



UNITAID

**END OF PROJECT EVALUATION OF THE MARKET ENTRY GRANT TO THE
DIAGNOSTICS FOR THE REAL WORLD ON SAMBA TITLED : “PROVIDING
ACCESS TO EARLY INFANT DIAGNOSIS AND VIRAL LOAD MONITORING BY
SAMBA – A POINT-OF-CARE NUCLEIC ACID DETECTION SYSTEM”**

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Executive Summary Report

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1. INTRODUCTION

Cambridge Economic Policy Associates (CEPA) was appointed by Unitaid to conduct an end of grant evaluation of the market entry grant to the Diagnostics for the Real World (DRW) titled “Providing Access to Early Infant Diagnosis (EID) and Viral Load (VL) Monitoring through Simple Amplification-Based Assay device (SAMBA), a Point-of-Care (POC) Nucleic Acid Detection System”. This document provides a summary of our evaluation findings, conclusions and recommendations. It includes a background to the grant (Section 2); the evaluation objectives and methods (Section 3); a framework for assessing market entry progress of the grant (Section 4); the evaluation analysis and key findings (Sections 5) and overall conclusions, lessons learnt and recommendations (Section 6).

2. BACKGROUND TO THE GRANT

While access to antiretroviral therapy (ART) has been significantly scaled up in countries with high HIV burdens, widespread access to POC diagnostics (and especially for EID) as well as VL testing technologies remains limited, especially in rural settings; and as such, innovative solutions are needed to reach the 90-90-90 targets.¹ Given the relative dearth of nucleic acid based POC products for EID or VL testing, appropriately adapted for resource-poor settings, the Unitaid Executive Board approved four market entry grants for POC EID, CD4 and VL testing in 2013 to support the creation of healthy markets, of which the grant to DRW for SAMBA was one. Importantly however, the other three grants were closed prematurely for various reasons.

The grant to DRW for SAMBA aimed at making available a new and alternative diagnostic platform in the market for VL and EID testing in resource-poor settings. there are two systems available at present – the SAMBA I system is for near-POC sites and the SAMBA II system is for true-POC sites, and offers a simple, heat-stable and robust technology. The Unitaid grant to DRW was for a total amount of US\$8.8m over a period of three years over January 2014-17 with five key areas implemented across six countries (Cameroon, Kenya, Malawi, Nigeria, Uganda, and Zimbabwe): (i) in-country product approvals and registrations through product validations and equivalency studies; (ii) impact evaluation studies (comparing the use of SAMBA against gold standard at intended settings); (iii) initiation of early implementation for patient diagnosis and monitoring, involving scale up manufacture of SAMBA test cartridges and instruments; (iv) building field capacity for early implementation, including supply of SAMBA VL and EID tests and instruments, site installation, tasking-shifting and training of field staff (largely for the initial studies under (i) and (ii)); and (v) obtaining other regulatory approvals, including World Health Organization Prequalification (WHO PQ), Expert Review Panel for Diagnostics (ERPD) and Conformité Européene In-Vitro Diagnostics (CE-IVD).

¹ UNAIDS: <http://www.unaids.org/en/resources/909090>

3. EVALUATION OBJECTIVES, METHODOLOGY AND LIMITATIONS

The objective of the evaluation was to assess how successful the grant has been in supporting market entry of SAMBA, as well as the progress made in achieving the grant logframe targets. Figure 3.1 sets out the evaluation framework, structured along the OECD DAC evaluation criteria, highlighting the main areas of review.

Figure 3.1: Evaluation Framework



A mixed-methods approach was employed for the evaluation, comprising document and data review, as well as stakeholder consultations in person and by phone with global stakeholders.² In addition, CEPA attended a day-long symposium on SAMBA organised by DRW in April 2018. To note, CEPA has not had access to the current business plan from DRW and hence it has not been possible to incorporate this in our analysis of plans and market potential of SAMBA.

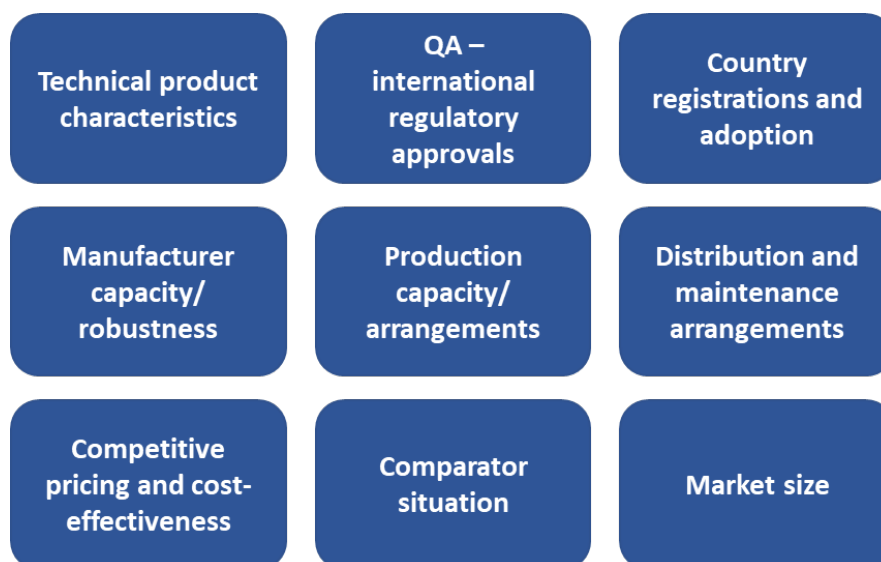
4. DEFINING MARKET ENTRY AND KEY PARAMETERS

In support our evaluation of SAMBA market entry, we believe that it is useful to have an exacting definition of market entry at the outset, in terms of the key barriers that need to be overcome to allow a product to “enter the market”. We view one of the weaknesses of the grant design as not having this clear definition – for example, the objectives defined in the grant logframe are not reflective of market entry objectives per se. Rather, and while we note that the SAMBA I and II instruments have been developed and are potentially ready for procurement, an appropriate definition of market entry would be in terms of whether the SAMBA system presents a technically viable, operationally feasible, competitively priced/

² Country visits and a higher number of country stakeholder consultations were initially planned as part of the evaluation methods but these were cancelled. This has implied a reduced country perspective in our evaluation.

cost-effective and accessible option for countries. This is reflected in what we view as the key parameters for market entry of the SAMBA system (Figure 4.1), being the critical barriers impacting/ preventing market entry of SAMBA, and are reflected upon throughout our evaluation.

Figure 4.1: Key market entry parameters for the SAMBA system



5. EVALUATION ANALYSIS AND KEY FINDINGS

5.1. Grant relevance

We assessed the grant relevance in terms of (i) relevance of the grant over time, given the evolving public health and market context and (ii) “fit” of the grant with Unitaids’ mandate and capacity, alongside alignment and complementarity with Unitaids’ broader diagnostic portfolio. These aspects are considered in turn below.

5.1.1. Evolving market and public health context

1. To what extent has the grant been a relevant investment by Unitaids, noting the evolving market and public health context?

At the time of grant approval in 2013, there was an expectation of high need for POC EID and VL testing, alongside expectations that POC devices would be “true POC”. There were multiple manufacturers developing technologies for POC platforms for EID and VL and it was not clear which of these manufacturers would succeed, with SAMBA showing a lot of promise.

During the course of the grant, two competitive products emerged: one from Cepheid (the GeneXpert) and one from Alere (the Alere q). Whilst there are advantages and disadvantages regarding all these products, both Cepheid and Alere are more established companies than DRW and their instruments and test kits are lower in price than the SAMBA. Cepheid in particular has an advantage through its existing footprint in countries, and both products have currently obtained CE-IVD and WHO PQ for their respective assays.

Further, since 2013, greater clarity has been obtained regarding market size estimates, with analysis concluding that the market cannot profitably sustain more than two companies. Furthermore whilst the market for POC testing is still evolving, the emerging evidence and our consultations have indicated that the current case for POC for EID is very relevant, but is still developing for VL testing.

As such, our finding is that while relevant at the time of approval, the evolving market and public health context has reduced the relevance of the Unitaid grant today to some degree.

5.1.2. Fit with Unitaid’s mandate and diagnostics portfolio

2. How does this market entry grant fit with Unitaid’s mandate and is there good complementarity with its diagnostics portfolio?

Facilitating market entry is core to Unitaid’s market and access mandate, and as not many global health organisations support market entry and have the risk appetite to take this on, we note that this grant was highly relevant intervention by Unitaid.

However, consultations highlighted that the Unitaid Secretariat does not have the necessary technical expertise and time required to drive and manage these types of grants, and as such, Unitaid rightly chose to contract out results assessments to an independent technical company with this expertise (Halteres Associates).

In terms of the fit of this grant within Unitaid’s broader diagnostic portfolio, of particular relevance is the alignment with the CHAI/Unicef grant (2012-2020, US\$149m), which is a grant that aims to expand access to innovative POC technologies for EID and VL monitoring of HIV in ten African countries.³ In essence, the intention was that the CHAI/Unicef grant could be leveraged for in-country scale up (should countries choose to purchase SAMBA and requisite procurement conditions be met, also supporting market entry). However, this has not worked out in practice as whilst DRW did submit an application for SAMBA in 2014 under the grant for the initial scale up phase to increase access to POC devices, they did not submit a response to the tender during the earlier phase in 2013 for independent evaluations to be conducted of the platforms and hence missed the opportunity for external validation in that instance.

We therefore consider that the market entry grant fits very well with Unitaid’s mandate and has been well planned and aligned with Unitaid’s broader diagnostics portfolio – in theory, although this alignment has not worked in practice.

5.2. Efficiency and effectiveness

With regards to efficiency and effectiveness, we reviewed: (i) whether grant activities were completed as planned and the value of outputs achieved; (ii) the implementation experience with SAMBA in terms of the advantages/ disadvantages of the technical product

³ Unitaid also funded the EGPAF grant over 2015 to 2019 which aims to increase access to POC EID in nine countries.

characteristics, distribution and maintenance arrangements, and country adoption to date; and (iii) the degree to which the achievement of grant outputs have contributed to facilitate effective market entry.

5.2.1. Delivery of planned activities and related targets

3. To what extent were grant activities on in-country product approvals, impact evaluation studies, early implementation, field capacity and regulatory approvals completed as planned?

As noted in Section 2, there were five key output areas for the grant, each with a number of activities to achieve the desired result. Most of the planned activities were carried out and completed, with DRW noting that the funding was much valued and enabled them to progress with all of these activities. Key points from our review are as follows:

- A number of **in-country product approvals** were obtained as of April 2018, including for SAMBA I and II EID and VL in Kenya, Uganda and Zimbabwe and specifically for SAMBA I for VL in Malawi.⁴ This has been particularly relevant for Zimbabwe where SAMBA was the first POC technology approved for use in country and has subsequently resulted in its uptake (see below). However, a challenge raised by multiple stakeholders is regarding the independence of the studies as they were commissioned and designed by DRW rather than a third party, and hence are not perceived as truly independent validations. The importance of independent evaluations and validations by external third parties, which was not facilitated through this grant, has been emphasised as being an important requirement for registration in some countries, and more broadly for supporting adoption/ demand.
- Despite a **reduction in the price** of test cartridges and devices by the end of the grant (reaching US\$37.40 for test cartridges for both SAMBA I and SAMBA II and US\$72,000 for SAMBA I and US\$18,000 for SAMBA II device costs), these remain significantly higher than its competitors. The prohibitive cost of both the instruments, as well as the tests, which can be reduced mainly through automation of the manufacturing process (which is currently not commenced and/or funded), has been raised in consultations as one of the most critical market entry barriers.⁵
- A notable success of the grant is that all of the SAMBA assays and instrument systems received **CE-IVD approval**, thus enabling procurement through the Global Fund.⁶ However, WHO PQ has not been sought for SAMBA I or II, and we understand that DRW submitted an application but then withdrew this and are now planning to apply

⁴ In-country product approval was not required for Nigeria.

⁵ SAMBA's current production limit is 300,000 tests and 1,500 machines per year. They are pursuing fundraising to fully automate their production as they estimate that US\$7-8m in capital is needed in order to fully automate their production line and to expand the assay menu for SAMBA. This process is estimated to take approximately 12-18 months to implement.

⁶ ERPD was then not required after CE-IVD approval was obtained.

for FDA approval instead for US market and PEPFAR procurement. While not strictly required for country access, lack of WHO PQ detracts from product competitiveness as countries and donors perceive WHO PQ as a 'gold standard', and as decisions are often jointly made between donors and country governments, the ability for countries to procure SAMBA is reportedly still reliant to a great extent on a product having WHO PQ. Also, in contrast, WHO PQ has been obtained for both Alere q and GeneXpert IV, as well as FDA for GeneXpert IV.

In summary, most of the activities and outputs under the grant were achieved, however, some key market entry barriers remain within the context of the scope of the grant including the absence of independent third party validations, higher test and device prices than competitors and lack of WHO PQ status.

5.2.2. Implementation of SAMBA

4. What has been the implementation experience with SAMBA?

From a technical standpoint, SAMBA offers several positive features that are demanded by users and needed for resource-poor settings. A number of these are at an advantage to those offered by competitors (e.g. simple to use, lack of toxic waste thus enabling less complex waste disposal plans), but there are some drawbacks too (e.g. SAMBA's semi-quantitative assay is calibrated to only distinguish above or below virologic failure at 1000 copies/ml).

With regards to distribution and maintenance, DRW arrangements have worked well to date for the small scale pilots, however there is a uncertainty regarding their capacity to manage these aspects at scale.

With regards to country adoption, there are currently 137 SAMBA machines placed across 47 sites in six countries across Africa. The vast majority of these are in Zimbabwe (105 machines), the only country to scale up SAMBA to date, whilst the other platforms have been used for evaluation studies (see Box 5.1). In addition, the Uganda Central Public Health Laboratory has approved Alere q, GeneXpert and SAMBA for POC EID use in order to pilot all three products simultaneously before scale up. The reasons reported by countries for not selecting SAMBA as their POC technology of choice were largely the high price and reduced country confidence in the product given the lack of independent evaluation and WHO PQ.

Box 5.1: Case study on the SAMBA order in Zimbabwe

Zimbabwe has placed an order at a value of US\$7m for SAMBA instruments and tests, and the experience to date has been positive as reported by Zimbabwean MoH stakeholders. According to consultations with DRW, the order is as follows:

- SAMBA II - 100 instruments and 57,600 tests for VL testing using Global Fund initial funding (there is continued support through to 2020).
- SAMBA II EID tests (expected to be approximately 10,000-12,000 EID tests). This will be through National AIDS Council (NAC) funding.
- SAMBA I re-agents (for the existing SAMBA I instruments) through NAC funding.

5.2.3. Grant design and gaps

5. Has the achievement of project outputs been an adequate contribution to facilitate effective market entry?

We considered the achievement of project outputs and whether these have been an adequate contribution to facilitate effective market entry of SAMBA, as per the overall ambition of this grant. Our analysis suggests the following:

Firstly, our view is that the grant scope and focus was too limited in relation to the range of market entry barriers facing the SAMBA technology. The grant mainly focused on registration in a handful of countries alongside securing international regulatory approvals, and while this is much needed, the primary issues for SAMBA have been with regards to its relatively high cost and risks with production. Whilst there has not been clear consensus in our stakeholder feedback regarding the best means to support competitive pricing and affordability, some suggestions from our stakeholder consultations included whether a larger/ different focus of investment in the form of either (i) a capital investment for automation, or (ii) a buy-down for procurement could have helped “tip the balance”. With regards to (i), our view is ultimately it makes sense to fund focused aspects that are the biggest barrier for market entry, also given “fungibility” in monies with all donor grants essentially serving as a subsidy of sorts of the manufacturer. In terms of (ii), there have been differing views from stakeholders regarding the value of buy-down for SAMBA specifically, alongside broader concerns that a buy-down intervention would not have been sustainable given that the market is not big enough to accommodate so many players.

Secondly, a number of stakeholders have strongly noted that the support for country by country registration and failure to secure WHO PQ has detracted from the international efforts at harmonising country registration requirements. While the need for country registration is not undermined, as is the broader work by Unitaïd to support harmonisation of regulatory frameworks in country, stakeholder feedback has been strong on the need to emphasise WHO PQ as a common regulatory standard for countries. Feedback has indicated that despite Unitaïd’s constant encouraging of WHO PQ to DRW, perhaps Unitaïd could have been more demanding/ strict, or potentially have more conditionalities (e.g. decision points for disbursing funds) during the grant.

Thirdly, and linked to the previous point, is that Unitaïd’s lack of requiring DRW to undergo independent evaluations from external third parties has also undermined international collaboration and country uptake/ adoption of the product. It would have been beneficial for the evaluation of the SAMBA technology to have been conducted by partners in addition to the evaluations conducted by DRW to aid country confidence and facilitate adoption.

Finally, we note that grant management for this market entry grant could have been more dynamic and agile, particularly given how dynamic the POC HIV diagnostics field has become. This could have potentially allowed for grant changes such as to account for the increasing significance of multiple assays during the grant.

We therefore conclude for this evaluation question that while the design of the grant did support some activities towards market entry, it did not go far enough to address the key market barriers of competitive pricing and manufacturer capacity, suggesting it could have been better designed.

5.3. Impact and scalability

In this evaluation dimension, we sought to assess the overall results/benefits of the investment made by Unitaid in terms of (i) the results and scale up potential that SAMBA has shown within the market for HIV diagnostics; (ii) the potential public health results from SAMBA for different scale up scenarios and (iii) the return on investment for Unitaid.

5.3.1. Market potential for SAMBA

6. To what extent has the grant supported the bringing to market of a viable option for HIV testing and monitoring? What is the market potential for SAMBA?

As previously discussed, SAMBA's main progress to date from a market entry perspective is as follows: (i) CE-IVD approval has been obtained; (ii) in-country approvals have been achieved in four countries;⁷ and (iii) there is one confirmed large-scale procurement in Zimbabwe and pilot-testing is currently underway in Uganda. In this evaluation question we considered the future market potential of SAMBA, considering the following key market entry parameters influencing the competitiveness of SAMBA as per our framework presented in Section 4: market size; comparator situation; competitive pricing and cost-effectiveness; and manufacturer capacity/ robustness.

Market size and comparator situation: Noting the expected growth in the POC VL and EID markets, independent assessments conducted by Halteres Associates and others have concluded that the market can comfortably support two manufacturers, realising automation of production and associated reductions in COGS and generating profitable business that ensures their sustainability over time. As discussed, Alere, Cepheid and DRW all offer comparable POC systems, with varying strengths and weaknesses. However, Cepheid is currently the market leader, particularly because of its existing footprint in countries, multiple WHO PQ assays and lower priced tests. Drawing on the Halteres Associates market estimates, and based on where the current market competitors are at (DRW, Cepheid and Alere) it is not clear as to which company will take the place as the second manufacturer in this market. Many stakeholders consulted for this evaluation were largely of the view that DRW has less likelihood of success than its competitors, however some also considered DRW to have potential to take the place as a more significant manufacturer in this market, supported by an expansion in its assays on offer.

⁷ Approval has only been obtained for SAMBA I (VL) in Malawi.

There is also a general caveat noted that given the dynamic nature of the POC diagnostics market, and the possibility of “market shocks” (e.g. if any company faces significant financial challenges or quality assurance issues, or is unable to meet a production requirement in time – as was the case with Alere recently), there may be greater space for a third manufacturer. Finally, it is also recognised that the POC nature of each of the competitor products is very different (i.e. near-POC, true-POC), and based on different country laboratory infrastructure and networks, alternate products may serve as a better fit.

In terms of **competitive pricing** and **cost-effectiveness**, Table 5.1. provides details on the comparative costs across the key HIV diagnostics manufacturers, based on Global Fund committed prices. As demonstrated, SAMBA is the most expensive.

Table 5.1. Cost comparisons for each competitor

Aspect	GeneXpert IV (Cepheid)	Alere q (Alere)	SAMBA II (DRW)
Equipment, cartridge and other costs			
Equipment cost	US\$17,000 for desktop version or US\$17,500 for laptop version	US\$25,000	US\$24,800 if less than 200 Assay Modules or US\$18,000 if more than 200 Assay Modules, as well as US\$1,750 for Tablet Module
Cartridge costs	US\$14.75 (at order threshold level of 1 500,000) to US\$16.80 (at order threshold level of <500,000)	US\$14.95 (for >800,000 orders) to US\$25.00 (for <200,000 orders)	US\$17.80 (for >1,000,000 orders) to US\$37.40 (for <150,000 orders)

Source: *The Global Fund HIV Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool.*⁸

In order to demonstrate cost-effectiveness, market experts consulted have recommended that an expansion of assays beyond HIV using the same cartridges and instruments would contribute to driving up demand for POC testing. Halteres Associates have suggested that ideally, this would include tests required by the same HIV cohorts targeted for the POC market, for example HCV, HPV, and MTB. Given a growing focus on integrative care, this would maximise the efficiency of the use of instruments, particularly given variability in demand for POC VL and EID testing. We understand that DRW does have plans to expand their assay development, which would support their competitiveness.

Finally, with regards to **manufacturer capacity and robustness**, we highlight that DRW faces challenges with regards to (i) its current production capacity (300,000 tests/annum with semi-automated production) and while this is not being fulfilled at present as its largest order from Zimbabwe fits well within this limit, there is a need for automation to facilitate scale-up and

⁸ Global Fund. HIV Viral load and Early Infant Diagnosis Selection and Procurement Information Tool. 2017. Available at: https://www.theglobalfund.org/media/5765/psm_viralloadearlyinfantdiagnosis_content_en.pdf

price reductions for which there is currently a funding gap, (ii) being a small company with its founders and scientists holding majority of the stock and 33 FTE staff being largely responsible for operations – a structure that does not support scale-up, including with regards to needed distribution and maintenance arrangements in countries; and (iii) lack of clarity/communication on longer term business objectives contributing to lowering of its credibility amongst stakeholders. We therefore conclude that there are a number of risks to DRW's capacity and strength of their business.

Overall, through SAMBA, DRW offers a comparable system to competitors in the market for POC HIV VL and EID testing. However, key priorities in the near-medium future to ensure its competitiveness in the market will require a clear, long-term funding strategy and business plan to improve its pricing and availability, bringing COGS down and seeking WHO PQ to provide confidence in the product by countries and donors.

Box 5.2. presents details regarding the achievements of the DRW grant against select Key Performance Indicators (KPIs) in the new Unitaid Strategy (2017–2021).

Box 5.2: Achievements of the DRW grant against select KPIs in the new Strategy (2017–2021).

Considering the framework of Unitaid's new 2017-21 strategy, with the strategic objectives of *innovation, access and scalability*, we assess that only the objective of innovation has been supported to date. By virtue of the SAMBA technology being available for procurement and the support of the Unitaid grant for country registrations, this objective has been supported.

However other access barriers remain a challenge. Lack of WHO PQ undermines the access barrier relating to *quality* as well as *demand and adoption*, and as noted previously, there are considerable challenges with regards to the *supply and delivery* and *affordability* of SAMBA.

5.3.2. Potential public health impact

7. What might be the public health potential of SAMBA in terms of serving as a POC platform for EID and VL monitoring?

We have modelled the potential public health impact in terms of deaths averted for SAMBA VL and for life years gained for SAMBA EID based on three scenarios of increasing scale-up in (i) Zimbabwe; (ii) the countries where SAMBA has been approved; and (iii) wider market entry in 10 high-burden countries in sub-Saharan Africa. Inputs and assumptions are largely similar to those used in the study by Halteres Associates, and further academic references have also been utilised. Given the hypothetical nature of the model, we do not present the results in this summary, although details are available with Unitaid.

5.3.3. Return on investment/ value for money

8. Does this grant represent a good investment from Unitaid and does it offer VFM?

In terms of return on investment, we note that many of the outputs of the grant were met. Furthermore, there is value in increasing the choice of diagnostic tools in the market in order to prevent monopolies from other POC devices. However, overall we conclude that as market entry has not been achieved to date and there are several challenges for market entry in the future, therefore the investment to DRW has provided limited return on investment, or VFM for Unitaid. Furthermore, DRW missed opportunities which the grant should have afforded, in particular obtaining WHO PQ approval (despite successfully attaining CE-IVD).

6. CONCLUSIONS, LESSONS LEARNED AND RECOMMENDATIONS

There have been a number of achievements that have resulted from Unitaid's investment to DRW. These include (i) most of the project outputs being achieved; (ii) Zimbabwe MoH placing an order for US\$7m, (iii) and a fostering of market competition within a fairly complex and challenging market structure. However, the three-year US\$8.8m investment by Unitaid, while having furthered some market entry objectives, has not resulted in resolution of a number of significant barriers that SAMBA presently faces, as reflected in its: (i) high pricing; (ii) lack of needed regulatory approvals, especially WHO PQ; and (iii) limited production capacity without automation. We therefore conclude that the Unitaid investment for SAMBA market entry has had limited success. While it is recognised that the investment was approved at a time when the market context was very different, our overall view is that the grant was not ambitious or dynamic enough given it did not focus on the more critical market entry barriers and adequately respond to the changing market situation.

Furthermore challenges with overall manufacturer capacity and robustness for scale up continue. As a diagnostics company, DRW is based on one product/ platform and hence is unable to leverage other products (e.g. for distribution, maintenance). To date, DRW has been built-up through donor grants rather than financial investments. There is no clear indication/ communication of a longer term business plan, which is also contributing to lowering of its credibility amongst stakeholders.⁹

With greater success from its competitors at present, there is growing consensus of a closing window of opportunity for DRW to address key market barriers for a stronger positioning in the market. At the same time, there is also a degree of uncertainty regarding the future of SAMBA and how the success may evolve with a suggestion for potential with its recent adoption and large-scale procurement in Zimbabwe (whether Zimbabwe's experience might validate the product and crowd-in other countries), alongside the "race" to create more optimal and cost-effective platforms through introduction of multiple assays (where Cepheid is in the lead at present, but DRW is also developing additional assays).

As such, the future potential for SAMBA remains unknown although at risk and we therefore recommend to DRW to undertake the following to improve competitiveness: (i) reconsider

⁹ As noted in the evaluation analysis, we understand that DRW has developed a business plan but this was not shared with us.

their application to obtain WHO PQ; (ii) adopt a more transparent approach on the business plan and to share elements of it with relevant stakeholders; (iii) consider expanding the SAMBA assay menu.

More broadly, we make the following recommendations to Unitaid in its approach to market entry grants:

- Unitaid should clearly define its approach and expectations for market entry grants and communicate this well to its partners.
- Unitaid should set out market entry related objectives and milestones for these grants, and steer away from public health related or activity based results monitoring.
- Unitaid should set up different arrangements for market entry grants as compared to its standard grant approach, reflecting the high risk nature of these grants. For example, there should be clear conditionalities on the funding disbursement linked to achievement of market entry milestones.
- Unitaid should ensure that market entry grants are approved based on an assessment of the market structure and potential (so as to position the market entry investment by Unitaid) as well as a review of the manufacturer's longer term business plan (as Unitaid's investment needs to be viewed in the context of "going-concern" with clear business objectives that may have been catalysed by the Unitaid investment). We view these as two essential prerequisites to market entry grant approval by Unitaid.
- Given the dynamic nature of the market and evolving evidence/ guidelines, these essential prerequisites should be constantly reviewed and revised as appropriate during the course of the grant, to ensure effective and results-oriented grant management by Unitaid.
- Unitaid should contract market entry grants to intermediaries with strong technical expertise in diagnostics and engaging with manufacturers.
- Unitaid should consider supporting the development of technical product profiles for needed technologies/ commodities, that reflect technical and operational characteristics required for resource poor settings, to set the base for product innovation.