NORWAY HEALTH TECH

Regulatory Compliance for MD/SaMD Training & Mentoring

Natale Rolim, PhD
MedTech Regulatory Consultant, RCC-MDR
ISO/IEC 27001 Lead Auditor Certified

NORWAY HEALTH TECH

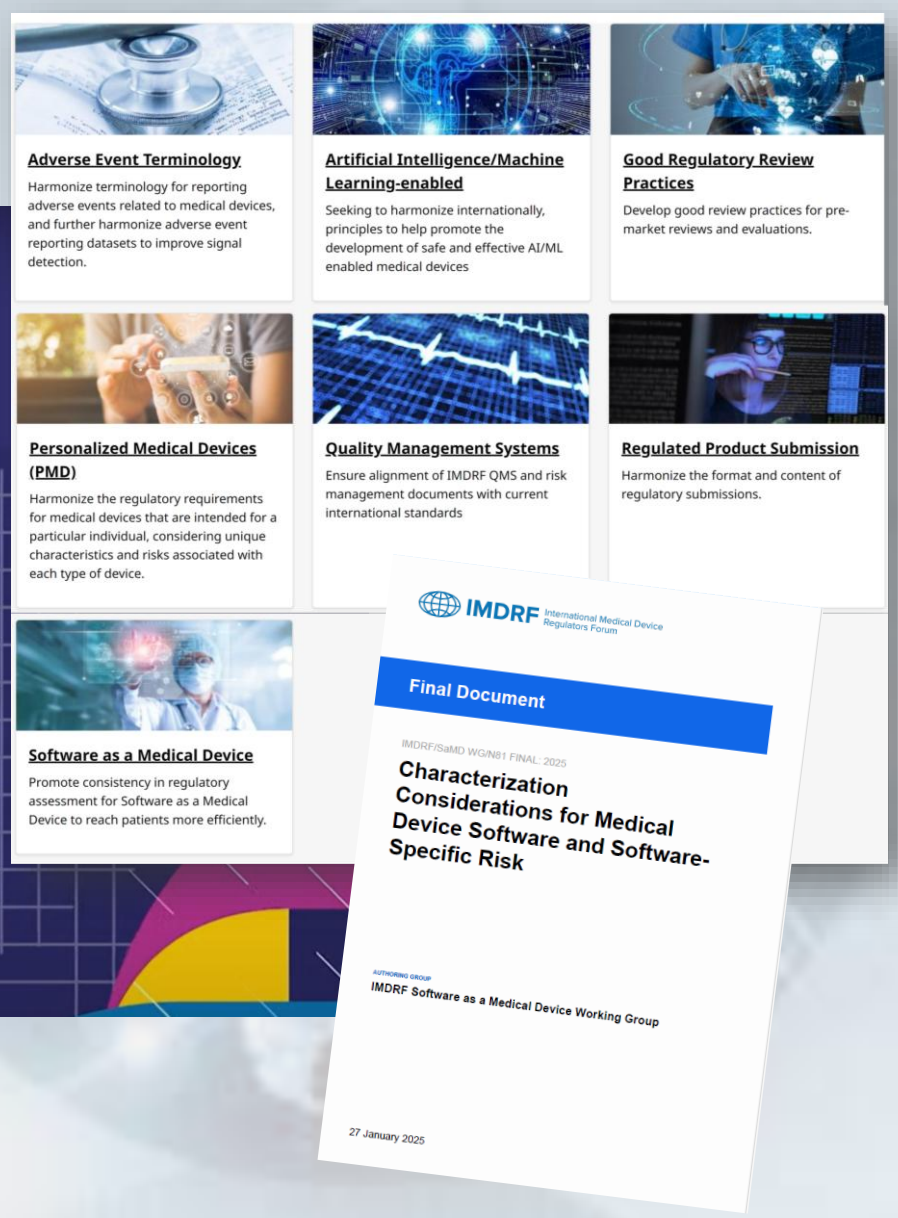
Regulatory Landscape DiGA & Hospital Reform

Innovation Norway

September 16th,2025

IMDRF International Medical Device Regulators Forum

The International Medical Device Regulators Forum



[Working groups | International Medical Device Regulators Forum]

Global Regulatory Approaches

	Regulatory Body	Device Classes (Risk-Based)	Market Approval	Quality System	AE Reporting
US	FDA (CDRH/CBER)	I, II, III	510(k), De Novo, PMA	21CFR 820 Transitioning to ISO 13485	MDR
Canada	Health Canada	I, II, III, IV	MDL (II-IV)	MDSAP certificate (ISO 13485+)	Vigilance System
EU	EC + Competent Authorities + NBs	I, IIa, IIb, III **(+Is, Im, If)**	CE marking under MDR	ISO 13485 + MDR-specific requirements	**Vigilance System**
Japan	Ministry of Health, Labour and Welfare + PMDA (review/safety)	I, II, III, IV	Notification, Certification, or Approval	QMS Ordinance (aligned with ISO 13485)	**Vigilance System**
Australia	TGA - Therapeutic Goods Administration	**I, IIa, IIb, III (+AIMD)**	ARTG inclusion	ISO 13485 via MDSAP accepted	**Vigilance System**

Digital Health & System Reform

Hospital Reform

- *Viable hospital-based outpatient care model*
- *Strengthen incentives for hospital-based outpatient treatments*
- *Leverage digital tools*

1 January 2025

Digital Health Applications (DiGAs)

Digital Healthcare Act, 2019

Make innovative and safe health interventions with a positive risk-benefit ratio rapidly accessible to patients.

- National competent authorities and agencies with official regulatory responsibilities in the healthcare system
- Digital Health Fast-Track – a formal pathway for reimbursing digital health apps
  - German **DiGA** programme (BfArM)
  - Austria, Belgium, France's PECAN scheme (multi-agency structure, coordinated submission)
  - Portugal – Whitepaper by EIT Health Innostars (06/2024)
  - And more …

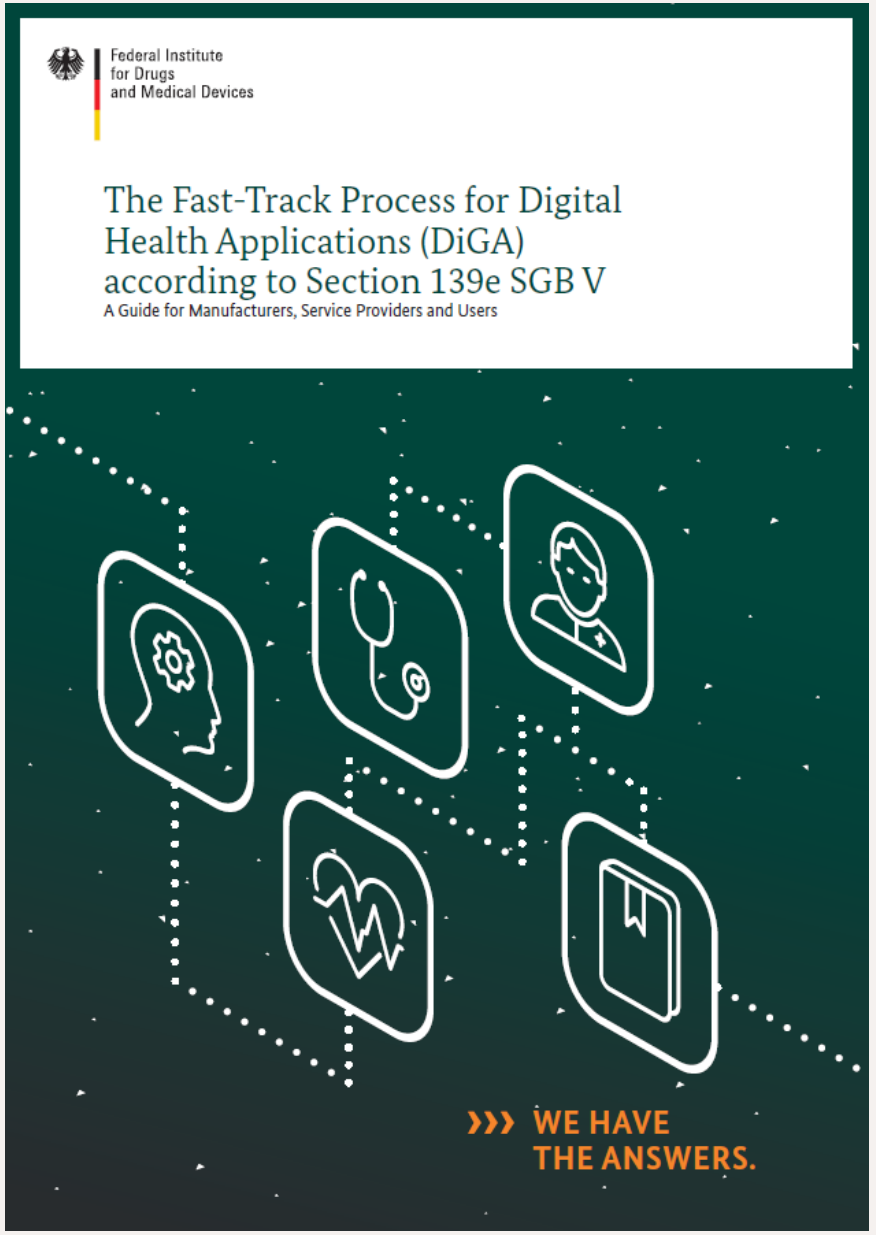
Digital health applications (DiGA)

Digital **medical devices** of low-risk classes that can support insured persons in treatment of their illness, injury or disability.

- Apps or browser-based applications
- Can be used either by the patient alone or by doctor and patient together
- Can be used in combination with other devices such as heart rate monitors, other DiGA or other software
- It must offer a "positive care effect" for the individual situation through its technology

What are “positive care effects”?

- **Medical benefits** - improves health status, quality of life, reduction of disease duration, and prolongation of survival.
- **Patient-relevant improvements of structures and processes** – provides practical benefits such as reminders, health data tracking, better communication with clinicians, or support while waiting for therapy. Adherence, patient autonomy, health literacy, facilitating access to care, patient safety, coping with illness-related difficulties in everyday life, reduction of therapy-related expenses and burdens for patients and their relatives, alignment of treatment with guidelines and recognized standards, and coordination of treatment procedures.



Digital nursing applications (DiPA)

Digital “assistants” used by care recipients or in the interaction of care recipients with relatives, other voluntary caregivers or authorized nursing care facilities.

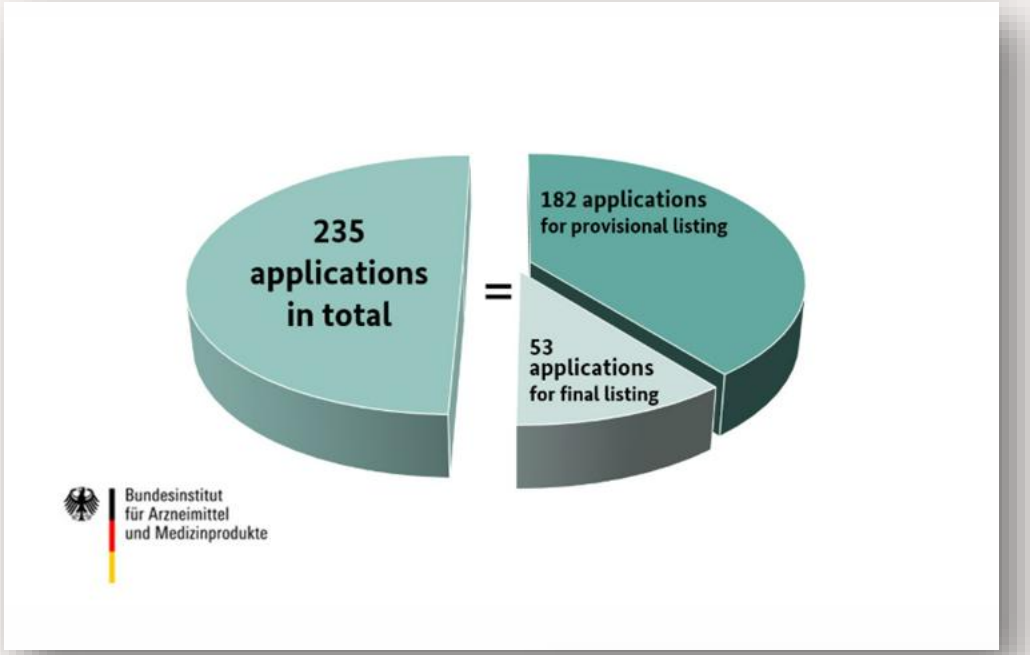
- To stabilize or improve the state of health of care recipients, or
- To improve communication with relatives and care professionals

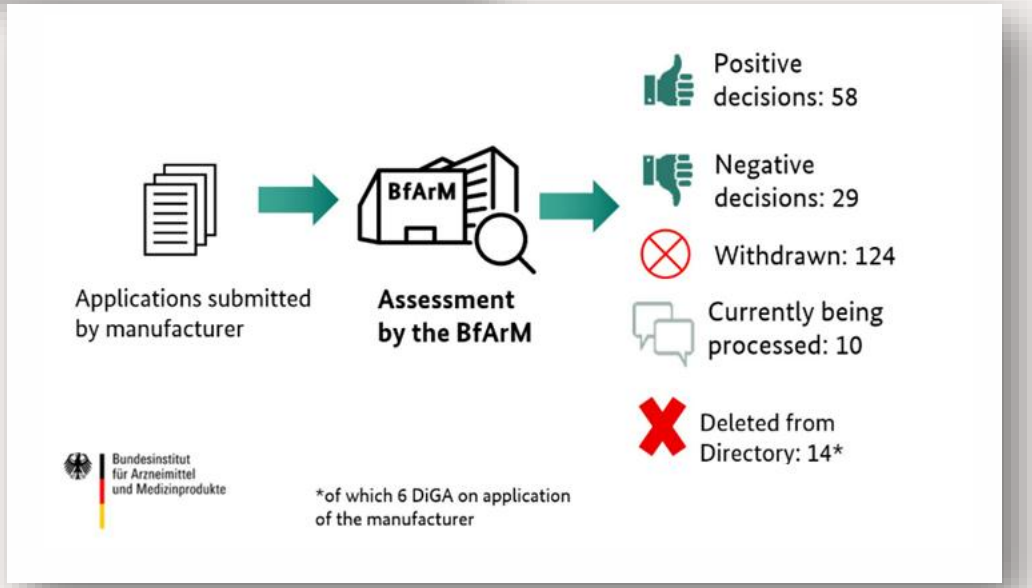
Prescriber: burses, care providers, or care institutions

Target group: care recipients in long-term or home care

(1b) Insofar as digital care applications are medical devices according to the applicable medical device regulations, the claim only includes digital care applications that are medical devices with a low-risk class according to Section 33a (2) of the Fifth Book.

DiGA: Applications Submitted & Assessments

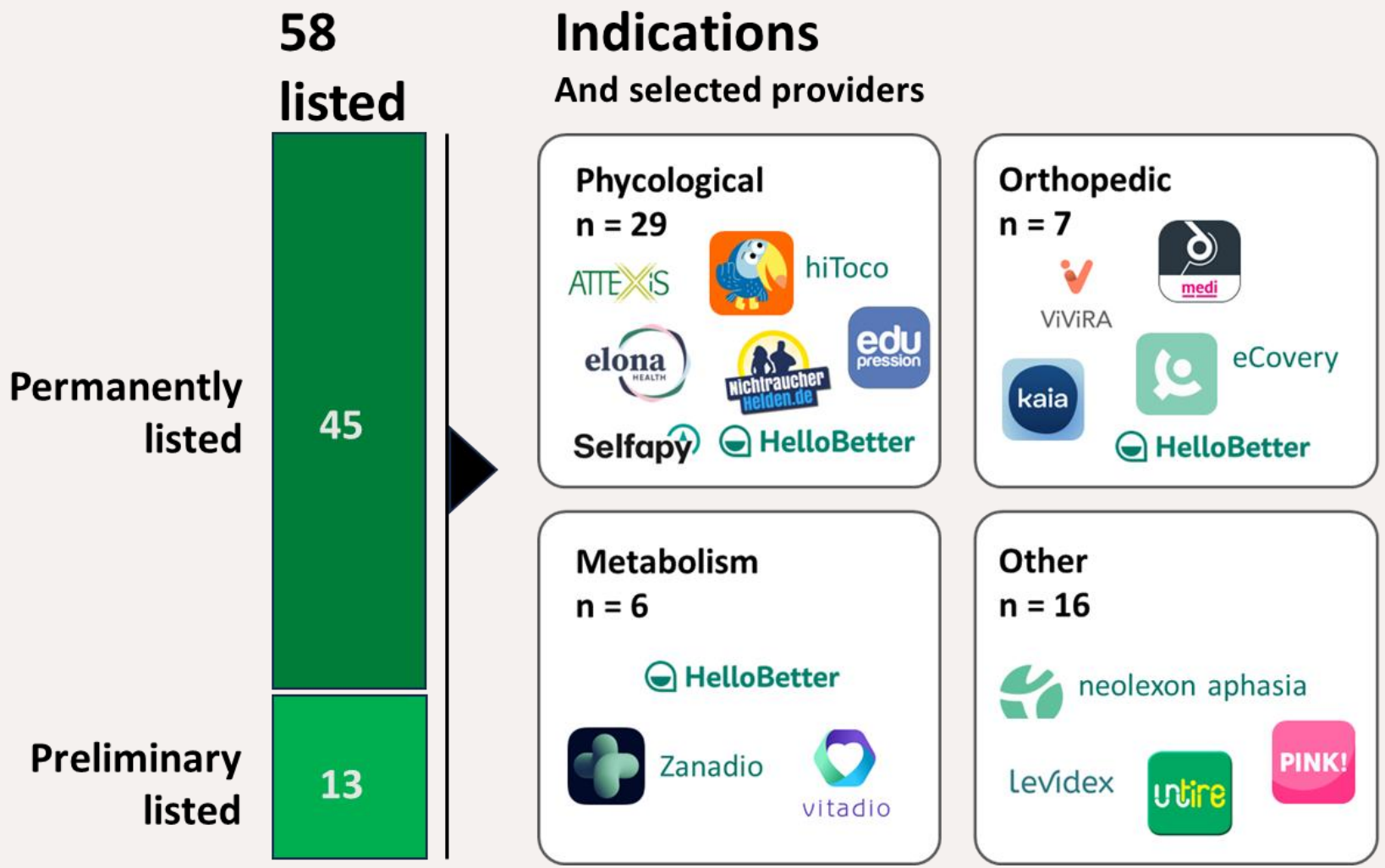




Directory | DiGA Directory

Graphics updated on 08/27/2025

DiGA Listings

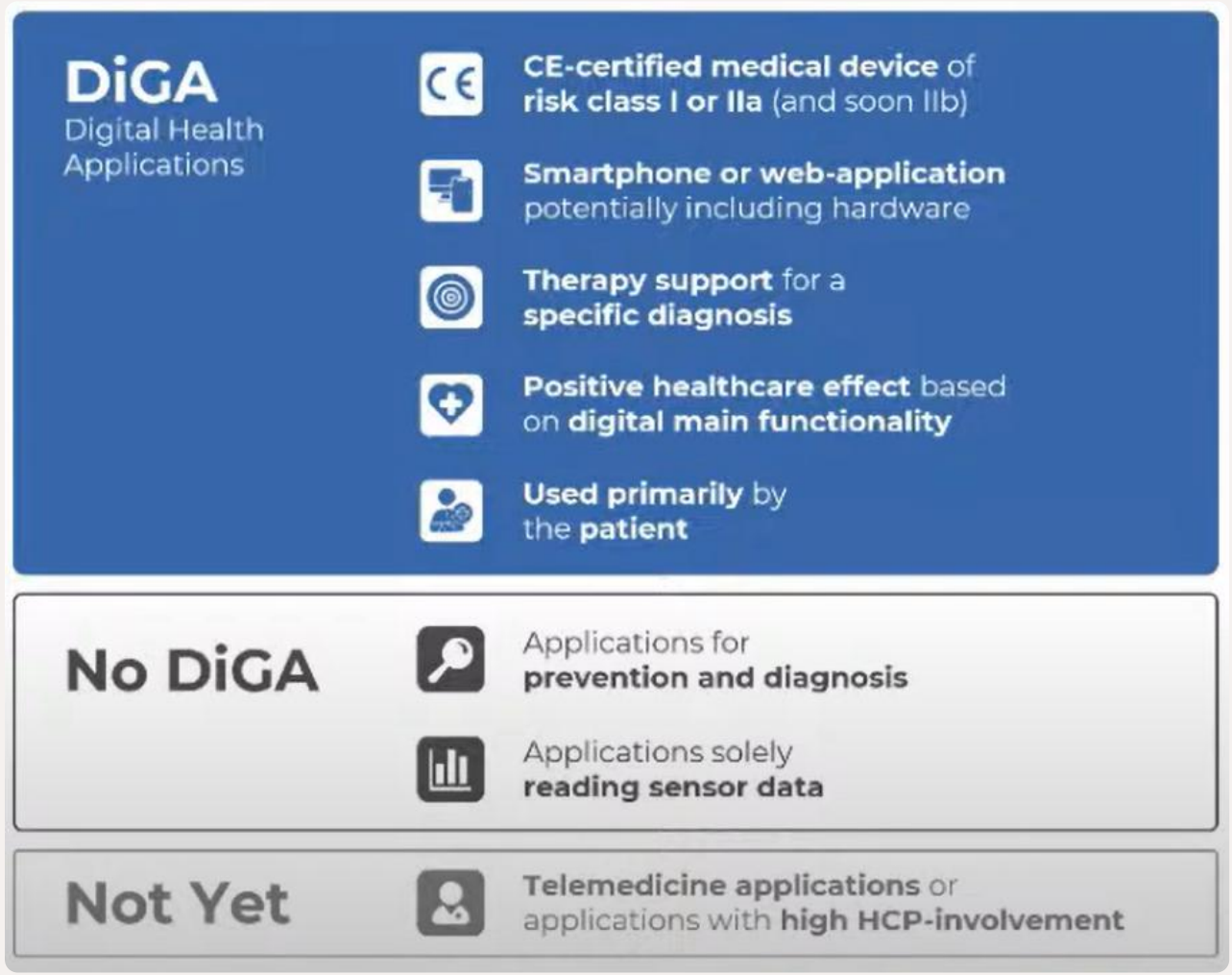


Directory | DiGA Directory

DiGA Basics

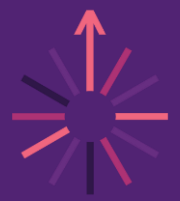
According to §33a SGB V

Reimbursement within the framework od standard care



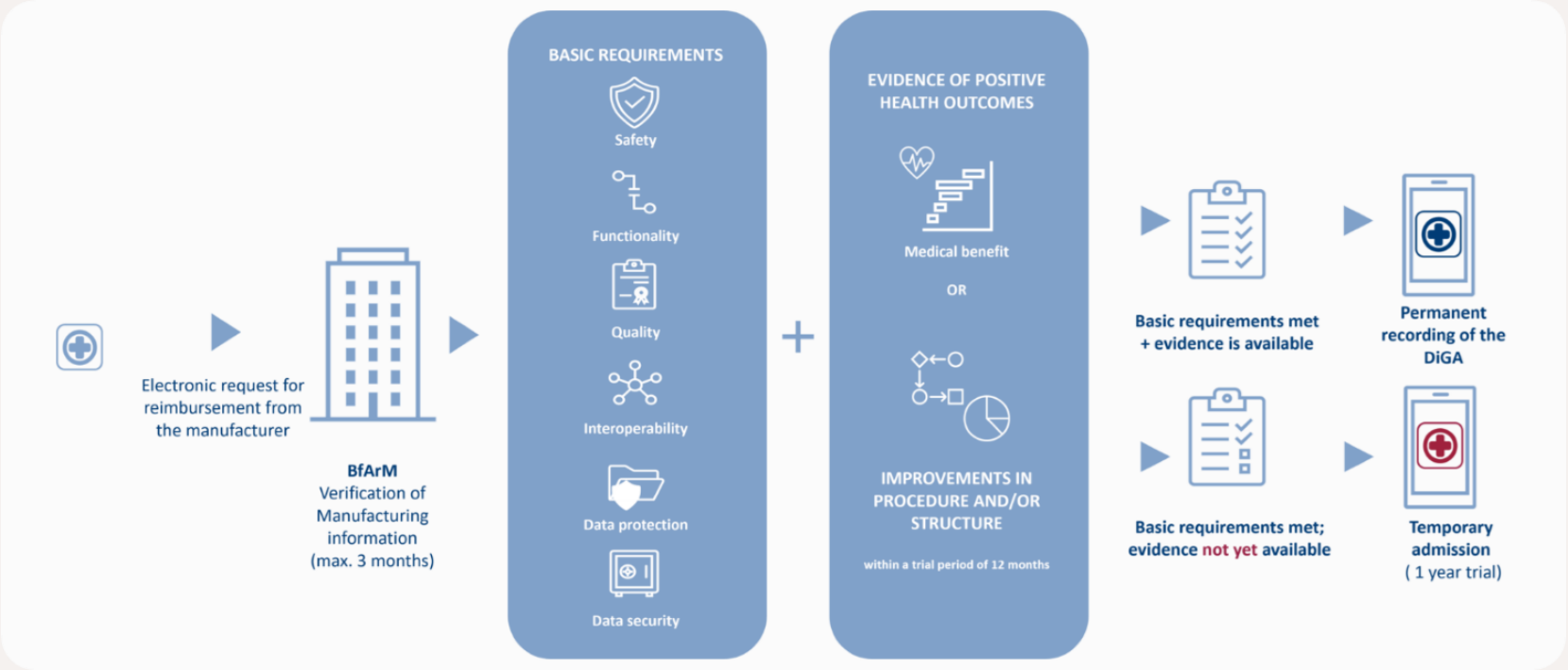
DiGA Directory

- **All available DiGA** can be sorted by diagnosis or ICD-10
- **General information** about the DiGA and its manufacturer
- **Other medical services** associated with the prescription (e.g. regular discussions of a diabetes diary)
- **Information on the security** and performance of the app (privacy, interoperability, etc.)
- **Scientific evidence that proves** the positive care effect of the app
- **Available prescription units** (dosage, application)
- **Reimbursable costs** by health insurance



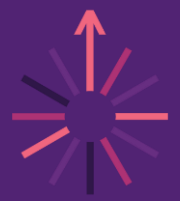
Directory | DiGA Directory

The DiGA Fast-Track Process



The DiGA Fast-Track Process

How does the submission process work and how long does it take?



DiGA Requirements

Section 139e SGB V

Technical Requirements

~140 requirements, including:
- ✓ **GDPR** compliance
- ✓ **ISO 27001** certification
- ✓ **Interoperability** with the healthcare system
- ✓ High **data security** standards
- ✓ **Accessibility** for targeted patient population
- ✓ Soon: **additional certificates**

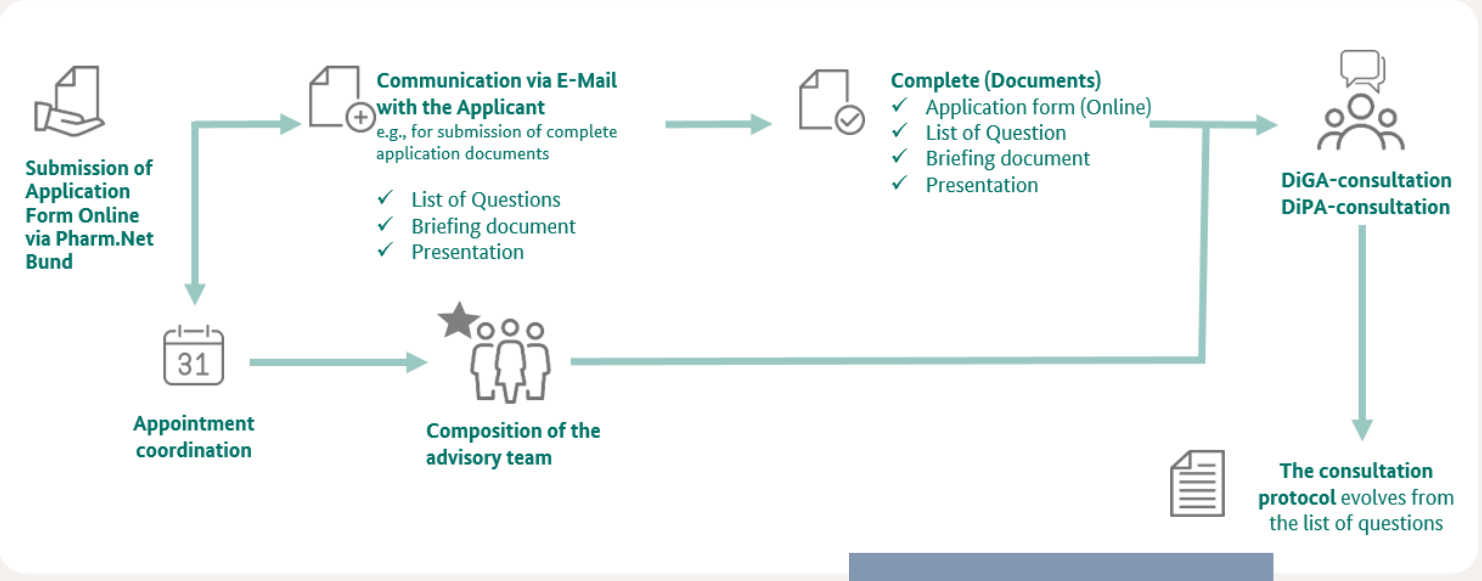
Evidence Requirements

Pilot study for preliminary listing:
- ✓ Proving **medical or organizational benefit**
- ✓ Including usually **40 to 80 patients**
- ✓ Accompanied by **extensive main study concept**

RCT for permanent listing:
- ✓ Proving **medical or organizational benefit** across subgroups
- ✓ Including usually **150 to 600 patients**
- ✓ **Control group** receiving standard-of-care treatment

DiGADiPA Consultation

The advice on digital applications is aimed at developers and manufacturers of DiGA/DiPA and offers comprehensive support and orientation on various topics.



DiGAV: 250 - 5,000 euros

Planned discussion topics

Select all that apply

- [ ] Procedural questions about the DiGA Fast Track
- [ ] DiGA accrual/DiGA capability
- [ ] Data protection, data security
- [ ] Other requirements for a DiGA
- [ ] Systematic data evaluation
- [ ] Study design for the trial study (please enclose study synopsis or protocol)
- [ ] Proof of the positive care effect
- [ ] Other*:

[BfArM - Consulting]

[PharmNet.Bund - Counselling]

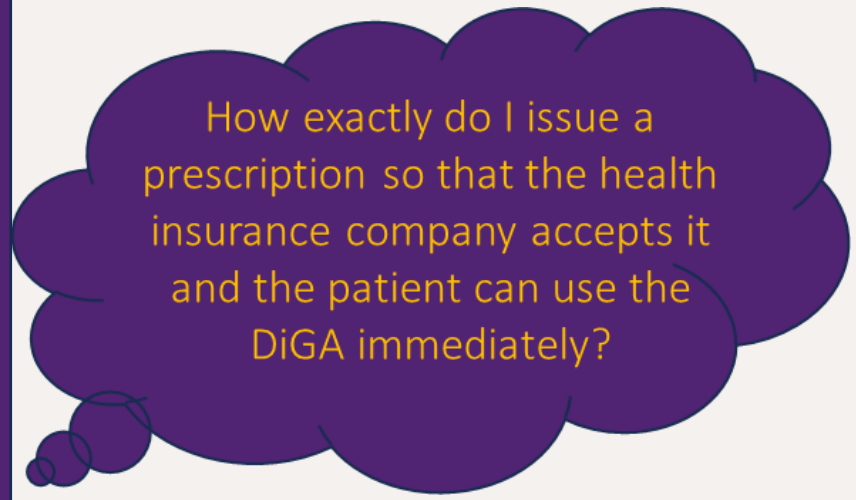
Bundesinstitut für Arzneimittel und Medizinprodukte

PharmNet.Bund

DiGA e-Prescription

Both initiatives are progressing simultaneously

- Prescriptions for DiGA can currently be issued and redeemed in **paper form**. Integration into the e-prescription or the electronic patient record has so far only been tested selectively and has not been standardised.
- Challenges: technical issues (incorrect prescription signatures and long response times from the TI), disrupts medical practices workflow (unstable data connections and difficulties with electronic signatures).



The answer is simple – if you know the right steps

- Over **1 million DiGA prescriptions** by end of 2024
- **81%** of prescriptions activated by patients
- **€234 million** spent by statutory health insurance (Sep 2020–Dec 2024)
- **Average cost:** €541 per prescription
- **Price range:** €119–€2,077, typically for 90 days (up to 365 days)

Sippli et al., Nature, 2025

DiGA Quick Checklist

- ❑ **CE mark**: MDR Class I / IIa
- ❑ **Evidence**: Clinical benefit or patient-relevant improvement; study or protocol ready
- ❑ **Data**: GDPR-compliant, IT security proven
- ❑ **Tech**: Interoperable, user-friendly, German language
- ❑ **BfArM**: Apply for listing (preliminary or permanent)
- ❑ **Pricing**: Free pricing 12 months → negotiate with insurers
- ❑ **Adoption**: Clear pathway (DiGA via physician prescription)

Hospital Reform Alignment

- **Digitalisation push**: Reform provides billions in hospital transformation funding. Hospitals will seek solutions that integrate with DiGA/DiPA-listed apps.
- **Continuity of care**: Reform emphasises networked hospital & outpatient care. DiGA/DiPA can bridge inpatient discharge and home care.
- **Outcome focus**: Both reforms and DiGA/DiPA reimbursement require proof of measurable patient benefit.

Tactical Product & Go-to-Market

- Modular, integrable components
- Concrete KPIs that resonate with hospital management under the reform
- German-language clinician and admin UX
- Local regulatory and reimbursement support

Thank you!

Export Program Germany

- Oct 17, 2025 High-Level Roundtable on “OUTPATIENTIZSATION”, Felleshus at Nordic Embassies
- Nov 5, 2025 Reimbursement System: Changes & Strategies to Address Underfunding
- Dec 4, 2025 *Boosting Sales Expertise & Success*, followed by networking

Germany Export Resource Group

A dedicated arena for Norwegian health companies aiming to succeed in the German market. The group facilitates the exchange of experiences, builds valuable networks, and strengthens collective expertise to accelerate market access in Germany.