results and findings to international community.	
Monitor new technological advances and developments (e.g. POC, DBS), and market changes (e.g. new prices from large suppliers), consider OPP options using DBS	OPP-ERA must be aware of market shifts, and remain relevant and competitive.
QA IN PHASE 2:	
OPP-ERA should ensure that Biocentric reagents and system are validated in other labs besides Necker and evaluated in other labs besides the project's labs in Abidjan and Cameroon, and that more objective voices speak in support of the company (not solely project members, who may be seen as too close to the company).	Address perceived conflict of interest/lack of objectivity as C. Rouzioux is both the inventor of the reagent test which Biocentric commercializes, and also performs the evaluations of this and other reagents in her laboratory.
Obtain necessary quality assurance recognition for procurement through major donors (GF, PEPFAR) (and obtain ERPD provisional PQ in the meantime)	Ensure sustainability of OPP through funding from international donors in future. Ensure credibility and quality assurance of OPP reagents and system

Conclusion:
Based on the analysis of findings, the evaluators find that Phase 1 of the project has confirmed that OPP presents a potential opportunity to expand access to VLT for a population in need at potentially lower cost than existing technologies. Phase 2 of the project would be a potential opportunity to expand access to VLT, in accordance with UNITAID'S market-based approach to filling gaps in the market. The project is run by a team of qualified, dedicated professionals who form the basis for an effective team for Phase 2, with some suggested improvements in management and implementation based on lessons learned from Phase 1. Implementation of Phase 2, however, is not without risks, requiring UNITAID, FEI and its partners to take critical actions identified to mitigate those risks. Lessons learned from this effort will also inform future investments in the diagnostics landscape.

2 BACKGROUND

UNITAID is an international facility, based in Geneva and hosted at the World Health Organization (WHO), for the purchase of drugs and medical supplies used in the global response to HIV and AIDS, malaria and tuberculosis. The institution was founded in September 2006 and is largely financed by new and creative financing mechanisms, with half of its funding coming from a special fee on airline tickets. Launched initially by the governments of Brazil, Chile, France, Norway, and the UK as a new effort to provide sustainable funding for HIV and AIDS, malaria, and TB efforts ("the International Drug Purchasing Facility"), UNITAID now supports 17 projects in 94 countries, with 10 implementing partners. It is now also backed by an increasing number of countries, including a number of developing countries in Africa, as well as the Bill and Melinda Gates Foundation. Its aim is to finance procurement of high-quality medicines and diagnostics for developing countries, thereby ensuring

high-quality treatment and diagnostic products are affordable and accessible --using "buy-side market leverage to make life-saving health products better and more affordable for developing countries" (*UNITAID web site*). "With its sizeable purchasing power, UNITAID negotiates price reductions, accelerates the pace at which products are made available, and brings quality-assured health products to market." (*UNITAID web site*).

In the fight against HIV and AIDS, UNITAID has played an important role by focusing on less-funded interventions, including paediatric medicines, second-line medicines and integrated prevention of mother-to-child transmission of HIV (PMTCT). By supporting interventions and helping to build markets for these products, UNITAID has worked to fill gaps in funding for HIV and AIDS treatment and diagnostics. In 2012, UNITAID announced a major new investment in point-of-care (POC) and decentralized HIV diagnostic products (especially CD4, Viral Load, and Early Infant Diagnosis), to enhance access to these critical diagnostics in more rural and remote settings where access has been a major challenge. Of UNITAID's six strategic objectives, the first one (Increase access to simple, POC diagnostics for HIV and AIDS, TB and malaria) relates to diagnostics, the reason for UNITAID's investment in this project to expand access to viral load testing for HIV and AIDS.

Although viral load testing is critically important to determine whether a patient's ART treatment is working (reducing the level of virus in his/her system), and when the patient should switch to a new regimen (e.g. 2nd line ARVs), UNITAID estimates that currently "less than 10% of HIV patients in low-income settings have access to viral load tests as they are expensive and usually only available in the central laboratories of capitals." (*UNITAID web site*). Viral load testing involves measuring the number of viral copies per millilitre (viral cp/mL) of plasma, necessary for monitoring the progression of disease and the body's response to treatment. It is "well established that viral load detects treatment failure well before CD4 count or clinical signs" (*UNITAID HIV and AIDS Diagnostics Technology Landscape. 4TH EDITION. June 2014, page 8 footnote*).

Despite WHO guidelines (2013) that now recommend viral load tests at 6 months and subsequently each year for all patients on ART, and whenever there is suspected treatment failure, only a few developing countries (e.g. South Africa, Botswana, Brazil) have widespread access to routine viral load testing for patients on ART. (*UNITAID HIV Diagnostics Technology Landscape, 4th edition*). Lack of access to this vital testing in most countries is due to their insufficient laboratory infrastructure and equipment, personnel capacity and skills, and sample transport networks, in addition to the prohibitive costs involved. Until recent years, viral load testing was not as much of a priority for countries (and was often seen as an expensive luxury, to come later) as was rapid testing, ART initiation, and CD4, as countries rapidly worked to scale up their HIV care and treatment programs.

For viral load testing (VLT), three components are required – 1) nucleic acid extraction system, 2) real-time PCR thermocycler (also known as amplification equipment), and 3) HIV amplification/quantification kit. Most viral load systems have historically been "closed" or "integrated" systems, manufactured by companies including Roche, Abbott, Siemens, bioMerieux and others, with their platforms being restricted to use of only their branded reagents and consumables. By contrast, OPP (open polyvalent platforms) are flexible, able to more interchangeably use reagents and consumables from different suppliers.

2.1 The OPP-ERA Project

This evaluation focuses on the OPP-ERA (Open Polyvalent Platforms for sustainable and quality access to VL in resource limited settings) Project financed by UNITAID and launched in March 2013. OPP-ERA is a Project whose aim is to improve access to new HIV monitoring technology – specifically viral load testing (VLT) and early infant diagnosis (EID) testing (which also uses viral load test systems), through the introduction of Open Polyvalent Platforms (OPPs). These are innovative systems that allow equipment and reagents made by different manufacturers to be used together, making the system more flexible, easy to use, and affordable for smaller labs. The aim is also to enable access to equipment that can more easily be used (and repaired) in more decentralized and resource-constrained settings, which may not be appropriate for the larger, integrated ("closed") viral load testing systems. OPP systems can be used for HIV viral load testing, early infant diagnosis (to detect HIV in infants under 18 months), and for detection of other pathogens.

2.2 History and Rationale for the OPP-ERA Project

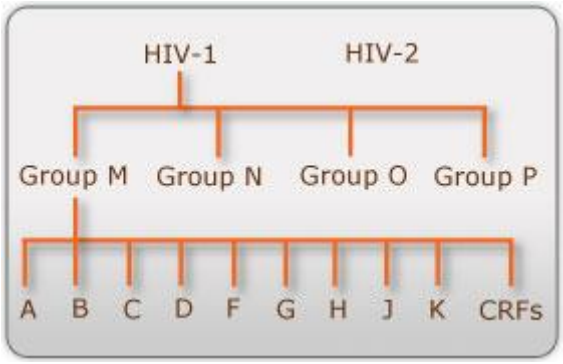
Although OPPs have been used in research, these systems were not yet widely used for regular HIV viral load testing in clinical settings in most countries. The concept of OPP is not that new: Myanmar, Laos, Viet Nam, Georgia and other countries, as well as private laboratories (e.g. Laboratoire guineo-Allemand) have used it, e.g. for Ebola, but not for HIV.

With the successful use of these systems in some developing country settings, founding members of the consortium implementing this project reportedly felt that OPPs should be considered for wider, more routine use, and to enable better detection of various strains and sub-types of HIV. This project was developed to test and demonstrate the feasibility of using OPP systems in resource-limited settings for routine viral load testing for patients on ARVs.

The project (originally known as "Pascal") was developed over several years, to address the need, both in developing countries and in countries such as France, to better diagnose and manage the various HIV strains (including the "non-B" strains prevalent in West Africa, which were prominent among patients presenting in France for treatment, many at Necker Hospital lab). HIV-1 is the dominant type of HIV worldwide, but within HIV-1 are a number of strains classified in groups, with the "M" group being the most dominant. Within the Group M are a number of sub-types of HIV (A, B, C, D, F, G, H, J and K), dominating in various geographic regions, and with different transmission and progression rates. B has been the most common sub-type found in North and South America, Europe, Japan and Australia. Most ARVs were developed to combat sub-type B, but appear to be effective against the other sub-types as well. However, it is thought that some subtypes are more likely to develop resistance to certain drugs (http://www.avert.org/hiv-types.htm). Diagnostic technologies and reagents were developed (largely by US, European, and Japanese manufacturers) to address the diagnostic needs in Europe and other developed countries, but neglected the strains (especially other than B) and circulating recombinant forms (CRFs) from other countries (including West Africa). Some VL tests in fact were only sensitive to sub-type B HIV. Therefore, viral load (essential for monitoring and managing HIV treatment) can be underestimated by existing VL technologies without adequate sensitivity to sub-types other than B, with serious treatment repercussions. This was the reason Prof. Christine Rouzioux, a principal founder of the project, expert in sensitivity of tests for different HIV strains, directing the Necker lab in Paris, notes that she was motivated to develop a new viral load test that could accurately measure strains other than sub-

type B. She notes that as many as 50% of her HIV positive mothers presenting in her hospital are from West Africa, hence non-B sub-types are very common in this laboratory (as they are in West Africa).

Figure 1 Various sub-types of HIV



http://www.avert.org/hiv-types.htm

In addition to monitoring of non-B type HIV, Prof. Rouzioux and the other project founders reportedly wanted to find ways to benefit from the flexibility of OPP platforms, and the ability to monitor/diagnose other pathogens (polyvalence). MSF and others have noted the desirability of having laboratory equipment that is able to detect multiple diseases, to facilitate laboratory operations and equipment needs, and enable a patient to be tested at once for various diseases. *(Undetectable – How Viral Load Testing can Improve HIV Treatment in Developing Countries – MSF. July 2012).*

Although a goal of the UNITAID project (as discussed in the original proposal) was ease of access to VL through potential for increased use of Point-of-Care (POC) technologies, most VL testing is still done in the laboratory, using complex equipment. Several POC platforms are being developed, but there is as of yet no widespread use of POC for VL. Being molecular biology, even at its most simple application (whether in OPP or integrated systems), viral load diagnostics are complex and require fundamental technical and human resource capabilities. There are also significant complexities in sample handling, manipulation and preparation of samples before testing, procurement of disposable items, cool and cold chain requirements for reagents, short shelf life for reagents, properly managing the steps in the testing process, prescribing, interpreting and reporting on the results/findings.

Because VL testing is done in the laboratory, blood samples have to be taken and sent for VL testing, leading to complications and challenges with transport of these fragile samples, and with ensuring test results get back to the patient and treating physician. An added complexity is the need to centrifuge the blood to extract plasma within 6 hours of being taken from the patient. Plasma must then be kept refrigerated during storage and transport, adding challenges and costs to the whole transport requirements.

The OPP-ERA project's stated goal is to provide an additional alternative to the larger, closed systems – to provide countries with additional VL capacity to expand access to this vital testing, including in smaller laboratories and more remote areas. These may not be strictly point of care (POC) (in that

these VLTs still may not be performed in a rural clinic or treatment site), but their aim is similar – simplifying and increasing broader access beyond the centralized, larger laboratories.

Table 1: A brief comparison of some main parameters of closed/integrated systems and OPP systems

	Closed/integrated system	OPP system
Installation and infrastructure requirements	Lab infrastructure, electricity, air conditioning. Cold chain required.	Less sophisticated lab infrastructure, electricity, air conditioning. Cold chain required for amplification reagents. Less space necessary.
Size of system	Big (293 kgs), with two large machines (large automated extractor and thermocycler), with computer	Smaller (52 kgs), with manual or semi-automated extraction (extraction, thermocycler, computer)
Approximate price of equipment (varies by type, by country, by deal)	$100,000-$230,000 (including installation and training and software)	Extractor (Diasorin): $17,000 Thermocycler (Roche): $25,000 (including software, installation and training) = $42,000 Labs often double up on extractors and amplifiers (x2) = $84,000
Maximum throughput per day	288	192
Human resource requirements	2 qualified lab technicians - the different machines on the market require more or less input from the lab technician.	2 qualified lab technicians -requirements for sample manipulation are close to the same, even if machinery comes from different suppliers.
Maintenance needs	The big, closed systems are fragile, because they have many moving parts inside. (If one part malfunctions, the whole system stops). There are challenges with after-sales support, representation of companies in the region. Can only be serviced and repaired by the supplier's company. Equipment failure is reported as frequent even in high-level labs. Requires an engineer from the supplier to visit, and VLT is interrupted until this is done.	More flexible. Easier to maintain, less risk of break-down. Recommended to double up on extractors/thermocyclers to build in redundancy to system (if one machine breaks down, testing can continue). Equipment that is sturdier: the amplification machines (thermocyclers) reportedly last for many years, and require little maintenance. The extractors can either be repaired by lab staff with online support or replaced by the supplier. Systematic replacement is the policy used by Diasorin for their extractor. The size of the machines allows for relatively modest cost of replacement, because they are easier to ship (e.g. as was reportedly done in Guinea and Swaziland).
Calibration required	Yes	Yes (but reportedly more can be done by lab staff, as equipment is simpler)
Waste created	Large volume of waste including plastics most often disposed of in the environment	Substantially less waste generated
Time to run set of tests	Typically 5-6 hours	8 hours

Source of data: FEI interviews, Phase 2 OPP-ERA proposal

3 OBJECTIVES AND CONDUCT OF THE EVALUATION

The aim of this evaluation is to assess the progress made towards the overall objectives of the OPP-ERA project, and to develop recommendations for phase 2. The evaluation covers the project period of March 2013 through September 2014. As much as possible, this evaluation has attempted to take into consideration the work done during the no-cost extension period which was underway and due to finish December 31, 2014. The deliverables are this evaluation report, recommendations to UNITAID on how to improve effectiveness and efficiency of project planning, and recommendations to UNITAID and the project implementers for Phase 2 of the project.

This evaluation has been conducted before the UNITAID Executive Board (UNITAID's governance body) meeting (December 11, 2014) when the Board was expected to decide on directions, funding, and priorities for Phase 2 of the project – and whether the project will indeed be granted a Phase 2 stage and funding. Phase 2 is tentatively budgeted at $13.7M for a two-year timeframe (Jan 2015-Dec 2016), with $12.8M in UNITAID funding, and almost $1M ($962,883) co-funded by the project's consortium of organizations. This evaluation report will serve as an additional background document for the Board to assist in making its decisions about the project.

3.1 Evaluation Team

Euro Health Group (EHG) is an ISO 9001 certified health consulting company based in Denmark, specialized in procurement and supply chain management (PSM), M&E, health care development, health policy and health care reform, and public health financing. The EHG evaluation team was composed of two international consultants (Team Leader Jennifer Lissfelt; and Principal Evaluator Julie Pasquier) who also conducted a January 2013 evaluation of the UNITAID PQDx project (and hence had some background in UNITAID projects), and who have extensive experience with international health projects focused on HIV, TB and malaria, including experience in all of the priority countries of the project. Both have worked extensively in the area of Procurement and Supply Management (PSM), and on M&E of HIV programs, and have also conducted numerous program/project evaluations. They were supported from EHG HQ for overall coordination and quality management.

3.2 Evaluation Approach

The evaluation team has conducted this evaluation in 7 weeks (Oct-Dec 2014) through:

- **Documents Review**: The evaluation team has reviewed both the UNITAID and FEI web sites, and documents available therein. The UNITAID team has also provided (through Drop Box) copies of the project MOU and annexes, logframe, budget, and inception, interim and annual project reports from FEI. Other documents provided include country MOUs, implementation files including financial documents, procurement documents, meeting notes, mission reports, and a Business Plan for Phase 2. Also included are numerous amendments, feedback documents, and meeting notes, which indicate how the project has been modified or adapted in its initial phase. Over 165 documents were provided. The evaluation team also reviewed a large number of relevant external documents from WHO, CHAI, MSF, the Global Fund and others.

- **Primary Data Collection**: The evaluation team met with the UNITAID project team in Geneva on Nov 11, 2014 and with FEI and the implementing partners in Paris on Nov 12-13, 2014, to seek their feedback on the operations and results of the project so far. Following these meetings, key country contacts were contacted in the four pilot countries, by phone/Skype. (Note: the evaluators attempted to contact a significant number of persons in each of the 4 countries, but were only able to reach 2-3 in each country within the timeframe of the data collection). In addition, telephone interviews were conducted with experts from USAID, the Global Fund, MSF, GIZ, Biocentric, WHO, USAID, GIZ, the national reference laboratory of Georgia, and the Clinton Health Access Initiative (CHAI). Additional interviews were conducted prior to the final revised report submission in January 2015, including Anatolia, the WHO Diagnostics Advisor, a diagnostics expert from the London School, and a representative of the MOH in Cameroon. Interviews and questions were based on documents reviewed and issues identified. These meetings and discussions greatly enriched the evaluation findings, providing significant context and nuance, and a wider perspective on the project than documents alone can provide.

- **Lessons learned and Value for Money, Risk mitigation for Phase 2:** The team reviewed the Business Plan drafted by FEI for Phase 2, and assessed how the Business Plan addresses the lessons learned in Phase 1 (as documented in project reports, and learned from project stakeholders), with a view to ensuring Value for Money and managing potential risks for the next phase. This was a key expressed interest of UNITAID, for presentation to the Board for their decision making for Phase 2 of the project.

The EHG evaluation team has examined the objectives and key performance indicators of this project, as specified in the project's Logical Framework (logframe), and their performance to date vis-à-vis these indicators (developing a table – in section 4.4 below -- to measure and succinctly present these findings). Achievements of the project were measured relative to objectives, outputs and outcomes as established in contractual agreements and project plans. It is too early to expect any actual impact on the targeted beneficiary populations, beyond the actual viral load tests being performed where previously no VLT (e.g. Burundi and Guinea) or many fewer tests (e.g. Cameroon and Cote d'Ivoire) were offered. It is therefore beyond the scope of this evaluation to be able to measure and attribute any such larger impacts to this project. However, this evaluation has attempted to measure outputs, outcomes, and where possible, impact. A future evaluation could better assess the impact on patients and their treatment, once more VLT has been conducted, through discussions with PLWHA and other civil society groups representing HIV patients.

3.3 Evaluation Schedule

The evaluation was conducted in 3 phases, as follows:

1: Inception and Design Phase

During this preparation phase, the team had preliminary discussions and planning communications with UNITAID, obtained access to the project documents, began reviewing the documentation, and began to develop questions and plans for stakeholder interviews and data collection. An Inception Report for the evaluation was also prepared and delivered to UNITAID.

2: Data Collection and Analysis

This phase included a comprehensive review of project documents. The team assessed the monitoring indicators and established a framework to measure project activities. During this phase, the evaluation team met with and spoke by phone or Skype with numerous stakeholders, to supplement the documentation and to solicit further insights and feedback on the project. This included interviews with UNITAID and the project implementers in Geneva and Paris the week of Nov 10-14, 2014, and phone/Skype interviews with stakeholders in the 4 pilot countries, as well as numerous outside partner organizations.

3: Reporting and Dissemination of Findings

The evaluation report and recommendations were drafted and submitted Dec 4, 2014 to UNITAID, to present lessons learned, suggested ways to improve efficiency and effectiveness of UNITAID project planning, and potential improvements to enhance value for money and to mitigate risk in Phase 2 of the project. Based on the comments and feedback from UNITAID and the grantee, this Final, revised Evaluation Report and Recommendations was produced in January 2015.

3.4 Limitations

The evaluation team faced some limitations in conducting this project evaluation, although the team endeavoured to overcome these limitations. These included the following:

- Lack of access to the latest project financial and narrative report (submitted by FEI to UNITAID Nov 7, in the midst of the evaluation)
- Large collection of selected documents (over 160) provided by UNITAID in numerous files and sub-folders necessitated sorting, organization and prioritizing
- Additional documents provided during the course of the evaluation (e.g. latest logframe, received Nov 27) necessitated rapid review late in the analysis and writing process
- Short timeframe meant that not all respondents were available for interviews
- Difficulty in reaching many in-country respondents (for technical and non-technical reasons). All contacts provided for each country (7-8 per country) were called, however only two to three could be accessed per country. The list of respondents reached mainly contains those from the original contact list who happened to be reachable.

4 EVALUATION FINDINGS

The evaluation focuses on the objectives and key performance indicators set for the project, and attempts to provide objective measures of how the project is performing, where there is success and where there is room for improvement. The evaluation team also developed recommendations to enhance the project in Phase 2. This was done through analysis of quantitative results, as well as qualitative feedback from project stakeholders and beneficiaries (both through interviews and phone discussions, and through review of previous discussions, meetings, and feedback from stakeholders and project reports).

The evaluation seeks to: 1) examine the technical achievements and results of the project, and successes and challenges to date as compared with the project workplan and logframe; 2) assess the effectiveness of the project's management and implementation; and 3) assess how well it is

integrated with the global efforts of UNITAID and with the overall efforts (of multiple organizations) to improve the quality and access of diagnostics for HIV and AIDS. UNITAID has also requested a specific focus on programmatic and financial risks, and ways to mitigate these for Phase 2 of the project.

4.1 General Cross-Cutting Findings

This evaluation attempted to examine the project from multiple angles, various points of view, and using various criteria or metrics including delivery on project indicators and objectives, management, relevance to the needs on the ground, value for money, market impact and effect on supply and demand factors, sustainability, and others. A few general findings of the evaluation team are the following:

- VALUE AND RELEVANCE OF PROJECT: The project was found to be valuable and relevant in supporting expansion of viral load testing to more patients. The OPP reagent is reportedly currently the only VL reagent to adequately detect non-B types of HIV. The project continues to work toward its objective of making VL easier, cheaper, and more accessible, although there is still work to be done on both the supply and demand sides. The project has seen some shifts in objectives, given the realities in the industry – e.g. for now, POC is not a major focus, as there is no widely established technology yet for POC in VL.
- MARKET IMPACT: There is a benefit to the project in helping to disrupt the current VL market, which is dominated by a few large suppliers of integrated VL systems (with many of these systems idle, not working for various reasons even where they are installed). As PSM issues (including lack of supply of reagents) has reportedly been a major factor in the non-functioning of these integrated systems, OPP-ERA must be certain that supply channels and country capacity to manage these are well taken into account to build sustainability for OPP, or the OPP systems may face some of the same challenges in future as the integrated systems have, reducing their impact and usefulness. With only one amplification reagent OPP supplier (Biocentric) for now, which still does not have WHO or CE IVD prequalification, the supply side for OPP is still not developed. QA for amplification reagents was a major blockage/delay in Phase 1, although the implementer notes progress on this front, with more potential suppliers identified, and greater emphasis for suppliers to attain their international QA accreditation. Longer-term market impact will have to be measured further into the project's implementation.
- TIMELINESS: The project comes at a critical time, when the international community (including WHO, which is critical) are focusing more on VL and its importance to sound HIV treatment. With new WHO guidelines (2013) recommending routine viral load testing for all patients on ART, and increasing attention to VL by the international health community, demand from countries for access to VL is set to expand greatly. The resulting market shifts will impact and be impacted by the use of OPP for VLT in some countries.
- MANAGEMENT CHALLENGES AND RISK: The risk-averse nature of UNITAID and caution about making the investment in this project has led to some micromanagement and difficult relations. All innovative, pilot projects must incur risk in order to test a new concept. The biggest risk project implementers noted to the evaluation team is if Phase 2 is not awarded and funded quickly after the December Board meeting, as they note that everything will stop (staff, procurement, field trips, testing). The appearance of conflict of interest in QA and product

selection may be a major constraint on the project's reputation and ability to gain broader support. This can be rectified.

- COMMUNICATIONS CHALLENGES: OPP-ERA is a complex project and topic area, prone to significant misunderstandings, even within the project team (e.g. between project implementers and project funder UNITAID). Management and reporting/communications challenges have exacerbated some misunderstandings. French vs. English communications are also a challenge (implementers are Francophones, but all reporting and most communications with UNITAID must be in English). There seems to be a reputation issue or attitude toward the project among some international partners in the appearance/ impression among some that the project is too French-focused, too "cliquey" in favour of French organizations, too restrictive to only French-speaking countries. (Also a natural tension, with GF's new funding model focus on highest prevalence countries, whereas the project focuses on countries with lower prevalence).
- PSM CHALLENGES: Cold chain and other infrastructure and PSM challenges remain – including the need to keep amplification reagents at -20C, short shelf life of reagents, need for constant energy supply and computer with loaded software, need for sterile laboratory conditions, air conditioning, dedicated area to avoid contamination of samples. So even "simpler" more user friendly systems like OPP still require laboratory capacity and trained human resources. The project will need to keep a strong focus on this area (and consider additional support, if needed) to ensure testing can continue and be sustainable. A stated problem for all countries was purchasing of local supplies for small items (pipettes, etc), so this was changed for phase 2 (to have more central procurement of consumables). There remain QA challenges for amplification reagents (lack of PQ'd suppliers).
- COUNTRY RESPONSE: The project is working with 7 laboratories in 4 pilot countries, with more planned for Phase 2. The project has been well received in the 4 pilot countries (according to all country stakeholders interviewed), but with significant "hand holding", infrastructure development and capacity building required (although it could be argued that a similar level of support would be required to install and implement VLT on integrated platforms – this need for support is not unique to OPP but rather a requirement to execute VLT in a developing country, on any system). Phase 1 of the project was really not an "implementation phase" as it was named – rather, it was more like a feasibility/assessment/set-up phase. Phase 2 would be much more about implementation and roll-out in these and other countries, and building replicability (it is hoped) elsewhere. The demand side, while set to grow exponentially with the new WHO guidelines, still needs work, to make countries demand VL and be comfortable with OPP vs. more known Roche or Abbott brand names. UNITAID had a valid question about the project's ability to roll out to more countries, when the 4 pilot countries demanded so much hand holding and the project had so many delays to get up and running in Phase 1. Country capacity (and the presence of trained laboratory technologists) remains a challenge for wide replicability and sustainability. This is something the project must focus on in Phase 2, to ensure continuity and sustainability for VLT.

4.2 Project Start-up and Launch

Following the UNITAID Proposal Review Committee (PRC) rejection of the initial two proposals (submitted beginning in 2011) for this project (due to questions of technical feasibility and impact on the market), the third submission was successful, on a reduced basis. The lead project implementer, France Expertise International (FEI) reportedly found it difficult to find the right balance in proposals

to satisfy the need to be both sufficiently ambitious and cautious in the project's goals. Initially, proposals were rejected for having goals that were too low, and then for being too ambitious. There was also reportedly some reluctance at UNITAID to fund a project to work in these lower prevalence Francophone countries, given worldwide funding constraints and prioritization by Global Fund and others of highest impact countries. UNITAID reportedly preferred that the project focus only on the economic and market aspects of the work (desiring a somewhat "hands off" approach in countries), however the project implementing team reportedly stressed the need for in-country efforts. Challenges at the beginning of the project included questions around feasibility, lack of a business plan, and a proposal that was "not too solid" (without sufficient market analysis) according to at least one central respondent.

After requests for clarifications and setting 5 conditions (business plan for phase 2, strengthening the market component, addressing intellectual property issues, ensuring a regulatory approach in each country, and instituting a strong QA approach), the UNITAID Board approved a pilot phase 1 for 16 months (March 1, 2013-June 30, 2014), with UNITAID funding of $2.4M, over $500,000 of additional funding (17% of the total of $2.9M) from the implementing partners, and an agreement to work in 4 pilot countries (Burundi, Cameroon, Cote d'Ivoire, and Guinea). An MOU was signed on Feb 11, 2013. FEI reportedly signed quickly (in 3 days) with UNITAID, without a logframe in place, and without sufficient review and discussion of the workplan and budget, according to some respondents.

Phase 1 included an "inception" phase of the project (March-Sept 2013), followed by the "launch" phase, according to the MOU. During this Phase 1, the lead project implementer, France Expertise International (FEI) worked with the other project partners (ANRS, Esther, Solthis, Sidaction) in the consortium to test the OPP concept and to develop a full Business Plan for scaled-up commercialization of OPP viral load testing. This phase 1 is intended as a preparatory phase for phase 2, to develop a procurement strategy and plan for the four project target countries and the deployment of OPPs in these countries and beyond.

The first 6 months of the project were dedicated to visits from the coordinator virologist to the countries, assessing and preparing countries, designating and working with local coordinators, signing MOUs with the 4 countries, forming pilot committees, assessing and validating sites (2 per country, except Burundi which has one) in each country, measuring equipment and refurbishment needs in sites, devising training plans, visits by the procurement expert to help prepare tender documents, having an open meeting with equipment and reagent suppliers (June 2013 in Paris), and issuing the Tender for Lots A, B, and C (the various components of the OPP VLT system). Delays were then encountered due to the lack of quality assured suppliers for Lot C (as discussed further in other sections of this report), necessitating a compromise on the QA policy, to enable suppliers with their WHO prequalification in process to participate in the tender and supply the project.

Although there was meant to be one year of project activities (March 2013-March 2014), followed by a four-month (April-June 2014) bridge to phase 2; following submission of the phase 2 proposal, a no-cost extension was requested and granted in June 2014 (due to the delays encountered), for the period July 2014 through December 2014. This has meant that Phase 1 has had a timeframe of 22 months. Phase 2 has been proposed to run for another 2 years (Jan 2015 through Dec 2016).

4.2.1 Country Activities

In June 2014, the new laboratory construction (in Donka, Conakry Guinea, by Solthis) and renovation works (in ANSS Burundi by Sidaction and in LNSP Guinea by Solthis) were completed. By July 2014, equipment and products were delivered to the 7 laboratory sites in the 4 countries, suppliers visited and trained in-country staff (Biocentric and Roche reportedly coordinated and worked with the laboratory staff in countries to learn the procedures), and the project began VLT in the sites in August 2014. Burundi (where Sidaction is the lead implementer and where some 4500 ART patients are monitored although almost no VL was being done) and Guinea (where Solthis is the lead implementer, and where no VL was being done 2012-2013, although some 8900 ART patients needed monitoring through the 2 laboratories) reached their testing targets quickly, project documentation shows. They were oversubscribed, in fact. Cameroon (where Esther is the lead implementer and where some 7800 ART patients would be monitored) had previously only done VL on patients considered to be already failing on treatment, so the project team worked with the laboratory counterparts there to address this issue of demand among prescribers. In Cote d'Ivoire (where Esther is the lead implementer and where some 10,500 ART patients are monitored through the 2 laboratories) the government provides some funding for VL and there is actually some history with OPP for VLT (in work done with Esther there since 2008) although VLT was not being prioritized. Testing has now been underway since August 2014 (3 months) in the four pilot countries. By late September, nearly 2 months after starting VL testing, some 3505 VLTs had been performed on the OPP systems in the 7 laboratories. The responsible laboratory technicians in each laboratory sends the VL results to the country technical supervisors, who share these results each week with the coordinator-virologist, who reviews and tracks this data with the scientific director at ANRS. All of the laboratories were also reportedly enrolled in the QCMD/ANRS International Quality Assurance programme.

Table 2: Specifics in each of the 4 countries included in phase 1

Country	Labs involved	ART patients served in the labs	Lead Partner	Project Activity Specifics
Burundi	ANSS	4500	Sidaction	-No VLT had been done in country in 2013 -National protocol was 2 VL tests per year -"Cemetery" of broken down lab equipment at INSP -INSP plays key role in coordination, training -Large FHI project focusing on labs, sample handling network -Small country, maximum 4 hours to get anywhere by road
Cameroon	CPAG LQT	7800	Esther	-Patients were being charged for their VLT ($50/test), project helped reduce this to $20 -Country was only doing VLT for suspected treatment failure -Sample handling system is functioning well using truckers and couriers -Centre Pasteur de Cameroun (CPC) plays key role in coordination, training
Cote d'Ivoire	CeDReS Cepref	10,500	Esther	-Some OPP for VLT was done previously, under project with Esther from 2008 -Some government support for VLT, although VLT was

				not considered a priority -PEPFAR and other partners were not prioritizing VLT -Sample handling is benefiting from existing CD4 sample handling system, adding onto that system
Guinea	LNSP Donka	8900	Solthis	-New lab for VLT built by Solthis (with Solthis funds) -Renovations made on LNSP lab -Strong champion for VLT (HIV lead doctor) -Clinical experts committee organizes flows of samples. -National PSM committee helps ensure stock-outs and other PSM disruptions are avoided

4.2.2 Country Feedback

The feedback obtained from the 4 countries when the evaluators contacted them by phone/Skype was remarkably similar and positive. The respondents reached expressed great enthusiasm about the project and were eager to continue and to scale up. At the moment they are bound to a maximum of 81 tests per week, since this is what the reagent stock procured will permit until the end of phase I (end of 2014).

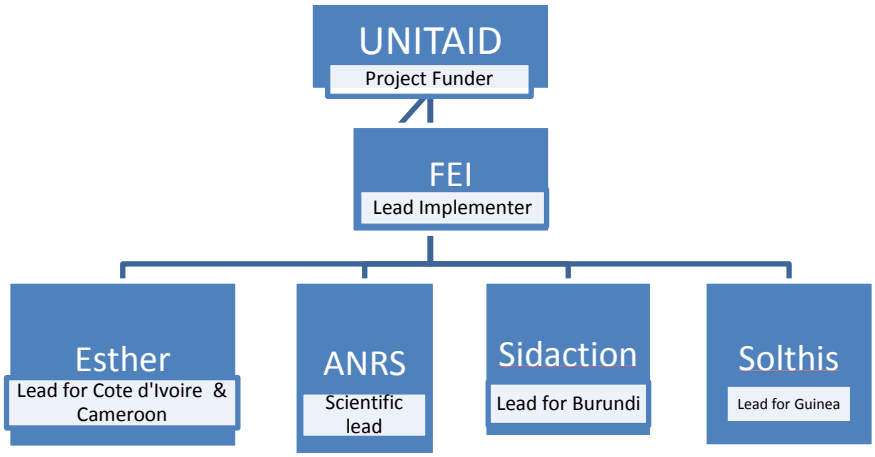
Since the contacts for the respondents in country were provided by FEI and implementing partners and they were largely people involved with the project, the evaluators noted that there might be a bias as the respondents directly or indirectly benefit from the project (e.g. even a national HIV lab director not managing the project or compensated by the project benefits, in that his lab is a beneficiary). However their enthusiasm and support for OPP-ERA can also be explained by the fact that the laboratories selected in phase 1 went from not performing VLT to performing VLT and being confident in doing so. In countries like Burundi and Guinea this is the first time that routine VLT is being done. It was reported that the laboratory technicians in charge of performing the tests are doing so in addition to their normal work load without specific remuneration for this and that this might become problematic in phase 2, when the number of tests to be performed will be scaled up. This will likely be an issue that the project will have to address in Phase 2. Respondents noted that few technical issues have occurred with the purchased devices and that they could all be resolved without interruption of viral load testing. An official from the MOH in Cameroon noted that OPP-ERA covers a very small proportion of the need for VLT in his country (where there are 135,000 patients on therapy, and the 5000 tests conducted under OPP-ERA are a small contribution to overall testing). This official also expressed some concerns about ensuring the quality of the tests for the laboratory in Garua in the North of Cameroon, with the great distances for transporting samples (5000 km) and the hot climate. He notes that this lab chosen by the project is in a very challenging area, and he feels there is no information regarding the measures taken in order to properly implement routine VLT there. Therefore, the project will need to ensure this concern is addressed, and that QA steps are taken to monitor these tests and how they are transported, as they continue their program in Cameroon.

4.3 Project Structure, Implementation and Management

The evaluation examined the partnership between UNITAID and FEI over the implementation period of the OPP-ERA project since 2013, and the functioning of the consortium of partners (sub-grantees) working under FEI. Through interviews and discussions with key project staff, consultants, implementing partners, country counterparts, Global Fund, suppliers, WHO, CHAI and others, the

evaluation team sought to understand the actual and perceived functioning of the consortium, the challenges and benefits it provides, and to develop recommendations on how it could be strengthened in future.

The project has two lead organizations – FEI (under the French Ministry of Foreign Affairs) for administration and management, and Esther (another agency of the French government – under the Ministry of Foreign Affairs and Ministry of Health, with 50% of its funding from international donors and 50% from the French government) as a founding member . FEI is the lead implementer under this UNITAID project, and manages the other partners as sub-grantees. ANRS provides the top scientific advice/support for the project. Sidaction and Solthis (well established French civil society organizations working in HIV and AIDS in numerous countries) round out the consortium, which forms a network of experts with long experience and presence in the pilot countries. FEI signed a consortium agreement with the ANRS, ESTHER, SIDACTION and SOLTHIS in June 2013 and in July 2013.



4.3.1 Collaboration among Partners

Members of the consortium have worked together before, and literally speak the same language. All report that their communication with each other and FEI are good, with regular meetings, information sharing from FEI on UNITAID requests, etc. They note that they have developed tools to help them with project management (e.g. lab update sheets, checklists, etc). Laboratories in countries reportedly communicate directly with the FEI virologist on technical issues, and the virologist liaises with field staff and sub-grantees, as well as the Market Analyst, and ANRS scientist as needed.

There is widespread positive feedback on the project from consortium members, its goals and implementation so far, while respondents also recognize the technical and implementation challenges that OPP-ERA has faced. Consortium members note the good complementarity (of skills, geographical placement, expertise) among members, but also the occasional inconvenience of working through a consortium (in that it can take time to make decisions and move things along). They also note the positive importance of competition among the members – at times respondents noted that they are spurred on to faster performance by this competition with their partners.

OPP-ERA Steering Committee meetings are reportedly held once a month, chaired by FEI, with representatives from each organisation present to discuss project progress, issues, etc. In addition, there are reportedly regular, ongoing communications as needed between the implementing partners to resolve problems on the ground, address questions, coordinate visits, etc.

The consortium partners appear to constitute a very committed, experienced, and geographically well placed set of implementers with the necessary skills and country experience and relationships to properly manage OPP-ERA in the pilot countries, often integrating the activities into their other, ongoing country work with the country HIV programs and laboratories.

4.3.2 Project Management and Human Resources:

Human resources issues and staff turnover, both at UNITAID and at FEI, during phase 1 appear to have had some negative impact. There is a widespread feeling (expressed by respondents) that communications and relations between the project staff and UNITAID improved with the arrival of the new UNITAID Technical Officer for HIV in July 2013 (whereas there was some reported delayed feedback and decision making and communication with the former Technical Officer). The project's Operations Manager position was originally posted at Esther, however FEI has now taken over this position to have in house all project management positions (although this post is not yet filled, as FEI awaits word on Phase 2 funding in order to fill the post). The Project Manager at FEI left and was replaced in July 2014, just as testing was getting under way in countries and the project was gaining traction.

Project reporting was supposed to be done every 6 months (semi-annual and annual reports), with some additional deliverables (e.g. market study, QA approach, etc). However, there have reportedly been many ad hoc requests from UNITAID for reports and feedback, which has meant a heavy reporting burden (and a large volume of documents) for the project team. The resulting compilation of project documents is confusing in that there are numerous versions of different documents, and numerous types of similar documents (e.g. consolidated market study, market studies, market issues, baseline market assessment, etc). The project would benefit from a more streamlined approach to reporting and documents management. (This would greatly benefit future evaluations, to more easily enable them to ensure a thorough inventory and review of project documentation).

For phase 2, FEI's plan is to have 3 project managers (for finance, M&E, and market). FEI has taken over all coordination of the project, whereas partner organizations manage its implementation.

4.3.3 Programmatic Reporting/Deliverables

As identified in section 11 of the MOU, OPP-ERA is required to submit an Inception Report within six months of project start and a Final Programmatic Report on completion of Phase 1 (now due April 15, 2015, per the MOU no-cost extension amendment). The requirements for the Inception report specify several components that are essentially stand-alone reports, such as a programmatic report on progress toward project goals, objectives and outputs; a procurement strategy; country plans; quality assurance policy; monitoring and evaluation framework; draft business plan; and procurement selection reports. The MOU also includes the Project Proposal for Phase 2 and a Full Business Plan as stated goals of the project. The Project Plan developed by FEI, annexed to the MOU, promised various project activities with several main deliverables including market assessments,

business plan outline, a training report, report on use of OPP for TB (by ANRS), a report to the Board, and a Phase 1 report. The project has also produced mission reports (on country visits), procurement tracking documents, a "Phase 1 Implementation Report" (which might be the "programmatic report on progress…toward project goals" mentioned above, required as an annex to the Inception Report), and others. UNITAID has required reporting from FEI every 6 months on both programmatic and financial status and activities; and has also requested various ad hoc reports (e.g. justification for change in QA policy) over the course of Phase 1.

There is significant inconsistency in how documents have been named and titled, as well as naming conventions for the electronic files (and often, lack of date, author and other details on these documents), and the file structure used to archive these documents. There are also a vast number of documents, feedback, revisions, comments on feedback, etc., all of which made a thorough review of all project documents (more than 160) rather challenging for this evaluation.

All reports due as of the time of this evaluation appear to have been submitted to UNITAID. A timeline developed by the evaluators and included as Annex IV of this report identifies when project reports were submitted as well as when key project events took place. Reports required by the MOU are highlighted in the Annex in bold text. The Final programmatic report on progress and results for all of Phase 1 is only due 30 April 2015.

From FEI's perspective, programmatic reporting has been demanding and has entailed a considerable review process. From UNITAID's perspective, programmatic reporting from FEI has required considerable revisions and clarifications. It is possible that some of the back and forth required is partly a result of miscommunication due to language differences. Regular programmatic communications between FEI and UNITAID are described as open and good.

4.3.4 Financial Review

This brief overview is based on interviews at UNITAID and FEI, and a review of a very limited number of financial documents and related correspondence. At the time of preparing this evaluation, the financial report for Jan-Dec 2013 was the most recent financial report available. The semi-annual financial report for January-June 2014, which was only submitted to UNITAID in November, was not available to the evaluators. It is worth mentioning that many of the documents reviewed (including budgets) do not indicate the date the document was produced, making comparison of multiple versions of the same document difficult.

Reporting – According to UNITAID, financial reporting from FEI has improved, but the initial budget and financial reports submitted reportedly had problems with calculation errors, confusion with exchange rates, and some difficulties with consistency and clarity. The previous issues with mistakes in financial reporting have frustrated UNITAID and have caused UNITAID to spend more time scrutinizing the numbers and verifying calculations of subsequent reports than they would like. Requests by UNITAID for clarifications or corrections to reports, however, have been responded to and corrected by FEI. With the exception of the most recent report, financial reports have been submitted on time for each 6-month period. The most recent financial report was submitted late with UNITAID approval, because of concurrent preparation of the proposal for phase 2.

Spending – Project spending in the first months of the project was much slower than anticipated because of programmatic delays in procurement. Only $500,000 of $2M budgeted for 2013 was spent during the period due to the PSM delays. Spending is reportedly back on track with the overall budget for Phase 1 of the project, according to interviews with FEI and UNITAID. The procurement delays early in the project prompted an agreement between UNITAID and FEI to extend the project for 6 additional months at no additional cost to UNITAID. According to correspondence, the project extension did require a reallocation of funds that were budgeted for procurement of commodities to cover personnel costs for the additional six months of the project. With the reduction in commodity procurement, the target number of VL tests to be done in Phase 1 was reduced from 32,000 to 20,025. However, reallocation of the budget could not be analyzed or confirmed from the budget files provided.

Financial Controls – An assessment of financial controls is beyond the scope of work for this evaluation, but the initial problems with errors in financial reporting do raise some concern in this regard. UNITAID will reportedly undertake a complete audit of project expenditures for Phase 1 in mid-2015. It is also worth noting that FEI's independently audited financial statements for 2013 confirm that the organization's books and accounting practices are deemed to be in accordance with general accounting practices. No accounting anomalies were identified by the auditors, according to their report.

Co-funding- FEI and its implementing partners have provided co-funding for phase 1, and this is planned again for Phase 2. According to budget documents, the consortium agreed to contribute $503,536 in co-funding for phase 1. In interviews, FEI reported that they and their implementing partners contributed more of their own resources to the project (e.g. to engage additional staff) than originally planned. UNITAID reported that the co-funding amounts contributed by the implementing partners were not entirely clear or consistent. Similarly, the evaluators could not directly verify co-funding amounts from the documentation provided.

Disbursement- Actual disbursements of funds from UNITAID to FEI are made in response to semi-annual requests from FEI. FEI manages disbursements to the sub-grantees. Disbursement requests to UNITAID are based on estimated expenditures for the subsequent six months of operations. According to UNITAID, some $2.2M has been disbursed so far. Disbursement requests for procurement are submitted as needed. As with financial reporting, UNITAID has noted some frustration with errors in disbursement requests.

Procurement – Procurement is discussed in the section below. Documents indicate that FEI, as lead project implementer, commits to overall coordination of the project, as well as fiduciary responsibility to run the project in accordance with the MOU signed between FEI and UNITAID. This includes responsibility at FEI for all procurement under the project, including managing contracts in coordination with the field-based implementers to ensure delivery and support to countries as committed by the contracted suppliers.

In sum, financial management appears to be handled adequately, but would likely benefit from a full-time financial/procurement manager at FEI under Phase 2. Weaknesses with financial reporting in

the early part of the project appear to have been corrected to a great extent, but there is still room for some improvement.

4.3.5 Procurement Review

International procurement

The OPP-ERA project produced a detailed Procurement Procedure document (May 27, 2013), which guided project procurement decisions in line with international and UNITAID (as well as FEI) principles and practices. OPP-ERA's international procurement was conducted following best practice and in line with UNITAID policy, however the process took much longer than expected due to the lack of suppliers fully meeting the requirements, namely quality assurance certifications and the ability to quantify non-B types of HIV. This delay was the major hurdle of the project, as countries were waiting to begin testing, and phase 1 had to be extended as a result.

With the size of this procurement being quite small, one could not expect major price reductions as can be obtained when buying in larger volumes. The project procured 11 extractors, 6 thermocyclers, and reagents for 20,025 tests, which were delivered and installed in the 4 countries June 27-Aug 8, 2014. The quantity of reagents procured represents what is necessary to perform 81 to 162 tests per week in 7 laboratories for about 6 months – meaning to run the amplification machine in each laboratory once or twice per week.

The price of reagents bought in Phase 1 was $16 per test, which, as OPP-ERA points out in their report to the Board (Sept 2014), represented a significant price reduction (47-68%) from the price for tests on integrated platforms in these countries (which was reportedly at $25-50 at the time, as reported by the project in their mission reports following field research). Some suppliers of integrated systems have recently (late 2014) announced negotiated or access program prices of approximately $10 per test for VL reagents, although it remains to be seen where these prices will apply (perhaps only in high-volume countries – at present these prices appear to largely apply in South Africa and some East African countries), and what the price will include (and not include). In phase 2 OPP-ERA believes they will obtain a reagent price of $10 in their countries, as the project notes volumes will be higher and they have had offers from CE IVD certified suppliers for as low as $5 (although these did not quantify non-B type HIV. During Phase 1, VL tests for lower prevalence countries were in the range of $30-60 per test (*OPP-ERA Business Plan – Sept 2014*), although it is evident that costs are somewhat unclear across countries and comparison reports, with great variation among countries, buyers, platforms, depending greatly on order volumes and depending on what is included in the costs (reagents only, consumables, use of machines, etc). AIDS.About.Com (*Oct 29, 2014 article*) provides a range of $24-44 per test for VLT globally, with reagents and consumables constituting some 50-75% of that cost. The African Society for Laboratory Medicine (*May 5, 2014 presentation in Lusaka, Zambia*) gives a price range of $10.50 to $55 for a viral load test (reagents and consumables) across 12 African countries. MSF reported in 2012 that "In Africa, costs can range between US$20-100 to run one test, depending on the technology, test, laboratory and elements included." (*MSF – "Undetectable – How Viral Load Monitoring can Improve HIV Treatment in Developing Countries" July 2012*).

Only 2 qualified suppliers were prepared to enter the market for each of the three Lots, namely:

- **Diasorin** and **Lifescience** for Lot A (extraction equipment and kits),
- **Lifescience** and **Roche** for Lot B (thermocyclers), and
- **Biocentric** and **Anatolia** for Lot C (amplification reagents)

This is very few when compared with the number of suppliers on the market. It will be important in phase 2 that the project better communicate with potential suppliers and increase their participation in the selection process so that data and experience from a larger number of suppliers can be gathered and the potential of OPP better maximized without limiting the system to too few suppliers or too few options for equipment pairing.

The Phase 1 international procurement procedure concluded with an OPP platform consisting of:

- Arrow extractor and RNA extraction kits provided by **Diasorin**,
- A Lightcycler thermocycler provided by **Roche**,
- HIV-1 amplification/quantification reagents provided by **Biocentric**

Anatolia (a Turkish company, operating internationally) was not selected for Lot C, despite their CE IVD certification, because their reagents reportedly did not perform adequately in quantifying the non-B sub-types of HIV which are prevalent in the pilot countries. Biocentric, although lacking CE IVD or WHO certification (although its WHO PQ is in process, as mentioned), was selected (through a revised QA procedure) because their tests showed excellent results with B and non-B sub-types and the project notes it is the "reference competitor" to Roche in this area. (See Annex III for comparison chart provided by Biocentric).

According to the **Anatolia** respondents interviewed, the CE IVD certification of their test makes it fit for purchase by major funding organisations like the Global Fund. According to Anatolia, so far they have sold their VLT reagents in Turkey, Jordan, Egypt, the Czech Republic, Togo, Djibouti and Italy in combination with amplification and extractor equipment and reagents from many different brands. Anatolia notes that their price per test kit is $6 (for amplification phase only) and can be reduced depending on quantity ordered. Anatolia sells reagents for many other pathologies as well as their own hardware (integrated and OPP). They do not appear to know about the potential donor based market for VLT and have not heard about the Global Fund or PEPFAR, nor do they seem to be aware of the WHO prequalification process. They noted that they were somewhat disappointed with how long it took (after their product had been tested in hospital Necker) for the project to respond to them. They note that they did not know about the lack of sensitivity of their test in a Western African context. They explained that the OPP-ERA project informed them by email that 1) their "assay was not compatible with our kit's acceptance criteria, indicating a sensitivity and linearity problem of the assay"; and 2) "The deviations of quantification higher than 0,7 log copies/ml of the expected values obtained with the Roche system". The tests were repeated in November but in mid-January (at the time of the interview for this evaluation), Anatolia said they were still awaiting the results. The Anatolia respondents interviewed noted that they were surprised to hear about Biocentric and their success with the OPP-ERA tender, given their lack of real time PCR kits, and the fact that their test is CE IVD certified for research use only.

A potential recommendation could be to improve project communications with suppliers like Anatolia. It would be beneficial for such suppliers to understand the technical aspects clearly but

also to be able to understand the potential of the international donor market and how it is structured (WHO prequalification, etc).

We provide some detail on **Diasorin** and **Biocentric** below. (Roche is a known multinational company, one of the world leaders in diagnostic equipment and viral load platforms. Roche's participation in the tender – and eventual selection to participate in this procurement – is taken by the project as a positive sign of the willingness of integrated platform suppliers to work with OPP, and potentially a sign of their interest and understanding that this is a market of the future).

The Selected Devices and Suppliers

Diasorin is a manufacturer of extractor machines from Norway. It has a partnership with the reagent manufacturer Biocentric, which is authorized to sell and maintain Diasorin devices. In this procurement, the extractor was purchased directly from Diasorin. Biocentric reagents have reportedly proven to be very compatible with the Diasorin extractor. The dossier for prequalification submitted to the WHO is for the association between Diasorin extractor and Biocentric reagents only (Biocentric also has submitted a dossier to the WHO PQDx for manual extraction). WHO does not require a reagent manufacturer to specify the device used for amplification, therefore communicating that the choice of the amplification device is not critical for the quality of the test and that compatibility is automatically assumed between amplification reagents and amplification devices. However, should Biocentric become WHO-prequalified it will only be prequalified in association with the Diasorin extractor, limiting the range of OPP possibilities for Biocentric until a new dossier in association with a new extracting device is submitted to the WHO PQDx. The Biocentric dossier was submitted 2.5 years ago (in 2012) to the WHO PQDx, and reportedly remains under review, with continuing requests from WHO for clarifications, etc. (the latest being for an internal control to be provided by Biocentric – which Biocentric is reportedly working to provide). One of the reasons this process is taking so long is reportedly that this is the first time an open platform is being pre-qualified by the WHO PQDx and the protocol for prequalification has been developed during the process. It is expected by WHO that subsequent pre-qualifications will take less time.

Biocentric is a relatively new and relatively small reagent producer based in France, producing reagents for different pathogens. It produces reagents that are particularly efficient at quantifying a wide spectrum of HIV types, especially non-B types which are underestimated by other reagent manufacturers and are very common in West Africa. According to the latest data from the analysis in the Necker laboratory in Paris, the Biocentric reagent enabled a more precise quantification (see Annex III) of non-B virus than Roche reagents. This test that Biocentric uses was reportedly originally created by Christine Rouzioux in the Necker laboratory in Paris years ago, as the reagents available on the market proved to be insufficient in detecting and quantifying HIV among the very diverse population of patients in Paris, many of whom were from West Africa. The test was provided to Biocentric for production and to be made readily available in Necker hospital and elsewhere.

Although there appears to be no financial association between Christine Rouzioux and Biocentric, this is not always perceived as such, and some experts question not so much the declared lack of financial conflict of interest but more the invention bias there can be when performing comparative analysis including a test one has invented. When performing comparative analysis of different

reagents in Necker laboratory, the project notes that different suppliers are always invited to take part. This question of conflict of interest might be more an issue of perception than an actual issue, however the OPP-ERA project would benefit from getting external validation of these test results (in other labs) and completely removing any perception of conflict or bias.

Biocentric recently obtained ISO certification and notes the company is confident that its reagents will be WHO prequalified in the next 4 months, after they have built into every test an internal control. WHO PQDx, which is bound by a confidentiality agreement on issues regarding manufacturers, did not deny the information during an interview. However the ability for those reagents to be purchased through funding from the major donors (especially Global Fund and PEPFAR) is critical for the sustainability of the project, and for that Biocentric needs to be quality approved by stringent regulatory authorities, in compliance with the QA policies of these donors. In order not to run any risk it is strongly advised that Biocentric seek in parallel WHO PQDx, CE IVD and ERPD (GF expert review panel for diagnostics) certifications beginning in 2015. The fact that Biocentric did not qualify for the last ERPD was a true missed opportunity that was reportedly due to a misunderstanding about the documentation required.

Some have questioned the ability of Biocentric, as a small company, to become a reliable player on the international market (which most estimate is dominated at 80% by Roche and Abbott). Indeed Biocentric is still in the investment phase and should the market not materialise early enough there might be a risk for the company's viability before it can fully enter the market. However, this risk is mitigated by the fact that Biocentric does not only produce viral load tests, but has other products and clients in its portfolio. Another perceived risk is the ability of Biocentric to supply in large quantities to meet the demand of the international market. However, this risk also appears to be mitigated, in that experts note that production capacity for reagents can be scaled up relatively easily and cheaply once the initial investment has been made, and is not comparable to what is needed to scale up the production of equipment.

Biocentric has a number of clients in the world (Laos, Central African Republic, Haiti, Cambodia) who are using their reagents on OPP systems (see OPP-ERA Business Plan). The company and some respondents noted that Biocentric provides innovative service including supplying a whole kit of items required for testing (gloves, consumables etc). Biocentric notes that they have produced an Excel-based quantification tool which they or a country can use to quantify and calculate everything they will need to conduct tests, based on the numbers of tests they intend to perform. This tool helps to ensure all reagents and consumables are covered and quantified adequately. If desired, Biocentric can supply a country/purchaser with the whole package of items. This is a service which larger manufacturers do not provide, although often the ability to perform tests in a country can fail due to something as simple as the lack of gloves or another consumable item which was not procured. Biocentric noted that they also provide maintenance contracts, if desired, for approximately €1700 a piece for the Diasorin extractor machines.

The small size of Biocentric represents a risk for OPP-ERA if it is the only supplier of reagents, which is currently the case, and which defeats the purpose of OPP. It is hoped that in phase 2 more suppliers (of all components of the OPP platform) will bid and can be selected to participate. It will be important for OPP-ERA, in expanding beyond West Africa (e.g. to Vietnam), to allow other

manufacturers that may not be as good as Biocentric in quantifying non-B types to enter the project. If the project works in areas where non-B types are not as prevalent, it should consider working with these other suppliers, with their reagents that work well for other sub-types. (See recommendations section of this report).

Local procurement:
The project used local procurement for small generic supplies as well as classic laboratory equipment like refrigerators. There were challenges in countries with this local procurement, which were resolved with the help of the local implementing partners. The lessons learned include the need to plan well ahead of time, as the issues encountered were diverse and difficult to foresee. Many of the issues were due to the fact that they were introducing new procurement processes for VLT. The countries now report feeling quite confident about locally procuring some supplies, as they say they have identified reliable suppliers. However, in order to avoid some of the issues encountered in phase 1, phase 2 is planning to have most of the items procured internationally, though for sustainability purposes it will be important to also gather experience on the local market especially for new countries, and to ensure that countries can conduct this kind of procurement on their own.

Regulatory, QA and IP
UNITAID has requested the project to ensure they work on a regulatory pathway, to ensure registration of the OPP platforms wherever they are working. However, the project notes that there is not a current regulatory system for in vitro diagnostics in most countries. The project notes that they will work with WHO, the London School, regional entities, and others to support registration and approval of the OPP suppliers in each country.

Regarding quality assurance, as noted above, the project developed a revised QA policy to enable the use of Biocentric reagents while their WHO PQ is still pending. It is recommended that Biocentric and the other suppliers obtain certification by WHO, CE IVD, and/or FDA to enable their procurement in future under the major funding organizations including Global Fund. International respondents interviewed noted that they feel the OPP concept is more complicated than integrated solutions, and therefore there is a strong need to see concrete evidence of viability. They noted that recognized prequalification will go a long way to alleviate concerns.

For quality control, the project has conducted QC on the VLTs performed in each country, with data monitored weekly by the project virologist and Prof. Rouzioux at Necker Laboratory. This QC has reportedly proven the high quality of tests performed so far. The project notes that external QC was planned for late 2014, by ANRS/QCMD. It will be important, as the project scales up and works in more countries and conducting more VLTs, to ensure the QC checking can continue (and that QC can be built into the training and capacity building efforts in country, for future monitoring).

Regarding potential intellectual property concerns with the equipment and reagents in the pilot countries and the countries to be added to the project in Phase 2, the project appears to have investigated this issue and to have a process to manage it. Project staff note that the main patents involved in the OPP system have expired in the developed world, and that these products have not obtained patents in the project countries. In addition, as part of its procurement procedures, the project requires participating suppliers to certify that they are “free to operate” in the market, as

part of the bid/contract they sign with the project. It appears that there is minimal, if any, IP risk posed by the OPP platforms in the project countries. Any future risk (e.g. in additional countries, including middle-income countries such as Vietnam where there may be more patents) must be monitored, and suppliers must take responsibility to ensure they are following international law and the patent laws of the country involved.

4.4 Technical Achievements and Results

For each project objective and activity, the evaluation team assessed the achievement to date vs. the targeted indicator, through a review of project reports, stakeholder feedback, available data on prequalified diagnostic products, and on procurement of these products.

The questions below represent a preliminary list of core questions the evaluation has attempted to answer (in accordance with the TOR), in addressing the five main identified areas of focus for the evaluation (relevance, effectiveness, efficiency, impact, risk mitigation). The evaluation team will also, however, build upon these questions and will seek to answer additional questions that arise during the research.

4.4.1 Key Research Questions and Findings:

Questions for the evaluation	Findings
Relevance:	
1. Are the outcome(s) and impact(s) of the grant aligned with UNITAID's overall mission to contribute to the scale-up of and access to treatment for HIV and AIDS, malaria and TB for the most disadvantaged populations in developing countries using innovative global market based approaches?	Yes. It increases the access to VLT and better patient monitoring. This also leads to cheaper overall cost of treatment as resistance is monitored, and the switch to second line drugs is only made when appropriate. OPP constitutes an innovative market based approach.
2. How does the grant contribute to one or more of UNITAID's six strategic objectives?	Strictly speaking OPP-ERA does not apply to the 6 strategic objectives. **Objective 1** is specific to POC, and OPP is a laboratory based approach which can however be implemented in lower-level labs than the integrated platforms. POC for VLT remains very limited and uncertain. **Objective 2**: is specific to paediatric medicine, and OPP is a diagnostic approach which can improve access to early infant diagnosis (will be piloted in phase II) **Objective 3:** is specific to medicines, however OPP has the potential to improve clinical treatment of HIV and co-infections such as viral hepatitis through improved access to diagnostics.
Effectiveness:	
1. Are the outputs of the grant consistent with the objectives and expected outcomes as described in the project plan? If changes have been made, has the UNITAID Secretariat been involved	Yes, documented

Questions for the evaluation	Findings
in discussions about the changes?	
2. Were the outputs of the project achieved within the timeframe specified in the initial project plan?	No: unexpected delays occurred during the procurement phase, most of them outside of the grantees' control. UNITAID was kept informed. A no-cost extension was granted to the project.
3. What are the main factors influencing the achievement or non-achievement of the outputs or overall outcomes across all countries and within each beneficiary country?	The procurement delay is the main factor that has influenced the outcome, as core activities started late. No other major obstacles to implementation observed. The fact that the project initiated VLT where none or little was being done before in the target countries generated enthusiasm and good will from country stakeholders.
4. What factors have been considered to ensure that value for money has been achieved?	One the main objectives of OPP is to reduce the cost of VLT for routine patient monitoring and to bring VLT to settings where it was previously not available. Procurement was conducted according to good practices of international open tenders, , and co-financing from implementing partners was granted to the project (See VFM section of report for more details).
Efficiency:	
1. Can the grant Implementers and their partners demonstrate that national authorities are aware and participating in grant activities at the national level?	Yes, this is documented and was verified during the interviews conducted with respondents from all 4 countries.
2. How cost efficient and cost effective is grant implementation?	Grant implementation was conducted with a small team in Paris and capitalised on existing networks and structures from partner organizations. The small size of the coordination team sometimes meant they could not deliver reports and other documents on time.
3. Were challenges raised with the UNITAID Secretariat in a timely manner and did the Secretariat participate in resolving these challenges?	Yes, there appears to have been regular communication with UNITAID and resolution of issues together.
4. Was the grant's procurement model designed to identify and solve procurement-related problems (where applicable)?	Yes to some extent, but the novel nature of the approach compelled the project to adapt and adjust along the way.
5. Were there any issues related to potential diversion of products, counterfeit or quality?	No. No issues documented or mentioned of any diversion or mismanagement.
6. Is the grantee implementation arrangement efficient?	Yes: the fact that implementing agencies all have HQ's in Paris eased the implementation and coordination among them. For phase 2 FEI and ESTHER will be merged which should further simplify the implementation arrangements.
Impact:	
1. Can the grantee report on impact as	Yes, all the targets in the revised logframe will be

Questions for the evaluation	Findings
originally framed in the project plan and LogFrame? If not, has the grant impact been measured in another way?	achieved by the end of phase 1. The original number of tests performed was revised downward (reduced to finance the no cost extension).
2. Where relevant, can the grantee attribute UNITAID's financial support for medicines, diagnostics or preventive products purchased to patients tested or treated in each beneficiary country?	Yes – direct attribution (VLTs performed using systems and reagents funded by UNITAID)
Learning & Risk mitigation:	
1. Have lessons learnt been documented and widely disseminated by grantees and UNITAID?	No. The UNITAID market landscape for HIV diagnostics document, which is the reference for international stakeholders, hardly even mentions OPP although it discusses details of other technologies further down the pipeline. The grantee appears to have communicated little with external partners during phase 1. This should be greatly improved in phase 2.
2. Have programmatic and financial risks been identified and tracked over the course of grant implementation?	Yes, to some extent (and risks are addressed in the Business Plan). The project entails little financial risk, considering that while testing the OPP approach UNITAID is financing the introduction of routine VLT in 4 countries at a price below previous market price. So even if OPP was found not to be sustainable as an approach for VLT the money invested by UNITAID will have had a public health impact. Supply and demand risks are being addressed.
3. Have the lessons learnt been reflected in the proposed Business Plan for Phase 2?	Only to some extent: there is value in scaling up in the 4 existing countries under OPP and gathering experience on polyvalence ability and EID. However all but one of the expansion countries proposed are also situated in West Africa. One of the main lessons of phase 1 was that there was only one supplier of amplification reagents that qualified because of its ability to detect the non-B HIV prevalent in this area. To fully test the potential of OPP it would be important to also source from suppliers that could qualify under GF/PEPFAR, to promote OPP outside of the UNITAID context, and beyond the project countries. This would mean expanding beyond West Africa.
4. Have the findings and recommendations of mid-term evaluations or audits (where relevant) been used to improve grant performance?	NA: the funding for this project was originally granted for phase 1 only. The current evaluation is the first one conducted.

4.4.2 Performance Against Logframe Indicators and Targets

The table below summarizes the OPP-ERA's progress through November 2014 toward the revised logframe indicator targets that were accepted as a part of the no-cost extension agreement finalized

in June 2014. All indicator targets have been met at this point. Achievement of target indicator O2.1 (number of operational platforms) was met late due to procurement delays, but the timing did not negatively impact achievement of other project targets. The target for indicator O1 (staff trained) was exceeded considerably, which bodes well for phase 2 ramp-up. While interim targets for indicators P1 and P2 (number of patients tested) were met, the end of project targets for these indicators are significantly higher. Whether the project will achieve these end-of-project targets will be determined in December 2014.

Logical Framework		
Indicator	**Target**	**Current Status – Nov 2014**
Goal (Impact) : To demonstrate that a viable alternative to "integrated systems" and "closed machines" for VL testing is possible in resource-limited settings		
Indicator G1: Name of certified suppliers willing to enter the market per lot	2 names per lot (June 2014)	**END OF PROJECT TARGET MET.** Lot A: Daan diagnostics, Diasorin & Life technologies. Lot B: Roche & Life technologies.Lot C: Biocentric & Anatolia.[1]
Indicator G2: Name of certified suppliers entering the market per lot	1 name per lot (June 2014)	**END OF PROJECT TARGET MET.** Lot A: Diasorin. Lot B: Roche. Lot C: Biocentric.[1]
Indicator G3: Market size in 28 core target market countries estimated	28 countries estimated market size (Sept. 2014)	**END OF PROJECT TARGET MET.** [2] Market size estimates provided
Outcome: OPP is used in the 4 target countries		
Indicator P1: % patients on ARV who have received a VLT using OPP at least once over phase 1 in selected treatment sites	24% (EOP-Dec. 2014) 3% (Interim - Sept. 2014)	**INTERIM TARGET MET.**[3] Cameroon: 4%, Cote d'Ivoire: 6%, Burundi: 6%, Guinea: 8%[4]
Indicator P2: # of VLT performed by target countries	16,019(EOP- Dec 2014) 2, 496 (Interim – Sept 2014)	**INTERIM TARGET MET.**[3] 3,505 VLT performed by 25 September 2014
Output 1 : Enhanced capacities of laboratories to perform VL monitoring using OPP		
Indicator O1: # of staff trained on use of OPP for virological monitoring of HIV infected patients	80 (June 2014)	**END OF PROJECT TARGET EXCEEDED.**[4] 244 trainees
Output 2: OPP is operational in the 4 target countries		
Indicator O2.1: # of operational platforms established in target countries	7 (June 2014)	**TARGET MET LATE.**[5] Platforms operational in 7 laboratories in August 2014.
Indicator O2.2: # of VLT delivered	20 025 (Sept 2014)	**END OF PROJECT TARGET MET.**[4] 20,025 tests delivered by August 2014

[1] 2013 Annual Report Annex 4
[2] Business Plan Annex 1, Table 2.7: Scenarios for the demand forecasting for VLT in a 5-year period (2013-2018)
[3] OPP-ERA Phase One Implementation Report, submitted 29 September 2014.
[4] Reporting OPP-ERA_Semi-Annual Report_211114.xlsx, Excel file from FEI 26-11-2014
[5] OPP-ERA Phase One Implementation Report, submitted 29 September 2014.

Output 3: OPP is more affordable in the 4 target countries		
Indicator O3: Price tracked for purchased VLT (extraction +amplification reagents)	$20 (June 2014)	**END OF PROJECT TARGET MET.**[4] The cost of reagents procured was **$16 per test. (**47% to 68% lower than the cost per test for other platforms in the focus countries)

Logframe Source: Excel File "OPP-ERA Simplified logframe_updated June 2014"

Directly below is a table that compares the original indicator targets with the revised indicator targets that were approved with the no-cost extension in June 2014. The number of tests and the due dates for various indicators were changed in response to the delay in procurement.

Indicator	Original target (2013 Logframe)	Change from Original Target (June 2014 Logframe)
Indicator G1	2 names per lot – June 2014	No Change
Indicator G2	1 name per lot – June 2014	No Change
Indicator G3	market size in 28 countries - Due June 2014	Due by Sept. 2014
Indicator P1	30% patients with VLT by June 2014	3% by September 2014 24% by December 2014
Indicator P2	19,610 VLT taken by June 2014	2,496 by September 2914 16,019 by December 2014
Indicator O1	80 trained by June 2014	By December 2014
Indicator O2.1	7 established labs by June 2014	No Change
Indicator O2.2	Equipment and Supplies for 32,000 VLT delivered by June 2014	Equipment and Supplies for 20,025 VLT delivered by September 2014
Indicator O3	$20 reagent cost per test by June 2014	No Change

4.4.3 Major Achievements of the Project:

The OPP-ERA project has had some achievements in meeting or over-performing on all of their established logframe indicators. Through the project consortium and leveraging the expertise and country presence of project partners, OPP-ERA has introduced and/or expanded routine VLT in the four pilot countries, and established systems (sample handling, communications, data capture and reporting) to ensure that the feedback loop on test results functions as it should. Some 3505 VL tests were performed (and quality control checked) under the project, having the desired effect of proving the feasibility of OPP working properly in these countries, if the necessary support is in place (whereas, even where the equipment is in place, often the integrated systems have not been working). The project team noted that they have worked on the "latent demand" for viral load testing in countries (demand which hasn't been sufficiently expressed, but which exists and is growing, as numbers on treatment grow and guidelines for diagnostics increasingly insist on VL) by working with officials and laboratory personnel in the countries, and they say they have attempted to quantify the real needs for VLT. The project has also assisted in developing and/or enhancing laboratory infrastructure and personnel capacity for VL in these countries, through laboratory improvements, training, and mentoring. From the supply side the project has worked to disrupt the status quo in the somewhat stagnant and under-performing VL market (where an "equipment cemetery" of idle equipment is prevalent, and only 10% of eligible patients are getting VLT) , by enabling OPP to compete and prove that it can complement the use of larger, integrated systems, providing countries with an additional alternative for VLT. The project identified suppliers for Lots A,

B and C and obtained interest from a number of suppliers, interestingly including Roche which was one of the winning suppliers (for thermocyclers). The project has addressed (albeit in a temporary way) the QA challenge faced by the lack of PQ'd amplification reagent suppliers, while making plans to work to change this QA dynamic in Phase 2.

4.4.4 Major Challenges of the Project

The most significant challenge to the project, which delayed their progress for phase 1, was the lack of prequalified suppliers for the amplification stage of the VLT process. Although Biocentric's reagents were submitted to WHO for prequalification, this process has not been completed, and no other suppliers were both prequalified/certified and proven to be able to accurately measure viral loads for non-B sub-types, prevalent in the project's target population. This led to a revised QA process for the project, and leaves open questions for Phase 2. Other challenges included the difficulty of OPP-ERA to adequately define the market niche they were targeting, although UNITAID would like more firm figures, and this is reportedly being addressed for Phase 2. The project had some reporting and communications challenges – between partners and with UNITAID, as well as with the outside world. This was due to the challenge of properly communicating this complex project and technical aspects/objectives, and some possible English-French language difficulties. The lead implementer's reporting and delays in delivering these documents have reportedly caused UNITAID to sometimes doubt their capacity to deliver, whereas UNITAID's feedback and critiquing of project documents have led to some feelings of frustration and of being micromanaged on the team. There have been challenges in meeting the business and market-oriented focus of UNITAID and the need to mitigate risks, while implementing a pilot project in which market impact can be difficult to measure and risk is inherent. The appearance or impression among some that there was some conflict of interest – that this project was in fact meant to create a market for Biocentric (which some felt the project founders were too close to, or even compensated by) remains a challenge for the project to address in Phase 2. Challenges in countries included infrastructure and capacity building needs, and the need to change the mind-set among some prescribers who were not previously prescribing VLT, or have used it only to confirm suspicion of ART failure, or only for patients with financial means.

4.4.5 Observed or Measured Impacts to Date

Although, as mentioned previously, it is premature and beyond the scope of this evaluation to measure true impact in the form of health outcomes or real market change, the project can claim at least some impacts – both in improved standards of care in the countries, and on the VL marketplace. The project has enabled VLT to be performed in countries/laboratories where reportedly little or no VLT was happening before the project. 3505 VL tests were conducted through September 2014, a number that would have been much lower without the project – meaning over 3,000 patients who would otherwise not have received the service, benefited from proper VL. Country feedback and project documents confirm that the project has worked closely with local authorities and experts, and that these counterparts are appreciative of the progress made. Given the volumes of plastic garbage generated by the integrated systems, and the greatly reduced volumes created by the OPP systems, one can assume that there is less plastic waste in the countries' landfills from the VLTs performed than there otherwise would be. The quality control checking on the tests performed confirmed that the tests have been of high quality, and the communications/ feedback protocols established by the project have enabled the test results to be used for proper

case management. The project team notes that they have worked to encourage suppliers to participate in the tenders for these OPP systems, and reportedly plans more such activity in Phase 2. An interesting (perhaps telling) impact to date is the participation (and contracting) of Roche as a supplier of thermocyclers for these OPP systems, perhaps indicating a willingness of such large suppliers to collaborate and compromise as the VL market opens up to more players and begins to use OPP as an additional option, to complement the integrated platforms. It remains to be seen whether the impacts of the project so far are temporary, or can be built upon and sustained for the long term.

4.5 Integration with UNITAID and Global Efforts to Improve Access and Quality of Diagnostics for HIV and Malaria

This project falls under UNITAID's strategic objective #1 (Increase access to simple, POC diagnostics for HIV and AIDS, TB and malaria), although the project is not currently focused on POC technology as these are not yet widely available or feasible for VLT. However, the characteristics of POC which are desired to enhance access (ease of use, lower weight and size, easier maintenance, flexibility, etc.) are largely offered by OPP systems, enabling these systems to be more accessible to smaller laboratories than the larger, integrated systems.

The UNITAID OPP-ERA project aims to help improve access to viral load testing (VLT) and early infant diagnosis (EID) through the introduction of innovative Open Polyvalent Platforms (OPPs), which both introduce greater flexibility and accessibility of the required technology, and disrupt the current viral load market which has been dominated by very few large suppliers since the inception of large-scale ART treatment globally in 2002. The current market environment has in reality meant that only an estimated 10% of patients on ART (who should all be monitored by viral load) have had access to these critical tests.

The objectives of the project are very much in line with the overall UNITAID objectives of impacting the market for HIV products and improving access and prices. The OPP-ERA project fits well within the objective of enhancing access to important HIV diagnostics, to shaking up the market, to reducing costs, to increasing availability to simpler and more efficient systems including POC while still ensuring quality is assured. The project has not yet fulfilled all of these objectives in Phase 1, but evidence shows it has had an impact. It is difficult to directly attribute current and ongoing market shifts (price reductions announced by Roche, wider use of routine VLT as recommended by WHO and emphasized by UNAIDS, new competitors and technologies, etc) to the OPP-ERA project, but the project's Phase 1 has operated during a period of great change in the viral load environment and can be seen as a contributor to the market changes taking place.

4.6 Analysis of Lessons Learned in Phase 1

Some main lessons regarding supply, demand and technology characteristics of the potential OPP market were identified during Phase 1 that required the project to make critical adjustments during Phase 1 of the project. The table below describes the adjustments that were made in phase 1 as well as proposed adjustments that the OPP-ERA project team says would be made in phase 2 in response to the lessons learned.

MAIN LESSONS LEARNED IN PHASE 1	
PHASE 1 ADJUSTMENTS	**PHASE 2 PROPOSED MITIGATION EFFORTS**
SUPPLY	
OPP-ERA adopted a negotiated procurement strategy for Lot C combined with a stringent interim QA plan. OPP-ERA obtained a 6-month no-cost extension due to delayed procurement. Number of tests procured was reduced to 20,025 to fund the extension. Training plan was rescheduled due to delayed procurement. A set of amplification reagents were chosen for quality evaluation in Hôpital Necker and in field evaluations in Abidjan and in Cameroon. (October to December 2014.)	Project will take multiple measures to encourage suppliers to enter quality certification process: provide detailed information on WHO procedures to suppliers, assist potential suppliers in preparing dossiers for certification. Procurement procedure has been revised to consider alternative methods of verifying quality. Amplification reagents that are not certified but meet international quality standards will be tested at the Necker laboratory and in target countries as part of a two-stage evaluation. Project will conduct laboratory evaluations of new reagents to strengthen suppliers' PQ dossiers. Project activities aimed at increasing market incentives for manufacturers to develop and supply effective products for focus countries and other low-resource countries.
TECHNOLOGY	
Strict quality standards and testing were developed and implemented. Laboratory tests were conducted to confirm compatibility of equipment and reagents.	Calls for tenders will include strict minimum technical requirements to help mitigate any incompatibility concerns. Tenders for amplification/quantification reagents will be required to include documentation that identifies which thermocyclers have been used successfully with their reagents. Tender evaluation process for thermocyclers will include lab testing and demonstrations of thermocyclers with selected amplification reagents. Phase 2 deliverable of lessons learned from Phase 1 will include an analysis of compatibility of OPP, and identification of each supplier's responsibility in case of incident. Country lab staff will receive training on OPP VLT process, reporting, and use of internal positive controls in QA monitoring. QA approach includes monitoring and verification of VLT results at three levels: Country Technical Supervisor (CTS); Internal reporting and quality monitoring; and external

MAIN LESSONS LEARNED IN PHASE 1	
PHASE 1 ADJUSTMENTS	**PHASE 2 PROPOSED MITIGATION EFFORTS**
	quality control from Coordinator-virologist.
DEMAND	
Project quantified unmet needs for HIV-VLT within the focus countries. Assessment of demand in target counties identified multiple factors that contributed to low demand and that need to be addressed in phase 2: - limited inclusion of VLT in national strategies, - cost of reagents and equipment, - insufficient funding, - non-functioning or poorly maintained equipment, - lack of procurement expertise, - limited technical training and information for labs and prescribers, - lack of proper regulatory frameworks.	Project will work with health authorities in focus countries to develop national VLT strategies for scale-up. Project will develop guidelines and best practices for focus countries on laboratory requirements and preparation, HR requirements and training, specimen logistics, algorithms, cost-effectiveness studies, procurement and distribution. Project will provide training for prescribers in focus countries to ramp up demand. Project will continue discussions with GF and PEPFAR regarding funding of OPP. Project will conduct a workshop at the end of Phase 2 to share project experiences and lessons learned with other low-resource countries. Project will promote the OPP model in regional and international events. Project will assist target countries in quantifying unmet needs and demand forecasts. Project will develop transition plans and provide training for PSM in target countries. Project will support demand in other countries, through development of guidelines in the project countries, and reduction of prices of other suppliers. Project will cover not only the reagents, but all the costs necessary for the development of the VL networks: equipment, maintenance, trainings, and support to national authorities.

From interviews and the documents review, the evaluators feel that the project team responded appropriately to the lessons learned in phase 1 and have proposed important efforts for phase 2 in response to these lessons. Nonetheless, limited availability of supply, potential incompatibility between supplies and equipment, and possible slow growth in demand for tests remain key risks to the project timeline and to the project's overarching goal of the development of a functioning market for OPP. Some of these risks and challenges for Phase 2 are discussed in later sections of this report.

4.7 Value for Money Analysis

It is early in the overall project cycle of OPP-ERA to make an in-depth assessment of whether UNITAID's investment has achieved value for money. In response to a question on VFM posed in the TOR for this evaluation, the evaluators found that the project design and implementation so far includes many factors that help ensure that value for money will be achieved. The following is a short description of these efforts to ensure VFM:

- POTENTIAL COST SAVINGS OF OPP- Phase 1 has shown that VLT can be performed in low resource environments at a lower overall per test cost on OPP than tests performed on integrated systems, in the project's target markets (given the lower reagent price attained, and lower equipment costs and maintenance needs compared to the larger, integrated systems). This finding of potential cost savings of OPP is important and critical to verifying proof of concept for proceeding to the next phase of the project. (However, a detailed cost-effectiveness analysis and thorough cost comparison of all costs across platforms and technologies is recommended, though beyond the scope of this evaluation).
- PROCUREMENT PROCESS – From the documentation reviewed, it appears that the competitive tendering process for reagents and equipment for the first procurement was stringent and helped ensure that the products were obtained at the best price available. Multiple efforts were reportedly taken to identify, inform and encourage potential suppliers to bid on the procurement opportunity. The project specifications were detailed. The bidding evaluation process was well considered and thoroughly documented. Supplied items were tested to ensure compliance with quality standards. The negotiated procurement process developed for Lot C successfully responded to the lack of acceptable bids.
- ADJUSTMENT FROM LESSONS LEARNED - Important lessons that were learned in the procurement process have been well documented and adjustments have been incorporated into the next phase of the project. The procurement process in Phase 1 identified several adjustments for Phase 2 that should strengthen the competitive bidding environment and support development of a sustainable market. Adjustments include the need to revise bidding specifications to ensure compatibility and quality, to provide more information and assistance to potential bidders about international bidding, to help bidders compile dossiers for international tendering, and to encourage and help bidders obtain required quality certifications for products and facilities. The project will also reportedly continue to identify and reach out to other potential bidders.
- OPEN PLATFORM DESIGN – An underlying premise of the project design is that OPP allows for procurement of equipment and of extraction and amplification reagents separately. Components can be procured independent of one another so replacement reagents in the future can also be obtained through competitive bidding, unlike with integrated systems. As noted previously in this report, it will be critical for the project to more fully exploit the benefits of OPP in future, through participation of more suppliers and more certifications of equipment/reagent pairings, so as not to have such a limited choice of qualified options.
- TESTING FOR OTHER DISEASES- A premise that will be tested in phase 2 is that OPP can be used appropriately and effectively for diagnosis of other diseases such as TB, HBV, and HCV (polyvalence). Confirmation of this premise would allow pooling of laboratory resources and

infrastructure for diagnostics, leveraging the value for money of UNITAID's investment. This is also of great interest to countries, and could lead to greater efficiencies in their lab operations.

- REPLICATION – An important desired outcome of Phase 2 is development of a successful field-tested model of OPP for VLT. If the OPP model is determined to be successful enough for possible replication in other targeted low- and middle-income countries, the value of UNITAID'S original project investment will be further magnified.
- POTENTIAL MARKET NICHE – OPP directly addresses a potential market niche or need for VLT. POC systems (also still in the testing phase) have a low throughput and are best suited to small testing environments. Integrated systems are good for relatively high or very high throughput and are best suited for main, centrally located laboratories. OPPs have a medium to high throughput and are well suited for medium sized, regional or district lab settings.
- VFM ARGUMENT IN COST PER TEST IN PHASE 2 - The value for money section of the phase 2 proposal compares the estimated total cost per test under phase 2 ($36 per test) with the average total cost per test for integrated systems ($40) as an indication that the project will provide value for money. For this argument, the total phase 2 cost per test is calculated by dividing the total cost/funding of OPP-ERA Phase 2 ($13,758,954), including all personnel and support costs, by the number of tests to be conducted (382,768). It is important to note that this straightforward comparison looks at the costs of phase 2 only, so while it may be useful for the decision to fund phase 2, it may not be an accurate indicator of value for money for the project as a whole (including the Phase 1 investment). A thorough cost-effectiveness analysis across different platforms is needed, and taking into account current changes in the marketplace (including new price and equipment offerings) but was not in the scope of this evaluation.
- EXAMINING THE COUNTERFACTUALS – As noted, the OPP-ERA project has operated in a changing VLT environment, after over a decade of under-utilization of existing VLT capacity (with "equipment cemeteries" growing in many countries and 90% of eligible patients not being tested). After some years of domination by a few suppliers of integrated VL systems and little testing happening compared to the real need, the market is changing with the new WHO guidelines and UNAIDS push for routine VLT from 2013 (90-90-90 UNAIDS initiative pushing for 90% diagnosed, on treatment and virally suppressed), and with more testing options and recently announced (but not yet fully implemented) price reductions (although it remains to be seen whether broad access to VLT will result from these new price offers). As noted above, the project is not meant to present a total solution or replacement for integrated VLT, but does present another option that includes more suppliers and products, occupying a different niche that can apply in various lab settings. The essential counterfactual of this project – what would have happened in the absence of this intervention, and/or with other potential interventions - is the lack of testing that was happening in the project countries prior to OPP-ERA, despite the existence of integrated machines in most of them. Once the project is further into its implementation phase, a thorough cost analysis and cost-benefit review, as recommended in other sections of this report, would help to determine the benefit/viability of continued investment in this (OPP) investment, vs. other potential interventions. It is at this stage impossible to gauge whether investing in OPP will have greater impact than might other investments to increase VL testing in countries. However, OPP appears to be a welcome addition to the VLT options for countries (given the feedback received for this evaluation), and the project

has met its testing targets and other objectives despite a late start. With POC, DBS, price reductions and other potential methods and technologies to expand VL access in the pipeline, there are potential areas of progress on many fronts in the effort to increase the use of routine VLT, in addition to the promise of OPP. It appears that there is value to the effort to pilot OPP for VLT, as a promising additional alternative to other efforts under way, as a potential market shaker and important component in the field of options. When one compares the status quo in the project countries prior to the project's intervention (little to no VLT), real benefit is evident. The counterfactuals are changing as the market changes, and UNITAID and the project will need to keep re-examining these, to ensure that OPP-ERA is providing a valuable contribution to the effort to make VLT more widely accessible and sustainable, rather than investing in some other type of effort. Efforts to ensure more suppliers are qualified and can participate in OPP tenders will further help to provide a valuable competitive addition to the VL marketplace.

- TREATMENT SAVINGS FROM VLT – Although not solely attributable to OPP, implementation of VLT in the target countries in phase 2, in accordance with new WHO protocols, can significantly reduce the need to switch to second line ARV treatment, as patients whose viral loads are properly monitored can be managed and remain on 1st line for longer periods. Experts note that, without adequate VLT, mistakes can be made and patients may be switched to 2nd line ART too soon when the problem may not have been failure with the 1st line regimen. As second line treatment can cost as much as ten times the cost of first-line treatment, considerable savings in the cost of treatment could be achieved as a result of increased VLT and proper patient management under Phase 2. In addition, by monitoring patients' viral load, physicians will also avoid the risk of continuing treatment with regimens that are failing and causing resistance to develop (a health threat to the patient and the public), resulting in more virulent and infectious disease. VLT determines when a patient truly needs to shift to a new ART regimen.
- COST SHARING- Funding from UNITAID is leveraged by co-funding provided by the implementing consortium partners. In phase 1, the consortium funded a new lab construction in one country, significant renovations in two other laboratories and upgraded computing facilities in 5 of the 7 laboratories. According to budget documents, the consortium agreed to contribute $503,536 in co-funding for Phase 1, equal to about 17% of the overall budget or $1 for every $4.77 invested by UNITAID. Similarly, $962,883 of the total funding for phase 2 will be provided by the implementing consortium ($655,027 in cash and $307,856 of in kind contributions) (*OPP-ERA Phase 2 Proposal).*

In sum, important steps have been taken in project implementation and project design to achieve cost efficiency and effectiveness. Phase 1 has been somewhat successful in testing proof of concept and developing systems so that value for money for UNITAID's investment is maximized. It is important to emphasize, however, that there has only been one round of procurements. To further ensure value for money in phase 2, OPP-ERA may want to re-examine proposed spending in Phase 2, to consider some reallocation of the budget from commodity procurement to other activities that are identified as risks to market development and roll-out. A thorough assessment of value for money should be attempted during phase 2, when the project is more fully functioning in its countries. At that point, the potential sustainability and longer-term value for money of the investments made by the project might also be analysed. It will also be important to update the baselines (and counterfactuals) used by the project to measure its ongoing effects, as the VLT environment changes, with more suppliers, more competitive pricing, and more testing happening

worldwide. These market changes will impact on the project's effectiveness and the viability of OPP as an option for VLT, given new potential market entrants and new pricing schemes.

4.8 Market Impact and Niche

4.8.1 Market Niche for OPP

Currently the market for viral load testing in HIV patients is largely untapped, in that needs are not met in the quantity of tests needing to be performed, and the methodologies currently available present drawbacks in terms of cost, accessibility, maintenance, and other factors. This has been shown over the last 10-15 years in many countries (including the project's countries) where integrated platforms/machines are present but are idle for lack of reagents, maintenance, or other issues. There are 3 main options for viral load testing in countries

1- Integrated platforms like those of ROCHE, ABOTT, BIOMERIEUX, SIEMENS currently prequalified by WHO PQDx
2- Open platforms (OPP)
3- Point-of-Care platforms (POC)

Integrated platforms are the most common approach for VLT, however the main limitation for expansion of routine VLT in the developing world is the high price of viral load tests, which is driven by the nature of those platforms, mainly:

- High investment needed to purchase the machine
- Once the machine is purchased the labs are restricted by the manufacturer to purchasing their own reagents and other necessary supplies
- They are highly technical devices with many moving parts, which are reported to break down often, requiring frequent maintenance

At the moment there is only one POC device in the market (the SAMBA test) and it is reportedly only in use in Uganda and Malawi (through MSF). There is still little information about the potential for the expansion of this technology. Although some consider the pipeline for POC very promising, it has been seen as promising for some years already, without a clear indication of when these systems could be more widely used for VLT. In the absence of POC, there is increasing focus on use of DBS (dry blood spot) technology to facilitate transport of blood samples from remote areas to labs for VL analysis. DBS analysis may become a greater necessity in future in order to overcome the infrastructure challenges in some countries, and therefore the need for OPP to work with DBS may become greater.

The concept of OPP is to counter the above-mentioned drawbacks of integrated platforms by combining devices for extraction and amplification from various suppliers and having them run on a variety of different reagents, resulting in a lower starting investment (lower equipment costs) needed and lower running costs (lower reagent costs). Since this combination of devices is mechanically less sophisticated, the machines are also reportedly less likely to break and can more easily be replaced.

Phase 1 of the OPP-ERA project has proven (through its weekly QC checks) that the capability of OPP to perform quality VLT is similar to that of integrated platforms. Phase 2 will need to demonstrate the versatility of the method in combining the different parts from different suppliers, and the impact on prices.

FEI believes the project's foremost niche to be francophone countries where their network of organizations is working, with higher and lower HIV prevalence rates, and where some OPP is already in use. However, the wider potential market for OPP is broad – these platforms can be used both in central labs in high- or lower-prevalence countries to supplement integrated platforms, or in more peripheral labs in low- or high-prevalence countries:

1) The potential for OPP in High Throughput Laboratories (level 4 and 3)

In high throughput countries/laboratories where savings can be made by using OPP as opposed to using integrated systems: In some countries the cost of qualified laboratory staff is negligible when compared to the budget needed for the reagents and other supplies. In Georgia's central laboratory (the only one doing VLT for the country, running some 1000 tests per week given the country's protocol of 4 VLTs per ART patient per year), for example, qualified laboratory technicians are not scarce and are relatively inexpensive when compared to the price of reagents. Potential savings realised on a per-test price can result in significant budget savings especially in high throughput laboratories and would compensate for the cost of the increased need for laboratory technicians to reach the same throughput as with an integrated platform.

Taking into consideration the high volumes of VLT involved in countries like Swaziland, for instance, the MSF laboratory expert consulted noted that the price per test would be the most decisive factor in making the choice between integrated and open platforms. OPP platforms are a useful addition to the lab capacity in a high-prevalence country like Swaziland, according to this respondent.

Pricing is becoming all the more relevant as the Global Fund is expected to phase out of upper-income low-prevalence countries like Georgia in the coming years, which makes these countries very interested in any options to reduce the price per test (especially in a country like Georgia, where the patient monitoring protocol is a minimum of one VLT per 4 months). The OPP systems will need to be able to compete with price reductions being announced by the large suppliers of integrated platforms (e.g. Roche), but given the $5-6 per test price for reagents offered to OPP-ERA by some suppliers in Phase 1, and given the expected larger volumes and larger pool of potential suppliers, compelling pricing of OPP reagents appear to also be on the horizon. It will be important to expand the availability of these OPP systems beyond the project's pilot countries in future.

Countries where big donors (PEPFAR, GF) are phasing out and which need to purchase laboratory equipment with their own funds (e.g. Georgia). Even where there is ongoing GF and PEPFAR support, experts consulted note that the trend has been toward more support for drugs and less for labs, so the laboratories have to compete for scarce resources with the other program needs.

It will be critical for phase 2 for the OPP-ERA project to produce data on the cost of usage (not just the cost of purchasing the equipment and the reagents), taking all costs into account so that countries can make informed decisions between integrated and closed platforms basing decisions on total cost of ownership rather than isolating reagent costs only. It is recommended, as mentioned, that a thorough cost analysis and cost-benefit analysis be done across platforms and countries.

High throughput laboratory where space is a limiting factor: this is a serious problem in the reference laboratory in Georgia, and in many other countries. The smaller OPP systems can be useful in these smaller laboratory spaces.

2) The potential of OPP for Low and Medium Throughput Laboratories (e.g. District Labs)

Lower and medium-throughput laboratories are a logical target for OPP, both in high-prevalence and lower-prevalence countries, as the larger integrated systems may not be advantageous in these settings. The project notes that in the mid- and lower-prevalence countries, the number of VLT done on integrated platforms has not increased in many years (despite Global Fund and PEPFAR funding to purchase the equipment and other supplies), and the prices remain very high.

These laboratories in lower prevalence countries are of lower priority for the big laboratory equipment manufacturers, and where there are integrated platforms installed in these laboratories, they are reportedly often not functioning for a variety of reasons, including lack of reagents supplies and lack of maintenance by the manufacturer (due to lack of field presence, lack of maintenance contracts, etc). As long as these lower prevalence markets are considered low-priority for the integrated platform suppliers, market dynamics do not change: the price per test for reagents in those countries has remained high, and it is very difficult to get good support from the manufacturer for maintenance. These lower-prevalence countries, therefore, present a natural opportunity for alternatives such as OPP, which can at once provide a VLT option for the countries, while also building the market there (through making more testing a reality) and potentially building interest among the other manufacturers (including the large ones) who may see a potential market where before there was none. While the future market dynamics are unclear, this allows OPP to effect some impact on these markets.

The laboratory experts among the respondents to this evaluation largely reported that the maintenance needed for integrated platforms is higher than that of OPP. In the 4 pilot countries few technical issues were reported with the OPP system. There was a a consensus among laboratory experts consulted (both within and external to the project) to say that amplifiers (thermocyclers) need close to no maintenance and are extremely sturdy machines. The small size of the extractor machine also reportedly made it easy to be shipped back to the supplier for replacement. In Guinea one extractor did not function after installation. The company (Diasorin) shipped a new one and the non-functioning machine could be shipped back in the packaging received for the new one. Since the extractor machines are used in tandem (with 2 functioning at once) break-down of one machine does not lead to the interruption of service that is seen with integrated platforms.

Both integrated and open platforms need good laboratory infrastructures and qualified laboratory technicians, even if they are placed in peripheral areas (e.g. district labs). These decentralized areas will be a prime location for POC devices, when and if they are available for VLT.

3) Areas of the World with a High Prevalence of non-B HIV Sub-types (e.g. West Africa)

The reagents from Biocentric are currently reportedly better able to quantify non-B HIV sub-types than other reagents on the market, which are said to substantially under-quantify these virus types (C. Rouzioux/Necker Lab, Biocentric). The new integrated platform from Roche has reportedly improved in this field, but according to the findings of the ANRS, it is not at the level of Biocentric yet and this new Roche platform is still very rarely found in West Africa. The ability of different devices and reagents to appropriately quantify non-B types needs to be addressed in phase 2 and translated into public health outcomes (see recommendations). It is recommended that an independent validation/evaluation of the OPP reagents be conducted, outside the Necker and project country labs, and a thorough comparison should be made with other reagents, across a variety of technical parameters including non-B detection.

4.8.2 Market Impact and Outlook for OPP

Reportedly only 10% of VL equipment capacity in Africa (outside of South Africa) is being used. Of a current equipment capacity in Africa to conduct 2M viral load tests per year, only 200,000 tests are being conducted currently, according to CHAI and other experts consulted. Similarly, the OPP-ERA project notes that in the 7 target countries for Phase 2, only 11% of ART patients were getting VLT before the project. All of this is despite growing patient numbers and demand for VLT. So OPP-ERA is entering a market (for VLT) where there is significant unmet need (some 90%). By supporting entry of OPP, the project plans to "create healthier market conditions by creating competition on prices, but also on technologies" (*Report to the Board Sept 2014*).

Currently the OPP-ERA project focuses on low-prevalence countries were routine VLT was not done previously. The project has reinforced and structured these countries' system to run routine VLT, in theory creating a demand that can be sustained if the reagents can be authorised for purchase under GF or PEPFAR funding (as these are the two largest funders by far). The project talks about in this way helping to develop the "latent demand" for VLT – a demand that is there, even if it had not been expressly defined before. This demand is expected to grow substantially in the years ahead, as countries begin to follow new WHO guidance and scale up their testing. UNAIDS and CHAI estimate that global need for VLT will be almost 30 million tests in 2015, rising to over 40 million in 2018, almost doubling from the 21 million tests needed in 2013 (*GF Strategic Reviews in Procurement and Market Dynamics - Day 2 – HIV Diagnostics (GF Presentation, Geneva 2 Oct 2014*). UNITAID would prefer to have clearer "real" or "expressed" demand numbers from the project for their countries, but these are thought by the project to be a major under-estimation of real potential demand, as there is more work to do to build this demand in country, for routine VLT.

It is likely that as countries do more VLT using OPP, suppliers will become more interested, seeing potential testing volumes where they did not exist before, and suppliers of integrated platforms will start pursuing business in the lower-prevalence markets, in addition to their current focus areas in high-prevalence countries. They can do this by promoting their integrated platforms through their

strong marketing forces (teams of sales reps), by offering more competitive prices on their integrated systems. But they may also opt to become suppliers within OPP platforms, as most suppliers of integrated platforms also supply thermocyclers, extractors (both of which are classic laboratory machines) and the necessary reagents for these machines. As noted, the Roche thermocycler was the machine which ended up being selected within phase 1 of OPP. OPP is seen as a less profitable model for VLT integrated platform suppliers, as they will be in constant competition with other suppliers on price, however they might begin to see greater potential in this market, as countries adopt OPP VLT as an additional alternative to the integrated platforms. Roche's participation in the Phase 1 tender is an indication of this interest.

The variety of different potential combinations of devices within OPP platforms makes it very difficult to make predictions about the development and size of the market in the future, but it will be advantageous for countries to be provided an alternative to integrated systems (which have not worked sufficiently to ensure VLT access to date), and if given the ability and capacity to procure qualified and affordable OPP systems, countries will likely respond. This will especially be the case, if confusion about these platforms and inter-compatibility of parts are clarified, and the platforms are proven to work across disease areas (polyvalence), which would represent a major competitive advantage, and a major efficiency for country labs. Phase 2 should provide more information about the different types of devices and reagents available, and their inter-compatibility. In Phase 2, OPP-ERA should make efforts to inform countries and international donors about the feasibility and quality of tests performed in addition to HIV VLT. This polyvalence is an expressed desire for countries to simplify their diagnostic requirements and processes – not only for HIV, but other diseases.

Taking into account the new WHO guidelines (2013) for HIV treatment, should some OPP combination be authorised for procurement under GF and PEPFAR and countries informed about this alternative to purchasing integrated systems, OPP for VLT may become a popular choice in many countries. This is why in phase 2 the project will need to work with quality assured suppliers (qualified for GF and/or PEPFAR funding) and broadly communicate to the international community about OPP and its advantages.

4.8.3 OPP Business Plan and Phase 2 Proposal

Clearly drafting a business plan for OPP is challenging as it does not fit in the classical model where one device from one supplier is envisaged; it is therefore difficult for OPP to fully address issues that would comprise a classic business plan.

Generally the business plan submitted by OPP-ERA specifically aims at providing answers to questions as raised by UNITAID. Some of the questions asked are by their nature very difficult to answer as the project is not focusing on a specific product but on an innovative market approach combining different suppliers. Phase I focused on showing that the approach is technically sound (which the project has largely done), but it is only in phase 2 that the OPP full scale market approach can be implemented, where several suppliers will compete for the supply of one or more out of the 3 lots to procure for a complete OPP system. To some extent, it appears that the UNITAID Secretariat would benefit from a better understanding of this project, which is not comparable with any of its existing projects and for which many of the parameters used to judge it do not apply as well as to the

other projects. This also indicates that the project consortium of implementers has not adequately communicated the OPP approach to UNITAID.

The below lists major areas which the evaluators feel would benefit from clarifications in the Business Plan:

Market size estimation
The OPP business plan does not provide much information regarding the size of the market. In the 7 Phase 2 countries, the project notes that there were some 1.6 million persons living with HIV and AIDS, and some 417,926 adults on ART in 2013.

If the number of people on ART therapy worldwide was almost 13 million at the end of 2013 (Kaiser Family Foundation and UNAIDS - http://kff.org/global-indicator/arv-treatment/ and www.UNAIDS.org), and only 10% overall are having routine viral load testing, the potential unmet need for VL is over 11 million people, or at least 11 million VL tests per year globally. And, as noted earlier, UNAIDS and CHAI estimate that global need in 2015 (given the new WHO guidelines) will be for 30 million tests, and for over 40 million in 2018. Although OPP-ERA has never tried to claim that this (or any fraction of this) is its potential market niche, it has struggled to quantify the OPP market at all, even in their target 28 countries as defined in the business plan. But it would seem that with good in-country preparation through technical assistance (especially in the market vacuum currently existing in low- prevalence countries) funding (through big donors like GF and PEPFAR) and appropriate communication on the concept of OPP, a portion of this potential global market will transform into actual market as the global demand for VLT keeps on increasing.

Communication
OPP is not really new and quite a number of laboratories are already using this methodology for various tests including for VLT (e.g., Myanmar, Laos). It would be interesting in phase 2 to explore more about the existing OPP platforms in the world and capitalise on the experience gathered so far. There seems to be very little awareness about OPP as an option for VLT in the international public health community around diagnostics; the acronym appears to be unknown to many, and there is very little information about OPP available outside of the documents generated by the project. For instance the UNITAID diagnostic landscape document (June 2014) which is considered as a reference in this field, does not provide any information about OPP beyond the fact that it exists. On the other hand it provides details on other technologies that are further behind in the pipeline.

So there seems to be a discrepancy between what is being done in laboratories (where OPP is still limited, but growing in use for other diseases) and what is communicated in the public health world, where OPP is considered as something new and unexplored, complex and for which many doubts remain relating to quality. Phase 1 of OPP-ERA worked to address the quality concerns through their routine weekly QC checking of VL tests performed, and these quality concerns can be further addressed in Phase 2 once quality certifications are obtained (from WHO, CE IVD) and by conducting additional, external testing. The project has not sufficiently spread the word about OPP, nor communicated about the methodology in the public health world.

It will be critical in phase 2 to have a communication strategy in order to spread the word about OPP and present it as a true option for VLT, and to stimulate discussions and better involvement of the international community in the OPP VL effort.

Market Entry

The fact that OPP platforms already operate in many laboratories (whether they do VLT or not) is evidence that there is a market for OPP. So a proper communication strategy and the inclusion of OPP within what can be financed through GF (through quality recognition by CE IVD, FDA, WHO PQDx, and/or ERPD) is likely to enable rapid scale-up of OPP for VLT.

One advantage of the integrated platforms is that they are promoted by big multinational companies with worldwide networks and very successful marketing strategies at all levels. The nature of OPP combines different devices and reagents from different companies (most of which are small) and therefore does not benefit from the same forces to support market entry. Since in most target countries the laboratory community reportedly understands well which laboratory is working with which devices, once one OPP has reached the country the rest of the laboratory network in that country will likely quickly learn about its main properties. If the price per test is noticeably lower than those of integrated platforms, there will be a strong incentive for all countries to go for OPP as they try to maximise the value of their GF grants and cut costs.

The OPP-ERA Business Plan does not address the communication strategy for OPP, although this should be a critical focus for phase 2.

Marketing Prerequisites for OPP

The fact that many integrated platforms are placed in labs around the world but are not being used in many places (for various reasons, forming a growing "equipment cemetery" as it was called in Burundi) shows that countries cannot perform routine VLT without proper preparation and planning, as well as ongoing management of the equipment and required supplies. It is necessary to prepare the laboratories and their staff, to plan with the regulatory authorities and properly prepare doctors on how to use VLT for patient monitoring, and to help them budget for and plan for the regular procurement of all needed supplies and reagents to run the tests. As many respondents noted, it is unlikely that routine VLT can be successfully implemented (on integrated or OPP platforms) in most countries without technical assistance to support the effort. In this regard there is little difference between integrated platforms and OPP, which are both at risk if proper planning, procurement and supply management (PSM), and day-to-day maintenance are not observed. It will therefore be very useful for the project to develop a tool kit on how to prepare countries and labs for routine VLT, including the ongoing PSM costs and requirements to conduct the testing. .

Phase 2 Expansion

The aim of the OPP-ERA project is to explore the feasibility of OPP, which should ideally be done in different country settings across the world. The new countries chosen for expansion in Phase 2 (Burkina Faso, Sierra Leone, and Vietnam) were reportedly chosen mainly based on the geographic base and experience of the implementing partners, and their status as having medium or low prevalence of HIV (and hence their lesser priority for large donors). These countries are not necessarily presenting a vastly different country contexts from which to draw lessons, to those countries already involved in Phase 1.

There is value in expanding within the existing 4 countries to test how well OPP can scale up at the national level, as the project plans to do. But it is probable that the lessons to be learned from new

expansion countries like Burkina Faso and Sierra Leone will be similar to those from the 4 existing OPP-ERA countries. It might be beneficial to not limit testing of the platforms to francophone African settings. Viet Nam represents an interesting new setting for OPP-ERA, and more such countries could be identified in order to strategically create a precedent in different geographical areas, while remaining within what is feasible to be done with the funding provided. It would be a missed opportunity if OPP became tagged as a francophone approach for francophone countries with low prevalence only.

Future Trends in the Market

As mentioned, most experts (including UNAIDS, CHAI, and others) expect that, with the updated WHO guidelines (2013) and new attention internationally to the importance of routine VLT, there should be greatly increased volumes of VLT globally. At the same time, however, global funding reductions (GF, PEPFAR) since the financial crisis may mean even less funding for diagnostics (which have struggled for funding vs. drugs and treatment), as some see a constant competition for resources and limited funds for laboratories. As one respondent noted, and as a recent GF conference (*GF Strategic Reviews in Procurement and Market Dynamics - Oct 2014*)showed, funding currently does not meet the need for potential scale-up of diagnostics in most countries for 2015.

Although price has been a major obstacle to access to VLT globally, these prices are coming down, at least in some high-volume markets. Some suppliers of integrated systems have recently announced negotiated or access program prices of approximately $10 per test for reagents, although it remains to be seen where these prices will apply, and what the price will include, and how this will translate into real access on the ground in countries.

As mentioned, point-of-care (POC) technology for VLT is also considered a coming trend, with several platforms in the pipeline but only one system currently being piloted in two countries. Another trend is an expected increased reliance on Dry Blood Spot (DBS) technology, due to difficulties with sample handling and transport of full blood samples (which are fragile and degrade quickly). “The introduction of the use of DBS with some of the laboratory-based viral load platforms (Roche Taqman, Abbott RealTime, and bioMérieux EasyQ®), and its use for EID testing, help to make the sample transport process more manageable, removing some of the time pressure” (*UNITAID landscape doc, pg85*). However, at present, according to at least one respondent, neither Biocentric nor Roche VL reagents reportedly work well with DBS (Abbott and bioMerieux are more successful with DBS for VL and EID, according to this respondent), but this might be an important requirement in future, especially if VLT remains fairly centralized (e.g. in capital cities), necessitating transport of blood samples from patients to the lab in often less-than-ideal conditions.

4.9 Potential Risks, and Risk Mitigation for Phase 2

4.9.1 Phase 2 Plans

The OPP-ERA project has submitted a Proposal, Report to the Board, and Business Plan to UNITAID for Phase 2, which is proposed for two years (Jan 2015 through Dec 2016). According to these project documents, plans for Phase 2 include the following:

- Work in 7 countries (selected for being francophone, relatively high prevalence, having some OPP experience and presence of project partner organizations): Burkina Faso, Burundi,

Cameroon, Cote d'Ivoire, Guinea, Sierra Leone, and Vietnam. Sierra Leone, Burkina Faso, and Vietnam would be new to the program.

- Country-developed proposals for Phase 2 – for new sites, quantification, selection of sites for polyvalence testing, etc.
- Targets of 298,782 VLT and 13,210 EID tests (estimated to cover 38.9% coverage of VLT needs in the project countries in 2016), with purchase of 369,768 total reagents
- Greater focus on polyvalence – testing for additional disease areas (TB, Hep B, Hep C) with pilot studies (using certified reagents) in 3-4 sites to demonstrate feasibility of polyvalence use of OPP, to diagnose co-infections in PLWHA
- Increased access to VLT and EID on OPPs through
  - increased affordability (target price of $10 for reagents, down from $16 in phase1, with target for consumables at $1-1.50)
  - availability of QA'd equipment and reagents (by working with suppliers and with WHO PQ program and other bodies on OPP certification issues including compatibility)
  - developing a complete model for OPP implementation/delivery (with national strategies and guidelines)
  - EID testing in 4 of the 7 countries
- VLT in Phase 2 will be performed in (according to the Business Plan):
  - the 7 Phase 1 sites from February 2015 to December 2016 (with no interruption of services between Phases 1 and 2);
  - 6 new sites which are already equipped and using OPP (2 sites in Vietnam, 2 sites in Burkina Faso, 1 site in Cameroon and 1 site in Burundi), from July 2015 to December 2016;
  - 10 new sites to be equipped (3 in Cameroon, 3 in Ivory Coast, 3 in Burundi, 1 in Sierra Leone), from July 2015 to December 2016.
- Transition Needs Assessments in 2015 in each country (to plan for needed capacity building on procurement, plans for how to transition to other funding sources, etc)
- Training and capacity building, including building capacity of labs to build sustainable demand for the future. To include a workshop to bring together all country representatives, to review, discuss learnings from phase 1. Phase 1 countries will be mobilized to help prepare and train other countries (project will have TORs for this). Support will be leveraged through other mechanisms as well, including the French 5% Initiative.
- Greater focus on communications by project implementers
- HR changes on the project team: another virologist, 3 project managers at FEI

4.9.2 Potential Financial and Programmatic Risk

As UNITAID considers launching the next phase of the OPP-ERA project, and expanding into more countries with more testing, there is the need to assess potential risks involved, and efforts to mitigate these risks – and whether the project team has sufficiently considered these risks in their planning. As mentioned elsewhere in this report, a project such as OPP-ERA is meant to test a concept, to disrupt the status quo in the market, and to adapt to lessons learned for future replicability of the effort. There is an inherent risk to such projects, in that unforeseen challenges arise, certain planned activities may not work as planned, and project money may be lost in the process. Given this reality, project funders like UNITAID should not be too risk averse, and should defend the importance of accepting a reasonable level of risk as part of any innovative effort. However, project implementers, as stewards of the funds invested in their project, have a responsibility to foresee and manage risk as much as possible.

The project has identified a number of risks, and proposed risk mitigation strategies in their Business Plan for Phase 2. These are listed below, with comments inserted from the evaluation team in reaction, in the third column. In addition, the evaluators list some other potential risks observed during this evaluation, which were not listed in the Business Plan. These are covered after the table below.

RISKS IDENTIFIED IN OPP-ERA BUSINESS PLAN		
Risk	**Risk Mitigation Strategy**	**Evaluators' comments**
One supplier for reagents -- PQ of amplification reagents takes longer than expected. PQ processes delay new suppliers' entry into the market.	Support to PQ of other suppliers to strengthen their dossier, activities to inform and incentivize suppliers to enter the PQ processes. The consortium will engage in regular discussions with PQ structures.	*Critical to broaden source of amplification reagents beyond Biocentric only (otherwise whole OPP concept is at risk). Critical to obtain QA for Biocentric. Critical to liaise with PQ authorities and other suppliers. But also critical to maintain arm's length from suppliers when procurement decisions are made (avoid conflict of interest). Project should also consider working with additional suppliers, and expansion of OPP VLT to other countries (in addition to Vietnam), where non-B HIV is not prevalent (not to restrict project only to West Africa).*
Disinterest from national authorities or from manufacturers	Specific communication activities planned in Phase 2	*Agreed that communications with country officials and suppliers are critical. Also need to inform Global Fund and international community, lab world, to build their interest and support.*
Intellectual Property	IP risks have been analyzed by an IP expert for OPP-ERA	*Seems sufficient. Yet, project will need to be aware of potential new risks, as new products/suppliers enter, and new countries are involved.*
Maintenance issue (compatibility)	Diagnosis procedure performed by the lab technician will allow identification of the problem and of the supplier involved. Lab techs are trained on this procedure during project's training sessions. CTS and coordinator-virologist will monitor all maintenance issues.	*Project will need ongoing work with both country buyers (and lab techs) and with suppliers – to ensure they know their rights and responsibilities for maintenance and follow-up. Lack of maintenance contracts or follow-up has led to many idle closed systems worldwide. However, compatibility issue goes beyond question of maintenance, and is a major question for countries and partners re: how to ensure various components in OPP can work together.*
Defensive reaction from competitors (e.g. sudden price decrease)	Benefits would overcome risks	*There are numerous competitive risks on the horizon, including falling prices. OPP-ERA will have to prove benefits of OPP beyond price/cost only (and improve communications with countries and buyers to make sure these are understood widely).*

RISKS IDENTIFIED IN OPP-ERA BUSINESS PLAN		
Risk	**Risk Mitigation Strategy**	**Evaluators' comments**
National frameworks are not in place for IVD registration; challenge to support registration for reagents procured	Project will have discussions with regulation projects and harmonization initiatives (London School, regional organizations, etc), to identify solutions and potential actions.	*This appears to be a minor risk in the short term, as most countries do not register IVDs, but rely on PQ from WHO, etc. This makes it all the more critical that OPP-ERA work with suppliers to obtain their international QA certifications.*
In some countries, patients must pay for VLT, but many patients can't afford it. This would impact the number of VLT performed.	Information and training sessions with prescribers, and discussions with national authorities on the VLT price and its evolution.	*Issue of cost recovery from patients appears to be a controversial one, with many supporting it, saying it does work, and that it ensures greater sustainability in future. However, project may want to have some basic system whereby indigent patients or others unable to pay are still able to get their VLT. There is ethical problem (which TGF and others would be very against) in only providing VLT to those who can pay. TGF would not allow this, if they provided funding for VLT.*
Country management capacities; Non-homogenous demand (genetic diversity)	Technical assistance to governments for national implementation, and potential support by FEI upon request by the countries through the French 5% Initiative	*Ongoing TA will be essential to overcome management and coordination capacity issues (including around PSM) in countries. Need to leverage support from other entities, including 5% Initiative. Project may also want to consider demand in wider set of countries – e.g. with other sub-types – and work with broader set of suppliers whose reagents test for these.*

The following additional risks have been identified by documents and respondents in this evaluation process. They are categorized under programmatic, reputational, supply-side, and technical risks.

Programmatic risk:

- The biggest risk expressed by the project implementers is the fear that approval and initial disbursement for Phase 2 are not received expeditiously. Project activities (including retaining field staff, procurement of reagents (with 2-3 month lead time), etc would come to a stop on Dec 31, and put the whole project's progress (and momentum gained in the last few months) at risk. (This is considered a big risk, as the Board meeting is December 11, and weeks of holidays fall thereafter).

Proposed mitigation: Rapid decision making on Phase 2, with expedited initial disbursement to the project implementer to ensure no gap in funding stops the work on the ground.

- Risks to sustainability of project efforts, if systems on the ground in countries are not well developed, people trained, and interest in VLT built. Market development and support activities are as important to project success as are procurement of OPP systems components.

Proposed mitigation: Carefully gauge progress in countries, weigh options for potential re-allocation of project resources if required, toward regulatory, management, operations, training or other support needs on the ground.

Reputational risk:

- Risk of appearance of conflict of interest (COI) of OPP-ERA project, if the project is seen as "too close" or affiliated with the one supplier of OPP reagents being used (Biocentric). Even without any actual COI, the appearance of it (due to proximity with C. Rouzioux, validation at Necker Lab, disqualification of Anatolia reagents at Necker lab, etc) has some partners complaining and disavowing the project. COI also applies to procurement processes, where the project needs to ensure objectivity and arm's length decision making on all procurements. If the project is working closely with suppliers, the project should not also be the only judge of whether these suppliers win the procurement contract.

Proposed mitigation: Ensure that QA tests are also conducted at external, independent laboratories (not affiliated with the project). Ensure that decision making committee on procurements includes objective experts (not part of the project team) to provide objectivity.

Supply-side risks:

- Risk of Biocentric as a small company -- can they withstand the costs and delays of various certifications and quality controls before they can increase sales? Risk if Biocentric (or other small company suppliers) cannot manage the after-sales support, maintenance, follow-up needs of countries (as has happened with other small companies, eg. Partec for CD4).

Proposed mitigation: Work with Biocentric and other suppliers to properly assess their capacity, and ability to follow up with countries as needed. Consider need to partner with other companies working in these countries, to take advantage of their network/representatives in the region. (E.g. as Partec did for CD4 in Africa, licensing to a company with a good network on the ground).

- Risk of potential incompatibility between machines and reagents – how can the project be certain that reagents will work with various equipment, etc? For now, Biocentric's amplification reagent is seeking WHO PQ for running on the Diasorin thermocycler only…what about on other machines?

Proposed mitigation: Test reagents with various types of equipment. Work with suppliers to prove their equipment/reagents work with others. Thoroughly analyze and document compatibility of equipment/reagents, and note any problems/issues around compatibility. Share this information with countries and all partners (who have many questions around this issue).

- QA risk -- risk if WHO PQ (already more than 1 year in process) and CE IVD qualification are not obtained for Biocentric. GF and Pepfar will not allow procurement if the product is not PQ'd (so what happens after UNITAID funding ends?). How will other small suppliers also manage the investment and time required to secure QA certifications?

Proposed mitigation: Work with the WHO PQDx program, liaise with the program to ascertain the status of PQ processes, document lessons learned by Biocentric's long process, share lessons with other suppliers. Encourage Biocentric and other suppliers to also obtain CE IVD certification as a minimum standard. Help suppliers understand the WHO and other international agencies' requirements and processes.

- POC – what if new POC technologies enter the market in 2015? Will they take the place of what OPP-ERA is trying to do in these countries? Will they have a better system for VL?

Proposed mitigation: As POC has been a goal of the project (and UNITAID) in this effort to increase access to VLT, the project should communicate with POC suppliers, and discuss with WHO PQDx, investigate potential for reagent suppliers to supply/work with these new POC devices. Even though it is generally understood that POC will not replace lab-based VLT, the project should remain aware of this technology and its status in the market.

Technical risk:

- Capacity of reagents to work with dry blood spot (DBS) technique -- as this is reportedly becoming an important norm in diagnostics (and many see it as a standard in the future), facilitating sample transport and storage, there is a risk if the project suppliers don't have good capacity for DBS, whereas some integrated suppliers do have DBS capacity.

Proposed mitigation: Work with suppliers to investigate issues limiting their potential with DBS -- What are possibilities for suppliers to develop their reagents' ability to work well with DBS? Remain aware of the status of DBS in the diagnostics environment, and ensure the project responds to market demands in this area.

5 RECOMMENDATIONS

In order to enhance OPP-ERA project effectiveness and efficiency, UNITAID should take into consideration the recommendations made in the 3 tables below.

1) TO UNITAID SECRETARIAT: ENHANCING UNITAID PROJECT PLANNING & EFFICIENCY USING LESSONS LEARNED FROM PHASE 1

Urgent Recommendations	Details	Rationale
If Phase 2 is approved UNITAID should urgently disburse a sufficient amount to avoid interruption of VLT in existing target countries	The 4 phase I countries will soon run out of reagents, near the end of phase I.	Interruption of the routine established for VLT would be detrimental for the patients, stakeholders in the countries and the credibility of the project overall. Should the Board decide against funding phase 2, it should strongly consider approving bridge funding for reagents until another funding source is identified.
The Board should make a rapid decision on Phase 2	Existing staff contracts end Dec 2014. New staff should be recruited quickly for phase 2 to begin in February 2015.	It will be critical for phase 2 to capitalize on existing human resources to avoid any implementation delays, especially given the small size of the team and the current unfilled positions. Any new staff positions planned for phase 2 will need to be filled quickly to avoid delays.

Areas for improvement	Recommended Actions	Rationale and Issues to be addressed
Communication between UNITAID and OPP-ERA, including reporting	Communicate more through regular meetings (virtual or actual) and less through document exchange.	Both UNITAID and OPP-ERA have the correct impression that they are not well understood by the other. UNITAID is under the impression that this project is very high risk which appears somewhat unjustified, given the comparatively modest budget of OPP-ERA. This project is quite different from other UNITAID-funded projects and needs more background information and explanation. Some of the questions and issues raised by UNITAID indicate that the project is not fully understood.
	OPP-ERA needs to better align its communication with the tools and concepts used by UNITAID and ensure the project and UNITAID are using the same terminology and communication tools.	E.g. Results logframe (remained unfilled until recently), market landscape (OPP-ERA should use the same terminology and criteria for market segmentation)

Areas for improvement	Recommended Actions	Rationale and Issues to be addressed
	Improve and streamline reporting and document management in phase 2. Reduce document/ reporting burden (reduce number of ad hoc reporting requests, reduce feedback loop and report revisions required). Systemize and standardize the archiving of documents for common understanding and easy access	Phase 1 of the project has produced a large volume of documents during its short implementation period including deliverables and ad hoc requests. The numerous documents pertaining to the project are very difficult to track (lack of dates and authors and titles, no clear version tracking).
Communications about OPP	UNITAID should promote communication and meetings between OPP-ERA and stakeholders in the diagnostic community (WHO PQDx, GF, PEPFAR, CHAI etc). OPP needs to better communicate about the project and adapt its communications to the target audience (public health or technical). OPP-ERA should communicate about the results obtained in phase I to provide proof of concept (technical results and QA and QC of the tests). Publish the data officially.	Contrary to what some project respondents felt, there does not appear to be any firm stance against the project or its objectives from USAID, PEPFAR, GF. Rather, there appears to be a lack of information and knowledge of the project. Since OPP is not well known outside the project, there is little external feedback on OPP to UNITAID. So far the project has had little communication to the wider HIV and diagnostics community. The latest market landscape document, an important reference in the IVD sector, barely mentions OPP despite is growing use and the document's discussion of other devices further away in the pipeline. This is surprising, with 2 grantees working on OPP projects under UNITAID funding.
Communication between strategic grantees	UNITAID should establish direct communication between the OPP-ERA and WHO PQDx projects. Establish direct communication between MSF project grantee and OPP-ERA grantee	The sustainability of OPP is highly dependent on the WHO PQDx program, but both projects appear somewhat misinformed about each other. Currently there is only communication between Biocentric and PQDx through the dossier submission. Since both projects are working on OPP, valuable lessons can be exchanged, especially as MSF is working on OPP in a high-prevalence area and is also running VLT on integrated platforms in countries like Mozambique. At the moment both projects appear to be only vaguely aware of each other's activities.

Areas for improvement	Recommended Actions	Rationale and Issues to be addressed
General recommendations for UNITAID beyond the scope of OPP-ERA:		
Recommended Actions		**Rationale and Issues to be addressed**
Refine UNITAID Strategic Objective #1 ("Increase access to simple, POC diagnostics for HIV and AIDS, TB, and malaria") to include diagnostics that are not POC, including OPP. Consider revising to "increase access to simple, accessible diagnostics for HIV and AIDS, TB, and Malaria".		POC will probably never fully replace the need for laboratory based VLT. (UNITAID's strategic objectives were only adopted in April 2013, after the project was conceived and began).
Refine the Value for Money (VFM) argument for the project. Also take into consideration the opportunity cost, or the cost of not doing VLT		The project should promote not only the importance of VLT for proper patient monitoring and justify the cost in this way but should argue that this cost is well worth it to help avoid ART failure, keeping patients on 1st line (at much lower cost) for longer, keeping them healthy and less infectious, etc. This should be emphasized in addition to the VFM argument made by the project in its proposal (justifying the overall project cost).

2. TO UNITAID SECRETARIAT AND OPP-ERA: ENHANCING EFFECTIVENESS AND EFFICIENCY OF IMPLEMENTATION FOR PHASE 2

Areas for improvement	Recommended Actions	Rationale and Issues to be addressed
External Communication	Develop and implement a communication strategy for OPP	The acceptance of OPP after UNITAID support will depend on the international and local diagnostic community being aware of it as an option for VLT.
	Define strategic target audience and plan to meet key stakeholders (international donors, regulatory authorities, QA agencies, in country stakeholders, suppliers)	Many experts in the field do not know about the project, or what OPP means or are not aware of the potential advantages of the approach. There appears to be no negative stance from big donors about OPP, but rather just a lack of information.
	Develop a technical and non-technical (public health) communication strategy for different	The project is not sufficiently engaged with the international diagnostics community, which will be critical for the sustainability of the OPP

Areas for improvement	Recommended Actions	Rationale and Issues to be addressed
	audiences. Systematically participate in diagnostic conferences, e.g. presentations from Phase 1 countries about their experience with OPP Enhance project web site Include communication related targets in phase 2 logframe	approach beyond UNITAID support. The project should clarify confusion -- that the objective is not to replace the large, integrated VL systems in use, but to complement them, and offer an alternative to allow VL to be conducted more widely, in less central labs.
Communication between UNITAID and OPP-ERA	Improve communications and reporting (and documents management) for the project	There have been frustrations on both sides with the reporting requests, quality and timeliness of reporting, and miscommunications. Project implementers have spent a significant amount of time responding to UNITAID information requests, and UNITAID has spent time seeking clarifications due to a lack of clarity or completeness at times. There should be better alignment of terminology, use of tools and concepts (e.g. logframe results report) for the project. Documents management and archiving requires improvement.
Phase 2 expansion plans	Scale up as planned in existing countries Consider the issue raised in several phase 1 countries regarding the fact the laboratory technicians are not being remunerated for the extra work which they perform for VLT and seek solution to this issue in a sustainable way Expand in new countries outside of West Africa, in addition to Vietnam	Experience needs to be gathered about: • how well OPP can scale up, • how an OPP network in country can cover the need for VLT • support for testing different pathogens and performing EID With the scale-up of OPP and the increased number of tests to be performed in each lab, this will become more of an issue especially since the novelty factor of finally being able to perform VLT will most probably fade, leading to potential morale issues as work loads increase. It is critical that phase 2 provides data about the full potential of OPP in

Areas for improvement	Recommended Actions	Rationale and Issues to be addressed
		different regions and different markets. One lesson learned is that if phase 2 is restricted to mainly West Africa it may be bound to one reagent supplier (because of the need to diagnose non-B types of HIV) which defeats the objective of OPP and limits its potential to lower the price of VLT.
	Expand outside of the Francophone community in phase 2	One of the concerns among the international diagnostic community is that this project would not be viable outside of the support of the Francophone community/agencies. This could be addressed by the choice of other targets for expansion in phase 2.
	Work more closely with other organizations on the ground in countries, leverage project activities	The project implementers could seek ways to cost-share or leverage with other groups working in their labs in countries (e.g. FHI in Burundi, building sample network).
	Consider additional spending on support activities on the ground if needed.	PSM, maintenance, operations, and general capacity in countries have been obstacles to VLT worldwide (and led to a "cemetery" of VL equipment in many places).
Gathering market information about OPP and viral load	Consider running in parallel OPP with integrated platforms, analyzing and documenting the differences in terms of cost, usage, maintenance, training, staff time, test quality, consumables needed, waste produced etc.	The views about OPP among respondents are quite divergent; people using OPP who were contacted are enthusiastic about the approach and compare it very favourably to integrated platforms (sometimes despite their lack of experience on integrated platforms). Others mainly in the international diagnostic community have little to no experience of OPP and have therefore more sceptical views.
	Reconsider target markets (niche) to include markets where VLT price is paramount to all other criteria	For example, lower-prevalence, higher income countries like Georgia which does not reportedly qualify for Abbott and Roche discounted prices, and where donors including GF are phasing out. This country (and perhaps other similar countries), has relatively good infrastructure and access to inexpensive qualified lab staff in abundance (see section on target market for OPP).

Areas for improvement	Recommended Actions	Rationale and Issues to be addressed
	Try to generate information about the full cost per test for integrated platform and for OPP (for different throughput scenarios) Gather and clearly map information about compatibilities between different equipment and different reagents In phase 2, do not limit the procurement to only one type of combination for OPP as was done in phase 1 (Diasorin, Roche and Biocentric). Also target those that can already qualify for procurement under GF. Enhance communication with suppliers, ensure they are aware of procurement opportunities and quality requirements. Try to liaise more with industry to get access to market data Keep some level of procurement at the local level for countries to establish the supply channels which they will need for routine VLT	There appears to be inadequate information about this: prices per test are given but it is often unclear what is actually included in the price, which often only includes the price of reagents. This information will be critical for countries to make informed decisions in choosing their approach for VLT. One of the big concerns in the international diagnostic community about OPP is the potential lack of compatibility between different suppliers of reagents and extracting machines. OPP-ERA needs to provide experience about the ability of the approach to run on different devices to truly demonstrate its potential to activate market forces. Big market players all have access to common statistics about the market and may share some information with the public sector. Roche as one of the players in OPP phase 1 could be approached for this. OPP in phase 2 is planning to procure internationally what was procured locally in phase 1 because of challenges encountered and to avoid delays. Some level of local procurement might however be very useful for countries to learn valuable lessons about the reliability of their supply channels, which will need to be established further for ongoing routine VLT supplies in future.
Adequate VLT for sub-types of HIV prevalent in West Africa (and also common in Western	OPP-ERA needs to communicate the laboratory findings on the unequal abilities of reagents to quantify non-B HIV types by	One of the lessons learned in phase 1 is that common reagents used for VLT worldwide are inadequate for quantifying non-B HIV virus. According to ANRS findings, only Biocentric reagents are fit for this purpose (and to

Areas for improvement	Recommended Actions	Rationale and Issues to be addressed
Europe)	relating them to health outcomes: what is the risk of not using Biocentric reagents, e.g. what percentage of patients could get wrongly diagnosed as a result Address appearance of Conflict of Interest/ lack of objectivity (even if none exists) regarding the choice of Biocentric as the only reagent in settings with high prevalence of non-B types. OPP-ERA should ensure that Biocentric reagents and the system are validated in other labs besides Necker and evaluated in other labs besides the project's labs in Abidjan and Cameroon, and that more objective voices speak in support of the company (not merely project members, who may be seen as too close to the company). There is a need for external, objective QA. Explore options to have the results evaluated/ endorsed by other external laboratory/experts, possibly outside of the francophone context. Upon full validation of the results, broadly communicate those results within the diagnostic community and especially WHO PQDx and other regulatory authorities	a lesser extent Roche version 2 integrated platforms which are not yet very widespread). This would mean that the classic VLT approach and most reagent suppliers are not the best choice for quantification of HIV viruses in geographical areas with non-B. Awareness about this issue within the international diagnostic community will be essential to avoid unnecessarily exposing patients to risks and to stimulate the industry to produce better tests (Roche has already made a step in this direction). Among the international diagnostic community, there is a perceived conflict of interest/lack of objectivity as C. Rouzioux is both the inventor of the reagent test which Biocentric commercializes, and also performs the evaluations of this and other reagents in her laboratory. It is important that the validity of these evaluations is no longer questioned.
Quality assurance	Obtain necessary quality assurance recognition and certifications, to enable procurement through major donors (GF,	While awaiting WHO PQ, Biocentric should apply to ERPD in early 2015 for provisional PQ, and also apply for CE IVD in parallel. The aim should be for Biocentric to be quality assured for procurement through GF by

Areas for improvement	Recommended Actions	Rationale and Issues to be addressed
	PEPFAR)	mid-2015. Since phase 1 has focused on only one combination of devices it will be essential for the sustainability of the project for this platform to be available for purchase within GF grants. By the end of phase 2 there might already be experience gathered by countries using OPP under GF funding.
	OPP-ERA should actively take part in the debate about diagnostics and QA for VLT.	OPP-ERA should not be working in isolation but be part of the discussion (not just reactive) and actively contribute to the dialogue on QA and diagnostics approaches for VLT (see recommendations on communication).
In-country requirements and PSM (procurement and supply management) needs for OPP	Work on systematizing and standardizing the approach and producing a toolkit for the introduction of OPP in countries	To avoid the risk that their systems stall or become idle in labs (as so many integrated platforms have done) OPP systems must be accompanied by adequate systems to ensure regulatory support, sample handling and results feedback, good prescribing practices, adequate laboratory infrastructure and training, good procurement practices, etc.
	Scan other stakeholders' initiatives within the international diagnostic community to design tools to facilitate OPP introduction in countries	As CHAI, WHO and perhaps other organizations have developed "tool kits" for OPP use, the project should review these, and use what they can to help explain/ facilitate OPP use for viral load.
	Establish clear focus on PSM (procurement and supply management) issues and efforts of the project, to address widespread concern about capacity to manage ongoing VLT in countries.	A major concern within the international diagnostic community is the question of countries' ability to manage the maintenance and supplies for OPP, due to the need to manage numerous suppliers, as opposed to just one in the case of integrated platforms. This concern appears not fully justified as the small sizes of the OPP platforms allow for shipment of replacement machines in case of failure (see procurement section). However, it is important that the project address this concern and clearly establish rights and responsibilities for the components (through SOPs for countries, for example), and include the necessary support guaranties in purchase contracts. Ensure that companies participating in sales of OPP platforms and supplies have clear lines of responsibility and follow-up in

Areas for improvement	Recommended Actions	Rationale and Issues to be addressed
		terms of break-downs and after-sales support, training, etc.

3. TO UNITAID SECRETARIAT AND OPP-ERA: RISK MITIGATION FOR PHASE 2

Risk Areas	Specific Risks	Risk Mitigation Recommendations (see also above)
Supply-side risks	Biocentric is the only supplier which could be identified for adequate detection of non-B type of HIV	Broadly communicate about the issue to strategic stakeholders in order to raise awareness of the risk for patients and stimulate other suppliers to improve their tests for quantification of non-B types of HIV.
	Questionable ability of small suppliers (like Biocentric) to provide country support (can they afford investment?)	Ensure procurement from different manufacturers for each lot so that the project is not dependent on one, focus on potential suppliers with CE IVD, who may already be well established. Consider selection additional target countries for phase 2 expansion outside of West Africa.
	Biocentric's current lack of QA recognition threatens the sustainability of the project, as it still does not qualify for procurement under major donors including GF	While awaiting WHO PQ (and doing the necessary steps to ensure internal controls), Biocentric should apply to ERPD for provisional PQ, and also apply for CE IVD. UNITAID should establish direct communication between PQDx grantee and OPP-ERA grantee.
	Multiple suppliers with unclear responsibility when system breaks down or needs support (and for training, installation, other responsibilities)	Clarify responsibilities in maintenance contracts. Make sure that extractors are installed in two's and that technical failure of machine under a maintenance contract can lead to shipment and replacement of the machine rather than repair, if preferred.
	Issue of compatibility of components from diverse suppliers	Develop overview of compatibilities for potential OPP devices showing which components from which suppliers will or will not work together (mainly which extractor with which reagent). Focus on devices already approved by a stringent regulatory authority and fit for purchase under major donors.

Risk Areas	Specific Risks	Risk Mitigation Recommendations (see also above)
	OPP devices are at risk of joining the "equipment cemeteries" which can be seen in many laboratories in poor resource settings	Ensure that prerequisites (infrastructure, training, regulatory framework, sample logistics, etc.) for the introduction and maintenance of OPP are well communicated and established prior to the installation of OPP platforms. Prepare toot kit to be used for introduction and management of OPP in new countries.
Lack of international support	Appearance of COI or lack of objectivity in comparative results of reagent suppliers. Project perceived as francophone –or only viable with support of francophone agencies Lack of awareness and understanding about OPP	Have tests validated/endorsed externally Expand outside of West Africa Design and implement communication strategy for OPP targeting strategic stakeholders from the international community, GF, WHO PQDx etc.
Lack of demand and market sustainability in countries	No or low demand because of insufficient knowledge or awareness about OPP Endgame/sustainability after UNITAID funding Doubt about the ability of the project to be sustainable in countries, given the time and effort required to get started in the 4 pilot countries. Concern is not only ability to conduct the VLT, but feedback loop of data/ information /results to physicians and patients for accurate interpretation and appropriate action.	It will be paramount for OPP to design and implement a communication strategy for OPP. Essential for UNITAID to include OPP in its market landscape review. Make sure some combination of devices for OPP can be procured under major donor funding. Push for suppliers to apply for WHO PQDX as a great QA recognition and marketing tool. VLT requires preparation and for the system to be viable in country. The project should attempt to assess and quantify the needs for technical assistance and support for the introduction and ongoing operation of OPP. The project should seek longer-term support (e.g. French 5% Initiative) that can help sustain the project's efforts after the project ends.
Risk of inaccurate costing, and technical risks	Hidden costs in OPP platforms, vs. integrated all-in costs/pricing	Phase 2 should provide information on the full costs of usage (and total costs of ownership) for both integrated platforms and OPP (see above recommendation table). Develop PSM SOP and

Risk Areas	Specific Risks	Risk Mitigation Recommendations (see also above)
		checklist for OPP VLT, to clarify for countries all items required for the whole VLT process.
	Big manufacturers of integrated platforms may lobby against OPP platforms if they feel their market is being threatened.	OPP-ERA must implement a communication strategy about OPP. The project should put the focus on the polyvalence of the platform, and its role as an addition to larger integrated systems, and should continue to make efforts to integrate big manufacturers within OPP like with Roche in phase 1.
	Technological advances, including POC and systems using dry blood spot (DBS) for VLT, may threaten market for OPP. OPP may need to work toward better compatibility with DBS analysis, as DBS becomes more essential to increase access to testing.	It is reportedly unlikely that POC will fully replace the need for laboratory based VLT performed on plasma. However, the project should be aware of DBS potential compatibility among suppliers, and consider this in its selection criteria in future. This could be newly evaluated at the end of phase 2.
Procurement for phase 2	Ensure good procurement practice in phase 2, ensuring objective decision making and no appearance of conflict of interest	Since phase 2 will need to work on stimulating the supply side and will probably provide support to suppliers in submitting dossiers, it will be important to have external evaluators participate in product/supplier selection decisions, to avoid any conflicts of interest.
Procurement and supply management for OPP in country	Risk of inadequate management of suppliers, reagents, components, timely ordering, monitoring expiry dates, etc.	Address PSM challenges that are a major reason VLT is not done in so many countries (due to lack of reagents, expired reagents, lack of consumables, lack of maintenance contracts, lack of procurement planning, lack of awareness of complete kit/contents of all that is required to do VL). Develop and distribute toolkit for introduction and operation of OPP.

6 CONCLUSIONS

Based on the analysis of findings, the evaluators find that Phase 1 of the project has confirmed that OPP presents a potential opportunity to expand access to VLT for a population in need at potentially lower cost than other existing technologies. Development of a market for OPP through Phase 2 would be consistent with UNITAID'S market-based approach and would fit into an unfilled market niche. The evaluators found that OPP-ERA is run by a strong team of qualified, dedicated professionals who form the basis for an effective team for Phase 2, with some suggested improvements in management and implementation. Implementation of Phase 2, however, would not be without risks, requiring UNITAID, FEI and its partners to take critical actions identified to mitigate those risks.

Even with the risks identified, the downside to UNITAID of funding Phase 2 appears relatively limited. Even in the event that the OPP-ERA project is not successful in fully developing a market for VLT using OPP, funds invested by UNITAID would have financed actual VLT monitoring for patients who did not have access to it previously and would have established systems and capacity in country for performing routine VLT at a price that is competitive with existing integrated platforms in those countries. Lessons learned from this effort will also inform future investments in the diagnostics landscape.

ANNEXES

ANNEX I: TOR FOR THE EVALUATION

TERMS OF REFERENCE

1.1 Objectives of the activity

Grant evaluations support the UNITAID Operations team by providing a forum for independently assessing each completed UNITAID grant to determine whether or not the grant met its objectives and delivered what it agreed with UNITAID to deliver within a specified timeframe.
Grant performance is assessed over the first phase (phase 1) of the grant. Where a project has been the subject of a mid-term evaluation, the evaluation team should take into consideration whether or not the recommendations of that previous evaluation have been followed by the Implementer and where relevant, by UNITAID.

1.2 Activity coordination

All grant evaluations are coordinated by the M&E Team of UNITAID Operations. Evaluators will work closely with the UNITAID Secretariat to undertake reviews of the grants using official documents, evaluation checklists, questionnaires and other associated tools.

1.3 Work to be performed

Evaluators should consider project achievements and lessons learnt as a result of the implementation of the UNITAID grants. The evaluation reports will be widely disseminated and available to all UNITAID Stakeholders, including the general public via UNITAID's website (www.unitaid.org/impact). Project impact should be evaluated from two perspectives:

- Market impact (intentional and unintentional) for the products provided under the project agreements; and
- Public health impact for the beneficiaries of the medicines, diagnostics and related products provided through the project.

To improve the grant evaluation process, UNITAID has revised its evaluation framework and guidelines to capture the country perspective of its grants, where applicable. Because UNITAID does not have offices or representatives based in countries, there is a need to evaluate progress at the country level, including following up on the provision of products and other services in the countries supported by UNITAID grants. Country level performance is critical to ensure proper transition and scale up of successful interventions by donors and countries. Table 1 presents the revised evaluation framework as a series of questions to be addressed by evaluators when performing a grant evaluation. Improved guidelines include:

- more specific terms of reference for country-level verification of grant achievements, including random, specific field checks where relevant to the grant during the mid-term evaluations;
- corroboration of grant achievements by national governments or beneficiary countries, manufacturers and/or partner organizations including those that are involved in the

transition of grants to more secure funding sources, i.e. the GFATM, PEPFAR and other international organizations working in public health;
- assessment of value for money achieved by each grant;
- better use of evaluation findings by UNITAID Portfolio teams and grantees to take specific actions in grant management and/or planning for future grants of a similar type; and
- increased visibility of UNITAID's role in grant achievements at the country level.

Specific information about the grant under evaluation for the HIV portfolio can be found in the Annex of these TOR.

Table1. UNITAID's Evaluation Framework

Relevance:
1. Are the outcome(s) and impact(s) of the grant aligned with UNITAID's overall mission to contribute to the scale up of and access to treatment for HIV and AIDS, malaria and TB for the most disadvantaged populations in developing countries using innovative global market based approaches? 2. How does the grant contribute to one or more of UNITAID's six strategic objectives?
Effectiveness:
1. Are the outputs of the grant consistent with the objectives and expected outcomes as described in the project plan? If changes have been made, has the UNITAID Secretariat been involved in discussions about the changes? 2. Were the outputs of the project achieved within the timeframe specified in the initial project plan? 3. What are the main factors influencing the achievement or non-achievement of the outputs or overall outcomes across all countries and within each beneficiary country? 4. What factors have been considered to ensure that value for money has been achieved?
Efficiency:
1. Can the grant Implementers and their partners demonstrate that national authorities are aware and participating in grant activities at the national level? 2. How cost efficient and cost effective is grant implementation? 3. Were challenges raised with the UNITAID Secretariat in a timely manner and did the Secretariat participate in resolving these challenges? 4. Was the grant's procurement model designed to identify and solve procurement-related problems (where applicable)? 5. Were there any issues related to potential diversion of products, counterfeit or quality? 6. Is the grantee implementation arrangement efficient?
Impact:
1. Can the grantee report on impact as originally framed in the project plan and LogFrame? If not, has the grant impact been measured in another way? 2. Where relevant, can the grantee attribute UNITAID's financial support for medicines, diagnostics or preventive products purchased to patients tested or treated in each beneficiary country?
Learning & Risk mitigation:
5. Have lessons learnt been documented and widely disseminated by grantees and UNITAID? 6. Have programmatic and financial risks been identified and tracked over the course of grant implementation? 7. Have the lessons learnt been reflected in the proposed Business Plan for Phase 2? 8. Have the findings and recommendations of mid-term evaluations or audits (where relevant) been used to improve grant performance?

1.3.1 Deliverables

The contractor should submit the following deliverables by the dates determined for each evaluation:

Deliverable
1. An Inception report outlining the process for the evaluation.
2. A draft final report to UNITAID and the grantee assessing each project under evaluation and a finalized report which will be made available to the public on the WHO/UNITAID website.
3. Written recommendations and advice to the WHO/UNITAID Secretariat on how to improve the effectiveness and efficiency of WHO/UNITAID project planning based on lessons learnt through the end of project evaluation process
4. Written recommendations and advice to the WHO/UNITAID Secretariat and the Grantee on specific considerations for setting up the next phase of the Project, in case of the Board approval, including, but not limited to: • Specific recommendations to improve the effectiveness and efficiency of implementation • Specific recommendations on risks and risk mitigation strategies

1.3.2 Response time

To be determined for individual evaluations.

1.3.3 Delivery time

To be determined for individual evaluations.

1.3.3.1 Confidentiality

Given the sensitivity of information made available for evaluations, contractors will be required to sign a confidentiality undertaking for each individual contract.

Annex: Description of project to be evaluated

Open polyvalent platforms for sustainable and quality access to Viral Load in resource limited settings

HIV

Description

*No-cost extension from 1 July 2014 to 31 December 2014.
OPP-ERA Phase 1 – The Project improves access to viral load testing (VLT) and early infant diagnosis (EID) for adults and children living with HIV through the introduction of innovative Open Polyvalent Platforms (OPPs). During Phase I of the Project, the lead project implementer, **France Expertise International (FEI)**, will work with other partners to develop a full Business Plan for scaled-up commercialization of VLT/OPP, prepare a proposal for the second phase of the Project, develop a procurement strategy and plan for the 4 project target countries and commence deployment on OPPs in these countries.

Project Status

Active

Countries

- BURUNDI
- CAMEROON
- GUINEA
- CÔTE D'IVOIRE

Grantees

- FEI

2. DISBURSED TO GRANTEES (Amount ($USD)Disbursed to grantees total)

C: $1,923,520

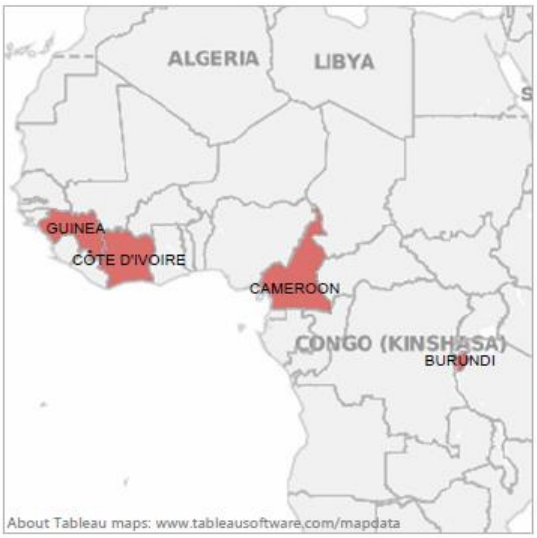
3. EB APPROVED BUDGET CEILING

C: $2,400,000

4. MOU AMOUNT

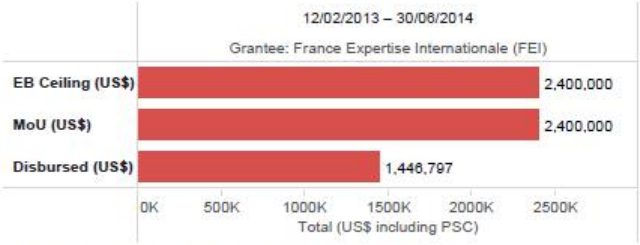
C: $2,400,000

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



1 Simple, point-of care (POC) diagnostics

Strategic Objective 1: Simple, point-of-care (POC) diagnostics
The Project improves access to viral load testing (VLT) and early infant diagnosis (EID) for adults and children living with HIV through the introduction of innovative Open Polyvalent Platforms (OPPs). During Phase I of the Project, the lead project implementer, France Expertise International (FEI) has been working with other partners to develop a full Business Plan for scaled-up commercialization of VLT/OPP, prepare a proposal for the second phase of the Project, develop a procurement strategy and plan for the 4 project target countries and commence deployment of OPPs in these countries.



Financial data as of 31 December 2013.

Grant Performance

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

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

Update on OPP-ERA

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

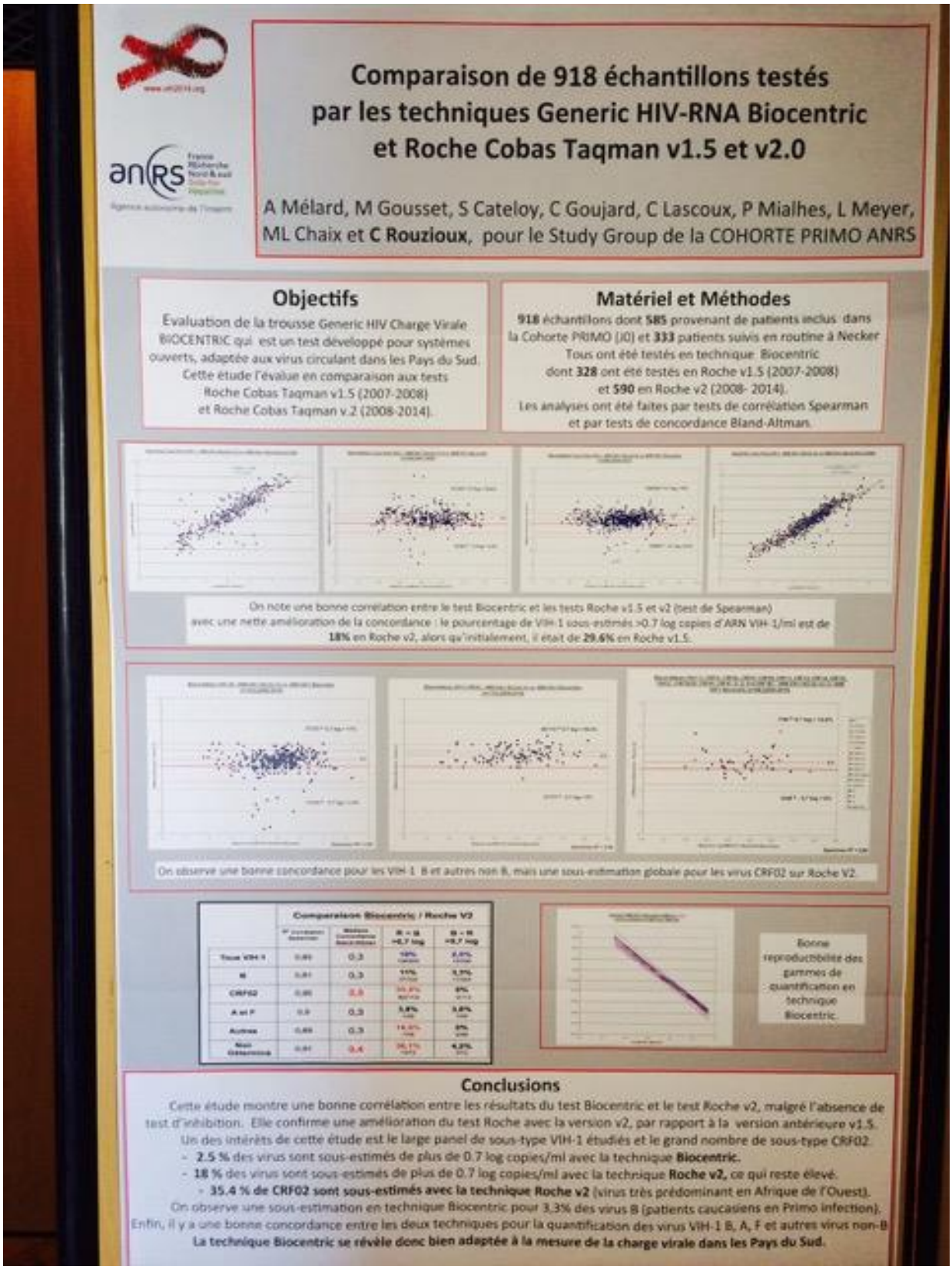
As of 31 December 2013.
For more information, visit www.unitaid.org/impact

ANNEX II: Key Indicators for the Project (according to revised logframe June 2014)

Logical Framework		
Results	**Indicator**	**End of Project Target**
Goal (Impact) : to demonstrate that a viable alternative to "integrated systems" and "closed machines" for VL testing is possible in resource-limited settings		
Indicator G1	Name of certified suppliers willing to enter the market per lot	2 names per lot (June 2014)
Indicator G2	Name of certified suppliers entering the market per lot	1 name per lot (June 2014)
Indicator G3	Market size in 28 core target market countries estimated	28 countries estimated market size (due Sept 2014 (originally due June 2014)
Outcome: OPP is used in the 4 target countries		
Indicator P1	% patients on ARV who have received a VLT using OPP at least once over phase 1 in selected treatment sites	3% by Sept 2014, 24% by Dec 2014 (original target was 30% by June 2014)
Indicator P2	# of VLT performed by target countries	2,496 by Sept 2014, and 16,019 by Dec 2014 (original target was 19,610 VLT by June 2014)
Output 1 : Enhanced capacities of laboratories to perform VL monitoring using OPP		
Indicator O1	# of staff trained on use of OPP for virological monitoring of HIV infected patients	80 trained by Dec 2014 (original target was June 2014)
Output 2: OPP is operational in the 4 target countries		
Indicator O2.1	# of operational platforms established in target countries	7 (June 2014)
Indicator O2.2	# of VLT (equipment and supplies) delivered	20,025 VLT by Sept 2014 (original target was 32,000 by June 2014)
Output 3: OPP is more affordable in the 4 target countries		
Indicator O3	Price tracked for purchased VLT (extraction +amplification reagents)	$20 reagent cost per test (by June 2014)

Source: Excel File "OPP-ERA Simplified logframe FINAL" saved 12/17/2013

ANNEX III – POSTER PRESENTED TO COMPARE BIOCENTRIC REAGENTS TO ROCHE REAGENTS (presented by C. Rouzioux, provided by Biocentric)



ANNEX IV – PROJECT TIMELINE FOR PHASE 1

OPP - ERA TIME LINE OF DOCUMENTS AND KEY EVENTS

Activity/Doc	Admin & Coord	Procurement	Country	Mkt Analysis	Reporting	Financial	Month	Year
Project Agreement for Phase 1 signed	X							
First Disbursement Request - $1,040,000 Approved						X	Feb	
							Mar-Apr	
Procurement Procedure		X						
International Competitive Bidding (ICB) Information Notice		X					May	
Country Mission Reports			X					
							Jun	
Agreement Amendment (no cost extension to 31 Jan 2015)	X							
Market Dynamics Assesssment Preliminary Results				X			Jul	
ICB Information meeting		X						
FAQ Tender		X						
OPP-ERA – UTD Meeting , Paris	X						Aug	
Financial Report Submitted						X		2
Call for Tenders Released		X					Sep	0
Inception report submitted					X			1
Baseline Market Assessment				X				3
Business plan outline					X			
Procurement proceedure		X						
Country operational plans			X				Oct	
M&E framework	X							
Country Mission reports			X					
Tender Submissions Due		X						
Call for Tender Selection Report		X					Nov	
Revised budget submitted						X		
Call for Expressions of Interest for Lot C - Negotiated Procedure		X						
Procurement Selection Report Approved by UNITAID		X					Dec	
Quality Assurance Approach Phase 1 (FINAL VersionDate?)					X			
Annual Financial Report Sumitted						X		
							Jan-Feb	
Second Disbursement Request -$488,796.10 Approved						X	Mar	
Phase 1 Annual Report Submitted					X			
Lot C Submissions Received		X						
Lot C Selection Report		X					Apr	
Lot C Selection Report Approved by UNITAID		X						
Third Disbursement Request- $476,723 Approved						X		
							May	
Consolidated Market Analysis				X				
OPP-ERA Phase 2 Proposal - Revised					X		Jun	
OPP-ERA Phase 2 Proposed Budget						X		
OPP-ERA – UTD Meeting, Paris	X							
Lots A, B & C Delivered to Burundi, Cameroon, Ivory Coast and Guinea		X						2
Incountry Training			X				Jul	0
VLT Begun			X					1
Incountry training			X				Aug	4
VLT Begun			X					
Phase One Implementation Report (BP annex)					X			
Report to the Board					X			
OPP-ERA Phase 2 Business Plan					X			
Intelectual Property Report (BP Annex)				X			Sep	
Market Landscape Observations (BP Annex)				X				
OPP-ERA Phase 2 Proposed Budget						X		
OPP-ERA Phase 2 Proposed Logframe	X							
OPP-ERA Phase 2 Quality Assurance Plan (BP annex)					X			
							Oct	
Semi-Annual Financial Report (deadline extended)						X	Nov	
							Dec	
							Jan	2015

PROJECT PHASE ONE

Inception Phase
Market Analysis and Incountry Prep

Country Operational plans
Agreements with Beneficiary Countries
Procurement strategy and Plan
Quality Assurance Plan
M&E Framework

Launch Phase
Market Development & Operational Support

Commodity Procurement
Laboratory Set up
Country Training
Start VLT
Business Plan for Scaled Up Commercialization
Revised Project Proposal for Phase 2

No Cost Extention

ANNEX V: Persons Contacted

Name	Position	Contact Details	Involvement in OPP-ERA Project
UNITAID TEAM			
Smiljka de Lussigny	Technical Officer, HIV & Project lead for Diagnostic projects, including OPP-ERA	Email: unitaid@who.int Tel.: +41 22 791 55 03	Funding organization
Dr. Kate Strong	Monitoring and Evaluation officer	strongk@unitaid.who.int	Funding organization
Gauri Khanna	M&E, including logframe	khannag@unitaid.who.int	Funding organization
Lorenzo Witherspoon	Procurement Advisor	Witherspoonl@unitaid.who.int	Funding organization
Cecile Langely	Finance Officer	langelyc@unitaid.who.int	Funding organization
Carmen Perez Casas	Technical Officer, Market Dynamics	Perezc@unitaid.who.int	Funding organization
Philippe Duneton	Deputy ED	Dunetonp@unitaid.who.int	Funding organization
FEI			
Intissar Bel Hadj	Project manager	intissar.bel-hadj@diplomatie.gouv.fr +33143176565	Implementer
Audrey Giret	Project Director	audrey.giret@diplomatie.gouv.fr	Implementer
Eric Nerrienet	Coordinator-virologist	+33143176428	Implementer
Cristina D'Almeida	Market Analyst	+33143176434	Implementer
ANRS			
Christine Rouzioux	Scientific Director (appointed by ANRS to provide scientific expertise and technical advice on the project)	+33663197659	Implementer
ESTHER			
Arnaud Laurent	Project Director	+33153175201	Implementer
Gilles Raguin	Esther Director	+33153175158	Implementer
SIDACTION			
Florence Thune	Training officer	+33153264974	Implementer
Olivia Sylla	Project country supervisor	+33153264978	Implementer
SOLTHIS			
Sophie Calmettes	Operations Director	+33153615368	Implementer
Etienne Guillard	Project country supervisor	+33153615364	Implementer
In Ivory Coast			
M. Samuel Doukou,	Chargé de projet OPP-ERA ESTHER	samuel.doukou@esther.fr +225 57869851	Implementer, (position funded by the project)

Dr. ABO Kouamé	Directeur autoritées Nationales PNLS	kwagny@gmail.com +225 22420717	National partner and member of OPP-ERA local steering committee. Beneficiary of the project.
In Cameroon			
Amadou Hamadou	Chargé de projet OPP-ERA	Laboratoire.cameroun@esther.fr; + 237 79504151	Implementer, position funded by the project
Madeleine Mbangue	Chef service laboratoire, Hôpital Laquintinie de Douala	madombangue@yahoo.fr ; +237 99954689	National partner and implementer, beneficiary of the project
Dr MABOULI NKOMOM Floribert	Cameroon Ministry of Health representative	Médecin de Santé Publique Chef de Service de la Prise en Charge des Cas SDLVIH/SIDA / DLMEP / MINSANTE Tel: (00237) 71687655 / 99950777	National partner, beneficiary of the project
In Guinea			
Abdoulaye TOURE	Responsable Projet OPP-ERA Membre du Copil	abdoulaye.toure@solthis.org +224666912127	Implementer, position funded by the project
Dr. Youssouf KOITA	Coordonnateur National PNCSP Membre du CoPil	koitay@yahoo.fr +224664345909	National partner and member of OPP-ERA local steering committee. Beneficiary of the project
Pr. Mohamed CISSE	Directeur Comité Médical Technique	cissebibi1@gmail.com +224664345356	Beneficiary of the project
In Burundi			
Francine KABATESI	INSP Référent Charge virale	kabafifi2002@yahoo.fr +25778731730	National implementing partner.
Donavine HAKIZIMANA	INSP Directrice du laboratoire	donahakiza@yahoo.fr +257 77 738 220	National partner and member of OPP-ERA local steering committee. Beneficiary of the project
Pélagie Nimbona	ANSS Bujumbura Point focal Prescription CV	pelanimb@yahoo.fr +257 77 736 556 + 257 78 850 307	National partner, implementer and member of OPP-ERA local steering committee. Beneficiary of the project
Others			
Vincent Wong	Senior Technical Advisor – HIV Testing and Counseling USAID Global Health Bureau - Office of HIV	vwong@usaid.gov +1 571 309 1273	External

	and AIDS		
Martine Guillerm	Global Fund Laboratory specialist	Martine.Guillerm@theglobalfund.org + 33 9 80 53 92 52	External
Joëlle Daviaud	Global Fund Quality assurance Specialist grant management support	Joelle.Daviaud@theglobalfund.org +41 794 53 16 82	External
M. Marc Tordjeman	Director Biocentric	biocentric@biocentric.com +33 4 94 29 06 30	Supplier
Silvia Rath	Director LGA Laboratoire Guinéo-Allemand Beneficiary of the Pandemic Preparedness Initiative from the GIZ	+224 628186863 +49 17629391995 silvia.l.rath@gmail.com	External
Irena Prat	Technical officer, DLT, WHO (dossier review) Prequalification of Diagnostics Programme	prati@who.int	External
Javier Goiri	MSF Deputy Programme Manager	javier.goiri@geneva.msf.org	External
Roberto de la Tour	Laboratory Advisor, MSF-OCG Tel +41 22 849 84 15 Fax +41 22 849 84 88	Roberto.DELATOUR@geneva.msf.org Tel +41 22 849 84 15 Fax +41 22 849 84 88	External (beneficiary/ implementer of other UNITAID project)
Trevor Peter	Senior Scientific Director, Diagnostics Team – Clinton Health Access Initiative (CHAI)	tpeter@clintonhealthaccess.org	External
Marika Karcheva	Director of Tbilisi national reference laboratory	Kmarika79@yahoo.com	External
Dr. Rosanna Peeling	Director of Diagnostics at LSHTM (London School of Hygiene and Tropical Medicine)	Rosanna Peeling Professor and Chair of Diagnostics Research Dept of Clinical Research, ITD London School of Hygiene & Tropical Medicine | Keppel St | London WC1E 7HT | UK T: +44 (0)20 7927 2529 rosanna.peeling@lshtm.ac.uk	External
Dr. Jessica Markby	WHO HIV Diagnostics Advisor	Treatment and Care Team Department of HIV and AIDS World Health Organisation Avenue Appia, 20 CH-1211, Geneva 27 Tel: +41 22 7918163	External

		Email: markbyj@who.int	
Dr. Elif Akyüz	Director, Anatolia	Anatolia Geneworks Inc. Egitim Mh. Kasap Ismail Sk. No:10/23 Kadikoy 34722 ISTANBUL-TURKEY Tel: +90 216 330 04 55 www.anatoliageneworks.com	Potential Supplier
Ms. Ayşe Kanneci	Overseas Sales Manager, R&D Anatolia	(ayse.kanneci@anatoliagenetik.com	Potential Supplier

ANNEX VI: Documents Reviewed

- "Agreement for a Project to Support Open Polyvalent Platforms for a Sustainable Access to Quality and Affordable Viral Load Testing (VLT) in Resource Limited Settings" Between the World Health Organization and France Expertise Internationale, signed 11/02/2013
- "UNITAID Correspondence to FEI, dated 14 July 2014, amending agreement". Pdf document - Fully signed 1st Amendment_FEI
- List of Annexes to Memorandum of understanding FEI & UNITAID
- FEI PHASE 1 - Annex 1A Project Plan (Final 8 February 2013)
- FEI PHASE 1 - Annex 1B Indicative list of questions for business plan (Final 8 February 2013)
- FEI PHASE 1 - Annex 3 Financial reporting template final 28 02 2013
- FEI PHASE 1 - Annex 3 Financial reporting template final 28 02 2013
- FEI PHASE 1 - Annex 4 Roles and responsibilities (including key personnel) revised 15 August 2014
- FEI PHASE 1 - Annex 5 Fraud and Loss Reporting Template - updated 07-11-2012
- FEI PHASE 1 - Annex 6 Procurement procedure 09-2013 final
- FEI PHASE 1 - Annex 7 Quality Assurance approach July 2014
- FEI PHASE 1 - Annex 8 Country operational plans 2013 (undated- file saved 1 Oct 2013)
- FEI PHASE 1 - Annex 9 Three years OPPERA project proposal (8 February 2013)
- OPP-ERA Simplified logframe FINAL (undated)
- Reporting template OPP-ERA FINAL
- Definissant le Cadre de Collaboration entre Le Ministere de la Sante Publique et Le Grouplment d'interet Public "Ensemble pour Une Solidarite Therapeutique Hospitaliere en Reseau pour La Mise en Oeuvre des Projets de Lutte Contre le VIH/SIDA et SES Co-Infections au Cameroun" CONVENTION CADRE No 20110901/MINSANTE/GIP ESTHER/2011
- "Accord Relatif a la Mise en Oeuvre du Projet <<OPP-ERA>>" Burundi, signed 12/07/2013
- "Protocole d'Accord signé entre Le Ministere de la Santé et de la Lutte Contre le Sida & France Expertise Internationale (FEI), & Emsemble pour une Solidarité Thérapeutique Hospitaliere en Réseau (GIP ESTHER) Relatif a La Mise en Oeuvre de Projet <<OPP-ERA>>, Septembre 2013. Guinée
- "Template Accord pays <<OPP-ERA>>, UNITAID" undated
- "Annual Report Responses to UTD Feedback". Undated Word document – 3.FEI-Annual report_answers to financial questions.
- "Project: OPP-ERA, UNITAID Feedback on the 2013 Annual Report". Undated Word document – 2. OPP-ERA 2013 annual report UTD feedback final.
- "OPP-ERA Annual report, OPP-ERA PHASE 1". Undated Word document- 1. OPP-ERA ANNUAL REPORT
- "Completed Checklist for Semi and Annual Reports. Undated Pdf document- ANNEX 1_Completeness check_signed
- "Table 2.7: Scenarios for the Demand Forecasting for VLT in a 5-year Period". Undated Word Document - ANNEX 2. Demand forecast

- "OPP-ERA Call for Expressions of Interest for Procurement of HIV-1 RNA amplification/quantification kits". Undated Pdf document - ANNEX 3. OPP-ERA_Call for EOI_HIV-1 Amplification Kits_OK
- "ANNEX 4. Reporting template" Undated Excel document.
- "ANNEX 5. Updated staff table" Undated Word document.
- "ANNEX 6. Communication and synergies" includes an untitled table with basic details for important events and "synergy" meetings. Undated Excel document
- "Improving the monitoring of people living with HIV through better access to Viral Load Testing and Early Infant Diagnosis of HIV" Undated Pdf document- ANNEX 6.1_ICASA Poster.
- "OPP-ERA UNITAID feedback on the Inception report" undated Word document - 1. OPPERA inception report UNITAID Feedback.
- "Response to UNITAID feedback on the Inception report and deliverables" undated Pdf document - 2. OPP-ERA-FEEDBACK RESPONSE from FEI.
- "OPP-ERA Project Market Team's answers to the questions raised by UNITAID concerning the Baseline Market Assessment study (Annex 1 of OPP-ERA's Inception Report)" November 2013. Pdf document - 3. ANNEX 1_Market issues from FEI.
- "OPP-ERA Inception report for Reporting period: 1 March – 31 August 2013" Submitted 1st October 2013, Updated 4th October" Word document - Inception report OPP-ERA_Draft 3
- "Baseline Market Assessment, An Economic Analysis from the Supply-Side Perspective" Benjamin Coriat and Cristina d'Almeida. Pdf document - ANNEX 1 Baseline Market Assessment.
- "BUSINESS PLAN Outline, 1st draft, September 27, 2013. Pdf document - ANNEX 2 BusinessPlanOutline.
- "OPP--ERA PHASE 1 PROCUREMENT PROCEDURE; ANNEX 3" May 27 2013. PDF document - ANNEX 3 Procurement procedure.
- "OPP-ERA – Rapport de la mission Passation de Marchés – Burundi – Mai 2013". Bernard Abeillé. PDF document - ANNEX 3.1 Burundi Procurement Mission report.
- "OPP-ERA – Rapport de la mission Passation de Marchés – Cameroun – Mai 2013". Bernard Abeillé. PDF document- ANNEX 3.2 Cameroun Procurement mission report.
- "OPP-ERA – Rapport de la mission Passation de Marchés – Côte d'Ivoire– Mai 2013". Bernard Abeillé. PDF document- ANNEX 3.3 CI Procurement Mission report.
- "OPP-ERA – Rapport de la mission Passation de Marchés – Guinée – Mai 2013". Bernard Abeillé. PDF document- ANNEX 3.4 Guinea Procurement mission report.
- "Identification of OPP-ERA Phase 1 sites Burundi, Cameroon, Côte d'Ivoire, Guinea Conakry and needs assessment, Summary of mission reports in April 2013". Eric Nerrienet. May 2013. Pdf document -FANNEX 4 Summary needs assessment.
- "Mission OPP-ERA Evaluation des Besoins Burundi". Eric Nerrienet. Undated pdf document- 4.1 Mission report Nerrienet OPPERA_Burundi.
- "Cameroun,Mission OPP-ERA Rapport Evaluation des Besoins". Eric Nerrienet. Undated pdf document - ANNEX 4.2 Mission report Nerrienet Cameroon_
- "Cote D'Ivoire, Mission OPP-ERA Rapport Evaluation des Besoins". Eric Nerrienet. Undated pdf document - ANNEX 4.3 Mission report Nerrienet OPPERA sites Cote d Ivoire april 2013.

- "Burundi [coverpage mis-titled, should say Guinea], Mission OPP-ERA Rapport Evaluation des Besoins". Eric Nerrienet. Undated pdf document - ANNEX 4.4 Mission report Nerrienet OPPERA sites Guinea april 2013
- "Annex 5 Country Operational plans". undated pdf document - ANNEX 5 Country operational plans.
- "OPP-ERA Phase 1 Training plan". Undated pdf document- Annex 6 ANNEX 6_Training plan.
- "OPP-ERA Phase 1 M&E plan. Undated pdf document - ANNEX 7. OPP-ERA_Plan de suivi évaluation Inception report.
- "Revised Logframe for Open Polyvalent Platforms for a sustainable access to quality and affordable VLT in resource-limited settings" Undated Excel document - ANNEX 7_FEI_Simplified logframe_revised.
- "OPP-ERA Project, Open Polyvalent Platforms (OPP) for a Sustainable Access to Quality and Affordable Viral Load Testing (VLT) in Resource-Limited Settings (Summary)." Undated Word document- Brief Summary of the _OPPERA_Project - author UTD
- "Market Dynamics Assessment, Main Issues and preliminary results". Benjamin CORIAT and Cristina d'ALMEIDA. Undated Word document - 1. OPP-ERA_MKT ASSESSMENT_PRELIMINARY RESULTS.
- "OPP-ERA, Equipment Suppliers". Undated Word document 2. OPP-ERA Market study_Suppliers.
- "Consolidated Market Assessment". Cristina d'Almeida and Benjamin Coriat. Undated pdf document - 3. CONSOLIDATED MARKET STUDY_final_6 june 2014.
- "Project: OPP-ERA, UNITAID feedback on a set of questions from FEI (part 2). 9 July 2014. Word Document - UTD response to FEI Ph2 business plan Part 2.
- "Untitled and undated Word Table listing details on installation of equipment for Burundi, Cameroon, Ivory Coast and Guinea." Word Document - Equipment installation follow-up OPP-ERA.
- "Cameroun Note de synthèse". Undated Word document - 2013-10 note Cameroon OPPERA.
- "OPP-ERA First Disbursement Request. 13 Feb 2012". Pdf document - OPP-ERA_1st disbursement request from FEI.
- "Memorandum from UTD to UNITAID dated 14 Feb 2013-Request for Approval of the 1st disbursement $1,040,000 to FEI". Pdf document - UNITAID Disbursement Decision FEI $1.04m
- "Memorandum from UNITAID to UDT dated 17 April 2014-Request for third disbursement for OPP-ERA project". Word document - 3rd_FEI Disbursement Recommendation Memo April 2014.
- "Fund Movement Report and disbursement request table" Untitled Excel document - Disbursement Lot A_B CL review.
- "Fund movement report and Disbursement Request table" Undated Excel document - Disbursement Lot A_B.
- "Disbursement Request for commodities – Lots A & B, dated 20 March 2014". Pdf document- Disbursement request_AB_signed.
- Excel document - Project financial overview for FEI April 2014.
- Email with subject line RE Disbursement request Lots A and B - dated 4/7/2014. MSG file - RE Disbursement request Lots A and B.

- Approved memo dated 17 April 2014 requesting Third disbursement for OPP-ERA Project. Pdf document - UTD approval 3rd Disbursement for FEI
- "Fund movement report and Disbursement Request table" Undated Excel document - Disbursement Lot C CL review.
- "Fund movement report and Disbursement Request table" Undated Excel document - Disbursement Lot C
- "Disbursement request dated 10 July 2014 for Lot C commodities." Pdf document - Disbursement request Lot C.
- "Memorandum Request for the Fourth Disbursement for OPP-ERA Project, dated 21 Aug 2014. Word document - FEI Disbursement Recommendation Memo Lot C August 2014.
- Excel document - Project financial overview for lot C August 2014.
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- "Memorandum Request for the Second Disbursement for OPP-ERA Project, dated 6 March 2014". Pdf document - Approved disbursement request_FEI.
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- "Memorandum Request for the Second Disbursement for OPP-ERA Project, dated 6 March 2014." Word document - FEI Disbursement Recommendation Memo.
- Project Financial Overview dated 3/17/2014 - Excel document - Project financial overview for FEI 2. Xlsx
- "OPP-ERA Annual financial Report, 31-Dec -13" Excel document - OPP-ERA_Annual financial report_2013 AUDITED_FINAL_V2,
- "OPP-ERA Revised Financial Report March-August 2013, 31-Aug-13." Excel document - 2. FEI financial report_REVISED_SQY_20130114_UTD
- "OPP-ERA Budget – Internal Phase 1 (Revised)" Excel document - OPP-ERA-BUDGET_REVISED 2014
- "UNITAID Correspondence Approving Revised Budget", 4 Feb 2014. Pdf document - UTD approval revised budget 2014
- "AGENDA for OPP-ERA Meeting 30 Aug 2013". Word document - 2013-08 Agenda meeting UTD-OPP-ERA.
- "UTD-FEI working meeting Discussion Topics and Action Steps, OPP-ERA Project" 30 Aug 2013. Word document - OPPERA Follow up actions_Meeting 30082013.
- "Note for the Record: UNITAID-FEI Bi-weekly Update Call" 16 May 2013. Word Document - UTD-FEI MTG NFR_16.05.2013.
- "Note for the Record: UNITAID-FEI meeting" 19 July 2013. Word Document - UTD-FEI MTG NFR_19.07.2013
- "Ordre Du Jour OPP-ERA – UTD Meetings 19-20 June 2014, Paris". Word document: Agenda meeting UTD-OPP-ERA 19-20 juin
- "OPP-ERA Project working meeting Discussion Topics and Action Steps, Paris, 20 June 2014". Word document - OPPERA meeting NFR 20140620
- "Mission Report Burundi OPP-ERA PHASE 1". Bernard Abeillé. May 2013. Word document - Burundi Aide-rapport mission Abeillé_OK
- "Mission Report Cameroun OPP-ERA PHASE 1". Bernard Abeillé. May 2013. Word document - Cameroun rapport mission Bernard Abeille_OK

- "Mission Report Côte d'Ivoire OPP-ERA PHASE 1". Bernard Abeillé. May 2013. Word document - CI Aide-Memoire Bernard Abeille_OK
- "Mission Report Guinee OPP-ERA PHASE 1". Bernard Abeillé. May 2013. Word document - Guinee Aide-Memoire Mission Bernard Abeillé_OK
- "OPP--ERA Phase 11 Procurement Procedure Annex 3". May 27 2013. Pdf document - Procurement procedure (also annex 3 from inception report)
- "International Competitive Bidding (ICB): Information Notice, Procurement of Amplification and Extraction Equipment and Kits for the Construction of for Open Polyvalent Platform (OPP)." 1 June 2013. Word document – Avis Général_ENG.
- "Appel d'offre International (Aoi) : Avis General, Acquisition d'extracteurs, de Kits d'extraction Arn, de Thermocycleurs Destines a l'execution de Reactions Rt-Qpcr et de Kits d'amplification pour Vih-1 pour la Mise en Place de Plateformes Polyvalentes Ouvertes (OPP). 1 June 2013. Word document – Avis Général_OPP-ERA_V3.
- "Presentation for Information meeting, FEI Call for tender for the implementation of Open Polyvalent Platforms". 7-20-2013. Powerpoint Presentation - 2. PrésentationFEI-RéunionInfoAO-072013_V5
- "OPP-ERA Réunion d'information à l'attention des fournisseurs intéressés par l'appel d'offres (avis d'information publié le 03 juin) Questions – réponses" 9 July 2013. Word document - 3. Réunion d'information - fournisseurs OPP-ERA_FR.
- "OPP-ERA Information meeting for suppliers interested in International Call for Tenders (Notice of Information published the 3rd of June) Questions and Answers". 9 July 2013 Word document - 4. Réunion d'information - fournisseurs OPP-ERA_ANG
- "Attendance List for OPP-ERA Suppliers Information Meeting, Tuesday 9 July 9AM - 11AM5". Excel document – 5.Attendees.xls.
- "International Call for Tenders for Purchase of Automated Nucleic Acid Extraction Systems, Nucleic Acid Extraction Kits, Thermocylers (RT-qPCR) and associated equipment (computer and software) and HIV-1 RNA amplification/quantification kits for installing Open Polyvalent Platforms (OPP) in Burundi, Cameroon, Cote D'ivoire, and Guinea (September 11th, 2013)" Word Document - 1. DAO-OPP-ERA-Complet.
- "Email dated Fri 9/13/2013 3:31 PM with subject: RE: OPP-ERA Phase 1 - procurement and final approval of procedure" MSG file - 1. UTD approval call for tenders.
- "Procurement of Automated Nucleic Acid Extraction Systems, Nucleic Acid Extraction Kits, Thermocylers (RT-qPCR) and associated equipment (computer and software) and HIV-1 RNA amplification/quantification kits. Q&A Fiche. Pdf document dated 11/1/2013- OPP Call for tender Q&A fiche.
- "OPP-ERA Call for tender, Q&A 2. Questions on Section 1 / Instructions for Bidders". Pdf document dated 11/1/2013 - Q&A 2 OPP-ERA Call for tender
- "Q&A 3 OPP-ERA Call for tender". Pdf document dated 11/1/2013 - Q&A 3 OPP-ERA Call for tender.
- "OPP-ERA Call for tender Selection Report". Pdf document dated 1/17/2014 - OPPERA procurement selection report.
- "Email dated Fri 12/6/2013 8:17 PM with Subject Re: OPP-ERA Procurement selection report." MSG file - UTD approval OPP-ERA Procurement selection report.

- "OPP-ERA Call for Expressions of Interest" 17 December 2013. Pdf document - 1. Letter_Invitation_EOI_OPP-ERA.
- "OPP-ERA Procurement of HIV-1 RNA amplification/quantification kits" Pdf document - 2. OPP-ERA_Call for EOI_HIV-1 Amplification Kits.
- "ANNEX 2 Technical offer forms for Procurement of HIV-1 RNA amplification/quantification kits" Word Document - 3. ANNEX 2 Technical offer forms.
- "OPP-ERA, UNITAID feedback on the Quality assurance approach Phase 1". undated DRAFT. Word document - OPPERA quality assurance approach UNITAID Feedback draft.
- "OPP-ERA, UNITAID feedback on the Quality assurance approach Phase 1". Undated FINAL. Word document - OPPERA quality assurance approach UNITAID Feedback FINAL
- "OPP-ERA, UNITAID feedback on the Quality assurance approach Phase 1, draft with comments " 12 18 13. Pdf document - Quality assurance approach_Phase 1 GY comments 12.18.13
- "Quality Assurance Approach OPP-ERA Phase 1". 10/12/2013 Pdf document- Quality assurance approach_Phase 1.
- "Email dated Wed 3/26/2014 5:59 PM with Subject: Re: QA procedure updated". MSG document - UTD approval QA procedure updated.
- "Email dated Tue 2/18/2014 4:18 PM with subject: RE: OPP-ERA QA approach/Lot C". MSG file -Alternative QA approach Lot C UTD approval.
- "Appendix 1 - Internal Quality Policy Criteria". Undated table. Pdf document- APPENDIX 1 QUALITY_POLICY_CRITERIA.
- "Appendix 2 – Quality Policy – General Process" Undated schematic. Pdf document - APPENDIX 2 QUALITY_POLICY_PROCESS.
- "Appendix 3- Updated procurement timeline" Undated timeline graphic. Pdf document - APPENDIX 3 UPDATED PROCUREMENT TIMELINE.
- Excel document - MinimumQualityCriteria_InternalPolicy_V3_20140325
- "Quality Assurance Approach - OPP-ERA Phase 1". 10/12/2013. Word document - Quality assurance approach_Phase 1_V2.
- "Quality Assurance Approach OPP-ERA Phase 1" 10/12/2013. Undated Interim Pdf document - 1. INTERIM QA APPROACH.
- "Internal Quality Policy Criteria" Undated Annex table. Pdf document - 2. ANNEX 1_QUALITY PROCEDURE CRITERIA.
- "Updated procurement timeline" Undated Annex graphic. Pdf document - 3. ANNEX 2 TIMELINE.
- "Appendix – Quality Policy – General Process" Undated Annex graphic. Pdf document - 4. ANNEX 3 QUALITY_POLICY_PROCESS
- "OPP-ERA UNITAID feedback on the Quality assurance approach Phase 1" Undated FINAL. Word document - OPPERA quality assurance approach UNITAID Feedback FINAL.
- "Quality Assurance Approach, OPP-ERA Phase 1" Undated final. Word document - QA APPROACH_PHASE 1_FINAL.
- "WHO Good practices for selecting and procuring rapid diagnostic tests for malaria" 2011. Pdf document - Good practices selecting procuring RDT malaria.
- "Procurement policies and requirements" Monika Zweygarth. 23-25 Sep 2013. Pdf document - UN Procurement policies and requirements.

- "Email dated Fri 4/25/2014 9:49 AM with subject Re: Lot C selection report". MSG file - UTD response to initial Lot C selection report.
- "Confidential Report, OPP-ERA Restricted Call for Tender Selection, Lot C and purchase HIV-1 amplification/quantification kits". Pdf document - 1.Lot C Selection report.
- "Procurement of HIV-1 RNA amplification/quantification kits Restricted Call for Tenders UTD-002". Undated Annex. Pdf document - 2. ANNEX 1 OPP-ERA_Restricted Call_HIV-1 Amplification.
- "Annex 1. Evaluation for purchase" Undated Annex table. Pdf document - 3. Annex 2.1 Evaluation for purchase.
- "Annex 2. Eligibility for Evaluation" Undated annex table. Pdf document - 3. Annex 2.2 Selection for further evaluation.
- "Confidential Report, OPP-ERA Restricted Call for Tender Selection". Undated. REVISED. Pdf document - 1. Lot C Selection report.
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- "Annex 1. Evaluation for purchase" Undated Annex table. REVISED Pdf document - 4. Annex 2.1 Evaluation grid for purchase.
- "Anatolia evaluation Table 1" 17/02/14. REVISED Pdf document - Anatolia evaluation ANNEX 1.
- "Lot C Selection Report clarifications" undated, untitled list of questions and responses. Pdf document - Lot C Selection Report clarifications.
- "OPP-ERA Restricted Call for Tenders" 3 April 2014. Pdf document - 1.Letter_OPP-ERA_FEI_Invitation to submit.
- "Procurement of HIV-1 RNA amplification/quantification kits, Restricted Call for Tenders UTD-002". Pdf document - 2. OPP-ERA_Restricted Call_HIV-1 Amplification.
- "Annex 1 Tender Forms". Word document - 3. FORMS.
- "OPP-ERA Flyer, Improving the monitoring of people living with HIV through better access to Viral Load Testing and Early Infant Diagnosis of HIV". Pdf document - FEI-OPP-ERA-Flyer-ENG-web.
- "OPP-ERA Flyer, Améliorer le suivi des personnes vivant avec le VIH à travers un accès aux tests de esure de la charge virale VIH et au diagnostic VIH des nourrissons. Pdf document - FEI-OPP-ERA-Plaquette-Presentation-WEB.
- "Appendix 1: Proposal Details (Sections 1 To 4)" Pdf document - Appendix 1 2.
- "OPP-ERA, Phase 1 Implementation Report" 29 September 2014. Pdf document APPENDIX_IMPLEMENTATION_REPORT_PHASE1.
- "Quality Assurance Plan, OPP-ERA Phase 2". September 2014. Pdf document - APPENDIX_QA_PLAN_OPPERA_PHASE2.
- "Report to the Board of UNITAID on Phase 1 Implementation (March 2013-December 2014) and Submission of Phase 2 (January 2015-December 2016). December 2014. Pdf document - OPPERA-REPORT-BOARD.

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- "Observations on the Market Landscape of laboratory technologies addressed to HIV-1 RNA monitoring, A Progress Report". Cristina d'Almeida and Benjamin Coriat. September 2014. Pdf document - BP-Appendix1 - Market Landscape Observations.
- "Intellectual Property Report Related to real time PCR (qPCR) technologies addressed to the quantification of HIV-1 RNA, Preliminary Results." Cristina d'Almeida. September 2014. Pdf document - BP-Appendix2 - Intellectual Property Report.
- "Polyvalence: Preliminary results of suppliers". Undated table. Pdf document - BP-Appendix3 - Polyvalence_Prelimenary results.
- "Proposal Cover Page". Pdf document - 1.FEI-Proposal-Narrative-OPP-ERA-Phase2.
- "Rapport du commissaire aux comptes, Exercice clos le 31 decembre 2013." Pdf document - 3.Appendices2-continued-FEI- AUDIT-REPORT.
- "Logical Framework OPP-ERA Phase 2". Undated. Pdf document - 4.FEI_OPPERA_PHASE2_LOGFRAME.
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- UNITAID HIV/AIDS Diagnostics Technology Landscape. 4TH EDITION. June 2014
- Documents on WHO Prequalification of Diagnostisc program: http://www.who.int/diagnostics_laboratory/evaluations/en/http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/WHO PQ
- Viral Load: Current Technologies and the Pipeline, including Point-of-Care Assays. PowerPoint presentation by Maurine M. Murtagh. Consultation on Viral Load Monitoring for African HIV Treatment Programmes. Cape Town, South Africa. 18-20 April 2013
- Excel file from OPP-ERA Semi-Annual Report to UNITAID – Nov 2014 (received Nov 26 from Intissar)
- OPP-ERA Simplified Logframe Updated June 2014 (received from FEI Nov 27, 2014)
- OPP-ERA No-Cost Extension revised June 11, 2014 (received from FEI Nov 27, 2014)
- Project OPP-ERA – UNITAID Feedback on the no-cost extension request – 4 June 2014 (received from FEI Nov 27, 2014)
- Undetectable – How Viral Load Testing can Improve HIV Treatment in Developing Countries – MSF. July 2012
- African Society for Laboratory Medicine – Presentation May 5, 2014 – Lusaka, Zambia
- Article: Point-of-care viral load testing potentially cost-effective in southern Africa (28 March 2013), by Carole Leach-Lemens (www.aidsmap.com)
- Article: Cost of Viral Load Tests Hindering Global HIV/AIDS Progress (Oct 29, 2014. Aids.about.com)
- GF Strategic Reviews in Procurement and Market Dynamics - Day 2 – HIV Diagnostics (GF Presentation, Geneva 2 Oct 2014)
- CHAI WEB SITE announcement - Improving Access to Viral Load Testing for HIV Patients in Developing Countries (Dec 1, 2014)

ANNEX VII – EVALUATION FRAMEWORK

METHODOLOGIES:		Document Review	Measure Progress against Indicators	Key Informant Interviews
Primary Evaluation Questions and Research Tasks	**Relevance**	- OPP-ERA Reports - UNITAID Reports	- Progress against stated objectives	- UNITAID Staff - FEI staff - Target Country Representatives - Partner organisations
	Effectiveness	- OPP-ERA project Reports	- Progress against stated objectives by reporting period - Identify obstacles to expected progress	- FEI staff - Suppliers - Target Country Representatives - Partner organizations
	Efficiency	- OPP-ERA project Reports	- Progress reports & Timelines - Progress against indicators	- Target Country Representatives - FEI staff
	Impact	- OPP-ERA project Reports	- Review of logframe - Progress toward main Impact indicator	- Target country representatives - FEI staff - Partner Organizations
	Learning & Risk Mitigation	- OPP-ERA project Reports - Business Plan	- Review of logframe and results	- UNITAID staff - FEI and implementers - Country contacts