MARKET OPPORTUNITIES IN DIABETES CARE & TECHNOLOGY

TRENDS, INSIGHTS & OPPORTUNITIES

July 2022

HEALTH TECH ENTERPRISE

Medtech Navigator

The Medtech Navigator (www.medtechnavigator.co.uk), part-funded by the European Regional Development Fund (ERDF), is a three-year programme, delivered by Health Enterprise East Ltd. (trading as Heath Tech Enterprise) to facilitate knowledge exchange between the medtech industry, many of whom are small and medium sized enterprises (SMEs), the NHS, and academia. The programme seeks to enable companies to identify potential market opportunities in a variety of specific disease areas and apply for Innovation Grant funding through the programme, thereby engaging SMEs in new R&D projects that are both customer-focussed and collaborative in nature. This will allow the creation of partnerships between clinicians, academics, and industry to develop novel medical technologies which will improve healthcare and quality of life for patients and the healthcare market of the future.

Health Tech Enterprise

At Health Tech Enterprise, we believe in improving healthcare through technology and innovation. We work with the NHS, medical technology industry and government organisations to help turn innovative ideas into products and services that will benefit patients.

Our experienced team offers clients a diverse range of business and innovation management services. Our strengths include IP management, technology commercialisation, health economics and strategic market access advice.

Based in Cambridge, we work with over 25 NHS organisations nationally and medtech companies globally. Our aim is to help our clients address the challenges faced along the product development pathway, connecting them with relevant healthcare experts and funding opportunities.

Report Summary

This report discusses the potential of innovative technologies to empower patients, transform the outcomes, and reduce costs across the diabetes care pathway. Globally, we are witnessing an ever-increasing disease burden associated with increasingly comorbid and ageing populations. Further, the impact of COVID-19 pandemic has underscored the importance of establishing a critical care system that is more budget-efficient, personalised and provide digitally enabled care across the NHS. Developments in AI, genomics, glucose monitoring and delivery systems, applications, wearables, and smartphone technologies can help address some of these challenges. Innovative UK SMEs are contributing to major breakthroughs that will lead to improvements in the diabetes care pathway over the next few years. The report will look at market opportunities in diabetes care, highlights some of the innovative SMEs tackling this area and review the patent landscape.

1. Background

Currently more than 4.9 million people in the UK have diabetes and over 13 million people are now at increased risk of type 2 diabetes (T2D)[1]. Increasing prevalence of diabetes is one of the leading causes of high mortality and morbidity rate globally[2]. The NHS spends at least £10 billion a year on diabetes which is about 10% of its entire budget and almost 80% of the money the NHS spends on diabetes is on treating complications like amputation, blindness, kidney failure and stroke[3].

NHS Diabetes Prevention Programme & Diabetes treatment and care programme

The NHS Long Term Plan[4], published in 2019, highlights the key aims and objectives for improving the nation's health and funds specific new evidence-based NHS prevention programmes including the T2D NHS Diabetes Prevention Programme. The programme is a joint commitment by NHS England, Public Health England and Diabetes UK, and supports those at high risk of T2D to reduce their risk. Chapters one and two set out a range of actions the NHS will be taking to prevent T2D and reduce the variation in the quality of diabetes care.

The NHS Long Term Plan also set out a range of actions that the NHS is taking to reduce variation in access to services and patient outcomes, improve quality of treatment and outcomes for people living with type 1 (T1D) or type 2 (T2D) in the Diabetes treatment and care programme. The NHS Low Calorie Diet Programme supports low calorie diets for people living with obesity and T2D and the NHS Digital Weight Management Programme supports adults living with obesity who also have a diagnosis of diabetes or hypertension or both, to manage their weight and improve their health[5]. The programme is the largest undertaking of its kind in the world and over 100,000 people have already benefited since its introduction in 2016, with further commitment to fund the Programme over the next five years, including a new digital option to widen patient choice and target inequality.

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[1] https://www.diabetes.org.uk/about_us/news/diabetes-diagnoses-doubled-prevalence-2021#:~:text=Our%20analysis%20also%20shows%20that,2%20diabetes%20in%20the%20UK
[2] Sin Yee Tan, Joyce Ling Mei Wong, Yan Jinn Sim, Su Sie Wong, et al. (2019). Type 1 and 2 diabetes mellitus: A review on current treatment approach and gene therapy as potential intervention, Diabetes & Metabolic Syndrome: Clinical Research & Reviews, Volume 13(1), https://doi.org/10.1016/j.dsx.2018.10.008.
[3] https://www.diabetes.org.uk/professionals/position-statements-reports/statistics
[4] https://www.longtermplan.nhs.uk/
[5] https://www.england.nhs.uk/diabetes/treatment-care/

Digital technology implementation

The NHS Long Term Plan describes the strategy for providing and upgrading technology and providing digitally enabled care across the NHS. The programmes offer digital support to provide new opportunities to improve patient experience and outcomes and deliver services in a more efficient way, reducing the burden on clinicians and the public. The Healthier You NHS Diabetes Prevention Programme or the Healthier You programme, identifies people at risk of developing type 2 diabetes and refers them onto a nine-month, evidence-based lifestyle change programme. The service is available both face to face and digitally and can be used as per convenience. Healthy Living[6] is a free online service designed to provide advice and information to people living with type 2 diabetes, to help them better manage their condition. NHS also support self-management and care of people living with type 1 diabetes via free digital online service such as MyType1 Diabetes[7] and DigiBete[8].

The role of Innovation and Technology

Advancements in diabetes technologies enable primary care providers to give personalized care which addresses individual patient's needs[9]. Healthcare teams need help to support patients in choosing the device or program best suited to their needs and skills and provide ongoing education and training. Most patients consider adaptability of devices as a desirable characteristic, which directly relates to improved glycemic control[10]. Technologies that are user-friendly and effective in performing automated tasks reduce the burden of disease[11]. Diabetes education is key to approaching an optimal use of diabetes technologies[12].

Developments in diabetes technology play an increasing role in the management of diabetes and can be classified into two major categories: devices for glycaemic self-monitoring [such as self-measured blood glucose (SMBG) meters and continuous glucose monitoring (CGM) meters] and insulin delivery systems. Insulin is usually self-administered by an injection pen, or sometimes a pump in T1D. Connected ("smart") injection pens provide the potential for further advantages in monitoring, calculating the insulin dosage, and compliance. Automated insulin delivery devices include insulin pumps with continuous subcutaneous insulin infusion (CSII) and closed-loop systems (sensor-augmented pumps, integrated with a

[6] https://healthyliving.nhs.uk/

[7] https://www.mytype1diabetes.nhs.uk/

[8] https://www.digibete.org/

[9] Bode B, King A, Russell-Jones D, Billings LK. Leveraging advances in diabetes technologies in primary care: a narrative review. Ann Med. 2021 Dec;53(1):805-816. doi: 10.1080/07853890.2021.1931427.

[10] Naranjo D, Suttiratana SC, Iturralde E, et al. What end users and stakeholders want from automated insulin delivery systems. Diabetes Care 2017; 40: 1453–1461.

[11] Naranjo D, Tanenbaum ML, Iturralde E, et al. Diabetes technology: uptake, outcomes, barriers, and the intersection with distress. J Diabetes Sci Technol 2016; 10: 852–858.

[12] Tanenbaum ML, Adams RN, Hanes SJ, et al. Optimal use of diabetes devices: clinician perspectives on barriers and adherence to device use. J Diabetes Sci Technol 2017; 11: 484–492.

real-time CGM) are predominantly used by people with T1D[8]. Technology solutions such as automated bolus calculators (ABCs), CGM, intermittently viewed continuous glucose monitoring (iCGM) or flash glucose monitoring, implantable long-term CGM sensors, integrated systems, telemedicine, applications, wearables and smartphone technologies empower patients and improve self-care by offering increased safety, support and comfort. However, cost associated with these technologies, lack of healthcare system coverage, achieving adherence and the learning curves involved are the barriers that limits the widespread adoption[13]. With diabetes technologies forming a key part of The NHS Long Term Plan and increasing use of diabetes devices in children and younger people who are approaching transition to adulthood, an ongoing increase in the implementation and access to diabetes technologies is likely to be observed The NHS Long Term Plan[14].

2. Market size

Analysing the market size and unmet needs of innovative technologies in diabetes care

The Medical device market is projected to grow from an estimated USD 455 billion in 2021 to USD 658 billion in 2028[15] and the global paediatric healthcare market is expected to generate around USD 15,984 million by 2025. There are 1.8 billion young people in the world today; 40% of the global population is under 24, creating significant future healthcare market opportunities[16]. Technological advancements in the area of precision medicine, genomics, artificial intelligence, insulin monitoring and delivery devices, apps or software or digital tools for diabetes prevention care or treatment have the potential to change how diabetes is diagnosed and managed and how this lifestyle disease is prevented.

Genomics, Artificial Intelligence and Precision Medicine

Precision medicine refers to the goal of leveraging extensive patient-level phenotypic and genotypic data to tailor care recommendations, and thereby improve health outcomes.

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[13] Alcántara-Aragón V. Improving patient self-care using diabetes technologies. Ther Adv Endocrinol Metab. 2019 Jan 28;10:2042018818824215.

[14] NHS England. The NHS Long Term Plan. NHS, 2019. www. longtermplan.nhs.uk.

[15] Medical Device Market Size, Share &COVID-19 Impact Analysis, By Type (Orthopedic, Devices, Cardiovascular Devices, Diagnostic Imaging, In-Vitro Diagnostics, Minimally Invasive Surgery, Wound Management, Diabetes Care, Ophthalmic Devices, Dental Devices, Nephrology, General Surgery, and Others); By End User (Hospital & ASC's, Clinical and Others), and Regional Forecast 2021–2028; Fortune Business Insights. Available online: https://www.fortunebusinessinsights.com/industry-reports/

[16] Dimitri P, Pignataro V, Lupo M, Bonifazi D, Henke M, Musazzi UM, Ernst F, Minghetti P, Redaelli DF, Antimisiaris SG, Migliaccio G, Bonifazi F, Marciani L, Courtenay AJ, Denora N, Lopedota A. Medical Device Development for Children and Young People-Reviewing the Challenges and Opportunities. Pharmaceutics. 2021 Dec 17;13(12):2178. doi: 10.3390/pharmaceutics13122178. PMID: 34959459; PMCID: PMC8706877.

Precision child health necessitates the integration of large datasets, including but not limited to genomic data[15]. Developments in fields of genomics and artificial intelligence will improve our understanding of disease profiles, influence the type of treatment undertaken and enable a shift to preventative by predicting the population at risk, screening and surveillance and early treatment. However, an issue that needs to be addressed is the safe, consented, and transparent sharing of data[17]. The global genomics market size was valued at USD 20.1 billion in 2020 and is expected to expand at CAGR of 15.35% from 2021 to 2028[18] (Figure 1). Functional genomics held the largest revenue share of 32.0% in 2020. The products segment dominated the market in 2020 with a revenue share of 69.3%.
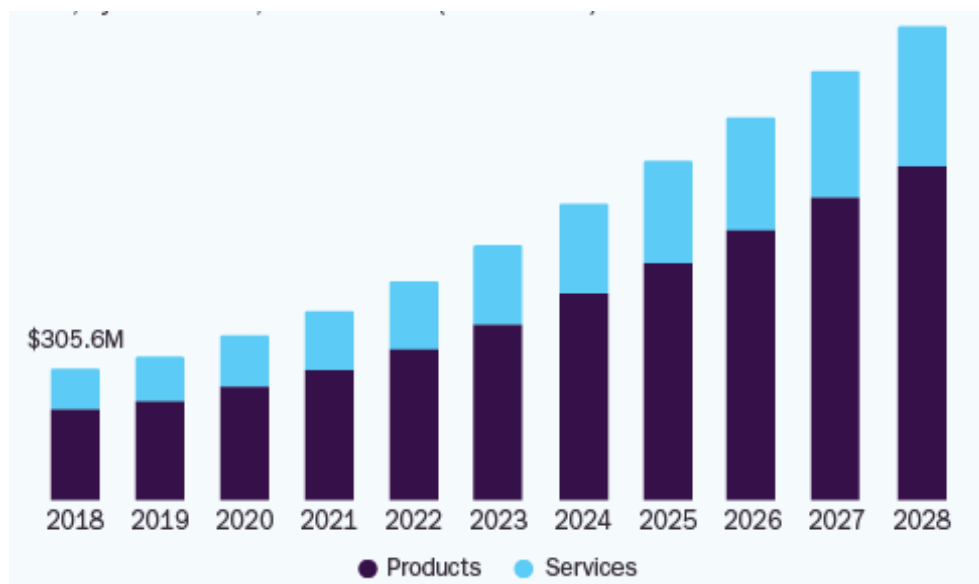

Figure 1. UK genomics market size, by deliverable, 2018-2028 (USD million) (picture adopted from GrandViewResearch report, 2021).

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[17] Royal College of Surgeons of England. Future of Surgery. London: RCS England; 2018.
https://publishing.rcseng.ac.uk/doi/full/10.1308/rcsbull.2019.264
[18] Genomics Market Size, Share & Trends Analysis Report by Application & Technology.
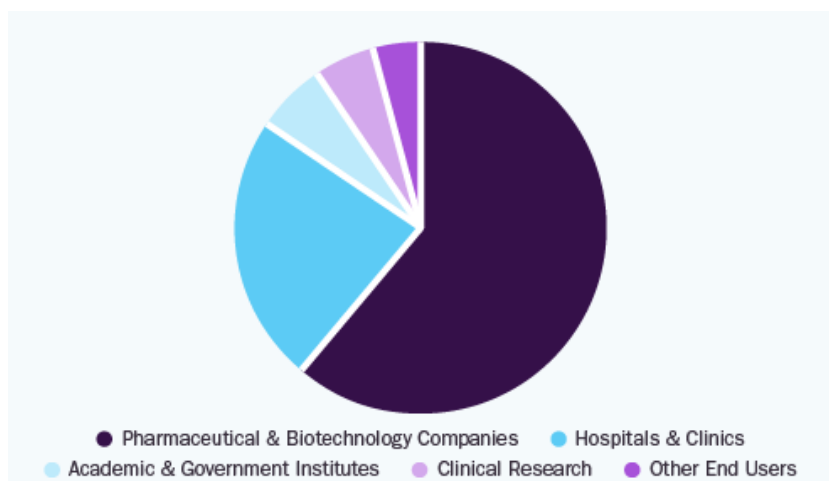https://www.grandviewresearch.com/industry-analysis/genomics-market

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Figure 2. Global genomic market share, by end-use, 2020 (picture adopted from GrandViewResearch report, 2021).

Pharmaceutical and biotechnology companies held the largest genomic market share of 60.3% in 2020[17] (Figure 2). Growing demand in genomic technologies, which owes to the possibility of low-cost sequencing has attracted many new players to the market. North America dominated the market with a share of 36.7% in 2020 owing to an increase in the number of research programs, a high number of strategic partnerships, and a rise in regulatory approvals by the U.S. FDA. Changing regulations for reimbursement and usage are anticipated to further propel the adoption of genetic tests in this region[18].

Artificial Intelligence (AI) in the healthcare market was valued at $8.23 billion in 2020, and is projected to reach $194.4 billion by 2030, growing at a CAGR of 38.1% from 2021 to 2030[19]. The growth is propelled by an increase in the volume of healthcare data, rise in complexities of datasets, improvements in the computing power and decline in hardware costs, surge in number of cross-industry partnerships, collaborations and a rise in the imbalance between the size of the health workforce and patients. The COVID-19 pandemic favoured the growth of the AI market in healthcare and proved its possibilities in various applications such as medication management, treatment plans, personalized medicines, patient monitoring care and drug discovery.

AI and machine learning have expanded the potential in the field of diabetes care. Principles of machine learning have been used to build algorithms to support predictive models for the risk of developing diabetes or its consequent complications. Patients are increasingly being empowered for self-management of diabetes, and both patients and health care professionals are benefitting from clinical decision support. AI allows a continuous and burden-free remote monitoring of the patient's symptoms and biomarkers. AI will introduce

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[19] AI in Healthcare Market by Offering, Algorithm, Application, and End: Global Opportunity Analysis and Industry Forecast, 2021—2030. https://www.alliedmarketresearch.com/artificial-intelligence-in-healthcare-market

a paradigm shift in diabetes care from conventional management strategies to building targeted data-driven precision care[20].

The global AI in diabetes management market size was estimated at USD 452.69 million in 2021 and expected to reach USD 590.45 million in 2022 and is projected to grow at a CAGR 30.60% to reach USD 2,247.24 million by 2027[21]. The key players in the field are Vodafone Group Plc, XBIRD, Virta Health Corp, DreaMed, Sweetch, Hedia, Sensyne Health plc, GlucoMe, Google Inc., Wellthy Therapeutics Pvt Ltd, Medicsen, IBM Corporation, Apple Inc., PredictBGL, Livongo Health, Tidepool, Diabnext, TypeZero Technologies, Inc., Medtronic, Glooko Inc. Global artificial intelligence in diabetes management market by types include glucose monitoring devices, diagnostic devices, insulin delivery devices and others[22].

Blood Glucose Monitoring Devices

The global blood glucose monitoring devices market size was valued at 11.71 billion in 2021 and is expected to expand at a compound annual growth rate (CAGR) of 8.0% from 2022 to 2030 according to GrandView Research. The key drivers of the market are the rising incidence of diabetes, increasing geriatric population prone to diabetes, increasing awareness regarding diabetes preventive care and new product launches further fuels the market growth. According to the International Diabetes Federation, in 2021, around 537 million people were diagnosed with diabetes, this number is expected to increase to 643 million by 2030 and 783 million by 2045[23].

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[20] Ellahham S. Artificial Intelligence: The Future for Diabetes Care. Am J Med. 2020 Aug;133(8):895-900. doi: 10.1016/j.amjmed.2020.03.033. Epub 2020 Apr 20. PMID: 32325045.

[21] Market Research.com https://www.marketresearch.com/360iResearch-v4164/Artificial-Intelligence-Diabetes-Management-Research-31413484/

[22] Healthcare Market Reports https://healthcaremarketreports.com/reports/artificial-intelligence-in-diabetes-management-market/5807/

[23] Grand View Research Reports https://www.grandviewresearch.com/industry-analysis/blood-glucose-monitoring-bgm-devices-market
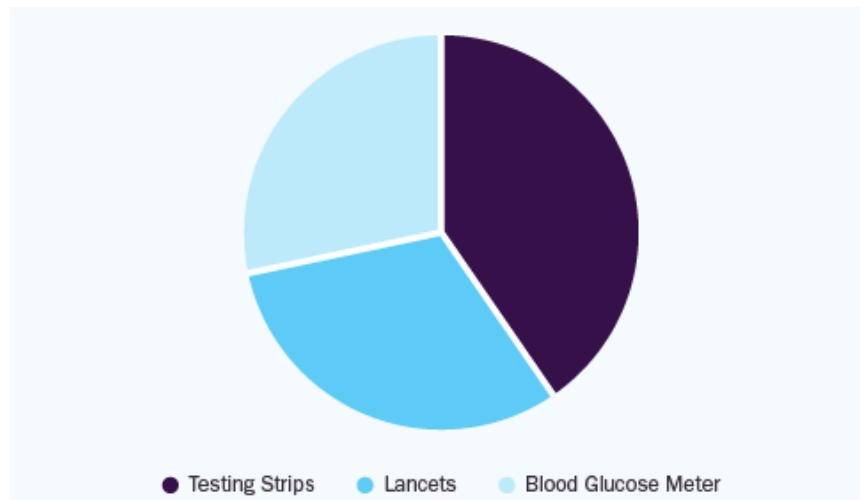
Figure 3. Global self-monitoring devices market share, by product, 2021 (%)) (picture adopted from GrandViewResearch report).

The hospital segment held the largest revenue share of over 40.0% in 2021 and is anticipated to lead the market over the forecast period due to improving infrastructure and increasing healthcare expenditure in hospital and the additional provisions it has to store and transfer patient information[24]. The home care segment is expected to register the fastest growth rate during the forecast period (2022-2030). The home-based glucose monitoring is revolutionized by the self-monitoring of blood glucose and is the most widely used method of short-term glucose monitoring throughout the world. Self-monitoring blood glucose devices accounted for the largest revenue share of over 65.0% in 2021 owing to the ease of use and low cost. It is sub-segmented into blood glucose meter, testing strips, and lancets. The testing strips segment accounted for the largest revenue share in 2021 owing to the high usage of these strips and affordability (Figure 3).

The continuous blood glucose monitoring devices segment is expected to register the highest growth rate during the forecast period. It is sub-segmented into sensors, insulin pumps, and transmitter and receiver. The transmitter and receiver segment held the largest revenue share in 2021.

North America led the market with a revenue share of over 35.0% in 2021 owing to its well-established healthcare sector. The increasing prevalence of obesity, high cost of treatment, technological advancements, and new product launches are also expected to drive the regional market. Europe is expected to capture a significant revenue share over the forecast period due to an increase in the geriatric population, improvements in the healthcare sector and the implementation of advanced medical products.

Major players in the global blood glucose monitoring devices market include Abbott Laboratories, Medtronic plc, F. Hoffmann-La Roche Ltd., Ascensia Diabetes Care, Dexcom, Inc., Sanofi, Novo Nordisk, Insulet Corporation, Ypsomed Holdings, Glysens Incorporated.

Digital Diabetes Management

Digital health has the potential to increase patient engagement, reduce access barriers, and enhance patient-centred care in patients with diabetes. The global digital diabetes management market was valued at US$ 19.02 billion in 2021 and is projected to reach US$ 90 billion in 2030[24] The major industry leaders operating in the digital diabetes management are focusing on providing innovative products and introducing advanced technologies in this market. The smart insulin pump segment is expected to have the highest growth during the forecast period (2022-2030) due to the launch of the bluetooth enabled insulin pumps which provides access to data on the mobile phones. By type, the type 1 diabetic patient segment will have a larger market share of the digital diabetes management market during the forecast period because of the dependency of patients on insulin. The European market is expected to have the largest market share during the forecast period due to the presence of a large number of suppliers in this region and the introduction of good reimbursement rules and policies.

Key players in this field include Bayer AG, Medtronic, AgaMatrix, Roche Diagnostics, Dexcom Inc. LifeScan Inc., One Drop, Abbott Laboratories, Ascensia Diabetes Care, ACON Laboratories, ARKRAY Inc, and Insulet Corporation (Digital Diabetes Management Market Size Precedence Research report 2022).

Point of care testing

The global point of care diagnostics market size was valued at USD 46.65 billion in 2021. The market is projected to grow from USD 36.37 billion in 2022 to USD 51.94 billion by 2029, exhibiting a CAGR of 5.2% during the forecast period. The demand for quality point of care diagnostics kits rapidly increases with acute and chronic diseases worldwide and technological developments in diagnostic kits have resulted in fewer manual errors and emerged as a prominent driving factor for the market. This is expected to boost the adoption of point of care diagnostics kit in emerging and lower economic countries. However, high cost associated with the technologies used for virus clearing, lack of accuracy of POC diagnostics, preanalytical errors could limit the adoption of POC testing[31].

The global point-of-care glucose testing market size was valued at USD 3.1 billion in 2021 and is expected to expand at a compound annual growth rate (CAGR) of 4.1% from 2022 to 2030[25]. Type 1 diabetes constitutes the vast majority (90%) of diabetes in children and young people. In 2019, there were an estimated 36,000 children in the UK with diabetes under the

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[24]https://www.globenewswire.com/news-release/2022/06/09/2459675/0/en/Digital-Diabetes-Management-Market-Size-to-Hit-US-90-Bn-by-2030.html.

[25] https://www.grandviewresearch.com/industry-analysis/point-of-care-glucose-testing-market

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age of 19, up from 31,500 in 2015[26] and in US around 210,0000 children and adolescents younger than age 20 years were diagnosed with diabetes[27]. The high market share is attributable to the higher sales of diabetes rapid diagnostics kits available over the counter, without a prescription and help the patients in self-testing and monitoring their glucose levels.

Insulin delivery device

The global insulin delivery devices market size was valued at USD 12.5 billion in 2021 and is anticipated to expand at a CAGR of 7.4% from 2022 to 2030[28] Insulin delivery devices including syringes, injection pens, pumps, and jet injectors are used to deliver insulin to diabetic patients. The insulin injection pens segment held the largest revenue share of 36.5% in 2021 owing to its advantages over other products. Factors such as its high adoption rate, user-friendly design, and rising popularity among consumers contributed to the largest revenue share of this segment. The home care segment dominated the insulin delivery devices market and accounted for the largest revenue share of 48.9% in 2021 (Figure 4). It is anticipated that the home care segment will maintain its position in the market for insulin delivery devices during the forecast period. The key factors resulting in significant growth of the segment are increasing awareness of diabetes care and the growing adoption of insulin delivery devices amongst patients for home use.

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[26] Diabetes. RCPCH State of Child Health. https://stateofchildhealth.rcpch.ac.uk/evidence/long-term-conditions/diabetes/#:~:text=In%202019%2C%20there%20were%20an,up%20from%2031%2C500%20in%202015.&text=Type%201%20diabetes%20constitutes%20the,unable%20to%20produce%20any%20insulin
[27] Diabetes in youth. Centers for Disease Control and Prevention. https://www.cdc.gov/diabetes/library/reports/reportcard/diabetes-in-youth.html#:~:text=Of%20the%20estimated%2026.9%20million,younger%20than%20age%2020%20years.&text=The%20increasing%20frequency%20of%20both,clinical%20and%20public%20health%20concern

[28] Grand View Research report https://www.grandviewresearch.com/industry-analysis/insulin-delivery-devices-market
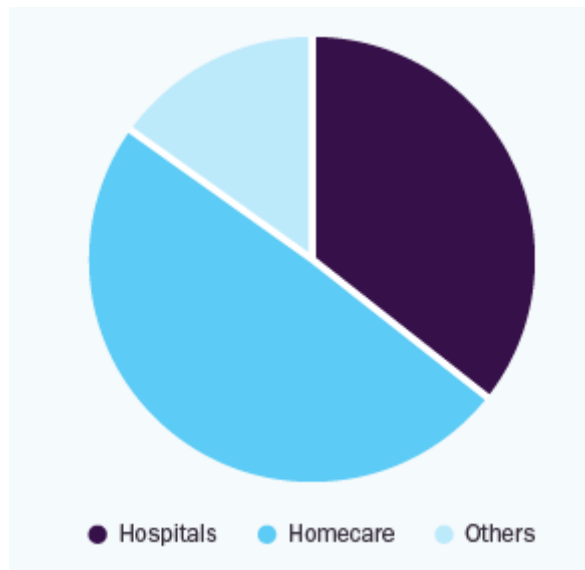
Figure 4. Insulin delivery devices market share, by end use, 2021 (%) (picture adopted from GrandViewResearch report).

The use of insulin devices at home saves on consultation costs, hospital or clinic fees, and waiting time. The advanced devices, including pumps, pens, and injectors, are small in size, highly portable, and can be used anywhere at any time.

North America dominated the market for insulin delivery devices and accounted for the largest revenue share of 37.5% in 2021[29] (Figure 5). In Asia Pacific, the market for insulin delivery devices is expected to grow fast over the forecast period. Developing economies, such as China and India, are expected to witness the highest growth during the study period due to the presence of a large population base suffering from diabetes and its rising awareness amongst individuals. The market for insulin delivery devices is ruled by three major players, namely, Novo Nordisk, Eli Lilly, and Sanofi. Other prominent players in the insulin delivery devices market include Biocon Ltd., Ypsomed AG, Wockhardt Ltd., Medtronic, Abbott Laboratories, F. Hoffmann-La Roche, Ltd[30].

[29] Global Market Insights Report. https://www.gminsights.com/industry-analysis/insulin-delivery-devices-market

[30] https://www.grandviewresearch.com/industry-analysis/insulin-delivery-devices-market
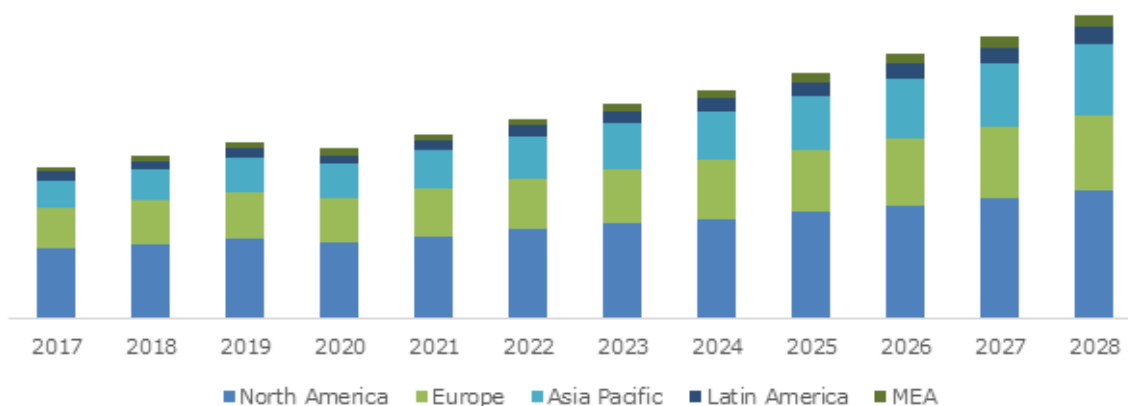
Figure 5. Global Insulin delivery device market, by region 2017-2028 (USD million) (picture adopted from Global Market Insights report).

3. SMEs tackling unmet needs in innovation and technology for diabetes care

A number of innovations are being developed and commercialised to align with the specific challenges identified within the NHS Long Term Plan. The following summary highlights some of these innovations by small and medium sized companies, for the prevention, management and treatment of diabetes.

The CamAPS® FX solution (camdiab.com) is an easy-to-use hybrid closed loop system to manage glucose levels in people with type 1 diabetes. The closed-loop app automatically adjusts insulin delivery on the patient's insulin pump based on their glucose readings from their CGM. The solution is approved for all patients over 1 year old.

Glucomen day cgm (A.Menarini diagnostics) provides real time CGM, one blood glucose data every minute. The GlucoMen Day CGM Sensor is wearable and easy to apply and remove. The long-lasting electrochemical sensor measures the glucose levels for two weeks. Real time cloud data sharing to GlucoLog cloud platform allows caregivers and medical staff to monitor glycaemic trend.

The artificial pancreas (Inreda Diabetic BV) is a dual-hormone closed loop system that regulates blood glucose levels by administering insulin and glucagon. The device is intended for people with diabetes who are treated with insulin, for use at home. It consists of two sensors wirelessly transmitting measurements to the device; insulin and glucagon administered automatically via two infusion sets.

Simplicity (CeQur) is a mealtime insulin patch using a flexible cannula. Doses are administered by squeezing the buttons on the sides of the device based on the dose prescribed by medical professionals. The patch can be worn for three days, reduces the

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hassle of carrying insulin pens and needles but one long-acting insulin injection a day may still be needed.

Kaleido (ViCentra) is a rechargeable insulin pump that last for 3 days connected wirelessly via bluetooth to a handset. It uses disposable infusion sets and insulin cartridges and micro pulse delivery. The kaleido calculator on the handset is used to calculate boluses.

NovoPen® 6 & NovoPen Echo® Plus (NovoNordisk) are smart insulin pens that automatically record insulin dosing information about each injection so that the information can be viewed in conjunction with blood glucose data by transferring data to a preferred management app.

My life Ypsopump (Ypsomed) is a modular insulin pump system controlled by smart phone app. It provides automatic correction of high and low glucose levels. Targeted to be released 2022.

T:slim x2 (Air Liquid healthcare) is an advanced hybrid closed loop technology aimed at increasing the time blood glucose is in range, by predicting and helping reduce highs and lows. It uses micro-delivery technology, a flat insulin cartridge, touch screen, rechargeable battery that lasts seven days and integrates directly with dexcom G6 CGM. The t:slim X2™ Insulin Pump is up to 38% smaller than other CGM enabled pumps and can hold up to 300 units of insulin.

DBLG1 (Diabeloop) is a hybrid closed-loop system consisting of a bluetooth-connected CGM, a pump, and the DBLG1 algoritym. DBLG1 is a self-learning algorithm that automates and personalizes the treatment of Type 1 diabetes. The DBLG1 artificial intelligence analyses the data real time, taking into account physiological, historical and data entry context, to determine the correct insulin dose to administer.

The U-Needle concept (Rocket innnovations) would replace subcutaneous infusion that now administers the insulin and glucagon infusion. U needle is only 1.5 mm in length, and the drug delivery channel is only 0.15 mm in diameter for intradermal injection. The U-Needle™ infusion set concept need to be tested clinically to see if intradermal microneedles will deliver insulin faster than subcutaneous infusion needles, without leakage. It will consist of infusion needles, glucose and other sensors integrated in one system. Atom sharp needles produced by silicon manufacturing technology mean the needle doesn't wear out and can be reused without need for lubrication. Promising for bi-hormonal artificial pancreas systems.

Mysugr pro (MySugr) is an app used in combination with medical devices that automatically transfers diabetes data from connected devices via bluetooth and analyses them to identify patterns. The software provides clear reports in pdf, excel or in app.

Diabeo (Voluntis) is a mobile app that incorporates SMBG recordings and an insulin bolus calculator that uses algorithms that take into consideration carbohydrates, exercise, clinician set parameters, correction facto and basal dose. It provides bi weekly telephone calls with healthcare professionals.

K'Watch Glucose ([PK Vitality](#)) aims to disrupt the CGM market by measuring blood sugar levels using its SkinTaste technology; a biosensor array that uses micro-needels to collect and analyse chemical compositions in the interstitial fluid. It then integrates these readings with other digital biomarkers collected via its smartwatch. The device is still in development with
first In Human trial at AMCR Institute in November 2021.

4. Patent landscape review

The patent landscaping was conducted for technologies that supports diabetes care over a period of ten years from 2012 until June 2022 in the following areas of self-monitored blood glucose, CGM, automated insulin delivery system, artificial intelligence, insulin pen smart pen insulin pump integrated pump system, combined insulin pump and sensor system, apps or software or digital tools for diabetes prevention care or treatment. As a note, all charts displayed in patent landscaping section shows one document per application and is calculated using the latest publication.

Geographic territories and application trend in countries of origin

Around 50% of the earliest applications pertaining to diabetes care were filed in China, followed by 35% in US and 6% in EPO, indicating the countries where majority of organisations are based, or which countries companies want to first capitalise in. The information available could be used by companies to plan their filing strategy – ensuring their portfolio covers the top jurisdictions, making them an attractive acquisition target. It might also help to identify untapped markets for this technology. A yearly application trend of the top countries within the search field gives an indication of the geographical markets targeted by the technology field and how direction changes over time, to help identify patenting trends and shifts in markets (Figure 6a and 6b).
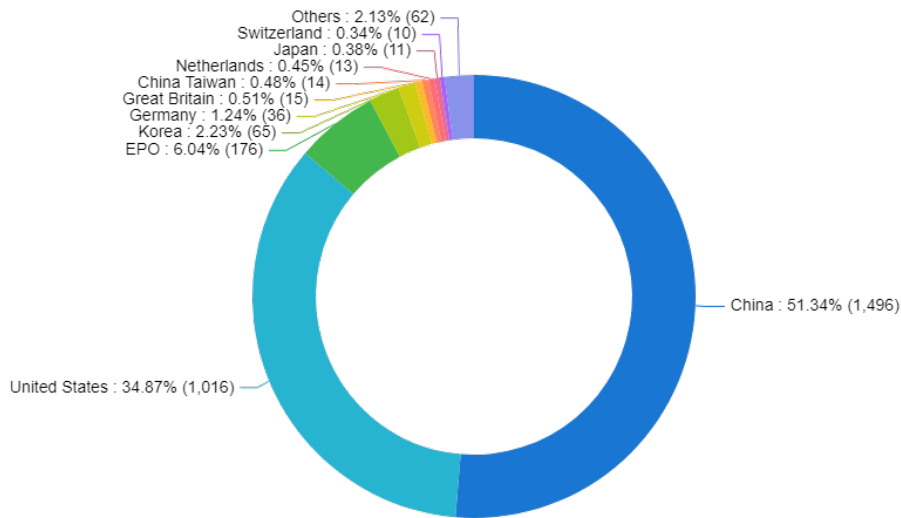
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Figure 6a. Geographic territories where patent applications were filed in the area of diabetes care technologies.

Figure 6b. Geographic territories and application trend in countries of origin.

IP5 Territory distribution

Analysing the origin and protection of the diabetes care technology space in IP5 (EP, CN, JP, KR, US) as in gives a picture of which country, out of the top five largest intellectual property offices, the technology field originates from and is more heavily protected in (Figure 7). This helps to understand if organisations are typically protecting their invention in their own market or extending this to more profitable markets elsewhere.
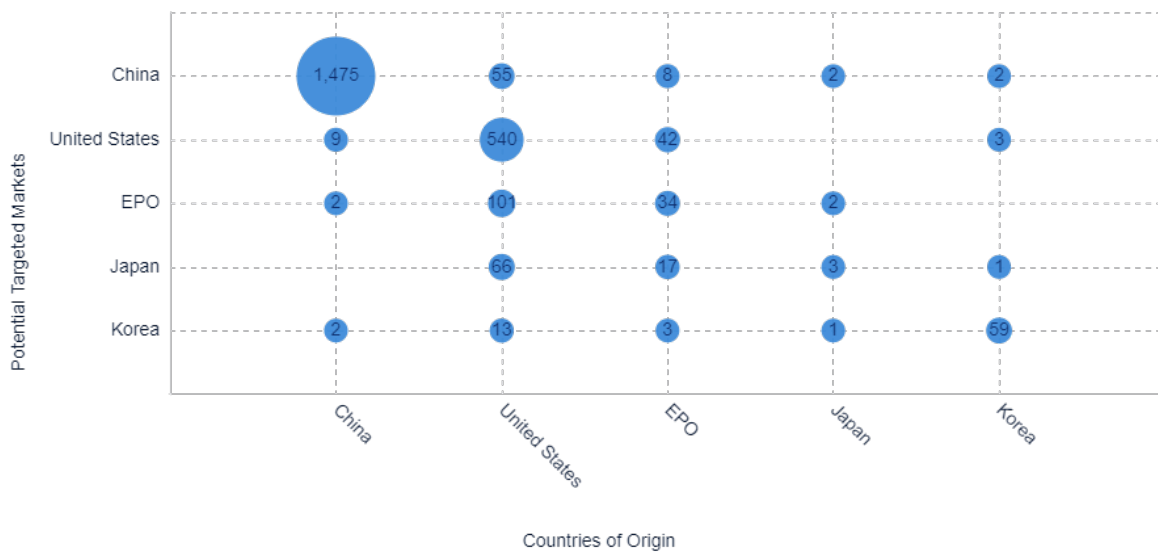
Figure 7. Diabetes care technology space in EP, CN, JP, KR and US.

Key Technologies

Visualising the major technology areas helps to understand alternative applications of the technology and find potential opportunities for licensing and white space. To allow us to tap into the heart of the patent scene, data was extracted and tabulated using what is known as the Cooperative Patent Classification (CPC) system – an internationally recognised and implemented classification system for patent publications, born out of a collaboration between the European Patent Office (EPO) and the United States Patent and Trademark Office (USPTO). Description of all CPC codes used in this report can be found in table 1 (appendix).

The largest proportion of patents, around 43% lies in the CPC code of A61M5 for "Devices for bringing media into the body in a subcutaneous, intra-vascular or intramuscular way; Accessories therefore (Figure 8 and 9).
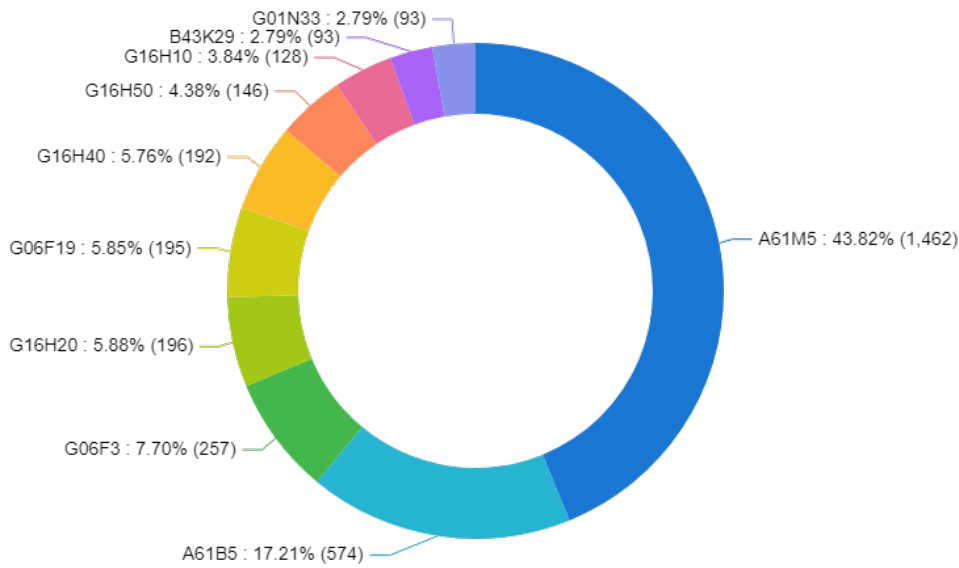
Figure 8. Top CPC codes depicting the proportion of filed patents in diabetes care technology space from 2012- 2022.

Application trend of key technologies

Yearly application trend of the major technology areas over the last ten-year period represented here could be used to understand how investment into different technologies has changed over time. The A61M5 category "calculating health indices, for individual health risk assessment" tops the CPC class with increased activity over a period of ten years from 2011.
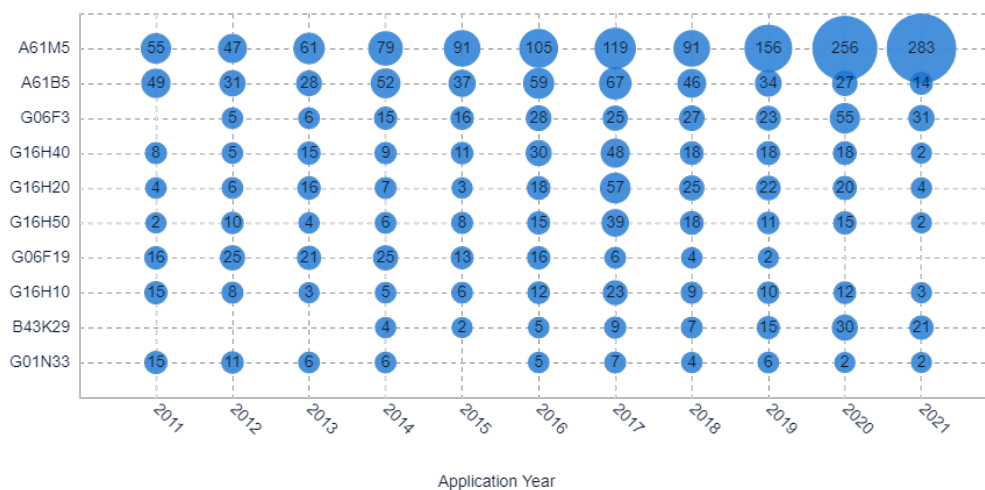

Figure 9. Yearly application trend of major technology areas from 2011- 2021.

Geographic distribution of key technologies

To identify the top markets for commercialisation and the commercial potential of different countries, we analysed the distribution of key technologies across the top 10 countries (Figure 10). The top CPC code G16H50/30 (ICT specially adapted for   for   calculating health indices; for individual health risk assessment) in the diabetes care technology space accounts for the high proportion of the patents in China followed by G16H40/67 which represents patents in ICT specially adapted for the management or administration of healthcare resources or facilities; ICT specially adapted for the management or operation of medical equipment or devices for remote operation.
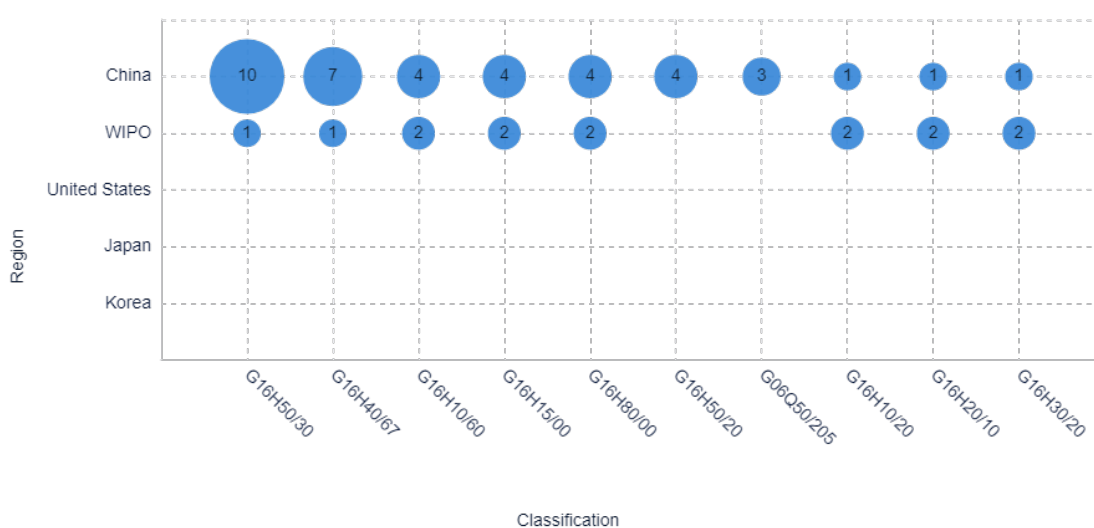

Figure 10. Geographic distribution of key technologies in diabetes care from 2012- 2022.

Major players in diabetes care technologies & geographic distribution of top assignees

The top assignees identified within different key diabetes care technology space (corresponds to the top CPC classes) are Roche Diabetes Care, F. Hoffmann-La Roche & Co, Medtronic Minimed, Bigfoot Biomedical, Dexcom, Tandem Diabetes Care, Abbott Diabetes Care Inc, The Regents of the University of California. The information regarding major players in key diabetes care technologies could help to locate potential partners for licensing, potential threats of litigation, and targets for invalidation.

Technology focus and Geographic Distribution of Top Assignees of Top Assignees

Analysing the technology focus of the top assignees by visualising the presence of organisations in different technology classifications, as well as the variance of technology in their portfolio helps to understand current investment in various technology fields and

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identify licensing opportunities and partnerships (Figure 11). The geographic distribution of top assignees (Figure 12) helps to understand if companies are competing in similar geographies or if their targeted markets are different.
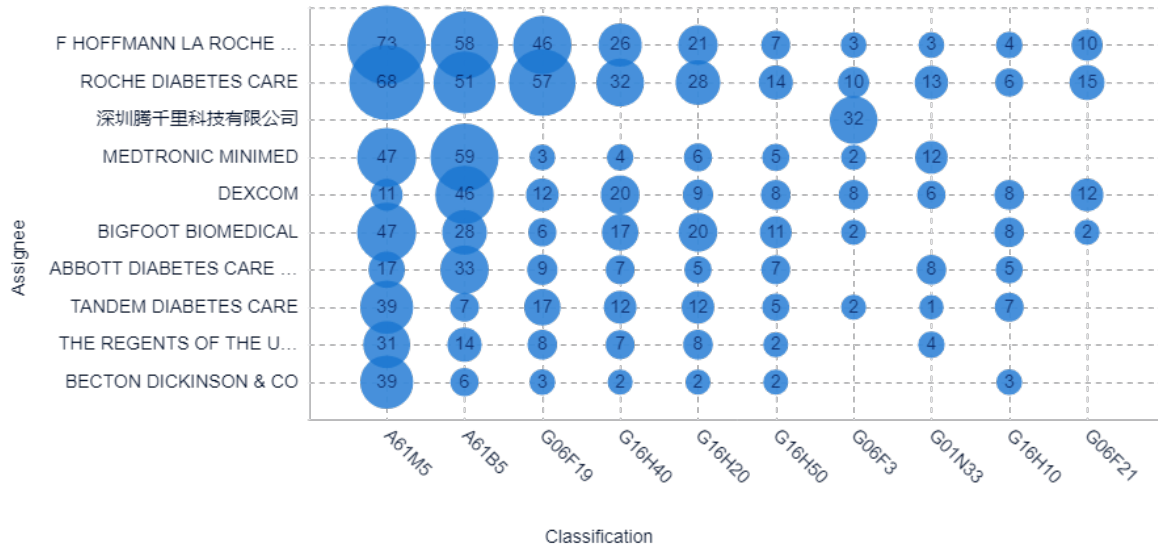

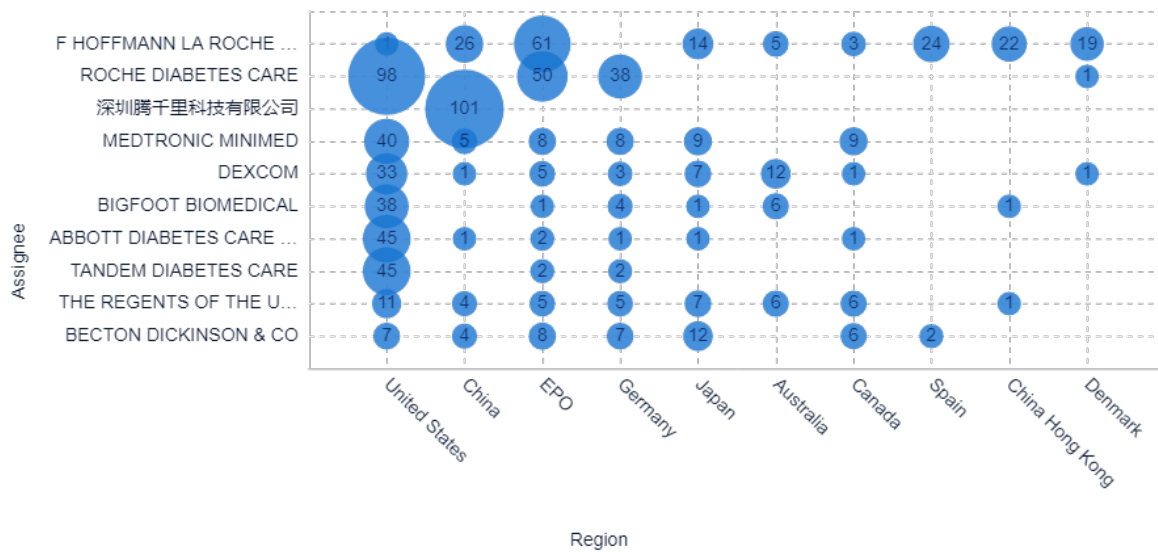Figure 11. Technology focus of top assignees in diabetes care technology space.

Figure 12. Geographic distribution top assignees in diabetes care technology space.

5. Appendix

Table 1. Cooperative Patent Classification (CPC) sub system describing innovations in diabetes care technology.

CPC	Description
A61M5	Devices for bringing media into the body in a subcutaneous, intra-vascular or intramuscular way; Accessories therefor, e.g. filling or cleaning devices, arm-rests ({vaccination appliances for veterinary use A61D 1/025} ; tube connectors, tube couplings, valves or branch units specially adapted for medical use A61M 39/00; containers specially adapted for medical or pharmaceutical purposes A61J 1/00; {combinations of vial and syringe for mixing or transferring their contents A61J 1/20; holders for containers for collecting, storing or administering blood or medical fluids A61J 1/16})
A61B5	Measuring for diagnostic purposes (radiation diagnosis A61B 6/00; diagnosis by ultrasonic, sonic or infrasonic waves A61B 8/00); Identification of persons
G06F3	Input arrangements for transferring data to be processed into a form capable of being handled by the computer; Output arrangements for transferring data from processing unit to output unit, e.g. interface arrangements
G06F19	Digital computing or data processing equipment or methods, specifically adapted for applications (specially adapted for specific functions G06F 17/00, data processing systems or methods specifically adapted for healthcare informatics G16H)
G16H10	ICT specially adapted for the handling or processing of patient-related medical or healthcare data (for medical reports G16H 15/00; for therapies or health-improving plans G16H 20/00; for the handling or processing of medical images G16H 30/00)
G16H20	ICT specially adapted for therapies or health-improving plans, e.g. for handling prescriptions, for steering therapy or for monitoring patient compliance
G16H40	ICT specially adapted for the management or administration of healthcare resources or facilities; ICT specially adapted for the management or operation of medical equipment or devices
G16H50	ICT specially adapted for medical diagnosis, medical simulation or medical data mining; ICT specially adapted for detecting, monitoring or modelling epidemics or pandemics
B43K29	Combinations of writing implements with other articles
G01N33	Investigating or analysing materials by specific methods not covered by groups G01N 1/00 - G01N 31/00