

#### More information: www.expandai.de



#### About us



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- Direktor DFKI Lübeck

Artur Piet, M.Sc.

- AI & Data Science



#### Robert Pietrzynski, B.Sc.

Software Developer, Backend

ISCHE INFORMATIK





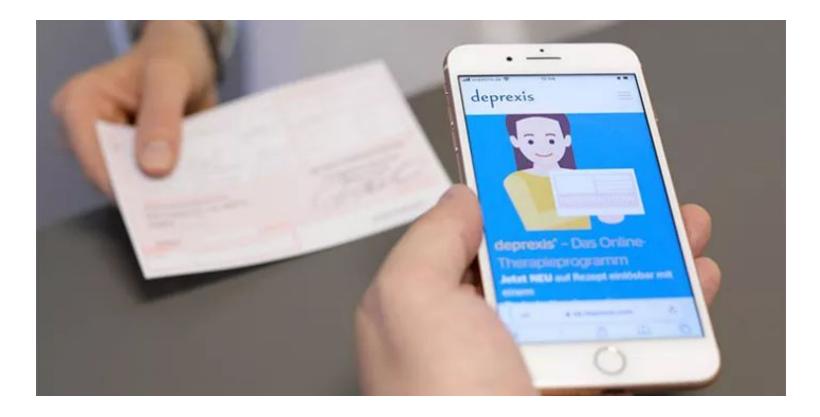




### **DiGA Demonstrator**



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:**

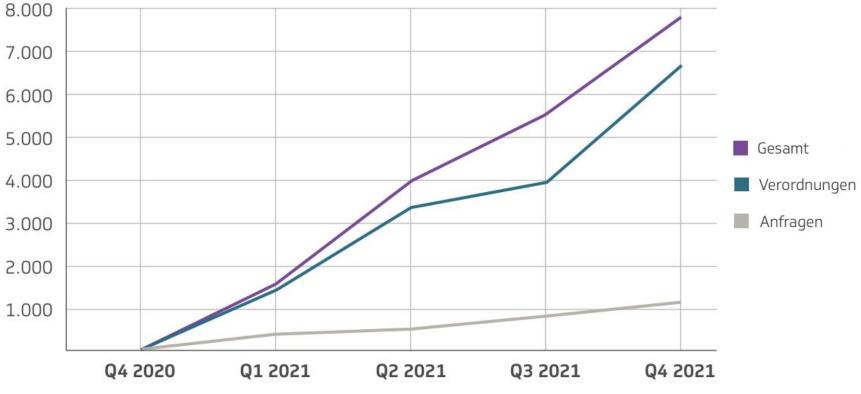
DiGAs must demonstrate measurable positive effects through scientific studies.

#### **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



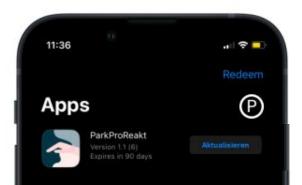
DiGA-Report 2022 – DiGA-Versorgung



### **Inspiration:** ParkProReakt

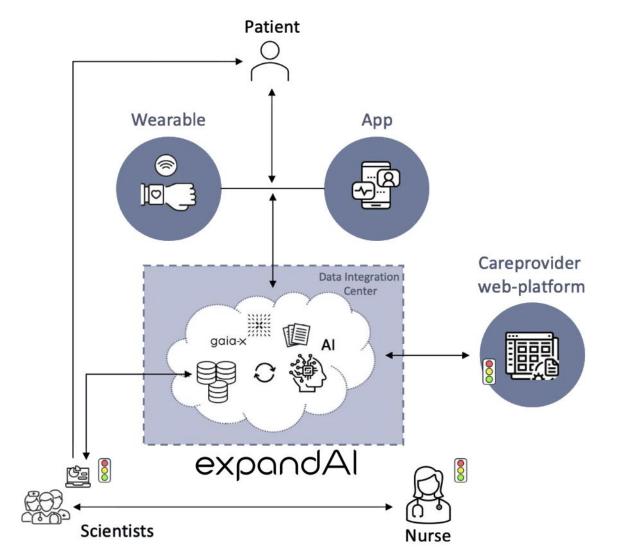
# ParkProReakt - Evaluation of a proactive approach to health care in Parkinson's disease: a study protocol for a randomised controlled trial

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





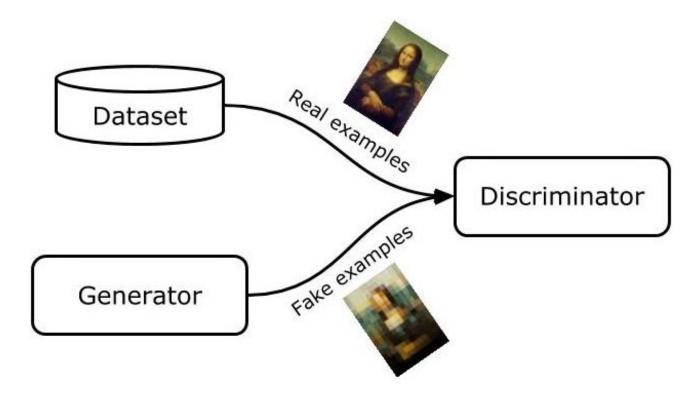
#### **DiGA Demonstrator Overview**



### **Data for our Demonstrator**

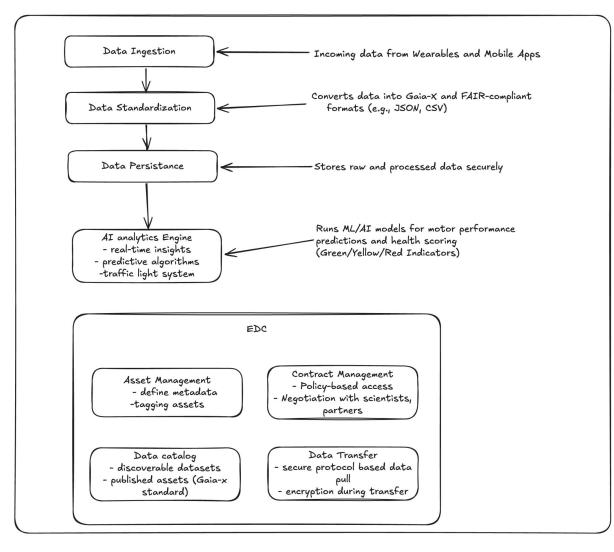
We used only data generated using GAN (Generative Adversarial Network).

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 <u>Sovity</u> 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.



# Demo

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69b210ec-c05f-4236-	<u>086d9d7</u> female	03/12/1955	10/09/2024	2011		View FingerTaps	View Scores	📀 View 🖋 Edit	Delete
8c4a9ec4-f2bb-4ed9-9055-f4600	<u>699ec6a</u> female	27/02/1953	11/09/2024	2020		View FingerTaps	View Scores	📀 View 🖋 Edit	Delete
b82d79f2-c8a0-4e9a-b5de-7e5da	<u>f94d317</u> male	11/05/1951	11/09/2024	2014		View FingerTaps	View Scores	📀 View 🖋 Edit	Delete
cbd4e861-471d-44c7-a91c-c77320	<u>0dc0a57</u> female	25/02/1991	11/09/2024	2014		View FingerTaps	View Scores	📀 View 🖋 Edit	Delete
<u>d9a1186a-733a-4a2f-9dac-6c00cd</u>	<u>197cc5b</u> female	26/12/1959	10/09/2024	2016	•	View FingerTaps	View Scores	📀 View 🖋 Edit	Delete
fe89e731-0420-43bd-a8dd-5173f0	<u>)4f34f7</u> male	11/12/1998	10/09/2024	2001	•	View FingerTaps	View Scores	📀 View 🖋 Edit	Delete

#### **Patient Overview**

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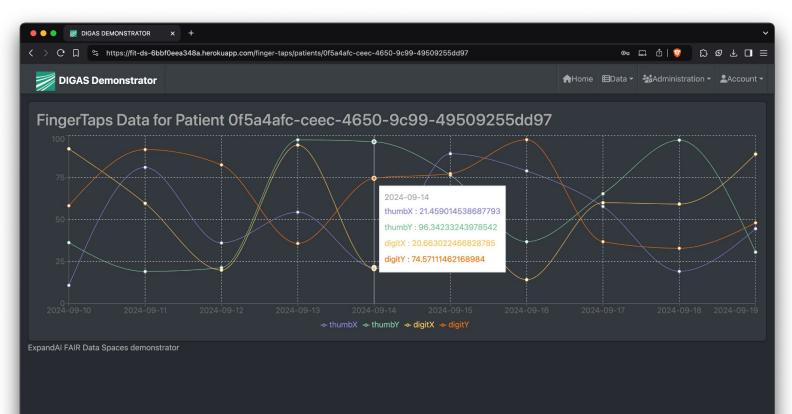


#### **Dashboard - Data Visualisation Feature**

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<u>53cefb0f-7158-49fa-9fb6-b1b4dd35bbbe</u>	male	14/06/2002	10/09/2024	2008		Viev	View Scores	💿 View 🖋 Edit 🧻 Delet	e
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<u>d9a1186a-733a-4a2f-9dac-6c00cd97cc5b</u>	female	26/12/1959	10/09/2024	2016	•	View FingerTaps	View Scores	📀 View 🖋 Edit 🥫 Delet	e
fe89e731-0420-43bd-a8dd-5173f04f34f7	male	11/12/1998	10/09/2024	2001	•	View FingerTaps	View Scores	Ø View	e



### **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)

- ...

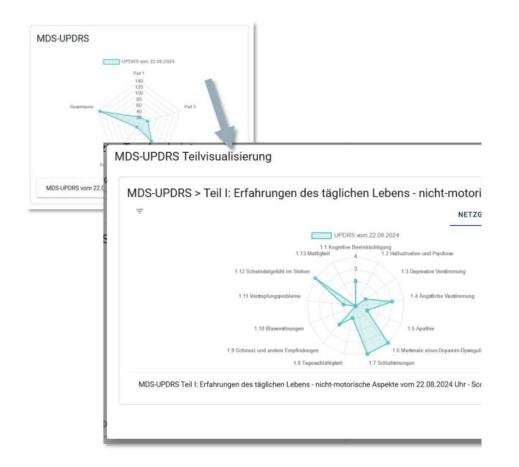
- In-App clinical Parkinson tests like:
  - Finger Tapping Data and Scores
  - Hand-Rotating Data and Scores

- ...

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



### **Example: Additional Data Visualisation**







#### Inspiration: ParkProReakt

# **Example: Symptoms Visualisation**

wDS-u	JPDRS > Teil I: Erfahru	ngen des taglicr	ien Ledens - nicr	NETZGRAFIK	SCORE-BALKEN
Teil I					
Teil II	10	20	30	40	
Teil III Teil IV	hrungen des täglichen Leben ive Beeinträchtigung: leicht ination und Psychose: normal sive Verstimmung: mild		spekte		
	iche Verstimmung: moderat				
	hie: mild	1000			
	male eines Dopamin-Dysregulie	erungssyndroms: <mark>schw</mark>	er		
	afstörungen: schwer sschläfrigkeit: mild				
C	nerz und andere Empfindungen:	leicht			
	senstörungen: normal				
	stopfungsprobleme: mild				
	windelgefühl im Stehen: schwe	r			
1.13 Mat	tigkeit: normal				

#### Inspiration: ParkProReakt



#### **Dashboard - Edit Patient Data Feature**

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ld ▲ Gender ≑ Birth Date ≑ Created At ≑ Year Of Diagnosis ≑ Status FingerTaps Scores	
0f5a4afc-ceec-4650-9c99-49509255dd97 male 17/10/1958 10/09/2024 2019 🔶 View FingerTaps View Soc	ores 🕜 View
52ddd4f3-db56-4a7b-816c-74a56728233d female 19/06/2003 11/09/2024 2020  View FingerTaps View Soc	ores 🧿 View
53cefb0f-7158-49fa-9fb6-b1b4dd35bbbe male 14/06/2002 10/09/2024 2008	ores 📀 View
602ee011-1d48-489c-96c3-f7b8d66fe402 male 18/05/1964 10/09/2024 2019 Ciew FingerTaps View Sco	ores 🧿 View 👕 Delete
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#### **Edit Patient Data Feature**

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