



Germany's AI for Health (AI4H) Maturity: *Current State and Near-Future Prospects*

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- Introduction – Germany’s Health System in Facts & Figures;
- Recent Digital Health Legislation Amendments in Germany;
- Current State of Digitalization of Health Information System;
- Current State of Electronic Patient Record;
- Current State of Electronic Prescribing;
- Current State of Digital Therapeutics;
- Prospects with Secondary Use and AI;
- Upcoming Developments – Digital Act;
- Concluding Remarks.



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- **Germany** is the world's 3rd largest healthcare market, with the total health expenditure **€474 billion** in 2022 (13.2% of GDP, per capita €5,699);
- **Multi-payer insurance system**: 88% (74m) covered by 96 SHK funds, 10.5% by PHI (8.7m);
- Employs 7.5m people; has 1,887 hospitals, 102,000 physicians' practices, 44,500 dentists' practices, 20,500 psychologists/psychotherapy practices; 18,460 pharmacies (2022);
- Until recently – one of the lowest digitalization levels in Europe: in a study by Bertelsmann Stiftung in 2018, Germany's Digital Health Index score was second lowest among 17 countries, at 30 (compared to NHS' 70, Spain's 71, Denmark's and Israel's 72, and Estonia's 82).
- In 2019-2021, Federal Ministry of Health operated the **Health Innovation Hub (hih)**, to drive the digital transformation of Germany's healthcare system;
- In 2023, the new **Digital Health Strategy** was approved by the Federal Ministry of Health



- In 2015, Germany passed its first eHealth law, including introduction of a nationwide **Telematics Infrastructure (TI)** and various digital health services.
- **gematik (Gesellschaft für Telematikanwendungen der Gesundheitskarte)** established in 2005, serves as the German healthcare system's competence center for Health IT and the Electronic Health Card (eGK).
- It is one of Europe's largest IT projects and employs around 260 IT-, e-Health, and project-experts.
- Currently gematik acts as the **National Digital Health Agency (Nationale Agentur für Digitale Medizin)**.

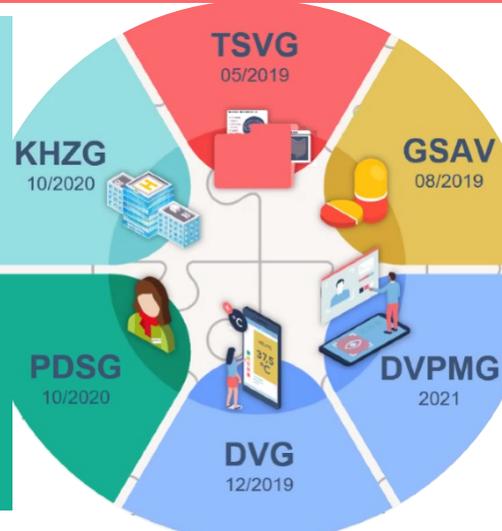


Appointment Service and Supply Act (Terminservice- und Versorgungsgesetz): Law promoting legally insured patients to get faster appointments with a doctor, including using a mobile application

Hospital Future Act
(Krankenhauszukunftsgesetz):
Investment of € 4.3b (€3b federal and
€1.3b states) on digitalization of
hospitals and IT security

Patient Data Protection Act
(Patientendatenschutz-gesetz):
provisions on e-prescriptions and
electronic patient record (ePA)

Digital Care Act (Digitale-Versorgungs-Gesetz): Digital health apps prescribed by doctors and psychotherapists, reimbursed by health insurance company; reimbursement of telemedicine; foundations of ePA; secondary use of anonymized health data.



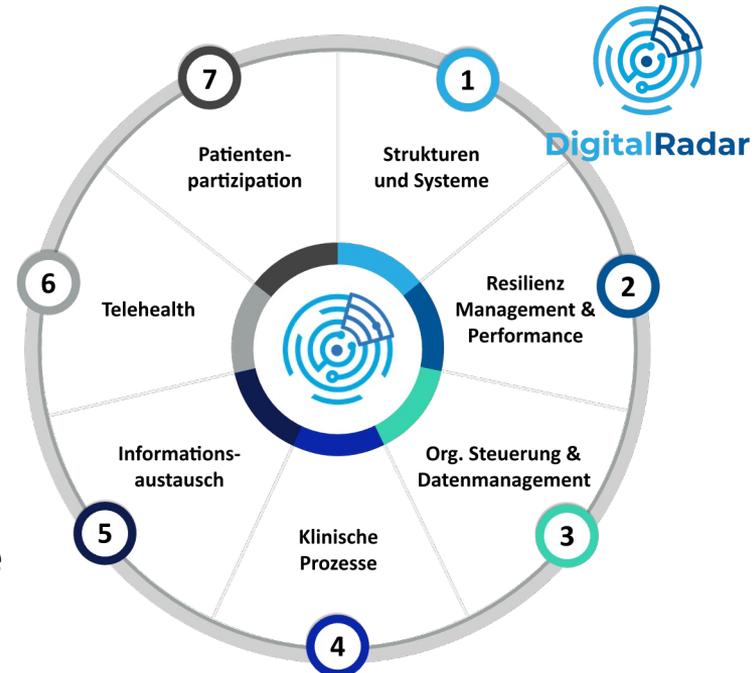
Act for Safety in Supply of Pharmaceuticals (Gesetz für mehr Sicherheit in der Arzneimittelversorgung): Roadmap for gradual introduction of the e-prescription

Digital Supply Care Modernization Act
(Digitale Versorgung und Pflege-
Modernisierungs-Gesetz): More
telemedicine and modern networking
in healthcare system



Current State

- **“Digital Radar”** (aka DigitalRadar Krankenhaus) was developed to assess the digital maturity of hospitals in Germany, commissioned by the BMG in May 2021.
- First measurement in June, 2021, second in June, 2023.
- **Total 1,624** hospitals participated in the survey: 33.7% public, 37.4% non-profit, 28.9% private hospitals.
- Criteria for assessment in seven dimensions.
- Average DigitalRadar score 33.3 / 100 points.
- Best performance in **Structures and Systems, Resilience Management & Performance**, lowest in **Information Exchange, Patient Participation** and **Telehealth**.



Digitalization of HIS

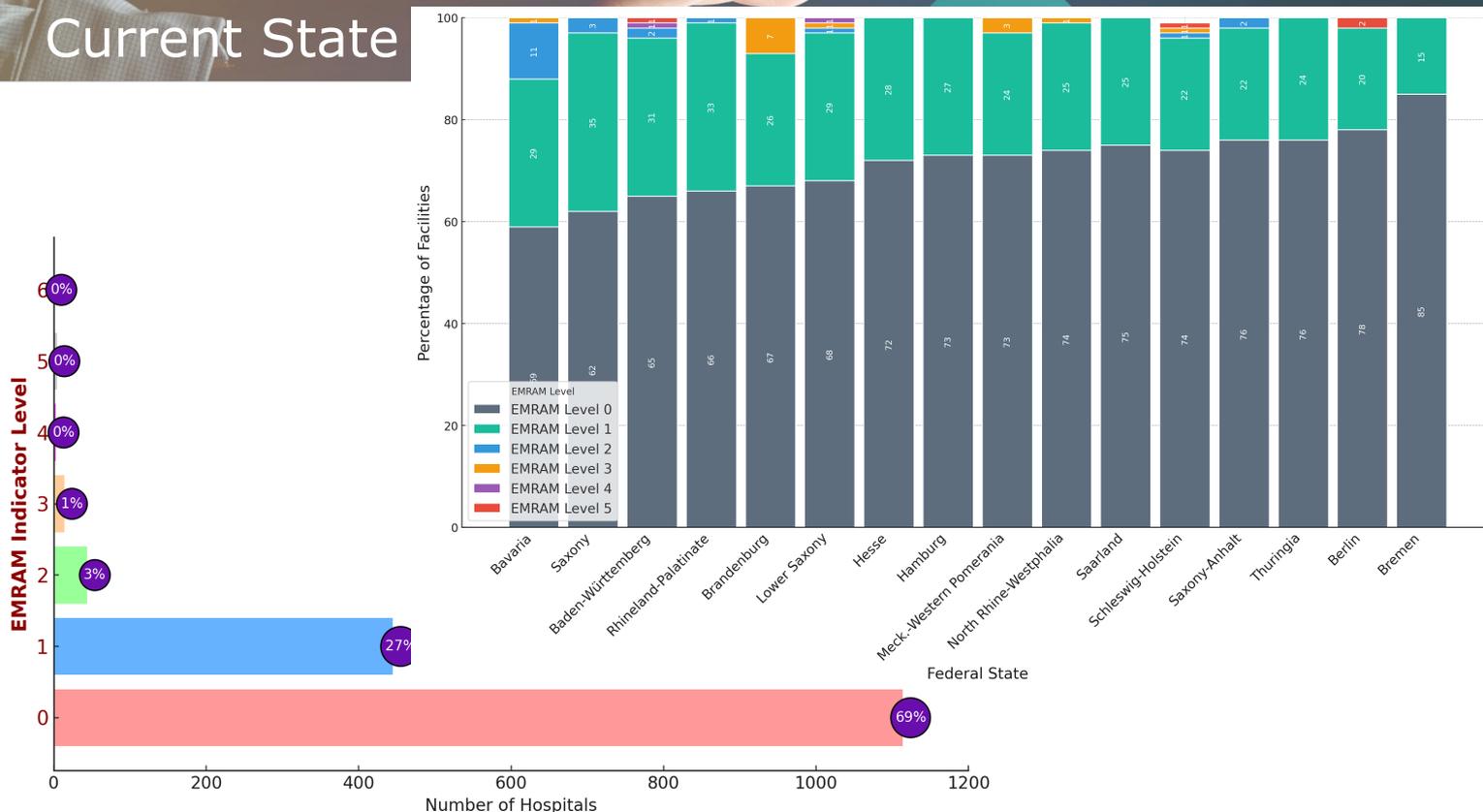


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INSTITUTE OF
TECHNOLOGY



Current State



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Source: DigitalRadar, interim report, Pictures: www.digitalradar-krankenhaus.de

Current State

- Rollout of the nationwide HER (*elektronische Patientenakte, ePA*) began in January 2021;
- **ePA Version 2.0** (Current):
 - Primarily for managing documents;
 - Includes vaccination records and examination booklets.
- **ePA Version 2.5** (Expected in 2023):
 - Includes e-prescription records, lab results, and certificates of incapacity to work;
 - Allows anonymized data for academic research;
 - Allows more interactions between patients and HCPs.
- **Low uptake and limited usage** – less than 1% of eligible population have downloaded ePA (approximately 700,000 citizens); less than 200,000 documents uploaded (as of mid-2023).

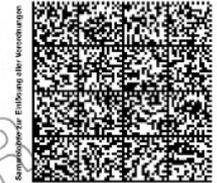
Current State

- About 760 million prescriptions filed each year;
- Piloting in 2022, up to now nearly 3m e-prescriptions;
- **Nationwide rollout of *E-Rezept* began July 1, 2023;**
- Will become mandatory for SHK-doctors Jan 1, 2024;
- Operated through the Electronic Health Card (eGK):
 - App from gematik, or printout with QR-code;
- Utilizes Telematic Infrastructure (TI) for communication;
- **99%** pharmacies connected to Telematic Infrastructure;
- App supports medication reminders and compatibility checks.

Ausdruck zur Einlösung Ihres E-Rezeptes

Nr. Dr. Erika Freifrau von Mustermann
geboren am 13.12.1987

ausgestellt von Dr. Monika Freifrau von Mustermann
Praxis für Innere Medizin
030/4266666
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ausgestellt am 13.12.2022



Teil 1 von 4 ab 13.12.2022
1x AZITHROMYGIN Abz 250 mg
Filmtabletten / 6 St. M2
morgens und abends 1
PZN:01065018 kein Austausch



2x Ibuprofen / 800mg /
Retard-Tabletten / 20 St
0-1-0-1

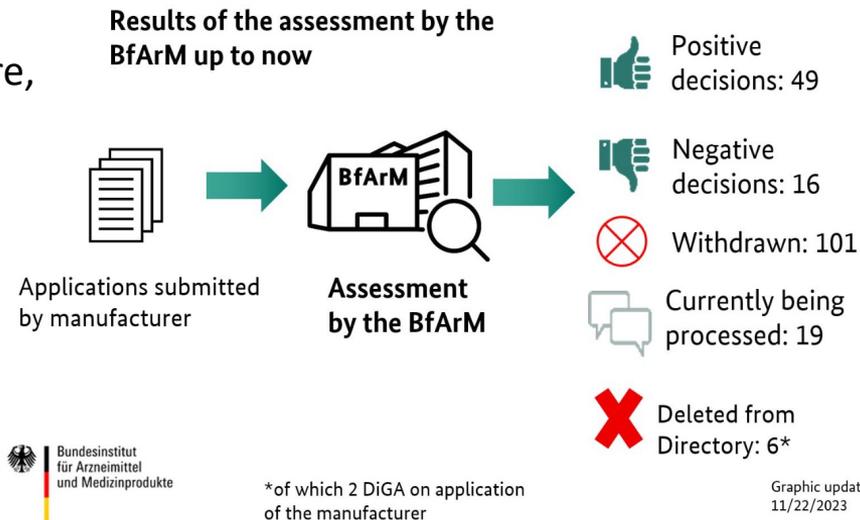


Rezeptur
1x Aluminiumchlorid-
Hexahydrat-Gel 15% (HRP
11.24.)



Current State

- **DiGAs** (*digitale Gesundheitsanwendung*) – apps that have gone through the formal nationwide regulatory and reimbursement process, and can be prescribed to insured patients and reimbursed by the insurance.
- Must demonstrate either a positive effect on care, or improvement in clinical care processes.
- **BfArM** (Federal Institute for Drugs and Medical Devices) checks the safety, functionality, quality and interoperability, data protection and data security => entered in a public DiGA directory.
- A Fast-Track procedure for inclusion in the BfArM directory is done under three months.



■ EU-Wide and National Projects on Data Use:

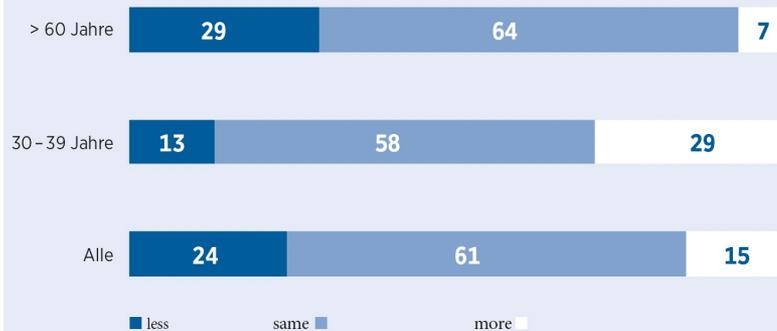
- HealthData@EU Pilot – the Health Data Lab (HDL) is a unit of the Federal Institute for Drugs and Medical (BfArM), Germany;
 - Towards European Health Data Space – BfArM, Gematik.
 - Gaia-X & HEALTH-X dataLOFT – an international initiative involving business, science, and politics to shape European data infrastructure.
- Medical Informatics Initiative (MII), HighMed, Netzwerk Universitätsmedizin (NUM) – created a decentralized health data infrastructure, a relevant preliminary work for the EHDS.
- Challenges – Interoperability, Data Exchange, Data Privacy & Security.



AI startups growing, trust remains an issue

Survey: If your doctors tell you that they work with artificial intelligence - how does this affect your trust? 1,000 respondents

Source: AI.Hamburg



The most valuable German AI start-ups in the healthcare sector, enterprise value, in million euros (estimated)



- Two new legislation packages are currently discussed in the Bundestag (Nov 2023):
- **Digital Act** – *Gesetz zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz – DigiG)*:
 - Introduction of opt-out electronic patient file (ePA) by Jan 2025 for statutory health insured;
 - Digital medication plan and e-prescription standardization from 2024;
 - Expanded use and integration of Digital Health Applications (DiGA) in treatment;
 - Removal of telemedicine reimbursement limits, promoting easier access;
 - Establishment of a digital advisory board at gematik for data protection and usability guidance;
 - Recommendations on data protection, security, usage, and user-friendliness.

- Two new legislation packages are currently discussed in the Bundestag (Nov 2023):
- **Health Data Use Act** – *Gesetz zur verbesserten Nutzung von Gesundheitsdaten (Gesundheitsdatennutzungsgesetz – GDNG)*:
 - Aims to make health data easier and quicker to use for public good purposes;
 - Establishment of a national data access and coordination center for health data;
 - A decentralized health data infrastructure with a central data access and coordination point is being set up;
 - The amendment is intended to reduce bureaucratic hurdles and strengthen research;
 - An opt-out procedure will also be introduced for the release of data from the electronic patient file in order to make the data from the file more usable for research purposes;
 - Important part is further strengthening of health data protection measures.

Concluding Remarks

- Germany began its quest towards digitalization nearly 20 years ago, but until recently lagged behind.
- The Telematics Infrastructure (TI) serves as a reliable and secure backbone for nationwide data exchange.
- Applications such as ePA, E-Rezept, DiGAs, have recently been introduced but uptake remains very low.
- The level of digitalization of HCPs remains extremely low, with almost no EMRAM Stage 3+ hospital.
- Prominent yet sporadic and fragmented data projects.
- Significant efforts underway to boost adoption and prepare the health system for digital transformation.



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