OPEN HEALTH

# Digital Therapeutics Landscape in Europe:

## *The Cases of Germany and the UK*

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# Introduction

The COVID-19 pandemic is a global tragedy that has affected many lives. The general response to the outbreak comprised in many countries, among other things, a lockdown. The impact of the pandemic on public and social life is generally considered detrimental, but it has also clearly demonstrated opportunities and benefits of the use of digital solutions in healthcare around the globe.[1] For example, when the COVID-19 outbreak started, millions of people in China turned to online doctors and online health tools to find the needed support for their health.[1] The global upswing in willingness to use digital solutions represents an unprecedented opportunity to establish healthcare 4.0 for the benefit of patients.

It is anticipated that investments in digital health instruments, in particular digital therapeutics (DTx), will continue to accelerate after the COVID-19 pandemic, with an estimated market compound annual growth rate (CAGR) of 20,8% from 2017 to 2025. (see Figure 1).[2]

However, for the effective and safe proliferation of DTx, public institutions at all levels must create appropriate frameworks that ensure data privacy and protection.

The aim of this paper is to describe and analyze the current and developing institutional frameworks for the integration of digital health solutions into the healthcare system at the European Union (EU) level, in Germany, and in the United Kingdom (UK). Considering the relatively new fields of digital health, and DTx in particular, it is important to define them before continuing.

DTx fall within the broader field of digital health, which is defined in the World Health Organization (WHO) guidelines for digital interventions[3] as:

*"a broad umbrella term encompassing eHealth (which includes mHealth), as well as emerging areas, such as the use of advanced computing sciences in 'big data', genomics, and artificial intelligence."*

Many governments do not have a specific definition for DTx per se and DTx usually fall within the broader definition of digital health technologies or digital health applications. In the present paper, we refer to the German definition of digital health applications as defined in § 33a, book 5 of the German Social Security Code[4]: A medical product of a low-risk class in accordance with the Medical Device Regulation 2017/754[5] that relies on digital technologies and supports patients or healthcare providers in the detection, monitoring, treatment, or abatement of illnesses. Alternatively, it supports the detection, treatment, abatement, or compensation of injuries or disabilities.

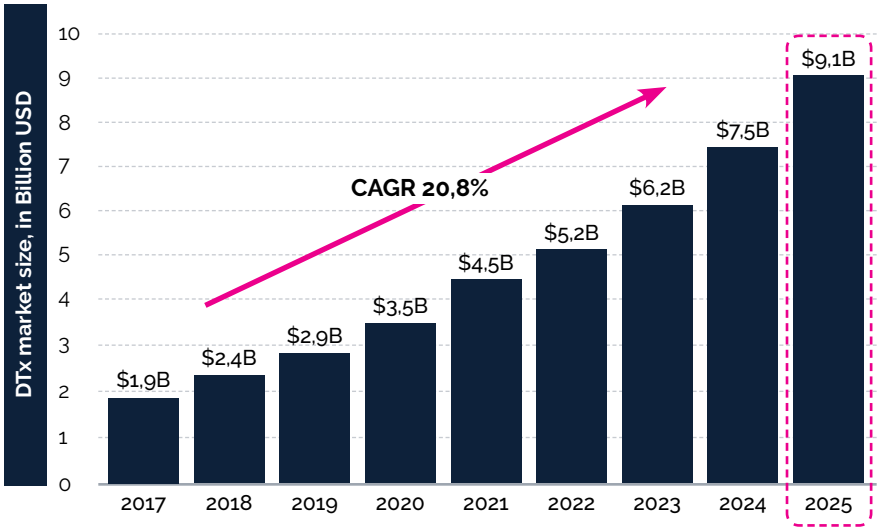


***Figure 1:*** *DTx market growth by 2025[2]*

**Abbreviations:** B, billion; CAGR, compound annual growth rate; DTx, digital therapeutics; USD, United States dollars

# Digital Transformation of Health and Care in the European Union

While respecting member states' responsibilities to define their own health policy and manage their own health services and medical care,[6] the EU is using hard and soft instruments to regulate and facilitate the digitalization of health and healthcare across member states.

First, under the new Medical Device Regulation (2017),[5] software applications can be categorized as medical devices if they meet certain medical purpose criteria defined in Art. 2. The regulation details new rules for determining the risk classification of medical devices, including Rule 11 that specifically addresses software. The directive imposes higher regulatory standards for medical devices than before, such as the involvement of notified bodies, stricter quality management system (QMS) and documentation requirements, and increased requirements for clinical trials.

Second, several policies have been implemented at the EU level to facilitate digital transformation of health and healthcare. One of the most important is the **Transformation of Health and Care in the Digital Single Market**[7] which, in line with the digital single market strategy,[8] gives direction and proposes specific actions to improve:

1) **Secure access and exchange of health data,**
2) **Pooling of health data for research and personalized medicine,** and
3) **Citizen empowerment and person-centered healthcare.**

Other relevant policies combine digital transformation objectives with the aim of addressing the issues related to an aging population. Relevant examples are:

- **The Blueprint for a Digital Transformation of Health and Care in an Ageing Society,**[9] which aims at innovating health and care provisions for the elderly, and
- **The Active and Assisted Living (AAL) program,**[10] which supports applied research on innovative information and communication technology (ICT)-based services for aging well.

Third, several initiatives involving a variety of stakeholders have been launched across the EU to stimulate and guide digital transformation of healthcare. A clear example is the **DigitalHealthEurope project**,[11] which coordinates information sharing, multi-stakeholder collaboration, and identification of best practices. The project also supports stakeholders with practical advice on EU funding instruments and financing resources. Another relevant initiative is the **EU mHealth Innovation & Knowledge Hub**.[12] This Europe-wide project aims to collect and share national experiences on digital health and to support countries and regions in setting up large-scale digital health programs.

# Digital Transformation of Health and Care in the European Union (continued)

Looking ahead, the current German presidency of the EU council promises to represent a turning point for the EU's public health and healthcare actions for digitalization.[13] Germany is the first country to have set up a national health technology assessment (HTA) and reimbursement framework for DTx, and have announced in their presidency program, among other things, the ambition to:

1) **Expand the EU's digital sovereignty** and
2) **Build a strategically well-positioned European healthcare industry.**[14]

It is very likely that priorities set during the German EU Council presidency in 2020 will remain priorities in 2021 under the two subsequent presidencies of Portugal and Slovenia, due to their collaboration in the "trio presidency" program.[15]

## GERMAN COUNCIL PRESIDENCY EVENTS (2020)

### SEPTEMBER

- **04** Towards a Common European Health Data Space in Times of COVID-19 Bottlenecks and Solutions From a Cluster Perspective
- **09** Presidential IT Directors Group Meeting

### NOVEMBER

- **04** Interprofessional Collaboration in the Health Sector in the Age of Digitalization
- **10** Health Innovation – the European Health Data Space and Real-World Evidence
- **11** High-Level Conference "Digital Health 2020 – EU on the Move"
- **12** Meeting of the European eHealth Network
- **20** Doctors Going Digital: How to Future-Proof Skills
- **23** Digital Health: NOW! Acting Jointly for a Digitised and Value-Based Healthcare in the EU
- **25** Digital Fundamental Rights in the EU: A Digital Code of Ethics for a New Era
- **26** 21st Century Challenges for the eHealth National Competence Centers in Europe

***Figure 2:*** *Events addressing digitalization in healthcare during the German EU Council Presidency in 2020*[16]

# Germany: Spearheading Patient Access to Digital Therapeutics

Germany has taken the lead in Europe in driving patient access to DTx. To accelerate the digital transformation of the German healthcare system to the benefit of the patient, the German Ministry of Health established the health innovation hub (hih)[17] in April 2019.[18] The hih is intended as a neutral platform to foster dialogue between all relevant stakeholders to align and strengthen innovation in the healthcare sector. Important themes of the hih are the implementation of electronic medical records, care digitalization, interoperability, the application of artificial intelligence, and the evaluation and assessment of health technologies. Another example of how various stakeholders in the German market are defining a framework for collaboration is the Health Reality Lab Network (HLaN),[19] which was established in April 2018. HLaN offers networking services to connect start-ups with companies or health insurers and promote cooperation. The aim is to reduce time to market and create long-term business relationships. Furthermore, HLaN provides financial support from public funds and helps developers with industry expertise, market tests, and the evaluation of their product regarding efficacy and user acceptance.

The greatest leap in the transformation of the German healthcare system and patient access to DTx was made when the German Ministry of Health implemented the Digital Healthcare Act in December 2019.[4] This act stipulates that digital health applications (*Digitale Gesundheitsanwendungen,* DiGa) are considered to be medical products and can be prescribed by doctors as well as reimbursed by the statutory health insurance funds (*Krankenkassen*). To be granted reimbursement within the statutory health insurance, digital health applications will need to be listed in a dedicated directory and developers will need to negotiate the price with the National Association of Statutory Health Insurance Funds (*GKV-Spitzenverband,* GKV-SV). The assessment and approval of the applications, as well as the administration of the directory, fall under the remit of the Federal Institute for Drugs and Medical Devices[20] (*Bundesinstitut für Arzneimittel und Medizinprodukte,* BfArM). With the broadening of its remit, the BfArM now acts as a HTA body for health applications, in addition to being a regulatory agency in the traditional sense.

# Germany: Spearheading Patient Access to Digital Therapeutics (continued)

To list of a health application in the BfArM directory for digital health applications (DiGA directory), certain criteria must be fulfilled,[21] such as:

- **Evidence for patient-relevant benefit** in terms of medical benefit and/or care delivery (i.e., structural and/or process improvements),
- **Specific requirements regarding security, functionality and quality** (e.g., CE-marking, interoperability, robustness, complying with consumer protection regulations, user-friendliness, quality of medical content, patient safety), and
- **Satisfaction of privacy and data security concerns** that fulfill national laws and General Data Protection Regulation (GDPR)[22] requirements.

The regulation[24] and guidelines[25] for the BfArM DiGa directory listing process further detail the criteria and are summarized in Figure 3. Of particular interest is that the regulation and guidelines further clarify how to generate evidence for the benefits claimed by developers. Evidence for both medical benefit and care delivery improvements can be provided by quantitative, controlled retrospective, or prospective studies as long as they meet internationally recognized scientific standards and are considered suitable for the demonstration of the claimed benefit.

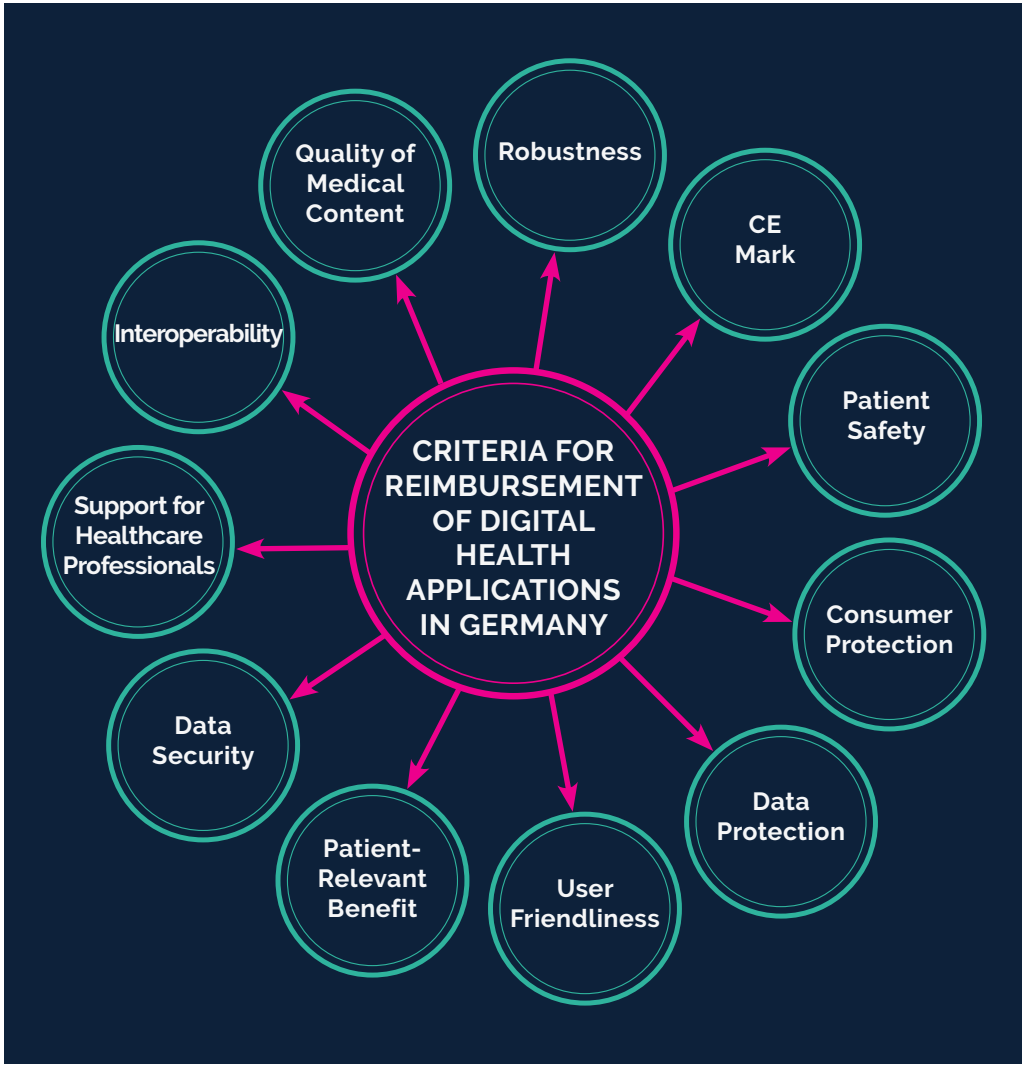


***Figure 3:*** *Criteria for reimbursement approval of digital health applications in Germany*

# Germany: Spearheading Patient Access to Digital Therapeutics (continued)

To ensure timely access for patients, digital health applications will undergo a so-called "fast-track" HTA,[24] (see Figure 4) which shows some similarities to the Act on the Reform of the Market for Medicinal Products (AMNOG)-based HTA for pharmaceuticals in Germany. For example, the "fast-track" allows a time window of 12 months after directory listing when the price can be freely set. This time window should be used by the developer to generate and submit evidence for patient-relevant structural or process improvements. (e.g., supporting measures related to treatment coordination, adherence and active patient participation in therapy, access to healthcare, alleviation of hurdles in everyday life due to illness, or relief of therapy burden.)[23]

As announced at the digital health application conference[25] on 22 April 2020, organized by the hih, the approval process for the first digital health applications began with the launch on May 2020 of the platform that is to be used by developers to apply for listing of their DiGa in the BfArM directory.

To date, only a small number of digital health applications are reimbursed by select statutory health insurance funds (*Krankenkassen*), because reimbursement has only been possible by means of individually negotiated contracts with each insurance fund.[26] An example is the logopaedic app neolexon,[27] which has partnerships with 52 out of a total of 105 public health insurance funds.[28]

The implementation of the Digital Healthcare Act will open a new market in both the digital and healthcare industry in Germany, paving the way for the development and application of many more DTx. In addition, the Digital Healthcare Act may serve as an example to other (EU) countries of how to manage patient access to DTx.

# Germany: Spearheading Patient Access to Digital Therapeutics (continued)

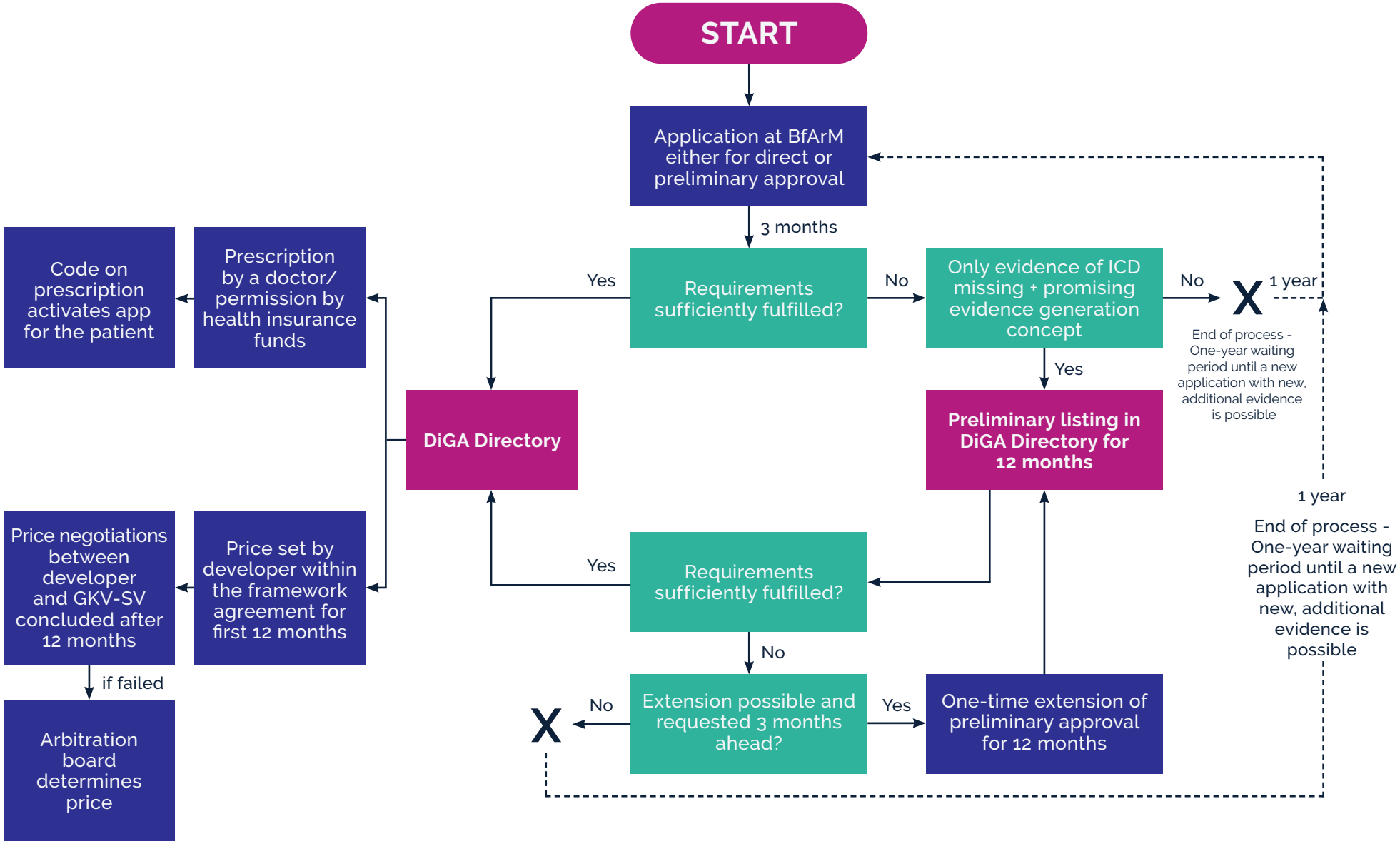


***Figure 4:*** *German "Fast-Track" reimbursement and pricing process for digital health applications*[30]

**Abbreviations:** BfArM: *Bundesinstitut für Arzneimittel und Medizinprodukte*; DiGa: *Digitale Gesundheitsanwendungen*; GKV-SV: *GKV-Spitzenverband*; ICD: Improved Care Delivery

# The UK: Accelerating the Digital Transformation of Healthcare

A second country that is on the front line of digital transformation in healthcare is the UK. In the UK, the DTx framework seems to be integrated within the broader National Health Service (NHS) efforts to digitalize the healthcare system, whereas in Germany a legal framework was established by the Ministry of Health. Nevertheless, in both countries the existing stakeholder collaborations are at the core of the structural implementation of DTx.

The newly formed NHSX organization is a joint unit of teams from the Department of Health and Social Care, NHS England, and NHS Improvement that is focused on driving digital transformation of health and social care.[30] NHSX reports directly to the Secretary of State and the Chief Executive of NHS England and NHS Improvement and aims to provide a clear national policy framework as well as clear standards and application programming interfaces (APIs) suitable for the NHS.[32] Moreover, the NHS[31] itself also actively supports innovations in healthcare for selected products.[32] The NHS Innovation Accelerator (NIA)[33] provides funding, mentoring, and networking opportunities for outstanding innovations with high impact. It is expected that the NIA could help save £38 million for the NHS by applying innovations at NHS sites,[32] further highlighting the recognition of the importance of digital innovations in healthcare by the NHS. Although there are clear differences in their composition and functioning, the NHSX and NIA seem to have similar roles as hih and HLaN in Germany.

NHS Digital[a] is another recently formed public body that evolved from the Health and Social Care Act 2012.[34] NHS Digital works in close collaboration with the Department of Health as well as NHS England to set standards regarding evidence of clinical safety, security, and technical stability.[35] It also assesses health applications and digital tools.[36]

Complementing the standards developed by NHS Digital, the National Institute for Health and Care Excellence (NICE) developed and published an evidence standards framework for digital health technologies in March 2019[38] as part of a working group led by NHS England and in collaboration with Public Health England and local and regional stakeholders.[39] The NICE criteria ensure that the digital health


[a]NHS Digital is the trading name of the Health and Social Care Information Centre (HSCIC), which was established in April 2013 by the Health and Social Care Act 2012.[35]

# The UK: Accelerating the Digital Transformation of Healthcare (continued)

technology is clear about its purpose, the benefits to patients and medical practitioners, and the outcomes it achieves. The evidence provided must also be grounded in the best and most up-to-date knowledge, derived from research, clinical experience, and patient preferences.

On a national, regional and local level, the following collaborations have also been established:

- **Academic Health Science Networks (AHSN)**,[39] nationwide networks aimed at spreading innovation at pace and scale
- **MedCity**,[40] a regional cluster organization that aims to accelerate life science initiatives and innovation
- **DigitalHealth.London**,[41] a collaborative program specific to the city of London

All three initiatives act as impartial and independent connection points between the NHS, academia, and industry, facilitating collaboration, logistics, and information sharing.

On a national level, the Accelerated Access Collaborative (AAC)[42] program is a collaboration between a large number of stakeholders, including NHSX, NHS Digital, NICE, the AHSN, and various patient groups and government and industry bodies. The objective of the AAC is to streamline the adoption of new innovations in healthcare, ranging from medicines, diagnostics, devices, and digital products to pathway changes and new workforce models. The AAC provides a single front door for innovators to the entire NHS. It consolidates access to testing and evidence generation counseling, adoption and dissemination plans, and funding strategies for developers.

It is the role of NICE to assess DTx if they are classed as medical devices.[43] Health applications are assessed as medical devices if they gather, analyze, and interpret data to make a diagnosis, prescribe a medicine, or recommend treatment.[44] There are two routes by which NICE assesses new medical device technologies:

- **Medtech Innovation Briefing (MIB)**[45] – this is more rapid and informal and is not classed as official NICE guidance, and
- **Medical Technologies Evaluation Programme**[46] – this is classed as official NICE guidance.

Currently 87 health applications are listed in the NHS Apps Library[47] that are either free of charge, privately paid, or free upon prescription of a general practitioner (GP). One example is Changing Health,[48] which requires a referral from a GP and helps patients with type 2 diabetes to better manage their condition and thereby improve health outcomes.

Figure 5 shows that the high-level criteria which digital health applications need to meet[49] in the UK are comparable to the requirements in Germany.

# The UK: Accelerating the Digital Transformation of Healthcare (continued)

The legal and accreditation frameworks in the UK and Germany serve similar functions but are arranged differently, reflecting the general differences between the healthcare systems. In the UK, digital health applications must meet specific criteria to be accredited by the NHS and listed in the NHS Apps Library, which is administrated by a public body (NHS Digital). Guidance or advice on evidence standards for new DTx in the UK is provided by NICE, which is experienced in the assessment of pharmaceuticals and medical devices. In contrast, BfArM is tasked with administrating the DiGa directory, setting HTA standards, and conducting appraisals for DTx in Germany, effectively turning the regulatory agency into another HTA body.

Comparable to Germany, the minimum standards to demonstrate effectiveness in the UK are high-quality observational or quasi-experimental studies that present comparative data.

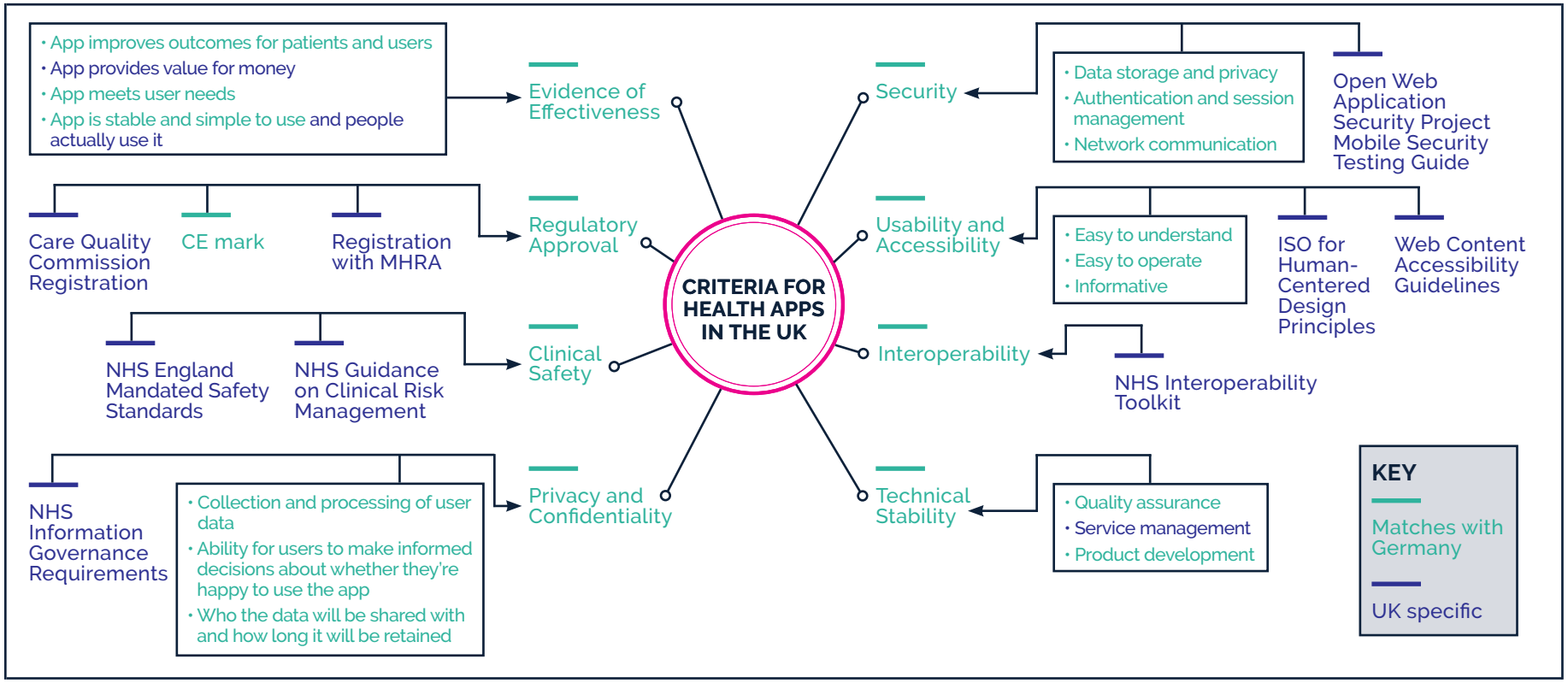


***Figure 5:*** *Criteria for digital health applications in the UK and topics and guidelines the applications need to cover.*[44]

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

# Conclusions

With the implementation of the Digital Healthcare Act, Germany's approach for patient access to DTx became more aligned with that of the UK. Although specifics differ, both Germany and the UK:

- **Implemented a registry for accredited applications,**
- **Assigned a remit for evaluation of digital health applications to regulatory bodies,**
- **Defined the same top-level requirements to be listed in the registry, and**
- **Require similar evidence for demonstrating effectiveness.**

However, with the new act, Germany has arguably overtaken the UK in terms of institutionalizing patient access to DTx: the UK's NHS does not reimburse all approved health applications whereas Germany's statutory health insurance funds do. In Germany, the framework was set up by the Ministry of Health under political willingness of the minister and is to some extent aligned with the pharmaceutical and medical device legislation and reimbursement system. In the UK, the framework was developed by the NHS itself, without the influence of political actors, as part of a long-standing holistic and efficiency-driven approach towards digitalization of the healthcare system, of which DTx are just a part.

The outcomes of Germany and the UK's approaches will provide important lessons for other European countries, who are likely to follow suit by implementing national frameworks to regulate and facilitate the evaluation, prescription, and reimbursement of DTx. This move is likely to be beneficial for most distributors of DTx who aim to have their intervention prescribed and reimbursed, as it would require undergoing only a single process per country instead of one for each formulary committee and/or healthcare insurer. Subsequently, it will be interesting to see if a collaboration like European Network for Health Technology Assessment (EUnetHTA) and the European Joint Clinical Assessment for pharmaceuticals will also be applied to the area of DTx.

# OPEN Health's DTx Capabilities

The German and UK systems have similar yet distinct approaches to integrating DTx and digital health. The frameworks of these two countries may or may not be used as examples for future developments in other countries. OPEN Health is monitoring the developments in the area of digital healthcare very closely and we are prepared to address the specific needs of DTx developers and their partners to help you access markets and integrate your innovative solutions across different healthcare systems, globally.

## We can help you navigate the European DTx landscape by providing:

- Strategic advice and in-depth analysis of your target markets
- Support with the development and implementation of an evidence generation plan, specifically in the areas of health economics, real-world evidence and patient-centered outcomes
- Support with preparation for authority consultation and reimbursement submission
- Support with the development and implementation of communications towards healthcare providers and patients.

***If you want to know more about our support in this area, please contact us by visiting our website:***

***www.openhealthgroup.com***

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OPEN Health brings together deep scientific knowledge, global understanding, and broad specialist expertise to support our clients in improving health outcomes and patient wellbeing. We are united as one flexible organization, harnessing the power of the collective to solve complex challenges. Being built from cohesive partnerships across a range of specialist sectors gives us the ability to approach opportunities from fresh perspectives, creating solutions and innovations for market access and medical communications that are informed by the experience and knowledge of the many.

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.

OPEN Health – Established as many. **United as one.**

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