Preventing the leading cause of blindness

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1 Executive summary

List of Acknowledgements
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Lina Freudenberg, CEO of Agaplesion Pflegedienst München for giving us insights about medical care in German nursing homes;

Our Mission
Catcheye in collaboration with Fraunhofer Portugal developed a professional device what is arguably the most affordable and ease-of-use eye fundus solution. We strive to prevent the leading cause of blindness which is namely Diabetic Retinopathy by providing accessible, affordable and automated retina screenings to diabetics. The utilization of the device can help to mitigate the risk of diabetics having Diabetic Retinopathy.

Our Service
Our target users are diabetics. Catcheye offers services including detection of potential threats of Diabetic Retinopathy and annual reminder service. Meanwhile, the operation of device mitigates the need for expertise of an eye doctor.

The Market
The US is our entry market because our market research has shown that there are 19 million people with diagnosed diabetics and the number is growing. The price of eye screening is still very high.

Our Competitive Advantage
Catcheye's marketing strategy is to emphasize the best value for money and accuracy of detection. We distinguish from our competition by completely eliminating the need for expertise during annual eye screening check-ups, meanwhile ensuring high accuracy. Our accuracy is currently still under development as we improve the algorithm. We strive to achieve a competitive accuracy by the end of this year.

Financial Projections
Based on the size of the market and the defined market area, our revenue projections after launch for the first year are $400k in 2021, $2.7m in 2022, $9.2m in 2023.

Start-up Financing Requirements
We are seeking for a pre-seed of 160k, which will enable us to further develop the algorithm and perform trials. For 2020 we will need $440.000 in another round of funding. To perform a full-scale launch in 2021 we will then need an additional 1 million dollars to cover the production costs and salaries and a marketing campaign to increase awareness about Diabetic Retinopathy.

2 Problem and solution

2.1 Case and Case Provider

Our team worked on the Case “Eye Fundus Scope” provided by the Master Thesis Researchers David Melo and Miguel Santos of Fraunhofer AICOS in Portugal.
The Fraunhofer research team develops a 3D printed portable eye fundus camera that allows taking photos of the retina with a smartphone. Deep learning algorithms are trained to detect Diabetic Retinopathy (initial use case) but there is potential for future development into different fields such as the detection of tumours [1], Alzheimer [2] and cardiovascular risk factors [3].

2.2 Problem

Diabetic Retinopathy is a diabetes complication that affects the patient’s eyes condition. Specifically, it is caused by damage to the blood vessels of the light-sensitive tissue at the back of the eye (retina). Diabetic Retinopathy leads to the development of visual impairments and blindness. Many patients have lost their eyesight gradually and the situation badly affects their quality of life. Currently, 1 in 11 adults has diabetes which represents 420 million people worldwide, while this number is steadily increasing [4]. Studies show that ⅓ of all Diabetic patients will actually develop Diabetic Retinopathy throughout their lifetime [5]; every Diabetic is at risk of developing the condition.The longer patients have diabetes and the less controlled their blood sugar is, the more likely they are to develop this eye complication. Thus, it is urgent to give more importance to the Diabetic Retinopathy and provide suitable interventions and early prevention methods.

2.3 Need

Yearly exams can prevent 95 percent of diabetes-related vision loss as they allow to initiate early treatment [6]. However, 60% of Diabetics do not attend the required yearly follow-up eye exams. In the U.S., more than 50% of Americans with diabetes miss their annual eye exams [7].
One key reason for that is that is that the disease does not show any symptoms at early stages, so patients tend to overlook the importance of eyesight check ups thus forgetting about the required appointments.
Another reason is the imbalanced healthcare service development between areas. In rural areas in the US and elsewhere, the closest dedicated eye specialists could be several hours’ drive away, which discourages patients from making an appointment and showing up at annual exams [8]. In a developed country like the US, 25% of the counties did not have an optometrist or ophthalmologist [9]. the number of ophthalmologists trained to identify the signs of diabetic retinopathy is insufficient as there are only 59 of them for every million citizens [10]. This means that if all the diagnosed American diabetics were attending the

annual checkups as required, each ophthalmologist would have to examine more than 3 of them each day, including weekends and holidays. Not to mention that they have a number of other eye conditions to follow and operations to perform.
Additionally, eye exams are not part of the regular Diabetes monitoring. The standard monitoring is performed by a primary healthcare provider such as a General Practitioner.
Besides, the price of eye screening can also be an obstacle for patients. The costs for a Diabetic Retinopathy screening in the US was found to be 116 USD per patient per screening [11] . It is fairly common that in the US, people do not get an annual eye exam because their health insurance only covers one every two years.
In conclusion, there is a clear need to provide accessible, affordable and partially automated retinal screenings to Diabetic patients.

2.3 Market

Currently, 1 in 11 adults has diabetes which represents 420 million people worldwide, while this number is steadily increasing. Catcheye focuses on a market entry in the US, because here are already now 23 million people with diagnosed diabetics who are at risk of developing Diabetic Retinopathy [12]. The average price of one eye screening in the US is as high as 116 dollars, as mentioned above [11]. Thus, a solution of accessible, affordable, automated way of eye screening is urgent. Also, the US has a wide network of Retail Clinics providing primary health care services to citizens including Diabetic patients. This channel allows for relatively easy access to the target users.

2.4 Solution

Catcheye focuses on offering more accessible, affordable and automated retina screenings to Diabetic patients. Catcheye uses the portable Eye Fundus Scope Technology developed by Fraunhofer AICOS in Portugal. Taking a closer look at our technology, our solution consists of three main parts:

1. 3D-printed portable fundus camera to scan the retina and a regular mobile phone to capture the image, see Figure 1.
2. Our AI risk level analysis then detects early signs of diabetic retinopathy and flags potential threats. Once Diabetic Retinopathy is detected, the patient will be recommended to visit an ophthalmologist to perform a detailed analysis.
3. The annual reminder function offer users a reminder service of their screenings. Through providing email and personal information, a reminder will be automatically sent to patient’s email box.

Figure 1. Technical Solution and application

Nature of the Innovation in the proposed solution

Our AI-powered solution eliminates the need for expertise of an ophthalmologist. Not just an ophthalmologist can perform the exams, but anyone with simple training can undertake it as the actual screening task is done by the algorithm.

The AI risk analysis of data algorithms also enables accuracy improvement of detection.

Role and impact of ICT technology in the proposed solution

ICT technologies such as data analysis and machine learning improve the accuracy of Diabetic Retinopathy detection.

3 Business modelling and planning

3.1 Business modelling

3.1.1 Customer Segments

We have a niche market as our initial customer segments. This segment of the customers have the following characteristics and needs

1. They are a Diabetic patient in the United States
2. They need regular diabetes monitoring checkups (each Diabetic)
3. They require convenient access to a medical expertise for eye screening without having to travel far or book an appointment
4. They need affordable means of getting an eye screening

3.1.2 Customer Channels

Our initial primary channel to reach our customer segment are retail clinics in the United States. A retail clinic is a category of walk-in clinic located in retail stores, supermarkets and pharmacies that treat uncomplicated minor illnesses and provide preventative health care services [13]. Through them, we aim to reach the diabetic patients. Thus, we are ultimately in a B2B2C business model. There are currently more than 2000+ and growing retail clinics in the United States. There are two market leaders, Walgreens and CVS pharmacies who own ⅔ of the US Market [14]. By partnering with this major leaders we can distribute our value proposition in ways that are fast, efficient and cost-effective to both patients and the clinics.

3.1.3 Customer Relationships

We will have automated services that are going to continuously maintain good relationship with clients. Since patients usually require a continuous follow up of the screening based on the severity of the condition, our automated system can send regular screening reminders and personalized suggestions to the patient's smartphone. Besides this, there will be personal assistance from the retail clinics themselves as they are staffed by nurse practitioners and physician assistants.

3.1.5 Key Activities

Some of the key activities to execute our value proposition would be as follows:

1. Improvement of early DR detection screening algorithm to reach an accuracy that is trustable; Preferably above 98%
2. Platform development for automated customer reminders and personalized suggestions
3. Research and development of the Eye Fundus Camera Housing to lower the cost of manufacturing while still maintaining the quality of the images.

4. Marketing and promotion of the product together with spreading awareness about the opportunity to prevent chances of having DR by performing early screening exams
5. Marketing activities to promote the solution as trustworthy and affordable.

3.1.6 Key Resources

Our key physical resources include 3D printing machines and spherical lenses to produce the device. This will be replaced by cost effective supply chain solutions during mass productions.
Our intellectual resources will include patents to the device and trade secret for the AI screening algorithm that detects early sign of DR through fundus images.
Similarly, our key human resource include machine learning engineers and scientists who can improve the algorithm, sales person with good network in the United States to partner up with retail clinics.

3.1.7 Partner Network

We will be maintaining a couple of key partners. One of them will be with manufacturers of spherical lenses that can provide us with the best lenses in a cheaper price to reduce the manufacturing cost, Our next partner will obviously be retail clinics through which both of us can get mutual benefits. Some other idea of partnership ideas can be with news agency for the purpose of marketing or with other (public) healthcare providers such as insurances that have an interest in keeping patients healthier.

3.1.8 Finances

The main goal of the conducted financial analysis was to pre-validate a business model and estimate accurately the fundraising needs at all growth stages of the company. We made several assumptions supported by best available data on the websites of our competitors, industrial reports as well as interviews with experts from the industry.

Cost Structure

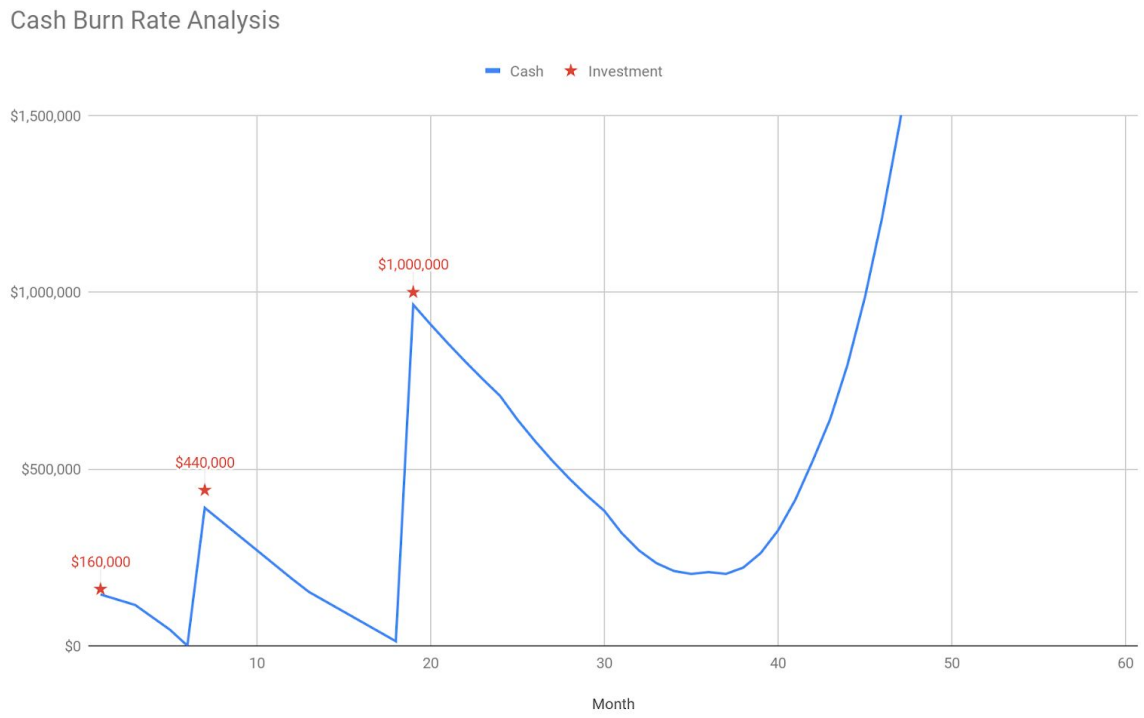
Our costs include variable costs: fundus camera production cost and customer acquisition costs, as well as fixed costs: mainly salaries, but also costs related to conducting and getting all necessary tests, approvals, consulting and sales activites. We assumed $800 as a production cost of fundus camera device, which has to be delivered to each retail clinic. Furthermore $15 CAC was assumed for each new customer. There is no additional marketing spending for retained customers.

Revenue Streams

Our business model being revenue sharing, our revenue depends strictly on number of patients being screened at the retail clinics. Per patient per screening, $30 of revenue is assumed.

Investment needs

Given our assumptions we arrived at $600 000 initial investment need split into two rounds according to defined milestones. Further $1M will be needed after product launch mainly for growth purposes. On figure X one can see cash burn rate analysis given our assumptions.



3.1.9 Market potential of the proposed business

We expect the market for diabetic retinopathy screening in the US to be worth now more than $746M and expected to surpass $1B in 2040. Given proposed business model the reach will be geographically limited to locations of retail clinics. Taking into account only patients who frequently visit such clinics the market potential is $134M now and more than $300M in 2040.

3.1.10 Benefit/competitive advantage of the product or service

The main competitive advantage of our product is that it completely eliminates the need for presence of experienced professional during diabetic retinopathy screening, therefore it is easier and cheaper to access for patients.

3.2 Business planning

3.2.1 Global market trends

Currently there are 425 million diabetics worldwide, according to the International Diabetes foundation. That represents 1 in 11 adults [4]. These figures are only expected to grow in the

future. By 2045 the total number of diabetics is projected to rise above 649 million [15]. As stated above, every diabetic is at risk of developing diabetic retinopathy.

3.2.2 Go-to-market / market access approach

The US, which is our target market, has high rates of diabetes. 30.3 million, or 9.4% of the total population, has diabetes and 23.1 million of them are diagnosed, as stated by the American Diabetes Association. Prevalence of diabetes is especially high among seniors as 25.2% of those age 65 and above have it.

Number of ophthalmologists trained to identify the signs of diabetic retinopathy is insufficient as there are only 59 of them for every million citizens [10]. This means that if all the diagnosed American diabetics were attending the annual checkups as required, each ophthalmologist would have to examine more than 3 of them each day, including weekends and holidays. Not to mention that they have a number of other eye conditions to follow and operations to perform.

The channel with which we plan to reach as many diabetics as possible are retail clinics. This is a rapidly growing market segment in the US, estimated to be worth well above $7 billion by 2025 [16]. Currently the number of retail clinics in the US is estimated at over 2800 [17].

We aim to negotiate a partnership with a leading pharmacy chain that operates retail clinics. These include Walgreens and CVS, who together control two thirds of the market [14]. In order to do this, we plan to hire a local salesperson to represent us in the US. As the market is consolidated, communication takes less effort due to a limited number of partners to reach out to. As these negotiations will be starting, we will be on our way to obtain the FDA premarket notification, which will make convincing our partners easier.

Our next goal will be to organize a pilot program at 10 retail clinics of a selected partner. This is scheduled for Q3 of 2020. It will enable us to test our product with the first customers, allowing for final improvements before the US wide product launch.

In order to raise awareness and draw customers to our partner retail clinics, we will be starting a marketing campaign simultaneously with the launch of our product in the beginning of 2021.

3.2.3 IPR aspects

The key to securing our position in the market is to protect our algorithm, which is used to identify symptoms of diabetic retinopathy. This solution has to be cleared by the FDA’s premarket notification, which, once obtained, will represent an additional barrier to any competitor.

There are competitors with similar devices and AI capabilities, but none are combined in one solution offering. Neither are they present in the retail clinic market. Therefore we can strike

an exclusive deal with the pharmacy chains and establish a strong position ahead of our competitors.

3.2.4 Financial forecast

We have calculated our operating costs, consisting of predominantly of salaries, to $5k per person per month. During Q3 2019, when will be training the algorithm, 3 full time employees are needed.

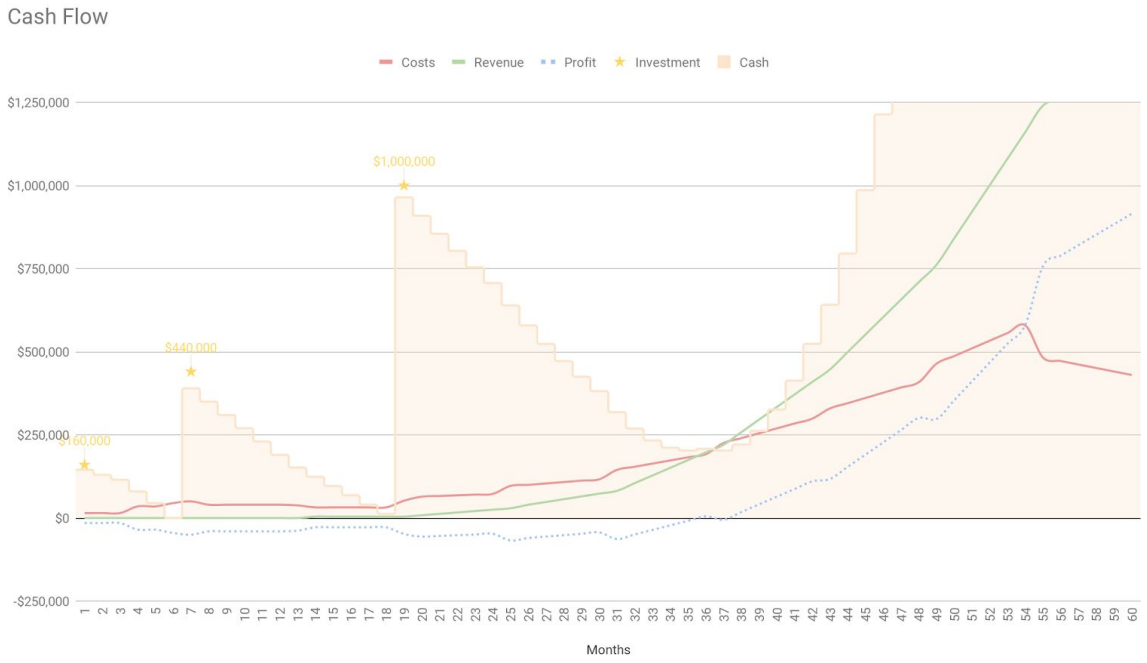
For the trials, scheduled for Q4 2019, we will be adding two more employees. Additionally, we have factored in the costs of performing test needed to submit an application for FDA premarket notification next year. These tests include IEC 60601-1 and IEC 60601-1-2, which are mandatory for any medical device containing electronics, Biocompatibility & toxicity testing as our device will be in direct contact with patients skin and finally the Performance bench testing, that evaluates the algorithm success rate [18]. Budget for these tests is $40k.

In the beginning of 2020, we will submit the FDA premarket notification documents and will have to pay the $10k application fee [19]. We have allocated additional $10k to consult these documents with an expert before submitting them.

Consulting costs will be continuing on throughout H1 2020 with the same amount set per each month to support our negotiation process with the partners on the US market. These will be largely done by a new employee a salesperson, whose salary is budgeted to $5k per month since January 2020.

In order to conduct the trials at first retail clinics, we will have to manufacture the first 10 units of our fundus cameras, costing us $800 each. As the trial starts, so will our customer acquisition costs, which we have estimated to $15 per customer.

After launch the salaries of all 6 employees will be raised by additional $2k per person per month, resulting in total monthly operating expenses of $42k. More costs will be due to manufacturing of fundus cameras to supply the retail clinics as we expand to new locations. Additionally, we have allocated $10k per each month after launch to cover the marketing campaign.



3.2.5 Financial and/or social return of the proposed business

We expect to break even in mid-2020, which will be 3 years since the start of our operation.

In 2021, the first year after launch, we will be present in 190 clinics and generating $400 thousand in revenue. This figure will be growing exponentially together with the number of partner clinics and by 2022 it should rise to $2.7 million coming from 970 clinics. In 2023 predict revenue of $9.2 million and presence 2470 in locations.

The benefit that we aim to bring on a societal level is to help prevent the leading cause of blindness for working age population in the US. Thanks to prevention, additional healthcare expenditures, both public and private, can be avoided along with the struggle associated with losing one's eyesight. This will be done by making the retina screening accessible to anyone at an affordable cost. Our marketing will assist in raising awareness about the disease even beyond the scope represented by our customers.

3.2.6 Contingency planning and risk assessment

The first risk we will be facing is achieving a satisfactory success rate during trials after the development our algorithm. This has to be met in order to proceed with any subsequent steps. It is also why our first funding round is dedicated solely to this effort and only when successful will we be seeking a second round.

Our product has to be cleared by an FDA premarket notification. This process can take between 3 to 6 months, which is reflected in our timeline. As our competitors have previously

separately acquired the same clearance for both a physical device and an algorithm highly similar to ours, this should not pose an issue [20].

The US retail clinic market is consolidated our success stands and falls with the ability to make a deal with at least one of the larger pharmacy chains. We aim to mitigate this risk by hiring a well experienced local salesperson with and to supplement their knowledge by investing in consulting services early on in the negotiation process.

Last notable risk is low turnout of diabetic patients that would undergo our screening at partner retail clinics. This is why we have planned a marketing campaign to raise awareness both about the risks associated with diabetic retinopathy and the about the availability of the examination provided.

Our funding rounds are designed is such a way that we will have sufficient funds to sustain our operation throughout the process. The first two funding rounds will provide us with 24 months of runway and the following series A round does include reserves in case of delayed break-even.

3.2.7 Strategy for funding

Funding will be needed at several stages during the process of developing our product and bringing it to the market (Figure 2).

The first investment required to start our operation is a pre-seed of $160k scheduled for beginning of Q3 of 2019. This would enable us to further develop the algorithm and perform trials to check its real-life performance. The pre-seed round will be partly covered by founders themselves, supplemented by FFF's. Nevertheless, additional support will be needed either from an angel investor or a start-up accelerator or incubator.

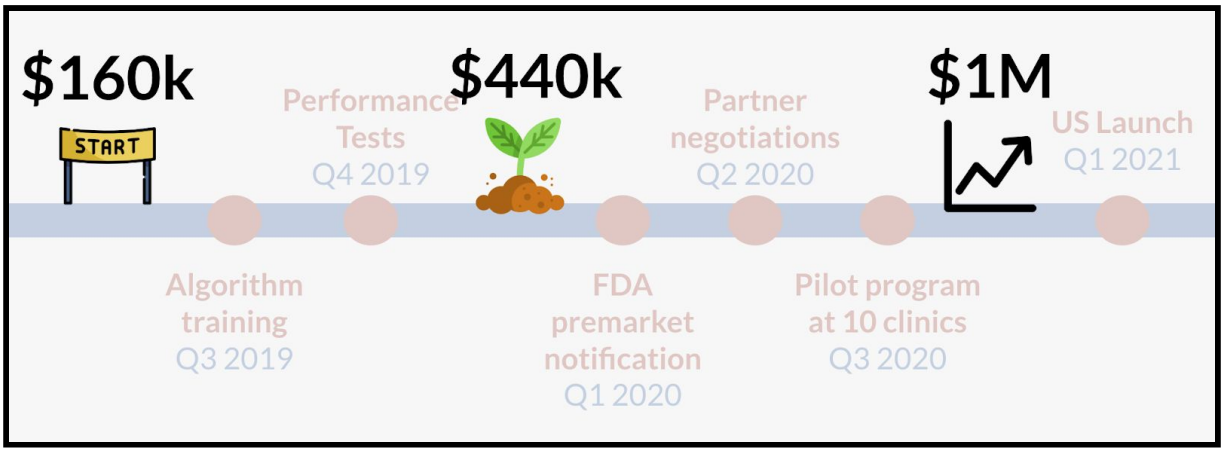


Figure 2. Funding stages mapped on the business development milestones

Provided that the tests are successful, we will be seeking additional $440k in our seed round. This will cover expenses for the FDA clearance process, negotiations with partners and the pilot programme, all planned for 2020. The seed round should be covered by an investment coming either from an angel investor or a venture capital firm. We would like to

maintain the relationship with our past investors, but also should be at a point where it would make sense to contact venture capital firms.

After a promising pilot stage, $1 million will be needed to launch the product on the US market and sustain our growth until break-even point. For the A series funding we will again first be going to our previous investors and possibly to our newly acquired partners, the pharmacy chains operating the retail clinics serving as our channel.

4 Business development process

The business development process for the catcheye project can be segmented into an ideation and research phase and a business model definition phase.
The research phase consisted of an initial technology exploration (4.1), structured brainstorming (4.2), market research and segmentation (4.3) and expert interviews (4.4).
During the business model definition phase, the team chose the final business model and defined the value proposition for user and customer (4.5), developed the financial plan including calculations of the TAM, CAC and CLTV, prediction of capital needed and prediction of revenue (4.6) and lastly defined corresponding milestones for achieving break even and growth (4.7).

4.1 Technology Exploration

The first step of the business development process for the team was to get familiar with the technology developed by Fraunhofer AICOS. The technology experts of Fraunhofer provided an introduction into the technology and demonstrated its usage.

Conclusions from this phase:
The demonstration allowed the team to get first ideas about potential use cases and the current usability of the device.

4.2 Structured Brainstorming

4.2.1 Brainstorming: Diverge

The next step was to ideate a large amount of potential use cases and ideas associated with the EyeFundusScope. For this purpose, each team member came up with at least five ideas individually and presented them to the team. While presenting the idea, another team member could add on similar ideas they have had. In this process, we created an Affinity Map of associated ideas (figure 1).
In the next step, we aimed to understand whether the product ideas were new, or already existing and whether the business would operate in a new or an existing market. We thus

organised the associated idea clusters into a 2x2 Matrix consisting of the areas Products (existing vs. new) and Markets (existing vs. new), see figure 1.

4.2.2 Brainstorming: Converge

Our objective was to converge our large list of ideas into feasible, topic-related ideas.
In the process of converging from our large amount of ideas to a smaller amount of ideas, we first individually wrote down associated throughs and feedback for the ideas listed. We then discussed the feedback. Next, we excluded ideas which were either not part of the theme “longer independent living” or not feasible.

Figure 1. Cluster of ideas on the matrix Products x Markets. Ideas in yellow post-its, comments and feedback in red post-its.

Conclusions from this phase:
After the exclusion of ideas that were not feasible or not fitting the theme of the Summer School, the following ideas remained:

1. Professional assessments (e.g. pilots)
2. At home testing device
3. General Practitioner
4. API (e.g. for Glasses shop that has device)
5. Optical Training Devices for medical students
6. Mobile Retina Scanner for mobile clinics/remote areas
7. Health Booth (Retina Booth)
8. Public rental for medical devices (e.g. library)
9. Elderly care / nursing homes

4.3 Market Research and Segmentation

The objective of the market research was to identify the 3 most promising ideas to research in-depth as well as to understand the competitive landscape of Eye Fundus Cameras.
We split the task for researching the diverse topics and defined the research targets into the following sub-categories: Current procedure (i.a., for example current eye examination process for patients in nursing homes), competition, potential paying customer (e.g. insurance), potential user (e.g. diabetic / general public), market size, obstacles (e.g. legal and privacy issues) and further remarks. We also performed a general competition research online and technical research to understand the future of deep learning approaches in interpreting retinal scans.
We then presented the results of our research to each other. Appendix 7.1 shows an overview about the most important findings related to our ideas which helped us decide on the main ideas, customers and users to focus on.

Our analysis of the competitive landscape showed that there are many players in the field - but that all of them still require an *ophthalmologist for the analysis* of the retina image (see figure 2).

	Accuracy	Affordability	Minimal expertise required	AI Automated
catcheye	✓ ★	✓	✓	✓
D·EYE		✓	✓	
JEDMED	✓			
WelchAllyn	✓	✓		
Professional Fundus Cameras	✓			

★ Algorithm Under Development

Figure 2. Overview of competitors

Our unique value proposition hence is that the image is screened and pre-evaluated by an algorithm and potential threats can be flagged without the involvement of an expert. Besides, the research of technical capabilities showed, that in the future deep learning approaches could be used to identify many more eye diseases and, beyond that, even tumours [1], Alzheimer [2] or cardiovascular risk factors [3].

Conclusions from this phase:
Considering all our research, we individually voted on which ideas we found most promising. Through the voting, we selected the following ideas for further exploration:

1. General Practitioner

2. Mobile Retina Scanner
3. Pharmacies / Health Booth
4. Nursing Homes

4.4 Expert Interviews

Our interview with experts had the overall objective to validate our understanding of the market and potential use case for the EyeFundusScope. We aimed to learn whether the experts considered an implementation of our solution ideas as feasible.

4.4.1 Ophthalmologist

In the interview with the opthalmologist at José de Mello Saúde hospital our hypothesis was that in the near future, more illnesses could be diagnosed with the EyeFundusScope.
We also aimed to understand how the current process of examining eye diseases such as the diabetic retinopathy is working. Our hypothesis was that the ophthalmologist looks at the eye and makes a “live diagnosis” of the condition.

We learned that currently an optometrist trained on the professional devices takes photographs of the retina. The medical doctor, then, does the diagnosis based on the images.
The ophthalmologist also explained that the analysis of the retina is not a useful approach for identifying diseases such cardiovascular risk factors or diagnosing diabetes itself. By the time the disease affected the eye and shows on the retina, the disease would already be at a late stage. As a consequence, the EyeFundusScope could not be used as a general screening or prevention tool for the public.

Conclusions from this phase:
As a team, we drew the conclusion that we should focus on Diabetic Retinopathy and thus on diabetic patients as our target user group because screenings of the general public is not a useful preventive approach to identify other diseases.

4.4.2 Director of nursing home

We contacted an acquainted director of a nursing home in Germany to understand how elderly residents in nursing homes receive medical care, if diabetic or blind patients receive specific support in the facilities and who is paying for their doctor visits. Our objective was to identify whether nursing homes could be a potential customer acquiring our device. The value proposition would be that nursing homes could save expenses on doctor visits such as transport and caregivers, as well as to avoid the financial consequences that arise when a diabetic patient turns blind.
In general, the director explained, the nursing homes have to think twice about each spent Euro which is why they would not like to acquire an EyeFundusScope for their nursing home. Besides, the coverage system of medical costs works differently in each of the 16 states inside Germany. Sometimes nursing homes cover, sometimes insurances, in other cases the patients themselves.

Conclusions from this phase:
As a consequence, we decided to drop the “Nursing Homes” scenario because of the following reasons: The system of nursing homes is scattered and they are often run by individuals, they have a very limited budget, and there is uncertainty about who would be the paying customer due to many different systems even within the same country.

4.4.3 Investor in the Healthcare Sector

During the mid-term pitch, we presented our idea of placing the EyeFundusScope in pharmacies. In the following discussions with an expert and investor in the Healthcare sector, we learned that pharmacies are a difficult customer segment due to the scattered market of pharmacy ownership between and even within countries. Also, general practitioners, at least in Portugal, might not acquire additional medical equipment if this is not generating a clear additional revenue for them. We were also suggested to consider a subscription model for our service.

Conclusions from this phase:
We concluded to exclude our ideas “General Practitioner” and “(European) Pharmacies” based on this feedback.

4.4.4 The users: Focus group with seniors

In a moderated focus group at Fraunhofer AICOS, the new technologies developed by Fraunhofer and the seniors’ general opinion about new technologies were discussed.
The discussions showed that seniors are inclined to use new technologies if they are introduced to them by their relatives, especially children. When it comes to new *medical* technologies, the seniors trust their doctors’ opinion and usually prefer consulting a medical expert, if required.

Conclusions from this phase:
For our use case, these findings suggested that the EyeFundusScope should be operated by a trained person with some sort of medical background and it should be placed inside the patient’s community as this is a trustful environment.
As a consequence, we dropped the “mobile retina scanner” idea, as this includes a nurse to travel in a remote area to perform the scans. In this scenario, there would be a major marketing campaign required and cooperations with existing medical trust figures (such as GPs) to motivate individual patients to attend the screenings.

At the same time, the feedback suggested that the “Health Booth” would be a good scenario to follow up with.

4.5 Choosing a Business Model

4.5.1 Selection of final business model

The final business model emerged from a combination of the ideas “Pharmacies” and “Health Booth” - placing the EyeFundusScope in the Retail Clinics in the US, inside the patient’s community. Reasons for this selection were that the Retail Clinics already offer primary care and basic healthcare services at affordable prices to US citizens [21]. Among these services is already the offering of diabetes monitoring [22].
By now, already 18% of US citizens have visited the clinics [23]. The market is growing: in the US it is estimated to reach USD 7.3 billion by 2025 [16]. Similar concepts are currently piloted in the European Market, for example in Germany [24]. The US is a good entry market due to its size (23 million diagnosed Diabetics) [12]. Also, there are two market leaders only, Walgreens and CVS pharmacies who own ⅔ of the US Market which allows us to scale widely using just two partners [14].

The chosen business model approach is a B2B2C and a revenue sharing model. Catcheye provides the EyeFundusScope to Retail Clinics in the US. These retail clinics perform retinal check-ups on diabetic patients. The patients pay a fixed amount to the Retail Clinic. The clinic keeps a 25% commission and catcheye receives a 75% margin per performed examination.

4.5.2 Defining value proposition for patients

The business model was thought to be attractive for the patients because of the following reasons:

- Retail Clinics are located *inside* the patients community so they are easily accessible
- Patients can pay for the check-ups as this is a common model in the US (possibly with reimbursement) and the check-ups would be relatively affordable
- Retail Clinics symbolise medical expertise, which patients need to generate trust
- Retail Clinics are already frequented by Diabetics. These patients perform diabetes monitoring. However, the currently have to visit an ophthalmologist for eye check-up. Our service catcheye allows them to perform this check up in the Retail Clinic near them

4.5.3 Defining value proposition for Retail Clinics

The business model was thought to be attractive for the retail clinics because of the following reasons:

- Receive commission, increase profits
- Diversify offering
- Increase customer loyalty
- Draw customers in the stores to make purchases

The retail clinic market is competitive and growing market which is why the assumption was made that the clinics would like to achieve better or at least similar service offerings.

4.6 Development of Financial Plan

Calculate Total Addressable Market

There is more than 30M diabetics in the US and each of them requires annual screening in order to prevent diabetic retinopathy. However according to the statistics 38% of them are still not diagnosed. As such we are not considering them to be our customers yet. Therefore we arrived at 18.5M of diagnosed diabetics. As this group is spread throughout US we will not be able to reach all of them. We limited our total addressable market to only those patients that are customers of retail clinics. According to the survey conducted among US citizens, 18% of them have visited such clinics within the last year. Therefore we expect our market to be 3.3M of diagnosed diabetics visiting retail clinics. With growth of population, increased prevalence of diabetes and better diagnosis, this number will grow to 7.5M in 2040.

CAC and CLTV

Initially our devices will be placed in retail clinics, which will become our main distribution channel. Therefore some of the current customers of retail clinics will automatically become our customers. Despite this fact, we will need to perform some marketing activities in order to raise awareness of diabetic retinopathy and possibility of such screening in the retail clinic. We assumed a $15 CAC for each new customer. We expect 50% of acquired customers to return in 1 year or earlier, as each diabetic requires screening at those intervals and we are going to send reminders to those who shared with us their contact information after the first screening. Using formula X for LTV calculation (assuming 0.5 churn rate and 75% gross margin) we arrived at LTV value of $60, which leaves us with promising CAC/LTV ratio of 4.0.

Formula X: LTV=(REVENUE*MARGIN)/CHURN

Prediction of capital needed

As the product is not yet fully developed, first 12 months will be devoted to improving algorithm, obtaining certifications and negotiating partnerships. During this period we assume spending of $448 000 and additional $200 000 for completing the pilot in 10 clinics at almost no revenue. After the pilot and launch we are going to enter growth phase.

4.7 Next Steps: Development of milestones and timeline

The next steps to continue this project would be to validate the business model and concept with users and customers. This would require to have interviews with Diabetes patients in the US and visit Retail Clinics and conduct observations possibly of Diabetes monitoring sessions. Also, initial discussions with the US Retail Clinics have to follow to understand if they are interested in such a device and partnership and how the actual device and check-up could be integrated in their routine.

Collaborations with Fraunhofer have to be discussed to understand how a partnership and business model works when our company catcheye uses their technological innovation.

For the purpose of catcheye's business plan - factoring out that we do not have the right to use Fraunhofer's technology and would still need to validate our business model in detail - we set up milestones for the next 2.5 years (figure 3).

As a first step, we need to develop the algorithm and perform trials to check its real-life performance by the end of 2019. By Q1 2020, we plan to perform the FDA clearance process which enables us to have serious negotiations with partners (US Retail clinics) and pilot the programme at 10 retail clinics by Q3 2020. By Q1 2021, we have the target to launch US wide through our partners. This of course requires large-scale production of the EyeFundusCameras and related software which should take place in advance. Also, marketing, and sales initiatives will run in the US.

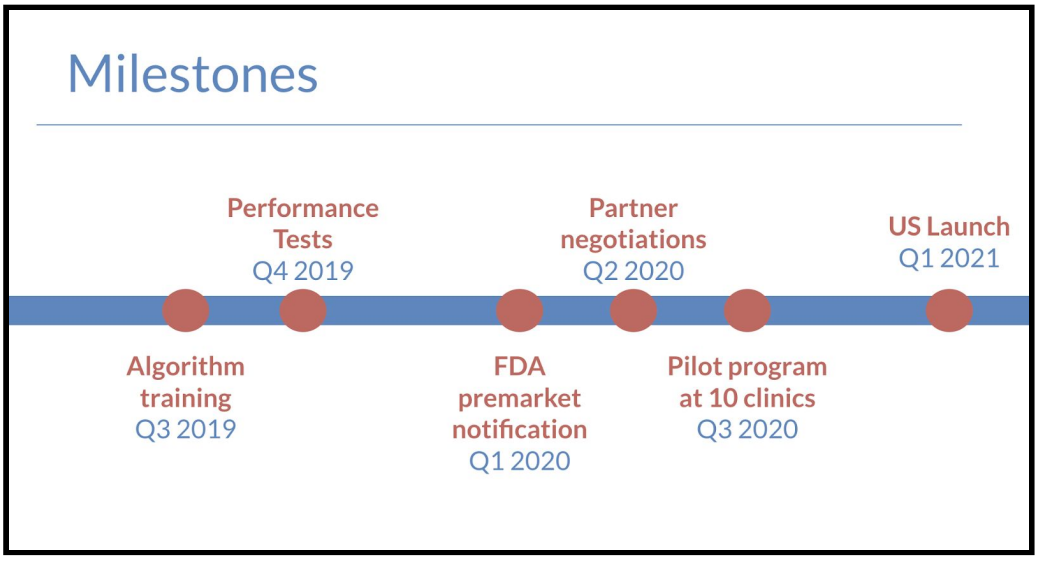


Figure 3. Milestones for the upcoming 2.5 years

4.8 List of contributors

1. **Technology Experts**
David Melo, Fraunhofer Portugal (https://www.linkedin.com/in/david-melo-5b8355131/)
Miguel Santos, Fraunhofer Portugal
(https://www.linkedin.com/in/miguelsantos32/?originalSubdomain=pt)

Introduction into EyeFundusScope Technology, sharing of product presentation, answering questions about device costs, estimated price when manufacturing at larger scale and plans for performing clinical tests

2. Nursing Home Expert
Lina Freudenberg
CEO of Agaplesion Pflegedienst München

https://www.kma-online.de/aktuelles/koepfe/detail/neue-geschaeftsfuehrerin-beim-agaplesion-pflegedienst-muenchen-a-40309

Information about medical care inside a nursing home, who is responsible and paying for medical check-ups, specific care provided to Diabetics

5 Self evaluation

Self Reflection - Naima Volz

In total, I think we did a good job as a team. We managed to evolve through various ideas and business model iterations throughout the process to come up with a good solution, business model, business plan and pitch in the end.
However, the team organization, roles and processes were not clearly defined at the beginning. In retrospect, it would have been useful to set common expectations and objectives with regards to the Summer School project instead of immediately diving into the actual work. Also, it could have helped to define the preferences, working styles, learning goals and also development areas of each individual. This would make it easier for everyone to feel comfortable in the team and to benefit from the experience.
Sometimes during the process, it was not clear who is doing which task, especially in the Research phase. Market research can easily overlap and different content can be researched. We tried to mitigate that through creating a detailed Excel Sheet and information points to be filled. Still, it sometimes felt like we were making little progress during this research phase.
We then did a good job in narrowing down the ideas. We first gathered information on the market and business potential of the idea and then voted democratically on which ideas to follow; and everyone accepted the outcome. Lastly, we allocated our individual strengths well towards the end of the project, in parallel finalising the financial calculations, researching some more market data and working on the pitch. We also discussed the slides and final pitch text together in detail and managed to achieve a good final presentation which was also valued by the jury.
I contributed to the team with some knowledge of design thinking which helped in narrowing down the ideas and improved the design of the pitch slides so that they are more appealing to the audience. I wrote the team document which was provided to the jury during the final pitch session. Lastly, I held the pitch which is an activity that I actually enjoy doing if I get enough preparation time.

I learned a lot about the healthcare market and challenges when aiming to launch a product in this market such as to define an actual paying customer, deal with a scattered system of healthcare providers, a lack of budget of certain institutes and the special needs of the end-user in this field. I also learned more about defining a business model and financial plan for revenue estimates and funding needs.

In respect to my own competencies, I sometimes found it hard to maintain a positive spirit when another iteration had to be performed which is something I have to learn. In terms of “hard skills” my knowledge about financials, defining revenue models and investment needs is not well developed and requires more practice.

Self Reflection - Feiyi Su

Our team did a really good job. Our team did not define roles but everyone knows individual strengths. We collaborated with each other and made decisions together. We tried to start with brainstorming and came up with many innovative ideas. We continued to refine and evolve our ideas and business model, resulting in a go-to-market solution finally.

In retrospect, it would be better to divide task clearly. At the beginning of the research stage, we were doing some research overlapping a lot. We quickly adjusted and made excel sheets for summarizing what we had found. The most important thing was that we narrowed down our scopes and clarified our direction to the goal so that everyone could strive to reach the same goal. We respected each other’s ideas and thoughts and voted for making decisions, enabling more effective and productive works. Everything went smoothly because we shared information and discussed a lot. We also prepared slides and final pitch together.

My contribution was mainly on research phase. I tried to help team with knowledge of finding competitions and collecting data of current situation.

I learned a lot from the entire project. I learned a lot about healthcare market and existing challenges. I learned about how to launch a new product in healthcare market. It is vital doing the prophase research about the problem, user’s needs, market size and business model. I also learned about defining a business model and financial calculations and revenue estimates and funding needs for starting a new business. Moreover, I learned about soft skills of presentation.
I missed with competence about financial analysis skills. I need more practice about it. The “soft” skill I also missed often made me hard to express myself so it also needs a lot of practice.

Self reflection - Filip Finfando
Overall it was a valuable experience to work on this task with this team. We were 5 dedicated students, each of us taking full responsibility for delivering the final pitch and this report. Our workflow followed the structure prepared by summer school organizers. We undertook all tasks according to the proposed sequence asking for help of the mentors if needed. At the beginning of each group work session we assured every member of the team undestands the task in the same way and we identified action points on what kind of research or slides needs to be done. Later, to each action point we assigned a responsible person. Depending on the nature of the task we were organizing results of our work in a shared documents, spreadsheets or slides which were constituting the final pitch deck. At the end of the session we summarized what has been done, main insights from research work and defined further action points if necessary. After each full day of work we defined

high-level bullet points describing the current state of our product and business model to ensure we are all on the same page with our idea and we all know what to say during pitching time the next morning. There were no clear roles defined as everyone was expected to pitch and everyone shared similar competences, except when we were told to assign roles explicitly during the exercises.

It was exciting to contribute on each phase of the project development, however there was no time for everyone to dig deep down into each of the tasks we were facing. Therefore each of us focused strictly on topics related to tasks assigned to them. Personally, I devoted significant amount of time to initial market research in various countries, reading technical papers to fully understand potential and limitations of the technology we were working on and financial analysis in order to assess our fundraising needs and validate whether our business model is financially sustainable.
I was lucky enough to be randomly selected as a presenter for a practice pitch twice, so I definitely practiced my public speaking and presentation skills. During the group work sessions it was interesting to try various methods for better team collaboration. Additionally it was exciting to learn how it is to work on delivering a real product to the market. Thanks to cooperation with Fraunhofer and other institutions the experience during this exercise was very close to a real one. Overall, during this summer school I developed better soft skills in general. What I found missing is good information presentation skills and data visualization skills. I would like to develop further in this area to easily and quickly create beautiful presentations in my future career.

Self reflection - Vojta Šafránek
Firstly I would like to say that I enjoyed working with our team, as everyone was actively contributing and provided valuable input. I also liked the fact that we have been introduced to a product and skipping the ideation process for once. This way we forced to work on a topic bit out of our comfort zone and expertise. That meant that most of our time was spent on research. While the company visits and opportunities to ask questions were present in the programme, I would wish to have more of them.
We haven’t assigned any formal roles, but we always broke down the upcoming task into actions to be done by individual team members. Sometimes this may have resulted in a bit of an unnecessary overlap. Also I think that we may have underestimated the time necessary to communicate our findings to the rest of the team. I do believe though that we all managed to get the most important points across while being able to listen to others. This is needed in order to build a common understanding, which should never be assumed.

I have learned about the importance of the whole team being on the same page before. But the fact that this time we didn’t know who is going to pitch and explain our idea until the very end has put even more weight to this fact. Anyone in a startup should be able to explain its business and getting two different explanations in the same team would be a red flag to any potential investor.
I especially liked how went through our pitch, carefully deciding on what needs to be said and putting all of our research together. We made sure that the pitch flow makes sense and explains all our key decisions while providing the facts and figures that justify them.

In the end I think that we were able to come up with a convincing business model able to generate a continuous stream of revenue. This was certainly not an easy task, as the technology assigned to us had a quite limited scope of use. It made us think hard about what channels we can use to reach the largest amount of paying end-users and how to.
I have learned a lot about an industry that was previously completely unknown to me. It was interesting trying to navigate the healthcare systems while trying to find out who is the key stakeholder to whom we need to sell our solution. I feel like I've been able to build on what I have learned at the business courses that I took during my first year of the EIT Masters. Similarly everyone has brought their own experience to the table. Therefore, we have learned the most from each other.

Self reflection - Rachhek Shrestha

Our team had different technical background tracks like Data Science, Human Computer Interaction from different Universities. Everyone had an entrepreneurial mindset. We did our best to have a common objective that is to build a solid business model for an existing technology. Intially I think we had very well organized team during brainstorming phase when creative ideas were being generated by everyone in the team.Later on the responsibilities and roles were open for taking by anyone who felt comfortable. Our team did a great job in terms of market research, preapring questions for asking to relevant people, pivoting efficiently when a market idea didnt seem feasible, giving constructive criticism to each other's point of view and maintaining consistent enthusiasm until the end.
Our process was that we all laid down our ideas first on the table, picked the top ones that everyone agreed on and did individual research on it. We discussed openely and worked on it for a few days. We then pivoted to another market and model when it didn't seem feasible anymore. We did this until we were quite confident about our strategy.The roles were often self assigned in the team and everyone was trying to contribute to the main topic.
Individually I contributed during the market research phase, gaining insights from the opthamologists and technology team at Fraunhofer by asking relevant questions, building the initial financial model by calculating yearly operating costs, helping the team pivot to our final market by discovering Retail clinics in the US and overall by providing critical and constructive criticisms wherever necessary.
I learnt many things and gained a new experience of solely constructing a business model of an existing technology. Knowing the limitation and boundary of the technology provided, I learnt how to adapt it in a way so that it appeals to investors. Some other learnings are
1. A good technology by itself is not enough, it needs a good business model.
2. Changing a business model can sometimes make the technology more successful.
3. Challenges and opportunities in the health and tech sector
4. I learnt about the trends in longer living. I was not aware that there are so much opportunites in the aging population market
5. I learnt that subscription model can be a good alternative when the device we are trying to sell is expensive
6. I learnt that requesting the investment in a series of stages comes across as more trustable.

In terms of the things that i missed for my competencies, I would say public speaking skills and developing detailed financial plans.

6 References

[1] *Member Portal*. [Online]. Available: https://www.vsp.com/eyewear-wellness/eye-health/retinal-exam.

[2] A. Sandoiu, “Eye scan may detect Alzheimer's disease in seconds,” *Medical News Today*, 30-Oct-2018. [Online]. Available: https://www.medicalnewstoday.com/articles/323515.php

[3] R. Poplin, A. V. Varadarajan, K. Blumer, Y. Liu, M. V. Mcconnell, G. S. Corrado, L. Peng, and D. R. Webster, “Prediction of cardiovascular risk factors from retinal fundus photographs via deep learning,” *Nature Biomedical Engineering*, vol. 2, no. 3, pp. 158–164, 2018.

[4] “Home.” International Diabetes Federation - Home, idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html.

[5] Yau, Joanne W.Y., et al. “Global Prevalence and Major Risk Factors of Diabetic Retinopathy.” *Diabetes Care*, American Diabetes Association, 1 Mar. 2012, care.diabetesjournals.org/content/35/3/556

[6] Member Portal. [Online]. Available: https://www.vsp.com/eyewear-wellness/eye-health/retinal-exam.

[7] “Sixty Percent of Americans with Diabetes Skip Annual Sight-Saving Exams.” American Academy of Ophthalmology, 3 Nov. 2016, www.aao.org/newsroom/news-releases/detail/sixty-percent-americans-with-diabetes-skip-exams.

[8] E. Mullin and E. Mullin, “The first AI approved to diagnose disease is tackling blindness in rural areas,” Quartz, 06-Sep-2018. [Online]. Available: https://qz.com/1371580/can-ai-deliver-on-its-promise-to-close-the-gap-between-rural-and-urban-health-care/.

[9] D. M. Gibson, “The geographic distribution of eye care providers in the United States: Implications for a national strategy to improve vision health,” *Preventive Medicine*, vol. 73, pp.

30–36, 2015.

[10] “Number of Ophthalmologists in Practice and Training Worldwide,” *International Council of Ophthalmology*. [Online]. Available: http://www.icoph.org/ophthalmologists-worldwide.html.

[11] Byrne, Margaret M., et al. “Cost of a Community-Based Diabetic Retinopathy Screening Program.” Diabetes Care, American Diabetes Association, 1 Nov. 2014, doi.org/10.2337/dc14-0834.

[12] “Statistics About Diabetes,” American Diabetes Association. [Online]. Available: http://www.diabetes.org/diabetes-basics/statistics/.

[13] “What is a Retail Clinic?,” Solvhealth.com. [Online]. Available: https://www.solvhealth.com/faq/what-is-a-retail-clinic.

[14] J. E. Dalen, “Retail Clinics: A Shift From Episodic Acute Care to Partners in Coordinated Care,” The American Journal of Medicine, vol. 129, no. 2, pp. 134–136, 2016.

[15] “Home,” International Diabetes Federation - Home. [Online]. Available: https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html.

[16] “U.S. Retail Clinics Market Worth $7.3 Billion By 2025: CAGR: 20.3%,” Market Research Reports & Consulting. [Online]. Available: https://www.grandviewresearch.com/press-release/us-retail-clinics-market-analysis.

[17] “Number of retail clinics in the U.S. 2008-2018,” Statista. [Online]. Available: https://www.statista.com/statistics/307264/number-of-us-retail-clinics/.

[18] “FDA 510(k) Submission Costs: The Startup Guide,” Kaydian Insights. [Online]. Available: https://kaydianinsights.com/guides/fda-510k-submission-costs/.

[19] Center for Devices and Radiological Health, “MDUFA User Fees,” U.S. Food and Drug Administration. [Online]. Available: https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/fy-2019-mdufa-user-fees.

[20] DEPARTMENT OF HEALTH & HUMAN SERVICES. Letter Communication. [Online]. Available: https://www.accessdata.fda.gov/cdrh_docs/pdf14/K141922.pdf

[21] “Retail Clinics and Surprise Bills are Changing Healthcare Customer Behavior,” Healthcare Weekly, 07-Nov-2018. [Online]. Available:

https://healthcareweekly.com/retail-clinics-and-surprise-bills-are-changing-behaviors-in-healthcare-customers/

[22] “How CVS Health is Transforming Diabetes Care,” CVS Health. [Online]. Available: https://cvshealth.com/about/our-offerings/cvs-caremark/how-cvs-health-is-transforming-diabetes-care.

[23] Civis. “Understanding Retail Clinic Patients” [Online]. Available: https://www.civisanalytics.com/wp-content/uploads/2018/11/RetailClinics_Whitepaper2018_v.pdf

[24] R. D. Ä. Deutscher Ärzteverlag GmbH, “Gesundheitskiosk berät mehr als 3.000 Menschen im im ersten Jahr,” Deutsches, 10-Sep-2018. [Online]. Available: https://www.aerzteblatt.de/nachrichten/97737/Gesundheitskiosk-beraet-mehr-als-3-000-Menschen-im-im-ersten-Jahr.

7 Appendix

7.1 Important findings about the main ideas

Idea	Customer & User	Important findings
Professional assessments (e.g. pilots)	Customer: Military (State) User: Pilots	Not promising: Already equipped with device, have their own ophthalmologists, Market sizes highly dependable on the countries, Military funded by public money, high barrier to entry, most demanding market, they look for way more conditions than those covered by our device
At home testing device (selling to private market)	Customer & User: Diabetic Patient	Not promising: 1000 Euro is a very expensive cost if the product is just used once per year
General Practitioner	Customer: GP or insurance User: Diabetic / Regular GP patient	Promising: for areas with poor medical resources or lack of ophthalmologists; Reduce workload of opthalmologist, allow patients to visit GP instead of ophthalmologist and save time or combine it with a regular visit; could be used to detect further illnesses such as cardiovascular diseases, Alzheimer, (
API (e.g. for Glasses shop that has device)	Customer: Optician/Insurance User: Regular optician visitor	Promising: for any venue that already has the images of retina and needs to annotate them; could be combined with regular visits of optician; Channel of optician might not frequently be visited by patients; scattered market across and within countries
Optical Training Devices for medical students	Customer: Universities User: Medical Students	Not promising: more devices per student thanks to the lower cost, portable so that they can train at home, their diagnosis can be automatically checked against the DL algorithm; BUT devices can only be sold once, algorithm checks could be licensed, user of fundus scope does not need a medical training
Mobile Retina Scanner	Customer: Rural hospitals / mobile doctors User: Diabetic Patients with mobility	Promising: Useful for patients with mobility impairment or living in remote areas that currently do not have any access; BUT Market size/budget of areas that are remote is usually lower; The device can not replace the professional equipment of an ophthalmologist: Potentially low quality of scan due to motion, non-stabilized system, artifacts like shadows and lights in the

	impairment or living in remote areas	optics
Health Booth (e.g. in pharmacies)	Customer: Health Kiosk companies / Pharmacies/ Insurances / End-user Customer: Diabetic and general public	<u>Promising:</u> Local accessibility, inside the patient's community, pharmacies want to be competitive and expand offerings; patient already performs "health behaviour"; Health booths /kiosk wide-spread in the US, they include services like testing the eyesight and Diabetes check-ups but NOT YET scans for DR, growing market; BUT scattered market across and within countries, not available in many countries, currently mainly in US
Public rental for medical devices (e.g. library)	Customer: State/Insurances/Patient User: General Public	<u>Not promising:</u> only available for doctors, end-users would be difficult to reach and train if it/s a one time usage; market access difficult as no rental of medical devices is common
Elderly care homes	Customer: Nursing Homes / Insurances Diabetic patient residing in nursing home	<u>Promising:</u> High market needs, high prevalence of diabetes at the age of living in nursing homes, diverse models such as subscription model possible; BUT small budget of nursing homes, scattered market across and within countries