Overview of the digital health innovation for the German healthcare system

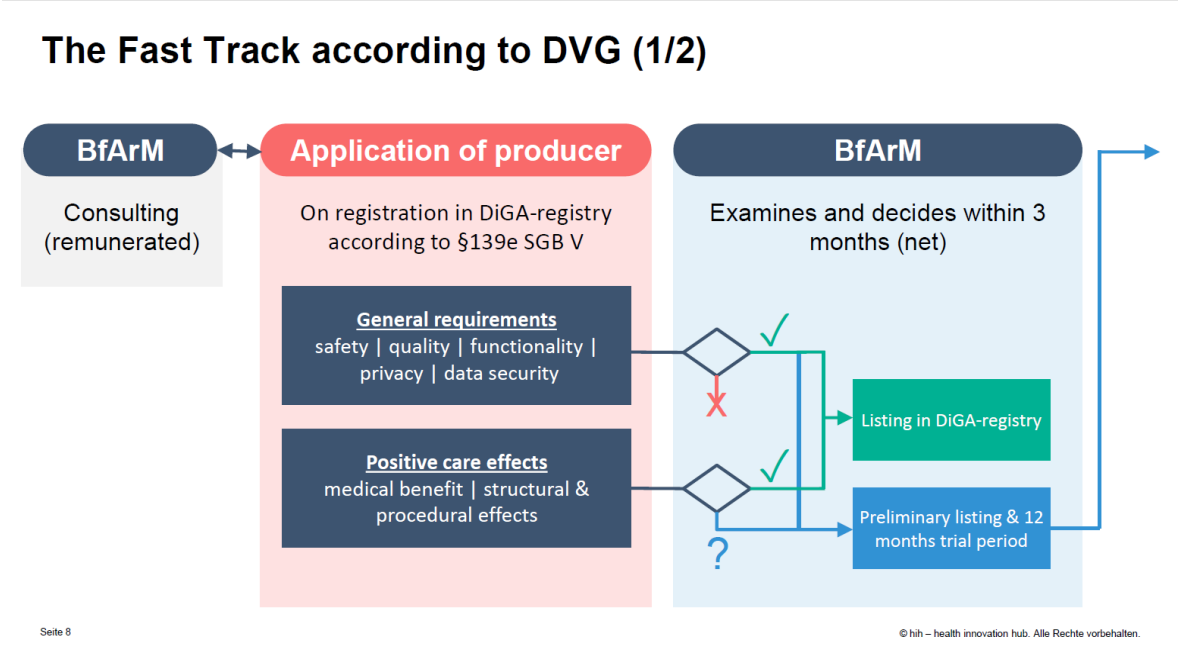
In late 2019, Germany passed the Digital Healthcare Act (DVG) which, among other things, created a regulatory and reimbursement pathway for digital health applications in the German market. As part of DVG, the Fast-Track Process for Digital Health Applications (known by their German acronym, DiGA, or "apps on prescription") allows for digital technologies to be introduced into clinical practice and reimbursed by Germany's statutory health insurers, with a concomitant goal of collecting real-world performance data to accelerate high quality, digitally-driven healthcare.

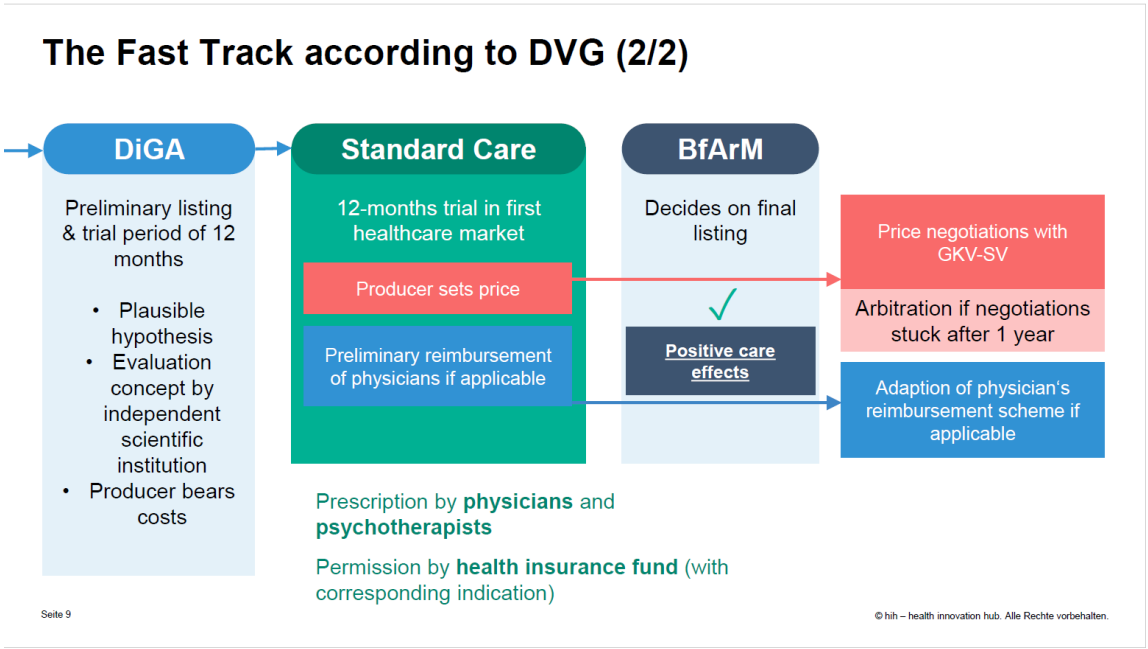
The "Fast-Track" pathway establishes market access for certain categories of digital health applications —namely those that meet the definition of lower-risk medical devices and are primarily used by patients rather than physicians. When such products meet prespecified requirements related to safety, functionality, quality, data protection, data security, and interoperability, they are eligible for regulatory review and subsequent entry into a directory of regulated, reimbursable DiGA.

An important prerequisite for reimbursement coverage is that a DiGA has completed an assessment by the German Federal Institute for Drugs and Medical Devices (BfArM), which leads to a formal listing in the BfArM's directory of reimbursable digital health applications (DiGA directory). Following listing in the DiGA directory, Manufacturers of digital technologies enrolled in the Fast-Track process have 12

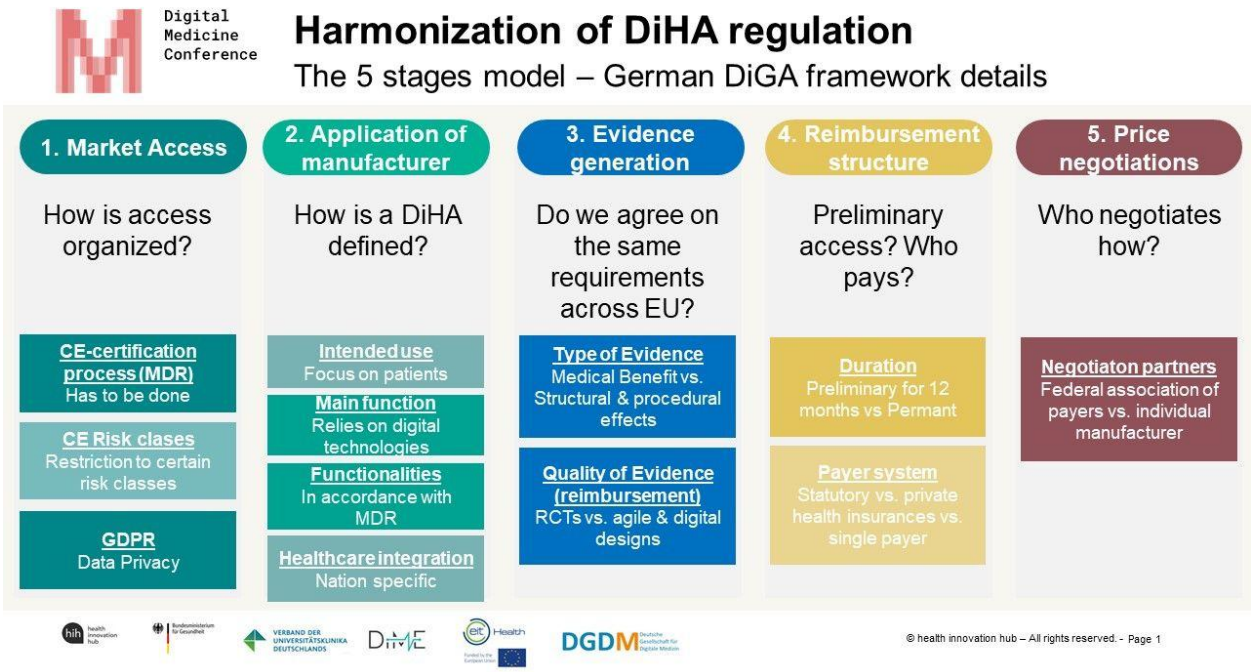
months to demonstrate patient-centered, positive effects of care. This may be defined as either:

1. A medical benefit (i.e., a therapeutic improvement by positively influencing patient-relevant endpoints such as quality of life, reduction in disease duration, improved survival), or
2. Patient-relevant improvements in structure and process, such as adherence, better coordination of treatment processes, health literacy, patient safety, patient autonomy, etc.





In contrast to European markets, both the US business environment and the US regulatory environment are hospitable to the use of real-world data (RWD). This is due to both the private sector landscape, in which a number of large, data-driven health technology companies have access to large amounts of patient-level data as well as the progressive regulatory environment, with roadmaps for real-world evidence (RWE) dating back to 2018.



Hih - DiMe partnership

Our goals

To **accelerate innovation in evidence generation** related to digital health applications and **speed the use of high-quality digital medicine products** in routine care by addressing the maldistribution of innovative policy vis-a-vis expertise in novel approaches to health research and evaluation.

Our commitment

DiMe and hih committed to over a year-long partnership to advance innovation in evidence generation to support broad acceptance of digital health applications.

Define the global **priorities for innovation in real-world evidence** (RWE) generation for digital health applications	Provide aspiring medical entrepreneurs and researchers a chance to learn from international experts and **gain hands-on experience in the design of novel, high-quality evidence-generation studies** for DiGA
To convene a group of researchers and industry committed to developing **approaches to challenges associated with the use of real-world data** for regulatory and clinical decision-making such as lack of interoperability and non-representative data sets.	Build a **trans-Atlantic collaborative community** that includes academics, payers, regulators, policymakers, digital health innovations, and more committed to the high-quality evaluation of digital medicine products using real-world data sets and novel methodologies

Resources:

- Listen to DiMe's journal club to learn more about The Fast Track Process for Digital Health: Germany's Digital Health Reforms in the COVID-19 Era: Lessons and Opportunities for Other Countries.
- Read hih colleagues' Harvard Business Review article, Want to See the Future of Digital Health Tools? Look to Germany.
- Listen to hih-DiMe's launch event to learn more about examples of novel approaches to health evaluation research: Priorities for innovation in real-world evidence (RWE) generation.

About hih

Through the end of 2021, the hih served as a think tank, sparring partner, and implementation supporter for the German Federal Ministry of Health and its subordinate authorities, among others. The team was set up as a point of contact and bridge between all major stakeholders of the German health care system.

For more information about hih, please visit the hih's LinkedIn page.

About the Digital Medicine Society

Founded in 2019, the Digital Medicine Society (DiMe) is the first professional organization for experts from all disciplines comprising the diverse field of digital medicine. Together, we drive scientific progress and broad acceptance of digital medicine to enhance public health.

DiMe is a 501(c)(3) non-profit organization dedicated to advancing digital medicine to optimize human health. We do this by serving professionals at the intersection of the global healthcare and technology communities, supporting them in developing digital medicine through interdisciplinary collaboration, research, teaching, and the promotion of best practices.

For more information about DiMe and to view our work please visit DiMe's website.