FLYING HEALTH

GTAI - Medica

CONFIDENTIAL

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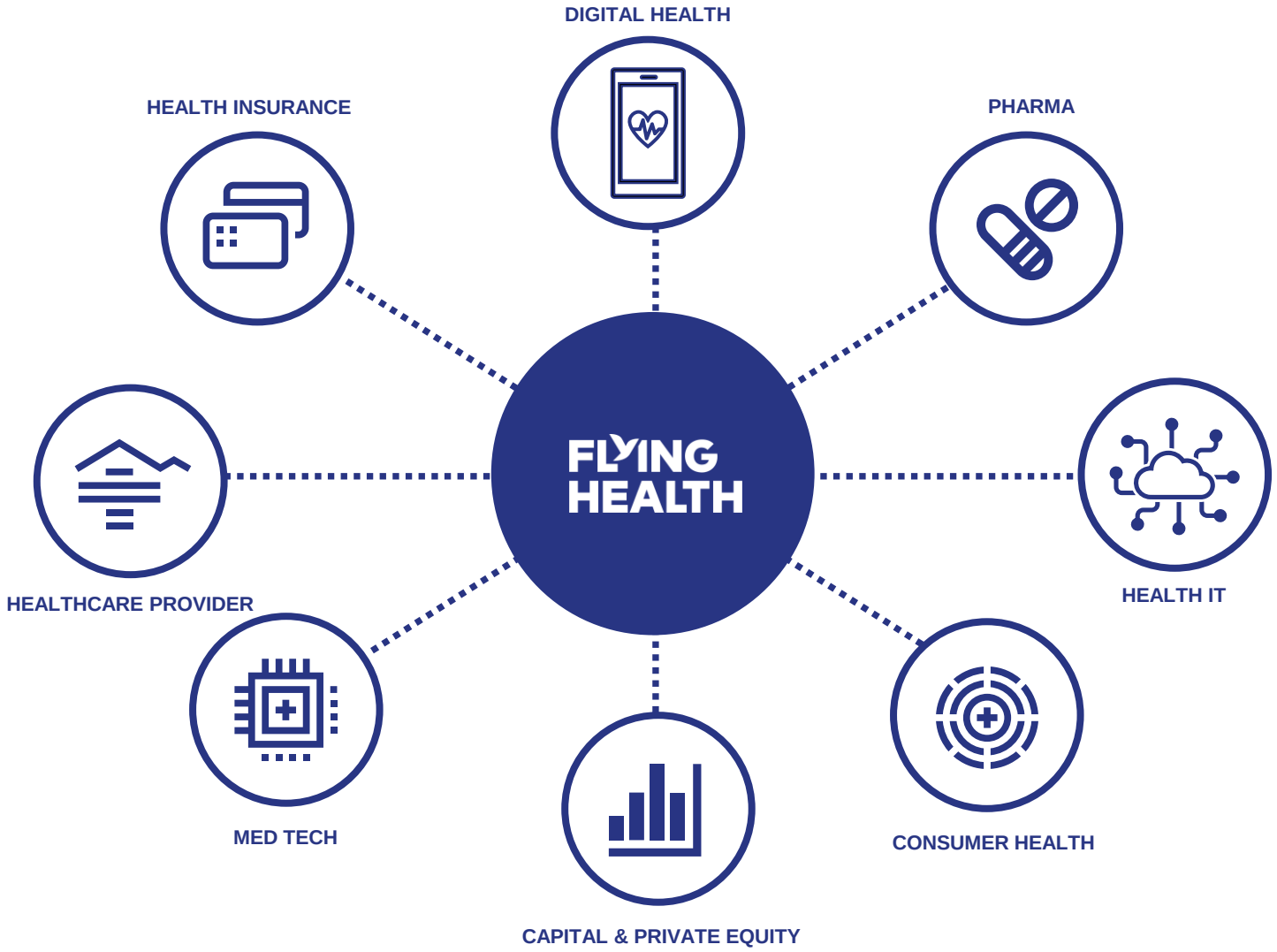
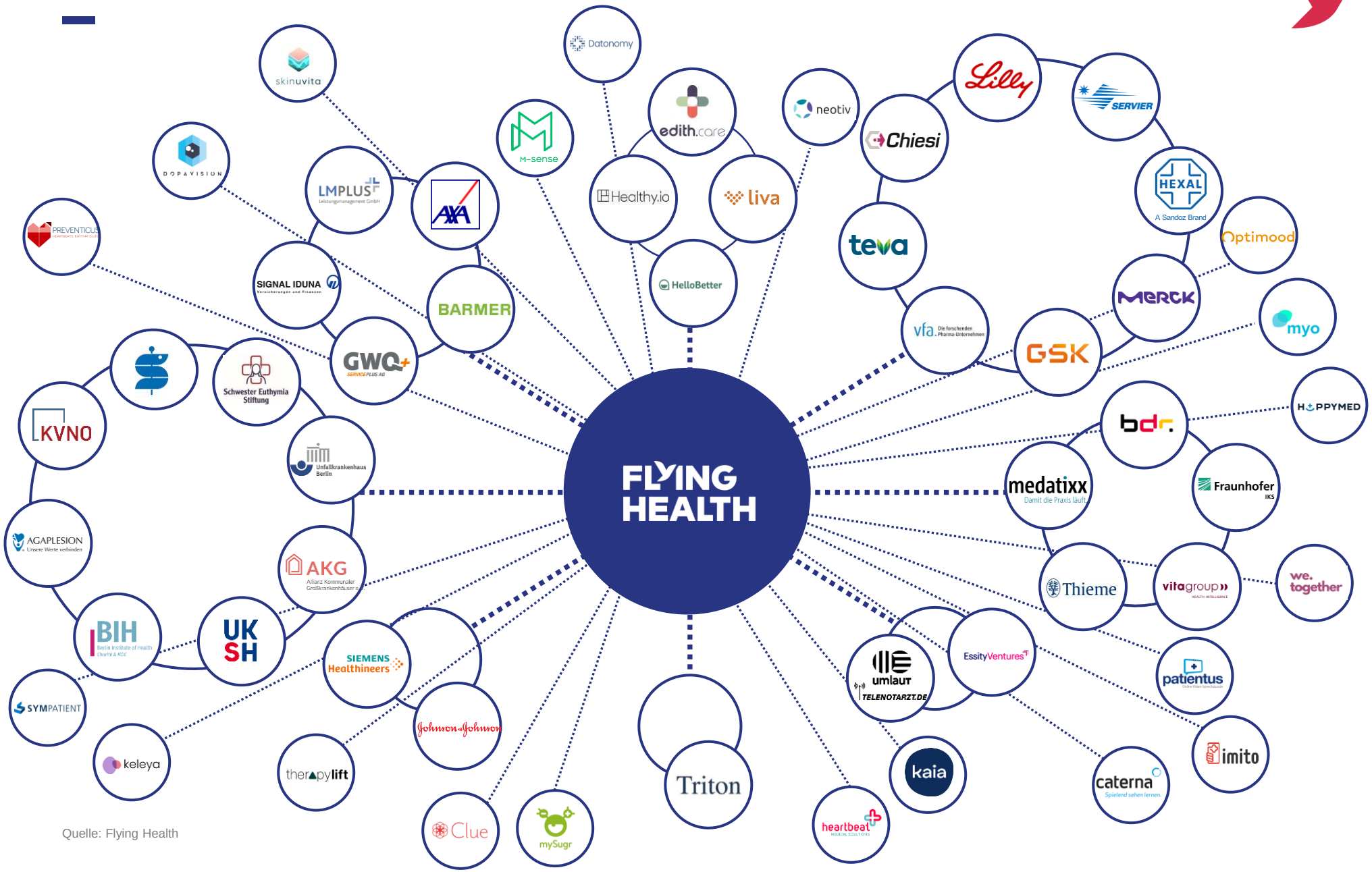
Flying Health is the leading ecosystem for health innovation

We foster diversity within the stakeholders and organizations and enable a cross-industry collaboration.



Source: Flying Health

Our startup community accelerates innovation



Quelle: Flying Health

Doctors are allowed to prescribe DIGAs (e.g. medical apps)

The DigiG brings some changes for DiGA

20% of the price should be success-based in the future (incl. a success measurement accompanying the application)

DiGA must be drug agnostic and not exclusively for the control of active therapeutic products

Pregnancy will be another possible indication for DiGA in the future

DiGA definition is expanded to risk class IIb under MDR (medical use only and direct permanent intake)

The National Association of Statutory Health Insurance Funds should simplify the redemption process for patients

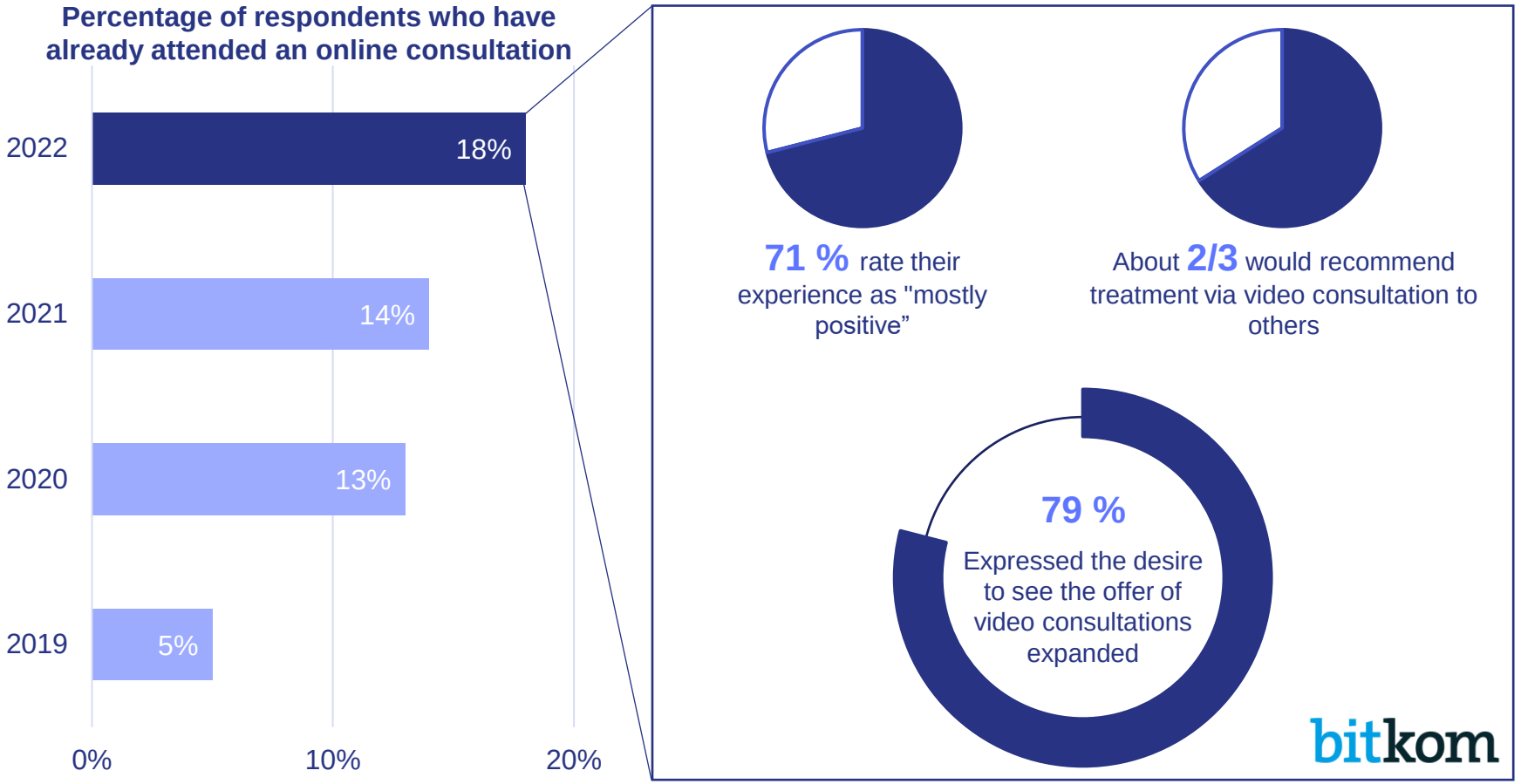
Hardware to be made available as a loan product in the future

Source: Kabinettsentwurf Gesetzes zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz – DigiG)

Tele-consultations will be strengthened

Video consultation is increasingly used and well rated

As the results of a survey by Bitkom e.V. show, the trend toward increasing use of video consultation will continue in 2022. Thus, 18 % of respondents said they had already used an online consultation, compared with 14 % in 2021. The survey also revealed that many of the users were satisfied with the service and would like to see it expanded.



Source: Telemedizin: Pandemie treibt Nutzung von Videosprechstunden voran; Pharmazeutische Zeitung; 24/05/2022

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DE: 50 % consult "Dr. Google" first

The market research institute Consumerfieldwork found out in a survey that ~ 50 % of Germans first consult "Dr. Google" when they have symptoms of illness. 38.1 % go to their family doctor and ~ 12 % ask friends, family, medical reference services or a pharmacist. Online portals (e.g. Net Doktor, Apothekenumschau) provide information for 2 out of 10 respondents.

~ 50 % of Germans consult "Dr. Google";
38.1 % consult the family doctor;
~ 12 % ask friends, family, medical reference books or the pharmacist;
2 out of 10 inform themselves on online portals

Source: Die meisten Menschen suchen bei Google; Handelsblatt Inside Digital Health, 15/02/2021

Picture: In-online; 28/11/2018

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Survey results show: The digital patient is already here

The Digital Health Report published by Doctolib in collaboration with the market research institute GIM shows that the desire for more flexibility and time savings plays an important role for many patients and that digital tools are a popular means of achieving this goal.

- **70%** of the patients surveyed would like to have the option of **booking appointments digitally.**

- **60%** of the patients surveyed would like to be able to **order prescriptions digitally.**

- **55%** of the patients surveyed would like to **receive their results digitally.**

Doctolib & GIM | RELEVANCE COUNTS.

Source: Umfrage bei Ärzten und Patienten: Digitalisierung ist noch ausbaufähig; Ärzteblatt; 10/06/2022

Key points from the Digital Act (DigiG) for video consultations

Expansion of video consultations & teleconsultations

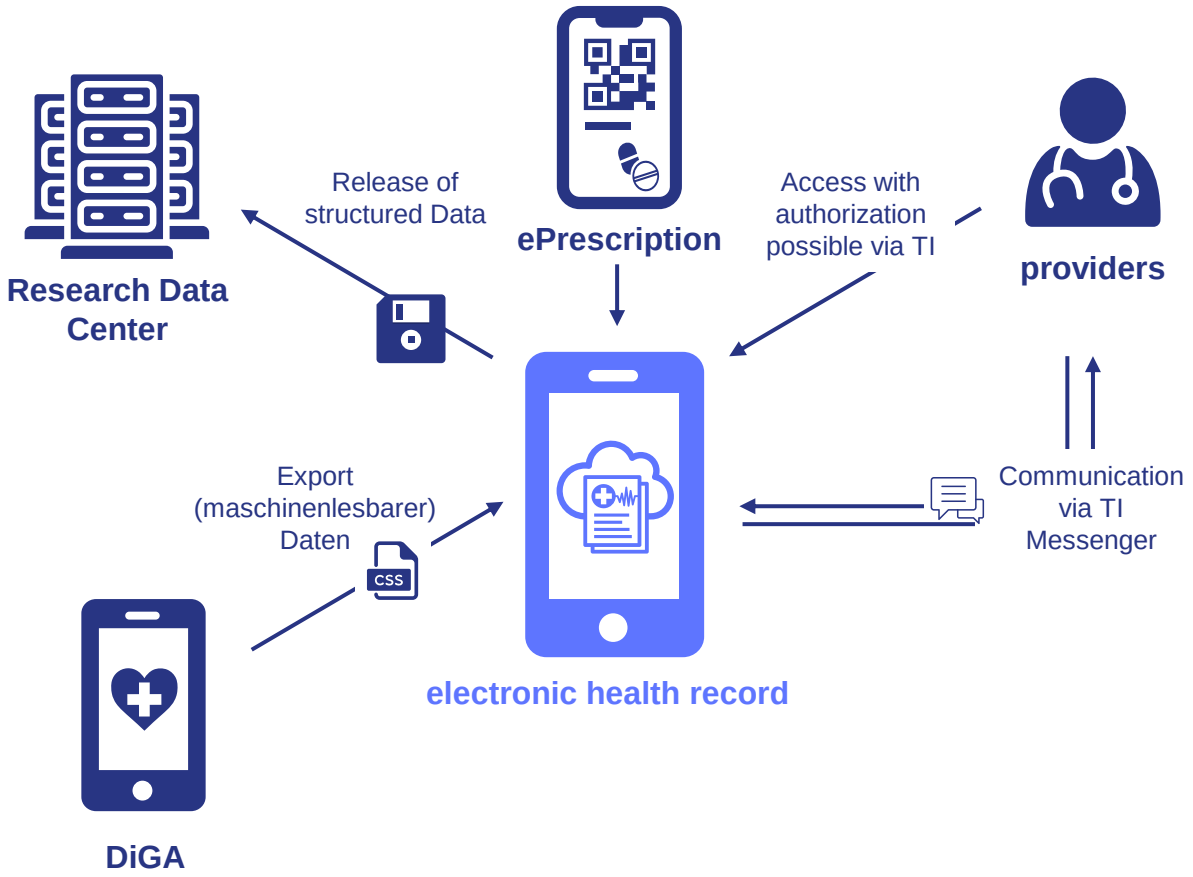
- Quality-oriented further development of video consultation hours and teleconsultations (e.g., quality-oriented remuneration, specifications for ensuring the quality of care).
- Limitation of service volumes for video consultations will be lifted
- Assisted telemedicine will be available in pharmacies (incl. regulation of remuneration).

Steps overdue with regard to telemedicine; actual implementation will be critical to impacting care

Quelle: Flying Health; RefE Entwurf eines Gesetzes zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz – DigiG), Bearbeitungsstand 05.07.2023

Access to an electronic health record for every insured person

The ePA is set to become the hub of healthcare



Quelle: Flying Health

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Electronic health record to be put on new track as opt-out ePA

80%

By 2025, 80 percent of all insureds should have an ePA and by the end of 2025, 80 percent of all ePA users with at least one medication should have an electronic medication plan

Partial views in ePA with all core information for routine treatment of complex diseases (diabetes, oncology).

Aggregation of structured data for use in value-added services (e.g., interaction check).

ePA advancement for real-time algorithms/AI-based care interventions and public health measures.

ePA becomes a portal covering all social security codes (e.g. health insurance, accident insurance, pension insurance)

80 percent of all lab results in ePA by 2027

Source: Flying Health

Key points from the Digital Act (DigiG) for electronic health record

Development from ePA to opt-out ePA

- Opt-out ePA starting 15.01.2025
- First expansion stages are eMP, patient summary file and laboratory findings (with mandatory filling)
- Special rules for data on HIV infections, mental illnesses, abortions and genetic data
- GKV have to transfer up to 10 documents to ePA twice in the first 24 months

Filling:

- Physicians are obliged to transfer data processed as MIOs to the ePA (for eMP: updating by physicians and pharmacists, without request by patients).
- Patient's right to transfer additional data, provided they are part of the current treatment case and are processed electronically.
- Explicit consent required for transmission and storage of results/analyses of genetic examinations
- Obligatory information for physicians when storing data on HIV infections, mental illnesses and abortions

Contradiction

- Objection-based ePA for creation, filling and release
- Insured persons can object to access by individual authorized persons (group/individual) and to the processing of data in the ePA in general, or only to the transmission and storage of individual data records/documents or groups of data records/documents.
- Sharing of data for research purposes should be possible 6 months after provision of the ePA (also objection-based)

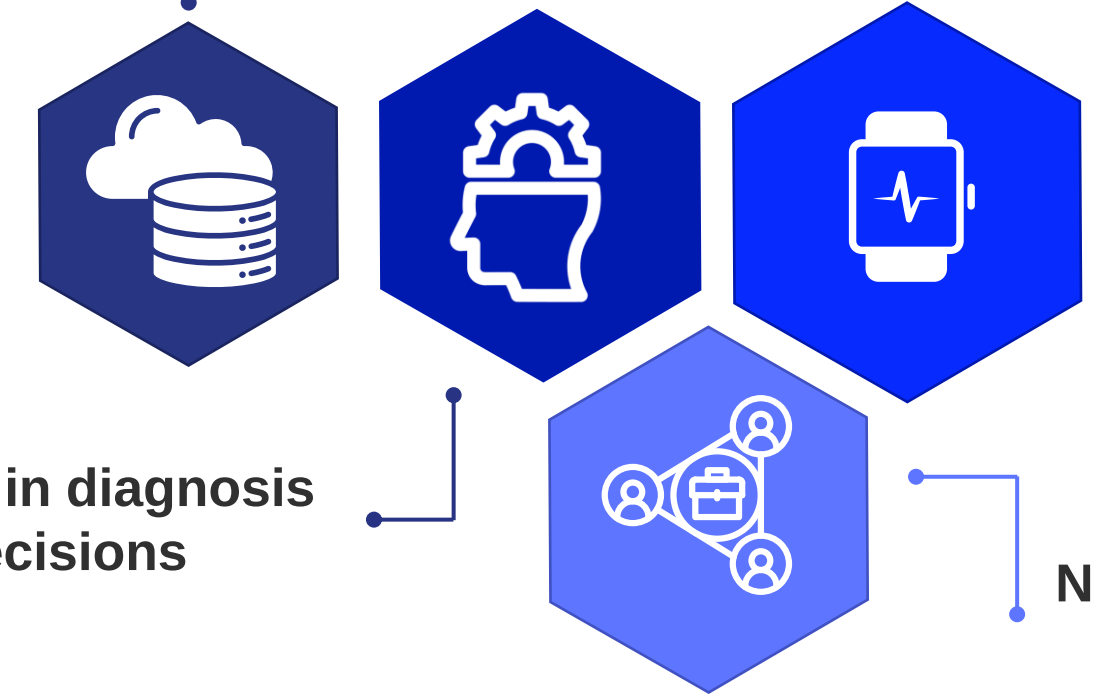
Quelle: Flying Health; RefE Entwurf eines Gesetzes zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz – DigiG), Bearbeitungsstand 15.06.2023

Improved access to patient data for research

4 Key developments in the context of digital health over the coming years

Increasing need and relevance for health data (usage)

Extended use of sensors & biomarkers for digital diagnostics



Leverage of AI in diagnosis and therapy decisions

New Care Concepts

Source: Flying Health

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The use of health data holds considerable market potential

A survey by McKinsey shows that **6,4 Mrd. Euro** could be saved through data transparency (e.g. duplicate examinations).

WHO analysis calculates **five deaths every minute** due to incorrect medical treatment.

Two-thirds of all medical diagnoses are based on or confirm **laboratory medical tests**.

Approximately **7.1 million inpatient surgeries** are performed each year. In addition, there are outpatient operations.

A study by the University of Witten/Herdecke showed that **25,000-58,000** patients die each year as a result of medication errors.

Approximately **130 million X-ray examinations** are performed each year.

Source: Rheinische Post, 25/11/2023 | DW.com, 14/09/2019 | McKinsey & Company, 24/05/2022 | Statistisches Bundesamt, 05/04/2023 | Bundesamt für Strahlenschutz, 05/04/2023 | Statistisches Bundesamt, 05/04/2023 | BMG, 04/04/2023 | Berufsverband Deutscher Laborärzte, 05/04/2023 | ABDA Report, 05/04/2023

The GDNG is expected to come into force in February 2024.

Key points from the Health Data Use Act (GDNG) for the Research Data Center (FDZ)

Right of application

Beneficiaries = natural and legal persons within the EU

- Purpose reference, instead of stakeholder reference
- There is no longer a list of authorized users
- Possible purposes of data use are clearly defined (e.g. improving the quality of care, supporting political decision-making processes)

Working group on secondary use

- Participants include, for example, self-government, federal and state authorities, patient representatives, health care institutions.
- Can comment on secondary use at the request of the BfArM

ePA-Data

- Should flow automatically and pseudonymized to the FDZ.
- Opt-out can be issued via the ePA
- The ePA is used to document the data that has been extracted.

Linking of FDZ and cancer registry

- Linking takes place by means of a research identification number (generated on an occasion-related basis) in pseudonymized form.
- Further details are to be clarified in the BMG legal ordinance (e.g. technical procedure, uniform application process).

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Contact

Serap Konak
Senior Consultant

EMAIL konak@flyinghealth.com