2022

Business Development Plan

NEW PRODUCT DEVELOPMENT

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Business Case Summary

About the Business

The intervention defined in this document consists of two parts, a digital platform that is the user's touchpoint and allows for deep insights into one's health. Alongside a physical product, consisting of a kit with replaceable cartridges (figure 1), supporting a sensitive experience where the user can take care of themselves without the stigmas attached to public displays of medical procedures.

The DiCart service described in this document offers a novel solution to an emotional and behavioural problem often found with traditional diabetic care products. The literature discussed highlights that many existing products often fail to be sensitive to the user's needs in the vulnerable moments in the daily actions required to maintain glycemic goals. The Australian Bureau of Statistics (2022) tells us that there are 1.3 million people in Australia with diabetes today, where 1 in 5 have type 1 diabetes (T1D)—suggesting a not-so-insignificant amount of those managing T1D actively with insulin in Australia. Investment sought after will relieve the short-term pressure found in costs of setting up manufacturing, distribution and development.

Figure 1. DiCart, physical product. Band, lid, cartridges, and body.

Mission Statement

To empower those managing diabetes with products and services that accommodate the users with thoughtful and sensitive experiences. In addition, to remove the public stigma found in the daily medical rituals a large portion of the population performs.

Product & Service Scope

The Problem

The problem aims to define and understand the relationships people who experience T1D have with their chronic condition. Literature has long identified that social-environmental influences how youth manage chronic illnesses (Helgeson et al., 2015). Maintaining T1D's glycemic goals is paramount to long-term good health in individuals, thus emphasising the importance of effective medical devices that offers accurate care and enable an emotionally sensitive experience. However, personal accounts of those experiencing T1D have long described it promoting anti-social situations for the individual so that they may perform the necessary actions to tend to themselves from perceived judgment by their peers (Kanstrup, 2014). These examples of anti-social behaviour outline the problems identified. Therefore, the proposed DiCart services aims to address the identified social behaviour issues and seamlessly integrate into peoples lives without external judgment.

The Solution Overview

The proposed solution, DiCart (**Di**-*betic* **Cart**-*ridge*), aims to solve the problems mentioned earlier by offering the necessary treatment in a package sensitive to the user's needs and wants through the use of intuitive design solutions. The DiCart system comprises several components that cohesively integrate into the patient's lifestyle.

1. The DiCart kit contains several single-use *needle cartridges* of insulin that employ a colour coding system to categorise the types of insulin encapsulated.
2. Smartphone app that talks to active blood-glucose monitoring systems that can report to the user upcoming injection times.
3. The subscription model supports the regular supply of cartridges to the users.

The solution offers a system that is effective at treatment without taking up significant mindshare of the user by employing intelligent technologies and colour-coding to offer seamless experiences. Synergising with blood-glucose monitoring devices, a typical interaction with the DiCart will often be quick and sensitive to the user's needs. Typically, a notification will reach the user through their wearables or smartphone, indicating a timeframe to use a particularly coloured cartridge. The platform will use predictive models to make assumptions about eating habits and glucose intake, offering suggestions at the moment. The user can choose to ignore the notification briefly if not possible, or it will not pose a health risk, or accept the recommendation and apply the correctly coloured cartridge designed to be inconspicuous to enable the procedure in public without having to remove themselves from social situations.

Scope

Physical

Investment sought after within the project's scope will involve the development of manufacturing processes and distribution network. Investment in manufacturing will offer high-quality tooling and processes required to meet stringent medical device standards set forth by the Therapeutic Good Administration (TGA) and other international regulatory bodies. It is also essential to develop distribution centres in dense population areas that will work as delivery hubs that can ship quickly and cheaply to users. These centres are vital to long term success and viability as there are cold-storage requirements for insulin to ensure safety. In addition, this hub and spoke model distribution model will enable pleasant experiences with our user-base and allow greater flexibility within the business.

Digital

Capital will also be directed into a digital product that can both accompany the kit and enhance the experience and operate on its own. The digital product, a smartphone app, will be the user's main touch point with the system. It will employ prediction algorithms to develop a tailored model that can work with the user to provide the best health care that is also sensitive to their needs. Opportunities are available to expand the scope of the app into other diabetic products other than the kit and cartridge to enable an even further personalised experience for users. The app intends to surpass its competitors' offerings with meaningful continual development that other options fail to deliver, with the subscription-based business model ensuring long-term viability.

Product Classification

The DiCart system would be considered a breakthrough in its product class. This system represents a departure from traditional interventions that are often the most accessible for the most significant portion of those affected by T1D. However, the risks involved with this unique approach may include low subscriptions due to the public misunderstanding of the importance of a system like this represents. Thus it is crucial for the success of the intervention to present its vision clearly to its target audience and future investors. Other risks include regulatory approval, as the kit intends to have the manufacturing of not only bespoke syringes but also pre-filling insulin across several SKU's. It is also vital to emphasize the distribution network that supports the regular delivery of insulin many will rely on, highlighting yet another potential risk that needs to be considered. Despite these risks, the opportunities available to the DiCart are enormous. They should be investigated appropriately, as many identified competitors continue to develop slowly, and remain naive tp the sensitivity to the situation, many are in with T1D. This gap will mean the DiCart will be trivial to separate the brand from the rest of its competition where it can offer unique services not found previously.

The Need - Target Market

Summary

With those who experience T1D as the defined target market, the DiCart service establishes its developed experiences for those users. However, many other tertiary users aid DiCart's market success. Medical practitioners will likely be the ones that educate the patient and recommend our service to the target demographic. Family and significant others play an important supporting role for many with T1D and may be necessary to adhere to glycemic goals. The public is also a third-party user where it is often found that the perception of oneself in public informs the actions someone takes when maintaining glycemic control.

Personas

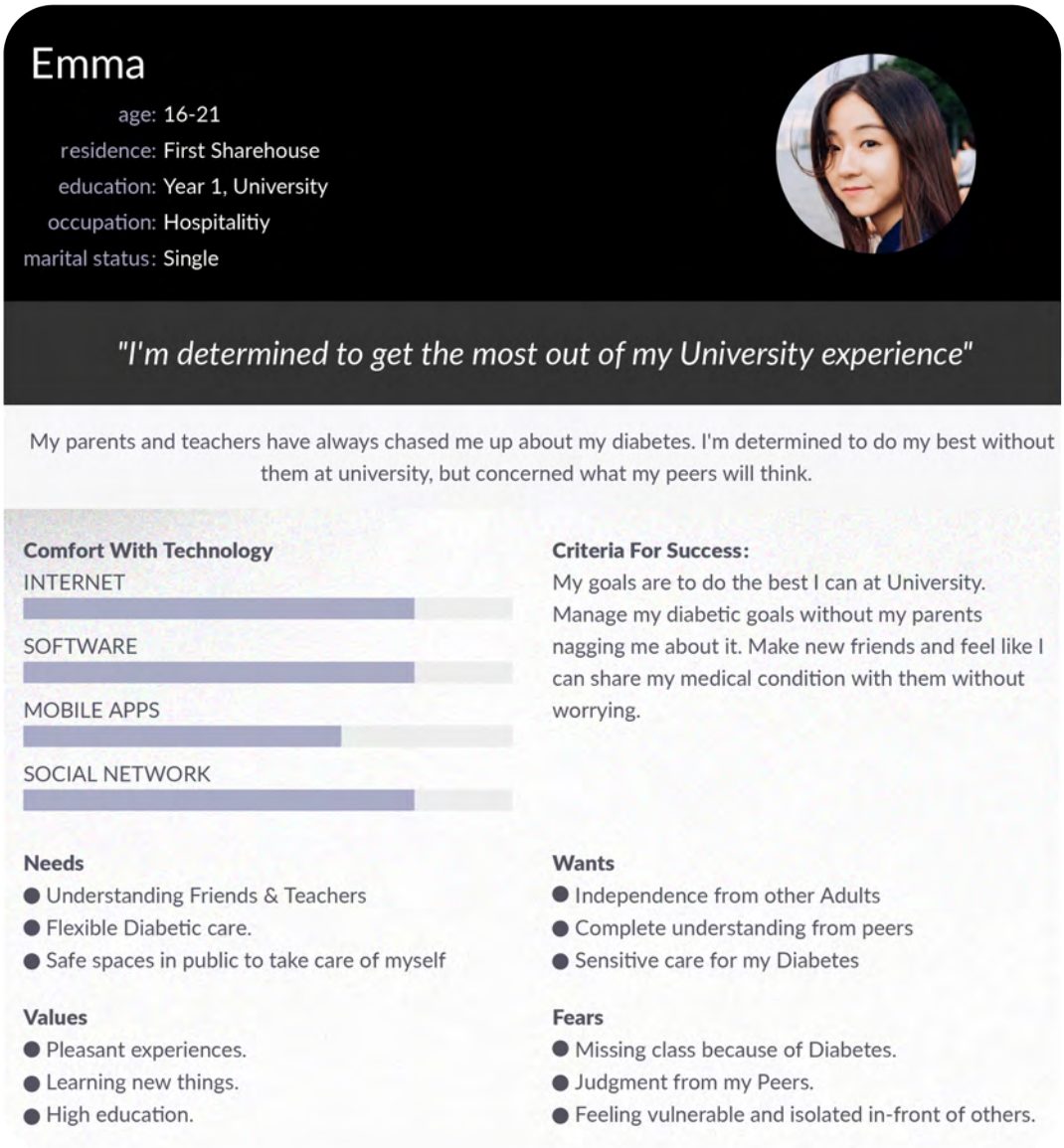

Figure 2. Emma, student persona based on research from Dayte et al., 2015; Helgeson et al., 2015.

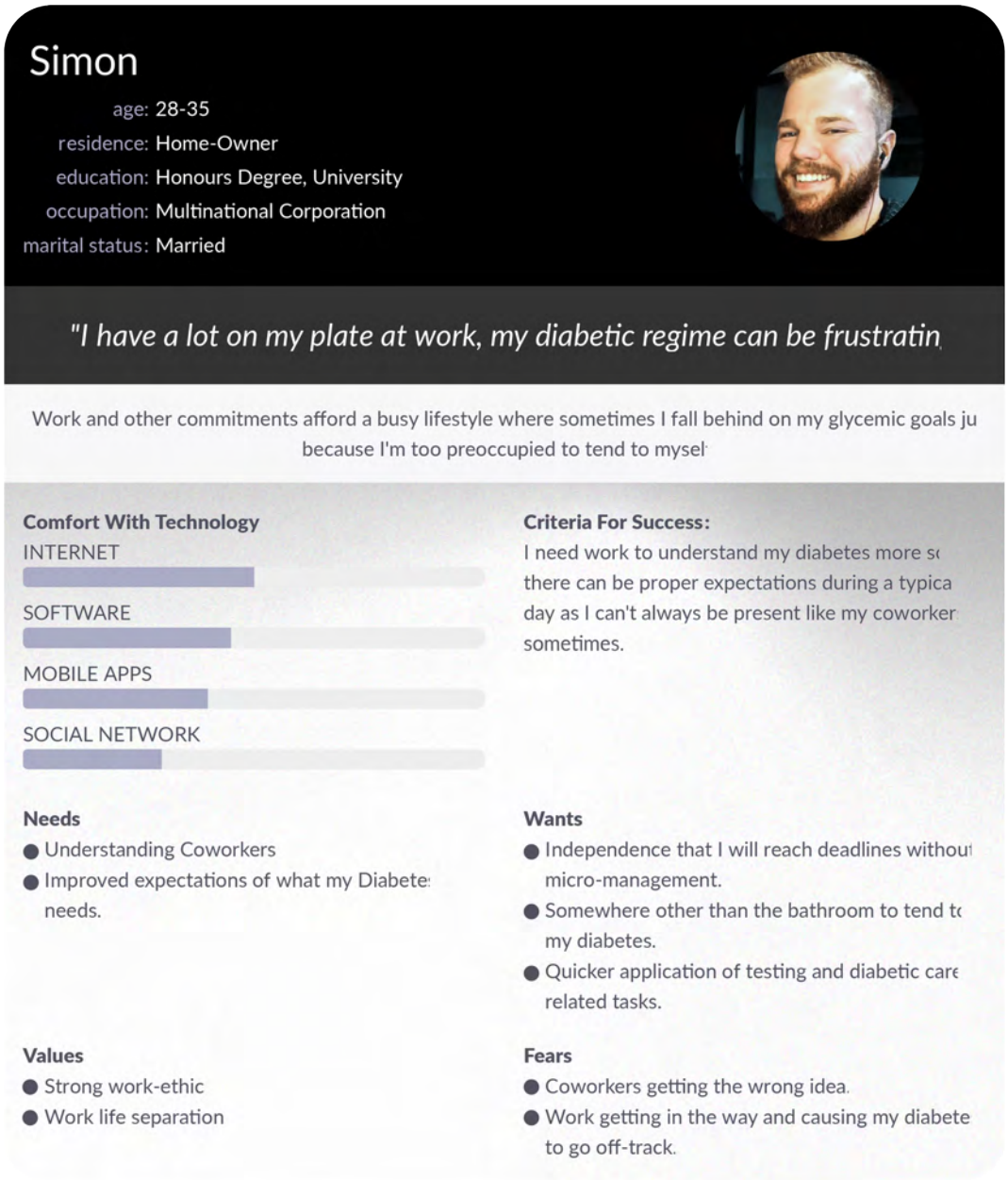

Figure 3. Simon, corporate white-collar. Another potential user base that the DiCart would be well suited for.

Journey Maps

Before the DiCart

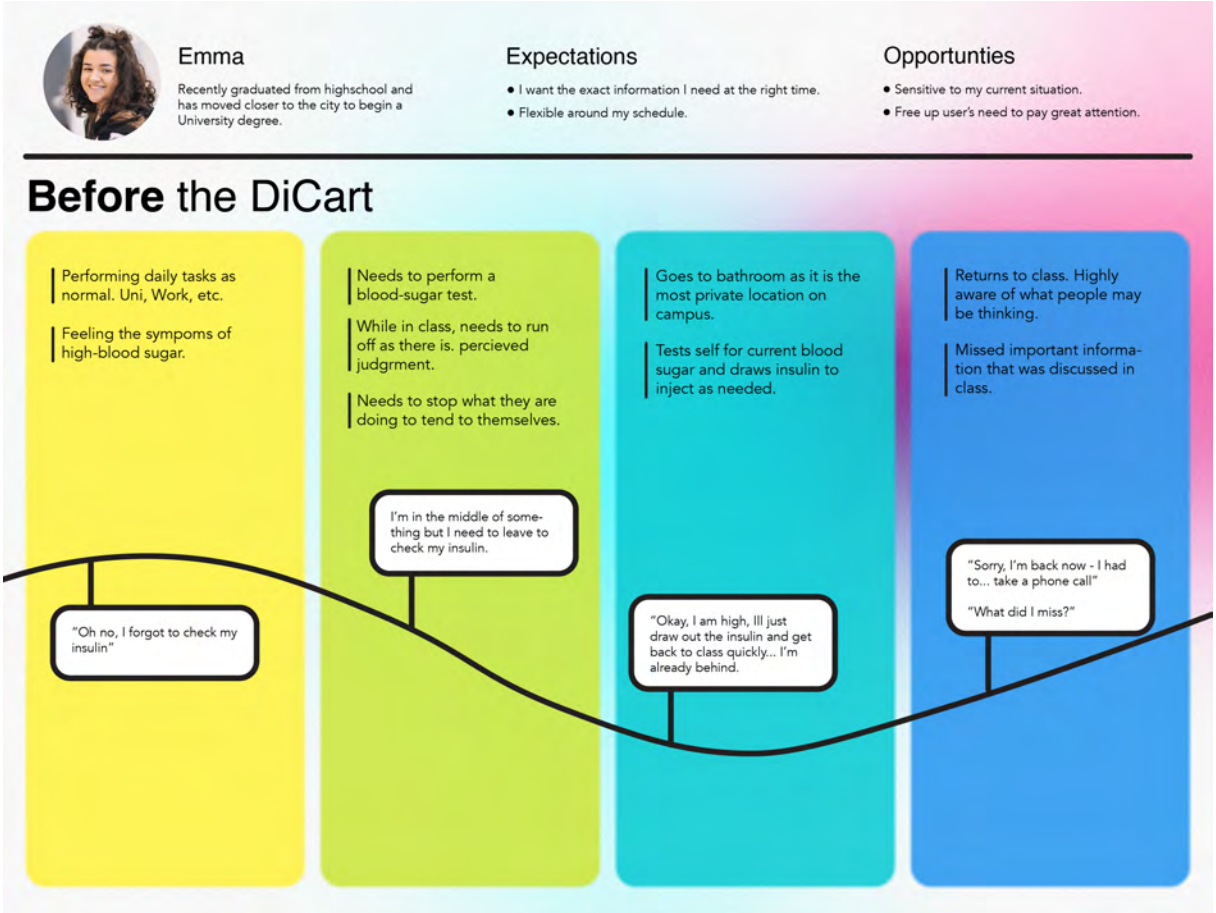

Figure 4. Journey Map, BEFORE the DiCart service.

After the DiCart

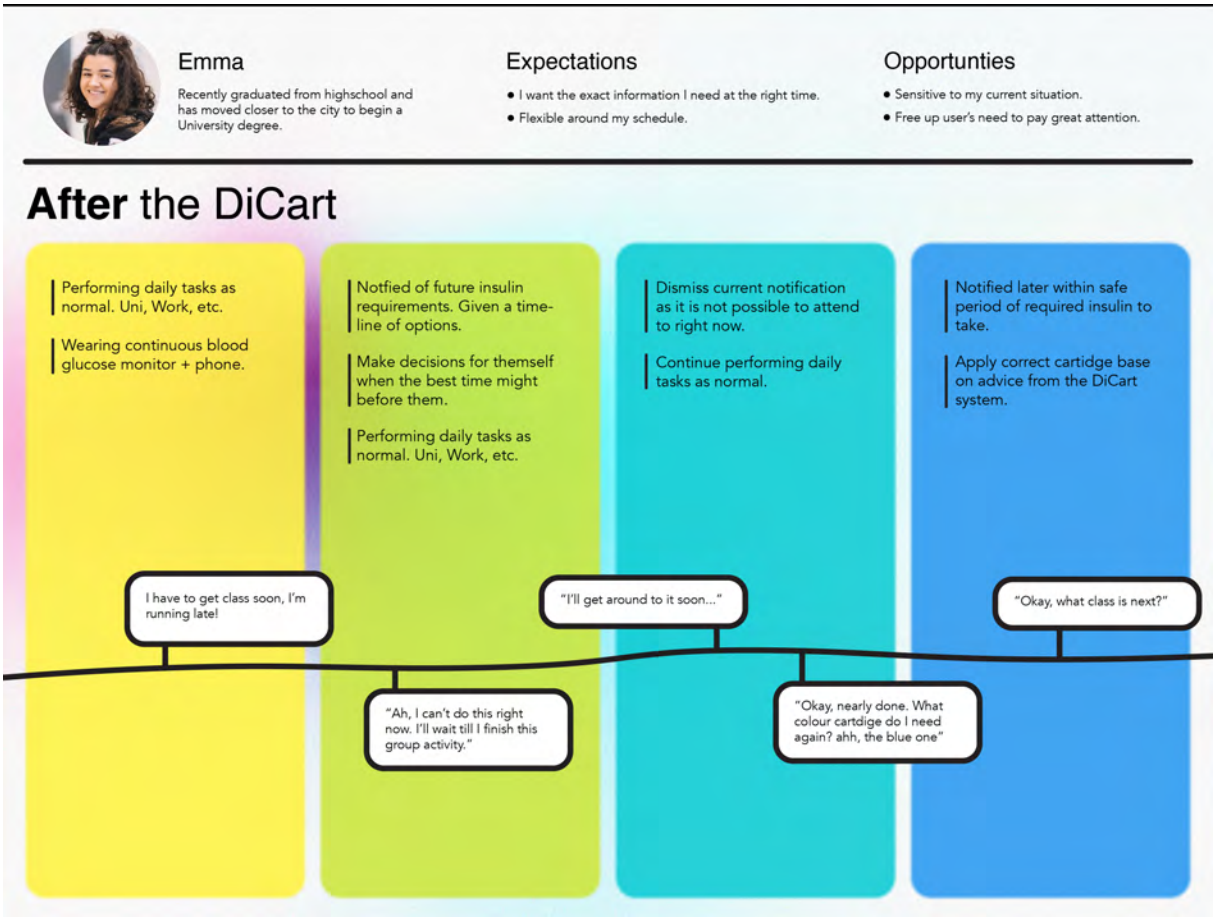

Figure 5. Journey Map, AFTER the DiCart service.

Supporting Data

Only 21% of all adolescents who have type 1 diabetes (T1D) meet their prescribed glycemic goals set by their medical practitioners (Datye et al., 2015). Research also indicates that these goals become challenging due to rapid changes in one's body and social environment. They suggest that marked changes, such as first attending University or career employment, reduce the opportunities needed to maintain glycemic goals required due to T1D. Hood et al. (2010) highlights the core issues many existing interventions have, where much of their focus is on immediate behaviour processes, rejecting the emotional, social and family processes—finding that this dissonance is unlikely to impact glycemic control. Kanstrup (2014) surmises this analysis finding that many self-management diabetic technologies "rely on a naive assumption that once data is collected and presented to the individuals, they will draw appropriate inferences unproblematically". However, it is often found that this seldom is the case; thus, these traditional technologies fail to afford effective treatments.

SERVICE TIMELINE AND COSTINGS

TIMELINE

The project described will take time to setup and begin manufacturing before distributing to patients. It is expected to take up to **twelve months** to gain TGA approval for the medical device, during this time however it will be possible to develop the software associated and develop manufacturing and distribution processes. With the aid of investment, it is expected to take roughly **two years before the public release**. Closer to release public marketing and medical practitioner eduction programs can begin so that it may be quickly deployed.

PRODUCTION

Physical

Ultimately two physical components are needed to be manufactured along with cooperation with Insulin manufacturers. The two pieces that are needed to be manufactured include the kits and cartridges (figure 6). The kit will be produced with less frequency when compared to the cartridges as it is required only once upon initial purchase of the service and is expected to be replaced once only every few years. Injection moulding is the most common method of manufacturing for traditional sy-

ringes and it will be utilised here. This method is also favoured for the kit's production. Concerns exist with the cartridge manufacturing as there are stringent regulation surrounding its safe production. Investment will be key to the successful manufacturing of these cartridges where sterile workplaces are required, increasing initial cost. However, the kit may be produced with third-party injection moulding manufacturers, at least initially, to improve the effectiveness of the investment sought after.

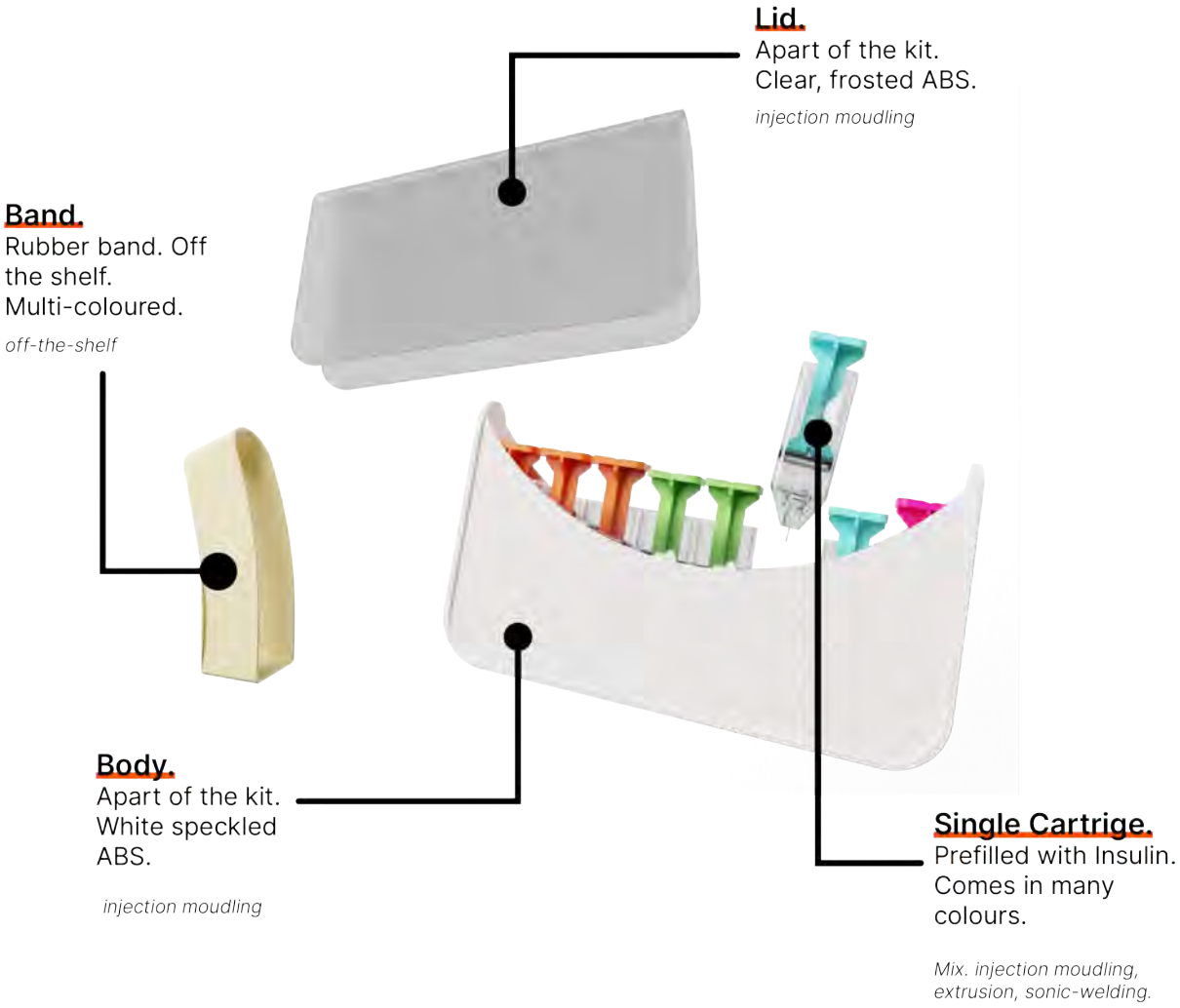

Figure 6. Production requirements of each component of the kit and cartridge.

Digital

The digital platform is just as crucial to the success of the DiCart system as the physical components are. The digital component will include a **web platform** and a **smartphone application** (figure 7) that interfaces with the user and external data sources such as continuous glucose monitors. The costs involved will be backend service infrastructure that includes app hosting on cloud providers such as AWS and developer salaries. Building the MVP is expected to be a higher upfront cost. However, ongoing development will remain consistent and minimal compared to other production costs. Initial and continual software development will be an essential asset. Thus attention must be also focussed on this process. Software development must be completed closely with designers to ensure a streamlined and cohesive experience sensitive to the user's behaviours and emotions.

Figure 7. DiCart application mock-up.

COSTINGS

Other than investments, expected revenue will be generated using a subscription-based model; for our context *Insulin as a Service* (IaaS). While this revenue model is typically preferred for cheaper short-term costs, the benefit our consumers will be attracted to is the predictable and recurring service that takes care of the acquisition of insulin and paraphernalia. Benefits for the business include predictable revenue over time that is attractive to potential future investors and further opportunities to develop deeper relationships with the user base.

The operating costs found will include:

- Cartridge and Kit manufacturing.
- Facility maintenance.
- Distribution centre overhead and shipping costs.
- Research and Development
    - User Research.
    - Software development.
- Marketing and Sales

USE OF FUNDS

The investment sought after will fulfil much of the setup costs expected to be present. A large amount of attention is focused on the manufacturing stages to ensure they are up to code and the quality expected from medical devices. Figure 8 breaks down how the invested funds will be employed to develop, manufacture, and distribute the DiCart service to its target market. The total investment required to fulfil the goals is estimated to be roughly $8 million

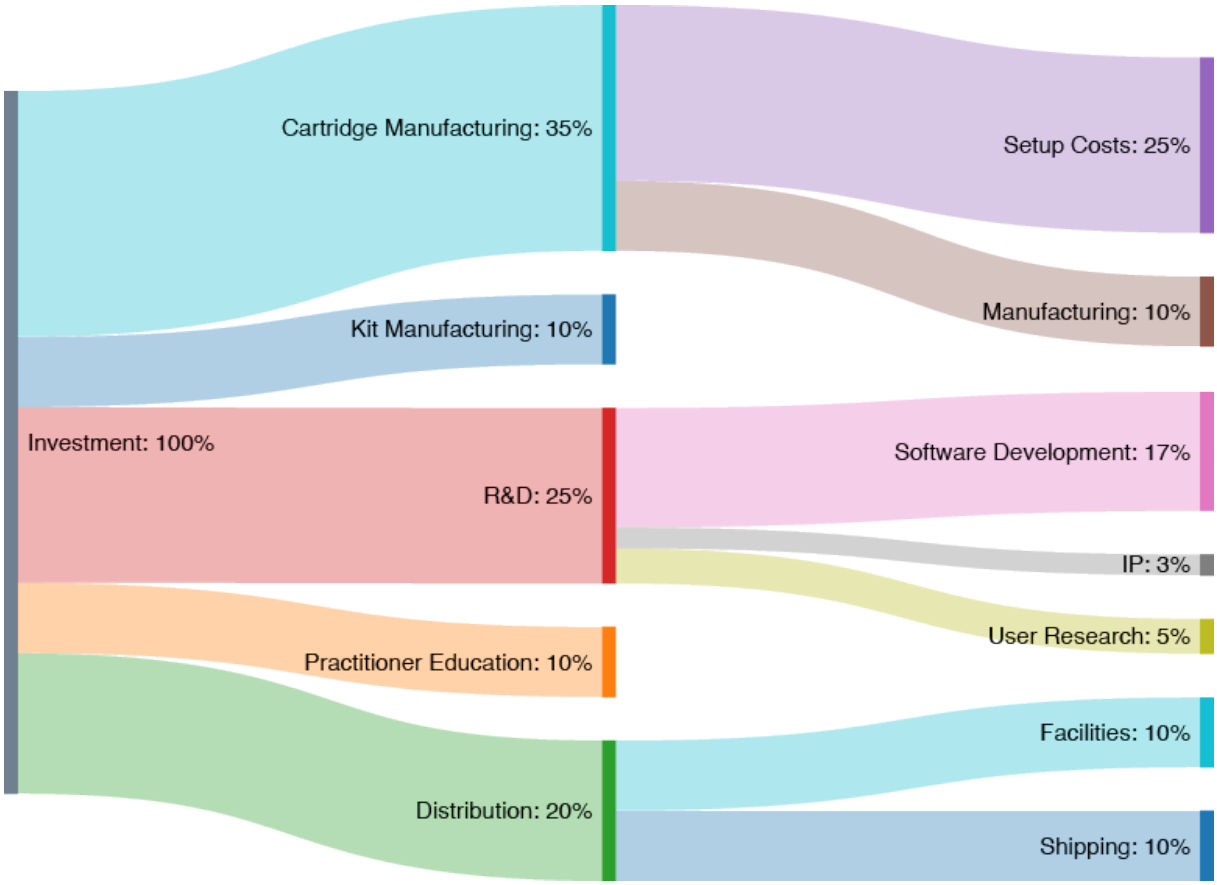

Figure 8. Use of funds breakdown by percentage in a sankey chart.

SERVICE ANALYSIS

VALUE PROPOSITION CANVAS

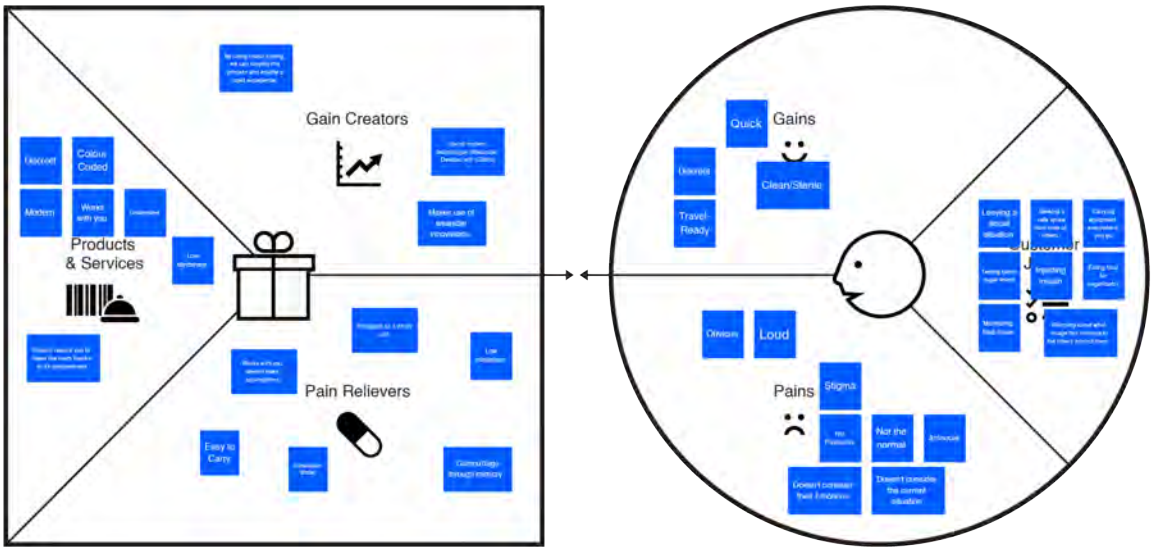

Figure 9. Value Proposition Canvas for the DiCart

BUSINESS MODEL CANVAS

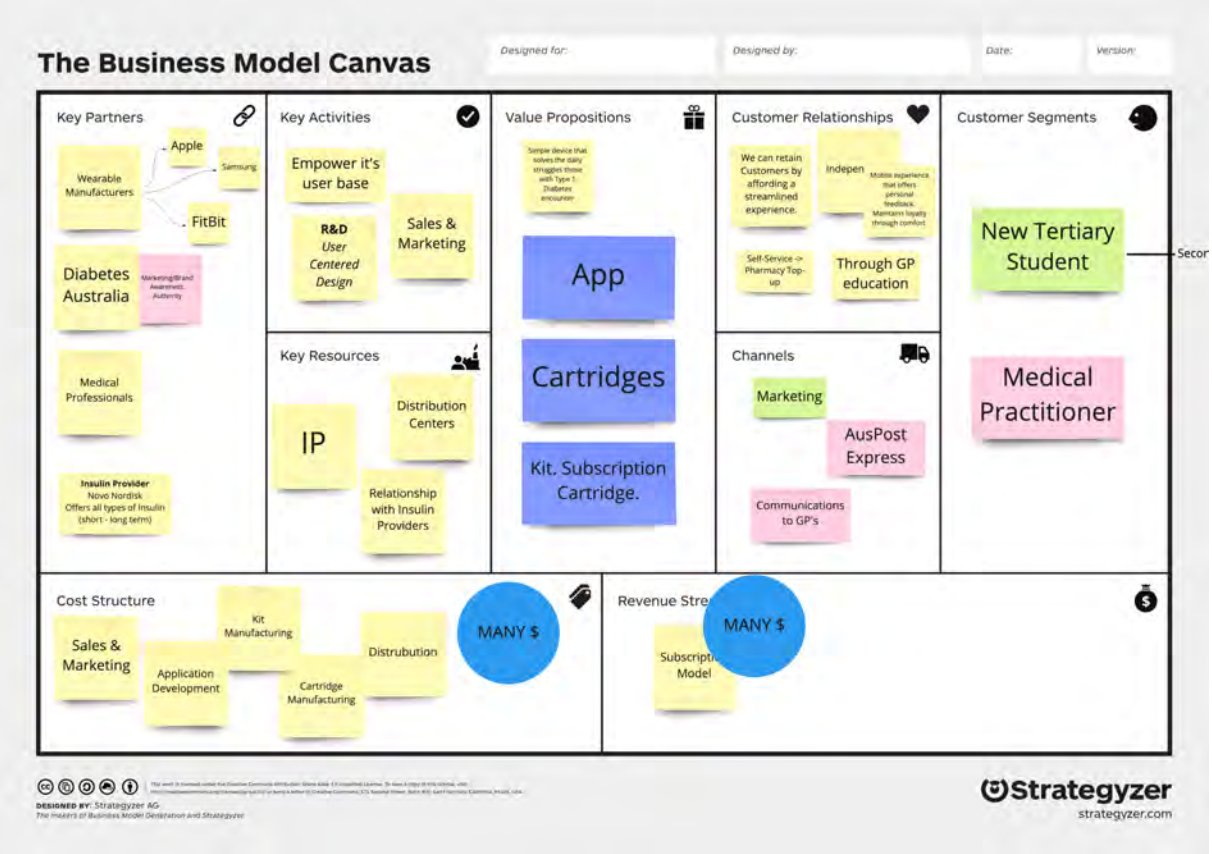

Figure 10. Business Model Canvas for the DiCart

MARKET ANALYSIS

SUMMARY

Industry research reports a growth of 7.2% since 2015 in the diabetic care device industry, rising to nearly $40b in 2020 with expected growth of 6.6% by 2025 (Wood, 2022). This indicates that the market is healthy and may continue to grow as the population and technology increase. Market leaders in advanced diabetic care devices include Dexcom, Medtronic and Lifescan. All of these companies and more offer a wide range of services and products, from traditional diabetic blood glucose readers to app integrated continuous blood glucose monitors with insulin applicators that can continually monitor and adjust insulin levels just as a pancreas would (Dexcom, 2016; LifeScan, n.d.; Medtronic, 2015).

MARKET SIZE AND SHARE

It is estimated that 5.3% of Australians have diabetes, where every 1 out of 5 people with diabetes requires daily management of their insulin and blood glucose levels. This demographic is the defined market size for DiCart to work with while within the Australian borders. However, research tells us that many with T1D still struggle with daily life and maintain their glycemic goals. These pain points identified are where DiCart will aim to be successful in capturing the market share where competition continues to fail its users with a streamlined and sensitive experience.

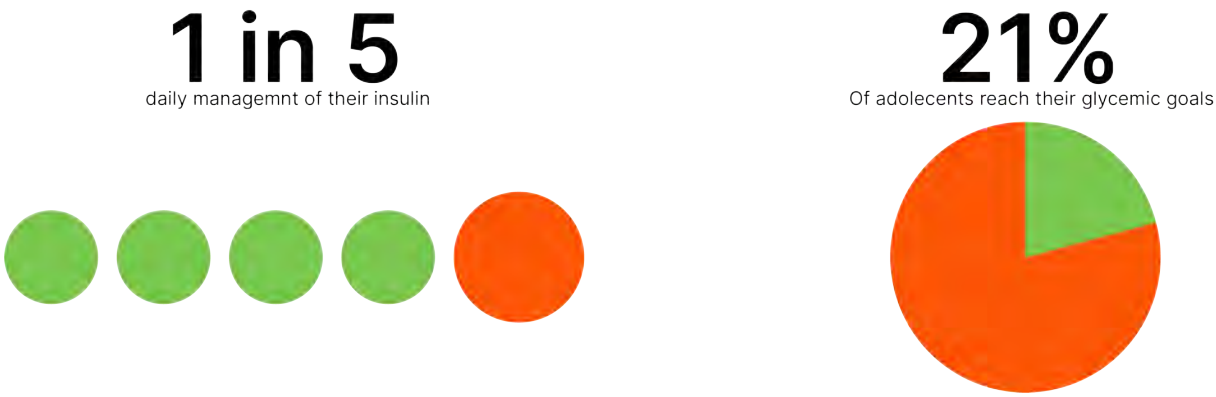

Figure 11. Whose affected by T1D and how many are failing to reach goals.

PESTLE ANALYSIS

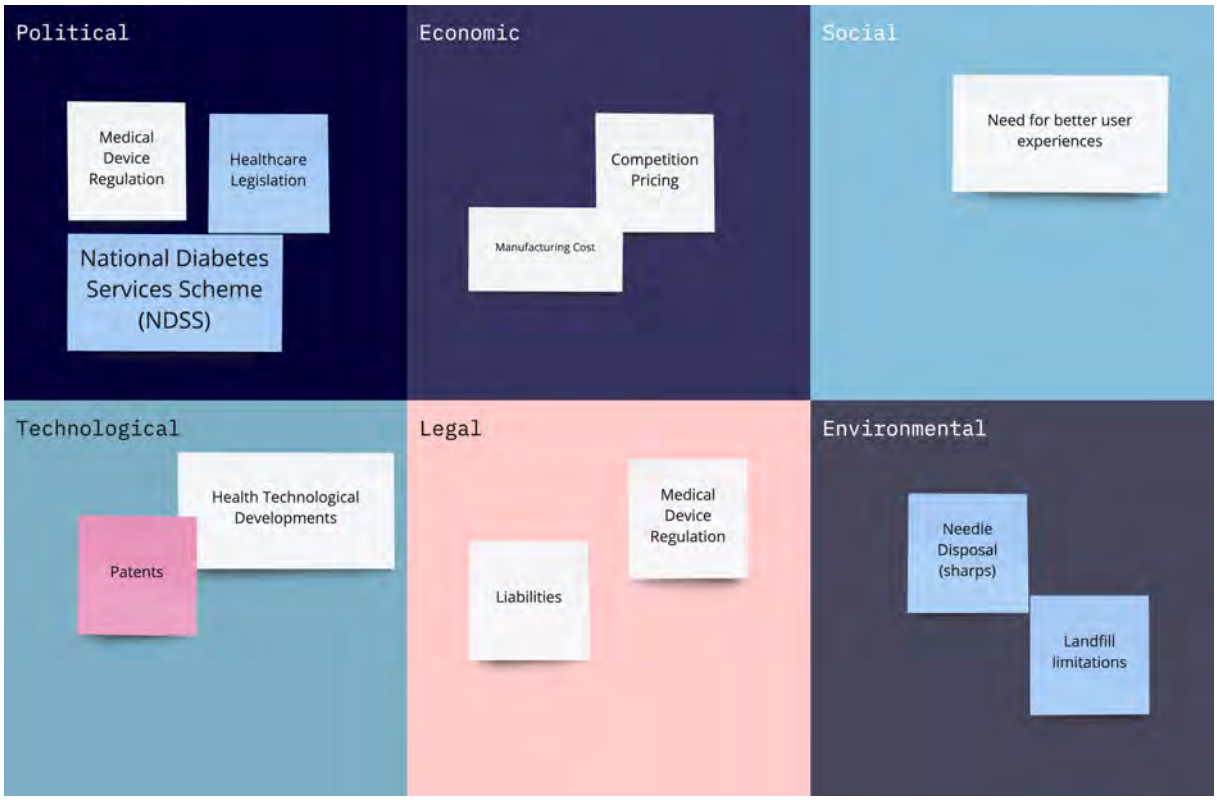

Figure 12. Pestle Analysis

COMPETITIVE ADVANTAGE

Medtronic InPen™ Smart Insulin Pen

The InPen by Medtronic, shown in figure 13, constitutes a two-part system, including the smart insulin pen and a mobile phone app. The insulin pen links to a mobile phone and records the amount of insulin applied each session. The app then offers historical insights into the user's specific glycemic regimen. However, insights are limited to just history, and unlike DiCart's proposed software, it is un-reactive to what is happening at any given moment. Another difference found is in the business model, where the InPen is designed to be refilled and regularly serviced with new needles from a pharmacy by the user. On the other hand, the DiCart offers an at-home service, with kit refills delivered regularly without the user's need to intervene. These differences in the scope afford two very different experiences. While there are benefits found in the InPen, the DiCart aims to solve many issues related to those without the time or patients to maintain T1D constantly. This departure in service is found in how the app works, reacting to situations and offering solutions, unlike a much more manual process found with the InPen.

Figure 13. Medtronic InPen Smart Insulin Pen and accompanied app (Medtronic, 2021)

Medtronic MiniMed™ 770G Hybrid Closed Loop System

Medtronic's MiniMed is an all in one solution that offers all-encompassing care from testing blood sugar to pumping insulin (figure 14). It is designed to be a turn-key solution to T1D where little thought is needed to maintain its ongoing successful care. However, systems such as the MiniMed series do not come cheap and will often cost upwards of USD 8,000 without insurance or government support schemes. This cost can be massive for many people, especially those described in the persona section. This is why many often desire DiCart's service as a subscription business model, thanks to the cheaper short-term costs involved. Another way the MiniMed may fail its user is perhaps found in how it functions primarily where it automatically, without instruction, applies insulin. This could leave the user feeling out of control in situations and may promote a level of disconnect from one's own body. On the other hand, by not forcing care on people, DiCart lets the user maintain control throughout their care.

Figure 14. Medtronic MiniMed™ 770G Hybrid Closed Loop System.

SUCCESS METRICS

Success for DiCart is tied directly to the number of subscriptions that the service has with its users. In the short term, high uptake of subscribers will be the measure of success, whereas long-term success involves many users that have maintained subscriptions over more extended periods. These two time-frames will indicate a product that has proven to be needed by many experiencing T1D, where its innovations have successfully solved existing issues.

Metrics

- Subscriber revenue **greater than 35%** of operating costs.
- Users remaining **subscribed for longer than 1 year.**
- Referrals from existing users to new users greater than two new users for every one from referral.

EXIT STRATEGY

In the event of poor cash flow thanks to high manufacturing costs and the low cartridge subscriber rate. It is possible to pivot the software application to support any insulin applicator. Applying the developed algorithms makes it viable for the business to become a software company and offer mobile apps that perform much of the tasks defined without the assumed kit and cartridge setup. This strategy enables a more advanced application and, if successful, long term opportunities for a future product once a large enough install base has been achieved.

IP STRATEGY

IP is crucial to the long-term success of the DiCart service. The most crucial protection sought after will include the investigating design registration of the cartridge colour system. The critical innovation we present is using software to offer suggestions that will correspond to pre-filled insulin cartridges that are colour coded to ease of use. Branding will be maintained to a high-level and will protected by appropriate trademarking.

Future development of the DiCart also includes success in international markets. Thus, patent applications through the PCT should be made as soon as possible to ensure that the product is appropriately protected abroad.

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Emma

Recently graduated from highschool and has moved closer to the city to begin a University degree.

Expectations

- I want the exact information I need at the right time.
- Flexible around my schedule.

Opportunties

- Sensitive to my current situation.
- Free up user's need to pay great attention.

After the DiCart

Performing daily tasks as normal. Uni, Work, etc.

Wearing continuous blood glucose monitor + phone.

Notfied of future insulin requirements. Given a time-line of options.

Make decisions for themself when the best time might before them.

Performing daily tasks as normal. Uni, Work, etc.

Dismiss current notification as it is not possible to attend to right now.

Continue performing daily tasks as normal.

Notified later within safe period of required insulin to take.

Apply correct cartidge base on advice from the DiCart system.

I have to get class soon, I'm running late!

"Ah, I can't do this right now. I'll wait till I finish this group activity."

"I'll get around to it soon..."

"Okay, nearly done. What colour cartdige do I need again? ahh, the blue one"

"Okay, what class is next?"

Emma

Recently graduated from highschool and has moved closer to the city to begin a University degree.

Expectations

- I want the exact information I need at the right time.
- Flexible around my schedule.

Opportunties

- Sensitive to my current situation.
- Free up user's need to pay great attention.

Before the DiCart

Performing daily tasks as normal. Uni, Work, etc.

Feeling the sympoms of high-blood sugar.

"Oh no, I forgot to check my insulin"

Needs to perform a blood-sugar test.

While in class, needs to run off as there is. percieved judgrment.

Needs to stop what they are doing to tend to themselves.

I'm in the middle of some-thing but I need to leave to check my insulin.

Goes to bathroom as it is the most private location on campus.

Tests self for current blood sugar and draws insulin to inject as needed.

"Okay, I am high, Ill just draw out the insulin and get back to class quickly... I'm already behind.

Returns to class. Highly aware of what people may be thinking.

Missed important informa-tion that was discussed in class.

"Sorry, I'm back now - I had to... take a phone call"

"What did I miss?"

The Business Model Canvas

Designed for:

Designed by:

Date:

Version:

Key Partners

Wearable Manufacturers

Apple

Samsung

FitBit

Diabetes Australia

Marketing/Brand Awareness. Authority

Medical Professionals

Insulin Provider
Novo Nordisk
Offers all types of Insulin (short - long term)

Key Activities

Empower it's user base

R&D
User Centered Design

Sales & Marketing

Key Resources

IP

Distribution Centers

Relationship with Insulin Providers

Value Propositions

Simple device that solves the daily struggles those with Type 1 Diabetes encounter

App

Cartridges

Kit. Subscription Cartridge.

Customer Relationships

We can retain Customers by affording a streamlined experience.

Indepen

Mobile experience that offers personal feedback. Maintains loyalty through comfort.

Self-Service -> Pharmacy Top-up

Through GP education

Channels

Marketing

AusPost Express

Communications to GP's

Customer Segments

New Tertiary Student

Seconda

Medical Practitioner

Cost Structure

Sales & Marketing

Application Development

Kit Manufacturing

Cartridge Manufacturing

Distrubution

MANY $

Revenue Stre

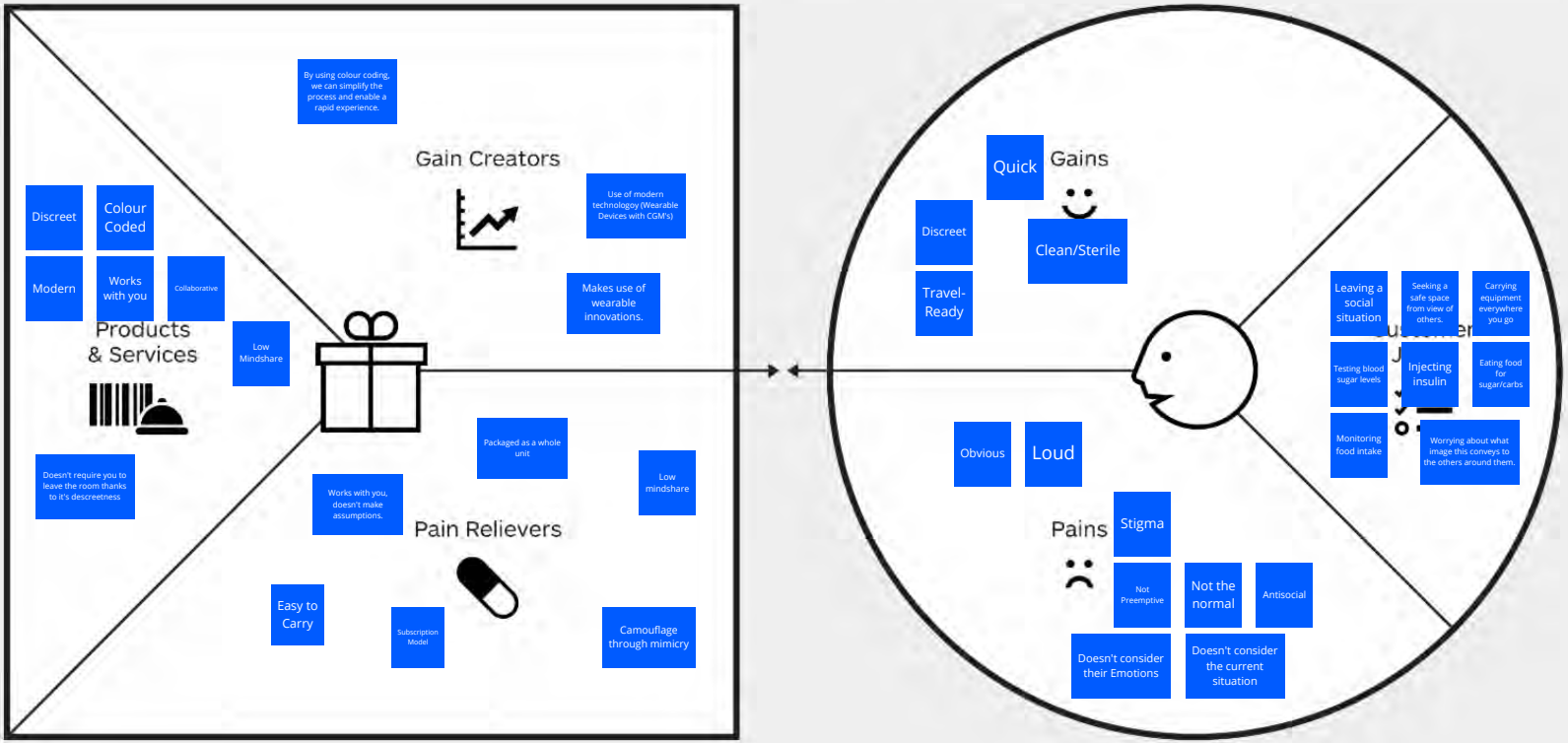
Subscripti Model

MANY $

The Value Proposition Canvas

Value Proposition

Customer Segment



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