“Health Data Lab at BfArM – Concepts for Use and Evaluation / Interaction with European Activities (EHDS)“

Prof. Dr. Karl Broich, President BfArM | DGRA Annual Congress May 2023
Overview

Digital Health - Update from Germany

Health Data Lab at BfArM
• Concepts for use and evaluation
• Connection on EU level towards EHDS

Reliable data collection, exchange and further use: (technical and semantic) Interoperability

The growing digital ecosystem - Step by step to the big picture
GEMEINSAM DIGITAL
Digitalisierungsstrategie für das Gesundheitswesen und die Pflege

PERSONENZENTRIERTE VERSORGUNGSPROZESSE
- Gleichberechtigte digitale und analoge Versorgung
- Nutzerzentrierte digitale Versorgung und Verwaltung
- Digitale Transformations- und Gesundheitskompetenz

QUALITATIV HOCHWERTIGE DATEN
- Bedarfsgerecht, einfach und sicher verfügbar
- Strukturiert und interoperabel
- Verknüpfbar für Versorgung und Forschung

Menschenzentriertes digitales Gesundheitsökosystem

FUTURISTISCHE VERNETZUNG MITTELS TI

NUTZENORIENTIERTE TECHNOLOGIEN UND ANWENDUNGEN

REGULATORISCHE RAHMENBEDINGUNGEN
- Planungs- und Rechtssicherheit
- Wettbewerb
- Finanzierung und Vergütung

GOVERNANCE, AKTEURE, ROLLEN
- Neue Modelle der Zusammenarbeit
- Klare Rollen und Verantwortlichkeiten
- Kooperative Umsetzung

TRANSFORMATIONSANSATZ
- Transparente Umsetzungsplanung
- Fortschrittsmessung
- Information, Kommunikation und Partizipation

Prof. K. Broich | DGRA Annual Congress 2023 | 03.05.2023
Update - Digital Devices: App on Prescription – the DiGA-Fast Track
Results of the assessment up to now

- 169 applications in total
- 17* positive decision (final listing)
- 28 positive decision (provisional listing)
- 5** deleted from directory
- 15 negative decisions
- 91 withdrawn
- 13 currently being processed

* 7 out of the 17 finally admitted DiGA provided proof during the trial phase
** 2 out of the 5 deleted DiGA were deleted on application of the manufacturer
European/international activities

**European Taskforce for Harmonised Evaluation of Digital Medical Devices in the EU**
- Taskforce member, Co-Chair Working Packages 2 - clinical evidence of DMDs

**EU HORIZON - Development and harmonisation of methodologies for assessing DHTs in Europe**
- member

**Internationaler Austausch zum Thema DiGA mit...**
- DK (DKMA), NL, BE (KCE), AUT (AGES), Korea (MFDS), USA (FDA)...
- planned: FR (HAS), FIN (FinCCHTA), UK (NICE)
**Together Digital – Next steps for DiGA & DiPA: Extension and combination with other therapy services**

Digitization strategy of the Ministry of Health for the healthcare and nursing sectors – planned implementations:

***short-term:***

<table>
<thead>
<tr>
<th><strong>Telemedicine</strong></th>
<th>Mapping of more comprehensive telemedical care concepts involving physicians in DiGA</th>
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</thead>
<tbody>
<tr>
<td><strong>Risk classes</strong></td>
<td>DiGA extension to medical devices - risk class IIb</td>
</tr>
<tr>
<td><strong>Interoperability</strong></td>
<td>Possibility for DiGA and DiPA to read data from the ePA, if necessary and useful</td>
</tr>
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***mid- to long-term:***

<table>
<thead>
<tr>
<th><strong>Care processes</strong></th>
<th>DiGA as an integral component of digitally supported care processes (e.g. in DMP)</th>
</tr>
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<tbody>
<tr>
<td><strong>Data export to ePA</strong></td>
<td>Automated transfer of data from DiGA use to ePA → possibility of data use for research purposes</td>
</tr>
<tr>
<td><strong>Interoperability</strong></td>
<td>Stronger interconnectivity of DiGA, DiPA and other digital applications in the sense of an interoperable, digitally supported health- and care system</td>
</tr>
</tbody>
</table>
DiGA as Part of German e-Health Structure: Interoperability
National Competence Centre for Medical Terminologies / Semantics Centre at the BfArM

**SNOMED CT global clinical terminology is introduced in Germany**
Licenses issued through Germany’s MII

**Standardisation & Semantics (inter-)national:**
- Publication of official classifications such as
  - ICD-10-GM (§§ 295 und 301 SGB V)
- Implementation ICD-11 in Germany
- Maintenance of classifications, medical terminologies, thesauri, nomenclatures and other conceptual systems as a service for the health care system

**SNOMED-CT**
- Routine licence for health care

**DVG / DiGA Ordinance:**
- Commitment to interoperable design of DiGA taking into account recognised standards (HL7/SNOMED CT, ...)

**Interoperability - terminology / technically**
Provision of structured data through the use of coding systems

- SNOMED CT
- ICD-10-GM
- OPS
- ICF
- LOINC
- ATC

MIO Patient (short) Health record
MIO Vaccine pass
MIO Maternity pass
MIO Children`s U Booklet
Aims of the HDL

Developing the new environment and processes in an agile way in close collaboration with researchers towards the aims of the HDL:

Research
- Iterative and interactive research processes
- Transparency and predictability of the application process
- Direct data processing with new possibilities for data access

Scalability
- Efficient processing of applications even in case of increasing demand
- Continuous improvement of data usability

Security
- Modern IT-security methods
- Minimisation of re-identifikation risk
BfArM - Overview

BfArM represented in various comitees / working groups (e.g., CHMP, PRAC, COMP, DARWIN EU,...)

Administration

Quality Management

Media and Public relations

European Union, international Cooperation

Artificial Intelligence

Coordination

Monitoring - supply of narcotics and precursors

Innovation Office,
Advice,
Change Management

Identify trends
Supporting innovations
Advice processes
Guiding change processes

Federal Opium Agency
Cannabis Agency

Risk detection & assessment

Pharmacovigilance
Clinical Trials
DIGA, DIPA

Code systems and Registers

Classifications (ICD-10)
Terminologies
Orphanet

Licensing devisions

Research

HDL

RWD and RWE at BfArM

The main focus of the Health Data Lab (HDL) is:
- providing claims and EHR data for secondary use
- R & D focuses on optimizing the research process & data driven decision making
- Enabling RWE research

The Research Division
- Conducts research based on several data sources, e.g.:
  - Secondary data (pharmacoepidemiology)
  - Primary data
  - Genetic data (pharmacogenomics)

To enable synergies it is paramount that:
- Researchers (e.g. research division) have deep knowledge about the data generating processes
- Data providers have deep knowledge of the requirements of researchers to optimise the research process
Data Characteristics

- 73 million people with statutory health insurance in Germany
- Information from all health care sectors linked on the individual level
- Longitudinal data starting from 2009
- Interoperability with established code systems (e.g. ICD10, ATC)

Outpatient Data
- ID of doctors / institution
- Quarter
- Doctor ID
- Diagnoses (ICD-10)
- Localization
- Date of service
- Number and type of Procedures: OPS codes
- Dental procedures
- …

Personal information
- Year of birth
- Sex
- insurance coverage times
- Insurance status
- Place of residence
- Reason for leaving insurance
- Death
- …

Prescriptions
- PZN (Central pharmaceutical number)
- ATC
- Date of prescription
- ID of doctors / institution
- Quantity / fraction
- Date of prescription
- Number of product prescriptions
- …

Inpatient Data
- Dates of admission and discharge
- Hospital ID
- Department
- Admitting doctor
- Primary and secondary diagnoses (ICD-10)
- Localization
- Type of treatment
- Procedures
- DRGs
- …

Others
- Aids and remedies
- Midwife care
- Digital Health Applications ( DiGA )
- Volunteered electronic health records
- …

Others
- Prescriptions
- Inpatient Data
- Personal information
- Outpatient Data
- Others
Electronic Health Record (eHR)

Voluntarily shared electronic Health Records:

- 2023: Structured medical information objects (MIO) in HL7/FHIR®
- E.g.:
  - Digital certificate of vaccination
  - Digital maternity record
  - Digital child examination booklet

https://mio.kbv.de
https://www.hl7.org/fhir/
Typical Data Provisioning Process

- Process to **find** data is unclear

- Process to **access** data is unclear, especially when several data sources need to be linked

- Usability and safety of **processing** the data is unclear, especially concerning processing environment
Data Provisioning Process @HDL

User finds required data through metadata catalogue and application form

HDL provides anonymised training data in a secure processing environment (SPE)

User develops analysis within SPE

HDL provides aggregated results

HDL evaluates results regarding re-identification potential

HDL runs analysis on original data and obtains aggregated results
Homepage

https://www.healthdatalab.de/
Fully Digital Data Application Process
Next Steps....... 

Participation:  
**TEHDAS:**  
“Joint Action Towards the European Health Data Space”

**Point & Click UX, AI-readiness**  
**Automatisation with AI (Analysis, ETL, Performance)**

**Funded by Federal Ministry of Health:**  
„Artificial Intelligence at the Health Data Lab - Investigation of anonymisation methods and AI-readiness “

Participation:  
**EHDS2 - Pilot project**  
Co-Lead of WP5  
IT-Infrastructure

https://ec.europa.eu/health/ehealth/dataspace_de  
https://tehdas.eu/
Synthetic Data and AI-readiness

Aims
• Creating synthetic data with AI-methods and comparing them with „classically“ anonymised data
• Evaluation of AI-readiness
• European connectivity

Duration
November 2021 - December 2024

Partners
• InGef – Institute for Applied Health Research Berlin GmbH
• Berlin Institute of Health at Charité (BIH)
• Fraunhofer Institute for Digital Medicine MEVIS

Blog article: https://www.bfarm.de/EN/News/Blog/_docs/2022-03-10-forschungsdatenzentrum.html
# Proposal for a regulation - The European Health Data Space (EHDS)

<table>
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<tr>
<th>Primary use</th>
<th>Secondary use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients</strong> receive access to and control over electronic health data</td>
<td>Establishment of a cross-border data infrastructure (<em>MyHealth@EU</em>)</td>
</tr>
<tr>
<td></td>
<td>Establishment of a European data platform (<em>HealthData@EU</em>), accessible via data access bodies</td>
</tr>
</tbody>
</table>

Publication date: 3 May 2022

Source: Adapted from Federal Ministry of Health
Proposal for a Regulation - The European Health Data Space

Source: European Commission
Joint Action **Towards the European Health Data Space** with the following pillars:

- Reliable data governance system and principles for cross-border data use
- Data quality
- Secure infrastructure und interoperability
- HDL supports TEHDAS as part of a delegation coordinated by Federal Ministry of Health

**EHDS Initiative TEHDAS**

https://ec.europa.eu/health/ehealth/dataspace_de
https://tehdas.eu/
Health Data@EU Pilot for a European Health Data Space on Secondary Use of Health Data

- Aim: Setup of a first version of the EHDS and testing of medical use cases
- Co-funded by EU Commission (EU4Health Programme)
- Project start: October 2022
- Planned duration: 24 months
- Coordination: Health Data Hub
- Participants: 17 partners
  (national nodes, ERICs, European agencies and research institutions)

https://ehds2pilot.eu/
Health Data@EU Pilot for a European Health Data Space on Secondary Use of Health Data

Selected use cases

- Mobilise and chain clinical and genomic data to enhance our understanding of colorectal cancer (led by ELIXIR)

- Foster a better understanding of the risks of thrombosis in COVID-19 patients (led by the European Medicines Agency)

- Compare COVID-19 testing, vaccination and hospitalisation between the general population and vulnerable subpopulations (led by Sciensano - Belgium)

- Compare care pathways for cardiometabolic diseases in European countries and build prediction models, using artificial intelligence (led by the Health Data Hub - France)

- Demonstrate the feasibility of using the EHDS to carry out infectious disease surveillance, focusing on antimicrobial resistance (led by the European Centre for Disease Prevention and Control)

https://ehds2pilot.eu/
Advantages of the HDL

➔ The HDL enables RWD projects with **timely, representative and homogeneous data**

➔ Increased **data diversity** by linking data (eHR) and coming sources (inter-)nationally (EHDS)

➔ Strong **data protection** by organisational design and innovative methods (AI)

➔ **Research-friendly workflow** with more options for data provision is being continuously optimised with user feedback
**Real4Reg**

*Horizon Europe Project*

Development, Optimisation & Implementation of AI-Methods for RWD Analyses in Regulatory Decision-Making & HTA along the Product Life-Cycle

Duration: 2023-2026, ~ 7 Mio €

**Consortium:** 10 Partners, 6 EU countries, **Lead:** BfArM

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### Objectives

- Unlocking potential of AI methods in the regulatory and HTA context
- Usable standards in RWD use
- Guidance and training in RWE use and RWD analyses for health regulatory and HTA bodies across all EU countries
- Acceptance and impact of RWD and synthetic data along the product lifecycle

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### Needs and Outcomes

**Analytic solutions**

**Usable standards**

**Guidance & training**

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**Impact**

**Value**

**Use**
Overall methodology

**Pre-Authorisation & Evaluation**

- **Use Case 1**: Analytical solutions developed in and applied on European national register data & statutory health insurance data
  - **Description of Study Population**: Amyotrophic Lateral Sclerosis, Breast Cancer
  - **Study Design**: Historical Control
    - Amyotrophic Lateral Sclerosis, Breast Cancer

**Post-Authorisation**

- **Use Case 2**: Safety & Intervention
  - Fluoroquinolones
- **Use Case 3**: Effectiveness
  - SGLT2 Inhibitors

**Use Case 4**: Usable standards for data quality, common data model, analytical workflows

Reflection from interfaces between AI/ data science, epidemiology, NCAs, clinical science, payer, industry, patients
Conclusion and Outlook

BfArM#digital & change readiness:
with FDZ, DiGA/DiPA, coding systems, current AI approaches and (EU-)RWE projects for regulatory tasks at a central location in the dynamically growing digital health ecosystem

Exploiting opportunities – identifying challenges and address them together

Defining framework and rules

BfArM - openness for AI-approaches
Thank you very much for your attention!

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