

# Europe Digital Therapeutics Market By Product Type (Software and Devices), By Application (Treatment/Patient Care-Related Applications and Preventive Applications), By Sales Channel (Business-to-Business and Business-to-Customer), By Country, Competition, Forecast and Opportunities, 2020-2030F

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## Abstracts

Europe Digital Therapeutics Market was valued at USD 1.94 Billion in 2024 and is expected to reach USD 3.93 Billion by 2030 with a CAGR of 12.43% during the forecast period. The Europe Digital Therapeutics Market is driven by several key factors, including the increasing demand for personalized healthcare solutions, advancements in technology, and the growing prevalence of chronic diseases. Digital therapeutics (DTx) offer evidence-based, clinically validated interventions through digital platforms, enabling patients to manage conditions such as diabetes, cardiovascular diseases, mental health disorders, and chronic respiratory diseases. The rise in chronic disease rates across Europe is prompting a shift towards more accessible, cost-effective, and scalable treatment options like digital therapeutics. The adoption of mobile health applications and wearable devices has facilitated the widespread acceptance of digital health solutions. Regulatory support from European healthcare agencies, including the European Medicines Agency (EMA), is also driving growth by ensuring that DTx products meet safety and efficacy standards. In 2021, Belgium's INAMI-RIZIV introduced a reimbursement program for Digital Therapeutics (DTx) that are CE-marked medical devices, closely following the fast-track process for DTx in Germany. However, despite these regulations, no DTx have yet attained the highest tier of the mHealthBelgium validation pyramid, which is required for government funding. The increasing focus on remote patient monitoring and virtual healthcare models, accelerated by the COVID-19 pandemic, has further boosted the demand for digital

therapeutics in Europe.

## Key Market Drivers

### Rising Prevalence of Chronic Diseases

Europe is witnessing a steady rise in chronic diseases such as diabetes, hypertension, obesity, cardiovascular diseases, and respiratory disorders. The World Health Organization (WHO) has highlighted chronic diseases as the leading cause of death and disability in Europe, which has led to an increased demand for long-term disease management solutions. Traditional healthcare models often struggle with the continuous monitoring required to manage chronic diseases effectively, which makes digital therapeutics an attractive alternative. Cardiovascular disease is the leading cause of death in Portugal, with atherosclerosis being the most prevalent underlying pathophysiological condition. According to a study titled, "Profiling chronic diseases and hospitalizations in older home care recipients: a nationwide cohort study in Sweden", in Sweden, 9% of the population aged 70 and older depend on formal healthcare, and the majority of them experience multiple chronic diseases. Half of the healthcare recipients have five or more chronic conditions. The wide range of prevalent diseases presents a varied picture of morbidity among those receiving healthcare services. Nearly two-thirds of healthcare recipients are hospitalized at least once during a two-year follow-up period, with falls and decompensated heart failure being the most common causes.

DTx platforms allow patients to manage their conditions from home, reducing hospital visits and helping prevent complications. For example, mobile apps can guide patients with diabetes in real-time on managing their blood sugar levels, making it easier for them to stick to their treatment regimens. This convenience and ability to track symptoms remotely are compelling drivers of DTx adoption across Europe.

### Growing Focus on Personalized Medicine

Personalized medicine is becoming a key focus in healthcare, as treatments tailored to individual patients' genetic profiles, lifestyles, and environmental factors have shown to improve outcomes. Digital therapeutics align well with this trend by offering highly personalized, patient-specific interventions. DTx solutions often use data-driven algorithms to customize treatment protocols based on a patient's unique condition, medical history, and real-time data. This personalized approach is particularly beneficial for managing chronic conditions, mental health issues, and neurological disorders, where treatment responses vary widely between individuals. The European healthcare

system, which places emphasis on improving patient outcomes and satisfaction, is increasingly adopting personalized digital therapeutics to offer more effective, individualized care. The shift toward precision medicine supports the growth of the DTx market in Europe, as healthcare providers and patients alike see the value in customized treatment plans.

### Regulatory Support & Reimbursement Policies

Europe's regulatory environment plays a crucial role in the growth of the digital therapeutics market. The European Medicines Agency (EMA) and other national regulatory bodies are increasingly supporting digital health solutions, ensuring that they meet the required safety and efficacy standards. Regulatory approval gives digital therapeutics credibility, and this fosters confidence among healthcare providers, patients, and investors. Reimbursement policies across European countries are evolving to include digital therapeutics, recognizing them as legitimate treatment options. Some European nations, such as Germany, have introduced reimbursement pathways for digital health solutions, making them more accessible to patients. As reimbursement policies improve and more health systems offer financial support for DTx interventions, adoption is likely to grow. The regulatory clarity and reimbursement mechanisms in place are driving the development and implementation of digital therapeutics in Europe.

### Improved Healthcare Efficiency and Cost Reduction

Digital therapeutics offer significant potential for improving healthcare efficiency and reducing costs. Healthcare systems in Europe are facing increasing pressure due to the rising burden of chronic diseases and an aging population. The need for more sustainable, cost-effective care solutions has led to the adoption of digital therapeutics, which reduce the need for in-person consultations, hospital stays, and emergency interventions. DTx platforms enable continuous monitoring of patients, making it possible to detect issues early and prevent complications before they require expensive interventions. This shift from reactive to preventive care helps reduce the long-term costs associated with chronic disease management. By enabling remote care, digital therapeutics alleviate the strain on healthcare infrastructure, reducing the demand for hospital resources and allowing healthcare professionals to focus on more complex cases.

### Strategic Partnerships and Investments

The growing interest in digital therapeutics has attracted significant investments from private companies, venture capitalists, and major healthcare organizations. Pharmaceutical companies, health insurers, and digital health firms are increasingly forming strategic partnerships to develop and commercialize DTx products. In January 2022, The Stockholm-based Digital Therapeutics (DTx) company Alex Therapeutics and world-leading pharmaceutical company Pfizer have joined forces to provide evidence-based, clinically validated, and personalized digital therapies to patients. Together, the companies cover a broad range of expertise in the fields of medicine, marketing, clinical validation, AI, software development, and psychology. The partnership will initially focus on Germany, one of the world's largest unified healthcare markets. These partnerships help combine expertise in healthcare, technology, and data science, resulting in the creation of innovative solutions that meet the complex needs of patients and healthcare providers. The influx of investments is further accelerating the development of new digital therapeutics products, while increasing competition in the market. As more healthcare systems and insurance providers recognize the value of digital therapeutics, funding and strategic collaborations will likely continue to increase, ensuring the rapid growth and widespread adoption of digital therapeutics across Europe.

## Key Market Challenges

### Regulatory and Compliance Challenges

One of the primary challenges facing the Digital Therapeutics (DTx) market in Europe is the regulatory landscape. While the European Medicines Agency (EMA) has made strides in approving digital health solutions, regulatory frameworks are still in development for digital therapeutics, creating uncertainty for manufacturers, healthcare providers, and patients. Digital therapeutics often fall into a grey area in terms of regulation since they blend software with therapeutic outcomes. Unlike traditional drugs or medical devices, which have well-defined approval processes, digital therapeutics may require a combination of software regulatory standards and medical device regulations. This lack of clarity can lead to delays in product approval and market entry.

The complexity of regulations varies by country within Europe, which complicates the process for companies looking to enter multiple markets simultaneously. Different European countries have varying levels of regulatory readiness and approaches toward digital health. For instance, Germany's digital health reimbursement pathway is more developed compared to some other European nations. Manufacturers may need to adapt their products to comply with different regulatory frameworks, which can be resource-intensive and time-consuming.

The dynamic nature of digital technologies also presents another challenge for regulators. As digital therapeutics evolve rapidly, it becomes difficult for regulators to keep pace with innovations. The lag in regulatory updates can create uncertainty for developers, especially when their products undergo continuous iterations or when new features are added. The lack of standardized regulations and approval processes across Europe slows down market penetration, making it difficult for DTx companies to scale their operations effectively across borders. Until these regulatory frameworks become more harmonized, companies may face challenges in navigating approval processes, which could ultimately impact market growth.

### Integration into Traditional Healthcare Systems

Another significant challenge for the Europe Digital Therapeutics Market is the integration of digital health solutions into traditional healthcare systems. While many healthcare systems in Europe are investing in digital solutions, they still face barriers when it comes to the widespread adoption and integration of digital therapeutics into existing workflows. Traditional healthcare systems are often slow to adopt new technologies, and many healthcare professionals remain unfamiliar with DTx platforms or hesitant to incorporate them into their practices.

Healthcare providers may be resistant to using digital therapeutics due to a lack of awareness or training. Digital therapeutics require integration into Electronic Health Record (EHR) systems, patient management systems, and other healthcare IT infrastructures. This integration can be a complex and costly process, especially in healthcare systems where technology infrastructure is outdated. The healthcare workforce may also require training on how to use these new tools effectively, which takes time and resources.

Many healthcare providers may question the efficacy and cost-effectiveness of digital therapeutics, particularly in comparison to traditional interventions. While clinical evidence supporting the effectiveness of digital therapeutics is growing, it may not always meet the level of evidence required by healthcare professionals, particularly when compared to well-established treatments. Overcoming these challenges requires more robust clinical trials, education for healthcare providers, and better integration with existing healthcare systems to make DTx a mainstream part of patient care.

### Key Market Trends

## Technological Advancements and Innovation

Technological advancements are one of the primary drivers of the Digital Therapeutics market in Europe. With rapid progress in mobile health technologies, artificial intelligence (AI), big data analytics, and wearable devices, the development of digital therapeutics has been accelerated. Modern technologies enable continuous monitoring of health data and allow the personalization of treatments based on real-time information. These innovations have made it easier for patients and healthcare providers to manage health conditions remotely. In November 2023, Better and Stratiteq are unveiling their strategic partnership, designed to transform healthcare solutions. By combining the strengths of Stratiteq and Qinshift, particularly in data management and custom software development, and incorporating openEHR into their service offerings, this collaboration holds significant potential for the healthcare sector. It will benefit not only Sweden but also global markets where Qinshift operates. Wearables like fitness trackers, smartwatches, and medical-grade devices help monitor parameters such as heart rate, glucose levels, or oxygen saturation, providing clinicians with valuable insights that enable more accurate interventions. These advancements in digital health tools are transforming healthcare delivery, making it more efficient, accessible, and patient-centric. As new technologies continue to emerge, digital therapeutics are likely to become even more effective and integrated into mainstream healthcare practices.

## Increased Adoption of Remote Patient Monitoring

The COVID-19 pandemic played a pivotal role in accelerating the adoption of remote patient monitoring (RPM) and telemedicine across Europe. Social distancing measures and the increased demand for healthcare solutions that reduce in-person visits created a surge in the need for virtual healthcare services. Digital therapeutics, often integrated with remote monitoring capabilities, allow patients to manage their health conditions without leaving their homes. Patients with chronic conditions, such as heart disease or diabetes, can monitor their symptoms and receive timely interventions from healthcare professionals. The benefits of remote care, such as convenience, cost savings, and enhanced patient outcomes, have contributed to the growing demand for digital therapeutics. Even beyond the pandemic, remote patient monitoring is expected to remain a key component of healthcare systems in Europe, further driving the adoption of digital therapeutics.

## Segmental Insights

## Product Type Insights



Based on the product type, software is currently the dominant segment over devices. Digital therapeutics (DTx) primarily encompass software-driven solutions that provide evidence-based therapeutic interventions through mobile applications, online platforms, and digital tools. These software platforms are at the core of the digital health revolution, offering treatments for chronic diseases, mental health conditions, and other therapeutic areas. Unlike devices, which often require more complex hardware components and infrastructure, software-based solutions offer greater scalability, lower costs, and can be quickly adopted by healthcare providers and patients alike.

The primary reason software is leading the market is its ability to deliver flexible, accessible, and cost-effective therapeutic interventions. DTx software enables real-time monitoring, symptom tracking, and patient engagement through mobile apps, websites, and cloud-based systems. These applications allow for continuous management of conditions like diabetes, hypertension, and mental health disorders, without the need for expensive and complex devices. Software solutions can also be easily updated and improved over time, making them more adaptable to the needs of patients and clinicians. This ease of scalability and continuous improvement is a key driver of the growing market adoption of digital therapeutics software.

### Application Insights

Based on the application, treatment/patient care-related applications are currently dominating over preventive applications. This is largely due to the significant need for managing chronic diseases and conditions that require ongoing therapeutic interventions. Treatment-focused digital therapeutics address a wide range of health conditions, including diabetes, cardiovascular diseases, mental health disorders, and respiratory conditions, offering evidence-based, clinically validated solutions. These applications aim to help patients manage their conditions in real-time through digital platforms such as mobile apps, wearable devices, and online tools, making them highly relevant in healthcare systems across Europe.

The growing prevalence of chronic diseases in Europe, including diabetes, hypertension, and obesity, has created an increasing demand for continuous patient care. Traditional approaches often involve periodic visits to healthcare providers, but digital therapeutics can bridge this gap by offering continuous, remote monitoring and personalized care. Treatment applications enable patients to track their symptoms, receive real-time feedback, and adjust their treatment regimens accordingly, leading to improved outcomes and better disease management. This approach is particularly

important for managing complex, long-term conditions where consistent monitoring and intervention are critical for preventing complications.

## Country Insights

Germany was dominating the Europe Digital Therapeutics Market. As Europe's largest economy and a leader in healthcare innovation, Germany is at the forefront of adopting digital health technologies, including digital therapeutics (DTx). The country's robust healthcare system, strong regulatory framework, and progressive digital health policies have made it a key player in the European market for digital therapeutics. A major factor contributing to Germany's dominance is the introduction of the Digital Healthcare Act (DVG), which was enacted in 2019. This act has paved the way for the reimbursement of digital health solutions under the statutory health insurance system, facilitating broader access to digital therapeutics for patients. The law allows doctors to prescribe digital health applications that have received approval from the Federal Institute for Drugs and Medical Devices (BfArM). This regulatory support has created a clear pathway for digital therapeutics to be integrated into the German healthcare system, providing a significant advantage over other European countries where reimbursement systems for DTx are still developing.

Germany's healthcare system is also highly advanced, with a high level of infrastructure, a broad adoption of electronic health records (EHRs), and widespread use of telemedicine, all of which are essential for the successful implementation of digital therapeutics. This infrastructure allows for seamless integration of DTx solutions into existing patient care workflows, enhancing patient engagement and improving treatment outcomes. Germany is home to a number of prominent pharmaceutical and biotechnology companies, many of which are collaborating with digital health startups to develop and commercialize digital therapeutics solutions. This collaboration between tech firms and pharmaceutical giants drives innovation and accelerates the development of new, evidence-based digital treatments.

## Key Market Players

Mindable Health GmbH

Cara Care

Kaia Health Software GmbH



HealthHero

GAIA AG

ResMed Germany Inc.

Sidekick Health Germany GmbH

Ada Health GmbH

Flatiron Health GmbH

Wellster Healthtech Group GmbH

#### Report Scope:

In this report, the Europe Digital Therapeutics Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

- Europe Digital Therapeutics Market, By Product Type:

  - Software

  - Devices

- Europe Digital Therapeutics Market, By Application:

  - Treatment/Patient Care-Related Applications

  - Preventive Applications

- Europe Digital Therapeutics Market, By Sales Channel:

  - Business-to-Business

## Business-to-Customer

### · Europe Digital Therapeutics Market, By Country:

Germany

France

United Kingdom

Italy

Spain

Russia

Poland

Bulgaria

Finland

Portugal

### Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Europe Digital Therapeutics Market.

### Available Customizations:

Europe Digital Therapeutics Market report with the given market data, TechSci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

### Company Information

Detailed analysis and profiling of additional market players (up to five).

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