**Requirements to apply for DIGA registration**
- Security
- Quality
- Product Performance
- Data Privacy
- Data Security
- Care Delivery Improvements
- Medical/HTA/Other Benefits

**Added value of the DVG**
- Clear set of criteria for listing/entry into public health market
- 12-month trial in standard care under real conditions
- Final decision: 12-24 months

**Healthcare Market**
- 240 billion public spending (2018)
- 73 million patients (Statutory Health Insurance)

**DVG**
"Digitale Versorgung Gesetz" means digital healthcare act

**Criteria**
- Medical Product Class I or IIa under MDR
- Main function relies on digital technologies
- Intend use is centered around the patient, possible to include the doctor
- Product functions:
  - Detection (monitoring)
  - Treatment
  - Palliation/Abatement of pain
  - Compensation of diseases
  - Injuries

**Germany’s New Law for Digital Health Apps**
- Summer 2020
- Any doctor in Germany will be allowed to prescribe health apps

**Prescribed apps can be reimbursed by the country’s statutory health insurance**

**DIGA**
Digital Health Applications (Digitale Gesundheitsanwendungen)