The Future of Digital Therapeutics (DTx)

Bringing Patients Closer to Holistic Healthcare

Introduction:
The Future of Digital Therapeutics (DTx)

In recent years, pharmaceutical companies have been focusing on **Digital Transformation (DX)** to accomplish business objectives such as enhancing corporate value and gaining a competitive edge.

The pharmaceutical industry is utilizing cutting-edge digital technologies and data to not only enhance the effectiveness of current processes, but also transform the way the business functions. This includes streamlining the entire value chain, from research and development to manufacturing, sales and marketing, and corporate management.

Additionally, pharma companies are also collaborating with IT and healthcare companies to create value through new initiatives such as **Digital Therapeutics (DTx)** and **Digital Medicine**.

This whitepaper focuses on Digital Therapeutics (DTx), a novel initiative in the pharmaceutical industry.

Chapter 1 defines DTx and its value in NTT DATA's vision of patient-centric medicine (MX).

The following chapter explores the trends of DTx in three countries: the United States, which was among the pioneers in adopting digital health and DTx initiatives; Germany, one of the first countries in the European Union to venture into DTx initiatives; and Japan, where the DTx market is currently expanding. **Chapter 2** also outlines the DTx market and its projected expansion in the future.

Chapter 3, distinguishes DTx from conventional medicine and digital health applications, summarizes the value of DTx for pharmaceutical companies, and introduces possible use cases for DTx beyond the scope of treatment.

Lastly, in **Chapter 4**, we present two recent case studies: 'Building of a DTx Distribution Platform Offering Digital Therapeutic Services' and 'Digital Health App Development for DTx Approval.'

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1.1 What is DTx?

Definitions of Digital Therapeutics (DTx) in each country

This section defines DTx and goes on to explain its contribution in the realization of patient-centric medicine in the subsequent section. To organize the definition, we will first review the definitions of DTx in each country.

The Digital Therapeutics Alliance (DTA), the industry organization that has established the concept of DTx in the U.S. and elsewhere, defines DTx[1] as:

- DTx (Digital Therapeutics) is a high-quality software program to prevent, manage, and treat disease, supported by clinical research and other evidence (MEDI). It is subject to regulatory review and approval as necessary to support product labeling regarding risk, efficacy, and intended use.

The BfArM (Federal Agency for Medicines and Medical Devices), an administrative agency under the German Federal Ministry of Health and Welfare responsible for the examination, licensing, and approval of pharmaceuticals and medical devices, defines DiGA (Digital Healthcare Application)[2] as:

- It is intended to detect or alleviate disease and is a product that supports diagnosis and is based primarily on digital technology. Whether this is the case is determined by the BfArM evaluation procedure.

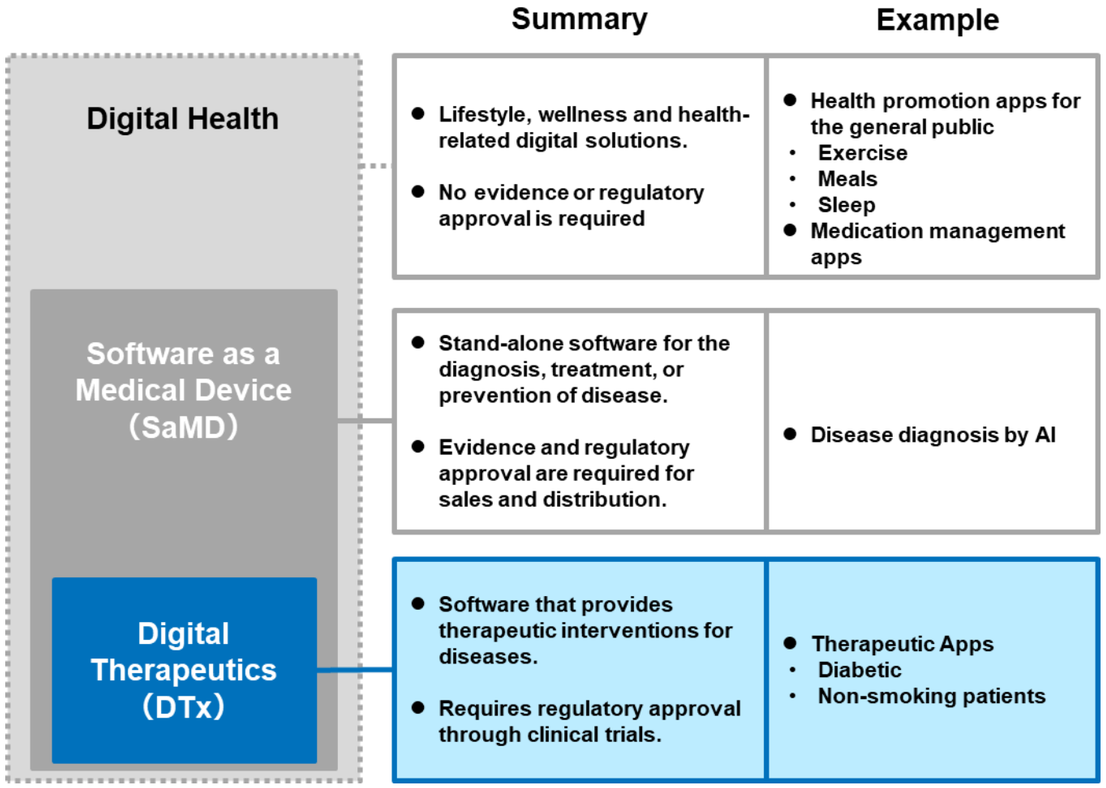
The Japan Digital Therapeutics Promotion Study Group (now the Japan Digital Health Alliance) defines DTx[3] as:

- Management and medical intervention to treat diseases using digital technology, either software-driven or a combination of software and hardware.

While there may be differences from country to country, a common definition of DTx is, “a digital health product that is intended for therapeutic purposes, has clinical data showing efficacy, and has been approved and authorized by a regulatory authority.”

Positioning of DTx in Digital Health

Digital technologies (e.g., apps) have been frequently developed to treat diseases, manage medications, and track health status. These digital technologies are collectively referred to as ‘digital health’. Among them, standalone software that is intended for diagnosis, treatment, and prevention of diseases and whose sale and distribution require pharmaceutical approval is called ‘programmed medical device’ (SaMD: Software as a Medical Device). Among SaMDs, applications used for therapeutic purposes are positioned as ‘Digital Therapeutics (DTx).’



1.2 Patient-centric Medicine and the DTx Connection

As defined in the previous section, DTx is “a digital health product that is intended for therapeutic purposes, has clinical data showing efficacy, and has been approved and authorized by a regulatory authority.” This section provides an overview of the value of DTx in patient-centric healthcare. We further explain how pharmaceutical DTx can innovate the patient-centric healthcare experience.

What is Patient Centricity?

Patients have become more active participants in their own healthcare and medical decision-making due to an increased awareness of their rights and the widespread dissemination of information. The idea of 'Patient Centricity' has been introduced to promote an approach that prioritizes the patient and emphasizes their unique needs and experiences within the healthcare and pharmaceutical industries.

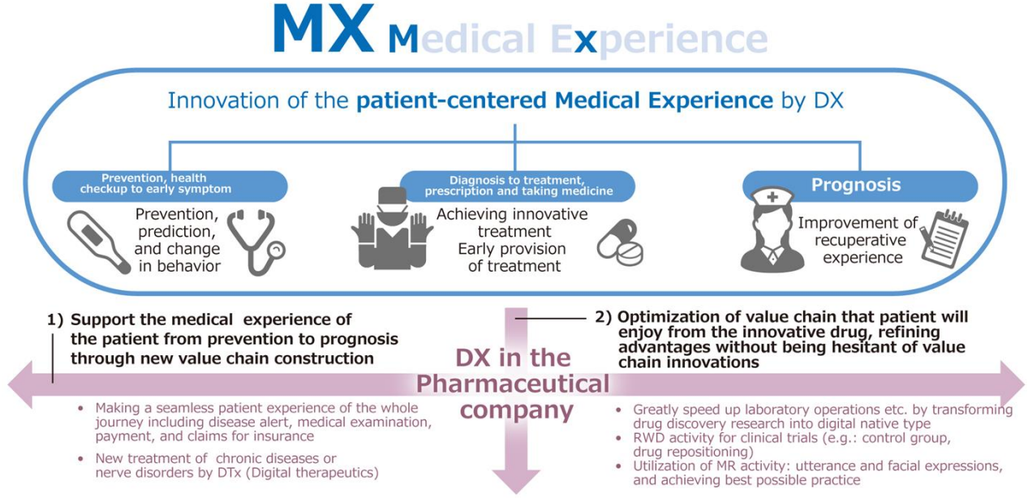
According to the Japan Pharmaceutical Manufacturers Association (JPMA), patient centricity in corporate activities refers to, the use of feedback obtained directly from patients or through their families or patient groups. Patient centricity in corporate activities is defined as “the utilization of patients’ voices obtained directly from patients or through their families or patient groups in corporate activities.”

This activity in corporate drug development is defined as, “corporate activities that respond to patients’ ‘desire to know’ in addition to utilizing patients’ voices in the development process from concept planning, clinical trial planning, and implementation to approval and submission.”[1]

Innovation of Patient-centric Medical Experience (MX) through Medical DX

Digital technology excels in creating a feedback cycle where information is effectively conveyed to patients and their individual voices are incorporated into product development. The evolution of digital technology will be an important enabler of personalized medical experiences tailored to provide a seamless medical experience from the perspective of consumers. The key role of medical and pharmaceutical players will be to bring about innovation in ‘patient-centric medical experience (MX)’ through medical DX.

For MX innovation, collaboration among academic research institutions, medical institutions, healthcare administration, and the private sector is essential. The efforts of the pharmaceutical industry are particularly important. The pharmaceutical industry may approach MX innovation in two directions: ‘Transformation of the pharmaceutical value chain’ and ‘Realization of a seamless healthcare experience from disease prevention to prognosis.’



Transforming the Pharmaceutical Value Chain

As a driver of patient-centric medicine, pharmaceutical companies are expected to continuously create innovative drugs. Traditionally, the drug development process relied heavily on analog and manual experimental work, demanding long years and huge costs. However, we believe that the accuracy and speed of output can be dramatically increased by promoting DX in drug discovery research. This includes the introduction of AI, IoT and sensing technologies in basic research, use of Real-World Data (RWD) such as electronic medical records and medical checkup data, and the adoption of digital biomarkers in clinical trials.

Realization of a Seamless Medical Experience from Disease Prevention to Prognosis

In patient-centric medicine, it is important to provide new products and services that encompass the entire patient journey from prevention to prognosis, including means that are not limited to medicine, to provide holistic support for a healthy lifestyle.

Traditionally, contact between healthcare providers and patients has been limited to visits to the hospital or prescriptions at pharmacies in the event of an illness or injury. However, with the recent proliferation of smartphone apps and wearable devices, the scope of healthcare has expanded, and the patient experience is more seamlessly integrated into daily life. For example, vital data can be used to detect danger signs for diseases such as heart failure, and alerts can be sent from these apps to prevent the onset of the disease. In the field of preventive prognosis, non-medical industries are expected to compete, but pharmaceutical companies, with their extensive knowledge in diseases, will develop new approaches to achieve patient-centric medicine.

1.2 Patient-centric Medicine and the DTx Connection

The Value of DTx in Patient-centric Medicine

While digital technologies are transforming the pharmaceutical value chain and preventive prognosis to innovate MX, there are several ongoing efforts to digitize the treatment and patient experience itself. DTx has recently garnered attention as a science-based treatment for lifestyle-related diseases and psychiatric disorders.

We believe that this new therapeutic agent will contribute to patient-centric medicine in three ways:

Providing Innovative Treatments for Unmet Medical Needs

DTx is expected to be effective against diseases for which no effective treatment has been discovered. For example, lifestyle-related diseases such as heart disease, cancer, and Alzheimer's affect many patients worldwide, but it has been difficult to alleviate their symptoms with tablets alone. Effective treatment also requires a proactive improvement in patients' lifestyles. However, the introduction of DTx in combination with conventional medications is expected to improve the effectiveness of treatment even for other psychiatric disorders such as depression and ADHD.

Increased Treatment Efficacy in RWD Collection and Comprehensive Medical Support for Disease Prevention and Prognosis

DTx can accumulate data on a patient's health condition, lifestyle, and medication information from the comfort of their home, which is a black box in a conventional medical examination.

Furthermore, if a system is in place to link the collected data with the doctor, the patient's physical and mental burden of visiting the hospital for medical examinations can be reduced.

DTx plays a crucial role in disease and relapse prevention. Based on data collected through the application and software, it is useful in detecting the risk of disease onset for individual patients and constructing treatment plans to prevent or alleviate diseases. The system will significantly contribute to the realization of healthy living through its health status coordination and alert functions for chronic diseases and other illnesses that require long-term follow-up.

Collection of Consumer Data with Potential for Developmental Use Cases

While DTx is expected to significantly improve the patient-centric healthcare experience, there are also substantial benefits on the development side for pharmaceutical and IT companies. The patient information on usage patterns obtained through DTx devices is diverse and can be regarded as an asset.

In addition to its medical uses in developing and improving pharmaceuticals, healthcare programs, and personalized medicine, DTx is expected to have developmental use cases in the food and insurance industries. For instance, combining consumer data with patient life logs in these sectors.

Chapter 2:
DTx Trends and Future Market Outlook by Country

2.1: DTx Trends in Each Country
2.2: Growth Prospects of the DTx Market

2.1 DTx Trends in Each Country

Digital Health and DTx Trends

Digital health is being addressed around the world as a solution to ‘soaring healthcare costs and human resource shortages’ due to the rapid aging of the population and the ‘maturing technological infrastructure’ of wearable technology, AI, machine learning, and other technologies.

In recent years, the new computerized physician order entry (CPOE) system has been introduced in many countries around the world. The spread of the coronavirus pandemic has led to a surge in demand for contactless, on-demand treatment, creating an environment that is accelerating the spread and adoption of DTx solutions globally.

This chapter summarizes DTx trends in three countries: the United States, one of the first countries to undertake digital health and DTx initiatives; Germany, one of the pioneers in the European Union to start DTx initiatives; and Japan, where the DTx market is currently expanding.

- **United States**

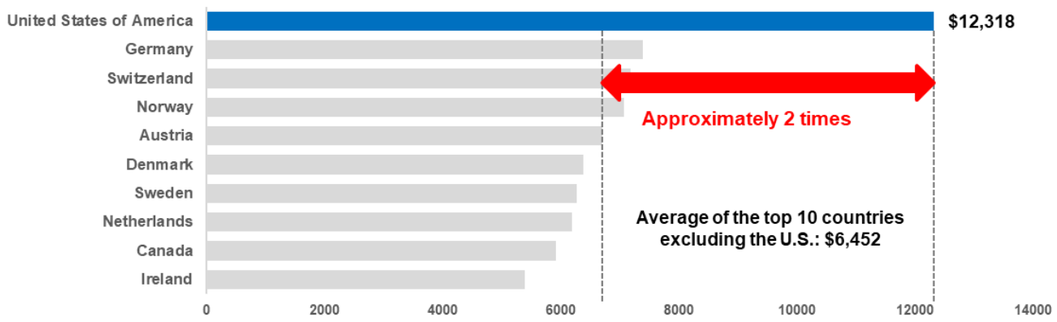
Digital Health and DTx Initiatives Advancing in the U.S.

While digital health and DTx initiatives are active around the world, the United States has been quick to take them on. There are three main reasons for this.

The first is the increase in lifestyle-related diseases. The prevalence of chronic diseases in the U.S. has skyrocketed over the past decade, and by 2022, approximately 43% of Americans, or 133 million people, have one or more chronic disease.[1] Second is the excessive cost of healthcare. The U.S. is the only developed country that does not have universal healthcare, and its healthcare expenditures as a percentage of its overall economy are higher than those of other countries. It has the highest per capita healthcare cost in the OECD, at $12,318 per person. While there is an initial cost to patients to use DTx, it has the potential to reduce total healthcare costs overall by improving disease management and reducing the need for more expensive treatments, encouraging patients to use DTx.

The third is early institutional development of DTx. In the U.S., regulatory authorities have established a department dedicated to digital health and have developed approval guidelines and processes that are tailored to the unique characteristics of DTx, which are different from those of conventional medical devices. In addition to that, the world's first DTx industry association has been established, encouraging companies to act on DTx.

DTx efforts in the U.S. have become more active for these three main reasons. The specific systems and examples in the U.S. are explained further.



DTA, an Industry Association, and FDA, a Regulatory Agency

In 2010, Welldoc, a U.S.-based company, introduced BlueStar®, a treatment assistance application for type 2 diabetes, making it the first DTx product in the world. The app was approved by the U.S. Food and Drug Administration (FDA).

In 2017, the Digital Therapeutics Alliance (DTA) was established, expanding the concept of DTx in the United States and globally.

In September 2020, a dedicated digital health division was created under the FDA's Center for Devices and Radiological Health (CDRH) to advance DTx approval.

Adapted Guidelines and Expedited Approval Process for DTx

To bring a DTx product to market, evidence supporting its medical efficacy is required, and approval from the regulatory agency in each country is necessary. The United States is one of the quickest to develop a system of approval guidelines and processes. Under the U.S. guidelines, software that functions as a standalone medical device in digital medicine is clearly distinguished from existing medical devices and evaluated according to newly established criteria.

Furthermore, the U.S. approval process includes a pre-certification program. The FDA pre-approves each company's software design, validation, and maintenance capabilities, as well as risk management and transparency. Companies that pass pre-approval then have a simplified review process for new DTx. This allows for a faster approval process in the U.S.[3]

DTx Product Case Studies in the U.S.

The FDA has approved more than 40 DTx products since 2017. Below are three select case studies: Welldoc's **BlueStar®**, the world's first FDA-approved product. Akili's **AKL-T01**, the world's first game-based digital therapy approved by the FDA, and Arcade Therapeutics' **ABM-02**, which is seeking FDA approval.

Case 1: Welldoc - BlueStar® (Diabetes)[4]

BlueStar® is a digital therapy application developed by Welldoc for diabetics and is the world's first DTx approved medical device by the U.S. Food and Drug Administration (FDA) in 2010. The system can manage blood glucose levels, blood pressure, medication, diet, and exercise for diabetes patients. The collected data is analyzed by AI and optimized coaching is provided to individual patients in real time, enabling them to not only reduce their blood glucose levels but also improve their overall health.

Case 2: Akili - AKL-T01 (ADHD)[5]

AKL-T01 is a digital therapeutic app developed by Akili for the treatment of Attention-deficit/hyperactivity disorder (ADHD) in children between ages 8 to 12. The app is a game-based therapy that is controlled on a smartphone or tablet. AKL-T01 is designed to activate the brain's prefrontal cortex, which is believed to play a fundamental role in cognitive function. The FDA has approved AKL-T01 as the world's first game-based digital treatment for ADHD and other disorders. These approvals are based on data from five clinical trials involving more than 600 children diagnosed with ADHD.

Case 3: Arcade Therapeutics - ABM-02 (Depression)[6]

Arcade Therapeutics combines cognitive neuroscience and mobile gaming to treat psychiatric disorders, building on more than a decade of NIH-supported clinical research and R&D in the therapeutic areas of anxiety, stress, and addiction. The company is the first to apply mobile game-based neurocognitive training technology to the treatment of anxiety, stress, and addiction. Arcade Therapeutics’ ABM-02 is a game-based DTx for the treatment of depression. The company is seeking FDA approval for ABM-02 as the first game-based treatment for depression based on the findings from clinical trials and validation.

2.1 DTx Trends in Each Country

- **Germany**

Germany is Making Progress in the EU

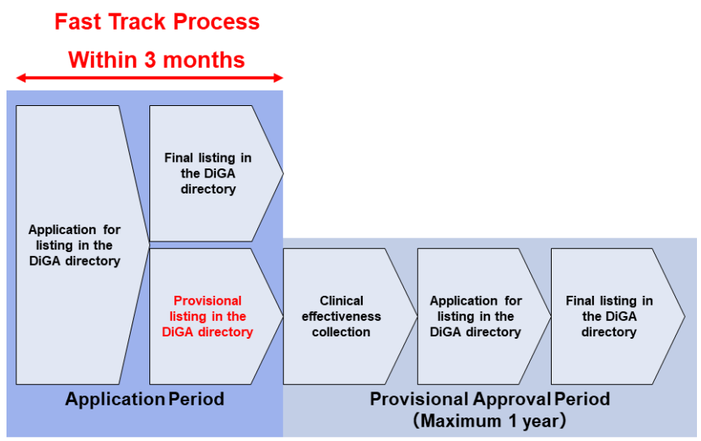
Trends in DTx initiatives differ from one member state to another in the EU, making it difficult to provide a general explanation. Therefore, this section focuses on Germany, a member country of the EU that is making progress in DTx initiatives.

DVG Facilitated DTx Use in Germany

In Germany, the shortage of doctors and the increase of chronic patients are social problems, and DTx is emerging as a significant solution. In December 2019, Germany enacted its own Digital Healthcare Act (DVG), which takes various measures to improve healthcare through digital technology. The DVG stipulates that DTx prescribed with insurance reimbursement does not require patient payment[7], further promoting the use of DTx in Germany.

Regulators BfArM and DiGA Directory

To be approved as a DTx in Germany, a drug must be added to the DiGA Directory (DTx List) maintained by the BfArM (Federal Office for Medicinal Products and Medical Devices).



FastTrack System and Provisional Approval System

In addition to the DiGA Directory, two other systems accelerate DTx approvals in Germany: the **FastTrack System** and the **Provisional Approval System**. The FastTrack System allows DTx to be approved within three months of application. The Provisional Approval System allows for provisional additions to the DiGA directory even if they have not actually been in operation. They must meet DiGAV and should have gone into effect in December 2019, the same month as DVG.

If a provisionally approved DTx can demonstrate sufficient medical efficacy within a maximum of one year, it will receive full approval for addition to the DiGA directory. On the contrary, if its efficacy cannot be proven, it will be removed from the directory. No other country has such a system in place to allow the rapid provision of DTx.[8]

DTx Product Case Study in Germany

In the German DTx market, GAIA AG and GET.ON are two companies of interest. The DiGA Directory has two types of authorizations, full and provisional, and as of January 31, 2024, there were 30 DTx with full authorizations in the DiGA Directory.

Two representative examples of DTx with full authorization, GAIA AG and GET.ON, are presented below.[9]

Case 1: GAIA AG - Deprexis (Depression)[10]

Deprexis is an interactive, online self-help program designed to support the treatment of depression or depressed moods in patients over the age of 18. The program is intended to complement usual medical care (general practitioners, specialists, psychotherapists, etc.).

Deprexis is based on established psychotherapy approaches and procedures, specifically cognitive behavioral therapy (CBT). In terms of efficacy, patients who use Deprexis in addition to their usual medical care have been shown to have fewer depressive symptoms than those who receive usual medical care alone.

Case 2: GET.ON Institute for Online Health Training GmbH - HelloBetter Panic (Panic disorder and square phobia symptoms)[11]

HelloBetter Panic is an interactive psychotherapy program designed to treat the severity of panic disorder and control the symptoms of panic disorder-associated square phobia.

The program has proven to have a positive supportive effect on patients with prior psychotherapy experience through randomized controlled trials. Additionally, the program's 12-week online course provides psychological education using text, video, and audio. Patients are trained to become familiar with and gradually overcome their fears by actively confronting anxiety and external stimuli.

2.1 DTx Trends in Each Country

- **Japan**

The DTx Market is Gaining Momentum in Japan

In Japan, the market is currently expanding and DTx is expected to be in full swing from 2026, with widespread use expected to begin around 2030. Japan is one of the world's most aged societies with an extremely low birthrate. With multifactorial-related diseases such as lifestyle-related diseases and psychiatric disorders on the rise, DTx as a new therapeutic tool is attracting attention.

PMDA and MHLW as Regulatory Authorities

With the enactment of the Pharmaceuticals and Medical Devices Act in November 2014, a new category of medical device program was established, and that program alone is now reimbursable by insurance.

In Japan, the Pharmaceuticals and Medical Devices Agency (PMDA) and the Ministry of Health, Labour and Welfare (MHLW) are responsible for the approval of DTx.

Institutional Development of DTx in Japan (DASH for SaMD)

In November 2021, the Japanese Ministry of Health, Labour and Welfare (MHLW) formulated the **DASH for SaMD** (Package Strategy for Accelerating the Commercialization of Programmed Medical Devices) with the aim of establishing an institutional infrastructure for the regulatory approval for SaMDs, including DTx.

Various strategies are clearly defined, for example, the use of the 'Identification of Change Plan Confirmation Procedure System (IDATEN System)' to realize a review system that considers the characteristics of SaMD.[12][13]

Promotion Strategy for Practical Application (DASH for SaMD2)

In September 2023, **DASH for SaMD2** was formulated to further promote practical application of DTx. The plan includes new measures such as the consideration of a two-step approval process. In November 2023, the MHLW issued the **SaMD Version Rebalancing Notice** as a result of this two-step approval process.

In conclusion, the DTx market in Japan is expected to grow further due to promotion strategies and institutional arrangements.[14][15]

Programmed Medical Device for Disease Treatment (DTx)

Stage 1 Approval

Even if the target clinical significance has not been established, Stage 1 approval is given for a restricted purpose to the extent that a certain level of efficacy can be statistically confirmed through preliminary clinical trials. This approval is granted for the relief of specific symptoms or improvement of conditions, in addition to test results related to performance evaluation.

Stage 2 Approval

Once clinical evidence has been established (post-marketing clinical trials, Real-World Data, etc.), an application for approval of partial change of approved items is filed to obtain Stage 2 approval, if necessary.

Glossary:

IDATEN System

The IDATEN System approves improvement plans for medical devices according to the characteristics of the device. The system is expected to promptly respond to version upgrades after approval.

SaMD Version Rebalance Notification

The official name is 'Handling of Two-step Approval Based on the Characteristics of Programmed Medical Devices' (Pharmaceuticals and Medical Devices Agency Public Notice No. 1116/2), based on the characteristics of SaMD in response to the Rebalance Notice issued in November 2017. The Rebalance Notice refers to the MHLW's notice that allows approval review without conducting new pre-marketing clinical trials (clinical studies) by implementing consistent measures to ensure safety and efficacy from pre-marketing to post-marketing to deliver new medical devices to patients more quickly.

Approved DTx Product Case Studies in Japan

As of December 2022, more than 30 companies have been conducting DTx-related R&D in Japan, and several pharmaceutical companies are planning to introduce overseas DTx products.[16] CureApp's CureApp SC was launched in Japan in December 2020 and as of December 2022, there are three DTx products that have been approved for medical device manufacturing and marketing. **CureApp SC**, the first MHLW-approved DTx, and SUSMED's **SUSMED Med CBT-i®**, which was subsequently approved are introduced below:

Case 1: CureApp Inc. – CureApp SC (Smoking Cessation Treatment)[17]

CureApp SC is a nicotine dependence treatment application developed by CureApp, a Japanese company. It is the first treatment application to be approved by pharmaceutical regulatory bodies and covered by insurance in Japan.

CureApp SC is a digital therapy that approaches the psychological dependence of nicotine through the application and leads patients to a healthier lifestyle by changing their thinking and behavior.

According to a multicenter Phase III clinical study conducted in Japan, the intervention group had a significantly higher continuous abstinence rate (63.9%) from weeks 9 to 24 compared to the control group (50.5%).

Case 2: SUSMED Co., Ltd. - SUSMED Med CBT-i® (Insomnia Disorders Treatment)[18]

SUSMED Med CBT-i® is a smartphone app developed by SUSMED for the treatment of insomnia disorders and has been approved for manufacture and sale as a medical device in Japan. It is used to administer Cognitive Behavioral Therapy (CBT-I) to patients with insomnia disorders. Following the instructions prompted by the application over a nine-week period produces therapeutic effects on insomnia symptoms.

DTx Product Case Studies in Japan (under development)

DTx has been developed in recent years using various innovative technologies, one of which is VR. BiPSEE is currently working on VR digital therapy for the treatment of mental illness and is also seeking approval of **BiPSEE Depression**.

Case 3: BiPSEE - BiPSEE Depression (Depression)[19]

BiPSEE is a MedTech startup founded in 2017 by psychosomatic physicians to research and develop medical evidence-based VR digital therapies for the treatment of mental disorders.

BiPSEE Depression is a digital and personalized cognitive behavioral therapy that helps in the treatment of depression in combination with medical treatment. This solution consists of (1) technology for measuring cognitive function and optimizing treatment plans, (2) cross-platform data synchronization system technology, and (3) technology for evaluating treatment effectiveness by quantifying medical requirements.

It can acquire and analyze data during, before and after patient treatment via devices such as VR and smartphones and reflect it in the treatment program.

2.1 DTx Trends in Each Country

Summary of Trends in Each Country

The U.S. and Germany are actively working on DTx, but with distinct characteristics. The U.S. is ahead in terms of the number of DTx approvals and practical application, while Germany has made noteworthy progress on the institutional front, with unique efforts to promote DTx use through public medical insurance and establishing a speedy approval process. The DTx market in Japan is expanding, and since institutional arrangements are being actively discussed, future DTx proliferation is expected.

As mentioned above, flexible guidelines and processes that study the characteristics of DTx can be put in place to facilitate its growth.

Currently, various countries are stepping up discussions on institutional arrangements for DTx and we can expect the market to expand further. Based on approval cases in various countries, most of the cases are not of large pharmaceutical companies but of smaller IT companies. We believe that the trend of collaboration between IT companies and pharmaceutical companies will continue to grow.

As reforms of regulatory systems in each country progress, the potential for profitability of DTx will also increase, boosting participation from pharmaceutical companies and transformation of the industry.

2.2 Growth Prospects of the DTx Market

DTx Market Size to Expand Worldwide

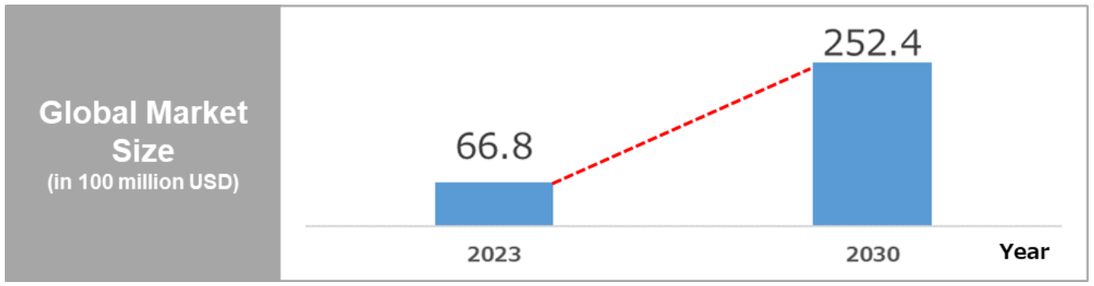
As illustrated in the previous section, DTx is being developed in many countries and the market size is expected to expand. In this section, we will look at the projected size of the market worldwide and in Japan, based on research reports from other companies.

Global DTx Market Size Forecast

According to a market research report by Global Information Corporation, the market is expected to reach US$25.24 billion by 2030 from US$6.68 billion in 2023, growing at a compound annual growth rate of 20.9% during the forecast period. “DTx adoption is growing at a fast pace due to factors such as the rising number of patients with chronic diseases and increasing investment in DTx.” On the other hand, the report also discusses how “lack of awareness and access to DTx programs in emerging markets, resistance from traditional healthcare providers, and uneven payment models are all factors that are hindering growth in this market.”[1]

DTx Market Size Forecast in Japan

DTx is still in its infancy in Japan and specific market size figures have not been disclosed. However, Yano Research Institute estimates the potential growth of the market from 3 billion yen in 2025 to 30 billion yen by 2030, indicating a growth trend. There are more than 60 projects in the pipeline.[2]



Chapter 3:
Value of DTx and its Evolving Use Cases in Pharma

3.1: The Value of DTx in the Pharmaceutical Industry

3.2: Future Developmental Use Cases

3.1 The Value of DTx in the Pharmaceutical Industry

Value of DTx

This chapter provides an in-depth explanation of the value of DTx. Section 3.1 introduces the ‘value of DTx for pharmaceutical companies’ that could revolutionize their business structure, followed by an explanation of ‘future developmental use cases’, which will create new value as DTx becomes more widely used.

Key Value of DTx in the Pharmaceutical Industry

DTx for pharmaceutical companies derives its value from two unique factors: **pharmaceutical approval** and **healthcare application**. Specifically, DTx is a pharmaceutical product that has been approved by pharmaceutical regulatory bodies, which means that it can be profitable on a standalone basis and contributes to conventional medical care (synergistic effect).

Since DTx also has the characteristics of a healthcare application, ‘creation of contact points between pharmaceutical companies and patients’ and ‘acquisition of data that cannot be obtained from conventional clinical practice’ are representative values.

- **Monetization on a Standalone Basis**

Firstly, DTx is different from healthcare applications, which are mostly meant to improve health. DTx can be monetized on its own through regulatory approval.

As with ordinary pharmaceuticals, the official price of DTx as a prescription drug is determined by regulatory approval and insurance coverage. In Japan and other countries where public medical insurance is commonly used, the official price is determined, and public medical insurance is applied when prescribing the drug. This allows pharmaceutical companies to expect a certain level of revenue. On the other hand, non-SaMD healthcare apps for the purpose of health promotion, can have unstable profitability compared to DTx, as their prices may fluctuate depending on the needs of consumers and market conditions.

More healthcare IT companies are entering the DTx business due to the potential for a stable revenue stream.

- **Contribution to Conventional Medicine (Synergies)**

Since DTx requires regulatory approval, we can assume that it will create value in terms of contribution to conventional medicine. For example, synergy can be created by allowing the same physician to prescribe DTx in combination with conventional drugs. If the physician prescribes an antihypertensive drug to a patient suffering from hypertension, the same physician can additionally prescribe DTx, thereby promoting synergistic effects of digital solutions in combination with existing drugs that have been prescribed.

For pharmaceutical companies, the various biomarkers obtained from DTx will enable a more detailed understanding of the duration of the effect of existing drugs. Utilizing this detailed data will pave the way for advanced research and development.

- **Networking between Pharmaceutical Companies and Patients**

In conventional pharmaceutical sales, drugs are provided to patients through dispensing pharmacies based on a physician's diagnosis and prescription. On the other hand, it has been difficult for pharmaceutical companies to directly access the final dosage information of patients.

The progression of DTx will transform the traditional structure of drug provision, which prevents direct contact with patients, enabling pharmaceutical companies to obtain their own patient contact information. Patients will be able to use DTx to share their medical conditions and other data in real time not only with medical professionals but also with pharmaceutical companies.

Pharmaceutical companies that manage DTx will be able to independently obtain contacts and data from a wide range of patients. This data is utilized in R&D and marketing strategy planning to form a new source of competitiveness for pharmaceutical companies.

- **Limited Data Acquisition from Conventional Clinical Practice**

Pharmaceutical companies can leverage the benefits of DTx more effectively, enabling them to access data that was previously unavailable through conventional clinical practice.

Until now, patient data that could be obtained from clinical sites was restricted to data obtained at the time of clinical trials in accordance with the clinical trial plan and diagnostic records in electronic medical records.

With DTx, however, it is now possible to obtain data on patients' daily living conditions, a so-called ‘blank period’ that could not be obtained until now.

By linking and utilizing data from this blank period with existing data from electronic health records and PHRs, pharmaceutical companies can promote the transformation of their value chains. In addition to the pharmaceutical industry, we anticipate the emergence of businesses that leverage data integration from various industries beyond healthcare.

3.2 Future Developmental Use Cases

Utilization in Healthcare and the Pharmaceutical Value Chain

We believe that the data collected through DTx will be valuable not only in therapeutics, but also in innovating the pharmaceutical value chain, marketing, healthcare, food, insurance, and other industries.

- **Utilization in the Pharmaceutical Value chain**

Innovative Drug Discovery Using New Data

One of the latest trends in the pharmaceutical industry is **personalized medicine**, catering to the needs of each individual patient. DTx can capture daily data including health status, during the time between diagnosis and treatment, and provide a new level of information that can be used to develop innovative drugs. The capture of data during the non-diagnosis period is expected to facilitate more efficient disease analysis and target identification during the drug discovery process.

Facilitate Clinical Trials and Cost Optimization

Optimization of the clinical trial process to ensure efficacy and safety is essential for rapid drug delivery. The data obtained from DTx can contribute to cost and operational efficiency in this process. For example, by using DTx as a digital biomarker capture tool, pharmaceutical companies can better track the progress of clinical trials.

Also, the concept of ‘patients and subjects themselves evaluating the efficacy and safety of new drugs,’ has been gaining importance in recent years. DTx could provide data to supplement patient-reported outcomes (PROs), which tend to be subjective information.

Advanced Monitoring

To provide comprehensive support for healthy living to patients, it is necessary to closely monitor and provide guidance on the health status of each individual patient even after the drug has been provided. In this post-marketing monitoring process, daily patient data can be collected through DTx to evaluate the overall effectiveness of treatment, including DTx, and to track the response to specific drugs, which varies from patient to patient.

Since the effectiveness of drugs can be continuously captured, it serves as a remote communication contact point. It also promotes patient engagement, such as sharing correct dosing instructions and improving treatment adherence.

Enhanced Marketing Strategies

Data obtained through DTx can be of immense value in improving the patient experience and marketing strategies of pharmaceutical companies. Pharmaceutical companies can use daily patient data to refine sales forecasts for related drugs and other products. It will also enable the collection of data for more detailed analysis of patient dynamics that vary by region and time of year, leading to the optimization of sales resources, sales strategies, and channels.

Furthermore, we believe that RWD will contribute to evidence generation in proving the effectiveness of existing drugs increasing in market share.

Innovative drug discovery using novel data

Facilitate clinical trial processes and cost reduction

Advanced monitoring

Sophisticated marketing strategies

3.2 Future Developmental Use Cases

● Utilization in Healthcare

Data obtained through DTx will be utilized across a wide range of applications in healthcare and pharmaceuticals. This section introduces examples of DTx utilization focused on government bodies, food manufacturers, and insurance companies.

Utilization by Government and Municipalities

A significant role of local governments is to understand the health status and disease prevalence in citizens, and to plan, propose, and implement insurance-related measures in response to these conditions. This data can be used to prioritize and evaluate measures for health issues that need to be addressed in the community.

Utilization by Food Manufacturers

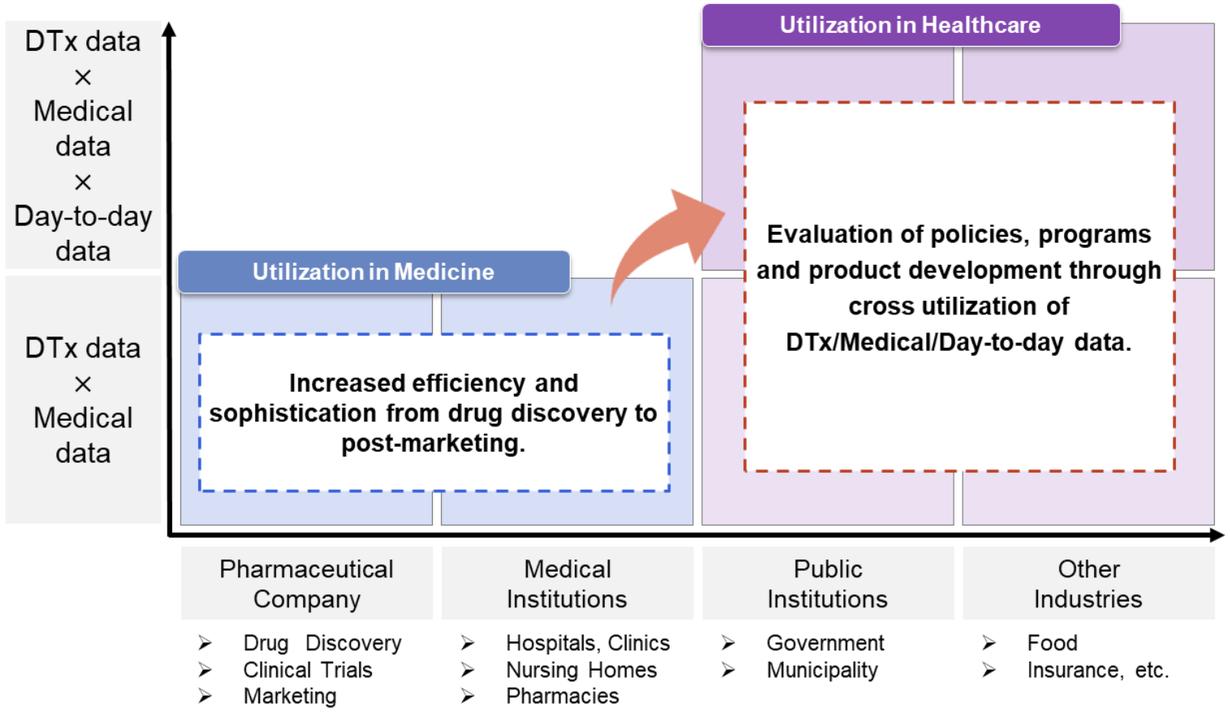
For food manufacturers to provide safe and healthy products, it is essential to understand consumer preferences and health conditions in the development, production, and marketing of their products. The collection and analysis of consumer health data through DTx can contribute to the development of new products and the improvement of quality and effectiveness of existing products. We believe that consumer data on daily activities will be effective in optimizing marketing strategies and measuring the effectiveness of sales promotion channels.

Utilization by Insurance Companies

Insurance companies propose suitable insurance plans for the insured based on risk assessment. Data collected through DTx can be used to predict risk by assessing the insured person's health status and designing appropriate insurance plans.

It is also beneficial in terms of health promotion support for the insured during the insurance period. For example, it can serve as an indicator to provide incentives such as discounts and health services to individuals with safe levels of health behavior and treatment adherence.

The data is instrumental in minimizing risk, improving customer satisfaction, and establishing a sustainable business model.



Chapter 4:

Initiatives to Promote DTx

4.1: DTx Distribution Platform

4.2: Digital Health App Development for DTx Approval

4.1 DTx Distribution Platform

NTT DATA's Initiatives as a Starting Point

As established in the previous chapter, DTx is expected to create value that could not be obtained from conventional pharmaceutical practices or digital health applications.

The data obtained from DTx is utilized in pharmaceuticals and in collaboration with other industries, NTT DATA is leading various initiatives as a launch pad to creating value through the widespread use of DTx.

In this chapter, we will focus on two initiatives that NTT DATA is co-developing with clients:

DTx distribution platform construction and **Digital health application development for DTx approval**.

Building a DTx Distribution Platform Offering Digital Therapeutic Services[1] [2]

We are co-creating a distribution platform with Shionogi to promote DTx and provide treatment through mobile applications and other means.

Background of Initiatives

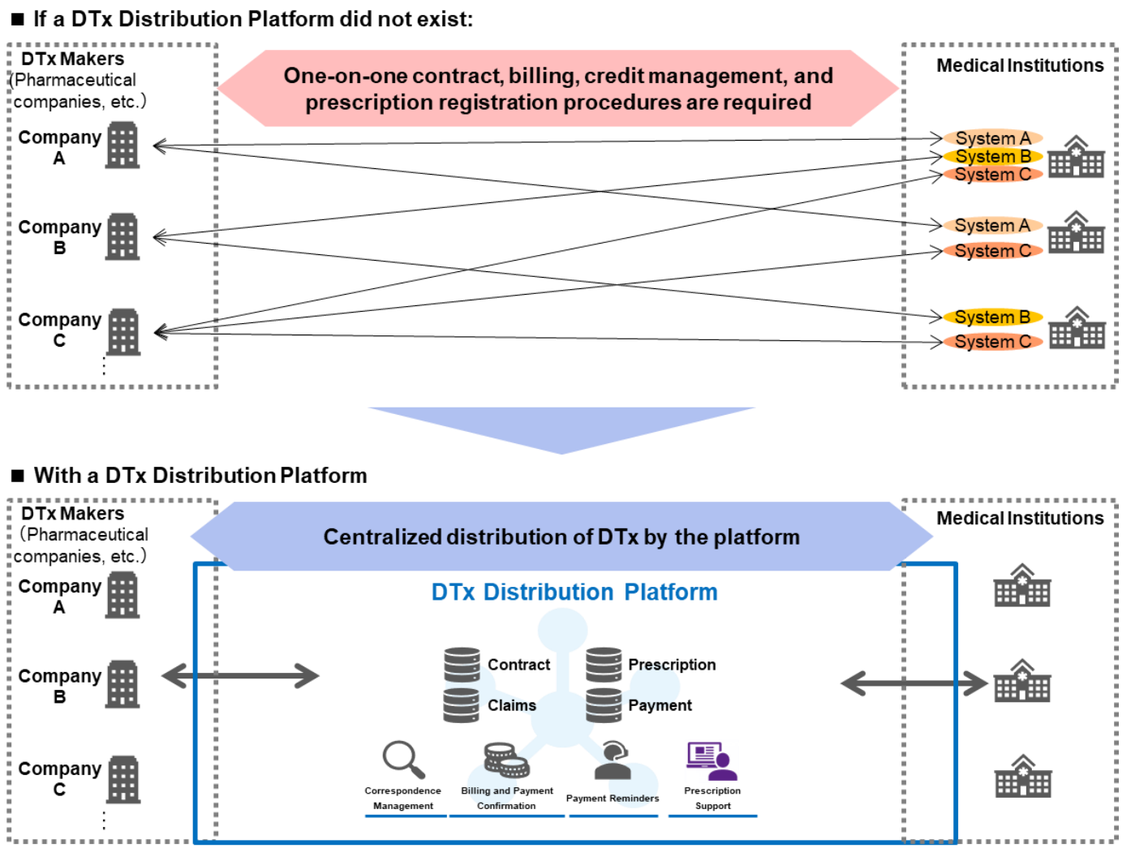
DTx, or Digital Therapeutics, refers to digital products that provide evidence-based therapeutic interventions for the treatment, management, and prevention of diseases and conditions. It is expected to be a new modality in a wide range of medical and healthcare fields. However, since the process of prescribing DTx differs from conventional medical pharmaceuticals, there is a need to consider and establish new mechanisms to deliver DTx to patients safely and efficiently.

Healthcare institutions and DTx providers typically have individual contracts on a one-to-one basis for prescription registration and billing. However, if the contract processes and payment specifications vary from among providers, it may become burdensome for healthcare institutions to handle administrative procedures. Therefore, Shionogi, NTT DATA Japan, NTT DATA KANSAI, and QUNIE have decided to collaborate in the construction and standardization of an information infrastructure platform to promote the dissemination of DTx.

Platform Overview

The platform is scheduled to be launched in 2025. It aims to standardize and centralize the coordination of necessary information between patients, healthcare institutions, and DTx providers. It also consolidates various functions such as contracts, billing, and prescription registration between healthcare institutions and DTx providers, aiming to reduce the burden on both parties and establish a safer and more efficient prescription and distribution system.

Shionogi, NTT DATA Japan, NTT DATA KANSAI, and QUNIE will continue to collaborate with government agencies and companies that share the same vision of contributing to the progress of DTx through the construction of this platform.



4.2 Digital Health App Development for DTx Approval

Digital Health App Development for DTx Approval

NTT DATA Italia is collaborating with a multinational pharmaceutical company to design and develop a digital solution for hypertension, complementing its existing hypertension medicine portfolio. The solution is undergoing a UX Study in Italy to demonstrate its usability and efficacy, in preparation for future developments as a Digital Therapeutics solution.

Background

Hypertension currently affects 1.28 billion adults aged 30–79 worldwide (according to WHO – 2023). Despite the vast array of drugs available, only 40% of hypertensive patients have controlled blood pressure, significantly impacting healthcare expenditure. In this context, technology significantly addresses the root problem by increasing patient awareness and optimizing the doctor-patient relationship. For our client, the solution represents a tangible tool to streamline its relationship model with doctors and patients, offering truly patient-centric services and tools. Additionally, it represents an opportunity to gather real-world data for research and take the first step toward entering the expanding digital health market.

Key Features

The solution works as a shared e-diary that simplifies the management of the hypertensive condition for all the stakeholders involved. It consists of an integrated digital system including a patient app, a dashboard managed by healthcare professionals, and an app dedicated to a supporting person, motivating the patient in the real world. The application is a valuable companion for patients throughout their care journey. It enhances therapy adherence by giving visibility to an asymptomatic condition and fosters behavioral change through applied games, conversational interaction, and human-like communication.

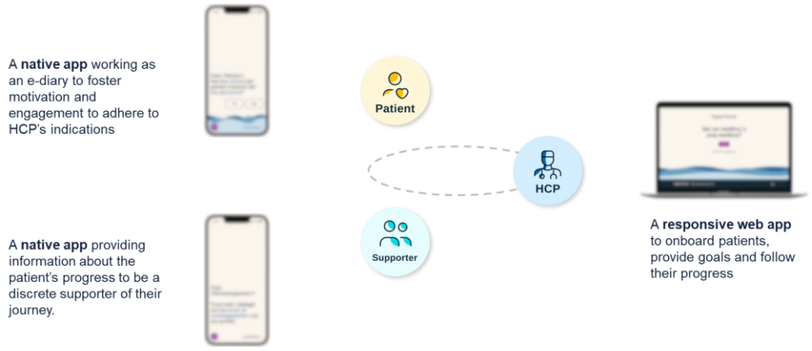
For healthcare professionals, it aids in setting clear lifestyle goals and bridges the information gap between visits. The portal offers an overview of patients' clinical status, blood pressure trends, and therapy adherence, simplifying patient management and enhancing care quality. To ensure seamless and continuous usage, Tangity, NTT DATA's global unit specialized in strategic and product design, collaborated with end-users (patients and physicians), client stakeholders, and key opinion leaders in co-designing the solution. To maximize its value, the solution will evolve into a DTx solution: a high-quality software program for preventing and treating physical and mental illnesses. As a DTx, it could be prescribed and reimbursed by national healthcare systems, with the generated data holding clinical significance. To achieve this, the solution must undergo a clinical trial to be classified by European authorities as a medical device.

Potential

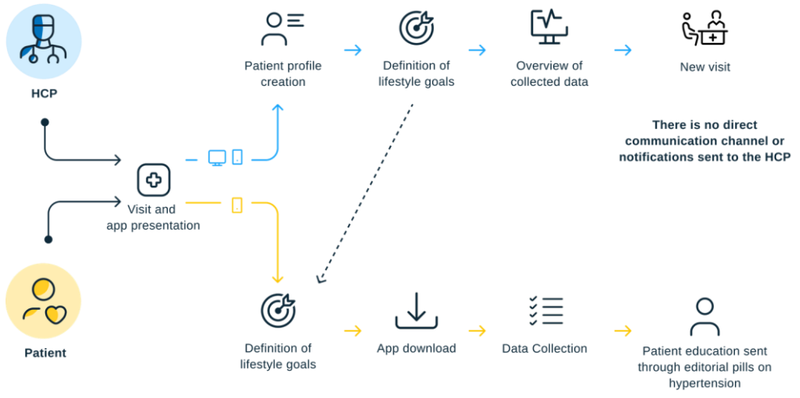
The solution is one of the pioneering digital health platforms for hypertension in Italy, with a potential reach exceeding 1 million patients in 5 years based on client estimates. Moreover, it offers flexibility and adaptability for multiple applications as it has been designed with full scalability to other nations and medical domains.

For NTT DATA, this experience represents a significant opportunity to engage with leading pharmaceutical companies across Europe and beyond, as they express interest in venturing into the digital health sector for various fields of therapy.

The solution works as an integrated ecosystem with a dedicated touchpoint for each actor involved



Complementing the drug therapy, it is a valuable ally throughout the healing process



Glossary

Tangity (https://tangity.global/en)

In 2020, a group of designers from NTT DATA Design Network came together to create a new brand. Our focus is on designing and developing innovative new services that prioritize the concept of **service design** and consider the importance of user experience in business creation. As of 2024, NTT DATA Design Network has more than 950 members in 16 offices around the world, including Japan, Italy, Germany, and the UK.

Tangity

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