



The Digitisation of Diabetes: Opportunities and Challenges for Industry

A FirstWord FutureViews Report

The Digitisation of Diabetes: Opportunities and Challenges for Industry

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Subject synopsis

There is a growing body of evidence that digital technologies can improve existing solutions to prevent and treat diabetes by enabling better consumer engagement and encouraging behavioural and lifestyle changes.

A number of digital programmes have been clinically proven to improve health and lower the cost of care.¹ Innovative payers, providers and employers are offering programmes (e.g. web-based interventions,² mobile apps,³ telephone support,⁴ interactive games,⁵ and real-time monitoring)⁶ to members and patients as part of their coverage to enable patients to take a more active role in self-management.⁷

In addition, these digital technologies are enabling payers to proactively engage with consumers and to generate data that can be analysed to provide insights that help developers to identify areas of unmet medical need, enhance their offerings and personalise the solution to each patient, generate customer loyalty and improve patient satisfaction.

Pharmaceutical and medical device companies continue to explore the role of digital technologies to provide more personalised and targeted treatments and day-to-day management of diabetes.^{1,8} Two areas that have received a lot of attention and investment are in the improvement of blood glucose monitoring and insulin

1 Kaufman N., Khurana I. Using Digital Health Technology to Prevent and Treat Diabetes *Diabetes Technol Ther.* 2016 Feb 1; 18(Suppl 1): S-56–S-68. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4761854/>

2 Nobis S, Lehr D, Ebert DD, Baumeister H, Snoek F, Riper H, Berking M Efficacy of a web-based intervention with mobile phone support in treating depressive symptoms in adults with type 1 and type 2 diabetes: a randomized controlled trial *Diabetes Care* 2015;38: 776–83

3 Arnhold M, Quade M, Kirch W. Mobile applications for diabetics: a systematic review and expert-based usability evaluation considering the special requirements of diabetes patients age 50 years or older *J Med Internet Res* 2014;16: e104

4 Quan J, Lee AK, Handley MA, *et al.* Automated telephone self-management support for diabetes in a low-income health plan: a health care utilization and cost analysis *Popul Health Manag* 2015. [Epub ahead of print] DOI 10.1089/pop.2014.0154

5 Theng Y-L, Lee JWY, Patinadan PV, *et al.* The use of videogames, gamification, and virtual environments in the self-management of diabetes: a systematic review of evidence *Games Health J* 2015;4: 352–61. [Epub ahead of print]; 10.1089/g4h.2014.0114

6 Lim S, Kang SM, Kim KM *et al.* Multifactorial intervention in diabetes care using real-time monitoring and tailored feedback in type 2 diabetes *Acta Diabetol* 2015. [Epub ahead of print]; DOI 10.1007/s00592-015-0754-8

7 Holmen H, Torbjørnsen A, Wahl AK, *et al.* A mobile health intervention for self-management and lifestyle change for persons with type 2 diabetes, part 2: one-year results from the Norwegian randomized controlled trial RENEWING HEALTHJUMIR *Mhealth Uhealth* 2014;2: e57

8 Knox E, Glazebrook C, Randell T *et al.* SKIP (Supporting Kids with diabetes In Physical activity): Feasibility of a randomised controlled trial of a digital intervention for 9-12 year olds with type 1 diabetes mellitus. *BMC Public Health.* 2019 Apr 3;19(1):371. doi: 10.1186/s12889-019-6697-1.

dosing.^{9,10} There has been a flurry of activity as leading medtech players in diabetes such as Abbott, Dexcom, and Medtronic seek to improve continuous blood glucose monitoring and insulin pump technologies.¹¹

Diabetes continues to attract interest and investment from large pharma and insulin delivery companies and this has resulted in a number of high-profile partnerships between them and glucose monitoring specialists, as well as with digital tech companies. Recent partnerships have included Abbott/Tandem Diabetes Care,¹² Abbott/Sanofi/Novo Nordisk and Medtronic/Novo Nordisk,¹³ and Astellas/Welldoc,¹⁴ among many others. Increasingly, traditional glucose monitoring and insulin delivery companies are engaging with digital tech specialists and patient advocates to support them in the development of their digital offerings to ensure they are addressing patient needs and improve connectivity between glucose monitoring and disease management.¹⁵

A number of mobile apps and tools have been developed that close the loop between blood glucose tracking and insulin delivery, and several digital platforms have emerged including DayTwo, Viome, Omada, and Glooko, among many others, to help the personalisation and management of pre-diabetic patients and those with Type 2 diabetes. Some developers are already looking beyond glucose control and at the wider picture of diabetes management and cardiovascular health in the quest to improve health outcomes, as pharmaceutical companies have done with drug development.¹⁶

9 Yaron M, Sher B, Sorek D *et al.* A randomized controlled trial comparing a telemedicine therapeutic intervention with routine care in adults with type 1 diabetes mellitus treated by insulin pumps. *Acta Diabetol.* 2019 Jun;56(6):667-673. doi: 10.1007/s00592-019-01300-1. Epub 2019 Feb 19.

10 Retrieved from <https://medtech.pharmaintelligence.informa.com/MT126039/Tandem-Wins-FDA-Clearance-On-First-StandAlone-Glycemic-Controller>

11 FirstWord MedTech. Devices for Diabetes Patients Spur Growth at Medical Firms. Retrieved from <http://www.firstwordmedtech.com/node/1021118?tsid=33>

12 FirstWord MedTech. Abbott, Tandem Diabetes Care to develop integrated diabetes management solutions. Retrieved from <http://www.firstwordmedtech.com/node/1023715?tsid=33>

13 FirstWord MedTech, Abbott partners with Sanofi, Medtronic joins forces with Novo Nordisk to integrate glucose monitoring into smart insulin pens. Retrieved from <http://www.firstwordmedtech.com/node/1022636?tsid=33>

14 FirstWord MedTech, Astellas and Welldoc Enter into Strategic Alliance for Digital Therapeutics. Retrieved from <http://www.firstwordmedtech.com/node/1025252?tsid=33>

15 Yaron M, Sher B, Sorek D *et al.* A randomized controlled trial comparing a telemedicine therapeutic intervention with routine care in adults with type 1 diabetes mellitus treated by insulin pumps. *Acta Diabetol.* 2019 Jun;56(6):667-673. doi: 10.1007/s00592-019-01300-1. Epub 2019 Feb 19.

16 Livongo Study Demonstrates Sustained Blood Pressure Reduction for People Living with Both Diabetes and Hypertension Outside Traditional Care Settings. Retrieved from <http://www.firstwordmedtech.com/node/1025008?tsid=33>

Despite the considerable potential that digital enablement can offer to patients, concerns regarding data privacy have been raised by end-users and this has resulted in device manufacturers tightening up their cybersecurity to protect consumer personal data, particularly when transferring information across continents. For example, Glooko recently was awarded privacy shield certification for policies to safeguard diabetes patients' data.¹⁷ However, one of the main challenges for all mobile applications is retention of the end-user. Developers are exploring ways to provide regular feedback and personalise data to increase patient engagement and encourage them to maintain an active role in disease management throughout the course of the patient journey.

This report aims to provide insights from experts in the field on the latest digital enabling technologies that are making a mark on diabetes management. It will provide up-to-date case studies and discuss different approaches that developers have taken to support patients, physicians and payers to improve their control over this chronic, autoimmune metabolic disease and to avoid the long-term consequences of inadequate management. The report will also identify areas of unmet need and paths for future development.

¹⁷ Glooko Earns Privacy Shield Certification for Policies to Safeguard Diabetes Patient Data. Retrieved from <http://www.firstwordmedtech.com/node/1025933?tsid=33>

Research methodology and objectives

The report is based on interviews with four medical diagnostic experts that have experience with digital technologies in medical devices and are involved in product development in the medtech arena. It looks at the current and future opportunities in digitising the diagnosis, treatment and management of diabetes.

Experts interviewed:

- **Alexander Fleming, MD**, Executive Chairman, Kinexum (Co-moderator) Endocrinologist and metabolic disease specialist. Former FDA CDER leader in medical reviews that resulted in landmark approvals of metformin, the first statin, and other medicines.
- **Athena Philis-Tsimikas MD**, Corporate Vice President for the Scripps Whittier Diabetes Institute, La Jolla, CA in May of 2008. Prior to that time, she led the institute and subsidiary corporation, The Whittier Institute for Diabetes, as the Executive Director and Chief Medical Officer since 2004.
- **Heidi Soto**, Area Business Manager, MannKind Corporation, formerly a territory manager for Insulet Corporation and Senior specialty sales representative for Eli Lilly's Diabetes and Endocrine Business Unit. She has a proven track record in marketing and sales, selling a portfolio of products to physicians, pharmacists, nurses, hospitals, and medical staff involved in patient care, features, benefits, and services.
- **Professor Mike Trenell**, founder and CEO of Changing Health, is a clinical scientist with a specialist interest in healthcare innovation and strategy. In 2016 he was appointed founding Director of the UK National Institute for Health Research Innovation Observatory (NIHR) and provides strategic insight to the National Institute for Health and Care Excellence (NICE), Department of Health, NHS England, National Institute for Health Research, academia and industry.

Key research objectives

- Identify the innovative approaches that companies are adopting in the digitisation of diabetes.
- Identify key challenges that product developers face when going digital.
- Discuss recent strategic alliances and applications of digital enabling technologies in the medtech arena.
- Identify where companies are applying digital enabling technologies in the diagnosis, treatment and management of diabetes.
- Identify areas for investment and future development of digital technologies in diabetes.

Key insights summary

- Diabetes is a serious, long-term condition that has a major impact on patients and on their families. However new technologies such as continuous glucose monitors (CGMs), hybrid closed-loop systems (artificial pancreas) and smart insulin pens are helping to normalise patients' lives and alleviate the daily burden of the disease.
- Companies are adopting different digital strategies to educate, motivate and support the medical needs of Type 1 and Type 2 diabetics on their treatment journey. Mobile apps (mApps) allow real-time collation of information that can be shared with medical professionals to adapt therapies and reduce the risk of hypo- and hyper-glycaemia and to avoid long-term complications.
- The market is becoming increasingly competitive, and device manufacturers are teaming up with digital specialists to enhance their products and offerings. AI algorithms are being developed that can now sift through large volumes of data captured from devices and electronic health records to identify patients at risk and to flag up issues and comorbidities. However, data security and interoperability between electronic platforms remains an issue.
- The mApp market has exploded, supporting health and wellbeing as well as offering medical guidance on titrating treatments. However, further work is needed to refine these tools to take into consideration other comorbidities, personalise coaching and make them easier to use.
- Hybrid closed-loop systems that mimic the pancreas have become more widely used by both Type 1 and Type 2 diabetics, but more work is needed to ease their use and refine the algorithms so that they truly reflect the physiological needs and normalise blood glucose levels in response to the patient's dietary needs.
- Pricing and reimbursement of medical devices still remain a challenge, and the shift towards value-based care places greater pressure on device manufacturers to demonstrate that their products can improve long-term, predetermined health outcomes.

- New opportunities exist to facilitate the use of devices and mApps, improve interoperability and data sharing, and enhance provider and patient education. Paediatric diabetes is on the increase and prevention, rather than treatment, of diabetes is a growing area for development. New dual-hormone pumps are showing their potential in helping to improve the lives of Type 1 and Type 2 diabetics.
- Digital technologies are at a crossroads when it comes to connecting devices, electronic health platforms, providers and patients to more effectively prevent and manage their disease in a sustainable and timely manner. A key part of this requires the aggregation of all healthcare data and to create automated algorithms to identify, educate and encourage patients that are at risk to use the products more effectively.

Issues and insights

Current application of digital enabling technologies in diabetes management

Issue summary

Diabetes is a serious, long-term condition that has a major impact on the lives and well-being of individuals, families, and societies worldwide. The three main types of diabetes are Type 1 diabetes mellitus, Type 2 diabetes mellitus, and gestational diabetes mellitus. According to the International Diabetes Federation (IDF), diabetes is categorized among the top 10 causes of death in adults worldwide. The disease was estimated to have caused four million deaths globally in 2017, with annual global health expenditure on diabetes for the year estimated to be US\$727 billion.¹⁸ Since 2000, the IDF has reported the national, regional, and global occurrence of diabetes. In 2009 it was estimated that 285 million people had diabetes (Type 1 and Type 2 diabetes combined), increasing to 366 million in 2011, 382 million in 2013, 415 million in 2015, and 425 million in 2017.¹⁹

In 2019, the IDF reported that nearly half a billion people (9.3% of adults aged 20-79 years) are living with diabetes worldwide. The estimated number of adults (20-79 years) living with diabetes has increased by 62% during the past 10 years: from 285 million in 2009 to 463 million at current estimates. According to data compiled by the IDF, the prevalence of diabetes in women in 2019 is estimated to be 9.0%, and 9.6% in men (See [Figure 1, page 22](#)). Going forward, the IDF estimates that this number is expected to increase to 578 million (10.2%) in 2030 and 700 million (10.9%) in 2045.

In response to this growing prevalence, pharmaceutical and medical device companies continue to explore the role of digital technologies in providing more personalised and more targeted treatment options, as well as more effective means

18 International Diabetes Federation. IDF Diabetes Atlas, 8th ed. Brussels, Belgium: International Diabetes Federation; 2017

19 Saeedi P, Petersohn I, Salpea P *et al.* For 2019 and projections for 2030 and 2045: Results global and regional diabetes prevalence estimates from the International Diabetes Federation, Diabetes Atlas 9th Edition, *Diabetes Res Clin Pract*, 2019 Sept 10; 157:107843. doi: 10.1016/j.diabres.2019.107843. Epub 2019 Sep 10

of day-to-day management of diabetes. Rapid advances in imaging technologies and in-vitro diagnostics, alongside improvements in computing power, data collection and processing have resulted in a paradigm shift in medical diagnostics. This is because Artificial Intelligence (AI) algorithms can be trained, while the quality of learning, particularly inferential learning, allows the black box to learn without rule-based programming and to model and evaluate biological processes more rapidly than ever before.²⁰ Accordingly, new AI-driven medical diagnostics are evolving that can enable practitioners to more accurately diagnose and treat diseases.

While the use of technology to facilitate diabetes self-management is not a new concept, the wider adoption of technology through the increased availability of device choices, in tandem with the emergence of innovations, has led to an increase in the variety of technological self-management strategies available to patients.²¹ The remote monitoring of patients using wearables, connected devices, and mobile apps has enabled the continuous collation and facilitation of medical information which allows healthcare professionals, carers, and patients to monitor compliance, send medication reminders, and flag up medical issues as they arise (See [Figure 2, page 23](#)).

In the case of diabetes, technology is primarily used to supplement the care provided by healthcare professionals by offering both educational and motivational support. For example, technology can extend the reach of diabetes education and support when primary care resources are insufficient, or patient resources and access to care are limited.²² Furthermore, education can be provided using technological resources so that patients learn new practices and routines related to diabetes management. In this instance, technology can support the daily diabetes self-management activities of blood glucose monitoring, exercising, healthy eating, taking medication, monitoring for complications, and problem-solving.²³

20 Hasham, M. AI and the Medical Devices Sector Compliance Navigator. 2018 July 10. Retrieved from <https://complianc navigator.bsigroup.com/en/medicaldeviceblog/ai-and-the-medical-devices-sector/>

21 Hunt CW. Technology and diabetes self-management: An integrative review, *World J Diabetes*, 2015 Mar 15; ;6(2):225-33. doi: 10.4239/wjd.v6.i2.225

22 Glasgow RE, Kurz D, King D *et al*. Twelve-month outcomes of an Internet-based diabetes self-management support program. *Patient Educ Couns*. 2012 Apr;87(1):81-92. doi: 10.1016/j.pec.2011.07.024. Epub 2011 Sep 15

23 Hunt CW. Technology and diabetes self-management: An integrative review, *World J Diabetes*, 2015 Mar 15; ;6(2):225-33. doi: 10.4239/wjd.v6.i2.225

In addition, it has been found that the visual feedback of clinical information, including these self-management activities, improves patients' ability to see how diabetes is affected by their behaviours and promotes decision-making and problem-solving. Studies conducted by Song *et al.* (2009) indicate that the monitoring of self-management behaviours can be motivational and allows for more frequent contact between patients and healthcare providers, which can lead to necessary changes in self-management activities and treatment plans.²⁴

When considering the use of mobile phones, evidence suggests that mobile health applications can be used to deliver health services and self-management tools, as well as overcome barriers to provider access by offering alternatives to in-person diabetes intervention delivery and support.²⁵ In addition, mobile phones provide patients with the ability to process and communicate data in real time.²⁶

In recent years, a multitude of mobile health apps have been developed to support effective self-management of patients with Type 1 and Type 2 diabetes.²⁷ At present, there are more than 900,000 mobile apps available in the Apple App Store and more than 700,000 apps in the Google Play Store.²⁸ Within the healthcare sector, apps are supporting the management of illnesses, and are aimed at promoting health awareness and well-being. In 2013, the number of health-related apps increased to 31,000, while those specifically targeting patients with Type 1 and Type 2 diabetes have also increased.²⁹ Research conducted by Quevedo *et al.* (2019) found that out of 794 registered apps directed at diabetes, the primary function of most of the apps was to act as a blood glucose diary.

24 Song M, Choe MA, Kim KS *et al.* An evaluation of Web-based education as an alternative to group lectures for diabetes self-management. *Nurs Health Sci.* 2009 Sep; 11(3):277-84. doi: 10.1111/j.1442-2009.00458.x. Epub 2009 Jun 23

25 Goyal S, Cafazzo JA. Mobile phone health apps for diabetes management: Current evidence and future developments. *QJM.* 2013 Dec;106(12):1067-9. doi: 10.1093/qjmed/hct203. Epub 2013 Oct 8

26 Arnhold M, Quade M, Kirch W. Mobile applications for diabetics: A systematic review and expert-based usability evaluation considering the special requirements of diabetes patients age 50 years or older. *J Med Internet Res.* 2014 April 9; 16(4):e104. doi: 10.2196/jmir.2968

27 Ingraham N. Apple: 900,000 apps in the App Store, 375,000 iPad-optimized, 28 million copies of mountain lion sold. 2013 June 10. Retrieved from <https://www.theverge.com/2013/6/10/4412918/apple-stats-update-wwdc-2013>

28 MHealth Watch Mobile health care apps growing fast in number. 2013. Retrieved from <https://mhealthwatch.com/mobile-health-care-apps-growing-fast-in-number-20052/>

29 Quevedo, RA, Wagner AM. Mobile phone applications for diabetes management: A systematic review. *Endocrinol Diabetes Nutr.* 2019 May; 66(5):330-337. doi: 10.1016/j.endinu.2018.11.005. Epub 2019 Feb 8

In the case of general web-based interventions, this medium provides opportunities to offer diabetes education and support, as well as motivation for self-management behaviours. Web-based interventions include education, goal-setting, tracking of behaviours, patient feedback, and support. It has been found that web-based learning provides easy access without time or location restrictions and allows users to work at their own pace.³⁰ A Cochrane review of computer-based diabetes self-management interventions found a small beneficial effect on blood glucose control with a larger effect noted in mobile phone-based interventions.³¹ The study concluded that mobile phone interventions may be more effective due to convenience, increased contact with the intervention, and cues and feedback provided through the phone.

Research conducted by DRG Digital in 2018 found that insulin manufacturers Novo Nordisk and Sanofi deliver the best online experiences for patients with Type 2 diabetes in terms of website design, patient support, apps, and social profiles.³² Four other pharmaceutical companies (including Merck, Eli Lilly, AstraZeneca, and Johnson & Johnson) were also assessed, in terms of content and asset integration. DRG undertook the study to create a benchmark for pharmaceutical companies in order to evaluate their own digital assets and look at the overall competitive landscape in Type 2 diabetes. The study is the first in a planned series, with future studies set to delve into other therapeutic areas in a similar way.

As part of efforts to further enhance patient experience, in April 2018 Novo Nordisk launched its first chatbot (named Sophia), built specifically for people with diabetes. The chatbot directly answers questions and addresses patient concerns, or forwards or redirects when it does not know the answer. It also learns through human interactions and is designed to consistently improve over time by addressing questions and needs.

30 Glasgow RE, Kurz D, King D *et al.* Twelve-month outcomes of an Internet-based diabetes self-management support program. *Patient Educ Couns.* 2012 Apr;87(1):81-92. doi: 10.1016/j.pec.2011.07.024. Epub 2011 Sep 15

31 Pal K, Eastwood SV, Michie S *et al.* Computer-based diabetes self-management interventions for adults with type 2 diabetes mellitus. *Cochrane Database Syst Rev.* 2013 Mar 28;(3):CD008776. doi: 10.1002/14651858.CD008776.pub2

32 Bulik, B. Digital diabetes mavens Novo Nordisk and Sanofi top new patient experience ranking. 2018 Oct 29. Retrieved from <https://www.fiercepharma.com/marketing/digital-diabetes-mavens-novo-and-sanofi-top-new-study-type-2-online-experiences>

So far, Sophia has had more than 11,000 conversations and has been asked more than 27,000 questions by patients using Novo Nordisk's Cornerstones4Care.com website. Sophia was created after the company noticed spikes in online traffic to its Cornerstones4Care.com website between 11pm and 1am, reinforcing the need for information outside standard Healthcare Practitioner (HCP) hours. Cornerstones4Care debuted in 2011 as an omnichannel patient support system that includes offline, email and telephone support along with the online digital presence. The Sophia concierge is one of the steps Novo Nordisk is taking to advance technology into AI and other areas like voice assistants, as it moves to offer patients more than just medications.

Novo Nordisk had been planning to launch its first connected insulin pens, NovoPen 6 and NovoPen Echo Plus, in early in 2019,³³ although as this report went to press, the devices were not yet available on the market. The smart insulin pens are designed to synchronise dosing data with digital platforms developed by companies such as Dexcom, Glooko, Roche, Abbott, Medtronic, and others. The data generated from these pens can be integrated with additional patient information derived from continuous glucose monitoring systems and other blood glucose meters, and can then be delivered to patients on their digital diabetes management systems. These management systems include Glooko's mobile app and Roche's mySugr and Accu-Check Smart Pix.

Novo Nordisk's smart pens were developed based on clinical studies conducted in 2017 with Glooko, which combined Novo Nordisk's content and resources from its existing Cornerstones4Care online programme and Glooko's technology to synchronize blood glucose and activity data from almost any available diabetes or exercise device.³⁴

Elsewhere, Merck, along with Luminary Labs and Amazon Web Services, have come together to launch the 'Alexa Diabetes Challenge' as a means to envisage how voice technology can help improve health and quality of life for patients with chronic diseases such as Type 2 diabetes. Merck's long-term plan is to create tools

33 Lovett L, Novo Nordisk's soon-to-be-released insulin pens will connect to Glooko's diasend platform February 18, 2019 Mobei Health News. Retrieved from <https://www.mobihealthnews.com/content/novo-nordisks-soon-be-released-insulin-pens-will-connect-glookos-diasend-platform>

34 Glooko Novo Nordisk and Glooko advance their digital health collaboration with launch of unique integrated app for improved diabetes management July 12, 2017. Retrieved from <https://www.glooko.com/press-release/novo-nordisk-glooko-c4c/>

for other chronic diseases using the same Amazon Lex smart platform and the voice-enabled Alexa home system. While mobile apps are already commonplace, this is the first contest to build on a voice-enabled home system. These digital technologies are enabling payers to proactively engage with consumers and to generate data that can be analysed to help developers to identify areas of unmet medical need, enhance their offerings, personalise the solution to each patient, generate customer loyalty, and improve patient satisfaction.

Questions

- In what ways are medtech companies currently applying digital technologies to improve the diagnosis, treatment and management of Type 1 and Type 2 diabetes?
- Are there any specific technology platforms, devices, and emerging innovations that are driving this field forward faster than others?
- In what ways are digital technologies enabling medical device manufacturers to build direct relationships with patients and to educate and support them in the treatment/management of their condition and build brand loyalty?

Key insights

- **Different digital strategies for Type 1 and Type 2 diabetics.** Diabetes is a spectrum of conditions. Patients with Type 1 diabetes lack the ability to produce sufficient levels of insulin and are therefore reliant on the parenteral admission of insulin to regulate their blood glucose. These patients are motivated and quick adopters of technologies and devices that enable them to lead a 'normal' life.³⁵ Conversely, patients with Type 2 diabetes are insulin-insensitive and may modify their condition through diet and oral agents. Their reliance on insulin is less than patients with Type 1 diabetes, and they tend to be less motivated and slower to adopt new glucose monitoring technologies or treatments. Developers therefore need to be fully *au fait* with patients' medical needs and drivers in order to penetrate the market and establish brand loyalty.

35 Milios, M. Motivation How to Take Action — Even When You Don't Really Feel Like. Published November 21, 2011, updated December 3, 2014 Demystifying It. Retrieved from <https://www.diabetesselfmanagement.com/managing-diabetes/emotional-health/demystifying-motivation/>

- **Digital apps, a cost-effective solution for Type 2 diabetes.** Digital apps provide a cost-effective means towards helping people living with Type 2 diabetes better manage their disease by offering guidance with life care management and the tracking of glucose levels. These apps not only support the management of illnesses but are also aimed at promoting health awareness and well-being in a cost-effective manner.
- **Opportunities to adopt digital technologies for customising diabetes care.** The adoption of digital technologies presents developers with unique opportunities to tailor the care that diabetics receive and may help reduce the need for traditional face-to face interventions. For instance, while patients with Type 2 diabetes may not need, or are less motivated, to take on the latest CGM tech or insulin pumps, there are significant opportunities to expand the use of digital tech for the remote management of these patients.
- **Closed-loop systems provide an innovative solution for Type 1 diabetics.** The launch of several hybrid closed-loop systems that mimic the action of the pancreas on insulin release have helped many patients with Type 1 diabetes to normalise their lives. However, there is a need to make the devices and mApps simpler to use, both for the healthcare provider and end users.
- **Better diagnosis, management, and glycaemic control.** Innovation is dependent on patient needs. Better diagnosis of the disease is being driven by diabetes associations and research foundations that directly support and interact with the diabetes community, unlike pharmaceutical companies that cannot easily do so due to compliance guidelines. The value of collecting patients' clinical data and storing it in centralised facilities such as on electronic health records is also being recognized as a method of helping manufacturers understand what kind of adjustments should be made to help patients achieve better glycaemic control.
- **CGMs greater penetration in Type 1 than Type 2 diabetes.** While patients with Type 1 diabetes are more likely to adopt CGM technology because of their greater clinical need for close monitoring of their glucose levels, the launch of Abbott's FreeStyle Libre system in the US tipped the scales for CGM, making it affordable and accessible for a wider patient population. It also provides the means of educating patients with Type 2 diabetes about the importance of better glucose monitoring.

- **Digital technologies building patient confidence.** Major players in the diabetes market, in terms of pharmaceutical and medtech manufacturers, want to build brand loyalty with customers by employing a strategy involving great patient interaction and sharing of medical information. This has led to corporate partnerships where an insulin manufacturer teams up with medical device and digital technology companies to provide a more holistic approach to diabetes management.
- **Digital technologies are building relationships and educating the end-user.** Quality of life for patients is a major objective that digital technology companies are striving to achieve. While older adults who developed Type 2 diabetes may look at their condition entirely differently from those who developed Type 1 diabetes as a child, all patients want to live a disease-free life if possible, or at least a life that is not dominated by managing or being concerned about their disease. Therefore, improving how people feel about their condition, their confidence in managing it, and their ability to prevent the complications that arise from diabetes, is a key consideration for all those in the diabetes healthcare sector.

Supporting quotes

Different digital strategies for Type 1 and 2 diabetics

“I think we have to recognize that diabetes is a spectrum of people between the two major types, Type 1 and Type 2. Type 1 patients typically are highly influenced and motivated and tend to be adapters of technology whereas Type 2 diabetics tend to be older, less likely to embrace technology. Therefore, strategies to penetrate the Type 2 market are not the same as Type 1 patients. For instance, people with Type 2 diabetes rarely use an insulin pump, and that’s not likely to change for a couple of reasons; they have better therapies that obviate the need for insulin pumps, and many people don’t have absolute insulin deficiency.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“In the context of Type 2 diabetes, digital alternatives to the traditional, face-to-face approach of diabetes prevention and management interventions are now clinically validated, widely recognised to improve outcomes, and are being delivered at scale. Changing Health’s own digital technology for Type 2 diabetes management, which comprises a platform on which users can deliver behaviour change programmes, is being commissioned at scale to empower users to sustain positive lifestyle

changes and better manage their condition. Separately, Changing Health is also one of five providers delivering the digital stream of the NHS Healthier You Diabetes Prevention Programme (DPP). Our programme combines digital education on lifestyle, metabolism and Type 2 diabetes with personalised health coaching delivered over the phone.”

Mike Trenell, founder and CEO of Changing Health

“The Type 1 patient tends to be either juvenile or [they are] adults that have Type 1 but they’ve lived with it [and been] diagnosed at a later age. That’s a much smaller market, so that is more the insulin pumps and CGM, the closed-loop systems. For the Type 2 patients, traditionally, it’s always been orals, more than insulin injections, [for treatment]. If you have a very savvy doctor, he or she may push a pump onto their patient. I’ve seen that doctors are very comfortable with continuing to treat their Type 2 patients with multiple daily injections; they may still be doing orals, but as the disease progresses, they are switched over to insulin. We’re seeing doctors putting Type 2 patients on Abbott’s Libre and the Type 2 population are adopting newer technology. We’re also seeing new pens that are tracking patients’ total daily insulin doses, and it’s also communicating with apps for those patients. I just think that it’s going to take a little while longer for people to really get comfortable [with these new technologies] and for the pharmaceutical companies to really educate and change the habits of the doctors in the area.”

Heidi Soto, Area Business Manager, MannKind Corporation

“People with Type 2 that have reached the stage where they need a pump are beginning to look a little bit more like Type 1. They probably have a very reduced ability to secrete insulin from their beta cells. And the converse is also true too, people with Type 1 are beginning to look a little bit like Type 2, in the sense that our entire population is getting more obese, insulin resistance is getting higher, and even if you have Type 1 now, all of a sudden you may begin to have a level of insulin resistance on top of your insulin deficiency. What we really need are algorithms that can take into account what is the actual insulin resistance or insulin sensitivity, and then adjust recommendations (or AI-directed protocols), whether it’s for insulin delivery with a pump, via multiple daily injections, or other medications. This includes the oral medications you’re providing in order to account for the levels of insulin resistance and sensitivity.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

Digital apps a cost-effective solution for Type 2 diabetes

“What excites me about digital apps in particular is that they are cost-effective, relatively low-energy approaches which help people with Type 2 diabetes to manage their disease, starting with simple apps that can assist in losing weight, which is obviously an important part of managing the disease. Outside improving the diet, I see digital apps that help with both life care management and tracking glucose levels, glucometers as opposed to continuous glucose monitoring, which is not going to be typically used in the Type 2 world.”

Alexander Fleming, MD, Executive Chairman, Kinexum

Opportunities to adopt digital technologies to personalise therapy

“Digital support for Type 2 diabetes prevention and management, delivered via smartphone, tablet or web app, is proven to improve outcomes and increase uptake. That’s because, unlike face-to-face interventions, participants aren’t required to travel to attend a classroom session at their own expense during the working week. This recognition has led to these programmes being commissioned at scale.”

Mike Trenell, founder and CEO of Changing Health

Closed-loop systems provide an innovative solution for Type 1 diabetics

“In type 1 diabetes, you have so-called closed-loop systems, which consist of the insulin pumps, that are controlled by real-time measurement of glucose levels, that contain glucose monitoring technology. That’s a very exciting prospect for people with Type 1 diabetes. Insulin is not likely to penetrate the Type 2 market in the foreseeable future. Apps that collect data and to some extent manage it and can convert it into advice for testing and dosage are increasingly being used.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“I think innovation is dependent on patient needs. For example, a closed-loop system that is truly closed-loop or a glucagon that is stable. Now we have a powdered glucagon that never existed before that’s being marketed by Lilly. But there are lots of different hormones that are responsible for blood glucose regulation; that is what would be of interest to research and provide products that would address medical needs.”

Heidi Soto, Area Business Manager, MannKind Corporation

“Insulin pumps impact a small segment of Type 2 diabetes patients because oral and non-insulin injectable agents are doing such a phenomenal job. But there is no doubt that there will be some that will still benefit. And developers haven’t probably maximized that market yet.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

Better diagnosis and management and glycaemic control

“I would say [disease] diagnosis is being driven by diabetes associations such as the ADA [American Diabetes Association] or JDRF, the Juvenile Diabetes Research Foundation. They are the organizations that are supporting the diabetes community. Whereas, the pharmaceutical companies and manufacturers can’t target patients directly [when it comes to diagnosis] as that’s not within compliance guidelines.”

Heidi Soto, Area Business Manager, MannKind Corporation

“I think the value of data is recognized, particularly in Type 1 patients. These data help to understand what kind of adjustments should be made to help the patients’ management of the glycaemic control. Having all the data that can be collected and that are relevant to the condition is certainly very valuable, and for many Type 1 patients, they are all over it.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“From my perspective, electronic medical records (EMRs) offer a good opportunity for a digital approach whereby everybody across those hospital and ambulatory environments are using one EMR, so you can now pull out information, diagnostic criteria, and identify people with diabetes, prediabetes or even a gestational diabetes category. You can pull out people that are at risk for diabetes and stratify them based on laboratory data and risk characteristics, even on data such as the number of hospitalizations each year or the last 10 years. The EMR holds a lot of useful data.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

CGMs greater penetration in Type 1 than Type 2 diabetes

“There are many cases where patients are actually taking the initiative and developing their own closed-loop systems. That’s a relatively small group of people but it highlights the spectrum of patients who are involved. In the Type 2 world I think we’re not going to see penetration of these technologies nearly as much, even though I think CGMs could benefit a lot of people, particularly those who have to be on insulin. The real vanguard is going to be the Type 1 patients.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“The biggest impact that I’ve seen in the last two years specifically, is the CGM market and the platform. The tables were turned when Abbott launched Libre in the US; it really tipped the scale around CGM, making it affordable, accessible and educating patients because they went after the Type 2 market, which is something that Dexcom didn’t really do. Dexcom focused on Type 1s and making it mainly accessible to them, because of coverage and marketing. Whereas when Abbott came into the market space, that really turned things into really helping the diabetes community, specifically the Type 2s, have access to this technology.”

Heidi Soto, Area Business Manager, MannKind Corporation

“I think two different things impact CGM penetration. One is the desire to reduce comorbid conditions and then the other is the desire to decrease acute hypoglycaemia. The overall goal is to avoid long-term complications 10 to 15 years down the line. This is probably moderated by some genetics components because there are some people that can have perfect control and still develop some of the comorbid conditions, but control of glucose does play a very significant role. Obviously CGMs are allowing us to get there much better by controlling glucose levels. A CGM that’s connected to a pen or pump definitely provides better control than either of these alone. Also, the ability to share data via cloud-based management is another part of the digitization of medicine that is contributing to better care. This allows patients, providers, health coaches, and care givers to view aggregated data and communicate with each other.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

Digital technologies are building relationships and educating the end-user

“All of the major players in the diabetes world, both on the pharmaceutical side and the technology side, want to build brand loyalty, and part of that strategy involves integration. You see corporate partnerships where an insulin manufacturer partners with a digital [and medical] technology company to provide a more holistic approach. Now, you can say that this is just a marketing strategy, but I think it certainly has a very positive effect of getting people to do better by putting all the tools to bear on their problem, and so the question is how successfully has this been done? The potential is readily understood. The actualization is going to be slower in coming.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“As an example of how Changing Health can create brand loyalty for medical device manufacturers, Changing Health partnered with Nemaura, which supplies users with a non-invasive blood glucose monitoring device. The partnership gives users access to a Changing Health behaviour change programme, bespoke to Nemaura. This allows users to learn how to better manage their condition, make a sustained lifestyle change and monitor the effect on their diabetes in real time. It's one of the first such partnerships, showing Nemaura users how their device, and the accompanying behaviour change programme, is empowering them to better manage their health. That creates real potential to increase brand loyalty.”

Mike Trenell, founder and CEO of Changing Health

“There are certainly health coaching programmes that have been developed, which are not as intensive in their recommendations regarding insulin dosage but focus on encouraging patients to go out and exercise a little bit more or make changes in their diet. But any app that supports drug dose adjustment must be accountable for patient safety, so you must consider the legal ramifications.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

Digital technologies building patient confidence

“Patients want to live a disease-free life if possible, or at least a life as free of managing or being concerned about the disease as possible. There are older adults who developed Type 2 diabetes and they look at their condition entirely differently than those who had Type 1 diabetes as a child. They’re very different situations, but in general, all patients want to obviously be free of complications, and be free of worry about hypoglycaemia which is really the biggest life-limiting challenge for people who have to be on insulin. The quality of life for patients is a big target for these technologies, improving how people feel about their condition, their confidence for managing it, and their ability to prevent the complications of diabetes.”

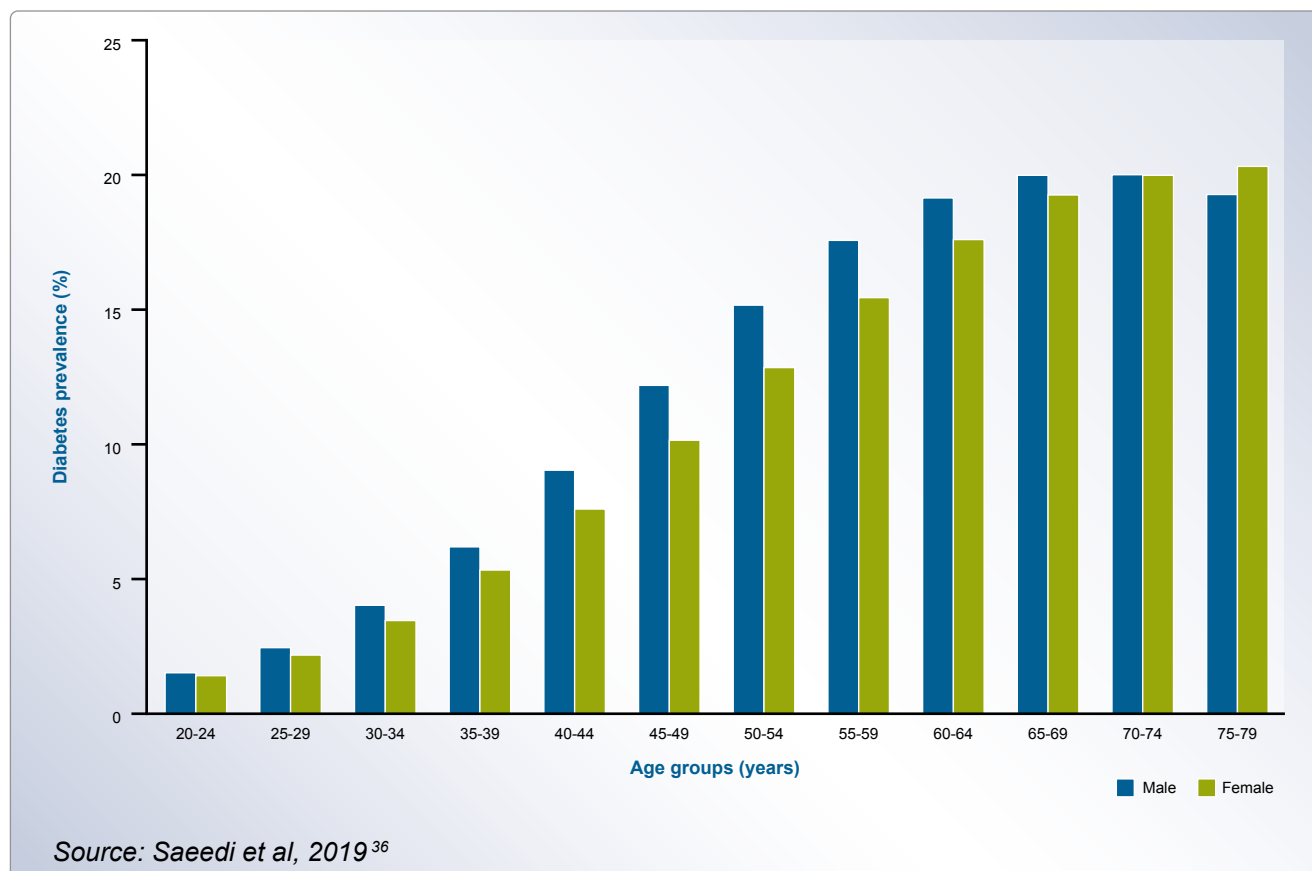
Alexander Fleming, MD, Executive Chairman, Kinexum

“Smart pens have been in the market here for about a year now, and that has filled a huge gap in the diabetes space, mainly for Type 2 patients. I know Type 1s can use it too, because it allows a patient to basically get rid of their log book for the most part and be able to track everything in that one device. It makes the management so much more seamless and more manageable for the patient.”

Heidi Soto, Area Business Manager, MannKind Corporation

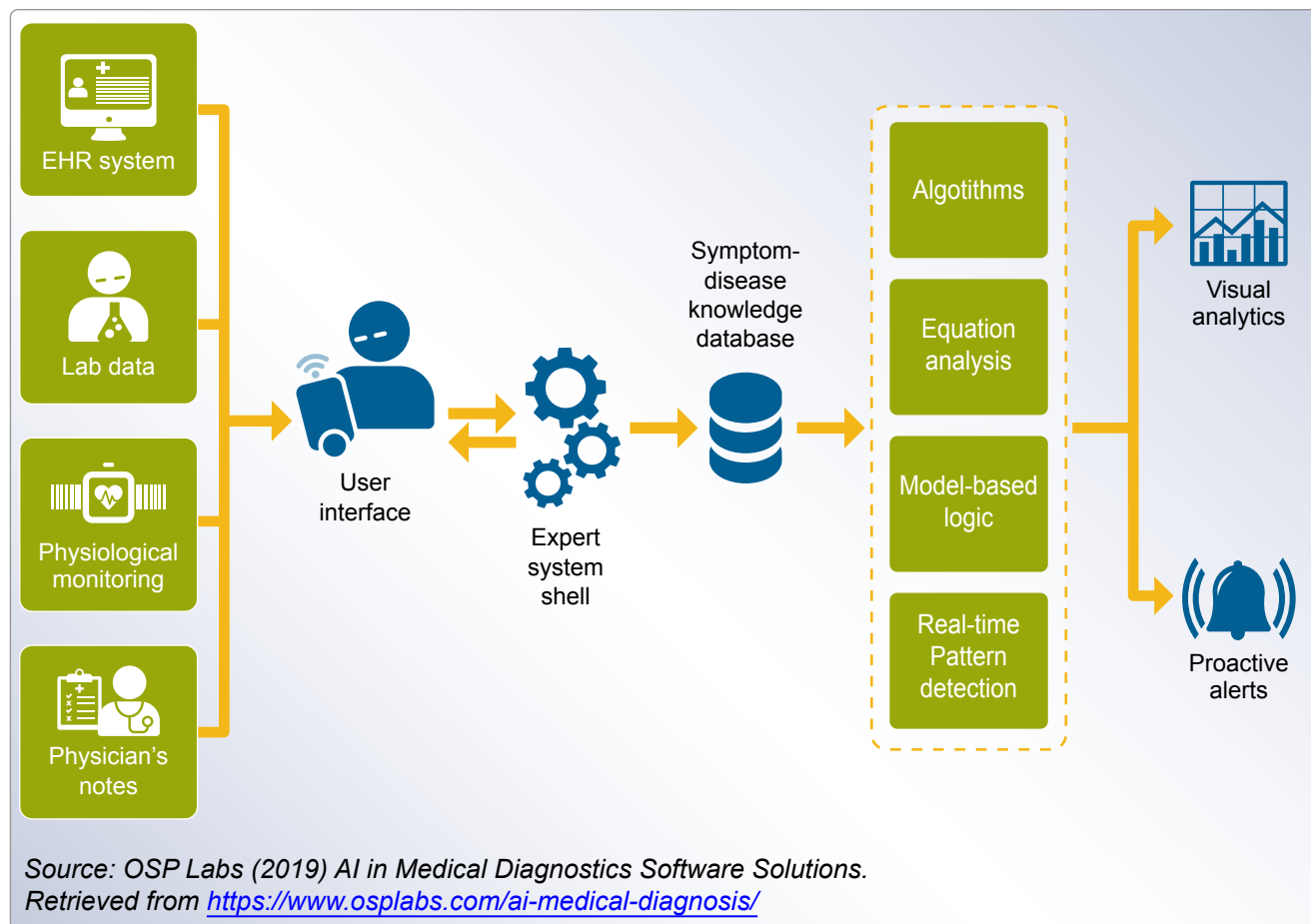
Intelligence exhibits

Figure 1: Diabetes Prevalence by Age and Sex in 2019



36 Saeedi P, Petersohn I, Salpea P *et al*. For 2019 and projections for 2030 and 2045: Results global and regional diabetes prevalence estimates from the International Diabetes Federation, Diabetes Atlas 9th Edition, *Diabetes Res Clin Pract*, 2019 Sept 10; 157:107843. doi: 10.1016/j.diabres.2019.107843. Epub 2019 Sep 10

Figure 2: Interface between digital technologies and end-users



Strategic alliances and investment in digital technologies

Issue summary

Pharmaceutical and medical device manufacturers continue to explore the role of digital technologies in order to provide more personalised and more targeted treatment options, as well as the day-to-day management of diabetes. There has been a flurry of activity as companies such as Abbott, Dexcom, and Medtronic develop new devices to improve the continuous monitoring of blood glucose.

According to a recent analysis by Informa's Meddevicetracker, CGMs are the driving force in the overall growth of the global blood glucose monitoring devices market, which is forecast to reach US\$13bn in 2023, with a CAGR of nearly 11%.³⁷ Sales of CGMs, which allow people with diabetes to track their blood glucose levels 24/7, with real-time readings every five minutes, and to monitor fluctuations, are expected to surpass revenue volume of traditional blood glucose meters (BGMs) by 2021. The report also noted that CGMs are expected to reach total sales of US\$9.3bn, nearly triple the volume of BGMs, which is expected to reach US\$3.5bn in 2023.³⁸

The total blood glucose monitoring devices market is divided into two segments – traditional blood glucose meters and complementary products, and CGMs and accessories – and is expected to grow from US\$7.7bn in 2018 to US\$13bn in 2023, with a CAGR of 10.5%.

The blood glucose monitoring market is highly fragmented with few major manufacturers boasting a global market presence, with the remaining manufacturers either confined to other local or region-specific manufacturers. Data published by Mordor Intelligence in 2020 indicate that the CGM market is dominated by Abbott, especially since the launch of its wearable CGM system Freestyle Libre in terms of overall market share (See [Figure 3, page 38](#)). Other major players include Roche, Medtronic, Ascensia Diabetes Care, and Dexcom.

37 Webb, M. Market brief: Abbot, Dexcom help drive continuous glucose monitoring market; 30% expected growth by 2023. 2019, Dec 26. Retrieved from <https://medtech.pharmaintelligence.informa.com/MT126051/Market-Brief-Abbott-Dexcom-Help-Drive-Continuous-Glucose-Monitoring-Market-30-Expected-Growth-by-2023>

38 Mordor Intelligence. Global blood glucose monitoring market: Growth, trends and forecast (2020-2025). 2020, Jan. Retrieved from <https://www.mordorintelligence.com/industry-reports/global-blood-glucose-monitoring-market-industry>

In 2018, North America, especially the US, held the largest share in the blood glucose monitoring market, due to the large patient pool and wide acceptance of advanced technologies. This was followed by Europe, which showed moderate growth. The Asia-Pacific region, Latin America, the Middle East and Africa showed low growth due to economic affordability (See [Figure 4, page 38](#)).

Given that diabetes continues to attract interest and investment from large pharmaceutical companies, this has resulted in a number of high-profile partnerships between pharma, medtech and healthtech companies in recent years. Examples include Abbott's partnerships with Sanofi, Novo Nordisk, and Tandem Diabetes Care, among others; Nemauro Medical and Changing Health; Astellas and Welldoc; and Livongo and Dexcom, to name a few. Pharmaceutical and medtech companies are placing particular emphasis on finding 'connected care solutions,' or solutions that transmit patient data between different service providers, that enable better-integrated care.

Focus is also shifting to finding solutions that improve patient monitoring in order to address irregularities quickly.³⁹ Better data availability and data transparency are key drivers for developing and using new digital solutions in the most effective way. However, there is often still a need for advice on fundamental issues, such as defining the overall vision and strategy for digital solutions or designing the optimal direct or indirect monetization strategy. For these reasons, partnerships between pharmaceutical and medtech firms, as well as with Information Technology (IT) specialists, have begun to play a key role.

The need for interoperability between diabetes devices is widely recognized in the industry. Tandem's t:slim X2™ insulin pump was the first to receive US Food and Drug Administration (FDA) clearance in a new device category called alternate controller enabled (ACE) infusion pumps, early in 2019.⁴⁰ The t:slim X2 insulin pump is capable of remote software updates using a personal computer and features integrated continuous glucose monitoring. The special controls for ACE pumps

39 The Journal of mHealth. 72% of pharma and medtech companies hope to launch new business models with digital solutions. 2019, May 2. Retrieved from <https://thejournalofmhealth.com/72-of-pharma-and-medtech-companies-hope-to-launch-new-business-models-with-digital-solutions/>

40 Abbott Press Release. Abbott and Sanofi partner to integrate glucose sensing and insulin delivery technologies to help change the way diabetes is managed. 2019, Sep 16. Retrieved from <https://abbott.mediaroom.com/2019-09-16-Abbott-and-Sanofi-Partner-to-Integrate-Glucose-Sensing-and-Insulin-Delivery-Technologies-to-Help-Change-the-Way-Diabetes-is-Managed>

create the opportunity for a reliable and secure communication with compatible external devices, such as Abbott's *FreeStyle Libre* system, which provide people with diabetes the ability to select tools and tailor their diabetes management to best meet individual needs.⁴¹ The FDA's new interoperable designations for the various components of automated insulin delivery systems are therefore making integrations of advanced technologies more straightforward, thus underpinning partnerships such as that between Abbott and Tandem ([Table 1, page 34](#)).

While medtech companies will continue to innovate on their own, they may find an advantage in partnering with consumer-tech companies, which would allow greater access to consumers and sophisticated data analytics. Partnerships with consumer-tech firms could help medtech companies innovate and stay relevant as healthcare turns increasingly to prevention and wellness.⁴² It is foreseen that data collected from the hardware will soon be more valuable than the hardware itself, given that what will differentiate medtech companies from each other will be their ability to harness data gathered by their devices and use it to improve the well-being of patients, thus anticipating health issues and helping patients change the day-to-day behaviours that affect their health.

Questions

- Do medtech companies need to forge strategic alliances with IT specialists to maximise their digital technologies business opportunities?
- What has fuelled recent partnerships, acquisitions, and divestments between medtech companies and digital specialists during the last five years?
- What key factors will ensure that investment continues in this field?

41 Abbott Press Release. Abbott and Tandem Diabetes Care Exploring new integrated solutions to improve diabetes management. 2019, Oct 15. Retrieved from <https://abbott.mediaroom.com/2019-10-15-Abbott-and-Tandem-Diabetes-Care-Exploring-New-Integrated-Solutions-to-Improve-Diabetes-Management>

42 Berg J. MedCity News. Partnerships with consumer-tech firms could help medtech companies innovate and stay relevant as healthcare turns increasingly to prevention and wellness, according to a new report from Deloitte. 2019, Oct 2. Retrieved from <https://medcitynews.com/2019/10/new-report-says-partnerships-key-to-future-success-for-medtech-firms/>

Key insights

- **Big data driving partnerships.** The complexity of the data that is emerging, in multiple forms, is making it increasingly important for large companies to either acquire the capability of processing the information themselves, or to partner with organizations that can complement what they do. Partnerships that would have been considered inconceivable a few years ago are now taking place as companies recognise that one size does not fit all, and end-users need elements of different products and services in a single solution.
- **Lifestyle, weight and diabetes management top of the agenda.** As the needs of health systems and patients' attitudes evolve, data-driven approaches to treat and prevent long-term conditions are transforming how people access care. Apps that help users to manage weight and support weight loss are helping to prevent diabetes, as well as enable diabetics to better manage their disease.
- **Different patient mindsets.** Type 1 diabetes patients as a group tend to embrace technologies, including digital apps, insulin pumps, and CGM systems, which typically involve phone apps that are integrated into the system itself. Because of the way diabetes is differentiated between Type 1 and Type 2 sufferers, Type 1 patients exhibit more loyalty to an app due to less frequent changes in their regime, unlike Type 2 patients who may have to change their treatment protocols every 9+ months.
- **Price and reimbursement tied to clinical outcomes.** Insurers of chronic diseases are moving towards paying for performance, and precedence will be given to technologies that encourage better clinical outcomes. In the US, medical devices fall into the category of 'durable medical equipment', forming a different part of the patient plan. These contracts last for up to four years, so once a patient has chosen a medical device or a pump, they are committed to it for four years if they stay with the same health insurance provider.
- **Interoperability and data security remain a challenge.** Issues surrounding data security remain a challenge. As such, companies are spending a lot of money on developing secure cloud-based platforms. For instance, diabetics are particularly concerned with how secure data is in relation to insulin pumps, to prevent anyone hacking into the pump or into the medical device with the aim of injuring and causing harm to a patient. There are also significant challenges for

healthcare practitioners to navigate through all the different apps and devices currently on offer, since every company is using a different platform and has a different approach. Improvement in interoperability is essential to improve the communication between digital technologies, users, and healthcare practitioners.

Supporting quotes

Big data driving partnerships

“I think the complexity of the multiple forms of data that are becoming available, has made it increasingly important for large companies to either acquire the capability of productively using that information or to partner with organizations that can complement what they do. We have also seen some major changes in the terrain, for example, Sanofi, which has had the biggest diabetes franchise of all pharma companies, has actually pulled out of diabetes innovation. I mean, they’re still going to maintain their existing products, but it was quite a shock that they’re actually getting out of the R&D side of diabetes. I think that’s a real concern from the macro-level that there’s a great attraction of targeting cancer with the sophisticated approaches, advanced therapies and so forth, and that is diverting investment away from chronic disease, diabetes in particular. I do see this as a big challenge.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“We’re going to see lots of partnerships in 2020 that would have been considered unlikely a couple of years ago, as companies start to recognise that one size doesn’t fit all and that end-users actually need elements of different products and services in the same package. I predict we’ll see sectors like big pharma, diagnostics, and digital health coming together to provide a single service to the end-user.”

Mike Trenell, founder and CEO of Changing Health

“I think device manufactures have a lot of medical expertise that they pulled in internally plus they do reach out to professionals all the time to advise and consult. With digital technologies they are seeking partnerships for both medical and engineering solutions if they do not have the depth internally.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

Lifestyle, weight and diabetes management top of the digital agenda

“I think one of the major disappointments is that you’ve got so many more therapies and technological approaches for people with Type 2 diabetes than Type 1 diabetes, but overall, there’s been very little progress made in getting glycaemic control better than it has been in the past. I think that just speaks to challenges in penetrating the market to prescribe therapies, and complying with patients and their caregivers to do that. That involves a lot of lifestyle factors and development, and it is very tough to deal with. Again, the positive thing is that you can start to use more of these apps that help to manage weight, support weight loss, and this can help to prevent diabetes as well as to better manage it.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“As health systems’ needs and patients’ attitudes evolve, data-driven approaches to treating and preventing long-term conditions are transforming how we access care. Disruptors are taking us closer to precision medicine and true patient-centricity, improving outcomes at scale with tech. The ‘enablers’ of digital health innovation – that is, regulators and governmental organisations – are smoothing the route to market for earlier stage start-ups and allowing for clinical validation at scale for those at mid-stage.”

Mike Trenell, founder and CEO of Changing Health

“The main challenge is that each individual with diabetes requires a personalised approach, so it’s a bit difficult to create standardized algorithms that apply across an entire population. Every person has so many different things that apply; one standard algorithm doesn’t necessarily achieve the outcome you’re looking for, and might put them at risk as well. In the future AI could help support physicians and help guide recommendation but I don’t know if anyone has enough data to allow the extensive level of personalization that is required. Maybe the UK National Health Services Database has enough, due to its long history of capturing aggregated data. Additionally, I am not sure if a patient will accept recommendations made by an AI-driven protocol. Recommendations in real-world environments not only incorporate evidence-guided approaches and best practice, but also the psychologic position of each patient.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

Commercial challenges for digitising diabetes technologies and education

“I think we see a tale of two different patients, and the Type 1 patients who are clearly, as a group, embracing technology in general. That includes the digital apps and it includes, of course, insulin pumps and continuous glucose monitoring. Those products typically involve phone apps that are integrated as part of the system. They make it more convenient to use and monitor for the pump, and to collect the data which in turn give feedback for better management of the conditions. That is happening much more in the Type 1 community.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“Patients are more likely to be involved with their app use if they are Type 1 because of the way the disease differentiates for Type 1s versus Type 2s. Type 2s may only stay on a drug perhaps nine to 11 months, and maybe then have a new drug added on their treatment protocol. Their consistency or loyalty to that app may not be there as much because it’s basically a journey of adding more medications for these patients.”

Heidi Soto, Area Business Manager, MannKind Corporation

“I think education of how to use these smart devices is important because often providers don’t know how to use them and some of the devices are still a bit complex to use. The pen with the best built-in algorithms is the InPen which was designed by a person with Type 1 diabetes. He created some amazing algorithms that work similar to pump calculations and reports for communication purposes, but it still has some operational difficulties that can create challenges for older and even younger people. We need to get simpler devices from the app connectivity to inserting cartridges. If we could easily allow patients to use them that could change the way patients care for their own disease.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

Price and reimbursement tied clinical outcomes

“Type 2 patients that are not even on insulin, or at least if they are, it’s a low basal dose, they would not require as much concern over glucose monitoring, and continuous glucose monitoring is pretty low. We’re just not seeing the uptake of the technology in the Type 2 world in general, and that’s probably not going to change. But clearly, that is where the world is going in terms of paying for care of chronic disease; it is moving towards paying for results and not for effort. I think part of the

solution is going to be in having technologies that will actually finally encourage better performance, and better clinical outcomes. But we'll have to document it, and so to the extent that you have the glucose data, you can actually show, and much more readily, these patients who are controlling their glucose levels better."

Alexander Fleming, MD, Executive Chairman, Kinexum

"When we look into medical devices, they don't go under the pharmacy benefit in the US for insurance. They go under diagnostic tool coverage, which would be for the CGMs. Abbott was very smart [with their CGM strategy]; they can now bill the Abbott Libre through either the pharmacy benefit or they bill it through their diagnostic benefit for the patients. Conventional diabetes medical devices, they fall into durable medical equipment, so it's a different part of the patient's plan. Plus, those are contracts that last about four years so once a patient has picked up a medical device or a pump, they are committed [to stay] with it for four years if they stay with the same health insurance. If they change to a new health insurance because they got new employment, then they can get another device maybe within a year or two or earlier, before the contract is up."

Heidi Soto, Area Business Manager, MannKind Corporation

"Reimbursement in the U.S. is tied to performance measures, for instance. HbA1c [haemoglobin A1c] levels is the gold standard in Type 2 patients; it would be much more difficult to measure complications and reimbursing based on the success of reducing complications. We're going to be looking at things that are more graspable such as glucose levels and hospitalizations, and utilization of healthcare resources."

Alexander Fleming, MD, Executive Chairman, Kinexum

"Here in the UK, Health Secretary Matt Hancock is, of course, champion of all things digital. Having launched an entirely new NHS organisation, NHSX, to accelerate digital innovation in healthcare, health service chiefs now plan to 'take a step back and let the innovators innovate.' They'll move to a demand-led system of 'collaboration, iterative development, testing and learning in real-world settings.' That's good news for patients and innovators alike; a more hands-on approach to adopting new treatments in the UK, spearheaded by a dedicated NHS organisation, means commissioners can horizon scan more effectively while digital health companies can clinically validate and scale their products more quickly."

Mike Trenell, founder and CEO of Changing Health

Interoperability and data security remain a challenge

“I think [data] security is just going to be a continued challenge, and one that is the cost of doing business. It just has to be done; like protecting any other digital technology, it’s all part and parcel of the digital world we live in. We do have particular examples of where there have been security breaches, and measures are needed to be sure that there is no harm done in the systems that people are using.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“The US market is very litigious. The whole privacy thing is not that big of a concern to the US market as people are used to signing legal agreements when they’re accepting a product or app. But data security, on the other hand, is a big deal, and companies spend a lot of money on security platforms to make sure that the data is secure. People are concerned how secure the data is specifically with insulin pumps for example, so that no one can hack into the pump or hack into the medical device to injure and cause damage to that patient.”

Heidi Soto, Area Business Manager, MannKind Corporation

“Connectivity and data storage are still an issue. The information does not have to be all in one EMR, but we need to have a designated place to store and retrieve information that could integrate and aggregate all the needed information. It would be hugely useful for healthcare professionals to share information. Cloud-based technologies play a role and allow us all to access information faster to make better health decisions.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

“Interoperability is a very important development and the FDA has had a lot to do in encouraging that, following the approval of an inter-operative continuous glucose monitor approach. It’s hard to compete using a system that doesn’t work with other devices, and particularly insulin pumps. It’s good that it is happening, and it will make it more and more feasible to use all these technologies together. There’s still a lot of room for improvement. There are systems that still have glitches relaying to each other and limit the number of different technologies that can be used. In other words, the continuous glucose monitor has only so many ports that can talk to other devices, and so these are technical issues must be worked out but overall these interoperative technologies can be used and completely deployed by patients and with some confidence.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“Because every company is using a different platform and doing things differently, that’s a challenge for healthcare practitioners because of all the different apps and devices they’ve got to download in the office. Companies are spending the money to allow the patient to upload their information on their own and link it into an account so the doctors can view it online. I see a lot of the success of these apps, and in the patient’s wellbeing, when a platform makes it easy for the patient to upload their information into a cloud or some database that can be linked to the doctor.”

Heidi Soto, Area Business Manager, MannKind Corporation

“I would say that most people with diabetes feel secure with current data storage approaches. There have been a few questions from my patients that want to communicate with healthcare professionals securely yet easily and there are still no good ways to do this. People want to use their existing means of communicating such as text or their usual email for communication, but this still isn’t considered secure for health information. I think if people’s data and information were inadvertently released and it impacted their job, that would raise their level of concern, so data security is essential as some people may not understand the potential risks. They really just want a rapid way to communicate.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

Intelligence exhibits

Table 1: Examples of recent alliances and partnerships in the diabetes arena

Partnership	Deal details	Date
Abbott/ Sanofi	<p>Abbott entered into a partnership agreement with Sanofi to integrate its glucose sensing and insulin delivery technologies that would further simplify how people with diabetes manage their condition. The two companies are taking an innovative approach to connected care by developing tools that combine Abbott's revolutionary FreeStyle Libre system with Sanofi's insulin dosing information for the development of future smart pens, insulin titration apps and cloud software.⁴³ Abbott's FreeStyle Libre technology is a sensor-based glucose monitoring system that reads glucose levels through a sensor that can be worn on the back of the upper arm, thereby eliminating the need for finger sticks. The system has secured partial or full reimbursement in 34 countries, including Canada, France, Ireland, Japan, the UK and the US.⁴⁴</p> <p>The non-exclusive collaboration will initially enable data sharing, at the consent of the user, between Abbott's FreeStyle Libre mobile app and cloud software, and Sanofi's connected insulin pens, apps and cloud software which are currently in development. This data sharing will enable people with diabetes and their doctors to make better-informed treatment decisions relating to medication, nutrition, and lifestyle. Sanofi is currently developing connected pens, apps, and cloud software that will be compatible with the FreeStyle Libre system and its matching digital health tools. The two companies aim to launch this 'connected ecosystem' within the next few years, pending local regulatory approvals.</p> <p>As part of its expansion into diabetes digital therapeutics, Abbott further announced in October 2019 that it was entering into a partnership agreement with US-based Tandem Diabetes Care Inc., to develop and commercialize integrated diabetes solutions that combine Abbott's world-leading FreeStyle Libre glucose-sensing technology with Tandem's innovative insulin delivery systems to provide more options for people to manage their diabetes.</p>	September 2019

43 Abbott Press Release. Abbott and Sanofi partner to integrate glucose sensing and insulin delivery technologies to help change the way diabetes is managed. 2019, Sep 16. Retrieved from <https://abbott.mediaroom.com/2019-09-16-Abbott-and-Sanofi-Partner-to-Integrate-Glucose-Sensing-and-Insulin-Delivery-Technologies-to-Help-Change-the-Way-Diabetes-is-Managed>

44 Abbott Press Release. Abbott and Tandem Diabetes Care Exploring new integrated solutions to improve diabetes management. 2019, Oct 15. Retrieved from <https://abbott.mediaroom.com/2019-10-15-Abbott-and-Tandem-Diabetes-Care-Exploring-New-Integrated-Solutions-to-Improve-Diabetes-Management>

Table 1: Examples of recent alliances and partnerships in the diabetes arena *continued*

Partnership	Deal details	Date
Nemauro Pharma/ Changing Health	<p>Nemauro Pharma Ltd entered into a partnership agreement with fellow British firm Changing Health.⁴⁵</p> <p>The partnership is aimed at utilizing CGM data and daily glucose trend data provided by Nemauro's non-invasive SugarBEAT CGM, combined with Changing Health's evidence-based digital health coaching solutions to improve how people with Type 2 diabetes and pre-diabetes can manage, reverse and prevent their disease.</p> <p>Changing Health's current programmes for weight management, Type 2 diabetes management, and Type 2 diabetes prevention combine one-on-one health coaching that is rooted in behavioural psychology, with digital education tailored to the user's own needs. Changing Health is also partnering with NHS England to deliver digital support for up to 600,000 people with Type 2 diabetes, and is also one of five digital providers on the NHS Healthier You Diabetes Prevention Programme (DPP).</p>	December 2019,

45 Nemauro Medical News. Nemauro Medical and Changing Health announce partnership to provide award-winning diabetes behavioural change services. 2019, Dec 17. Retrieved from <https://nemauromedical.com/nemauro-medical-and-changing-health-announce-partnership-to-provide-award-winning-diabetes-behavioral-change-services/>

Table 1: Examples of recent alliances and partnerships in the diabetes arena *continued*

Partnership	Deal details	Date
Astellas Pharma/ Welldoc	<p>Astellas Pharma entered into a collaboration and licensing agreement with US-based Welldoc, aimed at jointly developing and commercializing Welldoc's BlueStar technology in Japan and other key Asian markets for patients with diabetes, as well as collaborating to broaden the adoption of BlueStar in the US market, and jointly developing and commercializing digital therapeutics in other medical areas globally.⁴⁶</p> <p>BlueStar is a digital health solution that has been approved by the US FDA for use by healthcare providers and their patients aged 18 years and older who have Type 1 or Type 2 diabetes. BlueStar not only assists patients in managing their disease by capturing, storing, and transmitting blood glucose data, and tracking medication, diet, activity, and exercise, but also uses individual patient treatment data and machine learning to provide tailored motivational, behavioural, and educational coaching messages to aid in diabetes self-management.</p> <p>BlueStar is sold as both a prescription and non-prescription digital health solution for diabetes and is currently marketed in the US and Canada. BlueStar also comes with a diagnosis support system for physicians, which allows patients to share data on blood glucose levels, medication, and physical conditions, as well as the status of progress, with physicians before examination. Under Astellas' Strategic Plan 2018, the company is committed to developing Rx+™ programmes, which aim to create new, clinically relevant healthcare solutions that combine expertise gained from its prescription drug (Rx) business with technology and knowledge from different fields.</p>	November 2019

46 Cision PR Newswire. Astellas and Well doc enter into strategic alliance for digital therapeutics. 2019, Nov 20. Retrieved from <https://www.prnewswire.com/news-releases/astellas-and-welldoc-enter-into-strategic-alliance-for-digital-therapeutics-300962552.html>

Table 1: Examples of recent alliances and partnerships in the diabetes arena *continued*

Partnership	Deal details	Date
Livongo/ Dexcom	<p>Livongo announced that it was partnering with Dexcom Inc. to offer Livongo Members the ability to synchronize data from Dexcom's G6 Continuous Glucose Monitoring System with the Livongo platform, thereby providing patients with access to key insights and Health Nudges™ from Livongo's Applied Health Signals platform, based on the company's CGM data.⁴⁷ The Dexcom G6 Continuous Glucose Monitoring system accurately measures glucose levels just beneath the surface of the skin and sends data wirelessly every five minutes. The G6 device includes a slim, water-resistant sensor that is discreet, easy to insert, and is FDA-approved, to make diabetes treatment decisions without the need for confirmatory finger sticks or calibration.</p> <p>The system features customizable alarms and alerts to warn users of dangerous glucose levels, even while they are asleep. Livongo's strategy of partnering with other innovative organizations across the healthcare ecosystem enables it to enhance its AI+AI engine and thereby provide an even better experience for Livongo Members. Through the partnership, Livongo can now aggregate data from the Dexcom's G6 Continuous Glucose Monitoring System, cross-reference with proprietary blood pressure and weight data from its connected devices, and then use advanced data science to interpret that data and offer Members personalized health insights, or "Health Nudges", based on the individual's comprehensive health profile. Joint Livongo and Dexcom Members will also have access to 24/7 support from Livongo's certified health coaches in order to manage their diabetes.</p> <p>A 2019 study in collaboration with US pharmaceutical major, Eli Lilly and Company, demonstrated that Livongo for Diabetes Members were more empowered and less distressed in diabetes self-management, when compared to non-Members. A separate study published in the Journal of Medical Economics in 2019 found that the Livongo for Diabetes Program delivered a US\$88 per member monthly reduction in medical spending for Livongo Members and that employers experienced a positive return on investment in one year.⁴⁸</p>	January 2020

Source: Author's own research, 2020

47 Livongo Press Release. Livongo and Dexcom partner to integrate Dexcom's G6 Continuous Glucose Monitoring System into Livongo's Applied Health Signals platform.

Retrieved from <https://ir.livongo.com/news-releases/news-release-details/livongo-and-dexcom-partner-integrate-dexcoms-g6-continuous>

48 Whaley CM, Bollyky JB, Lu W *et al.* Reduced medical spending associated with increased use of a remote diabetes management program and lower mean blood glucose values, *J Med Econ*, 2019, Sep ;22(9):869-877. doi: 10.1080/13696998.2019.1609483. Epub 2019 May 8

Figure 3: Global Blood Glucose Monitoring Market by Market Share (2018)

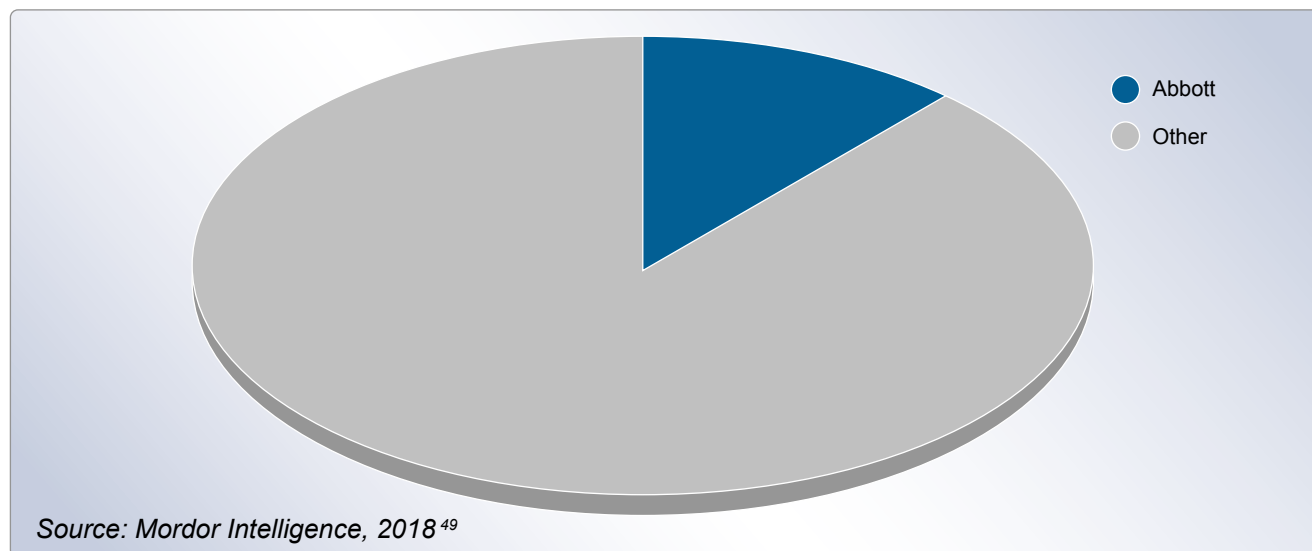
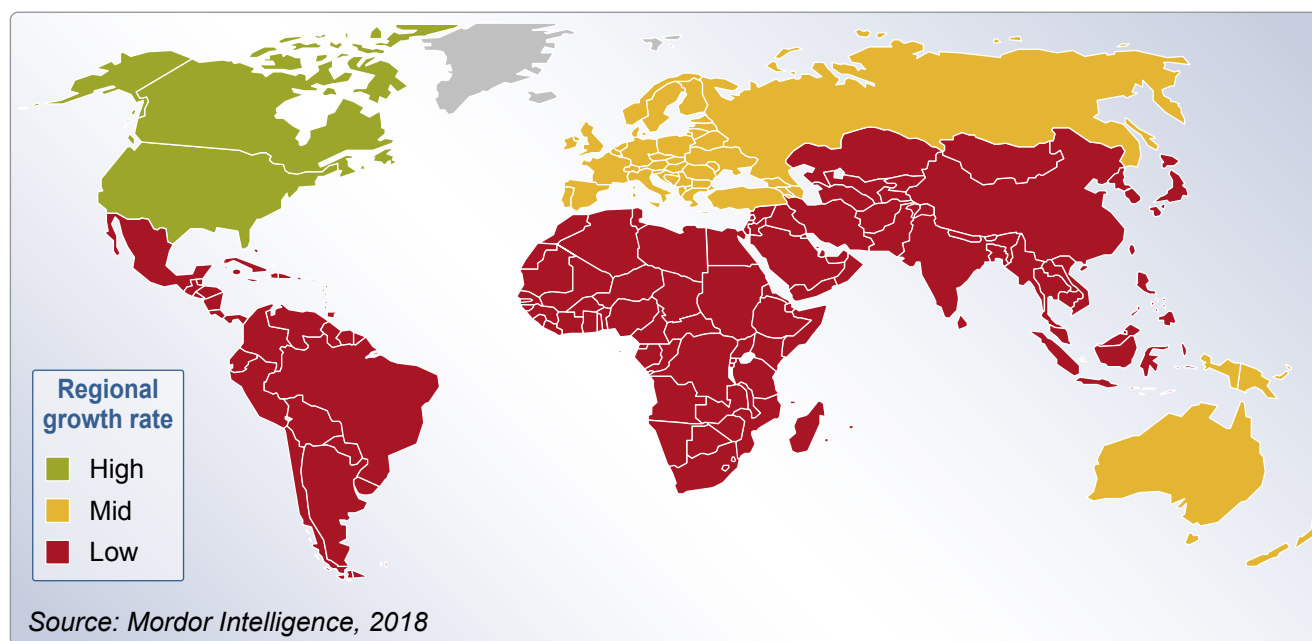


Figure 4: Global Blood Glucose Monitoring Market, Growth Rate by Region (2018)



49 Mordor Intelligence. Global blood glucose monitoring market: Growth, trends and forecast (2020-2025). 2020, Jan. Retrieved from <https://www.mordorintelligence.com/industry-reports/global-blood-glucose-monitoring-market-industry>

Challenges and solutions

Issue summary

The most commonly used method of blood glucose testing continues to be the finger prick test, which consists of analysing a drop of blood resulting from a finger prick. However, this method has significant drawbacks as it does not allow for continuous monitoring, and is invasive, cumbersome and expensive.⁵⁰ As an alternative, CGM technology provides people living with diabetes real-time readings of their blood glucose levels via a sensor that is inserted under the skin. The technology offers continuous measurement of current glucose levels and provides insight on the direction and rate of change in glucose levels. This information allows people with diabetes to optimize dietary intake and exercise and make informed care decisions regarding mealtime and correct insulin dosing.⁵¹ CGM also enables people with diabetes to respond immediately and appropriately to a decrease in glucose levels, or to prevent acute glycaemic events.

Although CGM devices significantly empower diabetic patients, they still present some limitations that make them unattractive for pre-diabetic patients and diabetics. Commercially-available CGMs can be worn for a limited number of days (usually between seven and 14 days) and most devices still require finger prick calibration. In addition, CGMs are quite expensive, which may further limit their use for continuous daily glucose monitoring, especially in pre-diabetic patients. Despite these imperfections, recent research has revealed that CGM devices do overcome the limitations of self-monitoring of blood glucose through glucometers by providing a complete glucose profile and a detailed history of the patient's nocturnal glucose levels.⁵²

While CGMs are helping to improve glucose control in diabetic patients, several non-invasive (without skin penetration) technologies are also emerging. These devices are leveraging techniques such as Raman spectroscopy, fluorescence technology,

50 Porumb M, Stranges S, Pescape A *et al.* Precision medicine and artificial intelligence: A pilot study on deep learning for Hypoglycaemic events detection based on ECG. *Sci Rep.* 2020, Jan 13; 10(1):170. doi: 10.1038/s41598-019-56927-5

51 American Diabetes Association. New for Time-in-Range targets during Continuous Glucose Monitoring presented today at the ADA's Scientific Sessions. The Advanced Technologies & Treatments for Diabetes (ATTD) Congress. 2019, Jun 8. Retrieved from <https://www.diabetes.org/newsroom/press-releases/2019/new-recommendations-for>

52 Beck RW, Riddlesworth T, Ruedy K *et al.* Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. *JAMA.* 2017, Jan 24; 317(4):371-378. doi: 10.1001/jama.2016.19975

optical coherence tomography, and optical polarimetry, all of which aim to exploit the changes in the chemical and physical tissues' properties determined by glucose variations. Although these devices show considerable promise, the underlying technology still needs improvement, in order to make them more accurate, more comfortable to wear, operate, maintain, and calibrate. Nonetheless, advances are being made on several fronts ([Table 2, page 50](#)).

At the American Diabetes Association's (ADA) annual conference held in June 2019, interest from physicians and investors in adopting CGM technology continued to surge, amid growing use of the technology by Type 1 diabetes patients. It was also noted that manufacturers are similarly looking to exploit the under-penetrated insulin-dependent Type 2 diabetes market, which currently has a population of at least 1.5 million people in the U.S.⁵³ Evidence suggests that CGM is continuing to build momentum towards becoming the standard of care for Type 1 diabetes patients, but data also suggests an increased interest in CGM use within intensively-managed Type 2 diabetes patients.

The ADA meeting was also a platform for publicising a new international consensus on Time-in-Range (TIR) standards, which were developed by a group of 43 physicians, researchers, and individuals with diabetes, who were tasked with creating guidance on how to best interpret and report CGM data for various Type 1 and Type 2 patient groups, including pregnant women and older individuals. The group's objective was to develop evidence-based, clinical CGM targets to supplement the currently agreed-upon metrics for CGM-derived times in glucose ranges (within target range, below target range, above target range) in order to provide guidance for clinicians, researchers, and individuals with diabetes to utilize, interpret, and report CGM data in routine clinical care and research. Although unified recommendations for the use of key CGM metrics have been established, formal adoption by diabetes professional organizations and guidance in the practical application of these metrics in routine clinical practice have been lacking.

While the panel maintained that CGM-based glycaemic targets must be personalized to meet the needs of every individual with diabetes, the group reached consensus on glycaemic recommendations based on data extracted from large pre-CGM clinical

⁵³ American Diabetes Association. New recommendations for Time-in-Range targets during Continuous Glucose Monitoring presented today at the ADA's Scientific Sessions. The Advanced Technologies & Treatments for Diabetes (ATTD) Congress. 2019, Jun 8. Retrieved from <https://www.diabetes.org/newsroom/press-releases/2019/new-recommendations-for>

trials, CGM randomized controlled trials, and expert opinion. These recommendations were as follows: a target range of 70-180 mg/dL [3.9-10.0 mmol/L] for individuals with Type 1 and Type 2 diabetes and 63-140 mg/dL [3.5-7.8 mmol/L] during pregnancy, along with a set of targets for the time in the target range per day. It was concluded that “In a clinical practice setting, TIRs are both appropriate and instrumental outcome measurements that, like A1C levels, are an integral component of treatment decisions.” Thus, the adoption of a common consensus has significant implications on clinical practice; as TIR continues to become more prevalent in clinician offices, it can be expected that more and more patients will be recommended CGM, which as it stands, is the only tool available to measure time in range.⁵⁴

According to Viral Shah, assistant professor of medicine and paediatrics at the Barbara Davis Centre for Diabetes at the University of Colorado, in Denver, US, “a CGM, coupled with an insulin pump, offers patients more flexibility, because the algorithm in the embedded sensor modulates insulin delivery throughout the day and night, which helps patients stay within set glycaemic targets.”⁵⁵ Developing systems that help patients achieve better glycaemic control therefore remains a major goal of insulin pump manufacturers. To this end, insulin pump manufacturers aim to improve TIR, or time spent in ‘normal glucose levels’, to 80% or more, helping diabetic patients maintain normal glycaemic levels most of the time.

According to a report published by Research and Markets in 2019, global sales of automated insulin pumps (and supplies) are expected to increase at a double-digit CAGR of more than 12%, rising from US\$2.9 billion in 2018 to US\$5.1 billion in 2023.⁵⁶ The global insulin pumps market is divided into two types: traditional insulin pumps and disposable insulin pumps. While traditional insulin pumps are currently dominating the market, with a share of 55.7% in 2016, disposable insulin pumps are expected to reach sales of US\$ 3.9 billion in 2023, up from US\$ 2.1 billion

54 Rachal M. Device interoperability, CGM for Type 2 patients among ADA 2019 standouts. 2019, Jun 10. Retrieved from <https://www.medtechdive.com/news/device-interoperability-cgm-for-type-2-patients-among-ada-2019-standouts/556495/>

55 Webb M. Market Intel: After a year of partnerships, insulin pump manufacturers will face fierce competition in 2020. 2019, Dec 9. Retrieved from <https://medtech.pharmaintelligence.informa.com/MT125985/Market-Intel-After-A-Year-Of-Partnerships-Insulin-Pump-Manufacturers-Will-Face-Fierce-Competition-In>

56 Research and Markets. Diabetes Management: Insulin pumps market (2019). 2019, Sep. Retrieved from https://www.researchandmarkets.com/reports/4846720/diabetes-management-insulin-pumps-market-2019?utm_source=BW&utm_medium=PressRelease&utm_code=q4zpk&utm_campaign=1306218+-+Global+Insulin+Pumps+Market+is+Set+to+Grow+at+a+CAGR+of+Approximately+12%25%2c+Reaching+More+Than+%245bn+by+2023&utm_exec=cari18prd

in 2016.⁵⁷ The North American region holds the largest market share of the global insulin pumps market, standing at 45.1% in 2016 (See [Figure 4, page 38](#)). This is due to increasing technological advancement in the healthcare industry and a growing diabetic population. The European market is expected to reach US\$ 2.7 billion in 2023, up from US\$ 1.5 billion in 2016; while the Asia Pacific region is expected to be the fastest growing market with a CAGR of 8.9% during the forecast period 2016-2023.⁵⁸ Market drivers include the increasing prevalence of diabetes, low market penetration, strong demand, growing awareness and adoption, good reimbursement, good safety/efficacy, improvement in glycaemic control/time-in-range, technological innovation, expansion of indications (e.g. to younger patients, Type 2 insulin-dependent users), and highly lucrative insulin sets/disposables (pump supplies).⁵⁹

The insulin pumps market is dominated by four major players and several innovative start-ups. These include Ireland's Medtronic Plc. and US-based Tandem Diabetes Care Inc., Insulet Corp., and Valeritas Inc. According to a report published by Research and Markets (2019), three of the four major players, Medtronic Plc., Insulet Corp., and Tandem Diabetes Care Inc., are planning to introduce their next-generation hybrid closed-loop systems in the US as competitors race to produce more advanced, 'fully closed-loop' automated systems using AI and other improved features to more closely mimic the function of the human pancreas ([Table 3, page 51](#)).

Automated insulin pump systems, such as Medtronic's MiniMed systems, typically cost from US\$4,000 to US\$7,000 or more, not including disposables/consumables, which can add thousands of dollars per year.⁶⁰ In view of this, manufacturers are aware that there is a strong need to lessen patient burden, pain, and device complexity, while improving accuracy and glycaemic control, and lowering healthcare costs. In June 2017, Medtronic announced that it had signed an

57 Market Reports World. Global insulin pump market: Estimation and forecast, 2017-2025. 2017, May 20. Retrieved from <https://www.marketreportsworld.com/global-insulin-pump-market-10850836>

58 Market Reports World. Global insulin pump market: Estimation and forecast, 2017-2025. 2017, May 20. Retrieved from <https://www.marketreportsworld.com/global-insulin-pump-market-10850836>

59 Research and Markets. Diabetes Management: Insulin pumps market (2019). 2019, Sep. Retrieved from <https://www.researchandmarkets.com/reports/4846720/diabetes-management-insulin-pumps-market-2019>

60 Webb M. Market Intel: After a year of partnerships, insulin pump manufacturers will face fierce competition in 2020. 2019, Dec 9. Retrieved from <https://medtech.pharmaintelligence.informa.com/MT125985/Market-Intel-After-A-Year-Of-Partnerships-Insulin-Pump-Manufacturers-Will-Face-Fierce-Competition-In>

agreement with health insurer Aetna Inc. under which payment for its insulin pump systems will be tied to how well diabetes patients fare after switching from multiple daily insulin injections.⁶¹ The deal marked the latest example of how medical device manufacturers are moving toward contracts for prescription drugs and medical devices in order to bring down the soaring costs of healthcare by tying reimbursements to whether or not the products achieve their intended results. Medtronic already has an agreement with United Health Group Inc. that is moving toward including patient outcomes and other metrics, such as total cost of care. The company is also in discussion to establish similar deals with other insurers as part of its efforts to providing value-based healthcare.

Questions

- What are the key challenges of bringing digital technologies and commercial mApps to the diabetes market, and how can these challenges be overcome?
- What strategies are companies using to overcome interoperability issues and to gain a foothold in the CGMs arena?
- What smart delivery strategies are companies applying to improve insulin devices to improve patient convenience and improve disease management?
- What are the key challenges and opportunities that small and large medtech companies face when developing new closed loop systems?
- What impact, if any, could digitised all-in-one solutions have on this paradigm shift in pricing models toward value-based care?
- How motivated are diabetic patients in using digital technologies and what strategies are your company adopting to engage, personalise, and incentivise end users to improve their retention?
- What are medtech companies doing to address patients' concerns regarding data privacy?

61 Berkrot B. Reuters Health News. Medtronic deal with Aetna ties insulin pump payment to patient results. 2017, Jun 26. Retrieved from <https://uk.reuters.com/article/us-medtronic-aetna-diabetes/medtronic-deal-with-aetna-ties-insulin-pump-payment-to-patient-results-idUKKBN19H1GB>

Key insights

- **mApp environment rapidly evolving.** There is a proliferation of mobile health apps serving the diabetes community, ranging from simple apps that collect and manage data to those that give advice about how much insulin should be used. Although it is impossible for the regulators to oversee all health apps, they retain the discretion on which apps they will regulate and which they will not. One of the challenges facing digital health innovators is to avoid duplicating work as there is significant overlap. The aim is to provide end-users with the most patient-centric product or service possible.
- **mApps support health and wellbeing engaging with end-user and tackling comorbidities.** Several different apps support health and wellbeing, either through providing education, the management of patient's eating habits, or the management of insulin dosing regimens. Increasingly, companies are focusing on coaching diabetics to take a more active control in the management of their condition.
- **Manufacturers widely adopting digital technologies.** The 'digiceutical concept' is beginning to emerge, where an approved pharmaceutical therapy is combined with an app that is integral to using the product. This is becoming increasingly common for chronic disease therapies in general, and for diabetes in particular. Abbott, Insulet, Eli Lilly, Medtronic, Novo Nordisk, and many other diabetes players all have digital platforms to support patients.
- **Sharing data and addressing privacy concerns.** Dexcom's digital technology, as an example, allows an individual to view a user's information with up to five people, on five smart devices, and track the information with them. This digital integration can help overcome some psychological aspects such as loneliness and feelings of being 'left out' as is often experienced by diabetic patients.
- **High bar to enter for closed-loop systems arena.** For large companies, one of the incentives to take on a digital product as part of their pharmaceutical product is to provide a competitive edge. However, smaller companies are quick and nimble and increasingly finding niches where they can be very effective in competing against larger firms. Smaller firms can embrace and adapt technologies that are complementary to what larger manufacturers are developing.

- **Shift towards value-based care.** There is a big emphasis for companies to focus on paying for performance versus services rendered. Anything a company can do to demonstrate that it is improving outcomes is important in justifying the cost of a product or device. The US is looking to manage medical costs based on actual benefits that they provide and insurers are contracting with pharmaceutical and medical device companies on the ability to achieve predetermined health outcomes.

Supporting quotes

mApp environment rapidly evolving

“Mobile health apps have exploded; certainly in diabetes, there is a spectrum ranging from simple apps that collect and manage data to those that actually give advice about how much insulin to use, for example. Those apps do need to be regulated because they have the potential to do harm if they’re not accurate, or not reliable for other reasons. As you know, the FDA has said that they’re not going to regulate all health apps, because that it would be impossible for them to do so, but it retains discretion on what apps it will actually regulate, and those that they will not. In general, there are apps that tell patients what to do in terms of using a drug, like insulin, which is a challenging therapy to use. Those will continue to be regulated.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“The challenge used to be overcoming regulatory barriers to allow for clinical validation at scale. Now that regulation is catching up with innovation, there are a lot of start-ups making the jump from a good idea to a minimum viable product (MVP). The challenge is to make sure we, as digital health innovators, are partnering up rather than duplicating work. There can be lots of overlap in the good ideas that health tech companies are having, so we need to work out what makes each of us unique then seek out new partnerships, like medtech and digital health, to give the end-user the most patient-centric product or service possible.”

Mike Trenell, founder and CEO of Changing Health

“I think with mApps ease-of-use is a barrier. There are a few that are approved by the regulators and we need oversight from a safety perspective without becoming too overbearing. For instance, coaching apps: there’s room for those. Some are more generic and focus on health and wellbeing, while others are more specific for diabetes, relating to diet and activity, but they don’t take into account some of the psychological approaches that could make these recommendations more

effective. We've conducted a number of the studies, both our own and with companies developing their versions, with coaching mApps, and it's not easy to do. Primary care physicians can't stand having to do all the titration required for insulin to get someone on the right dose, and although some very good apps have been developed for this purpose, they are still not so easy to use for either the provider or the patient. If you can't make it easy, they're just not going to use it, unfortunately. There's great value if the developers could figure it out how to make a mApp that is easier to use; there's a huge market potential for that out there."

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

mApps support health and wellbeing engaging with end-user and addressing comorbidities

"There are a lot of apps out there that are resources for encouraging weight loss – for example, people like being given the calorie count of different foods – or the sorts of apps that fall more or less in the 'buyer beware' category. In other words, the FDA will not be looking at or reviewing them or be concerned that they're accurate, and that's going to be something of a challenge. But there will be products which are maybe not as good as others, or not as accurate as those others in doing what they are meant to do, and getting actual clinical trial data will be unusual for those kinds of products. They just don't have the resources to do trials to support their utility or their accuracy. That's going to be a challenge to be sure that the consumers are not using products that fall short of what would be a reasonable standard."

Alexander Fleming, MD, Executive Chairman, Kinexum

"We're ensuring Changing Health is engaged by running regular user experience (UX) audits to keep tabs on exactly how people are using our platform, when and for how long, identifying their pain points to make their user journey as positive as can be. There should never be an end to that process, so we've set up a dedicated team focused on continually improving that UX in response to ever-changing user preferences."

Mike Trenell, founder and CEO of Changing Health

"There are different apps around either education, around management of whatever they're eating, management of their insulin, even apps with telling the patients how many grams of carbs are in different food, they can actually count everything.

There are a lot of different apps out there that the patients could use in order to help manage their diabetes, some of which are regulated and others that are not.”

Heidi Soto, Area Business Manager, MannKind Corporation

“I think we need to tie in comorbidities to get the entire picture of the patients and I’m not sure how companies can do that. Right now, it would be self-entry by the patient to provide, let’s say, a cholesterol level, blood pressure, or other comorbid conditions. Whereas if you can somehow tie this to the electronic medical record where you are getting all that information in one place and you can link it up, then you can provide recommendations related to it. I think it’s important how many times the morbidity associated with diabetes is hypertension or dyslipidaemia, high cholesterol levels, which are driving the development of cardiovascular disease. So you need to take into consideration the entire health picture.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

Manufacturers widely adopting digital technologies

“I think there certainly is the expectation that digital technologies are going to be used more and more by companies that have good products, pharmaceutical products. We have the so-called ‘digiceutical’ concept, which combines an approved pharmaceutical therapy with an app that is integral to using the product. That may become more common for chronic disease therapies in general and for diabetes in particular.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“I think it’s becoming the norm for big manufacturers to be able to provide some type of app for their patients. For smaller ones, they’re not the norm. It really depends on how big the pockets are of the manufacturer. I would say Novo Nordisk, Eli Lilly, Medtronic, Insulet, and Abbott, all have platforms to support the patients like that, with apps. The apps may not be geared towards diagnosis, but for education, to support the patient in the management of their disease, so it’s more of a diagnostic tool. Smaller companies are more reliant on their website helping patients pull through the medication or a medical device, providing access to a patient support centre that the patients can call in to get help with their questions around the treatment, the use of the device, the dosing, and even formulary coverage through their insurance.”

Heidi Soto, Area Business Manager, MannKind Corporation

Sharing data and addressing privacy concerns

“Dexcom’s digital technology allows somebody else to be able to view that user’s information with up to five people on five smart devices and track the information with them. This also helps address the aspect that diabetic patient can feel lonely and left out. That they’re being supported and sharing information is a huge aspect of the diabetes success rate for these patients.”

Heidi Soto, Area Business Manager, MannKind Corporation

“Research suggests patients or users are generally happy for digital health innovators to gather data on their health, provided they know how it’s used and that it’s secure. Changing Health has trained and qualified a GDPR practitioner, whose job it is to ensure user data is kept secure. In addition, we spent seven months working towards and achieving ISO27001 certification, which is the gold standard of data security.”

Mike Trenell, founder and CEO of Changing Health

High bar to enter closed-loop systems hybrid

“I think one motivation for a company to take on a digital product as part of their pharmaceutical product is to provide a competitive edge, but it’s not something that necessarily has to be beyond the reach of smaller companies. If they want to be competitive in a chronic disease management setting, it may be the opportunity for smaller companies to come in and be much leaner, and be able to find the niches where they can be very effective and compete against the larger companies. I would hope it would open more potential for smaller companies to get a leg up in embracing and adapting the technologies that are complementary to what they’re developing.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“I think innovation is dependent on patient needs. For example, a closed-loop system that is truly closed-loop or a glucagon that is stable. Now we have a powdered glucagon that never existed before that’s being marketed by Lilly. But there are lots of different hormones that are responsible for blood glucose regulation; that would be of interest to research and provide products that would address medical needs.”

Heidi Soto, Area Business Manager, MannKind Corporation

“I love the hybrid closed-loop systems that are being developed by so many in the industry, for example, MiniMed 670G from Medtronic and Control IQ from Tandem. Others are close behind, such as Tidepool and OmniPod from Insulet Corporation. Adding this technology raises the level of safety and allows tighter glucose control. There are definitely still glitches that do not make the process optimal for the patient nor for the providers, so there’s absolutely room for improvement there. I believe all the companies are working on them. It’s not a true closed loop where you can eat something and the amount of insulin that’s injected is fast enough to counter the rapid rise in glucose. The pumps and algorithms don’t have the full ability yet to anticipate and react to what you’re about to eat, or if you’re going to go out and exercise. They are trying to replicate the human beta cell. It’s incredibly hard, but they have come a long way and they’re trying to improve it.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

Shift towards value-based care

“I do think that there is a big emphasis for companies to focus on paying for performance versus just the services rendered. It continues to be a challenge for companies to justify the cost that they’re charging and probably the best example even in general medicine is the high cost of insulin products, and whether that cost is justified. Anything a company could do to show that it’s improving outcomes is going to be important to justify the costs or the price that is being charged. The US is evolving more to the British model and looking at management of medical costs based on actual benefits that they provide, a pay-for-performance model that really squeezes every company to justify the cost of what they’re selling.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“15 to 20 years ago, doctors could write the product and then the patient could get it dispensed without having to put up a fight. Now the insurances are the ones that are contracting with pharmaceutical and medical device companies. They’re obviously being driven by prices and cost-effectiveness and not by what is the most clinically successful product for their patient. Now doctors have to follow a certain protocol implemented by insurance companies, where they may want the patients to first try A, then, if that doesn’t work then they’ve got to try B and so on. They may go through a cascade of the products.”

Heidi Soto, Area Business Manager, MannKind Corporation

Intelligence exhibits

Table 2: Recent advances in glucose monitoring from leading academics

Warwick University, January 2020	<p>A team from the University of Warwick in the UK announced that they had discovered a pathway to avoid the conventional and painful method of checking blood sugar levels using finger prick tests, by developing technology that detects low blood glucose levels through a wearable sensor.⁶² The approach is based on using an AI sensor attached to a device that works with Electrocardiogram (ECG) signals. The sensor detects low blood sugar levels by tracking the person's heart rate and is made possible because of the way the ECG readings change when glucose levels fall below 4 mmol/L. The AI system is then used to recognise low blood sugar levels compared to normal readings. Two small pilot studies have been carried out to test the technology, with results indicating that it was about 82% effective at detecting hypoglycaemia.</p>
National University of Singapore (NUS)	<p>The pH Watch leverages existing pulse oximeter chips found in fitness trackers and smartwatches, which measure the heart rate and oxygen saturation levels of users. Pulse oximeters consist of red and infrared light sensors that sit between the skin and the device. A pulse oximeter emits visible red and invisible infrared light onto the users' skin and calculates the difference between the wavelengths of the two lights to determine the oxygen content in the blood. The pH Watch can therefore simultaneously monitor the pH value of a user's sweat, along with heart rate and blood oxygen saturation values in real-time, and currently has an accuracy rate of about 90%.⁶³ It is the first demonstration of a reusable sweat sensor that can be readily integrated into any smartwatch containing a pulse oximeter. The team is currently investigating other biomarkers in sweat, and exploring the use of other existing sensors to detect more sweat biomarkers.</p>

Source: Authors own research

62 Warwick University News and Events. Artificial Intelligence (AI) can detect low glucose levels via ECG without finger prick test. 2020, 13 Jan. Retrieved from https://warwick.ac.uk/newsandevents/pressreleases/artificial_intelligence_ai/

63 NUS News. Dehydrated, low on sugar or at risk of skin infection? Wearable sensor made by NUS researchers can tell from your sweat. 2020, Jan 13. Retrieved from <http://news.nus.edu.sg/research/low-power-highly-responsive-and-reusable-sweat-ph-monitor>

Table 3: Recent development in closed-loop systems

<p>Medtronic</p>	<p>Medtronic was the first company to gain FDA approval for its MiniMed 670G hybrid 'closed-loop' system in September 2016, with the product achieving market launch in June 2017. The company led the insulin pumps market in 2018 with a 75% market share, which was based on total sales of MiniMed pumps and related supplies, yielding revenues of more than US\$2.1bn.⁶⁴ Insulet Corp. ranked second with a 17% global market share and an estimated US\$496m in sales revenue from its OmniPod line. Tandem ranked third, with a 6% market share and US\$184m in sales. The company has made significant inroads by re-establishing itself in recent years due to its innovative pump design and technology. Valeritas ranked fourth, with a 1% market share and US\$26m in revenues.</p> <p>In February 2019, Medtronic received Breakthrough Device designation from the US FDA for its Personalized Closed Loop (PCL) insulin pump system, which is currently in development.⁶⁵ The PCL technology is designed to automate insulin delivery in a manner that is real-time, personalized and adaptable to the user. The system will also provide insights and predictive diagnostics unique to the individual, with the aim of dramatically simplifying diabetes management for the patient. Medtronic's acquisition of Israeli nutrition data start-up Nutrino Health in November 2018 is playing a key role in the accelerated development of this breakthrough technology.⁶⁶ Under the programme, the FDA will provide Medtronic with priority review and interactive communications regarding device development and clinical trial protocols, through to commercialisation decisions.</p> <p>Medtronic's next-generation MiniMed 780G's algorithm is expected to be more accurate and is designed to provide automatic correction boluses, which the MiniMed 670G does not currently provide. It is anticipated that the MiniMed 780G system, which is expected to be launched in 2020 (pending FDA approval), will compete against another advanced hybrid closed loop algorithm, Control-IQ, from Tandem Diabetes (see below).</p>
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64 Webb M. Market Intel: After a year of partnerships, insulin pump manufacturers will face fierce competition in 2020. 2019, Dec 9. Retrieved from <https://medtech.pharmaintelligence.informa.com/MT125985/Market-Intel-After-A-Year-Of-Partnerships-Insulin-Pump-Manufacturers-Will-Face-Fierce-Competition-In>

65 Medtronic Press Release. Medtronic receives FDA Breakthrough designation for developing personalized closed loop insulin pump system for diabetes management. 2019. Feb 19. Retrieved from <http://newsroom.medtronic.com/news-releases/news-release-details/medtronic-receives-fda-breakthrough-designation-developing>

66 Hale C. Fierce Biotech. Medtronic to acquire AI nutrition firm Nutrino for its digital diabetes projects. 2018, Nov 29. Retrieved from <https://www.fiercebiotech.com/medtech/medtronic-to-acquire-nutrition-ai-firm-nutrino-for-its-digital-diabetes-projects>

Table 3: Recent development in closed-loop systems *continued*

<p>Tandem Diabetes Care Inc.</p>	<p>In December 2019, Tandem received FDA clearance for its t:slim X2 pump system with Control-IQ, the company's latest advanced hybrid closed-loop algorithm.⁶⁷ The algorithm makes Tandem's insulin pump the first FDA-cleared automatic insulin delivery system.</p> <p>The Control-IQ technology uses CGM values, in conjunction with other variables, such as Insulin on Board (IOB), to predict glucose levels 30 minutes ahead and adjust insulin delivery accordingly. If glucose values are predicted to drop below 112.5 mg/dL, basal insulin delivery is reduced, and when it is predicted to be below 70 mg/dL, basal insulin delivery is stopped. If glucose values are predicted to be above 160 mg/dL in the next 30 minutes, basal insulin will be increased. If glucose values are predicted to be above 180 mg/dL, Control-IQ technology calculates a correction bolus with a target of 110 mg/dL, and delivers 60% of that value up to once an hour as needed. Control-IQ technology also offers optional settings for sleep and exercise that will change the treatment values to better match the different physiologic needs during these activities.</p> <p>While Tandem now has Control-IQ, it said it will continue to offer its Basal-IQ predictive low glucose suspend technology, as an option for patients who prefer a system designed specifically to help prevent lows. Basal-IQ was FDA-cleared in June 2018 and CE-marked in April 2018.⁶⁸</p> <p>Tandem has approval to market its t:slim X2 pump as an interoperable pump, a designation that allows the device to be connected and integrated with different CGMs and connected meters. This marks a significant selling point over rivals that may not have integrated glucose monitors.</p>
<p>Source: Author's own research</p>	

67 Tandem Diabetes Care press release. Tandem Diabetes Care announces FDA clearance of the t:slim X2 insulin pump with Control-IQ advanced hybrid closed-loop technology. Retrieved from <http://investor.tandemdiabetes.com/news-releases/news-release-details/tandem-diabetes-care-announces-fda-clearance-tslim-x2-insulin>

68 Tandem Diabetes Care. t:slim X2 insulin pump. Retrieved from <https://www.tandemdiabetes.com/en-gb/home>

New Commercial Opportunities for digitisation of diabetes

Issue summary

Continuous glucose monitoring (CGM) devices

Over the last 20 years, CGM technology has improved greatly. These devices not only help patients with diabetes to monitor their glucose levels over time, but also allow for dynamic information creation that indicates the direction of glucose change. This allows users to observe the influence of diet, exercise, and insulin dosing on the patient's glucose level in real-time (See [Table 4, page 66](#)).⁶⁹ Studies have shown that CGM use can increase time spent in normo-glycaemia and decrease the frequency and severity of hypoglycaemic events.⁷⁰

Future CGMs will need to improve upon the lag time of current devices to allow for better monitoring and management during physical exercise and periods of rapid glucose changes. As these products continue to develop, it is anticipated that sensors and transmitters will become smaller and lower profile, making them easier and more comfortable to wear. In addition, new adhesive strategies will need to be employed to keep these devices in place as the lifetime of a sensor continues to improve. While CGMs are currently being used in hybrid closed-loop systems with insulin pumps, it can be expected that increased collaborations between medical device manufacturers, pharmaceutical companies and tech specialists, will make currently-available CGM devices compatible with other independent insulin pumps, with the goal of developing closed-loop systems in the future.

69 Allen N, Gupta A. Current diabetes technology: Striving for the artificial pancreas. *Diagnostics (Basel)*. 2019, Mar 15;9(1). pii: E31. doi: 10.3390/diagnostics9010031

70 van Beers CA, DeVries JH. Continuous glucose monitoring: Impact on Hypoglycaemia. *J. Diabetes Sci. Technol.* 2016, Nov 1;10(6):1251-1258. Print 2016 Nov

Insulin pumps

Over the last 50 years, insulin pumps have continued to advance and improve in terms of precision and convenience. It is currently estimated that more than one million people worldwide use an insulin pump for diabetes management, including nearly 400,000 patients with Type 1 diabetes in the US.⁷¹ Insulin pumps are small devices that deliver short-acting insulin subcutaneously via a small cannula self-placed by the patient every few days. They are designed to provide a near-continuous low dose of insulin delivered frequently in small boluses to mimic the actions of the β cells of the pancreas and allow for bolus delivery of insulin at mealtimes, or when needed for rapid correction of glucose.

Insulin is administered through a small tube called a cannula that is inserted into the subcutaneous tissue with a small needle and is taped to the skin. While some insulin pump systems have tubing that runs from the device's insulin reservoir to the insertion site, some insulin pumps are tubing-free (See [Tables 5 page 67](#) and [6 page 68](#)). These tubing-free systems stick directly to the skin with a cannula that is inserted into the subcutaneous tissue below the pump.

Insulin pumps have been shown to improve glycaemic control resulting in a lower HbA1c. For example, a study of paediatric patients with Type 1 diabetes conducted by Karges *et al.* (2015) showed that patients using insulin pump therapy had lower rates of severe hypoglycaemia, lower incidence of diabetic ketoacidosis, lower HbA1c, and lower total daily insulin doses than matched patients on multiple daily insulin injection therapy.⁷² In addition, insulin pumps allow patients increased flexibility in their routines and account of insulin action time, which aids in lowering the risk of insulin stacking. As these pump systems continue to evolve, more closed-loop systems will emerge onto the market. At present, multiple closed-loop systems are currently in development, each having unique algorithms that are being designed to deliver insulin based on glucose levels measured with a connected CGM system.⁷³

71 Campbell A. Diabetes Self-Management. Ways to deliver insulin: Inhalers and insulin pumps. 2019, Sep 18. Retrieved from <https://www.diabetesselfmanagement.com/managing-diabetes/treatment-approaches/ways-deliver-insulin-inhalers-insulin-pumps/>

72 Karges B, Rosenbauer J, Holterhus PM *et al.* Diabetes Patienten Verlaufsdokumentation (DPV) Initiative. Hospital admission for diabetic ketoacidosis or severe hypoglycaemia in 31,330 young patients with Type 1 diabetes. *Eur. J. Endocrinol.* 2015, Sep 17(3):341-50. doi: 10.1530/EJE-15-0129. Epub 2015 Jun 18

73 Allen N, Gupta A. Current diabetes technology: Striving for the artificial pancreas. *Diagnostics (Basel)*. 2019, Mar 15;9(1). pii: E31. doi: 10.3390/diagnostics9010031

Hybrid closed-loop insulin delivery systems

With the emergence of the first commercially available hybrid closed-loop system, the Medtronic 670G, diabetes care advanced a step closer to developing an artificial pancreas. These systems have been shown to increase the percentage of time spent in glucose range for users, with multiple studies demonstrating a reduction in the incidence and severity of hypoglycaemia in patients using closed-loop systems, in both paediatric and adult diabetic patients.⁷⁴

According to Allen *et al.* (2019), there are currently four main types of control algorithms being employed in the development of closed-loop systems. Model predictive control (MPC) algorithms are the most commonly used; these aim to predict glucose levels, as well as adjust insulin delivery based on that prediction. Another algorithm is the proportional integral derivative type, which responds to real-time measured glucose values. Fuzzy logic algorithms determine insulin doses based on CGM data in the way that an expert clinician would make insulin adjustments. In addition, there are bio-inspired algorithms that utilize a mathematical model to determine insulin doses based on how β cells would act in response to glucose in the body.⁷⁵

Across the globe, several systems are currently in development or are undergoing clinical trials (See [Table 7, page 69](#)). As technology relating to diabetes management continues to develop further, systems will ideally require less and less management from the patient and the provider. In addition, the length of time these devices can be worn is likely to increase, while integrated CGM systems will require less calibration and significantly fewer finger sticks. It can also be envisaged that meal-time insulin may no longer become a requirement, and as such, the patient would not be required to enter carbohydrates consumed.

74 Kovatchev BP, Renard E, Cobelli C *et al.* 3rd. Safety of outpatient closed-loop control: First randomized crossover trials of a wearable artificial pancreas. *Diabetes Care* 2014, Jul;37(7):1789-96. doi: 10.2337/dc13-2076. Epub 2014 Jun 14

75 Trevitt S, Simpson S, Wood A. Artificial pancreas device systems for the closed-loop control of type 1 diabetes: What systems are in development? *J. Diabetes Sci. Technol.* 2016, May 3;10(3):714-23. doi: 10.1177/1932296815617968. Print 2016 May.

Questions

- How might medtech companies leverage information derived from patient-centric programmes to improve/expand their medical device offerings to the diabetic community?
- Significant advances have been made in the development of personalised closed-loop insulin pump technology. How might this change the future landscape of diabetes management?
- What additional opportunities do you believe exist for companies to harness the power of real-time data and AI/ML to empower and enable pre-diabetic/diabetic patients to take more control of their health and wellbeing?
- Looking beyond the creation of closed-loop systems, or creating apps to connect CGMs and insulin pens, where will be the next step of digital transformation?
- Are there new opportunities to target pre-diabetics and to focus on prevention rather treatment/cure?

Key insights

- **Regulatory support for digital technologies and certification of mApps.**
At present, regulators such as the FDA do not have the capacity to regulate all of the digital apps that are available on the market today. Going forward, technologies such as diabetes apps that go beyond health and wellbeing will need to be fully validated to gain healthcare professional support and build patient confidence.
- **New opportunities to improve coaching and sustain lifestyle changes.**
Some large companies have begun to offer 'wellness', as opposed to disease management, as a product. This has come from the realisation that having an app on the phone is not going to be as effective as having an app paired with some type of human interface (such as coaching for example), which can act as a means of complementing what the app itself can provide. In the UK, whole service packages have been designed to encourage virtual coaching through technology systems, to reduce obesity and thereby prevent Type 2 diabetes.
- **Leverage patient-centric programmes, expand device offerings and incentivising patients.** The advent of artificial intelligence (AI) has enabled digital technologies to support healthcare professionals in their work and is set

to improve diagnosis, treatment, and management of the condition which can be tailored to the individuals' needs.

- **Personalized closed-loop insulin pumps continue to be driven by Type 1 diabetes.** There are dozens of companies that are attempting to accurately mimic the role of the pancreas β cells insulin dynamics through development of truly closed-loop systems. Whilst this technology is not yet a reality, technological and scientific advances indicate that an artificial pancreas will become a reality in the near future.
- **New opportunities for multifunctional delivery devices.** There are significant opportunities for pharmaceutical and medical device companies to work more closely together to design a system that can deliver insulin and glucagon, or a DPP-4, GLP-1, through the same site.
- **Education is critical**, particularly for people at risk of Type 2 diabetes. In the US market, there has been a lot of investment in education platforms relating to diabetes, risk factors, and comorbidities. Companies are continuing to educate patients through different digital apps and online internet tools, or websites regarding the use of a product, as well as how to utilise devices to better manage diabetes and improve their quality of life.
- **Paediatric diabetics a growing unmet need.** The paediatric diabetes market is an untapped market despite the growing incidence of children and adolescents with Type 2 diabetes; many Type 1 patients are now being diagnosed in childhood. Access to CGM systems and insulin pumps can effectively aid paediatric diabetic management and avoid long-term complications of the condition. Digital technology will have a significant role to play in addressing paediatric medical needs.
- **Prevention of diabetes is a growing area of development.** Modifying deeply-ingrained lifestyle habits is very challenging. Education relating to the prevention of diabetes should begin at school-age in order to identify children and adolescents who are at risk. Technologies such as mobile apps and computer games can help. In the UK, for example, there are plans to expand the NHS Diabetes Prevention Programme (DPP) and make it available across the country to those in need; the programme has already supported 300,000 people with diabetes.

- **Sustainable prices:** The US is a unique environment because it is being driven by insurance companies and pharmaceutical manufacturers without any type of price oversight. People are at the mercy of whatever pricing is implemented by the manufacturer, unlike in Europe, where healthcare is subsidised and regulated by the government. The development of sustainable pricing models that reflect the value that digital-enabled devices can bring to diabetes and other chronic diseases is essential if patients are to continue to access innovative solutions that allow them to live a normal life.

Supporting quotes

Regulatory support for digital technologies

“I do think the regulator, the FDA, is doing a very good job in encouraging interoperability, and being sure that the systems that have some potential for harm are properly tested and that there is sufficient follow-up in the market of performance. I think their challenge is where to get involved with more simple digital technologies. The FDA obviously don't have the bandwidth to watch everything; they will necessarily focus on those systems that involve making treatment recommendations. They will not be involved in the vast majority of digital apps that are on the market today.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“All these apps have to go through the FDA; that's the biggest challenge. Then who's going to write the application? How user-friendly is it? What platform is going to be rolled out in: Apple or Android?”

Heidi Soto, Area Business Manager, MannKind Corporation

“I think as a field, digital apps are stepping up to the plate and trying to offer the useful products for preventing and then managing diseases like diabetes. There has been really an explosion in these products but the challenge in part will be for the consumer to find the right product, and be able to choose among the many different choices and pick the right product for the individual. The UK has been good about having a certification system. We don't have that in the US for diabetes apps. I think that's something that has needed a credible resource for informing consumers and patients about products that they can rely on.”

Alexander Fleming, MD, Executive Chairman, Kinexum

New opportunities to improve coaching and sustain lifestyle changes

“We’re already seeing large established companies and those that have grown into very large companies like Omada Health and others offering wellness, as opposed to disease management, as a product. I think that brings up an important point that just having an app on the phone is not going to be as effective as having an app paired with some kind of human interface, such as coaching or a way of complementing what the app itself can provide. We have already seen in the UK whole service efforts to encourage virtual coaching through technology systems, to reduce obesity and thereby prevent Type 2 diabetes.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“With real-time data we can see exactly what action a person could take to, for example, stabilise their blood sugars and when. Looking longer-term, we’ll also be able to use that data to predict when a person would most benefit from support to sustain a lifestyle change. For example, we’ll know when a person might be most likely to be tempted by a takeaway based on their existing lifestyle data and knowledge of their usual traits and habits, then send a motivational message to their phone in the form of a notification, to help them on track and cook something fresh instead.”

Mike Trenell, founder and CEO of Changing Health

“No matter the amount of education and new drugs, the A1C remains the same; the mortality of diabetes remains the same or even higher. One of the aspects that is missing is the emotional and psychological aspects of diabetes. A lot of people will not take care of their diabetes because psychologically they’re not well; they’re depressed, unhappy, and they don’t have the emotional support, network or a family system. That component is completely unaddressed. It all goes down to personal accountability, the socioeconomic aspects; the lower the level, socioeconomically and educationally, the worse the outcomes are going to be for the patient, unfortunately.”

Heidi Soto, Area Business Manager, MannKind Corporation

Leverage patient-centric programmes, expand device offerings and incentivise patients

“I think that’s going to be done increasingly and it’s also coming from the healthcare side itself in an attempt to make healthcare delivery more patient-centric. That means digitalising. But, that’s in the process as well, so you have apps or web portals that help your patients with obesity. Those in turn can then relate to digital technology systems that are contenders with this monitoring data. It could be provided to the physician through a patient portal. There’s all kind of variations in how technology is going to be presented to the patient. But I think starting with the integration of pharmaceuticals and technology.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“The big development of this decade will be artificial intelligence. It won’t be supplanting actual human intelligence, but rather, supporting healthcare professionals to do their jobs more effectively. Artificial Intelligence is set to make precision medicine a reality: improving outcomes by delivering exactly the right care, to the right person, at the right time. So, there’s much talk of the ‘robots taking our jobs’, but we’re not there yet. In the meantime, it’s important to remember that artificial intelligence won’t be replacing the most valuable form of AI in healthcare any time soon: actual intelligence.”

Mike Trenell, founder and CEO of Changing Health

“Incentives may be available through individual health insurance plans for the person where an employer may go ahead and offer them a \$500 incentive if the patient goes and gets their physical each year or they walk 10,000 steps a day for the next six months, lose weight. These incentives are tied to apps and are being managed and tracked by the insurance providers.”

Heidi Soto, Area Business Manager, MannKind Corporation

Personalised closed-loop insulin pumps continue to be driven by Type 1 diabetes

“In the Type 1 domain, we are seeing real intensity of different services and companies that are in the mix. There are dozens of companies that are specifically attempting to integrate management of Type 1 control, and that is a very different situation from the large Type 2 diabetes population where it’s not nearly the [same] penetration of insulin pump use and continuous glucose monitoring. I think there will be a slow growth and uptake of those technologies in the Type 2 world but, by and large, patients that have Type 2 diabetes are trying to stay off insulin. The availability of therapies that allow them to do that is growing.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“I see that the closed-loop market is going to be changed by a small company. Medtronic has been in that space for over 30 years and it’s basically the same pump with a few gadgets and improvements. Other companies like Bigfoot, [Tandem with its] t:slim, [Insulet with] OmniPod, Animas, and V-Go, are really changing this space in response to patient needs.”

Heidi Soto, Area Business Manager, MannKind Corporation

“I do believe it’s feasible to develop an artificial pancreas and patients are already coming together and creating their own solutions. Some doctors, and I work in the Beverly Hills area, are actually hacking the pumps with their patients and creating their own closed-loop systems because there is a huge need there.”

Heidi Soto, Area Business Manager, MannKind Corporation

New opportunities for multifunctional delivery devices

“There are significant opportunities for pharmaceutical and medical device companies to work more closely together to design a system that’s able to deliver insulin and glucagon or a DPP-4, GLP-1 through the same site so everything is communicating, and all these other hormones that play a role and blood glucose homeostasis are controlled. At the same time, addressing all of the other things that are also important to ensure that the patient is using less insulin so that they have less hypo/hyper-glycaemia. It’s more of an allopathic approach than an individual approach. But that would require a huge amount of collaboration from all of the different manufacturers to ensure that they’re able to stabilise these drugs in some type of delivery device.”

Heidi Soto, Area Business Manager, MannKind Corporation

“People are working on dual hormone pumps; trying to replicate what the alpha and the beta cell are doing, to replicate what the human body is doing; the closer you can get to replicating that, I think the better off our patients will be. The only reason we haven’t done more of it is we’ve been constrained by the ability of the pharmaceutical firms to create appropriate formulations of glucagon and other counter-regulatory hormones. That’s the limiting factor. But it would be good if we could replicate the entire process.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

Education is critical

“Education is so important, particularly for people at risk of Type 2 diabetes. Education needs to start early but the problem is that healthcare providers are under big pressure in their clinics, and they see a lot of patients and they don’t have themselves the time to do much educating. Apps can help to close some of that gap. But there needs to be still a human interface that becomes available at some point, whether it be on the regular basis or just as needed when the app itself is not doing the job.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“More patient-centric programmes and interventions mean more engaged users and thus, better data. With better data, medical device and digital health companies can provide a more effective or appropriate health intervention, like a motivational boost to make a healthy meal choice, or a warning of a predicted spike in blood glucose, in real time. It’s taking us closer to precision medicine.”

Mike Trenell, founder and CEO of Changing Health

“In the US market there’s been a lot of investment on education platforms around diabetes, risk factors and comorbidities. Companies are continuing to educate the patients through different apps and online internet tools or websites around the use of a product and how to utilise that product to better manage diabetes so that they can have better outcomes.”

Heidi Soto, Area Business Manager, MannKind Corporation

Paediatric diabetics a growing unmet need

“We have a big problem with obesity increasingly in the older children, than young children. That is a terrible thing to behold. It’s bad enough to get Type 2 diabetes in later adulthood where you have fewer years to do damage. But we’ve got to really focus on the children and adolescents with Type 2 diabetes as almost an emergency. Many of the Type 1 patients are beginning to have their disease start in childhood. It’s a huge challenge to manage a child with Type 1 diabetes. It’s a nightmare for parents to have a child where they have to worry about hypoglycaemia occurring at night. [In that situation] having a continuous glucose monitor is extremely important and insulin pumps can be important as well. They’re really two entirely different situations with different kinds of solutions. But I would say that there’s a role for digital technology certainly in both cases.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“I think that’s an untapped market because even doctors that have patients with diabetes are postponing insulin therapy and treatment. I think [there should be] a national campaign about pre-diabetes or early onset of diabetes, a non-branded national educational campaign around the myths and the facts of pre-diabetes. And then in having that company partner up with the ADA, JDRF, different organizations across the US to really start an education blanket around the US to help start changing the mind-set, to get a discussion started. It would be very smart for a company to provide education to medical schools in the country so that they can begin to train these early adopters.”

Heidi Soto, Area Business Manager, MannKind Corporation

Prevention of diabetes is a growing area of development

“I think Type 2 prevention is probably one of the more approachable propositions in public health in the sense of knowing what will move the needle. The problem is we’re talking about modifying deeply-ingrained habits and that is very challenging. Clearly, the earlier we start in life, the better. That starts with school-age education in identifying young people with risks and jumping on the problem as soon as it can be done. The technologies that are available can certainly help there. Ironically, it’s also the apps and the fact that the smartphones and the computer games that are part of the problem within their lifestyle. It’s taking the good with the bad.”

Alexander Fleming, MD, Executive Chairman, Kinexum

“There are plans to expand the NHS Diabetes Prevention Programme (DPP), on which Changing Health is one of the five digital providers, nationwide, [and will be] eventually available for anybody who needs it. With over 12 million people at high risk of Type 2 diabetes in the UK, there’s a huge opportunity here to empower people to change their lifestyle and behaviours to prevent Type 2 diabetes at scale. It’s the first national programme in the world and has already supported 300,000 people.”

Mike Trenell, founder and CEO of Changing Health

“Pre-diabetes presents a huge opportunity for developers. There is already a lot of information in the EMRs to allow identification of this group of people but how you actually intervene is another question. No one’s ever tried. In the United States, there are over 88 million people with pre-diabetes and if we were to intervene on just a small portion of them, you’re going to make a huge difference.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

Sustainable prices

“The US it’s just such a unique environment because it is being driven by insurance. It is being driven by pharmaceutical companies and there hasn’t been any type of price oversight. I know that now there’s legislation that is trying to change that and in certain states they’re capping off the insulin co-payments at \$30 a month. Where this is more of the capitalistic-driven environment by corporations, that oversight is not there and regulated. People are at the mercy of whatever the corporations are going to do with the pricing whereas in other countries, like Europe, it is subsidised and regulated by the government.”

Heidi Soto, Area Business Manager, MannKind Corporation

Take home message

“We’re already well into the digitalisation of diabetes and prevention. You’ve got many different products already available and it’s a spectrum ranging from simple to complex, and integrated with another technology like an insulin pump. It’s going to be increasingly important for most people with diabetes, both Type 1 and Type 2. Increasingly we’ll see it in the management of Type 2 diabetes. I hope that we’ll see more progress made in preventing Type 2 diabetes. That’s really the much-preferred option, of course: to prevent the disease and not just have to manage it after it starts. We’ve got a number of different products that can help prevent it,

and I'm hoping that we'll see greater uptake. Part of that is encouraging people at risk to use these products and that's probably where healthcare providers could do a better job, right?"

Alexander Fleming, MD, Executive Chairman, Kinexum

"The most successful patient-facing medtech and digital health products will be those that put the user first and foremost in everything they do. A customer-centric approach reflects a genuine and empathetic understanding of each user's needs, wants, and even their limitations, and should be based on 'real' as opposed to theoretical or modelled patient behaviour. In the words of the Department of Health & Social Care policy paper, 'Services designed around users and their needs are more likely to be used, help more people get the right outcome for them, and so achieve their intent, [and] cost less to operate by reducing time and money spent on resolving problems.' "

Mike Trenell, founder and CEO of Changing Health

"First of all, it's about understanding the market, and the patients they are marketing to. There are a lot of different gaps that have unmet needs right now. What is their goal of the app or technology? Can they collaborate with other companies to bring it to the market to address specific patient need? I think there is a disconnect between what has worked in the past. We all know that patients with diabetes don't live in that lab; we need to consider the real aspects of what diabetes means for the real patients that are living with it day-to-day and day-in and day-out. The smaller companies are creating waves in this space because they are finding answers to questions that big corporations have failed to address."

Heidi Soto, Area Business Manager, MannKind Corporation

"I think that cloud-based aggregation of all the data is extremely important. It could be Apple, Amazon or Google, device manufacturers, health systems, EMR developers, the government or an independent entity, but someone needs to take the lead. The aggregation of all the data would be huge because then you can begin to figure out how to best identify your patients, how to risk stratify them, how to create automated algorithms to intervene, all those things. You also need to look at the interventions that take place and analyse if these were effective, or not. This will drive the future directions that are taken. Everything else is like the frosting on the top of the cake. If you can get your insulin pen devices to work better, or the apps to be simpler, pumps that react more rapidly, all those would be fabulous.

But you could do a lot for the entire picture if you could identify and intervene with the currently existing tools for both diabetes and the pre-diabetes populations. If all those things could come together; you could refine your algorithms for intervention much better if you had all the data in one place.”

Athena Philis-Tsimikas MD, VP, Scripps Whittier Diabetes Institute, La Jolla

Intelligence exhibits

Table 4: An overview of currently available CGM systems

	Abbot Freestyle Libre	Dexcom G6	Medtronic Guardian Sensor 3	Senseonics Eversense
FDA approved age	18 years and above	2 years and above	14 to 75 years	18 years and above
Mean absolute relative difference (MARD)	9.4% ⁷⁶	9% ⁷⁷	8.7% ⁷⁸	8.8% ⁷⁹
Duration of use	14 days	10 days	7 days	90 days
Calibration	Not required	Not required (but can be if desired)	2 required daily (recommend 3-4 daily)	2 required daily
Display options	Scanner	Receiver, smartphone, Tandem X2 (may share with up to 5 devices)	Medtronic insulin pump, Smartphone (may share with up to 5 devices)	Smartphone (may share with up to 5 devices)
Warm up time	1 hr	2 hrs	2 hrs	24 hrs
Alarms	No	Yes	Yes	Yes
Approved insertion sites/ procedure	Arm	Abdomen (2 years and up), Upper buttocks (2-17 years)	Abdomen	Upper arm (implanted in office)

Source: Allen et al, 2019⁸⁰

76 Abbott Diabetes Care. Freestyle Libre 14 day system. Retrieved from <https://provider.myfreestyle.com/freestyle-libre-product.html>

77 Dexcom. Dexcom G6 CGM System. Retrieved from <https://www.dexcom.com/g6-cgm-system>

78 Medtronic Diabetes. Guardian sensor 3. Retrieved from <https://professional.medtronicdiabetes.com/guardian-sensor-3>

79 Eversense Diabetes. The 90-day Eversense sensor is changing lives. Retrieved from <https://www.eversenseddiabetes.com/sensor>

80 Allen N, Gupta A. Current diabetes technology: Striving for the artificial pancreas. Diagnostics (Basel). 2019, Mar 15;9(1). pii: E31. doi: 10.3390/diagnostics9010031

Table 5: An overview of currently available insulin pump systems in the US

	Medtronic 670G	OmniPod DASH	Tandem X2
FDA approved age	7 years and above	All ages	6 years and above
Dosing increments	Basal: 0.025 units/hour Bolus: 0.025 units	Basal: 0.05 units/hour Bolus: 0.5 units	Basal: 0.001 units/hour at greater than 0.1 units/hour Bolus: 0.01 units at greater than 0.05 units
Tubing	Tubing lengths: 18", 23" & 32" Can be disconnected from infusion site	Patch Tubeless	Tubing lengths: 23", 32" & 43" Can be disconnected from infusion site
CGM integration	Medtronic Guardian Sensor 3	Dexcom G5/G6	Dexcom G5/G6
Hypoglycaemia prevention	Yes Low glucose suspend with Sensor 3	No	Yes Basal-IQ with G6 only
Closed loop available	Yes Auto mode	No	No
<i>Source: Allen et al, 2019⁸¹</i>			

81 Allen N, Gupta A. Current diabetes technology: Striving for the artificial pancreas. *Diagnostics (Basel)*. 2019, Mar 15;9(1). pii: E31.
doi: 10.3390/diagnostics9010031

Table 6: An overview of insulin pump systems available outside of the US

System	Description
Kaleido Insulin Pumps⁸²	<p>The Kaleido insulin pump is newly available in Europe. This pump's unique features include the option of placing the infusion site with variable lengths of tubing to accommodate for different locations on the body, and the option to place the insulin pump on the skin with an adhesive or in a pocket. The system also comes with two rechargeable pumps that can be used interchangeably, along with a handset that controls insulin delivery via Bluetooth technology. The pumps are water resistant up to a depth of 3.3 feet for up to 1 hour. However, the pump charging station and handset must be kept dry.</p> <p>Kaleido is manufactured by ViCentra B.V., with headquarters in Utrecht, the Netherlands, and an operating company in Bristol, UK. Kaleido was launched in the Netherlands in 2018, and in the UK in April 2019. The system has about 500 active users.</p>
Accu-Chek Insulin Pumps⁸³	<p>The Accu-Chek Combo system first became available in the US in 2012 following approval by the FDA. The system was comprised of an insulin pump and glucometer that was connected via Bluetooth technology. Although Accu-Chek insulin pumps are no longer supported in the US, they are still prominent in Europe and continue to support glucometers within the US.</p> <p>The most recent systems, the Accu-Chek Spirit Combo and Accu-Chek Insight, are currently supported in many countries around the world and offer some advantages. The systems, which comprise of an insulin pump and smart glucometer, allow the patient to change pump settings and use a bolus calculator without directly changing settings on the pump by input through the Bluetooth connected glucometer. The Accu-Chek Insight also allows patients to use pre-filled insulin cartridges instead of filling cartridges manually when replacing insulin.</p> <p>The Accu-Chek insulin pumps are manufactured by Roche Diabetes Care and are available in countries including France, Germany, UK and Australia.</p>
Sooil Dana Diabecare Insulin Pumps⁸⁴	<p>South Korean manufacturer Sooil Developments has three insulin pumps currently available on the market: Dana Diabecare R, Dana Diabecare RS Remote System and Dana Diabecare IIS insulin pumps. The pumps are currently available in multiple countries in Europe and Asia.</p> <p>The Dana Diabecare R model features a connected glucometer and lightweight design. The system also allows for remote control of pump settings through an Android-based smartphone application. The Dana Diabecare RS Remote System was released in 2018 and connects with smartphone applications for both Android and iOS systems via Bluetooth technology. The Dana Diabecare IIS insulin pump is less expensive than comparable insulin pumps and is also lighter and smaller in size.</p>

Source: Author's own research, 2020

82 Kaleido. ViCntra announcers Kaleido launched in the UK. 2019. Apr 29.
Retrieved from <https://www.hellokaleido.com/en/news/vicentra-announces-kaleido-launch-in-uk>

83 Roche Press Release. Roche Diagnostics Accu-Check combo insulin pump system now available in the United States.
Retrieved from <https://www.accu-check.com/news/accu-check-combo-available>

84 Sooil Developments Products. Retrieved from <http://www.sooil.com/eng/product/insulin-iis.php>

Table 7: New Diabetes Technology Expected in 2020

Company	Technology	Description
Tandem Diabetes Care	Control IQ	Control IQ is currently the most advanced commercial closed-loop system available. Tandem announced in January that it has launched the software in the US, along with a new mobile app that will enable automatic uploads of diabetes device data to its t:connect web platform. New features for the mobile app will be gradually unveiled from mid-2020 onwards. The system will include data display and the integration of other health data, eventually offering full mobile phone control of the t:slim X2 insulin pump via the app.
	t:sport mini-pump	Having received authorization to launch Control-IQ, Tandem is pushing forward the US FDA review of its new mini insulin pump, named t:sport, to mid-2020. The new Tandem mini pump is a hybrid of sorts: it is nearly half the size of the t:slim X2 pump and comes without any display screen at all. The t:sport will have a 'stick-to-your-body' adhesive feature as well as the t:slim's trademark pigtail insulin tubing that attaches to the infusion set for insulin delivery. The company hopes the new device will give customers a choice of how they wish to use it: either via smartphone app, or as a separate receiver device.
Insulet Corporation	OmniPod Horizon Closed Loop pump	In 2019, Insulet launched the OmniPod DASH system, which combines a tubeless, waterproof wearable pod that provides up to 72 hours of non-stop insulin delivery with an easy-to-use, touch-screen, Bluetooth-enabled Personal Diabetes Manager (PDM) that looks like a normal smartphone. The company also launched a 'Do-It-Yourself' version of the loop system that is compatible with the OmniPod tubeless pump. Now in 2020, Insulet is hoping to launch its official automated insulin delivery system called OmniPod Horizon, that will have potential smartphone mobile app control.

Table 7: New Diabetes Technology Expected in 2020 *continued*

Company	Technology	Description
Medtronic Plc.	780G	<p>Medtronic's 780G, its next-generation advanced hybrid closed loop system, will have the basic form of the company's 6-series models, incorporating a vertical 'modern' design compared to older models that had a horizontal shape.</p> <p>The 780G will use a new algorithm which is more accurate and reliable, and will provide automatic correction bolusing, automatically adjust for missed meals, and allow an adjustable glucose target down to 100 mg/dL (compared to the 670G's set target of 120 mg/dL).⁸⁵ The system also aims to achieve 80% user time-in-range (TIR) compared to the existing 71% TIR shown in data on the 670G.</p> <p>More importantly, this Bluetooth Low Energy (BLE)-enabled pump-CGM combination device will allow for remote software updating, as offered by Tandem's t:slim X2. Users will therefore not be required to buy a whole new device each time a new feature is launched. The system will also have the built-in BLE necessary for data-sharing connectivity. Medtronic has already submitted the BLE-connected component of the device to the FDA in the US.</p> <p>Clinical trials are ongoing and should be completed by mid-2020, with an anticipated launch by end 2020.</p>

⁸⁵ Tenderich A. Diabetes Mine. New diabetes technology to watch for in 2020. 2020 Jan. Retrieved from <https://www.healthline.com/diabetesmine/diabetes-tech-spectations-2020#Also-coming,-a-bit-later>

Table 7: New Diabetes Technology Expected in 2020 *continued*

Company	Technology	Description
Dexcom	G7 CGM System	<p>Dexcom's next-generation G7 CGM system is a collaboration with Verily (formerly Google Life Sciences). Some of the major revisions that the G7 will offer include:⁸⁶</p> <p>Extended Wear of 14-15 days: This adds four to five additional days compared to the current 10-day wear of the Dexcom G6. As with the G6, no finger stick calibrations will be required.</p> <p>Fully Disposable: Unlike Dexcom's CGM models to date, the G7 will be fully disposable, so users will not have a separate transmitter with a three-month battery life. Instead, the sensor and transmitter will be fully integrated, and once the sensor has lapsed, the user will be able to dispose of the whole integrated unit.</p> <p>Thinner: The G7 will be the thinnest generation of its CGM sensors released to date.</p> <p>Decision Support: It is expected that the new G7 will have more software features, such as dosing assistance and interaction features.</p> <p>Although Dexcom hasn't yet filed the G7 with the US FDA, the company is planning for a limited launch in late 2020, followed by a broader commercial launch in 2021.</p>
MannKind Corp.	Afrezza using Bluetooth connectivity	<p>Afrezza is the only rapid-acting insulin available that can be inhaled. MannKind is launching a BluHale Pro in 2020, specifically designed for healthcare providers. Using Bluetooth connectivity, the BluHale Pro will monitor inhalation technique for doctors to use in training new patients. The unit is compatible with Android, iPhone, and Microsoft devices.</p> <p>The unit flashes a green light if the Afrezza is inhaled properly and a red light if it is not. Doctors can view the tracked data in these instances and then offer patients advice on how best to use Afrezza. BluHale Pro will eventually be able to track and share dosing data as well.</p>

86 Tenderich A. Diabetes Mine. New diabetes technology to watch for in 2020. 2020 Jan. Retrieved from <https://www.healthline.com/diabetesmine/diabetes-tech-spectations-2020#Also-coming,-a-bit-later>

Table 7: New Diabetes Technology Expected in 2020 *continued*

Company	Technology	Description
Xeris Pharmaceuticals	Gvoke HypoPen	In late 2019, Xeris Pharmaceuticals received US FDA approval for the world's first ready-to-use stable liquid glucagon emergency pen (like an EpiPen) for diabetes rescue. The Gvoke HypoPen is expected to be launched in July 2020. However, the company opted to launch its pre-filled syringe option, Gvoke Pre-filled Syringe, first. The HypoPen is self-contained and is designed for quick one-time use and disposal. Once injected, the pen auto-retracts and locks so it cannot be used again. The non-insurance cash price will be US\$280 per injector, the same as the pre-filled syringe.
Eli Lilly and Company	Ultra-Rapid Lispro Insulin (URLi)	Ultra-Rapid Lispro Insulin (URLi) is a new and even faster-acting mealtime insulin. Recent clinical data has shown that URLi clocked in at 13 minutes compared to Humalog and other mealtime insulins that took as long as 27 minutes to start impacting glucose levels. ⁸⁷ It also reduces post-meal spikes more dramatically. In 2019, Lilly submitted URLi to the US FDA as well as regulators in Europe and Japan. The US pharmaceutical major is expecting to receive regulatory approval in all three markets in 2020.
	New Hybrid Patch Pump	Lilly's hybrid closed-loop system remains in development and the company plans to present information on early feasibility data during the course of 2020.

⁸⁷ Tenderich A. Diabetes Mine. New diabetes technology to watch for in 2020. 2020 Jan. Retrieved from <https://www.healthline.com/diabetesmine/diabetes-tech-spectations-2020#Also-coming,-a-bit-later>

Table 7: New Diabetes Technology Expected in 2020 *continued*

Company	Technology	Description
Beta Bionics	iLet Bionic Pancreas System	<p>In December 2019, Beta Bionics received 'Breakthrough Device' designation from the U.S. FDA for its investigational iLet Bionic Pancreas System.</p> <p>The iLet Bionic Pancreas System is a pocket-sized, wearable investigational medical device that is designed to autonomously control blood-sugar levels and is similar to an insulin pump. However, unlike other insulin pump therapy, the investigational system is designed so that users only need to enter their body weight for the iLet to initialize therapy.⁸⁸ Once entered, the iLet begins controlling blood-sugar levels automatically, without requiring the user to count carbohydrates, set insulin delivery rates, or deliver bolus insulin for meals or corrections.⁸⁹</p> <p>The iLet is designed to function as three medical devices in one. It can be configured as an insulin-only bionic pancreas, a glucagon-only bionic pancreas, or a bihormonal bionic pancreas using insulin and glucagon.</p> <p>Initial release of the system is anticipated in 2020 as an insulin-only device, with the addition of glucagon expected in the coming years</p>
WaveForm Technologies	WaveForm Technologies Cascade CGM system	<p>WaveForm Technologies is a wholly owned subsidiary of AgaMatrix Holdings LLC., and is the developer of the WaveForm Technologies Cascade CGM system.</p> <p>Real-time glucose data provided by the Cascade CGM facilitates blood glucose control through informative glucose trends, predictive and customizable alerts, as well as personalized glucose reports. Persons aged two years and older, including pregnant women and those requiring dialysis treatment, can use the Cascade CGM in making diabetes treatment decisions.</p> <p>In November 2019, WaveForm Technologies received CE Mark (Conformité Européenne) approval for its Cascade CGM system.⁹⁰ The company anticipates filing an application with the US FDA for clearance of the CGM system in 2020, with US commercialisation anticipated in 2021.</p>

Source: Source: Author's own research, 2020

88 Beta Bionics Press Release. Beta Bionics receives Breakthrough Device designation for the iLet Bionic Pancreas System. 2019, Dec 10. Retrieved from https://c17f9645-5692-4d88-a77f12866da2c9fb2.filesusr.com/ugd/9cfe47_ca8edb468f44e89f9b22aa06512fec.pdf

89 Beta Bionics Press Release. Beta Bionics receives Breakthrough Device designation for the iLet Bionic Pancreas System. 2019, Dec 10. Retrieved from https://c17f9645-5692-4d88-a77f12866da2c9fb2.filesusr.com/ugd/9cfe47_ca8edb468f44e89f9b22aa06512fec.pdf

90 Cision PR Newswire. WaveForm Technologies Inc. awarded CE mark approval for their continuous glucose monitoring system, 2019, Nov 5. Retrieved from <https://www.prnewswire.com/news-releases/waveform-technologies-inc-awarded-ce-mark-approval-for-their-continuous-glucose-monitoring-system-300952002.html>

Abbreviations

Abbreviation	Meaning
AI	Artificial Intelligence
ACE	Alternate Controller Enabled
ADA	American Diabetes Association
AHCL	Advanced Hybrid Closed Loop
AID	Automated Insulin Dosing
APPS	Mobile Applications
BGM	Blood Glucose Meters
BLE	Bluetooth Low Energy
CAGR	Compound Annual Growth Rate
CE	Conformité Européenne
CGM	Continuous Glucose Monitor
DPP	Diabetes Prevention Program
ECG	Electrocardiogram
FDA	Food and Drug Administration
GDM	Gestational Diabetes Mellitus
HCP	Healthcare Practitioner
IDF	International Diabetes Federation
IT	Information Technology
MARD	Mean Absolute Relative Difference
mHealth	Mobile Health
Medtech	Medical Technology
MPC	Model Predictive Control
NHS	National Health Service
NUS	National University of Singapore
PCL	Personalized Closed Loop
PDM	Personal Diabetes Manager
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes Mellitus
TIR	Time in Range
UK	United Kingdom
URLi	Ultra-Rapid Lispro Insulin
US	United States