

Diabetes Global Industry Overview

2023

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Introduction

Aging Analytics Agency has released a new report titled "Diabetes Global Industry Overview 2023" which includes diabetes market analysis as well as the use of advanced technology to assist those who suffer from diabetes.

Diabetes technology is rapidly changing and improving and can be beneficial for all those living with diabetes. While many diabetes sufferers use self-monitoring of blood glucose and insulin injections or insulin pens, these tools are being replaced by more advanced technologies that provide more useful data and greater convenience. Advanced tools such as continuous glucose monitors (CGMs) provide real-time data to help people with diabetes to avoid experiencing low and high blood sugar levels.

All data are based on scientific and clinical evidence and can be used by healthcare professionals, R&D professionals, and investors in the diabetes market.

Executive Summary

Diabetes mellitus, more simply called diabetes, is a serious, long-term (or "chronic") condition that occurs when raised levels of blood glucose occur because the body cannot produce any or enough of the hormone insulin or cannot effectively use the insulin it produces.

Global food consumption and nutrient intake have altered during the past four decades due to increased income and urbanization. Although meal patterns may be minimally different between different parts of the our planet, they tend to have many features in common. The traditional diets, high in fiber and low in fat, was recently replaced by a kind of "Western diet", which is rich in fat, saturated fats, sodium, cholesterol, free sugars, and added sugars. An increase in snacking on junk foods particularly by school children is noticeable. As a result number of cases with diabetes is constantly growing.

Diabetes Around the World



Types of Diabetes

Four Main Types of Diabetes			
Type 1 diabetes	historically known as juvenile diabetes		
Type 2 diabetes	historically known as adult-onset diabetes		
Gestational diabetes	where non-diabetic pregnant women develop high blood sugar levels		
MODY*	relatively uncommon, dominantly inherited diabetes with at least 13 subtypes		

* MODY - maturity-onset diabetes of the young

Diabetes is a chronic health condition that affects how body uses food for energy.

There are four main types of diabetes: Type 1 diabetes, Type 2 diabetes, gestational diabetes, and a maturity-onset diabetes of the young – a relatively uncommon, dominantly inherited form of diabetes with at least 13 subtypes. Dominant inheritance means an abnormal gene from one parent can cause disease. This happens even when the matching gene from the other parent is normal. The abnormal gene dominates.

With all four, prompt diagnosis is critical – and so is compliance with your diabetes treatment. Over time, high blood sugar levels can damage blood vessels and raise risk of developing certain health problems (some life-threatening), so it is important to begin treatment.

This report investigates to what degree genetic determinants influence the well-known regional differences in incidents. We also identify genetic risk factors that may initiate the autoimmune process or promote already ongoing β -cell damage in Gulf countries.

Structure of Diabetes Market by Company Type

Diabetes is a chronic metabolic disorder characterized by an increase in the blood-glucose level resulting from a relative insulin deficiency or insulin resistance or both. It imposes a significant burden on patients and society. An increase in the incidence of diabetes due to ageing, obesity, and unhealthy lifestyles is one of the factors contributing to the growth of the diabetes market, which is part of the Longevity Industry ecosystem.

Today, the diabetes market straddles the science, medicine, and high technology markets. Leading manufacturers and healthcare providers are focusing on technological innovations and the development of advanced products in order to gain a substantial share of the market.

Diabetes technologies have significant economic potential, as evidenced by the increase in the capitalisation of the healthcare market, the market's stable growth, and the active development and improvement of technologies in this area.

Structure of the Diabetes Market



Longevity Industry for Diabetes





Key Global Findings



537 million adults globally are living with diabetes, and 3 in 4 of them live in low- and middle-income countries. More than 540 million adult people in the world have impaired glucose tolerance, related to Type 2 diabetes. Furthemore, in 2021, nearly 7 million deaths around the globe were the result of diabetes. All of these despite the fact, that there is more than \$970B of healthcare expenditure for diabetes treatment.

Global Diabetes Estimates in 20-79 Age Group



Impaired glucose tolerance (IGT) is a condition in which blood glucose levels are above the normal range but below the diabetes diagnostic threshold. The terms "prediabetes", "non-diabetic hyperglycaemia", and "intermediate hyperglycaemia" are in use as alternatives. The importance of IGT is three-fold: first, it signifies a higher risk of developing Type 2 diabetes in the future; second, IGT indicates an already heightened risk of cardiovascular disease (CVD); and third, its detection opens the door to interventions that can lead to the prevention of Type 2 diabetes. Progression from IGT to Type 2 diabetes is linked to glucose levels (measured by the extent of hyperglycaemia) along with risk factors such as age and weight.

Diabetes Global Market Analysis

Market at a Glance: Diabetes Companies



Distribution of Companies by Category, %

Distribution of Companies by Country, %

The **majority** of companies that offer diabetes services are located in the **USA**, the home of **72%** of the whole range of companies analysed in the report. The USA is distantly followed by the **United Kingdom**, **India**, and **Canada**, which together host **9%** of the world's diabetes companies.

The main domains in which these companies offer services are P4 Medicine, mHealth, and Wellness & Fitness, which account for 63.3%, 9.1%, and 6.4% of all companies respectively.

Market at a Glance: Diabetes R&D Centres



Distribution of R&D Centres by Country, %

Most R&D centres that conduct diabetes research are located in the USA, where 81% of all analysed R&D centres are located. The USA is followed by Australia at 5% and the United Kingdom and India at 2% each, with the remaining 9% evenly distributed across 7 countries: Canada, Cyprus, Iraq, Japan, South Africa, Switzerland, United Arab Emirates.

The largest domain in which diabetes research is being conducted is P4 Medicine, with 76.5% of research centres studying this field.

Market at a Glance: Diabetes Investors



More than half of the investors in the diabetes industry are from the USA (746 investors, ~52%), while ~10% are split between the UK (76 investors) and China (71 investors). India, Canada, Japan, France, Germany, Israel, and Switzerland each host 1.5-4% (20-55 investors) of the global number of investors. Overall, the top 10 countries host 79% of the world's diabetes industry investors.

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Global Diabetes Diagnostics

Quality of Diabetes Diagnostics by World Region



Global Proportion of Undiagnosed Diabetes by Region, %

Diabetes can be easily detected during a routine screening exam and blood test. However, it can frequently go undiagnosed for years unless a physician draws a blood sample to check blood glucose levels.

The diagnostic biomarkers for diabetes, as established by the WHO, include **2-hour glucose level** and **fasting glucose level**. The Revisions for the 2010 Clinical Practice Recommendations now include the use of **glycated haemoglobin (HbA1c)** as a diagnostic criterion for diabetes, with HbA1c values \geq 6.5% being diagnostic.

Children and adolescents with diabetes are more likely to present with **symptomatic hyperglycemia** (polyuria, polydipsia, and weight loss) than **adults**, who are often **asymptomatic** at the time of diagnosis.

Globally, the level of undiagnosed diabetes is around 40%, with most developed regions being at around this level. The highest levels of undiagnosed diabetes are in Africa (60%), South-East Asia (57%), and the Western Pacific Region (56%).

Geography of Diabetes Diagnostics

Global Proportion of Undiagnosed Diabetes by Region, %



We found more than **530 companies** specialising in diabetes diagnostics.

The USA is the leader in this market, hosting more than 65% of diagnostic companies for diabetes (349 companies). The remaining 35% are distributed fairly evenly among other countries.

The country with the second highest number of companies is the UK (21), followed by India (17), China (11), and Australia (11), which together account for below 15% of the world total.

Structure of Diabetes Diagnostics Market

Proportion of Diagnostic Companies by Application



More than half of diagnostic companies on the global market (~55%) offer diagnostic services such as on-site testing, at-home testing, and clinical diagnostics). Around 30% of companies produce devices for patient monitoring and remote control of glucose levels.

Advanced medical devices used for the early diagnosis of diabetes, along with growing advances in diagnostic testing and imaging techniques, are supporting the growth of the global diagnostic labs market. However, in the last decade, the principles and methods of diabetes diagnostics have not changed dramatically. The share of companies biomarkers is tiny in discovering new comparison to other sectors. Less than 2% of diagnostic companies are developing AI for **Diagnostics** (analysis of biomarkers), while 3% are investigating innovative Digital Biomarkers (new methods of remote self-diagnostics) and 4% are discovering new systemic, genomic, physiological, and other biomarkers.

Dynamics of Diabetes Diagnostics Market (2000-2022)



Cumulative Number of Diabetes Diagnostics Companies



We found more than **530 companies specialising in diabetes diagnostics.** In the last 22 years, there has been nearly a **four-fold increase** in the number of companies – from 122 in 2000 to 444 in 2022. But **the saturation of the market with these types of companies is obvious**. If we look at the absolute numbers each year, we notice a constant drop in the number of new companies. While the period of 2010-2015 saw an average of 20 new companies entering the market every year, in 2020, there were only 10 new companies and **in 2022, we saw only 3 new companies**, the lowest number since 1900. One reason for this outcome is the prioritisation of COVID-19 diagnostics, while another is the absence of new methods of diabetes diagnostics and low levels of technological progress in this area, leading to market stagnation.

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The Market at a Glance: Diabetes Diagnostics



Total Investment Funds by Sector

Proportion of Diabetes Diagnostics Companies by Revenue

The majority of companies that offer diabetes diagnostics have an annual revenue in the range of \$1M-\$10 M. These companies tend to be small, with fewer than 50 employees. Only two very large companies are represented in this market: Roche Diagnostics (a Swiss manufacturer of diagnostic tests) and Medtronic (an American medical device company).

The biggest sector in terms of funds received is Devices for Glucose Monitoring, which garnered more than \$6.5 M in funds. This sector includes patient monitoring, devices, and software for glucose control.

Effectiveness Comparison of Diagnostic Approaches



Predictability of Diagnostic Method

Application of Innovative Approaches for Diabetes Management



Case Study: AI for Diagnostics







Genome Medical is a secure online tool with three unique services that can help people assess and lower their personal risk for developing hereditary diseases such as cancer and diabetes. It automatically extracts key details about a person's medical history directly from their electronic medical record; allows people to exchange medical information with their family members in order to create a comprehensive family medical history; and creates and delivers scientifically supported personalized screening and treatment recommendations based on the person's individual risk.

Lumind is a connected desktop lamp for diabetics that reminds patients to regularly check their blood glucose levels. The colour of the light represents glucose status: blue means that the sugar is too high, red signals that it is too low, and green indicates that patient is in a good range. A slight pulsation of the light suggests a new check-up on patient's levels. The patient can easily enter their own blood glucose readings into the Lumind app on their smartphone, and the app will synchronise with Lumind wirelessly. That way, partners or family members can be involved remotely in the patient's life with diabetes.

Eyenuk is a MedTech company that is developing an AI screening tool for risk assessment and disease surveillance. The company's first product, the EyeArt AI Eye Screening System, is the most extensively validated AI technology for the autonomous detection of diabetic retinopathy. Eyenuk has the aim of screening every eye in the world to ensure timely diagnosis of life- and vision-threatening diseases, including diabetic retinopathy, glaucoma, age-related macular degeneration, stroke risk, cardiovascular risk, and Alzheimer's disease.

Case Study: Glucose Level Control

Senseonics...

Senseonics is a medical device start-up company in Germantown, Maryland, USA (near Washington, D.C.) developing transformative glucose monitoring products intended to enable people with diabetes to live their lives with ease and confidence. Utilising breakthrough fluorescence sensing technology, the Senseonics continuous glucose monitoring (CGM) system is currently being designed to be the first fully implantable CGM that remains highly accurate and stable throughout its long sensor life.



DexCom is a leader in continuous glucose sensing technologies and focuses entirely on those technologies. DexCom is currently focused on creating an implantable sensor that would perform for a long period of time without being rejected by the body. The Dexcom G6 Continuous Glucose Monitoring System sends glucose numbers to a smart device every 5 minutes without fingersticks or scanning. Trend arrows show where and how fast the user's numbers are heading, facilitating better management decisions.



Intuity Medical develops blood glucose monitoring systems for diabetes management. Their POGO Automatic Blood Glucose Monitoring System is the world's first automatic, FDA-cleared one-step blood glucose meter that combines lancing, blood collection, and analysis into a single 10-test cartridge. It provides a convenient and discreet solution for millions of patients who need to test their blood glucose regularly. The company was founded in 2002 and is headquartered in Fremont, California.

Case Study: Innovative Diagnostics

NEURO**Metrix**®

🐼 Mellitus



Intuity Medical Metabolomic Diagnostics is a DeepTech company specialising in the development of novel biomarker-based diagnostic solutions for complex diseases. The company has developed an effective pipeline to first identify diagnostic biomarker panels and then translate these panels into clinical assays ready for application in the clinical laboratory. This pipeline combines the biomarker multiplexing capabilities of Mass Spectrometry, a powerful analytical technology, with the company's own informatics and statistics solutions to deliver diagnostic innovation.

NeuroMetrix is a medical device company focused on the diagnosis and treatment of the neurological complications of diabetes. The company currently markets products for the detection, diagnosis, and monitoring of diabetic neuropathies such as diabetic peripheral neuropathy and median neuropathy (carpal tunnel syndrome). DPNCheck is a fast, accurate, and quantitative nerve conduction test that is used to evaluate nerves for evidence of peripheral neuropathy, such as diabetic peripheral neuropathy (DPN). The device measures nerve conduction velocity and the response amplitude of the sural nerve, a nerve in the lower leg and ankle.

Mellitus is dedicated to advancing diabetes detection and monitoring through products based on GCD59, a biomarker of glycaemic load that is unique because of its direct relationship to the complications of diabetes. Its premier application is a patient-friendly test for gestational diabetes, enabling more timely intervention to improve the health of both mother and child. The company plans to commercialise its products through strategic partners as it expands indications to benefit all individuals with diabetes.

Medical Facilities for Diabetes

The Integrated Diabetes Care Pathway

Interaction of Medical Care Pathways and Diabetes Events



People with diabetes have the right to expect timely, accessible. uniformly and high-guality care. However. diabetes care is complex and multidirectional due to the multifaceted needs of patients. Care should be delivered in a wide range of clinical settings by healthcare professionals with diverse skills and backgrounds. The diabetic care pathway improves the deliverv of effective care, facilitates critical evaluation of that care, and strengthens multidisciplinary communication. It promotes a uniform standard of care delivery in a wide variety of clinical settings

Key Medical Services for Diabetes

Structure of Diabetes Medical Sector



Geographical Distribution of Medical Centres for Diabetes Treatment

Number of Medical Centres for Diabetes by Country



We found more than **1,840 medical centres** specialising in diabetes treatment.

The USA is the world leader in this market, containing 1,466 medical centres, or around 78% of the world total.

After the USA, the highest numbers of medical centres for diabetes are located in India (58), Canada (51), the UK (42), Japan (29), and Australia (24).

In other countries, the number of medical centres varies from 1 to 4.

Structure of Hospital Services for Diabetes



Diabetes Medical Centres by Type of Service

Diabetes Medical Centres by Specialisation

More than 1,800 of the companies selected for analysis offer hospital services for patients with diabetes (>60%). Around 45% of them specialise directly in diabetes treatment, while 20% provide treatment diabetes complications and an additional 36% do not have any narrow specialisation.

These clinics provide a range of different types of services for diabetic patients, including diabetes treatment (51% of clinics), prevention (22%), screening (12%), managing patients' health and quality of life (6%), residential and home care (6%), and rehabilitation (3%).

Dynamics of the Diabetes Clinic Market (2000-2022)

Number of New Diabetes Diagnostics Companies by Year, 2000-2022



We found more than **1,800 medical centres and clinics specialising in diabetes diagnostics.** In the last 23 years, the number of clinics has **more than doubled** from 567 in 1999 to 1,329 in 2022. But **the market saturation of this type of service has been apparent since 2019**. As shown on the graph, the period between 2000 and 2007 represents the "industry breakthrough" era of diabetes diagnostics, with an average of 38 new clinics per year. The market then experienced a period of relative stability between 2008 and 2016, before a period of industry collapse from 2017 onward, marked by a reduction in investments and a marked decline in the annual number of new companies. In the last two years since the COVID-19 pandemic, 2021 and 2022, only 13 new diabetes diagnostics clinics have been opened.

Cumulative Number of Diabetes Diagnostics Companies, 1999-2022

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The Market at a Glance: Diabetes Medical Centres



Proportion of Diabetes Medical Centres by Revenue Range

Distribution of Diabetes Medical Centres by Number of Employees

The majority of diabetes medical centres have an annual revenue between \$1M and \$10M. Most of these clinics are small companies with fewer than 50 employes. The world's biggest diabetes clinic is Sutter Health (USA), a network of hospitals and physicians in northern California. Besides treating diabetes, its services include ambulatory surgery, cardiology, children's health, complementary medicine, cosmetic surgery, diabetes, home health/hospices, mental health, oncology, orthopaedics, pregnancy and childbirth, sleep disorders, transplant services, and weight loss surgery (bariatrics). The company supports acute care hospitals, as well as physician organizations; medical research facilities; home health, hospice, and occupational health networks; and long-term care centres.

Case Study: Medical Centres



Virta delivers a treatment that is clinically proven to reverse Type 2 diabetes and other chronic metabolic diseases. The company's approach helps people to lower their blood sugar levels and lose weight while eliminating the need for medications, including insulin. Virta practises an effective and sustainable form of carbohydrate restriction. A fully virtual, physician-led care team provides proactive care whenever and wherever patients need it.



Livongo (part of Teledoc Health) provides telehealth services for diabetic patients and a data science and technology-enabled platform for the detection of diabetes. Its services include unlimited supplies, virtual coaching, and a smart meter that helps patients to control their diabetes.



DarioHealth is a digital therapeutics company engaged in the development and commercialisation of patented and proprietary technology. The most common chronic conditions often occur together, and research is proving the value of a unified digital therapeutics platform. DarioHealth's approach is directed towards the treatment of chronic disease as a complex disorder. For example, diabetes is treated together with obesity and high blood pressure.

Better Support for People with Diabetes



Global Proportion of Diabetes Companies Offering Certified Care

In the past, many people with Type 2 diabetes were treated by their primary care physician rather than an endocrinologist, who is trained to treat diabetes - who may not have had any special training in the complexities of Type 2 diabetes management. Today, there are many specialists who can help. Since the 1980s, certified diabetes educators have transformed diabetes management, according to the ADA. These professionals, who are now called certified diabetes and education care specialists (CDCES), take a comprehensive approach to teaching diabetes management and specialise in educating and supporting diabetes patients to optimise their health. Diabetes educators can also connect patients to dietitians, physical therapists, and mental health experts trained to help with the condition.

R&D for Diabetes

Categorisation of R&D Institutions for Diabetes and their Proportion in the Market



Key R&D Categories for Diabetes

The diabetes R&D sector includes three main categories: universities, **BioTech** companies, and **medical centres**. They have close cooperation with big pharmaceutical corporations in the creation of new medical products and innovations. All R&D are focused on common projects driven by a common enthusiasm; common teams consisting of scientists on both sides; and the exchange of scientists between cooperating organisations and common laboratories. As an example, some new targets come from outside the laboratories of big pharmaceutical companies, but the validation of the target and the translation of the target into a molecule interacting with it is a strength of the pharmaceutical industry. Typical assets of the pharmaceutical industry include the screening of huge libraries, the optimisation of molecules with regard to efficacy and safety (including early absorption, distribution, metabolism and elimination [ADME]), the production of large amounts of molecules for preclinical and clinical studies, and other preclinical and clinical development activities. For this reason, many instances of cooperation between big pharmaceutical companies (e.g., Eli Lilly and Boehringer), between big pharmaceutical companies and smaller BioTech companies (e.g., Boehringer and Zealand), and between pharmaceutical companies and academia (e.g., Sanofi and Charité) are already working on new targets and approaches.

Geographical Distribution of R&D and Scientific Labs, 2023

UNIVERSITY OF Karolinska Institutet Maastricht University UNIVERSITY CIHR IRSC Europe IRCM OF ALBERTA Imperial College OUES DE MONTR 522 London ee **WINSELSPITAI** MEDIC North 10 AARHUS UNIVERSITY America & Stanford University Steno Diabetes Center Copenhagen Middle UNIVERSITÀ DEGLI STUDI DI MILANO Washington University in St. Louis Caribbean MAYO (28) 서울대학교 SCHOOL OF MEDICINE East & 1,114 North سديةللطب Sidra Medici Africa South East 102 UT Health UNIVERSITY OF MINNESOTA 7 Denver Asia VANDERBILT CU IN THE CITY MEDICAL 香港中文大學 163 CENTER **5** NŬS 5 Western 12 Ö Pacific unesp THE UNIVERSITY 23 of ADELAIDE MONASH University

Regions With the Highest Number of Pharmaceutical Companies for Diabetes

There are more than 2,100 R&D sites globally. The biggest scientific hub is the USA, where there are >975 research centres investigating diabetes. The most important are the National Institute of **Diabetes** and **Digestive and Kidney Diseases** (NIDDK), the University of Colorado (Denver). the University of Minnesota, Yale University, Washington University MC, Mayo Clinic, and the University of Texas (San Antonio).

The second most significant hub is **Europe**, which has more than **520 research centres**.

Global Diabetes Research Activity

Annual Numbers of Published Articles, 2000-2022



There has been a high level of R&D global publication activity in the period from **2000-2022**, at **33K articles per year**. The average number of articles even continued to increase during the COVID-19 pandemic.

As shown in chart, from 2000 to 2012, the total number of articles published was as low as 11-20K articles. Gradually, the number of publications increased, reaching 30-50K articles during the period of 2013-2019 and >60K articles during the years 2020-2022.

The highest number of publications about diabetes come from the USA (more than **40K articles in 2022**).

Innovation Levels in the Diabetes Industry

Annual Number of Patents, 2010-2022



In the report, we evaluated the level of innovation of the diabetes industry by measuring the number of published patents. The average number of patents for diabetes in the years 2010-2022 was at the level of ~5K documents per year.

The annual number of patents has gradually decreased since 2015: in **2021**, there were **23% fewer patents** than in 2015.

The highest number of patents come from the USA and Europe (more than 2.5K papers in 2022).

The most frequently patented inventions were new compounds for the regulation of glucose levels.

Big Pharma's Intellectual Property for Diabetes



Big Pharma Companies by Number of Patented Inventions

The big pharmaceutical companies are conducting a huge investigation into new antidiabetic approaches. The leaders in the number of patented technologies are Merck, Roche, Sanofi, and Eli Lilly (more than 1,000 patents), although there are no real breakthrough approaches. High-throughput screening allows big corporations to test a large number of new molecules, although most of these patented compounds never reach the practical application stage. This is the only strategy to protect intellectual property and maintain competitiveness in the market.

Another common risk management technique is to enter into a strategic partnership with other firms. Partnerships and joint ventures allow for corporations and even nonprofits to share in the upside of a potential finding while limiting their overall investment. Currently, Pfizer and Biogen are two of many companies involved in partnerships with the Juvenile Diabetes Research Fund (JDRF), a nonprofit charity. The JDRF is currently involved in more than 20 projects that have the potential to be big winners in treating and eventually curing Type 1 Diabetes.

PharmTech for Diabetes

Distribution of Pharmaceutical Companies Producing Antidiabetic Drugs

Countries by Number of Pharmaceutical Companies for Diabetes



We found more than 70 **biopharmaceutical companies** that produced drugs against diabetes.

The USA is the leader in this market, containing more than 55% of companies (43 manufacturers).

Europe takes second place among world regions, taking up 17% of the market (14 manufacturers), followed by South-East Asia, which accounts for 12% of the market.

The rest of the world accounts for only 6% of manufacturers.

Anti-Diabetes Drug Production by Country



Proportion of Non-Insulin Brands by Countries

Number of Insulin Brands by Country

The main strategies of glucose level control in diabetic patients are therapeutic treatment by medical insulin and non-insulin drugs. Insulin production dominates in European countries (~69%), with the most popular form being human insulin. Advanced insulin therapy (rapid-acting, long-acting, and short-acting) is used more often in the USA and Canada.

Among other countries, China, India, and Brazil have the highest rate of production of anti-diabetes drugs. They mostly produce generic drugs or drugs licensed by bigger companies.

Structure of PharmTech for Diabetes



Pharmaceutical Companies by Product Type

Antidiabetic (Regenerative Medicine) Drugs by Type



The modern pharmaceutical market for diabetes consists mostly of three main subsectors: Therapeutics (38.7%), Drug Delivery (32.3%), and Devices (24.7%). Since 2010, the number of antidiabetic regenerative medicines has increased due to the approval of cell therapies (Regenerative Medicine) for wound healing, including cell therapy and gene therapy; however, the Regenerative Medicine subsector still enjoys only a 4.3% share of the market. The majority of these regenerative medicines belong to the categories of Small Molecules (56.4%) and Biologics (35.9%) such as recombinant insulin, antibodies, and other proteins. The remaining 7.7% belong to the categories of Cell Therapy (5.1%) and Gene Therapy (2.6%).

Global Anti-Diabetes Drug Market Analysis



Proportion of Anti-Diabetes Drugs by Mechanism of Action

Proportion of Key Companies

At present, the competition in the diabetes market is fierce. Traditional Insulin is still the most popular drug category and accounts for about half of the market. The rest is shared among GLP-1 receptor agonists (17%), DPP-4 inhibitors (21%), and SGLT2 inhibitors (6%), which are regarded as the rising stars. The current global diabetes market is mainly divided between four giant monopolies: Novo Nordisk, Sanofi, Eli Lilly, and Merck. Combined, they account for about 72% of the market.

Insulin Production Market: Trade Flows

Geographical Distribution of Insulin Exports, 2022



Between 2012 and 2022. Denmark. France, and Germany exported the majority of insulin – by net weight – to all our study country regions. Study countries in Africa received 27.2% of their insulin imports from countries that themselves do not create it and may be "passing through" insulin elsewhere. The sourced from remainder was imported from France (27.1%), Germany (19.1%), Denmark (17.5%), India (4.1%), China (3.7%), and other manufacturers (1.0%). Study countries in Asia received almost half (46.4%) of their insulin from India. Most of the insulin (92.1%) exported by Mexico and Brazil to the study countries was for those located in the Americas, and most insulin exported from China (93.7%) was bound for study countries in Africa.

Top 25 Countries in Insulin Market, 2023



The first two charts describe the absolute value of medical insulin export and import in USD millions by the country. The biggest exporters are Germany, France, the USA, and China with the financial equivalent of exporting more than one billion dollars per year (data for the 2022 year). On the other hand, these countries are the biggest importers of medical insulin. Analysis of the export-import ratio shows that Denmark, Germany, and the USA are export-oriented countries where insulin export dominates in the pharmaceutical industry. However, China and France are insulin consumers in the global market.

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Key Insulin Manufacturers, 2023



Short-Acting Insulin (Insulin glulisine)

SANOF

Only three companies – **Novo Nordisk, Sanofi**, and **Eli Lilly** – supply insulin to patients. These companies are commonly called the "Big Three" because they control over **90% of the global insulin market**. The remaining share of the global insulin market is split among approximately seven insulin manufacturers. Other companies selling insulin have been identified globally, though they are likely to be distributors of other manufacturers' insulin products.

Source: Drug Bank

Key Manufacturers of Hypoglycemic Agents for Glucose Control, 2023

DPP-4 inhibitors (a phosphodiesterase inhibitor used to prevent postoperative thromboembolic events)

SGLT2 inhibitors (used to manage hyperglycaemia in Type 2 diabetes)

GLP-1 antagonists (used for regulation of insulin and glucagon secretion, slows gastric emptying to improve glycaemic control)



Oral hypoglycaemic agents make up a majority of the global diabetes market. The entry of generic providers of a new wave of diabetes medications has begun to emerge and is set to change the market structure. A number of hypoglycaemic agents have already received priority review, including glibenclamide tablets from Pharmadax and metformin hydrochloride tablets and sustained-release tablets from CSPC. Both have been accepted by the FDA.

Big Pharma companies are still dominating the global diabetes market. Last year, the top 5 performers were Janssen, AstraZeneca, Novo Nordisk, Sanofi, Bayer, Boehringer Ingelheim, GSK, and Eli Lilly.

Key Manufacturers of Medicine for Diabetes Complications, 2023

Lisinopril (An ACE inhibitor used to treat hypertension, heart failure, and acute myocardial infarction)

Simvastatin

(An HMG-CoA reductase inhibitor used to reduce the risk of myocardial infarction and stroke)

Glyburide (A sulfonylurea used in the treatment of non-insulin dependent diabetes)

Becaplermin (A recombinant human PDGF for treatment of ulcers due to diabetic neuropathy)

Icosapent Ethyl (Small molecule for reduction of synthesis, enhancing clearance of triglycerides)



Cardiovascular disorders are the most common diabetes complication, so more than half of non-insulin drugs are used to reduce the risk of heart failure, acute myocardial infarction, and stroke. The leaders among pharmaceutical companies are **Actavis** and **Sains**, which produce therapeutic small molecules such as Lisinopril, Simvastatin, and Glyburide.

The pharmaceutical giants **Eli Lilly** and **Sanofi** produce Becaplermin for the treatment of diabetic ulcers.

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HLS Therapeutics Inc.

Clinical Trials for Diabetes

Diabetes Clinical Trials, 2010-2022

~2100 ongoing diabetes clinical trials in the world **>1400** clinical trials for Type 2 diabetes

10% of the trials involve the investigation of new non-insulin medicines

25%

of clinical trials are sponsored by pharmaceutical companies

24 clinical trials for new diagnostic approaches

305 Ongoing clinical trials in Phases 3-4

Geography of Clinical Trial Sponsors, 2023

Countries by Number of Pharmaceutical Companies for Diabetes



More than 2,100 active clinical trials are ongoing in the world. North America is the biggest research hub for diabetes, containing more than 53% of clinical trial sponsors. The sponsors of clinical trials in the USA and Canada are research and medical centres.

More than 24% of clinical trials are sponsored from Europe. The leaders among European sponsors are industrial companies such as Novo Nordisk (125 clinical trials) and AstraZeneca (23 clinical trials)

Other world regions together account for less than 10% of clinical trials.

Diabetes Clinical Research Activity in the Gulf Region

Diabetes Clinical Trials by Status



ClinicalTrials.gov listed nearly more than 2,400 trials for different types of diabetes. For analysis we include active (*"recruiting"*, *"not yet recruiting"*, *"enrolling by invitation"*, *"active, not recruiting"*) and not active (*"suspended", "terminated", "completed"*, *"withdrawn", "unknown status"*) trials. Most clinical trials are for Type 2 diabetes (more than 1,400). The **average number** of clinical trials is **970 studies per year**.

After 2019, the annual number of clinical trials **dropped by 15%** in 2020 and, by 2022, had **dropped by 25% less** compared to 2019. This is the result of the two-year-long COVID-19 pandemic and the subsequent global crisis emanating from the war between Russia and Ukraine – two of the world's major clinical trial hubs.

Diabetes Clinical Research Activity in the Gulf Region





Among active clinical trials for diabetes (but not for complications), Type 2 diabetes is the most popular (more than 140 clinical trials). The number of clinical trials is spread fairly evenly between each phase (from 1 to 4). A significant proportion of drugs and medical devices for Type 2 diabetes are currently entering the market. In this segment of clinical research, there have been no recent breakthrough innovations or technologies. Nearly all innovations only improve current available medical approaches such as insulin modifications, improvement of drug delivery, and the upgrading of devices and software.

Gestational diabetes and Type 1 diabetes are more difficult to treat, and as a result, fewer clinical trials for these indications are successful. Only 30% of trials for Type 1 diabetes and 8% of trials for gestational diabetes reach Phases 3 and 4.

Top International Companies Providing Clinical Trials, 2023

Companies by Number of Active Clinical Trials in Ukraine



Diabetes is an attractive area for clinical research. Most pharmaceutical and BioTech companies had 1-3 active trials in 2022. The most significant players in the market are **Novo Nordisk** (Denmark), **DexCom** (USA), **Eli Lilly** (USA), **AstraZeneca** (UK), **Sanofi** (France), and **Abbot** (USA).

These companies provide their clinical research in **Phases 3-4**, which is toward the end of the process where safety and effectiveness are measured against existing standard treatments.

Two of the pharmaceutical companies with the most clinical trials – Novo Nordisk and Sanofi – have more than 125 clinical trials underway.

DexCom is a company that develops, manufactures, and distributes continuous glucose monitoring systems for diabetes management.

Clinical Trials Structure by Type of Investigation, Q2 2023

Proportion of Clinical Trials by Approach



The investigation of new therapeutic approaches accounts for 41% of the total number of clinical trials. More than half of the 41% are studying a new form of biologics that includes recombinant human insulin and antibodies against PCSK9, VEGF, and GLP1. Small molecules account for 28% of clinical trials, while other approaches make up less than 10% of the total.

Structure of Clinical Trials in the Gulf Region, 2023



Proportion of Clinical Trials by Indication

Proportion of Clinical Trials by Activity, 2010-2022

As of 2022, more than 70% of clinical trials in Gulf Region between 2010 and 2022 are completed (133 trials), almost 25% are active (46 trials), and around 4% are withdrawn (8 trials).

Type 1 diabetes (TD1) accounts for the highest percentage of clinical trials (95 trials, 51%). Diabetes complications – which include diabetic nephropathies, macular edema, arthropathies, and gestational diabetes in pregnancy – takes second place (39 clinical trials).

Comparison of Insulin and Oral Hypoglycemic Agents in Clinical Trials



Innovations for Diabetes

Glucagon-like Peptide 1 (GLP-1) Agonists



Proportion of GLP-1 Modulators by Phase

Proportion of GLP-1 Modulators by Indication

There is a class of Type 2 diabetes drugs that not only improves blood sugar control but may also lead to weight loss. This class of drugs are commonly known as glucagon-like peptide 1 (GLP-1) agonists. Due to the high potential of GLP-1 agonists to reduce blood sugar, a number of pharmaceutical companies have placed high hopes on this business. The real star in this market is Novo Nordisk. In September 2019, the FDA approved Rybelsus (semaglutide) oral tablets to improve blood sugar control in adult patients with Type 2 diabetes, along with diet and exercise. Other notable mentions in the GLP-1 sector include Baolijian, Gmax Biopharm, and CS Bio. The competition in this field is set to become more intense in the future.

Dipeptidyl Peptidase-4 (DPP-4) Inhibitors for Diabetes



Proportion of DPP-4 Inhibitors by Indication

Proportion of DPP-4 Inhibitors by Phase

At present, the global DPP-4 market has been divided by imported original drugs. Pharmaceutical companies are still in the process of seeking breakthroughs. The major applications of DPP-4 inhibitors are metabolic disorders, diabetes mellitus, and Type 2 Diabetes. Furthermore, major international pharmaceutical companies have already moved onto a product upgrade. Many of them are actively developing long-acting and even ultra-long-acting forms of DPP-4 inhibitors. Due to that trend, most DPP-4 inhibitors are marketed and many updated drugs are at Phase 3 of clinical trials, at the preregistration stage, or at the registration stage.

SGLT2-protein Modulators for Diabetes



Proportion of SGLT2-protein Modulators by Indication

SGLT2 Inhibitors are used to treat Type 2 diabetes. They work by removing excess glucose by blocking reabsorption through the kidneys. Recent studies have shown these drugs to have a positive effect on the heart and kidneys, and Bayer's heart and kidney disease drug Kerendia is considered a rival to well-established SGLT2 diabetes medications. In 2021, according to data unveiled from the Figaro-DKD trial, Kerendia appeared to offer additional heart and kidney benefits when used in patients already taking an SGLT2 inhibitor.

Proportion of SGLT2-protein Modulators by Phase

Insulin: The Promising Future of Insulin Therapy in Diabetes



In terms of product category, most companies focus on human insulin and its long-acting formulation. However, some have already moved into the research and development of insulin lispro, insulin glargine, insulin aspart, and a variety of premixed dosage forms. Gradually, an increasing number of pharma companies are shouldering their way into the fierce diabetes contest. In the future, to maintain a sizable share in the global market, it will be not only be necessary to ensure product quality, but also very important to deeply understand the needs of the market. Developments in basal insulin formulations are aiming for longer and flatter time-action profiles. Insulin degludec is currently the longest-acting insulin analogue available on the market, exhibiting the lowest risk of hypoglycaemia. It is produced by Novo Nordisk, Sanofi, and Eli Lilly.

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Alternative Routes of Insulin Delivery

Device for Rapid-Acting Inhaled Insulins



Tortoise-Shaped Pill Injects Insulin Into Stomach



The traditional subcutaneous route of insulin administration relies heavily on patient compliance, which is influenced by psychosocial issues, patient training, and the impact of injections on quality of life. Therefore, efforts are being invested into developing alternative routes of insulin delivery. In recent years, two rapid-acting inhaled insulins obtained FDA approval in the USA. Pulmonary bioavailability allows these insulins to control postprandial glucose excursions, but long-term pulmonary safety is still being investigated. The oral route is also of significant interest due to its simplicity and because it involves more physiological first-pass metabolism. However, ensuring mucosal absorption of insulin while avoiding enzymatic degradation in the gastrointestinal tract remains a challenge. New formulations of oral insulin containing protease inhibitors and mucosal absorption enhancers have ensured these molecules' integrity and bioavailability, leading to some clinical efficacy in Phase 2 trials. Ingestible injection systems containing small needles made of compressed insulin that is then injected into the stomach mucosa have shown promising data in animal studies. As of yet, none of these agents have been considered economically viable, as the amount of insulin required when administered orally is exorbitant because only a small fraction of administered insulin is actually absorbed. Nevertheless, these noninvasive insulin treatments remain of interest and could represent new paradigms for the future treatment of diabetes.

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Diabetes Management Options Available on the Market



Recent advances in the diabetes care paradigm have brought us into a new era of care. Among these are digital medicine products, including continuous glucose monitors, connected insulin pens, and advanced hybrid closed-loop insulin pumps, as well as the monitoring of diabetes outcome metrics such as HbA1c and, increasingly, time-in-range (TIR, which can be defined as the percentage of time a PwD spends in their glucose target range). However, despite these advances, significant care gaps persist and demonstrate a need for improvement in blood glucose management.

Conclusions

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- The majority of companies offering diagnostic and healthcare services are in the USA (over 72%). The main domains in which these companies offer services are P4 Medicine, mHealth, and Wellness & Fitness, which account for 63.3%, 9.1%, and 6.4% of all companies respectively.
- Most R&D centres that conduct diabetes research are located in the USA, where 81% of all analysed R&D centres are located. The USA is followed by Australia at 5% and the United Kingdom and India at 2% each, with the remaining 9% distributed between 7 countries: Canada, Cyprus, Iraq, Japan, South Africa, Switzerland, and the United Arab Emirates.
- More than half of investors in the diabetes Industry are from the USA (746 investors, ~52%), ~10% of investors are located in the UK (76 investors) and China (71 investors). India, Canada, Japan, France, Germany, Israel, and Switzerland each host 1.5-4% (20-55 investors) of the total number of investors. Overall, the top 10 countries by the number of investors host 79% of total investors.
- Artificial Intelligence (AI) is becoming more popular, but only 2% of companies are developing AI for Diagnostics (analysis of biomarkers), while 3% are investigating innovative Digital Biomarkers (new methods of remote self-diagnostics) and 4% are discovering new systemic, genomic, physiological, and other biomarkers.
- Around 50% of patients have licensed healthcare. Meanwhile, ~20% of medical centres and clinics provide treatment of diabetes complications, and 35% of clinics lack a narrow specialisation. Diabetes clinics provide a range of different types of services for diabetic patients: diabetes treatment (>50% of clinics), prevention (22%), screening (12%), management of patients with diabetes and improving their quality of life (6%), residential and home care for patients (~6%), and rehabilitation (3%).

Conclusions

- The biggest players on the market are Novo Nordisk (Denmark), DexCom (USA), Eli Lilly (USA), AstraZeneca (UK), Sanofi (France), and Abbot (USA). These companies provide their clinical research in Phases 3-4 later stages of the drug development process in which safety and effectiveness are measured against existing standard treatments.
- The main strategy for diabetes management is still glucose level control. The most common drug for this purpose is human insulin. Advanced insulin therapy (rapid-acting, long-acting, and short-acting), as well as diabetes management by non-insulin medicine, is used the most in the USA and Canada. Among other countries, China, India, and Brazil have the highest amount of production of anti-diabetes drugs. They produced mostly generic drugs or drugs licensed by bigger companies during the period studied in the report.
- The modern pharmaceutical market for diabetes is divided mainly into three subsectors: Therapeutics (38.7%), Drug Delivery (32.3%), and Devices (24.7%). Since 2010, the number of antidiabetic regenerative medicines has been boosted after the approval of cell therapies (Regenerative Medicine) for wound healing, including cell therapy and gene therapy, but these drugs still represent only 4.3% of companies in the market. This 4.3% can be further divided into Small Molecules (56%) and Biologics (35%) such as recombinant insulin, antibodies, and other proteins as well as Cell Therapy (5.1%) and Gene Therapy (2.6%).
- At present, competition in the diabetes market is fierce. Traditional insulin is still the most popular drug category and accounts for about half of the market. The rest is shared among GLP-1 receptor agonists (17%), DPP-4 inhibitors (21%), and SGLT2 inhibitors (6%), which are regarded as the market's rising stars. The current global diabetes market is mainly divided into four giant monopolies: Novo Nordisk, Sanofi, Eli Lilly, and Merck. Together, they account for about 72% of the market.

Aging Analytics Agency: Value Proposition



Aging Analytics Agency is the only specialised analytics agency that focuses exclusively on the emerging Longevity Industry. We are recognised internationally as the premier analytics agency for advanced data analysis, industry reports, and next-generation infographics on ageing and Longevity.

Aging Analytics Agency focuses on three key activities:			
Providing Commercial Services	Preparing Open-Access Reports	Building Big Data Analytics Platforms	
Conducting customised case studies, research, and analytics for internal (organisational) use, tailored to the precise needs of specific clients.	Producing regular open-access and proprietary analytical case studies on the emerging topics and trends in the Longevity Industry.	Offering customised analysis using specialised interactive industry and technology databases, IT-platforms, and Big Data Analytics Dashboards.	
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