



# A.I.-based digital therapeutics in diabetes management

Žygimantas Foktas

Dissertation written under the supervision of Professor Henrique Martins

Dissertation submitted in partial fulfilment of requirements for the MSc in  
Business, at the Universidade Católica Portuguesa, January 2024.

### **Abstract**

The Diabetes Mellitus is a global health challenge which underscores the need for advanced technologies to provide effective management solutions. The integration of DTx and AI could offer new solutions for diabetes management which are much in need given the widespread prevalence and the need for personalized care. Therefore, this study seeks to explore AI's impact and challenges in the field of digital therapeutics for diabetes management. The research delves into potential applications, effectiveness, and challenges within digital therapeutics. It also examines the transformative impact of AI on healthcare, particularly in enhancing treatment personalization, predictive care, and patient education through advanced monitoring systems.

Research included the use of primary data and secondary data. This included literature review, semi-structured interviews and analysis. Results include the identification of AI's potential in personalizing care, enhancing predictive analytics, improving patient outcomes and healthcare efficiency. It also uncovers significant challenges such as regulatory complexities, data privacy concerns, adoption barriers due to stakeholder resistance, and healthcare system integration issues.

This thesis also advocates for further research in broader geographical contexts and deeper insights from a diverse range of experts. Nonetheless, it suggests that AI, with its unique capabilities, holds promise for revolutionizing diabetes management, calling for strategic approaches to overcome existing limitations and fully harness its potential.

## Sumario

O Diabetes Mellitus é um desafio global de saúde que sublinha a necessidade de tecnologias avançadas para fornecer soluções eficazes de gestão. A integração de DTx (Terapêuticas Digitais) e IA (Inteligência Artificial) tem o potencial de trazer novas soluções para a gestão do diabetes, que são muito necessárias dada a sua prevalência generalizada e a necessidade de cuidados personalizados. Este estudo explora o impacto e os desafios da IA no campo da terapêutica digital para a gestão da diabetes. A investigação incidiu sobre as aplicações potenciais, a eficácia e os desafios do uso de IA e terapêuticas digitais na gestão desta doença. Ela também examina o impacto transformador da IA na saúde, particularmente no aprimoramento da personalização do tratamento, cuidado preditivo e educação do paciente através de sistemas de monitoramento avançados.

A pesquisa incluiu o uso de dados primários e secundários. Os resultados incluem a identificação do potencial da IA na personalização dos cuidados de saúde, no uso e melhoria de ferramentas de análise preditiva, melhoria dos resultados em saúde dos doentes e um aumento da eficiência dos cuidados de saúde. Foram encontrados também desafios significativos tais como: complexidade regulatória, preocupações com a privacidade dos dados, barreiras à adoção devido à resistência das partes interessadas e problemas de integração no sistema de saúde.

Esta tese também defende pesquisas adicionais em contextos geográficos mais amplos e insights mais profundos de uma gama diversificada de especialistas. No entanto, sugere que a IA, com suas capacidades únicas, tem promessa de revolucionar a gestão do diabetes, chamando por abordagens estratégicas para superar as limitações existentes e aproveitar plenamente seu potencial.

### **Acknowledgments**

First, I would like to extend my heartfelt thanks to my thesis supervisor, Henrique Martins. His invaluable guidance was vital throughout this research. My gratitude also goes to the experts, who helped with their insights during interviews, enriching this study immensely.

Lastly, I am deeply thankful to my family and friends for their unwavering support, which was crucial to my journey. Their contribution is immeasurable.

## Table of Contents

Abstract .....	2
Sumario .....	3
Acknowledgments .....	4
Table of Contents.....	5
List of Figures .....	7
List of Tables.....	8
List of Abbreviations.....	9
Chapter1: Introduction .....	10
Chapter 2: Background .....	12
2.1. Healthcare.....	12
2.1.1. <i>Current challenges</i> .....	12
2.1.2. <i>Future of Healthcare</i> .....	12
2.2. Diabetes Mellitus.....	13
2.2.1. <i>Types</i> .....	13
2.2.2. <i>Diagnostics</i> .....	14
2.2.3. <i>Treatment and management</i> .....	15
2.3. AI and Digital Therapeutics of diabetes management .....	18
2.3.1. <i>Digital therapeutics</i> .....	18
2.3.2. <i>Digital therapeutics in diabetes management</i> .....	20
2.3.3. <i>Artificial Intelligence</i> .....	21
2.3.4. <i>AI in Diabetes Management</i> .....	22
Chapter 3: Research Methodology .....	24
3.1. Research Design .....	24
3.2. Data collection – Expert interviews .....	24
Chapter 4: Analysis and Discussion.....	28

4.1. Current landscape .....	28
4.2. AI-based digital therapeutics benefits and effectiveness .....	28
4.3. Patient view on AI-based digital therapeutics .....	29
4.4. Challenges to implementation and development.....	29
4.5. Implications for business models used for promotion .....	30
4.6. Future landscape.....	30
4.7. Scenario analysis .....	31
Chapter 5: Conclusions .....	34
5.1. Limitations and recommendations .....	34
5.1.1. <i>Limitations</i> .....	34
5.1.2. <i>Recommendations</i> .....	35
5.2. Main findings .....	35
5.2.1. <i>Current usage of A.I.- based digital therapeutics in diabetes management</i> .....	35
5.1.3. <i>Theoretical and practical implications</i> .....	37
Bibliography .....	38
Appendices .....	51
Appendix I: Summarized answers of Expert Interviews.....	51

**List of Figures**

Figure 1: Conceptual position in relation to current therapeutic choices ..... 19

**List of Tables**

Table 1: Current and future devices for diabetes diagnostics and management.....	15
Table 2: Overview of Interviewees.....	25
Table 3: Coded categories based on Expert Interviews.....	26
Table 4: Summary of Scenarios.....	31
Table 5: Summary of Industry Experts' Interviews.....	51

**List of Abbreviations**

<b>AI</b>	Artificial Intelligence
<b>ANN</b>	Artificial Neural Networks
<b>CGM</b>	Continuous Glucose Meters
<b>CBT</b>	Cognitive Behavioral Therapy
<b>COVID-19</b>	Coronavirus Disease 2019
<b>DL</b>	Deep Learning
<b>DTA</b>	Digital Therapeutics Association
<b>DTx</b>	Digital Therapeutics
<b>FDA</b>	Food and Drug Administration
<b>FPG</b>	Fasting Plasma Glucose
<b>FTA</b>	Few Touches Application
<b>GLP-1</b>	Glucagon-Like Peptide-1
<b>iCGM</b>	Integrated continuous glucose monitoring
<b>IT</b>	Information Technology
<b>MDR</b>	Medical Device Regulation
<b>ML</b>	Machine learning
<b>PBM</b>	Pharmacy Benefit Manager
<b>SGLT2</b>	Sodium-Glucose Cotransporter-2
<b>T1D</b>	Type 1 Diabetes
<b>T1DM</b>	Type 1 Diabetes Mellitus
<b>T2DM</b>	Type 2 Diabetes Mellitus

## Chapter 1: Introduction

Diabetes mellitus is a chronic metabolic disorder that affects millions of people worldwide. Statistics show that in 2021 alone, approximately 536.6 million people were living with diabetes, and in 2045, it is projected that 783.2 million people around the world will be affected by the disorder (Sun et al., 2022). The burden of diabetes extends beyond its health costs. Economic costs impact individuals' quality of life and life expectancy (Davies et al., 2018). Technological advancements can improve the diagnosis, prevention, management, and treatment of both acute and chronic medical conditions, offering benefits such as scalability, effectiveness, accessibility, and tailored approaches (Ramakrishnan et al, 19).

Recent advancements in Artificial Intelligence (AI) are said to have opened new options in healthcare (Alami et al, 2021) and in diabetes management in particular (Mintz and Brodie, 2019). The digital age and findings with AI bring new opportunities that can help take another step in developing a new category of therapies – digital therapeutics (DTx) (Salsabili et al., 2023). Digital therapeutics, a new type of medical therapy, can be defined as “*an evidence-backed intervention delivered through specialized software to prevent, manage, or treat health conditions*” (Dang et al, 2020). These products, developed for diverse disorders including diabetes, oncology management, and neuropsychiatric conditions like anxiety, depression, and substance abuse, are evolving the landscape of digital-based healthcare solutions (Hong et al, 2021).

AI can add a powerful contribution in many areas of society including healthcare (Nazar et al, 2021). . Future shows that the combination of IT (information technology) architecture with high volumes of data and the adequate digital tools has the potential to make all healthcare smarter where AI will work with a lot of data (Greco et al, 2020). Demand for higher level healthcare is highly increasing and hospitals in many countries have shortage of healthcare specialists. Even healthcare institutions now aim to catch latest technological developments to keep up with high standards of patients (Bohr and Memarzadeh, 2020). DTx digital medicine applications has potential to vary from remote patient monitoring, such as glucose meters that transmit data to mobile apps, to digital diagnostic documents (Ellahham, 2020). Digital therapeutics are said to be transforming technical and ethical aspects of healthcare settings and reshaping the doctor-patient relationship and the healthcare delivery system (Topol, 2019). Moreover, the business landscape in diabetes care is rapidly evolving, with an increasing emphasis on digital therapeutics. The global diabetes care devices market, valued at approximately USD 26 billion in 2021, is expected to grow significantly in the coming years (Grand View Research, 2022).

With AI's potential to transform healthcare delivery, especially in chronic conditions like diabetes (Ellahham, 2020; Nomura et al., 2021) there is a need to investigate the impact and

challenges of AI in the rapidly evolving field of digital therapeutics for diabetes management. Therefore this research focuses on understanding potential applications, effectiveness, and associated challenges in the context of AI-based digital therapeutics in diabetes management.

The aim of the study is to provide an in-depth exploration of the current landscape and future potential of AI in improving diabetes care, alongside identifying strategies to navigate and address these existing barriers. It seeks to address three fundamental research questions:

**RQ1:** What are practical challenges for companies encountered when integrating AI-based digital therapeutics into healthcare systems for diabetes prevention?

**RQ2:** What are the strategies that businesses can use to promote AI-based digital therapeutics for diabetes prevention among healthcare providers, payers and consumers?

**RQ3:** What are the economic benefits of AI-based digital therapeutics in terms of reduced healthcare costs, and how businesses quantify these benefits?

In this research on AI-based digital therapeutics in diabetes management critically examines both the benefits and risks. It explores potential issues like data privacy breaches, the opaque nature of AI decision-making, and the varying reliability of AI in different clinical contexts. By providing a balanced analysis, my thesis contributes to a deeper understanding of these technologies, highlighting the need for robust, safe, and effective healthcare solutions, and offering insights into how potential risks can be mitigated.

By exploring the challenges and implications of integrating AI into diabetes care, this thesis contributes to a critical area of healthcare innovation, providing insights that could influence future medical practices, policy decisions, and the development of new, technologically advanced treatment modalities. The research emphasizes the importance of strategic approaches to overcome challenges and maximize AI's potential in diabetes management. It calls for more in-depth research to broaden understanding and improve AI's efficacy in this field, highlighting its role in transforming patient care and enhancing the efficiency of healthcare systems.

This research will include the following steps. Chapter 2 will review existing studies on AI in healthcare, digital therapeutics and diabetes management. Chapter 3 will describe research methods, including data collection and used analysis techniques. Moreover, chapters 4 and 5 will analyze and compare data gathered from expert interviews with literature review and present the findings. Finally, Chapter 6 will include summary of main findings, theoretical and practical implications, limitations and future direction of this topic.

## **Chapter 2: Background**

### **2.1. Healthcare**

Healthcare's origins are deeply rooted in ancient civilizations, where it was intertwined with religious and cultural beliefs (Risse, 2012). Over time, significant milestones, such as the development of the Hippocratic Oath and the advent of the scientific revolution, have shaped healthcare into a more structured and ethical practice (Jonsen, 2000). The 20th century marked an era of rapid advancements. The discovery of antibiotics, the development of vaccines, and technological innovations like electronic health records and telemedicine have revolutionized healthcare (Laxminarayan et al., 2013; Bashshur et al., 2020). AI and Digital Therapeutics may well be equivalent hallmarks in 21<sup>st</sup> century medicine.

#### ***2.1.1. Current challenges***

Despite significant advancements in the field, healthcare today faces many challenges. Access to care remains an important issue, with disparities evident across different socio-economic, geographic, and demographic groups (Baum et al., 2019). The escalating costs of healthcare services are a global concern, burdening individuals and healthcare systems (Papanicolas et al., 2018). Ensuring high-quality and safe services is a continuous battle, with issues such as medical errors and hospital-acquired infections being areas of concern (Baker et al., 2020). The healthcare workforce is grappling with challenges like professional shortages, burnout, and the need for continuous education and training (Dyrbye et al., 2020). Moreover, integrating technological advancements into healthcare systems brings challenges, including ensuring patient privacy and data security (Kruse et al., 2020). Finally, the COVID-19 pandemic has highlighted the need for robust healthcare infrastructure and rapid response capabilities, underscoring the importance of pandemic preparedness (Legido-Quigley et al., 2020). Recent reports show progress in these areas, yet preventive care practices are still not optimal, risk factors remain common, and diabetes complications are widespread (Geiss et al., 2005).

#### ***2.1.2. Future of Healthcare***

Looking into the Future, healthcare is expected to undergo further transformation. Advances in genomics and biotechnology are leading the way toward more personalized treatment approaches tailored to individual patients' genetic profiles (Ashley, 2020). Digital health is anticipated to expand significantly, with the growing use of telemedicine, wearable technology, and artificial intelligence offering new ways to deliver and manage healthcare (Bokolo Jr., 2021). There is also a growing

emphasis on developing sustainable healthcare models that effectively balance quality, access, and cost (Emanuel, 2020). Strengthening global health security to better prepare for future pandemics and health crises has become a priority, as has the focus on health equity and addressing the social determinants of health (Kluge et al., 2020). In essence, the future of healthcare lies in embracing technological advancements, personalized medicine, sustainable practices, and a global approach to health security and equity. Artificial intelligence is already enhancing various aspects of healthcare and is likely to become essential for more intelligent and efficient clinical operations and care in the future. As data becomes more secure and interoperable, AI will play a crucial role in analytics, insights, and decision-making within health plan, pharmacy benefit manager (PBM), and health system companies (Almalawi et al., 2022).

## **2.2. Diabetes Mellitus**

### **2.2.1. Types**

*Diabetes mellitus* is a collective term for chronic metabolic conditions described by high or elevated blood glucose levels due to failed or insufficient insulin production in the body. The term "diabetes" itself was coined by the Greek physician Aretaeus in the 2nd century. However, it wasn't until the 20th century that the distinction between Type I and Type II diabetes became clear (Bliss, 1982). There are four different clinical types of diabetes: type one (when the destruction of pancreatic beta cells leads to a complete shortage of insulin production), type two (when there is high insulin resistance and inadequate insulin production to overcome it), gestational diabetes (which affects only pregnant women with low glucose tolerance) and there is part of other specific genetic defects or influence of drugs (American Diabetes Association, 2010; Mayfield, 1998).

**2.2.1.1. Type I diabetes.** The journey of Type I Diabetes (T1D) spans several centuries. Ancient Egyptian documents as early as 1500 BC mention symptoms akin to diabetes (Papachristoforou, Rousso, & Mavromati, 2021). Type 1 diabetes, representing 5-10% of all diabetes cases, is increasing globally and has significant immediate and long-term effects. Its strong genetic link, mainly through the HLA complex, is well-established, yet its clinical onset triggers are largely unknown. Effective management involves a multidisciplinary team focusing on insulin administration, blood glucose monitoring, meal planning, and screening for related conditions and complications. The major health risks associated with type 1 diabetes arise from microvascular and macrovascular diseases (Daneman, 2006). The development of Type 1 Diabetes Mellitus (T1DM) progresses through three stages, classified by the presence of hyperglycemia and related symptoms

like polyuria and thirst. While there's no cure, and patients require lifelong insulin therapy, advancements like insulin pumps, continuous glucose monitoring, and hybrid closed-loop systems are emerging (Kapil et al, 2020). Despite improved microvascular and macrovascular complication management through intensive glycemic control, most T1DM patients still develop these complications (Katsarou et al., 2017). Recent years frequent self-monitoring of glucose is essential, and interstitial glucose monitoring methods like continuous glucose monitoring (CGM) and flash glucose monitoring (FGM) are becoming more popular than traditional methods. These systems typically use a sensor inserted under the skin, secured with an adhesive patch, and are used for periods of 6 to 14 days (Asarani et al, 2020).

**2.2.1.2. Type II diabetes.** Type II Diabetes Mellitus (T2DM) is a multifactorial disease primarily characterized by insulin resistance and an eventual decline in insulin production. Its insidious onset is often tied to modifiable lifestyle factors such as sedentary behavior and a calorie-dense diet, leading to obesity - a significant risk factor. Genetics also significantly influence the susceptibility to T2DM, with numerous genes implicated in its pathogenesis (McCarthy, 2010). Today, T2DM has escalated to epidemic proportions globally. As per the 2021 statistics, over half a billion individuals between the ages of 20 and 79 live with diabetes, a figure anticipated to swell to 643 million by 2030 and 783 million by 2045 (IDF Diabetes Atlas, 2021). Urbanization and associated lifestyle transitions drive this surge, particularly in developing nations (Zhou et al., 2020). The challenge of T2DM management is multi-pronged. Maintaining blood glucose at target levels is often arduous due to T2DM's progressive nature. The disease also presents with various complications, such as heart disease and microvascular damage, complicating patient care. The financial impact is likewise significant, encompassing direct medical costs and indirect costs related to reduced productivity (Bommer et al., 2018).

### **2.2.2. Diagnostics**

Diagnostic of diabetes is made by plasma glucose criteria, fasting plasma glucose (FPG), using oral glucose tolerant test or A1C criteria (average A1C level is below 5.7%). These tests are used to evaluate, diagnose, or detect patients who could have prediabetes (ElSayed et al., 2023). The newest advancements in data science extend benefits in the diagnosis of diabetes. Many studies show how machine learning and AI techniques are implemented for diabetes prediction methods like artificial neural networks (ANN), support vector machines, or gradient-boosting decision trees (Chang et al., 2023). *Table 1* presents a list of existing devices used for diagnostics and management, as well as possible future developments.

**Table 1.***Current and future devices for diabetes diagnostics and management (original from Author)*

<b>Category</b>	<b>Existing devices</b>	<b>Future of emerging devices</b>
Insulin Delivery	Traditional insulin syringes, Insulin pens, Insulin pumps (Stockl et al, 2007)	Smart insulin pens, advanced insulin pumps (with more automated features) (Sangave et al, 2019)
Glucose Monitoring	Blood glucose meters, Continuous Glucose Meters (CGM) (Poolsup et al, 2013)	Non-invasive glucose monitoring technologies, implantable CGMs (Hassan et al, 2019), (Sharng et al, 2022)
Integrated Systems	CGM and insulin pump combo (Siegmond et al, 2013)	Fully automated closed-loop systems (Artificial Pancreas) (Åm et al, 2023)
Data management	Mobile apps for diabetes management, electronic health record integration (Peeples et al, 2013)	Advanced AI-driven analytics for personalized treatment, integrated health platforms connecting patients and healthcare providers (Aggarwal et al, 2020)
Lifestyle Management	Nutrition and exercise apps (Brzan et al, 2016)	AI-based predictive systems for lifestyle intervention, wearables with more advanced health tracking features (Romero-Tapiador et al, 2023)

**2.2.3. Treatment and management**

Since prevention or treatment for diabetes is improving, effectively managing the life-altering aspects of the disease remains the most successful approach to control it. Measuring glucose levels in the blood, which is a primary factor, was crucial to enhancing life expectancy (Bruen et al., 2017). In past decades, scientists have made remarkable progress in diabetes wearables technology, and outpatient care has shown significant benefits and great results. Technologies help people enhance glycemia control, boost patient well-being, lower hypoglycemia risk, and lower the rate of hospital admissions due to diabetes-related necessity (Avari et al., 2023). Recent technological advancements have introduced wearables, smartphones, and other devices that help to monitor and track symptoms or disease status of following patients (Ellahham, 2020). The future of diabetes management is poised at the intersection of technology, personalized medicine, and patient-centered care. Artificial intelligence (AI) and machine learning are expected to be crucial in predicting diabetes-related complications and personalizing treatment regimens (Contreras & Vehi, 2021). Wearable health

technology and intelligent insulin delivery systems are also areas of active research and development (Garg et al., 2021).

**2.2.3.1. Treatment and management of Type I.** T1D management is a complex endeavor arising from the autoimmune destruction of insulin-producing cells in the pancreas (Atkinson, Eisenbarth, & Michels, 2014). Lifelong reliance on insulin and constant blood glucose monitoring are the pillars of managing this condition. The relentless nature of this disease also imposes considerable psychological burdens (Hilliard et al., 2013). The landscape of T1D treatment has evolved dramatically. The advent of recombinant human insulin in the 1980s marked a pivotal change (Johnson, 1983). Modern developments include various insulin analogs and technological innovations like continuous glucose monitoring (CGM) systems and insulin pumps, enabling finer control over blood sugar levels (Pickup, 2012). The horizon of T1D treatment holds promise, with cutting-edge research in areas like beta-cell replacement, immunotherapy, and artificial pancreas systems. These innovative approaches aim to restore insulin production, prevent autoimmune destruction, and automate insulin delivery respectively (Shapiro et al., 2000; Herold et al., 2019; Russell et al., 2019).

In digital therapeutics, significant strides have been made in T1D care, especially during the pandemic, underscoring the importance of remote healthcare. A study by Gomez et al. (2020) showed that a digital diabetes management system considerably enhanced glycemic control (Gomez et al., 2020). Peters et al. (2021) shed light on the positive impacts of a T1D-specific mobile health app, which led to greater patient engagement and satisfaction, underscoring the utility of digital tools in chronic disease management. Moreover, integrating machine learning into digital therapeutics marks a new era. Chen et al. (2022) developed a machine learning algorithm to predict blood glucose levels, offering tailored advice and aiding clinical decision-making.

**2.2.3.2. Treatment and management of Type II.** T2DM treatment is a tapestry woven with lifestyle modifications, oral medications, and, potentially, injectables. Metformin is the cornerstone of pharmacotherapy, though recent drug classes such as SGLT2 inhibitors and GLP-1 receptor agonists have shown promise due to their additional benefits. Bariatric surgery is also acknowledged for its efficacy in T2DM patients with obesity (Rubino et al., 2016). The horizon of T2DM therapy is seeing a shift toward individualized care. Precision medicine is on the rise, aiming to tailor treatments based on personal genetic makeup and environmental factors. Pharmaceutical innovations continuously unveil new treatments to regulate glucose levels better and improve insulin action (Ahlqvist et al., 2018).

The field of digital therapeutics has undergone substantial growth in T2DM. These evidence-informed digital interventions use health technology to manage the disease, exemplified by improved adherence to lifestyle changes and medication bolstered by instant feedback mechanisms (Torous & Roberts, 2020). In 2020, research by Fagherazzi et al. (2020) illustrated the success of DTx in managing T2DM. Subsequently, a 2021 review by Chen et al. affirmed the effectiveness of mobile health apps in ameliorating T2DM outcomes, integrating DTx into conventional diabetes management (Chen et al., 2021). By 2023, DTx has not only advanced in sophistication but has also gained wider acceptance among patients and healthcare professionals, becoming an integral part of diabetes care as per clinical guidelines, which signals a transition to more integrative, patient-centric treatment models (Jethwani et al., 2020). Proper knowledge and accurate guidance are crucial for patients and their caregivers who are actively engaged in handling DTx devices like subcutaneous insulin pumps. Over the past twenty years, the dependability of pump technology has significantly enhanced, resulting in a growing number of diabetes patients using them (Bombaci et al, 2022).

#### ***2.2.4. Future of diabetes treatment***

There is considerable excitement surrounding the next generation of diabetes medications. Agents such as the newer GLP-1 receptor agonists are proving to be quite effective in managing blood glucose and offering additional cardiovascular advantages (Marso et al., 2016). Researchers are also delving into therapies that don't rely on the incretin system, potentially offering similar benefits with a reduced risk profile (Pratley & Aroda, 2018). On the cutting edge of T2DM treatment are endeavors like gene editing and stem cell therapy. While still predominantly experimental, these approaches hint at a future where the root causes of T2DM could be addressed at the cellular or genetic level, potentially restoring the body's ability to regulate blood glucose naturally (Domínguez-Bendala et al., 2019; Balboa et al., 2021). The advent of closed-loop insulin delivery systems presents a leap forward in T2DM management. These systems, often called the pancreas, are making strides in automating insulin delivery in response to real-time glucose levels, mimicking the natural insulin secretion of a non-diabetic pancreas (Tauschmann & Hovorka, 2018). Digital health, which includes telemedicine and mobile health apps, has seen a significant rise in adoption, providing tailored diabetes care that extends beyond traditional healthcare settings. These digital platforms show promising patients manage their diabetes more effectively, with studies indicating that they can lead to better glucose control and reduced diabetes-related stress (Bonoto et al., 2017). The realm of digital therapeutics is expanding with mobile applications at the forefront, employing sophisticated algorithms and machine learning to offer personalized diabetes management guidance. Furthermore, wearable devices are

being explored for their potential to track glucose and forecast changes in glucose levels (Istepanian et al., 2021).

### **2.3. AI and Digital Therapeutics of diabetes management**

Advancements in healthcare are unfolding rapidly across three major dimensions: healthcare technology, healthcare delivery, and computer science/information technology (IT). Healthcare technology is seeing breakthroughs from the human genome project, innovative pharmaceuticals and nutraceuticals, and advanced medical devices. Concurrently, healthcare delivery is evolving with novel disease management methods, the adoption of evidence-based care, and the integration of mind-body medicine. In the realm of computer science and IT, significant progress is being made in data processing speed and storage, mobile personal computing, cloud computing, artificial intelligence, networking, and biometrics, all contributing to a transformative shift in the healthcare sector (Sriram and Reddy, 2020). In essence, artificial intelligence is the replication of human intelligence processes by machines, particularly computer systems. These processes include learning, reasoning, and self-correction. Initially, AI systems are exposed to large datasets to learn basic patterns and information about specific conditions or diseases. However, AI transcends being just a vast database. After the initial learning phase, these systems are designed to evolve and refine their capabilities, becoming more precise and efficient in their tasks (Padhy et al., 2019). It is anticipated that with access to vast, structured data sets and ample computational power, the predictive accuracy of AI in diabetes will see considerable enhancement. This advancement is expected to greatly improve the precision of models used for predicting diabetes-related outcomes (Nomura et al., 2021).

#### **2.3.1. Digital therapeutics**

Digital therapeutics is the newest form of medical treatment, using evidence-based usage by heavily developed software programs to improve or treat patients (Hong et al., 2021). However, there is no consensus on how to comment DTx among various countries (Wang et al., 2023). DTx is a component of the more significant digital health and digital medicine parts, and each of them has clinical significance and regulatory checks. Digital health is used more to collect and use patient health information, including doctor or telehealth consultation, and software is used more to maintain clinical care when digital medicine can diagnose a specified illness and treat a patient (Phan et al., 2023). Digital Therapeutics Association (DTA) emphasizes that DTx products combine cutting-edge technology with top-tier design, clinical support and data security. DTA legitimizes all stakeholders

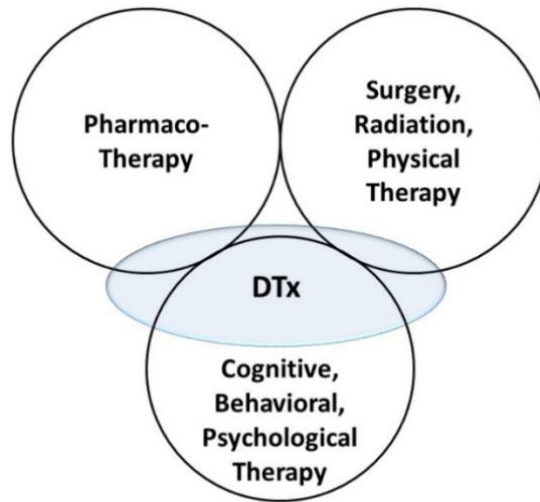
(patients, healthcare providers, and payers) by providing accessible gear for addressing a range of conditions through data-driven interventions (Dang et al., 2020).

The increasing prevalence of chronic diseases, compounded by population aging and other health trends changes, poses significant challenges for healthcare systems around the world. In the expanding telehealth landscape, DTx can deliver evidence-based cures for disease maintenance and further steps (Carrera et al., 2023). Digital therapeutics from 2021 is commonly referred to as the “fourth wave”. The “tree waves” before were more into remote monitoring and digital telehealth applications but there was a big problem to improve patient commitment. Consequentially, patients were not interested in digital products because of integration problems in clinical workflow (Dang et al., 2021). In addition to the challenge mentioned before, an increasing number of DTx tools integrate AI (with involvements of machine learning (ML) or deep learning (DL) to improve DTx effectiveness in medical predictions. However, enabling ML and DL potential often demands loads of high-quality data, which can complicate specific diseases in the healthcare sector (Forcier et al., 2019). DTx Can be a valuable complement and, in some cases, a game changer for traditional biomedical treatments. Additionally, DTx enables healthcare providers to remotely gather real-time patient data by improving the efficiency of consecutive office visits (Patel and Butte, 2020).

Currently, DTx products are so flexible that they take prominent place in the medical market, giving people and healthcare specialists the opportunity to improve the whole healthcare system. Many software or devices help people with various medical conditions like diabetes, oncology treatment, or neuropsychiatric disorders (Hong et al., 2021). Also, DTx products are situated in the stage where they can comfortably change settled treatment methods, like cognitive behavioral therapy (CBT) or reminiscence therapy. *Figure 1* presents conceptual positions in relation to current therapeutic choices (Chung, 2019).

**Figure 1.**

*Conceptual position of digital therapeutics in relation to current therapeutic choices (from Chung (2019))*



### ***2.3.2. Digital therapeutics in diabetes management***

The inception of digital therapeutics in diabetes management traces back to the advent and evolution of digital technology and the escalating need for individualized, easily accessible, and cost-efficient care solutions. Initially, this field focused on digital record-keeping and patient management systems but has expanded to include more advanced, interactive tools (Tarricone et al., 2020). Various methods are employed in digital therapeutics for diabetes management, from smartphone applications and telehealth services to sophisticated data analysis and artificial intelligence applications. Smartphone apps, for example, provide a means to monitor glucose levels, track insulin doses, and log dietary information, often in conjunction with wearable technology for immediate monitoring (Hou et al., 2019).

Integrating AI and machine learning has also brought about predictive models, contributing to more accurate and personalized treatment plans (Contreras & Vehi, 2018). Adopting digital therapeutics in diabetes care is not without challenges. Concerns about the security of data and maintaining patient confidentiality are paramount, given the sensitive nature of health data these systems manage (Siegel, 2020). The issue of the digital divide is also prominent, as unequal access to technology can worsen healthcare disparities (Lyles et al., 2019).

In addition, fitting digital tools into existing healthcare frameworks and ensuring compatibility among different systems presents difficulties (Or & Tao, 2019). Another significant issue is sustaining user engagement and adherence to digital therapeutic programs, which is essential for long-term effectiveness (Eberle et al., 2019).

The Future of digital therapeutics in diabetes management could be good if demands gonna overcome current obstacles and further innovations. Progress in personalized medicine and incorporating genomic information into digital platforms may offer more specific and efficient treatment approaches (Topol, 2019). Utilizing emerging technologies like blockchain for securing data and augmented reality for patient education could also enhance the effectiveness and security of digital therapeutics (Klonoff, 2019; Bresnick, 2020).

### ***2.3.3. Artificial Intelligence***

Artificial Intelligence is the cornerstone of computer science. It constitutes a scientific advancement wherein machines are designed to execute tasks falling in the realm of human intelligence (Aggarwal et al., 2022). The evolution of artificial intelligence started in 1951 with the development of the first AI program by Christopher Strach. The main break in AI development was in 1956 when John McCarthy, at the Dartmouth conference, introduced the term "Artificial intelligence" and made a significant step in AI history. In the following decade, AI research was on expert systems, but without powerful computers and large quantity of data, it was hard to move forward (Alowais et al., 2023).

Focusing on the realm of machine learning and the connection of AI, it can be described as a system's capacity to accurately comprehend external data, assimilate knowledge from that data, and subsequently employ these acquired insights for the accomplishment of objectives and tasks, all the while demonstrating flexible adaptability (Meske et al., 2020). The creation of AI has been overseen by specific parts of engineers, scientists, programmers, and systems architects. The team that worked for them had problems improving the broad spectrum of human diversity encompassing factors like gender, age, geographical origin, and economic status (Akter et al., 2021). In simpler terms, the AI creation team tries to emulate the neural processing of the human brain using computers. Creators' hinge on three critical components: computational systems, data management, and algorithms. The last thing that empowers AI to have the ability to make and, understand different patterns and, most of the time, give meaningful insights replicating human intelligence (Rodgers and Nguyen, 2022).

Artificial intelligence paves the way for a valuable generation in enterprises, industries, and old society. More profound research helps to understand AI's significance in numerous aspects, leading to widespread adoption within various business sectors (Ansari et al., 2022). Nowadays, artificial intelligence has become an integral part of everyone's life, both as a subject of ongoing discussion and pervasive technology, and AI professionals' teams continue to contribute to a growing list of achievements, with the results of their research permeating various aspects of our daily lives.

Moreover, AI-driven machine learning methods have enabled the identification of individuals through their unique attributes, including facial features or vocal patterns. (Shadbolt, 2022).

AI can be categorized into two main types: automation and augmentation. Automation replaces human tasks, and augmentation takes human intelligence and insights for better decision-making. These categories help across organizational processes and can improve company products and services if employees or the company is using AI (Enholm et al., 2022).

During years AI brings us a profound revolution in the field of medicine, with the potential to significantly enhance the experiences of clinicians and patients. Findings show continuous efforts to monitor and disseminate pivotal advancements in medicine with the help of AI (Rajpukar et al., 2022). However, adopting digital technologies and software in healthcare institutions has created challenging scenarios for software developers and healthcare professionals (Prakash et al., 2022). Nowadays, AI technologies can serve as potential allies to broaden human capabilities when it's possible to enable the delivery of necessary care to patients whenever required, and it is essential to understand that human and machine harmony cannot be separated (Chen and Decary, 2020). But AI systems are developing very fast as they improve by using a lot of data and can offer opportunities to enhance disease treatment patient care, streamline healthcare management, and even reduce some human errors and costs (Lee and Yoon, 2021). Still, AI cannot replace medicine experts or healthcare specialists due to deep insights (Kumar et al., 2023).

#### ***2.3.4. AI in Diabetes Management***

Rapid diagnosis and early prevention are essential for managing the disease (Kumar and Suresh, 2021). Traditional in vitro biosensors like glucose meters and glycohemoglobin test kits are commonly used for diabetes diagnosis and long-term management, as they directly measure key indicators of the disease. The significant market size and high demand for these tests position diabetes as an ideal model for developing innovative sensor approaches (Brien et al, 2021)

Effective self-management is crucial for meeting diabetes treatment objectives. Technologies like mobile phones and Bluetooth® are instrumental in supporting self-management and lifestyle modifications for chronic conditions, including diabetes (Thompson et al, 2023). The introduction of continuous glucose monitoring sensors has significantly transformed glucose monitoring in diabetes therapy. Current market leading CGM sensors are mostly minimally invasive, using a needle electrochemical sensor to measure glucose levels in the subcutaneous tissue, although there are also systems based on optical sensing technologies. The growing availability of CGM sensors is driving the creation of various applications, such as tools for retrospective CGM data analysis and mobile

apps that integrate CGM data with other vital diabetes management information like medication, dietary intake, and physical activity (Vettoretti et al., 2018).

Significant advancements are also anticipated in the interoperability of continuous glucose monitoring systems with other devices, such as medical devices for diabetes therapy, activity trackers, and various physiological wearable sensors. The FDA has recently categorized a new class of CGM devices as integrated continuous glucose monitoring (iCGM) systems. These are designed to function as part of an integrated system, compatible with other medical devices and electronic interfaces. This classification is expected to expedite the market entry of iCGM devices, enhancing the scope and effectiveness of diabetes management technologies (Cappon et al., 2019).

### **Chapter 3: Research Methodology**

This study investigated the impact and challenges of AI in the rapidly evolving field of digital therapeutics for diabetes management. With AI's potential to transform healthcare delivery, especially in chronic conditions like diabetes, this research focused on understanding its applications, effectiveness, and associated challenges in the context of DTx (Ellahham, 2020; Nomura et al., 2021). The following research questions were used to guide the analysis:

**RQ1:** What are practical challenges for companies encountered when integrating AI-based digital therapeutics into healthcare systems for diabetes prevention?

**RQ2:** What are the strategies that businesses can use to promote AI-based digital therapeutics for diabetes prevention among healthcare providers, payers and consumers?

**RQ3:** What are the economic benefits of AI-based digital therapeutics in terms of reduced healthcare costs, and how businesses quantify these benefits?

#### **3.1. Research Design**

The research used three main methods: i) literature review, ii) interviews with experts and iii) scenario analysis. Literature review was performed using papers found in Google Scholar data base. The search was based on keywords like diabetes mellitus, digital therapeutics, diabetes management, AI in healthcare and diabetes, innovation. Papers used for research were dated from 2017 to 2023, which resulted in 126 papers used for research. Adopting a qualitative research approach, this study used semi-structured interviews to gather in-depth insights from industry professionals, academicians, and specialists in DTx and this. This approach is ideal for exploring these experts' nuanced perspectives and experiences (Davis, 2018). Finally, scenario analysis allowed to simplify interactions between variables, and aid in strategic planning by exploring different potential futures and their implications. This also deepened understanding of key drivers, interdependencies, and helped to identify uncertainties and risks in the field.

#### **3.2. Data collection – Expert interviews**

In-depth semi-structured interview guide was created, focusing on integration and application of AI in DTx for diabetes, challenges and ethical considerations in implementing AI-based solutions. Also, perceived effectiveness and patient outcomes, as well as the future trajectory of AI in diabetes management and DTx were discussed (Ellahham, 2020; Joshi et al., 2023). The study employed purposive sampling to select participants with specific expertise in DTx and AI in

diabetes management. This targeted approach ensured the collection of rich, relevant data from knowledgeable sources (Taylor, 2019).

Participants were categorized into: Business owners - professionals who are actively involved in the development or implementation of DTx solutions in diabetes management businesses, DTx Experts in Diabetes Management - specialists who focus on integrating DTx into diabetes management, providing insights into specific challenges and opportunities in this area, academic experts - professors and researchers specializing in digital health, AI technologies, and diabetes care, offering a theoretical and research-oriented perspective (Brown, 2021). The average interview duration was 41:20. In total, 89 requests were sent for potential interviewees, resulting in final 10 interviews conducted with industry professionals (*see overview of Experts in Table 2*). Interviews were conducted via Zoom/Microsoft Teams and recorded. Data was analyzed using thematic analysis, as outlined by Brown and Clarke (2021), which is an effective method for identifying themes and patterns in qualitative data (*see categories in Table 3*). Summarized responses per question can be found in *Appendix I*. It is important to note, that question number 6 received very poor answers due to lack of shared knowledge and newness of the field discussed.

The research adhered to the highest ethical standards, ensuring informed consent, confidentiality, and voluntary participation. Ethical approval was obtained from the institution's ethics committee (Green et al., 2020).

**Table 2.**

*Overview of Interviewees (original from Author)*

Code	Current position/Background	Male/Female	Form of data collection
IA	Principal, healthcare innovator	Male	Online synchronous communication
IB	Business development director	Male	Online synchronous communication
IC	Invited Assistant Professor	Male	Online synchronous communication
ID	CEO at diabetes management product company	Male	Online synchronous communication
IE	CEO	Male	Online asynchronous communication
IF	Resident Specialist, lecturer, Digital Health Scientific Advisor, Governing Council Member at WFPHA	Male	Online asynchronous communication

IG	Owner consulting company, ex-Chief Digital Officer	Male	Online asynchronous communication
IH	Founder, Managing director and Digital Strategist	Female	Online asynchronous communication
II	Product manager	Male	Online synchronous communication
IJ	Chief product officer	Male	Online synchronous communication

**Table 3.**

*Coded categories based on Expert interviews (original from Author)*

Category	Key words and phrases
1. Current landscape	<p>Shift towards predictive care is transformative step;</p> <p>Numerous AI-driven startups and solutions in diabetes field;</p> <p>Adoption rates remain low;</p> <p>Stakeholders are not ready for a change;</p> <p>Tools already used: software that connects CGM and insulin pump data, Artificial pancreas concept, lifestyle intervention app, software to predict treatment needs and assessing probability of treatment rejection.</p>
2. Benefits and effectiveness compared to traditional methods	<p>Insulin titration (insulin dosage);</p> <p>Lifestyle intervention and cognitive behavior therapy;</p> <p>Decision support for clinicians;</p> <p>Volume and quality of data collected;</p> <p>Personalized and differentiated care decisions;</p> <p>Predictive capability;</p> <p>More precise and lower costs;</p> <p>Continuous support;</p> <p>Very effective if patients actively engage with their condition;</p> <p>Effectiveness is highly individual and cannot be quantified uniformly;</p> <p>Potential in exposing inefficiencies;</p> <p>Effectiveness varies across different technologies.</p>
3. Patient view on AI-driven	<p>Largely depend on guidance from healthcare professionals;</p> <p>Largely depend on design and user experience of tools;</p>

tools in diabetes care	Initial skepticism due to lack of digital familiarity; After training/demonstrations recognition of ease of use and improvement; Young ones and tech-savvy patients adapt faste.
4. Challenges to implementation	Validating the effectiveness; Data protection laws; Ethical and practical challenges – “black box” nature of AI systems; Combining different regulations; Gaining trust from physicians; Training and educating physicians; Difficulties in accessing necessary data and compensating data suppliers; Business model; Gaining approval for market presence, market readiness.
5. Business models	Depends on the market and healthcare system; EU holds lower willingness to pay than U.S. market; Importance of partnering with employers; Engaging with other players in challenging; Value-based procurement; Public reimbursement;
6. Future landscape	Influence of technologies like AID, non-invasive blood glucose measurement, generative AI, integrated language models, and humanoid robotics; Future hinges on strength of effectiveness evidence; Crucial role in containing costs; Changes in regulations; Exploring new business models and new partnerships is important; Sensor technology will become smaller and more comfortable; Greater patient involvement in their own healthcare; Increasing attention to prevention; Improved access to care; Ability to understand disease outside healthcare settings; Will require time and may initially increase healthcare costs.

## Chapter 4: Analysis and Discussion

### 4.1. Current landscape

In literature review it is discussed that currently digital therapeutics are strongly transforming various aspects of healthcare settings, doctor-patient relationship and entire healthcare system (Topol, 2019). Recent technological advancements have introduced wearables, smartphones, and other devices that help to monitor and track symptoms or disease status of following patients, that significantly improve the care (Ellahham, 2020). Experts also emphasized the increasing number of AI-driven startups and solutions in diabetes field (IA, ID). Moreover, growing availability of CGM sensors is driving the creation of various applications, such as tools for data analysis and mobile apps that integrate data with other vital diabetes management information (IA, IB, ID, IC, IG, II, IJ). This also presents transformative shift towards predictive care (IB), as a machine learning algorithms allows prediction of blood glucose levels, offering tailored advice and aiding clinical decision-making (Nomura et al., 2021; Chen et al., 2022).

However, the increasing costs in healthcare has become a burden, limiting access to care around the world (Papanicolas et al., 2018; Baum et al., 2019). This was also confirmed by interviewee IB. Moreover, experts emphasized that adoption rate of new technological advancements remains low (IB, ID, IG), which is mainly being driven by various stakeholders being not ready for change (IC) and lack of strong effectiveness evidence (IB, IG). Finally, there is a lot of ambiguity around various regulations for development and adoption (ID).

### 4.2. AI-based digital therapeutics benefits and effectiveness

Literature findings showed that current methods to diabetes treatment are high in economic costs, which results in impacting the quality of life of the patients (Davies et al., 2018). However, experts suggest that AI-based digital therapeutics can enable more precise calculation of costs, which would initially result in lowering them too (IB, IC, ID, II, IH, IJ). Moreover, it was discussed that potential applications of DTx are vast – from remote monitoring to digital diagnostic documents (Ellahham, 2020). Experts suggested that AI could play a key role in insulin titration, which is extremely valuable in Type I diabetes management (IA, IB, IC, ID, IG), lifestyle intervention and cognitive behavior therapy, which is crucial for prevention of Type II diabetes (IA, ID, IE, IG, IJ), and play an important support role in decision making for clinicians (IB, IC, ID, IJ). As systems are developing fast, they improve by using a lot of data (IA, IB, IC, IF, IH) and can offer opportunities to enhance disease treatment patient care, streamline healthcare management, and even reduce some

human errors and costs (Lee and Yoon, 2021). Higher volume and quality data collected by AI-based solutions, would enable this (IA, IB, IC, IF, IH). Additionally, according to experts, the most significant benefit of AI-based digital therapeutics compared to traditional methods its ability to provide more personalized and differentiated care decisions (IA, IB, IC, ID, IE, IF, IG, II, IJ), “a stark departure from traditional one-size-fits-all approaches” (IE). Finally, over traditional methods, these solutions allow more continuous support for patients, like real-time feedback on the data (ID, IE, IH).

Regarding the effectiveness, experts suggested that it depends on a few critical things. Firstly, it can be extremely effective if patients engage with their condition (IA). Expert IH also suggested, that such innovations could encourage self-management among patients. IA and IB noticed, that the effectiveness is highly individual and cannot be quantified uniformly. Expert IF noticed that more research needs to be available to compare effectiveness. ID, IG and IH added that effectiveness varies across different technologies. Expert IC also suggested that AI-based digital therapeutics holds potential in exposing inefficiencies in current methods used. However, expert IE claimed that AI-based digital therapeutics are already proving more effective than traditional methods due to personalized and adaptive approach.

### **4.3. Patient view on AI-based digital therapeutics**

Some authors argued that patients are not interested in digital products because of issues in clinical workflow (Dang et al., 2021). This complicates patient commitment to new solutions. However, interviewed experts suggested that initial skepticism towards these solutions comes from lack of digital familiarity (IA, IB, ID) but that it also strongly depends on provided guidance from healthcare professionals (IA) and of the design of the tools and how they support user experience (IG, II, IJ). It was noted, that after initial training and demonstration of tools, recognition of ease of use improved significantly (IA, II, IJ). IE suggested, that data privacy, user-friendliness, and clinical validation are key factors in encouraging patients to use the product. Finally, experts noticed trends that young people and tech-savvy patients are more eager to use and adapt to the technologies faster (IA, IJ).

### **4.4. Challenges to implementation and development**

There is no doubt that there are numerous challenges to solve for successful implementation of AI-based digital therapeutics in healthcare and diabetes management. Literature revealed such challenges as ensuring high-quality and safe services (Baker et al., 2020), low patient commitment, and lack of readiness of stakeholders and regulations. Meanwhile, as the most significant challenges

to implementation, experts mentioned existing data protection laws (IB, IC, IE, IF, IH, II, IJ) and combining different regulations for development and adoption (IA, IE, IG, II, IJ) or no regulation at all (IF). Expert IE is saying that reliance on technologies will exclude some certain groups. These issues complicate the process of getting approval for market presence (IA, IC, ID) and going through clinical trial processes (IE, IF) which is very complex as diverse populations and conditions involves extensive validation (IE). Moreover, choosing the right business model is a complex challenge which significantly affect the success of implementation (ID, IG, II, IJ). IE also noticed, that accessibility and affordability may also rely on reliance on technologies like smartphones or internet connectivity, as it may exclude certain groups. Expert IC also discussed the difficulties in accessing necessary data and compensating data suppliers for it. Finally, it was noted that such challenges as ethical and practical ones like “black box” nature of AI systems (IC), limits gaining trust from physicians (IA, IB, IC, ID) and requires additional training and education (IA, IB, IC).

#### **4.5. Implications for business models used for promotion**

Previously it was discussed, that choosing the right business model is one of the main challenges in promoting AI-based digital therapeutics in healthcare and diabetes management. When considering the business models, experts suggested that it can widely depend on the market and healthcare systems (IA, IG, II). For instance, it was noted that patients in EU holds lower willingness to pay than U.S. market (IA, IH). Expert IB also emphasized the importance of partnering with and enabling employers, as engaging with other players in the market is extremely challenging. Most of the interviewees suggested using value-based procurement (IC, IG, II, IJ), which is outcome focused, uses life-cycling costing, involves extensive stakeholder engagement, and emphasizing sustainability and social value. Expert IH discussed that payment methods, like fee-for-service vs value-based healthcare, will play crucial role in determining how these tools are reimbursed. Also, IE suggested that subscription models for recurring revenue, collaborations with healthcare providers for integration, direct-to-consumer approaches with freemium models, and licensing agreements with pharmaceutical or healthcare entities would be the most successful. Expert ID also suggested focus on public reimbursement, when governments or other public bodies compensate individuals/organizations for specific costs.

#### **4.6. Future landscape**

Literature analysis revealed that the digital health trend is here to stay (Bokolo Jr., 2021) as well as global diabetes care devices market is expected to grow significantly in upcoming years. It is

expected that AI will play string role in analytics, insights, and decision-making within health plan, pharmacy benefit manager, and health system companies (Almalawi et al., 2022). This was also supported by experts interviewed. IE suggests that AI-based digital therapeutics will reshape healthcare systems by improving efficiency, resource allocation and preventative care. Experts also expect significant influence of technologies like AID, non-invasive blood glucose measurement, generative AI, integrated language models and humanoid robots (IA, IB IC, ID, IG, II, IJ). It is also expected that sensory technologies will become smaller and more comfortable (IA, II). They also emphasized that success will strongly hinge on strength of effectiveness evidence, changes in regulations (IB, IF, IG, IH). Experts suggested that changes will require time and may initially increase healthcare costs (IB, IC, ID, IE, IG), but with garter patient involvement in their own care (IB, ID, IG), increasing attention to prevention (IC), and improved access to care (ID, II, IJ), AI-based digital therapeutics can reshape the healthcare and diabetes treatment and management. Expert IF is saying that next decade innovation will be simpler than we think when world will combine data science and artificial intel. Finally, most of the experts agreed that the next 5 to 10 years will be critical in development and acceptance of AI-based digital therapeutics role in diabetes treatment and management.

#### 4.7. Scenario analysis

To fully understand and forecast AI-based digital therapeutics role in diabetes treatment and management, scenario analysis was also performed. The insights gained from literature analysis and expert interviews are the ground for the Two-Axis Method scenario planning. It involves using high uncertainty contextual factors for structuring possible scenarios and their probabilities. This method is one of the most widely used, as it has simple frame for identifying different storylines (Ramirez & Wilkinson, 2013). The chosen uncertainties and dimensions included technological advancement and integration (degree to which AI advance and successfully integrate into digital therapeutics) and healthcare system adoption and integration (extent to which healthcare systems adopt these technologies and regulatory environment adapts to accommodate). Table 3 presents scenarios, their probabilities and factors that pose an influence. Probabilities were assumed considering the research findings obtained in literature review and expert interviews.

#### Table 4.

*Summary of Scenarios (original from Author)*

	Scenario 1	Scenario 2	Scenario 3	Scenario 4
--	------------	------------	------------	------------

<b>Technological advancement and integration</b>	High	High	Low	Low
<b>Healthcare system adoption and integration</b>	High	Low	High	Low
<b>Probability</b>	25%	35%	20%	20%
<b>Factors that increase the probability</b>	Rapid AI development, increasing global digital healthcare trends, proactive regulatory reforms	Fast-paced AI advancement, industry investment in technology	Adoption of digital health solutions by healthcare systems, supportive policy environment	Persistent technical challenges in AI, conservative regulatory environments, lack of funding
<b>Factors that decrease the probability</b>	Technological limitations, slow regulatory changes, concerns about data privacy	Healthcare system inertia, varied global regulatory environments, cost constraints	Technical complexities in AI, funding issues, data integration challenges	Growing recognition of digital health benefits, incremental technological improvements

First scenario assumes significant advance of AI technologies and their flawless integration into digital therapeutics, while at the same time healthcare systems rapidly adopting these technologies. It also assumes high supporting frameworks introduced by regulatory bodies. Second scenario keeps high advancements in technological success, but their adoption is hindered by resistance to change in healthcare systems and challenges in regulatory environments. Third scenario assumes the opposite – healthcare systems are well prepared, but AI advancements face challenges in integration and development. Finally, fourth scenario assumes both, low advancement and adoption, due to various significant challenges.

These scenarios also reveal several important things. First, synchronizing technological development with healthcare system readiness is key. High technological advancements do not automatically translate into effective healthcare integration. Second, external factors like regulatory reform, industry investment or technical challenges significantly impact the trajectory of digital health integration. Moreover, the supportive role of policy environments and funding is extremely

important in facilitating or hindering the adoption. Finally, varying probabilities suggest that healthcare sector must be prepared for different rates of change and innovation as well as global diversity in systems and tech development.

In conclusion, for AI-based digital therapeutics to play an important role in diabetes management multiple challenges need to be solved. Without proper readiness, technology could not be adopted for wide usage. However, as technology holds numerous benefits and efficiencies over current systems, it can be concluded that it has potential to play a transformative role.

## Chapter 5: Conclusions

The final chapter of this thesis summarizes main findings, limitations and implications on the research, as well as recommendations for future research.

### 5.1. Limitations and recommendations

Next paragraphs will discuss limitations of experts' interviews, that have an impact on describing findings of research and recommendations for researchers that might do studies on similar topics.

#### 5.1.1. Limitations

**5.1.1.1. Expert interviews.** Interviews were used and conducted with business owners, A.I. experts, one university professor and experts in healthcare (diabetes) sphere. Although semi-structured interviews offered multiple benefits, they were also subject to several limitations:

- AI expertise: because AI is not a new technology all in computers creations and other things but in healthcare AI is going rapidly fast in recent days, so it's a challenge to find A.I. experts that could be suitable candidates for an interview.
- Scope: semi-structured interviews could cover only limited scope of and may have some subjectivity and personal bias.
- Time zone and schedule: another challenge is different time zones or busy schedules of the experts, which results sending responses via e-mail. This limits the possibility to ask follow up questions or answer any doubts interviewees may have.
- Response variability: depth of the answers varies a lot, making it difficult to get full analysis.

**5.1.1.2. Implications on findings.** The chosen Two-Axis Method for scenario planning also has some limitations and potential implications on the study. This is a complex process of identifying the key critical factors to use for the planning. These scenarios were based on literature analysis and experts' interviews, which might not bring enough insights for more concrete planning (survey insights could be added potentially). Moreover, in these scenarios, probabilities are based on hypothetical situations, starting with a baseline of 25% probability. This could result in missing some of the relevant factors to capture full picture.

Nonetheless, scenarios underscored important implications into the future of AI-based digital therapeutics in diabetes management. First, there is a critical need for synchronizing tech advancements with healthcare system readiness, as high advancements do to necessarily translate into

effective integration. Moreover, external factors like regulatory reforms, industry investment or technical challenges impact the trajectory of digital health integration, which needs supportive policy environments and funding to facilitate adoption. Also, varying probabilities reveal that sector must be prepared for different rates of change and diversity in systems and tech development. Finally, despite the challenges, AI-based digital therapeutics in diabetes management holds significant potential and can play a transformative role, given the numerous benefits and efficiencies over current systems.

### **5.1.2. Recommendations**

There are also several recommendations that researchers could use when conducting studies on similar topics:

- Broader expert sample: in future other researchers could take a larger sample of experts.
- Patient surveys: another suggestion is to conduct a survey with patients who are already using AI-based digital therapeutics or the ones who could be potential users. This would allow to get a wider understanding of AI-based digital therapeutics suitability in diabetes management.
- Wider geographical scope: there is a possibility to investigate a wider geographical view (for example North and South Americas, Australia and Asia). These insights would also benefit the research.
- Inclusion of additional experts: other additional experts like IT professors, data specialists or privacy experts could be used for more additional insights.

## **5.2. Main findings**

Based on findings in literature review, experts' interviews and scenario analysis, a summary of main findings is provided below.

### **5.2.1. Current usage of A.I.- based digital therapeutics in diabetes management**

The adoption of AI in diabetes management is marked by several innovative approaches that significantly enhance patient care:

- Personalized treatment plans, where AI algorithms tailor recommendations based on individual patient data, such as lifestyle factors, ensuring each patient's unique needs are addressed.

- AI's integration into Continuous Glucose Monitoring systems has revolutionized glucose monitoring, providing real-time, accurate feedback. This advancement allows for better-informed decisions by both patients and healthcare providers.
- Automated insulin delivery systems have been transformed by AI, especially for Type 1 diabetes patients, by automating and optimizing insulin dosing. Healthcare providers benefit from AI tools that offer predictive analytics, aiding in the anticipation and management of potential complications.
- AI-driven apps and platforms are redefining patient education and engagement, offering interactive ways to learn about diabetes management and encouraging better self-management practices.

The integration of these digital therapeutics with telehealth services is a significant development, reflecting the digital evolution in healthcare. Cappon (2019) mentioned that FDA also integrated continuous glucose monitoring, that are compatible with other diabetes tracking devices and electronic interfaces and can be improved in future. These diverse applications of AI are not only improving patient outcomes but are also paving the way for more innovative healthcare solutions in the future.

### ***5.1.2. Main challenges and limitations of A.I.-based digital therapeutics adoption***

Incorporating AI-based digital therapeutics into diabetes management encounters numerous and varied challenges:

- Among the most significant is the complexity of regulatory landscapes, particularly in regions like Europe, where regulations such as the Medical Device Regulation (MDR) and the AI Act impose stringent compliance requirements.
- Gaining the trust of healthcare professionals, especially physicians, is another major challenge due to the inherent "black box" nature of AI, where the decision-making process is not transparent or easily understood. This issue is compounded by the complexity of managing data access, ensuring privacy and security, and maintaining transparency and fairness in AI algorithms.
- The rapidly advancing nature of technology in the healthcare sector presents a continual challenge in integrating new AI-based solutions into existing therapeutic frameworks and practices.

- Economic considerations, such as the development and deployment costs of these therapeutics, also pose significant barriers, particularly in ensuring equitable access across different segments of the population.
- Collaboration and communication among various stakeholders are essential in overcoming these challenges. This includes the need for effective partnerships between technology developers, healthcare providers, policymakers, and patients. Such collaboration is crucial for aligning interests, overcoming barriers in communication, and facilitating the adoption and effective use of AI in diabetes care.

Addressing these multifaceted challenges is key to the successful integration and utilization of AI-based digital therapeutics in diabetes management, paving the way for more innovative, efficient, and patient-centric healthcare solutions.

### ***5.1.3. Theoretical and practical implications***

The responses from the expert interviews on AI-based digital therapeutics in diabetes management, while not explicitly addressing theoretical and practical implications in a summarized form, do offer insights into the evolving role of AI in healthcare. For DM management and clinicians, the adoption of AI-based digital therapeutics into diabetes management signifies the shift towards more personalized and efficient patient care, but will require adaptability and continuous learning. As for DTx companies and regulators, complex task of ensuring that tech innovations align with healthcare regulations, which will need to include close collaboration, is going to be in place. There is no doubt that health policy makers also play a crucial role in the industry. For them, the main task will be to create policies that encourage integration of AI into healthcare. These policies need to address ethical, privacy and funding challenges. Finally, academics are encouraged to delve deeper into the efficacy, ethical standards, and long-term impacts of AI-based digital therapeutics in diabetes management, underscoring the need for comprehensive research in this field.

### Bibliography

Aggarwal, K., Mijwil, M. M., Al-Mistarehi, A. H., Alomari, S., Gök, M., Alaabdin, A. M. Z., & Abdulrhman, S. H. (2022). Has the Future started? The current growth of artificial intelligence, machine learning, and deep learning. *Iraqi Journal for Computer Science and Mathematics*, 3(1), 115-123.

Aggarwal, N., Ahmed, M., Basu, S., Curtin, J. J., Evans, B. J., Matheny, M. E., ... & Thadaney-Israni, S. (2020). Advancing artificial intelligence in health settings outside the hospital and clinic. *NAM perspectives*, 2020.

Ahlqvist, E., Storm, P., Käräjämäki, A., Martinell, M., Dorkhan, M., Carlsson, A., Vikman, P., Prasad, R. B., Aly, D. M., Almgren, P., Wessman, Y., Shaat, N., Spégel, P., Mulder, H., Lindholm, E., Melander, O., Hansson, O., Malmqvist, U., Lernmark, Å., Lahti, K., ... & Groop, L. (2018). Novel subgroups of adult-onset diabetes and their association with outcomes: a data-driven cluster analysis of six variables. *The Lancet Diabetes & Endocrinology*, 6(5), 361-369.

Akter, S., McCarthy, G., Sajib, S., Michael, K., Dwivedi, Y. K., D'Ambra, J., & Shen, K. N. (2021). Algorithmic bias in data-driven innovation in the age of AI *International Journal of Information Management*, 60, 102387.

Alami, H., Lehoux, P., Denis, J. L., Motulsky, A., Petitgand, C., Savoldelli, M., ... & Fortin, J. P. (2021). Organizational readiness for artificial intelligence in health care: insights for decision-making and practice. *Journal of Health Organization and Management*, 35(1), 106-114.

Almalawi, A., Khan, A. I., Alsolami, F., Abushark, Y. B., Alfakeeh, A. S., & Mekuriyaw, W. D. (2022). Analysis of the exploration of security and privacy for healthcare management using artificial intelligence: Saudi hospitals. *Computational Intelligence and Neuroscience*, 2022.

Åm, M. K., Teigen, I. A., Riaz, M., Fougner, A. L., Christiansen, S. C., & Carlsen, S. M. (2023). The artificial pancreas: two alternative approaches to achieve a fully closed-loop system with optimal glucose control. *Journal of Endocrinological Investigation*, 1-9.

American Diabetes Association. (2010). Diagnosis and classification of diabetes mellitus. *Diabetes care*, 33(Supplement\_1), S62-S69.

American Diabetes Association. (2022). Standards of Medical Care in Diabetes—2022. *Diabetes Care*, 45(Supplement 1), S1-S2.

Ansari, M. F., Dash, B., Sharma, P., & Yathiraju, N. (2022). The Impact and Limitations of Artificial Intelligence in Cybersecurity: A Literature Review. *International Journal of Advanced Research in Computer and Communication Engineering*.

Årsand, E., Frøisland, D. H., Skrøvseth, S. O., Chomutare, T., Tatara, N., Hartvigsen, G., & Tufano, J. T. (2012). Mobile health applications to assist patients with diabetes: lessons learned and design implications. *Journal of diabetes science and technology*, 6(5), 1197-1206.

Asarani, N. A. M., Reynolds, A. N., Boucher, S. E., de Bock, M., & Wheeler, B. J. (2020). Cutaneous complications with continuous or flash glucose monitoring use: systematic review of trials and observational studies. *Journal of diabetes science and technology*, 14(2), 328-337.

Ashley, E. A. (2020). Towards precision medicine. *Nature Reviews Genetics*, 21(9), 545-555.

Atkinson, M. A., Eisenbarth, G. S., & Michels, A. W. (2014). Type 1 diabetes. *Lancet*, 383(9911), 69-82.

Avari, P., Lumb, A., Flanagan, D., Rayman, G., Misra, S., Dhatariya, K., & Choudhary, P. (2023). Continuous glucose monitoring within the hospital: a scoping review and summary of guidelines from the joint British diabetes societies for inpatient care. *Journal of Diabetes Science and Technology*, 17(3), 611-624.

Baker, R., Camosso-Stefinovic, J., Gillies, C., Shaw, E. J., Cheater, F., Flottorp, S., & Robertson, N. (2020). Tailored interventions to address determinants of practice. *Cochrane Database of Systematic Reviews*, (4), CD005470.

Balboa, D., Saarimäki-Vire, J., & Otonkoski, T. (2021). Utilizing pluripotent stem cells for uncovering diabetes pathogenesis. *Current Diabetes Reports*, 21(4), Article 10.

Bashshur, R., Doarn, C. R., Frenk, J. M., Kvedar, J. C., & Woolliscroft, J. O. (2020). Telemedicine and the COVID-19 pandemic, lessons for the Future. *Telemedicine and e-Health*, 26(5), 571-573.

Baum, F. E., Freeman, T., Sanders, D., Labonté, R., Lawless, A., & Javanparast, S. (2019). Comprehensive primary health care under neo-liberalism in Australia. *Social Science & Medicine*, 245, 112595.

Bliss, M. (1982). *The Discovery of Insulin*. University of Chicago Press.

Bohr, A., & Memarzadeh, K. (2020). The rise of artificial intelligence in healthcare applications. In *Artificial Intelligence in healthcare* (pp. 25-60). Academic Press.

Bokolo Jr., A. J. (2021). Exploring the adoption of telemedicine and virtual software for the care of outpatients during and after the COVID-19 pandemic. *Irish Journal of Medical Science*, 190(1), 1-10.

Bombaci, B., Passanisi, S., Alibrandi, A., D'Arrigo, G., Patroniti, S., Aversa, S., ... & Lombardo, F. (2022). One-year real-world study on comparison among different continuous subcutaneous insulin infusion devices for the management of pediatric patients with type 1 diabetes: the supremacy of hybrid closed-loop systems. *International Journal of Environmental Research and Public Health*, 19(16), 10293.

Bommer, C., Sagalova, V., Heesemann, E., Manne-Goehler, J., Atun, R., Bärnighausen, T., & Vollmer, S. (2018). Global economic burden of diabetes in adults: projections from 2015 to 2030. *Diabetes Care*, 41(5), 963-970.

Bonoto, B. C., de Araújo, V. E., Godói, I. P., de Lemos, L. L. P., Godman, B., Bennie, M., ... & Guerra Júnior, A. A. (2017). Efficacy of mobile apps to support diabetes care: A meta-analysis and literature review. *JMIR mHealth and uHealth*, 5(3), e4.

Bresnick, J. (2020). Exploring novel strategies for health engagement with augmented reality. *Journal of mHealth*, 7(2), 30-34.

Bruen, D., Delaney, C., Florea, L., & Diamond, D. (2017). Glucose sensing for diabetes monitoring: recent developments. *Sensors*, 17(8), 1866.

Brzan, P. P., Rotman, E., Pajnkihar, M., & Klanjek, P. (2016). Mobile applications for control and self management of diabetes: a systematic review. *Journal of medical systems*, 40(9), 1-10.

Busnatu, Ș., Niculescu, A. G., Bolocan, A., Petrescu, G. E., Păduraru, D. N., Năstasă, I., ... & Martins, H. (2022). Clinical applications of artificial intelligence—An updated overview. *Journal of clinical medicine*, 11(8), 2265.

Cappon, G., Vettoretti, M., Sparacino, G., & Facchinetti, A. (2019). Continuous glucose monitoring sensors for diabetes management: a review of technologies and applications. *Diabetes & metabolism journal*, 43(4), 383-397.

Chang, V., Bailey, J., Xu, Q. A., & Sun, Z. (2023). Pima Indians diabetes mellitus classification based on machine learning (ML) algorithms. *Neural Computing and Applications*, 35(22), 16157-16173.

Chen, J., Allman-Farinelli, M., & Wong, A. (2021). Efficacy of mobile health interventions on diabetes and obesity treatment and management: Systematic review of systematic reviews. *JMIR mHealth and uHealth*, 9(4), e15697.

Chen, M., & Decary, M. (2020). Artificial intelligence in healthcare: An essential guide for health leaders. In *Healthcare Management Forum* (Vol. 33, No. 1, pp. 10-18). Sage CA: Los Angeles, CA: SAGE Publications.

Chen, M., Zhao, H., & Teo, K. (2022). Machine learning for predicting blood glucose level in a type 1 diabetes mellitus patient: A case study. *Journal of Diabetes Science and Technology*, 16(2), 423-430.

Chung, J. Y. (2019). Digital therapeutics and clinical pharmacology. *Translational and Clinical Pharmacology*, 27(1), 6-11.

Contreras, I., & Vehi, J. (2018). Review of artificial intelligence for diabetes management and decision support. *Journal of Medical Internet Research*, 20(5), e10775.

Daneman, D. (2006). Type 1 diabetes. *The Lancet*, 367(9513), 847-858.

Dang, A., Arora, D., & Rane, P. (2020). Role of digital therapeutics and the changing Future of healthcare. *Journal of Family Medicine and Primary Care*, 9(5), 2207.

Dang, A., Arora, D., & Rane, P. (2020). Role of digital therapeutics and the changing future of healthcare. *Journal of Family Medicine and Primary Care*, 9(5), 2207.

Dang, A., Dang, D., & Rane, P. (2021). The expanding role of digital therapeutics in the post-COVID-19 era. *The Open COVID Journal*, 1(1).

Davis, M. (2018). Interview Techniques in Qualitative Research. *Journal of Social Research*, 22(1), 30-40.

Domínguez-Bendala, J., Pastori, R. L., & Ricordi, C. (2019). Prospects for stem cell-derived islet transplantation in the Treatment of Diabetes. *Current Opinion in Organ Transplantation*, 24(6), 677-682.

Dyrbye, L. N., Shanafelt, T. D., Gill, P. R., Sinsky, C. A., West, C. P., Satele, D., ... & Tutty, M. A. (2020). Effect of a professional coaching intervention on the well-being and distress of physicians: A pilot randomized clinical trial. *JAMA Internal Medicine*, 180(10), 1406-1414.

Eberle, C., Stichling, S., & von Jan, U. (2019). Review of the effectiveness of disease-specific mobile health apps in patients with diabetes. *JMIR mHealth and uHealth*, 7(2), e12695.

Ellahham, S. (2020). Artificial intelligence: the Future for diabetes care. *The American journal of medicine*, 133(8), 895-900.

ElSayed, N. A., Aleppo, G., Aroda, V. R., Bannuru, R. R., Brown, F. M., Bruemmer, D., ... & American Diabetes Association. (2023). 2. Classification and diagnosis of diabetes: standards of care in diabetes—2023. *Diabetes care*, 46(Supplement\_1), S19-S40.

Emanuel, E. J. (2020). Which country has the world's best health care? *Public Affairs*.

Enholm, I. M., Papagiannidis, E., Mikalef, P., & Krogstie, J. (2022). Artificial intelligence and business value: A literature review. *Information Systems Frontiers*, 24(5), 1709-1734.

Fagherazzi, G., Goetzinger, C., Rashid, M. A., Aguayo, G. A., & Huiart, L. (2020). Digital Health Strategies to Fight COVID-19 Worldwide: Challenges, Recommendations, and a Call for Papers. *Journal of Medical Internet Research*, 22(6), e19284.

Forcier, M. B., Gallois, H., Mullan, S., & Joly, Y. (2019). Integrating artificial intelligence into health care through data access: can the GDPR act as a beacon for policymakers? *Journal of Law and the Biosciences*, 6(1), 317-335.

Frias, J. P., Bastyr, E. J., Vignati, L., Tschöp, M. H., Schmitt, C., Owen, K., ... & Haupt, A. (2021). Long-term efficacy of tripeptide, a novel dual GIP and GLP-1 receptor agonist, in patients with type 2 diabetes. *Diabetes Care*, 44(5), 1083-1090.

Garg, S. K., Rodbard, D., Hirsch, I. B., & Forlenza, G. P. (2021). Managing new-onset type 1 diabetes during the COVID-19 pandemic: challenges and opportunities. *Diabetes Technology & Therapeutics*, 23(7), 1-13.

Geiss, L., Engelgau, M., Pogach, L., Acton, K., Fleming, B., Roman, S., ... & Vinicor, F. (2005). A national progress report on diabetes: successes and challenges. *Diabetes technology & therapeutics*, 7(1), 198-203.

Gomez, A. M., Henao Carrillo, D. C., & Munoz-Velandia, O. M. (2020). Impact of a digital diabetes management system on the management of Type 1 diabetes. *Diabetes Technology & Therapeutics*, Grand View Research. (2022). Diabetes care devices market size, share & trends analysis report by product (blood glucose monitoring devices, insulin delivery devices), end-use (hospitals, homecare), region, and segment forecasts, 2022-2030. Retrieved from [Grand View Research website]

Greco, L., Percannella, G., Ritrovato, P., Tortorella, F., & Vento, M. (2020). Trends in IoT based solutions for health care: Moving AI to the edge. *Pattern recognition letters*, 135, 346-353.

Green, L., Jones, D., & Smith, J. (2020). Ethical Considerations in Digital Health Research. *Health Ethics Journal*, 18(4), 200-210.

Hassan, R. S., Lee, J., & Kim, S. (2019). A minimally invasive implantable sensor for continuous wireless glucose monitoring based on a passive resonator. *IEEE Antennas and Wireless Propagation Letters*, 19(1), 124-128.

Hilliard, M. E., Harris, M. A., & Weissberg-Benchell, J. (2013). Diabetes resilience: A model of risk and protection in type 1 diabetes. *Current Diabetes Reports*, 13(6), 786-793.

Hong, J. S., Wasden, C., & Han, D. H. (2021). Introduction of digital therapeutics. *Computer methods and programs in Biomedicine*, 209, 106319.

Hou, C., Carter, B., Hewitt, J., Francisa, T., & Mayor, S. (2019). Review of mobile phone applications and their impact on glycemic control (HbA1c) in diabetes self-management. *Diabetes Care*, 42(11), 2078-2089.

IDF Diabetes Atlas. (2021). IDF Diabetes Atlas, 10th edition. International Diabetes Federation. Retrieved from <https://www.diabetesatlas.org>

Istepanian, R., Jovanov, E., & Zhang, Y. T. (2021). Introduction to the special section on m-Health: New horizons for health through mobile technologies. *IEEE Transactions on Information Technology in Biomedicine*, 8(4), 405-414.

Jethwani, K., Ling, E., Mohammed, M., Myint-U, K., Pelletier, A., & Kvedar, J. C. (2020). Diabetes digital app technology: Benefits, challenges, and recommendations. A consensus report by the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) Diabetes Technology Working Group. *Diabetologia*, 63(2), 229-241.

Johnson, I. S. (1983). Human insulin from recombinant DNA technology. *Science*, 219(4585), 632-637.

Jones, R. (2020). Challenges in Qualitative Research. *Qualitative Research Review*, 8(1), 22-29.

Jonsen, A. R. (2000). A short history of medical ethics. \*Oxford University Press

Joshi, S., Singal, A., et al. (2023). Fitterfly Diabetes CGM Digital Therapeutics Program for Glycemic Control and Weight Management in People With Type 2 Diabetes Mellitus: Real-world Effectiveness Evaluation. *JMIR Diabetes*. doi: 10.2196/43292.

Joshi, S., Singal, A., et al. (2023). Fitterfly Diabetes CGM Digital Therapeutics Program for Glycemic Control and Weight Management in People With Type 2 Diabetes Mellitus: Real-world Effectiveness Evaluation. *JMIR Diabetes*. doi: 10.2196/43292

Kapil, S., Saini, R., Wangnoo, S., & Dhir, S. (2020). Artificial pancreas system for type 1 diabetes—challenges and advancements. *Exploratory Research and Hypothesis in Medicine*, 5(3), 110-120.

Katsarou, A., Gudbjörnsdóttir, S., Rawshani, A., Dabelea, D., Bonifacio, E., Anderson, B. J., ... & Lernmark, Å. (2017). Type 1 diabetes mellitus. *Nature reviews Disease primers*, 3(1), 1-17.

Klonoff, D. C. (2019). Exploring the use of blockchain technology for diabetes data: A proof of concept. *Journal of Diabetes Science and Technology*, 13(4), 647-653.

Kluge, H. H. P., Wickramasinghe, K., Ripplin, H. L., Mendes, R., Peters, D. H., Kontsevaya, A., & Breda, J. (2020). Prevention and control of non-communicable diseases in the COVID-19 response. *The Lancet*, 395(10238), 1678-1680.

Kumar, A., & Suresh, K. (2021). Diabetes mellitus: a stitch in time saves nine early diagnosis and management minimizes complications-a case study. *Global Journal of Obesity, Diabetes and Metabolic Syndrome*, 8(2), 014-017.

Kruse, C. S., Stein, A., Thomas, H., & Kaur, H. (2020). The use of Electronic Health Records to Support Population Health: A Systematic Review of the Literature. *Journal of Medical Systems*, 44(11), 1-11.

Laxminarayan, R., Duse, A., Wattal, C., Zaidi, A. K., Wertheim, H. F., Sumpradit, N., ... & Cars, O. (2013). Antibiotic resistance—the need for global solutions. *The Lancet Infectious Diseases*, 13(12), 1057-1098.

Lee, D., & Yoon, S. N. (2021). Application of artificial intelligence-based technologies in the healthcare industry: Opportunities and challenges. *International Journal of Environmental Research and Public Health*, 18(1), 271.

Legido-Quigley, H., Mateos-García, J. T., Campos, V. R., Gea-Sánchez, M., Muntaner, C., & McKee, M. (2020). The resilience of the Spanish health system against the COVID-19 pandemic. *The Lancet Public Health*, 5(5), e251-e252.

Lyles, C. R., Aulakh, V., & Jameson, W. (2019). Strategies to improve care for patients with diabetes through digital health. *Journal of General Internal Medicine*, 34(2), 320-327.

Marso, S. P., Daniels, G. H., Brown-Frandsen, K., Kristensen, P., Mann, J. F., Nauck, M. A., ... & Steinberg, W. M. (2016). Liraglutide and the risk of major cardiovascular events in type 2 diabetes: Results from a randomized trial. *New England Journal of Medicine*, 375(4), 311-322.

Mayfield, J. (1998). Diagnosis and classification of diabetes mellitus: new criteria. *American Family Physician*, 58(6), 1355-1362.

McCarthy, M. I. (2010). Genomics, type 2 diabetes, and obesity. *The New England Journal of Medicine*, 363(24), 2339-2350.

Meske, C., Bunde, E., Schneider, J., & Gersch, M. (2022). Explainable artificial intelligence: objectives, stakeholders, and future research opportunities. *Information Systems Management*, 39(1), 53-63.

Miller, T., & Smith, H. (2019). Ensuring Research Validity and Reliability. *Research Methods Journal*, 10(4), 44-50.

Mintz, Y., & Brodie, R. (2019). Introduction to artificial intelligence in medicine. *Minimally Invasive Therapy & Allied Technologies*, 28(2), 73-81.

Naik, N., Hameed, B. M., Shetty, D. K., Swain, D., Shah, M., Paul, R., ... & Somani, B. K. (2022). Legal and ethical consideration in artificial intelligence in healthcare: who takes responsibility?. *Frontiers in surgery*, 9, 266.

Nazar, M., Alam, M. M., Yafi, E., & Su'ud, M. M. (2021). A systematic review of human–computer interaction and explainable artificial intelligence in healthcare with artificial intelligence techniques. *IEEE Access*, 9, 153316-153348.

Nomura, A., et al. (2021). Artificial Intelligence in Current Diabetes Management and Prediction. *Current Diabetes Reports*, 21(12), 61. doi: 10.1007/s11892-021-01423-2.

Nomura, A., Noguchi, M., Kometani, M., Furukawa, K., & Yoneda, T. (2021). Artificial intelligence in current diabetes management and prediction. *Current Diabetes Reports*, 21(12), 61.

Or, C. K. L., & Tao, D. (2019). Impact of consumer health information technology on outcomes in patient self-management of diabetes: A meta-analysis and narrative review. *International Journal of Medical Informatics*, 124, 31-48.

Padhy, S. K., Takkar, B., Chawla, R., & Kumar, A. (2019). Artificial intelligence in diabetic retinopathy: A natural step to the future. *Indian journal of ophthalmology*, 67(7), 1004.

Papachristoforou, R., Rousso, D., & Mavromati, E. (2021). From mummies to modernity: A brief history of the evolving diagnosis and Treatment of diabetes. *Journal of Diabetes Research*, 2021, 6642258.

Papanicolas, I., Woskie, L. R., & Jha, A. K. (2018). Health care spending in the United States and other high-income countries. *JAMA*, 319(10), 1024-1039.

Patel, N. A., & Butte, A. J. (2020). Characteristics and challenges of the clinical pipeline of digital therapeutics. *NPJ digital medicine*, 3(1), 159.

Peeples, M. M., Iyer, A. K., & Cohen, J. L. (2013). Integration of a mobile-integrated therapy with electronic health records: lessons learned.

Peters, A. L., Garg, S. K., & Jovanovič, L. (2021). The 21st century person with diabetes: The role of technology in diabetes care. *Endocrinology and Metabolism Clinics of North America*, 50(2), 249-261.

Pickup, J. C. (2012). Insulin-pump therapy for type 1 diabetes mellitus. *New England Journal of Medicine*, 366(17), 1616-1624.

Poolsup, N., Suksomboon, N., & Kyaw, A. M. (2013). Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. *Diabetology & metabolic syndrome*, 5, 1-14.

Prakash, S., Balaji, J. N., Joshi, A., & Surapaneni, K. M. (2022). Ethical Conundrums in applying Artificial Intelligence (AI) in healthcare—a scoping review of reviews. *Journal of Personalized Medicine*, 12(11), 1914.

Pratley, R. E., & Aroda, V. R. (2018). The Future of basal insulin supplementation. *Diabetes Care*, 41(Supplement 1), S152-S158.

Rajpurkar, P., Chen, E., Banerjee, O., & Topol, E. J. (2022). AI in health and medicine. *Nature Medicine*, 28(1), 31-38.

Ramirez, R., & Wilkinson, A. (2013). Rethinking the 2× 2 scenario method: Grid or frames?

Risse, G. B. (2012). *Mending bodies, saving souls: A history of hospitals*. Oxford University Press.

Rodgers, W., & Nguyen, T. (2022). Advertising benefits from ethical artificial intelligence algorithmic purchase decision pathways. *Journal of business ethics*, 178(4), 1043-1061.

Romero-Tapiador, S., Lacruz-Pleguezuelos, B., Tolosana, R., Freixer, G., Daza, R., Fernández-Díaz, C. M., ... & Carrillo de Santa Pau, E. (2023). AI4FoodDB: a database for personalized e-Health nutrition and lifestyle through wearable devices and artificial intelligence. *Database*, 2023, baad049.

Rubino, F., Nathan, D. M., Eckel, R. H., Schauer, P. R., Alberti, K. G., Zimmet, P. Z., ... & Cummings, D. E. (2016). Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: A Joint Statement by International Diabetes Organizations. *Diabetes Care*, 39(6), 861-877.

Russell, S. J., Hillard, M. A., Balliro, C., et al. (2019). Day and night closed-loop control using the integrated Medtronic hybrid closed-loop system in type 1 diabetes at diabetes camp. *Diabetes Care*, 42(7), 1208-1214.

Sangave, N. A., Aungst, T. D., & Patel, D. K. (2019). Smart connected insulin pens, caps, and attachments: a review of the future of diabetes technology. *Diabetes Spectrum*, 32(4), 378-384.

Shadbolt, N. (2022). "From So Simple a Beginning": Species of Artificial Intelligence. *Daedalus*, 151(2), 28-42.

Shang, T., Zhang, J. Y., Thomas, A., Arnold, M. A., Vetter, B. N., Heinemann, L., & Klonoff, D. C. (2022). Products for monitoring glucose levels in the human body with noninvasive optical, noninvasive fluid sampling, or minimally invasive technologies. *Journal of diabetes science and technology*, 16(1), 168-214.

Shapiro, A. M., Lakey, J. R., Ryan, E. A., et al. (2000). Islet transplantation in seven patients with type 1 diabetes mellitus using a glucocorticoid-free immunosuppressive regimen. *New England Journal of Medicine*, 343(4), 230-238.

Siegel, A. (2020). Considerations for data protection in telehealth and telemedicine. *Journal of Law and Biosciences*, 7(1), Isaa020.

Siegmund, T., Kolassa, R., & Thomas, A. (2013). Clinical update on insulin pump therapy in combination with continuous glucose monitoring. *Minerva Endocrinol*, 38(2), 133-143.

Sriram, R. D., & Reddy, S. S. K. (2020). Artificial intelligence and digital tools: future of diabetes care. *Clinics in Geriatric Medicine*, 36(3), 513-525.

Stockl, K., Ory, C., Vanderplas, A., Nicklasson, L., Lyness, W., Cobden, D., & Chang, E. (2007). An evaluation of patient preference for an alternative insulin delivery system compared to standard vial and syringe. *Current medical research and opinion*, 23(1), 133-146.

Tarricone, R., Cucciniello, M., Armeni, P., Petracca, F., Desouza, K. C., & Hall, L. (2020). Mobile health divide between clinicians and patients in cancer care: A cross-sectional international survey. *JMIR mHealth and uHealth*, 8(9), e20283.

Taylor, E. (2019). Purposive Sampling in Qualitative Research. *Innovative Research Methods*, 7(2), 58-67.

Thompson, A. N., Dawson, D. R., Legasto-Mulvale, J. M., Chandran, N., Tanchip, C., Niemczyk, V., ... & Nalder, E. (2023). Mobile Technology–Based Interventions for Stroke Self-Management Support: Scoping Review. *JMIR mHealth and uHealth*, *11*(1), e46558.

Topol, E. J. (2019). The convergence of human and artificial intelligence in high-performance medicine. *Nature Medicine*, *25*(1), 44-56.

Torous, J., & Roberts, L. W. (2020). Needed Innovation in Digital Health and Smartphone Applications for Mental Health: Transparency and Trust. *JAMA Psychiatry*, *77*(5), 439-440.

Turner, A. P., Chen, B., & Piletsky, S. A. (1999). In vitro diagnostics in diabetes: meeting the challenge. *Clinical chemistry*, *45*(9), 1596-1601.

Vettoretti, M., Cappon, G., Acciaroli, G., Facchinetti, A., & Sparacino, G. (2018). Continuous glucose monitoring: current use in diabetes management and possible future applications. *Journal of diabetes science and technology*, *12*(5), 1064-1071.

Wang, C., Lee, C., & Shin, H. (2023). Digital therapeutics from bench to bedside. *npj Digital Medicine*, *6*(1), 38.

White, E., & Black, S. (2022). The Ethical Implications of AI in Healthcare. *Medical Ethics Journal*, *22*(1), 12-19.

Williams, G., & Lee, A. (2019). The Future of Digital Therapeutics. *Digital Health Review*, *5*(2), 80-88.

Zhou, B., Lu, Y., Hajifathalian, K., Bentham, J., Di Cesare, M., Danaei, G., ... & Collaboration, N. C. D. R. F. (2020). Worldwide trends in diabetes since 1980: a pooled analysis of 751 population-based studies with 4.4 million participants. *The Lancet*, *387*(10027), 1513-1530.

## Appendices

### Appendix I: Summarized answers of Expert Interviews

The following pages include summarized responses of Expert Interviews, sorted by interview questions (*see Table 5*).

**Table 5.**

*Summary of Industry Experts' Interviews*

<b>Q1: Define AI-based digital therapeutics in the context of diabetes management?</b>
<p><b>IA:</b> The interviewee defines AI-based digital therapeutics in diabetes management as encompassing two main areas. The first is insulin titration, involving algorithms that determine the necessary insulin dosage. This involves using sensor data or manually measured blood glucose levels to guide insulin pumps, patch pumps, or pens. The second area is lifestyle intervention and cognitive behavioral therapy. In Germany, programs like DGAS provide digital therapeutic tools and smartphone apps that help patients understand the impact of nutrition on their metabolism. These applications use intelligent algorithms to tailor learning content and feedback based on patient inputs, blood glucose levels, and nutrition diaries.</p>
<p><b>IB:</b> The speaker defines AI-based digital therapeutics in diabetes management as systems like the artificial pancreas, which combine continuous glucose monitoring with an insulin pump, using personalized algorithms. They view this as a key application of AI in healthcare. AI also plays a significant role in providing decision support for clinicians, handling the vast data from continuous glucose monitors. Traditionally limited to biannual measurements like HbA1c levels, AI now enables the analysis of hundreds of daily data points, facilitating personalized treatment and dose adjustments. The speaker acknowledges the potential of AI-driven therapeutics in managing the volume of patient data, while also noting the challenges posed by data protection laws like GDPR. They are optimistic about the advancements in AI for effective disease management.</p>
<p><b>IC:</b> The speaker discusses the role of AI-based digital therapeutics in healthcare, focusing on orthopedics. They describe an AI-assisted workflow in primary care that helps determine whether a patient needs hip replacement surgery or medication, aiming to improve efficiency and reduce unnecessary hospital referrals. The importance of a national health record is emphasized for a comprehensive patient history. The speaker also highlights the use of AI in selecting prostheses and supporting anesthesiologists, as well as in post-surgical care and monitoring. The conversation then touches on Patient Reported Outcome Measurements (PROMs) and Experience Measurements (PREMs) as part of value-based healthcare. The speaker suggests that these AI and</p>

<p>digital therapeutic strategies, while not specific to diabetes, are broadly applicable across healthcare sectors, including diabetes management.</p>
<p><b>ID:</b> The speaker defines AI-based digital therapeutics in diabetes management as having multiple use cases. A primary application is in insulin management, where AI algorithms adjust insulin dosing based on blood glucose levels. Another use case involves decision support for healthcare professionals. Additionally, the speaker mentions their specific application of AI, which utilizes computer vision algorithms to analyze food photos uploaded by patients to their app. This technology provides patients with real-time feedback on their diet, suggesting improvements for better diabetes management.</p>
<p><b>IE:</b> AI-based digital therapeutics for diabetes management refer to the use of artificial intelligence (AI) technologies in creating software programs or applications designed to treat or manage diabetes. These solutions leverage AI algorithms to analyze patient data, including blood glucose levels, lifestyle patterns, and other relevant information, to provide personalized interventions. This may include real-time feedback, medication reminders, dietary recommendations, and adaptive treatment plans to help individuals with diabetes better control their condition. The goal is to enhance the effectiveness of diabetes management through tailored, data-driven interventions facilitated by AI.</p>
<p><b>IF:</b> AI-based digital therapeutics for diabetes involve the use of advanced algorithms and data analysis tools to personalize treatment, monitor patient progress, and provide real-time feedback and interventions. These tools analyse large volumes of data, including blood glucose levels, diet, physical activity, and other health markers, to optimize diabetes management and improve patient outcomes.</p>
<p><b>IG:</b> AI-based digital therapeutics in diabetes management focus on the benefits they offer to people with diabetes rather than the technology itself. In Type 1 Diabetes, they assist in precise insulin dosing, like the highly regulated Automated Insulin Delivery systems. In Type 2 Diabetes, their role can be as simple as providing reminders, with regulation varying based on the product's claims. These digital tools aim to simplify diabetes management for patients.</p>
<p><b>IH:</b> AI-based digital therapeutics (DHTs) in diabetes management are tools designed to improve prevention strategies for high-risk groups, manage diabetic patients remotely, especially those unable to attend in-person appointments, provide real-time health and metabolic data, encourage self-management among patients, and save time and costs associated with traveling to physical appointments.</p>

<p><b>II:</b> She perceives these therapeutics as a revolutionary blend of technology and healthcare. Utilizing AI, these solutions process extensive patient data to offer personalized treatment plans, making a significant leap in customizing diabetes care. They emphasize the role of AI in adapting treatments to everyone's health status and lifestyle nuances.</p>
<p><b>IJ:</b> He considers these digital therapeutics as a gamechanger when AI and healthcare goes on one way. Their focus is on employing AI algorithms to process detailed patient data for creating customized treatment plans, representing a shift towards individualized diabetes care.</p>
<p><b>Q2: What distinguishes AI-driven digital therapeutics from traditional diabetes management approaches?</b></p>
<p><b>IA:</b> The speaker contrasts traditional diabetes management in Germany with AI-driven digital therapeutics. In traditional methods, patients undergo routine physical checks and maintain paper-based diaries, providing limited data to healthcare professionals. AI-driven methods, however, use technologies like continuous glucose monitoring systems to gather extensive data, enabling more effective therapeutic decisions. The main distinction between traditional and digital care lies in the volume and quality of data collected, allowing for a more holistic understanding of the patient's health and influencing better care decisions, including aspects like nutrition habits.</p>
<p><b>IB:</b> The speaker explains that while diabetes is well-researched and traditional management follows refined clinical guidelines, AI-driven digital therapeutics distinguish themselves by handling vast amounts of data to provide nuanced, day-to-day management. The key differentiator of AI in diabetes is its predictive capability, as opposed to the reactive or proactive approaches of traditional methods. AI's predictive nature allows for more personalized and effective treatment decisions by analyzing patient data patterns. This shift towards predictive care is seen as a transformative step in diabetes management, moving beyond the limitations of conventional approaches.</p>
<p><b>IC:</b> The speaker explains how AI-driven digital therapeutics differ from traditional healthcare approaches, particularly in diabetes management. Traditional methods rely heavily on averages, such as average patient profiles and average costs, leading to standardized treatments. AI, on the other hand, enables personalized and differentiated care, allowing for more precise treatments and cost measurements. This individualized approach also changes the dynamics between healthcare providers and payers, like insurance companies and government agencies, by allowing for more specific negotiations on costs and treatments.</p>
<p><b>ID:</b> The speaker highlights two key distinctions between AI-driven digital therapeutics and traditional diabetes management approaches. Firstly, digital therapeutics provide continuous support to patients in between doctor visits, unlike the episodic nature of traditional care. This</p>

<p>continuous support is a major advantage. Secondly, AI tools offer a level of personalization in care that is not typically possible with traditional methods. These aspects—ongoing support and individualized treatment—set AI-driven digital therapeutics apart from conventional diabetes management.</p>
<p><b>IE:</b> AI-driven digital therapeutics revolutionize diabetes management by providing personalized, real-time interventions based on individual health data, a stark departure from traditional one-size-fits-all approaches. These solutions offer continuous monitoring, adaptive treatment plans, and predictive analytics, allowing for immediate adjustments and proactive care. Unlike the rigid structures of traditional methods, AI-driven systems are flexible, dynamically responding to changing patient conditions. The integration of diverse datasets, remote monitoring capabilities, and a focus on behavioral support further distinguish these digital therapeutics. While initial costs may be higher, the potential for long-term cost-effectiveness through reduced complications and hospitalizations underscores the transformative impact of AI in diabetes care.</p>
<p><b>IF:</b> Traditional diabetes management often relies on standardized treatment plans and manual tracking of blood glucose levels. In contrast, AI-driven digital therapeutics provide personalized and adaptive treatment plans, continuous monitoring, and proactive interventions based on real-time data, which can lead to more effective and efficient diabetes control.</p>
<p><b>IG:</b> AI-driven digital therapeutics distinguish themselves from traditional diabetes management approaches by offering a pathway towards precision or personalized therapeutics. This includes a tailored package of drugs, devices, and digital solutions, catering specifically to individual patient needs and conditions.</p>
<p><b>IH:</b> AI-driven digital therapeutics differ from traditional diabetes management approaches by leveraging big data. These tools use AI to predict and prevent diabetes-related complications, and future developments are expected to bring more automation, enhancing efficiency, speed, and access to care services.</p>
<p><b>II:</b> In her view, AI-driven digital therapeutics mark a significant advancement over traditional diabetes management methods. Traditional approaches often rely on generalized treatment plans, while AI solutions provide dynamic, data-driven personalization, adapting to the patient's evolving health data, offering a more proactive and precise management approach.</p>
<p><b>IJ:</b> He highlights the distinction between AI-driven digital therapeutics and conventional diabetes management. Unlike traditional methods that often apply general treatment plans, AI solutions provide tailored care that evolves with continuous patient data analysis, resulting in a more proactive and precise approach to managing diabetes.</p>

**Q3: Can you describe any AI-based digital therapeutic tools you have used or implemented for diabetes management?**

**IA:** The speaker discusses their knowledge of AI-based digital therapeutics tools in diabetes management, focusing on the integration of technology rather than specific tools due to non-disclosure agreements. They mention the prevalence of continuous glucose monitoring (CGM) sensors and insulin pump technology provided by various manufacturers. The speaker identifies the key AI breakthrough as the software that connects CGM and insulin pump data. This software can either be integrated into the pump itself or exist as an independent third-party device. They reference a graph, which they offer to share, illustrating the key players in CGM and insulin technology, and the AI-driven link between these components. The speaker considers this integration as the state of the art in AI for diabetes management as of 2023.

**IB:** The speaker describes their experience with AI in diabetes management, including working on a project to digitize clinical guidelines and collaborating on an artificial pancreas concept with Tidepool. They also mention an innovative blood glucose monitoring app that assists in lifestyle intervention by creating personalized meal plans. However, they acknowledge challenges in validating the effectiveness of such digital therapeutics, emphasizing the need for comprehensive studies to ensure their efficacy and reliability in improving patient care.

**IC:** The speaker is beginning a project involving AI-based digital therapeutics and is familiar with various tools in this field. They describe AI tools that analyze patient backgrounds to predict treatment needs in primary care, tools for selecting the best clinical equipment and materials, and tools for assessing the probability of treatment rejection. These tools are primarily predictive, aiding clinicians in making informed decisions throughout a patient's healthcare journey.

**ID:** The speaker describes their experience with a tool called Vitagio, an AI-based digital therapeutic tool for diabetes management. Vitagio analyzes patients' behavior and provides real-time suggestions for improvements in various aspects of their lifestyle. These suggestions cover nutrition, exercise, self-management, sleep, and mental well-being. The speaker also mentions being aware of numerous AI-driven startups in the diabetes field, indicating a growing interest and development in this area.

**IE:** Actofit can unlock the power of AI to revolutionize diabetes management. Imagine personalized insulin dosing based on predicted blood sugar trends, AI coaches analyzing your meals and offering real-time nutritional guidance, or early intervention for individuals at high risk. Actofit could become your AI-powered diabetes companion, providing 24/7 support, analyzing CGM data for proactive interventions, and guiding you towards a healthier future. By integrating

<p>these AI-powered features, Actofit can empower you to manage your diabetes effectively and live a life without limitations. Remember, data privacy, user-friendliness, and clinical validation are key to unlocking the true potential of AI in your diabetes journey.</p>
<p><b>IF:</b> I have personally not used specifically any digital therapeutics tools on a personal level, at this stage, I've mostly interacted with patients who used continuous glucose monitoring tools based on Dexcom technology. Nevertheless, I had the opportunity to explore further options and I've crossed paths with "Dario Health" that is establishing itself within the field of Digital Therapeutics, especially in Diabetes Management. Since I didn't have the opportunity to look into the inner workings of the app itself, I'm not in a position to guarantee whether its technology is based on AI techniques or not.</p>
<p><b>IG:</b> The AI-based digital therapeutic tool, "Insulin Dose Guidance," leverages advanced artificial intelligence to significantly enhance the management of diabetes. It offers personalized and precise insulin dosing recommendations, tailored to the unique needs of everyone. This tool represents a significant advancement in diabetes care, aiming to optimize treatment efficacy and improve overall patient outcomes by ensuring accurate insulin dosage.</p>
<p><b>IH:</b> No answer</p>
<p><b>II:</b> She highlights the company's development of AI tools like predictive blood glucose monitoring and intelligent insulin dosage calculators. These tools are designed to empower patients with deeper insights into their condition, enabling more effective self-management and real-time decision-making.</p>
<p><b>IJ:</b> He has been instrumental in developing various AI tools at their company. These tools, including advanced glucose monitoring and insulin dosing systems, are designed to enhance patient understanding and management of their diabetes.</p>
<p><b>Q4: How have patients responded to the use of these AI-driven tools in their diabetes care regimen?</b></p>
<p><b>IA:</b> The speaker notes that patient responses to AI-driven tools in diabetes care largely depend on the guidance they receive from healthcare professionals. Initially, many patients, particularly the elderly, show skepticism towards these technologies due to a lack of digital familiarity. However, with appropriate training and demonstration of benefits, patients often recognize the ease and improvement these tools bring to their diabetes management. The speaker acknowledges a generational difference in technology adoption, with younger patients adapting more quickly than older ones, but also notes exceptions to this trend.</p>

**IB:** The speaker observes that while patients who have used AI-driven tools for diabetes care generally respond well, overall adoption remains low. Projects like Tidepool show high engagement among patients actively involved in their care, but the penetration of digital health tools, including AI, in the broader patient population is still minimal. This limited uptake is attributed to slow adoption rates in healthcare and a lack of familiarity with technology among some patients.

**IC:** The speaker discusses the ethical and practical challenges of AI in healthcare, highlighting the "black box" nature of AI systems where creators may not fully understand the decision-making process. They raise concerns about accountability when AI tools make medical errors. Additionally, the speaker questions the ethics of freely donating personal health data for AI development, which often benefits companies financially. They suggest that individuals should receive compensation or benefits for their data. These issues form the core of the speaker's PhD work, focusing on data ownership, benefits, and ethical considerations in AI's application to healthcare.

**ID:** The speaker notes that the response to AI-driven tools like Vitagio in diabetes care has been positive. However, they acknowledge that the type 2 diabetes patient population is diverse, and not all individuals are motivated to make lifestyle changes. Therefore, their approach focuses on niche segments within the broader group of type 2 diabetes patients—those who are more inclined to utilize such products for managing their condition. This targeted approach helps in catering to patients who are likely to benefit most from the AI-driven tools.

**IE:** Patients have responded positively to the integration of AI-driven tools into their diabetes care regimens. The personalized nature of these interventions, offering tailored insights based on individual health data, has garnered enthusiasm. Real-time feedback and adaptive treatment plans have empowered patients, enabling them to make informed decisions about their lifestyle and treatment. The convenience of remote monitoring has been well-received, as it reduces the need for frequent in-person visits while providing continuous support. The predictive analytics embedded in AI tools have also resonated with patients, allowing them to anticipate and address potential health issues proactively. Overall, the adoption of AI-driven tools in diabetes management has generated a favorable response, with patients appreciating the enhanced personalization, convenience, and empowerment these technologies bring to their care.

**IF:** The evidence so far, with respect to Digital Therapeutics, points towards significant improvements in haemoglobin A1C levels but I think that much more work and research needs to be done, especially high-quality, rigorous clinical trials and real-world data studies.

<p><b>IG:</b> Patients' response to AI-driven tools in their diabetes care regimen largely depends on the design and user experience (UX/UI) of these tools. The effectiveness and acceptance vary based on the patient's type of diabetes and their treatment plan. For example, a person with Type 1 Diabetes on Basal Bolus therapy requires a different UX/UI experience compared to someone with Type 2 Diabetes treated with Basal Bolus. The success of these tools in aiding diabetes management hinges on how well they are tailored to meet the specific needs and preferences of different patient groups.</p>
<p><b>IH:</b> No answer</p>
<p><b>II:</b> She notes a diverse range of patient responses to AI-driven tools. While tech-savvy patients quickly embrace these tools for the enhanced control and insights they provide, others may need more support and education to fully utilize them.</p>
<p><b>IJ:</b> He has noticed diverse reactions from patients using AI tools. While some patients quickly adapt and find value in the enhanced control, prompting initiatives to make these technologies more accessible and user-friendly.</p>
<p><b>Q5: How effective are AI-based digital therapeutics in managing diabetes compared to conventional methods?</b></p>
<p><b>IA:</b> The speaker explains that AI-based digital therapeutics are effective in managing diabetes, especially when patients actively engage with their condition. This engagement can occur through various means, including apps, books for non-digital users, or visualization of data from sensors and technology. The effectiveness of digital therapeutics in diabetes management is highly individual and cannot be quantified uniformly, such as by stating a specific percentage increase in therapy success. However, digital therapeutics help patients engage more with their diabetes management, leading to better outcomes. The speaker emphasizes the diverse range of digital therapeutic tools available, each contributing differently to patient care.</p>
<p><b>IB:</b> The speaker indicates that AI-based digital therapeutics in diabetes management, offering real-time adjustments, are still in the process of proving their effectiveness compared to traditional methods. Traditional care, focusing on infrequent metrics like HbA1c, contrasts with the continuous monitoring capabilities of AI tools. However, the validation of these AI tools' effectiveness is challenged by slow healthcare adoption rates and the need for long-term studies. They note a lag in integrating new technologies into clinical practice, suggesting that it will take time for AI therapeutics to be fully recognized as effective in conventional healthcare settings.</p>
<p><b>IC:</b> The speaker discusses the early stages of AI in diabetes management, noting its potential to make healthcare more data-driven and affordable compared to traditional methods. They highlight</p>

AI's role in enhancing clinical decision-making and the efficiency of healthcare systems, emphasizing the need for quality-based systems, precise cost control, and patient-centric care. The speaker also sees AI as crucial in evaluating the true impact of healthcare innovations, differentiating between genuine and incremental advancements. They suggest AI could expose inefficiencies in the healthcare sector, leading to more effective use of resources and better patient outcomes.

**ID:** The speaker explains that the effectiveness of AI-based digital therapeutics in managing diabetes varies from one solution to another. In their specific case, they mention the validation of their tool, through three clinical studies. The results achieved with company were comparable to modern anti-diabetic drugs, showing a reduction in HbA1c levels by 0.9 points over three months, which they consider a significant achievement. They also note that while some other AI-driven solutions in diabetes management have achieved even greater improvements in HbA1c levels, the effectiveness varies across different technologies.

**IE:** AI-based digital therapeutics are proving more effective than traditional methods in managing diabetes due to their personalized, adaptive approach. These interventions utilize real-time data analysis to offer immediate feedback and predict blood glucose trends, leading to better glycemic control. The integration of diverse data and remote monitoring capabilities enhances their efficacy, providing continuous support and proactive interventions. This results in a more responsive, patient-centered approach to diabetes management, improving patient satisfaction and long-term health outcomes. Despite higher initial development costs, their potential for cost-effectiveness through reduced complications and hospitalizations highlights the significant advancements AI offers in diabetes care.

**IF:** Here again, the answer is, we need more research and a stronger evidence-base, or even better, if this research if available, it needs to be communicated much better and to a wider audience.

**IG:** The effectiveness of AI-based digital therapeutics in managing diabetes compared to conventional methods varies depending on the criteria used to measure success. These criteria could include:

- The cost of care.
- Improvement in HbA1c levels.
- Reduction in the frequency of hypoglycemic episodes, including severe ones.
- Fewer diabetic complications.
- Enhanced quality of life for patients.
- Reduced overall disease burden.

<p>Each of these yardsticks provides a different perspective on the effectiveness of AI-based digital therapeutics in diabetes management.</p>
<p><b>IH:</b> The effectiveness of AI-based digital therapeutics in managing diabetes compared to conventional methods is highly specific to each tool. Their impact depends on the tool's design objectives, the rigor of its testing, and how well it integrates into the healthcare context in which it is implemented. This indicates that there is no "one size fits all" answer regarding their effectiveness.</p>
<p><b>II:</b> Compared to traditional methods, she observes that their AI-based solutions have shown greater precision in managing diabetes. Patients using these tools have reported improved glycemic control and fewer complications, indicating a notable improvement over conventional diabetes care.</p>
<p><b>IJ:</b> In his observation, AI-based solutions offer a more precise management of diabetes compared to traditional methods, leading to improved control of blood sugar levels and fewer complications.</p>
<p><b>Q6:</b> Share any specific outcomes or success stories related to AI-based digital therapeutics in diabetes management?</p>
<p><b>IB:</b> The speaker explains that they are unable to share specific outcomes or success stories related to AI-based digital therapeutics in diabetes management. Their involvement has primarily been in the early stages of such projects, and they have not closely followed their progress into later stages or real-world applications. The speaker emphasizes that for them, success is not just about clinical effectiveness but also about real-world impact, and they have not explored or discussed real-world implications or studies in diabetes management with endocrinologists or other experts. Consequently, they are not in a position to comment on specific successes in this field.(IB)</p>
<p><b>IK:</b> He shares numerous instances where AI-based therapeutics have substantially improved patient outcomes in diabetes management, reducing emergency situations and enhancing overall health management.</p>
<p><b>Q7: What are the main challenges or limitations you have encountered in implementing AI-based digital therapeutics for diabetes management?</b></p>
<p><b>IA:</b> The speaker highlights regulation as a major challenge in implementing AI-based digital therapeutics for diabetes management. They explain that when AI is used in digital therapeutics (DTx) and leads to patients making their own therapeutic decisions, it raises the risk level in terms of medical device regulation (MDR) and CE marking. This complexity significantly complicates the go-to-market process. Additionally, the new AI Act being prepared by the European Union adds another layer of complexity to AI-based tools. Combining these regulatory areas multiplies</p>

the complexity levels, making the implementation of AI-driven digital therapeutics in healthcare a challenging endeavor.

**IB:** The main challenge in implementing AI-based digital therapeutics for diabetes management, as identified by the speaker, is gaining the trust of physicians. This challenge stems from AI's "black box" nature, where its decision-making process is not always clear or understandable to physicians, who are trained to base decisions on patient safety. Physicians may be hesitant to rely on AI results that do not align with their training or intuition. Overcoming this requires training physicians in understanding and interpreting AI models, a process that could take up to 10 to 20 years for full adoption. This trust issue is a significant barrier to the integration of AI in diabetes care.

**IC:** The speaker discusses the challenges in implementing AI-based digital therapeutics for diabetes management, highlighting the difficulty in accessing necessary data and the issue of compensating data suppliers. They also emphasize the importance of understanding and controlling AI algorithms, including their traceability and changes. A broader concern mentioned is the potential of generative AI to enter a positive feedback loop, leading to AI systems enhancing their learning autonomously and becoming exceedingly advanced. These challenges present both practical and philosophical considerations for the future of AI in healthcare.

**ID:** The main challenge in implementing AI-based digital therapeutics for diabetes management is the business model, especially in Europe where healthcare is typically free and covered by health insurance. This makes it difficult to market solutions directly to consumers. Finding a payer for the solution is crucial, with options like partnering with pharmaceutical companies, though this approach has its own challenges. Integrating these solutions into health systems and achieving reimbursement is ideal, but a significant hurdle remains in convincing doctors to prescribe digital apps, a relatively new concept in healthcare.

**IE:** Implementing AI-based digital therapeutics in diabetes management faces several challenges. Key issues include ensuring data privacy and security, achieving compliance with regulatory standards, and building trust among patients regarding their data protection. Integrating these tools with existing healthcare systems also presents interoperability challenges, requiring collaboration across healthcare providers, technologists, and regulators. Additionally, developing AI algorithms that cater to diverse patient populations and health conditions involves extensive validation and refinement. Accessibility and affordability issues arise due to the reliance on technology like smartphones and internet connectivity, potentially excluding certain groups. Resistance to adopting new technologies among healthcare professionals and patients, along with concerns about AI reliability, calls for clear communication and education.

<p>Ethical considerations, such as algorithmic transparency and data biases, also pose significant challenges. Addressing these requires a multidisciplinary approach to ensure successful integration of AI in diabetes care.</p>
<p><b>IF:</b> Keeping in consideration that I have not been directly involved in implementation but rather an observer at this stage in my career, if I look at my country, Malta, currently there is no regulation in place with respect to Digital Therapeutics. Therefore, implementation and procurement comes at a risk and you might have to backtrack if there are compliance issues. It also seems that the risk appetite is currently quite low, even if this means that we significantly improve our evidence behind already existing apps that have spread throughout different markets.</p>
<p><b>IG:</b> The main challenges or limitations encountered in implementing AI-based digital therapeutics for diabetes management include:</p> <ul style="list-style-type: none"> <li>• Navigating the evolving regulatory environment and balancing the factors of value versus risk and effort.</li> <li>• Recognizing that these technologies operate within ecosystems, which need to be aligned for the technologies to fully realize their value propositions.</li> <li>• Understanding the variations in these technologies and their applications across different health systems.</li> </ul>
<p><b>IH:</b> No answer</p>
<p><b>II:</b> Key challenges include integrating these solutions into diverse healthcare systems, ensuring data privacy and security, and adapting to various global regulatory standards. These challenges are seen as critical hurdles in the broader adoption of AI in diabetes care.</p>
<p><b>IJ:</b> He acknowledges several challenges in implementing AI solutions, such as ensuring compatibility with diverse healthcare systems and adhering to varying regulatory standards globally. Main thing is accessibility.</p>
<p><b>Q8: What impact AI-based digital therapeutics have on healthcare systems, particularly in diabetes management?</b></p>
<p><b>IA:</b> The speaker highlights the role of AI-based digital therapeutics in diabetes care, emphasizing their ability to help patients understand their disease outside of healthcare settings, thus improving the efficiency of healthcare systems. Regarding the market evolution of these therapeutics, the speaker notes the rapid technological advancements and initially predicted significant growth. However, they now see this as more uncertain due to new pharmaceutical products like Wegovia and Ozempic. They also mention the need for medical professionals to become familiar with digital</p>

<p>therapeutics, a relatively new field compared to traditional pharmaceutical products. This adaptation is essential for the effective integration of digital therapeutics into patient care.</p>
<p><b>IB:</b> AI-based digital therapeutics have the potential to significantly improve diabetes management by offering personalized lifestyle and treatment adjustments at a lower cost. However, challenges include low adoption rates due to conflicts with traditional healthcare practices and physicians' reluctance to recommend digital solutions they don't fully understand. Additionally, there's a lack of comprehensive evidence on the effectiveness of various digital therapeutics, leading to uncertainty about their benefits. This situation can result in added costs to the healthcare system rather than savings. The speaker emphasizes that integrating these therapeutics into standard care will require more time and may initially increase healthcare costs.</p>
<p><b>IC:</b> The speaker believes that AI-based digital therapeutics will fundamentally transform healthcare delivery but expresses concern that various stakeholders in the healthcare system, including providers, payers, and supervisors, may not be ready for this change. They anticipate resistance from these groups due to the perceived threat of such a significant shift. However, the speaker suggests that patients might adapt more quickly to AI-based therapeutics, recognizing the value these technologies bring to their healthcare experience.</p>
<p><b>ID:</b> The speaker highlights two major impacts of AI-based digital therapeutics on healthcare systems, particularly in diabetes management. Firstly, they can lead to significant cost savings. This is achieved through the reduction of medication needs and fewer visits to healthcare providers, mainly due to decreased health complications associated with diabetes. Secondly, AI-based digital therapeutics improve access to care, which is particularly beneficial given the large number of individuals with type 2 diabetes. These two advantages—cost reduction and improved access—are seen as the key contributions of AI-driven solutions to healthcare systems in managing diabetes.</p>
<p><b>IE:</b> AI-based digital therapeutics in diabetes management positively impact healthcare systems by improving efficiency, resource allocation, and preventive care. The personalized nature of AI interventions reduces unnecessary visits, potentially lowering the burden on healthcare providers. Remote monitoring fosters patient-centric care, and the data generated contributes to population health management, identifying trends and risk factors. While challenges exist, including initial costs and data privacy concerns, the overall effect is a more efficient, proactive, and patient-centered healthcare approach.</p>
<p><b>IF:</b> We have yet to see this impact. Much more work needs to be done on this. Nevertheless, I'm starting to see work on Reimbursement of Digital Therapeutics. The link between reimbursement, healthcare systems and digital therapeutics is monumental and critical as this will mean that digital</p>

therapeutics, especially once backed by a regional level regulatory and technical framework, have the potential to reach a much wider audience and have an even stronger impact.

**IG:** The impact of AI-based digital therapeutics on healthcare systems, particularly in diabetes management, is currently limited but gradually emerging in certain areas. In some mature health systems, like those at Mayo Clinic and Stanford, these digital therapeutics are beginning to demonstrate value. However, their widespread influence across the broader healthcare landscape is still in the early stages of development.

**IH:** The impact of AI-based digital therapeutics on healthcare systems, particularly in diabetes management, varies significantly depending on the specific healthcare system and its governance. Factors such as payment models (fee-for-service vs. value-based healthcare) play a crucial role in determining how these tools are reimbursed. This, in turn, affects their acceptance and adoption by clinicians. Therefore, the influence of AI-based therapeutics is not uniform and depends greatly on the context of the healthcare system in which they are implemented.

**II:** She believes that digital therapeutics are reshaping healthcare. By enabling more proactive and personalized care, these technologies hold the promise of reducing long-term healthcare costs and enhancing patient quality of life.

**IJ:** He believes that digital therapeutics are transforming healthcare, especially in diabetes care. These technologies aim to reduce costs and improve patient life quality by facilitating more proactive and personalized treatment with safe use of data and everyday updates.

**Q9: How do you see the market for AI-based digital therapeutics in diabetes evolving in the next few years?**

**IA:** No answer.

**IB:** The future of the AI-based digital therapeutics market in diabetes management over the next two years hinges on the strength of evidence supporting their effectiveness. Since diabetes poses a considerable cost burden to healthcare systems, payers, and employers, the potential of digital therapeutics to enhance efficiency and outcomes is significant. In clinical practice and health systems, strong evidence of improved care and efficiency could have a major impact, although this area faces the highest barrier to adoption. For payers and insurers, demonstrating cost reductions, even though measures like telehealth, could be influential. With employers, if digital therapeutics are shown to benefit mental health and offer short-term disease management benefits, even if not directly linked to clinical outcomes, they could see wider adoption. The degree and nature of the evidence will be key in determining the impact and adoption of these digital therapeutics across these sectors.

**IC:** The speaker predicts that the market for AI-based digital therapeutics, particularly in Western countries with aging populations, will evolve significantly in the next few years. They see AI playing a crucial role in containing healthcare costs by promoting preventive medicine. The speaker emphasizes AI's potential in preventing diseases, especially Type 2 diabetes, which is largely lifestyle related. They believe AI will not only be instrumental in treating patients after they become sick but also in preventing them from reaching a diseased state. Additionally, AI is expected to reinforce primary care and enhance the general well-being of individuals, reducing the need for more intensive secondary care.

**ID:** The speaker predicts significant evolution in the AI-based digital therapeutics market for diabetes in the coming years. They identify regulatory challenges, rather than technical ones, as the main hurdles to progress. An example is the artificial pancreas, which is technically feasible but hindered by regulatory barriers. The speaker is optimistic that these issues will be addressed within the next five years. They also anticipate large language models to revolutionize healthcare by enabling more personalized therapy content, significantly impacting the field of digital therapeutics.

**IE:** The market for AI-based digital therapeutics in diabetes is set to evolve rapidly in the coming years. Anticipated trends include increased adoption driven by growing awareness, advancements in AI algorithms, and positive patient outcomes. Continuous innovation, user-friendly interfaces, and seamless integration with wearables are expected. As evidence supporting effectiveness accumulates, there may be shifts in payer acceptance and regulatory frameworks, fostering strategic partnerships and collaborations between technology companies and healthcare providers. The market is poised for dynamic growth, refining technologies and solidifying their role in diabetes management.

**IF:** We have not arrived at the tipping point yet, but we're edging closer and closer. As we start seeing regulatory frameworks developing at a lightning pace especially in the past 1-2 years (within the EU), this needs to be accompanied with legal clarity. Once these are established then I believe that we can only see the demand increasing in the next few years.

**IG:** The market for AI-based digital therapeutics in diabetes is expected to evolve significantly in the coming years. Drawing a parallel to the trajectory of companies like (confidential), the domain of technology in diabetes care will need to demonstrate a clear and realized value proposition to thrive. The market's evolution will require considerable effort and resources ("muscle") to effectively address and integrate with the healthcare ecosystem.

<p><b>IH:</b> The evolution of the market for AI-based digital therapeutics in diabetes over the next few years will vary depending on the specific market and its digital maturity. Additionally, the maturity level of policies and regulations concerning digital therapeutics (DTx) tools will play a significant role. For example, markets like Germany, with established digital health applications (DiGa) policies, may experience more rapid developments and widespread use of these tools compared to markets lacking clear certification and/or reimbursement policies for DTx.</p>
<p><b>II:</b> She anticipates significant growth in the AI-based digital therapeutics market, driven by technological advancements and changing patient needs. The focus is on exploring new business models and forging partnerships to capitalize on these opportunities.</p>
<p><b>IJ:</b> He foresees significant growth in the AI-based digital therapeutics market, changed by data regulations, of course by technologies changes, interfaces that are not that hard to use.</p>
<p><b>Q10: What business models have proven most successful for companies in the AI-Based digital therapeutics?</b></p>
<p><b>IA:</b> The speaker discusses the success of business models for AI-based digital therapeutics, noting that it varies based on the market and healthcare system. In Europe, where healthcare is predominantly state-provided, people are less accustomed to paying out of pocket compared to the U.S., where individuals often pay significant sums for healthcare services, including emergencies. The extent and quality of care provided by European healthcare systems vary, but they generally offer a fundamental base of care. In Europe, there's a willingness to spend more on certain products that might help individuals, but this willingness to pay is more limited compared to the U.S. market.</p>
<p><b>IB:</b> The speaker suggests that partnering with employers is the most successful business model for AI-based digital therapeutics in diabetes. This approach leverages employers' direct impact on their employee-patients and aids in generating necessary evidence for the therapeutics' effectiveness. Engaging with payers is noted as challenging due to high competition and strict criteria, while partnerships with pharma companies come with their own complexities. Direct-to-patient models, where patients pay out of pocket, face barriers due to the perception that healthcare should be free. Therefore, targeting employers is seen as the most viable option financially, focusing on monetary success rather than solely on health outcomes.</p>
<p><b>IC:</b> The speaker discusses successful business models for companies in AI-based digital therapeutics, focusing on value-based procurement. This model requires that products, such as medicines or AI technologies, prove their effectiveness and provide value commensurate with their cost. The value is assessed not just in terms of clinical outcomes, but also considering patient-reported outcomes and experiences. A product that is significantly more expensive than its</p>

<p>competitors must demonstrate correspondingly higher benefits. The speaker also mentions the European Health Data Space, which provides data to justify the development and implementation of AI systems. This approach ensures that the price of AI technologies is justified by the value they create in healthcare.</p>
<p><b>ID:</b> The speaker identifies public reimbursement as the most successful business model for AI-based digital therapeutics. This model involves digital therapeutics being prescribed by doctors and covered by health insurers. They emphasize the importance of having these therapeutic solutions included in public health insurance schemes, ensuring that costs are borne by insurers rather than directly by patients. This approach allows for wider accessibility and adoption, as it integrates seamlessly into existing healthcare systems where prescriptions and insurance coverage are standard practices.</p>
<p><b>IE:</b> Successful business models for AI-based digital therapeutics include subscription-based models for recurring revenue, collaborations with healthcare providers for integration, direct-to-consumer approaches with freemium models, and licensing agreements with pharmaceutical or healthcare entities. Companies often adopt hybrid models tailored to their target audience and the evolving healthcare landscape.</p>
<p><b>IF:</b> This really and truly depends on the health system that is being targeted and its financing models.</p>
<p><b>IG:</b> The progression of this market will depend on several factors:</p> <ul style="list-style-type: none"> <li>• Who Drives the Change: It remains to be seen which organizations or entities will successfully lead and innovate in this space.</li> <li>• Geographical Focus: The United States is anticipated to be a key player or perhaps the leader in this evolution, given its substantial healthcare market and technological advancements.</li> <li>• Timing: The timeline for this evolution is uncertain, but it is expected to unfold soon.</li> </ul> <p>The success of AI-based digital therapeutics in diabetes will largely hinge on their ability to fit within and enhance the existing healthcare structures, proving their effectiveness and value in real-world settings.</p>
<p><b>IH:</b> The success of business models for companies in AI-based digital therapeutics depends on various factors. It varies based on the purpose of the tool, who benefits most from it, and which stakeholder(s) are most willing to pay for it. The effectiveness of a business model is not uniform</p>

<p>across all tools and contexts; it must align with the specific needs and incentives of the involved parties.</p>
<p><b>II:</b> Business models that prioritize accessibility and value, such as partnerships with healthcare providers. This models align with the economic realities of healthcare systems and ensure broader access to the company's solutions.</p>
<p><b>IJ:</b> Business models that merge patient accessibility with economic viability, like subscription services and collaborations with healthcare providers, have been identified as most successful, ensuring wider reach and sustainability.</p>
<p><b>Q11: What are the biggest market challenges you face in the AI-based digital therapeutics industry for diabetes?</b></p>
<p><b>IA:</b> The speaker highlights regulation as the biggest challenge in the AI-based digital therapeutics industry. Navigating regulatory processes and gaining approval for market presence and prescription use are key hurdles. Convincing healthcare professionals to adopt and prescribe these therapies is another significant challenge. The speaker notes variations in market entry barriers across Europe, with Germany having stricter requirements for public fund reimbursement. They emphasize the differences between a product being available on the market, prescribable, and being prescribed, underscoring the complexities in delivering AI-based digital therapeutics to patients.</p>
<p><b>IB:</b> The biggest market challenge faced in the AI-based digital therapeutics industry for diabetes, according to the speaker, is clinical inertia and resistance. This issue arises from the need for evidence-based and efficacious solutions in healthcare. The primary route for the administration and prescription of these digital therapeutics is through physicians, making their acceptance and endorsement crucial. However, convincing enough physicians to adopt and support these new technologies is a significant hurdle. Direct-to-patient approaches are limited in effectiveness as not all patients actively seek out or are familiar with the latest technologies. Therefore, gaining physician support is seen as the key challenge in achieving broader adoption of AI-based digital therapeutics in diabetes management.</p>
<p><b>IC:</b> The speaker identifies major market challenges in the AI-based digital therapeutics industry. These challenges include the existing healthcare systems' readiness to incorporate AI technologies, the willingness of healthcare participants to embrace change, and the need to shift from price-based to value-based procurement. They emphasize that this shift requires a fundamental change in approach, which many stakeholders, including hospital managers, practitioners, nurses, administrative staff, politicians, and even engineers, may not be ready for. The speaker notes that</p>

<p>these individuals often focus on specific aspects of their roles without fully considering the broader social impact of integrating AI into healthcare.</p>
<p><b>ID:</b> The speaker identifies the business model, particularly the aspect of market distribution, as the biggest challenge in the AI-based digital therapeutics industry for diabetes. A key component of this challenge is convincing doctors to prescribe digital solutions. Developing an effective strategy to distribute these digital therapeutics and gain the support of healthcare professionals for their prescription is crucial for success in the market. This challenge highlights the importance of aligning digital therapeutic solutions with the existing practices and preferences of healthcare providers.</p>
<p><b>IE:</b> The AI-based digital therapeutics industry for diabetes faces challenges such as ensuring robust data privacy, addressing interoperability issues with existing healthcare systems, and overcoming resistance to change among healthcare professionals and patients. Additionally, disparities in technology access, ethical considerations, and the need for ongoing workforce training pose hurdles to widespread adoption. Efforts to navigate these challenges require collaboration and careful consideration of regulatory and ethical frameworks.</p>
<p><b>IF:</b> I have not directly implemented an AI-based digital therapeutic myself. Nevertheless, from circumstantial evidence and after attending more than 6-7 years of Digital Health conferences, I see that the lack of regulation and legal clarity and communication being the major challenges ahead for Digital Therapeutics companies. My gut instinct so far and with the accelerated work happening so far, especially at an EU level, this might change sooner rather than later.</p>
<p><b>IG:</b> The most successful business model for companies in the AI-based digital therapeutics space, so far, has been offering free digital companion services that are funded by pharmaceutical companies. However, this model is viewed as potentially unsustainable in the long term. This approach allows patients to access digital therapeutics without direct cost, while pharmaceutical companies bear the expense, possibly as a strategy to complement their medication offerings or enhance patient engagement and outcomes. The sustainability of this model hinges on the value it delivers to pharmaceutical companies and its long-term financial viability.</p>
<p><b>IH:</b> Evidence base generation (proper and rigorous studies that prove the clinical utility and safety), regulations, and interoperability.</p>
<p><b>II:</b> She identifies the complex regulatory landscape and meeting the diverse needs of a global patient population as major challenges. Demonstrating the long-term value and cost-effectiveness of their solutions to healthcare providers and insurers is also a key focus.</p>

**IJ:** Business models that merge patient accessibility with economic viability, like subscription services and collaborations with healthcare providers, have been identified as most successful, ensuring wider reach and sustainability.

**Q12: What emerging technologies or innovations will significantly impact AI-based digital therapeutics for diabetes in the near future?**

**IA:** The speaker identifies two emerging technologies likely to significantly impact AI-based digital therapeutics for diabetes soon. First is Automated Insulin Delivery (AID), which is expected to be a key area of development. The second, and a topic not yet widely discussed, is non-invasive blood glucose measurement. Around 20 companies are working on methods to measure blood glucose levels without the need for finger pricking or skin sensors, like how an Apple Watch measures other vital data. The speaker believes that successful development in this area could be a breakthrough, particularly in the treatment of pre-diabetes and early-stage diabetes detection, areas where current healthcare systems have limitations. They also note that some companies are already announcing advancements in non-invasive technologies.

**IB:** The speaker highlights three emerging technologies and trends poised to impact AI-based digital therapeutics in diabetes significantly. First, generative AI will enhance apps and tools for lifestyle adjustments and dosage management, making them more conversational and user-friendly. Secondly, advancements in non-invasive Continuous Glucose Monitors, potentially integrated into everyday devices like the Apple Watch, will make diabetes management less invasive and more accessible. Lastly, the development of new, more efficacious diabetes treatments requiring less frequent administration could shift patient engagement with their condition. As treatments become less intrusive, diabetes might not dominate patients' daily lives as much, reflecting broader trends in chronic condition management. These innovations are expected to transform diabetes care by making it more user-friendly, less invasive, and altering patient engagement with their condition.

**IC:** The speaker discusses the impact of emerging technologies on AI-based digital therapeutics in diabetes care. They mention Boston Dynamics' robot, integrated with a language model, as an example of innovation. The future could see humanoid robots acting as primary care physicians, offering continuous support, especially to older patients. These AI-assisted robots would enable remote patient monitoring and data acquisition, reducing the burden on primary care systems. This shift could lead to less crowded hospitals and better care quality, particularly beneficial for diabetes management. However, the speaker notes potential resistance from medical associations to such technological advancements.

<p><b>ID:</b> The speaker believes that non-invasive Continuous Glucose Monitoring (CGM) systems are the emerging technology most likely to significantly impact AI-based digital therapeutics in diabetes management soon. The integration of continuous glucose measurement technology into devices like smartwatches is seen as a major advancement. This innovation could greatly change the industry by providing easy and ongoing monitoring of blood glucose levels without the need for invasive procedures. The speaker views this as the most interesting and potentially transformative technology currently being developed in the diabetes field.</p>
<p><b>IE:</b> Emerging technologies set to impact AI-based digital therapeutics for diabetes include advancements in AI algorithms, increased integration with wearables, and the development of more sophisticated remote monitoring solutions. Innovations in data analytics, particularly leveraging real-world evidence, will enhance the personalization and effectiveness of interventions. Furthermore, the integration of telehealth technologies, augmented reality, and continuous glucose monitoring systems is poised to play a pivotal role in shaping the near future of AI-based digital therapeutics for diabetes.</p>
<p><b>IF:</b> The biggest innovation that will happen in the next decade is much simpler than we think, it's the availability of data and related workforce competencies, including data science and artificial intelligence. With upcoming regulation pushing on a much more structured approach in health data (European Health Data Space) both for primary and secondary use, then inadvertently we should see significant improvements in the development of AI-based digital therapeutics. I have high bets on specific foundation models (multi-modal) will have an incredible impact. Imagine not just text, but images of diabetic feet and how should they be treated being a part of the equation, wound management, ophthalmology and much more. If we see diabetes in the bigger picture, it's not just about the clinical text data but it's also about the whole experience.</p>
<p><b>IG:</b> The most significant upcoming innovation in AI-based digital therapeutics for diabetes is likely the integration of advanced, non-invasive glucose sensing technology into devices like the Apple Watch. Additionally, identifying sustainable business models for digital therapeutics in suitable ecosystems is also crucial for their future impact.</p>
<p><b>IH:</b> Emerging technologies and innovations that will significantly impact AI-based digital therapeutics for diabetes soon include Large Language Models (LLMs). These advanced AI models have the potential to revolutionize the way information is processed, analyzed, and utilized in the context of diabetes care, enhancing the capabilities and effectiveness of digital therapeutics.</p>
<p><b>II:</b> This company are watching developments in non-invasive monitoring technologies. The integration of these technologies into broader health ecosystems is a primary area of interest.</p>

**IJ:** That company are keenly observing developments in non-invasive glucose monitoring and advanced predictive analytics, which are poised to significantly impact diabetes management in the future and improve patients satisfaction by using them.

**Q13: Describe the future of AI-based digital therapeutics in diabetes management heading in the next 5 to 10 years?**

**IA:** In the next 5 to 10 years, the speaker anticipates significant advancements in AI-based digital therapeutics for diabetes management. They expect a broader adoption of Continuous Glucose Monitoring (CGM) systems, particularly among type 2 diabetes patients, dependent on the investment levels of different European healthcare systems. Future developments include enhanced access to healthcare information through smartphones and the use of AI-powered tools like food recognition technologies. Sensor technology is predicted to become smaller and more comfortable. The integration of pharmaceutical treatments for weight loss with digital therapeutics tools, potentially AI-powered, is also expected, aiming to improve lifestyle and behavioral changes in patients. This integration is seen as a key element in sustaining effective diabetes management.

**IB:** Over the next 5 to 10 years, the speaker cautiously anticipates two potential developments in AI-based digital therapeutics for diabetes management. They hope for either the emergence of strong evidence proving the effectiveness of digital therapeutics or an increase in healthcare professionals actively seeking to use these technologies. Additionally, they foresee greater patient involvement in their own healthcare, driven by advancements in health technology like continuous glucose monitors and insulin pumps. This increased patient engagement could pressure the healthcare system to adopt more technological solutions. The speaker notes their perspective is from an observational standpoint, advising to consider their insights as part of a wider discourse on technology's role in diabetes care.

**IC:** The speaker, while not a diabetes specialist, envisions significant advancements in AI-based digital therapeutics for diabetes management in the next 5 to 10 years. They foresee insulin delivery becoming more sophisticated, with systems that can automatically adjust insulin levels based on real-time body data, improving the quality of life for patients. Another key area of development is in the prevention of diabetes, with AI providing constant monitoring and warning signs to help individuals avoid becoming diabetic. This could include humanoid robots acting like physicians, advising patients on diet and lifestyle changes. The speaker also speculates that type 1 diabetes might see advancements through genetic manipulation, though they acknowledge this is not their area of expertise.

**ID:** The speaker anticipates that over the next 5 to 10 years, there will be significant advancements in AI-based digital therapeutics for diabetes management, although predicting exact developments is challenging due to the rapid progress in AI. A key area of improvement is expected in artificial pancreas technology, reducing or eliminating the need for manual insulin injections. This technology is seen as a game-changer, likely to become more prevalent. Another significant advancement will be in personalizing self-management of diabetes based on data from non-invasive Continuous Glucose Monitoring (CGM) systems. As these systems become more widespread, they will enable better identification of factors causing glycemic spikes, such as certain foods or lifestyle choices. This capability will dramatically improve diabetes management by allowing for more tailored and effective interventions based on real-time glucose data.

**IE:** The future of AI-based digital therapeutics in diabetes management over the next 5 to 10 years holds promising advancements. Anticipate a landscape defined by increasingly sophisticated AI algorithms, offering unparalleled personalization in treatment plans and real-time monitoring. Integration with advanced wearables and continuous glucose monitoring systems will become more seamless, providing comprehensive data for precise interventions. The convergence of AI with telehealth technologies and augmented reality is expected to revolutionize patient engagement and education. Furthermore, collaborations between technology developers and healthcare stakeholders will likely drive regulatory acceptance, fostering widespread adoption and establishing AI-based digital therapeutics as integral components of diabetes care.

**IF:** With the popularisation of Artificial Intelligence, the increased acceptance of this kind of technology and also the increased investment by traditional pharmaceutical companies to further invest in Digital Health and Artificial Intelligence, I can safely predict that there will be growth in this area. We need to also keep in mind the epidemiology of diabetes that is overall increasing and therefore there will be increased pressure on existing health workforce and thus the need to be even more innovative than ever and move away from traditional diabetes management that is ultimately unsustainable and not scalable.

**IG:** In the next 5 to 10 years, the future of AI-based digital therapeutics in diabetes management is expected to undergo significant changes, especially if major players like Apple and Amazon transform the space. These companies have the potential to disrupt the current landscape of diabetes management, leading to "Triple Aim" outcomes - improving patient experience, enhancing health populations, and reducing healthcare costs. This shift could significantly impact the roles and strategies of existing players in the diabetes management sector.

**IH:** The future direction of AI, particularly in the context of digital therapeutics for diabetes, is challenging to predict without clear regulatory guidelines.

**II:** Looking ahead, she envisions a future where diabetes management is highly personalized, automated, and seamlessly integrated into patients' lives. The involvement of major tech companies and startups will be crucial in driving this transformation. The goal is to align with the enhancing individual care, improving population health, and reducing healthcare costs through innovative digital therapeutics.

**IJ:** He envisions a future where diabetes care is highly individualized, automated, and smoothly integrated into daily life. They anticipate the vital role of major tech companies and startups in driving this transformation, aiming to: enhance individual care and improving population health by use of one of the newest technologies.