

CAN YOU TRANSFORM ...

# Digital Therapeutics?

How can we harness the power of digital solutions to help  
EU citizens lead longer, healthier lives?



**EIT Health will award 2€  
million to the best proposal  
offering evidence-based,  
software generated solutions  
to prevent, manage or treat  
medical disorders or diseases**

- Although a relatively new field in healthcare, **DTx hold the promise of revolutionizing current medical practice.**
- **Traditional medicine has failed to provide fully effective treatments** in several therapeutic areas.
- Current medicine practice has been tailored towards **a reactive rather than preventive approach.**
- The world is getting older and therefore **providing sustainable and long-term care for elderly is becoming one of the most crucial healthcare challenges** of our time.
- **Technology is progressing far quicker than guidance and requirements** for obtaining regulatory approval for clinical use.



## 1. Background information

Digital therapeutics (DTx), defined by the Digital Therapeutics' Alliance (DTA) as “delivering evidence-based therapeutic interventions to patients that are driven by high quality software programs to prevent, manage or treat a medical disorder or disease. They are used independently or in concert with medications, devices or other therapies to optimize patient care and health outcomes.” While part of the larger sector of digital health, DTx are not to be mistaken with the vast amount of digital health and wellness technologies out there such as step trackers, sleep monitors or diet apps. DTx must undergo clinical studies, acquire approval and show distinct measurable health benefits in order to be launched into the market.

**Although a relatively new field in healthcare, DTx hold the promise of revolutionizing current medical practice as it has potential to benefit all stakeholders:**

- From the patients' point of view, DTx increase access to safe and effective therapies, provides personalized care based on the patients' needs and abilities and enables remote access to care, reducing the need for hospital visits.

- For physicians, DTx provide data on patient engagement and response to therapy, and effective self-management therapeutic options.
- Finally, from the payors point of view, DTx improve clinical and health economic outcomes on a wide range of disorders and diseases while increasing patient population access to treatments and reducing overall costs.





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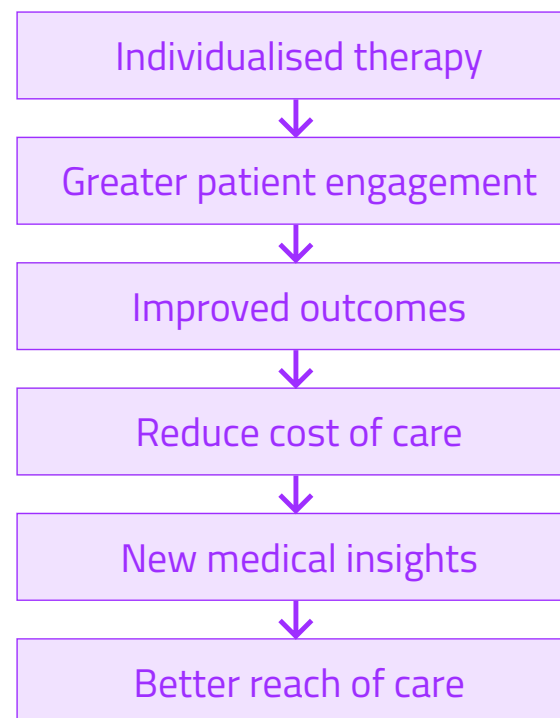


### 1. Background information

Overall DTx provide all partakers of the healthcare ecosystem with tools that enable data driven interventions throughout several therapeutic areas. Key representative DTx interventions, as identified by DTA, on the market or under development, include:

- Combined software and hardware program to improve asthma and COPD control and optimized healthcare utilization.
- Digital therapeutic utilizing adaptive sensory stimulus software for the treatment of ADHD, delivered through an engaging videogame experience.
- AI-based diagnostics and personalized therapeutics for paediatric behavioural healthcare.

### MAIN BENEFITS OF DTx\*



\*Source: IBM mini pulse survey of healthcare and life sciences professionals in Europe and the US.



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### 2. Opportunities

Patients living with a condition receive different courses of treatment based on the information gathered by medical professionals on limited clinical visits and from patient's accounts of symptoms, over a long period of time.

DTx provide the means to collect large amounts of information cost-efficiently, which can aid clinical decision making, regulate medication dosage and ensure patient treatment compliance.

DTx characteristics are making them very valuable options in areas that are poorly addressed by the healthcare system today such as chronic diseases and cognitive, mental and neurodegenerative disorders. For example, the use of DTx in chronic diseases aims to improve patient's engagement, medication adherence and increased monitoring, as well as providing preventive measures and individualized therapy. In addition, app-based solutions have proved their effectiveness as a therapeutic option for some mental health disorders such as drug addiction, insomnia or depression.

On the other hand, DTx have great potential as companions

of traditional drug treatments, where the possibilities are endless. For instance, DTx could provide pharma companies with data that goes far beyond clinical trials; which can be used to improve treatments, be offered as a medication monitoring tool that can help doctors make better decisions particularly useful in complicated cases or even as a guidance tool for patients to increase engagement and medication adherence.

## All in all, DTx could be a gateway to a new era of augmented medication.

Over the last few years, the exponential decrease in computational cost, better access to healthcare data and improvement of the quality and decrease in cost of sensor technology are enabling the incursion of DTx into medical practice. This coupled with initial regulatory interventions are building blocks for a value based, patient-centred standard of care.



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### 3. Current challenges

The world is getting older and therefore providing sustainable and long-term care for elderly is becoming one of the most crucial healthcare challenges of our time. Even though DTx hold enormous potential to improve health outcomes in a cost-effective manner, the incorporation of DTx in clinical practice will face various challenges.

First and foremost - the regulation. Technology is progressing far quicker than guidance and requirements for obtaining regulatory approval for clinical use. DTx pose specific challenges in the regulatory field due to the dynamic and ever learning nature of their therapeutic options.

Second, there are challenges around data gathering and data sharing including ethics, security and public perception.

DTx interventions must ensure an ethical and safe use of patients' health data.

Third, the proof of delivered value and cost reduction is paramount for payors. As for any disruptive therapy the path for reimbursement will be arduous. In addition, the cross-industry nature of DTx may require new innovative reimbursement models.

Finally, the integration of any data stream, particularly new data streams, into clinical workflows or with other technologies poses special challenges. Current electronic health record systems, which are not designed to easily capture or report provider-recorded outcomes, are not well positioned to accept diverse data from different devices and applications.

## SOLUTION

The proposed solution must solve an unmet need on one or more of the stages of a patient's journey



Preventive  
Care



Diagnosis and  
Prescription



New Therapeutic  
Solutions



Care  
Management



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### 4. Areas of intervention

IN ORDER TO ADDRESS CHALLENGES LISTED ABOVE, AMONG OTHERS, EIT HEALTH WOULD LIKE TO SEE SOLUTIONS FOCUSING ON ONE OF THE TOPICS OUTLINED BELOW:

#### Preventive care

DTx could significantly help in bringing healthcare from a reactive towards a more preventive approach. Digital solutions will not only be able to explain diseases better but more and more data will be available to analyse what healthy and normal states mean and to predict future health outcomes.

Furthermore, the ability to identify individuals at risk of developing an illness opens the path for possible intervention that could change disease progression before symptoms deteriorate, reducing long term cost for payors and significantly improving patient's health outcomes. EIT Health is looking for digital solutions that enable lifestyle behaviour changes in patients which will lead to clinically validated outcomes.

#### Diagnosis and prescription

Early diagnosis and detection of disease has been proven to significantly improve patient's health outcomes. Harnessing the power of digital and sensor technology can provide diagnostic information to aid healthcare professionals in making decisions on treatment that improves clinical outcomes. EIT Health is looking for solutions that will enable seamless gathering of patient's biomarkers and processing obtained data to give recommendations on the course of action to patients and healthcare professionals.



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## 4. Areas of intervention

### New therapeutic solutions

Traditional medicine has failed to provide fully effective treatments in several therapeutic areas such as rheumatology, musculoskeletal disease, pain management and chronic respiratory disease among others. As well as to ensure patient compliance especially in disorders in which treatment requires complex patient interaction, such as diabetes, in which patients must calculate the correct dosage of insulin. Moreover, in certain therapeutic areas like mental health current treatments create dependencies and have other undesired side effects. In order to improve patient's health outcomes, reduce side effects and increase treatment compliance, EIT Health is looking for DTx that act as a stand-alone treatment or complement existing treatments with potential to improve clinical outcomes.

### Care management

Current medicine practice has been tailored towards a reactive approach in which the healthcare system waits for a person to fall sick to administer treatment. This approach has been proven to be highly effective in treating acute illnesses which tend to be short lived, easily diagnosed and have a clear treatment. However, with the increase of life expectancy, it is calculated that 50% of the global burden of disease is due to chronic illnesses which are long lasting and therefore require a more proactive, patient-centred, frequent and continued care. Unfortunately, under current standard of care monitoring of chronic diseases is expensive, insufficient, require patient mobility and is sometimes inadequate. For that reason, EIT Health is looking for DTx that will enable patients and healthcare providers to continually optimize treatment of chronic conditions in a cost-effective, integrated way.





## 4. Areas of intervention

### New technology-driven interventions

Whether used as a standalone solution or as a complement to current medical practice in all different stages of a patient's healthcare journey DTx can harness new technologies to offer solutions that were simply not an option before. In order to leverage new technologies as

pathways for delivering digital medicine interventions with a direct impact on a disease, EIT Health is looking for DTx interventions that use new technologies such as, but not limited to:

<b>Virtual and Augmented Reality (VR/AR)</b>	Using computer-generated simulation of a real-life environment (VR) or enhancement atop of an existing reality (AR) to provide distinct and measurable improvements on clinical outcomes. Some examples of VR and AR already used as DTx are products to treat substance abuse disorders, gaming therapeutics to treat cognitive impairment and guiding solutions to improve outcomes on surgical procedures.
<b>Machine Learning (ML) and Artificial Intelligence (AI)</b>	Using ML and AI as digital therapeutics has enormous potential to improve clinical outcomes, however it also has its challenges. For ML and AI to be deemed reliable as DTx, the algorithms must be based on good quality data to ensure meaningful results, use statistically meaningful data sets so results can be reproducible, and have some transparency in the algorithms to ensure trust. Examples of the use of ML and AI as DTx include platforms to provide personalized mental healthcare treatments, improve medication adherence and provide personalized medication dosage among others.







## 4. Areas of intervention

### NEW TECHNOLOGY-DRIVEN INTERVENTIONS

<b>Internet of Things (IoT)</b>	IoT refers to the connection of devices to the Internet and to other connected devices. All these devices collect and share data about the way they are used and their environment. IoTs play a key role in DTx delivering data-driven solutions. Some examples of IoTs used as part of DTx are tracking devices used as part of behavioural intervention therapies and sensors that generate reports on medication usage that improve compliance.
<b>New sensor technologies</b>	In order to provide fully holistic data-driven interventions collection and gathering of reliable data is paramount. Because of this new, smaller, comfortable to use, long lasting and safe sensors could enable the development of highly reliable DTx solutions. For example, drug companion sensors that can assess the effectiveness of such drug and therefore be part of a DTx solution that uses that information to improve disease treatment.

All in all, the use of the aforementioned technologies by themselves do not constitute a DTx solution, however they do enable acquisition, processing and display of relevant medical data which is key for the delivery of patient-centred, value-based, data-driven therapeutic solutions.





## 4. Areas of intervention

### Cost-effective interventions

On a survey of healthcare and life sciences professionals in Europe and the US conducted by IBM, 43% of the surveyed professionals named reduced cost of care as one of the main benefits that will be realized by implementation of DTx into healthcare practice. DTx hold the promise of improving patient's health outcomes while lowering the economic burden of disease by reducing direct medical expenses via for example, helping patients adopt healthier behaviours, reducing hospital visits, increasing medication adherence or even substituting drug treatments. Thus, EIT Health is looking for therapeutic interventions that prove to reduce healthcare costs while improving health outcomes.

#### THE MAIN REQUIREMENTS



Software at the centre



Measureable clinical benefit



Cost efficient



Attractive to HCPs and patients





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### 5. Why is this a Wild Card challenge?

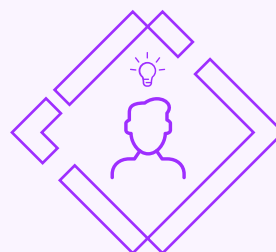
The use of DTx holds potential for a significant leap forward in clinical practice, however intrinsic characteristics of DTx call for collaboration of different domain industry players, such as pharma and digital health companies. As a pan-European network of relevant stakeholders, collaborating closely with each other, EIT Health is well positioned to accelerate the growth of a start-up targeting implementation of DTx in standard clinical practice and to scale-up of the solution across European markets.



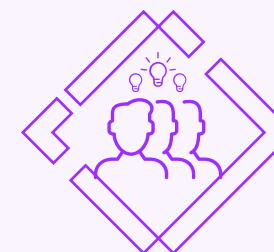
### WHO CAN PARTICIPATE?



Individuals with  
expertise / interest in DTx



Individuals with a  
proposed solution



Teams of 2-3 people  
with a proposed solution

All applicants must be in the EU or in Horizon 2020 associated countries



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