

WHITE PAPER



DTx

How stimulating Digital Therapeutics
will strengthen accessible,
engaged patient care
for better outcome

SUMMARY



The digital evolution in healthcare is making significant progress. Digital tools intended to deliver therapy via digital means are rapidly evolving. These Digital Therapeutics (DTx) applications deliver evidence-based therapeutic interventions to patients to prevent, manage or treat a medical disorder or disease, with a wide variety of purposes. **The nature of Digital Therapeutics is hence characterized by its software-driven therapy**, differentiating them from other digital health applications that rather support or monitor the patient without delivering therapy.

Digital therapeutics are designed and manufactured according to the latest standards for medical devices and comply with the European Union's Medical Device Regulation (EU MDR), hence being CE-certified as medical device. This means that they have proven their effectivity (being in line with medical device requirements based on strict clinical validations) as well as their safety and performance. In the Belgian medical device landscape, there is a lot of innovation going on in DTx and several concrete examples are given in the paper.

DTx strengthen the patient engagement for their therapeutic pathway under guidance of a healthcare professional. Rethinking the financing of such pathway is crucial to accelerate adoption and incentivize the possible use of DTx, rewarding the value they bring, ranging from improved quality of care and of life, to more personalized therapeutic approaches and healthcare savings. Therefore, **government initiatives should be taken to stimulate the adoption of DTx in the healthcare system as surrounding countries are doing nowadays.**

The Belgian healthcare authorities created the mHealthBelgium validation pyramid for mobile health applications, consisting of 3 levels and being the unique path towards national reimbursement for the use of such digital tools within a care path. **Why not applying the mHealthBelgium pyramid framework for more than pure mhealth applications, but embrace all DTx applications used by patients?**

THE TIME TO ADOPT DIGITAL THERAPEUTICS IS NOW.

Investing in Digital Therapeutics is investing in accessible and affordable care with better health management. beMedTech is calling the policy makers to enable easy and fast access to DTx applications through adequate innovation funding.

SETTING THE DIGITAL THERAPEUTICS SCENE

INTRODUCTION

The digital revolution in healthcare is making significant progress. Over the past five years, the capabilities for healthcare providers to make their care more accessible for patients through digital health has evolved rapidly. Different categories of digital health tools have become available and are making their breakthrough into standard care. These digital tools are predominantly supporting the clinical workflow and the follow-up and engagement of patients in their personalized care pathway.

Digital Therapeutics (DTx) deliver an evidence-based software-driven medical intervention to prevent, manage or treat a disease.

In addition to these digital health applications for care support, a very new category of therapeutic digital tools are now becoming available: they are intended to deliver therapy in a digital way. These Digital Therapeutics (DTx) applications deliver evidence-based therapeutic interventions to patients to prevent, manage or treat a medical disorder or disease. Such DTx applications cover a wide variety of purposes, from managing acute or chronic diseases in different clinical areas such as cardiology, neurology, diabetes or mental health to support patients during rehabilitation and finally even applying acute interventions or treatments.

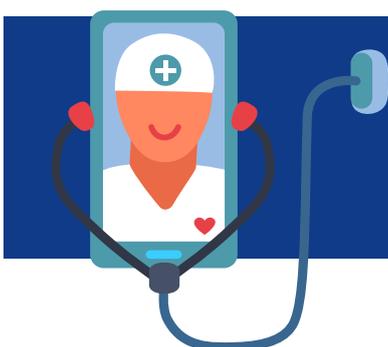
DIGITAL THERAPEUTICS IS A NEW CATEGORY OF MEDICAL DEVICES

Digital enablement is probably one of the most significant general progresses in the healthcare landscape. With the arrival of the Digital Therapeutics, a new era opens up in which patients can receive therapy itself through digital health tools. Digital Therapeutics strengthen the patient engagement for their therapeutic pathway under guidance of a healthcare professional. They are designed and manufactured according to the latest standards for medical devices and comply with the European Union's Medical Device Regulation (EU MDR), hence being CE-certified as medical device. This means that they have proven their effectivity (being in line with medical device requirements based on proper clinical validations) as well as their safety and performance. They can be software-only devices, but can also converge with specific hardware and sensors, approved for use in medical environment to provide a proper quantification of the therapeutic outcome. Digital Therapeutics can be used in a home setting as well as in a hospital or institutional environment. They have by definition to be safe and comply with the applicable e-health guidelines¹ and privacy regulations.

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The nature of Digital Therapeutics is characterized by its software-driven therapy. This differentiates the DTx applications from other digital health applications that support or monitor the patient without delivering therapy, like telehealth applications to remotely monitor patients, wellness and wellbeing applications, patient health records and other digital documentation systems, diagnostic systems, ...



Digital Therapeutics are always delivered under the guidance of recognized healthcare professionals. Therefore, integration in the overall therapy landscape - including supporting identified diagnostics, recognition as alternative for existing therapeutic approaches and appropriate reimbursement - become increasingly important to optimize accessibility for patients.

1. See the mHealthBelgium validation pyramid and in particular level M2: <https://mhealthbelgium.be/validation-pyramid>.

THE BELGIAN MEDICAL TECHNOLOGY LANDSCAPE IS ACTIVE IN DIGITAL THERAPEUTICS



Digital Therapeutics emerge in the global healthcare landscape. With significant progresses in USA, France, Germany and UK, we see confirmation of the need for digital therapy that is delivered to the patient in a seamless way using medical software-only devices or medical devices combined with other assets, e.g., sensors, actuators, implantables, ... In the Belgian medical device landscape, there is a lot of innovation going on in Digital Therapeutics.

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MULTIPLE PROVIDERS OFFER DTx APPLICATIONS IN DIFFERENT CLINICAL AREAS. WE HEREBY GIVE A NON-EXHAUSTIVE OVERVIEW OF APPLICATIONS IN DIFFERENT DOMAINS:



1. Digital Therapeutics for acute and chronic disease management

Therapy compliance is an important therapy success actor in chronic disease management. Providing DTx applications in stand-alone setup, combined with wearables or administration devices as a companion therapy or a fully Digital Therapy, offers a major opportunity to improve traceability of the effectivity of the therapy. In the Belgian market, different DTx applications are introduced to facilitate this healthcare improvement.

Example 1: DIABELOOP



Diabeloop's DBLG1 is a handheld with a self-learning algorithm and is used in combination with a pre-filled Accu-Chek Insight pump from Roche and the Dexcom G6 continuous glucose monitoring system to form a hybrid closed loop system for people with type 1 diabetes.

It is intended to relieve people affected by this chronic condition from having to make constant therapeutic decisions every day and night, and to allow them to live life without interruption. It automates Type 1 diabetes treatment. The algorithm analyses glucose measurements in real time. Every 5 minutes, a glucose value is transmitted to the device hosting the algorithm which calculates and adjusts the insulin delivery automatically.

The needed insulin doses are based on Diabeloop's DBLG1 algorithm which includes a combination of a published physiological model, a unique expert model and user-declared information about meal and physical activity. As users need to announce meal intakes and command the bolus doses to cover the meals and physical activity, Diabeloop's DBLG1 is considered "hybrid". The target value is achieved by a combination of basal, bolus and also rescue carbs recommendations. The system continually automates basal insulin delivery to maintain glucose levels in target range.

→ [More info](#)

Example 2: HELPILEPSY



Neuroventis' medical device software provides a platform for patients and healthcare professionals to manage neurological conditions. Through an application, patients self-manage their health and they can share data with their healthcare professionals. For patients with epilepsy, Neuroventis' platform delivers a first interactive psychological digital therapy program to improve self-management skills and increase quality of life. It consist of a 12-week program, combining personalized educational material, exercices and tools to effectively help patients in coping with their disease.

→ [More info](#)



2. Digital Therapeutics during acute care, intervention or treatment

Digital Therapeutics capabilities enable new approaches for patient interventions or treatment pathways.

Example 3: DIGITAL SEDATION



Digital Sedation Therapy is a novel software-driven digital therapy to relieve anxiety and pain before, during and after interventions without the use of medication. The Virtual Reality sessions with embedded clinical hypnotherapy and integrative therapy induce light, medium to deep sedation and are evidence-based in multiple randomized controlled trials compared to pharmacological approaches or clinical hypnosis. Oncomfort Digital Sedation offers specific sessions for adults and children for interventions from 2 to 120 minutes and for managing pain and anxiety during repetitive therapy cycles e.g. in oncology or burn care. It reduces the use of sedative or analgic medication up to 100% and has a positive outcome on patient and caregiver satisfaction, improves the workflow for caregivers taking away anxiety, pain or movement disturbances during therapy and has no reported side effects, which is a significant improvement compared to outcomes from pharmacological treatment.

→ [More info](#)



3. Digital Therapeutics for rehabilitation

Significant opportunities have been shown for integrating DTx in rehabilitation pathways, leading to treatments that are more personalized, interactive and more effective, hence delivering better quality of care, better patient support and often also better clinical outcome.

Example 4: MOVEUP THERAPY



In the field of rehabilitation after surgery, moveUP applies DTx for hip and knee arthroplasty patients and bariatric patients. moveUP strives to deliver a personalised, evidence based and most optimal treatment to patients, thereby delivering on value based healthcare. Patients prepare, recover & rehabilitate from their surgery through the means of a personalised and daily adapted treatment via the moveUP App and connected wearable sensors. Patients are followed up by a dedicated remote multi disciplinary health care team who assess the patient's status and progress via a medical dashboard. A combination of algorithms and health care professionals personalise and adapt the treatment on a regular basis. As a result the patient receives a daily personalised treatment consisting a.o. of care information, medication, exercise therapy, dietary & behavioural change and coaching. Next to orthopaedics and bariatrics, moveUP is being developed/tested in other domains like oncology, respiratory and conservative MSK treatments.

Note that the moveUP platform has the capabilities to be used both as a DTx as well as non-DTx Digital Health or Mobile Health application. The platform allows to enable/disable data driven algorithms that drive/adapt the treatment/therapy of the patient depending on the intended use and targeted treatment.

→ [More info](#)



4. Digital Therapeutics for other domains such as mental health

Currently there are probably no DTx applications in this domain already active on the Belgian market, but those are expected very soon. Lots of DTx products for mental health does exist in USA but also in neighbouring countries such as Germany and United Kingdom. They focus for example on treating a depression or burn-out while other are providing digital therapy to deal with fear, stress, anxiety or other mental problems. Some DTx examples that exist and have been approved nowadays in Germany are: HelloBetter, novego, deprexis, Mindable, etc.

MARKET ACCESS FOR DTx IN LINE WITH MEDICAL DEVICE REGULATION



DTx CONFORM MEDICAL DEVICE REGULATION WARRANTS SAFETY AND PERFORMANCE

A first step towards adoption of DTx in standard care is the approval of the therapy and/or therapeutic devices. The European Union's Medical Device Regulation 2017/745 (EU MDR) came into effect on 26 May 2021 with a stronger framework for validation of medical devices. The new MDR has a particularly large impact on medical device software (MDSW). On the one hand, the definition of a medical device has been enlarged, which results in much more healthcare-related software falling under the regulation with all of its implications.

On the other hand, those software tools, including DTx, will be categorized as class II (or higher) medical devices, meaning the certification has to be granted by a notified body. In the past, many software applications were categorized as class I, for which the company itself could mostly define the 'declaration of conformity', without the need of such official notified body. For details, see Rule 11 from the Annex VIII of the MDR².

Digital Therapeutics (DTx) are Medical Device Software and need to comply to the European Medical Device Regulation.

All new MDSW, including DTx, needs to comply to this regulation. Nevertheless, the second corrigendum to the MDR allows a grace period for the certification of MDSW which was self-certified class I under the previous Medical Devices Directive 93/42/EEC (MDD) but will be up-classified under the MDR. Such MDSW may rely on its current certification till maximum 25 May 2024. However, if any significant change takes place, certification has to be done under the new regulation. The grace period regarding certification should not be considered as a delay in compliance to the MDR. Manufacturers still have to set up quality management systems and procedures for risk management, clinical evaluation as well as post-market surveillance, and maintain these procedures, hence following all MDR requirements.

QUALITY GUARANTEED BY PROVEN BENEFITS

The need of a clinical evaluation assessment report is added to the requirements under the new Medical Device Regulation. This report proves the clinical benefits of the medical software, including the proof that the benefit is meaningful and measurable, and that it offers patient-relevant clinical outcome. Besides the evidence on clinical benefit, also clinical data has to be provided proving the safety and performance of the MDSW.

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USING THE EXISTING MHEALTHBELGIUM FRAMEWORK FOR DTx VALIDATION

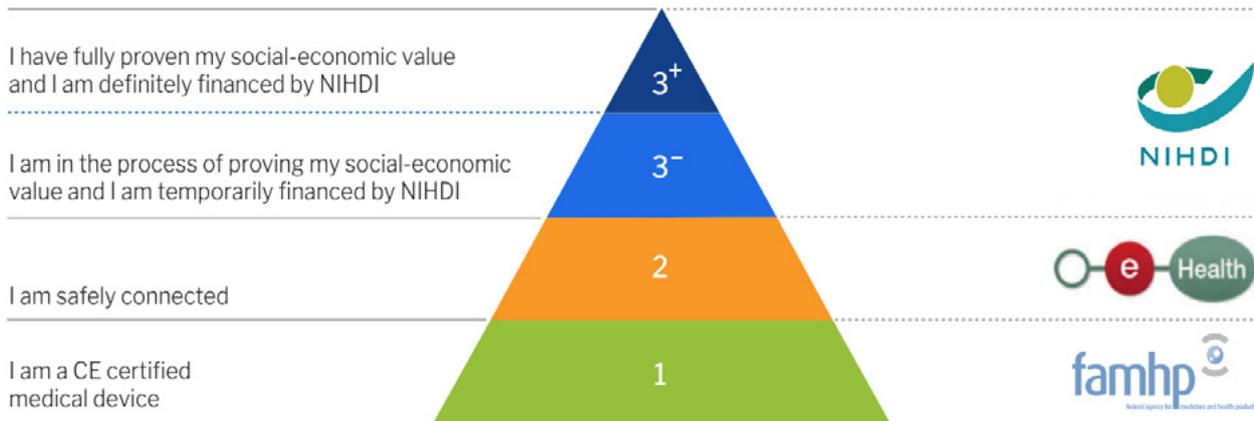
The Belgian healthcare authorities created the mHealthBelgium validation pyramid for mobile health applications, consisting of 3 levels and being the unique path towards national reimbursement for the use of such digital tools within a care path. Some DTx applications are mobile health applications and hence fit within the pyramid, but other DTx do not fit in this framework.

Nevertheless, the same criteria (namely compliance to MDR and GDPR in level M1, ICT criteria for safe communication and connectivity in level M2, evidence for reimbursement in level M3) are perfectly applicable for all DTx. Consequently, beMedTech is calling to apply the mHealthBelgium pyramid framework for more than pure mhealth applications, but embrace all DTx applications used by patients.

2. Rule 11 from the Annex VIII of the MDR states the following:

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
- a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb



ADOPTION AND FINANCING OF DTx APPLICATIONS



The breakthrough of innovative DTx will strongly depend on its fit in the current healthcare supply landscape. This requires integration within the clinical or therapeutic pathway on the one hand and appropriate financing on the other hand.

Both are of course directly interrelated. Integration of DTx in the corresponding pathway (existing or new to be created) is key to guarantee a smooth therapeutic workflow for patients and caregivers. Rethinking the financing of such pathway is crucial to accelerate adoption and

incentivize the possible use of DTx, rewarding the value they bring, ranging from improved quality of care and of life, to more personalized therapeutic approaches and healthcare savings.

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Given the nature of MDSW - software is by definition rapidly evolving - , one cannot apply the classical HTA (Health Technology Assessment) principles requiring large-scale evidence. Therefore, being on the market and having temporarily reimbursement would allow the collection of all required evidence about the true effectiveness and short-term impact. Moreover, the post-market surveillance, anyway now required under MDR, will also provide significant information on the acceptance, therapy compliance and real added value on the long term.

Government initiatives should be taken to stimulate the adoption of DTx in the healthcare system. In Germany, for example, the adoption of DTx has been stimulated through the provisional approval and reimbursement within the fast track of the DiGA framework (Digital Care Act), a mechanism that has been copied by France. In USA, the Breakthrough Devices Program and the Safer Technology Program (STeP) have given accelerated access to market for DTx applications.

Government initiatives should be taken to stimulate the adoption of DTx in the healthcare system.

In March 2022, 31 DTx applications has been reimbursed under the DiGA framework (include here reference to https://www.bfarm.de/EN/Medical-devices/Tasks/Digital-Health-Applications/_node.html via footnote), either for provisional or final listing. Oppositely, in Belgium there is only 1 application temporarily reimbursed while the mHealthBelgium framework already exists for a longer time.

CALL TO ACTION

MISSION FOR THE HEALTH COMMUNITY

Accessibility to care is a fundamental right for patients and important for better therapy adoption. Digital Therapeutics create a strong patient engagement and aim to make patients responsible actors in a strong therapy compliance for their acute care or chronic therapy.

DTx also entail the potential of better therapy compliance because of its continuous availability and because it provides informed therapeutic insights to the health care professional. All of this results in more efficient use of healthcare professional time and resources, thus creating a hybrid form of therapy. Adopting DTx into standard of care will make care more affordable with promise for improved long-term outcome.

Investing in Digital Therapeutics is investing in accessible and affordable care with better health management.

MISSION FOR THE POLICY MAKERS

beMedTech calls upon the Belgian federal government, the National Institute for Health and Disability Insurance (NIHDI) and other competent authorities to enable such easy and fast access to DTx applications through adequate innovation funding. A 'Fast Track to Funding' would accelerate adoption and offer healthcare providers the capability to use the full potential of DTx in standard care. Solid DTx frameworks are already in place in neighboring countries, Germany and France, so comparable modus could be introduced to follow those leading European countries.

beMedTech is calling the policy makers to enable easy and fast access to Dtx applications through adequate innovation funding.



The time to adopt Digital Therapeutics is now . beMedTech calls the health community and the policy makers in stimulating access and use of DTx through awareness creation and fast access to appropriate public funding.



The beMedTech Section Digital Therapeutics represents 9 companies, ranging from Belgian start-ups and scale-ups where digital health is the core business to multinational MedTech companies offering such digital applications as an additional tool in their broad product portfolio.



LEGAL DISCLAIMER:

The listed examples are purely illustrative of what is currently already available, without being exhaustive.. As a federation, beMedTech therefore does not guarantee the efficiency of the above-mentioned applications. "