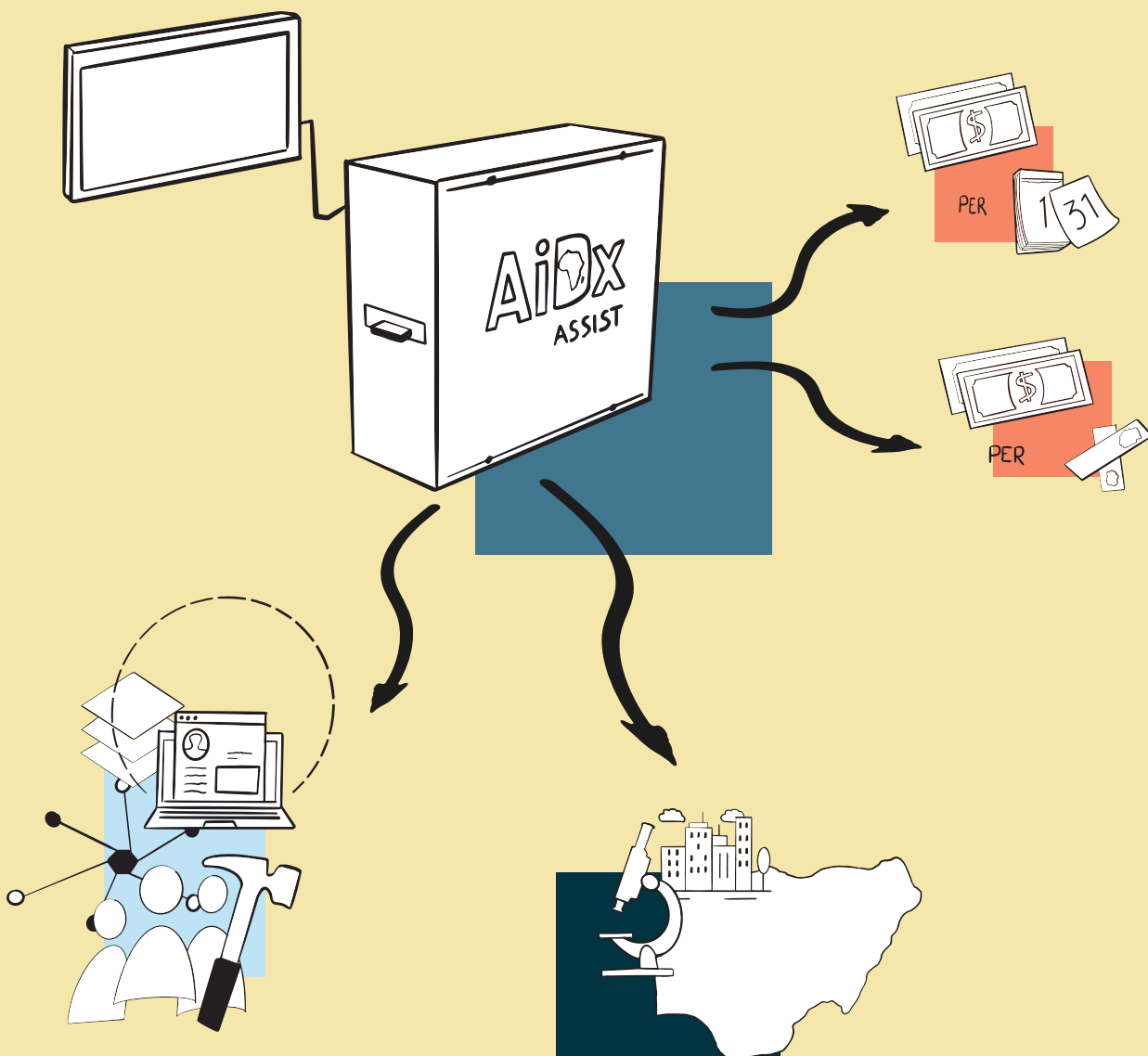


A proposition for the market introduction of the AiDx assist:

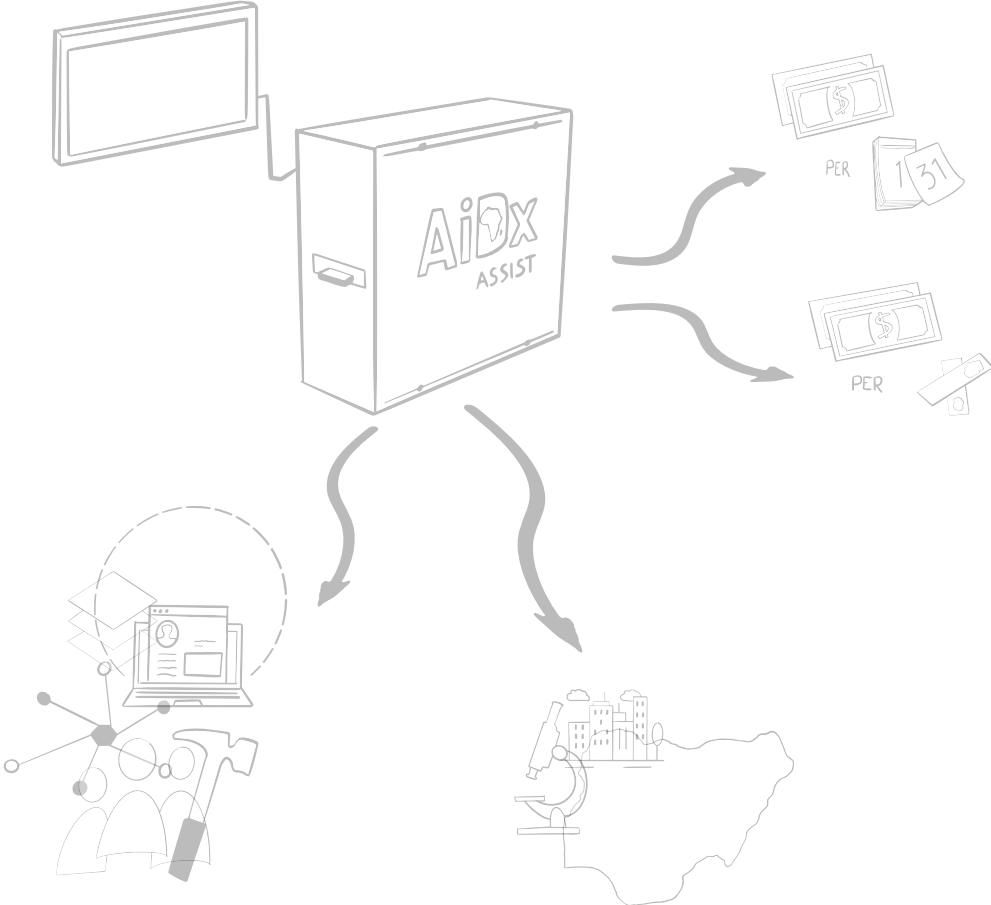
...an automated diagnostic device for the scope of emerging markets



Master thesis
by Koen Tijhuis

A proposition for the market introduction of the AiDx assist:

an automated diagnostic device for the scope of emerging markets.



Master Thesis
Koen Fabian Tijhuis

A proposition for the market introduction of the AiDx assist:
an automated diagnostic device for the scope of emerging markets

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Strategic Product Design
Industrial Design Engineering
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Abstract



Figure 1: Visualization of the AiDx assist

AiDx Medical is a medical start-up, a spin-off from the TUD, which Temitope Agbana currently leads. AiDx is developing an automated diagnostic device for emerging markets: the AiDx assist. AiDx has chosen Nigeria for the first market introduction since Temitope has his prime partners there. The idea for creating the start-up started with developing a device that can automatically detect malaria parasites in a blood sample as an improvement for the current gold standard microscopy method. This report summarizes the exploration into the malaria market in Nigeria, intending to create a proposition for a market introduction of the device: a proposition that is both viable and desirable for stakeholders in the market.

The AiDx assist shares many similarities with the current gold standard microscopy for detecting malaria parasites in a blood sample. However, there are three main advantages the AiDx assist has to offer when comparing the two. Because of the automation of the screening process, a pathologist saves time during the analysis, and this time can be spent on performing other diagnostic tests. Next to that, human errors are diminished, which improves the specificity of diagnostics. Lastly, the device can be upgraded to become a multi-diagnostic screening device since the technique that is being used for detecting malaria can also be used to perform other diagnostic tests. A few other companies are working on a similar device as the AiDx assist. The level of complexity within these devices is higher than within the AiDx assist. This results in an optimal specificity and sensitivity level but, therefore, also a higher price point. This is the reason the competitors mainly target the Western market with their products.

AiDx created the AiDx assist with the higher goal of making quick and reliable diagnostics available for everyone, from rural to urban areas, focusing on emerging markets. AiDx is a commercial start-up, which means they have to make enough profit to fulfil their mission of delivering this solution throughout Nigeria. AiDx wishes to supply existing health centres with their equipment, preferably with a B2B use-oriented PSS. An use-oriented PSS results in a more constant stream of revenue and a stronger relationship with the client.

The malaria diagnostics market in Nigeria is currently divided between microscopy and RDT. Almost all diagnostic tests for malaria are performed within Nigeria's primary health sector and laboratories; they can be compared to the GP in the Western world. The primary health sector in Nigeria can be divided into both the private and public sector. RDT is more commonly used in rural areas than in urban areas, where microscopy is the standard. The WHO qualifies microscopy as gold standard method for detecting malaria, that's one of the reasons many health clinics are still using this method for diagnosing.

The malaria market in Nigeria is highly saturated, especially since the introduction of RDT. RDT are increasingly popular, mainly due to the increase in the specificity, sensitivity, and trust level. Especially young lab technicians view RDT as the preferred option due to the easiness of use and speed. This given, it would be a strategic choice for AiDx to also look beyond malaria within the search for a strong positioning of the AiDx assist. Multiple directions have been explored in the quest for a value proposition beyond malaria. Still, the upgradability of the device has been defined as the most promising value proposition to work towards. Therefore the advice is given to AiDx to develop a multi-diagnostic device, starting with malaria and blood count. (Differential) blood count is the most performed test besides malaria. Also, it's a time-intensive diagnostic test to perform manually; thus there is a lot of room for improvement.

Market research showed that for a large segment of PHC and labs within the diagnostic market (almost all PHC and labs who are currently using manual methods for diagnosing people) a multi-diagnostic device could be interesting. The reason is that it improves their current diagnostics portfolio.

However, it's not recommended for AiDx to initiate their business with a complex use-oriented PSS around a multi-diagnostic device. AiDx is still a start-up in its infancy. The introduction of the described model is complex and requires an exemplary infrastructure that costs money to build and sustain. This is not something close to the current means of AiDx. Also, the multi-diagnostic device still has to be developed.

The advice is given to AiDx to divide market introduction into two horizons. Within the first horizon, AiDx could start serving a specific, small part of the market with a malaria-only diagnostic device; only luxurious labs and PHCs that generally use automated devices will be potential clients, since the advantages the AiDx assist poses appeal only to them. AiDx could introduce this malaria-only diagnostic device with a product-oriented PSS, in which the basic infrastructure is created for horizon two.

Within horizon two AiDx could introduce the multi-diagnostic device for malaria and blood count with a use-oriented PSS. To be able to become a use-oriented PSS supplier, AiDx will have to invest even more in the product and organization, compared to horizon 1. But when this step has been made AiDx could potentially grow rapidly since the potential market size is much bigger than the one from horizon one. To make profit AiDx needs to lease a minimum of 197 products.

All in all, the advice is to divide the market introduction into two horizons. In the first horizon AiDx could introduce their malaria-only diagnostic device with a product-oriented PSS to a relatively small client segment. In horizon two, AiDx could broaden their market share with a multi-diagnostic device that includes a use-oriented PSS.

Glossary

Abbreviations

PSS	Product-service-system
FBC	Full blood count
OEM	Original equipment manufacturer
SSA	Sub-saharan African
TUD	Technical University of Delft
AiDx	AiDx Medical
IDE	Industrial Design Engineering
EMR	Electronic medical record
TBC	Tuberculosis
RDT	Rapid diagnostic test
USP	Unique selling point
MVP	Minimum viable product
AI	Artificial intelligence
GP	General practitioner
USD	United States Dollar
B2B	Business to business
B2C	Business to consumer
WHO	World Health Organization
NTD	Neglected tropical diseases
NGN	Nigerian Naira
PAYG	Pay as you go
ROI	Return on investment
R&D	Research and development
PHC	Primary health center
PhD	Doctor of Philosophy
GP	General practitioner
PHC	Primary health center
MVP	Minimum viable product

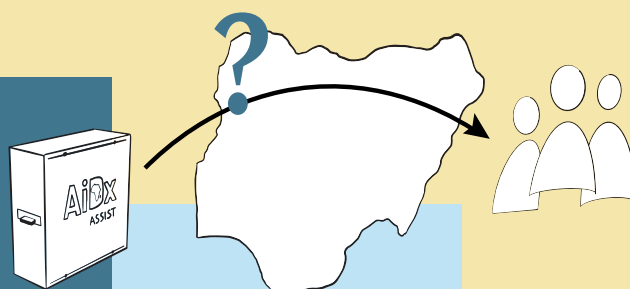
Definitions

Hematology	Hematology is the branch within healthcare which is concerned with studying blood related diseases. Analysis are focussed around blood and all its components. Blood diseases includes malaria, blood cloths, blood cancers and more.
Pathologist	A pathologist is a medical health worker who performs diagnostic tests in a laboratory.
Reagents	Reagents are a compound or substance that are added to a system to cause a chemical reaction. Within the diagnostic market the term reagent is often used to describe the asset that is needed to perform a diagnostic test with.
Specificity	The specificity of a test is defined by the chance of a negative result in patients who don't carry the diagnosed disease.
Sensitivity	The sensitivity of a test describes how many times a patient who carries a condition also actually tests positive
Neglected tropical disease	Neglected tropical diseases are disease common in emerging markets which are generally neglected by the big pharma. This means little research is done and little funding is available for these diseases. However the disease burden is inexorable high.
Minimal viable product	A minimum viable product, or MVP, is a product with enough features to attract early-adopter customers and validate a product idea early in the product development cycle. It can help receive user feedback as quickly as possible to iterate and improve the product.
Unique selling point	A unique selling point can be described as the essence of a product or service that makes it better than others.

The line-up

This chapter gives an introduction to the project and gives an overview of the steps which were taken within the project towards the end goal: creating a PSS around the automated diagnostic device of AiDx. Furthermore, it describes some design methods that are used throughout the project as a tool and guideline.

Figure 2: the main question visualised: how to implement the AiDx-assist in Nigeria



Introduction

This is the Master Thesis of Koen Tijhuis. It has been written as part of the master Strategic Product Design curriculum at the faculty of Industrial Design Engineering, which is part of the Technical University of Delft. The client for this project was AiDx Medical.

AiDx Medical is a start-up currently developing an automated diagnostic device to detect malaria parasites: the AiDx assist. The company is led by dr. Temitope Agbana (to be referred to further throughout the report as Temitope), an alumnus from the TU Delft. During his PhD, he observed the need in emerging markets for a more innovative way of detecting malaria parasites within blood samples. He wanted to develop a technique similar to the current gold standard, namely light microscopy, but then automated with extra advantages.

Temitope and his team found the solution to improve the current microscopy method in machine learning. For six years, Temitope and his dedicated team have been working on a digital microscope that uses the strength of machine learning and microscopic image tracking to detect malaria parasites: the AiDx assist. Malaria is chosen as a target disease, but with the same technique, the device could detect more conditions in a later stadium of development.

AiDx is a typical technology-driven start-up. They have mainly focused on developing the device and the machine learning program during their existence. The goal of this graduation project has been to dive deeper into the market of malaria diagnostics in emerging markets, to create a better understanding of how the AiDx assist could be positioned in the market in a viable and desirable way. Nigeria has been chosen as a focal point of this project. In the first place because Temitope knows this context best since he was born and raised there. Secondly, Nigeria's malaria market is the largest: 23% of all malaria cases can be found in Nigeria (World Malaria Report, 2020).

The main question of creating a proposition for a PSS around the AiDx assist is answered within this report in four sets of questions. An overview of these questions can be found underneath. The process wasn't as structured as this but rather reflective and iterative. However, to create a clear storyline, the report is divided into a chronological order of these sets of questions.

1. Who is playing

- How does the AiDx assist work?
- What are the benefits of the device compared to the current microscopy?
- What is in the DNA of AiDx Medical?
- What are the capabilities and wishes of AiDx Medical?

2. Where to play

- What does the market for malaria diagnostics look like?
- Which stakeholders are involved?
- What characteristics do the stakeholders have?
- What is the size of the diagnostic market for malaria?
- Who are the competitors now and in the future and what is their positioning?

3. How to score

- What are the possible value propositions that AiDx Medical can offer to stakeholders?
- What are the key B2B buyer criteria?
- What could the PSS look like?
- What does the B2B route-to-market look like?

4. What capabilities are needed to score

- How should the infrastructure around the organization of AiDx develop to be able to pursue the proposition?
- What partners do we need in the market?
- How should the product change to be able to fit the PSS?
- What does the financial model look like in the B2B positioning?
- How do we approach our clients? What message do we use to sell the AiDx assist?

Project approach

As a framework for the project, the double diamond approach as invented by the British Design Council in 2005 (Ball, 2019), has been chosen. The steps which were taken throughout the project are distilled from this approach and are visualized on the right.

As a start, it's essential to understand the scope we are dealing with: to understand better what the company AiDx and her device are capable of, what the diagnostic market looks like in Nigeria, and how others are solving the problem. Simply the discovery phase, which connects to steps 1 and 2.

After discovering the scope, it's important to define where the opportunity space lies within the market for the AiDx device. Next, we have to define and develop the relevant PSS elements for AiDx and the positioning they can start working with (steps 3 and 4). Lastly, the concepts are validated with potential clients: first, to understand if there is demand for the PSS, and second, to deliver a positioning that fits the client. Insights from the validation session should be used to concretize the concepts and give recommendations for the future.

The main framework for this project and the associated steps are deliberately kept simple. Due to the combination of the pandemic and a project in the scope of Nigeria, it was harder to gather information because a field trip was not a part of the possibilities. A lean approach helps to deal with the complexity of the scope and lack of information.

Next to the project fit, the framework helps to keep grip on the project in the dynamic phase where AiDx is in. AiDx is a start-up looking for a business case that fits its product best. However, they are still in a developing phase for their product. They are currently exploring which route to take as a company and simultaneously which external projects to invest in. This means there is no fixed point on the horizon where AiDx is working towards. Lean start-up mentality could help while tackling this project as described by Ries in his book *The Lean Startup* (2011).

This mentality demands from the designer, to think and behave as an entrepreneur. This is also the reason that the effectuation theory by Sarasvathy (2001) is used: as a guiding theory within this project.

Because the whole project was executed from a distance, information has mainly been gathered through desk research and extensive interviews with experts, stakeholders, and lab technicians. Throughout the project, interviews were found to be the most important source to gather data. The reason for this is the discrepancy between theory and practice. Interviews gave a more realistic image of the scope.



Effectuation theory

Throughout this graduation project, the effectuation theory has been used as a tool to approach the project. It's a framework of principles that helps answer how to get sellable products and services established. If we want to answer the main research questions, it's essential to take an entrepreneurial approach. The effectuation theory gives an insight into how expert entrepreneurs are solving these types of questions.

Sarasvathy (2001) was the one to introduce this terminology and theory. She based this theory on an extensive study of expert entrepreneurs. Sarasvathy used interviews to determine how expert entrepreneurs grew their venture from an initial idea into a million-dollar business. She generalized her findings into the effectuation theory: a set of decision-making principles expert entrepreneurs are observed to employ in situations of uncertainty. Effectual thinking is the inverse of causal thinking. Instead of selecting between given means to achieve a pre-determined goal (causal reasoning), a given set of means is used to imagine possible new ends.

Sarasvathy (2009) defined a set of principles to make it easier to understand what effectual reasoning concretely means. They can be found underneath. The first principle expert entrepreneurs are observed to use is that they understand their means. To imagine possibilities, it should be clear what you already have, know and are. This principle is always your starting point. The further you grow, the bigger the set of means becomes.

The second principle expert entrepreneurs employ is 'affordable loss'. Instead of first targeting for a return and looking for all-or-nothing opportunities, they tend to limit risk by understanding what they afford to lose at every step.

Within the third principle, expert entrepreneurs' behaviour towards surprises and bad news is summarized. The behaviour of expert entrepreneurs within the third principle originates in the invitation of the surprise factor. Surprises and bad news should be interpreted as potential clues for new markets.

The fourth principle summarizes the view of expert entrepreneurs towards stakeholders. Competitors are not necessarily seen as rivals but potential partners in crime, with whom you could co-create a new market.

The fifth principle contrasts strongly with causal reasoning, which has been strongly taught at the TUD, where inevitable trends are believed to shape the future: instead of believing in the effectual reasoning that a future is made and not predicted.

1. Bird-in hand

Start with your means: who are you, what do you have and whom do you know

3. Lemonade

Embrace surprises, use them as potential clues to create new markets

5. Pilot-in-the-plane

Focus on activities within your control, believe that your actions result in the desired outcome. The future is neither found nor predicted, but rather made.

2. Affordable loss

Focus on the downside risk instead of expected return

4. Patchwork quilt

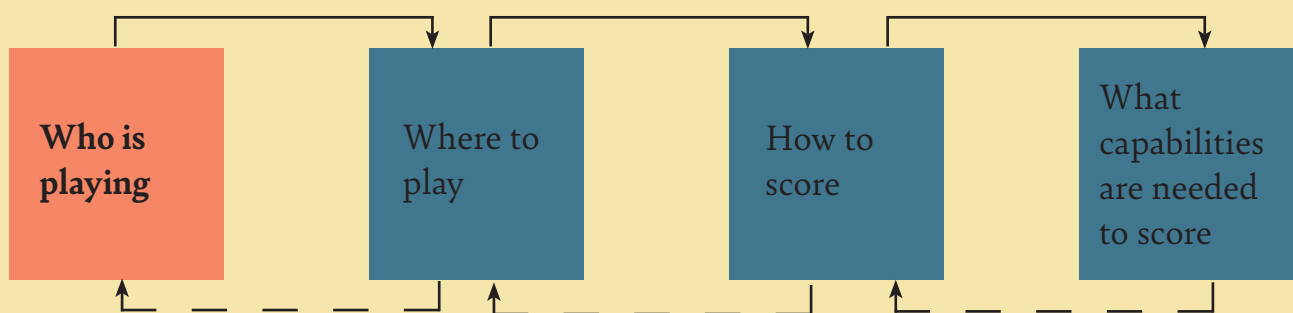
Be open to stakeholders and built partnerships, co-create new markets

Concluding

The project demands a lean and agile way of working, because of its dynamic character: the course of AiDx Medical as a start-up is constantly changing due to new insights from the field. This also affects the proposition for AiDx. Effectual reasoning is used as a tool to work towards a positioning for AiDx; principles that expert entrepreneurs tend to use are a guideline in the process. Lastly, many interviews were used throughout every stage of the project to validate data in the field because theory and practice are often not coherent in the scope of emerging markets.

Who is playing

Within this chapter, the means of the project are described. Before exploring the market and positioning possibilities, it's crucial to understand what the AiDx assist is capable of and what the characteristics of the company AiDx Medical are (the bird-in-hand principle as described within the effectuation theory (Sarasvathy, 2009)). Without defining the strengths of AiDx and the AiDx assist, it will be impossible to define a strong positioning for the device.



The AiDx-assist

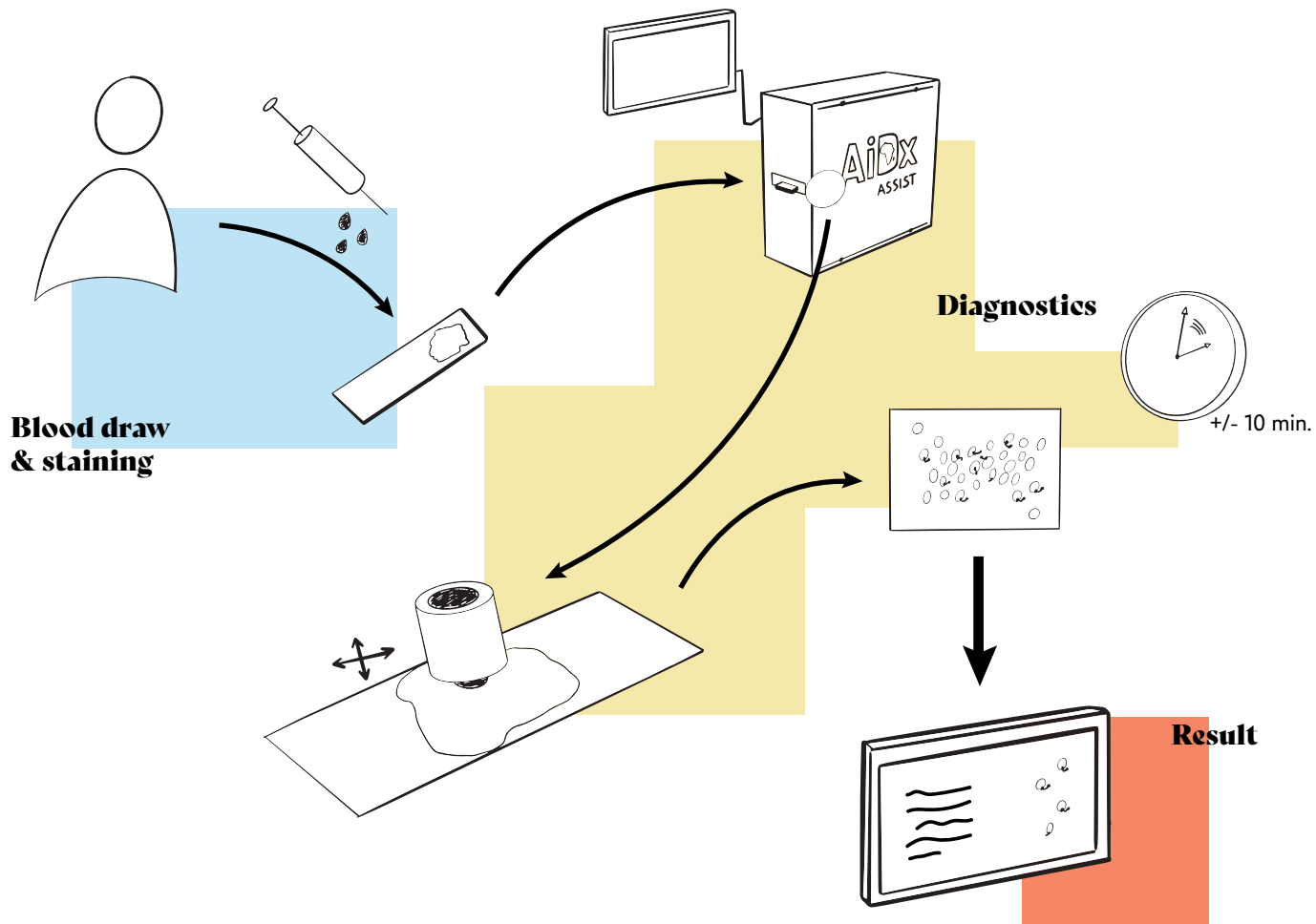


Figure 3: visualisation of how the device works



Figure 4: photo of the device in use by a local lab technician

The AiDx assist, as seen in figures 3 and 4, has been developed over the last six years by AiDx Medical. In short, it can be described as an automated diagnostic device that uses the strength of machine learning to analyze a blood sample. Currently, the device can detect malaria parasites within a blood sample, but soon it's also able to differentiate white blood cells (perform a differential blood count test). On a larger scale the device is also trained to detect hookworms. Because of the simplicity of the design, the internal program can be altered so that the device is able to run even more diagnostic tests (e.g. Schistosomiasis, Loa Loa). Moreover, in the future, it will be able to diagnose within different samples next to blood (e.g. stool, sputum and urine).

How does it work?

Like within light microscopy, blood needs to be first collected from the patient with a finger prick. The blood sample is smeared onto a standard glass slide which is globally available. After the blood has dried out the sample has to be stained with the Giemsa staining technique. Staining is crucial to differentiate between different white blood cells and the malaria parasite (WHO, 2016). This process takes around 20 minutes due the waiting time of the blood to dry out properly.

After preparing the blood sample, it can be inserted into the device. Hitting a button on the device is enough to make the diagnostics start. A camera will be activated and starts scanning the blood sample through a microscopic lens. The sample holder within the device is mounted to a movable platform that is able to move in a horizontal and vertical direction. This makes it possible to capture every frame of the blood sample. The camera makes a picture of every frame and the AI program analyses every photo. Analyzing the sample costs roughly 10 minutes. Thus the device can diagnose six samples per hour. A computer is incorporated within the device, enabling internal processing of the images. To read out the results, a screen is needed.

Comparison automated microscopy and gold standard microscopy

If we compare the gold standard microscopy and the AiDx assist, we can distinguish multiple similarities and differences. The **time to perform a test** is similar in both cases. Within both scenarios the same staining method is used which cost around 20 minutes. The screening time, automated vs. manual is also similar around 10-15 minutes. However within the automated screening process of the AiDx assist no pathologist is needed. Therefore the pathologist can **spend time on other diagnostic tests**, this is an advantage compared to the labour-intensive screening proces in gold standard microscopy.

The automation of screening also causes an **increase in sensitivity and specificity**. In practice, the specificity of gold standard microscopy is optimal. Unfortunately, this isn't always the case in theory because of inexperienced pathologists and time pressure during the diagnosing process.

The **price per test** will be similar in both diagnostic methods. In both cases, a glass slide is needed to perform tests. Within the diagnostics of the AiDx assist power is an extra asset that costs money, in gold standard microscopy it's the time spent on the test by a pathologist.

When looking at the price point of the device, the AiDx is much more expensive. A Chinese microscope, which is often used in the scope of Nigeria, costs only 300 euros (D. Bell, interview, September 28 2021). The AiDx assist will become significantly more expensive.

Upgradable in the future

The most significant advantage and USP of the AiDx assist compared to gold standard microscopy is the upgradability of the device. As mentioned before, the same screening technique used for malaria parasites can be used to detect NTD, TBC, and blood diseases.

The first diagnostic test to add as an option to the AiDx assist will be differential blood count. The same reagent is used to detect malaria parasites and to perform a differential blood count. The step towards performing this test is relatively small. With differential blood count as a basis, FBC is also the most performed test in Nigeria. Lastly, in more luxurious labs, blood count and malaria diagnostics are often combined to check the infection rates within a patient or to define what causes the febrile illness symptoms when it's not malaria.

Company

History

The idea for digital malaria microscopy came 6 years ago. During his PhD Temitope got the idea of creating a device that is able to detect malaria parasites. Temitope decided to bring his PhD research to a higher level and start with the start-up AiDx which has existed for almost 5 years now. Together with the help of other professors from the TU Delft he started this venture. (Montague, 2019).

It all started with the idea of developing a device which can automatically scan malaria parasites in a blood sample. To create a device with the same specificity and sensitivity as current gold microscopy diagnostic but without the need of a professional pathologist to run the test. They defined automatisation as a driver to push the amount of diagnostics performed on the long term in Nigeria. All in all, to improve the poor diagnostics in (rural) Nigeria. They started with developing the Excelscope, a portable device. However they couldn't manage to get the specificity they wanted, thus AiDx redesigned the device and created the AiDx assist.

Next to developing the AiDx assist Temitope and his team are also part of the bigger project INSPiRED, to create more INclusive diagnoStics for Poverty RELated parasitic Diseases in Nigeria and Gabon. Within this project AiDx supports by doing research into automated schistosomiasis detection within urine.

Current business operation

The AiDx assist is almost ready for deployment. Currently the focus of AiDx lies on technically finalizing the device so it can be brought to the market. The team of AiDx is both finalizing the code of the AI program but also optimizing the configuration and hardware of the device.

Next to finalizing the device there is a constant need of getting funding for AiDx, to be able to survive. This is solely for the reason that they are not selling devices yet. Funding is needed to keep operating as a company. They manage to receive funding by applying to research projects from NGOs and governments surrounding the theme of technical healthcare solutions for emerging markets.

The team of AiDx currently exists of Temitope whose task it is to lead the company. Next to Temitope, there is one other paid employee who works fulltime on the software of the device, with the main task of improving the code for image tracking. Next to that, two interns are onboard, one who is working on marketing of the device and another one who is improving the hardware of the device.

In figure 5, a visualisation has been added for the planning of AiDx within the duration of the graduation project. On the short term it is key for AiDx to get their device done and ready for the market. Therefore the performance of the device has to be officially approved and a local certificate has to be applied for. After that it's key to organise a launch event to find clients. It's important to have a solid business case by then, to be able to show something tangible to them. Investors are thereafter needed to roll out a network of devices.

Mission and vision

The current mission which is being communicated by AiDx is:

Make quick and reliable diagnostics available for everyone.

The bigger mission is to provide easy access to reliable and affordable point-of-need diagnosis across the various tiers of health care systems in the different parts of the world, with specific focus on the low income countries. To reach everyone, a big part of the business operation should take place in rural areas.

Temitope is a visionair who has a broad vision for the AiDx assist and the company AiDx. His dream is to create a multifunctional device that is able to detect multiple diseases. Next to the AiDx assist that is currently being developed he wants to create a device which is able to detect multiple NTD.

This device will be called the NTDx, a device that is able to detect diseases like chikungunya, chagas, schistosomiasis, microfilariae and more. Therefore the device needs to be able to detect parasites and worms within different substances: blood, urine and stool.

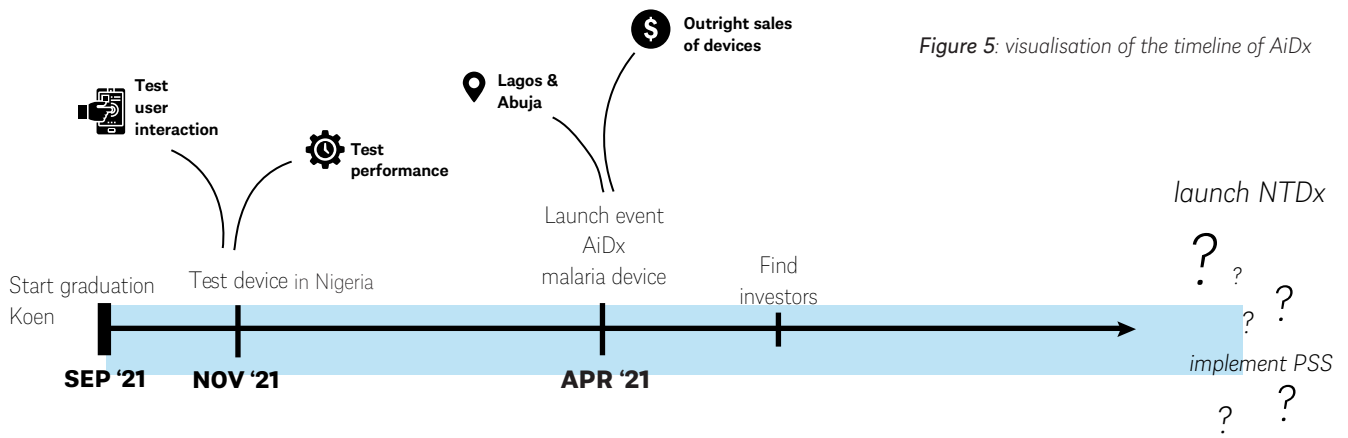


Figure 5: visualisation of the timeline of AiDx

Next to this development Temitope is also exploring the possibilities for a different market than Nigeria: Maroc. In Maroc he explored the context plus market and found next to some NTD that tuberculosis and UTI are a big problem. Just like the NTDx machine, he is envisioning to create a device which is able to detect multiple diseases that are widely present in Maroc. Therefore it must be able to also detect very tiny bacteria, which brings a new challenge in the hard- and software of the device. In figure 6 the potential future business propositions and visions of Temitope are visualised.

Within this project the AiDx assist has been taken as a boundary and scope to explore. It's important to kickstart AiDx as soon as possible and start exploring new ventures from there.

Restrictions, wishes and requirements for the positioning

To understand Temitope as entrepreneur better, an in-depth interview has been done, to define the means we have to work with while developing a positioning around the AiDx assist. The most important insights are mentioned underneath.

For a first market-introduction AiDx Medical is preferably looking for a B2B positioning. A B2C approach doesn't fit in the current strategy.

For the B2B positioning AiDx has a preference for an use-oriented PSS. This wish origins in the preference for a use-oriented pay-model, a pay-model which is often characterised by a subscription construction. This type of paymodel will generate a more constant income stream and results in a solid client base which can easily be targeted with newly developed devices or updates.

AiDx is open to co-venturing if the vision aligns with their vision.

(T.E. Agbana, interview, October 14 2021)

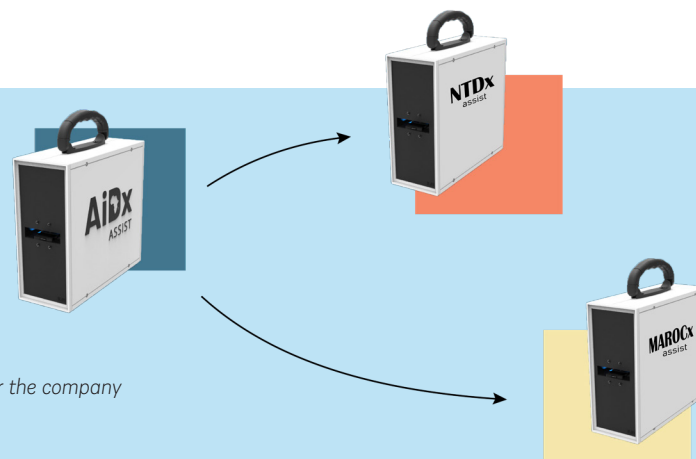


Figure 6: potential ventures for the company AiDx

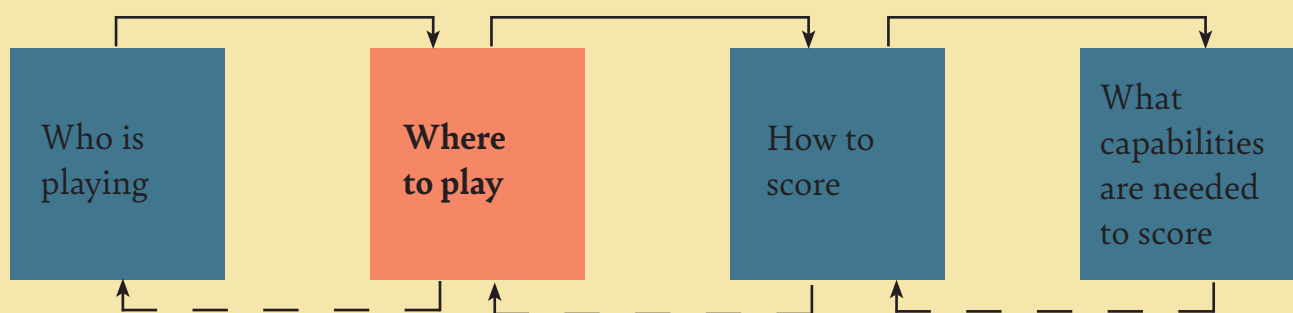
Concluding

The AiDx assist has three significant advantages compared to the gold standard microscopy method for detecting malaria parasites. First, diagnosing time is saved due to the automisation of the detecting process. Secondly human errors are diminished, because screening is done automatically rather than by an unexperienced pathologist. Third and last, the AiDx device is upgradable to other diseases. On the other hand the price point of the device will be a significantly higher than the current microscopes which are being used.

AiDx Medical is preferably looking for a B2B positioning with a use-oriented PSS. The reason for that is to have a constant stream of income and to build strong relationships with their clients. AiDx doesn't have the organisational skills (yet) to roll out health centers or laboratories themselves. The vision of AiDx is to provide easy access to reliable and affordable point-of-need diagnosis across various tiers of health care systems. One of the wishes is to also supply healthcenters in more rural areas with advanced and reliable diagnostics.

Where to play

This chapter describes the exploration within the health sector of Nigeria. Starting with an exploration into diagnostics of malaria: the initial product and market idea. From malaria as a basis more exploration has been done, by broadening the scope and rethinking the original sellable product and service. Also it contains an exploration into interesting ventures from other companies, to understand how they are creating value and if a mutual commitment is amongst the options. This exploration phase is based on desk research and backed up with multiple interviews with important stakeholders.



Healthcare market

General information

Nigeria is the country with the biggest population of Africa. According to the Worldbank, Nigeria had 206,1 million inhabitants in 2020 (Worldbank, 2020). To serve all people with proper healthcare, a big network of healthcare providers is needed. However this is something the country is struggling with, according to Lancet (2018): Nigeria ranked 142nd out of 195 countries for global healthcare access and quality.

In general the quality of healthcare is poor in Nigeria for multiple reasons. The quality of hospitals is bad because the government simply has not enough money to invest in them. This is also the reason that a big part of healthcare is delivered by private providers: providers who try to deliver better healthcare than the public sector. Furthermore, many BoP customers in Nigeria are not insured, this means many people have to pay for their own diagnostics and treatment in hospitals, also for malaria diagnostics. This poses problems for many patients since the minimum wage in Nigeria is only 30.000 NGN which equals to 72 USD per month. Many patients are shut down from care because they can't afford to get treated. (A. Onasanya, interview, October 6 2021)

Health care system Nigeria

Within Nigeria you can distinguish multiple levels of health care which are, on their turn, also divided into a public and private domain. In the right upper corner there is a schematic overview of what the health care system looks like.

Medical outreach posts and NGOs mainly deliver care to villages in rural area. But for most civilians, the primary health centers and private clinics are the first point of care, where basic diagnostics tests and treatment are delivered to patients. Within secondary health centers and private hospitals the variety of diagnostic tests and type of treatment is bigger than in the primary health sector. In tertiary health centers complex surgeries for cancers or heart diseases can be performed. (Stoevelaar, 2017).

A malaria diagnostic test is scaled as a basic diagnostic test and commonly performed test. Within this project we will mainly scope around the primary health centers, medical laboratories and private clinics because they perform most malaria diagnostic tests. However within those three, we can distinguish multiple differences. There are PHC and labs who are delivering general healthcare, but there are also many who are specialised in a specific type of healthcare, e.g. pregnancy, ENT clinics and more. The non-specific labs and PHC are the ones who are generally performing most malaria diagnostics tests.

Obviously there is also a big difference in the size and level of expertise between different PHC and labs. Within this project we'll make a difference between the advanced and luxurious clinics/ labs who have acces to automated diagnostic devices (like an automated hematology analyzer) and clinics/ labs who are mainly using manual methods to diagnose patients. Most of the PHC and labs who have acces to automated diagnostic devices are found in urban areas.

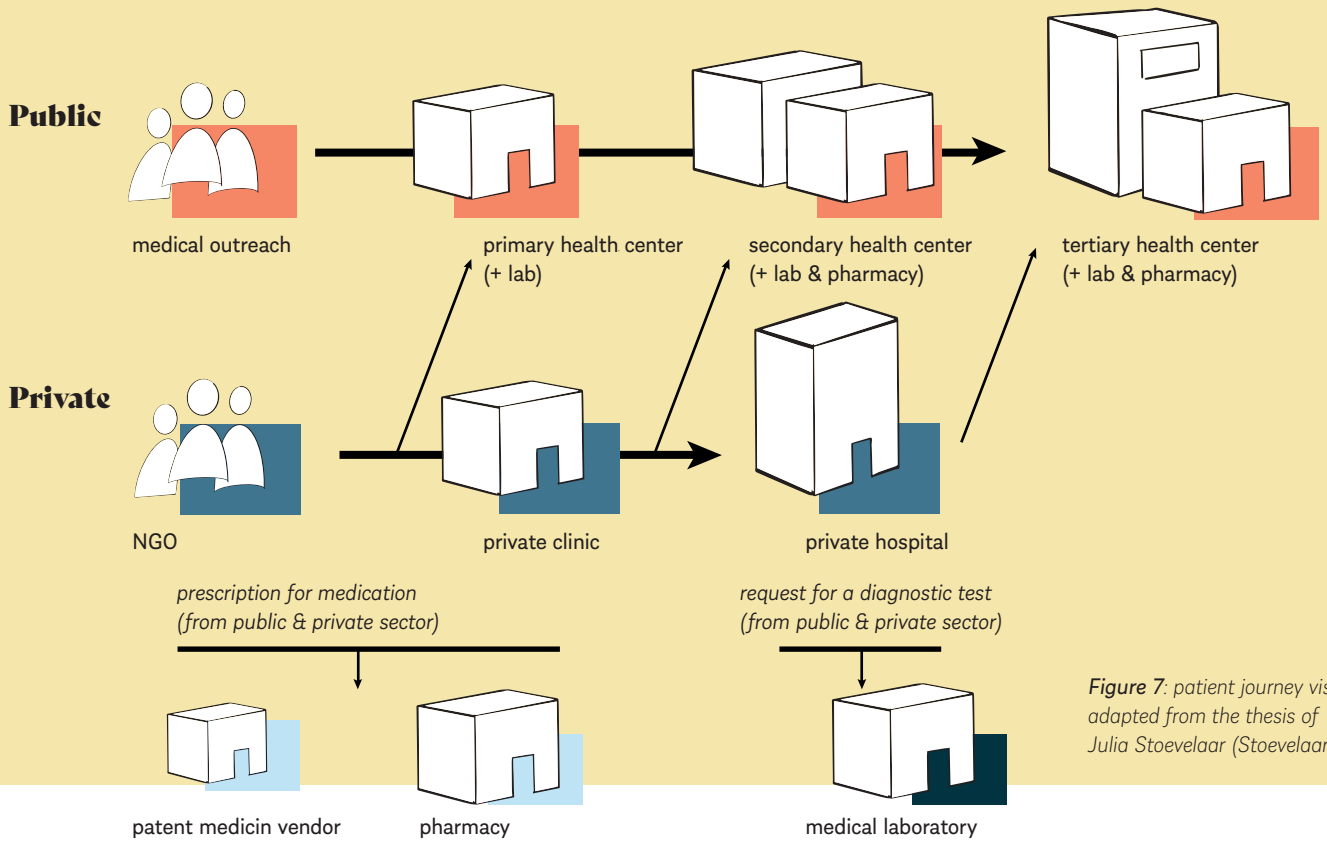
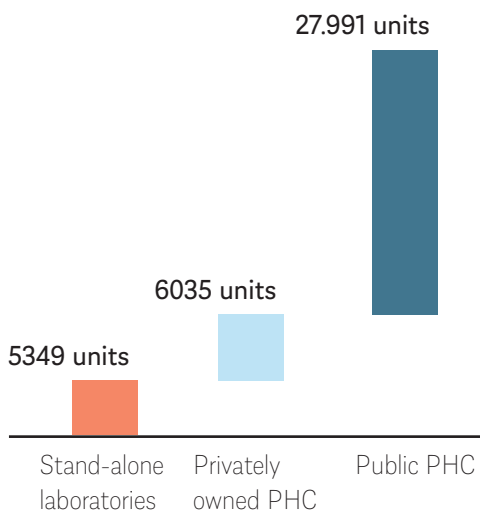


Figure 7: patient journey visualised, adapted from the thesis of Julia Stoevelaar (Stoevelaar, 2017)

Market size

Amount of labs and PHC



Only PHC and labs are visualised in the diagram since they perform most malaria diagnostic tests.

Figure 8

(Nigeria Health Facility Registry, 2022)
(Tribune online, 2021)

Percentage of centers with manual vs. automated diagnostic techniques as a standard

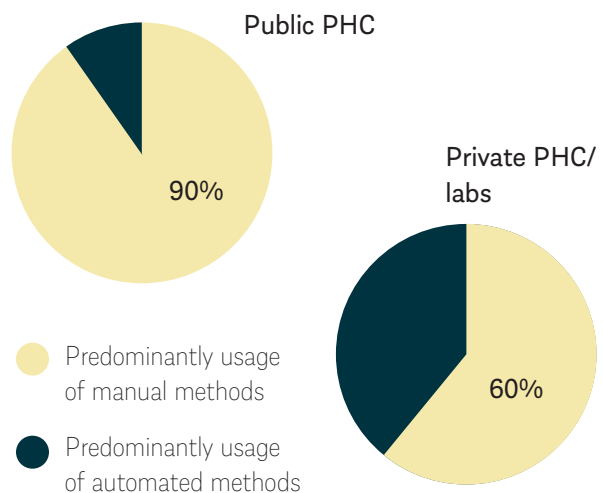
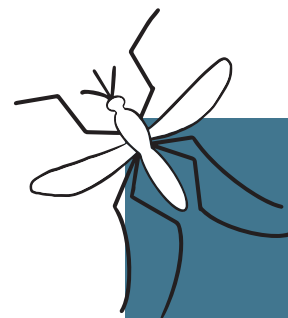


Figure 9

(Mr. Animashaun, interview, March 3 2022)

Malaria



Info on current state

Malaria is a febrile illness which means people who are infected with malaria show fever-like symptoms. Usually the symptoms appear 10-15 days after the bite of the mosquito and may be mild and thus difficult to recognize as malaria. When left untreated malaria can progress to severe illness and could cause death within 24 hours. Especially for children under 5 years old this is the case, which is the reason they need to be diagnosed and, if tested positive, to be treated directly. (WHO - Malaria, 2022)

Malaria is the biggest problem from all mosquito-borne diseases, affecting 229 million people yearly and caused death to 409,000 in 2019. Nigeria counts for 23% of all malaria cases which makes it the most infected country worldwide. (WHO, 2020).

Most of the infections and death cases occur in the rural areas of endemic countries. The reason is that people are still not aware of the severeness of the disease and don't immediately test when symptoms occur. Furthermore, accessibility to proper health facilities or pharmacies is scarce in the rural areas.

In Nigeria most money spent on malaria by the government comes from international funding programs (>90%) (WHO, 2020). Funding is an important asset within the fight against malaria and the key players are Global Funding, US Aid and World Bank. In West-Africa alone they spend 750 million every year. Most funding is being spent on mosquito nets and RDT, not so much on microscopic tests. (The Global Fund, 2022). Due to the big population in Nigeria the funding per person at risk is one of the lowest in West-Africa with 1 USD yearly (WHO, 2020). This means that most expenses are out-of-pocket for malaria patients, both for diagnostics as for treatment. The price of a single malaria test in Nigeria varies between 1000 and 2500 NGN (Mr. Animashaun, interview, March 3 2022).

Next to scarcity of diagnostic and treatment within the scope of malaria, a big problem in Nigeria is presumptive treatment. When having fever-like symptoms many people in Nigeria tend to get malaria treatment straightaway without getting diagnosed first. This is causing stock-outs in malaria treatment. Besides that, it also causes the risk that malaria parasites get immune to the treatment.

Diagnostics

Microscopy

Light microscopic examination is the "gold standard" according to the WHO. The reason is that microscopy is the most accurate way of testing, provided that the test is performed by a professional pathologist. It has the highest sensitivity and specificity rate of all testing methods available. Next to that one of the advantages is that you can quantify how many parasites you are dealing with per sample and thus how high the infection rate is. According to the severeness of the disease within a patient it's possible to choose the right treatment. The last advantage is that the pathologist could detect another disease than malaria, during the analysis of the blood sample. However in reality, well-trained pathologists and ideal staining are not the standard, this results in significantly lower specificity and sensitivity levels.

RDT

Rapid diagnostic tests (RDT) are immuno-chromatographic tests for detecting parasite-specific antigens in a finger-prick blood sample (WHO, 2011). They are widely available throughout endemic countries and they come in different forms from cassettes and cards to dipsticks. Pharmacies and PMV are the main distributors for RDT to patients. Currently it's the main method used for diagnosing people for the disease, mainly due to the three advantages it has compared to microscopy: price, easiness of use and no need for a professional pathologist to run the test.

The development of RDT is increasing rapidly, that's the reason the new school of lab technicians is rooting for RDT. RDT are getting increasingly more specific. Mologic and Global Access Diagnostics are developing RDT for malaria which are extremely more specific than the current RDT. (T.R. De Wit, interview, December 10 2021)

Use case diagnosing methods

The Malaria 2020 report (WHO, 2020) gives us insights into the amount of RDT that are being performed every year compared to microscopy. In 2020 a total of 22.621.211 RDT have been examined compared to 3.298.156 microscopic tests. As mentioned before, many RDT are distributed by NGOs who test large amount of people at once in rural areas and villages. Next to them the PMV and pharmacies are distributing them.

In the primary clinics and laboratories the microscopic method is still the standard. One of the biggest reasons that many health centers are still using the microscopic method is that they have more trust in them than RDT, despite the fact that research pointed out that in some use cases RDTs give a more accurate result than microscopy. (D. Bell, interview, September 28 2021).

The amount of tests that are done per health clinic depends on the size of the clinic/ laboratory, the season (during wet season there are more mosquitos) and the area (in some areas the prevalence of malaria is higher). On the right an indication is given of the amount of microscopic tests that is done per type of clinic monthly.

Big luxurious private hospital

1000 malaria tests per month

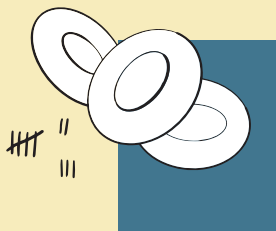
Medium sized PHC

400 malaria tests per month

Small lab

200 malaria tests per month

(O. Dare, interview, February 9 2022)
(Temitayo, interview February 11 2022)
(Mr. Animashaun, interview, March 3 2022)



The AiDx assist beyond malaria diagnostics: blood count

Blood count tests could be divided into two types: differential blood count and full blood count, differential blood count is just a part of the full blood count. Within a differential blood count the different types of white blood cells are counted. Extra measurements which are being done in a FBC are testing the levels of platelets, red blood cells, hematocrit and the proportion of red blood cells to the plasma. The last two are almost impossible to measure with the AiDx device without changing the whole device, due to the way the AiDx assist works. (Health Direct, 2022).

As described before, FBC is being used as a more general test to point out underlying diseases. It's used to check for three different reasons. Firstly to review the overall health of a patient. Secondly to diagnose for a medical condition like fever, an infection, anaemia (lack of red blood cells), tiredness or weakness, and more. Thirdly to monitor a medical condition and lastly to monitor medical treatment. (Mayo Clinic, 2020).

A FBC test can be done manually or with a hematology analyzer. In Nigeria, as described before, the amount of manual tests done is much more than tests done with a hematology analyzer. A full blood count is the most performed test within emerging markets as well as in Nigeria (Horton et al., 2019).

Competitors

This chapter has been added to create an understanding of what's already happening within the scope of malaria diagnostics. As described by the effectuation theory we shouldn't perceive competitors as enemies but as potential partners to start a co-venture with (Sarasvathy, 2009). Besides, AiDx might be able to learn from them on how (not) to introduce their device and technique on the market.

Within the field of malaria diagnostics AiDx faces multiple competitors. In general they can be divided into two groups: RDT and microscopy. Within those two groups you have the classical companies who are currently delivering the standard RDT and microscopes: established names which are hard to compete with if you don't bring anything new and unique. Next to them you also have some start- and scale-ups who are developing innovative diagnostic solutions. They try to gain market by developing techniques that are an improvement to the standard diagnostic solution. AiDx is one of them, but next to them you have multiple other start-ups and established companies who are also using innovative technologies to diagnose malaria. In figure 10 there is an overview of those competitors, they are categorized in the techniques they use and ranked vertically in the development of their business/ technology.

Next to the standard solutions for parasite detection we will focus within this report on the three closest competitors who built a similar device as AiDx. They can be found in figure 11 in the same row as AiDx. The three companies who managed to develop a similar digital microscopic device to detect malaria are Sysmex, Motic and Noul.

Sysmex is a company which already exists for 50 years and within their lifespan they have been working in the scope of hematology, pushing new innovations and setting new standards. In August 2020 they launched their device XN-31 which is, just like the device of AiDx, able to detect malaria parasites in a blood sample. Since then they have obtained approval in Japan for their automated analyzer. Their mission is to accelerate this move and expand further into Asia and Africa. However their main target market is still Europe, focusing on university hospitals, specialist hospitals and commercial labs. They claim their technology has an advance to significantly impact on malaria diagnostic approaches, therapeutic monitoring and efficacy, anti-malarial drug discovery and clinical trials. (Sysmex, 2022).

Motic is another company within the field of digital pathology. After developing their general line of products they also developed a device which is able to detect malaria parasites. Currently they focus on the Western market with their device. Their starting point is to introduce the device in a market which is not too familiar with malaria cases and in clinical settings to test how medicins are performing. Motic and Sysmex both serve the western market from origin. Since they changed their existing product to also serve the diagnostics of malaria, the device is very high-end. This brings a couple of advantages, which are that the specificity and sensitivity are optimal. On the other hand you need an experienced pathologist who is able to understand and use the device. Furthermore the device is expensive to produce. Those two reasons make it, within the scope of Africa, complicated to create a business case around the device. Especially when diagnosing for a disease which is widely spread and potentially cheap to diagnose with RDT. Noul is a young Korean company (founded in 2015) with a strong focus on the African and Asian market. Just like AiDx they are developing a device which is able to detect malaria parasites with the help of AI. Unlike Motic and Sysmex this is the only device in their portfolio. Their product is made suitable for the African market by making it robust with an incorporated screen. They furthermore developed a cartridge which is able to automatically create a stain, this removes the necessity of a professional pathologist to run the diagnostic, since making the stain is done automatically.

When we compare AiDx to the other companies from above we could conclude that AiDx is a runner-up. Both Sysmex and Motic have stronger resources since they are companies with an extended product portfolio outside the scope of malaria. This is due to the fact that they have been in the game for a very long time and they therefore have many other diagnostic solutions on the market. Furthermore their malaria device is already up and running and can be bought on their website. Noul is also slightly further in their development than AiDx since they are already in the process of getting their device approved for the market.

The main difference with the device that AiDx has developed and the others is the price point. The high end machines from all three companies drives up the price and inherently the price per test. The focus of AiDx has always been to create a digital microscope which is as cheap as possible. This is a big competitive advantage for AiDx, especially in the scope of emerging markets.

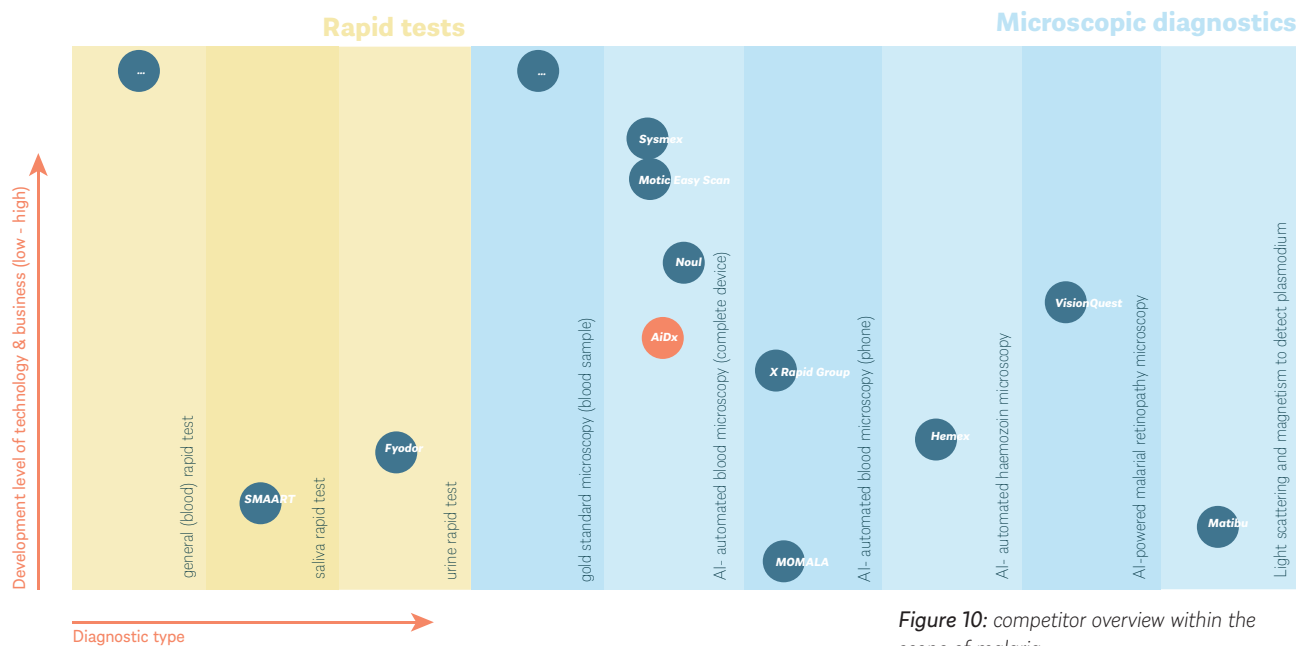


Figure 10: competitor overview within the scope of malaria

The input for this graph is based on information found on each website of every competitor.

	RDT	Gold standard microscopy	Sysmex/Motic	AiDx Medical	Noul
Price (USD)	Per test: 0,30 USD	Broadly used Chinese microscopes: 300 USD	Both expected around 10.000 USD	Not available yet.	?
Time to perform test	15 - 25 minutes	Screening: 10 - 15 min. *doesn't include staining	Screening: 1-6 min. *doesn't include staining	Screening: 10 min. *doesn't include staining	?
Pathologist needed	No expert needed	Yes, an expert, for the best result	For staining and check results	For staining and check results	Only for checking the result
Blood count available	No	Manual test could be done: +/- 1,5 hours	Included in device	Potential upgrade	?
Specificity/sensitivity	In theory less than microscopy	In theory higher than in practice	High	Potentially high	Potentially high
Define infection rate	Not possible	Yes possible	Yes possible	Yes possible	Yes possible

(Motic, 2021)
(Sysmex, 2022)
(Noul, 2022)

Figure 11: comparison AiDx Medical with competitors on several assets.



The step towards a multi-diagnostic device that includes blood count is amongst the possibilities. It's crucial to also get an understanding into the competitors within this field.

Normally a FBC is done with a hematology analyzer. Many other hematology analyzers are already on the market, both Sysmex and Motic have a big market share, next to companies like Abbott, Siemens, Beckman and multiple other Chinese and American companies. There is a large range of devices from simple to complex. The price range for simple (cheap) hematology analyzers is between 3000-6000 Euro. Within the cheaper price range the devices can't diagnose as quick (max. of 60 samples an hour) as the more expensive machines which diagnose till 200 samples an hour. More expensive machines are also able to detect more specifically or they can test more components within the blood. (Hospitals Store, 2022). Within emerging markets manual methods are also commonly used to perform the test, these are done with a general microscope.

Benchmarking within scope

Define attractive growth opportunities

Multiple diagnostic healthtech start-ups, scale-ups and companies are operating in the same or a similar scope. AiDx might be able to learn from them while setting up a PSS. That is the reason research has been done within those companies to understand how they are creating extra value to their medical service: in the search for a unique feature, selling point or collaboration. Next to that it has been an exploration if a hypothetical venture is amongst the possibilities.

MDaaS

MDaaS is an abbreviation for Medical Diagnostics as a Service. The goal of MDaaS is to build healthcare for Africa's next billion. Initially they started as a supplier of American and Chinese diagnostic devices in Nigeria. However they grew into a healthcare provider with clinics across five states in Nigeria. Clinics that focus on delivering affordable diagnostic services to low- and middle-income patients. They are growing fast. This is possible because of their tech-enabled diagnostic devices which allow them to diagnose a high volume of people. Next to building affordable primary healthcenters themselves they are working on a platform for more personalized, continuous and preventive care. Since MDaaS is operating within the same market as the target market of AiDx, this could be an interesting partner. (MDaaS, 2022); (O. Oni, interview, January 27 2022)

Ilara Health

Ilara Health is aiming to become a tech-enabled primary care network in Africa. Besides delivering innovative diagnostic devices to existing primary clinics with a lease model, they are offering them the option to become part of their network, to become a franchise of Ilara Health. In this way, clinics have always access to the technology of Ilara Health (up-to-date diagnostic devices). But they are also provided with expert support for digital campaigns, medical camps, marketing strategy, lab management system and an EMR. By investing in this network they are able to deliver much more value compared to when they would only stick to supplying diagnostic devices. Currently Ilara Health is active in Kenya, but they are planning to expand to other countries in Kenya. Ilara Health could be an interesting partner, since they are always looking for new diagnostic devices. (Ilara Health, 2022); (E. Popa, interview, November 1 2021)

PharmAccess

PharmAccess is a big international non-profit organization which operates in the scope of emerging markets. Unlike the others within this chapter they are not developing or delivering diagnostic devices themselves and they are not building health centers. In short they co-develop low-cost insurance platforms (mainly focussed around creating care bundles); they try to introduce quality standards within health clinics; they provide loans and business support to private healthcare businesses and they conduct independent academic research. This research also resulted in their idea for connected diagnostics, an interesting concept where AiDx could potentially serve a role. (PharmAccess, 2022); (T.R. De Wit, interview, December 10 2021)

Matibabu

Matibabu is, just like AiDx in an early stage of developing a viable business case surrounding their malaria diagnostic device. Matibabu decided to have little focus on the device within their communication to the outside world but rather focus on the platform 'Yotta' they are developing. A platform which is both an online notebook (EMR) and a dashboard to collect, to organize and to visualize disease data. In this way they are trying to create value for a greater network of stakeholders. From end patient, to government, to NGO and pharmaceutical companies. (Matibabu, 2022)

Delft Imaging

Delft Imaging, which also has her roots in Delft, started with a similar idea as AiDx. However with the focus on a different disease and diagnostic technique. They have developed a device which is able to diagnose TBC in a very accurate way. They brought this solution to Africa, where the disease burden for TBC is high and a big amount of patients can be diagnosed. Just like MDaaS they decided to build clinics themselves, after introducing their device on the market first. Since the device has been proven to work very efficiently and all certification is in place, the demand from governments and NGOs is high. Having (non-)governmental stakeholders as their first target customer causes a system of public procurement. Eventually their goal is to expand even more and to create full operating diagnostic centers within emerging markets with more diagnostic devices than just for TBC. Diagnostic centers which provide comprehensive diagnostic services with the highest possible quality. (Delft Imaging Systems, 2022), (F. Geerts, Interview, October 29 2021)

What can AiDx learn from their predecessors

After evaluating the three mature companies in the list that are closest to AiDx Medical, respectively MDaaS, Ilara Health and Delft Imaging, it's possible to draw some useful conclusions. All of them started with a relatively simple business model before investing in new opportunities via business model innovation. Both MDaaS and Delft Imaging started with outright sales of diagnostic devices, functioning as a supplier of diagnostic devices: MDaaS as a distributor of existing diagnostic devices and Delft Imaging with their own TBC diagnostic device. Ilara Health initiated their business as a lease company for existing diagnostic devices. As a first step to the market AiDx should also start with a business model which is close to the strengths of their organization. Currently AiDx is an OEM without too much experience in the market (yet), rolling out a very complex use-oriented PSS might therefor not be the best fit.

All three of the companies should also be kept in mind as potential partners. They are all making the step towards creating a network of diagnostic centers, the AiDx assist could potentially be implemented in some of those clinics.

The other two that are mentioned within this chapter, PharmAccess and Matibabu, give us an insight into attractive value propositions that could be pursued. Both connected diagnostics and data collection are distinguished as potential ways of creating more value. Further in the report these value propositions are explored for the malaria market.

Concluding

Almost all malaria diagnostics take place in the stand-alone laboratories and primary health centers across Nigeria. It's possible to divide them into two segments: luxurious automated labs/ healthcenters and manual labs/healthcenters. The first segment has access to automated diagnostic tests whereas the second segment hasn't. However both client segments share the fact that microscopy is (still) the standard technique of diagnosing for malaria. Most patients pay for the malaria expenses out-of pocket due to the little sponsoring by the government.

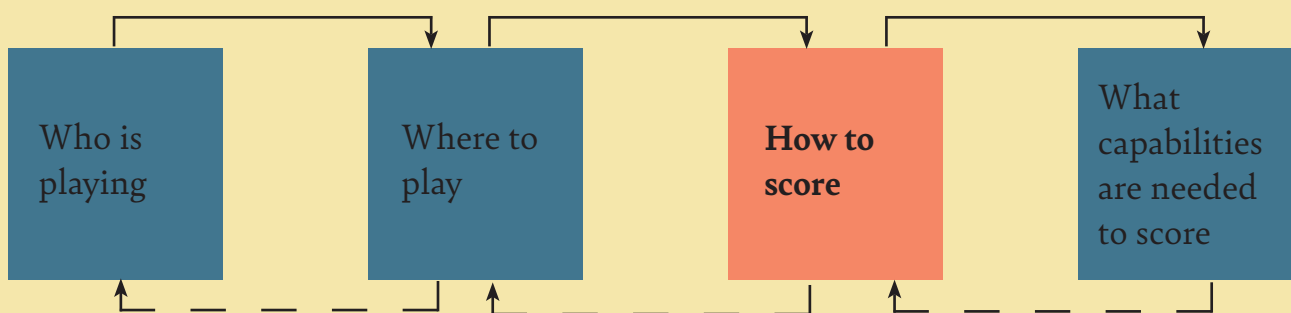
AiDx faces multiple competitors in the scope of malaria diagnostics. Next to RDT and general microscopy there are three other companies who have also developed an automated diagnostic device. The affordability, due to its simplicity, makes the AiDx assist stand-out compared to their most direct competitors.

After doing researching into other start-ups with similar ventures we can conclude that it's important to work step-by-step, by starting with a business model which is close to the means of AiDx. Also, MDaaS, Ilara Health and Delft Imaging, the companies which have been used as an example could be interesting venturing partners.

Blood count is the most performed test besides malaria within labs and PHCs, this is potentially an attractive growth opportunity for AiDx to dive into. Not only because of the extra value it gives to the device but also as a strategic step beyond malaria, since RDT are developing rapidly and the use of RDT is increasing.

How to score

This chapter describes how AiDx could match their product and organisation to the market. It explores what the central idea of the business case and the core of the PSS could be. After investigating the context and exploring possible directions for AiDx in previous chapters, this chapter is focussed around converging into a more concrete idea for a market introduction.



Define central idea & strategy

As described before, AiDx is preferably looking for a use-oriented PSS surrounding their AiDx assist. This chapter describes the underlying motive and poses supporting theory on product-service systems.

Product-service system

The goal of this project is to design a product-service system surrounding the existing AiDx device. A product-service system is a designed combination of tangible products and intangible services which are combined, so that they are jointly capable of fulfilling specific customer needs. Creating a PSS is a process of integrating a business model, product and a service with an innovative solution as end result. (Diehl, 2021)

A lot of research has been done into PSS. Tukker (2004) created a visual as seen in figure 12 to visualize the different PSS that exist.

A **product oriented** PSS is a PSS where the tangible product is still the basis. But unlike selling a pure product, multiple services are delivered as an add-on by the supplier. Services like maintenance and repair for example.

Within a **use oriented** PSS the ownership of the product remains with the supplier of the PSS. In this scenario the customer will use the product via a predetermined contract. Where sharing, pooling or leasing is the standard.

A **result oriented** PSS is based on delivering a result, within this model the client pays for the solution only.

Especially use- and result oriented PSS are increasingly popular. Within Europe many have been introduced over the last 10 years. The most typical example within the faculty of IDE is SwapFiets. Instead of selling a bike to the customer, transport on a bike is sold. A bike is leased to the customer with the promise that they will always have a working bike. For a fixed price per month the customer is able to ride the bike and SwapFiets will repair the bike directly when it's broken.

Besides Europe, also in emerging markets there is an increase in the amount of successful PSS that are being deployed. One great example is the PSS of SolarWorks, they created a use-oriented PSS. Their solution is to deliver energy solutions to rural areas who are not connected to the energy net. When becoming a client of SolarWorks, people within these villages are supplied with a solar system. This

solar system is paid back in a pre-defined amount of time which means at the end of the contract the client has full ownership over the product. During the time of the contract both maintenance and repair are included.

A PSS for the automated diagnostic device of AiDx will likely be closer to product-oriented or use-oriented model than a result oriented model. Unless for example a very innovative model is created around selling the solution of a malaria free life to patients directly. However the question remains whether the market is ready for these types of solutions.

In-depth interviews with Temitope revealed that AiDx prefers to pursue a use-oriented PSS. *So what could be the benefits for AiDx when chasing a use-oriented PSS compared to outright sales or a more product oriented system?* Multiple advantages are described by Diehl & Christiaans (2015) and are applied on AiDx.

AiDx will be able to distinguish themselves from the competitor by delivering a service which can't easily be copied.

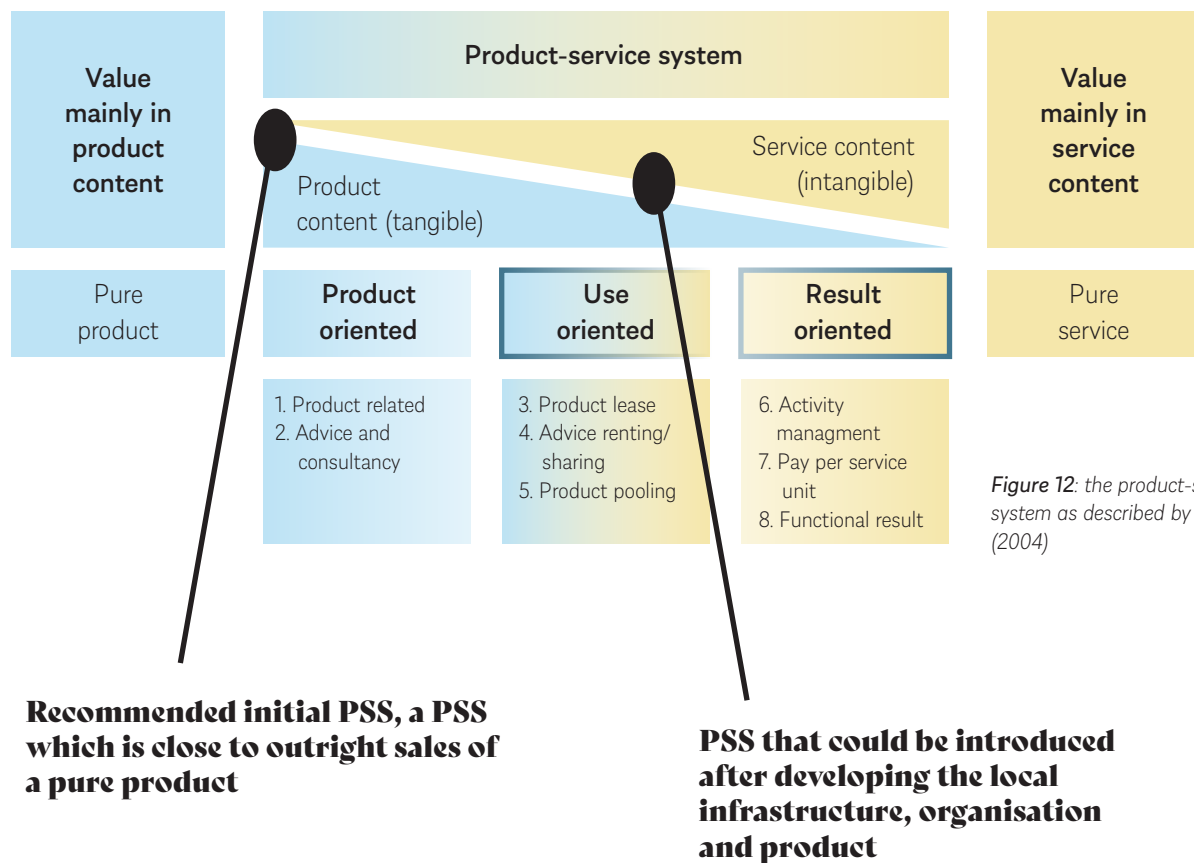
They are able to build long and strong relationships with clients. Next to that the service delivered is flexible and personalized.

An use-oriented PSS is highly flexible and AiDx could adapt quickly when the context changes or when the customer preference changes.

For customers the most important benefit is that they will not have to pay for the full value of the product, so PHC and labs who can't afford the whole product are also able to use the product.

Next to the advantages as mentioned by Diehl and Christiaans there are some other financial benefits to a PSS. Within a use-oriented PSS you are creating a system where recurring customers are the norm. Recurring customers means you create financial security. Furthermore, on a more operational level, it's interesting for investors, banks or in the case of AiDx for medical insurance companies.

Both a product-oriented as use-oriented PSS will be amongst the possibilities for AiDx to enter the market with. However when looking back at the conclusions from the last chapter, especially the ones that followed from benchmarking within the scope, we can conclude that the initial market introduction should be simple and close to the means of the company. With the current skill-set and organisation of AiDx it will be extremely hard to roll out an use-oriented PSS. For the first market introduction a more product focused PSS or outright sales is therefore advised.



Why not limit to malaria and outright sales of devices?

Next to the advantages of a PSS as described above, there are multiple other reasons why AiDx shouldn't limit herself to outright sales of an automated malaria diagnostic device.

The market for malaria is under pressure because of RDT. Once trust in RDT is built throughout the healthcare market, it will likely become an even more common diagnostic test for malaria (T.R. De Wit, interview, December 10 2021). Because of the simplicity, price point and easiness of use, a RDT is an appealing alternative to microscopy and even to automated microscopy.

It's recommended for AiDx to create a value proposition beyond malaria diagnostics only.

Lastly, as described later in this report, AiDx could improve their market share by expanding beyond outright sales of their devices. This is mainly due to the fact that many health centers can't afford to buy the machine out-of-pocket. An use-oriented PSS enables them to get access to the device of AiDx Medical.

Route to market

Within this chapter a strategy is proposed for AiDx how to continue with their quest towards the implementation of a viable business case around their automated diagnostic device. On the right page there is a summary of the exploration into potential propositions for AiDx to build a strong use-oriented PSS around; an exploration into opportunity spaces for AiDx Medical beyond malaria diagnostics only.

As concluded in the previous chapter it's wise for AiDx to wait with the introduction of an use-oriented PSS till they have invested in the infrastructure. In figure 13 a visualisation can be found of what the strategy for AiDx could look like.

Within horizon 1, AiDx could kickstart their business with a product-oriented PSS around a malaria-only diagnostic device (since this device is almost ready to deploy), where only basic service elements are added to the system (e.g. repair, maintenance and warranty). By investing in this PSS, setting up the business locally, building a client base, building brand awareness, they are simultaneously also laying the basis for horizon 2.

Horizon 2 is the step towards the desired use-oriented model. When the basis infrastructure is built; when AiDx has liquid assets; when AiDx has money to invest and when AiDx has a strong team both locally in Nigeria and in the Netherlands, they will have the means to move towards an use-oriented PSS.

Horizon 3 could be the step after horizon 2, where AiDx could start uncovering future opportunities by developing disruptive business models. In appendix 4, some of these routes are mentioned and visualised.

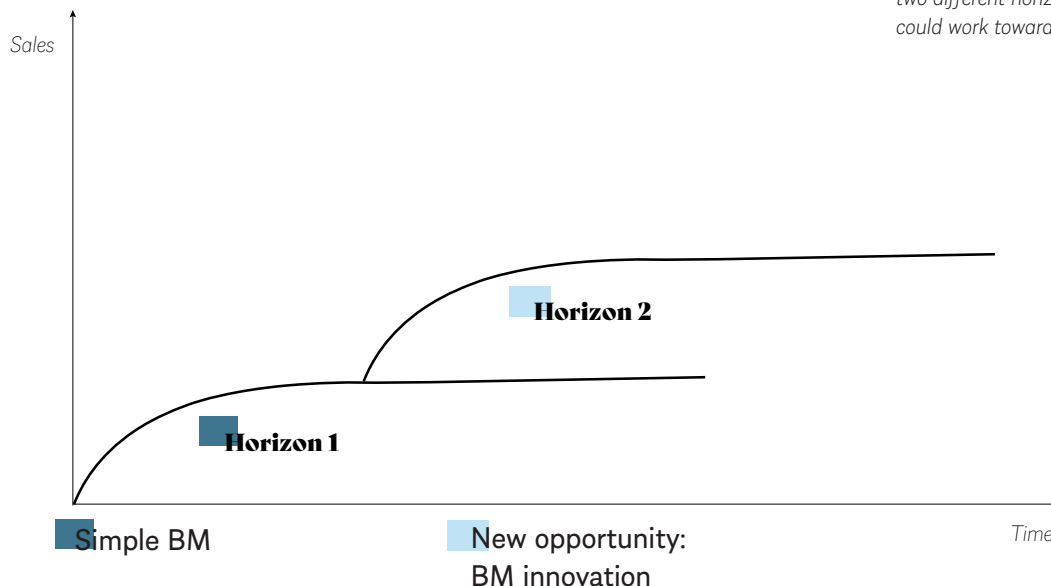


Figure 13: A visualisation with the two different horizons where AiDx could work towards

Focus:	Introduce a BM close to the capabilities of AiDx	Expand initial business model, roll out use-oriented PSS
Output:	Build the initial infrastructure for the product; R&D into the new opportunity; detailed planning for growth of BM	Business model innovation; look further into potential new ventures; expand business and product

Potential propositions horizon 2

1 Connected diagnostics

Connected diagnostics is a concept that is being developed by PharmAccess. Within connected diagnostics a system is created to connect patients to micro-funding. It roots in the thought of decentralizing the healthcare in emerging markets, where funding goes directly from the NGO to the end patient via a platform and not via the local governments.

Once a patient is diagnosed for a disease like malaria, they can check the result in the platform 'M-Tiba'. Once a patient is diagnosed positive, micro-funding is released into the online wallet of the patient. This micro-funding can be used by the patient to pay for the medicines which are needed as a cure for the disease. These medicines can be bought at certified PMVs or pharmacies.

For both the end patient as the NGO it's a win-win situation. For NGOs it creates transparency of where their funding ends up. A patient is able to get medicine for free within this system, thus they would probably choose for a M-Tiba qualified diagnostic center. This enables the system to grow rapidly.

The question is whether AiDx could join PharmAccess in their quest of creating a connected diagnostics system, if this would be a desirable and viable value proposition to focus on beyond malaria diagnostics only.

(van Duijn et al., 2021)
(T.R. De Wit, interview, December 10 2021)

2 Eradicate by mapping

The idea for this proposition derives from the trend of data management, the COVID-19 crisis and the business idea of Matibabu.

Within the fight against COVID-19 we have seen the importance of data collection. A large collection of data makes it easier to strategically build a network of providers which focus on prevention, diagnostics and treatment of the disease.

Since the AiDx assist promises the same specificity as microscopy and a digital result, the step towards data collection is small. As the core for an use-oriented PSS within horizon 2, the sales of data might be an interesting proposition. Instead of solely diagnosing people AiDx could try to create more value by putting their main focus on data collection.

This data could be sold to (non-)governmental organizations, who are working towards the higher goal of eradicating the disease. Eradication of malaria is possible, but only when there is enough data, AiDx could respond to this with the proposition of their device.

3 Upgradable multi-diagnostic device

As mentioned before within this report, a multi-diagnostic device has always been a vision of Temitope. Out of all other potential propositions that are being described in this chapter, this one is closest to AiDx and the AiDx assist. Closest to the means, as described by the bird-in-hand-principle (Sarvasthy, 2009). It won't be long before the AiDx machine is able to detect more than just malaria, so why not focus with the creation of a business case on this logic. As also quoted by Tobias Rinke de Wit in the interview with him:

“The future is multiplexing, there won't be a single test for a single disease anymore. All trends are pointing towards that direction”.

AiDx could start with adding a blood count analysis to the AiDx assist. The microscopic scale is the same as for malaria, the staining method is the same and the machine learning program will be close to the one for malaria parasites. In the future the AiDx assist could then also be upgraded with other diagnostic tests, for example sperm count (which also has a similar microscopic scale as malaria).

Match market, product, organization

After introducing the AiDx assist for malaria diagnostics on the market in Nigeria with a basic product-oriented PSS, AiDx could start building towards the second horizon. This chapter discusses the proposed value propositions that were found as most promising for horizon 2. For a successful launch, both the market, product and organization should have a green light. Underneath an overview is given into the combination of MPO: how the product or organization should change to be able to pursue a particular value proposition and if the market is ready on the short term for the business logic.



A green light means 'good to go', the M/P/O is ready for the particular value proposition.

An orange light means that it's a possibility, but development is needed within the M/P/O to be able to pursue the direction.

A red light means the M/P/O is not ready for this type of value proposition and will not be ready in the near future.

Connected diagnostics

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For AiDx, to be able to build a PSS around the business logic of 'connected diagnostics', a lot has to change within the product and organization. The product needs to be connected to a central database where funding is divided to the end patient. Within the organizational structure of AiDx this also means significant changes need to be made. However, this is not an impossible task within the coming years (in horizon 2), and thus an orange light is given to both the product and organization.

Only the market is not (yet) ready for the introduction of the concept of 'connected diagnostics'. Also it doesn't seem it will be in the near future. Governments within emerging markets are not willing to cooperate within connected diagnostics. They don't benefit from transparency within the healthcare industry. The main reason is simply corruption. Local governments prefer to divide international funding themselves. In this way they can take a cut themselves. Unfortunately corruption is still a great problem in SSA countries.

Or as Rinke Tobias de Wit quoted, "we should step away from the thought that African governments are there to help their inhabitants, they only think about themselves, how they can improve their own life". (T.R. De Wit, interview, December 10 2021).

Funding is needed for connected diagnostic to sustain. However for a NGO it's impossible to support this system if there is no permission from local governments. Governmental permission is needed to bring funding into the country. PharmAcces is trying hard to deploy this construction but currently this isn't a possibility. Therefore we can conclude that the market will not be ready any soon for this type of business logic.

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Eradicate by mapping

Just like within the business logic of 'connected diagnostics', AiDx would have to invest in a strong database that is connected to their devices. Within the organization of their business they might have to completely rethink their way of working. If data would become the main value proposition and main income stream, then a lot of data has to be collected throughout different areas in Nigeria. This means AiDx would have to move through the country to collect blood samples, which is a total different starting point than horizon 1. However it's not impossible to build this infrastructure.

But then also the market has to be ready for this type of value proposition, unfortunately this is not the case according to Mark Connell from the Malaria Atlas Project (the largest database for malaria worldwide). The main reason he poses is that there are multiple other ways of collecting data within the scope of malaria. Next to essays within the population, data is collected via predictive mosquito models, weather models, NGOs and more. (M. Connell, interview, January 31 2022).

Therefore, choosing data as your main income stream and value proposition becomes a real challenge. The data for malaria is simply not sellable (yet), no party has an incentive to pay for malaria data in Nigeria. Initiatives like MAP are not for profit and survive on both gifts and funding from the government.

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Upgradable diagnostics

For an upgradable multi-diagnostic device the market is green. Different client segments are open towards the idea of upgradable diagnostics, since it improves the current standard and enables the access to new techniques for diagnostic tests.

AiDx needs to keep improving their current device so it can actually run multiple diagnostic tests within the same machine. The first diagnostic test to develop should be (full) blood count. This has two reasons, firstly there is a high demand from the field: multiple labs are asking for a device which can do both malaria testing and FBC. Next to that, full blood count testing is a very common test to perform in Nigeria. A test which is increasingly popular in Nigeria, since a FBC says a lot about the general condition of a patient. Also it could point out, after testing negative on a malaria diagnostic test, where the fever of a patient could come from. After testing positive for malaria it could also be a relevant test, since the test can show how the body is reacting to the malaria infection and accordingly a doctor can specify what kind of treatment is recommended. Within the next part of the report, a summary is given on how the organization and product have to change to be able to dive into this value proposition.

Suitable client segment per horizon

This chapter describes the value proposition that fit the predefined client segments in the market. The question remains who AiDx should target respectively within the first horizon with their malaria diagnostic device and in the second horizon with their multidagnostic device for malaria parasites, blood count diagnostics (and more). The insights that are described in this chapter are derived from validation sessions in the market with multiple stakeholders and try to answer this question. A summary of the validation sessions can be found in appendix 7.

Figure 14

● ● ○ = level of match

	Product		PSS	
	Malaria-only AiDx assist	Upgradable AiDx assist	Product-oriented	Use-oriented
Private 'automated' PHC & labs	The reduction of time spent by a pathologist is an advantage. Within the private sector time is money. ● ● ●	Private automated PHC & labs already invested in automated devices for blood count which have better specifications than the AiDx assist. Upgradability is not an addition in this case. ● ○ ○	The bigger automated and luxurious PHC/ labs have enough financial means to invest in their own devices. ● ● ●	Within this segment they prefer owning devices over leasing out of profit maximisation reasons. ○ ○ ○
Public 'automated' PHC & labs	Within the public sector the diagnostic time is not necessarily a key driver to make an investment. ● ● ○	This client segment already has access to automated hematology analyzers and other automated diagnostic tests that the AiDx assist might be able to perform in the future. ○ ○ ○	The question remains whether the little amount of automated public PHC and labs are willing to invest in the benefits the AiDx assist brings compared to microscopy ● ● ○	Within this segment they prefer owning devices over leasing out of profit maximisation reasons. ○ ○ ○
Private 'manual' PHC & labs	The microscopes are already invested in for diagnosing for malaria. Implementation of a malariapony device might not be the most viable option for these PHC and labs. ● ○ ○	With an upgradable AiDx assist the PHC and labs get either access to a new diagnostic test or it removes the need to perform manual diagnostics. ● ● ●	These type of PHC and labs don't have the financial means to invest in an automated diagnostic device like the one of AiDx. ○ ○ ○	With a lease model the automated diagnostic device of AiDx comes within reach. ● ● ●
Public 'manual' PHC & labs	A manual method for diagnosing people seems to be sufficient. RDT is a solid alternative, infection rate is not particularly an important extra feature to sell to patients in basic labs. ● ○ ○	With an upgradable AiDx assist the PHC and labs get either access to a new diagnostic test or it removes the need to perform manual diagnostics. ● ● ●	These type of PHC and labs don't have the financial means to invest in an automated diagnostic device like the one of AiDx. ○ ○ ○	With a lease model the automated diagnostic device of AiDx comes within reach. ● ● ●

The insights from figure 14 show there seems to be a difference between the interest in the type of PSS on one side and the type of device on the other side within different client segments.

There is also less interest within this client segment in other diagnostic tests since they already use other automated devices for those tests.

In general the automated PHC/labs in both the public as private sector seem to be more interested in a malaria-only AiDx assist that they buy out-of-pocket. The urge of ownership is very high in emerging markets. Once they can afford a device they rather buy it over leasing.

The basic PHC/ labs that predominantly use manual diagnosing methods in their clinics seem to have more interest in a multi-diagnostic device. Since this enables them to get access to quicker and more reliable ways of performing FBC tests. However an use-oriented model is recommended here since they can't afford to invest in the AiDx assist.

Match AiDx Medical & MDaaS

After benchmarking within the scope, MDaaS global has been defined as an interesting potential partner. To gauge the interest of MDaaS in AiDx, the AiDx assist, a potential partnership and multiple designed business cases, an interview has been held with the CEO of MDaaS: Oluwasoga Oni. A summary of the interview can be found in appendix 7.

After the interview it is possible to conclude that MDaaS is interested in the device and the promised technicalities of the AiDx assist. For their current health centers MDaaS would be interested in the AiDx assist that is able to diagnose for malaria-only, for the same reasoning that is posed on the left page for private automated labs.

However in 2023 MDaaS wants to build smaller labs (spike labs). If the AiDx assist will be able to deliver what it promises to do and when it comes at the right price point, the multi-diagnostic device of AiDx could be a fit in these spike labs. Within the spike labs MDaaS is planning to run the barest minimum of diagnostic tests on site e.g. pregnancy, malaria etc. For more advanced tests, like blood count tests. the blood sample will be sent to their bigger labs for analysis.

However, if AiDx could deliver a device that is able to run multiple of the basic tests, read malaria diagnostics and blood count tests, that would be an ideal solution for this use case. It removes the need for MDaaS to send blood samples to bigger labs. Also the automisation of tests could save diagnostic time which can be used to perform other tests. This is an important asset for MDaaS, since they strive to do as much tests as possible (high volume, low margin is their motto). An AiDx assist could increase their turnaround time positively within the envisioned spike labs.

Within these labs an use-oriented PSS seems to be the preferred model. MDaaS is planning to build a large amount of spike-labs and they will not have the financial means to invest in an AiDx assist in every clinic.

Partnering up with MDaaS seems to be a strategic choice, because organizations like MDaaS can make AiDx Medical scale. AiDx could sell a batch of products at once to MDaaS, those could be implemented in their existing health clinics. Also MDaaS could be a supplier for multi-diagnostic devices for their new concept: spike labs. All-in-all MDaaS would be an interesting channel distribution partner for the AiDx.



Horizon 1:

Implement malaria diagnostic devices in their current health centers

Horizon 2:

Introduce multi-diagnostic devices in the spike-labs of MDaaS global

Concluding

Both a product-oriented as use-oriented PSS seem to be amongst the possibilities for AiDx to create a desirable business case around. However when looking back at the conclusions from the last chapter, especially the one that followed from benchmarking within the scope, we can conclude that the initial market introduction should be simple and close to the means of the company. With the current skill-set and organisation of AiDx Medical it will be difficult to kickstart the business with a use-oriented PSS. For the initial market introduction a more product focussed PSS or outright sales is therefore advised to AiDx Medical. This step is defined as horizon 1.

Due to the saturated malaria market it is recommended for AiDx to also build a value proposition beyond malaria diagnostics. With a value proposition that includes the desired use-oriented PSS. Multiple business logics have been explored as potential value propositions beyond malaria diagnostics but an upgradable device seems like the best fit due to the readiness of the market. Implementing the use-oriented PSS around a multi-diagnostic device is defined as horizon 2.

Then the question remained which PHC and labs could potentially be the client in both horizons. There seems to be a difference between the interest in the type of PSS on one side and the interest in type of device on the other side within the predefined client segments.

In general, the automated PHC/labs in both the public as private sector seem to be more interested in a malaria-only AiDx assist that they buy out-of-pocket. The urge of ownership is very high in emerging markets. Once they can afford a device they rather buy it over leasing. There is also less interest within this client segment in other diagnostic tests since they already use other automated devices for those tests.

The basic PHC/labs that predominantly use manual diagnosing methods in their clinics seem to have more interest in a multi-diagnostic device. Since this enables them to get access to quicker and more reliable ways of performing FBC tests. However a use-oriented model is recommended here since they can't afford to invest in the AiDx assist.

MDaaS is found as an interesting partner to start co-venturing with.

What capabilities are needed to score

This chapter describes how the product and organisation of AiDx has to change to serve the market, both for the first and second horizon. It answers the question of what paymodel fits the client segment best, which partners are needed, what the cost structure and revenue model consist of and what the key activities/ resources should be to grow into a healthy company. Also it emphasizes on the difference between the two horizons, how AiDx Medical should evolve from a product-oriented PSS which is focussed around delivering machines through outright sales to an use-oriented PSS supplier where AiDx remains the owner of the device.



Developing the two PSS

For the design of the two PSS a combination of PSS elements has been used, a list can be found in appendix 5. After creating multiple concepts (especially for the use-oriented PSS), which can be found in appendix 6, the concepts were validated within the market. According to the input of potential clients (PHC and labs) the designs have been sharpened or adapted. In appendix 7, a summary of the validation can be found.

Product-oriented PSS

As described in the previous chapters it's recommended for AiDx to initiate their business around a malaria-only diagnostic device with a product-oriented PSS. By already investing in this type of PSS the step towards a more use-oriented PSS becomes smaller.

Instead of just selling devices with outright sales, AiDx could already introduce some service elements. As seen in figure 15 a strategic start would be the introduction of repair and maintenance services and contracts. This could be delivered through different ways, as described in the visual by a standard monthly fee or through a fixed price per repairment, an insurance construction or else.

Repair and maintenance is a crucial asset within a use-oriented PSS. Within these type of systems, the ownership of a device remains with the supplier and a client pays for the usage of the device. If the device breaks down, the supplier, in this case AiDx, is forced to provide access to a working device as soon as possible. That's why it's recommended to invest in these services prior to horizon 2.

Next to repair and maintenance, AiDx could offer training for local healthworkers who are going to use the machine. This could be added as a free service within the sales price of a device or added as a paid service.

To be able to deliver such services as described before, the infrastructure has to be developed. Local offices need to be positioned and local handyman must be trained to deliver the services. Next to that distribution channels need to be created which includes the production chain and delivery of devices in Nigeria. This is just a fraction of all that has to be developed. The following chapters dive deeper into all assets that need to be developed to be able to do business in Nigeria.

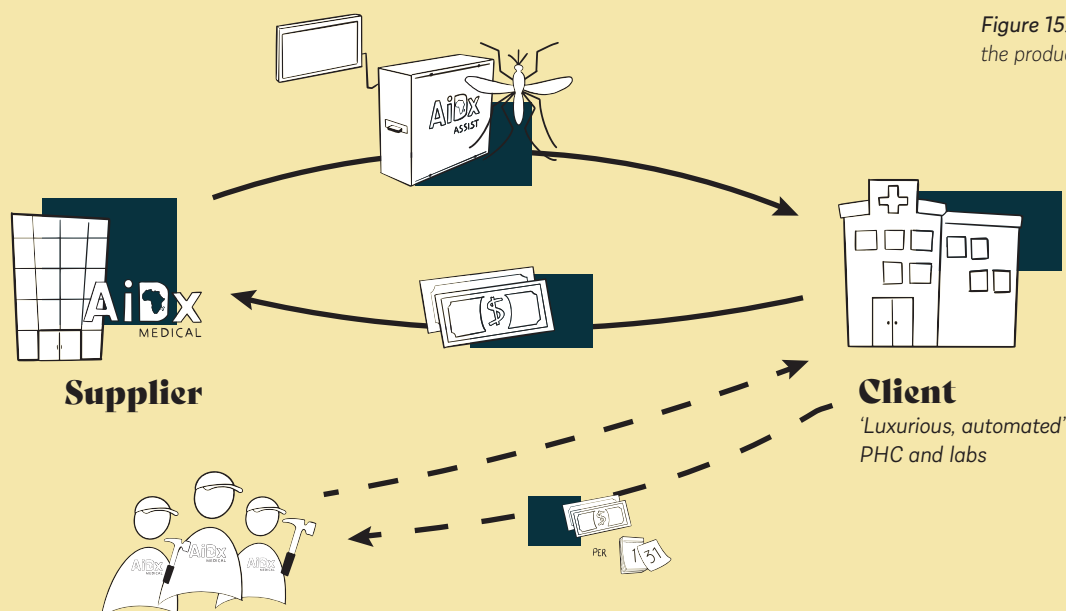


Figure 15: simple overview of the product-oriented PSS

Use-oriented PSS

On the next two pages a visualisation can be found of the proposed use-oriented PSS that is suitable for the client segment of basic private and public PHC and labs in Nigeria.

The concept is created by combining different PSS elements, those elements are inspired by business models of other PSS suppliers. A list can be found in appendix 5. As a starting point for the creation of the concept, first the type of paymodel has been defined. From earlier research and benchmarking within the scope we can conclude that the paymodel is the most crucial asset in a PSS within emerging markets. The available budget within the healthcare scope in emerging markets is little, that is the reason that it's extra important to introduce a business model which is potentially viable for the customer.

Next to the most promising use-oriented PSS as described on the next two pages, two other concepts, which can be found in appendix 6, have also been created and validated within the market. This is done with MDaaS, Clina Lancet Laboratories (Ibadan), Zoe Specialist Mission Hospital (Ibadan) and finally Mr. Animashaun who works in a public lab.

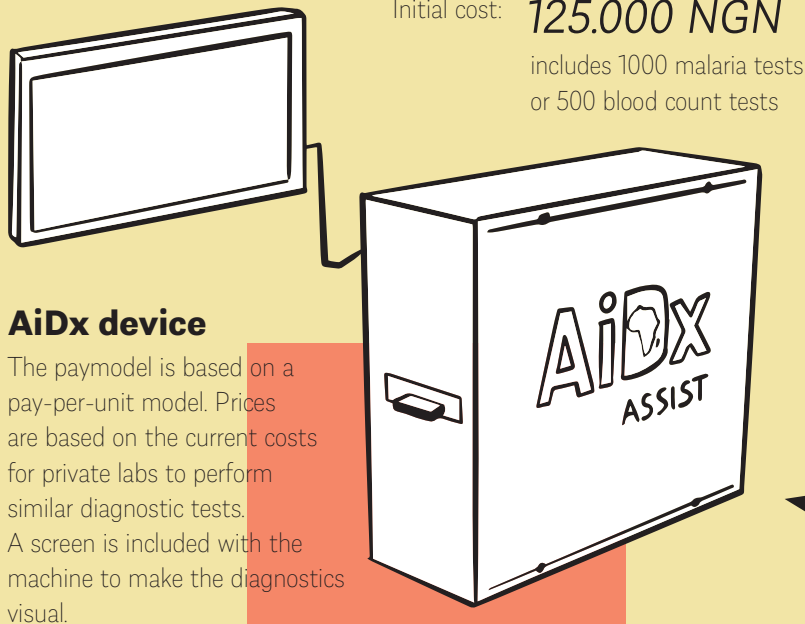
This reason that this concept fits this particular client segment best is mainly due to the type of paymodel. Multiple paymodels have been explored for the use-oriented PSS. However a pay-per-unit (pay-per-test) paymodel was pointed out as the best fitting paymodel. The familiarity with their own business case (charging patients for every test they perform) and low threshold of using the device (only pay what you test for) were the two most important reasons.



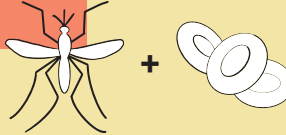
Also within the subscription model that have been tested, there is a danger of paying too much when there is less demand for diagnostic tests due to seasonal changes (in the wet-season there is a rise in the amount of mosquitos and malaria cases).

Besides that, within a subscription model clients might feel that they are tricked. They will be charged extra (for the same machine) if they want to detect multiple diseases. According to the client segment this feels wrong and is undesirable.

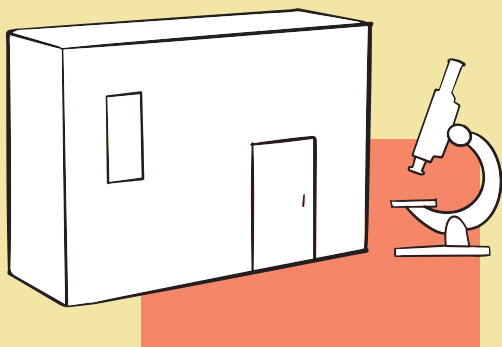
From page 46 onwards, more detailed information is given about the concept. Especially information that is focussed around the implementation of the PSS; how AiDx has to change as a company to start working with a use-oriented PSS; how the product has to change and what the cost-structure and revenue model looks like.

Proposition use-oriented PSS

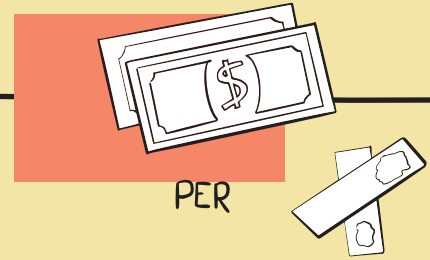


- Type of test**
- 1.  Differential blood count **250 NGN**
 - 2.  Malaria parasites **125 NGN**
 - 3.  **300 NGN**

Detecting malaria is as cheap as using a RDT: stimulate to use the AiDx device



“Basic” PHC and labs
Client



PER

Figure 16: overview of the use-oriented PSS

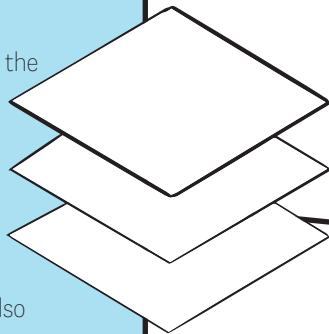


Values

Private laboratories can get access to an automated diagnostic device for multiple diseases without having to make huge investments. As they also charge their own clients with a fee per test, paying per test to AiDx is close to their current business. Revenue is shared with AiDx, the lab or PHC performs the test and AiDx promises to always deliver a working machine.

Data transfer to platform

Data is transferred from the device to the platform. The platform must be created to keep track of the amount of tests a laboratory has performed. Within the platform AiDx can also incorporate their paying system. Where clients are able to pay for the tests they perform. Besides an asset for sales, it can also be used to keep track on the status of the device.

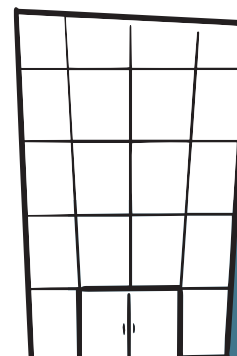


The basis of this concept is the paymodel that many healthcare clinics and labs currently use within their proposition. Many of them charge patients for every diagnostic test they perform with a standardized price per test. In this scenario AiDx is doing the same but on a B2B level.

From another perspective one could argue that revenue which is made by selling the test to the end patient is shared between the health clinic and AiDx in this scenario. A percentage of revenue made with a test is going to AiDx. This money is spent by AiDx on delivering the necessary service to their clients (training, maintenance and repair) and to do R&D (to be able to give their device future updates).

The price for a malaria test has been set to 0,3 USD (125 NGN) because this is a similar cost price as a RDT (Global Fund, 2020). The price for a blood count test is set at 0,6 USD (250 NGN) since in most private clinics patients are charged twice as much for FBC than malaria (Surjen Lab, 2022). The initial costs for the device will be 125.000 NGN, within these price 1000 malaria tests are included. This is done to set a small hurdle to attract only serious clients. When it's free every health center could demand the device without having a real incentive to start testing.

Within the concept AiDx needs to find a way to keep track of the amount of tests which are done by the client. A connection should be made between the device and a platform of AiDx to make this happen. An alternative could be to offer clients bundles with tests. Which means, if they used their bundle, the machine will automatically stop (similar to credit on a SIM or bank account).



Company



Effects of PSS on AiDx

This chapter focusses on the assets that are needed within the proposed use-oriented PSS. It describes the changes AiDx has to go through, as organisation and how the AiDx assist has to change, to be able to deliver the PSS. Evenso some changes have to be made witin horizon one, when implementeing the product-oriented PSS. On page 49 the difference between the two is highlighted. Besides information that has been retrieved through the analysis of other PSS suppliers like SwapFiets and SolarWorks, many of the insights that are described in this chapter are inspired on validation rounds with the potential clients.

Organization

Implementing the use-oriented PSS means AiDx has to transform from a start-up to an up-and-running company. Obviously this will greatly affect the general business operation, especially because the vision is to become more than an OEM; a PSS supplier.

As a start AiDx has to become a certified manufacturer of diagnostic devices in Nigeria (or screening devices, dependent on the final specifics of the AiDx assist). To be able to deliver devices to clients it's crucial that their product is proven by the authorities to be specific and sensitive enough. Without a (inter)national certificate and legislation it will be impossible to kickstart their business. It's also recommended to get WHO endorsement, this makes it easier for the device to become 'the standard' and to be found by potential clients.

Next to that AiDx will have to broaden their current resources, starting in the Netherlands. The team they currently have should be expanded. A business developer should be hired to develop the PSS further, for hardware and software development it's recommended to hire two FTE.

The key activities of AiDx within the designed PSS would be: sales, repair and maintenance, outsourcing production, distribution of devices and training of healthworkers. Therefore investments should be made in the local infrastructure in Nigeria.

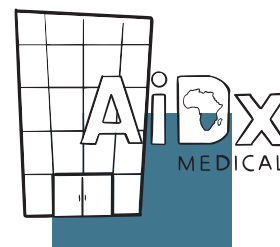
First it's important to have local offices/ workplaces throughout multiple cities, with a headquarter in the city of Ibadan where most partners of Temitope are located. The office is crucial for three main reasons.

1. Storage of devices
2. A workplace where devices can be repaired when it's not possible to repair them on location
3. A place where local employees can come together and work

Second, different type of local employees should be employed by AiDx in the local context. It's crucial to employ engineers who are able to repair and maintain the devices. They also need to be qualified to train local clients how to use the device. Next to the engineers some general managers are needed, who are responsible for the office and all local employees. Besides, it would also be important in this PSS to have a team that is responsible for sales and customer relations.

Thirdly, AiDx has to invest in a network of partners. These partners could help AiDx respectively with building a distribution network, getting local insurance, acces to finance and more.

Lastly AiDx needs to partner up with a platform provider that can create and maintain the proposed platform and data collection. Collecting data is extremely important within this PSS as described earlier and as described within 'the important service elements'.





Important service elements

Repair, maintenance and warranty

Within a PSS that is based on a use-oriented model it's extra important to design the guidelines for warranty, repair and maintenance. Since the ownership of the product is moved from the customer to the provider in the use-oriented PSS it's a necessity to set strict regulations on what the provided service will look like.

Research by Exner et al. (2017) also mentions the importance of maintenance while deploying an use or result-oriented PSS. Within their research they emphasize on having a proactive attitude towards maintenance and service. This will extend the lifetime of products. Capturing performance data could be an interesting way of timing maintenance and prevent malfunctioning of the device. Also the amount of tests that is being done by the health center or lab could potentially be tracked as a solution within preventive maintenance.

AiDx could also learn a lot from existing use-oriented PSS suppliers like SwapFiets, Splash or Solarworks in the way they are delivering service to their clients and the terms and conditions they designed to maintain a good customer-provider relationship. AiDx should create a similar basis as them.

Both SwapFiets and Splash Lease deliver a device to their customer which is in the same price range. SwapFiets delivers bicycles and Splash delivers washing machines, they are both doing this with a use-oriented model, more specifically with a lease model. Within both cases the device is being used intensively and thus there is a high chance that parts break down or malfunction over time. Since they still own the device it's their task to also repair the device when it breaks, because the contract states the client should always have a working device. There are limits however to this agreement. In the case of SwapFiets the user has to pay for a stolen bike or lost key. Splash charges customers only for improper use.

AiDx should strive for a similar service. When an AiDx assist breaks down they should set the promise that the client has a working machine within 24 hours. It would be terrible for both clinic and patient if manual diagnosing methods have to be used in a possible life-threatening situation.

Repairing the device must be free, unless the malfunction is caused by improper use of the device. E.g. when coffee is spilled onto the device or when the device is dropped from the table. When this happens the client should be responsible for a part of the costs, an amount which is fixed in the contract. Also when a device disappears, the client should be made responsible, otherwise there would be a risk of reselling.

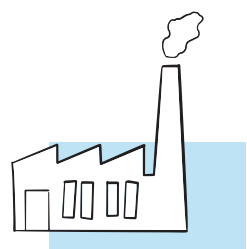
Trust will be a big factor within the client-provider relationship since it's very hard to prove whether improper use has been the case. Risk management, credit-insurance and explicit contracts should be used to minimize negative side effects.

Summarizing, it's key to create an explicit contract which sets rules to the client-provider relationship, especially in the way how the client interacts with the product. Next to that proactive maintenance will extend the lifetime of the device. Lastly, within the case of AiDx it's important that regular checks are being done to the deployed devices.

Production, transport & assembly

To be able to fully focus on the key activities, the process of production, transport and assembly must be streamlined.

Currently all parts of the AiDx assist are produced in China and shipped to the Netherlands where the device is assembled. When AiDx will choose a PSS to work with it's important to define where production and assembly will take place. The question remains whether it should take place in China, as it is now, move to another country or happen locally in Nigeria. It's a strategic choice which could give AiDx a competitive advantage when chosen rightly. Unfortunately it's outside of the scope of the report to do extra research into this topic.



Device

Some changes need to be made to the device, to make the use-oriented PSS implementable.

First, it's important to create a connection between every single device and a server or platform which is monitored by AiDx. Therefore it's important that the device will be connected with the internet throughout its lifetime. Or at least make a connection every now and then (every week at least) to synchronize data from the device to the server.

Keeping track on this data is not only crucial for charging the client per test they perform. It's also relevant for keeping track on the performance of the device. As mentioned before maintenance is very important within the designed PSS. If AiDx can track the performance per device it could intervene before a device critically fails, or they can plan a regular maintenance after a certain amount of test. It would also be desired to have remote access to the device, to be able to shut a device down when it malfunctions or when a client doesn't pay his bills.

Some adjustments also have to be made to the design of the device, emergency batteries should be added for when the net power supply is off. Something which happens occasionally in the scope of Nigeria. A hybrid system is the solution: the emergency battery charges when there is net power, when there is an electricity failure the device will be powered by the battery. A GPS tracker should also be added to the device, to avoid reselling and constant movement of devices. This is unwanted behaviour from clients.

Also R&D should be done in the reparability of the device. To define whether modules within the device can be altered so that the reparability of the device goes up.

Within the PSS concept the amount of devices that is needed by a client depends on the average amount of tests they run daily. The device can run a test within approximately 10 minutes, including switching between samples, a healthworker is able to run 5 tests an hour. This means that 40 diagnostic test can be ran every day. If the daily average of a client is higher they should be able to demand an extra device.



Financially

Within the PSS the initial costs for AiDx will be high. The reason is that AiDx will have to invest in devices, the infrastructure, personnel, sales and more without receiving instant ROI. Due to the paymodel that has been chosen, there is a constant flow of little revenue per customer instead of one fixed price per sale.

To be able to sustain as a healthy company, many paying clients are needed in the system. Especially because it's such a fragmented market, in which there are little bigger consortia of PHC and labs. Further in the report an overview is given into all costs that make up the use-oriented PSS. Later a revenue model is used to define how many paying customers are needed to cover all costs in a year.

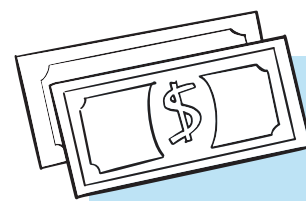
Without investors or a loan it will be impossible for AiDx to start the implementation of a PSS. This means finding investors should be priority number one.

There are multiple ways of getting investments to be able to kick-start the implementation of one (or multiple) PSS. The most promising are venture capital funds and crowd sourcing. Venture capital funds are similar to classic investors however they tend to take slightly more risk by investing in multiple small start-ups. Crowd sourcing companies like Lend-a-hand have a platform where start-ups like AiDx or other projects could be added to. When being added to the platform it allows consumers to micro-invest into the idea, with the promise of a yearly interest rate.

Partnering up with IFC could also be an interesting technique to grow as a company. IFC connects OEM, financial institution and healthcare providers in Africa. In this way they enable private health care providers to acquire advanced equipment which improves the quality and reliability of care provided.

Interesting venture capital funds are:

- Newton Partners** (who invested in MDaaS)
- Global Ventures** (focus on emerging markets)
- Villgro** (incubator of social enterprises)



Use- vs. product-oriented PSS

●●● = HIGH or YES
○○○ = LOW or NO

		Product-oriented PSS	Use-oriented PSS
Device	Blood count upgrade	○○○ Malaria-only diagnostic device	<p>●●●</p> <p>Within the previous chapter a description is given of how the organization and product should change in the proposed use-oriented PSS. The most crucial assets are described again in this table. This table emphasizes on the differences between the use-oriented PSS and the product-oriented PSS. The use-oriented PSS is used as a benchmark and thus all assets score maximum. The column on the left relatively shows what changes need to be made within the product-oriented PSS.</p> <p>As mentioned before in the report, AiDx could use the first horizon (introducing a product-oriented PSS as a first step towards an use-oriented PSS. As showed on the left in this table, many of the assets that are needed within the use-oriented PSS already need to be established in the use-oriented PSS. Especially within the organization.</p>
	Rural area proof	●○○ This client segment is mainly positioned in urban areas	
	Capture data	○○○ No, data is not a crucial asset within this system	
	Platform	○○○ A platform is not necessarily needed	
Organization	Local office	●●○ Yes, one or two buildings are needed for employees, storage and repair.	
	Personnel Nigeria	●●○ To deploy this system, investments have to be made into local employees.	
	Expand NL personnel	●●● The team has to be expanded, similar as in the use-oriented PSS	
	Need of partners	●●● Multiple partners are needed to deploy the PSS	
	Maintenance	●○○ The PHC/ lab owns the device, some might request maintenance	
	Repair infrastructure	●●○ Deliver repair as a service	
	Prior investments	●●● Investment in local offices, devices etc.	
	Trade-offs	By selling the devices directly to the client there is instant ROI. However this also means AiDx constantly needs to look for new customers to make profit.	
	Risks when introducing this concept	To make revenue AiDx constantly has to search for new paying customers. Amount of interested PHC and labs is limited.	Being the owner of the device brings risk: misuse of the device, carelessness, risk of stealing. Also huge investment costs.
	Benefits	Instant ROI. Next to selling devices AiDx could also sell other assets to the customer: repair and maintenance, reagents etc.	Many monthly paying customers (recurring clients). When the infrastructure has been developed it's easy to expand to other markets.

Figure 17: table in which the two PSS are compared with each other

Cost structure use-oriented PSS

This chapter has been added to give an indication what it means for the cost structure when deploying an use-oriented PSS. The cost structure helps to get an understanding of where the (hidden) costs are within the proposed business case for horizon 2. If there is a clear understanding into all costs that the business case brings, it's easier to define how many devices should be deployed to make profit. Within table 18 the costs are divided into two different sections: fixed costs and variable costs. The last column specifies where the variable is dependent of.

Type of costs	Fixed (yearly) (NGN)	Variable (NGN)	Variable dependent on
Device (raw components)	0	245.000	Amount of clients
Assembling (local engineer ^{**})	0	3.750 ^{***}	Amount of devices
24% tax (import duty, port tax, VAT) ²	0	59.000	Amount of devices
Rent office Netherlands & Nigeria	5.500.000 + 1.400.000	0	-
Employees Netherlands (4FTE, 2 interns) ¹	78.617.000 ^{****}	0	-
Fixed employees Nigeria (sales and GM ^{**})	3.600.000 + 7.200.000	0	-
Repair and maintenance (local engineer ^{**})	0	75.000 ^{*****}	Amount of devices
Repair and maintenance (replace components)	0	50.000	Amount of devices Seriousness of damage
Transport	0	11.500 ^{*****}	Amount of devices Location of production
Training clients (by local lab scientist ^{**})	0	7.500 ^{*****}	Amount of clients
Depreciation device (yearly)	0	61.000 ^{*****}	Amount of devices
R&D ^{*****}	7.000.000	0	-
Cloud management ³	5.500.000	0	-
Sales and promotion ^{*****}	2.500.000	0	-

^{**} Monthly salary (NGN)⁴, general manager: 600.000, sales manager: 300.000, mechanic 150.000

^{***} Based on half a day work per device per mechanic

^{****} FTE is set on a yearly salary of 40.000 euro, intern: 5000 euro yearly

^{*****} Assumption of 10 full days of repairing yearly for a mechanic per device

^{*****} Shipping costs China - Nigeria is 25 euro per device

^{*****} 1 full training day, training bij a local employee

^{*****} The assumption has been made that a device lasts for 4 years

^{*****} Estimation

General remark: a month contains 20 working-days

Exchange rate: 1 EURO = 462 NGN

Figure 18: table with an overview of different type of costs within the PSS

¹(Randstad, 2022)

²(Nations Encyclopedia, 2022)

³(On Audience, 2022)

⁴(Salary Explorer, 2022)

⁵(Nigerian Price, 2021)

Revenue model use-oriented PSS

Within this chapter an overview is given of how many paying clients AiDx needs within the proposed PSS to create enough revenue to make profit. It describes how many devices must be leased in a year to break-even. The calculation that is made on this page is just an indication. Much data is based on assumptions within this chapter and the chapter on the left.

An important note: since the calculation has only been added to give an indication of sales sizes, the calculation assumes that at the beginning and end of the year the amount of products leased is the same. When first introducing the PSS this obviously will not be the case, thus in the first year this amount will be significantly higher.

First, the revenue per client has to be calculated on a yearly base. Earlier in this report we've concluded that in many health centers and labs, malaria diagnostics and blood count tests are combined. Research in the field pointed out that within smaller clinics, the volume of diagnostic tests for both malaria and blood count is 200 tests monthly. In a medium-sized PHC this amount rises to 400 tests per month. The average of 300 diagnostic tests per month will be used within the revenue model to count with. As set earlier in the report a combined test of both malaria and differential blood count costs 300 NGN. The revenue per device per month follows from a simple calculation: $300 \times 300 \text{ NGN} = 90.000 \text{ NGN}$. This translates to an amount of 1.080.000 yearly.

To calculate the break even point within a year, we also have to take a look at the cost structure on the left. Since all variable costs are depended of the amount of devices leased, it's possible to add them up to each other. Per device, per year the variable cost are 512.750 NGN. The fixed costs are set per year on 111.317.000 NGN.

The following assumptions are made to simplify the calculation:

- Every client owns 1 device.
- The costs of the device, assembling, tax, transport and training is all paid for in the first year.
- The amount of devices that are being leased are the same at the beginning of the year and the end of the year.
- The amount of tests that is being performed per client is constant and the client always performs a combined test.
- The amount of personnel, cloud management, R&D, sales and promotion is sufficient to serve the amount of clients that is being calculated.
- Horizon 1 has been completely left out of the equation, outright sales are therefor not included.

To find the break-even point in units, we must find the intersection point of the formula of revenue and the formula of costs. Therefor we have to equate the two formulas. The formula for the revenue is $1.080.000 \times$ amount of units leased. The cost formula consists of the variable costs + the fixed costs: $512.750 \times$ amount of units leased + 111.317.000. Underneath the equation is solved:

$$\begin{aligned} 1.080.000x &= 512.750x + 111.317.000 \\ 1.080.000x - (512.750x + 111.317.000) &= 0 \\ 1.080.000x - 512.750x - 111.317.000 &= 0 \\ 567.250x - 111.317.000 &= 0 \\ 567.250x &= 111.317.000 \\ x &= 196,2 \end{aligned}$$

From 197 clients onwards, AiDx will start to make profit at the end of year 1 within the proposed use-oriented PSS.

When exceeding this amount, AiDx will start to make profit. Also within the second year, profit will be made since many costs that have been added to the calculation (the device, assembling, tax, transport and training) are not present in year two.

Promotion and sales

Promotion and sales will be an essential asset for AiDx when moving to the market in Nigeria. The recommendation is to hire a local sales manager to find new clients and develop marketing material.

The message that communicates the USP should be clear. For both client segments that have been defined within this report this message should be different, since the use-oriented and product-oriented PSS both focus on different values and client segments.

As described before, within the product-oriented PSS, AiDx should target the luxurious automated labs with a malaria-only diagnostic device. Both the automation of the diagnostic process as the reduction of human errors could be used as a selling point. Within promotion material AiDx could emphasize on these values and respond to the feeling of a potential client.

However AiDx could also quantify the values. For example: with an automated diagnostic device, pathologist save 10 minutes per test. The salary of a pathologist is 200.000 NGN per month, which equals to 1250 NGN per hour (Mr. Animashaun, interview, March 3 2022). This means per diagnostic test around 200 NGN is saved. The quantification could also be focussed around the higher specificity or sensitivity compared to gold standard microscopy.

Within the use-oriented PSS, the focus will be on the low-resourced PHC and labs. The use-oriented PSS gives them access to automated tests which saves them a lot of time, improves accuracy of tests and in some cases even creates access to tests they didn't have access to before.

Possible other selling points are:

- Free maintenance and repair
- Updates for other diseases that will become available in the future
- Possibility of digitalising data
- Little investment costs to start using the device

Next to targeting the defined client segment, AiDx could also try to target pharmacies or PMV. Since they are also often the first tier of care, there might be interest in the device with an use-oriented model. Also young lab technicians that are planning to open their own clinic are an interested target group.

On the right page two concept posters have been created that communicate the important values per client segment as described in this chapter.



The image shows a promotional poster for SolarWorks SW20. At the top left is the SolarWorks logo with the tagline 'sua energia, seu futuro'. The central image depicts a solar panel, a mobile phone, and two lamps. Below the image, the text 'SW20' is prominently displayed. To the right of 'SW20' is a list of features: '✓ 1 PAINEL SOLAR', '✓ 3 LÂMPADAS', and '✓ CARREGADOR DE CELULARES'. At the bottom, there are three boxes with pricing information: 'Valor de Entrada: 595Mts', 'Mensalidade: 295Mts', and 'Cash: 6500Mts'. At the bottom left, there is contact information: 'Linha do cliente +258 87 0000 87 / 84 4000' and 'www.solar-works.co.mz'. At the bottom right is the SolarWorks logo again.

Figure 19: promotion material from SolarWorks who operates in Mozambique

Save time on your malaria diagnostics

...by choosing for the automated malaria diagnostic device of AiDx Medical



Detect plasmodium falciparum

- Diagnose 6 samples per hour
- Automated process
- Results of diagnostics are shown on incorporated screen
- No expert needed to diagnose, only to check the result
- Diminish human errors within malaria diagnostics



The automated device of AiDx Medical can detect the plasmodium falciparum malaria parasite. The device uses standardized glass slides as reagent, which are locally available. The staining technique is similar as the gold standard microscopy: Giemsa staining.

The AiDx assist is certified by the WHO and has a ISO 13485 standard. The level of sensitivity and specificity of the device is determined on 95%.

Figure 20: potential poster that shows the value proposition for the product-oriented PSS

Choose for cheap upgradable diagnostics

...equip your lab or PHC with reliable, automated devices

Only 300 NGN to perform a combined blood count and malaria test



Differential blood count

250 NGN / test



Malaria parasites

125 NGN / test



Future hematologic and microscopic tests

Never worry about the maintenance and repair of the device! AiDx promises a device that always work.

Receive updates within the lifetime of the device which make it possible to perform even more diagnostic tests in the future.

To start using the device, new clients have to buy a package of 1000 malaria tests or 500 blood count tests for 300 USD.

AiDx
MEDICAL

Figure 21: potential poster that shows the value proposition for the use-oriented PSS

Concluding

The business proposition can be divided in two horizons, with two different client segments and PSS, respectively a product-oriented and use-oriented system. Within horizon 1, the first step of development should be made towards a rigid infrastructure that is also needed within horizon 2.

To transform into a PSS supplier, AiDx will have to invest in local employees, local offices, a network of repair and maintenance services, distribution network, finding investors and more.

The step from horizon 1 to horizon 2 forces AiDx to make some extra changes in their organizational structure but even more so to the device. Data collection will be an important asset within the use-oriented PSS, next to developing the multi-diagnostic feature of the device.

To give an insight in the cost and revenue structure of the use-oriented PSS an indication has been given when AiDx would break-even. If AiDx wants to break-even in a year they will have to lease minimally 197 devices. The main costs within the model are the variable costs of the device and the fixed salary of employees. The revenue comes from a pay-per-test structure which is the advised paymodel for the defined client segment.

For promotion and sales, the advice is to target both PSS in a unique way. Both client segments benefit from different value propositions, AiDx should target them accordingly.

Evaluate the game

Within this chapter the graduation project is evaluated. A final conclusion is drawn from all results that are presented within this report. Next to that a discussion is added to explain the limitations of the project. Furthermore, recommendations are given to AiDx Medical on how to extend this project and where to pay attention to. A reflection is also added to describe the personal progress. Lastly it contains a list of all references which were used throughout the report.

Final conclusion

The main challenge for AiDx Medical is to position their automated diagnostic device, the AiDx assist, on the market in Nigeria. Within this report, an answer is sought to the following research question: how to position the AiDx assist with a sustainable product-service system in the market?

After thorough research into Nigeria's healthcare and malaria market, it's possible to conclude that a major problem within the scope for malaria diagnostics is the level of market saturation. This given, in combination with the minor advantages the AiDx assist brings compared to gold standard microscopy, demands from AiDx to look beyond malaria diagnostics for a sustainable future positioning. However, this doesn't mean no one is interested in a malaria-only automated diagnostic device. Compared to the gold standard microscopy method, the AiDx assist has two little advantages. First, no lab technician is needed to perform the test. This 'free time' could be used to perform other diagnostic tests. Second, the diagnostics result will be more stable since there is little room for human mistakes because the analysis is done automatically. Validation within the field pointed out that these advantages attract some luxurious private primary health clinics and labs. Implementing an AiDx device in their portfolio can save them money in the long run.

Since the AiDx assist for malaria is almost ready to deploy, it would be strategic to target this particular client segment first in 'horizon 1' with a product-oriented PSS. Within this horizon, AiDx could start investing in the infrastructure in Nigeria: a local office, local employees, search for partners, build a distribution network and find potential clients. After trying to convince the potential client segment (luxurious automated PHCs and labs) to buy the AiDx assist, AiDx could make a step to the second horizon. A more sustainable horizon beyond only malaria diagnostics where the desired use-oriented PSS is the basis.

Multiple business logics have been explored as potential value propositions beyond malaria diagnostics in horizon 2. Still, an upgradable device seems the best fit due to the readiness of the market and the fit with the mission, vision and means of AiDx. A differential blood count is the desired diagnostic test to add to the device first since it's the most popular diagnostic test in PHC and labs after malaria. Furthermore, it uses a similar staining and screening method as malaria.

When expanding their business in horizon two and applying business model innovation, AiDx will dive into a market that is almost 7 times larger. Within this horizon they can pursue an use-oriented PSS and follow their mission of making diagnostics available to all, since a move is made towards more rural areas.

A multi-diagnostic device with a use-oriented PSS attracts basic PHC/labs that predominantly use manual diagnosing methods in their clinics. This device plus system enables them to access quicker and more reliable ways of both malaria diagnostics and blood count tests. An use-oriented model is recommended here since those PHCs and labs can't afford to invest in the AiDx assist.

The step from horizon one to horizon two forces AiDx to make some extra changes in the organizational structure and local infrastructure, but even more so to the device. Data collection will be an essential asset within this PSS, next to developing the multi-diagnostic feature of the device.

To give an insight into the cost and revenue structure of the use-oriented PSS an indication is made of how many devices AiDx would have to lease to break even. If AiDx wants to break even within a year they will have to lease minimally 197 devices. The main costs within the model are the variable costs of the device and the fixed salary of employees. The revenue comes from a pay-per-test structure, the advised pay model for the defined client segment.

For promotion and sales, the advice is to target both PSS uniquely. Both client segments benefit from different value propositions, AiDx should target them accordingly. Finally, a co-venture with MDaaS is concluded to be a perfect way of kickstarting AiDx as a company. Implementing the devices of AiDx in their upcoming 'spike labs' with a pay-per-test construction seems like an ideal fit, next to deploying malaria-only diagnostic devices in their current health centres. MDaaS could be the perfect distribution partner.

Discussion/limitations

During this project a proposition has been created around the current AiDx assist and the future possibilities close to the specifications of the AiDx assist (the step towards blood count). Other possible routes have been left out of the scope of this report, routes such as the NTDx for detection of diseases like schistosomiasis, worms and more. Therefore it's unsure whether that is a more viable, desirable and feasible route to focus on for AiDx Medical, now and in the future. Also, the base of the project has been a fully working device that can deliver what it has promised to deliver. To pursue the designed propositions, this promise must be kept: e.g. a sensitivity/ specificity level as high as 95%, a detection time of 10 minutes, and more.

The conclusions within this project are mainly based on qualitative research. Even so for the demand of the device and the designed proposition (with different validation rounds with potential partners). Although the market sizes have been defined, it's unclear how many percent of them are actually interested into one of the two propositions and if they would buy or lease the device against the designed value proposition. Quantitative research should be done to define this number. Next to this, some conclusions might have been framed as (too) black and white throughout the report. Some insights have been generalised to get a more clear picture of what a scenario looks like and how this translates into a proposition. The reality is always a bit more nuanced. For example, it could be the case that some smaller PHC/labs do prefer a subscription paymodel over a pay-per-test mode, or that some smaller PHC/ labs would prefer to start with a pay-per-test paymodel but also want to have the possibility to buy the device over time. Some more concrete validation sessions are needed to discover these extra research questions.

Because of the time-limit within the project and the broad research that has been done into the scope, some parts of the research will need some extra depth and attention before they are applicable in a real-life scenario. Especially around the product-oriented PSS. It's still unclear how many potential clients are willing to pay for the device, how many of them are interested to buy one and if the advantages the device bring actually outweigh the cheaper gold standard microscope. Also more research is needed into how the device should change in the described scenarios, how AiDx can obtain certifications, how a clinical trial should be set up, what the specific marketing should look like. All crucial questions, but impossible to answer without choosing a point of departure and proposition to work towards. That should be the focus point for AiDx.

Lastly it would have contributed positively to the research if an actual MVP was tested in the market. Now many insights remain hypothetical and theoretical. With a MVP the results could have been more realistic. Sometimes during validation sessions it felt like potential clients were not actually speaking the truth. Potentially, because they didn't dare to criticize the device or the presented PSS.

Recommendations

Within this chapter some recommendations are given to AiDx Medical from my own perspective. The whole report can be seen as summary of recommendations, since it describes possible propositions for AiDx. It's the task of Temitope and AiDx to decide what fits the company best. That's why within this chapter the recommendations are taken broader than this project and scope only, since the bigger question remains how to transform AiDx from a start-up to an up and running scale-up.

Choose focus point

Much time is spent by the AiDx-team on technically optimizing the device. Next to that, many international projects are applied for as funding opportunities, projects that have different bases. I believe it's important that AiDx chooses one starting point. To focus on the development of a NTDx device, the AiDx assist and simultaneously also exploring a market for Maroc is too much. It's recommended to narrow down and kick-start the business with one proposition. By choosing one vision, mission and focus point, AiDx will likely make quicker steps towards a market introduction.

It's important to choose a starting point and build on this proposition. AiDx should deploy their AiDx assist with a proper PSS as soon as possible. After deploying the device and creating the first revenue, only then should AiDx start exploring different promising leads again. The information they gather from the market about the implementation of the AiDx assist could help defining future steps. The way how AiDx operates should become even more lean and agile. By having quicker feedback loops.

To introduce the device to the market, it's crucial that AiDx receives local certifications and that the performance of the device is tested according to international standards (e.g. WHO 55 slide set, the official way of testing malaria diagnostic devices by WHO). Therefore clinical trials are needed.

Introduction of MVP

Feedback from the field is extremely important. AiDx should keep operating as a lean start-up, not only in the way how they explore new directions but also by actually deploying machines in the field. When the AiDx assist is ready they should test the main conclusions from this report with the different client segments, to validate their thoughts on the PSS and device.

Partnership

A smart partnership could fasten the process towards a market introduction of the AiDx assist. As mentioned in the report it is recommended to start partnering up with MDaaS, who could act as a distribution partner.

It might also be interesting for AiDx to get back on the table with Delft Imaging and to open up to other relevant stakeholders like Ilara Health. Those companies already created a network of PHC and labs in which AiDx might be able to join.

Upgrade device

Depending on the choice for the desired strategy and the type of device, AiDx will have to develop their device accordingly, to serve the value proposition.

In general it's recommended for AiDx to invest in a device that is 'rural-area' proof which means it's robust, it has an emergency battery for when the net power fails etc.

Also it would be interesting to check whether the staining procedure could be improved. Currently this takes two times the diagnosing time. If this will be improved, the competitive advantage compared to golden standard microscopy increases rapidly.

More research

As concluded in the discussion, some more quantitative research needs to be done within the market, to define the actual market sizes. It's recommended to broaden this research with more client segments than the ones that have been defined throughout the report as most promising client segments per PSS. Within the use-oriented PSS, also pharmacies and PMV could be interested in the idea of adapting the device plus the lease model. Within the product-oriented PSS, secondary and tertiary hospitals could also be included in the research, as some of them might also be interested in outright sales of the devices.

Reflection

After my initial graduation project for SolarWorks got canceled by the TU Delft due to COVID-19 restrictions, I was glad that I got in touch with AiDx to work on a somewhat similar assignment. My goal was to do my graduation project for a real client in the scope of emerging markets. This worked out well.

I really enjoyed being part of the start-up AiDx. It brought me a lot of knowledge into what it means to run a start-up, and which steps are important to take when. I want to thank Temitope for his openness and the way he embraced the insights I brought. Also executing this project in the midst of the development of AiDx as a start-up was exciting and kept me sharp throughout the project. Because during the timespan of the project I had to be flexible and dynamic myself, to process new insights from AiDx directly into my project. Next to learning about the way a start-up operates and which activities they deploy to keep running around, I also learned a lot about the ins and outs of the medical scope in emerging markets.

But the project did not go without a hitch. Throughout my study career I've always struggled a bit with working on a project totally alone, also this time that was the case. Within this graduation project I've found out once again that I prefer teamwork over individual work and that teamwork is also something where my strength lies. Next to that I was disappointed that I couldn't travel to Nigeria due to COVID-19 restrictions of the TU Delft. It would have been more efficient to understand the scope of Nigeria better and quicker. Not being able to go there has complicated the project and made it harder to get grip on the complexity of the scope. The healthcare market was a new context for me and especially healthcare in emerging markets is a complex combination. Because of the complexity of the scope and almost wanting to understand too much of it, I've explored many different directions within the project. Structuring these directions and thoughts was not always easy for me. It might have helped if I had adapted a more structured way of working. Lastly I felt that during certain moments in the project I was struck by a fixation on certain insights and ideas. This sometimes resulted in losing the general overview of what the project needed.

Besides the knowledge I gained I feel I also grew as a designer, both because of the positive and negative experiences. First I feel I gained some more hard skills like interviewing, due to all interviews which had been done throughout the project. But more importantly I believe I learned more about how to approach such a project. Because of the reflective way of working I'm already able to tell what I would do differently next time within a similar project. This indicates for myself that the intensity of this project helped to gain a better understanding in how to solve complex quests like this. This gives confidence for the future. Lastly I learned more about myself as a designer, which phases of a project I do and don't like and where my power lies as a designer.

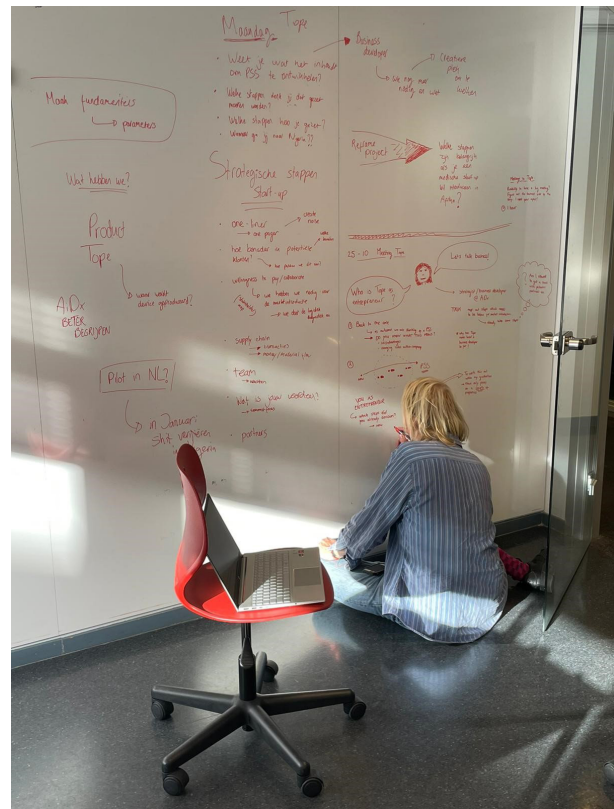


Figure 22: one of the endless brainstorm sessions at the faculty of IDE

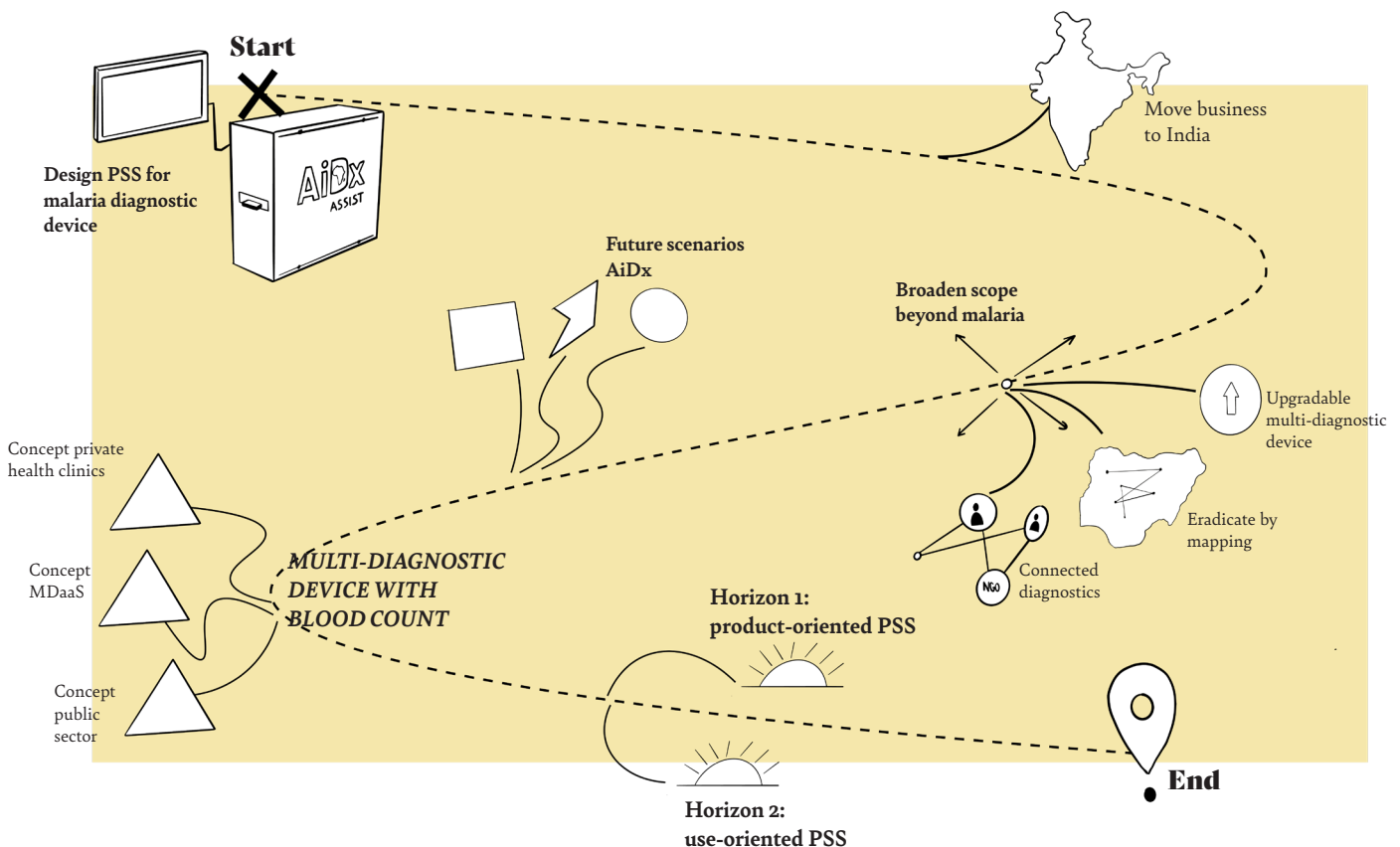
Actual process

The actual process within this project hasn't been as structured as described throughout the report. The road to the final proposition has been very reflective and iterative. One of the causes is the effectual way of approaching this project, by approaching the project as an entrepreneur which is trying to deploy his early ideas in the best possible way. Another reason was the different viewpoint from myself and Temitope: two different entrepreneurial spirits, they had to be aligned to find the best possible proposition. Another reason were the divergent insights over time. AiDx is constantly slightly changing their course as a start-up and the side projects they invest their time and effort in.

In figure 23, the route to the end result has been described. It clearly shows all side steps which have been taken throughout the project. These were explorations into possible business opportunities. Because of all side steps, the end result isn't as much worked out in detail. Simply due to lack of time.

Within the route the starting point is visualised clearly: creating a PSS around the AiDx assist whose main function it is to diagnose for malaria. The realisation came that we also have to look beyond malaria. Other markets have therefore been explored before broadening the scope of the device. This meant defining a broader business logic in which the AiDx device could play a role. After defining the most promising direction, multiple concepts have been designed for multiple potential client segments. All surrounding a multi-diagnostic device, a device which can also perform blood count tests, which is seen as the most desirable and viable option for the long term. As a conclusion, the introduction of the AiDx assist has been divided into two horizons.

Figure 23



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Appendix

The appendix consists of the following:

1. Project brief
2. Additional information malaria
3. Out-of-the box market exploration
4. Opportunities for horizon 3
5. Ideation PSS elements
6. Alternatives for an use-oriented PSS concept
7. Validation with potential clients



1. Project brief

DESIGN
FOR OUR
future



IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

! USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT

Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME

Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy". Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !



family name	<u>Tijhuis</u>	Your master programme (only select the options that apply to you):
initials	<u>K F</u> given name <u>Tijhuis</u>	IDE master(s): <input type="radio"/> IPD <input type="radio"/> Dfl <input checked="" type="radio"/> SPD
student number	<u>4491602</u>	2 nd non-IDE master: _____
street & no.	_____	individual programme: _____ (give date of approval)
zipcode & city	_____	honours programme: <input type="radio"/> Honours Programme Master
country	_____	specialisation / annotation: <input type="radio"/> Medisign
phone	_____	<input type="radio"/> Tech. in Sustainable Design
email	_____	<input type="radio"/> Entrepreneurship

SUPERVISORY TEAM **

Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair	<u>Jan-Carel Diehl</u>	dept. / section: <u>SDE/DfS</u>
** mentor	<u>Jo van Engelen</u>	dept. / section: <u>SDE/DfS</u>
2 nd mentor	<u>Temitope Agbana</u>	
	organisation: <u>AiDx</u>	
	city: <u>Rotterdam</u>	country: <u>Netherlands</u>

comments (optional) : Although both from the same section, I chose this team due to their different expertise and knowledge which complement each other. Respectively business experience and experience in emerging markets.

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v.



Second mentor only applies in case the assignment is hosted by an external organisation.




Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

Procedural Checks - IDE Master Graduation

APPROVAL PROJECT BRIEF

To be filled in by the chair of the supervisory team.

chair Jan-Carel Diehl date 15 - 09 - 2022 signature  Digitally signed by jdiehl Date: 2021.09.15 21:10:34 +02'00'

CHECK STUDY PROGRESS

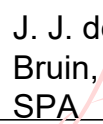
To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair. The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: 25 EC
Of which, taking the conditional requirements into account, can be part of the exam programme 25 EC

List of electives obtained before the third semester without approval of the BoE

YES all 1st year master courses passed

NO missing 1st year master courses are:

name J. J. de Bruin date 16 - 09 - 2021 signature  Digitally signed by J. J. de Bruin, SPA Date: 2021.09.16 13:35:52 +02'00'

FORMAL APPROVAL GRADUATION PROJECT

To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **. Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: APPROVED NOT APPROVED

Procedure: APPROVED NOT APPROVED

comments

name Monique von Morgen date 28 - 09 - 2021 signature _____

IDE TU Delft - E&SA Department /// Graduation project brief & study overview /// 2018-01 v30 Page 2 of 7
Initials & Name K F Tjhuis Student number 4491602
Title of Project Introducing automated diagnostics microscopy in SSA-countries

Introducing automated diagnostics microscopy in SSA-countries project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 10 - 09 - 2021 18 - 02 - 2022 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

Every year more than 400 000 people die because of malaria, a treatable disease (WHO, 2021). Preventive measures, diagnosing and treating is the cure to the disease. Especially during the COVID-crisis we've experienced the importance of diagnosing a disease to be able to map and treat it (Boehme, Hannay & Pai, 2021). Within the scope of malaria there is a lot of improvements to be made when looking at diagnostics. The current diagnosing methods standard microscopy and rapid testing are respectively expensive/ time consuming and non-accurate. Furthermore are they not widely deployed throughout malaria-infested countries.

AiDx is a start-up ran by Temitope Agbana who saw this gap and grabbed the opportunity to invent a more sophisticated diagnosing method. Together with his team he developed a device which is able to optically scan a blood sample and with the help of a quick and reliable AI-system it can diagnose whether the sample is infected with a parasitic disease like malaria or not and in which stadium the disease is. In short AiDx develops automated diagnostic microscopes which are low-cost, field compatible, reliable and which enables digital data storage and network connectivity (AiDx, 2021).

Currently AiDx is finalizing the device, making sure it technically works, to make it ready to deploy in the market. The main question however remains: what the introduction to the market will look like. AiDx has been a technology-driven start-up from the beginning, without a big focus on the business side. This is the reason I joined AiDx as a graduate student. I will put all my focus within the project on the business context and market introduction.

The challenge within the project is to research the complexity of the healthcare scope in sub-saharan African countries. Thorough research is needed to introduce the device on the market in a viable way.

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space available for images / figures on next page

Personal Project Brief - IDE Master Graduation

introduction (continued): space for images



image / figure 1: The automated diagnostics microscopic device from AiDx

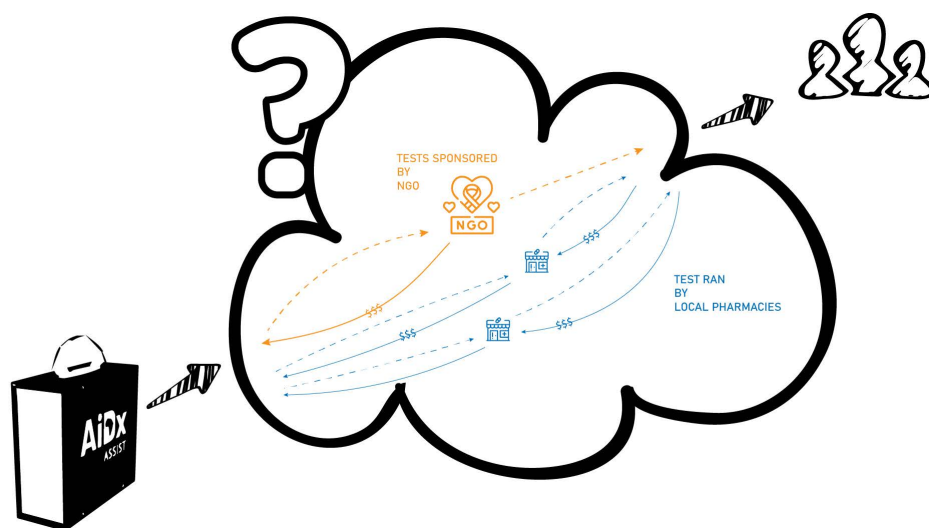


image / figure 2: How to introduce AiDx within the market? (schematic)

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

The automated diagnostic microscopic device from AiDx is technically almost deployable but the problem is that nobody yet validated what a full introduction on the market looks like, from A-Z. This leads us to the main challenge: to design a viable product-service system for the device.

Before the device of AiDx can properly be introduced on the market we need to research the scope and the context. This includes both a benchmarking study and a company analysis. We need to understand what makes the device so different from the other main diagnosing techniques (rapid testing and general microscopy). We have to understand what the current bottlenecks and limitations of the system are and what the vision, mission and strengths of AiDx and its device are.

After answering the main research questions and defining a solution space we can think about what the product-service system could look like (figure 2). Which elements need to be present in the system? For example who will deliver the service and where? How do we reach the end user? How is the device funded?

By combining all those different elements we will be able to design a complete product-service system.

To limit the scope I choose to only focus on one parasitic disease which is malaria. Furthermore I decided to pick one case study area in Nigeria (the city of Ibadan) as a focus point for the research. The reason for this is to both minimize the effect of overgeneralizing and making the project unmanageable. From this case study I might be able to create some more general recommendations for the bigger scope.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

Within this project I will investigate how we can introduce the AiDx device in Sub-Saharan African countries in a viable way. Research will give me more insights into the market, competitors, potential pay-models and partners. From these findings I will design the infrastructure of the product-service combination.

As mentioned before I aim to deliver a product-service system (PSS), this includes both the design of a business model and a service model. I'm planning to create minimally two different PSS concepts to be able to compare them with each other and validate which elements are desirable and could be feasible/ viable within the context of Ibadan.

I'll do the validation with both AiDx and experts in the field. The latter is extra important since it's impossible to do the actual research on location. After validating the two concepts I'll either combine them or pick the best one. This concept will be elaborated on till it's a complete proposition for the introduction of the device.

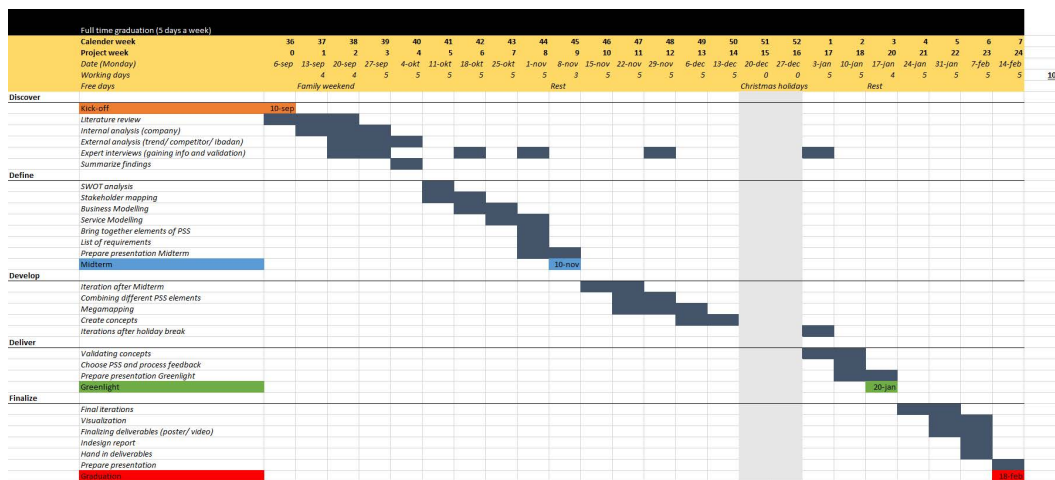
Since AiDx is in a phase where they want to use my results straight away, I have to be extra cautious that I deliver realistic results. By creating a product-service system-model which is backed-up with quantified data and research.

Personal Project Brief - IDE Master Graduation

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 10 - 9 - 2021 18 - 2 - 2022 end date



As a basis for the Gantt chart above I used a classical SPD structure. Within the project I will follow the following steps: 1. Internal research company (future vision & mission, status company) 2. External research (to learn/ get inspired and benchmarking) 3. Investigating the particular scope in Ibadan 4. Ideating (listing elements of PSS for a viable business and service model) 5. Combining ideas into 2 concepts (by combining PSS elements) 6. Validating concepts (with AiDx and experts) 7. Finalize concept (process feedback and create deliverables)

I planned a lot of expert meetings since it's a scope which is very different than the Netherlands, this makes it extra important to get information from experts or locals on location. Unfortunately I can't go myself to a SSA-country to do some research due to the COVID-restrictions. Furthermore I know from experience that it's very important to keep track on my report, so I'll start from week 1 with documenting my findings and creating a report.

The plan is to have 'lean and clean' contact with my two coaches, they will be available for questions/ feedback/ help all week long. Every 2-3 weeks we plan an official meeting with the three of us to discuss my progress. I'll work one day at the office of AiDx where I'm able to meet up with my Tope (mentor), this assures close contact with the company.

Taking some time off during a project to get some rest and set the mind straight has always worked very well for me. In the Gantt chart I've created one row in which I put the free days I'm planning to take and the reason why. During the start of the project I'm away for a family weekend. During the christmas holidays I also decided to take two weeks off to spend time with family and friends. After both my midterm and greenlight I am planning to take 1 or 2 days off to relax and start fresh in the next phase.

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, Stick to no more than five ambitions.

The reason why I set up this project goes back to my interests and hobbies. I've always been interested in travelling the world, exploring new cultures and their way of living. During my studies this hobby transformed into the interest of the scope of emerging markets and design for the bottom of the pyramid. Within this scope it's possible to make direct impact by improving living conditions/standards of people. Not only improving (already good) lives by introducing more luxurious products, which happens a lot in the scope of the Netherlands.

This is also one of the reasons I chose an entrepreneurial project in Kenya for my Minor, but also within the Master I tried to follow electives which provided me extra knowledge/ methods to solve problems within this particular scope. I ended up following Service Design and Sustainable Product-Service Systems.

Next to the electives I was also an intern at the municipality of Rotterdam. Where I was doing an individual research project into the collection of textile household waste. This gave me some experience in delivering a project and a recommendation-report from beginning to end. An experience which will be useful during my graduation project.

In general I see this graduation project as an opportunity for me to check whether this scope really fits me as a designer. If this type of project is something I would want to do in my professional life. Next to this it's also my first project which deals with the health sector, it would be interesting to see if this field attracts me.

Next to the professional experience I want to gain in this scope as described before, I have some extra learning ambitions in this project:

- Improve visualizing skills, present findings in a visually attractive and smart way
- Getting more acquainted with business design, how to align your business and stakeholders in a viable way
- Learn how a start-up can make impact in a very complex scope like the health sector and how to introduce a PSS on the market as a start-up.
- Get more experience in interviewing and translating the conversations into useful conclusions.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

/

2. Additional information malaria

General information

Malaria is caused by a parasite which is transferable via blood. When a mosquito bites an infected person the parasite can be transferred via the blood of the patient. An infected mosquito could, on her turn, infect a person again with her saliva when she bites. There are five Plasmodium parasites which can cause malaria. The most common one found in SSA countries is Falciparum, in Nigeria this accounted for almost 100% of all the malaria cases. The other parasites which can infect humans are Vivax, Ovale, Malariae. Vivax is dominant out of SSA countries, mainly found in Asia. Ovale and Malariae are representing a tiny percentage of infections in SSA countries. (WHO, 2020)

The WHO states that within the fight against malaria a solid combination of prevention, diagnostics and treatment is key. With the right measures it's possible to eradicate malaria completely. Over the past years multiple countries were given the stamp malaria-free country by the WHO. In 2021 alone both China and El Salvador were declared malaria-free by the WHO. (WHO - Malaria, 2022)

Prevention

Protecting people from the mosquito in endemic regions is mostly done with mosquito nets. Mosquito nets are an effective tool to prevent people from being stung. These nets are most effective if they have been impregnated with DEET or another anti-mosquito liquid. Mosquito nets are also the biggest asset within the fight against malaria where NGO spend their budget on. The Global Fund for example has distributed 188 million mosquito nets in 2020 alone (The Global Fund, 2022)

DEET, and anti-malarial drugs are other tools to prevent people from mosquito bites, thus preventing them from getting malaria parasites. These solutions however are often too expensive for people to widely use.

Another very effective tool against mosquitos is insecticides. However implementing this on a very high scale is enormously costly and a big logistic challenge.

The first vaccination for children aged 6 weeks to 17 months has been released in October 2021 by the pharmaceutical giant GSK. This is a huge step in the fight against malaria. According to the published results it could prevent 4 out of 10 cases of malaria. (Gallagher, 2021)

Unfortunately the vaccine is only effective for 2 years, more development is needed to improve the effect of the vaccine. Some new innovative players also entered the market with the goal to prevent people from malaria. The question arises whether they could be interesting to partner up with.

Treatment

In most cases in SSA-countries malaria is treated with ACT (artemisinin-based combination of therapies) since this is the most effective way to treat falciparum malaria. In some cases this treatment is supplemented with more antibiotics. All of the medicines come in pill-form.

According to the severeness of the disease and the patient (child or pregnant lady), the dose and type of ACT must be determined. Chloroquine is mainly used for treating vivax malaria.

3. Out-of-the box market exploration

Side track: move business to India

Throughout the project and within the search of a suitable market for the AiDx assist, India has been found as a promising opportunity. This has two main reasons. India is close to eradicating the disease, because of this it's increasingly important to test with a diagnosing method which is as specific as possible. As also stated by Nema et al. (2019), it's key to introduce innovative diagnostic devices which can test quicker, cheaper or more specific within the quest of eliminating the disease. Since a large part of the infections are currently still being missed. Also the market size in India is significantly bigger than in Nigeria. The first reason is that more tests are being done in India. The second reason is that the percentage of microscopic malaria tests is much higher in India than in Nigeria. In Nigeria much of the diagnostics is done with RDT. To specify in numbers (WHO, 2020):

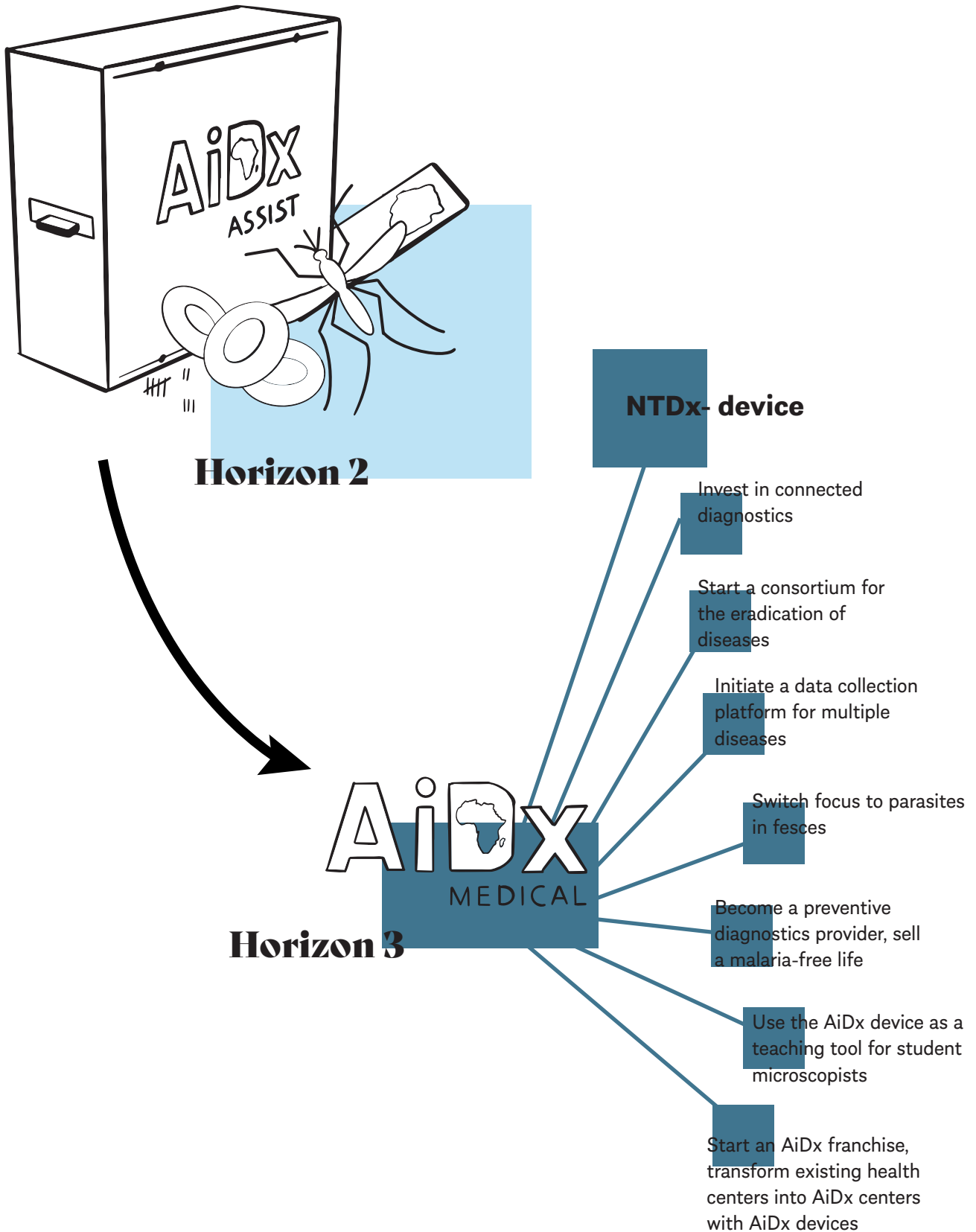
India - 113 969 785 microscopic tests (85% of all suspected cases)

Nigeria - 3 298 156 microscopic tests yearly (13% of all suspected cases)

However moving the business to India sounds more promising on paper than it actually is. If we reflect on the effectuation theory and the bird-in-hand principle we can already conclude that going to India is not the smartest move to make. The reason for this is that the Indian market is far beyond the means of AiDx. Temitope doesn't know anyone relevant stakeholders in India, doesn't know the culture and doesn't know how businesses are ran in India Furthermore it's extremely difficult to get accepted and respected as an outsider in India. This makes it extra hard to find a partner to start a venture with. The Indian market will (for now) thus be an closed opportunity.



4. Opportunities for horizon 3



5. Ideation PSS elements

To design multiple concepts for different client segments, we first need to create an understanding of the elements that make up a strong PSS. The most promising PSS elements have been visualised in figure 24.

The most important categories which are visualised on top of the table have been inspired partly by research and partly by interviews. The business model canvas from Osterwalder et al. (2011) was a source of inspiration, next to depth interviews with multiple stakeholders who already deployed PSS in emerging markets.

From this research it seems that defining the paymodel is the most important asset for the PSS in emerging markets. Because there is not much budget within the healthcare sector in Nigeria, the price for value is extra essential. Besides the paymodel, the service elements that are delivered to the client, the additions you have to make to your device and the resources and activities you need to deploy were seen as other important categories.

The different elements described in table 24 are found through extensive brainstorming and research into existing PSS providers. They have been used as a basis for creating the three PSS as described on the next pages.

Paymodel	Service elements	Resources/ activities	Device
Demographic pricing (higher price urban area)	Become a full integrator: also deliver medicines	Hire local engineers who can repair and train	Develop a EMR which is connected with internet
Penetration pricing (start with discount price/ free)	Free update of the AiDx-assist (depending paymodel)	Built local office	Screen on demand
Bundle pricing (combination of diseases)	Control data from the clients' patients	Become OEM for a local chain of healthcenters	Mixed power supply, both battery and net power
Razor blade model, charge for the reagents only	Revise device a certain amount of times per year	Develop and maintain patient database	Counter within device to count tests per device
Freemium (malaria is free, other diseases not)	Train health workers to use the device	Earn WHO endorsement, and be certified for Nigeria	Remotely controlled device
Price differentiation, with every disease, price drops	Free repair or a fixed amount(/ month) for repair	Partner up with fast-growing health suppliers	Data transfer from device to a server/ platform
Pay per diagnostic test which is done	Offer a trial	Partner up with with insurance pools	More specific reagents, no standard glass slides
Cost based vs value based pricing (outright sales)	Device includes maintenance	Fix an insurance at credit insurance companies	Demographic pricing (higher pricing urban area)
Split revenue with a partner clinic	Train local engineers to fix the machine	Find investors, venture capital, NGO and more..	Implement SIM-card for internet
PAYG - slowly paying back cost price of the device		Expand AiDx team: business developer, marketing manager	Within the platform there is a e-wallet which can be charged by the client by simply sending money. The client can test till the credit within the wallet is empty.
Combination of different paymodels			
Different paymodel depending on client			

Figure 24: table which includes the most promising PSS elements

6. Alternatives for an use-oriented PSS concept

Monthly subscription

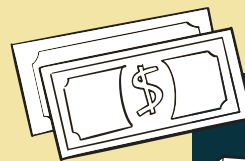
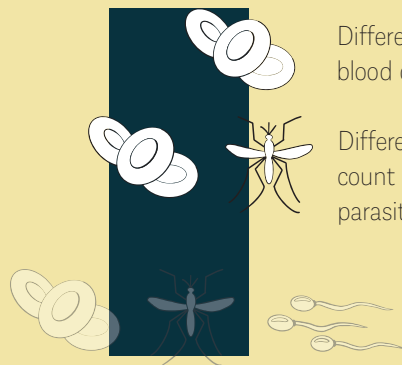
Differential blood count 100\$

Differential blood count plus malaria parasites 150\$

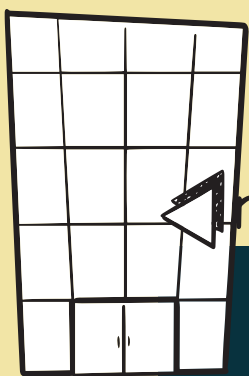
Future diagnostic analysis options (e.g. sperm count)

AiDx device

Depending on the wish of the client, the devices could be delivered with or without screen.



PER



mdaasglobal

Innovative medical scale-ups

Client



Values

Scale-ups like MDaaS or similar as MDaaS are growing fast and have the mentality of chasing topline revenue and growth. Therefore MDaaS needs to perform as much diagnostics as possible. Within this PSS they won't pay per test as described in the first business case and they can thus perform as many diagnostics as they can for a fixed amount per device per month. Viable this makes it more interesting for them. Next to that the automated and digital device fits perfectly in the type of company MDaaS is.

Cloud and connection with start-up platform

Test results should be updated to the existing platform of the client's platform immediately after the diagnostic has been performed.

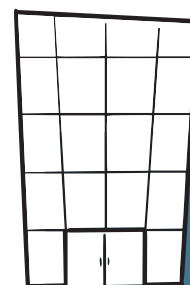
Company

The his concept is written towards innovative medical scale-ups, with MDaaS Global as a case study. In practice this concept would look more like a partnership than a supplier-client relationship. This commitment could mean fast growth within Nigeria (and beyond), for both. MDaaS is still a young company, constantly looking for new opportunities that's why a new method of diagnosing malaria (and blood count) should fit them perfectly. Also the visions of MDaaS and AiDx are aligned: making cheap, reliable diagnostics available for everyone.

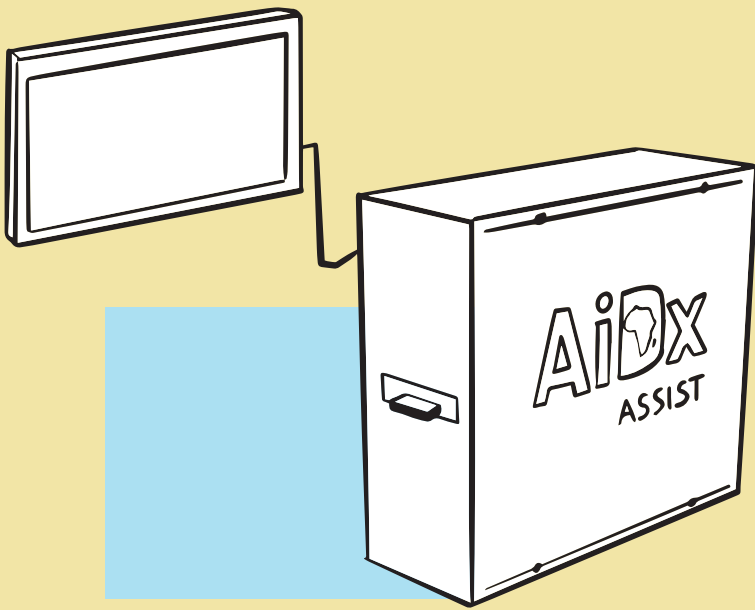
Other potential clients which are already mentioned before are Ilara Health and Delft Imaging.

The reason for picking this type of paymodel is described within the values on the left. The price within the drawing is an indication of what it could cost: 100 USD per month (1/5 of the production costs). This will be the price per device per month.

In this model AiDx will deliver multiple devices at once to the client. These devices must fit the current infrastructure of the client which means the output of the AiDx assist should be altered to the EMR of (in this case) MDaaS. This will be an investment money wise but also an investent in the future, since it makes the partnership stronger.

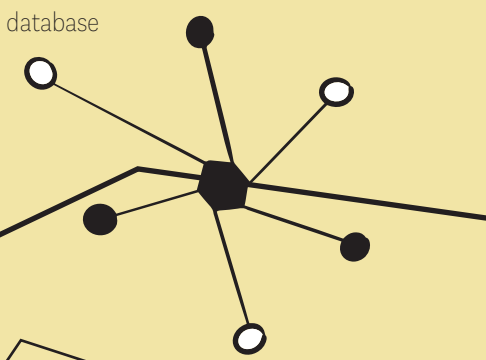


AiDx
MEDICAL



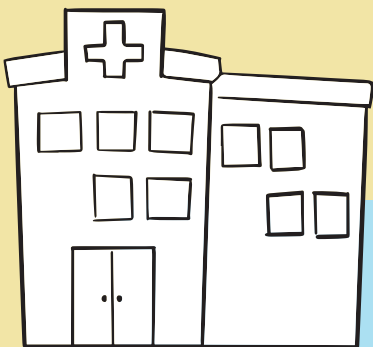
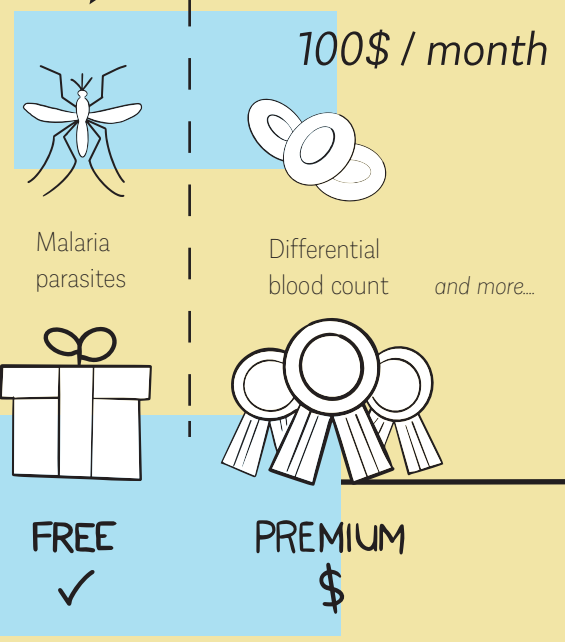
Data transfer

Anonymous patient data is transferred from device to the database of AiDx



AiDx device with a freemium service

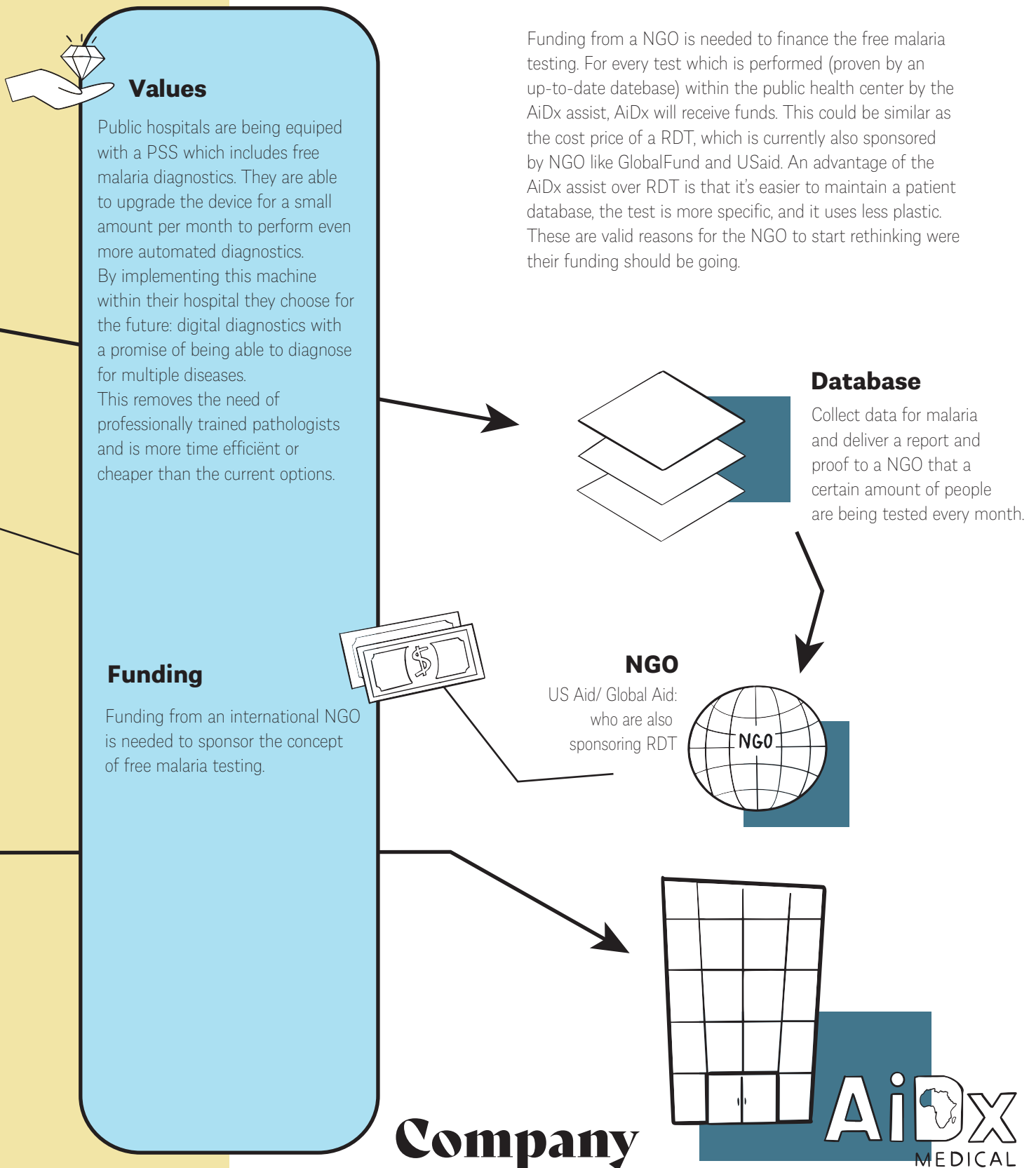
Public hospitals should have free access to the diagnostics of malaria, that is where AiDx is responding to within this business case. A minimum amount of malaria tests should be agreed on with the client to push them to diagnose a certain amount of people for malaria every month. If they want to upgrade the device to be able to perform more diagnostics they will have to pay a small amount every month.



Public hospital
Client

This concept has been added to show what a PSS could look like in the public segment. It is inspired on the concept of 'connected diagnostics', but it has been altered to make it more attractive to local governments. As explained before local governments don't benefit from transparency and decentralization. So within this concept public hospitals will still be responsible for the diagnostics and receive a free AiDx assist to diagnose with. Furthermore within this scenario malaria diagnostics will be free as it supposed to be, as stated by the WHO in their report 'Global Technical Strategy for Malaria' (2021) and like agreed on by the national Nigerian government.

Funding from a NGO is needed to finance the free malaria testing. For every test which is performed (proven by an up-to-date database) within the public health center by the AiDx assist, AiDx will receive funds. This could be similar as the cost price of a RDT, which is currently also sponsored by NGO like GlobalFund and USAid. An advantage of the AiDx assist over RDT is that it's easier to maintain a patient database, the test is more specific, and it uses less plastic. These are valid reasons for the NGO to start rethinking were their funding should be going.



7. Validation with potential clients

MDaaS Global

To validate the designed business cases interviews have been done with the client segments where the PSS was written towards. This chapter contains the insights from the validation with MDaaS. MDaaS is distinguished as a very important potential client within this report and the second business model has been written towards MDaaS.

As explained before, MDaaS is a modern, tech-enabled healthcare company in Nigeria. Their mission is to deliver accurate diagnostics to clinically-underserved communities. Currently they have eight fully operating clinics throughout Nigeria and they are expanding rapidly. At the end of this year they plan to have four more health care centers in place. Next to that they are also investing in a platform which focuses on delivering preventive healthcare.

General insights

Within their general business operation, MDaaS has the mission to create an integrated supply chain, for every medical device they use, they prefer to do maintenance and repair themselves. If parts break down they want to have the freedom to fix it themselves within the local context, with the help of local engineers. This mindset originated from their core business, being a OEM who delivers cheap and affordable diagnostic devices in Nigeria. For this reason they also prefer devices which are open, with software which can be altered to the needs of MDaaS. In the perfect case they can buy medical equipment in bulk from a supplier and subsequently cheaply spread it throughout Nigeria. This also has an effect on the type of machines they use. MDaaS prefers diagnostic devices which work with reagents which are locally available. Unlike a lot of Western machines, Siemens, Philips, Abbott (USA) which are tightly controlled. They come with closed system and you need to buy specific reagents. With Chinese machines for example, this is less of a problem since these machines are more open system, with the possibility to adapt them according to your needs. With specific reagents and a closed system this causes problems. Also price wise the specific reagents have a disadvantage, they come with a higher price than the local reagents, not only because they have to be bought via a certified supplier but also because of changes in the exchange rate of the USD and Naira and stock-outs. Within one lab MDaaS deploys specific machines which are rented from a supplier. Without making too many large investments they want to explore if they want to make microbiological diagnostics part of their services. A negative side effect is that MDaaS also has to buy specific reagents from the supplier, this costs a lot of money.

Validation on designed PSS and interest in device

In general MDaaS is interested in the device and its technical opportunities. For MDaaS it's especially important how the device performs. Next to that the price and the easiness of use are very crucial. To start using the device at all, it has to be adapted to the scope of Africa. Easiness of use is key and it should be adapted well to the use case of emerging markets. If there is a net power failure the machine must be able to run on batteries for example. Furthermore MDaaS highlighted the importance of an USP. Nigerian health centers, like MDaaS will compare the device to the alternative which is to hire a microscopist and buy a Chinese microscope. Most of the time they already have employees as a resource, so the AiDx assist has to compete with the Chinese microscope, devices which are cheap and easy to use. Chinese microscope are 300 USD or cheaper. Next to that the salary is really cheap from a lab technician. This makes the interest rate low for the device and a PSS where they have to share revenue. The AiDx device must offer something special before health centers will invest.

In general MDaaS would be more interested in owning diagnostic devices, in this they have full responsibility over the device and all profit made is directly for themselves. Without having to share revenue.

However in 2023 MDaaS wants to build smaller labs (spike labs), if the AiDx will be able to deliver what it promises to do and come at the right price point this could be a very interesting collaboration. Within the spike labs MDaaS is planning to run the barest minimum diagnostic tests on site eg. pregnancy, malaria. For more advanced test the blood sample will be sent to their bigger labs for analyses. But if AiDx could deliver a device which is able to run multiple basic tests that would be ideal for this use case. This removes the need for sending the blood samples to bigger labs. Within these labs a pay-per-test paymodel would be interesting. Because this removes the need for MDaaS to do big investments in devices and the automation of tests could save time per test. This is an important asset for MDaaS, since they strive to do as much tests as possible (high volume, low margin is their motto). It can increase turnaround time positively

As an indication for a price point for a pay-per-test system O. Oni mentions a price for 0.5 USD for a malaria test and 1.5 USD for a FBC test.

MDaaS is not interested in a connected EMR, since the configuration will be difficult and it will only add extra actions for his lab scientists.

Leasing an upgradable device from AiDx with a higher price per month, per extra diagnostic feature has a negative connotation. As potential client you might feel you're getting ripped off. Since you have to pay more per month for the exact same device. Only with some extra software.

O. Oni concludes the interview with the information that organizations like MDaaS can make AiDx machines scale because they already have many labs. MDaaS can be a channel distribution partner for the AiDx device if it works as promised. But only if the price and the business model is right for them.

MDaaS, all in all a possible partner in crime to start a co-venturing with.

“I am very curious about the price point, this will be a make or break for me, including the final business model AiDx will deploy. Let’s be honest, there are so many new devices out there, but it’s hard for medical entrepreneurs to gain traction, because the Western market is too sophisticated or they can’t compete with cheap alternatives in Africa. Key is to make the device very cheap for emerging markets.”

- Oluwasoga Oni

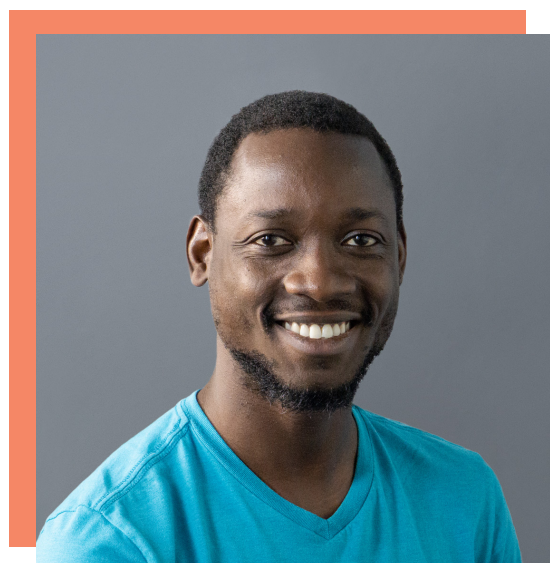
Concluding

MDaaS prefers to own diagnostic devices themselves in the bigger health care clinics that they currently have. This is mainly out of profit maximalisation reasons.

Also they want to have responsibility over their own devices and adjust them to their needs.

For one of their new projects: ‘spike labs’, the AiDx assist would be a perfect fit. A simple multi-diagnostic device to perform the basic diagnostic tests in rural areas. MDaaS wants to expand widely with their ‘spike labs’. The goal is to open many around the country. A PSS around the AiDx-assist which is centered around a fixed amount per test interests them. To keep initial investments low and the amount of functioning machines high.

Figure 25: portrait of the CEO of MDaaS



Zoe specialist mission hospital



Zoe Specialist Mission Hospital is a secondary health care facility in the urban area of Ibadan, and one of the bigger private hospitals in the area. Next to being a hospital they also have a laboratory within their facilities to diagnose patients. They perform numerous types of diagnostics tests within their clinic, including malaria and full blood count tests. Within their laboratory they run around 1000 malaria tests each month and around the same amount of FBC tests.

General insights

Within the Zoe Specialist Hospital, malaria is diagnosed with a microscopic test, the preferred test because it's the most specific test. FBC are done with a Chinese haematology analyzer. An interesting remark from Mr. Dare was that with most patients who are being diagnosed for malaria they also perform a FBC test.

A malaria test currently takes 10 minutes within the laboratory of Mr. Dare. A FBC is quicker and takes around 2 minutes. All diagnostics devices which Zoe Specialist Hospital is using are owned by them, since they are a big hospital they can afford to own their own devices.

Validation on designed PSS and interest in device

After introducing the designed PSS (which is centered around a pay-per-test paymodel) the feedback was loud and clear. There would only be interest from Mr. Dare if a price per test would be the same or cheaper as it currently is. This applies for both the malaria diagnostic which is currently done by microscope and for the FBC which is performed with a haematology analyzer. However this is not something which AiDx can live up to because the costs per test are similar to the current price per test, this would thus mean every test should be for free, which is impossible within this particular PSS.

The price per test for malaria diagnostics is the same because the reagents the AiDx-assist uses are the same as the ones which are currently being used (glass slides plus Giemsa stain). Since the tests are done automatically compared to microscopy you save some time per test when using the AiDx assist. But only with very high diagnostic volumes this will result in less employees, so this will also not result in a cheaper price per test. For the blood count analyses the same principle applies.

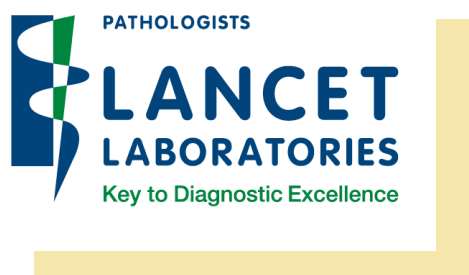
We can conclude that the interest in the designed PSS is very little. Besides also within leasing (renting) there is not much interest from Zoe Specialist Hospital. They prefer owning their machines since they are a bigger laboratory. Owning the machines generates more profit on the long term argues Mr. Dare.

Unlike the disinterest into the PSS suggest, there was interest into the AiDx assist. Especially into the promised technology and future possibilities of diagnosing multiple diseases with the same device. Also the fact that the gold standard microscopy for malaria will be done automatically by the device interested Mr. Dare. Also because the supervisor of the hospital was thinking of introducing RDT to diagnose for malaria because it's quicker and less labour-intensive. However the gold standard is preferred by Mr. Dare as a scientist. Mr. Dare mentioned that if he could save time with the AiDx device he would invest in it (buy the machine). Since it would be a better option than a RDT. However this is only possible when the staining time is diminished since the processing time of the image tracking is difficult to improve.

One last requirement from Mr. Dare for the AiDx assist is that it must have 90-95% specificity, otherwise he would stick to his microscopy.

(O. Dare, head of laboratory, February 9 2022)

Clina lancet laboratories



Clina Lancet laboratory is a private laboratory in the urban area of Ibadan. This lab is part of a big chain of laboratories which all go under the name of Clina Lancet. The company origins in South Africa and they are specialised in offering specialist pathology services. They don't offer treatment themselves but after a patient is being diagnosed they will be referred to the right place for treatment.

Within the specific lab in Ibadan they perform around 200 malaria tests on average each month and 160 FBC tests.

General insights

Many labs prefer a microscopic malaria test over a RDT, the reason is they trust their own analyses more than the result of a RDT.

Clina Lancet laboratories is an ISO standard lab, quality and specificity of their devices are really important. Mr. Temitayo emphasized that getting certified is key when wanting to sell your device, next to developing a device which can diagnose very specifically.

When a device breaks down within the laboratory of Clina Lancet it's fixed by a local mechanic. If the device is too complex then it will be sent back to the supplier, they then repair the device against a fixed fee.

Mr. Temitayo also confirmed that many of the malaria tests and FBC are ran on the same patient at the same moment, to be able to tell how bad the infection is, if there is one. Or to specify what the illness then could be (besides malaria). In 80% of the cases they run both tests together.

The prices of a FBC and a malaria test are set within the Clina Lancet lab at respectively 2500 NGN and 1000 NGN.

Validation on designed PSS and interest in device

The first respond of Mr. Temitayo was that it's not a common business model which is normally applied within the health sector in emerging markets. Especially not between the supplier of medical devices and the health centers. Outright sales is the standard. Especially for most of the bigger private laboratories, just like the laboratory where he works, who have the financial means to invest in machines. This is preferred because of profit maximisation. Paying per test wouldn't attract Clina Lancet for that particular reason. Also he doesn't see the value of the haematology function for his lab since they already invested in these devices. Devices which are faster than the AiDx device. Nevertheless there was interest in the malaria diagnostic function of the device because of the automisation of the microscopy test.

Mr. Temitayo saw a connection between this PSS and the way some OEM are introducing their devices. Some luxurious diagnostic devices have specific reagents which the customer (health center) has to buy otherwise the machine will not work. He preferred the proposed PSS over this system since you pay for the result and not for the reagent. Also, because the reagents are standard and you don't need to buy a big collection at once, the risk of expirement is little. Temitayo beliefs there will be demand for the designed PSS however, within smaller clinics, clinics who don't have acces to a haematology analyzer: smaller primary health centers or small private laboratories. This device could supply them with the means to run more complex tests and give a more specific treatment plan for malaria since the AiDx assist could perform the two tests at once. Pay as you run tests will attract small clinics because they don't have to make big investments. Also it makes it easier to open up a private laboratory, many pathologists would love to do this but don't have the financial means to invest in all devices. This could be a first step for them. As an indication for a fair fee per test Mr. Temitayo mentioned 20-30% of the price for which a test is sold to the patient.

Lastly Mr. Temitayo recommended to strictly regulate the use of the machines. He warned AiDx that a hidden counter must be implemented within the machine to be able to charge the client accordingly, otherwise health clinics will lie on the amount of tests they run.

