OPEN HEALTH

Assessing Digital Health Technologies, Including Digital Therapeutics (DTx), Across the Four Biggest European Markets

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Introduction

Since we released our last white paper on digital therapeutics (DTx) in Europe, much has changed on the landscape. Several European countries have established new assessment frameworks and evidence requirements for the evaluation of digital health products, including DTx. In this paper, we provide an overview of such frameworks and briefly discuss current DTx reimbursement policies.

Let's start by defining DTx: these are **medical devices that deliver evidence-based therapeutic interventions** 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, other devices, or other therapies to optimize patient care and health outcomes.

As described in the new European Union (EU) medical device regulations[1] and as further detailed in Germany's 2019 Digitale Gesundheitsanwendung (DiGA) regulation,[2] a DTx product "is not a digital application that serves only for the collection of data from a device or for controlling a device… *the medical purpose must be achieved through the main digital functions*."[2]

Now let's look at some relevant legislative developments at the EU level. Besides the new medical device regulation that defines and categorizes DTx,[1] the brand-new EU pharma strategy prioritizes digital health infrastructure in its objectives. One of the key pillars of the strategy is the revision of the EU pharmaceutical legislation.[3] The new pharmaceutical legislation aims to introduce elements of flexibility that allow adaptability to the new innovative ways medicines are developed and evidence is generated. The legislation should consider new possibilities in areas such as **digital and personalized medicine** and the **interplay of medicines and medical devices**. Options shall consider adaptations to the current authorization system, the possibility of new regulatory pathways, and the opportunity to change the scope of the centralized application procedure for innovative products.[3]

Thus far only a few countries in Europe (namely Germany, the UK, France, Belgium, and Sweden) have introduced detailed DTx policies. Among them, Germany and the UK were the first to pass legislation and issue guidelines specific to digital health products. These countries were also the first to introduce specific assessment frameworks for them, including DTx.

In this paper, we consider current or proposed assessment frameworks across the four biggest European countries: Germany, the UK, France, and Italy. We place particular emphasis on Germany, as it was the first country to focus on DTx products and invest in their integration into the healthcare system.

Assessment of DTx across major EU countries

Germany

In December 2019, the German Ministry of Health implemented the Digital Healthcare Act (Digitale Versorgung Gesetz, DVG),[2] which stipulates that digital health applications (Digitale Gesundheitsanwendung, DiGAs) are medical products and can be prescribed by doctors as well as be reimbursed by the statutory health insurance funds (*Krankenkassen*).[2] To be granted reimbursement, digital health applications need to be successfully assessed by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) and subsequently listed in a dedicated DiGA directory. As of May 2020, manufacturers can apply for approval. An overview of the application process is displayed in Figure 1.

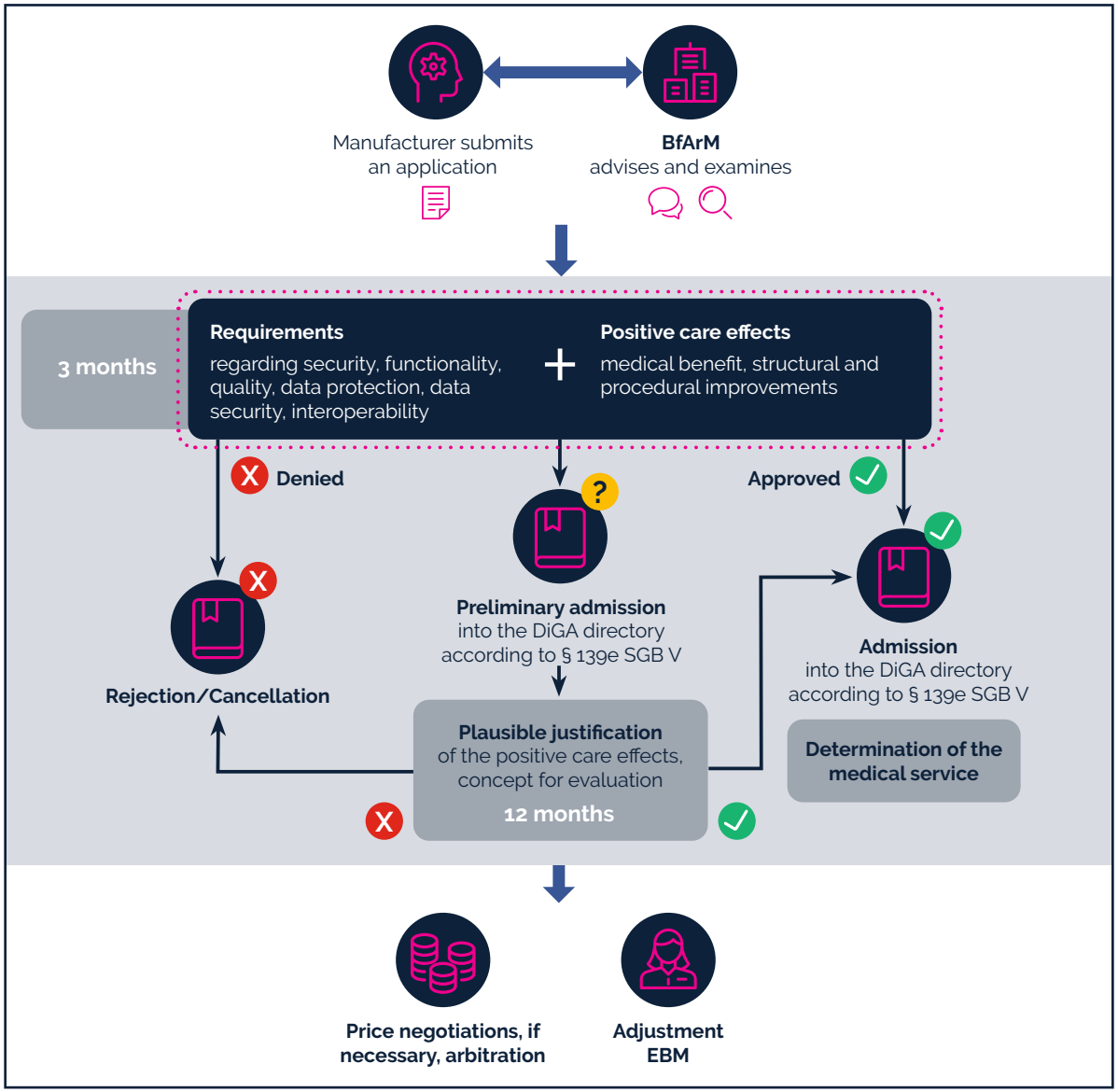


Figure 1: *BfArM application process*

Assessment of DTx across major EU countries (continued)

An important part of the application process is fulfilling the criteria detailed in the DiGA guideline[4] that permit listing a health application in the DiGA directory (Figure 2.). These criteria fall into two groups:

1. Requirements regarding **security, functionality and quality**, and **satisfaction of privacy and data security concerns** in line with national laws and the General Data Protection Regulation (GDPR),[4] and
2. Requirements regarding **evidence for patient-relevant benefits** in terms of medical benefit and/or care delivery.[4]

The first group of criteria (left side in Fig. 3) assess compliance with general requirements—that is, those not strictly health-related—such as more technical requirements, including those pertaining to CE marking (in line with the new EU regulations on medical devices), privacy, security, interoperability, safety, and overall quality.

The second group (right side in Fig. 3) assesses the effectiveness and impacts of DTx products. In this second group of criteria, we have two main components:

- **Structural and procedural effect assessment.** The criteria here consider healthcare system impacts, such as how the DTx product will affect burden of illness, standard of care, access to care, adherence, and patient safety. Here app developers are invited to submit healthcare system–related data such as epidemiology of the disease of interest, impact on the healthcare system, and behavioral research data. The most innovative aspects of the products listed focus on data generation methods and sources, with *real-world evidence* and *real-time data* that can be collected through the app itself being at the core (bottom left in Fig. 3).
- **The medical benefit assessment** looks at clinical outcomes, such as morbidity, mortality, quality of life, and adverse effects. The data required are in line with the requirements for pharmaceutical products, whereby the classical pyramid of evidence requirements for medical benefits includes *systematic literature reviews* and *randomized controlled trials* in first and second place, respectively (bottom right in Fig. 3).

Figure 2: *Criteria for DiGA assessment in Germany*

Assessment of DTx across major EU countries (continued)

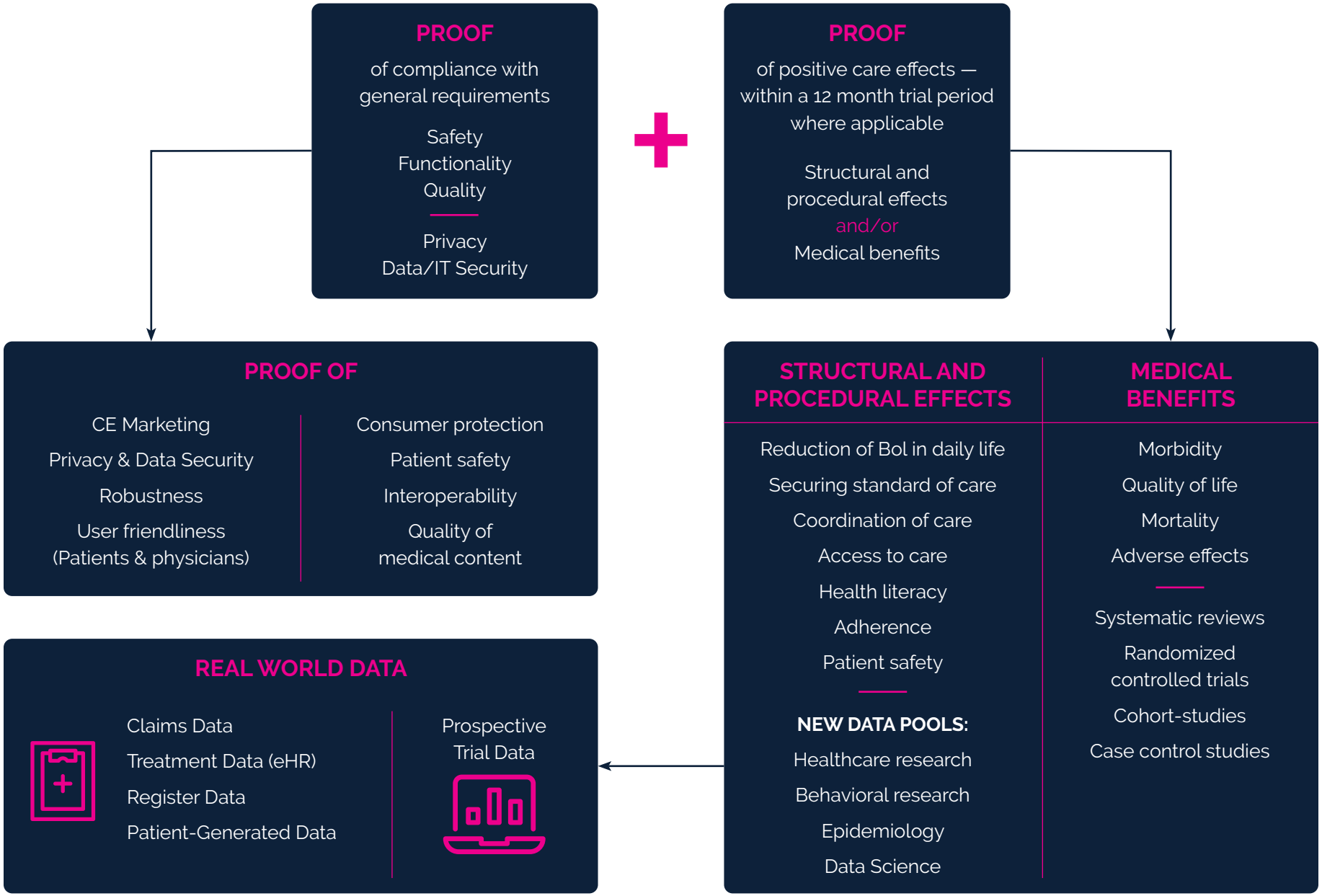


Figure 3: *Details of criteria for DiGA assessment*
Adapted from Health Innovation Hub: DVG–A Summary of Germany's New Law for Digital Health (2020)[4]

Assessment of DTx across major EU countries (continued)

Pricing and reimbursement

Following the listing of the product in the DiGA directory, reimbursement consists of two phases:[5]

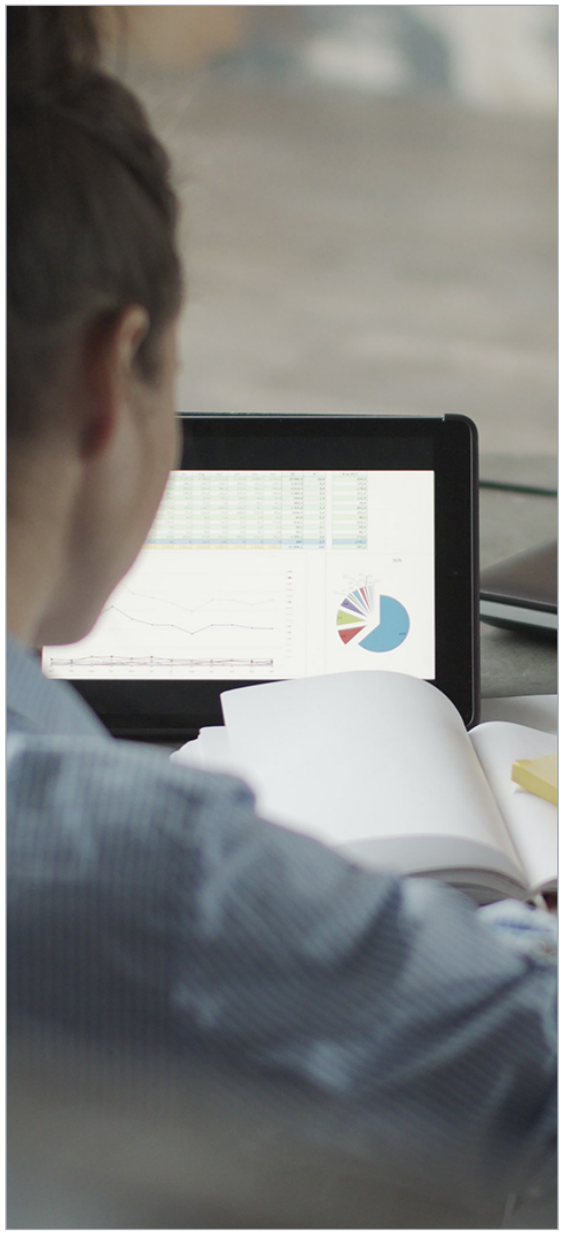
1. Manufacturers receive the ***actual price*** 12 months after the product's inclusion in the DiGA directory.
2. Manufacturers receive the ***renumeration sum*** starting from month 13 onward.

As of April 2021, a master agreement regulating the determination of actual prices, arbitration board procedures and costs, billing rules, and the negotiation procedure between manufacturers and the National Association of Statutory Health Insurance Funds (GKV-SV) is available.[5] Negotiations start six months after approval or as soon as evidence collection is completed for preliminarily approved DiGAs and should be completed after six months. Of note, an upcoming law may shift the beginning and total duration earlier.[6]

The actual price consists of the sales price as set freely by the manufacturer, corrected for average discounts, granted three months prior to application submission to BfArM.[5] Optional non-reimbursable services, functions, or hardware cannot be considered. The price will most likely range within maximum and threshold amounts, which are currently being negotiated.[6]

The actual price will be published in the DiGA directory, and the manufacturer has the opportunity to change it one time during the following 12 months.[5] For the renumeration sum, prices for identical apps in other European countries, if available, will be considered. Furthermore, generated evidence for medical or structural benefits, proof of quality and CE-conformity, the price for private payers, and the number of activations/prescription codes will play a role in the negotiations. Optionally, further studies, insights from real-world data, and usage data can be submitted. If negotiations fail, an arbitrations board will be involved.[5]

The GKV-SV raised concerns regarding the high prices of the DiGAs. The first ten ranged between €117 and €744, with most of them costing €400 to €500.[7] This may lead to a higher financial burden for insurance funds and payers. Consequently, the GKV-SV positions itself against freely set prices in the first year, or alternatively, demands maximum prices.[8] On the other hand, manufacturers argue that increased prices are linked to greater investments for fulfilling DiGA requirements and restrictions on advertisements in their apps.[9] Decisions on this matter are expected in the coming months.



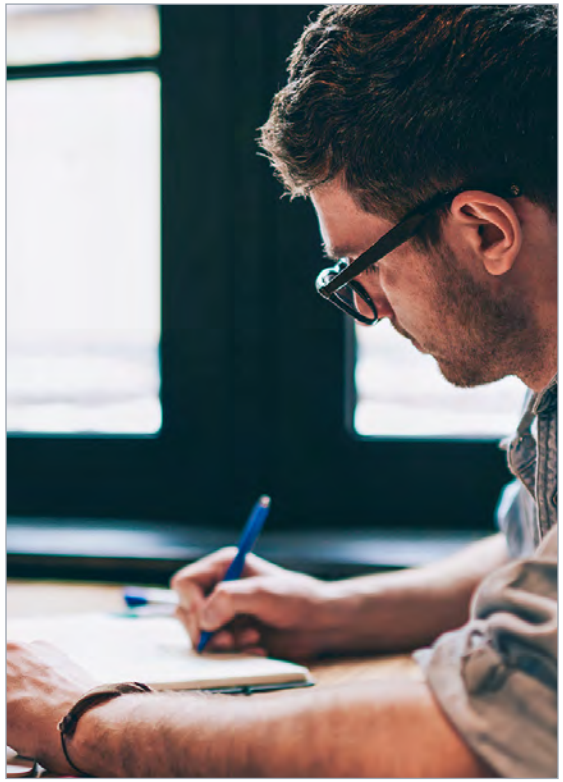
Assessment of DTx across major EU countries (continued)

Learnings from the first HTA submissions and DiGAs' arrival in care pathways

As of August 2021, BfArM had received 89 DiGA applications, of which 64 were filed for preliminary admission and 25 for final admission.[10] Four applications were rejected and a remarkable 42 applications were withdrawn by manufacturers. Twenty DiGAs successfully passed BfArM's assessment and were listed in the DiGA directory as of August 2021.[11] Of these, five DiGAs received final approval, whereas the remainder are listed preliminarily. Most manufactures (79%) submitted traditional randomized controlled trials as evidence.[10] Other study types were retrospective studies, registry studies, and prospective studies. Driving the large number of withdrawals and rejections were the quality of submitted or planned evidence and inadequate systematic data analysis. BfArM indicated that sample size and trial duration were insufficient, that pre-specification of study endpoints and study protocols was missing, or that studies of other, comparable apps were submitted.[10,12,13] In addition, postulated positive care effects have not been analyzed. Other reasons included incomplete submission or unsatisfactory data privacy and security measures. In such cases, it is likely beneficial to avoid an official rejection and potential loss of investors.[13] One of the issues may be a remaining lack of clarity in terms of required evidence, despite the involvement of scientific institutes for study concepts and the availability of a comprehensive guide published by BfArM.

Another important factor determining the success of DiGAs is uptake by patients and physicians. A survey among physicians from November 2020, a month after the first listings in the DiGA directory, revealed that every fourth physician would prescribe DiGAs, while approximately a third of the participants were opposed to integrating them into care.[14] Reasons included data privacy concerns, mistrust of the technology, or lack of information. An information deficiency was further substantiated by the proportion of physicians who were unsure whether to prescribe DiGAs in the future (15%) or did not know what DiGAs were (10%). A survey among patients from spring 2020 showed more optimism for DiGAs: approximately 60% of the participants could imagine using DiGAs.[15] However, the number was only 51% a year later.[16] Furthermore, prescription numbers show a slow uptake. An estimate of 3660 access codes was made available three months after the approval of the first DiGAs.[17] As of August 2021, the numbers increased to approximately 20 000.[10]

Altogether, more information and training for all stakeholders involved may be required for the future success of DiGAs. Manufacturers may benefit from increased transparency of BfArM's submission review and need to find a way to increase physician and patient trust in their products. Lastly, it would be of high interest to know whether physician and patient acceptance increases with a greater number of DiGAs listed and more experience with them.



Assessment of DTx across major EU countries (continued)

England

In England, the NHSx is the body designated to develop sound policy frameworks and standards for digital technologies that will be integrated in the National Health System (NHS). In 2021, NHSx published the The Digital Technology Assessment Criteria for Health and Social Care (DTAC), which sets new national baseline criteria that digital health products must meet to be allowed acceptance into the NHS.[18] The assessment criteria are divided into five core areas (Fig 4.):

1. **Clinical safety:** baseline clinical safety measures are in place and the organizations undertake **clinical risk management** activities.
2. **Data protection:** data protection and privacy are **"by design"** and the rights of individuals are protected.
3. **Technical assurance:** products are **secure and stable**.
4. **Usability and accessibility:** products have a **conformity rating** derived from being benchmarked against good practice and the **NHS service standard**.
5. **Interoperability:** data are **communicated accurately and quickly** while staying **safe and secure**.

Digital health products must meet these five criteria to be accredited by the NHS and listed in the NHS Apps Library. All criteria but usability and accessibility are assessed with a simple pass or fail (Fig. 4).

In addition to these five general criteria, **NHSx** worked closely with the National Institute for Care Excellence (NICE) to develop an evidence standards framework for DTx.[19] The framework, developed in 2019 and updated in 2021, describes the level of evidence needed to **demonstrate effectiveness and value based on a functional classification (tier system: A, B, and C; Fig. 5)**.

DTx products fall under the highest evidence requirement section, namely **tier C**, as they classify as interventions that aim to achieve one or more of the following objectives: change patients' behavior, improve self-management, and treat symptoms or diseases (Fig 5.).

On top of the classification, the framework of assessment describes the type of evidence required; a more detailed overview is available in Fig. 8. Two main types of standards can be distinguished:

1. **Effectiveness standards:** they assess clinical evidence obtained through *quasi-experimental or experimental studies* and/or *randomized controlled trials*.
2. **Economic impact standards:** they assess economic evidence obtained through *cost-consequence analysis, budget impact analysis*, or *cost-utility analysis* (required only if the technology is expected to have a substantial financial impact on the NHS).

THE 5 SECTIONS OF DTAC

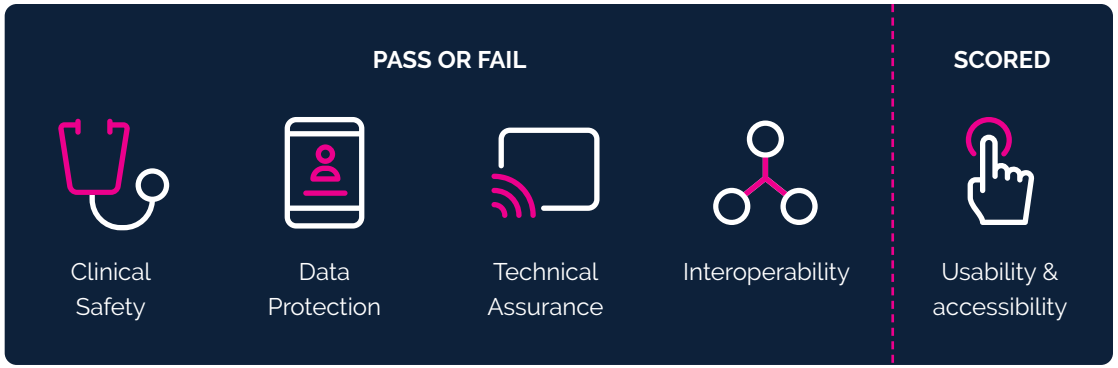


Figure 4: *NHSx: Five assessment criteria for digital health technology assessment*

Assessment of DTx across major EU countries (continued)

TIER C: INTERVENTIONS

Preventative behavior change

Address public health issues: smoking, eating, alcohol, sexual health, sleeping and exercise

Self-manage

Allows people to self-manage a specified condition. May include behavior change techniques

Treat

Provides treatment.

Guides treatment.

Active monitoring

Tracking patient location, using wearables to measure, record and/or transmit data about a specified condition. Uses data to guide care.

Calculate

A calculator that impacts on treatment, diagnosis or care

Diagnose

Diagnoses a specified condition

Guides diagnoses

TIER B: UNDERSTANDING AND COMMUNICATING

Inform

Provides information, resources or activities to the public, patients or clinicians. Includes information about a condition or general health and lifestyle.

Health diaries

Includes general health monitoring using fitness wearables and simple symptom diaries

Communicate

Allows 2-way communication between citizens, patients or healthcare professionals.

TIER A: SYSTEM IMPACT

System services

DHTs with no measurable patient outcomes but which provide services to the health and social care system

Figure 5: *NICE functional classification of digital health technologies*

Assessment of DTx across major EU countries (continued)

France

Digital health products including DTx fall within the category of "connected medical devices"[20] and are funded through the standard pricing and reimbursement procedure for medical devices, which closely mirrors the process for pharmaceutical products.[20] The assessments are performed by the French Economic Committee for Health Products **(CNEDiMTS)** and fall within the broader medical devices assessment procedure. Once assessed, products can be officially registered in the list of procedures and services reimbursed by the health insurance (the so-called LPP).[21] The assessment follows a two-step process beginning with a technical component for the determination of clinical value and innovativeness and—assuming if the DTx product is determined to have sufficient clinical value—price negotiation (Fig 6.):

1. **Technical assessment** by CNEDiMTS, which is divided into two parts:
   - **a)** An assessment of the **actual clinical benefit (ACB),** and
   - **b)** An assessment of the **clinical added value** in comparison with available therapies and the number of patients who might get benefits from the device.
2. **Tariff fixing:** The Economic Committee for Healthcare Products (CEPS) **sets a tariff** for reimbursement by the Ministry of Health, in negotiation with the manufacturer.
   - If necessary (based on the price and overall costs to the healthcare system), CEPS can ask to receive a medico-economic dossier, which will be assessed by CEESP.

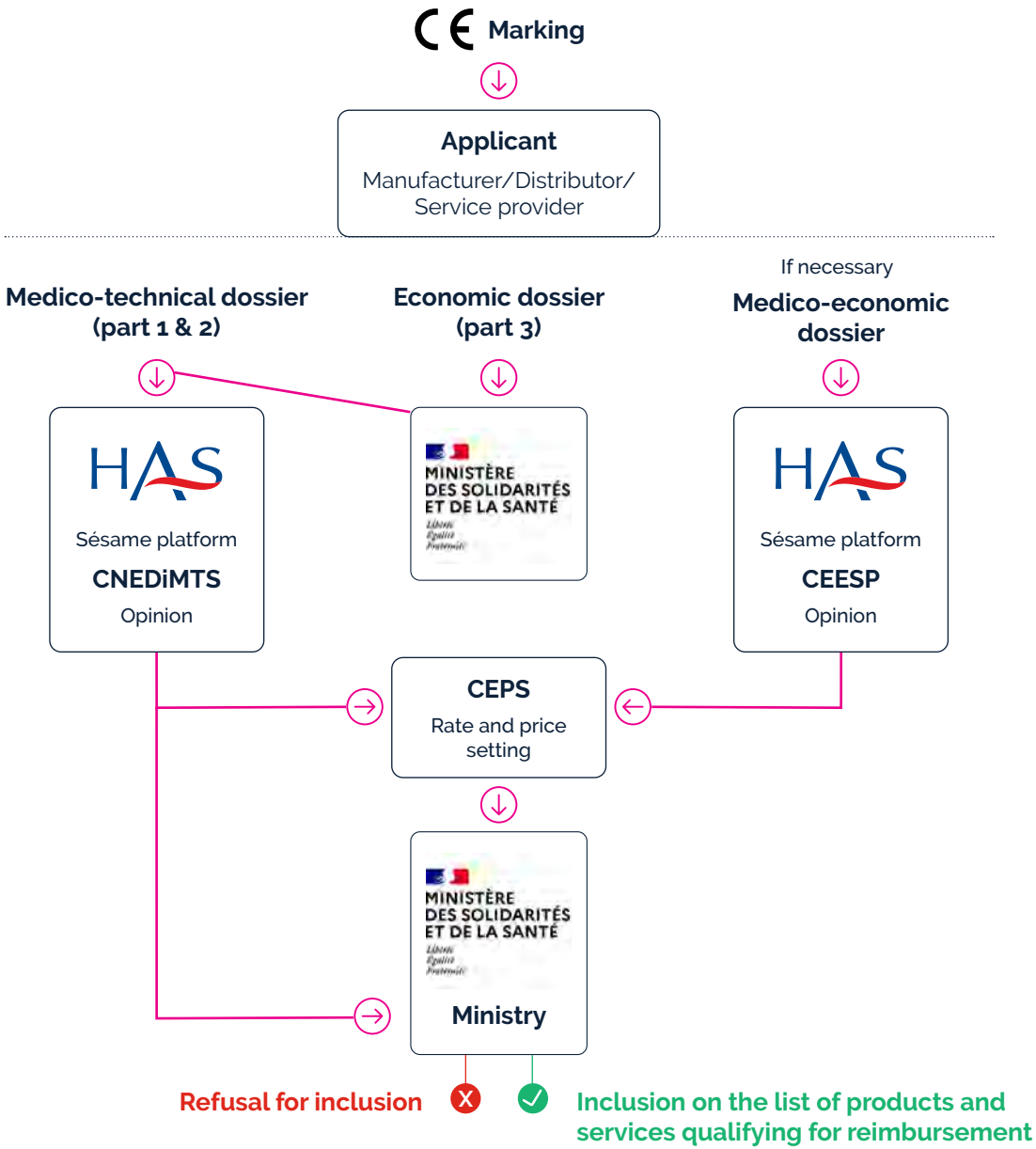


Figure 6: *Medical devices assessment pathway (including DTx) in France*

Assessment of DTx across major EU countries (continued)

Let's take a closer look at the first phase, technical assessment. In 2019, CNEDiMTS published Assessment of Medical Devices: Assessment Principles Established by the Medical Device and Health Technology Evaluation Committee (CNEDiMTS) to Determine the Reimbursement Eligibility of Medical Devices for Individual Use.[22] The document has a section on *"connected medical devices."* For these technologies, the regulatory assessment criteria are the same as for other medical devices. CNEDiMTS conducts a medical-technical evaluation that is initiated only when the submitted connected medical device satisfies the following four criteria:

1. Intended for use for medical purposes

2. Intended for individual use

3. Includes a telecommunication function

4. Accompanied by an application for reimbursement

Connected medical devices that satisfy the aforementioned basic requirements can then undergo the process of determining actual medical benefit. The principles that govern such assessment revolve around the product's benefits to patients and public health (Fig.6):

- The analysis of a **product's actual clinical benefit** includes analysis of the clinical evidence, in particular:
  - The product's place in the therapeutic, diagnostic, or disability compensation strategy, given all the other available therapies or diagnostic or compensation methods as determined through an examination of data found in the literature (in *SLRs, meta-analyses, etc.*)
  - Its therapeutic, diagnostic, or disability compensation effect, as well as undesirable effects or risks associated with its use, and—particularly for connected medical devices—the improvement of users' quality of life (as determined through *clinical trials*)
- The analysis of the **public health benefit** includes the analysis of the clinical added value, in particular:
  - The product's impact on the health of the population in terms of mortality, morbidity, and quality of life (determined through *epidemiological studies*)
  - Its capacity to address unmet needs, in view of the severity of the pathology or of the disability
  - Its impact on the healthcare system
  - Its impact on public health policies and programs

The difference between connected medical devices and traditional medical devices is primarily the post-registration phase. Connected medical devices can have specific characteristics related, **in particular, to** their very rapid technological development, their interaction with other devices/objects/platforms, and the algorithms on which their operation is based. Therefore, for as long as technology is evolving, the CNEDiMTS can request post-registration studies to be set up. These studies are used to confirm the benefit of digital health products in real-world use.[22]

Assessment of DTx across major EU countries (continued)

Italy

In Italy, there are yet no official frameworks or policy actions targeting the assessment and reimbursement of digital health products, including DTx. Nonetheless, there are active discussions ongoing for innovative legislations for reimbursement of digital therapeutics, particularly in relation to the **National Chronicity Plan**.

A recent white paper published by the Smith Kline Foundation looks at how DTx and digital health products in general can be integrated in the Italian healthcare system and proposes a framework for DTx assessment and integration.[23]

The white paper proposes that Italy adopt **HTA measures as has the UK (see the NICE evidence standards discussed above**). The proposal recognizes that traditional methods of evidence development are not necessarily applicable to DTx, primarily due to the rapid development times needed to reduce the risk of DTx obsolescence and due to the peculiarities of DTX that need to be considered in the study design phase (e.g., flexibility for minor software updates throughout the study period). Despite this, the proposal recommends the adoption of **randomized controlled clinical trials** as the standard for the assessment of statistically significant effects (Fig. 7). The proposal also suggests recognizing the potentially relevant role of real-world data evidence developed in real time through the apps as a key component in the assessment of DTx.

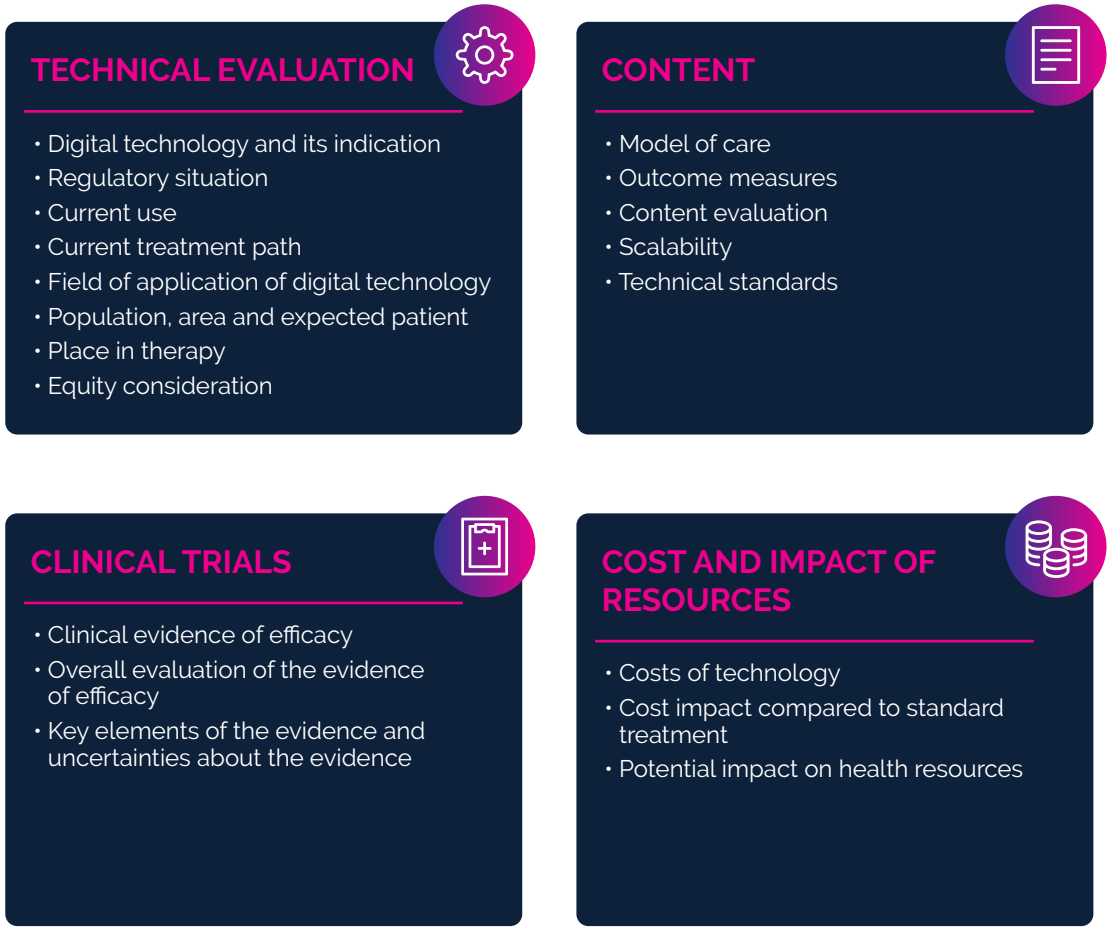


Figure 7: *Proposed DTx assessment criteria in Italy*

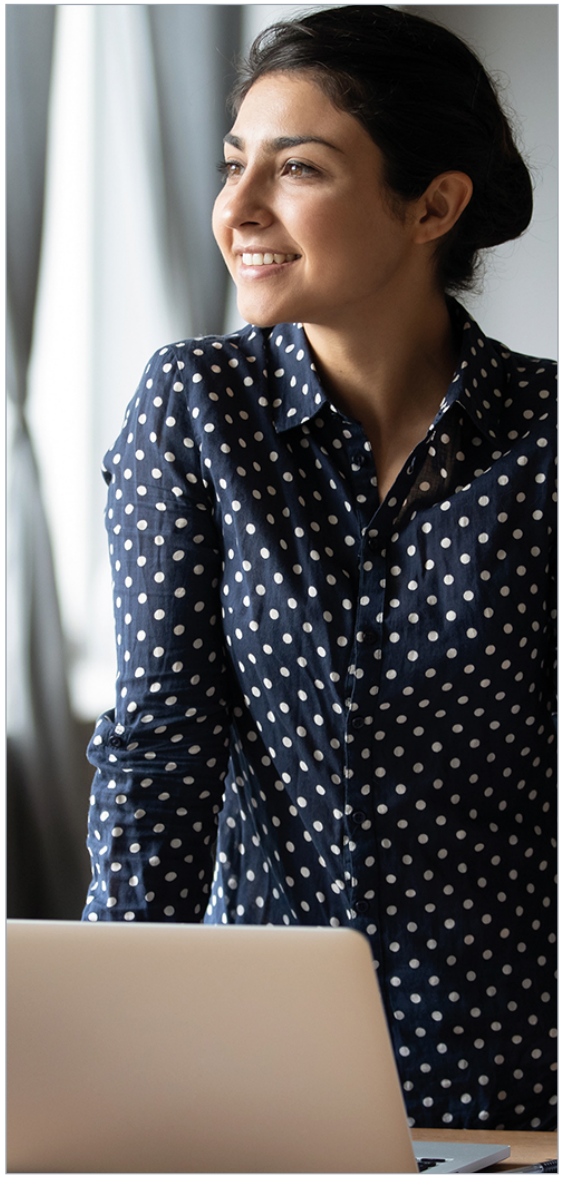
Comparison and conclusion

The COVID-19 pandemic has highlighted the need for more resilient and flexible healthcare systems worldwide. Digitizing healthcare systems is now a key priority for many countries and regions, including Europe, where efforts to integrate digital health products, including DTx, into the healthcare system are underway. Here we have analyzed assessment frameworks for digital health products and DTx across the four biggest European markets. Table 1 provides a summary of key stakeholders, HTA criteria, and current market entry scenario across these markets. Italy is the only one of the four that has not yet implemented any legislative or policy action for the assessment and integration of digital health products. However, there are active discussions taking place there now on how to assess and reimburse digital health products, including DTx.

Germany and the UK are arguably the two countries with the most advanced if heterogeneous frameworks for digital health products in place. Both countries have elaborated specific assessment criteria for digital health apps and particularly for DTx products. The minimum standards to demonstrate effectiveness in the UK, Germany, and France are high-quality observational or quasi-experimental studies that present comparative data. The best evidence generation options are randomized clinical trials presented alongside systematic literature reviews.

The main difference between Germany and the UK is the relevance of economic impact standards and cost-effectiveness evidence; these are required in the UK but not in Germany. France requires a medico-economic assessment only for products with significant financial impact. An interesting element that is present in the UK framework but not in the German one is the actual use and distribution of the product (top left Fig. 8). As we have seen previously, in Germany actual utilization of approved apps is a hot topic. Digital applications have had as yet little market penetration, only a handful of doctors prescribe them, and even fewer patients use them.

On the other hand, while in Germany and in France there is a single access point for reimbursement of digital health products at the national level, in the UK there is no national reimbursement pathway in place for digital health interventions. Several initiatives have been implemented to facilitate their integration, including The Innovation and Technology Payment (ITP) Evidence Generation Fund, which aims to incentivize the adoption of and centralize



Comparison and conclusion (continued)

funding of medical innovations deemed suitable for NHS-scale deployment, including digital health products.[24] The program ran from 2017 until 2021, and some of the most well-known apps reimbursed were MyCOPD, HeartFlow, and DrDoctor. It is still unclear how digital health products will be integrated into the NHS and reimbursed by it. One option is to integrate reimbursement through the NHS Supply Chain Operating Model (previously known as the New Operating Model), which was introduced into the NHS in 2018 to transform the way product procurement. The NHS Supply Chain aims to cover over 80% of NHS procurement by 2022 (up from 40%) and to become the national entry point for any product to be used widely throughout the NHS, including digital health technologies and DTx. At present, the developers of any digital health intervention are required to engage with local stakeholders within individual Clinical Commissioning Groups (CCGs) to secure funding. This seems to limit access to digital health products across the NHS and might disincentivize developers investing in the UK market.

Multiple countries have shown interest in the fast-track procedure established in Germany, as recently announced at a conference held by health innovation hub (hih).[10] Mostly European countries—e.g., France, UK, Italy and Spain, but also the US, Canada, China, and Israel—have requested detailed information on the DiGA fast-track procedure and its implementation. It was further mentioned at the conference that several European countries indicated ambitions for more harmonization in this field.[10]

We are now at a decisive moment for the transformation of healthcare. New digital health technologies, including DTx, promise to revolutionize the way we develop deliver, and value health innovations. Many countries around the globe are closely monitoring the developments in Germany, which is a front runner in the game. At OPEN Health, we will continue to actively engage in this essential discussion across the globe through our strong international network of professionals. We are happy to interact and work with all stakeholders. Feel free to contact us if you want to know more!

Comparison and conclusion (continued)

Countries	Relevant stakeholders	DHP/DTx-specific HTA	Technical evaluation	Clinical evaluation	Economic evaluation	DTx already approved	Centralized market entry
Germany	- BfARM (HTA) - GKV-SV (Price)	✓	✓	✓	X	✓	✓ DiGA
UK	- NHSx/NICE (HTA) - Local (Price)	✓	✓	✓	✓	✓	X
France	- CNEDiMTS (HTA) - CEPS (Price)	X	✓	✓	✓ §	✓	✓ LPP
Italy*	N/A	X	✓	✓	✓	X	X

Table 1: *Overview of assessment and access frameworks across countries*

*Only proposals; no active legislation yet in place. §Economic evaluation in France done only if the intervention would have a substantial financial impact on the system.

Abbreviations: DHP, digital health products; DTx, digital therapeutics

Comparison and conclusion (continued)

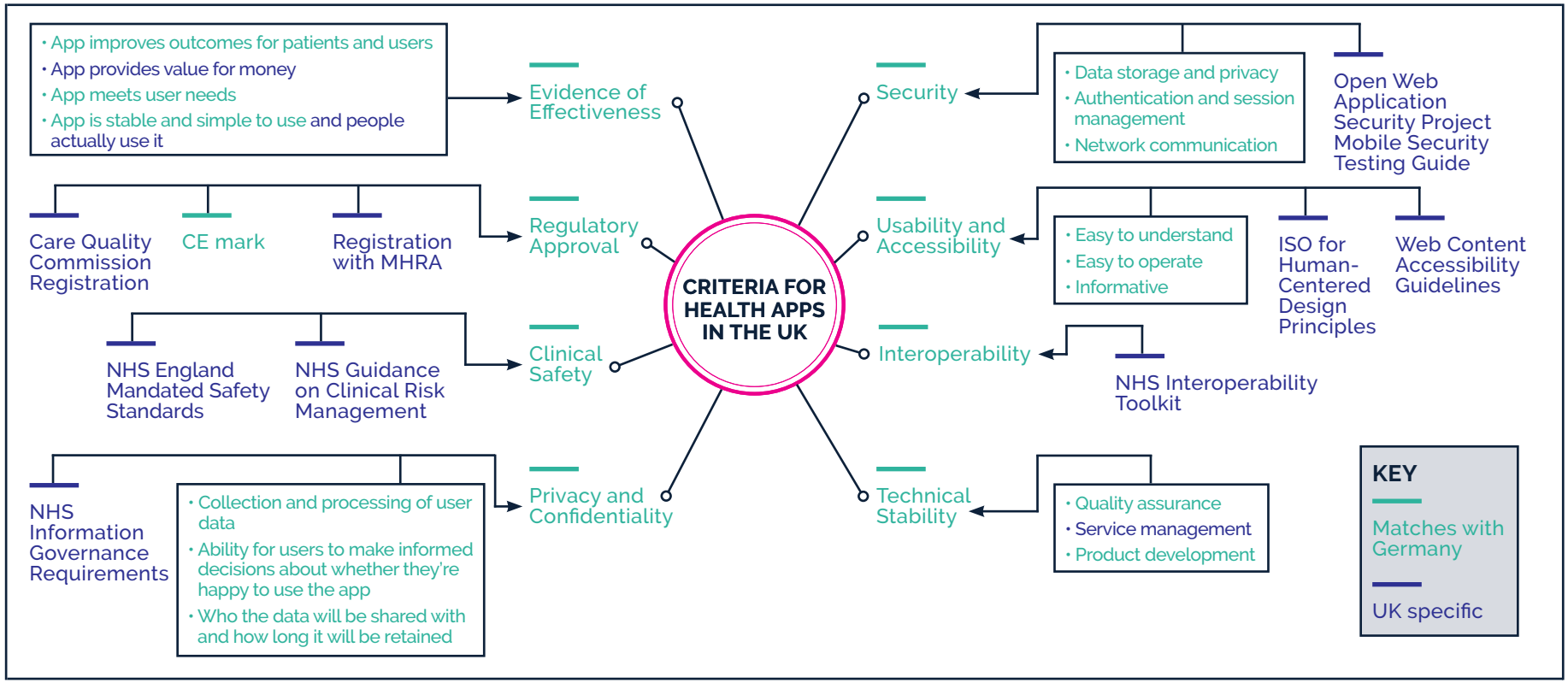


Figure 8: *Comparison of criteria for digital health products (including DTx) between the UK and Germany*

Abbreviations: ISO: International Organization for Standardization; MHRA: The Medicines and Healthcare Products Regulatory Agency; NHS: National Health Service

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Our global team of experts — many with PhD and PharmD degrees — work strategically alongside our client partners in Medical Affairs, Health Economics and Outcomes Research (HEOR), Market Access, and Commercial teams across a wide range of therapy areas.

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