

Rodger Burmeister, **Christina Erler (erler@fzi.de)**, Friedrich Gauger, Raphael J. Dressle, Bernd Feige

FZI Research Center for Information Technology



Advancing Sleep Research through Dynamic Consent and Trustee- Based Medical Data Processing

ICDS 2024

26.-29.05.2024



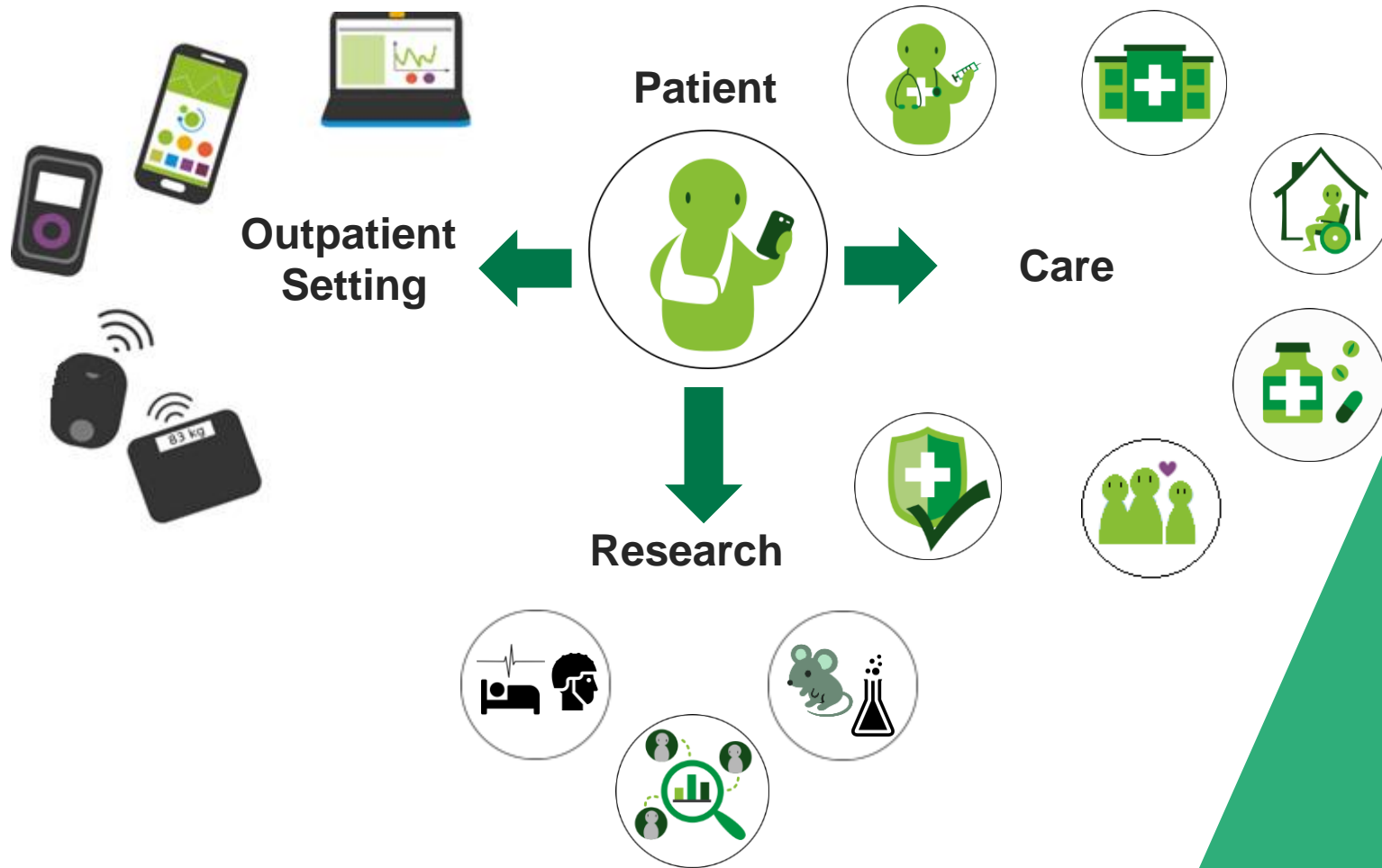
— Resume of the presenter



M. Sc. Christina Erler

- **Position:** Vice Department Manager of the division Medical Information Technology at FZI Research Center for Information Technology & PhD Student at Karlsruhe Institute of Technology (KIT)
- **Education:** Bachelor and Master degree in Computer Science at Karlsruhe Institute of Technology (KIT) in Germany
- **Research Interests:**
 - Focus on decentralized and distributed infrastructures in healthcare (e.g. with Blockchain/DLT)
 - Ensuring digital sovereignty (e.g. through data trustees, Self-Sovereign Identities)

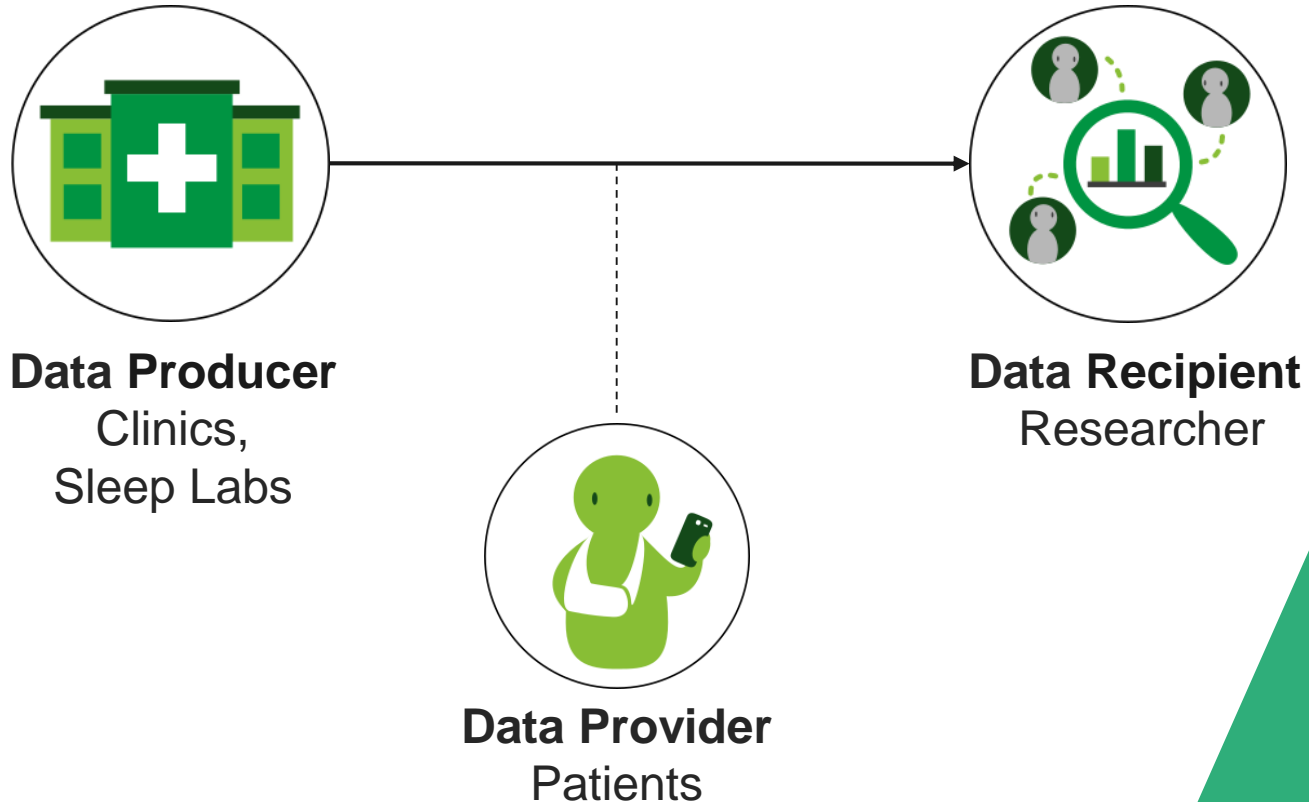
Motivation



- Extensive data collection in the healthcare sector by various stakeholders
- Enormous potential for research and personalized medicine

Motivation

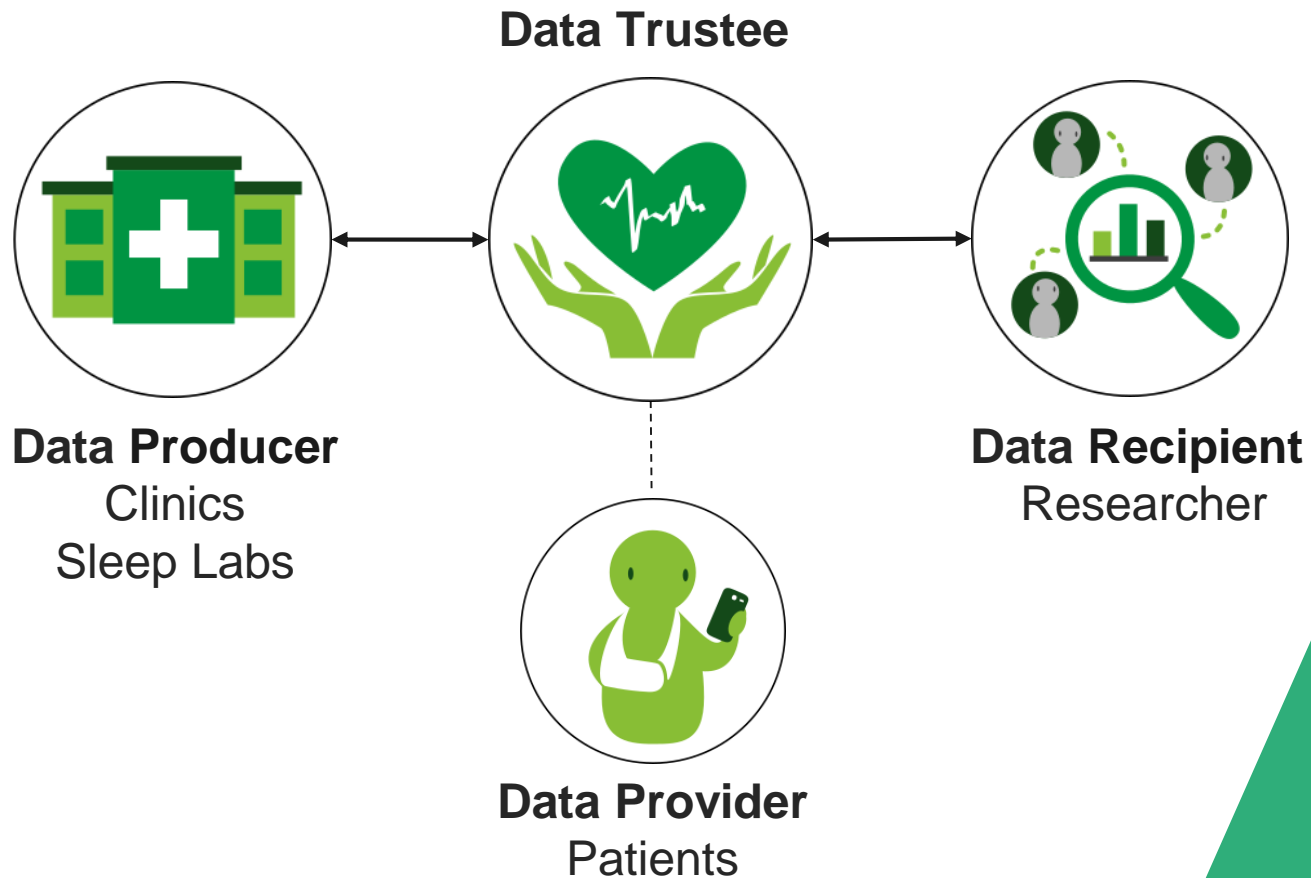
How can sleep data be provided to data recipients, considering the needs of the data providers and data producers?



- Exchange of sleep research data in Germany is often affected by:
 - Fragmentation
 - Institutional data silos
 - Bureaucratic and data security barriers
 - Missing transparency
 - Inefficiency
 - Data quality issues
 - Economic interests

Motivation

Solution: Data trustee as neutral and trustworthy intermediary between the stakeholders involved



- Self-determined, informed and responsible data sharing
- Cross-institutional access to sensitive health data is made possible by a central point of contact
- Privacy and liability concerns can be addressed
- Compliant data use (e.g. in research projects)

Initiatives for data trustees of medical research data



Source: <https://www.healthdatalab.de/>



Source: <https://www.ofai.at/research/nn/siesta/>



Source: <https://physionet.org/>



Source: <https://www.medizininformatik-initiative.de/>

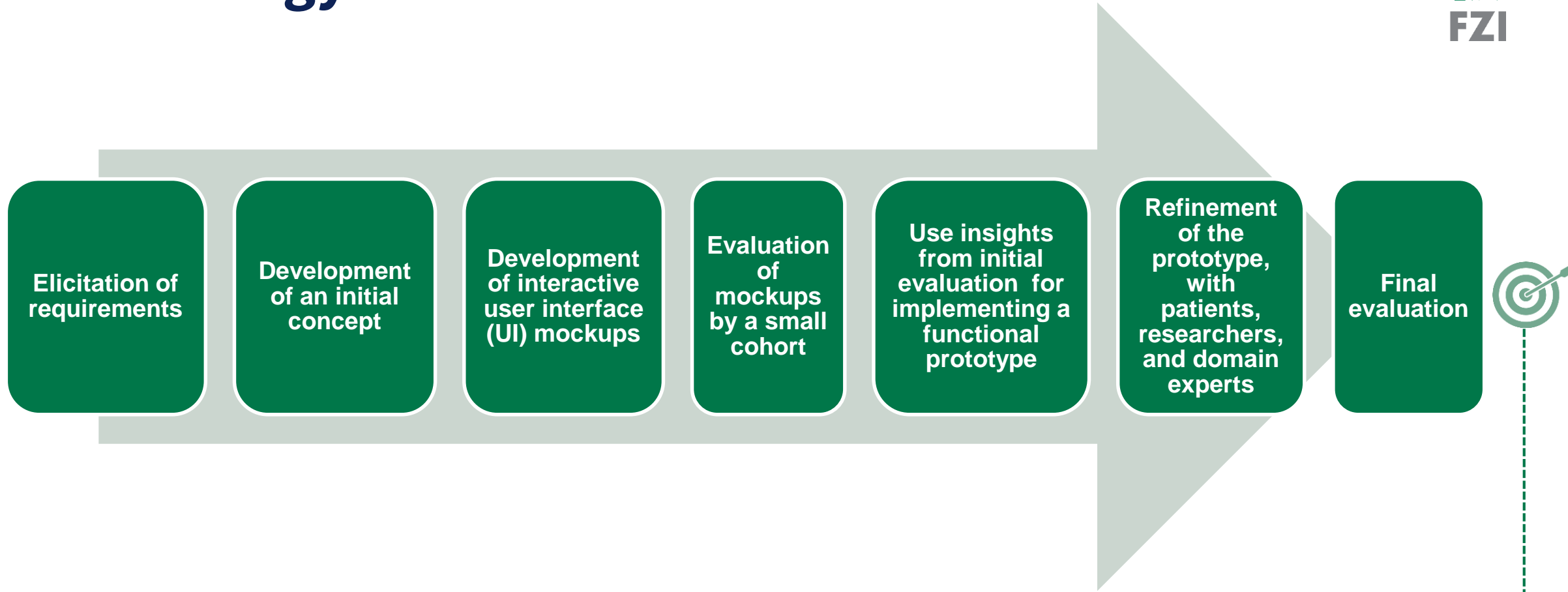


Source: <https://sleepdata.org/>



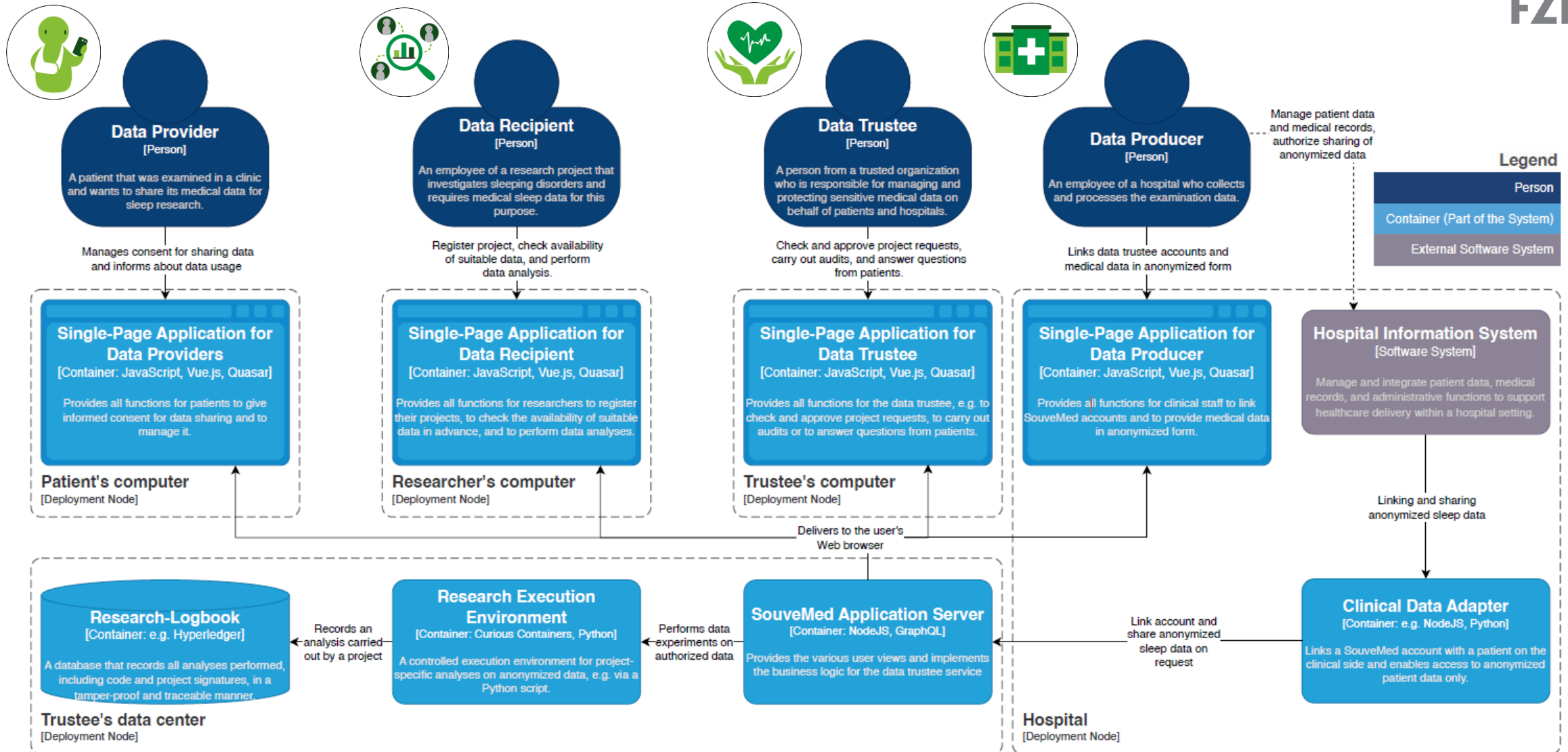
Source: <https://ehds2pilot.eu/>

Methodology



Goal: Design and evaluation of a **distributed data trustee** platform for **self-determined sharing** of **sleep medicine** research data

Distributed architecture for data trustee

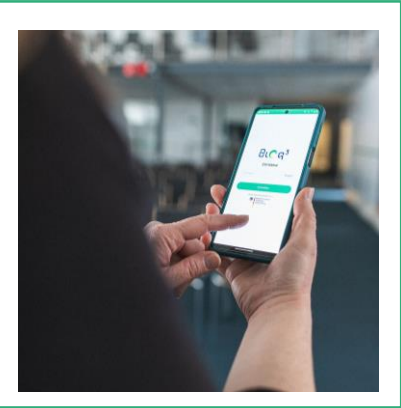
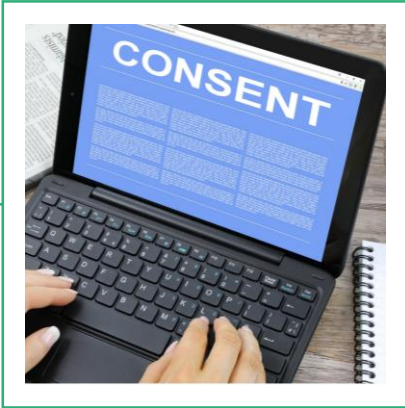


Informed consent process for patients



Challenges

Comprehensive understanding



Flexibility and control

Data granularity




Duration and withdrawal

Design of the informed consent process for patients

Solution



☰ SouveMed 

- Übersicht
- Kliniken und Datensätze
- Freigabe und Einwilligung
- Freigabearchiv
- Projektzugriffe
- Über SouveMed
- Kontaktmöglichkeiten
- Benutzerkonto

← Konfiguration Ihrer Freigabeeinstellungen

1. Vorbedingungen

Ich bestätige, dass ich über die [Chancen und Risiken](#) einer Datenfreigabe informiert wurde und an mindestens einem [persönlichen Aufklärungsgespräch](#) in einer Klinik oder einem Schlaflabor teilgenommen habe.

Ja, ich wurde über die Chancen und Risiken einer Datenfreigabe informiert.

2. Datenauswahl

Ich bestätige, dass die nachfolgend ausgewählten Datensätze von schlafmedizinischen Einrichtungen, die mich behandelt haben, an interessierte [Projekte](#) zur Erforschung von Schlaf und Schlafstörungen durch das [SouveMed-Projekt](#) weitergegeben werden dürfen. Für eine erfolgreiche Datenfreigabe muss hier mindestens ein Datensatz ausgewählt werden.

- Datensatz SM-70153C03**
Einrichtung: Charite Universitätsmedizin Berlin
Erhebungszeitraum: 2015-07-07 - 2015-07-09
Umfang: Diagnosecodes, Art der Schlafstörung, Fragebögen, Verbundene und abgeleitete Daten
- Datensatz SM-00635A63**
Einrichtung: Universitätsklinikum Freiburg
Erhebungszeitraum: 2020-05-19 - 2020-05-20
Umfang: Diagnosecodes, Art der Schlafstörung, Fragebögen
- Datensatz SM-30121K90**
Einrichtung: Universitätsklinikum Freiburg
Erhebungszeitraum: 2018-03-03 - 2018-03-05
Umfang: Diagnosecodes, Art der Schlafstörung, Video

3. Rahmenbedingung der Datennutzung

Meine [Patientendaten](#) werden an [Forschungsprojekte](#) nur in [pseudonymisierter Form](#) weitergeleitet, so dass keine [direkte Identifizierung](#) meiner Person möglich ist.

Wissenschaftliche Veröffentlichungen von Forschungsergebnissen auf Basis der weitergegebenen Daten

Hilfe zu den Freigabeeinstellungen

Auf der linken Seite können Sie Ihre persönlichen Bedingungen zur Weitergabe anonymisierter Daten an Forschungsprojekte konfigurieren. Am Ende des Formulars können Sie Ihre Freigabe rechtsverbindlich durch Ihr SouveMed-Passwort erteilen

Zunächst müssen Sie bestätigen an einem persönlichen Aufklärungsgespräch teilgenommen zu haben, dass Sie über die Chancen und Risiken informiert. Anschließend können Sie die Datensätze auswählen, welche an Projekte in anonymisierter Form weitergegeben werden dürfen. Dann müssen Sie festlegen welche Art von Projekten Sie unterstützen wollen und ob Sie auch über weniger dringliche Zufallsbefunde informiert werden wollen.

Bitte lesen Sie sich die Informationen aufmerksam durch und bestätigen Sie abschließend Ihre Freigabe rechtsverbindlich durch Eingabe Ihres SouveMed-Zugangspassworts. Eine zuvor gültige Freigabe wird durch Ihre neue Freigabe in seiner Gültigkeit ersetzt und in das Freigabearchiv verschoben.

Bei Fragen wenden Sie sich an Ihren Arzt

Dynamic consent that improves the process for patients in three ways:

- Personal consultation
- User-friendly App
- Coarse granular data management

Secure data requests and analysis for sleep researchers

Challenges

Data governance

- Central point of contact for legally compliant data requests and utilization



Data privacy and security

- Balancing the privacy and autonomy of patients and their data while enabling in-depth data analysis for researcher



Data quality and interoperability

- Standardisation issues in data and infrastructures
- Varying data quality and formats



Scalability and performance

- Ensuring scalability and performance while maintaining data security and privacy

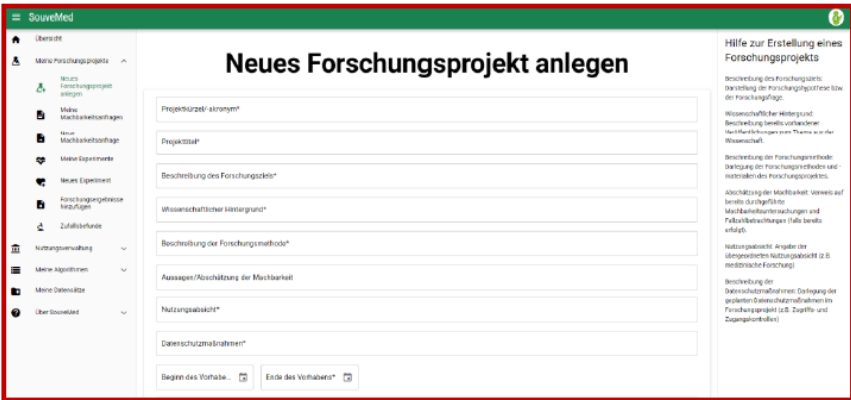


Transparency and reproducibility

- All relevant data, methods, tools, and parameters are accurately documented and transparent for authorized users.



Secure data requests and analysis for sleep researchers

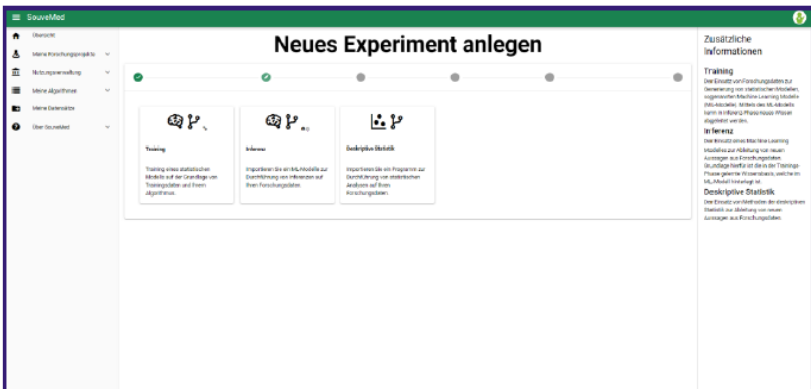


Step 1:
Create research project

Step 3:
Usage request and contract processing

Step 2:
Feasibility query

Step 4:
Data usage



Advancing Sleep Research through Dynamic Consent and Trustee-Based Medical Data Processing

Secure data requests and analysis for sleep researchers

Solution

Data governance

- Central point of contact
- User-friendly platform with clear governance policies and streamlined procedures
- Access for public and private research

Data privacy and security

- Facilitating collaboration and data sharing while protecting data privacy and security
- Pseudonymization of sleep data
- Providing a priori availability checks

Data quality and interoperability

- Standardizing sleep data descriptions using FHIR resources
- Implementing software adapters as uniform interfaces

Scalability and performance

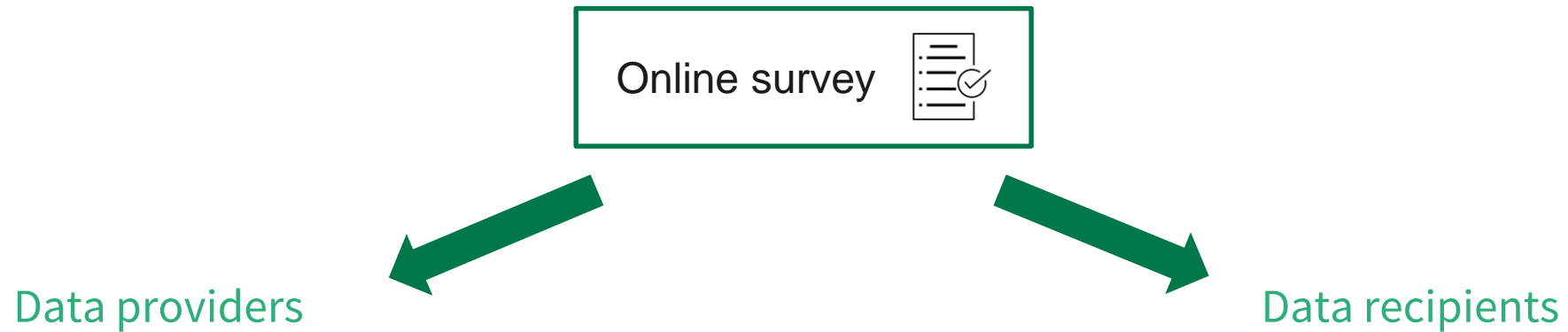
- Ensuring scalability and performance while supporting common data usage types, including descriptive statistics and machine learning through distributed architecture and container-based execution environments

Transparency and reproducibility

- Reproducibility of research experiments through unique data set IDs and container-based execution environments
- Tamper-proof logging to reduce the risk of misuse



Evaluation



Konfiguration Ihrer Freigabeeinstellungen

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Übersicht

Das Projekt SouveMed läuft seit Januar 2022 und seither sind...

- 57 Datengebennde registriert.
- 2 Schlaflabore und -kliniken angeschlossen worden.
- 3.241 Datensätze verfügbar.
- 120 Datennutzende registriert.

Ablauf zur Beantragung von medizinischen Daten

- SCHRITT 1: Forschungsprojekt anlegen
- SCHRITT 2: Machbarkeitsanfragen
- SCHRITT 3: Nutzungsanfrage & Antragstellung
- SCHRITT 4: Datennutzung

Buttons: NEUES FORSCHUNGSPROJEKT ANLEGEN, NEUE MACHBARKEITSANFRAGE STELLEN, NEUE NUTZUNGSANFRAGE STELLEN

Evaluation – Data provider

Methods

- Human-Computer Trust Scale (HCTS)
- Mobile Application Rating Scale (uMARS)
 - 3 aspects: functionality, aesthetics, subjective quality



Source: [21] Gulati et al.

- (1) I believe that there could be negative consequences when using (—)
- (2) I feel I must be cautious when using (—)
- (3) It is risky to interact with (—)
- (4) I believe that (—) will act in my best interest
- (5) I believe that (—) will do its best to help me if I need help
- (6) I believe that (—) is interested in understanding my needs and preferences
- (7) I think that (—) is competent and effective in (—)
- (8) I think that (—) performs its role as (—) very well
- (9) I believe that (—) has all the functionalities I would expect from (—)
- (10) If I use (—), I think I would be able to depend on it completely
- (11) I can always rely on (—) for (—)
- (12) I can trust the information presented to me by (—)

HCTS

SECTION B

Functionality – app functioning, easy to learn, navigation, flow logic, and gestural design of app

6. Performance: How accurately/fast do the app features (functions) and components (buttons/menus) work?
 - 1 App is broken; no/insufficient/inaccurate response (e.g. crashes/bugs/broken features, etc.)
 - 2 Some functions work, but lagging or contains major technical problems
 - 3 App works overall. Some technical problems need fixing, or is slow at times
 - 4 Mostly functional with minor/negligible problems
 - 5 Perfect/timely response; no technical bugs found, or contains a 'loading time left' indicator (if relevant)
7. Ease of use: How easy is it to learn how to use the app; how clear are the menu labels, icons and instructions?
 - 1 No/limited instructions; menu labels, icons are confusing; complicated
 - 2 Takes a lot of time or effort
 - 3 Takes some time or effort
 - 4 Easy to learn (or has clear instructions)
 - 5 Able to use app immediately; intuitive; simple (no instructions needed)
8. Navigation: Does moving between screens make sense; Does app have all necessary links between screens?
 - 1 No logical connection between screens at all /navigation is difficult
 - 2 Understandable after a lot of time/effort
 - 3 Understandable after some time/effort
 - 4 Easy to understand/navigate
 - 5 Perfectly logical, easy, clear and intuitive screen flow throughout, and/or has shortcuts
9. Gestural design: Do taps/swipes/pinches/scrolls make sense? Are they consistent across all components/screens?
 - 1 Completely inconsistent/confusing
 - 2 Often inconsistent/confusing
 - 3 OK with some inconsistencies/confusing elements
 - 4 Mostly consistent/intuitive with negligible problems
 - 5 Perfectly consistent and intuitive

uMARS

SECTION C

Aesthetics – graphic design, overall visual appeal, colour scheme, and stylistic consistency

10. Layout: Is arrangement and size of buttons, icons, menus and content on the screen appropriate?
 - 1 Very bad design, cluttered, some options impossible to select, locate, see or read
 - 2 Bad design, random, unclear, some options difficult to select/locate/see/read
 - 3 Satisfactory, few problems with selecting/locating/seeing/reading items
 - 4 Mostly clear, able to select/locate/see/read items
 - 5 Professional, simple, clear, orderly, logically organised
11. Graphics: How high is the quality/resolution of graphics used for buttons, icons, menus and content?
 - 1 Graphics appear amateur, very poor visual design - disproportionate, stylistically inconsistent
 - 2 Low quality/low resolution graphics; low quality visual design – disproportionate
 - 3 Moderate quality graphics and visual design (generally consistent in style)
 - 4 High quality/resolution graphics and visual design – mostly proportionate, consistent in style
 - 5 Very high quality/resolution graphics and visual design - proportionate, consistent in style throughout
12. Visual appeal: How good does the app look?
 - 1 Ugly, unpleasant to look at, poorly designed, clashing, mismatched colours
 - 2 Bad – poorly designed, bad use of colour, visually boring
 - 3 OK – average, neither pleasant, nor unpleasant
 - 4 Pleasant – seamless graphics – consistent and professionally designed
 - 5 Beautiful – very attractive, memorable, stands out; use of colour enhances app features/menus

App subjective quality

SECTION E

17. Would you recommend this app to people who might benefit from it?

| | |
|--------------|---|
| 1 Not at all | I would not recommend this app to anyone |
| 2 | There are very few people I would recommend this app to |
| 3 Maybe | There are several people I would recommend this app to |
| 4 | There are many people I would recommend this app to |
| 5 Definitely | I would recommend this app to everyone |
18. How many times do you think you would use this app in the next 12 months if it was relevant to you?
 - 1 None
 - 2 1-2
 - 3 3-10
 - 4 10-50
 - 5 >50
19. Would you pay for this app?
 - 1 Definitely not
 - 2
 - 3
 - 4
 - 5 Definitely yes
20. What is your overall (star) rating of the app?

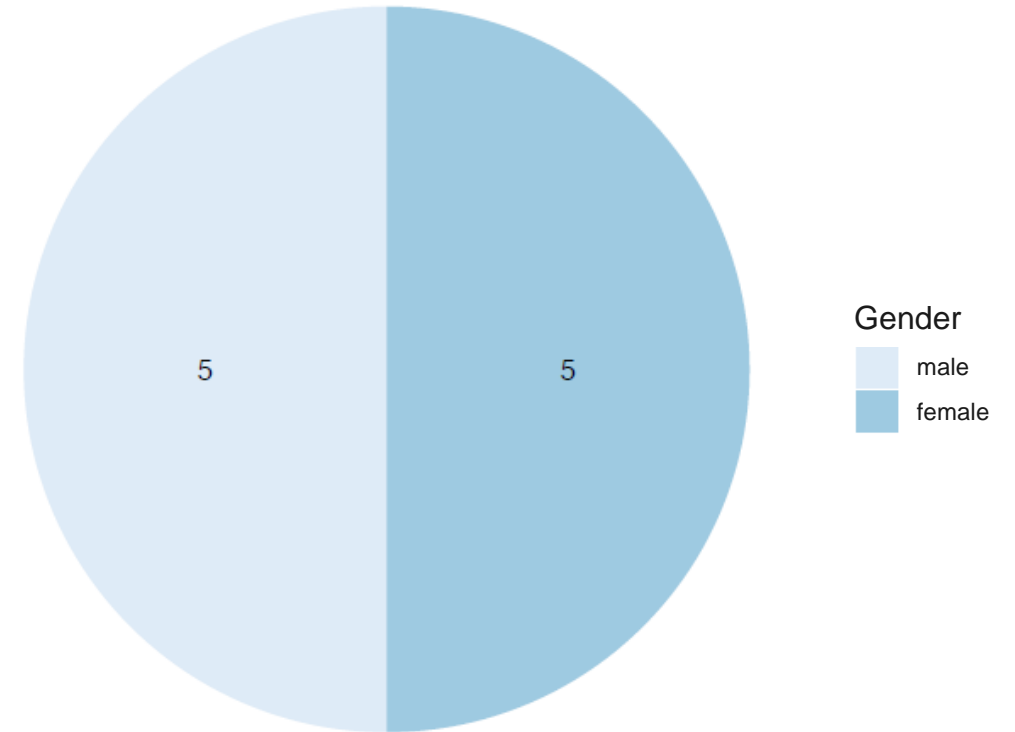
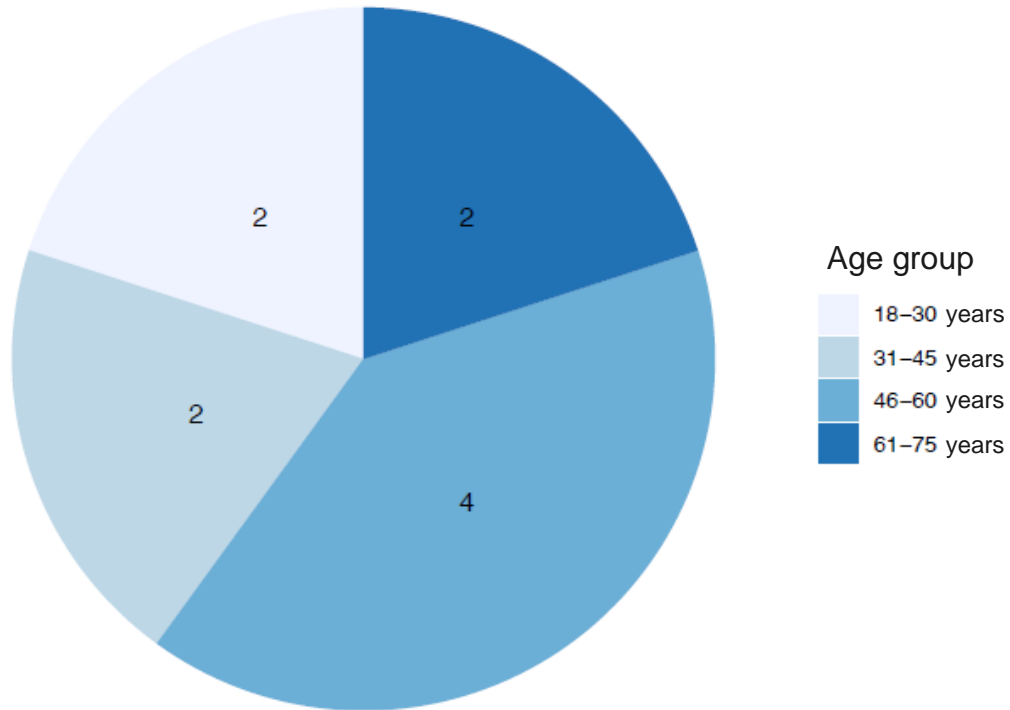
| | |
|---------|---------------------------------|
| 1 ★ | One of the worst apps I've used |
| 2 ★★ | |
| 3 ★★★ | Average |
| 4 ★★★★ | |
| 5 ★★★★★ | One of the best apps I've used |

Source: [19] Stoyanov et al.

Evaluation - Data provider

Age distribution and gender

- 10 data providers

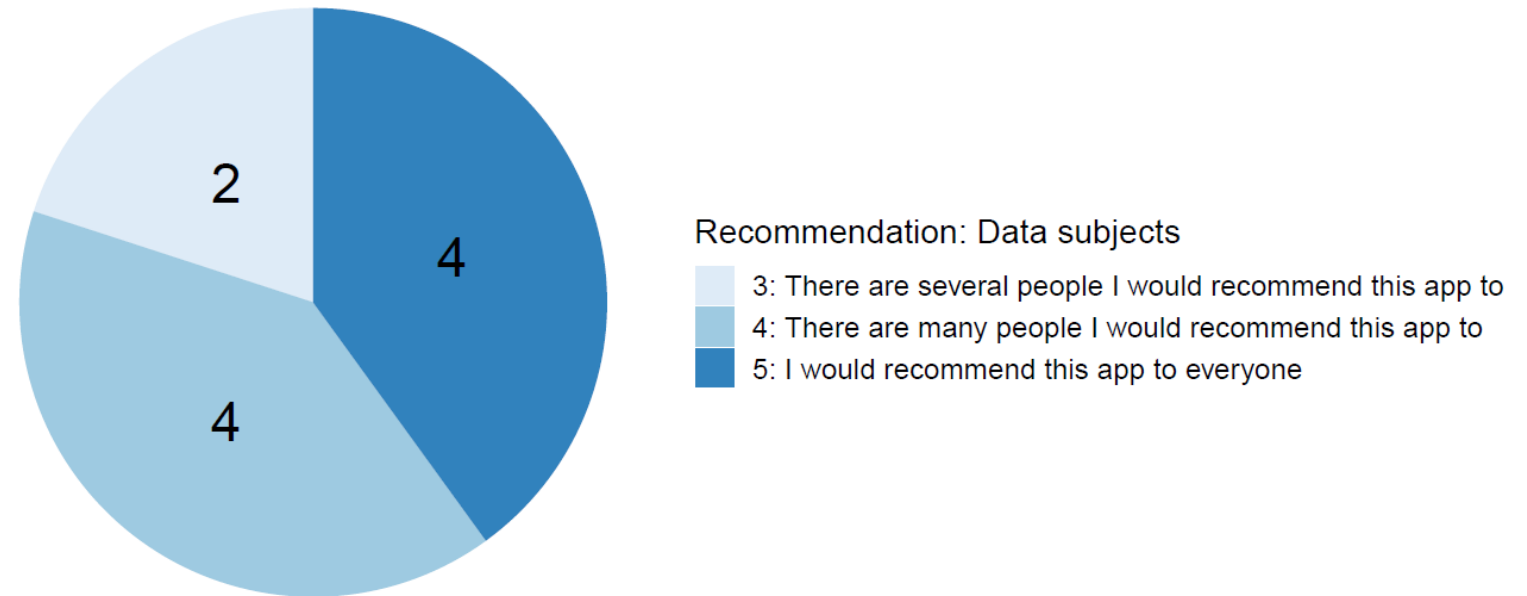


Evaluation - Data provider

Results

– Subjective quality:

- mean HCTS score: 4.28 (± 0.80)
- Functionality: 4.50 (± 0.81)
- Aesthetics: 4.23 (± 0.96)



(a) Results from the survey of data providers (subjects). No data provider selected the first two response options.

Evaluation - Data recipients

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uMARS

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App subjective quality

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| 4 | 10-50 |
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| 3 | |
| 4 | |
| 5 | Definitely yes |
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| | | |
|---|-------|---------------------------------|
| 1 | ★ | One of the worst apps I've used |
| 2 | ★★ | |
| 3 | ★★★ | Average |
| 4 | ★★★★ | |
| 5 | ★★★★★ | One of the best apps I've used |

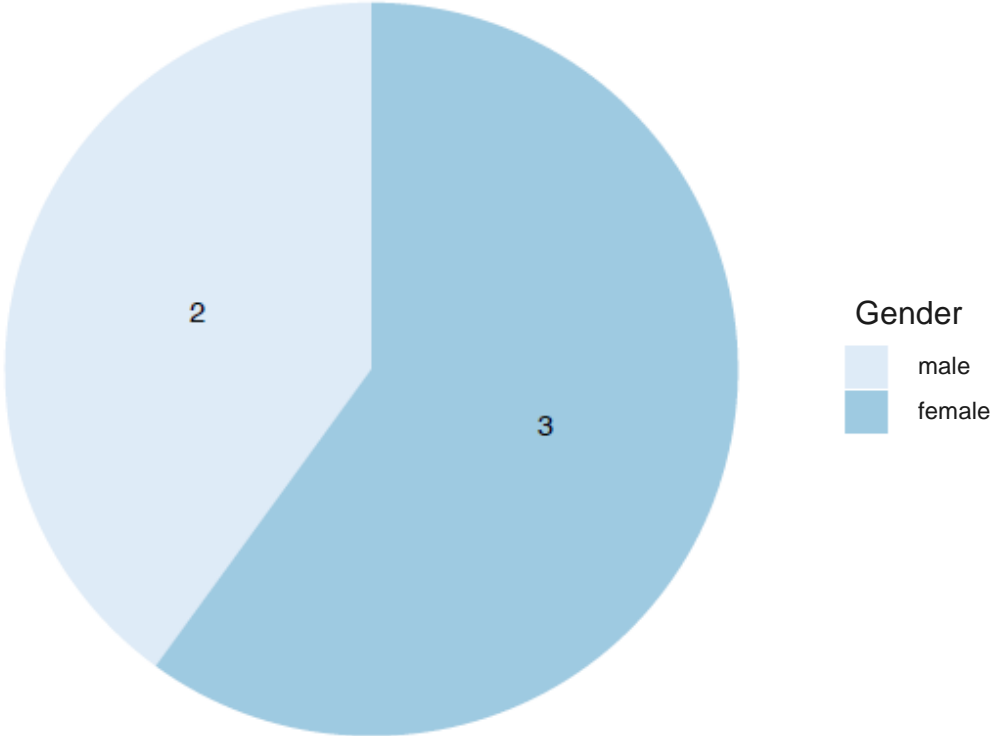
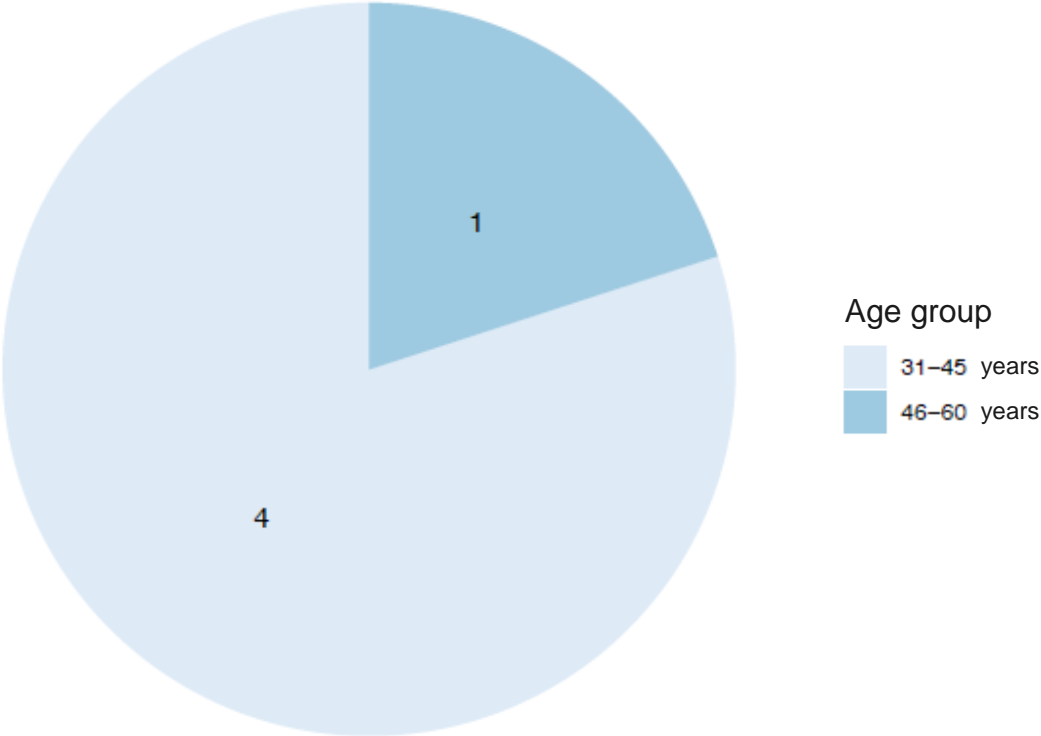
Source: [21] Gulati et al.

Evaluation - Data recipients



Age distribution and gender

- 6 data recipients

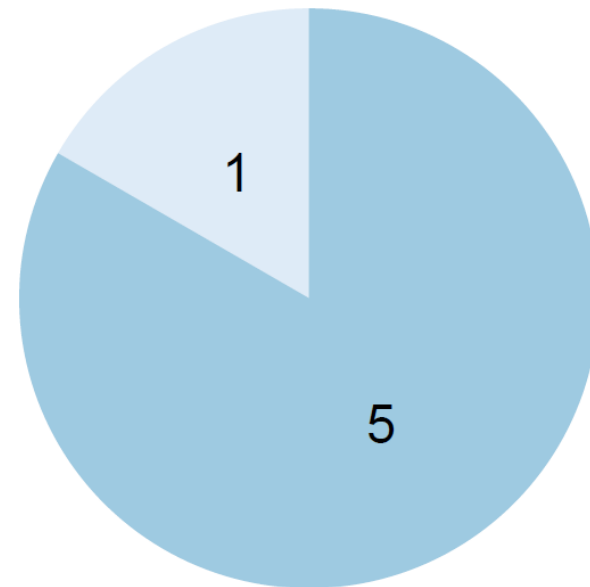


Evaluation - Data recipients

Results

– Subjective quality:

- Functionality: 4.58 (± 0.52)
- Aesthetics: 4.17 (± 0.71)



Recommendation: Data users

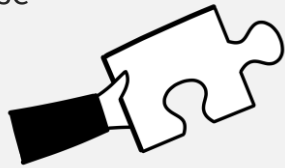
- 4: There are many people I would recommend this app to
- 5: I would recommend this app to everyone

(b) Results from the survey of data recipients (users). No data recipient selected the first three response options.

Discussion & Conclusion

Comprehensive approach

- Addresses needs of multiple stakeholders
- Ensures secure and ethical data sharing and use



User-friendly app

- Enhances patient comprehension and engagement
- Personalized consultation improve understanding and willingness to share



Digital consent process & good usability:

- Alternative to paper-based processes
- Streamlined digital process for data availability queries, requests, and reporting
- Crucial for system acceptance by both data providers and recipients
- Reduces barriers caused by legal uncertainties



Granular data management

- Empowers patients with control and autonomy over their data
- Strengthens patients' feeling of being respected as data providers



Trustworthy intermediary

- Patients feel their data interests are prioritized
- High level of trust through compliance with GDPR



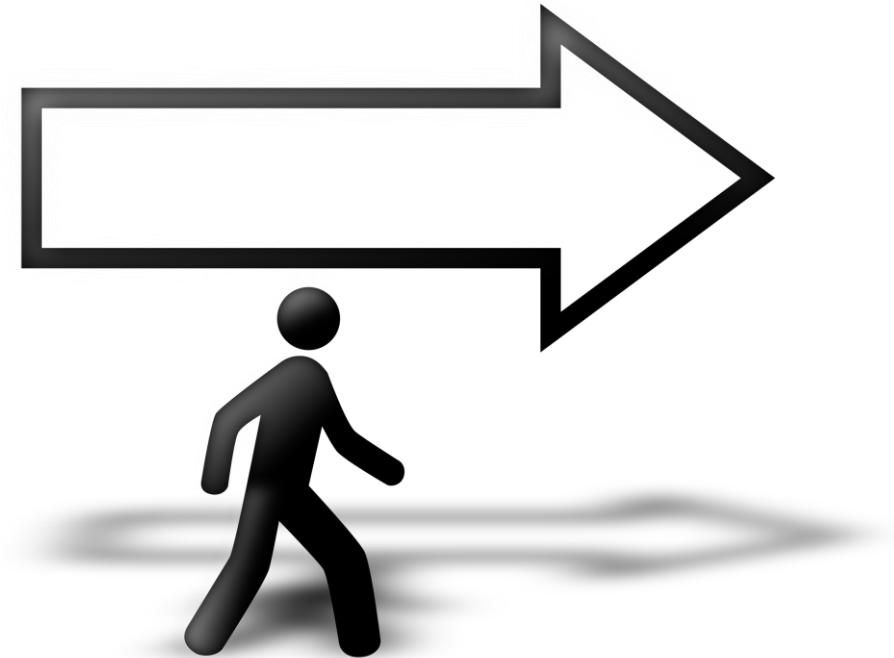
Centralized digital hub & robust security measures

- Consolidates all features into one system.
- Aligns with FAIR data principles
- Ensures privacy and interoperability
- Tamper-proof logging enhances traceability and detection of data misuse



Limitations & Future work

- Sample size of 16 may limit generalizability
- Findings may only represent part of the user population
- Provides initial impressions and preliminary solutions for design challenges
- Lays groundwork for further research in data trustee systems
- Highlights the potential of a decentralized, socio-technical data trustee system



Source: <https://cdn.hipwallpaper.com/i/85/2/a5zjkM.png>

Thank you for your attention!

Contact: Christina Erler
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