More information: www.expandai.de

About us

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- Universität zu Lübeck, Professor (Medical Informatics)
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Artur Piet, M.Sc.
- AI & Data Science

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- Software Developer, Backend

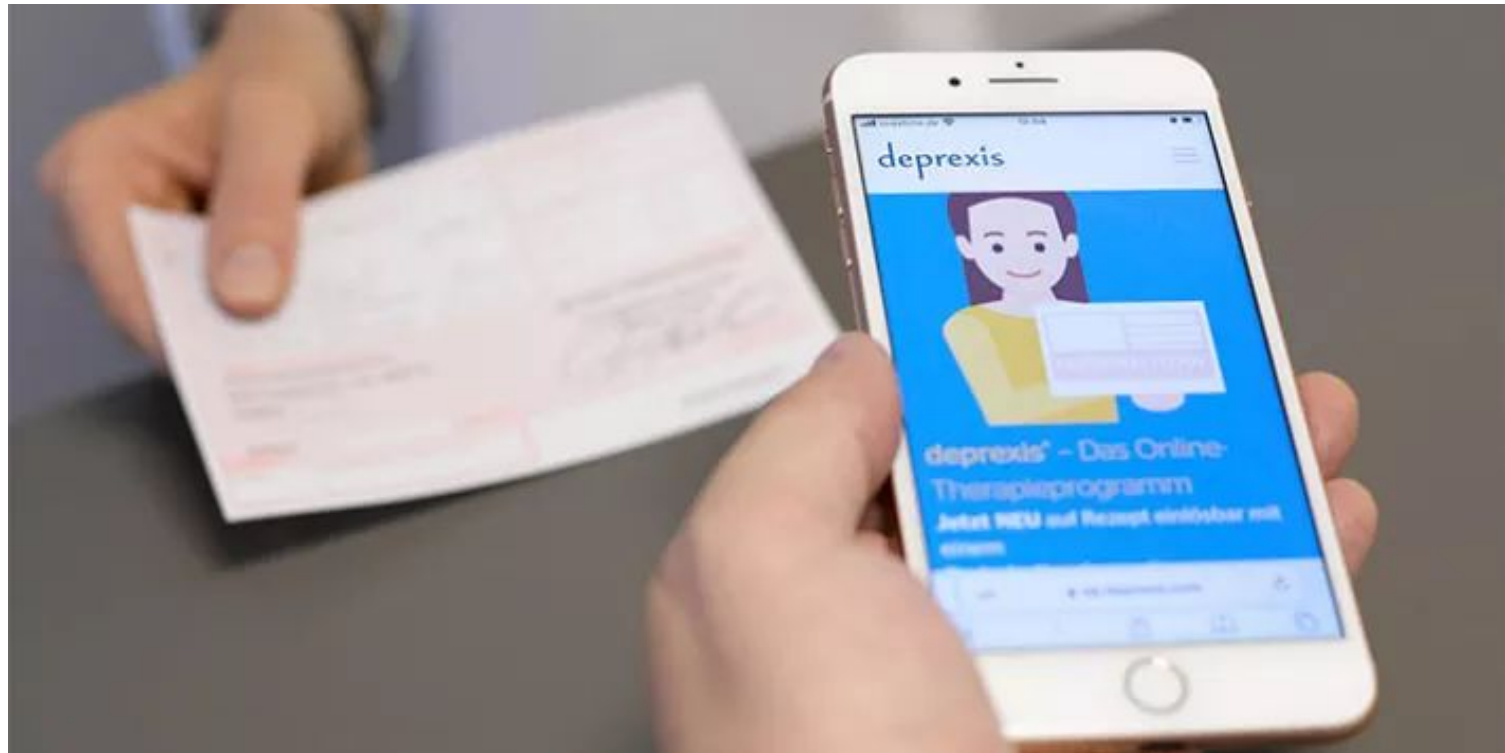UNIVERSITÄT ZU LÜBECK
INSTITUT FÜR MEDIZINISCHE INFORMATIK

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DiGA Demonstrator

FAIR Data Spaces

FAIR and Secure Data Sharing for Digital Health Applications

What is a DiGA?

DiGA (Digitale Gesundheitsanwendung, or "Digital Health Application") is a certified digital tool in Germany designed to help patients manage, treat, or prevent medical conditions.

Medical Purpose:
DiGAs are intended for the diagnosis, treatment or prevention of diseases. Examples include apps for managing diabetes, mental health disorders, chronic pain, or Parkinson.

Regulatory Approval:
To qualify as a DiGA, the app must be approved by Germany's Federal Institute for Drugs and Medical Devices. This ensures the app meets strict criteria for quality, safety, and data protection.

Evidence-Based:
DiGAs must demonstrate measurable positive effects through scientific studies.

Reimbursement by Health Insurers:
Once approved, DiGAs can be prescribed by doctors and are paid by health insurance providers in Germany. Which is very profitable for companies.

Increasing Relevance of DiGAs

Abbildung 6: Entwicklung der DiGA-Inanspruchnahmen pro Quartal und Markteintritte neuer DiGA im Zeitablauf

DiGA-Report 2022 – DiGA-Versorgung
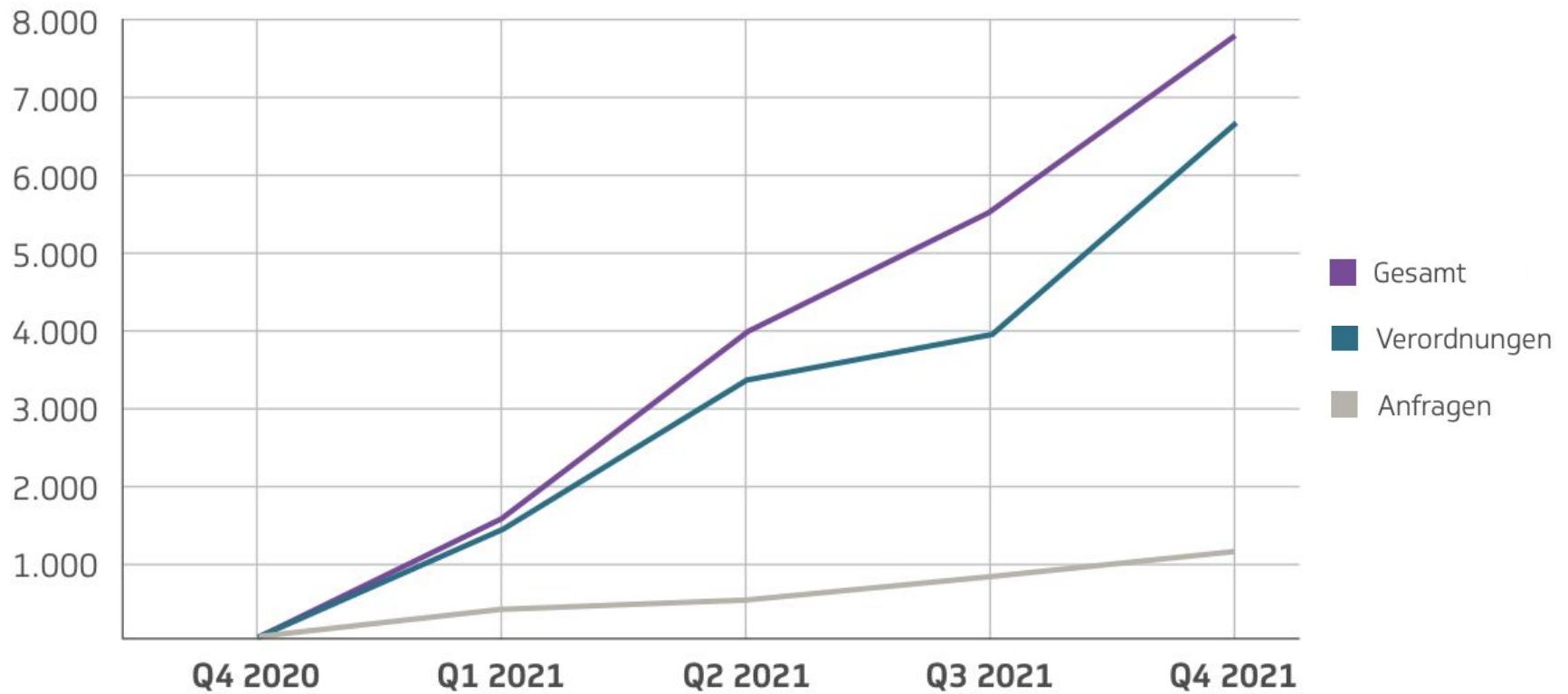
Inspiration: ParkProReakt

ParkProReakt - Evaluation of a proactive approach to health care in Parkinson's disease: a study protocol for a randomised controlled trial

Marlena van Munster[1,2,3], Johanne Stümpel[1,4], Anna J Pedrosa[1], Kati Niemand [1], Ingmar Wellach[5], Dirk Becker[5], Isabel Doblinger[5], Kristina Schmidt[5], René Reiners[6], Daniel Wolferts[6], Anika Martin[6], Marius Nisslmüller[6], Keywan Sohrabi[7], Volker Groß[8], Birgit Samans[8], Patrick Fischer[8], Mohammed Osman Ashraf[8], Rebecca Wichratz[8], Marcin Grzegorzek[9], Xinyu Huang[9,10], Artur Piet[9,10], Mona Irsfeld[9], Christian Trense[9], Paulina M. Olgemöller[11], Ümran Seven[11], Ann-Kristin Folkerts[11], Elke Kalbe[11], Hannes Böbinger[12], Jens Dapper[13], Lars Wohlfahrt[14], Max Geraedts[15], Natalie Altschuck[15], Linda Kerkemeyer[16], Carsten Eggers[1,17], David J Pedrosa[1,18]
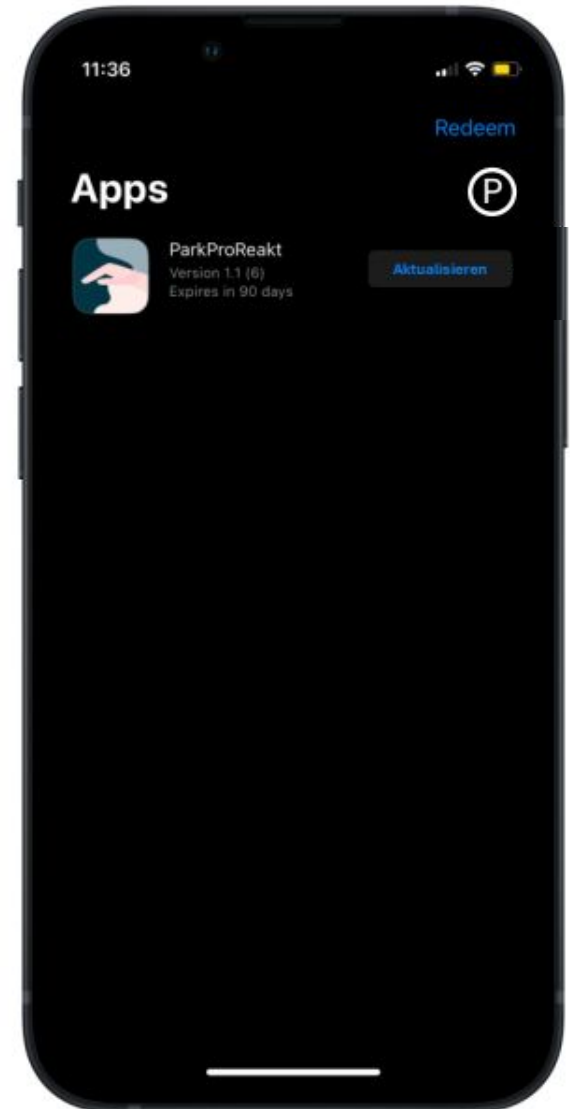
DiGA Demonstrator Overview
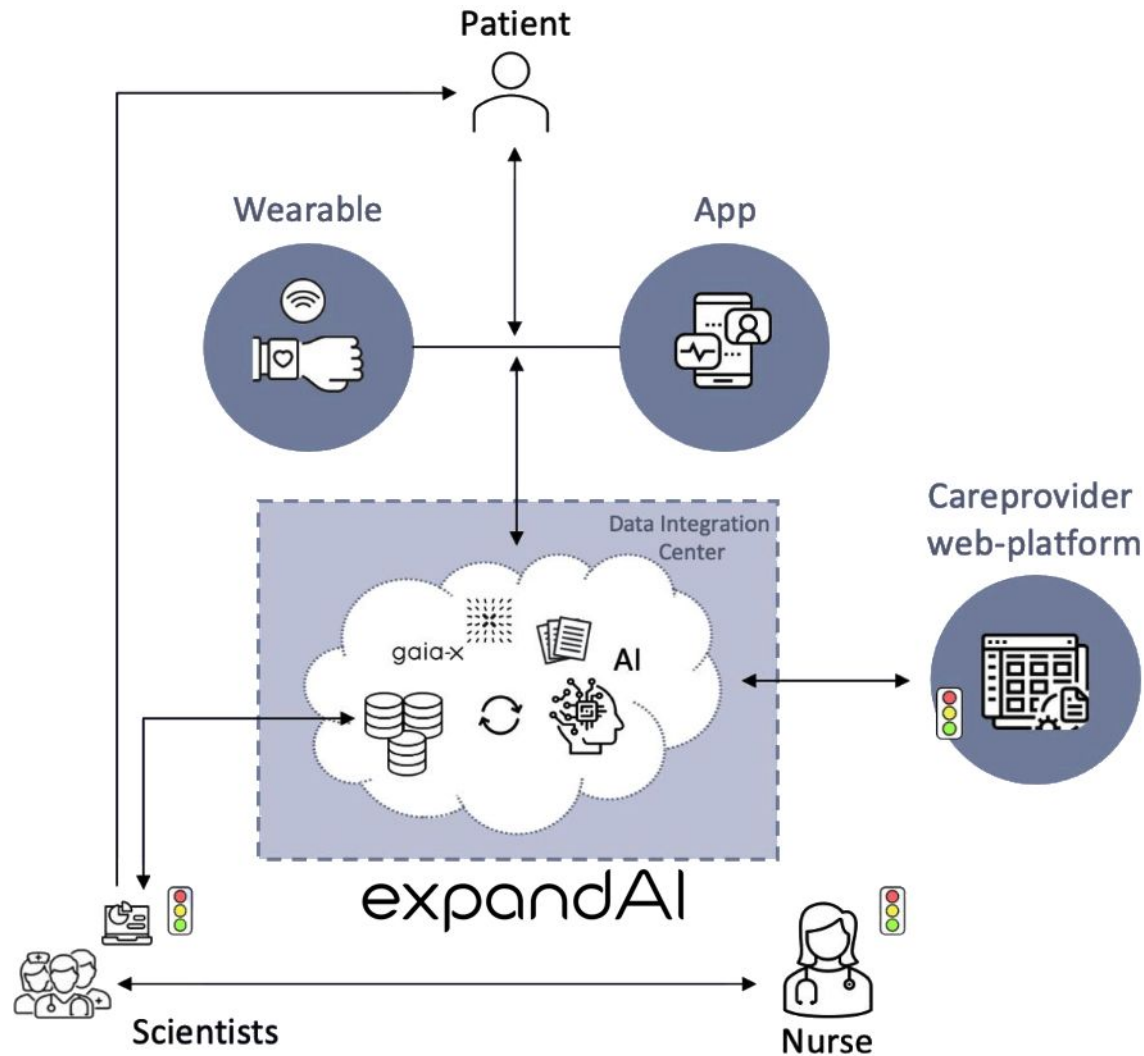
Data for our Demonstrator

We used only data generated using GAN (Generative Adversarial Network).
We did not utilize any real patient data.
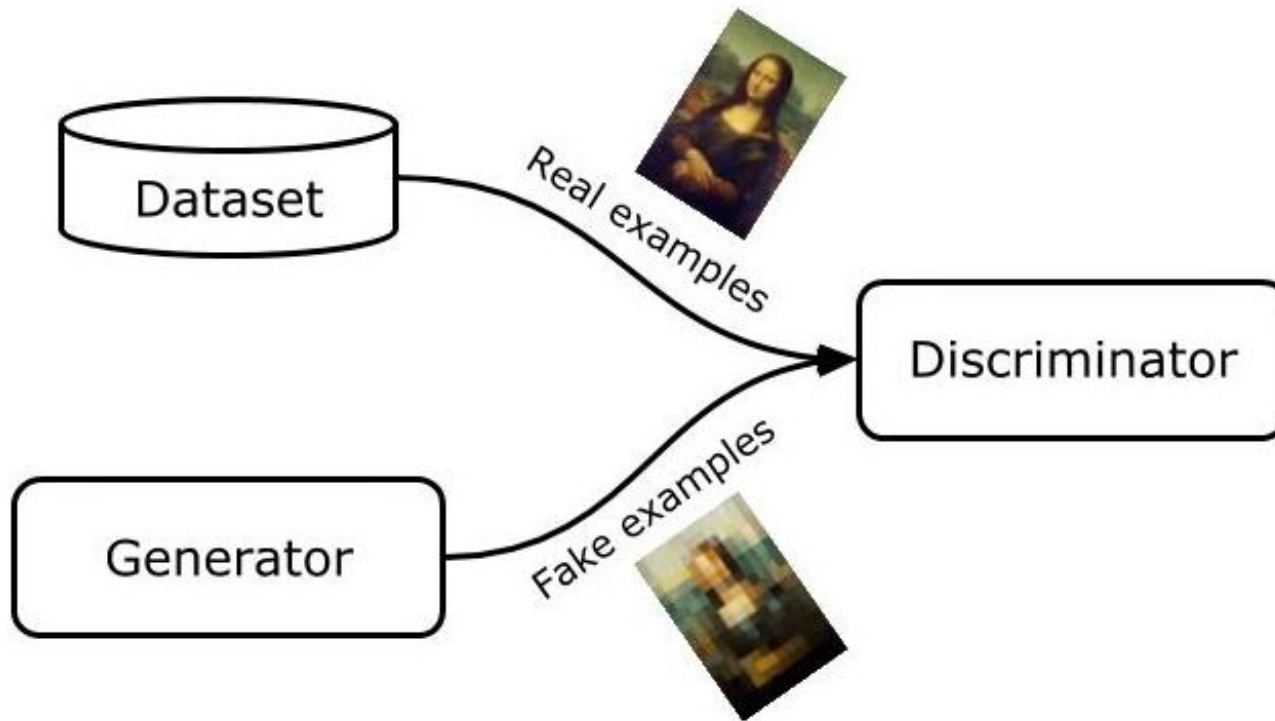
Data Integration Center
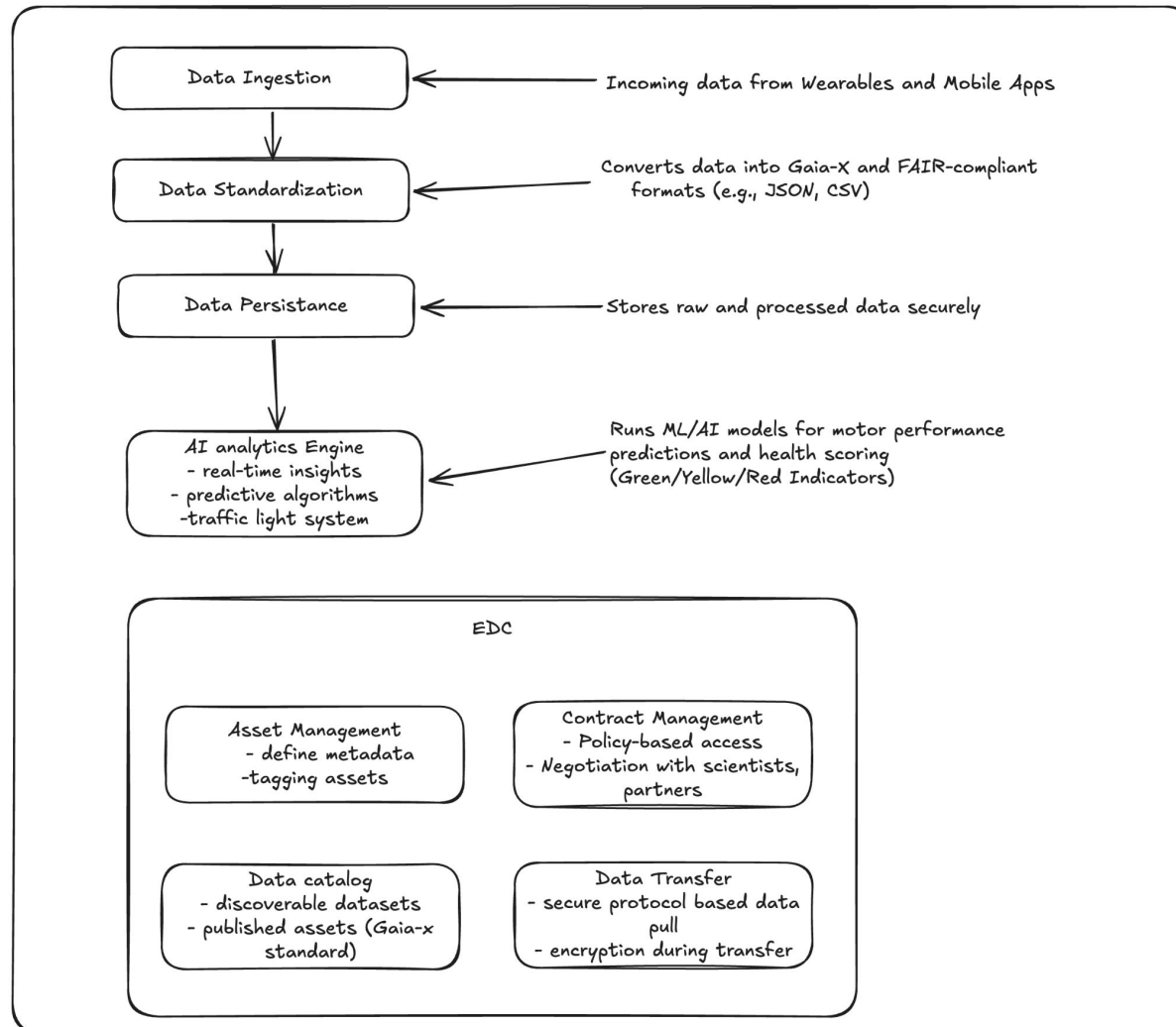
1. Our role of EDC in the Demonstrator

The EDC connector acts as the backbone for our secure, compliant, and FAIR data exchange. We use the Sovity connector, which enables:

• **Data Discovery:** Healthcare providers, researchers, and companies developing DiGAs can access available data.

• **Policy Management:** Enforce data access rules to comply with legal and ethical requirements (e.g., GDPR "DSGVO").

• **Secure Data Transfer:** Ensure data integrity and confidentiality when transferring data between participants in the ecosystem.

2. Incorporate EDC into Data Integration Center

Our Data Integration Center gathers and standardizes Parkinson's patient data from smartphones and smartwatches.
The EDC connector can be integrated into this workflow as follows:

1. Data as an Asset:

• Define patient health metrics (e.g., UPDRS, MoCA, …) as assets in the EDC.

• Use the EDC's REST API to make these assets discoverable in a controlled manner.

2. Access Policies:

• Create policies for who can access data and under what conditions.

• For instance, restrict data access for AI training while allowing doctors to view specific patient data for real time healthcare decisions.

3. Contract Management:

• Define data usage contracts between providers and consumers (e.g., researchers, healthcare providers).

4. Data Transfer:

• Use the Consumer-PULL workflow to transfer data securely.

• The consumer (e.g., a industry company training an AI algorithm module) negotiates the contract and retrieves the data for training.

3. Our EDC Integration Workflow: 2 Sides

As a Data Provider:

• Create assets for patient data (e.g., finger-tap metrics, scores, symptoms).

• Define policies for data usage (e.g., research purposes, clinical monitoring).

• Publish these assets to the EDC catalog for discoverability.

As a Data Consumer:

• Fetch the catalog to identify available data assets.

• Negotiate contracts based on policies.

• Retrieve data to integrate into their (AI-)pipeline.

4. FAIR (and Gaia-X Compliance)

• **Findability**: We publish patient health metrics as metadata in the EDC catalog.

• **Accessibility**: We enforce policies that define who can access the data and under what conditions.

• **Interoperability**: We use standard APIs (e.g., REST) and data formats to ensure compatibility with other systems.

• **Reusability**: We allow researchers, healthcare providers and DiGA companies to access anonymized or aggregated datasets for various use cases.

5. Implementation of our Traffic Light System

Our EDC connector enables real-time data transfer to provide updates on patient conditions. For example:

• A medical doctor accesses the system via the web platform.

• The platform fetches data (via EDC) to update the traffic light status:

- Green: Data shows normal metrics. No action.
- Yellow: Early signs of issues. PD Nurse will visit.
- Red: Critical condition. PD doctor will visit.

6. Deployment and Collaboration
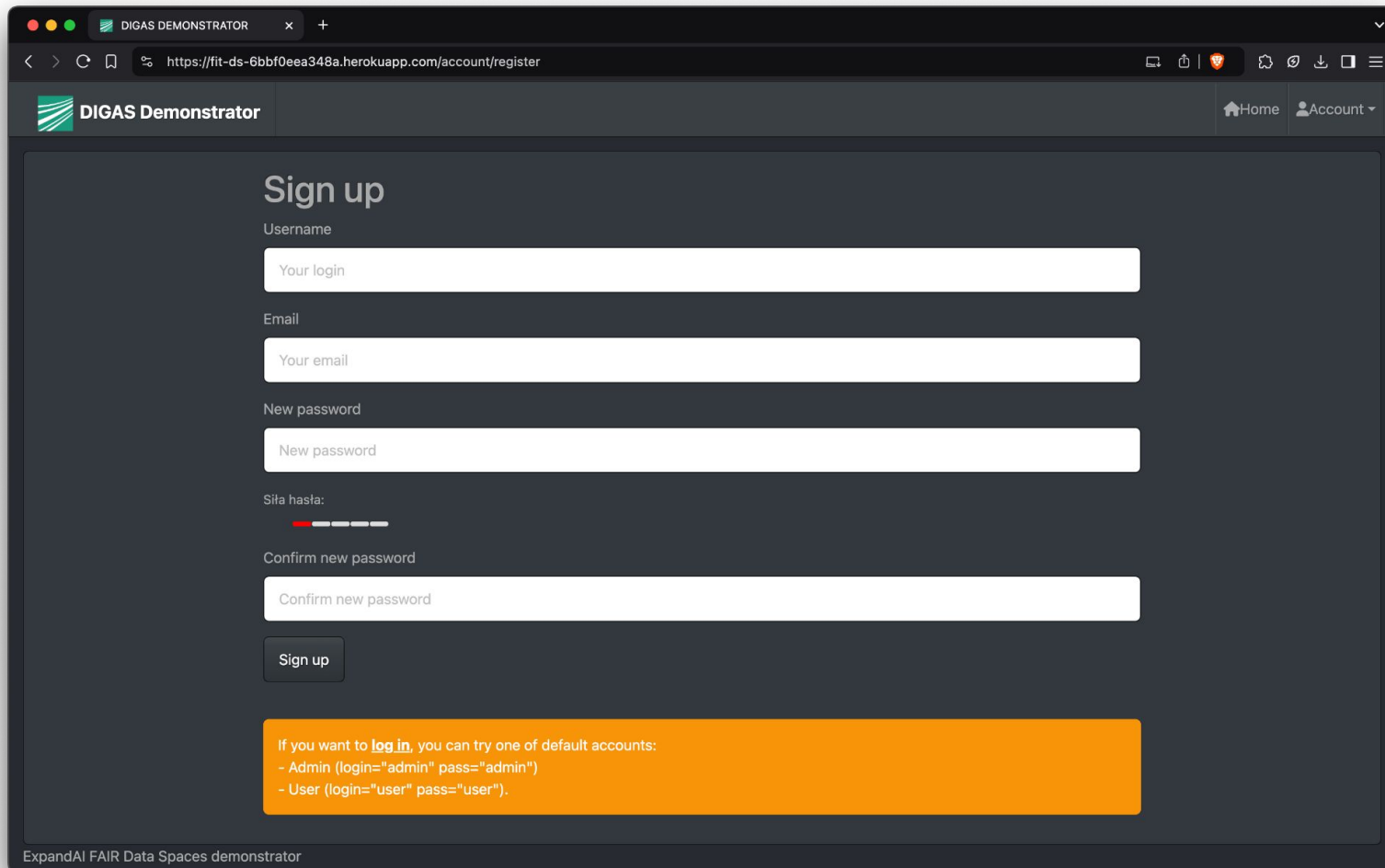
Our Deployment can take place in 3 steps:

• Deploy the EDC connector alongside our demonstrator backend (e.g., Spring Boot application).

• Configure the connector to interact with the data integration center.

• Enable access for scientific institutions and industry partners to enhance collaboration within the healthcare ecosystem.

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Demo

Sign Up Page

Login Page

Dashboard

Dashboard

Dashboard

Dashboard

Dashboard

Dashboard

Dashboard

Patient Overview

Dashboard - Data Visualisation Feature

Data Visualisation Feature (e.g. Finger Taps)
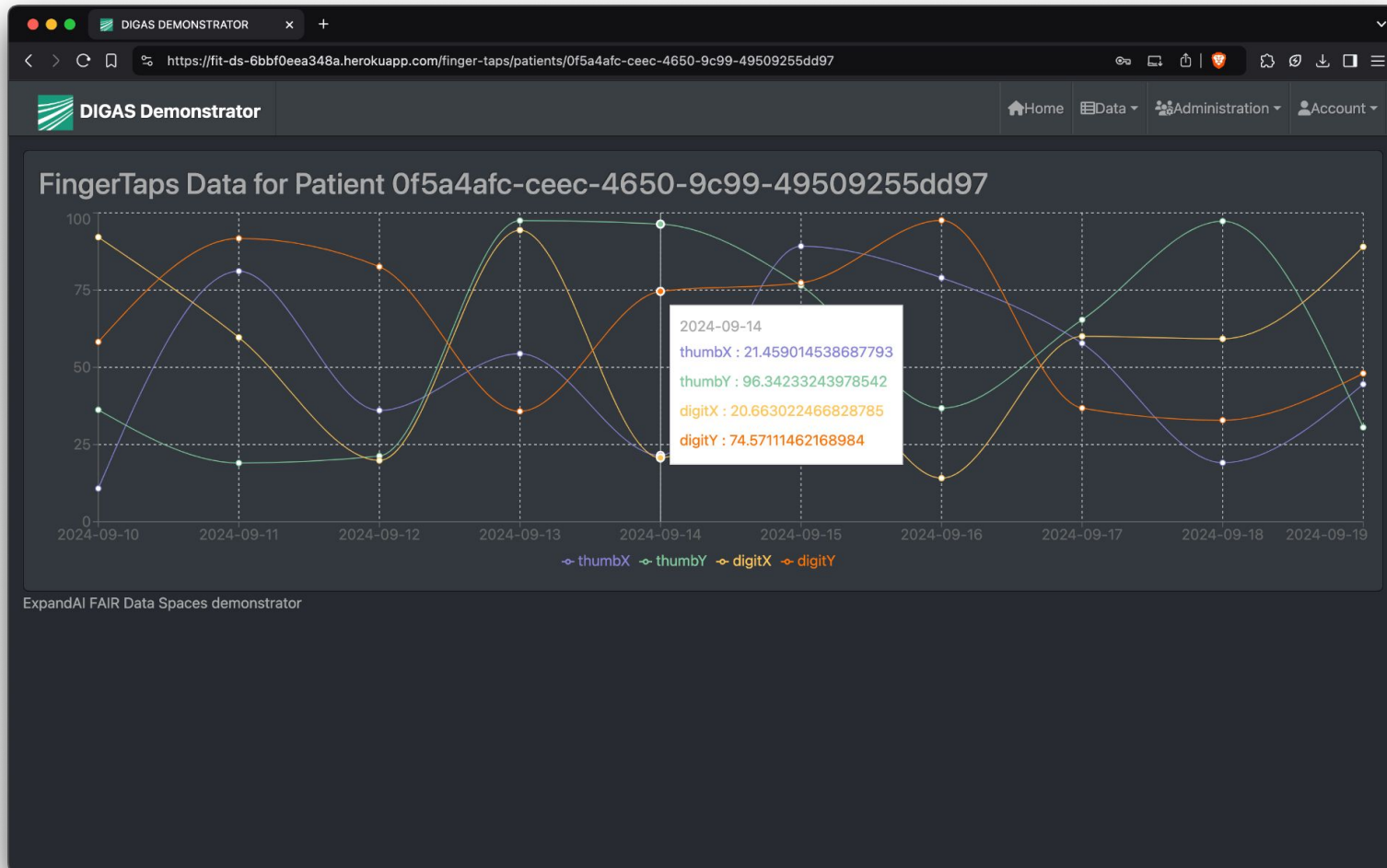
Data Visualisation Feature
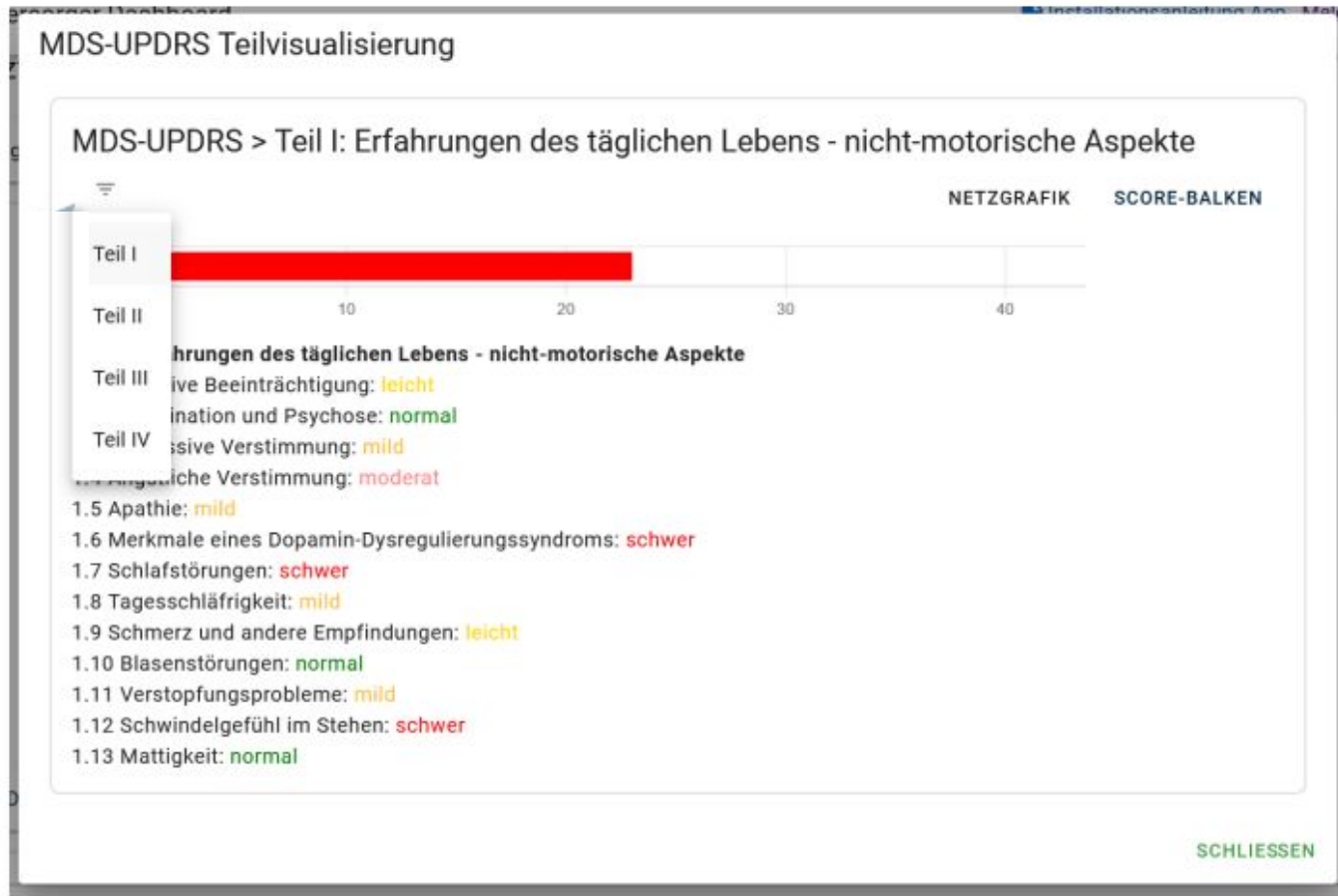
We can visualize various kinds of data, e.g.:

- Meta data of the patients (age, gender, …)

- Parkinson-specific data and scores like:
    - Year of diagnosis
    - UPDRS (Unified Parkinson's Disease Rating Scale)
    - MoCA (Montreal Cognitive Assessment)
    - …

- In-App clinical Parkinson tests like:
    - Finger Tapping Data and Scores
    - Hand-Rotating Data and Scores
    - …

- Symptoms, using a diary ("Symptom-Tagebuch")

Example: Additional Data Visualisation
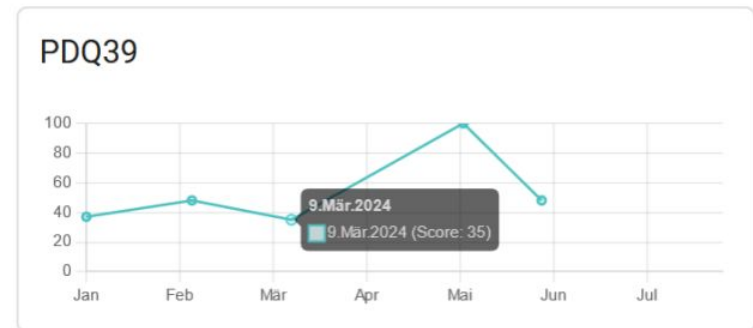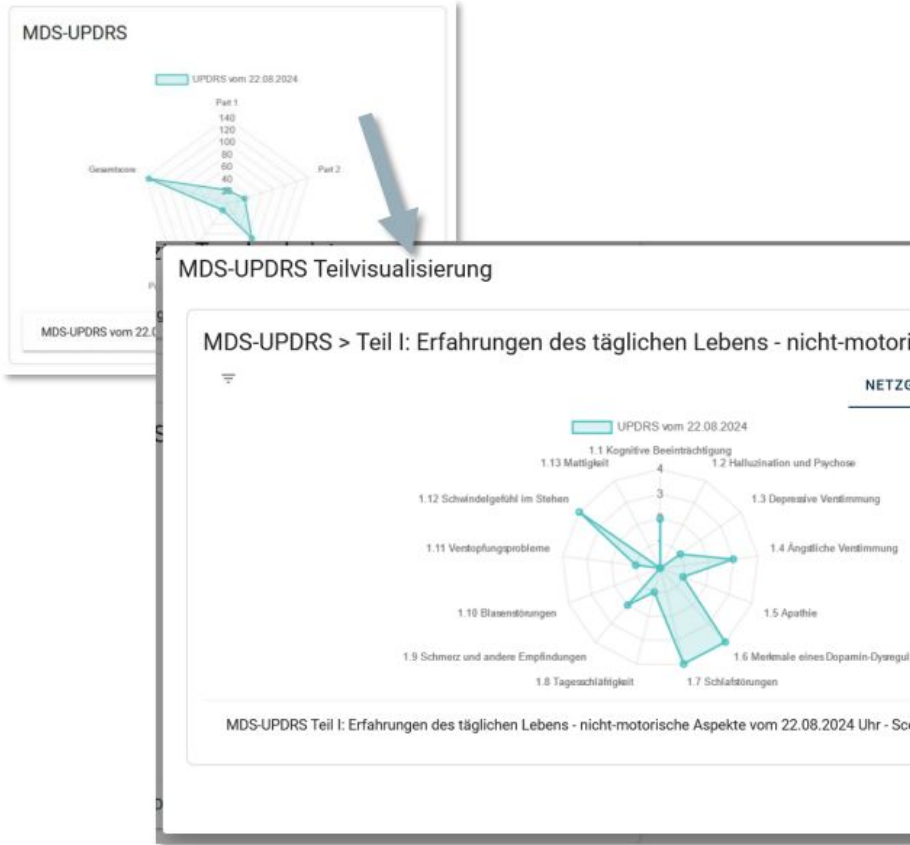
Inspiration: ParkProReakt

Example: Symptoms Visualisation
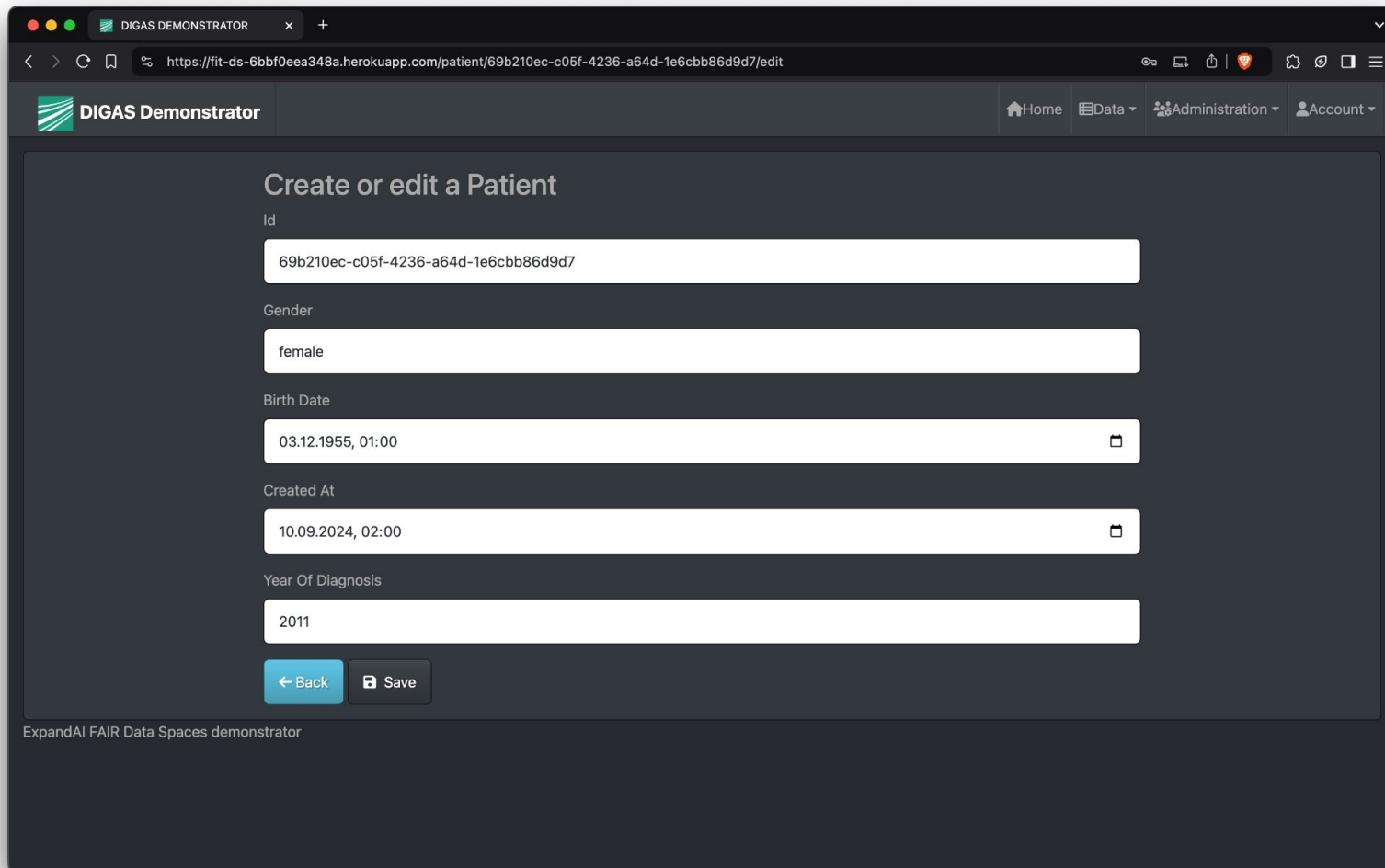

Inspiration: ParkProReakt

Dashboard - Edit Patient Data Feature

Edit Patient Data Feature

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