The European Health Data Space and Secure Processing Environments

An introduction by Maryam Khodaei Dolouei

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Network for Artificial Intelligence in Medicine

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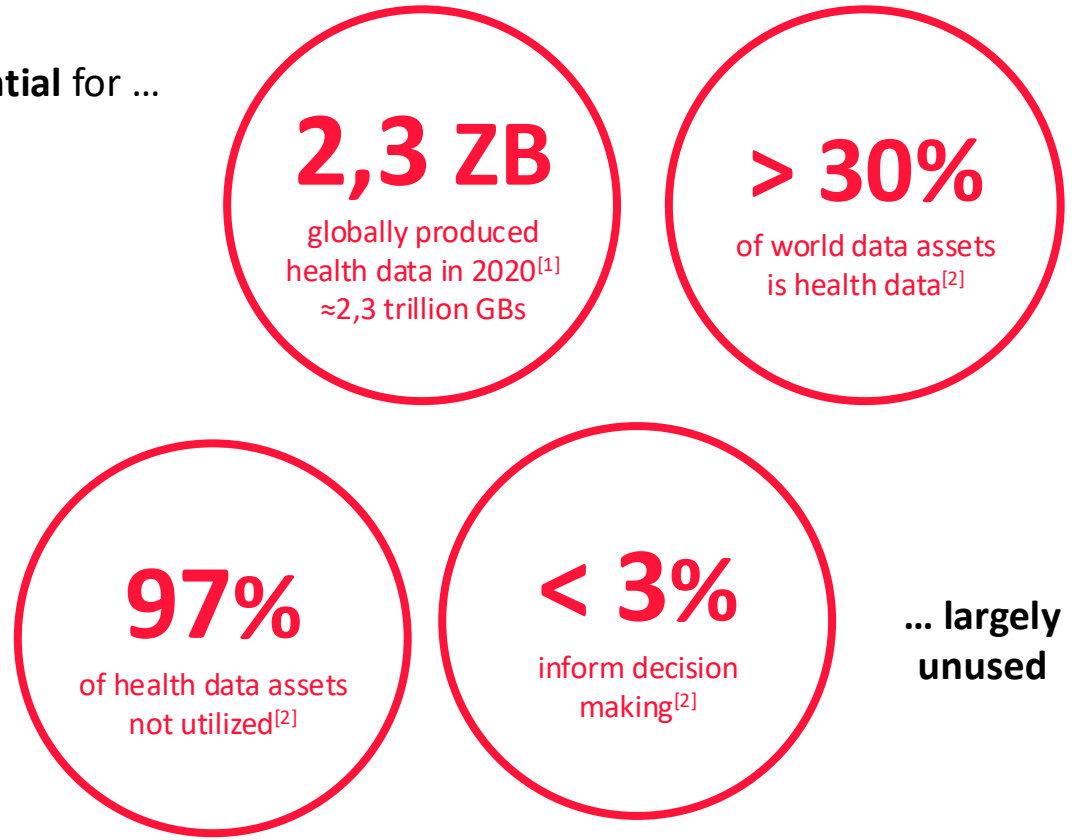
Health data

High potential - missed opportunities

Health data - high potential

Health data and AI offers **enormous potential** for …

- Precision medicine
- Early disease detection
- Health system optimization
- Drug development
- Public health surveillance
- Rare disease research
- …



[1] Estimation by Statista (https://www.statista.com/statistics/1037970/global-healthcare-data-volume)
[2] OECD (2025), *Facilitating the secondary use of health data for public interest purposes across borders*, OECD Digital Economy Papers, No. 376, OECD Publishing, Paris. https://doi.org/10.1787/d7b90d15-en

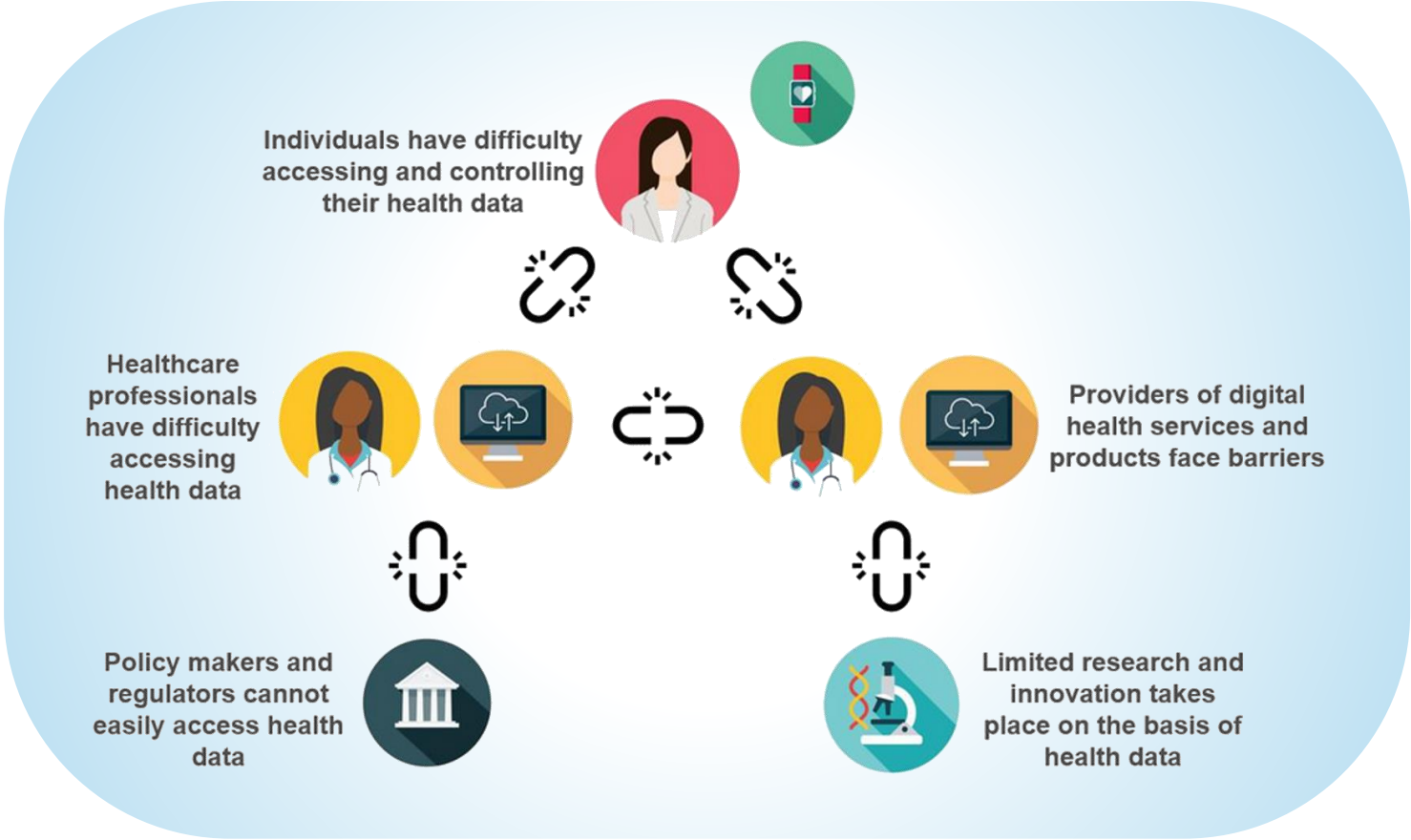
Health data - missed opportunities

Why is this potential not used?!

- Highly fragmented infrastructures
- Legal uncertainties
- Limited interoperability

To unlock the value of Europe's health data …

→ We need a **coherent regulatory and governance framework** that promotes innovation, while ensuring **data protection, transparency and public trust**



Adapted from: European Commission (2022), "A European Health Data Space" COM(2022) 196 final, CC BY 4.0

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The European Health Data Space

Unlocking the potential of health data across Europe

Enactment of the EHDS

- Unified framework for **health data exchange across EU** Member States
- EU-regulation enacted on **25th March 2025**
  - **directly legally effective** in all EU Member States
  - will come into force **gradually**
- MyHealth@EU (EHDS I)
  - **Primary use** of data (Routine Care)
- HealthData@EU (EHDS II)
  - **Secondary use** of data (Research)
- Related projects
  - TEHDAS2, HDP4Germany, EHDS2 Pilot, Xt-EHR, …
- Consent by default and **Opt-Out** option

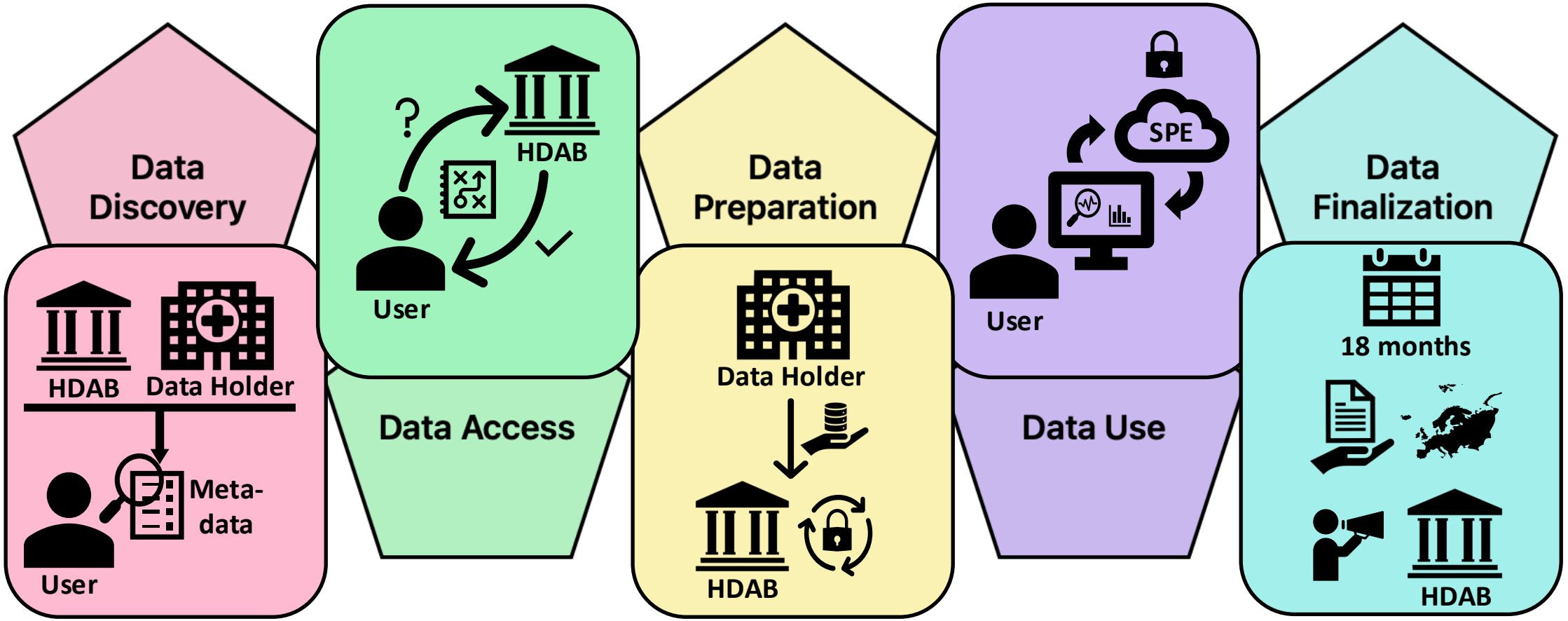
Key actors for data access

- **Health data holder**
  - An organisation or entity that **holds or controls electronic health data**
  - Examples: hospitals, research institutions, registries, or companies developing health or wellness apps

- **Health data user**
  - Person or organisation that **receives authorised access to health data** (e.g. researchers)
  - Data used for secondary purposes

- **Health data access body (HDAB)**
  - Public authority that **manages the access to health data**
  - grants **data access permits**
  - ensures **protection of individuals rights** and data security
  - provides **transparency** about who accesses which data for what purpose

Data User Journey



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Secure Processing Environments

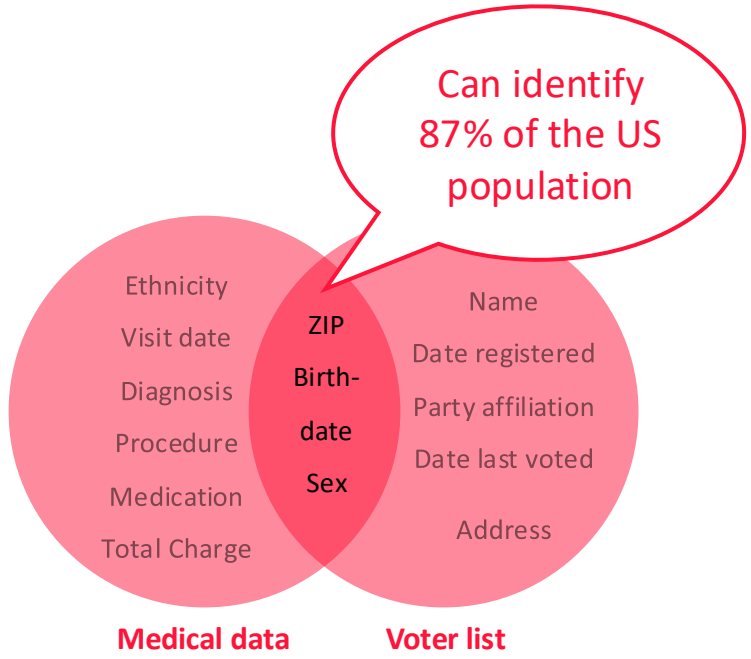
and why we need them

Risks of local data analysis

Data proliferation	Device and infrastructure risks
Multiple copies of the same dataset across institutions	Lost or stolen laptops
Difficult to control deletion and reuse, no central control	Unencrypted storage or backups
Limited oversight	**Data leakage risks**
No monitoring of analysis activities	Accidental sharing
Difficult to enforce usage restrictions	Insecure file transfers

Limits of anonymisation

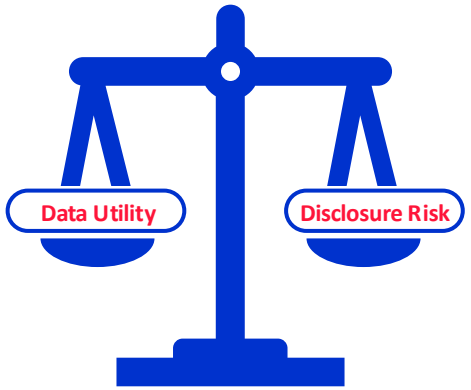
- **Re-identification of Massachussetts governor (1990s)**
  - was identified using „anonymised“ hospital discharge records and linking it with a 20$ voter registration list
- **„Netflix prize“ de-anonymisation (2008)**
  - 1 million $ for researchers who could improve recommendation system.
  - Released data of 500.000 anonymized subscribers (removed personally identifiable information)
  - Linking attack using IMDb
  - Highlighted the vulnerability of high dimensional, sparse datasets



Secure Data Processing in EHDS

Secure Data Processing as a combined approach of …

- Anonymisation or pseudonymisation
- Secure Processing Environments (SPE)
  - controlled highly secure digital environment to access and analyse health data
- Governance through HDAB

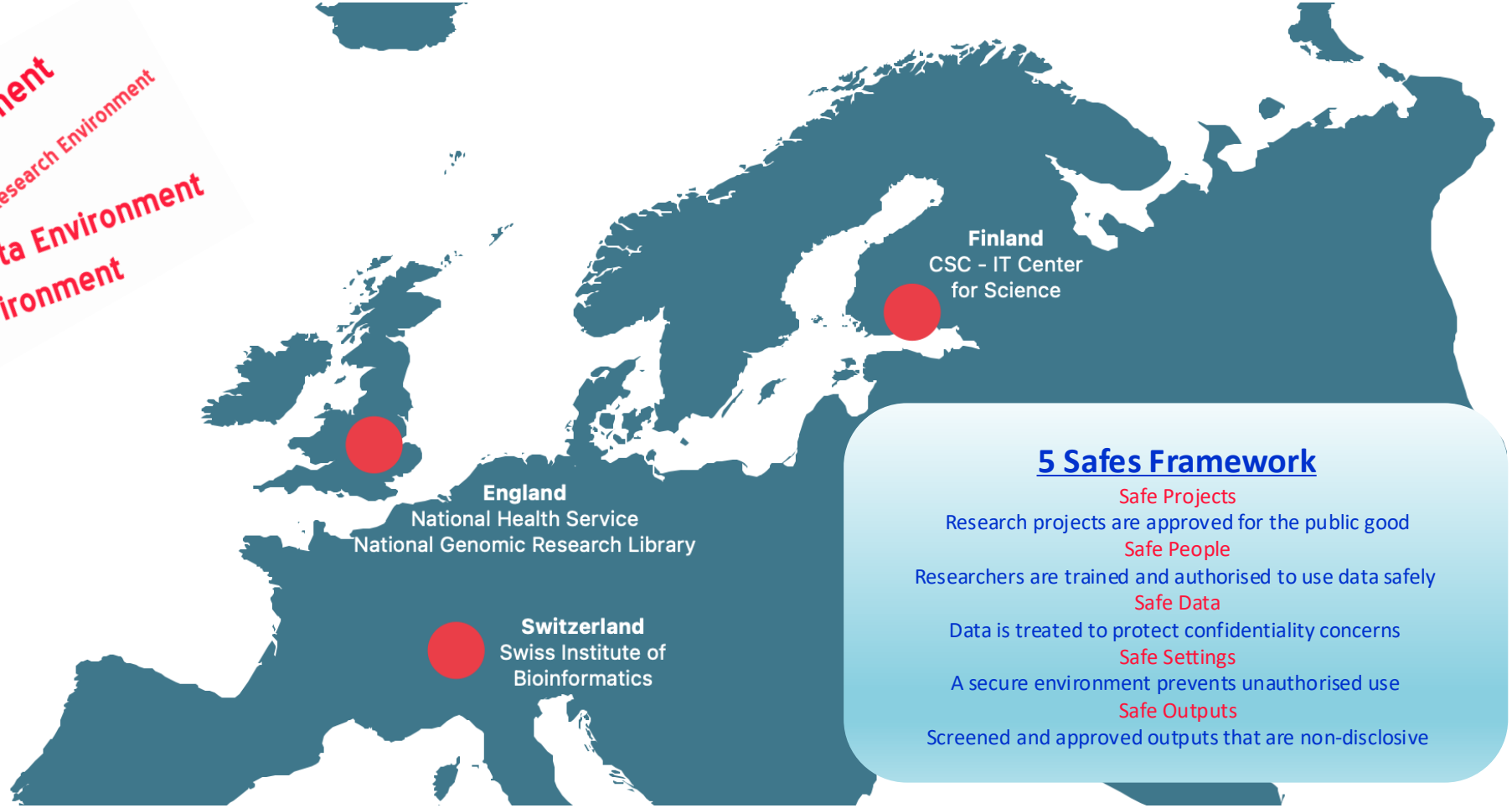


SPE must meet following criteria:

- **Data security:** Prevent unauthorised access, maintain confidentiality, and ensure data integrity
- **Restricted access:** Allow users to process only those data covered by a valid data permit, and only within the permitted scope
- **Controlled outputs:** Ensure that only non-personal data (aggregated, anonymised results) can be exported and only after authorisation by the HDAB

Examples in Europe

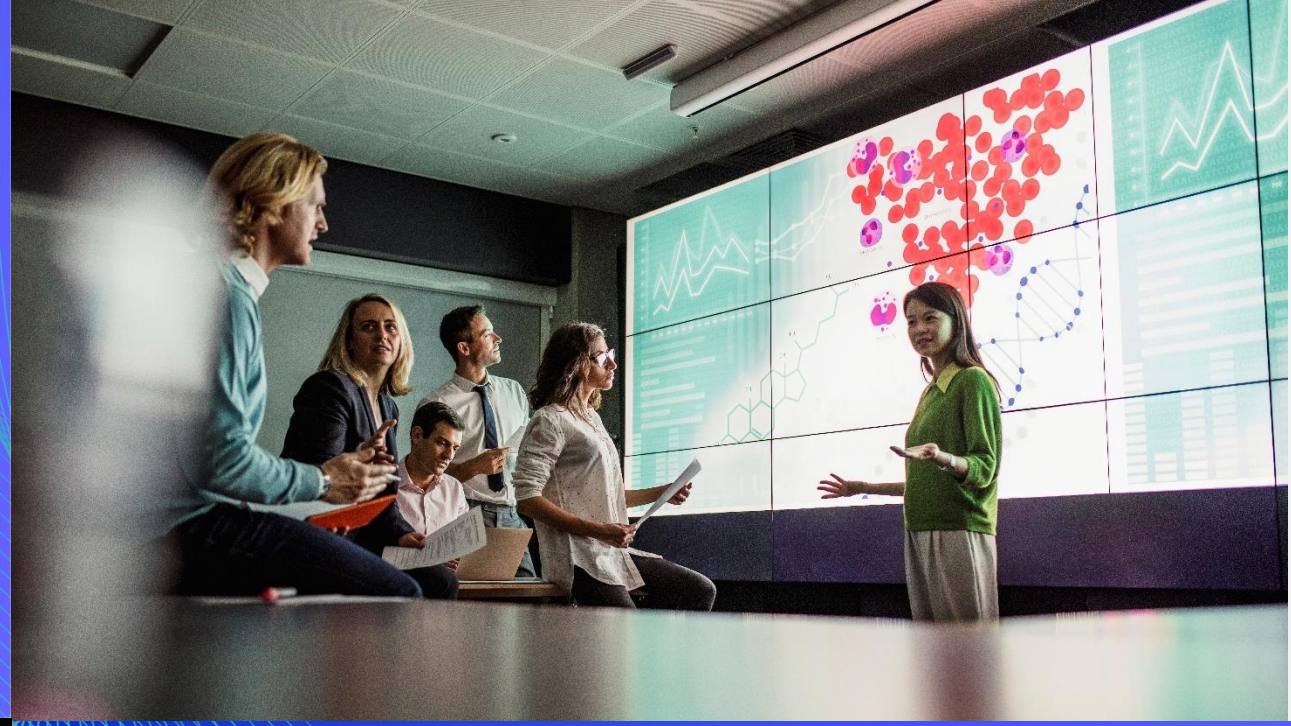
Data Safe Haven
Secure Processing Environment
Virtual Research Environment
Secure Data Environment
Trusted Research Environment



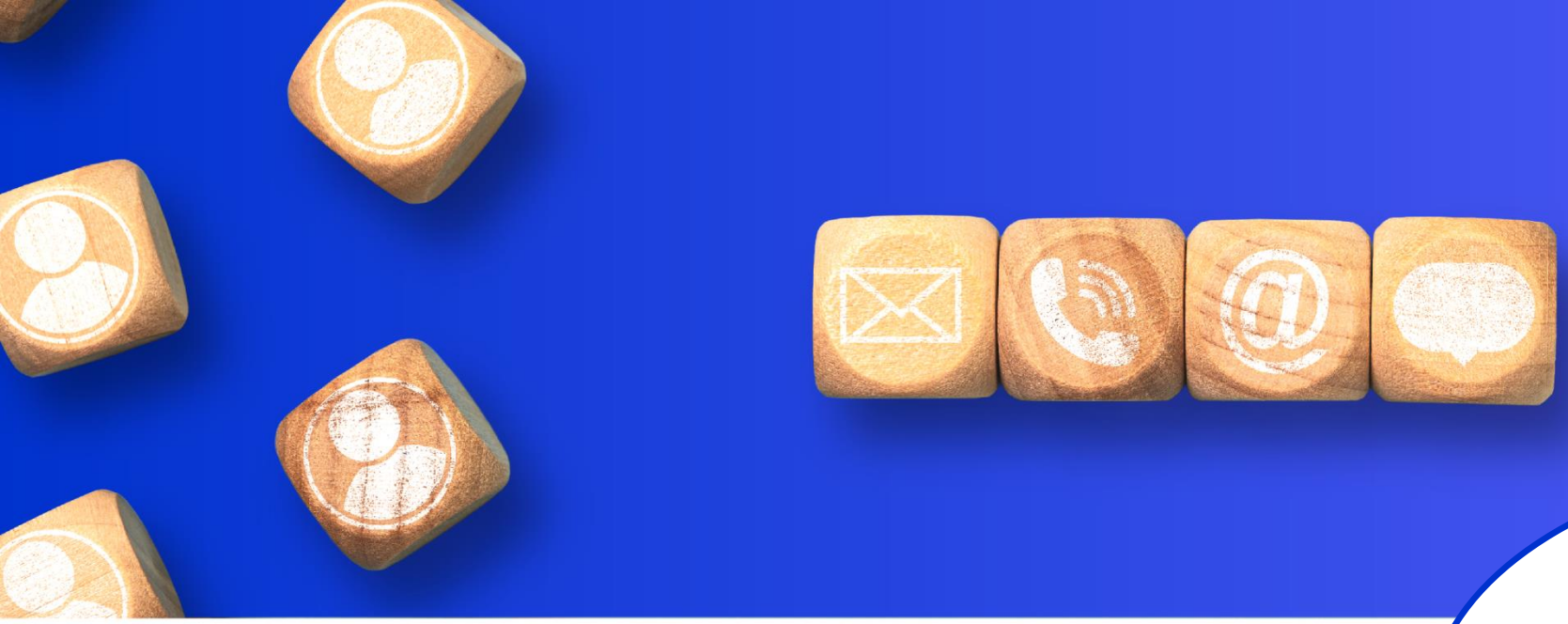
5 Safes Framework

Safe Projects
Research projects are approved for the public good
Safe People
Researchers are trained and authorised to use data safely
Safe Data
Data is treated to protect confidentiality concerns
Safe Settings
A secure environment prevents unauthorised use
Safe Outputs
Screened and approved outputs that are non-disclosive

KIMed - a network for Artificial Intelligence in medicine – aims to establish a powerful and secure processing environment in Saxony.



This infrastructure will enable the use of large, networked data sets in accordance with strict data protection guidelines.



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Interested in joining our network?

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MDS
Medical Data Science

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Thank You

UNIVERSITÄT LEIPZIG
Faculty of Medicine

TECHNISCHE UNIVERSITÄT DRESDEN

HOCHSCHULE MITTWEIDA
University of Applied Sciences

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Freistaat SACHSEN

This project is co-financed from tax revenues on the basis of the budget adopted by the Saxon State Parliament.

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