

# Fit4MedRob

Interoperability, Sovereignty, and  
Security

Legal–Technical Foundations of Data  
Spaces in the secondary use of data

F. Casarosa

European Health Data Space – secondary use  
of data and data subject rights - Warsaw 24  
March 2026

# Common data spaces: technical perspective

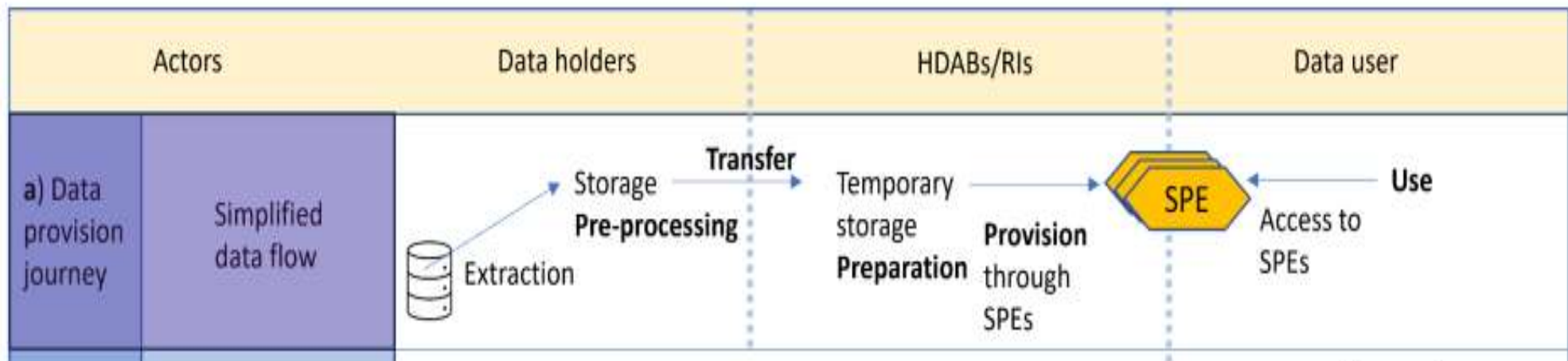
- From database management to data space
  - no schema is adopted in the design phase
  - integration is required only when needed
- Achieving a common understanding of data instead of a common structure
- Common features:
  - storage architecture, control, model, formats, schema, integration, leadership, query, data processing, governance, sovereignty, consistency and durability

# Selected aspects

- Digital Sovereignty
  - within the data spaces, data producers should have control over the data they share and the possibility to enforce their data usage rights. In practice, data producers should retain their rights as the original owners, enabling them to control who can use their data, for what purpose, and under which terms and conditions.
- Interoperability
  - Data producers should adopt standard data exchange APIs and data models for enabling and facilitate data sharing/exchange between smart solutions;
- Security
  - To enable data sharing, the exchange should ensure secure access and restrictions. Security solutions and exchange protocols must be standardised across all data-sharing space nodes and participants.

# Data space in EHDS

- Decentralised architecture that grants some leeway to national setups but relies on a harmonised (i.e. centralised) scheme that should facilitate data exchange.
- Cross-border infrastructure will be established, named HealthData@EU.
  - Art 75 EHDS clarifies the tasks and processes to be carried out on the platform, but no specific information about its structure is provided.
  - It will be the Commission that will adopt the **requirements, technical specifications and the IT architecture which shall ensure state-of-the-art data security, confidentiality, and protection of electronic health data** in HealthData@EU, within the timeframe of two years (Art 75(12) EHDS).



Data provision journey through the different actors. EHDS Pilot project – D7.2

# Selected dimensions: Digital sovereignty

- Individuals may opt out of data processing for secondary use (Art 71)
  - The exclusion will apply from the moment of opt-out + consent is provided to data controller
  - data subjects do not participate in the HealthData@EU
- Health data holders (data holders) are required to share the dataset containing electronic health data
  - Do not have any control over the subsequent use: decision lies in the hands of HDAB
  - Do not receive information on the results of the subsequent use: information is publicized by the HDAB

# Selected dimensions: Digital sovereignty

- Anonymisation of data: Possible? Effective? Counterproductive?
- Forums for data holders and data users
- Obligation to provide results to data holders

# Selected dimensions: Interoperability

- Commission is expected to adopt implementing acts on technical specifications and requirements for data quality standards (Art. 13), cross-border electronic health record exchange formats (Art. 15)
  - Limited results in harmonisation
- Research is not usually based on a single dataset but on an aggregated set of data from different sources
  - Is FHIR sufficient?

# Selected dimensions: Interoperability

- Technical – syntactic – semantic interoperability requires strong collaboration across MS
- Training for professionals

# Selected dimensions: Security

- Each HDAB should provide a 'secure processing environment', which should be subject to technical and organisational measures and security and interoperability requirements.
  - Definition in DGA, art. 2(20) : 'secure processing environment' *means the physical or virtual environment and organisational means to ensure compliance with Union law*



## Access

- Credentials for each individual
- Strong password
- Multifactor authentication
- Personal login
- Continuous monitoring
- Changes to authorised staff to be reported and approved by HDAB

## Data analysis

- Only pre-approved tools can be used
- Analytical tasks are defined in advance in the data permit
- Intermediate results stored in SPE with HDAB oversight
- No video calls/no screen recording
- Storage of data within the time limit of the data permit

## Results preparation

- Validation of outputs in line with data permit
- Anonymisation or aggregation methods to be applied for export
- Secure export mechanism

# Selected dimensions: Security

- High level of security and availability of computing resources able to adapt to the different workload requested (statistical inference v deep learning models)
- Public or third-party SPE? Centralised or decentralised?
- Harmonised features across MS (cross-border requests)?



Ministero  
dell'Università  
e della Ricerca



**Italiadomani**  
PIANO NAZIONALE  
DI RIPRESA E RESILIENZA



**PNC**

Piano nazionale per gli investimenti  
complementari al PNRR  
*Ministero dell'Università e della Ricerca*



Fit for Medical Robotics

**Thank you for your attention**



Ministero  
dell'Università  
e della Ricerca

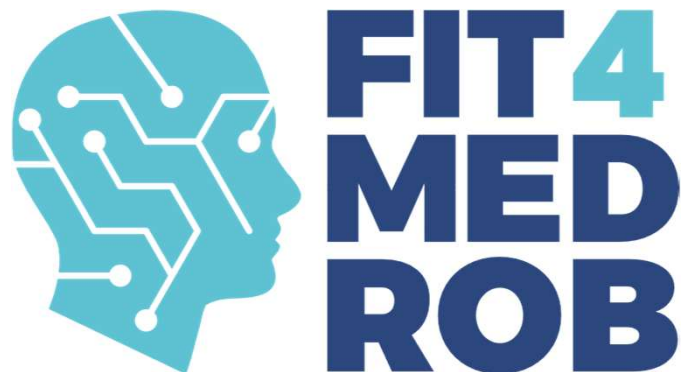


**Italiadomani**  
PIANO NAZIONALE  
DI RIPRESA E RESILIENZA



**PNC**

Piano nazionale per gli investimenti  
complementari al PNRR  
Ministero dell'Università e della Ricerca



Fit for Medical Robotics

## Project Info

- Starting date: **1 December 2022**
- Duration: **44 months**
- Funding: **126M€**
- Coordinating institution: **Consiglio Nazionale delle Ricerche**
- Scientific Director: Prof. **Christian Cipriani**
- Partners: **10 Academic Institutions, 12 Clinical Centers, 3 Companies**



[www.fit4medrob.it](http://www.fit4medrob.it)



[fit4medrob@legalmail.it](mailto:fit4medrob@legalmail.it)