Top-Funded Digital Health Companies Offering Services for Type-1 Diabetes Patients: Business Models and Scalability Considerations

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Abstract:

This paper aims to assess how the top-funded digital health companies in T1DM can create value for customers and which implications this has in terms of scalability. Med tech companies, academia, and policymakers should be able to make better strategic decisions based on the findings provided. Companies were identified using a leading venture capital database, PitchBook. Our analysis revealed that 50% of the thirty top-funded companies pursue a Layer Player strategy to generate value for T1DM patients. We recommend that companies in T1DM focus more on automated services such as conversational agents to improve scalability. In terms of scalability, many companies have room for improvement by increasingly relying on automated services, among other things.

1 INTRODUCTION

Diabetes Mellitus (DM) is a chronic, noncommunicable metabolic disease, characterized by hyperglycaemia. The disease either occurs because the pancreas cannot produce the required amount of insulin, or the insulin cannot be efficiently used by the body (WHO, 2022; American Diabetes Association, 2014). Currently, 422 million people worldwide are affected by diabetes, with 1.5 million deaths each year due to the disease or its sequelae (WHO, 2022). Retinopathy, nephropathy, neuropathy, renal failure, heart attacks, and strokes are only some sequelae of diabetes (Kulzer, 2022; American Diabetes Association, 2014).

Type I DM (T1DM) is a non-curable and non-preventable diabetes variant, affecting 9 million people worldwide (JDFR, 2022, WHO, 2022; International Diabetes Federation, 2020). Specifically, T1DM is an autoimmune reaction where

the body's defense system attacks insulin-producing cells (β-cells of the pancreas) (American Diabetes Association, 2014). The exact causes are yet unknown; however, it is assumed that both genetic and environmental factors have an influence (International Diabetes Federation, 2020). T1DM can occur at any age, with the highest incidence in children and adolescents. In addition to symptoms such as thirst, frequent urination, weight loss, fatigue, and blurred vision, those affected will die if they do not have access to insulin (WHO, 2022; International Diabetes Federation, 2020). The quality of life of those affected by DM is severely limited. Studies estimate that an affected person loses an average of 32 years of healthy life due to the disease (JDRF, 2022). To improve the situation, those affected must be diagnosed as early as possible and access to sufficient treatment must be ensured. In addition, further research is needed regarding prevention and cures (JDRF, 2022). To make T1DM more

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manageable, technologies are becoming increasingly important (Aitken, Clancy & Nass, 2017). Whereas in the past glucose levels were determined by blood samples with a syringe (IQWiG, 2021), scalable solutions have created new possibilities. Currently, partial closed-loop systems, where the basal insulin therapy and the pre-prandial delivery of bolus insulin are controlled automatically, are state-of-the-art. Depending on the degree of automation, these devices are often referred to as artificial pancreas or (hybrid) closed-loop systems (Boughton & Hovorka, 2019).

One of the pioneering companies in this area was Medtronic, which launched the first FDA-approved device in October 2016 (Dreyer, 2019).

To provide such a system, various devices must be connected, such as insulin pumps, glucose sensors, mobile applications, etc.). In this context, software applications are becoming increasingly important for two reasons. First, the real-time data collection and analysis. Second, the improved interaction between physicians and patients is made possible (Dreyer, 2019). Attention should be paid to the results of studies that have shown that in the complex and fragmented healthcare industry, it is difficult to provide a holistic system of high quality as a standalone company. Consequently, partnerships and ecosystem strategies increasingly seek to deliver superior patient value (Krause & Schnitzler, 2021, Choueiri et al., 2020).

In a system like this, individual companies must consider which business model is most promising for them. Scale-up of digital innovations in healthcare is vital to achieving population-wide impact. Therefore, this paper systematically assesses the business models of top-funded digital health companies offering services to T1DM patients. The objective of this paper is to assess how the top-funded companies in T1DM can create value for customers and which implications this has in terms of scalability. Med tech companies, academia, and policymakers should be able to make better strategic decisions based on the findings provided. The analysis of the value creation of these companies will furthermore give insights into their main revenue streams.

2 METHODS

2.1 Databases and Companies

We set out to investigate the business model of topfunded digital health companies globally focusing on T1DM. These companies were searched using primarily PitchBook, a comprehensive venture capital database used commonly by academics and investors (Retterath & Braun, 2020).

2.1.1 Search Rationale

The search terms were entered into PitchBook to identify companies that were relevant to the field of digital health in T1DM. At first, we identified the 10 top-funded companies in T1DM and screened all the relevant keywords. Second, we eliminated all the duplicate words and selected terms that focus on the digitalization of glucose monitoring in T1DM. Moreover, we only selected companies that received funding in the last five years to understand the current state of the art and to focus only on attractive investment opportunities for potential investors. An overview of the complete keyword search strategy for Pitchbook is shown in Table 1.

Table 1: The search strategy used in Pitchbook.

Search category	Search terms	
Industries, Verticals & Keywords	(glucose level management OR glucose level monitoring OR diabetes management OR diabetes management system OR type 1 diabetes monitoring OR glucose monitoring OR remote monitoring system OR insulin delivery OR diabetes care OR bionics pancreas OR type 1 diabetes treatment OR managing diabetes) AND (Digital Health OR HealthTech)	

2.1.2 Selection Criteria

Our main goal was to include only companies focused on technology-based digital health innovation. A filter to include companies that received at least a Series A financing was also applied when searching in PitchBook. In addition, we mainly focused on companies that are privately held and have completed an acquisition or merger. We also included companies from Asia such as China and South Korea as they met our search criteria.

Companies were excluded if their intervention (1) did not focus on patients; (2) were offering mainly T2DM solutions; (3) did not involve a digital solution as the main intervention component; and (4) did not receive funding within the last five years.

2.1.3 Selection Process

Our first iteration of data on PitchBook and Crunchbase revealed a lack of filtering between start-ups focusing on type 1 & 2 diabetes. Due to the large number of companies focusing on T2DM, we decided to search for the top-funded T1DM companies and select all the relevant keywords that were shown in the search result of PitchBook. We then gathered all the keywords and listed them.

115 companies in total were retrieved through our search strategy using Pitchbook. Duplicate keywords were removed, and the final list of companies was validated on the premise of our clustering criteria. Namely, digital health startups that offer digitized T1DM solutions. We then analyzed the website of the companies by reviewing their business models, focusing mostly on the keywords T1DM and digital health. After the comparison of our results, a consensus was reached.

2.2 Digital Health Intervention

The companies analyzed in this paper exhibit different levels of maturity in terms of digital health intervention.

Some companies are increasingly focused on monitoring using glucose sensors or smartwatches. Besides, other companies are more concerned about the prediction of blood glucose levels. Finally, there are also companies focusing mainly on hardware (e.g., insulin pumps) and "only" complement this with digital aspects.

Depending on their focus, the scalability of those firms can diverge. Their business models are analyzed before important aspects of scalability are discussed.

2.3 Business Model

With the help of business models, a company can be described holistically. The business model describes how a company creates, delivers, and captures value. Specifically, four questions are answered: Who is the target customer (who), what is the value proposition the company offers to the target customer (what), how does the value chain look like (how) and why does the company generate money (why) (Gassmann, Frankenberger, Choudury & Csik, 2020). With this, both external aspects (who and what), as well as internal aspects (how and why) of the business model, are considered.

3 RESULTS

We analyzed the 30 top-funded companies from 115 companies extracted from Pitchbook that met our inclusion and exclusion criteria. The overview of the 30 top-funded digital health companies in the treatment of T1DM can be seen in Table 2.

Table 2: 30 top-funded companies by rank with funding amount to date and the last date of funding.

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3.1 Layer Player as Main Value Creation Architecture Strategy

An important part of all the analyzed companies' value is generated by the possible transmission of information between software and hardware, making it thus possible to achieve the so-called closed-loop system. To do so, the companies use different valuecreation architecture strategies. Our analysis revealed that 50% of the thirty top-funded companies pursue a Layer Player strategy, meaning that they focus only on a specific step of the industry value chain. Consequently, these companies are highly specialized (e.g., sensor manufacturers) (Gassmann et al., 2020). Besides, 23% of the companies follow an Orchestrator and 20% an Integrator strategy. While Orchestrators combine various external products and services to create superior added value, Integrators cover the entire value chain independently (Gassmann et al., 2020). Finally, 7% of the companies cannot be assigned to one of the three value-creation architecture strategies unequivocally.

Since Layer Players and Orchestrators do not cover the entire value chain independently, most of them develop services and products that are compatible with those of other companies. For example, the companies studied that focus on developing a mobile application usually partner with external hardware manufacturers to ensure that the information collected by their sensors can be integrated into the mobile application.

In comparison, Integrators focus on developing a unique solution and in this way prevent any interoperability between them and the competition. This is known as Lock-In and helps companies retain their customers, as they face significant costs or penalties if they switch to a competitor (Gassmann et al., 2020).

3.2 Multiple Services Generated through Sensor as a Service

Among all the business strategies identified in the companies, the Sensor as a Service is the most used one (16 companies out of 30). Thus, the connection between the physical and digital world enabled by the closed-loop system helps companies to offer new services based on the data collected and processed. In fact, in addition to the main value of this system, namely automatic insulin monitoring, the companies analyzed offer several complementary services that create additional value for the main stakeholders. One of the most common offerings identified in the business models is real-time data insights that are

then displayed in an app. This not only provides patients with insight into their current diabetes status but also provides tools that help clinicians provide individualized, proactive management of their patients remotely. Another service that is growing from the data collected is the insulin delivery system, which automatically places an order for the patient if new insulin is needed.

Sensor as a Service also includes new offerings that can be made in the respective IoT ecosystem, allowing companies to generate an alternative revenue stream with additional stakeholders (Gassmann et al., 2020). This comes close to the strategy of Leveraging Customer Data. For example, some of the identified companies sell their data to research labs or other research-oriented organizations as an alternative revenue stream. Depending on national data privacy laws, this additional service is forbidden in some countries.

3.3 Subscription as the Main Revenue Stream

Regarding revenue streams, it should be noted that they differ from country to country. Therefore, it is hardly possible to make a general statement. Nevertheless, there is a trend towards subscription since T1 diabetics rely on the systems for the rest of their lives. In other words, monthly or annual fees are charged to use the services. Thereby, the company benefits from a steady income stream (Gassmann et al., 2020). In addition, companies with app-based products try to be profitable by employing a freemium model. In this case, the basic service is offered free of charge to attract potential customers. However, fees are charged to be able to use the whole offering (Gassmann et al., 2020). Some companies follow a similar strategy, where the main product is not offered for free but at a low price, and the money is earned with additional services (Add on) (Gassmann et al., 2020).

4 DISCUSSIONS

Our systematic analysis of the business models, according to the work of Gassmann et al., implemented by the 30 top-funded T1DM companies showed that 14 business model strategies were applied to a significant extent. We observed very limited diversity in terms of value-capturing mechanisms as most companies focus on the Subscription-Pattern. One potential reason is the high degree of regulation of the healthcare industry which

in the past has led to companies in the field taking advantage of "lucrative rights to exclude competitors" (Eisenberg et al., 2017) and no incentive to adjust their value-capturing mechanisms.

Additionally, due to the often high offer and environmental risks associated with medical product innovation, reducing the financial viability risk by implementing established value-capturing mechanisms reduces the overall risk exposure of the companies (Brillinger et al., 2020)

The complexity of T1DM, especially in children and adolescents (Desmangles, 2008), is also represented in our sample of companies. The fact that 50% of companies can be classified as a Layer Player and 23% as an Orchestrator, compared to only 20% as an Integrator supports the conclusion that most companies focus on a specific aspect of treatment (e.g., glucose measurement or insulin injections), and work together with a closely-knit network of industry partners, research institutions and experts to offer a complete value proposition to patients.

While all the companies included in this study offered at least one digital health service, some of these are enabled by a hardware component offered by the company (e.g., Bigfoot Biomedical's smart insulin pens). Companies offering medical devices have very different cost structures, risk-rewardprofiles, and business models compared to biopharma or tech companies (Steinberg et al., 2015). This also has implications for the scalability of the solutions offered. Even established companies in the medical device industry such as Abbott, Inc., have been hit hard by supply chain disruptions in recent years (Reuter, 2022). At the same time, many companies offering digital health solutions are not yet taking advantage of highly scalable solutions such as conversational agents but often relying on human operators (Keller et al., 2021).

Therefore, we recommend that companies in T1DM focus more on automated services such as conversational agents to improve scalability. As a result, the company's performance can be increased, which in turn can lead to higher funding.

5 LIMITATIONS

In our search for companies, we found few T1DM companies in regions other than North America, as we focused on the 30 best-funded companies. Indeed, the results show that the majority of the capital is in North America. In further research, it might be useful to evaluate more companies and use several databases

and not focus only on the best-funded firms to avoid this financial and geographical bias.

In our analysis of the business models, we focused primarily on the main strategies that we could find on the companies' websites. Nevertheless, each company has its own specificities in terms of how it creates and captures value. Future analysis of these specifics will be useful to better understand how services for T1DM patients can be improved and made scalable.

Finally, we did not include information on health outcomes or the users' experiences in our analysis. By addressing these aspects in further research, the benefits of digital health interventions, as well as the correlation to its business model, can be evaluated in more depth.

6 CONCLUSIONS

This paper aimed to assess how the top-funded digital health companies in T1DM can create value for customers and which implications this has in terms of scalability. Top-funded companies in T1DM exhibit different business models and scaling capabilities. In the sample, companies pursuing a layer player strategy, focusing on sensor technology, and using a subscription model are most common Our findings suggest that 50% of the thirty top-funded companies pursue a Layer Player strategy to generate value for T1DM patients. In terms of scalability, many companies have room for improvement by increasingly relying on automated services, among other things.

CONFLICTS OF INTEREST

T.K. is affiliated with the Centre for Digital Health Interventions (CDHI), a joint initiative of the Institute for Implementation Science in Health Care, University of Zurich; the Department Management, Technology, and Economics at the Swiss Federal Institute of Technology in Zurich; and the Institute of Technology Management and School of Medicine at the University of St Gallen. CDHI is funded in part by the Swiss health insurer CSS. CSS was not involved in the design, data collection, analysis, or interpretation of the results of this study. T.K. is a co-founder of Pathmate Technologies, a university spin-off company that creates and delivers digital clinical pathways. However, Pathmate Technologies was not involved in this study.

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