# Germany's DiGA Framework for Authorization and Commercialization of Digital Health Apps

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**ENABLING SECURITY & PRIVACY IN DIGITAL HEALTH**

# The Genesis of DiGAs

- Germany's Digital Healthcare Act (DVG) came into effect on December 19, 2019, introducing the "app on prescription" as part of healthcare provided to patients through digital health applications (in German: "digitale Gesundheitsanwendungen," hereinafter DiGA).
- Beyond "prescription apps", DVG enabled a myriad of additional benefits to doctors, patients and hospitals:
  - **Telehealth** and on-line consultations;
  - Eliminate the reliance on paper systems, furtherance of electronic patient records, especially **eHealth Cards** (eHC); and
  - Improve data availability for medical research, especially utilizing Artificial Intelligence (**AI**) and Machine Learning (**ML**) programs
- It is made possible by a **compulsory** participation in the digital network called Telematics Infrastructure (TI) that covers:
  - Medical, dental and psychotherapy practices
  - Hospitals and Medical Care Centers (MCC)
  - Laboratories
  - Pharmacies

# DiGA Authorization Process

- The Bundesinstitut für Arzneimittel und Medizinprodukte (**BfArM**, or the Federal Institute for Drugs and Medical Devices) manages the DiGA authorization process.
- A manufacturer of a digital medical device or software as a medical device (SaMD) can apply and BfArM **must** assess the application **if** any of the following apply**:**
  1. DiGA can provide a **medical benefit** in:
     - Improvement of the state of health;
     - Reduction of the duration of a disease;
     - Prolongation of survival;
     - Improvement in the quality of life;
  2. DiGA is **part of** the detection, monitoring, treatment, or alleviation of disease injury or disability
  3. DiGA **supports** the health behavior of patients or integrates the processes between patients and healthcare providers.

# DiGA Eligibility and Requirements

- A digital medical device **qualifies** as a DiGA if it is a medical device of the risk class I or IIa (EU MDR), its **medical purpose** is achieved through the main digital functions, and the app is used **only** by the patient or by the patient and the healthcare provider.

**This means that apps that are only used by the physician to treat patients are not eligible!**

- A DiGA **must** meet explicit requirements regarding safety and suitability for use, data protection, and information security and quality, especially interoperability.
- A DiGA manufacturer **must** demonstrate compliance via completed checklists as well as the evidence of compliance with regulatory requirements for medical devices.
- BfArM can request further evidence on individual quality features during the application assessment and check the accuracy of the information. In any case, you must provide free access (login data) of your DiGA to BfArM.

# DiGAs in Practice – Future

- Once approved, a DiGA can be prescribed to **any** of the 73 millions participants in the German statutory health insurance.
- DiGA reimbursement **must** be negotiated with German statutory health insurance and prices may vary with quality of evidence, but generally for each prescription period (90 days), the cost varies between €200 and €800.
  - The cost prices for the first year are set by manufacturers.
  - Beyond 1st year, manufacturers and insurers determine the price going forward.
- According to the latest findings of German agency Gematik, the digital health infrastructure of the country is making **progress**, moving from the electronic patient record to e-prescriptions.
- In 2021, Belgium and France announced plans to follow Germany and make digital therapeutics available through their respective healthcare systems.

# Questions?