June 2023

DIGITAL THERAPEUTICS POLICY REPORT

DTx policy pathways: the evolving scenario in Europe

Landscape Analysis & Converging Trends

Enhancing equitable access to digital healthcare

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This **Digital Therapeutics (DTx) Policy Report** stems from the partnership between the **Digital Therapeutics Alliance** (DTA) and **Healthware** to support the development of ecosystems that enable equitable patient, caregiver, and clinician access to safe and effective DTx products globally. This DTx Policy Report specifically aims to provide clarity on and inform the development of **adequate and enabling policies** for **Digital Medical Devices** and, specifically, DTx to drive **equitable access** to digital health care for all.

Authors:

Alberta Spreafico, *Managing Director Digital Health & Innovation, Healthware Group*

Megan Coder, *Chief Policy Officer & Founder, Digital Therapeutics Alliance*

Valeria Boccardo, *Digital Health, Value & Access Analyst, Healthware Group*

Emilie Lopes-Fernandes, *Program Lead, Digital Therapeutics Alliance*

Kristin Milburn, *Chief Marketing Officer & Managing Director Publications & Digital Health Ecosystem, Healthware Group*

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*In alphabetical order

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About us

Healthware

Healthware Group is a full-service agency and innovation consultancy, founded by digital health pioneer Roberto Ascione, providing marketing, advisory, customer engagement and media services, medical communications and education, and advanced technology capabilities.

Leveraging +20 years of digital health heritage and thought leadership, Healthware's dedicated Digital Health & Innovation division is a leading think tank, advisory and commercialization partner for digital medicines. Through its unique knowledge of the evolving scenario, interdisciplinary expertise, digital medicines Actionable Insights Database (AID) and ecosystem partnerships, it offers end-to-end support to ideate, scout, develop, validate, and especially launch and enable equitable access to and systemic adoption of digital medicines.

The media and community division offers premium content and platforms to gather insights, foster thought leadership, enable market shaping and create connections. Healthware Group has co-hosted and produced the premier global digital health conference, Frontiers Health, for nearly a decade.

With a team of 200+ professionals in Salerno, London, New York, Milan, Rome, Helsinki, and a joint venture with EVERSANA INTOUCH, Healthware Group has a combined reach of 2000+ people in over 15 offices across Europe, the US, and Asia. Additionally, the Healthware Global Network, one of the largest international networks of independent healthcare agencies, provides deep local expertise in over 25 countries.

Digital Therapeutics Alliance

Digital Therapeutics Alliance (DTA) is a global non-profit trade association of industry leaders and stakeholders with the mission of broadening the understanding, adoption, and integration of digital therapeutics into healthcare. DTA works to enable expanded access to high quality, evidence-based digital therapeutics for patients, clinicians, and payors to improve clinical and health economic outcomes. Founded in 2017, the Digital Therapeutics Alliance is a 501(c)(6) non-profit trade association of industry leaders and stakeholders engaged in the evidence-driven advancement of digital therapeutics.
As the leading international organization on digital therapeutic thought leadership and education, the Digital Therapeutics Alliance provides patients, clinicians, payors, and policymakers with the necessary tools to define, evaluate, and utilize DTx products.

DTA is mission driven to advance digital therapeutics globally by:

- Establishing the formal definition of a digital therapeutic and core principles to which all DTx products must adhere;
- Enabling clinicians and decision makers to adopt and integrate DTx products into healthcare to improve patient and population clinical and economic outcomes;
- Assisting policymakers as they work to recognize digital therapeutics within national and regional regulatory frameworks;
- Educating end users about DTx products and their short- and long-term value;
- Collaborating with DTA member companies and ecosystem stakeholders to optimize industry impact.

In June 2022, the Digital Therapeutics Alliance (DTA) and Healthware launched a Digital Therapeutics (DTx) Policy Coalition to support the development of ecosystems that enable equitable patient, caregiver, and clinician access to safe and effective DTx products globally.

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Contents

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Forward

In June 2022, the Digital Therapeutics Alliance (DTA) and Healthware launched a Digital Therapeutics (DTx) Policy Coalition to support the development of ecosystems that enable equitable patient, caregiver, and clinician access to safe and effective DTx products globally.

Aim & Mission. As a first step toward discussing and developing harmonised pathways for DTx recognition and scalability at the local, national, and regional levels, representatives from across Europe, Australia, and North America participated in the initial phase of this Coalition. Defining adequate appraisal criteria and access policies, while retaining local decision-making capabilities, is fundamental for appropriate, equitable, and systemic access to DTx.

Current Environment. The DTx policy scenario is rapidly evolving worldwide and national authorities are increasingly developing or refining fit-for-purpose appraisal criteria and access policies for DTx and the broader Digital Medical Device (DMD) category. However, without a harmonised globally recognized framework to build from, disparate national frameworks continue to emerge, resulting in a patchwork of fragmented policy frameworks that ultimately limits equitable and timely access to therapies within and across national jurisdictions.

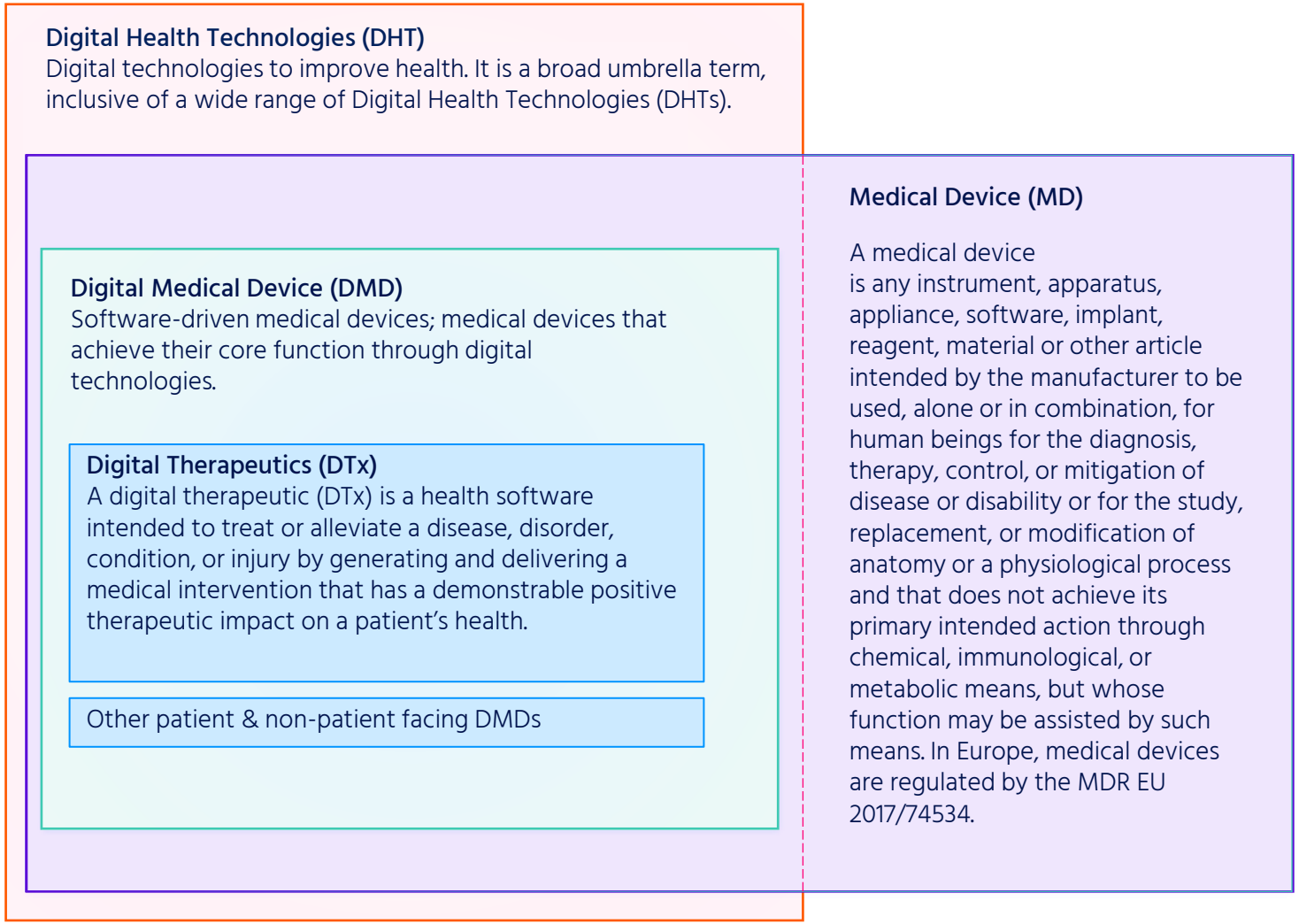
European Policy Report. The scope of this initiative is global, with this first DTx Policy Report focusing on Europe to:

- Provide clarity on existing and evolving policy frameworks;
- Map fit-for-purpose appraisal criteria being applied in countries with formal frameworks in place, analyzing requirements through the common lens of the Health Technology Assessment (HTA) Core Model®;
- Identify converging trends to inform areas of potential harmonization and scalability across Europe and globally.

DTA and Healthware are launching www.dtxpolicylandscape.org as a resource for ecosystem stakeholders, policymakers, and payors to engage, identify harmonizable standards, and scale best practices to enable the development of sound and enabling policies. Join our effort to deliver scalable, equitable digital healthcare to patients globally!

***Megan Coder**, Chief Policy Officer, Digital Therapeutics Alliance & **Alberta Spreafico**, Managing Director Digital Health & Innovation, Healthware*

Technologies in focus: DTx and Digital Medical Devices



- Digital health is the field of knowledge and practice associated with the development and use of digital technologies to improve health. It is a broad umbrella term, inclusive of a wide range of Digital Health Technologies (DHTs).
- The emerging definition of Digital Medical Devices (DMDs) is considered to be a subset of DHTs, referring to certified medical devices that are software-driven and achieve their core function through digital technologies.
- DMDs, as medical devices, are certified according to local regulations. In Europe, medical devices are regulated by the MDR EU 2017/74534.
- DTx are a subset of DMDs, which is a subset of DHTs.
- A **digital therapeutic** (DTx) is a health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health.

- This report primarily focuses on DMDs and DTx.

Note: refer to glossary for the definition of a medical device according to the MDR EU 2017/7453

Medical Device (MD) according the definition of local regulations*.

*Boxes representing each industry categorization do not correlate to the size of the ecosystem they represent.

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Methodological Insights: A common assessment framework

Multistakeholder engagement and expertise:

This DTx Policy Report is the result of:

- **Semi-structured interviews** with multistakeholder experts across a pool of countries in the European geographical region.
- **In-depth knowledge** and expertise from DTA and Healthware.

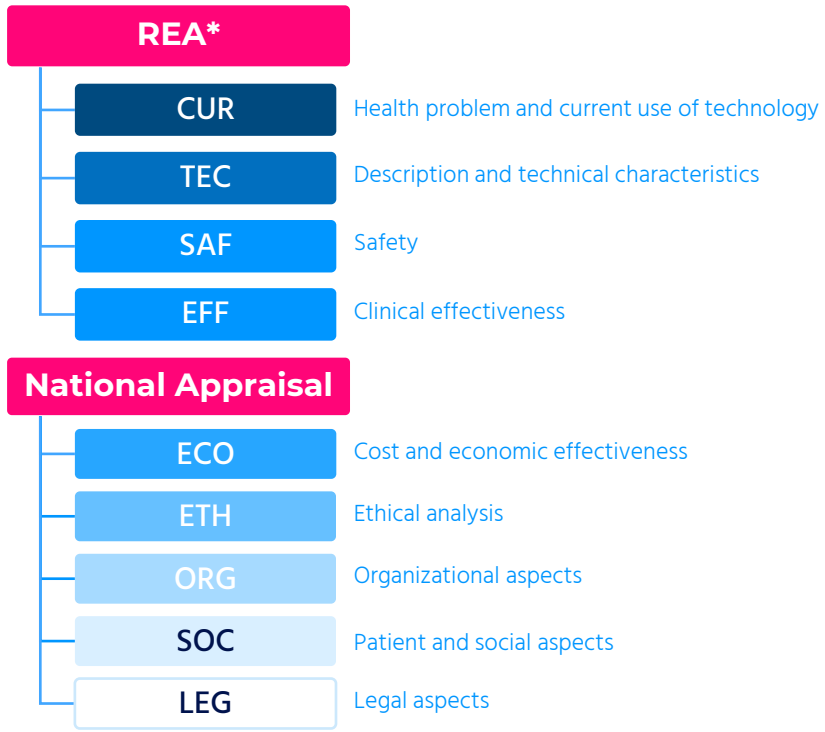
Current and evolving landscape:

- The DMD/DTx Policy scenario is currently evolving, with an increasing number of countries in the process of defining or reviewing appraisal and access criteria.
- We analyzed **existing frameworks** and integrated insights on **emerging trends**.
- Given the dynamic scenario, a snap-shot fixed in time would not provide comprehensive information. We will also regularly update the Report, to monitor and contribute to the evolving scenario.

Understanding DMD/DTx appraisal criteria through a common HTA framework:

- For countries with formal appraisal criteria and access policies for DMD/DTx in place, we **mapped fit-for-purpose requirements**.
- Appraisal criteria were categorized applying the **common "lens" of the HTA Core Model®** to identify areas of converging standards and inform dialogues on potential areas of harmonization and joint evaluation.

HTA Core Model® 9 Key Dimensions



The HTA Core Model®, developed by the European Network for Health Technology Assessment, provides a **standardized framework for conducting HTAs** across different European countries. It is intended to improve efficiency and consistency of HTA processes, and it is **already utilized to support decisions on which technologies should be reimbursed**.

*REA: Rapid relative Effectiveness Assessment

Evolving DTx Policy Landscape and Fit-for-Purpose Appraisal Criteria

- EU-4+England (UK)
  - Formal Existing Frameworks for DMD/DTx: Germany, France, England
  - Emerging Frameworks: Italy, Catalonia (Spain)

DMD & DTx policy overview

EU-4 + England (UK): Formal Frameworks for DMD/DTx

	Germany		France	England	
	Current scenario	Evolving insights	Current & Evolving scenario	Current scenario	Evolving insights
Classification	**DiGA:** Certified Medical Device (risk class I or IIa) digital-driven; patient-led; not focused on primary prevention	**DiGA** expected to include also: Medical Device up to risk-class IIb; telemedicine services with involvement of HCPs	**DMN**: Digital Medical Device (Dispositif Médical Numérique) with therapeutic or telemonitoring purposes.	**DHT:** DTx are a subset of the broader DHT category. DTx as **Tier C DHT**, which usually require being certified as a Medical Device.	
Fit-for-Purpose Appraisal Criteria	Defined specific appraisal/HTA criteria for the digital nature of DMD/DTx.		Defined specific appraisal/HTA criteria for the digital nature of DMD/DTx differentiated for therapeutic DMN vs. telemonitoring	Defined specific appraisal/HTA criteria for the digital nature of DMD/DTx.	
Reimbursement	Permanent or temporary listing and reimbursement through statutory health insurance		5-year national listing and reimbursement; renewable. Pathways differentiated for DMN with therapeutic purposes (regular medical device pathway) vs. telemonitoring.	Sub-national, local NHS organizations decide on P&R.	Potential pricing indications to be informed/suggested nationally
Early Access Pathway / Fast Track	**DiGA Fast-Track** 12-months temporary reimbursement if compliant with quality, security and interoperability pre-requisites		**PECAN**: 6 months temporary listing for DTx; 9 months for telemonitoring device. Then application to their regular pathways. [launched in Q2-2023]	**Early Value Assessment** (EVA) for MedTech pathways	
Pricing	Price set by manufacturer for the first 12-month; renegotiated with National Association of Statutory Health Insurance Funds (GKV-SV)		Pricing during PECAN: - Telemonitoring: flat-rate then renegotiated - DTx: *forthcoming*	Sub-national, local NHS organizations decide on P&R.	Potential pricing indications to be informed/suggested nationally
Agency of Reference	Federal Institute for Drugs and Medical Devices (BfArM)		Haute Autorité de la Santé (HAS)	MHRA, NHS, NICE	

Source: Healthware, Digital Medicines Actionable Insights Database (AID), last updated 1° June 2023 c

Germany Digital Health Applications (DiGA)
DMDs & DTx: Policy Overview

DMD/DTx

Current scenario

- **Digital Healthcare Act (2019):** specific ordinance (**DiGAV**) outlining the procedures and requirements for evaluating and reimbursing **Digital Health Applications** (Digitalen Gesundheitsanwendungen, **DiGA**).
- **DiGA defined as:**
  - CE-marked Medical Device, risk class I or IIa
  - Main function based on digital technologies
  - Medical purpose mainly achieved by way of its digital function
  - Supports the recognition, monitoring, treatment or alleviation of diseases or the recognition, treatment or alleviation or mitigation of injuries or disabilities. It does not serve primary prevention
  - Used only by the patient or by the patient and the HCP (not by HCP alone).
- **Permanent listing and reimbursement:** if technological, safety, interoperability, and functional pre-requisites and proof of clinical efficacy standards are met.
- **Fast-track process:** DiGA that meet pre-requisites are listed and reimbursed for 12-months conditionally on generating sufficient proof of clinical efficacy.
- **Appraisal process:** overseen by BfArM.
- **P&R:** price set by manufacturer for the first 12-month, then renegotiated with GKV-SV. Funding provided through statutory health insurance (GKB), covering 85% of the population.

Evolving scenario

BfArM's new **Healthcare Digitalization Strategy**, outlines 3 main goals:

- Consistent focus on people, patient sovereignty and activation
- Improving quality of care
- Increased cost-effectiveness and efficiency

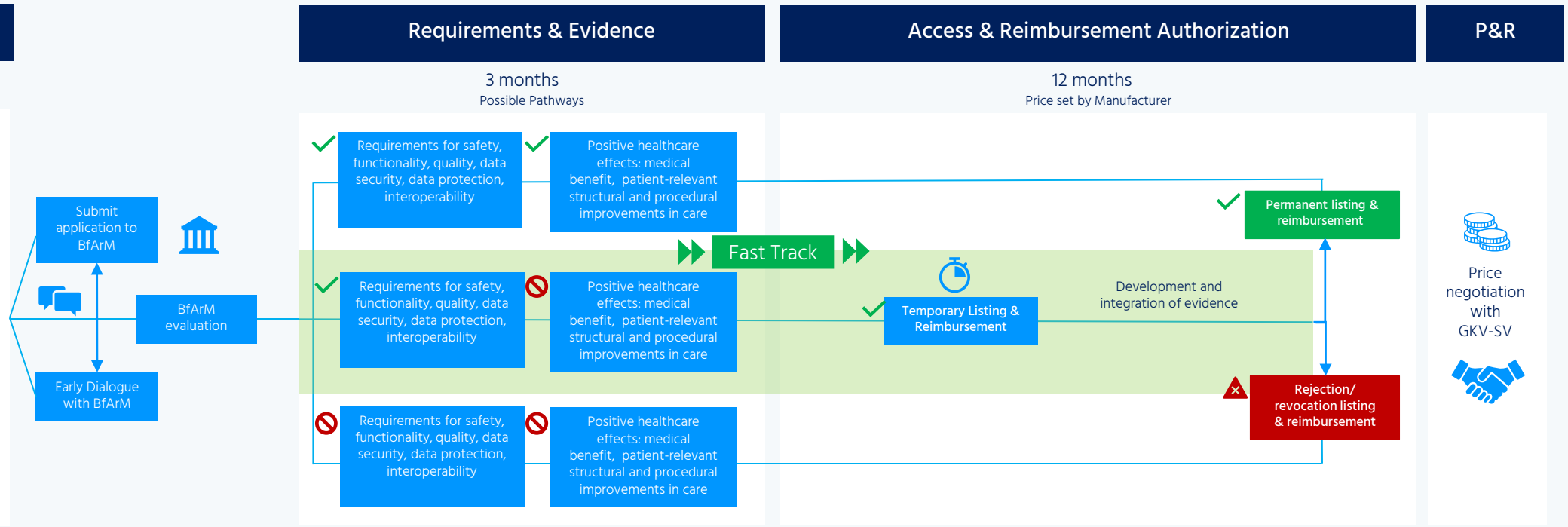
Updates for access and reimbursement pathways for DIGA, and nursing digital applications (DIPA), include:

- **Expanded classification of a DiGA** to include certified Medical Device up to class IIb and telemedicine services with HCPs
- DiGA and DiPA to become integral components of **digitally supported care pathways**
- **Accessibility** to DiGA through **Electronic Health Records**
- Consolidate and further develop the **Innovation Fund**
- **End-users** to be engaged early-on in DiGA development and validation
- **BfArM** remains the regulatory agency of reference. A **Digital Health Agency** may also be established, mostly focused on ICT system infrastructure.

Note: P&R stands for Pricing and Reimbursement

DiGA Value Assessment & Access Pathway

DMDs & DTx: Policy Overview



Type of HTA dimensions considered

Technical Characteristics (TEC)	Technical Characteristics (TEC)	Clinical Effectiveness (EFF)	Clinical Effectiveness (EFF)
Safety (SAF)	Safety (SAF)	Organizational Aspects (ORG)	Organizational Aspects (ORG)
Legal Aspects (LEG)	Patients & Social Aspects (SOC)	Current Use (CUR)	Current Use (CUR)
			Cost and economic effectiveness (ECO)

Source: Healthware, Digital Medicines Actionable Insights Database (AID); Bfarm, last updated 1° June 2023

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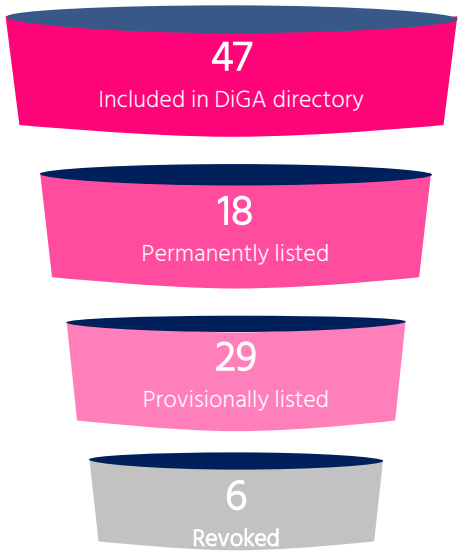
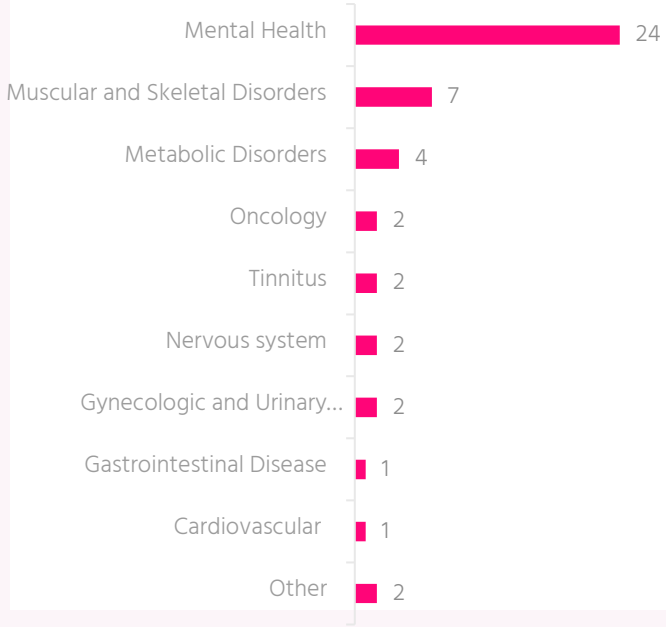
DiGA Highlights

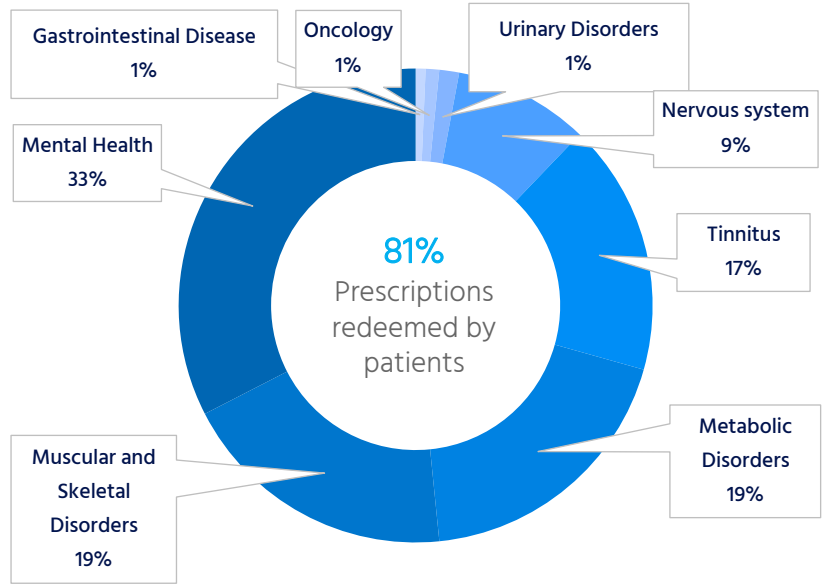
DiGA by listing and reimbursement status
(absolute number, May 2023)



DiGA by Therapeutic Area Targeted
(absolute number, May 2023)



DiGA prescriptions redeemed by patients
(% per therapeutic areas, September 2022)



- DiGA uptake
  - 47 DIGA listed in the DiGA directory in June 2023: 18 permanently listed and 29 temporary listed, 6 revoked (mostly due to insufficient proof of clinical value).
  - Listed DiGA address diverse therapeutic areas, although nearly half target mental health disorders.
  - DiGA prescriptions tripled from 2021 (50,1k) to 2022 (152,9k) and 81% of patients redeemed prescription codes to activate DiGAs.
  - Targeted strategies are still needed to increase awareness and systemic adoption, but uptake is growing.

- DiGA pricing
  - DiGA are reimbursed for a median price of nearly €500,00, although diverse license types exist – ranging from 1-time licence to 90-days.
  - Total expenditure for DiGA reimbursement reached €55.5 mln in September 2022, tripling from Sept. 2020.

Source: Healthware, Digital Medicines Actionable Insights Database (AID); Bfarm and GKV, last updated 1° June 2023

Listed DiGA examples

3 manufacturers currently provide 40% of listed DiGA

	Name of Listed DiGA	Target Indication as per DiGA Directory	Provisional reimbursement	Price (€) year 1 (set by manufacturer) and License Type	Permanent reimbursement	Re-negotiated price (€) and License Type
GAIA 7/47	Priovi - digital support for borderline treatment	Emotionally Unstable Personality Disorder: Borderline Type	✓	855,82 - One-Time License		
	Levidex	Psychological support in Multiple sclerosis [Encephalomyelitis disseminata]	✓	2077,40 - One time license		
	Optimune	Psychological support for patients with malignant neoplasm of the mammary gland	✓	952,00 - ninety days		
	Vorvida	Harmful alcohol consumption or alcohol dependence			✓	292,01 - ninety days
	Deprexis	Mild depressive episode; Moderate depressive episode; Severe depressive episode without psychotic symptoms; Recurrent depressive disorder, present mild episode; Recurrent depressive disorder, present moderate episode; Recurrent depressive disorder, currently severe episode			✓	210,00 - ninety days
	Elevida	Fatigue in multiple sclerosis			✓	243.00 - ninety days
	Velibra	Agoraphobia: With panic disorder; Social phobias; Panic disorder [episodic paroxysmal anxiety]; Generalized anxiety disorder			✓	230.00 - ninety days
HelloBetter 6/47	HelloBetter Sleep	Non-organic insomnia; Difficulty falling asleep and staying asleep	✓	599,00 - ninety days		
	HelloBetter Panic	Agoraphobia: With panic disorder, Panic Disorder [episodic paroxysmal anxiety]			✓	230,00 - ninety days
	HelloBetter Vaginismus Plus	Non-organic vaginismus; Non-organic dyspareunia			✓	235,00 - ninety days
	HelloBetter Ratiopharm Chronic Pain	Persistent somatoform pain disorder; Chronic pain disorder with somatic and psychological factors - Back pain; Fibromyalgia R52.1 Chronic uncontrollable pain	✓	599,00 - ninety days		
	HelloBetter Diabetes and Depression	Depression comorbid with Diabetes mellitus type 1 and type 2			✓	222,99 - ninety days
	HelloBetter Stress and Burnout	Problems related to difficulties in coping with life			✓	235,00 - ninety days
Selfapy 5/47	Selfapy's online course for chronic pain	Persistent somatoform pain disorder; Chronic pain disorder with somatic and psychological factors; Backache	✓	540,00 - ninety days		
	Selfapy's Online Course at Bulimia Nervosa	Bulimia nervosa; Atypical bulimia nervosa	✓	540,00 - ninety days		
	Selfapy's Online Course for Binge Eating Disorder	Binge eating in other mental disorders, other eating disorders	✓	540,00 - ninety days		
	Selfapy's Online Course on Generalized Anxiety Disorder	Generalized Anxiety Disorder			✓	479,52 - ninety days
	Selfapy's Online Course on Depression	Depression			✓	217,18 - ninety days

Note: DiGA ordered by manufacturer and listing data, latest listing first.

Source: Healthware, Digital Medicines Actionable Insights Database (AID), Bfarm, last updated 1° June 2023

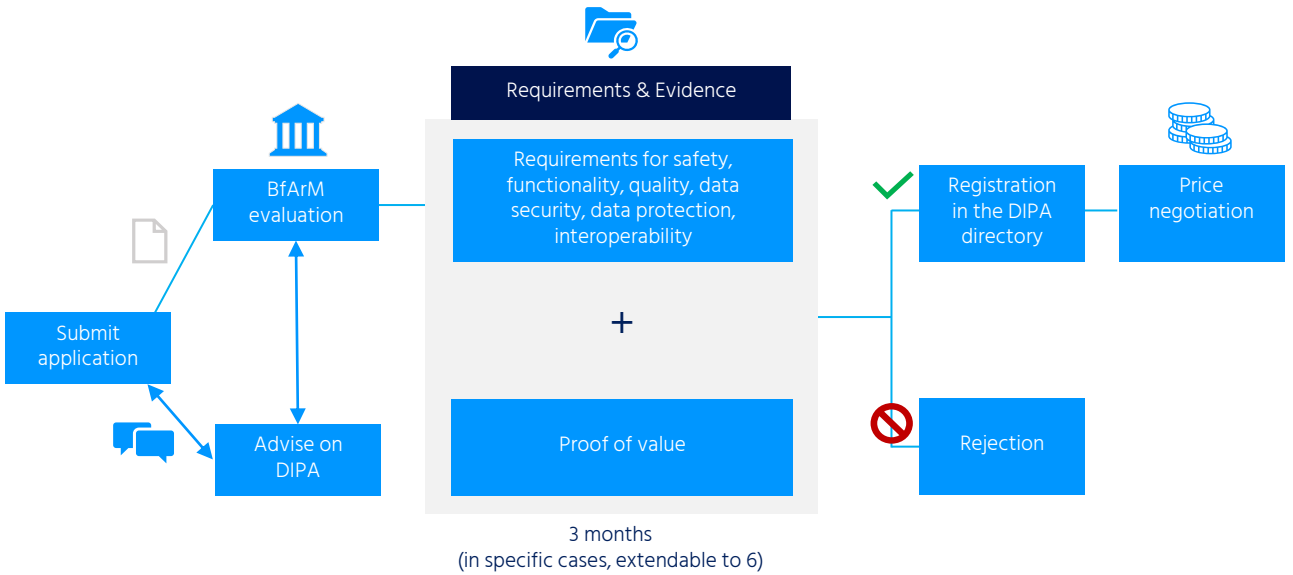
Digital Nursing Applications – DiPA

- In 2021, Germany defined a process to reimburse **Digital Nursing/ Assistance Applications** (DiPA) to enhance **homecare.**
- DiPA are **not meant to be prescribed** by HCPs. The person in need of care or an authorised representative/caregiver can apply for reimbursement.
- DiPA differ from a DIGA and are characterized by:
  - Can, but does not have to, be a certified Medical Device
  - Based on digital technologies
  - Serves the purpose of reducing an impairment
  - Can be used by those in need of care alone or in interaction with caregivers
  - Can also support caregivers specifically
  - Serves to support those in need of homecare

A DiPA does not:

- x Only read or control other device(s)
- x Primarily serve operational support of outpatient care
- x Primarily support general living or lifestyle needs, purely impart knowledge; or provide information and advice on the selection and use of welfare benefits and health services.

DiPA Value Assessment & Access Pathway



DIPA P&R considerations

Reimbursement for DIPA is set to a maximum cap per month. The individual bears additional costs beyond this reimbursement price cap.

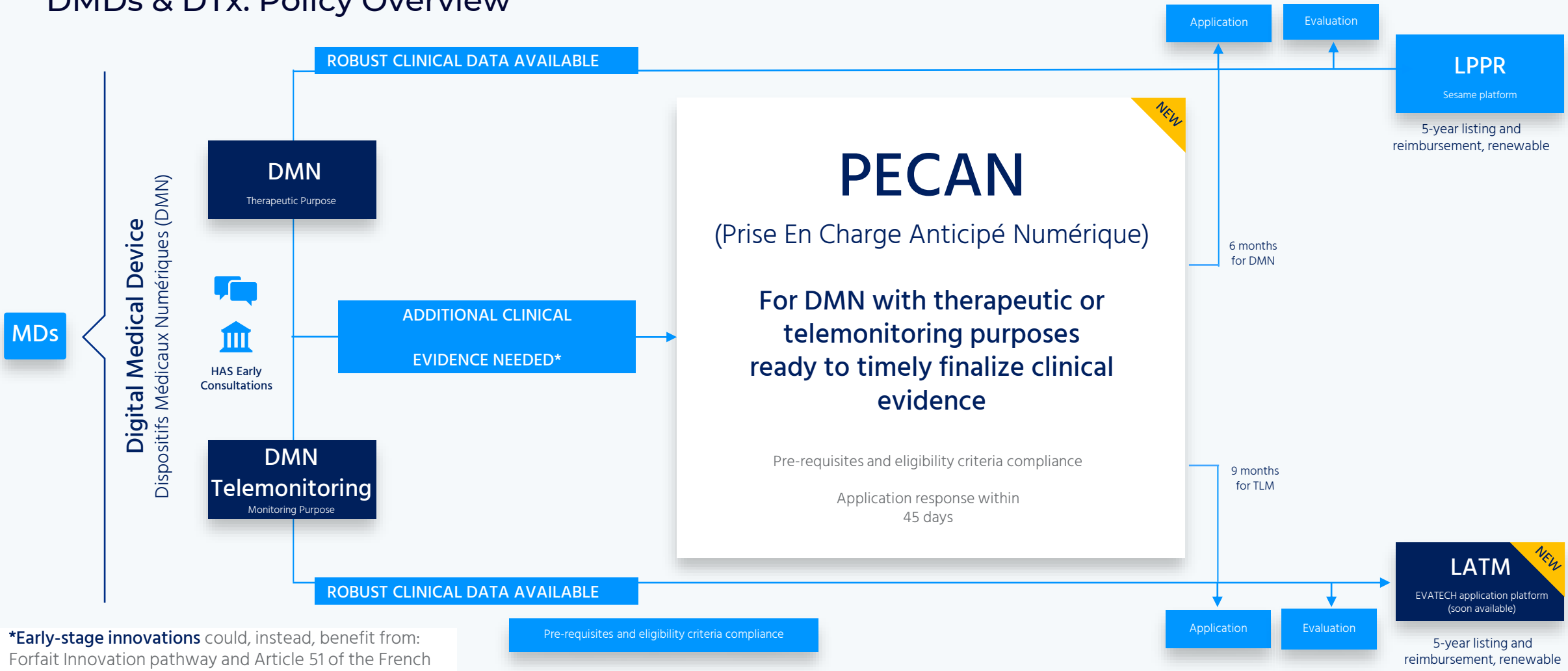
France Digital Medical Devices (DMN)

DMDs & DTx: Policy Overview

	Current scenario	Evolving scenario
DTx	In France, the scenario is evolving as we write! ▪ **Medical Device Pathway:** DTx can be appraised and made accessible through the ordinary Medical Device pathway (differentiated from the pathway for tele-monitoring devices). Medical Devices with a therapeutic intended purpose (DTx) that meet appraisal criteria are registered within the list of products and services qualifying for reimbursement (LPPR) for 5 years, with possibility of renewal. ▪ **Digital Medical Devices** (Dispositifs Médicaux Numériques, DMN): in March 2023, France formalized DMN as a sub-category of Medical Device. DMN are differentiated between DMN with a therapeutic intended use (as DTx), from those with (tele)monitoring purposes. ▪ **Early coverage pathway: PECAN** (Prise En Charge Anticipée Numérique): 6-months early coverage for DTx meeting pre-requisites, then application for regular LPPR listing. ▪ **HAS** is the institution of reference; the **CNEDiMTS** department evaluates medical and technical dossiers of medical devices; **ANS** and **CEPS** for P&R.	
Telemonitoring	▪ **ETAPES pilot program** (Expérimentation de Télémédecine pour l'Amélioration des Parcours en Santé, 2014 to 2021) allowed appraisal and reimbursement of selected telemonitoring solutions to enhance chronic disease management. Focused on: chronic respiratory failure, chronic heart failure, diabetes and chronic renal failure.	▪ **LATM listing:** a structural dedicated pathway for appraisal, access and reimbursement for Telemonitoring DMN was launched in Q1 2023 entailing 5-year listing and reimbursement. ▪ **PECAN** applicable to telemonitoring DMNs: early coverage for 9 months, then application for regular LATM listing.
Early-Stage Innovations	▪ **Forfait Innovation Funds:** for highly innovative solutions, targeting high-burden unmet needs and at an early stage of development.	

DMN Value Assessment & Access Pathway

DMDs & DTx: Policy Overview



***Early-stage innovations** could, instead, benefit from: Forfait Innovation pathway and Article 51 of the French Social Security Financing Law to support evidence generation around innovative healthcare models, technologies, and services.

MD: dispositif médical
DMN: dispositif médical numérique
TLM: telemonitoring

LPRR: Liste des produits et prestations remboursables
TAs: therapeutics area
LATM: Liste des activités de télésurveillance médicale

Source: Healthware, Digital Medicines Actionable Insights Database (AID), last updated 1° June 2023

HAS' Organizational impact map for Health Technology Assessment

HAS also provides indications for assessing the organizational impact of Health Technologies (HT*), including DMNs, in terms of impact on care processes, capabilities and skills required and societal implications. While not mandatory for the appraisal process, they are appreciated.

PART 1
Context Assessment

Is a conventional care solution available?

YES
The HT changes the existing conventional care in terms of Modifies how patients are treated

NO
The HT creates conventional care

PART 2
Macro-criteria

Macro-criterion 1.
Impacts of the HT in the care process

Macro-criterion 2.
Impacts of the HT and skills required of stakeholders on the capabilities

Macro-criterion 3.
Impacts of the HT on society or the community

PART 3
Stakeholders Concerned

Specification of diverse stakeholders potentially impacted by the HT

* HT: includes medicinal products, medical devices and diagnostic and therapeutic procedures

Listed DMN examples

DMN	Manufacturer	Solution Type & Target Indication	Reimbursement Status and Pricing
diabeloop	Diabeloop SA	Semi-closed loop system for automated management for adult type 1 diabetic patients	Approved for reimbursement in 2021 Légifrance
moovcare By Sivan	Sivan Innovation	Web-based software application for medical telemonitoring of relapses and complications in patients with lung cancer not progressive	Approved for reimbursement in 2022 Légifrance €399,60 (3-month license)
diabeo	Aptar – Voluntis / Sanofi- Aventis	Software application for remote medical monitoring for people with diabetes	ETAPES Process Price range for diabetes solutions: €330,00 min. - €375,00 max.
insulia	Aptar – Voluntis	Mobile application for remote medical monitoring of people with diabetes	ETAPES Process Price range for diabetes solutions: €330,00 min. - €375,00 max.

Note: non-exhaustive list

Source: Healthware, Digital Medicines Actionable Insights Database (AID), last updated 1° June 2023

England Digital Health Technologies (DHTs)

DMDs & DTx: Policy Overview

DMD/DTx

Current scenario	Evolving scenario

- **Classification:** England adopts the broader **DHT** classification. DTx are a subset, classified as **"Tier C" DHTs** – namely: DHTs for treating and diagnosing medical conditions or guiding care choices.
- **Medical Device Certification:** DTx are regulated as medical devices. CE-marking is still recognized, but in 2024 manufacturers will require a local certification instead – the UK Conformity Assessment (UKCA) mark.
- **NICE's Evidence Standards Framework:** evidence standards that DHTs should meet before being considered for commissioning or procurement by the NHS.
- **Digital Technology Assessment Criteria for health and social care** (DTAC, 2021): designed to be a rapid and accessible assessment criteria to assure DHTs meet minimum baseline standards for entry into the NHS.
- **P&R:** local NHS organizations play a leading role in defining pricing and reimbursement of DHTs.
- **Early Value Assessment (EVA)**: England has been piloting an EVA approach for medtech, including DHTs, targeting high-burden unmet need areas - mental health, cardiovascular, early cancer detection and in general medical technologies that boost healthcare capacity. The pilot phase was concluded with EVA now structurally adopted into the existing health programmes.

Note: P&R stands for Pricing and Reimbursement.

NHS's Digital Technology Assessment Criteria for Health and Social Care (DTAC)

- DTAC is the **national baseline assessment criteria for DHTs to enter into the NHS and social care.**
- DTAC has five core macro-assessment dimensions:
  - Clinical safety
  - Technical security
  - Data protection
  - Interoperability
  - Usability and accessibility (scored section)
- DTAC is intended to be one part of the procurement process, to be supplemented with additional specifications, evidence of value generation and further policy and regulatory requirements.

NHS's DTAC assessment criteria dimensions

Clinical Safety	✓
Technical Assurance	✓
Data Protection	✓
Interoperability	✓
Usability and Accessibility	100%

Overall assessment outcome

NICE's Evidence Standards Framework (ESF)

England

Evidence standards that should be available for DHTs to demonstrate their value in England's health and social care system.

DHTs are classified by function, stratifying evidence requirements by tiers based on the potential risk to users:

- **Tier A**: system impact - DHTs intended to save costs or release staff time, no direct patient, health or care outcomes.
- **Tier B:** understanding and communicating - DHTs for helping people and patients to manage their own health and wellness.
- **Tier C:** interventions (as DTx) - DHTs for treating and diagnosing medical conditions or guiding care choices. Includes DHTs with direct health outcomes, and those that are likely to be regulated medical devices.

24 evidence standards categorized in **5 groups** and related to phases of the DHTs product life cycle:

- Design factors
- Describing value
- Demonstrating performance
- Delivering Value
- Deployment considerations

Early Deployment (ED) standards for evidence-generation programmes exist to support companies with DHTs at an early stage of development to generate the required evidence-base. The ED subset of **15 ESF standards** can be used to assess DHTs in evidence-generation programmes.

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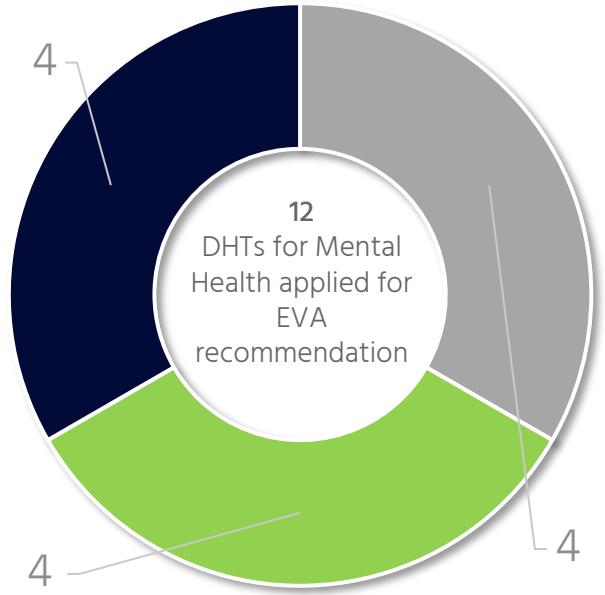
NICE's Early Value Assessment (EVA)

- **Rapid assessment for medtech, including DHTs:** EVA is envisioned to ensure that the most promising technologies that address and support a clearly defined system need can be timely assessed and where appropriate access may be granted conditional on further evidence generation.
- The EVA pathways are characterized by a rapid assessment based on **clinical efficacy** and **value for money**. Once a technology receives a conditional recommendation via EVA, it is authorized for trail use within the NHS as it gathers further supporting evidence, also real-world evidence.
- NICE's guidance will be reviewed on the basis of the evidence generated to make a recommendation on the routine adoption of these technologies across the NHS.
- In February 2023, the first HTA EVA evaluation report was published, recommending the adoption of 4 guided self-help digital solutions based on Cognitive Behavioural Therapy for children and young people with mild to moderate symptoms of anxiety or low mood.
- In May 2023, NICE recommended 8 digitally enabled therapies to treat depression and anxiety in adults through their pilot Early Value Assessment (EVA) pathways

Recommended

Guided self-help digital cognitive behavioural therapy for children and young people with mild to moderate symptoms of anxiety or low mood



Recommended

Digitally enabled therapies for adults with depression disorders

Recommended

Digitally enabled therapies for adults with anxiety disorders

Recommended DHTs examples

DHT recommended (manufacturer)	Therapeutic Area	Recommended Status	Note
▪ Lumi Nova (BfB labs) ▪ Online Social anxiety Cognitive therapy for Adolescents (OSCA) ▪ Online Support and Intervention for child anxiety (OSI) ▪ SPACE for anxiety for teens, low mood for teens, and low mood and anxiety for teens (Silvercloud).	Mild to moderate symptoms of anxiety or low mood	NICE EVA Recommended 8 February 2023	Guided self-help digital cognitive behavioral therapy for children and young people with mild to moderate symptoms of anxiety or low mood
▪ Beating the blues ▪ SPACE from anxiety (SilverCloud)	Generalised anxiety symptoms or unspecified anxiety disorder; Depression	NICE EVA Recommended 1 6 May 2023	Digitally enabled therapies to treat depression and anxiety in adults
▪ Perspectives	Body dysmorphic disorder (BDD)		
▪ Deprexis (GAIA/Ethypharm Digital Therapy) ▪ SPACE from depression (SilverCloud)	Depression		
▪ iCT-PTSD ▪ Spring	Post-traumatic stress disorder (PTSD)		
▪ iCT-SAD	Social anxiety disorder		
▪ Sleepio (Big Health)	Insomnia	NICE Recommended 20 May 2022	Evidence-based recommendations as a cost saving option for treating insomnia and insomnia symptoms. Price: £45 (excluding VAT) per person.

Note: non-exhaustive list

Source: Healthware, Digital Medicines Actionable Insights Database (AID) and NICE, last updated 1° June 2023

Catalonia (Spain) DMD & DTx Policy Overview & Appraisal Criteria

DMD/DTx

Current scenario

- **No specific formal classification** for DMDs and DTx – generally classified as Medical Device.
- **Servicio Catalán de Salud:** Regulatory and executive agency of reference for medical devices.
- **Mobile Application Certification Service: TIC Salut Social Foundation** evaluates and certifies digital technologies for remote care, manufacturers can voluntarily undergo this evaluation and certification which considers 4 categories:

Usability and accessibility	Technical Requirements
Security	Quality and usefulness

- Evaluation criteria are generally aligned with established HTA frameworks, although **fit-for purpose clinical impact evaluation criteria are yet to be defined.**

Evolving scenario

- **Dedicated assessment framework for DHTs**: specific appraisal criteria for digital health technologies are under development (expected to be forthcoming in 2023):
  - Being developed by the **Agency for Quality and Health Evaluation of Catalonia (AQuAS)**, commissioned by the Ministry of Health, in collaboration with the Spanish Network of Agencies for the Evaluation of Technologies and Health Benefits (RedETS).
  - Should define assessment domains and evidence standards for DHTs and DMDs according to their **risk classification**.
  - Focus on **remote/non-face-to-face, mobile health** and **artificial intelligence** enhanced care models.
- **Value-based procurement and innovation funds**: DMDs and DTx of proven value and that target high-burden unmet system needs could also potentially benefit from **value-based procurement and innovation funds**.

DMDs & DTx Appraisal Criteria:

Notes on appraisal Criteria applicable to Medical Devices & Mobile Health Applications while a dedicated framework is forthcoming

- While a dedicated assessment framework for DHTs is forthcoming, DMD/DTx, also according to **TIC Salut Social Foundation's Mobile Application Certification Service** are generally required to be:
  - **Certified** as medical devices
  - **GDPR** Compliant in accordance with Spanish Data Protection and Digital Rights Law
  - Compliant with **international interoperability standards, as well as interoperability with local** Catalonian interoperability platform (iS3) and Catalonian Personal Health Record (La meva Salut)
  - **Reliable in terms of technical stability and data security.**
- TIC's Mobile Application Certification also accounts for **navigability, readability, consistency, content organization, user experience** in terms of intuitive and agile management, also for vulnerable populations.

- Generally:
  - **Health economic** cost modelling should prove the technology is affordable and the reimbursement model suitable over time
  - **Ethical** considerations based on public health principals and medical practice are appreciated (eg. non-maleficence and beneficence, health maximization and justice, efficiency, respect for autonomy and proportionality)
  - **Organizational impact** considerations are appreciated (eg. waiting times, number of hospitalizations, readmissions).
- Dedicated **clinical evidence** requirements are forthcoming.

Italy DMD & DTx Policy Overview

DMD/DTx

Current scenario

- **No specific formal classification nor appraisal criteria for DMDs and DTx.**
- DMD and DTx would generally be considered as **Medical Device**, for which the **Ministry of Health** is the overarching Institution of Reference and tenders occur at **the Regional and sub-regional level.**
- In Italy, there is also the **Italian Medicines Agency** (AIFA), which could potentially play a role in the evaluation and access of DMDs if validated and brought to market in combination with pharmaceutical products.
- The National Institute of Health (**ISS**) also has two departments focusing on innovative technologies - the National Center For Telemedicine And New Assistive Technologies and the National Center for Innovative Technologies in Public Health.
- Three key scientific societies are dedicated to digital health: ASSD, AiSDeT and SIT.
- In 2021, the **Digital Therapeutics for Italy (DTxITA)** initiative advocated for the introduction of DTx into the national public healthcare service in in Italy.

Evolving scenario

- **Rapidly evolving scenario** since the COVID-19 pandemic and the National Recovery and Resilience Plan (PNRR). Over **6 billion Euros** to be invested in enabling digital health **infrastructure, telemedicine** and **homecare** capabilities across National and Regional Healthcare Services.
- The Italian National Agency for Regional Healthcare Services (**age.na.s**) was nominated as **Digital Health Agency** and could provide HTA indications.
- **Notion of telemedicine** formally adopted is expanding to include broader digital health services – including: televisits, teleassistance, teleconsultations; as well as continuous telemonitoring and not-continuous tele-control.
- **National Indications for the Provision of Telerehabilitation Services**: formally acknowledge DTx amongst possible enabling technologies.
- **Digital Health & DTx intra-parliamentary initiative**: launched in May 2023, it aims at defining the formal recognition, appraisal and P&R criteria for DMD and DTx with a technical scientific committee being defined.
- **DTxITA** initiative is also being re-launched and enhanced as **DTxITA24**

- There are DMD/DTx ready to be launched in Italy, there are also clinical trials being run in Italy on DTx specifically, and as certified medical devices they will be increasingly available privately: there is a need to define **dedicated appraisal**, **access** and **reimbursement** and **adoption criteria** applicable within the **National Healthcare Service** (SSN) to assure **equitable access and system integration and value generation.**

Digital Therapeutics to enhance the care pathways for depression across the national health service: expert proposals for Italy

- Healthware's Future Health Reports are leading multi-stakeholder Expert Opinions to define and drive evidence and consensus-based endorsement as to why, how and where DTx fit along care pathways and workflows.
- A recent Expert Opinion focused on integrating DTx across depression care pathways in the Italian national health service (SSN). Accounting for unmet needs and evidence-based scientific recommendations for the treatment of depression, experts agreed on the value of DTx to enhance care-as-usual within the SSN for mild, moderate, and severe depression, as well as for the prevention of relapses and management of subthreshold depression.

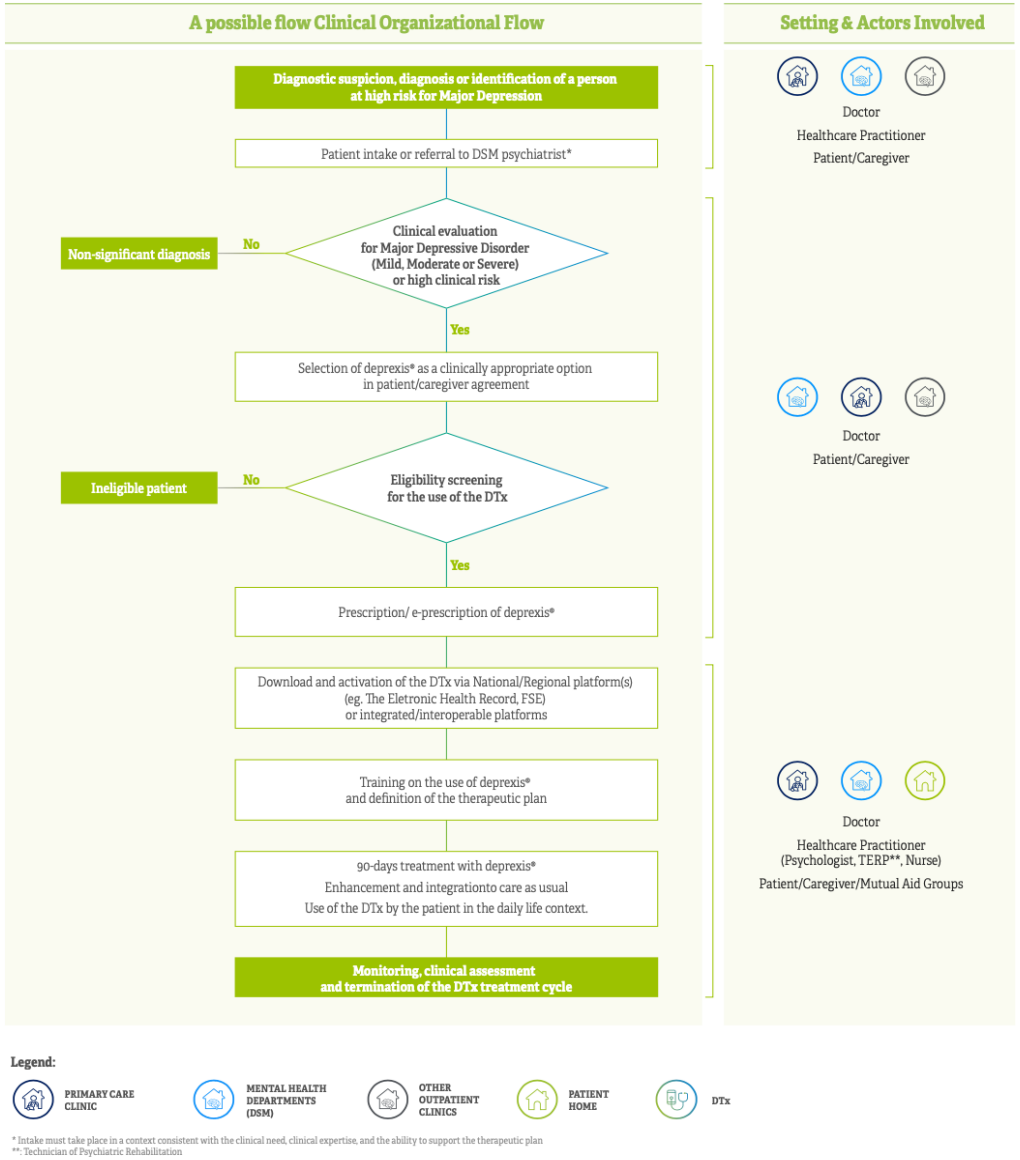


Figure 6: A possible clinical-organizational flowchart for the integration of a DTx for the treatment of major unipolar depression, as deprexis®, across the SSN care pathways

Source: A. Spreafico, F. Starace et. al. "Digital Therapeutics to enhance the care pathways for depression across the national health service: expert proposals for Italy". March 2023. Milano, Healthware Group S.r.l.

Evolving DTx Policy Landscape and Fit-for-Purpose Appraisal Criteria

Benelux

- Formal Frameworks for DMD/DTx in place: Belgium
- Emerging Frameworks: Netherlands

DMD & DTx Policy Overview
Benelux

	Belgium	Luxemburg	Netherlands
	Current scenario	**Current scenario**	**Current scenario**
Classification	▪ Some DMDs and DTx can be classified within the **Certified Health Applications** formally recognized by **mHealthBELGIUM** classified as: ▪ software application with medical purpose ▪ apps with CE-mark as a medical device ▪ apps that allow a patient to share health-related information with a healthcare professional	No formal classification for DMDs & DTx, they generally fall under the **medical device** category and are not subject to a distinctive product category	No formal classification for DMDs & DTx, they generally fall under the **medical device** category and are not subject to a distinctive product category
Fit-for-Purpose Appraisal Criteria	Defined specific appraisal/HTA criteria for the digital nature of DMD/DTx. ✓	-	-
Reimbursement	Statutory health insurance allows for reimbursement of certified medical applications that have positively met the appraisal criteria of 3-step validation pyramid (CE-mark, security and interoperability standards, health economic evidence) ✓	-	-
Early Access Pathway / Fast Track	**"Level 3 light"** in the validation pyramid allows for certified medical device health apps that meet technical and safety criteria and are in the process of proving their social-economic value to be temporarily financed by NIHDI. ✓	-	-
Pricing	Price negotiation with NIHDI, responsible for Level-3 of the evaluation pyramid ✓	-	-
Agency of reference	FAHMPH, Federal Agency for Medicines and Health Products eHealth platform NIHDI, National Institute for Health and Disability Insurance	Ministry of Health ("Ministère de la Santé") National Health Directorate ("Direction de la Santé")	MOH, Dutch Ministry of Health, Welfare and Sport

Source: Healthware, Digital Medicines Actionable Insights Database (AID), last updated 1° June 2023

Belgium mHealth: certified digital health apps

DMDs & DTx: Policy Overview

DMD/DTx

Current scenario

- In 2018, Belgium launched the mHealthBelgium initiative aimed at integrating certified mobile health applications in the healthcare system. In 2019, it led to the launch of the mHealthBelgium validation pyramid, reimbursement criteria and platform of certified medical software-based applications.
- Belgium applies a multi-level Validation Pyramid to assess software medical applications.

To be considered for inclusion in the mHealth Belgium platform software applications need to have a medical purpose and be:

- **Level 1:** certified as medical device in Europe; GDPR compliant; voluntarily notified to the Federal Agency for Medicines and Health Products (FAMHP)
- **Level 2**: meet interoperability standards to allowing for patients to share health information with HCPs and HCPs to diagnostic, treat or monitor patients remotely

To be considered for **reimbursement** medical software applications also need to:

- **Level 3-light**: have ongoing health economic evidence generation
- **Level 3-plus** having fully proven health economic value

mHealth Value Assessment & Access Pathway
DMDs & DTx: Policy Overview

APPRAISAL CRITERIA

Level 3.

- **M3-plus** (permanent listing & reimbursement): fully proven health economic value
- **M3-light** (temporary listing & reimbursement): Ongoing evidence generation

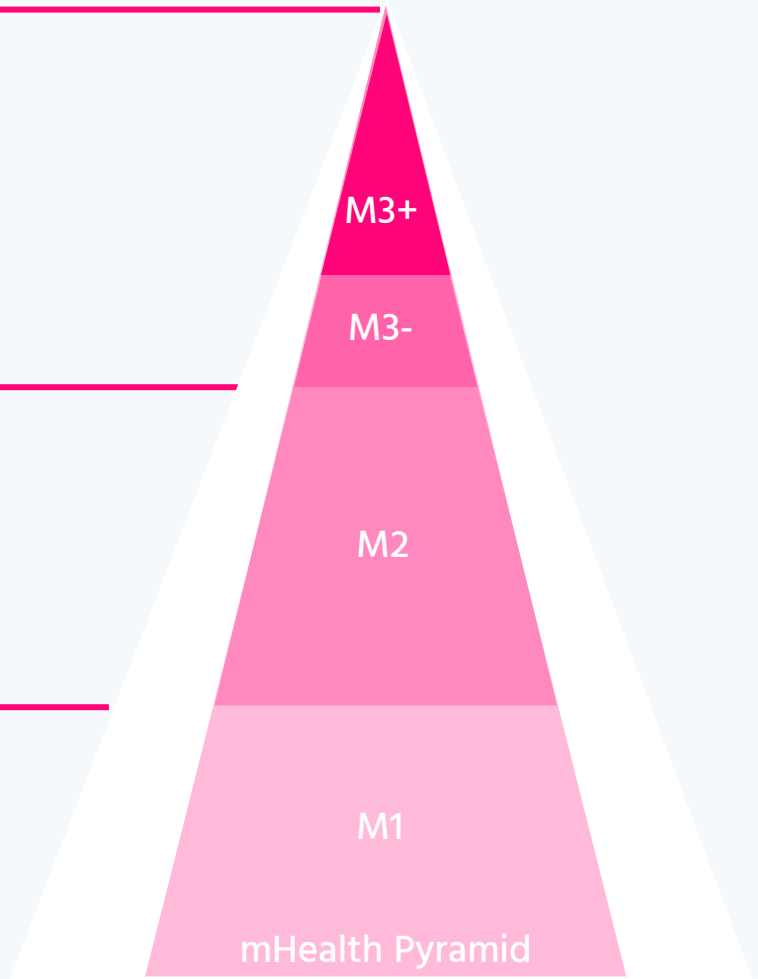
Level 2.

- **Interoperability:** interoperability and connectivity to the basic services of the eHealth platform

Level 1.

Basic criteria for an app:

- **Certified** as a Medical Device
- **FAMHP** notification
- **GDPR** compliance



INSTITUTIONS OF REFERENCE

NIHDI, National Institute for Health and Disability Insurance:

- Responsible for the refunding of medicines, medical devices and medical provisions.
- Responsible for level M3 within mHealthBelgium.

eHealth Platform

- Federal government institution
- Responsible for level M2 within mHealthBelgium

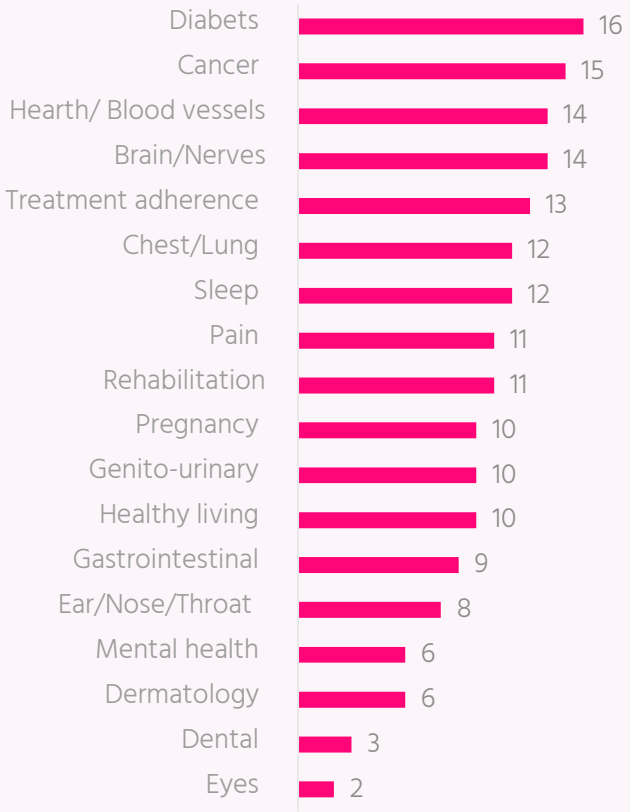
FAMPH, Federal Agency for Medicines and Health Products

- Competent authority for quality, safety and efficacy of medicines and health products, including medical devices.
- Responsible for level M1 within mHealthBelgium

mhealth Belgium Apps Highlights

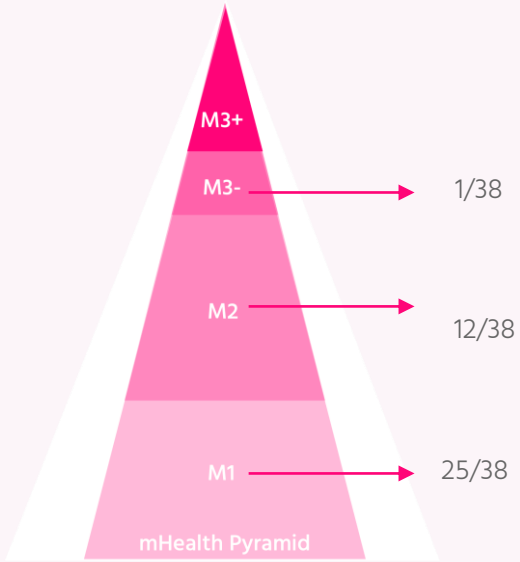
MhealthBelgium apps by Therapeutic Area Targeted

(absolute number, June 2023)



MhealthBelgium apps by Pyramid level

(absolute number, June 2023)



moveUP Coach App

By moveUP

Therapeutic area/ Indication

moveUP uses validated wearables to monitor activity and sleep quality

Reimbursement Status

M3-light
temporary listing & reimbursement

- CE-certified medical device
- Safety connected
- In process of proving sufficient health-economic value - **temporarily reimbursed by NIHDI**

Note:

The App is available for free and needs to be prescribed by the treating surgeon.
The service and wearable come at a monthly or weekly subscription, subject to reimbursement.

Note: MHealthBelgium Apps, latest update on June 1th, 2023

Netherlands DMDs & DTx: Policy Overview

DMD/DTx

Current scenario

- **No specific formal classification nor appraisal criteria for DMDs and DTx**. DMDs and DTx generally fall within the medical device category and access pathway.
  There are not fit-for-purpose appraisal criteria defined.
- **Institution of reference**: Dutch Ministry of Health, Welfare and Sport (MOH)
- **No centralized P&R system**

Health App Checker

Promoted by the Royal Dutch Medical Association since 2016 to support HCPs in evaluating the quality and reliability of health applications.

Focuses on **3 kinds of applications**:

- Applications certified as medical devices
- Applications that facilitate the efficient tracking, storage and sharing of information
- Applications that can support HCP-patient communication

Provides **3 kinds of services**:

1. Targeted search of a suitable health application to be used by patients and HCPs.
2. Evaluation of the reliability and quality of a health application.
3. Assistance in evaluating data protection and security compliance.

DMDs & DTx Appraisal Criteria

Notes on appraisal Criteria applicable to Medical Devices & Mobile Health Applications while a dedicated framework is forthcoming

- While a dedicated assessment framework for DHTs is forthcoming, DMD/DTx generally required to be:
  - **Certified** as medical devices
  - **GDPR** Compliant in accordance with Dutch Act of Medical Treatment Contracts
  - **Compliant with International interoperability standards, at local level** there is no strict interoperability requirement. Currently national guidelines and initiatives for a sustainable information ecosystem are being developed
  - **Reliable in terms of technical stability and data security,** subject to standardisations (NEN, ISO) and compliant with requirements set by the Dutch National Cyber Security Centre (NCSC)
- In terms of **accessibility** and **usability** there is no specific requirement, geographic accessibility is regulated as part of the healthcare market regulation

- Generally:
  - Distinctive **cost-effectiveness** assessment is not required for reimbursement at a national level. Instead, appropriate and efficient deployment is considered crucial by health care insurers who purchase the care and is eventually subject to the inspection of the Dutch Health Care Authority (NZa).
  - **Organizational impact** considerations are appreciated, and the social benefit must be shown
- **Clinical effectiveness** is a legal requirement for decision-making on the reimbursement of medical treatments and is basically applicable to all types of technologies (pharma, medtech, DTx, AI)

Evolving DTx Policy Landscape

Nordics

- Focus on countries with Emerging Frameworks for DMD/DTx: Finland, Denmark

DMD & DTx Policy Overview
Nordics

	Sweden	Finland	Norway	Denmark	Iceland
	Current scenario	Current scenario	Current & evolving scenario	Current & evolving scenario	Current scenario
Classification	No formal classification for DMDs & DTx, they generally fall under the **medical device** category and are not subject to a distinctive product category	No formal classification for DMDs & DTx, they generally fall under the **medical device** category and are not subject to a distinctive product category	No formal classification for DMDs & DTx, they generally fall under the **medical device** category and are not subject to a distinctive product category. **Evolving** The app evaluation context is being developed as a part of "**safer use of health apps**" national project; a model to integrate approved apps into public health services, available by prescription, as part of a central registry on helsenorge.no	No formal classification for DMDs & DTx, they generally fall under the **medical device** category and are not subject to a distinctive product category. **Evolving** Efforts are being made for the definition of evaluation pathways for health apps starting from projects such as "**National app guide**", led by the Danish Medicines Agency, and "**App in General Practice**"	No formal classification for DMDs & DTx, they **generally fall under the medical** device category and are not subject to a distinctive product category
Fit-for-Purpose Appraisal Criteria					
Reimbursement					
Early Access Pathway / Fast Track					
Pricing					
Agency of reference	Medical Product Agency (MPA), TLV	FINCCHTA, Finnish Coordinating Center for Health Technology Assessment	NoMA, Norwegian Medicines Agency	Danish Medicines Agency	IMA, Iceland Medical Agency

Source: Healthware, Digital Medicines Actionable Insights Database (AID), last updated 1° June 2023

Finland DMDs & DTx: Policy Overview

DMD/DTx

Current scenario

- **No specific formal classification nor appraisal criteria for DMDs and DTx.** DMDs and DTx generally fall within the medical device category and access pathway
- **Institution of reference:** FINCCHTA, Finnish Coordinating Center for Health Technology Assessment
- **No centralized P&R system**, medical devices are evaluated and purchased at the local district and hospital level
- **FINCCHTA's Digi-HTA** is a voluntary national-level assessment and quality certification for digital health services and products, providing a traffic light scoring model. Macro-dimensions assessed are **Effectiveness, Costs, Safety, Data protection and security, Usability and accessibility, Specific care process integration and technical aspects**
- **DHTs:** evaluated by Digi-HTA, including digital remote monitoring, home care, and rehabilitation services

Evolving scenario

- **Joint HTA Pilot program for DMD:** a project may be developed, within the context of the Next Generation Europe funded initiatives, for the definition of a possible joint HTA, P&R system and DMD catalogue across 4 pilot Regions

Denmark DMDs & DTx: Policy Overview

DMD/DTx

Current scenario

- **No specific formal classification nor appraisal criteria** for DMDs and DTx. DMDs and DTx generally fall within the medical device category and access pathway.
- **Institution of reference:** Danish Medicines Agency
- **No centralized P&R system;** medical devices are evaluated and purchased at the local regional, municipality, and hospital level.
- **Appraisal criteria:** not harmonized, but generally align with the HTA Core Model® Dimensions, with a particular emphasis and further focus placed on:
  - **Health economic impact**, especially with consideration on labor-saving
  - **Sustainability** and **environmental** impact (*forthcoming*)
- **National App Guide:** initiative led by the Danish Medicines Agency aimed at defining how to evaluate, approve, recommend the digital health applications.
- **Project Apps in medical General Practice (GP):** initiated by the Ministry of Health in collaboration with the Organisation of General Practitioners (PLO), Danish Regions, and MedCom aims to develop a technical platform and catalogue of qualified health apps to assist GPs in recommending and patients in using them. Digital health apps considered include self-monitoring, medication adherence, physician-recommended activities.

System Digital Readiness

High System Digital Readiness

While there is no specific pathway for DMDs and DTx, **system digital readiness is high**, so adoption is expected to scale rapidly once dedicated appraisal criteria and access pathways are defined.

System digital readiness and uptake enablers include:

- Well-structured **digital infrastructure** and platforms for **e-prescriptions**
- Established **digital patient summary** data within EHRs
- Effective and efficient **procurement pathways**
- High **digital health acceptability** from HCPs and patients

Evolving DTx Policy Landscape

Baltics

- Focus on countries with Emerging Frameworks for DMD/DTx: Estonia

Estonia DMDs & DTx: Policy Overview

DMD/DTx

Current scenario

- **No specific formal classification nor appraisal criteria** for DMDs and DTx. DMDs and DTx generally fall within the medical device category and access pathway.

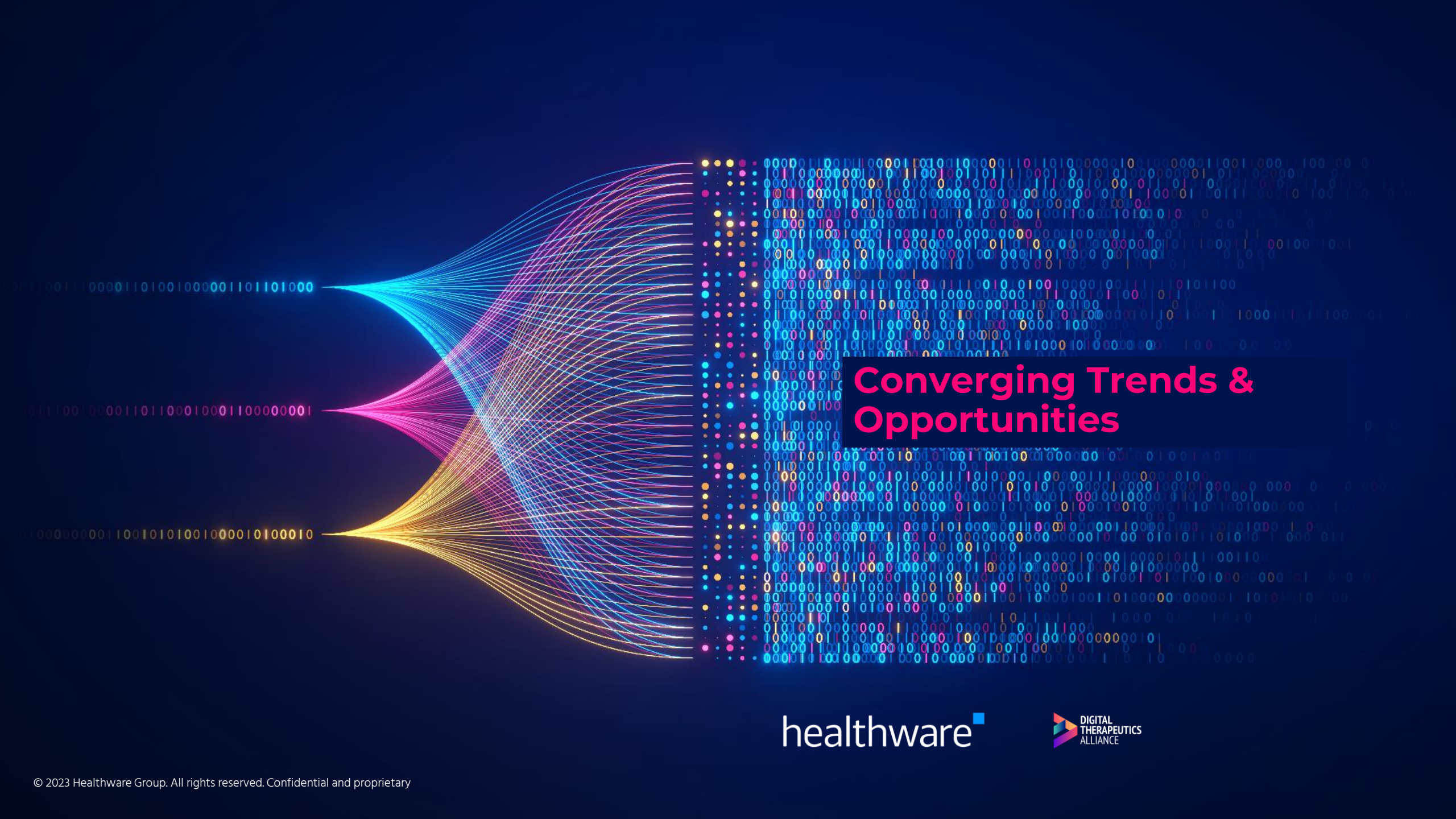
DTx Estonia was established in 2022 as the industry alliance **of Estonian digital therapeutics manufacturers.**

- It is partnering with Start-up Estonia to raise awareness across stakeholders.
- Members are working on DTx ranging across therapeutics areas – as migraine, dermatology, mental health and cardiometabolic diseases.

Evolving scenario

- Ongoing work to define a **possible evaluation criteria and reimbursement pathways through the Estonian Health Insurance Funds** could potentially account for:
  - Interoperability standards to exchange data with national databases
  - Certification as medical device
  - Supporting value evidence

- **System Digital Readiness:** Estonia has one of the world's most advanced digital societies with an advanced integrated data-driven eHealth system. All citizens have access to a unified Digital Patient Portal where all data recording health are accessible and recorded. Data from health apps can also be optionally integrated. Once DTx are made accessible, uptake could be significant



Converging Trends & Opportunities

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DIGITAL THERAPEUTICS ALLIANCE

Digital Medical Device (DMD) & Digital Therapeutic (DTx) Policies – Europe Overview

A patchwork of evolving frameworks

England

- DMD would fall within the broader notion of **Digital Health Technologies** (DHTs), DTx are Tier C DHTs
- DTAC assessment for DHTs
- **Local NHS organizations** play a leading role in funding and reimbursing
- **Early Value Assessment** (EVA) pathways for **DHTs** in high-burden therapeutic areas

Belgium

- DMD categorized as **certified medical device health applications**, some are also DTx
- Catalogued on the **mHealthBelgium platform**
- **3-steps validation pyramid** that assess quality and technical standards, as well as supporting clinical and health economic evidence to ultimately enable the possibility of reimbursement

France

- **Digital Medical Devices** (Dispositifs Médicaux Numériques, DMN) are formally acknowledged and differentiated by intended purpose: **therapeutic (DTx)** and those for **telemonitoring** purposes
- **DTx** follow the **medical device** appraisal and reimbursement pathway
- Dedicated **early coverage pathway** recently launched for telemonitoring DMN and forthcoming for DTx (Prise en Charge Anticipée Numériques, PECAN)

Germany

- DMD and some DTx fall within the definition of a **DiGA** (Digital Health Application)
- Dedicated DiGA appraisal and reimbursement pathway, coordinated by **BfArM**, allows for **permanent listing** as well as **temporary listing** with a dedicated **fast-track**
- Reimbursement through **statutory health insurance**
- **47 DiGA listed to date**, 18 permanently, 29 provisionally

Catalunia (Spain)

- **No specific formal classification** for DMD and DTx – generally classified as **Medical Devices**, for which the regulatory and executive agency is **the "Servicio Catalán de Salud".**
- **TIC Salut Social Foundation** certifies **mobile health applications** assessing usability, accessibility, quality, interoperability, safety and security standards
- DMD that target high-burden unmet needs and disorders, as in the field of mental health, could increasingly also benefit from **value-based procurement and innovation funds.**

Nordics

- **No specific formal classification** for DMD and DTx – generally, classified as **Medical Devices**
- Evolving scenario: **Norway**'s central registry for approved health apps; **Denmark**'s Apps in medical General Practice and the National App Guide; **Finland**'s FINCCHTA voluntary Digi-HTA and joint HTA Pilot program for DMD.

Estonia

- **No specific formal classification** for DMD and DTx
- Working on defining a **dedicated appraisal process** that may account for differences between digital medical devices and services; as well as interoperability with the national health database and level of supporting evidence
- The existing advanced **e-health infrastructure** could scale adoption once an appraisal and access process is in place

Italy

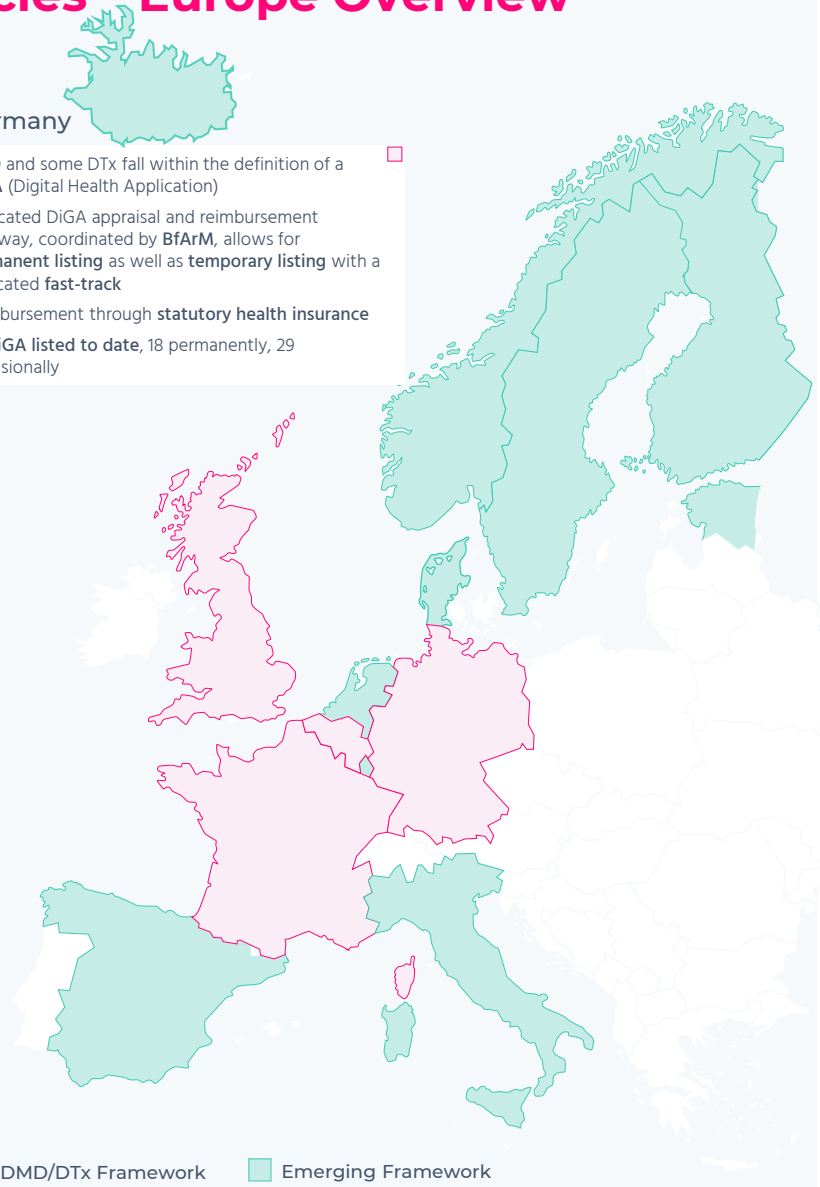
- **No specific formal classification** for DMD and DTx
- Within the «National Recovery and Resilience Plan» significant plans are dedicated to the digitalization of healthcare, including the creation of an enabling **National Telemedicine Platform** and **EHRs Infrastructure** with the possible evolution of a "**catalogue" of telemedicine and digital health services** to be activated at the National and/or Regional level.
- **National telemedicine guidelines** have been formally approved, and National Indications for **telerehabilitation** acknowledge DTx amongst enabling technologies..
- **Digital Health & DTx intra-parliamentary initiative:** launched in May 2023, it aims at defining the formal recognition, appraisal and P&R criteria for DMD and DTx.

Luxembourg

- **No specific formal classification** for DMD and DTx
- Initial stage, with **research projects** in the area of digital healthcare innovation
- **dHealth project**: pilot ongoing for Parkinson's disease based on:
  - development of applications and devices that collect patient symptoms
  - creation of communication systems between patients and healthcare professionals through digital applications

Netherlands

- **No specific formal classification** for DMD and DTx – generally classified as **Medical Devices**
- From 2016 there is a service called "**Medical App Checker**" able to provide support for medical professionals to identify the reliability of a mobile health app



Source: Healthware, Digital Medicines Actionable Insights Database (AID), last updated 1° June 2023

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DIGITAL THERAPEUTICS ALLIANCE

Diverse National Nomenclatures, But Converging Trends

DTx-relevant pathways continue to be developed at the local, national, and regional levels. This positive momentum is leading to greater patient access to DTx therapies yet is resulting in an increasingly **fragmented set of nomenclatures** to define digital technologies and **requirements** to assess and reimburse products.

However:

- The Digital Therapeutics Alliance is participating in **ISO's formal development process to develop an internationally-recognized definition of a DTx and related standards.**
- The converging trend across Europe is that of classifying **DTx as certified medical devices that are digital in nature and have a therapeutic intended purpose or component.**
- The broader trend in Europe is also that of defining **fit-for-purpose appraisal criteria for medical devices that are digital/software-based in nature**.

Global Geographic Clusters	Country	DTx Product Category Recognition
Asia Pacific	**Australia**	Software as a Medical Device (SaMD)
	China	Software as a Medical Device (SaMD)
	Japan	Software as a Medical Device (SaMD)
	South Korea	Digital Therapeutics (DTx)
North America	**Canada**	Digital Health Technology (DHT)
	United States	Digital Health Technology (DHT)

☐ Formal DMD/DTx Framework ☐ Emerging Framework

Europe Geographic Cluster	Country	DTx Product Category Recognition
EU4 + England	**Germany** ☐	Digital Health Applications - Digitale Gesundheitsanwendungen (DiGA) [Note: only a subset of DTx products qualify as DiGA]
	France ☐	Digital Medical Devices - Dispositifs Médicaux Numériques (DMN) with a therapeutic intended purpose (as DTx) or monitoring purpose
	England (UK) ☐	Digital Health Technology (DHT)
	Catalunia (Spain) ☐	No specific formal classification; generally categorized as Medical Device
	Italy ☐	No specific formal classification; generally categorized as Medical Device.
Benelux	**Belgium** ☐	Certified Digital Health App (mHealth)
	Luxembourg ☐	No specific formal classification; generally categorized as Medical Device
	Netherlands ☐	No specific formal classification; generally categorized as Medical Device
Nordics	**Finland** ☐	No specific formal classification; generally categorized as Software as a Medical Device (SaMD)
	Sweden ☐	No specific formal classification; generally categorized as Medical Device
	Norway ☐	No specific formal classification; generally categorized as Medical Device
	Iceland ☐	No specific formal classification; generally categorized as Medical Device
Baltics	**Estonia** ☐	Digital Health Apps

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DIGITAL THERAPEUTICS ALLIANCE

DMD & DTx comparative policy overview
EU-4 + England (UK): More Established Frameworks

	Germany		France	England		Belgium
	Current scenario	Evolving scenario	Current & evolving scenario	Current scenario	Evolving insights	Current & evolving scenario
Classification	DiGA: Certified MD (risk class I or IIa) digital-driven; patient-led; not focused on primary prevention	**DiGA** expected to include also: MD up to risk-class IIb; telemedicine services with involvement of HCPs	**DMN**: Digital Medical Device (Dispositif Médical Numérique) with therapeutic or telemonitoring purposes.	**DHT**: DTx are a subset of the broader DHT category. DTx as Tier C DHT, which usually require being certified as a Medical Device.		**mHealth Applications:** software app with medical purposes, CE-mark, allow a patient to share health-related information with a HCP
Fit-for-Purpose Appraisal Criteria	Defined specific appraisal/HTA criteria for the digital nature of DMD/DTx. ✓		Defined specific appraisal/HTA criteria for the digital nature of DMD/DTx differentiated for therapeutic DMN vs. telemonitoring. ✓	Defined specific appraisal/HTA criteria for the digital nature of DMD/DTx. ✓		Defined specific appraisal/HTA criteria for the digital nature of DMD/DTx. ✓
Reimbursement	Permanent or temporary listing and reimbursement through statutory health insurance ✓		5-year national listing and reimbursement; renewable. ✓ Pathways differentiated for DMN with therapeutic purposes (regular medical device pathway) vs. telemonitoring.	Sub-national, local NHS organizations decide on P&R. ✓	Potential pricing indications to be informed/suggested nationally	Statutory health insurance allows for reimbursement of certified medical applications that have positively met the appraisal criteria of 3-step validation pyramid ✓
Early Access Pathway / Fast Track	**DiGA Fast-Track** 12-months temporary reimbursement if compliant with quality, security and interoperability pre-requisites ✓		**PECAN**: 6 months temporary listing for DTx; 9 months for telemonitoring device. Then application to their regular pathways. [launched in Q2-2023] ✓	**Early Value Assessment** (EVA) for MedTech pathways ✓		Level "3 light" CE-marked apps meeting technical and safety pre-requisites and in the process of proving social-economic value are temporarily financed by NIHDI. ✓
Pricing	Price set by manufacturer for the first 12-month; renegotiated with GKV-SV		Pricing during PECAN: - Telemonitoring: flat-rate then renegotiated - DTx: forthcoming	Sub-national, local NHS organizations decide on P&R.	Potential pricing indications to be informed/suggested nationally	Price negotiation with NIHDI, responsible for Level M3 of the evaluation pyramid
Agency of Reference	BfArM		HAS	MHRA, NHS, NICE		FAHMPH mHealth Belgium Platform NIHDI

Source: Healthware, Digital Medicines Actionable Insights Database (AID), last updated 1° June 2023

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DIGITAL THERAPEUTICS ALLIANCE

Converging and Diverging Trends
DMD/DTx Classification & Policy overview: formal frameworks

Converging Trends for DTx

Classification as:

- Certified Medical Device
- Specifically, based on software/digital technologies

In Germany, France, England, and Belgium, DTx would in all cases fall within the classification of **certified medical devices, and more specifically, based/driven by a digital/software component.**

Fit-for-purpose HTA requirements:

Countries have defined or are **defining fit-for-purpose multidimensional requirements adequate for digital/software based/driven medical devices**, as DTx:

- Whether within the broader Medical Device regulatory pathway (France, LPPR); or through dedicated Digital Health Technologies assessment frameworks (England); or more specific Digital Health Application dedicated pathways (Germany, Belgium) and Digital Medical Device early access pathways (France, PECAN)

Fast Track & Early Access Pathways:

Countries are converging in **enabling early access of DMDs/DTx and evidence generation in a real-world setting:**

- For solutions that meet **technological and security prerequisites**
- For solutions that can **generate proof of value within a limited timeframes**
- For solutions that have **high potential for positive impact / address high-burden unmet needs**

Diverging Trends for DTx

Differentiation by intended purpose:

- Differentiated pathways for devices with **therapeutic vs. monitoring** intended purpose (France)

Differentiation by risk class:

- Differentiated pathways for **level of risk class** (Germany, Belgium)

Centralized vs. local Pricing & Reimbursement:

- While in Germany and France, the assessment and P&R process takes place at the national level, in England local NHS organizations play a leading role in funding and reimbursing DHTs, although the evolving scenario suggests more national-level indications might be forthcoming.

Generally, while HTA have increasing elements of possible harmonization; procurement, pricing, and reimbursement models are nation–specific.

Source: Healthware, Digital Medicines Actionable Insights Database (AID), last updated 1° June 2023

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System Integration & Scale-up Readiness
Our considerations

- Adequate and fit-for-purpose appraisal criteria and access policies are essential to enable equitable access to DMD/DTx.
- However, for DMDs and DTx to be effectively integrated and adopted across health systems and care pathways, also **system readiness** in terms of, for example, **infrastructural technologies**, **enabling processes**; and **people's capabilities and culture** are key enablers for effective systemic adoption and impact.

- **Infrastructure readiness: important to enable equitable and seamless access to DMDs/DTx, systemic uptake and value from data generated.**

For example: widespread internet connectivity; e-prescriptions processes for DMDs/DTx; access to DMDs/DTx via EHRs; interoperability and integration of data generated via DMDs/DTx within national/regional platforms to effectively support person-centered care; reduced access barriers for HCPs and Patients and seamless user experiences in prescription, download and activation.

- **Procedural readiness: important to integrate DMDs/DTx within care pathways and workflows.**

For example: integrating DMD/DTx in care pathways and workflows; low access barriers for HCPs and Patients and seamless user experiences in prescription, download and activation.

- **Cultural readiness: important to assure stakeholders engagement and equitable and adequate adoption of DMDs/DTx.**

For example: widespread digital culture, awareness and competences; multistakeholder and target population engagement across all development, evaluation and adoption phases of DMDs/DTx; widespread and OL engagement, training and upskilling of all stakeholders.

System Integration & Scale-up Readiness

System Readiness

	Infrastructure	Procedural	Cultural
Germany	**Evolving Scenario** ▪ Digitization of supply and admin processes ▪ DiGA and DiPA will be able to both write data to the electronic health records, EHRs (ePA), but also to read data from the ePA if and to the extent that this is necessary and useful for personalizing the DiGA/ DiPA	**Evolving Scenario** ▪ Digital health and care applications (DiGA and DiPA) set to become integral components of digitally supported care processes. ▪ Enhance DiGA accessibility and reduction of technical barriers for DiGA adoption ▪ E-prescriptions for DiGA ▪ Accessibility to DTx through EHRs	**Evolving Scenario** ▪ Strengthening of digital health competences ▪ Early engagement of target population in the development of a DIGA to improve quality & acceptance
France	**Evolving Scenario** ▪ Unique platform for digital health applications	**Evolving Scenario** ▪ Probable prescription of DMN via e-prescriptions	**Evolving Scenario** ▪ Evaluation of organizational impact and value for diverse stakeholders, complementary to the clinical value
England	**Evolving Scenario** ▪ RWD collection through a common infrastructure to enhance research uses with differentiated accessibility levels for institutional/research bodies and manufacturers	**Evolving Scenario** ▪ Smooth user experience for both patient and HCP access to prescribe, activate and use DMD/DTx	**Evolving Scenario** ▪ Engagement of all stakeholders in evaluating and defining adoption processes (es. HCPs, Patients, Procurement Officers) ▪ Training programmes for all stakeholders

Source: Healthware, Digital Medicines Actionable Insights Database (AID), last updated 1° June 2023

Fit-for-Purpose Appraisal Criteria: Current Use, Technical & Safety

Formal frameworks: Converging and Diverging Trends

Converging Trends

Relevance of target need and demonstration on how the DMD/DTx fits and generates value with respect to the standard of care, existing processes and stakeholders.

Technical quality and safety standards converge in being:

- **Specific** for DMDs/DTx, fit-for-purpose.
- Focus on: medical device **certification**, data **privacy**, **interoperability** and technical **stability and security**.
- Typically considered **prerequisites** for early access pathways/fast-tracks.

	DMD/DTx HTA Requirements - Dimensions	GERMANY	FRANCE	ENGLAND	BELGIUM
CUR	Target population, condition and standard of care	→	→	→	→
Technical (TEC) & SAFETY (SAF)	Certified Medical Device	→	→	→	→
	CE marked EU Medical Device Regulation (MDR) 2017/745	→	→	⇄	→
	GDPR compliance	→	→	→	→
	Local Data Privacy Requirements	→	→	→	→
	Data storage	→	→	→	→
	International Interoperability Standards	→	→	→	→
	HL7 FHIR Interface	→	→	→	→
	ISO/IEEE 11073 Standard	→	→	→	→
	SNOMED CT Standard	→	→	→	→
	Local Interoperability standards	→	→	→	→
	Technical stability	→	→	→	→

Source: Healthware, Digital Medicines Actionable Insights Database (AID), last updated 1° June 2023

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DIGITAL THERAPEUTICS ALLIANCE

Fit-for-Purpose Appraisal Criteria: Current Use, Technical & Safety

Formal frameworks: Converging and Diverging Trends

Converging Trends

- Application of **international interoperability standards** is a converging trend. It will be key for systemic value generation of DMDs/DTx and contribution to pan-European initiatives – as the **European Data Space**.
- **GDPR (Regulation (EU) 2016/679) compliance** is converging, local applications may differ and sometimes imply additional requirements – encouraging further harmonization, as recommended by the EU commission (2021) is desirable.
- **CE-mark** allows for EU-wide harmonization. However, England will eventually diverge with a local UKCA-mark.
- **Technical stability and data security standards** tend to converge.

Diverging Trends

- **Different national dossier structure and applications, in addition to often supplementary interoperability and cybersecurity requirements and dedicated applications** increase fragmentation and limit convergence in increasingly harmonizable HTA dimensions – impacting timely and equitable access to DMD/DTx.

	DMD/DTx HTA Requirements - Dimensions	GERMANY	FRANCE	ENGLAND	BELGIUM
CUR	Target population, condition and standard of care	→	→	→	→
Technical (TEC) & SAFETY (SAF)	Certified Medical Device	→	→	→	→
	CE marked EU Medical Device Regulation (MDR) 2017/745	→	→	⤭	→
	GDPR compliance	→	→	→	→
	Local Data Privacy Requirements	→	→	→	→
	Data storage	→	→	→	→
	International Interoperability Standards	→	→	→	→
	HL7 FHIR Interface	→	→	→	→
	ISO/IEEE 11073 Standard	→	→	→	→
	SNOMED CT Standard	→	→	→	→
	Local Interoperability standards	→	→	→	→
	Technical stability	→	→	→	→

Source: Healthware, Digital Medicines Actionable Insights Database (AID), last updated 1° June 2023

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Fit-for-Purpose Appraisal Criteria: Evidence of Value
Formal frameworks: Converging and Diverging Trends

CLINICAL VALUE: EVIDENCE STANDARDS

Converging Trends

Classification as:

- **Peer-reviewed proof of clinical value** required
- **RCTs** are currently the gold standard and preferred level of evidence for appraisal and reimbursement decisions.

However, the evolving scenario also shows that countries are defining:

- **Early access pathways/fast track processes with a Coverage with Evidence Development (CED)** kind of entry agreements, to allow for timely and equitable access to DMDs/DTx that meet technical and safety pre-requisites, while further evidence is generated also in a real-world setting.
- **Other possible evidence standards** are being explored to prove clinical value sufficiency and that can be more in line with the digital nature of the device (e.g. observational studies, platform trials, digital placebo and others).
- **RWD** appreciated, but lack of **widely established standards and guidelines** for study design, secondary use of health data and recognition for post-marketing monitoring purposes.

Diverging Trends

- Evidence is currently required to be generated locally and transferability often to be proven through supplementary local studies.

  Where appropriate, greater transferability of clinical evidence and joint clinical evaluations would be important to enhance harmonization, scalability, and accessibility. This approach would also be coherent with the new European Regulation on Health Technology Assessment (2021).

Source: Healthware, Digital Medicines Actionable Insights Database (AID), last updated 1° June 2023

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DIGITAL THERAPEUTICS ALLIANCE

Fit-for-Purpose Appraisal Criteria: Evidence of Value

Formal frameworks: Converging and Diverging Trends

HEALTH ECONOMIC & ORGANIZATIONAL VALUE

Converging Trends

- **DMDs and DTx often entail, enable, and depend on organizational aspects** and have organizational impacts, reflected in the **converging trend** of appreciating considerations relative to organizational impact.

Diverging Trends

- **Evidence of health economic value** is not always required, although it clearly supports P&R processes. Where required, **methodologies and standards may differ** across countries.

ETHICAL & SOCIAL ASPECTS

Converging Trends

- **Technical accessibility and usability testing** are converging in terms of required standards.
- Generally, **equitable accessibility and usability** should be guaranteed for all.
- **Considerations over equity implications** are appreciated.
- **Early-engagement of and endorsement by end-users** is appreciated.

An emerging trend, especially in Nordic countries, is that of appreciating considerations relative to **environmental sustainability** as part of HTA process.

Source: Healthware, Digital Medicines Actionable Insights Database (AID), last updated 1° June 2023

OUR INSIGHTS

Countries are increasingly acknowledging the value and importance of enabling equitable access to DMDs and DTx. While a patchwork of frameworks are evolving at the national and local level, common trends are also emerging.

Some of our key takeaways and highlights include:

- **Classification:** while a commonly applied nomenclature is lacking, there is general convergence in formally recognizing the category of **Digital Medical Devices in Europe** – as certified, clinically-validated, software-based medical devices. **DTx are a subset of DMDs**.
- **Dedicated access pathways**: there is cross-country convergence, especially amongst countries with more formal frameworks in place, in defining access policies for DMDs that include mechanisms of **early access/fast track processes with Coverage with Evidence Development (CED) mechanisms.**
- **Fit-for-purpose HTA appraisal criteria:** it is essential to define HTA criteria that account for the digital-nature of the medical device:
  - **Technical quality, safety, and usability standards** tend to converge and are often considered **pre-requisites** for early access pathways/fast-tracks.
  - Greater **transferability of clinical evidence and joint clinical evaluations** would be important to enhance harmonization, scalability and accessibility. This approach would also be coherent with the new European Regulation on Health Technology Assessment (2021).
  - The **value of RWD** and the role of DMD for generating RWD is generally appreciated; however, guidelines for adequate study design, secondary use of health data, and recognition of RWE for post-marketing monitoring purposes are needed.
- **Systemic adoption and value generation:** it is important to enable and support **system readiness**, requiring adequate infrastructure, effective, seamless and integrated processes and workflows, and enhancement of stakeholders' capabilities, engagement and activation and broader digital culture development.

Reach out to know more

Alberta Spreafico

MD Digital Health & Innovation,
Healthware Group

alberta.spreafico@healthwaregroup.com

Megan Coder

Chief Policy Officer & Founder,
Digital Therapeutics Alliance

mcoder@dtxalliance.org

Emilie Lopes-Fernandes

Program Lead,
Digital Therapeutics Alliance

emilie@dtxalliance.org

Kristin Milburn

Chief Marketing Officer & MD
Publications & Digital Health
Ecosystem, Healthware Group

kristin.milburn@healthwaregroup.com

Annex

- Glossary and Abbreviations
- DTA-HW DTx Policy Coalition

Glossary

To facilitate the reading of the following document, definitions of key terms are provided below

- **Medical Device (MD)**
  A medical device is any Instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for the diagnosis, therapy, control, or mitigation of disease or disability or for the study, replacement, or modification of anatomy or a physiological process and that does not achieve its primary intended action through chemical, immunological, or metabolic means, but whose function may be assisted by such means. In Europe, medical devices are regulated by the MDR EU 2017/74534.

- **Digital Health Technology (DHT)**
  Apps, programs, and software used in the health and social care system. They may be standalone or combined with other products such as medical devices or diagnostic tests.

- **Digital Therapeutics (DTx)**
  A digital therapeutic (DTx) is a health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health.

- **Health Technology Assessment (HTA)**
  The systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational, and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform policy decision making.

- **HTA Core Model ®**
  HTA Core Model ® is a registered trademark that offers a *methodological framework* for the production and sharing of HTA information. The model consist in three components with a specific purpose: the *ontology* with the aim of defining specific research questions within a hierarchical structure, a *Methodological Guide* to help answer research questions and a *common reporting structure* to present results in a standardized "question-answer pair" format.

- **Intended Use**
  The term "intended use / intended purpose" is the objective intent of the manufacturer regarding the use of a product, process, or service as reflected in the specifications, instructions, and information provided by the manufacturer.

- **Real-World Data (RWD)**
  Real-world data are the data relating to patient health status and/or the delivery of healthcare routinely collected from a variety of sources.

- **Real-World Evidence (RWE)**
  Real-world evidence is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD. RWE can be generated by different study designs or analyses, including but not limited to, randomized trials, including large simple trials, pragmatic trials, and observational studies (prospective and/or retrospective)..

Abbreviations

- **AiSDeT,** Associazione italiana di Sanità Digitale e Telemedicina, Italy
- **ANS**, Agence du numérique en santé, France
- **APIs**, application programming interfaces, UK
- **ASSD,** Associazione Scientifica per la Sanità Digitale, Italy
- **BfArM**, Federal Institute for Drugs and Medical Devices, Germany
- **CEPS**, Pricing is negotiated with Economic Committee for Health Products, France
- **CGTS**, Health Terminology Release Centre, France
- **CI-SIS**, Interoperability Framework for Health Information Systems, France
- **CNEDiMTS**, National Committee for the evaluation of medical devices and health technologies, France
- **COPD**, Chronic Obstructive Pulmonary Disorder
- **DiGA**, digitalen Gesundheitsanwendungen, Digital Health Applications, Germany
- **DIGAV**, Digitale-Gesundheitsanwendungen-Verordnung, Digital Health Applications Regulation, Germany
- **DiPA**, Digitale Pflegeanwendungen, Digital Assistance Applications, Germany
- **DMN**, dispositif médical numérique, France
- **DTAC**, Digital Technology Assessment Criteria, England
- **EHIF**, Estonian Health Insurance Funds
- **EHRs**, Electronic Health Records System, UK
- **ESF**, Evidence standards framework, England
- **ePA**, *electronic patient* record, Germany
- **EVA**, Early Value Assessment, England
- **FAHMPH**, Federal Agency for Medicines and Health Products, Belgium
- **FINCCHTA**, Finnish Coordinating Center for Health Technology Assessment
- **GDPR**, General Data Protection Regulation
- **GKV-SV**, National Association of Statutory Health Insurance Funds, Germany
- **HAS**, Haute Hautoritè de la Santè, France
- **HCPs**, Healthcare professionals
- **HDS**, Hébergeur de Données de Santé, France
- **HL7 FHIR**, Fast Healthcare Interoperability Resources
- **HTA**, Healt Technology Assessment
- **ISO/IEEE**, Institute of Electrical and Electronics Engineers, Inc
- **LATM**, Liste des activités de télésurveillance médicale, France
- **LPRR**, Liste des produits et prestations remboursables, France
- **MDR**, Medical Device Regulation
- **MOH**, Dutch Ministry of Health, Welfare and Sport
- **MPA**, Medical Product Agency, Sweden
- **NHS**, Nation Health Service UK
- **NICE**, National Institute for Health and Care Excellence, England
- **NIHDI**, National Institute for Health and Disability Insurance, Belgium
- **NordDEC**, Nordic Digital Health Evaluation Criteria
- **P&R**, price and reimbursement
- **PECAN**, Prise en Charge Anticipée Numerique, France
- **PREMs**, patient reported experiences measure
- **PROMs**, patient reported outcomes measure
- **RCTs**, Comparative prospective studies
- **RWE**, Real World Evidence
- **SIT,** Società italiana Telemedicina
- **UKCA mark**, UK Conformity Assessment

DTA-HW DTx Policy Coalition
Mission & Vision

- The DTx Policy Coalition, envisioned and guided by the Digital Therapeutics Alliance and Healthware Group, aims to:
  - **Engage** ecosystem stakeholders to share perspectives, understand needs and scalable experiences
  - **Provide** clarity on existing and evolving nomenclatures, policy frameworks and appraisal criteria
  - **Identify** areas of potential convergence and harmonization across countries in Europe
  - **Inform and advocate** for policies that enable equitable access to DTx
  - **Support** the development of an environment which ensures equitable access to safe and effective DTx to patients and HCPs across Europe